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Results Reporting Pre & Post Punctuated Regulatory Rulings
Exploring Transparency & Accountability in Clinical Trials

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Examining Characteristics of Compliant Clinical Trials: Results Reporting Pre & Post Punctuated Regulatory Rulings

Exploring Transparency & Accountability in Clinical Trials

A Thesis

Submitted to the Faculty

of

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by

Jeanie Magdalena Gatewood

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of

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Dedications

This dissertation is dedicated to those whose lives and influence shaped my own course.

To Neville Jamshed Ranji—my partner and steady presence—thank you for your strength, your belief, and your unwavering encouragement during this next chapter. Your impact on this season of my life has been immeasurable..

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Abstract

Examining Characteristics of Compliant Clinical Trials: Results Reporting Pre & Post Punctuated Regulatory Rulings

Exploring Transparency & Accountability in Clinical Trials

Jeanie Magdalena Gatewood

Timely clinical trial result reporting ensures scientific integrity, ethical accountability, biomedical regulatory oversight, and public trust – as a critical component in bringing reliable and safe therapies to market. Although the U.S. Food and Drug Administration Amendments Act, Section 801 (FDAAA 801) (U.S. Food and Drug Administration, 2007), the Final Rule (U.S. Food and Drug Administration, 2017) and judicial rulings such as *Seife and Lurie v. U.S. Department of Health and Human Services* (United States District Court for the Southern District of New York, 2020) were designed to strengthen results-reporting obligations, a substantial proportion of trials fail to report primary endpoint data within the required 12-month window. Persistent non-compliance raises concerns about effectiveness of federal oversight and institutional forces shaping sponsor behavior.

This dissertation applies an expanded Legitimacy Theory framework to examine structural drivers of on-time results reporting. Using a quantitative, multivariate predictive design, this study integrates three major publicly available data sources—ClinicalTrials.gov, TrialsTracker.net, CMS ICD-10 Codes—to construct one of the largest analyses of reporting behavior to date (N ~ 147,000 interventional trials; N ~ 104,000 non-exempt trials spanning

2007 to 2024). Key variables include trial phase, funder type, therapeutic area, geographic location, and regulatory epoch. A main-effects logistic regression model evaluates how institutional legitimacy and structural characteristics influence compliance.

On-time reporting remains extremely low across the clinical research landscape. Across regulatory epochs, reporting declined rather than improved: 4.9% (2007–2016), 4.8% (2017–2019), and 2.0% (2020–2024), despite heightened policy and judicial rulings. Instead, disclosure is driven primarily by trial characteristics: later-phase studies outperform early-phase trials. Across epochs, later-phase trials consistently outperform early-phase trials (5.3% vs. 4.2%; 4.8% vs. 4.0%; and 2.1% vs. 1.8%, respectively). NIH-funded (9.2%) and independent investigators (5.5%) report more frequently than industry (3.6%) and academia (2.7%). U.S.-based trials reported at substantially higher rates than non-U.S. trials across all epochs (8.0%, 9.0%, 4.9% vs. 3.5%, 3.2%, 1.1%). Therapeutic area, however, does not independently influence reporting once structural factors are controlled. Notably, oncology—representing over half of trials—declined in relative reporting rank across 26 disease categories (2nd, 14th, and 21st across successive epochs.

These findings advance legitimacy-based insights of regulatory compliance and identify structural levers for improving transparency. They provide an empirical foundation and contribute to discourse emphasizing strengthened enforcement alignment, harmonized global expectations, and integration of reporting obligations into operational and funding workflows—essential to restore credibility in clinical research.

Keywords: Clinical Research Compliance, Results Reporting, ClinicalTrials.gov, Legitimacy Theory, Regulatory Enforcement, Trial Transparency, Research Integrity

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Chapter 1. Introduction

Given the growing complexity of clinical trials, evolving regulatory landscape, and increasing emphasis on patient-centricity, understanding the determinants of compliance with reporting requirements is both a practical and theoretical imperative. Transparency in clinical trial reporting is not just legally mandated but also constitutes a foundational component of scientific integrity and public trust in biomedical research (Jones, Handler, Crowell, Keil, Weaver, & Platts-Mills, 2013). ClinicalTrials.gov study records include structured fields that describe a trial's design and administrative profile (e.g., sponsor/responsible party, phase, intervention, outcomes, eligibility criteria, and study locations), as well as required summary results modules (participant flow, baseline characteristics, outcome measure results, and adverse events) when results are submitted. Under the Food and Drug Administration Act, Section 801 (FDAAA 801) (U.S. Food and Drug Administration, 2007) and the Final Rule, these elements are required for applicable clinical trials; when records are incomplete or results are not posted, key information needed for accountability and evidence synthesis remains unavailable to clinicians, patients, and reviewers (U.S. Department of Health and Human Services, 2016). Throughout this dissertation, compliance refers specifically to legally mandated clinical trials results reporting under FDAAA 801, defined as posting primary-endpoint results to ClinicalTrials.gov within 365 days of the trial's primary completion date.

Foundationally, reporting of clinical research results is a pivotal aspect of trial transparency and public accountability (Hartung, Zarin, Guise, McDonagh, Paynter, & Helfand, 2014). Unpublished trial results and failure to adhere to reporting responsibility have resulted in significant gaps in accessible data, leading to regulatory scrutiny, reputational risks for sponsors, and surrounding ethical concerns (Schmucker, Schell, Portalupi, Oeller, Cabrera, Bassler et al.,

2014). Prior studies have documented persistent data quality and completeness challenges. Registry-based analyses must account for missing or inconsistently reported fields. Empirical assessments of compliance are constrained by data structure and completeness (Chaturvedi, Mehrotra, Kumari, Gupta, Subramanya, & Saberwal, 2019).

For analytic purposes, compliance is defined as results posted to ClinicalTrials.gov within 365 days of primary completion date, consistent with FDAAA 801 and the Final Rule. The outcome is operationalized as a binary indicator (coded as 1 = primary endpoint results posted within 365 days; 0 = primary endpoint results not posted within 365 days).

This dissertation explores legitimacy-driven factors influencing compliance through lenses of expanded Legitimacy Theory, specifically examining and analyzing how regulatory shifts, funding types, study phase, therapeutic area, and geographic region impact adherence to legal and ethical mandates.

1.1 Background of the Study

Despite regulatory mandates, the challenge of non-compliance in clinical trial result reporting has persisted. Historical patterns of delayed or incomplete reporting have raised concerns about research transparency and trust in biomedical evidence. Mehra and Grazette (2020) describe how publication bias may steer trials with statistically significant or positive findings toward timely publication, while neutral or negative results are more likely to experience delay or remain unpublished—a “file drawer” effect. They further express concern that many industry-sponsored studies fail to meet publication deadlines, keeping hidden critical findings for months or even years, and therefore hindering medical progress. They also note that sponsor-related financial incentives may contribute to slower dissemination of unfavorable findings. Together, these mechanisms create a directional distortion in the evidence base,

whereby positive efficacy signals are overrepresented and safety or null findings are underreported, with implications for clinical decision-making potential and patient care options.

Furthermore, research by Rivero-de-Aguilar et al. (2024) documented discrepancies between reported results on ClinicalTrials.gov and published findings in multiple sclerosis trials. Inconsistencies such as these raise concerns about reliability of reported data, potential suppression of negative results, and broader impacts on clinical decision-making. Such lapses highlight weaknesses in enforcement processes and warrant necessity of further investigation into systemic drivers of non-compliance.

Clinical trials are foundational to evidence-based medicine, and commercialization of new therapies that drive pharmaceutical innovation and advancements in public health. Yet, compliance with results reporting remains inconsistent despite regulations and mandates such as the Food and Drug Administration Amendments Act, Section 801 (FDAAA 801) (2007), the Final Rule (2017) and the Seife v. HHS ruling (United States District Court for the Southern District of New York, 2020). These sequential regulations were intentionally introduced to enhance transparency; however, their effectiveness ultimately depends on systemic adherence to compliance norms and interventional pathways.

Regulatory milestones shaping compliance include:

- 2007 – FDA issued the FDAAA 801 mandate requiring reporting of primary outcome clinical trial results, within one year of attaining that primary outcome, on ClinicalTrials.gov.
- 2017 – The “Final Rule” strengthened compliance requirements and introduced fines of $10,000 per day for non-compliance with a requirement to report results on ClinicalTrials.gov – effective immediately and for all trials going forward.

- 2020 – The Seife v. HHS ruling expanded clinical trial reporting requirements retroactively to trials conducted between 2007-2017 (which were not included in the "Final Rule" mandate) and raised fines to $14,000 per day.

Despite these expanded sanction measures, persistent non-compliance continues, undermining trust in clinical trial accountability and transparency.

Compliance issues extend beyond a regulatory requirement; they are deeply tied to an evolution of expectations for clinical trial transparency and increasing demands for feedback from study participants and consumers over the past two decades. FDAAA 801 mandated public reporting of clinical trial results within 12 months of study completion to enhance that transparency, ensure public access to knowledge and insights gained, and rebuild public trust. However, many sponsors – commercial, academic, and even government-funded – continue to fail to comply (DeVito, Bacon, & Goldacre, 2020).

Yet, despite these motivating measures, limited enforcement has muted the deterrent effect of these measures and produced what resembles an "all bark, no bite" scenario. These challenges raise a critical empirical question: have strengthened regulatory mandates meaningfully improved compliance, and if not, which structural characteristics predict timely reporting behavior? To address this gap, this dissertation develops a theory-informed, predictive examination of trial-level factors associated with on-time reporting, moving beyond piecemeal descriptive studies toward an integrated, multivariate model grounded in Legitimacy Theory

Prior analyses indicate non-compliance is not merely a matter of regulatory oversight. It is also a reflection of behavioral challenges and structural design across industry (Kimbrell & Lawless, 2025; U.S. Food and Drug Administration, 2024). Research suggests failure to report results is influenced by multiple factors, including corporate financial concerns, phase-specific

constraints, therapeutic field market pressures, and regulatory disparities across geographic regions. Leveraging three publicly available data sources – ClinicalTrials.gov, TrialsTracker.net, and CMS ICD-10 codes – this study seeks to identify patterns, trends, and legitimacy-based drivers of compliance in clinical trial results reporting. A fourth dataset (FDA approvals) was manually compiled but, due to data quality, is reserved for future analyses beyond the scope of this dissertation.

1.2 Data Sources and Novelty of Data Integration

Data for this study originates from and integrates three primary sources, each of which contributes unique insights:

- **ClinicalTrials.gov** – The primary U.S. trial registry, mandated for public disclosure of study status and research results.
- **TrialsTracker.net** – A compliance monitoring tool tracking trial results reporting, estimating fines accrued due to non-compliance and subject to oversight action.
- **CMS ICD-10 Codes** – Provides disease-specific categorization that, when cross-walked, enables assessment of compliance trends across therapeutic areas.

An additional FDA approvals dataset was manually extracted and structured by the researcher; however, because the data remain incomplete and require substantial further cleaning, FDA approvals are positioned for future research rather than analyzed in the present study.

While each dataset contributes distinct information, the methodological contribution of this study lies in how these sources are integrated, as described below.

1.2.1 Significance of Data Integration:

While each of these datasets has been used independently or in isolation in prior research, no published study to the best of our knowledge, has comprehensively and systematically

merged or integrated them using both record-level matching and dataset-level aggregation within a single analytical framework. In this study, trial records were combined in two distinct but complementary ways to construct a harmonized longitudinal dataset.

First, records referring to the same clinical trial were joined across sources using shared identifiers to allow corresponding compliance indicators and study attributes to align at the individual trial level. Second, datasets were unioned where appropriate or necessary to append non-overlapping trial records across registries—thereby expanding coverage and creating a more complete aggregated trial population. Together, these sequential integration steps enabled construction of a unified, single dataset that preserves both record-level correspondence and dataset-level completeness across disparate sources.

Therefore, this study is among the first to create a harmonized dataset of ClinicalTrials.gov records, TrialsTracker.net compliance flags, and ICD-10–based therapeutic area indicators for evaluating long-term trends. Data integration enhances reliability of compliance appraisal and allows for deeper legitimacy-driven insights. This novel approach supports the study's ability to provide empirically backed insights for policy recommendations. Future research will extend this integrated framework by incorporating the FDA approvals dataset once fully curated.

1.3 Problem Statement

Despite clear federal regulations requiring timely disclosure of clinical trial results, non-compliance persists, creating material gaps in transparency, delaying medical advancements, and eroding public trust in research integrity. This persistent failure raises a deeper institutional question: why do organizations charged with advancing science fail to meet mandated reporting obligations, even under strengthened regulatory regimes? Drawing on Legitimacy Theory, this

study develops a predictive model to identify structural factors associated with on-time clinical trials results reporting. Non-compliance carries ethical, economic, and reputational consequences for commercial sponsors, academic medical institutions, and regulatory bodies alike. Accordingly, this study seeks to address the compliance crisis by examination of how regulative, cognitive, pragmatic, moral, and sociopolitical legitimacy pressures shape variation in reporting behavior.

Imagine: volunteering for a clinical trial, putting your trust in science… enduring months of uncertainty… hoping this investigational treatment might succeed where others failed…. But then – silence. No updates. No results. Nothing. This scenario is a painful reality for countless participants, reflecting a much larger issue: non-compliance with clinical trial transparency laws.

Results reporting is fundamentally an issue of research integrity, patient safety, and public trust. Nondisclosure of negative results may lead to biased clinical evidence, compromised patient safety, delays in critical medical advancements, and leaving consequential gaps in our knowledge base that actually affect patient care (Mehra & Grazette, 2020). Moreover, lack of FDA enforcement has led to a culture of selective adherence, where organizations weigh risks of non-compliance against business interests. Addressing this issue requires deeper understanding of systemic factors influencing compliance behavior.

A study published in *PLOS ONE* demonstrates data-sharing initiatives struggle due to institutional resistance to transparency and insufficient governance structures (Chen, Zhao, Cao, Petersen, Valente, & Cen, 2024). These findings indicate trial sponsors often cite concerns over competition, disputes regarding data ownership, or regulatory ambiguities as reasons for reporting delays, despite mandated timely disclosure requirements.

Additionally, financial implications of non-compliance are substantial. Recently, the FDA has begun issuing multiple Notices of Noncompliance (U.S. Food and Drug Administration, 2025), yet few penalties are subject to supervisory action. According to a 2020 study by DeVito et al., (2020), of Oxford University, published in *The Lancet* revealed a significant proportion of eligible trials remained non-compliant in posting their results, and over $63 billion in fines for non-compliance remain uncollected due to limited enforcement follow-through. Reluctance of regulatory agencies to impose financial consequences weakens deterrent incentives aimed at pushing compliance. Instead, a culture of selective adherence has been created, where organizations weigh risks of non-compliance against potential business benefits.

Non-compliance with clinical trial result reporting requirements presents a significant challenge for both business and research domains.

1.3.1 Business Problem

From a business perspective, non-compliance presents a critical risk for pharmaceutical companies, biotechnology firms, contract research organizations (CROs), and academic health centers (AHCs). Failure to report study outcomes may lead to substantial reputational repercussions, diminished public trust, and financial penalties – while also impacting investor confidence and long-term corporate valuation (IQVIA, 2024). The FDA has attempted to intensify its enforcement efforts, having issued "Notices of Noncompliance" to organizations that failed to meet reporting obligations, although financial penalties have been underutilized (2025). Such actions not only tarnish researcher and organizational reputation but also are designed to result in financial penalties, if pursued, could thereby affect investor confidence and market standing (2024). Despite regulatory mandates, financial incentives often outweigh compliance obligations, contributing to selective reporting behavior.

Additionally, lack of transparency resulting from such non-compliance can lead to dissemination of incomplete or biased information, which becomes embedded within the clinical evidence base, misleading investment decisions, and contributing to resource misallocation. Distorted investment advisories have potential to result in misguided business decisions. For example, failure to disclose negative results, adverse events, or unfavorable clinical findings could result in unnecessary capital expenditures on nonviable drug candidates. Conversely frank disclosure could result in a "no go" decision for a compound, sounding a death knell, and pose existential consequences for small biotech companies, which are disproportionately affected due to the early-stage nature of their research, as they are often reliant on limited funding rounds and capitalized for "one shot on goal" products (Czobor & Skolnick, 2011).

In medical research, non-reporting undermines integrity of our scientific evidence base. Unreported or selectively reported trial results distort the evidence base, and can lead to ineffective or potentially harmful clinical practice. This does not solely breach ethical obligations to trial participants but also hampers advancements in scientific and medical knowledge (Wise, 2020). The importance of timely and accurate reporting is emphasized by initiatives like the AllTrials campaign. This effort advocates for registration and reporting of clinical trials to ensure complete and unbiased evidence as the basis for drug development (Sense about Science, 2013).

Altogether, failure to report clinical trial results is an important issue affecting both business operations as well as research integrity. Addressing this issue is essential to sustain public trust, uphold ethical standards, and foster continued advancement of medical science.

1.3.2 Research Problem

While previous studies have examined regulatory compliance broadly, calculated fines assessed at inflection points, or explored within specific disease contexts, few have

systematically applied Legitimacy Theory to explore or explain underlying systemic drivers of non-compliance. Thus, theory-driven insights remain limited as to how longitudinal, combined, and segmented trial characteristics—such as funding source, study phase, geographic location, and therapeutic area—impact reporting behavior.

There is a gap in theoretically grounded analysis focus of results-reporting compliance, leaving limited insights into how longitudinal regulatory shifts, funding structures, and therapeutic areas shape reporting behaviors.. This gap constrains comprehensive comprehension of underlying forces underlying variation. Understanding these legitimacy-based determinants is key for policymakers, regulatory bodies and study sponsors who aim to enhance compliance. This study aims to address that gap.

Table 1.1

Research Questions, Focus, and Legitimacy Representation

RQ	***Focus***	***Type of Legitimacy Represented***	***Rationale***
RQ1 – *"How did key events, like the Final Rule and Seife v. HHS, influence FDAAA 801 compliance over time?"*	*Temporal regulatory predictive shifts*	***Regulative*** *(Scott, 1995)*	*Directly examines law, coercive pressure, and formal institutional change.*
RQ2 – *"What patterns emerge across therapeutic indications, funding source, trial phase, and geographic contexts?"*	*Cross-sectional institutional predictors*	***Pragmatic, Moral, and Cognitive Sociopolitical*** *(Kaganer et al., 2010) (Suchman, 1995)*	*Examines taken-for-granted field norms, organizational incentives, ethical expectations, and local enforcement & resourcing.*

Building on these defined business and research problems, the following research questions emerge to focus empirical examination of how regulatory shifts influence compliance with FDAAA 801 results-reporting requirements. These questions extend the problem statement

into a testable framework connecting regulatory milestones with organizational legitimacy behaviors. Table 1.1 summarizes analytical focus and theoretical grounding of the legitimacy framework guiding this study.

1.4 Research Questions

To formally address the research problem, we examine how evolving legal mandates and organizational forces shape transparency behavior. This study is guided by the following research questions:

1. How did key events, like the Seife v. HHS ruling and the Final Rule, influence FDAAA 801 compliance over time?
2. What patterns emerge across therapeutic indications, funding source, trial phase, and geographic contexts?

1.5 Purpose of the Study

This quantitative study examines how legitimacy-driven structural factors influence compliance with on-time clinical trials results reporting. Descriptive statistics, cross-tabulations with chi-square tests, and a binary logistic regression main-effects model are employed to evaluate reporting patterns. This study:

- Investigates compliance trends over a 18-year period (2007-2024)
- Analyzes key predictive variables, including funding source, trial phase, geographic location, and disease focus
- Determines how regulatory enforcement milestones influence compliance.
- Examines whether compliance rates vary by therapeutic area, particularly between oncology and. non-oncology trials.

- Identifies data strata revealing divergent compliance patterns and their organizational implications.
- Assesses how compliance patterns change over time to reflect shifts in legitimacy pressures.

By synthesizing data from multiple publicly accessible and validated sources, this research provides actionable insights for policy improvements, sponsor compliance efforts, and enhanced accountability in clinical trial transparency. Future research will extend these analyses by incorporating FDA approvals and more complex interaction and moderation models beyond the scope of the present dissertation.

1.5.1 Significance of the study

This study contributes to a broader discourse of trial transparency, regulatory responsibility, and ethical effectiveness. A lack of reporting consistency has led to incompletely informed clinical decision-making, adoption delays for new therapies, and investment waste (Rivero-de-Aguilar et al., 2024). Recent analyses revealed discrepancies between ClinicalTrials.gov records and journal publications were, in fact, not occasional but systematic. This raises concerns about compliance behaviors, how they are shaped, and demands an investigation of institutional and regulatory pressures.

Moreover, a study on consequences of clinical trial result disclosures found reporting transparency had direct implications for both biopharma valuations and investment decisions (Chen et al., 2024). Both regulatory bodies and investors increasingly rely on publicly available trial data as they assess viability of new treatments. Therefore, non-compliance is not just a concern academically – it affects business operations, market confidence, and credibility. In examining systemic legitimacy-based drivers of compliance, this study aims to generate

actionable insights which support policy positioning, monitoring enhancements, and an environment of accountability in clinical trial results reporting.

This study contributes to both theory and practice by:

- Introducing Legitimacy Theory within the clinical trial compliance research arena
- Providing evidence-based recommendations to inform regulatory bodies compliance oversight and accountability efforts.
- Offering practical insights to sponsors, regulatory agencies, and policymakers in order to optimize trial transparency and enhance compliance monitoring.
- Identifying key areas for future research, particularly regarding evidence-based compliance interventions.

Beyond simply articulating the regulatory gap, this research supports compliance improvement by identifying key factors influential to trial sponsor adherence to reporting requirements. Findings will benefit multiple stakeholders:

- Regulators - Offering data-driven insights to enhance corrective strategies.
- Study Sponsors – Who benefit from derivative insight to improve reporting strategy, by risk mitigation, strengthened credibility with regulators and the public alike, by providing guidance on overcoming compliance barriers.
- Public Investors and Private Equity Firms – Which are reliant on clinical trial transparency, by improving biopharma valuation transparency and informed decision-making (IQVIA, 2024).
- The Public at Large - Increase confidence in trial transparency and ethical study conduct.

Rather than approaching non-compliance solely through a punitive lens, this study seeks to drive awareness, inform policy recommendations, and help guide organizations toward as they

strive for more effective compliance strategies. Most importantly, this research supports patients and advocacy groups by promoting greater transparency in trial disclosures.

1.5.2 Need for Predictive Modeling

While prior research has identified and depicts isolated compliance factors, no study has integrated geographic, therapeutic, and funding-based dimensions into a predictive model using a large, integrated dataset of registered interventional trials. By developing a comprehensive framework connecting trial characteristics with compliance outcomes, this study provides an evidence-based foundation for improving compliance monitoring, timely submission, and targeted remediation strategies.

The present dissertation estimates a main-effects logistic regression model; interaction and moderation models are conceptually specified and data-ready and reserved for future post-defense research.

1.6 Theoretical Framework (Brief Overview)

Grounded in Legitimacy Theory, this study conceptualizes organizational compliance as a function of regulative, cognitive, pragmatic, moral, and sociopolitical, legitimacy (Suchman, 1995) (Kaganer, Pawlowski, & Wiley-Patton, 2010) (Scott, 1995)

- **Regulative Legitimacy** (Scott, 1995) – Explains compliance as enforced by legal mandates, penalties, and external pressures.
- **Cognitive Legitimacy** (Suchman, 1995) – Views compliance as an ingrained industry norm, influencing adherence behaviors.
- **Pragmatic Legitimacy** (Suchman, 1995) – Suggests compliance is strategic, benefitting organizations by preserving industry relationships and investor confidence.

- **Moral Legitimacy** (Suchman, 1995) – Links compliance to ethical obligations and public expectations.
- **Sociopolitical Legitimacy** (Kaganer et al., 2010) – States compliance is driven by legal mandates and external pressures.

This study integrates these dimensions into a conceptual model which predicts compliance status based upon legitimacy-based influences.

Thus, organizations comply not solely because they are legally required to (regulative legitimacy), but also because doing so is in alignment with industry norms (cognitive legitimacy), ethical obligations (moral legitimacy), or strategic benefits (pragmatic legitimacy) (Kaganer et al., 2010).

Application of Legitimacy Theory permits this research to examine how different clinical trial stakeholders – sponsors, regulators, and investors – respond to compliance requirements and interpret the FDAAA 801, the Final Rule (2017), and the Seife v. HHS ruling (2020).

This study investigates whether non-compliance is a weak enforcement function (regulative legitimacy), in consideration of competitive advantage (pragmatic legitimacy), or a simple norm from a broader institutional perspective (cognitive legitimacy).

Further illustrating this research framework, this study adopts the following conceptual model (Figure 1.1), which maps relationships between regulatory shifts, trial characteristics, legitimacy perceptions, and compliance outcomes.

1.6.1 Conceptual Model

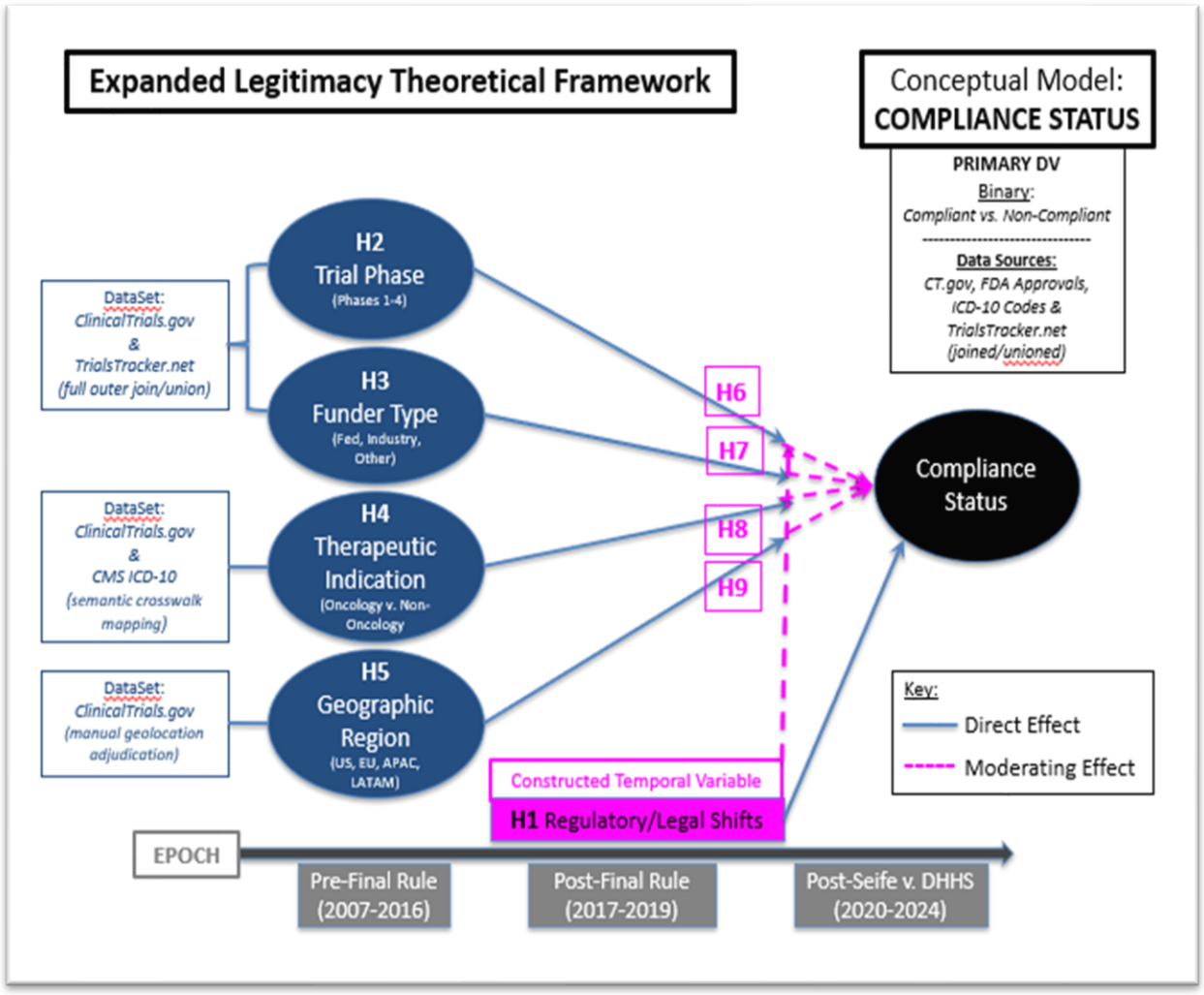

Figure 1.1

Conceptual Model of Clinical Trial Results Reporting Compliance Status

This model visually represents how different predictive variables – such as funding source, therapeutic area, study phase, and geographic region – inform compliance behavior through legitimacy-driven modes. A detailed discussion of this framework, which includes hypotheses and empirical support, is provided in the following Chapter 2.

1.6.2 Hypotheses Overview

To understand factors that influence compliance with ClinicalTrials.gov results reporting requirements, this study proposes a set of nine hypotheses. The hypotheses are grounded in legitimacy theory, which proposes organizations conform to cognitive, moral, pragmatic, regulative and sociopolitical expectations to maintain credibility in the eyes of key stakeholders.

The first set of hypotheses (H1–H5) examine direct effects of regulatory rulings, legal shifts, institutional factors, and trial characteristics on compliance behaviors. Specifically, this study posits compliance improves following key regulatory and legal interventions such as the FDAAA 801 implementation, the Final Rule, and the Seife vs. HHS decision (2020). It also investigates whether compliance varies by trial phase, funding type, therapeutic area, and geographic location – factors theoretically associated with different dimensions of legitimacy.

The second set of hypotheses (H6–H9) conceptually specifies the moderating role of regulatory and legal shifts. These hypotheses test whether influence of the independent variables on compliance is altered by regulatory rulings, reflecting how the evolving legal landscape shapes organizational behavior. Although data have been prepared to support future moderation analyses, the present dissertation empirically tests only the main-effects model (H1–H5); H6–H9 are reserved for post-defense research.

Together, these nine hypotheses provide a structured approach for exploring compliance drivers viewed through integration of a theoretical lens of legitimacy.

1.6.2.1 List of Hypotheses

This study advances nine hypotheses grounded in expanded Legitimacy Theory to examine determinants of clinical trial results reporting compliance. In the empirical chapters of this dissertation, H1–H5 are estimated using a main-effects logistic regression model, H6–H9 are

retained as a conceptual roadmap for future work. Hypotheses H1–H5 test direct effects of regulatory epoch, trial phase, funding source, therapeutic area, and geographic region on compliance behavior. Hypotheses H6–H9 specify moderation effects of regulatory and legal shifts across these same domains and are retained as a theoretically motivated extension for future research.

Table 1.2

Alignment of Legitimacy Dimensions, Research Questions, and Hypotheses

Legitimacy Type	***Key Hypotheses***	***RQ***
Regulative	H1, H6–H9	RQ1
Cognitive	H2, H6	RQ2 / (mod RQ1)
Pragmatic	H3, H7	RQ2 / (mod RQ1)
Moral	H4, H8	RQ2 / (mod RQ1)
Sociopolitical	H5, H9	RQ2 / (mod RQ1)

To clarify how these hypotheses cluster across theoretical domains, Table 1.2 summarizes alignment of legitimacy types with related hypotheses and research questions. This integrative view reinforces consistency between the study's conceptual and analytical frameworks.

In empirical chapters of this dissertation, H1–H5 are estimated by a main-effects logistic regression model; H6–H9 are retained as a conceptual roadmap for future work. Hypotheses, their associated legitimacy dimensions, and rationale are formally specified in Table 1.3.

Table 1.3

Hypotheses, Legitimacy Dimensions, and Rationale

Hypothesis	***Dimension***	***Rationale***
H1: *Compliance with ClinicalTrials.gov results reporting correlates positively with key regulatory/legal shifts.*	**Regulative**	Tests whether regulatory shifts (*Final Rule*, *Seife*) improved compliance over time.
H2: *Later-phase trials show higher results reporting rates than early-phase trials.*	**Cognitive**	Later phase trials being institutionalized, thus compliance a taken-for-granted expectation.
H3: *Government-sponsored trials demonstrate higher—but not total—compliance than commercially sponsored studies.*	**Pragmatic**	Publicly funded entities face stronger stakeholder expectations for transparency.
H4: *Oncology studies exhibit stronger adherence than non-oncology trials.*	**Moral**	High-visibility therapeutic fields face stronger ethical and societal expectations for transparency.
H5: *U.S.-based trials show higher compliance than trials in under resourced regions.*	**Sociopolitical**	Strategic compliance tied to regulatory exposure, jurisdictional oversight, and reputational advantage.
H6: *Regulatory shifts moderate relationship between trial phase and compliance, so later-phase strengthens post-regulatory change.*	**Cognitive & Regulative**	Tests whether institutionalized norms respond to renewed enforcement pressures.
H7: *Regulatory/legal shifts moderate the relationship between funding type and compliance, widening the gap between industry and government sponsors post-change.*	**Pragmatic & Regulative**	Examines interaction of organizational incentives with external enforcement.
H8: *Regulatory shifts moderate the relationship between therapeutic area and compliance, such that oncology shows stronger after change.*	**Moral & Regulative**	Tests whether ethical field norms strengthen under renewed coercive legitimacy.
H9: *Regulatory/legal shifts moderate the geography–compliance relationship, so U.S. trials show increasing compliance post-change.*	**Sociopolitical & Regulative**	Captures the interplay of enforcement, incentives, and legal jurisdiction.

Note: Legitimacy dimensions follow Scott (1995), Suchman (1995), and Kaganer et al. (2010).

A detailed discussion of these hypotheses, their theoretical foundations, and empirical justification is provided in Chapter 2. Chapter 4 focuses on empirical estimation of the main-effects hypotheses (H1–H5), with H6–H9 highlighted as a trajectory for future moderation work.

1.6.3 Definition of Key Terms

- **ClinicalTrials.gov**: The official U.S. clinical trial registry, managed by the National Institutes of Health (NIH), serving as central repository for clinical trial registration and results reporting. Sponsors are legally required to report study results within 365 days of study completion under the FDAAA 801 (2007).
- **CMS ICD-10 Codes**: A Center for Medicare & Medicaid Services (CMS) classification system for diseases and medical conditions. In this study ICD-10 codes are used to categorize and crosswalk clinical trials by therapeutic area (e.g., oncology vs. non-oncology) to assess compliance variations in reporting compliance by disease category.
- **Cognitive Legitimacy:** A dimension of Legitimacy Theory wherein compliance presents as an ingrained industry norm, rather than a conscious strategic decision (Suchman, 1995). This study examines whether certain trial types (e.g., late-phase) exhibit stronger reporting behaviors due to industry-wide norms or institutionalized expectations.
- **Compliance Status**: A binary measure (Compliant/Non-Compliant) indicating whether clinical trial results were reported to ClinicalTrials.gov within the legally mandated time limit. In this study compliance is defined as posting results within 365 days of primary completion. This outcome is operationalized in the dataset as CTG_Compliant_TF (1 = results posted within 365 days; 0 = results not posted within 365 days). Compliance is assessed based on the FDAAA 801 (2007), reaffirmed by the Final Rule (2017), and subsequent executive measures such as Seife v. HHS (2020).

- **FDA Approvals Database**: Regulatory dataset manually extracted from FDA approval documents, webpages, archives and compiled into a structured dataset by this researcher. This dataset is reserved for future research to examine if results reporting compliance correlates with regulatory approval; it is not analyzed in the present dissertation.
- **Food and Drug Administration Amendments Act, Section 801 (FDAAA 801) (2007)**: The first federal mandate requiring public disclosure of applicable clinical trial results within 365 days of study completion to ClinicalTrials.gov, aimed to enhance transparency, research integrity, and public trust in biomedical research.
- **Final Rule (Code of Federal Regulations, 2017)**: An FDA clarification and expansion of FDAAA 801, issued in response to persistent non-compliance. This Rule strengthened reporting requirements, specified civil monetary penalties (up to $10,000/day), and expanded scope of trials subject to reporting obligations.
- **Legitimacy Theory**: A theoretical framework explaining why organizations comply with regulations based on perceived legitimacy, emphasizing regulatory pressures, institutional norms, and societal expectations. This study applies Suchman's (1995) original legitimacy theory, Scott's (1995) Regulative Legitimacy, and Kaganer et al. (2010) expanded Sociopolitical Legitimacy dimension to analyze clinical trial reporting behavior.
- **Moral Legitimacy**: A dimension of Legitimacy Theory wherein compliance is driven by ethical considerations and societal expectations (Suchman, 1995). This study evaluates whether trials in high-stakes or high-visibility areas (e.g., oncology) exhibit distinct reporting behavior due to heightened public scrutiny.

- **Non-Compliance Fines**: Financial penalties assessed for failure to report clinical trial results in accordance with FDAAA 801 and the Final Rule. Initially set at $10,000 per day, fines were increased to $14,000 per day following Seife v. HHS (2020). Despite theoretical accrual of over $100 billion in fines, application remains limited.
- **Pragmatic Legitimacy**: A dimension of Legitimacy Theory wherein organizations comply based on self-interest, such as preserving favorable relationships with regulators, investors, and industry stakeholders (Suchman, 1995). In clinical trial context, sponsors might report results – or not - to preserve organizational viability, credibility. or market reputation to stakeholders.
- **Regulative Legitimacy**: A dimension of Legitimacy Theory describing compliance driven by legal mandate, enforcement means, and regulatory penalty (Scott, 1995). In this study, regulative legitimacy is operationalized through compliance with FDAAA 801, the Final Rule, and subsequent FDA administrative efforts.
- **Seife v. HHS ruling (United States District Court for the Southern District of New York, 2020)**: A landmark federal court decision that retroactively expanded results reporting obligations to include trials conducted between 2007–2017, and increased daily non-reporting penalties from $10,000 to $14,000 per day.
- **Regulatory Milestones**: Key policy events establishing and reinforcing clinical trial transparency requirements.
- **Temporal Context (Constructed Variable)**: A time-based analytical variable categorizing trials into Pre-Final Rule, Post-Final Rule, and Post-Seife v. HHS periods to assess whether reporting rates changed following major regulatory interventions.

- **Therapeutic Area Compliance Disparities**: Differences in compliance based on disease focus areas (e.g., oncology, neurology, cardiovascular). This study explores whether oncology trials demonstrate higher compliance due to heightened scrutiny, institutional and industry norms – and offers a novel study-specific database to support future therapeutic area analyses.
- **TrialsTracker.net**: A public compliance monitoring platform developed by researchers (DeVito et al., 2020) in collaboration with Oxford University and published in *The Lancet* . Their platform estimates accrued fines for non-reported and late-reported trials, and enhances transparency in global clinical trial results reporting.

1.6.4 Scope and Limitations

The scope of this study is limited to publicly available U.S.-registered clinical trials data from three primary sources: ClinicalTrials.gov, TrialsTracker.net, and CMS ICD-10 Codes. An additional FDA approvals dataset was curated for future research and is not included in the current analyses.

This does not measure sponsor intent, investigator motivation, nor qualitative organizational factors which may contribute to non-reporting behavior. Additionally, because this analysis is centered in U.S. regulatory frameworks governing FDA oversight, findings may limit generalizability to international compliance contexts. Future research should explore global regulatory regimes, cross-national compliance disparities, and internationally scalable solutions.

1.7 Summary

This chapter introduces the research problem, theoretical framework, and study significance, presenting key research questions and hypotheses which guide this research. It establishes the importance of clinical trial results reporting compliance and the role of

legitimacy-based factors in shaping adherence to regulatory mandates. We introduce Legitimacy Theory as this study's theoretical framework, identify gaps, and formulate hypotheses to explore trial characteristics, regulatory shifts, and institutional factors in how they shape compliance behaviors.

This research problem is examined from both business and research perspectives, illustrating financial, ethical, and transparency risks associated with reporting non-compliance. Integration of three public datasets supports our effort to identify patterns previously unexplored and inform improvement strategies. The integrated dataset also lays groundwork for future extensions that will add FDA approvals and more complex modeling beyond the main-effects logistic regression presented in this dissertation.

In Chapter 2, our literature review will delve deeper into:

- Historical context of trial reporting regulations and enforcement trends.
- Prior studies on compliance gaps, enforcement patterns, and legitimacy-driven behavior.
- Legitimacy Theory foundation, as it applies to regulatory compliance.
- Development of hypotheses and conceptual model to guide empirical analysis.

The next chapter will review relevant literature on compliance gaps, procedural trends, and legitimacy-based behaviors, setting stage for empirical analysis.

1.7.1 Organization of this Dissertation

This dissertation is organized into five chapters, each building upon the prior to provide a comprehensive examination of clinical trial result reporting compliance. This scaffolding is intentionally designed to guide a reader from foundational background and theoretical introduction, illustrating and illuminating methodology, findings, and implications derived from our study.

Chapter 1: Has introduced the research problem, theoretical framework, and study significance, presenting an outline of key research questions.

Chapter 2: Will present a comprehensive literature review, where we summarize prior research on clinical trial compliance, regulatory influence, and legitimacy-based frameworks – indicating where/if there are gaps or interdigitation.

Chapter 3: Will detail research methodology, including original and derivative data sources, statistical methodology, and applied analytical approach.

Chapter 4: Will present study findings, inclusive of statistical results, inferences, and thematic interpretations.

Chapter 5: Will discuss findings in broader context of existing literature, summary findings, and contributions to the body of theoretical research. We will conclude with appropriate policy implications, recommendations for practice application, suggested directional guidance, and proposals for future further research.

Chapter 2. Literature Review

2.1. Theoretical Foundation & Literature Review

This section establishes and develops the theoretical foundation guiding the study by integrating legitimacy theory within broader empirical research on situational regulatory compliance and organizational behavior. Drawing on an extensive interdisciplinary literature, this review moves beyond narrow, purely legalistic, deterrence-driven frameworks to examine a multidimensional perspective for understanding how regulative, cognitive, moral, and sociopolitical legitimacy mechanisms are interpreted, responded to, internalized, and ultimately shape compliance responses to FDAAA 801 over time.

The works synthesized in this section span foundational sociological theory, institutional and organizational scholarship, and applied regulatory research, to collectively inform conceptual framing of compliance as a legitimacy-seeking behavior. This synthesis provides insight as to how legitimacy-based behaviors emerge in response to shifting legal mandates, normative pressures, and field-level expectations—as well as operationalization of key constructs used in the study's empirical analyses.

Together, this systematically organized body of literature grounds the study's conceptual model. This section informs intellectual scaffolding for hypotheses and modeling strategy, and motivates selection of legitimacy dimensions examined empirically in later chapters.

