Re: ONC Draft Trusted Exchange Framework (TEF) and U.S. Core Data for Interoperability (USCDI)

Submitted electronically

Dear Dr. Rucker:

Enclosed are the comments of Health Level Seven (HL7) International on the ONC Draft Trusted Exchange Framework (TEF) and the proposed U.S. Core Data for Interoperability (USCDI). Based on input from HL7’s diverse workgroups, we offer general considerations and detailed recommendations in a number of important areas. As we note in our comments, HL7 stands ready to continue to contribute to this process as a critical subject matter expert.

HL7 is a not-for-profit, ANSI-accredited standards developing organization (SDO) dedicated to providing a comprehensive framework and related interoperability standards, including the rapidly emerging and evolving HL7 Fast Healthcare Interoperability Resources (FHIR®), the Consolidated Clinical Document Architecture (C-CDA), and the widely used V2 messaging standards. HL7 International is comprised of members representing healthcare providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

As the global authority on standards for interoperability in healthcare, HL7 is a critical leader and driver of standardization. HL7 standards and implementation guides – including those for HL7 FHIR®, provide the underpinnings for connected, patient-centered health care and an information highway for precision medicine.

This letter includes our high-level comments. Appendix 1 provides more detailed comments and Appendix 2 provides technical comments regarding security.

Key high-level comments include the following:

**Overarching Comments**

Overall, HL7 supports ONC’s goals for the draft TEF and USCDI. They are based on solid principles for all stakeholders: a single minimum set of rules from which to operate, pursuing more efficient approaches to sharing, building on existing initiatives, and focusing on private sector consensus standards and a private
sector Recognized Coordinating Entity (RCE). We also welcome ONC’s recognition that HL7 standards are a critical part of the interoperability ecosystem.

HL7’s high level comments are as follows:

• **Principles:** Key principles to be incorporated as the TEF and RCE are rolled-out include:
  o Largely private sector-led coordination
  o True balanced stakeholder collaboration and transparency.
  o Enforceable agreement terms
  o The RCE should have demonstrated experience and capabilities relevant to the intended tasks
  o Use of RCE-developed and maintained operational, use-case specific implementation specifications/guides referenced from the Common Agreement
  o Use of robust testing tools
  o Pilot-testing and controlled roll-out
  o Provisions for security testing/monitoring

• **RCE** - The private sector RCE, while not an SDO, should exhibit many of the characteristics of successful SDOs, including transparency, non-profit status, technical competence, significant relevant experience, broad stakeholder engagement and governance that appropriately balances relevant interests.

• **Implementation Specifications/Guides** - Technical detail, including specific standards and implementation specification/guide references, should be moved from the legal agreement (the Common Agreement) to an RCE managed use-case specific set of implementation specifications/guides.

• **Standards Requirements** - The references to the ONC 2015 Certification Edition and the ONC Interoperability Standards Advisory (ISA) should be noted as being informational. The RCE - in collaboration with stakeholders - should finalize the specific standards and implementation guides to be used within the Trusted Exchange Framework through a set of use case-specific RCE implementation guides. Neither the 2015 Certification Edition nor the ISA were designed for the purpose of incorporation by reference into a trusted exchange framework or a legal Common Agreement. Particularly, the ISA includes standards with a range of maturity levels and in some cases multiple standards for a given use case.

• **Scope and Pace** - The scope and proposed implementation pace of these new initiatives, including the schedule for updates, are overly ambitious.

• **Timetables** - The timetables for action once a standard is “adopted” (e.g., 12 months) are far too aggressive in many cases. The “clock” should not start running until after pilot tested and RCE implementation specifications/guides are available for an agreed to case. Following this availability, a reasonable timeframe for new data classes would be 24 months or more while some changes, such as minor updates to existing standards, might be implemented much more quickly.

The timetable for prescribing new standards in the USCDI needs to take into account the time required for standards development, pilot-testing, and evaluation, as well as for developing, testing, and refining the associated implementation specifications/guides. The processes for managing the USCDI should also take account of the need to periodically review and update standards, and to replace, deprecate, and phase out obsolete standards.
• **Sustainability** – Financial sustainability should be a focused consideration of the Trusted Exchange Framework and Common Agreement process (including specifically economic drivers for adoption and sustainability of the new RCE and QHIN entities).

