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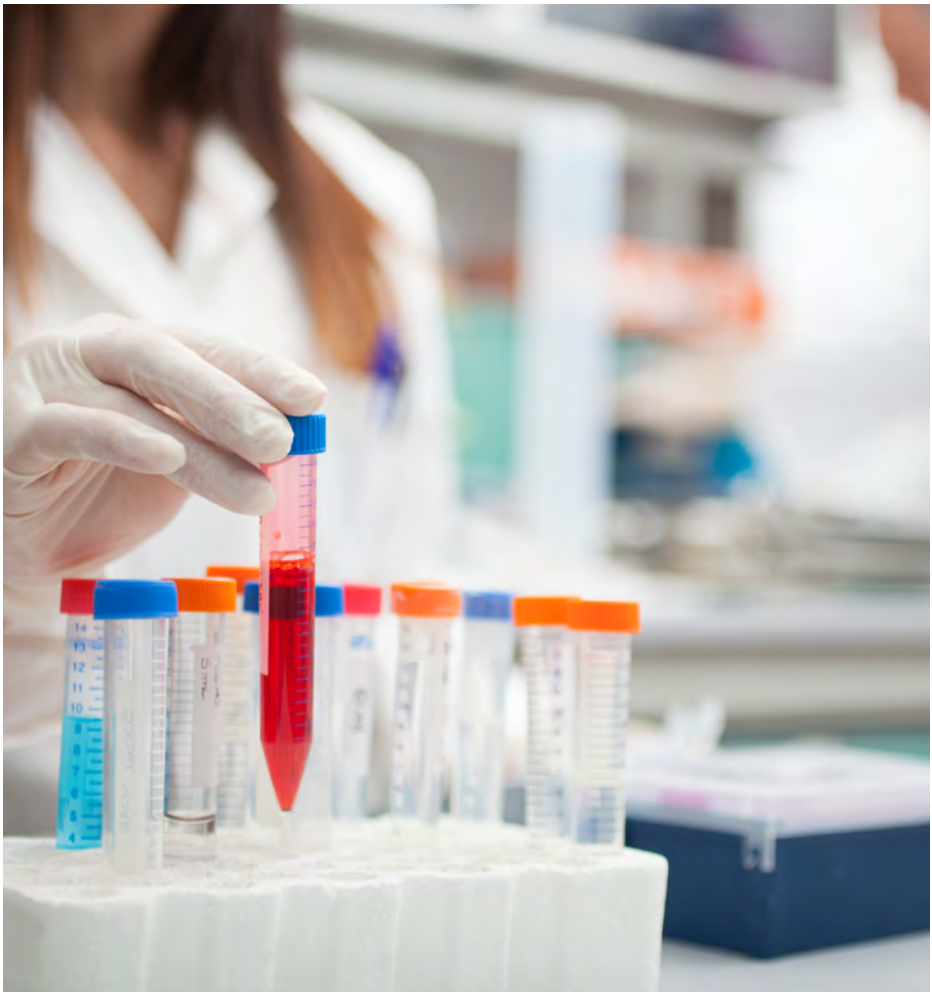
The data science CRO model for outsourcing in clinical trials

Denise Lee, managing director of Metronomia Clinical Research GmbH, discusses the outsourcing challenges of the future.



Data science contract research organizations (CROs) are providers of clinical research services focused on domain expertise, programming skills, and knowledge of mathematics and statistics, to extract meaningful insights from clinical data. In 2012, I introduced a clinical research outsourcing model to our company, which included a data science CRO as a constant partner. Eight years later, I decided to join this data science CRO partner as managing director. This article outlines the reasons for incorporating a data science CRO into a clinical trials outsourcing model and my transition from sponsor to CRO.

In the summer of 2011, after my second maternity leave, I returned to work at a mid-sized, European pharmaceutical company to take on the leadership of clinical operations. At the time, the clinical operations team was miniscule, with 1.6 FTE, all in project management (PM). With a large portfolio of products to be clinically investigated over the next seven years – and a gap in PM resource, data management and biostatistical expertise – it was time to think strategically. A cry for help to the Department of Statistics at Ludwig-Maximilian University led us to Metronomia Clinical Research, a data science CRO in Germany. Rewind to September 2005, when I joined the company to complete two ongoing phase-2 studies managed by two different full-service CROs and to select a further CRO to manage the largest international phase-3 allergy study of the time.

