AN ECOSYSTEM APPROACH TO LABORATORY INTEROPERABILITY

APRIL 19, 2022

DISCLOSURE

- *SHIELD is a consortium of stakeholders devoted to creating laboratory data semantic interoperability. The SHIELD Strategic Plan* is the product of volunteers**. The Plan was vetted though a consensus process that involved the authors, contributors and the stakeholders**. **The Plan does not represent the policy or position of any government agency or private sector organization.** The Plan becomes a document that the non-government members of SHIELD will use to promote laboratory data interoperability in the future.*

**The Plan should be cited as: SHIELD Strategic Plan. MDEpiNet. 2022; **Listed in Appendices*

AGENDA

- Introduction to SHIELD
- Overview of SHIELD Strategic Plan
- Business Cases and Current State
- SHIELD in Motion
- Action Steps for SHIELD
- Next Steps

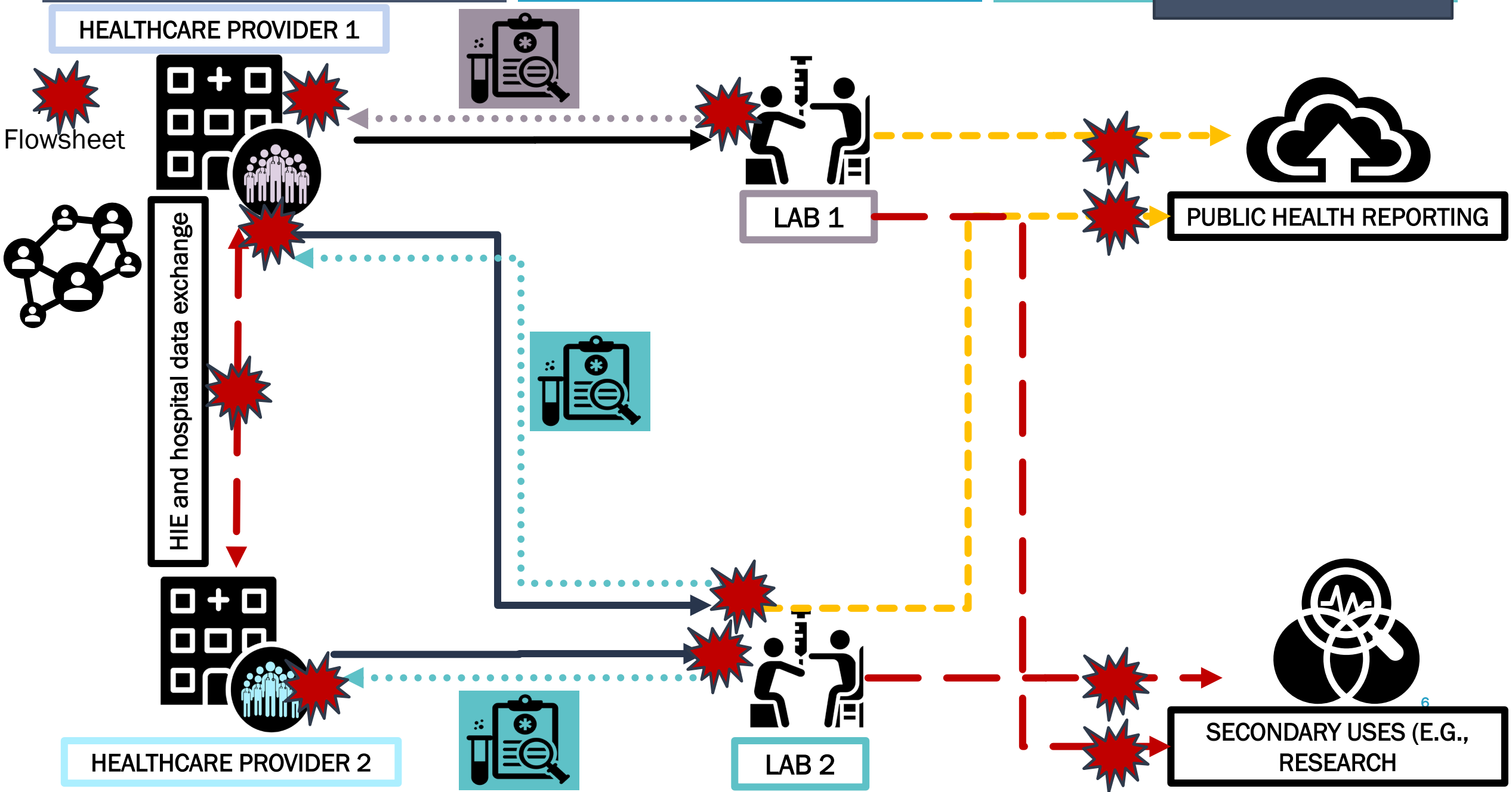
INTRODUCTION TO SHIELD

- SHIELD is a Public Private Collaborative
- Mission: To describe the SAME test the SAME way ANYWHERE in the Healthcare ecosystem
- Activities to date have included:
  - Bringing together critical stakeholders around the issue of laboratory interoperability
  - Coming to consensus about the nature of the problem
  - Creating a Plan proposing solutions to the problems

- Stakeholders
  - Laboratories
  - Professional Societies (Laboratory, Clinical, etc.)
  - IVD Manufacturers
  - Information System Vendors
  - Clinicians and Healthcare Providers
  - Standards Development Organizations
  - Government

STRATEGIC PLAN IN TWO STAGES

- Stage One = The Pilot
  - Harmonize coding of laboratory data
  - Create and improve data exchange infrastructure
  - Create tooling to enable automation and support implementation
  - The IVD Data Hub will provide real-world evidence needed by IVD manufacturers and other stakeholders. The Hub is modeled on existing medical and surgical specialty registries.
- Stage Two – The National Rollout
  - Must be based on solid tools and infrastructure, and a way for the 300,000+ labs in the US to adopt with ease as much as possible (e.g., align with incentives – or common goal to improve the ecosystem for everyone)


HEALTHCARE PROVIDER 1
Flowsheet
HIE and hospital data exchange
LAB 1
PUBLIC HEALTH REPORTING
HEALTHCARE PROVIDER 2
LAB 2
SECONDARY USES (E.G., RESEARCH

PAIN POINTS AND BUSINESS NEEDS ADDRESSED BY SHIELD

- Laboratory and EHR file maintenance
  - Staff intensive; High-levels of variability in code use; Maintenance heavy
- IVD Manufacturers
  - For every LIS there exists a new iteration of interface; Development and Maintenance Costs
- Information System Vendors
  - Creation of system-centric data ecosystems; Alignment better?; Shards larger health data ecosystem
  - User support costs; Ability/inability to rely on national standards for functionality?
- Clinicians
  - Lab Results lack consistency in detail across different lab providers, resulting in loss of meaning when merging into the patient's record or using for decision support and potential for subsequent patient harm

What system changes are expected from LIS? EHRs?

What impact does this have on clinicians?

What do IVD manufacturers need to do?

