

How can we integrate new technology and maintain data integrity?

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PRESENTATION OUTLINE



We love new technology
How do we use new technology
Maintaining data integrity
Simplified approach
Summary
Q&A

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WE LOVE NEW TECHNOLOGY

As an industry, we are not afraid of new technology. We are just slow!

Visualisation

Real world data

Metadata repository

Data lake, AI and Machine Learning

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How do we use new technology?

DATA COLLECTION

- Wearables
- Implants
- Cloud data

DATA STORAGE

- Project databases
- CDISC format
- Metadata

DATA ANALYSIS

- SAS
- R, Python
- Machine Learning and AI
- NONMEM

DATA REPORTING

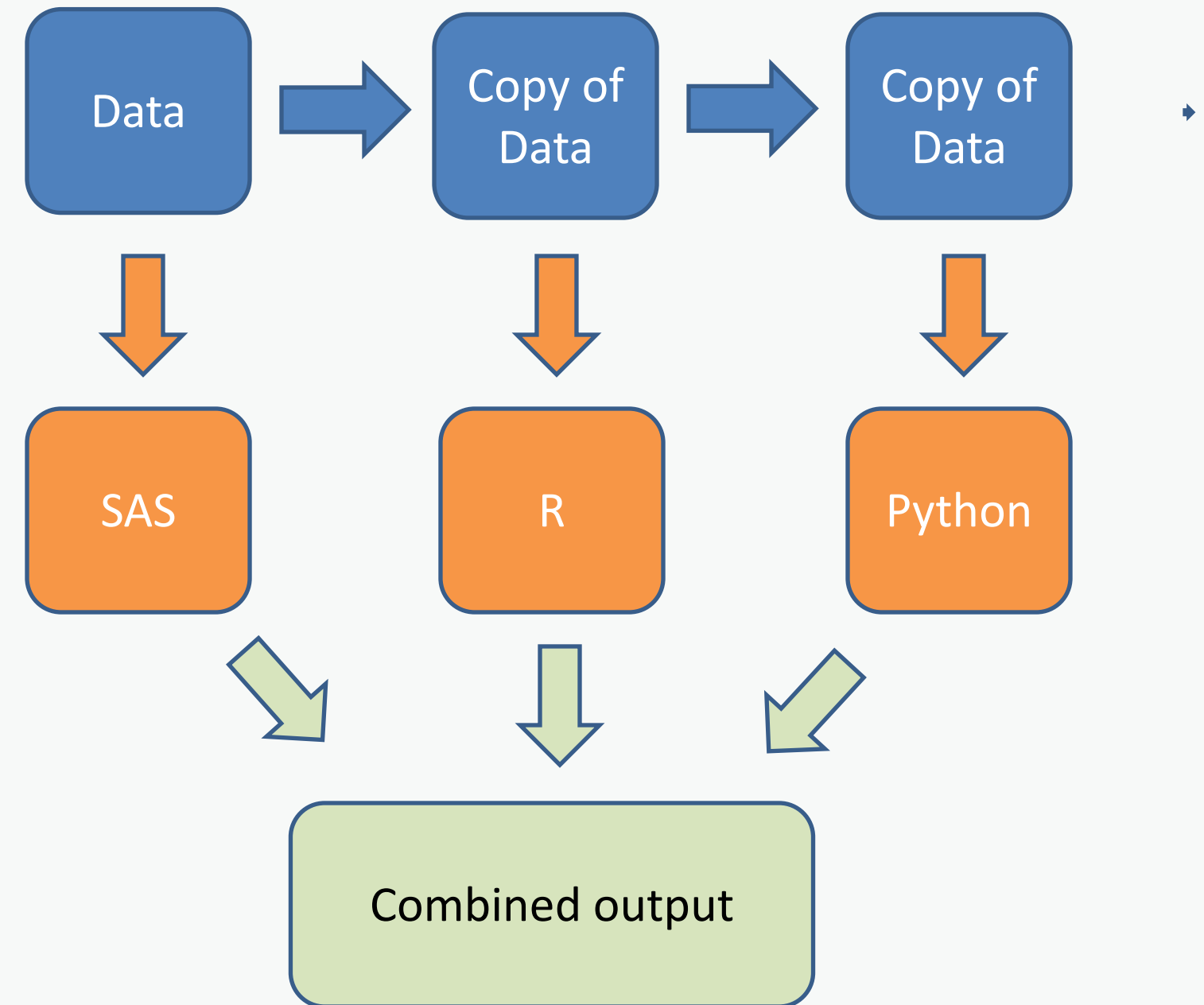
- PDF
- Visualisation tools
- Automatic presentation generation
- Submission tools

