

An Approach to Effectively Reproduce TFLs When Performing ADaM Conversion

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DH06 – PHUSE EU Connect 2022



AGENDA

- Background
- Approach
- Processes
- Examples
- Summary & Conclusion



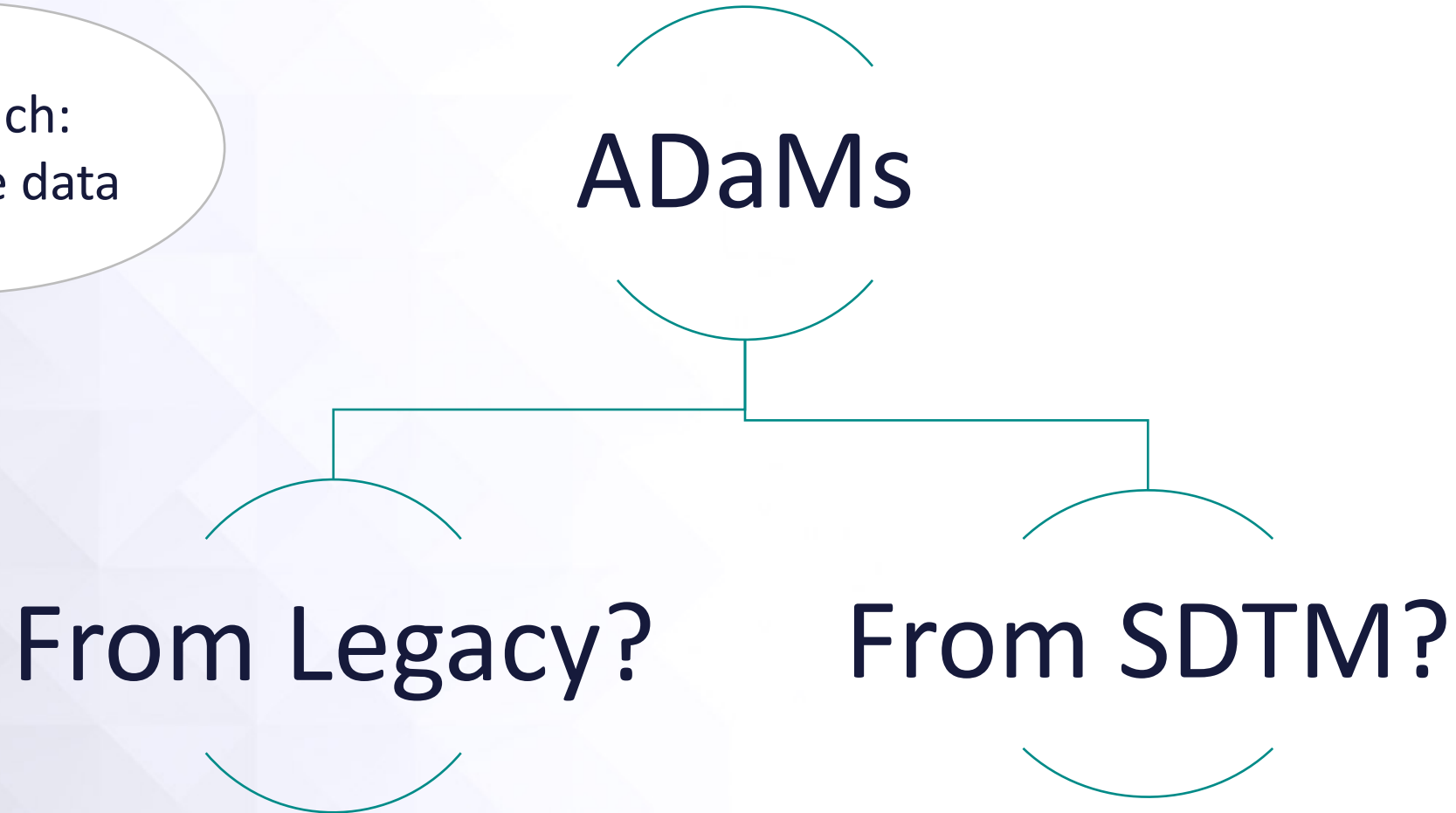
#Data #DataDriven
#DataStrategy #DataIntegration
#DataViz #DataStandards
#DataScience #Datagovernance
#HealthCare #DataAnalysis
#ClinicalTrials
#ArtificialIntelligence
#AdvancedAnalytics
#MachineLearning #Digital
#Chatbot #Biometrics #CRO
#ClinicalData
#LifeSciencesExperts
#Whodrug #MedDRA
#Pharmacovigilance
#ClinicalResearchLifeCycle
#MedicalWriting
#MedicalInformation
#MedicalReview #SDTM
#ADaM #CDISC #Innovation
#RegulatorySubmissions
#Protocol #Coding

