IQVIA TECHNOLOGIES

White Paper

Study Start-Up Challenges: Hard Realities, Effective Strategies

KERRY RANDALL, IQVIA Research & Development Solutions
RAPHAËLLE GILG, Novartis Pharmaceuticals
RODRIGO GUIMARÃES, IQVIA Technologies
ROSEMARY SHIREY, IQVIA Technologies

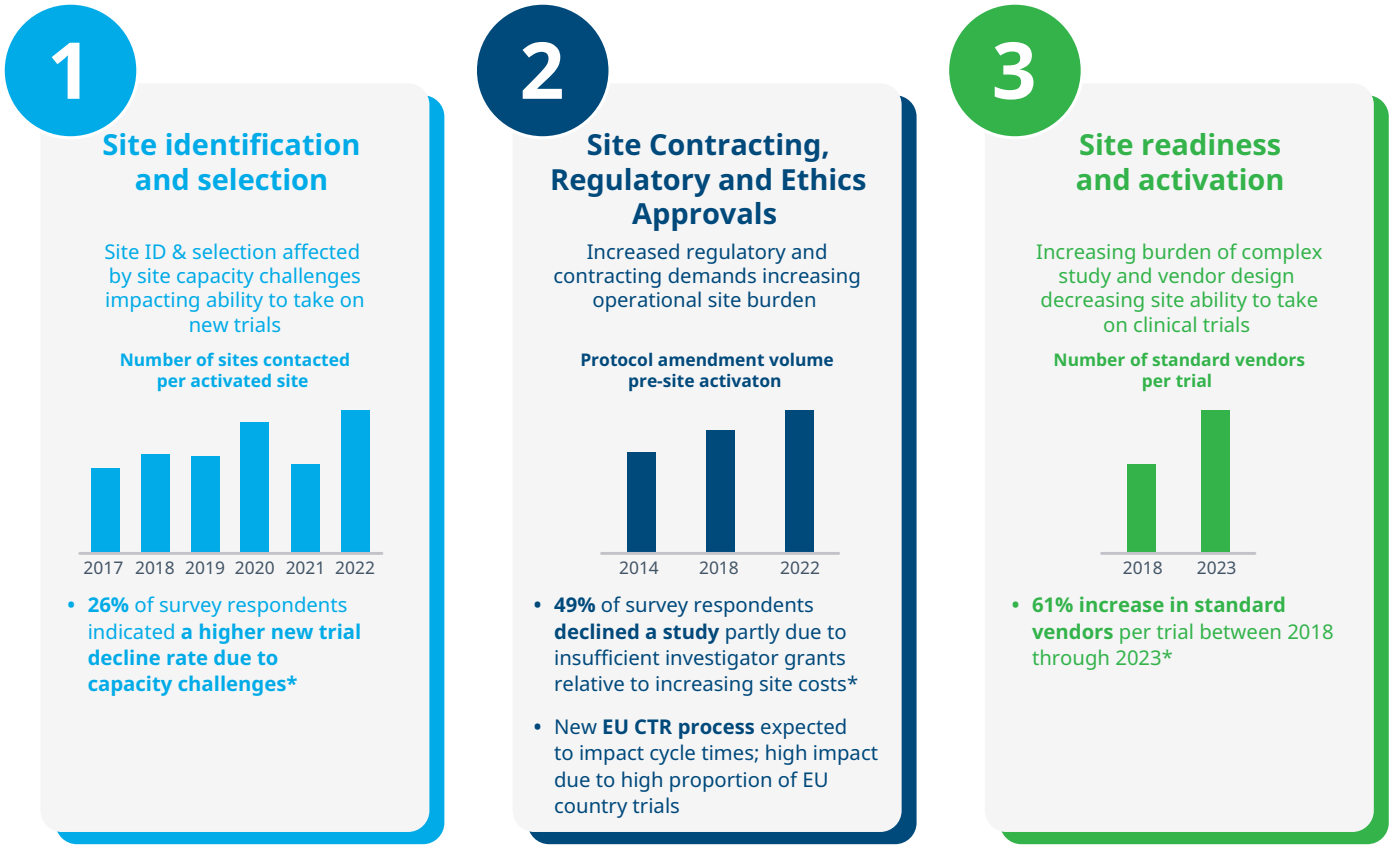
According to the Tufts Center for the Study of Drug Development, the average time between protocol approval and the first patient visit increased 45% between 2015 and 2021. This slowdown in start-ups causes delays in product launches and ROI. At the same time, speed-to-market is more important than ever, as exclusivity periods have been cut in half over the past two decades. Are there any effective strategies to reverse this trend of ballooning study start-up timelines?

