Every Sponsor's Top 10 Checklist for Selecting a CRO

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The due diligence and selection process of a CRO partner may seem daunting to start-up and mid-size life science companies with limited funds. Despite their size, smaller to mid-size companies are responsible for many of the groundbreaking innovations that currently address the otherwise unmet medical needs and improved outcomes of patients across the globe.

An international spotlight has recently been cast on one of the biggest-named CROs and the company's potential for public, financial reporting irregularities. Many veterans in the life science industry have stories to tell of how the relationship between the Sponsor and their CRO disintegrated before their eyes. Some experiences are more extreme than others. Most are a result of poor communication and accountability.

The angst that a failing CRO partnership produces for Sponsors and other current stakeholders, investors, and employees cannot be easily ignored. The viability and preparedness of a CRO to be selected as the vendor of choice is especially difficult to predict unless the Sponsor takes a holistic, objective approach, e.g., "no stone unturned," to their decision making and due diligence. Removing inherent biases like, "bigger is better" or "the cheapest price wins," is a must.

The damage of selecting a CRO poorly can hurt a Sponsor for years. The time lost developing a needed therapy, the resources spent that will not be recovered, and the reputation of the Sponsor are all at stake. And, these losses do not include the litigious avenues various parties pursue in an effort to remedy such irreparable harm.

We help our clients choose a CRO that is the best match for their needs and avoid buyers' remorse or the dissolution of the Sponsor-CRO partnership. To help Sponsors, we have compiled a brief Top 10 Checklist that can serve as a valuable guide when performing due diligence and selection processes for CRO partners. While there is no one-size fits all approach, this Top 10 Checklist is a helpful starting point that can be further expanded as necessary to help Sponsors de-risk the objectives of conducting a successful clinical trial.

Top 10 Checklist for Selecting a CRO

We also recommend that Sponsors use this Top 10 Checklist when developing a solid RFP for the purpose of evaluating potential CRO partners.

Expertise

A Sponsor's prospective CRO partner should have:

- Experienced teams with the subject disease and/or indication
- Experience in study phase
- A board-certified physician on the team
- Capabilities that cover the specific trial needs
- Experienced business development staff who communicate effectively and substantively
- A consultative, value-added, and transformational approach as true experts
- Regulatory experience with the entire clinical development and market approval process
- US ownership and experience with federally funded research (NIH, DoD, or other)

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Going Concern

A Sponsor's prospective CRO partner should have:

- The ability to release recent independent financial statements by a CPA firm for financial stability and long-term viability

Quality— Audits and Inspections

A Sponsor's prospective CRO partner should have:

- Consistently high quality, with no critical or limited major findings in audits and inspections
- A strong Quality Management System (QMS)
- Proven integration of ICH GCP E6R2 and/or ISO 14155
- Record of performing due diligence and audits of vendors

Flexibility

A Sponsor's prospective CRO partner should have:

- Routinely demonstrate a partial, functional, or full-service model for requirements defined by the Sponsor
- Utilize effective lines of communication
- Provide coverage of service lines in time zone of the Sponsor
- Be a fluid extension of the Sponsor's team

Cost

A Sponsor's prospective CRO partner should have:

- Transparency into pricing practices, exchange rates, and rate cards of staff
- A thorough explanation of service costs
- A detailed definition of pass-through costs
- An outline of their use of mark-ups
- A detailed travel policy and reimbursement procedure
- Language, in both their proposal and contract, that ensures the continuity of costs, and no surprises
- Descriptions of work that cause change orders

Compliance

A Sponsor's prospective CRO partner should have:

- A strong record of documented compliance with HIPAA, HITECH, the Privacy Rule, GDPR, and any other applicable law and regulation concerning data privacy and patient confidentiality
- Documented high cybersecurity standards
- A sound ethics program, for both research ethics and business ethics
- Errors, omissions, product liability insurance
- Part 11 compliance
- Compliance, when applicable, to 45 CFR 46, 21 CFR 320, and 21 CFR 820

Training and Education

A Sponsor's prospective CRO partner should have:

- Proof of ongoing continuous quality improvement (CQI) training programs and content for all staff

Turnover

A Sponsor's prospective CRO partner should have:

- Documented attrition rates
- Proof of relevant and specific hiring, training, retention, and advancement plans for all staff

Innovation

A Sponsor's prospective CRO partner should have:

- Intelligent solutions that incorporate current thinking of regulators to develop smarter, more efficient clinical trials
- Best-in-class technology and e-platform solutions that are Part 11-compliant
- Documented methods for streamlining patient recruitment, participation, drug compliance, and retention
- A strong track record of patient advocacy

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References

A Sponsor's prospective CRO partner should have:

- A mandatory minimum of three (3) references from life science executives or decision makers (not vendors) who can attest to successful collaboration of the Sponsor-CRO partnership

The Key Takeaway

The bottom line is that, as a Sponsor, the CRO should be viewed as an extension of you – your standards, your values, your behaviors, and your reputation. A Sponsor's business hinges on the successful execution of its research and development enterprise – its ability to help patients – and a successful CRO partnership is a key component of that success.

If you need assistance realizing your success with a CRO, please contact us.

About the Authors

Concetta Dudley, JD, MBE *is an experienced CCEP-certified attorney, business adviser and ethicist, with particular expertise with emerging companies, life science start-ups, technology development, research & bioethics, cultural competency, corporate compliance, and conflict management. Ms. Dudley is an attorney who has recently served as a fractional General Counsel for Inspirion Biosciences, a biorisk management company based in Frederick, MD. She also consults for and advises US and international organizations on business growth and technology commercialization. She mentors young and emerging companies, and trains new scientists in the areas of technology transfer and commercialization, biotechnology law and ethics, where she serves as a member of the Graduate Faculty at the Johns Hopkins University and University of Maryland Baltimore County. Learn more by connecting with her on LinkedIn, and by visiting her website at DudleyLegal.com.*

Alethea Wieland *is Founder and President of Clinical Research Strategies, LLC, an executive-level management consulting firm and contract research organization for the life science industry established in 2011. Her focus is on offering agile, flexible staffing models for clinical trial resourcing; training and managing resilient, high-performing clinical operations teams; and, mitigating risks of clinical trials by facilitating the best Sponsor-CRO partnerships who practice accountability, compliance, and transparency. She is an advocate of strong contractual arrangements, and frequently meeting with regulators and numerous stakeholders which results in a win-win mindset. She volunteers her time judging university pitch competitions and hackathons and produces content for her training academy. Learn more by connecting with her in LinkedIn, and by visiting her website, ClinicalResearchStrategies.com.*

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