Promise vs. Peril

Establishing standards for the broad adoption of AI in Healthcare

Derek Ritz, P.Eng., CPHIMS-CA

2021-04-22

I wish for us all to remain safe and well during this challenging time.

Apologies…

Agenda

- Quick introduction
- ISO Ad hoc Group 2 Report: AI in Healthcare
  - Scope of the report
  - High level findings and recommendations
- Regulation of AI in Healthcare
  - Approaches and issues
  - International progress
  - Canada’s progress
- Closing remarks
- Q&A

Introduction…

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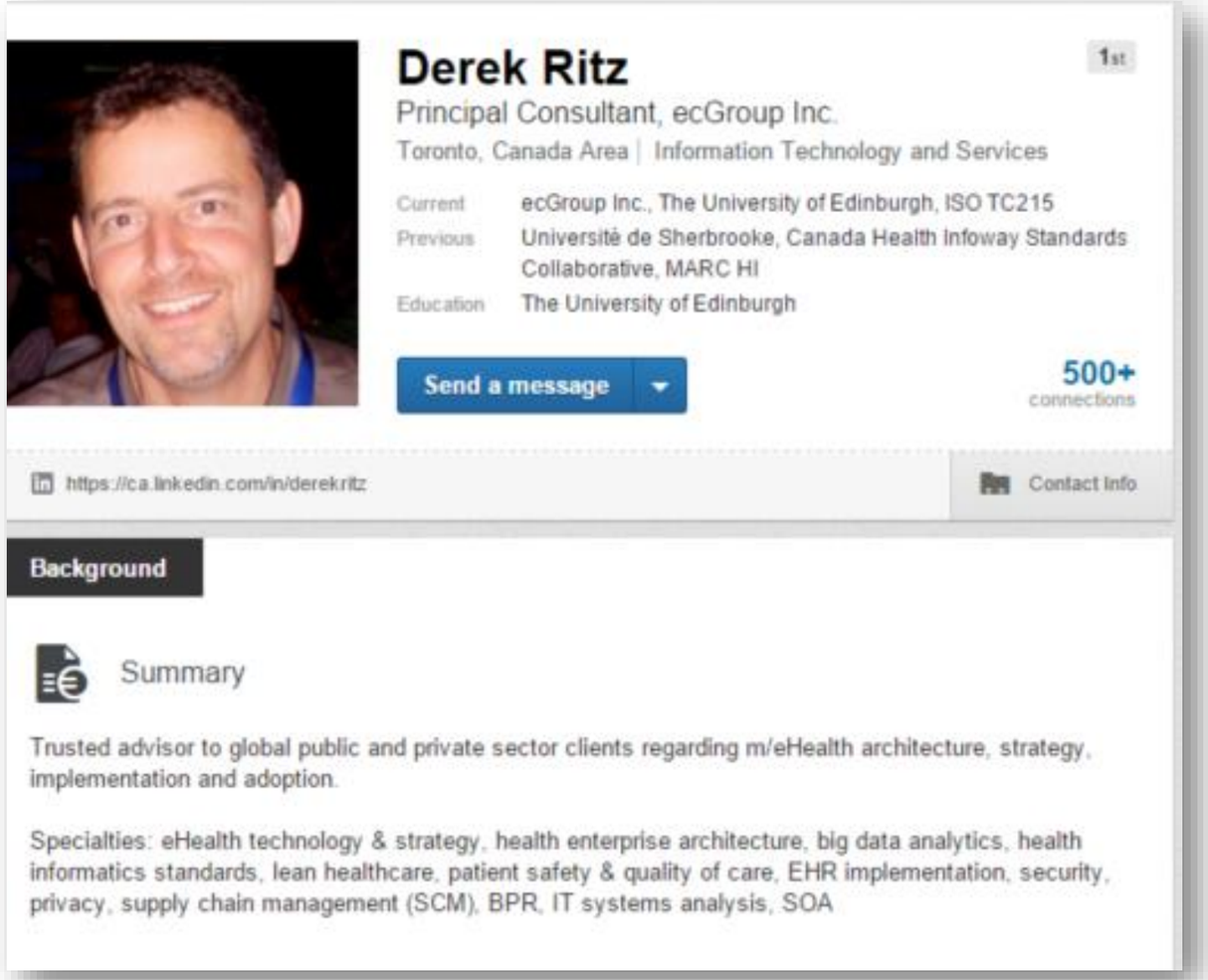

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Previous: Université de Sherbrooke, Canada Health Infoway Standards Collaborative, MARC HI

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Background

Summary

Trusted advisor to global public and private sector clients regarding m/eHealth architecture, strategy, implementation and adoption.

Specialties: eHealth technology & strategy, health enterprise architecture, big data analytics, health informatics standards, lean healthcare, patient safety & quality of care, EHR implementation, security, privacy, supply chain management (SCM), BPR, IT systems analysis, SOA

OpenHIE

World Health Organization · unicef · UNOPS · Joint Learning Network for Universal Health Coverage · The World Bank · ADB

Canada Health Infoway · Inforoute Santé du Canada

ISO · HL7 · IHE · HL7 FHIR Foundation Founder

ISO/TC 215 **N 3534**

ISO/TC 215 "Health informatics"
Secretariat: **ANSI**
Committee Manager: **Hawthorne Rachel Ms**

ISO TC215 AHG2 FINAL Report 20210301

Document type	Related content	Document date	Expected action
Decision / Resolution		2021-03-02	VOTE by 2021-04-03

Description

Per resolution 2020-83, AHG 2 has considered the comments received in N3423 and has submitted the attached as the final report.

