

Metadata driven approach for CDISC standards

PhUSE - Bridgewater, NJ
2014-08-20

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Bridgewater, NJ

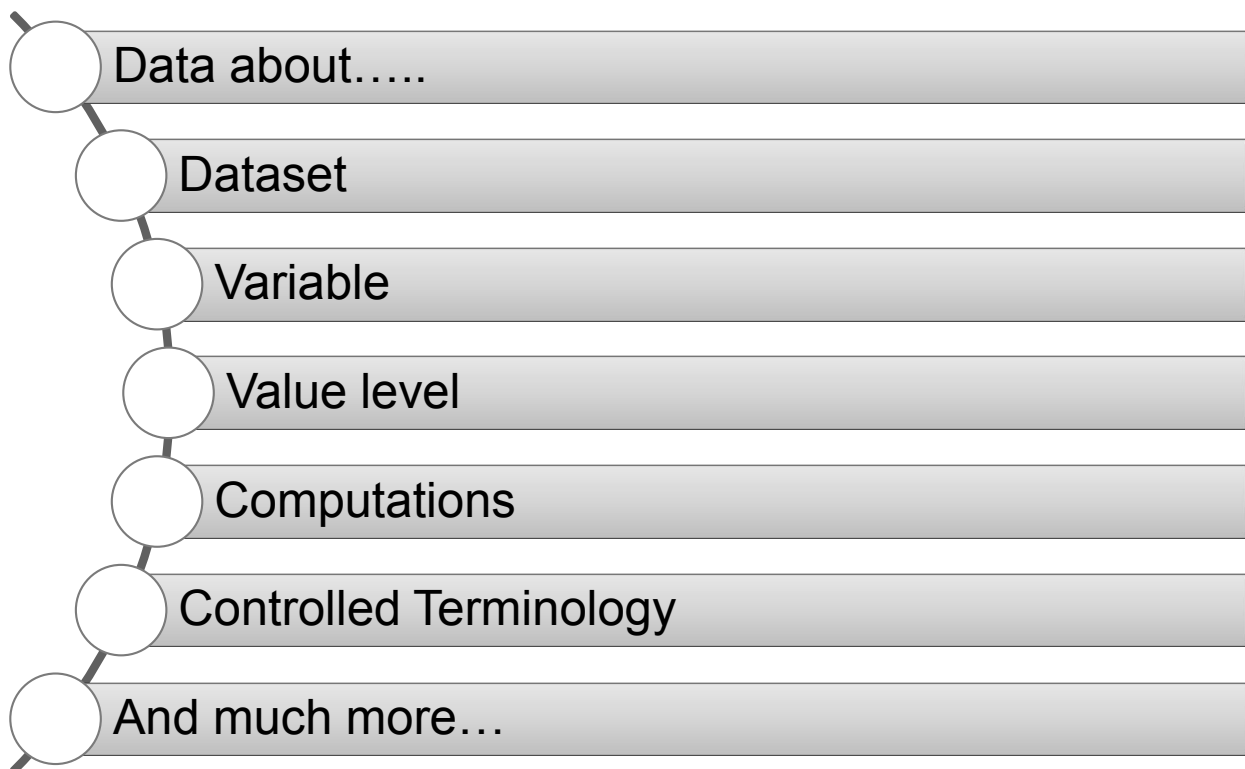