2.1.1 Overview of Core Legitimacy Theories

Suchman (1995), Scott (1995), Kaganer et al. (2010)

Legitimacy Theory provides a structured framework for comprehending why organizations comply (or fail to) with regulatory mandates. Reasons that organizations do not comply with regulations are not only because they are legally required to do so. Instead,

compliance is shaped by how stakeholders perceive legitimacy in those mandates (Suchman, 1995). This study is grounded in Legitimacy Theory, which states compliance is influenced by perceived legitimacy of regulatory mandates, institutional norms, and stakeholder's expectations. Application of this framework enables our study to analyze how regulatory credibility, funding legitimacy, and institutional deterrence shapes clinical trial reporting.

Specifically, our research rigorously applies Legitimacy Theory to the context of clinical trial results reporting, drawing from a range of perspectives related to this framework. Our expanded framework incorporates:

- **Suchman's Legitimacy Theory (1995)**: Compliance behavior as shaped by Pragmatic, Moral and Cognitive Legitimacy.
- **Scott's Regulative Legitimacy (1995)**: Compliance driven by legal mandates and deference to disciplinary channels.
- **Kaganer et al.'s Sociopolitical Dimension of Legitimacy (2010)**: Expanded Suchman's (1995) Pragmatic Legitimacy dimension for application in global settings.

By applying this multi-faceted approach, our study will analyze how regulatory credibility, funding legitimacy, and institutional influence in clinical research results reporting.

2.1.2 Definition & Details of Theoretical Foundation

2.1.2.1 Suchman and Foundation

Legitimacy as defined by Suchman (1995), "*is a generalized perception or assumption that actions of an entity are desirable, proper, or appropriate within some socially constructed system of norms, values, beliefs, and definitions*." (p. 574). This framework is instrumental in understanding how regulatory mandates, institutional norms, and stakeholder expectations shape compliance behavior in clinical trial reporting. A distinction between strategic and institutional

legitimacy perspectives is reinforced, where organizations either actively manage legitimacy for advantage (strategic) or are constrained by prevailing company norms (institutional). Suchman identifies three primary dimensions of legitimacy:

- **Pragmatic Legitimacy**: Based on audience self-interest and direct exchanges,
- **Moral Legitimacy**: Reflects adherence to societal values and ethical expectations, and
- **Cognitive Legitimacy**: Signifies taken-for-granted norms; renders behavior as inevitable.

This study applies Suchman's (1995) framework to analyze the intersection of compliance with clinical trial regulations – and demonstrates how legitimacy logic influences controls and adherence to reporting standards. Legitimacy theory is not an academic exercise, rather it has deep roots grounded in solid firmament and foundational organizational research.

One of the earliest works that explicitly defined organizational legitimacy as a strategic necessity was completed by Dowling and Pfeffer (1975). The authors describe how legitimacy is managed through strategic organizational actions. They further argue organizations actively pursue legitimacy by aligning activities with societal expectation and deployment of strategic legitimation tactics, like symbolic associations or narrative framing. Institutional theorists further elaborate on legitimacy as both a constraint and resource, shaping organization's behavior as they influence long-term viability (Dowling & Pfeffer, 1975). Suchman (1995) built on this prior perspective to define legitimacy as a generalized perception that an entity's actions are proper, appropriate, or desirable within socially constructed systems of norms, values and beliefs.

Meyer and Rowan (1977) introduced an idea of organizations adoption of formal structure is not necessarily for efficiency's sake, rather to gain legitimacy by conforming to norms, rules and expectations that have been institutionalized. They argued organizations operate within environments which shape structures through "myths", which are defined as widely

accepted practices which become “taken-for-granted”. Myths confer legitimacy, ensure stability and garner access to resources, even when they’re decoupled from factual operational needs. Organizations adopt ceremonial structures in alignment with society’s expectations, thus reinforcing legitimacy in the public eye while maintaining loose coupling between day-to-day activities and formal policy. This foundational work establishes legitimacy concept as a core force in firm behavior and set stage for Suchman (1995) for refinement and categorization of legitimacy into cognitive, pragmatic and moral dimensions (Meyer & Rowan, 1977).

Building on Meyer and Rowan’s insights, DiMaggio and Powell’s (1983) insights explain how organizations within a given industry become increasingly similar via institutional isomorphism—forged and categorized by normative, mimetic, and coercive pressure. Over time, they argue, organizations do not merely strive for competitive advantage, instead they conform to dominant professional norms, structures, and rules in an effort to maintain legitimacy. Normative isomorphism is said to arise from professionalization and shared educational and experiential backgrounds, whereas mimetic isomorphism results from a sense of uncertainty driving organizations to mimic successful peers, and coercive isomorphism is believed to stem from regulatory pressure and legal mandates. This framework seeks to illustrate how legitimacy is simultaneously a driver and outcome of organizational homogenization, which Suchman (1995) later reinforces in his conceptualization of legitimacy as dynamic and shaped by external forces (DiMaggio & Powell, 1983).

In the interim Zucker (Zucker, 1977) laid empirical groundwork for institutional legitimacy, explaining how legitimacy is embedded in culture and organizations over time. This work expanded legitimacy as a social construct, forming a foundational perspective which emphasized legitimacy’s cognitive dimension. Accordingly, legitimacy, once established, is

maintained via cultural persistence rather than continuous justification. Zucker also indirectly connects to Suchman's (1995) pragmatic legitimacy proposing institutional practices persist because they serve a functional role within institutions. Further, her findings – though not explicitly related to moral legitimacy – suggest deeply ingrained norms influence perception of what is deemed ethically appropriate within the organizational environment. Rather she focused on institutional legitimacy and how legitimacy becomes take for granted (Zucker, 1977).

In 1991, Jepperson and Meyer wrote a major expansion on foundational elements of institutional legitimacy, creating a strong precursor for Suchman's (1995) work. In their textbook chapter they described institutionalization as a process and further explored persistence of legitimacy. The authors explored conceptualization of institutions, institutional effects, and institutionalism by presenting an argument that institutions are stable, self-reproducing and persistent social patterns without continual mobilization. They distinguished institutionalization from social pattern or action, and emphasized the role of structured expectations and behaviors via taken-for-granted norms. Institutionalism is framed as both a phenomenon and structural perspective, keying in on the high degree of social construct in institutions as well as their role in shaping organizations and societal structures (Jepperson & Meyer, 1991). This perspective aligns with Suchman's (1995) view of legitimacy as a fundamental rationale through which institutions maintain stability and influence organizational behaviors.

Collectively, this foundational literature establishes legitimacy as a socially constructed yet strategically managed condition via which organizations secure stability, acceptance, and access to resources by conforming to institutionalized norms, expectations, and regulatory pressures. Suchman's (1995) framework synthesizes and formalizes earlier insights by integrating strategic action (Dowling & Pfeffer, 1975), institutional conformity and decoupling

(Meyer & Rowan, 1977), isomorphic pressures (DiMaggio & Powell, 1983), and taken-for-granted cognitive legitimacy (Jepperson & Meyer, 1991; Zucker, 1977) into a coherent, multidimensional conception of organizational legitimacy.

2.1.2.2 Scott and Foundation

W. Richard Scott's Institutions and Organizations (1995) expands on Suchman's (1995) legitimacy theory by introducing a comprehensive framework for understanding institutional influences on organizations. Scott identifies three pillars of institutions – normative, cultural-cognitive, and regulative – with each providing a distinct basis for legitimacy.

The normative pillar is focused on values that define acceptable standards within society. Legitimacy derives from adherence to professional expectations and social standards. Institutions align practices with norms to gain stakeholder approval and support, emphasizing moral and ethical conduct. This aligns with Suchman's (1995) pragmatic legitimacy dimension. Scott's (1995) cultural-cognitive pillar mirrors Suchman's (1995) cognitive dimension and pertains to common understanding shaping reality perception. Legitimacy, from this perspective, is attained by organizational action which is congruent with shared beliefs related to their environment. This would include alignment with taken-for-granted assumptions within an industry.

This novel concept is of a regulative pillar which emphasizes formal rules, mandates, and sanctions organizations are obliged to follow. In this context, legitimacy arises from conformity to established regulation and nimble navigation operating within legal frameworks. This pillar insists on the paramount importance of adherence to rules and compliance with regulatory standards. Scott notes organizations gain legitimacy by conforming to external rules, guiding acceptable behaviors and ensuring order within the institution's environment (Scott, 1995).

Scott's (1995) institutional framework advances Suchman's (1995) theory by distinguishing the foundations through which organizations establish legitimacy. While Scott's normative and cultural-cognitive pillars parallel Suchman's pragmatic and cognitive dimensions, his regulative pillar introduces formal rules, legal mandates, and sanctions as a distinct legitimacy mechanism. This regulative perspective is further strengthened by Oliver's (1991) strategic response framework, which demonstrates how organizations actively negotiate, comply with, or resist institutional pressures—positioning regulatory compliance as a dynamic, legitimacy-driven process rather than a purely mechanical obligation.

Informed by the work of Oliver (1991), who defined how organizations respond to regulatory pressures, the regulative pillar provides a perspective supporting compliance legitimacy. She expands institutional theory by integrating it with resource dependency developing a typology of strategic responses to institutional pressures. She further categorizes responses along a continuum from passive conformity (acquiescence) to active resistance (manipulation), denoting confounding factors such as legitimacy, efficiency, external pressure, and organizational autonomy in determining strategic choices made. Her work acknowledges organizations do not merely comply with norms but actively negotiate, navigate, and sometimes resist legitimacy pressure. Introduction of strategic agency provides a nuanced understanding of how institutions balance pragmatic, moral and cognitive legitimacy considerations.

In 2013 Scott built upon his earlier work further refining his three-pillar model of institutions. Most relevant updates regarding regulative legitimacy have to do with interplay between formal governance structures and informal norm dynamics. Stress is placed on how legitimacy is conferred by alignment with evolving regulatory norms. He acknowledges regulative legitimacy as an evolving construct which instead, shifts in response to market forces

and technological advances. This dynamic perspective reflects recent trends in regulatory science, including adaptive models and risk-based compliance frameworks (Scott, 2013).

Institutional complexity is contemplated when considering compliance strategies. Highlighted is how organizations manage competing regulatory pressures by employing strategic drivers such as partial compliance, decoupling, or symbolic adherence. This connects with recent theories of institutional logistics, illustrating firms can manipulate regulative legitimacy for competitive advantage. Finally, their 2013 edition pays more attention to international regulatory legitimacy and how multinational corporations, global institutions and cross-border regulatory bodies establish legitimacy. Interestingly, Scott (2013) incorporates contemporary discussions on transnational governance, particularly including the healthcare sector.

2.1.2.3 Kaganer and Foundation

Further expansion of legitimacy theory springs out of Kaganer et al.'s (2010) work in the IT field, where they sub-fractionated Scott's regulative legitimacy pillar, to cultivate his sociopolitical legitimacy model. However, this thought stream is not solely informed by Suchman (1995) & Scott (1995). Rather it has deep collateral roots.

From a macro-sociological perspective – and early precursor to sociopolitical legitimacy—Habermas introduced the idea that legitimacy is contingent on continuous justification by governing bodies (Habermas, 1973). Legitimation crisis and public confidence in institutions is described as a decline in confidence in administrative functions, leaders, and institutions. This was an expansion on Max Weber's classical sociological foundation, proposing modern societies face crises of legitimacy when systemic structures fail to justify authority in a way that can be widely accepted by a governed person or institution (Weber, 1922/1978). Then he argued these types of crises occur due to institutions' failure to establish effective structures

that achieve goals, and highlighted inability or unwillingness to maintain similarly (Habermas, 1973). This work underlined importance of institutional credibility and public discourse in shaping compliance behaviors – directly relevant to regulatory adherence in clinical trials results reporting. By tracing theoretical lineage from Habermas to modern legitimacy frameworks, we gain a stronger conceptual foundation for understanding why clinical trial sponsors comply – or fail to – with reporting mandates. This prepares for future regulatory interventions prioritizing legitimacy rather than signaling.

Moving head in time, Beetham (1991) wrote from a political legitimacy position wherein he differentiated legality from legitimacy and argued legitimacy must be socially recognized, and not simply legally imposed. He established a foundation for considering legitimacy as a sociopolitical construct which extends beyond rules of formality. His work examined the central issue of legitimation of power in political theory and analyzed relationships between various contemporary political systems and legitimacy. Beetham's assertion was that laws only function if they align with norms and values. This work provided a framework for comprehending sociopolitical aspects external to an organization (Beetham, 1991). This work was widely influential in the 1990's and bridges a gap between Weber (1922/1978) and later expansions of legitimacy theory. Beetham still plays a critical role in theoretical evolution leading up to Kaganer et al. (2010). His contribution help explain why regulatory enforcement struggles, due to legitimacy crises emerging when laws fail to align with broader industry norms and during absence of voluntariness (Beetham, 1991).

In the interim Aldrich and Fiol (1994) examined the role of legitimacy in emergence of new industries, highlighting distinctions between cognitive and sociopolitical legitimacy. They argued new ventures faced heightened risk due to a lack of institutionalized norms, established

market structure, and stakeholder confidence. Entrepreneurs are thought necessary to actively construct legitimacy as they leverage symbolic language, engage in strategic alliance building, and foster collective industry efforts in order to gain acceptance. This work built on institutional and ecological theories, and provided a framework for understanding how legitimacy influences industry growth and survival, making it a foundational contribution to discussion of legitimacy within the body of organizational theories (Aldrich & Fiol, 1994).

Following up, Tolbert and Zucker (1996) summarized and extended legitimacy and institutional theory together, further developing legitimacy as a stabilizing force in regulation. They refined and modernized early legitimacy and institutional work and looked at institutionalization over time, pivoting legitimacy's role in persistence and change. Their work "The Institutionalization of Institutional Theory" examined development and evolution of institutional theory in organizational research, arguing institutional theory had yet to fully standardize key concepts and methods, leading to a diverse range of applications across the body of work. The authors then introduce a three-stage model of institutionalization – habitualization, objectivization, and sedimentation – to explain how organizational structure becomes widely accepted and ingrained over time. Their design is critical to Kaganer et al.'s (2010) sub-dimension of sociopolitical legitimacy, as it contextualizes how digital infrastructures evolve into institutional norms via a process of theorization and adoption across organizations.

These prior works paved way for Kaganer et al.'s (2010) formalization of sociopolitical legitimacy integration into Suchman's (1995) framework, arguing legitimacy – while an internal organizational concern – is also shaped by external societal forces, namely regulatory bodies and advocacy groups. Here they extended legitimacy theory into compliance contexts explaining why firms comply (or not) based upon institutional expectations and external pressures. So while

Suchman classified legitimacy into cognitive, moral and pragmatic dimensions, Kaganer et al (2010) identifies sociopolitical legitimacy as a distinct force where regulations and laws gain legitimacy through social acceptance and political reinforcement .

All of this matters for clinical trials results reporting compliance because regulatory frameworks, like FDAAA 801 function when institutions (e.g., FDA and NIH) maintain sociopolitical legitimacy. A key reason why non-compliance persists may be due to trial sponsors not seeing threats as a credible political priority. However, public pressure, journalistic exposure (e.g., Seife v HHS (2020)), and advocacy efforts (e.g., the AllTrials campaign (2013)) act as sociopolitical forces driving compliance – often far more effectively than threat of financial penalties alone or at all.

Collectively, these foundational contributions conceptualize legitimacy as a dynamic sociopolitical process rooted in public justification, institutional credibility, and political reinforcement rather than formal legality alone. Building from Weber and Habermas through Beetham, Aldrich and Fiol, and Tolbert and Zucker (1994; 1991; 1973; 1996; 1922/1978), this literature demonstrates how legitimacy is constructed, contested, and stabilized through social recognition and external pressures over time. Kaganer et al.'s (2010) sociopolitical legitimacy extension integrates these insights into Suchman's framework by explicitly accounting for how public visibility, advocacy activity, and political attention shape compliance behavior—making it especially well-suited for examining clinical trial results reporting in a highly regulated and publicly accountable domain.

2.1.2.4 Reconciling Legitimacy Frameworks: Suchman, Scott, and Kaganer

Although Suchman (1995) and Scott (1995) articulated legitimacy frameworks in the very same year, they each approached in address of distinct but complementary dimensions of

organizational behavior. Suchman conceptualized legitimacy as audience-based perception, distinguishing pragmatic, moral, and cognitive legitimacy to explain organizational actions are viewed as appropriate, desirable, or taken for granted. In contrast, Scott framed legitimacy as an institutional arrangement, with emphasis on regulative, normative, and cognitive pillars which structure compliance via rules, pressures, values, and shared meanings. Rather than represent competing models, their respective frameworks operate at different analytical levels: Suchman explains legitimacy is granted and interpreted by stakeholders, while Scott explains legitimacy is imposed and sustained through institutional systems.

While the integration of Suchman's perceptual framework and Scott's institutional pillars clarifies why regulatory mandates coexist with uneven compliance, these perspectives alone do not fully account for how legitimacy is shaped by public visibility, political attention, and external scrutiny. Kaganer et al.'s (2010) extension of legitimacy theory addresses this gap by introducing sociopolitical legitimacy as a distinct mechanism through which compliance behavior is influenced by regulatory salience, advocacy activity, and broader political signaling. In contexts such as clinical trial results reporting—where enforcement is limited but public accountability is high—this sociopolitical dimension is essential for explaining why formal rules translate into compliance for some organizations but not others.

This study integrates all three perspectives to examine formal regulatory mandates governing clinical trial results reporting persisting alongside widespread behavioral non-adherence. By pairing Scott's focus on regulative authority with Suchman's emphasis on legitimacy perception, our analysis accounts for both presence of reporting rules and selective, uneven compliance patterns observed in practice. Collectively, their perspectives reinforce how organizations navigate legitimacy through adaptation, persuasion, and alignment with prevailing

cultural frameworks—yet they stop short of explaining how political visibility and external societal pressure shape compliance behavior, a gap addressed by Kaganer et al.'s sociopolitical legitimacy extension..

2.1.3 Empirical Application of Legitimacy Theories

2.1.3.1 How legitimacy perceptions influence compliance choices

While Suchman (1995) and Scott's (1995) research demonstrates legitimacy concerns influencing organizational decision-making, particularly in regulated environments, Hall et al. draw examples from agricultural biotech and genomics in forestry, where core concepts about legitimacy processes and institutional response align with clinical trial results reporting. Their discussion of cognitive legitimacy (knowledge-based acceptance) and sociopolitical legitimacy (normative and political acceptance) mirrors how clinical research sponsors, regulators, and public perception of compliance mandates. The paper provides insights into barriers to technology adoption based on stakeholder perception is a useful parallel to regulatory compliance choices (Hall, Bachor, & Matos, 2014).

Thomas & Lamm (2012) empirically examined how organizations make decisions based on pragmatic, moral, and cognitive legitimacy perceptions – identifying these as core drivers of compliance behavior. Their findings on how legitimacy pressure – as opposed to strict coercion – shapes managerial decision-making in context of sustainability adoption and organizational compliance behaviors . Though their focus is on sustainability initiatives, these findings extend to regulatory compliance, as each domain requires organizations to balance external legitimacy demand with internal strategic priorities. This decision-making framework has direct application to choices in clinical trials results reporting, where institutions and study sponsors assess

compliance based on both legal requirements (regulative legitimacy), as well as ethical obligations (moral legitimacy), in addition to industry norms (cognitive legitimacy).

Cognitive legitimacy plays a vital role in organizational compliance decisions, influencing how decision- makers, interpret and respond to regulatory mandates. Richter and Arndt (2018) provide empirical evidence as to how organizations cognitively process legitimacy pressures and rationalize compliance expectations in regulated environments. Their study found that firms assess legitimacy expectations in not simply legalistic terms, but also relative to stakeholder expectations, strategic advantage, and reputational concerns. Richter and Arndt's findings reinforce the concept that compliance decisions are not dictated solely by legal mandates but also by how organizations perceive both legitimacy of regulation itself, as well as actual authority of the external constraint body. This aligns with Suchman's (1995) concept of cognitive legitimacy, which proposes compliance emerges from shared norms and ingrained industry expectations, as opposed to legal compulsion.

Prior research on hybrid organizations suggests legitimacy-building occurs iteratively via pragmatic, moral, and cognitive stages, reinforcing compliance behaviors over time (Rosser, Ilgenstein, & Sager, 2021). This framework, applied to clinical trials, implies initial compliance with reporting mandates may be driven by instrumental concerns (pragmatic), but over time, adherence norms may become embedded within organizational routines (cognitive).

Across diverse regulatory and organizational contexts, these studies show how compliance decisions are mediated by legitimacy perceptions rather than dictated solely by formal enforcement. Read as a whole, they highlight how cognitive acceptance, moral obligation, and perceived stakeholder expectations shape whether organizations internalize, delay, or resist compliance mandates—directly informing analysis of clinical trial results reporting behavior.

2.1.3.2 Empirical research on legitimacy-driven rule adherence

Legitimacy Theory posits compliance is influenced by not only regulatory mandates, but also by a perceived legitimacy of those mandates (Scott, 1995) and (Suchman, 1995). Although Suchman didn't immediately follow with an advanced publication exploring Legitimacy Theory, he did later collaborate with David Deephouse in writing a book chapter which further refined and situated legitimacy as a core concept in organizational institutionalism (Deephouse & Suchman, 2008). In this work, they took on tracing evolution of legitimacy from Weber's (1922/1978) classical sociological foundation through to contemporary institutional theories.

Extension to institutional pressures and external expectations – including roles of mimetic, normative, and coercive isomorphism (DiMaggio & Powell, 1983) as they shape legitimacy behaviors is made. They elaborate on the multi-categorical nature of legitimacy by refining Suchman's (1995) dimensions, and incorporating others scholarly contributions. Legitimacy typology is reinforced as dynamically changing over time – via gaining, maintaining, and repairing functions. In regulatory contexts decision-making aligns specifically where institutions assess whether or not compliance is advantageous or even necessary.

Their chapter explores further how legitimacy influences access to strategic position, vital resources, and institutional longevity, supports Suchman's (1995) argument that legitimacy functions can be adopted as either an opportunity or a constraint (Deephouse & Suchman, 2008). Of particular value in context of regulatory compliance contexts is expansion of cognitive legitimacy as related to "taken-for-grantedness", bolstering perspective that legitimacy is most powerful when deeply embedded to the point of being unquestionable. They then also differentiate hierarchical ranking (status) from reflective of past performance (reputation), clarifying legitimacy represents broad social acceptance. From their perspective legitimacy is

foundational for organizations to effective leverage of status and reputation, and enduring success. Finally, Deephouse & Suchman (2008) confirm and extend Suchman's original legitimacy framework (1995). Their collaborative analysis reinforces legitimacy is not merely a passive positioning, but an actively managed attribute for evolving phenomena – including institutions which weigh perceived benefits and constraints in shaping legitimacy.

Hooghiemstra explored how corporate social reporting functions as a structure for impression management. She reinforced legitimacy theory as a dominant framework by explaining how organizations engage in public disclosures. Her study argued companies respond to media pressure and public scrutiny as they shape narratives surrounding corporate legitimacy, especially in response to a crisis – such as an environmental disaster. These findings align with legitimacy-driven rule adherence and demonstrate firms attempt to maintain social acceptance via communication strategy instead of actual substantive behavior adaptation. This perspective is directly reflective of regulatory compliance in clinical trials where sponsors shape public perceptions of adherence to FDAAA 801 mandates via strategically placed and timed disclosures in place of true compliance (Hooghiemstra, 2000).

Looking at Hooghiemstra's findings, practically applied, Deegan et al. (2002) explored corporate social and environmental disclosure practices as influenced by legitimacy theory, specifically in response to stakeholder pressure and public expectation. Their study showed strategic communication of compliance from firms maintained legitimacy in keeping with social norms – even when actual adherence to ethical standards is variable. Broader patterns in behaviors, including selective disclosure and full transparency avoidance were noted

Reinforcing these findings, O'Donovan (2002) examined how organizations use environmental disclosure as a means of securing, maintaining and even repairing legitimacy in

response to external pressure. Again, through a lens of legitimacy theory, his study illustrated how companies frame disclosures strategically in alignment with social expectation. Further, they influence stakeholder perception of their own environmental responsibility. These findings highlight voluntary corporate reporting as a role in legitimization process, particularly in public-facing industries. This study provides empirical research and demonstrates how organizations navigate complex compliance strategies discursively.

Palazzo & Scherer (2006) put forth an argument that corporate legitimacy is not solely derived from either cognitive nor pragmatic acceptance but must be justified through public discourse, deliberation. Their study explores how organizations navigate legitimacy by responding to shifts in societal norms, especially in environments where governance structure is unstable or even contested. This position aligns with broader legitimacy-driven rule adherence as it highlights the role of communication in justifying compliance maintenance while evolving with regulatory and societal expectation. Their findings are resonant with clinical trial sponsors who continuously justify their compliance decisions on a complex stage of regulatory scrutiny and public trust.

Reverte examined determinants of corporate social responsibility (CSR) disclosure by Spanish listed firms (Reverte, 2009), through a lens of legitimacy theory. His study found firms with a higher CSR rating tended to be larger, have greater exposure in media, and operate in environmentally sensitive industries. This suggests CSR disclosure may serve as a legitimacy-enhancing tool. On the other hand, financial performance indicators such as leverage, and profitability are not shown to significantly influence CSR disclosure practice. These interesting findings support arguments that firms primarily engage in CSR reporting to maintain legitimacy and to respond to stakeholder expectations, and not for direct financial benefit.

Legitimacy concerns shape corporate governance practices, particularly in uncertain regulatory environments. Schneider & Scherer (2013) examined how corporate governance in a risk society emphasizes challenges for business operating in weak regulatory environments. They highlight how firms must actively address legitimacy issues directly, rather than passively or reactively relying on regulatory frameworks. Their findings illustrate how firms operating in regulatory gaps must engage in proactive legitimacy management in order to avoid reputational risk and maintain stakeholder trust.

In context of clinical trial results reporting, weak regulatory oversight creates similar dynamics, where sponsors may exploit authority exercise gaps bypassing or delaying compliance obligations. Comparatively, corporations in loosely regulated industries engage in voluntary governance measures, stakeholder engagement, and strategically work to build legitimacy. This aligns with sponsors, especially those who operate across inconsistent oversight jurisdictions, wherein they may mirror opportunistic behavior observed in corporate governance – selectively complying with reporting mandates.

Hall et al.'s (2014) cognitive and sociopolitical framework for overcoming barriers to legitimization can be mapped to challenges in ensuring clinical trial compliance. Their research supports the idea compliance is shaped by institutional expectations, regulatory credibility, and stakeholder engagement. This paper contributes empirical support to the notion compliance behaviors are contingent on perceptions of legitimacy rather than purely regulatory mandates. Just as biotech and genomics firms must navigate public and institutional skepticism, clinical trial sponsor must work within regulatory constraints shaped by broader societal expectations.

Directly relevant to clinical trial sponsors, who weigh legitimacy of regulatory mandates, such as the Final Rule (2017) and Seife v. HHS (2020), against potential risks and benefits of

non-compliance. Unlike traditional monitoring models, legitimacy-based compliance proposes organizations do not simply follow regulations because of legal requirements but because they perceive compliance as necessary, beneficial, or burdensome within their own strategic framework. Further, Richter & Arndt highlight legitimacy-based compliance is variable and based on how organizations balance external regulatory pressures with internal strategic goals. Focus on corporate social responsibility (CSR) compliance is parallel to results reporting compliance as both require organizations to navigate legitimacy expectations as they consider institutional norms and operational constraints. On the other hand, while CSR compliance is often voluntary, clinical trial reporting is legally mandated–making my own study's focus on regulatory legitimacy controls particularly salient.

By interrogating how decision-makers cognitively process legitimacy expectations and what factors influence choices to conform or resists compliance pressures, this study builds on cognitive legitimacy framework assessing whether clinical trial sponsors comply based on legitimacy concerns as opposed to strict requirements. Richter & Arndt's (2018) findings provide a foundational empirical bases for better understanding how perception of regulatory legitimacy shapes decision-making in compliance contexts – a central inquiry of this dissertation.

Legitimacy of industry self-regulation (ISR), distinguishing between pragmatic and moral legitimacy was studied by Bowen in (2019). In this study pragmatic legitimacy was based on self-interest calculations, and moral legitimacy was based on moral approval. The author critiqued existing ISR schema and argued these fail to achieve stated public policy objectives and may, in fact, serve to reinforce industry control over governance. Bowen highlighted tensions between pragmatic and moral legitimacy, where ISR is used to preempt strict governmental oversight instead of attainment of genuine compliance. Their analysis proves relevant to clinical

trial transparency as industry-driven compliance may likewise prioritize corporate interests over regulatory adherence (Bowen, 2019).

Xu and Hsu (Xu & Hsu, 2020) examined how perceptions of legitimacy impact compliance behaviors in organizational settings, where organizations deploy monitoring systems, finding employees were more likely to adhere to workplace security policies when they believed monitoring systems were legitimate . These findings align with Scott's (1995) conceptualization of regulative, normative, and cognitive-cultural legitimacy – reinforcing the idea of legitimacy-driven perception and how it shapes compliance behavior across industries. The study provides empirical support for broader legitimacy-compliance implications, where individuals are less likely to resist compliance systems when they view them as legitimate. This framework is directly applicable to clinical trial sponsors, who assess legitimacy of compliance mandates prior to choosing whether to adhere to FDAAA 801's requirement.

Across regulatory and governance contexts, these studies demonstrate where organizations often respond to compliance demands through legitimacy-preserving strategies rather than full rule adherence. When enforcement is weak or ambiguous, firms rely on disclosure, narrative framing, and selective transparency to manage external scrutiny—patterns that closely parallel observed behaviors in clinical trial results reporting.

2.1.3.3 Legitimacy as a Strategic Resource in Organizational Adaptation

Legitimacy plays a critical role in organizational adaptation, especially for hybrid organization which integrate social and financial objectives. Cetindamar & Ntim (2018) established how regulatory legitimacy through legal structures such as Benefit Corporations (BCs) are designed to embed social and environmental commitments within a for-profit framework. Their study highlighted organizational challenges faced when aligning legal

mandates with actual practices. Emphasized is that while legal status might initially provide a foundation for legitimacy, sustained legitimacy requires an adherence to principles of clearly defined social purpose, transparency, and accountability. They found, despite formal regulatory frameworks, many BCs fail to meet reporting and transparency expectations. This, in turn, weakens perceived legitimacy and illuminates broader strategic implications where regulatory legitimacy as a standalone is insufficient. The authors state organizations must proactively engage in legitimacy-building behavior in order to maintain stakeholder trust and success navigation of institutional pressures (Cetindamar & Ntim, 2018)

Roussy et al. provide empirical evidence of how organizations proactively manage legitimacy in response to external regulatory and financial pressures. Their study of community health organization mergers highlights how pragmatic, moral, and cognitive legitimacy concerns drive institutional adaptation strategy (Roussy, Russell, Livingstone, & Riley, 2021). These findings are directly applicable to clinical trial sponsors, who face similar pressures in compliance with FDAAA 801 and its supervision measures. Rather than view compliance as purely regulatory, sponsors may strategically engage with legitimacy-driven behavior to maintain industry standing, stakeholder trust, and financial viability.

Catenaccio explores how corporations in contested industries employ discursive strategies to construct and maintain legitimacy amid public and regulatory scrutiny. Their study demonstrated organizations do not simply react to external legitimacy pressures but actively shape them through strategic messaging and narrative framing (Catenaccio, 2021). These insights are applicable to clinical trial sponsors who, similarly, engage in legitimacy management. This, through proactive compliance effort or via strategically positioning of non-compliance as operational necessity. Just as agri-biotech firms frame practices to gain legitimacy, clinical

research sponsors have ability to shape public and regulatory body perception – mitigating reputational risk associated with non-compliance.

Collectively, this literature shows legitimacy is not conferred by legal status or regulatory designation but must be continuously reinforced through strategic adaptation, transparency, and narrative alignment. In environments marked by regulatory complexity or contested oversight, organizations leverage legitimacy as a resource to navigate compliance expectations while protecting reputation and operational flexibility.

2.1.4 Legitimacy as Related to Clinical Trial Reporting Compliance

Legitimacy theory provides a critical lens to interpret why clinical trial sponsors comply with or disregard reporting mandates. According to Suchman's (1995), seminal work legitimacy is a generalized perception that an entity's actions are appropriate or desirable within a socially constructed system of norms, values, beliefs and definitions. This framing helps explain how clinical trial sponsors, particularly those in the biopharmaceutical sector, are influenced not only by regulatory mandates but also as a strategy for moral and pragmatic alignment with broader societal and stakeholder expectations – including regulators, funders, and the public – regarding transparency and ethics

Scott's (1995) institutional theory complements this view by articulating how organizational behavior is shaped by legitimacy. He categorizes legitimacy into three institutional pillars: regulative, normative, and cultural-cognitive forces. This triad framework provides a robust framework for analyzing how clinical trial sponsors may view transparency as a way to align with formal rules and legal obligations, professional standards and stakeholder norms, and shared understandings of good science and cognitive templates that define "how things are typically done" within credible research enterprises (cultural-cognitive).

Kaganer et al. (2010) further extend these legitimacy frameworks to information systems in healthcare by demonstrating how IT innovations – such as computerized physician order entry – must be framed as legitimate through institutional alignment, strategic messaging, and stakeholder persuasion. Their research findings are equally applicable and transferable to clinical trial reporting technologies and practices, which must be perceived as both operationally sound and ethically necessary in order to be widely adopted and complied with.

In the aggregate, these perspectives position clinical trial reporting compliance as a legitimacy-driven behavior shaped by regulatory authority, professional norms, and public accountability. When reporting requirements are perceived as aligned with ethical standards, institutional expectations, and societal trust, compliance is depicted as becoming more likely—even in the absence of strong enforcement.

2.1.4.1 Application of Legitimacy to Clinical Trial Compliance

Zucker's (1977) classic framework on institutionalization emphasizes compliance behaviors become entrenched and taken-for-granted over time. Her text suggests that as ClinicalTrials.gov norms mature to be more persistent, we should expect rising baseline compliance – suggesting consistent compliance is more likely once such behavior becomes habitual within trial management structures. Zucker reinforces this through the idea that institutionalization embeds rules and norms into organizational routines – unless undermined by weak enforcement or competing norms.

Deephouse and Suchman's (2008) synthesis argues regulative legitimacy arises when companies conform to formal expectations imposed by legal and regulatory bodies. They show institutional expectations shape organizational action. Applied to clinical trial contexts where sponsors face reputational and financial risks for noncompliance. This suggests sponsors pursue

FDAAA 801 compliance not solely to avoid penalties, but to maintain solid standing in a legitimacy economy governed by formal and informal norms.

Greenwood et al. emphasize organizations regularly navigate multiple, coexistent institutional logistics which shape legitimacy-seeking behaviors in complex fields. In context of clinical trial reporting, this multiplicity explains how compliance efforts – while reactionary to formal regulation (e.g., FDAAA 801) – also affords satisfaction of broader expectations from scientific, public, and policy stakeholders. The authors highlight how legitimacy is context-dependent and often negotiated across layers of moral and pragmatic rationales. This makes it particularly applicable to a multi-stakeholder environment of clinical research compliance. Their comprehensive volume helps explain how institutions internalize pressures and act in accordance with both unwritten expectations and formal rules, offering a theoretical grounding for sponsor variation in reporting compliance behaviors (Greenwood, Oliver, Suddaby, & Sahlin, 2008).

Kaganer et al. (2010) present legitimacy-building as a strategic, discursive act where actors frame innovations – like reporting platforms – as trustworthy, essential, and aligned with prevailing institutional vision. This insight is transferable to how trial sponsors shape compliance behaviors in pursuit of sociopolitical legitimacy within the community.

Scott (1995) identifies the regulative pillar and captures how institutions are rooted in rules, sanctions, and authority, thus comply due to coercive approaches. This directly maps to the FDAAA 801 requirement for ClinicalTrials.gov reporting. Compliance, in this view, is shaped by credible threat of legal action. Yet Scott also emphasizes normative and cognitive dimensions, helping to explain variation in compliance across geography and sponsor type even under uniform legal standards.

The FDA's Notices of Noncompliance and Civil Money Penalty Actions (2024) further illustrate the enforcement (regulative) leg of legitimacy. These noncompliance notices provide concrete examples of state statutes. Publicly disclosed actions increase coercive pressure and signal that trial sponsors are being held accountable to federal transparency standards. This signals increased willingness to enforce compliance through financial penalties, thereby enhancing salience of regulative legitimacy.

Morgan Lewis's (Kimbrell & Lawless, 2025) legal blog further frames FDA sanctions wherein firms interpret recent FDA actions as a potential shift in regulatory posture. In their blog post, an evolving compliance environment is illustrated, raising awareness among industry stakeholders about escalating risk for nonreporting. This external framing – that failing to comply risks reputational and legal legitimacy loss – reinforces a perception that compliance is not merely voluntary but expected.

To align theoretical framing with our empirical main effects model, this dissertation adopts a refined legitimacy-dimension mapping informed by literature and refined through committee guidance. Regulative legitimacy is operationalized through temporal shifts (epoch categories). Cognitive legitimacy underlies expectations that later-phase trials adhere more consistently to reporting norms. Pragmatic legitimacy is tied to sponsor type, where commercial versus government entities face distinct accountability pressures and reputational incentives. Moral legitimacy is represented by therapeutic area, capturing institutionalized expectations regarding scientific rigor, ethical obligations, and visibility. Sociopolitical legitimacy functions as an overlay for geographic region, where varying regulatory infrastructures shape compliance feasibility. These mappings directly inform interpretation of the main effects logistic regression model used in this study.

In sum, these perspectives position clinical trial reporting as an outcome of institutionalized norms, regulative authority, and sociopolitical signaling rather than legal mandate. When enforcement is weak or legitimacy signals are ambiguous, compliance fails to become taken for granted—resulting in persistent variation despite formal reporting requirements.

2.1.4.2 Why Legitimacy Theory is relevant for clinical trial compliance

Beetham (1991) argues legitimacy in governance depends on conformity to established rules, justifiability by shared beliefs, and expressed consent by those governed. Thus, derived from legality, common values, and compliance. These three components map cleanly onto compliance with trial reporting and supports the idea that trial sponsors seek legitimacy from multiple audiences—including regulators, patients, and funders—each applying different criteria. His model offers a bridge from philosophical underpinnings of legitimacy to actionable, empirical frameworks for understanding compliance failures.

Though focused on startups, Zimmerman and Zeitz (Zimmerman & Zeitz, 2002) categorize pragmatic, moral, and cognitive legitimacy as strategic assets organizations deliberately cultivate to gain stakeholder support and access resources. This work is relevant for its categorization of legitimacy types and their strategic utility – paralleling how trial sponsors can build legitimacy to attract institutional partnerships and secure funding. Although their focus is on entrepreneurial ventures, similar principles apply to clinical trial sponsors, who must build legitimacy to satisfy legal mandates like FDAAA 801 while meeting goals of public trust. In this context, compliance becomes a means of signaling institutional credibility and alignment with normative expectations. This highlights how legitimacy functions both as a regulatory and strategic imperative in clinical research.

Suchman (1995) remains foundational in delineating moral, pragmatic, and cognitive legitimacy, which together reflect stakeholder-driven rationale for why organizations strive to "do the right thing" beyond just legal requirements. While Kaganer et al. (2010) emphasize importance of institutional entrepreneurs who strategically align with prevailing vision and norm vision narratives to generate legitimacy. Contextually, in the clinical trials arena aligning reporting practices with societal demands for transparency and ethical research participation enhances legitimacy of sponsors, especially in a post-pandemic research environment that demands greater accountability.

Some organizations comply with clinical trial results reporting rules not only because it's ethically right (moral legitimacy) but also because it enhances reputation and stakeholder goodwill (pragmatic legitimacy). In the high-stakes context of clinical trials, not reporting may offer short-term strategic advantages (e.g., hiding unfavorable data), but does so at the cost of long-term reputational risk. This tension between ethics and strategy (values vs. utility) is a central theme in legitimacy theory and is explored in contemporary research as outlined in institutional perspectives on legitimacy by Greenwood et al., (2008) where organizations balance external pressures with internal value systems.

Crawford (Crawford, 2016), in studying homeopathy's marginalization within biomedicine, shows how lack of moral legitimacy can erode stakeholder trust – even during existence of legal compliance. She further shows how actors in disenfranchised or contested biomedical domains lean heavily on moral legitimacy to justify their position in a broader scientific ecosystem. This dynamic resonates in clinical trial reporting, especially where funders justify noncompliance based on internal logic or cost-benefit reasoning. This is analogous and

instructive for study sponsors who might meet formal reporting requirements but fall short of broader public expectations for true transparency.

Islam et al's research (Islam, Cooper, Haque, & John Jones, 2022) specifically examines how moral legitimacy (values-driven) and pragmatic legitimacy (utility-driven) interact to shape organizational compliance. They articulate a distinction between moral legitimacy (doing what's ethically right) and pragmatic legitimacy (doing what's strategically advantageous). Their work highlights that adherence to trial reporting expectations may be driven as much by reputational incentives as by intrinsic ethical commitments. This balance is especially salient in clinical trials, where failing to report results may offer short-term gains but long-term reputational risk.

This subset of studies show compliance with clinical trial reporting mandates reflects a balancing act between legality, ethical obligation, and strategic self-interest. Legitimacy theory therefore offers a powerful lens for explaining why sponsors may selectively comply, delay, or resist reporting requirements even when legal rules are clearly defined. Therefore, legitimacy theory is the right lens—as enforcement alone can't explain the phenomenon of reporting.

2.1.5 Additional Theories Supporting Compliance Research

While legitimacy theory provides conceptual focus for this study, several other compliance-relevant theories offer valuable alternate perspectives. These frameworks—particularly those rooted in regulatory economics, institutionalism, and responsive regulation—enrich our understanding of why organizations comply (or fail to comply) with reporting mandates. Though not adopted in this paper's predictive model, these theoretical lenses inform a broader landscape of compliance behavior in clinical research.

2.1.5.1 Regulatory Economics & Enforcement: Cultural or Cost-Benefit Compliance

Stigler (Stigler, 1971), in "The Theory of Economic Regulation," argues that regulation often serves the interest of those regulated, instead the public. Their perspective questions a purely altruistic motivation for compliance and provides a lens through which to view sponsor behavior in relation to regulatory requirements. Table 2.1 summarizes key regulatory economics and penalty theories that conceptualize compliance as a function of cost–benefit calculation, deterrence, and governance credibility, providing important context for understanding why reporting compliance may persistently lag under weak or inconsistent control regimes.

