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Market Report | Life Sciences Business Process

Navigating the Shift in the Pharma-CRO Engagement Model: Evolving Pharma Needs Signaling Change

February 2023: Complimentary Abstract / Table of Contents

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Introduction

The traditional pharma-CRO engagement models broadly based on a Full Services Partnership(FSP) or a Full Services Outsourcing(FSO) model are experiencing significant transformation in alignment with evolving business needs. Apart from the traditional levers of cost and scale, next-generation levers, such as technology-enabled compliance, advanced analytics for Real World Evidence (RWE), patient centricity, agile systems, and interoperable, integrated, and cloud-based digital platforms, can provide faster compliance, enable seamless information exchange, accelerate cost savings, and achieve top-grade efficiency. To better serve pharma needs, CROs have had to make strides toward enhancing their services portfolio with a focus on digital investments and changing their engagement models to futureproof themselves in the face of competition from IT/BPOs and disruptive startups.

The scope and methodology of this report includes:

- Traditional models of pharma-CRO engagement
- Evolving pharma needs
- CRO's digital investments
- Emerging models of pharma-CRO engagement

Scope of this report

Geography
Global

Industry
Market overview and digital investments of Clinical Research Organizations (CROs)

Services
Life sciences operations

Overview and abbreviated summary of key messages

This report examines the traditional engagement models of pharmaceutical enterprises and Clinical Research Organizations (CROs), evolving pharma needs, and challenges with existing CRO operations. It focuses on the digital investments made by CROs across artificial intelligence, analytics, and automation amidst stiff competition from IT/BPOs and startups and evaluates the evolving engagement models between pharma enterprises and CROs.

Some of the findings in this report, among others, are:

The genesis of CROs and models of pharma-CRO engagement

- From the genesis of animal testing, the CROs until the late 2000's served as single-stop-shop for pharmaceutical organizations
- Traditionally, CROs supported pharma enterprises across three levers – clinical services, talent supply/domain expertise, and cost benefits
- The contracting between pharma enterprises and CROs are broadly classified under two models – Full Services Partnership or Full Services Outsourcing

Changing pharma needs and the entry of IT/BPO, specialists, and startups in the provider mix

- The pharmaceutical needs have rapidly evolved from the traditional levers, such as domain expertise and cost savings, to cloud-based platform solutions, agile systems, patient-centric services, advanced analytics for RWE, and technology-enabled compliance
- Limited agility in operations, a dearth of digital skill sets, and an inadequate technology portfolio fundamentally limit the ability of CROs to serve the evolving pharma needs
- The service provider landscape that was once dominated by CROs has also seen the emergence of IT/BPOs, specialists, and now startups

Digital pivot by CROs and the road ahead of pharma-CRO engagement

- Several CROs such as IQVIA, Charles River Laboratories, and PPD have invested in digital solutions enabled with artificial intelligence, analytics, and automation
- CROs are also undertaking M&A efforts to add niche capabilities, expand scale, and reduce competition in the life sciences operations market
- As a result, the industry is experiencing new types of pharma-CRO engagement models such as initial innovation and strategic partnership

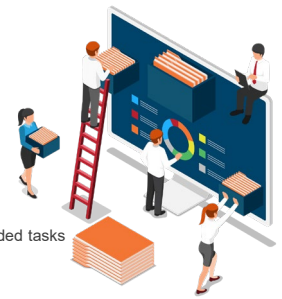
This study offers three distinct chapters providing a deep dive into key aspects of CRO market; below are four charts to illustrate the depth of the report

Traditional models of pharma-CRO engagement

Parameters	FSO model	FSP model
Services coverage	FSO model provides end-to-end services within one function, such as site identification, activation, patient recruitment, data management, clinical monitoring, and drug safety, within clinical trials	FSP model is a cafeteria-style model wherein specific well-defined services are offered to buyers that need quick scalability, higher efficiency, and functional integration
Type of buyer	Mostly engaged by small-sized pharmaceutical buyers who cannot afford multi-vendor or in-house services	The primary consumers are large and mid-sized pharma enterprises that look for specialist providers
When is it sought	FSO model is sought when the impetus is more on contractual relationships as the buyers prefer to have one service provider for a particular process	FSP model sought primarily because of: • Specialist services banking on innovation • Higher flexibility • Better efficiency and scalability for voluminous processes
Systems used	CRO systems and standard operating procedures	Often use clients' systems and their standard operating procedures
Pricing	Contracts are milestone or unit based; project manager is usually from the CRO	Contracts are FTE-based or unit-based; project manager is from the client side

