The Office of the National Coordinator for Health Information Technology

ONC presentation to CLIAC

August 21th, 2013

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Agenda

- **Opening Remarks -** Doug Fridsma, MD, PhD Director, Office of Standards and Technology, ONC
- **The Standards & Interoperability Framework**
- **CLIAC Recommendations**
- **ONC Relevant activities**
  - **Laboratory Initiatives Overview**
  - **Usability Overview**
  - **Structured Data Capture**
  - **Data Access Framework**
  - **Lab Reporting Workgroup**
- **Questions & Answers**

Office of Science & Technology

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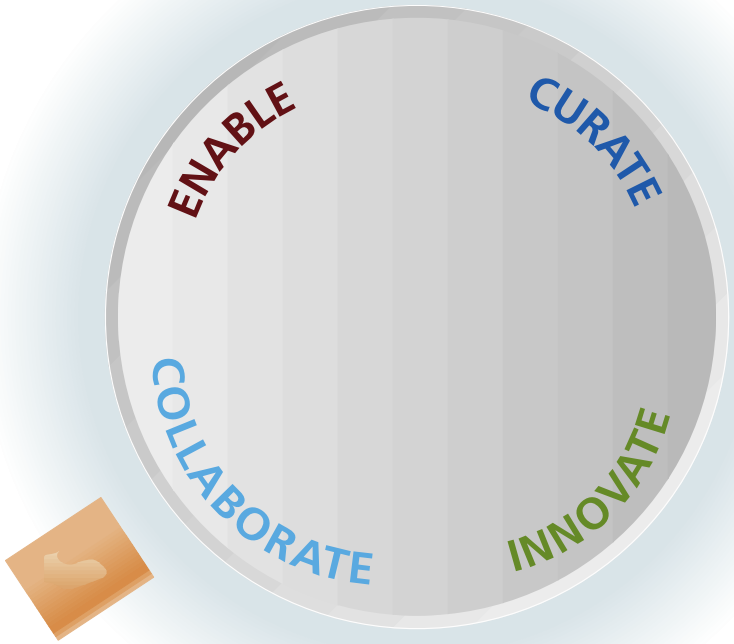
Enable stakeholders to come up with simple, shared solutions to common information exchange challenges

Collaborate with federal agencies to coordinate federal health IT priorities as manager of Federal Health Architecture

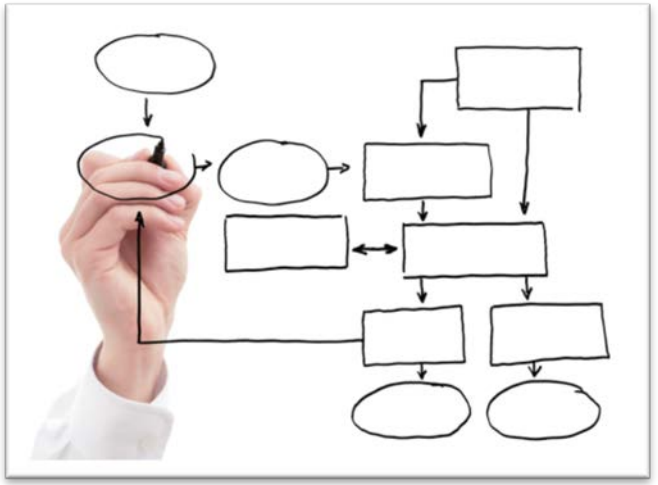


Curate a portfolio of standards, services, and policies that accelerate information exchange

Support Innovation through SHARP program, Innovation/Challenge Grants, and interfacing with International Standards community

ONC's Interoperability Strategy

- Leverage *government as a platform* for innovation to create conditions of interoperability
- Health information exchange is *not one-size-fits-all;* create a portfolio of solutions that support all uses and users
- Build in *incremental steps* – "don't let the perfect be the enemy of the good"



What is the S&I Framework?

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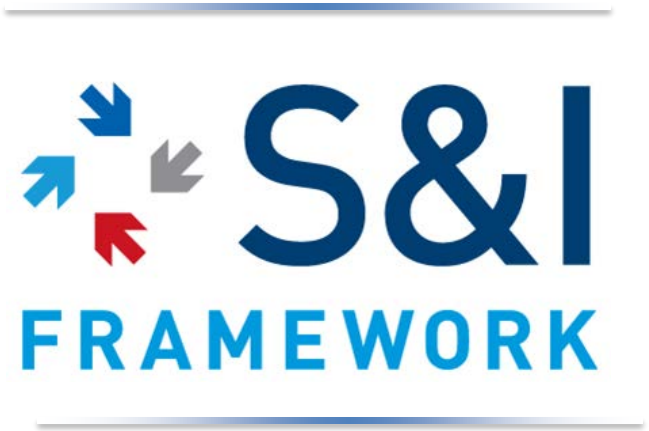
- The Standards and Interoperability (S&I) Framework represents one investment and approach adopted by the Office of Science & Technology (OST) to fulfill its charge of prescribing health IT standards and specifications to support national health outcomes and healthcare priorities.

- The S&I Framework is an example of "government as a platform"– enabled by integrated functions, processes, and tools – for the open community* of implementers and experts to work together to standardize.

** As of April 2013, 1100+ people had registered on the S&I Framework wiki, and 450+ people representing 300+ organizations had committed to the S&I Framework.*



