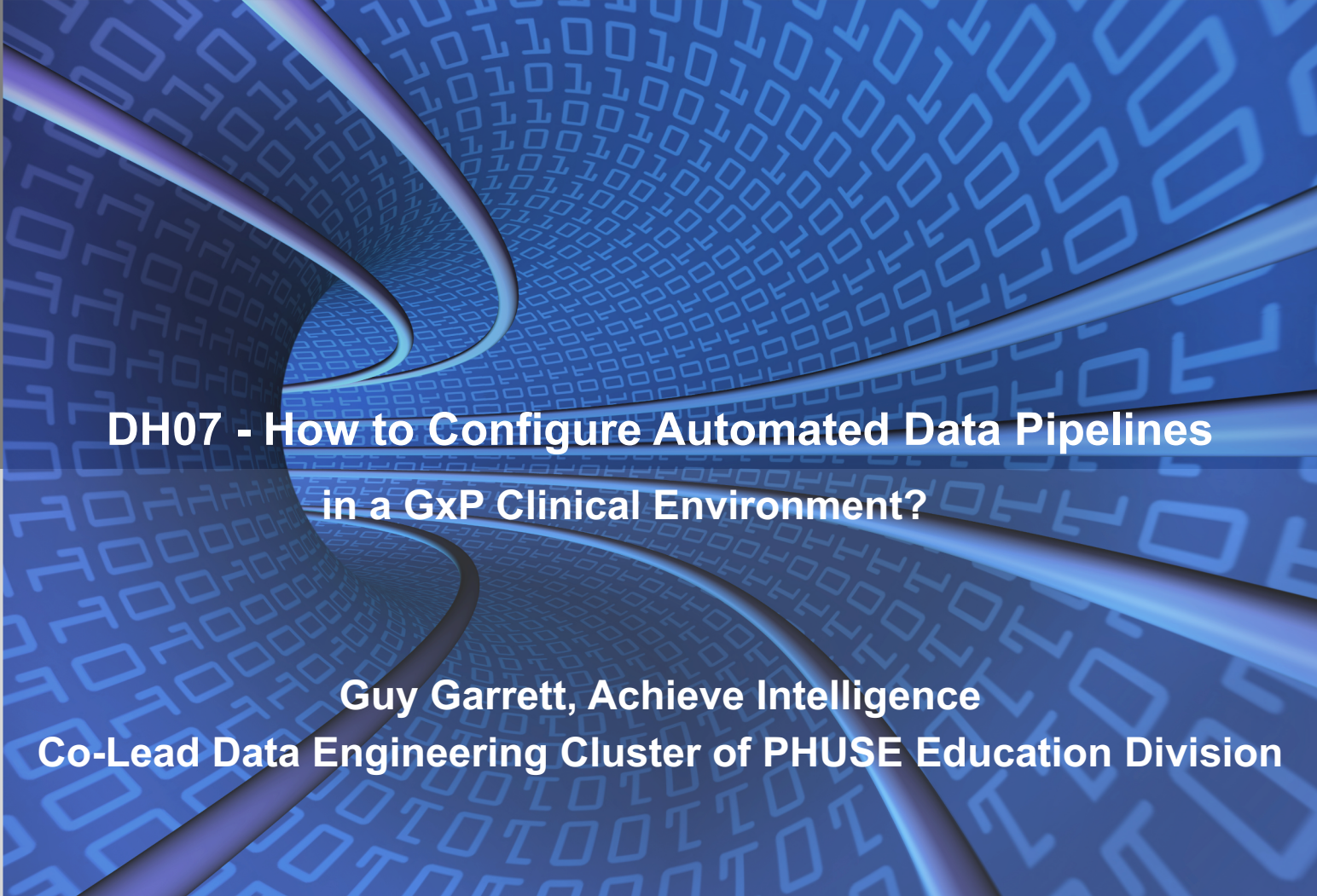




DH07 - How to Configure Automated Data Pipelines in a GxP Clinical Environment?

