



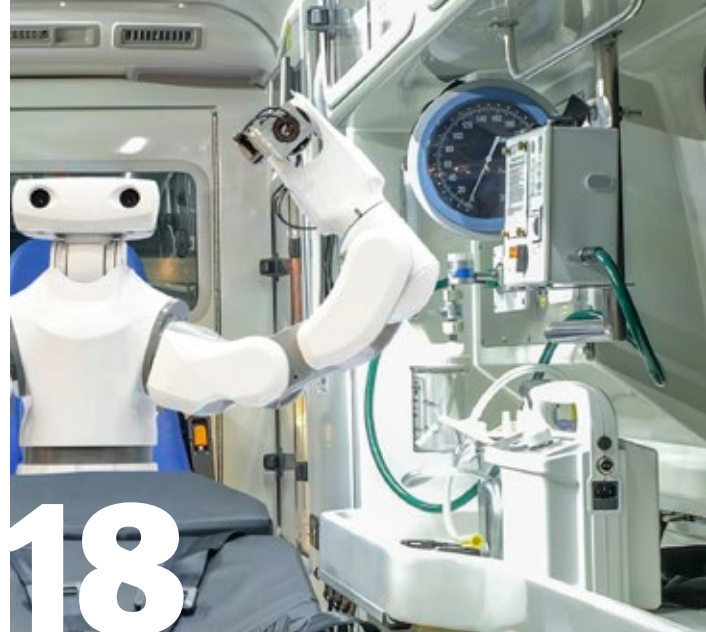
#137

# focus

Your gateway to International Standards

*The age of*  
**artificial  
intelligence**





#137



# ISO focus

November-December 2019



**ISOfocus** November-December 2019 – ISSN 2226-1095

*ISOfocus*, the magazine of the International Organization for Standardization, is published six times a year. You can discover more content on our Website at [iso.org/isofocus](http://iso.org/isofocus), or by staying connected with us on:



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# shaping our

# AI future

From transportation to healthcare, financial services to robotics, manufacturing and more, artificial intelligence – more simply known as AI – is making a tremendous impact on the way people around the world live and do business. According to market research firm IDC, spending on AI technologies is projected to reach USD 52.2 billion by 2021, creating strong economic growth opportunities around the globe.

To help unlock the promise of AI and remove barriers to its adoption, globally relevant and globally accepted voluntary consensus standards are key. The standards community has been up to the task, collaborating across industries and national borders to drive innovation.

In 2018, the joint technical committee ISO/IEC JTC 1, *Information technology*, of

ISO and the International Electrotechnical Commission (IEC) established subcommittee SC 42 on artificial intelligence. It is the first standards activity to focus on the entire AI ecosystem. After all, AI is not one technology, but a variety of software and hardware enabling technologies that can be applied in various ways in a potentially unlimited number of applications in almost every industry sector.

As the US member body to ISO, ANSI is proud to lead standardization activities in this space, working in close partnership with other national standards bodies to advance AI technologies. ANSI has served as the secretariat to ISO/IEC JTC 1 since its inception in 1987, and provided the Chair for the first and only ISO/IEC joint technical committee. The US also holds the secretariat and Chair positions of SC 42.

Charged with serving as the focal point for AI standardization, SC 42 also provides guidance to JTC 1 and other non-IT-focused ISO and IEC committees as they look to develop AI-related standards in their sector-specific application areas. The subcommittee has already established a large and diverse network of liaisons that act not only as collaborators on the work, but also as customers of the standards emerging from this activity.

As the wider industry, user and regulatory communities identify what sector-specific standards are needed for AI applications in the marketplace, SC 42 is busy developing horizontal standards to meet these needs in areas such as terminology, use cases and methods to ensure the trustworthiness of systems, including risk management. By bringing together experts and liaison organizations from a variety of disciplines, the SC 42 “ecosystem approach” not only addresses technical requirements and their solutions, but also focuses on broader non-technical issues such as ethical and societal considerations that impact and guide the development of technical standards.

