IDA SCIENCE AND TECHNOLOGY POLICY INSTITUTE

MEMORANDUM September 1, 2023

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Through:	Kristen M. Kulinowski Director, STPI
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Subject:	Summary of the Request for Information on Clinical Research Infrastructure and Emergency Clinical Trials (87 FR 64821)

On October 28, 2022, OSTP released the "Request for Information (RFI) on Clinical Research Infrastructure and Emergency Clinical Trials." This RFI was originally scheduled to close on December 27, 2022 but was extended to January 27, 2023. Seventy-seven responses (452 pages) to the RFI were received. STPI was asked to assist OSTP in summarizing the RFI results. This document represents that RFI summary.

Attachment: "Summary of the Request for Information on Clinical Research Infrastructure and Emergency Clinical Trials (87 FR 64821)

Summary of the Request for Information on Clinical Research Infrastructure and Emergency Clinical Trials (87 Federal Register 64821)

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Executive Summary

On October 28, 2022, the White House Office of Science and Technology Policy (OSTP) released the "Request for Information (RFI) on Clinical Research Infrastructure and Emergency Clinical Trials." This RFI was originally scheduled to close on December 27, 2022 but was extended to January 27, 2023. The RFI (the text of which is included as Appendix A) included six main issues for feedback, five of which included specific sub-parts for a total of 50.

Seventy-seven responses, in 452 pages, were received and analyzed by the Science and Technology Policy Institute (STPI). A total of 23 responses came from companies, with another 18 from academic health centers, research centers, or individuals from academia. The remaining responses came from professional associations (10 responses), stakeholder groups (eight responses), industry associations (five responses), advocacy groups (six responses), research entities (three responses), the federal government (one response), two individuals without academic affiliations, and one additional response (Clinical Trials TV). Of the responses, 46 were from U.S.-based companies, associations, or research entities and 13 from global/multi-national companies or international clinical trials networks. Academic responses (individual or organizational) included three from Illinois-based universities (Lurie Children's Hospital, Northwestern University, University of Illinois at Chicago Population Health Sciences Program); two from Georgia (both at Emory University), two from Maryland (Johns Hopkins and University of Maryland), two from Pennsylvania (Pennsylvania State University and the University of Pittsburgh Medical Center), one from California (Stanford University), one from New York (Weill Cornell), one from Missouri (Washington University), one from Massachusetts (Boston University Medical Center), one from North Carolina (Duke University School of Medicine), one from Tennessee (Vanderbilt University), and one from the District of Columbia (Georgetown University).

STPI's approach to analyzing the RFI followed the RFI's structure. We began by developing a deductive coding framework corresponding to the key phrases found in the RFI topics and sub-parts. We then extracted text from the RFI responses corresponding to each topic. Many responses were structured based on the topics in the RFI and so no judgement was needed to map particular blocks of text to individual topics; where responses were less well-structured, STPI staff judgement was used to relate portions of the response to corresponding RFI topics and sub-parts. Once the text corresponding to each RFI topic was extracted, we then mapped the text to the deductive coding framework to identify which responses were relevant to each portion of the RFI topics and to

summarize relevant responses. Where the RFI responses suggested that an alternative approach might produce a more useful summary, STPI staff inductively recoded the responses to identify relevant themes for the summary.

General support was stated in most responses for the primary issues represented in the RFI (e.g., building a centralized governance structure for emergency clinical trials [ECTs] response; increasing diverse participation and protecting vulnerable populations; standardizing an Emergency Master Agreement [EMA] in advance of an emergency). However, recommendations for specific ways to accomplish these tasks varied within and across groups of responses. Some specific key findings from this RFI summary include:

- There was support for building a centralized governance structure for emergency clinical trials response.
  - Activities suggested for a governing body by multiple responses included: redefining clinical trials, standardizing requirements, streamlining data capture and data access, simplifying or unifying human subjects review, and supporting recruitment of diverse populations.
  - Some responses recommended that a cross-agency advisory group consisting of community members (including representation from vulnerable and underrepresented groups), federal representatives, and other relevant stakeholder groups (including academic, industry, and advocacy members) be incorporated into the governance structure.
  - Some responses recommended that the governance structure should build upon existing networks, coordinating centers and systems.
  - Some responses recommended that the governance structure should make use of master protocols.
- Strong support was expressed in RFI responses for increasing diversity in clinical trials. There was also general consensus that increasing participation in trials generally would increase diversity.
  - Community outreach, decentralized clinical trials (DCT), digital health technologies (DHT) use, and leveraging the use of community-based care networks and retail pharmacy chains were considered effective processes for increasing diversity of clinical trials.
  - Responses recommended that the federal government provide funding to incentivize diverse sites to participate in emergency clinical trials, including identifying and providing readiness funding for sites likely to be in high-prevalence areas and that serve diverse populations and relying on networks with proven capabilities in recruiting diverse populations such as through participation in COVID vaccine trials or oncology trials.

  - Regulatory flexibilities, including licensing flexibility such as State licensing flexibilities (e.g., interstate compacts or conducting telehealth visits across State lines) were considered useful in incentivizing clinicians and sites to participate.

- Responses favored the idea that ongoing research should be supported in advance of an emergency ("warm base" research) to maintain readiness.
  - Responses identified a range of conditions that might be appropriate for warm base research. Non-communicable diseases (e.g., diabetes, heart disease, cancer), respiratory diseases (e.g., coronavirus), and other infectious diseases were some of the disease areas specifically named as most relevant to underserved communities.
  - Using warm base research as a means for providing ongoing clinical research training to community sites was a common theme in responses.
  - Responses varied as to whether warm base research would be better supported through a public-private partnership or a federal agency-managed effort, with different responses providing support for each approach.
- Responses supported the idea that an EMA should be pre-defined and adopted by sites willing to participate in emergency clinical trials.
  - Some responses considered negotiating and managing an EMA as a core function of the ECT governance structure.
  - Some responses expressed support for the idea that under an EMA, clinical protocols should be reviewed by a single institutional review board (IRB), although these responses identified that existing IRBs should be used rather than creating a wholly new IRB to serve the ECT network specifically.
  - Several responses proposed specific approaches to other potential EMA terms such as data use, publication, confidentiality, intellectual property, indemnification, and compensation for injury.
- Responses supported the need for international harmonization of ECT efforts and the idea that any U.S.-based ECT network should work closely with other countries' efforts and global coordination bodies such as the World Health Organization.
- The majority of responses received addressed governance (Topic 1) and diversity (Topic 2) but varied in their answers to the individual sub-parts of those topics. Very few responses were received to this RFI that addressed viable data capture (Topic 5). This was expected, in light of the companion RFI that OSTP issued regarding data collection for emergency clinical trials.[2]

- Many of the responses, both structured and unstructured, included requests that the federal government streamline regulatory processes, data sharing and use of electronic health records, and provide more support for existing and new clinical trials networks.

Contents

1. Introduction and Summary of Responses Received

A. Introduction and Approach

On October 28, 2022, OSTP released the "Request for Information (RFI) on Clinical Research Infrastructure and Emergency Clinical Trials." This RFI was originally scheduled to close on December 27, 2022 but was extended to January 27, 2023. The RFI included six topics, five of which included multiple sub-parts. Rather than present the text corresponding to each topic at the beginning of each section providing our analysis, the text of the entire RFI is included as Appendix A.

STPI's approach to analyzing the RFI followed the RFI's structure. We began by developing a deductive coding framework corresponding to the key phrases found in the RFI topics and sub-parts. We then extracted text from the RFI responses corresponding to each topic. Many responses were structured based on the topics in the RFI and so no judgement was needed to map particular blocks of text to individual topics; where responses were less well-structured STPI staff judgement was used to relate portions of the response to corresponding RFI topics and sub-parts. Once the text corresponding to each RFI topic was extracted, we then mapped the text to the deductive coding framework to identify which responses were relevant to each portion of the RFI topics and to summarize relevant responses. Where the RFI responses suggested that an alternative approach might produce a more useful summary, STPI staff inductively recoded the responses to identify relevant themes for the summary. Where RFI responses mentioned specific facts (e.g., organizations, pieces of legislation) but did not provide context regarding those facts, OSTP sponsors asked that STPI provide supplementary information and context. In those cases, the supplementary information can be found in footnotes.

B. Overall Summary of Responses

Seventy-seven responses to the RFI were received. The list of respondents can be found in Appendix B. STPI staff characterized the organization types of those respondents (Table 1). Twenty-three of these responses came from industry, with another 15 provided by professional and industry associations. Individuals and groups from academia provided 18 responses. The remaining responses came from stakeholder groups (eight responses), advocacy groups (six responses), individuals without academic affiliations (two responses), research entities (three responses), the federal government (one response), and one TV provider. Of the responses, 46 were from U.S.-based companies, associations, or

research entities and 13 from global/multi-national companies or international clinical trials networks. Academic responses (individual or organizational) included three from Illinois-based universities (Lurie Children's Hospital, Northwestern University, University of Illinois at Chicago Population Health Sciences Program); two from Georgia (both at Emory University), two from Maryland (Johns Hopkins and University of Maryland), two from Pennsylvania (Pennsylvania State University and the University of Pittsburgh Medical Center), one from California (Stanford University), one from New York (Weill Cornell), one from Missouri (Washington University), one from Massachusetts (Boston University Medical Center), one from North Carolina (Duke University School of Medicine), one from Tennessee (Vanderbilt University), and one from the District of Columbia (Georgetown University).

