

Managing never ending extension trials

DH01

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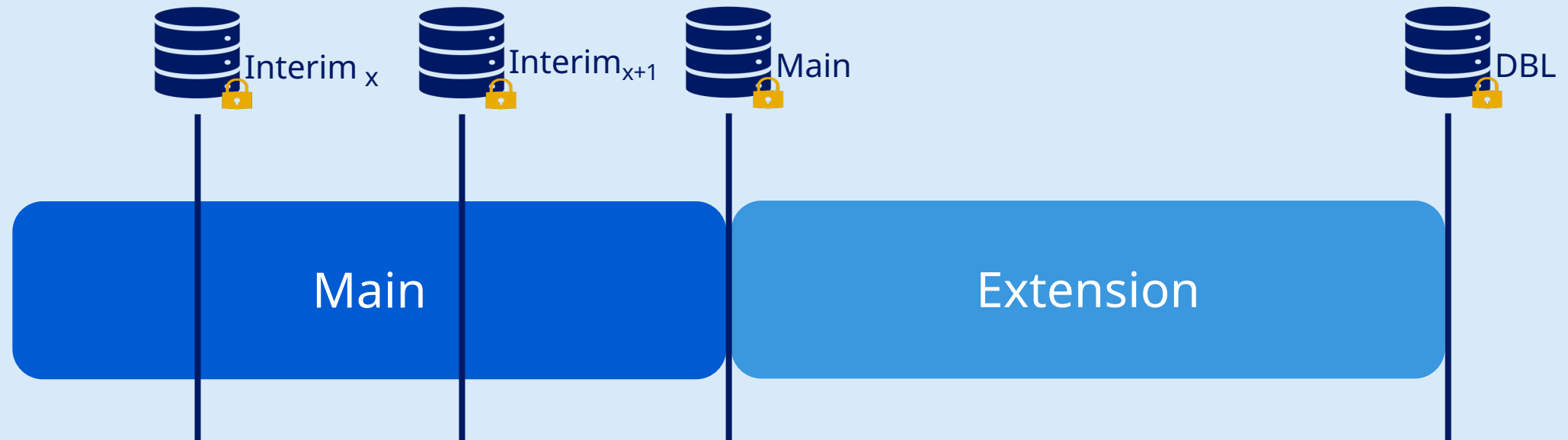
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1. Introduction
2. Interim Analyses
 - Handling data
 - Handling folder structure and programs
3. Summary

Agenda

Introduction



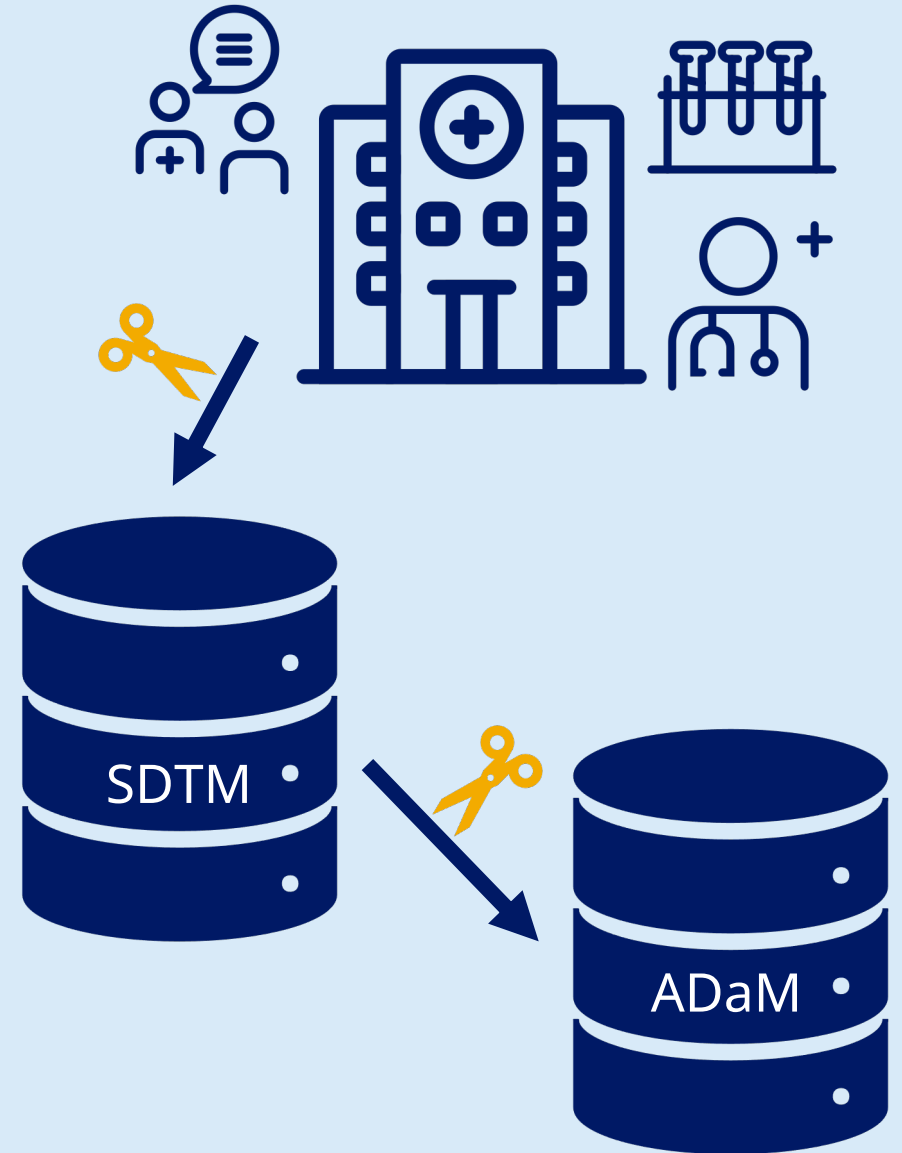
- Managing long-running Extension studies can be a challenge

