

Real-World and Late-Phase Case Study

Disease Registry With Pediatric and Adult Patients

Study Name A Real World Disease Registry for Pediatric and Adult Patients with a Rare Disease. A **12-year Registry**, with **five years follow up**.

Design and Type Observational, non-interventional, prospective, multi-center, multi-national, PASS Registry in **24 Countries** – Europe, North America, Middle East North Africa, Asia Pacific (Austria, Belgium, Canada, Czech Republic, France, Germany, Israel, Italy, Poland, Spain, Sweden, Switzerland, UK, USA, Belgium, Denmark, Finland, Norway, Turkey, UAE, Australia, Russia, S. Korea and Taiwan) in **500 sites** and with **2,150 patients**.

Purpose To fulfill FDA post-marketing commitments and the EU PASS requirements by collecting and evaluating safety and effectiveness data with the use of a biologic.



Situation

1. Various levels of affiliate involvement with site selection and site management activities in different countries.
2. Start-up in 24 countries required understanding of local and evolving requirements and different approaches.
3. Annual database cuts for manuscripts, other presentations and to fulfill safety and regulatory commitments.
4. Enrolled faster than expected.
5. Managing long-term budget planning and reconciliation across a long-term study.



Actions

1. Worked with sponsor to create dedicated affiliate engagement plans.
2. Utilized the Start-Up intelligence tool on Observational Research in PASS.
3. Syneos Health™ clinical, project management and data teams' proactive strategy planning three months prior to database transfer dates focusing on open queries and missing pages.
4. Through active monitoring of enrollment, Syneos Health identified the need for deployment of flexible resources.
5. Yearly budget and scope review meetings and reconciliation of actual versus expected.



Results

1. Clear lines of communication between Syneos Health, Sponsor Affiliates and Sites resulted in increased Site satisfaction.
2. Successfully completed timely start up activities across 24 countries.
3. Clean data available for analysis and decision making.
4. Maintaining site engagement, data quality and sponsor satisfaction.
5. Transparent budget and scope expectations and development for both sponsor and Syneos Health.

For More Information

About our Real World and Late Phase capabilities, please contact us at one of the numbers below.

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About Syneos Health

Syneos Health™ (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization. The Company, including a Contract Research Organization (CRO) and Contract Commercial Organization (CCO), is purpose-built to accelerate customer performance to address modern market realities. Learn more about how we are **shortening the distance from lab to life®** at [syneoshealth.com](https://www.syneoshealth.com).

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