• **Single On-Ramp** - We applaud the concept of simplified access to the exchange network through a “single on ramp,” but believe that, in practice, the primary goal should be a single on-ramp for those participating in each use case, with consistency across uses cases being pursued where it is appropriate and reasonably feasible.

• **Requirement Flexibility (QHINs)** - We urge ONC, in the final TEFCA, to provide more flexibility in the requirements for QHINs, and the technologies and permitted purposes that they must support. Recognizing ONC’s desire to have a limited number of QHINs, it is still important to have sufficient QHINs and Participants operating through this trust framework in order to deploy practical architectures based on current capabilities and technology maturity.

• **Technical Architecture** - A singular technical architecture across all use cases is not practical. For example, HL7 FHIR-based APIs may not be best or primarily implemented through the fully centralized, brokered architecture that underpins the proposed TEF.

• **Security** - The principles of persistent lifelong access control and sensitive data and security labels: are important in ensuring the security and privacy of information residing in health information networks and are currently missing from the proposed TEF. We recommend that a new subsection under the Principle 4 to be referenced in other places in the document as appropriate. HL7 describes specifics of this proposed subsection in our detailed comments below.

• **USCDI** - The USCDI approach provides a very helpful means to support the 21st Century Cures “all data” goal but we must to also be mindful of the need to manage the burden on health care providers for collecting and providing these data elements for exchange in standardized form. Regarding the idea of a standards maturity model in the USCDI, the references to standards should also identify specific implementation specifications/guides that have been piloted, used in production, and adopted in the context of proposed use cases. Each data class may involve different content and levels of granularity of interest depending on the use case to avoid having to “send everything always” rather than right-sizing data sharing. With respect to two proposed additions for the 2018 USCDI, we note the following:

  o **Data Provenance:** We agree that this data class is important to trusted exchange. However, HL7 is concerned that there are complexities with this data class that have not yet been appropriately vetted and may bring out challenges in implementation. We do not support inclusion in the 2018 USCDI.

  We note that labeling health care information for integrity and provenance is supported by HL7 privacy tagging vocabulary. HL7 Data Provenance CDA Implementation Guide provides a flexible overlay of the specific CDA elements that HL7 considers critical for persisting provenance and integrity metadata across the lifecycle of clinical content as it travels from the originating authors and is “touched” by many hands. In addition, HL7 FHIR has developed a Provenance Resource based on the best thinking of HL7, ISO and W3C on how effectively capture and chain provenance, integrity, reliability, authenticity, and confidence levels on the trustworthiness of content regardless of the syntax in which the
content is expressed or conveyed. We recommend that TEFCA seek to ensure “safe sharing” by referencing within an evolving standards adoption vehicle, such as the USCDI, as well as RCE implementation specifications/guides, interoperable approaches to ensuring patient safety and trust across the TEFCA ecosystem.

- **Clinical Notes**: In response to ONC’s request for input on addition of the Clinical Notes data class to the USCDI, HL7 recommends that the initial note types added to the USCDI be limited to reduce scope and complexity, with additional note types being added in future years. We specifically recommend that the notes initially selected for exchange should be those most commonly transmitted for care transitions: discharge summaries and visit summaries.

Lastly, we suggest that appropriate implementation timetables may vary between use cases within a single USCDI data class, e.g., a given data class may be available sooner for a single-patient access use case than for a multi-patient bulk exchange use case utilizing the same data class. We suggest that the USCDI makes this distinction by providing separate timetables for use of USCDI data classes based on use case.

In closing, we commend ONC for moving implementation of the 21st Century Cures Act forward with the Draft Trusted Exchange Framework (TEF) and the proposed U.S. Core Data for Interoperability (USCDI). Attached we provide further detailed comments to inform this process. Please do not hesitate to contact me to discuss them in more detail at cjaffe@HL7.org. We look forward to offering our ongoing assistance to ONC.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
Health Level Seven International

Cc: Genevieve Morris, Principal Deputy National Coordinator for Health Information Technology
Appendix 1: Health Level Seven (HL7) International Detailed Comments on the ONC Draft Trusted Exchange Framework (TEF) and the proposed U.S. Core Data for Interoperability (USCDI)

Below please find HL7's specific and in-depth comments on the Draft Trusted Exchange Framework (TEF) and the proposed U.S. Core Data for Interoperability (USCDI).