S&I Framework Coordination

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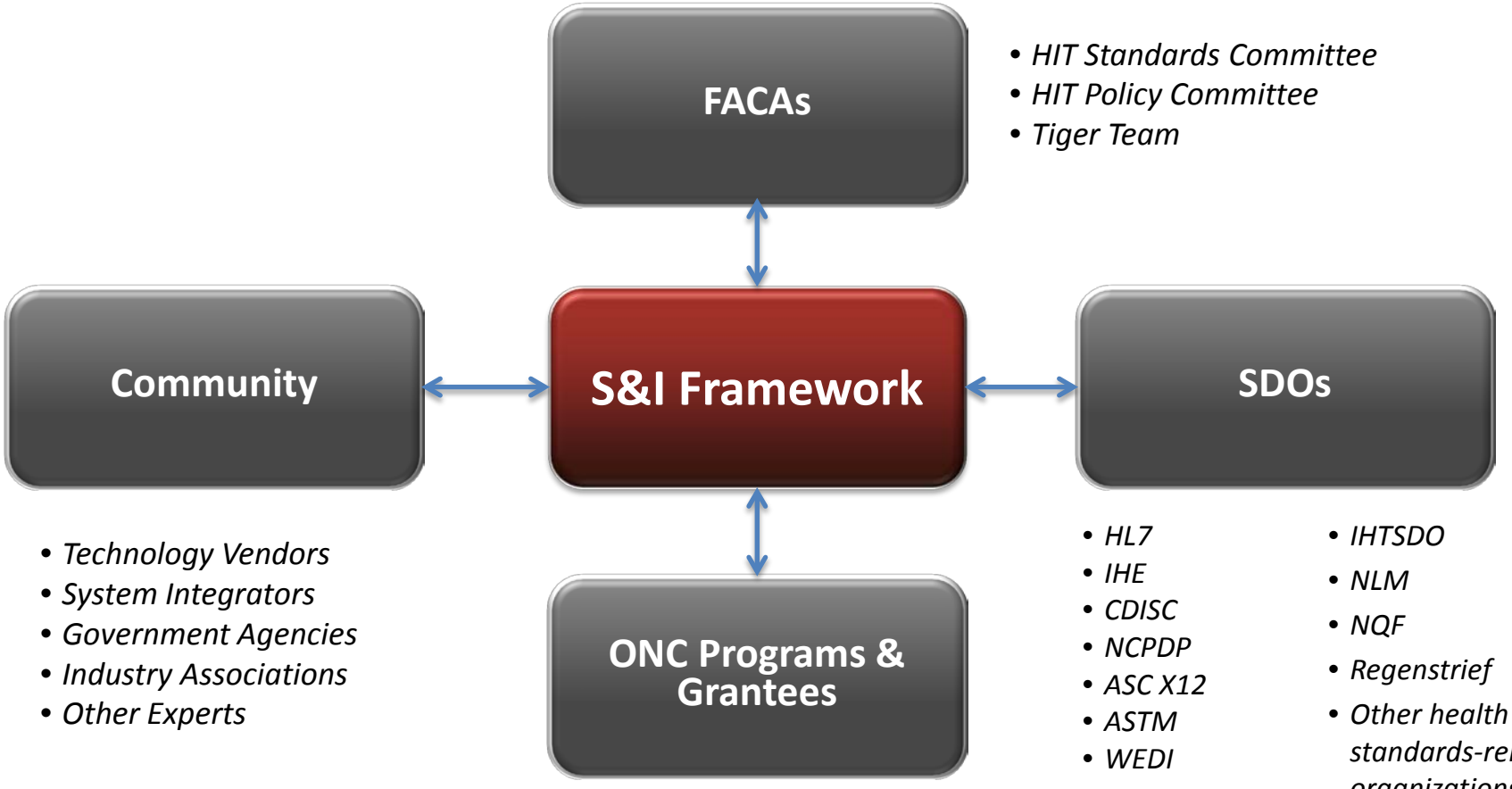

ONC Standards and Interoperability (S&I) Framework Lifecycle

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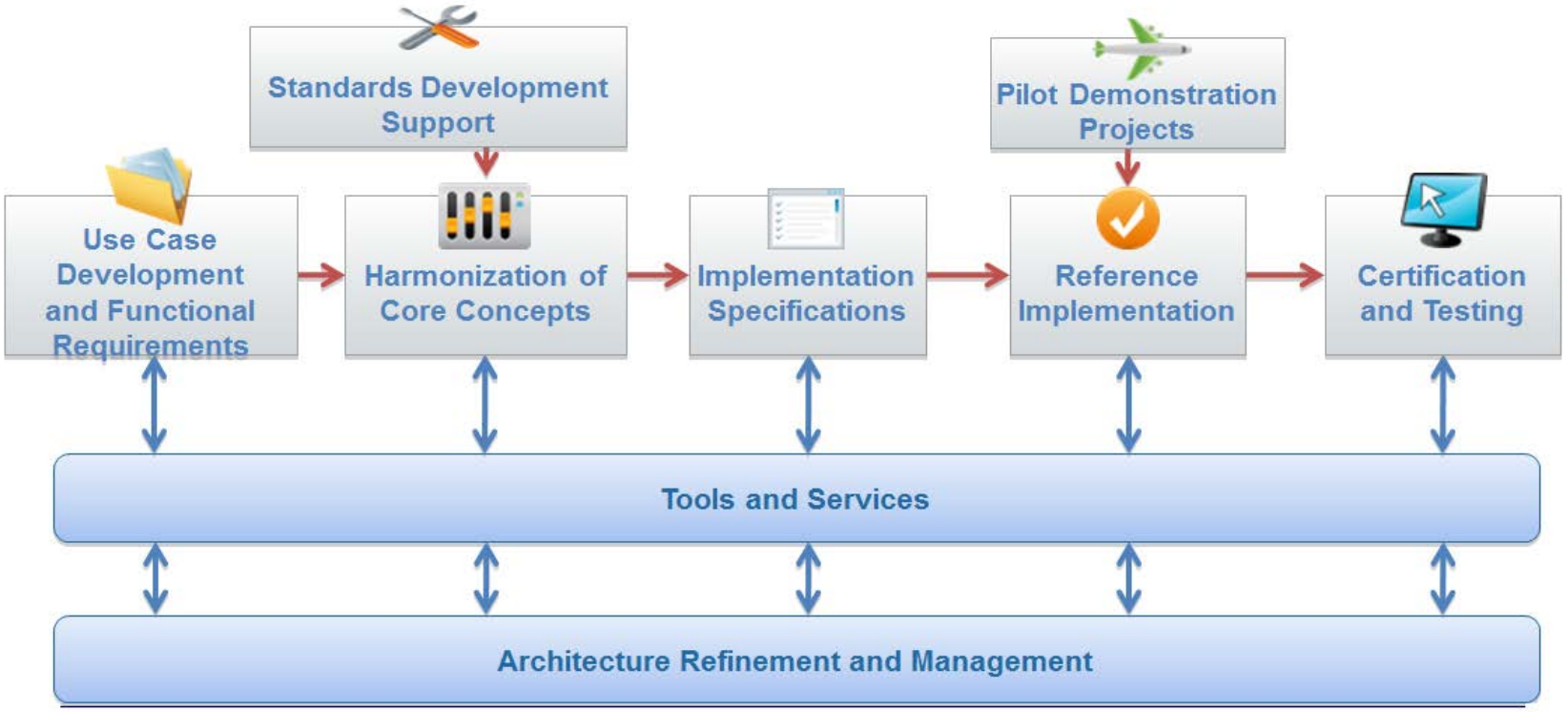
Our Missions

- Promote a sustainable ecosystem that drives increasing interoperability and standards adoption
- Create a collaborative, coordinated, incremental standards process that is led by the industry in solving real world problems
- Leverage "government as a platform" – provide tools, coordination, and harmonization that will support interested parties as they develop solutions to interoperability and standards adoption.