A need to:

- Align on the data in scope for each interim – How to cut it right?
- Manage programs to ease backwards assessment of late identified errors

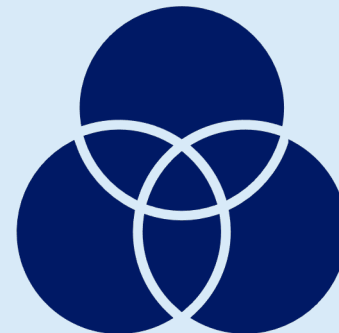
Data handling

- A growing number of studies with complex designs
→ An increasing need to cut data in Extension Studies for interim analyses
- No standard way of cutting data
ADaM?
SDTM?



Requirements

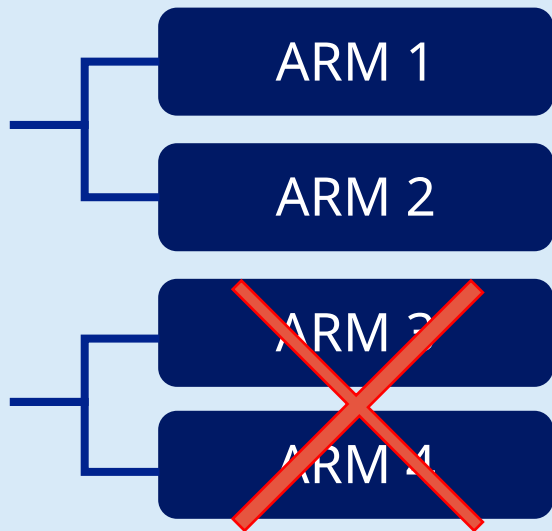
- 1) A standardized setup – but flexible enough to match requirements of the study in scope
- 2) Transparency on how data is cut
- 3) Easy to apply to new data and compare data changes between interims