Peltzman's (Peltzman, 1989) Economic Theory of Regulation asserts compliance emerges from a rent-maximizing equilibrium negotiated between stakeholders and political agents, rather than moral imperative. This cost-benefit approach explains why compliance is more likely when risks associated with noncompliance outweigh potential gains.

Ayres & Braithwaite (Ayres & Braithwaite, 1992) advance the Theory of Responsive Regulation and provide a regulatory pyramid where persuasion escalates to sanctions when cooperation fails. While their work embraces a dynamic control strategy, it also aligns with legitimacy theory by noting reputational capital organizations build via voluntary compliance.

Sutinen and Kuperan (Sutinen & Kuperan, 1999) offer a Socio-Economic Theory of Regulatory Compliance that integrates economic incentives with social norms, trust, and touches on legitimacy. Their model acknowledges that institutions and individuals – while operating on cost-benefit calculations – are also dependent on perceptions of fairness and legitimacy. This intricately links to moral and cognitive legitimacy drivers discussed in this paper.

Polinsky and Shavell (Polinsky & Shavell, 2000) present a foundational Economic Theory of Public Enforcement of Law, which asserts rational actors weigh expectations of cost

of penalties against hidden benefits of non-compliance. This calculus-based model highlights how weak corrective mechanisms, such as limited FDA penalties, might foster strategic underreporting of clinical trial results.

Fiene (Fiene, 2016) introduces the idea of a Regulatory Learning Model where compliance is conceptualized as an evolving organizational educational process, emphasizing that penalties alone are insufficient motivators of sustained compliance behavior. This work critiques compliance frameworks which are overtly reliant on deterrence, and emphasizes a need for reputational-driven motivators and learning-based mechanisms in shaping organizational responses to regulation. Building on this foundation, Fiene takes it a step further in development of his Theory of Regulatory Compliance, arguing substantial—rather than absolute—compliance represents a more practical and effective approach to public policy objectives. Drawing on data from over 10,000 service facilities, his work supports a compliance model driven by risk-based monitoring, than with uniform following of rules (Fiene, 2019). More recently, Fiene extends this perspective by explicitly addressing diminishing returns to compliance intensity and advocates for scalable, integrative monitoring approaches, reinforcing the view that regulatory effectiveness depends more on strategically targeted oversight, than maximal enforcement ((Fiene, 2023). The intersection of this set of contributions complement legitimacy-based explanations of compliance by highlighting the role of organizational learning, risk differentiation, and enforcement constraints in shaping observed compliance behavior.

Hossfeld's work positions remediation as a form of Managerial Sanction Theory whose legitimation offers a sociological take on cost-avoidance behaviors mirroring economic rationale. Here they present enforcement as a control strategy, positioning noncompliance as a rational

decision—supporting compliance as calculative behavior. Although informative, it veers from stakeholder perceptions captured holistically by Legitimacy Theory (Hossfeld, 2018).

Mehra and Grazette's (2020) "Untimely Trial Publication" frameworks study depicts delayed publication of clinical trial results within a risk-management framework, arguing organizations assess reputational exposure, penalties, and funding pressures in determining when and whether to report clinical trial outcomes. Notable, this work does not consider Legitimacy Theory, and was published prior to most recent relevant rulings, limiting its applicability to the current implementation context but offers useful conceptual groundwork.

Punctuated equilibrium theory, as articulated in public policy scholarship, provides an important lens for understanding and helps explain abrupt regulatory shifts following prolonged periods of institutional stability. Building on the foundational work of Baumgartner and Jones (Baumgartner & Jones, 1993), Matzke (Matzke, 2020) illustrates how policy systems typically evolve incrementally but can experience rapid transformation when triggered by exogenous shocks, salient events, or heightened public and political attention. Within the context of regulatory compliance, this perspective is particularly relevant for interpreting dramatic inflection points—such as major legislative reforms or court rulings—that recalibrate enforcement expectations and organizational behavior. Although punctuated equilibrium theory does not explicitly theorize legitimacy mechanisms, it complements legitimacy-based explanations by clarifying *when* and *why* compliance environments shift abruptly, thereby shaping the conditions under which regulative legitimacy pressures intensify and compliance behavior changes discontinuously rather than gradually.

Table 2.1

Regulatory Economics & Enforcement Theories

Author(s) & Year	***Theory Referenced***	***Summary***	***Relevance to Compliance Research***
Stigler (1971)	Economic Theory of Regulation	Regulation benefits regulated rather than the public; challenges assumptions of altruistic compliance.	Critiques assumptions of sponsor compliance driven by public good; explains self-interest.
Peltzman (1989)	Economic Theory of Regulation after Deregulation	Compliance arises from negotiation between stakeholders balances cost and control.	Explains compliance increase when perceived risk outweighs noncompliance benefit.
Ayres & Braithwaite (1992)	Responsive Regulation	Escalating enforcement model, persuasion to penalty; values reputational capital.	Highlights dynamic between voluntary compliance and deterrence.
Sutinen & Kuperan (1999)	Socio-Economic Theory of Compliance	Integrates incentives, norms, & legitimacy; highlights fairness and trust.	Aligns closely with moral/cognitive legitimacy frameworks.
Polinsky & Shavell (2000)	Economic Theory of Public Enforcement	Rational actors weigh costs of penalties vs gains of noncompliance.	Explains underreporting where penalties are low; examines deterrence vs. compliance
Fiene (2019)	Treatise on Theory of Regulatory Compliance	Compliance evolves via stakeholder pressure and reputation, not penalties.	Critiques overreliance on deterrence; builds on responsive regulation.
Fiene (2023)	Public Policy Theory of Diminishing Returns	Advocates for risk-based monitoring and partial compliance strategy.	Supports monitoring-based approach over rigid rule-following.
Matzke (2020))	Punctuated Equilibrium Theory (Public Policy variant)	Institutions craft policy gradually.	Rapid epoch punctuation by profound events; applicable to driving dramatic shifts.
Miceli & Mungan (2021)	Economic Theory of Optimal Law Enactment & Enforcement	Explores interaction of rule costs, monitoring, and strategic behavior.	Explains compliance gaps in weakly enforced regimes; evolution of deterrence theory.

Miceli and Mungan (Miceli & Mungan, 2021) develop an economic model of optimal law execution, balancing enactment and application. Focus is on interplay between rule

enactment costs, monitoring efficacy, and strategic responses by regulated entities. This analysis reinforces how compliance gaps often reflect rational responses to under-enforced regulations.

Ramachandran et al. (Ramachandran, Morten, & Ross, 2021) in "Strengthening the FDA's Enforcement of ClinicalTrials.gov Reporting Requirements" evaluate weak operationalization efforts and argue for more structured penalties – reinforcing how capped costs reduce incentive to comply. Their study empirically examines FDA's post-market administrative processes and supports action-focused models, wherein compliance is treated primarily as a full function of regulatory robustness. In doing so the authors reveal considerable gaps that undermine deterrence. Their findings suggest even when transparency rules exist, weak or inconsistent procedures can lead sponsors to rationalize non-compliance as a low-risk decision – but then stops there – a limitation opening the door for the present analytical research study.

Comprehensively these frameworks conceptualize compliance as a function of enforcement strength, economic incentives, learning effects, and regulatory design, offering important insights into why noncompliance may persist under weak oversight regimes. However, because these approaches largely assume rational cost–benefit calculation or escalating enforcement, they do not fully account for legitimacy-based perceptions, reputational considerations, and institutional expectations shaping clinical trial reporting behavior in practice.

2.1.5.2 Institutional Theory: Norm-driven behaviors across organizations.

Table 2.2 summarizes foundational institutional theory contributions that explain how norm-driven behaviors become embedded within organizations, providing context for understanding how clinical trial reporting practices may persist independent of formal incentive.

Table 2.2

Institutional Foundations of Norm-Driven Compliance Behavior

Author(s) & Year	***Theory Referenced***	***Summary***	***Relevance to Compliance Research***
Zucker (1977)	Institutionalization in Cultural Persistence	Describes how behaviors become normalized and persistent through shared meaning and routine practice.	Suggests compliance can become habitual once legitimacy norms are embedded in organizational culture.
DiMaggio & Powell (1983)	Institutional Isomorphism	Organizations conform through coercive, mimetic, and normative forces within their fields.	Describes compliance as a convergence of conforming to accepted norms and expectations of legitimacy.
Jepperson & Meyer (1991)	Institutional Effects Theory	Institutions shape patterned, automatic behaviors through internalized rules and expectations.	Explains how reporting duties become routinized within a regulatory system.
Beetham (1991)	Social-Scientific Concept of Legitimacy	Legitimacy stems when power is exercised according to justifiable, fair rules as perceived by stakeholders.	Aligns compliance with moral and regulative legitimacy foundations of rule-based governance.

Note: These institutional frameworks provide foundational context for norm-driven compliance behaviors but do not explicitly distinguish between moral, pragmatic, and regulative legitimacy pressures. As such, they are treated as complementary perspectives rather than the primary theoretical framework guiding this study**.**

Zucker's "The Role of Institutionalization in Cultural Persistence" (1977) illustrates how institutionalized behaviors become taken for granted within organizations, over time, contributing to a cultural persistence. This work introduces persistence through cognitive reinforcement, suggesting once compliance norms are embedded, they continue beyond instrumental rationality. While supportive of normative pathways to legitimacy, this framework is less applicable to understanding stakeholder pressure dynamics. Adjacent but not foundational to the current study, the writer infers habitual trial transparency could become a normalized institutional behavior if legitimacy norms are reinforced.

In “The Iron Cage Revisited“ DiMaggio & Powell (1983) theorize organizations conform to external pressures in order to maintain legitimacy in institutional fields. Their theory of institutional isomorphism explains how coercive (regulatory), mimetic (copycat), and normative (professional) pressures produce compliance practices that persist regardless of deterrence strength. Clinical trial sponsors, under this lens, may report results to match peers and signal conformity to regulators, funders, and journal editors. This partly explains why sponsors may adopt reporting practices regardless of the absence of follow-through controls. Though complementary to Legitimacy Theory, this framework lacks explanatory nuance regarding stakeholder perception and strategic differentiation.

Jepperson and Meyer’s (1991) “Institutional Effects and Environments” adds depth to institutional effects by showing how environments shape internal decision frames. Further, institutions are articulated as rule-like structures guiding and shaping behavior through embedded expectation, rather than strict signaling measures. This work highlights how compliance can become automatic and routinized if embedded in organizational practice and is relevant for understanding how some sponsors internalize reporting obligations. Although compelling, it does not directly distinguish between moral and pragmatic pressures in the way Legitimacy Theory does.

Beetham writes in “Towards a Social-Scientific Concept of Legitimacy” (1991) an approach to legitimacy from rule-of-law and consent-based perspectives, arguing legitimacy arises when rules are perceived as fair and justifiable. He further frames legitimacy in rule-based systems as a precondition for systemic stability, drawing connections between normative order and procedural fairness. This perspective is particularly applicable to compliance with trial results reporting laws, where perceived legitimacy of a mandate influences adherence rates.

While the framework in Beetham's paper connects legitimacy to systemic stability and rule-following, and is applicable to how norms around compliance emerge and persist – it remains conceptually more abstract than functional when applied to discrete trial reporting behaviors.

As a whole, institutional theory clarifies how compliance behaviors become normalized and persist through cultural reinforcement, professional norms, and structural expectations once legitimacy is fully institutionalized. Yet, because clinical trial results reporting has not yet achieved taken-for-granted status and remains subject to strategic interpretation and uneven adherence, institutional theory alone is insufficient for explaining observed compliance gaps, reinforcing the need for a legitimacy-focused framework.

2.2 Compliance Research Context & Clinical Trials Reporting

Compliance with trial results reporting requirements is central to safeguarding the scientific, ethical, and societal foundations of clinical research. Timely and complete disclosure of trial outcomes enables independent evaluation of evidence, reduces publication bias, supports informed clinical decision-making, and honors commitments to research participants whose involvement is predicated on contributing to generalizable knowledge (Chan, Hrobjartsson, Haahr, Gotzsche, & Altman, 2004; Dwan, Altman, Arnaiz, Bloom, Chan, Cronin et al., 2008). Failures to report results compromises the credibility of the biomedical research system as a whole (Riveros, Dechartres, Perrodeau, Haneef, Boutron, & Ravaud, 2013).

Beyond its scientific implications, results reporting compliance serves as a mechanism through which regulatory authorities and the public assess organizational accountability. Consistent non-compliance signals misalignment between formal regulatory mandates and organizational behavior, raising questions about governance quality, internal controls, and commitment to ethical standards. Conversely, sustained compliance reinforces perceptions of

legitimacy by demonstrating responsiveness to regulatory expectations and sensitivity to stakeholder scrutiny.

Importantly, compliance behavior in trial reporting has proven uneven across sponsors, therapeutic areas, trial phases, and geographic contexts, suggesting reporting outcomes are influenced by structural and institutional factors rather than uniform adherence to legal requirements (Ross, Tse, Zarin, Xu, Zhou, & Krumholz, 2012; Tse, Fain, & Zarin, 2018). This heterogeneity substantiates a need for empirical investigation into the determinants of compliance and non-compliance, particularly as regulatory regimes have evolved over time. Understanding how organizations respond to shifting transparency mandates provides critical insight into the mechanisms through which legitimacy is constructed, contested, and maintained within highly regulated research environments.

2.2.1 Regulatory Compliance in Clinical Trial Transparency

Regulatory compliance in clinical trial transparency occupies a distinctive position at the intersection of public accountability, ethical obligation, and organizational legitimacy. Unlike regulatory domains where compliance outcomes are largely internal or operational, clinical trial results reporting directly affects multiple external stakeholders, including patients, clinicians, regulators, policymakers, and the broader scientific community. As such, compliance in this context is a visible signal of organizational trustworthiness, responsibility, and adherence to socially endorsed norms governing biomedical research—rather than a procedural requirement.

Historically, the absence of enforceable transparency standards allowed selective disclosure and non-reporting of trial outcomes to persist, undermining scientific integrity and public confidence in the clinical research enterprise. High-profile cases—most notably the Spitzer–GlaxoSmithKline settlement—highlighted systemic deficiencies in voluntary disclosure

regimes and catalyzed broader recognition that market incentives and professional norms alone were insufficient to ensure consistent reporting behavior (Piller, 2015). These early enforcement actions functioned as precursors to more formalized regulatory intervention, foreshadowing the introduction of FDAAA 801 and subsequent rulemaking efforts aimed at institutionalizing transparency expectations across the clinical trials ecosystem.

From a legitimacy perspective, regulatory compliance in trial reporting reflects organizations' efforts to align with evolving societal expectations regarding openness, accountability, and ethical stewardship of human-subject research. Compliance behavior in this domain is shaped by legal coercion, reputational considerations, normative pressures within professional fields, and cognitive processes through which reporting obligations become routinized and internalized. As regulatory requirements intensifies and enforcement visibility increases, trial sponsors and research institutions face growing pressure to demonstrate conformity with formal rules and broader norms governing responsible research conduct.

2.2.1.1 Importance of Compliance in Trial Results Reporting

Clinical trial results reporting is essential for public trust, regulatory oversight, and prevention of consequences for non-disclosure. The Spitzer-GSK case serves as an evolutionary and historical precedent for disciplinary pathways prior to placement of formal regulatory frameworks and foreshadowing later federal FDAAA 801 and Final Rule efforts (Wood & Perosino, 2008). This case explores impact of litigation and legal challenge pressuring pharmaceutical companies into disclosing post-market research results, informing future transparency policies. Spitzer's lawsuit against GSK exposed selective reporting practice, and introduced the role of legal action in shaping compliance behavior (Piller, 2015).

By examining legal and policy dimensions of disclosure, Wood & Perosino (2008) demonstrate how enforcement via litigation serves as complementary or alternative to regulatory oversight, influencing compliance behavior in clinical trial reporting. This case set precedent for federal effort to mandate compliance through regulatory frameworks, reinforcing tandem importance of legal accountability as well as structured threat functions in trial results reporting.

2.2.1.2 FDAAA 801 (2007), The Final Rule (2017), and Seife v. HHS (2020)

Tse et al. (Tse, Williams, & Zarin, 2009) discussed implementation of FDAAA 801, mandating reporting of basic results by clinical trial sponsors on ClinicalTrials.gov enhancing transparency and public access to study findings. Their analysis points out early compliance trends, barriers to adherence, and the role of regulatory oversight in shaping reporting behavior. Their study of compliance clarified ambiguities in the rule and how pressure gaps contribute to underreporting. They state this set the stage for subsequent regulatory clarification, including the Final Rule (2017). Their findings provide critical context for assessment of evolving regulatory rulings and ongoing coercion challenges related to clinical trial transparency.

Despite increasingly explicit regulatory mandates, post-2020 compliance patterns suggest regulators and industry actors have entered a period of further weakened regulative legitimacy. Although the Seife v. HHS decision (2020) clarified retroactive obligations and raised the statutory penalty ceiling, constraining activity did not materially increase in frequency or magnitude. This regulatory "signal–action gap" has been noted as a catalyst for institutional drift, where organizations recognize existence of legal mandates but perceive little real consequences for non-adherence. As Suchman (1995) notes, when authority regimes fail to reinforce formal rules, regulative legitimacy erodes, allowing alternative logics — strategic, pragmatic, or resource-constrained — to dominate compliance behavior. Our post-2020 landscape therefore

reflects a paradox: stronger formal requirements, but weaker institutional reinforcement, and creates conditions ripe for long-run non-compliance.

2.2.1.3 Global vs. US compliance frameworks

Prior to issuance of the U.S. Federal mandate on results reporting concerns were being expressed regarding this matter, and public interest was noted. A strong argument was made by Wood and Gariby (2005) who critiqued ethics of withholding clinical trial data and urged public access to results as a moral obligation. Although dated, it contextualizes ongoing challenges of balancing proprietary interests with public health needs.

After FDAAA 801 was enacted, Lemmens and Telfer (Lemmens & Telfer, 2012) followed up with an argument for a legal right to know trial results, stating that transparency is a fundamental ethical obligation. It was therein he highlighted a gap between global ethical consensus and national legal frameworks. Later, Anderson et al (Anderson, Chiswell, Peterson, Tasneem, Topping, & Califf, 2015) quantified institutional non-compliance in trial results reporting. Their widely cited benchmark study was a strong cross-sectional analysis of U.S.-based compliance data under FDAAA 801, and serves as an empirical foundation for gap and trend identification. This study found significant noncompliance with FDAAA 801 among trials subject to mandatory reporting, underscoring weaknesses in the U.S. system. It also reiterates that penalties are rarely enforced, leading to persistent transparency gaps.

In the New England Journal of Medicine, Zarin et al (Zarin, Tse, Williams, & Carr, 2016) then defines key policy milestones under the Final Rule as a benchmark for U.S. compliance, and provides regulatory policy context and commentary. Their exposition frames compliance reporting, setting expectations post-Final Rule. Considered in context, Zarin and colleagues provide a detailed overview of the Rule's implementation. Therein, they note while U.S.

framework is among the most stringent, oversight gaps are evident. Their work contextualizes the Final Rule within global initiatives, asserting compliance frameworks elsewhere lack a combination of accountability modes and legal mandates found in the U.S.

Not content to just let it lie, Zarin (Zarin, 2017) provides follow-up commentary where they clarified key provisions of the Final Rule and the FDA's intent to strengthen U.S. reporting monitoring. However, the authors note the rule's success depends on willingness of institutions and sponsors to comply. They discuss how the Final Rule aims to close gaps in original FDAAA 801 law. She further articulates emphasis on clarity and standardization but notes potential barriers to institutional adoption. This authoritative explanation of the Final Rule and potential impact on intervention makes it an ideal benchmark for comparing with global frameworks. It definitively frames U.S. standards against which global frameworks can be compared.

Piller's (Piller, 2015) investigative journalism exposed many leading U.S. academic medical centers consistently fail to report trial results, despite mandates. This raised questions about institutional accountability and federal oversight. Mayo-Wilson et al., (May-Wilson, Heyward, Keyes, Reynolds, White, & Atri, 2018) conducted a confirmatory survey of academic organizations. Their paper illustrated inconsistent policies and practices related to trial registration and results reporting. These findings make clear institutional variability and lack of centralized sanctions. Finally, Keestra et al., (Keestra, Rodgers, Lenz, Osborne, Bruckner, & Lee, 2021) analyzed 30 U.S. academic medical centers and also found widespread noncompliance with reporting obligations. This research identified large-scale, systemic institutional failures in timely clinical trial results among top research centers. Findings reinforce systemic deficiencies in institutional accountability within a regulated U.S. system. They highlight both U.S.-specific gaps and reinforce need for predictive, theory-informed research.

On the Pharma side, Axson et al., (Axson, Mello, Lincow, Yang, Gross, Ross et al., 2021) examined transparency commitments across pharmaceutical companies and observed limited improvement despite public pressure. Findings support calls for stronger regulatory imposition and global harmonization. This work directly contrasts global vs. US practices. The authors review implementation shortfall and barriers. Interestingly they introduce legitimacy framing but solely around stakeholder duty. Probing the funding angle, Gaba et al., (Gaba, Siebert, Dupuy, Moher, & Naudet, 2020) evaluated funder policies and found wide variation in how and whether trial result disclosures are enforced. The writers evaluated data-sharing practices of global funders. Research reveals strengths and weaknesses in EU reporting mandates and systems, offering insights for FDAAA 801 comparison and global transparency benchmarks aligning with global framework gaps and penalty inconsistencies. This study demonstrates tension between aspirational policy and real-world implementation at global and national levels.

Meanwhile, across the Atlantic Ocean von Elm and Meerpohl (von Elm & Meerpohl, 2020) assessed legal and practical differences in trial result reporting between nations. This review explored global inconsistencies in clinical trial reporting and highlighted variation in international reporting standards and systemic action issues. They discuss inconsistencies in reporting norms and governance among countries – justifying a need for comparative compliance analysis. Their research reveals regulatory heterogeneity – not ethical unwillingness – accounts for many compliance inconsistencies. The authors support stronger international monitoring efforts, and advocate harmonized enforcement strategies. They call for greater transnational governance and better public accountability measures.

In the United Kingdom, Goldacre et al., (Goldacre, DeVito, Heneghan, Irving, Bacon, Fleminger et al., 2018) had already examined compliance with a requirement to report results on

the European Union Clinical Trials Register. Here they conducted, under non-U.S. frameworks, an EU trials audit. Their paper contrasts EU vs US compliance environments – useful for extension to global comparative analysis. Goldacre and colleagues revealed large-scale noncompliance among EU sponsors. They then created and launched a live EU Trials Tracker showing which EU institutions fail to report trial results in an effort to pressure institutions into improved reporting. This transparency tool has spurred both media coverage and institutional reform. This work exposed regulatory shortcomings despite clear legal mandates. Their research stands as a key canonical reference for EU vs. US comparison. Further, it identifies data silos, supervisory action variability, and laid groundwork justification for predictive modeling needs.

A subset of that same research team, DeVito e al., (DeVito, Bacon, & Goldacre, 2019) further quantified sponsor underperformance in EU reporting with an enriched data set. Tapping into their novel Trials Tracker, they conducted a statistical audit, and registry-based analysis. They conducted a robust statistical audit of trial sponsors' reporting habits under EU law; critical for framing legal vs. ethical compliance across global systems. These findings serve as the EU benchmark for transparency controls and a high-value dataset for global comparison and gap analysis of sponsor compliance. This work was foundational for cross-jurisdiction comparison.

With the resounding success of their EU Trials Tracker, DeVito et al (DeVito, Morley, Smith, Drysdale, Goldacre, & Heneghan, 2024) returned with an updated review of compliance levels post-regulatory reforms which supports claims about system maturity and gaps in governance. In their continuing work they explore the extent of result availability in EU Clinical Trial Register. While their initial investigation analyzed over 12,000 EU-registered trials and found significant variability in compliance across nations.. Their follow-up cross-sectional audit of 500 trials registered on EU CTR and found only 53.2% of EUCTR trials had results available,

some uniquely on EUCTR. They assert compliance is inadequate, with results for many trials missing from any dissemination route. This post-reform compliance review shows maturity of EU system and enforcement limits. Overall, they reveal strengths and weaknesses in EU reporting mandates and systems, offering insights for FDAAA 801 comparisons and global transparency benchmarks. This 2024 investigation confirms persistent reporting gaps despite policy frameworks. This is reflected in lack of results availability and ongoing issues in reporting compliance. The researchers most recent work identifies determinants of trial reporting in a European context; supports aforementioned gaps in laws and proposes continued cross-national comparisons. The authors advocate for harmonized statutes and transparency tools like TrialsTracker to close the reporting gap.

Further afield, and focusing on geographically-specific criteria, Nilsonne et al. (Nilsonne, Wieschowski, DeVito, Salholz-Hillel, Bruckner, Klas et al., 2024) assessed 417 interventional trials sponsored by Norwegian medical universities and found that only 42% had publicly available results, despite European regulatory requirements. The team used data from ClinicalTrials.gov and the EU Clinical Trials Register finding compliance varied significantly by institution. In this study, trials with industry involvement were more likely to report results, revealing disparities between public and private research actors. This small study emphasizes even within high-income countries with centralized healthcare and research infrastructures, regulatory compliance is inconsistent – thus providing a global benchmark against which U.S. frameworks can be analyzed. This research identifies determinants of trial reporting in a European context and proports gaps in enforcement and invites cross-national comparisons. The study also compares national to EU-level compliance. The author's assessment is of compliance in Norway—helpful for international benchmarking and understanding legal means. Herein, they

highlight widespread noncompliance with trial registration and reporting standards, echoing broader concerns applicable to FDAAA 801.

Focusing on France, Alix-Doucet et al., (Alix-Doucet, Vinatier, Fin, Lena, Range, Locher et al., 2024) studies reporting of interventional clinical trials in for compliance determinants. Their study evaluated France's compliance with EU reporting mandates, revealing underperformance in results submission, and highlighting gaps in national regulatory oversight. It emphasizes a mismatch between policy intent and operational execution. The author identifies determinants of trial reporting in a European context, supporting gaps in sanctions and calling for cross-national comparisons.

Shifting to a specific therapeutic indication focus, but expanded globally, Norwegian researchers Holtedahl et al. analyzed MSC trials from six international clinical trial registries (e.g., ClinicalTrials.gov, EUCTR). Their aim was to evaluate compliance across all registered MSC trials globally, making it international in scope. However, it is published by Norwegian researchers and is often cited in Nordic and European regulatory contexts. Holtedahl and colleagues conducted a systematic review of 124 interventional trials utilizing mesenchymal stromal cells (MSCs) for musculoskeletal disorders to assess compliance with trial registration and results reporting standards. Their study revealed that only 45% of trials were prospectively registered, and over 50% failed to report or publish these results. Frequent retrospective registrations and endpoint discrepancies were notable. Funding source was not associated with reporting compliance. Despite expectations for higher standards in EU-affiliated countries, findings affirm persistent gaps in transparency and enforcement – this mirrors concerns often associated with the U.S. FDAAA 801 framework. This study serves as a valuable comparator for evaluating international compliance (Holtedahl & Brox, 2024).

The World Health Organization's International Clinical Trials Registry Platform (ICTRP) and *Statement on Public Disclosure of Clinical Trial Results* (World Health Organization, 2015) established a global ethical standard requiring both trial registration and results reporting for all clinical trials, with the aim of promoting timely public disclosure of summary results. The Statement functions as a global policy declaration that articulates an ethical imperative for transparency. Importantly, the Statement provides multinational expectations without oversight channels. This distinction highlights a key asymmetry between globally articulated norms and the statute-based U.S. regulatory framework. As such this position Statement provides critical context for framing international compliance gaps and contrasts international ethical guidance with the FDA's U.S.-specific, legally enforceable mandates

WHO's Statement continues to set ethical expectations for clinical trial transparency (Chan, Karam, Pymento, Askie, da Silva, Aymé et al., 2025), urging all trials to be registered and results reported. However, without binding enforcement, practical global impact is limited. Unlike US FDAAA 801 framework and because WHO's position is non-binding, national governments retain discretion over governance – and controls explanations vary widely, with many countries lacking legal mandates. This creates wide variability in compliance rates, highlighting a gap across the globe when compared to United States' unique positions in codifying transparency as a legal requirement, rather than as an ethical guideline. While the WHO standard is aspirational and widely endorsed, especially by global funding sources and trial sites, its impact is constrained by broadly inconsistent legal enforcement across countries. Basically, it's a situation of global ethical imperatives without legal teeth.

Later, Gamertsfelder et al.'s (Gamertsfelder, Delgado Figueroa, Keestra, Rossi Silva, Borana, Siebert et al., 2024) expands this theme and outlines the World Health Organization's

international best practices for clinical trial transparency and emphasizes a global ethical imperative to register and report results. It contrasts aspirational global standards with binding legal frameworks of select nations like the U.S. In reviewing reporting of summary results in clinical trial registries.

Finally, Chan and colleagues (Chan et al., 2025) explored registry-based reporting norms. The team analyzed compliance across major global registries (e.g., EU-CTR, ClinicalTrials.gov, ANZCTR). Their findings revealed that while global registries often mirror the WHO's guidance, actual compliance rates diverge significantly—confirming weak enforcement outside the U.S. This study concludes the U.S. Final Rule monitoring offers a more robust model, though challenges remain in consistency and completeness. Chan et al. found that despite increasing registry coverage, many countries still fail to ensure result reporting compliance . The authors call for international alignment between registries, funders, and ethics boards.

This set of U.S. and international studies empirically demonstrate results reporting compliance is driven by the presence, credibility, and enforcement of national regulatory frameworks. By contrasting the legally binding FDAAA 801 regime with global systems that rely primarily on aspirational norms, this literature establishes a comparative context necessary for examining how legitimacy—rather than formal obligation—may shape reporting behavior.

2.2.2 Empirical Findings Literature on Non-Compliance Trends

2.2.2.1 Prior research on regulatory enforcement & non-compliance patterns

Recent empirical reviews continue to demonstrate compliance rates remain structurally low despite multiple regulatory inflection points. DeVito et al. (2020) reported even after the Final Rule took effect, fewer than 80% of legally required trials posted results. This leaves tens of thousands of studies non-compliant and billions in theoretical fines uncollected. Rivero-de-

Aguilar et al. (2024) similarly identified persistent discrepancies between ClinicalTrials.gov disclosures and corresponding journal publications. This suggests selective reporting practices are embedded in organizational routine. Additional analyses in PLOS ONE (Chen et al., 2024) highlight institutional resistance and data-ownership disputes as ongoing barriers to transparency. Collectively, current literature portrays compliance not as a temporary control lag but as a stable structural condition shaped by resource constraints, incentive misalignment, and weak sanctions.

Kesselheim & Mello provide a critical early examination of secrecy in clinical trials and consequences for medical transparency. Their findings indicate market forces and strategic decision-making often override regulatory obligation, with sponsors selectively choosing to disclose trial results based on commercial incentive (Kesselheim & Mello, 2007). This aligns with recent research which indicates compliance remains a function of enforcement strength and institutional reputation (DeVito et al., 2020). Despite FDAAA 801's intent to improve transparency, Kesselheim & Mello's findings suggest systemic non-compliance patterns are deeply rooted in industry culture, requiring more than policy mandate to achieve full adherence.

Empirical research has consistently shown persistent gaps in compliance with clinical trial result reporting, despite stringent legal mandates (Goldacre et al., 2018). Their study on the EU Clinical Trials Register found that only 68.1% of commercial sponsors complied with reporting requirements, compared to just 11% of non-commercial sponsors. These findings suggest regulatory formalities alone is insufficient to drive universal compliance, as compliance behavior appears to be shaped by institutional legitimacy, stakeholder scrutiny, and commercial incentivization rather than legal mandate alone. This aligns with prior research indicating compliance is often strategic and based on pragmatic legitimacy instead of strictly regulatory obligations (Suchman, 1995) (Scott, 1995).

Chen et al. (2024) demonstrate even when regulatory agencies mandate transparency, compliance remains inconsistent. In their study examining compliance with NIH's data-sharing policies within ClinicalTrials.gov, the authors found only 10.3% of principal investigators committed to sharing individual participant data (IPD), despite federal policies promoting open access. This highlights a broader pattern of selective compliance with regulatory mandates, a challenge that also extends to results reporting.

Viewed in aggregate, this body of work characterizes clinical trial reporting non-compliance as a durable institutional pattern, emerging from enforcement gaps, reputational calculus, and legitimacy-driven decision processes, with legal obligation functioning as a secondary rather than primary driver.

2.2.2.2 Differences in compliance based on trial characteristics

The New England Journal of Medicine (NEJM) published study findings which examined "selective reporting" of antidepressant trial results, as described by Turner et al (Turner, Matthews, Linardatos, Tell, & Rosenthal, 2008). Alarmingly, they uncover significant discrepancies between FDA-registered data and published outcomes. Their study found positive results were far more likely to be published, while negative or inconclusive results were often misrepresented or omitted entirely. Clearly, this creates misleadingly favorable impression of drug efficacy. This analysis revealed systematic differences in reporting practices based on trial funder type and therapeutic area, They emphasized the role of pharmaceutical industry sponsors in shaping public availability of clinical trial data . These findings highlighted critical importance for regulatory oversight and compliance logic which ensure transparency. This is especially necessary in high-stake therapeutic areas that include vulnerable populations and where selective reporting can have profound negative implications for patient safety and treatment efficacy.

Again, in 2015, NEJM published research from a sponsor type perspective. Anderson et al.(2015) analyzed compliance with ClinicalTrials.gov results reporting mandates noting widespread non-adherence – even after FDAAA 801 mandated disclosure. The researchers reveal industry-funded trials exhibited significantly higher compliance rates than those led by academic institutions or the NIH, indicating disparities across sponsor type. A major factor influencing compliance was presence of enforcement rationale as industry sponsors perceived higher regulatory and reputational risk compared to non-industry funders . These findings illustrate a gap between legal requirements and reporting behavior, reinforcing concerns about weak actions and voluntariness of compliance. Their study opened the door for broader discussion of regulatory legitimacy, compliance incentives, and effectiveness of policy in trial transparency.

In synthesis, these studies demonstrate clinical trial reporting compliance is patterned by trial characteristics such as sponsor type, funding structure, and therapeutic context. By showing how reporting behavior aligns with perceived enforcement exposure and reputational stakes, this literature positions trial attributes as central explanatory factors—making trial characteristics analytically indispensable to understanding compliance behavior.

2.2.3 Gaps in Compliance Literature

Despite a growing body of literature examining non-compliance with clinical trial results reporting, substantial gaps remain in how this issue is conceptualized, studied, and addressed. While legitimacy theory has been occasionally alluded to, or referenced, as a useful lens to understand reporting behavior, there has not yet been a study conducted where it served as a central and fully developed theoretical framework for data-driven interrogation. Existing studies often highlight potential causes or propose solutions based on opinion or anecdotal arguments, yet few provide a comprehensive account of drivers of compliance—or non-compliance.

Notably, although some empirical efforts have addressed specific factors—such as therapeutic area, funding source, geographic location, trial phase, or regulatory conditions—these investigations have tended to be narrowly scoped and siloed. Only a handful, such as the work of Goldacre and colleagues (2018) offer broader perspectives—even these rely on datasets predating key judicial and regulatory developments (e.g., *Seife v. HHS (2020)*). Further, although prior scholars have called for predictive models to improve transparency and enforcement, no published research to date has developed or tested a comprehensive predictive framework that accounts for multivariate and moderating factors across institutional and regulatory domains.

The following sections outline three critical gaps in literature:

(1) absence of a unified theoretical foundation in compliance research,

(2) limited integration of multivariable predictors and interaction effects, and

(3) lack of empirically tested predictive models that reflect recent policy shifts.

Considered in concert, these gaps establish rationale for this present study and its contribution to theory, practice, and public policy.

2.2.3.1 What past research has missed

Zarin et al. (2016) provided a pivotal policy overview of the FDA's Final Rule and its implications for clinical trial transparency, emphasizing ethical and institutional responsibilities of sponsors. However, this article stops short of empirically examining whether such responsibilities translate into improved reporting compliance behavior. They do not offer a predictive framework and don't explore multivariable drivers of reporting behavior. Further, while organizational accountability is mentioned rhetorically, arguments are not grounded from a theoretical perspective to interrogate how compliance decisions are made in practice.

Goldacre's introduction of TrialsTracker (2018) was an important step toward improving monitoring infrastructure for clinical trial reporting. Yet, despite highlighting widespread underreporting, their analysis focuses on descriptive compliance rates rather than predictive variables which explain the phenomenon. This study does not model interaction of multiple institutional or trial-level factors that could contribute to non-compliance. Additionally, while transparency is framed as a societal imperative, absence of a guiding theory limits ability to interpret sponsor behavior within broader organizational or reputational contexts.

Mayo-Wilson et al., (2018) identified inconsistent global standards and weak enforcement dynamics across institutions, reinforcing structural challenges to compliance. However, they do not offer a multivariate model to explain differences in behavior across organizations or sponsor types. Additionally, although the study implicitly raises issues of organizational legitimacy, it does not directly engage legitimacy theory as a means to understand strategic behavior or compliance motivations. This research is foundational but remains descriptive and institution-specific rather than offering generalizable insights grounded in theory or predictive modeling. The authors examine how academic institutions prepare for and implement trial registration and reporting policies. They note uneven capabilities and resource allocation. While these findings provide important insight into institutional readiness, the study does not assess how variations influence compliance outcomes across contexts. Focus remains on institutional descriptors rather than organizational adaptation, leaving a gap in understanding the strategic calculus behind reporting choices.

Swanson et al. (Swanson, Johnston, & Ross, 2021) explore discrepancies in trial registration and results reporting, particularly with respect to pivotal device trials. Their findings are useful in demonstrating selective reporting trends and modest improvements post-FDAAA

801. Still, their factor-based approach is limited to categorical comparisons, without accounting for interplay of multiple variables or influence of regulatory shifts over time. More critically, their work does not deliver a theoretical scaffolding. As such, providing an opportunity to contextualize behaviors within a framework – such as legitimacy theory—that could clarify organizational intent and sponsor response to public scrutiny.

Bashir and Dunn (Bashir & Dunn, 2022) analyze reporting patterns, uncovering disparities in compliance across sponsor types and trial phases. Their work introduces predictive markers related to early reporting behavior. However, it stops short of developing a formal predictive model that could guide enforcement or policy reform. Although this discussion touches upon public trust and systemic inequity, themes are not grounded in any explicit theoretical framework. As a result, their study highlights structural gaps and leaves opportunity to connect behavior to institutional legitimacy and strategic adaptation.

In providing a two-decade overview of ClinicalTrials.gov data, Gresham et al. offer valuable historical insights into the evolution of reporting practices. Yet, this study remains largely descriptive, tracking macro trends without isolating or modeling organizational, regulatory, or study-level variables as drivers of compliance decisions. While the authors recognize the role of evolving regulatory expectations, they do not investigate how entities strategically respond to these expectations. Theories of legitimacy or regulatory behavior to interpret such dynamics (Gresham, Meinert, Gresham, Piantadosi, & Meinert, 2022).

Hutchinson and colleagues (Hutchinson, Moyer, Zarin, & Kimmelman, 2022) raise critical questions about the informativeness of clinical trials and persistent disconnect between trial outcomes and applicable clinical utility. Their focus on design and relevance does not extend to compliance with results reporting or FDAAA 801 requirements. The paper lends us a key

opportunity to explore how legitimacy pressures and institutional factors influence trial informativeness or reporting behaviors. Most notably, while they discuss limitations of current reporting practices, no formal model is offered to predict or explain compliance outcomes across different sponsor types or trial characteristics.

Bruckner et al. (Bruckner, Yerunkar, Basegmez, Borana, Chavarría, Velarde et al., 2023) expose stark realities of noncompliance in pediatric clinical trials. They highlight concerning legal violations, existing even among vulnerable populations. While this brings into focus the urgency of strict enforcement, their study is focused on descriptive findings rather than analytical modeling. It does not explore organizational or environmental conditions that inform prediction such violations, nor does it account for multivariable influences or moderating factors. The authors do not invoke theoretical frameworks to understand critical reputational or institutional motivations behind continued noncompliance—even in high-stakes contexts involving children.

Lyons and Fagan offer an important cross-national perspective on transparency efforts in clinical trials, with a focus on evolving anonymization and data-sharing practices. Their paper emphasizes process adaptations and technology solutions without examining underlying behavioral or strategic choices driving compliance. It does not investigate why some organizations embrace transparency more robustly than others, nor does it explore legitimacy or regulatory theory to explain variations. The study's absence of a predictive framework limits its capacity to inform policy or guide corrective strategy in a structured, theory-informed manner.

DeVito et al (2024) return to audit of the EU Clinical Trials Register (EUCTR) and provide a compelling view of dissemination gaps across multiple registries . While their study quantifies result availability and publication lags, it does not identify predictors of compliance or develop explanatory models. Analysis is not conducted through a theoretical lens to understand

sponsor behavior across platforms or jurisdictions. Value of the registry as a data source is affirmed, and the study provides us with opportunity to frame compliance as a strategic response to legitimacy threats and institutional pressures.

Hopkins et al. (Hopkins, Modi, Rockhold, Hoffmann, Menz, Veroniki et al., 2024) assess lack of public accessibility of Clinical Study Reports (CSRs), revealing barriers to transparency in industry-sponsored trials . While their findings demonstrate a disconnect between regulatory approval and open data sharing, this analysis stops at cataloging availability rather than probing causal drivers. The study does not contemplate organizational legitimacy, stakeholder pressures, or strategic responses to regulatory environments. This permits us to develop a multivariate logistic progression or predictive model that might illuminate which factors explain decisions to officially release – or report – critical clinical trials insights.

Iken, Poolman, and Gademan's critique of data quality in ClinicalTrials.gov records reinforces limitations of using self-reported data in compliance research (Iken, Poolman, & Gademan, 2024). Their work highlights inconsistencies and missing data that undermine integrity of registry-based analyses. However, the paper does not offer a structured framework to explain why these quality lapses persist or how they relate to broader issues of legitimacy, trust, or organizational behavior. This study leaves room for us to investigate whether such irregularities correlate with specific trial or sponsor characteristics, and to model noncompliance as a function of multivariable dynamics.

When examined holistically, prior studies have mapped contours of clinical trial reporting non-compliance with remarkable consistency—documenting enforcement gaps, institutional variability, and transparency shortfalls across jurisdictions and sponsors. What remains underdeveloped is an empirically grounded, theory-driven account of how organizations interpret

regulatory expectations and translate them into reporting behavior across time, context, and trial characteristics. We aim to address that gap by coupling legitimacy theory with predictive modeling to identify institutional and structural determinants of compliance under FDAAA 801 and its evolving enforcement environment.

