



PHUSE US Connect 2021

Stream: Data Standards & Governance (DS)

Presentation No: DS09

Standards and Governed Data in the Clinical Data Pipeline

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Standards

Controlled Terminology Global TA
Indication
CDASH ADaM Ver 1 Inv. Product
Ver 2
SDTM *"Like"* Ver 3 Up-versioning
Ver n
FIHR
"Informed" labs *"Modelled After"*
eCRFs HL-7 biomarkers
diaries SupQual
Coding Dictionaries



***"40% LPV to
DBL cycle time
increase"***

2019 Tufts
Data Strategy
& Transformation Study



Standards

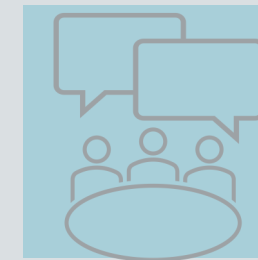
non-EDC

EHR

decentralized Trials

wearables

streaming data



“40% LPV to DBL cycle time increase”

2019 Tufts
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Need a governance process that starts at the beginning

“If you fail to plan, you’re planning to fail.”

A Data Strategy is the 1st Step in Improving:

EFFICIENCY

**ABILITY TO USE DATA TO
DRIVE DECISIONS**

OVERSIGHT

Which yields Improved:

