

Case Study

How to Add a New Randomized Part to an Ongoing Study in Three Weeks

Simplify™ Rapid Start Up of IXRS[®]3 IRT Supports Race against Cancer

When reconfiguring the existing IRT could delay the study for many weeks, could building a new IRT actually be quicker? In this case study, read about Almac's approach to rapidly accommodating protocol design configurations and data integration.

One of the world's leading biotechnology companies was focusing on area of highly unmet medical need and developing a pipeline of medicines with breakaway potential to treat some of the toughest cancers. The Sponsor had a longstanding relationship with Almac Clinical Technologies spanning more than two decades.

When the Sponsor learned from a regulatory agency that they would need to add a new part to the trial, they reached out for Almac's support on how best to proceed. The two companies worked together in a trusted partnership toward the shared goal of bringing life-saving therapies to patients sooner.



Challenge: **An Unexpected Turn of Events**

Since 2019, this Sponsor's studies had been run on Almac's customized IRT platform, IXRS. The phase 1/2 open label, non-randomized study started in the spring of 2019 to test monotherapies and combination therapies in advanced solid tumors in both Non-Small Cell Lung Cancer (NSCLC) and Colorectal Cancer (CRC) with the KRAS G12C mutation.

Nearly two years later, in February 2021, a federal regulatory agency required that a new randomized part be added to the study. The new part was to be a multicenter, open-label study comparing the efficacy and side effect profile of two different doses.

The compound was showing great promise in shrinking tumors. Every day of delay could have a direct impact on the lives of patients who faced poor outcomes. For many patients, this compound would be the last line of treatment.



Almac Solution: **Rapid IRT Platform Deployment with Simplify™ Start-Up Mode**

In the time since this program launched on Almac's IRT platform, Almac had begun building studies onto a new, state-of-the-art platform, IXRS®3. Almac also launched Simplify™, an IRT start-up mode that enables rapid configuration and implementation of the IXRS3 platform.

The same day that the regulatory requirement for the addition of a randomized study part was learned, Almac's senior management committed to finding a solution that could go live in as quickly as one week. Almac proposed two different solutions for consideration. Both involved treating the new, randomized dose comparison (Phase 2, Part B) arm as a new study and building it out as its own IRT, rather than modifying the existing study IRT, which would take much longer to deploy.

The first delivery option, which targeted system availability in one week, would be built with Simplify™. While the IRT would include all the functionality needed to meet the protocol design, such an extraordinarily short timeframe would only accommodate certain data transfers in the first release. This would allow patient enrollment to begin as quickly as possible, and a subsequent IRT release would then include additional integrations/data transfers.

The Sponsor selected a second proposed delivery option: it also used Simplify™ solution, but was able to accommodate both the protocol design configurations and all data integration needs within the initial IXRS release, in just a total of three weeks.



Results: System Availability for a New Study Part in Three Weeks

The project benefited from Simplify's low-touch, streamlined approach to startup, which aims to reduce the time commitment from clients. Streamlined requirements provide ease of creation and review, and Almac delivered the requirements the following day after the kickoff meeting. The Sponsor commented: "The structure of the requirements document was easy to digest - especially for team members who had not seen that sort of document before."

Almac delivered the IRT system just three weeks later, complete with the data transfers and integrations to various suppliers involved in the study (the Electronic Data Capture (EDC) vendor and the Contract Research Organization (CRO)). The clinical team worked on the protocol simultaneously with the IXRS system to get the EDC database and screening systems ready.

"Under the pressures of speed, you explored new transformative ways of working with the IXRS IRT system through Simplify, led impeccable coordinated hand-offs to ensure one task quickly led to the next, executed in parallel rather than serially where possible, and worked together to gain decisions and address challenges," the Sponsor added.

Enrollment for the ongoing study continued uninterrupted, and the randomized, dose comparison part has been enrolling patients for some time, generating data that will inform important dosing considerations.



Rapid deployment helped keep the clinical development on schedule, supporting the shared goal of speeding delivery of much needed therapy to patients with a devastating gene mutation. The feedback from the Sponsor was nothing but positive:



It wasn't just the speed with which Almac got the system up and running, but also Almac's ability to mobilize the right team members to drive this through to completion. For us, it was a hyper-care situation, and Almac understood that. The three-week delivery was a testament to the collaboration and cohesion among all of the players, yet another important example in the power of teamwork where our sum becomes greater than us as individual parts.

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