2.2.3.2 Studies examining compliance factors, but not predictive models

Hao et al. (Hao, Forgione, Guo, & Zhang, 2016) studied utility of improved clinical trial disclosure through a lens of financial forecast, depicting how quasi-regulatory standards such as those issued by the International Committee of Medical Journal Editors (ICMJE) (De Angelis, Drazen, Frizelle, Haug, Hoey, Horton et al., 2005), might enhance analyst performance. Their study makes a great case for the value of transparent reporting, yet it does not attempt to model drivers of compliance behavior itself. This analysis focuses on outcomes of disclosure rather than factors that influence whether and how sponsors comply. As such, it stops short of offering a predictive framework or multivariable explanation of compliance dynamics.

Reuber and Morgan-Thomas (Reuber & Morgan-Thomas, 2019) explore how organizations in ethically complex industries construct legitimacy through discourse, especially when norms are ambiguous or contested. While this work offers valuable insights into moral legitimacy and discursive strategies, it is conceptual and qualitative. Regulatory compliance in clinical research is not examined directly, thus a predictive model or empirical test of legitimacy responses in practice is not provided. Its relevance lies in informing future frameworks, and leaves modeling of behavioral outcomes to be later explored.

Hsu et al. (Hsu, Lee, Moon, & Oh, 2020) use a difference-in-differences approach to analyze effects of the FDAAA 801 reporting mandate on drug development processes – specifically, trial suspensions. Their work demonstrates a causal influence of enhanced

information disclosure on development decisions. This study is focused on economic impacts rather than compliance behavior itself so does not predict or model which trials or sponsors are more or less likely to comply. The legitimacy dimension of disclosure is implied but not empirically tested or grounded in theory.

Lindsley and colleagues assess prevalence of trial registration within systematic reviews, revealing surprisingly low compliance even in high-quality evidence syntheses (Lindsley, Fusco, Teeuw, Mooij, Scholten, & Hoft, 2021). While they highlight important structural shortcomings and raise methodological concerns, this analysis is descriptive. Their study does not explore predictors of noncompliance, nor does it attempt to model institutional or contextual variables informing registration behavior. This leaves a critical opportunity to explore the "why" behind these documented patterns.

South et al. examine how computer-assisted coding tools and artificial intelligence enhance adverse event reporting and trial data quality (South, VanHouten, Willis, Bradham, Duff, Hekmat et al., 2022). Their study shows potential of predictive technologies in improving data integrity and operational efficiency in clinical research workflows. This work is focused on coding accuracy, not inclusive of regulatory compliance, and so offers no modeling of sponsor or institutional transparency behaviors. It reinforces feasibility of predictive tools but does not bridge this capability into compliance research.

Shelly et al. explore absence of communication plans in global health clinical trials (Shelly, Logan, Skorochod, Wiyeh, Ndwandwe, Choko et al., 2023). Ultimately, they propose a best-practice template for sharing results with study participants. While their work addresses a critical ethical dimension of transparency, it does not examine compliance behavior within regulatory contexts. The study stops short of modeling how institutional, or trial-level

characteristics impact implementation of communication plans. It reinforces need for implementation standards but does not contribute a predictive lens or multivariable logistic regression framework.

Chen et al. (2024)conducted a large-scale analysis of data-sharing intentions across clinical trials, identifying patterns linked to funder type, trial phase, geography, and other variables . Their findings inform and suggest avenues for targeted enforcement. However, the study does not build a predictive model to test whether these variables interact – or their influence on actual compliance behavior. Additionally, while legitimacy implications are crystal clear – particularly pertaining to public trust and federal funding—the theoretical framework is absent. This work informs variable selection but not behavioral forecasting.

In combination, this body of work establishes transparency's influence on economic outcomes, ethical standing, operational quality, and stakeholder trust across clinical research ecosystems. What remains underdeveloped is an empirical framework integrating these insights into a predictive model of compliance behavior—and one that accounts for how institutional context, trial characteristics, and regulatory signals interact over time.

2.2.3.3 Need for theoretical grounding & legitimacy models to explain compliance

In 2012 Doshi et al. presented an initial compelling ethical critique of data secrecy in randomized clinical trials (RCTs), grounded in both moral obligation and scientific integrity (Doshi, Jefferson, & Del Mar, 2012). Their argument was for greater transparency in clinical study reports but stopped short of applying a formal theoretical framework to explain organizational resistance. The authors highlight legitimacy concerns implicitly, yet their work would benefit from an explicit application of legitimacy theory to understand why sponsors withhold data despite external pressure. raised urgent ethical concerns about RCT data opacity,

challenging the pharmaceutical industry to justify its resistance to disclosure. Building on this momentum, Doshi et al's., 2013 landmark paper introduced the Restoring Invisible and Abandoned Trials "RIAT" initiative (Doshi, Dickersin, Healy, Vedula, & Jefferson, 2013), a pioneering call to action aimed at correcting the scientific record by enabling third parties to publish or republish clinical trial results when original sponsors fail to do so transparently. While they exposed systemic failures in clinical trial result dissemination and emphasized a moral imperative for transparency, this publication stopped short of modeling *why* non-compliance occurs, omitting theoretical constructs such as legitimacy or stakeholder pressure. While it advocates for reform, it does not propose an explanatory framework for organizational behavior—leaving a gap this dissertation seeks to address.

Wang et al.(Wang, Song, & Zhao, 2014) demonstrate how three dimensions of legitimacy—cognitive, regulative, and normative—moderate perceived value and signaling power of early customer adoption in new ventures . This is a management-focused, theory-driven paper using legitimacy theory directly and about entrepreneurial legitimacy. They use legitimacy theory to explain how early customers' value depends on types of legitimacy. Findings reinforce the importance of legitimacy as a contextual variable influencing external stakeholder assessments, providing a strong empirical case for treating legitimacy not just as a status, but as a dynamic moderator of organizational outcomes. Although not specific to clinical trial compliance, their study exemplifies how legitimacy theory can explain why seemingly similar organizational behaviors (like early reporting or data sharing) yield different stakeholder responses based on contextual legitimacy cues. This supports a need for a legitimacy-based framework in analyzing compliance behavior in regulated sectors. This publication actively demonstrates how legitimacy theory deepens understanding of organizational behavior—

precisely the argument to make for clinical trial compliance research, as it models how legitimacy theory adds explanatory power and shows how legitimacy can and should be used to explain organizational behavior.

Monfardini et al. (Monfardini, Barretta, & Ruggiero, 2019) illustrate social reporting (SR) in public sector organizations does not automatically confer legitimacy, particularly when stakeholder engagement is weak or SR is perceived as a mere marketing tool. As their focus the authors examine stakeholder perceptions of SR in healthcare, and explicitly use a legitimacy theory framework. Their findings emphasize a critical need to understand types and sources of legitimacy—moral, pragmatic, and cognitive—as outlined by Suchman (1995), and show these forms do not align uniformly across diverse stakeholder groups. They specifically show how SR can fail to generate legitimacy due to lack of stakeholder alignment, inadequate engagement, and perceived performativity. Their study reinforces the value of legitimacy theory as a conceptual lens for explaining why voluntary disclosure efforts often fail to achieve their intended legitimation outcomes. This study critiques assumptions that reporting leads to legitimacy and calls for more grounded, theory-based models. This highlights a necessity of legitimacy-based models to meaningfully guide reporting practices and stakeholder trust-building. Accordingly, the researchers not only use legitimacy theory directly but also criticize why reporting without theoretical framing can fail, aligning exactly with our argument regarding research reporting.

Bourveau et al. (Bourveau, Čapkun, & Weber, 2020) provide quantitative evidence on downstream consequences of mandated clinical trial disclosures under FDAAA 801, showing reduced information asymmetry in capital markets and increased consumer-side vigilance through adverse event reports and product recalls. Shown are real effects of compliance (reduced information asymmetry, increased disclosures). Lacking, however, is grounding in organizational

values, stakeholder theory, or legitimacy constructs. While this study does not adopt a full legitimacy theory framework, it engages explicitly with economic legitimacy by examining how disclosure requirements influence sponsor behavior in response to stakeholder pressures. The authors imply compliance is not merely a regulatory checkbox but a strategic response to shifting expectations in financial and consumer environments. Offered up is a solid empirical foundation—that also highlights a need for theoretical frameworks to explain why these behaviors occur. This supports an argument legitimacy-based models offer a more powerful lens for understanding why organizations comply beyond legal compulsion.

Cleary et al., (Cleary, Jackson, & Ledley, 2020) demonstrates extensive public sector investment—over $187 billion by 2020—in basic biomedical research that underpins FDA-approved drug development. They provide compelling evidence of vast funding in early stage pharmaceutical innovation and frames data transparency as a necessary driver of public accountability. Yet, despite this contribution, there is no formalized enabling condition to ensure equitable return to the public sector, exposing a structural legitimacy gap in current biopharma innovation and reporting systems. This is firmly tied to FDA-approved drugs and exposing asymmetry between public investment and private returns, this study implicitly points to a normative legitimacy gap. Their paper goes on to implicitly makes evident a need for theoretically grounded compliance frameworks—particularly those informed by legitimacy theory—to ensure reporting aligns with public expectations of fairness, recognition, and reciprocity addressing an often-overlooked dimension. By quantifying NIH's contribution to foundational science behind FDA-approved drugs, the paper raises normative questions about who owes what to whom—yet it does not explore why sponsors fail to comply with reporting obligations despite public stakes. The study's silence on organizational or cultural explanations

renders visible a need for legitimacy-oriented theories that move beyond legal mandates, to model behavior more holistically. While it does not invoke legitimacy theory explicitly, this paper argues for systemic reforms that recognize public value and ethical obligations in reporting practices. This reinforces our argument compliance models must move beyond descriptive measures and incorporate normative legitimacy constructs (e.g., fairness, reciprocity, public accountability, equity, and value creation) to address imbalance between public investment and private reward.

Heredia et al. focused on clinical trial compliance in the specific geopolitical context of Peru.. This study critiques compliance patterns in the context of Latin America and low-resource environments, raising important questions about feasibility and institutional support. There they evaluate publication compliance rates of clinical trials registered in Peru and identify several structural and procedural factors influencing reporting outcomes. While this study quantifies predictors of noncompliance—such as study phase and number of participating countries—it stops short of theorizing deeper institutional or normative drivers behind those patterns. This is demonstrative of compliance challenges but without applying legitimacy theory or any robust theoretical scaffold. Absence of a legitimacy-based or organizational behavior framework limits the study's ability to generalize or explain compliance across broader contexts. This omission highlights a critical need for theoretical grounding in global compliance research (Heredia, Alarcon-Ruiz, Roque, De La Cruz-Vargas, & Quispe, 2020).

Abhayawansa & Adams' paper explicitly critiques lack of theoretical anchoring in non-financial reporting (NFR) frameworks, particularly related to Environmental, Social, and Governance (ESG) disclosure practices (Abhayawansa & Adams, 2022). The authors insist that improved compliance frameworks engage more seriously with legitimacy, especially concerning

pandemic and climate change risk and calls for legitimacy theory as a more appropriate lens. They argue, without such grounding, compliance and disclosure behavior and strategy is poorly understood and inadequately regulated. While this study focuses on sustainability rather than clinical research, its critique is universally applicable: without a legitimacy-based understanding of compliance, regulatory efforts miss underlying behavioral drivers. This supports a central claim that more theory-driven compliance modeling is overdue and indirectly supports this dissertation's claim regarding lack of theoretical grounding in clinical compliance.

Assor and Greenberg (Assor & Greenberg, 2022) examined how legitimacy is conferred upon healthcare research decision-making bodies through public discourse and stakeholder evaluation, using the Israeli Public National Advisory Committee (PNAC) as a case study. This study draws explicitly on the Accountability for Reasonableness (A4R) framework developed by Daniels and Sabin (Daniels & Sabin, 2002) and engages legitimacy theory to interpret institutional trust. This approach highlights both strengths and vulnerabilities in perceived procedural legitimacy. It addresses moral legitimacy, stakeholder trust, and the A4R framework – which is founded on four core ethical conditions: publicity, relevance, appeals, and enforcement—within context of healthcare resource allocation. This combination provides relevant parallels to clinical trial transparency and institutional compliance. This work provides a rare empirical bridge between theoretical models and health system governance, reinforcing the value of legitimacy theory in evaluating institutional behavior. Its use of stakeholder perceptions, trust metrics, and qualitative discourse analysis offers a transferable model for understanding compliance and institutional credibility in other health research contexts.

Islam et al.(2022) presents legitimacy frameworks in governance and apply legitimacy theory to explain organizational responses to soft regulatory guidelines, demonstrating how

companies manage disclosures to uphold pragmatic legitimacy while compromising moral legitimacy. Examines how companies respond to Australian Securities Exchange (ASX) soft regulation with selective anti-bribery disclosures Their analysis reveals how real-world external pressures—such as media or stakeholder expectations—interact with internal self-interest to shape selective compliance. The authors explicitly model how different legitimacy types explain regulatory adherence and disclosure gaps. A distinction between moral and pragmatic legitimacy is a critical differentiation for modeling why organizations may appear compliant while failing to disclose substantive risks, mirroring challenges in clinical trial transparency. This study exemplifies how legitimacy theory can provide explanatory depth that purely descriptive models overlook. It shows how pragmatic pressures override moral legitimacy, offering a theoretical explanation for why organizations comply selectively—a direct parallel to clinical trial result noncompliance. This mirrors FDAAA 801's “soft” accountability landscape, making it a powerful analog for the clinical research domain.

Morrow et al. (Morrow, Mintzes, Gray, Law, Garrison, & Dormuth, 2023) examined sponsor strategies for reporting clinical trial results, with attention to institutional pressures and reputational risk. This article provides an ethics-based analysis of clinical trial result reporting, emphasizing non-disclosure undermines informed consent and violates moral obligations researchers hold toward participants. Through qualitative interviews with stakeholders in Canadian research settings, the authors highlight how public reporting is framed not merely as a regulatory expectation but as a moral imperative grounded in reciprocity and trust. This study directly explores moral obligation and informed consent as ethical imperatives for result reporting. It also examines institutional pressure and reputation in sponsor behavior. Research Ethics Board. (REB) members were interviewed to provide insight into how clinical trial

reporting relates to ethical responsibilities and perceptions of moral legitimacy in research practices. Connected stakeholder expectations (participants, investigators, and REBs)—to behavioral norms—lays groundwork for moral legitimacy as a driver of compliance. While their study does not formally apply legitimacy theory, its normative stance aligns closely with moral legitimacy, reinforcing a need for theory-driven models that account for ethical accountability in compliance behavior. The study affirms relevance of sociopolitical and stakeholder dynamics, yet does not model them explicitly. Use of qualitative data demonstrates how perceived duties shape real-world reporting decisions — ideal for building a legitimacy-based explanatory model. Overall, we are offered a normative ethics foundation that aligns naturally with a call for more theoretically grounded frameworks.

Across the literature, studies demonstrate clinical trial reporting compliance is shaped by ethical norms, reputational pressures, stakeholder expectations, and strategic calculation—but is rarely explained through an integrated theoretical lens. While many contributions document consequences of disclosure or expose systemic transparency failures, few offer models which explain *why* organizations behave as they do under conditions of weak enforcement and competing legitimacy demands. This gap emphasizes a need for legitimacy-based frameworks.

2.3 Synthesis: Theory & Research Context

Synthesis of the theoretical perspectives and empirical research reviewed in preceding sections establishes a coherent interpretive lens for examining regulatory reporting compliance. Rather than treating legitimacy theory and related institutional frameworks as isolated explanations, this integration clarifies how regulatory mandates, organizational behavior, and stakeholder expectations intersect in practice. In doing so, we position legitimacy as a dynamic process rather than a static state attribute, shaped by evolving legal, normative, and sociopolitical

conditions—thereby bridging abstract theory and empirical compliance patterns examined in later chapters.

2.3.1 Connection & Context: Theories to Research

Building on this synthesis, we explicitly connect legitimacy-based theories to observable compliance and divergent compliance behaviors within regulated research environments. Prior scholarship demonstrates that organizations respond to regulatory demands through strategic actions aimed at maintaining or restoring legitimacy in the eyes of regulators, peers, and the public. Through both formal rule adherence and broader reputational positioning. These theoretical insights inform the study's central premise that clinical trial reporting behavior reflects underlying legitimacy dynamics shaped by regulatory pressure, organizational incentives, and reputational considerations

2.3.1.1 Legitimacy Theory explains reporting compliance v. non-compliance

Organizations in controversial industries, such as human tissue trade, establish moral legitimacy via discourse. In 2019 Reuber and Morgan-Thomas (2019) published a study highlighting how organizations strategically frame activities to align with societal values via discursive arrangements which normalize controversial practices. Discursive construction of legitimacy directly parallels how clinical trial sponsors justify compliance with regulatory mandates. This study explored how ethically fraught industries shape public perception of legitimacy connecting to moral legitimacy frameworks as an ethical obligation of trial sponsors.

This research offers a framework for understanding how compliance decisions in clinical trials are defended and rationalized. Importantly, legitimacy dimensions inform direct-effects hypotheses tested in this dissertation; moderation pathways remain theoretically meaningful but are reserved for future research due to data-quality constraints and committee guidance.

2.3.1.2 How variables align with legitimacy-based mechanisms

This study adopts a legitimacy-informed lens to examine how key clinical trial characteristics—trial phase, funder type, geographic region, and therapeutic area—relate to patterns of compliance with results reporting requirements. Each of these variables functions as more than just a predictor: they represent institutional pressures that shape sponsor behavior in alignment with broader expectations of legitimacy.

Building on Scott's (1995) three-pillar framework—regulative, normative, and cognitive-cultural—and legitimacy dimensions advanced by Suchman (1995), these trial features can be seen as expressions of how organizational behavior conforms to law, ethical norms, and institutional expectations. Together, these pillars explain how sponsors interpret what is expected, what is acceptable, and what is strategic. For instance:

- **Trial phase** aligns with **cognitive legitimacy**, particularly as Phase 2–4 trials are embedded in institutionalized norms of transparency and public accountability.
- **Funder type** often signals **pragmatic legitimacy**, with publicly funded or academic trials held to a higher ethical bar for disclosure.
- **Therapeutic area**, especially oncology, is seated at the **moral legitimacy** intersection—where cultural expectations of rigor and transparency are well-ingrained.
- **Geographic region** maps to **sociopolitical legitimacy**, as global disparities in infrastructure, remediation, and oversight influence results reporting.

Kaganer et al. (2010) offer relevant insight here, emphasizing legitimacy-seeking behavior often emerges in response to technological, regional, and institutional pressures. Their work reinforces the idea these trial characteristics are not just descriptive—but behavioral signals that shape how organizations decide whether and when to comply.

2.3.1.3 Legitimacy dimensions & compliance behavior conceptual relationship

This conceptual model connects characteristics of trials to observed compliance behavior via a legitimacy lens. Rather than treating compliance as purely legalistic, this model emphasizes how organizations anticipate stakeholder interpretation of their reporting behavior.

Deephouse and Suchman (2008) point out legitimacy is, at times, pursued not just through meeting technical requirements, but also by conduct in ways that appear socially appropriate and strategically sound. In many cases, reporting decisions are driven less by fear of penalty and more by a desire to retain credibility and alignment with expectations.

Suchman's (1995) definition of legitimacy as a "generalized perception that an entity's actions are desirable, proper, or appropriate" within a social constructs in a system of norms, values, and beliefs is core here. It anchors this study's interpretation of compliance not as a binary state, but instead as a fluid expression of alignment, or misalignment, with various dimensions of legitimacy.

By positioning each trial characteristic within legitimacy framework, this study proposes a model that moves beyond enforcement—exploring compliance as a behavioral response to perceived pressures of legitimacy. This more nuanced perspective is critical—especially in a space like clinical trials, where implementation of reporting rules has been irregular, and where legitimacy often carries more weight than regulation in isolation.

In alignment with these legitimacy-based predictions, the conceptual model includes five primary hypotheses (H1–H5) that represent the direct effect of key trial characteristics on reporting compliance. Alongside, four moderating effect hypotheses (H6–H9) examining conditioning effects by regulatory or legal shifts. The dual structure of this model (Figure 2.1) reflects a core premise of legitimacy theory: that organizational behavior is not only shaped by

static characteristics, but also by evolving or emerging contexts. Therefore, "Regulatory/Legal Shifts" (H1) is modeled as both a direct predictor of compliance and also as a moderator of relationships of H5 through H9. The following conceptual diagram contains solid arrows which represent direct effects, while dashed arrows represent moderating effects. This structure permits this model to capture both baseline impact of trial features and additional dynamic influence of shifting policy legislation on sponsor compliance behaviors.

2.3.2 Formulation of Research Hypotheses

Building on the expansive legitimacy framework presented in Sections 2.1 and 2.3.1, as supported by empirical patterns discussed in Section 2.2, the following hypotheses are proposed. These examine direct predictors of compliance (H1-H5) and moderating effects of regulatory and legal paradigm shifts (H6-9) in ClinicalTrials.gov results reporting compliance.

2.3.2.1 Epoch – On-Time Results-Reporting – (H1. Regulative Legitimacy)

Rationale:

Regulative Legitimacy (Scott, 1995) emphasizes organizational responses to policy shifts because reporting behavior is structurally sensitive to regulations and enforcement signaling. Thus, compliance should vary by regulatory epoch as these institutional conditions evolve over time (Scott, 1995).

In the trial reporting domain, successive regulatory milestones – including enactment of FDAAA 801, and implementation of the FDA Final Rule—were structured as governance inflection points to clarify requirements and strengthen accountability expectations (Zarin, 2017; Zarin et al., 2016). Large-scale audits of ClinicalTrials.gov demonstrate temporal variation in reporting behavior aligned with regulatory shifts, indicating sensitivity to evolving governance conditions rather than static sponsor characteristics When a regulatory environment

strengthens—via mandate clarification and oversight expansion—organizations exhibit increased compliant to preserve standing and credibility as law-abiding entities.

Hypothesis:

H1: Compliance with ClinicalTrials.gov results reporting correlates positively with key regulatory/legal shifts.

2.3.2.2 Trial Phase – On-Time Results-Reporting – (H2. Cognitive Legitimacy)

Rationale:

Cognitive Legitimacy reflects taken-for-granted expectations about what constitutes appropriate and complete conduct within a field. From this (Suchman, 1995) standpoint such resource-intensive studies embed established norms that value transparency and disclosure.

Later-phase trials operate in a highly visible public and stakeholder space, where norms of evidentiary completeness, public accountability, and disclosure are deeply institutionalized.. Because Phase 2–4 trials are closely tied to product approval pathways and clinical decisions, failure to report results is more conspicuous and poses a greater threat to perceived legitimacy, increasing expectation that results are made public. Empirical audits of ClinicalTrials.gov consistently document phase-stratified reporting patterns, demonstrating structured variation across development stages (DeVito et al., 2024)

Hypothesis:

H2: Later-phase trials show higher adherence with results reporting requirements than early-phase trials.

2.3.2.3 Funder Type – On-Time Results-Reporting – (H3. Pragmatic Legitimacy)

Rationale:

Pragmatic Legitimacy (Suchman, 1995) centers on perceived stakeholder benefit, reputation management, and access to continued resources . Publicly funded government and academic sponsors are embedded in institutional environments emphasizing public accountability, stewardship of taxpayer resources, and disclosure norms.

These sponsors often face fewer structural barriers, few strategic disincentives, and greater perceived benefits in compliance relative to resource-constrained settings (Deephouse & Suchman, 2008). Funding source signals alignment with societal transparency expectations relative to commercial entities operating under competitive and market pressures. These normative expectations reinforce higher compliance, even under modest enforcement conditions. Large-scale compliance assessments demonstrate meaningful differences in reporting behavior by sponsor type, supporting funder classification as a structurally relevant predictor (Anderson et al., 2015; Goldacre et al., 2018).

Hypothesis:

H3: Government-sponsored trials demonstrate higher—though not total—compliance rates then commercially-sponsored studies.

2.3.2.4 Therapeutic Area – On-Time Results-Reporting – (H4. Moral Legitimacy)

Rationale:

Moral Legitimacy (Suchman, 1995) reflects normative judgments about whether organizational actions align with societal expectations of ethical conduct, particularly in contexts involving heightened risk due to patient vulnerability, public scrutiny, and ethical stakes – increasing pressure for transparent and timely disclosure.

Therapeutic area can proxy moral salience, as some clinical domains carry elevated ethical stakes due to disease severity and has a strong influence over legitimacy expectations. Oncology research occupies such a high-profile, socially sensitive domain. Evidence of selective reporting and outcome distortion in high-impact therapeutic areas demonstrates reporting behavior varies systematically with clinical context and perceived moral obligation (Turner et al., 2008), reinforcing therapeutic area as a meaningful dimension of compliance behavior.

Hypothesis:

H4: Oncology clinical studies exhibit stronger adherence to results reporting requirements than non-oncology trials.

2.3.2.5 Location - On-Time Results-Reporting - (H5. Sociopolitical Legitimacy)

Rationale:

Sociopolitical Legitimacy emphasizes how regulations, political scrutiny, advocacy pressure, and public visibility shape organizational behavior by influencing infrastructure, oversight, and stakeholder expectations with which sponsors operate *(Kaganer et al., 2010).* Clinical trial reporting obligations are embedded within jurisdiction-specific enforcement environments, where regulatory capacity and transparency norms vary substantially.

Those conducting trials in the United States typically face threat of more powerful enforcement governance, clearer compliance pathways, stronger institutional oversight regarding disclosure mechanisms, and a heightened public expectation for transparency, increasing adherence to reporting requirements. Global registry audits and monitoring initiatives consistently document cross-jurisdictional variation in reporting practices, underlining geographic region influences as a meaningful predictor of compliance (Goldacre et al., 2018; von Elm & Meerpohl, 2020)

Hypothesis:

H5: U.S.-based trials show higher compliance compared to those conducted in resource-limited regions.

2.3.2.6 Trial Phase x Regulatory Epoch – (H6. Cognitive x Regulative Moderation)

Rationale:

Regulative Legitimacy conditions the strength of other legitimacy mechanisms by altering rule clarity (*Scott, 1995*). Implementation of FDAAA 801 and the Final Rule represented governance inflection points that intensified institutional signaling around transparency and accountability (Zarin, 2017; Zarin et al., 2016).

Viewed through a *Cognitive Legitimacy (Suchman, 1995)* lens, later-phase trials are governed by deeply institutionalized norms that treat public disclosure as an expected component of appropriate conduct, given their proximity to product approval and clinical decision-making. Furthermore, a sense of heightened oversight may magnify existing differences between trial phase-based norms (Anderson et al., 2015).

As policies evolve, later-phase trials—already subject to strong transparency expectations—may exhibit disproportionately amplified compliance as sponsors work to meet intensified legal scrutiny (Goldacre et al., 2018). When regulatory expectations are made more explicit and enforcement becomes foreseeable, taken-for-granted phase-based norms are likely to be reinforced (Institute of Medicine, 2015). Audits of trial reporting consistently demonstrate phase-stratified patterns of compliance, suggesting regulatory change operates by intensifying existing institutional expectations (DeVito et al., 2020).

Hypothesis:

H6: Regulatory and legal shifts moderate the relationship between trial phase and compliance, such that the positive effect of later-phase trials on compliance is stronger following regulatory changes.

2.3.2.7 Funder Type x Regulatory Epoch – (H7. Pragmatic x Regulative Moderation)

Rationale:

Regulative Legitimacy shapes organizational behavior by altering monitoring expectations, thereby conditioning how other legitimacy mechanisms operate *(Scott, 1995).* When regulatory regimes shift institutional signaling around accountability changes the strategic calculus of compliance (Ramachandran et al., 2021).

From a *Pragmatic Legitimacy (Suchman, 1995)* perspective, organizations are motivated to comply when doing so preserves reputational standing. Regulatory changes can accentuate any pre-existing compliance gaps between sponsor types and commercial counterparts, whose strategic priorities potentially lean toward protection of competitive advantage. Industry sponsors operate within competitive markets where disclosure is more tightly balanced against proprietary considerations, potentially dampening responsiveness to regulatory change (Deephouse & Suchman, 2008).

Empirically, sponsor and institutional context has been shown to structure trial dissemination behavior and transparency performance, including distinct patterns among publicly funded trials and academic organizations, supporting funder type as a meaningful compliance differentiator under shared regulatory requirements (May-Wilson et al., 2018; Ross et al., 2012). Collectively, these findings support the expectation that regulatory inflection points

can accentuate existing sponsor-type differentials as organizations recalibrate reporting behavior under heightened accountability salience.

Hypothesis:

H7: Regulatory and legal shifts moderate the relationship between funding type and compliance, such that the compliance gap between industry and government sponsors is more pronounced post-regulatory shifts.

2.3.2.8 Condition x Regulatory Epoch – (H8. Moral x Regulative Moderation)

Rationale:

Regulative Legitimacy strengthens or weakens compliance incentives by changing the perceived credibility attached to formal rules *(Scott, 1995).* As regulatory expectations become more explicit*, Moral Legitimacy (Suchman, 1995)* becomes more behaviorally "binding" in domains where ethical stakes are highly visible and where transparency is framed as part of responsible scientific conduct.

Therapeutic area can proxy moral salience because some fields are publicly constructed as higher-stakes, higher-vulnerability contexts—conditions that intensify normative expectations for timely disclosure (Turner et al., 2008). Oncology, in particular, operates in a socially sensitive arena where patient vulnerability, public scrutiny, and the ethical duties of reciprocity and trust are foregrounded, making transparency failures more morally consequential (Dwan et al., 2008).

The broader transparency literature documents systematic risks of selective reporting and publication bias in clinically consequential domains, demonstrating dissemination behavior is patterned and ethically motivated rather than purely technical (Chan et al., 2004). Relatedly, ethics-oriented work on trial transparency frames nondisclosure as a breach of obligation to participants—precisely the type of moral legitimacy pressure expected to be stronger in high-

stakes therapeutic contexts (Morrow et al., 2023). Thus, as regulatory regimes heighten accountability expectations surrounding results reporting, therapeutic areas with stronger moral salience—such as oncology—should exhibit a more pronounced compliance response relative to lower-salience domains.

Hypothesis:

H8: Regulatory and legal shifts moderate the relationship between therapeutic area and compliance, such that oncology trials display an even stronger compliance advantage after regulatory shifts.

2.3.2.9 Location x Regulatory Epoch – (H9. Sociopolitical x Regulative Moderation)

Rationale:

Regulative Legitimacy clarifies enforcement expectations, institutional accountability, and conditioning how organizations respond to external governance pressures (Scott, 1995). From a *Sociopolitical Legitimacy (Kaganer et al., 2010)* perspective, the translation of formal rules into compliant action is mediated by surrounding, political, advocacy, and oversight infrastructure. Policy shifts might widen compliance disparities across global regions (Heredia et al., 2020). As regulatory expectations become more explicit, translation of trial characteristics into compliance behavior is expected to vary across regulatory epochs.

Geographic location operationalizes sociopolitical legitimacy because sponsors operate within distinct regulatory ecosystems and public accountability regimes (Wood & Perosino, 2008). U.S.-based trials are embedded within a highly institutionalized transparency environment characterized by centralized registries, journal alignment, and civil society monitoring (Lemmens & Telfer, 2012). These trials are subject to sustained political attention to research accountability (Levi-Faur, 2005). In contrast, trials conducted in fragmented regulatory settings may face lower

public visibility, and greater implementation barriers—even under formally equivalent legal requirements (Drezner, 2001)

Empirical research documents substantial cross-national variation in registration and results reporting performance, indicating transparency outcomes are shaped by jurisdictional context in conjunction legal mandate (Riveros et al., 2013). Accordingly, regulatory inflection points that heighten clarity and accountability expectations are likely to amplify regional differences as sponsors embedded in high-scrutiny environments respond more strongly to intensified institutional signaling.

Hypothesis:

H9: Regulatory and legal shifts moderate the relationship between trial geographic location and compliance, such that U.S.-based trials display increasingly higher compliance than non-U.S. trials subsequent to regulatory changes.

2.4 Closing: Conceptual Model & Justification

2.4.1 The Research Model (Conceptual Model)

2.4.1.1 Visual representation of conceptual framework

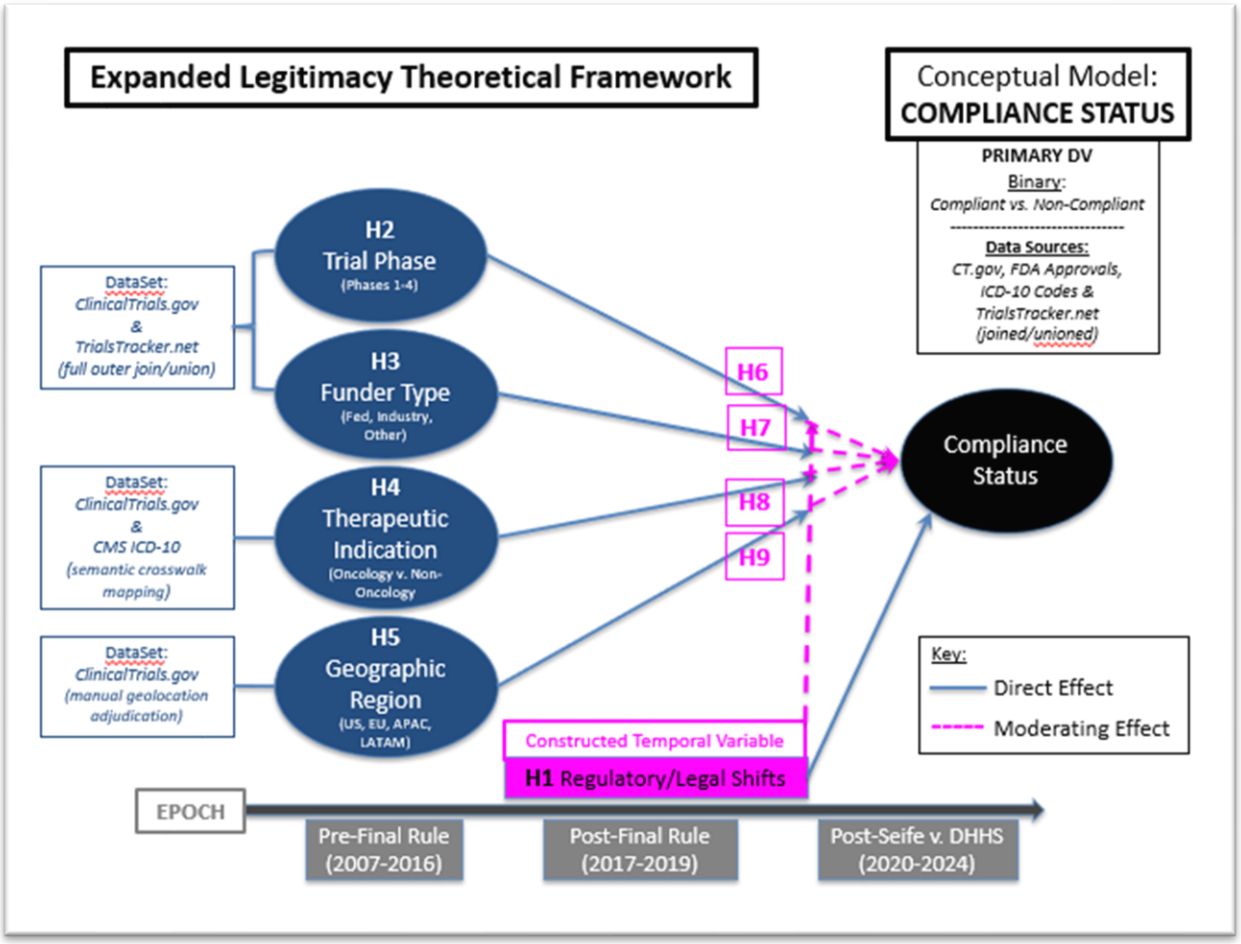

Figure 2.1

Reproduced Conceptual Model for Theoretical Framing

Note: Concept of legitimacy-based determinants of clinical trial results reporting compliance reproduced from Chapter 1, Figure 1.1, to support theoretical grounding.

Figure 2.1 presents the conceptual model guiding this study, illustrating how legitimacy-based apparatus link key trial characteristics, regulatory context, and clinical trial results reporting compliance.

Chapter 3. Data and Research Methodology

Although several prior studies have examined compliance with FDAAA 801, most focused on a narrow window immediately following the 2017 Final Rule — typically analyzing only those trials that became due between 2018 and 2019. These studies provide an important snapshot of early enforcement behavior, but capture only a small fraction of trials ultimately subject to the law. This, particularly true once the 2020 *Seife v. HHS* (United States District Court for the Southern District of New York, 2020) ruling clarified retroactive applicability of FDAAA 801 to trials initiated as far back as 2007.

In contrast to these early, limited-period analyses, our present study adopts a longitudinal design spanning the full regulatory landscape from 2007 through 2024. This broader analytic frame enables a more complete assessment of compliance behavior across all three enforcement epochs — FDAAA 801, the Final Rule, and *Seife v. HHS (2020)*—and aligns with the study's goal: Development of a theory-informed, predictive understanding of organizational reporting practices over time using a main-effects logistic regression model.

Chapter 3 outlines a methodological foundation for examination of compliance with FDAAA 801 results-reporting requirements through the lens of *Legitimacy Theory*. Building on the conceptual framework developed in Chapter 2, it describes how three core archival public data sources were integrated, cleaned, and analyzed creating a novel, multi-source dataset representing almost 150,000 interventional trials conducted between 2007 and 2024. All integration decisions were guided by a single principle: trial-level traceability through the NCT identifier.

Table 3.1

Chapter 3 Orientation: Structure, Purpose, and Data Overview

Section	***Focus and Purpose***	***Key Content / Data Sources***	***Alignment with Legitimacy Theory***
3.1 Research Design and Approach	Define quantitative, research design and theoretical framework. Introduce integration of public datasets enabling longitudinal analysis.	ClinicalTrials.gov, TrialsTracker.net, CMS ICD-10-CM, FDA Approvals Archive (exploratory only; not part of final analytic dataset	Establish overall institutional lens linking design to pragmatic, cognitive, moral, regulative, and sociopolitical dimensions.
3.2 Data Sources	Describe each dataset, coverage years, variables imported, provenance prefixes, and regulatory relevance.	Detailed comparative table of data sources; N = 147,288 after merge.	Ground study in observable institutional systems that generate (or fail to generate) legitimacy signals.
3.3 Data Collection, Transformation, and Operationalization	Define dependent and independent variables. Provide coding rules and sources.	Mapping; date normalization; exemption logic; tracking; validation checks. Compliance status, variable categories, exemption flag, regulatory epoch.	Demonstrate legitimacy through transparency and methodological accountability. Operationalize legitimacy constructs into measurable variables.
3.4 Analytical Strategy and Software	Outline phased analytic roadmap and software platform used for modeling.	Minitab 22.4 logistic regression	Link analytic phases to associated legitimacy dimensions.
3.5 Ethical Considerations and Data Integrity	Articulate ethical framework, provenance, and audit-trail documentation.	Public, non-identifiable data; audit logs; secure storage.	Center legitimacy through transparency, stewardship, and truthfulness.
3.6 Limitations of the Methodology	Emphasis on precision via FDAAA 801-specific archival dataset. Inherent limits in data completeness and generalizability.	Potential Bias, Mitigation, Forward Looking Statement	Capture legitimacy quantitatively. Reflect dimensions of institutional transparency to be explored more fully in future research.
3.7 Summary and Transition	Synthesize methodological stages and bridges to Chapter 4 (Results).	Overview of data pipeline, validation outcomes, and forthcoming analyses.	Position findings within legitimacy's empirical manifestation across compliance behaviors.

Table 3.1 provides chapter's structural overview, and summarizes the focus of each section, data sources applied, and their theoretical alignment within the broader legitimacy

framework. Each section to follow details a sequential stage of this process—from research design and data sourcing to analytical strategy and ethical considerations—demonstrating how the study's quantitative approach operationalizes cognitive, moral, regulative, pragmatic, and sociopolitical dimensions of institutional legitimacy.

3.1 Research Design

This study's research design was built upon integration of multiple complementary public datasets—ClinicalTrials.gov (in the dataset labeled and coded as CTG), TrialsTracker.net (in the dataset labeled and coded as TT), and CMS ICD-10-CM classifications—to form a single, cross-referenced foundation for longitudinal regulatory analysis. Integration across datasets was anchored on the National Clinical Trial (NCT) identifier, which served as the universal primary key linking ClinicalTrials.gov and TrialsTracker records at the trial level. Combined, these sources capture institutional, ethical, and procedural dimensions of clinical trial transparency across an evolving regulatory landscape of FDAAA 801 from enactment through expanded procedural reach established by *Seife v. HHS* decision in 2020. Exploratory work with a fourth source, the FDA approvals archive, was conducted but not incorporated into the final analytic dataset and is described separately in Section 3.2.4.

Integration of these datasets produced a novel, multi-source analytic framework encompassing 147,288 interventional trials and enabled examination of compliance behavior through combined lenses of Legitimacy Theory and quantitative institutional analysis. This design supports evaluation of structural determinants of reporting compliance within the evolving U.S. regulatory environment.

3.1.1 Research Purpose, Questions, and Model Alignment

This study is an examination of compliance with clinical trial results reporting requirements under the U.S. Food and Drug Administration Amendments Act of 2007, Section 801 (FDAAA 801) (2007) as well as subsequent deterrence frameworks, including the Final Rule (2017) and the legal precedent of *Seife v. HHS (2020)*. Despite these mandates, persistent non-compliance continues to raise concerns regarding regulatory effectiveness, research transparency, and erosion of public trust. Failure to report creates gaps in our biomedical evidence-base, hinders medical innovation, and exposes sponsors to reputational damage, financial penalties, and diminished investor confidence. Understanding systemic drivers of compliance—beyond statutory requirements remains an ethical, practical, and pressing policy-relevant imperative.

This study addresses two research questions:

1. **What key events, such as major legal rulings and regulatory changes, have influenced compliance with FDAAA 801?**
2. **What patterns emerge in compliance across therapeutic areas, funding sources, trial phases, and geographic contexts?**

To address these questions, this study tests two sets of hypotheses. The first five (H1–H5) assess direct effects of regulatory change and trial characteristics on compliance. These hypotheses are empirically tested using a main-effects logistic regression model. The remaining four (H6–H9) posit whether regulatory and legal shifts may moderate those relationships. These hypotheses are retained conceptually as theoretically meaningful and explicitly deferred to future research consistent with scope and data-quality considerations.

