Application of STPA to the U.S. Diagnostic Laboratory Data Ecosystem

2024 STAMP Workshop

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Addressing the Patient Safety Challenge

- Preventable medical errors are the **3rd leading cause of death** in the U.S. (Makary & Daniel, 2016)
- **Diagnostic errors** account for **6-17% of all adverse patient events** occurring in hospitals while resulting in **most** of the paid medical malpractice claims and preventable patient deaths (National Academy of Sciences, 2015)
- An estimated **800,000 Americans are seriously injured or die each year** across multiple care settings **due to misdiagnosis** of dangerous diseases (Newman-Toker et al., 2023)
- Study of closed claim malpractice data found that **92% of diagnostic errors within the EHR occurred during laboratory testing** (Krevat et al., 2023)
- Up to **70% of all medical decisions** are reportedly **predicated on laboratory test results** (Raymond et al., 2020)

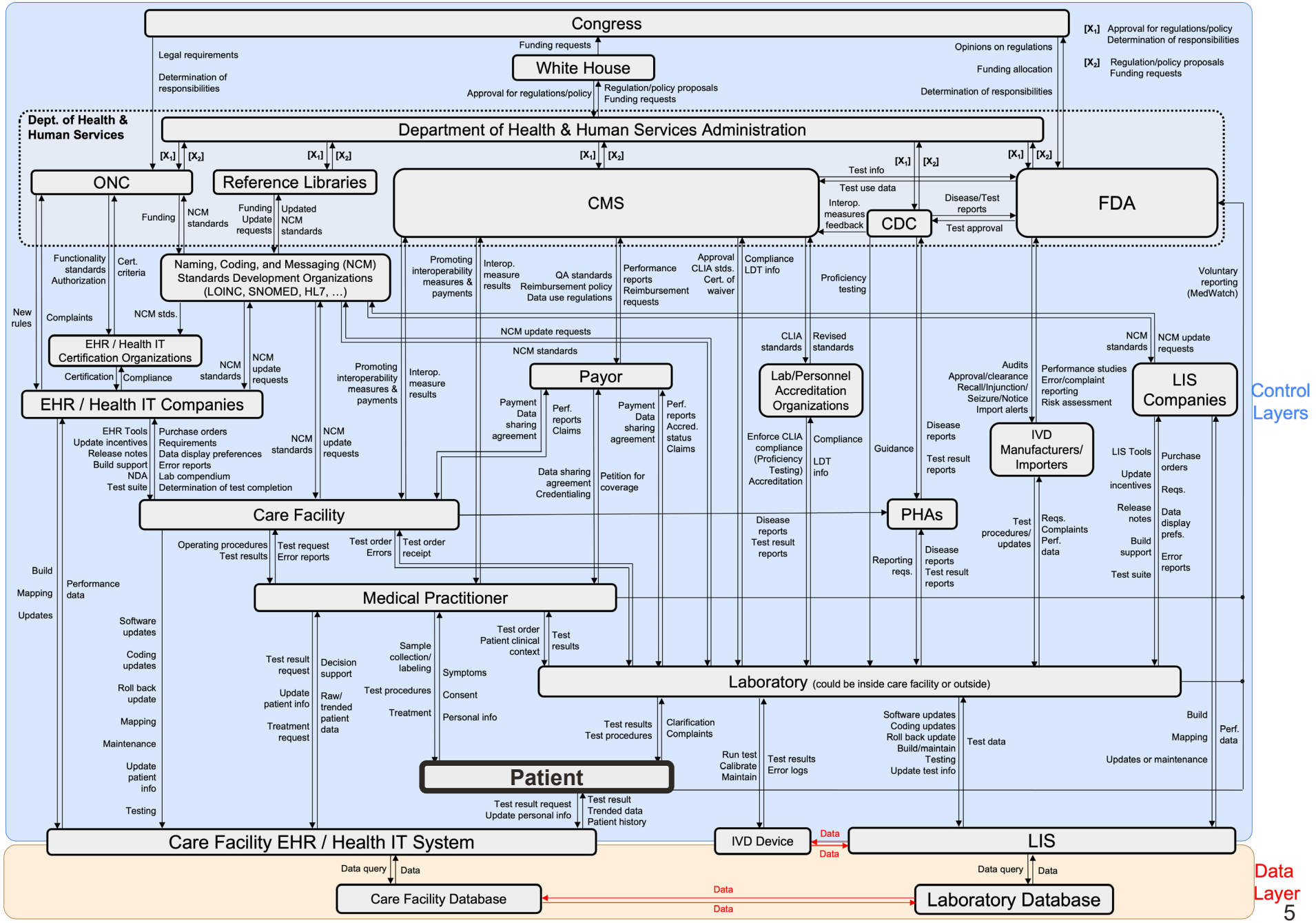
Setting the Goals of our System Analysis

