



Technical Challenges in the Transfer of Information

RAISE Community Workshop 6

Thursday, April 6, 2023, 2 – 3 PM ET

Summary

Overview of RAISE Community Workshop VI

During RAISE workshop VI, Susan Winckler, CEO of the Reagan-Udall Foundation, and Dr. Christine Lee-Flemming, Strategic Research Engagement Lead of the Office of Minority Health and Health Equity at the FDA, welcomed the workshop participants. During the session we heard four presentations. First, Dr. Carla Rodriguez-Watson, RAISE PI, summarized our previous RAISE workshops and their connection to workshop VI. Next, Dr. Sarah DeSilvey (Gravity) discussed how project Gravity addresses interoperability and how race and ethnicity are critical for health equity use cases. Then, Ryan Argentieri (ONC) talked about the United States Core Data for Interoperability (USCDI) and the progress of adopting interoperability standards. Our final presentation was by Dr. Bradley Malin (Vanderbilt) who spoke on the balance between the need for data privacy and sharing data. After the presentations, our citizen voice Dr. La Keita Carter (Institute for HEALing) joined our speakers on the virtual stage to engage in a discussion led by Lenel James (BCBSA).

Connecting the Dots: From Standards to Interoperability

Carla Rodriguez-Watson, PhD, MPH

Director of Research, Reagan-Udall Foundation for the FDA

Special thanks to the Office of the National Coordinator for Health Information Technology (ONC) for 1. laying the groundwork that allows for the understanding and assessment of health equity through Gravity Project & the Reagan-Udall Foundation as accelerators and 2. their assistance to HHS agencies to maximize the use of HHS-approved standards & authorities.

To level set, the RAISE project begins with the assumption that race and ethnicity (R&E) are critical for understanding population health and the real-world utilization and performance of medical products across racialized groups. We acknowledge that R&E alone do not answer all the questions; but are critical to understanding population health and the real-world utilization and performance of medical products across racialized groups. As such, R&E are important to the FDA. The question of whether or when race or ethnicity is, or is not, the appropriate variable is not in the scope of the RAISE project. Although issues of access to care frame our conversation, addressing access to care is not the focus of RAISE. The focus of RAISE is the part of the data continuum that includes reporting collection, curation, and integration of R&E data because that's where the corpus of real-world data currently lives and can be used to inform medical product evaluation.

In workshop six, we continued to move through our continuum. In previous workshops, we discussed the need for cultural connection and partnership to build the trust required for obtaining and reporting R&E. Our workshops have also touched on the definition of relevant standards and the technology that enables the operationalization of those standards for the collection and creation of R&E data. In this workshop, we discussed how these data can be made interoperable, and the tension between the need

for standardization, expressing individuality and being true to what has been reported to us by patients and the community. We also discussed the balance between data privacy and data exchange.

Gravity Project: The SDOH Data Standards Example of Tactics to Address Technical Challenges

Sarah C. DeSilvey, DNP, FNP

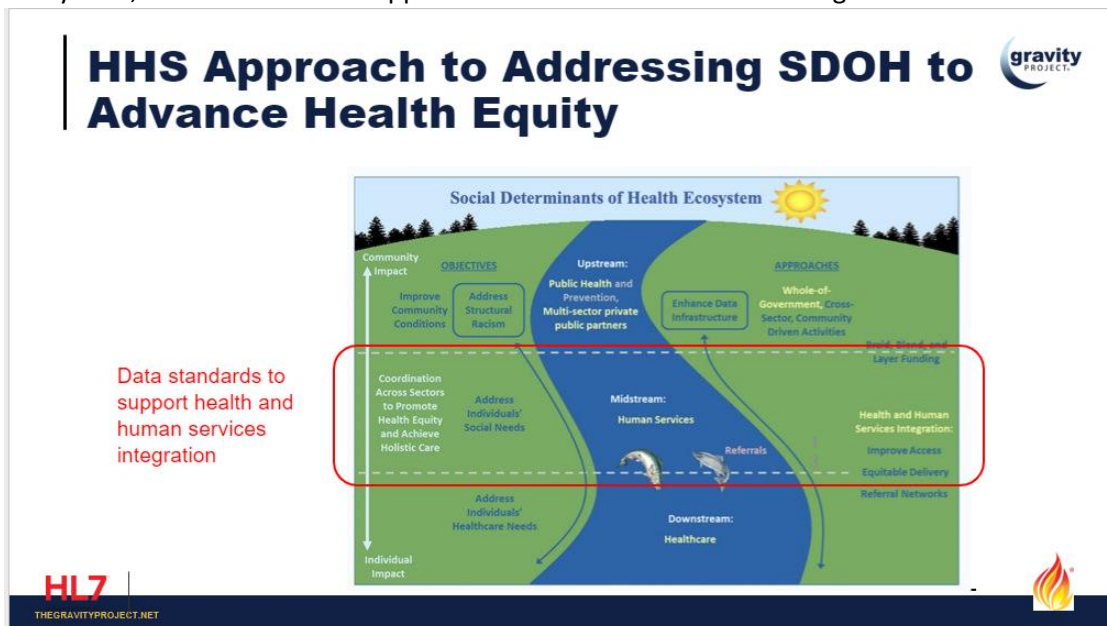
Director of Terminology, Gravity Project

