Using Real-World Clinical Evidence

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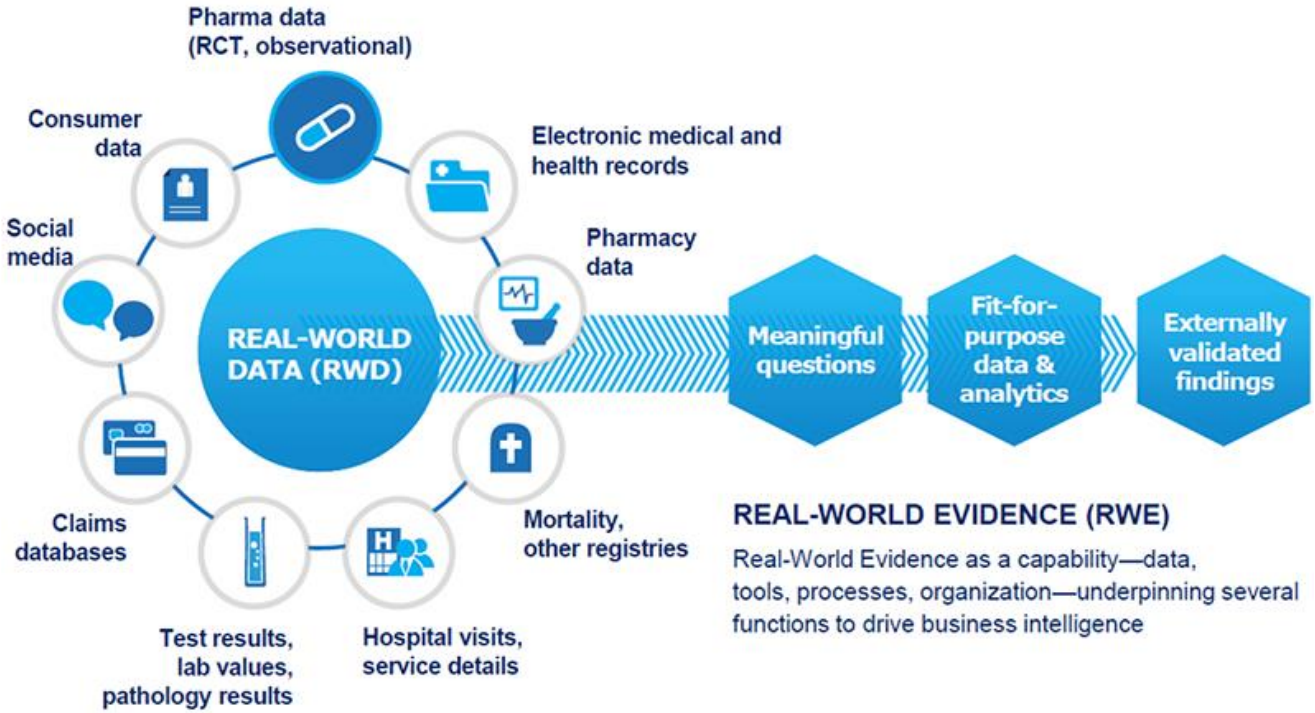
What is RWE?

