



How Do I Have ONE Interpretation of CDISC for All My Studies?
or

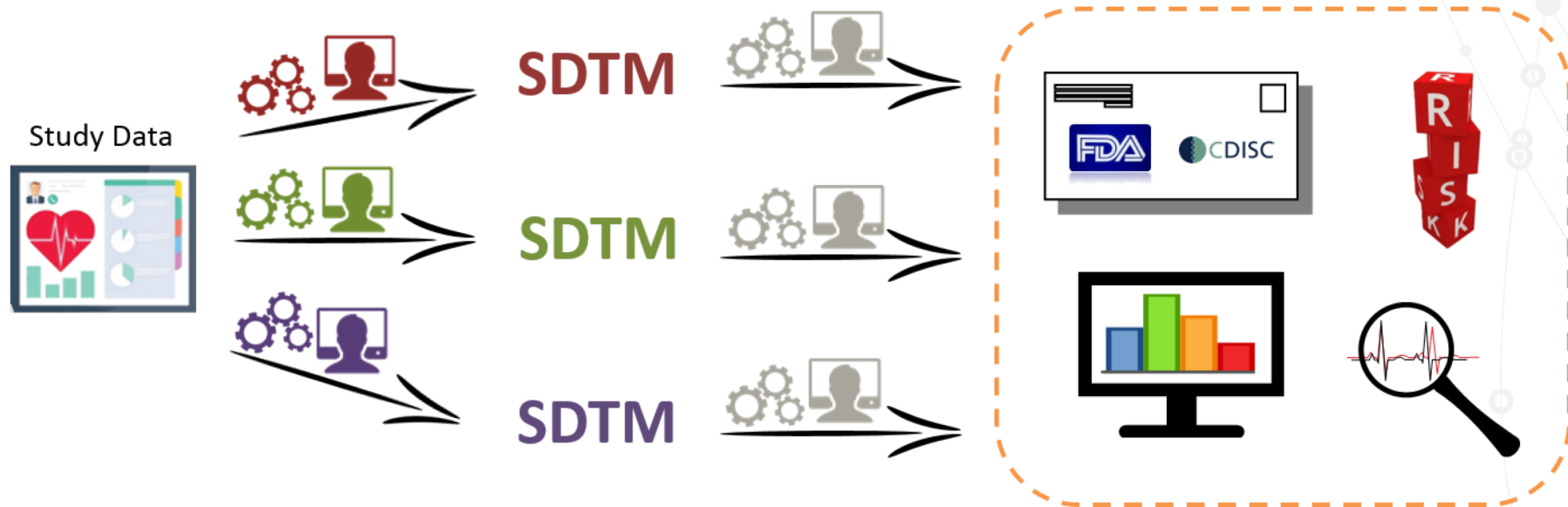
From EDC to SDTM – Faster & Better!

