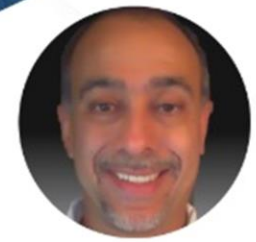
GLOBAL CLINICAL ENGINEERING ALLIANCE™

DECEMBER 8
7:00-8:00 PM UTC

WEBINAR

What Must a CE Know Regarding Digital Health



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GLOBAL CLINICAL ENGINEERING ALLIANCE™

What Must A Clinical Engineer Know Regarding Digital Health?

Stephen L Grimes, FACCE FAIMBE FHIMSS AAMIF
Strategic Healthcare Technology

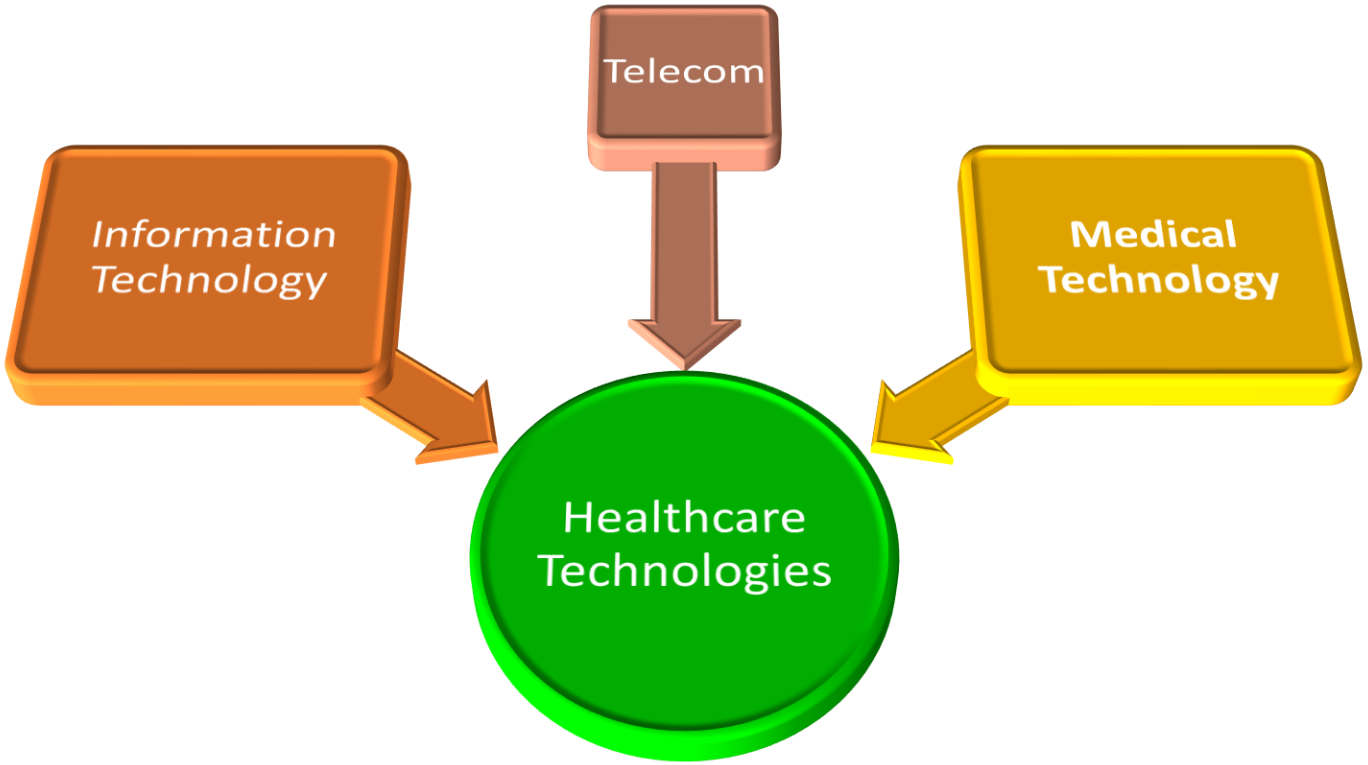
Wednesday, December 8, 2021
07:00 pm Universal Time (UTC)

AGENDA

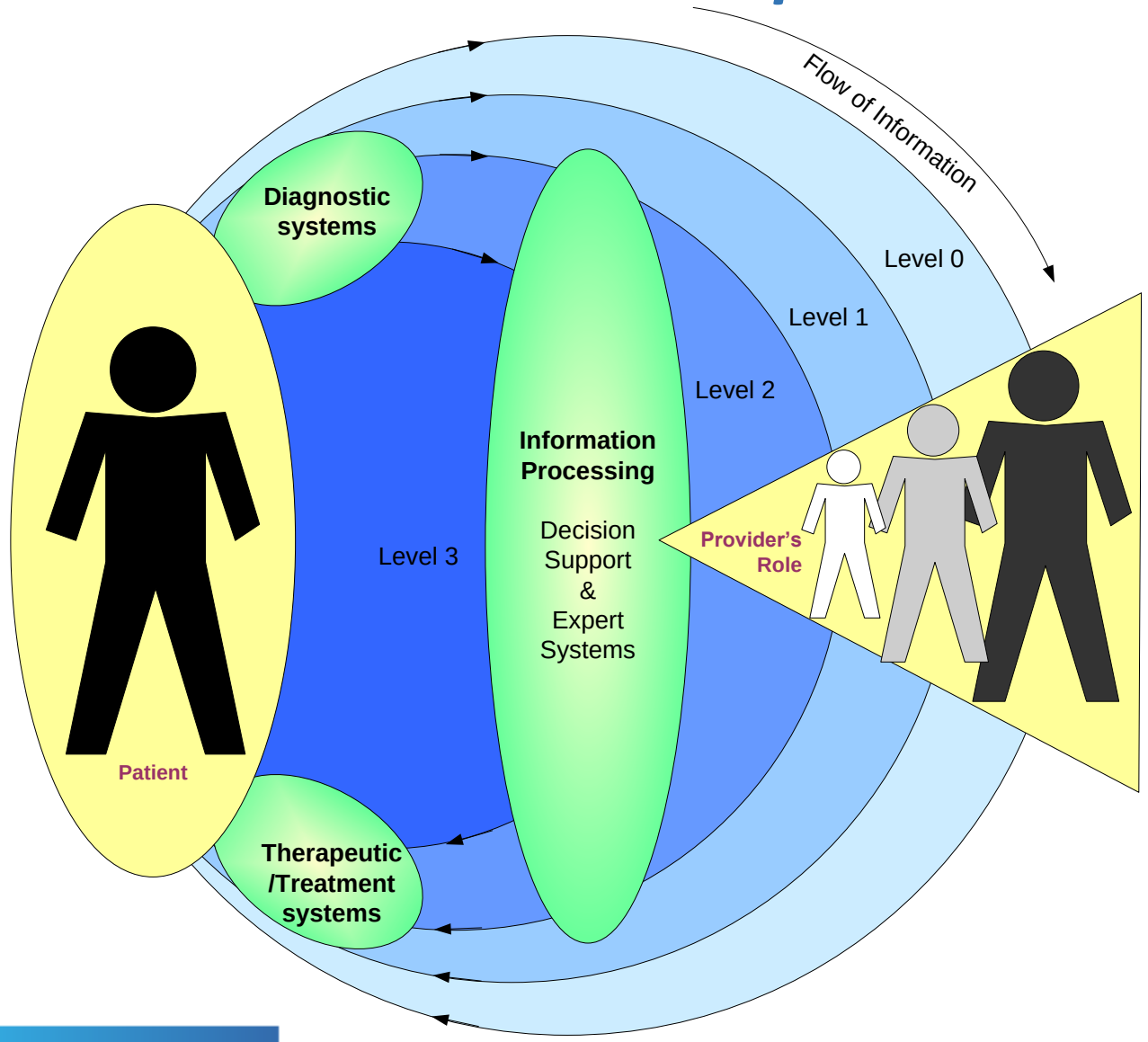
- Evolution of Digital Health
- Evolution of Clinical Engineering Roles in the Age of Digital Health
- Summary

Evolution of Digital Health

Since 2010
Convergence of Technologies has continued
Growing Number of Hybrid (i.e., Medical-Information-Telecom)
Digital Health Systems