Yale/YNHH Center for Outcomes Research & Evaluation (CORE)- Project Lead, ASN measure

Pediatric Faculty, Larner College of Medicine at the University of Vermont

The [Gravity Project](#) is a collaborative public-private initiative launched in May 2019 with the goal to develop consensus-driven data standards to support the collection, use, and exchange of data to address the social determinants of health (SDOH).

- To ground this talk with definitions:
 - Health equity is the state in which everyone has a fair and just opportunity to attain their highest level of health.
 - SDOH are the conditions in which people are born, grow, live, work and age which are shaped by the distribution of money, power, and resources.
- SDOH can offer both positive and negative factors. The negative factors are social risks; the adverse social conditions associated with poor health and social needs (patient-prioritized social risks). Equally important are protective factors, like cultural connectedness and spirituality, especially in family-centered and pediatric populations. These are the characteristics and strengths of individuals, families, communities, and societies that serve to mitigate risks and promote positive well-being and healthy development. These protective factors should be fostered when working with communities to try to combat social risks.
- The HHS approach to advancing health equity is demonstrated in the slide below. In the SDOH ecosystem, data standards to support health and human services integration are critical.



- The Gravity project has three use cases that demonstrate how race and social risks are intertwined:
 - The two are person-level activities: documenting social care data at patient/client encounters and tracking social care interventions to completion.

- The last use case is gathering and aggregating social care data for uses beyond the point of care for population, health quality, reporting risk stratification, research and policy and critical interventions to address the structural forces that perpetuate inequities.
- The Gravity Project uses three work streams to create community-centered social risk language for documenting individual level, and community level concerns: terminology, technical, and testing (pilots) the implementation. Terminology builds data to address and fill gaps critical to social risk documentation. The technical workstream leverages them within an HL7 Fire Accelerator Project and Implementation Guide to enable consistent exchange. Then, testing hypotheses from terminology and technical in real world settings.
- The Gravity Project has addressed 17 domains over the course of three years, covering terminology for screening, assessment, goal setting, and treatment interventions, all validated through pilots and implementation. For example, when thinking about food insecurity, there is terminology to identify the activity of screening, terminology to document diagnoses (ICD-10-CM Z59.41), terminology to document a person-centered goals and terminology to document interventions. All of these are standardized, evidence-based, commonly defined, and able to be leveraged for interoperability and exchange.
- The Gravity Project uses six [data use principles for equitable health and social care](#): the principle of improving personal health outcomes, the principle of improving population health equity, the principle of ensuring personal control, the principle of designing appropriate solutions, the principle of ensuring accountability; and lastly, the principle of preventing, reducing, and remediating harm.
- Based on the WHO Conceptual Framework for Action on the SDOH, R&E are not social risks independently, but cultural bias and discrimination can result in the stratification of privilege and resources by R&E. The same is true for gender, occupation, or sexual orientation. The result is stratification of health outcomes or health inequities, so actions to address inequities must consider racism and bias as a driver.
- For the Gravity Project, R&E data is critical for analyzing inequities and social risk. Based on this data, community interventions can minimize risks and enhance protective factors with the goal of health equity.
- In summary, the Gravity Project approaches R&E data to balance privacy, security, and risk to address health inequities. Please [join the Gravity Project community here](#). You can also [partner](#) with The Gravity Project on development of blogs, manuscripts, dissemination materials.

