

Implementation of Data Cut Off in Analysis of Clinical Trials

ANN CROFT

Data Cut Off (DCO)

First 10 subjects randomised in each arm

Independent Data Monitoring
Committee (IDMC)

First 30 subjects in Follow-up

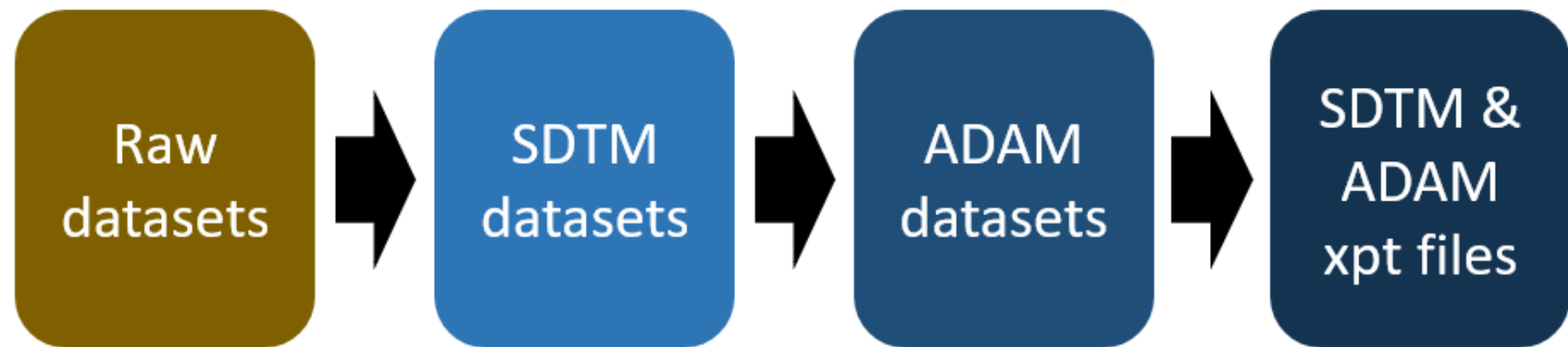
Data for all subjects up to week 12

When 374 events out of an expected
876 events

Interim Analysis

Blind Data Review (BDR)

When to apply DCO



Not Submitted

Submitted

When to apply DCO



Not Submitted

Submitted

Who

- ▶ Roles
 - ▶ Clinical team
 - ▶ Data Management
 - ▶ Programmer
 - ▶ Database Programmer, Statistical Programmer
 - ▶ Statistician
- ▶ Advantages
 - ▶ Consistent data
 - ▶ Allows for data to be cleaned more effectively

Types of data

Simple

- One date collected

Assessment based

- 2 dates (Assessment, Visit)

▶ If DEATHDAT > DCO then delete

▶ If VISITDAT > DCO or LABDAT>DCO then delete

Types of data

Listed

- Indicator question
- Date may exist

SUBJECT	LINE	CMANY	CMSTDAT	DCODT
SAMPLE_111	1	0		2017-10-01
SAMPLE_112	1	1	2016-08-24	2017-10-01
SAMPLE_112	2	1	2017-10-20	2017-10-01
SAMPLE_112	3	1	2016-12-30	2017-10-01
SAMPLE_113	1	0		2017-10-01

