



# Challenges and Solutions when using Real World Evidence: Industry View

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October 2017

# Achievements to Date

## Pre-market: Indication Expansion

- Cook Zilver PTX DES longer lesion indication
  - Leverage internal data
- Medtronic In.Pact Admiral DCB in-stent restenosis indication
  - Partner with VQI
- BD/Bard Lutonix DCB in-stent restenosis and longer lesion indications
  - Leverage internal data

## Post-market Surveillance

- Medtronic In.Pact Admiral DCB post-market surveillance for ISR indication
  - Partner with VQI
- BD/Bard Lifestent BMS post-market surveillance for popliteal indication
  - Partner with VQI

## 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

*RWE was appropriate and least burdensome to support the reasonable assurance of safety and effectiveness*



# Anticipated Uses for RWE

## Pre-market

- Expanding indications – still important, but incentives to move beyond
- Use of RWE performance goal to support single arm study for new technologies
- Randomized registries
- RAPID Phase IV discussion later this afternoon

## Post-market

- Already happening, especially with VQI
- Industry top priority: EU MDR clinical evidence requirements
- 2016 RAPID meeting this was not even a potential use
- Signal Management (coming up later...)



# Challenges for RWE

- Cost remains significant in current infrastructure
  - Data Access
  - Additional information often needed
  - Integrating core data elements into EHR and registries will help to further increase efficiencies and reduce costs
- Global acceptance unclear
  - EU-MDR?
  - Will RWE be adequate and cost-effective (pre-market? post-market?)
  - Japan?
    - PMDA developing new consultation category for RWE
    - Societies launching registries
- Is data quality adequate
  - NESTcc developing data quality framework





# Comments from Industry Partners?

Successes you have had?

Challenges you have faced?

Solutions you have developed?

