ISO / IEC AI Workshop Series

Inaugural Workshop

Wael William Diab
ISO/IEC JTC 1/SC 42 Chair
ISO/IEC AI Workshop Chair

ISO JTC 1 IEC
INFORMATION TECHNOLOGY STANDARDS
SC 42 – Artificial Intelligence

Welcome

Thank you for participating!

Participation Guidelines

Please use the Q&A function for questions

Please *do not use the chat function* for questions

This webinar is being recorded and will made available

Please keep your video off and audio muted unless speaking

INFORMATION TECHNOLOGY STANDARDS

SC 42 – Artificial Intelligence

Acknowledgments

Program Committee

- Heather Benko
- Norbert Bensalem
- Andrew Dryden
- Peter Deussen
- Rohit Israni
- Mike Mullane
- Catherine Nelson
- Wael William Diab

ISO

- Elisabeth Gasiorowski
- Catherine Infante
- Vivienne Rojas

IEC

- Stephen Dutnall
- Gabriella Ehrlich
- Ian Gardner
- Giulia Pizzi
- Laura Rocha

Program

SESSION 1

(24th May 13:00 – 16:00 UTC)

- Opening Remarks
- AI Applications
- Novel AI Standardization

SESSION 2

(25th May 05:00 – 08:00 UTC)

- Opening Remarks
- Emerging AI Requirements
- Emerging AI Technology Trends

SESSION 3

(25th May 22:00 – 26th 01:00 UTC)

- AI Applications
- Novel AI Standardization
- Closing Remarks

Session 1

Program	Talk Title	Track Chairs	Aprox Start Time (UTC)
Kickoff			13:00
Wael William Diab			
Opening Remarks			13:05
Gilles Thonet			
Phil Wennblom			
AI Applications		Rohit Israni Catherine Nelson	13:15
Mike Glickman	Health informatics and AI, the road to Interoperability		
Neil Frost	AI potential Applications in Transport		
Christophe Preube	AI finds awareness in standardization work – the White paper of ISO/TMB SMCC		
Novel AI Standardization Approaches		Peter Deussen Norbert Bensalem	14:25
Kimberly Lucy	Creating Trust in AI Through Standards: A Management System Approach		
Wo Chang	Data Quality for Analytics and Machine Learning		
Tim McGarr / Florian Ostmann	AI Standards Hub (UK)		
Viveka Bonde	Novel Standerdization Approach to AI Ethics		

Session 2

Program	Talk Title	Track Chairs	Aprox Start Time (UTC)
Kickoff		N/A	5:00
Wael William Diab			
Opening Remarks		N/A	5:05
Silvio Dulinsky			
Emerging AI Requirements		Catherine Nelson and Peter Deussen	5:10
Elham Tabassi	NIST AI Risk Management Framework		
Mariagrazia Squicciarini	The UNESCO Recommendation on the Ethics of AI - Setting the standards for a better and more inclusive future		
Liz Coll	Can standards deliver consumer trust and confidence in AI		
Daniel Loevenich	Evaluation Standards for Conformity Assessment of Trustworthy Cloud-based AI Applications		
Emerging AI Technology Trends		Norbert Bensalem and Rohit Israni	6:30
Shubhashis Sengupta	Emerging AI Trends – as seen by an Industry Practitioner		
Tilak Kasturi	How specialized AI drives value for Automotive Service Organizations		
William Uppington	AI Quality: The Next Big Challenge in AI		
Babak Hodjat	From Data to Decisions, and Back		

Session 3

Program	Talk Title	Track Chairs	Aprox Start Time (UTC)
Kickoff			22:00
Wael William Diab			
AI Applications		Rohit Israni and Catherine Nelson	22:05
Charalambos Freed	Safety considerations in autonomous products		
Hajime Yamada	Development of SRD 63416 “Ethical Considerations of AI when Applied in the AAL Context”		
Kenzo Nonami	AI Powered UAV and Future Prospects		
Fumihiro Maruyama	Use cases and AI application guidelines in international standardization		
Novel AI Standardization Approaches		Norbert Bensalem and Peter Deussen	23:30
Jochen Friedrich	AI Standardisation supporting regulatory needs		
Linzhing Meng / Mike Thieme	Developing a TS on assessment of machine learning classification performance		
Yonosuke Harada	Introduction of Governance Implications of AI Systems		
Paul Cotton / Milan Patel / Wei Wei	The foundational standards for AI – ISO/IEC 22989 and ISO/IEC 23053		
Closing Remarks		Wael William Diab	0:55
Wael William Diab	Overview and introduction of SC 42		
Program Committee	Insights from the workshop		

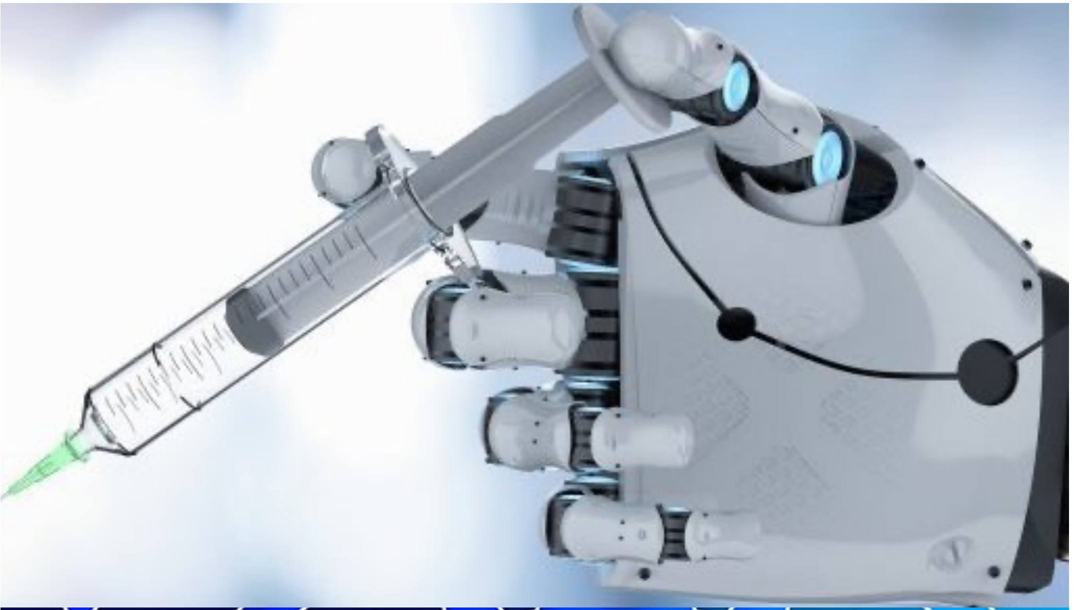
Thank you

Wael William Diab

wael.diab@gmail.com; Wael’s LinkedIn

Workshop Website

ISO/IEC AI LinkedIn Page



INFORMATION TECHNOLOGY STANDARDS

SC 42 – Artificial Intelligence

Introducing ISO/IEC JTC 1

Phil Wennblom

ISO/IEC JTC 1 Chair

ISO JTC1 IEC

INFORMATION TECHNOLOGY STANDARDS

SC 42 – Artificial Intelligence

Information Technology

- Utilized by every sector of the economy, enabling gains in productivity and increases in quality
- Touches nearly every person in the world, enabling a higher quality of life
- Characterized by innovation and a rapid rate of change

About ISO/IEC JTC 1

- Joint Technical Committee of IEC and ISO
  - "Standardization in the field of Information Technology"
  - Consistent IT deliverables across IEC and ISO
  - Building blocks for global markets that respond to the needs of businesses, consumers, governments, other organizations
- 35 P-members and 65 O-members
- Organized in 23 Subcommittees and 4 JTC 1 Working Groups
- More than 4500 active participants currently developing around 600 standards; more than 3200 published

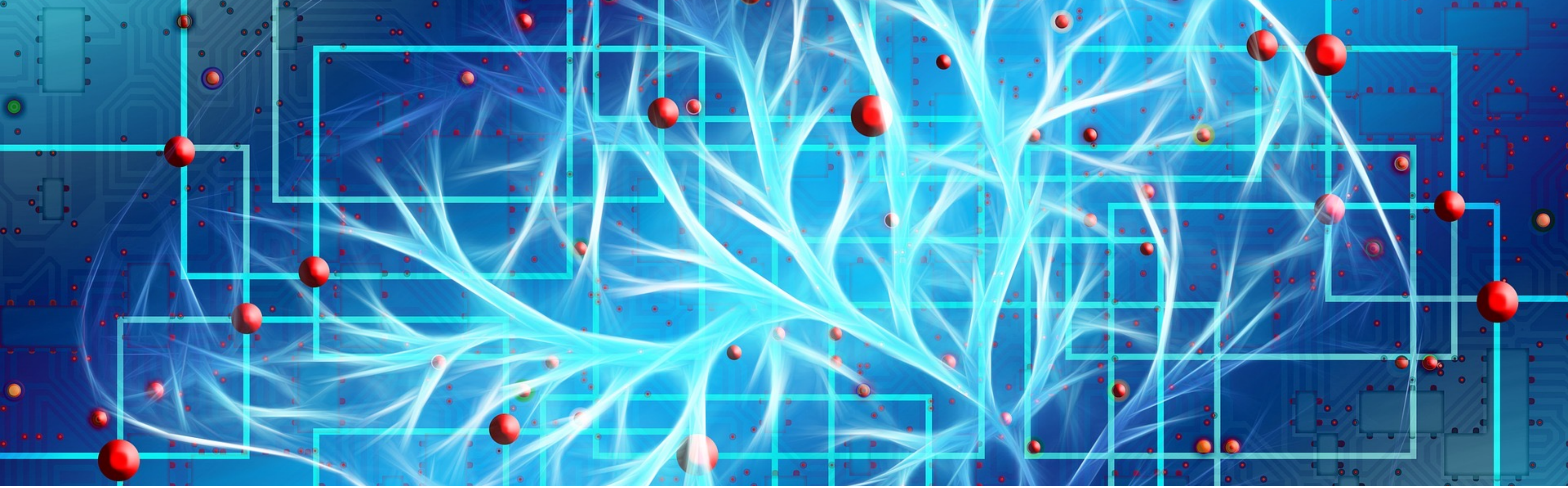
JTC 1 Focus

- Horizontal by design, JTC 1 develops information technology standards that are applicable across domains
  - Enable interoperability and expectations that result in higher quality experiences
  - Encapsulate expertise and best practices
  - Foundation for innovation
- JTC 1 works together with other IEC and ISO TCs and other organizations that are utilizing information technology to develop domain-specific standards
  - More than 400 liaisons (JTC 1 and its SCs)
  - Emphasis on effective cooperation/collaboration

Technology Areas

Coded character sets
Telecommunications and information exchange between systems
Software and systems engineering
Cards and security devices for personal identification
Programming languages
Digitally recorded media
Computer graphics, image processing
Interconnection of IT equipment (home electronics)
IT security techniques
Office equipment (printing)
Coding of audio, picture, multimedia (JPEG, MPEG)
Automatic ID and data capture (RFID)

Data management
Document description, processing
User interfaces
IT for learning, education, training
Biometrics
Cloud computing
IT Sustainability
IT governance
Internet of Things and Digital Twin
Artificial Intelligence
Brain-Computer Interface
Smart cities
3D printing and scanning
Trustworthiness
Quantum Computing



Summary

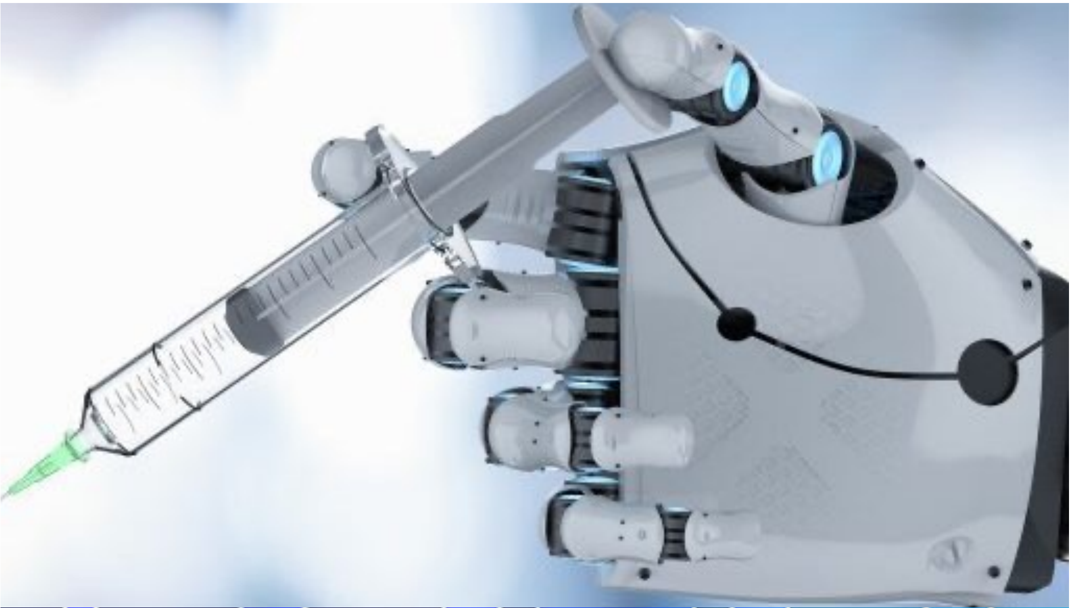
- JTC 1 welcomes your participation, your collaboration, and your cooperation
- Interested delegates and experts are encouraged to contact their national body or national committee to become engaged
- ISO and IEC Committees are welcome to establish liaisons with JTC 1 and its subcommittees
- Questions are always welcome

Thank you

Phil Wennblom

philip.c.wennblom@intel.com

jtc1info.org



AI potential Applications in Transport

Neil Frost

ISO TC 204 WG 20 Convenor

Date: 25 May 2022

ISO JTC 1 IEC

INFORMATION TECHNOLOGY STANDARDS

SC 42 – Artificial Intelligence

Introduction

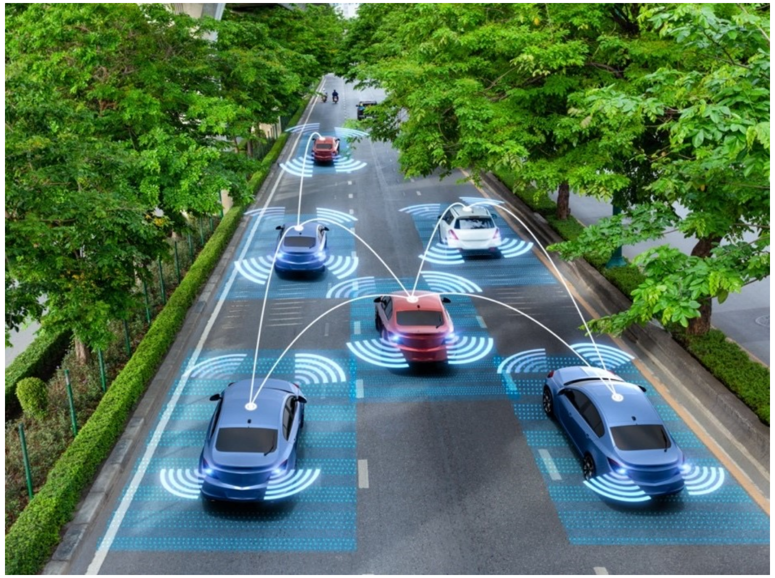
- Automated Driving – Multiple AI Applications
- Smart Networks – Possible AI Applications
- AI Applications for Users
- Conceptual Architecture
- The Future
- Q&A

INFORMATION TECHNOLOGY STANDARDS

SC 42 – Artificial Intelligence

Automated Driving - Multiple AI Applications

- Distance detection and object avoidance
- Lane Guidance
- Origin Destinations
- Optimal Route determination
- Information flow between vehicles in proximity
- Intersection management and guidance
- Vehicle Platooning



