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**IMDRF** International Medical  
Device Regulators Forum

# IMDRF /DITTA joint workshop

Artificial Intelligence in Healthcare  
*Opportunities and Challenges*

*Monday 16 Sept. 2019, Yekaterinburg*

## Overview of AI Standardization Activities

Pat Baird, Philips (pat.baird@philips.com)

*Global Software Standards, Philips – DITTA member*



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# ISO/IEC JTC1 SC42

Multiple working groups, developing standards for all industries:

WG1 – Foundational standards (terminology, framework)

WG2 – Big Data (vocabulary, reference architecture)

WG3 – Trustworthiness (incl. risk, robustness, bias)

WG4 – Use cases and applications

WG5 – Computational approaches

JWG1 – Governance implications of AI

AHG1 – Dissemination and outreach

Informally thinking about developing a QMS **standard**...





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# BSI-AAMI JOINT INITIATIVE FOR 'AI HEALTHCARE' STANDARDS

- UK-U.S. collaboration, with support from MHRA and FDA
- Research, surveys, in-depth discussions
- Stakeholder workshops (autumn 2018):
  - challenges, alignment to regulatory and standards landscape, information gaps, proposed solutions
  - terminology & categorization, alignment to IMDRF principles, next steps and priorities
- Position Paper published February 2019



The emergence of artificial intelligence and machine learning algorithms in healthcare:  
Recommendations to support governance and regulation

Position paper

Prepared by BSI and AAMI

**bsi.**

**MHRA**

**AAMI**  
Advancing safety in health technology



**JIRA**

**Medtech**  
Canada



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**abimed**  
Associação Brasileira da Indústria de Alta  
Tecnologia de Produtos para Saúde

**Kmdica**  
Korea Medical Devices Industrial  
Coop. Association

**ITAC**  
health



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# BSI-AAMI - RECOMMENDATIONS AND NEXT STEPS

- Create an international task force for AI in healthcare
- Map current standards and identify opportunities for new or modified content
- Develop scopes and proposals for new standards covering:
  - Terminologies and categorization
  - Validation processes
- Build a communications and engagement plan
- Current state: working on 2<sup>nd</sup> whitepaper as well as analysis of IMDRF

Essential Principles



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# OTHER STANDARDS: CONSUMER TECHNOLOGY ASSOCIATION (CTA)

- CTA is the trade association for the consumer technology industry (all consumer industries – not just healthcare)
- Established AI working group, published two whitepapers in 2018 – general introduction & use cases & AI standards committee (R13) & Health Care working group (R13 WG1)
- Plans include terminology and best practices for management and oversight of data, and a paper on trustworthiness. Scope includes consumer health, fitness, and wellness technology.



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## OTHER STANDARDS: IEEE

- P7000 “Engineering Methodologies for Ethical Life-Cycle Concerns Working Group”, for all industries; includes Transparency, Privacy, Personal Agents, etc.
- P2801 Recommended Practice for the Quality Management of Datasets for Medical Artificial Intelligence Recommendation
- P2802 Standard for the Performance and Safety Evaluation of Artificial Intelligence Based Medical Device: Terminology



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# PRE-STANDARDS: XAVIER HEALTH CONTINUOUS LEARNING SYSTEMS WG

- Started in late August 2017 at the Xavier University AI Summit
- Group of experts from medical device and pharmacology industries, academia, government
- Purpose:  
Maximize the advantages of artificial intelligence in advancing patient health by identifying how to provide a reasonable level of confidence in the performance of continuously learning systems in a way that minimizes risks to product quality and patient safety





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## PRE-STANDARDS: XAVIER HEALTH, CONTINUED

- Published 2018 paper on Good Machine Learning Practices – “what’s different about AI?”
- In October 2019 will publish a paper on Trustworthiness
- Next paper will be related to Risk Management



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# TERMINOLOGY CHALLENGES

- Agreeing to definitions often takes time, even when people are from the same industry
- Artificial Intelligence practitioners have their own set of terminology that sometimes conflicts with what we think of in medical devices
- “Validation” for medical devices often refers to meeting user needs; but “validation” in data science is making sure the data is valid (e.g. a negative heart rate is probably not a valid piece of data)
- “Bias” is something that data scientists try to eliminate, but I’ve talked to many caregivers that want algorithms to be biased towards their particular patient demographics



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# MANY KEY SUCCESS FACTORS ARE THINGS WE ALREADY KNOW...