PhUSE US Connect 2018



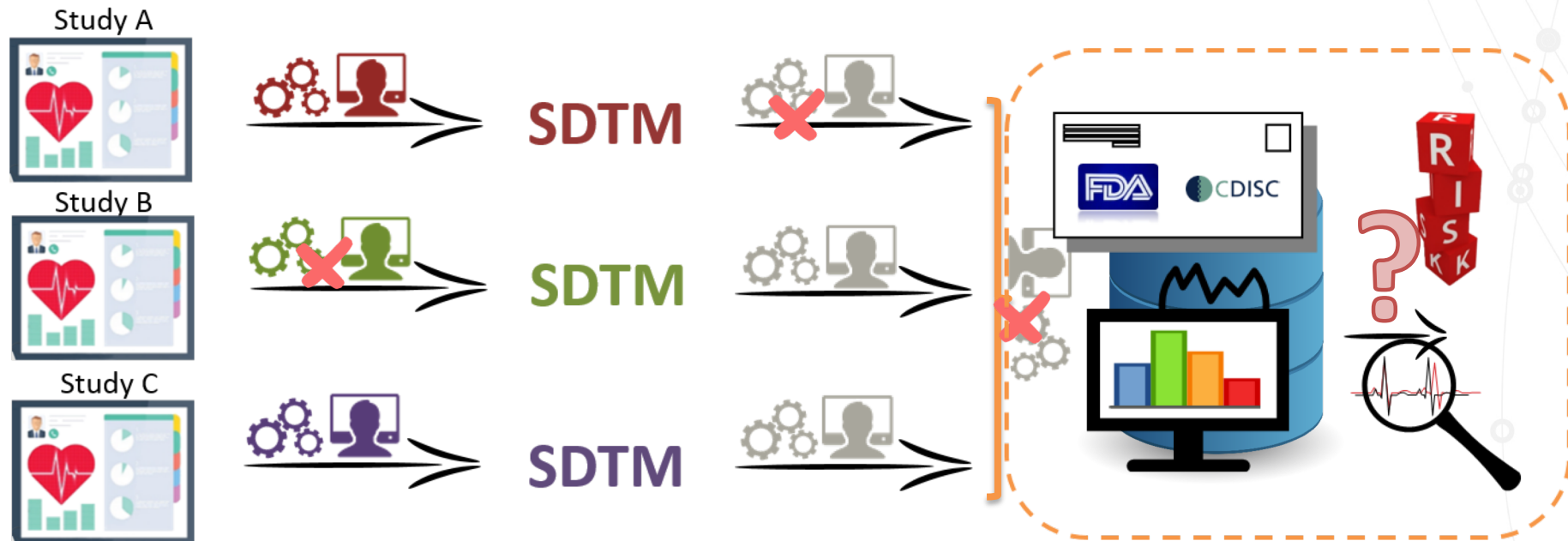
- Starting December 2016 - regulatory submissions mandate the use of SDTM
- Many sponsors embraced SDTM as their internal standard for representing clinical data
- **Challenges...**

CDISC STANDARDS - CHALLENGES



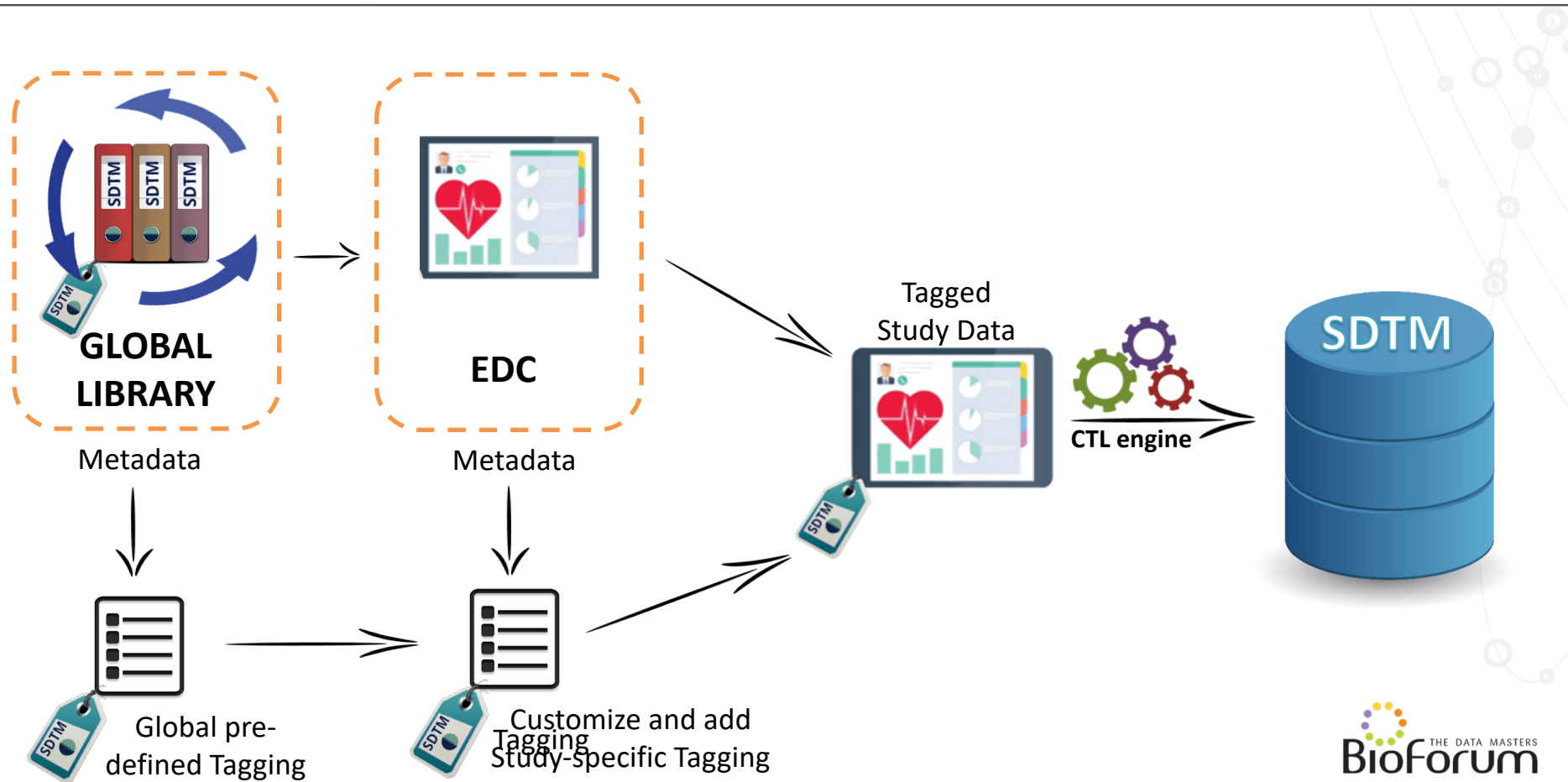
Same raw study data → different SDTM interpretations

