Insight Brief

Accelerating Study Start-up:

Lessons learned from regulatory and start-up functional service provider engagements

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Introduction

Study start-up time – the interval between site identification and completion – is a vital step that sets the tone for the entire clinical trial. Elements of site activation include contract negotiation and execution, regulatory and ethics submission and approval, import/export operations, and site preparation and activation. Ten years ago, the average start-up time for phase 2 and 3 studies was 27.4 weeks compared with the current figure of 31.4 weeks[1]. These delays can result in costs to the sponsor of $600,000 to $6 million[2].

Overall clinical trial complexity continues to increase, which may challenge the expertise of sponsor companies, including ones that acquire new assets or enter new indications and therapy types. Complex protocols may cause increased burden for patients and caregivers, creating problems in patient recruitment and retention. Use of technology may reduce the patient burden, enabling remote interactions with healthcare providers, as in decentralized clinical trials. However, technology may add to the burden for sites, which may have to manage many different platforms for different sponsors and trials, diverting resources away from core trial-related activities.

Protocol amendments also pose a growing challenge. According to a 2024 publication from the Tufts Center for the Study of Drug Development, 76% of protocols in phases 1 to 4 have at least one amendment, up from 57% in 2015.[3] The mean number of amendments per protocol has risen by 60%, from 2.1 in 2015 to a current figure of 3.3. These figures were based on data from 16 pharmaceutical companies and contract research organizations on 950 protocols and 2,188 amendments. Prior to protocol approval, IQVIA's Data-Informed Protocol Assessment (DIPA)[4] can help customers improve protocols by reducing patient burden, improving patient safety assessments and preparing sponsors for regulatory submission. DIPA feedback is based on historical data and experience, yielding a more robust protocol that can be used for discussions with regulatory bodies, potentially reducing the likelihood of protocol amendments being required.

OVERVIEW OF SERVICES IN-SCOPE FOR FUNCTIONAL SERVICE PROVIDER (FSP) REGULATORY AND START-UP (RSU) ACTIVITIES

Site activation – which involves bringing a site to the point where it is ready to recruit patients – includes the following activities:

- Site ID support, including CDA negotiation and execution
- Contract negotiation and execution, with negotiation of study budgets and contracts to compensate a site for research costs
- Regulatory and ethics submission and approval, including preparation of submission packages for regulatory authorities and ethics committees
- Import/export operations, including preparation of import/export license applications for drug and material shipment
- Site preparation and activation, with completion of all activities required for a site to be enrollment-ready

Challenges facing life science companies with in-house studies

Life science companies that carry out global studies in-house may face a variety of challenges, including delays in site activation. The many regulatory and cultural differences between geographies have wide-ranging implications, requiring expertise and up-to-date intelligence to avoid pitfalls.

Challenges facing life science companies with outsourced studies

Similarly, studies using external resourcing models also have the potential to encounter challenges. When clients make the decision to bring study start-up in-

house after initially outsourcing to a CRO, they become more fully aware of the high number and nature of tasks involved and the additional resources that are potentially required to manage these. In some cases, the life science firm takes the study back in-house to gain more control over timelines yet lacks capabilities in certain countries. Another challenge is the changing regulatory environment and the need to maintain detailed data and expertise relating to regulatory requirements for each country to ensure a robust regulatory and ethics submission strategy.

Key areas requiring support from an expert partner

Life sciences companies can benefit from support in several key areas of the study start-up process:

- Increased and current start-up expertise and regulatory intelligence, and the latest technology to reduce overall timelines
- Selecting sites that have access to the right patients, also taking into account other key variables such as potential conflicting trials and other factors that could influence sites' abilities to perform the trial successfully
- Managing the complexity of regulatory requirements to avoid longer approval timelines
- Streamlining contract and budget negotiations, for example, using site intelligence, skilled negotiators and technology to avoid the need for manual tracking
- Setting-up robust approaches to vendor coordination to allow sites to enroll patients rapidly regardless of protocol complexity

Many life science companies have separate regulatory and start-up groups. The regulatory groups from larger companies typically handle submissions in-house, while start-up groups often seek CRO support for activities such as contract negotiations, gathering key documents from sites, and vendor management support. Clients are particularly seeking IQVIA expertise to support compliance with the European Union Clinical Trials Regulation (EU-CTR),[5] which comes into full effect from January 2025.[6] This brings a range of new requirements, constraints and business risks.

The role of FSPs

IQVIA's extensive global footprint and regulatory and start-up expertise can fill in these resourcing gaps. Functional service provider (FSP) engagements can enable clients to bridge gaps in their internal resources for regulatory and start-up (RSU) activities while retaining close control and continuing to use their own standard operating procedures (SOPs) and other business processes. FSPs can provide the experts, knowledge and technology to fit each customer's specific needs, offering a dedicated resource to help the customer's team streamline trial delivery

IQVIA's customizable FSP start-up model

(Figures 1 and 2), and entirely run and managed by experts in this area. This group can provide fully

"IQVIA has a dedicated FSP regulatory and start-up group with over 600 permanent FSP staff in over 50 countries, covering all regions"

customizable FSP start-up models offering global reach and local expertise, while supporting all aspects of study start-up. Options include providing staff to work with client teams to direct and manage delivery of all required site activation, maintenance and regulatory activities for selected studies or multi-protocol programs.

The IQVIA FSP start-up group is able to leverage key attributes to create fully "fit-for-purpose" solutions to deliver an optimal start-up strategy for clients.