INFORMATION TECHNOLOGY STANDARDS

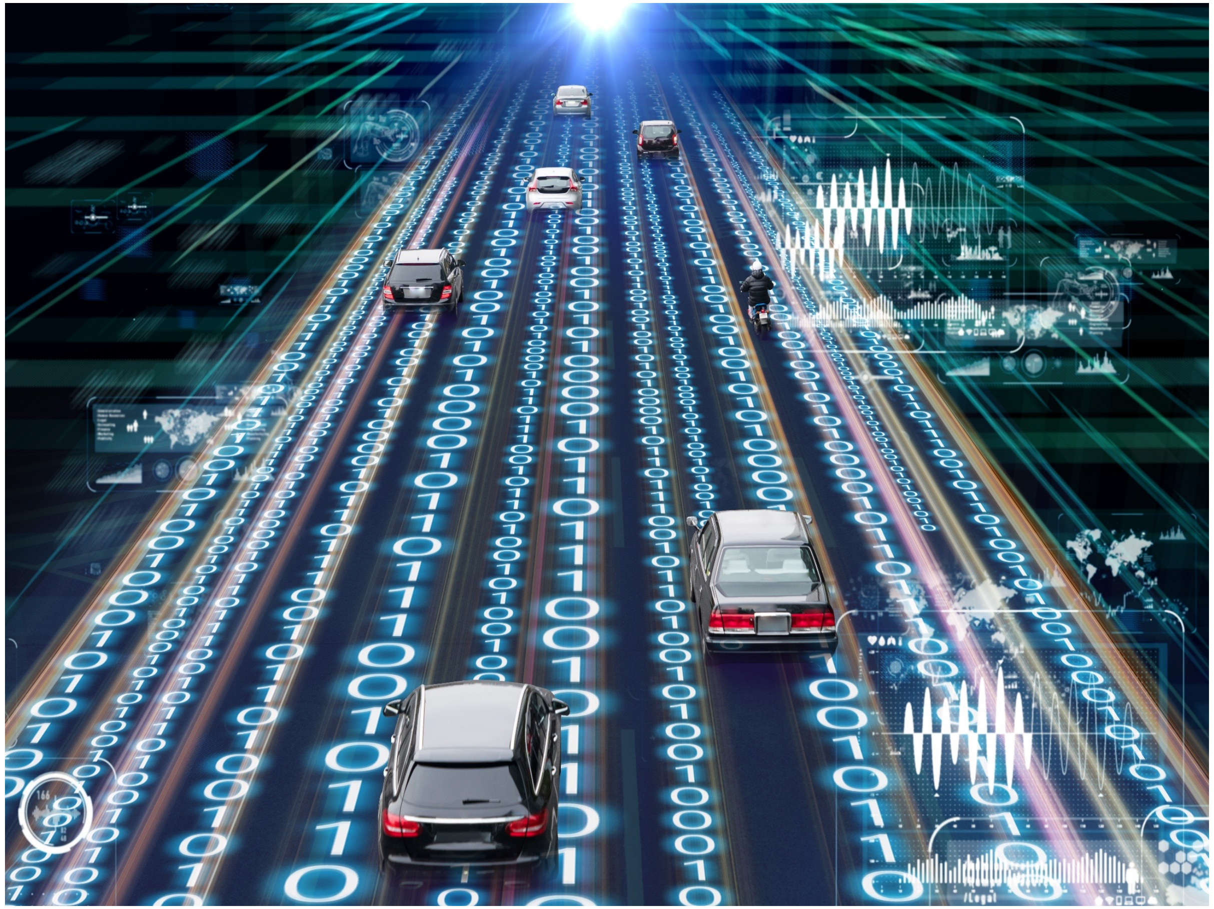
SC 42 – Artificial Intelligence

Smart Networks

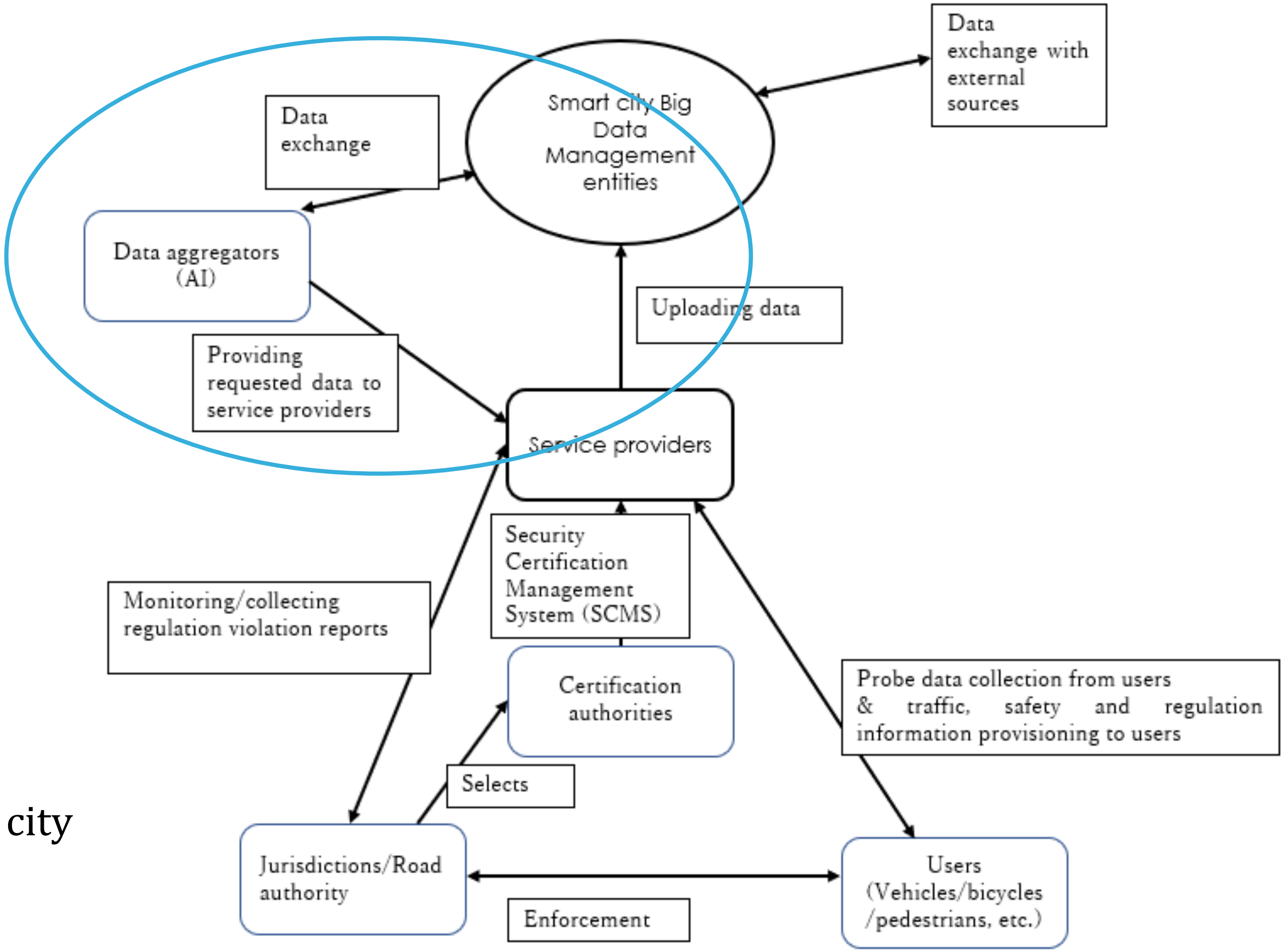
- Traffic signal optimization based on data fusion
- Congestion Traffic management efficiency
- Travel pattern recognition
- Priority Vehicle management
- Kerbside Parking Management
- Infrastructure Management

AI Applications for Users

- Optimized route for travel, private and public transport
- Cost determination and settlement for transport service
- Available services and selection
- Commuter demand and supply determination

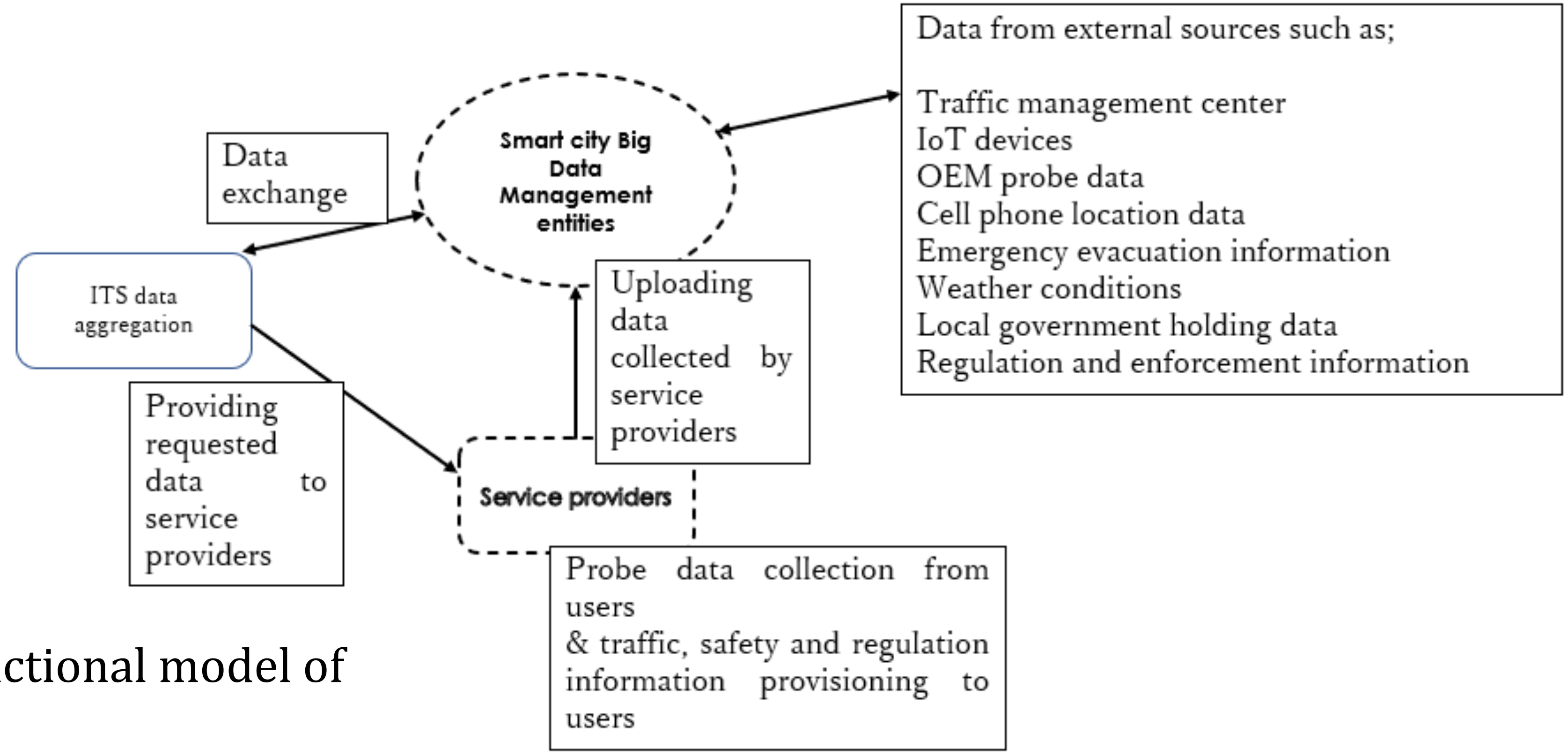


Conceptual Architecture



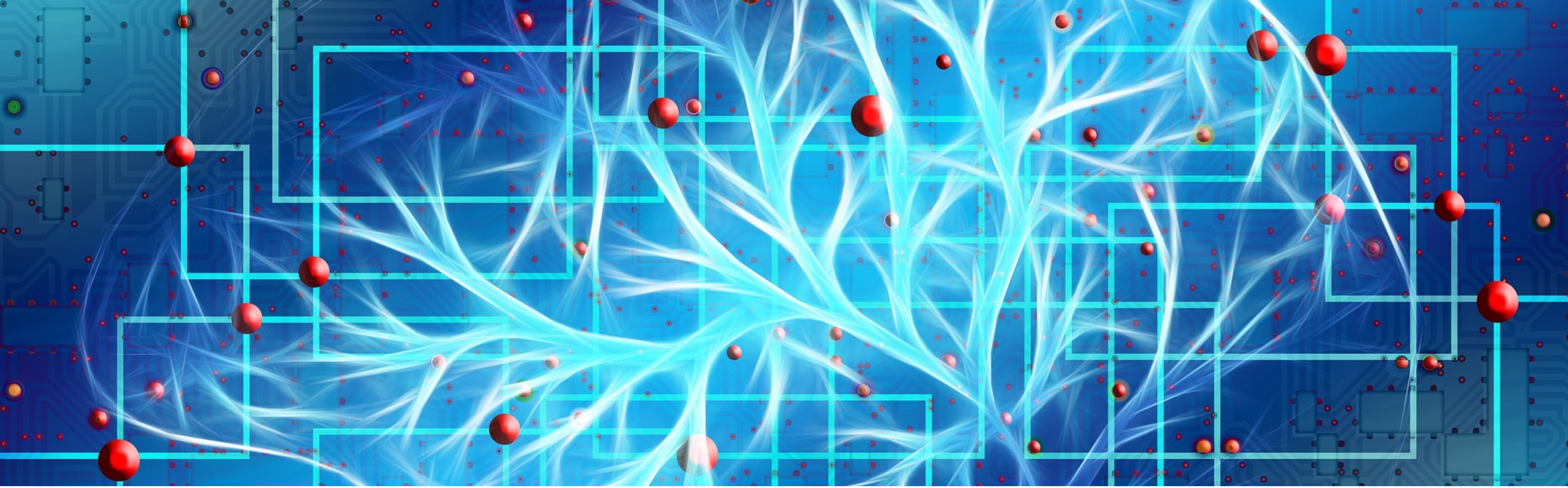
Role model conceptual architecture: Smart city ITS application service ISO/TR4445

Conceptual Architecture Cont.



An image of role model and functional model of ITS data aggregation servicer

Operational Vehicle in New Zealand and South Korea



Summary

There are a number of focus areas that require AI and BD solutions that make this an extremely interesting space.

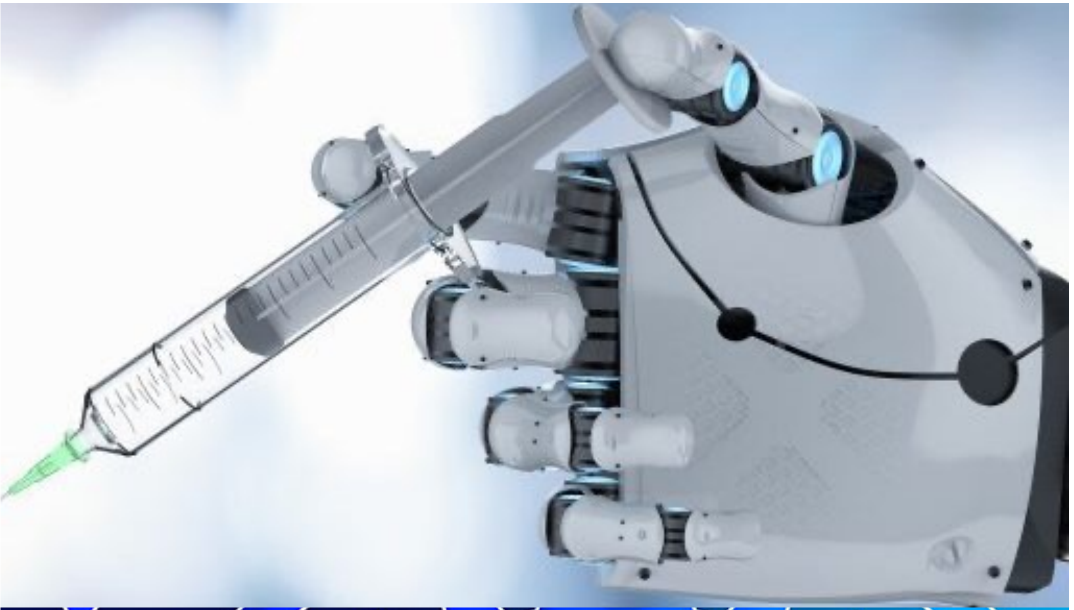
INFORMATION TECHNOLOGY STANDARDS

SC 42 – Artificial Intelligence

Thank you

Neil Frost

nfrost@isaha.co.za



DGUV
Deutsche Gesetzliche Unfallversicherung
Fachausschuss Maschinenbau,
Fertigungssysteme, Stahlbau

The whitepaper of ISO/TMB SMCC

2022-05-24

Christoph Preuße, Chairman ISO/TMB SMCC

ISO SMCC - member

Chairs of:

ISO/IEC JTC 1	*Information technology*
ISO/IEC JTC 1/SC 7	*Software and systems engineering*
ISO/IEC JTC 1/SC 17	*Cards and personal identification*
ISO/IEC JTC 1/SC 27	*IT Security techniques*
ISO/IEC JTC 1/SC 32	*Data management and interchange*
ISO/IEC JTC 1/SC 37	*Biometrics*
ISO/IEC JTC 1/SC 38	*Cloud Computing and Distributed Platforms*
ISO/IEC JTC 1/SC 40	*IT Service Management and IT Governance*
ISO/IEC JTC 1/SC 42	*Artificial intelligence*
ISO/TC 10	*Technical product documentation*
ISO/TC 10/ SC 10	*Process plant documentation*
ISO/TC 39	*Machine tools*
ISO/TC 39/ SC 10	*Machine tools - Safety*
ISO/TC 184	*Automation systems and integration*
ISO/TC 184/ SC 1	*Physical device control*
ISO/TC 184/ SC 4	*Industrial data*
ISO/TC 184/ SC 5	*Interoperability, integration, and architectures for enterprise systems and automation applications*
ISO/TC 199	*Safety of machinery*
ISO/TC 211	*Geographic information/Geomatics*
ISO/TC 261	*Additive manufacturing*
ISO/TC 292	*Security and resilience*
ISO/TC 299	*Robotics*

plus Chair of IEC SyCSM

The SMCC - whitepaper

The **overall goal** of the whitepaper is to facilitate for companies, and other stakeholders, to adapt to, and benefit from, the concept of Smart Manufacturing

”Manufacturing that improves its performance aspects with integrated and intelligent use of processes and resources in cyber, physical and human spheres to create and deliver products and services, which also collaborates with other domains within an enterprise’s value chain”

Source: Definition (ISO SMCC resolution 114/2017)

The whitepaper´s approach

… to explain Smart Manufacturing by utilizing models from innovation.

With certain regularity new disruptive technologies become available and pave the ground for a new wave of innovations.

When the effect of the new innovations is large enough, they will revolutionize the current norm of how things are seen and done.

The whitepaper´s presentations

In the whitepaper SMCC will present
new disruptive technology that are matured enough
for industry to leverage on,
they will be called "Enablers of Smart Manufacturing".

SMCC will also present

- a set of design principles, referred to as the Enablers for SM, that are of high relevance for achieving a successful implementation of Smart Manufacturing,

- the Effects that are foreseen with Smart Manufacturing

Technologies

Technologies behind the current revolution are largely connected to computer power and computational capabilities:

- *cheap (hence unlimited) data storage*
- *fast (hence responsive) computer and calculation power*
- *reliant (hence place-independent) communication*

Future effects

What **future effects** will it lead to?

