

6. Impact of the CDS evolution on business models

6.1) Historical background on business models

Newer technologies, evolving processes, and innovative clinical research strategies are impacting roles irrespective of CDM business models including in-house and outsourced teams in both FSP and full-outsourcing service models.

In the case of the **outsourced model**, the service provider (i.e., the CRO) must adapt its processes, technologies, and resource capability to meet the industry's evolving CDS expectations to remain competitive. These expectations are not separate or distinct between sponsor and CRO—this evolution is required for all organizations.

However, in the case of the **FSP model**, the system, process, and role dependencies between the service provider and the sponsor are integral to the business model itself. The evolution by the sponsor on any or all of these three dimensions has a direct impact on the service provider and its ability to operate in an FSP model. As a result, the sponsor and FSP provider (e.g., CRO, BPO, technology service provider) need to carefully plan and align their evolution toward CDS together to account for changes to systems, processes, and roles. It is also important to note that large scale FSP services may be provided by traditional CROs which have diversified through both the outsourcing and FSP models.

Traditional FSPs were established to flexibly augment resource capacities with experienced staff and, in some cases, as a way to reduce operational costs by converting fixed internal costs to discretionary lower costs. Unlike the outsourcing CRO model, the sponsor keeps the control over the data by having FSP staff using its systems and processes.

Small-scale FSP models used primarily for staff augmentation will require adjusting the staff selection to account for the evolving CDS responsibilities. The onboarding and training of FSP staff will likely be similar to the onboarding of sponsor's own employees.

Larger scale FSP models will require more significant adaptations. They are predominantly offshore to take advantage of lower cost of resources. The prospects of such savings led some sponsors to engage service providers to establish large offshore centers in a variety of countries and regions including India, South Africa, Mexico, Asia, and others. The model often followed the strategy of hiring and training a mix of fresh graduates (i.e., junior staff) and experienced resources to lower the overall wage costs and by delegating high volume and/or repetitive tasks to them to realize meaningful short-term ROI. As shown in figure 9, the scope initially included activities such as data entry of paper CRFs and diaries, discrepancy management and data reconciliation. In some cases, the scope included technically driven tasks such as database set-up, report programming, dataset creation and upgrade from legacy systems to newer technologies requiring migration of data.

Though the overall trend is still to shift toward offshore locations, there are instances where the high ratio of offshore junior FSP or CRO staff has resulted in an experience gap leading some sponsors to insource activities back to their own higher skilled resources. Additionally, in recent years, many sponsors have invested in their own operational CDM centers in low-cost locations, called "captive sites" leading to the insourcing of many of key roles.

Lastly, as the industry evolves, and as new options emerge, the viability of the lower cost and lower skill business models are being challenged for a number of reasons, including but not limited to the following:

- Increasing wages in established low cost locations
- Rising clinical research complexities requiring to up-skill R&D staff to a level where the training of existing FSP or CRO resources is not enough
- Increasing competition for the recruitment of advanced degrees in data sciences and statistics
- Reliability and cost-effectiveness of automation solutions based on RPA and IPA eliminating simple and repetitive manual tasks
- Variability in clinical study designs where one-size-fits all and predictable processes are becoming the exception
- Shift from reducing operational cost to eliminating the cost of non-quality by refocusing on first-time quality

So, business models will need to be adapted to newer perceptions in order to evolve their offering and reassess their model to ensure they subsist long term.

6.2) Business models of the future

While some providers will continue to focus their model on the transfer of non-core roles to them (i.e., resource enabled model), others are more radically reconsidering the model of the future in order to

invert the insourcing trend leading to the decline of the current models. Providers may benefit in delivering technology driven innovations that leverage their expertise and deep know-how of the sponsor's processes and systems (i.e., technology enabled model). The expectation is that the investment cost in technology enabled models and processes will be offset by long-term savings.

