



S-CUBED

Towards a Biomedical Concept Library: Creating and Sharing Biomedical Concepts

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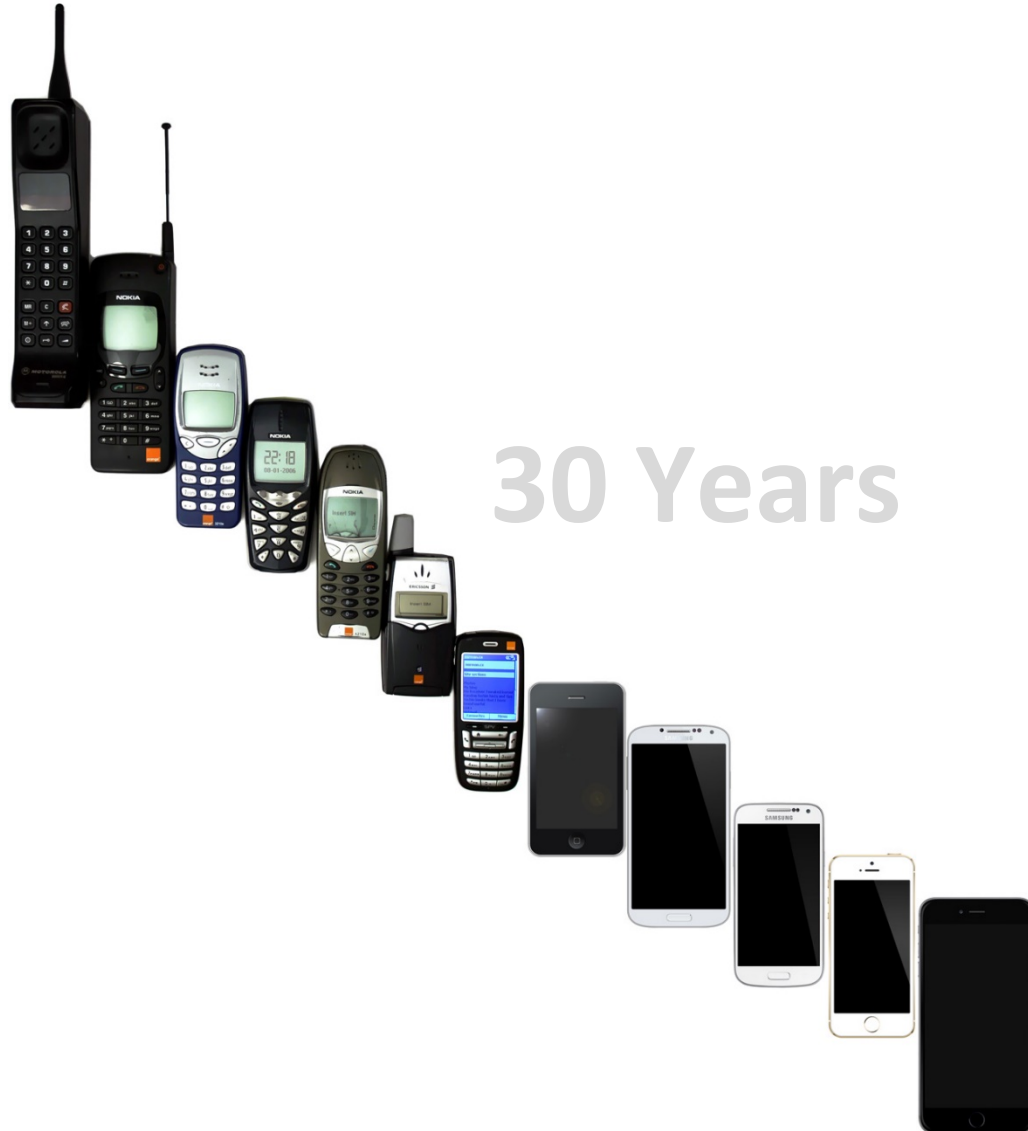
2019 11 03 V1



