Targeting PHIN Compliance through a COTS Package: A Case Study

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2nd Annual PHIN Stakeholder's Conference

May 27, 2004

"Mr. Osborne, may I be excused? My brain is full."

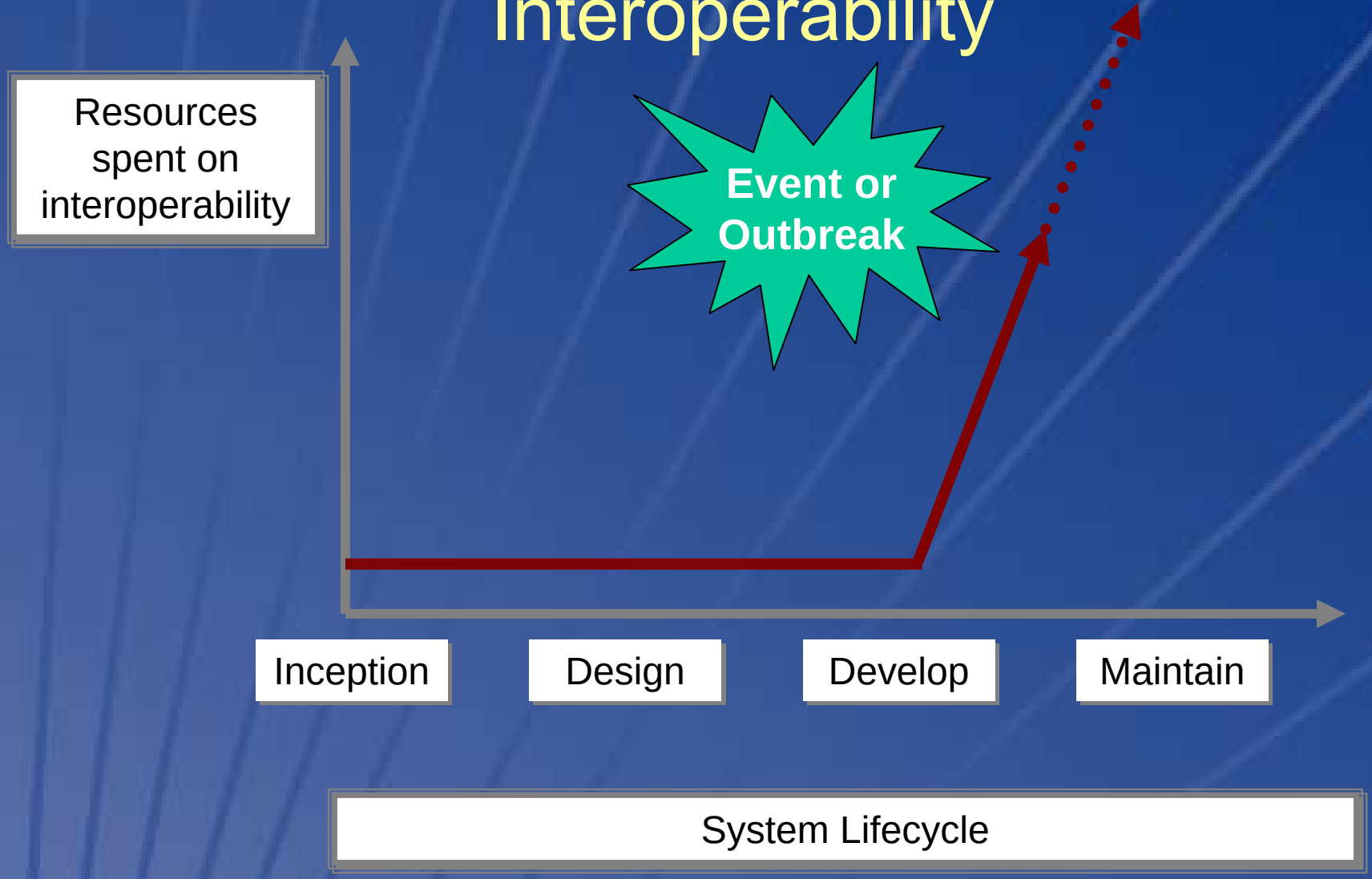
Agenda

- The CHALLENGE
- Our Approach
- STARLIMS and PHIN
- Our Challenges

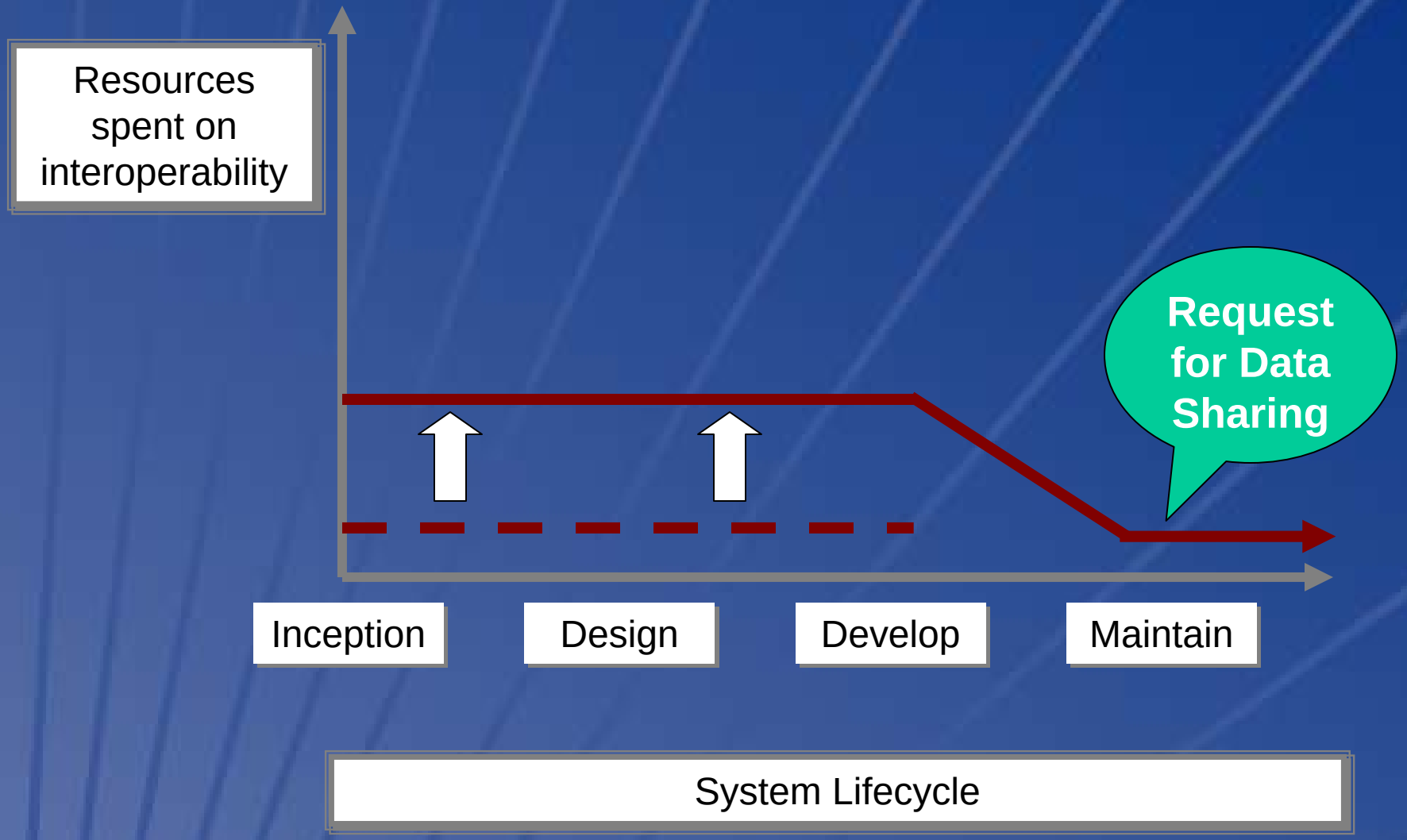
Our Standard Approach to Interoperability

