



## Health IT Standards Committee

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

# Precision Medicine Task Force

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Leslie Kelly Hall, co-chair  
Andy Wiesenthal, co-chair

May 17, 2016



# Agenda

- **Welcome, Opening Remarks**
- **Task Force Background and Charge**
- **Considerations**
- **Critical Pathways to Interoperability**
- **Recommendations**
- **Discussion**

# Precision Medicine Task Force Members

	Member	Organization	
<b>Co-Chairs</b>	Leslie Kelly Hall	Healthwise	
	Andrew M. Wiesenthal	Deloitte Consulting, LLP	
<b>Members</b>	Gil Alterovitz	Harvard Medical School	
	Dixie Baker	Martin, Blanck, and Associates	
	Mary Barton	National Committee for Quality Assurance (NCQA)	
	Stanley Crosley	Member, Drinker Biddle & Reath LLP	
	Steven Keating	MIT Media Lab and Mechanical Engineering	
	David McCallie, Jr.	Cerner Corporation	
	Matthew Might	Harvard University	
	Andrey Ostrovsky	Care at Hand	
	Ketan Paranjape	Intel	
	Eric Rose	Intelligent Medical Objects	
	Joyce Sensmeier	Healthcare Information and Management Systems Society	
	<b>Federal Ex Officio</b>	James Breeling	Veterans Health Administration (VHA)
		Teresa Zayas Caban	ONC
Christina Heide		HHS / Office for Civil Rights	
Betsy Humphreys		National Library of Medicine (NLM)	
Terry Rauch		Department of Defense	
Mitra Rocca		Food and Drug Administration (FDA)	
Jon White		ONC	
Maya Uppaluru	United States Digital Services (USDS)		

- ***Accelerate*** opportunities for innovative collaboration around pilots and testing of standards that support health IT interoperability for research
- ***Adopt*** policies and standards to support privacy and security of cohort participant data
- ***Advance*** standards that support a participant-driven approach to patient data contribution

- **Identify opportunities for ONC to support our federal partners'** Precision Medicine Initiative (PMI) efforts and related health IT/interoperability challenges, including National Cancer Institute, Food and Drug Administration, National Institutes of Health, and Department of Veterans Affairs.
- **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 such as FHIR and OAuth 2.0.
- **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.

# Precision Medicine Task Force Workplan

	Meetings	Task
✓	Friday February 12, 2016 10:00 AM-11:00 AM	<ul style="list-style-type: none"> <li>✓ Progress and status of current initiatives               <ul style="list-style-type: none"> <li>✓ NCI – PMI-Oncology</li> <li>✓ FDA – Precision FDA needs to harmonize data standards</li> </ul> </li> </ul>
✓	Friday February 26, 2016 1:00 PM - 2:30 PM	<ul style="list-style-type: none"> <li>✓ ONC – Computable Consent</li> <li>✓ NIH – Precision Medicine Initiative Progress &amp; Sync for Science pilots</li> <li>✓ Recap and discussion of issues to explore from other agencies</li> </ul>
✓	Wednesday March 16, 2016 1:00 PM-2:30 PM	<ul style="list-style-type: none"> <li>✓ Department of Veterans Affairs (VA)</li> <li>✓ Department of Defense (DoD)</li> </ul>
✓	Wednesday March 30, 2016 1:00 PM-2:30 PM	<ul style="list-style-type: none"> <li>✓ Findings and preliminary recommendations</li> <li>✓ Gaps in interoperability use cases - lab data, patient and provider access</li> </ul>
✓	Wednesday April 13, 2016 1:00 PM-2:30 PM	<ul style="list-style-type: none"> <li>✓ Discuss draft recommendations</li> </ul>
✓	Tuesday April 19, 2016 9:30 AM to 3:00 PM	<ul style="list-style-type: none"> <li>✓ Joint HIT Committee Meeting</li> <li>✓ Draft Recommendations to Joint Committee</li> </ul>
✓	Thursday April 21, 2016 1:00 PM-2:30 PM	<ul style="list-style-type: none"> <li>✓ Task Force Meeting to Finalize Recommendations</li> </ul>
✓	Wednesday, May 11, 2016 1:00 PM - 2:30 PM	<ul style="list-style-type: none"> <li>• Task Force Meeting to Finalize Recommendations</li> </ul>
➔	Tuesday, May 17, 2016 9:30 AM - 3:00 PM	<ul style="list-style-type: none"> <li>• Joint HIT Committee Meeting</li> <li>• Final Recommendations to Joint Committee</li> </ul>

# Interoperability Pathways Critical to PMI

## Overarching Questions

- What data sources are available?
- What are the known gaps regarding high value data needed for PMI?
- What efforts could be accelerated to help the work of PMI?
- Are there areas for which standards could be recommended to promote scalable and repeatable development for PMI?

