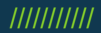




Practical solutions when analyzing incomplete disposition data



PhUSE US Connect 2018
06JUN2018

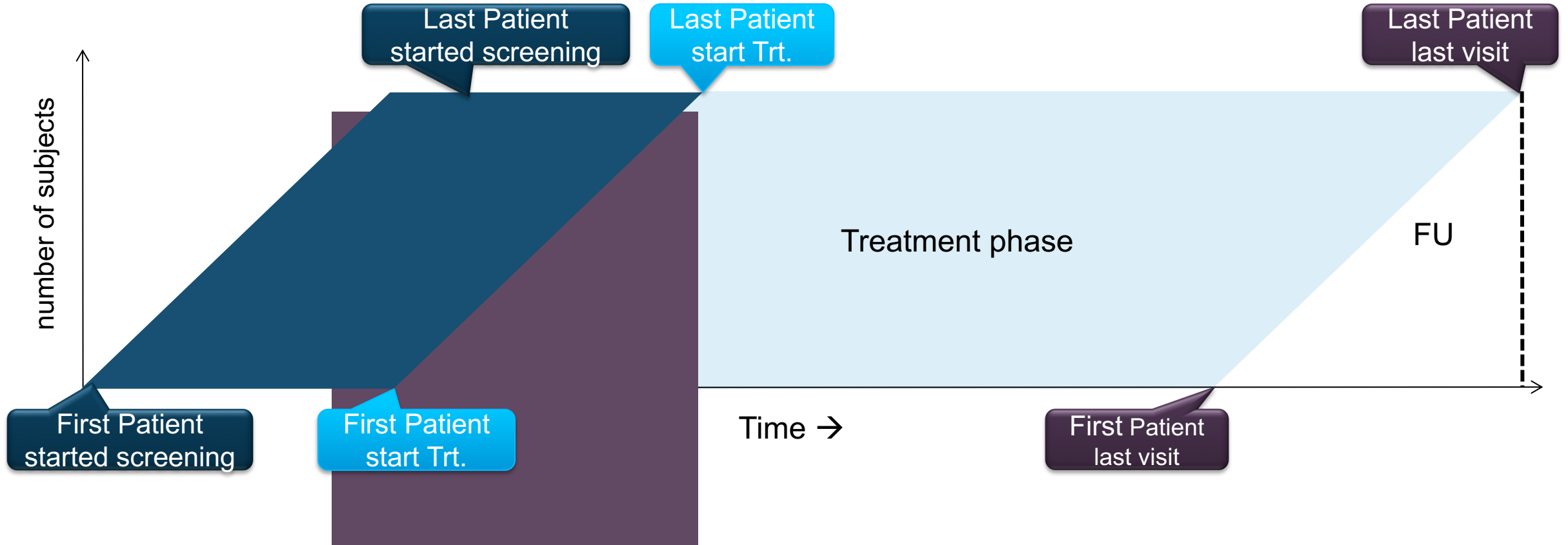
Srinivas Veeragoni

Dr. Juergen Lembcke

David Wei



Typical study phase





Agenda

- // Disposition Tables
- // Challenges in Completed Study
 - // Overlapping epochs
 - // Protocol allowed deviations
 - // Data after patient withdrawn
- // Ongoing Study
 - // Cutoff process and challenges
 - // censoring
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Disposition Tables

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Table: Sample - Overview of Subject Disposition

	Treatment A	Treatment B	Total
Enrolled			xx
Screening failures			xx
Assigned to treatment	xx (100.0%)	xx (100.0%)	xx (100.0%)
Study drug never administered	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Started treatment	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ongoing with study treatment	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Discontinued study treatment	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ended survival follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)