- **Dedicated governance structure:** IQVIA offers a stand-alone Regulatory & Start-Up unit with its own structure and governance, and with access to dedicated experts and leaders to support the model

- **Quality-driven excellence:** This includes rigorous team onboarding and training, with an RSU-dedicated line manager to manage staff performance, and quality management support
- **AI and other technologies:** Examples include IQVIA's machine learning based translation platform (ITP), spark system, and a tracking tool for live updates to support contract and budget negotiations

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- Real-time regulatory intelligence: IQVIA's proprietary Regulatory Intelligence Database uses real-time information to keep teams informed, helping ensure compliance with the latest regulatory standards
- Flexible, tailored solutions: These may include end-to-end start-up, or focus on selected aspects of start-up such as EU-CTR compliance or contract and budget negotiations
- Agility in talent acquisition: IQVIA's dedicated RSU talent acquisition teams ensure rapid resource deployment, utilizing the latest hiring technology, including the HireVue enterprise-level hiring platform

Addressing bottlenecks to accelerate study start-up

FSP partnerships can help address bottlenecks. Many clients lack the full range of internal resources and expertise needed to handle all aspects of study start-up in a timely way. An FSP solution provides an extension of resources and capabilities, while still using the sponsor's internal SOPs and other processes, sharing common goals with the client. This saves time since handoffs are minimal to non-existent.

Successful FSP engagements involve IQVIA teams becoming embedded within client teams, working day-to-day within the client's culture to fully understand all needs and processes, and cocreating solutions in partnership with the client. This customer-focused partnership avoids the bottlenecks that can arise in some outsourced projects. The FSP mindset is different

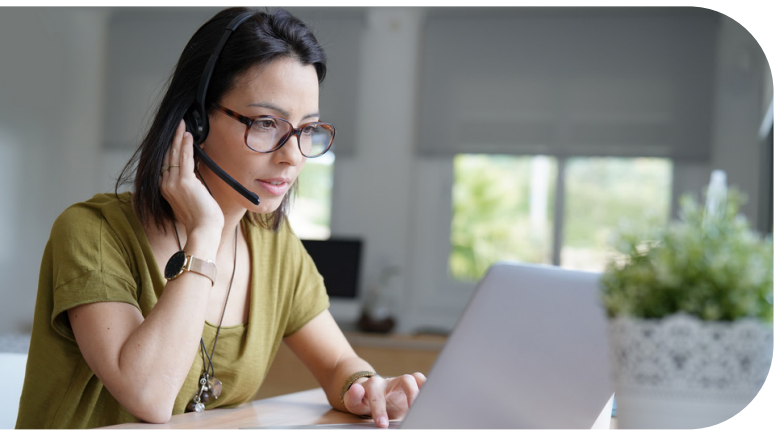
from full-service engagements, which involve full accountability for delivery, using the CRO's SOPs and other business processes, and gaining efficiencies from end-to-end project outsourcing.

For an FSP solution delivering trials in study start-up, engagements can involve providing role-ready experts as full-time employees (FTEs), or might be unit based, involving delivering elements of the start-up cycle, such as ethics submissions, execution of contracts, or uploading of EU-CTR applications. Recent examples of IQVIA RSU FSP engagements are shown in Sidebar 2.

Looking ahead: Advantages of bespoke solutions

Bespoke offerings ensure that clients can pick and choose the areas where they require support. FSPs can potentially reduce delays in cycle times by bridging gaps in resources, regulatory expertise or local knowledge. There is scope to avoid delays in regulatory and ethics committee filings, site contracting and other steps in regulatory and start-up processes. IQVIA brings core expertise in clinical trial start-up, including the ability to drive down cycle times and optimize start-up processes.

Overall, IQVIA can help customers optimize and simplify processes and reduce hand-offs, using robust planning, tracking and performance management at all stages. IQVIA has an exceptional range of integrated systems and tools with advanced reporting capabilities that can help streamline and accelerate processes. In addition, IQVIA is at the forefront of innovative research on applications of artificial intelligence/ machine learning (AI/ML) in regulatory and start-up activities. Once the regulatory environment is ready, AI is likely to yield efficiencies in these areas, enabling streamlining and automation to reduce the need for repetitive human tasks and avoiding human error. This will further strengthen IQVIA's toolbox supporting streamlined study start-up.



RECENT IQVIA RSU FSP ENGAGEMENTS

Examples of recent types of IQVIA FSP engagements include:

- Adding high-quality resources to a client team to enable timely overall start-up delivery, in a partnership focused on providing highly qualified people and building business processes
- Supporting client clinical trial expansion into Latin America, providing IQVIA expertise in multiple countries to develop necessary resources
- Managing site contracting and payments, including providing dedicated contract negotiators and incorporating IQVIA's clinical trial payments experts and technology
- Handling EU-CTR submissions, taking advantage of IQVIA's broad experience in this new area, as clients transition to new processes under this legislation

About the authors

CLAIRE RIELLY
Vice President Hybrid Strategy and Study Management, Clinical FSP

Claire heads the hybrid strategy for FSP and Study Management. Claire has oversight of both RSU and Clinical Project Management functions.

Over 20yrs clinical experience. She has a broad range of clinical experience. She began her career in clinical research in 1998 as a CRA and worked as a CRA; Clinical Lead and Line Manager in both CRO and Pharma settings

Since 2016, Claire has held leadership roles (Associate Director, Director, Snr Director) for multiple FSP accounts and became Regional Head for EMEA in 2019, driving, delivery, quality, people development, financial performance, and customer delivery for all FSP accounts cross the region. In January 2024 she took on her present role

IAN PEMBERTON
Vice President, Clinical Operations

Ian has over 27 years in clinical research and has worked in Pharma Companies and CROs in that time in a number of operational and leadership roles. Ian has spent the last 16 years working in IQVIA in Clinical, Project Management, Regulatory & Start up roles with the last 4 years leading the setup, implementation and oversight of Clinical FSP Models.

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