

**Special Notice: Request for Information**  
**DIGITAL HEALTH SOLUTIONS FOR COVID-19**

RFI Number: HHS-NIH-NCI-RFI-COVID19-01

**Contracting Office Address**

Department of Health and Human Services, National Institutes of Health (NIH), National Cancer Institute (NCI), Office of Acquisitions, Rockville, MD

This is a Request for Information (RFI) for market research. This is **NOT** a solicitation for proposals or quotations. The purpose of this RFI is to obtain knowledge and information for project planning purposes.

**Virtual Meeting for Industry Engagement**

NCI and NIBIB will host an interchange meeting to give industry an opportunity to communicate with acquisition personnel and program staff. The virtual meeting will be held on Friday, **May 29, 2020 from 2:00-3:00 PM EDT**. All interested organizations are **highly encouraged** to attend this meeting and seek clarification about any of the information discussed below before submitting a response. The virtual meeting will be held via WebEx. See Attachment 1 for WebEx information.

Written questions about this notice may be submitted electronically via email to [Digital\\_Health\\_COVID\\_RFI@mail.nih.gov](mailto:Digital_Health_COVID_RFI@mail.nih.gov) by 5:00 PM EDT on May 27, 2020.

**Purpose**

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) and the National Cancer Institute (NCI) of the National Institutes of Health (NIH) require services to develop digital health solutions to address the COVID-19 pandemic and enable new research into using digital health technologies to advance the public health response. The digital health solutions will facilitate approaches that leverage multiple data sources, privacy-preserving technologies, and computational tools for managing population health and individuals' lives during the COVID-19 pandemic. Such management could include, for example, assessing the readiness of individuals to return to work, calculating the risk of possible SARS-CoV-2 infection, identifying and tracing contacts of COVID-19 cases, monitoring the health status of infected individuals, or linking individuals to clinical trials of therapies or preventative interventions for COVID-19. Particular focus includes digital health solutions for traditionally underrepresented populations as well as those with diminished access to healthcare resources.

This effort will employ a hub-and-spoke technology implementation model, in which each supported digital health solution (the spokes) will be encouraged to share deidentified data and other digital assets it generates with an NIH-supported central data hub. The data hub will provide researchers a single access point to deidentified data, algorithms, and other capabilities

generated by the various digital health solutions. Standards that enhance interoperability will enable unambiguous linking of digital resources among the spokes of the hub. This will enable researchers, for example, to apply a risk classification algorithm developed in one spoke to individuals' health data that was collected by other spokes. The purpose of this notice is to obtain information for the “spokes of the hub”; not the hub itself.

## **Background**

In the midst of the COVID-19 pandemic, there is an urgent need to protect individuals from coronavirus exposure while allowing society to return to normal function as quickly as possible. At present, we have only the blunt tools of social distancing and quarantine to contain the epidemic. Being able to precisely deploy containment efforts only where needed may allow larger segments of the population to return to less restricted living and reduce the risk of recurrence of devastating local outbreaks.

Novel digital health solutions have the potential to improve care, understanding of health outcomes, and risk factors related to the COVID-19 pandemic. This is especially important in underserved populations, which are disproportionately affected by COVID-19 and often have limited access to healthcare services. This is also important in its potential to broaden the geographic understanding of factors related to exposure, spread, and containment.

The collection of large digital health datasets has potential privacy implications, so there is an equally urgent widespread interest in providing adequate privacy protections that enable the utilization of personal health data without unduly compromising civil liberties. Anecdotal evidence supports the notion that privacy concerns work against broad adoption of new technological data-collection solutions, so it is important to address these concerns transparently, while also balancing them against the need to interrupt the COVID-19 pandemic and facilitate society returning to normal.

Finally, there is a need for a high-quality COVID-19 research data set that can allow academic, public health, and translational researchers to make discoveries that might otherwise not be possible from individual, siloed data. Enabling new research into digital health technologies and the data generated by those technologies has the potential to advance the public health response and facilitate underlying approaches that could improve future epidemic and pandemic planning. Given the breadth and specialization of digital technologies that might be brought to bear on the COVID-19 pandemic, it is likely that there are research questions that can only be answered by integrating and analyzing data generated by multiple different technologies and solutions.

## **Project Requirements & Objectives**

**Interested organizations are asked to describe their solution that addresses one or more of the following project objectives:**

- A technological solution (such as a smartphone application, commercial wearable technology, computational modeling algorithm, or novel approach to data analysis and/or aggregation) that has one or more of the following abilities:
  - tracing user contact with individuals diagnosed with or suspected of having contracted COVID-19;
  - rapidly integrating commercial COVID-19 diagnostic test results, patient-reported symptoms, wearable sensor data, electronic health records, and/or other diverse data sources with central or decentralized databases;
  - determining likelihood of user having undiagnosed COVID-19;
  - determining risk to user of contracting COVID-19;
  - determining information that individuals, employers, government agencies, and others can use to evaluate risk of allowing individuals to return to normal work, travel, and public life activities;
  - determining information that healthcare providers can use to follow patients at home and intervene when/if physiological decompensation occurs;
  - matching individuals to clinical trials for COVID-19;
  - ascertaining patterns of movement that influence exposure, spread, and containment of COVID-19;
  - providing strong privacy protections to allow integration, analysis, and federation of existing datasets for the purpose of COVID-19-related research;
  - otherwise contributing to limiting the spread of COVID-19, improving the care of COVID-19 patients, or enhancing the safety of workplaces, modes of travel, or public spaces with regard to COVID-19.
- Direct access to relevant information to the intended target audience via a high-quality user interface.
- A plan for iterative updates to the solution in order to take advantage of additional actionable data, computational tools, and/or science as it becomes available. The offeror should specify how it will monitor the data, tools, and science that is relevant to its solution, a high-level overview of the process by which it will integrate relevant findings into its solution, and any potential advances it sees in its solution as a result of such updates.
- For solutions that collect user data, a set of privacy protections that exist as close to the user as possible. Individuals (e.g., users of smartphone applications) should be given every available opportunity to know how their data is being used, to opt-in to data collection, and to provide specific assent at any point in which the use of their data will expand.
- If personally identifiable information (PII) or protected health information (PHI) is collected and stored (e.g., on a device, in a platform), a plan for securing and protecting that information according to privacy laws and regulations. The offeror should describe capabilities to de-identify data for subsequent sharing for research purposes.
- A pilot to validate the performance, usability, user adoption, and reliability of the solution, to begin immediately upon completion of a minimal viable version of the solution. The pilot should include a scaled approach involving populations of increasing size. The offeror will provide a set of performance metrics it will use to evaluate the feasibility, utility, and adoption of its approach.

