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INNOVATION IN EVIDENCE GENERATION

SUPPORTING EXPEDITED ACCESS TO MEDICAL DEVICE TECHNOLOGIES

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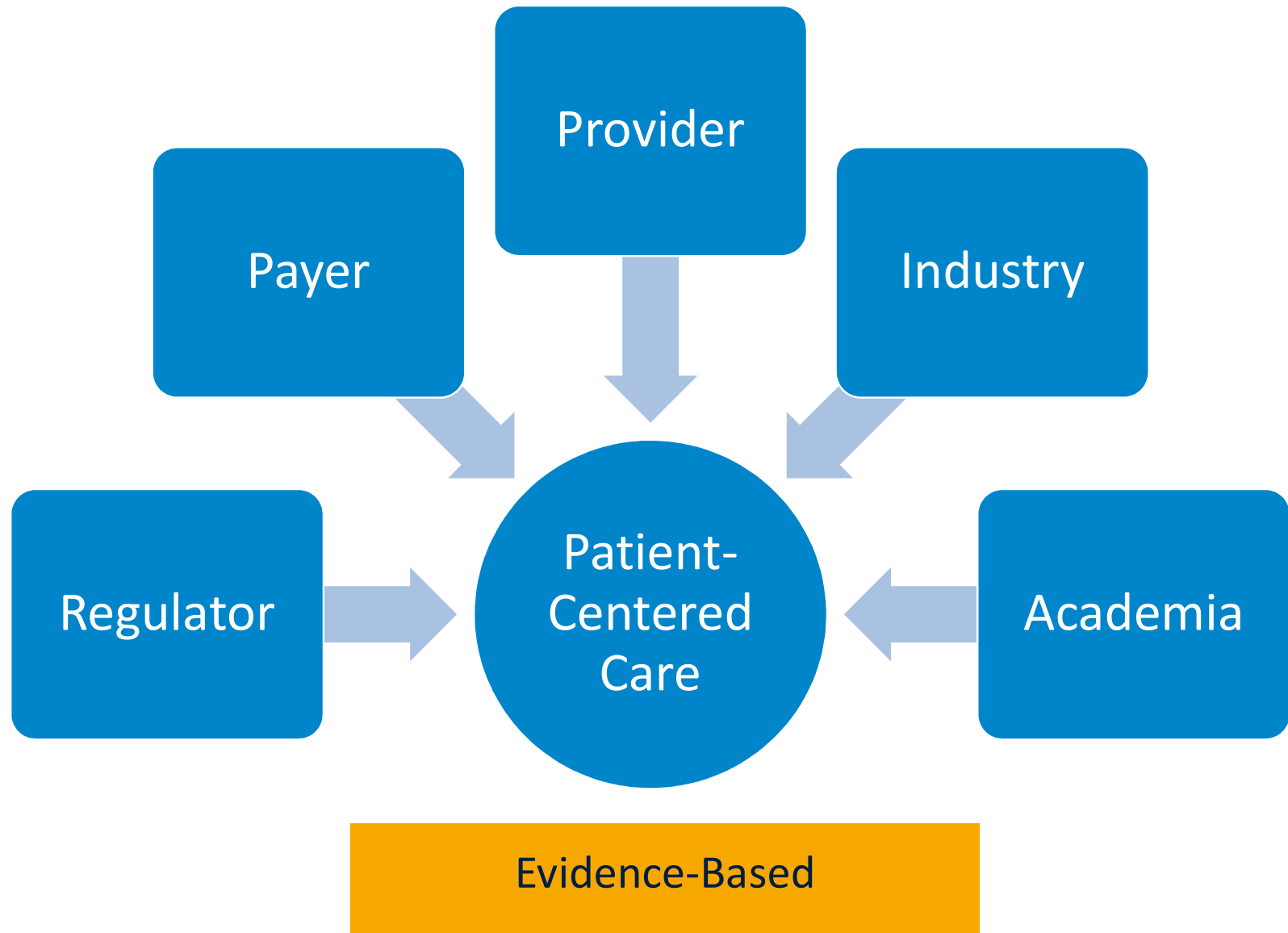
VP, Clinical and OMA - Medtronic Spine & Biologics

