

Posting Date: August 11, 2020 Due Date: September 11, 2020

Call for Expert Reviewers for the NESTcc External Reviewer Panel

Opportunity

In 2016, the U.S. Food and Drug Administration awarded a grant to the Medical Device Innovation Consortium (MDIC) to establish The National Evaluation System for health Technology Coordinating Center (NESTcc). NESTcc's mission is to accelerate the development and translation of new and safe health technologies, leveraging Real-World Evidence (RWE) and innovative research.

As NESTcc continues to establish itself as the leading organization for conducting efficient and timely high-quality RWE studies throughout the total product life cycle, in the health technology and medical device ecosystem, it seeks applicants interested in serving as compensated members of its External Reviewer Panel. NESTcc encourages a diverse group of individuals with Real-World Data/RWE experience to apply and is particularly interested in reviewers who have expertise in the following specialties:

- Regulatory (U.S. and/or international (e.g. EU MDR, APAC))
- Coverage/reimbursement/HTA
- HEOR/cost-effectiveness/healthcare resource utilization
- Methods in designing studies and collection of RWD
- Data Quality of RWE generated
- Epidemiology
- Biostatistics (e.g. statistical methodologies)
- Data science (e.g. machine learning, predictive modelling)
- Data engineering (e.g. software engineer in Hadoop, SQL, Hive)
- Safety (e.g. medical device safety, surveillance)
- Digital/Health Technology
- Software as a Service
- Mobile Applications
- mHealth

External Reviewer Review Opportunities

The charge for External Reviewers will be to aid in evaluating the quality and merit of protocols, preliminary results, and final results (research materials) from NESTcc projects in accordance with administrative compliance and responsiveness and against the scientific rigors of NESTcc's Methods Framework and Data Quality Framework. Evaluations should be as thorough as possible, outlining the strengths and weaknesses of the research materials as compared to the criteria within the Frameworks.



For each protocol, preliminary results, and final results, NESTcc will invite Reviewers to conduct a timely review based on the alignment of the research materials with the Reviewer's availability, experience, and technical background. A Reviewer will have the option to decline a particular protocol/project, while still staying on the External Reviewer Panel. Reviewers may be requested to review the same research materials up to two (2) times based on updates or revisions. Reviewers will be compensated for their review.

Expectations of External Reviewers

Reviewers will be expected to be available to participate for a calendar year upon being selected to be on the External Reviewer Panel, with the expectation to renew participation in subsequent years if deemed by NESTcc to be in good standing. Reviewers will also have to have a strong written command of the English language to participate on the Panel. NESTcc does not guarantee that reviewer will receive a protocol, preliminary results, and/or final results document for review during their dedicated period of performance.

Key Dates

Opportunity Posted	August 11, 2020
Applications Due	September 11, 2020
Applicants Notified	September 25, 2020
Mandatory Virtual Training	October 2, 2020
Session	3:00 – 4:00 p.m. ET

Application Submission and Selection Process

Applications must include 1) the completed <u>application form</u> and 2) the applicant's curriculum vitae. These application materials must be submitted by email to <u>NESTcc@mdic.org</u> by 5:00 p.m. ET on Friday, September 11, 2020.

Applications that meet the requirements listed above will be presented to the NESTcc Selection Team for review and selection. Interviews may be conducted.

Contact

Please contact NESTcc@mdic.org with any questions.