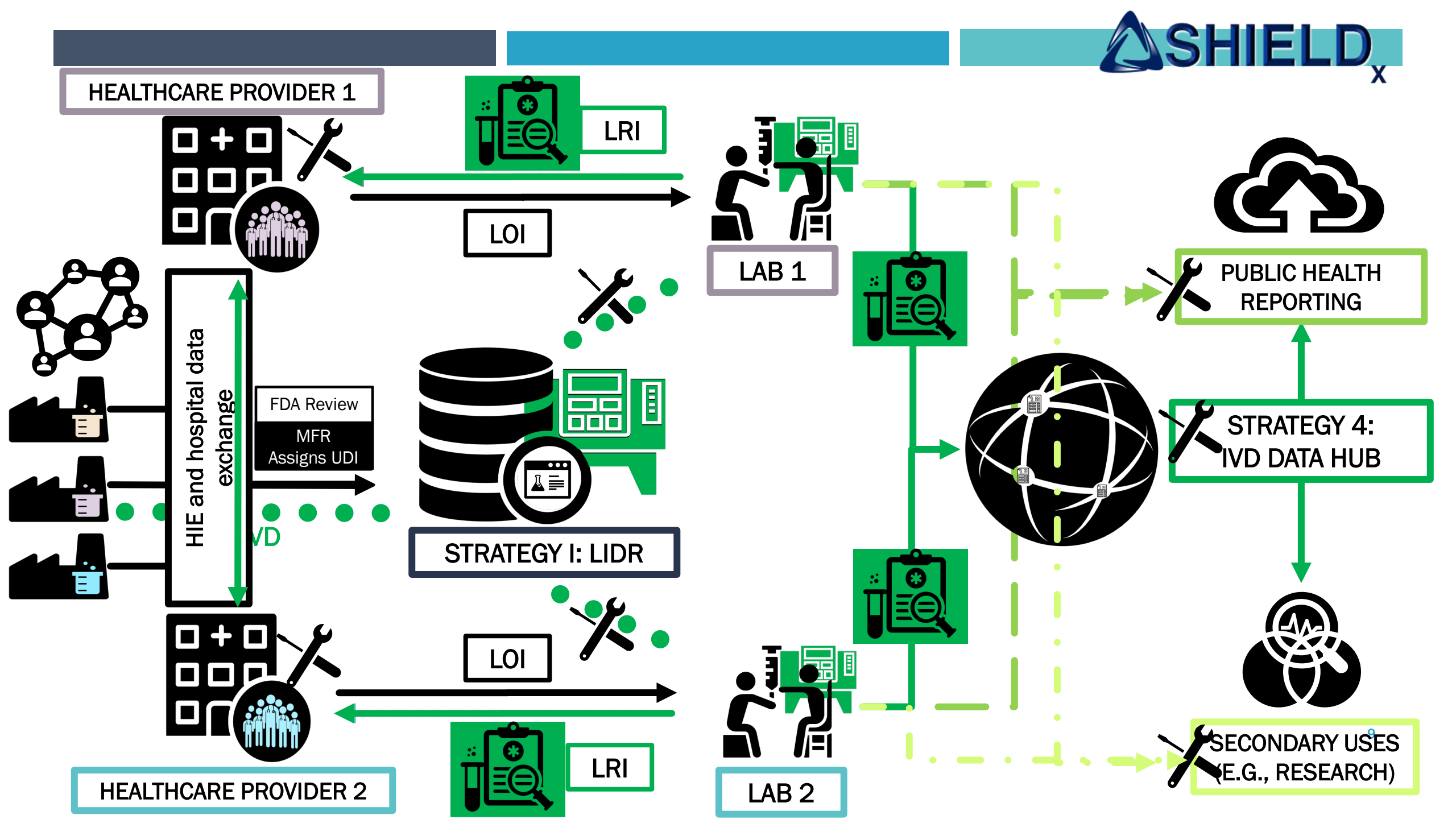
STAGE 1: DEVELOP TOOLS AND INFRASTRUCTURE

