



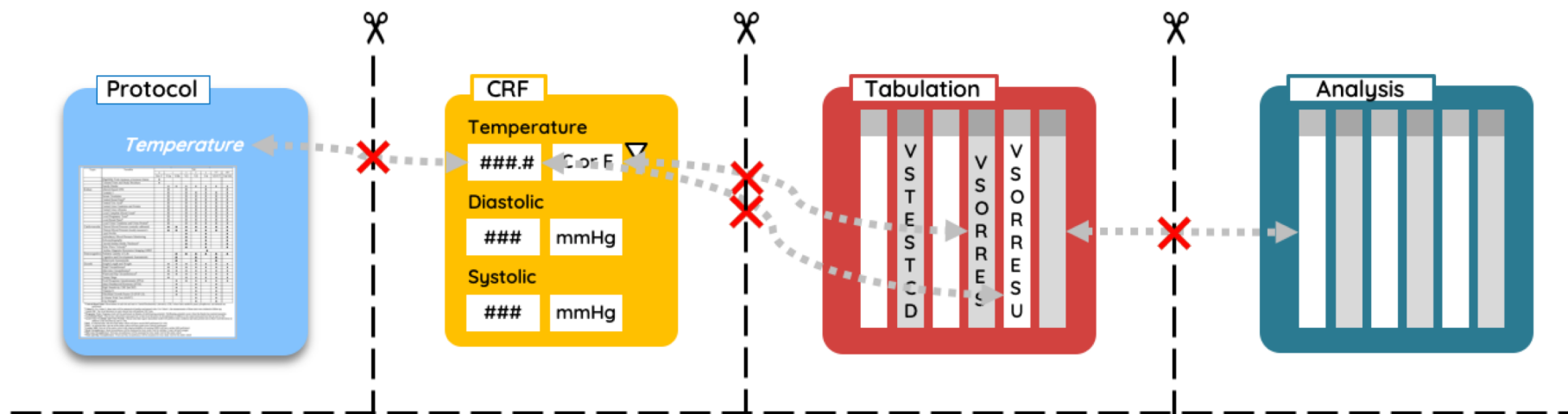
Removing Silos: Placing Data at the Centre

Dave Ibersen-Hurst, A3 Informatics

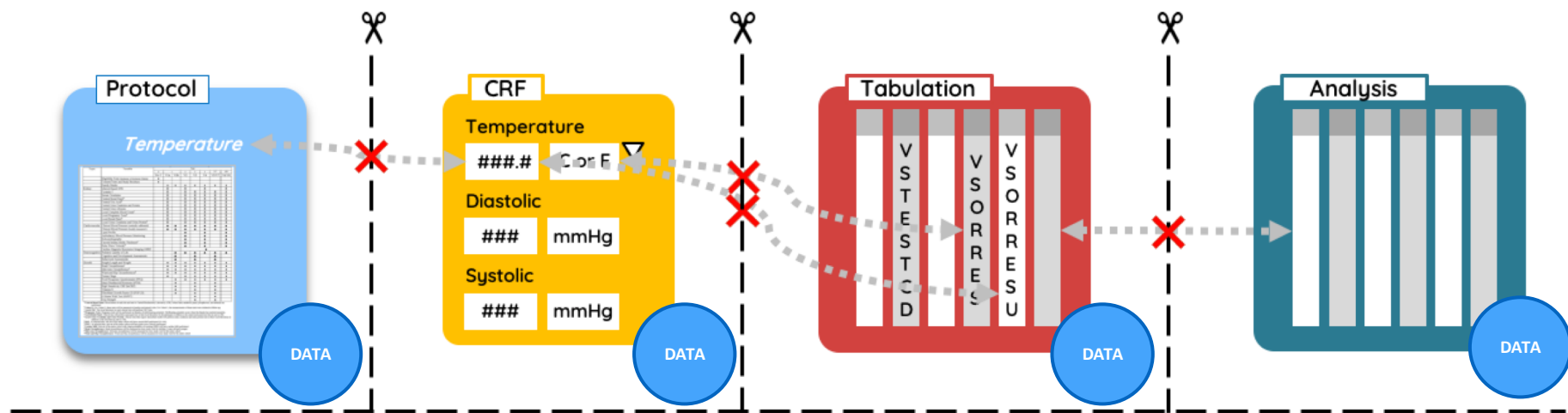
PhUSE US Connect

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Silos



Silos



- We create silos of data
- It is hard to link (trace / map) it all after the event