Recognized Coordinating Entity (RCE)

HL7 strongly supports the intended reliance on a private sector, stakeholder neutral Recognized Coordinating Entity (RCE). A private sector RCE will be best positioned to draw on the range of stakeholders involved in the exchange process, both public and private sector. We urge ONC to ensure that the RCE has transparent stakeholder input. This input should include feedback from the standards development community who are a critical private sector voice in finalizing and maintaining the TEF. HL7 stands ready to contribute to this process.

HL7 suggests also that the applicable standards and implementation specifications/guides should be documented through use-case specific “RCE Implementation Guides” outside the legal Common Agreement. We note that the reference to HL7 and the “API implementation guide” needs clarification as such a guide does not currently exist. We look forward to working with the RCE to establish the intended guidance as part of the “RCE Implementation Guides.”

Standards Reference and Implementation

HL7 agrees with ONC that SDOs should play an important role in identification and development of standards for prioritized use cases. HL7 also strongly supports the TEFCA’s intended reliance on private sector standards and appreciates the many citations of HL7 standards in the proposed TEF. HL7 suggests that such standards should be referenced in RCE use-case specific implementation specifications/guides rather than in the Common Agreement. In our experience, such implementation specifications/guides, which can be incorporated by reference, are the preferred means by which to specify standards and implementation specifications.

Also, it is critically important that there is no confusion around what specific standards and implementation specification/guides apply at a given point in time. HL7 is concerned that the proposed TEF and USCDI language, while seemingly intended to be specific, does not achieve the needed level of operational specificity and is not well suited to be included in a legal agreement such as the Common Agreement. Rather it should be executed through separate guidance documents as many exchange networks have successfully demonstrated. In addition, simple references to “C-CDA” or “FHIR” are insufficient. As gaps are identified and addressed, new versions of the necessary implementation specifications/guides will need to be introduced and promulgated. We believe that that the Common Agreement is not a suitable mechanism to identify the applicable standards and implementation specifications/guides; neither should the Common Agreement reference sources --such as the Certification Edition, Interoperability Standards Advisory, or other sources -- as it introduces ambiguity and may result in diverse implementations and use of immature or inappropriate standards.

HL7 strongly recommends that the applicable standards and implementation guides be documented through use-case-specific “RCE Implementation Guides” outside the Common Agreement, while the process to update these implementation specifications/guides should involve consideration of various sources such as the ISA and ONC Certification Edition to select applicable standards and implementation specifications/guides. The benefits of such an approach are: (1) a stable Common Agreement; (2) evolving “RCE Implementation Guides” with unambiguous references to specific standard and implementation guide versions; and (3) a process that considers the appropriate range of potential standards candidates.
We note that the discussion for Principle 4(a) states that “...Qualified HINs and their participants 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.” Although SDOs like HL7 can work to ensure that standards are developed in a manner that supports effective implementation, and can and do develop implementation specifications/guides to this end, we do not believe that SDOs can ensure that standards are actually implemented in an appropriate manner. Rather, SDOs should be encouraged to have standards and implementation specifications/guides that support effective operational implementation and adaption. SDOs can and should also be involved in assessing the accuracy of testing tools to enable validation of implementation accuracy, while development of such testing tools can inform the clarity of the specifications.

We also note that Principle 2.4 “Implementation of API” states that “[e]ach Qualified HIN shall implement the APIs necessary to perform its obligations hereunder within twelve (12) months of the date of the API Implementation Guide being formally adopted by HL7 on its public website and recognized by ONC on its public website.” This section refers to “the API Implementation Guide being formally adopted by HL7.” HL7 notes that we do not have an “API Implementation Guides”. Nevertheless, our view that such detailed standards references should not be in the TEF, we suggest that ONC reference the applicable FHIR implementation specification, such as the latest adopted US Core Implementation Guide and other implementation specifications/guides as they emerge and apply to the scope of TEF.