Types of data

Listed

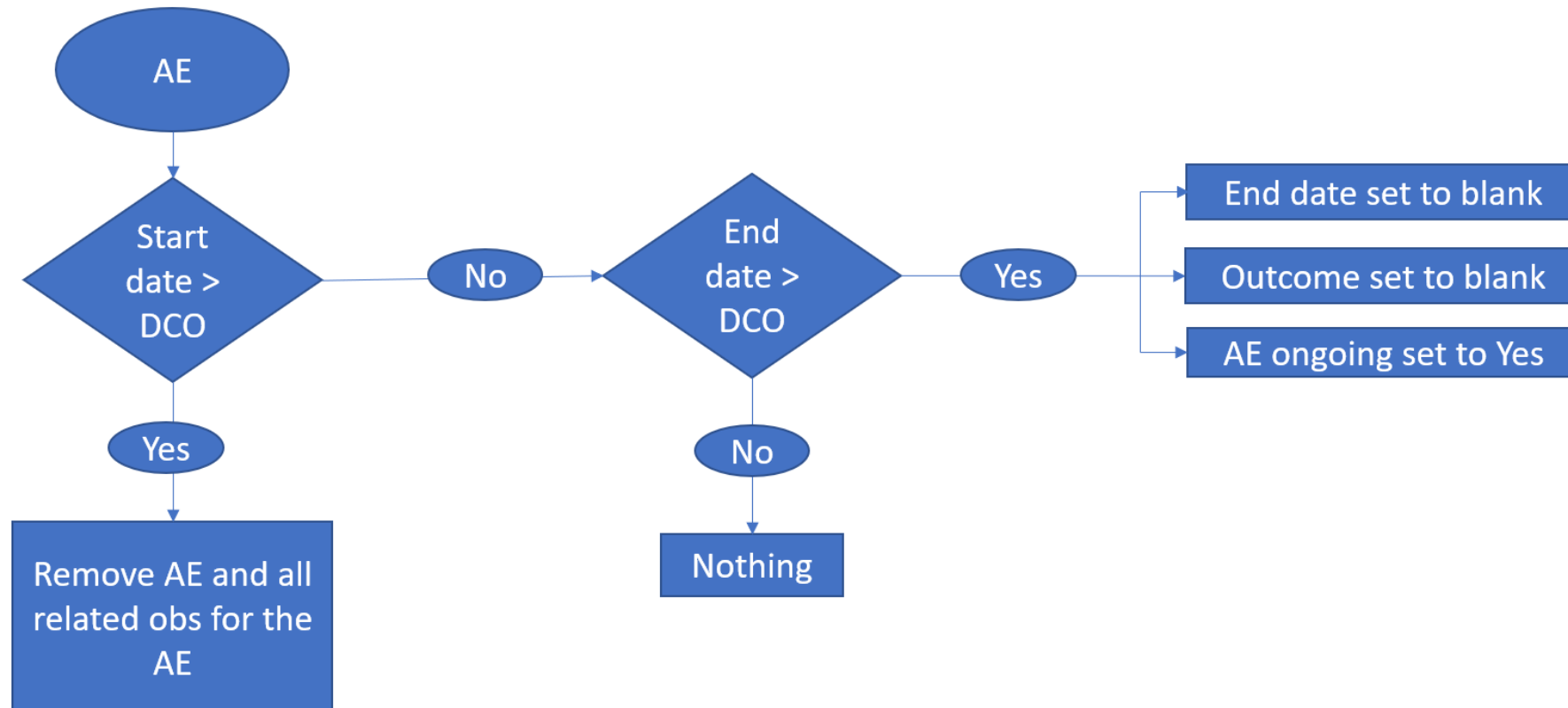
- One date collected

- ▶ Leave at least one record per subject
- ▶ The remaining record may be post-DCO
- ▶ Remove all information that would be available post DCO (end dates, outcomes, etc)

Types of data - Adverse Events

SUBJECT	AESTDT	AEENDT	AEOUT	ONGOING	DCODT
SAMPLE_121	2017-10-01	2017-10-01	Recovered/Resolved	NO	2017-10-13
SAMPLE_121	2017-10-02			YES	2017-10-13
SAMPLE_121	2017-10-07		Recovering	YES	2017-10-13
SAMPLE_121	2017-10-15			YES	2017-10-13

