A Funny Thing Happened on the Way to the Consensus Report

What Cloud Computing Tells Us About The Accelerating Evolution of the Validated State

June 30, 2022

Randy Horton, VP of Solutions and Partnerships, Orthogonal
Pat Baird, Regulatory Head of Global Software Standards, Philips (In absentia)

+

Pat & Randy also serve as Co-Chairs for the following AAMI Cloud Computing initiatives:

AAMI SM-WG10 - Software Management Working Group for Cloud Computing.
AAMI TIR115 - The Technical Information Report, currently in development.
AAMI CR510 (2021) – The original Consensus Report, published in 2021.

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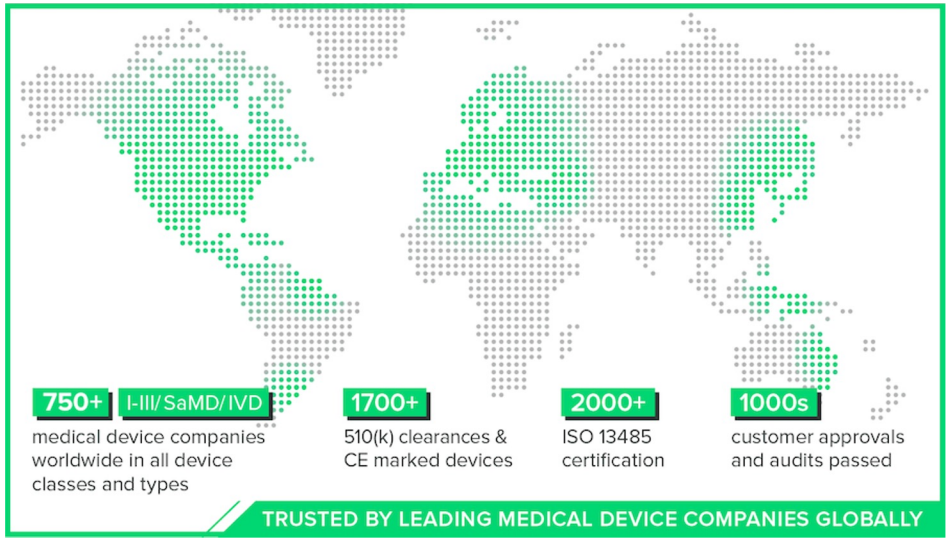
MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME.

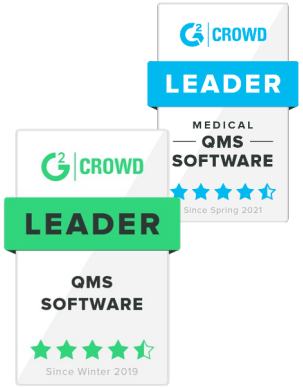
1.5M years industry experience

522k podcast listeners

182k+ look to us for the latest in quality

#1 blog and podcast in the industry





"Best eQMS I have ever used..."

This is the easiest eQMS I have used in the 20 years I have been in the Medical Device Industry. ***It is simple, intuitive and easy to use...*** We are successfully implementing a Quality Culture.

- Director of Regulatory Affairs & Quality Assurance

"Modern QMS Software and Outstanding Customer Service."

★★★★★

"Demystifying QMS and Regulatory Requirements"

★★★★★

"Makes your QMS Simple and Effective"

★★★★★

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Alternatively…

What Cloud Computing Teaches Us
About the Future of the Validated State

Compliant Integration of Third-Party Computing Technologies
Into the Operation of Medical Devices

Using 3rd Party Software and Data You Don't Fully Control
In the Operation of Your Medical Device

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A Conference Presentation in Two Acts

Act 1: The Creation of AAMI CR510:2021

- Why was this Consensus Report (CR) needed?
- What is the overall summary of this CR's guidance?
- What comes next?

Act 2: The Funny Thing That Happened on the Way

- Our "aha moment" about the future of the validated state
- How this altered our future course and what we hope to accomplish now

This is a story with a lot of big themes and different ideas

Economies of Scale

Evaluating tradeoffs and allowing informed decision making

Balancing Technology Advances, Innovation & Risk Management

Bringing innovation to risk management

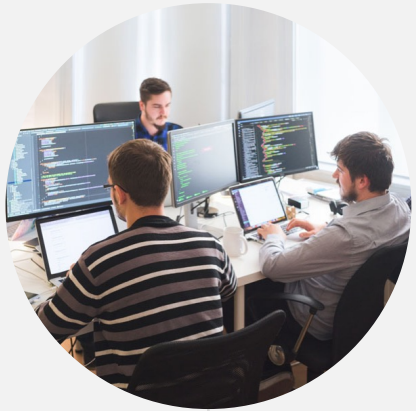
Discrete, well-defined, stand-alone medical devices evolving into always improving, highly interconnected devices

Act 1:
The Creation of AAMI CR510:2021

Assuming you already know the basics of…

Cloud Computing

Medical Device
Software Development



But how do they work together?

Survey Question #1

Do you know this musical?

The CR Team

+ A range of industry experts who spoke to us throughout this effort

Clay Anselmo,
Principal Quality &
Regulatory Consultant,
Shriner & Associates

Mike Attili,
President, Amaxo

Josh Schulman,
Chief Science Officer,
Joy Ventures

Bernhard Kappe, CEO
&
Randy Horton, VP of Solutions & Partnerships
Orthogonal

Pat Baird,
Head of Global Software
Standards, Philips

Nicola Zaccheddu,
Sr. Software Quality
Engineer, Philips

Artiom Kisselev
Master's student in Translational Medicine,
UCSF/UC Berkeley

Standard – the last step in evolution

Consensus Report
CR510:2021

Technical Information
Report (TIR) #115

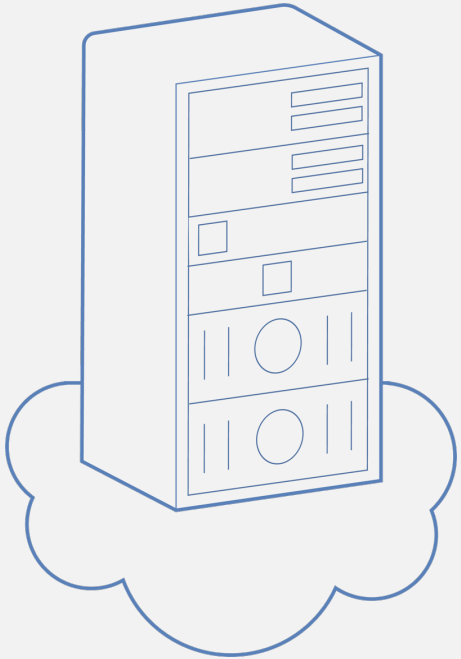
Standard (e.g., ISO, IEC)

Why did it take us 18 months to write a 9-page document?

