HIMSS Electronic Health Record Vendor Association

EHR Clinical Research Integration Project

Spring AMIA

Informatics Across the Spectrum

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Discussion Points

- HIMSS EHRVA Background
- Collaboration with PhRMA
  - PhMRA Education - 2006
  - HIMSS EHRVA / PhRMA / Life Sciences / Clinical Research Meeting – February 25, 2007
  - HIMSS EHRVA Pharmaceutical Industry Workgroup
- Future Opportunities

EHRVA Mission

Promote the rapid adoption of electronic health records that advance cost effective healthcare

Provide a unified voice and a forum for cooperation for the EHR vendor community

Strategic Plan focuses on these areas

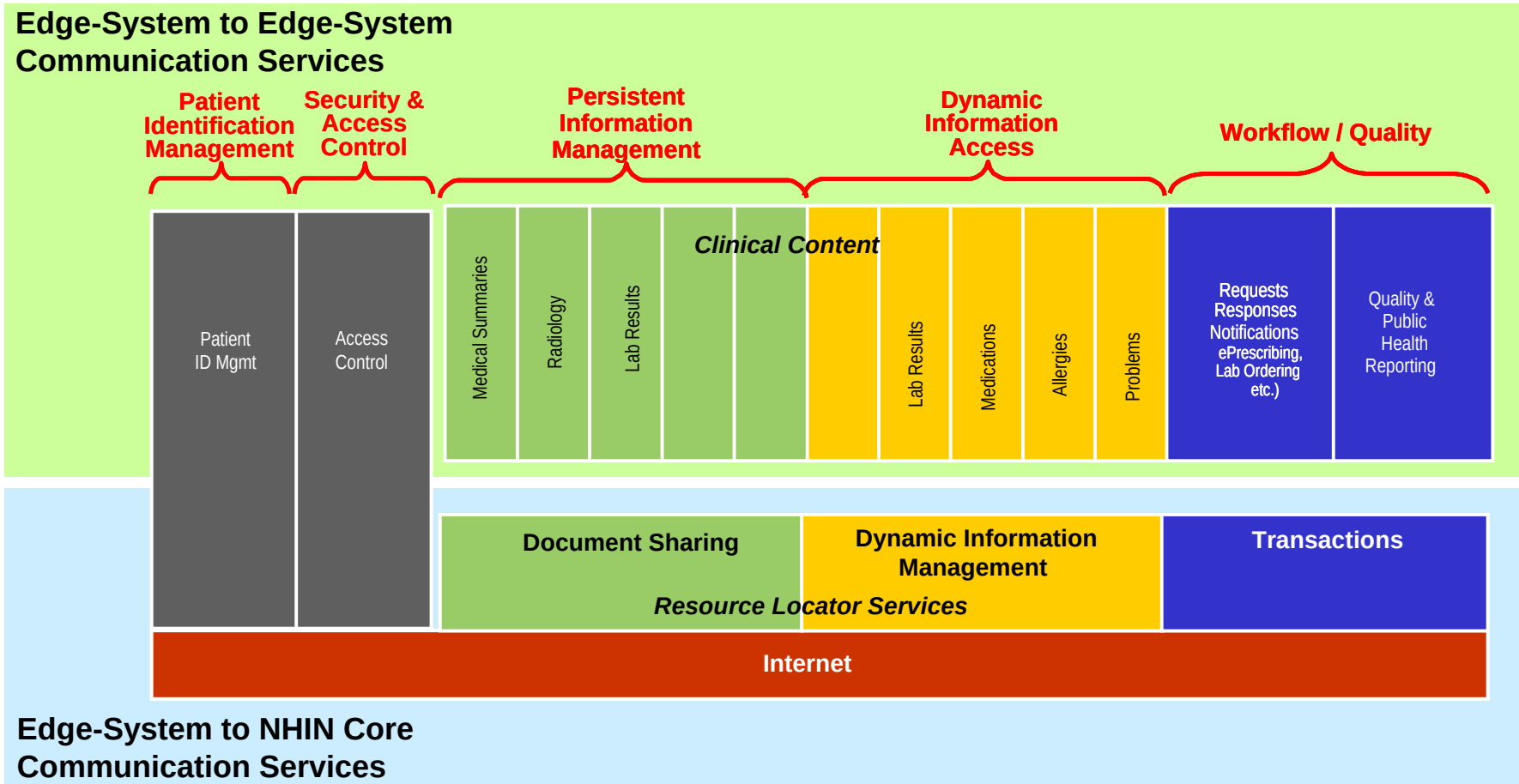
- Certification
- Interoperability
- Advocacy / Public Policy
- Quality