Evolution of Digital Health and the Impact on Provider Roles



0) *Clinician's direct observation and action in diagnosis and treatment*

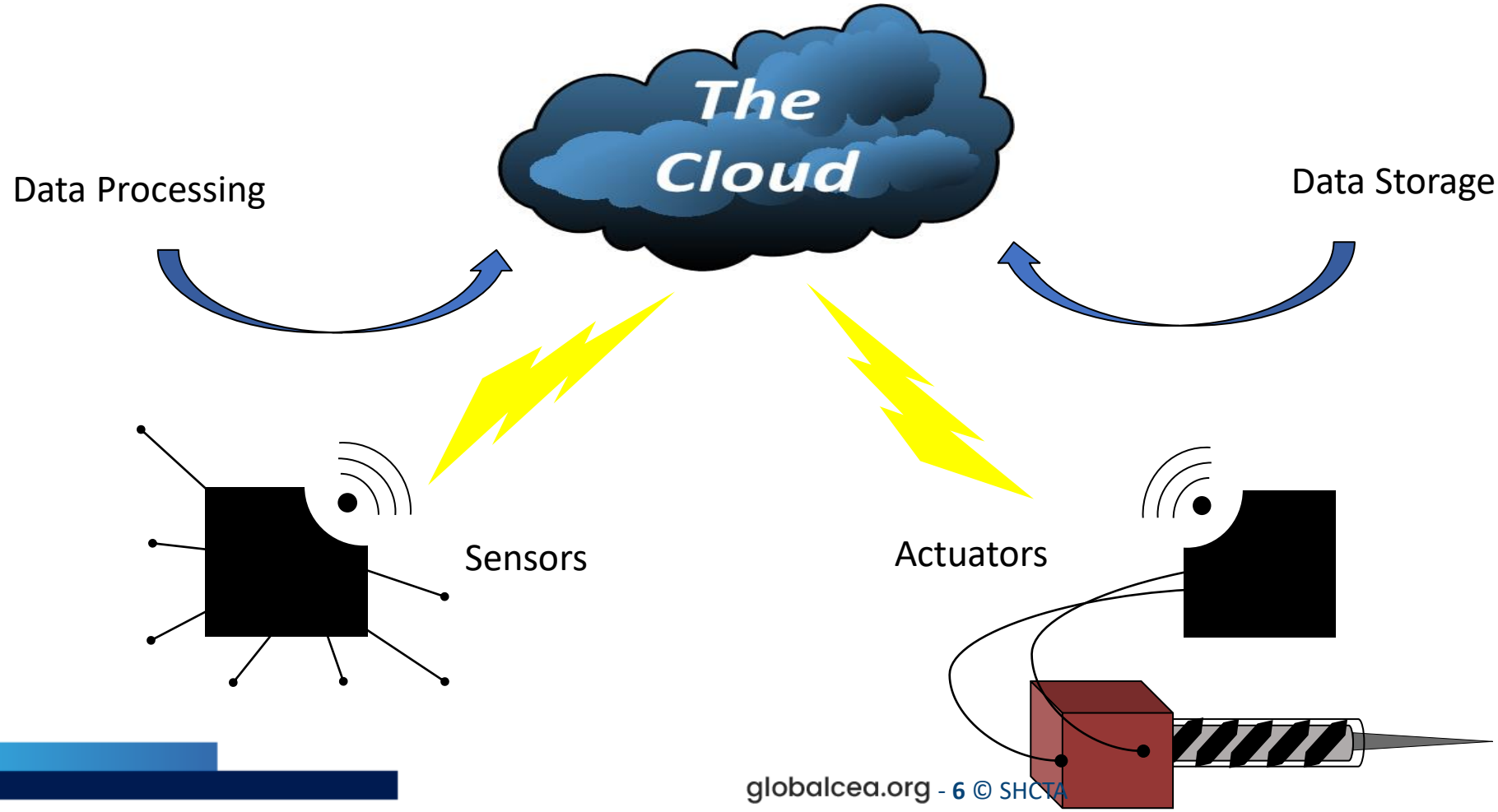
1) *Diagnosis and treatment by clinician augmented by medical devices*

2) *Diagnosis and treatment by clinician further augmented by clinical decision support systems and medical devices*

3) *Diagnosis and treatment directly done by expert & clinical decision support systems and medical devices*

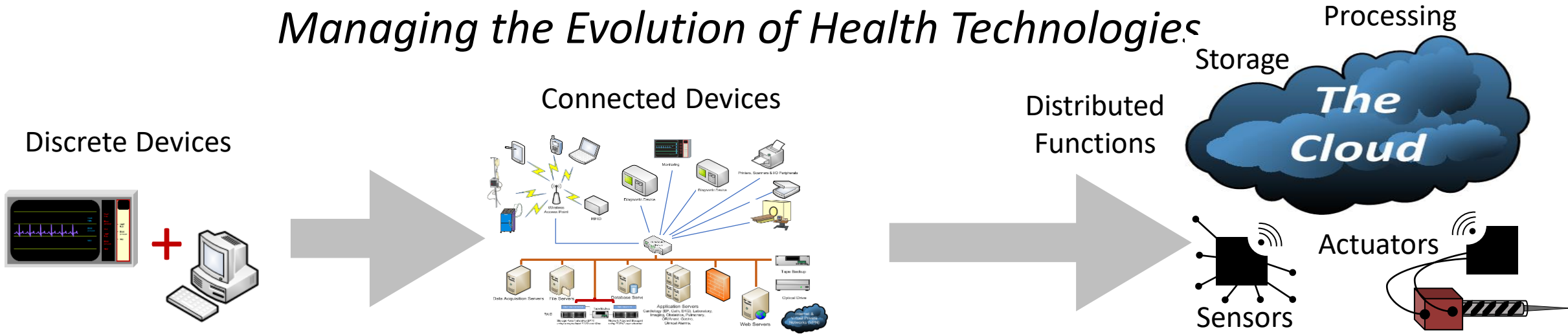
Evolution of Digital Health

Many traditional medical devices will be replaced by
Software-based “Smart” Medical Devices
Manufacturers are increasingly focused on software development



Evolution of Digital Health

Managing the Evolution of Health Technologies



BENEFITS

- centrally managed
- increased capabilities *(faster, more reliable diagnosis & treatment)*
- self-diagnostic
- self configuring
- self repairing

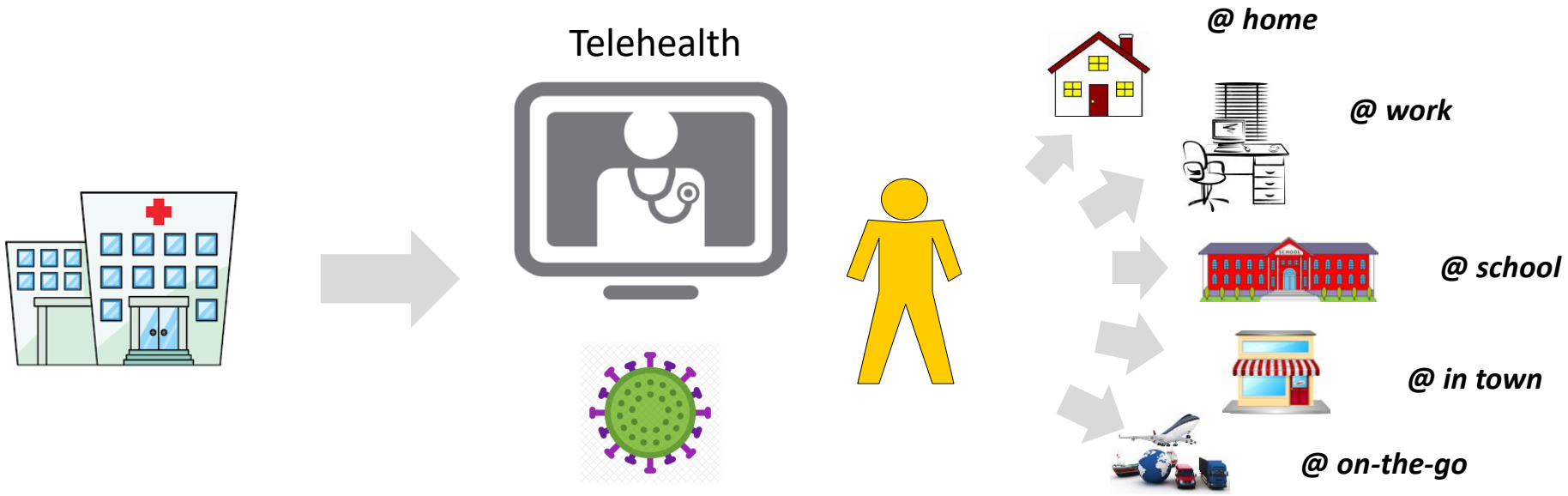
CHALLENGES

- increased complexity *(requires systems support)*
- multiple *single-points-of-failure* (SPoF)
- multiple vulnerabilities

Evolution of Digital Health

The world of <u>healthcare technology</u>: : Changes (over most recent 30 years)

Increasingly Diverse Healthcare Delivery Modes & Venues

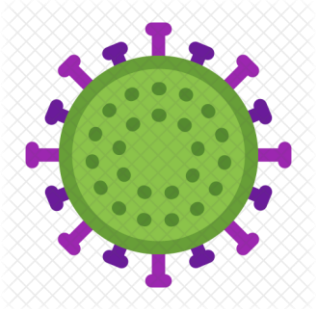


Accelerating due to
social & health changes
(e.g., COVID-19 virus)

Evolution of Digital Health

The changing world of <u>healthcare technology</u>

COVID-19 Has Accelerated Existing Trends



- moving toward telemedicine (legal impediments largely have been removed)
- technical capabilities (ability to diagnose & treat patients) have increased and are experiencing more widespread use
  - ✓ improvements in remote monitoring & examination
  - ✓ improvements in home treatment using new technologies
  - ✓ improvements in robotics
- technical capabilities for device management (e.g., update, monitor logs, troubleshoot)