mahipal.vanam@perceptservices.com

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What is metadata



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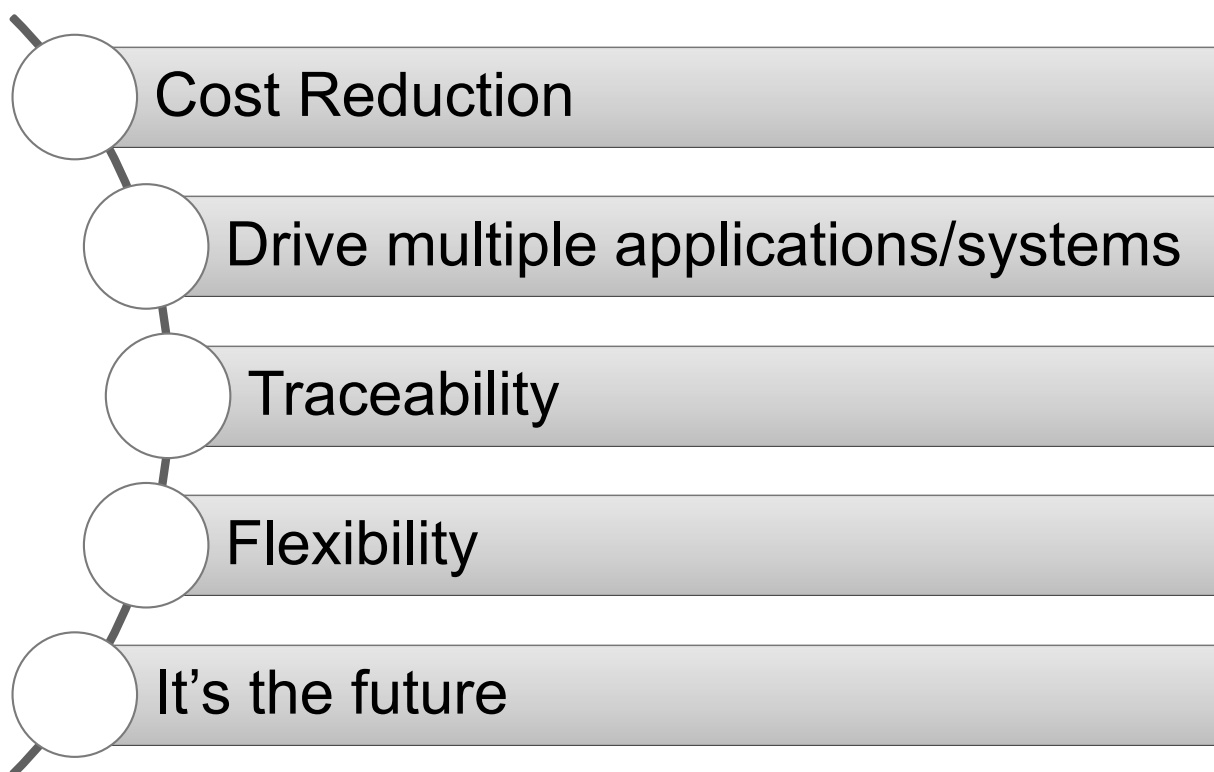
Challenges we face today