Mark Twain

"I apologize for such a long letter.
I didn't have time to write a short one."

The Scope of the Consensus Report



How do you maintain a validated state when part or all of a medical device (or QMS system) is operating on a 3rd party public cloud computing service that you don't fully control?

Fortresses to container ships: an evolution for medical devices

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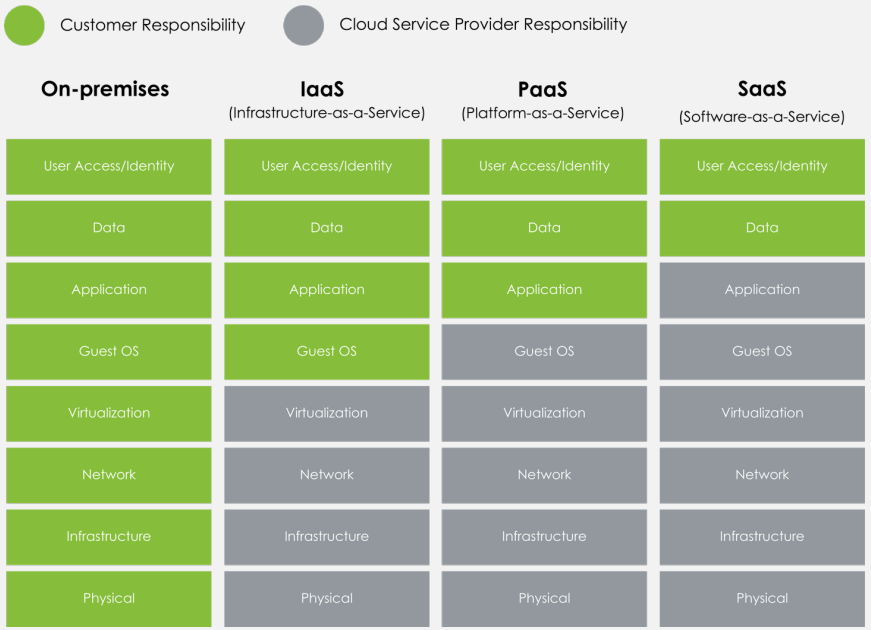
Cloud Computing in Medical Devices/QMS can have huge value for patients, providers, manufacturers and regulators

> “Cloud computing's rapid growth in this century is a story of the incredible power of economies of scale and the ways that applying that economic principle to the provisioning of server-side computing has had tremendous benefits in terms of cost, reliability, security, agility, and functionality.
>
> When compared to other computing platforms, one of the key strengths of cloud environments in general, and public cloud environments specifically, is that they constitute a platform where changes and updates can be frequently, rapidly, and widely deployed.
>
> Changes may include, for example, the on-demand scaling up or down of more computing power in the form of additional servers or software updates anywhere/everywhere adaptation of the environment to protect against cybersecurity threats.”

- AAMI CR510:2021

Fundamental Insight #1



- It's *not* OK to just "lift and shift"
- Lack of control over environment
- Rollbacks are typically not an option
- Amazing new features come with a new set of risks

Fundamental Insight #2

The economics of cloud computing compared to the economics of connected medical devices don't give our industry too much standing to demand fundamental paradigm changes.

And… we probably don't want to "uncloud" the cloud, as we benefit from it, too.

Fundamental Insight #3

"Under these conditions, *the best that can be achieved is an intermittently validated state.*"

- AAMI CR510:2021

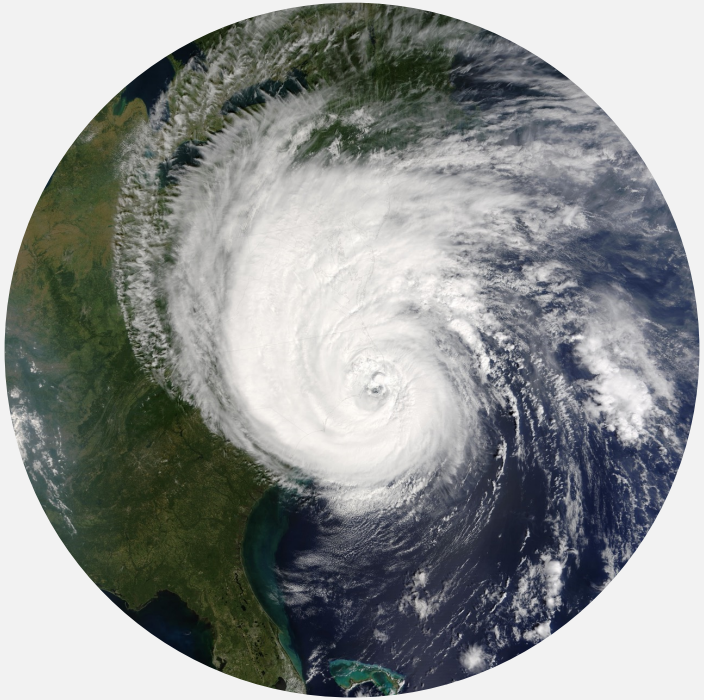
Fundamental Insight #4

An intermittently validated state is not an automatic deal breaker

"It is the consensus of the Application of Quality Systems to Medical Devices Team members that in many cases achieving an intermittently validated state with a high benefit/risk ratio is acceptable, *provided that medical device manufacturers understand and plan for the changes that may occur* in real-time on commercial cloud platforms and respond in an educated, thoughtful, and responsible manner to address the corresponding risk and ensure effectiveness and safety."