TC 215 members are now asked to vote on the following draft resolution:

Draft resolution 2021-07: ISO/TC 215 approves N3534 as the Final report from AHG 2.

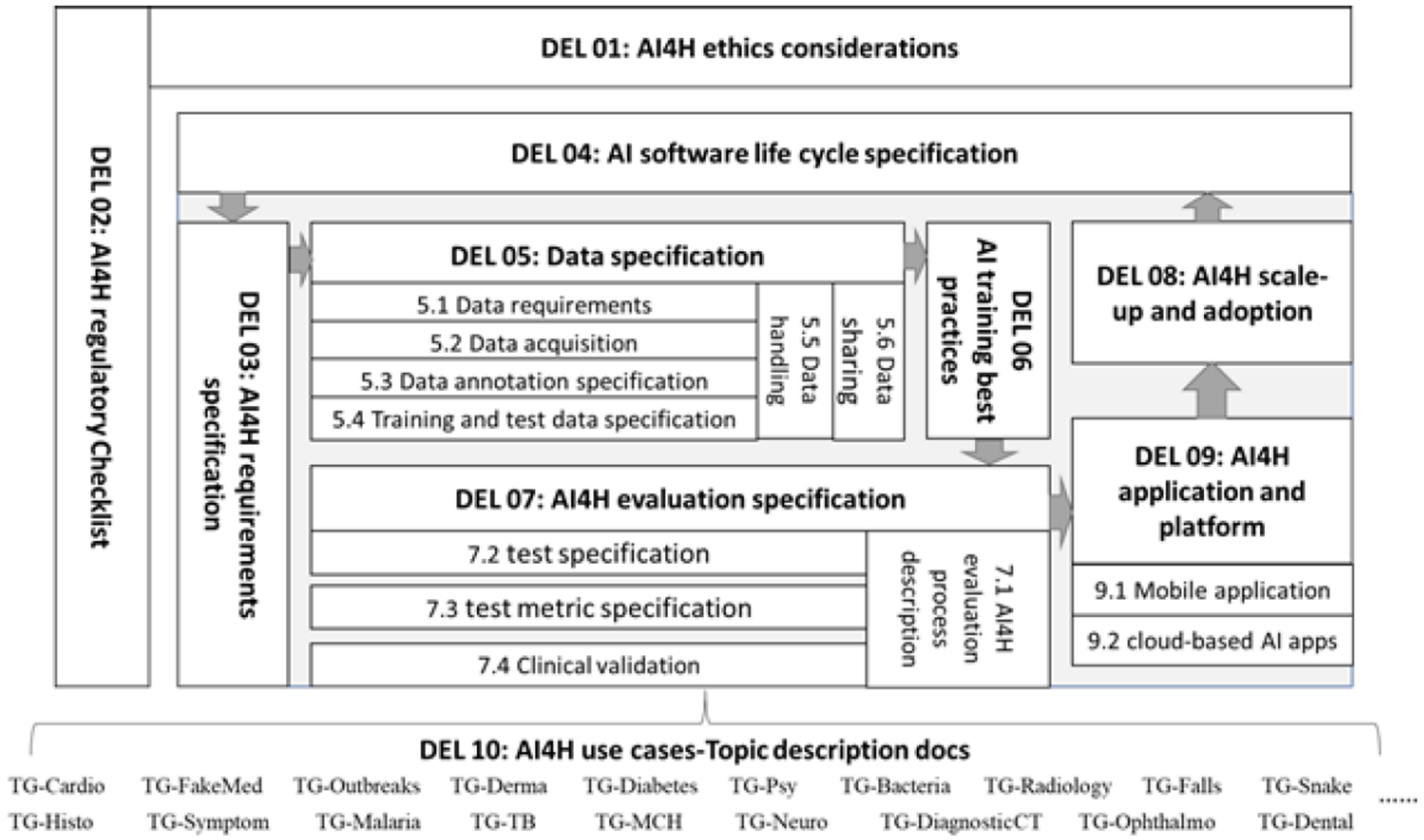
Scope of AHG2 and its report

- ISO TC215's Ad hoc Group 2 (AHG2) was struck with a mandate to explore the area of AI in Healthcare, generally, and to inform the TC regarding future work it should undertake in this area regarding standards development
- The AHG2 report is expected to be used internally

AHG2 axes of exploration

- Standards landscape
- Principles & requirements
- Regulations
- Considerations for low-resource environments (e.g. LMIC contexts)
- Skills / competence development
- Use cases
- Security & privacy

