



An Enforcement Problem

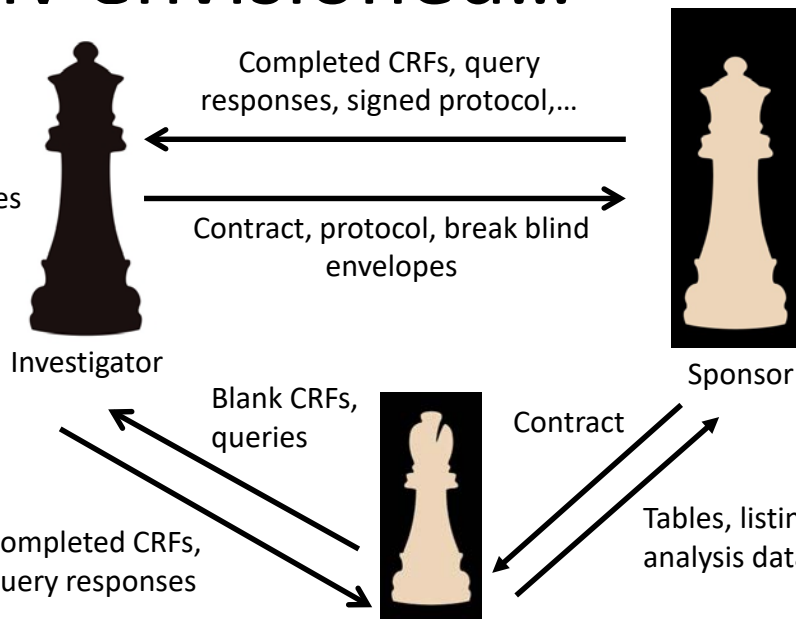
21 CFR 312 vs the Reality of Clinical Trials

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As originally envisioned...

- Case histories
- CRFs
- Locally interpreted images
- Local Lab results
- Regulatory binder

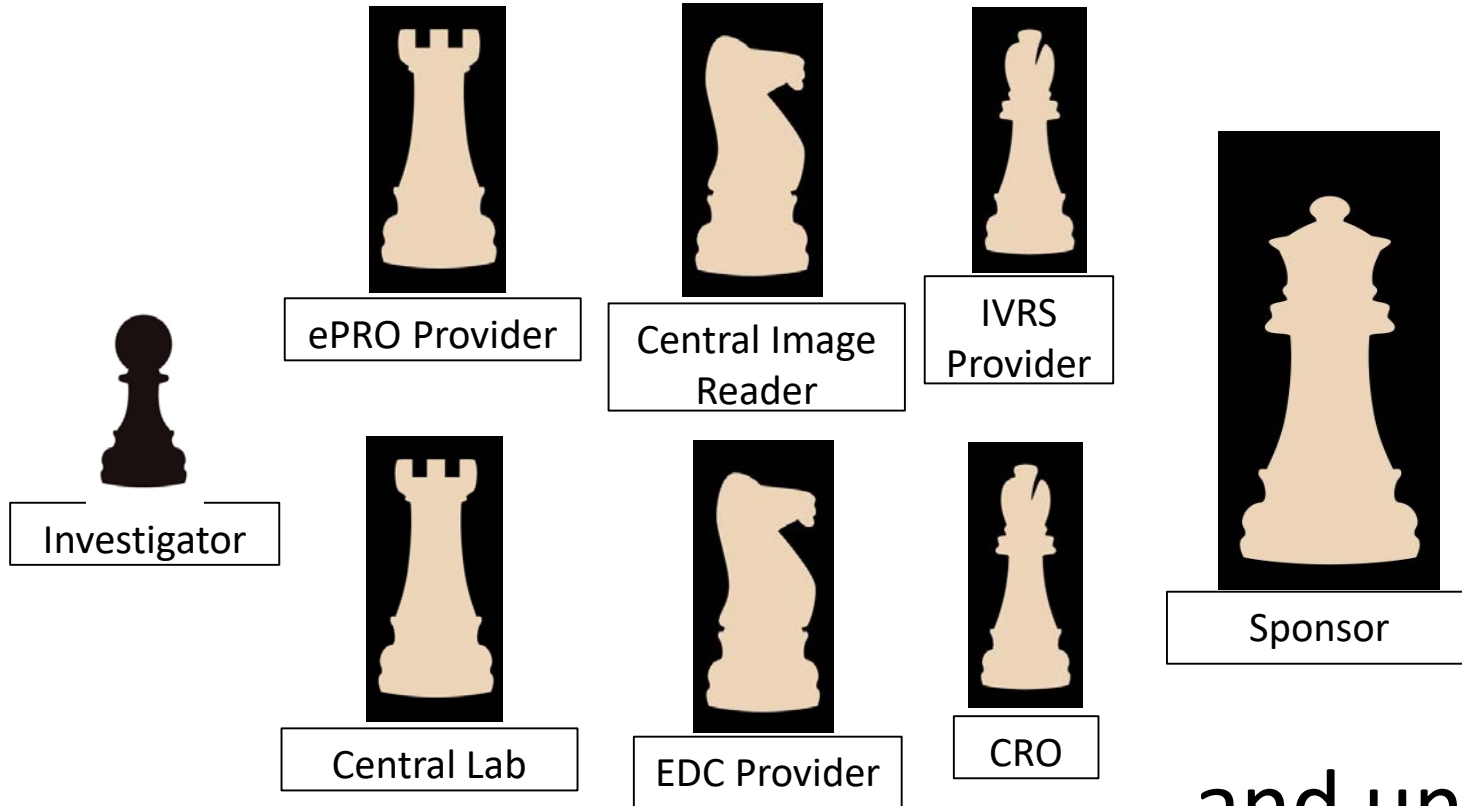


- Clinical
- Safety
- Monitors
- Trial Master File

Clinical Data Management and Biostatistics

...roles and responsibilities are clear

As currently implemented...



...and unintended