

Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AEDECOD	AEPRESP	AEBODSYS	AESEV		AESER
1	ABC123	AE	123101	1	NAUSEA	Nausea	Y	Gastrointestinal disorders	SEVERE		N
2	ABC123	AE	123101	2	VOMITNG	Vomiting	Y	Gastrointestinal disorders	MODERATE		N
3	ABC123	AE	123101	3	HEADACHE	Headache		Nervous system disorders	MILD		N
Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AEDECOD	AEPRESP	AEBODSYS	AESEV		AESER
1	ABC123	AE	123101	1	NAUSEA	Nausea	Y	Gastrointestinal disorders	SEVERE		N
2	ABC123	AE	123101	2	VOMITNG	Vomiting	Y	Gastrointestinal disorders	MODERATE		N
3	ABC123	AE	123101	3	HEADACHE	Headache		Nervous system disorders	MILD		N
Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AEDECOD	AEPRESP	AEBODSYS	AESEV		AESER
1	ABC123	AE	123101	1	NAUSEA	Nausea	Y	Gastrointestinal disorders	SEVERE		N
2	ABC123	AE	123101	2	VOMITNG	Vomiting	Y	Gastrointestinal disorders	MODERATE		N
3	ABC123	AE	123101	3	HEADACHE	Headache		Nervous system disorders	MILD		N
Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AEDECOD	AEPRESP	AEBODSYS	AESEV		AESER
1	ABC123	AE	123101	1	NAUSEA	Nausea	Y	Gastrointestinal disorders	SEVERE		N
2	ABC123	AE	123101	2	VOMITNG	Vomiting	Y	Gastrointestinal disorders	MODERATE		N
3	ABC123	AE	123101	3	HEADACHE	Headache		Nervous system disorders	MILD		N
Row	STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AEDECOD	AEPRESP	AEBODSYS	AESEV		AESER
1	ABC123	AE	123101	1	NAUSEA	Nausea	Y	Gastrointestinal disorders	SEVERE		N
2	ABC123	AE	123101	2	VOMITNG	Vomiting	Y	Gastrointestinal disorders	MODERATE		N
3	ABC123	AE	123101	3	HEADACHE	Headache		Nervous system disorders	MILD		N

Not Enough Data?

Phuse - Annual Conference 2017



Extension Studies

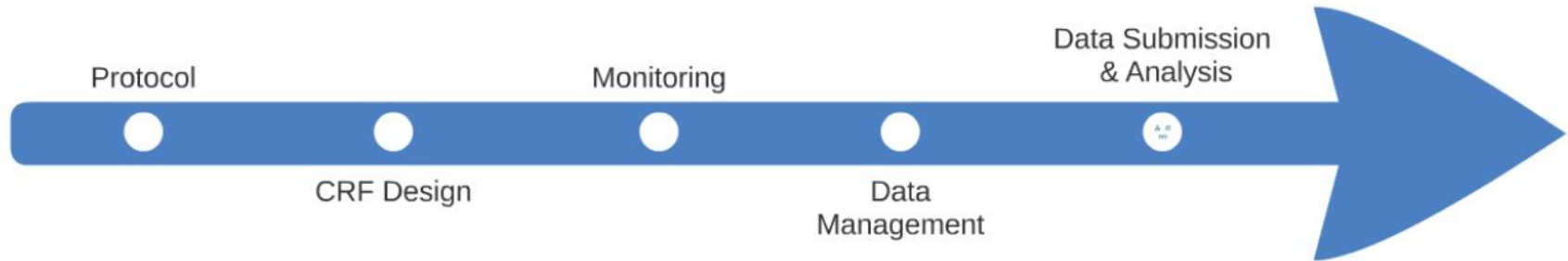
CDISC Submission Challenges and Scenarios