AGH2 – Standards landscape



ISO/IEC JTC1/SC42
ISO/TC 215

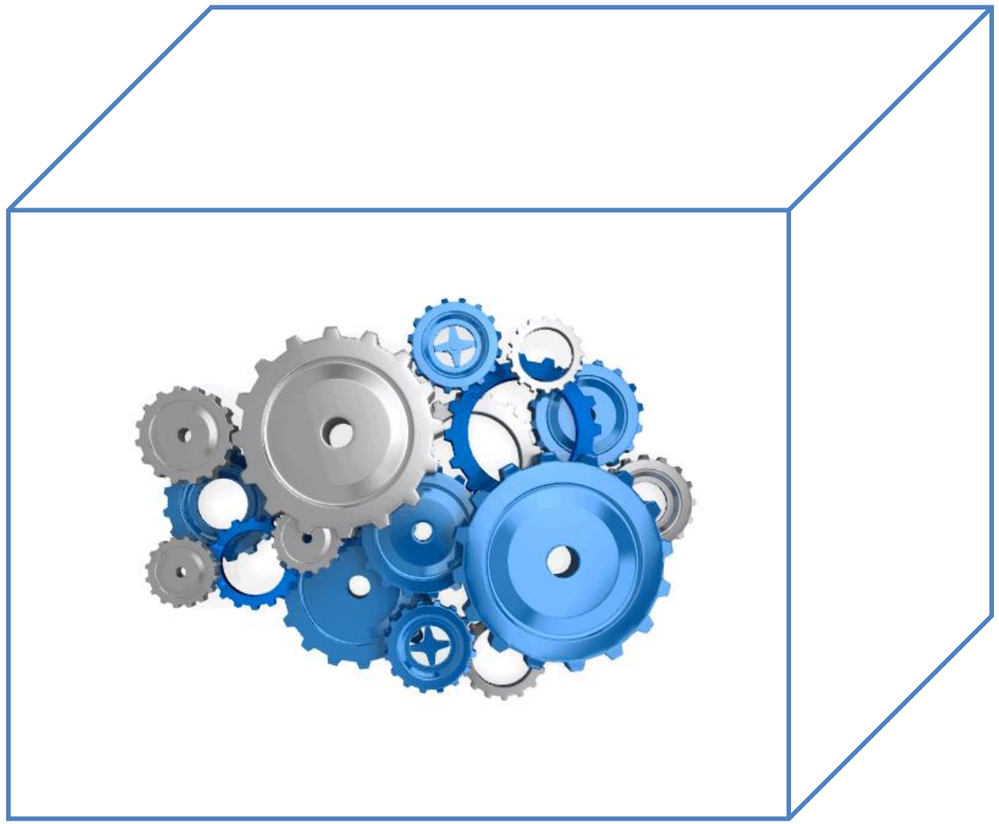
Collaborative research initiatives such as FAIR “Findability, Accessibilty, Interoperability, Re-use” and OpenData are focused on practical challenges of training data set availability.

WHO-ITU Focus Group on “Artificial Intelligence for Health” (FG-AI4H): https://www.itu.int/en/ITU-T/focusgroups/ai4h/Pages/default.aspx

