Background

NESTcc was established as an independent coordinating center through a cooperative agreement between the U.S. Food and Drug Administration and the Medical Device Innovation Consortium (MDIC) in 2016. NESTcc aims to drive the quality and efficient use of real-world data (RWD) to inform medical device development and evaluation throughout the total product life cycle (TPLC).

Mission

To analyze the timely, reliable, and cost-effective development of Real-World Evidence (RWE) to enhance quality and efficiency in the use of RWD to inform medical device development and evaluation.

Vision

To be the leading research organization within the health technology and medical device ecosystem for conducting efficient and effective research studies and programs.

Results

- NESTcc awarded a diverse slate of "Test-Case" research studies to examine the capabilities of the Research Network in various clinical areas, regulatory uses, and analytical approaches.
- NESTcc maintained closed oversight through periodic study reports to ensure the success of the study, but also to learn from the study experience (e.g., programmatic efficiencies, collaborations, scientific/technical activities).
- Utilizing these study progress reports, a thematic analysis was conducted to capture the overarching themes across the successes and challenges of generating RWE.
- Key learnings have been generated to further develop the NEST model, all while ensuring stakeholder-driven research questions.

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Methods

- To assess successes and challenges in the conduct of the study, semi-structured progress reports were developed to collect study experiences across the full slate of Test-Case in a consistent manner.
- Based on the collective monthly progress reports, a dataset for analysis was created from select answer fields deemed relevant to the assessment.
- Each answer field of the dataset was reviewed initially to identify constructs.
- Inductive and deductive analyses was applied in identifying themes.
- Further programmatic efficiencies and additional data quality/research methods guidance are being developed and applied at NESTcc.

Conclusion/Implications

- Research-driven collaborations yielded unique learning opportunities in enhancing the availability of siloed data sources for research.
- Additional efforts will need to be made to further apply methodological and data quality safeguards that may improve research integrity without burdening the progress of the study.
- Despite initial challenges in convening relevant RWD sources and expertise, NESTcc is well situated to catalyze research through clear and consistent guidance, expertise, and scientific standards in the conduct and validation of RWE studies.
- Further programmatic efficiencies and additional data quality/research methods guidance are being developed and applied at NESTcc.

Upcoming NESTcc Initiatives

- Continuous expansion of the Research Network based on geography, available data, and RWE research experience.
- Development of a national post-market active surveillance system capable of device adverse event (AE) signal detection and refinement to complement the current passive and voluntary mode of AE reporting.
- The NESTcc Research Methods Framework and Data Quality Framework released in 2020 will be refined based on key learnings, maturation of the Research Network.
- Programmatic efficiencies, collaborations, scientific/technical activities.

- Variability in data standards, methods of data capture, and RWE research experience.
- Data submitted from partnered sites received guidance/training on relevant fields to use.
- Existing data standards of registry, common data models, or study-specific case and control data formats.
- Differences in data standards between partnered sites require building study specific requirements, then a crosswalk to the study requirement per site.

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