



Contract Research Organisation Selection – Important Considerations

As part of our discovery and development series Dr Shailendra Singh CEO at Cellomatics Biosciences provides his insights into the important considerations which must be made when identifying and building partnerships with Contract Research Organisations

Introduction to Author/Expert

Dr Shailendra Singh is the CEO of Cellomatics Biosciences, with extensive experience in translational biology, assay development, and human-relevant disease modelling. His work focuses on bridging early-stage research with clinically meaningful outcomes through well-designed and robust experimental strategies.

1. Framing the CRO's Role in Early Discovery

In early discovery, the primary role of a CRO is to reduce scientific uncertainty, whereas in later stages the focus shifts toward delivering results within structured, regulated frameworks.

At the discovery stage, the science is still evolving. Hypotheses are not yet fully defined, and experimental approaches need to remain flexible. A strong CRO should therefore contribute to shaping the direction of the programme, rather than simply executing experiments.

In contrast, during later development, CROs typically operate within well-defined processes, with an emphasis on consistency, quality, and regulatory compliance.

A common misconception is that CROs can compensate for unclear scientific strategy or poorly defined biology. While CROs can refine and strengthen a programme, they cannot replace a clear hypothesis or decision framework. Similarly, more data does not necessarily lead to better decisions without clear objectives and context.

The most effective CROs identify gaps in study design, suggest improved or alternative approaches where needed, and ensure that experimental outputs are linked to downstream decisions. Less effective CROs tend to execute predefined tasks without challenging assumptions.

Ultimately, the most valuable CROs act as an extension of the sponsor's scientific team, combining technical expertise with critical thinking to support informed decision-making.





2. Defining Technical Needs (Before Selecting a CRO)

A common challenge is not the absence of data, but a lack of clarity around what decisions the data is intended to support. Many programmes begin with loosely defined biology, unclear endpoints, and no explicit success criteria, which can lead to delays and inefficiencies.

Before engaging a CRO, sponsors should clearly define the key scientific question, the therapeutic modality, what constitutes a meaningful result, and how outcomes will inform subsequent decisions. While a fully detailed plan is not required, a clear strategic direction is essential.

When it comes to assay strategy, co-developing the approach with a CRO can be particularly valuable in cases where the biology is complex or novel, where no standard model exists, or where clinical relevance is critical from the outset.

Sponsors should also reflect on key questions such as: What decision will this work support? Are the endpoints meaningful and actionable? What assumptions are being tested? And how will negative results be interpreted?

Clarity at the outset significantly improves the likelihood of successful outcomes.



3. Evaluating Scientific Depth & Capability

When assessing a CRO, it is important to evaluate not only what they do, but how they think. While many CROs can execute experiments efficiently, fewer can meaningfully improve study design, interpret results in context, or provide deeper scientific insight.

Strong CROs typically ask thoughtful and, at times, challenging questions, propose alternative strategies, and clearly communicate the limitations of their methods. In contrast, less effective CROs may align quickly with the requested scope without deeper scientific engagement.

Scientific strength is often reflected in subtle but important ways—for example, through suggestions to refine experiments, openness in discussing risks, and the ability to adapt approaches based on emerging data.

When reviewing track record, sponsors should look for experience in relevant biological systems or disease areas, familiarity with similar technologies, and evidence that data has informed decision-making. It is also important to engage directly with the scientific team who will deliver the work.

Transparency is critical. Access to raw data and clearly defined analysis methods is essential for building confidence in the results.

Ultimately, the objective is to partner with a CRO that supports confident decision-making, not just data generation.



4. Human-Relevant Models & Translational Thinking

Human-relevant models are those that closely reflect human biology and disease mechanisms. This often includes the use of primary human cells within systems such as co-cultures, spheroids, or organoids, combined with clinically meaningful readouts.

One of the key challenges in drug development is the reliance on models that are convenient to run but lack clinical relevance. This can result in data that does not translate effectively to patient outcomes.

When evaluating a CRO, sponsors should ensure there is a clear rationale for model selection, the use of multiple complementary systems to strengthen confidence, and endpoints that are aligned with clinical outcomes.

Advanced models, such as organoids, are particularly valuable when the biology is complex, when deeper mechanistic understanding is required, or when early risk reduction is important. However, simpler models can still be highly effective when applied appropriately and interpreted within their limitations.

It is important to recognise that no model is fully predictive. These systems provide guidance rather than certainty.

To improve translation, sponsors should begin with the intended clinical outcome, select relevant biomarkers, and design studies that assess both efficacy and variability.