In addition, we do not believe that 12 months is sufficient time for field implementation by QHINs, participants, and end users to be required/viable. HL7 recommends that the RCE work collaboratively with HL7, ONC, QHINs, and implementers to develop a workable timeline for implementation prioritizing use case and the necessary standards, technology, and infrastructure support these. The proposed timelines should also recognize the variations in use case requirements that may result in a USCDI data class being available at different timelines for different use cases, e.g., availability of a data class for single patient access vs. multi-patient bulk access. Neither IHE document exchange profiles nor FHIR implementation guides are currently available to support multi-patient bulk access to one or more data classes, but are available for single patient access. We suggest that the USCDI makes this distinction, and other use cases as appropriate, and at least indicates that USCDI data classes are candidate classes in the context of multi-patient bulk access.

Finally, HL7 appreciates the reference to HL7 standards as the primary building block to enable document and data element level data exchange. Those, in combination with the IHE’s document exchange profiles and various security standards have the ability to support a USCDI glidepath over time. We recognize that as use cases are further defined and gaps in standards support are recognized, increased development is required. HL7 stands ready to support the RCE and QHINs to further develop the necessary standards supporting those evolving use cases.

**Security**

The following overall principles are important in ensuring the security and privacy of information residing in health information networks and are currently not in the proposed TEF. We recommend that a new subsection be created under the Principle 4 and referenced elsewhere in the document as appropriate:

**Security: Persistent Lifelong Access Control:**

Every information processing entity participating in a QHIN that has control over PHI should enforce Persistent Lifelong Access Control to ensure that personal health information, at any time, and at the custody of any entity, before and after an exchange, will remain under access control protections in accordance with applicable policies are enforced. Applicable policies consist of:
- Overarching privacy policies such as those specified by federal or state laws; domain-specific regulations such as specified by a HIN, or by a healthcare consumer's consent directive per applicable privacy policies including an individual's right of access request, and
- Policies specific to an individual data item, also known as Handling Instructions or Handling Caveats, such as limitation on redistribution, or purpose of use.

Handling instructions are specific rules that apply to the use and processing of a data item after its release, which are issued by the originating Entity, recorded as labels on the data, and must be honored by any recipient entity across the network. Handling instructions are an important tool in ensuring a persistent access control system across policy domains.

**Security: Sensitive Data and Security Labels:**

As former National Coordinator for Health IT, David Blumenthal, MD has written, "[i]n the near future, electronic means of gathering and storing patient data will become normative. In the meantime, we will have to manage the problems that come with the territory. The key is to recognize patients' unquestioned right to control their health care fate, including their health information, and to minimize the risks of data sharing, maximize the benefits, and make it technologically safe and easy to participate."¹

In the midst of the biggest opioid epidemic in U.S. history, with deaths exceeding 40,000 per year, TECFA must ensure that patients seeking treatment for conditions likely to have significant additional privacy concerns are not discouraged from doing so. As acknowledged by legal requirements, certain types of health information (e.g. Substance Use Disorders, HIV, mental health, etc.) are considered more sensitive and require extra-care by processing entities in order to encourage those with these conditions to seek confidential treatment to the benefit of their lives and the lives of those around them.

In order to achieve compliance with these requirements, we recommend that every information processing entity participating in a QHIN that have control over PHI must be able to:

- Label data in their care with confidentiality, sensitivity, and labels for other differentiating criteria such as the applicable policy, provenance, and trust, as well as the handling instructions required by applicable policy.
- Ensure that the recipient entities are capable of understanding and honoring the security labels.
- Enable recipient entities to hold themselves accountable via accounting of disclosures.

[Note: A Security Labeling System has been standardized by HL7 and an upcoming white paper by the HL7 Security Working Group will provide a maturity model based on which entities will be able to specify minimum requirements in implementing a labeling system.]

¹ Data Withholding in the Age of Digital Health March 2017, David Blumenthal @ https://www.milbank.org/quarterly/articles/data-withholding-age-digital-health/
Security: Principle of Intended Purpose of Use:

As a major data privacy principle, the principle of Intended Purpose of Use states that any use of data must be restricted to the purposes of use for which it was intended at the time of receiving or collection. Repurposing, i.e. using information for the purpose other than what was intended, requires authorization by the originator of the information.

In health information networks, this principle means that when data is shared with an entity, the originator must specify the set of authorized purposes such as handling instructions, and the recipient must abide by these intended purposes, i.e. refrain from using data for any other purposes (repurposing) without getting reauthorization from the originating entity.