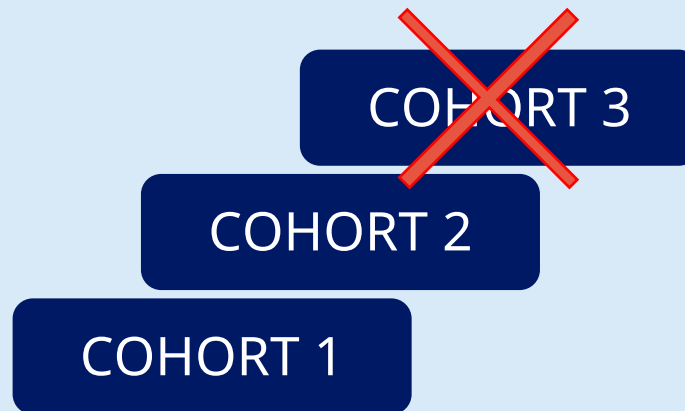
Standardized – but flexible



Example 1



Example 2

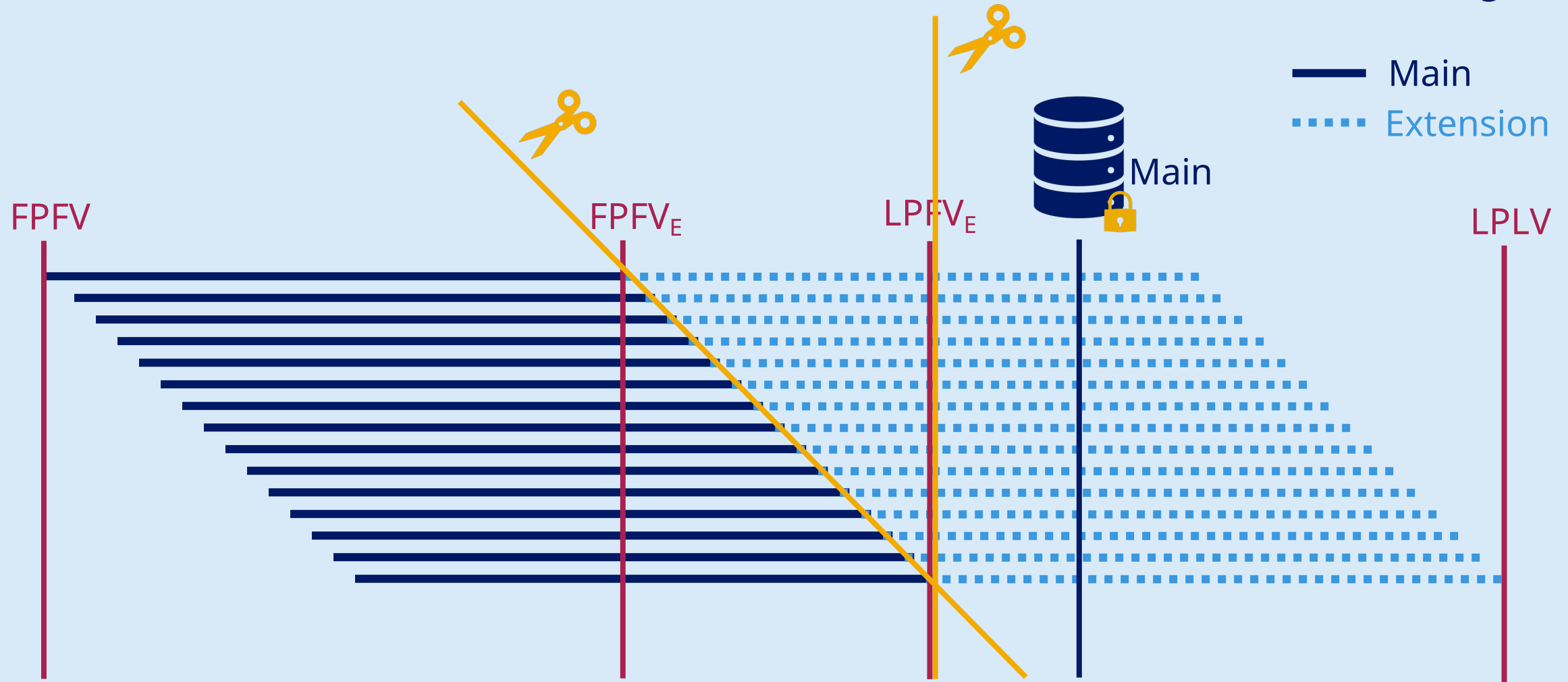


Example 3

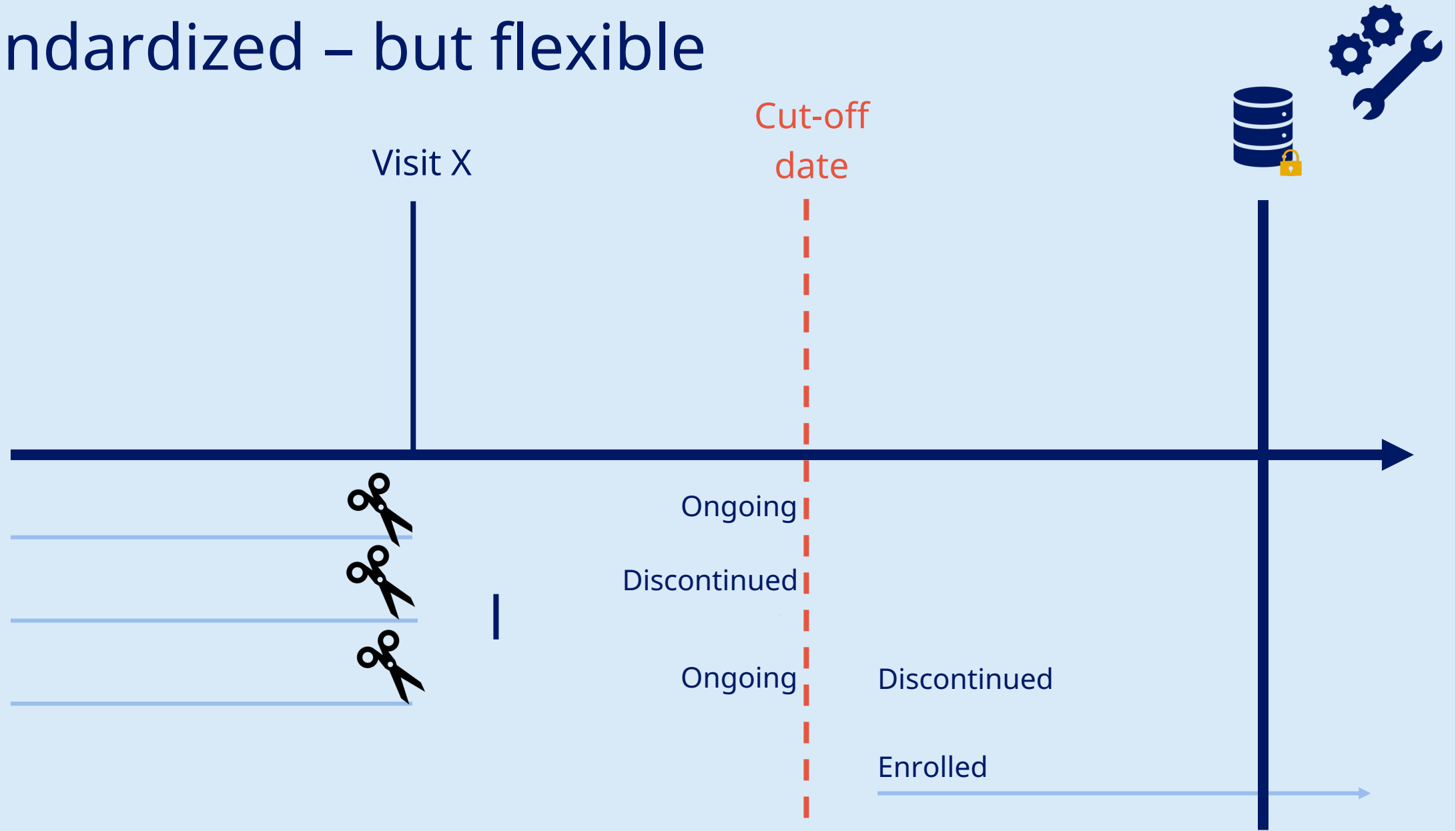


Participant List

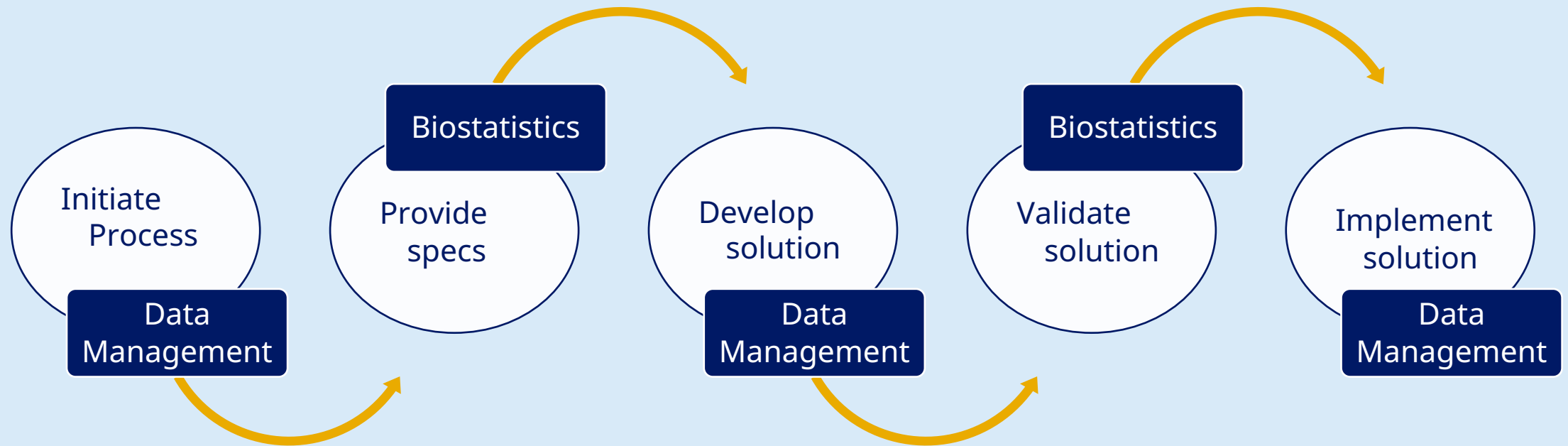
Standardized – but flexible



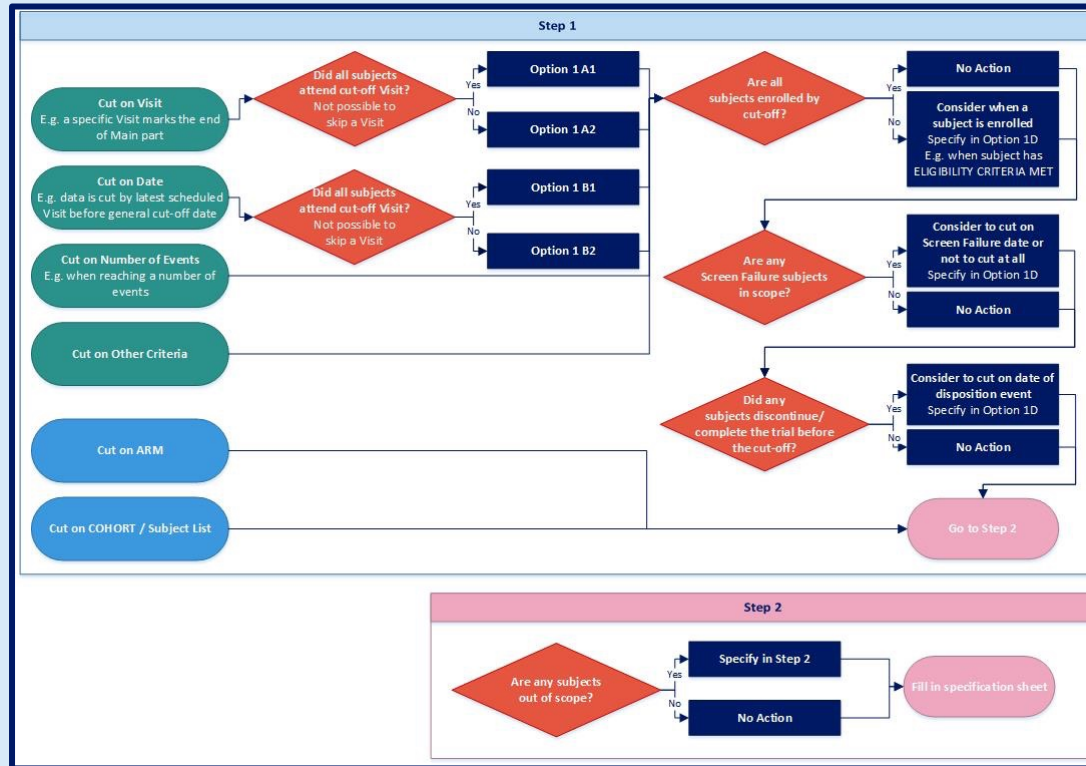
Standardized – but flexible



Transparency