CDISC STANDARDS - CHALLENGES



Analytics can't work with "broken data"

CONVERSION THROUGH TAGGING



What is it?

- A mapping language
 - unambiguously defines source-to-target mapping
- Human and machine readable
- Taking into account all (probable) mapping scenarios
- **Focus on 'what', not 'how'** → long manual SAS program turns into a single line of tagging instruction



SOURCE – DEFINES WHICH VALUES TO TAG

- All values
- A subset of values, examples –
 - ✓ All values in a given visit
 - ✓ First/last value
 - ✓ Highest/lowest value
 - ✓ Highest/lowest value in a given visit
 - ✓ ...

Source field can have multiple tags to cover different mapping scenarios.



TARGET KEY – DEFINES THE TARGET SDTM RECORDS

The exact domain and record/s in our target SDTM

- Eliminates ambiguities regarding placement of source values in the SDTM
- Examples –
 - ✓ Demographic (DM) record
 - ✓ Systolic blood pressure record in Vital Signs (VS)
 - ✓ Disposition (DS) milestone of randomization
 - ✓ ...

Subject and visit (if available) are by default part of our target key



MAPPING LOGIC – DEFINES HOW TO REPRESENT SOURCE DATA IN SDTM VARIABLES

Clearly define how we interpret the value/s and what we do with them

- Examples –
 - ✓ One-to-one mapping
 - ✓ Conditional mapping of values to one or more SDTM variable/s
 - ✓ Assignment or conditional assignment of values to one or more SDTM variable/s
 - ✓ ...



HUMAN & MACHINE READABLE

Source
All
Earliest
Visit1
Earliest-Visit1

Target Key
DM(all)
EX (EXTRT="WONDERPILL")
DS (DSCAT="MILESTONE", DSDECOD="RANDOMIZATION")
VS (VSTESTCD= "HR", VSTPT="10MIN POST", VSTPTREF="ADMINISTRATION")

Mapping Logic
One-to-one
DSSTDTC (ISO8601)
VSORRES + VSSTRESC/N (default conversion) + VSORRESU/VSSTRESU="BPM"



EXAMPLE #1 – VITAL SIGNS (HEART RATE)

CRF FIELD	Tagging
HR_result_10min	All values in VS (VSTEST="Heart Rate", VSTPT="10MIN") mapped to VSORRES + VSORRESU="BPM" + VSSTRESC/N/U (derived) + VSPOS="Standing"
HR_result_20min	All values in VS (VSTEST="Heart Rate", VSTPT="20MIN") mapped to VSORRES + VSORRESU="BPM" + VSSTRESC/N/U (derived) + VSPOS="Standing"