BACKGROUND

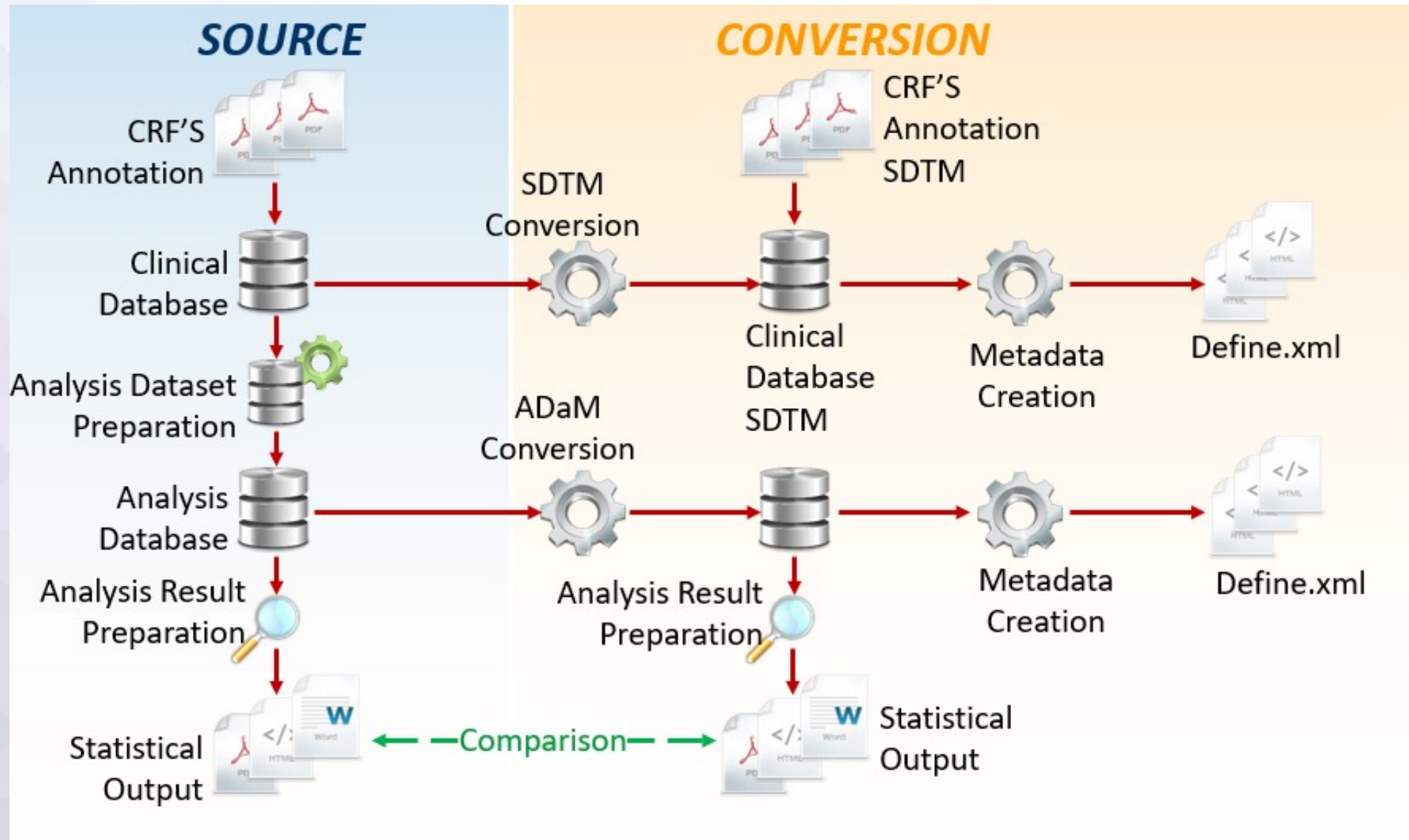
- Objective:
 - Submission of data to regulatory authorities.
- Requirement:
 - Standardized study data in CDISC format
- Process:
 - Conversion of several non CDISC databases into SDTM and ADaMs
- Evidence:
 - Ensure clinical study results are the same after conversion
- How?
 - Generate TFLs from ADaMs
 - Compare legacy TFLs and ADaM TFLs
- Challenges
 - Get full match