In my 15 years in clinical trial management, and from 2015 to 2020 as global head of clinical operations, I observed a general pattern of cooperation between our mid-sized company and CROs. The forming–storming–norming–performing model of group development introduced by Bruce Tuckman in 1965 helps to describe my experience. Tuckman believed that these phases are necessary and inevitable in order for a team to grow, face up to challenges, tackle problems, find solutions, plan work, and deliver results. Group development in sponsor-CRO teams generally occurs according to Tuckman's model, but with the added challenge presented by differences between the companies in terms of interests, locations, regional and company cultures, pain-points and other aspects.

The forming–storming–norming stages are known collectively as the transforming phase and are followed by performing and reforming phases, in the John Fairhurst TPR model. In new collaborations with CROs, parallels can be drawn between the transforming phase and the honeymoon phase seen in developing personal relationships. Simply put, CROs are eager to please new customers, and to secure these for future projects, and clinical research sponsors are enamoured by the features, scope and promises of the new partner. However, in the performing stage, CROs may find themselves struggling to deliver on promises and meeting sponsor expectations, inevitably leading some customers to fall into a state of disillusionment and potentially to switch CRO partners, foregoing the reforming phase completely. One goal of the reforming phase is to allow the group to look back on the collective experience together, capture best practices or lessons learned for future use, and prepare the group for a further round of transformation, saying goodbye to departing members and optimally integrating new members. Hence, a short or one-off collaboration between sponsor and CRO can often result in a loss of return on investment (ROI).

From this perspective, our ROI from collaborations with CROs was decisively low. It was uncommon for a CRO relationship to extend beyond two trials for outsourced clinical services (e.g., trial feasibility, country and site selection, regulatory submissions, clinical monitoring, and site and vendor management). Perhaps we were "unlucky" to have partnered with CROs that underwent insolvency, mergers and acquisitions, or assimilation into the acquiring companies, which led to unexpected and undesirable changes in teams, services,

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policies and pricing, and significant changes in staffing. In Joelle Herman's article *5 Major Challenges In CRO Outsourcing And How To Overcome Them*, the author states that "sponsor teams are under pressure to deliver results in a fast-paced research environment with resource constraints and operational risks, and the resulting situation can present several operational challenges related to CRO outsourcing", including:

- lack of specificity
- lack of transparency
- long timelines
- generalists versus specialists
- dedicated resources

Confronted with similar operational challenges, and following a series of one-off CRO relationships, a decision was taken to include a data science CRO as a single data centre, responsible for all clinical trial data from all sources and trials. This strategy gave prospect to the standardization, quality, integrity and security of our clinical data, irrespective of the CRO contracted. A data science CRO in our outsourcing model introduced efficiencies and risk-reduction measures we had previously not experienced, the most prominent being:

- Direct access to dedicated data science experts in stable and robust teams with low staff turnover
- Retention of knowledge and expertise acquired in our studies and our therapeutic area
- Development of standard formats, forms and libraries for generation of standardized outputs, reducing study set-up and close-out time, time to submission and costs
- Implementation of risk-based monitoring strategies independent of the clinical CRO for increased transparency of trial status and complimentary to sponsor oversight activities

Since joining Metronomia in 2020, my appreciation for the challenges faced by CROs has grown tremendously. Successful CROs must master the art of managing projects in the dark because no project runs as originally planned and scheduled. Successful CROs need to be equipped with an exceptional troop of contortion artists, bending and stretching themselves to accommodate last-minute changes, with sufficient back-up staff and projects for periods of unforeseen high and low activity, respectively. Finally, a lack of qualified and experienced candidates on the employment market, and the fierce scouting tactics of recruiters luring away staff, are the bitter reality CROs, as well as sponsors, encounter on a day-to-day basis.

My introduction of a data science CRO model of clinical trial outsourcing, and over eight years of successful implementation at my former company – together with my decision to join the very same data science CRO partner as managing director – are testament to the viability of the model for sponsors facing outsourcing challenges now and in the future. ●