Traditional resource enabled models

As an example, the figure below illustrates the evolution of the tasks delegated by sponsors to offshore FSPs over the last decade. Information was gathered through a survey of FSP delivery leaders in India on the evolution of the span and scope of tasks managed by large FSPs. During this time, FSPs were able to upskill their staff through training to meet the increase in responsibilities. Some tasks requiring cross-collaboration like database lock and analytics have not been yet transitioned to FSPs by all sponsors.

| Task Assignments to FSPs | | | |
|---------------------------------------|------|---------------------------|------|
| Tasks | 2010 | | 2020 |
| | FSPs | In-house & Captive | FSPs |
| Database Development | Most | Most | All |
| Specification Writing & UAT | Most | All | All |
| Data Entry (CRF or Paper diaries) | All | Most | All |
| Study Planning | None | All | All |
| Discrepancy Management | All | All | All |
| Study Management | Few | All | All |
| Dataset Creation | Most | All | All |
| Coding | Most | All | All |
| Database Lock | Many | All | Most |
| Analytics and Reporting | None | All | Many |
| Quality Control | All | All | All |
| External Data Reconciliation | Many | All | All |
| Mainly Out of Scope or Future Planned | | In scope or Limited Scope | |

Fig 9. The FSP Task assignments

The speed of change is expected to accelerate as a result of the trends highlighted in Part 1⁴. So, for resource enabled service providers, the opportunity lies in aligning resources needs to the sponsor's shift toward CDS. The transition requires a paradigm shift as simply up-skilling resources to the new clinical research approaches and emerging technologies may not be enough to adapt to changes in competencies, foundational knowledge, and soft skills.

Service providers will have to ensure their staff roles evolve to keep-up with the pace of change of sponsor's technologies and processes. It may become challenging for providers that only focus on resource availability. A parallel pace will require that providers continue to invest into their training to ensure alignment with the sponsor requirements. This is expected to put an ongoing burden on the providers to manage a long-term transformation while ensuring no impact on delivery. The demand from sponsors to source experts in technology like AI/ML solutions may lead to recruitment and

retention challenges. As sponsors start looking for future proof partners, providers will need appropriate recruitment approaches and investment in talent development and retention (i.e., training, reskilling and career development) to remain relevant.

Transition to technology enabled business models

In contrast, a few providers originally supporting resource enabled models are now delivering some of their services with higher predictability and quality through their own technologies as opposed to solely rely on the sponsor's technologies. Those providers are leveraging software as a service (SaaS) solutions which do not require complex integrations and can be used in addition to the sponsor systems.

Some examples include:

- ML based SDTM Mapping solutions
- SDTM compliance QC tools
- Metadata based eCRF Design creation tools
- EDC design QC tools

This approach allows the sponsor to leverage innovative technologies without the implementation costs. In return, the technology enabled provider can cater to higher quality services, minimize the reliance on hard to find experts and ultimately maximize revenues when technology ROI is realized. In addition to low footprint SaaS technologies, some providers are also offering the sponsors end-to-end services around more complex third-party solutions such as IRT, EDC and eCOA including the licensing of the solution from its technology providers. This has been facilitated by the fact that some technology providers have sub-contracted their services to large providers who gained expertise by delivering them.

In comparison, some technology providers are becoming service providers by leveraging the knowledge of their own technologies and the expertise of their delivery teams. So, we have seen both backward and forward integration of technology-to-service and service-to-technology models. This new paradigm seems to be in favor of all parties - sponsor can focus on their core R&D priorities while providers deliver the latest technology requirements and focus on innovations. In this model, the sponsor has the flexibility to retain core technologies and data in house and transfer the full management of operational study specific solutions to the technology enabled providers. This also potentially allows the sponsor to test emerging solutions flexibly prior to investing in a lengthy and costly implementation project.

The segment which will still remain out of the ambit of the above expectations will be highly specialized players in both technology and services. As mentioned in the reflection paper Part 1, there are several technology organizations developing RBM, DCT, eSource, supervised cleaning, future proof platforms and newer models capable of utilizing AI/ML. Such organizations may solely remain as innovators and providers will be required to collaborate with them by bringing in their services strength as well as technology support.

While these evolutions are not certain, we foresee that all models will need to transform to either scaled-up resource-enabled services or technology-enabled services by acquiring the desired knowledge and capabilities either internally or through relationships with partners. But regardless of the model, the CDS requirements and role expressed in the reflection papers do not change. It comes down to clear communication pathways and even clearer assignments of accountability.