APPROACH – ADAM CONVERSION

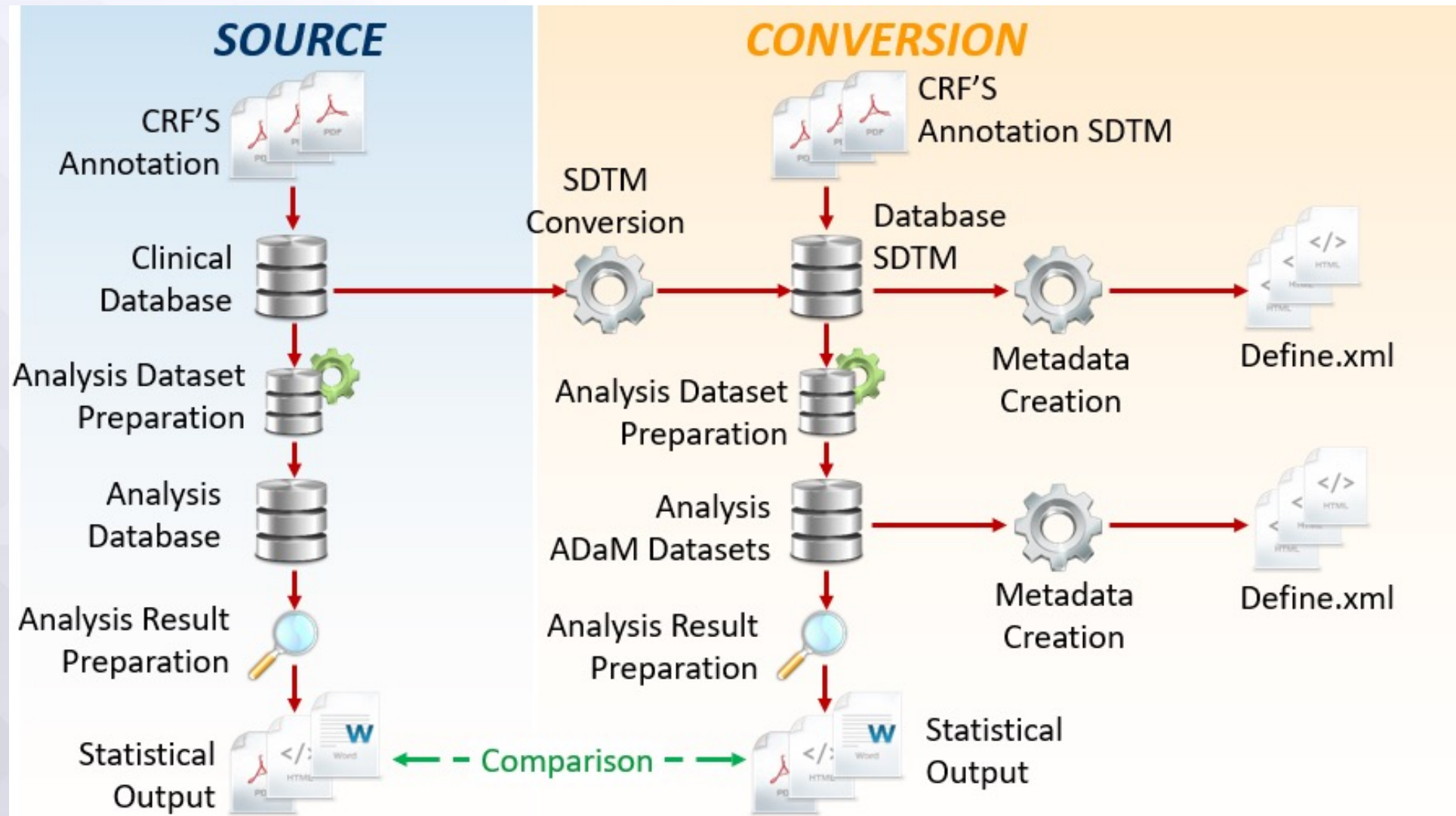
Approach:
#1 source data



ADAM FROM LEGACY



ADAM FROM SDTM



PROS AND CONS

OPTION 1 : ADAM CREATED FROM LEGACY

- **Advantages:**
 - Most derivations are available in analysis datasets
 - Decrease the risk of not being able to reproduce TFLs of the study report
 - Conversion from analysis datasets to ADaM datasets can start independently from creation of SDTM datasets
- **Disadvantages:**
 - No traceability between SDTM and ADaM