Transparency



Form for data entry, likely related to the trial cut-off process.

Fields include:

- Title: nn1234
- Trial: 4567
- Milestone Type: Interim DBL
- Deliverable Date: 31/10/2022
- Cut-off Type: Cut on Date: Actual Visit on/before Cut-off Date (SVSTOFC)
- VISITNUM: [Empty]
- Cut-off Date: 28/10/2022
- Specify Criteria: [Empty text area]
- Created By: VSQH (Amy, Shuk Man Heung)
- Created: 28/09/2022 16:04
- Attachments: There is nothing attached. Attach file

Apply and compare



Documentation of data cut

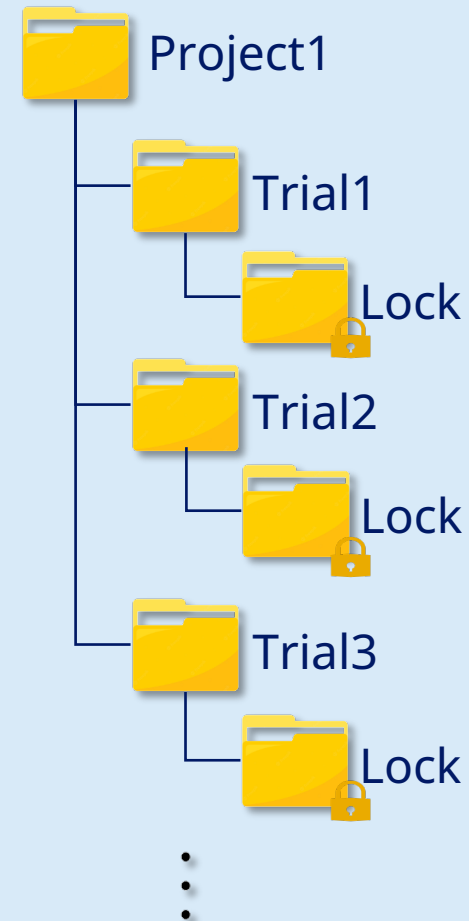
- Specification stored in SDTM programming specification document
- 3 supporting datasets
 - Subject-level cut-off criteria
 - Details of cut-off records
 - Summary of data cut-off