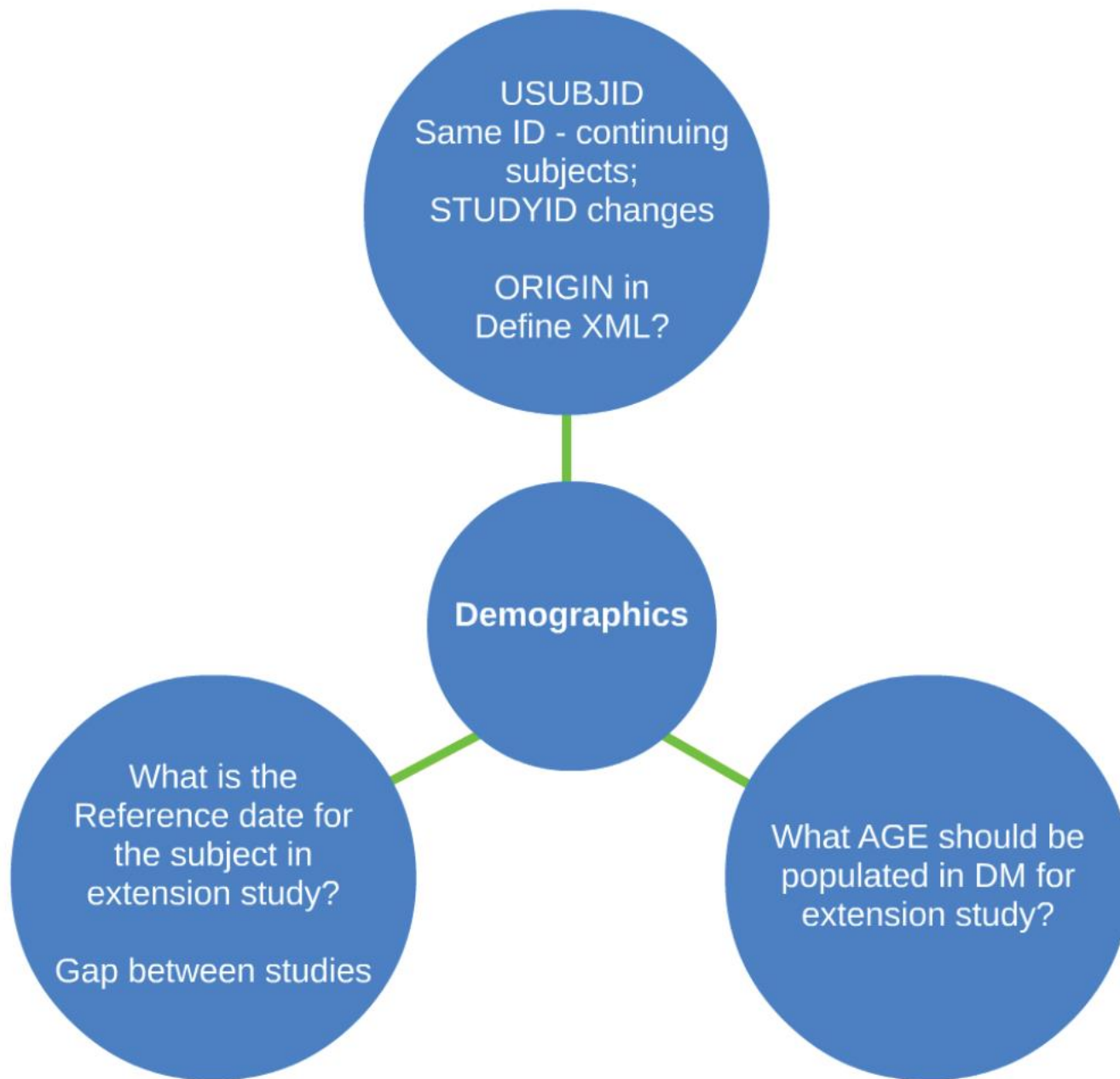
Sachin Bharadia
Director - Biometrics, Europe

Why extension studies?

