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Modernizing Consent to Advance Health and Equity



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**NATIONAL
HEALTH POLICY
CONFERENCE**

Speakers



Pooja Babbar

**Practice Lead, PBM Services
Point-of-Care Partners**

Pooja Babbar is Point-of-Care Partners' Practice Lead for PBM and Pharmacy Services and is currently the Vice-Chair of the NCPDP Board of Trustees. Pooja is a seasoned strategy and product leader focused on healthcare technology and policy. She has spent over two decades leading, and growing product strategy teams with her main focus on growing a company's revenue through a well-defined and focused product strategy. Pooja has her BA in Business Administration/Information Systems from the University of Washington and an MBA from the W.P. Carey School of Business at Arizona State University.



Daniel Stein

**President
Stewards of Change Institute**

Daniel is President of SOC Institute, a nonprofit "think-and-do-tank" and the Principal Investigator for the National Interoperability Collaborative. SOCI's mission is to improve equity, outcomes and operations, especially for underserved populations through responsible data sharing across all health and human services. Stein has been a thought leader, educator and advocate for interoperability for over 15 years. He holds an MBA from Yale School of Management and a BA from The Evergreen State College.



Mary Kratz

**Executive Vice President of
the Interoperability Institute**

Mary Kratz is the Executive Vice President of the Interoperability Institute, an affiliate organization of the Michigan Health Information Network group. Mary is a leader in the field of biomedical informatics, working at the intersection of interoperability, telemedicine and business development. As a senior Health Informatics Advisor to the United States Department of State, Mary implemented health information systems in over 40 countries, primarily low and middle-income countries in sub-Saharan Africa.



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Healthcare Informed Consent

Healthcare Informed Consent: A record of a healthcare consumer's choices that permits or denies identified recipient(s) or recipient role(s) to perform one or more actions, within a given policy context, for specific purposes and periods of time

Four Types of Informed Consent in Healthcare



Privacy: agreement to collect, access, use, or disclose (share) information



Research: consent to participate in research study



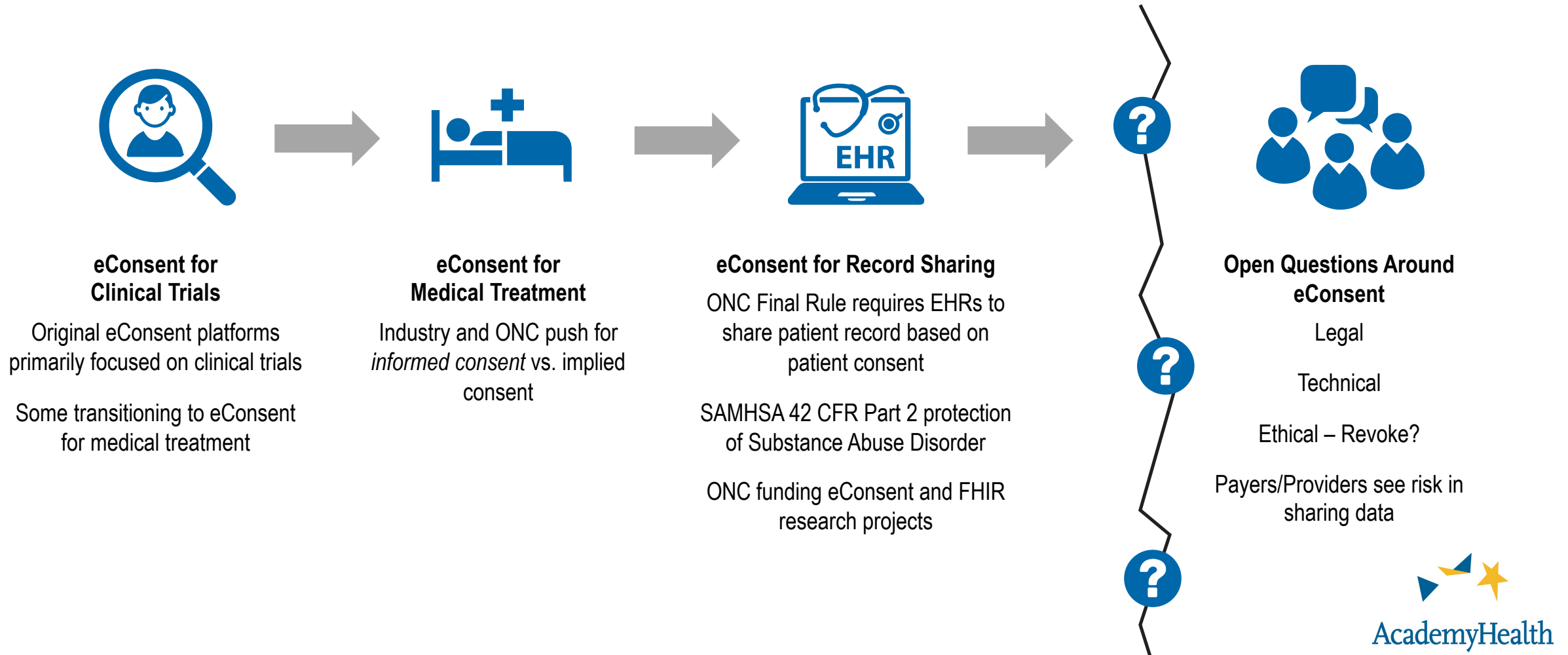
Medical Treatment: consent to undergo a specific treatment/procedure (or record of refusal to consent)