EHRVA members

EHRVA members

EHRVA Interoperability Roadmap

- **Five communication services building blocks**
- **Framework that supports incremental evolution**
- **Transparency between Edge Systems & Edge-Core interface**



EHRVA Pharmaceutical Industry Workgroup Members

Shelley Fichtner, PhRMA

Daijin Kim, Pfizer

Kraig Kinchen, Eli Lilly

Tanuj Gupta, AstraZeneca

Hima Kher, Bristol-Myers Squibb

Mitra Rocca, Novartis

Kim Slocum, KDS Consulting (Facilitator)

Justin Barnes, Noteworthy

Charlie Jarvis, NextGen

Don Schoen, Medinotes

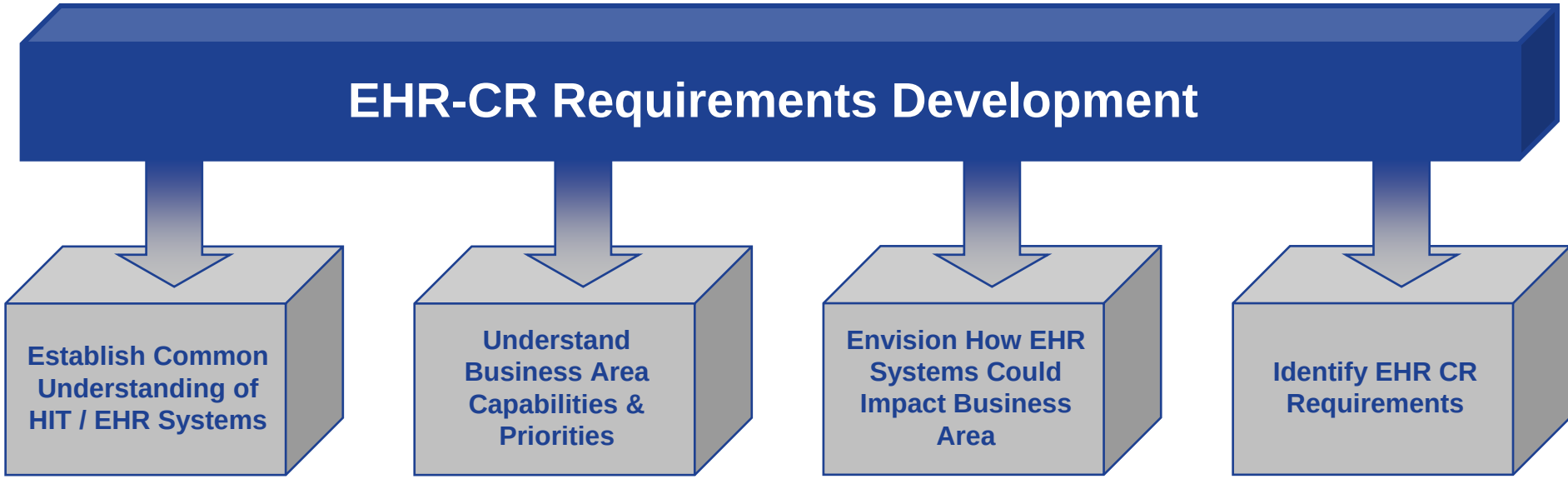
Charlene Underwood, Siemens Medical Solutions

Hugh Zettel, GE Healthcare

Education Topics – Potential “use cases”

- Electronic Health Records and Outcomes Research
- Matching Investigators and/or Patients to Clinical Trials
- EHR/EDC (Electronic Data Capture)
- Drug Safety and Surveillance
- Coordination of Care for Chronic Disease

