

Answers to Questions Regarding RFP 23-AS1001

Notes for reviewers of this document:

- As NESTcc extended the time to accommodate additional questions, this document is split into two sections.
 - The first section contains questions and answers (1 thru 80) received by July 26, 2023, and posted on July 31, 2023
 - The second section contains questions and answers (81 thru 102) received by August 04, 2023, and posted on August 09, 2023
- Throughout the document, questions are in bold and answers are not bolded.
- Names of individuals/organizations that submitted the questions have been removed.
- Questions have been grouped together intentionally if the same answer was appropriate for the questions.

Questions and Answers (1 thru 80) Submitted to NESTcc as of July 26, 2023, and Posted July 31, 2023

1. **Is the capture of all medical encounters related to specific U.S. patients, or all U.S. patients, within specific parameters (i.e. demographics, therapeutic areas, etc.)?**

Answer: No specific population is sought. Patients in the US covering a wide distribution of demographic and clinical characteristics are of interest.

NOTE: NESTcc welcomes identification of potential data partners by respondents to this RFP. However, it is not a requirement to identify and include data partners within the proposal. The intention is for the Central Data Operations Hub to incorporate data partners who are separately contracted by NESTcc into the active surveillance system hub-and-spoke infrastructure. Any information about potential data partners within a proposal (including any required parameters) should be presented separately, both in the proposal text and budget.

2. **What common data model, if any, is preferred, in the case of no FHIR-interoperability?**



3. **Please confirm that a selection of a CDM (and/or creation of a hybrid CDM) is in scope of this project.**
4. **Please clarify whether evaluation criteria for CDM candidate models have been finalized, and if so, what criteria have been selected for evaluating CDMS.**
5. **What are the specific data formats that will be utilized from each data partner?**
6. **What standards are expected for data interoperability and how is data harmonization to be managed across different sources?**
7. **What assumptions can we make about data partner infrastructure and each partner's ability to create and manage their infrastructure that will be part of the active surveillance system?**

Answer to questions 2-7 inclusive:

As mentioned on page 11 of the RFP, the OMOP common data model is currently preferred. With demonstration of no increase in budget, time, or other resources, and no loss of capability, other options presented within a proposal will be considered.

To the extent practical, we recommend use of FHIR standards for interoperability. Please provide clarity toward any anticipated deviations.

For purposes of developing a proposal, assume that all data partners are able to convert their data into an OMOP common data model with minimal assistance from the Central Data Operations Hub and that they have episode-based data collection for clinical care, patient-level demographic data, and standardized health system and provider data.

8. **What 'other electronic health data', if any, is of specific additional interest?**

Answer: The focus of the initial build is on development of a minimally viable system with a hub-and-spoke model including data sources with electronic health records (EHR). Preference will be given to systems that are flexible enough to integrate additional data sources as needed for active surveillance.

NOTE: NESTcc welcomes identification of potential data partners by respondents to this RFP. However, it is not a requirement to identify and include data partners within the proposal. The intention is for the Central Data Operations Hub to incorporate data partners who are separately contracted by NESTcc into the active surveillance system



hub-and-spoke infrastructure. Any information about potential data partners within a proposal (including any required parameters) should be presented separately, both in the proposal text and budget.

9. **Are any data currently available from MDIC or NESTcc in the current ecosystem, for linkage under the Data Coordination Center effort in order to meet the purposes of this anticipated effort?**
10. **How many Active Surveillance Data Partners responded to the RFI that was dated January 10,2022?**
11. **How many were selected to be AS Data Partners?**
12. **Does the winning vendor need to provide their own RWD partners, or can the vendor use existing NESTcc AS Data partners as well?**
13. **Given it is noted that data partners will be identified by NEST, are there already established relationships and Data Use Agreements with Data Partners of interest?**
14. **Throughout the RFP, the implication is that selected data partners already exist. Yet, in Attachment 1, there are requirements for scaling of the system and data architecture. What is the expectation of the responsibility for these requirements – does it belong to the hub or NESTcc? Is the hub expected to work with data partners that NESTcc has already contracted with or is the expectation that the hub will manage these data partners including their participation and scale?**

Answer to questions 9-14 inclusive:

NESTcc has not yet identified data partners for the active surveillance system. As additional background NESTcc issued an RFI for active surveillance data partners and initial use cases in January of 2022. NESTcc reviewing those responses as well as the capabilities of the [NESTcc Network Collaborators](#) (with whom agreements are established) and data source respondents of the recent RFI for the [NESTcc Medical Device Real-World Evidence Marketplace](#). This information will be shared and discussed with the entity selected to be Central Data Operations Hub for NESTcc's Medical Device Active Surveillance Program.

NOTE: NESTcc welcomes identification of potential data partners by respondents to this RFP. However, it is not a requirement to identify and include data partners within the proposal. The intention is for the Central Data Operations Hub to incorporate data partners who are separately contracted by NESTcc into the active surveillance system



hub-and-spoke infrastructure. Any information about potential data partners within a proposal (including any required parameters) should be presented separately, both in the proposal text and budget.

