February 20, 2018

The Honorable Donald Rucker, MD,
National Coordinator for Health Information Technology,
US Department of Health and Human Services
200 Independence Ave. SW
Washington, DC, 20201

Comments submitted at: exchangeframework@hhs.gov

Re: Draft Trusted Exchange Framework and Common Agreement (TEFCA)

Dr. Rucker:

AMIA appreciates the opportunity to comment on ONC’s Draft Trusted Exchange Framework and Common Agreement (TEFCA). We provide comments to the related US Core Data for Interoperability (USCDI) in a separate comment letter.

AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, public health experts, and educators who bring meaning to data, manage information, and generate new knowledge across the research and healthcare enterprise. As the voice of the nation’s biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

In response to ONC’s 2017 Request for Information on trusted exchange, AMIA recommended ONC develop policies to encourage four main goals:

- Coordination among existing private sector networks, as well as provide opportunities for new networks to emerge;
- Harmonization along the key dimensions of (1) data availability and (2) permitted purposes for which data can be exchanged;
- Alignment on biomedical and health data IT standards; and
- Development of a national patient identification system.

AMIA commends ONC for their proposals to harmonize networks’ permitted purposes and the data available for exchange. This basic level of harmonization has been absent among current

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networks, and without it, clinicians will be forced to rely on point-to-point exchange at increased costs to operational IT, increased burden to practice, and to the detriment of patient care. At a national level, the health system simply cannot optimize nationwide investments in health IT based on push-only exchange and contractual relationships that must be created anew for each step in the referral chain. In tandem, the TEFCA and USCDI represent a new paradigm for our national health IT infrastructure. And it is for this reason we urge diligence.

As we understand it, ONC is proposing a set of policy actions meant to enable: (1) nationwide provider access to their patients’ health information; (2) individual access to their health information electronically without any special effort; (3) population level data exchange; and (4) open and accessible application programming interfaces (APIs).

While these goals are laudable, the details of these policies will require further refinement and significant time to be operationalized. Specifically, we anticipate that the TEFCA requirements to enable bulk transfer and individual access will require much more work to develop consensus on executable solutions. We also anticipate that more work and experience will be needed with the type of consent management required by the TEFCA.

To address these important functions, AMIA recommends:

- **ONC develop a roadmap that details an implementation plan at least three years into the future;**
  - Development of a detailed roadmap and implementation plan should be articulated as a required component in the Cooperative Agreement, and the would-be Recognized Coordinating Entity (RCE) should discuss its vision for this roadmap as part of the selection process.

- **ONC establish pilot tests to inform this implementation plan;**
  - Specific pilots should focus on component pieces of the TEFCA including individual access, bulk transfer, and consent management. These tests should be clinically and geographically relevant, and reflect real-world care patterns that result in lessons essential to a nationwide rollout of the TEFCA.

- **ONC develop mechanisms to garner stakeholder feedback and public input along the way.**
  - We see the Health Information Technology Advisory Council (HITAC) and its subgroups as important inputs to the ongoing development of the TEFCA. However, we urge ONC to seek feedback from the wider stakeholder community, and we request that the RCE be required to hold open comment periods, listening sessions, and other accountability mechanisms.

A more detailed timeline and implementation plan will help stakeholders better understand how the TEFCA and USCDI are meant to be operationalized. Implementation plan(s) will also help ensure appropriate interactions with current policies, particularly the EHR Certification Program and CMS payment policies. While the USCDI articulates a year-over-year roadmap, the TEFCA does not
appear to acknowledge that fulfillment of its draft provisions will take several years to be operational across a majority of End Users. Development of a detailed roadmap and implementation plan should be articulated as a required component in the Cooperative Agreement, and the would-be Recognized Coordinating Entity (RCE) should discuss its vision for this roadmap as part of the selection process. Additionally, we recommend that the RCE conduct business in a public, transparent manner and develop an inclusive governance process. The Cooperative Agreement should stipulate that the RCE have a governance structure that includes a broad array of stakeholders, including representatives from the informatics community, standards developers, IT professionals, clinicians, public health, payers, HIEs, and individual / patient advocates.