S&I Framework Operating Metrics

As of 7/3/2013

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Timing

Framework Launch Date	Jan 7, 2011
First Initiative Launch Date	Jan 31, 2011
Elapsed Time since Initiative Launch (as-of today)	30 months

Participation & Process

# Wiki Registrants	2358
# Committed Members	727
# Committed Organizations	556
# Working Sessions Held	1,630
S&I Face to Face meetings	3
Standards Organizations engaged	35
S&I Monthly Newsletter Editions	17
SDS Newsletter Subscribers	1,908

Outputs

# Consensus Approved Use Cases	18
# Pilots Committed	33
# Pilot Vendors	42
Total Ballots	11
# Total HL7 Ballot Comments Received	2,953
# HL7 Ballot Comments Resolved	2,882

S&I Framework Initiatives List

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Initiative (chronological)
Transitions of Care
Laboratory Results Interface
Provider Directories
Certificate Interoperability
Query Health
Data Segmentation for Privacy
Electronic Submission of Medical Documentation

Initiative (chronological)
Public Health Reporting (Community-led)
Longitudinal Coordination of Care
Lab Orders Interface
Health e-Decisions
Automate Blue Button
Structured Data Capture
Prescription Drug Management Program
Data Access Framework

Status Key:

- Active
- Maintenance
- On hold

S&I Initiative Portfolio Snapshot

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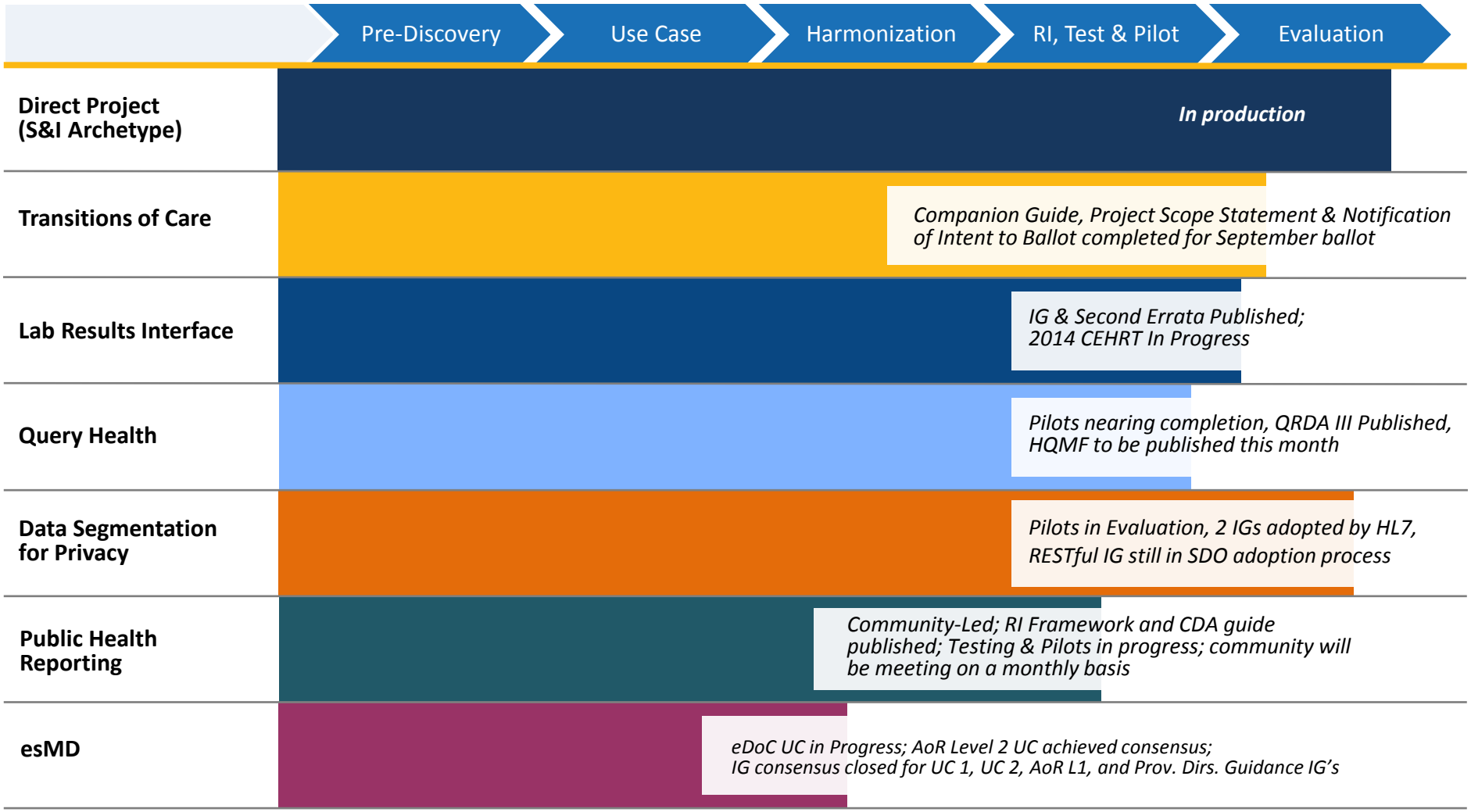

