

CASE STUDY

A COMPETITIVE RACE: ACCELERATING THE DEVELOPMENT TIMELINE WITH A MULTI-TRIAL IRT PROGRAMME

Time is always of the essence in clinical trials. But when competitors have the lead in bringing an alternative therapy to market, “the need for speed” takes on a whole new focus. This was the case with one top tier global pharmaceutical company that was just beginning its development programme for several infectious disease indications. Meanwhile, competitors for one of the compound’s primary indications were further along the regulatory pathway. Could Almac help the trial sponsor close the gap through technology to better manage patients, clinical supplies, and trial data?





WHEN THE “NEED FOR SPEED” TAKES ON A WHOLE NEW FOCUS

THE BUSINESS CHALLENGE: ACCELERATE DEVELOPMENT WITHOUT JEOPARDISING QUALITY

The sponsor had been working with Almac on other studies for several years, so engagements to develop Interactive Response Technology (IRT) for individual trials were common occurrences. But this request was driven by a degree of urgency that made it unusual: The company was eager to compress the timeline for every aspect of clinical trials that it could control. Could Almac help the sponsor accelerate its trial development—while, of course, remaining fully compliant with regulations and without compromising quality? Because of the competitive situation, all aspects of the development program were receiving high visibility within the client company. Senior management was monitoring performance with heightened attention, and work on every aspect of the compound was progressing at a fever pitch.

Meanwhile, the first two protocols in the programme included multiple dosing schedules for different patient cohorts, adding a level of complexity to the IRT system requirements.

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THE ALMAC SOLUTION: ACCOMMODATE MULTIPLE PROTOCOLS, STUDY PHASES IN ONE SET OF BASE CODE

Almac's team worked with the client's IRT, Clinical Operations and Clinical Supplies groups to understand the requirements of the first of several Phase II protocols. With such a long-range view, Almac's system designers were able to configure Interactive Voice and Web Response System (IXRS®), the industry's leading randomisation and trial supply management (RTSM) system, to accommodate multiple protocols with one set of "base code." Typically, subsequent studies come with fresh direction, requiring that development begin anew to create a separate IRT system that will support a different study design and set of endpoints—a process that normally takes several weeks.

A consolidated approach like this one, while expeditious, could raise quality concerns. It meant deviating from Almac's well-honed processes, performing certain functions out of the customary order and building the system to address future, speculative needs. The approach required that Almac developers not only foresee and consider future requirements, but design a system flexible enough to accommodate the changes that would inevitably be needed.

THE CLIENT RESULTS: TIME SAVINGS FROM CLOSE COLLABORATION AND A LONG-TERM VIEW

With the first study in the programme, the client was able to close enrolment ahead of schedule, in part because Almac's IXRS solution was deployed early, allowing enrolment to begin more rapidly. And, just as important, Almac was able to meet the ongoing and changing demands of the study without risking quality—any quality concerns were mitigated by the system's flexibility. For more than three years, the company's IXRS performance dashboards (presented in a stoplight format) have been coloured green, indicating no interruptions or performance issues.

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Because Almac teams were able to meet the client's needs so adeptly with the first two trials, the company has awarded all 18 trials in the programme to Almac. With this work has come a deeper degree of trust and a new level of partnership. Almac project managers are now consulted earlier on projects and are able to advise on more strategic, long-term issues, making recommendations based on foreknowledge of future protocols. The sponsor is benefiting from this close collaboration via more thorough systems planning, smoother transitions between study phases, and optimised timelines. Client representatives have remarked that Almac project managers operate as part of the sponsor's own team and not only understand what's required, but are able to anticipate it.

All our clients have unique needs.
That's why we develop unique solutions.

This is the **ALMACTOUCH™**



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