Table 1. STPI Characterization of RFI Responses by Organization Type

Organization Type	Number of Responses
Industry	23
Professional Association	10
Individuals (with academic affiliation)	9
Stakeholder Group	8
Advocacy Group	6
Academic Research Groups	5
Industry Association	5
Academic Health Centers	4
Individuals (no reported academic affiliation)	2
Research Entity (MITRE, BCG, RTI)	3
Federal Government	1
Other (Clinical Trials TV)	1

2. Analysis of RFI Topics

In this chapter, we analyze the responses to the individual topics and sub-topics in the RFI. The first six sections of this chapter (Sections A through F) correspond to Topics 1–6 of the RFI. The last section (Section G) is a summary of short or unstructured responses.

A. Topic 1: Governance for Emergency Clinical Trials Response

1. Overall Summary of the Response

Topic 1 of the RFI asked for information on governance for emergency clinical trials response. Forty responses included information relevant to emergency clinical trials governance or one of the 12 sub-topics related to governance (See Appendix C for more detail). The majority of responses were received from industry or industry associations (16) or academic affiliated individuals or groups (8). No individual response fully answered all 12 sub-topics, and most sub-topics were addressed by only a few responses. There was little consensus across responses (even within organization type) on any of the related sub-topics within this topic. Rather than attempting to summarize each sub-topic individually, this section of the RFI analysis focuses on the sub-topics that received the most attention from among the respondents.

2. Governance – General Points: Functions and Activities

- Many responses did not define in detail the functions that were included in their discussion of "governance structure." The BCG response (response #51) was notable for identifying separate functions such as overarching leadership, a clinical research agenda committee, a study leadership group, and a study execution group. Their response included two detailed models—one where the U.S. government drives study execution and serves as the leader of all four functions; in a second model, while the U.S. government provides overarching leadership, leads the clinical research agenda committee, and maintains the standing infrastructure that supports trials, separate sponsors (e.g., from industry) would lead study design and execution.
- Several responses (INSIGHT, Genentech, Association of American Medical Colleges [AAMC]) recommended a cross-agency advisory group consisting of community members (including representation from vulnerable and

underrepresented groups), federal representatives, and other relevant stakeholder groups across sectors (including academic, industry, and advocacy members).

- Activities suggested for a governing body by multiple responses included the following: redefining clinical trials (FABBS, Grimes & Yajima, IQVIA), standardizing requirements (AMIA, INSIGHT, streamlining data capture and data access (AAMC, ACRO, AWS, CONNECTS), and supporting recruitment of diverse populations (AWS, AdvaMed, BCG, Grimes & Yajima, Syneos). Several other responses suggested setting up a scientific advisory group (ACRO, Genentech, INSIGHT, Syneos) as part of the governance structure.
- A few responses suggested looking to other specific models that were not described in detail, including: Australia's model (Oracle), a network of networks model (SCCM, RTI), and the Centers for Disease Control and Prevention (CDC) advisory councils (Genentech).
- Several responses suggested lead groups for emergency clinical trials governance including OSTP (COGR), the Office of Pandemic Preparedness and Response Policy (BIO, SCCM, Stanford University, Genentech),[1] the National Security Council (eMed), and the Department of Health and Human Services [HHS] (INSIGHT).

3. Initiation of Emergency Clinical Trials and Tracking of Institutions, Networks and Sites that Might Be Able to Participate in Emergency Research

Responses related to these topics varied across commenters, but relevant responses included the following:

Initiation

- Link ECT initiation to public health emergency criteria (Oracle);
- Use the World Health Organization (WHO) designation of a pandemic or global emergency (Syneos Health, Duke SOM);
- Undertake a rapid assessment of pre-existing treatments that might be effective for the given pathogen at time of outbreak and focus initial clinical trials on the efficacy of those repurposed treatments while looking for potentially more effective treatments (CONNECTS);

[1] The creation of the Office of Pandemic Preparedness and Response Policy was authorized in December 2022 in Section 2014 of the Consolidated Appropriations Act, 2023 (Public Law 117-328). As of the publication of this summary, the implementation of the office is still ongoing.

- Consider scope, severity, and location; allow SMEs on governance committee to decide when coordinated large-scale clinical research is required based on specific occurrences (ICON GPHS);
- Consider whether the incident is poised to spread, the scale of the potential impact, the extent to which potential clinical outcomes are understood, and whether available therapies and other tools are adequate (BCG); and
- Initiation should be triggered by rapid, large-scale infection with significant morbidity and mortality (RTI).

Tracking institutions, networks and sites that might be able to participate in emergency research

- Use existing networks, coordinating centers and systems to track already-contributing or potentially contributing sites (Oracle, CONNECTS, Verily, RTI, MITRE).

4. Best Practices for Protocols, Enrollment, and Regulatory Interactions

- Responses related to the enrollment of vulnerable populations were generally similar to but less detailed than the responses provided for Topic 2b (increasing diversity in enrollment, discussed in Section B.3 of this chapter). However, several responses suggested that ensuring diversity of trial sites would promote enrollment of vulnerable populations and also allow for steady enrollment given that the diseases that are the subject of ECTs likely will be peaking at some network sites and less prevalent at other sites over the course of the trial period (Weill Cornell, INSIGHT, Verily, AdvaMed, BCG).
- The UK RECOVERY trial used a master protocol with few deviations from standard practice and minimal data entry to maximize enrollment and minimize training and effort (Grimes & Yajima). UK and Israel effectively used master protocols in COVID- 19 vaccine trials (Syneos Health).
- Keep protocol design simple (INSIGHT, ICON GPHS) and flexible (CONNECTS, RTI).
- Build future-looking protocols—where a task force creates, and IRBs review, a set of protocols covering a range of scenarios that can be deployed quickly in the event of an emergency (eMed).
- Include healthcare technology companies or other relevant groups in the development of guidelines and template development (Oracle, ICON GPHS, AAMC).
- Determine quality controls early (Verily).

- To assist in addressing international regulatory issues, include international membership in executive committees (INSIGHT) or expand U.S. Food and Drug Administration (FDA) influence in international issues (CONNECTS, Bio).

5. Data and Biorepositories

Few responses addressed data or biorepositories. The majority of the responses to the data or data access topics were provided by groups or individuals who also responded to a companion RFI regarding data collection for emergency clinical trials.[2] Their responses to this RFI topic were similar but also brief. General comments on data and biorepositories included the following:

- Keep data simple and collect only what is necessary (MD, INSIGHT, CONNECTS, ICON).
- Harmonize State and institutional requirements for research conduct and administration (Milken_FasterCures).
- Recommended models: UK Bio Bank (ACRO, Syneos), NIH's *All of Us* program (Oracle), Health Data Banks (HRBA), clinicaltrials.gov and the global trial registry (TranspariMED).
- Consider building a virtual biorepository, where samples held at multiple institutions are connected through a single portal or database and where samples can be shared rapidly through cross-network material transfer agreements or data transfer agreements (RTI).

B. Topic 2: Identifying and Incentivizing Research Institutions and Networks; Building Diversity and Equity

1. Overall Summary of the Response

Topic 2 of the RFI asked for information on identifying and incentivizing research institutions and networks, and increasing diversity in clinical trials. Forty-four responses were received that were germane to Topic 2 (See Appendix C for more detail). The majority of those responses involved individuals or groups associated with an academic institution (19) or industry/industry groups (14), with nine from advocacy or stakeholder groups. The remainder of responses were from unaffiliated individuals or other groups (U.S. Congress).

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[2] "Request for Information on Data Collection for Emergency Clinical Trials and Interoperability Pilot," Federal Register Document 2022–23489, 87 *Federal Register* 65259-65262, October 28, 2022.

2. Methods for Identifying Institutions and Sites

- Provide funding to incentivize networks to develop clinical trial sites to broaden existing networks (e.g., by engaging non-academic community hospitals to serve traditionally underrepresented populations with support [eMed Labs, Lilly, PPD, IQVIA, AAMC, INSIGHT, ACRO, McKesson, Regeneron, PRIM&R, Duke SOM, Boston Medical Center]). One group of responses focused on identifying and providing readiness funding for sites likely to be in high-prevalence areas and that serve diverse populations, regardless of whether they participate in existing networks (Lilly, ACRO, Regeneron, Duke SOM, Boston Medical Center). A second set of responses suggested relying on networks with proven capabilities in recruiting diverse populations such as through participation in COVID vaccine trials or oncology trials (PPD, IQVIA, AAMC, INSIGHT, ACRO, McKesson, Regeneron). Other points made were:
  - Provide funding to maintain networks, tested for responsiveness through regular "fire drills" (eMed).
  - Recruit non-academic community hospitals that serve diverse populations, including sites that were recruited during the COVID emergency, to serve as network clinical trial sites (INSIGHT, PRIM&R).
  - Fund an international network of coordinating centers to support emergency clinical trials (INSIGHT).
- Identify sites whose patient/disease populations are relevant during an emergency; will need flexibility in putting together clinical trials/networks in response (Lilly, Genentech, AWS, Regeneron, Boston Medical Center, Hopkins CTSA).
- Improve the network governance structure's situational awareness regarding existing networks and capabilities (AAMC, INSIGHT, ACRO, Hopkins CTSA).