- AAMI CR510:2021

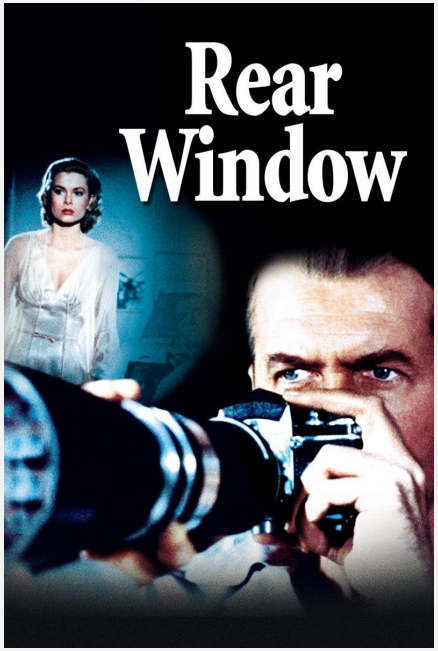
Fundamental Insight #5



Stop being surprised by the unexpected!

Instead, just plan for the unexpected to happen…again and again and again.

The noisy neighbor in movies and cloud computing



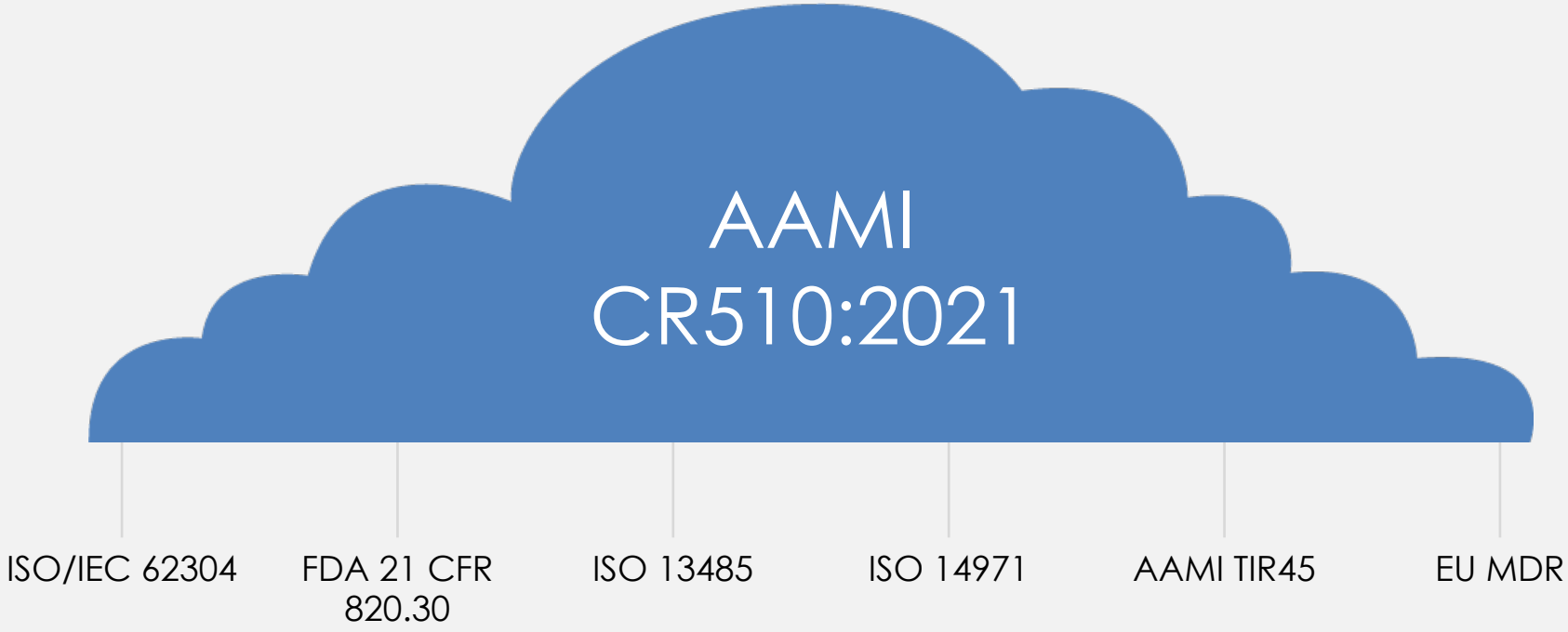
“6 Key Recommendations for Responsibly Embracing the Cloud for Medical Devices”

1. Identify the intended function of the cloud computing resources
2. Apply a risk-based approach to evaluating resources for your project or process
3. Identify the typical frequency of updates
4. Assess the vendor and its processes with a level of scrutiny
5. Establish a plan in case an update adversely affects the software
6. Develop a supplier monitoring process

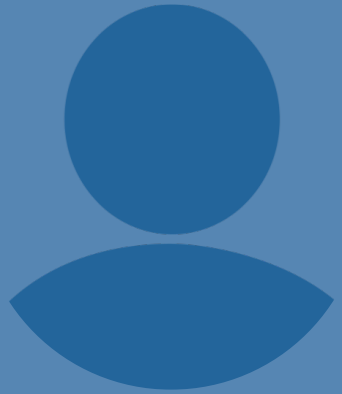
This is who we are.

This is what we do.