- 15. Will the government accept Contractor Performance Assessment Reports (CPARs) as the Letters of Support? If no, does the government have a preferred format or template for the Letters of Support?**

Answer: The RFP was issued by NESTcc which is part of the Medical Device Innovation Consortium (MDIC). MDIC is a 501(c)(3) public-private partnership. NESTcc will accept Letters of Support in any format or template.

- 16. Are we to include all expenses (e.g., cloud services, licensing) as ODCs?**

Answer: Yes, please include itemized expenses as other direct costs. NESTcc will discuss the structure of expenses with the selected entity in consideration of program flexibility and longevity.

- 17. Specification 5 under "Scope of Work" states "Second Device or COVID-19 specific device evaluation." We wanted to clarify if NESTcc is suggesting that instead of one of the two device proof cases presented under the "Scope" section (i.e., duodenoscope or cholecystectomy), a respondent could elect to use "COVID-19 treatment device or IVD" as an alternative to either of these use cases?**

- 18. What are the specifics of the proof-of-concept use cases? Are there any preferred devices to be prioritized for surveillance?**

Answer to questions 17-18 inclusive:

For the purposes of responding to this RFP, the use cases are duodenoscopes and cholecystectomy procedures. The final choice of use cases for development of the active surveillance program will be made after award, with input from FDA, NESTcc, and the selected vendor.



19. **When the term "result" is used throughout the RFP - what does this encompass? Could you please provide a definition and/or items that would constitute as the results?**

Answer: The result is the textual and visual information describing an identified potential signal.

20. **To ensure that we meet your budgetary considerations, we kindly request some additional information regarding the anticipated price range for this project. Understanding the approximate budget range will enable us to craft a proposal that not only meets your needs but also remains within the scope of your financial parameters. As discussed under "Review Process," we understand that cost is just one aspect of the overall evaluation criteria, and our proposal will also focus on demonstrating our capabilities, experience, and commitment to delivering a best-in-class program. If you are unable to provide an exact price range, any indicative figures or budgetary guidance you could share would be highly beneficial in guiding our proposal preparation.**
21. **Is there a set budget for this project or any constraints on resources that need to be taken into account while creating the proposal?**

Answer to questions 20-21 inclusive:

The intent of this RFP is to deploy a minimally viable system for active surveillance of two device areas which meets the requirements and aligns with the key aspects of a medical device active surveillance system as outlined in the RFP. NESTcc encourages respondents to provide clarity on costs for a minimally viable system and (separately) any recommended additions to assure system longevity and applicability across the breadth of marketed medical devices.

22. **As stated in the RFP, "the contract will include all appropriate Federal terms and conditions, including but not limited to those found in 45 C.F.R. Part 75 and the HHS Grants Policy Statement" and given that per Federal guidelines that there is no allowance for profit under a Cooperative Agreement, does the anticipated contract between MDIC and the contractor allow for the selected contractor to obtain any profit?**



Answer: Per Section 18.3.4 of the NIH Grants Policy Statement on Profit or Fee, a “recipient” or consortium participant cannot receive a profit, however, a “contractor” may. NESTcc will base its determination if the services requested under the RFP are better provided through an entity acting as a “subrecipient” vs a “contractor” as defined by the NIH and based on the entity’s response.

- 23. **Does the 15 page-limit apply to any of the following documents: cover page, table of content, and/or appendices?**
- 24. **Please confirm that the timeline, proposed budget, CVs, and letters of reference are excluded from the 15-page proposal limit.**
- 25. **Do sections 2, 3,4, and 5 have formatting instructions and/or page limits?**

Answer to questions 23-25 inclusive:

The 15-page limit applies to all aspects of the plan to establish the central data operations hub, inclusive of appendices. However, a single cover page and a table of contents may accompany the proposed plan.

There is not a page limit for presentation of timeline, budget, CVs and Letters of Support. Brevity and clarity throughout the proposal is appreciated.

- 26. **For the purposes of developing the proposed budget, are the key milestones intended to be Deliverables 1-13, or can applicants define the milestones?**

Answer: Items listed in the table of deliverables (beginning on page 7 of RFP) are the minimum set of required deliverables. Respondents are welcomed to include other key milestones relevant to their proposal.

- 27. **Will NESTcc or FDA host the central data operations hub?**
- 28. **Will the vendor own and manage the cloud infrastructure and provide the hub as a managed service?**

Answer to questions 27-28 inclusive:

NESTcc anticipates a cloud-based infrastructure for the active surveillance system, and



NESTcc anticipates that they will have a separate contract for hosting. However, alternatives will be considered with demonstration of increased capabilities and no increase in budget, time, or other resources.

Please provide itemized expenses as other direct costs for the option presented in your proposal.

29. Will the contractor be expected to execute any type of agreement or contract with the data partners identified by NEST?