**Guy Garrett, Achieve Intelligence
Co-Lead Data Engineering Cluster of PHUSE Education Division**

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[5 mins]

Current
State



[5 mins]

Automated
Pipelines



[5 mins]

Study
Specific
Data



[5 mins]

GxP
Implication

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[5 mins]

Current
State



[5 mins]

Automated
Pipelines



[5 mins]

Study
Specific
Data

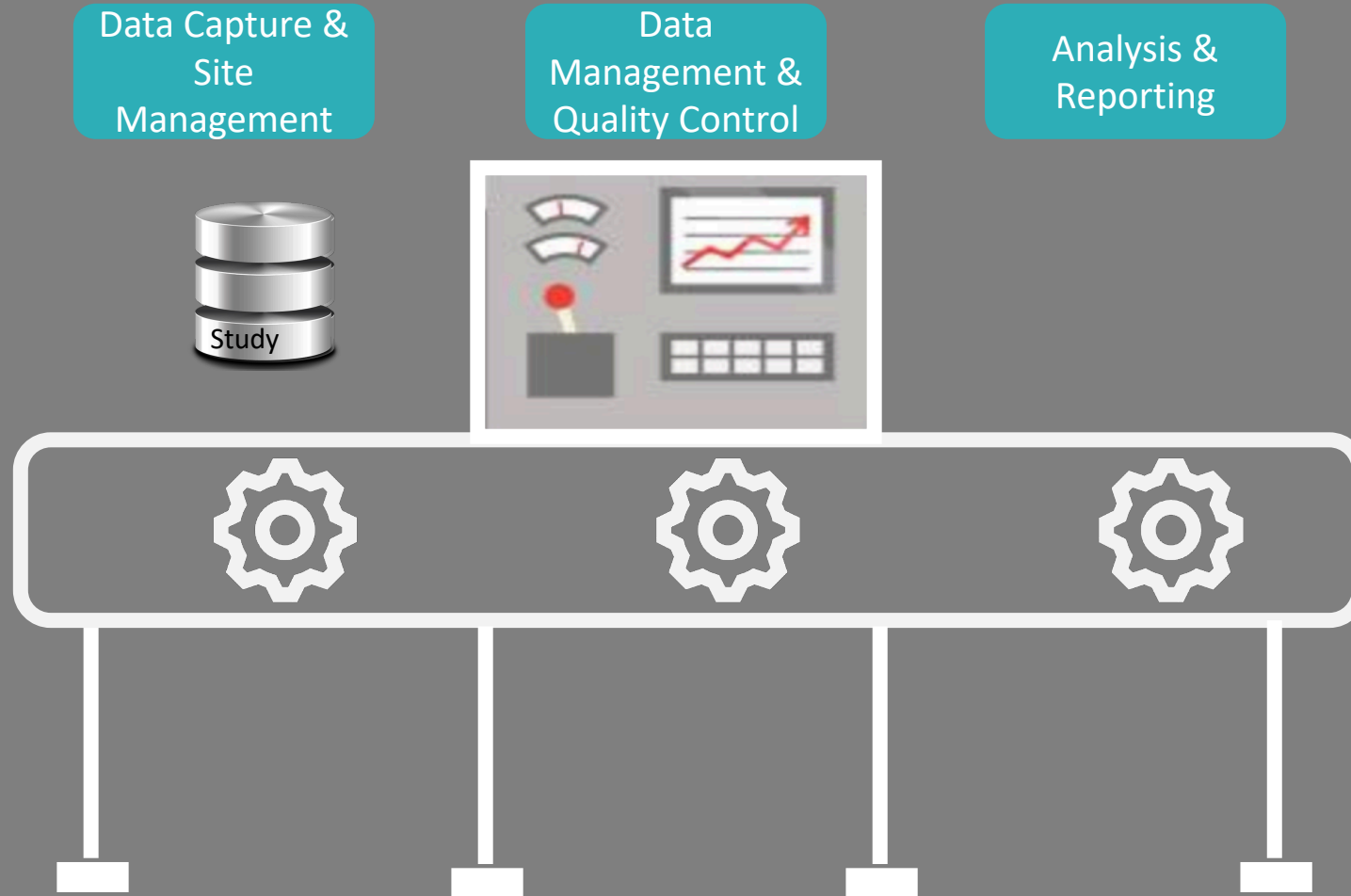


[5 mins]

