

THE IMPLEMENTATION OF SDTM STANDARDS FOR NON-SUBMISSION PURPOSES

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AGENDA

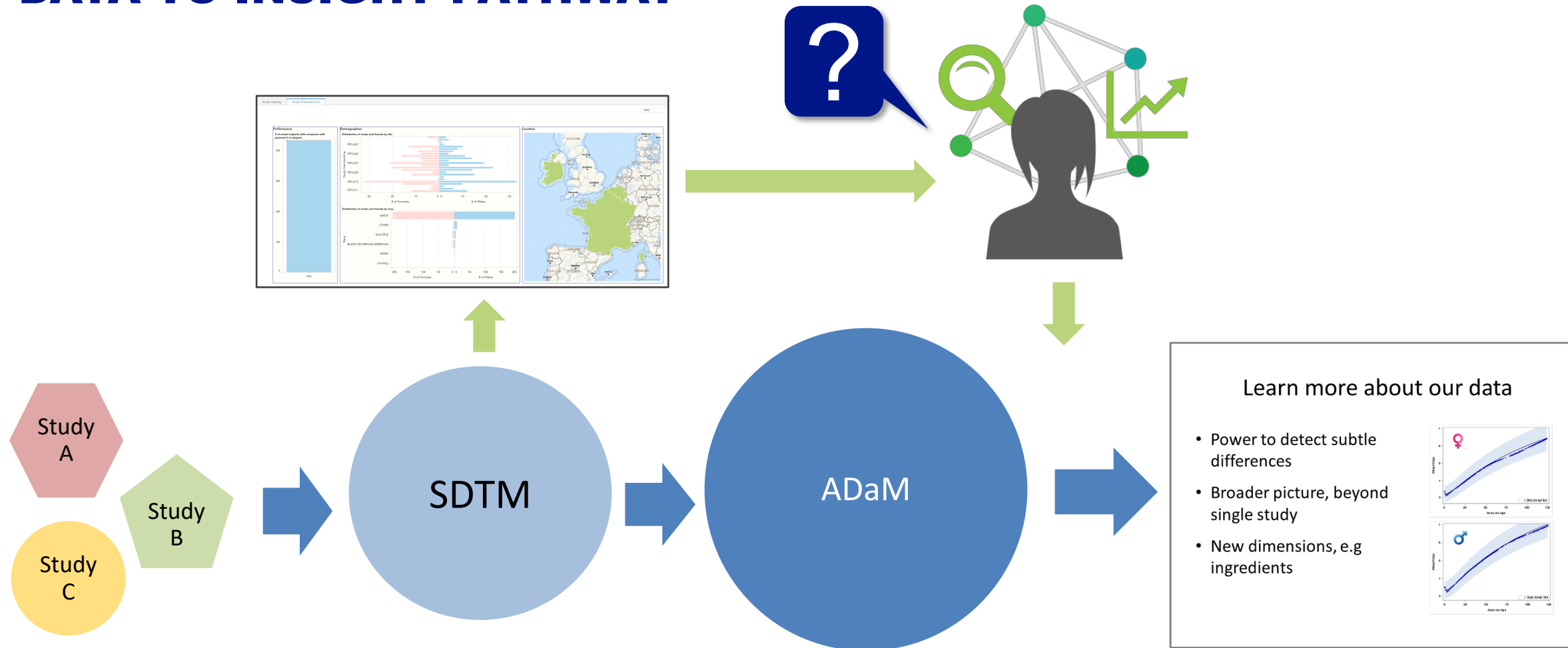
- Background
- Project scope
- Deliverables and submission standards
- SDTM implementation challenges
- Project approach
- Conclusions

BACKGROUND

- Value of data for future research
- SDTM legacy conversion project for early life infant nutrition studies
- Twenty-one infant nutrition clinical studies selected
 - Based on business relevance, features of the study



DATA TO INSIGHT PATHWAY



PROJECT SCOPE

- Initial
 - Demographics
 - Subject characteristics
 - Vital signs
 - Adverse events
 - Gastrointestinal tolerance
 - Concomitant medication
- Scope extension
 - Based on 'economics'

