

From Transactional to Translational: Bridging the Bench to Bedside Gap

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An Evolution in Sponsor CRO Relationships

In its genesis CRO and sponsor relationships were built around single points of contact, an overflow and capacity based business model with a “feast versus famine” business cycle and a transactional exchange of services. Circumscribed business engagements created environments that fostered discrete service requests, generic proposals and creation of CRO capabilities otherwise not available within sponsoring organizations.

However, permissive science resulted in innovative technology, and the targeting of refined patient phenotypes within unique indications demanding a transformation in reciprocal exchanges between sponsor and CRO. Current interactions therefore are more nuanced, strategic, appropriately characterized more frequently as a partnership rather than a transaction. In most respects, the CRO/sponsor relationship has evolved since its inception in much the same way as the science it has fostered.

Current CROs manage multiple contact points within and external to sponsoring organizations and provide services supporting pipeline and inflection points tailored to those objectives.

The globalization of clinical research also necessitates an operational footprint exploiting development opportunities existing internationally. Previously characterized as niche, differentiated activities now define the value of CRO contributions even when discrete services are requested—creating a bridge from bench to bedside, and transforming a transactional based relationship to a strategic one.

Integrated, Highly Effective Project Teams

The ability to provide and manage “resources” from discovery to commercialization is the modern CRO’s greatest asset. Staff who share experience within the pharmaceutical industry and the CRO space function as one integrated team. Membership and leadership of highly effective project teams evolve during program development to adjudicate the diverse, occasionally conflicting interests of multiple stakeholders dictating product success.

In a complex healthcare environment, the language of exchange also transcends that related to a product’s biological characteristics. Evolving regulatory sentiments and the overarching presence of a diverse audience who dictate formulary



placement and patient access necessitate an additional medium of exchange. Neither orderly, nor fully rational, these conflicting needs for data mandate that a CRO be capable of providing advice as well as services across the continuum of development.

Bridging the gap from discovery to development, from bench to bedside starts with appreciation of drug discovery processes informing a clinical program, especially in earlier phases when few patients, and single points of data inordinately drive decisions for program development. Access to clinical trialists—i.e., individuals steeped in trial methodology—who also have relevant basic research and drug development experience becomes an essential perspective to permit exploitation of product attributes within the initial phases of clinical research.

When proposed indications have few precedents, staff cognizant of evolving regulatory sentiments, with professional knowledge regarding standards of care internationally become invaluable. An ability to scale, create study infrastructure, exploit innovative technology, and create staff retention strategies to assure continuity is essential. Expertise in clinical trial methodology linked to operational acumen are the essential attributes of differentiated CRO services, and integrated highly effective project teams.

Building the Bridge Carefully to Cross it Quickly

Early phase clinical research creates and crosses critical inflection points in product development. Creating a bridge carefully, in order to cross it quickly and efficiently becomes a challenge in translational clinical research. Data derived during animal to man transitions, first in human studies, target engagement and proof of concept studies either greatly enhance the asset, or accelerate its demise. In this environment, “turnkey” clinical operations bereft of real-time scientific and medical oversight by both sponsor and CRO staff are an anathema. The number of patients evaluated is limited, signal detection occurs across multiple assessments (biochemical, physiological, clinical), and the evolving database of product attributes (e.g., safety, exposure, biodisposition) impact the resulting clinical program.

Additionally, acknowledging the adage to “begin with the end in mind,” data in aggregate must begin to speak to an “exit” strategy, a commercialization intent, by creating a platform where the

therapy combined with innovative therapy may have complementary or antagonistic effects requiring characterization before pivotal studies; and treatment sequences modeled in pharma co-economic studies



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value of a product (as opposed to its novelty) can be demonstrated. Combining the attributes of interventional research with a concurrent observational research program creates data points complementing those satisfying scientific and regulatory stakeholders.

For example, acknowledging the need for patient outcomes, not measures shifts patient eligibility and program design into different dimensions; comorbidities and concomitant medications excluded from earlier phase programs emerge as a major drivers of healthcare utilization; available

must be derived from clinical data. In essence, building bridges carefully, to cross inflection points quickly requires data to inform “translation” from development into commercialization.

It’s Chess, Not Checkers

Historical CRO/sponsor relationships can be characterized by an analogy to checkers; it was a predictable, slow, capacity driven business model with rare jumps and primarily transactional exchanges. Modern research and development efforts, in contrast, are closely aligned with chess—intuitive, strategic, and cognizant of multiple downstream events. CRO services must

be commensurate with this new paradigm. Having established processes, tools, infrastructure no longer provide differentiation for a CRO, but essential business attributes. It is the “value added” activity from integrated, highly functional project teams, and a visionary approach to clinical research which is foundational to business relationships. 