3. Effective Ways to Increase Diversity

All responses to this part of Topic 2 acknowledged the importance of increasing diversity in clinical trials and welcomed any efforts by OSTP or other federal entities to assist. There was also general consensus that increasing participation in general would increase diversity and that community outreach, decentralized clinical trials (DCT), digital health technologies (DHT) use, and leveraging the use of community-based care networks and retail pharmacy chains were effective for both. Six of the responses (ICON, Curebase, COGR, ACRO, Walgreens, Duke SOM) specifically called out retail pharmacy chains as partners because they are well-positioned to engage traditionally underrepresented populations due to their geographic distribution and ease of access. Most responses provided general advice with respect to best practices or specific methods by which to use

these tools to increase diversity. Partnerships with local community groups, diversifying the clinical trial staff, and building community trust were the most common suggestions for increasing diversity provided in the responses. General themes emerged, including:

- Pursue community outreach opportunities with historically underrepresented communities through engagement with groups such as community-based organizations, universities, and faith institutions (Milken, ASH, PhRMA, PPD, Medable, ICON, IDSA, Curebase, IDCRC, Regeneron, ACT@POC, CHI, Boston Medical Center, Johns Hopkins CTSA).
- Building trust is important (PhRMA, Lilly, PPD, ACT@POC, CHI, Duke SOM, Boston Medical Center) and can be facilitated through community outreach.
- Train a diverse health workforce to improve trust, facilitate diverse patient recruitment, and outreach/improve science (ASH, Lilly, Verily, IDSA, SWHR), including specific recommendations such as requiring all trial funders to submit diversity plans (ASH), developing funding, mentorship, or coaching programs to encourage individuals from underrepresented groups to become trial principal investigators (Lilly, SWHR), and encouraging network sites to conduct diversity assessments and to act on their results (SWHR).
- Broaden clinical trial eligibility criteria (PhRMA, ACOG, Johns Hopkins CTSA, Jeffrey Goldstein [individual], SWHR), with four responses (ACOG, Goldstein individual response, Johns Hopkins CTSA, SWHR) focusing specifically on pregnant and lactating populations; the Johns Hopkins response also mentioned prisoners, children, and the chronically ill and disabled.
- Initiate and maintain trial sites in underserved communities (Vir, PhRMA, PPD, Curebase, BCG, ACRO, Regeneron, ACT@POC, Duke SOM).
- Expand use of decentralized clinical trials and "bring your own device" (BYOD) trials that collect patients' data from their own devices as part of clinical protocols (Lilly, Medable, Verily, ICON, Curebase, BIO, Genentech, MITRE, AWS, Regeneron, Datacubed, CHI, Duke SOM, BIO, Johns Hopkins CTSA).
- Engage patients/community members in decision making early, including on trial design (PhRMA, AMIA, FAS).
- Informed consent across diverse populations requires special efforts and infrastructure such as translating consent language into multiple languages in culturally appropriate fashion, making available space for providing informed consent when patients arrive in family groups, and fashioning consent language specific for protected populations such as prisoners or pregnant populations, (Boston Medical Center, Care Access, Johns Hopkins CTSA).

4. Encouraging Participation

- Decentralized trials, remote participation, and making use of digital health technology are all means for encouraging participation by reducing the requirement for patients to travel to clinical sites (PhRMA, PPD, Medable, IDSA, BIO, Care Access, Datacubed, AWS, McKesson, DiMe, Alliance for Connected Care, CHI).
- Simpler trials that reduce patient data collection and physician workload (Curebase, Stanford) will encourage participation, as will patient-centered trials that reflect individuals' preferences for interaction, for example by combining remote and in-person contacts (Verily). The Stanford and ACT@POC responses mentioned the UK's RECOVERY trial as a potential model.
- Licensing flexibility such as State licensing flexibilities (e.g., interstate compacts or conducting telehealth visits across State lines) (Bayer, Genentech, BIO), limited waivers differentiating between medical licensing for trial conduct and for providing care (Bayer, Genentech), or national licensing to preempt State law for the conduct of emergency clinical trials (ACRO).
- Other areas suggested for regulatory flexibility include:
  - Federal anti-kickback statute (McKesson)
  - HIPAA/PHI restrictions (McKesson)
  - Informed consent waivers and exceptions to facilitate time-sensitive or life-saving treatment (ACEP/SAEM) or waivers to allow individuals in addition to study key personnel to perform consent procedures(Johns Hopkins CTSA)
  - Direct-to-patient shipment of investigational drugs (CHI)
  - Rolling FDA reviews of clinical data (CHI)
  - Use continual data flows from DHTs to address adverse events Simplified FDA approval of new indications for repurposed drugs (Eric Lenze [individual])
  - Streamlined contracting and data capture (Johns Hopkins CTSA)
- Compensating participants for participation or for travel expenses (IDSA, FAS, SWHR).
- Electronic consent so that participants could use their devices for consenting rather than in-person visits (PPD, Datacubed).
- Pharmacies/other clinical sites (e.g., drug treatment centers, home health care, mobile sites) [PPD, Syneos, NHLBI CoNNECTS, IDSA, Care Access, McKesson, DiMe, Berger (individual)].

- Federally Qualified Health Centers (FQHCs) are often located in communities with underrepresented populations, so involving FQHCs in clinical networks can facilitate recruitment of diverse patients to clinical trials (Syneos, Duke).

5. Communicating Interest and Site Information

Respondents did not directly address Topic 2d (how to recognize institutions and networks that are interested in emergency clinical research, and how to collect information from them). In general, information provided in response to Topic 2a (site identification) was the only information received that was relevant to Topic 2d. Specifically, to identify sites with appropriate patient populations, responses recommended collecting data on the potential participant population.

6. Best Ways to Provide Training in Clinical Trial Practice

Many responses to Topic 2 did not explicitly address best practices in training; those that did included the following responses:

- Use clinical research organizations (CROs) or other partners to improve training at sites (Keyrus, Oracle, ICON).
- Develop common/national standards for training (NHLBI Connects, Curebase).
- Provide DEI/culturally responsive training (Duke SOM, Boston Medical Center).
- Some additional individual comments:
  - Use virtual study coordinators to support multiple sites (NHLBI Connects).
  - Support junior and early career researchers by creating alternative opportunities to large-scale funded clinical trials (ACEP and SAEM).
  - Facilitate interdisciplinary and interprofessional research opportunities that incorporate all aspects of emergency care (ACEP and SAEM).
  - Training on the use of new technologies and innovations (including mobile apps and the BYOD model) in clinical trials (CHI).

C. Topic 3: "Warm Base" Research

1. Overall Summary of the Response

Topic 3 of the RFI asked for information on conducting "warm base" research, i.e. ongoing studies that gather data under a particular trial protocol and also serve the function of keeping trial sites ready to undertake additional research, such as emergency clinical trials. A total of 27 responses were received that were germane to Topic 3 (see Appendix C for more detail).

Responses to Topic 3a (diseases that should be targeted in warm base research) showed the widest variability within Topic 3 overall. Sickle cell disease, venous thromboembolism, respiratory diseases (e.g., coronavirus), and infectious diseases were some of the disease areas specifically named as most relevant to underserved communities. MITRE emphasized the need to address specific research topics in each disease area and provide a warm base network of tools and support for clinical trial sites.

Seven responses emphasized the need for long-term, community-based warm base research that incorporates the views of the local populations. Selected suggestions included using the National Institutes of Health (NIH)-based National Clinical Trials Network (NCTN) as a model (Syneos Health), tailoring the research to fit the needs of the region (e.g., Lyme disease in New England, diabetes research in southwest Louisiana; MITRE), and using existing public-private partnerships to build research capacity. An increase in funding for clinical trial research was also a common thread across responses (Milken, Syneos Health, UIC Population Health Sciences Program, Infectious Diseases Society of America).

Twenty responses provided input on how warm base research could be best implemented to provide training to inexperienced sites. Selected responses included investing in research infrastructure and capacity (AAMC), investing in and expanding public-private partnerships that support warm base research (1Day Sooner), and investing in and expanding existing and new platforms that assist in training and help manage workload at clinical sites (Curebase).

2. Disease Areas That Should Be Targeted through Warm Base Research

Several responses identified specific disease areas that should be targeted for ongoing research as part of warm base activities:

- Sickle cell disease and other high-health burden and unmet medical need diseases that impact traditionally underserved populations (African-Americans and Hispanics) (ASH, MITRE)
- Non-communicable diseases such as Type II diabetes, asthma, cancer, obesity, and cardiovascular or heart disease (Milken, Oracle, Curebase, ACT@POC, AWS)
- Infectious diseases such as coronaviruses, influenza, pneumonia (1Day Sooner, INSIGHT, Curebase, Oracle)
- Hematologic diseases (ASH)
- Region-specific disease foci: Lyme disease in the new England area; obesity/diabetes/cardiovascular disease in Southwest Louisiana (Care Access, Duke)

Some responses regarding the disease areas that could be targeted as part of ongoing warm base research also provided a rationale for the benefit of this research. For example, the 1Day Sooner response, which recommended a focus on coronaviruses, noted that this research would be valuable in bringing medical countermeasures, including vaccines, to market more quickly, and that such vaccines could both restrict viral mutation and serve as prototypes for countermeasures needed in future respiratory outbreaks from the same viral family. The Curebase response, in recommending a potential focus on heart disease and diabetes, saw the warm base effort as being valuable in supporting trials involving real-world data (RWD) or registries, which would allow for effective outreach to underrepresented populations and create an opportunity to train community physicians in clinical research.

3. How Warm Base Research Could Be Implemented

Responses to this topic varied. Some responses considered implementation in the context of the types of investment required:

- Need consistent funding to develop research infrastructure and capacity; development of community-based infrastructure to support clinical trials (Milken, 1Day Sooner, AAMC, UIC, IDSA).
- Establish incentives for clinical trial sites to complete non-vaccine work, including access to prequalified IRBs (IQVIA).
- Invest in warm base infrastructure, diagnostic capabilities, manufacturing capacity and supply chains (CSRI).