Subject and visit (if available) are by default part of our target key



EXAMPLE #2 – TREATMENT DATES

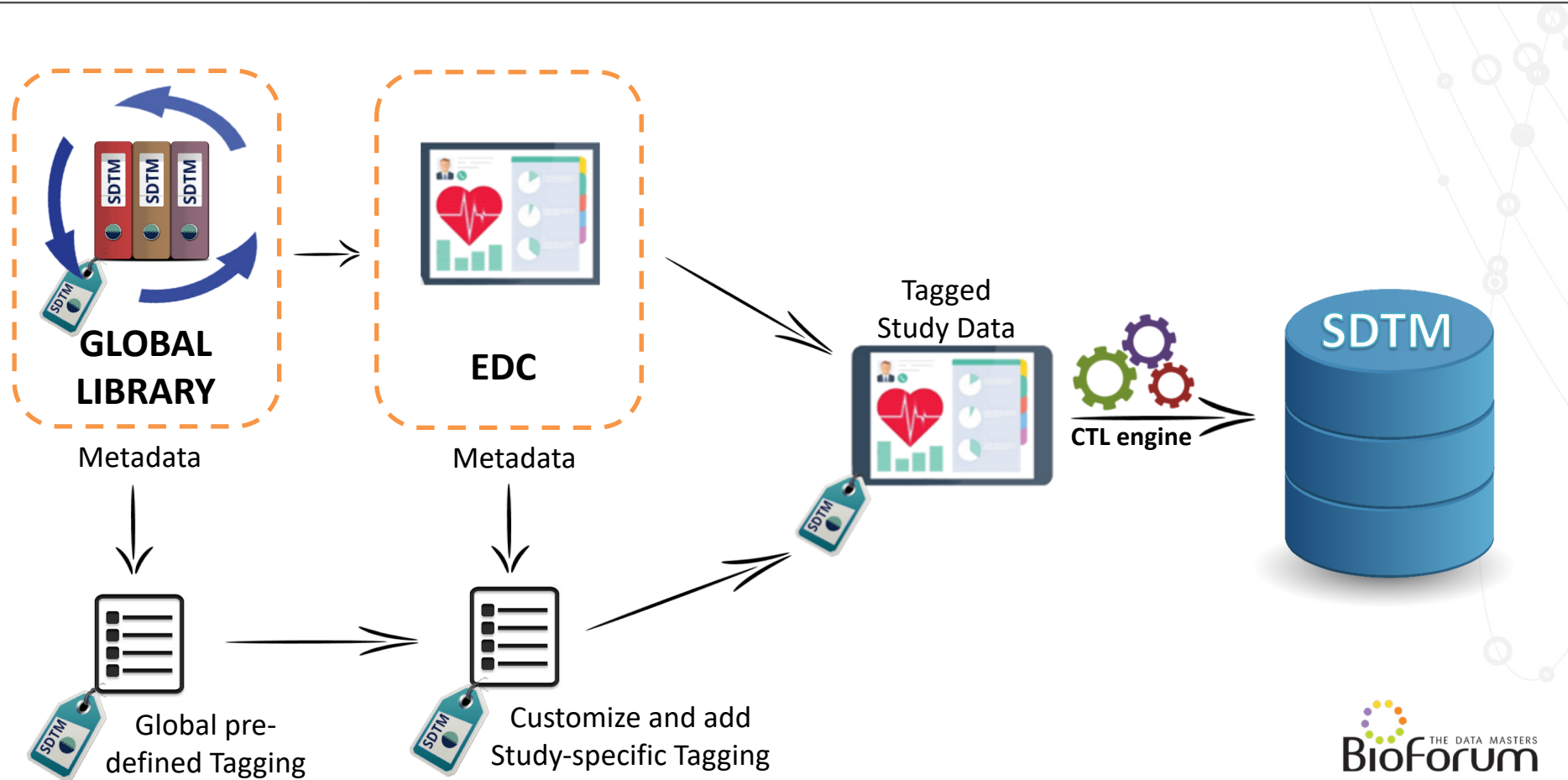
CRF FIELD	Tagging
Treat-date	First value in DS (DSCAT="MILESTONE", DSDECOD="RANDOMIZATION") mapped to DSSTDTC (ISO8601)