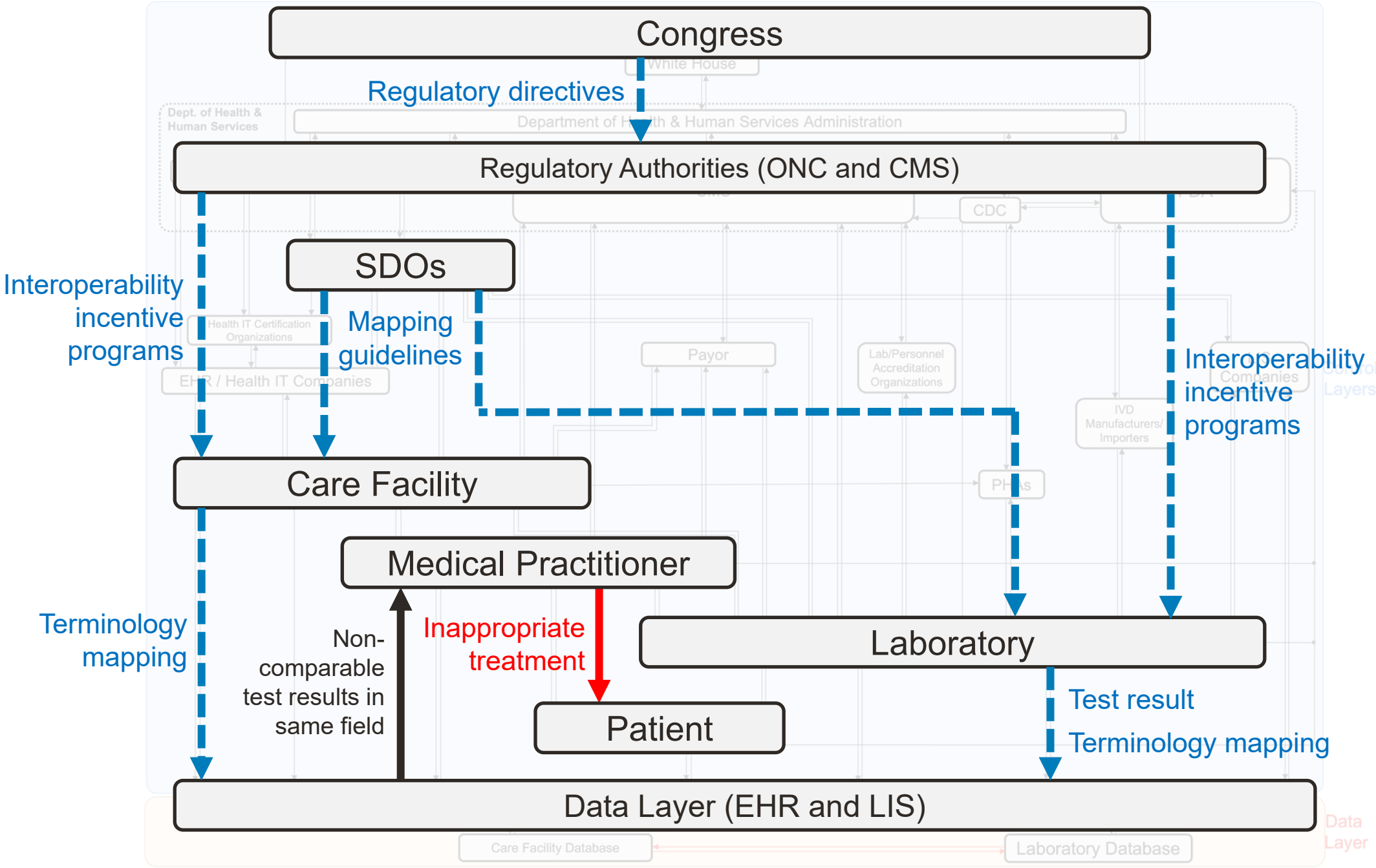
Losses	Hazards
L-1: Loss of life or injury to patient	**H-1:** Patients receive less than acceptable standard of care
L-2: Loss of reputation or trust in the laboratory ecosystem	**H-2:** Laboratory ecosystem stakeholders including patients lose trust in the laboratory data being collected, shared, analyzed and reported