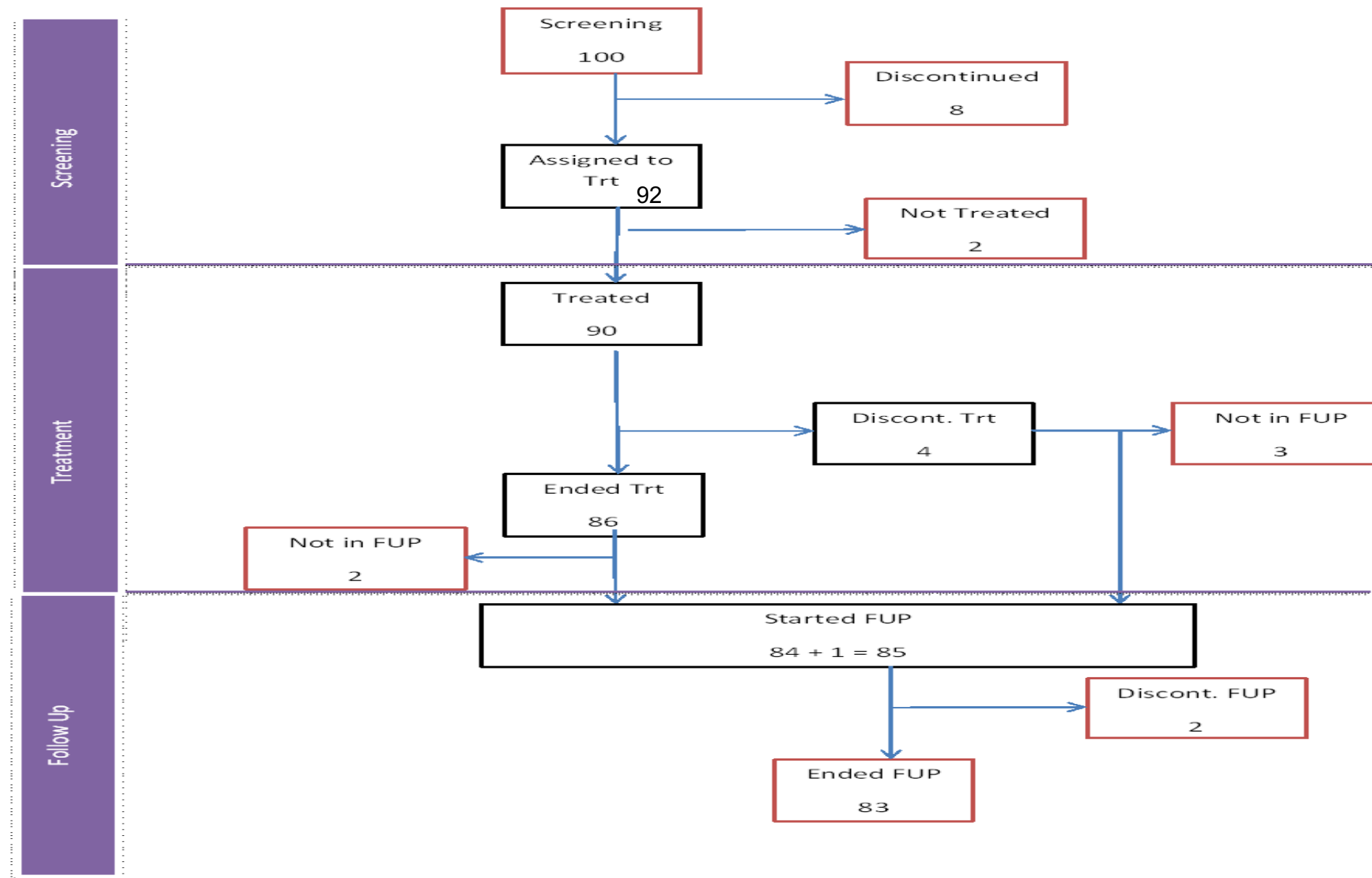
Disposition – Active follow-up

Disposition	Treatment A N=xx (100%)	Treatment B N=xx (100%)	Total N=xx (100%)
Number (%) of subjects			
Active follow-up performed	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Early discontinued active follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Primary reason			
Disease recurrence	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Progressive disease	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Adverse event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Death	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawal by subject	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Protocol violation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ongoing with active follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Challenges in Completed Study