The conceptual model positions these predictive variables and moderators within a framework of Legitimacy Theory, drawing on Scott's (1995) regulative institutional pillar and

Suchman's (1995) cognitive, moral, and pragmatic legitimacy dimensions as well as Kaganer et al.'s (2010) sociopolitical legitimacy framework. In this model, trial characteristics represent institutional pressures, wherein compliance behavior is envisioned as a strategic and normative response to these external pressures in context of a shifting regulatory landscape.

3.1.2 Approach

Grounded in Legitimacy Theory, this study seeks to identify how various trial characteristics–-such as study phase, therapeutic area, funding source, and geographic location—influence compliance behavior. Legitimacy Theory, as proposed by Suchman (1995) and expanded by Kaganer et al. (2010) positions compliance not only as a legal obligation but also as an organizational response to societal, political, and normative pressures. Their framing highlights how regulatory legitimacy is quite dependent on the public's acceptance and sustained credibility. Historical precedents, journalistic investigations, and advocacy campaigns (e.g., AllTrials) demonstrate sociopolitical pressures can be as significantly influential—if not more than monetary penalties in driving adherence.

By systematically applying this theoretical lens to longitudinal, multi-source data, this research aims to illuminate legitimacy-based determinants in compliance, and offer evidence strengthening regulatory strategy, improving transparency, and restoring public trust in clinical research efforts and findings.

3.1.3 Design

3.1.3.1 Justification for Quantitative, Non-Experimental Design

This study adopts a quantitative, non-experimental design in order to examine relationships between trial characteristics, regulatory events, and overall compliance with ClinicalTrials.gov results reporting requirements. Such a design enables a statistical test of

theory-derived hypotheses with no manipulation of variables, and makes it appropriate for archival data analysis across the large population of clinical research studies.

3.1.3.1.1 Justification of predictive modeling approach

Application of a predictive modeling approach to this study is both methodologically and practically justified by example of recent scholarly works examining transparency, compliance patterns, and regulatory behavior. While many previous studies focus on descriptive or post-hoc analyses of compliance (DeVito et al., 2024; Gresham et al., 2022), there is growing recognition predictive modeling surfaces systemic risk and signals where targeted intervention might be warranted. A shift from retrospective evaluation to forward-looking analyses aligns with a call for proactive governance in the clinical trial reporting ecosystem.

Lindsley et al. (2021) highlight current compliance gaps are poorly modeled, especially in predicting which studies are likely to fall short of reporting requirements. Likewise, Axson et al. (2021) emphasized a need for structured modeling frameworks to improve visibility into transparency initiative performance over time, particularly when supported by publicly available data. Incorporation of multiple data layers for this study—ranging from the Federal trial registration system to ICD-10 codes and FDA approvals data—mirrors the approach advocated by Chen et al. (2024), who demonstrated cross-platform data integration enhances predictive accuracy and policy applicability.

Importantly, recent policy-pertinent publications, including Smith et al.'s (Smith, Minichmayr, Standing, Giacomini, van der Graaf, & Peck, 2023), reinforces a necessity for predictive analytics for early-phase trials, where reporting non-compliance can have serious implications. The emerging enforcement landscape, reflected in the WHO's 2025 guidance (Chan et al., 2025) on registry-based result reporting, calls for analytical methods that not only

track trends but also forecast gaps in compliance. Predictive modeling therefore stands as a vital tool for alignment of regulatory expectations with real-world sponsor behavior.

Legitimacy theory, while initially used in conceptual or qualitative inquiry, has been shown to inform model-based approaches to compliance and organizational behavior. Reuber and Morgan-Thomas (2019) and Islam et al. (2022) illustrate how legitimacy perceptions can be treated as latent influences on decision-making and handily mapped onto measurable variables. This study advances that direction by linking legitimacy-aligned trial characteristics to binary compliance outcomes. This creates a structured pathway from theory toward predictive analysis.

Additionally, predictive modeling is particularly well suited to address very real-world action gaps identified in repeated research. Ramachandran et al. (2021) and South et al. (2022) highlight both inconsistencies in FDA follow-through and missed opportunities to leverage AI and structured data tools to identify chronic noncompliance. Predictive modeling not only fills a methodological void in the literature—it also enables deeper, legitimacy-driven understanding of study sponsor behaviors. By leveraging data across systems and anchoring analysis in regulatory and institutional theory, this study is positioned at the intersection of practical policy relevance and theoretical advancement.

To summarize, Chapter 2 establishes a theoretical foundation for examination of compliance behavior through the lens of *Legitimacy Theory*, emphasizing how pragmatic, moral, cognitive, sociopolitical, and regulative dimensions jointly shape institutional transparency in clinical research. Review of the theory demonstrates that despite the FDAAA 801 formal mandate, compliance remains uneven and poorly understood across sponsors, therapeutic areas, and regulatory rulings. The clear gap between *legal requirement* and *legitimate practice* surfaces a need for rigorous, data-driven inquiry capable of tracing what organizations report, and how

their reporting behaviors reflect broader accountability patterns. The following chapter details research design and analytic methods developed to meet that need — integration of complementary public datasets into a unified empirical framework allows measurement and modeling of legitimacy in action.

3.1.3.2 Rationale for Archival/Secondary Data Use

Given the research focus is on historical compliance behaviors within a regulatory context, this study relies exclusively on archival datasets from publicly available, and recognized authority sources. Integration of ClinicalTrials.gov, TrialsTracker.net, CMS ICD-10 codes, and exploratory review of FDA Approvals data allows for longitudinal, and multi-layered views of patterns in compliance—eliminating a need for direct research participant interactions.

3.1.3.3 Analytical Framework (Predictive Modeling)

This analytic framework employs logistic regression to quantify how key trial characteristics predict compliance with reporting requirements. Consistent with the refined study scope, this dissertation reports results from a single main-effects model that directly evaluates H1–H5. This approach extends prior transparency research (e.g., Goldacre et al., 2018; DeVito et al., 2019) by moving beyond descriptive statistics to identify predictors of non-compliance risk, in alignment with growing calls for proactive monitoring of the clinical trial reporting ecosystem.

3.1.3.4 Planned but Deferred Moderating/Interaction Effects

At design stage, the conceptual model specified interaction terms between trial characteristics and temporal regulatory milestones (Final Rule and Seife v. HHS) to test H6–H9. These moderation effects would assess whether influence of trial phase, funding type, therapeutic area, or geography changes significantly after key policy shifts. However, in consultation with the dissertation committee, interaction models are reserved for post-dissertation research. The

present study therefore reports only main-effects logistic regression model while clearly articulating H6–H9 as theoretically grounded but empirically deferred.

Although the conceptual model specifies moderating interaction effects between key trial characteristics and regulatory epochs (H6–H9), these analyses are intentionally deferred from the present dissertation. At the design stage, interaction models were specified and partially implemented; however, in consultation with the dissertation committee, the decision was made to prioritize estimation and interpretation of main effects in order to preserve analytic clarity and methodological focus within the scope of this study. Importantly, the interaction analyses represent an active and ongoing extension of the current work, for which data preparation and preliminary modeling have already commenced. These moderation effects are therefore articulated here as theoretically grounded and analytically motivated, but reserved for dedicated follow-on publication, ensuring their empirical treatment receives warranted depth and attention.

3.2 Data Source & Sample

Prior compliance studies have typically relied on constrained samples defined by early Final Rule deadlines. For example, analyses such as the groundbreaking DeVito et al. (2020) publication, examined only Applicable Clinical Trials (ACTs) and Probable Applicable Clinical Trials (PACTs) with primary completion dates and triggered reporting obligations falling between January 2018 and September 2019, yielding a denominator of 4,209 trials. While appropriate for characterizing early post–Final Rule performance, such restricted cohorts are often extrapolated to the whole data set yet omit a substantial body of trials subject to FDAAA 801 across the statute's full operational period, including those later and retrospective data set brought under disciplinary rules via the 2020 *Seife v. HHS* decision. This restriction reflected the

first cohort for which the 12-month results-reporting deadline had unequivocally passed—under the 2017 Final Rule implementation timeline.

Table 3.2

Data Sources and Regulatory Relevance

Data Source	***Coverage Years***	***Key Variables Imported***	***Provenance Prefix***	***Regulatory Relevance***
ClinicalTrials.gov (CTG)	2007–2024	NCT Identifier, Funder Type, Trial Phase, Primary Completion Date, Results First Reported Date, Conditions, Locations.	CTG_	Primary registry mandated by FDAAA 801. Authoritative record of trial registration and reporting status.
TrialsTracker.net (TT)	2017–2024	Results Reporting Status, Overdue Flag, Exemption Indicator, Days Late	TT_	Independent compliance-monitoring system built on CTG data. captures enforcement-related performance metrics and exemption flags.
CMS ICD-10-CM (ICD)	2023 (reference manual)	Diagnostic Chapter Codes (A–Z)	ICD_	Provides standardized classification for disease and therapeutic area coding. Allows aggregation of free-text trial conditions into structured categories.
FDA Approvals Archive (FDA) – exploratory only	2007–2024	Approval Year, Product Name, Division (CDER/CBER/Device), Notes on Linked Trials	FDA_	Explored to assess feasibility of linking product approvals to trials; not merged into final analytic dataset due to lack of identifier standardization (see Section 3.2.4).

Our present study addresses this limitation by constructing a comprehensive dataset of approximately 147,000 interventional trials registered on ClinicalTrials.gov from 2007 to 2024.

This full-scale sampling frame captures all trials potentially subject to reporting requirements across successive regulatory epochs and allows for a more rigorous comparison of compliance patterns, predictors, and temporal dynamics than previously possible.

Further, this study targets three primary data sources; each selected for unique regulatory relevance and potential to address different dimensions of institutional legitimacy. A fourth source, the FDA approvals archive, was systematically explored but ultimately excluded from the merged analytic dataset due to structural limitations; this exploratory work is documented in Section 3.2.4 and positioned as a bridge to future research. Collectively, these datasets provide complementary views of clinical-trial registration, reporting, classification, and disease categorization. Table 3.2 provides an overview of the regulatory relevance of each dataset.

3.2.1 Data Sample

This study focuses on clinical trials subject to results reporting requirements under FDAAA 801 (2007), spanning trials initiated between 2007 and 2024. All interventional clinical studies registered on ClinicalTrials.gov—defined as those in which participants are assigned to receive one or more interventions to evaluate biomedical or health-related outcomes–-constitute the primary target population. This definition aligns with the regulatory scope of FDAAA 801 and excludes observational studies, which are not held to the same federal reporting obligations.

Additionally, early-phase studies (Phase I and certain feasibility, expanded-access, or minimally invasive laboratory studies) are treated as exempt from FDAAA 801 requirements under 21 CFR 312.2(b) and 812.2(c). These studies are not legally obligated to report results.

Inclusion criteria encompasses all interventional trials with a valid “Start Date” entry within the respective range, regardless of trial phase, sponsor type, therapeutic area, geographic location, or results status. Studies outside the U.S. are also subject to jurisdiction because non-

U.S. entities typically register on *ClinicalTrials.gov* when intending to operate within the United States or pursue FDA approval. Exclusion criteria apply only to studies missing critical fields necessary for cross-dataset integration (e.g., funder type, study phase, location, or NCT number).

In order to examine potential influence of regulatory context, the sample is segmented simply into three temporal cohorts, or epochs:

1. Pre-Final Rule (2007–2016) – Epoch 1,
2. Post-Final Rule (2017–2019) – Epoch 2, and
3. Post-*Seife v. HHS* (2020–2024) – Epoch 3.

This stratification enables longitudinal comparison of compliance behaviors before and after two pivotal, punctuated regulatory events.

Importantly, this study retains trials with ambiguous or missing "Study Results" tags, acknowledging prior research which has shown ClinicalTrials.gov's binary result fields often misrepresent or mismatch actual reporting behavior.

The raw dataset includes 142,056 trials, offering comprehensive coverage and enabling multivariate logistic regression model segmentation across trial phase, funder type, location, and therapeutic areas. This large sample size provides strong statistical power for main-effects modeling and supports stratified analysis aligned with the study's legitimacy framework. It also establishes a foundation for more complex quasi-experimental designs in future research

The analytic window for the study is defined as January 1, 2007, through December 31, 2024. This scope reflects statutory, regulatory, and judicial milestones which collectively establish the full period of enforceable obligations for results reporting under federal law. The Food and Drug Administration Amendments Act of 2007 (FDAAA 801), enacted on September 27, 2007, first required sponsors of "applicable clinical trials" (ACTs) to submit results

information to ClinicalTrials.gov within twelve months of primary endpoint completion date. On January 18, 2017, the Department of Health and Human Services implemented the Final Rule (42 C.F.R. Part 11), clarifying definitions, expanding scope of covered trials, and introducing tougher reporting and penalty provisions. Subsequently, the *Seife v. U.S. Department of Health and Human Services* (S.D.N.Y., Feb. 24, (2020)) decision held FDAAA 801 unambiguously required basic results disclosure for pre-Rule, pre-approval ACTs, thereby retroactively confirming obligations applied to trials completed as far back as 2007.

To ensure stability of compliance measurement, this dataset is frozen as of December 31, 2024, corresponding to the end of the most recently completed calendar quarter at the time of acquisition. This analytic window enables both cross-sectional assessment and longitudinal comparisons across distinct regulatory epochs.

3.2.1.1 Definition of Clinical Trials Results Reporting (Compliance)

Throughout this dissertation, the term *compliance* refers specifically to clinical trial results reporting, defined as posting primary-outcome results to ClinicalTrials.gov within 12 months of the trial's primary completion date, as required under FDAAA 801 and reaffirmed by the 2017 Final Rule. In practice, regulators, journalists, and researchers commonly use "results reporting" and "compliance" interchangeably when discussing adherence to this legal requirement. To support clarity for both academic and practitioner audiences, I adopt the plain-language term *clinical trial results reporting* in most narrative sections, while retaining the term "compliance" when referring to legal criterion or binary analytic variable.

3.2.2 Data Sources

This study integrates data from three publicly available but independently maintained datasets. While each source has been used independently in prior research, no published study

has successfully combined these three into a single analyzable dataset. Their integration provides a multidimensional lens to examine structural drivers of reporting compliance:

- **ClinicalTrials.gov**

  The primary U.S. registry for interventional trials, mandated under FDAAA 801 providing structured data on study status, sponsor, phase, location, and result reporting.

- **TrialsTracker.net**

  A compliance monitoring platform built by DeVito, Goldacre, and colleagues (2020) at Oxford University–-and reported in *The Lancet*. It contains reporting status, exemption classification, publication links, and estimated regulatory penalties.

- **CMS ICD-10 Codes**

  A compendium of 64,830 standardized diagnostic codes and descriptions, and used to categorize cross-referenced therapeutic areas with trial condition data, enabling stratification and s thematic compliance analysis.

- **FDA Approvals Database (exploratory)**

  As described in Section 3.2.4, this curated set of FDA-approved products was assessed for linkage feasibility but not incorporated into the merged analytic dataset due to incomplete and non-standard identifiers.

The selected timeframe (2007–2024) corresponds to implementation of FDAAA 801, the Final Rule, and the *Seife v. HHS* decision (2020). This span allows for a regulatory and contextual analysis of reporting trends across shifting incentive environments.

3.2.3 Data Integration and Inclusion Logic

All three core analytic datasets were evaluated for completeness, interoperability, and regulatory relevance. ClinicalTrials.gov (CTG) served as the base dataset. TrialsTracker.net (TT)

records were then merged. Integration centered on NCT identifier as universal primary linking key, ensuring trial-level alignment across sources. One-to-many and many-to-one discrepancies were resolved through normalization and manual cross-referencing. Trials lacking NCT identifiers or interventional classification were excluded. Trials appearing in both datasets were horizontally merged, while TT-only records (Δ = +5,232 trials) were appended as additional rows. After iterative cleaning and validation, this process expanded the analytic frame and the merged dataset expanded from 142,056 unique ClinicalTrials.gov trials to 147,288 total records. A full outer join logic was applied to preserve and incorporate all matched, unmatched, and exempt trials. Each trial was assigned a merge status indicator ("Both", "CTG only", or "TT only") to preserve row-level provenance and enable sensitivity analyses. ICD-10 codes were cross-walked to CTG condition fields post-merge and do not alter the record count. This unified dataset underpins all analyses presented in Chapters 4 and 5. Findings from the FDA approvals exploration, while not part of this merged dataset, are preserved as methodological artifacts and future research prompts (Section 3.2.4).

3.3 Data Collection, Preparation & Transformation Methods

The process of preparing a master dataset for analysis required extensive data cleaning, harmonization, and validation across distinct public sources: ClinicalTrials.gov, TrialsTracker.net, CMS ICD-10-CM codes, and the exploratory work with the FDA Approvals archive. Each source differed in structure, scope, and completeness, demanding a multi-stage workflow designed to produce a transparent, reproducible, and analysis-ready dataset—hereafter referred to as Combined Master dataset.

Overall, preparation followed a seven-stage workflow, from manual scrubbing of free-text fields to construction of a harmonized master dataset. Figure 3.1 summarizes these stages and key decisions taken at each step.

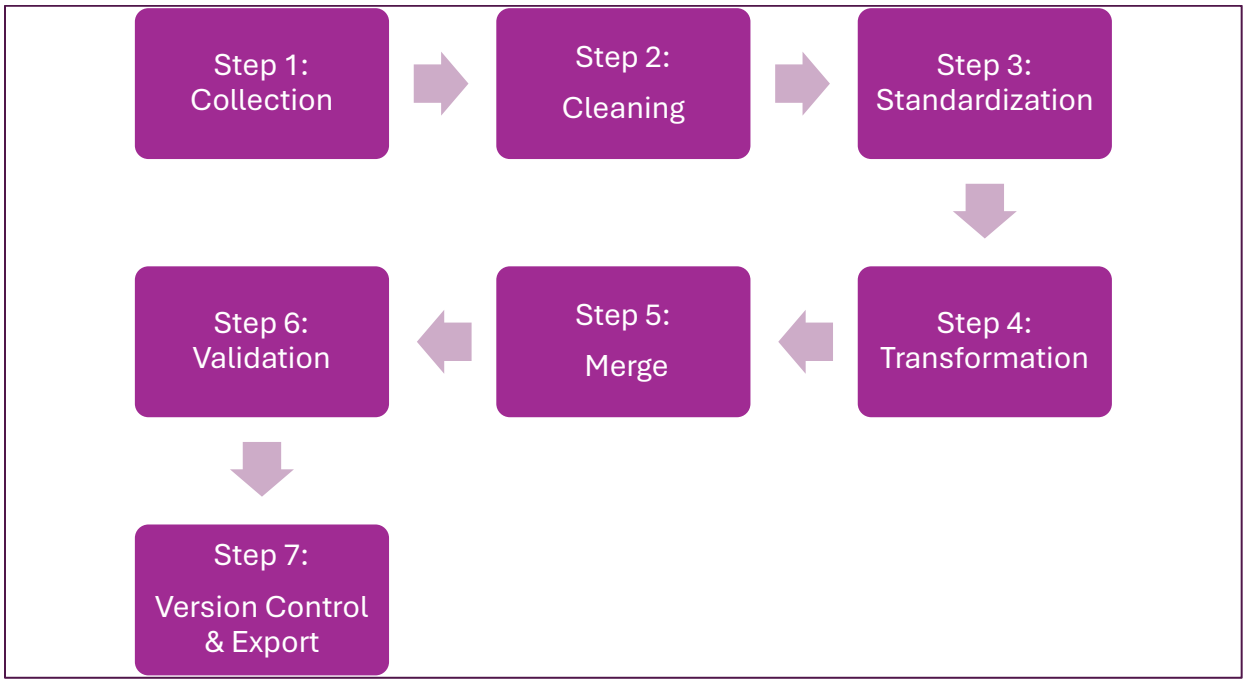

Figure 3.1

Workflow of Data Preparation and Integration

3.3.1 Data Collection

This study required assembly of a large, multi-source dataset to examine predictors of compliance with FDAAA 801 results-reporting requirements. Data collection integrated three primary analytic data sources— ClinicalTrials.gov, TrialsTracker.net, and CMS ICD-10 code classifications—with exploratory review of the FDA product-approvals archives.

ClinicalTrials.gov

The primary dataset consisted of interventional trials with start dates between January 1, 2007, and December 31, 2024 (n=142,056). Extracted fields included core registry metadata such

as NCT number, study status, sponsor and funder type, trial phase, outcomes, locations, and key timeline variables (e.g., start date, primary completion date, and results posting dates).

TrialsTracker.net

TrialsTracker provides a structured exportable database t monitors compliance with trial results reporting. Records were downloaded in full, with NCT number serving as a common linking key to merge with ClinicalTrials.gov data.

CMS ICD-10 Codes

Direct trial-level assignment of ICD-10 codes is infeasible due to the free-text nature of key ClinicalTrials.gov fields (e.g., “Study Title,” “Conditions,” “Interventions”). To overcome this hurdle, the full ICD-10 list was obtained from which a custom high-level crosswalk was developed, for step-by-step mapping of trial conditions to primary ICD-10 chapter categories (A–Z). This enabled systematic classification and recoding by therapeutic area while accommodating inconsistent terminology.

A manually created ICD-10 classification column was added adjacent to the “Conditions” field. Given variability of free-text condition entries (e.g., “AIDS,” “HIV Infection,” “Acquired Immune-Deficiency Syndrome”), clean coding was performed line-by-line by a trial executive with 35+ years of invaluable clinical expertise.

FDA Approvals

The FDA approvals archive is not designed for large-scale extraction. It requires manual retrieval of approval announcements from both current postings and multiple historical archives, many with different labeling conventions.

To ensure completeness, acquired approvals were cross-referenced with *Nature*’s annual FDA approvals report. Product identifiers ranged from standard generic names to company-

specific alphanumeric designations (e.g., ARV-471, PF-07850327) and study-specific identifiers (e.g., ER-102-BRCA). Because multiple trials and phases can underlie a single approval, each approval was matched to all known associated clinical trial NCT numbers and aggregated as such. Because of structural and identifier limitations described in Section 3.2.4, the approval records were ultimately excluded from the analytic dataset.

3.3.2 Data Cleaning and Standardization

Initial phased cleaning focused on ensuring internal consistency and formatting uniformity across CTG and TT datasets. The analytical sample was refined from an original 147,288 interventional trials to **109,065 non-exempt trials** subject to FDAAA 801 results-reporting requirements.

- Free-text condition fields from CTG were manually standardized and cross-walked to ICD-10 chapter categories (A–Z) using the CMS ICD-10-CM reference manual.
- Date formats were normalized through an Excel-based transformation pipeline that applied the EOMONTH method to partial dates (YYYY-MM → last day of month) and replaced malformed entries with null values.
- Location data were decomposed into *Country* and *Region* variables, then recoded to include "Global," "Multi-Country," or "Missing" as appropriate.
- Variable names were prefixed to preserve provenance (CTG_, TT_), and a Source field was added at the row level to document origin and facilitate audit tracking.

3.3.2.1 Condition Harmonization and ICD-10-CM Mapping

For TT-derived trials in which the CTG "Condition" field was blank, medical conditions were harmonized using a collapsed ICD-10-CM chapter framework. Each trial's CTG "Study Title" was reviewed for disease or therapeutic indication terms, which were then entered into a

CTG “Conditions” free-text field and cross-walked to ICD-10 chapter letters (A–Z). For example, trials referencing cancer, carcinoma, or lymphoma were coded to chapter C (neoplasms); those mentioning HIV, hepatitis, or sepsis were assigned to chapters A or B (infectious and parasitic diseases); diabetes indications were coded to chapter E (endocrine disorders); aortic disease to chapter I (circulatory system); anemia to chapter D (blood and blood-forming organs); COVID-19 to chapter U (emergency use); pain syndromes to chapter R (abnormal clinical and laboratory findings); and healthy volunteer studies to chapter Z (factors influencing health status). The U.S. ICD-10-CM system maintained by CMS and NCHS was used as the reference standard, ensuring consistency with U.S. regulatory and coding practices.

3.3.2.2 Geographic Harmonization

For TT records in which CTG “Location” free-text, CTG “Country”, or CTG “Region” were blank, geographic attributes were inferred from sponsor and funder information. Trials with NIH or U.S. Federal funders (where CTG “Funder Type” = NIH or FED) and sponsors clearly identifiable as U.S. institutions (e.g., named medical centers, universities, or organizations using “MD”/“M.D.” or “LLC”/“L.L.C.” suffixes) were coded as located in the United States and assigned to the North America region. Conversely, trials sponsored by entities such as the U.K. National Health Service (NHS) or clearly labeled European institutions were coded to their corresponding countries and regional groupings. This targeted imputation minimized missingness in location variables while preserving face-valid geographic classifications for use in regional compliance analyses.

3.3.3 Data Transformation

Following collection, extensive transformation was required to integrate the three core datasets (CTG, TT, and ICD-10) and to document exploratory attempts to link FDA approvals.

Coding Procedures and Crosswalk Development:

- Develop a custom ICD-10 collapsed chapter-level crosswalk to categorize conditions from ClinicalTrials.gov.
- Conditions were harmonized using ICD-10-CM chapter categories to derive high-level therapeutic-area groupings, including an oncology indicator used in the main models.
- Year–month Primary Completion Date entries were systematically converted to the final calendar day of the specified month to permit consistent calculation of due dates (+12-month FDAAA 801 reporting window) across trials.
- Exploratorily map manually compiled and curated FDA approval records to trial NCT numbers, harmonizing product names, scientific identifiers, and trial phases (see Section 3.2.4); these mappings were not retained in the final analytic dataset.
- Recode categorical variables for phase, sponsor type, funder type, and therapeutic area to ensure consistent classification across datasets.

3.3.3.1 Trial Phase Harmonization and Exemption Classification

For trials originating from TrialsTracker subset where CTG "Phase" fields were blank, study titles were manually reviewed and searched for explicit phase indicators. Trials whose titles referenced EARLY_PHASE1, PHASE1, PHASE1|PHASE2, PHASE2, PHASE2|PHASE3, PHASE3, or PHASE4 were recoded to standard values, whereas those without clear phase information were left uncategorized. Phase coding also informed exemption status: consistent with FDAAA 801 and 21 C.F.R. 312.2(b) and 812.2(c), all EARLY_PHASE1 and PHASE1 trials and clearly labeled feasibility or exploratory device studies were treated as exempt from mandatory results reporting. These trials were flagged in the Exemption variable and retained for descriptive context but excluded from inferential models focused on applicable trials.

Integration and Linking:

- Merge datasets using NCT numbers as primary key.
- Standardize date formats and aligned time frames across sources.

Handling Missing or Ambiguous Data Resolution:

- Backfill missing values from alternate data fields or corroborating datasets.
- Flag incomplete records for exclusion or separate analysis.
- Document unresolved inconsistencies for transparency and reproducibility.

Quality Checks and Validation:

- Perform duplicate detection and removal across merged datasets.
- Conduct manual spot checks confirm alignment of trial attributes with external sources.
- Verify accuracy of ICD-10 coding using random sampling and secondary reviewer checks, where feasible.

This integration process is intended to produce a novel, fully cross-referenced dataset that resolves limitations of siloed registry and approval records, enabling more robust analyses of compliance drivers.

3.3.4 Variables and Operationalization

Non-U.S. trials typically register on ClinicalTrials.gov only when engaging in U.S. sites or seeking FDA approval. The operationalization stage translated each conceptual construct into a measurable variable suitable for statistical modeling under Legitimacy Theory.

To capture longitudinal variation in the policy environment, each clinical trial record was assigned to a regulatory epoch corresponding to the major enforcement milestones of FDAAA 801. the term “regulatory epoch” refers to distinct policy-governance periods that define shifts in

compliance expectations and signaling behavior over time. regulatory epoch operationalizes the temporal dimension of FDAAA 801 implementation.

Table 3.3

Regulatory Epochs Used for Temporal Classification (FDAAA 801, 2007–2024)

Regulatory Epoch	***Coverage Years***	***Defining Policy Context / Milestone***	***Legitimacy Dimension Represented***
Epoch 1 – Pre-Final Rule	2007–2016	FDAAA 801 enacted; limited guidance and minimal enforcement. Compliance largely symbolic or voluntary.	Regulative legitimacy (weak formal authority) / Symbolic legitimacy emergent
Epoch 2 – Post-Final Rule	2017–2019	Final Rule effective Jan 18, 2017, clarified obligations and timelines for results reporting.	Regulative legitimacy formally codified but inconsistently applied
Epoch 3 – Post-Seife v. HHS	2020–2024	Federal court ruling closed retroactive loophole; confirmed applicability of FDAAA 801 to all post-2007 trials.	Regulative legitimacy re-asserted and enforcement credibility strengthened

Note: Coverage period extends through 2024, the latest date for which results could legally be due within 12 months of primary completion (U.S. Food and Drug Administration, 2007, 2017); *Seife and Lurie v. U.S. Department of Health and Human Services* (2020).

Here, time and law are embedded as analytical constructs — a direct bridge from theory (legitimacy → regulative change) to method (epoch coding). This classification reflects the study's theoretical emphasis on the regulative dimension of legitimacy — that is, how institutional actors respond to shifts in formal mandates and threat credibility.

Table 3.4

Variable Operationalization

Variable	***Operational Definition / Coding Source***
Compliance Status (DV)	*Binary:* *1 = results posted ≤ 365 days after Primary Completion Date.* *0 = not posted at all, or posted ≥ 366 days after Primary Completion Date.* *Calculated in Excel using FDAAA 801 12-month rule.*
Trial Phase	*Categorical variable (EARLY_PHASE1–PHASE4).* *Source: CTG_Trial_Phases field standardized per FDA/NIH taxonomy.*
Funder Type	*Nominal variable:* *NIH, FED, OTHER-GOV, INDUSTRY, INDIVIDUAL, OTHER.* *Recoded from CTG_Sponsor_Name following ClinicalTrials.gov PRS User's Guide (National Library of Medicine (ClinicalTrials.gov), 2024).*
ICD-10 Category	*Alphabetic A–Z chapter code.* *Derived from therapeutic condition text via manual mapping to CMS ICD-10-CM and custom crosswalk.*
Region (Geographic Location)	*Derived variable from CTG_Country_Name / Region_Adjusted.* *Coded as United States, Multi, etc., or specific global region.*
Exemption Flag	*Binary:* *TRUE = exempt per 21 CFR 312.2(b) / 812.2(c);* *FALSE = subject to FDAAA 801).* *Source: TT_has_exemption_TF and phase logic.*
Regulatory Epoch (Key Predictor)	*Time-based categorical variable:* *Pre-Final Rule (2007–2016), Post-Final Rule (2017–2019), Post-Seife v. HHS (2020–2024).* *Derived from Study Start Date.*
Dependent Variable Transformation	*Compliance with on-time results reporting identified as the computed field CTG_Compliant_TF;* *Validated against TT indicators where available, or calculated.*

To account for longitudinal shifts in regulatory environment influencing compliance behavior, trials were categorized by regulatory epoch. Table 3.3 summarizes epochs and their defining characteristics. This temporal coding structure was integrated alongside other harmonization variables — such as phase, funder type, ICD-10 category, region, and exemption

flag — to support comparative and multivariate analyses of compliance behavior across evolving regulatory contexts. Table 3.4 summarizes variables, coding sources, and transformation logic.

3.3.4.1 Construction of Compliance Indicators

Compliance indicators were recalculated directly from ClinicalTrials.gov fields using a fixed analytic cut-off date of December 31, 2024. For each trial, a due-date variable was defined as twelve months after the Primary Completion Date, consistent with FDAAA 801 Basic Results reporting requirements. If Primary Completion Date was missing or malformed, the due date was coded as missing and such trials were classified as "No Due Date" for descriptive purposes. A flag was set to 1 when a valid Results First Posted Date existed and 0 otherwise. These CTG-anchored indicators standardize compliance measurement across the full 2007–2024 window and permit both binary modeling (compliant versus non-compliant) and more granular descriptive analyses of timeliness and backlog.

For each trial, a due date was calculated as twelve months after Primary Completion Date using Excel's EDATE function. A binary compliance flag was then set to TRUE when Results First Posted Date was on or before this due date and FALSE otherwise, conditional on the trial being due as of December 31, 2024. These Clinical.Trials.gov-derived indicators serve as primary dependent variables for logistic regression models. TrialsTracker provided several historical compliance fields for a subset of approximately 16,000 trials between 2017 and 2020; however, pre-computed timeliness variables reflect TrialTracker.net's original pull date and were therefore excluded from analysis. Instead, ClinicalTrials.gov-anchored due-date and compliance logic were recalculated uniformly for all trials in the Combined Master dataset, with selected TrialsTracker.net fields retained only for validation and sensitivity checks. Derived compliance and calculations are explained in Table 3.5.

Table 3.5

Derived Compliance Indicators and Calculation Logic

Variable	***Purpose***	***Source Fields***	***Computation / Notes***
CTG_DueDate	FDAAA 801 12-month results-due date	Primary Completion Date	Calc as Primary Completion Date + 12 months (Excel EDATE).
CTG_Compliant_TF	Compliance with FDAAA 801 deadline	Results First Posted Date; CTG_DueDate	TRUE if posted ≤ DueDate; FALSE if posted late or not posted.
Exemption_Flag	Marks FDAAA-801 exempt trials	CTG_Phase; TT_has_exemption_TF	TRUE for Phase I, Early Phase I, or TT-flagged exempt.
Merge_Status	Row-level provenance	CTG vs TT NCT match	"Both," "CTG only," or "TT only," assigned after outer join.
TT_has_results_TF	Historical TT results indicator	TT export	Imported directly (matched trials only).
TT_days_late_Calc	Historical TT lateness metric	TT export	Imported as-is (not recalculated).

Note: Compliance logic does not use dynamic "as of" classifications (e.g., overdue, not-yet-due). All calculations are based on a fixed analytical cut-off date of December 31, 2024.

3.3.4.2 Operational Definitions

Each variable is defined and validated for frequency distribution, outliers, and coding consistency using source-specific metadata and coded to ensure replicability and validation – before inferential modeling. Variable transformations, including dummy coding for categorical independent variables, collapsing of underrepresented categories, and creation of time-relative measures (e.g., days from primary completion to results posting), are documented in a detailed data dictionary. The resulting structure allows for alignment of pragmatic (funder type), moral (therapeutic area), cognitive (study phase), sociopolitical (location) and regulative (epochal policy shift) dimensions of Legitimacy Theory with measurable predictors of compliance.

The dependent variable *Compliance Status* was operationalized to indicate on-time results reporting, consistent with the statutory requirement. Importantly, the definition of

compliance is constant across all three regulatory epochs, enabling temporal comparisons to reflect changes in behavior rather than changes in rule structure

TrialsTracker (TT) dataset was incorporated selectively to avoid conflating historical, pre-computed metrics with our present study's CTG-anchored compliance logic. Static timeliness fields such as TT's calculated number of days late, and related summary measures were not carried forward into the analytic dataset, because they reflect status as of TT's original pull date rather than December 31, 2024 analytic cut-off.

By contrast, a small number of TT-derived indicators were retained where they aligned directly with this study's aims: has_exemption flag was used as reference against which to compare independently derived exemption coding in CTG; is_act and is_pact flags provided context on statutory obligation for a subset of trials; and categorical status codes (e.g., overdue, reported late) were used for cross-validation. All inferential analyses in Chapters 4 and 5 rely on compliance variables recalculated from CTG fields, with TT indicators functioning as historical benchmarks and validation tools rather than primary data sources.

3.3.4.3 Variable Harmonization and Coding Rules

To integrate data from multiple origins without loss of lineage, all variable structures were aligned prior to merge. In addition, three binary indicators from TrialsTracker were retained to characterize statutory reporting obligations under FDAAA 801. The variable **is_act** flags trials that clearly meet the regulatory definition of an Applicable Clinical Trial (ACT) under the 2017 Final Rule (interventional design, FDA-regulated product, Phase II–IV, not a feasibility or withdrawn study). The variable **is_pact** flags pre-2017 trials conservatively classified as probable Applicable Clinical Trials (pACTs) based on interventional design, phase, and evidence of U.S. jurisdiction when product regulation is not explicitly specified.

Table 3.6

TrialsTracker FDAAA 801 Exemption Flags

Variable	***Description***	***Coding***
is_act	Indicator for trials which clearly meet definition of Applicable Clinical Trial (ACT) under FDAAA 801 2007 and 2017 Final Rule (interventional, FDA-regulated product, Phase II–IV, not withdrawn or feasibility).	1 = ACT; 0 = Not ACT
is_pact	Indicator for trials begun before Jan 18, 2017 but conservatively classified as probable ACTs (pACTs), Meeting criteria strongly suggesting FDAAA 801 coverage despite incomplete registry fields.	1 = pACT; 0 = Not pACT
has_exemption	Indicator for trials exempt from mandatory FDAAA 801 2007 reporting requirements. Exemptions typically include: Phase I drug studies, device feasibility studies, veterinary or laboratory-animal use, diagnostic device studies meeting noninvasive/low-risk criteria, and other categories outlined in 21 CFR 312.2(b) and 812.2(c).	1 = Exempt; 0 = Not exempt

Source: TrialsTracker.net; derived variable construct by the author as part of the analytic dataset.

Finally, **has_exemption** flags trials that appear exempt from FDAAA 801 results-reporting requirements (e.g., Phase I pharmacokinetic studies, device feasibility, or diagnostic-only investigations, or laboratory-only studies) consistent with 21 CFR 312.2(b) and 812.2(c).

Aligned, these variables differentiate trials clearly mandated to report results, those likely under mandate despite incomplete registry fields, and those legitimately exempt – at the time of their status, analysis, and publication in 2020. Details on ACT, pACT, and exemption flags are summarized in Table 3.6.

Key harmonization rules included:

- **Exemption Flag:** TrialsTracker.net binary flagged for whether or not an exemption was noted and retained from TT and inferred in CTG for Phase I and Early Phase I studies per *21 CFR 312.2(b)* and *812.2(c)*.

- **ICD-10 Category:** Assigned manually via ICD-10 Categorical Crosswalk. Application of clinical knowledge for ambiguous entries using condition text and title cues.
- **Trial Phase:** Standardized to the FDA/NIH convention (*EARLY_PHASE1, PHASE1, PHASE1|PHASE2, PHASE2, PHASE2|PHASE3, PHASE3, PHASE4*).
- **Region Adjustment:** CTG_Region_Adjusted created to isolate U.S. trials (if Country = "United States" then Region = "United States").
- **Funder Type:** Recoded using the *ClinicalTrials.gov PRS User's Guide (National Library of Medicine (ClinicalTrials.gov), 2024)* taxonomy—NIH, FED, OTHER-GOV, INDUSTRY, INDIVIDUAL, OTHER, and UNKNOWN.

For trials where CTG "Funder Type" was blank values were harmonized by cross-referencing CTG "Sponsor Name" field to align with ClinicalTrials.gov conventions. Sponsors such as the National Cancer Institute (NCI), NHLBI, NIAID, NIDDK, and the Eunice Kennedy Shriver National Institute were coded as NIH; entities such as Walter Reed, the U.S. Army, Air Force, or Veterans Affairs were coded as U.S. Federal (FED). State agencies and state-affiliated foundations were coded as OTHER-GOV. Academic institutions, universities, hospitals, and independent medical centers (e.g., Montefiore Medical Center) were coded as OTHER *unless* clearly functioning as commercial entities. Biopharmaceutical and biotechnology companies were coded as INDUSTRY. This harmonization resolved missing values and ensured funder classifications were consistent with ClinicalTrials.gov Protocol Registration and Results System (PRS) taxonomy.

These transformations produced consistent categorical variables and ensured each analytical dimension could be cross-referenced to its regulatory source.

3.3.4.4 Merge and Validation Procedures

A **full outer join** logic was performed manually in Excel to merge CTG and TT records using VLOOKUP and conditional matching procedures.

- NCT_ID served as the universal linking key after normalization (uppercase, eight-digit validation).
- Unmatched TT rows were appended beneath the CTG base to preserve all data, ensuring no record loss across the merge.

Validation included:

- Row-count reconciliation before and after merge (Δ = +5,232 TT-only trials).
- Random spot checks confirming correct TT variable alignment.
- Replacement of #N/A errors with null values for clean import.

The merged dataset expanded from **142,056** CTG trials to **147,288** total records. Version control was maintained through iterative file naming (CTG_TT_MASTER_YYYY-MM-DD.xlsx) and archival of Minitab session logs (.mpx, .docx, .txt) for transparency. After integration, each trial was assigned a Merge_Status flag indicating whether it appeared in both datasets ("Both"), only in ClinicalTrials.gov ("CTG only"), or only in TrialsTracker ("TT only"). This variable preserves row-level provenance and supports sensitivity analyses differentiating the full CTG reference population from the subset monitored by TrialsTracker. The overall merge decision logic is summarized in Figure 3.2.

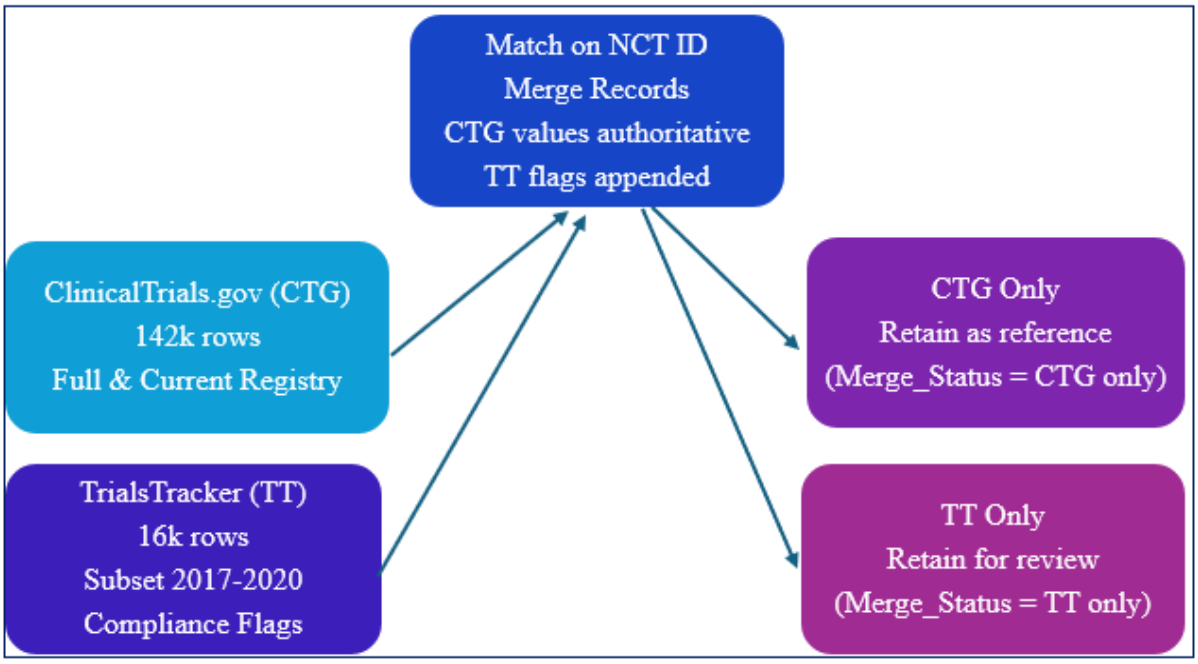

Figure 3.2

Merge Decision Flow: ClinicalTrials.gov (CTG) and TrialsTracker (TT) Datasets

Note: ClinicalTrials.gov served as reference dataset, given its comprehensive scope and currency. TrialsTracker records were merged on the common NCT identifier. Where records matched, ClinicalTrials.gov values were treated as authoritative for trial characteristics and TrialsTracker values were appended as historical compliance indicators. Records unique to ClinicalTrials.gov were retained as default reference population (DataSet_Source = CTG only), while records unique to TrialsTracker were retained for review (DataSet_Source = TT only). This full outer join strategy ensured all relevant trials were preserved and row-level provenance remained transparent.

