Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Meeting #11

Hans Buitendijk, Co-Chair

Shelly Spiro, Co-Chair

September 20, 2023

Call to Order/Roll Call

Mike Berry, Designated Federal Officer, ONC

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Roster

Name	Organization	Name	Organization
Hans Buitendijk* (Co-Chair)	Oracle Health	Shelly Spiro (Co-Chair)	Pharmacy HIT Collaborative
Pooja Babbrah	Point-of-Care Partners	Deven McGraw*	Invitae Corporation
Chris Blackley	Prescryptive	Ketan Mehta	Micro Merchant Systems
Shila Blend*	North Dakota Health Information Network	Justin Neal	Noble Health Services
David Butler	Curatro, LLC	Eliel Oliveira*	Dell Medical School, University of Texas at Austin
Steven Eichner*	Texas Department of State Health Services	Naresh Sundar Rajan*	CyncHealth
Rajesh Godavarthi*	MCG Health, part of the Hearst Health network	Scott Robertson	Bear Health Tech Consulting
Adi V. Gundlapalli**	Centers for Disease Control and Prevention	Alexis Snyder*	Individual
Jim Jirjis*	HCA Healthcare	Fillipe Southerland*	Yardi Systems, Inc.
Summerpal Kahlon	Rocket Health Care	Christian Tadrus	Community Pharmacy Owner
Steven Lane*	Health Gorilla	Sheryl Turney*	Elevance Health
Meg Marshall**	Department of Veterans Health Affairs	Afton Wagner	Walgreens
Anna McCollister*	Individual		

* HITAC Member   ** HITAC Federal Representative

Agenda

10:30 AM **Call to Order/Roll Call**

- Mike Berry, Designated Federal Officer, ONC

10:35 AM **Opening Remarks**

- Hans Buitendijk, Co-Chair

- Shelly Spiro, Co-Chair

10:40 AM **Task 3 Guest Presentations**

- Stephanie Garcia, Branch Chief, ONC

- Mark Dunnenberger, Assistant Vice President, Personalized Medicine and Pharmacogenomics, NorthShore University Health System

11:10 AM **Task 1 Review of Recommendations**

- Hans Buitendijk, Co-Chair

- Shelly Spiro, Co-Chair

11:50 AM **Public Comment**

- Mike Berry, Designated Federal Officer, ONC

11:55 AM **Task Force Work Planning**

- Hans Buitendijk, Co-Chair

- Shelly Spiro, Co-Chair

12:00 PM **Adjourn**

Opening Remarks

Hans Buitendijk, Co-Chair

Shelly Spiro, Co-Chair

Task 3 Guest Presentations

Stephanie Garcia, Branch Chief, ONC

Mark Dunnenberger, Assistant Vice President, Personalized Medicine and Pharmacogenomics, NorthShore University Health System

Sync for Genes

An Overview of ONC's Sync for Genes Project

Stephanie Garcia, MPH

Office of the National Coordinator for Health Information Technology

Pharmacy Interoperability and Emerging Therapeutics Task Force
September 20, 2023

Agenda

SYNC FOR GENES

**PHASE 5 OUTCOMES AND FUTURE OPPORTUNITIES**

RESOURCES

Sync for Genes: An Overview

Sync for Genes: Overview of Project Phases

Launched: 2017

Mission: Standardize sharing of genomic information between key stakeholders

- **Phase 1: Standardizing Genomic Data**
    - » Updated HL7® FHIR® clinical genomic specification

- **Phase 2: Integrating Genomic Data**
    - » Demonstrated connectivity and exchange of data

- **Phase 3: Laboratory Genomic Data**
    - » Interoperability of genomic data from laboratories

- **Phase 4: Sharing Genomic Data for Patient Care**
    - » Interoperability of genomic data between organizations and at least one data receiver, including patients or caregivers (if appropriate)

