Comments of
The Health Record Banking Alliance
In response to
Office of Science and Technology Policy (OSTP)
Request for Information (RFI) on Data Collection for
Emergency Clinical Trials and Interoperability Pilot
87 FR 65259 (Oct. 28, 2022)
Submitted on January 25, 2023 via *datacollectionforclinicaltrials@ostp.eop.gov*

The Health Record Banking Alliance (HRBA)[1] offers comments in response to OSTP's Request for Information on optimizing data capture for emergency clinical trials. *Please note: these comments complement, and should be read in conjunction with, HRBA's comments, also filed this date, in response to OSTP's Request for Information on clinical research infrastructure for purposes of conducting emergency clinical trials. Please refer to the Appendix in those companion comments for a schematic of Health Data Banks.*

Overview of HDBs and Clinical Research

As noted in HRBA's concurrently filed comments on clinical research infrastructure, Health Data Banks (HDBs) are secure, private- or public-sector institutions. HDBs will offer secure, encrypted repository accounts that patients and other consumers own and control, and where they can aggregate, store, and analyze their health data. Health data includes (and is not limited to) encounter reports – institutional medical records – at clinician offices and hospitals, pharmaceutical data, and payment information related to health care. This information can be integrated using software at the HDB to create longitudinal, problem-oriented Personal Health Records (PHRs), access to which consumers control.

Personal Health Records (PHRs) have been conceived primarily for applications in health care delivery. However, high-quality, longitudinal, patient-centered data sets in Health Data Banks (HDBs), available with patient consent via new information flows that HDBs make possible le, will be transformative for research as well. As they mature and are networked, HDBs will give researchers actionable, consented access to research-grade data sets, currently beyond practical reach. These data sets will come from aggregated medical record and patient-supplied data ("collectively, real-world data" or "RWD") aggregated and compiled in patients' HDB accounts. New, two-way communication channels enabled by HDBs will facilitate participation by a broad cross section of the public in medical research, including in ambitious projects exemplified by the Cancer Moonshot and the All-of-Us Research Program.

Given the potential comprehensiveness of the patient-specific PHR data sets that HDB PHRs will contain, and the fact that patient accounts can, depending on HDB business models and operating protocols, be permissioned to various extents for research, HDBs can be a data treasure for observational studies, for planning, accrual, and follow-up of interventional studies,

[1] The Health Record Banking Alliance, P.O. Box 6580, Falls Church, Virginia 22040, is recognized as a business league by the Internal Revenue Service under Section 501(c)(6) of the Internal Revenue Code.

and in some cases for use *during* the conduct of randomized controlled trials (RCTs). HDBs can facilitate natural history studies and epidemiological research. They can be a reliable source of data for external control arms. Capacity for executing post-market commitments and post-market evidence-generation can be built in. HDBs may also provide efficient channels for obtaining patient input to trial design and selection of clinical endpoints. The data normalization of PHR data that is possible with HDBs will support use of digital tools in clinical research, as well as advanced computational techniques such as synthetic data, digital twins, and generative AI.

HDBs as Emerging Technology for Clinical Trials Infrastructure

Because HDBs are a standing resource for health care, they are also a standing resource for research. What distinguishes HDBs from other sources of real-world data used today is that many HDB business models will readily support iterative, interactive, two-way flows of information between patients at one end, and researchers at the other. Because this adds confirmatory value, it encourages high levels of trust in baseline patient data sets. It also offers research flexibility in the face of the unexpected. That is, by definition, the very nature of a public health emergency with unknown diseases and unknown clinical endpoints. Many HDBs will bring two-way channels of communication with researchers even to community-based, front-line points of care. This will make it possible to include swaths of the public as active research participants.

HDBs' contributions will mostly occur as infrastructure supplements in the operational conduct of trials (e.g., planning, recruitment, follow-up).[2] An entire $200 billion industry consisting of pharmaceutical companies, contract research organizations (CROs), academic centers, research organizations, and others exists to perform the highly specialized and rigorous work of conducting randomized, multicenter, endpoint-driven, double-blinded, placebo-controlled clinical trials. This work necessarily includes the management of trial data. That industry has already made great advances in meeting the challenges of multi-site, point-of-care, and virtual trials as are envisioned in this OSTP initiative. Here HDBs will play a critical supporting role.

While HDBs are not yet a force in the U.S. health industry, OSTP should anticipate the possibility of their rapid growth in the coming years and prepare for the significant improvements and unexpected innovations they can bring to the clinical research enterprise.

For example, HDBs offer secure patient-centered data repositories and exchange infrastructure that can be shared reliably by medical practitioners and medical researchers. This is unprecedented. It eliminates costs and efforts that would arise from assuming that the clinical research enterprise and the health care delivery system will remain fundamentally separate domains as they have been for the past 60 years.