IQVIA Technologies asked Raphaëlle Gilg of Novartis Pharmaceuticals and colleagues Kerry Randall, Rodrigo Guimarães, and Rosemary Shirey to share their best practices in the webinar titled Practical Approaches to Faster Study Start-ups: Making Progress in the Face of Industry Headwinds. These industry leaders shared pragmatic, actionable steps that pharmaceutical and biotech companies of all sizes can implement to accelerate study start-ups and get innovative drugs to patients more quickly and efficiently.

Why is study start-up taking longer?

Preparing a site for start-up is complex, and since the COVID-19 pandemic, several factors have increased the time it takes to get to the first patient's first visit. Kerry Randall, who heads up site activation for IQVIA Research & Development Solutions (RDS) globally, reports that her organization is seeing a greater degree of effort needed to secure sites to begin a trial. When sites are in high demand and have limited capacity, sponsors and CROs see more new trials declined.

Figure 1: The current study start-up environment



*Source: IQVIA Site Survey, June 2023

"In the site identification space, we're seeing the impact of site capacity challenges on the level of interest to participate in clinical trials," stated Randall. "It's taking a lot more effort to sell the benefits of the study, which is reflected in the increase in the number of sites we need to contact to reach the quantity needed at a study level. While we see early signs that this is improving, it 's still one of our most significant headwinds."

A paucity of sites means that sponsors and CROs must contact an unprecedented number of investigators during their initial outreach to get the required amount of patients, which takes more time. Although many in the industry are working to improve site availability, scarcity remains one of the most significant factors in delayed study launches.

A second factor is contract negotiation timeframes. When sites have less capacity, staff are overstretched and take longer to respond to proposed budgets. Inflation also contributes to lengthier contract negotiations. In a recent survey by IQVIA RDS, 49% of sites reported declining a study at least partly because of insufficient investigator grants relative to inflation and the increased costs associated with running a trial in the current economic environment. Even when a study does move forward, these factors lead to multiple rounds of time-consuming budget negotiations.

Beyond budget negotiations, the European Union Clinical Trial Regulation 536/2014 (EU CTR) currently impacts contracting cycle times. It became mandatory for all new clinical trial agreements (CTAs) to follow EU CTR processes in January 2023. While EU CTR aims to overcome deficiencies in the previous Common Technical Document (CTD) process, it presents sponsors and CRO partners with the challenge of revamping internal processes and learning another new technology.

Finally, site readiness has become much more complex in recent years. Sites must manage many more requirements to be declared "open for enrollment." This complexity is reflected in the number of vendors IQVIA typically engages in its studies. Since 2018, they have seen more than a 60% increase in standard vendors per trial, adding to site capacity challenges and slowing site activation.