Some responses considered implementation in the context of partnerships and collaborations:

- Continue use of successful networks and partnerships (PhRMA, Oracle, RTI).
- Use a vendor/partner ecosystem to train research-naïve sites and provide surge capacity and staffing for emergency clinical trials (Oracle).
- Develop networks that focus on building capacity for research in rural and underserved communities (NHLBI, Curebase).
- Identify a network of sites and site leads committed to conducting trials, with representation from large academic institutions & community sites (Vir Biotechnology).
- Implement mechanisms that can test sites' ability to participate in the warm base network and to contribute reliable data (MITRE).

Some responses considered implementation in the clinical research context, including comments on protocol development, research approaches, patient recruitment, and statistical designs:

- Develop protocols targeting widespread health conditions and include an element of early diagnosis and/or health screening (Care Access).
- Create a research approach that fosters knowledge of applicable regulatory requirements, establishment of clinical investigations systems and processes, and data collection/analysis/reporting (COGR).
- Ensure companies are developing platforms and innovative solutions (e.g., digital health technologies) to help community hospitals anticipate upcoming research and develop research pipelines (Milken, Curebase).
- Ensure warm base research includes active planning to develop best statistical analysis designs for clinical trials; training and support for staff (NHLBI, Curebase).
- Prioritize robust representation of underrepresented groups to participate in warm base research (NHLBI, RTI, Curebase).
- Recruit a cadre of potential research participants in advance (who likely will be highly motivated) (Curebase).
- As part of the process of identifying which diseases to target for warm base research, collect community perspectives in addition to collecting localized disease epidemiology, risk factors and mortality data (IQVIA).

4. Mechanisms for Supporting Warm Base Research

The RFI asked if warm base research could be appropriately supported as a demonstration project, as a public-private partnership, or as an agency-funded effort.

- Four responses considered a multi-year agency-funded program to be the best option (Curebase, Oracle, IDSA, COGR) as such an approach could practically build on existing clinical trials infrastructure.
- Five responses suggested a public-private partnership as the best option (Milken Faster Cures, 1Day Sooner, ACT@POC, Duke, AdvaMed) because such an approach could speed technology development and because "warm base" research capacity would be most sustainable if the health care system incorporated it into standard workflows.

Some responses mentioned interim or second-best solutions. The Oracle, ACT@POC, and Regeneron responses suggested a short-term demonstration project (with the Oracle, COGR, and ACT@POC responses identifying the demonstration as a path toward the

agency-funded effort). The 1Day Sooner response identified an agency-funded program as being feasible, although a public-private partnership would be preferable. The Curebase response identified both demonstration and public-private partnerships as feasible, although an agency-funded effort was considered most practical. The IDSA response mentioned leveraging public-private partnerships in the context of an effort funded primarily by the federal government.

D. Topic 4: Emergency Master Agreement

1. Overall Summary of Responses

Twenty-four responses were received that were germane to Topic 4 (See Appendix C for more detail). Before providing detailed responses to Topic 4 and the following sub-topics, 16 responses provided high-level comments pertaining to an Emergency Master Agreement (EMA). Five of these responses (SCCM, Datavant, AWS, IQVIA, American Society of Hematology) expressed general support for an EMA or offered advice on developing an EMA:

- EMAs establish expectations and expedite the contracting and regulatory requirements, which allows for more nimbleness and flexibility in an emergency (SCCM). The SCCM response identified five essential elements of an EMA: pre-positioning prior to the emergency, flexibility, scalability, the ability to incorporate event-specific additions, and local context review to consider the needs of communities in which trials are being conducted.
- The development of standardized and pre-signed agreements for emergency clinical trials is one of the most effective means to accelerate emergency clinical research (Datavant).
- OSTP should consider using these kinds of agreements for non-emergency situations in areas such as cancer research (AWS).
- A focus group should be conducted to gather feedback on how to optimize the contracting process for emergency situations (IQVIA).
- Existing networks such as the American Society of Hematology Research Collaborative could provide an efficient way for the U.S. government to negotiate and develop EMAs (ASH).

Five of these responses (ICON, Council on Government Relations, AWS, FABBS, Curebase) shared examples as a reference for creating an EMA:

- Master Service Agreements offer an analogous example, since they provide basic terms for larger contracts and may include topics such as data ownership

rights, information accessibility, publication rights for trial data, and institutional review board considerations (ICON).

- The Federal Demonstration Partnership (FDP) has developed a fixed rate clinical trial subaward template and associated guidance document, which provides an analogous example. In addition, the response suggested the Accelerated Research Agreements Initiative and the model clinical trial agreement forms they developed: The Accelerated Confidential Disclosure Agreement, Accelerated Clinical Trial Agreement, and the CTSA Data Transfer & Use Agreement (COGR).
- The Trusted Exchange Framework and Common Agreement (TEFCA) offers potential starting points for the development of data sharing agreements (AWS).
- UK Research and Innovation (UKRI) offers a useful model for developing interdisciplinary teams that connect stakeholders and provide inputs on improved practices for clinical trial approval (FABBS).
- The Accelerated Clinical Trials Agreement offers an example template (Curebase).

Three of these responses (INSIGHT, AAMC, Oracle) provided general recommendations:

- Creating these agreements should be a responsibility of the governance structure (described under Topic 1). They should be concise and should enable international collaboration (INSIGHT).
- The process should begin with a comprehensive look at the impact of existing harmonization efforts and templates. One major question to address is how nationally-developed protocols will be coordinated with other clinical trials developed by industry, academic health centers and other organizations. (AAMC).
- The agreements should establish default legal terms, including terms that parties would accept to meet minimum legal/regulatory requirements. A mechanism could also be added for individual studies that need to define additional terms to override the default terms in specific circumstances. (Oracle).

Last, three of these responses (Keyrus, Care Access, Datavant) came from companies that expressed a desired role in the creation of an EMA framework:

- Keyrus offered to create an EMA focused on basic terms that could be relevant for any coordinated or large-scale emergency clinical trial, including provisions that allow for data gathering under common protocols, site coordination, and data access between sponsors and research partners.

- Care Access highlighted their interest in streamlining the contracting and activation of clinical research sites by enabling a single contract to be used for the activation of all study sites.
- Datavant highlighted their experience in areas relevant towards the development and support of a future Master Emergency Use Agreement, including use of de-identified data for site selection, and post-marketing surveillance.

2. Basic Terms of an Emergency Master Agreement: Data Collection, Publication of Trial Data, and a Proposed Single IRB under an Emergency Master Agreement

Two respondents (Oracle, Curebase) provided input on the topic of data collection and use, including ownership of the study data, as well as the right to collect, store, and use the data and specimens.

- Oracle responded that entities should have the right to collect and store data generated through the study, but should not include other sensitive materials such as patient medical records and source documents. In addition, they asserted that sponsors should have the right to use data towards applications such as publication, patient care, internal education, and noncommercial research. This data usage could be guided by agreements such as informed consent and signed authorizations.
- Curebase suggested that sponsors could share data with the individual research participants to provide access to their own health records.

One respondent (Oracle) provided input on the topic of publication and accessibility of trial data; Oracle suggested that participating institutions should be able to use and publish data generated from their own site, after a sponsor review process and removal of any confidential information. In addition, Oracle suggested that participating sites could be provided access to wide de-identified data upon the conclusion of publicly funded studies.

Five respondents (Oracle, RTI, Curebase, Genentech, NHLBI) indicated general support for a centralized IRB to facilitate trials; however, each had reservations about creating an IRB devoted to emergency clinical trials because it would be more efficient and effective to utilize an existing IRB than to create a wholly new IRB specialized for emergency clinical trials.

3. Additional Terms: Confidentiality, Patents/Intellectual Property, Control of Study Drug, Indemnification, and Compensation for Injury under an Emergency Master Agreement

Three respondents (Regeneron, Oracle, Advanced Medical Technology Association) provided input on "confidentiality" terms for an EMA. The Regeneron response suggested

that confidentiality should include patient health information, study materials, information related to the study, and inventions. The AMTA response suggested that confidentiality should extend to business information and processes developed during the course of the study. The Oracle response defined "confidentiality" as:

- "Confidential Information should include information disclosed and identified as confidential to the participating site by or on behalf of the sponsor to conduct the study and any data generated in performance of the study."

Three respondents (Regeneron, Oracle, Advanced Medical Technology Association) provided input on "patents/intellectual property" for an EMA. The Regeneron response focused on ownership of inventions during the study, while the AMTA response focused on sponsor rights to the data developed during the trial. The Oracle response proposed the following terms related to inventions during the study:

- "Any new inventions, developments, or discoveries made in the performance of the protocol, and which incorporate sponsor's confidential information ('Inventions') shall be promptly disclosed to sponsor. Title to Inventions which are enhancements, modifications, or improvements of the sponsor's study drug or study device and that are made during and in performance of this agreement shall reside with sponsor ('Sponsor Inventions')."

One respondent (Oracle) provided input on how to define "control of study drug" for an EMA:

- "Unless stated in writing by sponsor, all items are and will remain the sole property of the sponsor until administered or dispensed to study subjects during the study. Receipt, storage, and handling of study drug or study device will comply with all applicable laws and regulations, the protocol, and the sponsor's written instructions."

Two respondents (Regeneron, Oracle) provided input on how to define "indemnification" for an EMA. Regeneron's response suggested that indemnification should be limited to administration of study drug and proper performance of study procedures. The Oracle response defined "indemnification" more broadly, to include "any third-party claims … alleged to be caused by or arising from the conduct of the study or use of the study drug or device … or from the sponsor's use of the study results."

One respondent (Oracle) provided input on how to handle "compensation for injury" under an EMA: "If a study subject suffers an injury directly caused by a [study drug/device] and/or any properly performed procedures required by the protocol, sponsor shall reimburse for the reasonable and necessary expenses of diagnosis and treatment of any study subject injury," unless the injury resulted from negligence, willful misconduct, an

underlying or pre-existing condition, or an institution's failure to adhere to and comply with the protocol.