Break Down The Silos

PhUSE US Connect 2018

Paper RG06

It's Time To Change

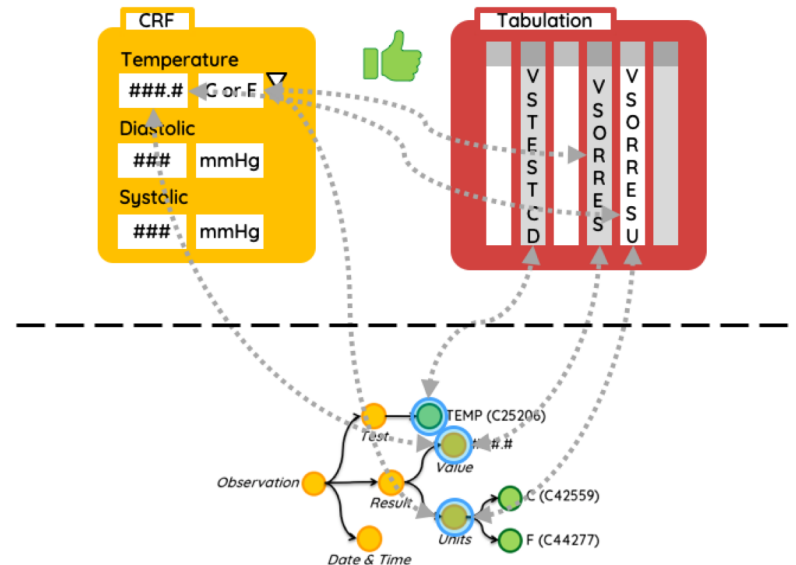
D Iberson-Hurst, Assero Limited & A3 Informatics ApS

INTRODUCTION

It is now nearly two decades since CDISC was formed, the FDA has accepted data using the CDISC Study Data Tabulation Model (SDTM) format since 2004 and studies starting after 17 Dec 2016 must be submitted in approved electronic formats. As an industry, we have come a long way, yet we still have silos, we still map and we cannot work in a seamless manner.

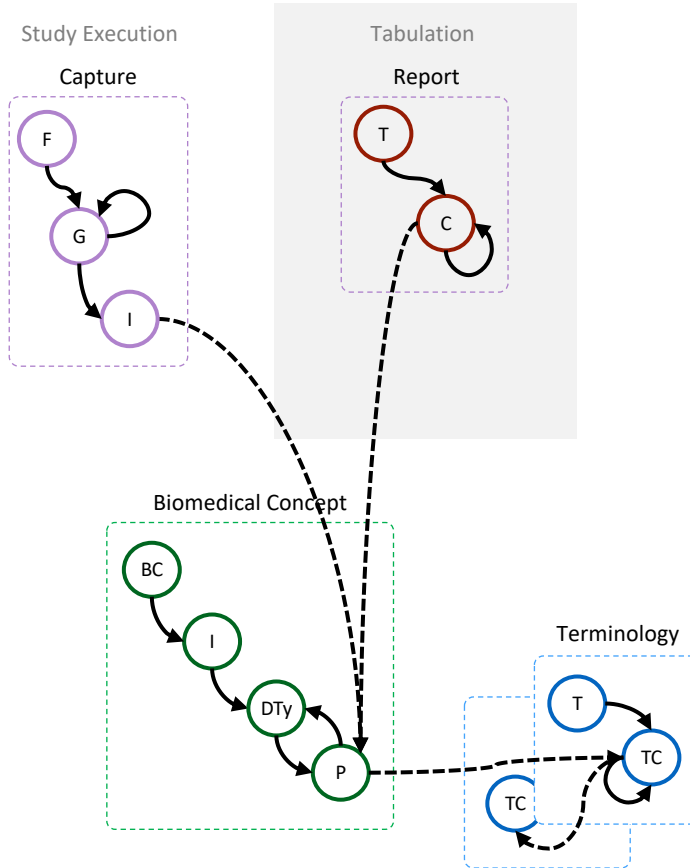
There may be a better way. This paper will discuss a vision in which the data are represented in their natural form and technology leveraged to allow for a more seamless process, where mapping is no longer required, silos are removed, and our standards become views of well-structured data, generated more via query rather than via code. However, the lights need to be kept on, work on today's studies need to continue. The paper will also address how we can move forward with the vision in an iterative manner, while still supporting current study work.