Evolution of Digital Health

Examples of technological advancements in healthcare

- robotics
- 3D imaging & printing
- telemedicine & remote monitoring
- micro- and nano- technologies
- individualized medicine (including use of genomics)
- connected, systems-of-systems, and cloud-based solutions (including IoMT, 5G)
- clinical decision support (CDS) & expert systems
- artificial intelligence (AI) & machine learning (ML)
- augmented reality (AR)

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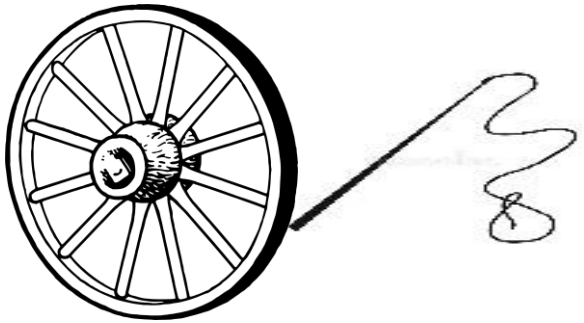
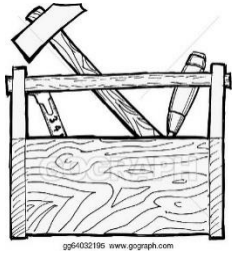
Evolution Digital Health

Demands an Evolution of CE Roles



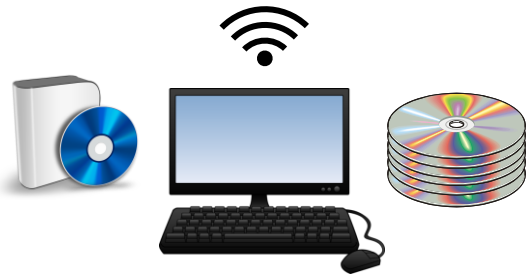
With

New Technology



there is a need for

New Services & Tools



which in turn require support roles to have

New Knowledge, Skills and Abilities

Evolution of Digital Health

$$New\ \text{Clinical Engineering (CE) Roles} = f(New\ Technology)$$

Clinical Engineering Roles are defined by the support requirements of medical technology

New Technology ≠ Old Technology ∴ New CE Roles ≠ Old CE Roles

Points to make

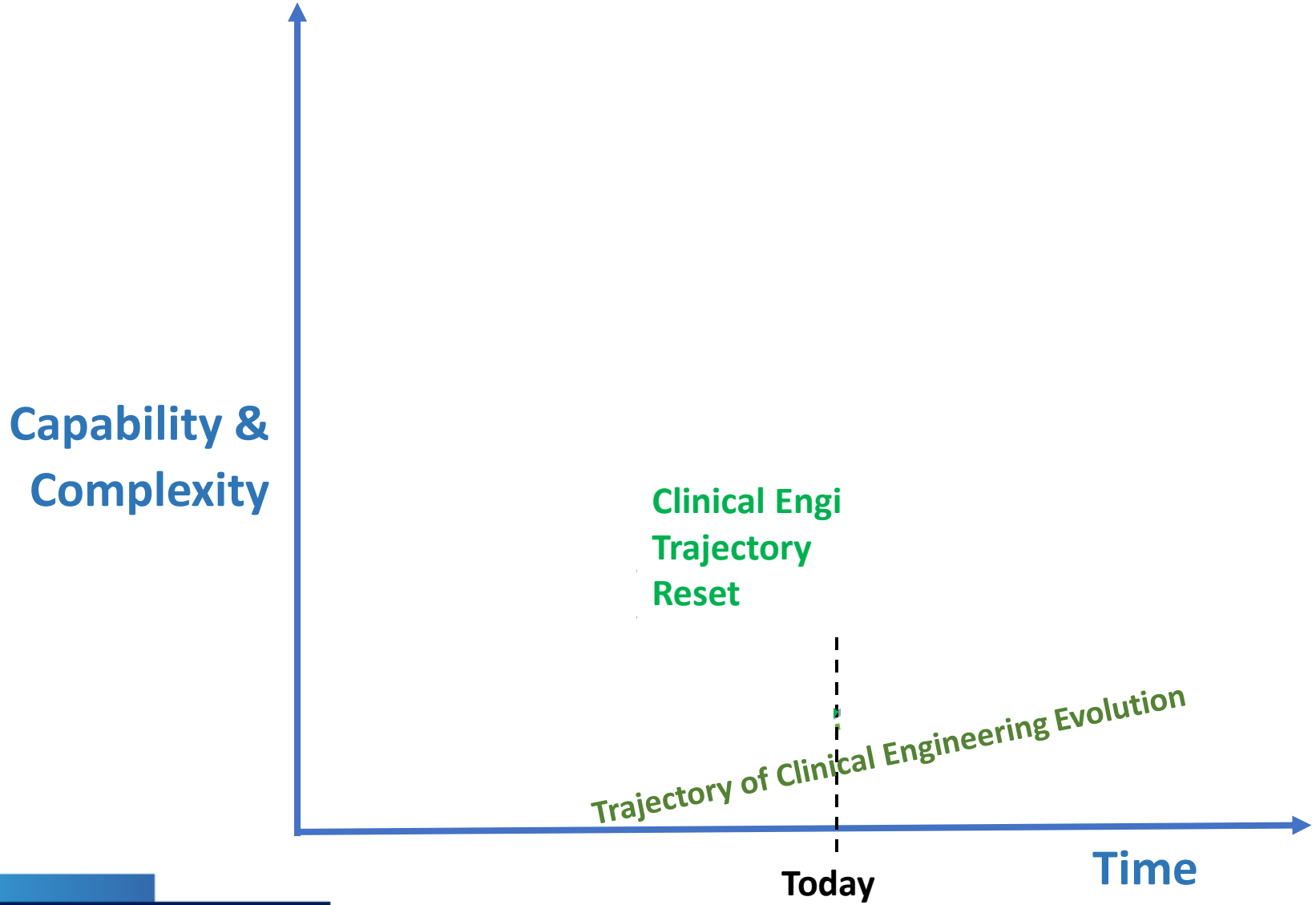
- Trends in technology
  - increasing convergence (i.e., medical, information & communications technologies)
  - increasing complexity … growing number of Systems of Systems (SoS)
  - increasingly capable (smart & software-based)
- Need for Evolution of Clinical Engineering Roles …

  i.e., What is roles are necessary to support selection, deployment, and support
  - focus on changing roles

    (not necessarily the same as historical roles because the needs are changing)
  - continuous education required

Evolution of Digital Health

Challenges for Clinical Engineering based on Rapid Evolution of Digital Health

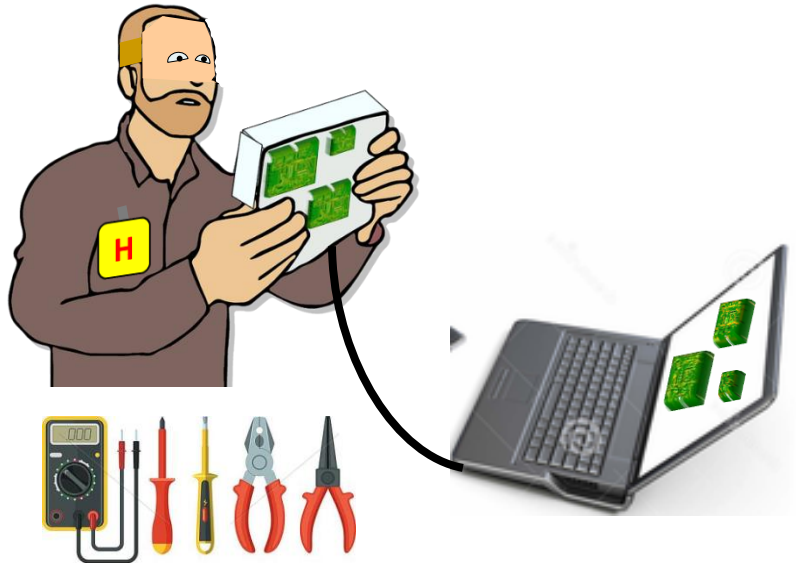


Evolution of Digital Health

The changing world of <u>healthcare technology</u>

COVID-19 Has Accelerated Existing Trends

Expert Technical Support for On-Site Technicians



TeleServices via Internet

Remote Diagnostics / Troubleshooting

Software Updates via Remote Access

Advanced Technical Support with Augmented Reality (AR)

