Science 37

Phase 2 | Rare Disease, Hepatology, Gastroenterology

Case Study: Cholestatic Pruritus in Patients with Primary Sclerosing Cholangitis (PSC)

Challenge

The trial faced significant recruitment hurdles due to the rare nature of Primary Sclerosing Cholangitis (PSC) and the strict eligibility criteria requiring patients to have moderate to severe pruritus. This limited the pool of eligible participants substantially. Additionally, the absence of any approved therapies for this condition and the presence of multiple competing trials made it more difficult to motivate patients to participate. Many potential participants were also unwilling to travel to traditional brick-and-mortar clinical sites, further shrinking the accessible patient population. As a result, recruitment fell about a year behind schedule, with traditional sites experiencing high dropout rates that threatened the study's overall progress.

Solution

To overcome these barriers, Science 37's Direct-to-Patient Site was added to the study, conducting in-home study visits that allowed patients to participate without the burden of travel. This approach extended the trial's reach beyond conventional clinical sites, making it easier for patients to enroll and stay engaged. Science 37 also activated direct outreach efforts through Patient Centra and Subject Well, platforms designed to identify and connect with eligible participants more efficiently. By partnering with hepatology specialists and launching targeted digital campaigns, Science 37 successfully raised awareness within the rare PSC community and helped drive patient recruitment to revive the study's enrollment trajectory.

Science 37 Results

Top Enrolling Site Globally

Multinational study spanning North America, Europe, Latin America, and Asia-Pacific

Enrollment Rescue Partner

Brought in to revitalize recruitment efforts and increase patient randomization

12

Patients Randomized

Scan to Learn More about Our Direct-to-Patient Site.

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FDA INSPECTED

The First & Only FDA-Inspected Direct-to-Patient Site

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Partnership with Catalent

Science 37 has partnered with Catalent to advance its Direct-to-Patient Clinical Trial Site model, ensuring study medications are delivered reliably and efficiently to participants' homes. For this study, Catalent's logistics infrastructure was tailored to meet both protocol-specific and individual patient needs, enabling secure and timely delivery of investigational therapies.

This collaboration has been especially impactful in rare disease research, where patients often face geographic and logistical barriers to traditional site-based participation. The Mirum study exemplifies this model in action. Catalent supported the study with centralized DTP storage and distribution, managing shipments from its Philadelphia facility and coordinating prescription workflows through secure channels.

The partnership also facilitated monitoring visits and streamlined returns, demonstrating flexibility in supporting small-scale rare disease trials. These operational efficiencies helped reduce patient burden and improve retention—critical factors in rare disease studies.

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The First & Only FDA-Inspected Direct-to-Patient Site