That domain separation underlies the RFI's Use Case. There, the first priority in preparing to conduct trials is to identify and incentivize clinical trial sites and then, secondarily, to rely on those sites to recruit research participants. HDBs obviate that first step and turn the second on its head. HDBs would enable the federal public health authorities to reach out directly to patients (potential participants) who meet the required medical profile. Then, secondarily, trial

sites or, if applicable, patients' own points of care could be identified and enlisted in the research.

Depending on particular HDBs' business models and operating protocols, many patients with HDB accounts will have already pre-consented for observational study. They will already have at least some familiarity with medical research. This reduces the friction of consenting them as participants in interventional trials, and provides a strong cadre of well-documented patients to become involved in trials. HDBs' two-way communications paths enabling convenient re-contacting of clinical trial participants provide pragmatic flexibility as new biomarkers of interest are identified over the course of trials.

These infrastructure features allow significant savings in time and cost. They demonstrate the kind of benefits from using HDBs early in a crisis as essential components of emergency trials infrastructure.

HDBs could simplify and expedite organizing clinical trials in other practical ways, beyond what is envisioned in the RFI's Use Case. These capabilities arise from researchers' interactive engagement with patients and at points of care. These contacts can occur well before a trial protocol is developed, enabling it to be developed using FDA's Patient-Focused Drug Development Guidance. Even while researchers are still working on the new molecular targets in the laboratory, HDBs will enable advance work with the nation's front-line providers and patient population. This can make ready a large cohort of participants, with background medical history data already entered.

The broad range of value that HDBs would bring to the clinical trials infrastructure suggests that OSTP consider broadening the scope of these RFIs. The work of designing trials begins in the very early, urgent, and normalized collection and analytics of raw real-world data at the emergency's very outset. This collection can be accomplished more reliably and efficiently at scale from HDBs than from EHRs. Once public health authorities have a stable, initial picture of the disease, protocols for *observational* studies, such as might contribute data to registries, can be developed – also by central federal authorities – and sent out to patients. In this way a robust knowledge base can be built early, helping to avoid research silos from forming in the chaos of the emergency. HDBs also are a direct-to-consumer channel for collecting the patient voice on any aspect of the research at scale.

Yes, technically rigorous RCTs are necessary before vaccines or treatments can be approved. And yes, such trials will require appropriately trained and equipped sites and staff, and the ability to deploy in communities and populations across the nation using remote patient monitoring devices and the like. However, the clinical trials industry is already prepared to conduct such centralized, multi-site, clinical trials (ironically known as "decentralized clinical trials" – see Decentralized Trials & Research Alliance), with all necessary specialized components, such as visiting research nurses, remote patient monitoring, lab protocols, electronic case report forms (eCRFs), and so forth.

Because lack of participants is a far greater problem for clinical trialists than lack of sites, HDBs offer an ideal infrastructure for recruitment of research participants. After all, most HDBs' account service protocols will have systems to notify account holders of research opportunities of interest to them. Further, under some HDB business models, HDB account holders who want to participate in research may already have been pre-consented for observational research, smoothing meaningful informed consent for trials.

In addition, regulatory authorities increasingly require post-trial follow-up on participants and post-market follow up on patients. They will surely insist on these protocols in cases of emergency outbreaks or epidemics. This is among the infrastructure functions that HDBs are suited for. Indeed, public health emergencies will generate interest in long-term epidemiological studies that may go on for many years after crises wane. HDBs can both facilitate those research communication channels and bring pre-crisis medical histories of the study participants into the studies.

In short, HDBs introduce radical innovations and nuanced enhancements in the clinical research space. OSTP can expect them lead to significant improvements in the efficiency and evidence-generation power of clinical research. These features will be tested in pilots.

Directing Federal Funding to Accelerate FHIR Standardization, and Away From TEFCA

Paragraph 9 of the RFI asks how TEFCA could be used to support clinical trials, whether under currently authorized "Exchange Purposes," e.g., Public Health, or under "a future research-focused Exchange Purpose." The answer is: TEFCA (as ONC is implementing it) is wholly unsuited to support clinical trials now and in the future.

HDBs are the alternative bundle of infrastructure technologies to support clinical trials and medical research generally, and OSTP can expect HDBs to begin emerging this year. The reason is that January 1, 2023 was the deadline by which initial versions of standardized FHIR-based application programming interfaces (APIs), required for EHR certification under ONC's Interoperability Rule, were required to become widely available to consumers via their third-party application programming interfaces ("apps").

Recognizing the likely emergence of HDB infrastructure will help guide OSTP in directing government funding and attention toward the goals set forth in this RFI – health data quality and communication flows to enable a robust clinical trial infrastructure and data capture, in emergencies and otherwise.

