Introducing the IVD Industry Connectivity Consortium

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Agenda

1. **Why we need to modernize analyzer connectivity**
2. **Foundation of IVD Industry Connectivity Consortium**
3. **Collaborations with leading standards organizations**
4. **Target outcomes for the clinical laboratory industry**

How does connectivity work today?

HIS, EMR

LIS, Middleware

Analyzer

Standards for Orders & Results:

HL7 2.x, HL7 3
HITSP C163 (built on HL7 2.5.1)
ELINCS (built on HL7 2.4)
IHE Lab LTW (built on HL7 2.5, 2.5.1)
Others (e.g. LIDDEx)

Standards for Orders & Results:

CLSI LIS-1 / LIS-2 (ASTM)
HL7 2.x, HL7 3.x
IHE Lab LDA (based on HL7 2.5, 2.51)

How does connectivity work today?

LIS, Middleware

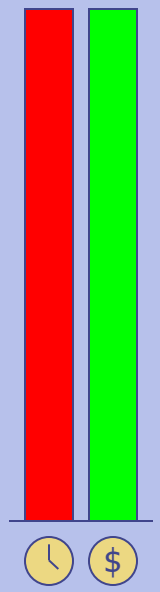
2. IT vendor develops driver based on interface spec for analyzer

3. Laboratory and vendors configure driver based on local lab configuration

1. Analyzer vendor develops custom ASTM interface for analyzer

4. Laboratory and vendors validate connectivity

Analyzer



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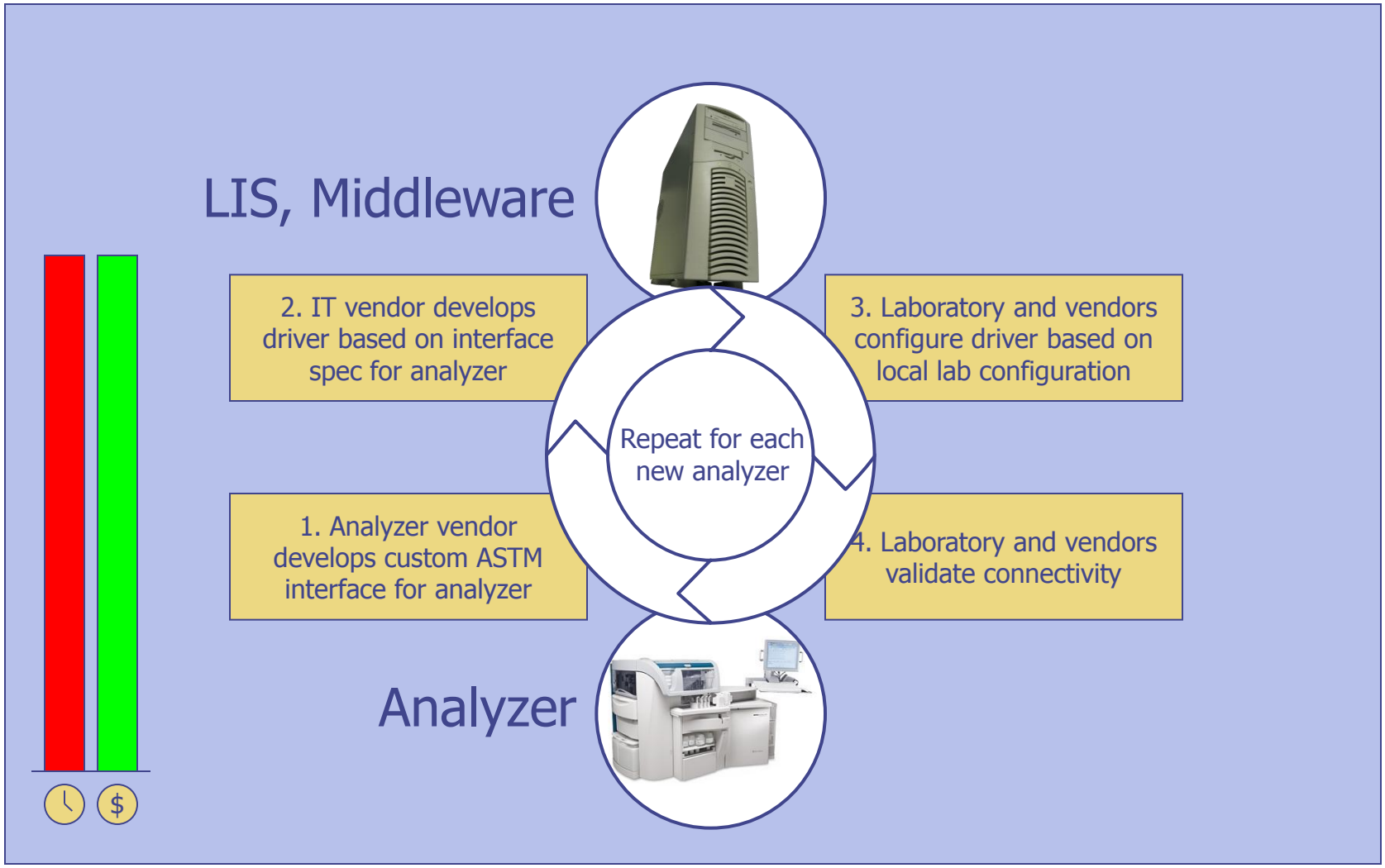