AAMI CR510:2021 is *additive guidance*



Feedback from a connected device guru at a cloud tech giant

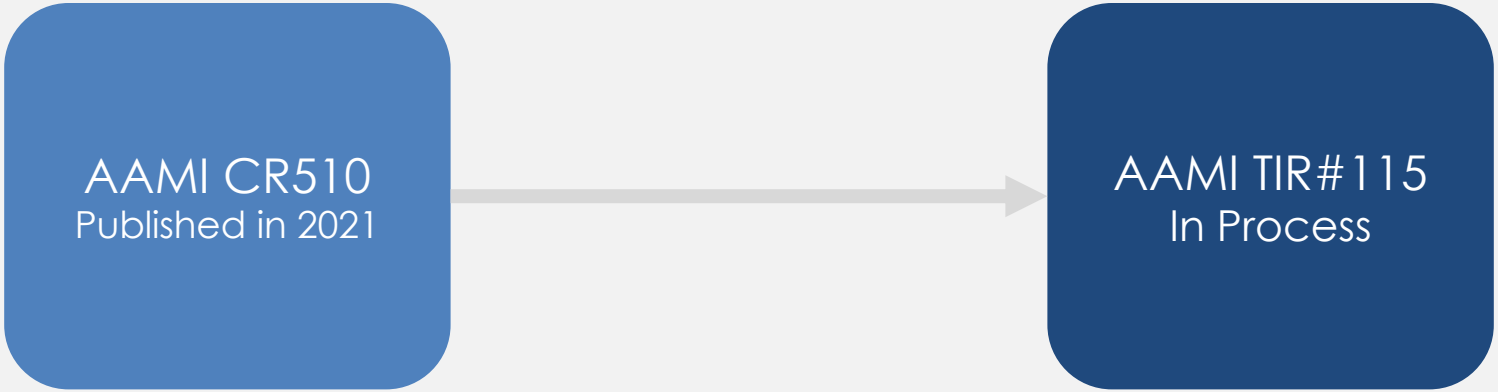


Senior Technical Architect for Major Cloud Service Provider with specialization in medical devices

"You can't see me through the phone, but I'm nodding yes with my head so vigorously that I just threw out my neck.

I'm so happy that *someone* is finally creating some formal guidance I can point at to make this point, because I've been making this argument for over a decade… and usually have been met with great resistance."

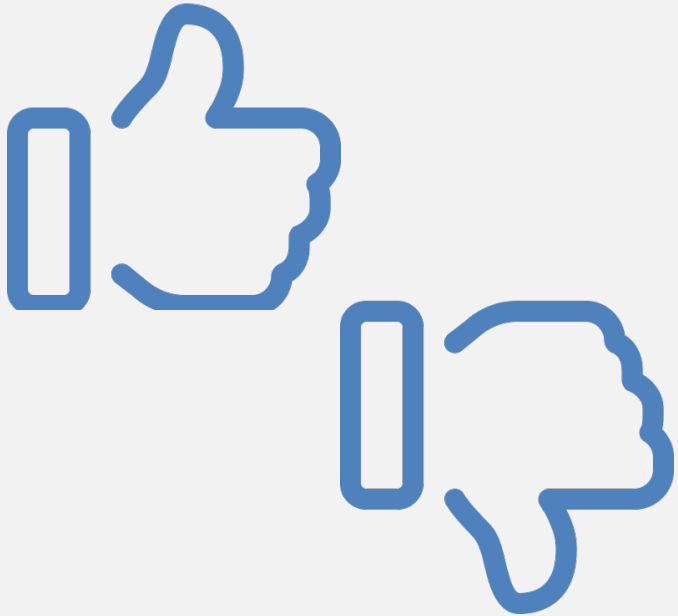
As Act 1 draws to a close…



What's next for Cloud Guidance?

- Spread the word about the CR
- Begin the TIR
- Publish insights along the way

Survey Question #2



Is AAMI CR510:2021 of value to you and your organization?

End of Act 1

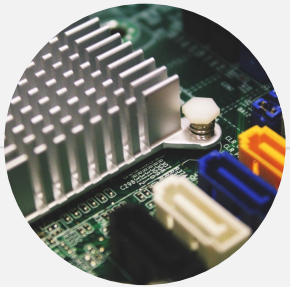
Act 2:

A Funny Thing Happened on the Way to the Consensus Report

Challenges to the “traditional” validated state

Modern Computing

Hardware



Software

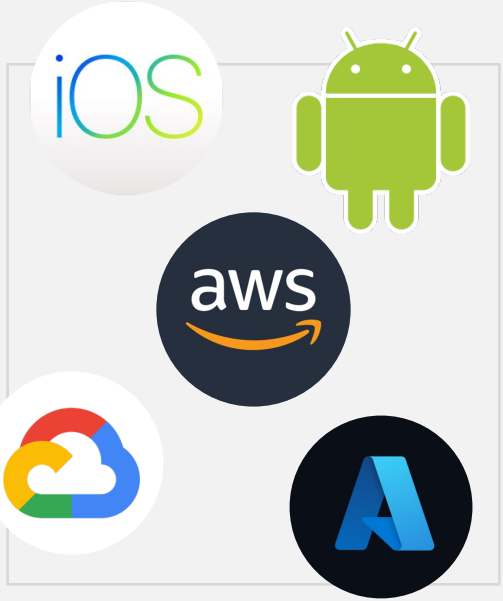
Data

Networking

It’s not just the public cloud…

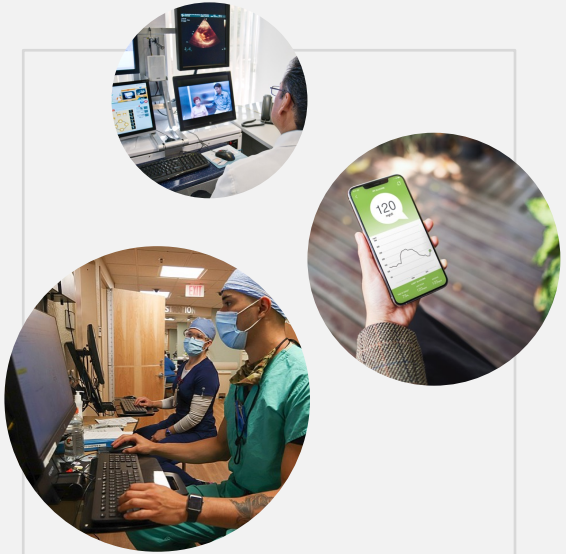
Challenges here, there and everywhere

Modern computing meets medical devices left, right and center



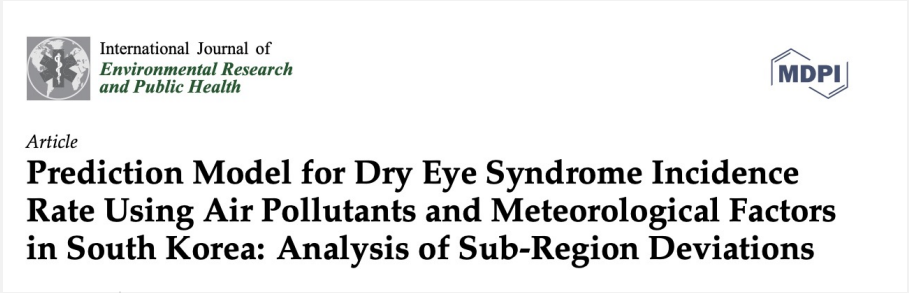
Utilization of
3rd party computing
infrastructures

Consumption of
3rd party software and
data services



Interoperability with
clinical systems via
APIs, SDKs, HL7/FHIR

Third-party data

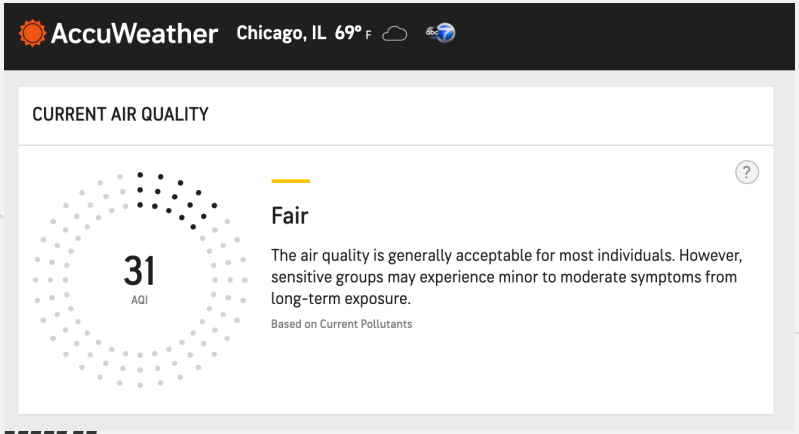


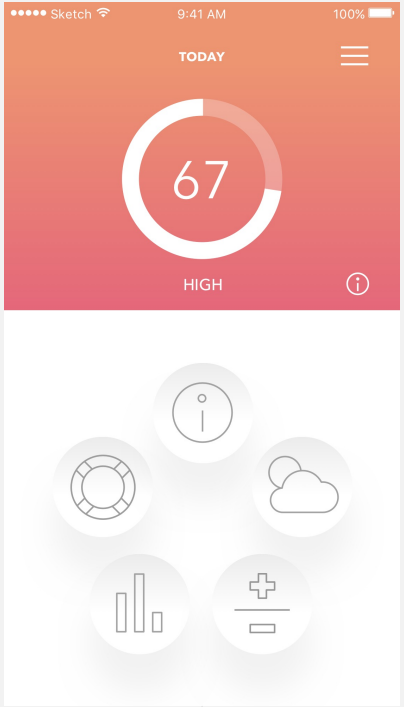
International Journal of *Environmental Research and Public Health*

MDPI

Article

Prediction Model for Dry Eye Syndrome Incidence Rate Using Air Pollutants and Meteorological Factors in South Korea: Analysis of Sub-Region Deviations





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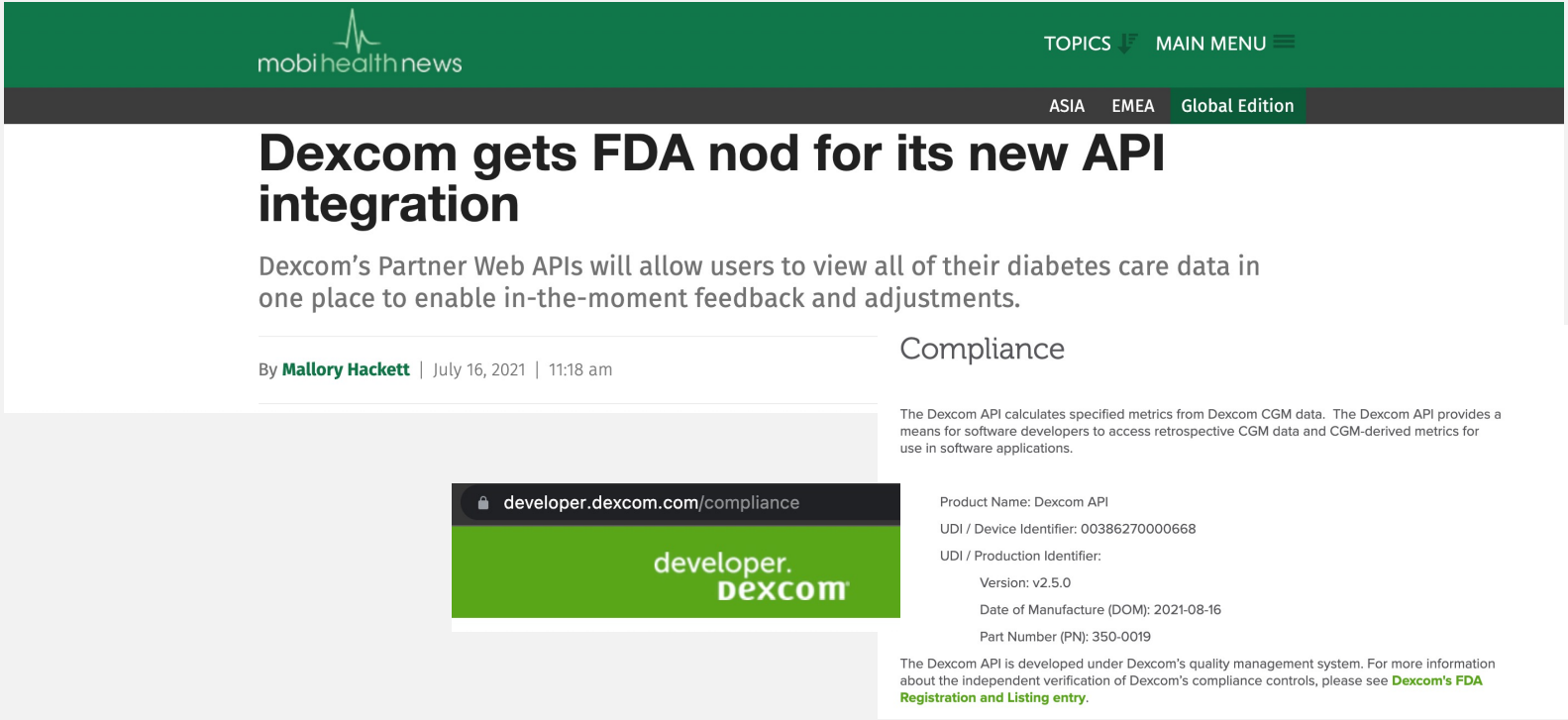
The application programming interface (API) *is* the medical device



