Cook Medical – EHR Data Extraction

RAPID Meeting

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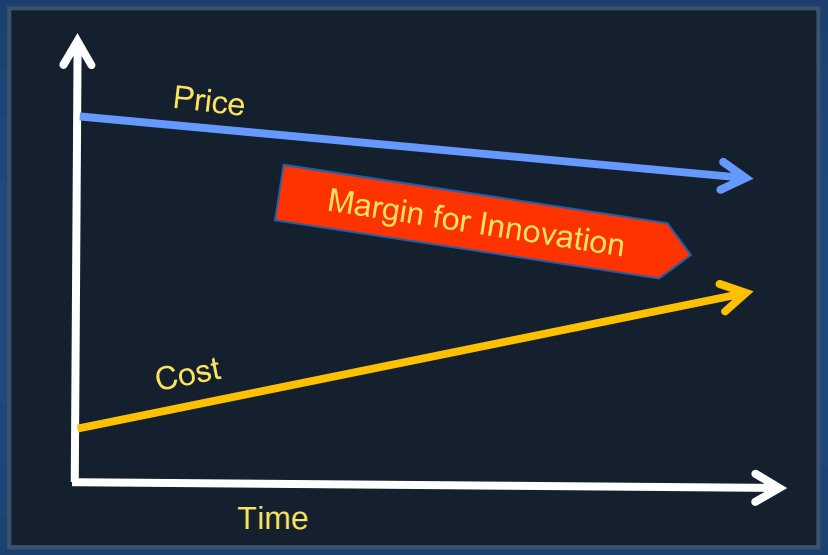
Research and the Economy

Conducting clinical studies in the U.S. is increasingly difficult due to:

- Long IDE procedural delays
- Financial disincentives
- Complex and expensive infrastructure



All resulting in increasing cost and decreasing performance.

Costs up. Taxes up. Regulation up. Prices down. Reimbursement uncertain.

Searching for More Efficient Data Collection

We have searched for novel approaches to conducting clinical studies using:

- Non-traditional infrastructure
- Modernized legislation
- More research-friendly venues

All while holding firm to basic fundamentals for clinical trial data:

- Protection of the rights, safety and welfare of research subjects
- Scientific integrity of trial methods
- Data quality and integrity
- Reliability as a basis for regulatory decision making

EHR + eCRF

To reduce the cost of data acquisition, query and monitoring, we are pursuing use of an electronic medical health record within which the data form information is captured.

Benefits include:

- More efficient and less costly data entry by study team (reduced cost of clinical research coordinators, monitors and auditors by capturing the medical record and study data in one location that is remotely accessible to the entire qualified study team)
- Reduced translation errors from the medical record to the data forms
- Reduced instance of missing data
- More efficient remote oversight by quality personnel and regulators.

Initial concept tests have uncovered emerging questions and observations from various stakeholders.

Audit Related Comments

- *"Clinical trial data cannot be stored in a medical record system because the medical record system must store source data, and the data on CRFs must be separate from source data; otherwise FDA will issue a 483 if CRF data cannot be verified against source."*
- *"Product tracking and accountability cannot be performed from an EHR."*
- *"The doctor seeing the patient participating in the clinical trial should not complete the CRF; a separate clinical research person should complete the CRF from the doctor's notes."*

These observations may be driven by past experience with BIMO inspections of clinical studies

- How much has real substance, and how much is myth?
- What is best venue for determining approaches to resolution?

Patient Rights Related Comments

- *"The informed consent does not provide all those who see medical records permission to see clinical trial data."*
- *"Monitoring personnel would have access to other patients' records."*
- *"Informed consent documents for medical care differ from informed consent documents for clinical studies, so EHRs may not capture the clinical trial IC document."*

What are the needs for patient consent to use of EHR data?

- Legal requirements?
- Societal/ethical requirements?

Are there options for addressing these issues in the revisions to the Common Rule currently underway?

Science Related Comments

- *"Randomization would be unblinded. Others with access to medical records could independently access , analyze and report clinical trial data prematurely."*
- *"Patients from multicenter studies may not be combinable because of differences in capture, definitions and practices between EHRs."*
- *"Availability of longer term patient data is often poor outside of the formal clinical study structure."*

Is it possible for additional controls to be added into EHR systems?

Are there analytical tools that can be applied to compensate for potential poolability questions?

What incentives might be possible (and affordable) to increase the proportion of patient capture at follow up?

Logistics Related Comments

- *"Clinical trials require many types of records that are not available in EHR, such as IRB correspondence, sponsor correspondence, trial management records, and monitoring reports."*
- *"Billing for clinical trial related costs is not covered in EHRs."*
- *"IRB reportable events would not be reported to the IRB from the EHR."*
- *"Expiration of IRB approval and annual resubmission would not be triggered by an EHR."*

As with previous concerns, these may be driven by prior experience and expectations from IDE studies

- Are there data collection approaches in which all IDE requirements need not apply?
- What is best mechanism for addressing such questions?

Summary

- The costs and complexities of clinical studies are increasing
- There is interest in novel alternative approaches that still maintain the basic fundamentals of clinical study data
- Initial tests of the clinical study from EHR concept have uncovered a number of questions; some may be more myth than reality, but all will need to be addressed
- At this point, more questions than answers are apparent; however, excitement remains about MDEpiNet work and projects such as this

Thank You!