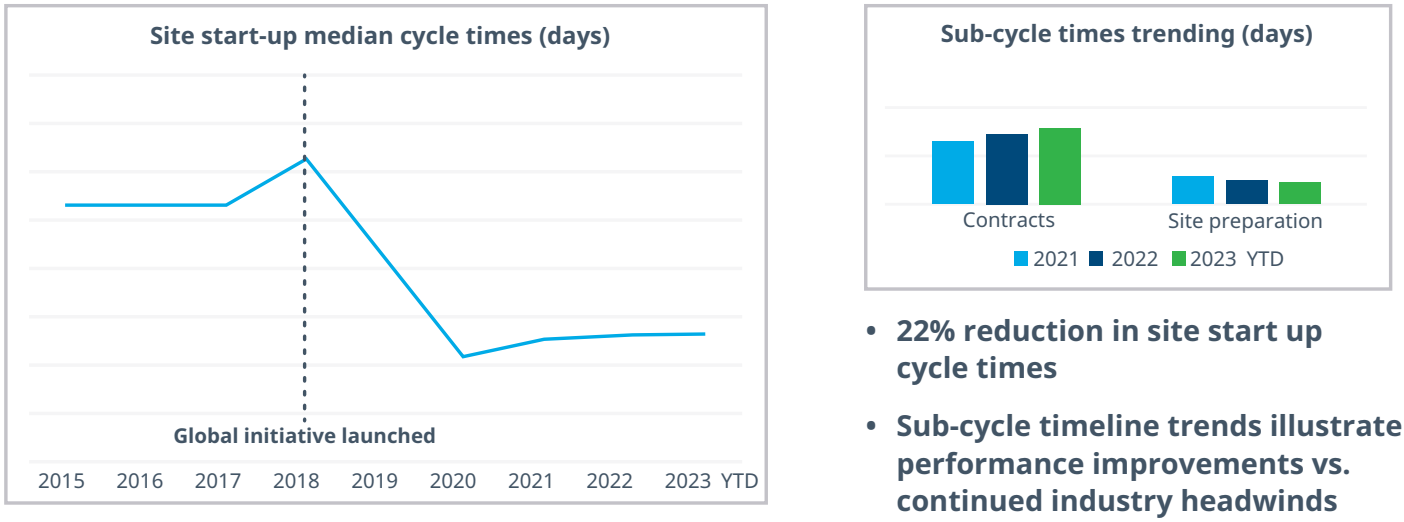
How are industry leaders improving start-up times?

IQVIA and Novartis have worked for many years to improve study start-up timelines. For example, in 2018, IQVIA RDS launched a global initiative focused on accelerating start-ups. Thanks to that initiative, they've seen a 22% reduction overall in their global median cycle time. But since the pandemic, cycle times have flattened. This indicates that some industry headwinds related to site activation have offset ongoing performance improvements. While IQVIA RDS has managed to reduce site activation timelines overall, the makeup of that timeline is shifting, as seen in Figure 2.

"In the site identification space, we're seeing the impact of site capacity challenges on the level of interest to participate in clinical trials."

— Kerry Randall, Vice President and Global Head of Site Activation for IQVIA R&D Solutions

Figure 2: IQVIA site start-up acceleration



"What this shows is that while we're improving overall, the makeup of our overall time to activate a site is shifting," said Randall. "If we look at contracting, the time it's taking to execute a site contract is increasing. On the flip side, the time it takes to activate a site post-approval is reducing. We have the right strategies and tactics to continue our downward trend for overall cycle times."

It has taken intense focus across three key components to keep start-up timelines from growing longer and longer since the pandemic:

1. SITE IDENTIFICATION AND SELECTION

Selecting suitable sites to maximize recruitment rates and deliver high-quality data is a significant focus for IQVIA RDS. According to Randall, RDS has leveraged its extensive experience and relationships with specific sites to streamline its selection process dramatically, and these positive changes have been well received by sites. Raphaëlle Gilg explained some of the strategies that Novartis Pharmaceuticals employs to select and activate sites.

"Having the right site in the right country at the right time is key to recruiting the right patients and obtaining the right data," stated Gilg. "Also, you need to balance experienced sites with ones new to clinical trials and dedicate enough time, resources, and technology to bring them up to speed in the industry. For example, at Novartis, we tap our medical team when needed to affirm recruitment timelines, build relationships with new investigators, and connect sites with technology partners to assist them best."

Site capacity challenges continue to impact start-ups. In recent years, the clinical research environment has changed dramatically, but concentrating on fundamentals, such as bringing data intelligence and local knowledge to the table, ensures that the right sites are selected and have the information necessary to make an informed decision regarding participation. IQVIA RDS invests in training and creates bespoke materials to help investigators understand if the study is right for them. Creating a suite of resources for sites reduces the amount of time investigators spend emailing back and forth to execute confidential disclosure agreements and questionnaires. Meanwhile, IQVIA builds relationships with site staff to track milestones and retain momentum.

"Technology plays a role here, too," explained Rosemary Shirey of IQVIA Technologies. "We equip the sites with tools to collaborate with us effectively right from the start – not just tech, but tech designed to support them. For example, the IQVIA Feasibility module is used by RDS and Novartis in the initial outreach and fosters a positive, easy site experience while still getting the sponsor and CRO teams the needed information. Study teams can also choose to host internal materials in permissioned areas of the IQVIA Investigator Site Portal to address site questions quickly and easily. Starting the sites out on the right foot includes giving them the resources they need to succeed as trial stakeholders."