- Lack of consistency across our work
- Consider 'Study' and 'Subject'. What do we mean by these ideas, concepts, notions, these things?

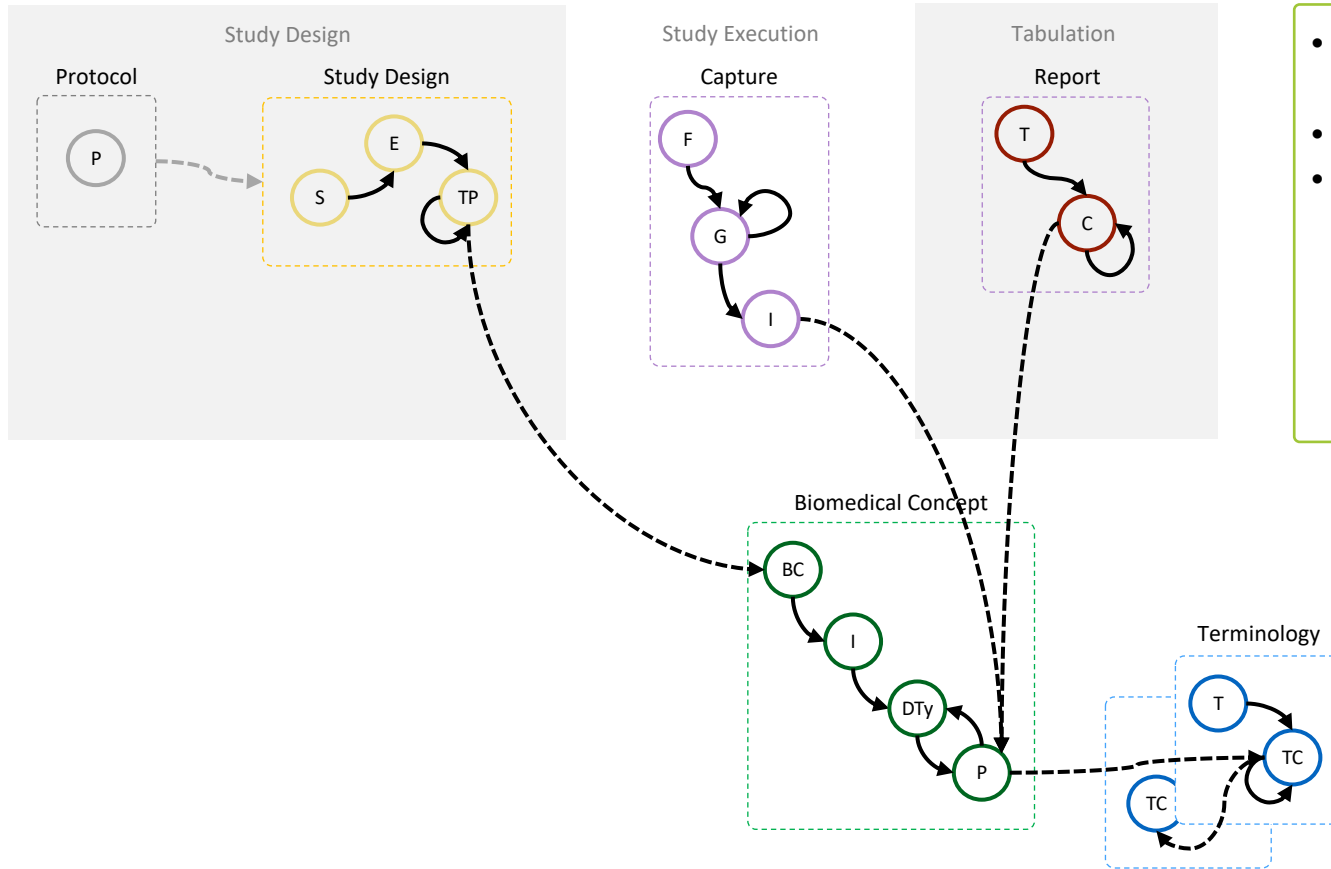


A Different Representation

- Can start to break out the models
- Loosely coupled
- Each with a single focus
- Able to use models independently, e.g. Terminology (e.g. CDISC, LOINC, MedDRA)
- Separation of data versus the reporting and manipulation of data