Frequency checks of merge status of the datasets was conducted via the variable DataSet_Source and confirmed a majority of records were unique to ClinicalTrials.gov. A smaller subset appeared in both datasets, and a minimal fraction were unique to TrialsTracker. This distribution pattern is consistent with ClinicalTrials.gov's broader scope (2007-2024 interventional trials) compared with the narrower TrialsTracker monitoring window. Table 3.7 summarizes this distribution.

Table 3.7

Distribution of Records by Merge Status

Merge_Status	***Count (n)***	***Percent (%)***	***Interpretation***
MATCHED (both CTG & TT)	8,666	8.29	• Trials present in both CTG and TT; • CTG values retained as authoritative, • TT compliance flags appended.
CTG only	95,330	91.21	• Trials uniquely found in ClinicalTrials.gov, reflecting its broader coverage (2007–2024).
TT only	516	0.49	• Trials uniquely found in TrialsTracker; • Retained for review as possible withdrawn or updated or historic-only records
Total	104,512	100.00	• All records accounted for; • no loss of data during merge.

Note: Dataset Source reflects post-merge record provenance. ClinicalTrials.gov serves as the authoritative reference dataset, with TrialsTracker records used to append independent compliance and exemption flags. Percentages may not sum to exactly 100% due to rounding.

3.3.5 Version Control and Export Documentation

Following harmonization, three analytical subsets were created:

1. **Phase1_All** – Early Phase 1 + Phase 1 (exempt).
2. **NonExempt_All** – All FDAAA 801-applicable trials.
3. **NonExempt_Phase2-4_All** – Applicable Phases 2–4.

Each subset was exported to Excel and imported into **Minitab 22.4** for descriptive statistics, logistic modeling, validation of variable integrity and category frequencies. All transformations were executed in **Microsoft Excel 365** and **Minitab 22**, with full documentation archived in Appendix D (Harmonization and Classification Workflow).

Importantly, as a methodological clarification relevant to data coverage, the construction of this integrated dataset also has implications for how prior empirical findings in the clinical trial reporting literature should be interpreted. Many existing studies rely on partial subsets of

ClinicalTrials.gov records, often excluding trials with missing, incomplete, inconsistently formatted, or unstructured free-text fields that could not be readily classified or analyzed. Through extensive data cleaning, harmonization, and manual resolution of thousands of incomplete or low-quality entries, the present study substantially expands the analyzable universe of trials beyond what has been feasible in prior work. As a result, this study evaluates compliance behavior across a broader and more fully representative population of registered trials, which may reinforce, refine, or in some cases challenge earlier estimates of effect size, statistical significance, or inferred behavioral patterns that were necessarily derived from more limited samples.

Simply put, because of how the data were prepared, the denominator is larger and more complete than in prior studies. This integrated sequence of data preparation, harmonization, and validation procedures establishes the analytical foundation for the modeling strategy described in the following section.

3.4 Data Analysis Plan, Analytical Strategy, and Software

This section bridges from data architecture to modeling plan and explicitly links each analytical phase to cognitive, pragmatic, moral, regulative, and sociopolitical dimensions of Legitimacy Theory and to set up Chapter 4's results narrative. This analysis operationalizes legitimacy theory within a compliance context—translating conceptual constructs into measurable predictors and direct variable. To address the study's two research questions and two sets of hypotheses, analysis proceeded in a staged fashion. Descriptive statistics and cross-tabulations first established baseline compliance patterns across epochs, phases, funder types, oncology status, and regions. Logistic regression then served as primary inferential framework, estimating influence of trial-level and organizational predictors on the likelihood of FDAAA 801

compliance. Standard model-fit diagnostics (e.g., pseudo-R^2, AIC/BIC, classification accuracy, ROC performance) were used to assess explanatory strength and overall predictive adequacy

The analytical strategy was designed to examine predictors of compliance with FDAAA 801 results-reporting requirements through a series of sequential, theory-aligned quantitative tests. Each analytical phase corresponds to one of the institutional dimensions of *Legitimacy Theory*—**regulative, cognitive, pragmatic, moral**, and **sociopolitical**—to ensure statistical interpretation remains conceptually anchored throughout.

3.4.1 Research Method, Primary Platform, and Validation Software

All quantitative analyses were conducted in **Minitab 22.4.0.0**, selected for its transparency in audit logging and ease of reproducibility and validation environment to cross-check descriptive frequencies, logistic-regression outputs, and significance tests. Minitab session files (.mpx) and audit logs (.docx, .txt) were archived to maintain a verifiable chain of analytic custody, consistent with Drexel DBA data-integrity requirements.

The analytic dataset (CTG_TT_MASTER_2025-10-21.xlsx, N = 147,288) was imported with categorical variables defined by coded labels, and date fields converted to numerical values to permit temporal segmentation. All analyses were performed on the **NonExempt_Phase2-4_All** subset unless otherwise specified. Exempt studies were excluded from inferential analyses but retained for descriptive comparison to explore voluntary transparency behaviors.

3.4.2 Analytical Framework and Model Sequence

Figure 3.3 summarizes the five-stage analytical workflow implemented in this study, progressing from exploration to inference. Each stage is described below.

Figure 3.3

Analytical Workflow for Compliance Modeling

Note: The figure illustrates the five-stage empirical roadmap progressing from descriptive diagnostics to inferential modeling and validation. Formal difference-in-differences and interaction models were considered but intentionally deferred to future research.

Step 1 – Preliminary Diagnostics

Descriptive statistics and frequency checks were conducted to assess missingness, outliers, and coding validity.

Step 2 – Descriptive & Comparative Analysis

Cross-tabulations and bivariate comparisons quantified compliance variation and identified legitimacy gaps.

Step 3 – Predictive Compliance Modeling

A main-effects logistic regression model tested hypotheses H1–H5 using odds ratios and confidence intervals.

Step 4 – Epoch-Focused Sensitivity Analysis

Stratified descriptive analyses contextualized regulatory timing effects without formal interaction modeling.

Step 5 – Robustness and Reproducibility Checks

Sensitivity tests and audit logs ensured analytic consistency and replicability.

This analytical roadmap operationalizes the study's theoretical model by aligning statistical inquiry with institutional-legitimacy constructs. Each stage of analysis aligns with the five-step empirical roadmap (Figure 3.3), progressing from descriptive exploration to inferential modeling and model validation. To enhance transparency and reproducibility, detailed definitions of constructed variables, coding decisions, and data handling rules are provided in Appendix B.

Specifically:

- **RQ1 – Regulative Legitimacy:** How did key events, like the *Final Rule* and *Seife v. HHS*, influence FDAAA 801 compliance over time?
- **RQ2 – Pragmatic, Moral, Cognitive and Sociopolitical Legitimacy:** What patterns emerge across therapeutic indications, funding source, trial phase, and geographic contexts?

Each hypothesis (H1–H9) maps to one or more of these dimensions, enabling a cohesive interpretation of quantitative outcomes through an institutional-theory lens.

3.4.3 Model Validation Diagnostics

To ensure the main-effects model met core statistical assumptions, a set of validation diagnostics was performed prior to interpretation. Variance inflation factors (VIFs) were examined for all variables to assess multicollinearity, with all values falling below commonly accepted thresholds. Goodness-of-fit was evaluated using deviance and Pearson chi-square statistics and the Hosmer–Lemeshow test, recognizing the latter can be overly sensitive in exceptionally large samples. Classification tables, ROC curves, and calibration plots were generated to assess discrimination and calibration; these performance results are summarized in Chapter 4 as part of Model Performance Validation narrative, while the present section documents underlying assumption checks as part of Model Validation.

3.4.4 Output Management and Data Visualization

Analytic results were exported from Minitab into structured tables and graphs for Chapter 4 presentation. Each output was labeled using the schema MTB_YYYYMMDD_AnalysisName and cross-referenced in the results narrative. Visualizations were rendered directly in Minitab using frequency-bar, heat-map, and odds-ratio plots to depict legitimacy gradients across predictors. Only statistically and substantively meaningful effects are reported; marginal trends are discussed qualitatively in Chapter 5.

3.4.5 Methodological Contribution & Research Impact

By unifying three disparate data sources into a single, analyzable dataset and developing a novel ICD-10 crosswalk to standardize free-text condition fields—this study overcomes long-standing interoperability and classification challenges that have hindered previous compliance research efforts. This approach enables robust multivariate predictive modeling required for the present main-effects analysis, and creates a reusable, high-value research asset. The harmonized dataset is intentionally designed to support future extensions, including interaction models and quasi-experimental designs once additional cleaning and variable development are complete.

This study's novel approach provides an empirical and methodological contribution to transparency in research. While most prior studies have been restricted to single sources, specific therapeutic registries, or focused descriptive reporting audits, this dataset advances the field by enabling cross-platform, multivariate, and theory-driven analysis. It also lays a foundation for future research and policy tools that could use this harmonized dataset for further examination, informative pressure prioritization, evidence-based risk modeling, and funding support decisions.

The resultant dataset has potential to accelerate future compliance investigations, support predictive logic modeling, and inform targeted policy interventions. In resolving entrenched data

silos, and harmonizing classification across trial registries and regulatory archives, this work lays groundwork for a new generation of transparency and accountability research in clinical trials.

3.5 Ethical Considerations and Data Integrity

3.5.1 No Direct Human Subject Interaction

This study involves no direct human participant interaction. Instead, it relies exclusively on secondary analysis of publicly available disseminated sources, and archival datasets (ClinicalTrials.gov, TrialsTracker.net, CMS ICD-10, FDA Approvals). As no identifiable private or health information is collected, the project qualifies as *exempt* from full IRB oversight under federal regulations human subjects research and experimentation (45 CFR 46.104). Because these data are publicly accessible and contain no personal identifiers, this study is absent of risk to individuals. Primary ethical considerations in this research relate to responsible use, interpretation, and reporting of aggregated trial regulatory information.

3.5.2 Transparency and Ethical Alignment

Unpublished results of clinical trials and failure to meet minimal statutory reporting requirements have created significant gaps in the scientific evidence base – with regulatory, reputational, and ethical implications for study sponsors. Non-compliance undermines public trust, and also our obligation to honor contributions of trial participants, by ensuring their collected data informs future health science. Just as initiatives like the *AllTrials* campaign and the World Health Organization's international best practices emphasize—timely and accurate reporting is an ethical imperative globally (Ghersi, Clarke, Berlin, Gulmezoglu, Kush, Lumbiganon et al., 2008; Sense about Science, 2013).

The ethical framework which guides this dissertation extends beyond regulatory compliance to encompass principles embedded in *Legitimacy Theory* itself — namely,

transparency, accountability, and fidelity to truth in scientific reporting. The analysis directly engages with consequences of noncompliance, treating data opacity as both an empirical and an ethical problem. By illuminating gaps between mandated disclosure and actual reporting, this study advances a dialogue on how institutions sustain or erode public trust in science.

While the United States has codified transparency requirements into laws (e.g., FDAAA 801 and the Final Rule), global compliance requirements remain uneven due to regulatory variations, rather than lack of ethical consensus. The gap created between legal obligations imposed on sponsors and universal standards for transparency. Address of these gaps is both scientifically necessary and ethically responsible, and may enhance legitimacy of study sponsors in our post-pandemic environment where public accountability has gained even more demand.

3.5.3 Ethical Context of Data Stewardship

Although the study engages with publicly available regulatory data, its deeper ethical commitment lies in addressing a systemic moral hazard of opacity in clinical research. Methodological rigor was applied to cleaning, verifying, and cross-referencing these data functions as a form of ethical remediation — an act of rebuilding trust through precision and transparency. By exposing where accountability breaks down, particularly in linking between trial registration and FDA approval, this research honors our ethical imperatives of accuracy, truthfulness, and stewardship underlying legitimate scientific practice.

3.5.4 Data Provenance, Confidentiality, Storage, Audit Trail Integrity, Security

All data used in this research are stored in access-controlled environments locally on an encrypted hard drive and backed up through secure institutional cloud storage compliant with Drexel University's policies and data security standards. Merged analytic files are maintained securely, with regular backups and version control in order to prevent unauthorized access and

data loss. Although these data do not contain personal identifiers, these safeguards ensure integrity and mitigate misuse risk.

To ensure reproducibility and data integrity, every transformation step — from raw import to analytic modeling — was documented through versioned files and audit logs. Primary datasets were stored under controlled naming conventions (CTG_TT_MASTER_YYYY-MM-DD.xlsx), and all subsequent Minitab sessions were archived as .mpx and .docx logs. Each analytic iteration is fully traceable to its source, creating a transparent and verifiable data lineage.

This approach aligns with open-science best practices, ensuring results are replicable and the logic of data transformation remains visible to peer reviewers and future researchers. All datasets and derivative files remain available for committee verification and are archived in Appendix A-D as part of the formal research audit trail.

3.5.5 Contribution to Ethical and Scholarly Discourse

By unification of four disparate public datasets, this study enables a deeper exploration of legitimacy-driven compliance patterns, providing a methodological resource for future research of clinical trial regulatory transparency. Beyond business implications, this analysis contributes to a greater global conversation regarding trial transparency as both an obligation but also a determinant of the public's trust in science.

3.6 Summary and Transition

This chapter outlined and detailed the methodological foundation of the study — from research design and data source integration to variable operationalization and analytical strategy — demonstrating how the CTG-TT Master dataset was built, validated, and prepared for quantitative analysis. By grounding in Legitimacy Theory, we address the study's central objective to identify legitimacy-driven factors which influence required compliance to post

results to ClinicalTrials.gov reporting system. Chapter 3 began by situating the research within a legitimacy-theory framework, then described how multiple public datasets were harmonized into a single, auditable structure of 147,288 interventional trials spanning 2007 to 2024. This design leverages a multi-sourced archival dataset, and cross-validation techniques to ensure both methodological rigor and analytical transparency.

Extensive cleaning, recoding, and cross-validation procedures ensured reliability of every variable used in analyses. This resultant dataset preserves full data provenance through standardized prefixes, row-level source identifiers, and comprehensive audit logs, thereby satisfying both methodological transparency and ethical accountability. Each step of data preparation was explicitly aligned with the study's theoretical model: pragmatic legitimacy (organizational incentives), moral legitimacy (ethical commitment to transparency), and regulative legitimacy (response to authority and policy events). By combining structured variables with carefully coded free-text fields, the methodology supports hypothesis testing, while also demonstrating practical realities and limitations of working with large-scale registry data. Through this design, the study contributes to academic discourse on regulatory compliance, advances methodological practices for registry-based research, and provides a scalable model for exploring additional predictors of non-compliance in other high-regulation industries.

The chapter also documented critical discoveries arising from exploratory work with FDA Approvals data. What was expected to be a straightforward linkage between approved products and their supporting clinical trials instead revealed a fragmented and non-relational archive. This finding—discussed further in Chapter 4—emerged as an empirical result in its own right, underscoring systemic opacity that continues to impede regulatory traceability.

Collectively, Chapter 3 established a rigorous empirical and ethical foundation for analyses that follow. In our next chapter we present descriptive and inferential findings derived from our integrated dataset, examining compliance behavior across trial phases, funder types, therapeutic categories, and regions. The next chapter represents results of statistical analyses, including descriptive statistics, model outputs, and tests of proposed hypotheses, and offers empirical insights into patterns and predictors of clinical trial results reporting compliance. In so doing, Chapter 4 begins to illuminate how legitimacy — in its many forms — manifests in actual reporting practices of respected clinical research institutions.

Chapter 4. Findings, Results, and Interpretation

This chapter presents empirical findings derived from an integrated dataset of 147,288 interventional clinical trials spanning 2007–2024. It begins with an overview of descriptive statistics and comparative analyses to establish foundational patterns of compliance across key dimensions — phase, funder, therapeutic category (ICD-10), region, and exemption status. Baseline distributions contextualize where transparency performance improved modestly, plateaued, or lagged. Subsequent sections present results of predictive logistic regression main effects model designed to assess how compliance behavior evolved in response to successive regulatory epochs — enactment of FDAAA 801 (2007), implementation of the Final Rule (2017), and enforcement expansion following Seife v. HHS (United States District Court for the Southern District of New York, 2020).

Descriptive results are organized in Section 4.2, followed by inferential results in Section 4.3. Each result is interpreted in relation to its corresponding hypothesis (H1–H9) and research question (RQ1–RQ2), and theoretical interpretation. Graphic visualizations highlight differences across epochs and subgroups, as well as illustrate interplay between regulatory rigor, ethical obligation, and organizational adaptation. We conclude with an integrative synthesis of empirical pattern theoretical interpretation, setting up for Chapter 5's discussion on implications for policy, leadership, and future research. Additional interpretive detail is provided in Appendix C.

4.1 Presentation of Findings with Supporting Data

4.1.1 FDA Approvals Exploration Findings

FDA Approvals data exploration yielded a surprising empirical outcome: absence of a coherent, relational approvals dataset capable of linking approved products to their evidentiary clinical trials. Despite regulatory importance, available records across FDA divisions (CDER,

CBER, Device Approvals, and those housed in the Wayback Machine) lack consistent identifiers such as NCT numbers, product identifiers, or trial phases. Early archives (2007–2012) were largely unsearchable document scans. More recent postings were only partially structured and still disconnected from the Protocol Registration System (PRS).

These findings, and subsequent attempts to merge files, is a finding in and of itself and demonstrates structural limitation in public FDA transparency. Absence of reliable structures to link product authorizations with trial data represents a systemic accountability gap.

4.2 Exploratory and Descriptive Findings

4.2.1 Baseline Descriptive Statistics: Overall Posting and Compliance Rates

This section presents baseline descriptive statistics for two key outcomes of interest: whether clinical trial results were posted to ClinicalTrials.gov and whether those results were reported within the legally required timeframe.

Across 147,288 registered interventional trials, only **3.20%** reported results within the mandated 12-month reporting window, establishing a baseline for interpreting all subsequent descriptive and inferential analyses (see Table 4.1).

- **Results Posting:**

  Overall, **27.15%** of trials had posted any results to ClinicalTrials.gov (M = 0.2715, SD = 0.4447).

- **On-Time Results Reporting:**

  Only **3.20%** of trials reported results within the required 12-month window following primary completion (M = 0.0320, SD = 0.1761).

Both outcomes were coded as binary indicators (0 = no, 1 = yes), reflecting whether results were posted at all and if reporting occurred within the legally mandated timeframe.

In totality, these findings demonstrate a substantial gap between trial completion and timely public disclosure, consistent with concerns documented in prior transparency research. Supplementary descriptive distributions of trial phase and regulatory epoch are reported in Appendix A.

4.2.1.1 Distribution of Key Study Characteristics

Across all 147,288 interventional trials included in the dataset:

- **Trial Phase Distribution:**

  The largest proportion of studies were classified as Phase 2 (27.47%), followed by Phase 3 (25.53%), and Phase 1 (20.78%). Only 1.24% were early-phase exploratory studies, while approximately 16% of records were missing or did not specify any study phase. This distribution reflects a predominance of mid- and late-phase trials of the overall clinical research landscape.

- **Funder Type Distribution:**

  A majority of trials were industry-sponsored (65.84%), followed by federally funded (0.52%), network-based (0.83%), and other government-sponsored (1.72%) studies. Approximately 4.6% of studies were categorized as “Other” funders. “Other” encompasses Academic Health Centers, Foundations, Advocacy Group to name a few. Finally, 0.03% had an “unknown” funder type. Predominance of industry-sponsored trials reveals the private sector’s continued central role in funding interventional research.

- **Therapeutic (ICD) Category Distribution:**

  Trials were distributed across a wide range of therapeutic domains. The most represented categories were oncology-related (16.05%), followed by infectious diseases (7.41%), and

cardiovascular disorders (6.13%). Other prominent categories included neurology (4.36%), endocrine/metabolic (3.14%), and gastrointestinal (2.77%) disorders.

- **Geographic Distribution:**

  Trials were conducted across 193 countries, with the United States representing the largest share (36.05%). Other majority countries included France (2.05%), Germany (2.32%), Canada (2.40%), and the United Kingdom (2.47%). Smaller percentages were distributed across Asia, Latin America, Africa, and the Middle East, indicating substantial global participation but clear concentration in North America and Europe.

4.2.2 Exemption Distribution

Approximately 25.9% of studies were not designed to assess therapeutic efficacy or safety outcomes. The resulting non-exempt dataset, viewed in Table 4.1, (N = 109,065) represents the true population subject to FDAAA 801 reporting requirements, and provides an analytical foundation for the descriptive phase of this study, enabling assessment of compliance patterns across trial phase, funder type, geographic region, and therapeutic category.

Table 4.1

Descriptive Overview of Study Sample

Variable	***Description***	***N***	***%***
CTG_Study_Results	Trials with any results posted	39,978	27.1 %
CTG_Compliant_TF	Trials posting results ≤ 365 days (compliant)	4,719	3.2 %
TT_has_exemption_TF	Trials legally exempt (1 = TRUE)	38,223	25.9 %
Non-Exempt Trials	Trials subject to FDAAA 801	109,065	74.1 %

Note: Based on CTG_TT_MASTER dataset (N = 147,288). Compliance = posting primary-outcome results ≤ 365 days after primary completion date.

This non-exempt denominator (N = 109,065) is used to ensure accuracy in reporting applicable trials. Key descriptive statistics are summarized in Table 4.1, providing an overview of the study sample, variables, and exemption distribution.

4.2.3 Phase-Level Compliance

Exploratory analysis compares compliance patterns across clinical trial phases to distinguish between exempt and non-exempt categories under FDAAA 801. Among Phase 1 and Early Phase 1 trials (N = 37,321), only 1.21% were compliant with posting primary outcome results within 365 days of the primary completion date.

Table 4.2

Compliance by Trial Phase

Trial Phase	***Exemption Status***	***n Compliant***	***% Compliant***	***Interpretation***
EARLY_PHASE 1	Exempt	**102**	1.1	Minimal voluntary reporting
PHASE 1	Exempt	351	1.3	Cognitive-signaling behavior
PHASE 2	Non-Exempt	1,280	3.9	Lowest required-phase compliance
PHASE 3	Non-Exempt	1,465	4.2	Incremental improvement
PHASE 4	Non-Exempt	1,490	4.4	Best performance among mandated

Note. Compliance is defined as results posted to ClinicalTrials.gov within 365 days of primary completion. Phase 2–4 trials are non-exempt under FDAAA 801 and subject to mandatory reporting requirements, whereas Early Phase 1 and Phase 1 trials are exempt under 21 CFR 312.2(b) and 812.2(c), reflecting voluntary disclosure behavior. Percent compliant is calculated within phase category, highlighting differences between voluntary and mandated reporting contexts.

By contrast, the Phase 2–4, non-exempt subset (N = 109,065) revealed a modest increase in on-time reporting, with 3.91% achieving compliance and 96.09% failing to meet statutory requirements. As shown in Table 4.2, compliance increased modestly from early exploratory to later confirmatory phases, although overall reporting rates remain quite low. This comparison

shows compliance is substantially higher once legal accountability is introduced (4.08% for mandated phases vs. 1.21% for voluntary phase 1), Indicating regulatory obligation – not developmental stage – drives reporting behavior. Improvement over Phase 1 appears meaningful in absolute terms. Phase distribution skews toward Phase 2 and Phase 3 trials, which aligns with the costly, resource-intensive nature of later-stage development. This suggests the bulk of regulatory-facing research efforts are focused on trials seeking pivotal efficacy and safety data rather than early exploratory or post-market studies.

4.2.3.1 Voluntary vs Mandated Compliance

- Phase 1 voluntary reporting = 1.21%
- Phase 2-4 non-exempt reporting = 4.08%

These values reinforce the pattern that mandated reporting produces higher compliance than voluntary reporting, even if both remain low in absolute terms. Although Phase 1 trials are exempt from FDAAA 801, 1.21% voluntarily posted results — indicating minimal but observable transparency signaling. By contrast, among Phase 2–4 trials legally obligated to report, only 4.08% achieved compliance. While higher than exempt groups, the rate remains exceptionally low highlighting limited adherence even when formal accountability applies.

4.2.3.2 Compliance by Phase (Non-Exempt Trials Only)

These Include:

- Phase 1|2 = 3.24%
- Phase 2 = 4.00%
- Phase 2|3 = 2.55%
- Phase 3 = 4.85%
- Phase 4 = 4.08%

4.2.3.3 Phase Results Interpretative Summary

Differences across phases are modest, suggesting regulatory obligation, rather than development stage — is the primary differentiator of compliance behavior. Even trials closest to FDA review fail to meet statutory requirements more than 95% of the time. The 1.21% voluntary reporting among Phase 1 studies indicates a weak form of moral, cognitive, or identity-based legitimacy, where a small minority of sponsors signal ethical commitment despite lack of regulative requirements.. A small minority demonstrated voluntary transparency — possibly signaling a form of *cognitive legitimacy* by alignment with broader norms of openness in early-stage innovation. Although Phase 1 studies are legally exempt from FDAAA 801 requirements, a small fraction (1.21%) voluntarily post results. Limited voluntary transparency reflects weak but observable legitimacy.

In contrast, Phase 2–4 trials — those directly subject to FDAAA 801 — exhibited slightly higher but still extremely low reporting rates (approximately 4%), suggesting coercion alone is insufficient to institutionalize compliance.

Later-phase trials (Phases 3 and 4) demonstrated marginally higher compliance, consistent with greater public visibility, regulatory scrutiny, and commercial stakes.

4.2.4 Compliance by Funder Type

Cross-tabulation of funder categories (N = 147,288) revealed substantial variation in reporting performance. Overall, on 4.0% of all trials were compliant with timely results posting requirements (≤365 days after primary completion date), as shown in Table 4.3.

NIH-funded trials achieved the highest compliance rate (9.16%), followed by independent clinician-investigators (5.48%) and industry-sponsored studies (3.57%). Federal agencies other than NIH averaged 3.67%, while academic and foundation-based “other” funders

reported 2.73%, and state or local government trials ("Other_Gov") demonstrated the lowest compliance (0.87%). Independent clinician-investigators' above-average compliance (5.48%) suggests compliance is driven by personal and professional identity-based legitimacy, rather than organizational systems or formal oversight systems.

Table 4.3

Compliance by Funder

Funder Type	***% Compliant (On Time)***	***N (Total Trials)***
NIH	9.16	2,532
Individual Investigator	5.48	219
Network	3.95	1,216
Federal	3.67	762
Industry	3.57	65,808
Other	2.73	74,177
Unknown	2.63	38
Other Government	0.87	2,536
All Funders	**4.01**	**147,288**

*Note***.** Percent compliant reflects results posted to ClinicalTrials.gov within 365 days of primary completion. N indicates total trials per funder category; funder classifications are based on ClinicalTrials.gov sponsor designations.

Industry sponsors demonstrate primarily pragmatic legitimacy, balancing compliance expectations against strategic interests, competitive considerations, and reputational risk. Moderate performance suggests calculated adherence, where disclosure is calibrated to maintain credibility but constrained by proprietary concerns.

The dataset reflects a heavily industry-driven research environment, with more than two-thirds of interventional trials sponsored by commercial entities. Despite dominant market share, industry compliance remains low (3.57%), reflecting a pattern of measured transparency—

sufficient to maintain regulatory goodwill and reputation, though constrained by proprietary considerations and complex internal approval pathways.

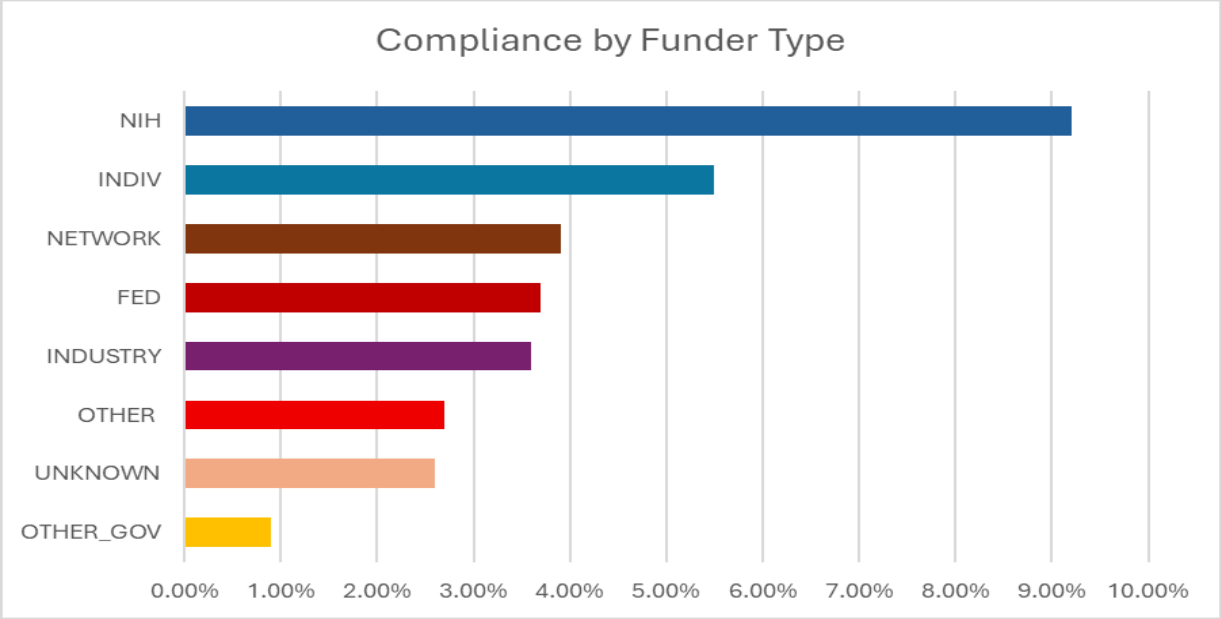

Figure 4.1

Compliance by Funder Type

Individual clinician-investigators also exhibit above-average compliance (~5.5%), outperforming several large and well-resourced organizational sponsors.

Patterns by Funder are illustrated in Figure 4.1, depicting compliance percentages across types in descending order.

4.2.5 Regional Compliance Patterns

Geographic analysis (N = 147,288) revealed U.S.-based trials exhibited the highest compliance rate at 7.41%. The higher U.S. compliance rate reflects presence of direct regulatory jurisdiction, which increases accountability for reporting. While other regions lagged considerably: Europe = 1.21%, Asia = 1.85%, and Middle East/North Africa = 0.86%. Multi-regional (“Global”) trials — those spanning multiple countries or continents — achieved a

modest 3.7% compliance rate. Many non-U.S. sponsors register trials on clinicaltrials.gov as a signal of intent to access U.S. markets or participate in multinational research, but this symbolic presence does not necessarily translate into results reporting. Geographic variation is presented in Figure 4.2, where US-based studies demonstrate the highest proportion of on-time results posting relative to other regions

Contrast between high U.S. compliance (7.40%) and near-zero rates in many non-U.S. regions reflects symbolic registration without substantive adherence, indicating regional differences are rooted in differential exposure to regulative authority. Persistent near-zero compliance suggests symbolic registration for visibility or future access to U.S. markets, rather than genuine conformity with reporting expectations.

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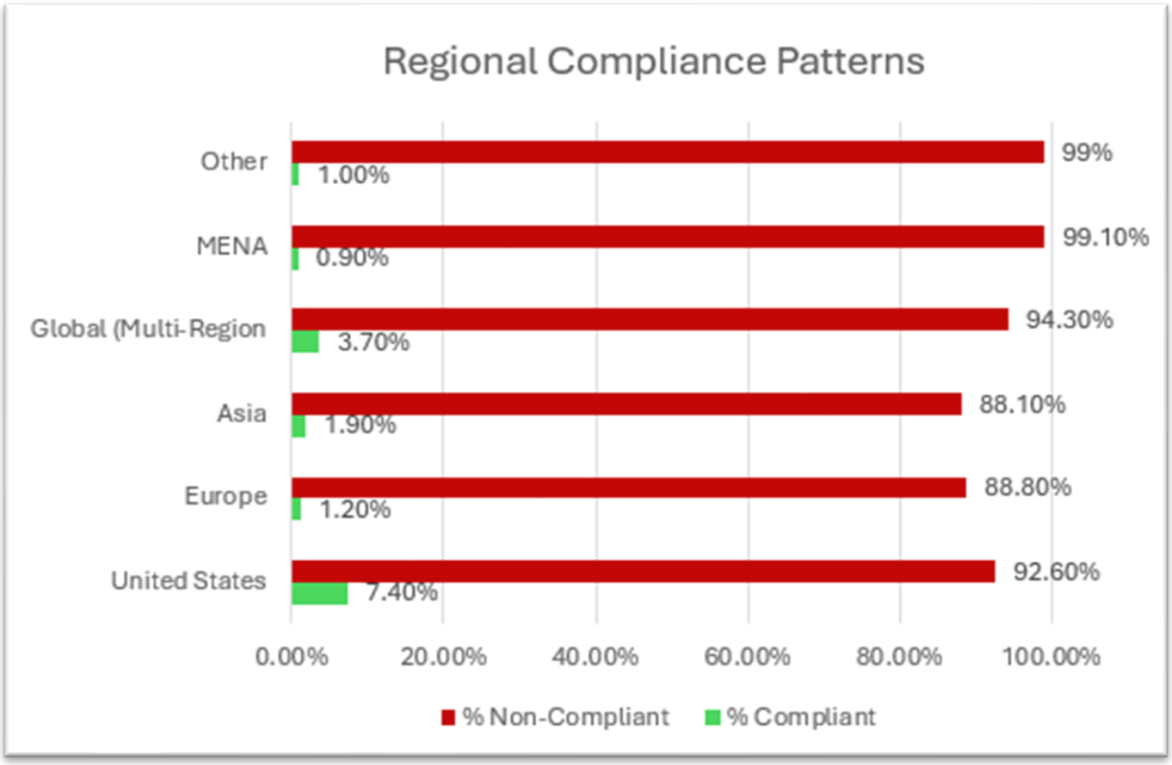

Figure 4.2

Regional Compliance Patterns

4.2.6 Therapeutic Category Differences

When stratified by ICD-10 disease category, results indicate notable heterogeneity across therapeutic domains. Trials addressing oncologic conditions (ICD-10 C) demonstrates an on-time compliance rate of 3.9%, slightly below the overall mean. Oncology's lower-than-expected compliance appears rooted in structural and operational factors — such as multisite trial complexity, adaptive designs, longer follow-up windows, and publication-coordination cultures — rather than lack of ethical salience. Oncology represents the largest ICD-10 category in the dataset, and it's compliance rate falls below the overall mean, an important empirical pattern for subsequent inferential testing. This finding is particularly striking.

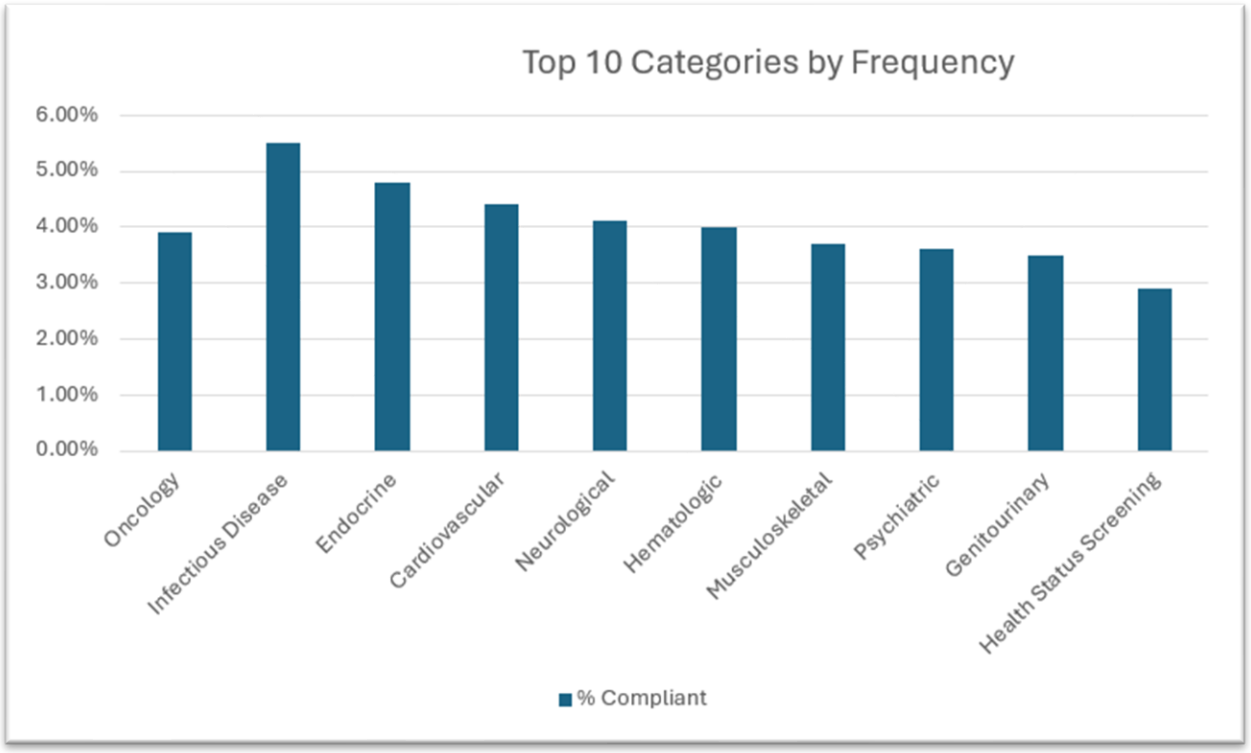

Figure 4.3

Compliance by Therapeutic Category (ICD-10)

Note. Oncology underperforms relative to other categories.

In contrast, smaller therapeutic areas such as infectious and endocrine disorders exhibited slightly higher compliance, approaching 5–6 %. Descriptive patterns also illustrate an important paradox: visibility and scientific prominence do not necessarily translate into transparency performance. Divergence of visibility and compliance highlights legitimacy in clinical research remains contested and often decoupled from behaviors that would substantiate it. High representation in infectious disease and cardiovascular domains further emphasizes continuing focus on high-burden diseases with significant public health impact. Differences across top performing therapeutic indication appear in Figure 4.3.

4.2.7 Synthesis of Descriptive Findings

Taken together, these exploratory findings reveal a consistent pattern: compliance with clinical trial results reporting remains markedly low, even in cohorts most directly bound by regulatory obligation. Descriptive data suggest compliance behaviors are unevenly distributed across institutional fields.

Table 4.4

Observed Patterns in Descriptive Compliance Analyses

Domain	***Empirical Observation***
Trial Phase	Voluntary trials (~1%) vs. mandated trials (Phases 2–4, ~4%)
Funder Type	Highest compliance among NIH-funded trials, followed by individual investigators, industry, public, and other funders
Region	U.S.-based trials (~7%) substantially outperform non-U.S. trials (≤ 2%)
Therapeutic Area	Oncology trials exhibit below-average compliance (~3.9%)
Overall	**Transparency remains selective rather than systemic across domains**

Note. Percentages reflect on-time results reporting within 365 days of primary completion. These descriptive observations establish baseline compliance patterns that frame interpretation of the primary logistic regression model.

NIH and independent investigators exemplify commitment; non-U.S. entities generally lag substantially behind U.S.-based trials. Across phases, regulatory obligation – not development stage – emerges as is the primary driver of compliance behavior. A summary of cross-sectional findings is provided in Table 4.4, consolidating patterns observed across phase, funder, region, and therapeutic area.

This foundation enables transition to predictive modeling. Forthcoming analyses (Section 4.3) evaluate which independent variables—such as phase, funder, therapeutic area, and geographic location—significantly influence likelihood of compliance and how these patterns evolve across regulatory epochs. Across three regulatory epochs, compliance behavior did not

follow a linear path of improvement. Instead, it cycled through successive legitimacy modes — cognitive, regulative, and ultimately symbolic.

This pattern reflects a broader institutional drift in which early commitment gradually gave way to procedural adherence and, by Epoch 3, symbolic performance. As regulative pressure intensified, legitimacy eroded, producing a plateau of "legitimacy fatigue," where sponsors complied sparingly but not enough to fulfill the ethical purpose of transparency.

4.3 Predictive Results Interpretation | Main Effects Logistic Regression

4.3.1 Model Specification and Overall Fit

The main effects model was estimated using binary logistic regression to predict whether trials reported results within the legally required timeframe. This model included five independent variables: regulatory epoch, trial phase, funder type, therapeutic area, and geographic region. Our analysis sample consisted of all non-exempt interventional trials with valid completion dates (N = 97,218).

Table 4.5 reports overall model fit and discrimination statistics for the main-effects logistic regression (Model A), in which on-time clinical trial results reporting (CTG_Compliant_TF; 1 = reported within 365 days) was regressed on regulatory epoch (Epoch 1, 2, 3), trial phase (early vs. later phase), funder type (NIH, industry, academia, independent), geographic region (U.S. vs. non-U.S.), and therapeutic area (oncology vs. non-oncology). These results demonstrate the model's adequacy for evaluating structural predictors of compliance.

Table 4.5

Model Summary Statistics (AIC, BIC, AUC, R^2)

Metric	***Value***
Deviance R^2	*0.0741*
Adjusted Deviance R^2	*0.0738*
AIC	*31,375.98*
BIC	*31,461.34*
AUC (ROC)	*0.7236*

Note: Values are based on the primary main-effects logistic regression model (Model A). AUC reflects model discrimination performance

Accordingly, model fit was evaluated using complementary metrics, including ROC analysis and calibration plots, which indicated acceptable predictive performance. Consistent with a predictive modeling objective, overall model performance was assessed using discrimination metrics rather than reliance on omnibus goodness-of-fit tests alone.