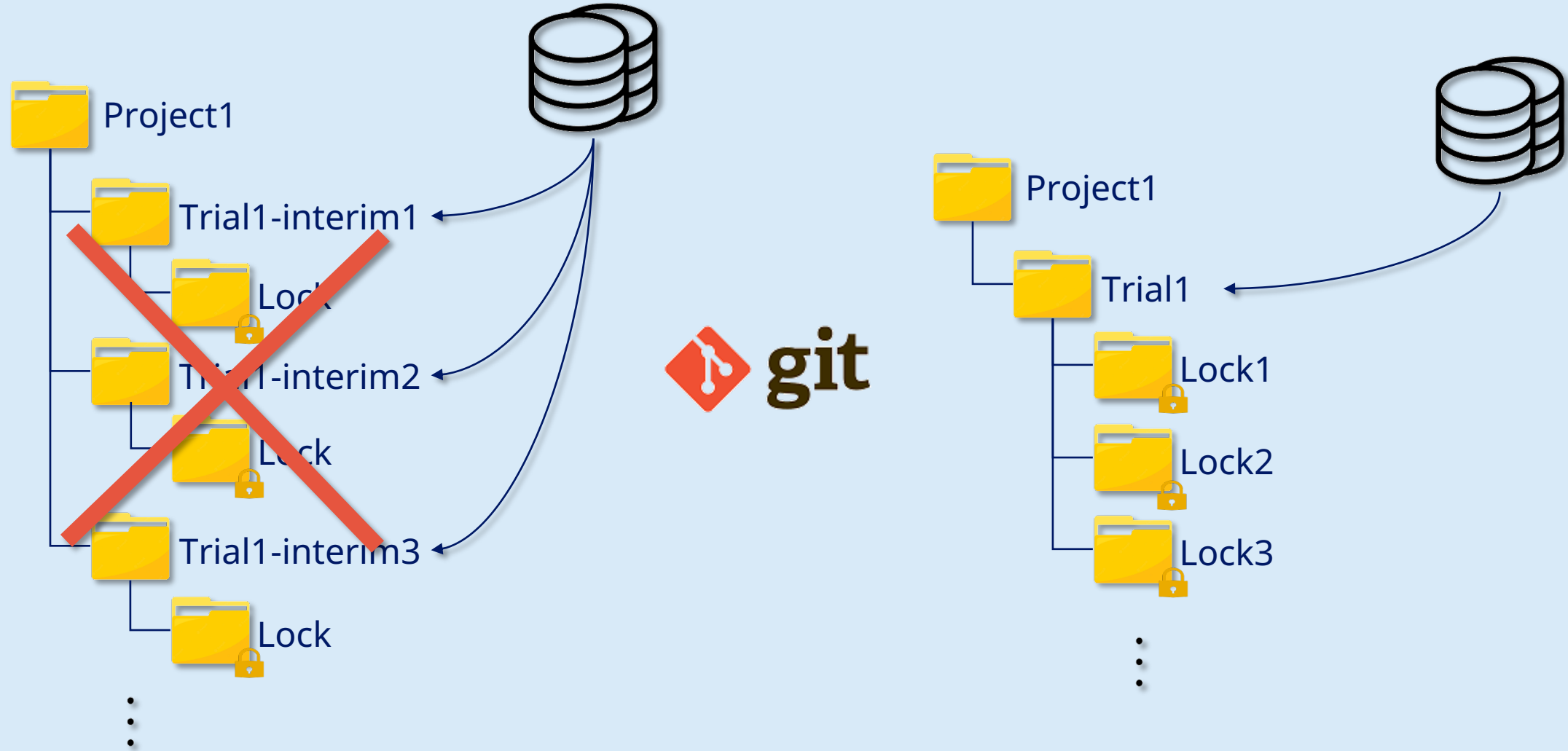
Subject		Criteria	
	Domain	Record	
		Domain	Count