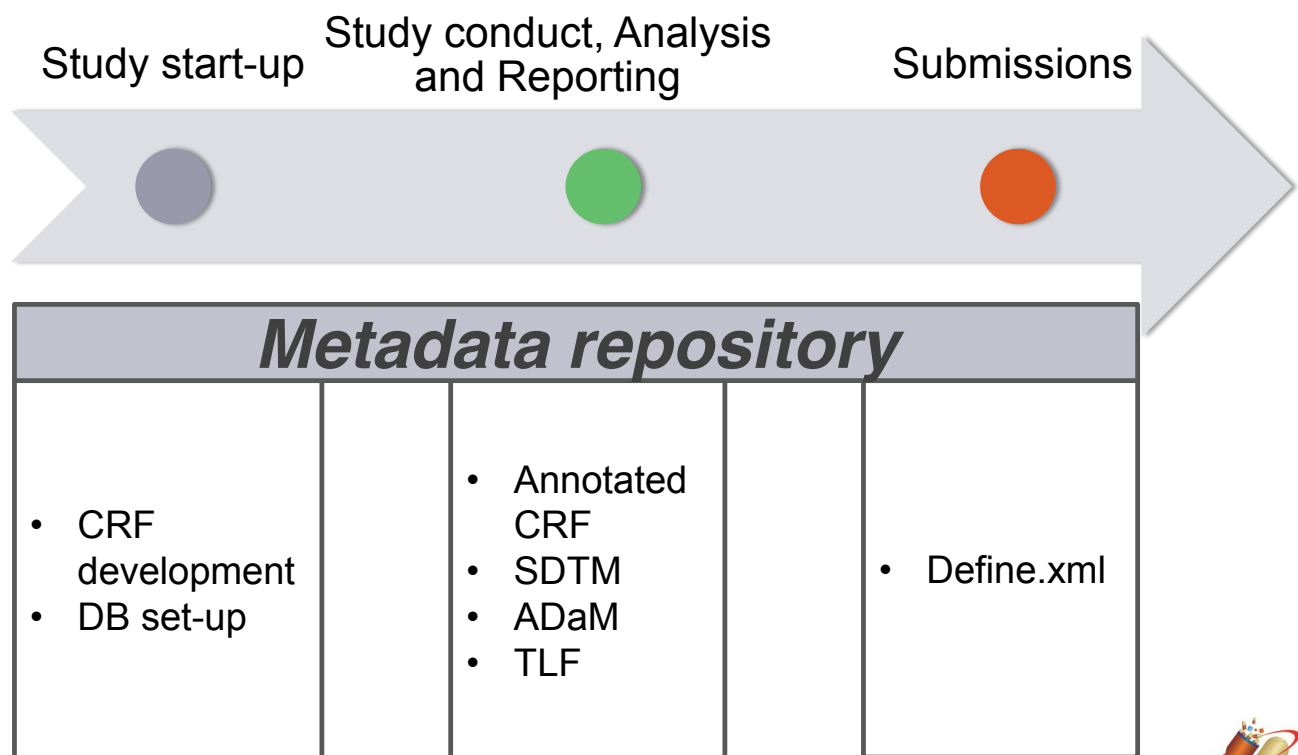
Advantages



Advantages_(continued)