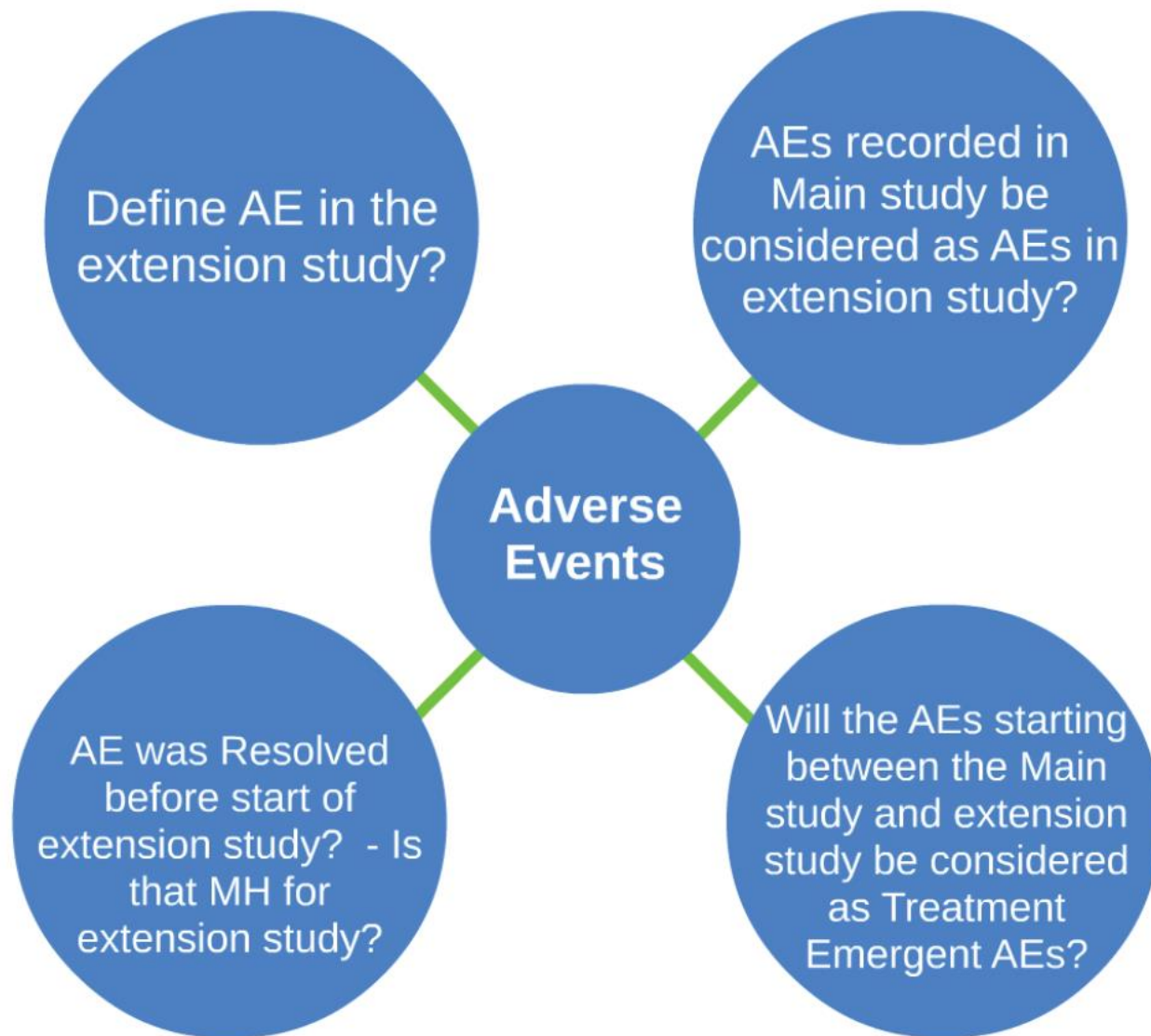
- Gather more patient-years of drug exposure
- New perception of the main study adverse effects
- Subjects get continued access to an effective but otherwise unobtainable drug
- However they do have their share of ethical complications

