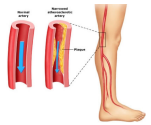
POTENTIAL PROJECT



UDI in Rapid Phase III: Improve decision making with better UDI data

OVERVIEW

Objective

Overarching- Use knowledge from earlier RAPID phases to improve auto-capture of UDI and GUDID data in RAPID registries and value of data for decision-making
Demonstration Project- Inform development of policy and best practices that improve quality of data submitted and stored in GUDID. Quality improvement measured as reductions in estimation and extrapolations for multiple clinical and regulatory uses.

Methodology

FDA, manufacturers and researchers conduct a joint data science analysis to refine UDI data collected at point of care and transmitted to registry data. Select 5 GUDID fields for 3-5 PAD device types under study for a RAPID Phase III approval. Determine the gap in existing UDI data necessary to improve researcher ability to compare device effectiveness across patient populations. Use manufacturer updates to GUDID data fields as one source for measuring statistical data quality for the device evaluation

Participants

Principal Investigators(TBD):
Ted Heise, PhD
James Tcheng, MD
Registry Owner (VQI,ACC?)
Terrie Reed, MSc
Behnaz Minaei, MSc

IMPACT

Expected Research Outputs

- Identification of hospital supply chain, clinical, and registry device identification requirements
- General method to conduct a data science analysis of a particular device type to improve UDI capture at point of care
- Measurable improvement in quality of GUDID data, incorporation into user datasets and evaluation of impact on clinical and regulatory decision making

Intended Impact for NESTcc

- Improved understanding of the device clinical, supply chain and research requirements for GUDID data
- Increase in UDI competency among FDA, clinical and manufacturer participants
- Generalizable data science methodology that can be applied to other device types and registries
- Identification of further GUDID data for improvement and UDI linkages that can be source of further study

Timeline

Data Science evaluation: June – September 2018
Change in GUDID data – June-December 2018
Evaluation of GUDID updates – January – June 2019

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Project: Improve decision making with better UDI data

Potential principle Investigators:

- Ted Heise, PhD, Cook Medical
- James Tcheng, MD, Duke University Medical Center
- Registry Owner (VQI,ACC?)
- Terrie Reed, MSc, FDA
- Behnaz Minaei, MSc, FDA

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Project: Improve decision making with better UDI data

Leverage knowledge gained from RAPID phase I &II to:

- Use the UDI and associated data from GUDID as core data for the devices being evaluated in RAPID Phase III registries
- Increase trust/value of data auto-populated from AccessGUDID in registry fields
- Provide instructions to participating manufacturers on specific requirements for updating UDI data

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Project: Improve decision making with better UDI data

Methodology:

- Use individual consultation between registry owner, FDA and manufacturer to update UDI records so that the data provides value across stakeholder groups
- Key fields requiring reviewing and update would potentially include
  - adding catalog numbers or reference numbers if not already present in the DI record
  - updating clinically relevant size fields to provide structured on the CRS's that physicians use to select the device and that are used to evaluate performance in patient populations
  - updating the description field from NA or something that is not meaningful to something that is meaningful to the registry and clinical community
  - evaluating the GMDN term assignment based upon discussions and collaboration with other manufacturers who have the same device types to ensure that the GMDN assignment is more consistent for the same device type used across multiple manufacturers

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Project: Improve decision making with better UDI data

Output:

Specific output would be updates to the records in GUDID that correspond to devices that will be evaluated as part of RAPID Phase III. The updates may differ by manufacturer and would be discussed across stakeholder groups represented in RAPID before being implemented

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Project: Improve decision making with better UDI data

Impact:

- Reduce gap between what UDI **users need** and what **manufacturersand regulatory authorities produce and monitor.**
  - Improve the global scannability of UDI at point of care
  - Improve the value of each UDID as a public good by reducing access barriers not only in the US but enabling linking to global UDID's using the UDI-DI
  - Improve device identification data submitted to support local and global regulatory decisions made using real world evidence

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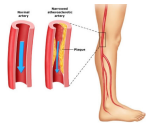
POTENTIAL PROJECT



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