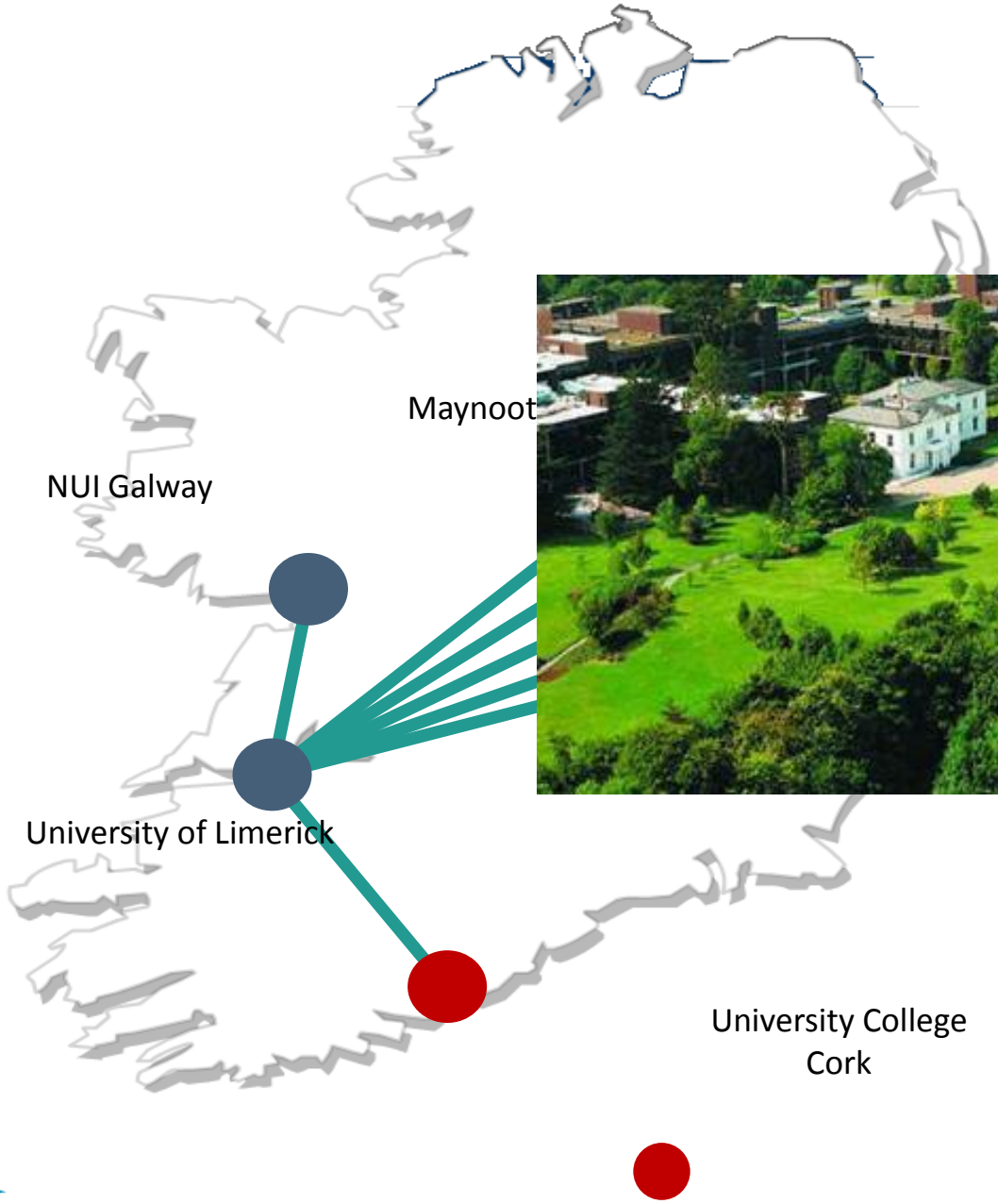
Lero THE IRISH SOFTWARE RESEARCH CENTRE

Overview of Lero Research

Dr Ita Richardson
June 2015

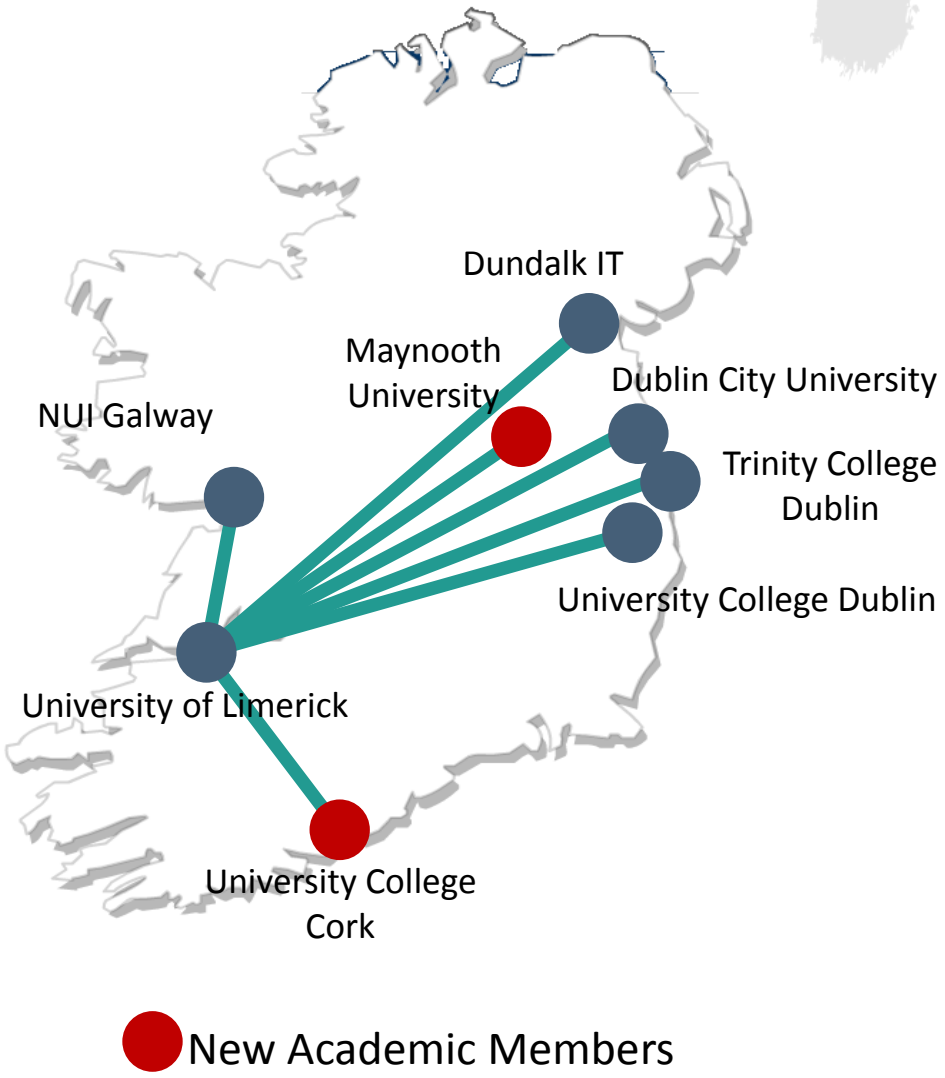
University of Limerick
Trinity College Dublin
DCU
UCD Dublin
OÉ Gaillimh NUI Galway
Dundalk Institute of Technology
UCC University College Cork, Ireland
Maynooth University National University of Ireland Maynooth


Maynooth
NUI Galway
University of Limerick
University College Cork

Limerick

Lero: A National Research Centre

- Funded as an SFI CSET in 2005, extended in 2011. Awarded over €60M in research funding from multiple sources
- Currently 40+ academics, 38 researchers and c. 70 PhD students
- Output to date: 324 journal papers, 25 books and 672 conference papers
- Worked with over 100 software companies in Ireland and the EU
- Recently announced funding as an SFI Research Centre 2015-2020 at a 50% greater scale with two new academic members



The Lero Research Centre Team

The quality of the applicants is the key strong point of the proposal… one can expect world-class output from its individual members