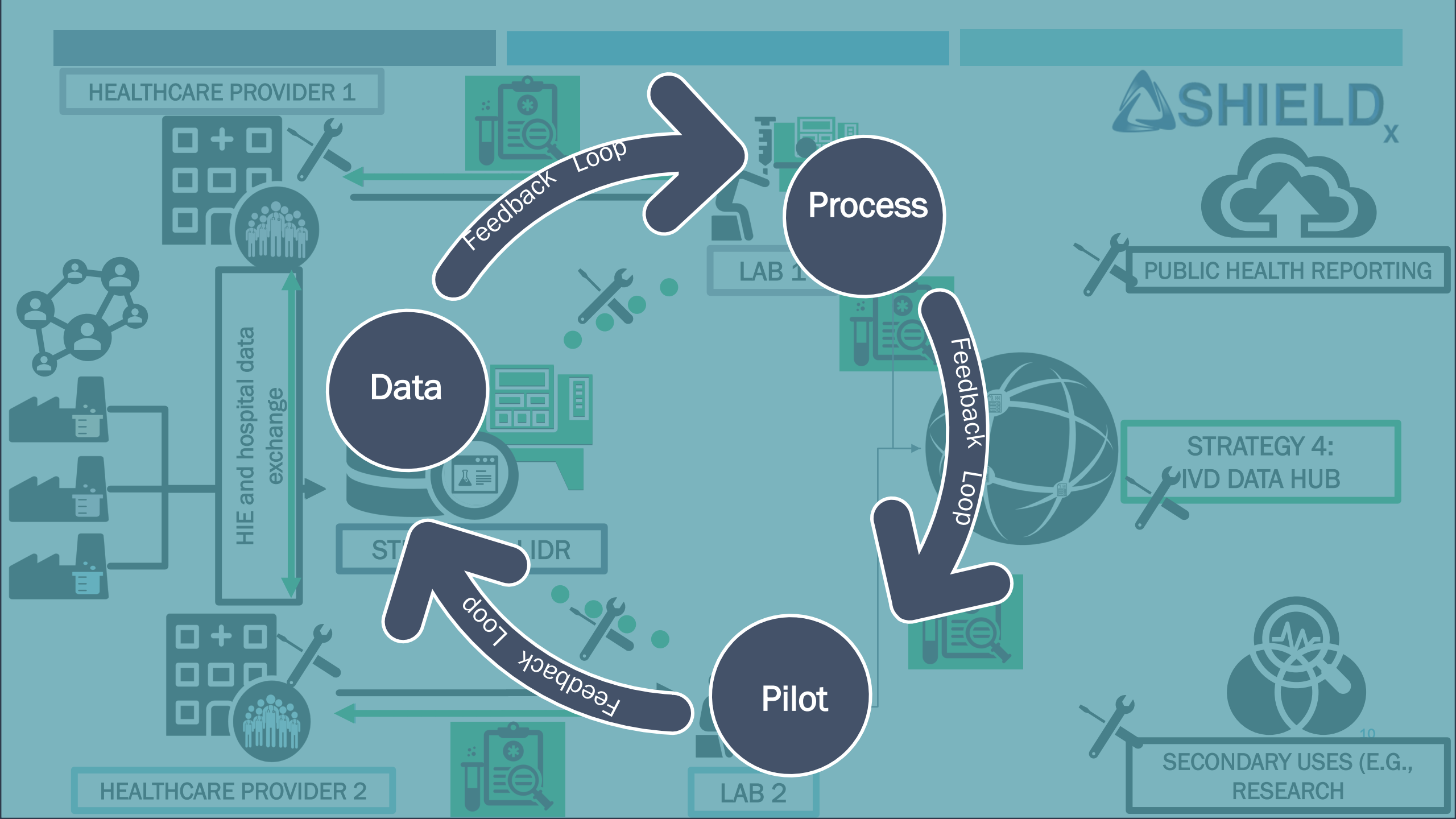
Creating a Functional, Sustainable Prototype: The Pilot