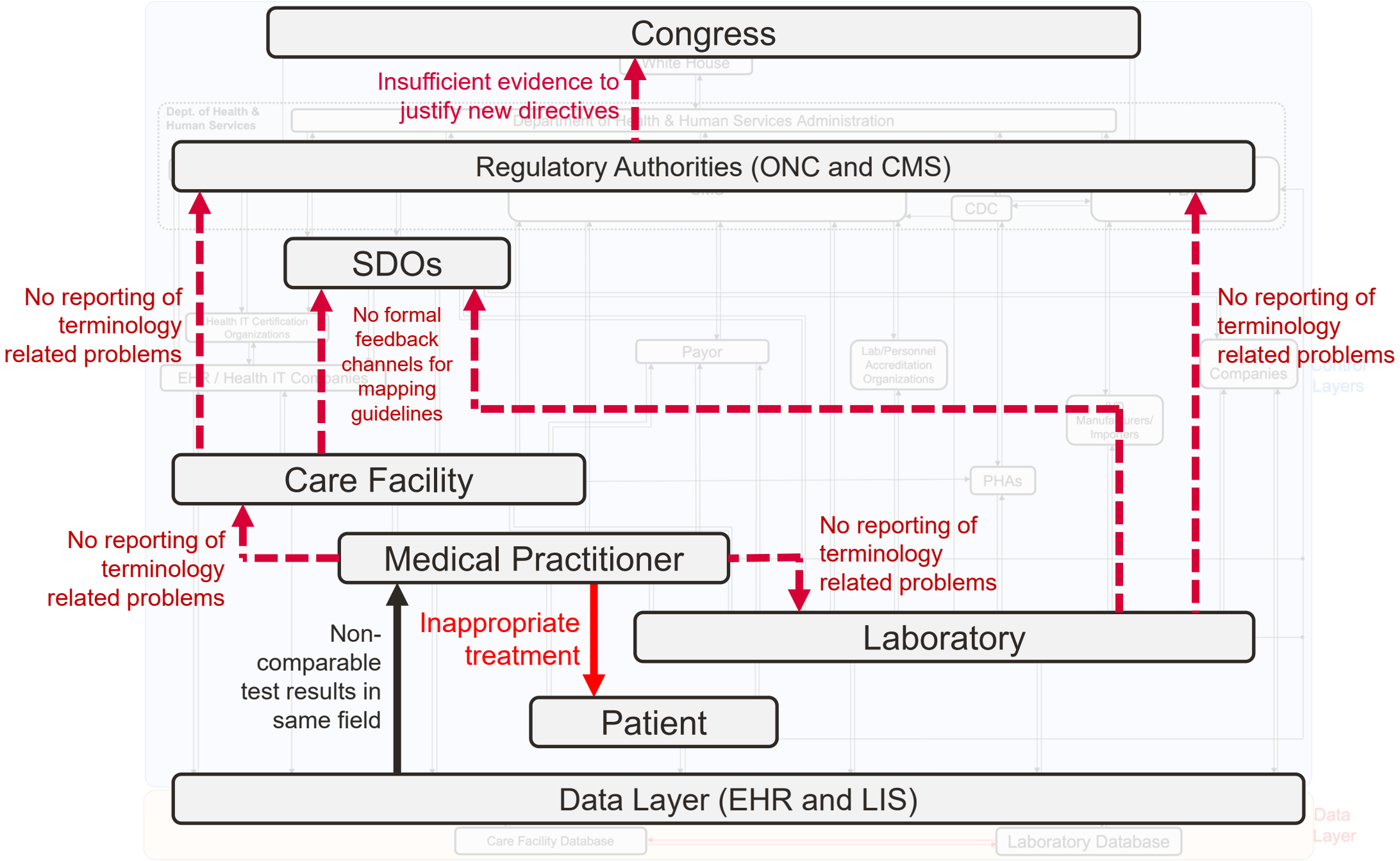
Using interviews to understand current system

