Conceptualizing a Data Infrastructure for the Capture and Use of Patient-Generated Health Data (PGHD)

HL7 PGHD Project Update

1/18/2017

High performance. Delivered.

What are patient-generated health data?

Patient-generated health data (PGHD) are **health-related data** created, recorded, or gathered by or **from patients** (or family members or other caregivers) **to help address a health concern.**

PGHD include, but are not limited to:

Health history

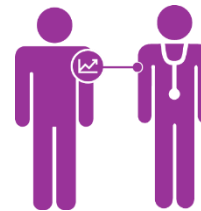Treatment history

Biometric data

Symptoms

Lifestyle choices

PGHD are distinct from data generated in clinical settings and through encounters with providers in two important ways:

Patients, not providers, are **primarily responsible for capturing** or recording these **data**.

Patients decide how to share or distribute these **data to** health care **providers** and others.

Patient-generated health data are referenced in:

21st Century Cures Act

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

Stage 3 Meaningful Use Rule

2015 Edition Certification Rule

ONC Interoperability Roadmap

Federal Health IT Strategic Plan

Precision Medicine Initiative

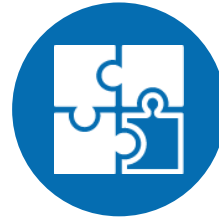# Overview of the PGHD Policy Framework Project

ONC is conducting a two-year project to develop a white paper with pilots for a policy framework for the capture, use, and sharing of PGHD for care delivery and research.

Team is investigating best practices, opportunities, and gaps in the use of PGHD in care delivery and research

Project will coordinate two pilots to test implementation of best practices identified in the draft policy framework
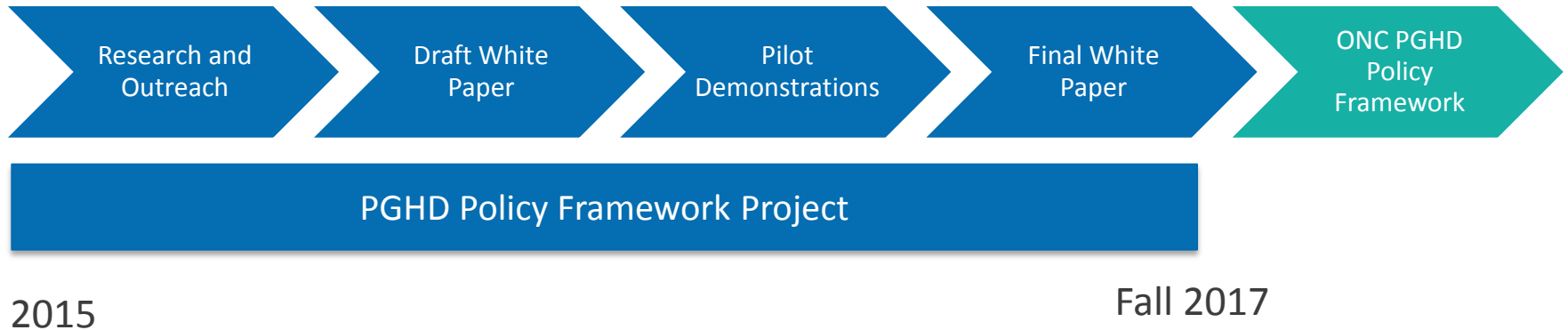
Output of project will inform ONC's long-term policy framework for the successful implementation of PGHD in care delivery and research through 2024

Project is one in a portfolio of projects at ONC that addresses the data infrastructure needed for Patient-Centered Outcomes Research (PCOR)

PGHD Policy Framework Project: General Timeline

Research and Outreach → Draft White Paper → Pilot Demonstrations → Final White Paper → ONC PGHD Policy Framework

PGHD Policy Framework Project

Fall 2015

Fall 2017

PGHD Policy Framework Project: Draft White Paper

- Draft white paper synthesizes key findings from research and outreach

- Discusses emerging trends and provides a vision for the future that enable PGHD capture, use, and sharing

- Describes opportunities, challenges, and enabling actions to create a collaborative health IT ecosystem

  » Key Stakeholders Identified:

    – Patients, Clinicians, and Researchers

  » Other Stakeholders Identified:

    – Technology, Payers, Health Plans, and Employers, and Government

PGHD Draft White Paper: Opportunities

Patients

- Improved patient experience and ability to engage in shared decision-making
- Reduced time, effort, and costs of patients visiting a clinical setting or research site and can improve workflow efficiencies