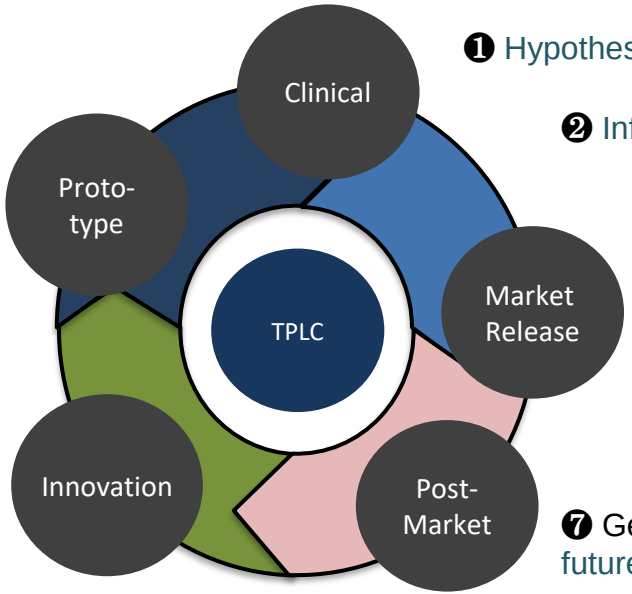

Pharma data
(RCT, observational)
Consumer data
Electronic medical and health records
Social media
Pharmacy data
REAL-WORLD DATA (RWD)
Meaningful questions
Fit-for-purpose data & analytics
Externally validated findings
Claims databases
Mortality, other registries
Test results, lab values, pathology results
Hospital visits, service details
REAL-WORLD EVIDENCE (RWE)
Real-World Evidence as a capability—data, tools, processes, organization—underpinning several functions to drive business intelligence

RWE Opportunities

- Understand device performance in real-world environment to inform benefit-risk
- Collect outcomes that are not well-suited to traditional clinical trials
- Reduce time/cost to answer important questions

Goal: Efficient generation of robust clinical evidence that can meet regulatory objectives

Potential Usages of RWE



❶ Hypothesis Generation (e.g. treatment effect estimation)

❷ Inform prospective trial design

❸ RWE as a control arm for a clinical trial

❹ Real-world data source as a platform to support a clinical trial

❺ Data collection framework for post-market condition-of-approval studies

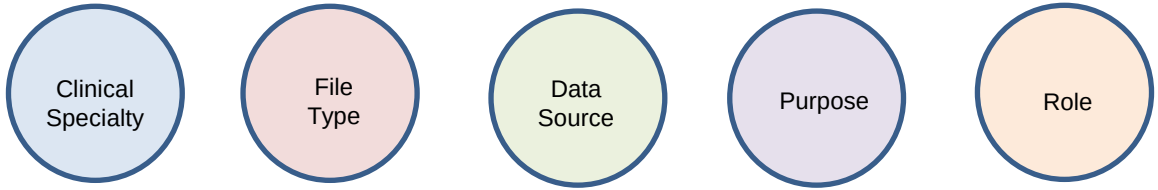
❻ Adverse event reporting

❼ Generate evidence to support indication expansions and future innovation

What has the U.S. done with RWE so far?

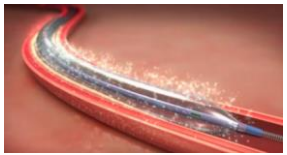
RWE Successes

March 2021 - CDRH published 90 examples of RWE used in medical device regulatory submissions



Clinical Specialty	File Type	Data Source	Purpose	Role
Cardiovascular Diagnostics General hospital Neurological Ophthalmic Orthopedics Surgical	510(k) De Novo PMA HDE	Medical records Claims Registry Literature	New device Use expansion Postmarket study Signal detection	Primary Supplementary Partnering Find patients

Cardiovascular Device Examples



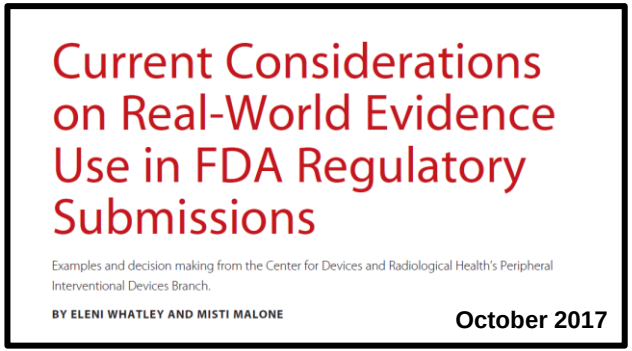
- Premarket indications expansions
  - US and global registry data
  - Published literature
  - Registry data as control arm
  - Prospective and retrospective analysis
- Postmarket studies
  - Global data collection
  - Registries capturing real-world use