Concept borrowed from presentation by Uwe Reinhardt 5/24/04

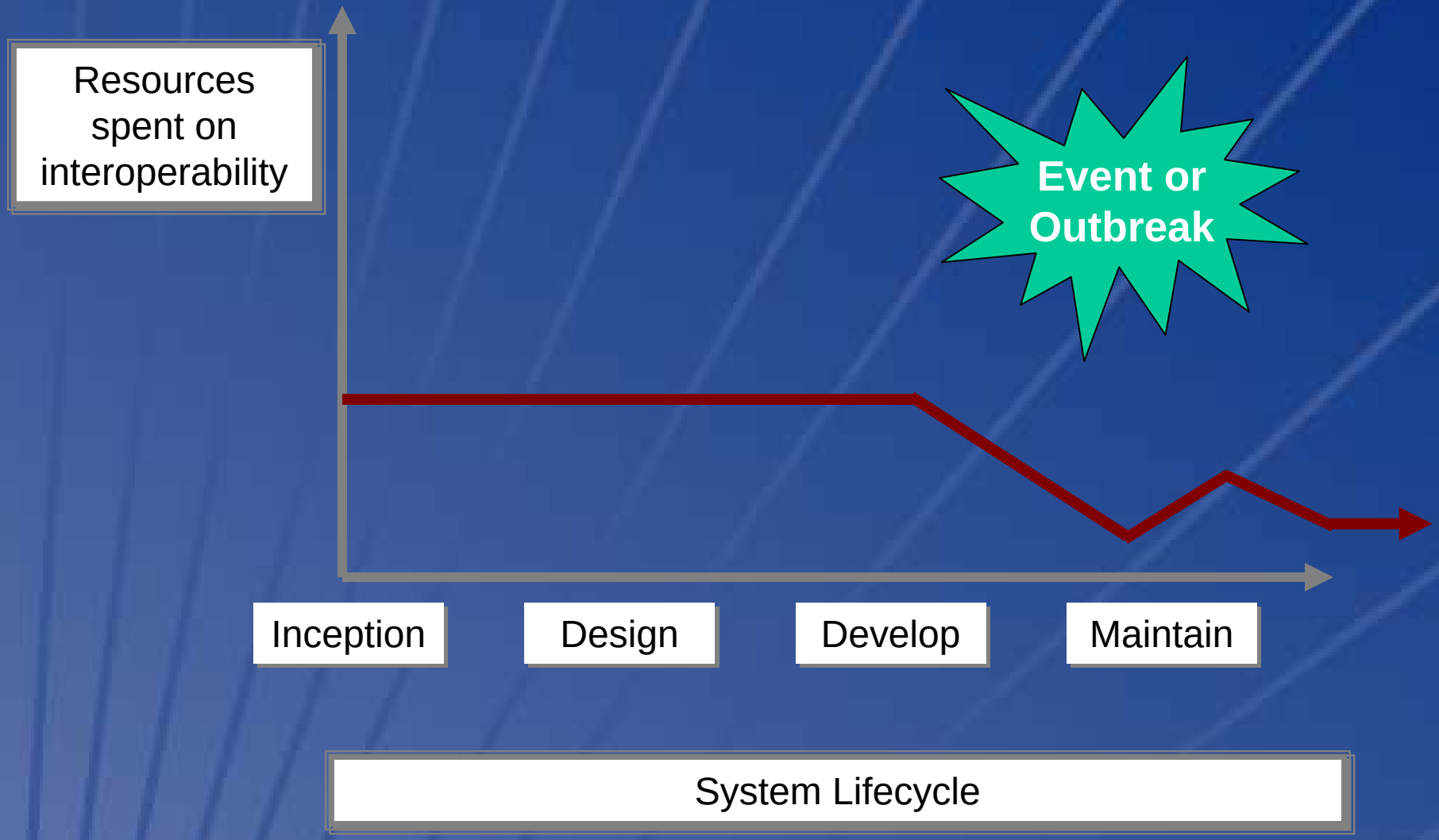
Our Standard Approach to Interoperability