Ultimately, successful translation relies on integrating evidence across multiple systems rather than relying on a single model.

5. Improving Translational Success

Most failures occur during the transition from preclinical to clinical stages. The issue is often not the lack of data, but that the data does not adequately predict human outcomes.

Common pitfalls include focusing on easily measurable endpoints rather than meaningful ones, relying on a single model, and overlooking variability. Translational thinking should be embedded from the beginning, rather than treated as a final validation step.

CROs can support this by aligning endpoints with clinical relevance, using multiple models to strengthen confidence, and designing studies that clearly inform decision-making. Rather than asking “does it work?”, **the more relevant question is: “does this increase confidence in clinical success?”**

Effective decision-making requires clear success criteria, integration of data from multiple sources, and stage-appropriate evaluation.

Balancing speed and robustness is essential. A practical approach is to use faster, simpler systems early on, followed by confirmation in more predictive, human-relevant models.

The goal is not simply to generate data, but to build meaningful evidence that supports confident decisions.



6. Designing the CRO–Sponsor Relationship

Successful partnerships are built on shared ownership of the science, with both sponsor and CRO actively contributing to the work.

This requires clearly defined roles, regular scientific discussions, and transparent data sharing. Sponsors should remain engaged throughout, particularly in interpreting results and guiding next steps.

Effective communication is key and typically involves regular meetings, structured milestone reviews, and timely resolution of issues.

Importantly, **unexpected or contradictory results should prompt discussion rather than dismissal, as these often provide valuable insights.**

7. Flexibility, Iteration & Program Evolution

Change is an inherent part of early discovery. Sponsors should therefore work with CROs that can adapt to new data, operate in an iterative manner, and openly communicate limitations.

Strong CROs evolve alongside the science rather than adhering rigidly to initial plans.

To enable efficient and reliable progress, it is important to establish clear decision points, adopt flexible study designs, and maintain robust data tracking systems.

Scope changes are inevitable and should be managed proactively by planning for flexibility, agreeing on change management processes, and maintaining transparency around trade-offs.

CROs suited to early discovery tend to engage in scientific dialogue, prioritise learning, and manage uncertainty effectively, whereas those optimised for fixed protocols are better suited to later-stage work.

Selecting the right CRO therefore depends on aligning their operating model with the needs and stage of the programme.

8. Selecting the Right CRO Partner

Key selection criteria include scientific expertise, the ability to contribute to study design, transparency, high-quality and accessible data, and effective communication.

Specialised CROs often provide deep expertise in specific areas, while integrated CROs offer broader service coverage and convenience.

For complex programmes, a network of specialised CROs can often deliver greater value, provided coordination is managed effectively.

9. Future Outlook

CROs are increasingly evolving from service providers into strategic scientific partners. Sponsors will expect them not only to execute studies, but also to contribute to experimental design, data interpretation, and overall programme strategy.

Emerging technologies will play a significant role in this shift. AI will support experimental design and data analysis, advanced models will improve predictive capability, and automation will enhance speed and consistency. However, **success will continue to depend on high-quality data and strong scientific judgement.**

To future-proof their strategies, sponsors should prioritise partners who demonstrate adaptability, robust data infrastructure, and a collaborative approach.

Flexible, modular partnerships are likely to become more important than rigid, long-term agreements. As drug discovery becomes increasingly complex, data-driven, and collaborative, CRO partnerships must evolve accordingly.



Closing Insight

Translational Focus – Start with the clinic in mind.

If early experiments are not designed with clinical outcomes in mind, there is a risk of generating data that is scientifically interesting but not strategically useful. A strong CRO partner should help anchor the work in translational relevance from the outset.

Collaborative Mindset – Treat your CRO as part of your team.

CRO is an extension of your project team and the quality of collaboration including sharing of ideas and frequent discussions often has a greater impact on success than technical capability alone.



Cellomatic Biosciences is a laboratory-based Contract Research Organisation (CRO) specialised in Oncology, Immuno-oncology, Immunology, Inflammation and Respiratory therapeutic areas.

Based in the UK at Colwick Quays Business Park, Nottingham, our experienced scientific team offers bespoke and innovative preclinical in vitro bioassay services to support our client's drug development programmes. We work with diverse group of global clients including early start-ups, virtual/small to medium sized Biotechnology and Pharmaceutical companies.

Our scientific personnel have expertise in diverse technologies and therapeutic areas. We offer complex cell-based models in the form of monocultures, co-cultures or 3D cultures to replicate in vivo physiology as closely as possible.

Find regulatory consulting partners at
www.pharmaserviceshub.com



**Pharma
Services
Hub**