4. Gathering Input from Key Stakeholders on Emergency Master Agreement Terms

Four respondents (Oracle, Duke SOM, COGR, SCCM) provided suggestions on the best way to get input of key stakeholders on EMA terms. Two of these respondents (Oracle, Duke SOM) highlighted the potential to leverage established networks and programs, with the Duke SOM response specifying the NIH ComPASS and Community Engagement Alliance (CEAL) programs as particular groups that could be engaged in discussions on EMA terms. The COGR response noted that emergency clinical research benefits from international collaborations, so that guidelines for promoting (or restricting) international collaboration and data sharing should be incorporated into the EMA. The SCCM response, which suggested a network-of-networks approach to organizing and governing emergency clinical research, noted that this approach would facilitate convening stakeholders around development of EMA terms.

5. Approaches to Facilitating Stakeholders' Understanding and Adoption of the Emergency Master Agreement Framework

Two respondents (Oracle, Duke SOM) suggested approaches to facilitating stakeholders' understanding and adoption of the EMA framework. The Oracle response suggested that OSTP could partner with clinical research organizations and health IT organizations to provide outreach within the broader healthcare community on EMA frameworks. The Duke SOM response commented that the National Center for Advancing Translation Sciences (NCATS) Streamlined, Multisite, Accelerated Resources for Trials (SMART) IRB offers an example approach towards a streamlined IRB review process.

E. Topic 5: Identifying Viable Technical Strategies for Data Capture; Gathering Information About a Potential Data Capture Pilot

1. Overall Summary of Responses

Topic 5 of the RFI asked for information on viable technical strategies for clinical trial data capture, noting that this topic would be the subject of a separate RFI. Six responses received were germane to Topic 5 (See Appendix C for more detail). Three industry responses (Keyrus Life Science, ICON, and Datacubed) wished to offer data capture and management services to the data capture pilot mentioned in the RFI.

The response from the American Medical Informatics Association (AMIA) encouraged OSTP to leverage resources from across the federal government and to implement data principles such as FAIR (findable, accessible, interoperable, and reusable).

Links to several scientific publications with resources were provided. The response also suggested bolstering the public health informatics workforce, including by establishing national centers of excellence for public health informatics. Finally, this response emphasized the importance and privacy and recommended the use of informed consent when collecting and working with data.

The response from the Consortium for State and Regional Interoperability (CSRI) expressed anticipation for a future data capture RFI. It said that interoperable State health data networks are well positioned to support the data capture needs of clinical trials.

The response from Genentech applauded the use of "real world data" in regulatory decision making. The response also criticized the FDA on several points. Genentech suggested using technologies that became more widespread during the pandemic, such as QR codes, mobile passes, and RFID tags, to collect "constantly accessible" data from participants. However, they noted the importance of maintaining patient privacy. Finally, the response suggested exploring methods to present collected data in accessible ways that accommodate varying levels of health literacy.

The Health Record Banking Alliance commented that a clinical trial infrastructure could be built on a foundation of patient-centric health data banks (HDBs).

Additional comments on this topic were collected in response to OSTP's companion RFI on data collection for clinical trials, and those responses are summarized in a separate document.

F. Topic 6: International Coordination and Capacity

1. Overall Summary of Responses

Topic 6 of the RFI asked for information on international coordination of emergency clinical trials response. A total of 25 responses were coded to Topic 6 (see Appendix C for more detail). Under Topic 6, there were cases where a response was addressed to a particular sub-topic even though concepts associated with that response might have been more germane to a different portion of the RFI. In those cases, STPI staff summarized the information as the responses presented it and added footnotes to indicate where we did so.

Fourteen responses emphasized the need for an overarching governance structure for international coordination of emergency clinical trials. Most companies suggested either to expand on the work of established multilateral networks such as WHO, the Scientific Advisory Group for Emergencies, International Coalition of Medicines Regulatory Agencies (ICMRA), and Africa CDC (Eli Lilly, PPD Development, Weill Cornell Medicine, RTI International, ACRO, IQVIA, ICON GPHS); or to create a new international governing entity, perhaps modeled after the UN Security Council (NHBLI Connects, Syneos Health). A new entity could have rotating or permanent membership,

have international oversight, review, and approval powers, and would be uniquely positioned to coordinate emergency activities government, non- and for-profit, and private networks. In the absence of such structure, some responses highlighted supporting existing partnerships between CROs that currently support local governments and institutions.

Three responses highlighted the importance of a centralization of physical and electronic resources in preparation for the next emergency or pandemic. Suggestions included a single national system of trial participants linked by electronic health records to facilitate coordinating trials with international partners (Duke University School of Medicine), the adoption of a standard, global label for investigational products (Vir Biotechnology), and a centralized warm base of readily deployable clinical supplies (IQVIA, Vir Biotechnology). Creating a global label with input from regulatory agencies from around the world would significantly reduce regulatory and security restrictions placed on supplies and medications. This label could be supplemented with local language translations and preparation materials to assist pharmacies. Respondents pointed to the global lack of availability of laboratory and other medical supplies during the COVID-19 pandemic as the primary need for a centralized supply of clinical supplies that can be readily deployed.

Two responses pointed to using existing software and making public (e.g., clinicaltrials.gov) and private databases available that could assist in harmonization efforts for clinical trial data collection and analytics (Oracle America, IQVIA). One response suggested the FDA expand use of current mutual recognition and inspection reliance agreements (BIO). This effort could ease regulatory burden related to manufacturing and inspections, and reduce conflicting and redundant work.

Four responses suggested collaborative methods that could increase harmonization efforts (including Connected Health Initiative, Quantum Leap Healthcare Collaborative, FAS). This includes increasing public-private partnerships, increasing interagency efforts, and increasing the overall federal capacity to conduct clinical trials.

2. Designing Clinical Trials that Coordinate with International Efforts

- Support and leverage the International Coalition of Medicines Regulatory Agencies (ICMRA), the International Council on Harmonization (ICH), and WHO (ICON GPHS, Eli Lilly, IQVIA).
- Design trials in collaboration with international partners at the outset (RTI)
- Coordinating clinical trials internationally will require technology solutions that can accommodate large numbers of diverse studies (e.g., size, complexity, geography) (Oracle).
- Create a protocol assessment mechanism to fast-track emergency trial protocols; in parallel, create a new pandemic or emergency regulatory agency, modeled

after the UN Security Council, to coordinate emergency activities across public and private networks (Syneos).

- Ensure diversity-related measures are reflected in international settings, such as enrolling population experiencing the greatest disease impact; ensuring low- and middle-income countries (LMIC) are part of the next emergency pandemic response (Eli Lilly).
- Create a central reserve of essential clinical equipment and supplies for rapid deployment (e.g., saline and IV pumps) (IQVIA).
- Develop a single national system of trial participants (linking electronic health records) for rapid randomization of large numbers of participants for trials to facilitate coordinating trials with international partners who have nationalized health systems (Eli Lilly, IQVIA, Duke).
- Establish agreements with international clinical trial networks and other bodies in advance to facilitate implementation of any large-scale trial protocols initiated by the U.S. (NHBLI).
- Engage trusted multilateral entities such as WHO, Africa CDC; philanthropy entities such as Wellcome Trust, BMGF; and non-governmental organization (NGOs) such as CEPI/GAVI; (Syneos, IQVIA).
- Create a single global Data Safety and Monitoring Board for trials that can periodically preview preliminary data generated by multiple trials (Duke).

3. Identifying International Sites Fit for Trials

- Develop software platforms with capacity to automate and simplify clinical trial start-up and allow teams to collaborate globally to identify (trial) sites using historical site data (Oracle).
- Identify sites already participating in funded networks and incentivize networks to develop trial sites in non-academic community hospitals serving underrepresented populations (Duke).
- Invest in strengthening global vaccine site networks (Syneos).
- Partner with NGOs and CROs that are active in LMIC regions and can serve as trusted partners to local governments and institutions (IQVIA).

4. Overcoming Regulatory Barriers That Delay International Expansion

- Develop methods for cross-agency communication practices, clinical study protocols, and other information sharing during emergencies or pandemics (ICON, IQVIA).

- Adopt a standard, global label for investigational products to allow the reliable flow of supplies internationally; allow for drug importation to occur concurrently with clinical trial application submissions (Vir Biotechnology).
- Software platforms that can facilitate site identification globally and use extensive analytics to provide visibility into patient enrollment and progress should be compliant with global regulatory requirements such as Good Clinical Practice (Oracle).
- The emergency clinical research network should pursue global improvements (particularly in LMICs) to the regulation of clinical trials, such as cloud-based approaches for sharing data with regulators in multiple countries simultaneously (Eli Lilly).
- Work with FDA to explore expanded use of mutual recognition and mutual inspection reliance agreements (BIO).
- Develop alignment among the various international regulatory initiatives (e.g., World Health Assembly [WHA] Resolution 75.8, CEPI 100 days mission, ICMRA) (Vir Biotechnology).

5. Tracking International Clinical Trial Initiatives and Harmonization of Efforts

The responses specific to this sub-topic of Topic 6 interpreted "tracking" and "harmonization" in a variety of ways, including discussing the types of personnel who might be necessary, technological mechanisms, and partnerships and collaborations.

