Scenario Experience

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Does your experience match the scenario flow-chart?

Sanofi/Covance response:
Scenario 1: The SEND datasets generated were prepared after the report was finalised/approved as a data-exchange exercise, so the workflow differed greatly. Datasets were created by the CRO, the Sponsor reviewed them, and interacted with the CRO to finalise the datasets. For the most part.

MPI Research, w/ Lilly et al. response:
Scenario 1: The "CRO generates final datasets" step is not generally performed if everything was fine from the previous round.
Scenario 2: An additional path is required when the Sponsor provides PK files in SEND format. Handling differs depending on whether Sponsor conventions match the CRO's, making integration either plug-and-play or requiring extra manipulation.

Do you have any experiences with re-work initiated by an FDA request? How long did it take?

Sanofi/Covance response:
This was not done as the datasets were not part of a current submission.

MPI Research, w/ Lilly et al. response:
Use of the OpenCDISC Validator and resolving issues removed the need for FDA feedback. During the pilot, Sponsors required dataset re-generation per validator findings. This wrapped up in a few days.

What were the challenges and solutions for the scenarios?

Sanofi/Covance response:
Addressing study numbering, animal numbering, and conventions for arms and sets defined by the Sponsor.

MPI Research, w/ Lilly et al. response:
The biggest challenge is mapping trial design and exposure for non-boiler-plate cases, which must now be defined using an interface.

What would you want to do differently in the future?

Sanofi/Covance response:
(No response provided.)

MPI Research, w/ Lilly et al. response:
Work through "template" cases for common designs.

What would you need to work out in advance to ensure a smooth process?

Sanofi/Covance response:
Defining expectations ahead of time would reduce rework and dataset questions.

MPI Research, w/ Lilly et al. response:
With expectations defined early, everything goes smoothly.

Were there any areas that you were unable to resolve?

Sanofi/Covance response:
No.

MPI Research, w/ Lilly et al. response:
No.

Timing — How long did it take?

Sanofi/Covance response:
Approximately 1 week, depending on complexity and number of endpoints.

MPI Research, w/ Lilly et al. response:
Packaging takes a few days to a couple of weeks depending on complexity.

What activities determined the project length (critical path)?

Sanofi/Covance response:
– Complexity of study design
– PK data inclusion

MPI Research, w/ Lilly et al. response:
– PK data
– Complexity of study design
– Complexity of lot regimen
– Manually collected data

Do you have any guides for estimating effort?

Sanofi/Covance response:
No.

MPI Research, w/ Lilly et al. response:
Begin with a baseline tox study and add workload chunks for PK or unusual designs.

How many times have you done this? Is this the first experience?

Sanofi/Covance response:
1 study with 1 CRO.

MPI Research, w/ Lilly et al. response:
20–25 studies for about 10 Sponsors.

If you have done this several times, what was the learning curve?

Sanofi/Covance response:
N/A

MPI Research, w/ Lilly et al. response:
A few studies to hit a stride; special designs create additional bumps.

How long did each phase take?

Sanofi/Covance response:
A few hours to several days.

MPI Research, w/ Lilly et al. response:
Estimation: 0–1 hour
Doing/closing: hours to days
IT support: 0–2 hours

What tools (software) did you use?

Sanofi/Covance response:
CRO tool.

MPI Research, w/ Lilly et al. response:
Custom add-on to reporting solution.

Were any domains not provided? Why?

Sanofi/Covance response:
Yes — some domains are not collected or cannot be provided.

MPI Research, w/ Lilly et al. response:
No, but non-GLP studies may omit domains to reduce costs.