Implementing a National Cancer Clinical Trials System for the 21st Century

Interactions with Industry, FDA breakout, perspective from an Informatics Vendor

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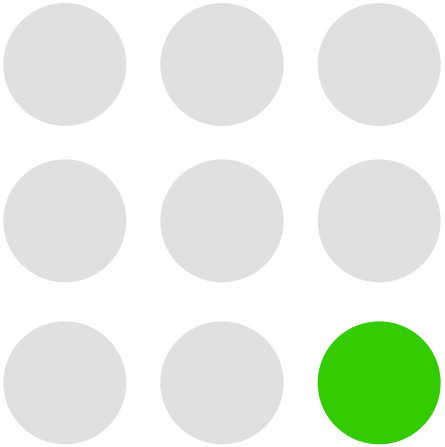

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What we need based on the IOM report

- Focus on infrastructure and research processes, not systems
- Interoperability
  - Standards design – this is difficult
  - Common sources of authority for People (Sites, Users, Subjects) “above” the study level – this is less difficult
- Use best practices from outside of clinical research
  - Focus on planning and execution as a single problem
  - Design processes that cross organizational (Department, CG) barriers and create measurable management metrics
  - Take a metric-based approach to defining success and creating operational standards
  - Leverage commercial platforms

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