January 25, 2023

Office of Science and Technology Policy

RE: RFI on Clinical Research Infrastructure and Emergency Clinical Trials

Comments submitted electronically via
datacollectionforclinicaltrials@ostp.eop.gov

The American Medical Informatics Association (AMIA) appreciates the opportunity to provide input to the Office of Science and Technology Policy (OSTP*) Request for Information (RFI) on Clinical Research Infrastructure and Emergency Clinical Trials.* AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, and public health experts who bring meaning to data, manage information, and generate new knowledge across the health and healthcare enterprise.

AMIA commends OSTP for its focus on efforts to protect the public health in cases of national emergency. An established research infrastructure, uniform protocol for the conduct of emergency clinical trials, and responsible data sharing and oversight requirements should be viewed as necessary components of a national preparedness plan. Only with integrated, longitudinal data at the patient level, can we monitor acute events, formulate appropriate interventions for harm prevention and reduction, fairly allocate resources to mitigate effects in a timely way, and track, predict and measure the effectiveness of interventions. The integrity and security of our health data infrastructure and nation should be a priority to support situational awareness and enable coordinated leadership action.

Clinical Trial Governance and Standards

AMIA supports a federally coordinated and harmonized national regulatory and/or policy framework for the conduct of emergency clinical trials, as well as data acquisition, management and sharing policies with rapid, reliable reporting of results to one centralized authority, with results easily distributed to engaged participants. These requirements should include, emphasize and leverage digital health data resources for standardization of data elements, interoperable data sharing, population health and reporting of results.

Given the emergency nature of these clinical trials, pre-determined yet flexible standards for data elements, clinical trial study design, requirements to research large populations of patients, and technological infrastructure needed to support these processes, requires strong multi-agency and multi-stakeholder coordination.

Emergencies often result in changing the rules for how we do things and may compromise individual rights to protect public health. To prevent long-term compromise to individual rights, such as autonomy and privacy, it is important that justification for an emergency clinical trial is clearly defined, along with what would constitute an end.

When clinical trials are accelerated, oversight might be less stringent. In these cases, transparency is paramount. This includes transparency about deviations from normal clinical trial protocols (in terms easily understandable by the public), and transparency about data as they emerge so the public can participate in the oversight process.

Regarding standards, stakeholders and experts from the FHIR Accelerator community, in particular, Gravity and Vulcan, should be included in planning to support advancing technological standards for the infrastructure needed to execute an emergency clinical trial system that is proactive as well as reactive. Standards for data captured should align with USCDI V.4, as the data elements in V.4 are increasingly comprehensive and can potentially support a baseline federated model for data capture in emergency clinical trials. Given the population-level data needs, data sharing/exchange, and data reporting, it is recommended that stakeholders from the SMART/BULK FHIR be consulted and included to provide standards tracking patients enrolled in study sites.

Data Sharing

The advantages of data sharing can only be realized with appropriate levels of investment in underlying infrastructure, including tools for managing, storing, and indexing increasingly large and diverse data sets, as well as human resources for curating shared data. AMIA encourages OSTP to leverage resources across federal agencies and programs to develop necessary infrastructure for emergency clinical trials. We also encourage the incorporation of the FAIR data principles (findable, accessible, interoperable and reusable) to optimize the use of resources and data.

The conduct of clinical trials in emergency settings without technological enablement/assistance would slow innovation in our data and tech-rich healthcare ecosystem of the 21st Century. Digital data technology is an asset in this context, one that will need stakeholder engagement to steward, coordinate and organize. Marquis-Gravel (Technology-Enabled Clinical Trials | Circulation (ahajournals.org) addresses transforming evidence generation. JAMIA has published several studies focused on technology and clinical research that may provide guidance for the development of emergency clinical trial requirements. For example: NelsonSJ et al (EHR-based cohort assessment for multicenter RCTs: a fast and flexible model for identifying potential study sites | Journal of the American Medical Informatics Association | Oxford Academic (oup.com) addresses study site identification. WynerZ et al (FDA MyStudies app: a reusable platform for distributed clinical trials and real-world evidence studies | JAMIA Open | Oxford Academic (oup.com) addresses privacy, engagement, and extensibility in mobile clinical research. Zayas-CabaanT et al (National health information technology priorities for research: A policy and development agenda | Journal of the American Medical Informatics Association | Oxford Academic (oup.com) focuses on policy considerations.

Additionally, an integral component of data management, especially in cases of emergency, is an investment in public health informatics workforce training to build competencies and capacity at every level where information is generated, managed, and used for population health. We also encourage the establishment and sustainability of Centers of Excellence for public health informatics to serve as models of best practice for the nation. These Centers could be mobilized for

technical resource and practice runs, including focused inclusion of under resourced and underserved communities.

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

Planning and engagement with traditionally excluded communities for clinical trial research in emergency situations will require advanced engagement and intentional co-design with these communities. FloresL et al (Assessment of the Inclusion of Racial/Ethnic Minority, Female, and Older Individuals in Vaccine Clinical Trials - PubMed (nih.gov) provide insights into how to engage these communities. Cunningham-Erves (Engagement of community stakeholders to develop a framework to guide research dissemination to communities - Cunningham-Erves - 2020 - Health Expectations - Wiley Online Library) provides some practical insights and experience for engagement of traditionally-excluded communities in clinical trials. It is recommended that researchers and scholars, including many of our AMIA members from these communities be engaged in policy and planning efforts for emergency clinical trials.

Data Privacy and Protection

Consideration of data privacy and protections may be understated in this RFI. In all cases, data sharing should preserve and protect an individual's privacy and autonomy. An individual's privacy protections must be consistently maintained, and their privacy preferences respected across clinical, research, community services, and commercial use of their health data.

Informed consent requires clearly worded, understandable explanations of how an individual's health data will be used and the circumstances in which it will be disclosed. Health data must always be collected, managed, and shared in ways that minimize the risk of reidentification of individuals. For emergency clinical trials, solutions are needed to support and manage enduring and/or emergent consent, where participants can update their consent preferences real time.

The threat of communicable risk, contaminant risk, and other threats to public health necessitates broad access to health data, but there must be severe penalties for misuse.

Thank you or your consideration of these comments. If you have any questions, please contact Tayler Williams, AMIA Public Policy Manager, at twilliams@amia.org.

Sincerely,

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