PROJECT SCOPE

- Raw data inventory based on:
 - Protocol
 - CRF
 - Datasets

- Informed decision

Item	Domain (preliminary)	Effort per category per activity							Number of studies	Study A			Study B			Study C		
		Design	Map	Prog	Val	PM	TOT			P	C	D	P	C	D	P	C	D
Enrollment									20									
Enrollment details	Demographics (DM)																	
Visit details																		
Actual subject visits	Subject Visits (SV)	x	x	x	x	x	x		21									
Planned/expected subject visit date	Trial Visits (TV)								21									
Visit windows/ranges	Trial Visits (TV)								6									
Extra contact moments	Subject Visits (SV)								18									
									3									
Subject (birth) details																		
Demographics	Demographics (DM)	x	x	x	x	x	x		21									
Birth characteristics	Subject characteristics (SC) / Vital Signs (VS)																	
Remaining subject (birth) details																		
Did any problems occur during pregnancy/delivery	Custom-event domain / AP custom-event domain	x	x	x	x	x	x		4									
Eligibility/randomisation																		
Informed consent(s)	Demographics (DM) / Disposition (DS)	x	x	x	x	x	x		21									
Inclusion criteria	Inclusion/Exclusion Criterion Not Met (IE) / Trial Inclusion/Exclusion Criteria (TI)								21									
Exclusion criteria	Inclusion/Exclusion Criterion Not Met (IE) / Trial Inclusion/Exclusion Criteria (TI)								21									

(SUBMISSION) DELIVERABLES

Regulatory submission (FDA) components	Nutricia project
SDTM dataset	Required
Trial design tables	Nice-to-have; not included
Define.xml	Desired; not included
Annotated CRF	Required
Reviewer Guides (RG)	Nice-to-have; not included
Study Data Standardization Plan	Not used and not considered relevant at this point
Legacy Data Conversion Plan and Report	Not used; documented in mapping design and specifications
SAS transport files	Not used

SOME SDTM IMPLEMENTATION CHALLENGES

- Specific nutrition concepts not entirely addressed in CDISC standards
 - No standard domain available to represent gastrointestinal tolerance data
 - Limited terminology for faecal microbiology parameters, only 4 standard terms vs. 66 parameters in our studies
- Variable length restrictions in CDISC standards
 - --TEST: "Clostridium Histolyticum Group and Clostridium Lituseburense Group"
 - >40 characters
 - --TESTCD: "CHIS150CLIT135"
 - >8 characters

SOME SDTM IMPLEMENTATION CHALLENGES

- CRFs of legacy studies not designed with SDTM in mind
 - Date of first intake of study formula not always captured; how to populate RFXSTDTC (Date/Time of First Study Treatment)?
- Data issues
 - Data collected via paper CRF and diaries; need for exception handling

Diary week 1 – day 1 Date (dd/mm/yyyy): 30/02/2018

Gastrointestinal symptoms
Did the subject suffer from the following symptoms today:

	Absent	Mild	Moderate	Severe
Vomiting	☒	☐	☒	☐
Flatulence	☐	☒	☐	☐
Diarrhoea	☐	☐	☒	☐
Constipation	☐	☒	☐	☐
Cramps	☐	☐	☐	☒

SOME SDTM IMPLEMENTATION CHALLENGES

- Substantial variation in study design, CRF, dataset structure and naming conventions

if number of infants > 1, please answer questions a) and b)

a) Order in delivery:

☐ First child
☐ Second child

☐ Third child
☐ > Third child

Order in household:

☐ First child

☐ Third child

☐ Second child

☐ Fourth child onwards

Birth order

**Same
concept?**

☐ First child

☐ Third child

☐ Second child

☐ > third child

PROJECT APPROACH

- SDTM implementation outsourced from Nutricia Research to OCS Life Sciences
- Tuned approach early in the project
 - From 'delivery' model to 'delivery-and-collaboration' model
 - Regular meetings with Nutricia domain experts to make the best implementation choices



LESSONS LEARNED / RECOMMENDATIONS

- SDTM is a usable standard for non-submission purposes
 - Best to strive for full conformance
 - Other submission components applicable to varying degrees
 - Some SDTM requirements outdated (8 char. limitation)
- Outsourcing SDTM conversion can be successful
 - Seek close collaboration and have SDTM expertise on both sides
 - Spend time pre-analysing the data structure and variability

Thank you!

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