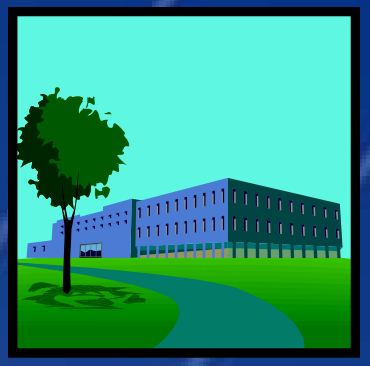
A New Approach to Interoperability

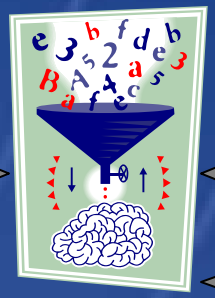


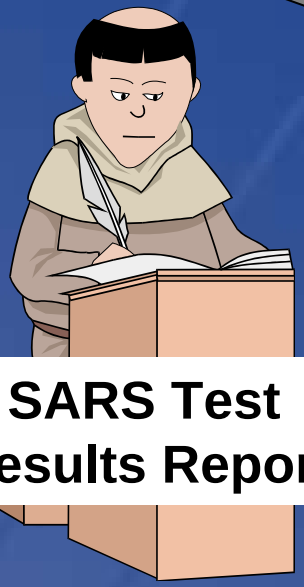
A New Approach to Interoperability



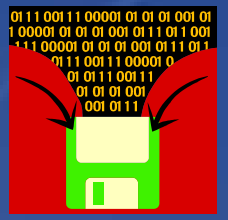
The CHALLENGE







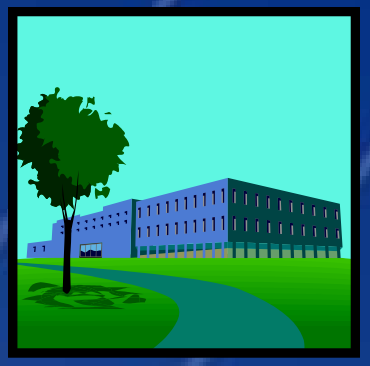
SARS Test Results Report

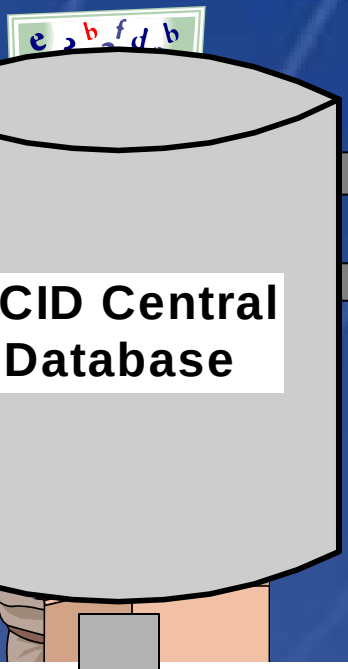


The CHALLENGE

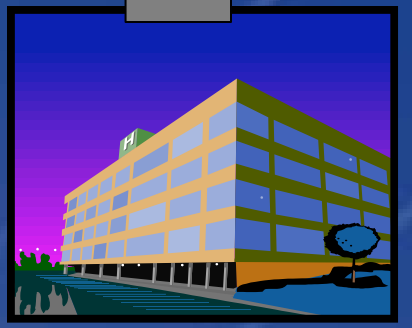
- Integration within NCID
  - Implementing STARLIMS in all NCID labs provides ‘seamless’ integration across the center