GxP
Implication

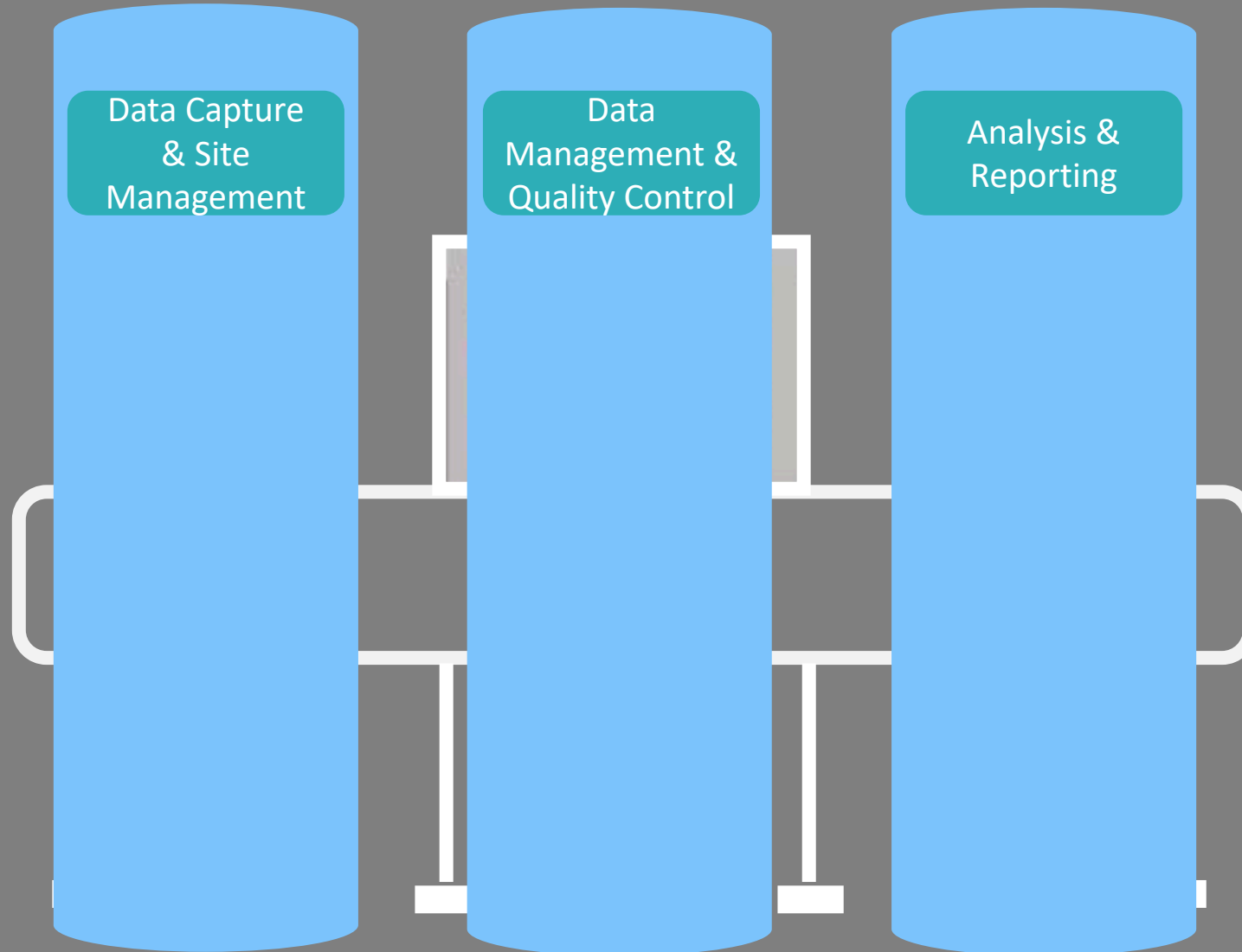
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Assembly Line