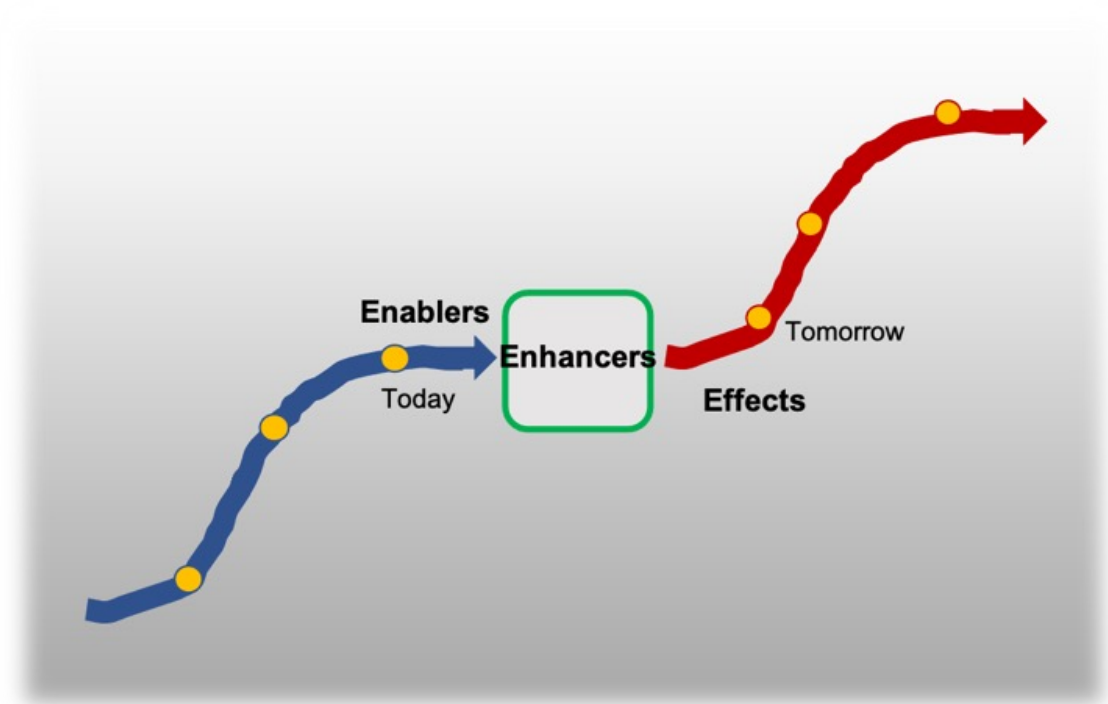
- Circular manufacturing;
- Model based Manufacturing;
- Lights out factories;
- Product personalization
- Preventive and predictive maintenance;
- Edge automation;
- Servitization;
- Data-driven business models

Needed principles

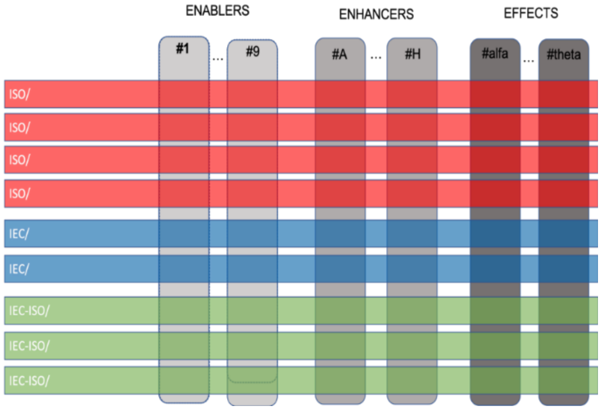
What **principles** are needed to enhance the development?

- Terminology and reference models;
- Concepts related to decentralization, modularization and virtualization.
- Integration and interoperability vertically and horizontally;
- Digital twin and digital thread;
- Product transparency;

Enablers – Enhancers – Effects



Be beneficial



The „SMCC-matrix“

Standards : ISO, IEC and ITU for

- the enablers
- treating the enhancers
- the effects

Roadmaps for Enablers – Enhancers – Effects to get a „SMCC-matrix“

Appendix with **definitions of used terminology**

Thank you very much for your attention

Christoph Preusse

Chairman SMCC
c.preusse@bghm.de

Health informatics and AI, the road to Interoperability

Michael L. Glickman

Chair, ISO TC/215 Health informatics

President, Computer Network Architects

ISO JTC 1 IEC

INFORMATION TECHNOLOGY STANDARDS

SC 42 – Artificial Intelligence

No Global Consensus on AI definition

- Different definition used by regulators, providers, standards organizations, developers
- International Medical Device Regulators Forum (IMDRF) working towards publishing glossary in Q2 2022
  - IMDRF started with 16 different definitions
  - EU proposed 6 different definitions
  - Eventually, IMDRF decide to not define AI at all

What is AI? FDA…

- **Artificial Intelligence** has been broadly defined as the science and engineering of making intelligent machines, especially intelligent computer programs (McCarthy, 2007). Artificial intelligence can use different techniques, including models based on statistical analysis of data, expert systems that primarily rely on if-then statements, and machine learning.

- **Machine Learning** is an artificial intelligence technique that can be used to design and train software algorithms to learn from and act on data. Software developers can use machine learning to create an algorithm that is 'locked' so that its function does not change, or 'adaptive' so its behavior can change over time based on new data.
  Some real-world examples of artificial intelligence and machine learning technologies include:
  - An imaging system that uses algorithms to give diagnostic information for skin cancer in patients.
  - A smart sensor device that estimates the probability of a heart attack.

NOTE: AI encompasses wide spectrum of software tech ranging from simpler "if -> then" statements, look up tables to Machine Learning to Deep Learning.

Medical devices based on "medical device data" and using ARTIFICIAL intelligence technology to achieve their intended use (i.e., medical use)

NMPA AI Definition

- **AI MD has a clear definition** from "AI Medical Device Registration Review Guideline"**(No. 8, 2022) on March 9,22**
- AI Medical Device[1] is the medical devices based on "**medical device data**" and using **artificial intelligence technology** to achieve their **medical purposes** (i.e, medical use)
- Medical device data: 1)**medical images**(X-Ray, CT, MRI, U/S, etc.); 2) **physiological signals,** e.g ECG, EEG; 3)IVD- **pathological images**, etc.); 4)data generated by non-MD with medical use, e.g. digital health product generated ECG data, etc.

NMPA AI Classification

- AI MD will be **Class II** or **Class III** (SaMD or medical device with AI SW component belongs to Class III);
- Classify as **CAD** (Computer-aided detection/diagnosis/triage) or **non-CAD** (e.g. process optimization, image quality/speed improvement, automatic measurement/segmentation, 3D reconstruction) **by clinical unities.**

NMPA AI Class III practice in China

Local AI players

- **30** of 31 **local players**[2] got NMPA AI SaMD clearance
- Smooth AI clearance with faster innovation as **NMPA requirement fully incorporated into local R&D process** including **Chinese population training data**, validation by Chinese physician and **clinical trial** data;

MNC

- **Only 1** MNC got NMPA Class III clearance—**CAD from Siemens** with intl clinical trial data & FDA clearance;[3]
- GE & Siemens has not cleared AI features with system[3]
- Philips NMPA submissions got rejected by NMPA mainly due to 1) Lacking of China-GCP compliant clinical trial evidence for CAD; 2)No Chinese population training dataset

BU	AI feature	Remark for NMPA rejection
MR	MRCAT-Brain	× No Chinese population in training dataset; china clinical study required.
EDI-ISP-12	ClearRead	× Requested to submit as SaMD
	LNA CAD	× No GCP compliant clinical study data
	CT Pulmo	× No GCP compliant clinical study data

Note: [1] "AI Medical Devices Registration Review Guidelines" (No.8, 2022), March 9, 2022"; [2] see appendix for details; [3]informal reg intelligence for GE/Siemens, not available on NMPA website

Confidential

Definitions in Standards

ISO/IEC JTC1 SC42 is developing a series of standards for AI, across all industries. It is hoped that these standards can be used as the basis for sector-specific standards such as healthcare. Our details might be different, but the general concepts are (hopefully) the same (an earlier draft of this definition was considered by IMDRF.)

> AI System: Engineering system that generates outputs such as content, forecasts, recommendations or decisions for a given set of human-defined objectives.

What is AI ? Physicians Viewpoint…

"Artificial intelligence constitutes a host of computational methods that produce systems that perform tasks normally requiring human intelligence. These computational methods include, but are not limited to, machine **image recognition**, natural language processing, and machine learning. However, in health care a more appropriate term is "**augmented intelligence**" (AI), reflecting the enhanced capabilities of human clinical decision making when coupled with these computational methods and systems."

Augmented intelligence in health care (AMA Board of Trustees, 2018)

Terminology challenges: If you can't agree on what to call it, there's no way you can agree on what it should do

Artificial Intelligence practitioners have their own set of terminology that sometimes conflicts with what we think of in Health informatics.

- "AI" might mean multiple techniques that lead to 'intelligent' behavior, but is often used to talk specifically about "Machine Learning"
- "Validation" for medical devices often refers to meeting user needs; but "validation" in data science is making sure the data and model are valid.
- "Bias" is something that data scientists try to eliminate, but many caregivers want algorithms to be biased towards **their particular patient demographics**.
- "Supervised" learning sounds as if there is someone that is supervising the software as it is learning (like you supervise a new employee.) But data scientists use this to mean data that is labelled (vs. an unlabeled pile of information)

Why should I care?

Machines will not replace physicians but **physicians using AI will soon replace those not using it."**
AI-augmented multidisciplinary teams: hype or hope? (Di Ieva, 2019) The Lancet

"Interest in artificial intelligence in healthcare soared in 2019 with investors pouring $4 billion into the sector across 367 deals… That's up from nearly $2.7 billion invested in healthcare AI in 2018 across 264 deals." "Healthcare led AI investment, topping the $2.2 billion raised by financial and insurance AI."

Fierce Healthcare coverage of CB Insights Report

AI will be critical in meeting the care needs of a growing, aging population facing projected physician shortages. However, concerted effort is needed to assure this tech advances the quintuple aim.
National Academy of Medicine Report on AI (Matheny et al., 2019)

FIGURE S-1 | Advancing to the Quintuple Aim
SOURCE: Developed by publication editors

Example of FDA Cleared AI: IDx-DR Screening retinal images to detect retinopathy

- Diabetic retinopathy is when high blood sugar levels damage blood vessels in retina
- Retinal images are uploaded to a cloud server where IDx-DR software analyzes and tells doctor “more than mild diabetic retinopathy detected; refer to an eye care professional” or “negative for more than mild diabetic retinopathy; rescreen in 12 months”
- Note that this product provides a screening decision without having the clinician also interpret the results, and is therefore usable by healthcare providers not normally involved in eye care.

Source: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm604357.htm

Why now? What is driving this?

There have been several AI Winters in the past – why is AI warming up again? Why do we think this might be the last Winter?

Two + one reasons:

1. IoT / Big Data
2. Video games!
3. The IoMedical Things

Please consider the following:

Types of AI Applications in Healthcare

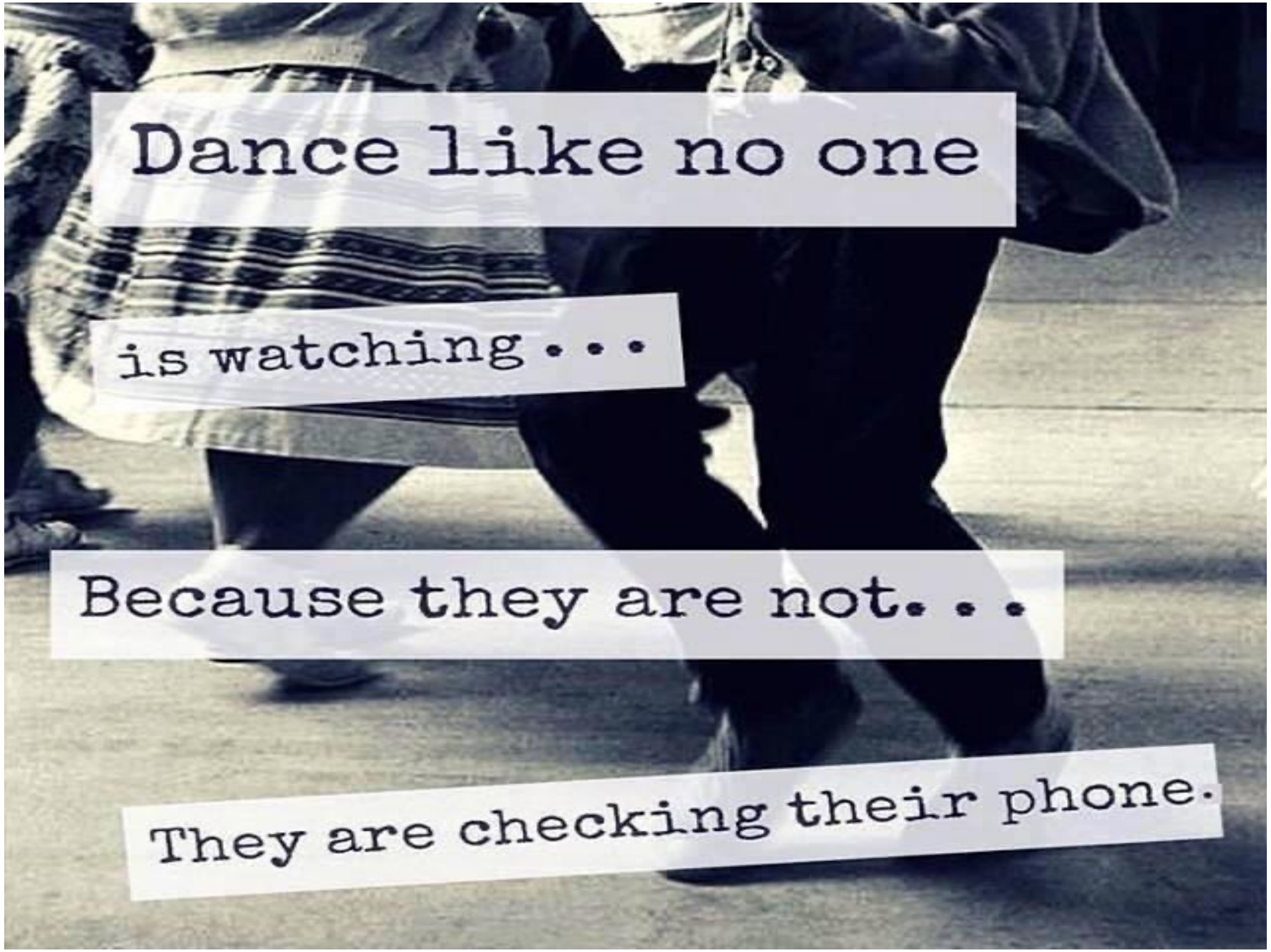
Artificial Intelligence will bring significant improvements to healthcare in many ways

- Improve diagnosis and effectiveness of therapy
- Managing population health
- Managing hospital operations
- Managing manufacturing operations
- Managing post-market activities

New Technology = New Risks

Pedestrian fatalities rose 11% in 2016, ‘distraction’ as a contributing factor.

As we gain new skills, what do we give up?



INFORMATION TECHNOLOGY STANDARDS

SC 42 – Artificial Intelligence

Model Diversification – Refinement & Drift

- Many of us have a long history of working in an environment that is slow to change, and therefore we offer a generic solution to meet common healthcare problems.
- However, with Continuously Learning Systems (CLS), the system **wants** to change. It wants to be customized for a particular customer. A CLS system can learn about a local population and can optimize for that particular hospital.
- But the manufacturer is responsible for configuration management and change control. The manufacturer is responsible for root cause analysis when something goes wrong and the application doesn't perform as it should.

Model Diversification – Refinement & Drift continued..

- **If every hospital is different, how can you compare performance? How do you handle performance claims that change over time**?

- DRIFT: Even if you lock a system and don't allow changes, patient populations **DO** change over time, and the performance you had 5 years ago might not be the level you are at today. Medical practice also changes over time and that may have an impact to performance.

  - **Therefore, having a completely locked system isn't necessarily the best idea either**…

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.

I propose that we handle data according to these rules:

- 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 document – when talking about tissue samples !!

Image source: https://xkcd.com/1838/

Levels of Autonomy

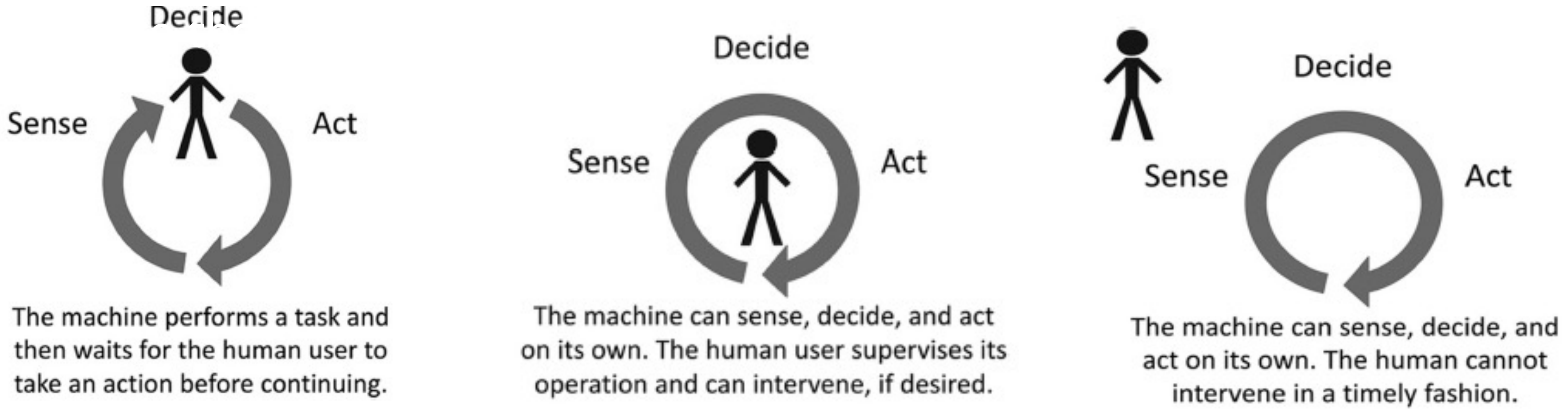
The automotive industry is also looking at autonomy -- this table is from an automotive standard,

SAE J3016

SAE level	Name	Narrative Definition	Execution of Steering and Acceleration/ Deceleration	*Monitoring* of Driving Environment	Fallback Performance of *Dynamic Driving Task*	System Capability *(Driving Modes)*
***Human driver* monitors the driving environment**						
0	**No Automation**	the full-time performance by the *human driver* of all aspects of the *dynamic driving task*, even when enhanced by warning or intervention systems	Human driver	Human driver	Human driver	n/a
1	**Driver Assistance**	the *driving mode*-specific execution by a driver assistance system of either steering or acceleration/deceleration using information about the driving environment and with the expectation that the *human driver* perform all remaining aspects of the *dynamic driving task*	Human driver and system	Human driver	Human driver	Some driving modes
2	**Partial Automation**	the *driving mode*-specific execution by one or more driver assistance systems of both steering and acceleration/ deceleration using information about the driving environment and with the expectation that the *human driver* perform all remaining aspects of the *dynamic driving task*	**System**	Human driver	Human driver	Some driving modes
***Automated driving system* ("system") monitors the driving environment**						
3	**Conditional Automation**	the *driving mode*-specific performance by an *automated driving system* of all aspects of the dynamic driving task with the expectation that the *human driver* will respond appropriately to a *request to intervene*	System	**System**	Human driver	Some driving modes
4	**High Automation**	the *driving mode*-specific performance by an automated driving system of all aspects of the *dynamic driving task*, even if a *human driver* does not respond appropriately to a *request to intervene*	System	System	**System**	Some driving modes
5	**Full Automation**	the full-time performance by an *automated driving system* of all aspects of the *dynamic driving task* under all roadway and environmental conditions that can be managed by a *human driver*	System	System	System	**All driving modes**

Loopy Humans - to what degree are "humans in the loop" ??

