270-F1]

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Request for Information (RFI) on Data Collection for Emergency Clinical Trials and Interoperability Pilot; Extension of Comment Period

AGENCY: White House Office of Science and Technology Policy (OSTP).

ACTION: Request for Information (RFI) on Data Collection for Emergency Clinical Trials and Interoperability Pilot; Extension of Comment Period.

SUMMARY: On October 28, 2022, the Office of Science and Technology Policy (OSTP) published in the **Federal Register** a document entitled "Request for Information (RFI) on Data Collection for Emergency Clinical Trials and Interoperability Pilot." This RFI, issued by OSTP in partnership with the Office of the National Coordinator for Health Information Technology (ONC), invited comments on how to optimize data collection for clinical trials carried out across a range of institutions and sites, both in emergency settings and in the pre-emergency phase. OSTP and ONC are seeking input on viable technical strategies to distribute clinical trial protocols and capture clinical trial data using common application programming interfaces (APIs). OSTP and ONC also seek information about whether there is value in a pilot or demonstration project to operationalize data capture in the near term, for example within 6–12 months of the close of comments on the RFI. In response to requests by prospective commenters that they would benefit from additional time to adequately consider and respond to the RFI, OSTP has determined that an extension of the comment period until January 27, 2023 is appropriate.

DATES: The end of the comment period for the document entitled "Request for Information (RFI) on Data Collection for Emergency Clinical Trials and Interoperability Pilot," published on October 28, 2022 (87 FR 65259), is extended from December 27, 2022 to January 27, 2023.

ADDRESSES: Comments submitted in response to 87 FR 65259 should be submitted electronically to *datacollectionforclinicaltrials@ostp.eop.gov* and should include ''Data

Collection for Clinical Trials RFI'' in the subject line of the email. Due to time constraints, mailed paper submissions will not be accepted, and electronic submissions received after the deadline cannot be ensured to be incorporated or taken into consideration.

Instructions: Response to this RFI (87 FR 65259) is voluntary. Each responding entity (individual or organization) is requested to submit only one response. Please feel free to respond to one or as many prompts as you choose. Please be concise with your submissions, which must not exceed 10 pages in 12-point or larger font, with a page number on each page. Responses should include the name of the person(s) or organization(s) filing the comment.

OSTP invites input from all stakeholders, including members of the public, representing all backgrounds and perspectives. In particular, OSTP is interested in input from health information technology (health IT) companies, app developers, clinical trial designers, and users of health IT products. *Please indicate which of these stakeholder types, or what other description, best fits you as a respondent.* If a comment is submitted on behalf of an organization, the individual respondent's role in the organization may also be provided on a voluntary basis.

Comments containing references, studies, research, and other empirical data that are not widely published should include copies or electronic links of the referenced materials. No business proprietary information, copyrighted information, or personally identifiable information should be submitted in response to this RFI (87 FR 65259). Please be aware that comments submitted in response to this RFI (87 FR 65259) may be posted on OSTP's website or otherwise released publicly.

In accordance with FAR 15.202(3), responses to this notice are not offers and cannot be accepted by the Federal Government to form a binding contract. Additionally, those submitting responses are solely responsible for all expenses associated with response preparation.

FOR FURTHER INFORMATION CONTACT: For additional information, please direct questions to Grail Sipes at 202–456– 4444 or *datacollectionforclinicaltrials@ostp.eop.gov*.

SUPPLEMENTARY INFORMATION: In accordance with the 2022 National Biodefense Strategy for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security (National Biodefense Strategy) and the American Pandemic Preparedness Plan (AP3), OSTP, in partnership with the National Security Council (NSC), is leading efforts to ensure that coordinated and large-scale clinical trials can be efficiently carried out across a range of institutions and sites to address outbreaks of disease and other emergencies.[1] On October 28, 2022, OSTP, in partnership with ONC, published in the **Federal Register** a document inviting comments on how to optimize data collection for clinical trials carried out across a range of institutions and sites, both in emergency settings and in the pre-emergency phase (87 FR 65259). OSTP and ONC are seeking input on viable technical strategies to distribute clinical trial protocols and capture clinical trial data using common APIs. OSTP and ONC also seek information about whether there is value in a pilot or demonstration project to operationalize data capture in the near term, for example within 6–12 months of the close of comments on the RFI. The RFI was issued to seek input from a broad array of stakeholders on a range of topics related to data capture in the clinical trials context, including ways in which ONC standards and frameworks for interoperability might be leveraged to further the goals of the RFI. The document stated that the comment period would close on December 27, 2022. OSTP has received requests to extend the comment period. An extension of the comment period will provide additional opportunity for the public to consider the RFI and prepare comments to address the topics listed therein. Therefore, OSTP is extending the end of the comment period for the RFI from December 27, 2022 to January 27, 2023.

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[1] *See* Notice of Request for Information (RFI) on Clinical Research Infrastructure and Emergency Clinical Trials, published October 26, 2022 (87 FR 64821).

Submitted by the White House Office of Science and Technology Policy on November 15, 2022.

Stacy Murphy,

Operations Manager.

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