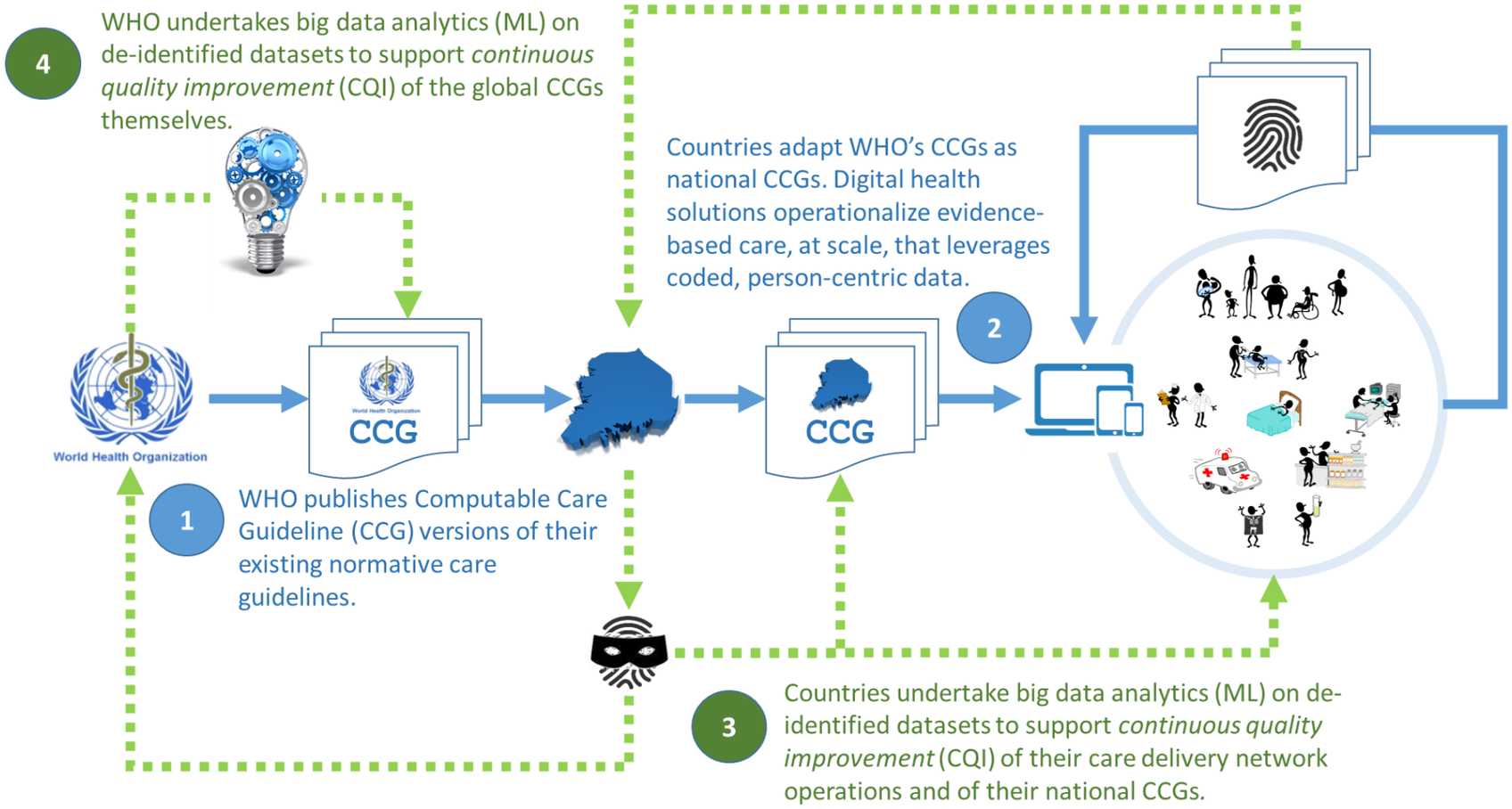
AHG2 – Principles & Requirements

- Value Perspectives:
  - enhancing patient experience
  - improving population health
  - reducing per capita health care costs
  - safe-guarding/improving the work-life of health care providers
  - improving business processes
  - equity and inclusion

- Requirements / Constraints:
  - privacy
  - accountability
  - safety and security
  - transparency and explainability
  - fairness and non-discrimination
  - human control of technology
  - professional responsibility
  - promotion of human values



AHG2 – Considerations for LMICs



AHG2 – Skills & Competence

8.3. Recommendations

1. Develop an ISO/TC 215 TR on AI education, including gap analysis, using as example the ISO/TC 215 TR 18638 on privacy educations in health organizations.
2. * Add to the ISO/TC 215 Information Governance Task Force a task to assess safety, privacy and security topics related to AI education.
3. Add to the ISO/ISO/TC 215 Personalized Digital Health Informatics Task Force a task to assess topics related to AI education.
4. Collaborate with ISO/JTC 1/SC42, ITU/WHO on AI education initiatives.

Security & Privacy

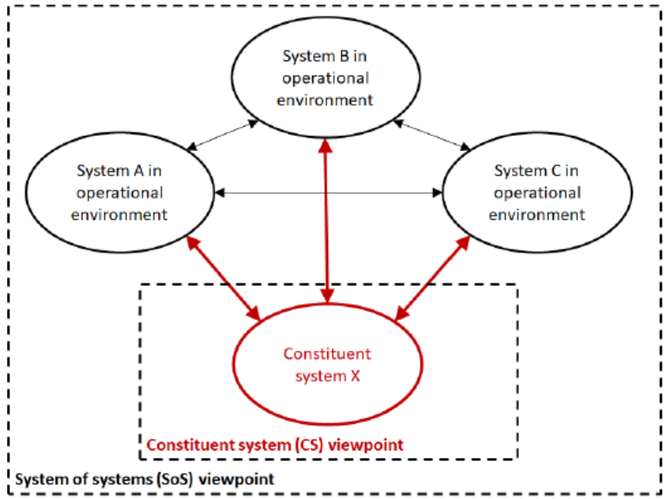
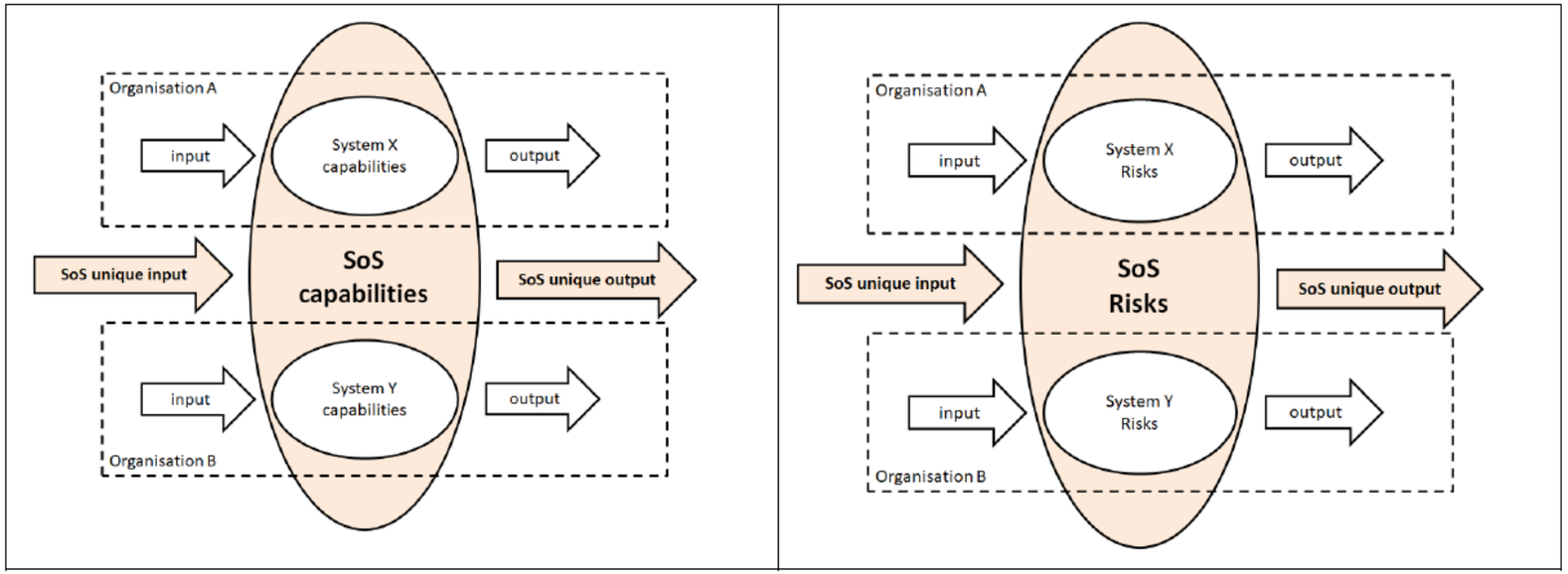


Figure 3: System of systems (source ISO/IEC/IEEE 21839)



A system of systems (SoS) creates a “permutations and combinations” challenge.
The **emergent capabilities** of the SoS are a potential source of significant value.
The **emergent risks** are a potential source of concern.