- ***SFI*** *Scientific Review*

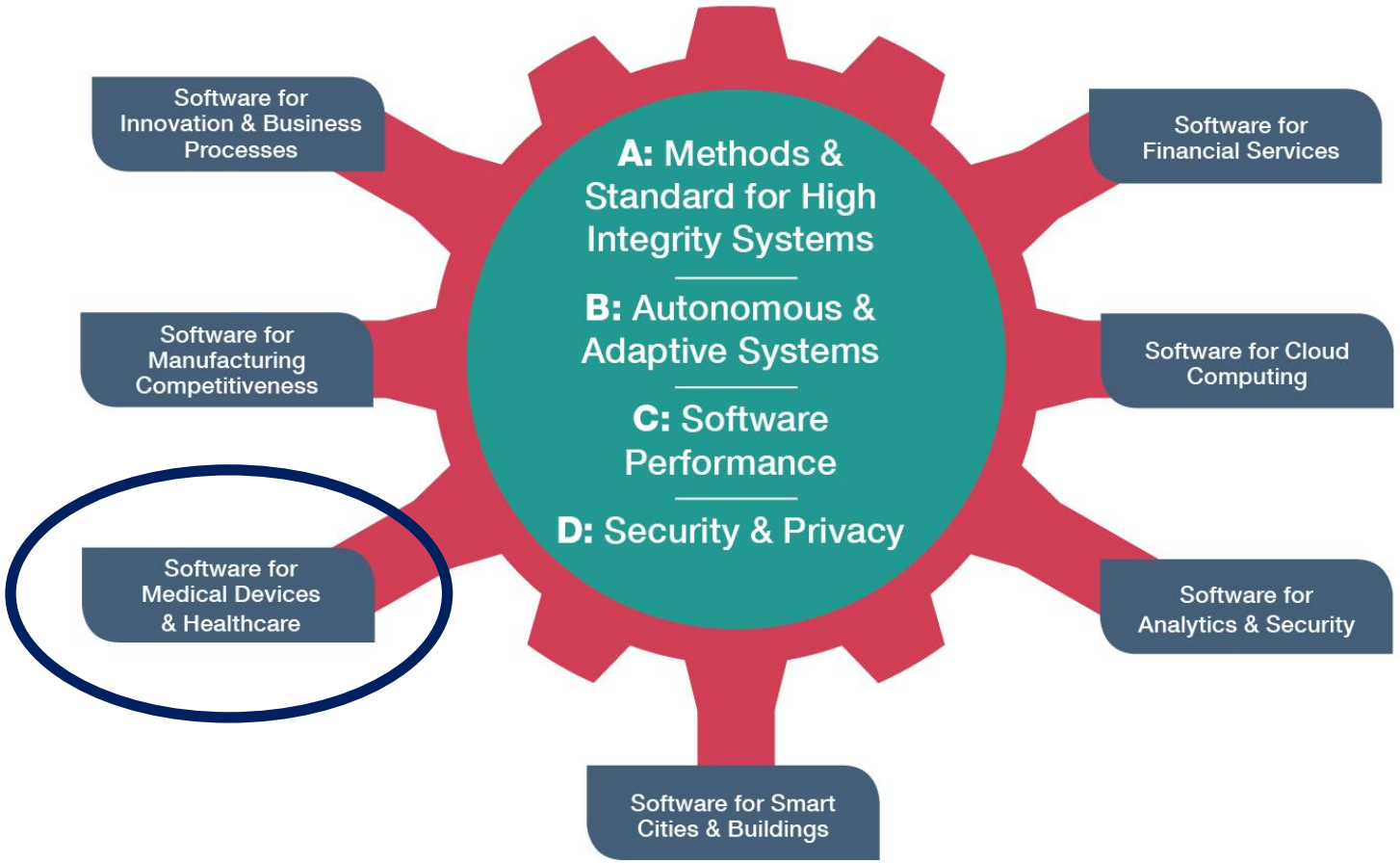
Academic T

- World class – best research in Ireland from all the universities
- 70,000 citations
- 6 Spinouts, 26 patents (+ 20 pending)
  11 licences and 5 standards

stry Team

- International household names to small local companies
- Multiple industry sectors
- Committed ~€14m in contributions (€4.6m cash)

Lero Hub & Spoke Research



- Hub comprises four core research areas
- Spokes focus on key priority areas addressing challenges faced by industry partners

Lero Metrics: 5Ps

Publications

- Quantity–> Quality
- Top journal/conferences
- Impact/ citations

Personnel

- Postdocs
- PhDs
- Industry-based Phds (D.Eng)
- Parnas Fellow

Projects (Funding)

Practice Impact

Prestige

ARCH
Applied Research for Connected Health

Lero THE IRISH SOFTWARE RESEARCH CENTRE

Medical Device and Healthcare Research

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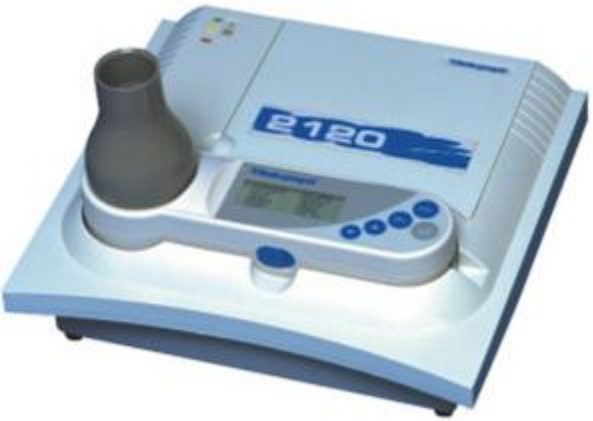
Software embedded in Medical Devices

Software within Medical Devices

Up to 70% of budget on software related activities



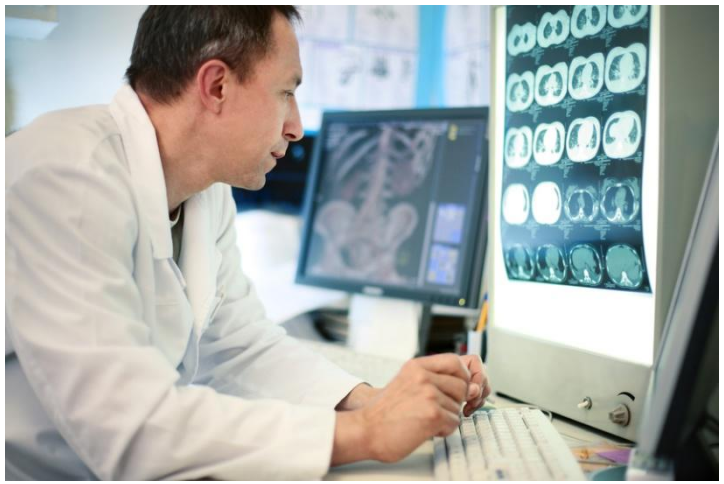
Medical Device Software - External

Software in Medical Device production lines

Healthcare software

Software manipulating Clinical data

Health Information Systems



RESEARCH CHALLENGES (SOFTWARE)
Medical Devices and Healthcare

How can Software Engineering processes comply with regulations?

How can we ensure the correct use and implementation of software in healthcare situations?

How can we Connect software, technology, data and processes for use by differing stakeholders?

