

## UNDERSTANDING CRO 3.0:

### *Understanding the past, present and future roles of CROs in early phase drug discovery*



June 6, 2017

As the race is constant to bring new drugs to market, pharmaceutical and nutraceutical companies and science entrepreneurs turn to contract research organizations (CROs) to provide or supplement research processes. This puts an emphasis on providing pharma and entrepreneurs with custom assays, tools and information that improve their workflow efficiency and speed to market. This article examines how CROs influence the research environment and how they can alter their roles to support pharma and science entrepreneurs in intense market competition, reducing the exorbitant time and cost associated with early phase drug discovery. It explores the roles of CROs' progression in helping pharma and entrepreneurs move confidently forward from the early discovery phase in the past, now and in the future.

#### **CRO 1.0**

##### **Emergence from necessity**

When pinpointing the birth of the pharmacology discipline, some point to the pioneering physiologists of the 1800s who focused on finding potential therapeutic compounds from the human body such as measuring chloroform in the blood, isolating epinephrine from the adrenal glands, or histamine from the pituitary. During this same period, scientists turned to plants to identify active ingredients like salicylic acid (aspirin) isolated from the bark of a willow tree. Or later, they identified fungi that manufactured antibacterial agents. Small apothecaries around the world expanded into the business of wholesale drugs spawning giant pharmaceutical companies, such as Merck, Shering, Burroughs Wellcome, Eli Lilly, Squibb, and Upjohn.

Throughout the early 1900s, there was an explosion of new pharmaceutical advances with the discovery of sulfonamides, antibiotics, hormones, psychotropics, antihistamine and new vaccines. After the thalidomide tragedy of the early 1960s and subsequent changes in the FDA (the Kefauver-Harris Drug Amendments Act), pharmaceutical firms responded with greater investment in safety by adding preclinical testing, often partnering with academic institutions for this work. However, over time universities and colleges became increasingly difficult to partner with as their costs increased and university tech transfer offices often adopted an aggressive stance to protect any intellectual input by faculty. Length of time to market increased. Today, drug approval can take between 9.5 and 15 years, accounting for early-phase discovery, animal testing and human clinical trials, at an average cost of \$1+ billion.

Commercial fee-for-service research filled a need for the pharmaceutical industry by providing high quality services, often at a cheaper cost than the pharmaceutical companies could complete in house.



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This research had the advantage of clearly leaving all IP in the hands of the sponsoring pharmaceutical company. The roots of the pharmaceutical CRO industry go back to Charles River Laboratories in the 1950s. They provided research animals for their clients. Early on, CROs were built to meet a specific FDA regulation, whether it was testing for the potential of cardiac toxicity, measuring drug pharmacokinetics, or conducting human clinical trials.

Now, a new breed of CRO has formed to serve the industry's needs in the pre-FDA required space in early drug discovery. The founders of Likarda recognized the shift toward more outsourced early discovery work and founded the company to fill that niche. Unlike later-stage CROs that sell the same service to all clients, such as a specific toxicity test, early discovery projects are different and require looking for every potential agent. That makes this type of discovery research challenging because every client brings a new problem and needs highly technical answers.

## **CRO 2.0**

### **Alleviate time and cost hurdles**

Currently, drug development and associated research is costly, complicated and lengthy, thus science entrepreneurs often struggle in the early drug discovery phase. Pharmaceutical and nutraceutical companies find themselves in a similar situation. When developing their own drugs, early discovery research for a compound is essential, but the cost and time involved with in-house assays may be prohibitive. Both form partnerships with contract research organizations that offer comparable research and can customize time, price and scalability.

With more drug development, including early screening and testing, being outsourced to CROs there are advantages and disadvantages that must be considered. Pharmaceutical and nutraceutical companies and science entrepreneurs face multiple challenges in outsourcing research. One, academic partnerships can extend a project, adding cost, due to the natural complications and layers inherent in a university environment. Two, large-scale CROs are not able to scale down to meet the funding or time scheduling requirements, especially for smaller businesses. Three, specific test service offerings do not always match the compound-required data. Despite the challenges, the ability to relieve company personnel to manage projects through CROs, rather than simultaneously conduct multiple in-house experiments, can dramatically reduce the total cost and time required to reach a go/no-go decision point.

Over the past five years, Likarda researchers have become adept at understanding the client's needs, often designing unique assays specific to the intent of the test compound. All in a time and cost-sensitive manner. Scientific tools, such as proprietary micromold plates provide better predictability and shorter timeframes. For us, discovery is not just about testing. It is about taking time to understand our client's goals and customizing a process to match, explaining the why and how along the way. It is giving the client the proof needed to move forward with confidence. It is being a partner without compromising intellectual ownership, plus alleviating time and cost hurdles.



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Multifaceted early phase research tools and processes let clients confidently navigate a complex market. Using our proprietary 3D screening approach, we have tested different drugs with known effects in humans using the conventional pharmaceutical approach, as well as our 3D cell clusters. Results from our 3D approach better mimic how the drugs work in humans or animals. Scalability is critical, and our work in high-throughput robotic assays means a higher volume of experiments in less time. Ultimately, Likarda's research and analytic services are designed to evolve with science in ways that empower a client to reach goals faster and more affordably than anticipated. Currently, those involved in early phase drug discovery take advantage of the custom assays and 3D screening in order to capitalize on potential breakthroughs quicker than ever before.

### **CRO 3.0**

#### **Identification and Development of Early Phase Discovery Opportunities**

The challenges inherent in early phase drug discovery present an opportunity for CROs to play a meaningful role in supporting pharma and science entrepreneurs in the drug development race. The traditional long timeline and cumbersome cost of early phase drug discovery research brought about an increased need for better testing procedures in a shorter amount of time than larger CROs or academic researchers were able to deliver.

To confidently bring life-changing drug and compounds to market faster, pharmaceutical and nutraceutical companies and science entrepreneurs need to take a closer look at the early phases of discovery. They must identify opportunities and take advantage of the testing new-generation CROs offer, such as 3D custom assays.

As large organizations face fierce market competition and smaller companies struggle with research funding, not to mention finding CROs that accept their projects, both will seek partnerships with research facilities like Likarda. By doing so, they can and will confidently reach the go/no-go decision point quicker based on research that better mimics the drug in humans, while reducing the time and cost associated with bringing life-changing drugs to market.

Aemmich A.A., Bowden M.E. (2005) Chemical & Engineering News, Emergence of pharmaceutical science and industry: 1870-1930, American Chemical Society, <https://pubs.acs.org/cen/coverstory/83/8325/8325future.html>

Kaiser H. (2008) From the plant to chemistry – the early history of “rheumatic medication”. Z. Rheumatol. 67(3):252-262.

Miller R. (1981) History of clinical pharmacy and clinical pharmacology. 21(4):195-197.



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