Considerations for Clinical Trial Transparency and Disclosure in Mergers and Acquisitions

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In today's biopharmaceutical landscape, mergers and acquisitions (M&A) are a common strategic tool for growth, portfolio expansion, and pipeline optimization. But while business objectives often dominate the dialogue, one important area of clinical development that is frequently under-prioritized is clinical trial transparency and disclosure (CTT). Whether inheriting ongoing trials from another sponsor or transferring your own studies to a new entity, ensuring compliance and continuity in clinical trial transparency is not only a global regulatory expectation – it also builds trust with patients, regulators, and the public. From study registration to data sharing and patient communication, CTT obligations extend beyond regulatory compliance. A proactive, organized approach is essential to avoid reputational damage, regulatory noncompliance, or erosion of patient trust.

Clinical Trial Registries: First Impressions Matter

One of the earliest—and most visible—elements of clinical trial transparency is registration on public registries such as ClinicalTrials.gov, EU CTIS, and other national platforms. When M&A activities involve inheriting trials or transferring sponsorship, the new sponsor must ensure compliance with registration standards and their individual sponsor commitments. Some considerations include:

- Ensure easy to understand protocol information – such as Inclusion/exclusion criteria, study objectives, and brief title – reflecting plain language principles.
- Publication of secondary outcome measures prespecified in the protocol.
- Protecting commercially sensitive information – such as exploratory endpoints and dosing information.

These elements not only ensure regulatory compliance but also represent your organization's commitment to patient-centric communication and scientific integrity.

Results Disclosure: Timeliness, Completeness, and Consent

Timely results disclosure is a critical regulatory requirement. Delays or incomplete submissions—especially post-acquisition—signal poor governance and can trigger penalties. There must be clear agreement on who will publish what information, and when.

Does the acquiring or transferring sponsor have the clinical data needed to publish structured results completely and within mandated timelines?

- Incomplete data transfer during an M&A event can lead to *unintentional noncompliance*.

Moreover, commitments made in the informed consent form (ICF) around patient communications—such as creating and sharing plain language summaries (PLS)—must be honored and clearly addressed:

- Will the new sponsor honor existing communication commitments?
    - If not, is there a communication plan to inform patients of the change in policy?
- How will PLS documents be made available to participants?
    - Will patients from the study know how to find the PLS after the study is transferred to a new sponsor?

Organizations need a consistent ethical framework for deciding when and how to notify participants of any deviations from the ICFs and prior transparency promises.

Data Sharing: Aligning Policies and Protecting Privacy

Post-acquisition clinical trial portfolios frequently raise complex data sharing questions. Were commitments made to share data with researchers, or is this only a potential in the future? In either case, teams must:

- Ensure a thorough transfer of all datasets and metadata.
- Confirm whether any data sets have already been anonymized and published for sharing. If so, continuity must be preserved to ensure privacy is maintained for patients involved in the study.
- Review ICFs to confirm whether data sharing was permitted by participants. If not, ethical review or policy adjustments may be needed.

Ensure the new sponsor has the data and documents to complete anonymization to meet all global regulatory data-sharing initiatives such as EMA Policy 0070 and Health Canada's PRCI. If a product submission has already occurred, but document publication is upcoming or ongoing, who will be responsible for completing this work?

These complexities require close coordination with clinical, legal, and data privacy teams. Inadequately addressing anonymization and data-sharing obligations can damage scientific collaborations or breach ethical obligations.

Proactive Planning: The Case for a CTT M&A Checklist

Given the breadth and depth of clinical trial transparency and disclosure responsibilities, it is recommended to operationalize a formal checklist or process as part of the M&A due diligence and integration process. A Clinical Trial Transparency (CTT) M&A checklist should include:

- Verification of registration status, content accuracy, and outcome completeness
- Confirmation of result posting timelines and data readiness
- Review of ICF commitments to patients on communication and data use
- Plan for future patient communications around transparency
- Assessment of historic and future data sharing practices and documentation readiness
- Identification of systems, stakeholders, and processes used by both entities
- Agreement on timelines and responsibilities to meet all CTT compliance and commitments

M&A teams should be engaged proactively to ensure CTT is not an afterthought—avoiding scenarios where the new sponsor is unable to meet regulatory requirements or uphold ethical CTT commitments.

Final Thoughts

Clinical trial transparency should not be a post-deal cleanup exercise—it should be a strategic and ethical imperative that is part of the M&A planning process. Whether transitioning your studies to a new sponsor or inheriting clinical trials as part of a portfolio acquisition, advance planning can safeguard regulatory compliance, scientific integrity, and patient trust. A structured approach with a dedicated transparency checklist provides the foundation for managing risk and upholding the commitments made not just to regulators, but to trial participants and the broader scientific community.