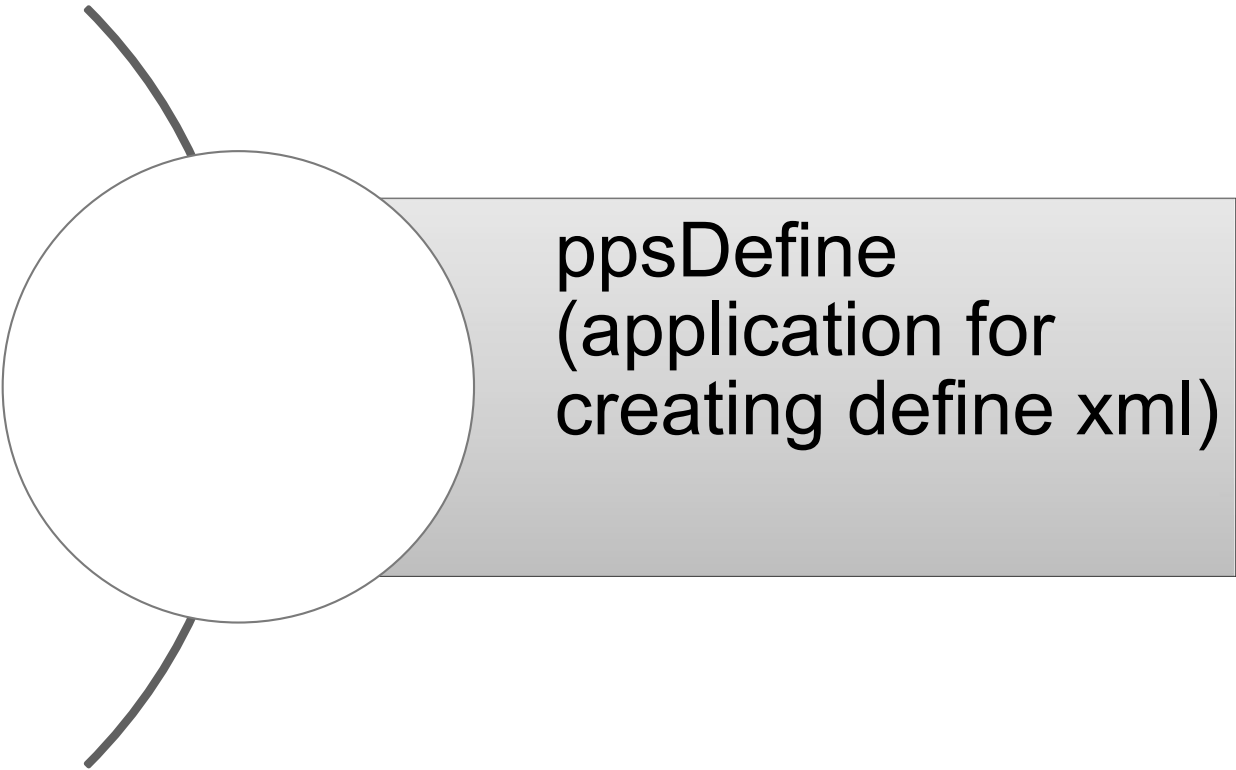
Metadata driven trial activities



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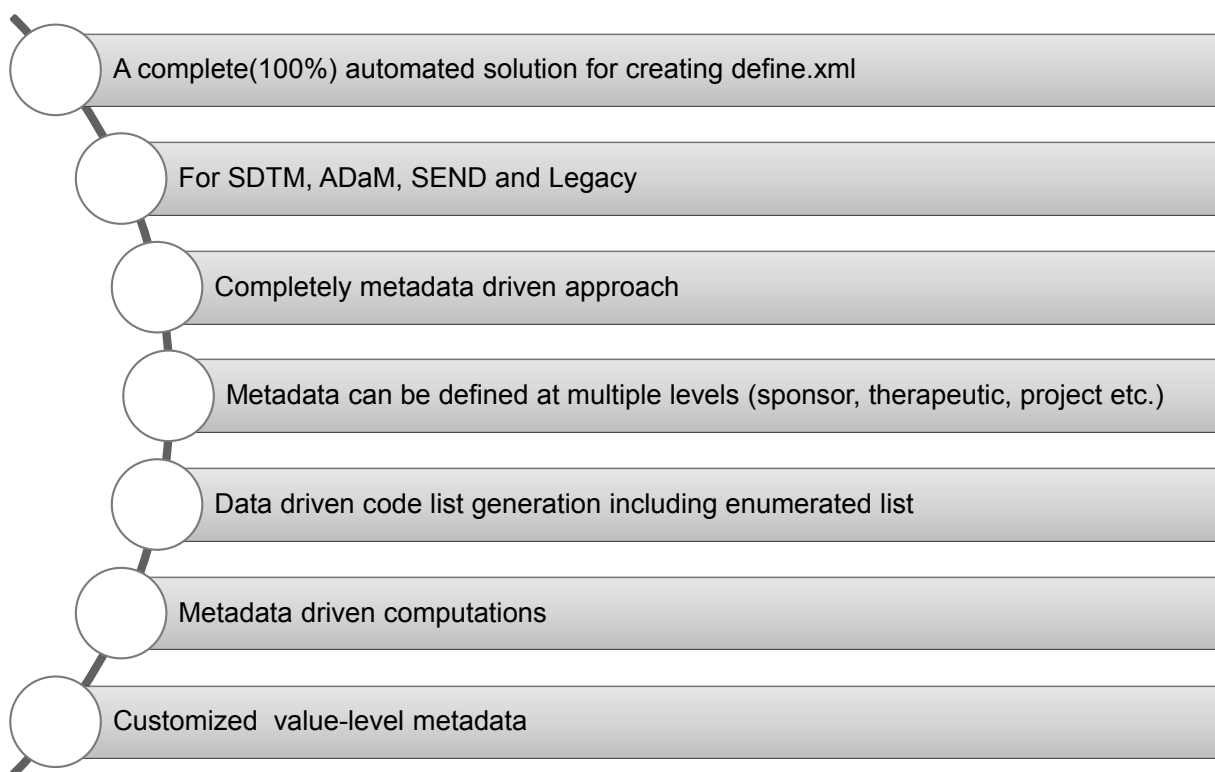
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Define XML generation



ppsDefine
(application for
creating define xml)

