Health IT Standards Committee

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

Precision Medicine Task Force

Draft Recommendations
April 19, 2016

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

Agenda

- **Welcome, Opening Remarks**
- **Task Force Background and Charge**
- **Discussion of Recommendations**
  - **Critical Pathways to Interoperability**
  - **Parking Lot Items for Future Consideration**
- **Discussion**
- **Recap & Next Steps**

Precision Medicine Task Force Members

	Member	Organization
Co-Chairs	Leslie Kelly Hall	Healthwise
	Andrew M. Wiesenthal	Deloitte Consulting, LLP
Members	Gil Alterovitz	Harvard Medical School
	Dixie Baker	Martin, Blanck, and Associates
	Mary Barton	National Committee for Quality Assurance (NCQA)
	Stanley Crossley	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
Federal Ex Officio	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)

ONC Role in Precision Medicine Initiative

- 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

Task Force Charge

- Identify opportunities for ONC to support our federal partners' 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 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-type 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	✓ Progress and status of current initiatives ✓ NCI – PMI-Oncology ✓ FDA – Precision FDA needs to harmonize data standards
✓	Friday February 26, 2016 1:00 PM - 2:30 PM	✓ ONC – Computable Consent ✓ NIH – Precision Medicine Initiative Progress & Sync for Science pilots ✓ Recap and discussion of issues to explore from other agencies
✓	Wednesday March 16, 2016 1:00 PM-2:30 PM	✓ Department of Veterans Affairs (VA) ✓ Department of Defense (DoD)
✓	Wednesday March 30, 2016 1:00 PM-2:30 PM	✓ Findings and preliminary recommendations ✓ Gaps in interoperability use cases - lab data, patient and provider access
✓	Wednesday April 13, 2016 1:00 PM-2:30 PM	• Discuss draft recommendations
➔	Tuesday April 19, 2016 9:30 AM to 3:00 PM	• Joint HIT Committee Meeting • Draft Recommendations to Joint Committee
	Thursday April 21, 2016 1:00 PM-2:30 PM	• Task Force Meeting to Finalize Recommendations
	Wednesday, May 11, 2016 1:00 PM - 2:30 PM	• Task Force Meeting to Finalize Recommendations
	Tuesday, May 17, 2016 9:30 AM - 3:00 PM	• Joint HIT Committee Meeting • Final Recommendations to Joint Committee

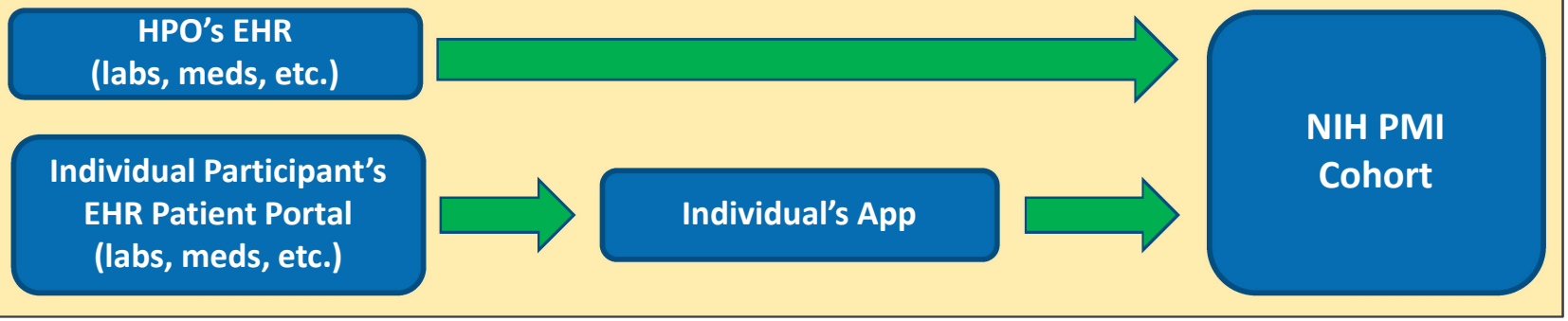
Interoperability Pathways Critical to PMI
Overarching Questions

- What data sources are available?
- What are the gaps?
- What are the known gaps re: 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
Areas of Opportunity

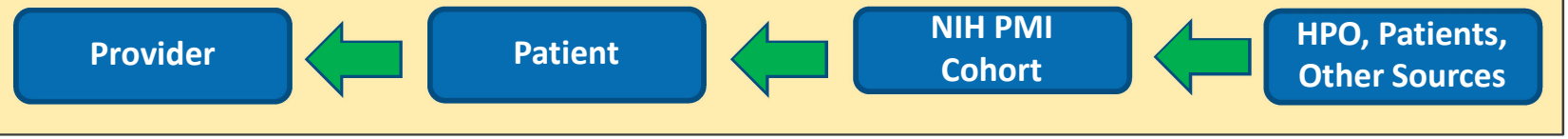
What data sources are available? What are the gaps?
What are the known gaps re: high value data needed for PMI?