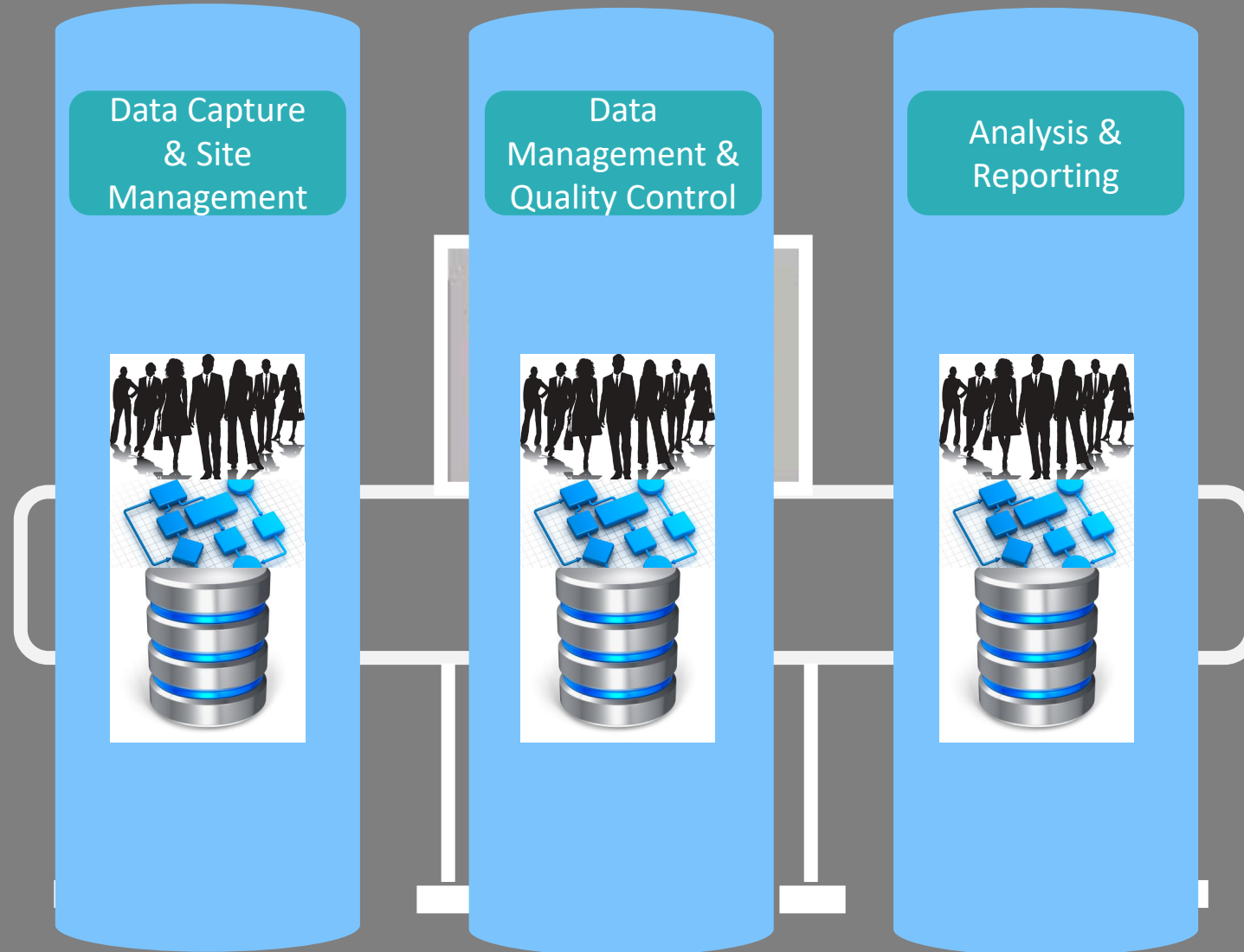


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Functional Silos



Functional Silos



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[5 mins]

Current
State



[5 mins]

Automated
Pipelines



[5 mins]

Study
Specific
Data



[5 mins]

GxP
Implication

Automated Pipeline



Automated Pipeline: Common Data



Study
Specific
Data

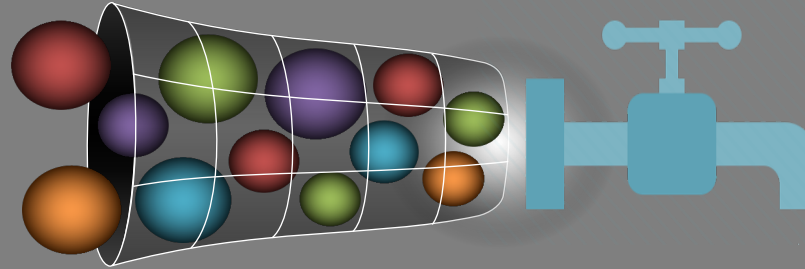


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Automated Pipeline: Common Data