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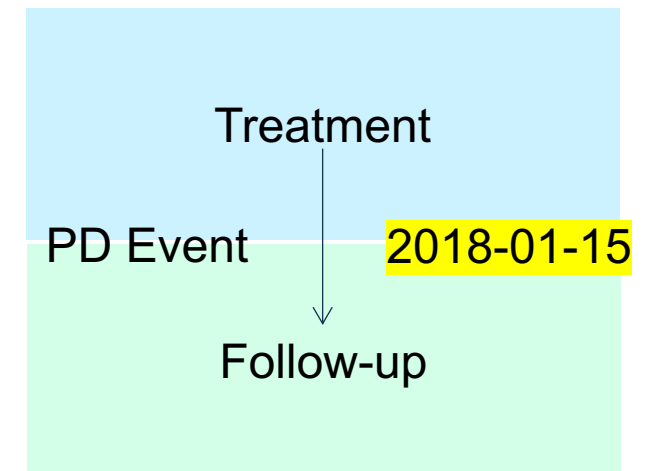
Example for Disposition Overview (Completed Trial)





CHALLENGE 1 : OVERLAPPING EPOCHS

DOMAIN	USUBJID	ETCD	SESTDTC	SEENDTC	EPOCH
SE	101	TRT	2018-01-01	2018-01-15	TREATMENT
SE	101	FU	2018-01-15	2018-03-15	FOLLOW-UP



DOMAIN	USUBJID	DSDECOD	DSCAT	EPOCH	DSDTC	DSSTDTC
DS	101	PD	DISPOSITION EVENT	TREATMENT? OR FOLLOW-UP?	2018-01-15	2018-01-15

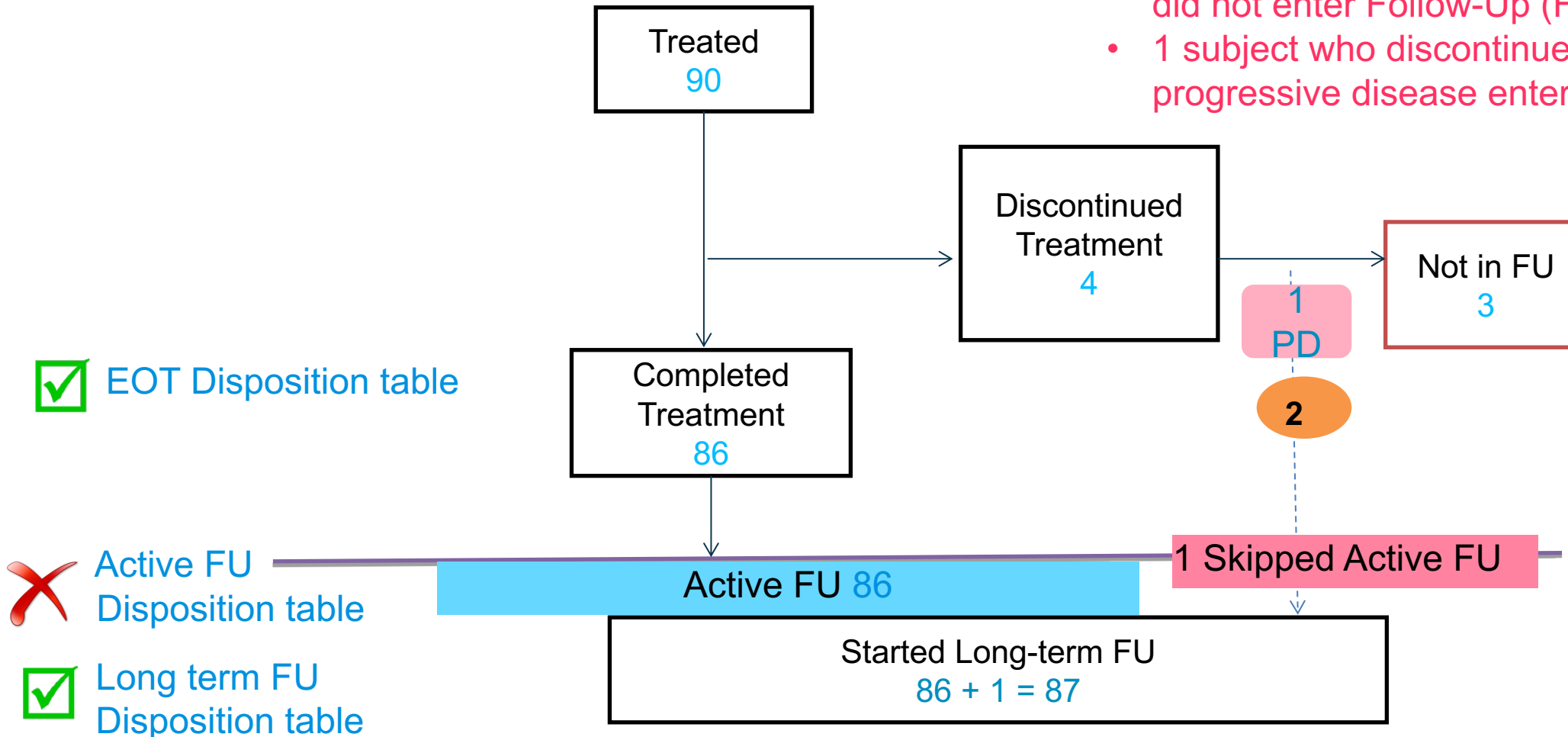
IF EOT page **not** completed before the event

