

PHIN Requirements for Laboratory Systems



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Topics

- Evolution of the business case
- Functional requirements for response
- System behavior
- PHIN functional requirements for LIMS
- PHIN standards
- Standards map
- Where do I start
- Compliance



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Evolution of a Business Case

- Bio-terrorism threat brought new emphasis to improving laboratory infrastructure
- Anthrax events of 2001 highlighted weaknesses in surge capacity and communications
- Political realization of issues brings opportunity for improvement
- Need for consolidation on requirements and standards underscored
- Public Health organized to act on requirements



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Response Requirements

In order to effectively respond to large scale events, the laboratory infrastructure must have:

- Increased surge capacity
- Enhanced mutual assistance capacity
- Enhanced reporting capacity
- Improved automation of laboratory processes



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PHIN Laboratory Requirements

- Ability to receive and respond to electronic orders
 - Could initially include web interface for manual entry
 - HL7 orders
 - Order acknowledgement
 - Order notification
 - Order forwarding – mutual assistance
- Ability to create and transmit electronic results
 - Could initially post results to secure web site
 - HL7 result formats



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PHIN Laboratory Requirements

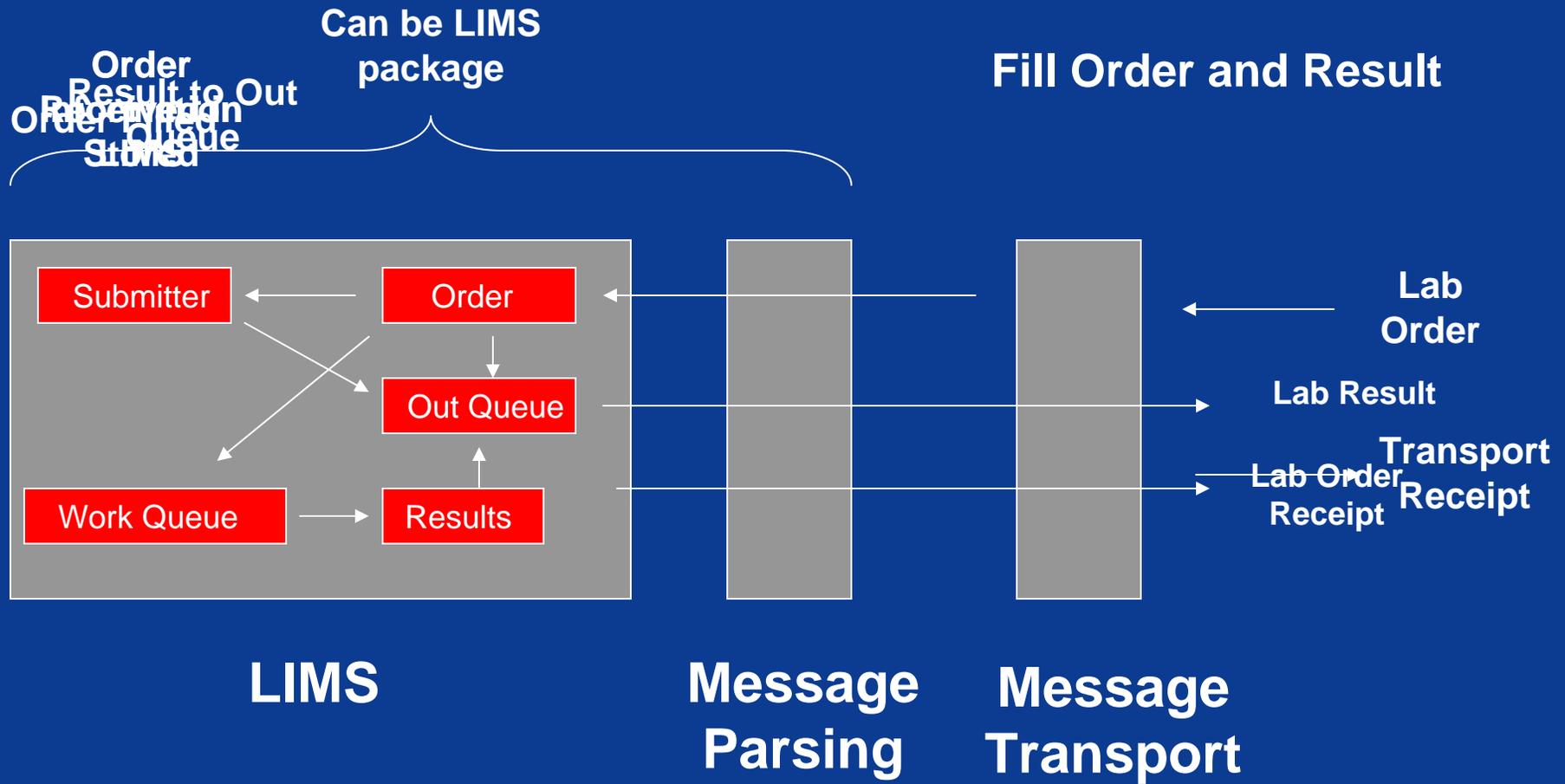
- Ability to route electronic messages to multiple recipients
 - ebXML protocol
 - PHIN Messaging system available
- Ability to uniquely identify samples and test subjects
 - Object Identifiers (OIDs)
 - Global identity = domain namespace + identifier
- Ability to use standard terminology