Things Change



Technology Advances



30 Years



REST API

20 Years

Silos



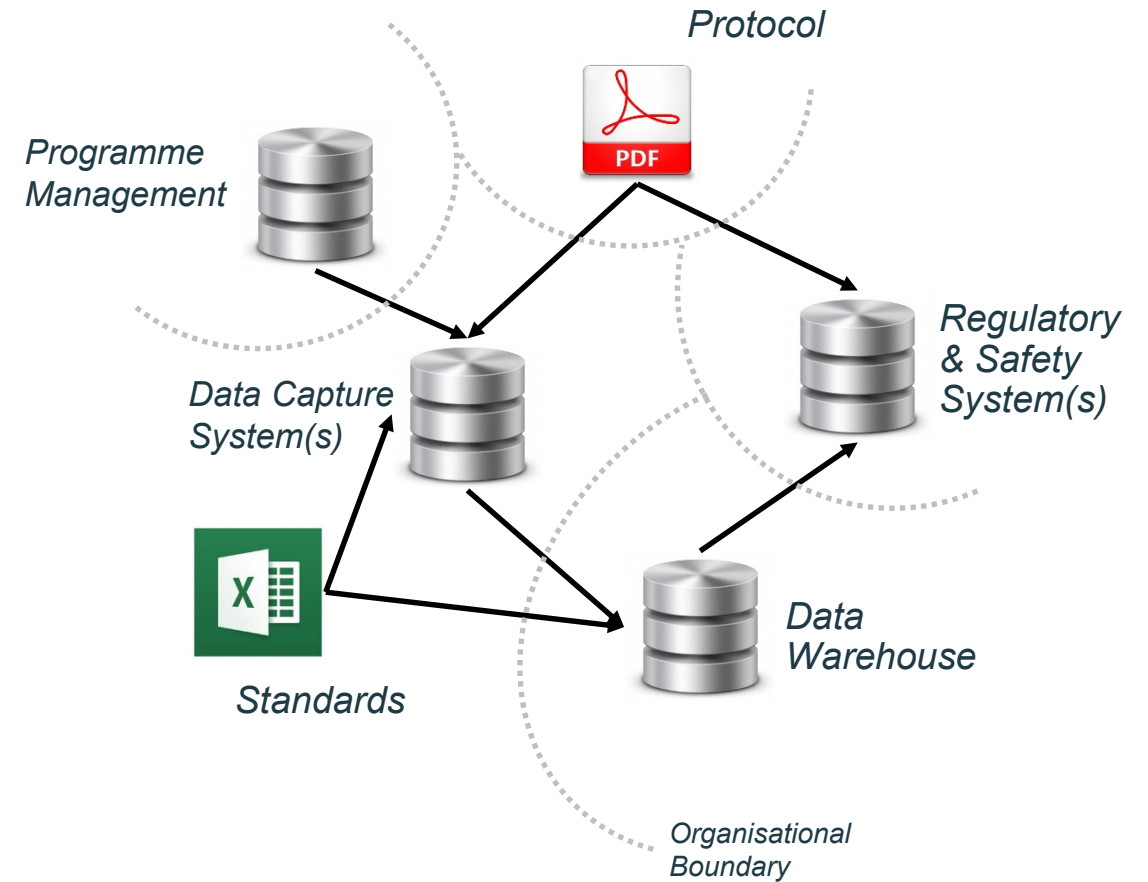
Silos ... but connected



Clinical Research and Silos

Why Clinical Research suffers from silos:

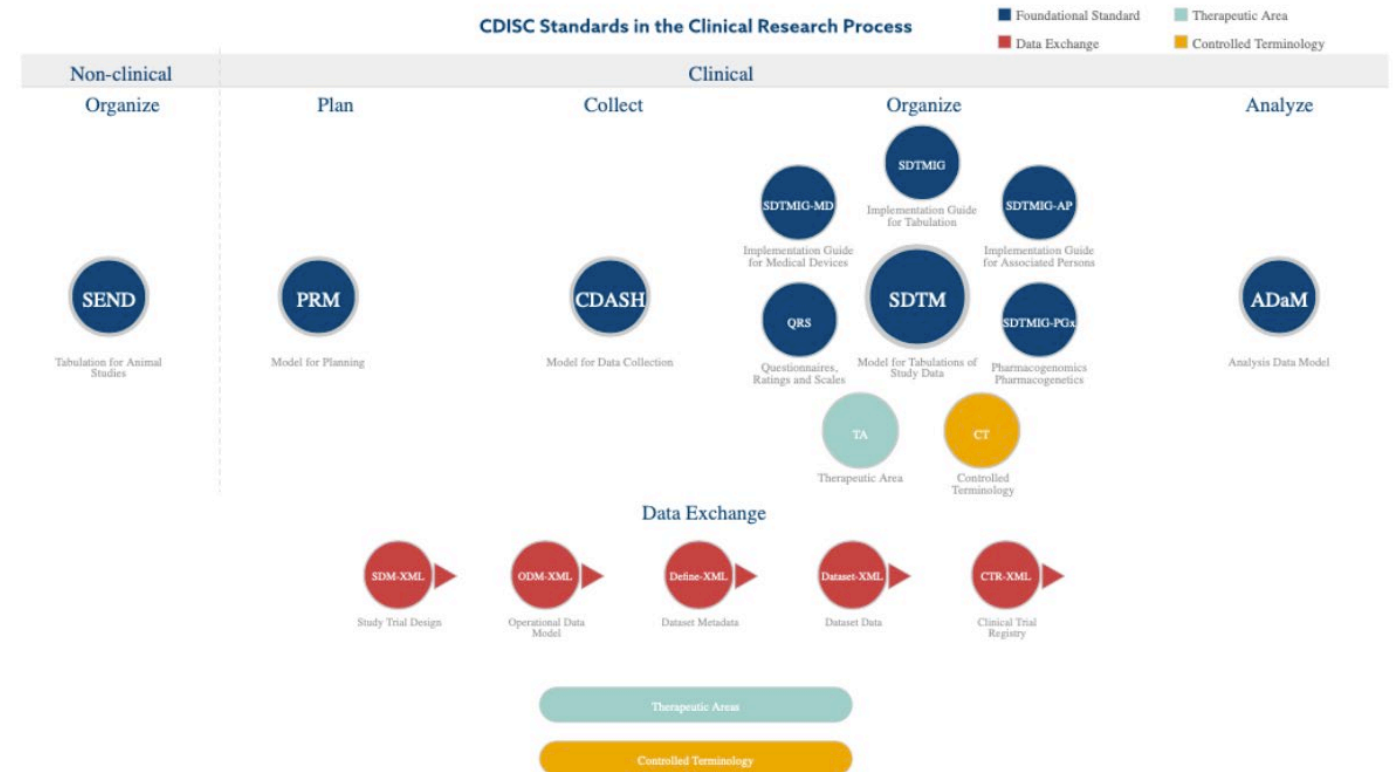
- Length of clinical programmes
- Number of clinical studies in a programme
- Diversity of systems
- Organizational Silos
- A world of Excel and PDFs
- Outsourcing
- Complexity
- We build in one silo, send it onto the next
- We end up with copies of the data for each different purpose
- Standards