A simple model of Autonomy



FDA Position – AI/ML Enabled SaMD

Adaptive artificial intelligence and machine learning technologies differ from other software as a medical device (SaMD) in that they have the potential to adapt and optimize device performance in real-time to continuously improve health care for patients.

- The FDA is considering a total product lifecycle-based regulatory framework for these technologies that would allow for modifications to be made from real-world learning and adaptation, while still ensuring that the safety and effectiveness of the software as a medical device is maintained.

Good Machine Learning Practice Principles

The FDA, Health Canada, and MHRA published a draft set of GMLP Guiding Principles. These principles will help guide the development of future standards and regulations.

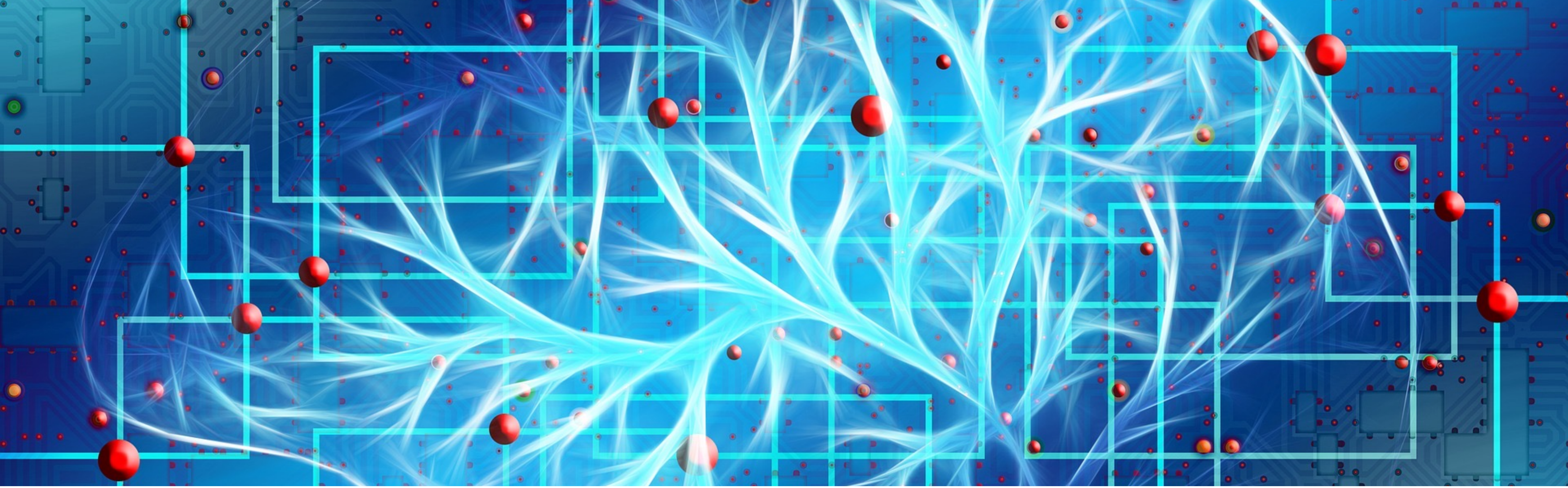
Good Machine Learning Practice for Medical Device Development: Guiding Principles	
Multi-Disciplinary Expertise are Leveraged Throughout the Total Product Life Cycle	Good Software Engineering and Security Practices are Implemented
Clinical Study Participants and Data Sets are Representative of the Intended Population	Training Data Sets are Independent of Test Sets
Selected Reference Datasets are Based Upon Best Available Methods	Model Design is Tailored to the Available Data and Reflects the Intended Use of the Device
Focus is Placed on the Performance of the Human-AI Team	Testing Demonstrates Device Performance during Clinically Relevant Conditions
Users are Provided Clear, Essential Information	Deployed Models are Monitored for Performance and Re-training Risks are Managed

TC215 Task Force 5 Application of AI to Health Informatics

In 2019, ISO/TC 215 started a project to assess the impact that AI will have on future TC215 projects, and after publishing the report, established a Task Force to help TC215 develop those standards.

TF5 has been created to (among other things..)

Develop Definitions
Maintain a Standards Landscape of what other committees are developing
Support use cases
Consider educational projects
Liaison and collaborate with other organizations.



Summary

We intend to continue Collaboration & Planning between ISO and IEC for Health informatics and AI Standards reflecting the “vertical domain of Health

We should be a chapter in the book of AI across all industries, not write our own book

INFORMATION TECHNOLOGY STANDARDS

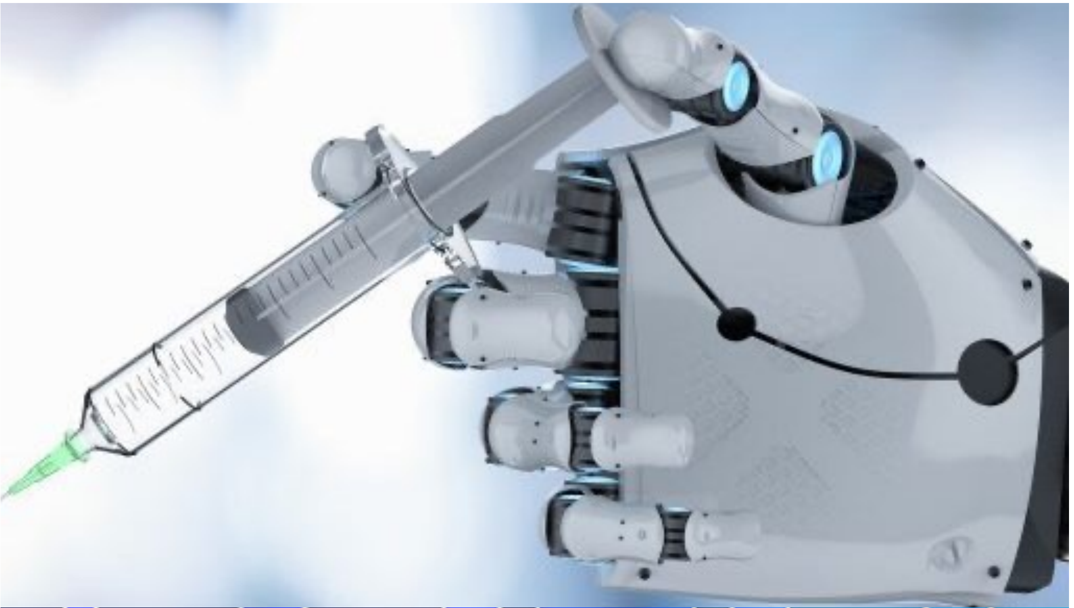
SC 42 – Artificial Intelligence

Thank you

Michael L. Glickman

MGlickman@CNAInc.com

Chair, ISO/TC215 Health informatics



Creating Trust in AI Through Standards: A Management System Approach

Kimberly Lucy

Director, GRC Standards

Microsoft

ISO JTC 1 IEC

INFORMATION TECHNOLOGY STANDARDS

SC 42 – Artificial Intelligence

Introduction

Artificial intelligence has the power to affect virtually every aspect of human life, from work to healthcare to leisure. At the same time, the damage that can be created by such powerful systems is immense if left unchecked. **How can AI be developed and used in a way that is responsible and that leads to trust and assurance for consumers and other stakeholders**? And **what is the role of standards in creating this trust and assurance**?

ISO JTC1 IEC
INFORMATION TECHNOLOGY STANDARDS
SC 42 – Artificial Intelligence

Two components of this presentation—both critical aspects of management systems standards that create trust in AI

The “traditional” approach

The AI Management System (AIMS, ISO/IEC 42001) as central component of a governance, risk, and compliance ecosystem

The “novel” approach

Conformity assessment/certification of management systems + products/service certification that can lead to a joint certification model for AI

Background: What is a management system standard? What is ISO/IEC 42001 (AIMS)?

- Management System Standard:
  - Based on a common "High-Level Structure" with required management clauses (all MSS have these)
  - Focused/scoped to a particular domain or sector (e.g. information security, privacy, AI)
  - Stresses an iterative process of continuous improvement for an organization
  - Risk-based
  - Organizations can be certified by a third-party to the applicable MSS

Current AIMS Structure

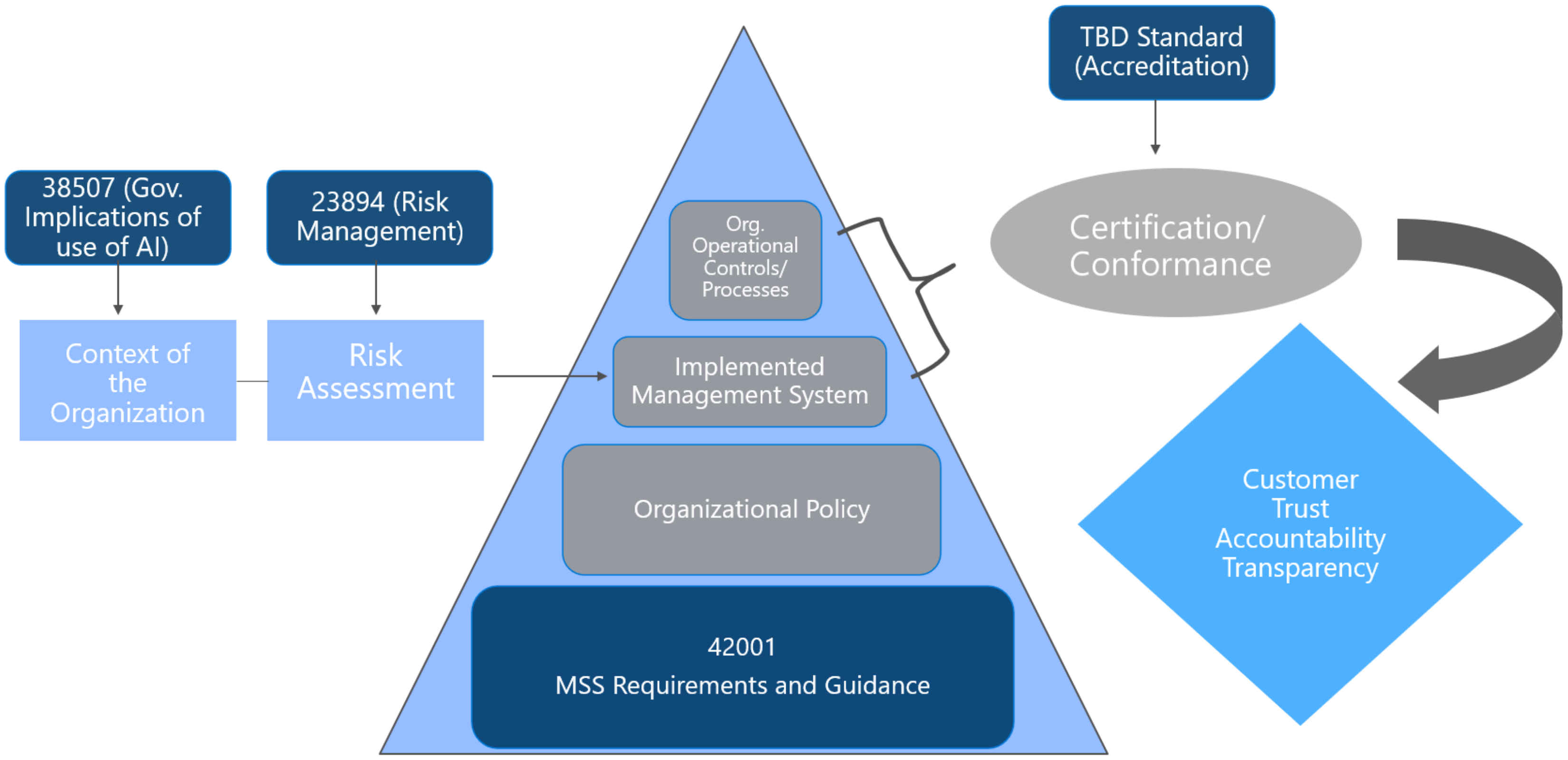
Management Clauses	Annex A Controls + Annex B Guidance
• Context of the organization • Leadership • Planning • Support • Operation • Performance Evaluation • Improvement	• Policies related to AI • AI management framework • Resources for AI • Assessing impacts of AI systems • AI system life cycle • Data for AI systems • Information for interested parties of AI systems • Use of AI systems • Third-party Relationships

AIMS “fast facts”

- Scope of standard allows organizations to define what “responsible AI” means for them, depending on the context of their organization—want organizations to think about responsible AI, with the flexibility to address this within their own operational environment
- System level controls (Annexes A and B) align well with requirements in draft EU AI Act
- Controls are written at an abstract level to allow organizations the flexibility to add more granular detail depending on their context (particularly regulatory context); they are not meant to cover regulatory requirements 1:1
- Written with a strategic approach to other SC42 standards, particularly governance, risk, and compliance (next slide), which complement AIMS and can be used by organizations to help implement a GRC ecosystem of standards to enable trust and assurance

The governance, risk, and compliance (GRC) ecosystem approach

Hypothetical AI MSS Ecosystem use in an organization



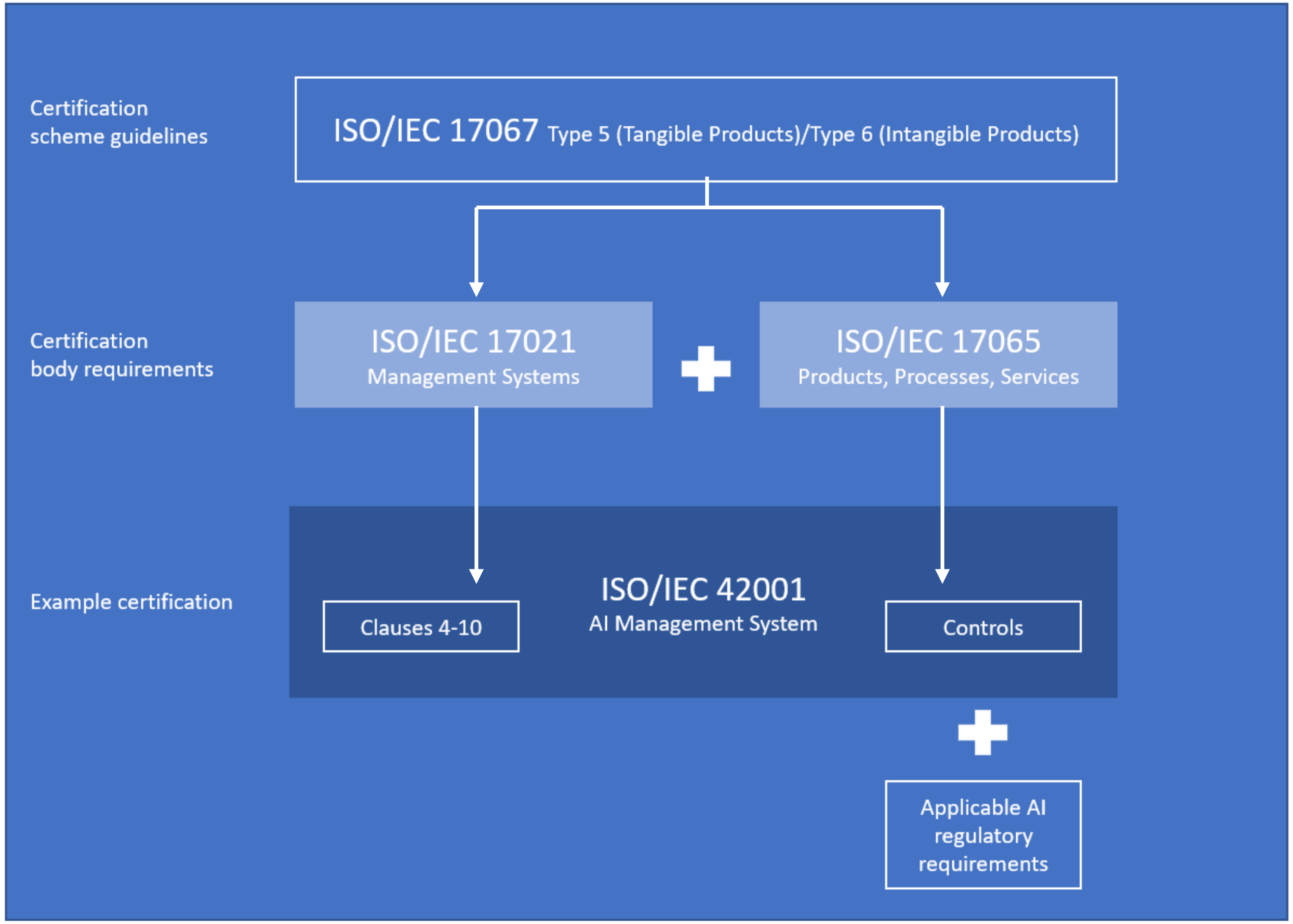
How can AIMS/management systems certification lead to customer/public trust?

- Management systems certifications, particularly those for IT products or “digital services” have a history of being the primary international certification mechanism (e.g. ISO/IEC 27001)
- Customers have come to recognize and rely on management system certification for assurance and trust that organizations are doing the right thing, and that products/services can be trusted
- Supply chains heavily rely on management system certifications as methods of mutual trust and assurance

Will management system certification alone be enough, particularly for higher risk AI systems?