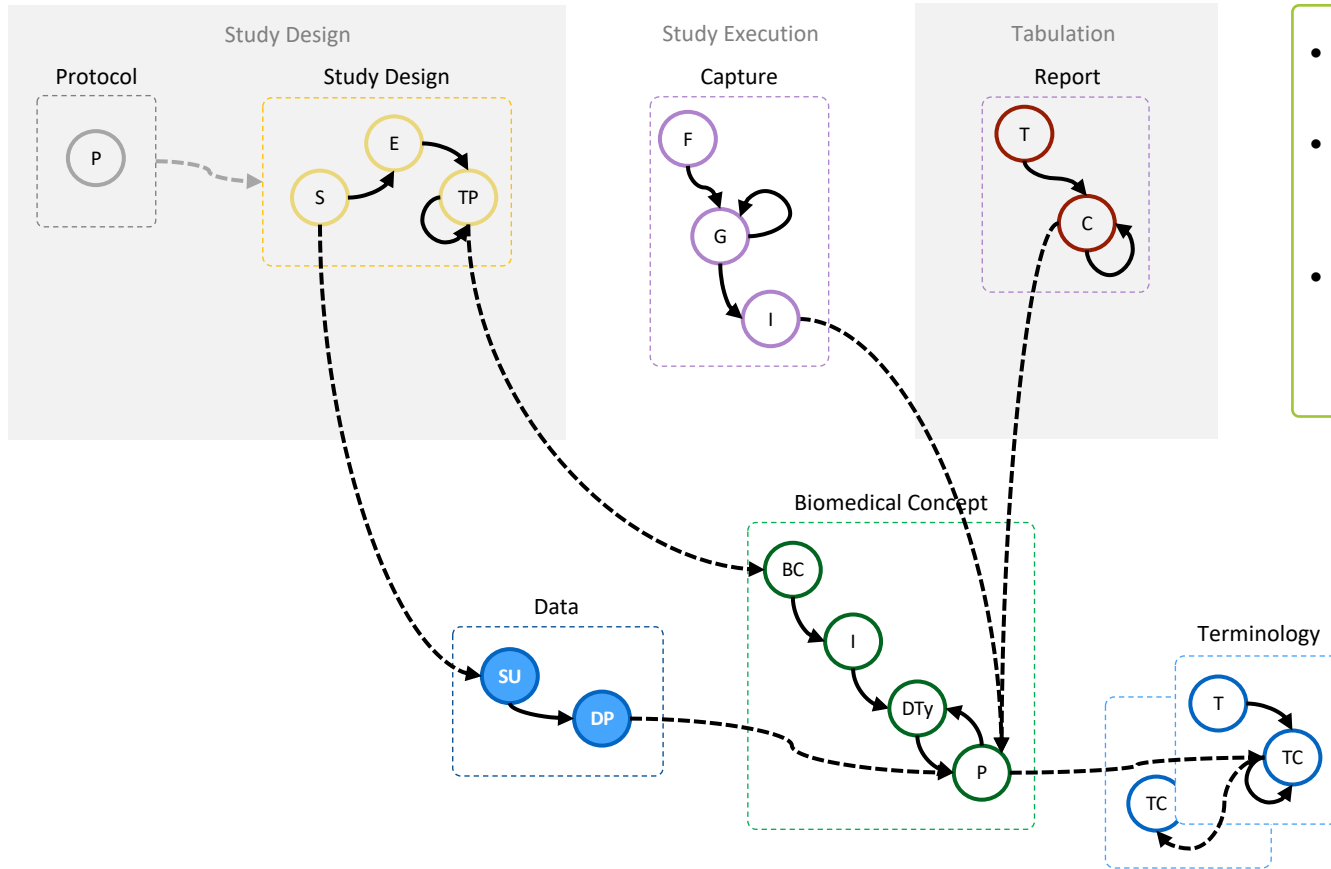


Add Protocol - Critical



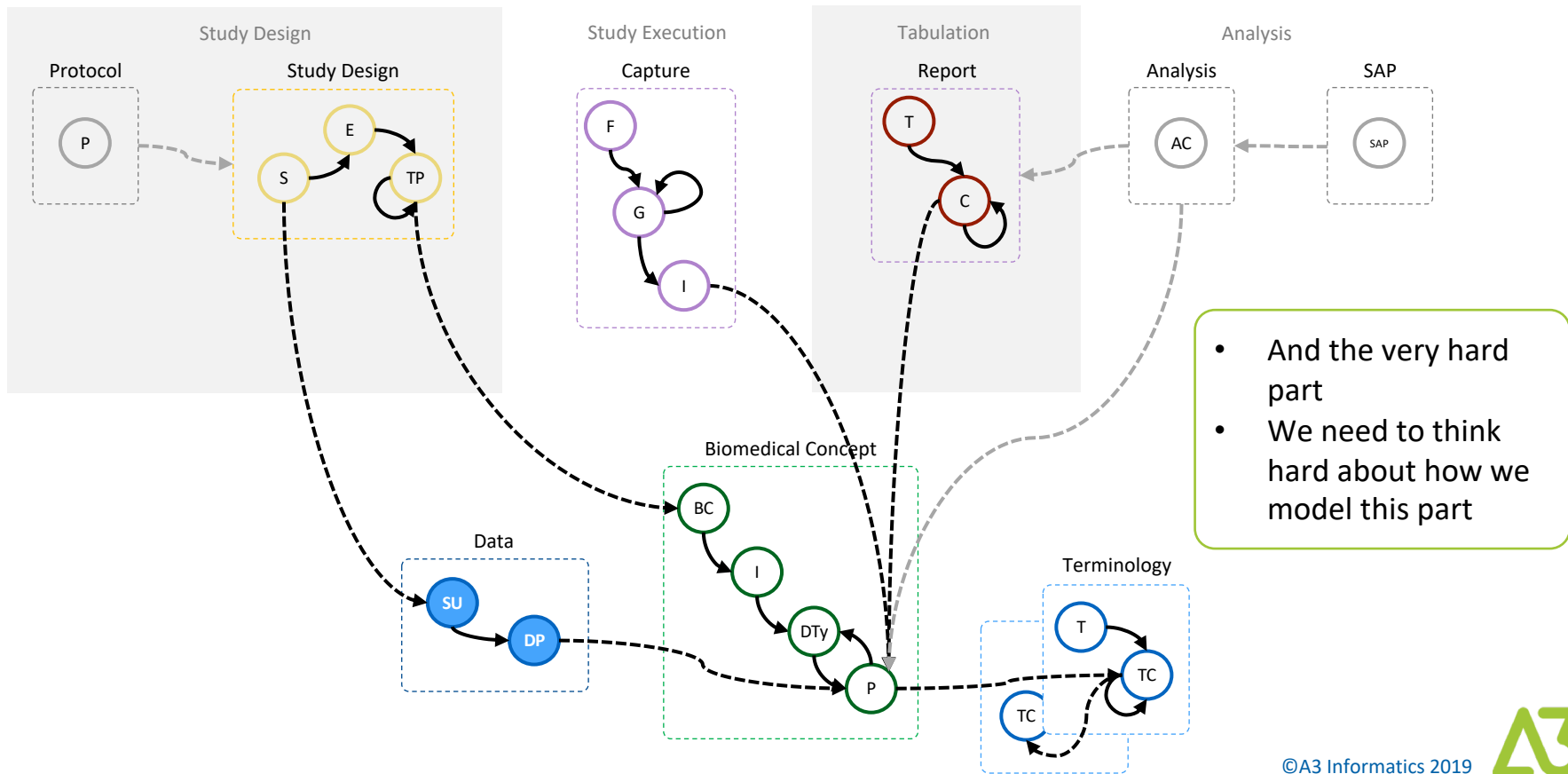
- Add in protocol and study design models
- Significant gain
- Often we miss this piece. Not having this in the machine involves spending significant effort in working out what goes where

