Scenario Experience

Question	Sanofi/Covance	CRL	MPI Research, w/ Lilly et al.
Does your experience match the scenario flow-chart? >If not, where does it differ? Which way is better? >If x happened instead of y, what was the impact? Is there a recommendation from these differences?	Scenario 1: The SEND datasets generated were prepared after report was finalized/approved as a data exchange exercise so the workflow differed greatly. Data sets created by CRO, Sponsor reviewed datasets and interacted with CRO to address questions to finalize the datasets.		For the most part. **Scenario 1:** The "CRO generates final datasets" step is not generally performed if everything was fine from the previous round. **Scenario 2:** there is an additional path necessary to split the case where the Sponsor provides the PK files in SEND format. The handling varies whether or not the Sponsor adheres to the CRO's conventions on such things as the USUBJID formation, representing either a plug-and-play situation or one requiring additional manipulation to incorporate with the main package.
Do you have any experiences with re-work initiated by a request from the FDA. How long did the process take, and what can you share about the experience?	This was not done as the datasets were not part of a current submission.		Use of the OpenCDISC Validator with resolution of any issues it uncovered removed the need for a feedback loop with the FDA. During the pilot (and before a publicly available validator), there were cases where the sponsor was actively working with the FDA and required re-generation of datasets per some validator findings. In this case, the process went pretty smoothly, wrapping up in a few days. However, that was not "real" production.
What were the challenges and solutions for the scenarios?	How do we address study numbering and animal numbering conventions as well as conventions for arms and sets that have been defined by Sponsor		The biggest challenge is mapping trial design and exposure for non-boiler-plate cases. This is something that previously did not have to be done, and has to be learned and then defined by the preparer using an interface.
>What would you want to do differently in the future?			Work through "template" cases for some of the more common designs.
>What would you need to work out in advance to ensure a smooth process?	Expectations that were defined ahead of time would reduce rework and questions about datasets.		With expectations set ahead of time (decoupled from the study timeline), everything goes smoothly.
>Where there any areas that you were unable to resolve?	No		No.
Timing >How long did it take?	It took Covance approx. 1 week to prepare dataset this would also depend on the complexity and number of endpoints		Packaging of a submission takes between a few days to a couple weeks, depending on the complexity of the contents and the number of endpoints.
>What were the activities that determined the length of the project (critical path)?	Complexity of study design and if PK data part of datasets could increase the timeline PK data		Complexity of study design Complexity of lot regimen Manually collected data (e.g., paper or Excel) PK data
>Do you have any guides on estimating the effort to do the work?	No, not at this time		Starting with a barebones tox study (inlife, path, clinpath), estimate the total work for that. Then think through any add-on sets of endpoints or circumstances which equate to a chunk of work, such as adding pk, or adding a crazy study design, etc. This can give you a rule of thumb for estimating the effort behind individual studies.
>How many times have you done this? Is this the first experience?	1 with 1 CRO		20-25 studies for about 10 Sponsors
>If you have done this several times, can you describe the learning curve?	N/A		It takes a few studies to hit a stride. Special cases that pop up (such as a special study design that hasn't been done in SEND yet) can represent an additional bump as they come along.
>How long (calendar time, person hours) did each phase take? (determining what needs to be done, doing the work, confirming /closing the project)	Few hours to several days		Estimation: 0-1 hour. Doing the work/closing: Anywhere from a few hours to several days for a reports person, and 0-2 hours for an IT resource to assist.

What tools (software) did you use?	CRO tool		Custom-developed add-on to reporting solution.
Were any domains not provided? Why?	Yes, some domains are not collected while others currently cannot be provided by CRO		No, but there could be cases where they are not, to cut down on costs for non-GLP studies where the Sponsor just wants key data to subsume into their own system for discovery/mining purposes.