Progress, Challenges, and Incentives to Adopting Interoperability Standards

Ryan Argentieri

Deputy Director, Office of Technology

The Office of the National Coordinator for Health Information Technology (ONC)

Founded in 2004 by executive order and established in statute in 2009, [ONC](#) is charged with formulating the federal government's health IT strategy to advance national goals for better and safer healthcare through an interoperable nationwide health IT infrastructure.

- To ensure patients get the best healthcare, providers should have the best technology available. This happens through coordination, adoption, and harmonization of open standards, and more recently through implementation and the exchange of information. Application programming interfaces (APIs) are an important part of this conversation. Open APIs and apps make it easy to check bank accounts, buy stocks, or order meal delivery on a smartphone.

- There is a new rule that requires all certified technology developers to deploy a standard FHIR (Fast Healthcare Interoperability Resources) API to prevent business and technical barriers to information-sharing. This will create a climate for innovation as apps can now be developed that will work across all EHR (electronic health record) systems.
- ONC was also tasked with establishing and overseeing a human health services (HHS) wide approach for incorporating standard health IT requirements language in all applicable HHS funding programs, contracts, and policies; and providing direct ONC assistance to HHS agencies to maximize the use of HHS-approved standards and authorities. This is to advance health equity by laying the foundation to manage data to improve health outcomes, especially for the patients who are most at risk.
- USCDI is the minimum data set for key EHR functions, interoperability, and patient access. The [USCDI website](#) has details about the versioning process and where different data elements/data classes are on the maturity, scale, and versioning process each year. The current USCDI version is in the process of being updated, and ONC is [accepting feedback](#) on its content until April 17, 2023. Data elements from the current version are outlined in the slide below.

USCDI **USCDI Version 3 (July 2022)**

Allergies and Intolerances <ul style="list-style-type: none"> Substance (Medication) Substance (Drug Class) Reaction 	Clinical Tests <ul style="list-style-type: none"> Clinical Test Clinical Test Result/Report 	Health Status/ Assessments <ul style="list-style-type: none"> Health Concerns Functional Status Disability Status Mental / Cognitive Status Pregnancy Status Smoking Status 	Patient Demographics/ Information <ul style="list-style-type: none"> First Name Last Name Middle Name (Including middle initial) Suffix Previous Name Date of Birth Date of Death Sex Ethnicity Tribal Affiliation Sex Sexual Orientation Gender Identity Preferred Language Current Address Previous Address Phone Number Phone Number Type Email Address Related Person's Name Related Person's Relationship Occupation Occupation Industry 	Procedures <ul style="list-style-type: none"> Procedures SDOH Interventions Reason for Referral
Assessment and Plan of Treatment <ul style="list-style-type: none"> Assessment and Plan of Treatment SDOH Assessment 	Diagnostic Imaging <ul style="list-style-type: none"> Diagnostic Imaging Test Diagnostic Imaging Report 	Immunizations <ul style="list-style-type: none"> Immunizations 	Unique Device Identifier(s) for a Patient's Implantable Device(s) <ul style="list-style-type: none"> Unique Device Identifier(s) for a patient's implantable device(s) 	Provenance <ul style="list-style-type: none"> Author Organization Author Time Stamp
Care Team Member(s) <ul style="list-style-type: none"> Care Team Member Name Care Team Member Identifier Care Team Member Role Care Team Member Location Care Team Member Telecom 	Encounter Information <ul style="list-style-type: none"> Encounter Type Encounter Diagnosis Encounter Time Encounter Location Encounter Disposition 	Laboratory <ul style="list-style-type: none"> Test Values/Results Specimen Type Result Status 	Vital Signs <ul style="list-style-type: none"> Systolic blood pressure Diastolic blood pressure Heart Rate Respiratory rate Body temperature Body height Body weight Pulse oximetry Inhaled oxygen concentration BMI Percentile (2 - 20 years) Weight-for-length Percentile (Birth - 24 Months) Head Occipital-Frontal Circumference Percentile (Birth - 36 Months) 	Clinical Notes <ul style="list-style-type: none"> Consultation Note Discharge Summary Note History & Physical Procedure Note Progress Note
Goals <ul style="list-style-type: none"> Patient Goals SDOH Goals 	Health Insurance Information <ul style="list-style-type: none"> Coverage Status Coverage Type Relationship to Subscriber Member Identifier Subscriber Identifier Group Number Payor Identifier 	Medications <ul style="list-style-type: none"> Medications Dose Dose Unit of Measure Indication Fill Status 	Problems <ul style="list-style-type: none"> Problems SDOH Problems/Health Concerns Date of Diagnosis Date of Resolution 	Health Insurance Information <ul style="list-style-type: none"> Coverage Status Coverage Type Relationship to Subscriber Member Identifier Subscriber Identifier Group Number Payor Identifier