We traditionally think of supplier quality as only applying to raw materials, sub-assemblies, etc.

**For Machine Learning, the training data is the “raw material” – bad raw material results in poor quality finished product.**



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# SUCCESS FACTOR: GOOD DATA HANDLING PRACTICES

One challenge is that AI seems mysterious and magical, and people think we need a whole new way of thinking about it.

Consider these rules for handling data:

- Keep records / retain information on the origin of the sample
- Sourcing, processing, preservation, testing and handling should be done in a safe manner
- Protect against contamination, viruses

*Note: these concepts are already captured in IMDRF GRRP WGN47 FINAL: 2018*



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# SUCCESS FACTOR: CLS

Continuous Learning Systems (CLS) are a source of uncertainty. Just like people, CLS systems learn over time – how an application performs now might be different than how it performed a year ago – and that makes people uncomfortable.

Or, perhaps we can think of a CLS update as a type of **calibration activity**...

The point is that we already know many good practices that simply need to be adapted for AI.

# ITU/WHO Focus Group AI for Health

- Artificial Intelligence for Health (A4IH) offers substantial improvements for public and clinical health, e.g. early detection, diagnosis and risk identification, treatment decision support, self-management, improved outcomes, ...
- For world-wide adoption, need evaluation standards on effective AI for Health
- Focus Group AI for Health (FG-AI4H) created July 2018; open platform
- FG-AI4H goals: standardized framework for benchmarking and evaluation of AI solutions



# Focus Group Operation



## Process steps:

- A) Community:** Creating and extending a community around a health topic
  - B) Proposals:** Solicitation of AI for health proposals
  - C) Evaluation:** Setting up evaluation criteria including data sets and metrics
  - D) Report:** Publishing reports about the evaluation and the results
  - E) Dissemination:** After successful use of an AI for health solution in practice, repeat FG-Ai4H process steps (A-E)
- 
- All steps (A-E) require strong voluntary participation, while being monitored and documented by ITU or WHO officials.
  - Most of the work will be conducted using on-line tools and virtual meetings.
  - It is envisioned, that the number of health topic communities will be large 100+



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# WORLD HEALTH ORGANIZATION AND ITU-T