- Create a global group of technical experts, perhaps under the auspices of the ICMRA or ICH, to facilitate pre-pandemic preparation, information sharing, and priority setting[3] (Eli Lilly).
- Employ a clinical trial management system (CTMS) tool to standardize clinical operations workflows and provide real-time visibility of data across trial management processes (Oracle).
- Harmonize regulatory policies between countries: for example, some countries allow electronic signatures, while some require wet-ink signatures (Vir Biotechnology, BIO).
- Use existing databases to track and make available key pieces of clinical trial information (e.g., WHO's ICTRP, clinicaltrials.gov); databases need to be

[3] Although the Eli Lilly response mentions international considerations as part of the Topic 1 response related to governance of the ECR effort ("international effort is critical"), their response in Topic 6 provides detail regarding the roles of international efforts in pre-pandemic planning that is more extensive.

mined with analytics to create live visualization dashboards, highlight diversity of samples, display chronological data sets, etc. on a regional and global scale (ICON GPHS).

G. Summary of Short/Unstructured Responses

A total of 37 responses did not specifically indicate which RFI topics they were responding to. Unstructured responses were largely from companies, member organizations, medical centers, and universities. Some of the respondents who submitted unstructured comments were AWS, McKesson, Association of Clinical Research Organizations, Walgreens, Regeneron Pharmaceuticals, Bayer, Boston Medical Center, and Emory University.

Several of these responses were from companies that included employee biographies and described the technological capabilities that the companies can provide (Keyrus, PPD Development, Syneos). While these responses did acknowledge the general significance of the RFI, they either responded to clinical trial challenges specific to the COVID-19 pandemic (e.g., vaccine availability, funding) or did not offer recommendations. The remaining responses that were germane to the RFI topics generally included recommendations for improved infrastructure and governance models, increasing data sharing (or a central database of widely accessible clinical trial data), building and incentivizing established and new clinical trial networks, alleviating existing legal and regulatory burdens that hinder national and international collaboration, and the importance of public-private partnerships in clinical trial networks. These responses are incorporated into the sections above.

Appendix A.
RFI Text

AGENCY:

Office of Science and Technology Policy (OSTP).

ACTION:

Notice of Request for Information (RFI) on clinical research infrastructure and emergency clinical trials.

SUMMARY:

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), the White House Office of Science and Technology Policy (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. Efforts in this area could include the establishment of a U.S.-level governance structure and outreach to a wide range of institutions, clinical trial networks, and other potential trial sites that can participate in emergency research, both domestically and internationally. A further goal of this emergency clinical trials initiative is to support the expansion of clinical research into underserved communities, and increase diversity among both trial participants and clinical trial investigators. Building U.S. capacity to carry out emergency clinical trials will enlarge and strengthen the U.S. clinical trials infrastructure overall.

DATES:

Interested persons and organizations are invited to submit comments on or before 5 p.m. ET on December 27, 2022.

ADDRESSES:

Interested individuals and organizations should submit comments electronically to emergencyclinicaltrials@ostp.eop.gov and include ‘‘Emergency 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 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 8 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 research institutions, clinical trialists, health care providers interested in clinical research, contract research organizations (CROs) and other clinical trial service providers, pharmaceutical and biotechnology companies, and community health care organizations. 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. Please be aware that comments submitted in response to this RFI 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 emergencyclinicaltrials@ostp.eop.gov.

SUPPLEMENTAL INFORMATION:

Background: Currently, the U.S. clinical trials infrastructure is not well prepared to carry out coordinated, large-scale clinical research in the event of an outbreak of infectious disease or other public health emergency. As was seen in the initial stages of the COVID–19 outbreak, different institutions and networks tend to implement their own research protocols and capture and store their own data. The lack of a coordinated approach to clinical trials research in emergency settings has slowed the development of actionable information, which has in turn delayed the availability of vaccines, therapeutics, and diagnostics; and may also impede the tracking of the outbreaks themselves. Without some

mechanism to coordinate and organize research on a larger scale in an emergency setting, researchers and decisionmakers are left with a series of relatively small, often inconclusive studies, and assembling data for larger-scale analysis is challenging. In addition, and very significantly, our current approach to clinical research in the emergency setting excludes many patients and health care providers in underserved areas, and has contributed to a lack of diversity among clinical trial participants and among the investigators who lead clinical trials.

The National Biodefense Strategy calls for the U.S. government to maintain and build upon the domestic clinical trials infrastructure, with the addition of international sites as appropriate, to ensure readiness to ''expedite the evaluation of safe and effective vaccines, therapeutics, and diagnostics for all segments of the population during a nationally or internationally significant biological incident.'' In addition, establishing an emergency clinical trials governance structure, developing the terms of an Emergency Master Agreement to accelerate response, and identifying a network of available sites are among the key goals towards implementation of AP3. In line with these provisions, OSTP (in partnership with the NSC and other EOP components) is leading an effort to ensure that the U.S. can carry out more coordinated and potentially larger-scale clinical trials in emergency situations. These emergency situations could include emerging outbreaks with epidemic or pandemic potential, even in advance of any declaration of a public health emergency (PHE) under section 319 of the Public Health Services Act. By strengthening

U.S. capacity to address such outbreaks and other biological incidents, OSTP's emergency clinical trials effort also aims to build and enhance U.S. clinical research capacity overall.

We seek comment below on potential governance models for the emergency clinical trials effort. One possible approach would include a centralized U.S.-level structure drawing membership from Federal agencies with relevant expertise. Governance functions might include determining when coordinated and potentially large-scale clinical research is needed, including research on countermeasures, to address outbreaks of disease or other biological incidents. As noted above, research on an outbreak or incident may sometimes be needed in advance of any section 319 PHE declaration; we solicit comments below on the criteria that should be applied to determine when emergency clinical research may be needed, and how that determination might be communicated to institutions and clinical trial networks that can participate in carrying out the research.

Another governance function might be to oversee the development of emergency clinical trial protocols, in coordination with stakeholders external to the U.S. government. The trials and other studies needed in emergency settings could vary in complexity. Some might be relatively simple studies designed to measure the scope of an outbreak or the course of a disease, in which the data captured from patients might overlap to a large extent with the data that would be gathered in the course of treatment. Other studies, including

those designed to evaluate the efficacy and safety of investigational vaccines, therapeutics or diagnostics, would be more complex and could require more or different data elements from those that would be captured in the course of standard medical treatment. In some cases, study designs used in connection with prior outbreaks could provide useful models for developing protocols to address a new emergency. We request comment below on how a governing entity could best work with stakeholders to develop emergency clinical trial protocols.

We also seek comment below on how emergency clinical trial data should be managed to facilitate researchers' access to data and the analysis of results across a range of participating sites. One potential model would be to collect data from emergency clinical trials in a centralized data repository or small set of repositories, with a central biorepository for biospecimens collected during trials.

In order to ensure that coordinated, large-scale clinical trials can be carried out in the event of an emergency, OSTP seeks comment on how best to identify institutions and networks that have an interest in participating in these studies, and how to create or enhance incentives for them to participate wherever possible. In particular, OSTP seeks comment on how to ensure that trial sites in underserved areas are included, and how to increase diversity both among study participants and among the investigators who lead trials to completion. We also solicit feedback below on how to identify an adequate number and distribution of clinical trial sites, including trial sites located outside of the U.S. This could include sites that may currently be affiliated with a U.S.-based trial network, as well as other international sites. We would appreciate receiving comments on how the domestic emergency clinical trials effort overall can be designed to coordinate with international research and preparedness initiatives.

We are aware that in advance of an outbreak or other emergency, there may be value in having networks and sites begin carrying out clinical trials to create a ''warm base'' of clinical research capacity. ''Warm base'' is a term used to refer to studies that not only gather data under a particular clinical research protocol, but also serve the function of keeping trial sites in a state of readiness to undertake additional or future research. ''Warm base'' studies could address infectious diseases such as influenza, or other medical conditions that are of interest to researchers and communities, such as cancer and heart disease.

To participate in a clinical trial, a site needs to have staff familiar with applicable regulatory requirements and with the appropriate procedures for collecting data and submitting it to a study sponsor. When ''warm base'' research is initiated, site staff have an opportunity to gain familiarity with these procedures. ''Warm base'' research is a way to expand the number of sites that are able to participate in clinical trial research, which builds U.S. clinical trial capacity overall while enlarging the network of sites that can be available to carry out emergency clinical trial research when the need arises. We request

comment below on a variety of issues related to ''warm base'' research, including disease areas that might be targeted and how ''warm base'' research can be implemented to provide targeted training for trial sites, as appropriate to staff roles. Given OSTP's goals of increasing diversity among clinical trial participants and among investigators, and of increasing capacity for clinical research in underserved areas, we are particularly interested in how those goals might be served through the implementation of ''warm base'' research.

In recent emergency settings, we have seen that the launch of clinical trials across separate institutions or networks can be delayed by the process of coming to agreement on certain key issues, such as data sharing and the publication of results. We seek comment below on the possibility of developing a framework of key terms that can be developed in advance of an emergency and integrated into clinical trial agreements for emergency clinical trials when needed. For purposes of this RFI, we refer to such a framework as an ''Emergency Master Agreement.'' The goal of an Emergency Master Agreement would be to shorten the time it takes to get emergency clinical trial research started across a range of sites, by facilitating agreement on key terms in advance. Certain basic terms could be relevant for any coordinated or large-scale emergency clinical trial, such as provisions that allow data gathered under common protocols from a range of sites to be collected and made readily accessible to researchers beyond the institutions where the trial was conducted. Other basic terms might include central management of biospecimens and the use of a single Institutional Review Board (IRB). In addition to these basic, core terms, an Emergency Master Agreement could include additional terms that might only be needed for certain types of study protocols (e.g., if an investigational agent is being tested). We solicit input below on a range of issues related to the potential creation of an Emergency Master Agreement.