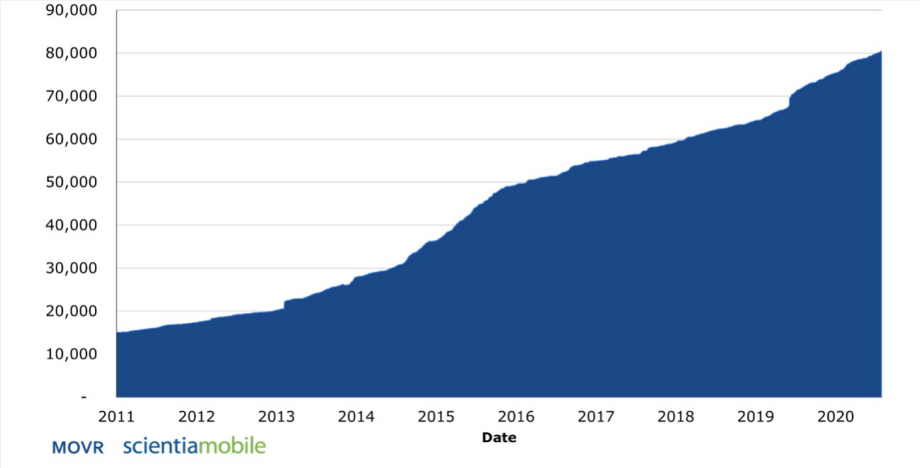
Always shout FHIR in a complex healthcare ecosystem!

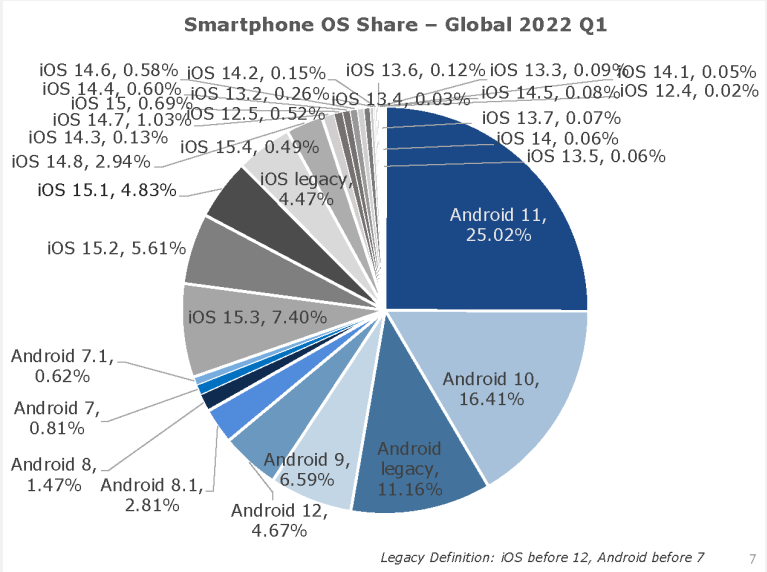
"FHIR breaks healthcare data into manageable chunks that can easily be exchanged with other systems."

- Sam Schifman, Chief Architect, FHIRWorks

It's a wild world of smartphones and tablets

Device Profile Fragmentation over a Decade
(the unique combinations of device brand, model, and operating system)





Data from ScientiaMobile's quarterly Mobile Overview Report (MOVR):
https://www.scientiamobile.com/movr-mobile-overview-report/

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“The Cloud” is a vast oversimplification





