

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

David Thompson, PhD
Senior Vice President
Real-World Evidence Consulting
INC Research / inVentiv Health

ISPOR 6th Latin America Conference
Sao Paulo, Brazil
16 September 2017



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

> 3 © 2016 All Rights Reserved | CONFIDENTIAL



EMRs & Observational Research: Square Peg in Round Hole?

Characteristic	EMRs	Obs Research
Data collected for ...	Individual patient health tracking & physician orders support	Population research
Patients included	All in practice	Selected based on protocol
Provider-induced variability in data collection	Lots	Minimal
Practice-based customization of data collection	Encouraged	Highly discouraged
Data formats	Structured & unstructured	Structured & controlled vocabularies
Timing of data collection	Tied to patient encounters	Tied to protocol
Data quality assurance	Limited	Research specific validation rules
Data standards	HL7	CDISC

> 4 © 2016 All Rights Reserved | CONFIDENTIAL





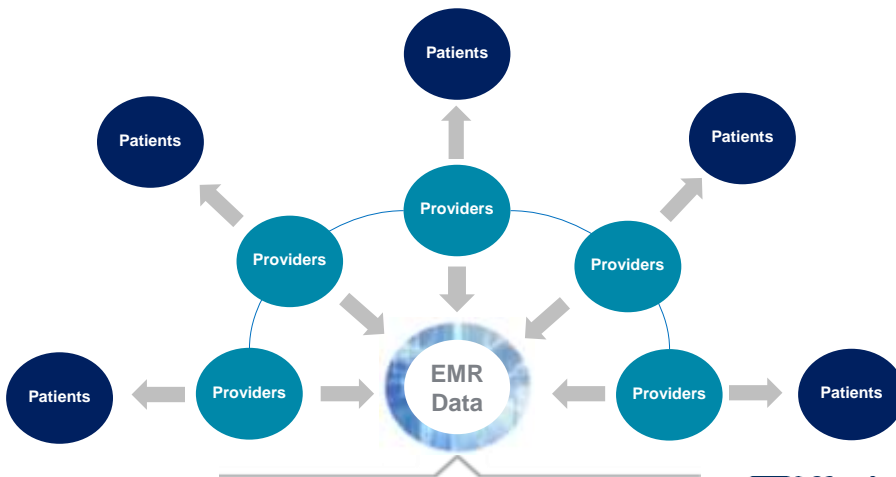
Role of EMRs in Prospective Observational Research



- > 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
- > Registry CRFs 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

> 7 © 2016 All Rights Reserved | CONFIDENTIAL



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

> 8 © 2016 All Rights Reserved | CONFIDENTIAL