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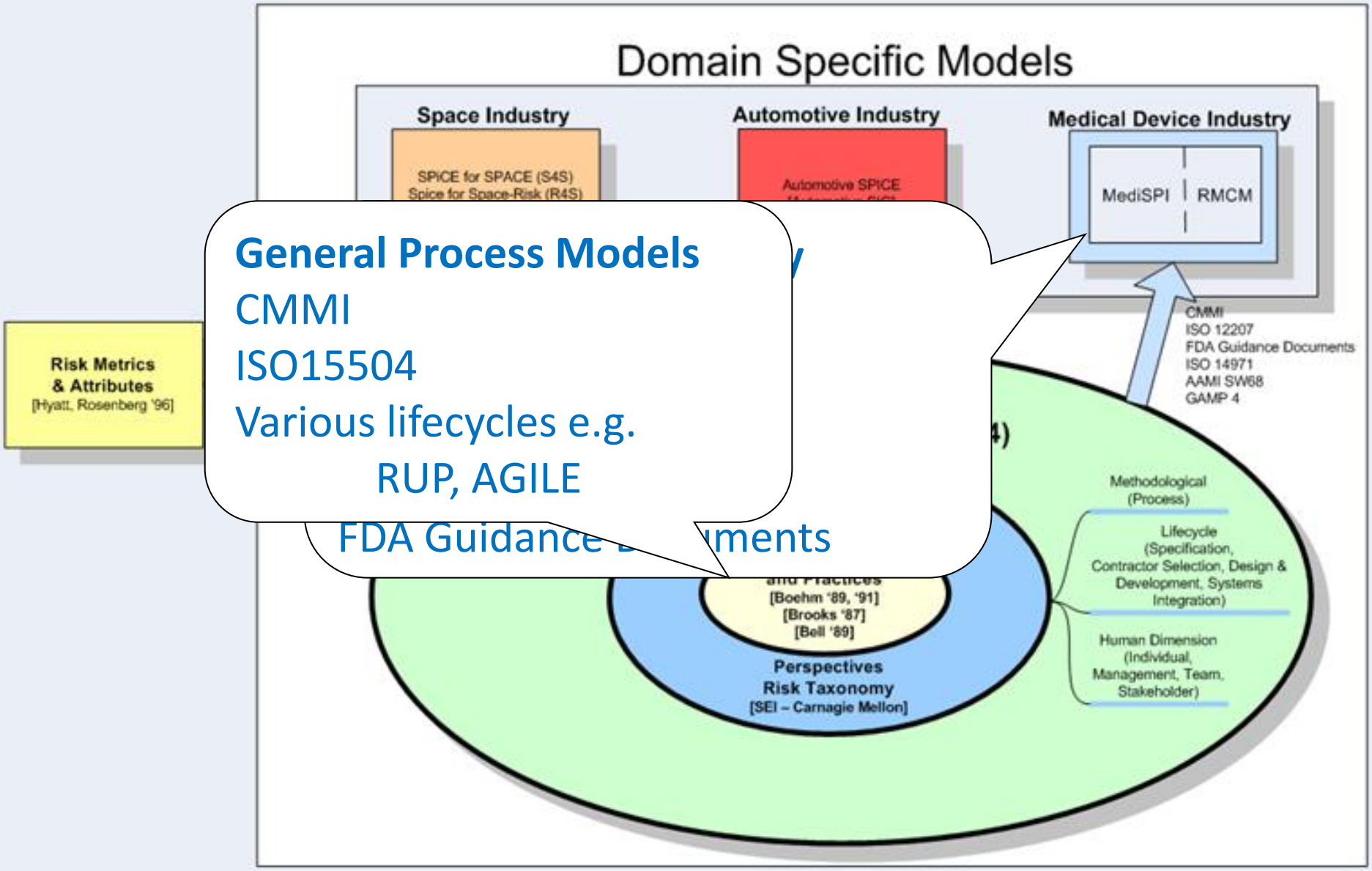
EU Directives - 2007, 1993

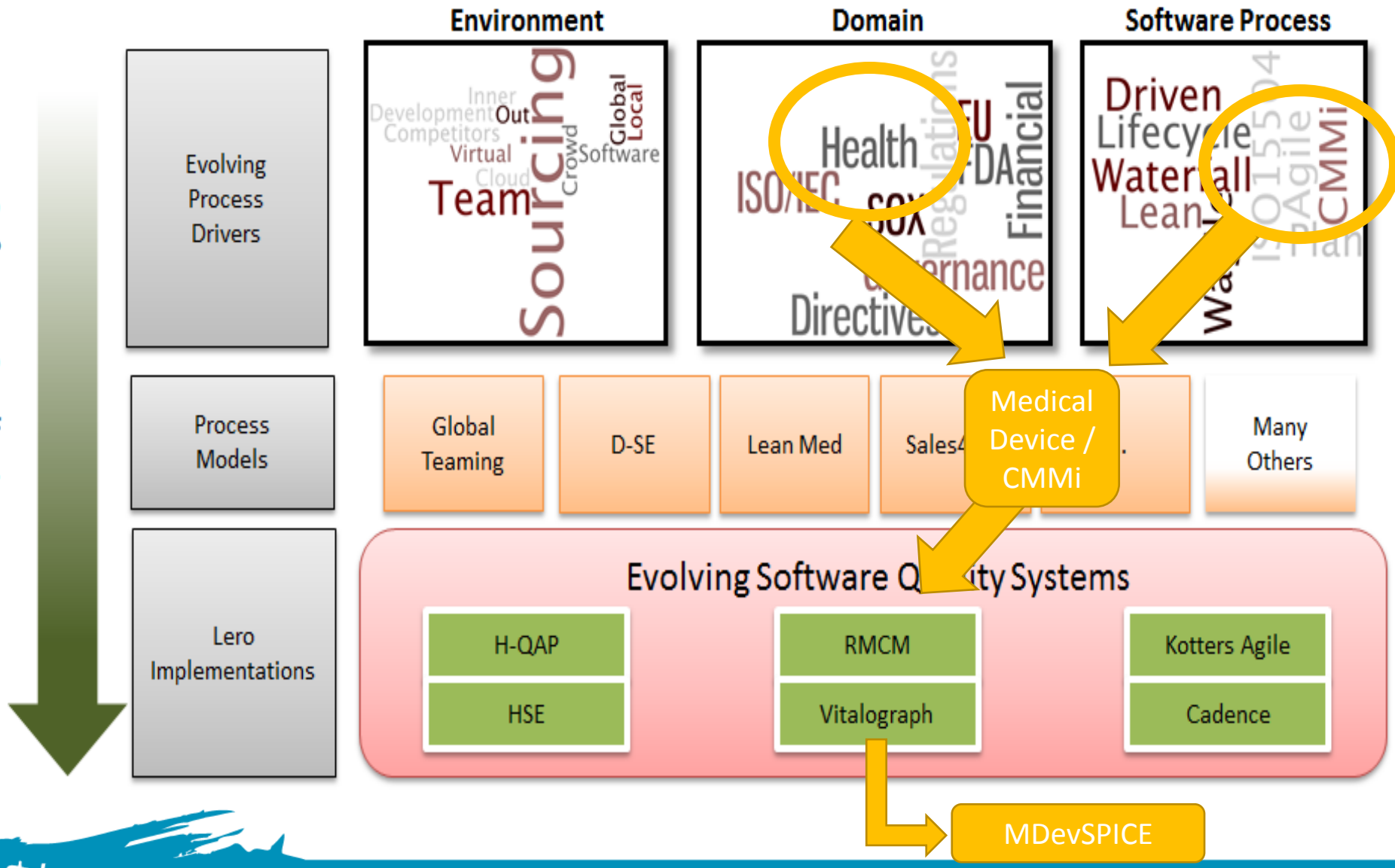
- ….software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device. Software for general purposes when used in a healthcare setting is not a medical device

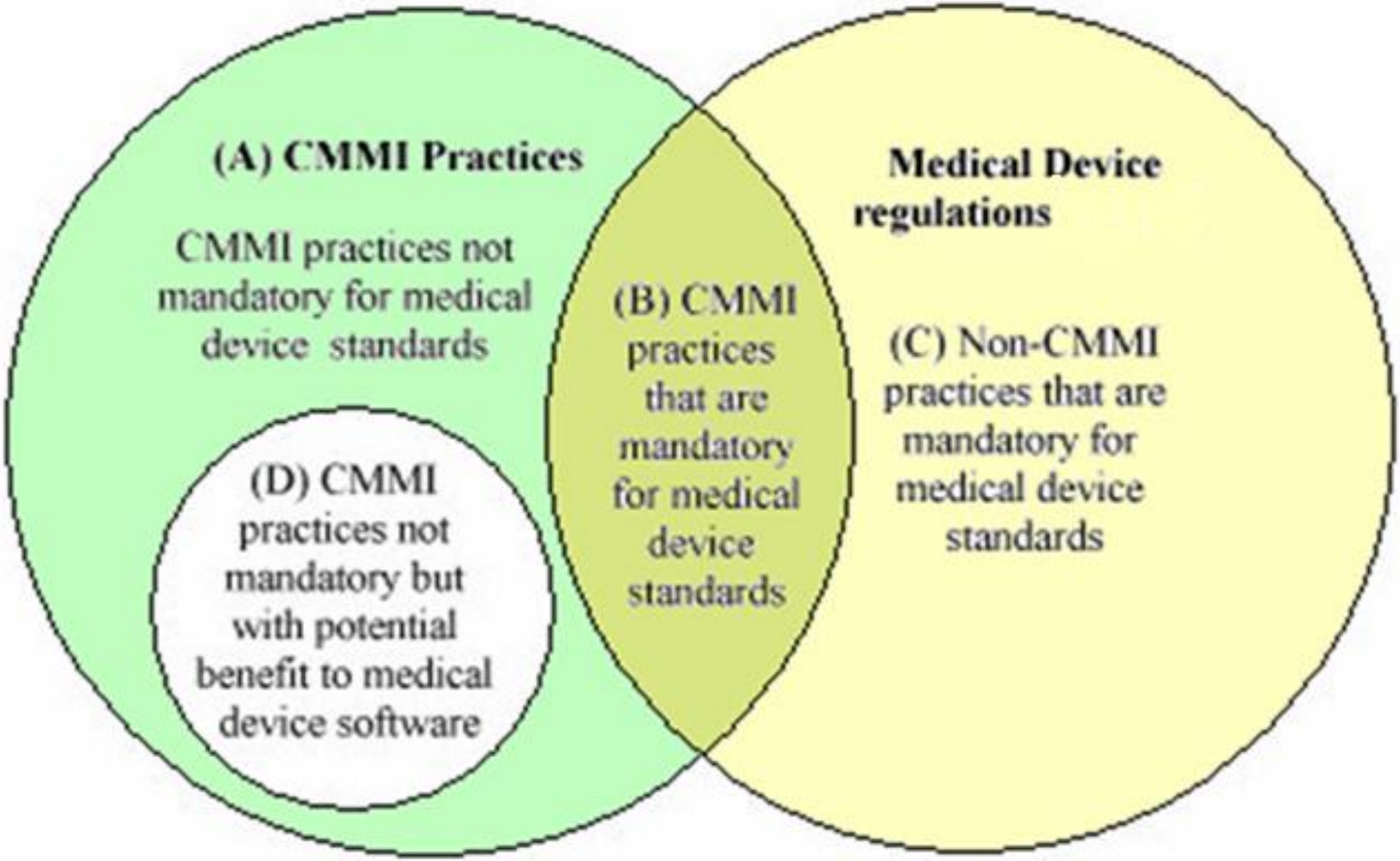
- 'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of: - diagnosis, prevention, monitoring, treatment or alleviation of disease injury or