The model demonstrated strong predictive capability given the heterogeneous dataset. As shown in Figure 4.4 (ROC Curve), the Area Under the ROC Curve (AUC) was 0.7236, indicating good discriminative performance. In practical terms, the model reliably distinguishes compliant from non-compliant trials approximately 72% of the time, substantially exceeding chance (AUC = 0.50). The full contingency table and chi-square test statistics for the Epoch × Compliance analysis are reported in Appendix D (Table D.1).

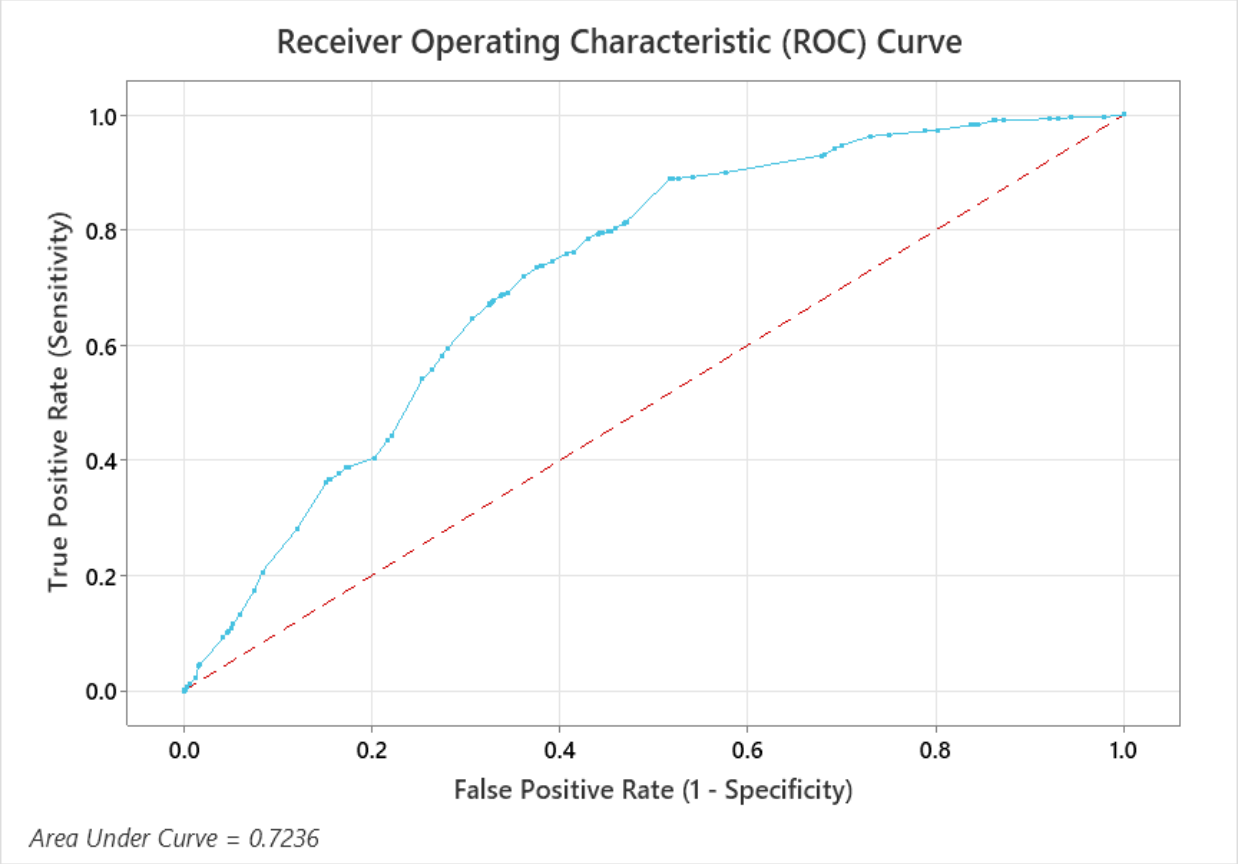

Figure 4.4

Receiver Operating Characteristic (ROC) Curve - Main Effects Model

Note: ROC curve displays model discrimination for predicting FDAAA 801 compliance using the main effects logistic regression model. Area Under the Curve (AUC) = 0.7236.

Table 4.6 reports Deviance and Pearson χ^2 statistics goodness-of-fit tests returned p = 1.000 non-significant results, indicating no evidence of lack of fit. The Hosmer–Lemeshow test χ^2 value was statistically significant; however, this result is a well-documented limitation of the test in exceptionally large samples (N > 90,000), where trivial deviations between observed and expected values can produce statistically significant results - rather than substantive indication of poor model performance.

Table 4.6

Goodness-of Fit Tests

Test	*Degrees of Freedom*	*Chi-Square*	*p-value*
Deviance	97,210	31,357.98	1.000
Pearson	97,210	92,764.87	1.000
Hosmer–Lemeshow	7	162.13	< .001

Note: Deviance and Pearson goodness-of-fit tests indicate no evidence of lack of fit. The Hosmer–Lemeshow test is statistically significant, a known artifact in exceptionally large samples, and does not indicate substantive model misfit. Model discrimination and calibration were evaluated using ROC and calibration plots.

Observed compliance increases monotonically across predicted-probability deciles, and sensitivity rises as specificity declines. Threshold analysis identified an empirical tipping point at predicted probabilities of approximately 0.08–0.09 as shown in Figure 4.5. Below this region, compliance is predominantly symbolic — registration without results reporting. Above this region, observed compliance rises sharply, marking a shift toward substantive legitimacy. This supports theoretical framing selective transparency reflects underlying legitimacy dynamics rather than random variation.

Collectively, these performance indicators confirm the model provides a stable, interpretable foundation to examine how structural factors — regulatory epoch, trial phase, funder type, therapeutic area, and regional location — shape likelihood of timely reporting.

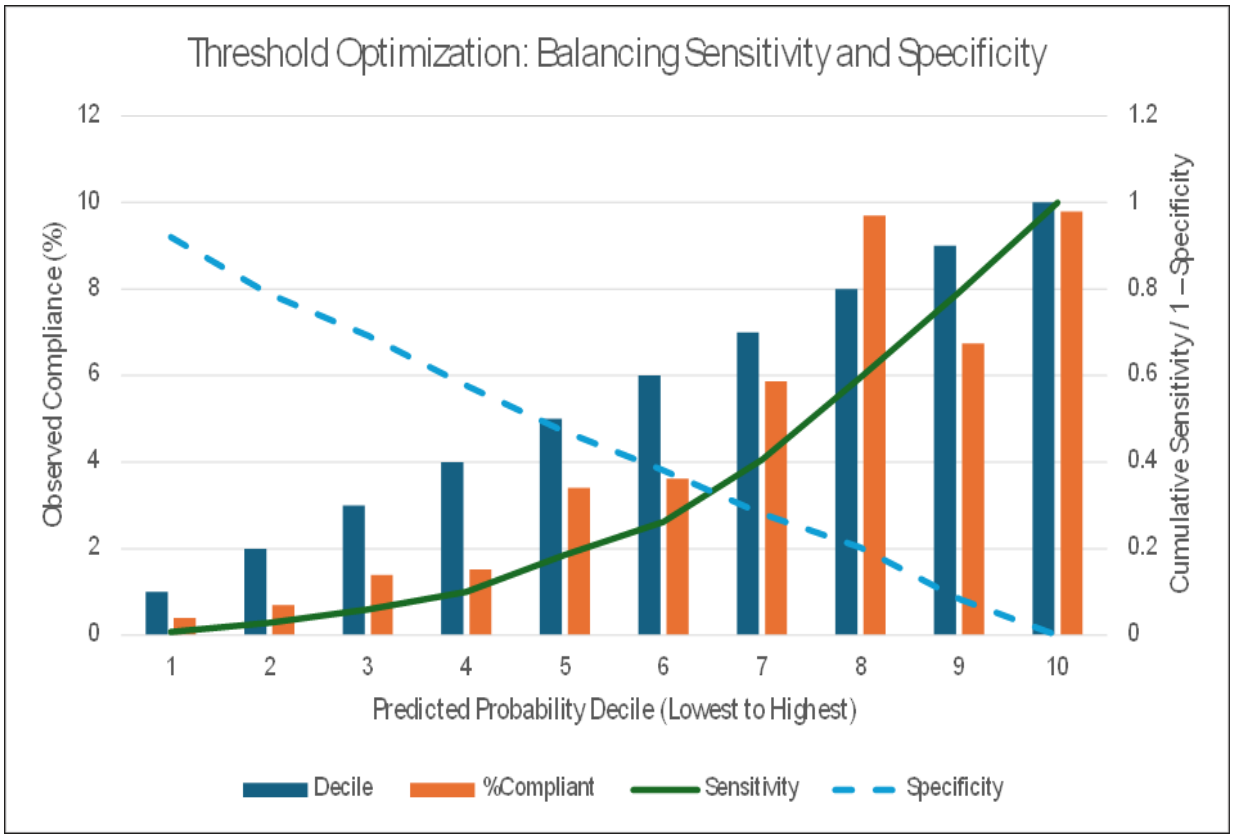

Figure 4.5

Threshold Optimization Plot

Note: Threshold plot depicts observed compliance rates and corresponding sensitivity–specificity tradeoffs across predicted probability deciles.

4.3.2 Main Effects: Logistic Regression and Interpretation of Results

Unified, the compliance environment is driven primarily by cognitive (phase), pragmatic (funder), and sociopolitical (regional) legitimacy forces, with moral and regulative legitimacy failing to generate improvement over time, thereby directly informing RQ1 and RQ2

Table 4.7 presents odds ratios, confidence intervals, and interpretive focus for the main-effects logistic regression model, summarizing how regulatory, cognitive, pragmatic, moral, and sociopolitical factors independently relate to clinical trial results reporting compliance.

Table 4.7

Logistic Regression Odds Ratios Model: Main Effects

Variable	***Level / Contrast***	***OR***	***95% CI***	***p-value***	***Interpretive Focus***
Epoch	E2 vs E1	1.04	[0.96, 1.13]	**.293**	No meaningful change after Final Rule implementation
	E3 vs E1	0.45	[0.41, 0.50]	**< .001**	Significant decline in compliance post-Seife
Phase	Late vs Early	1.33	[1.24, 1.43]	**< .001**	Later-phase trials show modestly more compliance
Funder	Govt vs Industry	1.29	[1.12, 1.49]	**< .001**	Public-sector accountability increases compliance
	Other vs Industry	0.87	[0.81, 0.94]	**< .001**	Reduced accountability among "Other" funders
ICD	Oncology vs Non-Oncology	1.06	[0.98, 1.14]	*.171*	No evidence of moral legitimacy advantage
Region	US vs Non-US	5.01	[4.62, 5.50]	**< .001**	US highest compliance; Jurisdictional influence
	Global vs Non-US	4.36	[3.93, 4.84]	**< .001**	Cross-jurisdictional oversight increases reporting

Note: OR = Odds Ratio. Confidence intervals are 95%. Model overall performance statistics include AUC = 0.7236; Deviance R^2 = 7.41%; indicating moderate predictive discrimination for compliance behavior in a large highly heterogeneous dataset.

Results from the model indicate several independent variable domains significantly shape timely results reporting:

- **Regulative legitimacy effects weakened over time**: The Final Rule period (E2 vs. E1) produced no improvement (OR = 1.04, p=.293), while the Seife v. HHS era (E3 vs. E1) shows a substantial decline (OR = 0.45, p < .001.
- **Cognitive legitimacy remains evident**: Later-phase trials exhibit 33% higher odds of compliance (OR = 1.33, p < .001), although absolute compliance levels remain low.

- **Funder-type differences reinforce pragmatic legitimacy:** Government-funded trials outperform industry (OR = 1.29, p<.001), whereas "Other" funders odds lagged (OR = 0.87, p<.001).
- **Moral-legitimacy for oncology is not supported:** Oncology show no compliance advantage (OR = 1.06, p = .171).
- **Sociopolitical legitimacy emerged as the strongest driver:** U.S.-based trials (OR = 5.01, p < .001) and global multi-region studies (OR = 4.36, p < .001) are far more likely to comply than non-U.S. trials.

4.3.3 Calibration and Model Validation

The model demonstrates good practical reliability for predicting compliance. As shown in the Calibration Plot, predicted probabilities align closely with observed values across most deciles, and tracks near the 45-degree reference line. Minor deviations at the lowest and highest deciles reflect the sparse-event nature of the outcome (~4% compliance).

Table 4.8

Model Validation Statistics

Concordance	***Somers' D***	***Gamma***	***Deviance R^2***
~71%	0.45	0.46	7.41%

Note: Deviance R^2 reflects explained variance; concordance, Somers' D, and Gamma reflect rank-order discrimination.

Validation metrics shown in Table 4.8: Concordance (~71%), Somers' D (0.45), and Gamma (0.46) indicate strong rank-order discrimination. Explained variance (Deviance R^2 = 7.41%) is consistent with established benchmarks for regulatory-behavior models in organizational and health services. A deviance R^2 of 7.41%, while modest in absolute terms,

aligns with published benchmarks for regulatory-behavioral prediction models and reflects well-documented difficulty of explaining institutional non-compliance with structural variables alone.

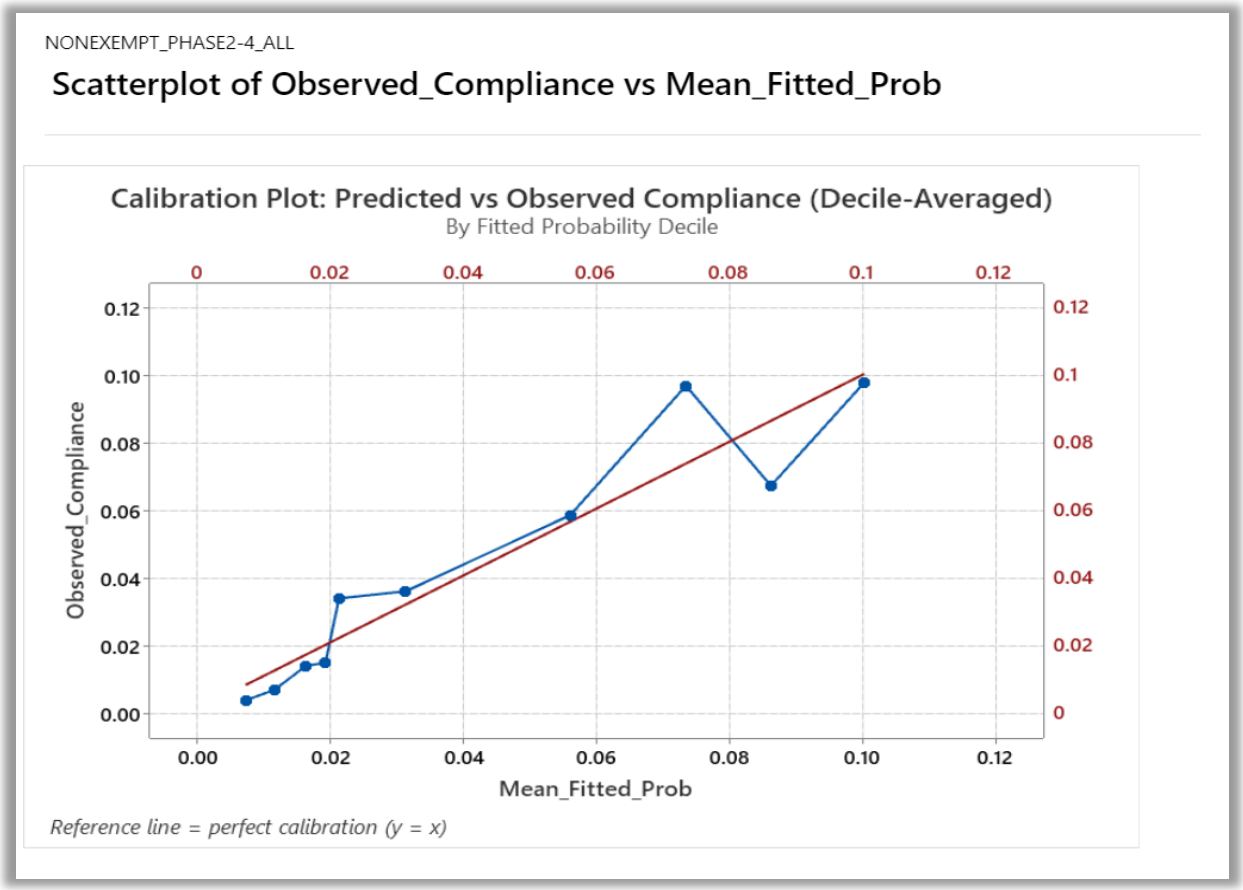

Figure 4.6

Calibration Plot: Predicted vs Observed Compliance

Note: The scatter/line plot showing the curves for predicted vs observed compliance. Dots represent observed compliance; the reference line indicates perfect calibration (y=x).

Consolidated, these diagnostics confirm the model is stable, well-calibrated, and interpretable for evaluating structural predictors of results reporting.

4.3.4 Predictive Results in Relation to Hypotheses

Predictive results provide a direct empirical test of the five hypotheses (H1-H5) specified for the main effects model and, collectively, address RQ1 (regulatory epochs) and RQ2 (structural characteristics). Four interaction-based hypotheses (H6-H9) remain theoretically meaningful but were not estimated empirically in this dissertation and are treated as directions for future research (see Chapter 5). The interpretation below aligns findings with our legitimacy theory framework. Table 4.9 summarizes the direction and strength of empirical support for each hypothesis (H1–H5), aligning main-effects regression findings with their corresponding legitimacy dimensions and research questions.

4.3.4.1 Regulatory Shifts and Research Question 1 (H1; Conceptual Basis for H6-9)

The main effects model shows regulatory epochs did not increase compliance, contradicting core expectations of H1. Transition from Epoch 1 (2007–2016) to Epoch 2 (2017–2019) produced no significant improvement (OR = 1.04, $p = .293$), and shift from Epoch 1 to Epoch 3 (2020–2024) produced a meaningful decline (OR = 0.45, $p < .001$). These results demonstrate stronger formal regulation did not translate into stronger behavioral compliance.

Consistent with this pattern, the conceptual moderation hypotheses (H6–H9) — which posit regulative changes would strengthen cognitive, pragmatic, moral, and sociopolitical legitimacy pressures — are not supported empirically in this dissertation, because interaction terms were not included in the estimated main effects model. Instead, these hypotheses inform the interpretive and future-research agenda discussed in Chapter 5.

4.3.4.2 Structural Predictive Variables and Research Question 2 (H2-H5)

Table 4.9

Summary of Hypothesis Testing Results

Hypothesis	***Statistical Result (OR, p-value)***	***Supported***	***Legitimacy Interpretation***
H1 - Regulative (Epoch)	E2 vs E1: OR = 1.04; E3 vs E1: OR = 0.45, p < .001	**Not Supported**	Regulatory tightening did not increase compliance; Regulative legitimacy collapsed post-2020.
H2 - Cognitive (Phase)	Late > Early: OR = 1.33, p < .001	**Supported**	Later-phase trials exhibit higher Cognitive legitimacy; maturity improves adherence.
H3 - Pragmatic (Funder)	Govt > Industry: OR = 1.29, p < .001	**Supported**	Government/NIH sponsorship confers Pragmatic legitimacy, raising compliance.
H4 – Moral (Condition)	Onc < Non-Onc: OR = 1.06, p = .171 (ns)	**Not Supported**	Oncology does not display a moral-visibility advantage; virtue ≠ compliance.
H5- Sociopolitical (Location)	US vs Non-US: OR = 5.01, p < .001	**Supported Strongly**	Geography is the dominant sociopolitical legitimacy force; U.S. infrastructure / norms drive higher compliance.

Note: OR = Odds Ratio. ns = not significant. All effects estimated from the main effects logistic regression model on non-exempt FDAAA 801–regulated trials (N~ 97,000). Support = statistically significant at p <.05. Legitimacy interpretations derived from theoretical dimensions described in Chapter 2 (regulative, cognitive, pragmatic, moral, sociopolitical).

In contrast, structural independent variables produced clearer empirical patterns.

- **H2 (Cognitive legitimacy – Study Phase)** received partial support.

  Later-phase trials (Phase 2–4) were more likely to comply than earlier phases (OR = 1.33, p < .001), but overall compliance remained extremely low (~4%).

- **H3 (Pragmatic legitimacy – Funder type)** was supported.

  Government and NIH-funded trials were significantly more compliant than industry trials

(OR = 1.29, p < .001), while "Other" funders lagged behind, consistent with gradient of accountability.

- **H4 (Moral legitimacy – Therapeutic indication)** was not supported.

  Oncology trials showed no compliance advantage (OR = 1.06, p = .171), contradicting expectations scientific prestige would translate into higher compliance.

- **H5 (Sociopolitical legitimacy – Regional location)** received strong support.

  U.S. trials were far more compliant than trials conducted elsewhere (OR = 5.01, p < .001), highlighting geography as a dominant sociopolitical legitimacy force.

Table 4.10

Hypothesis by Legitimacy Dimension

Legitimacy Type	***Associated Hypotheses***	***Supported?***
Regulative	H1, H6- H9 (conceptual)	H1 Not supported; H6–H9 Not empirically tested
Cognitive	H2	Partially supported
Moral	H4	Not supported
Pragmatic/Moral	H3	Supported
Sociopolitical	H5	Supported

Note: Legitimacy dimensions follow Scott (1995), Suchman (1995), and Kaganer et al. (2010)

Table 4.10 synthesizes hypothesis outcomes by legitimacy dimension, illustrating which forms of legitimacy are empirically supported in explaining clinical trial results reporting compliance and which remain unsupported or conceptually reserved for future study.

4.3.4.3 Integrative Interpretation

These results reveal a clear pattern: legitimacy forces arising from organizational norms, identity, and jurisdictional context—not regulation alone—drive compliance behavior. Research Question 1 receives no empirical support in the sense that regulatory tightening did not increase compliance. Research Question 2 is substantially affirmed: structural characteristics of trials and sponsors are more predictive of reporting behavior than statutory changes.

Regulative legitimacy did not strengthen over time; instead, the Seife v. HHS period is associated with a sharp decline in compliance odds. Cognitive legitimacy manifests in slightly higher adherence among later-phase trials, pragmatic legitimacy in superior performance of government and NIH-funded studies, and sociopolitical legitimacy in the dominance of U.S. and global multi-region compliance. Moral legitimacy, operationalized through oncology, does not show expected advantage.

Synthesized, main effects results support a view of transparency as selectively institutionalized: compliance is most common where cognitive maturity, pragmatic accountability, and sociopolitical scrutiny intersect, but remains weakly coupled to formal regulatory escalation.

4.4 Robustness and Reproducibility Checks | Predictive and Inferential Findings Synthesis

Robustness checks confirmed main findings were stable across alternative specifications. Excluding rare categories (< 1% frequency), re-running the model on slightly restricted samples, and examining classification performance at alternative probability thresholds did not materially alter direction or significance of epoch, phase, funder, or region effects. All analytic steps were documented through Minitab session logs and versioned datasets, supporting reproducibility and

providing a transparent audit trail that aligns with ethical and methodological commitments outlined in Chapter 3.

4.5 Summary of Findings

Descriptive, predictive, and inferential analyses reveal a consistent pattern: compliance with FDAAA 801 remains extremely low, even among trials most bound by law. Across nearly 100,000 non-exempt trials, compliance hovers near 4%, with only modest improvements in later-phase studies.

Structural characteristics — not regulatory milestones — explain most variation. Phase maturity provides a small but meaningful cognitive-legitimacy boost (supporting H2), funder identity remains a strong pragmatic driver (supporting H3), and geography emerges as the strongest sociopolitical determinant (supporting H5). In contrast, expected moral-legitimacy advantages for oncology do not materialize (contradicting H4). Importantly, regulatory epoch effects do not support for H1, indicating no evidence regulatory tightening increased compliance within this archival dataset. Interaction hypotheses H6–H9 were not empirically tested..

Compliance does not improve following the Final Rule (2017) or Seife v. HHS (2020), confirming regulatory tightening did not influence behavior. Instead, U.S. infrastructure and norms, NIH stewardship, and later-phase visibility remain primary forces shaping whether trials report results.

These findings collectively illuminate both Research Question 1 and Research Question 2, highlighting structural and institutional characteristics — rather than statutory requirements alone — drive reporting behavior in contemporary clinical research.

4.6 Transition

Chapter 4 has established the empirical landscape of clinical trial results reporting under FDAAA 801, showing where compliance is concentrated, where it is scarce, and how key institutional characteristics shape probability of timely disclosure. In Chapter 5, these findings are interpreted through the broader lens of Legitimacy Theory, translated into implications for regulators, sponsors, and research institutions, and used to outline a forward-looking agenda for monitoring, policy design, and future scholarly inquiry.

Chapter 5. Conclusions and Recommendation

5.1 Introduction

This chapter synthesizes and interprets the empirical findings presented in Chapter 4, translating statistical results into substantive insights about clinical trial transparency and organizational behavior. Moving beyond descriptive and inferential outcomes, it examines what the main-effects logistic regression model reveals about how frequently—and under what institutional, regulatory, and organizational conditions—clinical trials comply with FDAAA 801 results-reporting requirements.

Grounded in legitimacy theory, this chapter situates the findings within broader regulative, cognitive, pragmatic, moral, and sociopolitical dynamics, illuminating how compliance behavior reflects beyond legal obligation to include institutional expectations and strategic responses to enforcement environments. We then articulate the study's theoretical, practical, and policy implications; clarify its contributions to scholarship; acknowledge limitations; and identify targeted opportunities for future research.

5.2 Integrated Implications for Theory and Practice

Viewed through the lens of Legitimacy Theory, this study illustrates how, whether, and when organizations post their trial results is shaped less by statutes and more by how sponsors interpret expectations around reputation, identity, and jurisdiction. Table 5.1 synthesizes the study's core findings through a legitimacy lens, summarizing how trial characteristics align with cognitive, pragmatic, moral, regulative, and sociopolitical legitimacy mechanisms to explain patterned compliance behavior.

Table 5.1

Summary of Legitimacy Interpretation

Domain	***Legitimacy Interpretation***
Trial Phase	Partial Cognitive Legitimacy; Regulative Pressure Weak
Funder Type	Pragmatic Legitimacy Gradient
Region	Sociopolitical Legitimacy Confined to U.S. Jurisdiction
Therapeutic Area	Oncology Moral Legitimacy Paradox
Overall	Transparency is selective, not systemic.

5.2.1 Phase-Based Cognitive Legitimacy Dynamics

Theoretical Interpretation:

Phase-based patterns observed in this study indicate later-phase trials are incrementally more likely to post results within the required timeframe than early-phase trials, although overall compliance rates remain uniformly low. From a legitimacy perspective, this pattern aligns with cognitive legitimacy mechanisms: as trials progress toward later phases, they become more visible to regulators, payers, clinicians, and the public, and more tightly linked to shared expectations about how "serious" or consequential trials ought to behave.

In Suchman's (1995) terms, organizations appear to engage in selective conformity, aligning more closely with taken-for-granted norms in portions of trial portfolios subject to heightened scrutiny, while exhibiting weaker adherence in less visible or consequential segments. These findings suggest trial phase exerts stronger behavioral influence than formal rule articulation alone.

Practical Implications

From an operational perspective, the modest increase in on-time reporting among later-phase trials suggests regulatory, clinical, and data-management teams already recognize trial phase as a signal of importance and external scrutiny. However, persistently low absolute compliance rates—even among trials closest to regulatory decision-making—signal a critical gap between perceived importance and executed transparency.

This gap indicates Phase 2–4 operational workflows should be explicitly oriented toward timely public disclosure by:

- integrating ClinicalTrials.gov reporting into standard study close-out procedures,
- coordinating registry submission timelines with journal publication strategies, and
- treating results posting as a core compliance obligation rather than a peripheral administrative function.

5.2.2 Practical Legitimacy Dynamics Across Funder Types

Theoretical Interpretation

Variation across funder types reveals how legitimacy operates in patterned logic embedded within funding structures, professional identities, and administrative routines. NIH-funded trials exhibit the strongest alignment with pragmatic legitimacy, where results reporting appears integrated into the core architecture of sponsored research itself. Within this context, posting results is less an external mandate and more an expected continuation of publicly funded scientific work—an extension of "how research is done" rather than a discrete obligation.

Investigator-initiated trials reflect a different, but equally compelling, legitimacy pathway. Here, results reporting often appears anchored in professional identity and ethical self-concept. Clinician-investigators may experience disclosure as part of their obligation to patients,

peers, and the scientific record, even in absence of robust infrastructure. This form of legitimacy normative rather than bureaucratic, arising from internalized standards of scientific citizenship.

Industry-sponsored trials, by contrast, display a contingent orientation toward legitimacy. Reporting behavior appears calibrated to reputational exposure, competitive considerations, and regulatory relationships. Transparency gains traction when it reinforces credibility with regulators, investors, or the public, suggesting legitimacy in this context is strategically negotiated. Posting results becomes most salient when it aligns with strategic incentives or mitigates external risk.

Across funder types, these patterns illustrate that funding structures fundamentally shape the institutional meaning of results reporting. Legitimacy functions as an organizing principle influencing whether transparency is treated as intrinsic, aspirational, or instrumental.

Practical Implications

From an applied perspective, funder-specific legitimacy pathways point toward differentiated strategies for strengthening transparency. NIH-funded research demonstrates how embedding results reporting into grant oversight mechanisms—such as progress reporting and close-out procedures—normalizes disclosure as a routine component of publicly accountable science.

Investigator-initiated trials illustrate the sustaining power of professional norms and ethical commitment, suggesting that reinforcing mentorship, education, and peer expectations may be as equally influential alongside formal infrastructure in promoting timely reporting.

Industry-sponsored trials highlight a different leverage point: transparency improves most reliably when it is reinforced through reputational signals, regulatory engagement, and external accountability, rather than positioned as a statutory obligation. In practical terms, this suggests

integrating results reporting expectations into contracts, study budgets, milestone planning, and performance evaluation processes might exert greater influence than incremental rule expansion. Aligning transparency with existing operations allows results reporting to function as a visible marker of organizational credibility.

5.2.3 Therapeutic Category and Moral Legitimacy Implications

Theoretical Interpretation

Paradoxical underperformance of cancer trials highlights the limits of moral legitimacy and represents one of the study's most striking findings.

Cancer research carries strong moral expectations: high patient visibility, intense advocacy, substantial public and philanthropic investment, and clinical urgency. Yet oncology trials do not report results more reliably or more promptly than other therapeutic areas in this dataset; if anything, they report less frequently on time.

This "oncology paradox" finding extends legitimacy theory by demonstrating moral legitimacy in narrative and reputation does not automatically translate into behavior. High moral salience appears insufficient, on its own, to ensure trial results are posted within required timeframes. Moral expectations require institutional reinforcement and operational alignment to shape reporting behavior.

Practical Implications

Oncology's lower rates of on-time results reporting suggest field-specific challenges—such as extended trial timelines, cooperative group coordination, complex endpoints, and competitive publication strategies—necessitate tailored safeguards to preserve patient and public access to clinical trial results.

Improving cancer transparency therefore requires regulatory reinforcement aligned with institutional incentive, clearer accountability structure within cooperative groups and industry–academic partnerships, and deeper integration of disclosure practices in trial management workflows.

Oncology illustrates prestige does not guarantee transparency; moral legitimacy claims must be matched with operational systems which sustain consistent disclosure behavior to sustain public trust.

For practitioners, this suggests improving results reporting in oncology will likely require a combination of regulatory reinforcement and field-specific operational solutions—for example, standardized results-posting roles within cooperative groups, clearer rules for timing relative to publications, and trial management systems that track registry posting as a core deliverable.

5.2.4 Geographic Context and Sociopolitical Legitimacy

Theoretical Interpretation

Geographic patterns observed in this study reveal how sociopolitical legitimacy is shaped—and conditioned—by jurisdictional context. Trials conducted within the United States demonstrate substantially higher odds of timely results reporting than trials conducted exclusively outside U.S. borders. Multiregional trials that include U.S. sites similarly exhibit stronger reporting performance than single-region, non-U.S. studies. These patterns suggest proximity to U.S. regulatory oversight brings with it heightened reputational visibility and clearer accountability expectations.

From a legitimacy perspective, this finding highlights the role of jurisdiction as a conduit through which sociopolitical pressure is translated into behavior. ClinicalTrials.gov occupies a distinct position within the U.S. regulatory ecosystem, where transparency norms are reinforced

by professional scrutiny and public expectations. For international sponsors, engagement with the registry appears closely tied to anticipated interaction with U.S. regulators or markets, positioning registration as a signal of alignment with U.S. research norms.

The geographic gradient also points to a subtle decoupling between symbolic and substantive legitimacy.

Registration may function as an outward-facing indicator of conformity, while results disclosure remains more tightly anchored to institutional environments in which trials are conducted and overseen. In this sense, sociopolitical legitimacy associated with U.S. jurisdiction exerts a stronger gravitational pull on reporting than generalized global transparency norms.

Practical Implications

From an operational and ethical stewardship perspective, regional variation in results reporting emphasizes a need for clearer continuity between trial registration and disclosure expectations in multinational research. As global clinical development continues to expand across diverse regulatory environments, disparities in infrastructure, oversight capacity, and enforcement mechanisms shape how transparency obligations are interpreted and enacted.

Strengthening results reporting across regions therefore calls for deliberate alignment among ethics approvals, sponsor contracts, and cross-border collaboration frameworks. Explicit linkage of registration to reporting milestones—communicated clearly to international sponsors and embedded within trial governance structures—can help ensure participation in U.S.-facing research pathways carries consistent expectations for public disclosure. Such alignment supports equitable access to trial outcomes for patients and communities, regardless of where studies are conducted, and reinforces transparency as a shared responsibility within the global enterprise.

5.2.5 Cross-Cutting Implications

Viewed collectively, patterns identified across phase, funder type, therapeutic area, and geographic context reveal a results-reporting environment shaped by selective adherence and evolving legitimacy dynamics. Organizations tend to disclose trial outcomes most reliably when reporting aligns with institutional identity, mission-driven norms, or jurisdictional expectations—such as in NIH-funded research, U.S.-based studies, or later-phase trials subject to heightened scrutiny. In contrast, disclosure practices vary more widely in settings where oversight is diffuse and incentives are less clearly articulated.

These patterns reflect long-standing institutional dynamics described in the organizational literature, where formal structures coexist with uneven implementation (Bromley & Powell, 2012; Meyer & Rowan, 1977). Rather than indicating wholesale disengagement, reporting behavior appears responsive to strategic assessments of visibility, relevance, and consequence, consistent with Oliver's (1991) framework of organizational responses to institutional pressure. As regulatory expectations expand without parallel alignment of monitoring systems or operational support, symbolic alignment increasingly substitutes for sustained behavioral change—a condition conceptualized in this study as legitimacy fatigue.

Empirically, this dynamic is evident in the study's central descriptive finding: trials do not post results within the required 12-month window, including trials clearly subject to FDAAA 801. Cross-validation with external benchmarks reinforces prior observations of persistent inconsistency (Kaplan, Koong, & Irvin, 2023). In this context, absence of timely results becomes analytically meaningful in its own right—an observable transparency signal precisely where regulatory legitimacy would be expected to be most influential.

Viewed in aggregate, these findings suggest strengthening real-world results reporting requires engagement with institutional logics and operational systems shaping organizational behavior. Durable improvement is most likely when transparency expectations are integrated into routine practice rather than positioned as episodic compliance events.

Across empirical, theoretical, and applied dimensions, this study advances an integrated approach to understanding and addressing trial reporting behavior. By consolidating fragmented data sources, extending legitimacy theory into a contemporary regulatory context, and translating findings into actionable insights, the analysis offers a pathway toward meaningful impact.

From a practical standpoint, effective strategies to strengthen reporting should focus on:

- Aligning interventions with institutional cultures and incentive structures (e.g., grant monitoring in publicly funded research, reputational accountability in industry-sponsored trials, governance norms within cooperative groups);
- Embedding posting expectations into study workflows, contracts, and close-out procedures; and
- Making results disclosure more visibly consequential for organizational reputation, funding continuity, and regulatory relationships.

Sustained gains in transparency are most likely when results reporting becomes an ordinary feature of organizational practice — part of "how work is done" — rather than a discretionary or deferrable task.

5.2.5.1 Practical Contribution

From a policy and implementation perspective, this research addresses persistent gaps between regulatory intent and operational reality by offering evidence-based insights for regulators, academic medical centers, and commercial sponsors. Findings support more targeted

approaches to enforcement prioritization, sponsor education, and governance reform, informed by an understanding of how visibility and legitimacy shape compliance behavior (Hossfeld, 2018; Voinea & van Kranenburg, 2018).

The analysis also aligns with emerging policy perspectives emphasizing criticality of closing structural and procedural gaps enabling inconsistent reporting practices (Kimbrell & Lawless, 2025). By identifying where and why transparency falters across institutional contexts, the study provides a foundation for interventions that reinforce disclosure through systems designed to support consistent execution.

Ultimately, by bridging legitimacy theory with operational realities, this work positions legitimacy as a practical and predictive lens — capable of explaining variation in compliance behavior and guiding efforts to improve transparency across the clinical research enterprise.

5.3 Contributions to Scholarship

This dissertation advances scholarship on institutional theory and clinical trial transparency through five interrelated contributions:

- **A legitimacy-based explanation of results reporting behavior**, demonstrating how cognitive, moral, pragmatic, and sociopolitical legitimacy mechanisms shape compliance with disclosure mandates;
- **A reassessment of regulatory influence**, showing how formal mandates operate unevenly across institutional contexts and why legal requirements, absent institutional alignment, fail to generate durable transparency practices;
- **Identification of key legitimacy-linked predictors of compliance**, revealing systematic variation in reporting behavior by trial phase, funder type, therapeutic area, and geographic jurisdiction;

- **An applied legitimacy framework for organizational and policy action**, translating theoretical insight into actionable guidance for sponsors, regulators, and oversight bodies; and
- **A methodological contribution enabling these insights**, through construction of an integrated, longitudinal dataset combining ClinicalTrials.gov, TrialsTracker, and ICD-10 classifications; illustrating how large-scale archival sources can be systematically harmonized to evaluate trial-level reporting behavior at scale.

5.3.1 Empirical Contribution

This study delivers a comprehensive empirical assessment of clinical trial results reporting compliance under FDAAA 801. By integrating data across ClinicalTrials.gov, TrialsTracker.net, and CMS ICD-10 classifications, the analysis reveals reporting patterns obscured in single-source analysis.

The integrated dataset captures longitudinal compliance behavior across jurisdictions, funder types, therapeutic areas, drug development phase, and regulatory epochs, enabling detection of structural asymmetries and persistent reporting gaps that single-source audits cannot surface or detect. In doing so, the study establishes a robust empirical foundation for evaluating under what institutional conditions transparency emerges. This evidence base supports both retrospective assessment and forward-looking identification of risk areas within the clinical research enterprise (IQVIA, 2024; Mehra & Grazette, 2020).

5.3.2 Theoretical Contribution

Theoretically, this dissertation advances legitimacy theory by demonstrating its explanatory power within a highly regulated biomedical domain. Drawing on Suchman's (1995) seminal work in defining pragmatic, moral, and cognitive legitimacy, and incorporates Scott's

(1995) framework of regulative legitimacy, the study reframes clinical trial sponsors as legitimacy-seeking actors operating within layered regulatory, professional, and sociopolitical environments Kaganer et al. (2010),

The findings show results reporting behavior is patterned by how legitimacy is constructed and reinforced across institutional contexts — through funding mechanisms, therapeutic narratives, jurisdictional oversight, and organizational identity. Consistent with Deephouse and Suchman's (2008) view of legitimacy as strategically cultivated, transparency emerges as a selective, situational practice instead of an automatic response to regulation.

By extending insights from Kaganer et al. (2010) and Islam et al. (2022) into the domain of clinical trial transparency, this study positions legitimacy theory as a framework capable of explaining persistent compliance variation despite clearly articulated legal mandates. Legitimacy is shown to operate as a measurable force shaping observable organizational behavior.

5.3.3 Positioning Relative to Existing Literature

This dissertation corroborates and extends a well-established body of research documenting chronic underperformance in clinical trial results reporting. Early analyses by Zarin, and Tse and Zarin (Tse & Zarin, 2009; Zarin, 2017) demonstrated fragmented reporting practices and limited behavioral change following major regulatory milestones. The present study confirms those patterns at scale, showing timely results disclosure remains rare across the broader population of interventional trials.

Subsequent audits by Anderson et al. (2015) and real-time monitoring by DeVito, Bacon, and Goldacre (2020) document persistent delays across sponsor types, even among organizations with substantial regulatory infrastructure. Across scope and timeframe, their findings converge with present evidence: most trials exceed mandated reporting timelines, if reporting results at all.

The present analysis extends prior work by integrating multiple data sources, expanding the temporal window, and examining variation across funder type, geography, and therapeutic area. Patterns reported by Axson et al. (2021) and Nilsonne et al. (2024) regarding sponsor and regional differences are reinforced, particularly among non-U.S. and non-commercial entities. Oversight assessments by the FDA (2025) and the DHHS Office of Inspector General (2022) further contextualize these findings, highlighting the limited enforcement environment within which persistent noncompliance unfolds.

Collectively, the literature and present findings converge on a clear conclusion: regulatory mandates alone have yet to reshape reporting behavior at the trial level. This study advances the field by explaining who the outliers in performance are, while that gap persists.

5.3.4 Methodological Contributions

Methodologically, this study makes a distinct contribution by constructing a longitudinal, legitimacy-oriented compliance dataset through the systematic harmonization of large-scale, heterogeneous data sources. The integrated dataset combines ClinicalTrials.gov records spanning 2007–2024, TrialsTracker compliance determinations, and CMS ICD-10 mappings of therapeutic focus. A fourth dataset capturing FDA approval information was collected and evaluated but reserved for future research due to data-quality constraints.

Unlike prior studies that rely on single registries or descriptive audits, this approach enables both cross-sectional and temporal analyses of compliance behavior across institutional contexts. The resulting dataset supports legitimacy-informed modeling of reporting behavior, allowing identification of patterns, disparities, and predictors undiscernible within siloed systems.

In addition, this study introduces predictive modeling into a literature dominated by retrospective audits. By operationalizing legitimacy-related variables within a logistic regression framework, the analysis demonstrates how compliance risk can be identified proactively rather than retrospectively documented. This methodological contribution provides a replicable foundation for future research aimed at improving transparency through earlier intervention and targeted oversight.

