RAPID Industry Survey Results (13 participants)

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March 20, 2019

Positive Experiences using Real World Evidence to support regulatory decisions

- Interpretation is broader
- Existing registry instead of separate post approval study. Collect more data in shorter timeframe at lower cost.
- Ability to link to CMS for longer term data
- The outcome of this project (RAPID) will be impactful to future studies.

Challenging experiences using RWE to support regulatory decisions

- Data quality may vary (3)
- Very time consuming to get project started since many stakeholders had to devote resources and align on approach
- CMS database not set up well for research
- Unclear of expectations for Adverse Event Reporting. Does it overlap with MDR requirements?
- Existing FDA forms are not set up well to accept RWE (e.g., Refuse to Accept checklist questions)
- Many challenges getting agreement from large team. Important for building consensus but requires longer project timeline.
- Long term follow-up compliance not ideal

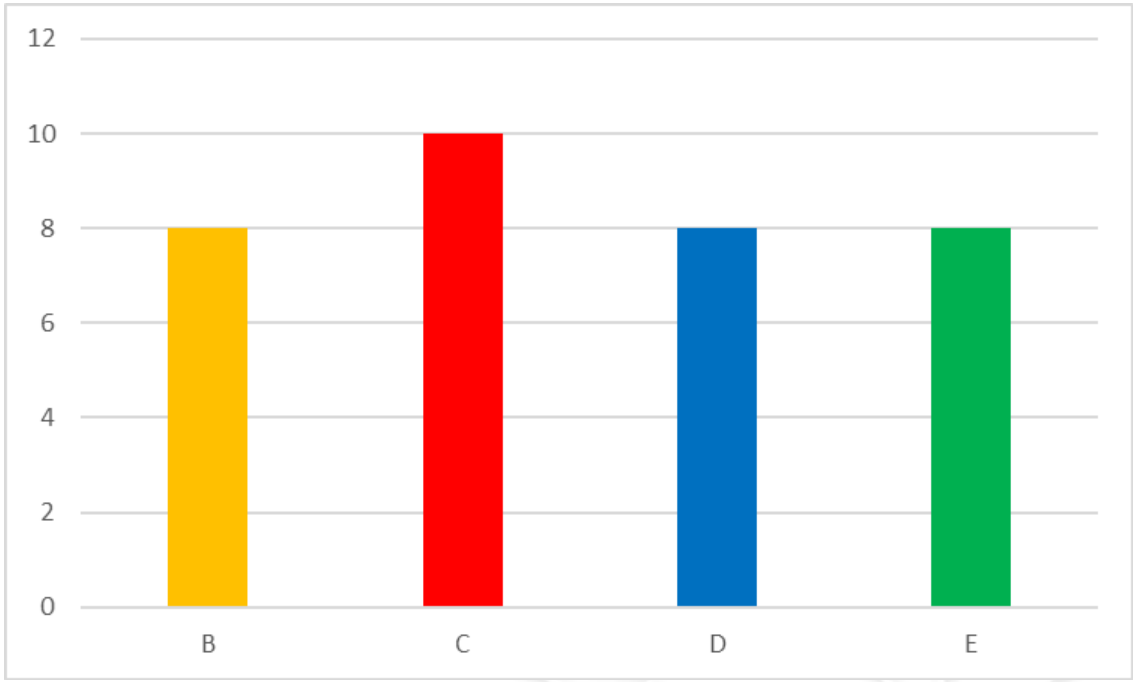
Top Priorities for Phase III

Yellow: Combine VQI with other data sources

Red: Incorporate RAPID core data elements into other registries (domestic or international)

Blue: Tie VQI to claims data for longer term follow up

Green: Collect Real World Data to support EU MDR clinical evidence requirements



Most Common #1 Choice

Green: Collect Real World Data to support EU MDR clinical evidence requirements

Blue: Tie VQI to claims data for longer term follow up

Red: Incorporate RAPID core data elements into other registries (domestic or international)

Yellow: Combine VQI with other data sources