Security & Privacy

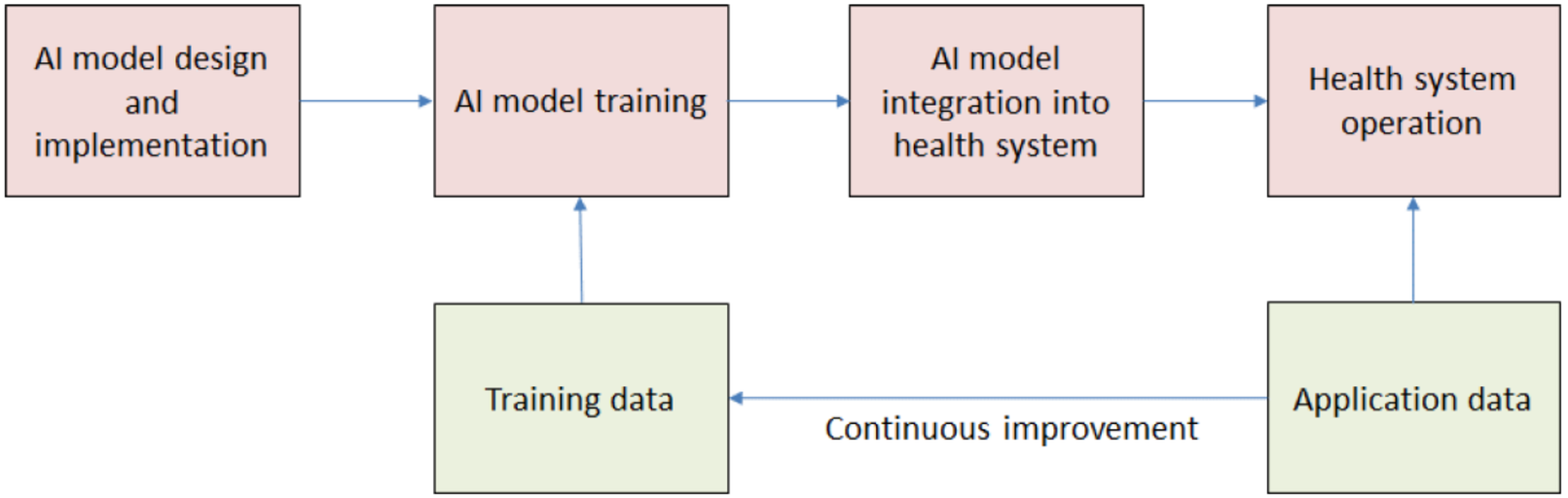


Figure 5: Example of AI system lifecycle

CQI-based approaches may be leveraged to mitigate risk.

