

Timelines, Tight Timelines, And Even Tighter Timelines In A Phase I Environment

RPL DataManagement is a preferred data management provider for several biotech and pharmaceutical companies. This preferred provider status is something we are proud of and we aim to adapt our working processes to meet our clients needs, providing this does not compromise the integrity of the clinical trial data.

The Challenge

One of our clients with whom we have preferred provider status had placed a group of studies with RPL DataManagement, all of which had tight yet achievable timelines. Three months into one of the studies we were approached by this client to see if we could reduce the database lock timelines from 4 weeks to just 11 days, as the data was required to determine if the drug's development would move into Phase III.



The challenge was familiar; the degree of reduction in timelines was something new. Immediately upon looking at our internal workload calendar we were able to determine that 2 other database locks were planned for the same week. This information was immediately relayed to this client and we told them we would need to do a thorough investigation of the three database locks and staff availability to determine if we could change the scope so drastically.

Comment:

“Rapid and constant communication with the client was key at this stage so they knew we were dealing with their request efficiently and that we were making a serious attempt to deliver on their request. In these situations it is essential not to panic and make promises you cant deliver on just to keep a client happy. Data management, statistical analysis and report writing is a very methodical business and your approach must mirror this method.”

All deliverables for the study in question had to follow the clients specifications, such as the format of data sets, layout of tables and listings, and the format and content of the Clinical Study Report. Due to our long standing relationship with this client this did not pose a concern as all staff were familiar with the clients specifications.

Adapting to change is nothing new to RPL DataManagement. Each client has preferred methods for recording, analysing and reporting data. Understanding these preferences and being able to adapt them to our accredited standard processes is a skill we apply for each study we manage.

Comment:

“RPL DataManagement do have a standard set of templates for all components of the data management process from CRF design through to final reporting. We can use our accredited standard processes and templates in cases where a client does not have a preference or their own standard templates.”



How we made the request a reality

Coordinating the activities leading up to database lock was the most challenging part of the request. A coordinated plan was already in place, however the deliverable dates throughout the process had to be modified to meet the new timelines. This had to be achieved without compromising accuracy and quality in conjunction with ensuring we did not slip up on timelines for the database lock of the other two studies.

Comment:

“The RPL DataManagement team are a close knit group of data management professionals with an unparalleled enthusiasm and commitment to their work. Each member of the team immediately offered themselves up for the additional work and two members of staff who were due to be on annual leave delayed this leave period by a week in order to help out their colleagues.”

A detailed CRF retrieval plan was swiftly put together with the study monitors. In order to achieve the goal, CRF pages were collected immediately following the each subjects last visit. These pages were monitored straight away before being sent through to data management for processing.

Query turn around times in a normal situation range from 2-5 business days, dependant on the study timelines. However in this situation queries had to be turned around within 24 hours or less, irrespective of the day of the week. A detailed plan including staffing rotas was put in place to ensure this could be achieved. In addition, all electronic transfers from the third party laboratory had to be carefully planned in order to ensure all data was received with enough time to resolve any laboratory queries. All tasks typically associated with database lock were scheduled by the hour rather than by the day.

A schedule for all of the above was put together in less than two business days. The client was involved in this scheduling process each step of the way to guarantee we maintained their standards and to ensure they were kept fully aware of the plan so they could report back internally to their associated teams.

Comment:

“Our consistent dialogue with the client during this interim planning stage was essential and ensured their confidence in our ability to deliver was maintained. It also meant that when it came down to getting on with the database lock they left the team to get on with the task at hand, thus helping to increase the time efficiency needed to complete the undertaking.”

The Final Result

The customer entrusted us to deliver according to their standards under extremely tight timelines. Proudly we were able to deliver database lock 11 calendar days, (as requested), following last patient last visit. The final Clinical Study Report was delivered 94 calendar days after DBL, almost three weeks ahead of schedule. The other two studies scheduled for database lock in the same week were locked according to their own schedules.



The net result was a very happy client who understood the efforts RPL DataManagement went to make their request a reality. This client has subsequently placed three further studies with us in the first quarter of 2009.

Comment:

“The luxury of having all staff involved in the study in one location certainly helped to make the planning and subsequent delivery of this undertaking more readily achievable. RPL DataManagement prides itself in maintaining the entire team in one location rather than spreading the work globally. Some data management providers will outsource some components of data management around the globe as a means of introducing perceived cost efficiencies, however implementing this strategy can make tasks such as the one we were asked to perform in this instance prohibitive. RPL DataManagement maintain the model they employ is the most flexible for their clients, allowing them to perform tasks others would be pushed to match.”

**We know we can help your business. We always rise to the challenge
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