5.4 Limitations and Boundary Conditions

This study operates within structural constraints inherent to large-scale, registry-based research. These limitations arise primarily from data architecture, classification logic, and nature of publicly disclosed regulatory information rather than from analytic design choices.

Several variables required operational harmonization across heterogeneous sources. Trial phase and exemption status were derived using established regulatory categories, with Early Phase 1 and Phase 1 trials serving as primary operational markers of exemption. Although this approach reflects prevailing regulatory practice, incomplete metadata in some records introduces classification ambiguity at the margins. Similarly, funder type was standardized using ClinicalTrials.gov categorical fields, which may compress hybrid sponsorship arrangements—such as commercial and government collaborations, and completely obscure academic or advocacy foundation funders—within broader groupings.

Therapeutic classification relied on U.S. ICD-10-CM mappings applied to heterogeneous free-text condition entries. Multinational trials may align more naturally with WHO ICD-10 conventions, introducing modest variation in therapeutic categorization across regions. Geographic location coding required comparable harmonization, as free-text entries varied widely in granularity, spelling, and regional conventions.

Manual recoding of free-text fields remains a structural challenge in registry-based research. Despite clinical expertise, explicit decision rules, and repeated cross-checks, large-scale harmonization introduces classification noise. Importantly, this type of error is non-directional: it attenuates subgroup differences rather than creating artificial inflation.

Collectively, these constraints highlight the importance of more standardized, machine-readable registry architectures. They also clarify that observed effects reflect reporting behavior within existing disclosure systems rather than analytic artifacts.

5.4.1 Reliability, Completeness, and Known Limitations

Each data source contributing to this analysis brings complementary strengths and limitations. ClinicalTrials.gov is the most comprehensive U.S. registry for trial reporting, yet relies on sponsor self-reporting and lacks automated validation for key compliance indicators. Funding categories such as “OTHER” and “OTHER_GOV” may obscure underlying accountability structures or public–private arrangements.

TrialsTracker.net provides structured compliance assessments but depends on algorithmic parsing of registry data and inherits any underlying inaccuracies present in the underlying ClinicalTrials.gov records. CMS ICD-10 classification requires interpretive mapping, particularly when translating heterogeneous free-text condition descriptions into standardized categories.

The analytic strength of this study lies in the integration of these sources. By combining registries rather than relying on any single system, the analysis enables triangulation and enhances inferential stability.

5.4.2 FDA Approvals Data Exploration: What Should Be Obvious – Is Not

The original study design anticipated linkage between registered clinical trials and FDA approval records. Exploration of FDA approval archives revealed substantial structural fragmentation across divisions and time periods. Approval records varied widely in format and accessibility, and many lacked standardized identifiers—such as NCT numbers—necessary for reliable linkage.

Older approval documents often appeared as scanned archival materials with inconsistent formatting, while more recent records improved in presentation but remained incomplete. Independent cross-checks with external approval summaries confirmed similar limitations. (see examples FDA (2008) and FDA (2018). The resulting many-to-many relationships between trials and approvals rendered systematic merging unreliable. Cross-referencing with the journal *Nature*'s annual "Novel Drug Approvals" tables confirmed similar limitations (Hughes, 2008).

The absence of standardized identifiers created both one-to-many and many-to-one relationships between clinical trials and approvals, rendering automated or even rigorous manual merging unreliable ("garbage in / garbage out"). Independent analyses of FDA approval reporting, corroborate this limitation. Accordingly, the FDA approvals dataset was excluded from the analytic file used for regression modeling.

The final integrated dataset used in all descriptive and regression analyses combines ClinicalTrials.gov as the base population with TrialsTracker.net records via NCT_ID linkage, with ICD-10 codes applied post-merge for therapeutic classification. FDA approvals variables are not included in the statistical models presented. Kaplan et al. document variability in the agency's annual decision listings and highlights an absence of standardized cross-links between approval records and supporting clinical trials (Kaplan et al., 2023).

Following consultation with the dissertation chair, FDA approval data were excluded from the analytic dataset and deferred to future research. Approval-linked variables are absent from the models reported in Chapters 4 or 5. Nevertheless, this exploratory work surfaced a structural transparency gap: when approved products cannot be systematically traced to their supporting trials, verification of reporting compliance becomes inherently constrained. This observation aligns with judicial and oversight concerns regarding the visibility of clinical evidence underlying marketed products (United States District Court for the Southern District of New York (2020).

5.4.3 Methodological Limitations and Potential Bias

This study relies on secondary, self-reported registry data and therefore reflects regulatory reporting behavior rather than clinical outcomes, trial quality, or sponsor intent. Compliance is examined as a proxy for ethical transparency within the regulatory system, instead of a direct measure of scientific merit.

Free-text fields for therapeutic focus and geographic location required extensive manual harmonization. Although systematic coding rules and quality checks were applied, scale alone introduces residual variability. Complementary datasets introduce parallel constraints: algorithmic exemption flags may misclassify edge cases, and interpretive ICD-10 crosswalks warrant continued validation by domain experts.

Taken together, these methodological boundaries are consistent with the realities of large-scale regulatory research. These boundaries temper interpretation while preserving the direction of observed associations.

5.4.4 Scope, Mitigation, and Analytic Boundaries

Numerous steps were taken to mitigate known risks associated with large-scale archival research, including cross-validation across multiple data sources, stratified analyses of incomplete records, and systematic data harmonization procedures. These measures improve internal consistency and analytic reliability. However, limitations inherent to registry-based research — particularly reliance on the accuracy, completeness, and timeliness of publicly disclosed information — remain structural features of the research environment and resist full resolution through post hoc correction.

5.4.4.1 Focus, Purpose, and Generalizability

The scope of this study is intentionally focused on interventional trials subject to FDAAA 801, a design choice to strengthens internal validity and regulatory clarity while narrowing generalizability to other study types such as observational research, behavioral interventions, or early device feasibility studies. As a secondary, archival analysis, findings reflect patterns of regulatory reporting behavior rather than clinical outcomes, trial quality, or sponsor intent. Compliance is therefore examined as a proxy for ethical transparency within the regulatory system, instead of a direct measure of scientific rigor or patient impact.

5.4.4.2 Legitimacy Theory Alignment and Data Constraints

Legitimacy constructs in this study are operationalized through observable institutional behavior — specifically, timely posting of trial results — rather than through direct measurement of stakeholder perceptions, discourse, or trust. While this approach enables precise quantification of regulative legitimacy, pragmatic, sociopolitical, moral, and cognitive legitimacy are and remain indirectly inferred.

These constraints reflect limits of archival data rather than conceptual weakness. Partial visibility of legitimacy dynamics observed here is consistent with legitimacy theory itself, which anticipates opacity and decoupling when normative alignment lags behind formal regulation.

5.5 Recommendations: Observations and Opportunities for Improvement

Findings from this study indicate formal regulatory expectations, in isolation, have not produced consistent or timely posting of clinical trial results. Observed reporting patterns instead reflect structural, jurisdictional, and operational dynamics that decouple registration from public disclosure. The recommendations below are grounded in empirical evidence from the integrated dataset and align directly with legitimacy and institutional mechanisms identified throughout the analysis.

5.5.1 Platform Design and Data Integrity Considerations

Conclusions in this study point to a structural limitation in the current design of the ClinicalTrials.gov Protocol Registration System for transparency, oversight, and downstream analytic validity. Specifically, heavy reliance on unstructured free-text fields for core trial attributes — including condition, geographic location, and funder classification — introduces substantial variability, ambiguity, and data loss. In constructing the integrated dataset for this study, thousands of records required cleaning, standardization, or recovery from incomplete, inconsistent, or non-interpretable entries, anomalies effectively limiting inclusion in prior empirical analyses.

To strengthen integrity and usability of the registry, greater reliance on structured fields — with controlled vocabularies and clearly defined categorical options — should be prioritized, reserving free-text entries for contextual explanation rather than primary classification. In particular, current dropdown options for *funder type* and *trial phase* obscure meaningful

distinctions in how research is financed and conducted; the absence of a clearly defined "academic" or institutionally funded category fails to reflect a substantial segment of real-world trial sponsorship. Addressing these design limitations would enhance regulatory oversight, reinforce public accountability, and strengthen the evidentiary base future compliance research.

5.5.2 FDA – Enforcement Design

Current enforcement practices under FDAAA 801 remain largely symbolic, with limited issuance of penalties and minimal operational follow-through. Geographic variation in reporting behavior suggests disclosure obligations are interpreted unevenly, particularly among non-U.S. sponsors engaging with U.S. regulatory pathways. When registration is treated as a terminal administrative step rather than an ongoing transparency commitment, results reporting becomes detached from trial oversight.

Strengthening enforcement coherence requires aligning expectations across ethics approvals, study contracts, and institutional policies, coupled with clearer communication of U.S. reporting requirements throughout the trial lifecycle. Reinforcing disclosure obligations at multiple touchpoints would shift the environment from episodic reminders to predictable accountability.

5.5.3 Global Harmonization

Persistence of non-reporting among non-U.S. sponsors registered on ClinicalTrials.gov highlights misaligned expectations across international registries. When registration in one platform does not clearly establish corresponding obligations to disclose results elsewhere, reporting responsibilities become fragmented.

Greater interoperability across major registries would help establish shared expectations for timely public disclosure, supported by harmonized timelines, reciprocal recognition of

enforcement actions, and coordinated oversight mechanisms. Embedding reporting obligations into multinational ethics review processes and study contracts would further operationalize transparency as a continuous responsibility. Such alignment would shift results reporting from a jurisdiction-bound compliance task to a shared ethical norm owed to research participants and the public.

5.5.4 NIH Grant-Monitoring Model

NIH-funded trials demonstrate the most consistent on-time results reporting in this dataset, offering a practical model for embedding transparency into routine research governance. Reporting improves most reliably when disclosure expectations are integrated into grant monitoring, study close-out procedures, and institutional oversight, positioning results posting as a standard component of the research lifecycle.

Extending NIH-style monitoring requirements to other federal agencies, cooperative groups, and public funding bodies would strengthen accountability by requiring documented proof of results posting prior to formal grant close-out. Complementing automated reminders and linking future funding eligibility to demonstrated reporting performance would assert and align institutional incentives with public transparency obligations. Such measures reposition results reporting as a routine deliverable rather than a discretionary task.

5.5.5 Oversight System Recommendations

Variation in reporting performance across institutions reflects fragmentation in oversight responsibilities among regulatory, funding, and human-subject protection bodies. When transparency expectations operate in parallel rather than in coordination, accountability diffuses within sponsor and institutional structures.

A more unified oversight approach—aligning expectations across agencies such as the FDA, NIH, and OHRP—would elevate results reporting as a core governance responsibility. Requiring formal institutional certification of reporting compliance, modeled on existing financial or regulatory attestations, would further embed transparency into organizational accountability frameworks. Standardized compliance toolkits and mandatory trial-tracking systems can operationalize expectations, ensuring reporting deadlines remain visible, managed, and met across the research enterprise.

5.5.6 Implications for Enforcement Mechanisms

Evidence from this study suggests durable improvements in reporting behavior depend on continuous institutional reinforcement rather than episodic intervention. Passive, self-attestation–based compliance models offer limited traction where transparency carries substantial public interest implications.

More active, surveillance-oriented approaches — analogous to proactive safety monitoring — would increase visibility of reporting performance and strengthen accountability throughout the research lifecycle. Public-facing dashboards flagging overdue trials, integration of reporting metrics into FDA review materials, and incorporation of historical reporting performance into funding and ethics review decisions would reinforce disclosure as an enduring professional obligation. These measures support a transition from symbolic rule-setting toward reporting practice, embedding transparency as a continuously monitored public accountability signal..

5.6 Recommendations for Future Research

This dissertation establishes a foundation for the next phase of transparency research—one that moves beyond documenting gaps toward explaining, predicting, and ultimately reducing

them. The directions outlined below are intentionally practical, scalable, and ethically grounded, offering clear entry points for scholars, regulators, and practitioners committed to improving public access to clinical trial evidence. In parallel, future research should evaluate how strengthened governance environment following *Seife v. HHS (2020)*, combined with the NIH's expanding grant-monitoring systems, may shift sponsor behavior from symbolic registration toward durable, routine trial transparency and public-facing practices.

5.6.1 Post-Market Legitimacy and Lifecycle Transparency

One of the most consequential unanswered questions in clinical research transparency concerns what happens *after* regulatory approval. Future studies should examine whether results-reporting behavior changes once products enter the marketplace and public scrutiny shifts from development to clinical use. Linking trial registries to FDA approval records would allow researchers to assess whether transparency strengthens, plateaus, or fades across the product lifecycle. Such work would clarify whether disclosure obligations function as temporary regulatory checkpoints or as enduring ethical commitments to patients and clinicians..

5.6.2 Methodological and Analytical Extensions

Registry-based transparency research would benefit substantially from automation and scale. Applying subsets of artificial intelligence (AI) such as machine learning (ML) techniques, and the deeper subset of natural language processing (NLP) to free-text fields — particularly therapeutic focus and geographic location — would reduce manual burden while improving consistency and reproducibility. Beyond classification, future models could incorporate financial indicators, regulatory correspondence signals, and market or policy shifts to better capture the institutional forces shaping reporting behavior.

Better yet, the rapidly emerging field of integrated intelligence (II) where human and machine learning combine, offers significant promise, particularly when informed by patient experience and practitioner expertise. These extensions would support earlier identification of at-risk studies and move transparency research from retrospective audit toward proactive insight.

5.6.3 Fine-Grained Timeliness of Penalty Modeling

Current compliance measures treat "late" reporting as a binary outcome. Future research should leverage day-level timeliness data to model *how late* results are posted from resources such as DeVito, Goldacre, and colleagues' (2020) FDAAA TrialsTracker – and under what conditions delays accumulate. Time-to-event analyses, financial-risk simulations, and sponsor-level delinquency profiles would deepen understanding of delay dynamics and illuminate how economic incentives and enforcement timing influence behavior. This work would help translate transparency expectations into measurable, policy-relevant risk signals..

5.6.4 Expansion to Moderation and Interaction Models

This study focused on main effects to establish foundational relationships. A natural next step is to examine how regulatory shifts reshape those relationships. Moderation models testing interactions between regulatory epochs and trial characteristics — such as phase, funder type, therapeutic area, and geography — could clarify when legitimacy pressures intensify, weaken, or realign. Such analyses would advance legitimacy theory by revealing how institutional forces evolve over time rather than operating as static influences.

5.6.5 Global Registry Alignment and Cross-Platform Transparency Analysis

Because non-U.S. sponsors demonstrated extremely low compliance despite registering on ClinicalTrials.gov, future research could explore global registry behavior. This pattern may reflect "symbolic adoption" (Bromley & Powell, 2012; Meyer & Rowan, 1977) and may reflect a

form of symbolic harmonization, in which organizations mirror formal expectations of global transparency frameworks without engaging in substantive behaviors those frameworks intend. In multi-jurisdictional regulatory systems, such symbolic alignments is common where harmonization pressures exist but accountability capacity is uneven (Drezner, 2001; Levi-Faur, 2005)

The persistent gap between trial registration and results reporting among non-U.S. sponsors invites focused cross-registry analysis. Comparative studies spanning ClinicalTrials.gov, EU CTIS, ISRCTN, and WHO ICTRP could identify whether transparency deficits are registry-specific or systemic. Examining patterns of registration without reporting across platforms would shed light on symbolic alignment versus substantive disclosure and inform efforts to harmonize expectations across global research systems.

5.6.5 Oncology-Specific Transparency Pathways

Oncology's paradoxical underperformance in timely results reporting warrants focused investigation, particularly given oncology's central role in clinical innovation and patient impact, its distinctive reporting patterns warrant dedicated study. Future research should examine how cooperative group structures, publication norms, complex endpoints, and sponsor–academic partnerships shape disclosure timelines. Qualitative inquiry with oncology investigators and research administrators would complement quantitative analyses and help identify stewardship practices that support timely transparency without compromising scientific rigor.

Provided oncology's ethical stakes and translational impact, understanding and addressing drivers of delayed results reporting is essential to ensuring scientific progress is matched by transparency owed to patients, participants, and the public.

Closing Perspective

Considered in concert, these directions outline a research agenda focused forward on anticipating and correcting transparency failures, as opposed to just documenting them. Advancing clinical trial transparency is a matter of trust, evidence accessibility, and ethical accountability.

The work ahead invites collaboration across disciplines, methods, and institutions to ensure the knowledge generated through clinical research is shared as openly and responsibly as the public expects — and deserves.

5.7 Summary

This dissertation demonstrates meaningful public reporting of results in clinical research cannot be achieved through regulation alone. Stronger enforcement and clearer harmonization of results-reporting standards are needed, but these controls must be accompanied by institutional practices which embed transparency into routine operations. NIH-funded trials give us a glimpse as to how integration of reporting into grant-monitoring systems can produce somewhat more consistent compliance. Sponsors with structured workflows, mission-linked accountability, or personal ethical commitments show substantially higher adherence than organizations without such internal procedures.

International underperformance highlights additional structural gaps. Strengthening funder education, establishment of shared expectations among multinational regulatory bodies, and integration of reporting milestones into trial governance frameworks may reduce global patterns of symbolic registration without substantive disclosure. Even within the United States — where transparency norms and reputational pressures are strongest — compliance remains

poor, indicating jurisdictions with established expectations still require ongoing oversight and institutional reinforcement in order for those expectations to be realized in practice.

Overall, our findings show transparency emerges when institutional mission, identity, incentives, and jurisdictional context align with disclosure norms. By documenting stagnant compliance across successive regulatory epochs, this dissertation introduces the concept of **legitimacy fatigue** — a condition in which expanding formal requirements produce diminishing behavioral returns. This phenomenon captures a central insight of the study: transparency is not a regulatory output but a function of institutional culture, collective norms, and perceived legitimacy of disclosure itself.

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Appendices

Appendix A –- Descriptive Sample Distributions

Appendix A provides supplementary descriptive tables and figures documenting distribution of non-exempt Phase 2–4 clinical trials across study phase and regulatory epoch. These materials support descriptive statistics reported in Chapter 4 and are included to enhance transparency, reproducibility, and auditability of the analytic sample.

A.1 Trial Phase Distribution

- **Tally table (counts and percentages)**
- **Bar charts (counts and percentages)**

Table A.1

Distribution of Trials by Clinical Trial Phase (Non-Exempt Phase 2–4 Trials)

Tally

CTG_Trial_Phases	Count	Percent
PHASE1|PHASE2	10859	10.39
PHASE2	40435	38.69
PHASE2|PHASE3	4597	4.40
PHASE3	25063	23.98
PHASE4	23558	22.54
N=	104512	

Note: Count and percentage distribution of non-exempt Phase 2–4 interventional clinical trials by ClinicalTrials.gov phase designation within final analytic sample (N = 104,512).

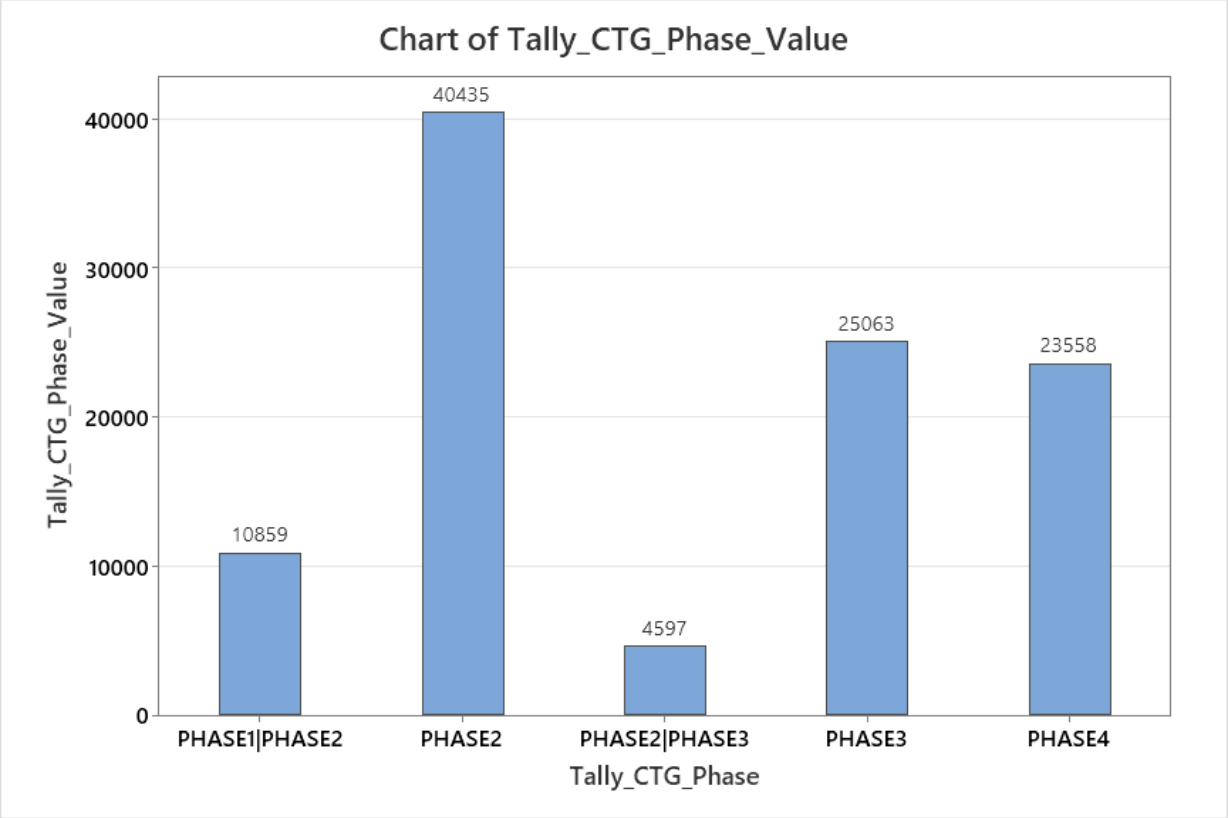

Figure A.1

Count of Trials by Clinical Trial Phase

Note: Visualization of absolute number of non-exempt Phase 2–4 trials across ClinicalTrials.gov phase categories in the analytic sample.

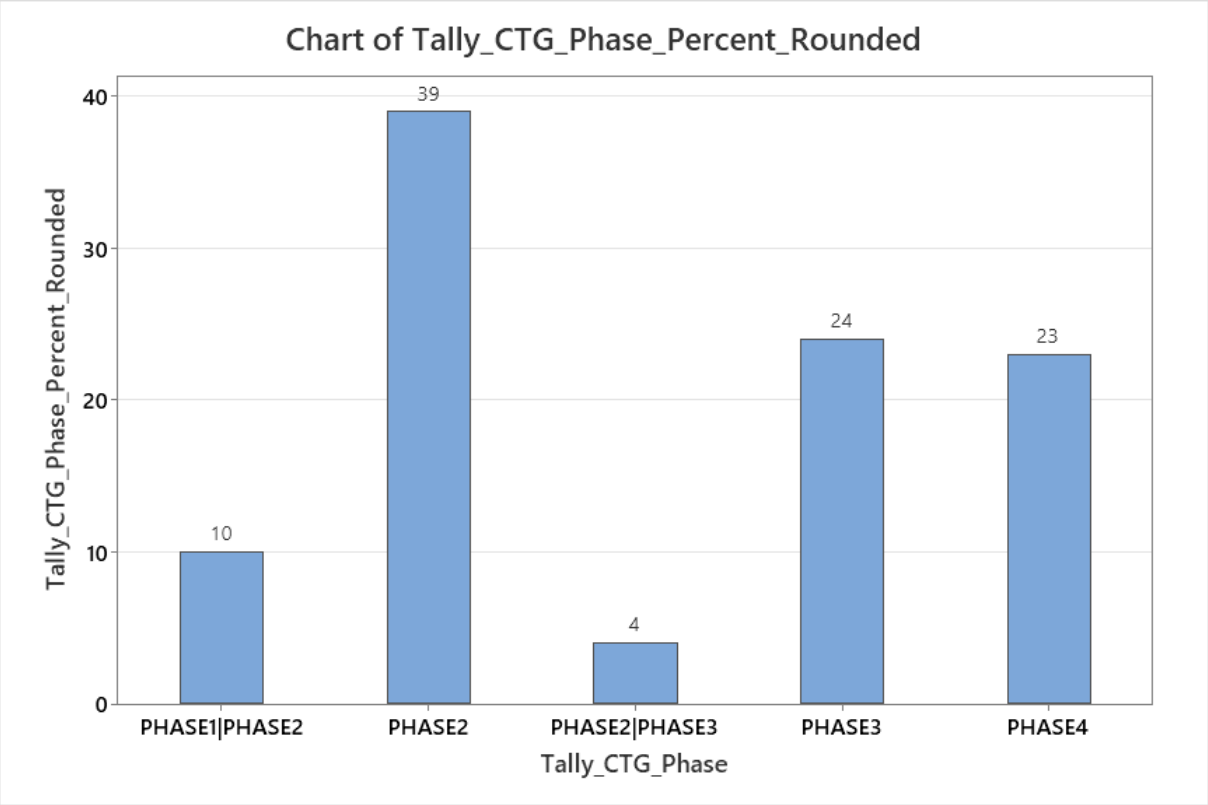

Figure A.2

Percentage Distribution of Trials by Clinical Trial Phase

Note: Figure displays relative percentage distribution of non-exempt Phase 2–4 trials across ClinicalTrials.gov phase categories, calculated within the analytic sample**.**

A.2 Regulatory Epoch Distribution

- **Tally table (counts and percentages)**
- **Bar charts (counts and percentages)**

Table A.2

Distribution of Trials by Regulatory Epoch

Tally for Discrete Variables: Epoch

Tally

Epoch	Count	Percent
E1_2007_2016	56912	54.45
E2_2017_2019	19130	18.30
E3_2020_2024	28470	27.24
N=	104512	

Note: Count and percentage distribution of non-exempt Phase 2–4 trials categorized by regulatory epoch based on study start date alignment with major FDAAA 801 enforcement milestones**.**

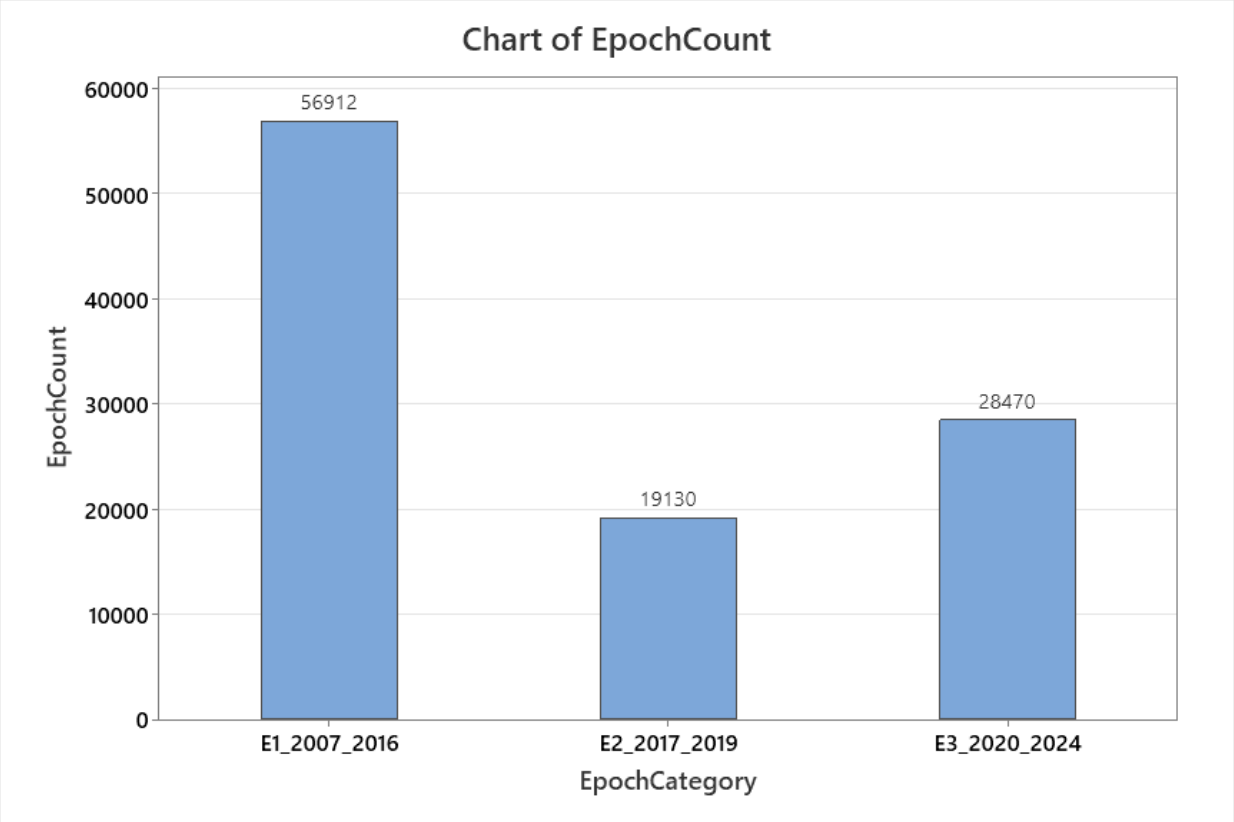

Figure A.3

Count of Trials by Regulatory Epoch

Note: Illustration of absolute number of non-exempt Phase 2–4 trials initiated within each regulatory epoch defined for the study period**.**

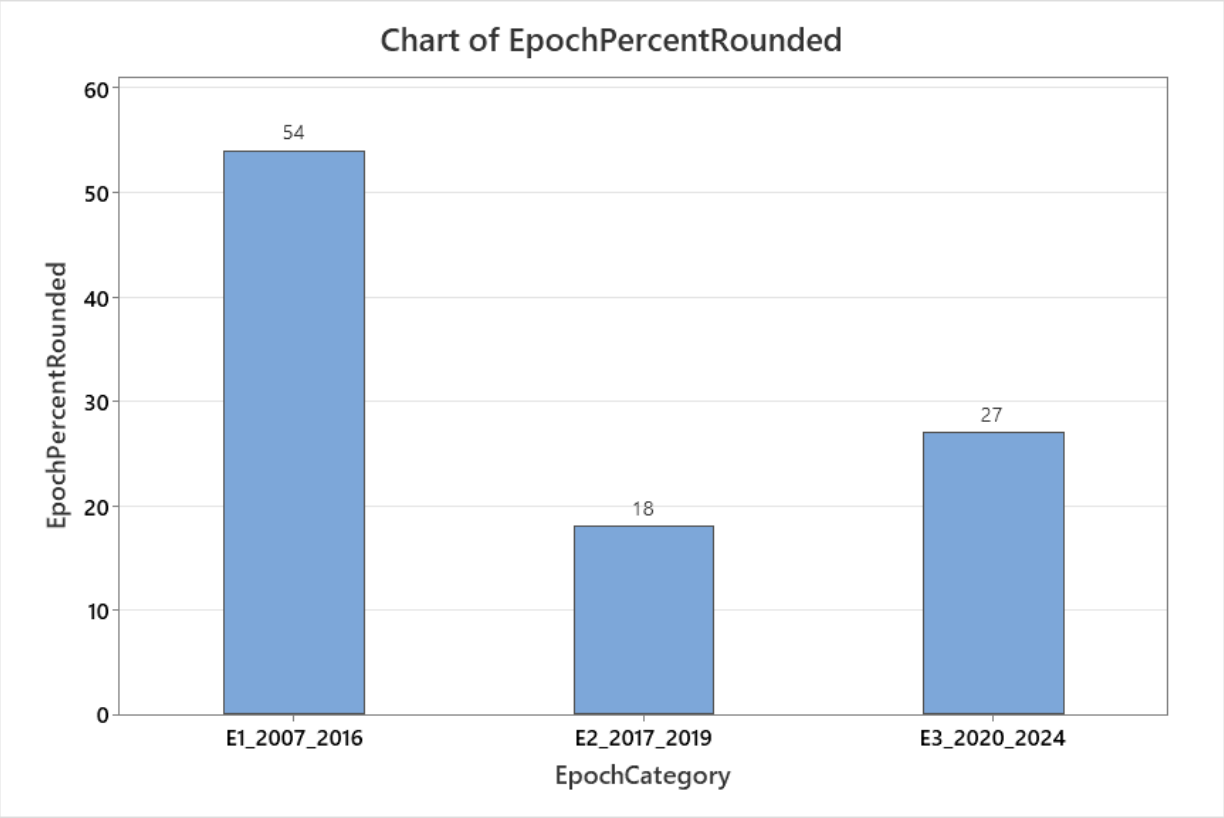

Figure A.4

Percentage Distribution of Trials by Regulatory Epoch

Note: Figure depicts relative percentage distribution of non-exempt Phase 2–4 trials across regulatory epochs, reflecting temporal composition of the analytic sample

Longitudinally, these descriptive distributions establish the baseline structure of the analytic sample and provide the empirical foundation for the epoch-based compliance analyses presented in Chapter 4.

Appendix B — Variable Construction & Coding Decisions

B.1 Constructed Variable Definitions

CTG_Trial_Phases

CTG_Trial_Phases represents clinical development study phase designation as reported in ClinicalTrials.gov. Phase designations were extracted directly from registry metadata. Because phase information is inconsistently reported across records—particularly for later-phase or combined-phase studies—this variable reflects the raw phase values prior to analytic collapsing. Trials with no phase designation were reviewed separately for exemption status.

B.2 Classification Logic and Temporal Cutoffs

Epoch Classification Logic (Date Cutoffs)

Each trial was assigned to a regulatory epoch based on its study start date, aligning trial start date with major regulatory milestone affecting results-reporting expectations. Epoch 1 (2007–2016) captures the post-FDAAA 801 enactment but pre-Final Rule period; Epoch definitions were established a priori and reflect the FDA Amendments Act (FDAAA 801) (2007), the Final Rule (2017), and the *Seife v. HHS* decision (2020).

Classification Logic and Temporal Cutoffs

Regulatory epochs were defined as follows:

- **E1 (2007–2016):** Post-FDAAA 801 enactment, pre-Final Rule enforcement
- **E2 (2017–2019):** Initial Final Rule implementation period
- **E3 (2020–2024):** Post-Seife ruling and heightened enforcement scrutiny

This temporal structure allows compliance behavior to be examined in relation to evolving regulatory clarity and enforcement credibility.

B.3 Decision Rules and Inclusion Criteria

Phase Collapsing (Phase 2–4)

For analytic purposes, trial phases were collapsed into a Phase 2–4 category to address sparse cells, reduce misclassification bias, and reflect the shared legal obligation for results reporting among later-phase interventional trial, and ensures sufficient cell sizes for stable statistical inference while preserving regulatory interpretability.

Non-Exempt Trial Inclusion

Only non-exempt interventional trials subject to FDAAA 801 reporting requirements were included in the analytic sample. Exempt studies—including Phase 1 trials and trials lacking applicable device or drug oversight—were excluded to ensure regulatory comparability.

B.4 Data Management - Quality Considerations and Exclusions

Missingness

Missing values were assessed across all constructed variables. Trials missing essential fields required for regulatory classification (e.g., start date, phase, or completion status) were excluded from inferential analyses.

Ambiguous Phase Coding

Trials reporting ambiguous or nonstandard phase designations (e.g., “Not Applicable”) were retained only when sufficient contextual information supported inclusion in the non-exempt Phase 2–4 analytic sample.

Data Exclusions

Exclusions were applied conservatively and documented to prioritize regulatory relevance, analytic validity, and reproducibility. No imputation was performed for regulatory classification variables.

Jointly, these definitions and decision rules establish a transparent and reproducible framework for variable construction. All coding choices were made prior to inferential testing reflecting both regulatory intent and practical data limitations in large-scale registry analysis.

B.5 H1 Interpretation Framework

Step	*Analytical Focus*	*Evidence / Reasoning*
1. Observed Trend *(Empirical Fact)*	Compliance rates across epochs declined slightly rather than increased: • E1 (2007–2016): 4.88% • E2 (2017–2019): 4.81% • E3 (2020–2024): 1.97% Overall compliance = 4.08%. The Chi-Square Test ($\chi^2 = 442.99$, $p < .001$) confirms significant variation among epochs.	Statistically significant differences exist, but the direction is *downward*, not upward.
2. Comparison to Expected Pattern *(Hypothesis)*	H1 expected: Compliance should increase following major regulatory/legal shifts (Final Rule, *Seife v. HHS*), reflecting stronger enforcement and institutional adaptation.	The actual pattern contradicts the hypothesis — compliance decreased after these milestones.
3. Theoretical Outcome *(Support vs. Contradiction)*	The data do not support H1. Rather than demonstrating a positive correlation between regulatory tightening and compliance, the pattern suggests that heightened enforcement did not translate into behavioral improvement.	This framework evaluates an empirical gap between *regulatory intent* and *organizational response*.
4. Legitimacy Interpretation	The decline in compliance despite stronger rules reflects weak regulative legitimacy. Organizations appear to comply symbolically (registering trials) but not substantively (reporting results). This suggests that enforcement mechanisms under FDAAA 801 — even post-*Seife* — have lacked coercive credibility and that compliance remains largely performative rather than institutionalized.	The persistence of symbolic adherence aligns with theoretical expectations that policy without practical enforcement fails to shift behavior, reinforcing the theme of *institutional decoupling*.

B.6 Data Provenance Indicator

Merge_Status

A categorical variable was created during dataset integration to track the provenance of each trial record following the merge of ClinicalTrials.gov and TrialsTracker data. *Merge_Status* indicates whether a trial record was present in both sources (“Both”), only in ClinicalTrials.gov (“CTG only”), or only in TrialsTracker (“TT only”). This variable was used exclusively for data validation, reconciliation, and audit purposes during dataset construction and was not included as an analytic variable in descriptive or inferential models.

The harmonization and classification workflow used to integrate ClinicalTrials.gov and TrialsTracker records is described in Section 3.3.5; Appendix B documents the resulting variable definitions and coding decisions.

Appendix C — Extended Descriptive Interpretation

Table C.1

Epoch Distribution and Interpretive Characterization of Clinical Trial Compliance Context

Epoch	*Count*	*Percent*	*Interpretive Notes*
E1 2007–2016	56,912	54.45%	Represents majority of trials, reflecting the surge of registrations following expansion of ClinicalTrials.gov but preceding meaningful enforcement. Compliance behaviors during this era were largely symbolic, reflecting weak regulative legitimacy.
E2 2017–2019	19,130	18.30%	Marks transitional years of the Final Rule's initial enforcement, indicating gradual institutional adaptation to formalized requirements and incremental strengthening of moral legitimacy expectations.
E3 2020–2024	28,470	27.24%	Reflects renewed acceleration in trial initiations and increasing recognition of transparency obligations following the *Seife* decision and COVID-19–era scrutiny, suggesting growing normalization of compliance as a cognitive legitimacy behavior.

Note: Epochs are defined based on major regulatory milestones associated with FDAAA 801 implementation, the 2017 Final Rule, and the *Seife v. HHS* decision. Percentages reflect the proportion of non-exempt interventional Phase 2–4 trials within each regulatory period (N = 104,512).

Appendix D – Supplementary Statistical Tests

Appendix D presents the full contingency tables and inferential statistics supporting the Epoch × on-time reporting analysis summarized in Chapter 4. Specifically, this appendix reports the cross-tabulation of regulatory epoch by clinical trial results-reporting compliance, along with Pearson chi-square and likelihood ratio test statistics.

These supplementary results supply the statistical foundation for evaluating differences in compliance proportions across regulatory periods and substantiate the hypothesis testing and interpretive conclusions discussed in the main text.

Table D.1

Epoch × Compliance Analysis

Epoch	*Count (0 = Noncompliant)*	*Count (1 = Compliant)*	*Row % Compliant*
E1_2007_2016	54,133	2,779	4.88%
E2_2017_2019	18,209	921	4.81%
E3_2020_2024	27,908	562	1.97%
All	100,250	4,262	4.08%

Note: Cell entries report observed counts with row percentages in parentheses.
CTG_Compliant_TF = 1 indicates results posted within the legally required reporting window.

Table D.2

Cross-Tabulation of Regulatory Epoch by Results Reporting Compliance (CTGCompliantTF)

Tabulated Statistics: Epoch, CTGCompliantTF

Rows: Epoch Columns: CTGCompliantTF

	0	1	All
E1_2007_2016	54133	2779	56912
	95.12	4.88	100.00
E2_2017_2019	18209	921	19130
	95.19	4.81	100.00
E3_2020_2024	27908	562	28470
	98.03	1.97	100.00
All	100250	4262	104512
	95.92	4.08	100.00

Cell Contents
Count
% of Row

Chi-Square Test

	Chi-Square	DF	P-Value
Pearson	442.988	2	0.000
Likelihood Ratio	509.531	2	0.000

Note: Table D.2 reports observed counts and row percentages of compliant and non-compliant trials across regulatory epochs. Pearson $\chi^2(2) = 442.99$, $p < .001$; Likelihood Ratio $\chi^2(2) = 509.53$, $p < .001$.

Vita

Jeanie Magdalena Gatewood was born and raised in New York and currently resides in North Carolina. She is the Principal of Gatewood Global, a clinical research advisory firm, and a healthcare strategist specializing in oncology research, clinical trial operations, and the integration of emerging technologies within regulated environments.

Mrs. Gatewood earned her Doctor of Business Administration from Drexel University's LeBow College of Business. She also holds a Master of Business Administration from Long Island University, a Bachelor of Science in Health Administration from St. Joseph's College, and an Associate of Science in Nursing from the University of the State of New York. Jeanie has completed executive professional coaching certifications through New York University.

With more than two decades of experience in healthcare, technology transformation, and clinical research leadership, Jeanie has held executive and director-level roles at Parexel (TMAC), IQVIA (Inteliquet), Fox Chase Cancer Center (Temple Health), NYU Langone Medical Center, and AstraZeneca's Aptium division. She has led enterprise modernization and post-acquisition integration across academic medical centers and global biopharmaceuticals, and has supported First-in-Human cellular therapy programs. Mrs. Gatewood advises investors and healthcare technology organizations as an GLG Network Expert Member.

Jeanie's scholarly work examines transparency, and institutional legitimacy in clinical trial reporting, with emphasis on governance and regulatory change. Mrs. Gatewood has authored and presented more than seventy scholarly and professional works in national and international forums. Grounded in both clinical practice and executive leadership, Her professional path reflects a sustained commitment to accountability, equity, and service—values shaped by her upbringing and strengthened through the support of her family.

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