

Uncertainty-Certainty Matrix for Differential Monitoring Studies

Richard Fiene PhD

Penn State Prevention Research Center

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The purpose of this research abstract is to explore the possibility of utilizing the Uncertainty-Certainty Matrix (UCM) not only in validation and reliability studies in licensing decision making but also with differential monitoring studies. The UCM has been proposed for use in licensing decision making but this would be an extension of this thinking to studies that involve validating licensing decisions such as when key indicators are used in comparison with comprehensive reviews of rules, and in the development of risk rules as part of the risk assessment methodology. This new Differential Monitoring 2x2 Matrix can also be used to depict the relationship between full and substantial regulatory compliance and the nature of rulemaking.

The basic premise of the DMM: Differential Monitoring Matrix is similar to the original thinking with the UCM but there are some changes in the formatting of the various cells in the matrix (see Table 1). When it comes to regulatory compliance decision making a 2 x 2 matrix can be drawn with the possible outcomes as is indicated in Table 1 where each individual rule is either in (+) or out (-) of compliance. Also, there is the introduction of a high regulatory compliant group (+) and a low regulatory compliant group (-) which is different from the original UCM.

Table 1

DMM Matrix	High Group (+)	Low Group (-)
(+) Rule is In Compliance	(++)	(+-)
(-) Rule is Not In Compliance	(-+)	(--)

By utilizing the format of Table 1, several key components of differential monitoring can be highlighted, such as key indicators and risk assessment rules, as well as the relationship between full and substantial regulatory compliance.

Regulatory compliance is grouped into a high group (+), generally this means that there is either full or substantial regulatory compliance with all rules. The low group (-) usually has

10 or more regulatory compliance violations. Individual rules being in (+) or out (-) of regulatory compliance is self-explanatory.

Tables 2-8 below will demonstrate the following relationships:

Table 2 depicts the key indicator relationship between individual rules and the high/low groups as indicated in red. In this table, the individual rule is in compliance with the high group and is out of compliance with the low group. This result occurs on a very general basis and should have a .50 coefficient or higher with a p value of less than .0001.

Table 3 depicts what most rules look like in the 2x2 DMM. Most rules are always in full compliance since they are standards for basic health and safety for individuals. This is especially the case with rules that have been weighted as high-risk rules. Generally, one never sees non-compliance with these rules. There will be a substantial number of false positives (+-) found with high-risk rules but that is a good thing.

Table 4 depicts what happens when full compliance is used as the only criterion for the high group. Notice that the cell right below (++) is eliminated (-+). This is highly recommended since it eliminates false negatives (-+) from occurring in the high group. As will be seen in Table 5, when substantial compliance is used as part of the high group sorting, false negatives are re-introduced. If possible, this should be avoided, however in some cases because of the regulatory compliance data distribution it is not always possible where not enough full compliant programs are present.

Table 5 depicts what occurs when substantial compliance is used as part of determining the high group. False negatives can be reintroduced into the matrix which needs to be either eliminated or reduced as best as possible. If substantial compliance needs to be used in determining the high group, then there is a mathematical adjustment that can be made which will impact the equation and essentially eliminate false negatives mathematically (see the research note at the end of this research abstract).

Table 6 depicts what happens if the individual rule is particularly difficult to comply with. Both the high performers as well as the low performers are out of compliance with the rule.

Table 7 depicts a situation where the programs are predominantly in a low group with few at full or substantial regulatory compliance which is indicative of poor performing programs. Very honestly, this is generally not seen in the research literature, but it is a possibility and one to be in tune with.

Table 8 depicts a terrible individual rule which predicts just the opposite of what we are trying to do with programs. Obviously, this rule would need to be rewritten so that it fits with the essence of regulatory compliance in helping to protect individuals.