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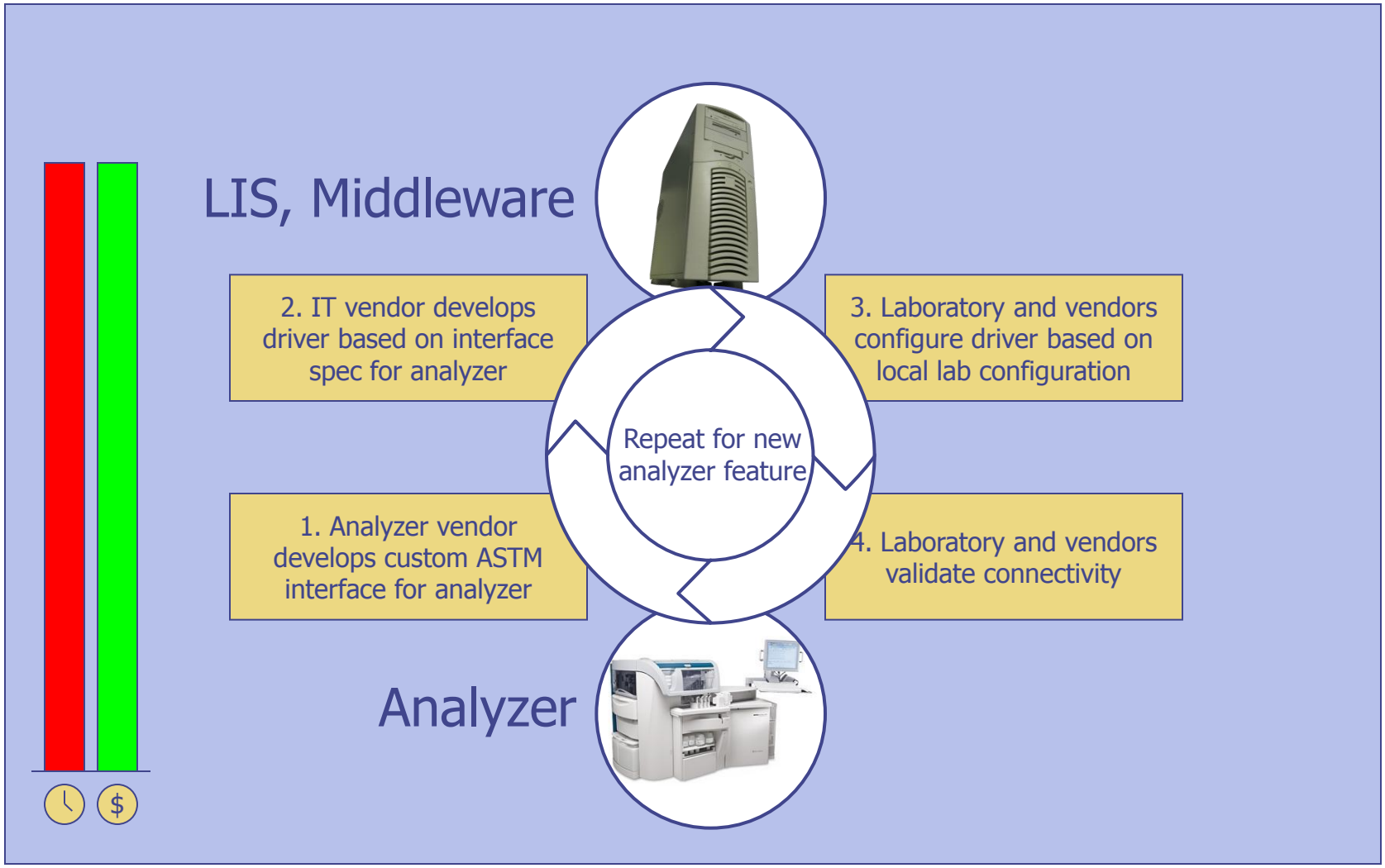