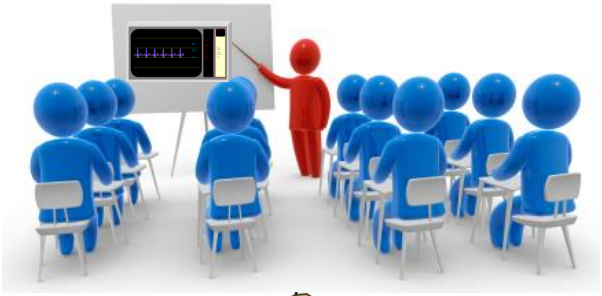
Evolution of Digital Health

The changing world of <u>healthcare technology</u>

COVID-19 Has Accelerated Existing Trends

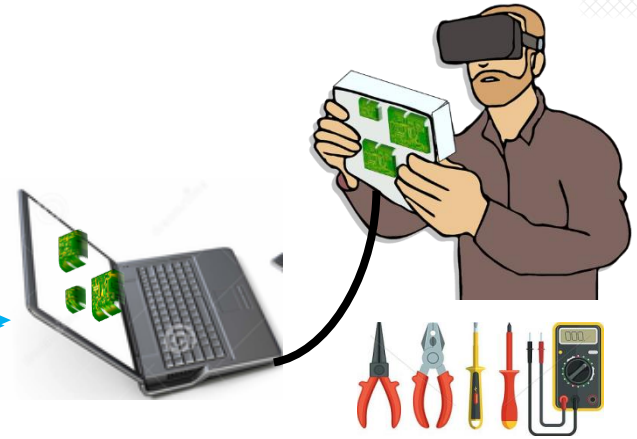
College & University Education

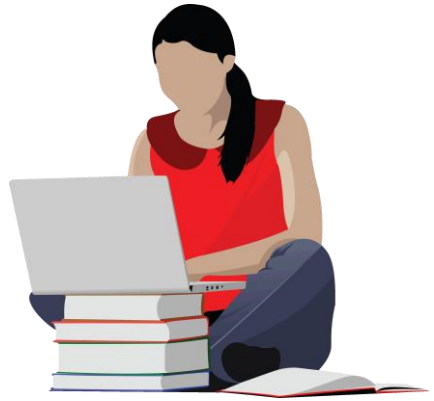
Operations & Technical Training



Conferences for Professional Development

Transforming to On-Line and On-Demand





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Evolution of Digital Health

Summing up - Other Challenges

- Medical and Information Technology will continue to evolve in ways that blur lines between our old ideas
  - ✓ when is a computer (or when is software) a medical device?
  - ✓ medical equipment manufacturers will primarily focus on software that will be hardware platform agnostic
  - ✓ future of clinical data analysis and storage is in cloud
- Rapid technology innovations will place increasing burdens on
  - ✓ regulators who are challenged to regulate effectively without stifling innovation
  - ✓ healthcare organizations who are financially constrained but want new technology in order to effectively compete for patients
  - ✓ existing clinical engineering & information technology infrastructures that must collaborate, acquire new tools and learn to prioritize in order to address greatest risks if they hope to support new technologies (e.g., ITIL, vulnerability assessments, risk & security management)

Evolution of Digital Health
Summing Up

- Clinical Engineering & Information Technology Services need to take steps necessary to modify their trajectory in a manner that better aligns and supports converging & evolving technologies
- redefine clinical engineering roles (originally defined decades ago) in a manner that reflects how best to apply CE education, skills and experience to meet both today's support needs and future support needs
- better define education, skill, experience and certification requirements for the clinical engineering professionals so the in position to fill new roles
- develop guides and standards that define clinical engineering & information technology roles & responsibilities in a manner that ensures seamless collaboration and support of increasingly integrated, hybrid systems
- identify key organizations (e.g., in U.S., it is ACCE, AAMI, HIMSS, CHIME) that have best potential to facilitate necessary changes to technology support including developing underlying stakeholder roles & relationships

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Thank You!

Stephen Grimes
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Software as a Medical Device (SaMD): Impact in Clinical Engineering

Ricardo Silva, PhD, CCE

Acknowledgement

This presentation is based of “Software as a Medical Device (SaMD): Clinical Evaluation” by the International Medical Device Regulators Forum (2017).

IMDRF International Medical Device Regulators Forum

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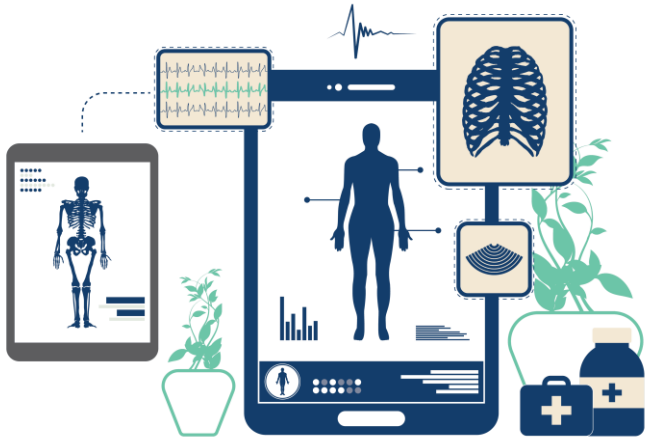
Medical Purpose Software

- Software in a Medical Device (sometimes referred to as “embedded” or “part of”);
- Software as a Medical Device (SaMD).
  - Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.
  - SaMD may be run on a server, a workstation, a mobile platform, or other general purpose hardware platform.



General Principles

- “utilizes an algorithm (logic, set of rules, or model) that operates on data input (digitized content) to produce an output that is intended for medical purposes”

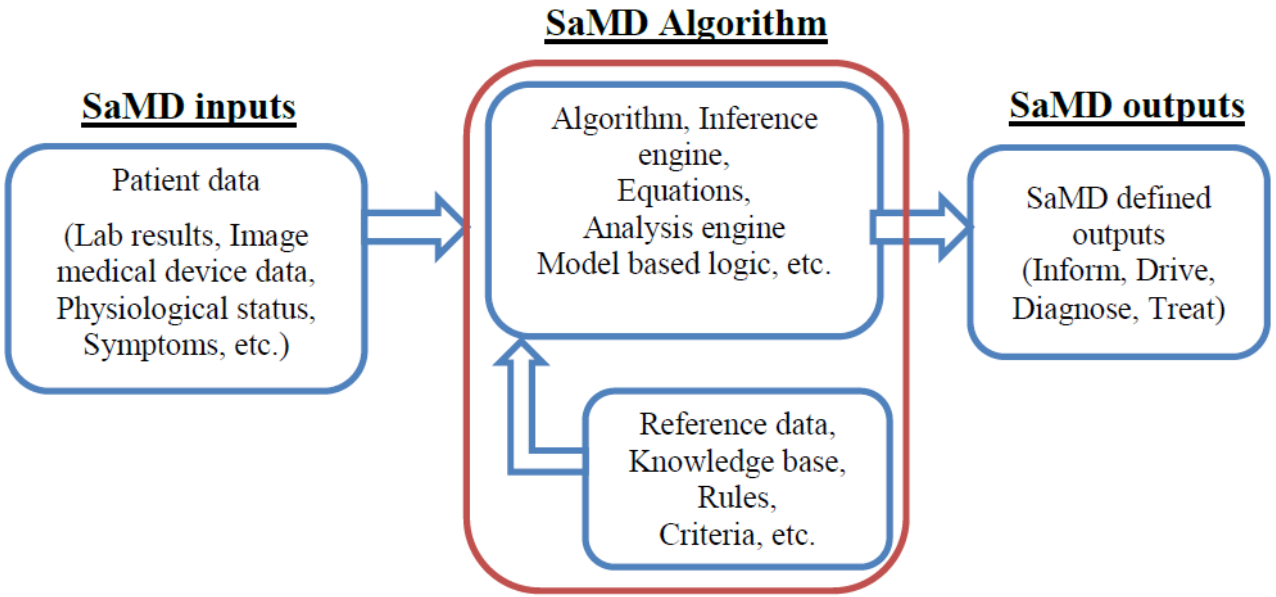
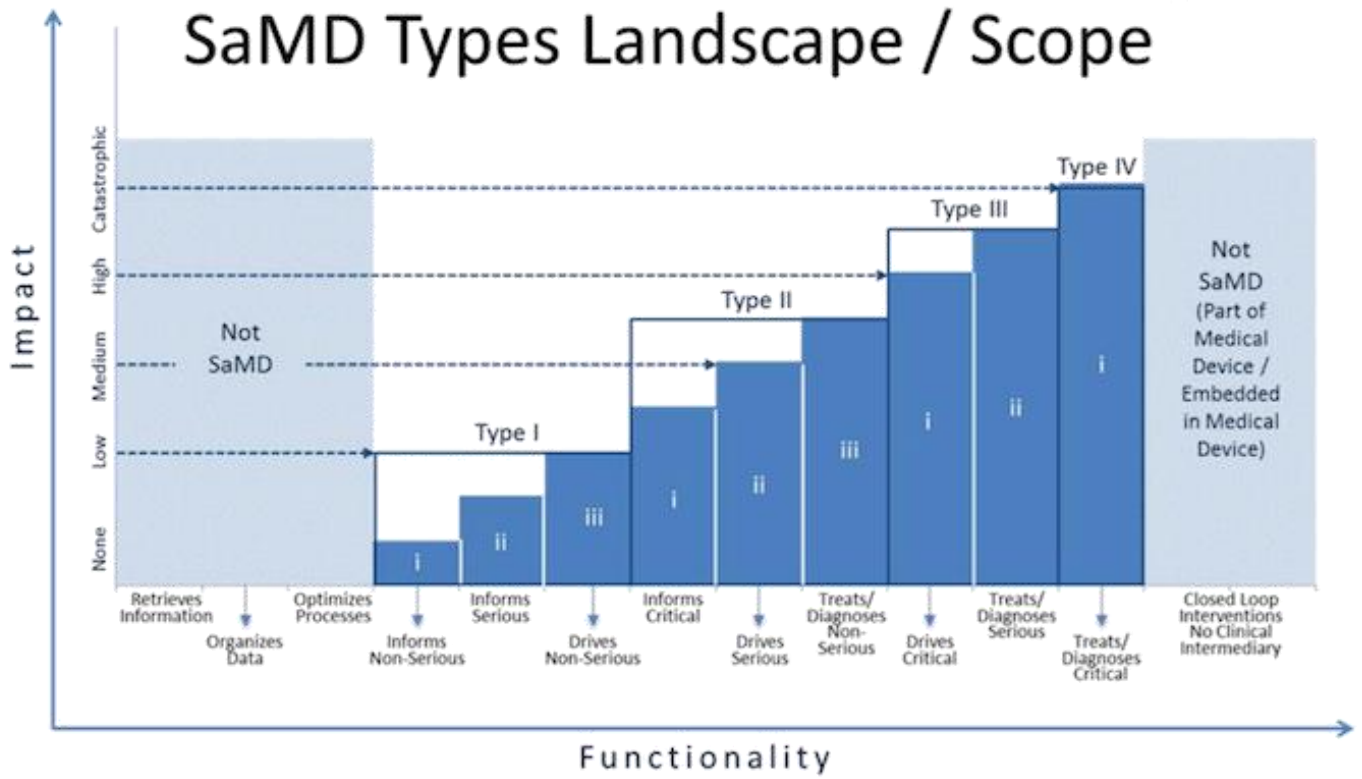