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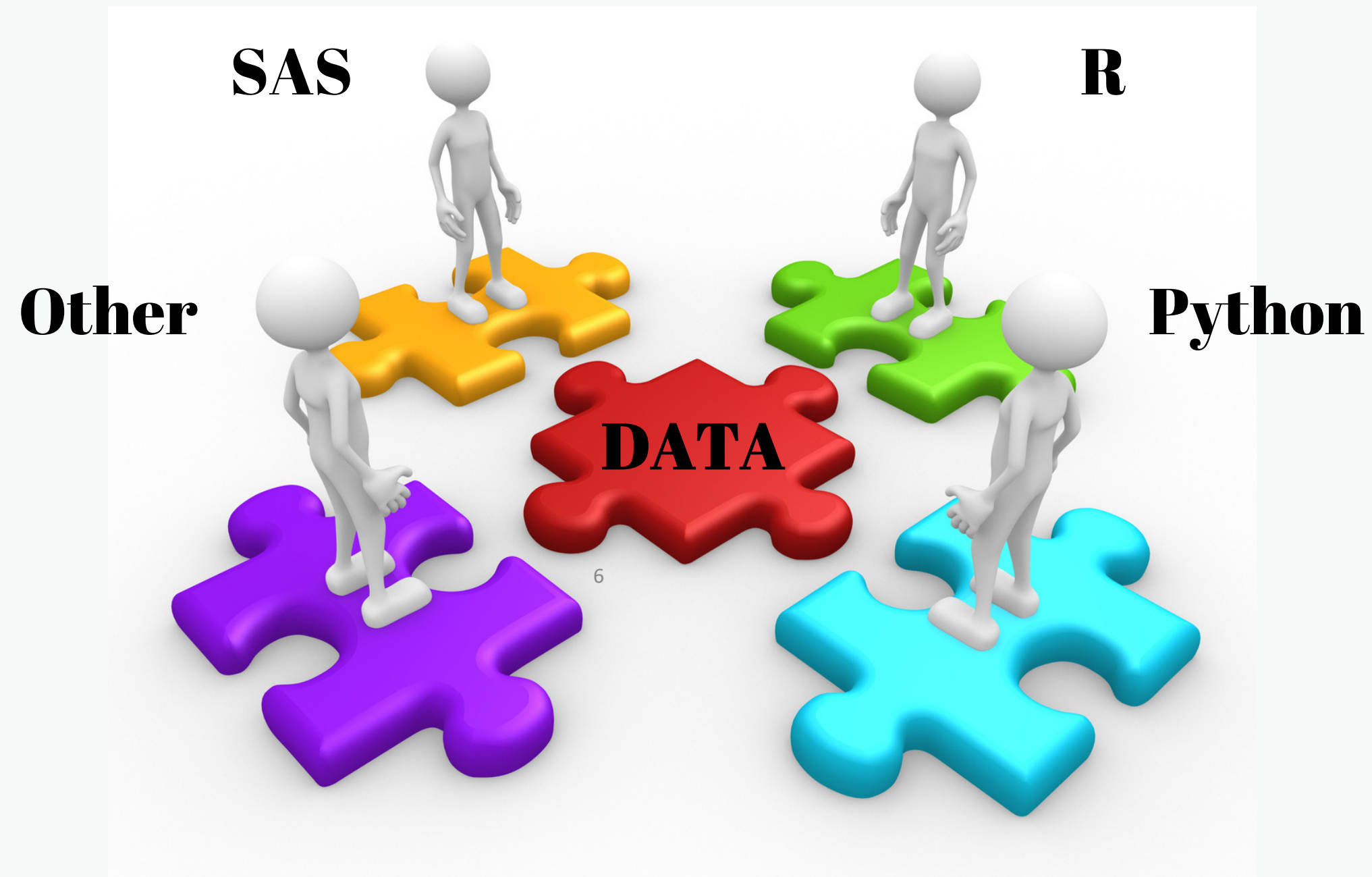
Problem – Data integrity

For each new tool, we often end up with an additional copy of the data, bringing data integrity into question.