IF EOT page is completed before the event



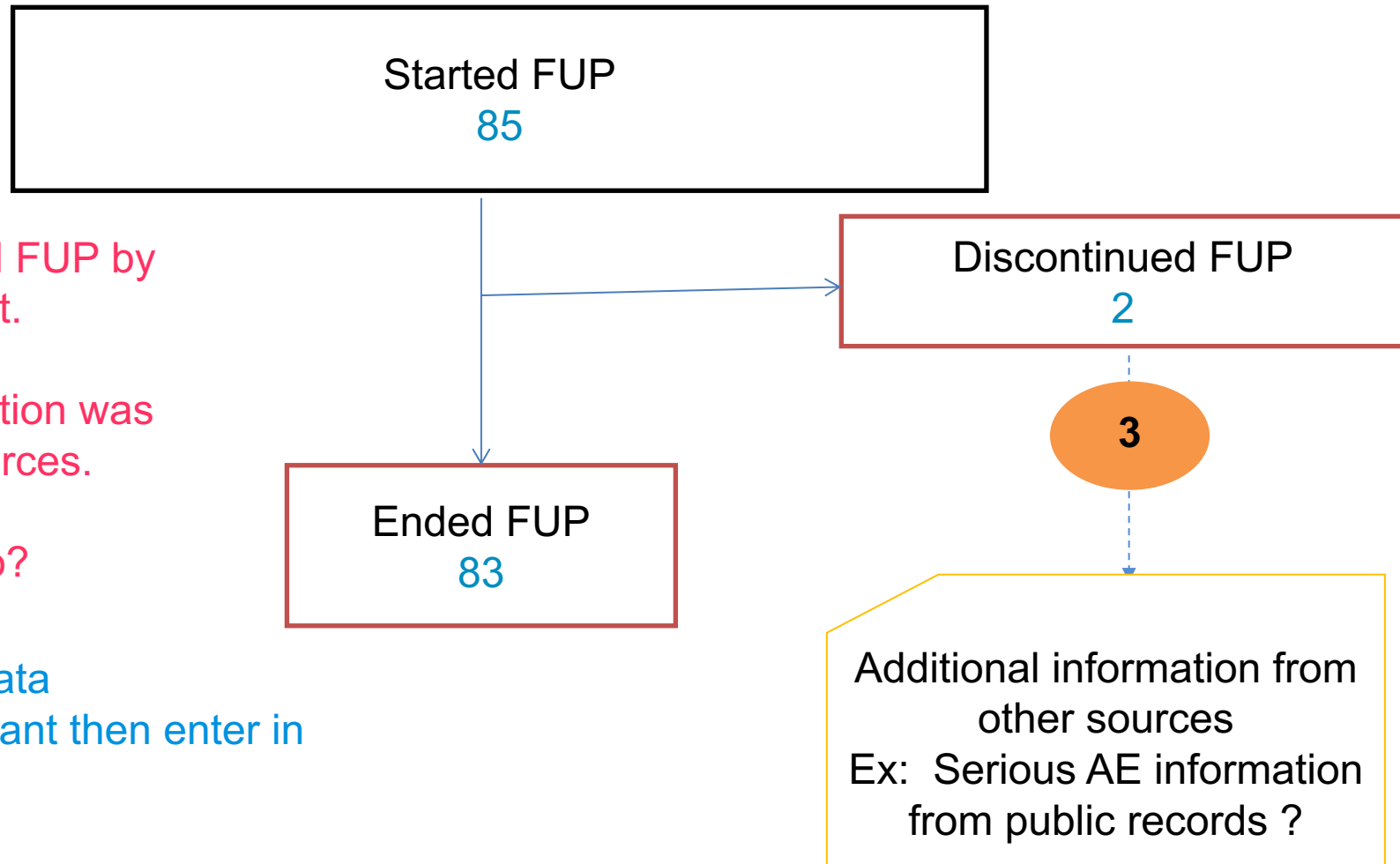
CHALLENGE 2 : PROTOCOL allowed deviations in patient flow