Medtronic
Further, Together

TOPICS

- Driver for Innovation in Evidence Generation
- Transforming Evidence Generation
- Critical Roles of Real-World Data (RWD) and Real-World Evidence (RWE)
- Applications of RWD and RWE
- Optimizing Evidence Generation
- Factors to Successful Adoption of RWD and RWE

HEALTHCARE ECOSYSTEM



DRIVER FOR INNOVATION IN EVIDENCE GENERATION

NEEDS

- Early Access to New Technologies of Public Health Importance
- Evidence-based VBHC
- Evidence to Inform Care Pathway Decision (Multifactorial)
- Patient-centered Care (e.g. which population benefits most?)
- Increased Requirements on Safety Surveillance

OPPORTUNITIES

- Growing Availability of RWD
- New Data Analytic Methodologies
- IT Infrastructure
- Willingness of Multi-stakeholder Engagement



**FAST ACCUMULATION OF DATA
REFLECTING REAL-WORLD PRACTICE**

TRANSFORMING EVIDENCE GENERATION

Well Controlled Clinical
Trials/Studies



RWD/RWE from Routine
Clinical Practice

Efficacy

Can It Work?

- Selected populations
- Highly controlled setting
- Optimized to show Efficacy

Effectiveness

Does It Work?

- Diverse patient population
- Diverse surgeon skills
- Diverse hospital settings