Figure 9 - SaMD Basic Programming Model

State of Healthcare Situation or Condition	Treat or Diagnose	Drive Clinical Management	Inform Clinical Management
Critical	IV	III	II
Serious	III	II	I
Non-Serious	II	I	I

SaMD Category



Clinical Evaluation of SaMD

- “set of ongoing activities conducted in the assessment and analysis of a SaMD’s clinical safety, effectiveness and performance as intended by the manufacturer”

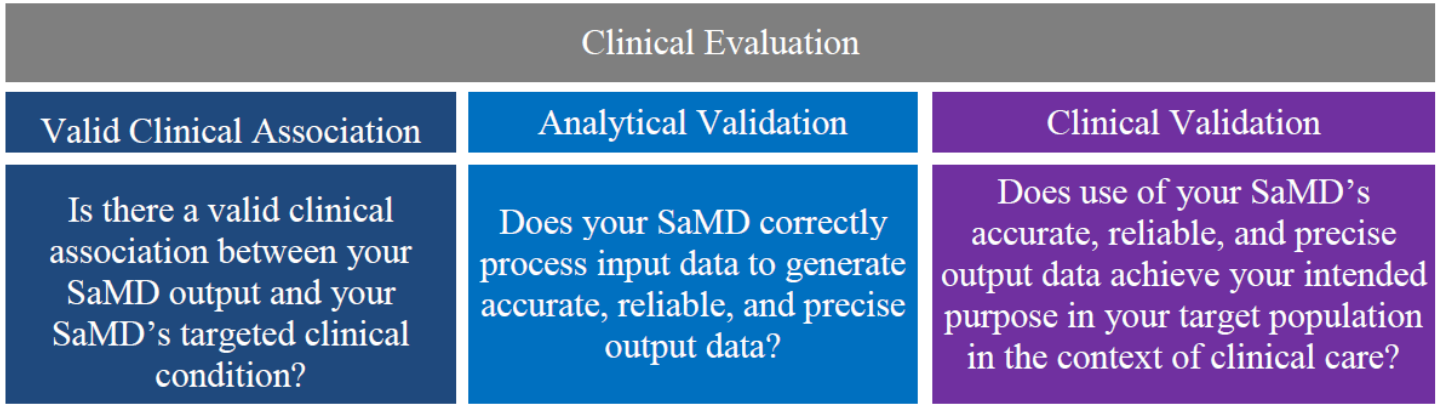


Figure 4- Clinical Evaluation Process

Clinical Evaluation Processes

- (Pre-Market) the manufacturer generates evidence of the product's accuracy, specificity, sensitivity, reliability, limitations, and scope of use in the intended use environment with the intended user and generates a SaMD definition statement.

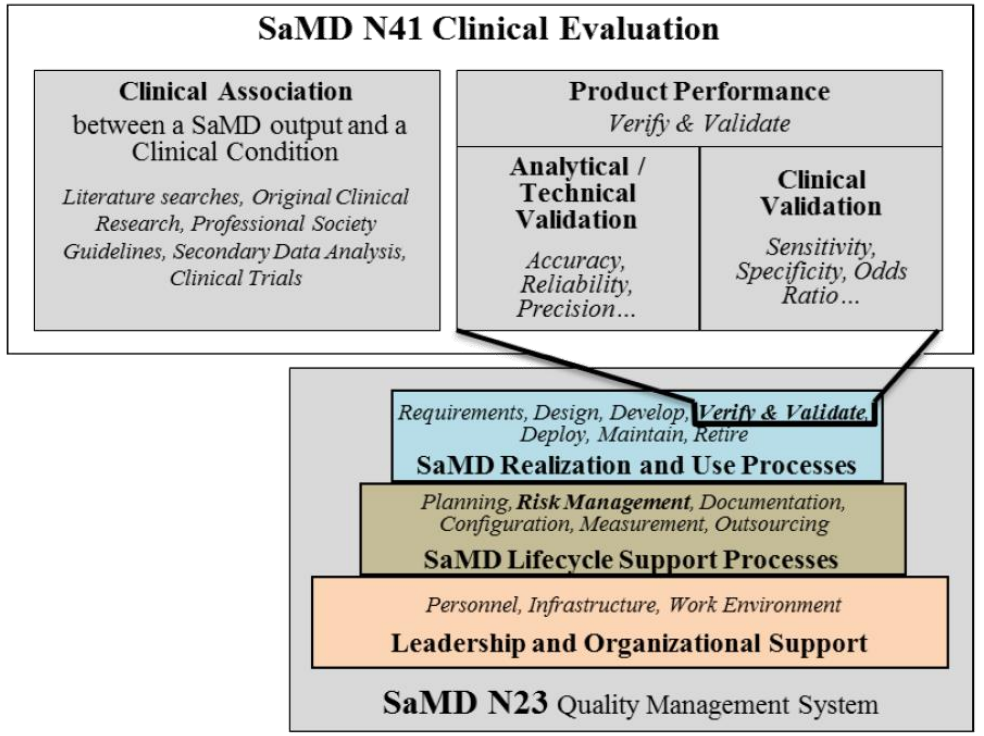


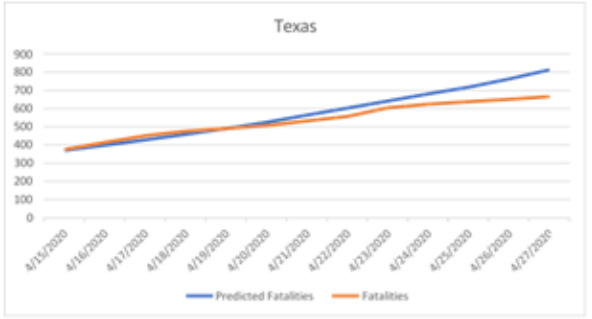
Figure 11 - SaMD Clinical Evaluation Landscape

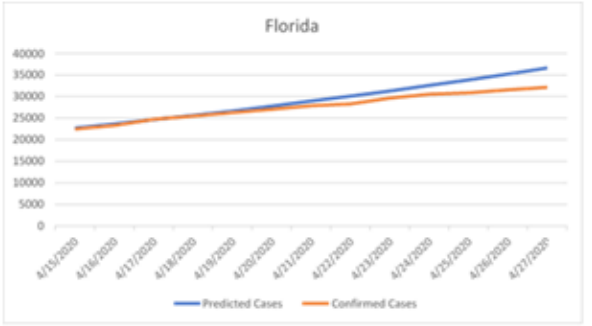
Valid Clinical Association

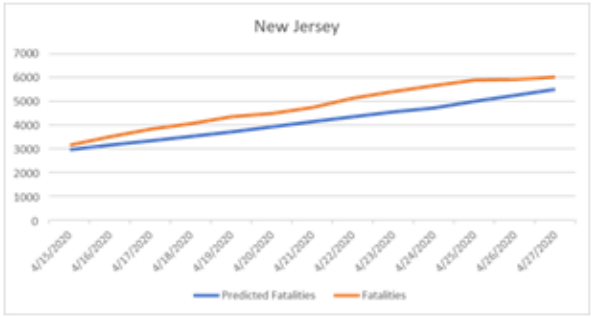
- Examples of existing evidence
  - Literature searches
  - Original clinical research
  - Professional society guidelines
- Examples of generating new evidence
  - Secondary data analysis
  - Perform clinical trials