As we explain below, OSTP should recommend to the President that the federal government redirect funding away from TEFCA and toward FHIR standardization. The goal is to speed standardizing and expanding FHIR APIs.

OSTP also should seek legislation to authorize a regulatory framework for the emerging Health Data Bank industry. A regulatory framework is essential to protect the public, earn its trust, and assure rapid expansion of HDB infrastructure for clinical trials and other care and research purposes.

Conserving federal resources for these purposes is imperative. OSTP should therefore seek Presidential directives to revise ONC's implementation of the Trusted Exchange Framework and Common Agreement (TEFCA) under the 21st Century Cures Act. The Cures Act's statutory *network-preservation mandate* is optimally implemented by encouraging replacement of the fax system – the de facto standard at present for exchanging health records – with secure, point-to-point digital pathways via HDBs. This will *preserve clinicians' and hospitals' networks*, endowing them with new flexibility in a patient-centered system architecture.

It is necessary to emphasize that the TEFCA mandate in Section 4003 of the Cures Act *does not specify preservation* of *any particular categories of health information networks, and does not specify that TEFCA preserve HIEs or networks of HIEs.* Rather, architecting TEFCA to preserve *hospital and medical office health information networks* is sufficient to meet the Cures Act's network preservation requirement for TEFCA.[3]

The President should therefore require ONC to discard the current, initial iteration of TEFCA and create a wholly new version of TEFCA. The re-conceptualized TEFCA should be based on, and support, nationwide, secure, point-to-point, FHIR-based, streamlined health data exchange. This is a drastic change; but it is necessary in order for TEFCA implementation to bolster, rather than detract from, other features of the Interoperability Rule and the patient-centric policy objectives enacted in the Cures Act.

Policy objectives and technological reality support HRBA's stark recommendation here. Designing TEFCA (as ONC has done) to attempt to preserve moribund Health Information Exchange (HIE) networks is ultimately futile. HIEs are unwieldy, institution-centered system designs. They are not patient-centric or even patient friendly. And they therefore will not be friendly to researchers, including the clinical trial community, seeking to streamline, strengthen, and accelerate clinical trial processes.

HIEs were created to try to help moving health data among providers, hospitals, insurance entities, and other institutions because routine, efficient, point-to-point, digital data transfer among disparate EHR systems was impossible. When HIEs were created, no national, digital, health information exchange standard existed to move data routinely stored in disparate, siloed EHR systems. *Now that the era of standardized FHIR-based data exchange is beginning, some HIEs may elect to convert to Health Data Banks. Other HIEs, now obsolete, will go out of business.*

ONC's current design for TEFCA under the Common Agreement requires TEFCA signatories – QHINs and downstream participants and sub-participants – to respond to nationwide query messages seeking data on particular patients. This discredited "shotgun query" or "record locator query" design cannot feasibly be implemented. It would overwhelm networks' capacities for throughput, create unsolvable patient matching problems with associated privacy rule violations, and so create cascading liability issues.

The idea of making record locator problems worse (as TEFCA does) by inserting regional brokers and disparate, local, voluntary exchanges only makes the system more costly and chaotic, and even more fraught with security and privacy issues. Access control and user authentication are well known problems that multiply at an accelerated rate with scale in such systems. There is no longer any reason to continue to support this inefficient, error-prone architecture.

Supporting clinical trial research, whether or not in emergency conditions, requires streamlined communication between researcher and patients for recruitment, ongoing protocol execution, and follow-up. These requirements cannot be met by TEFCA's SOP for

[3] The full text of Section 4003 of the Cures Act, titled "Interoperability," is available at https://www.healthit.gov/sites/default/files/facas/2018-02-23_TEF_TF_21stCenturyCures_4003_508.pdf

Individual Access Services.[4] It is beyond cumbersome, in practical effect a barrier to patients' use of TEFCA to obtain their complete medical records and communicate those records to their providers and to trialists and other researchers.

It is noteworthy how far the SOP for Individual Access Services departs from the Cures Acts *mandatory* specifications set out in reporting requirements for certification in sections 4002 of the Cures Act as it amends HITECH sections 3001(c)(5) and adds section 3009(a), as follows:

- EHR data must be exchangeable "*without special effort"* on the part of users. (Patients and physicians are among "users" under the Cures Act.) (HITECH as amended, new §3000(10)(A), as added by Cures Act §4003(a); emphasis added.)

- EHR data exchange must allow "*complete* access, exchange, and use of all electronically accessible health information for authorized use [under applicable law]." (HITECH as amended, new §3000(10)(B), as added by Cures Act §4003(a); emphasis added.)