TRANSFORMING EVIDENCE GENERATION



Clinical Trials/Studies

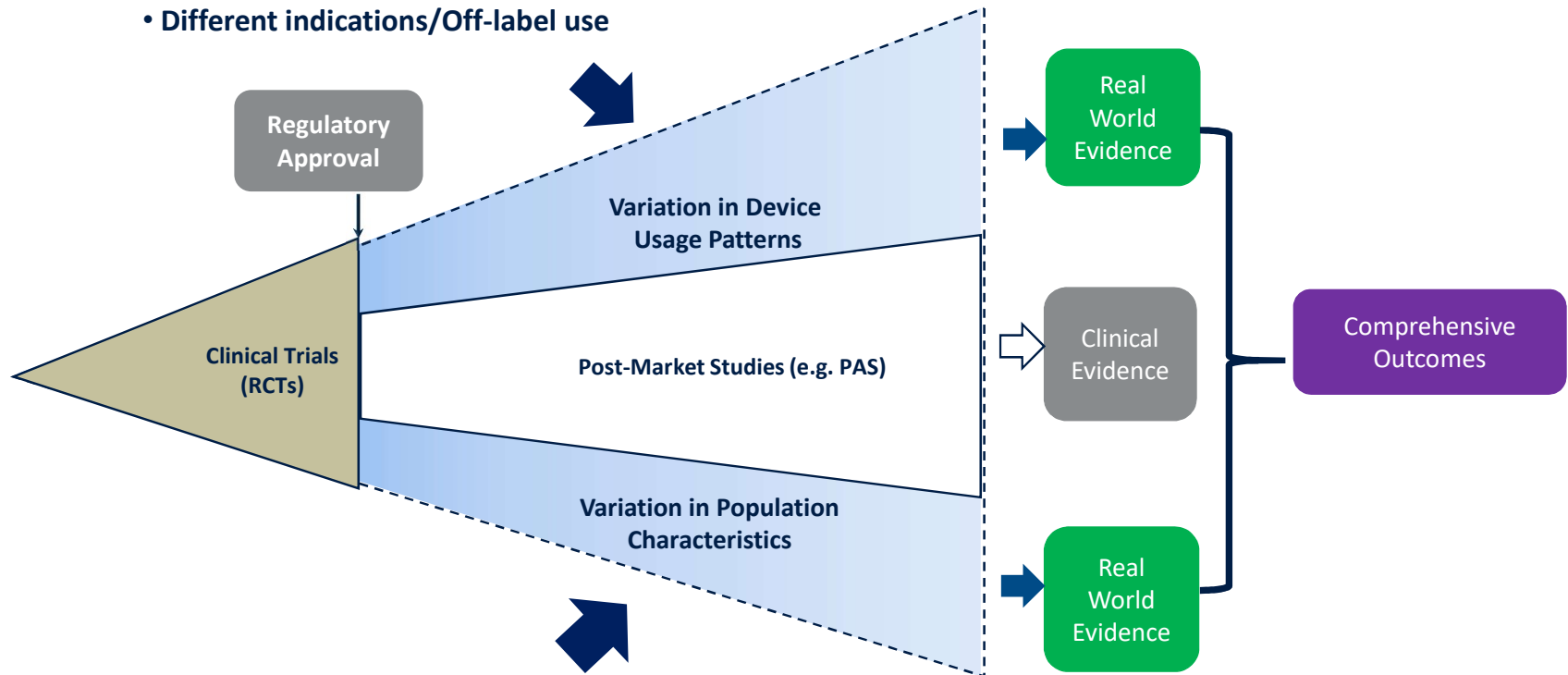


Real World Evidence

*http://medcommsnetworking.com/presentations/shaw_070716.pdf

CRITICAL ROLES OF RWD AND RWE

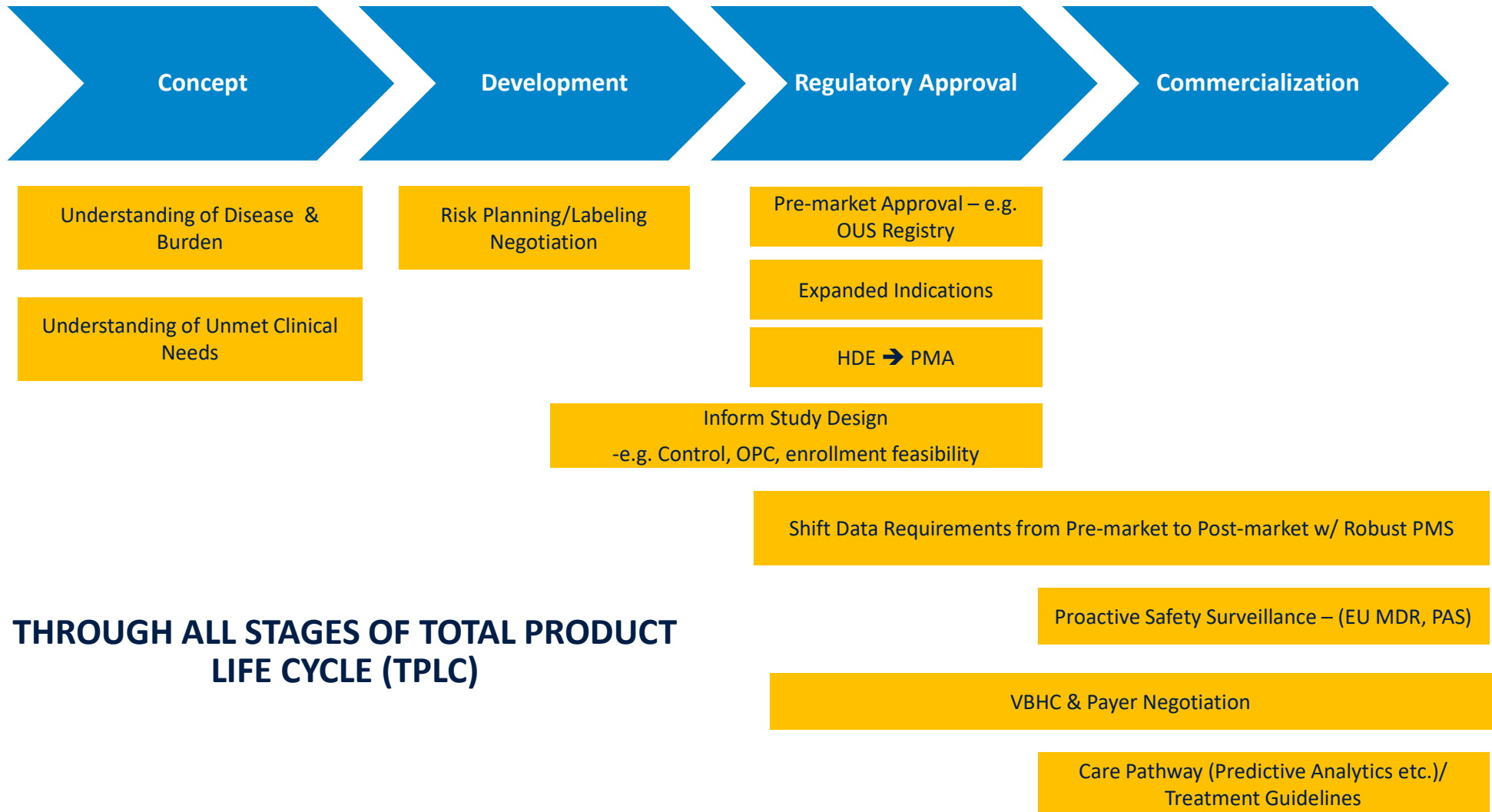
- Different patient populations –age, race, ethnicity and gender distribution
- Variation in severity level of concomitant diseases
- Different (Unstudied) concomitant therapies
- Variation in care pathways
- Different indications/Off-label use