Advance Care Directives: consent to access instructions for potentially needed medical treatment (eg, DNR)

Healthcare eConsent Evolution

DRIVERS: Industry and ONC Funding and Rule-Making

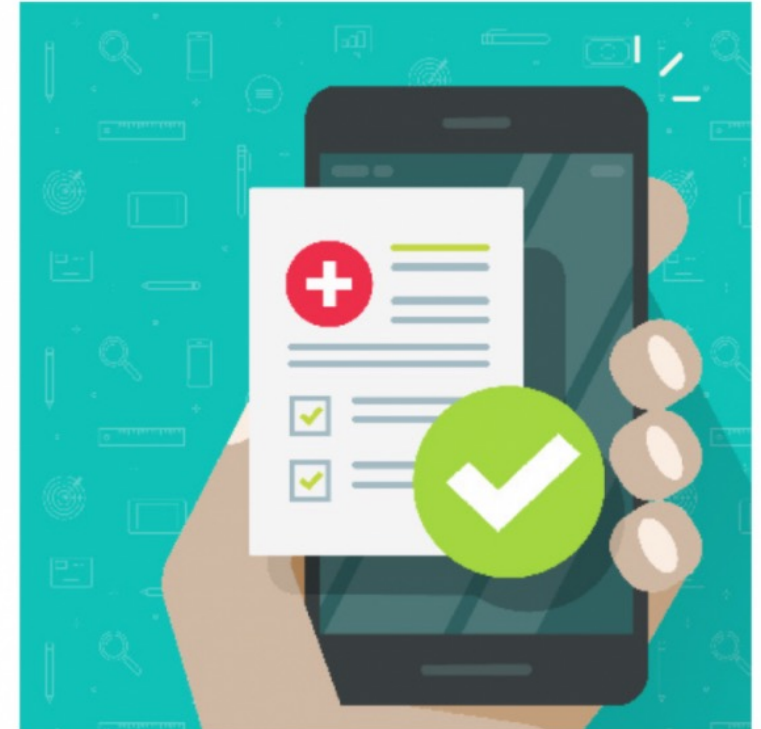


Scan Background and Context

- SOCI's National Interoperability Collaborative has brought together hundreds of professionals to focus on improving interoperability across health and human services for 4 years
- In 2020/21, SOCI led the *National Action Agenda to Advance Upstream Social Determinants and Equity (NAA)* to identify actionable recommendations for post-Covid systemic change
- NAA's top-priority action recommendation was **improving informed consent**; it's been our focus since January 2021
- The Consent Scan report is the product of a six-month research process with scores of volunteers across the US