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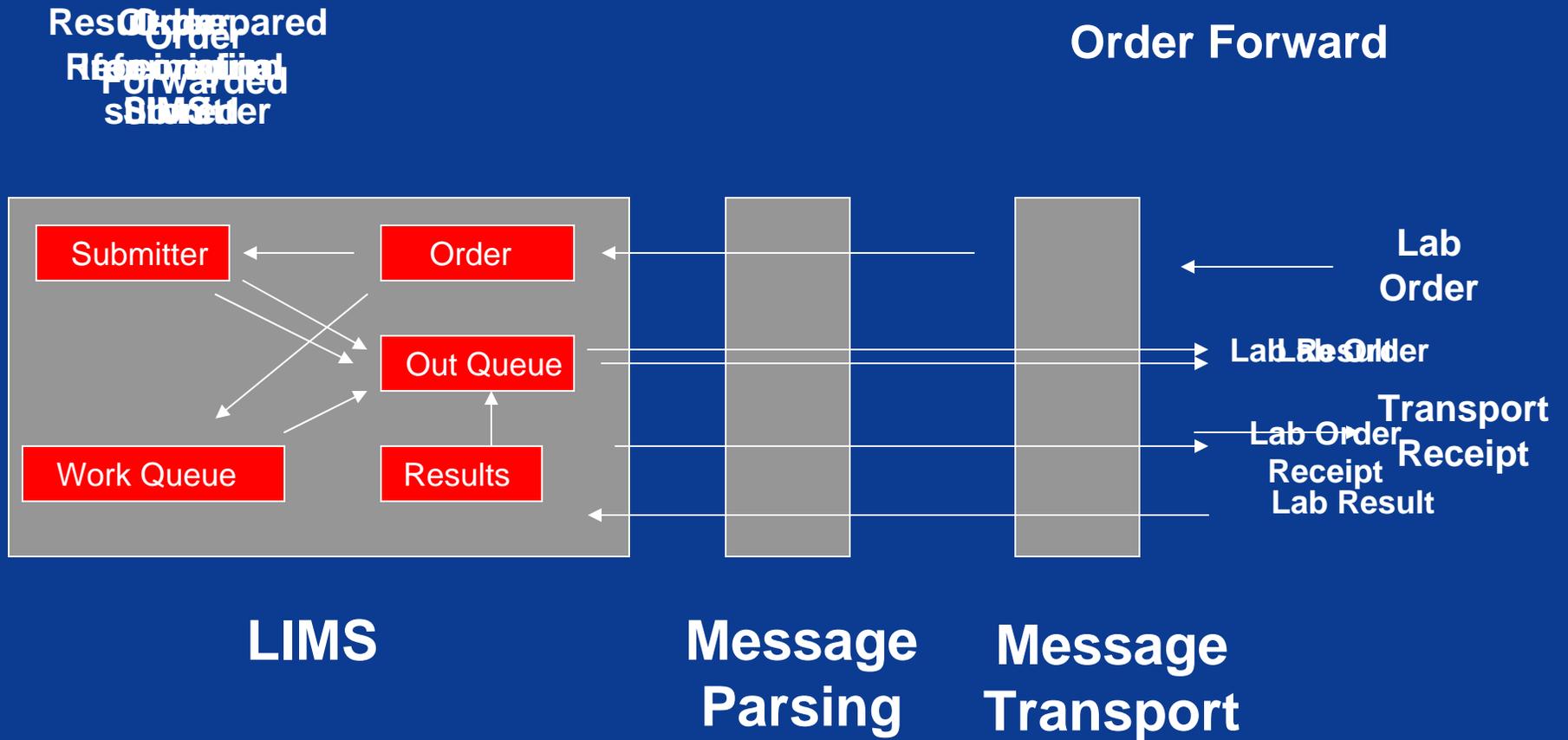
System Behavior



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System Behavior



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Relevant PHIN Standards

- Message format
 - HL7 order V2.X
 - HL7 result V2.X
 - HL7 query – result, status V2.X
 - Others where appropriate and not supported in HL7
- Terminology
 - LOINC
 - SNOMED
 - HL7
 - CPT
- Namespace Identifiers (OIDs)
 - Archetype specification
 - Global uniqueness = Namespace + local unique ID
- Secure, Reliable Messaging
 - Internet base message transport via ebXML
 - PKI encryption
 - Addressing to appropriate partner organizations



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Requirements Map

Response Requirement	PHIN Requirement
Enhanced Surge Capacity	Order messages, order response, order forwarding, ebXML messaging
Enhanced Mutual Assistance	Order forwarding, ebXML messaging, result receipt
Enhanced Reporting	Result messages, ebXML messaging
Laboratory Automation	Implement LIMS, order response and result automation



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Where Do I Begin?

- It depends on your starting point
- If I don't have a LIMS?
 - Implement a system
 - Vendor product
 - Build
 - Message parsing and transport
 - Refer to available documentation
 - APHL/PHII document on LIMS requirements
 - PHIN Requirements for Laboratories
 - Starting from scratch can be beneficial
- If I have a robust LIMS but it does not message?
 - Refer to documentation above
 - Begin implementing processes for messaging
 - Implement outbound HL7 result first



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Messaging Tools 101

- Message Mapping/Parsing
 - Many commercial tools available for HL7 V2.X
 - Possibility of CDC delivered components
 - Remember: Parsing tools only parse, your system must store and respond to messages
 - If you can map data to a flat file export, you can map to a simple HL7 2.X message
- Message Transport
 - PHIN Messaging System is available
 - Requires some integration work with your LIMS



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How do I know I am compliant?

- Certification and conformance
 - Certification team created for support and conformance testing
 - Conformance measured on functional and interoperability requirements
 - Provides certification and trouble shooting for message implementations
 - Provides guidance on appropriate implementation guides
 - Complete certification process is being documented
 - CDC will host message conformance testing site
 - CDC PHIN Vocabulary Service will be available for vocabulary registration and code set download



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Questions?



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