Security & Privacy

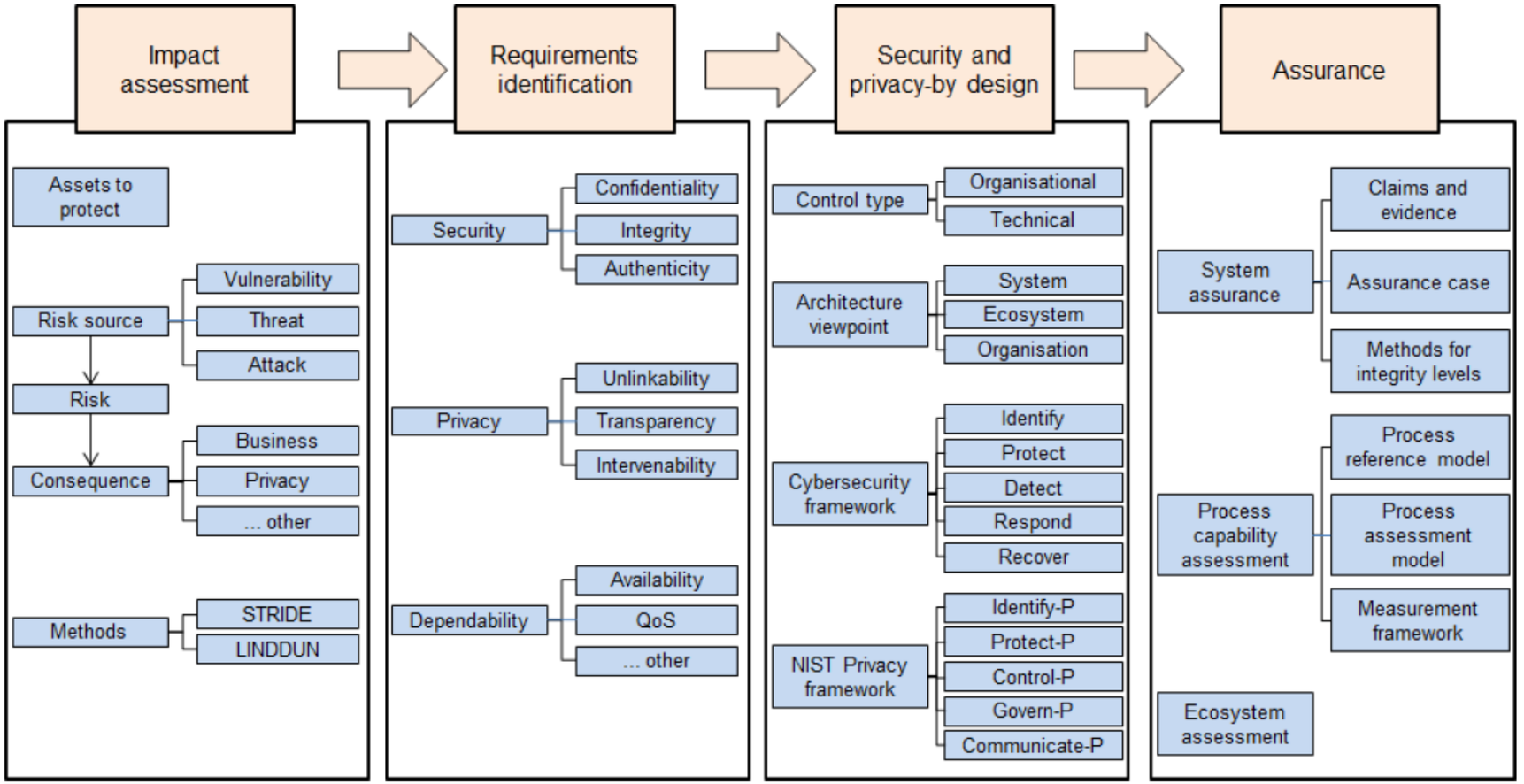


Figure 6: Example of overall practice for trustworthiness

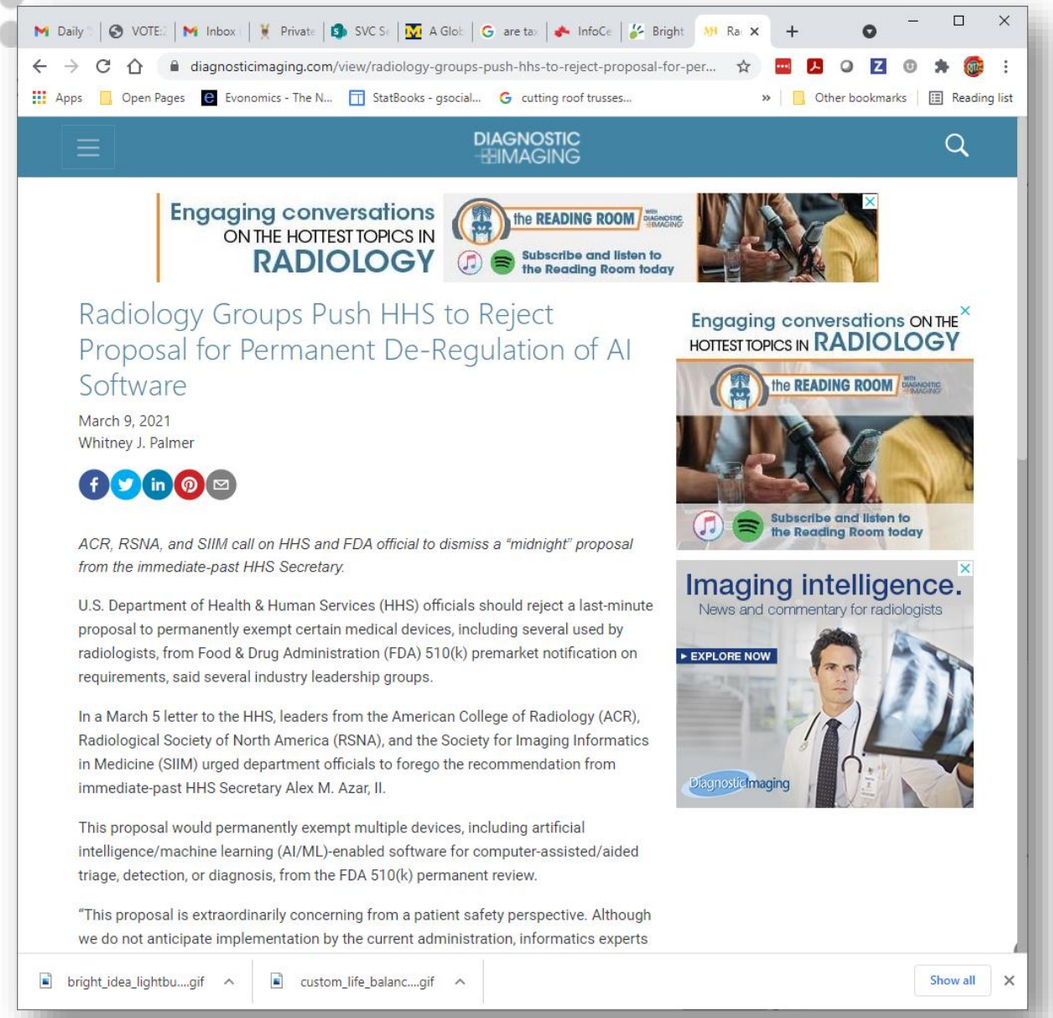
Formal approaches (e.g. ISO/IEC 24028) may be leveraged.

