PPD® LABORATORY SERVICES CASE STUDY

Leveraging the Preclarus® Technology Portfolio to Generate Cleaner Data, Faster and with Reduced Site Burden

BACKGROUND

A leading pharmaceutical company engaged PPD, Thermo Fisher Scientific's clinical research business, to gain insights into site performance, drive efficiencies in future trials, and reduce site burden and time spent investigating and resolving lab data discrepancies (queries). In the customer's portfolio of 41 trials, 413,000 samples were received. Eighty-one percent of the samples (336,825) were submitted with traditional paper requisitions and 19% with electronic laboratory requisitions (eReqs). From those samples, 31,293 lab data queries were generated by sites—with each query needing an estimated five minutes of hands-on time to resolve*. Queries from these trials resulted in the equivalent of 156,465 minutes, which is 2,608 hours or 325 days to clean the data. (Figure 1)

Figure 1: Queries with partial use of Preclarus electronic laboratory requisition (eReq)

41	413K	31K+	5 min	>2,600	≈325
trials	samples	queries	per query*	hours	business days

***Note:** Not including time to research the issue and determine resolution.

OBJECTIVES

- Improve the efficiency and quality of data captured from sample lab requisitions
- Reduce site burden
- Provide trial managers greater visibility into sites and address issues in real-time and head off downstream impacts

SOLUTION

To meet the objectives, the central lab team recommended the customer use PPD's proprietary Preclarus® investigator site portal with the eReq functionality. The site portal allows sites to electronically submit patient and sample data prior to shipment to the lab through the eReq functionality. This approach to capturing patient and sample data at the time of collection enables real-time quality control to reduce data queries, eliminates paper requisitions and error-prone manual data entry and improves overall sample chain of custody.

PPD customers who have used eReq across hundreds of trials have experienced these benefits. Data from a customers' two recent studies (Figure 2) shows that the use of eReq resulted in far fewer queries. Sites enrolled in Study 1 did not use eReq while the same sites enrolled in Study 2 used eReq for 94% of the samples.

The two studies used the same two sites (A and B), a similar number of samples and were similar in complexity. The customer analyzed total samples received, the number of samples requisitioned by paper vs. eReq and the total number of queries. In Study 1, 88 queries were generated from 888 samples collected (10%). An equivalent number of samples were collected in Study 2 and generated 17 queries (2%), **a reduction of more than 80%** of queries generated with eReq.

Lab Query Management in Clinical Trials

Consolidation and standardization of data during clinical trials from several sources is necessary to increase operational efficiency and expedite regulatory review. With lab data typically comprising 70% of the data required for regulatory submission, the volume of lab data queries and time required to resolve them can have a significant impact on study timelines.

RESULTS/IMPACT

Queries are generated in response to issues arising because of the specimen collection process, including missing paper requisition forms and missing or incorrect patient data. EReq enables customers to overcome queries that arise from lack of good documentation practices (GDP) by quality checking requisition information as it is being entered into the system so that errors can be corrected in real-time and not require a separate query for resolution.

In Figure 2, the two sites experienced an 80% reduction in lab data queries when eReq was used. Extrapolating these results to our test case of 41 trials would reduce the number of queries from more than 30,000 to about 6,200. The resulting time savings (approximately 260 days) is also significant (Figure 3).

Figure 2: Queries with and without eReq from two studies and two sites

	Site	Total Samples Received	Total Queries	eReq Samples	Paper Req Samples	eReq Usage %	Query / Samples Received
Study 1	A	729	61	0	729	0%	8%
	B	159	27	0	159	0%	17%
	A & B	**888**	**88**	**0**	**888**	**0%**	**10%**
Study 2	A	655	12	612	44	93%	2%
	B	107	5	106	1	99%	5%
	A & B	**762**	**17**	**718**	**45**	**94%**	**2%**

Through interactive web portals, PPD team members can access and customize dashboards that are shared with the customer's clinical teams. These include:

- The **Project Management Dashboard**, which sheds light on patient enrollment and collection kit inventories.
- The **Site Compliance Dashboard**, which allows comparative evaluation of sites in real time.

Preclarus enables clinical teams to access data specifically tailored to their role and receive instant notifications and alerts of data anomalies. By closely monitoring site performance, the PPD and clinical teams identify trends and address trial deviations, improving overall data quality and trial efficiency.

Figure 3: Extrapolation of results from Sites A and B (Figure 2) to our 41-trial test case (Figure 1) shows the potential reduction in queries and time savings with use of eReq

***Note:** This does not include the time needed to research the issue and determine resolution.

CONCLUSION

Use of the Preclarus system, including utilization of eReq, greatly reduces the appearance of queries in clinical trial data sets, lessens site burden, accelerates data lock and results in significant time savings. In conjunction with the full suite of Preclarus tools, customers who leverage PPD's trial management expertise can make necessary process adjustments more efficiently—and ultimately improve clinical trial outcomes.

With increased use of eReq, queries can be reduced up to **80%.**

PROJECTED IMPACT OF PRECLARUS AND EREQ FOR 41 TRIALS TEST CASE

- **Reduced queries by 80%**
- **Saved 260 business days**
- **Reduced site burden**
- **Improved data quality**
- **Improved clinical trial efficiency**
- **Accelerated database lock**

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