Based on the Principle of Least Privilege, entities must request data only for the minimum purposes required to conduct business and health information networks should:

- Label outgoing data with the intended purposes of use.
- Ensure that where appropriate (e.g. in the case of some entities), access control is enforced to make sure that requesters will only receive information for the purposes for which they are authorized (e.g., prohibited from requesting for HIPAA permitted purposes that are not appropriate or authorized given the nature of their business). For example, an End User that is a research facility should be restricted to requesting and receiving information only for the purpose of Research and not for Payment. Entity-specific Authorized purposes can be identified in the on-boarding process based on the nature of the entity’s business.

Privacy

We also suggest that ONC and the RCE use the following cross-HIN approach to harmonize healthcare consumer privacy protections in the TEF:

- Encourage states to harmonize privacy legislation, allowing all health care records to be collected and shared in accordance with each HIN’s default consenting process at the appropriate juncture.
- Establish opt-out by default for collection, access, use and disclosure of health information governed by HIPAA as allowed within some HINs (recognizing that this may be a two-stage authorization process for collection and sharing by some HINs), while giving all healthcare consumers continuous opportunity to opt-in, in whole or part, to specific to collect, access, use, or disclose by recipient by purpose of use.
- Ensure that all HINs implement security labeling to distinguish sensitive conditions governed by laws that preempting or go beyond HIPAA (such as Mental and Behavioral Health, HIV, Sickle Cell, Drug/Alcohol Abuse, Military Sexual Trauma, Sexual Abuse, Minor’s Health as a matter of policy) to enable cross HIN policy bridging to ensure that the recipient has the capability to enforce the sender’s policies, including re-disclosure.
- Ensure that all HINs support the ability of healthcare consumers, whether the HIN operates under an “opt-in” or “opt-out” regime, to permit consumers to manage the collection, access, use, or disclosure of their health information to any recipient by purpose of use independently via their HIPAA Right of Access.

TEF and USCDI: Stages in Programs

More evaluation and detail should be given by ONC regarding the staging and sequencing of standards for specific use case implementation specifications/guides in these programs. Use case implementation
specifications/guides incorporated by reference in the Common Agreement should include bundles or packages of standards that work together to achieve successful use case scenario outcomes. A sequence of pilot testing and subsequent implementation of standards included in each use case implementation guide should be based on priorities determined through open, transparent, multi-stakeholder governance.

The proposed timeframe of no less than 12 months for mandatory updates to data classes and/or APIs by QHINs is too aggressive and does not take into consideration the complete lifecycle of implementing system changes, beginning from analysis through go-live. Further, this timetable does not take into account the possibility of other HINs not operating on the same data class sets or versions and therefore will require customizations and testing to ensure data is being transmitted appropriately and accurately. HL7 recommends mandatory implementation no less than 24 months after publication of final standards to allow for successful change management and implementation of new data classes.

**USCDI**

Generally, we note that timelines are sensitive to certain capabilities (e.g., document vs. data element) and use cases (e.g., single patient access vs. multi-patient bulk data exchange) and therefore a singular timeline per data class is therefore not practical. In that context, we offer a number of considerations regarding the proposed USCDI data classes and the proposed timing.

**USCDI: Question of US Readiness for Fields Beyond CCDS:** In considering when additional data elements in the USCDI must be used under TEFCA and other programs, it is instructive to recognize that Meaningful Use Stage 3 and equivalent MIPS ACI measures have already been postponed due to the burden of implementation on vendors and providers, which must use now slated for 2019. Many new ways of exchanging data – API Access, HIE Receive/Incorporate/Clinical Information Reconcile including using network queries, and Patient Generated Data are all new requirements for providers (hospitals, clinicians, and other venues of care with less evolved health IT). New data classes have also been added to the C-CDA, including Care Plan fields, some demographics, and UDI. The certification for all of these requirements is still in progress by many vendors and is not widely used by all yet. HL7 is concerned that there is no field evaluation of this new functionality or types yet, although we are encouraged by recent announcements enabling API based access to an individual patient’s data across multiple providers using the patient’s phone for Argonaut Version 1 enabled HIT. In this context, we question the addition of new data classes at the proposed pace in the USCDI and as well as the capabilities to support these data classes in the TEF. This is a highly aggressive goal to be achieved without information that will be gained from the MU Stage 3 rollout results. The U.S. will struggle to be ready to effectively add new data classes (clinical notes and provenance) initially, and under the proposed timeline for candidate data classes because of this.