- **Phase 5: Standardizing Genomic Variant Sharing and Interpretation for Clinical Knowledge**
    - » Interoperable sharing and interpretation of annotated genomic variants at the point of care
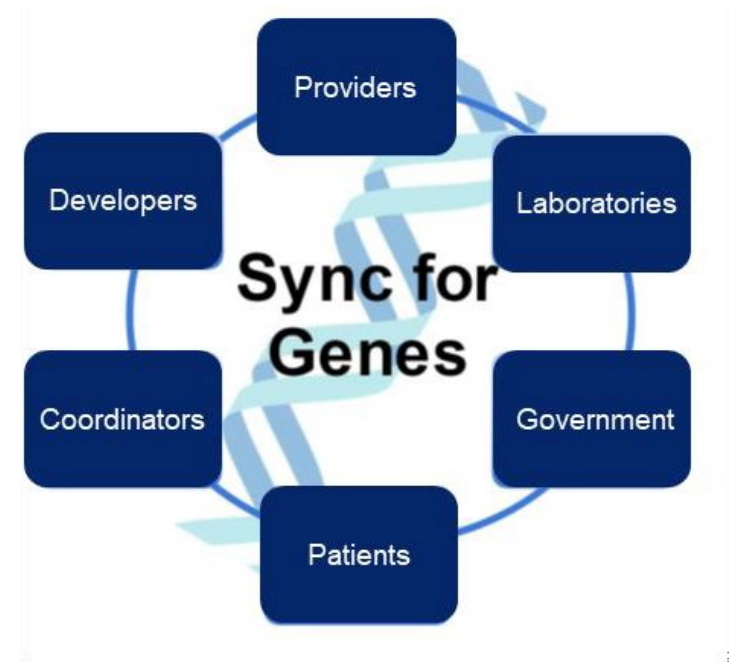
Sync for Genes: Foundational Themes

| Adoption | Implementation | Integration | Use |

- Strategic development and adoption of genomic standards (e.g., FHIR®, GA4GH)

- Support and coordination for implementors

- Targeted education and training on the use of standards and solutions

- Phased approach to make progress on larger industry challenges

Phase 5 Outcomes and Future Opportunities

Phase 5 Outcomes

Sync for Genes Phase 5 made progress in standardizing genomic variant sharing and interpretation for clinical knowledge

Collaborated with a panel of experts and a demonstration site to build on progress from earlier phases

CHLA/Elimu team demonstrated sharing of dynamically annotated genomic information using GA4GH-encoded knowledge and HL7® FHIR®

Strategic recommendations were developed to standardize genomic variant sharing and interpretation for clinical knowledge

Work remains to coordinate existing standards with current and future requirements and expand implementation and use of standards
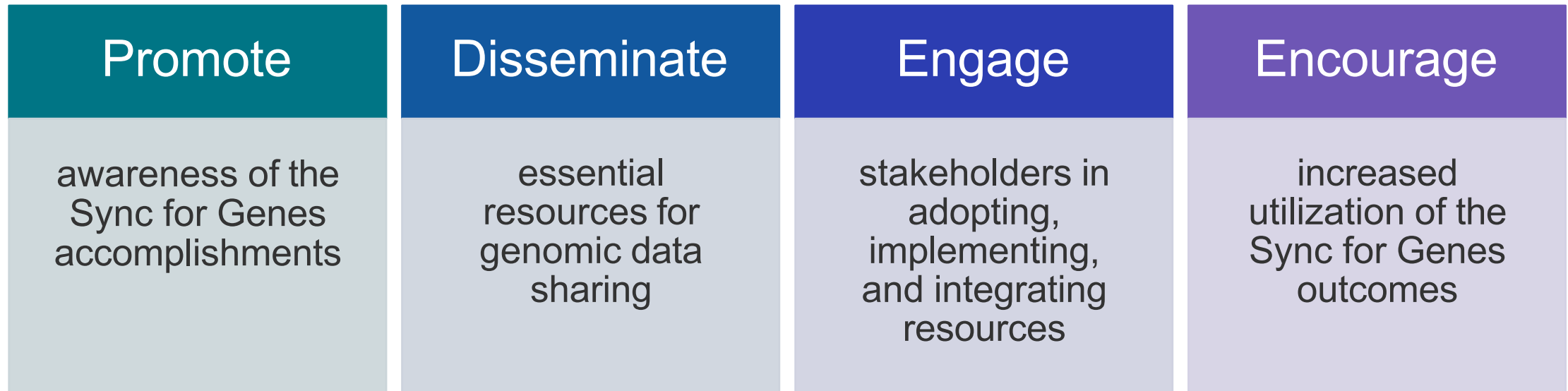
Phase 5 Panel: Summary of Findings

Challenges	Findings
Standards development	Extend and harmonize existing standards to support new data types and use cases rather than develop new standards
Standards-based content	Improve interoperability by harmonizing genomic annotation across domains
Implementation of genomic standards	Develop or encourage an environment where implementers could evaluate standards before installation, document best practices and recommendations, and share lessons learned to lower barriers to adoption
Infrastructure (hardware and software) to support genomics	Find and support platforms that guide institutions responsible for developing infrastructure to support genomic data
Use of genomic data	Lower the barrier of use by the care team and patients by employing thoughtful clinical decision support (CDS)
Training and education	Encourage and support robust training, education, and support to enable the standardized representation, exchange, and use of genomic data and knowledge