Integration
The CHALLENGE
Across NCID



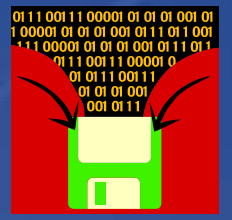


NCID Central Database



SARS Test

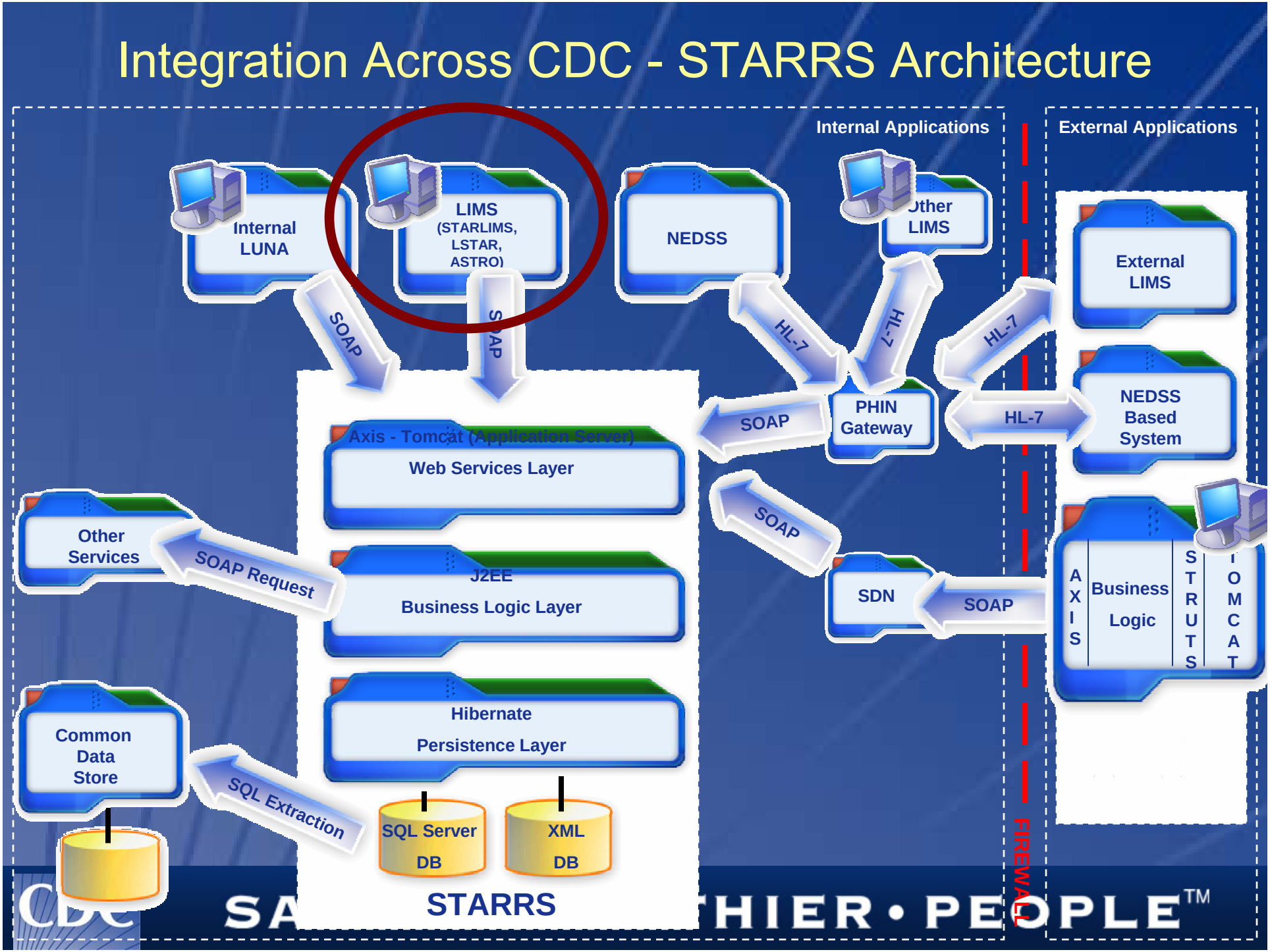
SARS Test Results Report



The CHALLENGE

- Integration within NCID
  - STARLIMS in all NCID labs provides 'seamless' integration
- Integration within CDC
  - STARRS integrates systems across the organization

Integration Across CDC - STARRS Architecture



The CHALLENGE

- Integration within NCID
  - STARLIMS in all NCID labs provides 'seamless' integration
- Integration within CDC
  - STARRS integrates systems across the organization
- Interoperability within the Public Health Information Network (PHIN)

Interoperability within the PHIN – Our Approach

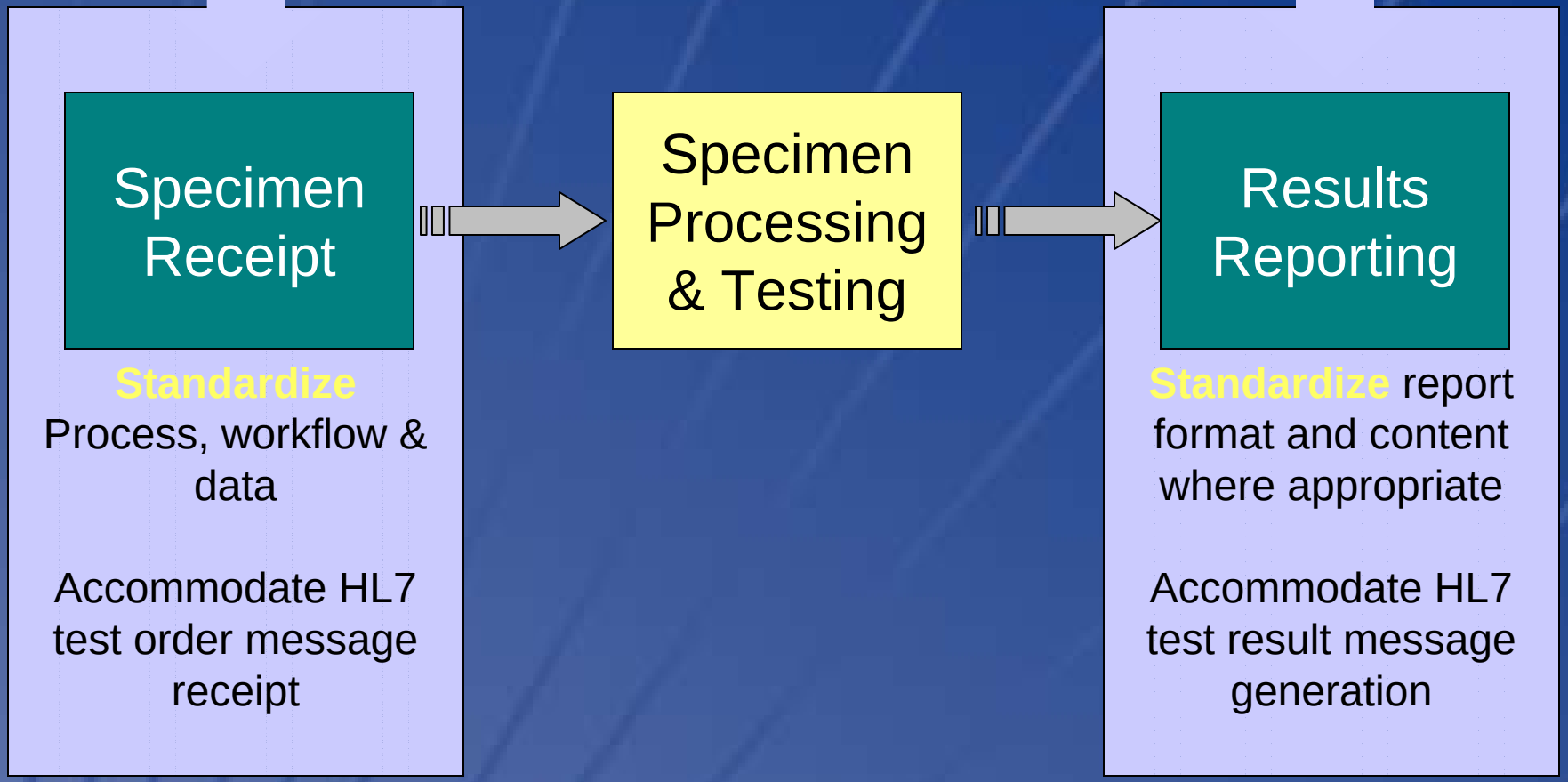
- Standardized Vocabulary
- HL7 Messaging
- Data Model
- Architecture
- STARLIMS and Public Health

Our Approach - Overall (1 of 3)

- Within NCID, we will be implementing in 80+ labs that have unique characteristics that affect sample control, test representation and results reporting
  - Bacteriology
  - Virology
  - Mycology
  - Parasitology
- Our goal is to balance the Agency's need to standardize with the Lab's needs to support many different processes and workflows

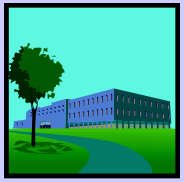
Our Approach - Overall (2 of 3)

Standardize process, workflow and data where appropriate



Our Approach - Overall (2 of 3)