Pilot tests will enable both ONC and private sector stakeholders to better understand the impacts of both explicit and implicit TEFCA policies. Pilot testing will allow the TEFCA to scale with more buy-in from stakeholders, and it will increase the likelihood that this “glide path” approach will be successful. Pilot tests will also satisfy 42 U.S.C. 300jj–11(c)(9)(B)(iii) which requires pilot testing of the TEFCA. By focusing on the component pieces of (1) individual access, (2) bulk transfer, and (3) consent management, stakeholders would not be engaging in mini-TEFCAs; rather, these tests would result in lessons essential to a nationwide rollout of the TEFCA. Ultimately, these early networks will form the foundations for a learning health system. We need to be thoughtful in how we establish this foundation.

We also recommend that these tests be clinically and geographically relevant, which means including representative care settings (e.g. community hospitals, health systems, SNFs, ambulatory, LTPAC, etc.) and reflect patient care patterns (rather than two leading academic medical centers on the east and west coast), and capable of informing other use cases like bulk transfer to support data science, analytics, and population-level research. It is important to reiterate that proofs of concept are insufficient. Our healthcare system is too diverse for proofs of concept to be broadly applicable. Rather, these tests must answer specific questions, or establish specific processes, meant to inform the overall strategy. With this in mind, we offer three specific pilot tests for consideration: (1) individual access; (2) bulk transfer; and (3) consent management.

**Individual Access**

The fulfillment of HIPAA’s Right of Access is, perhaps, the most important and the most achievable aspect of the TEFCA. Our long-standing assumptions that IT systems must serve only the institutions that pay for them, as opposed to the individuals who should benefit from them, is challenged in this age of democratized medicine. While the capabilities of clinical systems must improve and evolve to give clinicians the right information on the right patient at the right time,

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individual access empowers patients to be stewards of their own health, and has the potential for far-reaching, systemic improvements.\textsuperscript{4,5,6} The TEFCA should dramatically improve the availability of data for patient care, but the individual access use case will dramatically alter the fundamentals of our national healthcare system by making patients first order participants in their care.

AMIA recommends that the pilot test seek to answer or demonstrate the following about the individual access use case:

1. Current capabilities
   a. Understand how current technology and functionalities (e.g. 2015 Edition Certification) could meet the HIPAA Right of Access use case within a single institution or care setting, including through application programming interfaces (APIs)
   b. Identify gaps in current standards, implementation guides, technology, functionality, and process

2. Cross-organizational access
   a. Understand how an individual could leverage their HIPAA Right to Access to aggregate data from across treating clinician settings
   b. Identify gaps in current standards, implementation guides, technology, functionality, and process

3. Third-party access
   a. Understand how an individual could use a third-party application to access data from across treating clinician settings through a single access point
   b. Identify gaps in current standards, implementation guides, technology, functionality, and process

4. Payer and Business Associate Access
   a. Understand how an individual could access their data from payers and other business associates

5. Evaluation of HIPAA Right to Access
   a. Evaluate how demonstration of the HIPAA Right to Access is impacting care delivery (e.g. workflows, data use, etc.) and look for ways to mitigate unintended consequences

\textsuperscript{5} Mohsen, M., Aziz, H. (2015). The Blue Button Project: Engaging Patients in Healthcare by a Click of a Button Perspectives in Health Information Management. 2015 Spring; 12(Spring); 1d.
Bulk Transfer
Population Level requests represent a new and exciting opportunity for quality improvement,7 population management and public health,8 clinical research,9 and cost-effectiveness research.10 Recent advances in computing power and bandwidth capacity make this use case an incredibly enticing and important component of the TEFCA.11 However, there are numerous legal and technical aspects of this functionality that need attention, including:

1. Guidance for stakeholders (clinicians, payers, researchers, etc.) to understand the application and limitations of HIPAA in the context of bulk access, with specific examples including:
   a. Using bulk transfers to support accountable care and alternative payment model participation;
   b. Use cases for various kinds of research;
   c. Specific examples of how payers can and cannot utilize this aspect of the TEFCA will also be helpful;
2. Development of systems and controls meant to assure that data are used only for permitted purposes;
3. Demonstration on how specific data classes (and not others) can be queried so that such information can be integrated with clinical workflows;
4. Guidance on consent management (see below);
5. Consideration of the significant new security risk that comes with requesting multiple patients at once, with both process guiderails and voluntary recommendations to reduce this risk; and
6. Evaluation of how this functionality has impacted care delivery, and identification of any negative, unintended consequences.

Consent Management
We understand that work is already underway to develop a scalable solution to consent management, and that several institutions have existing systems and processes in place to manage consent. Given the variability in consent policy for data exchange, we anticipate that consent management will be a pervasive challenge. Deliverables from these pilots should not only

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11 See All of Us Research Core Protocol Version 1 at: https://allofus.nih.gov/sites/default/files/allofus-initialprotocol-v1_0.pdf
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demonstrate the ability to manage individual consent across geographies and institutions, but also include:

1. Development of specifications that assure:
   a. The data structures that are used to represent consent are sufficiently robust to cover all use cases;
   b. The technical changes that HINs need to make to represent standardized consent structures are not excessively complex;
   c. The workflow changes that participants and end users must put into place to address standardized consent models are not overwhelming; and
   d. Patients can comprehend the consent policies across the network.
2. Development of a matrix of state laws that shows how states manage PHI differently; and
3. Development of a minimum standard to protect patients who wish to minimize their data sharing.

Below we outline our understanding of the TEFCA’s mechanics and operative concepts, and we discuss provisions outlined in Part A of the TEFCA. Should you have any questions or require additional information, please contact AMIA Vice President for Public Policy Jeffery Smith at jsmith@amia.org or (301) 657-1291 ext. 113. We, again, thank ONC for the opportunity to comment and look forward to continued dialogue.

Sincerely,

Douglas B. Fridsma, MD, PhD, FACP, FACMI
President and CEO
AMIA

Peter J. Embi, MD, MS, FACP, FACMI
President & CEO
Regenstrief Institute
AMIA Board Chair

(Enclosed: Detailed Comments to TEFCA, Part A)
Overview

ONC rightly identifies that the current landscape is resultant from different networks, established to serve different customers, to achieve different use cases. AMIA supports the stated goal of the TEFCA “to provide policies, procedures, and technical standards that build from existing [Health Information Networks] HIN capabilities and enables them to work together to provide that single ‘on-ramp’ to Electronic Health Information regardless of what health IT developer they use, health information exchange or network they contract with, or how far across the country the patients’ records are located.” AMIA supports the virtual nature of a TEFCA “on-ramp,” and encourage ONC to avoid a ridged on-boarding process that could be exceedingly expensive and duplicate costs spent and processes used by existing HINs and provider organizations. We also supports the four outcomes identified by the TEFCA, including:

1. Providers can access health information about their patients, regardless of where the patient received care;
2. Patients can access their health information electronically without any special effort;
3. Providers and payer organizations accountable for managing benefits and the health of populations can receive necessary and appropriate information on a group of individuals without having to access one record at a time (Population Level Data), which would allow them to analyze population health trends, outcomes, and costs; identify at-risk populations; and track progress on quality improvement initiatives; and
4. The health IT community has open and accessible application programming interfaces (APIs) to encourage entrepreneurial, user-focused innovation to make health information more accessible and to improve electronic health record (EHR) usability.