The US is also pleased to convene one of SC 42’s working groups focused on the development of standards for big data. From agriculture to finance, big data standards will help to advance industry sectors that rely on extensive data sets and data-processing systems. It’s an emerging and rapidly changing technology space that will impact IT systems and the external industry sectors served by them, so standards to guide its development are crucial. Three standards in the field of big data have already been published and a big data reference architecture standard is due for release soon. Moreover, a newly approved work item on process management frameworks for big data analytics has been added to the roster for this working group.

The active role of the US in the success of this work, which has produced more than 3000 JTC 1 International Standards to date, underlines our country’s commitment to fostering innovation and effective collaboration in this broad-reaching technology space. Beyond these ISO/IEC activities, dozens of US-based standards organizations are also making great strides in providing standardization solutions for AI-related technologies and applications that meet the needs of their stakeholder groups and industry sectors.

ANSI is proud to support transformative AI technologies through engagement and leadership in international standardization activities. This is a pivotal time to be involved in standards for AI, and ANSI is excited to be at the forefront, working in partnership with other national standards bodies to facilitate globally relevant standards. Our collective work will help to propel the wide-scale adoption of AI and big data systems, enabling next-generation applications in virtually every industry, and changing the future of technology for people around the world. ■



Photo: Bachrach  
S. Joe Bhatia, President and CEO, American National Standards Institute (ANSI).

This is a pivotal time  
to be involved in  
standards for AI.



Swipe up

Meet Maria and Katie from the Communication team reporting on **#ISOWeek2019**. ▶



Lynette Ntuli gave an inspirational speech on strategy. ▶



A five-minute break with **ISOfocus**, ISO's flagship magazine. ▼



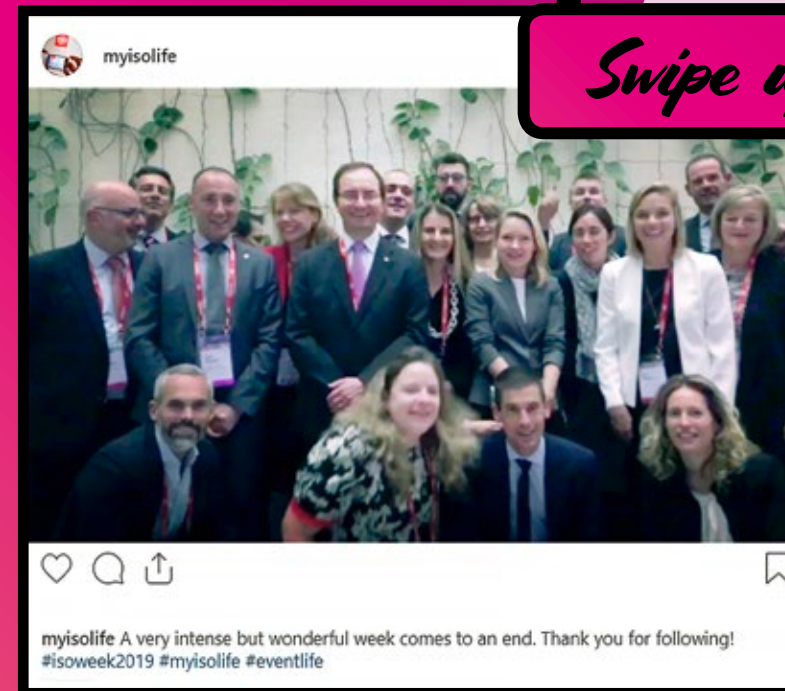
# Follow us on Instagram!

**@myisolife** has now been converted to a “travelling” account! Every month, a new staff member from the ISO Central Secretariat will take the account and bring us behind the scenes into the world of standardization. Here are a few pics from this year's ISO General Assembly in Cape Town, South Africa.



◀ Sazi and Neo from our **#southafrican** member SABS that hosted the event.

