McKesson Specialty Health

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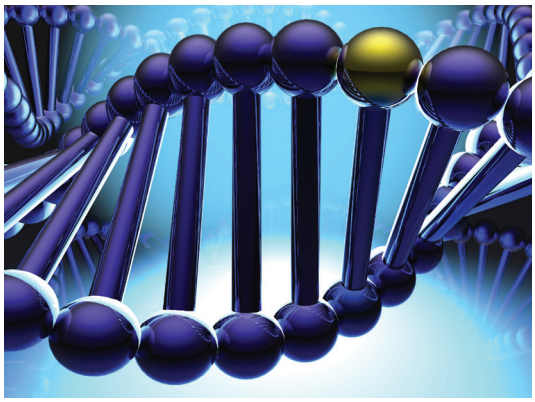
Pharmaceutical & Biotech Solutions

Accelerating cancer trials in rare tumors

An innovative approach supports the future of personalized medicine



Case Study:

A unique research model addresses a pharmaceutical sponsor's identification and enrollment obstacles for a cancer trial targeting patients with a rare tumor type.

AT A GLANCE

Need: A pharmaceutical sponsor was developing a targeted therapy for a rare carcinoma tumor and anticipated enrollment challenges. Using the traditional industry method meant that the sponsor would have to preselect and open numerous sites to screen and identify 10 patients who would meet the study criteria. The sponsor needed a different approach that would allow the efficient identification of the required patient population within the planned timeline.

STAR, coupled with the centralized services of US Oncology Research, helped a pharmaceutical sponsor realize significant efficiencies and exceed accrual expectations ahead of schedule.

Approach: To meet the unique challenges and requirements of the trial, US Oncology Research developed an approach called STAR - Selected Trial for Accelerated Rollout. STAR is an operational model that allows for pre-screening of potentially eligible subjects upfront and only opens sites where subjects are identified. The sponsor provided upfront visibility to the study protocol, which was applied across the full scale of the US Oncology Research network and allowed investigators to immediately prescreen for eligible patients. The trial was only opened at locations where eligible patients were identified. Additionally, the sponsor further streamlined trial execution by employing US Oncology Research's centralized services including budgeting, contracting, regulatory document collection and Institutional Review Board review processes.

Results: By allowing the sponsor to concentrate on sites where eligible subjects were being treated, STAR created efficiencies and reduced costs associated with site start up, management, and monitoring – saving the sponsor time and keeping the costs within budget. The STAR model allowed US Oncology Research to exceed accrual goals for the sponsor—accruing 130 percent of the enrollment target, approximately two months ahead of schedule.

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US Oncology Research