1 Near term recommendation (2016): focus on EHR data first (labs, meds, etc.)



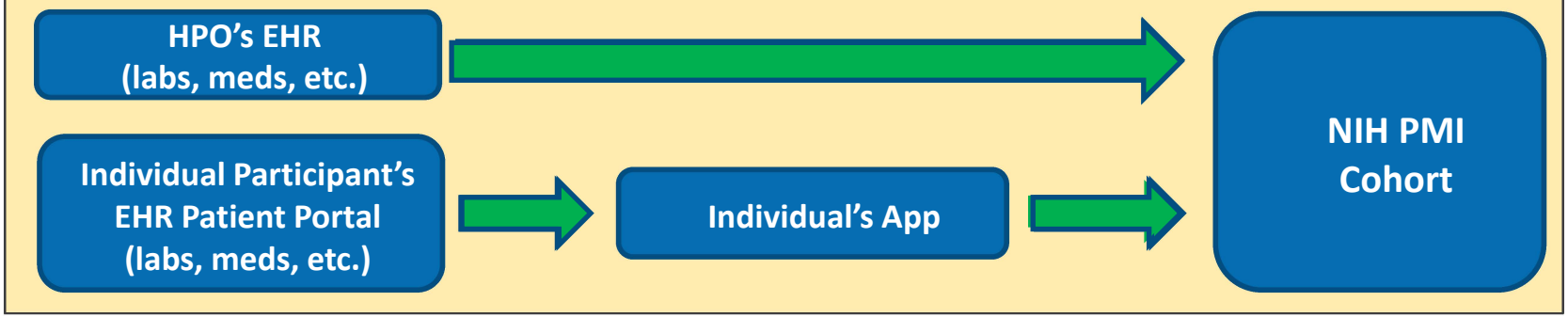
2 Mid term focus (2017): enable data gathering from other independent non-provider sources

3 Long term (2017-2018): return an individual participant's aggregated data from multiple sources, and eventually research results



Interoperability Pathways Critical to PMI
Near-term recommendations

1 **Near term recommendation (2016): focus on EHR data first (labs, meds, etc.)**

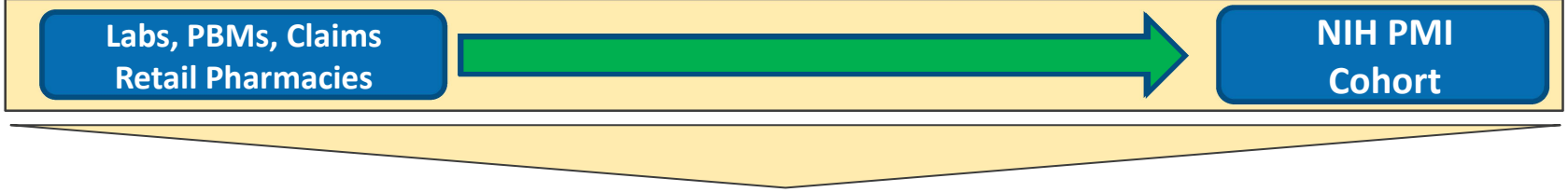


Detail

- Participants should be constrained to using a specified EHR export format(s) and that data recipients may need to anticipate level of effort, depending on their internal data models to translate data once they receive it. Consensus-based models to consider may include:
  - Data Access Framework (DAF) and Argonaut
  - PCORnet, Sentinel
  - NCI
  - Observational Health Data Sciences and Informatics (OHDSI)
  - Veterans Administration mapping to Observational Medical Outcomes Partnership (OMOP)
- Individual Data: Use consistent FHIR-based API (e.g., Sync for Science, Argonaut) for data donation
  - 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 evolves, the Task Force recognizes that it is still evolving

Interoperability Pathways Critical to PMI
Mid-term Recommendations

2 **Mid-term recommendations (2017): enable data gathering from other independent non-provider sources**



Detail

PMI should consider data sources, in addition to the EHR, that promote completeness of longitudinal patient information about, examples include:

- **Meds** - EHRs typically do not have dispensing data; no feedback loop re: patient adherence.
  - Med history could be sourced from PBMs or retail pharmacies
  - Current list of meds from other EHRs, patient portals, or PBMs and retail pharmacies
  - Was the med filled? (Retail pharmacy, PBM)
  - Did the med work? (EHR – maybe physician notes?)
- **Labs**
  - Commercial labs & hospital labs: what challenges will exist with pulling data from each?
  - What practical differences exist between lab data in the EHR vs. data directly from the labs?
  - Which has better fidelity?
- **Claims**: What's available? What are the benefits and limitations of each data source?