## Structure:

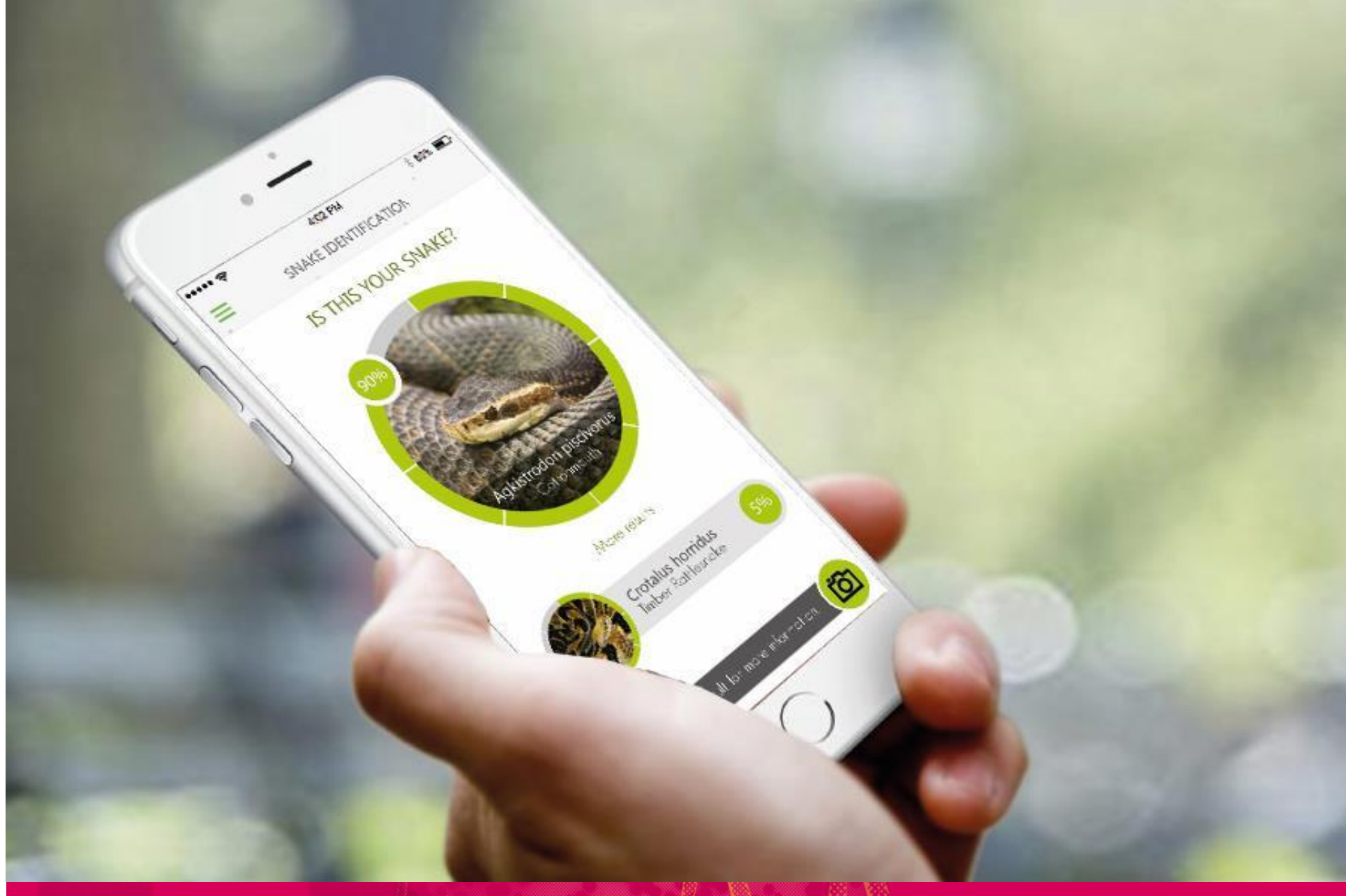
- Expert panel (clinical)
- Establishing benchmarking platform (infrastructure)
- Data & solution quality assessment committee
- Data handling committee
- Regulatory committee (coming soon!)
- Example projects:
  - Outbreak detection
  - Fall predictions
  - Dermatology
  - Neuro cognitive disease

## Snakebite: A global health crisis

- **Snakebite** is responsible for **over 100,000 human deaths** and **400,000 victims of disability** globally every year
- **Snake identification** is key for **adequate clinical management** of patients
- **Snake identification** is very **complex** and **clinicians** are **not herpetologists**