New Data Classes and Elements Data Element Reclassified

- Through USCDI, ONC's goal is to have a solid, well-established springboard in place for data elements across the many millions of different data owners and users. This means meeting everyone's interest and needs across the board and adjustments for patient protection as technology continues to modernize.
- USCDI+ is an extension of USCDI that ONC provides to USCDI+ partners, in collaboration with their key stakeholders, who need to establish, harmonize, and advance the use of interoperable datasets that extend beyond the core data in the USCDI to meet agency or use-case specific programmatic requirements. The program goals are to:
 - Collaborate across USCDI+ partners, healthcare providers, and the health IT community to inform and support health IT advancement for priority use cases.
 - Adopt standards across relevant partners, including federal agencies, clinical stakeholders, the health IT community, public health agencies and users of health IT.
 - Implement specifications to ensure that the use of standards is aligned across federal programs and with key partners, including state, local, tribal, and territorial governments, across specialties and sites of service, improving interoperability on a national scale.

- USCDI+ is a rolling, iterative process where new cases are built upon existing work and can be updated and shared at regular intervals. Partners across the ecosystem can adopt these models for data capture and exchange to ensure better treatment, prevention, and research for all patients.
- Contact [ONC](#) via their website or the Health IT Feedback Form: <https://www.healthit.gov/form/healthit-feedback-form>.

The Tension Between Race and Data Privacy

Bradley Malin, PhD

Vice Chair, Department of Biomedical Informatics

Co-Director, Center for Genetic Privacy & Identity in Community Settings (GetPreCiSe)

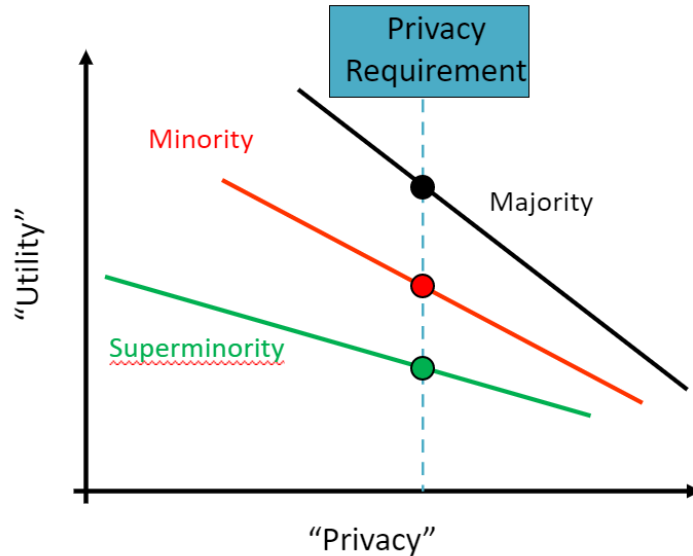
Co-Director, Health Data Science Center (HEADS)

