

SHIELD Strategic Plan
Systemic Harmonization and Interoperability
Enhancement for Laboratory Data
2021

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 through 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.*

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)

CURRENT STATE

HEALTHCARE PROVIDER 1

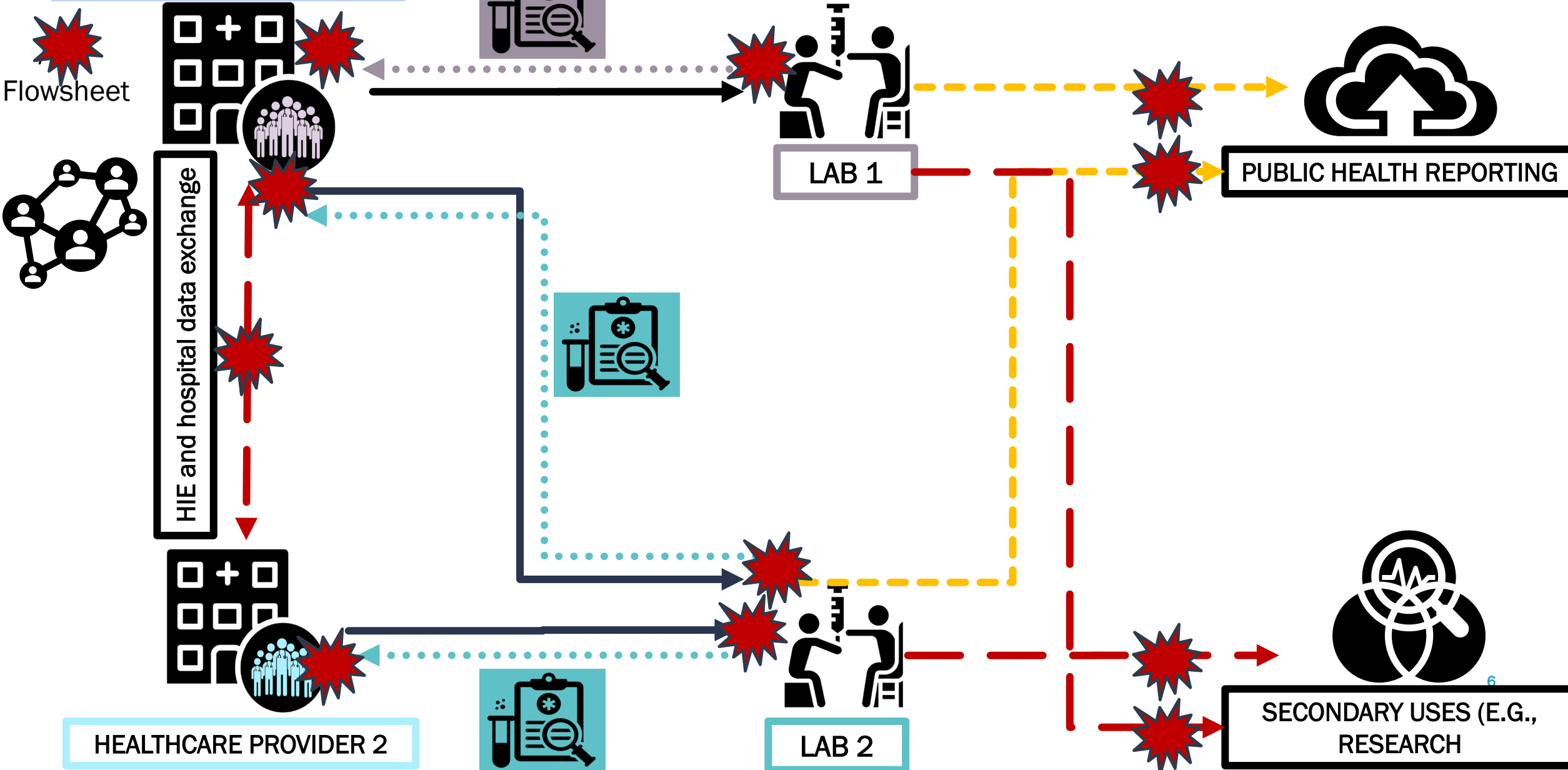
HEALTHCARE PROVIDER 2

LAB 1

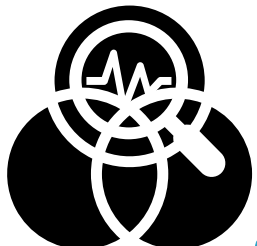
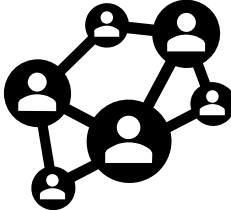
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PUBLIC HEALTH REPORTING

SECONDARY USES (E.G., RESEARCH)



Flowsheet



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:
Establishing the
Laboratory
Interoperability Data
Repository (LIDR)
and related
infrastructure

