The Global Biotech Boom

How an industry grew to lead health care innovation and how CROs are adapting to meet their needs.

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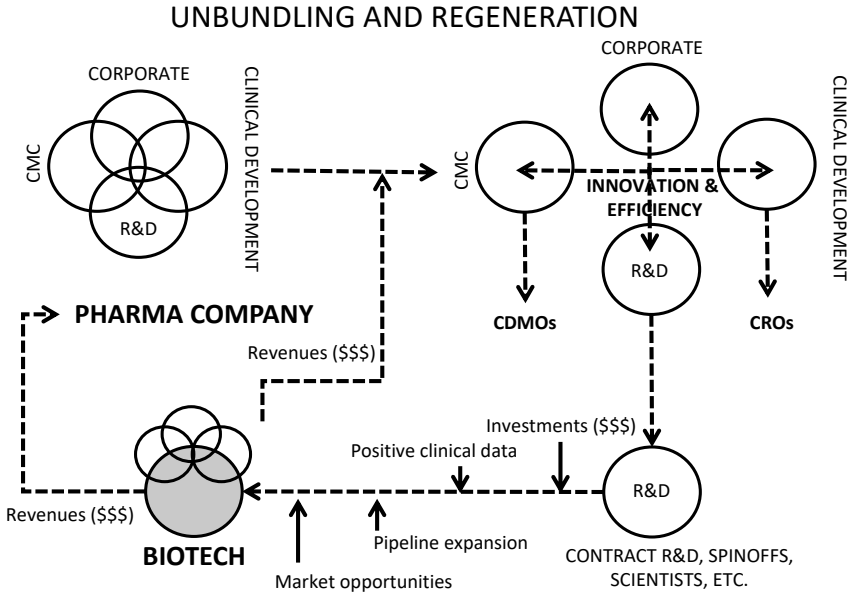
The global paradigm for health care innovation has fundamentally changed. At the turn of the millennium, large pharma companies were the hub for traditional research and development initiatives. Fast-forward 20 years and biotech now is leading this charge with fast-paced innovation—and the associated development risk—to provide the next generation of medicines.

The competition is fierce, speeding up time to market for life-changing therapeutics for patients worldwide. To keep pace with this marked shift to biotech drug development activity, clinical research organizations have created new models and resources to help biotech meet the global demand for innovative new options for patients, such as cell and gene therapies and other technologies.

Outsourced innovation and the birth of biotech

As a result of the millennium R&D crisis, which increased clinical development timelines, competition and associated costs to bring a new medication to the market, pharmaceutical companies had to rethink their R&D strategies. The pharmaceutical industry is resource intensive and characterized by a fierce competition in time to market. The necessity to maintain its profit margin over time despite the increasing costs of drug development led to the birth and growth of a flourishing outsourcing market.

However, even after the initial resizing of its clinical development, the pharmaceutical industry had yet to cope with its R&D, looking for alternative models to increase efficiency, speed and efficacy. Therefore, along with the standard internal R&D model (make), venture capital (VC) departments also were created to scout outside innovation (buy) for partnering and future potential acquisition. This led to the next stage of outsourcing with the birth of contract R&D, the launch pad of the biotech industry.



CDMO = Contract manufacturing and development organization; CRO: Contract research organization
R&D = Research and development

Figure 1: Birth of a biotech

Some of the key advantages are clear. For example, making performance-based investments to de-risk failure. But with time and under the right blend of investments, innovation and market opportunities (luck!), "contract R&Ds" can turn into a successful new biotech company.

Biotech now represents a new era for the rapid development of new medicines with new timelines and cost structures. The industry is moving toward more efficient development models and embracing the role of outsourcing to help build infrastructure to be most effective, or to scale when needed.

New models from CROs are enabling further biotech expansion

Demands of a rapidly growing biotech company put stresses on development processes, timelines and workforces. When drug development is globalized, companies must navigate local regulations that can vary significantly by country. This can get particularly complex when hiring

Global reach	A wide geographical coverage is needed to make resources available anywhere, depending on new location of the growing biotech.
Local expertise	Due to the complexity of local labor regulation, expertise in local requirements is needed to ensure that any solution offered follows specific requirements. Modern global CROs have a local HR presence in all offices and are already equipped for this purpose.
Dedicated business unit	There are many cross-functional teams needed to bring clinical development from managerial and financial to resourcing and legal competencies. Once the needs of the growing biotech are clear, the best solution would come from a consensus from this team.
Financial modeling	Biotech can rapidly evolve in any direction (upscaling, switching, downsizing and return). Accurate financial modeling and forecasting is needed to measure profits level evolution at every stage.
Vision	The needs of a growing biotech are beyond cost-containment strategies. For long-term success, a clear vision statement is needed between CROs and biotech that supports strong strategy designed to grow together.

Table 1: Factors important to the business needs of biotechs

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local teams, while requiring local expertise and knowledge of requirements.

Contract research organizations (CROs) have long offered a selection of resourcing models to the drug development industry. Large pharma, with an existing global presence, tend to use outsourcing models for containment, i.e., a strategy aimed to reduce resource utilization, rather than one focused on upscaling. Interestingly, for a growing biotech, upscaling models can address the needs of rapid expansion in response to pipeline and company growth. For many biotech, traditional resourcing models such as staffing (too small?) or functional service outsourcing (too large?) might not be the best solution for a growing biotech, so alternative models should be investigated to evolve as the biotech company is growing.

A hybrid model can potentially represent a new, more customized option, where biotech companies can make the best choice depending on the stage of their company’s development. Table 1 describes the features of this new tailored model and its application in biotech companies’ lifecycle management.

Leading health care innovation

To help accelerate the new paradigm for drug development, CROs must keep pace with the resourcing needs of biotech to meet global demand for new therapeutics. This will require new creative ways to combine operational models for biotech to position CROs as global extensions of biotech teams. In the short term, we will see more combinations of different models that form seamless, flexible options designed to evolve with the need of each biotech. **CP**