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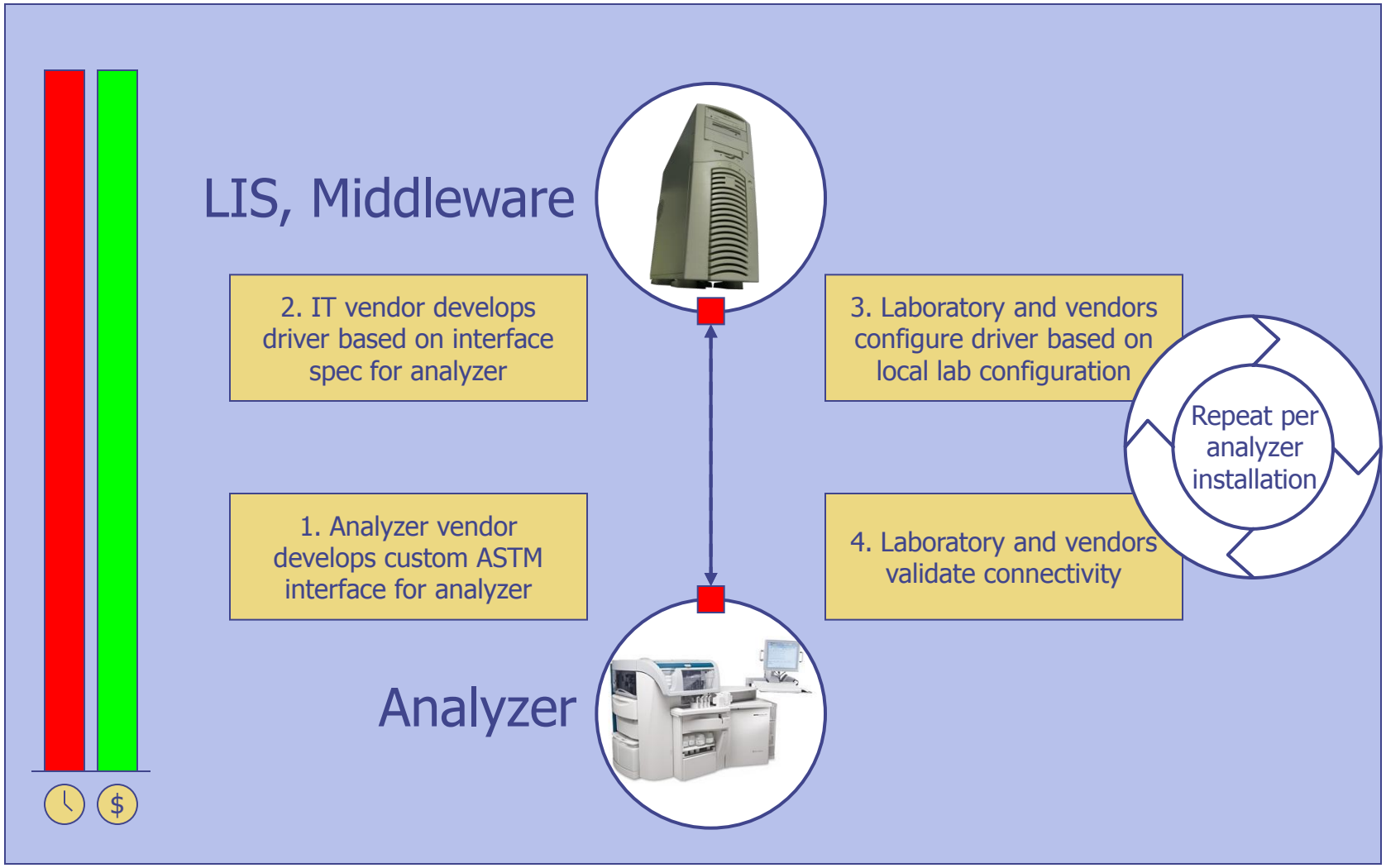