- Potentially not—but it will be a key component!
- AI will likely be highly regulated in many cases (e.g., EU AI Act)
- “Productization” of intangible/digital services like AI—expectations by regulatory authorities and others for certification “equal” to that of tangible manufactured products
  - Accreditation of certification takes place under ISO/IEC 17065 for products/services rather than ISO/IEC 17021 for management systems in this case
- There are several problems to be solved in this space—primarily that digital services/intangible products have not historically been certified under 17065. However, there is a potential solution…

Novel approach to using management system for trust and assurance in a changing regulatory landscape: Joint certification

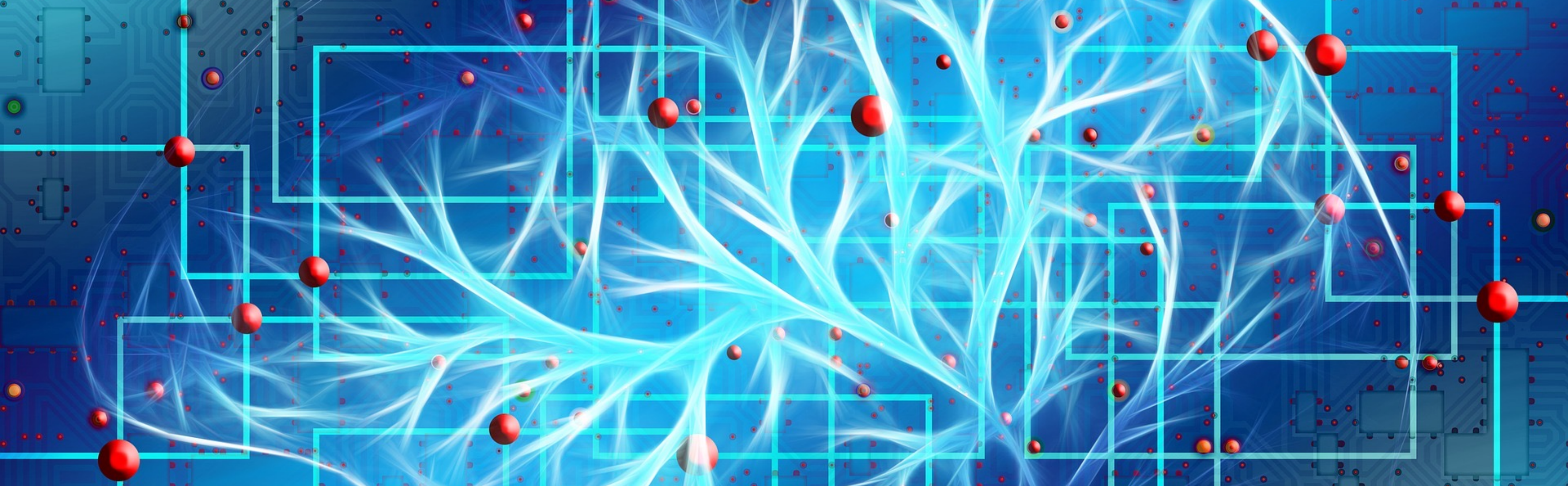


For more information on the joint certification topic, see the following whitepaper:

[A Joint Certification Approach for Digital Services and Regulatory Compliance]

INFORMATION TECHNOLOGY STANDARDS

SC 42 – Artificial Intelligence



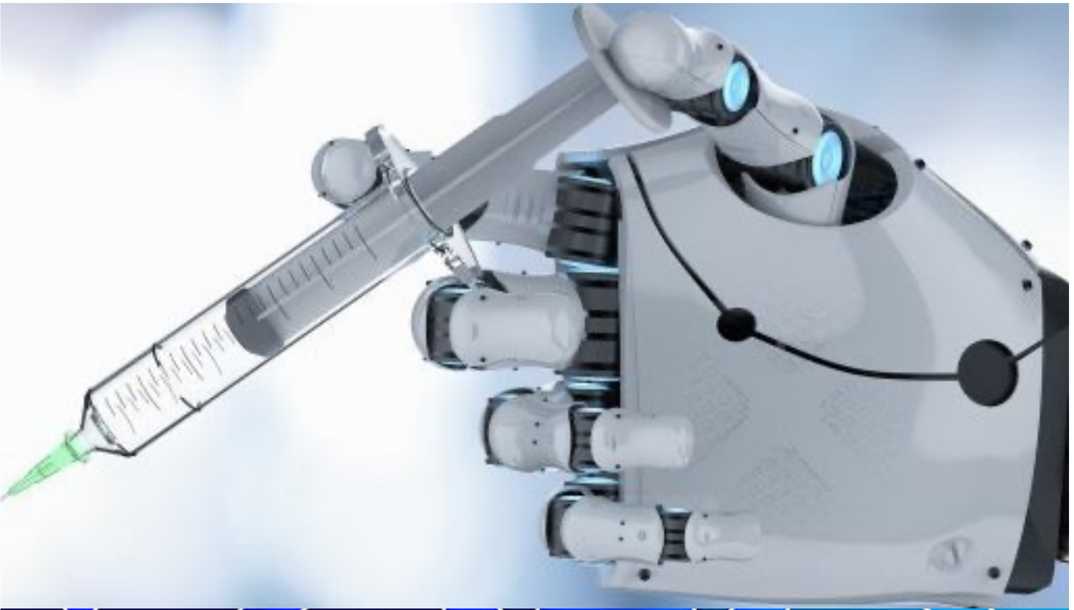
Summary

An AI management system will be a key component for providing trust an assurance for users of AI systems. Whether in a more traditional form via an organization’s GRC ecosystem and MSS certification, or as part of the novel approach to joint certification for management system and digital services, AIMS will be the foundation on which trust is created.

Thank you

Kimberly Lucy

kilucy@microsoft.com



ISO/IEC JTC 1/SC 42(AI)/WG 2(Data) Data Quality for Analytics and Machine Learning (ML)

Wo Chang

Digital Data Advisor

ISO/IEC JTC 1/SC 42/WG 2 Data Working Group, Convenor

National Institute of Standards and Technology, US

wchang@nist.gov

May 24, 2022

Motivations – Why data quality is important?

The success of AI machine learning has led to substantial improvements comparable to human performance and beyond across a variety of application domains. However, data quality for training, validation and verification plays a vital role, especially in the areas of *accuracy, precision, credibility, consistency, completeness, safety, security, privacy/societal/ethical concerns, etc.*

Sample Domains

Sample Applications

Healthcare

- Electronic Health Records
- Precision Medicines
- Drug Discoveries
- Care Management
- Lab Testing Services
- Others…

Autonomous Vehicles

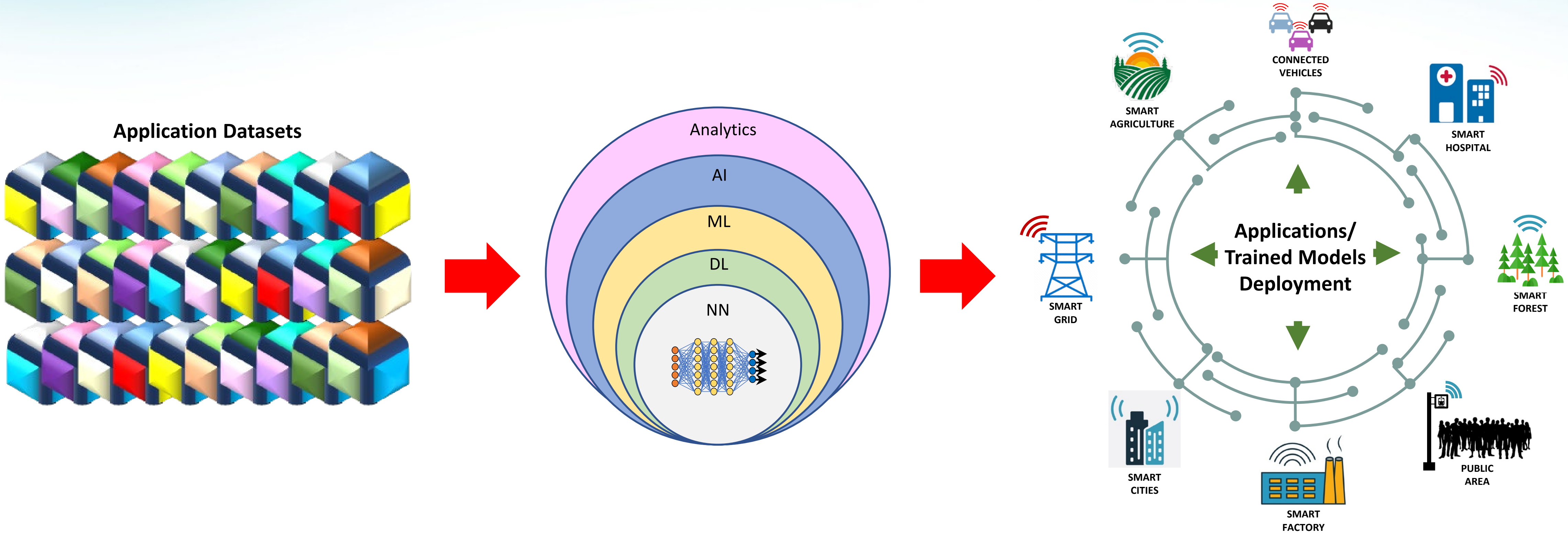
- Drones
- Self-driving Cars
- Vehicle-to-Vehicle Communications
- Unmanned Aerial Vehicle
- Others…

Financial

- Stock Market
- Electronic Commerce
- Online Transaction
- Banking
- Insurance
- Others…

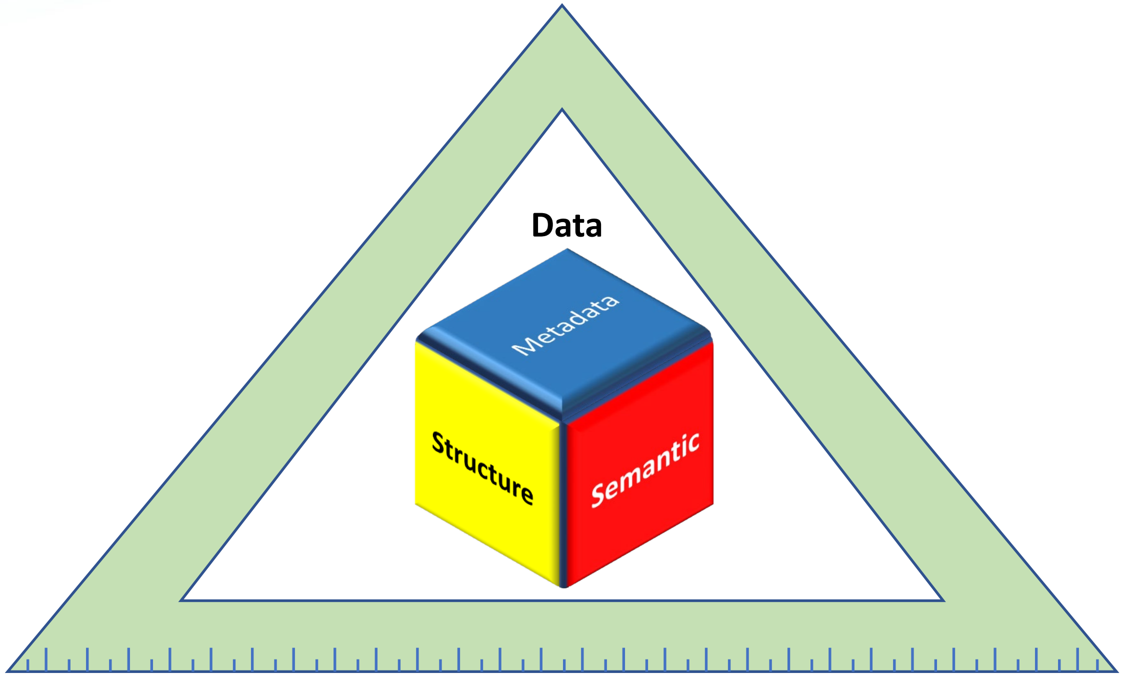
Data Empower Analytics/AI to Meet Applications Need

Data as oil to analytic/AI engine to solve complex application problems.



Data Quality for Analytics and Machine Learning: *Issues*

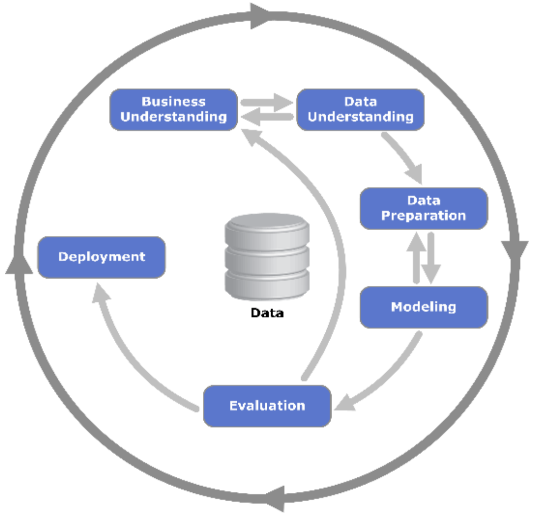
Data (structure, semantic, and metadata) quality impacts (wrong data produce wrong trained models) analytic/AI models results influence applications.



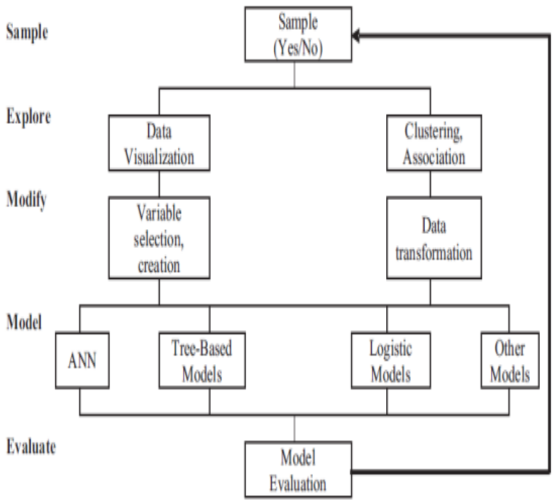
Data Quality for Analytics and Machine Learning: *Overall Goal*

To provide effective data quality for analytic and machine learning in the areas of measures, process, and management at each stage of the data life cycle across different levels of the organization.

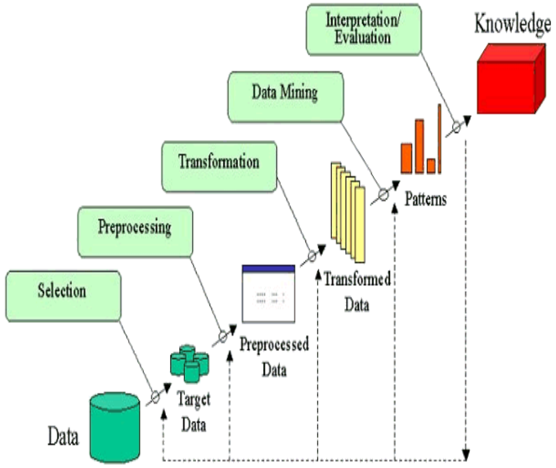
Sample Existing Data Life Cycles Management with Specific Goals



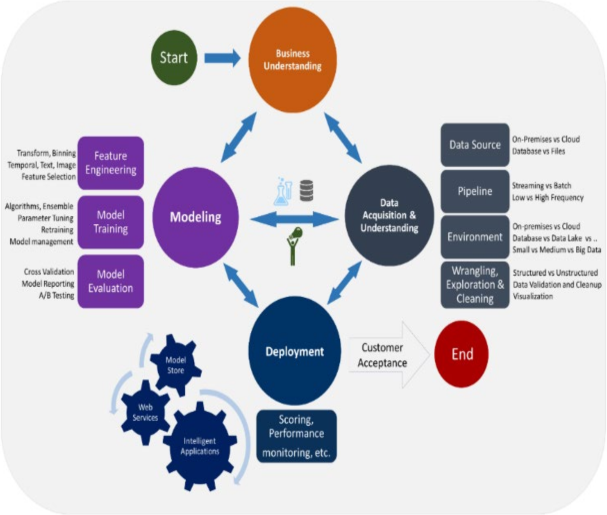
CRISP-DM
(Cross Industry Standard Process for Data Mining)



SEMMA
(Sample, Explore, Modify, Model, and Assess)



KDD
(Knowledge Discovery in Databases)



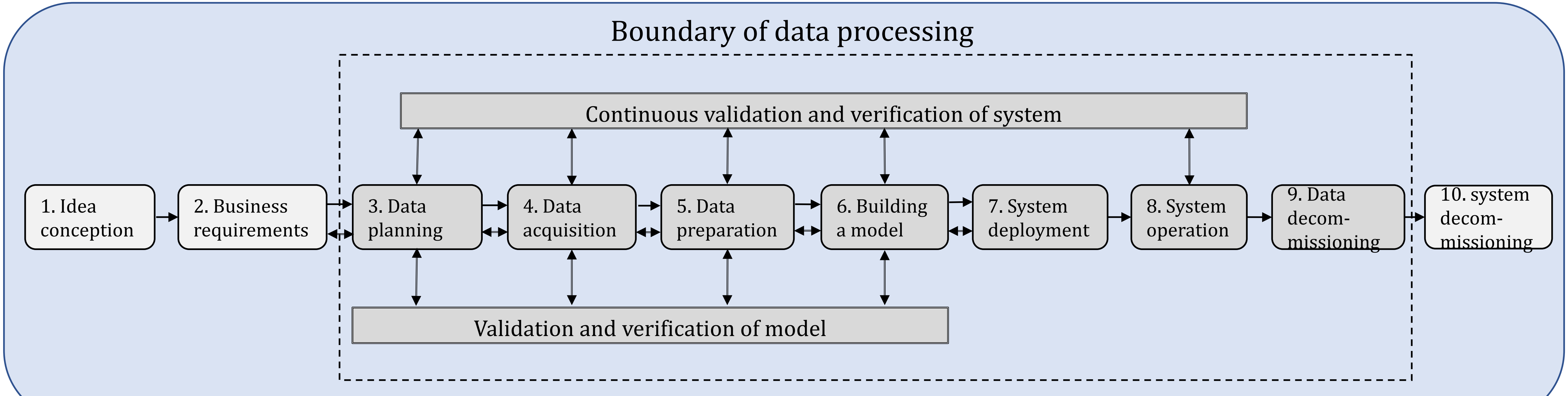
DSL
(Data Science Lifecycle)

ISO/IEC AI Workshop Series, Novel AI Standardization Approaches Track, Wo Chang, NIST/ITL, May 24, 2022

Data Quality for Analytics and Machine Learning: *Data Life Cycle*

ISO/IEC 8183 provides an overarching data life cycle framework that is instantiable for any AI system that is applicable across different levels of the organization from idea conception to system decommissioning stages with common terminologies and processes.