From a technical perspective, OSTP is also seeking input on how best to operationalize both protocol distribution and data capture in a forthcoming RFI.

Information Requested: Respondents may provide information for one or as many topics below as they choose.

1. Governance for emergency clinical trials response.

    a. Descriptions of models that could be used to establish a U.S.-level governance structure for emergency clinical trials. As noted above, one possible approach would be a centralized U.S.-level structure drawing membership from Federal agencies with relevant expertise.

    b. Criteria that should be applied in determining when coordinated and potentially large-scale clinical research is needed to address an outbreak of disease or other biological incident, including signals or indicators that should be taken into account.

c. Once a need for emergency clinical research is determined, factors relating to the outbreak or incident (e.g., scope, location, severity) that should be considered in determining what types of studies are needed.

d. Methods for communicating the decision to begin emergency clinical research to institutions and clinical trial networks that can participate in carrying out the research.

    1) Mechanisms for tracking institutions, networks and sites that might be able to participate in emergency research, to ensure adequate potential for enrollment and adequate geographic coverage, domestically and internationally.

e. Criteria for establishing a target number and location of sites needed to support clinical trials in case of emergency.

f. Procedures whereby the U.S. Government, together with external stakeholders, could oversee the development of clinical trial protocols and, where appropriate, the selection of investigational agents. It would be particularly helpful to get input on whether there is a role for public-private partnerships in this context.

g. Best practices, including "quality by design" principles, for designing trials so that they capture the data needed without unnecessary complexity that can complicate execution.

h. Best practices for designing trials that can enroll vulnerable populations, such as the pediatric population, as needed in particular circumstances.

i. Optimal ways to manage interactions with domestic and international regulatory bodies.

j. Appropriate entities to handle projecting and tracking enrollment at study sites, monitoring the progress of clinical trials, and data management; whether existing entities could be engaged or adapted to carry out these functions for coordinated, large-scale emergency clinical trials.

k. Appropriate ways to structure a data repository and a biorepository for emergency clinical trial data and specimens. As noted above, one potential model would be to collect data and biospecimens in centralized repositories. We would also appreciate input on whether existing entities could be engaged or adapted to handle these repository functions.

l. Criteria that should be applied to govern researchers' access to emergency clinical trial research data."

2. Identifying and Incentivizing Research Institutions and Networks; Building Diversity and Equity.

    a. Methods for identifying institutions and sites that may have an existing interest in or familiarity with emergency clinical trial research. This might include those that currently receive government funding, those with a focus on infectious disease research, and/or those that have worked with CROs.

    b. Effective ways to increase diversity among study participants and investigators, and to expand clinical research sites into underserved areas. It would be helpful to get input on whether and how the following approaches could be useful:

        1) Community outreach.

        2) Use of decentralized clinical trial (DCT) design elements, or other innovative approaches such as trials conducted at the point of care.

        3) Use of technological innovations, such as digital health technologies (DHTs), that would allow remote participation or otherwise limit the need for participants to travel.

        4) Building on existing programs that target diversity in clinical research, including initiatives within research institutions and public-private collaborations.

        5) Leveraging the networks and community access of retail chains, including retail pharmacy chains.

        6) Leveraging community-based care networks such as Practice-Based Research Networks (PBRNs) and Federally Qualified Health Centers (FQHCs).

    c. Incentives that can be identified or enhanced to encourage participation in emergency clinical trial research.

        1) As described above and in the forthcoming RFI on data capture for Emergency Clinical Trials and Data Collection Pilot, we are seeking information on how to create a pilot program enabling clinical trial data collection across a wide variety of trial sites that is easy for health care providers to use and can be scaled up for use in emergency research settings. It would be helpful to receive comments on whether the opportunity to participate in such a pilot could create an incentive for institutions and sites to participate in emergency clinical research studies.

    d. Once interested institutions or networks are identified,

1) Effective ways to recognize and communicate their commitment to emergency clinical research to the health care community and to the public.

2) Information that should be collected from interested sites, for example by means of a short questionnaire to assess characteristics of patient population, level of training that would be required, etc.

e. The best ways to provide training in clinical trial practice (including regulatory requirements such as Good Clinical Practice (GCP)) where needed, targeted as appropriate to staffs' roles, including staff at sites that may not have participated in clinical trials previously.

3. "Warm Base" Research

a. Disease areas that should be targeted in protocols for "warm base" clinical research. It would be helpful to get comments on:

1) Disease areas that are most relevant to communities, including underserved communities and those that may have little experience with participating in clinical research.

2) The extent to which "warm base" research should target infectious disease, versus other conditions such as cancer, heart disease, or rare disease; and the size or scope of site networks that would be needed to study various conditions.

b. How "warm base" research could best be implemented to provide training to sites that are inexperienced with clinical trial research, and to create a basic level of surge capacity at the staff level for emergency clinical trial research. We would appreciate input on other training mechanisms that could be used as well.

c. Whether "warm base" research could be appropriately supported as

1) A demonstration project with commercial partnership.

2) A public-private partnership.

3) An agency-funded program.

4. Emergency Master Agreement

a. Basic terms that might form part of an Emergency Master Agreement, including the following.

1) Data collection and use, including ownership of the study data and biospecimens; entities that have the right to collect, store, and use the data and specimens; banking of biospecimens for further research.

2) Publication/accessibility of trial data, including availability of data prior to publication and publication rights.

3) Use of a single IRB across all participating trial sites. As a related point, it would be helpful to get feedback on whether an IRB should be established that is primarily devoted to emergency clinical trials.

b. Additional terms for an Emergency Master Agreement that could be added or modified depending on the complexity of the protocol, and on other factors such as whether a private sector sponsor or an investigational agent is involved. It would be helpful to have input on terms such as the following:

1) Confidentiality.

2) Patents/intellectual property.

3) Control of study drug.

4) Indemnification.

5) Compensation for injury.

c. The best ways to get the input of research institutions, clinical researchers, community groups, and other key stakeholders on the content of Emergency Master Agreement terms.

d. Approaches to facilitating stakeholders' understanding and adoption of the Emergency Master Agreement framework.

1) Any models for such adoption in related areas, such as the NCATS SMART IRB Platform.

5. Identifying viable technical strategies for data capture; gathering information about a potential data capture pilot. This topic will be the subject of a separate RFI on data capture.

6. International coordination and capacity.

a. Designing the overall domestic emergency clinical trials effort in a way that coordinates with international clinical research efforts. It would be helpful to receive comments on how to facilitate the participation of foreign-run clinical trial networks and other foreign bodies in coordinated, large-scale emergency clinical trial protocols initiated by the U.S.

b. Methods for identifying international sites that might be available to participate in emergency clinical trials, including international sites associated with U.S.-run networks as well as foreign-run international sites.

c. Overcoming regulatory barriers that delay expansion of U.S. trials into international sites, or otherwise interfere with clinical research across borders.

d. The best way to track the clinical trial research initiatives being pursued under the G7 Trials Charter and Quad leaders' commitment to pandemic preparedness, and to harmonize U.S. emergency clinical trials efforts with these international initiatives.

Dated: October 19, 2022.

Stacy Murphy,

Operations Manager.

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Appendix B.
List of Respondents by Organization Type

- Industry (23 respondents)
  - Amazon Web Services
  - Bayer
  - Care Access
  - Curebase
  - Datacubed Health
  - Datavant
  - Eli Lilly
  - eMed Labs
  - Genentech
  - ICON Government and Public Health
  - IQVIA
  - Keyrus
  - McKesson Corporation
  - Medable
  - Oracle America
  - PPD Development (ThermoFisher)
  - Quantum Leap Healthcare Collaborative & OpenClinica
  - Regeneron Pharmaceuticals
  - Syneos Health
  - Verily Life Science
  - Vir Biotechnology
  - Walgreens
  - YonaLink

- Academic Health Centers/Academic Research Groups/Individuals from Academia (18 respondents)
  - Alfred L'Altrelli – Individual from UPMC Presbyterian-Shadyside
  - Boston Medical Center; Boston University
  - Cosby Stone – Individual from Vanderbilt University
  - Duke University School of Medicine
  - Eric Lenze – Individual with nonspecific academic association
  - INSIGHT Clinical Trials Network
  - Jeffrey Goldstein – Individual from Northwestern University
  - John Hopkins CTSA; Trial Innovation Network
  - Kevin Grimes, Rieko Yajima – Individual respondents from Stanford University
  - Natalie Dean – Individual from Emory University
  - NHLBI CONNECTS
  - Nicholas Gaudino – Individual from Georgetown University
  - Niel Thomas – Individual from Pennsylvania State University Hershey
  - Seema K. Shah, Ravi Jhaveri, Larry Kociolek, and Jennifer Kusma –
  - Individual respondents from Lurie Children's Hospital
  - South Shore Health
  - UIC Population Health Sciences Program
  - University of Maryland; Emory University
  - Weill Cornell Medicine
- Professional Associations (10)
  - American College of Obstetricians and Gynecologists
  - American Medical Informatics Association
  - American Society of Hematology
  - Association of Clinical Research Organizations
  - Digital Medicine Society
  - Federation of Associations in Behavioral and Brain Science
  - Infectious Diseases Society of America and the HIV Medicine Association