**AMIA Recommendation: AMIA supports these four goals in principle.** As stated above, we believe there is a need to develop a detailed, three-year-plus roadmap and pilot tests for key aspects of the TEFCA, which will better position ONC to achieve the four goals it articulates.

ONC says the Trusted Exchange Framework focuses on broadly applicable use cases that are structured to address the areas of greatest need while also allowing existing HINs and trust frameworks to vary as appropriate to meet more specialized use cases that are specific to their own Participants. As permitted and pursuant to an Authorization and to the extent permitted under Applicable law, these uses cases are termed “Permitted Purposes” and include:

1. Use or Disclosure for Treatment, Payment, Health Care Operations;
2. Public Health;
3. Individual Access; and

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12 Population Level: a type of exchange of Electronic Health Information of multiple individuals in a single transaction, sometimes referred to as a bulk transfer.
13 Under Section 4002 of the Cures Act, the Secretary is required under rulemaking to publish application programming interfaces that allows health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces or successor technology or standards, as provided for under Applicable Law, including providing access to all data elements of a patient’s electronic health record to the extent permissible under applicable privacy laws.

**AMIA Recommendation:** AMIA supports harmonization along the dimension of permitted purpose for use of data acquired through the TEFCA. To facilitate better understanding of how these Permitted Purposes could provide value, we recommend that ONC and OCR publish scenario-based guidance on the TEFCA Permitted Purposes. AMIA agrees with the rationale to align networks along these broad use cases. However, we note that the HIPAA Privacy Rule “minimum necessary standard”\(^\text{14}\) is not uniformly understood and subject to wide variation in interpretation. Stakeholders are likely to raise concerns over the breadth, for example, of allowing bulk access to EHI for purposes of Health Care Operations, even though it is defined at 45 C.F.R. §164.501 of the HIPAA Rules. ONC and OCR should develop FAQs in accordance with processes already utilized, or created FDA-style guidance documents to help stakeholders better understand these Permitted Purposes.

Below, in Table 1, we offer comments and recommendations related to Part A – Principles for Trusted Exchange.

*Table 1: Principles for Trusted Exchange & AMIA Comments*

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<tr>
<th>Principle (and Subparts)</th>
<th>AMIA Comments &amp; Recommendations</th>
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<tr>
<td>Principle 1: Standardization</td>
<td>Adhere to industry and federally recognized technical standards, policies, best practices, and procedures.</td>
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<td>A. Adhere to standards for Electronic Health Information and interoperability that have been adopted by the Secretary of the U.S. Department of Health &amp; Human Services (HHS) or identified by ONC in the Interoperability Standards Advisory (ISA).</td>
<td>Principle 1A says “Qualified HINs should adopt and use standards and implementation specifications that are referenced in the 2015 Edition final rule and the ISA.” Principle 1A also states that “proprietary’ standards—that is, standards that incorporate or require the use of patented technologies or other intellectual property (IP)—should be avoided unless adequate commitments have been made to license all standards-essential IP pursuant to Reasonable and Non-Discriminatory (RAND) terms.” Principle B describes the importance of implementation guides, structured vocabularies, accurate translation and adapter services, and testing and onboarding programs.</td>
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<td>B. Implement technology in a manner that makes it easy to use and that</td>
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\(^{14}\) 45 C.F.R. 164.514(d)(1) – (5)  
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| allows others to connect to data sources, innovate, and use data to support better, more person-centered care, smarter spending, and healthier people. | At a minimum, we noted, the TEFCA and ISA should be mutually reinforcing documents. We see Principle 1A as fully embracing this recommendation; thus, we fully support Principle 1A. Further, we note that the TEFCA requirement regarding proprietary standards is consistent with our Health IT Standards & Interoperability Principles, Policy Position 1: The development and management of HIT standards as a public good, operated in a nonprofit, non-proprietary basis, with low barriers to review, reference, or use.  
While we support Principle B in spirit, we note that much more funding and work is needed for “easy to use” interoperability. The focus on standards, implementation guides, structured vocabularies, and testing is correctly placed, but ONC must look for ways to make more progress across these areas through future policy development. We also reiterate our call for interoperability testing. |

