Role of EMRs in Patient Registries & Other Post-Marketing Research

David Thompson, PhD
Dan Levy, MS
29 March 2013
Your Presenters

David Thompson, PhD  
Senior Vice President and Global Head of Emerging Businesses, Quintiles Outcome

Dr. David Thompson is responsible for Quintiles Outcome’s EMR data assets and analytics, provider networks and professional associations, and health economics and outcomes research (HEOR) functions. Dave is a health economist with 25 years of experience consulting to the life sciences industry on health economics & outcomes research, including work in economic modeling, retrospective database analysis, trial-based economic evaluations, and patient-reported outcomes. His work has been global in nature, with extensive experience in North American & European markets as well as the emerging markets, particularly Latin America. He has published ~50 articles in peer-reviewed medical journals and is a frequent presenter at and contributor to the International Society of Pharmacoeconomics & Outcomes Research (ISPOR), functioning as Editor-in-Chief of ISPOR Connections since 2008. Dave holds a PhD in Economics from the University of Massachusetts.

Dan Levy, MS  
Chief Technology Officer, Quintiles Outcome

Dan Levy has direct responsibility for all aspects of IT strategy and implementation at Quintiles Outcome. Prior to his role as CTO, Dan was Vice President of Engineering at Outcome Sciences responsible for the delivery of real-world and late phase solutions. Previously, Dan was Vice President of Engineering at Formation Systems and brings with him 20 years of technology and management experience. Over the past several years, Dan has played an active role in industry standards interoperability initiatives and is a member of IHE contributing to the Quality, Research, and Public Health Domain and to the development, implementation, and education of the RFD profile. Dan is a member of CDISC and an author and instructor of the Healthcare Link training course. Dan holds a BA in General Science from Brandeis University and an MS in Systems and Software Engineering from Boston University.
Contents

• EMRs & registries:
  > Square peg in round hole?
  > Why we force the issue

• Role of EMRs in planning & executing registry studies:
  > Patient & site identification
  > Patient recruitment
  > Data collection & reporting

• EMRs & registries in the era of health-care reform:
  > Comparative effectiveness research (CER)
  > Meaningful use criteria
  > Registry of Patient Registries (RoPR)
Today’s Webinar Audience

- Academia
- Biostatistician
- Clinical Operations
- Epidemiology
- Health Economics/Health Outcomes
- Medical Affairs
- Market Access
- Pharmacovigilance
- Regulatory Affairs
- Risk Management
- Other

- 33.56%
- 23.49%
- 14.43%
- 7.38%
- 5.70%
- 5.70%
- 3.36%
- 2.35%
- 2.01%
- 1.34%
- 0.67%
Polling Questions

- A small number of polling questions have been added to today’s webinar to make the session more interactive
EMRs & Registries
Polling Questions

- What is your experience in conducting patient registry studies?
  - No experience
  - Some experience
  - Significant experience
Polling Questions

- What is your experience in conducting EMR-based research?
  - No experience
  - Some experience
  - Significant experience
Some Bold Assertions

To be backed up by what follows …

• If it’s not already, the word “interoperability” will soon become part of every clinical operations manager’s vocabulary

• People think it’s easy to link EMRs & registries, but people are often wrong

• EMRs are poised to become to registries & clinical trials what GPS has become to navigation

• In the era of health care reform, EMRs will become indispensable to post-approval research—and post-approval research will become indispensable to EMRs
## EMRs vs Registries

**Square Peg in Round Hole?**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>EMRs</th>
<th>Registries</th>
</tr>
</thead>
<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>
</tr>
<tr>
<td>Provider-induced variability in data collection</td>
<td>Lots</td>
<td>None</td>
</tr>
<tr>
<td>Practice-based customization of data collection</td>
<td>Yes</td>
<td>No</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>
</tr>
</tbody>
</table>
Role of EMRs in Registries

Facilitating the Process

**Planning**
- EMR databases can be used to assess protocol feasibility
- EMR databases can be used to prescreen patients for eligibility

**Recruitment**
- 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

**Execution**
- Registry CRFs can be programmed into EMRs to facilitate data capture
- EMRs can autofeed data to registry CRFs
Role of EMRs in Registries