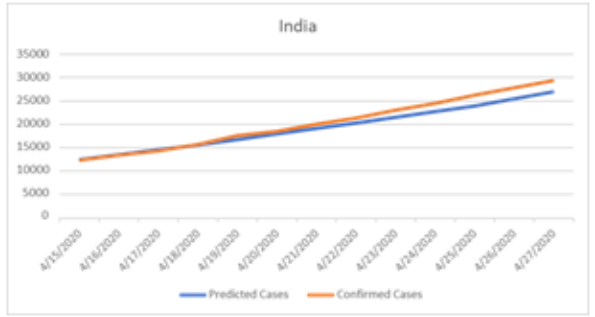
Valid Clinical Association

- SaMD has been tested in your target population and for your intended use; and that
- Users can achieve clinically meaningful outcomes through predictable and reliable use.
- **Covid-19 Prediction with eXtreme Gradient Boosting Regressor**
- https://globalce.org/index.php/GlobalCE/issue/current









Analytical / Technical Validation

- Confirms and provides objective evidence that the software was correctly constructed
- Demonstrates that (a) the software meets its specifications and (b) the software specifications conform to user needs and intended uses.
- **Análisis de Imágenes de Rayos X por Medio de Redes Neuronales Artificiales**
- Ecuadorian Science Journal

Clinical Validation

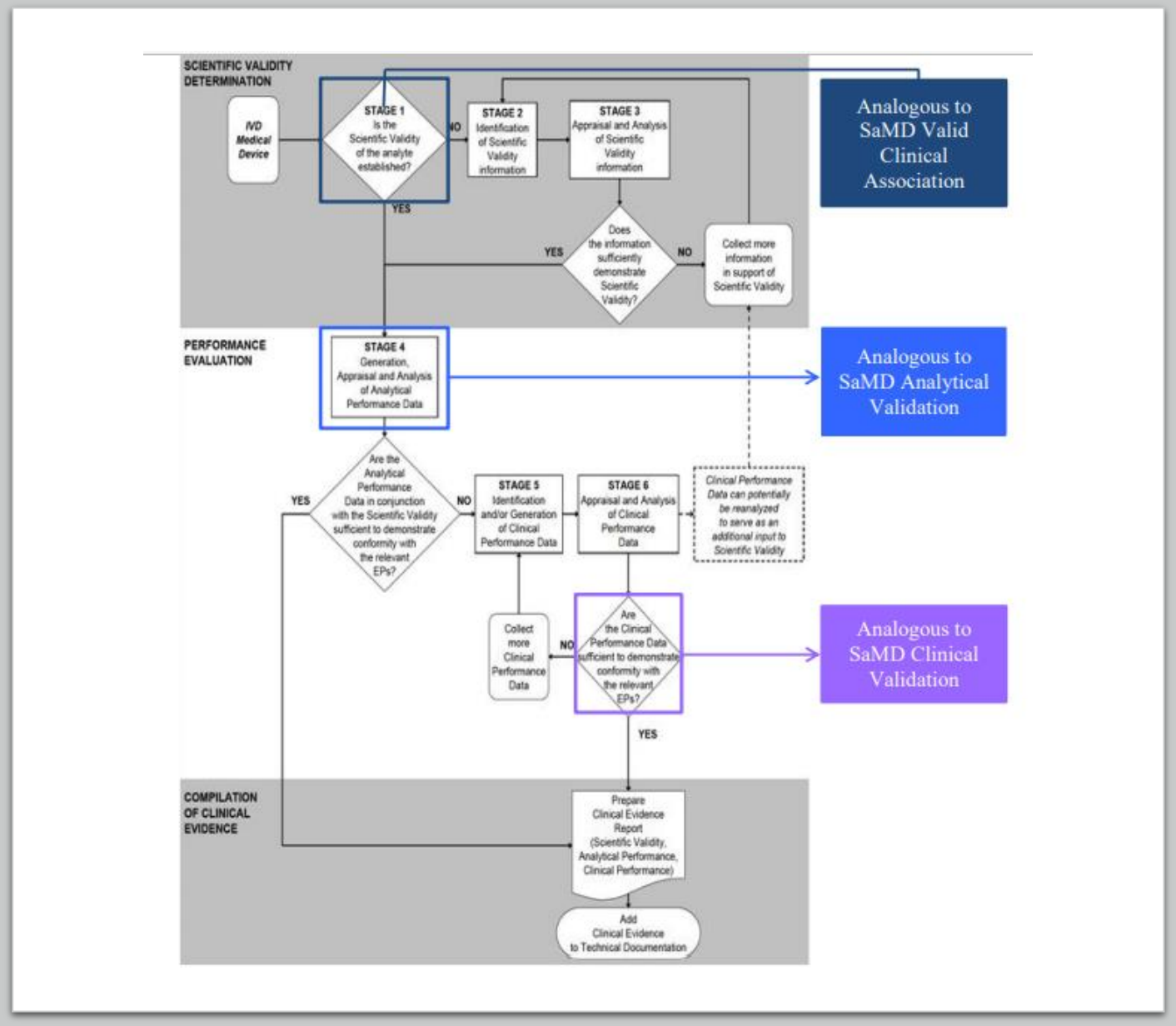
- SaMD has been tested in your target population and for your intended use; and that
- Users can achieve clinically meaningful outcomes through predictable and reliable use.

LFA SARS-CoV-2

	Positive	Negative	Total		
Positive	180	0	180	97.83%	SENSITIVITY
Negative	4	487	491	100.00%	SPECIFICITY
Total	184	487	671		
PPV	100.00%	95% CI	100.00%	to	100.00%
NPV	99.19%	95% CI	98.41%	to	99.96%

SaMD Clinical Evaluation Process

- Comparison of SaMD Clinical Evaluation Process to Process for Generating Clinical Evidence for IVD Medical Devices.



SaMD Lifecycle (post-market)

- Safety data,
- Performance studies,
- Clinical evidence generation,
- new research publications,
- SaMD output to a clinical condition,
- Direct end-user feedback,
- Performance of the SaMD.