Specimen Receipt

Standardize
Process, workflow & data

Accommodate HL7 test order message receipt

Specimen Processing & Testing

Allow for the necessary flexibility required within the lab

Maintain standards in the background

Results Reporting

Standardize report format and content where appropriate

Accommodate HL7 test result message generation

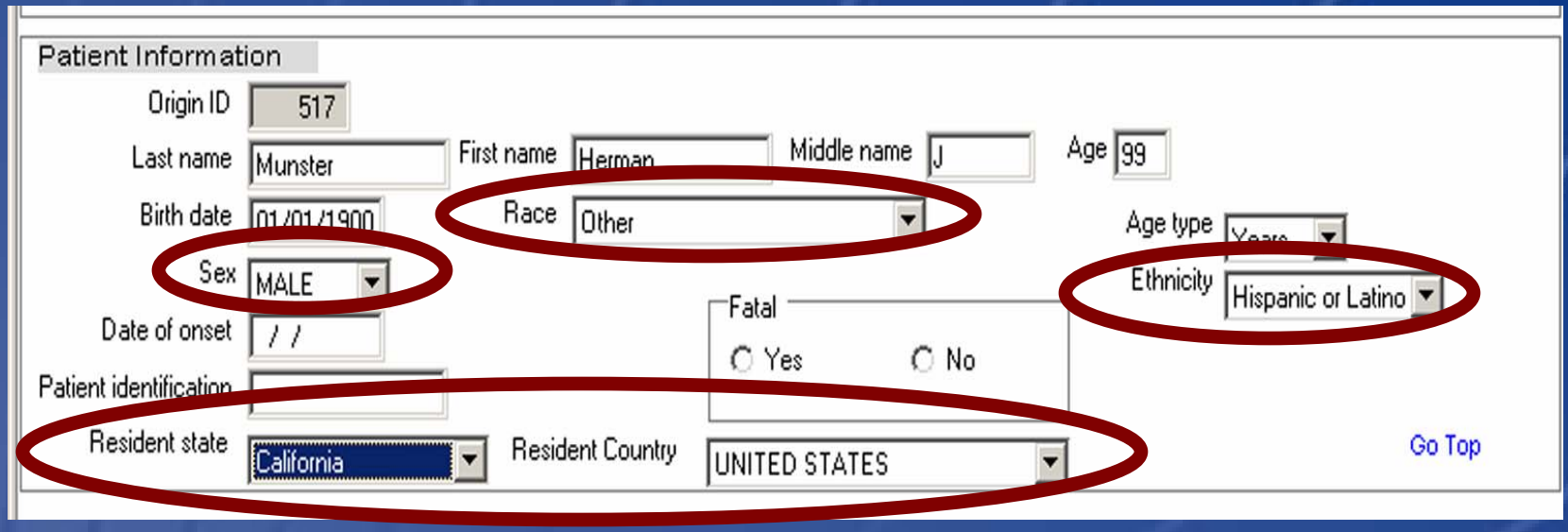
Our Approach
Standards Based Vocabulary (1 of 12)

- Specimen Receipt
  - Demographics
  - Case Description
  - Test Requests
- Results Reporting
  - Tests
  - Results
- Integrating the PHIN Vocabulary Service (VS)

Our Approach
Standards Based Vocabulary (2 of 12)

- Specimen Receipt
  - Demographics
    - Patient
      - Race, Ethnicity, Gender (HL7 2.5)
    - Submitter / Organization
      - Submitters maintained one time in one database
    - Location
      - State and Country (FIPS)

Our Approach
Standards Based Vocabulary (3 of 12)



Our Approach
Standards Based Vocabulary (5 of 12)

- Specimen Receipt
  - Case Description
    - Diagnosis - SNOMED CT
    - Organism Suspected – SNOMED CT
    - Specimen Type – SNOMED CT

Our Approach
Standards Based Vocabulary (4 of 12)

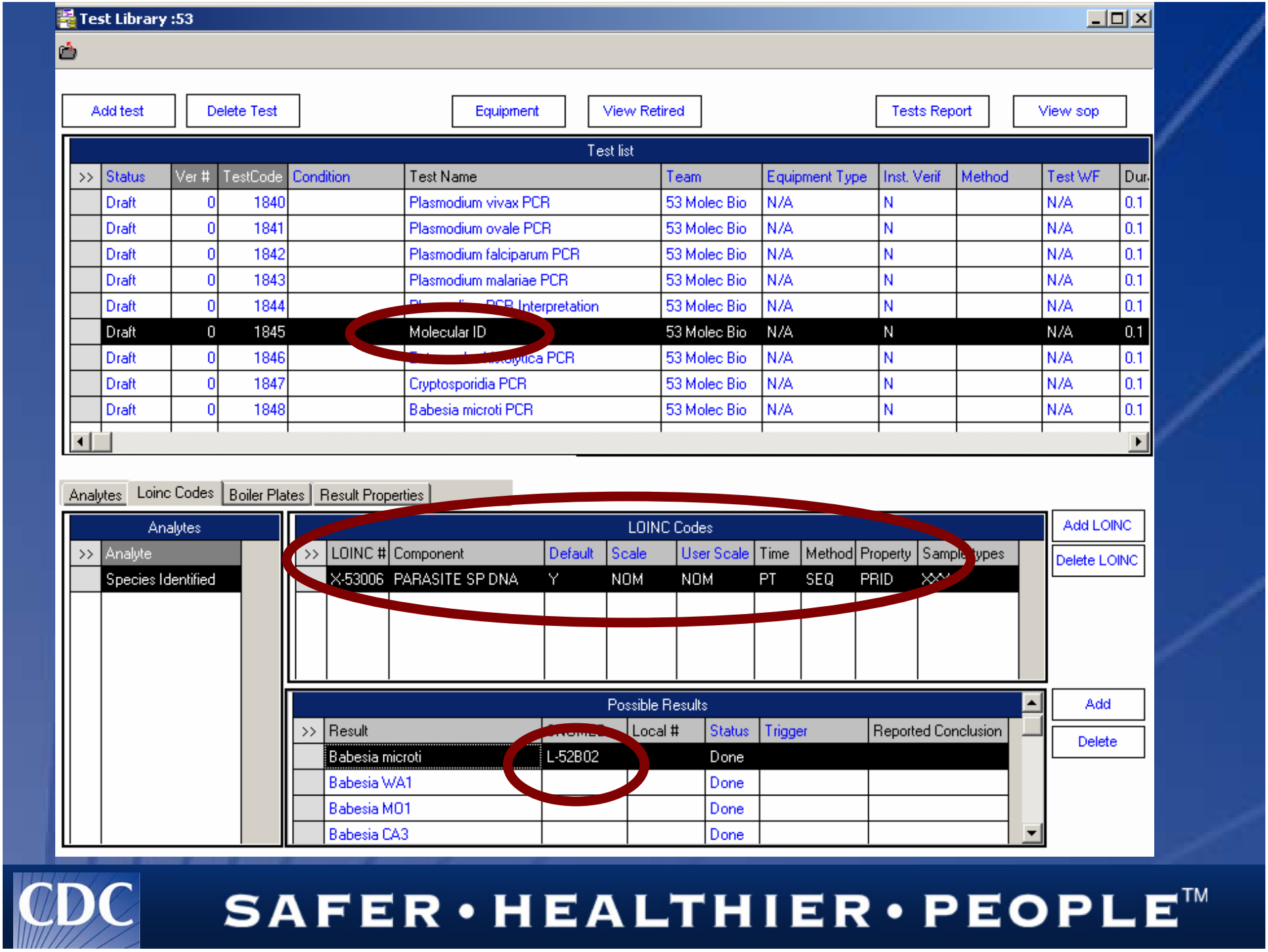
- Specimen Receipt
  - Test Requests
    - Current implementation allows free text entry for test requests
    - Paper DASH Form is still being used
    - Many specimens come in through Central Accessioning
      - The labs will perform necessary interpretation of requested tests
    - System will process LOINC codes for test requests that are generated through an HL7 Message in future implementations