Common
Data

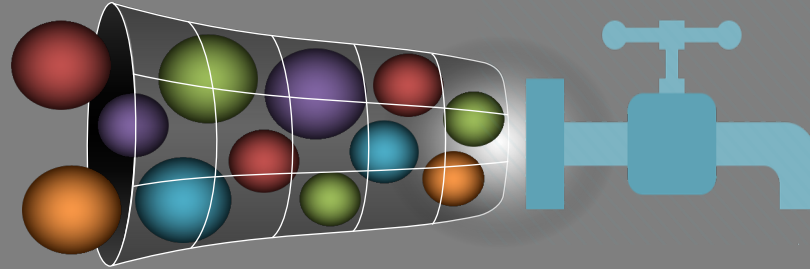


Study
Specific
Data



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Automated Pipeline: Common Data



Study
Specific
Data



Common
Data



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[5 mins]

Current
State



[5 mins]

Automated
Pipelines



[5 mins]

Study
Specific
Data



[5 mins]

GxP
Implication

Study Specific Data



Study Specific Data: Example



Intraocular pressure (IOP) is the fluid pressure inside the eye.

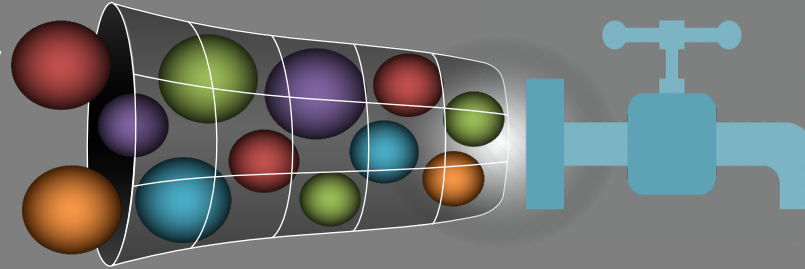
Tonometry is the method eye care professionals use to determine this.

IOP is an important aspect in the evaluation of patients at risk of glaucoma.

Most tonometers are calibrated to measure pressure in millimetres of mercury (mmHg).

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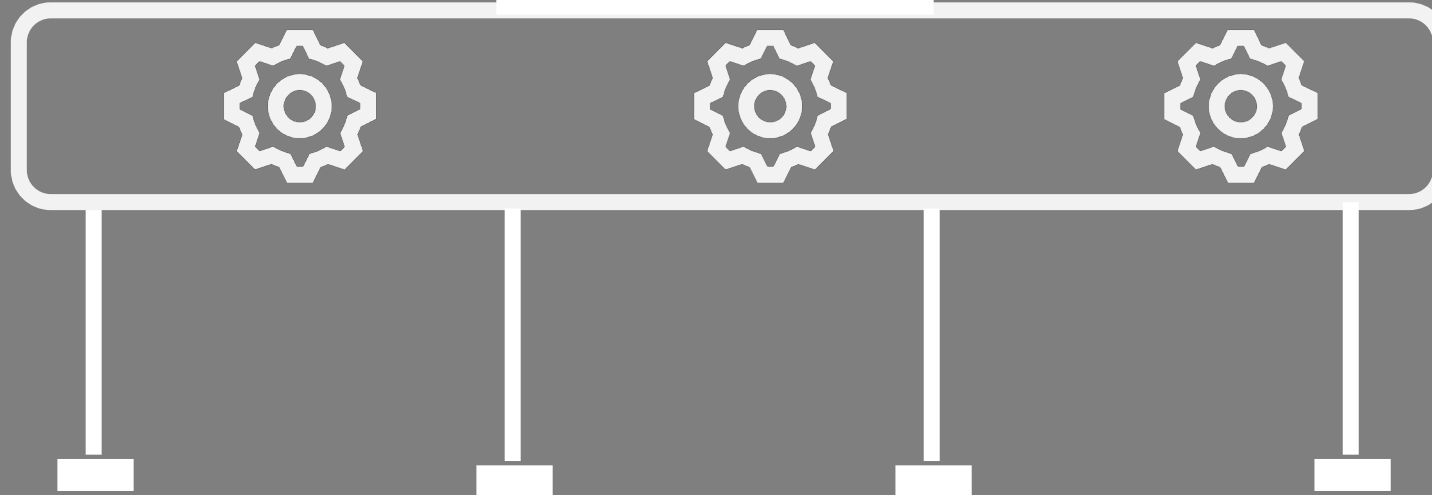
Study Specific Data: Programmed Manually