OPTION 2 : ADAM CREATED FROM SDTM

- **Advantages:**
 - Clear traceability path from SDTM to ADaM
 - Can be reused for similar studies
- **Disadvantages:**
 - Difficulty in replication / confirmation of analysis derived or imputed variables
 - Differences when reproducing TFLs

APPROACH – ADAM CONVERSION

Approach:
#2 TFLs

All TFLs

Perfect but
time consuming
and more risk of
discrepancies

Unique TFLs

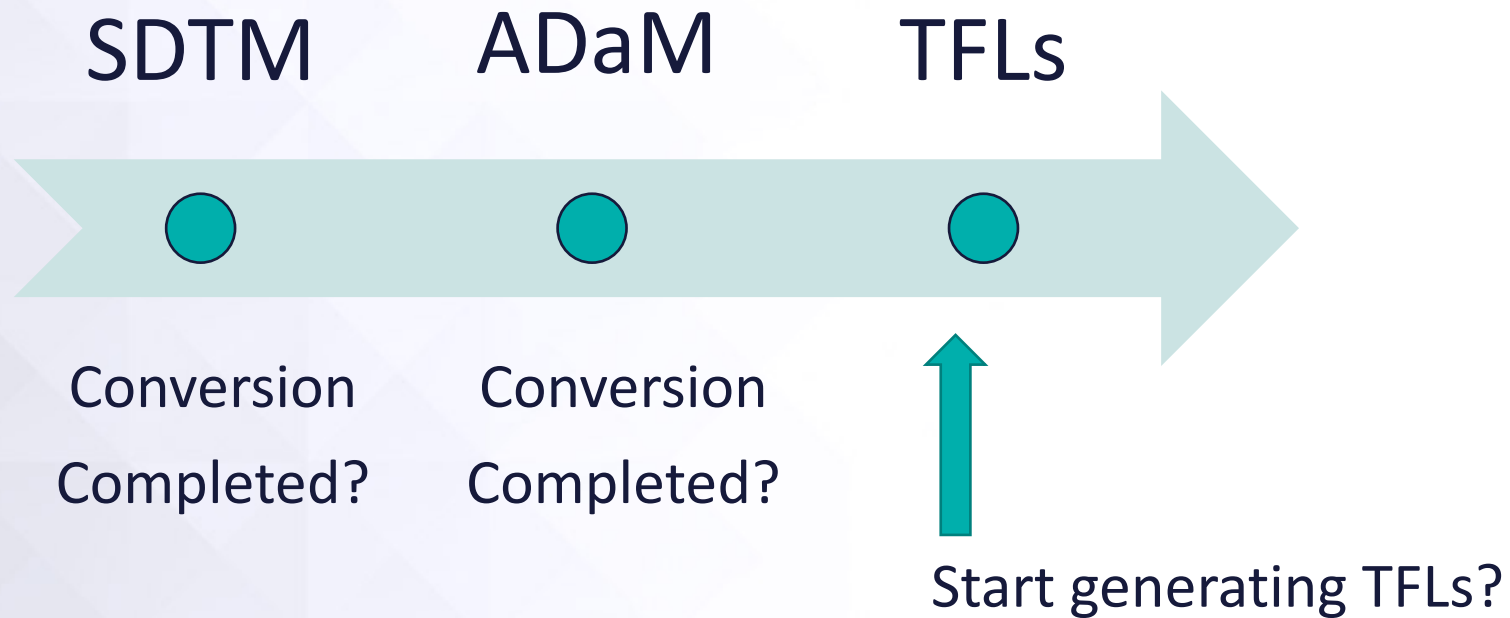
Good but not all
data can be
perfectly used in
the future

