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

ASCPT 2017

Lokesh Jain
Director, Quantitative Pharmacology and Pharmacometrics
Merck

Brandon Swift
Scientific Advisor, Clinical Pharmacology Modeling and Simulation
Quintiles IMS

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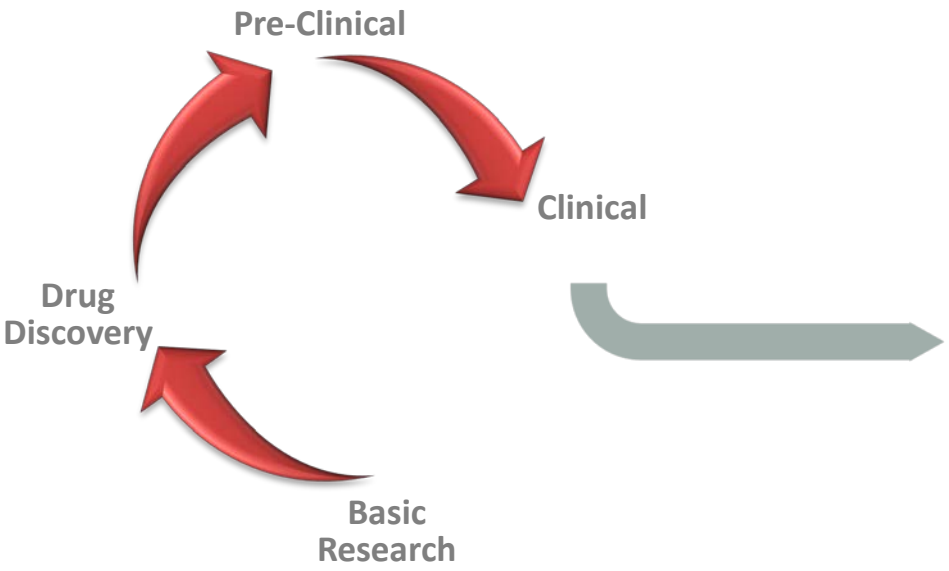
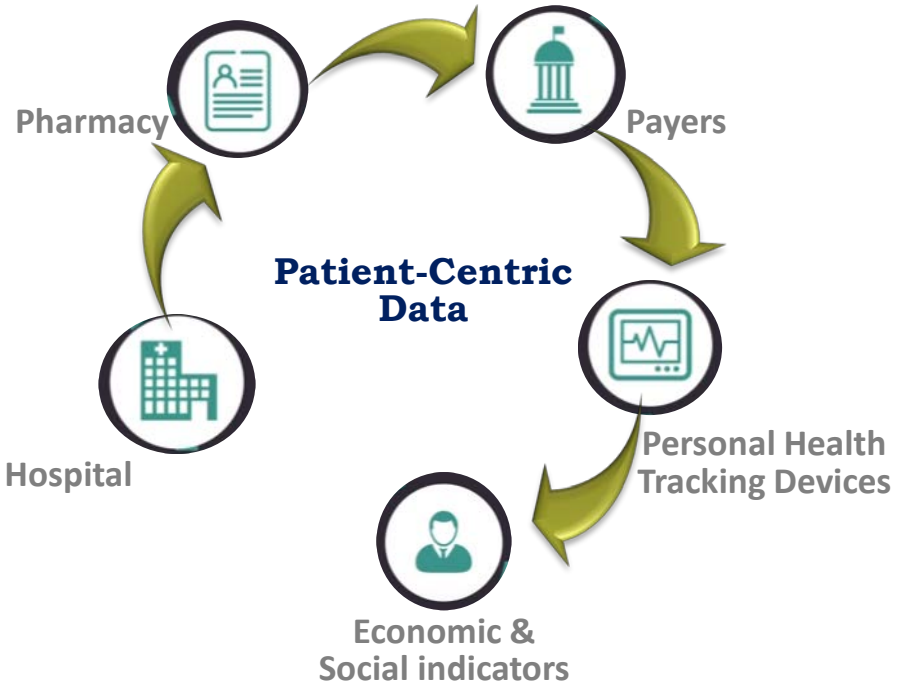
Use of RWD to Support Pre-approval Decisions or Vice-Versa Has Been Limited