- 4 discontinued treatment and 3 of them did not enter Follow-Up (FU).
- 1 subject who discontinued due to progressive disease entered long term FU



CHALLENGE 3: Data after patient withdrawn from study

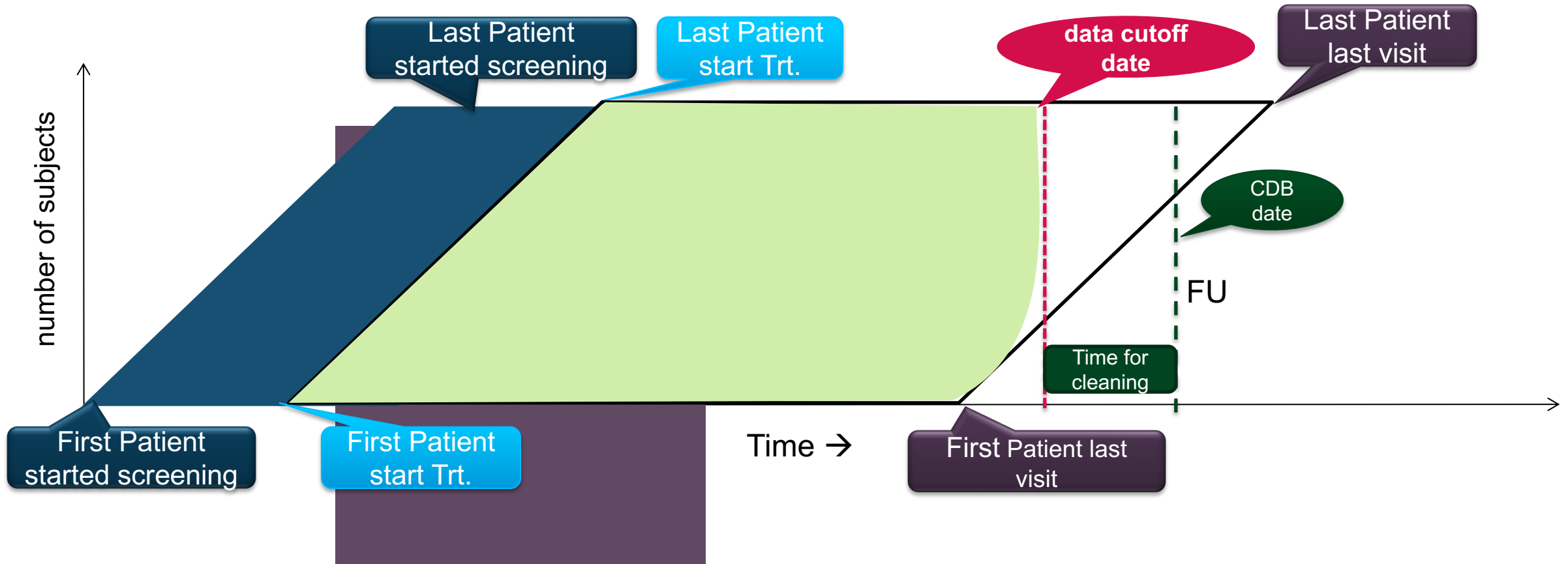
- 2 Subjects discontinued FUP by withdrawing the consent.
- Later additional information was received from other sources.
- What to do with this info?
 - ✓ Verify the source data
 - ✓ If reliable and relevant then enter in appropriate phase
 - ✓ Report