Evolving pharma needs

Traditional levers	Modern pharma needs
Domain expertise • Regulatory complexities • Therapeutic nuances • Innovative trials (such as adaptive trials)	**Technology investments to ensure faster compliance**
Managing costs • Increasing trial costs • Extended timelines • Increased transactional activities	**Advanced analytics capabilities for RWE**
Resource scalability • Workforce competence • Utilization of in-house resources for value-added tasks	**Integrated, interoperable, and cloud-based platforms**
Operational efficiencies • Better compliance • Consistent quality of work	**Agile systems** **Patient-centricity**



Challenges with current CRO services

Limited agility in operations

- Rigid and less flexible operational processes in a rapidly globalizing world built on real-time connectedness makes CRO oversight difficult for sponsors leading to continuous quality management challenges
- Sponsors have multiple studies running concurrently with multiple CROs, each one having their own method, preferred SOPs, and therapeutic-specific nuances
- This leads to an opaque, non-standardized oversight process that leads to multiple inefficiencies across the entire process

Dearth of digital skill sets

- The explosion of high-volume data due to new AI-enabled modalities, such as RWE, has created demand for digital skill sets that require nuanced capabilities such as advance data analytics/science
- While CROs have the clinical talent pool, only a few are equipped to provide limited analytical talent. The current staffing pool does not meet the demands of clinical data scientists who can use big data and RWE to derive meaningful insights
- As a result, CROs are unable to provide agreed upon quality assurance, cost savings, and value maximization to pharma enterprises

Inadequate technology portfolio

- While a lot of CROs have invested in technology solutions, the current systems are standalone and disconnected
- This affects information sharing and reporting across different applications and study partners, eventually impacting trial speed, efficiency, governance, and at times compliance with standards
- The widespread usage of manual processes and redundant channels, such as e-mails, paper shipments, and spreadsheets in critical processes, such as study start-up, further adds to delays in overall trial processes, leading to cost overburden

Digital investments by the CROs

CRO digital investments

charles river

- Charles River Laboratories (CRL) partnered with Valence Discovery to leverage its artificial intelligence platform for molecular property prediction, generative chemistry, and multi-parameter optimization
- CRL and Valo Health launched Logica, an AI-powered drug solution that translates the clients' biological insights into optimized pre-clinical assets to create a computation-powered, unified, target-to-candidate offering

IQVIA

- IQVIA leverages machine learning with a generative adversarial network to automate generation of new compounds and reduce the search space
- IQVIA also leverage AI to mine existing drugs for drug repurposing programs and improve the probability of clinical trial success

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Life Sciences Business Processes

Published | Planned | Current release

Reports title	Release date
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Pharmacovigilance and Complaint Management Operations Service Provider Profile Compendium 2021	April 2021
Life Sciences Operations – Services PEAK Matrix® Assessment 2021	June 2021
Life Sciences Operations – Service Provider Compendium 2021	September 2021
Life Sciences Operations – State of the Market Report 2021	September 2021
MedTech – The Next Colossal Wave in Life Sciences Outsourcing	April 2022
Life Sciences Operations – PEAK Matrix® Assessment 2022	June 2022
Life Sciences Operations – Provider Compendium 2022	September 2022
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Life Sciences Sales & Marketing Operations PEAK Matrix® Assessment 2023	Q1 2023
Labeling & Artwork – Emerging Trends and Players	Q1 2023
Life Sciences Sales & Marketing Operations – Provider Profile Compendium 2023	Q2 2023
Life Sciences Sales & Marketing: State of the Market Report 2023	Q2 2023
Life Sciences Operations PEAK Matrix® Assessment 2023	Q3 2023
Evolution of Clinical Trial Operations	Q3 2023

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