Drug-Development Cycle



Real-World



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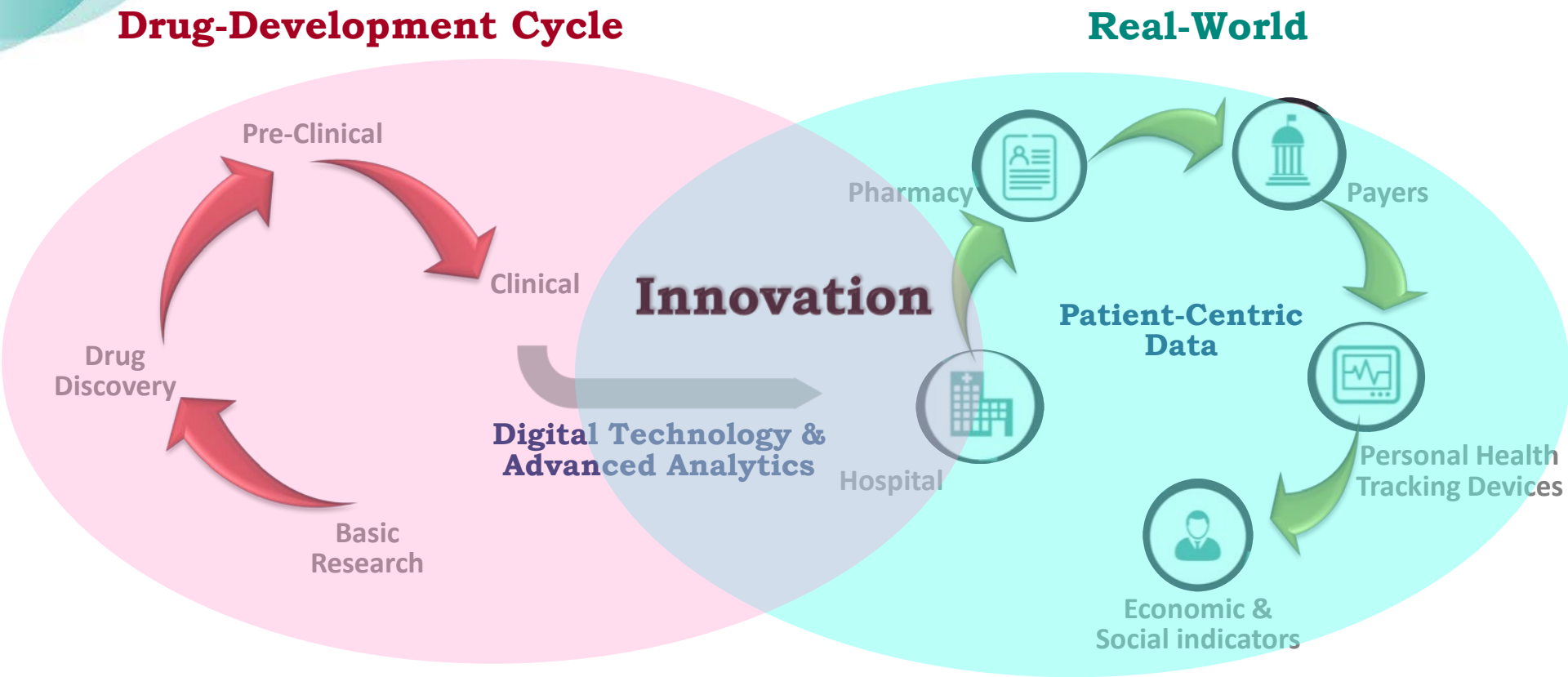
Digital Technology & Advanced Analytics Are Enabling Greater Access and Utilization of RWD



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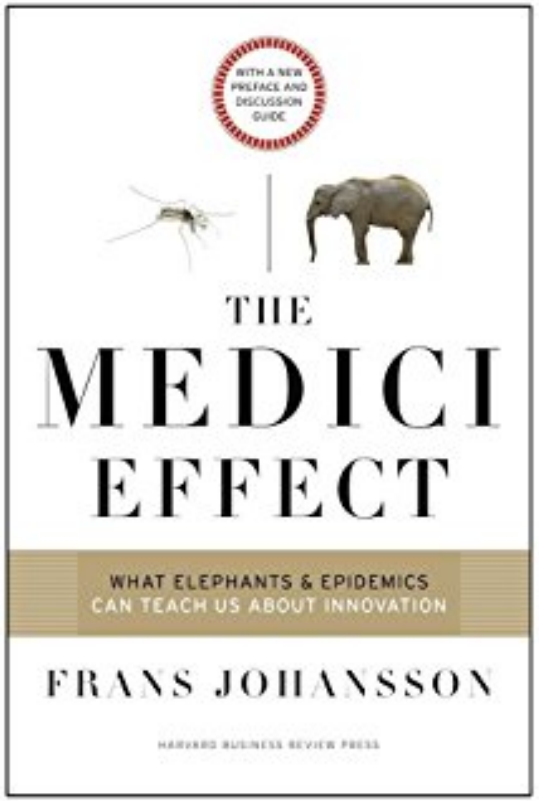
A Remarkable Opportunity for Innovation at the Intersection of Two Fields

