

Long Term Follow-up (LTFU) Model: Efficient solutions for long term study success

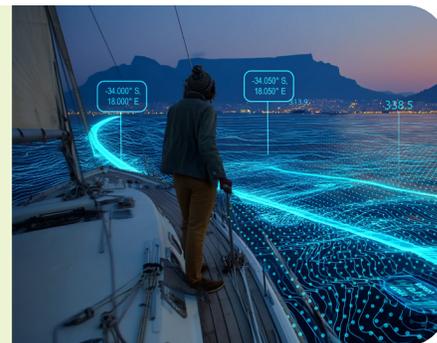


Start your FSP journey toward smarter, faster global trials

Your FSP challenges solved

What challenges are holding your business back?

- Is the cost of traditional follow-up models limiting your ability to run efficient long term safety programs?
- Are you facing difficulty maintaining compliance and oversight for long-term safety reporting across years of shifting regulations?
- Are resources constrained by the administrative burden of tracking patients across multiple sites, countries and stages of follow-up?



What is our Long Term Follow-up Model?

Long Term Follow-up (LTFU) Model is a specialized Clinical Functional Service Provider (FSP) model designed to support sponsors in managing long duration post-study activities that continue well after the main clinical trial has ended. This covers long-term operational requirements that may continue for years, such as safety monitoring, fulfilling regulatory obligations, gathering data, overseeing participants or carrying out post-trial surveillance.

Unlocking tangible benefits for your business

- Benefit from Fortrea's global FSP operational and regulatory experience, designed to deliver reliable long-term follow-up monitoring
- A tailored **LTFU Model** is personalized to your specific studies and can unlock greater predictability and cost efficiency
- Release valuable resources, enabling you to focus on new or ongoing studies

Long Term Follow-up Model in action

Challenge:

The sponsor had multiple cell therapy studies nearing completion of their primary endpoints, each requiring up to 15 years of individualized, long-term follow-up. Sites were spread across regions, patients were at different stages of follow-up and maintaining all feeder study sites created significant administrative, financial and operational burden for the sponsor.

Goal:

Streamline long-term follow-up management while maintaining required safety oversight, reduce site burden and support efficient patient transition from interventional trials into long-term follow-up protocols.

Solution:

- Implemented a central Principal Investigator (PI) model in the U.S., consolidating all follow-up under a single investigator
- Supported eConsent, PROs and tech-enabled patient engagement tools
- Used Fortrea mobile clinicians to collect required blood samples
- Expanded model planning to identify central PIs ex-U.S. for global alignment

Value delivered:

Approval

FDA acceptance of the protocol

Reduce

Yielded a significant budget reduction

Fortrea FSP: Innovative solutions, powered by experience

Our **LTFU Model** is an innovative clinical FSP solution, powered by deep industry experience.

With over 6,400+ FSP staff across 70+ countries, Fortrea is one of the largest FSP CROs in the world. Our global infrastructure supports in-country, regional, on-, near- and off-shore models, offering you flexibility and scalability. We can help you accelerate timelines, reduce risk and maximize portfolio performance where you need it most.

Backed by 120+ cross-functional relationships and a dedicated recruitment team, we bring deep knowledge and proven capabilities to every engagement. Long term, decade-plus alliances and industry recognition underscore our commitment to quality and innovation. This commitment is reflected in our continuous investment in technology, enabling us to deliver efficient, high-quality solutions.

Contact our Clinical FSP team today

Let Fortrea's **Long Term Follow-up Model** drive consistency and accelerate your business.

Contact your Fortrea representative today to start your journey toward smarter, faster global trials.

LEARN MORE at fortrea.com