The Holy Grail of Regulatory Science: Identifying the "Right Rules"

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Regulatory science has made tremendous strides in the past 20-30 years in developing as a science. This has been particularly evident in the pharmaceutical area led by the industry and the FDA. The focus on establishing the science and clinical trials has been very robust. However, there has been one area where it has been difficult to ascertain within regulatory compliance the identification of specific rules/regulations that may be having a differential positive impact on outcomes for clients from a safety and quality perspective.

However, if we look to other industries that are equally regulated, such as the human services, there has been a great deal of experimentation with doing just that, finding if there are rules that have a differential positive impact on outcomes for clients, in other words, identifying the "Right Rules" or as the title implies, the "Holy Grail of Regulatory Science". Regulatory science is about rules and regulations and determining how well they improve overall safety and quality of products produced or services provided. This can be any type of product or service in any industry. Rules are everywhere. We are not just talking about drugs and medical devices although these have led the way in the regulatory science arena. There are rules for banking, finance, transportation, restaurants, power plants, child care centers, personal care homes, assisted living, hospitals, etc., the list goes on and on.

The area that needs to be looked at a bit more closely to see if some of the methodologies and metrics developed there have broader applicability is the human services arena, in particular early care and education. There does not appear to be a similar avenue of inquiry in the other industries but they may be able to learn from the latest developments in the human services and early care and education/child care. The specific methodologies or metrics being referred to are the risk assessment and key indicator methodologies being developed in order to determine overall safety and quality concerns for children in early care and education settings. Risk assessment is what its name suggests, rules that place clients at increased risk of mortality or morbidity. Key indicators are rules that statistically predict overall regulatory compliance and quality.

When risk assessment and key indicators are used in tandem, the resultant approach points us in the direction of attempting to find the "right rules" that both statistically predict overall safety and quality while also protecting clients at the same time. This is exactly what regulatory science is all about. These two methodologies and the resultant differential monitoring approach

puts us on a trajectory of the most cost effective and efficient way of achieving the goal of regulatory science or as the title suggests, "The Holy Grail" of regulatory science.

The regulatory science field has had great success via clinical trials to find what drugs and medical devices are safe and improve the overall quality of life for patients. Could the above approach help to improve on these initial successes to produce even better results related to the specific rules that need additional emphasis and selection while others may eventually fall away? This will take a good deal of experimentation to see if these methodologies and approach from the human services has more broad-based applicability or not.

Why search for the "right rules"? Why not just look at the rules in the aggregate? Because of the theory of regulatory compliance and the ceiling or diminishing returns effect where substantial regulatory compliance is significantly more effective when compared with quality than full regulatory compliance. So, it makes sense to identify individual rules which may have an increased differential positive impact on client outcomes. It appears that there is a non-linear relationship between regulatory compliance and quality but there still remains a linear relationship between regulatory compliance and safety. This is an interesting dual relationship when it comes to regulatory compliance. At least this is what has been found in the human services, in particular, early care and education. The question for the future is: Does it apply to other regulatory science arenas, such as: banking, financing, pharmaceuticals, etc. Are there specific rules related to these industries that have an increased differential positive impact on client outcomes? What are the "right rules" for these industries, the regulatory science "Holy Grail"?!

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If the above risk assessment and key indicator methodologies are of interest, please check out the following website (Research Institute for Key Indicators Data Laboratory associated with the Penn State Prevention Research Center (link is listed below)) for additional information and details on how to use the methodologies. The methodologies are open course and in the public domain in the best interests of open science.

https://rikinstitute.com

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