We need to ensure that the quality and availability of the existing CCDS can be reliably available and consistent whether received via a C-CDA pushed with NHIN Direct or via IHE XDS/XDR, via an EHR Open API (e.g., US Core FHIR Implementation Guide US Core Implementation Guide, based on FHIR Version 3.0.1), and patient generated data (no standards). The more systems are connected, the more we will see variability of data and data for clinicians to reconcile, as well as for administrators to patient match and incorporate and for addressing discrepancies and quality issues. Adding additional data classes could overload an already challenging situation, when more experience must be gained with the pending MU/MIPS/Certification changes before adding additional data classes.

**USCDI: Standards:** HL7 commends ONC on its overall intent and focus on standards through the USCDI. This is an excellent model to move, in steep-wise fashion toward the “all data”
interoperability definition in 21st Century Cures. To achieve success in its overall standards program, a complete lifecycle of standards should be conceptualized within the USCDI. A standards lifecycle must include, at a minimum, discrete stages for standards development, testing, evaluation, adoption, implementation, use, maintenance, and deprecation or discontinuation of obsolete standards.

**USCDI: C-CDA and FHIR References:** HL7 is concerned about how the terms C-CDA and FHIR are used in the USCDI. They appear as complementary pairs in many places. This parallel does not acknowledge the major difference between these two specifications, including both purpose and nature and maturity of implementation specification. In addition, a specific FHIR specification or implementation guide should be referred to in the USCDI and in implementation specifications/guides maintained by the RCE. (for example, the US Core FHIR Implementation Guide US Core Implementation Guide, based on FHIR Version 3.0.1. or a more current specific version.)

While support is available in these standards for the proposed data classes, only C-CDA has been certified to the 2014 Certification Edition and 2015 Certification Edition. There is no certified EHR functionality or IHE Profile compliance proven for EHR vendors in relation to FHIR API compliance. Also, the specific sections, fields, resources, and attributes are not obvious from the naming of C-CDA or FHIR, so it is hard to verify if these really are supported. HL7 recommends that it be made more clear that further work is required for all data classes, not only candidate and emerging data classes, to arrive at the necessary level of specifications to support frictionless interoperability with accompanying robust testing tools that can validate conformance to applicable standards and implementation specifications/guides.

**USCDI: Unclear and Ambitious Timing and Scope:** The USCDI implies data requirements for 2018, 2019, 2020, and beyond. HL7 recommends that the document clearly indicate that the date for a specific version of the USCDI does not drive or imply when the version must be used, while acknowledging that actual specification of required use will likely emerge through the TEFCA process and other programs.

**USCDI: Recommendation on Clinical Notes Types:** HL7 recommends that the note types initially selected for exchange should be those most commonly transmitted for care transitions: discharge summaries and visit summaries. We also recommend that the note types be limited to reduce scope and complexity, with additional note types added gradually in future years.

**USCDI: Data Provenance:** HL7 agrees that this data class is important for the success of a trusted exchange. Although the available standards appear to support this data class, it has not been widely discussed, developed and implemented. Areas that require further discussions include provenance for reconciled data, aggregated data and patient generated data. HL7 is concerned that there are complexities with this data class that have not yet been appropriately vetted and may bring out challenges in implementation. As such, we do not believe that it should be added to the 2018 USCDI, rather be a candidate for either 2019 or 2020.

**USCDI: Prioritization of Data Classes:** The candidate data classes and emerging data classes lists contain data classes that seem much more attainable as required data classes for the near term in the TEF than clinical notes and data provenance. HL7 recommends including such data classes in lieu of clinical notes and data provenance, particularly if we accept that availability of data classes in documents using C-CDA may progress at a different pace as the same data classes accessed through data element level queries using FHIR. For example, data classes addressing as discharge instructions, diagnostic imaging reports, pathology, and microbiology may be close enough to share through C-CDA documents, while further work would be required for FHIR based APIs.
Additionally, we suggest that cognitive and functional status could be moved into the candidate category as part of documents, although not yet as part of data element level queries using FHIR.