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<th>Principle 2: Transparency</th>
<th>AMIA Recommendation: We view these principles as reasonable. However, we note that the implementation of</th>
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<td>A. Make terms, conditions, and contractual agreements that govern the exchange of Electronic Health Information easily and publicly available.</td>
<td>These principles articulate that Qualified HINs should make terms and conditions of participation easily available and publicly accessible; specify both the minimum set of permitted purposes and any additional permitted purposes for using EHI; and follow privacy practices regarding use and disclosure. Principle 2C also requires “capability to document and/or capture patient consent,” “not impede the ability of patients to access and direct their own Electronic Health Information to designated third parties,” and “policies and procedures to allow a patient to withdraw or revoke his or her participation in the exchange of his or her Electronic Health Information on a prospective basis.”</td>
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<td>B. Specify and have all participants agree to the permitted purposes for using or disclosing ePHI or other</td>
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19 Ibid.
### Principle (and Subparts) | AMIA Comments & Recommendations
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Electronic Health Information. | Technology and processes necessary for Principle 2C will present a challenge today. Presumably, Qualified HINs will include HINs and participants across state lines, which have differing “applicable laws” for use and disclosure of EHI and for which different kinds of consent are required for different kinds of conditions. Even for the TEFCA Permitted Purposes of TPO, public health, individual access, and benefits determination, variances exist across applicable laws. AMIA recommends that functionality to accommodate these provisions be prioritized and tested as part of the consent management pilot tests recommended above.

C. Publish, keep current, and make publicly available the Qualified HIN’s privacy practices. | 

| Collaborate with stakeholders across the continuum of care to exchange electronic health information, even when a stakeholder may be a business competitor. | 

### Principle 3: Cooperation and Non-Discrimination

**A. Do not seek to gain competitive advantage by limiting access to individuals’ Electronic Health Information.**

Principle 3A states that “Qualified HINs and their participants should not treat individuals’ EHI as an asset that can be restricted in order to obtain or maintain competitive advantage.” It goes on to say that Qualified HINs “should not implement technology in a manner that permits limiting the sharing of data,” “should not use contract provisions or proprietary technology implementations to unduly limit connectivity,” and “should not [price fees and other costs] to interfere with, prevent, or materially discourage the access, exchange, or use of EHI,” with competitors.

**AMIA Recommendation:** We support this policy concept, and see it aligned with similar work related to the Cures Act and other Information Blocking provisions at HHS. In comments submitted to ONC regarding the TEFCA RFC, AMIA recommended ONC conceptualize the TEFCA as a pre-competitive public good. This enables an environment where businesses can compete on services, not infrastructure. The TEFCA should encourage the default expectation is one of sharing, using standard protocols, and uniform data reuse policies.

