Harnessing the Value of Anonymous Patient Level & Emerging EMR Data Sources

Real World Data & Evidence

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Real-world data (RWD) is transforming healthcare

RWD is patient level data collected outside a randomized clinical trial (RCT)

ONLY WAY TO ANSWER KEY QUESTIONS to create a common understanding about real-world situations and outcomes

INCREASED ROBUSTNESS AND TIMELINESS with larger datasets and advanced technologies

DIRECT-FROM-PATIENT INSIGHTS through direct interactions and social media data

IMPROVED HEALTHCARE PERFORMANCE in terms of science, outcomes, and business results
Reflecting a seismic shift in evidence evaluation

**THE PAST**

**RCT**
Controlled trials, manufacturer led

**Few**
Few evaluators at launch, mostly regulators and large payers

*Efficacy and Safety*
Initial view of benefit-risk

**THE PRESENT**

**RCT and RWE**
Shift to secondary patient-level data across sources

**Many**
Many groups over time including clinical and small payers

*Almost everything*
Insights on environment, outcomes, costs, comparative effectiveness
An “RWE System” is required to leverage & optimize the information

- A foundation of real-word data (RWD) from ever expanding sources
- Data that can be used for multiple purposes, consistently across the globe
- Innovative technology and analytic advances that quickly generate new insights
- Optimal organizational performance by tapping into uniquely rich insights
Future Vision: Real-world Evidence (RWE) ecosystem
An environment for building deeper insights to benefit the entire enterprise
RWE Ecosystem will be fueled by supply and demand

**Supply**

- Increasing cost pressures
- New treatments to fund
- Providers at risk for quality, costs
- More informed patients
- Search for differential value
- Need for R&D, clinical trial efficiency
- Explosion in volume of electronic patient data
- Ability to bring data across silos
- New technologies and methodologies
- New stakeholders conducting analysis

**Demand**

- High stakeholder scrutiny
  - Increasing cost pressures
  - New treatments to fund
  - Providers at risk for quality, costs
  - More informed patients
  - Search for differential value
  - Need for R&D, clinical trial efficiency
Supply: Growth in RWD & increased value in linking data

- Supply: Growth in RWD & increased value in linking data
- Pharma data (observational)
- Consumer data
- Disease registries
- Electronic medical records
- Lab/Biomarkers data
- Mortality data
- Social media data
- Pharmacy data
- Hospital data
- Claims databases
Demand: Capture a piece of the $1B opportunity

**DEVELOPMENT**

- $100m-$200m
- CLINICAL DEVELOPMENT*

**LAUNCH**

- $100m
  - INITIAL PRICING & MARKET ACCESS*
- $150m
  - PLANNING & TRACKING

**IN-MARKET**

- $200-$600m
  - SAFETY & VALUE DEMONSTRATION
- $200-$300m
  - COMMERCIAL EFFECTIVENESS

**PRODUCTIVITY & COST SAVINGS**

- $100m

*Selected operational opportunities only; excludes increased R&D pipeline throughput and better pricing
Crafting patient journeys to establish current value, safety

**Diagnosis**
- Patient presents
  - What? was their health and care like before diagnosis
  - Who? is being treated
- Diagnostic Process
  - How? Were they diagnosed
  - For What? condition or situation
- Referral if mandated by system
  - Who? did they see

**Treatment**
- Treatment Choice
  - What? treatment did they receive?
- First Dose
  - When? Did they receive treatment?
- Treatment monitoring
  - How many? are stabilized

**Follow-Up**
- Monitoring
  - What Outcomes? and costs result
- Maintenance
  - How long? do they maintain benefit?
- Treatment Switching/ Modification
  - What? happened
- Patient Outcomes
  - What are they saying about it
Increasing product performance throughout lifecycle

**DEVELOPMENT**
- Improved internal operations
- Risk planning and label negotiation
- Evidence for launch

**GROWTH PHASE**
- Follow up safety and effectiveness in real life
- Evidence to support value dossier during payer negotiations
- Reinforce positioning, broaden use

**MATURE PHASE**
- Improved engagement with external stakeholders
- Follow-up real life outcomes, value of drug

**TIME**
- Launch
- Conditional pricing review
- New competition
- New formulation/indication
- Competitor goes generic
EMR is an emerging source of clinical insights

- Dictation (e.g., MP3, WAV)
- Progress notes, SOAP (often custom templates)
- Scanned images (e.g., JPEG, GIF, TIF, BMP)
- Digital templates (e.g., forms, EPSDT, growth charts, custom templates)
- Free form handwriting (e.g. notes written on a tablet)
- External sources (e.g., hospitals, lab-x, fax, emails, letters)
- Network (e.g., Windows, Novell)
- Microsoft documents
RWE requires a shift in Analytics

**The goal:** getting from unstructured real-world data to *finding the patterns and structure that lead to insights*

**Traditional analytics** provide a foundational understanding of the current world

- **Descriptive analytics** to explain what is happening today
- **Diagnostic analytics** to explain why it is happening

**Advanced analytics** are key to driving real breakthroughs and better outcomes

- **Predictive analytics** to model, forecast and simulate future outcomes
- **Prescriptive analytics** to show how to achieve the best outcomes and address variability/risk
Generate Real World Evidence with an eye for applying it

**Understand and prioritize questions and business needs**
- Develop all RWE solutions for a purpose
- Align scientific and business needs

**Create information platform with the right RWD**
- Protect patient privacy
- Source and structure big data at the appropriate breadth and depth

**Analyze information to deliver rigorous insights**
- Leverage and pioneer new methodologies, technologies to ensure meaningful insights

**Apply insights to deliver results**
- Create new applications and services to help use RWE insights to improve outcomes and performance
- Increase the awareness and credibility of RWE to further its use
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Case study: Enhancing RCT results with RWE

Is the rate and timing of hemoglobin (Hb) decline in cancer patients receiving chemotherapy in pooled RCT representative of the real world?

Pooled data from six RCTs of darbepoetin alfa analyzed

Replicated analysis using US community oncology clinic EMR database

Analysis verified RCTs, increasing confidence in results

CONFIRMED

RWE unlocks the potential of all life science functions

- Translational research
- Drug pathways
- Target population/product profile
- Trial simulation, recruitment
- Pragmatic clinical trials (pRCTs)

- Support launch pricing (dossier, CED)
- New pricing mechanisms
- Ongoing value differentiation
- Launch/promotion planning
- RWE-enabled marketing (e.g. Undertreated)
- Segmentation

- Drug utilization/monitoring
- HE modelling
- EMR enabled outcomes research

- Local burden of illness/disease/costs
- AE/signal detection
- FDA/EMA responses

- Custom data sourcing
- Evidence platforms
- T-shaped data network strategies

R&D

HEOR and Safety

Commercial & Market Access

RWE platform developers