An Illustrative Example

• Quintiles Outcome developed The American College of Rheumatology Clinical Registry, a tool that assists ACR members in:
  > Practice improvement
  > Patient management
  > Participation in quality improvement programs (eg, PQRS, PIM)

• Objective is to assess the long-term quality of care & drug safety in patients with:
  > Rheumatoid arthritis
  > Osteoarthritis
  > Osteoporosis
  > Gout
  > Juvenile idiopathic arthritis
Role of EMRs in Registries

EMR Databases Can Generate Heat Maps of Potential Patients

Number of EMR Patients, Rheumatoid Arthritis
National EMR Database, Research Patients*
176,884 Patients among 556 Provider Organizations in 311 Zip 3-digit Areas

*Research Patients: 12+ Months, 1+ Office Visits, 3+ Other Dates
2010 Population Estimates: Nielsen Claritas, Displayed at 0.25 degree grid
## Role of EMRs in Registries

### Zeroing In On Specific Providers & Patients (Fictitious)

<table>
<thead>
<tr>
<th>PRACTICE NAME</th>
<th>NATIONAL PROVIDER ID</th>
<th>ENCRYT PED PATIENT ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPRINGFIELD USA HEALTH PL</td>
<td>NPI0123456789</td>
<td>PT000064</td>
</tr>
<tr>
<td>SPRINGFIELD USA HEALTH PL</td>
<td>NPI0123456789</td>
<td>PT000193</td>
</tr>
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<td>SPRINGFIELD USA HEALTH PL</td>
<td>NPI0123456789</td>
<td>PT000204</td>
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<td>SPRINGFIELD USA HEALTH PL</td>
<td>NPI0123456789</td>
<td>PT000595</td>
</tr>
<tr>
<td>SPRINGFIELD USA HEALTH PL</td>
<td>NPI0987654321</td>
<td>PT002468</td>
</tr>
<tr>
<td>SPRINGFIELD USA HEALTH PL</td>
<td>NPI0123443210</td>
<td>PT000022</td>
</tr>
<tr>
<td>ANYTOWN AMERICA PROVIDE</td>
<td>NPI0123443210</td>
<td>PT000022</td>
</tr>
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<td>ANYTOWN AMERICA PROVIDE</td>
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<td>PT004892</td>
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<td>PT008642</td>
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<td>ANYTOWN AMERICA PROVIDE</td>
<td>NPI2468086420</td>
<td>PT009000</td>
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<tr>
<td>GARDEN CITY PHYSICIAN GR</td>
<td>NPI0022446688</td>
<td>PT000100</td>
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<tr>
<td>GARDEN CITY PHYSICIAN GR</td>
<td>NPI0022446688</td>
<td>PT002024</td>
</tr>
</tbody>
</table>
EMR & Registry Interoperability

So what’s the problem?
Polling Questions

- What is your level of experience with interoperability?
  - None
  - Have heard of it
  - Have used it in a project
  - Using it in a project
Before Interoperability

Secondary use of EMR data requires data re-entry

- Re-entry of EMR data for quality reporting
- Re-entry of EMR data for clinical trials
- Re-entry of EMR data for registries
- Re-entry of EMR data for safety surveillance

Data entry into EMR is convenient
Example Data Entry Room

Slide courtesy John Weiler, MD, PhD
After Interoperability

Secondary use of EMR data is automated

Data entry into EMR is convenient

- EMR data transfer for quality reporting
- EMR data transfer for registries
- EMR data transfer for clinical trials
- EMR data transfer for safety surveillance
EMR & Registry Interoperability

*So what could this look like?*
Role of EMRs in Registries

ACR Registry Home Page

<table>
<thead>
<tr>
<th>Quick Links</th>
<th>Patient Form Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Patient</td>
<td>Complete Forms - Physician:</td>
</tr>
<tr>
<td>Find Patient</td>
<td>32</td>
</tr>
<tr>
<td>Patient Reminder Letters</td>
<td>Incomplete Forms - Physician:</td>
</tr>
<tr>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Disease Information</th>
<th>Review Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>RA - Patient Information</td>
<td>Benchmarking Report</td>
</tr>
<tr>
<td>RA - References</td>
<td>Data Download Tool</td>
</tr>
<tr>
<td>OP - Patient Information</td>
<td></td>
</tr>
<tr>
<td>OP - References</td>
<td></td>
</tr>
<tr>
<td>GOUT - Patient Information</td>
<td></td>
</tr>
<tr>
<td>GOUT - References</td>
<td></td>
</tr>
</tbody>
</table>