AHG2 – Use cases

- Categories:
  - AI technologies and applications (e.g. ML, NLP, CDS, etc.)
  - AI in a clinical encounter
  - AI in clinical, public health and research sub-specialties (e.g. radiology, dentistry, etc.)
- Classification axes:
  - What type of AI algorithms or approach are being used?
  - Where is the solution being applied?
  - What is the target user group for the application?

Ref: ISO TR 24291

AHG2 – Use cases (example)

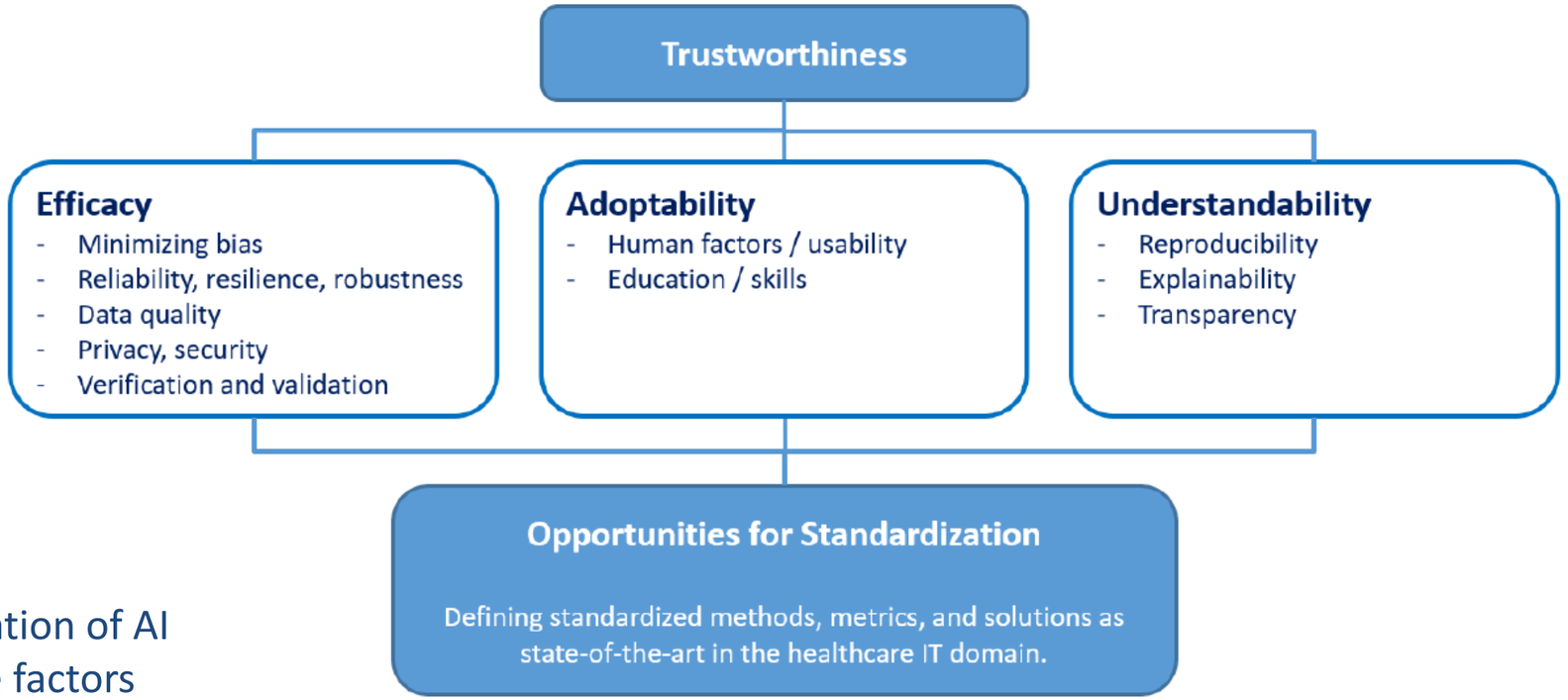


Machine Learning AI (ML)

