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<th>USUBJID</th>
<th>ASEQ</th>
<th>AETERM</th>
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**Not Enough Data?**
Why extension studies?

- Gather more patient-years of drug exposure
- New perception of the main study adverse effects
- Subjects get continued access to an effective but otherwise unobtainable drug
- However they do have their share of ethical complications
Challenges
USUBJID
Same ID - continuing subjects; STUDYID changes
ORIGIN in Define XML?

Demographics

What is the Reference date for the subject in extension study?
Gap between studies

What AGE should be populated in DM for extension study?

SDTM Challenges
SDTM Challenges

- Define AE in the extension study?
- AEs recorded in Main study be considered as AEs in extension study?
- AE was Resolved before start of extension study? - Is that MH for extension study?
- Will the AEs starting between the Main study and extension study be considered as Treatment Emergent AEs?
SDTM and ADaM Challenges

Main Study
Baseline / Visit Specific Data

Extension Study
SDTM

Extension Study
ADaM
3 ways to alleviate these pain points

- Answers to these questions, discussed and analyzed – Protocol Stage
- Proper traceability from EDC to CSR – Define.XML and SDRG
- Documentation of the decisions
Extension Studies - CDISC Submission Challenges and Scenarios

Thank You