Swipe up



◀ Curtain call for ISO staff. Thank you for following **#myisolife**!

**@myisolife** is about showing the faces, the people, and the flavour that make up the world of standardization. We'll see you on “the gram”!





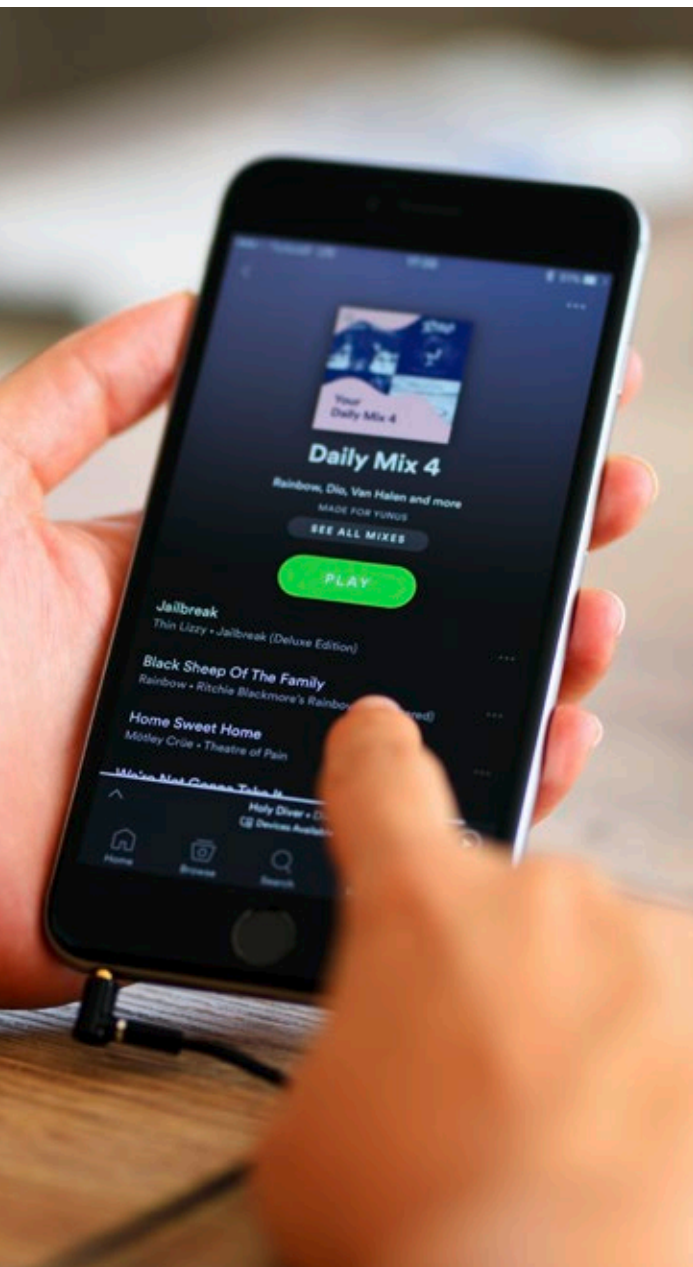
# Embracing the power of technology

AI is a new and fast-changing field, full of innovators and disruptors.



by Kath Lockett

Just how worried should we be about killer robots? Amidst all the talk about how artificial intelligence (AI) is threatening society, some experts believe AI shouldn't be feared. Here's why we can embrace the power of technology.



Artificial intelligence (AI) is everywhere. AI recommends movies and restaurant choices, prevents cars from crashing, books flights, tracks taxis, identifies financial fraud and creates playlists to work out to. In the 1950s, AI was defined as machines operating in ways that were regarded as “intelligent”, or equal to tasks performed by humans. Since then, computer use and data generation have increased enormously, with current estimates of 2.5 quintillion bytes being produced every day.

