CASE STUDY

A customized functional service outsourcing model for localized submissions and study start-up

At Fortrea, no single functional service provider (FSP) outsourcing model is the same. To deliver comprehensive support and meet the unique needs of the sponsor, our FSP model combines and integrates multiple disciplines and services.

This case study shares one example of how Fortrea created a custom functional service solution for a global pharmaceutical company to manage a high volume of submissions to Ethics Committees (ECs) as well as regulatory agencies.

Developing a coordinated response

The sponsor needed resources to advance their portfolio of clinical trials in both the Republic of Ireland and the UK. At the time, the UK had just completed BREXIT earlier in the year (2020).

Based on the sponsor's anticipated volume of studies, Fortrea designed an FSP model where a dedicated team would oversee and manage start-up and EC submissions while collaborating with other Fortrea teams to manage regulatory support for health authority submissions.

Starting with a pilot period for the implementation, Fortrea supported eight initial submissions as they simultaneously prepared for the complete transition by hiring staff, reassigning internal staff and providing essential training.

IMPLEMENTING FORTREA'S FUNCTIONAL SERVICE SOLUTION

To meet aggressive start-up timelines for a portfolio of clinical trials, Fortrea offered a functional service blend of support as they:

- **Manage a high volume of submissions with Ethics Committees (EC) and the UK's MHRA (Medicines and Healthcare products Regulatory Agency)**
- **Adapted to regulatory changes associated with the EU Regulation No 536/2014 for the Clinical Trials Regulation (CTR)**
- **Delivered high-quality, on-time submissions with >98% compliance**

Fortrea

After four months of the pilot, the next three months of the transition period involved handling 120 submissions in the UK and 52 in Ireland. During this time, Fortrea set up several processes to help meet the sponsor's timelines. For example, Fortrea:

- **Designed a tracking tool** specifically for this service model
- **Assigned a start-up service manager** to act as a point of contact to enhance communication and escalate any issues experienced by Fortrea or the sponsor
- **Connected and aligned study teams** as the Fortrea Start-Up Service Team managed the start-up process on individual studies and handled the day-to-day start-up operations between the sponsor's study teams and Fortrea teams
- **Incorporated metrics** to further align the service model with the focus of driving start-up timelines and delivery, as needed

Evolving to address regulatory changes

After the pilot and transition period, Fortrea's regulatory team responded to changes associated with the regulatory submissions in the UK and the EU-CTR (EU Regulation No 536/2014 for the Clinical Trials Regulation). By providing localized expertise, the team handled any associated challenges as they:

- **Acted as liaison** and provided consultative support to address regulatory issues and queries from the sponsor
- **Adjusted to regulatory processes** to ensure the sponsor met all the new requirements for submissions
- **Supported the transition** of studies affected by the EU-CTR implementation in Ireland and the "combined review" process in the UK

Evaluating collaborative practices

With the functional service model and customized processes, Fortrea helped the sponsor achieve their study start-up timelines. Some of the keys to success included:

- **Promoting open communication** to keep up to date with changes and sharing updates with the team
- **Enabling comprehensive oversight** and coordination to ensure a consistent approach with the sponsor
- **Deploying targeted training** on regulatory changes and adapting the corresponding systems and tools

Demonstrating commitment to an ongoing collaboration

Despite facing high volumes of submissions and changing regulations, Fortrea achieved >98% compliance. Based on Fortrea's commitment to expedite submissions and improve start-up timelines, the sponsor has renewed their contract and designated Fortrea as a preferred vendor. Fortrea looks forward to the ongoing collaboration as they maintain their focus on high-quality project delivery.

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Together, exceptional is possible

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