Documents and Help | News and Announcements
Role of EMRs in Registries

ACR Registry Encounter Entry Page
Role of EMRs in Registries

Example EMR Interface
Role of EMRs in Registries

Example EMR Patient Charts (Fictitious)
# Role of EMRs in Registries

**Example EMR Labs (Fictitious)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Reference Range</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRON, TOTAL</td>
<td>43 mcg/dL</td>
<td>40-175 mcg/dL</td>
<td>XO</td>
</tr>
<tr>
<td>LD</td>
<td>205 U/L</td>
<td>100-200 U/L</td>
<td>XO</td>
</tr>
<tr>
<td>PHOSPHATE (AS PHOSPHORUS)</td>
<td>4.2 mg/dL</td>
<td>2.5-4.5 mg/dL</td>
<td>XO</td>
</tr>
<tr>
<td>URIC ACID</td>
<td>10.1 mg/dL</td>
<td>2.5-7.0 mg/dL</td>
<td>XO</td>
</tr>
<tr>
<td>COMPREHENSIVE METABOLIC PANEL W/EGFR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLUCOSE</td>
<td>100 mg/dL</td>
<td>65-99 mg/dL</td>
<td>XO</td>
</tr>
<tr>
<td>UREA NITROGEN (BUN)</td>
<td>9 mg/dL</td>
<td>7-25 mg/dL</td>
<td>XO</td>
</tr>
<tr>
<td>CREATININE</td>
<td>1.8 mg/dL</td>
<td>0.50-1.20 mg/dL</td>
<td>XO</td>
</tr>
<tr>
<td>EGFR NON-AFR. AMERICAN</td>
<td>&gt;60 mL/min/1.73m2</td>
<td>&gt; OR = 60 mL/min/1.73m2</td>
<td>XO</td>
</tr>
<tr>
<td>EGFR AFRICAN AMERICAN</td>
<td>&gt;60 mL/min/1.73m2</td>
<td>&gt; OR = 60 mL/min/1.73m2</td>
<td>XO</td>
</tr>
<tr>
<td>BUN/CREATININE RATIO</td>
<td>15 (calc)</td>
<td>6.22 (calc)</td>
<td>XO</td>
</tr>
<tr>
<td>SODIUM</td>
<td>141 mmol/L</td>
<td>135-146 mmol/L</td>
<td>XO</td>
</tr>
<tr>
<td>POTASSIUM</td>
<td>2.0 mmol/L</td>
<td>3.5-5.3 mmol/L</td>
<td>XO</td>
</tr>
<tr>
<td>CHLORIDE</td>
<td>105 mmol/L</td>
<td>98-110 mmol/L</td>
<td>XO</td>
</tr>
<tr>
<td>CARBON DIOXIDE</td>
<td>21 mmol/L</td>
<td>21-33 mmol/L</td>
<td>XO</td>
</tr>
<tr>
<td>CALCIUM</td>
<td>9.3 mg/dL</td>
<td>8.6-10.2 mg/dL</td>
<td>XO</td>
</tr>
<tr>
<td>PROTEIN, TOTAL</td>
<td>7.5 g/dL</td>
<td>6.2-8.3 g/dL</td>
<td>XO</td>
</tr>
<tr>
<td>ALBUMIN</td>
<td>4.9 g/dL</td>
<td>3.6-5.1 g/dL</td>
<td>XO</td>
</tr>
<tr>
<td>GLOBULIN</td>
<td>2.6 g/dL (calc)</td>
<td>2.2-3.9 g/dL (calc)</td>
<td>XO</td>
</tr>
<tr>
<td>ALBUMIN/GLOBULIN RATIO</td>
<td>1.9 (calc)</td>
<td>1.0-2.1 (calc)</td>
<td>XO</td>
</tr>
</tbody>
</table>
Role of EMRs in Registries