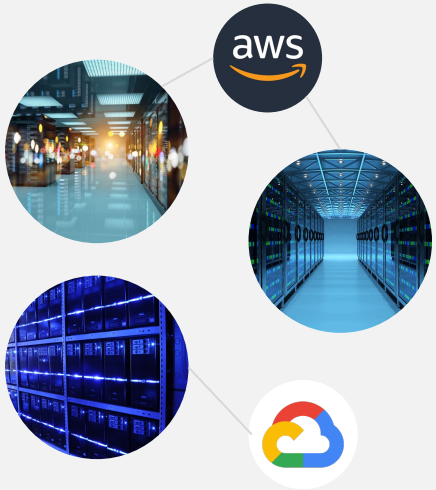





The Cloud of Clouds

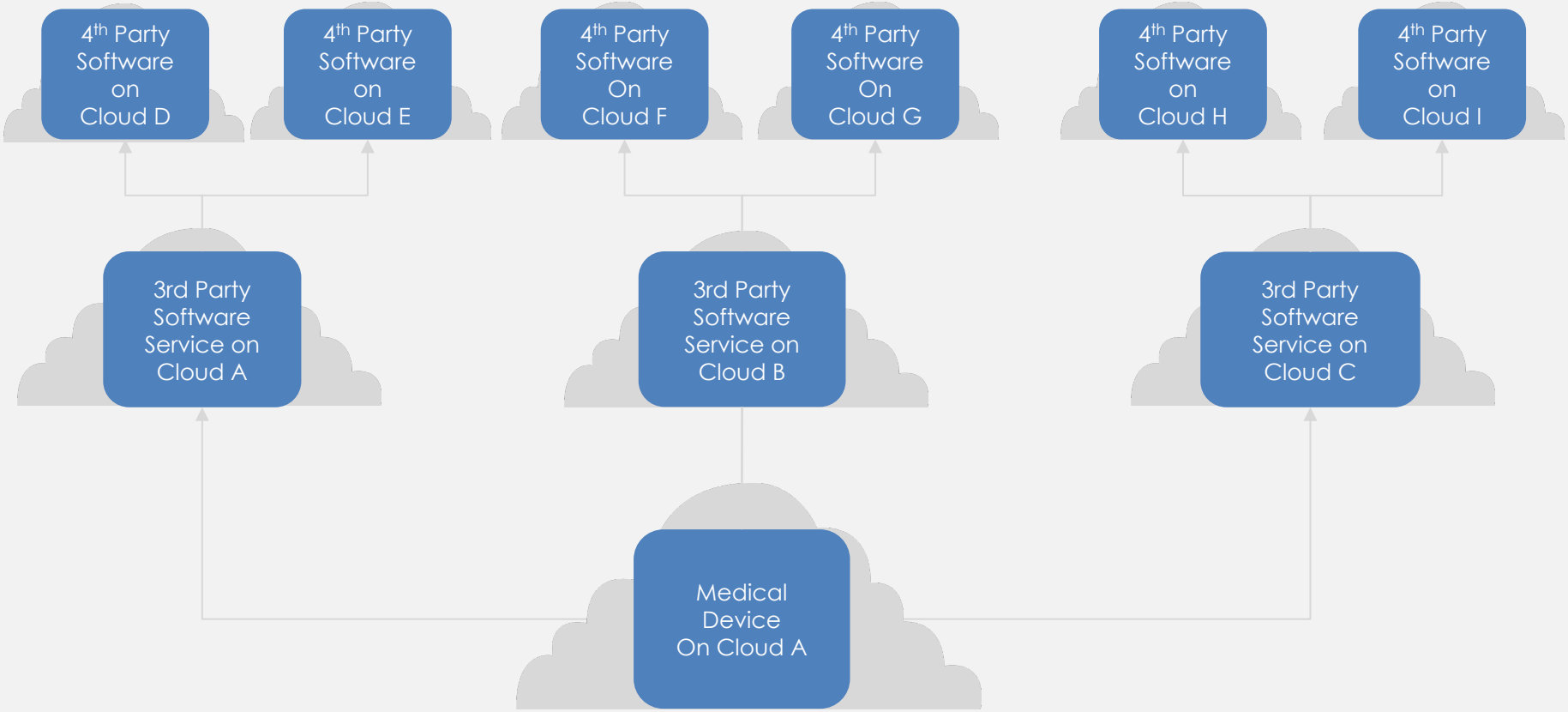
Cloud Deployments
across
multiple data centers

Hybrid Cloud:
In-house data center +
public cloud data centers



Deployments
across multiple
cloud vendors

But wait… it gets even more even more complicated!



Survey Question #3

Who else needs a bit of validation right about now?

Fundamental Insight #6

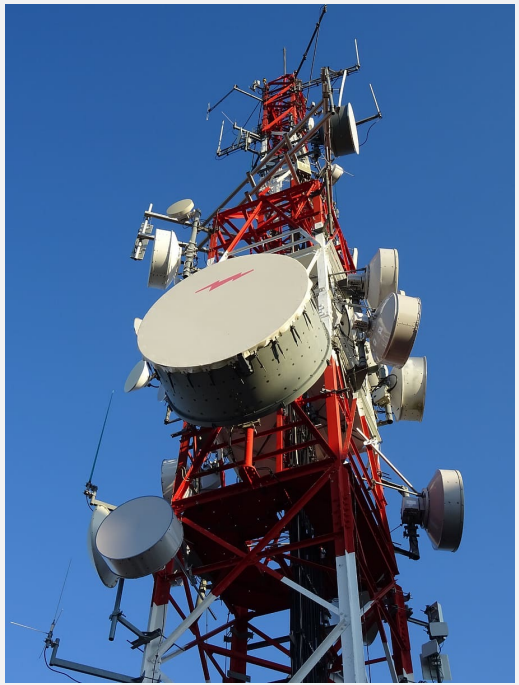
(Pronounced as *tiny gives*)

Fundamental Insight #7

At an abstract level, an intermittently validated state from any modern technology is okay…

But only if we acknowledge it, thoughtfully and consistently analyze the risks, mitigate those risks, and decide what our devices can and can't do on a technology not under our full control

Relevance that goes beyond medical devices

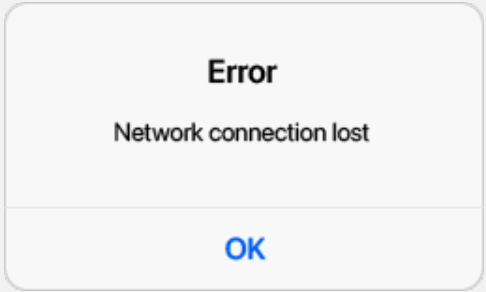


- What changes can occur between validations?
- How likely it is that each change will impact safety or effectiveness?
- What can be done to detect those changes?
- How long will it take to correct or mitigate them?
- What harms could occur before correction or mitigation?