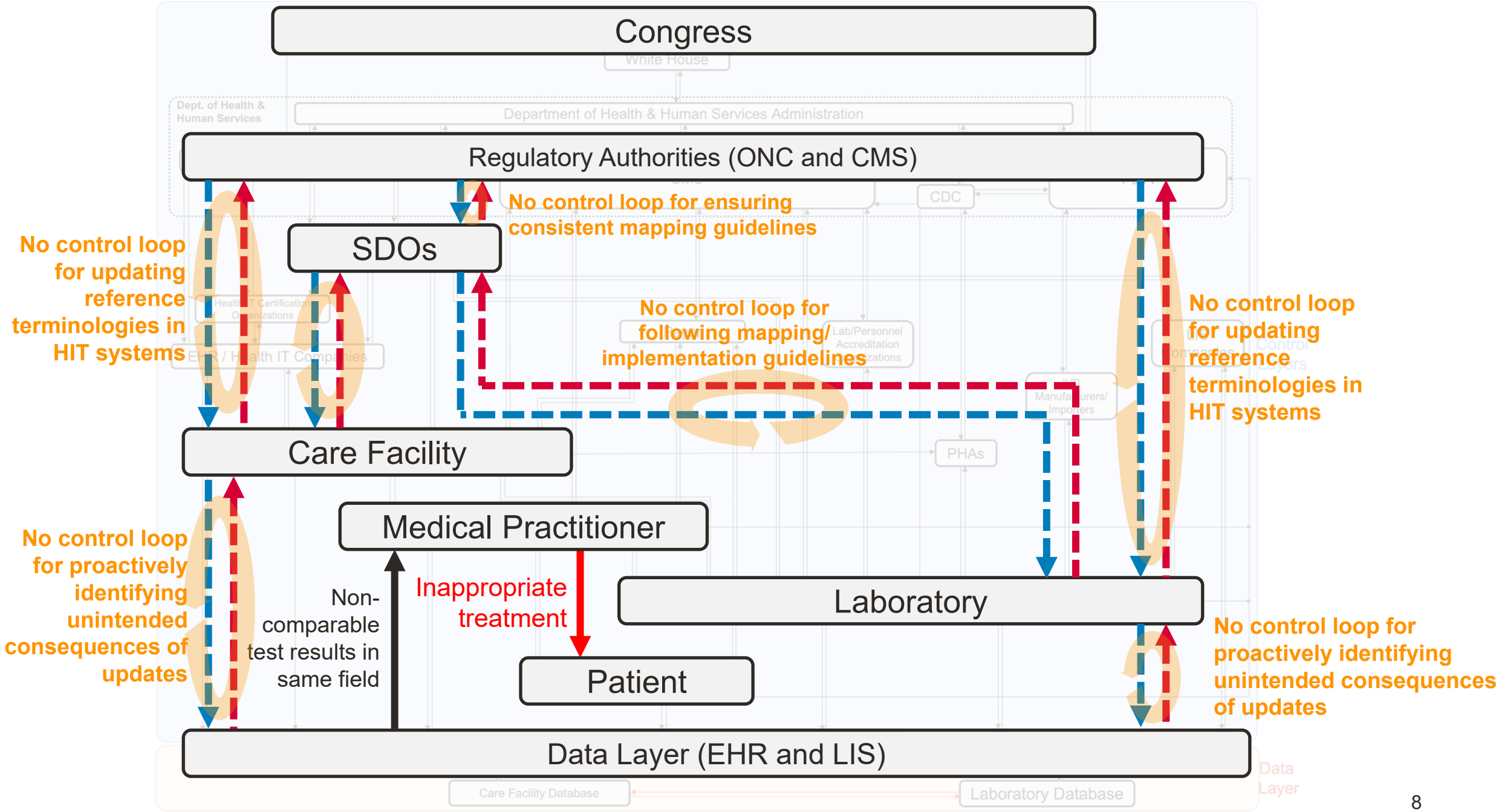
50 Stakeholders interviewed

Detailed Control Structure




Congress
Regulatory directives
Regulatory Authorities (ONC and CMS)
SDOs
Interoperability incentive programs
Mapping guidelines
Interoperability incentive programs
Care Facility
Medical Practitioner
Terminology mapping
Non-comparable test results in same field
Inappropriate treatment
Laboratory
Test result
Terminology mapping
Patient
Data Layer (EHR and LIS)


Congress
Insufficient evidence to justify new directives
Regulatory Authorities (ONC and CMS)
SDOs
No reporting of terminology related problems
No formal feedback channels for mapping guidelines
No reporting of terminology related problems
Care Facility
No reporting of terminology related problems
Medical Practitioner
No reporting of terminology related problems
Laboratory
Non-comparable test results in same field
Inappropriate treatment
Patient
Data Layer (EHR and LIS)


Congress
Regulatory Authorities (ONC and CMS)
SDOs
Care Facility
Medical Practitioner
Laboratory
Patient
Data Layer (EHR and LIS)
No control loop for ensuring consistent mapping guidelines
No control loop for updating reference terminologies in HIT systems
No control loop for following mapping/ implementation guidelines
No control loop for updating reference terminologies in HIT systems
No control loop for proactively identifying unintended consequences of updates
Non-comparable test results in same field
Inappropriate treatment
No control loop for proactively identifying unintended consequences of updates