S&I Initiative Portfolio Snapshot, continued

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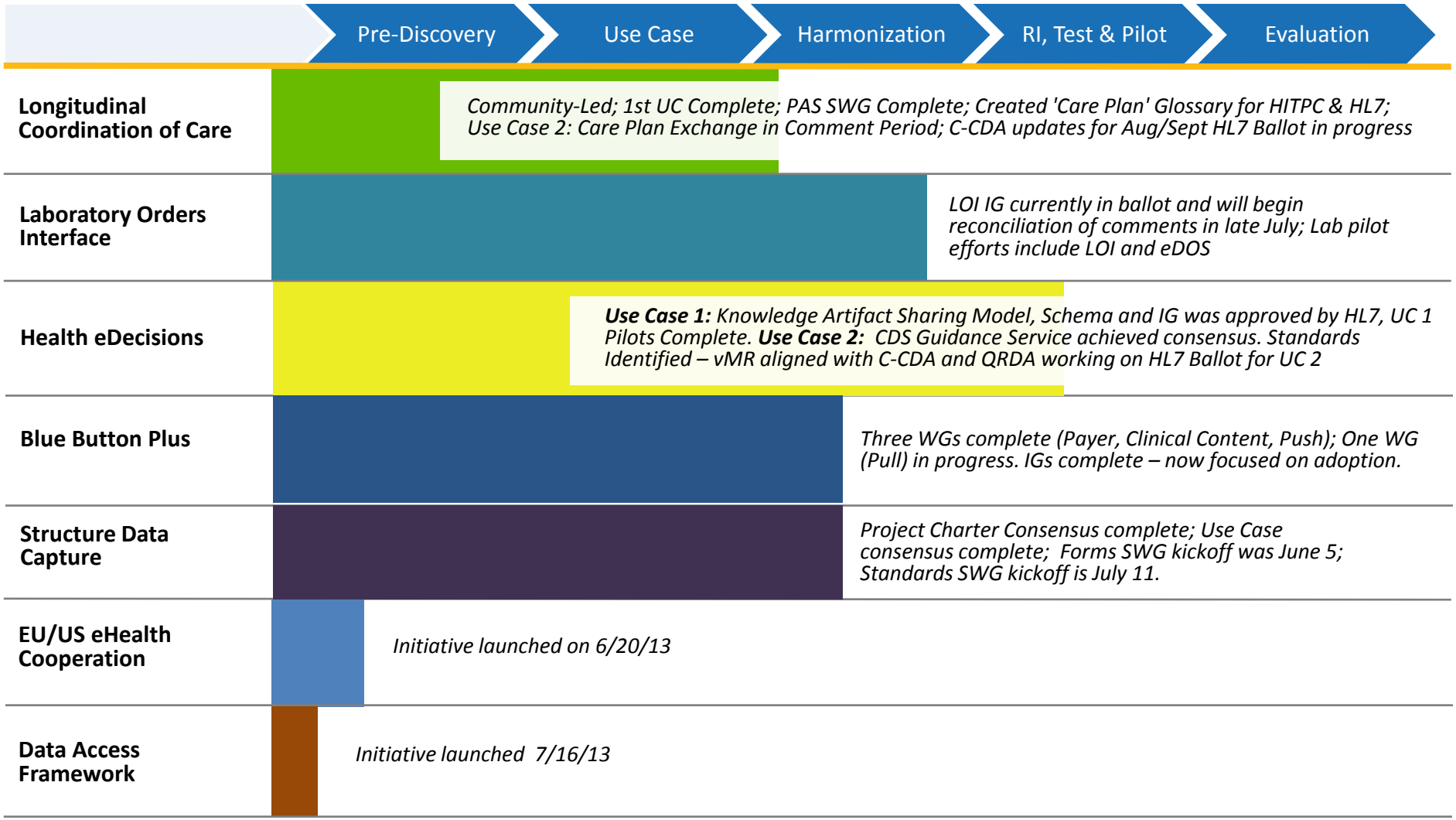

S&I Framework Pilots

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- S&I Pilots website indicates geographically where all pilots are located

CLIAC 2012 Recommendations

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- ***Recommendation, Part* 1: *Laboratory experts with experience in***
- *hospital, ambulatory or public health settings should be members of key*
- *Office of the National Coordinator (ONC) advisory committees and*
- *other agency groups that* are *setting standards and policies for*
- *laboratory information in electronic health records.*

- ***Recommendation, Part* 2:** *Provider usability* is *an important strategy*
- *for mitigation of these patient safety risks. Further work in this area*
- *should be supported.*

- ***Recommendation, Part* 3:** A *national system for reporting EHR*
- *laboratory related safety events and near* misses *should be established*
- *to clearly define their prevalence, understand the underlying* causes
- *and stimulate the design of broad-based solutions.*

- ***Recommendation, Part* 4:** A *catalogue of various solutions for*
- *laboratory data should be created using work that has already been*
- *done and considering areas of expertise [e.g., human factors] that may*
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Laboratory Results Interface - LRI

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- **Mission:** To address the challenges of laboratory reporting to ambulatory primary care providers. Primarily driven by the needs of internal medicine, family practice and pediatrics, but may also be leveraged by other providers and settings.

- **Summary of Accomplishments**: The Laboratory Results Interface Initiative analyzed two identified HL7 implementation guides that were under consideration for the Lab Reporting Interface specification, and evaluated the content of the guides against the Lab Reporting Interface Use Case Requirements. This enabled the Workgroup to write an Lab Results Implementation Guide that was submitted and balloted through HL7.

- **Main Deliverable(s):**

  HL7 Version 2.5.1 Implementation Guide :Laboratory Results Interface for US Realm, Release 1 - The Laboratory Results Interface implementation guidance for electronic reporting of laboratory test results to ambulatory care providers in the US Realm.

Laboratory Orders Interface - LOI

- **Mission:** The Laboratory Orders Interface Initiative is focused on the creation of an Implementation Guide (IG) for the ambulatory setting that builds on the architecture and design of the California HealthCare Foundation's (CHCF) EHR-Lab Interoperability and Connectivity Specification (ELINCS) Laboratory Orders and the Health Level Seven (HL7) Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 - US Realm (July 2012)(LRI IG).

- **Summary of Accomplishments**: The Laboratory Orders Initiative has developed an IG that, when broadly adopted by clinical laboratories and ambulatory EHR systems, will obviate the requirement to define a new specification each time an EHR system-LIS orders interface is implemented.

- **Main Deliverables:** *HL7 V 2.5.1 Implementation Guide: S&I Framework Lab Orders Interface, Release 1 – US Realm DSTU* - The Laboratory Orders Interface implementation guidance for electronic ordering of laboratory tests in the US Realm.

Laboratory Orders Interface - eDOS

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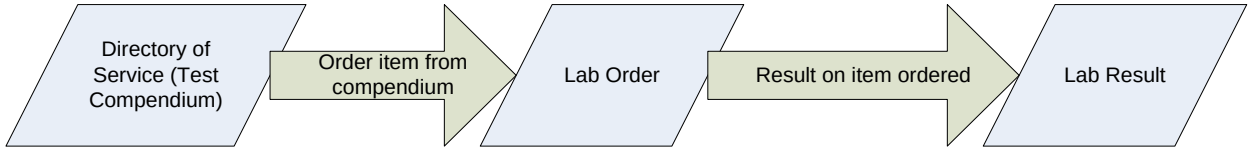
Mission: The eDOS sub workgroup is focused in providing an electronic interchange of a laboratory's Directory of Services (DOS) in a structured format. This implementation guide, is intended to provide all necessary information to help an Ordering Provider properly request laboratory tests consistent to aide patient diagnosis.