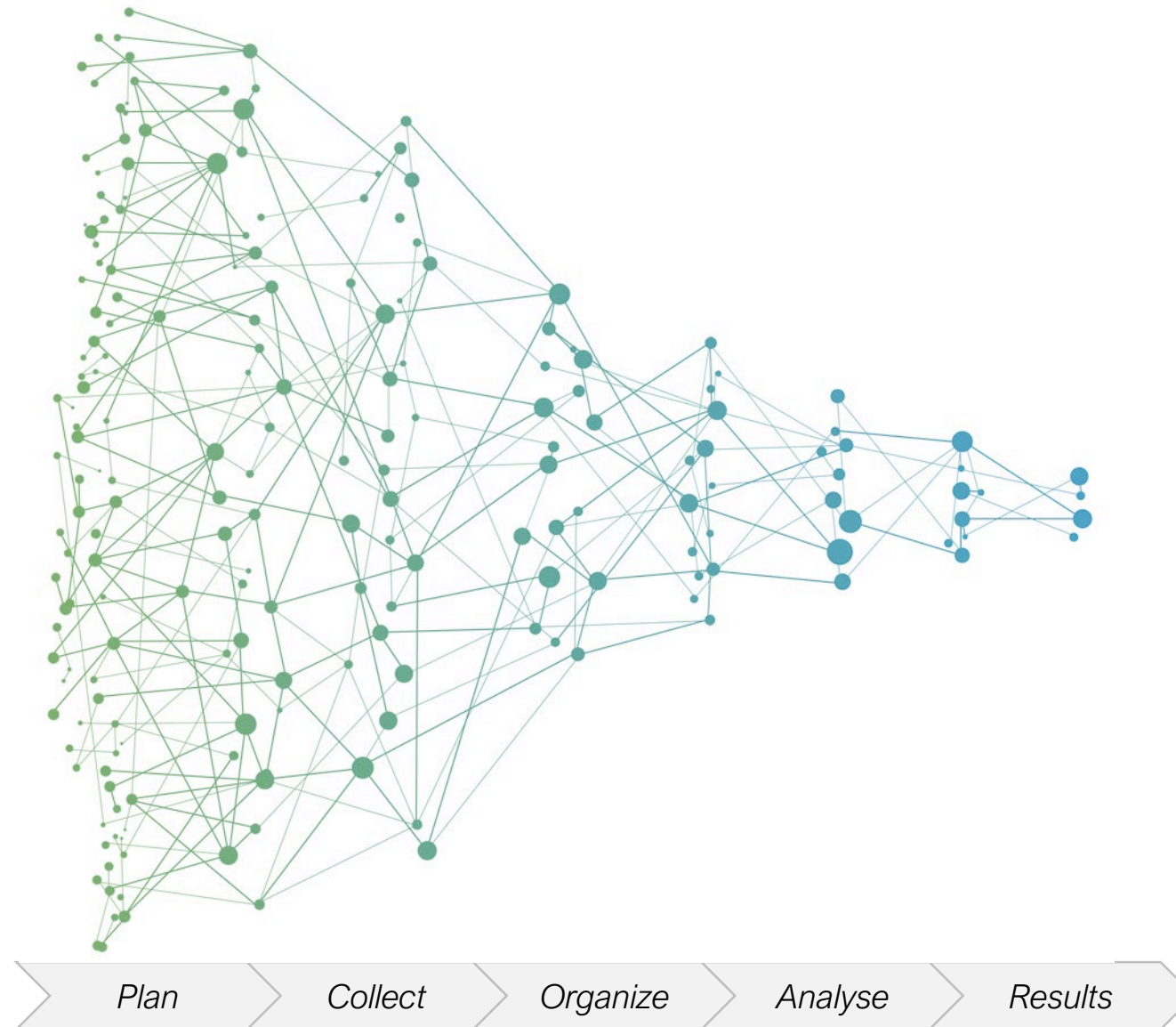
Data Standards

Play a big role in our work

- Multiple Standards
- Different types of standards
 - Data Exchange (XML)
 - Content
 - Terminology
- Developed since 2000
- **Developed in Silos**
- Traditionally delivered as PDF
- Moving to electronic
 - MS Excel
 - XML
 - RDF
- Submission for regulatory approval of products requires use of the standards