Source: G. Alcoba

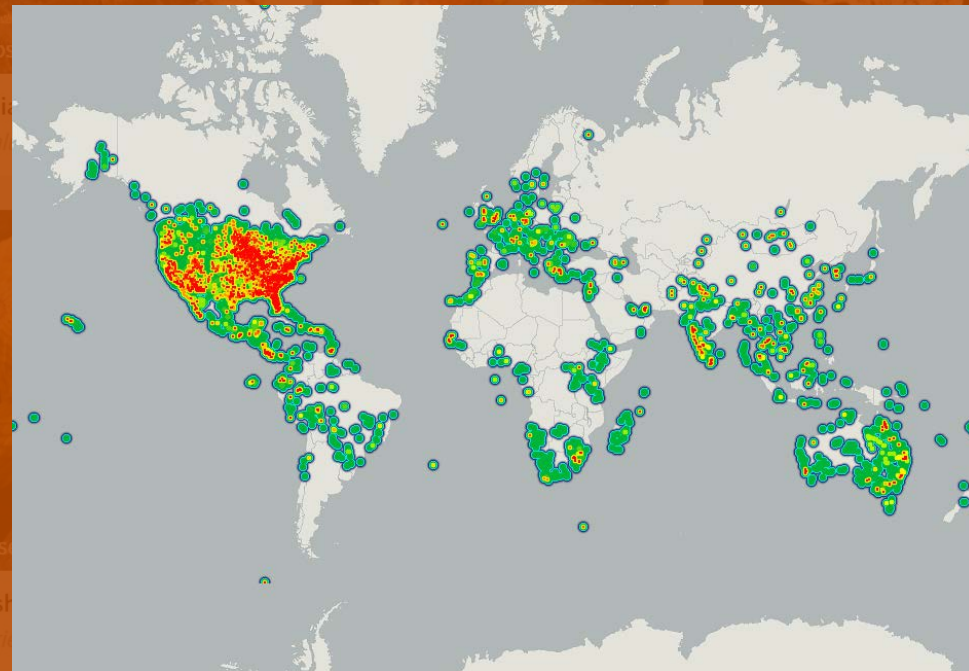


# Growth

HerpMapper  
predicted +50,000 images in 2019



HerpMapper





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# DAISAM WORK GROUP: DATA AND AI SOLUTION ASSESSMENT METHODS

- Charter is to develop a quality assessment approach for candidate AI applications. Includes both data quality and solution(algorithm) quality
- Reviewed 50+ existing standards and guidance documents and created a library of 200+ questions. This was the basis to develop a draft assessment.
- At September 1 - 4 meeting, received feedback from WHO team & am in the process of updating the assessment.
- This is an iterative process – start with an initial set of assessment questions, topic teams will have topic-specific thoughts, individual projects will think of their own criteria, etc (e.g. identify new risks..)
- This is a collective learning environment & information is being captured for future use.



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## POSSIBLE (NEAR FUTURE) NEXT STEPS

1. Existing Guidance documents + Xavier whitepapers = WHO Quality Assessment
2. WHO + CTA + AAMI/BSI = ISO/IEC standards for health software
3. Monitor IEEE, ISO SC42, UL for ideas & potential conflicts





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## LINKS (1/2)

### Xavier

2017 Conference: <https://www.xavierhealth.org/events/ai-2017>

2018 Conference: <https://www.xavierhealth.org/ai-summit-presentations>

2019 Conference: <https://www.xavierhealth.org/ai-summit>

Initiative: <https://www.xavierhealth.org/xavierai>

Whitepapers: <https://www.xavierhealth.org/cls-working-team>

### BSI - AAMI

<https://www.bsigroup.com/en-GB/about-bsi/media-centre/press-releases/2019/february/bsi-issues-position-paper-on-the-emergence-of-artificial-intelligence-and-machine-learning-algorithms-in-healthcare/>

### CTA

<https://www.cta.tech/Research-Standards/Standards.aspx?cat=ArtificialIntelligence>



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## LINKS (2/2)

ISO AI Committees:

<https://www.iso.org/committee/6794475.html>

IEEE AI Committees:

<https://ethicsstandards.org/p7000/>

<http://sites.ieee.org/sagroups-7000/>

<https://sagroups.ieee.org/aimdwg/>

WHO ITU-**T “AI for Good”**

Home page: <https://www.itu.int/en/ITU-T/AI/Pages/default.aspx>

Healthcare: <https://www.itu.int/en/ITU-T/focusgroups/ai4h/Pages/default.aspx>

Whitepaper: [https://www.itu.int/en/ITU-T/focusgroups/ai4h/Documents/FG-AI4H\\_Whitepaper.pdf](https://www.itu.int/en/ITU-T/focusgroups/ai4h/Documents/FG-AI4H_Whitepaper.pdf)



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Thank you!  
Спасибо!

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