The eDOS work effort will:

- Validate that the current Informative Implementation Guide meets the objective through a pilot of eDOS
- Align the IG with the in-scope tests in the Lab Result Interface (LRI) IG



Status of Laboratory IGs

- **HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 – US Realm (LRI IG)**
  - *Published July 2012, In MU 2014 Edition*

- **HL7 Version 2.5.1 Implementation Guide: Laboratory Orders Interface for US Realm, Release 1 – US Realm (LOI IG)**
  - *2nd ballot reconciliation is in progress now*
  - *Target to publish this fall*

- **HL7 Version 2 Implementation Guide: Laboratory Test Compendium Framework, Release 2 – US Realm (eDOS IG)**
  - *1st ballot reconciliation is in progress now*
  - *Target to publish this fall w/LOI*

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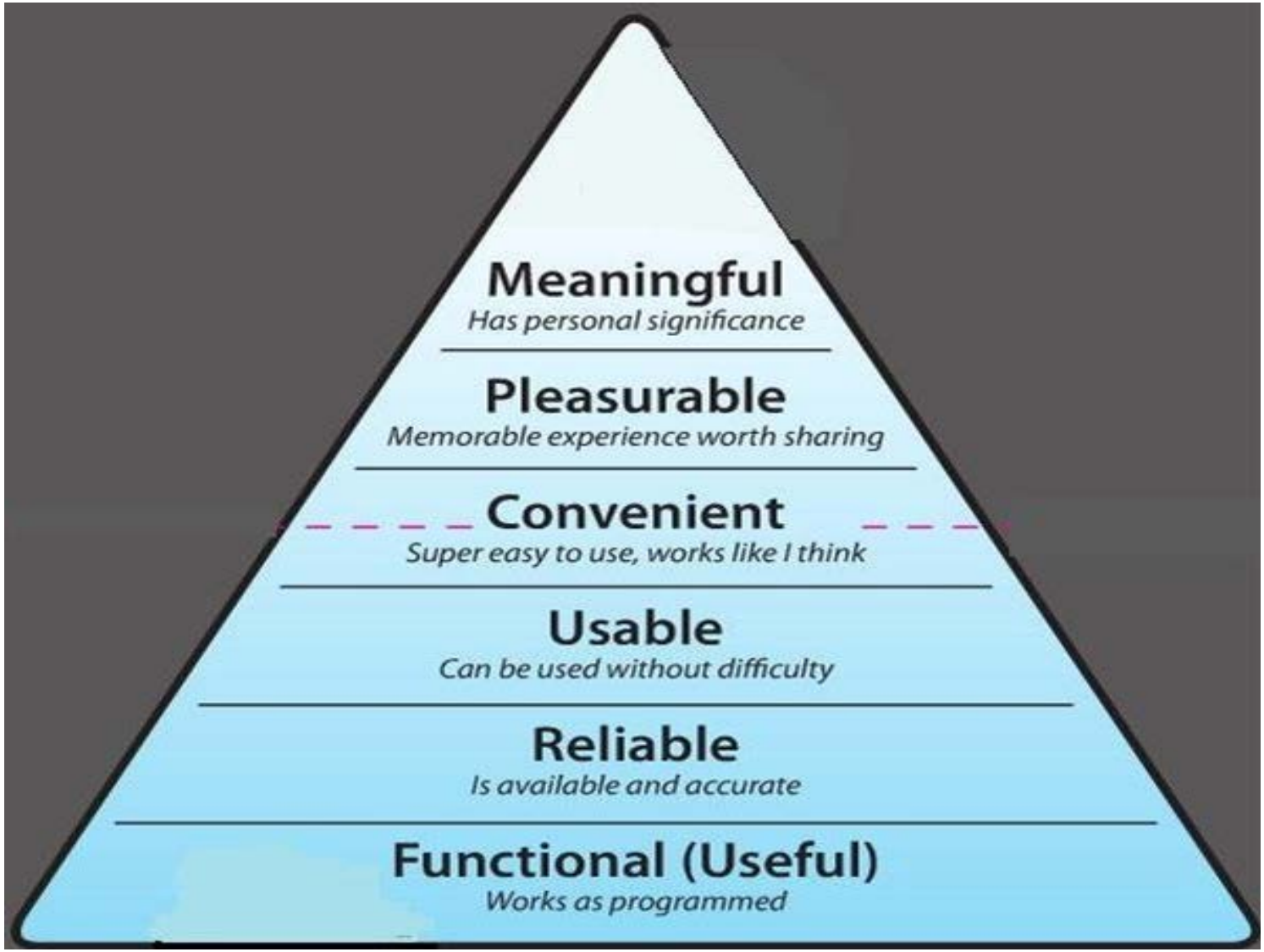
Usability / User Experience

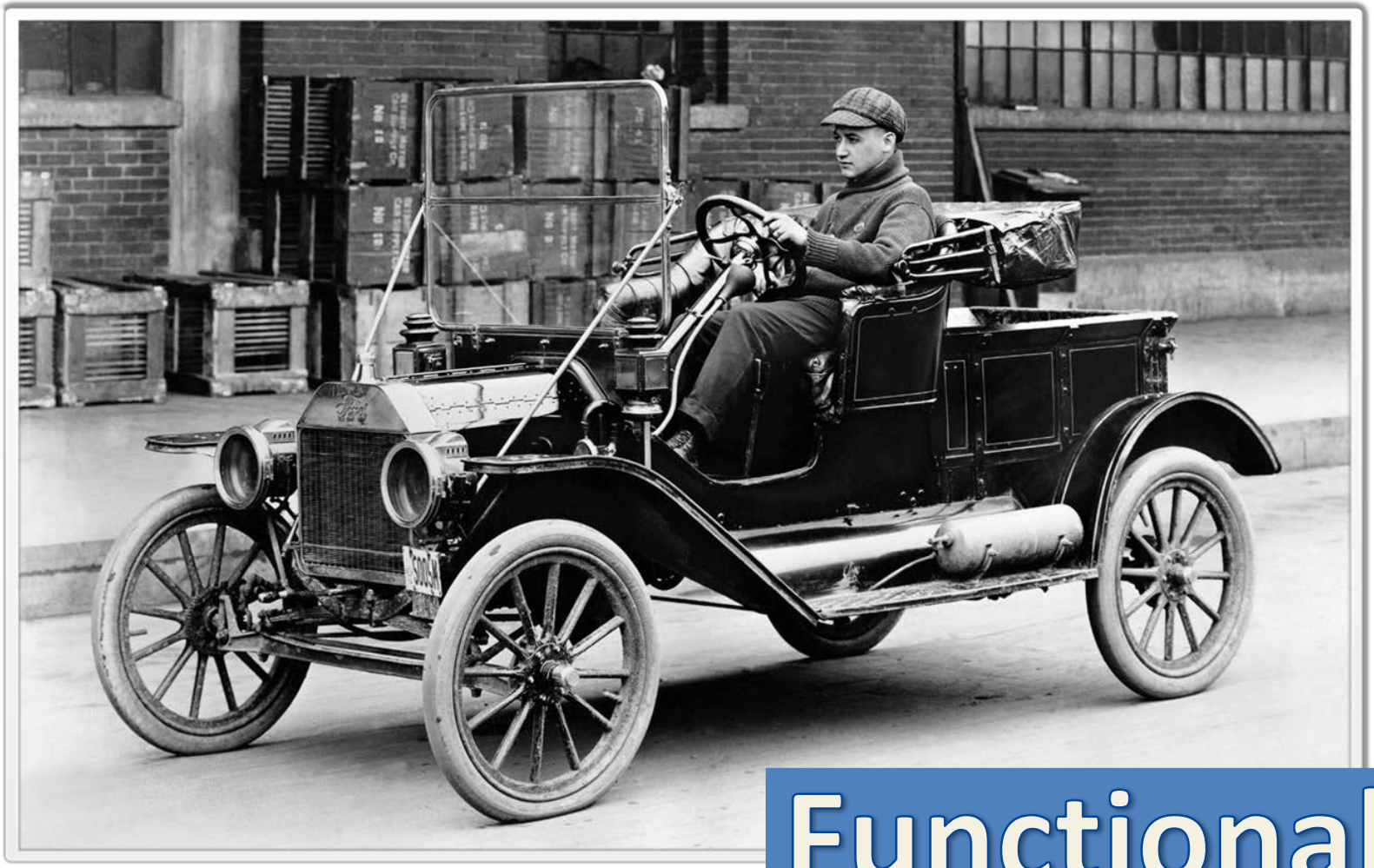
Key points:

- Usability is one component of a continuum of user experience
- Usable products are safe
- Safety is important
- Therefore usability is important

Usability / User Experience



Usability / User Experience



Functional

Usability / User Experience

Reliable

Usability / User Experience

Usability / User Experience

Convenient

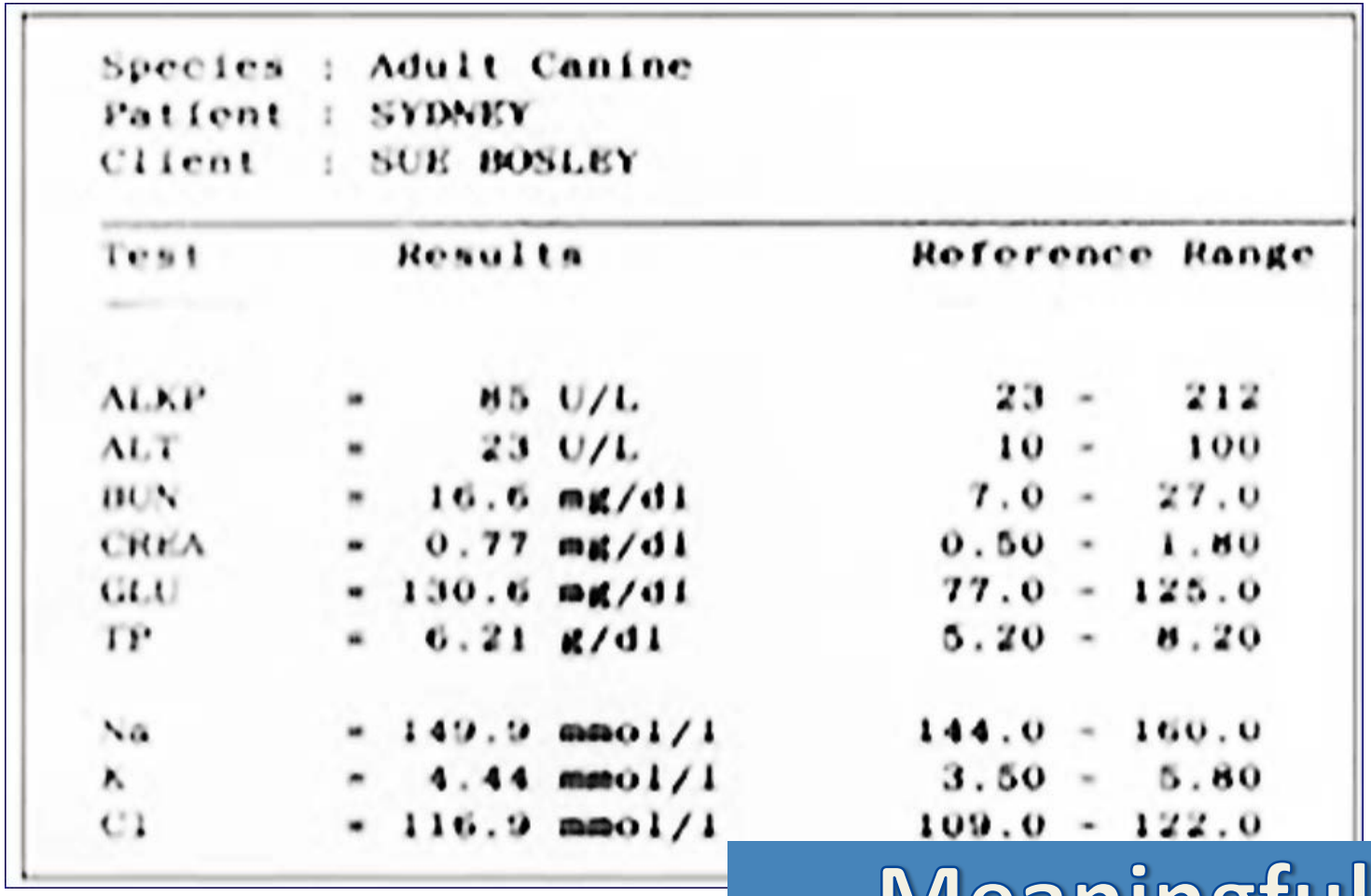
Usability / User Experience

Pleasurable

Usability / User Experience

Meaningful

Usability / User Experience



Species : Adult Canine
Patient : SYDNEY
Client : SUE BOSLEY

Test		Results		Reference Range		
ALKP	=	85	U/L	23	-	212
ALT	=	23	U/L	10	-	100
BUN	=	16.6	mg/dl	7.0	-	27.0
CREA	=	0.77	mg/dl	0.50	-	1.80
GLU	=	130.6	mg/dl	77.0	-	125.0
TP	=	6.21	g/dl	5.20	-	8.20
Na	=	149.9	mmol/l	144.0	-	160.0
K	=	4.44	mmol/l	3.50	-	5.80
Cl	=	116.9	mmol/l	109.0	-	122.0