Our “Study” World



Our “Study” World



Our World IS NOT Rectangular

Plan

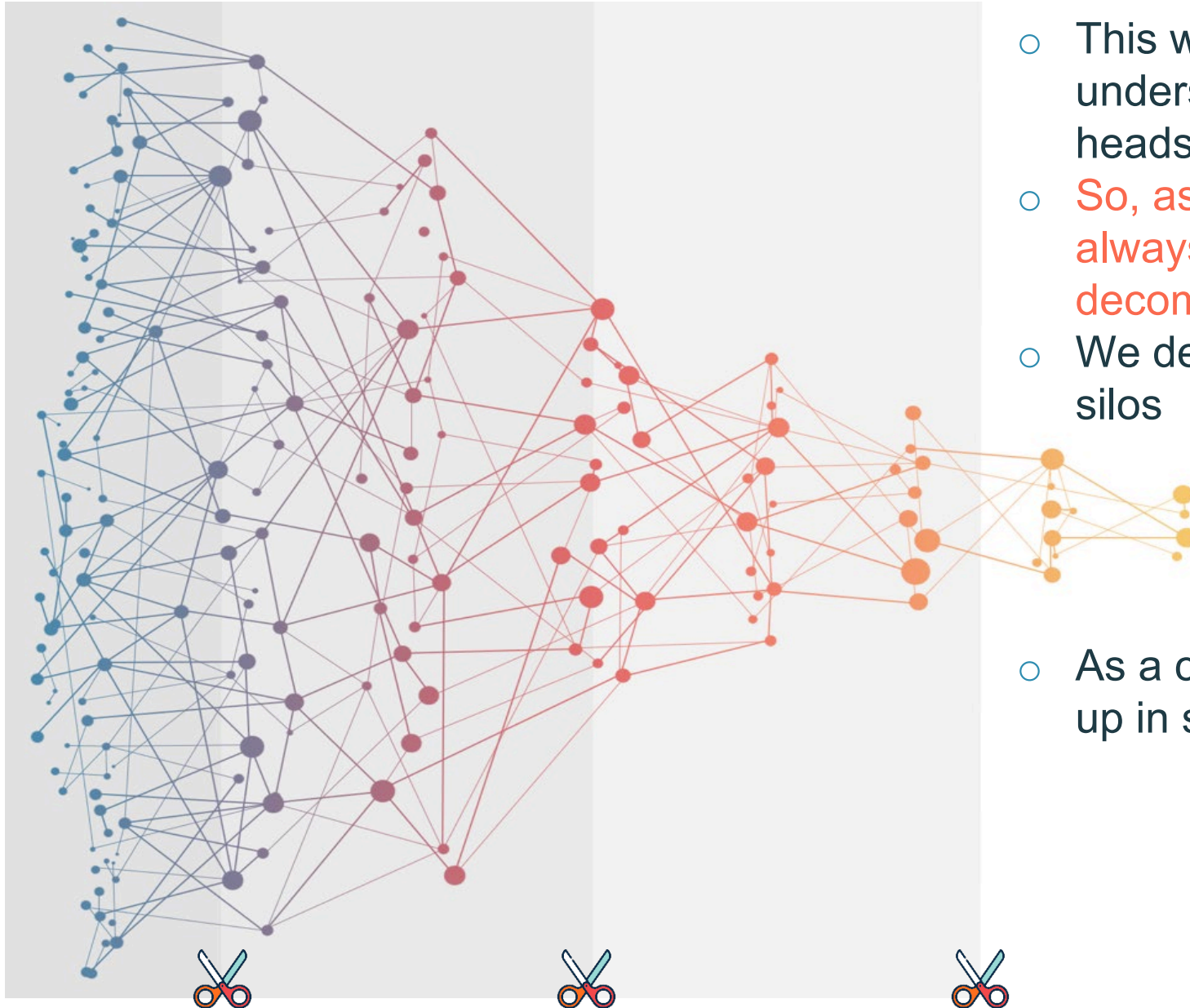
Collect

Organize

Analyse

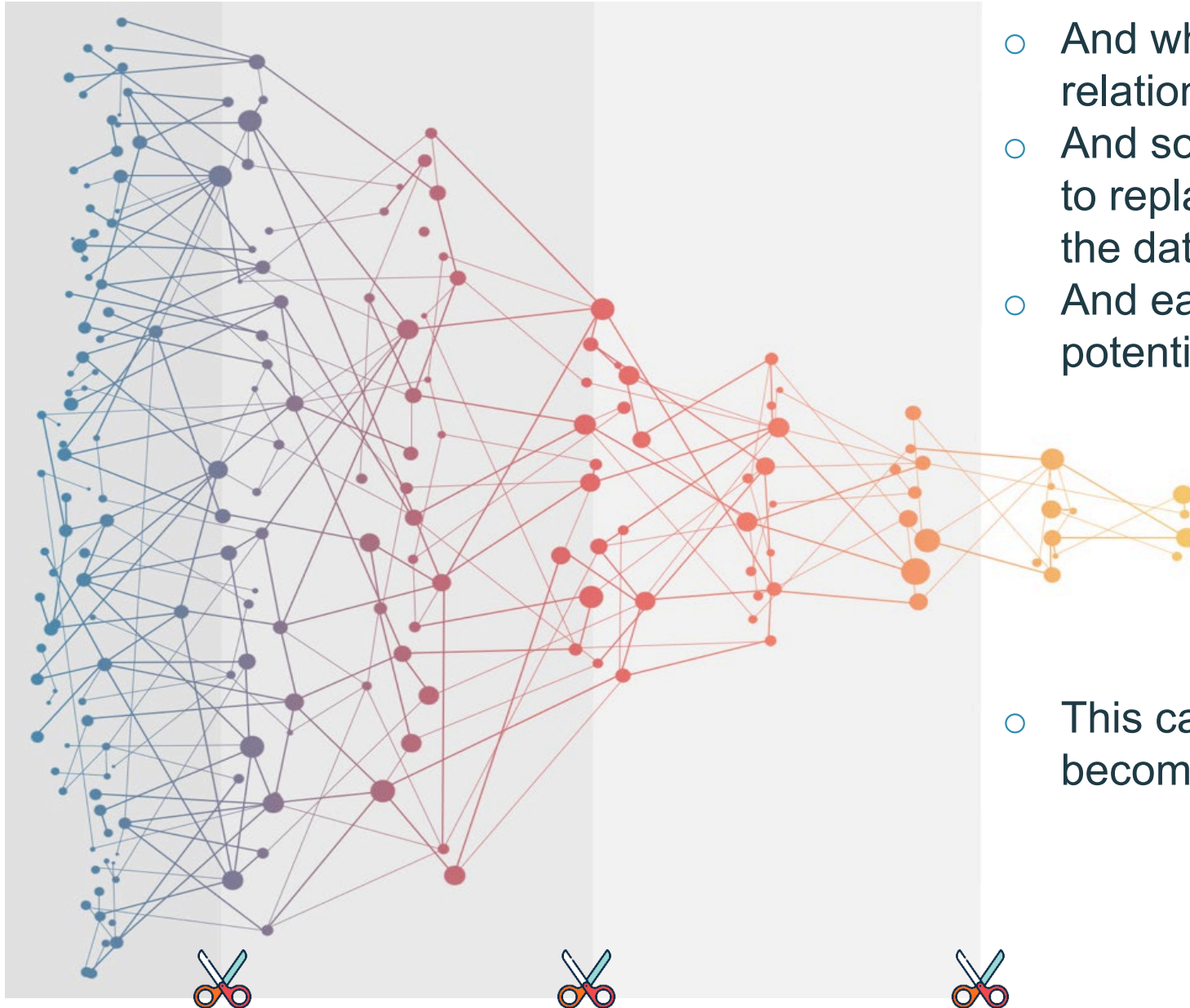
Results

Our Silos



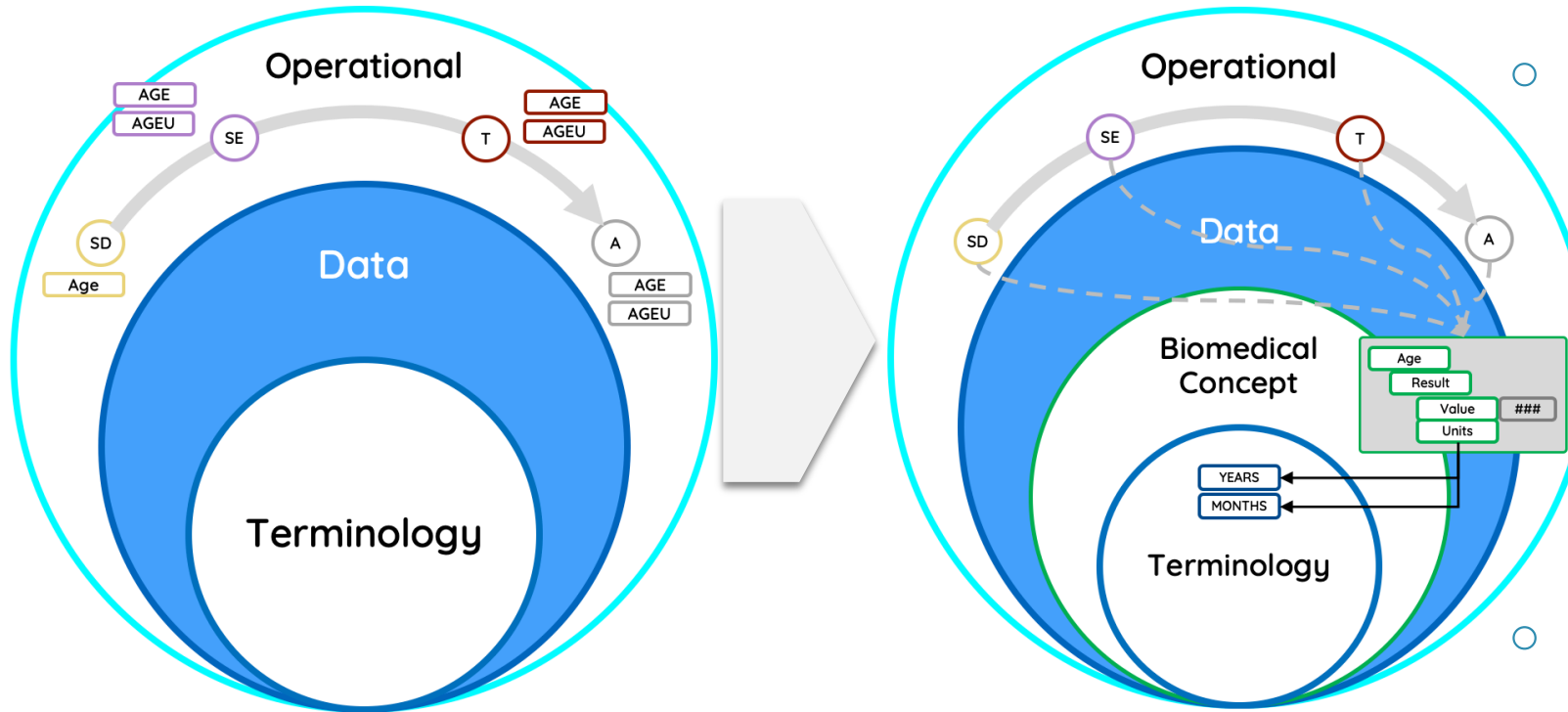
- This world is just too big to understand, too big to fit into our heads
- So, as humans, we did what we always do, we cut it up, we decomposed the problem
- We developed our standards in silos
- As a consequence our data ends up in silos

Our Silos



- And where we cut we lost the relationship
- And so later we use programmers to replace those relationships, stitch the data back together
- And each programmer / company potentially does it differently
- This causes issues, e.g. data becomes difficult to pool

