Innovation at the Intersection of Clinical Trials and Real-World Data to Advance Patient Care

ASCPT 2017

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Use of RWD to Support Pre-approval Decisions or Vice-Versa Has Been Limited

Drug-Development Cycle

Real-World

Drug Discovery → Basic Research → Pre-Clinical → Clinical → Drug Discovery

Pharmacy → Payers

Hospital

Personal Health Tracking Devices

Economic & Social indicators

Patient-Centric Data
Digital Technology & Advanced Analytics Are Enabling Greater Access and Utilization of RWD

**Drug-Development Cycle**

- Drug Discovery
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- Pre-Clinical
- Clinical

**Real-World**

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- Payers
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**Digital Technology & Advanced Analytics**

- Hospital
- Economic & Social indicators

**Innovation**
Far better chance of breaking new ground when different perspectives come together

- Frans Johansson
Inclusion of RWD in Healthcare Decisions Will Improve Utilization of Healthcare Resources and Patient Outcome

Impact on Healthcare

- Personalized Medicine
- Patient-Centered Care
- Healthcare Delivery Redesign
- Healthcare Quality
- Comparative Effectiveness Research
Integration of RWD in R&D Will Improve Development and Commercialization of New Medicines

- Unmet Need/Disease burden
- Early Prediction of RWD Effectiveness vs. SoC
- More Patient (Value) - Centric Pipeline
- Reduce DD time and improve attrition

Clinical Trial Design
- Trial population
- Endpoints
- Conduct

Impact on R & D
Drug Companies Are Using M&A and Joint Ventures to Acquire Beyond-the-Pill Products and Services

- IMS Health
- QuintilesIMS
- SANOFI
- onduo
- verily
- IBM Watson Health
- Panasonic
- Bayer HealthCare
- Truven Health Analytics
- LabCorp
- Galvani Bioelectronic
- GSK
- GlaxoSmithKline
- Otsuka
- IBM
- Sanara Ventures
- Philips
- TEVA
PDUFA VI

6. Enhancing Use of Real World Evidence for Use in Regulatory Decision-Making

As we participate in the current data revolution, it is important that FDA consider the possibilities of using so-called “real world” data as an important tool in evaluating not only the safety of medications but also their effectiveness. To accomplish this will require an understanding of what questions to ask, including how such data can be generated and used appropriately in product evaluation, what the challenges are to appropriate generation and use of these data, and how to address such challenges.

The New England Journal of Medicine

Sounding Board

Real-World Evidence — What Is It and What Can It Tell Us?

Rachel E. Sherman, M.D., M.P.H., Steven A. Anderson, Ph.D., M.P.P., Gerald J. Dal Pan, M.D., M.H.S., Gerry W. Gray, Ph.D., Thomas Gross, M.D., M.P.H., Nina L. Hunter, Ph.D., Lisa LaVange, Ph.D., Danica Marinac-Dabic, M.D., Ph.D., Peter W. Marks, M.D., Ph.D., Melissa A. Robb, B.S.N., M.S., Jeffrey Shuren, M.D., J.D., Robert Temple, M.D., Janet Woodcock, M.D., Lilly Q. Yue, Ph.D., and Robert M. Califf, M.D.
Symposium Speakers

**Drug-Development Cycle**

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- Pharmacy
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- Economic & Social indicators
- Patient-Centric Data

**Craig White, Quintiles IMS**
RWD and Applications in Healthcare and R&D

**Vasu Chandrasekaran, Merck**
Overview of RWD and Analytics
Symposium Speakers

**Dyfrig Hughes, Bangor University UK**  
Clinical Trials to RWE

**Pravin Jadhav, Otsuka**  
Impacting Clinical Development using RWD

Drug-Development Cycle

- Pre-Clinical
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Real-World

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- Payers
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Patient-Centric Data