Add Data

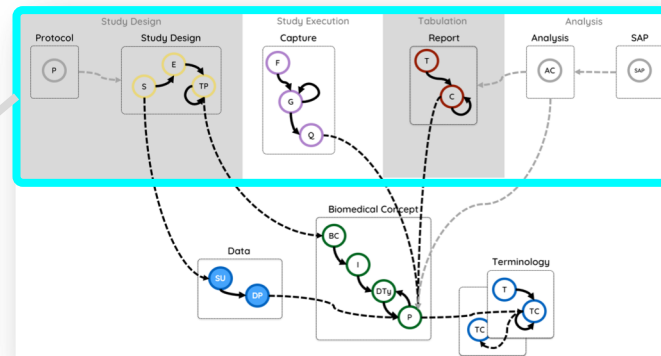
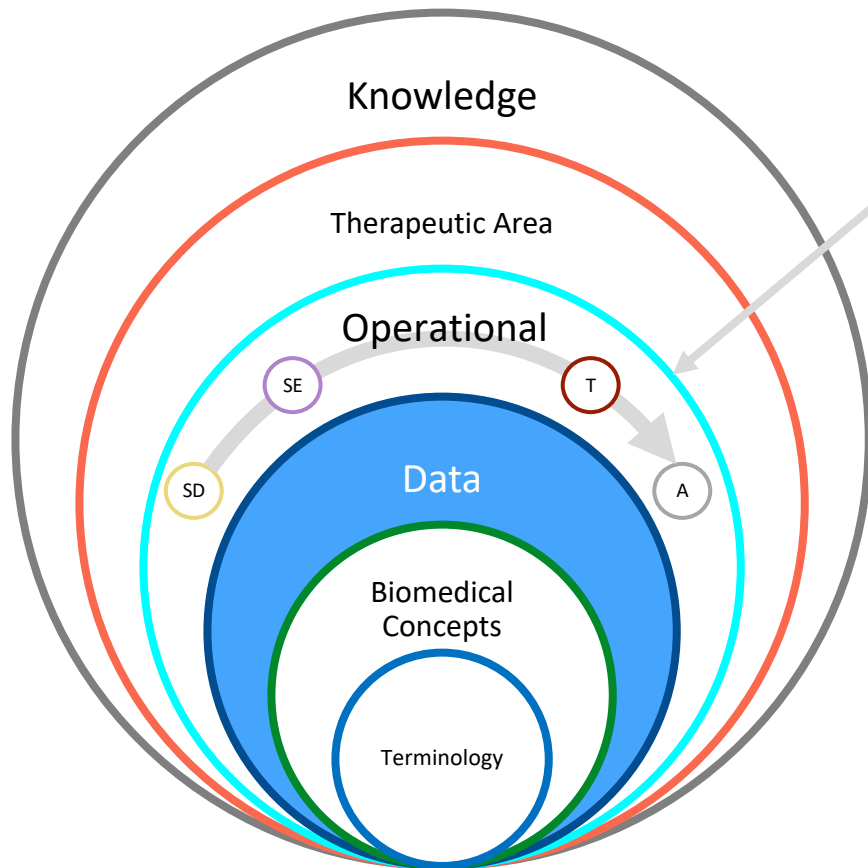


- Link the data in the right place
- Consistent representation of data
- We have one world, our design and our data

