

ADaM-Based Centralised Monitoring

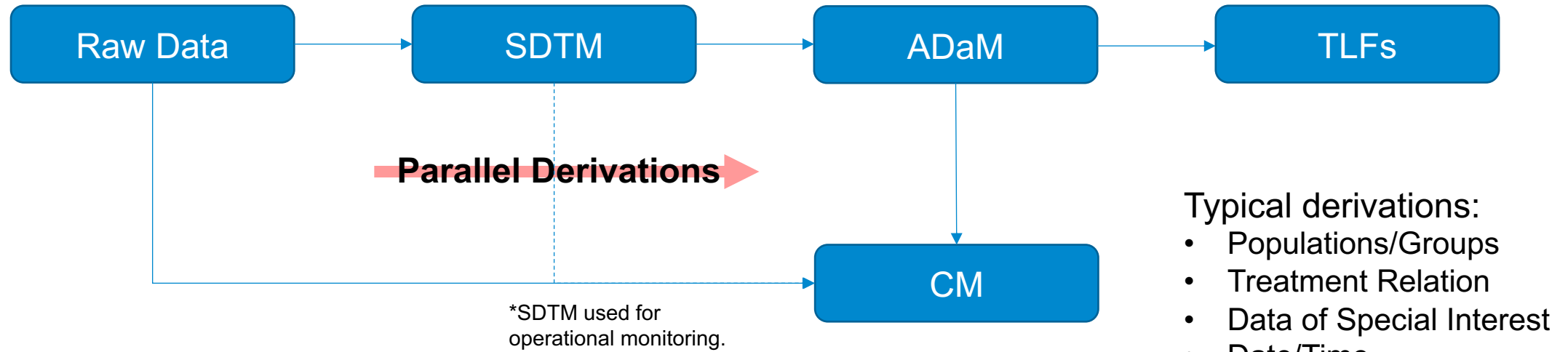
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PHUSE Connect, EU 2019

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Data Flow

Traditional to current



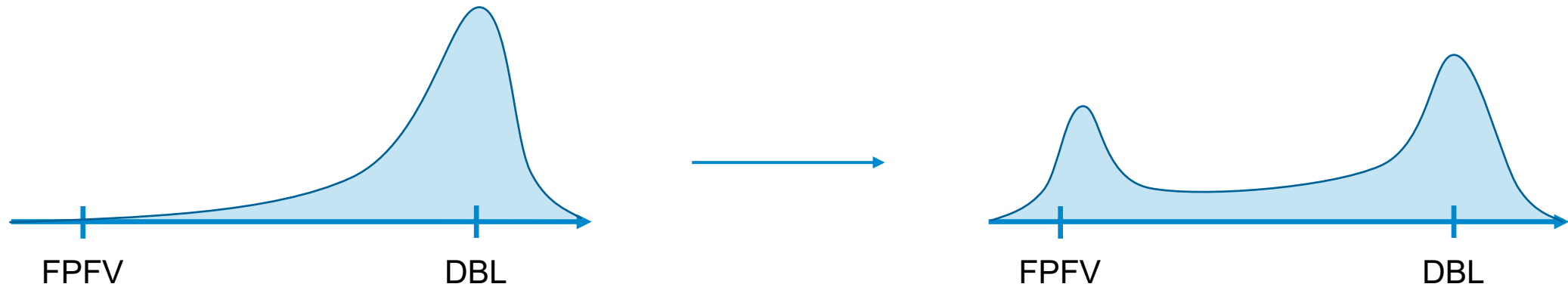
Typical derivations:

- Populations/Groups
- Treatment Relation
- Data of Special Interest
- Date/Time
- Summaries
- Endpoints

Trial Timelines

Early days of data derivation

Centralized Monitoring on ADaM introduces deliverable in early trial conduct.



Ongoing discussions with monitor during conduct.

Make Stakeholders See

Data visualizations

For data visualizations we use Qlik Sense®.

It allows for interactions with data through the visualisations.

<DEMO>

Qlik Sense data integrated in daily update cycle.

Challenge 1

The Need for Speed

ADaM in early trial conduct

- Availability of SDTM?
- Data is partial or not yet collected.

In Ferring*:

- SDTM readily generated from pre-SDTM data.
- Metadata for eCRF specification used as basis for test-SDTM data generation.
- ADaM development on test-SDTM.

* EU Connect 2018, PP12: [NEED FOR SPEED – Accelerating Centralized Monitoring](#).

Challenge 1

The Need for Speed

ADaM in early trial conduct

- Availability of SDTM?
- Data is partial or not yet collected.

Generally:

- Only a subset of datasets need to be set up early.
- Data standardization ensures code reusability.
- Other study data may be useful as 'test'-data.
- ! Programs need to be robust to missing/mixed data.

Challenge 2

When data is

Missing data handling may differ for CTR and CM.

The CTR assumes final data, CM expects updates.

- Statuses 'pending', 'ongoing' and 'missing' needed for CM.
- Should not remain at trial conclusion.

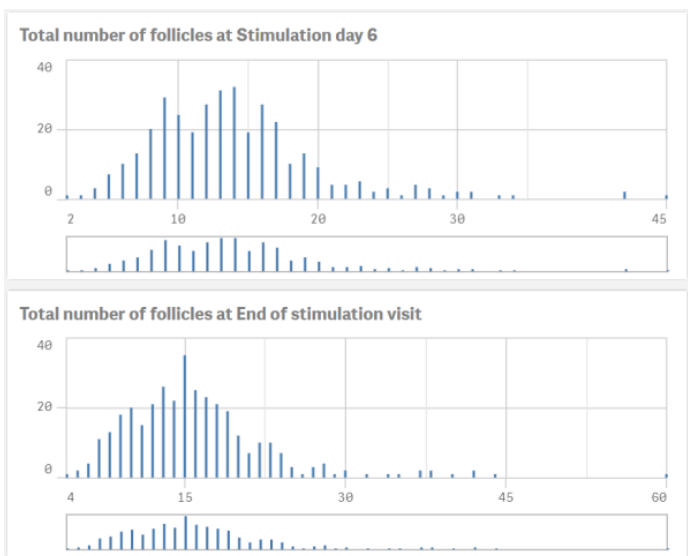
Careful implementation or CM add-on programs may be needed.

Additional Benefits

Scrutiny & traceability

Benefits to the quality of the trial:

- More discussion of endpoint definitions in the clinical team.
- Extra chance of detecting data/derivation issues.
- Use of ADaM labels across outputs increases traceability.



Total number of follicles by visit and stratum - Full Analysis Set

Stratum	TREATMENT A		TREATMENT B	
	Median	[IQ-range]	Median	[IQ-range]
Visit: Stimulation day 6				
All observations	XX.X	[XX.X; XX.X]	XX.X	[XX.X; XX.X]
Stratum A	XX.X	[XX.X; XX.X]	XX.X	[XX.X; XX.X]
Stratum B	XX.X	[XX.X; XX.X]	XX.X	[XX.X; XX.X]
Visit: End of stimulation visit				
All observations	XX.X	[XX.X; XX.X]	XX.X	[XX.X; XX.X]
Stratum A	XX.X	[XX.X; XX.X]	XX.X	[XX.X; XX.X]
Stratum B	XX.X	[XX.X; XX.X]	XX.X	[XX.X; XX.X]

[IQ-range] = Inter-quartile range

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Conclusions

The primary benefit of ADaM-based CM is not in overall workload.
There are fewer derivations but of higher complexity.

The benefit is in quality and alignment.

Connect with us!



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