30. Will each data partner pay for their own active surveillance infrastructure?

Answer to questions 29-30 inclusive:

NESTcc will execute contracts (or other agreements) with data partners for the medical device active surveillance system which will include any associated costs. However, if the respondents should indicate any associated costs/infrastructure required by data partners within their response to the RFP.

31. Will NESTcc or FDA be responsible for selecting the specific IRB for IRB approval or exemption as stated in requirements 4 and 5?

Answer: NESTcc will select a central IRB for approval or exemption. However, should the respondent have an IRB they would recommend, it should be included in their response for consideration.

32. Will NESTcc or FDA pay for IRB application, review, and other IRB-related fees?

Answer: Respondents should provide IRB-related fees as itemized expenses in other direct costs.

33. In reviewing the Active Surveillance System for Medical Devices I was curious as to whether this solution would include performance or operational data from the medical devices directly? The capability of devices reporting performance results with



remotely updatable test parameters exists in other industries. Adopting standards for this data seems like it would be highly beneficial.

Answer: We agree that operational and performance data directly from medical devices would be informative and that standards would be highly beneficial. This is not planned within the development of a minimally viable system for medical device active surveillance. However, NESTcc is interested in systems that are flexible and that could consider such data in the future should it become available.

34. Are there any limitations on an individual or organizational units being a part of more than one application?

Answer: NESTcc does not prohibit an organization or individual from being part of more than one proposal. However, if an organization or individual is part of multiple proposals, then the proposed role and function must differ across the proposals (i.e., only one proposal with each role/function is permitted).

NOTE: NESTcc will contract with data partners and data connectors separately from the Central Data Operations Hub.

35. Are there any limits or restrictions on a submitting organization or contact PI being allowed to be in a supporting role in a separate application?

Answer: NESTcc does not prohibit an organization or individual from being part of more than one proposal. However, if an organization or individual is part of multiple proposals, then the proposed role and function must differ across the proposals (i.e., only one proposal with each role/function is permitted).

NOTE: NESTcc will contract with data partners and data connectors separately from the Central Data Operations Hub.

36. Is the RFP open to registered companies/organizations outside of the USA?

37. Are there any offshore staffing restrictions?

Answer to questions 36-37 inclusive:

Organizations outside the US are welcomed to respond. There are not restrictions for staffing outside the US.

38. Could the 3rd party audit and security certification process be finalized after the nominal end date of the project (April 2024)?

39. We notice the PoP is 6-7 months but many IRB processes and data use agreements between a new central hub with participating data partners historically take at least that long to set up and execute. What is MDIC's expectation of how quickly such things can take place? This is all the more important considering this statement: "Notifying FDA of a potential signal, including the ability to share de-identified event- and patient-level information with the FDA, when requested by the FDA." Although de-identified, the use of UDI and other patient-level information creates a higher risk of re-identification that is likely to require more governance considerations from participating data partners that might require special governance between those partners and the FDA.

40. The period of the performance of the contract does not allow adequate time to complete the tasks detailed in the RFP unless substantial parts of the tasks required have already been completed (e.g., quality assurance on 2-6 data partners health data, NLP/tokenization of devices, protocol development and approval for monitoring/surveillance plan). Simply put, it is not possible to complete tasks 1-13 in 6-7 months unless some of them are already completed. Please clarify the expectations.

41. Should the execution of a contract take place on or near October 15, 2023, do you anticipate any flexibility with the period of performance?

Answer to questions 38-41 inclusive:

NESTcc acknowledges that the timeline in the RFP is ambitious. NESTcc encourages respondents to provide realistic timelines within their proposals, highlight factors contributing to any extended timeframes, and demonstrate understanding of the desire to obtain a cost-effective minimally viable system for two device areas within a short timeframe. While there may be some flexibility in the period of performance, rationale for an extended timeframe is needed.

42. **Is the expectation to leverage the learnings (as per Active Surveillance Roadmap) or are there technical artifacts that could/should be reused (e.g. infrastructure elements, NESTcc Cloud, etc.)?**
43. **What happened to the work already done with the simulation, development and testing of a pilot federated cloud environment?**

Answer to questions 42-43 inclusive:

NESTcc anticipates that learnings from the previous work, including the previous pilot work and the Active Surveillance Roadmap, will be incorporated into the minimally viable system. The technical artifacts from previous work will be made available to the selected vendor after a contract is signed.

44. **Please confirm that the preferred option for the hub is to work in a fully federated mode (analytical methods applied on the data at the source, no raw data movement)? Is bringing granular data into the hub (in a privacy preserving manner) a less preferred alternative?**

Answer: Confirmed that a fully federated model (analytical methods applied on the data at the source, no raw data movement) is anticipated for the minimally viable active surveillance system.

45. **Since only existing data is in scope, how many data sources should we assume for the two pilot use cases? What data will these sources contain (electronic health records (EHR), claims, registries, patient-monitoring devices, etc.)?**

Answer: As indicated on page 8 of the RFP, data from at least one data partner is anticipated for the first use case and at least two data partners are anticipated for the second use case. Additionally, integrating up to 6 data partners into the system is also in scope. These data sources will be EHR.