The Tricky Bit

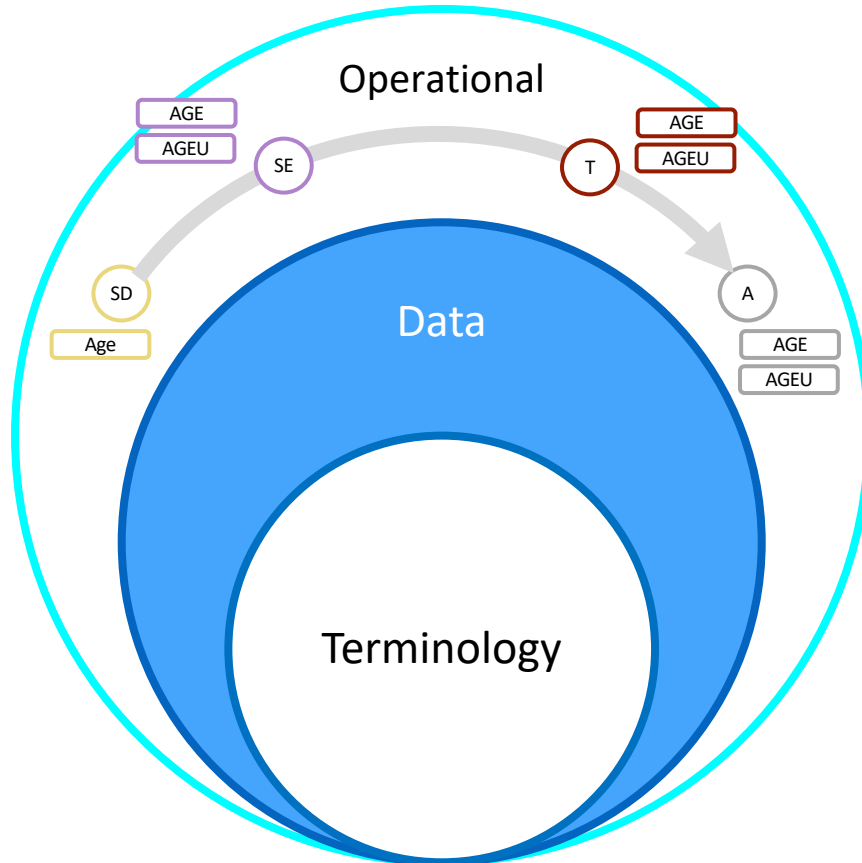


Another Representation



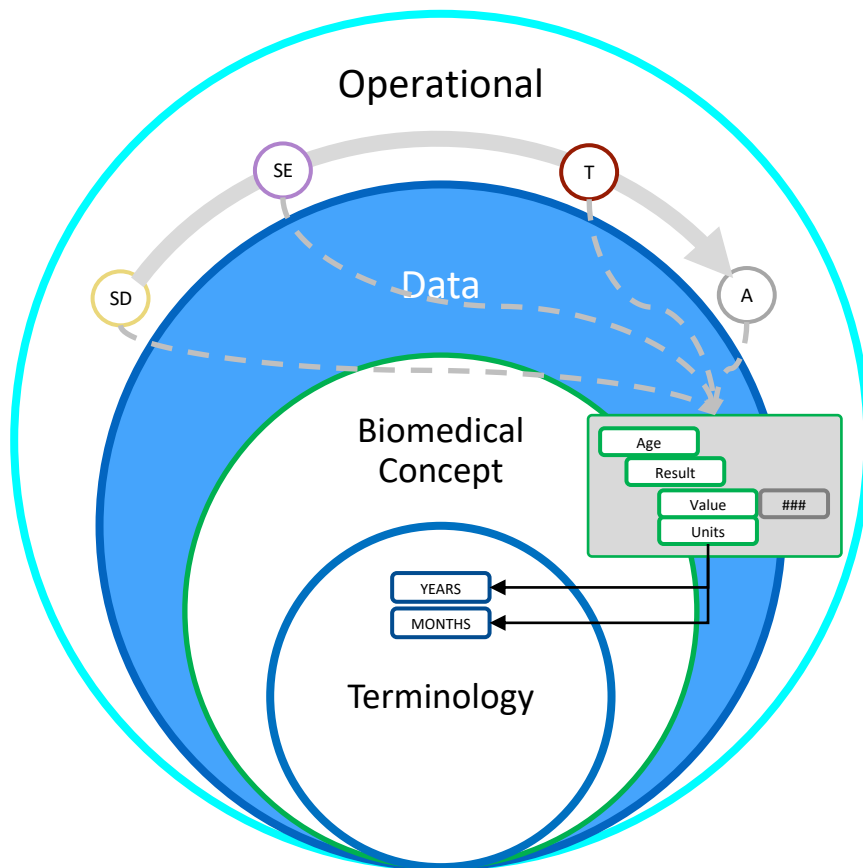
- We can represent in an 'onion' manner.
- We build up
- We can use pieces without the complete picture but we know it will fit into the bigger picture.