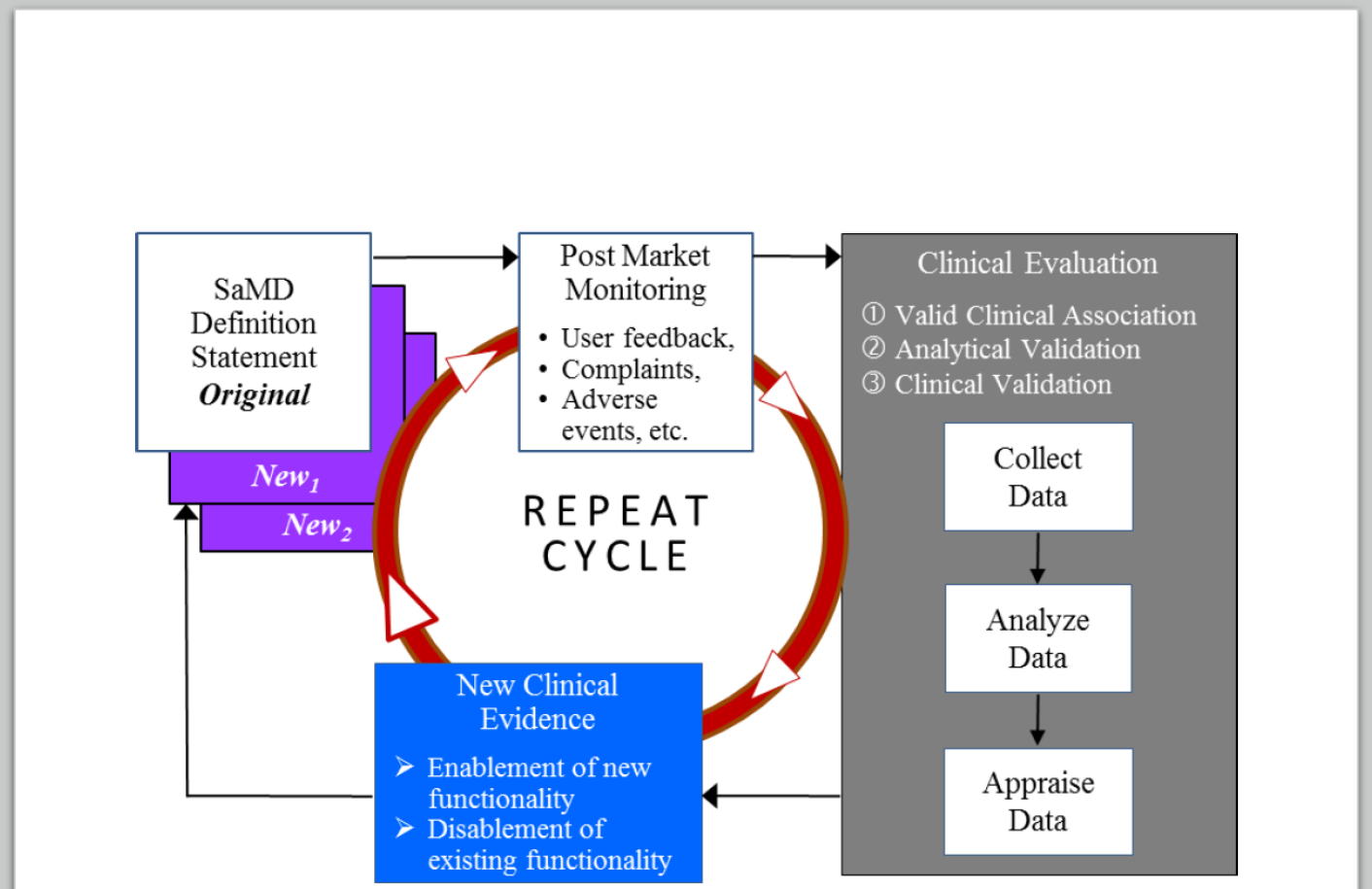
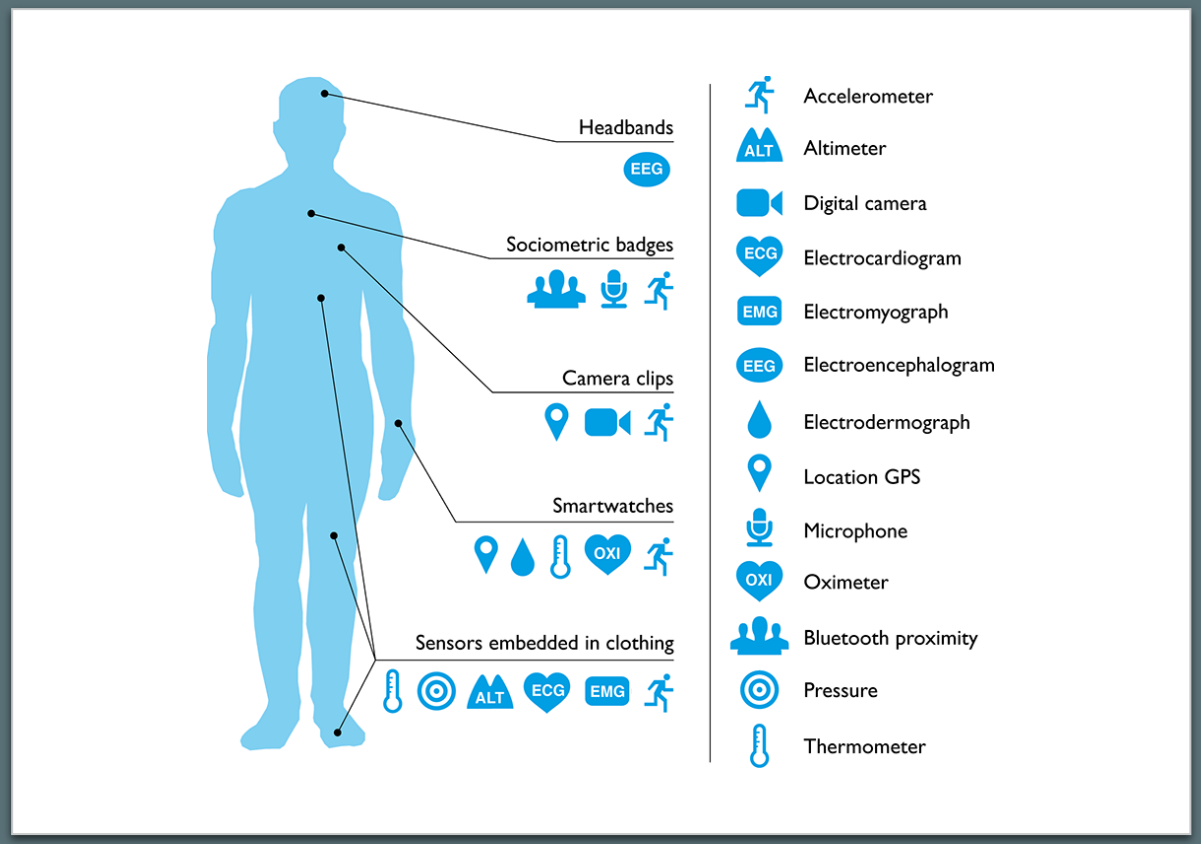
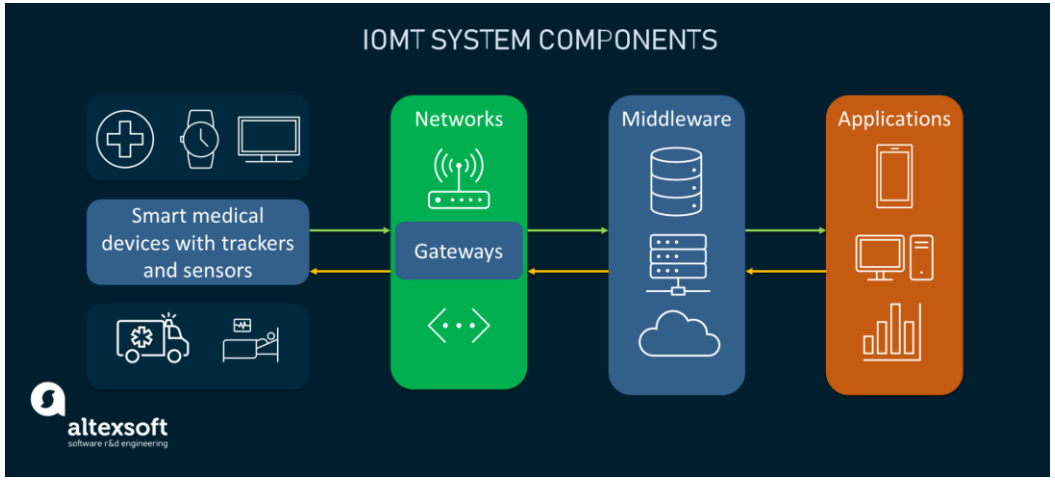


Figure 14 - Pathway for Continuous Learning - Use of Real World SaMD Performance Data in Ongoing SaMD Clinical Evaluation

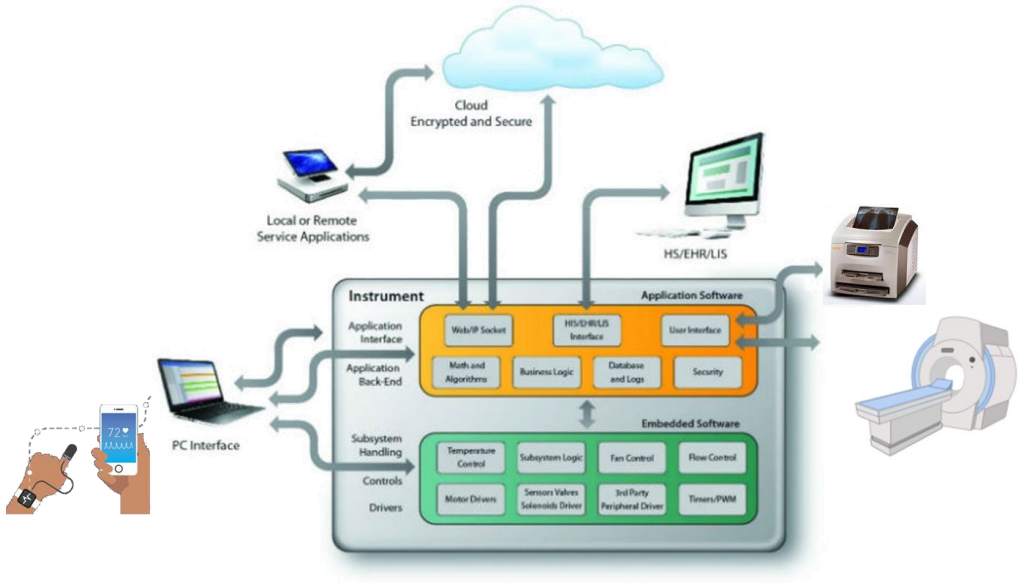
Wearable Devices & IoMT





Enabling Environment

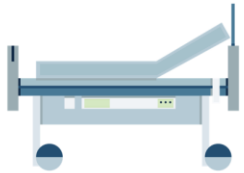
- These devices often run unsupported operating systems, have multiple vulnerabilities, and high-risk scores.



Use Case 2. Reducing Risk

The Weakest Link in the Healthcare Cybersecurity Chain

25%	20%	40%
of all medical devices in the clinical ecosystem run on legacy OS	of all medical devices in the global clinical ecosystem run the unsupported Windows 7 OS	of all medical devices in the global clinical ecosystem run a Windows OS*.



*Windows Server 2008/R2, Vista, 2003/R2, XP, 2000, 98, and older.

https://www.cynerio.com/blog/a-peek-into-our-webinar-3-ways-you-havent-thought-of-for-using-automation-in-healthcare

Core Challenge: Keeping track of IoMT devices in real time.

