



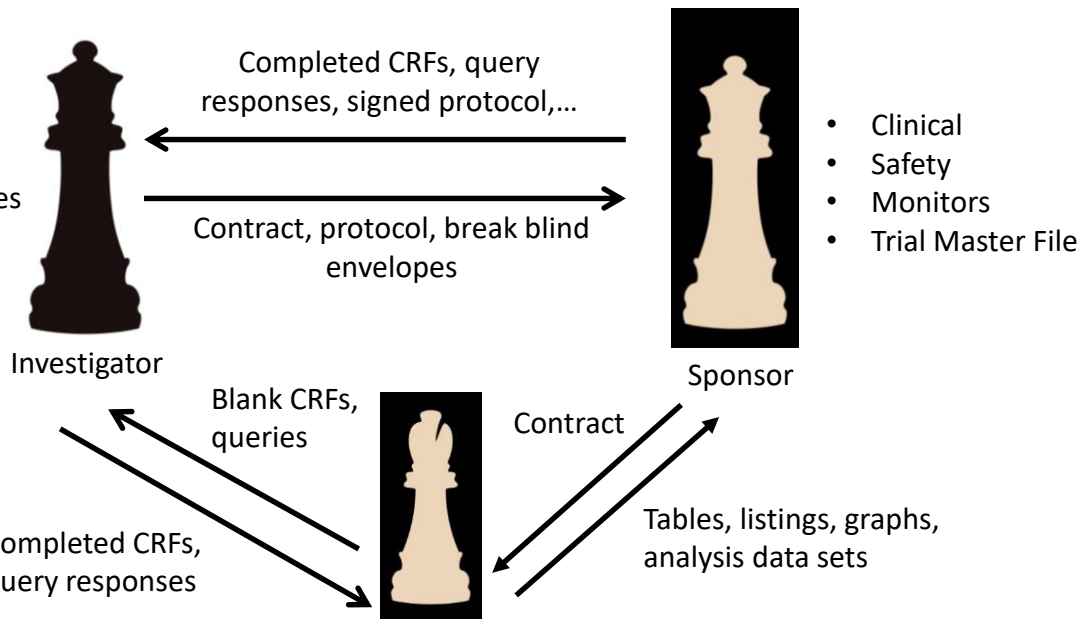
An Enforcement Problem

21 CFR 312 vs the Reality of Clinical Trials

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Primary Consultant, Validant

As originally envisioned...

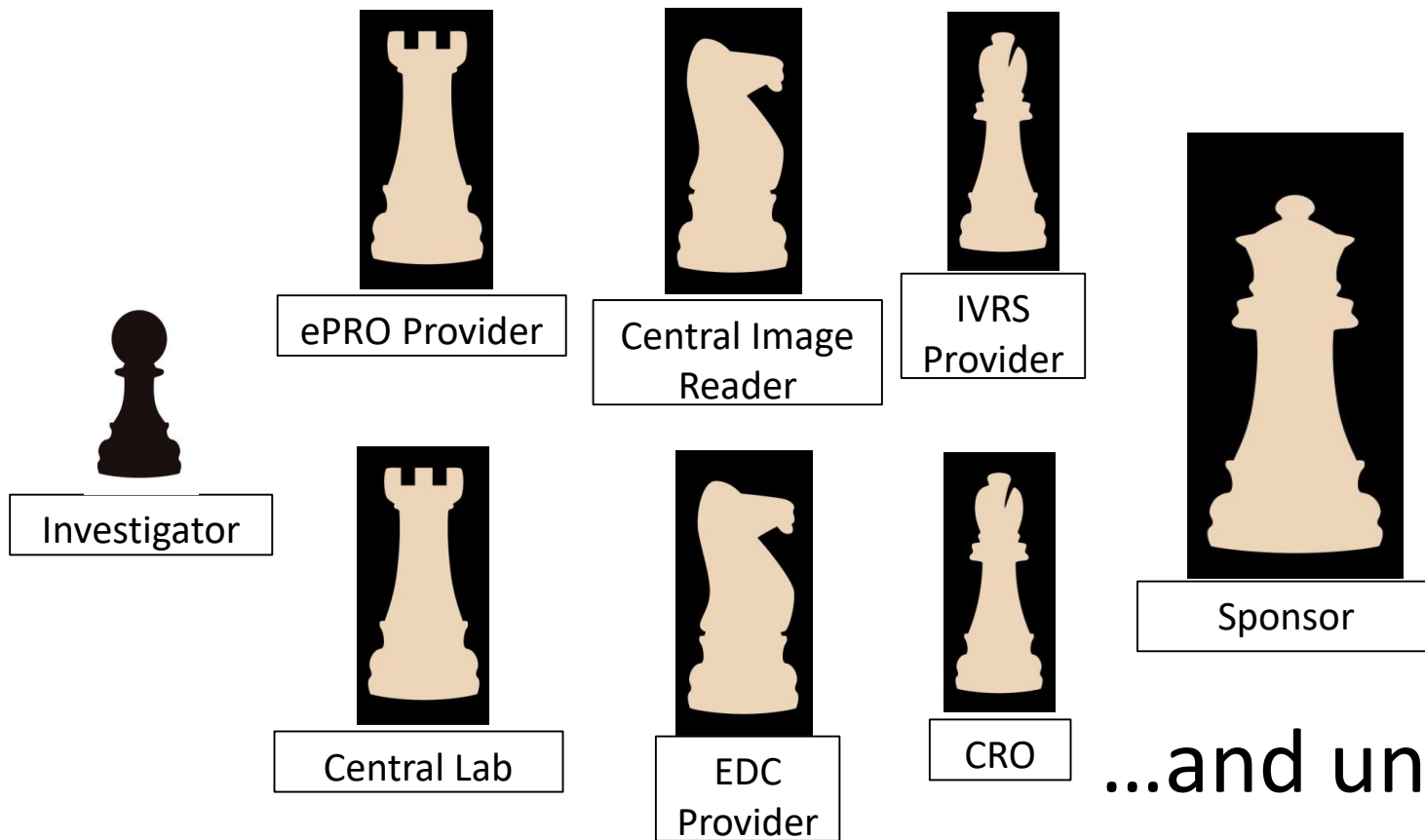
- Case histories
- CRFs
- Locally interpreted images
- Local Lab results
- Regulatory binder



Clinical Data Management and Biostatistics

...roles and responsibilities are clear

As currently implemented...



...and unintended