Evolving Methods for Real-World Evidence Generation in Mature & Emerging Markets

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Workshop Objectives

• General objective is to compare and contrast traditional versus novel methods for the conduct of prospective observational research

• Specific objectives include:
  − Describe how electronic medical records (EMRs) can impact study planning, patient identification & recruitment, and data capture
  − Provide a case study of a recent disease registry conducted in the Latin America region using traditional methods
Prospective Observational Research: Traditional vs Novel Methods

Traditional paper-based approaches to patient identification & data collection

Newer electronic approaches to patient identification & data collection

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<thead>
<tr>
<th>Characteristic</th>
<th>EMRs</th>
<th>Obs Research</th>
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<tbody>
<tr>
<td>Data collected for …</td>
<td>Individual patient health tracking &amp; physician orders support</td>
<td>Population research</td>
</tr>
<tr>
<td>Patients included</td>
<td>All in practice</td>
<td>Selected based on protocol</td>
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<tr>
<td>Provider-induced variability in data collection</td>
<td>Lots</td>
<td>Minimal</td>
</tr>
<tr>
<td>Practice-based customization of data collection</td>
<td>Encouraged</td>
<td>Highly discouraged</td>
</tr>
<tr>
<td>Data formats</td>
<td>Structured &amp; unstructured</td>
<td>Structured &amp; controlled vocabularies</td>
</tr>
<tr>
<td>Timing of data collection</td>
<td>Tied to patient encounters</td>
<td>Tied to protocol</td>
</tr>
<tr>
<td>Data quality assurance</td>
<td>Limited</td>
<td>Research specific validation rules</td>
</tr>
<tr>
<td>Data standards</td>
<td>HL7</td>
<td>CDISC</td>
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Role of EMRs in Prospective Observational Research

> EMR databases can be used to assess protocol feasibility
> EMR databases can be used to prescreen patients for eligibility

EMR networks can be tapped into to identify potential investigators based on current patients
EMRs can be used to remind providers of registries
EMRs can be programmed with pop-up boxes indicating potential patient eligibility

EMR networks can be programmed into EMRs to facilitate data capture
EMRs can autofeed data to registry CRFs

EMR Systems Create Provider/Patient Networks
Retro-to-Prospective Hybrid Study Designs

Combine insights from retrospective analyses of EMR data

With prospective data collection from patients in these analyses

As well as the physicians who treated them

To reduce longitudinal follow-up & overall costs of study execution

A Cost Spectrum of Study Designs

- Studies involving different kinds of data sources naturally array across the cost spectrum according to time & effort in data collection

- Historically, much has been done on either end of the spectrum, but not much in the middle

- Novel approaches leveraging EMR databases for data analysis & patient outreach are providing design alternatives in mid-range of costs