Domain Specific Models
Space Industry
SPICE for SPACE (S4S)
Spice for Space-Risk (R4S)
Automotive Industry
Automotive SPICE
Medical Device Industry
MediSPI
RMCM
CMMI
ISO 12207
FDA Guidance Documents
ISO 14971
AAMI SW68
GAMP 4
Risk Metrics
& Attributes
[Hyatt, Rosenberg '96]
General Process Models
CMMI
ISO15504
Various lifecycles e.g.
RUP, AGILE
FDA Guidance
uments
Methodological
(Process)
Lifecycle
(Specification,
Contractor Selection, Design &
Development, Systems
Integration)
Human Dimension
(Individual,
Management, Team,
Stakeholder)
[Boehm '89, '91]
[Brooks '87]
[Bell '89]
Perspectives
Risk Taxonomy
[SEI – Carnagie Mellon]

Effect on Software Industry

- Standards not developed specifically for software development
- Software Engineers must be aware of regulatory requirements
- Software Engineers must be able to adapt software process to support regulatory requirements
- Software process models have not been developed based on regulatory requirements
  - Capability Maturity Model Integrated
  - ISO15504


Environment
Domain
Software Process
Evolving Process Drivers
Process Models
Lero Implementations
Software Quality Improvement
Sourcing
Team
Out
Inner
Development
Competitors
Virtual
Cloud
Crowd
Software
Global
Local
Health
Financial
Directives
Driven
Lifecycle
Waterfall
Lean
CMMi
Global Teaming
D-SE
Lean Med
Many Others
Medical Device / CMMi
Evolving Software Quality Systems
H-QAP
HSE
RMCM
Vitalograph
Kotters Agile
Cadence
MDevSPICE


(A) CMMI Practices
CMMI practices not mandatory for medical device standards
(D) CMMI practices not mandatory but with potential benefit to medical device software
(B) CMMI practices that are mandatory for medical device standards
Medical Device regulations
(C) Non-CMMI practices that are mandatory for medical device standards

Regulations

- Code of Federal Regulations – Title 21 Section 820 (21CFR820 2009)
  - Food & Drug Administration (FDA) Regulation
- Sec 820.181 – Device Master Record
  - Equivalent to Requirements Specification
- Sec 820.184 Device History Record
  - Class I software - traceability and identification

Requirements Development SG1 Develop Customer Requirements

No.	Deliverable	Legislation
SP 1.1	Documented methods for need elicitation	21CFR820 – Section 181/184 – Device Master Record(DMR) /Device History Record(DHR) – Production process specifications
SP 1.2	Customer Requirements	DMR
SP 1.2	Customer constraints on the conduct of verification	DMR
SP 1.2	Customer constraints on the conduct of validation	DMR

RD: SG1 Checklist

SP 1.1	**Are stakeholder needs being recorded?**
SP 1.1	**Have business goals being documented?**
SP 1.1	**Have any relevant legal requirements been elicited?**
SP 1.2	**Is there any missing information which at the end of the requirements consolidation which needs to be addressed? There should be none.**
SP 1.2	**Are all conflicts resolved, and the decisions and reasoning documented?**

Risk Management

Goal	CMMI® Activities	CMMI® Activities required to meet regulatory requirements	Additional Activities required to meet regulatory requirements)
SG 1: Prepare for risk management	6	6	10
SG 2: Identify and Analyse Risks	9	4	4
SG 3: Mitigate Risks	9	6	6
Sub Total	**24**	**16**	**20**
GG2: Institutionalise a Managed Process	10	6	0
GG3: Institutionalise a Defined Process	2	0	0
GG4: Institutionalise a Quantitatively Managed Process	2	0	0
GG5: Institutionalise an Optimising Process	2	0	0
Total	**40**	**22**	**20**

RESEARCH CHALLENGES (SOFTWARE)
Medical Devices and Healthcare

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How can we e, technology, data and process ering stakeholders?

Medical Device Standards combined with Software Standards

MDevSPICE

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Analysis

- Published Research
  - Medical Inquiries, Academic Research, Standards and Regulations (Medical and Software)
- Use of Software & Technology
  - Participant observation, Study of Documentation, Interviews, Focus Groups, Workshops

Results: Hospital Information Systems

- Information systems used hospital wide
- Information systems used specifically by single departments
- Information systems are used personally by clinicians
- No integrated electronic patient record (EPR)
- Primary medical record is paper based

Results: Clinicians

- Healthcare needs to evolve with technology

HOWEVER Clinicians do not understand:

- Quality Requirements in the Clinical Environment for use of technology
- Regulations regarding the development of software which includes excel and mobile phone apps
- Risk involved in manipulating data from a certified Medical Device