Systemic Factors

Addressable by SHIELD

Addressable by the rest of the ecosystem

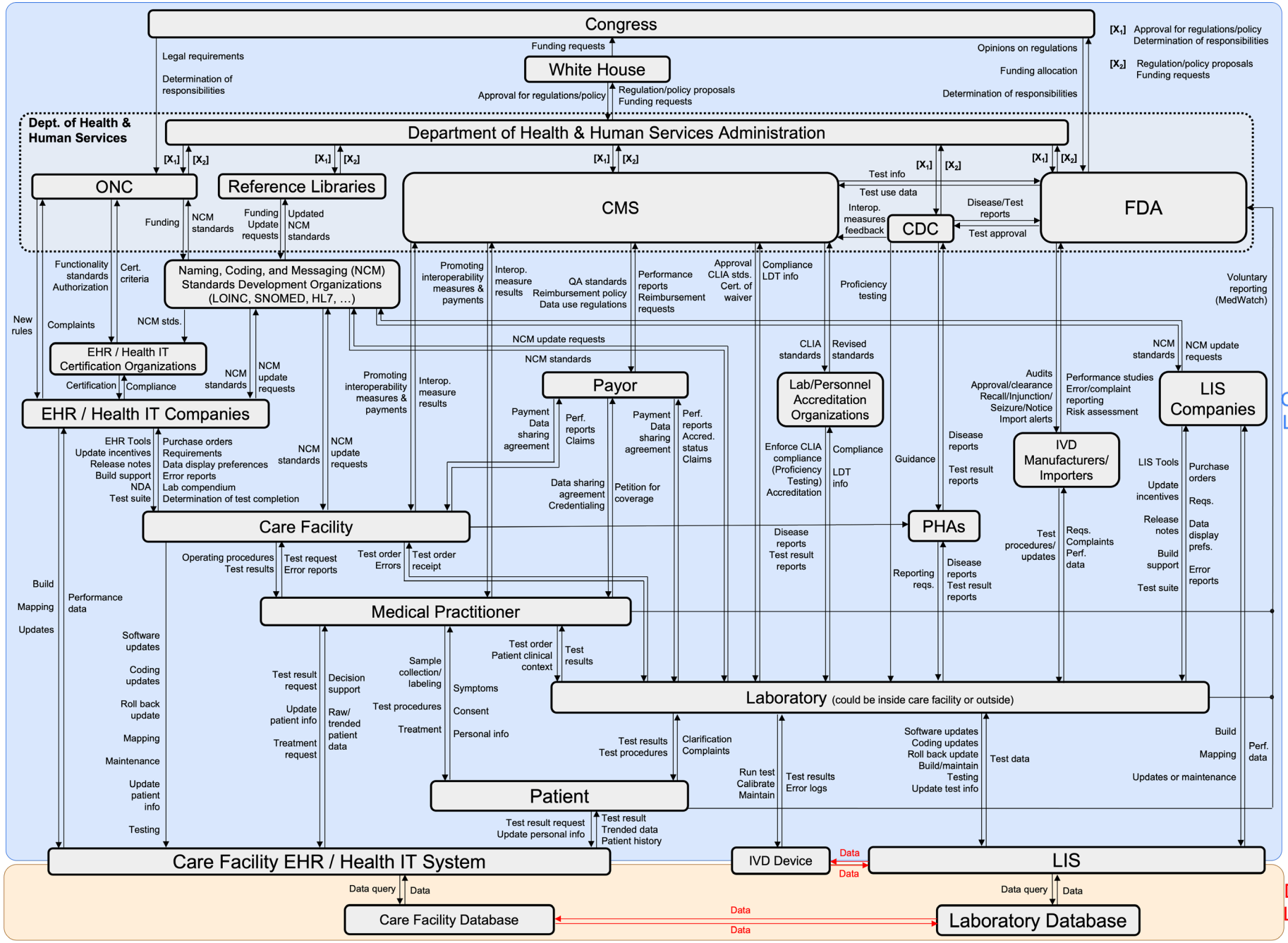
Decentralized and missing oversight	Inadequacies and gaps in laboratory data standards	Inaccurate perceptions of data and HIT risks
Lack of a systems view by system participants	Inadequate regulatory emphasis on HIT safety	Flawed communication and coordination

Systemic Factor	Recommendation	Action Item(s)
Decentralized and missing oversight	**1**: Assign responsibility for addressing gaps in the regulatory oversight of laboratory data exchanges between system components that are regulated by different agencies.	
	2: Identify the data and standards needs of regulatory agencies and ensure they have the ability to use them appropriately.	
	3: Encourage the identification of regulatory gaps in other areas of the laboratory ecosystem through additional systems-theory-based analyses.	
Inadequacies and gaps in laboratory data standards	**4**: Reference libraries must develop a knowledge base that establishes a ground truth for naming, coding, and mapping of reference terminologies to particular laboratory tests, and stakeholders must be incentivized to use it.	
	5: Appropriate groups must be assigned responsibility for identifying gaps and weaknesses in laboratory data standards and for establishing a reporting channel for problems related to them.	
	6: SDOs must continuously support users by identifying and eliminating ambiguities in implementation guides for HIT standards.	

Systemic Factor	Recommendation	Action Item(s)
Inaccurate perceptions of data and HIT risks	**7:** Proactively and retroactively investigate systemic sources of diagnostic error.	
	8: Create a consolidated national database for HIT safety reporting that can be used to identify trends and opportunities for improving patient safety outcomes. It should include information about HIT not behaving as users intended and allow understanding how features of HIT design may have contributed to “user errors.”	
Lack of a systems view by system participants	**9**: Educate the healthcare community on systems engineering and systemic approaches for solving problems, including tools to accomplish this goal.	
	10: Establish appropriate control loops for updates to standards and HIT.	

