

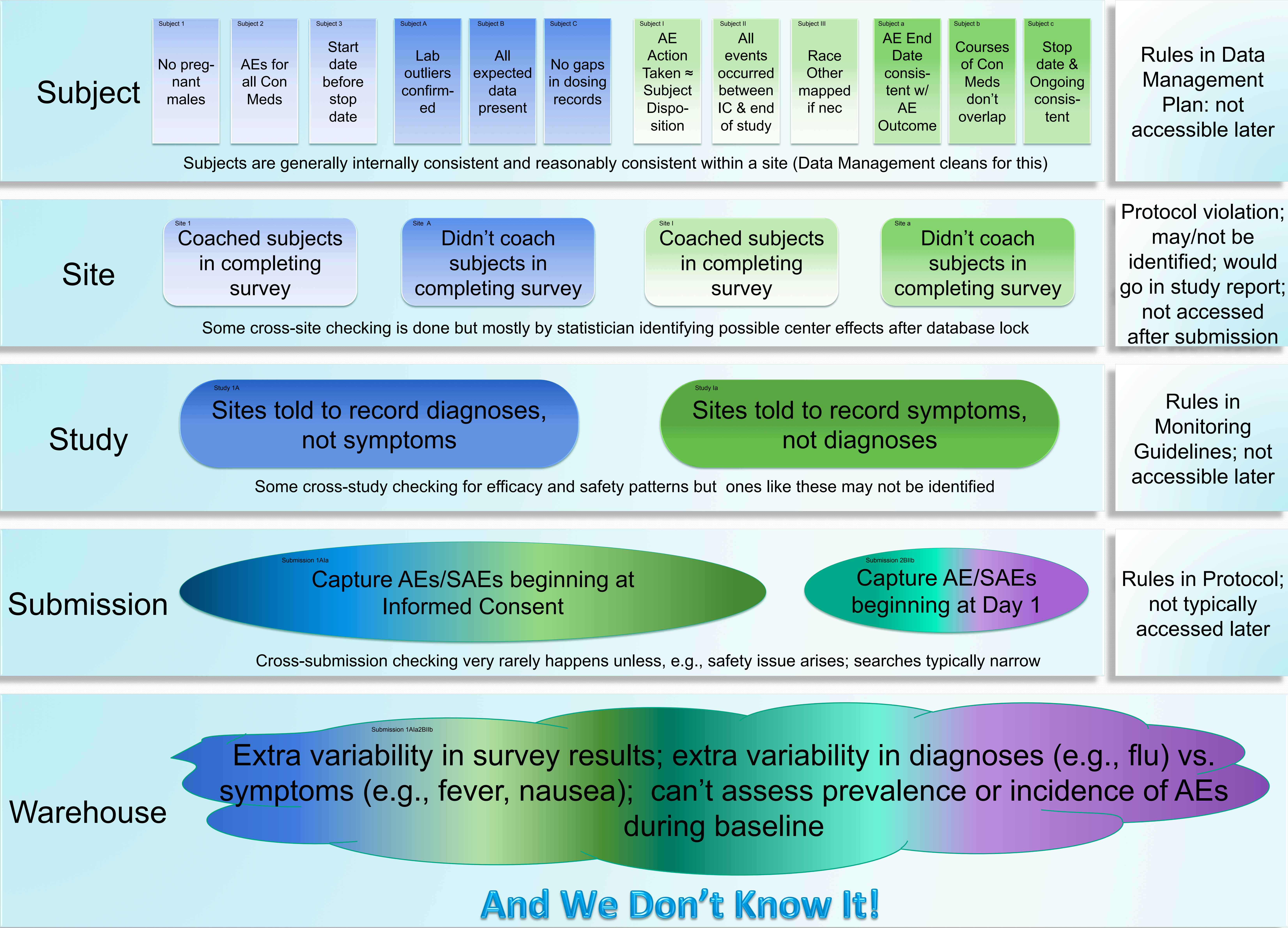
We Don't Know What We Don't Know

Judging Data Fitness for Use in Submissions

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

What We Don't Know Gets Bigger



And We Don't Know It!

How to Know:

1. Reviewers: ask for the rules - Data Management Plans, Monitoring Guidelines, Programming Assumptions, Analysis Plans, & more robust Reviewer Guidelines.
 2. Sponsors: design data rules on a program rather than study level. Convey them to outsourcing partners.
- Longer term...*
3. Develop a schema for rules to travel with the data, perhaps becoming part of metadata.



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