

Throwing Data over the Wall: The Next Big Threat to Data Quality

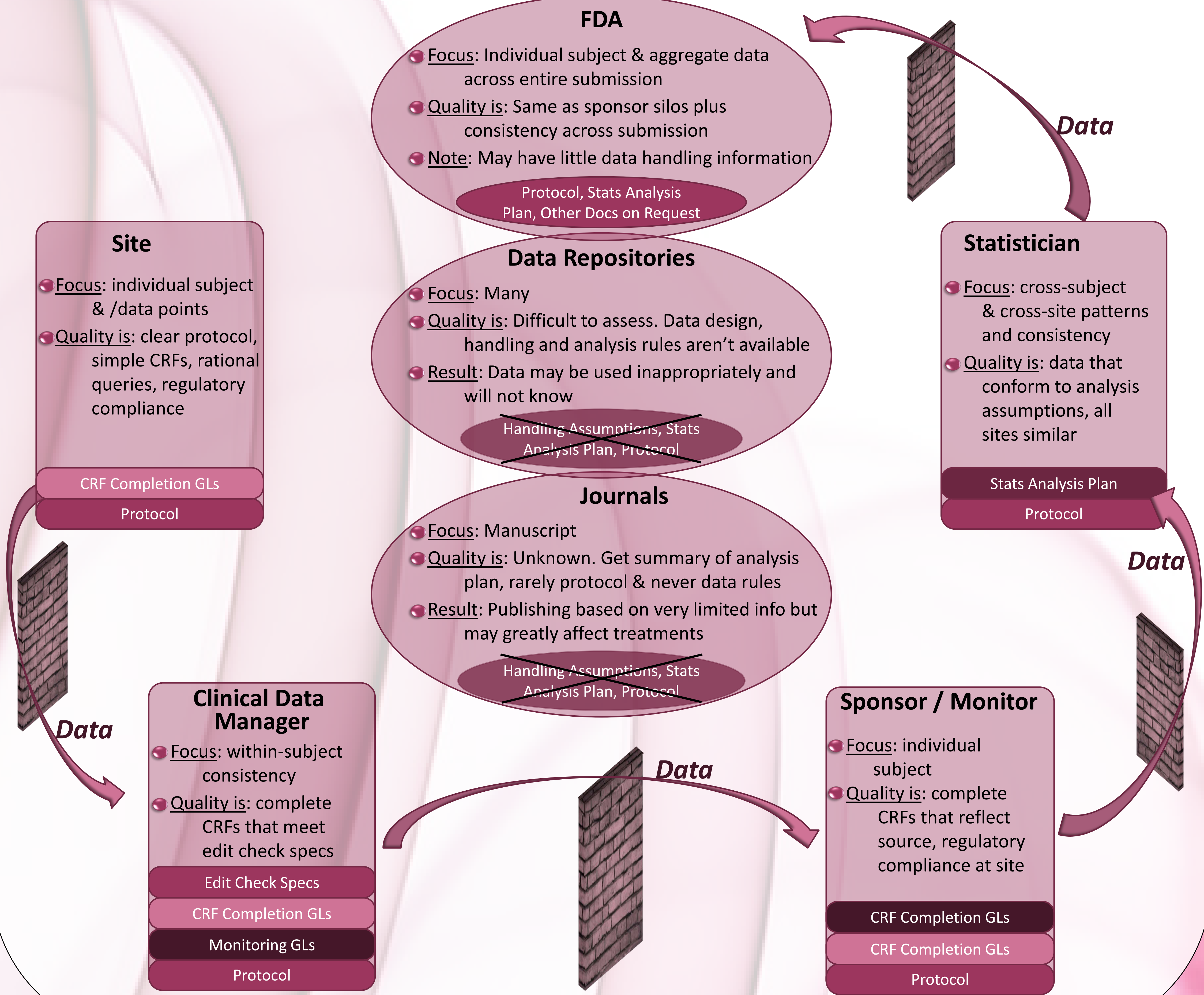
Premise

- Each group defines “quality” differently
- Groups don’t understand others’ data rules
- Data are “tossed over the wall” to the next group
- Data rules are lost as the data travel among groups
- Don’t know how the data can be used, posing a threat to quality

Possible Solutions

- Centrally-recorded in-depth cross-silo exchange in plain language to define who does what to/with the data
- Build quality into study processes so data issues can’t be repeated
- Sometimes data rules must differ, so rules must travel with the data
- CDISC’s machine-readable protocol could help to record rules (e.g., when to start collecting AEs/SAEs)
- ICH E3 Clinical Study Reports Part 9.6 Data QA could be used to describe these rules

Documents Defining Data Rules Don’t Stay with the Data



Groups see only inside their silos

Examples



Better collaboration could result in a better outcome

Data handling rules are lost