Our Approach
Standards Based Vocabulary (6 of 12)

- Results Reporting
  - Tests
    - (Unsolicited Observation Result Message - ORU-R01)
    - LOINC used for Observation Identification (OBX-3)

Our Approach
Standards Based Vocabulary (7 of 12)

- LOINC Assignment
  - Assign LOINC codes in an unobtrusive manner
  - Allow the labs to use local nomenclature to identify tests and track the corresponding LOINC code for messaging
  - Local codes used where a suitable standard does not exist
  - We are working with CDC vocabulary working group to request additions to both LOINC and SNOMED CT (CDC speaks with one voice)


Test Library :53
Add test
Delete Test
Equipment
View Retired
Tests Report
View sop
Test list
>> Status Ver # TestCode Condition Test Name Team Equipment Type Inst. Verif Method Test WF Dur.
Draft 0 1840 Plasmodium vivax PCR 53 Molec Bio N/A N N/A 0.1
Draft 0 1841 Plasmodium ovale PCR 53 Molec Bio N/A N N/A 0.1
Draft 0 1842 Plasmodium falciparum PCR 53 Molec Bio N/A N N/A 0.1
Draft 0 1843 Plasmodium malariae PCR 53 Molec Bio N/A N N/A 0.1
Draft 0 1844 53 Molec Bio N/A N N/A 0.1
Draft 0 1845 Molecular ID 53 Molec Bio N/A N N/A 0.1
Draft 0 1846 53 Molec Bio N/A N N/A 0.1
Draft 0 1847 Cryptosporidia PCR 53 Molec Bio N/A N N/A 0.1
Draft 0 1848 Babesia microti PCR 53 Molec Bio N/A N N/A 0.1
Analytes
Loinc Codes
Boiler Plates
Result Properties
Analytes
>> Analyte
Species Identified
LOINC Codes
>> LOINC # Component Default Scale User Scale Time Method Property Sample types
X-53006 PARASITE SP DNA Y NOM NOM PT SEQ PRID
Add LOINC
Delete LOINC
Possible Results
>> Result Local # Status Trigger Reported Conclusion
Babesia microti L-52802 Done
Babesia WA1 Done
Babesia MO1 Done
Babesia CA3 Done
Add
Delete

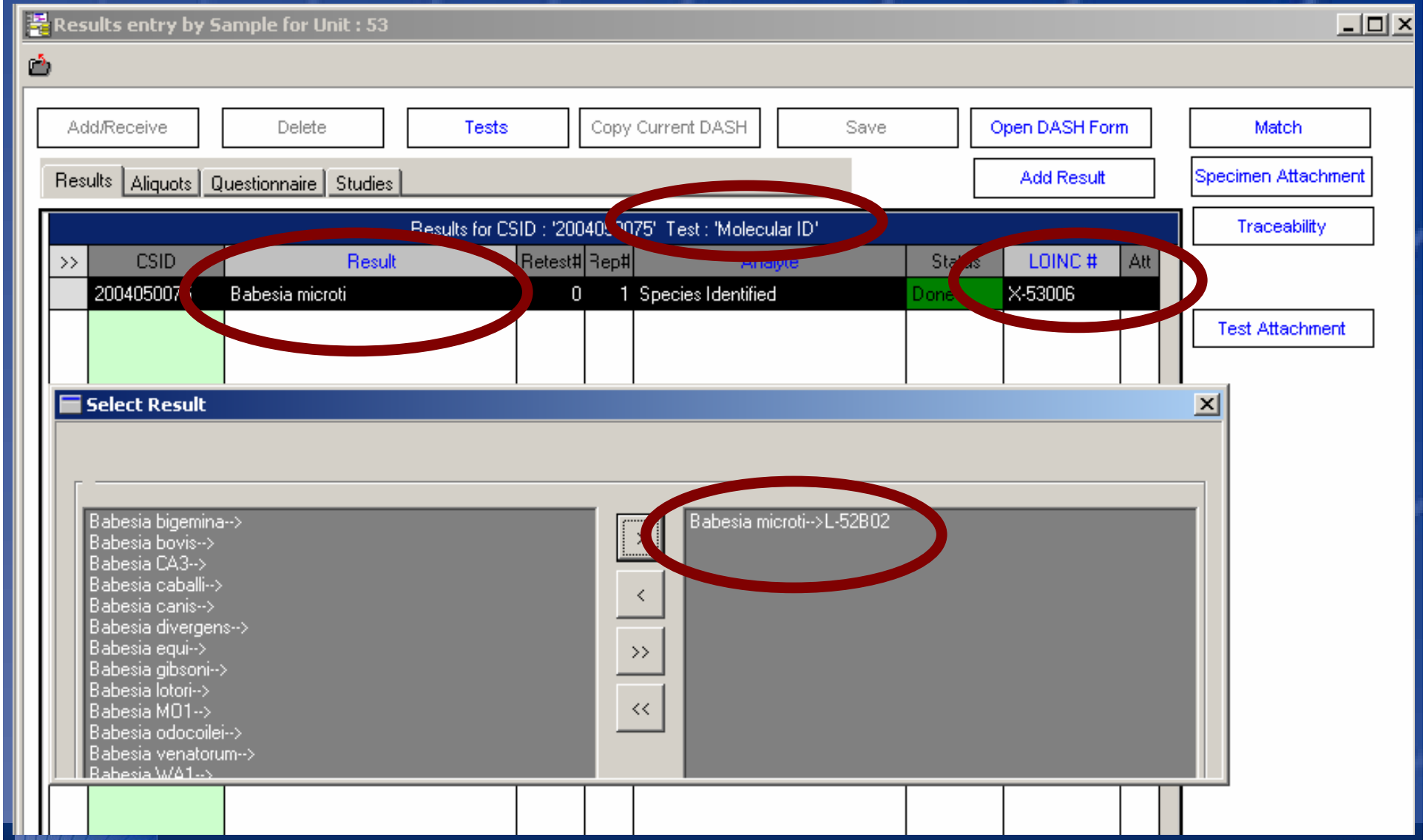
Our Approach Standards Based Vocabulary (9 of 12)