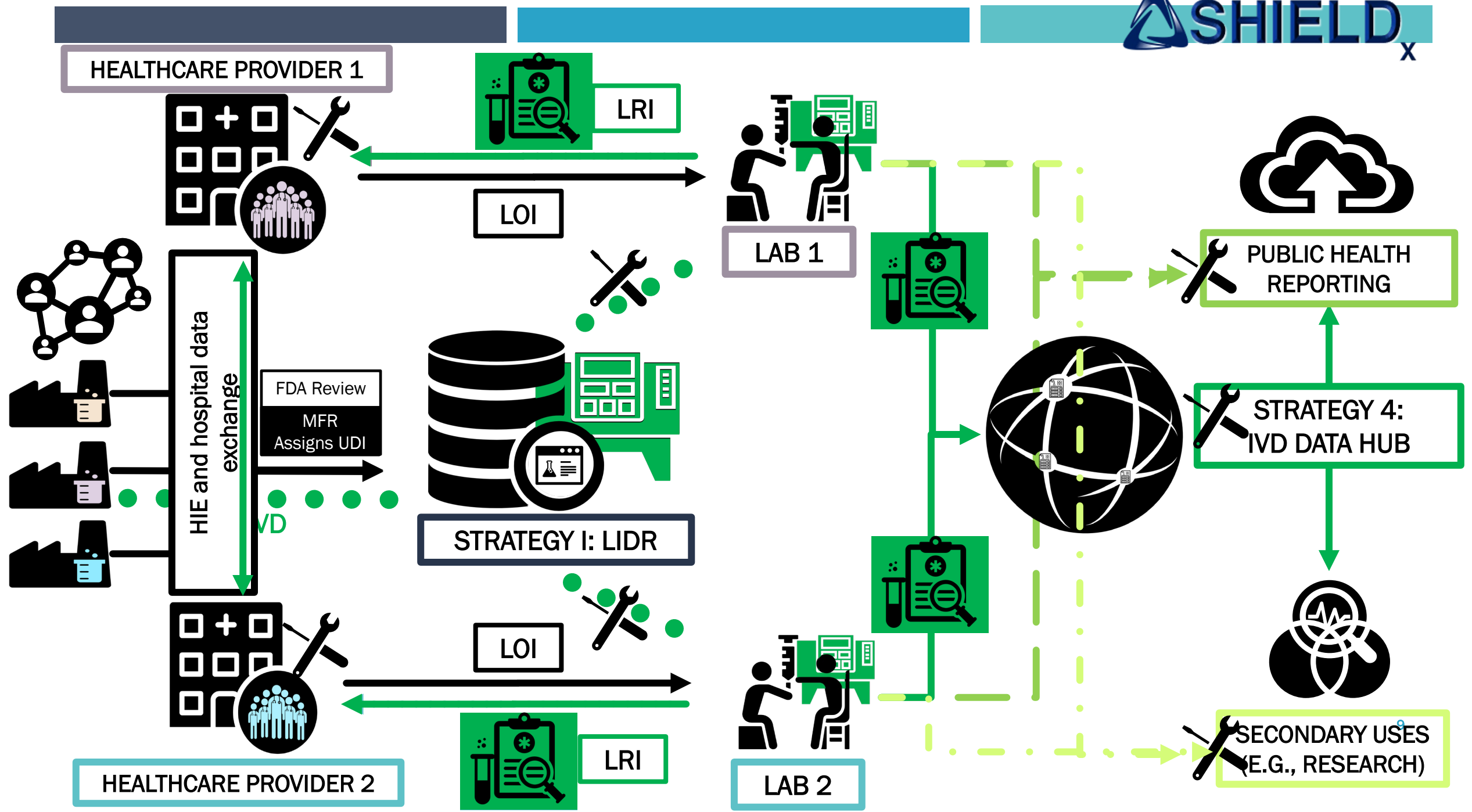
Strategy 2:
Ensure the flow of
the knowledge
throughout the
healthcare system

Strategy 3:
Tooling and
Knowledge
Management

Strategy 4:
Creation of a
National IVD Data
Hub

Cross Strategy Feedback Loops:

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



HEALTHCARE PROVIDER 1

SHIELD_x

Process

PUBLIC HEALTH REPORTING

Data

HIE and hospital data exchange

STRATEGY 4: IVD DATA HUB

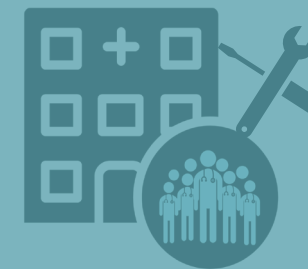
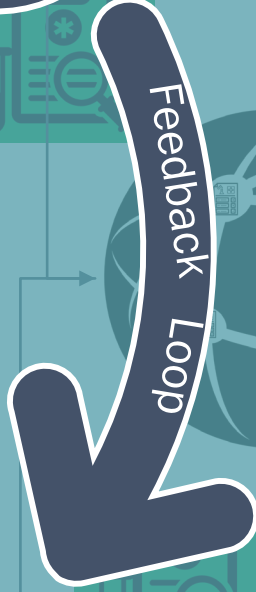
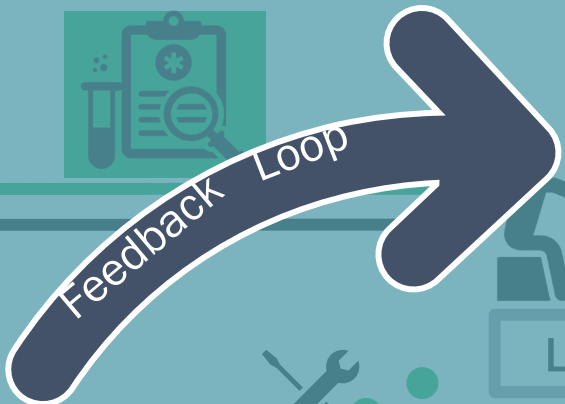
STANDARD

Pilot

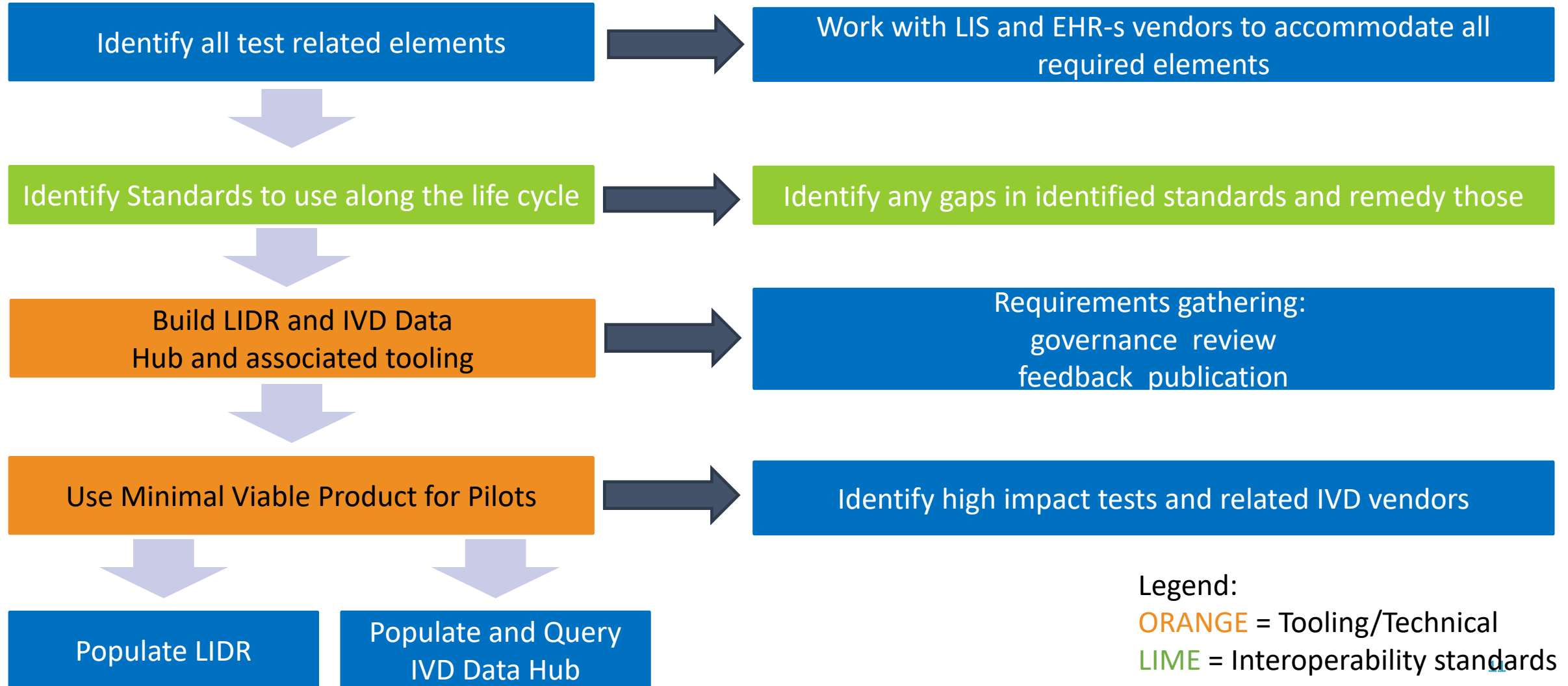
SECONDARY USES (E.G., RESEARCH)

HEALTHCARE PROVIDER 2

LAB 2



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

The background of the slide is a repeating pattern of light blue speech bubbles, each containing a dark blue question mark. The bubbles are scattered across the entire page. On the far left, there is a vertical dark blue bar. The text 'Q&A DISCUSSION' is centered in the middle of the page in a white, bold, sans-serif font.

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 |