Define XML automation by ppsDefine



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Data flow

Metadata repository



Dataset specifications



Dataset creation



Create define.xml

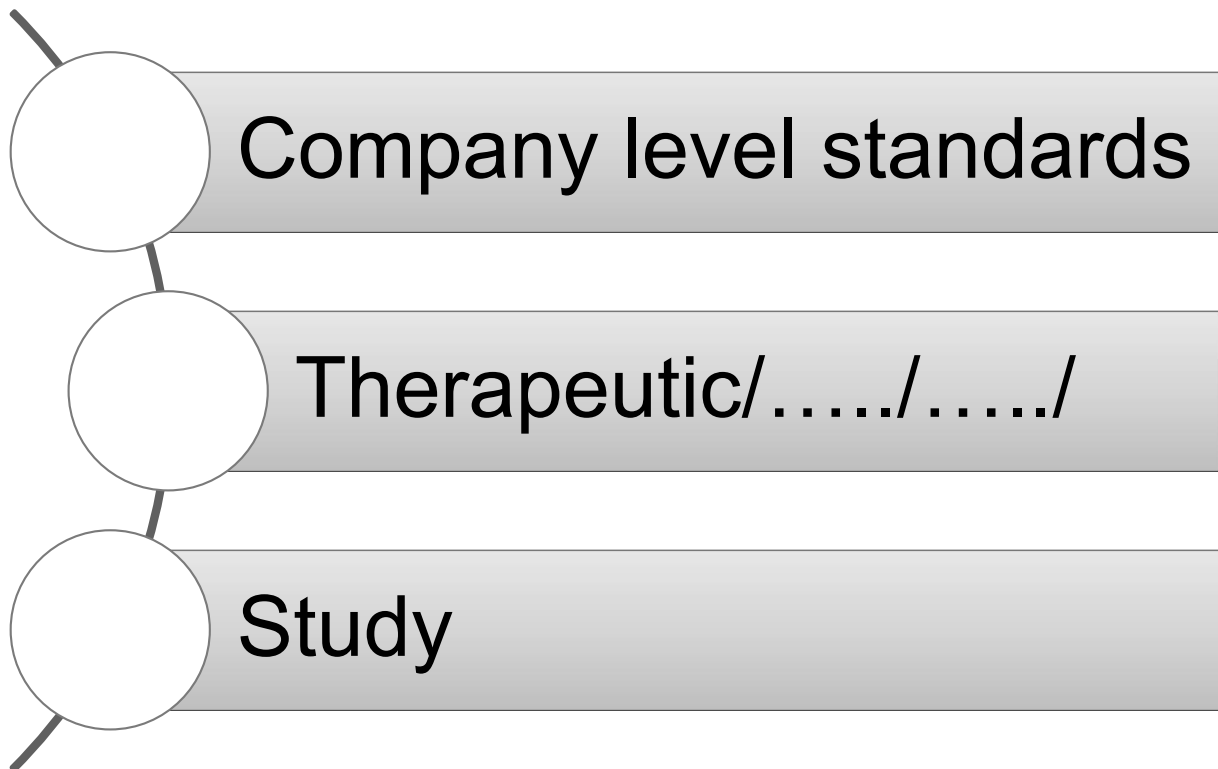
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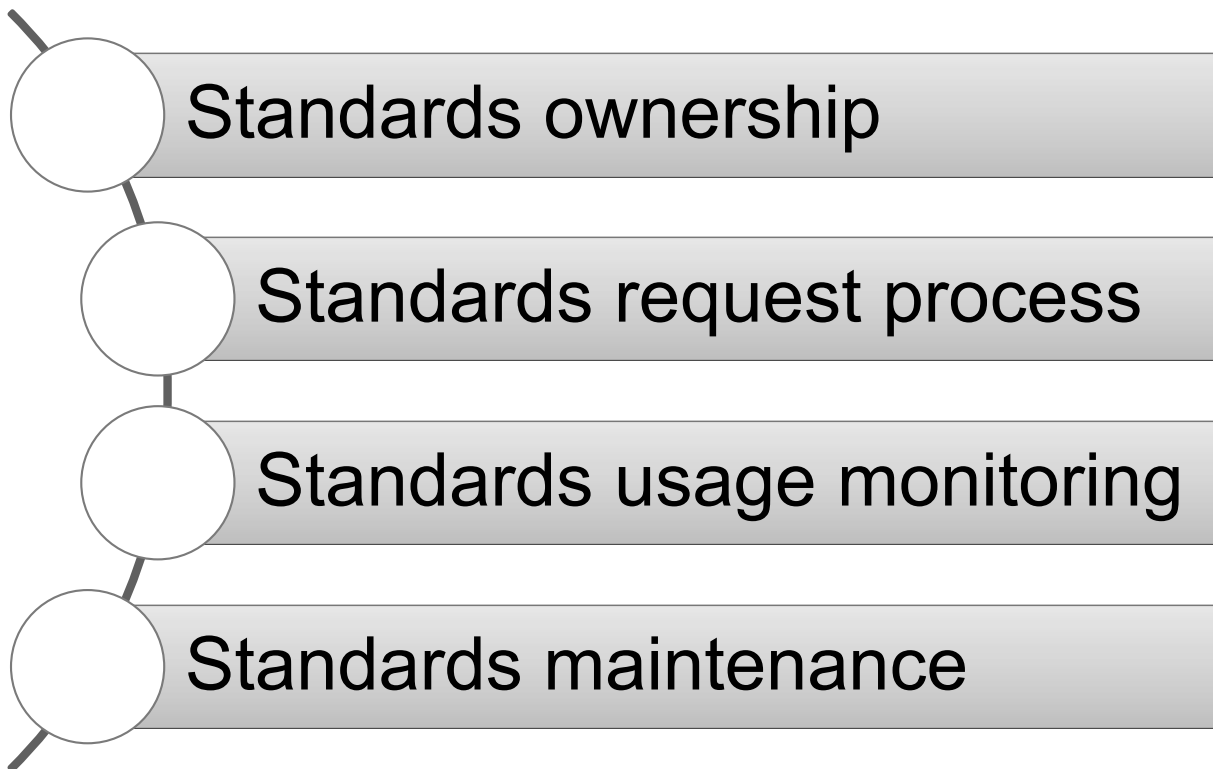
Traceability