Example EMR Progress Note and Trigger (Fictitious)

![EMR Progress Note Example](image)

- **Assessment**
  - **DX**
  - **Rule Out**
    - Gout
    - Gouty tophi of other sites
    - Chondrocalcinosis due to pyrophosphate crystals, ankle and foot
    - Monitoring Medication Therapy

- **Visit Date:** 03/19/2008

The image shows a fictitious EMR progress note with the patient's name as Jones, Ben (903). The note includes a list of active problems with associated differential diagnoses and rule-out conditions. The screenshot is from a computer interface, showing the EMR system with various options and functionalities for patient charts and documentation.

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[Image: EMR Progress Note Example]

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[Image: EMR Progress Note Example]
Role of EMRs in Registries

Hyperlink ‘Surfaces’ ACR Encounter Form
Role of EMRs in Registries

Interoperability Means Same Form ‘Surfaces’ in Different EMR
EMR & Registry Interoperability

So how does it work?
Identify EMR Trigger Mechanism

Different triggers for different use cases

<table>
<thead>
<tr>
<th>Trigger Mechanism</th>
<th>Registry Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis Code (ex: ICD-9)</td>
<td>Disease Registry</td>
</tr>
<tr>
<td></td>
<td>Condition Registry</td>
</tr>
<tr>
<td>Procedure Code (ex: CPT)</td>
<td>Health Services Registry</td>
</tr>
<tr>
<td></td>
<td>Disease Registry</td>
</tr>
<tr>
<td>Treatment or Medication</td>
<td>Exposure Registry</td>
</tr>
<tr>
<td></td>
<td>Product Registry</td>
</tr>
<tr>
<td>Medication Discontinuation</td>
<td>Drug Safety Reporting</td>
</tr>
<tr>
<td>Device Replacement</td>
<td>Device Safety Reporting</td>
</tr>
</tbody>
</table>
Retrieve Form for Data Capture

RFD – an IHE Standard developed by CDISC

Adapted from slide courtesy of Dave Iberson-Hurst
CHAPTER 11: Interfacing Registries With Electronic Health Records

Available at: http://effectivehealthcare.ahrq.gov
Polling Questions

- Would your organization consider this type of workflow useful to improving investigator experience?
  - Yes
  - No
  - Don’t Know
EMRs & Registries in the Era of Health Care Reform
# Era of Health Care Reform

## EMRs, Registries & Meaningful Use Criteria

<table>
<thead>
<tr>
<th>Stage 1</th>
<th>Data Capture &amp; Sharing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronically capturing health information in a standardized format</td>
<td></td>
</tr>
<tr>
<td>Using that information to track key clinical conditions</td>
<td></td>
</tr>
<tr>
<td>Communicating that information for care coordination processes</td>
<td></td>
</tr>
<tr>
<td>Initiating the reporting of clinical quality measures and public health information</td>
<td></td>
</tr>
<tr>
<td>Using information to engage patients and their families in their care</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stage 2</th>
<th>Advance Clinical Processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>More rigorous health information exchange</td>
<td></td>
</tr>
<tr>
<td>Increased requirements for e-prescribing and incorporating lab results</td>
<td></td>
</tr>
<tr>
<td>Electronic transmission of patient care summaries across multiple settings</td>
<td></td>
</tr>
<tr>
<td>More patient-controlled data</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stage 3</th>
<th>Improved Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improving quality, safety, and efficiency, leading to improved health outcomes</td>
<td></td>
</tr>
<tr>
<td>Decision support for national high-priority conditions</td>
<td></td>
</tr>
<tr>
<td>Patient access to self-management tools</td>
<td></td>
</tr>
<tr>
<td>Access to comprehensive patient data through patient-centered HIE</td>
<td></td>
</tr>
<tr>
<td>Improving population health</td>
<td></td>
</tr>
</tbody>
</table>
Era of Health Care Reform

EMRs, Registries & Comparative Effectiveness Research

INITIAL NATIONAL PRIORITIES FOR
COMPARATIVE EFFECTIVENESS RESEARCH

IOM National Priorities Committee Definition

Proceeding from the definitions in Table 2-1 and the preceding considerations, the committee developed the following working definition of CER to guide its deliberations:

Comparative effectiveness research (CER) is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.
Patient-Centered Outcomes Research Definition Revision:
Response to Public Input

CONSENSUS DEFINITION as of February 15, 2012
Updated as noted below on April 20, 2012 (original version available here)

Patient-Centered Outcomes Research Working Definition

Patient-Centered Outcomes Research (PCOR) helps people and their caregivers communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options. This research answers patient-centered questions such as:

1. “Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”
2. “What are my options and what are the potential benefits and harms of those options?”
3. “What can I do to improve the outcomes that are most important to me?”
4. “How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?”
Era of Health Care Reform

EMRs, Registries & CER (cont)

RICHARD L. KRAVITZ, NAHUA DUAN, and JOEL BRASLOW

University of California, Davis; University of California, Los Angeles

Evidence-based medicine is the application of scientific evidence to clinical practice. This article discusses the difficulties of applying global evidence ("average"
measured as population means) to local problems (individual patients who might depart from the population average). It argues that the decision of most treatments in clinical trials can be misleading and bad because the data are a complex mixture of beneficial effects for some, little or bad effects for some, and harm for a few. Heterogeneity of treatment effects reflects the risk of disease, responsiveness to treatment, vulnerability to injury for different outcomes. Recognizing these factors, policymakers and practitioners can make better use of the evidence, research design, population characteristics, and US Food and Drug Administration.

Heterogeneity of Treatment Effects: Implications for Guidelines, Payment, and Quality Assessment

Sheldon Greenfield, M.D., Richard Kreuzitz, M.D., M.S.P.H., Nahua Duan, M.D., and Sharon K. Kaplan, M.D., M.S.P.H.

Department of Health Policy Research, University of California-Irvine School of Medicine, Irvine, California, USA; Center for Health Services Research in Primary Care, Lawrence J. Ellison Ambulatory Care Center, University of California-Irvine, Orange, California, USA; Center for Health Services Research in Primary Care, Lawrence J. Ellison Ambulatory Care Center, University of California-Irvine, Orange, California, USA.

ABSTRACT

Randomized controlled trial results may not always apply to current practice. For example, randomized controlled trials often test interventions in a single, well-defined setting, but patients in real-world practice may differ in important ways. The results of these trials may not be directly applicable to real-world practice. This study used a population-based approach to examine the extent to which randomized controlled trials can be applied to real-world practice. The study used a population-based approach to examine the extent to which randomized controlled trials can be applied to real-world practice. The study used a population-based approach to examine the extent to which randomized controlled trials can be applied to real-world practice. The study used a population-based approach to examine the extent to which randomized controlled trials can be applied to real-world practice.

Limitations of Applying Summary Results of Clinical Trials to Individual Patients

David M. Kent, M.D., M.S.

The need for risk stratification

There is growing awareness that the results of randomized controlled trials might not be applicable to individual patients. This is particularly true for patients with complex medical conditions, such as diabetes, heart disease, and cancer. In these cases, the benefits and risks of new treatments are difficult to predict, and the optimal treatment strategy may be different for different patients. This is a challenge that clinicians and researchers face every day, and it requires a more nuanced approach to clinical decision-making. The implications of these findings for clinicians, researchers, and policymakers are significant, and they highlight the need for continued efforts to improve the translation of evidence into practice.
Era of Health Care Reform

The Registry of Patient Registries (RoPR)

• Recognizing proliferation and growing importance of patient registries, the Agency of Healthcare Research & Quality (AHRQ) initiated RoPR:
  > A searchable central listing of patient registries
  > Similar to (and linked with) clinicaltrials.gov
  > RoPR can be found at: https://patientregistry.ahrq.gov

• Primary objective is to promote collaboration, reduce redundancy & improve transparency in registry research

• Secondary objectives include:
  > Encourage & facilitate use of common data elements & definitions in similar conditions
  > Provide a central repository of searchable summary results
  > Offer researchers a search tool to locate existing data to request for use in new studies
  > Serve as a recruitment tool for researchers and patients interested in participating in patient registries
Era of Health Care Reform