Resources

Sync for Genes Resources Toolkit

Promote	Disseminate	Engage	Encourage
awareness of the Sync for Genes accomplishments	essential resources for genomic data sharing	stakeholders in adopting, implementing, and integrating resources	increased utilization of the Sync for Genes outcomes

Designed to cater to the wide range of partners who play a role in the genomic data sharing ecosystem

https://www.healthit.gov/sites/default/files/page/2023-08/Sync_for_Genes_Toolkit_508.pdf

Core Resources

Sync for Genes

- https://www.healthit.gov/topic/sync-genes

HL7 FHIR Standard

- https://www.hl7.org/fhir/?ref=learnmore

HL7 Genomics Reporting Implementation Guide

- http://hl7.org/fhir/uv/genomics-reporting/STU2/

HL7 FHIR Genomics Implementer Guidance

- https://hl7.org/fhir/r4/genomics.html

HL7 Clinical Genomics Work Group

- https://confluence.hl7.org/display/CGW

Global Alliance for Genomics and Health (GA4GH)

- https://www.ga4gh.org/genomic-data-toolkit/regulatory-ethics-toolkit/framework-for-responsible-sharing-of-genomic-and-health-related-data/

Thank You!

Phone: 202-690-7151

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YouTube:
https://www.youtube.com/user/HHSONC