Compliance



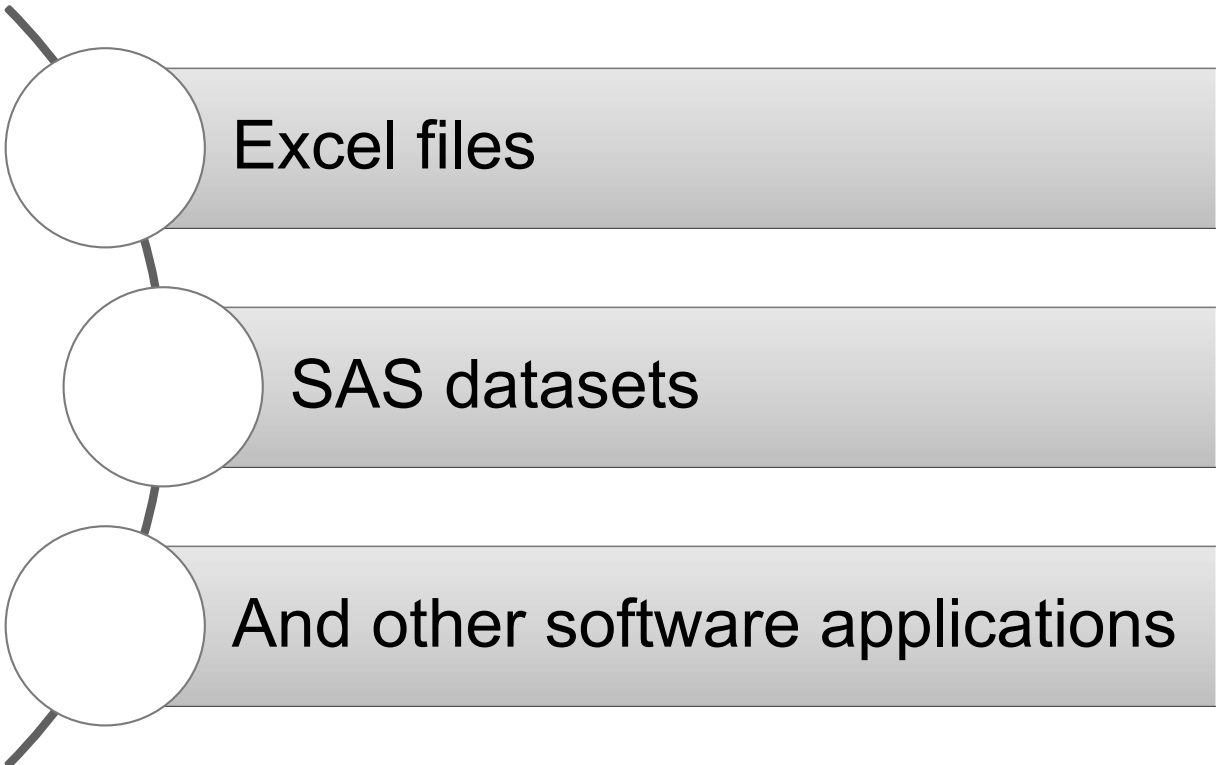
Governance



Standards Libraries



Metadata storage



Excel files

SAS datasets

And other software applications