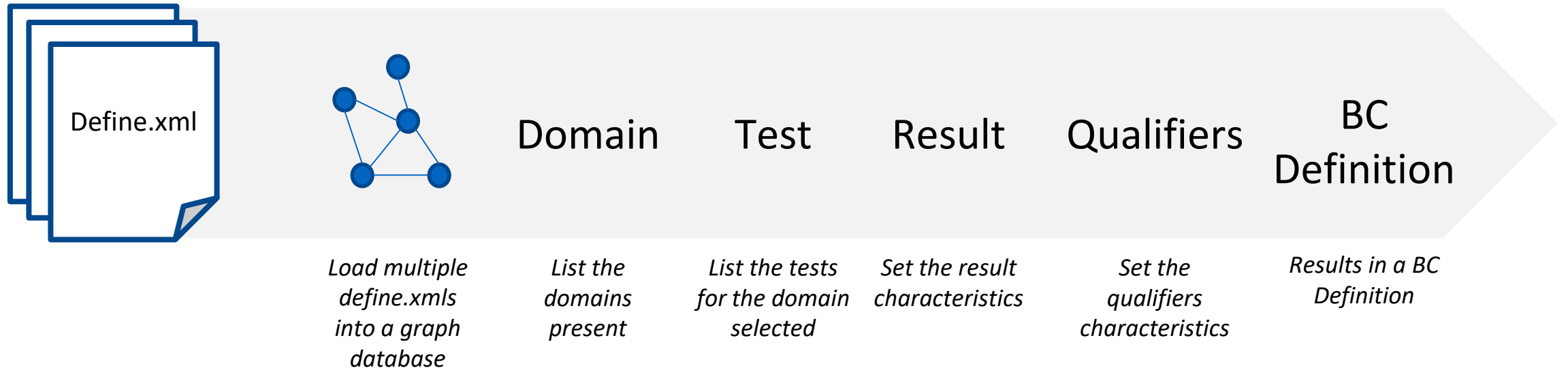
Biomedical Concepts



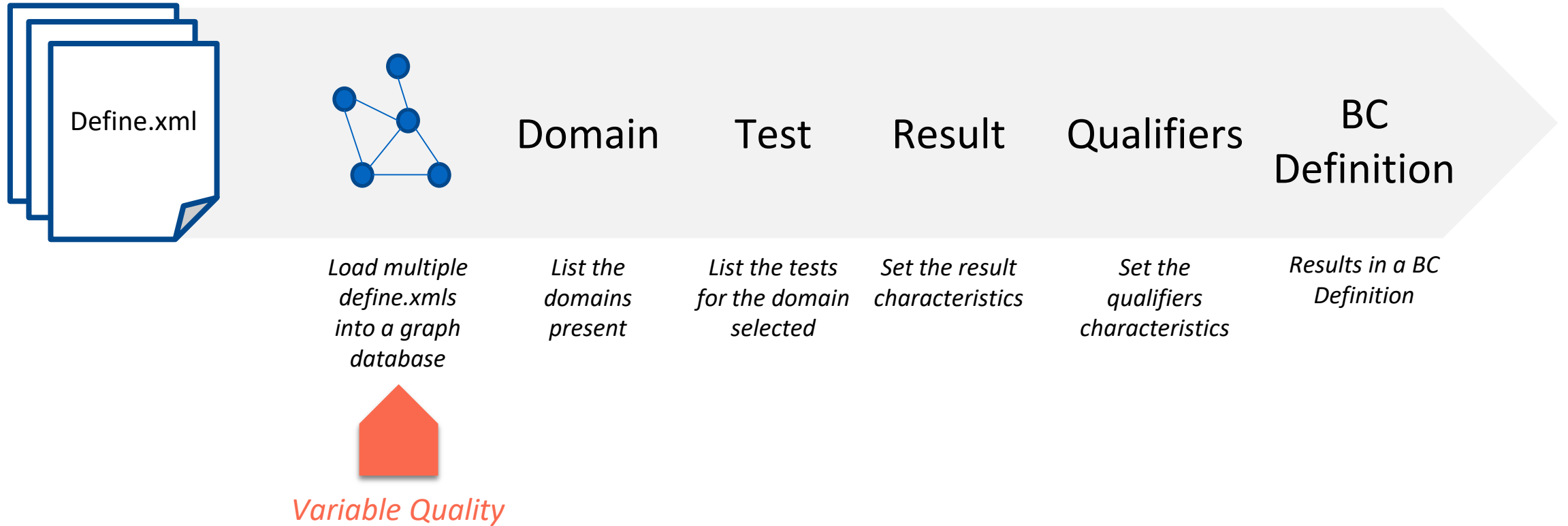
- Biomedical Concepts (BCs) allow us to bridge the silos
- The CDISC 360 project is looking at BCs
- But people say we require too many, too large a task

- But we have the large majority of the information
- We are not creating any new knowledge
- It is in our data ... and our define.xmls