- EHR data exchange cannot be implemented by ONC in ways that restrict "exporting *complete information sets*" as part of access to, or exchange of, health information. (HITECH new §3022(a)(2)(C)(i), as added by Cures Act §4004; emphasis added.) This means export of all of a patient's health records in the EHR system if a patient so requests.

- EHR data exchange must allow "access *to all data elements* of a patient's electronic health record" permitted by privacy laws. (HITECH new §3001(c)(5)(D)(iv) as added by Cures Act §4002; emphasis added.)

- EHR data exchange *cannot* be implemented by ONC in ways that *"are likely to substantially increase the complexity or burden"* of access to, or exchange of, health information. (HITECH new §3022(a)(2)(B) as added by Cures Act §4004; emphasis added. This provision perforce imposes a specific requirement for nationwide standardized exchange.)

- EHR data exchange must be enabled through the use of application programming interfaces or *successor technology or standards*. (HITECH new §3001(c)(5)(D)(iv) as added by Cures Act §4002; emphasis added. FHIR-based data exchanges and HDBs are successor technologies.)

- EHR data exchange must provide *the patient or an authorized designee* with a *complete copy* of his or her health information from an electronic record *in a computable format*. (HITECH new §3000(10)(B) as added by Cures Act §4003;

[4] TEFCA's numbingly elaborate Individual Access Services SOP is available at https://rce.sequoiaproject.org/wp-content/uploads/2022/09/Final-SOP-IAS-Exchange-Purpose-Implementation.pdf .

emphasis added.)

TEFCA's SOP for Individual Access Services fails all these specifications. It is a formidable barrier to convenient, comprehensive use by patients and consumers for health data exchange purposes in, among other settings, clinical trials.

To recapitulate: the Interoperability Rule supplies the first, FHIR-based iteration of a national, digital, health data exchange standard; and the standard will expand rapidly and infinitely with the Interoperability Rule's Standards Version Advancement Process. Federal funds should be spent on accelerating expansion of FHIR-based exchange standards under the Standards Version Advancement Process (SVAP). The goal is to support an ever-widening, and ever-deepening, scope of medical specialty data requirements and associated research protocols.

In these comments, we ask OSTP to recommend to the President that he intervene with the Secretary of HHS. The aim is to require ONC to reconceptualize and reformulate TEFCA. That is startling, because ONC has devoted time, significant federal funding, and commitment to implement an institution-centric vision of the Cures Act's TEFCA mandate. That includes designating an expensive "Recognized Coordinating Entity" to help develop and maintain TEFCA's Common Agreement for the benefit of HIEs.

But TEFCA, as ONC now is implementing it, is more than just a stark misuse of federal resources to sustain antiquated and unnecessary HIEs. *ONC's TEFCA architecture defies sound cybersecurity design principles. It envisions a complex mass of cobbled-together network nodes and pathways, and unwieldy, convoluted operating procedures that invite security penetration. The network architecture is suffused with specific vulnerabilities, all gratuitous weaknesses. This TEFCA cannot, for any practical purposes, be secured to a satisfactory level. It is the opposite of ONC's goal of "a universal floor for [trusted] interoperability across the country."*

TEFCA at present is therefore not a network architecture to rely on for biodefense or any other national security purpose, including, and not limited to, emergency clinical trials.

We emphasize that the network of networks and turgid operating procedures envisioned in ONC's current plans for TEFCA are also unsuited – inefficient past the point of being dangerous – for medical research purposes.

If forced to use this version of TEFCA, the clinical trial community – 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 – will face constant unnecessary recruitment obstacles, process delays, ongoing regulatory compliance problems, and constant undue expense.

Conclusion

Health Data Banks' emergence will create new, technologically advanced infrastructure that is available at all times for clinical trials – especially important in emergencies. The federal government should direct its funding, attention, and support to accelerating development of FHIR-based health data exchange to make HDBs ever more capable. Funding for more rapid

standardization of FHIR resources under the Implementation Rule's Standards Version Advancement Process is crucial to achieving these goals as quickly as possible.

In parallel, OSTP should recognize that ONC's implementation of TEFCA as it now stands is an obstacle to secure, effective nationwide health data exchange – where what is needed simply is FHIR-based, point-to-point data exchange to replace today's reliance on facsimile. TEFCA's insecure architecture is intolerable. To fulfill its responsibilities to the country, OSTP should begin the process of conceptualizing TEFCA anew, so it can be implemented in consonance with the Cures Act's basic policy goal of organizing health data around patients, not institutions or networks of institutions. This is a call for Presidential intervention.

Respectfully submitted,

The Health Record Banking Alliance

/s/ Richard D. Marks
Richard D. Marks, Vice President
richardmarks@earthlink.net