**ABILITY GET NEW THERAPIES
TO PATIENTS SOONER**

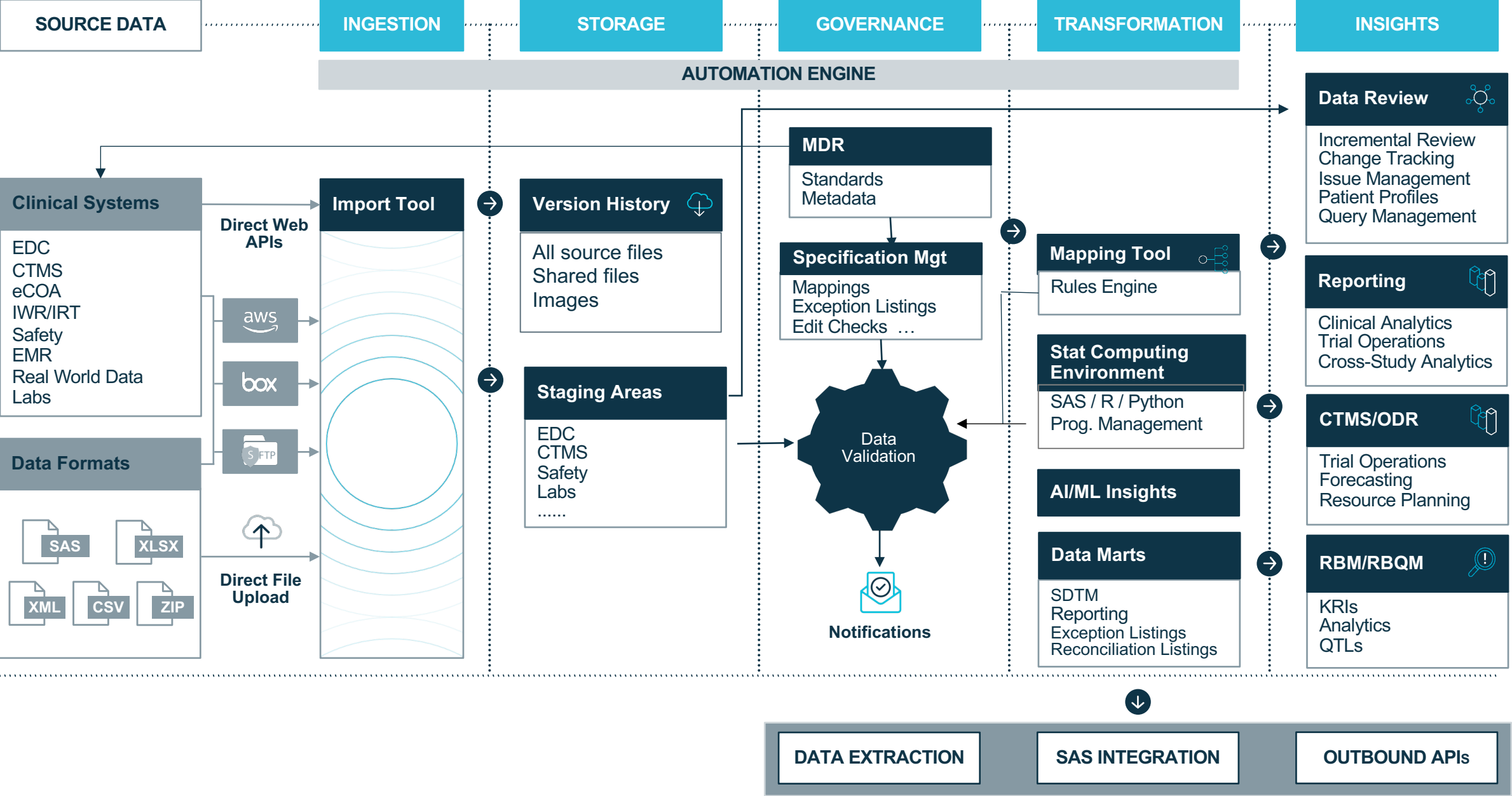
BUSINESS BOTTOM LINE

**EASE OF MEETING
REGULATORY EXPECTATIONS**

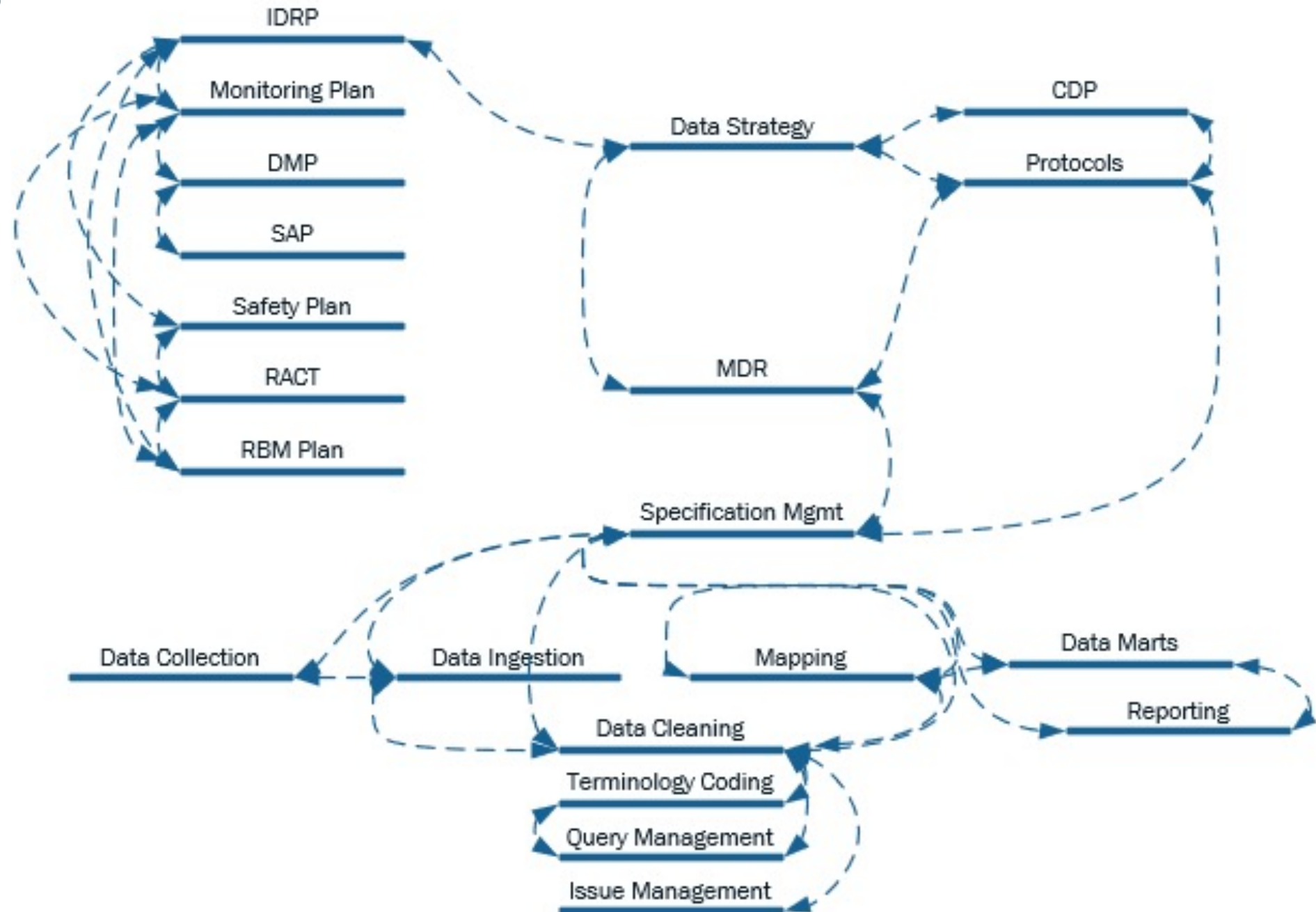


Lots of Plans





Ecosystem Web





Thank you

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