Key TFLs

Limited to the
submission

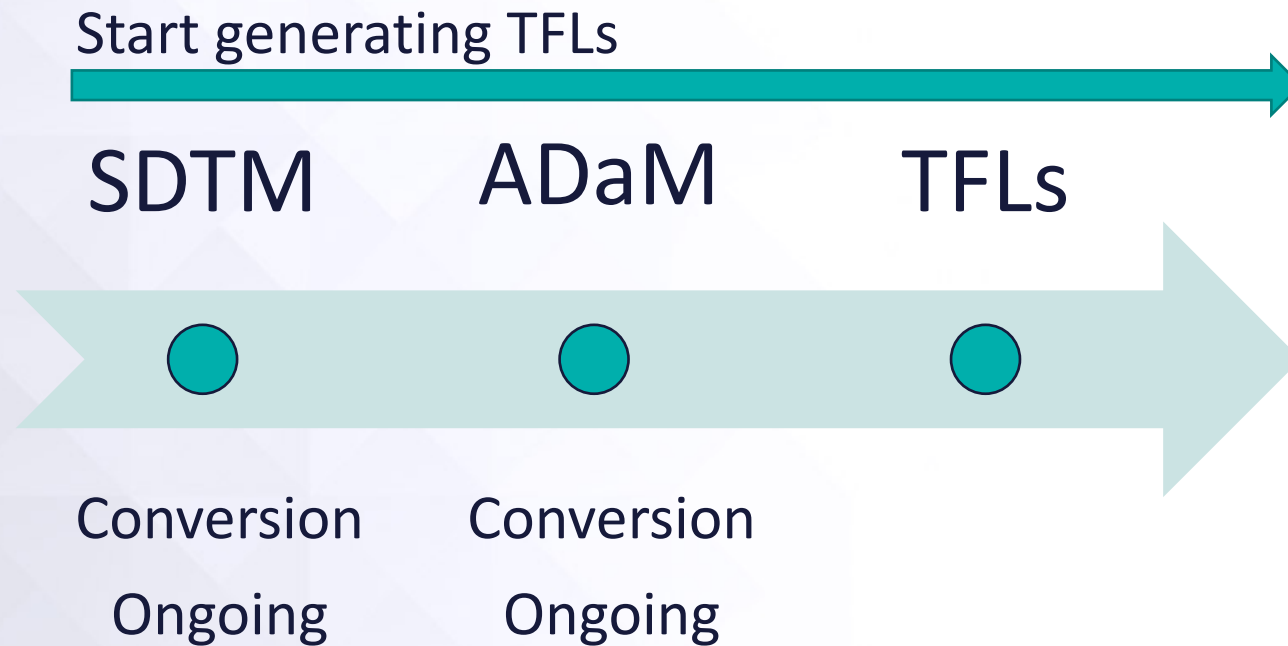
APPROACH – ADAM CONVERSION

Approach:
#3 process



APPROACH – ADAM CONVERSION

Approach:
#3 process



APPROACH – ADAM CONVERSION

Approach:
#4 Inputs

- What we have:
 - Programs?
 - TFLs in Word format?
 - Specifications?
 - CSR?