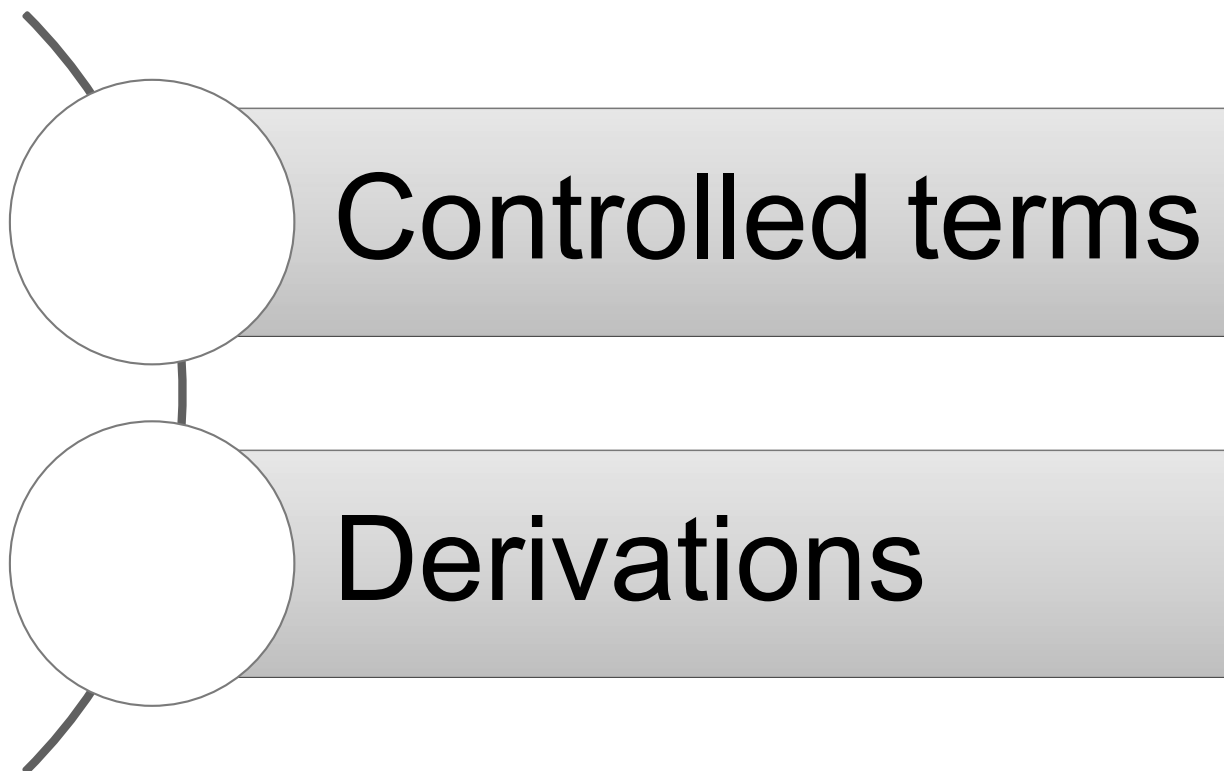
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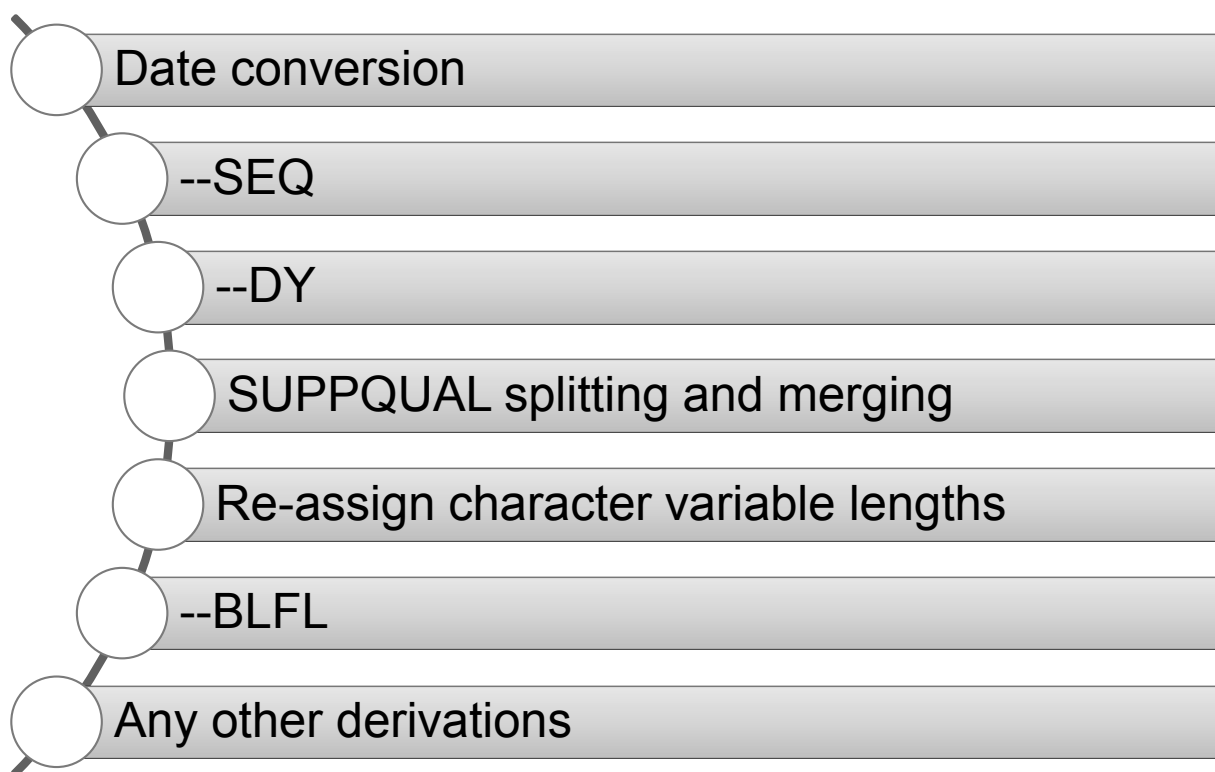
Controlled Terminology