Software Quality Improvement

Evolving Process Drivers

Process Models

Lero Implementations

Environment

Domain

Software Process

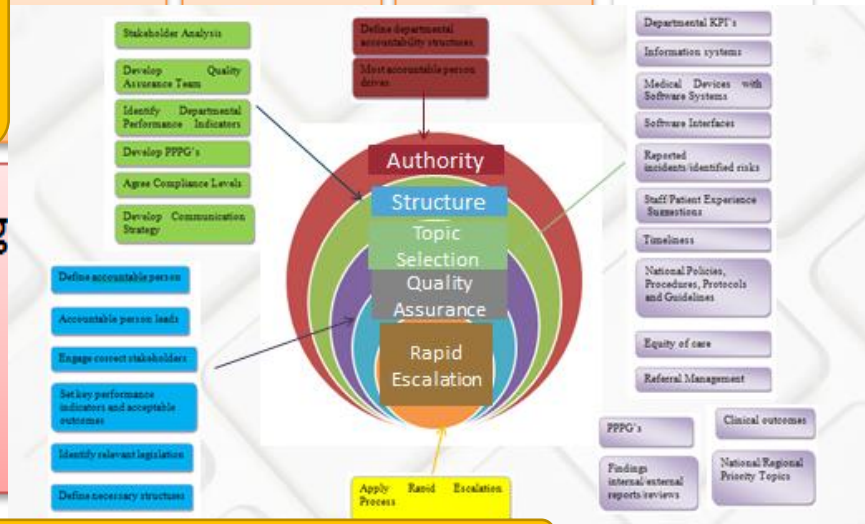
Global Teaming

Health care/ Quality

Evolving

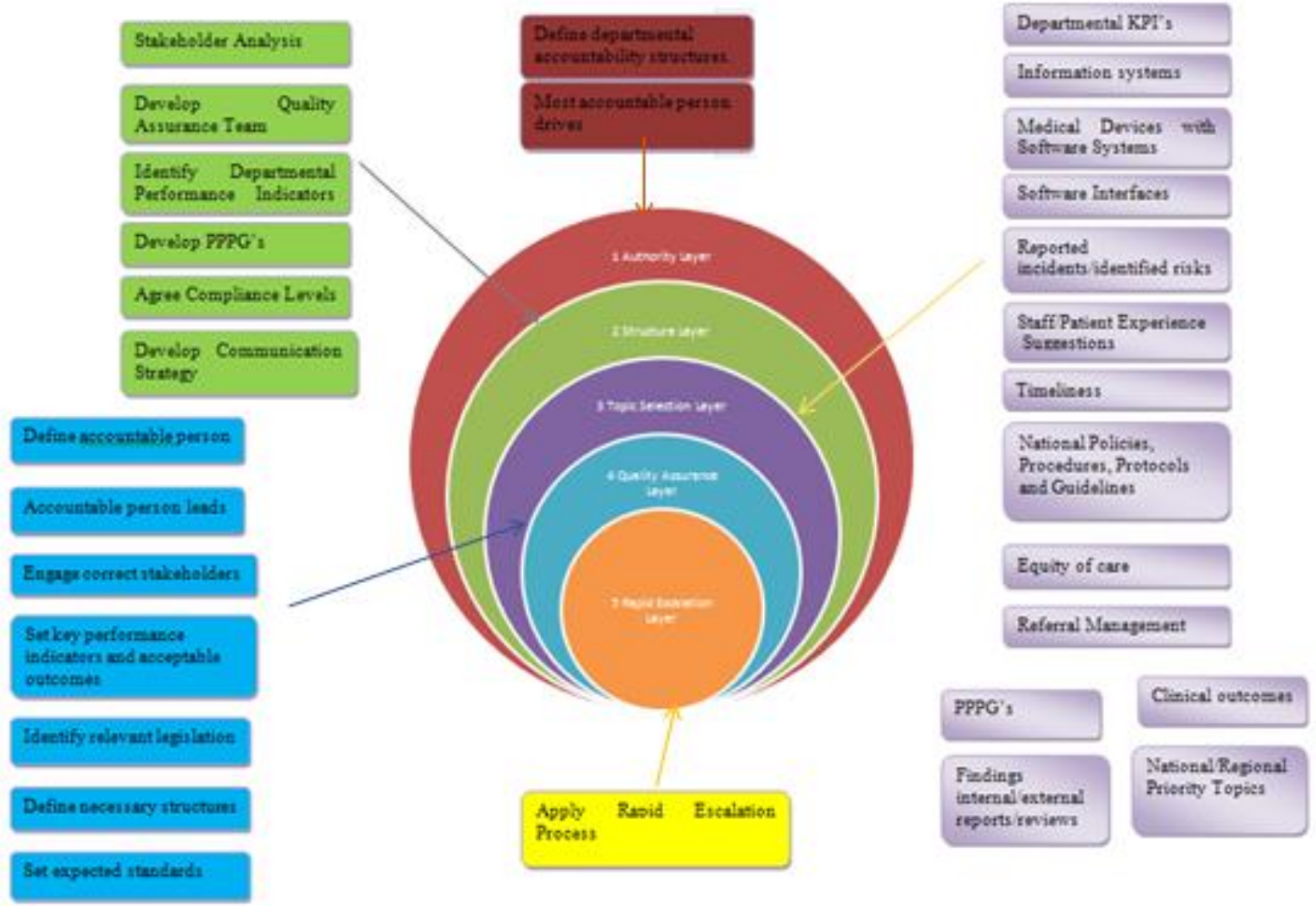
H-QAP

HSE



Quality Management System

Hospital Quality Assurance Program: H-QAP



H-QAP Layers and Protocols

Structure Layer

- Stakeholder Analysis
- Develop Quality Assurance Team
- Identify Departmental Performance Indicators
- Develop PPPG's
- Agree Compliance Levels
- Develop Communication Strategy

Structure Layer: Implementation

- Focus on Radiology Department
  - Correct diagnosis within acceptable timeframe
  - Radiation ALARA principle
    - As Little As Reasonably Achievable
- Quality Requirement
  - Software engineers ensures MD software correct
  - Physicist calibrates MD
  - Radiographer uses MD correctly
  - Radiologist reviews and reports diagnosis

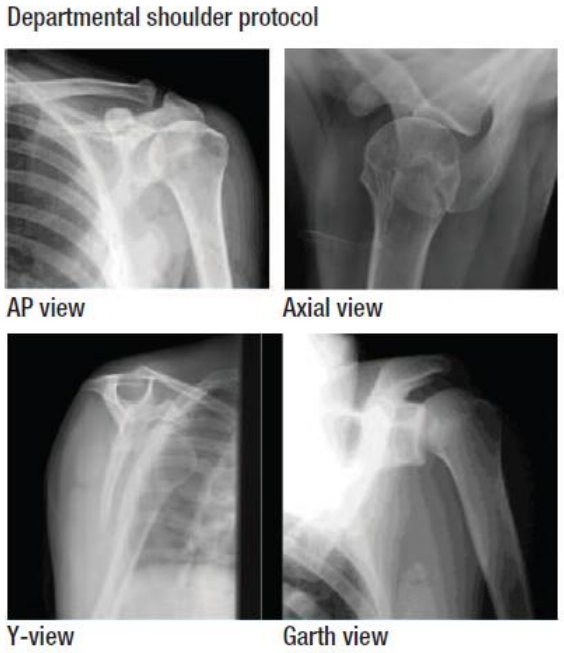
H-QAP Layers and Protocols

Quality Assurance Layer

- Define accountable person
- Accountable person leads
- Engage correct stakeholders
- Set key performance indicators and acceptable outcomes
- Identify relevant legislation
- Define necessary structures
- Set expected standards

Quality Assurance Layer: Implementation

- Focus on Shoulder X-Ray measures regarding:
  - Policies regarding angle, contrast, view
  - Standards for shoulder imaging
- Defining data collection
  - Percentage of incorrectly taken x-rays
  - Number of times patients were x-rayed
- Data reporting defined



H-QAP Layers and Protocols

H-QAP Implementation: Improvement from 54% to 95% compliance in X-Ray department

RESEARCH CHALLENGES (SOFTWARE)
Medical Devices and Healthcare

How can Software Engineering processes comply with regulations?

How can we ensure the correct use and implementation of software in healthcare situations?

How can

and proce

Implementing Quality in Health care Software

Software Quality Management Systems

RESEARCH CHALLENGES (SOFTWARE)
Medical Devices and Healthcare

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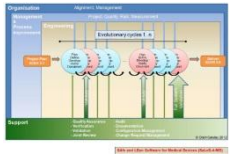
Smart Travel

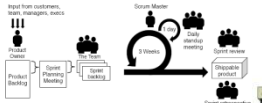
Smart Health (Connected)

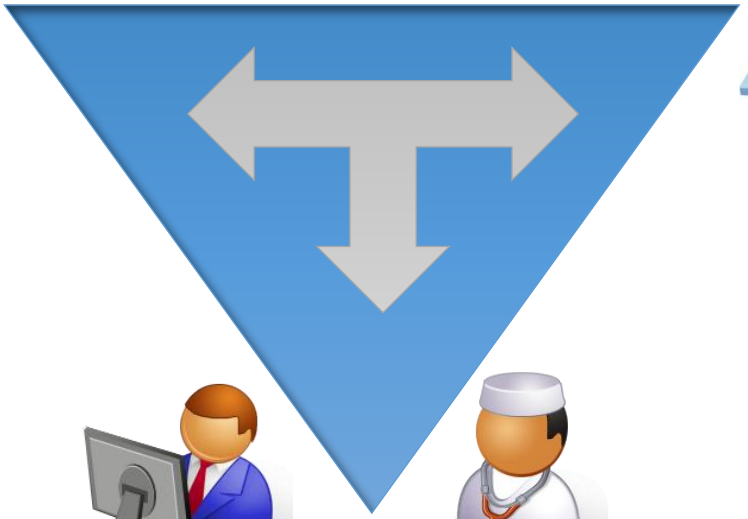
How does ‘Smart’ happen?