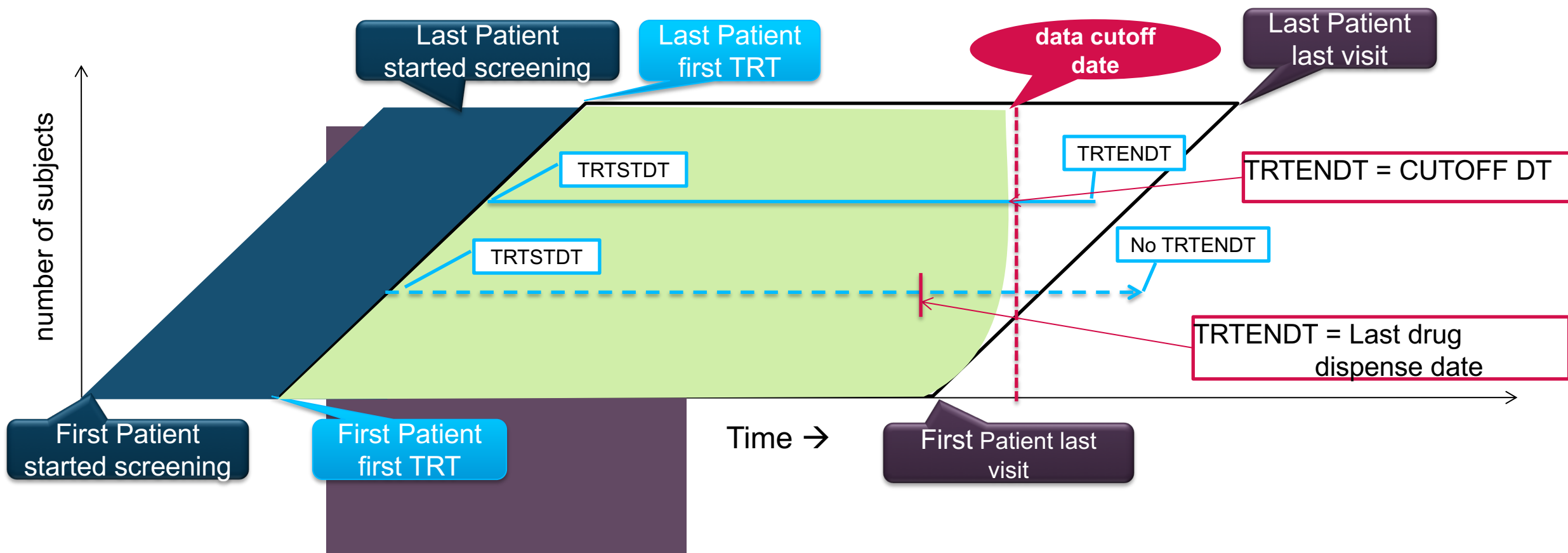
Ongoing Study

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