# Interoperability Pathways Critical to PMI Considerations

- Volume, complexity and new sources of data will necessitate emphasis on access and query based exchange versus the actual transfer of large datasets
  - » Data volume will be beyond that of current EHR ecosystem
  - » PMI data requires consideration of new data sources which bring complexity
    - Data for care directly from the patient
    - Genomic and other data from research platforms (e.g., NIH Cohort), laboratories and disease registries
    - PCORnet and others device data as well
- PMI (e.g., genetic) data remain uniquely valid over time, therefore, data validity and availability must be persistent over time

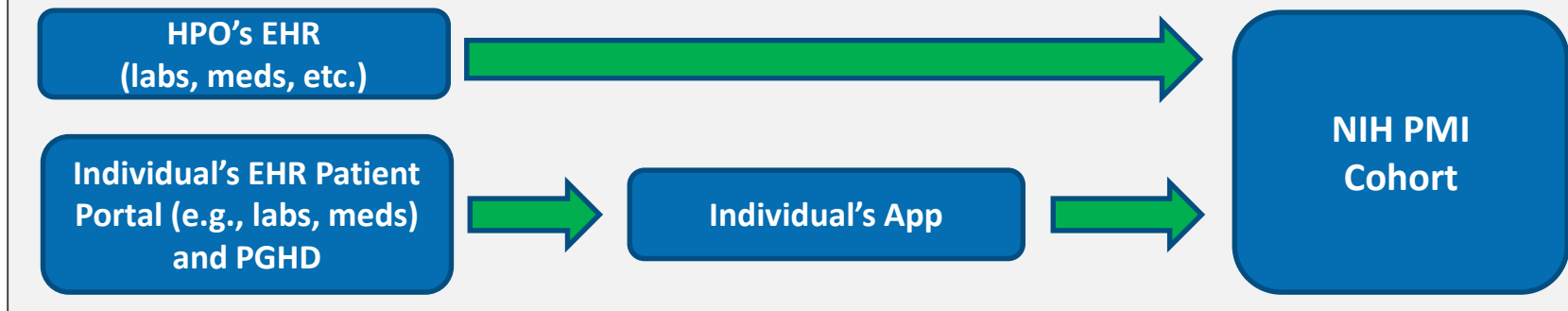


# Interoperability Pathways Critical to PMI Considerations

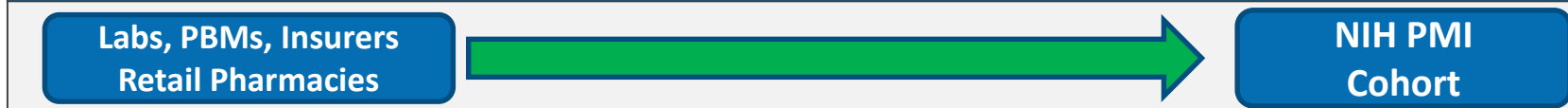
- Data standards should be interoperable by design to accelerate timelines
  - » Requires use of existing standards
  - » Acceleration and coordination of some standards initiatives to support PMI
  - » Acceleration of access patient generated health data (PGHD)
  - » Interoperable design should be informed by ONC's Interoperability Roadmap, NIH guidance, and others development and procurement

# Three Interoperability Pathways Critical to PMI as Discussed by the Task Force

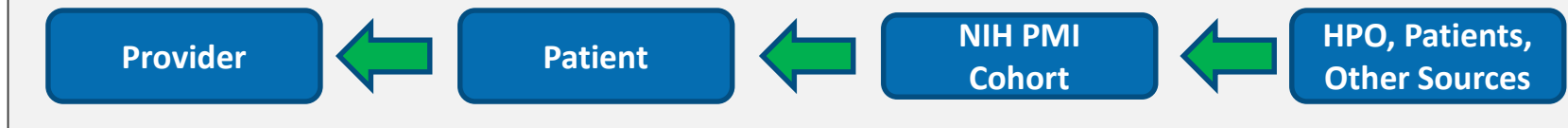
## 1 Focus on EHR data first (e.g., labs, meds)



## 2 Enable data gathering from other independent non-provider sources



## 3 Accelerate ability to return an individual participant's aggregated data from multiple sources, and eventually research results



# Recommendations

Recommendations fell under three main categories

- A. Interoperability and Data Reciprocity
- B. Policy Considerations
- C. Standards and APIs

# Recommendations

## A. Interoperability and Data Reciprocity (1 of 3)

- **ONC should consider the following to promote PMI:**
  - » 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
    - Guidance should facilitate the exchange of phenotypic data
  - » Engage stakeholders to accelerate
    - Definition of minimum data set and standards for PMI, PGHD and phenotypic data
    - Include vocabulary where gaps exist using existing standards and efforts
  - » Provide ongoing guidance
    - Use Technical Expert Panel(s) (TEP) to enhance participant understanding of utilizing various data sources (e.g., validity overlap, provenance)
    - Roadmap of current efforts that support PMI (e.g., ONC Tech Lab)
    - Inform the research community on interoperability with EHRs and standards in general (non-regulatory is the bias of the Task Force)