Strategy 1:	Strategy 2:	Strategy 3:	Strategy 4:
Establishing the Laboratory Interoperability Data Repository (LIDR) and related infrastructure	Ensure the flow of the knowledge throughout the healthcare system	Tooling and Knowledge Management	Creation of a National IVD Data Hub

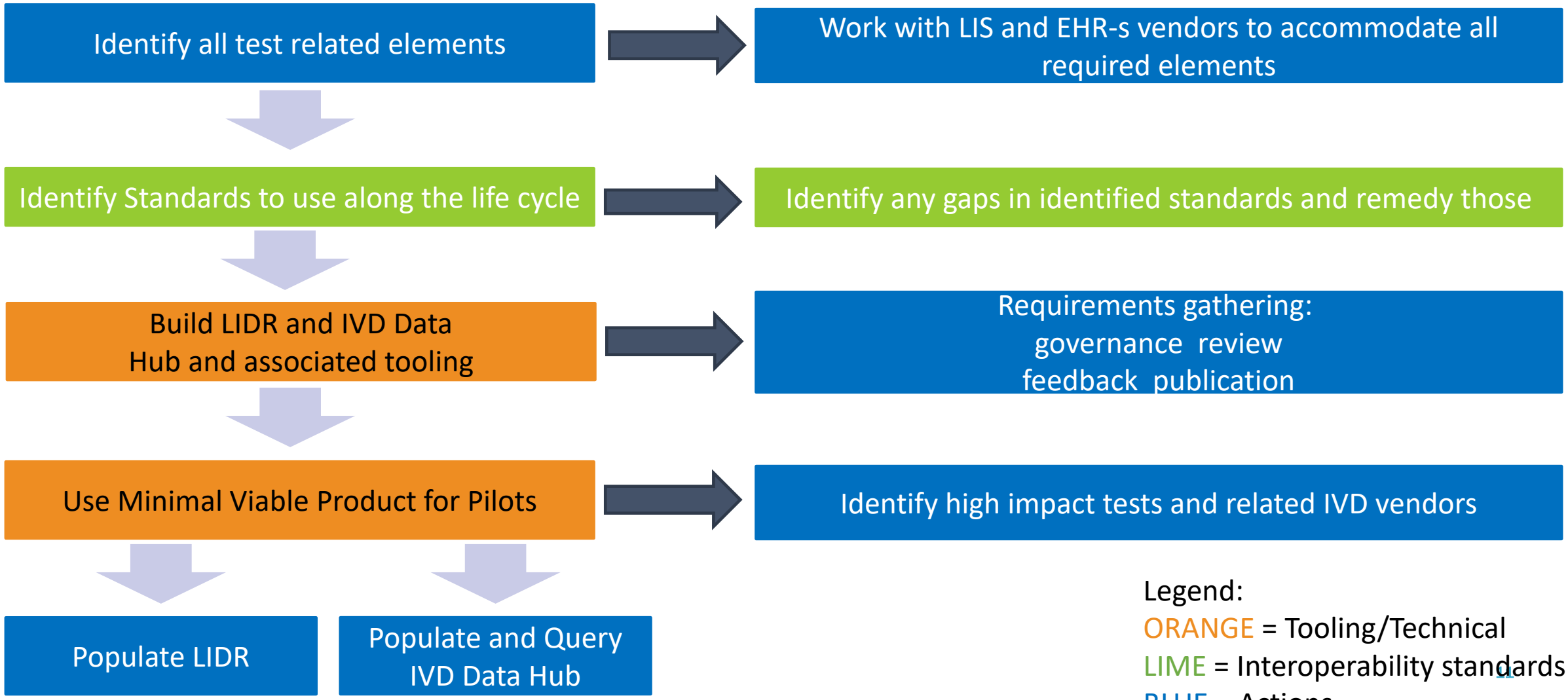
Cross Strategy Feedback Loops:

Data → Process → Pilot → Data → Process → Pilot → Data → Process → Pilot


HEALTHCARE PROVIDER 1
LRI
LOI
LAB 1
PUBLIC HEALTH REPORTING
HIE and hospital data exchange
FDA Review
MFR Assigns UDI
STRATEGY 4: IVD DATA HUB
STRATEGY I: LIDR
LOI
LRI
SECONDARY USES (E.G., RESEARCH)
HEALTHCARE PROVIDER 2
LAB 2


HEALTHCARE PROVIDER 1
HIE and hospital data exchange
Feedback Loop
Process
LAB 1
PUBLIC HEALTH REPORTING
Data
Feedback Loop
STRATEGY 4:
IVD DATA HUB
Feedback Loop
Pilot
HEALTHCARE PROVIDER 2
LAB 2
SECONDARY USES (E.G., RESEARCH

Action Steps for Pilot



Legend:
ORANGE = Tooling/Technical
LIME = Interoperability standards
BLUE = Actions

BUILDING GOVERNANCE FOR LONGEVITY

- Inclusion of ALL stakeholders:
  - Data creators:
    - Laboratorians (Clinical and Public Health Laboratories and professional societies)
    - IVD vendors
    - Laboratory Information and Electronic Health Record system vendors, middleware vendors
    - Standards Development Organizations
  - Data users:
    - Providers
    - Patients
    - Public Health (at the local, state and federal level)
    - Regulatory Agencies
    - Research community

NEXT STEPS FOR SHIELD

- Socialize SHIELD Strategic Plan
- Reorganize SHIELD
  - Update Committee structure to support implementation of the Strategic Plan
  - Create governance to oversee those components of SHIELD that need it (like LIDR)
  - Ensure continued participation of all stakeholders
- Identify funding sources for each component of SHIELD where needed

Q&A DISCUSSION

GLOSSARY OF TERMS/ACRONYMS

Abbreviation	Description
CDC	Centers for Disease Control and Prevention
CDISC	Clinical Data Interchange Standards Consortium
CMS	Centers for Medicare & Medicaid Services
EHR-s	Electronic Health Record system
EUA	Emergency Use Authorization
FHIR	Fast Healthcare Interoperability Resources
FDA	Food and Drug Administration
IICC	IVD Industry Connectivity Consortium
IVD	In vitro diagnostics
LAW	Laboratory Analytical Workflow Profile
LIDR	Laboratory Interoperability Data Repository

GLOSSARY OF TERMS/ACRONYMS

Abbreviation	Description
LIMS	Laboratory Information Management System
LIS	Laboratory Information System
LIVD	LOINC – IVD Test Code (LIVD) Mapping
LOINC	Logical Observation Identifiers Names and Codes
MVP	Minimum Viable Product
ONC	Office of the National Coordinator
RWD	Real-World Data (RWD) are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.
RWE	Real-World Evidence (RWE) is the clinical evidence regarding the usage and potential benefits, or risks of a medical product derived from analysis of RWD.
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
UDI	Unique Device Identifier