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| **NEST Coordinating Center**  [www.nestcc.org](http://www.nestcc.org)  Posting Date: December 4, 2017 |
| Indication of Interest: December 15, 2017  Due Date: January 17, 2018 |

**National Evaluation System for health Technology Coordinating Center (NESTcc)**

**Establishing the Value of Using Real-World Evidence for Regulatory and Coverage Decisions Case-Studies in Medical Technologies**

Request for Proposal (RFP) Submission Form Template

**Instructions**

*Please provide the information requested below. Send your completed form as a PDF along with any other relevant documentation to NESTcc Project Manager Hither Jembere at* [*NESTcc@mdic.org*](mailto:NESTcc@mdic.org) *by January 17, 2018, 5 p.m. EST. This template shows where reviewers may expect to find information to evaluate each of the review criteria. Your Project Proposal must not exceed 10 pages. You may delete italicized instructional text.*

**Administrative Information**

*Include the names and titles of key personnel. Indicate a project lead, lead organization, and primary phone. Any additional administrative information may be provided by adding additional fields to the table.*

|  |  |
| --- | --- |
| **Required Field** | **Administrative Information** |
| Project Lead, Title |  |
| Project Lead E-mail |  |
| Project Lead Phone Number |  |
| Lead Organization |  |
| Lead Organization Address |  |
| Administrative Contact |  |
| Administrative Contact E-mail |  |
| Administrative Contact Phone Number |  |
| *[ADD ADDITIONAL ROWS IF NEEDED]* |  |

**Project Proposal**

***Instructional Note:*** *Your responses to the following sections A-D should not exceed 10 pages.*

1. **Identification and Selection of Case-Studies**

* *Describe the proposed process for identifying and selecting significant examples of successful use of Real-World Data for regulatory and coverage purposes to the FDA and/or payers.*
* *Describe a plan for selecting unsuccessful cases in order to identify barriers and learning from these examples.*
* *List sources of information to be used. The following sources may be considered:*
  + *Publicly-available data (e.g., data from the FDA website and other public sources)*
  + *Data shared by medical device manufacturers*
  + *Developing an RFI to industry manufacturers willing to share information and be the subject of a case-study*
* *Describe the proposed process for prioritizing and selecting case-studies. Considerations should include a range of:*
  + *Types of devices (Class II, Class III, imaging and diagnostic technologies)*
  + *Types of regulatory decisions (e.g., approvals, clearances, expanded indications for use, post-market safety studies, development of objective performance criteria or goals, surveillance studies)*
  + *Study designs (observational and interventional)*
  + *Small and large manufacturers, including venture-capital funded companies that have developed products that have gained market approval*
  + *Consumer-facing technologies that have received FDA approval*
* *Outline how the case-studies will be described in the report, including but not limited to, the following aspects:*
  + *Regulatory or coverage use-case, including the relationship between regulatory and coverage approvals*
    - *A strategy to review the logical possibilities of various decisions:* 
      * *Positive regulatory approval and positive coverage approval*
      * *Positive regulatory approval and lack of coverage approval*
      * *Lack of regulatory approval and lack of coverage approval*
  + *Data source and data quality processes*
  + *Methodological approach*
  + *Timing of evidence generation and regulatory or coverage decision-making*
  + *Unique lessons learned*

1. **Analysis of the Return on Investment**

* *Describe the proposed approach to evaluate the financial return on investment (ROI) to industry of generating evidence for regulatory or coverage purposes using Real-World Data.*
  + *Recommend appropriate metrics to evaluate ROI (e.g., cost savings, days saved, information generated that could not otherwise have been generated).*

1. **Future Directions and the Role of NESTcc**

* *Outline a final report section that will review the current state-of-play, lessons learned from the case-studies, challenges and gaps, and the role of NESTcc in accelerating adoption.*

1. **Dissemination of Findings**

* *Recommend ways to disseminate the learnings from the project to industry stakeholders, including materials, blogs, meetings, and journal submissions.*

**Deliverables Timeline**

*Include a timeline for completing the required deliverables within the period of performance (March 1, 2018 – August 1, 2018). These deliverables represent a minimum set of required deliverables. Additional deliverables can be proposed by adding rows to the table.*

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| **ID** | **Deliverable** | **Proposed Submission Date** |
| 1a | Work Plan Outlining Project Approach: Draft Work Plan |  |
| 1b | Work Plan Outlining Project Approach: Final Work Plan |  |
| 2a | Request for Information (RFI): Draft RFI |  |
| 2b | Request for Information (RFI): Final RFI |  |
| 2c | Request for Information (RFI): Public RFI Posting |  |
| 2d | Request for Information (RFI): Compilation of All RFI Responses |  |
| 2e | Request for Information (RFI): Process for Reviewing RFI Responses |  |
| 3a | Targeted Collection of Case-Studies for Analysis: Approach to Identify Case-Studies |  |
| 3b | Targeted Collection of Case-Studies for Analysis: Process for Selecting Case-Studies |  |
| 3c | Targeted Collection of Case-Studies for Analysis: Selection of Case-Studies |  |
| 4a | Analysis of Case-Studies: Draft Framework for Analysis, including ROI |  |
| 4b | Analysis of Case-Studies: Final Framework for Analysis, including ROI |  |
| 5 | Data Analysis |  |
| 6a | Synthesis Presentation: Draft Presentation |  |
| 6b | Synthesis Presentation: Final Presentation |  |
| 7a | Final Report: Draft Report |  |
| 7b | Final Report: Final Report |  |

**Proposed Budget**

*Include a proposed budget for all services provided that includes proposed hourly rates for all personnel who will be supporting the project, as well as expected costs and expenses. The budget may be submitted as a separate attachment.*

**Attachments**

*List any attachments included in your submission. The following attachments are required:*

* *Curriculum Vitae (CVs) of potential investigators, including experience with projects of a similar nature (experience with medical device evidence is preferred)*
* *Up to 3 Letters of Support*

**To learn more about NESTcc, visit our website (**[**www.nestcc.org**](http://www.nestcc.org)**) or email us at** [**NESTcc@mdic.org**](mailto:NESTcc@mdic.org) **with any additional questions.**