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<td>Principle 4: Security and Patient Safety</td>
<td>Exchange electronic health information securely and in a manner that promotes patient safety and ensures data integrity.</td>
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<tr>
<td>A. Ensure that Electronic Health Information is exchanged and used in a manner that promotes patient safety, including consistently and accurately matching Electronic Health Information to an individual.</td>
<td>Principle 4A focuses on the need for a “core set of demographic data,” to accurately match patient data, and “standard nomenclatures” that are consumable by receiving systems to improve data integrity. It also states that Qualified HINs “should work collaboratively with standards development organizations (SDOs), health systems, and providers to ensure that standards, such as the C-CDA, are implemented in such a way that when Electronic Health Information is exchanged it can be received and accurately rendered by the receiving healthcare organization.”</td>
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<td>B. Ensure providers and organizations participating in exchange have confidence that the appropriate consent or written authorization was captured, if and when it is needed, prior to the exchange of Electronic Health Information.</td>
<td>Principle 4B notes that HIPAA Rules do not require consent for TPO, unless it is to share ePHI for Health Care Operations with another CE that does not have a relationship with the patient. It notes consent requirements are variable across state and federal laws, depending on the type of data and the state, and says that a “Qualified HIN’s ability to appropriately and electronically capture a patient’s permission to exchange or use their EHI will engender trust amongst other Qualified HINs seeking to exchange with that network.”</td>
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<td>Principle 5: Access</td>
<td>Ensure that patients and their caregivers have easy access to their electronic health information.</td>
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<td>AMIA Recommendation:</td>
<td>We appreciate and agree with the need to consistently capture standardized demographic data. We recommend that existing evidence be used to select mandatory demographic identifiers that already exist (such as name, birth date, and mother’s first name) that when used in combination can accurately and uniquely identify an individual. Evidence further suggests value in alternate secondary identifiers of lesser value that when combined may be used to replace missing mandatory identifiers to accurately and uniquely identify individuals. We also recommend work be initiated to coordinate Connectivity Broker requirements for a master patient index, record locator services, as well as a master provider index, to ensure accurate patient matching.</td>
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<td>Principle 5A articulates individuals’ rights conferred by HIPAA to access and transmit their EHI as well as learn how their information is shared and used by CE and BAs. It specifically references the Fair Information Practice Principles (FIPPs) that articulate how networks “should provide reasonable opportunities for individuals to review who has accessed their individually identifiable health information or to whom it has been disclosed, in a readable form and format.” It further articulates that Qualified HINs and their participants should not limit third-party applications from accessing individuals’ EHI via an API when the application complies with TEFCA requirements and is directed by the individual.</td>
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<td>Principle 5B articulates that “Qualified HINs and/or their participants must maintain policies and procedures that allow a patient to revoke his/her participation in the Qualified HIN on a prospective basis,” and states that such policies and procedures must be easily and publicly available and the process for revoking participation must be easily accomplished by patients.</td>
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**AMIA Recommends:** We support these Principles. In our comments to ONC’s TEFCA RFC we strongly recommended that the TEFCA be leveraged to improve access for patients’ data. “A core use case this framework could be demonstration is the patient’s right to access provided by HIPAA. A patient should be able to request a digital copy of their data maintained by all stakeholders within the TEFCA.”

We note that significant work will be required to fulfil Principle B:

1. Detailed policies will need to be created such that all QHINs can adopt them,
2. Significant re-work will be required by HINs to implement the policy once developed;
3. Participant workflows will need to change;


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<td>(4) Data communication, management, and storage rules will need to be developed for third-parties who are not CEs; and</td>
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<td>(5) A standardized vetting mechanism will be needed to ensure the safety and security of EHI when transmitted to, stored by, and received from third-parties who are not CEs.</td>
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<td>Exchange multiple records for a cohort of patients at one time in accordance with Applicable Law to enable identification and trending of data to lower the cost of care and improve the health of the population.</td>
<td>Principle 6 describes a set of use cases that depend on an ability to exchange multiple patient records at one time (i.e. population level or “bulk transfer”), rather than potentially performing hundreds of data pulls or pushes for a panel of patients. It says that “Qualified HINs should provide the ability for participants to both pull and push population level records in a single transaction.”</td>
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<tr>
<td>A. Enable participants to request and receive multiple patient records, based on a patient panel, at one time.</td>
<td><strong>AMIA Recommendation:</strong> While we support this principle, some members have expressed doubt as to the feasibility of this functionality for many End Users. They are concerned that End Users will be overrun with data and data requests. Other members are more confident, and have experience with these kinds of queries. Still others have expressed concern about the mechanism for ensuring that a request is valid, that the requesting entity has authorization to receive this information, and that the entire process could become a new cybersecurity risk. Should ONC seek information from any of these groups, AMIA would be happy to arrange a discussion.</td>
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