Study
Specific
Data

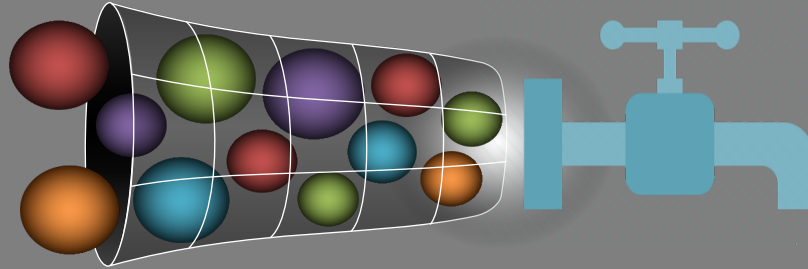


Common
Data



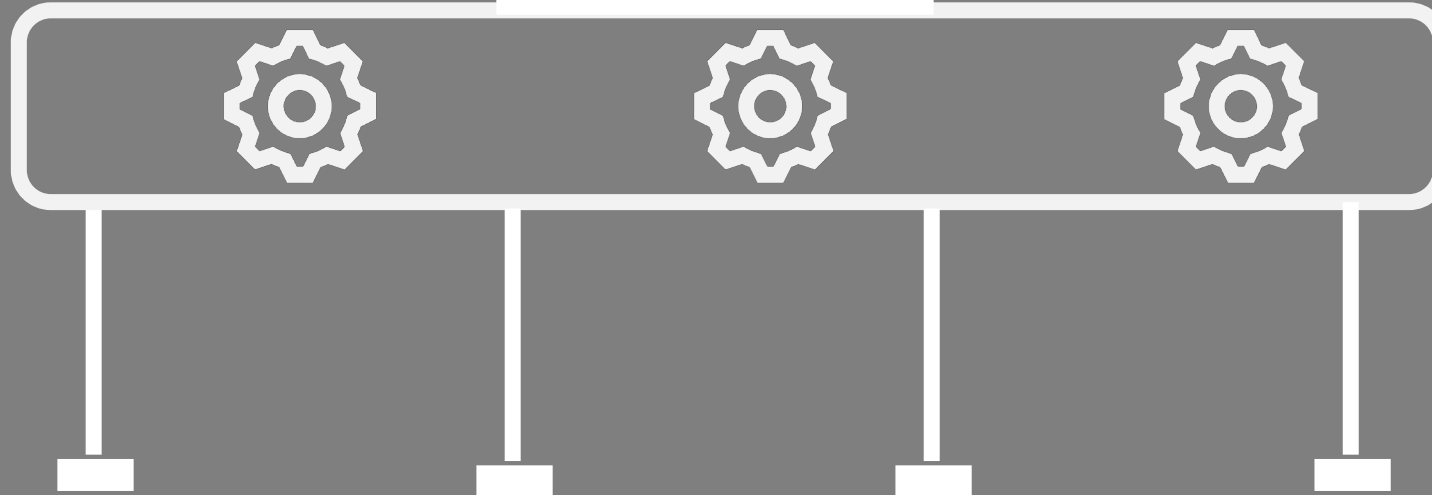
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Study Specific Data: Programmed Manually