RoPR Screen Shots – Search Engine
Era of Health Care Reform
RoPR Screen Shots – Registry Profile

Knee Arthroplasty Registry
RoPR ID: 169
NCT ID – NCT0123457
History of Changes

Registry Profile

REGISTRY DESCRIPTION

<table>
<thead>
<tr>
<th>Registry Title</th>
<th>Knee Arthroplasty Registry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version</td>
<td>1.1</td>
</tr>
<tr>
<td>Last Updated On</td>
<td>April 18, 2012</td>
</tr>
<tr>
<td>First Received</td>
<td>March 2, 2012</td>
</tr>
<tr>
<td>Brief Description</td>
<td>The purpose of the Knee Arthroplasty Registry is to improve quality of care for knee arthroplasty by measuring adherence to 15 quality measures.</td>
</tr>
<tr>
<td>Long Description</td>
<td>The Knee Arthroplasty Registry measures the quality of care delivered to patients receiving knee arthroplasty at multiple centers, both academic and community-based, across the United States. The primary outcomes evaluated by the registry include the quality of care delivered, long-term patient outcomes (up to 5 years), comparative effectiveness, and postmarketing surveillance.</td>
</tr>
<tr>
<td>Geography and Location</td>
<td>National, United States</td>
</tr>
</tbody>
</table>

REGISTRY CLASSIFICATION AND PURPOSE

<table>
<thead>
<tr>
<th>Registry Classification</th>
<th>Disease/Disorder/Condition Service, Encounter Other: Knee Arthroplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registry Purpose</td>
<td>Clinical Practice Assessment Quality Improvement</td>
</tr>
</tbody>
</table>

CONTACT AND CONDITIONS OF ACCESS

<table>
<thead>
<tr>
<th>Interested in Being Contacted</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organization</td>
<td>Orthopedic Quality Initiative</td>
</tr>
</tbody>
</table>
Conclusions

Coming Back to the Bold Assertions

• If it’s not already, the word “interoperability” will soon become part of every clinical operations manager’s vocabulary
  > Potential time & cost savings of tapping into EMRs for research purposes are too great to go unrealized
  > Many stakeholders—CROs, EMR providers, life sciences companies, government agencies—have skin in this game so the interoperability issue will be forced

• People think it’s easy to link EMRs & registries, but people are often wrong
  > Just because medical records data & registry data are both captured electronically doesn’t mean they are automatically compatible
  > Fortunately, people are often industrious too and the health information technology challenges of interoperability will be met
Conclusions

Coming Back to the Bold Assertions

• EMRs are poised to become to registries & clinical trials what GPS has become to navigation
  > Access to aggregated EMR data permits preliminary searches of eligible patients & creation of ‘heat maps’ showing high-yield geographic clusters
  > Availability of national provider identifiers permits zeroing in on specific providers & their eligible patients—all while maintaining patient privacy

• In the era of health care reform, EMRs will become indispensable to post-approval research—and post-approval research will become indispensable to EMRs
  > Key trends in health care reform—provider incentives, patient-centered research—all serve to elevate the importance of EMRs to post-approval research
  > Other trends in health care reform—meaningful use criteria, accountable care organizations, need to demonstrate return on stakeholder investment—elevate importance of post-approval research to EMRs
In the end, what we’re after is …

this!

not this!
Thank You!

david.thompson@quintiles.com
daniel.levy@quintiles.com
Upcoming Events

Post-Approval Summit
May 7-8, 2013
Conference Center at Harvard Medical School, Boston, MA
www.postapproval.org

Key Topics:
- Comprehensive Approaches to Evidence Development for Safety and Effectiveness
- Evolving Roles of the RCT and Observational Research
- Big Data: Leveraging EHR and Health System Data for Safety and Effectiveness
- Updates on Changing Safety and Risk Management Requirements
- Comparative Effectiveness, Market Access and HTA
- Approaches and Models for Addressing Multi-Stakeholder Demands

April GRP Webinar
Evolving Initiatives and Approaches to Meeting Rare Disease Research Needs through Effective Registries
April 24, 2013 10:00 AM - 11:00 AM EDT
Register: https://www1.gotomeeting.com/register/448651784