

Health IT Standards Committee

A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT



July 22, 2016

Karen DeSalvo, MD
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. DeSalvo,

As a follow-up to the previously approved recommendations¹ from the Health Information Technology Standards Committee (HITSC) Precision Medicine Task Force (Task Force), the HITSC reconvened the Task Force to identify standards needed to support the President's Precision Medicine Initiative (PMI)². This transmittal offers these recommendations, which are informed by the Task Force's deliberations. The Task Force was charged with the following:

1. Identify opportunities for the Office of the National Coordinator for Health IT (ONC) to support other Federal agencies with PMI efforts related to health IT and interoperability challenges (e.g., National Cancer Institute, Food and Drug Administration, National Institutes of Health, and Department of Veterans Affairs)
2. Identify opportunities for ONC to collaborate with industry and pilot the use of standards to enable data donation and patient access through application programming interfaces (APIs) using standards (e.g., FHIR and OAuth 2.0)
3. Identify standards for uses cases to support interoperability of data types that are critical to PMI research and prioritize piloting the exchange of those data types based on a phased approach, that would incorporate most structured/coded data first and add additional data types in subsequent pilot phases

The HITSC approved the attached presentation of recommendations³ from the Task Force at its May 17, 2016 meeting.⁴ A summary of the recommendations to ONC follows.

ONC should consider the following actions:

- Include an inventory of standards focused on, and used in, the PMI in the 2017 Interoperability Standards Advisory (ISA) to inform the research community and ensure continuity across the ecosystem. This guidance should facilitate the exchange of phenotypic data.
- Engage stakeholders to accelerate the definition of the minimum data set and standards for PMI, patient generated health data (PGHD), and phenotypic data that can be shared with NIH.
- Work with NIH to educate patients and providers of their data access rights and uses of data.

¹ https://www.healthit.gov/sites/faca/files/PMTF_Transmittal_Letter_2015-09-25_v2.pdf

² <https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative>

³ HITJC_PMTF_Presentation_2016-05-17_update.pptx

⁴ <https://www.healthit.gov/FACAS/calendar/2016/05/17/joint-hit-committee-meeting>

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ONC should assist NIH in considering the following actions in the PMI Cohort Program implementation:

- Focus on three critical pathways to promote interoperability:
 1. Capture existing EHR data to accelerate quick data collection (e.g., laboratory results, medications, data from health provider organizations [HPOs])
 2. Enable data gathering from other independent, non-healthcare provider sources (e.g., laboratories, pharmacy benefit managers [PBM], insurers, retail pharmacies)
 3. Accelerate ability to return an individual participant's aggregated data from multiple sources, and eventually research results to promote patient engagement and data use
- Data access
 - Use policies and tools (e.g., FHIR-based APIs) to enable patient-mediated data donation
 - Grant individual participants access to their aggregated PMI data which may promote participation, retention, and engagement of PMI cohort members
 - Define and accelerate near-term individual means of access to genomic/phenotypic data
- Consent and authorization
 - Include strong identity proofing assurances during direct enrollment consistent with Web Content Accessibility Guidelines (WCAG)⁵; inform patients of implications of identifiers used, and obtain consent for their use and clarify if consent applies to copies
 - Employ a framework enabling new and/or expansive consent as new data needs emerge
- Data formats
 - Constrain participants a specified EHR export format(s)
 - Consider use of consensus-based models⁶ to facilitate exchange and planning
- Data sources, apps and APIs
 - Promote standardization and use of patient generated health data (PGHD) by HPOs
 - Facilitate reciprocal queries from EHR for patient specific aggregate requests of PGHD
 - Promote use of FHIR-based APIs for data donation, connecting to EHRs and data return for patient use⁷
 - Extend existing resources⁸ to accelerate exchange

We appreciate the opportunity to provide these recommendations.

Sincerely yours,

/s/

Lisa Gallagher

Co-Chair, Health IT Standards Committee

/s/

Arien Malec

Co-Chair, Health IT Standards Committee

⁵ <https://www.w3.org/WAI/intro/wcag>

⁶ Data Access Framework (DAF), Argonaut, PCORnet, Sentinel, NCI Cloud Pilots, Cancer Genomic Data Commons, Observational Health Data Sciences and Informatics (OHDSI), Veterans Administration mapping to OHDSI

⁷ Sync for Science, Argonaut, SMART

⁸ Meaningful Use Common Data Elements