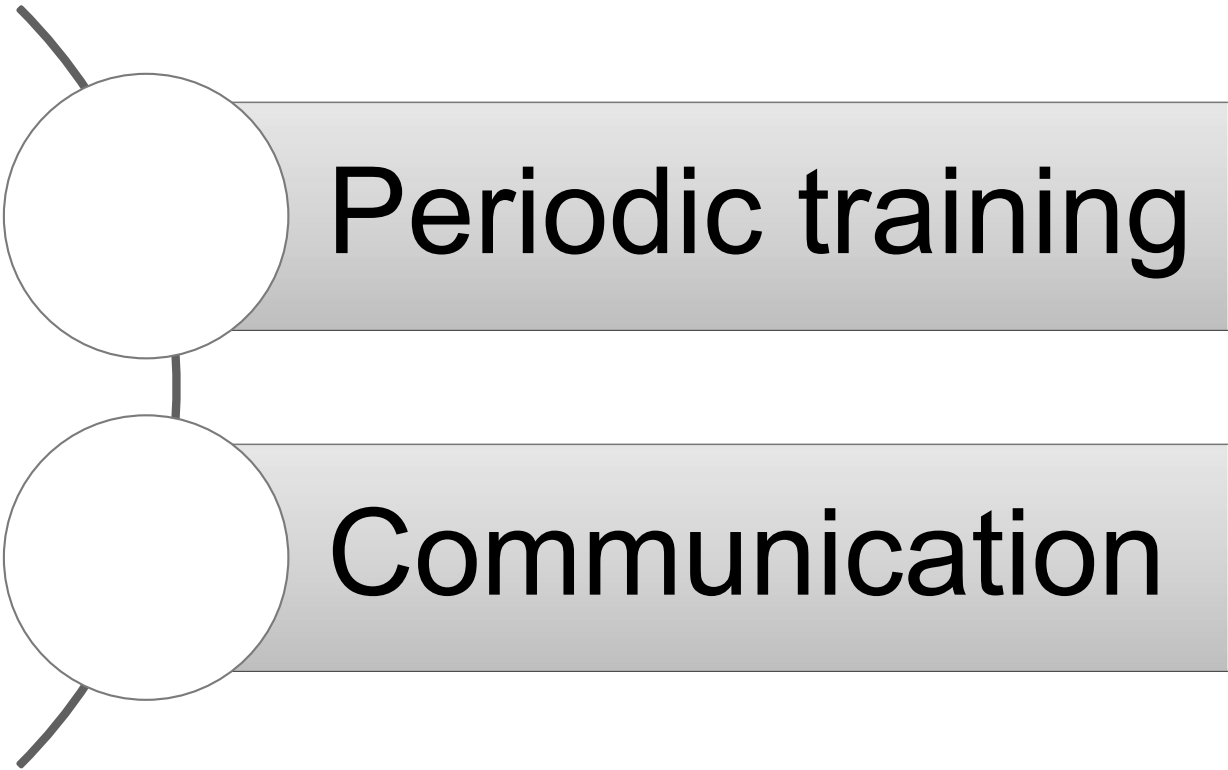
Value-Level Metadata



Macro Library



Training



Periodic training

Communication

Questions?

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Thank You!

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