APPROACH – ADAM CONVERSION

Approach:
#4 Inputs

- What we have:

- Programs ✓

 T_15_1.sas

 T_15_1a.sas

 T_15_1b.sas

 T_15_1c.sas

 T_15_1d.sas

 T_15_1e.sas

Automatic checks using proc compare in SAS

```
/*Compare against legacy table*/  
data prod_&tfl_name.;  
    set data.v_&tfl_name.;  
    format _all_;  
    informat _all_;  
    attrib _all_ label=' ';  
run;  
%mini_vlength(data=prod_&tfl_name.);  
  
ods listing file="&w_path.\Stats\Table\Lst\&study.\&tfl_name..lst";  
proc compare base=prod_&tfl_name. compare=comp_&tfl_name. listall;  
run;
```

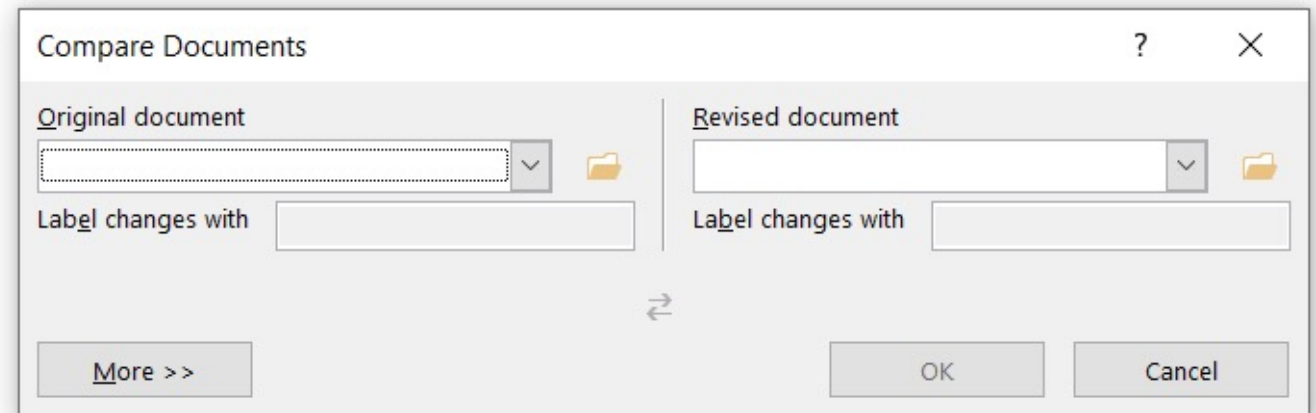
APPROACH – ADAM CONVERSION

Approach:
#4 Inputs

- What we have:
 - Programs X
 - TFLs in Word format ✓

Name

- V_F_15_2_2f
- V_F_15_2_2g
- V_F_15_2_2h
- V_F_15_2_2i
- V_F_15_2_2j
- V_F_15_2_2k
- V_F_15_2_2l
- V_F_15_2_2m



Automatic checks using compare
functionality in Word

APPROACH – ADAM CONVERSION

Approach:
#4 Inputs

- What we have:
 - Programs X
 - TFLs in Word format X
 - Specifications ✓
 - CSR ✓

