EHR Data Methodologies in Clinical Research: Perspectives from the Field

Charge for the Meeting

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Broadening the conversation from “Big Data” to “Big Data Analytics”

Data Scientist: The Sexiest People of the 21st Century

Meet the people who can coax treasure out of messy, unstructured data.
by Thomas H. Davenport and D.J. Patil

When Jonathan Goldman arrived for work in June 2006 at LinkedIn, the business networking site, the place still felt like a start-up. The company had just under 8 million accounts, and the number was growing quickly as existing members invited their friends and colleagues to join. But users weren’t seeking out connections with the people who were already on the site at the rate executives had expected. Something was apparently missing in the social experience. As one LinkedIn manager put it, “It was like arriving at a conference reception and realizing you don’t know anyone. So you just stand in the corner sipping your drink—and you probably leave early.”
A Lifecycle View of Clinical Research

T1 Biomedical Research

Basic Research Data

Pilot Studies

New Research Questions

Study Design & Approval

Study Setup

Recruitment & Enrollment

Study Execution

EHR Data

Required Data Sharing

Submission & Reporting

Evidence-based Review

Public Information

Outcomes Reporting

Clinical Practice

EHR Data

Evidence-based Patient Care and Policy

Outcomes Research

Investigator Initiated T1 → T2 Translational Research

Industry Sponsored Commercialization

From: C Broverman, Partners
How EHRs could accelerate clinical research (Front-end)

<table>
<thead>
<tr>
<th>Trial Step</th>
<th>EHR potential role</th>
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| Study set-up       | ▪ Query EHR database to establish number of potential study candidates.  
▪ Incorporate study manual or special instructions into EHR “clinical content” for study encounters |
| Study enrollment   | ▪ Implement study screening parameters into patient registration and scheduling.  
▪ Query EHR database to contact/recruit potential candidates and notify the patient’s provider(s) of potential study eligibility. |
| Study execution    | ▪ Incorporate study-specific data capture as part of routine clinical care / clinical documentation workflows  
▪ Auto-populate study data elements into care report forms from other parts of the EHR database.  
▪ Embed study-specific data requirements (case record forms) as special tabs/documentation templates using structured data entry.  
▪ Implement rules/alerts to ensure compliance with study data collection requirements  
▪ Create range checks and structured documentation checks to ensure valid data entry |
How EHRs could accelerate clinical research (Back-end)

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<tr>
<th>Trial Step</th>
<th>EHR potential role</th>
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<tbody>
<tr>
<td>Submission &amp; Reporting</td>
<td>• Provide data extraction formats that support data exchange standards</td>
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<tr>
<td></td>
<td>• Document and report adverse events</td>
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<tr>
<td>Evidence generation</td>
<td>• Assess congruence of new findings and existing evidence with current practice and outcomes (incorporate into meta-analyses)</td>
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<td>• Submit findings to electronic trial banks using published standards.</td>
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<tr>
<td>Evidence-based clinical care</td>
<td>• Implement study findings as clinical documentation, orders sets, point-of-care rules/alerts</td>
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<td>• Monitor changes in care and outcomes in response to evidence-based clinical decision support</td>
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<td>• Provide easy access to detailed clinical care data for motivating new clinical trial hypotheses</td>
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Figure. The Tapestry of Potentially High-Value Information Sources That May be Linked to an Individual for Use in Health Care

Scope and Focus

1. EHR data as it is, not as we want it to be
   – Good, bad, ugly, missing, inconsistent
2. EHR data as collected in routine clinical practice
   – Detailed, intimate, biased, clinical workflows
3. How to support multiple discovery agendas and methods
   – Research designs, objectives, cohorts/populations
4. Living in a networked world
   – Scalability, sharability, integration, harmonization
Rules for the Meeting

• Four panels with specific focus
  – Speakers ~ 10 minutes each
    • Only 1-2 clarifying questions
  – Lots of time for full panel/participant interactions to end of session

• All external experts will participate in the all post-presentation discussions

• Key findings will be published as post-workshop report 4-6 weeks after meeting