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CASE STUDY

Overcoming Operational Hurdles in a High-Stakes Stroke Trial

Introduction

Argenica Therapeutics, a biotechnology company developing novel neuroprotective therapies, partnered with ProPharma, their CRO, to conduct a Phase 2 trial evaluating ARG-007 in patients with acute ischaemic stroke (AIS) undergoing endovascular thrombectomy. The study aimed to assess safety, with preliminary efficacy assessments and pharmacokinetics included in the study design, marking a critical step toward later-stage development.

The Challenge

Argenica Therapeutics faced a complex and competitive study environment in its Phase 2 IV infusion SEANCON trial of ARG-007 in acute ischaemic stroke patients. Key challenges included:

- **Patient recruitment in the emergency care setting:** Numerous site stakeholders, including first responders, ED staff, stroke unit personnel and a clinical study team were required. Patients were often presenting out of hours, requiring sites to act quickly. This includes assessing eligibility, obtaining consent, randomizing patients, and administering investigational product, all within a narrow treatment window.
- **Unpredictable presentation of eligible patients and recruitment ahead of target:** Emergency event-driven studies pose challenges in predicting recruitment rates.
- **Data collection in emergency care setting:** Comprehensive data collection in rapidly evolving situation can lead to missing data.

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The Solution

A multi-faceted strategy was implemented to overcome these challenges:

- **Patient journey mapping:** Initial patient journey maps, reflecting various clinical scenarios, were provided to all sites. This practical resource enhanced staff confidence and supported timely, accurate randomisation during patient care.
- **Recruitment reminders:** Laminated study reminders were provided to Emergency Departments to keep ED staff aware of the study when patients arrived.
- **Data quality and oversight:** Data dashboards and analytics provided a clear picture of data status and where to allocate resources. Having only experienced CRAs meant they could be seamlessly directed to any high-volume site to provide on-site and remote support.
- **Investigator engagement in oversight and data quality:** Investigators were updated on potential concerns and given the option to pause recruitment if workloads became overwhelming. CRAs and sites worked together to ensure adequate support for quality oversight, avoiding recruitment pauses.
- **Enhancing communication:** Regular, timely updates kept sites informed about recruitment and tips for addressing challenges.

The Results

The trial was executed successfully, delivering meaningful outcomes:

- **Recruitment:** Recruited 93 patients in 12.5 months across 8 sites.
- **Primary endpoint achieved:** ARG-007 was safe and well tolerated, with no significant difference in treatment-emergent adverse events compared to placebo.
- **No drug-to-drug interactions observed:** ARG-007 could be safely administered regardless of thrombolytic use.
- **Efficacy signal observed:**
    - In a predefined subgroup of high-risk 'rapid progressors' with slow collateral circulation, a 15% mean infarct volume reduction (5 mL model-adjusted mean) was seen, consistent with the study hypothesis and informing future trial design.
    - Efficacy trend over placebo in exploratory functional endpoints of cognition, independence in daily activities, and quality of life across all patient subgroups.
    - 23% more ARG-007 treated patients reporting no cognitive impairment compared to placebo at Day 90 as measured by the Montreal Cognitive Assessment (scores > 22)
    - 8% more ARG-007 treated patients compared to placebo reporting independence in daily activities as measure by the Barthel Index (scores > 90)
- **On-time database lock and data read-out:** Database lock was achieved as planned, without pause to recruitment, supporting timely reporting of results.

Impact

This Phase 2 study confirmed safety, generated an efficacy signal in a predefined high-risk patient subgroup, with encouraging functional outcome improvements, and provided valuable insights into patient selection, dosing, and imaging strategies.

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