2. CONTRACTING AND APPROVALS

The next component is the contracting and approval space, which is crucial to the start-up journey. Technology improves efficiency in these areas, but structuring organizational resources between specialized roles versus a consolidated point of contact is a balancing act. In the past two years, IQVIA RDS has minimized handoffs internally and reduced touch points with sites to alleviate their workforce burden. For example, with the feasibility process, IQVIA leverages local knowledge to understand where they need specialization while keeping the goal of having one point of contact with the site to facilitate communication and support.

The IQVIA Feasibility module allows RDS and Novartis to remain flexible and adjust their site search based on the size of the country, the type of study, and the site load. The submissions management functionality in the Site Activation module keeps site momentum high through the regulatory approval process. It provides a single source of truth for tracking everything related to the site to ensure they are ready to move forward.

"We've been working with IQVIA Technologies for several years to accelerate study start-ups by creating a consistent experience for sites."

— Raphaëlle Gilg, Strategy and Operations Manager for Novartis Pharmaceuticals

3. SITE READINESS AND ACTIVATION

Sites are increasingly burdened with myriad tasks required to begin a study while coping with time constraints. Careful planning, such as front-loading essential tasks to remove them from the critical path sooner, accelerates site activation. In the past, sponsors would wait for CTA approval before activating sites. But to fight the trend of delayed studies, sponsors and CROs need to prioritize site activation while waiting for approval to launch the study as soon as possible. Technology platforms that allow for early access to training, especially cross-trial training that provides credits for sessions already completed for other trials, also accelerate site activation.

How is Novartis improving study start-ups?

Site start-up will always be a key focus across the industry, given that any acceleration here directly impacts and supports enrollment. Novartis is focused on several areas — looking critically at roles and processes and investing significantly in tech-centered solutions to support their work end-to-end.

"Novartis has significantly invested in technology to support site readiness," explained Gilg. " We've been working with IQVIA Technologies for several years to accelerate study start-ups by creating a consistent experience for sites. They can find exactly what they need and only what they need. The technology platform has enabled us to streamline documentation strategies to ensure compliance with local regulatory bodies without completing unnecessary paperwork."

A favorite system of research sites, Novartis Connect provides communication, training, and documentation. Sites can pose questions and access relevant information quickly. The system uses a variety of modules to guide sites through the entire process, streamlining critical path components to improve efficiencies.

Novartis and IQVIA RDS have been driving faster study start-ups through the Investigator Site Portal, with modules for feasibility, site activation, site training, site engagement, and more. Novartis has branded its IQVIA Investigator Site Portal implementation as Novartis Connect.

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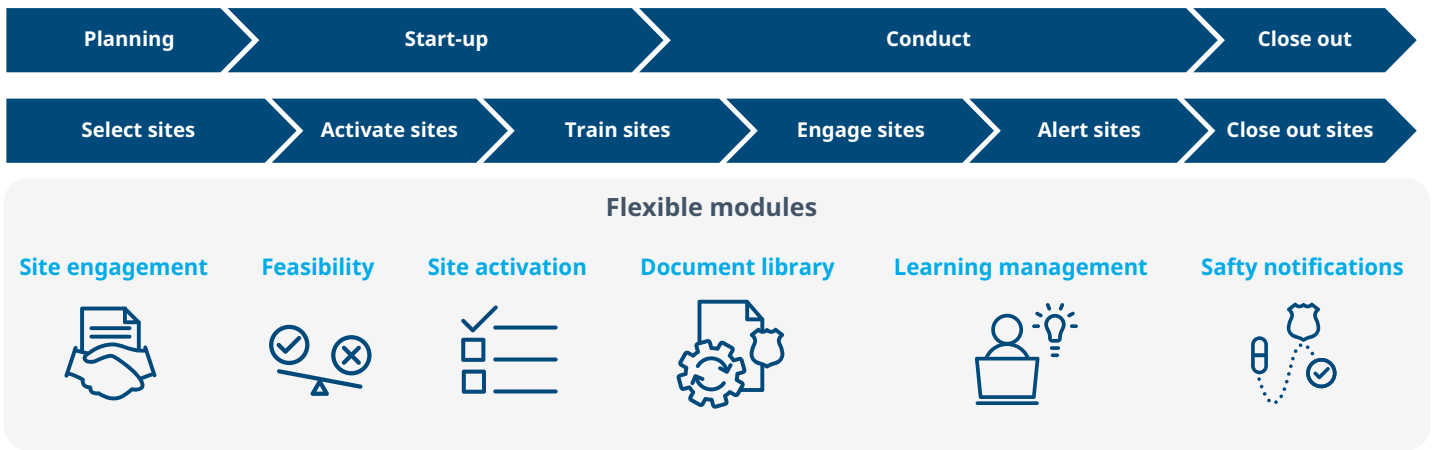
For IQVIA RDS, the Site Activation module provides powerful workflows to track the status of documents. It also provides a catalog of standardized templates that can be used across multiple sites and builds country-specific workflows to comply with local regulations, creating targeted actions for each milestone and assigning them to the correct stakeholders. For site selection, the Feasibility module pre-populates data previously provided by the site so that the same question isn't asked over and over again from trial to trial. As a result, sites can complete feasibility surveys in less time, which leads to faster site selection. Study planners can observe progress by country or region and use the dashboard features to compare investigator responses. Site selection decisions can be made within the tool, or data can be exported for further analysis.