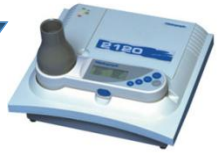


Processes

Technology

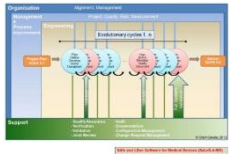






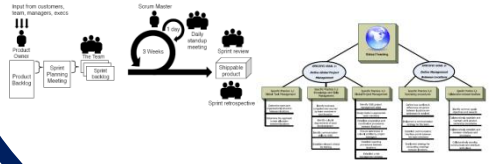
People

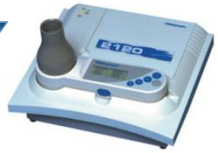
Research Interest: Connected Health



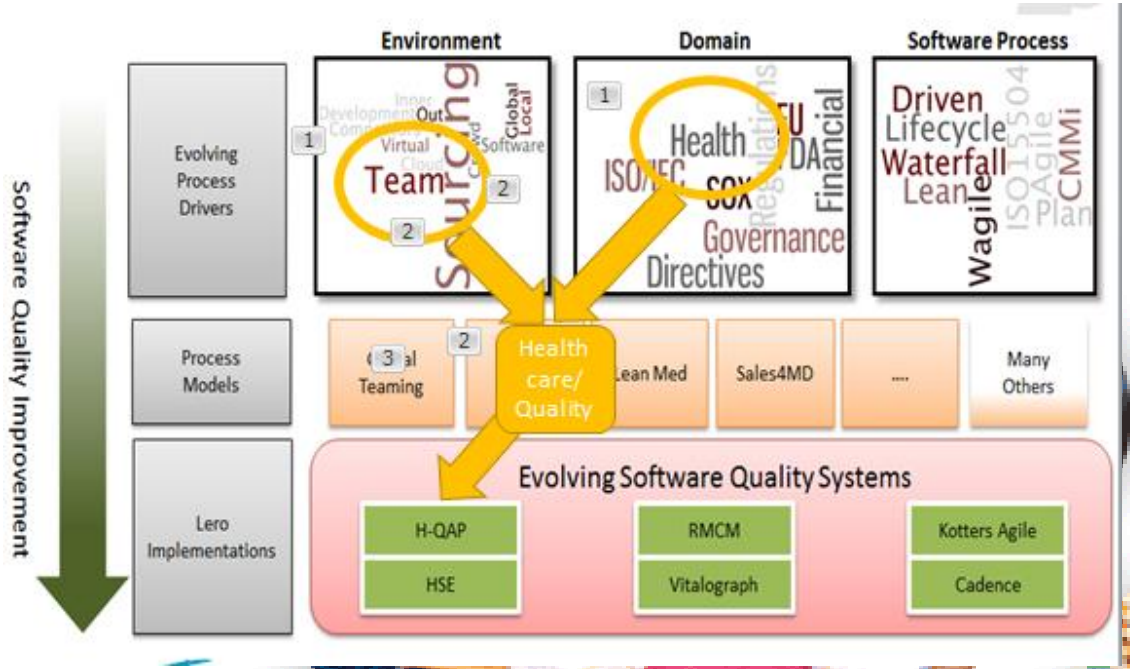
Processes

Technology





People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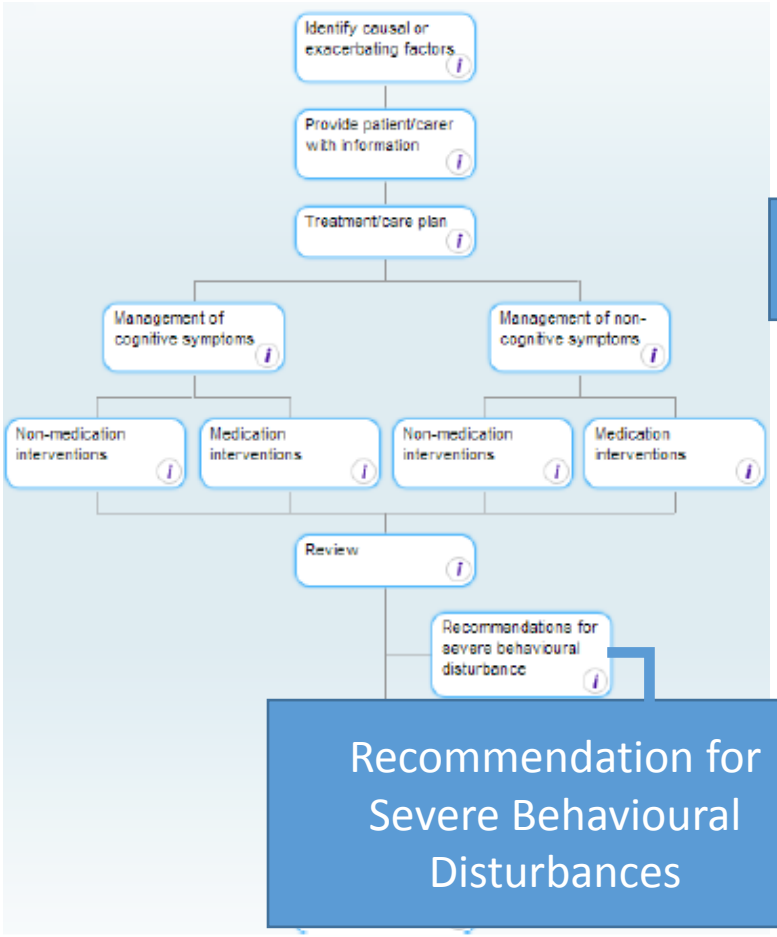
Team
Sourcing
Out
Virtual
Global
Local
Software
Health
Financial
Governance
Directives
Driven
Lifecycle
Waterfall
Lean
Agile
CMMi
Teaming
Health care/ Quality
Lean Med
Sales4MD
....
Many Others
Evolving Software Quality Systems
H-QAP
HSE
RMCM
Vitalograph
Kotters Agile
Cadence