Streamlining folder and program setup

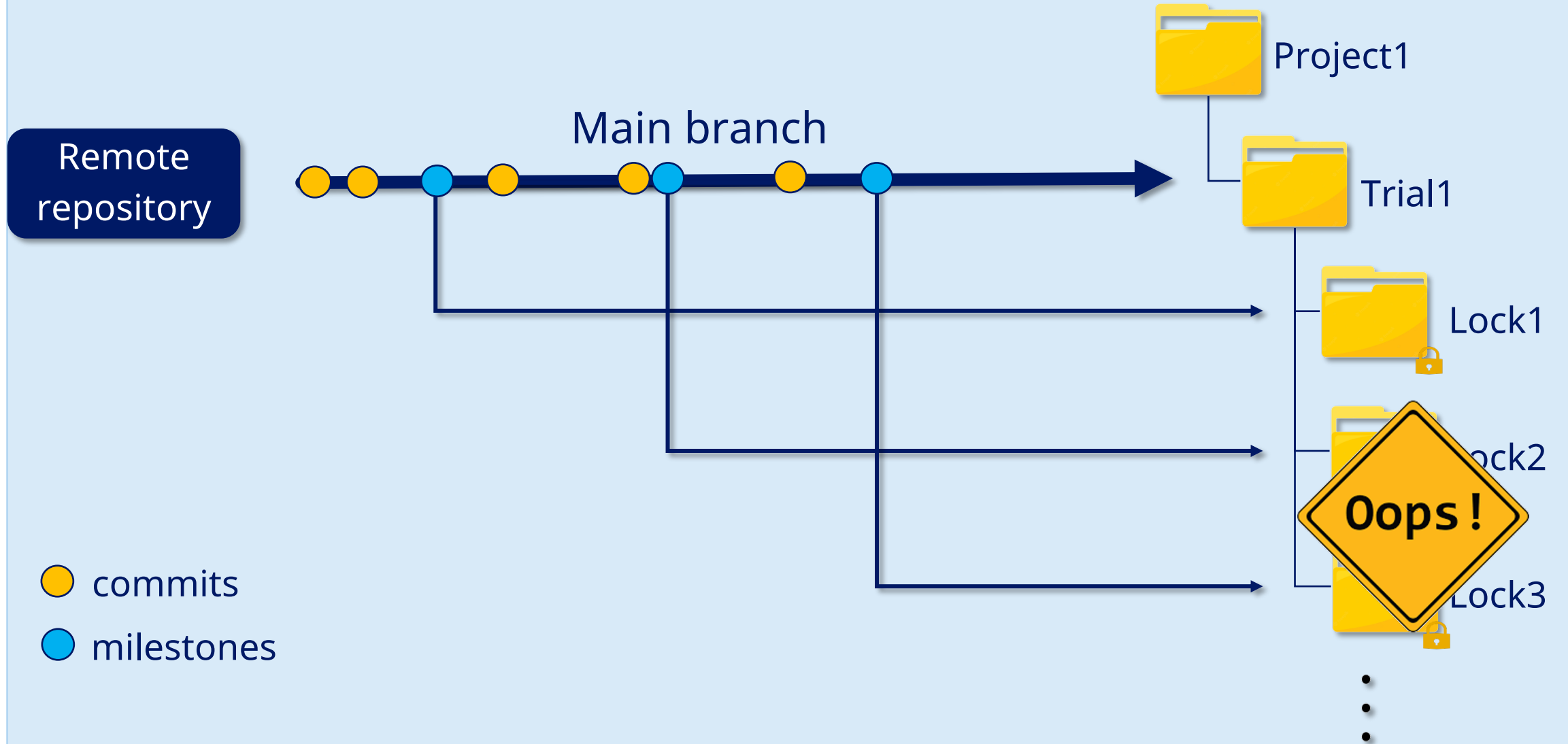
- The usual setup is one project with many individual trials (covering one reporting period)
- Extension trials have become more common
- Current setup does not facilitate such trials very well