46. Please confirm that no prospectively collected datasets are in scope of this project.

Answer: NESTcc anticipates that continued data accrual from the data sources will be incorporated into ongoing active surveillance (with data refreshing at least monthly, preferably more frequently).

47. Please clarify what types of data you mean when stating the implementation of a federated health system may include an "allowance for identification and sharing of encrypted data for individuals across data sources"

Answer: This section references the ability to identify continuity of care and experience for patients between data sources (e.g., via horizontal federated learning) while maintaining patient privacy and protections.

48. Are federal employees allowed to be included as collaborators in the vendor proposal? If yes, can you elaborate on the process for this?

Answer: Federal employees are generally not able to engage in outside employment or activities that conflict with official duties and responsibilities. If a respondent intends to include federal employees as collaborators, then NESTcc encourages the employee to reach out to the Office of Ethics and Compliance to ensure no conflict of interest. Further, if a federal employee is included within the proposal, please provide the CV for that individual within the proposal along with documentation that the person has discussed this potential "outside activity" with their supervisor.

49. Are there specific adverse events of interest that the vendors should focus on when developing the active surveillance plans/protocols (e.g. for duodenoscopes, devices used in cholecystectomy procedures, etc.)?

Answer: Assessment of death, reintervention, and rehospitalization is anticipated for all devices. The two use cases were provided so that respondents can focus their proposed approach using these two specific device areas.



50. Are staffing governance oversight in the scope of the request or only in defining the framework, SOPs and policies?

Answer: Please include staffing governance oversight for the active surveillance system within the proposal.

51. What is the expected deliverable from the [NLP/]tokenization step? Should it provide privacy or input for an analytical module?

52. The criteria for data partners identified by NEST include “sufficiently linked medical claims and electronic health records (EHR) and other electronic health data to capture all medical encounters over a period of at least 1 year for U.S. patients and with sufficient granularity to capture brand and version (ideally via Unique Device Identifier [UDI]).” Given the expectation that NLP/AI/ML is listed as part of the device surveillance analysis, how is sufficiency defined for data partner selection?

53. The criteria for data partners identified by NEST include “sufficiently linked medical claims and electronic health records (EHR) and other electronic health data to capture all medical encounters over a period of at least 1 year for U.S. patients and with sufficient granularity to capture brand and version (ideally via Unique Device Identifier [UDI]).” Given the expectation that NLP/AI/ML is listed as part of the device surveillance analysis, how is sufficiency defined for data partner selection?

Answer to questions 51-53 inclusive:

The expectation is that NLP/tokenization would likely be needed to identify patients using the device as well as categorization for up to five additional variables which are not adequately identified using standard coding (e.g., variable derivation from clinical notes rather than [or in addition to] procedure codes). Availability of clinical notes will be needed to complete this effort. Both patient privacy and input for an analytical module are anticipated.

NOTE: NESTcc welcomes identification of potential data partners by respondents to this RFP. However, it is not a requirement to identify and include data partners within the proposal. The intention is for the Central Data Operations Hub to incorporate data partners who are separately contracted by NESTcc into the active surveillance system



hub-and-spoke infrastructure. Any information about potential data partners within a proposal (including any required parameters) should be presented separately, both in the proposal text and budget.

54. **The submission needs to include "prior experience conducting similar engagements (experience with medical device evidence preferred)" as an attachment. Can you elaborate on what you are looking for in this document? Is this information meant to be part of the CVs, or is this organizational past performance?**

Answer: Organizational past performance is welcome. Letters of Support regarding this past performance are preferred.

55. **The timeline on page 1 lists a project start date of September 30, 2023. The timeline on page 10 lists a contract executed date of October 15, 2023. Can NESTcc elaborate on the start date projection being listed before the contract execution date?**

Answer: The anticipated project start date and anticipated contract execution date is September 30, 2023.

56. **Do the concepts of Collaborator Cloud and Collaborator On-prem zones still apply and should be adopted for this project?**

Answer: NESTcc is amenable to any cloud-based approach which meets the requirements specified in the RFP.

57. **From a design standpoint, is the intent of the Active Surveillance system to monitor all devices everywhere, all the time, for each device's total life cycle?**

58. **How do you define a successful implementation of the surveillance system?**

Answer to questions 57-58 inclusive:

The intent of this RFP is to deploy a minimally viable system for active surveillance of two device areas which meets the requirements and aligns with the key aspects of a



medical device active surveillance system as outlined in the RFP. The long-term intent of the system is to better understand the safety of medical devices as used within clinical practice. NESTcc encourages respondents to provide clarity on costs and resources for development of this minimally viable system and (separately) any recommended additions to assure system longevity and applicability across the breadth of marketed medical devices.