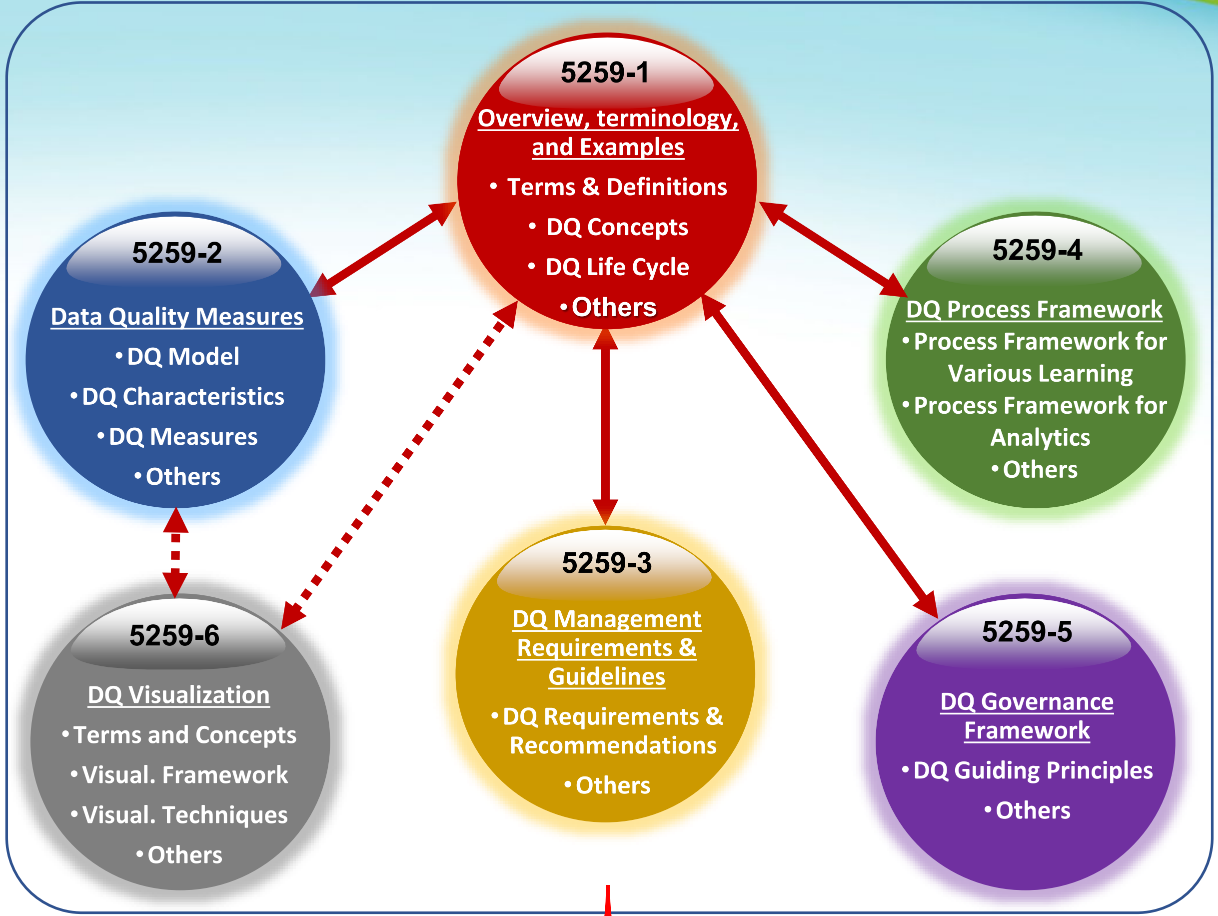
ISO/IEC 8183 AI Data life cycle framework

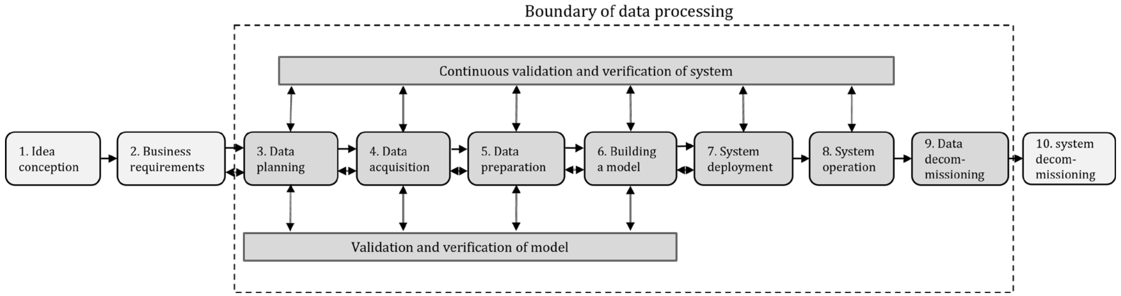


ISO/IEC 8183 AI Data life cycle framework (under DIS balloting)

ISO/IEC 5259-*x* Data Quality for Analytics and Machine Learning

A holistic approach is needed to oversee the implementation and operation of data quality measures, data quality management requirements and guidelines, and data quality process for various types of analytics and machine learnings with adequate controls throughout the ISO/IEC 8183 AI Data Life Cycle Framework.





ISO/IEC 8183 AI Data life cycle framework (under balloting)

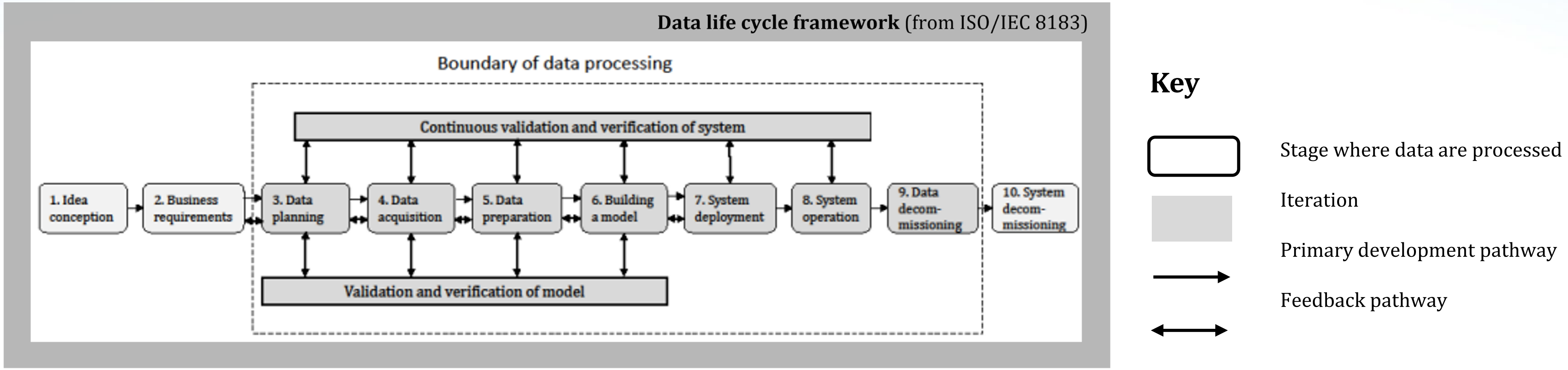
Leverage Available Standards

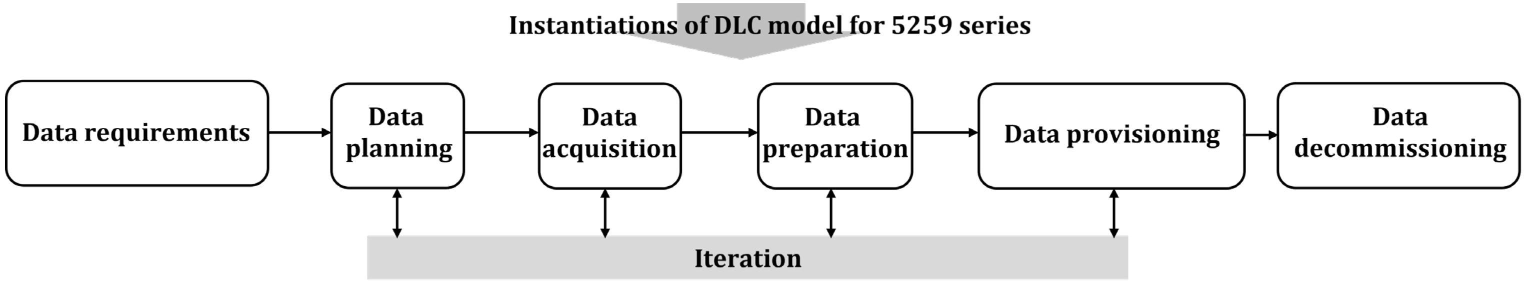
ISO/IEC 8183*	ISO/IEC 25012	ISO/IEC 38500	ISO/IEC 38505
ISO/IEC 22989	ISO/IEC 25024	ISO/IEC 38502	ISO/IEC 38507
ISO/IEC 23053	ISO/IEC 8000-61	"*" – under DIS balloting	

ISO/IEC 5259-1 Overview, terminology, and examples

Working Draft (Subject to change)

Scope: *This document provides the means for understanding and associating the individual documents of the ISO/IEC "Artificial intelligence — Data quality for analytics and ML" series and is the foundation for conceptual understanding of data quality for analytics and machine learning. It also discusses associated technologies and examples (e.g. use cases and usage scenarios).*

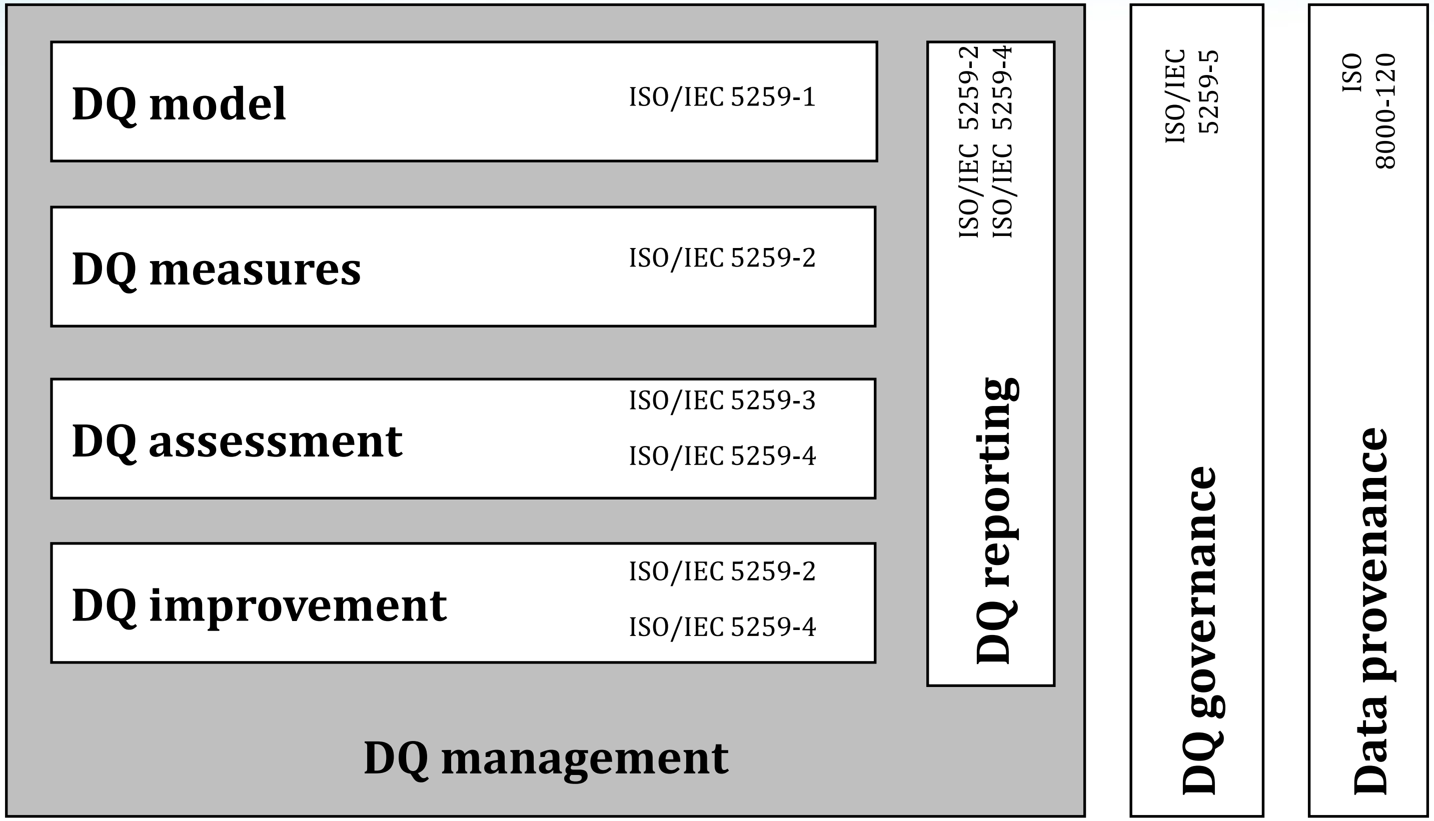




ISO/IEC 5259-1 Overview, terminology, and example

Working Draft (Subject to change)

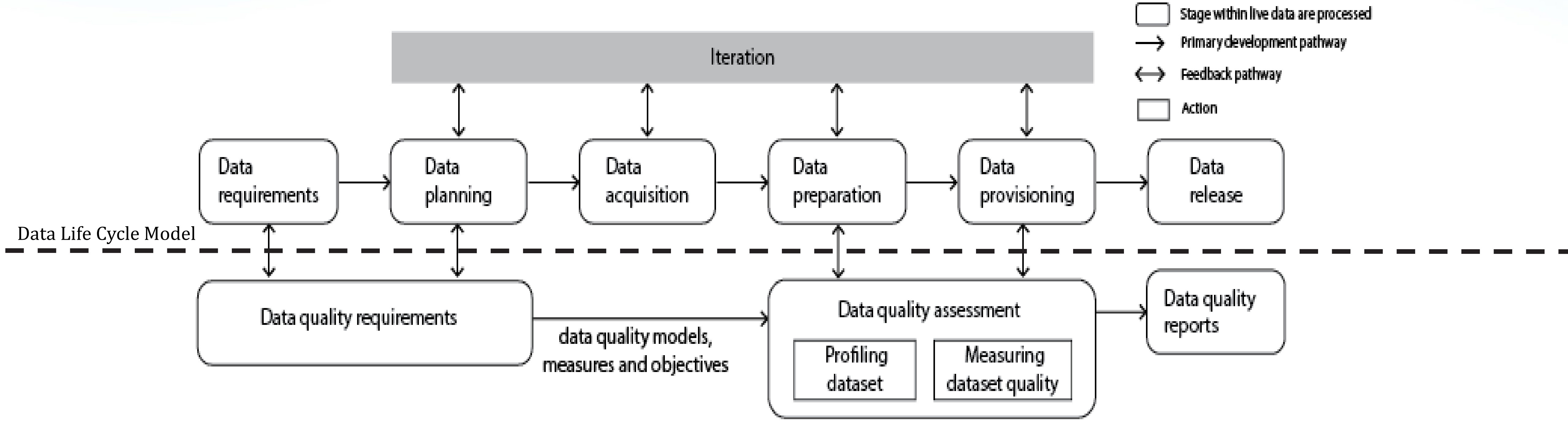
DQ Concept Framework for Analytics and Machine Learning



ISO/IEC 5259-2 Data Quality Measures

Working Draft (Subject to change)

Scope: *This document provides a data quality model, data quality measures and guidance on reporting data quality in the context of analytics and machine learning (ML). This document builds on ISO 8000 series, ISO/IEC 25012:2008 and ISO/IEC 25024. The aim of this document is to enable organizations to achieve their data quality objectives and is applicable to all types of organizations.*

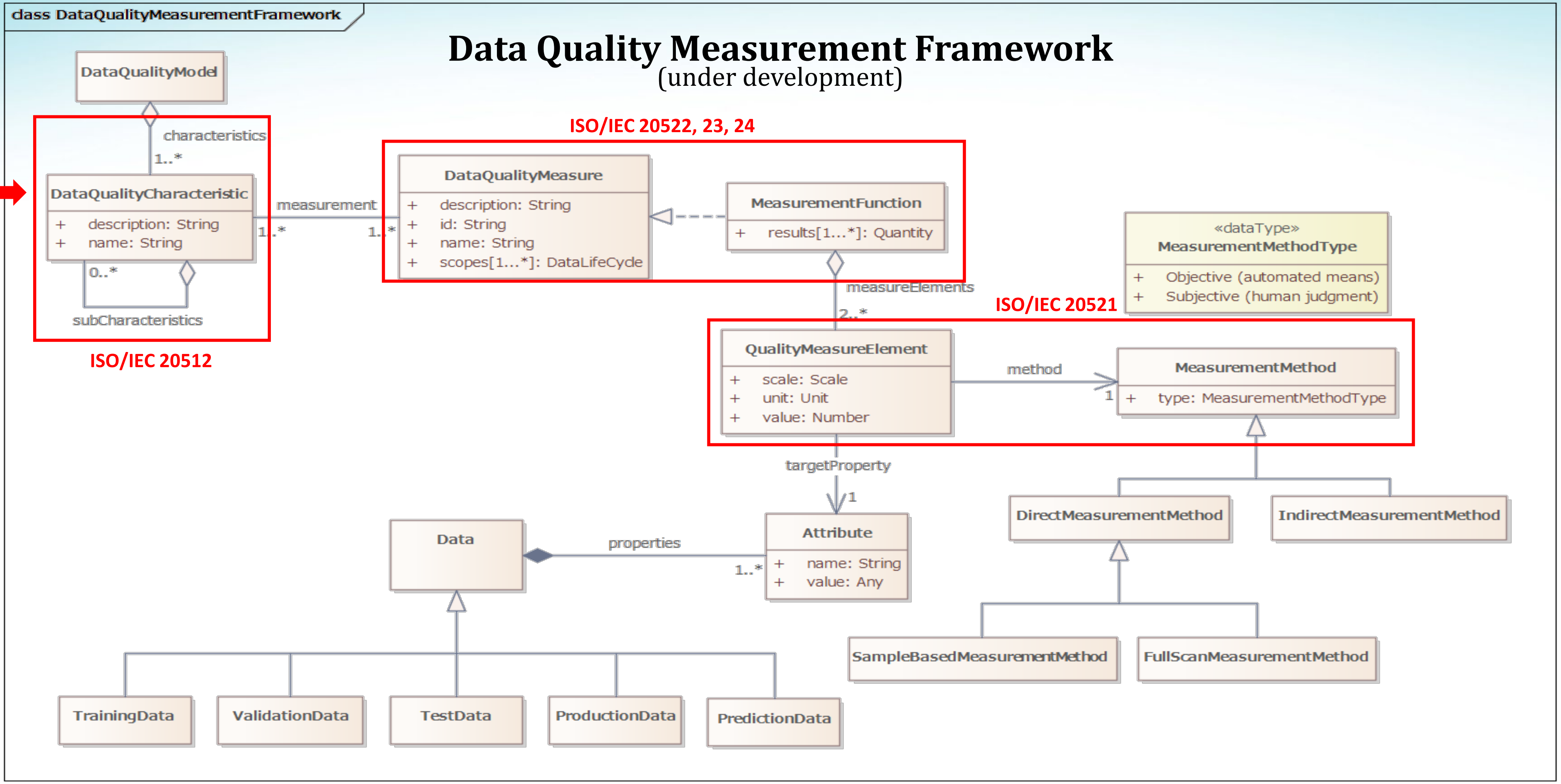


ISO/IEC 5259-2 Data Quality Measures

Working Draft (Subject to change)