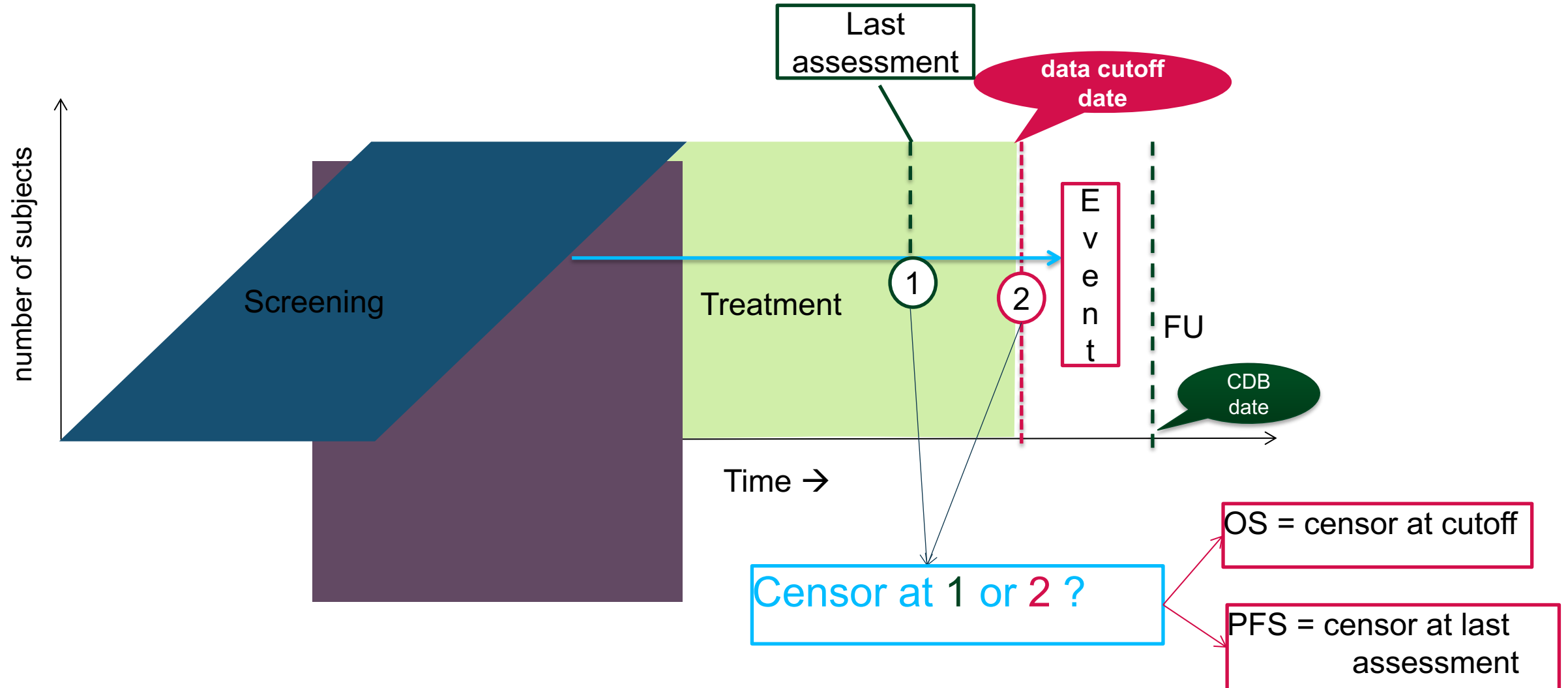
Typical study phase with cutoff applied