- LOINC Challenges
  - Many of our tests are not represented in the current LOINC database
    - Will be submitting requests for new LOINC codes
  - New tests are developed in the labs on a regular basis
  - We are wrestling to find the appropriate level of granularity

Our Approach
Standards Based Vocabulary (10 of 12)

- Results Reporting
  - Tests Results
    - (Unsolicited Observation Result Message - ORU-R01)
    - SNOMED CT used for Observation Results (OBX-5)
      - Assign SNOMED CT codes in an unobtrusive manner

Our Approach Standards Based Vocabulary (11 of 12)

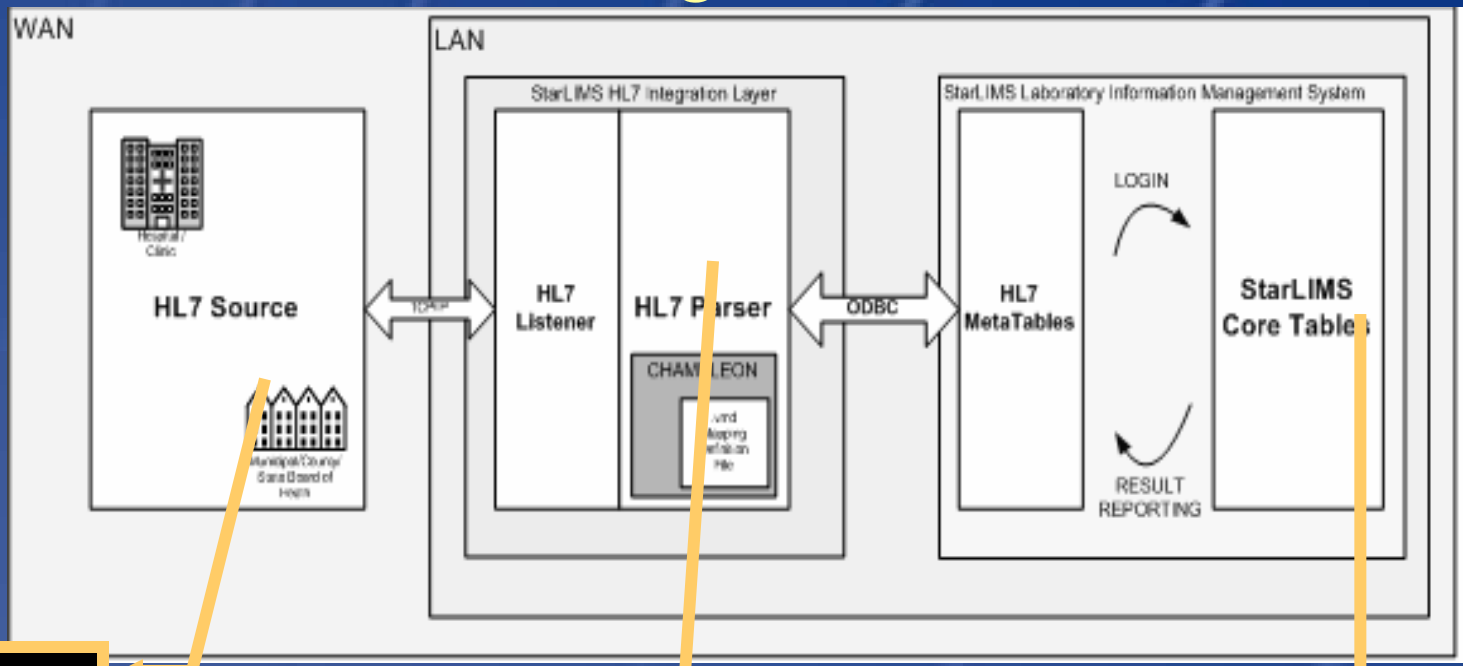


Our Approach
Standards Based Vocabulary (12 of 12)

- PHIN-VS
  - Our current implementation of vocabulary is fairly manual and stand-alone
  - We plan on integrating with PHIN-VS as it becomes available
    - PHIN-VS will provide a coordinated, multi-organizational system for distributing standard PHIN vocabulary
    - Vocabulary versioning
    - Utilize condition mapping tables

HL7 Messaging
STARLIMS™ HL7 Configuration Tools

STARLIMS provides the capability to create and receive HL7 Messages



Listener can be configured to communicate HL7 via :
- TCP/IP protocols
- Polling a directory for a file
- Web Service

HL7 grammar and mapping functions are configured via Chameleon

Login and Reporting Actions are written as STARLIMS macros. These use LOINC and SNOMED CT translation tables to translate between STARLIMS test / result naming conventions and PHL observation terms