CRF FIELD	Tagging
Treat-date	All values in EX (EXTRT="WONDERPILL") mapped to EXSTDTC (ISO8601)
Dose	All values in EX (EXTRT="WONDERPILL") mapped to EXDOSE + EXDOSU="mg" + EXROUT="ORAL"

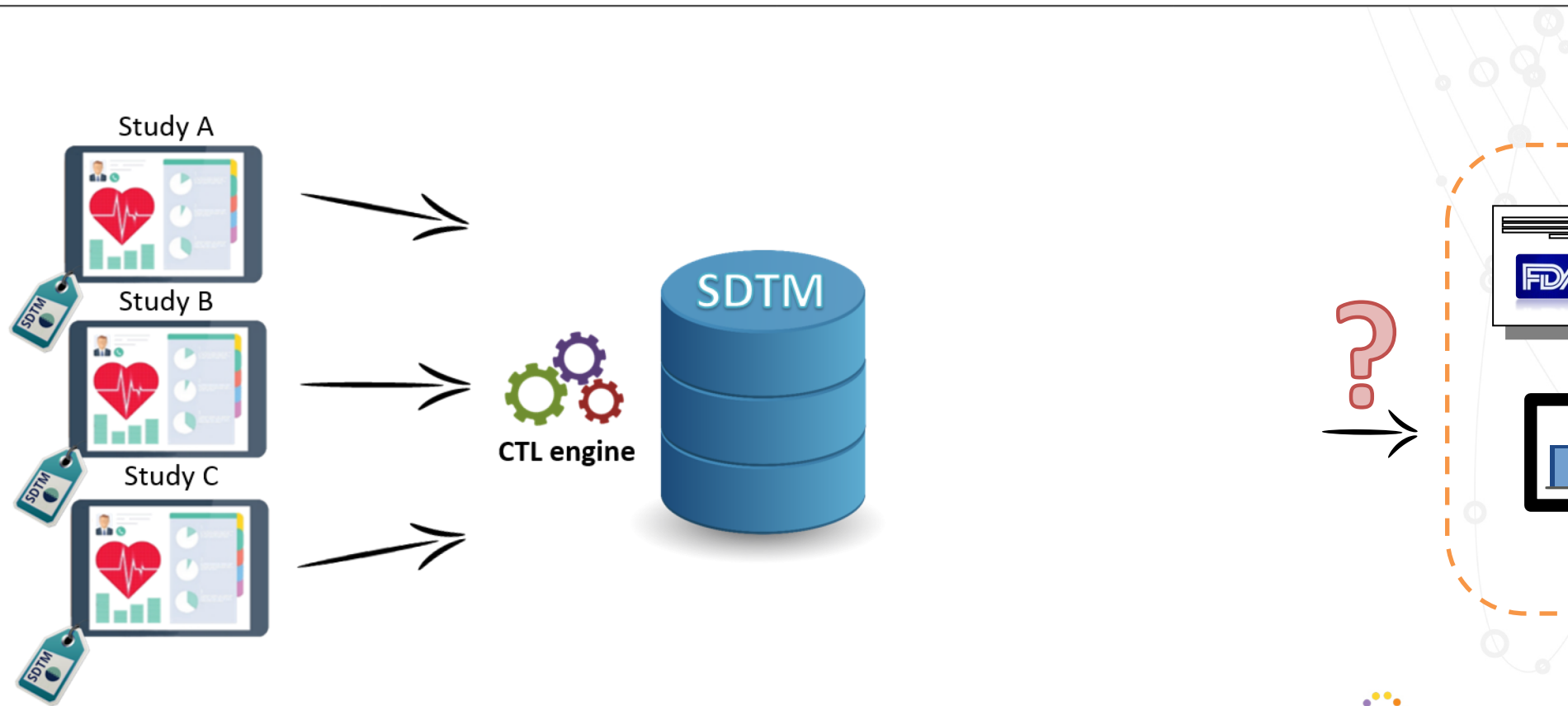
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CONVERSION THROUGH TAGGING



CONVERSION THROUGH TAGGING



- *Data analytics is moving forward fast, but data quality is holding us back*
 - *Better and faster is possible*
- 



Thank you

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