59. What exactly does actionable findings mean to the FDA?

Answer: Page 1 of the RFP indicates interest in "... a timely assessment leading to actionable findings..." This phrase is intended to acknowledge that within signal detection there is a tension between identifying signals and noise and to convey that preference will be given toward entities that have experience and expertise in surveillance which accounts for the need to decrease the noise among potential signals.

60. Is the FDA indicating that the purpose of an AS system is to create future regulatory measures or to correct existing regulatory measures?

Answer: The medical device active surveillance system is part of a broader program described in the [Medical Device Safety Action Plan](#) to "optimize postmarket data collection, quality, completeness, and analysis, and develop a comprehensive framework for the timely evaluation and management of significant postmarket safety signals."

61. Is there a possibility that medical device manufacturers would use the FDA/NESTcc system for all things regulatory including, PMS, PMCF and all pre and post market studies?

62. In the RFP statement "...In addition, the data structure developed for the active surveillance system will be viable for generation of real-world evidence fit for purpose for regulatory decisions." Can FDA/NESTcc confirm that data from this AS system will be of sufficient quality to support regulatory decisions such as indication expansion?

Answer to questions 61-62 inclusive:



Once developed, the medical device active surveillance system (and the Central Data Operations Hub, data partners, etc associated with it) is expected to be part of the [NEST Marketplace](#) which will host organizations engaging in various aspects of RWE to provide the broadest range of solutions for all stakeholders to utilize fit-for-purpose RWD to generate RWE for medical devices in a robust yet streamlined fashion.

63. Is it possible that all healthcare organizations be required to participate with their patient data in an FDA sponsored Active Surveillance System?

Answer: The intent of this RFP is to deploy a minimally viable system for active surveillance of two device areas which meets the requirements and aligns with the key aspects of a medical device active surveillance system as outlined in the RFP. Data from at least one data partner is anticipated for the first use case and at least two data partners are anticipated for the second use case. Additionally, integrating up to 6 data partners into the system is also in scope.

Expansion of the system will depend on many considerations and the data requirements for the future will be evaluated as we gain experience with the initial system.

64. What is meant by “RWE fit for purpose for regulatory decisions”?

Answer: The RWD used in the medical device active surveillance system are fit-for-purpose to generate clinical evidence suitable for signal detection.

65. It’s suggested that reporting potential signals to FDA be via API. Is there an API endpoint already created at the FDA level within their current dashboards? If not, will vendor be given access within FDA to make that available?

Answer: The endpoint is under development and sufficient information will be made available to the selected entity to develop the API.

66. In Attachment 1 the requirement to “automate data cleansing and transformation including validation and quality checks of the associated processes”. Given that all patient-level data will be behind a firewall as a requirement for Data Partners in the same attachment, how does the RFP envision ongoing validation occurring since data cleansing would need to take place prior to aggregation?
67. Is the provisioning, configuration and operation of each data partner’s active surveillance system infrastructure considered within the scope of what we should propose?

Answer to questions 66-67 inclusive: NESTcc anticipates that the Central Data Operations Hub will provide parameters for potential data partners and that only data partners meeting these parameters will be considered for the minimally viable system. Additionally, NESTcc anticipates that the Central Data Operations Hub will develop a data transformation and quality check module. As part of onboarding each data partner to the active surveillance system, the Central Data Operations Hub will work with the data partner to map their data into the format needed to use the modules.

68. **Note: there are inconsistencies in the scaling part of Attachment 1. It is not clear whether MDIC wants to maintain 3 projects or 20 at any given time:**
- *Plan to scale such that within two years after initiation, AS system is capable of no fewer than 3 surveillance projects in parallel without service degradation*
 - *Plan to scale such that within two years after initiation, AS system is capable of maintaining no fewer than 20 ongoing surveillance projects without service degradation*

Answer: The intent is to ensure that 3 sets of analytics can be running simultaneously (computer/IT infrastructure requirement) and that 20 projects can be ongoing within the same calendar time (broader resourcing requirement).

69. **Data Specifications:**
- **Are there specific regulations or standards for handling and storing the extant data?**
 - **Can you provide any estimates as to the volume of data to be processed?**

Answer: Please provide the parameters you use for handling and storing extant data as well as the volume of data to be processed as part of your proposal.

70. System Requirements:

- **Could you clarify what are the specific technical requirements and performance criteria for the system?**
- **What are the specific criteria for testing the system, including alpha and beta stages?**

Answer: Development of the specific technical requirements and performance criteria is anticipated to be included in the “architecture and specifications” deliverable. The proposed criteria for testing the system are anticipated to be initially presented in the work plan and finalized within the “architecture and specifications” deliverable.

71. Are there any high availability and/or disaster recovery requirements?

Answer: Within the proposal, please provide resourcing and cost estimates for parameters of 90% availability and a recovery time objective of five business days for any major loss in business continuity (e.g., inability to send/receive modules) for the Central Data Operations Hub.