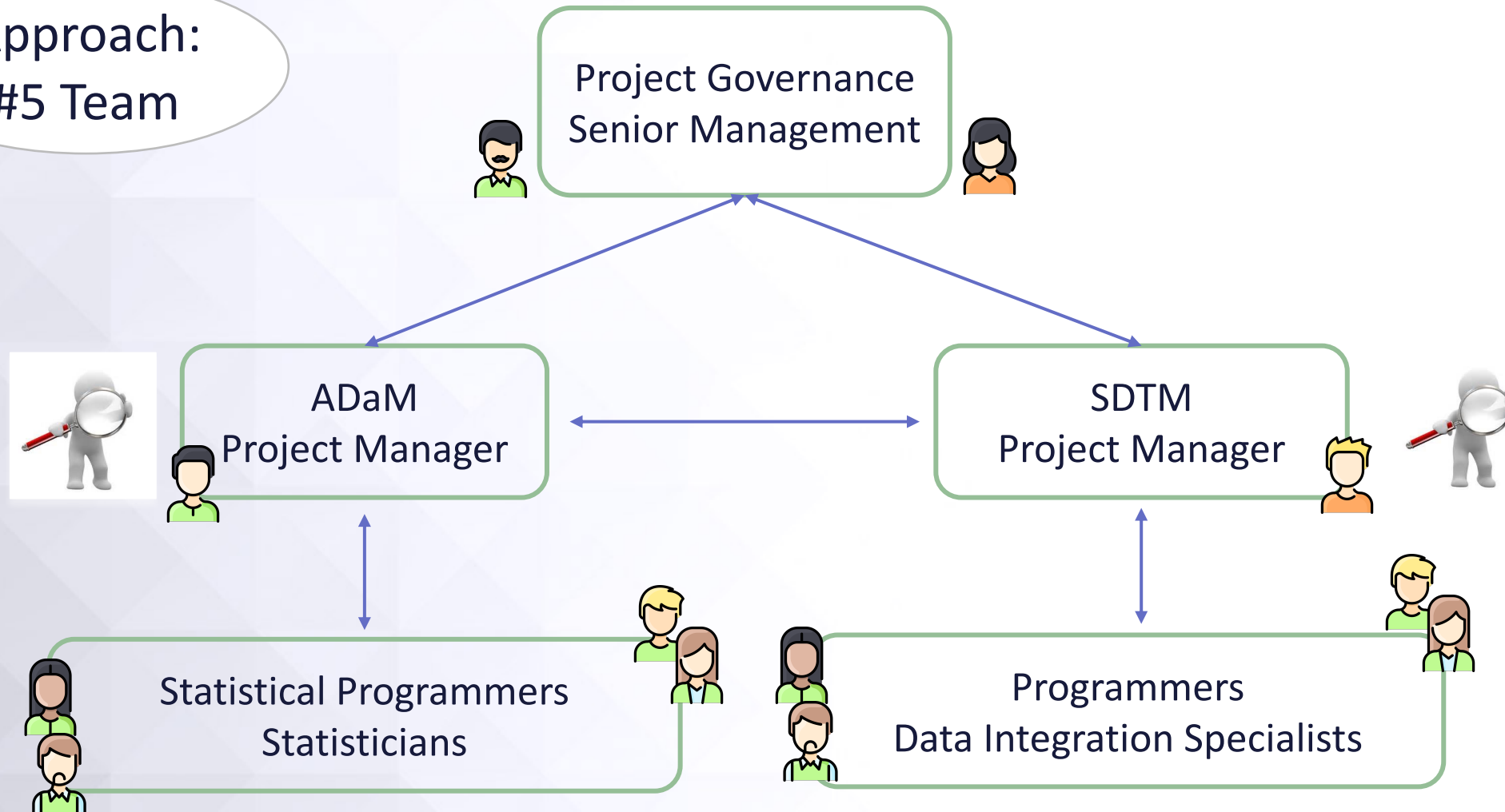
PDF Format

DEMOGRAPHICS		
Age	N	941
	Mean (SD)	11.88 (2.9)
	Median (Q1, Q3)	12.10 (9.5, 14.4)
	Min, Max	5.9, 17.6
Sex		
Male	n/N (%)	403/941 (42.8%)
Female	n/N (%)	538/941 (57.2%)