Vanderbilt University Medical Center

Accenture Professor of Biomedical Informatics, Biostatistics, & Computer Science

Vanderbilt University

- There are several challenges related to sharing R&E data. One main issue is that the data that has been collected and shared for decades is primarily focused on populations that are historically Caucasian. This causes a lot of challenges with research and trying to derive any type of clinical decision support technology.
- There has been this push for diversity, and one of the initiatives is an NIH sponsored program called [All of Us](#). The program is working to collect data on about one million people in the United States, including electronic medical records data, survey responses and biological specimens. The program currently has data from approximately 600,000 individuals with more than 50% of the population from an underrepresented group.
- *All of Us* data is made available for research is through tiers of access. The first tier is public access where anyone can see what type of data is available (mainly summary statistics) without logging in. In this tier, there are also sandbox environments where individuals can build statistical processing and work boxes.
- The second tier requires registration and is available to anyone within a trusted academic organization. This will eventually be expanded to all citizen scientists. The data in this tier is available in such a way that there's a low risk of re-identification of the participants. The story of Bill Weld illustrates why this is important. In the 90s, data was collected from hospital discharge databases in the State of Massachusetts. The data set included quasi-identifiers like zip code, birthday, and gender. This information, when cross referenced with publicly available data from voter registration lists, identified Bill Weld as the only person with this combination of variables. This type of identification has been replicated in many different situations, and it's been shown that in the United States these variables are relatively unique, even before adding R&E.
- Data privacy is great in principle, but only useful when there is data or populations of a sufficient size. There is a challenge in allowing information at this level of granularity to be available publicly as it can be leveraged under various circumstances for identification purposes. For example, the registered tier in *All of Us* is generalized as it has many SDOH and R&E. Program participants of Middle Eastern ethnicity are grouped with other ethnicities as the small numbers will make individuals easy to identify.
- The real challenge is the privacy-utility tradeoff. More privacy may lead to less utility, and the tradeoff is even larger for minority and super minority populations as there is already less data on these populations to begin with. The slide below demonstrates a privacy operating threshold that is the same for all populations. There's a lack of fairness with respect to the populations.



- The question in these situations is ‘what is fair?’ Minority data tends to be amended more than the majority populations. If this persists, we continue to learn more about majority populations and end up making better policies for majority populations. This is really the artifact of the rich get richer. With data access, the goal should be to try to rebalance the population with respect to fairness.
- The *All of Us* tiered levels of access (Public, Registered, and Controlled) are summarized in the diagrams below. For questions, Dr. Malin can be reached by [email](#) and the *All of Us* data can be accessed [here](#).

Tiered Levels of Access



- Public
 - Can be accessed without logging in
 - Summary statistics only
- Sandbox Environments
 - jupyter
 - Terra
 - Google Cloud Platform
- Registered
 - Available to anyone within a trusted organization... plans to expand out to citizen scientists
 - Individual-level data with low risk of re-identification
- Controlled – released last year (100k human genomes)!
 - Available to researchers in a trusted organizations
 - More detail, more risk, but still designated as non-human subjects



Demographic Fields	Registered Tier	Controlled Tier
Date of Birth	Random Shift (one year)	Year of Birth
Dates of Events	Random Shift (one year)	No change
Date of Death	Random Shift (one year)	No change
Geolocation	Generalize (US State)	Generalize (ZIP-3)
Marital status	No change	No change
Own or rent	No change	No change
Race/Ethnicity	Generalize	No change
Sex/gender	Generalize	No change
Sexuality	Generalize	No change
Education	Generalize	No change
Employment status	Generalize	No change
Born in US or not	No change	No change
Annual household income	No change	No change
Death cause	Suppress	No change
Living situation	Suppress	No change
Active duty/military	Suppress	No change
Genomic data	Suppress	No change
Motor vehicle accidents	Suppress	Suppress
Free Text	Suppress	Suppress

Moderated Discussion

Moderator: Lenel James, MBA
 FHL7, Business Lead – Health Information Exchange & Innovation
 Market Solutions, Blue Cross Blue Shield Association

Discussants:

- Workshop Champion: Bradley Malin, PhD
- Citizen Voice: La Keita D Carter, PsyD, LD

- *Ryan Argentieri*
- *Sarah C. DeSilvey, DNP, FNP-C*

The moderated discussion took questions from the chat as well as those posed by our moderator to further expand on the workshop's presentations. The conversation emphasized that trust is key for data collection and sharing. Issues may be identified in clinical settings, but they are solved in communities. Highlights from the discussion:

- There are many groups of people, including racial and ethnic minorities, that are hesitant to give any information to any health care provider. Particularly in mental health care settings, knowing that information is being shared across many different agencies or platforms creates even more hesitance.
- With telehealth, the use of technology in general can inspire paranoia and suspicion.
- One of the most important factors in data collection and sharing is trust. Even after trusting the initial collector of the data, is there trust in what they're going to do with the data after the fact? There is a tendency, particularly in the biomedical research world, to have a clear separation between what happens in primary care versus the reuse of the data. Once the data gets reused for various investigations, there's a lack of documentation and a lack of transparency that can cause apprehension and a lack of data sharing.
- There is a notion of the potential for stigmatism and the misuse of information. There aren't currently oversight boards with respect to how information is going to get re-used for any type of subsequent application. This has caused a lot of trust issues that that have not completely been addressed.
- There is active work in reference to R&E data collection with the Pilots Affinity Group and the Robert Wood Johnson through new pilots focusing on exchange of SDOH to address health equity and public health use cases. These are built in alignment with the CDC public health use developed in partnership with Gravity. There are also some pilots that focused on data sovereignty and the needs of tribal nations to address public health and population health.
- ONC works very closely and is aligned with reimbursement requirements of SAM (System for Award Management) and CMS to make sure that the providers are aligned with the technical requirements and specifications in the health IT certification program.
- The EHR platforms need to strike a fine balance between what's technically possible and specified and patient empowerment.
- ONC awards small grants for human services, interoperability, or for technical assistance to accelerate the adoption of new and novel approaches. Lately, these have been focused on health equity and human services data interoperability.
- In many communities, particularly communities of color, word of mouth is more effective than science. A grandmother's experience of something and extended family's knowledge of that experience may carry more weight than the advice from a physician.
- Issues may be identified in clinical settings, but they are solved in communities. The food banks, community organizations, or stores that give out food on a Sunday have been in the ecosystem long before the health care system as solution finders and trusted partners.

- When people see that technology can be used to provide some benefit to them or the populations that they represent, there will be a greater opportunity for the collection, sharing and use of the data where technology might play a role in creating some type of data lineage.

Hot Takes and links from the Chat

- The Certified Health IT Developer must update their product(s) and provide those updates to its customers by December 31, 2022: https://www.healthit.gov/sites/default/files/page/2022-09/Cures-Update-Cert-Criteria-2022%20Deadline%20Fact-Sheet_508.pdf
- USCDI versions and how they are being used is here: <https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>
- Standards Bulletins are here: <https://www.healthit.gov/topic/standards-technology/onc-standards-bulletin>
- As for CMS, more info here: <https://ecqi.healthit.gov/dqm> and you will continue to see more about USCDI+ and the quality domain in the next few weeks.
- E-consent discussion: <https://www.healthit.gov/news/events/discovery-workshop-econsent-birth-end-life>
- On the Lantern website, a lot of the systems seem to be using older versions FHIR and while it's improving there are still a number of systems lagging (https://lantern.healthit.gov/?tab=dashboard_tab)
- LEAP awards: <https://www.healthit.gov/topic/onc-funding-opportunities/leading-edge-acceleration-projects-leap-health-information>
- SDOH Interoperability Forum (highlights great work done by Dr. DeSilvey et al): <https://www.healthit.gov/sites/default/files/2022-06/ONC-SDOH-Information-Exchange-Learning-Forum-061422.pdf>
- HRSA work with health centers: <https://bphc.hrsa.gov/data-reporting/uds-training-and-technical-assistance/uniform-data-system-uds-modernization-initiative>

Please join us for future RAISE Workshops:



Community Workshop Series

**1st & 3rd
Thursday
of the
month at
2 pm ET**

#	Date / Time (ET)	Key Theme
1	Jan 26 / 2-4 pm	Opportunities to Improve Race & Ethnicity Data in Health Care
2	Feb 2 / 2-3 pm	Collecting Better Data I: Incentives, Framework, Mission
3	Feb 16 / 2-3 pm	Collecting Better Data II: System Infrastructure
4	Mar 2 / 2-3 pm	Creating Safe Space I: Reporting Race 101
5	Mar 16 / 2-3 pm	Creating Safe Space II: Capturing Race and Ethnicity Data
6	Apr 6 / 2-3 pm	Technical challenges in the transfer of information
7	Apr 20 / 2-3 pm	Factors & Impact of Missingness, Misclassification, and Measurement Bias
8	May 4 / 2-3 pm	Advanced Analytics – Novel Ways to Apply Existing Race & Ethnicity Data
9	May 18 / 2-3 pm	Advanced Analytics - Interim Solutions When Race & Ethnicity are Missing
10	Jun 1 / 2-3 pm	Reactions to Barriers, Opportunities & Proposed Solutions
11	Jun 15 / 2-4 pm	Summary - Visioning & Next Steps