Using EHRs to Support Research



- **NHIN Slipstream Project – AstraZeneca, Bristol-Myers Squibb, Pfizer, Wyeth**
- **Electronic Health Records and Clinical Research – Pfizer**
- **Implications of Electronic Health Records for the Pharmaceutical Industry – Astra Zeneca**

Use Cases

- Clinical Trial Data Collection
- Clinical Trial Recruitment
- Understand Disease Progression
- Understanding Disease Mechanism
- Epidemiology (Study disease prevalence in populations)
- Document Management for Clinical Trials
- Drug Safety Surveillance
- Outcomes Research
- Support Regulatory Approval
- Audit Medication Workflow
- Trial Subject Compliance
- Virtual Phase IV trials
- Study Drug Use Post-Launch
- Remote Site Monitoring

Clinical Research Requirements

Requirements are grouped by category and can be filtered by use case or system type.

	Req #	Requirements Description	Clinical Research Use Cases													System Type				
			Understanding Disease Mechanism	Clinical Trial Data Collection	Clinical Trial Recruitment	Document Management for Clinical Trials	Understanding Disease Progression	Drug Safety Surveillance	Epidemiology	Outcomes Research	Support Regulatory Approval	Remote Site Monitoring	Study Drug Use Post-Launch	Audit Medication Workflow	Trial Subject Compliance	Virtual Phase IV Trials	EMR	EHR	PHR	Other System(s)	
3		**1. Data Capture & Interfaces**																			
4	1.1	Ability to interface clinical modules within a provider organization (eg. registration, lab, CPOE, radiology, etc...).	X	X	X		X	X	X	X	X		X	X	X	X	X				This will ena patient's me systems wit
5	1.2	Ability to connect data from EMR systems from many different provider organizations to create a patient's complete longitudinal record.	X		X		X	X	X	X	X	X	X	X		X	X	X	X		This may inc Record Loc other health
6	1.3	Ability to interface clinical modules with insurance company & pharmacy systems in order to capture insurance eligibility and medication/treatment costs.								X			X				X	X		X	
7	1.4	Ability to connect EMR/EHR systems with regulatory systems, research systems, clinical trial sponsor systems, and/or other 3rd party systems.	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	This will ena patients' lon external sys
8	1.5	Ability to connect eMAR, CPOE, pharmacy systems with the EMR system in order to capture a patient's complete medication information/history.	X	X	X		X	X		X	X		X	X	X	X	X	X	X	X	Enables one medication
9	1.6	Ability to connect the EMR/EHR with other systems used for physician credentialing in order to register physicians as investigators.		X	X						X						X	X		X	
10	1.7	Capture patient clinical data that may have been entered via transcription.	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	
11		**2. Identity & Confidentiality**																			
21		**3. Data Content**																			
56		**4. Data Exchange**																			
64		**5. Functionality**																			
78		**6. Data Access/Authentication/Audit & Logging**																			
87		**7. Data Quality/Data Integrity (Standards)**																			
96		**8. Data storage**																			
102		**9. Other Systems Capabilities**																			
133		**10. Non-System requirements**																			

Use cases from IHE/CDISC Demo (HIMSS 2007)

Clinical Trial: Lab and Image Data

Sponsored by Novartis

Powered by

Novartis

Siemens

SAS

Clinical Trial: Visit Workflow

Sponsored by Eli Lilly and Company

Powered by

Cerner Corporation

Phase Forward

IBM

Drug Safety

Sponsored by Pfizer

Powered by

Sentrx/Relsys

Allscripts

Accenture

SAS

Disease Registry

Sponsored by Genzyme

Powered by

•Outcome

•Allscripts

•Digital Infuzion

•SAS

•Assero/IPL

Collaboration Opportunities

Help private sector develop a roadmap to shared value

- Mutual understanding of business processes, use case and priorities
- Leverage Use Case Development

Continue to invest in EHR/EDC initiatives

- Standards, IHE & CDISC
- Controlled Medical Vocabulary

Interoperable EHRs to be certified; work to make sure that what is certified meets your needs

- Clinical Labs
- E-prescribing
- Quality (i.e., Adverse Events)
- Population Health