DQ Characteristics

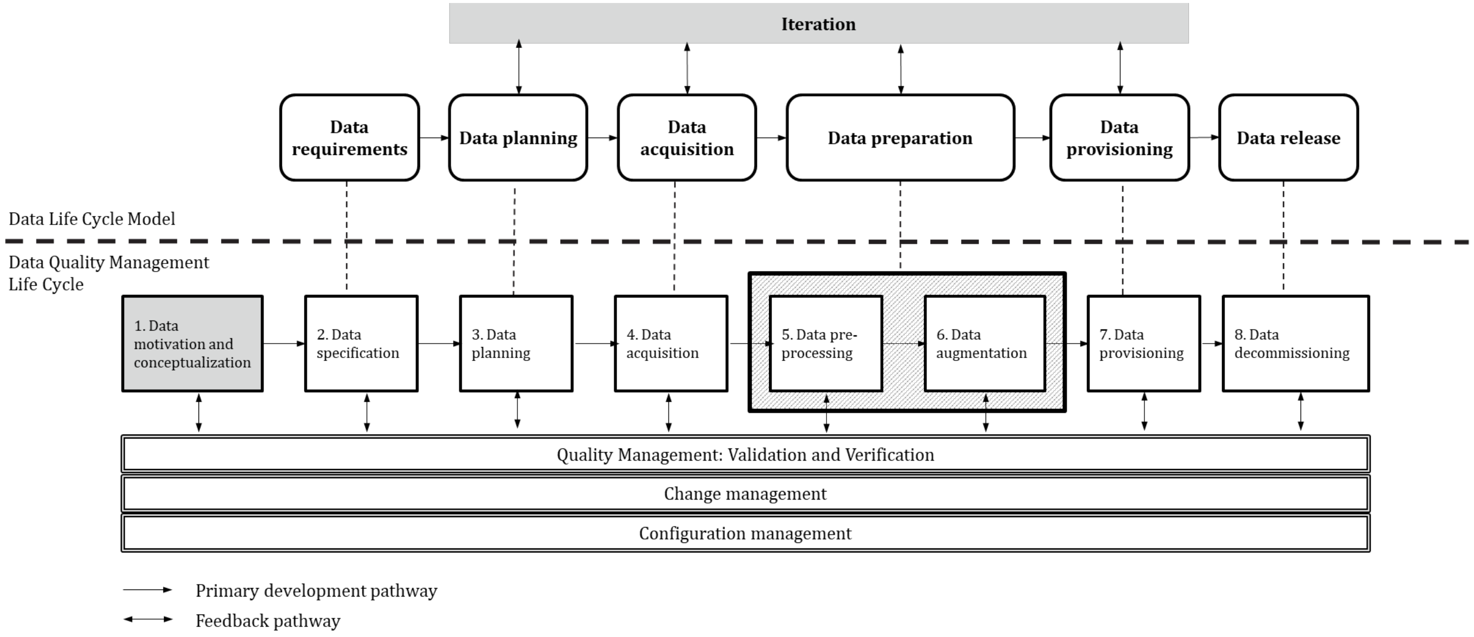
1. Accuracy
2. Precision
3. Completeness
4. Representativeness
5. Consistency
6. Relevance
7. Data scalability
8. Context coverage
9. Portability
10. Timeliness
11. Currentness
12. Identifiability
13. Auditability
14. Credibility
15. Understandability
16. Balance
17. Effectiveness
18. Similarity



ISO/IEC 5259-3 DQ Management Requirements & Guidelines

Working Draft (Subject to change)

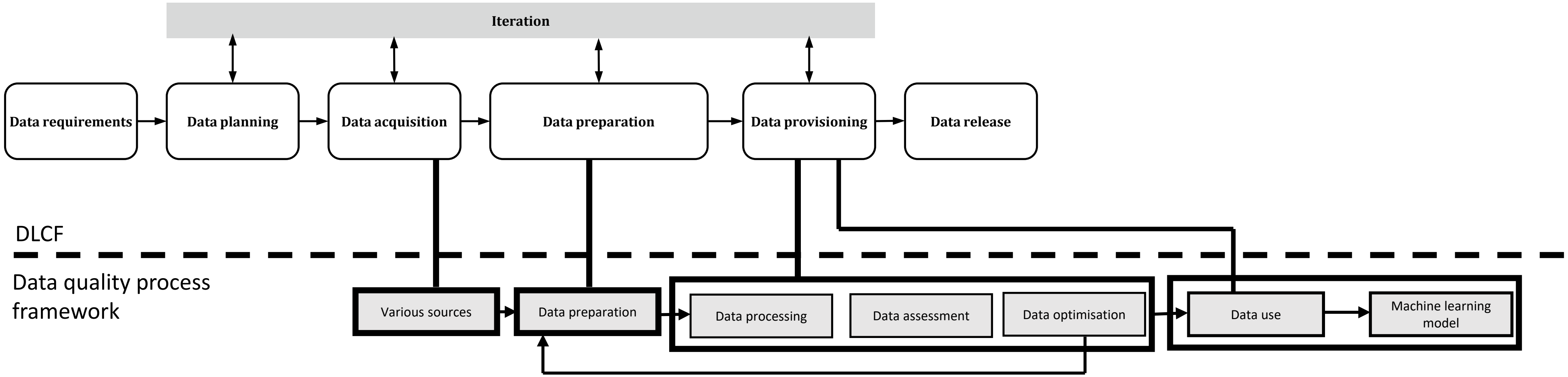
Scope: *This document specifies requirements and provides guidance for establishing, implementing, maintaining and continually improving the quality for data used in the areas of analytics and machine learning. This document does not define a detailed process, methods or metrics. Rather it defines the requirements and guidance for a quality management process along with a reference process and methods that can be tailored to meet the requirements in this document. The requirements and recommendations set out in this document are generic and are intended to be applicable to all organizations, regardless of type, size or nature.*



ISO/IEC 5259-4 Data Quality Process Framework

Working Draft (Subject to change)

Scope: *This document provides general common organizational approaches, regardless of type, size or nature of the applying organization, to ensure data quality for training and evaluation in analytics and machine learning. It includes guidelines for (a) supervised machine learning with regard to the labelling of data used for training machine learning systems, including common organizational approaches for training data labelling; (b) unsupervised machine learning; (c) semi-supervised machine learning; and (d) reinforcement machine learning. This document is applicable to training and evaluation data that comes from different sources, including data acquisition and data composition, data pre-processing, data labelling, evaluation, and data use. This document does not define specific services, platforms or tools.*

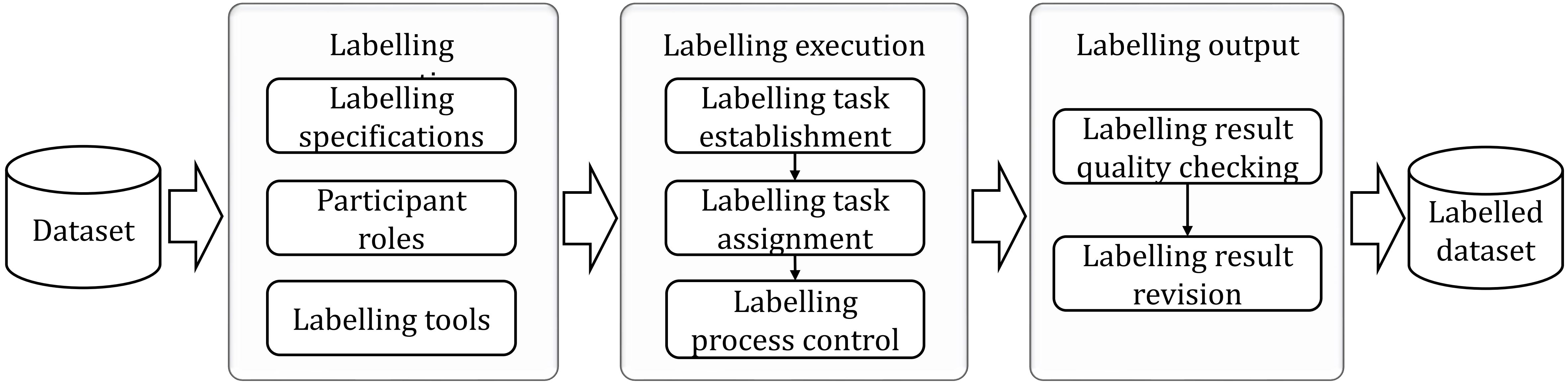


ISO/IEC 5259-4 Data Quality Process Framework

Working Draft (Subject to change)

Typical data labelling methods can include object annotation, bounding box, key-point annotation, instance segmentation and semantic segmentation. Data can be labelled manually by a human annotator or automatically by using pseudo-labelling. Pseudo-labelling is the process of using a model trained on labelled data to predict labels for unlabeled data.

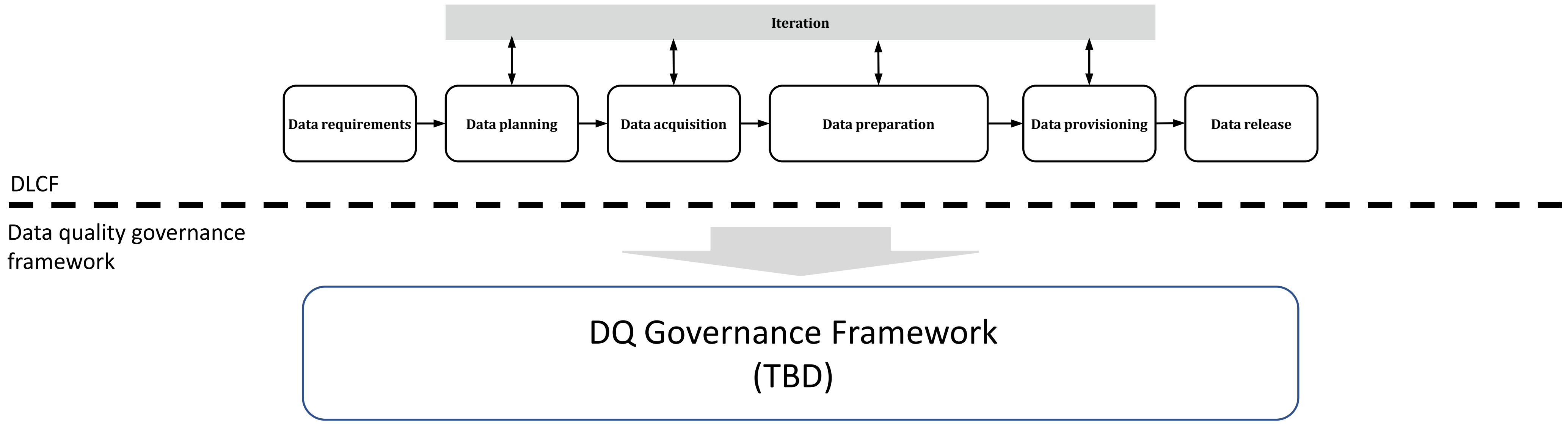
Data Labelling Process



ISO/IEC 5259-5 Data Quality Governance Framework

Working Draft (Subject to change)

Scope: *This document provides a data quality governance framework for analytics and machine learning to enable governing bodies of organizations to direct and oversee the implementation and operation of data quality measures, management, and related processes with adequate controls throughout the data life cycle. This document can be applied to any analytics and machine learning. This document does not define specific management requirements or process requirements specified in 5259-3 and 5259-4 respectively.*



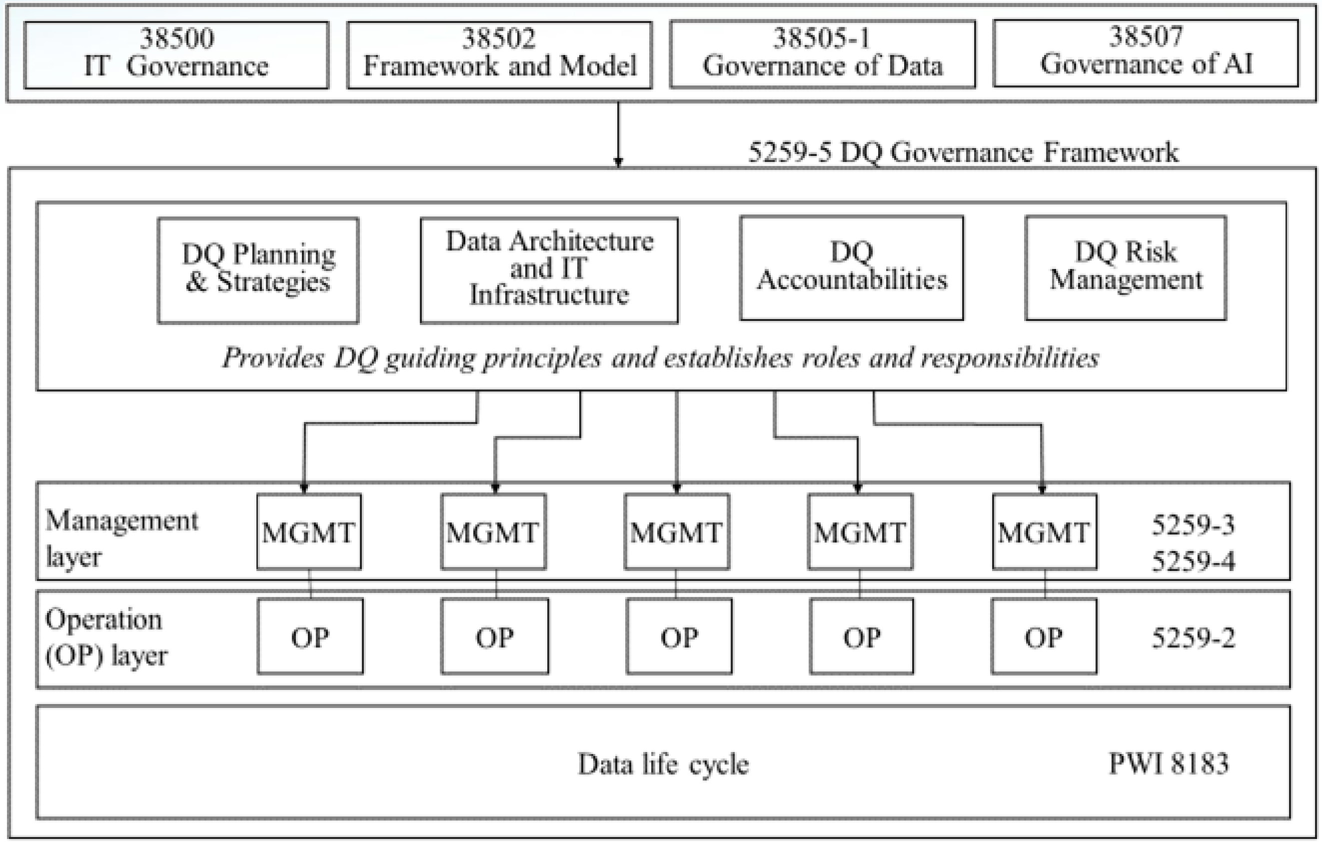
INFORMATION TECHNOLOGY LABORATORY

NIST National Institute of Standards and Technology U.S. Department of Commerce

ISO/IEC 5259-5 Data Quality Governance Framework

Working Draft (Subject to change)

Relationship between Data Quality Governance Framework and 5259 projects



ISO/IEC 5259-6 Data Quality Visualization

Under Exploration

Scope: *This document is an overview of data visualization within the context of Artificial Intelligence (AI) and Machine Learning (ML) applications. It is intended to provide examples of where data visualization may be employed by various stakeholders at different stages of the AI life cycle.*

Concept of Framework for Data-Quality-Driven Visualization for AI

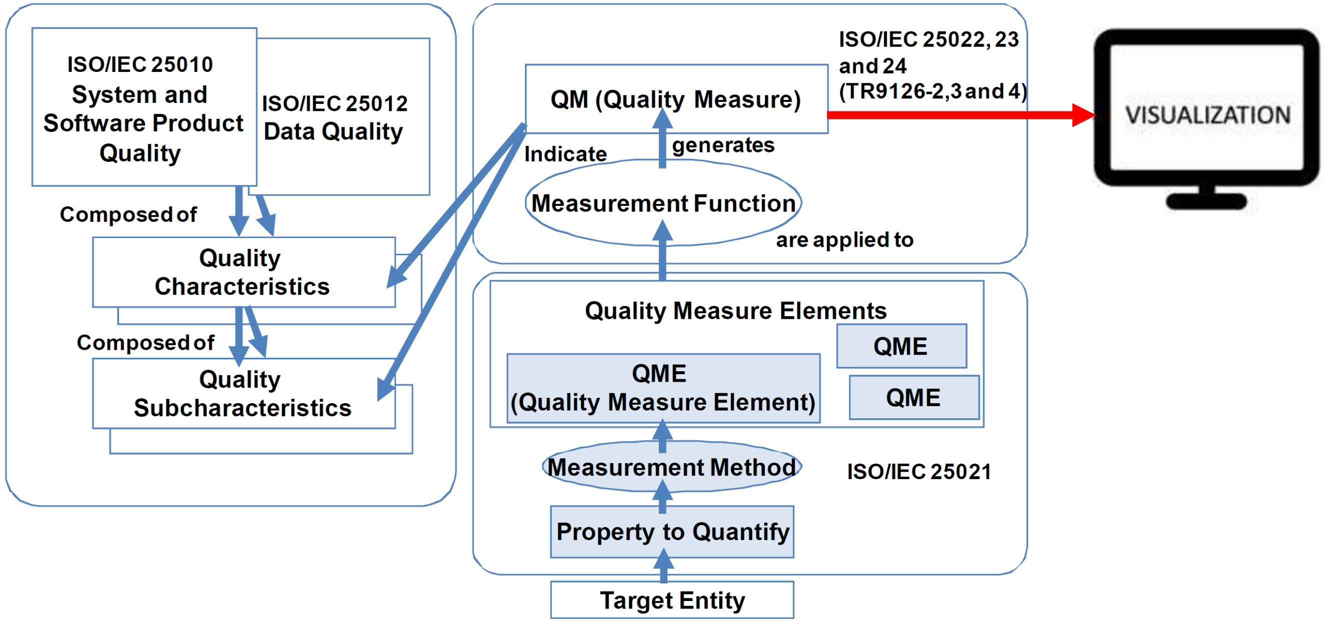


Figure 5 — Relationship among property to quantify, measurement method, QME and QM
(Source: ISO/IEC 20521:2012)