72. Scope of the Project:

- **Are there specific criteria or thresholds for signal detection and reporting?**

Answer: NESTcc anticipates that decisions on thresholds and reporting will be determined jointly by NESTcc, FDA, and the selected entity and will be highly dependent on the chosen active surveillance methodologies.

73. What are the expectations regarding the reporting structure and frequency of updates [for project management]?

Answer: We anticipate weekly meetings, monthly updates, and quarterly reports.

74. Are there any specific methodologies or approaches you prefer for project management, e.g., Agile, Waterfall, etc.?

Answer: Agile is preferred. Proposed alternatives will be considered.

75. Security and Privacy:

- **Could you clarify the specific security and privacy standards the system must adhere to? Are there any specific industry or regulatory standards to be followed?**
- **What measures are expected to protect patient privacy and data confidentiality?**

Answer: The active surveillance system is intended to align with the following privacy and security standards

- Minimally required: HIPAA, FISMA, ISO 27001, ISO 27701
- Preferred (required within 2 years): ISO 13485, ISO 22301, benchmark to National Institute of Standards Technology
- Preferred: GDPR, ISO 20000

76. Regulatory Compliance:

- **What are the compliance requirements related to FDA regulations?**
- **How should the system address potential regulatory changes in the future?**

Answer: The medical device active surveillance system will be developed under the requirements for research on marketed medical products and should ensure all applicable expectations are met.

77. What rights to the following items will be sought by NESTcc and MDIC? Items include specifications, architecture design, SOPs and security/compliance plans, analysis protocols, extracted best practices, and any non-obvious and unique inventions potentially patentable. Will the rights be:

- **“Government purpose rights,” which allow the government to use, modify, reproduce, release, perform, display, or disclose the software within the**

government without restriction and outside the government for a government purpose or,

- **"Unlimited rights," allowing NESTcc and MDIC unrestricted use for any purpose.**

What commercial rights will be granted to the winning applicant?

Answer: NESTcc and MDIC anticipate unlimited rights to use the developed system IP. Specific ownership rights will be agreed with the selected entity/organization and take under consideration section 18.4.2 of the NIH Grants Policy Statement on Intellectual Property.

78. What is the vision of NESTcc, MDIC, and the FDA regarding the transition of the Active Surveillance platform to a commercial embodiment for scaling, expansion, and diversification of products supported and evolution of the infrastructure platform? Will NESTcc, MDIC, or the FDA oversee the following areas for the very long term, or is there a vision to hand off one or more of these areas to commercial industry:

- **the evolution and promulgation of the product and technical roadmap,**
- **the clinical / device signal management and prioritization roadmap,**
- **management, upgrade, expansion, and systems management of the AS operations center,**
- **support and management of the core hub and spoke network design and implementation to incorporate new data partners,**
- **the onboarding of new data partners from a technical and training standpoint,**
- **expanding the AS to include manufacturers for access to crucial device data early in the onboarding of new medical devices into the AS system.**
- **scalability to support Class I, II, and III products in the United States, as well as expansion internationally?**

Answer: The current RFP is for the initial build of a minimally viable active surveillance system. NESTcc anticipates that we will maintain oversight of the system through this initial build and integration into the NEST Marketplace.

79. What is the best way for me, [person, organization], to get involved with promoting UDI adoption at the point of care to capture critical surveillance data?



80. Who can we introduce ourselves to, outside the scope of these discussions related to RFP 23-AS1001 for us to establish a working, contributing relationship?

Answer to questions 79-80 inclusive:

Please reach out to NESTcc@mdic.org to initiate discussions outside the scope of this RFP.

Questions and Answers (81 thru 102) Submitted to NESTcc as of August 04, 2023, and Posted Aug 09, 2023

81. We wanted to clarify whether this engagement contemplates the hosting of PHI?

Answer: Data partners will likely have access to Protected Health Information (PHI) for patients within their data source. It is anticipated that the Central Data Operations Hub may need to assist with deidentification of PHI to transition data into the chosen Common Data Model (CDM) and that only data in the CDM will be hosted and accessed for the Active Surveillance (AS) system. Thus, NESTcc does not anticipate that PHI will be hosted for AS.

82. The RFP refers to linked data from multiple sources able to capture all clinical utilization relevant to AS. Should the response address data linkage, or should it presume that data partners have already achieved linked data in the OMOP CDM and will make that available for queries?

Answer: NESTcc anticipates that the Central Data Operations Hub will have a plan to develop a (horizontal) federated model in which analytic methods are applied on the data at the source for the minimally viable active surveillance system – with no direct linkage across data sources, yet allowing for patient’s data across multiple data sources to contribute to AS. It is anticipated that some data sources may have linked claims and electronic health records (EHR) and that *these* linkages would already be performed by the data partner.

83. The Scope of Work (1) references “confirm interoperability of data between sites.” Please confirm that this data refers to model learnings and analytics results, and not de-identified data or PHI data. [RFP Reference p. 5: Scope of Work (1)]

Answer: NESTcc anticipates that a CDM and other considerations of interoperability will be necessary to develop the (horizontal) federated learning to identify patients and attributes



across multiple data partners' data sources. Therefore, confirmation of this interoperability of data between sites would be expected, both to onboard new data partners and with each refresh of data.