Systemic Factor	Recommendation	Action Item(s)
Inadequate regulatory emphasis on HIT safety	**11**: Assign regulatory oversight of HIT safety to ONC or another appropriate group. Include the explicit directive to develop and include safety-related certification criteria for HIT and the ability to limit the inclusion of "hold harmless" clauses in HIT contracts.	
	12: Establish incentives for using certified HIT throughout the entire healthcare ecosystem.	
Flawed communication and coordination	**13**: Develop formal processes for inclusion of laboratorians in the multidisciplinary teams responsible for decisions about laboratory data needs, representations, and interfaces at care facilities.	

Conclusion


Congress
White House
Department of Health & Human Services Administration
Dept. of Health & Human Services
ONC
Reference Libraries
CMS
CDC
FDA
Naming, Coding, and Messaging (NCM) Standards Development Organizations (LOINC, SNOMED, HL7, …)
EHR / Health IT Certification Organizations
EHR / Health IT Companies
Payor
Lab/Personnel Accreditation Organizations
LIS Companies
IVD Manufacturers/ Importers
Care Facility
PHAs
Medical Practitioner
Laboratory (could be inside care facility or outside)
Patient
Care Facility EHR / Health IT System
IVD Device
LIS
Care Facility Database
Laboratory Database
Legal requirements
Determination of responsibilities
Funding requests
Approval for regulations/policy
Regulation/policy proposals
Funding requests
Opinions on regulations
Funding allocation
Determination of responsibilities
[X1] Approval for regulations/policy Determination of responsibilities
[X2] Regulation/policy proposals Funding requests
Test info
Test use data
Interop. measures feedback
Disease/Test reports
Test approval
Funding
NCM standards
Funding Update requests
Updated NCM standards
Functionality standards Authorization
Cert. criteria
Promoting interoperability measures & payments
Interop. measure results
QA standards
Reimbursement policy
Data use regulations
Performance reports
Reimbursement requests
Approval CLIA stds. Cert. of waiver
Compliance LDT info
Proficiency testing
Voluntary reporting (MedWatch)
New rules
Complaints
NCM stds.
NCM update requests
NCM standards
CLIA standards
Revised standards
Audits
Approval/clearance
Recall/Injunction/
Seizure/Notice
Import alerts
Performance studies
Error/complaint reporting
Risk assessment
Certification
Compliance
Payment Data sharing agreement
Perf. reports Claims
Payment Data sharing agreement
Perf. reports Accred. status Claims
Data sharing agreement Credentialing
Petition for coverage
Enforce CLIA compliance (Proficiency Testing) Accreditation
Compliance
LDT info
Guidance
Disease reports
Test result reports
EHR Tools
Update incentives
Release notes
Build support
NDA
Test suite
Purchase orders
Requirements
Data display preferences
Error reports
Lab compendium
Determination of test completion
LIS Tools
Update incentives
Release notes
Build support
Test suite
Purchase orders
Reqs.
Data display prefs.
Error reports
Operating procedures
Test results
Test request
Error reports
Test order
Errors
Test order receipt
Disease reports
Test result reports
Reporting reqs.
Test procedures/ updates
Reqs.
Complaints
Perf. data
Build
Mapping
Updates
Performance data
Software updates
Coding updates
Roll back update
Mapping
Maintenance
Update patient info
Testing
Test result request
Update patient info
Treatment request
Decision support
Raw/ trended patient data
Sample collection/ labeling
Test procedures
Treatment
Symptoms
Consent
Personal info
Test order
Patient clinical context
Test results
Test results
Test procedures
Clarification
Complaints
Run test
Calibrate
Maintain
Test results
Error logs
Software updates
Coding updates
Roll back update
Build/maintain
Testing
Update test info
Test data
Build
Mapping
Updates or maintenance
Perf. data
Test result request
Update personal info
Test result
Trended data
Patient history
Data
Data
Data query
Data
Data query
Data
Data
Data
Control Layers
Data Layer

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- Safe Health Systems, Inc.
- SNOMED International
- State University of New York at Buffalo
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Questions, Comments, Observations,
Discussions, Feedback, Follow-up