Challenges



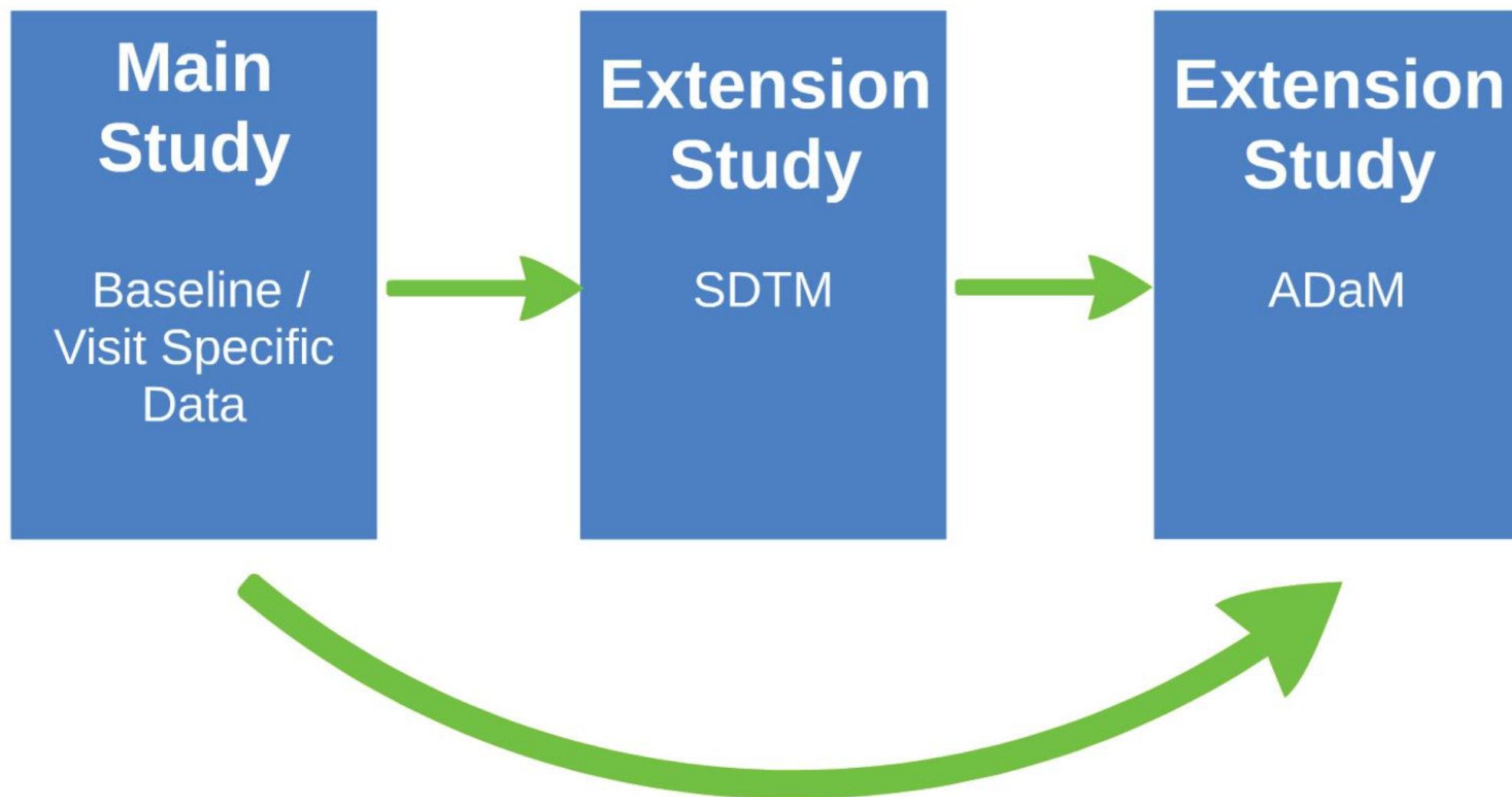


SDTM Challenges



SDTM Challenges

SDTM and ADaM Challenges



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