Reducing complexity will reduce time and cost

- Time and money spent on interfacing should be spent elsewhere
- The ideal endpoint is plug and play interoperability
- Complexity can be reduced via elimination of variability in standards implementation at three layers:
  - Use Case Layer (major variation)
  - Messaging Layer (major variation)
  - Low Level Layer (minor variation)

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Mission

To create and ensure adoption of an interoperable connectivity paradigm to reduce the complexity and variability of data exchange between IVD testing systems and healthcare informatics systems

"reduce the complexity and variability of data exchange"

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"interoperable connectivity paradigm"

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To create and ensure adoption of an interoperable connectivity paradigm to reduce the complexity and variability of data exchange between IVD testing systems and healthcare informatics systems

"create and ensure adoption"

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To create and ensure adoption of an interoperable connectivity paradigm to reduce the complexity and variability of data exchange between IVD testing systems and healthcare informatics systems

"between IVD testing systems and healthcare informatics systems"

Scope: Absolutely Global

- Most labs may be country-oriented, but most IVD products are sold globally
- We have to balance differences between Europe, US, Japan, and others
- We have to ensure that national efforts keep globalization in mind (e.g. HITSP)

Scope: Types of data flows

In Scope:

- IVD Test Orders (Patient & Quality Control)
- IVD Test Results (Patient & Quality Control)

Out of Scope (Potential Future Effort):

- Calibration Data
- Configuration Information
- Process Status Monitoring

Scope: Types of IVD testing

In Scope (Priority Order):

1. Clinical Chemistry
2. Immunoassay
3. Hematology
4. Hemostasis
5. Microbiology
6. Molecular

Out of Scope:

- Point of Care
- Anatomic Pathology
- Imaging

Scope: Types of IT systems

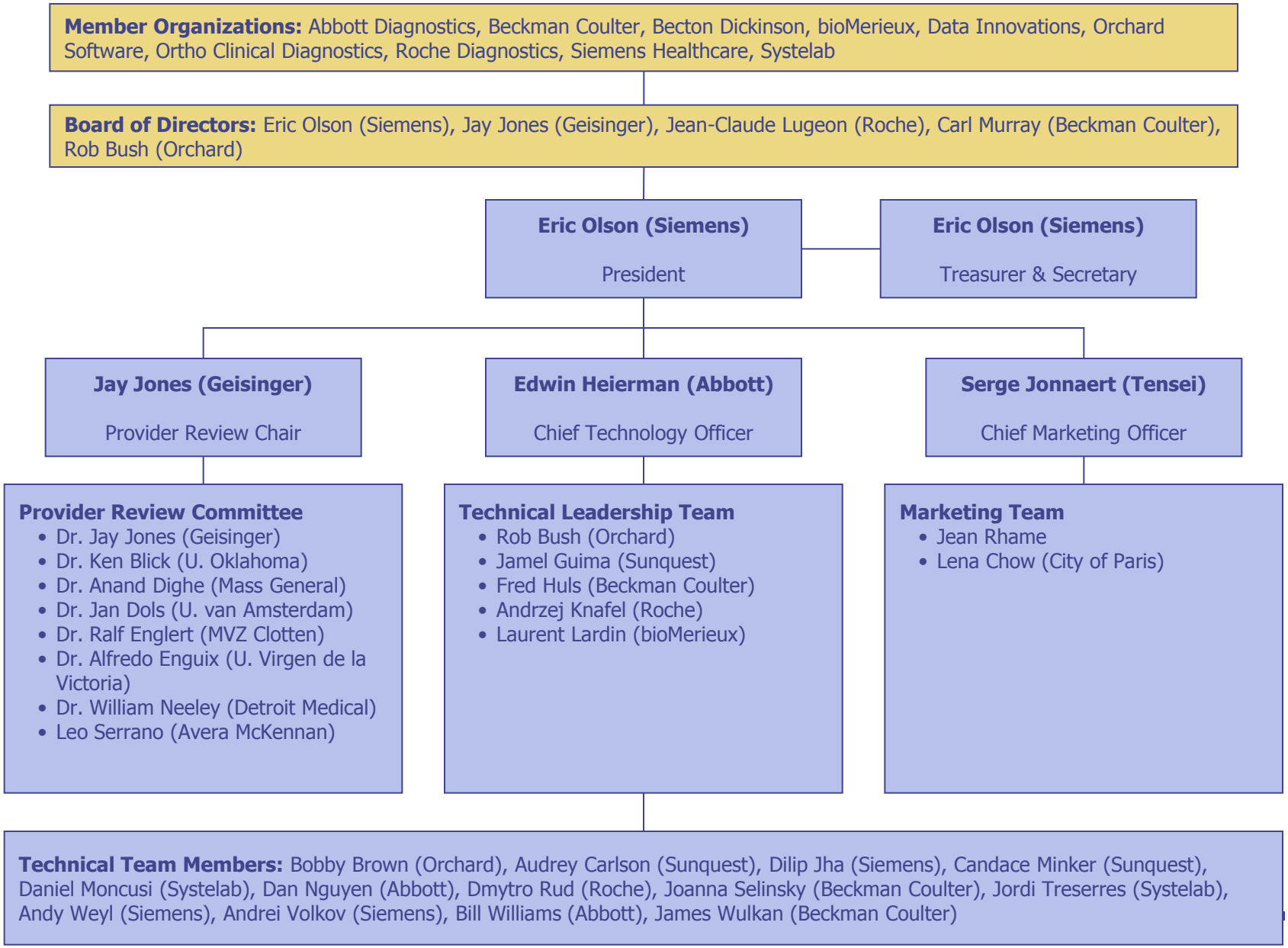
In Scope:

- IICC will cover the transmission of orders and results between IT systems and IVD analyzers
- IICC will not attempt to distinguish the roles of different types of IT systems (e.g. LIS, middleware, automation manager)

Out of Scope:

- IICC will not attempt to standardize the features of IT systems – only their external connectivity
- IICC is not specifically focused on middleware

IVD Industry Connectivity Consortium (IICC)



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IICC has partnered with CLSI, IHE, and HL7

Technology Adoption
- Partner with CLSI
- Laboratory standards publication, e.g. a new LIS standard

Use Case Layer
- Partner with IHE
- Build on the work of IHE's LDA (Lab Device Automation)

Message Layer
- Partner with HL7
- Build on the work of HL7's v2.x Standard

Low Level Layer
- Partner with HL7
- Build on the work of HL7's MLLP (Minimal Low Level Protocol)

Partnership with IHE LAB

- Leverage the talents of the active members of IHE LAB
- Build from LDA profile that is the closest our industry has come to achieving interoperability
- Utilize IHE's approach to constraining standards
- Utilize IHE's approach to demonstrating conformance
  - Connectathons
  - Showcases

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Development of new IHE Laboratory Profile

- Split LDA (Laboratory Device Automation) into two profiles
  - LDA
    - Automation Manager
    - Pre/post processor
  - LAW (Laboratory Analytical Workflow)
    - Analyzer Manager
    - Analyzer
- Create international implementation guide that defines the minimum set of interactions required for plug-n-play
  - Provides basic functionality
  - Optional interactions can be supported though configuration changes

Extend Existing IHE Use Cases that Provide Partial Coverage

- Unsolicited new Work Order Step (WOS) download
- Unsolicited WOS update or cancel
- LD query for WOS for specific specimen(s)
- WOS manually entered at LD
- Upload to AM final results generated on LD
- Rerun decided on LD
- Rerun decided on AM

Define New Use Cases

- LD query for WOS for all specimens
- LD informs AM about WOS validity status
- Upload to AM preliminary results generated on LD
- Retransmit results to AM
- AM informs LD about observation validity status
- Pooling of patient specimens
- Reflex test decided on LD
- Reflex test decided on AM

Define Behavior and Messages for LAW Profile

- IHE Laboratory Technical Framework Volume I contains use case and transaction definitions
- IHE Laboratory Technical Framework Volume II contains message (HL7) definitions