- 84. The capability to deploy NLP is a valuable target, but it will be difficult to achieve necessary governance, text deidentification, model training, and clinically relevant analyses within the 8 month timeline. Would NESTcc prefer that the response to this RFP focus on establishing a platform that includes NLP capabilities, or that the response map out a complete cycle of NLP application to the test cases extending beyond 8 months?**

Answer: NESTcc acknowledges that the timeline in the RFP is ambitious. NESTcc encourages respondents to provide realistic timelines within their proposals which are needed to achieve all of the requirements as stated within the RFP, highlighting factors contributing to any extended timeframes, and to demonstrate understanding of the desire to obtain a cost-effective minimally viable system for two device areas within a short timeframe.

- 85. In the hospital setting where adverse events, diagnosis, and device incidents may be captured and coded in a structured format, will there be a requirement to perform coding of unstructured data such as those events that are abstracted from free text data, examples of which are operative reports, diagnostic procedures, imaging reports, discharge summary reports, consultation reports, hospital medical device incident reports, etc.**

Answer: NESTcc does anticipate that use of free text data will be needed for the medical device AS system. As indicated on page 4 of the RFP, the design and development of a system may depend on the types of devices being monitored. Please consider the two use cases provided in the RFP as you put together your proposal.

- 86. Will the AS System utilize the FDA's existing product dictionary that details the Product Code, Device Name, Device Classification, etc. to allow for continuous monitoring of these devices when associated with any adverse events?**
- 87. There are different coding dictionaries that are used in EHR, Registries, Claims and Manufacture's adverse event and product complaints databases. Examples of these are the ICD9 Codes, MedRA, IMDRF, etc. There are no mapping between these dictionaries except for limited codes between MedDRA and IMDRF. Will there be a required and preferred medical coding dictionary that will be used in the AS System that will allow for consistency of coding of adverse events/diagnosis for data analysis?**

Answer to questions 86-87 inclusive: Potential data partners will utilize a myriad of coding schema and also have unstructured data. The intention is for the Central Data Operations Hub to incorporate data partners who are separately contracted by NESTcc into the active surveillance system hub-and-spoke infrastructure. NESTcc anticipates that the Central Data



Operations Hub will provide parameters for potential data partners and that only data partners meeting these parameters will be considered for the minimally viable system.

88. **For post-market surveillance, are all class 1 to 3 devices used in the two indications in #1 above be included in the signal detection or just specific class and product codes?**

Answer: NESTcc anticipates that a minimally viable system for AS for the two use cases listed on would (at a minimum) include the devices listed on page 4 of the RFP and would not limit signal detection to a specific class or product code.

89. **The Scope of Work (4) and (5) requires active surveillance with two devices. Please confirm that these analyses must be performed sequentially and cannot be performed in parallel. [RFP Reference p. 6: Scope of Work (4) and (5)]**

Answer: As indicated on pages 7 and 9 of the RFP, lessons learned from the initial testing of the first device will be used to inform later AS modules. NESTcc is amenable to any timelines which allow for this to occur.

90. **How many patients does the FDA plan to include during the development of the AS System?**

Answer: As indicated in the requirements (page 13 of RFP), at least 10 million patients contributing at least one year of data are preferred for the minimally viable AS system.

91. **Will the existing MAUDE and MDR reports, which have been reported to the FDA related to devices used in duodenoscopy, or cholecystectomy procedures need to be integrated with the AS system including new reports that are submitted to the FDA?**

92. **REP Section 3 - Regarding data partners, we'd like to add additional types of data resources, such as MDR and literature data. Can NESTcc confirm this is okay?**

Answer to questions 91-92 inclusive: Medical Device Reports (MDR) from the Manufacturer and User Facility Experience (MAUDE) and literature data are outside the scope of this project.

93. **The RFP describes the twin goals in the federated AS program of distributed learning to reduce data movement from its source and the ability to conduct data quality and signal detection analyses efficiently. Based on NESTcc's and data partner's governance principles, will an architecture that uses distributed methods to identify a cohort of at-risk persons, and then a cloud-based system that stores data for those cohorts in separate enclaves under control of each data partner, but allows for uniform and rapid analyses, be responsive to the RFP's requirements?**

Answer: The system described above would differ from the approach described in the RFP. As

indicated in the requirements (page 11), an alternate system model *may* be considered during the proposal stage, with demonstration of increased analytic capabilities at no increase in budget, time, or other resources.