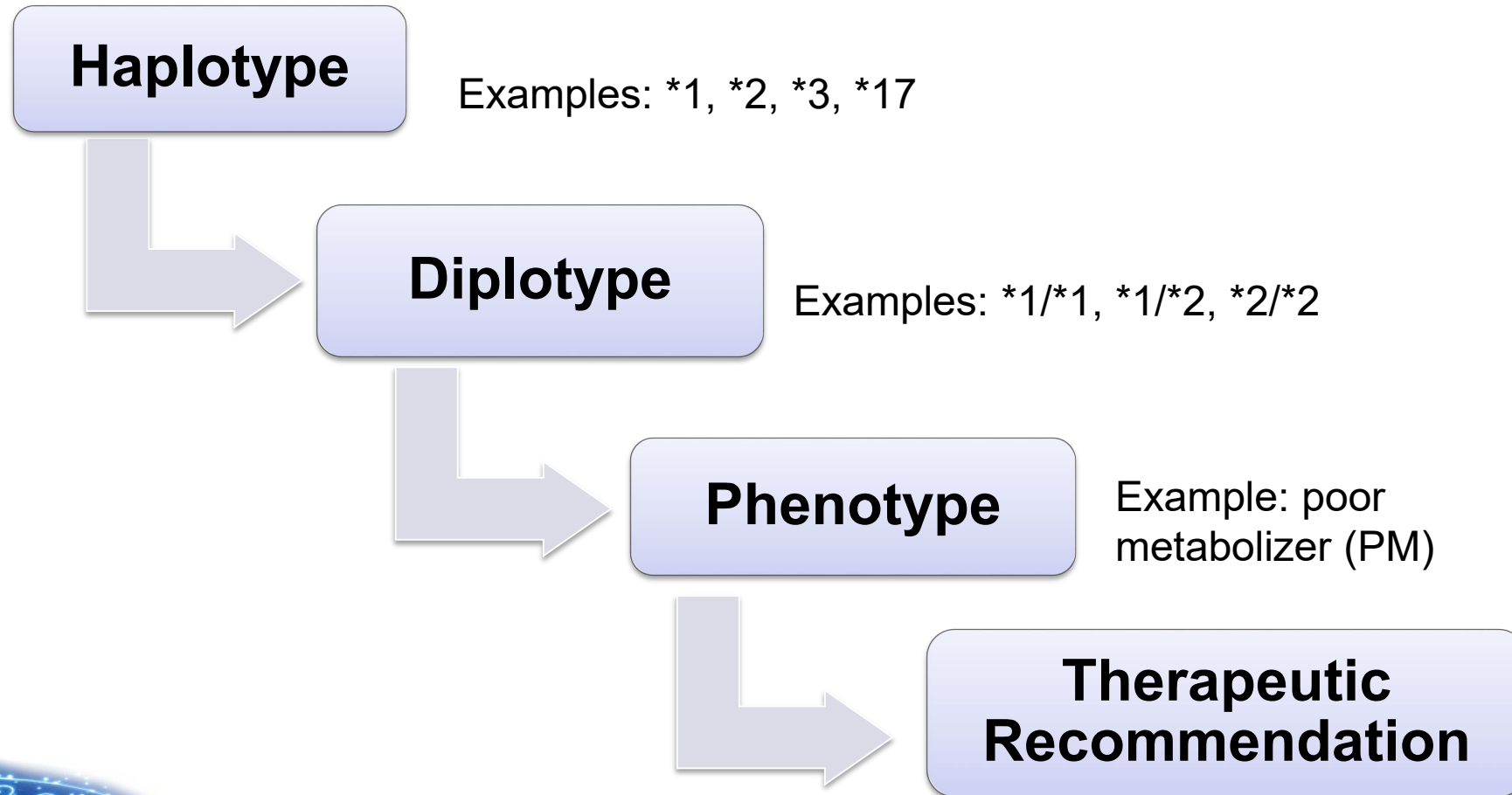**HealthIT.gov**

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Mark Dunnenberger, Assistant Vice President, Personalized Medicine and Pharmacogenomics, NorthShore University Health System

Pharmacogenetic Interpretation Process

Haplotype

Examples: *1, *2, *3, *17

Diplotype

Examples: *1/*1, *1/*2, *2/*2

Phenotype

Example: poor metabolizer (PM)

Therapeutic Recommendation

NorthShore
University HealthSystem
Center for Personalized Medicine

* allele nomenclature

*1 denotes the default reference allele

- Based on the subpopulation in which the gene was initially studied
- May not necessarily indicate the most common allele in all populations
  - » CYP3A5*3 is the reference allele in whites

All other * alleles denote haplotypes where variants have been observed

- First investigator to report a variant: *2
- Second investigator to report a variant: *3

```
—— ACG ——— TTC —— TTC ———————  *1

—— ACA ——— TTC —— TTC ———————  *2

—— ACG ——— TTC —— TTG ———————  *3
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Kalman LV, Agundez JAG, Appell ML et al. Clin Pharmacol Ther. 2016;99:172-85.

How results come from labs

- *CYP2D6* results that contain *1/*10. May have copy number and/or activity score.

- How many different result values have we seen?

- 25 different value

*1/*10	*1/*10; 2
*1/*10+*36	*1/*10; COMPLEX (intron2: 3, exon9: 2, intron6: 3)
*1/*10 X3N; 1.5-2.25	*1/*10; complex (intron2: 3, exon9: 2, intron6: 3)
*1/*10 X4N; 1.75-3.25	*1/*10x2; 3
*1/*10 XN; 1.5-3.25	*1/*10 (with duplication); 3; 2.25
*1/*10+*36; 1.25	*1/*10+*36; 2; 1.25
*1/*10; 2; 1.25	*1/*10+*36x2; 3; 1.25
*1/*10+*68; 1.25	*1/*10; COMPLEX (intron2: 3, exon9: 2, intron6: 2); 1.25
*1/*10; 1.25	*1/*10; COMPLEX (intron2: 3, exon9: 2, intron6: 3); 1.25
*1/*36x2N+*10; 1.25	*1/*10; COMPLEX (intron2: 4, exon9: 2, intron6: 4); 1.25
*1/*10+*36; 2	*1/*10; COMPLEX (intron2: 4, exon9: 3, intron6: 4); 2.25
*1/*10+*36x2; 3	*1/*10+*36x2N or *1x2N/*36x2N; 1.25-2
*1/*10+*68; 2	

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Communication between Health System and Community Pharmacies

Task 1 Review of Recommendations

Hans Buitendijk, Co-Chair

Shelly Spiro, Co-Chair

Public Comment

To make a comment please
Use the Hand Raise Function

If you are on the phone only, press "*9" to raise your hand

*(Once called upon, press "*6" to mute/unmute your line)*

All public comments will be limited to three minutes

You may also email your public comment to onc-hitac@accelsolutionsllc.com

Written comments will not be read at this time,
but they will be delivered to members of the task force and made part of the public record

Task Force Work Planning

Hans Buitendijk, Co-Chair

Shelly Spiro, Co-Chair

Upcoming Meetings

Month	Task Force Meeting Dates	HITAC Meeting Date
September	27	
October	4, 11, 18, 25	October 19 (TF Update)
November	1	November 9 (Final Recommendation and Vote)

Adjourn