Types of data - Adverse Events

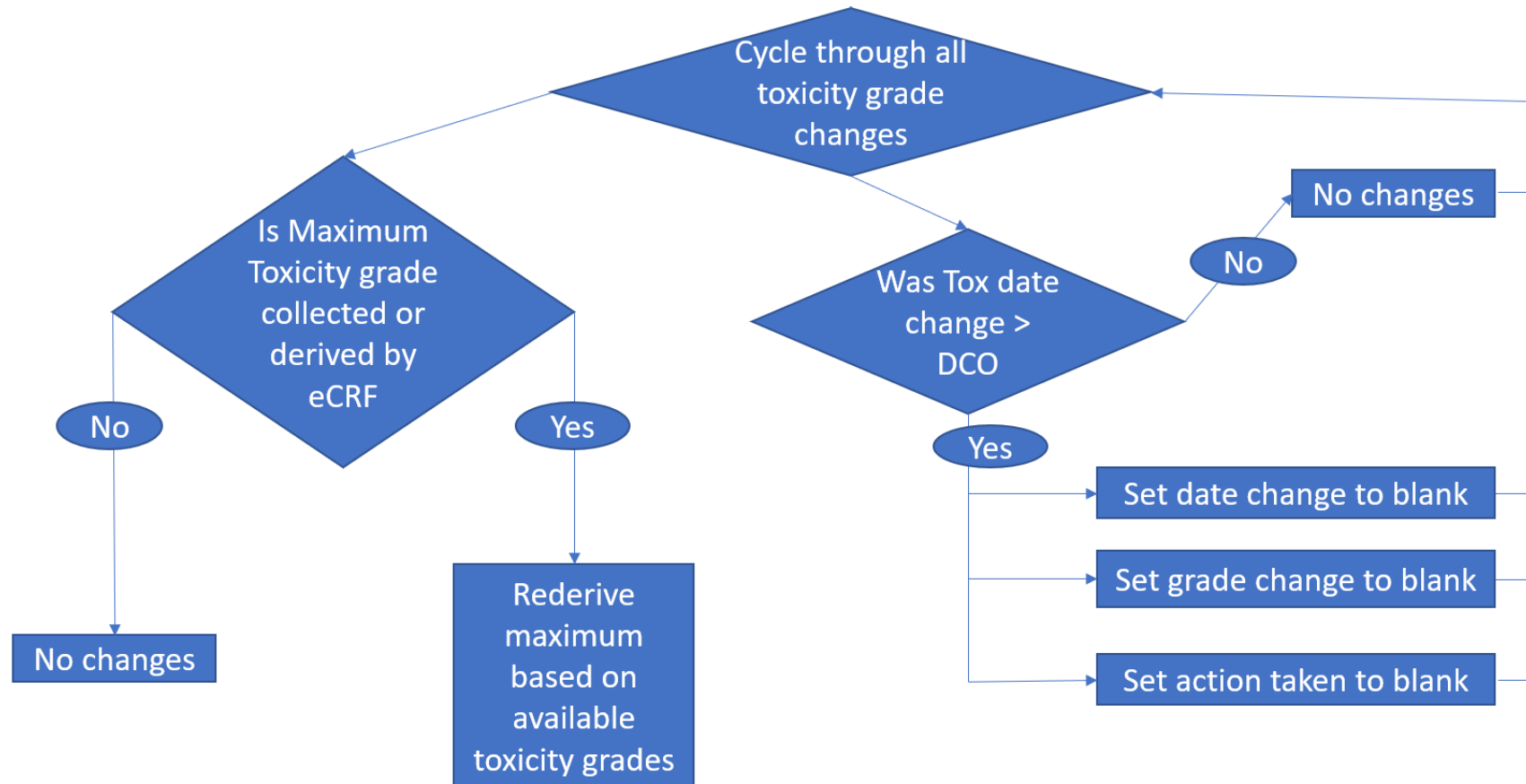


Types of data - Adverse Events

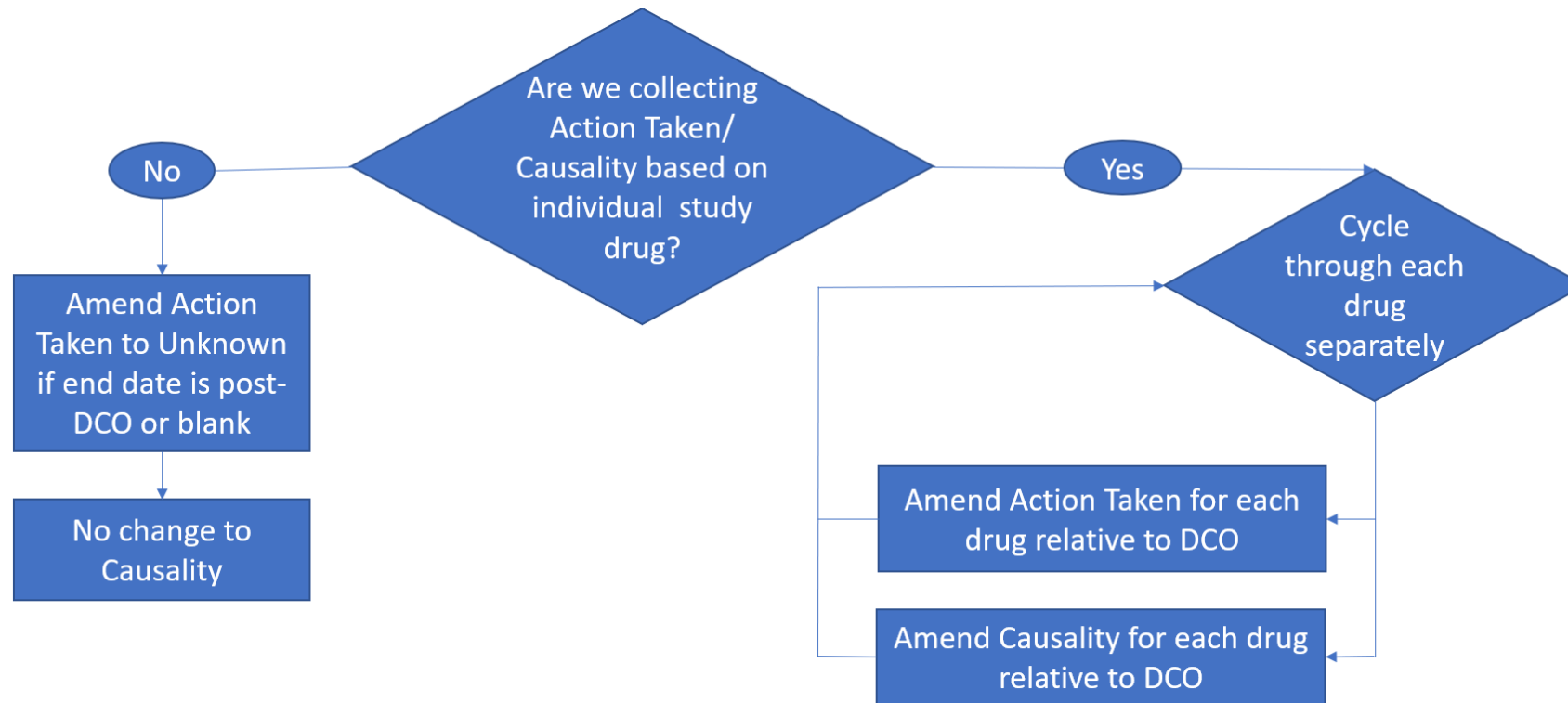
SUBJECT	AESTDT	AEENDT	AEOUT	ONGOING	DCODT
SAMPLE_122	2017-09-27	2017-10-12	Recovered/Resolved	NO	2017-10-13
SAMPLE_122	2017-10-01	2017-10-07	Recovered/Resolved	NO	2017-10-13
SAMPLE_122	2017-10-07			YES	2017-10-13
SAMPLE_122	2017-10-15	2017-10-16	Fatal	NO	2017-10-13

TOXGRDST	TOXGR1CH	TOXGR1DT	TOXGR2CH	TOXGR2DT	TOXGR3CH	TOXGR3DT
2						
2	3	2017-10-02				
2	3	2017-10-09				
4	5	2017-10-16				

Types of data - Adverse Events



Types of data - Adverse Events



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SURVIVE

SUBJECT	STATUS	SURDAT	CONDAT	DCODT
SAMPLE_131	ALIVE	2017-10-29	2017-10-29	2017-10-29
SAMPLE_133	ALIVE	2017-07-07	2017-07-20	2017-10-29
SAMPLE_133	ALIVE	2017-10-28	2017-10-28	2017-10-29
SAMPLE_134	ALIVE	2017-07-07	2017-07-08	2017-10-29
SAMPLE_134	DEAD	2017-10-31	2017-11-02	2017-10-29

DEATH

SUBJECT	DTHDAT	DCODT
SAMPLE_133	2017-10-30	2017-10-29
SAMPLE_134	2017-10-31	2017-10-29

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RECIST

- ▶ Most important – Date of Scan
- ▶ Assessments done after the DCO are included
- ▶ Different methodology from Assessment based design

Conclusion

- ▶ Clear outline
 - ▶ Ensure everyone knows what data is included in the DCO
- ▶ Data traceability and data integrity
 - ▶ Specifications
 - ▶ Correct people applying the DCO
- ▶ DCO principles
 - ▶ Ensure implementation is suitable to data
 - ▶ Allow for Simple, Assessment, Listed, Adverse Event, Survival, RECIST