The following tables 2-8 will depict the above relationships with results highlighted in red:

Table 2

Key Indicators	High Group (+)	Low Group (-)
(+) Rule is In Compliance	(++)	(+-)
(-) Rule is Not In Compliance	(-+)	(--)

Table 3

Risk Rules	High Group (+)	Low Group (-)
(+) Rule is In Compliance	(++)	(+-)
(-) Rule is Not In Compliance	(-+)	(--)

Table 4

Full Compliance	High Group (+)	Low Group (-)
(+) Rule is In Compliance	(++)	(+-)
(-) Rule is Not In Compliance		(--)

Table 5

Substantial Compliance	High Group (+)	Low Group (-)
(+) Rule is In Compliance	(++)	(+-)
(-) Rule is Not In Compliance	(-+)	(--)

Table 6

DMM Matrix	High Group (+)	Low Group (-)
(+) Rule is In Compliance	(++)	(+-)
(-) Rule is Not In Compliance	(-+)	(--)

Table 7

DMM Matrix	High Group (+)	Low Group (-)
(+) Rule is In Compliance	(++)	(+-)
(-) Rule is Not In Compliance	(-+)	(--)

Table 8

DMM Matrix	High Group (+)	Low Group (-)
(+) Rule is In Compliance	(++)	(+-)
(-) Rule is Not In Compliance	(-+)	(--)

Tables 2 – 8 demonstrate the different results based on the relationship between individual regulatory compliance and if a program is either a high performer or a low performer. These tables are provided as guidance for understanding the essence of differential monitoring and regulatory compliance which has various nuances when it comes to data distributions. This research abstract hopefully can be used as a guide in determining from a data utilization point of view how to make important regulatory compliance policy decisions, such as: which rules are excellent key indicator rules, which are performing as high risk rules, importance of full compliance, what to do when substantial compliance needs to be employed, are there difficult rules to comply with, how well are our programs performing, and do we have less than optimal rules that are in need of revision.

Research Note:

Over the past decade in doing research on the Regulatory Compliance Key Indicator Metric (RCKIm) it has become very clear that false negatives needed to be controlled for because of their potential to increase morbidity and mortality. When dealing with regulatory compliance and full compliance as the threshold for the high grouping variable in the 2 x 2 Regulatory Compliance Key Indicator Matrix (RCKIm)(see matrix below), false negatives could be either eliminated or reduced to the point of no concern.

However, in the event that substantial compliance rather than full compliance is used as the thresh old for the high grouping variable in the 2 x 2 Regulatory Compliance Key Indicator Matrix (RCKIm) this becomes a problem again. There is the need to introduce a weighting factor. In utilizing the RCKIm, the following equation/algorithm is used to produce the Fiene Coefficient (FC):

$$FC = ((A)(D)) - ((B)(C)) / \text{sqrt}(WXYZ)$$

This RCKIm needs to be revised/updated to the following in order to take into account the need to again eliminate false negatives being generated by the results of the

equation/algorithm; this can be accomplished by cubing B:

$$FC^* = ((A)(D)) - ((B^3)(C)) / \text{sqrt}(WXYZ)$$

By this simple adjustment to cube (B = False Negatives) it will basically eliminate the use of any results in which a false negative occurs when substantial compliance is determined. The table below displays the variables of the Regulatory Compliance Key Indicator Matrix (RCKIm).

RCKIm	High RC Group	RC Low Group	
KI In Compliance	A	B ³	Y
KI Violations	C	D	Z
Totals	W	X	

In the above examples, FC can be used when the High RC Group is at full regulatory compliance, but FC* needs to be used when the High RC Group is including substantial as well as full regulatory compliance. By using both equations/algorithms, it better deals with the results of the Regulatory Compliance Theory of Diminishing Returns.

The results should clearly show that only positive (+) coefficients will become Regulatory Compliance Key Indicators versus those rules that do not show any relationship to overall regulatory compliance (0), but now the negative (-) coefficients will more clearly show when any false negatives appear and clearly not include them as Regulatory Compliance Key Indicators. This is a major improvement in the Regulatory Compliance Key Indicator methodology which clearly demonstrates the differences in the results. It provides a gateway in those regulatory compliance data distributions where substantial regulatory compliance is heavily present while full regulatory compliance is not. This could become a problem as the regulatory science field moves forward with the use of the Regulatory Compliance Theory of Diminishing Returns.