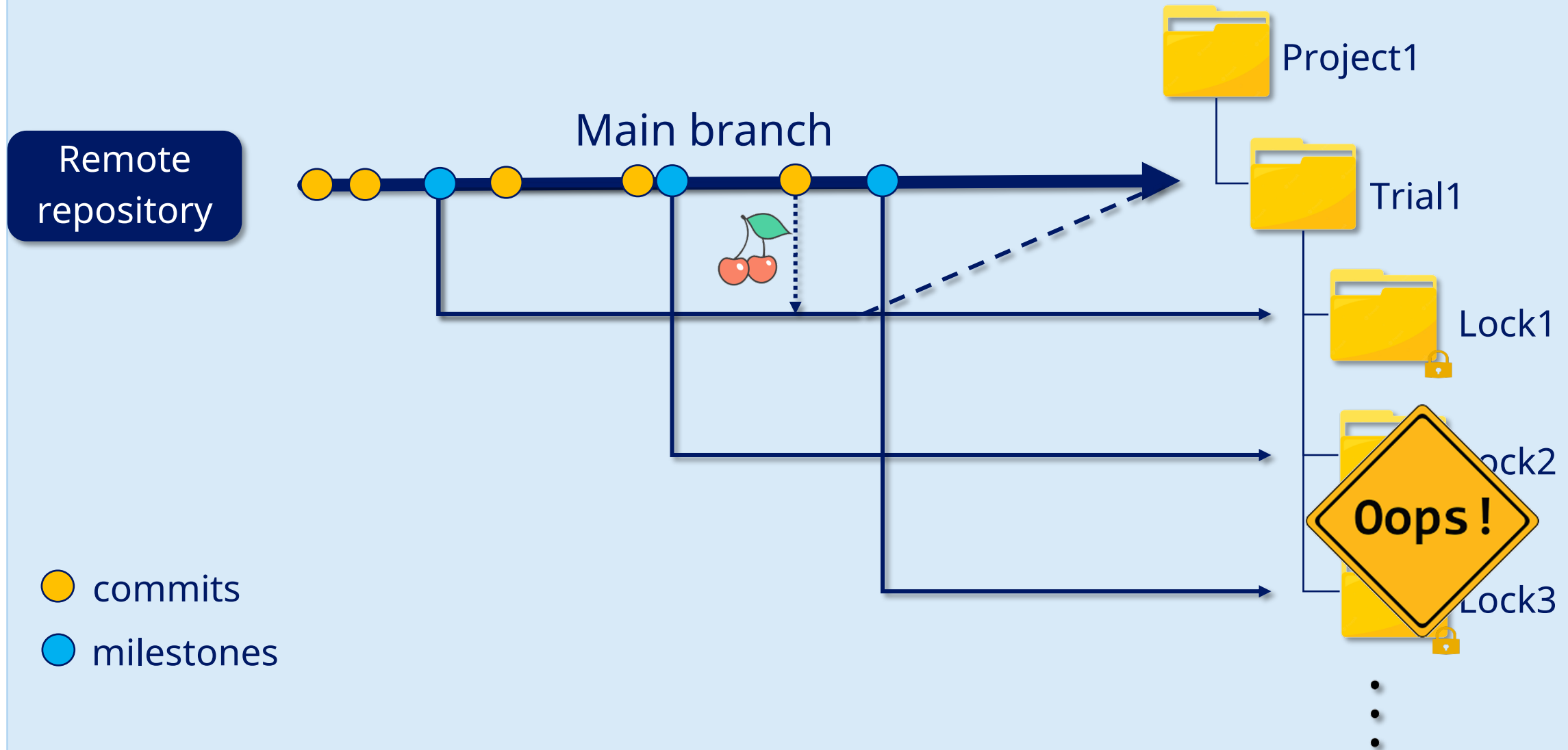
Flow



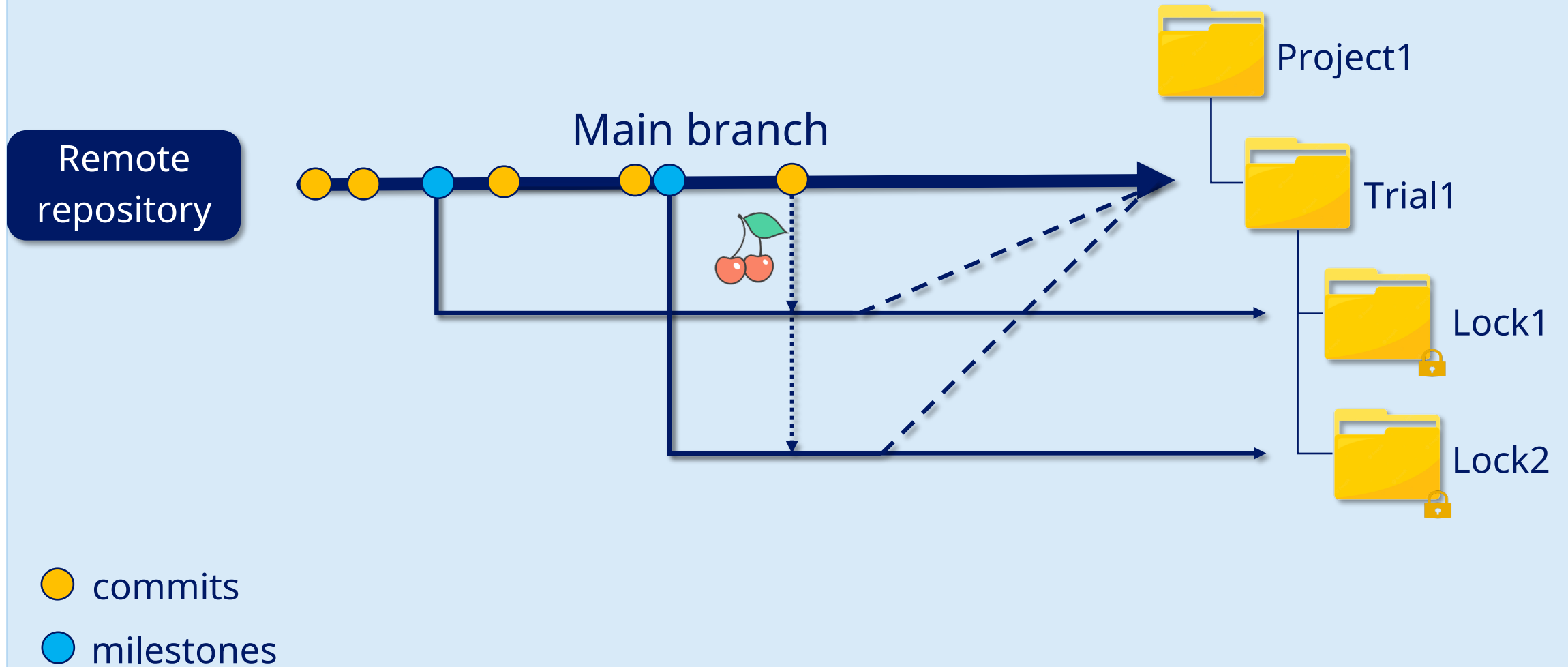
Prog flow



Prog flow



Prog flow



Summary

- Managing never-ending Extension trials with interim analyses can be challenging
- We now have:
 - A solution for handling data
 - Standard, but flexible
 - Transparent in process, responsibility and documentation
 - Easy to apply and compare
 - A solution for handling program and data flows
 - Decreasing the amount of manual work
 - Keeping track of programming changes throughout the trial
 - Easy to evaluate consequences of updates

Thank you for your attention



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