

Clinical Governance & Oversight: what is the challenge?

OVERSIGHT ISN'T ALWAYS FUN. BUT THIS IS KEY FOR YOUR PROJECTS AND STUDIES. YOU ARE AWARE OF THIS PART, OF COURSE

There is no glory in oversight and governance. There is no virtual reality to immerse. There are no dazzling 3D images. There is nothing that makes people: "That is very interesting and cool!"

Instead, governance is decidedly un-attractive. It is tedious. It is painstaking diligence. It is an ethical review. It is checking, double checking and checking one more time for good measure. It is an exercise in patience that challenges even the most "detailed" people. It is a seemingly endless chore.

It is also the most important enterprise strategy in drug development. Given the enormous amount of work involved with oversight, governance and project management, it's no wonder cross-functional teams bring this to table for discussions. But its proponents — most notably that who have succeeded with it — insist that the end result is worth the tremendous effort.

It is amazing how much data embedded within each department / function. There are 100s of data points relevant to the concerns about each area even though there are about 1000s of data points out there.

Governance is key to breaking through the stubbornly siloed culture of some of the organizations.

Data as a strategic asset

Governance is the vessel that organizations can use to take the necessary steps in transforming data into actionable, enterprise-wide insights while ensuring regulatory compliance and patient safety.

Companies still haven't embraced the true value of governance. There is better awareness of governance, but it is still in an infantile state. People are exhausted from putting so much effort into the data that they haven't progressed beyond that point. Life science companies need to recognize data as a strategic asset instead of a byproduct of the IT system.

Corporations are recognizing the importance of governance through formation of committees designed to work as think tanks for devising an analytics strategy. But they have been reticent to take the necessary next steps.

The committees think they are addressing governance, but there are multiple challenges with that because it is not a true governance process – it's a reporting piece that ends up being an IT system project and not an organizational strategy. Organizations need to wrap their heads and hands around the data value chain – how data is acquired, how it is aggregated and put into a version of truth.

'One source of truth'

Deeply immersing in data and information governance is as daunting a task as it is, not doing anything about the flood of data may be more damaging. There is so much data, we need to channel it in a way people don't feel bottlenecked by the centralization of the data. We need to make it accessible and balancing access with the governance of data that is consistent and accurate is a constant challenge

Creating just teams or committees may not suffice and needs to be backed by a robust IT platform. It can be a hard sell to certain groups and aim to try not to let people bypass the process. Ultimately your goal is to have a successful centralized place to access data that has been scrubbed, with numerators and denominators appropriately defined and that people who use the information will trust it for clinical and business decisions.

Uncovering un-attractive

Governance is an arduous process that requires a lot of heavy lifting in the form of diligence by an organization's brain trust and workforce. It is deeply introspective, exhaustive and laborious. It is decidedly unglamorous.

Sometimes the data is correct but the information is wrong. When it comes to governance, it is actually happening in many healthcares, just not on an overarching basis. Most times it seems like the analysis of governance is myopically on visualization, as if it was a beauty contest. But that is like grading a restaurant based on presentation and not the food quality.

The un-attractiveness also extends hardest part of the governance process – taking ugly definitions of data and mapping them to business-friendly terms. Giving the business user a nice view of the data is critical, but it doesn't obviate the 'garbage-in, garbage-out' scenario.

As the pharma business model shifts to being paid by value, not volume, companies need to alter their thinking about the maze data travels through the enterprise and taking steps to streamline it.

'Implied obligation' to patients

There is still a long way to go across the industry with understanding, acceptance and adoption of governance. Organizations know it is needed, but they are under pressure from different initiatives and don't always realize that governance can assist across the organization in many ways.

Ultimately, information governance initiatives are going to increase patient safety and quality of care through the ability to share trusted, reliable, accurate information with patients, clinicians, and securely to the community increasing the health of populations ultimately

Don't 'boil the ocean'

Most organizations are trying to boil the ocean, aggregating all data sources, trying to cleanse the data along the way. All this to have the value drop due to the time lag in getting the heavy lifting done before a business team member can gain value from it.

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