  - Society for Women's Health Research
  - Society of Academic Emergency Medicine and American College of Emergency Physicians
  - Society of Critical Care Medicine
- Stakeholder Groups (eight respondents)
  - Alliance for Connected Care
  - Association of American Medical Colleges
  - Coalition for Advancing Clinical Trials at the Point of Care
  - Connected Health Initiative
  - Consortia for State and Regional Interoperability
  - Council on Government Relations
  - Decentralized Trials and Research Alliance
  - Good Clinical Trials Collaborative Coordinating Center
- Advocacy Groups (six respondents)
  - 1Day Sooner
  - Federation of American Scientists
  - Institute for Advanced Clinical Trials for Children
  - Milken/FasterCures
  - Public Responsibility in Medicine and Research
  - TranspariMED
- Industry Associations (five respondents)
  - Advanced Medical Technology Association
  - Biotechnology Innovation Organization
  - Health Record Banking Alliance
  - Healthcare Leadership Council
  - PhRMA
- Research Entities (three respondents)
  - Boston Consulting Group
  - MITRE
  - RTI International

- Non-affiliated Individuals (three respondents)
  - Mitchell Berger – Individual Respondent
  - Dragan Adzic – Individual Respondent
- Other (two respondents)
  - Letter from Members of Congress (Kelly Caster, Elizabeth Warren, Brian Fitzpatrick, Lois Frankel, Robin L. Kelly, Lauren Underwood)
  - Clinical Trials TV – Media/TV Channel

Appendix C.
Responses by Topic

Author(s) or POC	Organization	T1- Governance	T2- Incentives/ Network Selection/DEI	T3- Warm Bases	T4- Emergency Master Agreements	T5- Data capture	T6- International
Dunne, Dianna	Milken/FasterCures	x		x			
Castor K., Warren E., Fitzpatrick B., Frankel L., Kelly R., Underwood L.	Members of Congress		x				
Josey, Karen	Keyrus	x	x	x	x	x	
Mina, M.	eMed Labs, LLC	x					
McLeod, S.	Association of Clinical Research Organizations		x		x		x
Brodsky, R.	American Society of Hematology	x	x	x	x		
Anderson, B.	Amazon Web Services			x	x		x
Pritchett A., Apostalaros M.	PhRMA		x	x			
Slone, P.	McKesson Corporation		x				
Goldsack, J.	Digital Medicine Society		x				x
Sabo, J.	Eli Lilly	x					x
Kirkby, M.	PPD Development (ThermoFisher)	x		x			x
Madre, L.	Medable	x	x				
John, Charley	Walgreens		x				

Author(s) or POC	Organization	T1- Governance	T2- Incentives/ Network Selection/DEI	T3- Warm Bases	T4- Emergency Master Agreements	T5- Data capture	T6- International
Daniele, A.	Weill Cornell Medicine	x					x
Alexander T. Limkakeng Jr	Society of Academic Emergency Medicine and American College of Emergency Physicians		x				
Jerrold Johnson	Oracle America, Inc.	x		x	x		x
Stephan Keith, Jamie Hernandez, Gino Girardi, Michael DiFiore, Nicholas Kenny	Syneos Health	x		x			x
Gretchen Purcell Jackson	American Medical Informatics Association	x				x	
David Stephens and Kathleen Neuzil	University of Maryland and Emory University		x				
Katharina Krapp	INSIGHT Clinical Trials Network	x	x	x	x		x
Doug Stoss	Vir Biotechnology	x		x			x
Ebony Coates	Regeneron Pharmaceuticals		x		x		
Sangy Panicker	Public Responsibility in Medicine and Research		x		x		
Kim Quaintance-Lunn	Bayer		x				
Douglas Fridsma	Datavant		x		x		
Enli Lewis	1Day Sooner			x			
Jennifer Sculley, McKinley sherrod, Lynn Gerald, Hugh Musick, Lauren Castro, Jerry Krishnan	UIC Population Health Sciences Program	x		x			
Sonia Thomas	NHLBI CONNECTS	x		x	x		x
Laura Evans, Vikramjit Mukherjee, Lauren Sauer	Society of Critical Care Medicine	x		x	x		

Author(s) or POC	Organization	T1- Governance	T2- Incentives/ Network Selection/DEI	T3- Warm Bases	T4- Emergency Master Agreements	T5- Data capture	T6- International
Madelynn Valu	Consortium for State and Regional Interoperability	x		x		x	
Katie DeGeorge	Federation of Associations in Behavioral and Brain Science	x	x		x		
Tevan Locke	Coalition for Advancing Clinical Trials at the Point of Care		x	x			
Laura Fegraus	Verily Life Science, LLC	x					
Kate Mullis	ICON Government and Public Health Services	x		x	x	x	x
Derick Brown	RTI International	x		x	x		x
Brian Scarpelli	Connected Health Initiative		x				x
Craig Lipset	Decentralized Trials and Research Alliance	x	x				
Sara Hoopchuk	Infectious Diseases Society of America and the HIV Medicine Association	x	x	x			
Christopher Adamec	Alliance for Connected Care		x				
Laura Needham	Curebase, Inc			x	x		
Adam Asare, Cal Collins, Karyn DiGiorgio, Bailey Smith, Jeff Matthews	Quantum Leap Healthcare Collaborative & OpenClinica		x				x
Susanna Naggie	Duke University School of Medicine	x		x	x		x
Leslie Harden	Biotechnology Innovation Organization	x	x				x
Kris West	Council on Government Relations	x		x	x		

Author(s) or POC	Organization	T1- Governance	T2- Incentives/ Network Selection/DEI	T3- Warm Bases	T4- Emergency Master Agreements	T5- Data capture	T6- International
Grace Wickerson	Federation of American Scientists		x				x
Niel Thomas	Penn State Hershey		x				
Tara Frederici	Advanced Medical Technology Association	x		x	x		
Najaf Shah	Boston Consulting Group	x					
Jhanna Chesley	Boston Medical Center/BU		x				x
Don Harder	Care Access	x		x	x		
Brett Kleger	Datacubed Health		x			x	
Eric Lenze	N/A		x				
Daniel Ford	Johns Hopkins CTSA and Trial Innovation Network		x		x		x
Cindy Jackson	Institute for Advanced Clinical Trials for Children		x				
Jeffery Goldstein	Northwestern University		x				
Kevin Grimes, Rieko Yajima	Stanford University	x					
Seema K. Shah, Ravi Jhaveri, Larry Kociolek, and Jennifer Kusma	Lurie Children's Hospital		x				
Mitchell Berger	N/A		x				
Cosby Stone	Vanderbilt University		x				
Gav Martell	YonaLink, Inc.	x	x		x		
Monica Veldman	Genentech	x			x	x	
Matthew Thomas	Healthcare Leadership Council		x				
Andrew Barnhill	IQVIA	x		x	x		x

Author(s) or POC	Organization	T1- Governance	T2- Incentives/ Network Selection/DEI	T3- Warm Bases	T4- Emergency Master Agreements	T5- Data capture	T6- International
Heather Pierce	Association of American Medical Colleges	x		x	x		
Duane Blackburn	MITRE	x		x			
Stephanie Smith	South Shore Health		x				
Alfred L'Altrelli	UPMC Presbyterian-Shadyside	x	x				
Stefan Gold	Good Clinical Trials Collaborative Coordinating Center	x	x				x
Natalie Dean	Emory University	x	x				
Till Bruckner	TranspariMED	x					x
Lindsay Horan	Society for Women's Health Research		x				x
Nicholas Gaudino	NA	x	x				
Richard Marks	Health Record Banking Alliance		x				x

Appendix D.
Abbreviations

AAMC	Association of American Medical Colleges
ACEP	American College of Emergency Physicians
ACOG	American College of Obstetricians and Gynecologists
ACRO	Association of Clinical Research Organizations
ACT@POC	Coalition for Advancing Clinical Trials at the Point of Care
ACTIV	Accelerating Covid-19 Therapeutic Interventions and Vaccines Partnership (NIH)
AMIA	American Medical Informatics Association
ASH	American Society of Hematology
AWS	Amazon Web Services
BIO	Biotechnology Innovation Organization
BCG	Boston Consulting Group
BMC	Boston Medical Center
BMGF	Bill & Melinda Gates Foundation
BU	Boston University
BYOD	Bring your own device
CEAL	Community Engagement Alliance (NIH)
CEPI	Coalition for Epidemic Preparedness Innovations
CHI	Connected Health Initiative
COGR	Council on Government Relations
CROs	Clinical research organizations
CSRI	Consortium for State and Regional Interoperability
CTMS	Clinical trial management system
CTSA	Clinical Translational Science Awards
DCT	Decentralized clinical trial
DHT	Digital health technologies
ECT	Emergency clinical trial
EOP	Executive Office of the President
FAIR	Findable, accessible, interoperable and reusable
FAS	Federation of American Scientists
FDA	U.S. Food and Drug Administration
FQHC	Federally Qualified Health Centers
GCP	Good Clinical Practice
GPHS	Government and Public Health Services (ICON)
ICH	International Council on Harmonization
ICMRA	International Coalition of Medicines Regulatory Agencies

ICTRP	WHO International Clinical Trials Registry Platform
IDCRC	Infectious Diseases Clinical Research Consortium
IDSA	Infectious Diseases Society of America
IRB	Institutional Review Board
LMIC	Low- and middle-income countries
MCM	Medical countermeasures
NCATS	National Center for Advancing Translation Sciences
NGO	Non-governmental organization
NHLBI	National Hearth Lung and Blood Institute
NICTN	National Clinical Trials Network
NIH	National Institutes of Health
NSC	National Security Council
OSTP	Office of Science and Technology Policy
PBRN	Practice-Based Research Networks
PHE	Public health emergency
PhRMA	Pharmaceutical Research and Manufacturers of America
PRIM&R	Public Responsibility in Medicine and Research
RFI	Request for Information
RWD	Real-world data
SAEM	Society for Academic Emergency Medicine
STPI	Science and Technology Policy Institute
SWHR	Society for Women's Health Research
UKRI	UK Research and Innovation
WHO	World Health Organization