ISO/IEC 5259-6 Data Quality Visualization

Under Exploration

Sample Data Quality Measure from ISO/IEC 25012	Inherent/System Dependent	Phase in System Life Cycle	Stakeholders	Quality Measurement Requirements	Visualization Requirements	Applicable Visualization Methods	Examples
Accuracy	I	Inception, Development	Developer, Consumer	Sampling reflects the real world	Index or bar chart	Chart/graph	Multiplot of features
Completeness	I	Inception	Developer, Regulator	Statistically large data sample	Index	Chart/graph	Multiplot of features
Consistency	I	Inception, Development, Deployment	Developer	Data samples have same dimensions and features	Index/bar chart	Chart/graph	Group cluster plots
Credibility	I	Deployment	Consumer	Limited bias and impartial sampling	Index	Chart	Histogram
Current-ness	I	Inception thru Deployment	Developer, Regulator	Age of the data remains reflective of reality/use case	Time date	Numerical	Numerical
Accessibility	I/D	Development	Regulator, Consumer	High up time and available to stakeholder	N/A	N/A	Index by access method and stake holder/privilege
Compliance	I/D	All	Regulator, Developer	Regulator ensures data gathered per applicable norms	N/A	Index chart of criteria	Glyph of compliance criteria
Confidentiality	I/D	All	Consumer, Regulator, Developer	Domain dependent	N/A	Numerical/ index	N/A
Efficiency	I/D	All	Developer	Only what is used to answer a question/problem is in the data	N/A	Index	N/A
Precision	I/D	Development	Developer	Meets the intended application	Numerical	Numerical	N/A
Traceability	I/D	All	Regulator, Developer	Lineage is tracked	Index	Chart	Flow chart
Understandability	I/D	All	Regulator, Consumer	A stake holder can assess the data	Index or binary	Index	Multiplot by stake holder
Availability	D	All	Consumer	Data exists	Index	Index	Check list
Portability	D	Development	Developer	Data can be transferred to other systems for other application	Check list	Check list	N/A
Recoverability	D	Development	Producer, Developer	Data is stored in a manner as to be redundant and errors can be fixed	Check list	Check list	N/A

ISO/IEC 8183 and ISO/IEC 5259-x Projects Timeline

ISO/IEC Standard	Approved	DTR/WD	TR/CD	DIS	FDIS	IS
8183 (IS) AI data life cycle framework	02/07/22	--	02/07/22	05/01/22 Ballot issued	12/01/22	05/01/23
5259-1 (IS) Data quality for analytics and machine learning (ML): Part 1: Overview, terminology, and examples	07/30/20	12/21/20 WD23	08/21/22	03/21/23	01/28/24	05/27/24
5259-2 (IS) Data quality for analytics and machine learning (ML): Part 2: Data quality measures	12/31/20	06/17/21 WD14	02/13/23	09/20/23	04/20/24	09/20/24
5259-3 (IS) Data quality for analytics and machine learning (ML): Part 3: Data quality management requirements and guidelines	07/30/20	12/21/20 WD12	08/21/22	03/21/23	01/28/24	05/27/24
5259-4 (IS) Data quality for analytics and machine learning (ML): Part 4: Data quality process framework	07/30/20	12/21/20 WD14	08/21/22	03/21/23	01/28/24	05/27/24
5259-5 (IS) Data quality for analytics and machine learning (ML): Part 5: Data quality governance framework	02/17/22	05/31/22 WD1	03/13/23	03/11/24	10/11/24	03/10/25

SC 42/WG 2 Overview and Officers

Title: Data

Terms of Reference: Standardization in relation to data in the context of artificial intelligence, big data, and data analytics

Officers

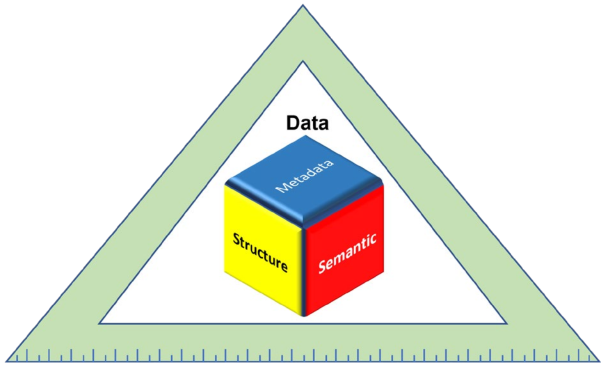
- Convenor: Wo Chang
- Secretary: Heather Benko
- Editors: Gautam Banerjee (24668), Colin Crone (8183 PWI), Suwook Ha (5259-1), KyoungSook Kim (5259-2), Martin Saerbeck (5259-3), Wanzhong Ma (5259-4), Gyeung-Min Kim (5259-5)

Membership

310+ Experts from 27 National Bodies: Australia, Austria, Belgium, Canada, China, Denmark, Finland, France, Germany, India, Ireland, Israel, Italy, Japan, Korea, Luxembourg, Netherlands, Norway, Poland, Portugal, Russian Federation, Singapore, Spain, Switzerland, United Arab Emirates, United Kingdom, United States

Questions?

Please contact: wchang@nist.gov



The Alan Turing Institute bsi. NPL

Introduction to the AI Standards Hub

Florian Ostmann (The Alan Turing Institute)

Tim McGarr (BSI)

Background and introduction

GOV.UK

Press release

New UK initiative to shape global standards for Artificial Intelligence

The Alan Turing Institute, supported by the British Standards Institution (BSI) and the National Physical Laboratory (NPL), will pilot a new UK government initiative to lead in shaping global technical standards for Artificial Intelligence.

From: Department for Digital, Culture, Media & Sport, Office for Artificial Intelligence, and Chris Philp MP

Published 12 January 2022

The Alan Turing Institute

bsi.

NPL

Department for Digital, Culture, Media & Sport

Office for Artificial Intelligence

The AI Standards Hub’s mission

– **Advance responsible AI** by unlocking the potential of standards as a **governance and innovation mechanism**.

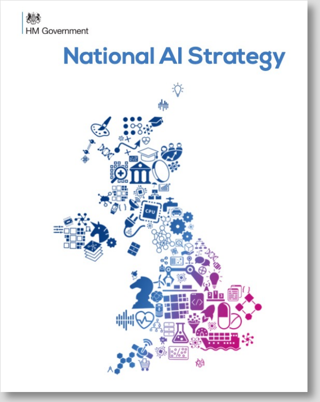
– **Empower stakeholders** to navigate the international AI standardisation landscape and become **actively involved** in it.

  ➤ **Participation in the development of standards**

  ➤ **Informed use/assessment of published standards**

Motivation for the AI Standards Hub

1) AI standards are **increasingly important** as a **governance** and **innovation** mechanism



GOV.UK

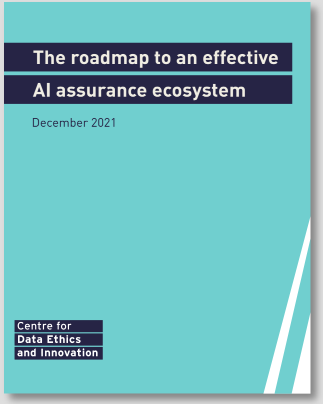
Policy paper

Digital Regulation: Driving growth and unlocking innovation

The Plan for Digital Regulation sets out the government's overall approach for governing digital technologies in order to drive growth and innovation.

From: Department for Digital, Culture, Media & Sport

Published 6 July 2021



Motivation for the AI Standards Hub

1) AI standards are **increasingly important** as a **governance** and **innovation** mechanism

2) AI standardisation touches on the **interests of many stakeholders**
   - AI developers
   - Procurers of AI
   - Users of AI
   - Consumers / civil society
   - Regulators & policymakers
   - Academic researchers

3) The AI standards landscape is **increasingly complex** and **rapidly evolving**

Pillars of activity

1. AI standards observatory
2. Connecting and community building
3. Education, training, and professional development
4. Research and analysis

Signing up

Register for updates and **provide input** to shape the AI Standards Hub:

www.aistandardshub.org

Contact details:

Florian Ostmann fostmann@turing.ac.uk

Tim McGarr Tim.McGarr@bsigroup.com

ISO/IEC JTC 1 SC 42 Novel AI Standardisation Approaches

Viveka Bonde

ISO JTC1 IEC
INFORMATION TECHNOLOGY STANDARDS
SC 42 – Artificial Intelligence

Introduction of SC 42

- Committee on AI standardization under the joint initiative on Information Technology (JTC 1)
- IEC and ISO produce international standards and with participation by country – one country one vote
- Collaboration with long established sister ISO and IEC committees covering a broad range of app domains
- Works with JTC 1 committees producing horizontal stds in key areas such as security, cloud, IoT, governance

ISO JTC1 IEC
INFORMATION TECHNOLOGY STANDARDS
SC 42 – Artificial Intelligence

Societal Concerns and Ethics

Overview

- Adoption of transformative technologies like AI have impacts that go beyond the technology

- AI-specific trustworthiness issues e.g. reliability, privacy, security, explainability, controllability

- Emerging issues related to the **context of use of the technology,** e.g. algorithmic bias, safety directives in industrial AI, eavesdropping

- AI ethical considerations not limited to SC 42 but extend to ISO/IEC TCs in their applications

Societal Concerns and Ethics

Motivation and current focus areas

- Standards can mitigate ethical issues allowing for broad **responsible adoption**.
- Stakeholders include:
  - industry,
  - regulatory,
  - technologists,
  - interest groups, app domain, society at large

Societal Concerns and Ethics

Motivation and current focus areas, cont.

- Ethical considerations and societal concerns **considered across entire SC 42 program**

○ **Dedicated** projects

– **Overview** of AI ethical and societal concerns with tie-in to trustworthiness and exemplary use cases

– PWI on **AI best practice guidance for mitigating ethical and societal concerns**

○ **Integrated into and enabled by entire SC 42 deliverables portfolio**. For instance,

– Governance, Management System Standards (MSS) – 42001 (AIMS), use cases, application guidelines, safety etc.

- SC 42 **collaborating** with other work programs such as OECD, UNESCO, European Commission

Societal Concerns and Ethics

TR 24368 - Overview of ethical and societal concerns

- **Links to traditional standardization work by adding the non-technical ethical perspective necessary to address ethical and societal concerns of an AI system and applications:**
  - **The ethical and societal layer may be emerging as part of "Harmonized Standards" (new legislative framework).**
- **Addressing that an ethical and societal concern with an AI system and application often depends upon the particular social, economic or physical context of its development, implementation, audience and use.**
  - **Practices for building and using ethical and socially acceptable AI. Organization's management process.**
  - **Stakeholder considerations for building and using ethical and socially acceptable AI**
- **Visionary element: Enable support and a starting point for other international projects**

Key Topics: Societal Concerns and Ethics

Overview of ethical and societal concerns

Example fundamental sources: ISO 26000:2010, ISO 31000:2018, ISO/IEC 38505-1:2017, ISO/IEC 27001:2013.

- **22989; provides standardized AI terminology**
- **23894; provides guidelines managing AI-related risks**
- **24027; bias in AI-systems**
- **24028; introduction AI system transparency and explainability**
- **24030; use cases of AI applications**
- **38507; guidance on governance implications**

Societal Concerns and Ethics

Overview of ethical and societal concerns

- Takes into account the context of use of the technology by looking at both technology capability and non-technical requirements such as business requirements, regulatory and policy requirements, application domain needs, and ethical and societal concerns
- Translating the above into technical requirements
- Building foundational standards that allow communities to build upon such as terminology, use cases, application guidance and reference architectures.
- Linking technology innovation communities such as proprietary implementations, research and open source communities

Societal Concerns and Ethics

Overview of ethical and societal concerns

- General all-embracing document
- Has encouraged interdisciplinary expert participation and contribution
- Practical document, organizational focus
- Hands on approach; tangible product - how to address AI themes and principles in practice
- Themes and Principles: Addressing AI systems' and applications' potential misuse, abuse and disuse

Societal Concerns and Ethics

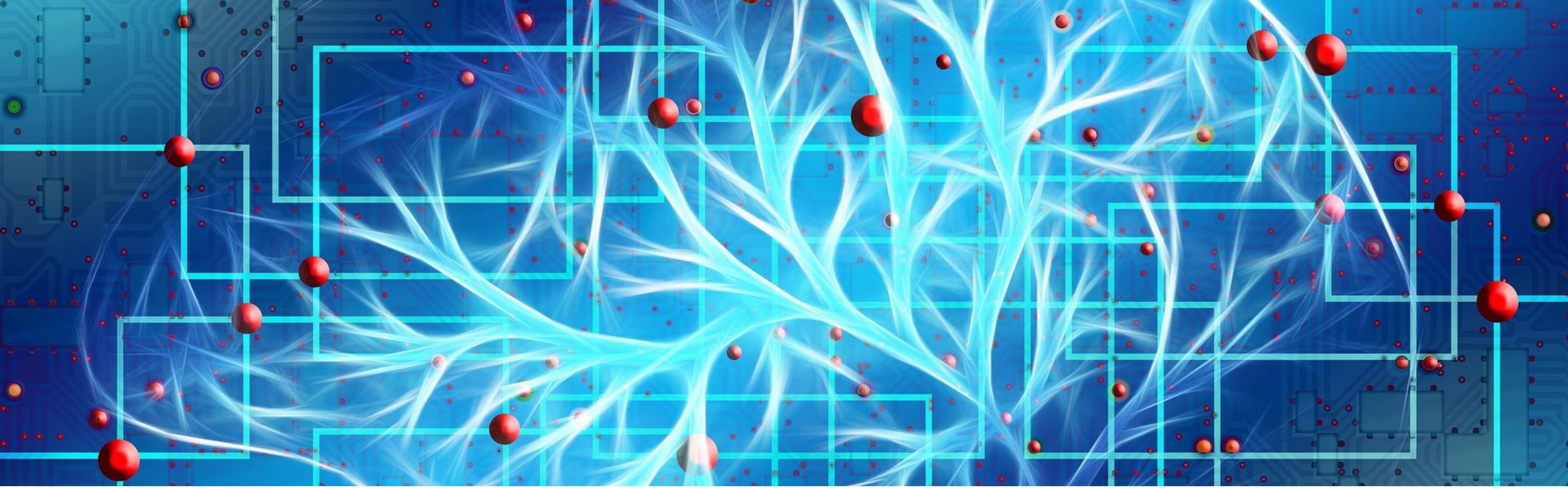
Novel AI Standardization Approaches

- **Align technical experts with non-technical experts**
- **Necessity to apply expertise inter-disciplinary for creation of ethical AI**
- **Interplay conformity assessment: The specification of general ethical themes and principles, guidance, considerations - facilitate due diligence of AI systems, on a system/technical level + organizational/ethical level – enhancing public confidence and trust**

Societal Concerns and Ethics

Novel AI Standardization Approaches

- International standardization creates a level playing field in markets throughout the world
- New approach legislation feasible
- Importance of conformity assessment
- AI stakeholders: standards define requirements - making compliance with themes and/or principles understandable by concrete guidance



Result:
Interplay between legislation, conformity assessment and standardization

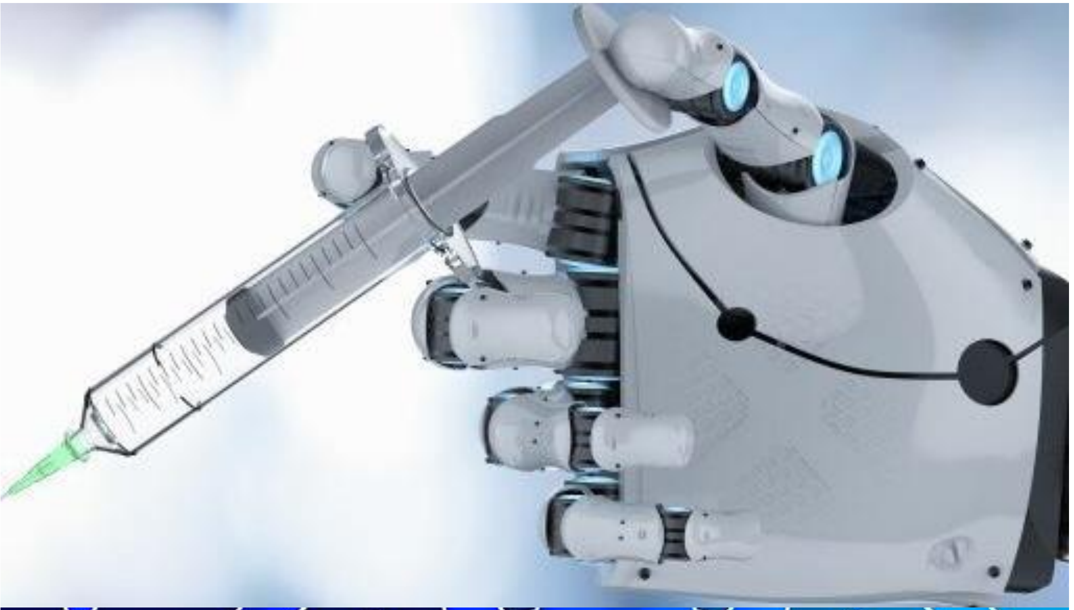
<u>Standardization element:</u>
- The link between legislation and conformity assessment stage
- Complement the requirements of legislation
- Facilitates conformity assessment
- Why: Flexible, inclusive and responsive. Expression of the principles of subsidiarity and proportionality

Thank you

Viveka Bonde

viveka@bondebarzey.com

www.bondebarzey.com



ISO JTC 1 IEC
INFORMATION TECHNOLOGY STANDARDS
SC 42 – Artificial Intelligence