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Interoperability Pathways Critical to PMI
Mid-term Recommendations, continued

2 **Mid-term recommendations (2017): enable data gathering from other independent non-provider sources**

Detail

(continued from previous slide)

Policy and Technical Considerations

- Gathering patient data from a variety of sources will have implications to:
  - Identity Matching
    - Use of a patient identifier for cohort participants will likely be necessary
    - The Task Force recognizes that significant efforts are underway to support this capability
  - Consent and Authorization
    - Consideration should be given to ensuring patients understand the implications of such an identifier and consent regarding its use
- PMI should consider means of patient mediated data donation to reduce needs for probabilistic matching

Interoperability Pathways Critical to PMI
Long-term Recommendations

3 **Long-term (2017-2018): return an individual participant's aggregated data from multiple sources, and eventually research results**

Detail

- Return of an individual participant's aggregated data, in dynamic, compelling visualizations may be critical for retention and engagement of participants
- Patients should have the option to access computable raw genetic testing and sequencing data because these raw data are among the most potentially useful to patients in the long term
- It's important to determine how this could work in the near term, potentially more accelerated
- Current trends around increasing demand for patient data access will increase sensitivity to this
  - NIH could consider a participant-facing API that would allow an individual to pull their aggregated data from the cohort to the app of their choice
  - Should leverage existing and emerging standards (e.g., FHIR)
  - Groups with relevant strengths and experiences (e.g., Open Humans, PatientsLikeMe, others)

(continued on next slide)

Interoperability Pathways Critical to PMI
Long-term Recommendations, continued

3 **Long -term (2017-2018): return an individual participant's aggregated data from multiple sources, and eventually research results**

Detail

- **Policy and Technical Considerations -** The Task Force recognizes that a number of efforts are underway to address items below, however would like to highlight their importance
  - Privacy and security implications of returning an individual's aggregated data
  - Clarification of related policy considerations would facilitate patient data access and return of research results (e.g., CLIA, HIPAA)
  - Liability issues of working with genomic data with respect to what a researcher is obligated to disclose back to the patient
  - Granularity of permissions
  - Options related to types of data patients would like to access / receive

Recap & Next Steps

Appendix: Parking Lot Issues, Past Presentations Q&As

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)

Priority Data Types – NCI & FDA

- Imaging, lab, and molecular characterization methods, (e.g., pathology, radiology, clinical labs)
- Detailed therapeutic data (including medications, dosage, administration protocol)
- Diagnostic information, and outcomes (response measured by 3D radiography, RECIST, etc.
- Time to relapse, co-morbidities, survival
- Pipeline with 3 steps – FDA focused on #2 then #3
    1. Instrument
    2. Software
    3. Clinical interpretation

Priority Data Types - VA (continued)

- **Chemical Analysis Axiom MVP Biobank Array**
  - eQTLs Markers
  - New Exome / LoF Content
  - Exome Content
  - Multiethnic Data
  - ADME
  - VA Custom Disease Variants
- **CDW Phenome Data Domains**
  - Lab Results
  - Pharmacy Fills
  - Radiology Procedures
  - Clinical Orders
  - Clinical Notes
  - Vital Signs
  - Immunizations
  - Health factors
  - Consults
  - Appointments
  - Encounters
  - Admissions
  - Surgeries
  - Oncologist

Additional Findings
Follow up questions to NCI

- What is your vision to include PGHD in the cloud offering?
  - The GDC plus the Cloud Pilots form the foundation of a national database to house and integrate genomic information from tumors with clinical response data (e.g., tumor shrinkage) and outcomes information as a resource for scientists, health care professionals, and patients.
- Is the cloud pilot primarily for research users?
  - Yes, that is correct.
- Will EMRs query your pilot for patient specific data in care, or will you be a repository for analysis and quality only?
- Aggregate (blinded) or patient specific?
- Does you design currently envision patient access directly to their data?
  - This knowledgebase will be useful to clinicians actively treating patients and will assist in selecting the optimal treatment based on the available characterization and outcome data.
  - While patient-specific data access is not currently in scope for this knowledgebase, patient engagement is an important consideration for the NCI PMI strategic planning.

Additional Findings
Follow up questions FDA

- Once products are tested on your app, will they then be FDA approved?
  - » No

- Or how will the successful testing be used, certifications? Other?
  - » PrecisionFDA is a beta regulatory research project and not for clinical or production use.
  - » Its use does not imply FDA endorsement. The challenge will be used to learn, and potentially build better tools for testing.

- Will product testing results be publically available?
  - » Users of PrecisionFDA may conduct experiments utilizing data, software, tools in the community area and make results of those experiments available to the community. The intent of publishing information and results on PrecisionFDA is to engage the community toward advancing regulatory science.
  - » Participants of the first PrecisionFDA challenge are required to publish their comparisons and VCF files; however, they may also publish other data, such as software used, etc. to inform the community and gain feedback from the community.

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