Summary of Baseline Standard Selection

- Considered ASTM, HL7 v2.x, and HL7 v3
- Basic Messaging Requirements:
  - Evaluated standards against basic messaging requirements
  - Reviewed with domain experts
  - HL7 v3 (89%) > HL7 v2.x (83%) > ASTM (37%)
- Use Case Considerations:
  - Developed IICC Use Cases using IHE as a starting point
  - Evaluated standards support for use cases
  - HL7 v3 (91%) = HL7 v2.x (91%) > ASTM (59%)
- Low Level Considerations:
  - Established low level scope and requirements
  - Evaluated standards support for low level recommendations
  - HL7 v3 (68%) > HL7 v2.x (62%) > ASTM (55%)
- Evaluated Nontechnical Considerations

Baseline Standard Selection Status

Calculate the scores and combine it in the standard evaluation matrix with the analysis by Use Cases, Messaging, and Low Level Protocol teams.

Project Name:	**IICC Messaging Standard**	**Description:**	**Selection of Baseline Standard and Partner SDO**
Team Leader:	**Andrzej J. Knafel**	**Team Members:**	**Dan Roberts (Siemens); Daniel Moncusi (NTE); Ed Harshberger (BioMerieux); Oday Hameed (Abbott); Sarkis B. Abadjian (Beckman Coulter)**

	Scoring (modify as needed)		HL7 v2.x			HL7 v3			CLSI LI2 / ASTM E1394		
	Item Weight	**Score Criteria**	**Response**	**Item Score**	**Total Score**	**Response**	**Item Score**	**Total Score**	**Response**	**Item Score**	**Total Score**
General comment / statement about the offer			**Technical concepts older, but well maintained. Popular in the LIS and complex Lab Automation. Stable base for the future.**			**Technical concept future oriented, but low popularity, cumbersome in implementation and high resource demand.**			**Technical concept not state of art. Very popular at device level.**		
Technical Information											
Fulfillment of the use cases & data requirements	**15**	None = 0% ... Full = 100% (based on a separate requirements coverage analysis)		91%	13.7		91%	13.7		59%	8.9
Support for messaging requirements	**15**	None = 0% ... Full = 100% (based on a separate requirements coverage analysis)		83%	12.5		89%	13.4		37%	5.6
Support for low level requirements	**5**	None = 0% ... Full = 100% (based on a separate requirements coverage analysis)		62%	3.1		68%	3.4		55%	2.8
Complexity of implementation	**15**	High complexity = 0, Moderate = 0.5, Low complexity, tools and support available =	Moderate	1	15.0	High	0	0.0	Moderate	1	15.0
Total Technical Information	**50**				**44.2**			**30.4**			**32.2**
Organizational Information											
Ease of adoption by IVD and LIS vendors	**20**	Limited = 0, Adequate = 0.5, Exclint = 1	Adequate	0.5	10.0	Poor	0	0.0	Adequate	0.5	10.0
Future potential of the standard protocol	**10**	Limited = 0, Adequate = 0.5, Exclint = 1	Adequate	0.5	5.0	Excellent	1	10.0	Poor	0	0.0
Standard development process of the SDO	**5**	Poor (cumbersome or chaotic) = 0, Adequate = 0.5, Exclint = 1	Adequate	0.5	2.5	Adequate	0.5	2.5	Adequate	0.5	2.5
Standard development and publication timeline	**5**	Unacceptbl long and no IICC influence =0, Accptbl length / freq =0.5, Driven by IICC =1	Acceptable	0.5	2.5	Acceptable	0.5	2.5	Acceptable	0.5	2.5
SDO cooperation model	**8**	Poor influence =0, Adeq. (voting in existing committee) =0.5, Dedicated committee =1	Adequate	0.5	4.0	Adequate	0.5	4.0	Excellent	1	8.0
Licensing model and publication model	**2**	Poor = 0, None/Accptbl = 0.5, Good (low cost and easy available) = 1	None/Acceptable	0.5	1.0	None/Acceptable	0.5	1.0	None/Acceptable	0.5	1.0
Total Organizational Information	**50**				**25.0**			**20.0**			**24.0**
Total Score (technical & organizational)	**100**				**69.2**			**50.4**			**56.2**

Evaluation input by technical teams

Resulting score

Evaluation Score Summary

- HL7 v2.x: **69.2**
- HL7 v3: **50.4**
- ASTM 1394 / CLSI LIS-2: **56.2**