Meaningful

Usability / User Experience

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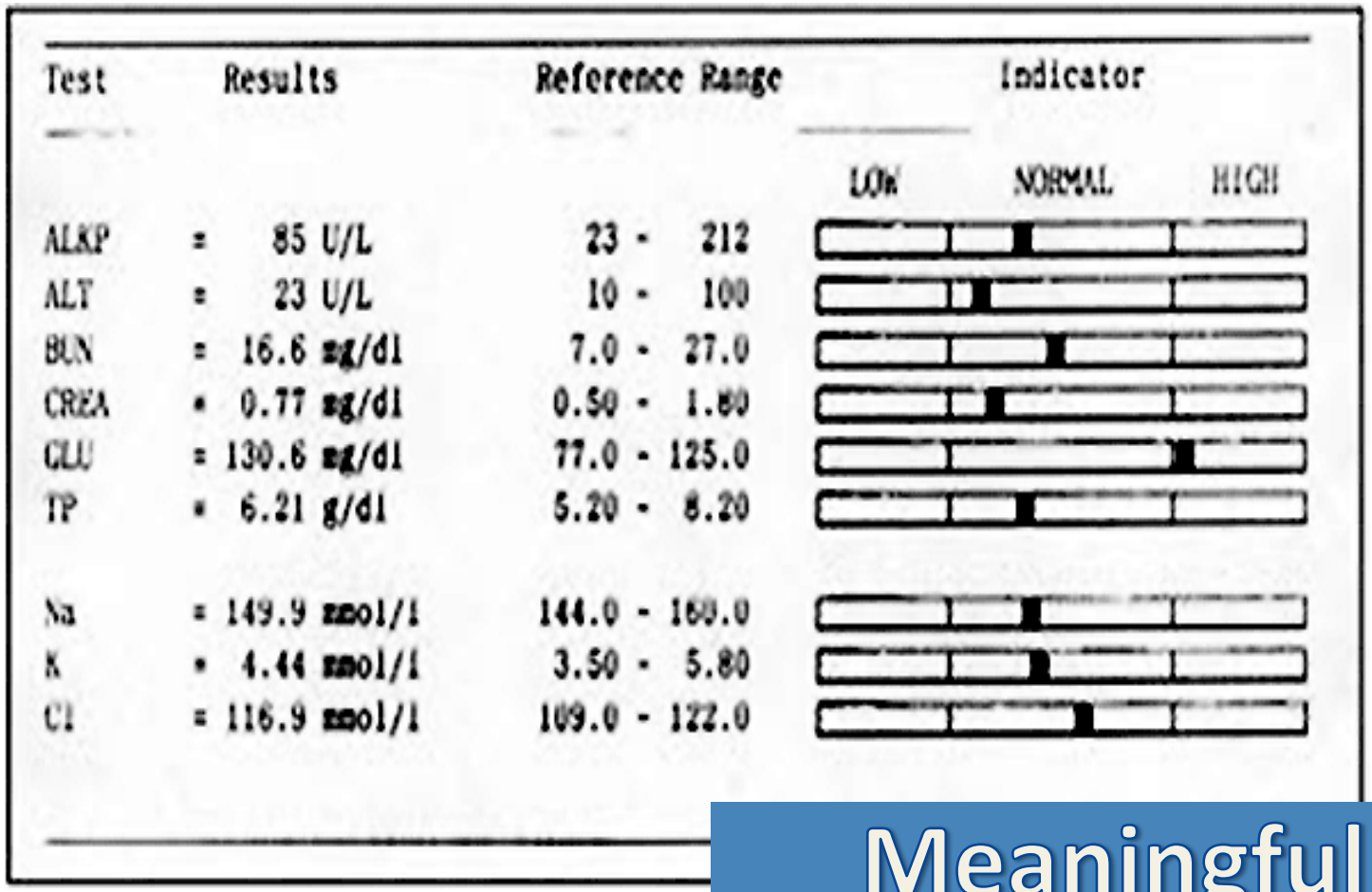

Test	Results	Reference Range	Indicator
			LOW NORMAL HIGH
ALKP	= 85 U/L	23 - 212	
ALT	= 23 U/L	10 - 100	
BUN	= 16.6 mg/dl	7.0 - 27.0	
CREA	= 0.77 mg/dl	0.50 - 1.80	
GLU	= 130.6 mg/dl	77.0 - 125.0	
TP	= 6.21 g/dl	5.20 - 8.20	
Na	= 149.9 mmol/l	144.0 - 160.0	
K	= 4.44 mmol/l	3.50 - 5.80	
Cl	= 116.9 mmol/l	109.0 - 122.0	

Meaningful

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Structured Data Capture (SDC)

- One of 10 active Initiatives under the ONC S&I Framework
- Launched on January 23, 2013 in partnership with NIH NLM and AHRQ
- Key area of focus is enabling the collection of structured data within EHRs to supplement data collected for other purposes specific to:
  - Clinical research (Patient Centered Outcomes Research/ Comparative Effectiveness Research) (NLM FOCUS)
  - Patient safety event reporting (AHRQ FOCUS)