# Recommendations

## A. Interoperability and Data Reciprocity (2 of 3)

- Consider high value, non-EHR data sources to promote completeness of longitudinal patient information
- Encourage use of standard APIs (e.g., FHIR) to source data
  - » Meds
    - History, lack dispensing, adherence data, complete lists of current meds, feedback on efficacy and effectiveness
    - Potential sources: PBMs, retail pharmacies and physician notes
  - » Labs
    - Consider challenges in pulling data from commercial and hospital labs
    - Explore practical differences between lab data in the EHR vs. data directly from the labs to determine which set may have greater fidelity and value
  - » Claims
    - Determine how claims data enhance understanding of the patient and the sources
- Consider means of patient mediated data donation to reduce probabilistic matching

# Recommendations

## A. Interoperability and Data Reciprocity (3 of 3)

- Individual participant's access to their aggregated PMI data will promote participation, retention and engagement
  - » Data return should offer dynamic, compelling visualizations to promote its use
  - » Patients should have access to computable, raw genetic testing and sequencing data
    - These data are among the most potentially useful to patients in the long term
  - » Patients will need provider support on the implications of their genetic data
- ONC should work with NIH to define near term means of access and accelerate individual access
  - » Recommend that patient-facing portals that enable individuals to access all data types (e.g., labs, meds, genomics)
  - » Portals should allow individuals to use apps and APIs based on existing, and emerging standards (e.g., FHIR)
  - » Draw from stakeholders with relevant strengths and experiences (e.g., Open Humans, PatientsLikeMe, Open Notes)

- ONC should work with NIH to educate patients and providers of data access rights and uses
  - » Access rights should be consistent with protected health information (PHI) access standards
  - » Consider *The Framework for Responsible Sharing of Genomic and Health-Related Data\** in developing data exchange principles
  - » Enrollment should include notification of the use of the patient NIH ID
    - To accommodate results return and future use cases based on Sync 4 Science recommendations, notification should be sent back to EHR with patient consent
  - » Encourage direct enrollment to include strong assurance and identity proofing
    - Equivalent to the current patient portals model
    - Use direct language
    - Employ Web Content Accessibility Guidelines (WCAG) accessibility and enrollment

- Gathering patient data from a variety of sources will have implications to:
  - » Identity Matching – the Task Force recognizes that significant efforts are underway to support this necessary capability
  - » Consent and Authorization
    - Inform patients of implications of identifiers used and consent regarding their use
    - Clarify in consent if it applies to copies of the data
    - Employ a consent framework that enables new and/or expansive consent as new data needs emerge
    - ONC should work with HHS Office of Civil Rights (OCR) should confirm if consent is required for a provider to receive access to NIH data when a covered entity enrolls a patient in PMI
  - » Data access rights
    - Should apply to genomic and phenotypic information
    - Use notification to patients and providers when data is harvested



- The Task Force recognizes that efforts are underway to address:
  - » Access
    - Clarification of related policy that would facilitate patient data access and return of research results (e.g., CLIA, HIPAA)
    - Privacy and security implications of returning an individual's aggregated data
    - Options related to types of data patients would like to access / receive
  - » Liability and Consent
    - Liability issues of working with genomic data with respect to what a researcher is obligated to disclose back to the patient
    - Granularity of permissions
    - Patient notification / consent to ongoing, or further, use of data for research

- **Data Formats**

- » Participants should be constrained to using a specified EHR export format(s)
- » Data recipients may need to anticipate a certain level of effort to translate data
- » Consensus-based models can facilitate exchange, models to consider:
  - Data Access Framework (DAF) and Argonaut
  - PCORnet, Sentinel, NCI Cloud Pilots and Cancer Genomic Data Commons, Observational Health Data Sciences and Informatics (OHDSI)
  - Veterans Administration mapping to (OHDSI)

- **Individual Data**

- » For data donation and return to patient use consistent FHIR-based APIs (e.g., Sync 4 Science, Argonaut, SMART)
- » New FHIR resources may not be needed immediately; an extension of existing resources may help (e.g., existing MU CDEs)
- » FHIR will become more necessary as it continues to evolve

- Data Sources
  - » ONC should encourage HPO enrollment to include PGHD when possible
    - Patients will act as an exchange mechanism among their providers and as a data source for data not captured in EHRs
    - Promote standardization for use of PGHD (e.g., Genetic Alliance) especially in enrollment
    - Recognize that standards are evolving
  - » ONC should encourage use of EHRs as sources for:
    - Episodic and demographic information, labs, meds, histories, etc.
    - Common Clinical Data Set minimum bar
- ONC should encourage standards based app and API implementation to:
  - » Enable patients to connect to EHRs with apps and APIs
  - » Enable patient to mediate exchange of the data (e.g., via CDS) to NIH cohort
  - » Provide ability for reciprocal queries from EHR for patient specific aggregate requests of PGHD

# Appendix: Parking Lot Issues

# Parking Lot Items for Future Potential Task Force Work

- Demographic data
  - » Recommendations to improve structured data around race, ethnicity, gender, sexual orientation?
  - » What are the highest priority demographic data types for PMI?
- Define specific activities or pilots ONC could lead to support and advance progress
- Patient rights and ownership of genomic pattern data
- Record locator services and identity management
  - » This work will be executed by the Coordinating Center awardee
- Genomic data (not for short-term consideration)