Modernizing Consent to Advance Health and Equity

A NATIONAL SURVEY OF KEY TECHNOLOGIES, LEGAL ISSUES AND PROMISING PRACTICES




Stewards of Change
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Thanks to Our Participants



*Sincerest thanks to our many partners,
including the Robert Wood Johnson
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Robert Wood Johnson Foundation



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“As we’re moving into this next generation of adding more complexity to the data sources . . . it is incumbent on us to really step up the game and make sure that we have true informed consent and that we have an appreciation for how people can be educated about who is seeing their data and when. . . . We’re going to have to sort out a way to create an interoperability between public health and social care systems in particular.”

Karen DeSalvo, MD, MPH, Chief Health Officer Google;
ONC National Coordinator (former)
HL7 35th Annual Plenary, 9/20/2021

Basis for Consent Scan

The Problem:

- Consent processes and systems are antiquated, and information is distributed across the web in myriad systems that are not easily accessible
- These systems obstruct information sharing within and across sectors; a critical need for improving racial equity, socioeconomic disparities, and improving outcomes
- Data Sharing and Interoperability are difficult, if not impossible, and potentially unethical without Informed consent

The Goal:

- Improve health, well-being and equity through dramatically improving Consent Services; learn from prior and promising practices
- Implement a proof-of-concept demonstration project to guide development of a replicable Utility model

Voices from the Community

Bronx Community Research Review Board: Keys to progress on consent are: having a broad context, building trust and understanding the value of relationships.

'It should be about relationality, relationality, relationality. . . Data is not going to matter in the absence of remediating harm and shaping relationships'

- Consent isn't just about the individual asked to provide it
- It's a big problem if consent moves primarily to apps
- Service providers and other professionals don't always understand the implications and consequences of their requests for consent

Voices from the Community (cont.)

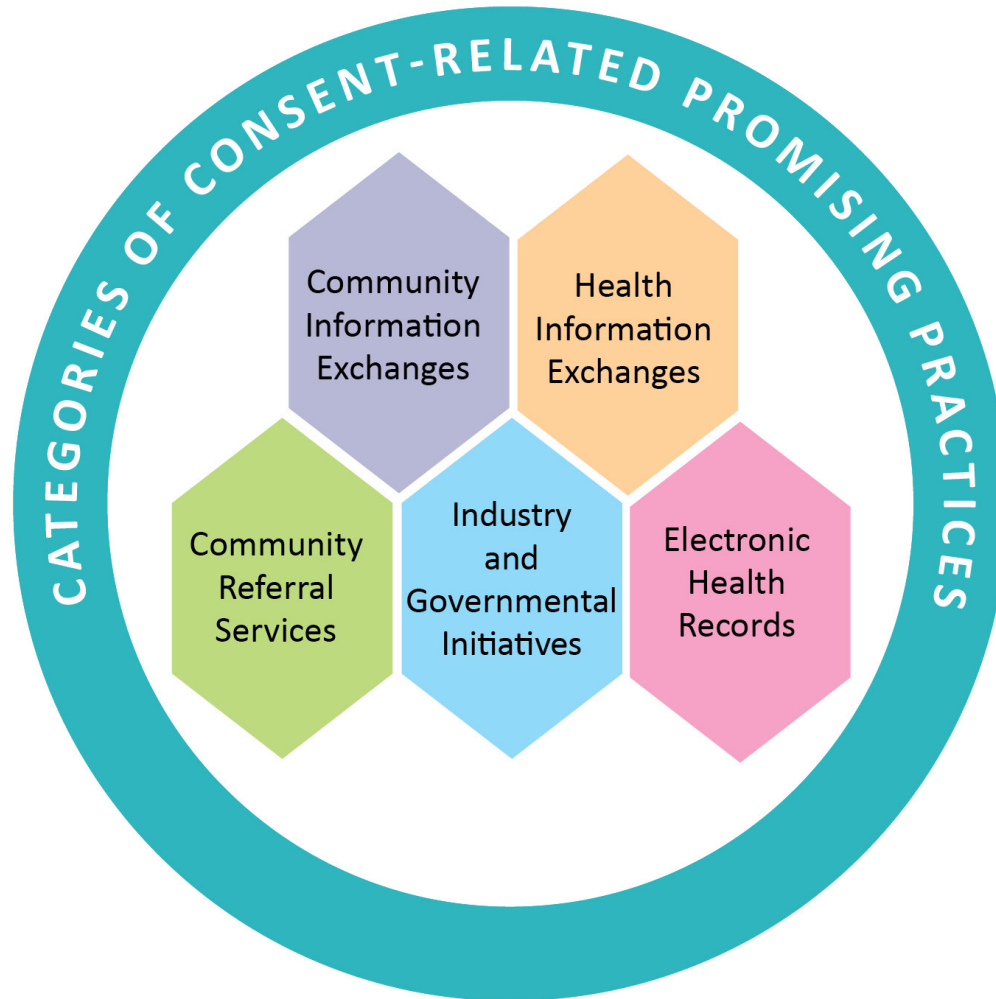
- Consent isn't just about the individual asked to provide it
- It's a big problem if consent moves primarily to apps
- Service providers and other professionals don't always understand the implications and consequences of their requests for consent