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

- Frans Johansson



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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

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Integration of RWD in R&D Will Improve Development and Commercialization of New Medicines

Impact on R & D

Unmet Need/ Disease burden

Early Prediction of RW Effectiveness *vs.* SoC

More Patient (Value) - Centric Pipeline

Reduce DD time and improve attrition

Clinical Trial Design

- Trial population
- Endpoints
- Conduct

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

imshealth™ + QUINTILES® → QuintilesIMS™

IBM Watson Health

SANOFI + verily → onduo

IBM + TRUVEN HEALTH ANALYTICS™

Panasonic

BAYER Bayer HealthCare Diabetes Care

Alphabet (Google, Google ventures, Google fiber, Google capital, Google CALICO, YouTube, Google AdWords) 45%

Galvani Bioelectronics

gsk GlaxoSmithKline 55%

LabCorp Laboratory Corporation of America

COVANCE SOLUTIONS MADE REAL™

SANARA VENTURES

PHILIPS

TEVA

Otsuka + IBM

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21st Century Cures Act Requires FDA to Expand the Role of Real World Evidence

By **Bethany Hills** & **Benjamin Zegarelli** on December 19, 2016

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.

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

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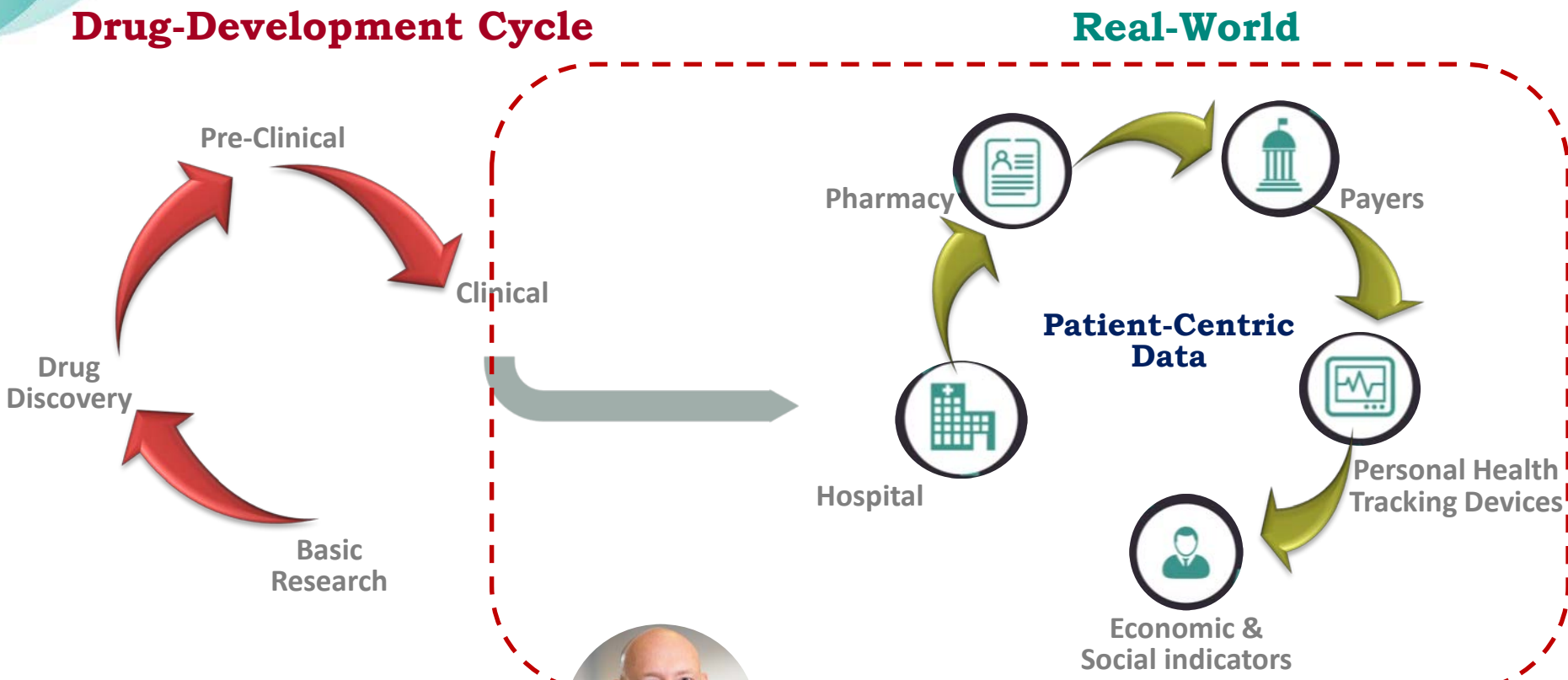
Symposium Speakers