"Technology is part of the solution," explained Gilg. "It's not the whole solution, but a necessary piece that underpins everything we're doing."

Figure 3: IQVIA Investigator Site Portal/Novartis CONNECT



About the authors

KERRY RANDALL
Vice President and
Global Head of Site Activation for
IQVIA R&D Solutions

Kerry Randall is Vice President and Global Head of Site Activation for IQVIA R&D Solutions. Kerry leads a worldwide team focused on getting sites to a point where they can enroll patients into clinical trials. She joined IQVIA in Singapore as Head of the APAC Global Business Operations team in 2011, then returned to the UK in 2016 to lead a similar EMEA team. Her passion for process improvement and organizational development led her to roles in study start-up and site activation. Kerry holds a BSc in Economics from University College, London, and an Executive MBA from INSEAD (Singapore).

RODRIGO GUIMARÃES
Vice President of Global Site
Activation for IQVIA R&D Solutions

Rodrigo Guimarães is the Vice President of Global Site Activation for IQVIA R&D Solutions. Rodrigo has more than 20 years' experience in clinical development with pharmaceutical and contract research organizations. He joined IQVIA in 2006 and has served in leadership positions at regional and global levels in site start-ups, investigator contracts, clinical operations, and real-world evidence operations. He has also served as President of ABRACRO (Brazilian CRO Association). Rodrigo currently heads Country Site Activation teams, overseeing a 1,300-employee workforce responsible for delivering site ID, regulatory submissions, and investigator contracts, ensuring clinical sites are ready to enroll. He earned degrees in Pharmacy and Biochemistry from the University of São Paulo, a specialization in business administration from the Sydney Business Academy, and an MBA in business administration from Fundação Getulio Vargas.

RAPHAËLLE GILG
Strategy and Operations Manager
for Novartis Pharmaceuticals

Raphaëlle Gilg is the Strategy and Operations Manager for Novartis Pharmaceuticals. Raphaëlle started her career as a nurse in cardio intensive care units. With a passion for novel ways of treating patients, she moved into clinical research, first becoming a Clinical Research Associate and then moving into different roles across the industry. Raphaëlle leads Novartis Site Engagement from the Business Operations side, striving to establish positive and efficient site-sponsor relationships, continually addressing study start-up and site initiation timelines, and finding solutions that best empower study teams to access key study documents and information easily, removing administrative burden.

ROSEMARY SHIREY
Associate Director of Client Services
for IQVIA Technologies

Rosemary Shirey is the Associate Director of Client Services for IQVIA Technologies. Rosemary has more than 10 years' experience working within the clinical research space and currently leads Client Services for the IQVIA Investigator Site Portal (formerly DrugDev). She supports and collaborates with sponsors and CROs, helping their study teams start up and conduct trials more efficiently by applying technology in innovative ways to solve site challenges. Rosemary graduated from Harvard University with a degree in History and Science.

CONTACT US

OrchestrateYourTrials@iqvia.com

iqvia.com/investigatorsiteportal

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04.2024.TCS. BCS2024-1003-04APR