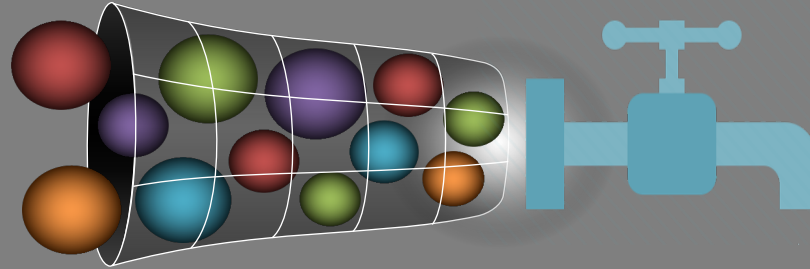
Study
Specific
Data

Common
Data



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Combined Common & Study Specific Data



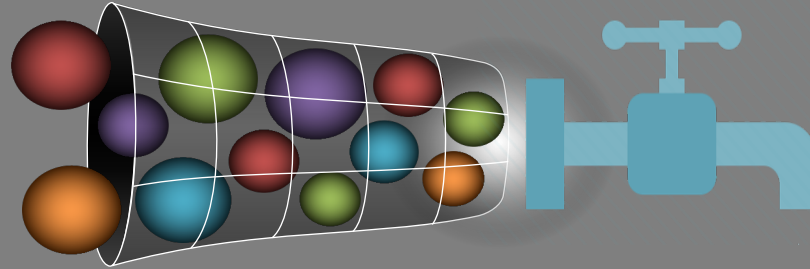
Combined
Study
Data

```
select *  
from a, b
```



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Automated Output

Combined
Study
Data

SDTM

ADaM

Others



Automated Output: Example Code

```
1 SELECT DISTINCT
2     'C' || [fac].[compound_key] || '_' ||
3     SUBSTR ([vie].[compoundname], 1 + INSTR ([vie].[compoundname], ' '))
4     || '_' || 'T' || [fac].[trial_key] AS 'STUDYID',
5     'DM' AS 'DOMAIN',
6     'T' || [fac].[trial_key] || '_' || 'P'
7     || [fac].[patient_key] AS 'USUBJID',
8     'Patient_' || [fac].[patient_key] AS 'SUBJID',
9     [gender] AS 'SEX',
10    [vie].[VISIT_ACTUAL_DT] AS 'DMDTC'
11 FROM    [visitview] AS [vie],
12         [visit_fact] AS [fac]
13 WHERE   [vie].[trial_key] = [fac].[trial_key]
14         AND [vie].[compound_key] = [fac].[compound_key]
15         AND [vie].[patient_key] = [fac].[patient_key]
16         AND [vie].[visit_key] = [fac].[visit_key]
17 GROUP BY [vie].[patient_key]
18 HAVING MIN ([fac].[visit_key])
```

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[5 mins]

Current
State



[5 mins]

Automated
Pipelines



[5 mins]

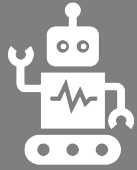
Study
Specific
Data



[5 mins]

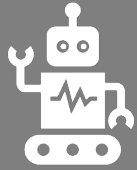
GxP
Implication

GxP Implications



- ✓ Automated pipeline code is **Write-Once-Use-Many**

GxP Implications

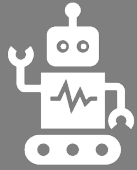


✓ Automated pipeline code is **Write-Once-Use-Many**



✓ Validation effort is reduced across studies

GxP Implications



✓ Automated pipeline code is **Write-Once-Use-Many**

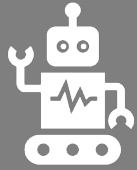


✓ Validation effort is reduced across studies



✓ Single pipeline = adherence to standards

GxP Implications



- ✓ Automated pipeline code is **Write-Once-Use-Many**



- ✓ Validation effort is reduced across studies



- ✓ Single pipeline = adherence to standards

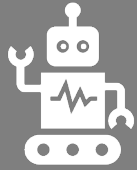


or



- ✓ Centralised database and/or directory-folder structure support

GxP Implications



✓ Automated pipeline code is **Write-Once-Use-Many**



✓ Validation effort is reduced across studies



✓ Single pipeline = adherence to standards



or



✓ Centralised database and/or directory-folder structure support



✓ Faster delivery of submission artefacts

Many Thanks:

phuse education division: **data engineering cluster**

Special Thanks:

Renu Shukla

Marius Mostert

Martin Houben

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Thank You