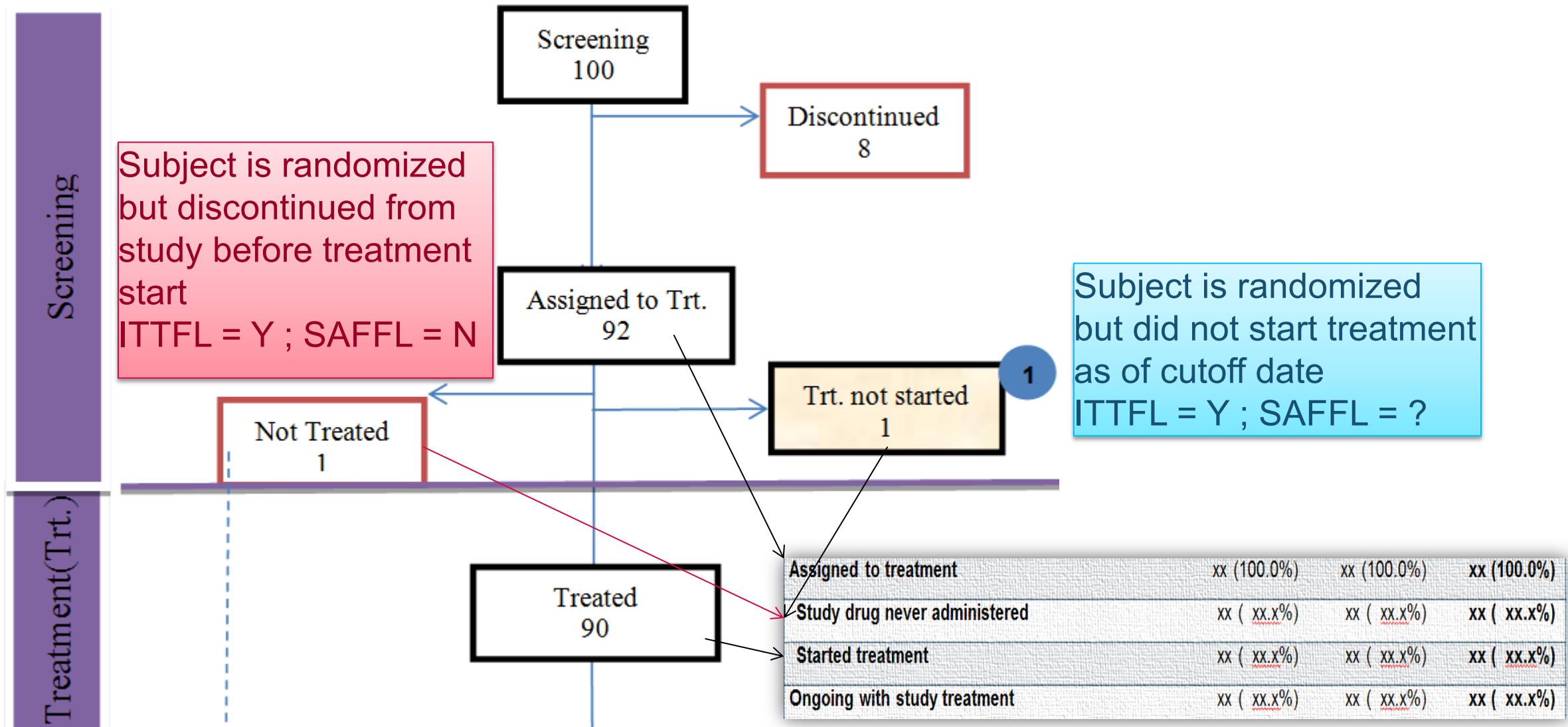
Populating Treatment end date after cutoff



“CENSORING” Subjects with information lost due to cutoff



1 ACCOUNTING FOR SUBJECTS WITH MISSING INFORMATION





Treatment (Trt.)



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Summary

- // There are challenges in analyses of disposition data both for a completed study and an ongoing trial with the subjects still ongoing in the study treatment with cutoff dates applied and dirty data
- // care should be taken during study designing, CRF development, data collection and cutoff execution to collect and store required information for analysis
- // Disposition flow charts will help visualize the patient flow across different epochs
- // very important to document all the assumptions and algorithms in the define files and reviewers guide
- // submission of analysis programs proactively with supporting Analysis Results Metadata (ARM) will help avoid some of the relevant Information requests



Thank you!

Acknowledgements: Rene Wentzeck
Ankur Mathur



Questions ?