'There's no such thing as a single-issue struggle because we do not live single-issue lives.'

'If I can't have an interactive relationship, I don't want it.'

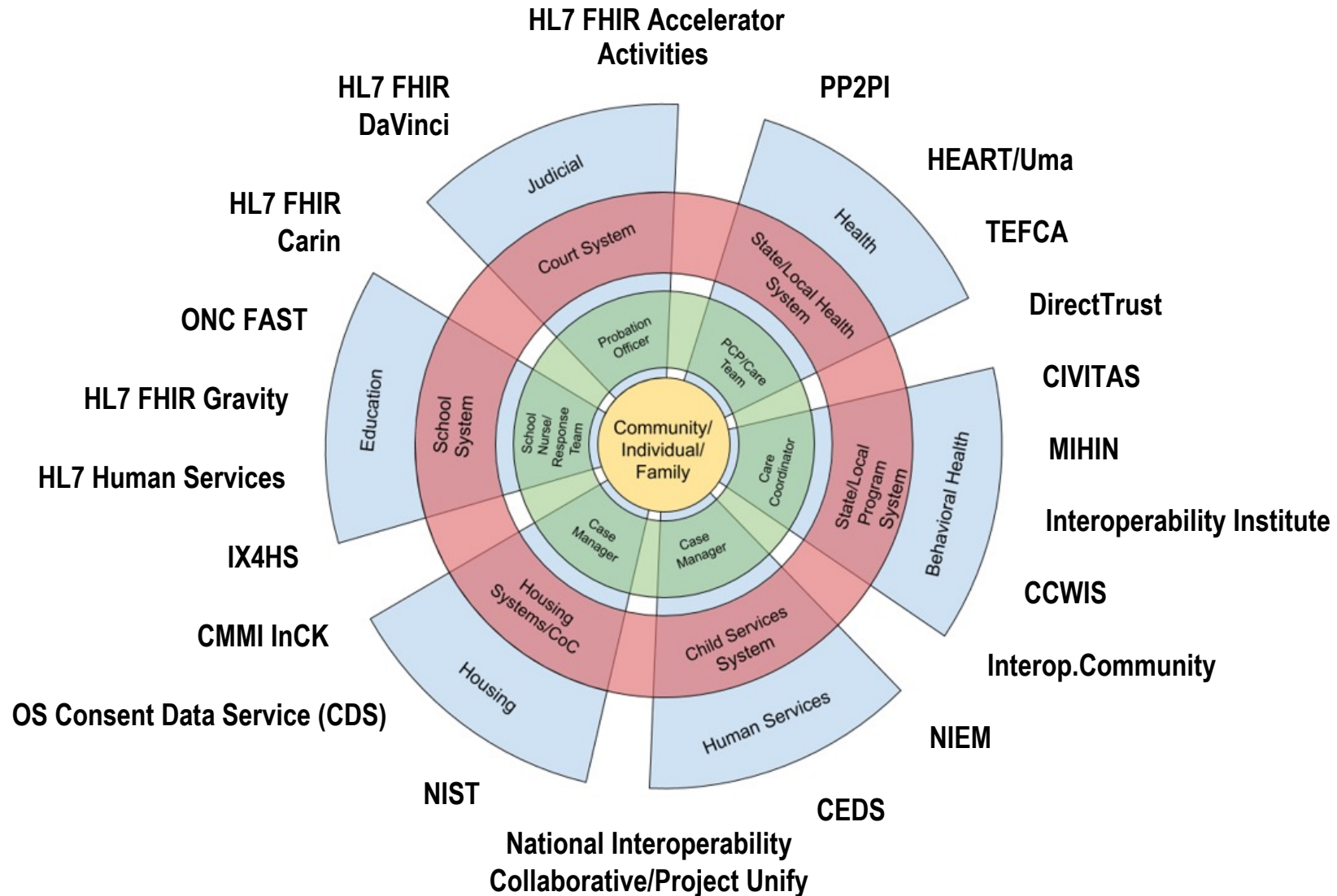


Promising Practices



The report segments promising practices into five main areas

Consent Service Utility Ecosystem



Introducing the Interoperability Community

InterOp.Community

is an emerging collaboration to advance the healthcare interoperability via the use of open platforms and open-source software.



Meld.Interop.Community



Open Source-Code Development

- <https://github.com/Interop-community>
- FHIR® DSTU2, STU3, R4 and R5
- Ability to create, edit, delete and/or import data
- Containerized architecture

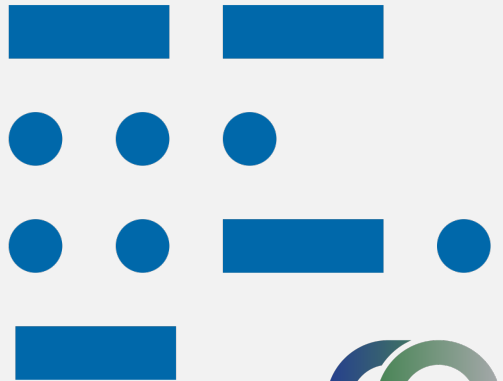
A growing number of applications

- Patient Data Manager
- Synthetic EHR
- Bilirubin Risk Chart app
- CDS Hooks
- Inferno Validator
- Consent Data Service

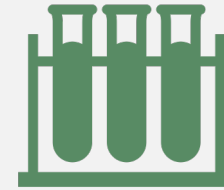


Open-Source Software (OSS) and An Open Proving Ground (Sandbox)

Open-Source Code Base



Simulate



Innovate



Training



Validate



Collaborate



MELD

Meld INSTANTIATED OPEN SANDBOX
PROVING GROUND

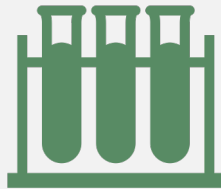
CoP's Use the Meld Open Proving Ground or Commission New Proving Grounds



InterOp.Community



Simulate



Innovate



Training



Validate



Collaborate



Meld OPEN SANDBOX PROVING GROUND



CoP1



CoP2



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eConsent Activity Landscape

SAMPLING of eConsent Activities



Potential Use Cases in eConsent Community of Practice



Advance Care Planning



**Maternal and Infant
Health**



**Social Services/Health Equity
(Project Unify)**



**Early Medical Intervention
and Education**



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Resources

- Stewards of Change Institute: <https://stewardsofchange.org/>
- Interoperability Institute: <https://interoperabilityinstitute.org/>
- Project Unify: <https://hub.nic-us.org/groups/project-unify>

Contact information

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