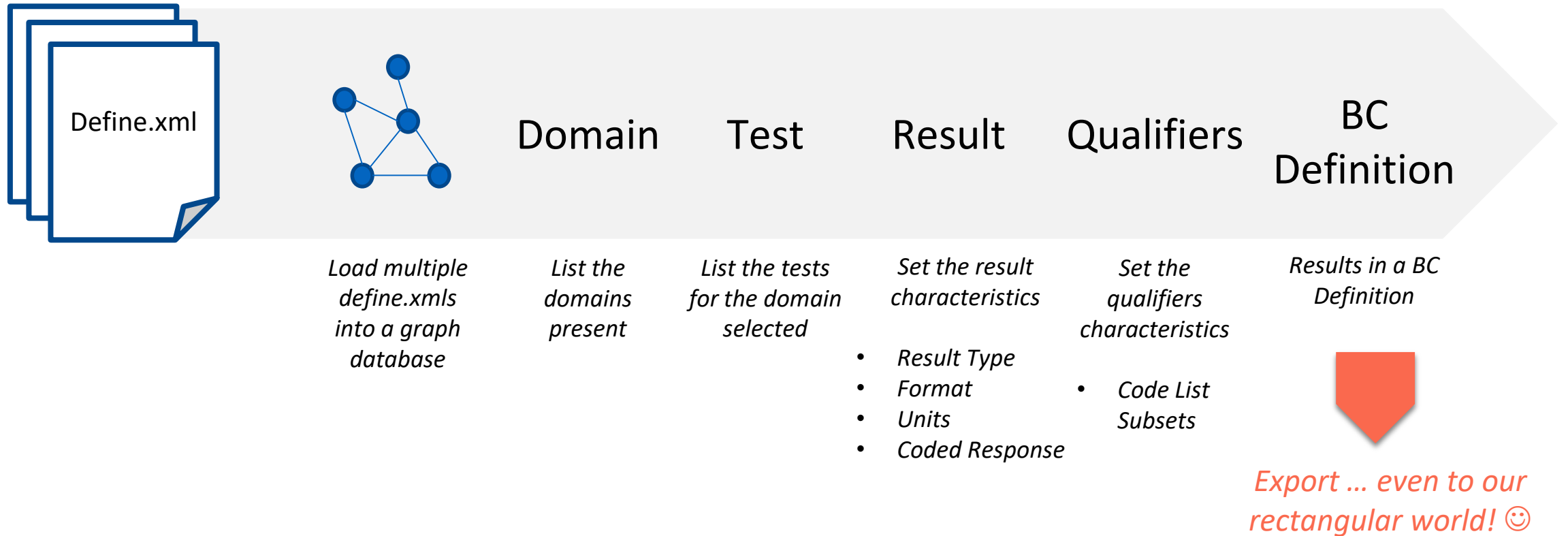
Process Overview



Process Overview

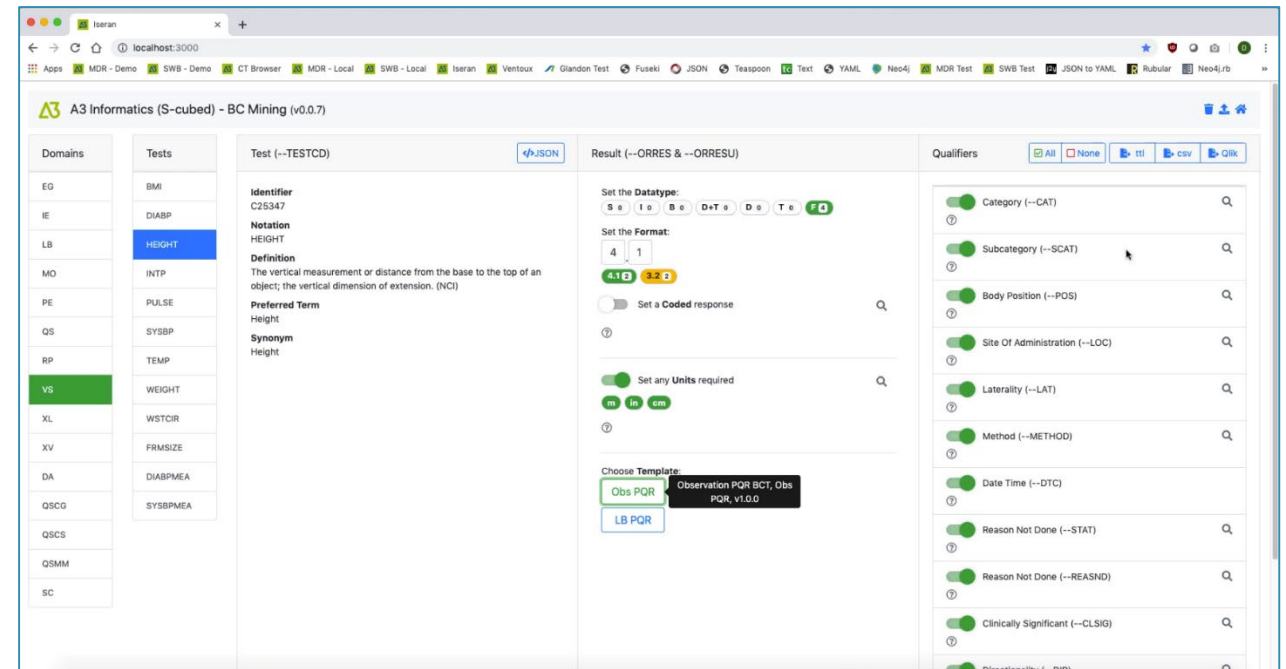


Process Overview



Summary

- We can leverage our current knowledge
- We can mine that knowledge to create draft BCs
- They can then be curated by humans
- The task can be sub-divided such that it is performed quickly
- It is not a technical challenge, it is a question of will
- We need to move forward faster





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ice from the base to the top of an
(tension. (NCI)

[JSON](#)

Result (--ORRES & --ORRESU)

Set the Datatype:

[S](#) [o](#) [I](#) [o](#) [B](#) [o](#) [D+T](#) [o](#) [D](#) [o](#) [T](#) [o](#) [F](#) [4](#)

Set the Format:

[4](#) [1](#)

[4.1](#) [2](#) [3.2](#) [2](#)

☐ Set a Coded response

[?](#)

☒ Set any Units required

[m](#) [in](#) [cm](#)

[?](#)

Choose Template:

[Obs PQR](#)

Observation PQR BCT, Obs
PQR, v1.0.0

[LB PQR](#)

Qualifiers

☒ All ☐ None

☒ Category (--CAT)

[?](#)

☒ Subcategory (--SCAT)

[?](#)

☒ Body Position (--POS)

[?](#)

☒ Site Of Administration (--LOC)

[?](#)

☒ Laterality (--LAT)

[?](#)

☒ Method (--METHOD)

[?](#)

☒ Date Time (--DTC)

[?](#)

☒ Reason Not Done (--STAT)

[?](#)

☒ Reason Not Done (--REASND)

[?](#)

☒ Clinically Significant (--CLSIG)

[?](#)