

National Evaluation System for health Technology Coordinating Center (NESTcc)
Cloud Infrastructure for NESTcc Active Surveillance System RFP

NESTcc Responses to Submitted Questions | Posted November 25, 2019

- 1. Is it a mandatory requirement that the infrastructure be FedRAMP and FISMA compliant, or is this one of the evaluation criteria?**

Yes, this is a mandatory requirement.

- 2. Is the contract term of the Active Surveillance Pilot and use of the cloud Infrastructure for NESTcc Active Surveillance System the same length (i.e., one year)?**

As listed in the RFP, the period of performance for each Phase is as follows:

Phase I: March to June 2020

Phase II: July to December 2020

In principle, we think the pilot system can be built and tested in four months, after which Phase II will be started to expand capabilities and number of users. Extensions will be considered with appropriate justification.

- 3. Will FDA-MDIC-NESTcc be contracting directly, outside of this contract, with the selected Data Collaborators for their assistance/participation in the NESTcc Active Surveillance pilot work?**

NESTcc has separate contracts in place with Network Collaborators.

- 4. Which of the publicly announced NESTcc Real-World Evidence (RWE) Test-Cases do you think will make up the first set of Active Surveillance work pilots in Phase I and Phase II?**

It is not envisioned that any of the currently announced 20 Test-Cases will be part of Phase I or II of building NESTcc's Active Surveillance capabilities.

- 5. What are the expected FedRAMP impact levels for the NESTcc Active Surveillance System?**

We expect that cloud-service offerings for this opportunity will need to have the capability to implement FedRAMP impact levels of moderate and high.

- 6. Are there any small business or socioeconomic requirements?**

No.

7. Are you soliciting responses from multiple cloud providers, or is your intent to use Amazon Web Services?

We are soliciting responses from any cloud or service providers that have the capabilities described in the RFP.

8. Are there any existing AWS accounts and existing services currently implemented by MDIC – NESTcc and/or by Network Collaborators?

At MDIC/NESTcc, there are currently no existing cloud services. Among Network Collaborators there is a variety of cloud environment implementations, from no available cloud services to full implementation of cloud platforms by many different service providers using a variety of products.

9. There is no mention of a Solution Architecture deliverable for the demo platform. Is the Phase I demo platform deliverable meant to be inclusive of a supporting solution architecture?

Yes, a solution architecture is a deliverable item as part of Phase I and Phase II.

10. Will the chosen provider be presenting the demo platform architecture to a collective MDIC-NESTcc technical team that is part of the NESTcc staff who are assigned to the project, inclusive of the Network Collaborators who are involved in the effort?

It is envisioned that the demo platform capabilities will be developed collaboratively with Network Collaborators, FDA, and NESTcc staff, which will include technical expertise.

11. What is the anticipated make-up of the NESTcc staff who will manage the day-to-day activities of the project, (i.e., roles, responsibilities, skill sets)?

This needs to be determined based on the specific needs and use of the system as it is being developed and scaled. To facilitate this, a system maintenance plan, including required staff, is part of the response to the RFP.

12. Are there any preferred delivery methodologies? Is the NESTcc team familiar with and open to conducting the project following an Agile delivery methodology?

We are comfortable with an Agile delivery methodology. We envision a collaborative environment where the platform can be developed with the cloud service provider, NESTcc staff, FDA, and Network Collaborators.

13. The Budget spreadsheet is clear in its intent to understand all professional services-related costs. Does NESTcc need to understand cloud services costs of the initial demo platform, or is that expected to be defined during the effort as the solution architecture is defined, initially for the demo platform and subsequently for the Phase 2 platform?

We understand that it may be difficult to price out the cloud service for Phases I and II, since the cloud service's capabilities need to be defined in more detail. This definition will happen through a collaborative process with Network Collaborators, FDA, and NESTcc staff. As we scale and build the platform further based on needs and capabilities, especially related to Phase II, we assume a more accurate cost estimate can be provided at that time. However, an estimate of the anticipated cost is required for the RFP response, as it is a factor that we consider in the selection process.

14. What Enterprise services will overlap in the new cloud environment and require integration (such as monitoring, logging, DNS, SMTP, etc.)?

This will be determined based on the solution architecture for Phases I and II, developed through a collaborative effort of Network Collaborators, NESTcc staff, FDA, and the cloud service provider. Specific needs currently include at least the implementation of a hybrid cloud infrastructure with IaaS and PaaS capabilities. These capabilities include access control, monitoring, logging, data ingestion, cleaning and data quality assessments, standard and advanced/customized statistical analyses, and dashboard creation for outcomes of interest related to medical devices and the functionality of the cloud infrastructure as a whole.

15. What Identity providers / Identity Access Management solutions and processes are in place and need to be integrated to the cloud environment?

The hybrid cloud infrastructure will live at NESTcc and at each of the Network Collaborators. It is necessary to provide stakeholders – which may be the Network Collaborators themselves, NESTcc staff, FDA, or others – with appropriate access to specific data environments, datasets, or only specific data elements as part of a dataset and results. These access controls may look different between different projects flowing through the system (either at a user group or individual access level).