Clinicians

- Visibility into a patient's adherence to a treatment plan
- Timely intervention before a costly care episode
- Ability to develop personalized care plan based on the needs and preferences of each patient
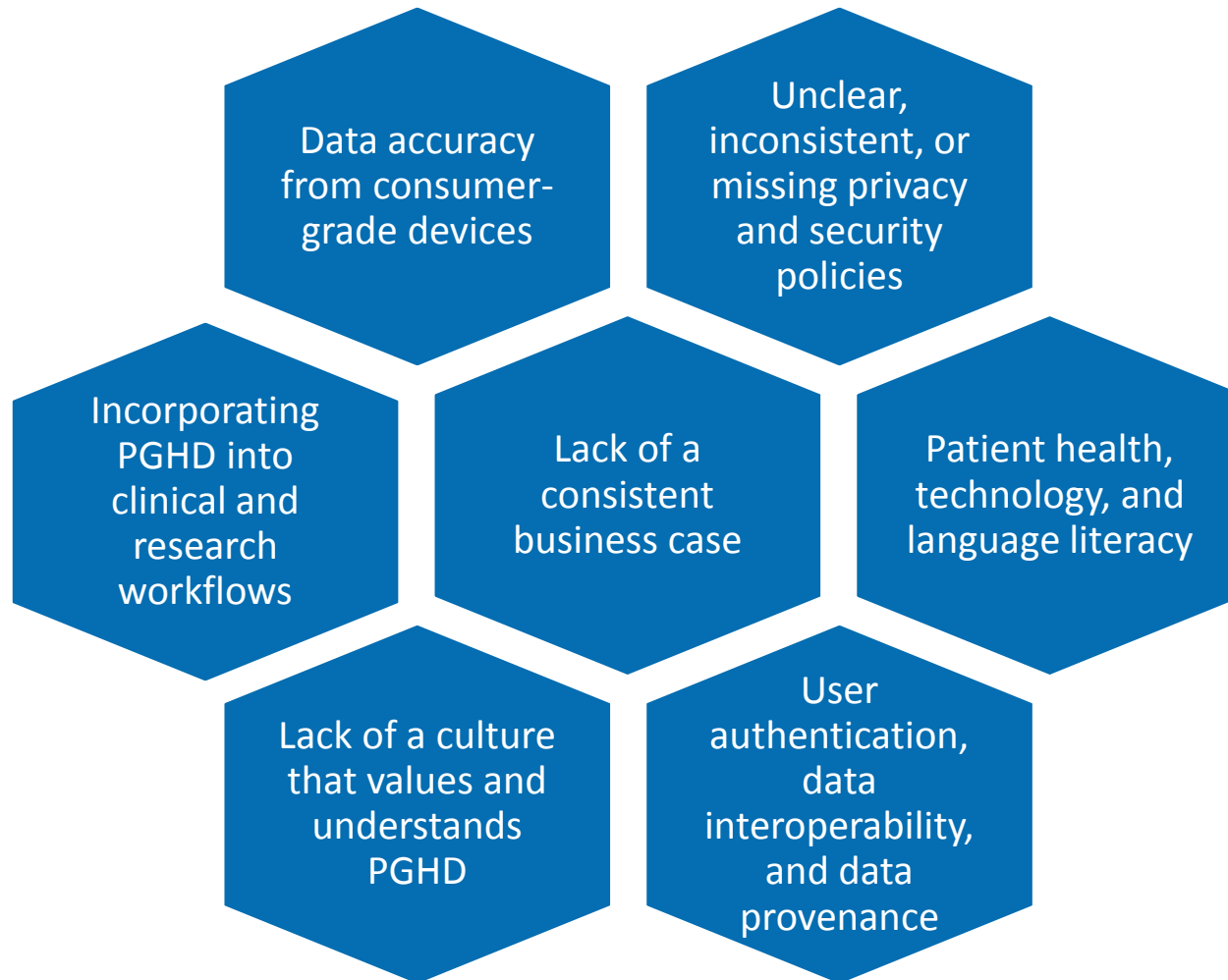
Researchers

- Access to a larger pool of participants and research data
- Ability to monitor adherence to study protocols

PGHD Draft White Paper: Challenges

A complex web of technical and cultural challenges may impede the successful capture, use, and sharing of PGHD in research and care delivery settings.

Data accuracy from consumer-grade devices

Unclear, inconsistent, or missing privacy and security policies

Incorporating PGHD into clinical and research workflows

Lack of a consistent business case

Patient health, technology, and language literacy

Lack of a culture that values and understands PGHD

User authentication, data interoperability, and data provenance

PGHD Draft White Paper: Enabling Actions for Patients and Caregivers

Patients and Caregivers

Enabling Action to Consider for the Policy Framework

- Encourage patients and caregivers to collaborate with clinicians and researchers to determine how capturing, using, and sharing PGHD can be valuable for managing their health.
- Support active patient participation in testing the functionality and usability of devices and in reporting feedback directly to manufacturers.

PGHD Draft White Paper: Enabling Actions for Clinicians

	Enabling Action to Consider for the Policy Framework
Clinicians	• Support clinicians who work within and across organizations to incorporate prioritized PGHD use cases into their workflows. • Foster collaboration between clinicians and developers to advance technologies supporting PGHD use. • Identify and communicate benefits, challenges, and best practices of PGHD use to help strengthen the evidence for clinical value and business case. • Encourage clinicians to use PGHD to support patient data donation and participation in research.