Data Access Framework - DAF

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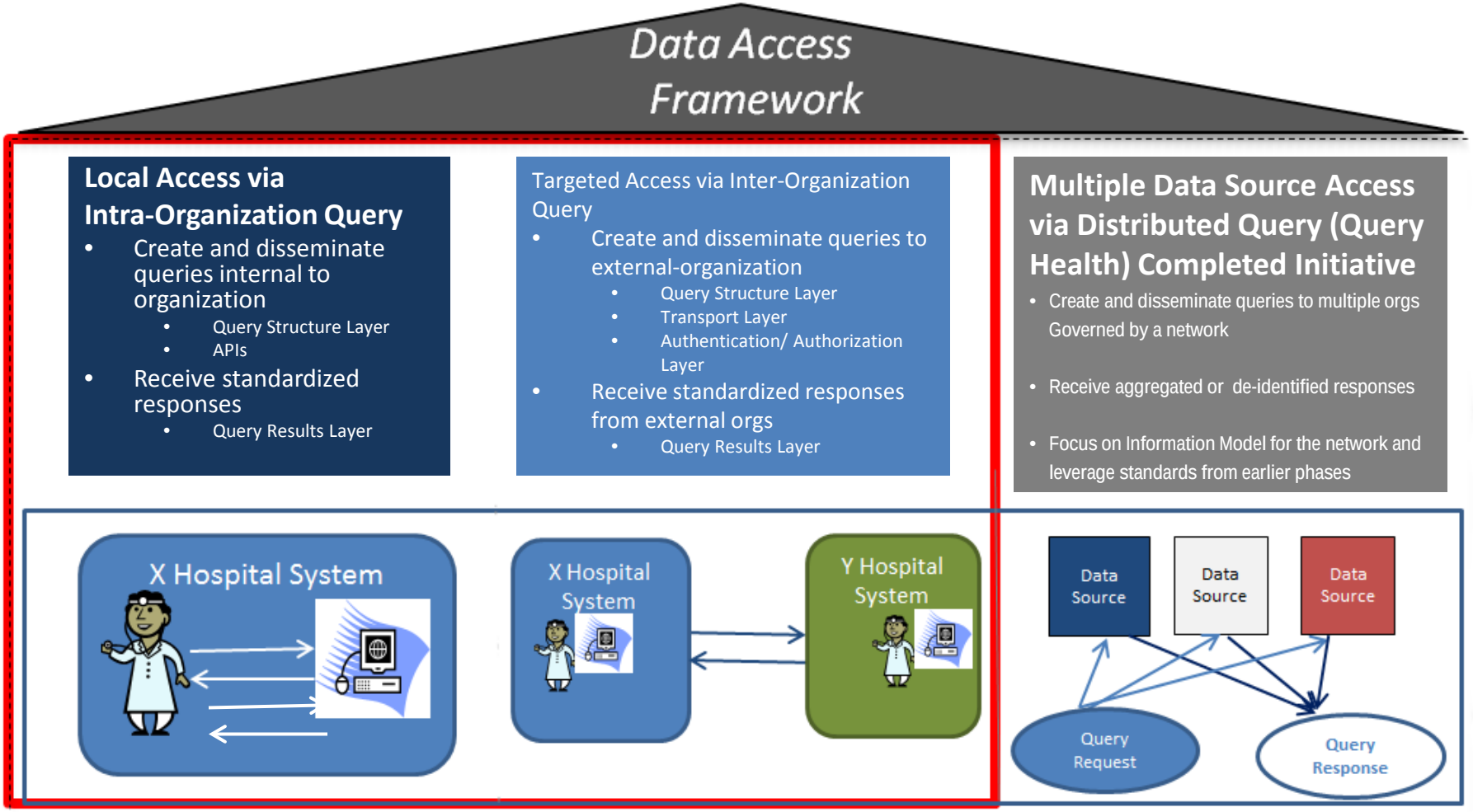

Data Access Framework - DAF

- One of 10 active Initiatives under the ONC S&I Framework
- Launched on July 16th
- Key areas of focus are:
  - Identifying standardized API's that allow applications to query data in a consistent manner across EHRs.
  - Empowering providers to manage their patients effectively across care settings by accessing the appropriate data required for treatment and care transitions.
  - Allowing innovative applications outside of the EHR to provide value added functions to improve patient care by accessing EHR data within an organization.
  - Establish the incremental path that builds the necessary infrastructure to scale data access nationally.

CLIAC 2012 Recommendations

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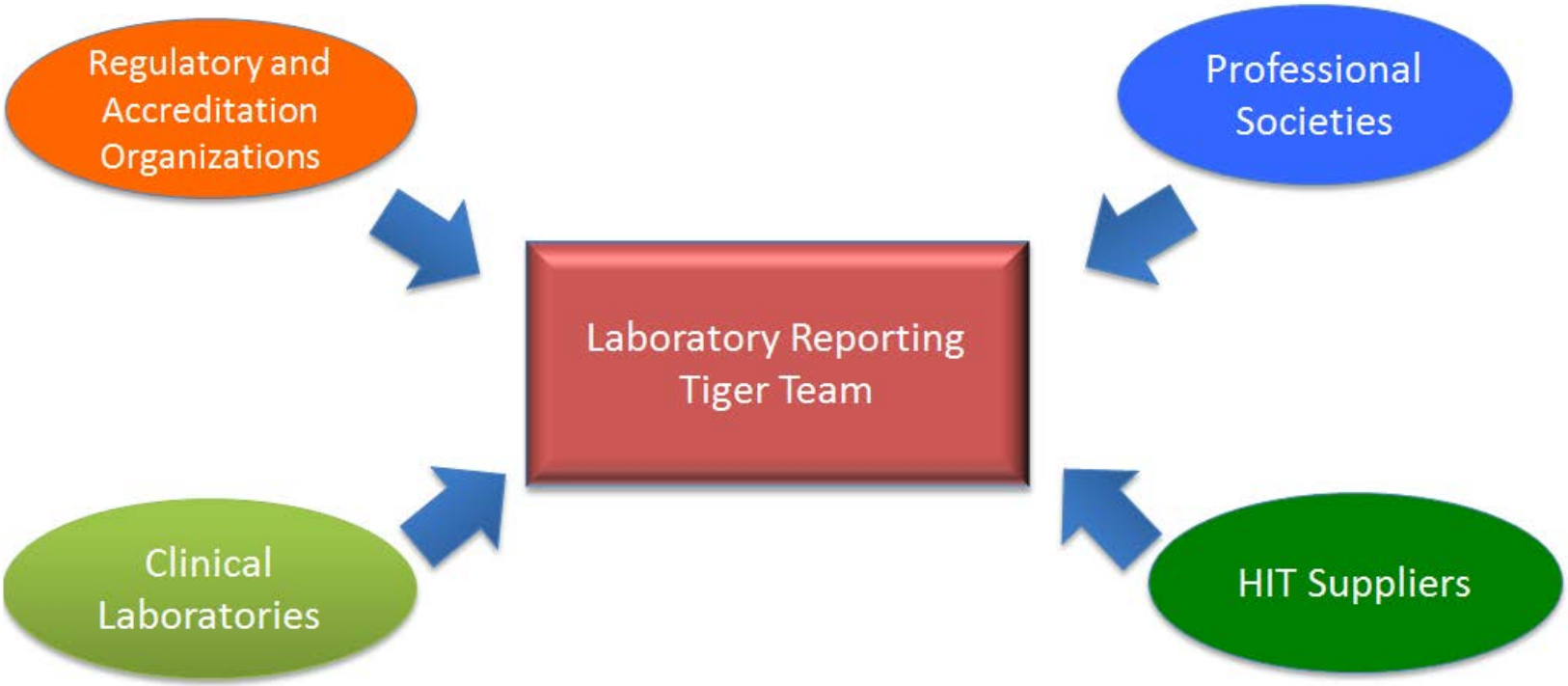
Laboratory Reporting Tiger Team



- CLIAC and its member's professional organizations are represented multiple times (CLIA CDC CAP API)
- At least 6 Pathologists are in regular attendance

Summary and Thanks

- ONC appreciates the thoughtful recommendations
- There are multiple workstreams underway operationalizing recommendations
- We've employed broad Industry, clinical and regulatory involvement
- We appreciate the help to-date
- We count on your continued involvement and engagement

- Questions & Answers