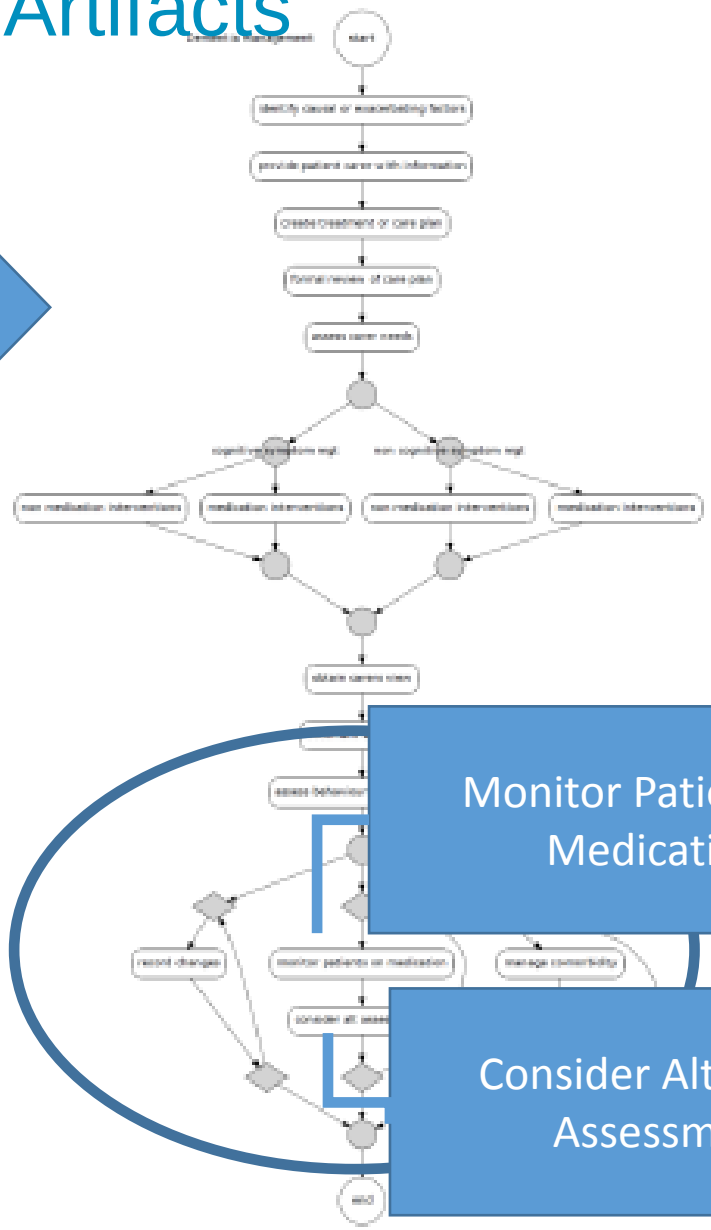
MODELLING

Map of Medicine



Recommendation for Severe Behavioural Disturbances

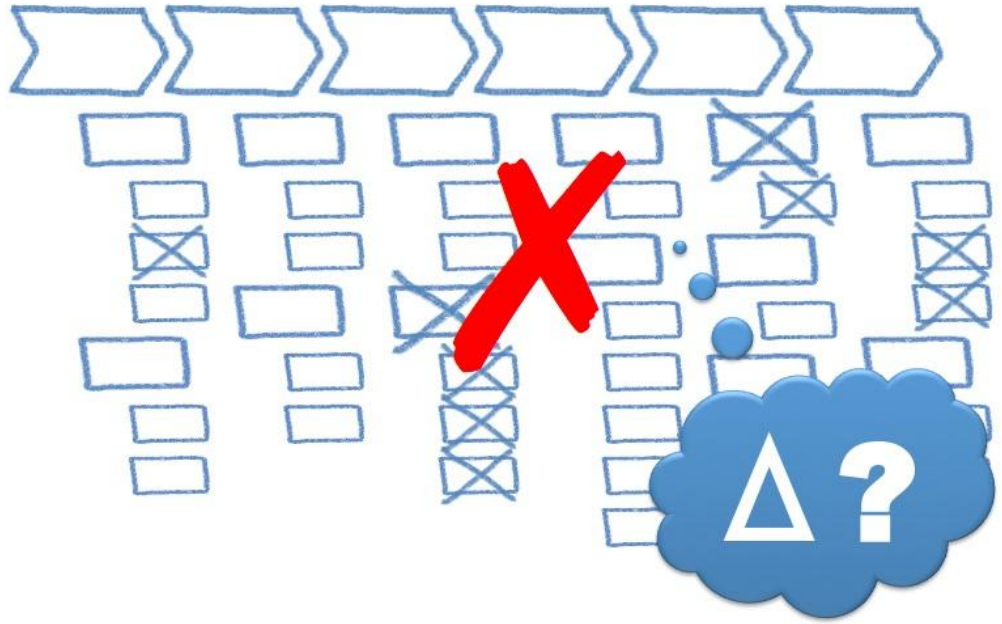
Adding Resources, Activities, Artifacts



Monitor Patients on Medication

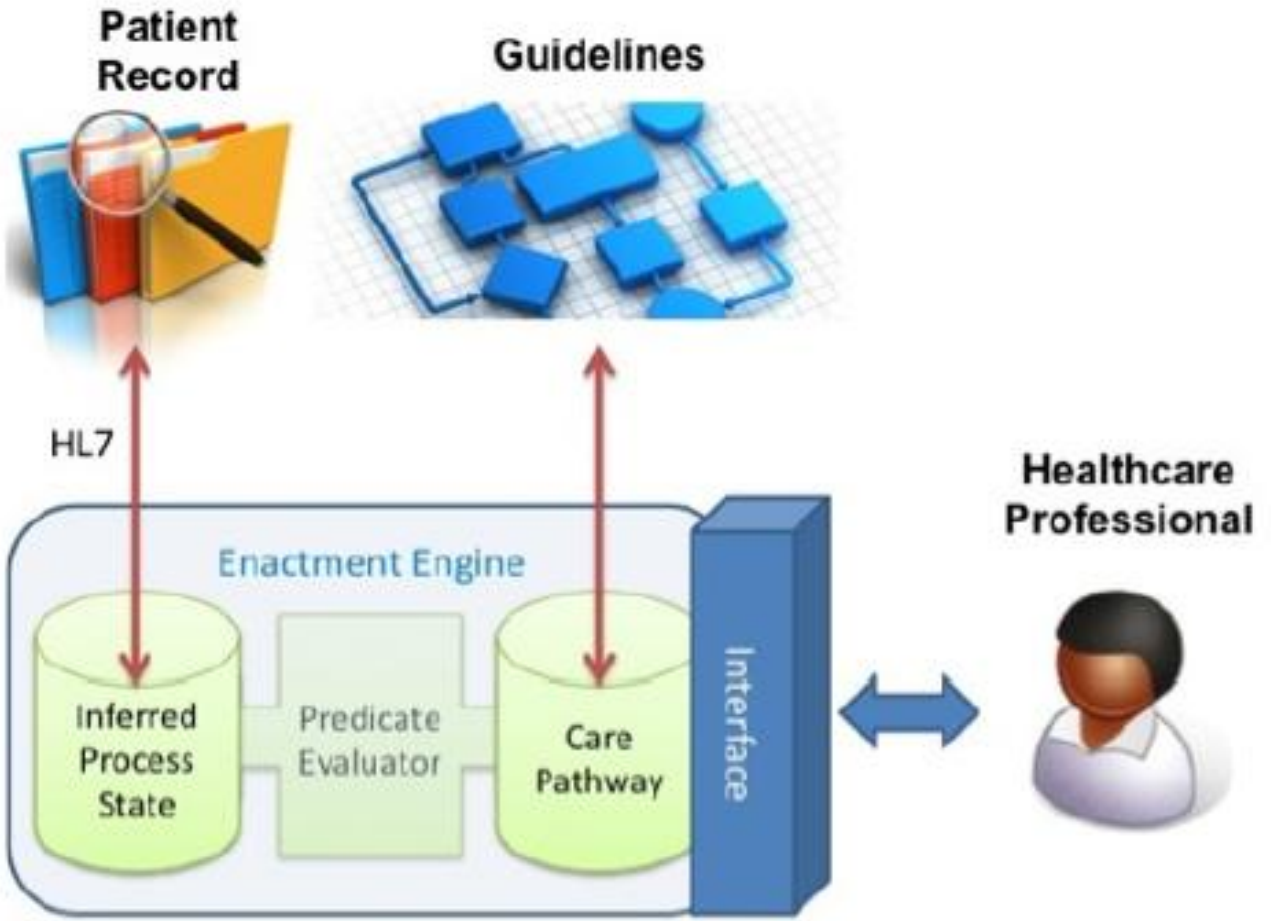
Consider Alternative Assessments

TAILORING

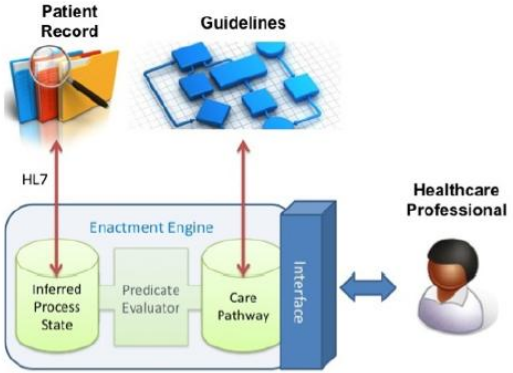


HUMAN COMPUTER INTERACTION

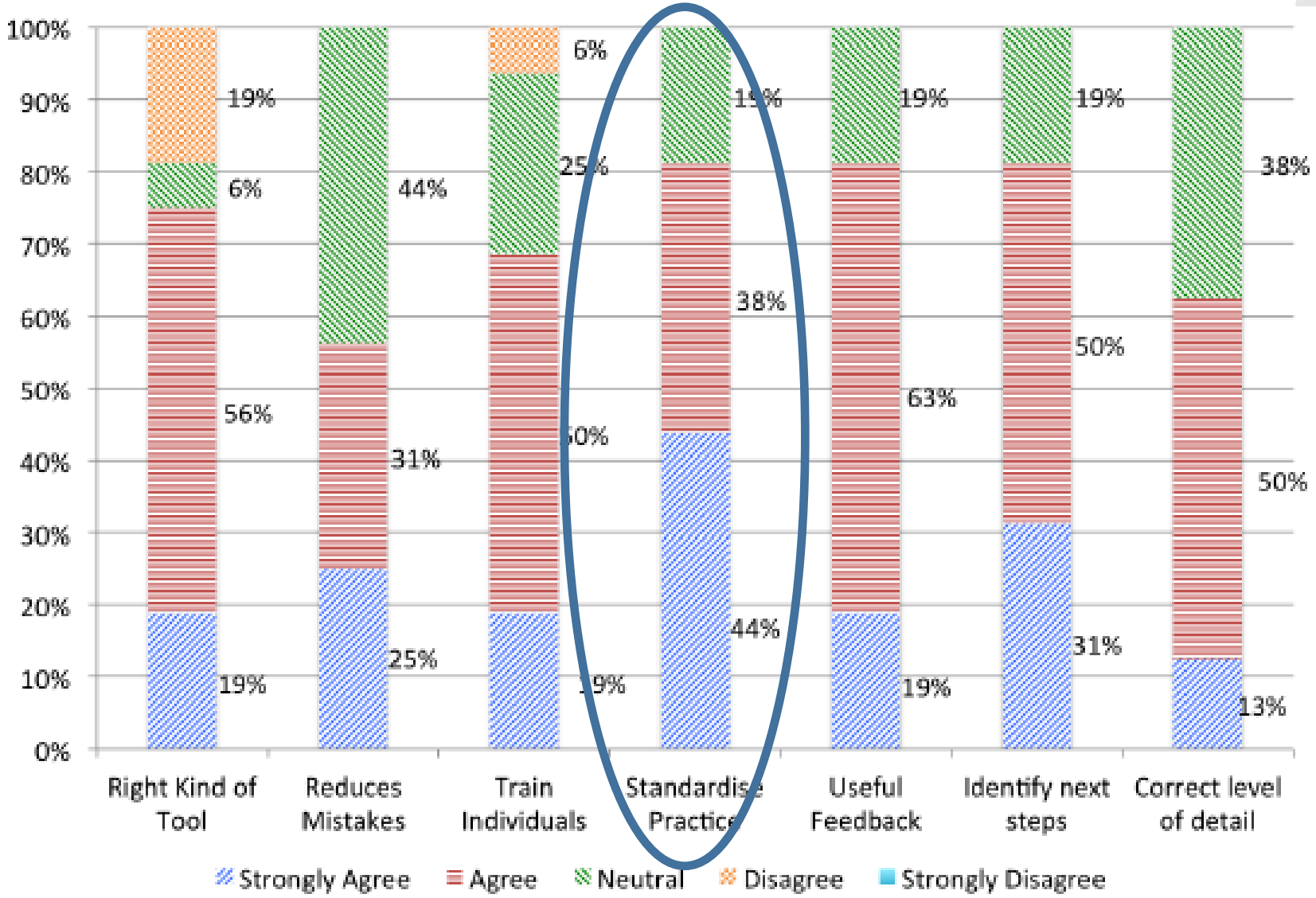
Implementation: Architecture



Implementation: Decision Support System



System Evaluation: 19 experts



RESEARCH CHALLENGES (SOFTWARE)
Medical Devices and Healthcare

How can [illegible]eering processes comply w[illegible]

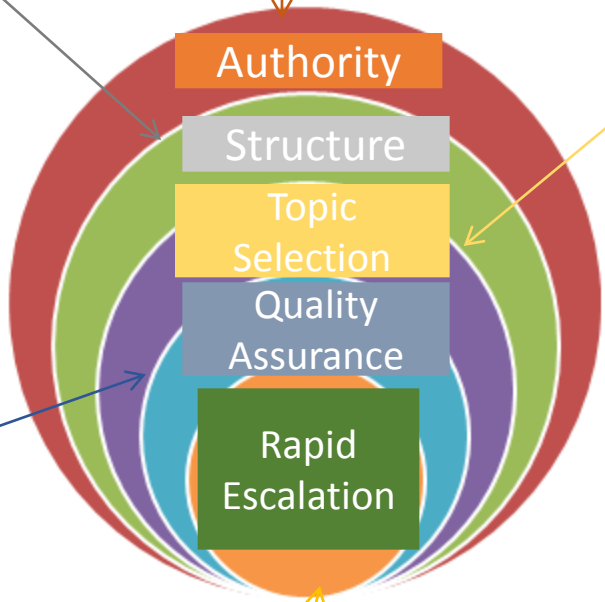
How can [illegible]re in healthcare situations?

Process Models, Tailoring, Implementation

Implementation of Process Solutions

How can we Connect software, technology, data and processes for use by differing stakeholders?

Hospital Quality Assurance Program



- Stakeholder Analysis
- Develop Quality Assurance Team
- Identify Departmental Performance Indicators
- Develop PPPG's
- Agree Compliance Levels
- Develop Communication Strategy

- Define departmental accountability structures.
- Most accountable person drives

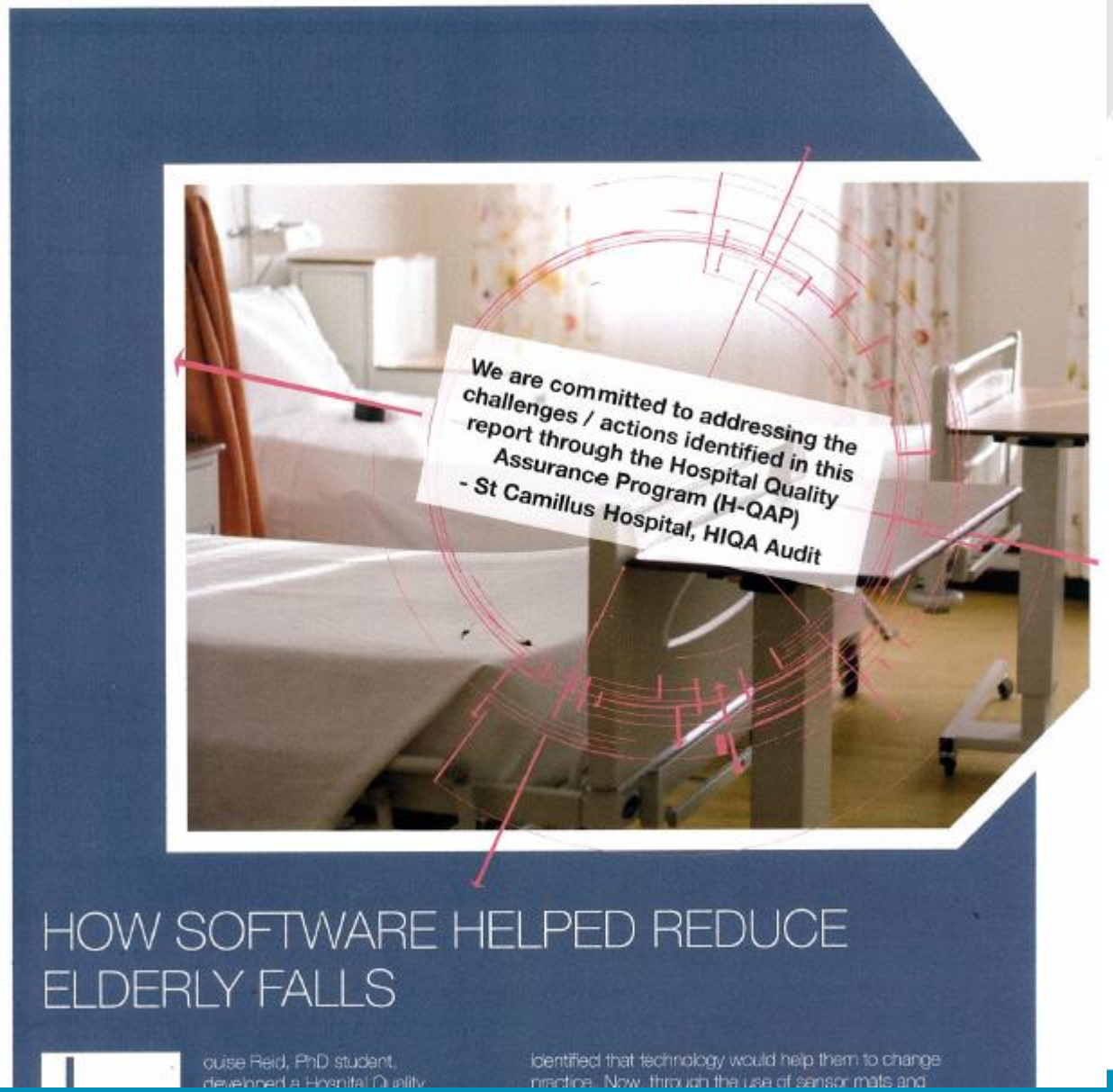
- Departmental KPI's
- Information systems
- Medical Devices with Software Systems
- Software Interfaces
- Reported incidents/identified risks
- Staff/Patient Experience Suggestions
- Timeliness
- National Policies, Procedures, Protocols and Guidelines
- Equity of care
- Referral Management

- Define accountable person
- Accountable person leads
- Engage correct stakeholders
- Set key performance indicators and acceptable outcomes
- Identify relevant legislation
- Define necessary structures
- Set expected standards

- Apply Rapid Escalation Process

- PPPG's
- Clinical outcomes
- Findings internal/external reports/reviews
- National/Regional Priority Topics

Hospital Quality Assurance Program



Connected Health into the future!

Identifying Medical practices

Understanding how Technology can support Medical Practices

Modification of Medical practice enhanced by Technology & Software

Implementation and Evaluation

Regulation will be important!

If you want to develop Software for Connected Health solutions

- Inter-disciplinary team
- Qualified (experienced) Software Engineer on your team
- User-centric
  - Not Technic-centric!
- Understand whether they are ‘wellness’ or ‘Medical Device’
- Build in (allowance for) Regulations from the start!

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Acknowledgement

- This work was partially supported by Science Foundation Ireland Research Centre grant 13/RC/2094, by ARCH – Applied Research in Connected Health funded by Enterprise Ireland / IDA and by European Commission through TRANSFoRm, DG INSFO (FP7 247787).