- Inventory discovery
- Ongoing monitoring
- Device location
- Utilization and mitigating risk

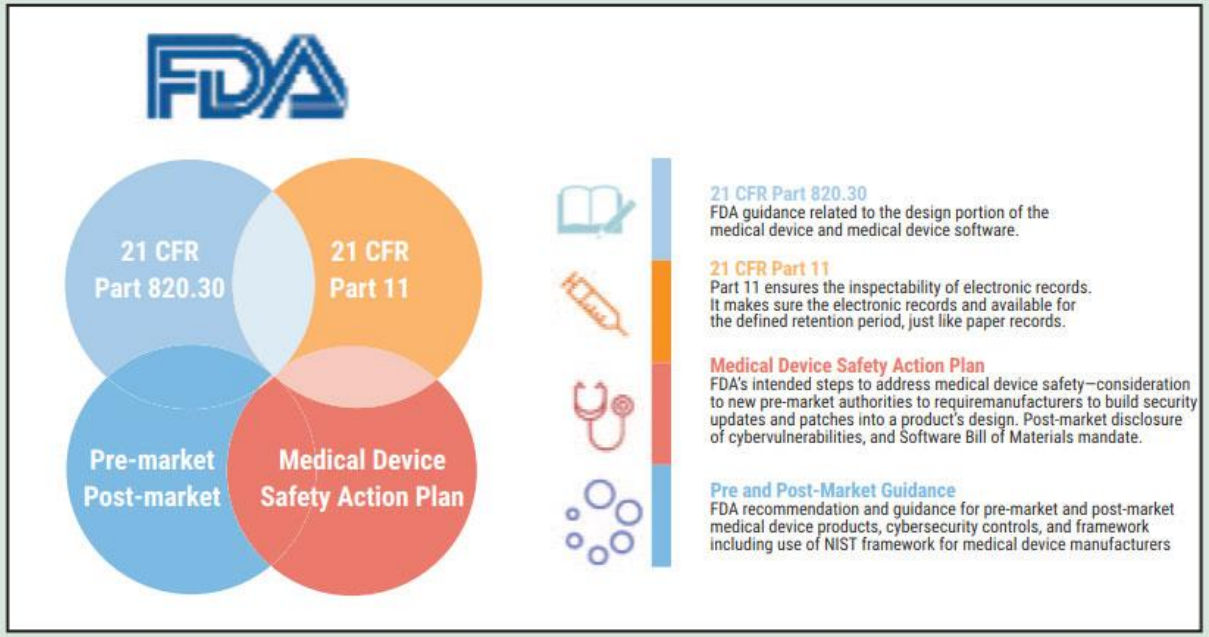
Use Case I. Actionable Visibility

https://www.cynerio.com/blog/a-peek-into-our-webinar-3-ways-you-havent-thought-of-for-using-automation-in-healthcare

Security

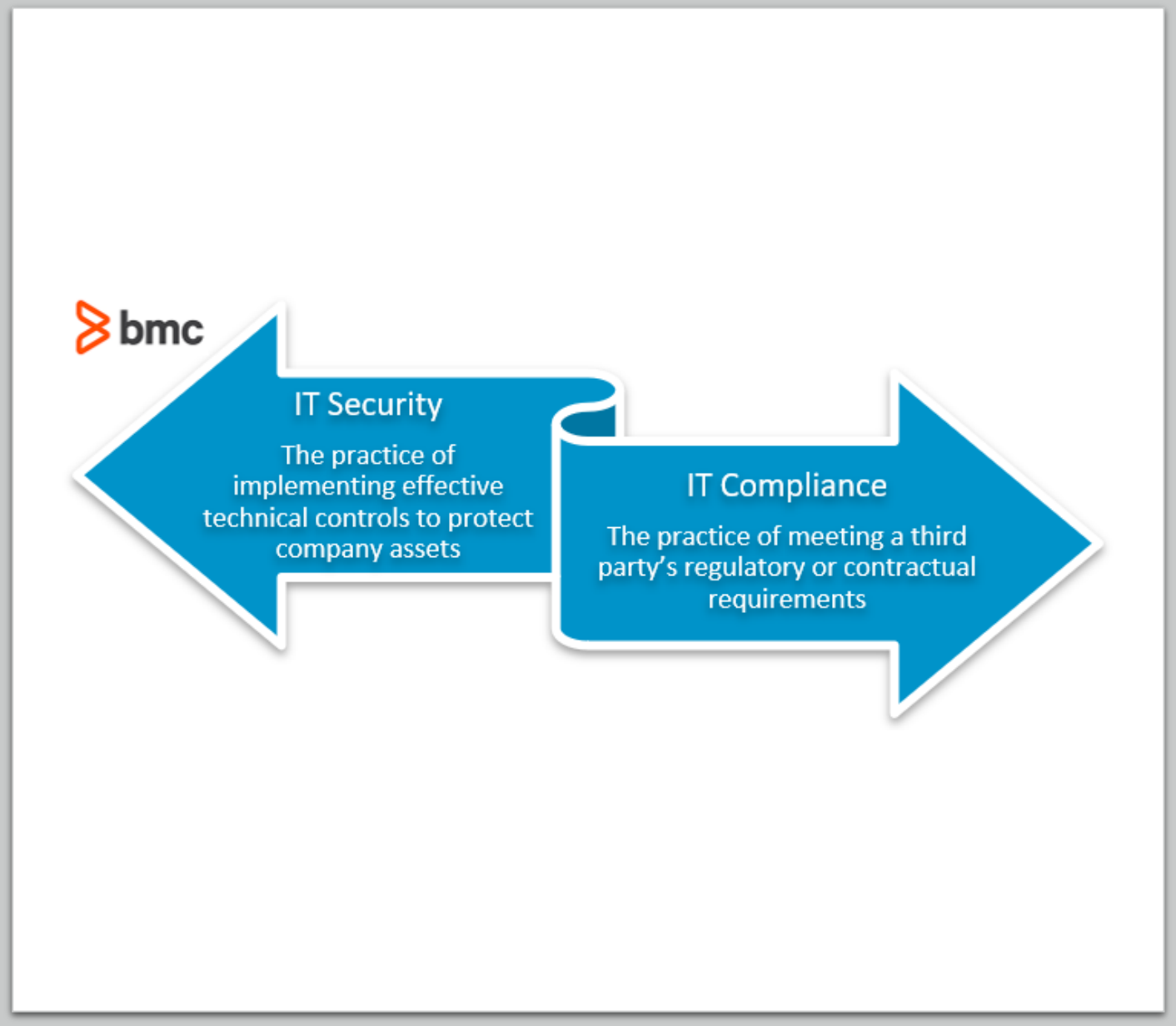
- FDA Guidance on Medical Device Accessories (December 30, 2016)

Figure 1—US Regulatory Guidance for Medical Device Cybersecurity



Regulatory Structure

- FDA – medical devices
- FCC – wireless spectrum
- OCR – HIPAA/HITECH
- FTC – Breach Notification Rule
- ONC – standard development & coordination
- DEA – no controlled substances without in-person exam
- Informed Consent
- Privacy & Security compliance



Thank you

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Thank you!

Name: Ricardo Silva

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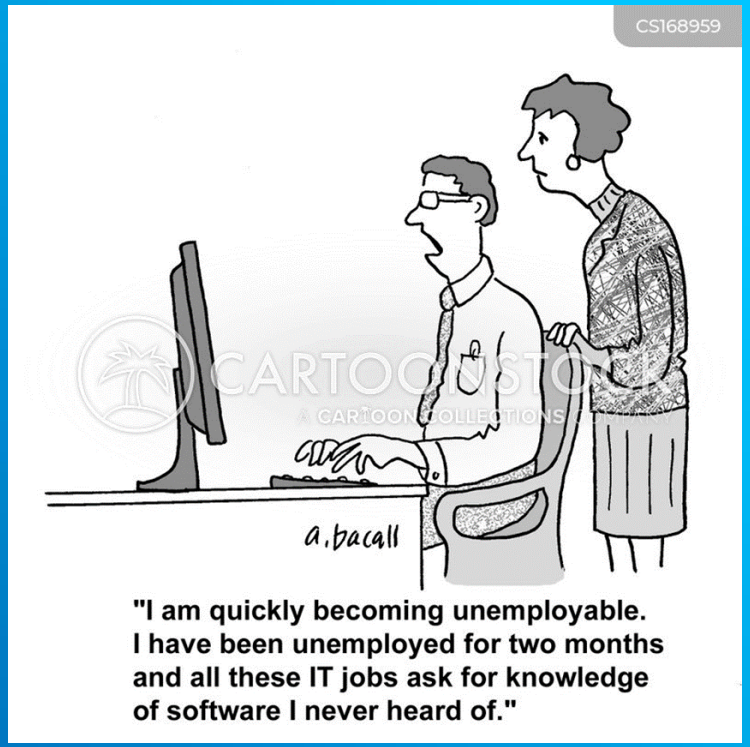

Q&A

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A list of additional topics and dates for next webinars will be soon published on our website www.GlobalCEA.org

THANK YOU
for your participation