Johnson Johnson MEDICAL DEVICES COMPANIES

The Future of Global Evidence Generation: Advancing the role of innovative data and methods

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Diversity of Real-World Data (RWD) Types

Large Retrospective Real World Databases (e.g., insurance claims, EHR, billing records, labs, national data sources (e.g. NHANES, HCUP), other Big Data platforms) Data from Registries, Postmarketing surveillance studies

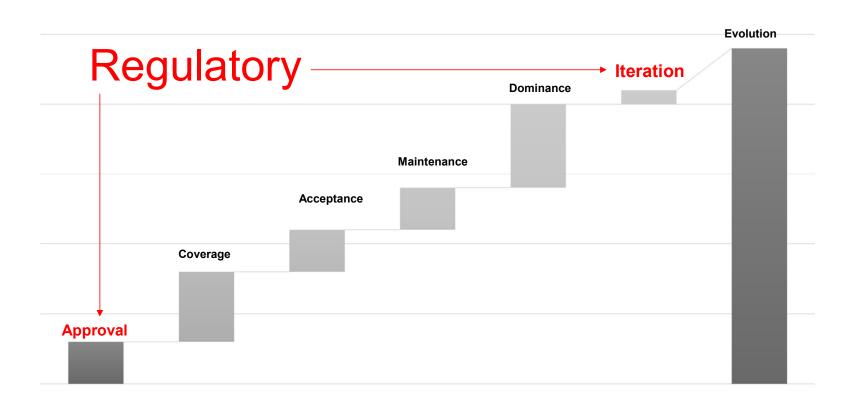
Complaints data and Adverse Events

Health System and Customer Data (e.g., IDNs, hospitals, clinics)

Procedure generated data

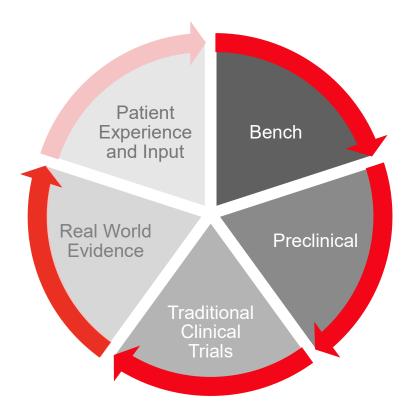
Other Data Sources (e.g. genetics, sensors, mobile health, device generated data, social media)

Total Product Life Cycle Evidence Generation Needs

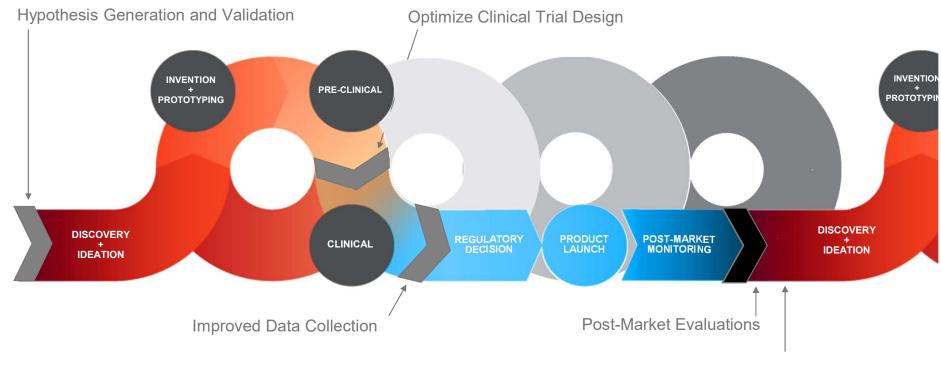


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Integrated New Types of Clinically-Relevant Data into an Evolving Evidence Portfolio



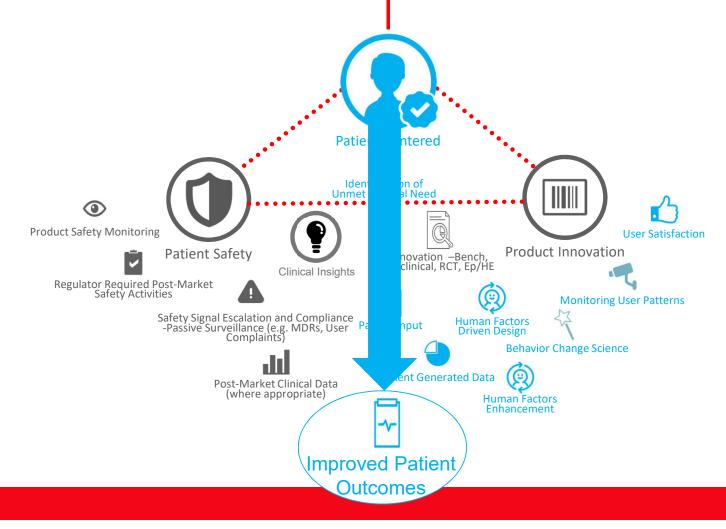
Opportunities to Integrate RWD into the Total Product Life Cycle



Hypothesis Generation and Validation

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Advancing the Role of Novel Data in Innovation



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Addressing key technical challenges

- Promote mechanisms to access RWD
 - Leverage existing sources of RWD (e.g., registries)
 - Linking data sources to enable long-term follow-up
 - Create mechanisms to support and collect better data on patient care and recovery (e.g., digital tools)
- Collaborate to create shared resources and tools
 - Establish criteria to assess the fit-for-purpose for RWD
 - Develop appropriate analytic methods
 - Advance the science of patient input
 - Identify opportunities to gather data on hard to capture products (e.g., plates, screws, surgical tools)
- Support globally harmonized practices and policies
 - Addressing the evidentiary needs of various regulatory bodies (e.g., EUMDR)