94. **We are used to submitting budgets to our office of sponsored projects in a standard NIH budgetary format, which follow the SF424 rules and use the R&R Budget Form. Are those forms what you are expecting to be submitting with? Is this a sub recipient under the prime U-01 and not a federal contract?**
95. **Is it acceptable to submit personnel budget using percent effort applied to a fixed salary+fringe rate, or should we translate this into hours worked and an hourly rate? If hourly invoicing is preferred, what variation from the proposed number of hours worked is expected?**
96. **I have an additional question regarding the budget instructions for this RFP. The document refers to a budget submitted using hourly rates; however, as an academic research institute, we typically manage our budgets based on percent effort of personnel needed to complete the project aims. Is it allowable to submit a budget in this format rather than using hourly rates? In addition, can you clarify whether federal budget guidelines (such as the current federal salary cap) should be applied?**
97. **Please confirm the contract type will be Time & Materials. [RFP Reference p. 7: “A proposed budget that includes proposed hourly rates for all personnel who will be supporting the project, as well as expected costs and expenses based on a timeline of meeting key milestones.”]**

Answer to questions 94-97 inclusive:

Budget:

- We will accept any budget formats that meet the submission guidelines stated on page 7.
- We ask that the budget clearly and separately identifies the **hours** and personnel associated with each of the six sections in the SOW (pages 5-6) and that the expenses and costs for each deliverable (pages 7-9) are delineated. If you typically budget by percent effort, we recommend converting percent effort to hours for purposes of providing a budget.
- If there are any questions after receipt, NESTcc will seek clarification and if needed, will request reformatting, but budget formatting will not disqualify a proposal as long as it provides the requested information in the RFP.

Award:

- Please refer to question twenty-two (22) and its answer above in this same document.
- For clarity, entities can submit as a “subrecipient” or a “contractor” as defined by the NIH. Also, the agreement will be made between the entity and MDIC on behalf of NESTcc and will



be considered a “subaward” as MDIC/NESTcc is the prime awardee with the Federal Government.

- NESTcc will select the entity (either a “subrecipient” or a “contractor”) as based on a series of elements that allow the best solution to be provided for the program while following the NIH guidelines.

98. Please confirm FDA or MDIC will have agreements in place with data partners will allow patient-level data to travel directly to FDA. [RFP Reference, Attachment 1, Patient privacy and compliance, p. 12.]

Answer: NESTcc will execute contracts (or other agreements) with data partners for the medical device active surveillance system and will discuss options for data sharing with FDA. The Central Data Operations Hub should (minimally) plan for sharing aggregated data with FDA within the minimally viable system.

99. Given that the RFP scope of work will be funded by a cooperative agreement, please provide context on the overall scope of work under the entire U01FD006292 award. [RFP Reference p. 1: “This project will be supported by a sub-award from Federal Award Identification Number (FAIN) U01FD006292.”]

Answer: Award U01FD006292 for Continuation of the National Evaluation System for Health Technology (NEST) Coordinating Center (CC) - (U01) Clinical Trial Optional is a multi-year co-operative agreement consisting of four (4) specific major aims:

- 1) To support the implementation of the NEST through sustainable multi-stakeholder partnerships.
- 2) To develop new systems of data collection and/or analysis to permit prospective active medical device postmarket risk identification;
- 3) To support development of and access to high quality data sources that can be used in comprehensive evaluation of medical device performance and associated outcomes by multiple stakeholders; and
- 4) To develop methodological approaches and/or systems that facilitates the use of real-world evidence for regulatory decision making, and for uses by other stakeholders, throughout the entire device lifecycle.

This RFP is primarily intended to support “aim 2.” However, the work performed under this RFP may be leveraged for other aims under the co-operative agreement.



100. Your email below indicates “NESTcc will provide any additional supplemental material to prepare the proposals no later than July 31, 2023”. I didn’t receive anything. Is there anything additional you will share other than the RFP document?

Answer (Note: The following answer was provided via email).

Thank you for reaching out for clarification. The comment about providing any additional materials was provided in the event NESTcc received questions by July 31 which would’ve resulted in additional materials being generated, we would have provide them. There were no questions raised thus far that require additional materials. However, since we did extend the opportunity to submit questions until the close of business tomorrow, August 4, additional materials may still be distributed as appropriate.

101. In the RFP: “Up to 3 Letters of Support from references demonstrating relevant capabilities required to perform the work outlined in this RFP” In the Question Response: “NESTcc will accept Letters of Support in any format or template.” And “There is not a page limit for presentation of timeline, budget, CVs and Letters of Support. Brevity and clarity throughout the proposal is appreciated.”

102. I wanted to ask if there was a strict 3 letter of support limit? The way the RFP and response reads would tend to encourage omni-bus letters of support from multiple supports and organizations relevant to supporting the proposal and to try to coordinate all of them signing together. This may not improve clarity or brevity, and I wanted to ask about guidance in this regard. Are 3 letters of support attached to the proposal a hard limit to the application and am I interpreting the no-length limit correctly?

Answer to questions 101-102 inclusive:

As indicated in the RFP, a maximum of 3 Letters of Support may be provided. There is no strict limit to the length of these letters, however brevity and clarity is appreciated. We recommend that letters be targeted to showcase the capabilities of the entity to enact the proposed plan with an emphasis on similar previous work.