- Data is sent from one environment to another for usage with different tools
- Later output is combined into one report
- Little documentation of:
 - **What** was sent
 - **Who** sent them
 - **When** were they sent



Using the same data across systems reduces integrity issues



Integrating New Technology

Container for tools

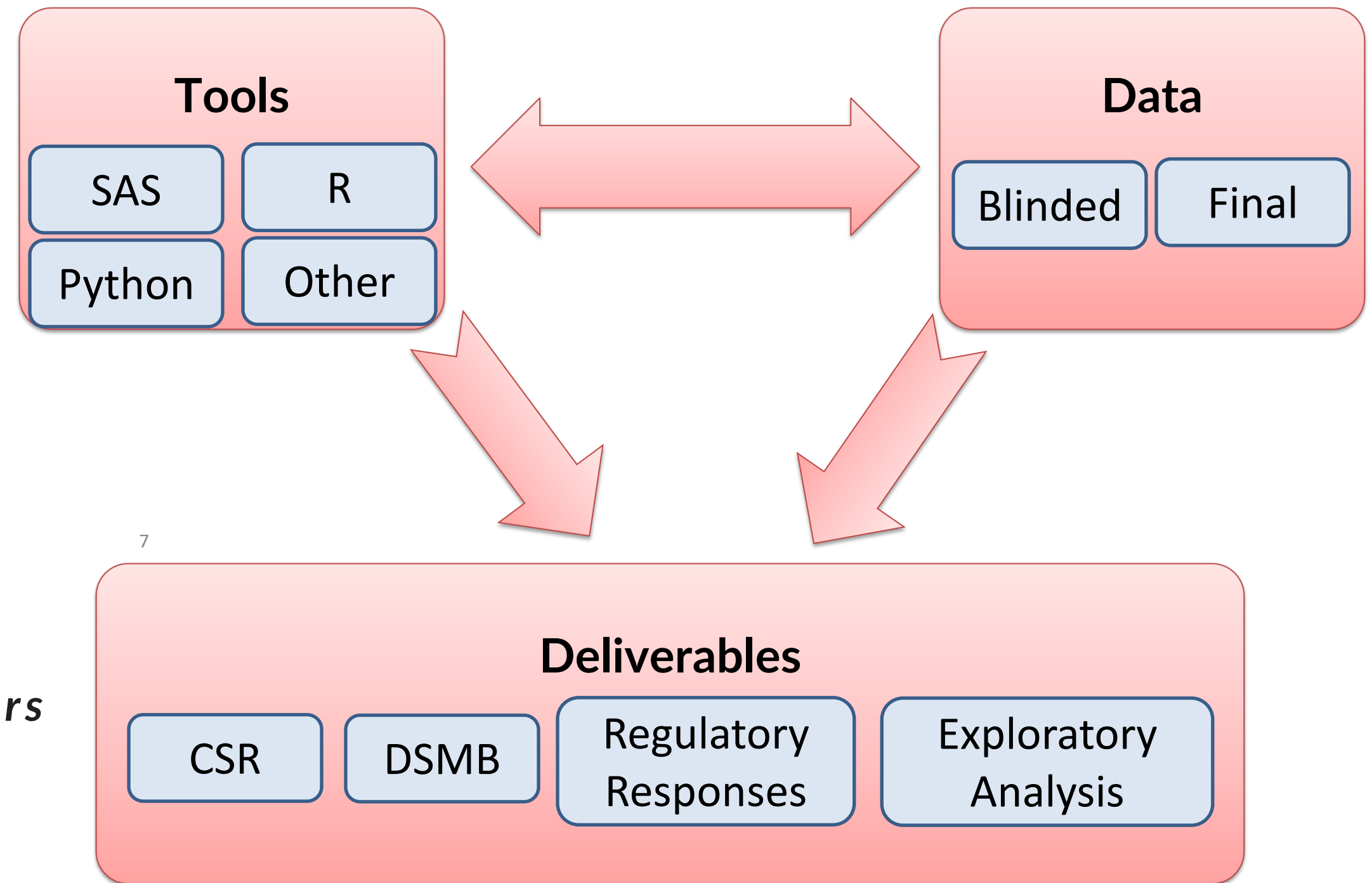
- GxP applications in one
- Non GxP in another
- Easy to add more applications

Container for data

- Each snapshot stored separately
- Different data types group by snapshot
- Metadata tracks all data movement

Deliverables drawing from containers

- SDTM, ADaM, TFLs, DSMB, Publications
- Easy to group by data snapshot
- Everything is version controlled



Key items to maintain data integrity

Package

- Think of every item as a package
- Each package has its own metadata
- Metadata stays with the package

Where

- Where did the package come from?
- Was it new/updated/moved/copied
- What tool is it coming from? SAS/R/...

Who

- Who performed the action on the package?
- Track all IDs who created/updated/moved/copied the package

When

- Document all dates/times of change
- When did the package move from one system to another?
- When was it created/updated/copied

SUMMARY

Separate tools container

- Allows easy process to add/remove tools

Data governance

- Store metadata of each package
- Track metadata in a central location through all the actions performed on a package

Separate deliverable items from tools

- Having a separation container for the deliverable items allows the usage of GxP and non-GxP tools as required

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Challenges

- Tool should work in the background and should minimise burden to the end user
- QUALITY must be delivered ON TIME

Question



Answer

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