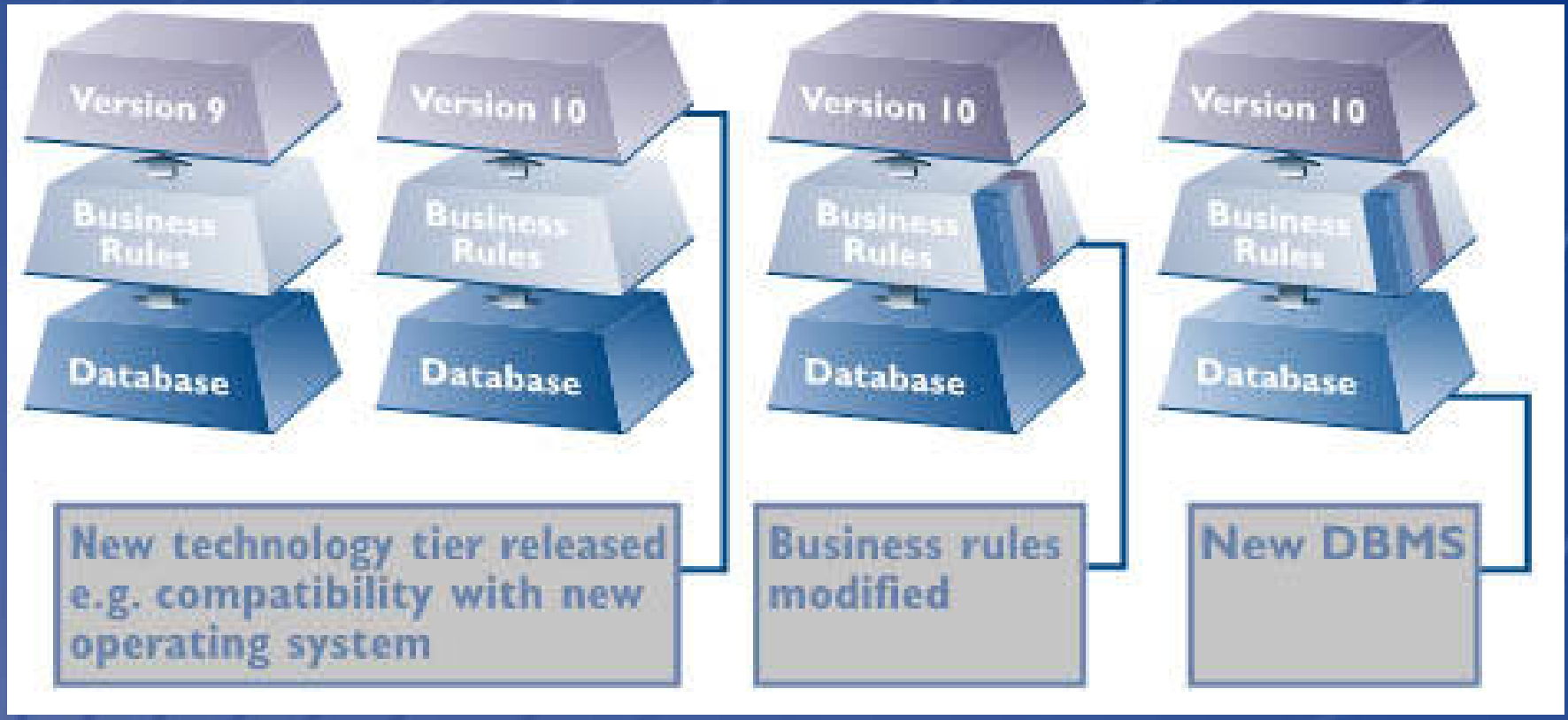
Data Model

- CDC Working Groups
  - Architecture
  - Vocabulary
  - Messaging
  - Data Model
- Specimen Identifiers
- Case and Patient Identification

Architecture (1 of 2)

- n-Tier Architecture
  - Application Layer
    - The .exe is “Black Box” to CDC
  - Database
    - Central STARLIMS NCID Db
  - Business Rules
    - Separate from Db and allows unique workflows in a lab
- Functions can be deployed through Web Services
- STARLIMS offers a light client interface – MyLIMS.com
  - May be used in the future

Architecture (2 of 2)



Source: http://www.starlims.com/solutions/FutureProofing.htm

STARLIMS and PHIN (1 of 5)

- HL-7 and PHIN communication protocols
- LOINC and SNOMED CT CT compliant

STARLIMS and PHIN (2 of 5)

- Support for all 16 Business Processes as defined by Association of Public Health Laboratories (APHL) and Public Health Informatics Institute (PHII)

STARLIMS and PHIN (3 of 5)

- Web Services – extend STARLIMS functionality from the lab to the enterprise
  - Self-contained, self-describing modular applications that can be published, located and invoked across the web
- STARLIMS SOAP client
  - Can be accessed by any Windows automation clients such as VB, C, C++, Excel and Delphi.
- STARLIMS Web Services framework exposes key LIMS elements such as Sample Login, Results Entry and a variety of other information distribution capabilities

STARLIMS and PHIN (4 of 5)

- Sample accessioning and Meta Data recording
- A repository for analytical process Best Practices
- Workflow design and management
- A collaboration platform for exchanging data and system content
- Tools for managing information related to mutual assistance, surge capacity and disaster recovery

STARLIMS and PHIN (5 of 5)

- Electronic signature
- Full Audit Trail
- Chain of Custody
- Role-based authorization within the application

Our Challenges (1 of 4)

- Implementing STARLIMS as part of a larger picture – many parts of which are moving
  - Standards
  - STARRS
  - Vocabulary Service
  - OIDs
  - Real-life

Our Challenges (2 of 4)

- Technical Capability vs. Policy and Process needs
- Enforcing policy with application implementation
- We are implementing 80+ Small Businesses

Our Challenges (3 of 4)

- We must balance the advantage of a COTS with the need to support many diverse workflows (customization)
- The project team is spread over two locations (Atlanta, GA and Hollywood, FL)
- The implementation must accommodate the legacy processes with the new world of PHIN

Our Challenges (4 of 4)

- PHIN Standards – Theory vs. Practice

Sources

- STARLIMS Solutions for Public Health
- STARRS_Overview_2.0-2.ppt
- http://www.starlims.com
- PHIN Vocabulary Service (VS) – Daniel Pollack
  - NCID IT Seminar - March 26, 2004

Questions?