Premise:

- Are data “fit for use”? It depends upon how we want to use them.
- We must know the rules used to define, capture, database, clean, report and analyze them, including (in)consistencies in business rules among sites, studies, and submissions. Today we don’t.
- Data fit for use within a study may be unfit when aggregated with other studies.
- Rules are documented but are often unavailable to those using the data, especially later

How to Know:

2. Sponsors: design data rules on a program rather than study level. Convey them to outsourcing partners.
3. Longer term...
4. Develop a schema for rules to travel with the data, perhaps becoming part of metadata.