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

Vasu Chandrasekaran, Merck
Overview of RWD and Analytics

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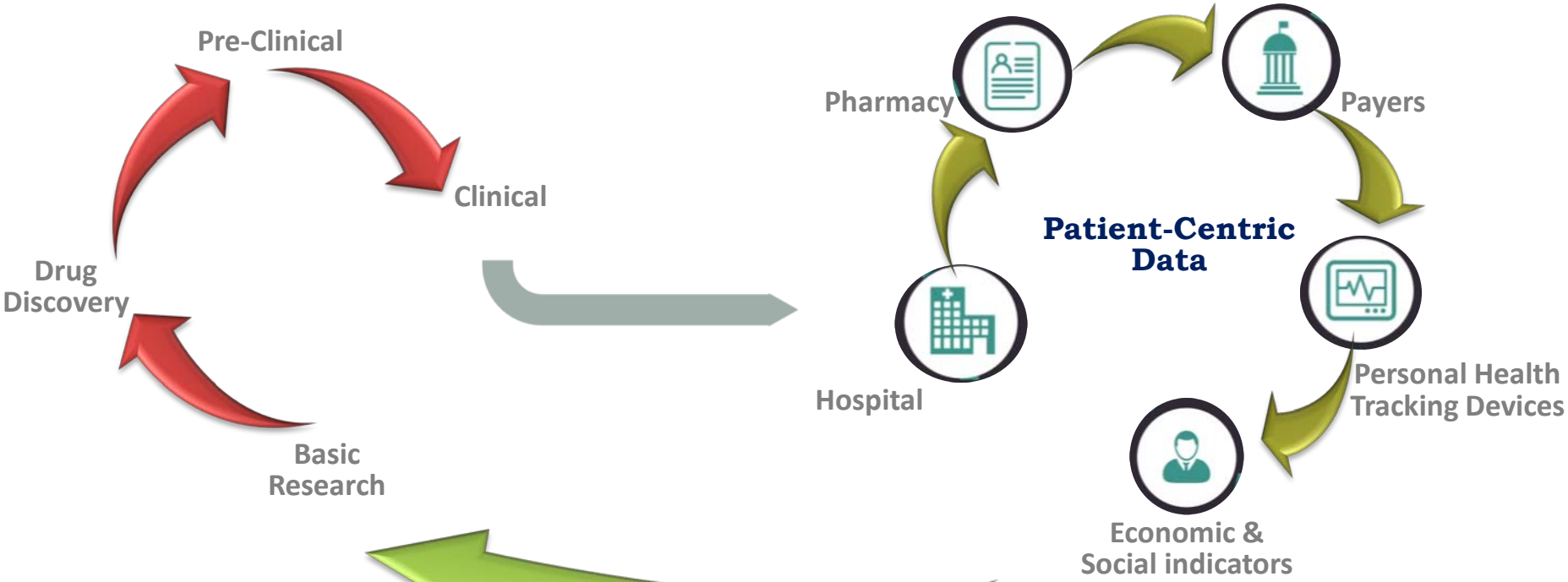
Symposium Speakers

Dyfrig Hughes, Bangor University UK
Clinical Trials to RWE

Drug-Develop… …ycle

Real-World



Pravin Jadhav, Otsuka
Impacting Clinical Development using RWD

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