Registry Examples

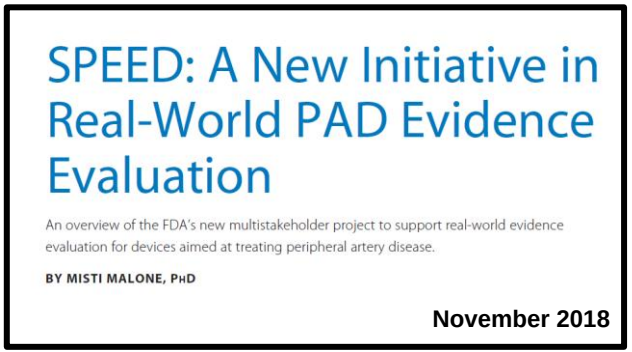
- VISION (***V****ascular* ***I****mplant* ***S****urveillance &* ***I****nterventional* ***O****utcomes* ***N****etwork*)
  - Use insurance claims data to evaluate safety and effectiveness of vascular devices
- EP PASSION (***E****lectro****P****hysiology* ***P****redictable* ***A****nd* ***S****u****S****tainable* ***I****mplementation of* ***N****ational registries)*
  - Sustainable mechanism to collect pre-market and post-market data on implanted electrophysiology devices

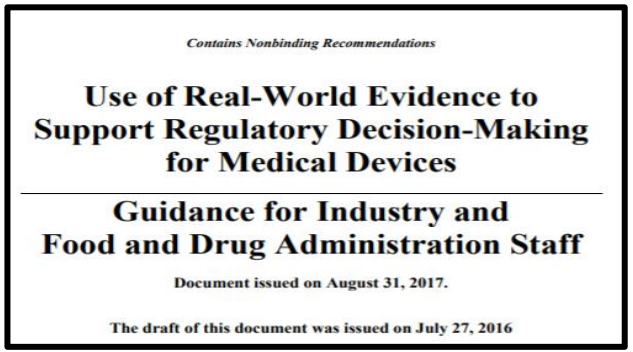
Example: RAPID
(**R**egistry **A**ssessment of **P**eripheral **I**nterventional **D**evices)

- Advance a total product lifecycle approach for the evaluation of PAD devices
- Multi-stakeholder collaboration of clinicians, medical professional societies, regulators, device manufacturers, and clinical research organizations
- Project examples:
  - Establish minimum core data set for clinical/regulatory use
  - Develop performance goals using registry data
  - Address emerging post-market safety signals


Current Considerations on Real-World Evidence Use in FDA Regulatory Submissions
Examples and decision making from the Center for Devices and Radiological Health's Peripheral Interventional Devices Branch.
BY ELENI WHATLEY AND MISTI MALONE
October 2017


MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM
Real-World Clinical Evidence Generation: Advancing Regulatory Science and Patient Access for *In Vitro* Diagnostics (IVDs)
A Framework for Incorporating Real-World Data and Evidence Into Pre- and Postmarket Regulatory Decision-Making for IVDs
August 2020


SPEED: A New Initiative in Real-World PAD Evidence Evaluation
An overview of the FDA's new multistakeholder project to support real-world evidence evaluation for devices aimed at treating peripheral artery disease.
BY MISTI MALONE, PHD
November 2018


Contains Nonbinding Recommendations
Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices
Guidance for Industry and Food and Drug Administration Staff
Document issued on August 31, 2017.
The draft of this document was issued on July 27, 2016

What are some important RWE-related considerations?

RWE Quality

- Will data be “fit for purpose?”
- Relevance
  - Are the study results, endpoints, population, etc appropriate to address the regulatory questions of interest?
- Reliability
  - Is there sufficient control of data capture, quality, and integrity?

Regulatory Impact

- Regulatory uncertainty can pose a risk
- Understand and communicate how collection and use of RWE impacts other regulatory processes and requirements
  - Patient protection
  - Clinical trial notification requirements
  - Data monitoring/auditing
  - Institutional research requirements

Some Current Trends

- Use of RWE in a global environment
  - Value of regulatory guidance and published examples
  - Alignment of clinical/regulatory definitions
- Reducing burden related to RWE collection
  - Reusability/interoperability of data collection mechanisms
- Applying RWE principles to emerging digital health technologies
  - Collecting safety/effectiveness data to support DH regulatory goals
  - Using DH tools (e.g. apps) to collect safety/effectiveness data for other medical devices

Closing Thoughts

- Collection and regulatory use of real-world clinical evidence across the total product lifecycle can facilitate timely access to safe and effective medical devices
- Education on approaches to using RWE can reduce uncertainty
- As RWE application is becoming increasingly global, further multi-national engagement may be beneficial

Thank you!

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