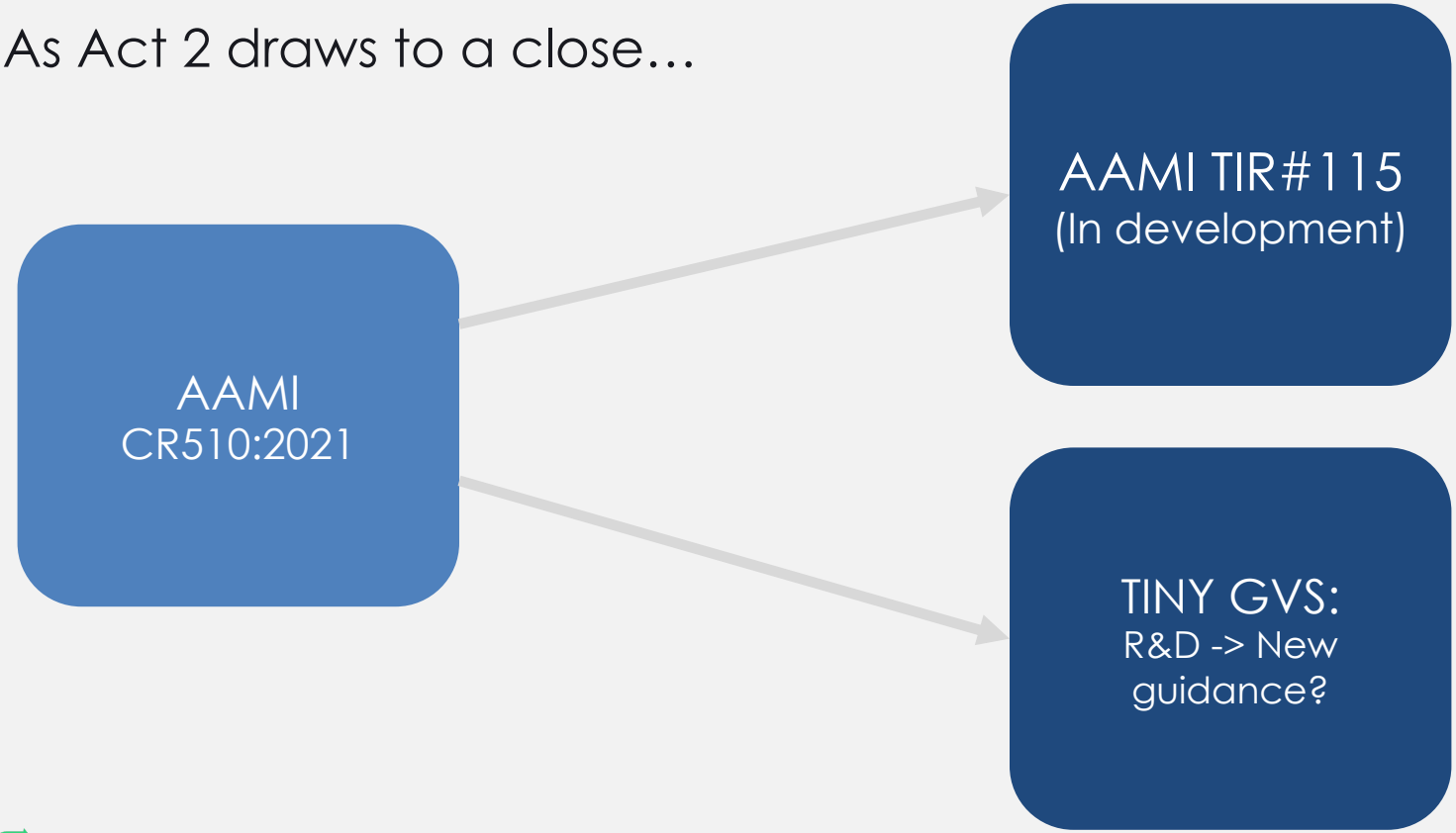
Fundamental Insight #8

Just because you can use a cool technology… doesn't mean you should!

Designers of wearable defibrillators know that certain functions in their devices can *never* risk this:



As Act 2 draws to a close…



What would TINY GVS look like?

A set of recommendations that can be applied across all computing tools and architectures

- Solar plexus for other guidance documents living in the TINY GVS era (AI, cloud, smartphone, clinical decision support, EHR interoperability, telemedicine, etc.)
- Best and Worst practices
- Align with other evolutions in medical device sector
- Lessons learned from other industries with mission critical systems

Survey Question #4

"This Is Not Your Grandmother's Validated State"

Is it a real thing?

Q&A

Please ask us **tough and skeptical questions**…

Or contact us:

Cloud.Consensus@orthogonal.io
pat.baird@philips.com
rhorton@orthogonal.io

Further Reading

- AAMI CR510:2021 - Appropriate use of public cloud computing for quality systems and medical devices
- Anselmo, C., Attili, M., Horton, R., Kappe, B., Schulman, J., Baird, P. 2021. *Hey You, Get On the Cloud:* 100 *Safe and Compliant Use of Cloud Computing with Medical Devices*. Biomed Instrum Technol 1 January 101 2021; 55 (1): 1–15. doi: https://doi.org/10.2345/0899-8205-55.1.1 102
- Michelle Miller, Nicola Zaccheddu; Light for a Potentially Cloudy Situation: Approach to Validating Cloud 104 Computing Tools. Biomed Instrum Technol 1 May 2021; 55 (2): 63–68. doi: https://doi.org/10.2345/0890-105 8205-55.2.63 106
- Operating Medical Devices in Cloud: Experts build consensus on safety (MedTech Intelligence webinar video, slides and transcript) - https://orthogonal.io/insights/operating-medical-devices-in-cloud-experts-build-consensus-on-safety/
- ScientiaMobile's Mobile Overview Report (MOVR) - https://www.scientiamobile.com/movr-mobile-overview-report/

There is no fate but what we make.

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