- A means to transmit data and other digital assets derived from use of the technology into an NIH-supported data hub for research purposes. The offeror should provide details for sharing both de-identified data as well as data that can be unambiguously linked to other sources in the NIH-supported data hub, such as data generated by other solutions. Plan for possible models for data linkage should describe approaches to be pursued, such as a trusted broker model or privacy-preserving data linkage models. The plan should address how data standards, best practices, and documentation will be leveraged to enhance data findability, accessibility, interoperability and reuse.
- A plan for how a public roll-out of the solution could be accomplished following the validation pilot phase, while incorporating modifications and additional considerations that arise during the validation phase.
- If implementation of the solution will be in conjunction with public health authorities, employers, health care providers, or other partners, a description of the partnership with the relevant partner.
- For solutions that might require regulatory oversight, e.g. in the area of clinical decision support, a plan for contact with appropriate U.S. regulatory bodies (e.g. FDA in the form of pre-submission meetings and/or breakthrough device designation), as early in validation phase as possible.
- A plan to address any public reporting requirements and other applicable regulations to the methods proposed.

## Information Sought

NCI seeks to obtain knowledge and information for project planning from organizations that are interested in and capable of performing the work described herein. Based on the information provided in this notice, organizations may submit a capability statement, which is encouraged to cover the following points:

- (1) A description of your organization's solution to address the stated project objective(s)
- (2) A list of prospective personnel and affiliated organizations/institutions who would potentially be involved with a brief summary of their relevant experience;
- (3) a summary of successful adoption of similar technologies or other relevant past performance or experience that would assist with demonstrating capability to successfully deliver the proposed solution;
- (4) A high-level, rough order of magnitude cost and time estimate for your solution, using the following phasing milestones:
  - a. Delivering a digital health technology customized for addressing the COVID-19 pandemic, while also enabling new research that leverages the data and other digital assets generated by the technology. The technology would be able to be rapidly deployed within 4 to 8 weeks of the start of a contract for pilot validation.
  - b. Perform an initial pilot study to assess the performance, usability, and reliability of the technology for achieving its intended purpose.
  - c. Share de-identified data and other digital assets derived from use of the technology for research purposes.

- d. Deliver a report that includes assessment of the outcomes of this first phase, including the feasibility and utility of the approach for achieving its intended purpose, and recommendations for potential movement into a subsequent phase
- (5) Address whether the organization would consider it feasible to enter into a fixed price contract based on achievement of milestones for this type of project.

Anticipated NAICS code for this acquisition is 541715, Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology), which has a size standard of 1,000 employees.

### **Information Submission Instructions:**

1. **Page Limitations:** A tailored submission is required in response to this RFI. **General brochures will not be reviewed.** Interested organizations are asked to state the objective(s) from the Technical Scope section that their solution addresses. The page limitation for this RFI is **10 pages**.
2. **Cover Page:** Provide a cover page with the business concern's name, Small Business Administration size standard(s), point of contact and contact information (email and phone), organization's address, and DUNS number (if available).
3. **Delivery Point:** All information sent in response to this Request for Information notice must be submitted electronically (via email) to [Digital\\_Health\\_COVID\\_RFI@mail.nih.gov](mailto:Digital_Health_COVID_RFI@mail.nih.gov) in Microsoft Word or Adobe Portable Document Format (PDF). The subject line must specify HHS-NIH-NCI-RFI-COVID19-01.
4. **Response Date:** Electronically submitted responses are due no later than **5:00 PM (Eastern Daylight Time) on June 5, 2020**.

**DISCLAIMER AND IMPORTANT NOTES:** This notice does not obligate the Government to award a contract or otherwise pay for the information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. The Government, at their sole discretion, may contact interested parties that respond to this inquiry to conduct additional exchange of information and/or market research. **THERE IS NO SOLICITATION AVAILABLE AT THIS TIME.** However, should such a requirement materialize, no basis for claim against the NCI shall arise as a result of a response to this Request for Information or the NCI's use of such information as either part of our evaluation process or in developing specifications for any subsequent requirement(s).

**Confidentiality:** Respondents shall mark confidential, privileged, proprietary, trade-secret, copyrighted information, data, and materials with appropriate restrictive legends. The Government will not publicly disclose proprietary information obtained as a result of this notice. Unless otherwise marked, the Government reserves the right to use information provided by

respondents for any purpose deemed necessary and legally appropriate. The Government will presume that any unmarked information, data, and materials were furnished with an “unlimited rights” license; assumes no liability for the disclosure, use, or reproduction of the information, data, and materials. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s).