1. Convert to Word using Adobe Acrobat Pro
2. Extract numbers from Word and save them in Excel
3. Upload Excel into SAS

TEAM STRUCTURE

Approach:
#5 Team



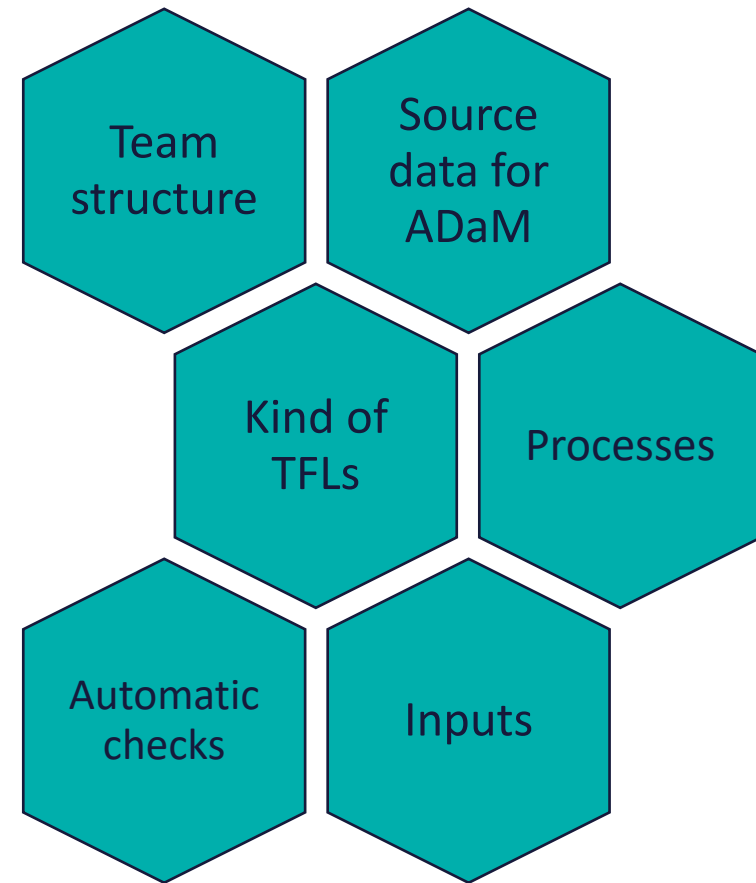
REPRODUCING OF TFLS - STATUS

Approach:
#6 Checks

Study						
Table ID	Table Name	Program Name	Programmer	Domain Used	Status	Comments
T_15_1	Baseline - Patient Characteristic Summary - Demographics and Socioeconomic Status - All Patients	T_15_1	CPE	ADSL	OK	Perfect Match
T_15_1a	Baseline - Patient Characteristic Summary - Current Psychiatric Disorders and Other Co-morbidities - All Patients	T_15_1a	CPE	ADSL	OK	Mismatch due to leading questions
T_15_1_1	Baseline - Medical History - All Patients	T_15_1_1	CPE/AKH	ADMH	OK	Perfect Match
T_15_1b	Baseline - Demographics and Socioeconomic Status Summary - Comparing All Enrolled Patients to Patients Contributing Post-Baseline Data	T_15_1b	CPE	ADSL	OK	Missing data are not correctly mapped in SDTM

SUMMARY AND CONCLUSION

- This approach allows an automatic comparison between legacy and ADaM TFLs to facilitate the review from Sponsor side and to avoid manual checks.
- It is an important step to make sure that computational algorithms were implemented in the mapping, and the subsequent programming was accurate.



The background of the slide features a blurred image of several hands raised, suggesting an interactive Q&A session. On the left side, there is a decorative geometric pattern of overlapping triangles in shades of light blue and grey.

THANK YOU FOR YOUR ATTENTION
Q&A

CONTACT



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Statistical Programmer/ Biostatistician

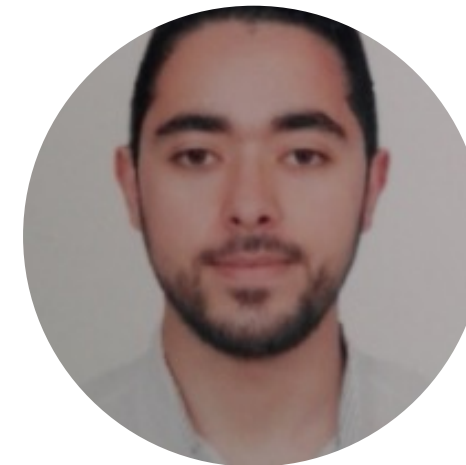
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