

IQVIA™ IMPROVES EFFICIENCIES AND DELIVERS CONSISTENT QUALITY WITH INTEGRATED FSP MODEL

Provides multiple functional resourcing provider (FSP) services to maximize clinical development efforts

THE CHALLENGE -

A large multi-national pharmaceutical firm needed to move from a mixed model of vendors to a standardized approach that ensured ownership and access to its clinical data at any time.

With data accessibility a critical component, the ideal partner would have strengths in multiple services, including data management, clinical monitoring, biostatistics, safety and others.

THE SOLUTION

The customer consolidated vendors in an FSP model, selecting a single vendor per country. The customer chose IQVIA™ as a key part of its 12 clinical monitoring vendors, including a mix of global and local providers.

As the provider with the largest remit, IQVIA offers dedicated monitoring and operational resources (start-up, maintenance, close out) in approximately 60% of the firm's countries, including 31 countries across Europe, North America and Asia. The specific clinical roles include CRAs, CTAs and CTA line managers.

While still working with a multi-vendor FSP model, the customer chose IQVIA to provide the most resources and volume of deliverables, based on our FSP and clinical expertise.





THE RESULTS

IQVIA worked with the customer to build a global model, delivered locally, to provide consistency across 50+ countries where the customer runs studies.

The early days of this IQVIA FSP partnership started with functional silos. IQVIA is now working in a cross-functional and integrated FSP model and offering the data visibility the customer requires.

IQVIA's performance led to the customer engaging with IQVIA for additional FSP services including centralized monitoring with global data management, biostatistics, safety, regulatory support and more. Governance supports the FSP model design and evolves continuously based on customer needs.

EVOLVING THE PARTNERSHIP

ADDITIONAL NEED: CONSISTENT DELIVERY

The customer established two critical components relevant for all FSP providers: 1) ability to predict delivery via review of outstanding data, and 2) timely access to real-time data available from the customer systems.

The customer defined strict targets for data flow (CRA data entry by sites) where 90% of all pages need to be entered within seven days. The same applied for query resolution. This was to ensure timely data entry by site staff to support:

- · Patient safety oversight
- · High quality regulatory submission
- · Timely study data quality & oversight
- Early indicator of investigator performance

IQVIA provides data flow delivery, for IQVIAowned countries, above target with an exceptionally high volume of work (~60% of all monitoring resources).

Results: Due to focused and regular operational review of monitoring and site-oriented actions, IQVIA consistently provides better results than other FSP providers, across all key data performance areas.

- IQVIA's CRF pages are submitted faster than the stated 88% goal
- Queries are resolved faster than other FSP vendors with 92% answered within the time range, exceeding the customer targets

ADDITIONAL NEED: DRIVING SYNERGIES

Given IQVIA owns the provision of several FSP functions, the customer asked IQVIA to combine multiple functions, including centralized monitoring and data management, under one provider.

Solution: IQVIA established a consolidated crossfunctional project review covering 130+ studies to ensure milestone delivery. We also developed an interservice communication strategy to increase awareness among functions, share trend analysis, and facilitate discussions between teams.

ADDITIONAL NEED: GAINING EFFICIENCIES

The customer wanted to develop a highly advanced risk-based monitoring (RBM) strategy to leverage a combination of site and centralized monitoring and enable greater efficiency in how they allocate monitoring resources and ensure quality.

Solution: IQVIA partnered with the customer to develop an RBM monitoring solution.

Results: IQVIA delivers a dedicated team of Central Monitors to support the global execution of this RBM study execution approach.

The partnership continues to progress and IQVIA remains an important partner to drive that evolution. By incorporating advanced analytics and innovative technologies to improve study quality and enhance patient safety, we are delivering higher levels of efficiencies for the customer.



97% on-time submission (vs. 90% goal)