Leveraging Real-World Data and Analytics in the Device Industry

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Agenda

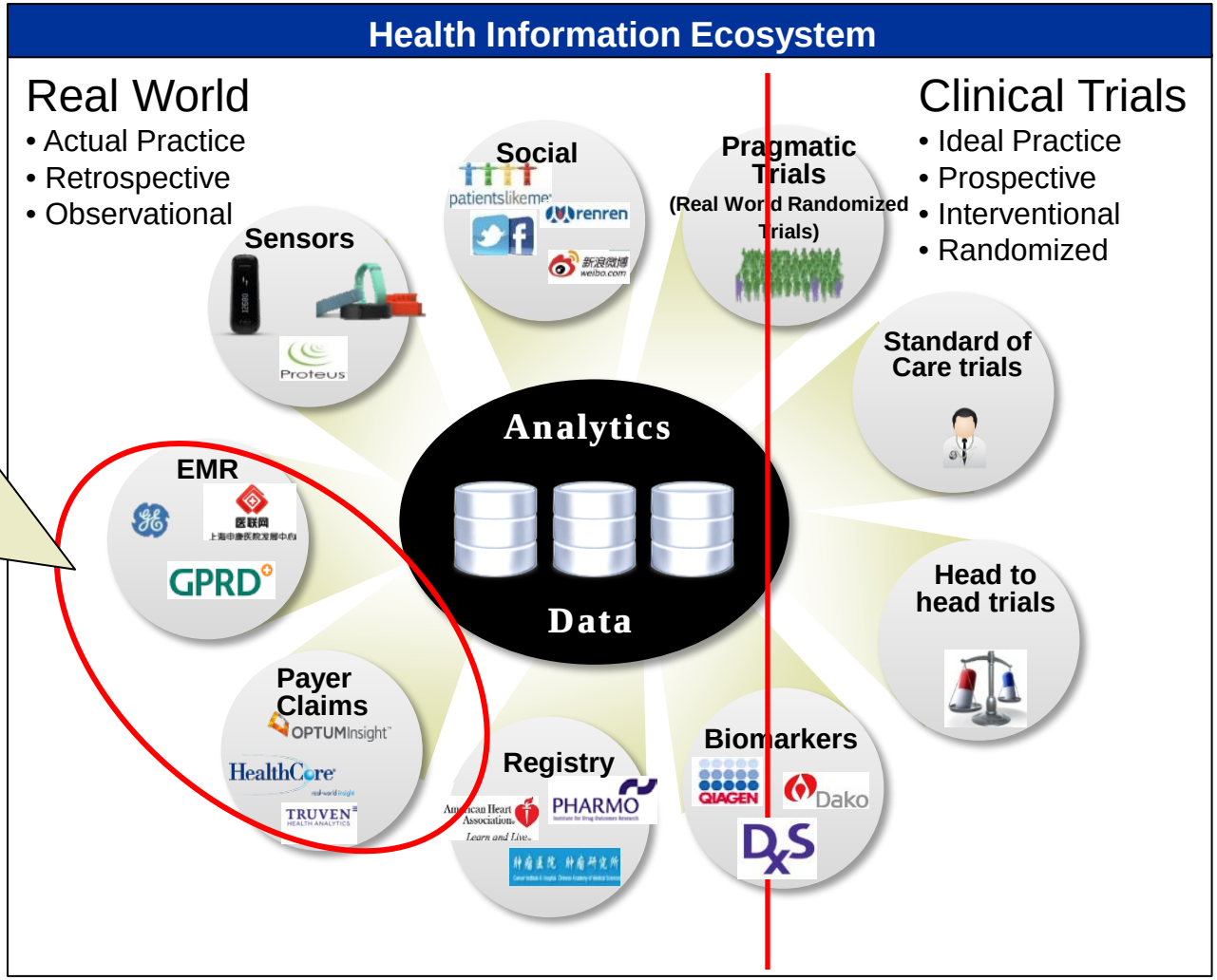
1. Overview
2. What is Real World Data (RWD)?
3. How is RWD Currently Used?
4. What are Medical Devices & Why are they Different?
5. What are some of the challenges in using RWD for Medical Devices?
6. What does the future hold?