Repetition



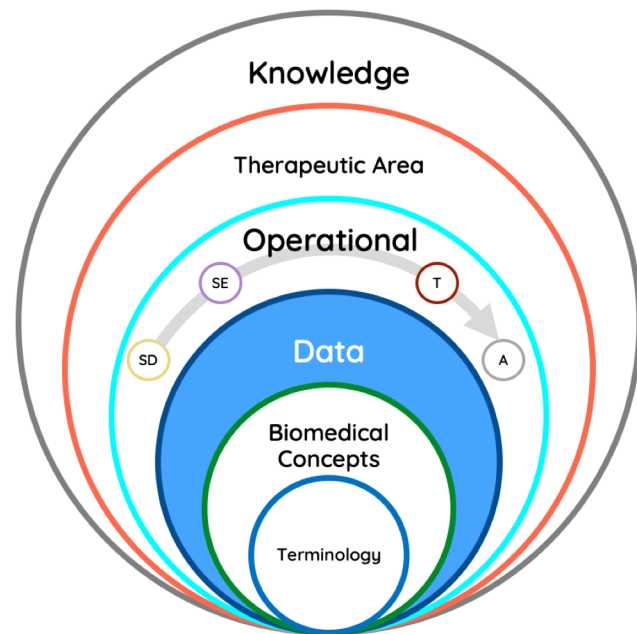
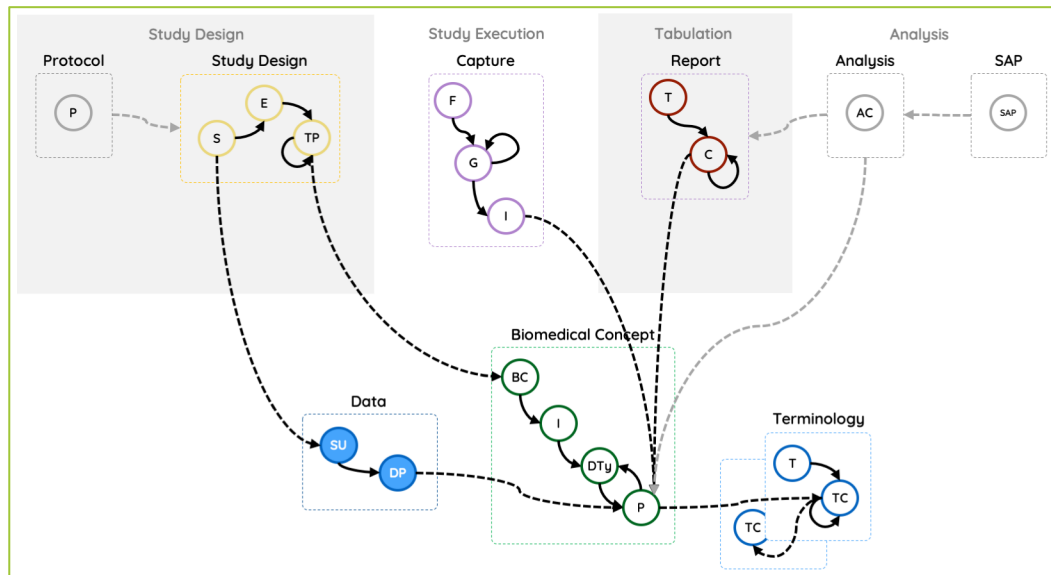
- We are very good at repeating information across the life-cycle
- Simple example across our four major silos

Linking

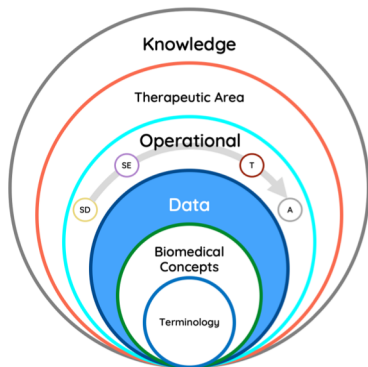
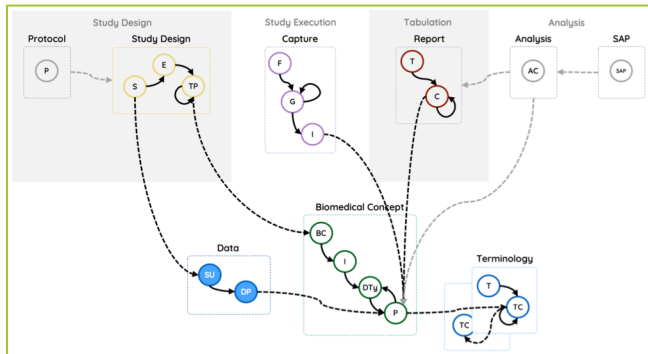


- By building the correct data definitions and using that for our data storage we can improve
- We eliminate repetition
- We break down silos
- We start, definition by definition, to improved our world
- Get gain consistency across studies
- We gain better building blocks

A Better Organized World



A Better Organized World



- Understand our world better
- Small focused models linked together
- Independently re-usable
- Focused on our data
- Separate our data from how we report
- Define once, refer to many
- We have much source material – “the nice thing about standards are there are so many to choose from” – we need to organize it all better
- We need to be wary of the “build the big canonical model” trap – we have BRIDG
- We need to refine and better organize what we have

Questions & Answers

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