PGHD Draft White Paper: Enabling Actions for Researchers

Researchers

Enabling Action to Consider for the Policy Framework

- Call for increased funding for studies that investigate the benefits, challenges, and best practices of using PGHD in care delivery and research.
- Motivate researchers to design and develop studies that incorporate PGHD.
- Expand methods for data donation to research studies.
- Explore alternative approaches to providing and adhering to consent.

PGHD Draft White Paper: Enabling Actions for Policymakers

Policymakers	**Enabling Action to Consider for the Policy Framework**
	• Prompt collaboration with industry to strengthen model practices, consumer education, and outreach that support the private and secure capture, use, and sharing of PGHD.
	• Call for increased funding for programs that aim to further understand the impact of PGHD use as part of delivery system reform and advanced health care models.
	• Suggest review of medical malpractice and liability laws at the state level and how they intersect with legal cases involving use of PGHD.

PGHD Draft White Paper: Enabling Actions for Developers and Standards Bodies

Developers and Standards Bodies

Enabling Action to Consider for the Policy Framework

- Suggest developers improve usability and accessibility and implement user-centered design principles into products that capture PGHD.
- Increase adoption of strong privacy and security practices regarding PGHD capture, use, and sharing by developers and support transparency with consumers about these policies.
- Challenge standards bodies to address the needs of the PGHD ecosystem and to increase the pace of standards development for capturing and integrating PGHD.

PGHD Draft White Paper: Enabling Actions for Payers and Employers

Payers and Employers

Enabling Action to Consider for the Policy Framework

- Continue to motivate clinicians to capture and use PGHD through reimbursement programs.
- Continue to incorporate incentives to use PGHD into their insurance plans and wellness programs.
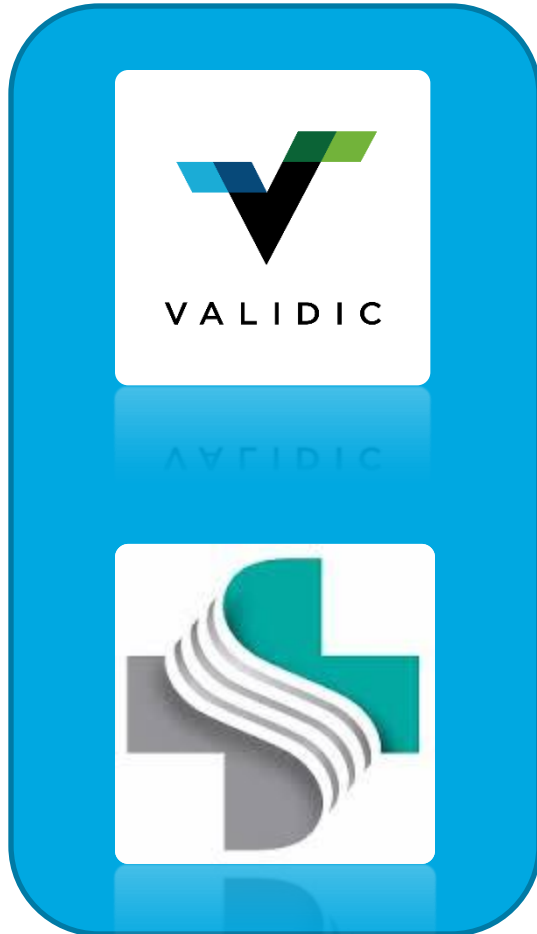
PGHD Pilot Demonstrations

Purpose

- To implement and test the policies and workflows identified in the white paper to support the capture, use, and sharing of PGHD in health care delivery and research settings

Goal

- To use insights from the pilot findings, combined with public comments and feedback from the joint Consumer Task Force of the Health IT Policy and Standards Committees, to inform updates to the draft white paper

PGHD Pilot Demonstrations: Validic and Sutter Health

» Jointly with Sutter Health, Validic will test personalized care using remotely collected PGHD from a multitude of devices across large patient populations

» The pilot will focus on people suffering from diabetes to research the infrastructure and workflows needed to implement and scale PGHD initiatives

» Sutter Health will conduct ethnography to identify areas of improvement to further patient and provider engagement

PGHD Pilot Demonstrations: TapCloud and Amita Health

» TapCloud is working with AMITA Health to gather PGHD and associated clinical results across several medical areas such as orthopedic surgery, stroke, behavioral health, and kidney transplant

» TapCloud will connect patients and clinicians outside the clinical setting with the goal of identifying how patients feel (symptoms, pain, well-being), rather than gathering only biometric or process data such as number of steps or blood pressure

ONC PGHD Helpful Links

- **Draft White Paper for a PGHD Policy Framework**

  » https://www.healthit.gov/sites/default/files/Draft_White_Paper_PGHD_Policy_Framework.pdf

- **PGHD Information on HealthIT.gov**

  » https://www.healthit.gov/policy-researchers-implementers/patient-generated-health-data

- **Consumer Task Force**

  » https://www.healthit.gov/facas/collaboration-health-it-policy-and-standards-committees/joint-hitpchitsc-task-forces/consumer-task

- **ONC Playbook - Chapter 4, Integrate Patient-Generated Health Data**

  » https://www.healthit.gov/playbook/pe/chapter-4/