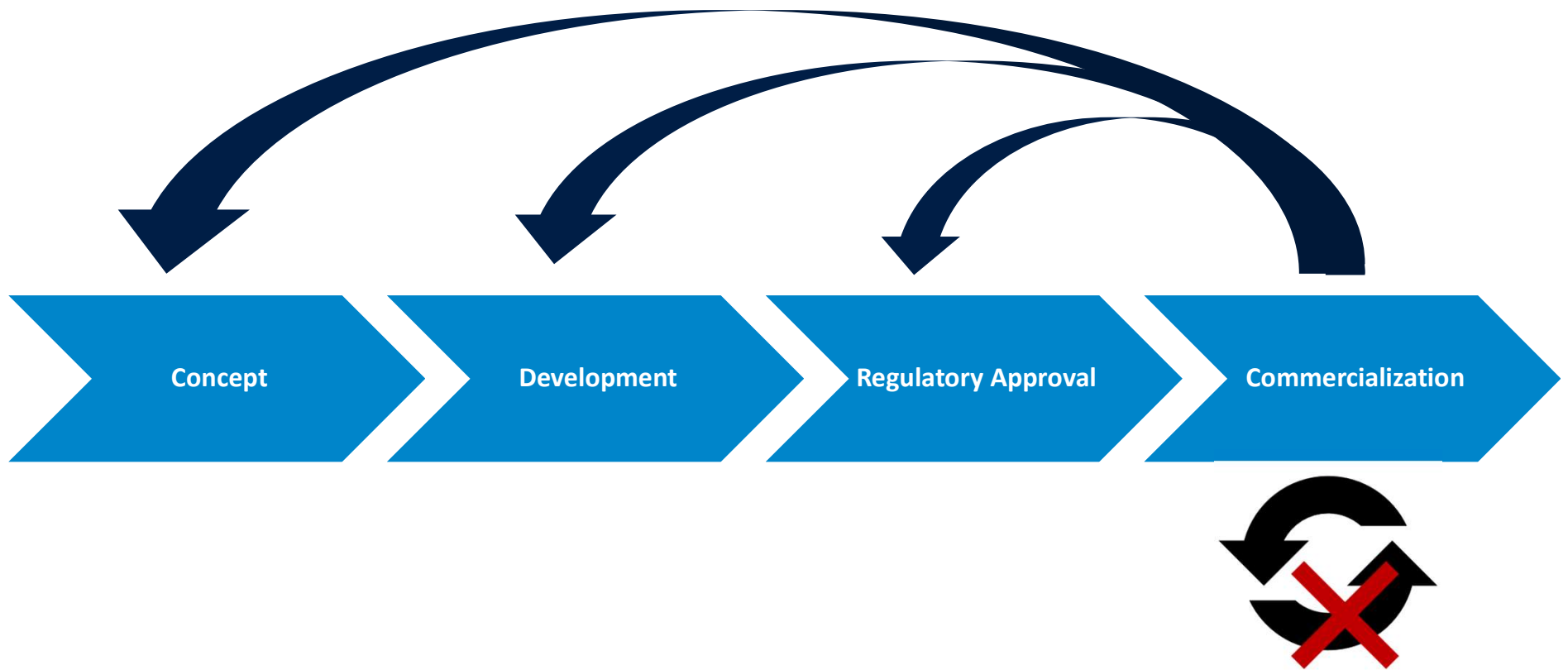
RWD/RWE PROVIDES INSIGHTS NOT POSSIBLE SOLELY FROM CLINICAL STUDIES

*https://sites.duke.edu/diss2017/files/2017/09/S2B_MitchDeKoven_DISS2017.pptx

APPLICATIONS OF RWD AND RWE



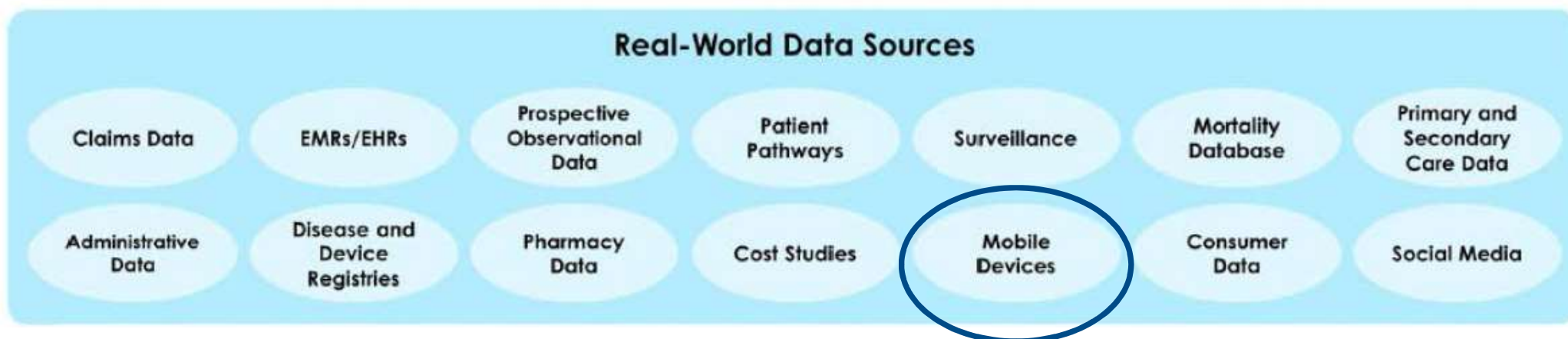
APPLICATIONS OF RWD AND RWE



FACILITATE CONTINUUM OF EVIDENCE GENERATION AND LEARNING

IMPROVE DECISION MAKING AND OUTCOMES THROUGH ALL STAGES OF TPLC

MOBILIZING RWD/RWE GENERATION



Patient-Driven/Facing

- Mobile Apps
- Wearables/Sensors



- High frequency patient data collection
- Cost effective longitudinal follow-ups
- Reduce lost-to-Follow-up
- Objective patient outcomes (Orthopaedics) in a real-world setting

OPTIMIZING EVIDENCE GENERATION

- Clinical Studies and RWD/RWE provides different aspects of evidence to support device performance and safety
- They complement each other
 - Opportunities to shift data from pre-market to post-market
 - RWD/RWE in lieu of PAS
- They do not necessarily have to be sequential
 - Our goal is to timely fill knowledge GAP (can it work → does it work?)
 - Hybrid of clinical study and RWD/RWE to support regulatory decision
 - Embedded clinical studies in routine clinical practices - mimicking real-world setting
- Fit-for-Purpose approach → Focus on ability to address regulatory/scientific questions based on strengths and limitations of Clinical Study and RWD/RWE

FACTORS TO SUCCESSFUL ADOPTION OF RWD/RWE

Engagement & Sustainability

- Full engagement of all stakeholders
- Value Proposition that resonates with each stakeholder
- Robust business models for all the required stakeholders to make this work

Data Quality & Robustness

- Don't underestimate the challenges of getting reliable / clean data for the required data models
- Establish Quality criteria and understand the limitation of each type of RWD
- Still requires robust Data Mining & Sampling Plan

Governance, Privacy and Legal

- Data ownership, access, usage and interpretation
- Leveraging technologies in order to minimize data transfers
- Fit-for-Purpose: procedural level vs aggregated

Learn by Doing

- Get Started
- Multi-stakeholder engagement
- Where/how to apply – Guidance and Training are critical

THANK YOU