There is an explosion in use of Real World Data (RWD) to support decisions by all healthcare stakeholders

Providers' and Physicians' financial incentives are starting to align, and they, as well as Payers, are increasingly looking for evidence of better outcomes and value, often using their own RWD.

The pressure is on device manufacturers to better understand how their products actually deliver value in the real world, and to whom.

Real World Data: an essential part of our Ecosystem



Although most of the focus has been on EMR and Payer Claims Data, increasingly other sources of RWD are being integrated into health systems

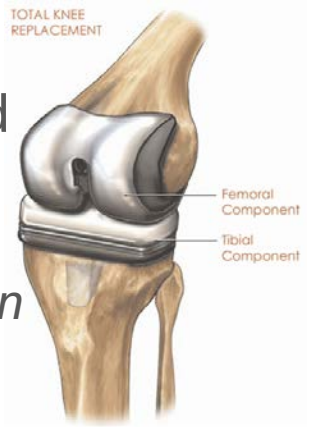
EMR = Electronic Medical Records
Payer Claims = the administrative records of health insurance companies and employers (billing records)

How RWD is currently used?

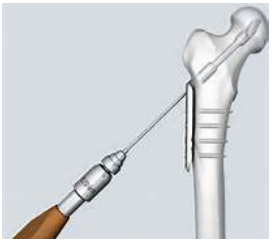
Value Source	Capabilities
Demonstrate Value	• Comparative Effectiveness • Cost Effectiveness • Device Reimbursement & Profitability Analysis
Drive Innovation	• Identify unmet clinical need • Input for product design specifications • Enhance clinical trial design & execution • Simulate clinical trial findings / reduce the need for clinical trials
Gain Customer Insights	• Understand customer business model, procedure base and pain points • Benchmark customer performance • Identify opportunities for improvement
Ensure Patient Safety	Track product safety outcomes through • Registries • Administrative claims databases • Electronic Medical Records • Social Media Sources

What are Medical Devices?

A device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: …



- *intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or*
- *intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.*



http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051512.htm

What makes Medical Devices different?

- Hospitals are often the primary customer for a medical device.
- The skill, experience and technique of the physician can have a major impact patient outcomes.
- There is often rapid, incremental improvements in many medical devices: 510(k) approval.
- Identification of specific medical devices is often difficult in administrative data.

Challenges in the Hospital Market

- Overall excess capacity
- Have very high fixed costs (buildings & equipment)
- Often have some degree of local market power
- Often are “Non-Profit” with conflicting goals
  - Community Service Mission
  - Reputation
  - Attract patients & physicians
- Reimbursement models vary by payer
  - Medicare under prospective payment system
  - Commercial typically under negotiated contract

Identifying Medical Devices in administrative data

Current State

- Unique CPT / HCPCS codes may be available

- String Searches using the hospital detailed charge descriptions

- Building a library of devices using NLP / Fuzzy matching of string characters between FDA registrations and hospital charge descriptions

Future State

- Unique Device Identifier regulations implemented

- A UDI includes:
  - Device identifier, to a device model, and
  - Production identifier, includes current production information, eg. lot or batch number, serial number and/or expiration date

- UDI anticipated to make its way into electronic data over the next 2 years

6 Major Trends ACCELERATE the shift in Healthcare

Features and benefits replaced by the quantification of safety and value.

Major Trend	Impact
1. The expansion of ACOs, bundled payments & pay-for-performance*	• Align the incentives of payers and providers for cost containment and improved outcomes
2. The proliferation of EMRs and 'Meaningful Use' (of EMR) requirements+	• Digitizes information that has been locked in medical records and not available for analysis
3. The integration of EMR and Payer Claims data	• Provides an environment which enables deeper analysis of the comparative effectiveness of alternative treatments
4. The implementation of Universal Device Identification over the next 3 years	• Will allow the easy identification of specific medical devices for analysis without text mining.
5. The rapid adoption of 'Quantify Me' devices by patients	• Further enriches the data environment with patient behavioral and outcome information
6. The implementation of point-of-care clinical decision support tools	• Enables ACOs to more directly influence physician treatment choices

Customers will make Value Based Decisions **<u>using their own data</u>**

* ACOs = Accountable Care Organization

\+ Meaningful Use = as part of HITECH, physicians and hospitals not only have to have EMRs but must demonstrate that they are making meaningful use of them in order to qualify for additional payments and avoid penalties.

What will the future hold?