Diagnosis

Radiology

AHG2 – Regulation

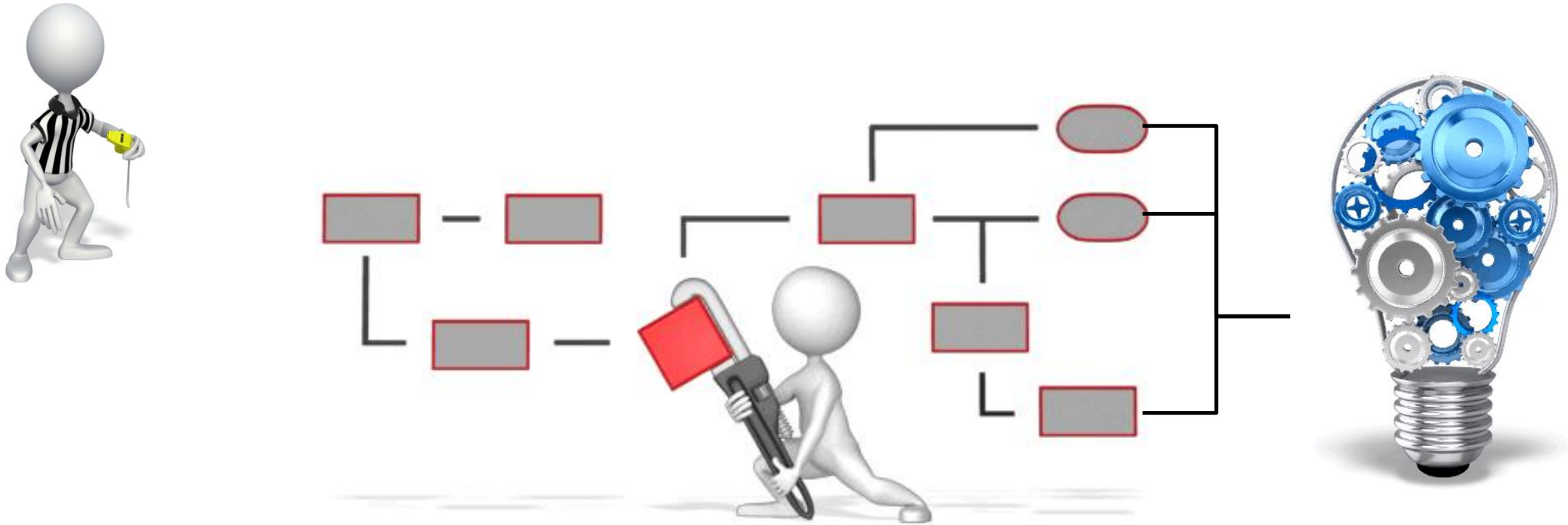


The overarching theme on the application of AI in Healthcare is related to **TRUST**. The factors related to this may be grouped according to Efficacy, Adoptability, and Understandability. These factors point to the areas where standardization, and regulation, can be expected to add value.

AHG2 – Regulation

- Definitions and Frameworks:
  - Unambiguous and widely adopted definitions are needed
  - Frameworks for categorizing different “AI Solutions” need to be codified to support the work of regulatory organizations in defining their risk-based frameworks (e.g. MDR, IMDRF)
  - Words with different meanings in computer science vs. healthcare need to be disambiguated (e.g. validation).
- Standardized methods:
  - Measure and reduce bias
  - Measure reliability
  - Assess reproducibility in non-deterministic systems
  - Criteria for algorithm explainability and/or transparency
- Software lifecycle:
  - Existing frameworks for SaMD or SiMD need to be mapped and updated if necessary

Regulating AI in Healthcare



Approaches and issues

- There are markets that place higher value on innovation than on risk mitigation; they have a different “appetite for risk”.
- Conventional techniques for regulating SaMD have relied on quality-related specifications typical in the medical device field (e.g. ISO-13485). These don’t map especially well to “emergent risk”.
- Many of the more cutting edge approaches are not from the family of “transparent algorithms”. Should they be allowed?
- RCT-based approaches have a strong selection bias… and these can significantly undermine AI techniques that rely on large datasets characteristic of the target population.

International initiatives – US FDA

- The AI/ML-Based Software as a Medical Device Action Plan outlines five actions that the FDA intends to take, including:
  - Further developing the proposed regulatory framework, including through issuance of draft guidance on a predetermined change control plan (for software's learning over time);
  - Supporting the development of good machine learning practices to evaluate and improve machine learning algorithms;
  - Fostering a patient-centered approach, including device transparency to users;
  - Developing methods to evaluate and improve machine learning algorithms; and
  - Advancing real-world performance monitoring pilots.

International initiatives – US FDA

- **“The plan outlines a holistic approach based on total product lifecycle oversight to further the enormous potential that these technologies have to improve patient care while delivering safe and effective software functionality that improves the quality of care that patients receive. To stay current and address patient safety and improve access to these promising technologies, we anticipate that this action plan will continue to evolve over time.”**

https://www.fda.gov/news-events/press-announcements/fda-releases-artificial-intelligencemachine-learning-action-plan

International initiatives – EU

April 21, 2021: first-ever LEGAL framework for regulation of AI.

https://digital-strategy.ec.europa.eu/en/library/proposal-regulation-european-approach-artificial-intelligence

International initiatives – EU

- “Faced with the rapid technological development of AI and a global policy context where more and more countries are investing heavily in AI, the EU must act as one to harness the many opportunities and address challenges of AI in a future-proof manner. To promote the development of AI and address the potential high risks it poses to safety and fundamental rights equally, the Commission is presenting both a proposal for a regulatory framework on AI and a revised coordinated plan on AI.”

What is Canada's approach?

- Advanced therapeutic products (ATPs) are drugs or **devices** that our current regulations were not designed to handle because they're so novel, complex and distinct.
- We're establishing a new pathway for ATPs based on new provisions in the Food and Drugs Act from June 2019. This pathway will let us authorize ATPs in a flexible and risk-based manner. This approach is also known as a "**regulatory sandbox**" and will only be used when:
  - sufficient evidence exists to support the safety of the product
  - the products are so novel, complex and unique that existing rules under the Food and Drugs Act cannot appropriately accommodate them

What is Canada’s approach?

- Establishing a sandbox allows us to tailor regulatory requirements for a specific product type. It addresses the product's unique characteristics while maintaining high standards for patient safety, product quality and efficacy.
- Regulating products in a sandbox will require consultation with:
  - those directly involved in development and use of these products, such as hospitals, start-ups, small- and medium-sized enterprises and other innovators
  - other health system players, including:
    - international regulators
    - health technology assessors

NOTE: The COVID-19 pandemic affected the timelines for implementation of the ATP pathway and concierge service. We remain committed to advancing this initiative and will engage with stakeholders to inform our approach.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&
A