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Effective Design and Implementation of Sponsor/CRO Governance — Reducing Risk While Enhancing Transparency

Governance board meetings have always been an important venue to ensure quality and maintain a healthy and productive relationship between sponsors and CROs. As the demands of the clinical research industry continue to evolve with a pandemic now amongst us, the need for effective program governance is more important than ever.

Like any good governance process, these structured executive committees become a part of the fabric of communication and decision making between sponsors and CROs. The cadence of meetings are about more than status updates — they are an opportunity for leaders from sponsor and CRO to work together to ensure the strategic priorities of both organizations are clearly defined and communicated and to identify gaps between strategic intent and operational execution.

Effective governance also serves as a place to proactively define risk strategies, including where to make trade-offs, how to identify and manage risks, raise visibility and action to ensure risk minimization, and agree upon the systems to be implemented for prompt and appropriate response.

These meetings serve as more than a governance infrastructure for a clinical trial. They are intended to serve as a foundation for both organizations to establish transparency and trust, which allows them to make more informed decisions to deliver the best possible outcomes and to protect each other's business.

Transparency is always critical for effective clinical trial management. During the current pandemic, transparency and communication have proven to be critical in enabling fast decision making and clear documentation.

Moving Forward Together

Since the COVID-19 pandemic began, leaders at Advanced Clinical have participated in multiple governance board meetings with clients who are facing tough choices for their trials. Like many sponsors, some of their sites are temporarily closed due to shelter-in-place rules, patients are delaying or cancelling visits, and site staff are navigating their way through remote site monitoring until lock-down orders cease.

In each of these governance meetings, which now occur via videoconference, we've had to determine if and what changes must be made to protect the safety of patients, how and whether the trial is in any immediate risk, and whether any of these risks and response strategies impact the projected outcome of the trial.

As a unified governance board, our goal is always to help sponsors rapidly identify and implement appropriate response plans to mitigate the delays while maintaining patient safety and data integrity. During this current pandemic, this could not hold more truth.

These are difficult decisions to make. Every delay in bringing a drug to market can translate into missed opportunities for patients to access life-saving drugs and millions of dollars in lost revenue. And for some organizations, the impact of the pandemic directly challenges their strategic goals. If a treatment's value potential is based on its ability to be first to market, or to capture a certain patient population before a competing drug is approved, these delays are forcing sponsors reexamine their decisions to continue, their pipeline priorities, and to rethink future market opportunities.

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For some trials, such as those that involve elective procedures, it means temporarily pausing study activities. In these cases, we are helping them connect with potential subjects, and schedule future visits based on projected site openings so they are ready to ramp-up once restrictions are lifted.

In other trials, we are helping our sponsors rapidly adopt telemedicine, remote monitoring, and virtual recruiting models. In these cases, we've been able to leverage our COVID-19 risk mitigation plan, which is based on Transcelerate's Risk-Based Monitoring Initiative, and our pre-defined remote monitoring SOP.

Melissa Mauriber
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None of these decisions have been easy. They require sponsors and sites to change the way they operate, to re-evaluate trial plans and timelines, and to adapt to regulatory guidance documents that have shifted frequently.

The trust and transparency we have successfully built through months of prior governance meetings allows us to make informed decisions with confidence.

As we move forward through this pandemic, we encourage sponsors to take advantage of the value of joint governance boards. While it may be easy to delay these meetings when there are more "urgent" issues to tackle, the only way to shift out of fire-fighting mode is to build a communication infrastructure, establish mutual goals, develop a risk response plan, implement the plan, and begin monitoring results. Leveraging the collective expertise of the governance board and the established mission can be the best way forward through any challenge in clinical research. PV

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