Much of this data is output, or information, collected from daily use of mobile phones, social media and the Internet. This information is commonly known as “big data” and is where AI steps in to help. AI uses machine learning to analyse this data in real time at a speed and volume no human ever could. Not surprisingly, the private sector has embraced AI and increasingly uses it to gain more accurate information on purchasing behaviour, financial transactions, logistics and predicting future trends.

The United Nations recognizes the power of AI and is working with the private sector on “data philanthropy” so information such as surveys, statistics and consumer profiles can be used for public good. For example, researchers are using satellites and remote sensors with AI technology to predict extreme weather events that affect agriculture and food production in developing countries.

With this in mind, ISO – in conjunction with its sister organization, the International Electrotechnical Commission (IEC) – has identified the need to develop standards for AI that can benefit all societies. The ISO/IEC JTC 1/SC 42 subcommittee for artificial intelligence was established two years ago and has already



Not surprisingly, the private sector has embraced AI.

published three standards relating to big data, with 13 other projects in development. Chaired by business and technology strategist Wael William Diab, it will develop and implement a standardization programme on AI to provide guidance for other ISO committees developing AI applications.

### Setting boundaries

SC 42 has a broad scope of AI development that includes basic terminology and definitions, risk management, bias and trustworthiness in AI systems, robustness of neural networks, machine-learning systems and an overview of ethical and societal concerns. Twenty-seven member countries are participating in this programme with another 13 countries observing. Ray Walshe, Assistant Professor of ICT Standardization at Dublin City University, Mr Wo Chang, Digital Data Advisor for the Information Technology Laboratory (ITL) of the National Institute of Standards and Technology (NIST) in the United States, and Dr Tarek Besold, Scientific Advisor of Neurocat in Berlin and Chief Behavioural Officer (CBO) at Telefonica Innovation Alpha Health in Barcelona, are three key members of this committee. Do they identify with Peter Parker when he became Spiderman? With great power comes great responsibility.

Dr Besold isn't daunted. “AI is a new and fast-changing field, full of innovators and disruptors. We need to define the state-of-the-art and common-sense definitions of AI mechanisms and technologies. Yes, developing norms and standards is a big task and interoperability is vital because AI is so far-reaching. AI is part of many futures as a tool rather than the leader.”



SC 42 is “building from the ground up,” says Chang. “We provide interoperable frameworks and performance tools in the form of standards on AI and big data, which can then be shared with government and private enterprise. These frameworks set the AI ‘boundary conditions’ that can be defined using probabilities to determine the risk factors. Not just boundaries, but a safety net that uses risk management in implementing them.”

It remains up to governments around the world to decide what they regulate. Ray Walshe says that “the public needs to recognize that there is a difference between standardization, legislation and regulation. Ninety percent of the world’s data has been generated in only the past two years. This is an incredible mountain of both structured and unstructured data to be stored, aggregated, searched and correlated for the myriad of businesses, governments and researchers who provide tools and services. Governments and private industry will often use International Standards as a reference to regulation, to ensure that industry, societal safety and ethical concerns are met”.

### Tricking AI

Safety of data and how it is used remains a concern in society, especially when the dreaded “computer error” is mentioned. Mathematics emerges as the crucial ingredient. Dr Besold says AI programs play a “numbers game”, with researchers generating attacks and defences on AI systems, trying to “trick them” and developing solutions to the problems they discover.

AI focuses on high specificity, which means that it’s tailored to a specific task, Besold says. “AI takes away the time-consuming and boring programming from people, but it still needs rules and measures that are set by humans. If you apply safety boundaries to the self-driving car, it’s obvious that this technology needs safeguards and standard definitions. Is it an acceptable risk to run over an elderly person or a small child? Neither is acceptable, of course, and we want to help governments and industries accept and use the measures we recommend.”

“Probability in risk assessment is the key word,” Wo Chang agrees, and he uses cats as a rather powerful example: “If you take image recognition, you’ll see that an effective system will highlight an error if the program has not experienced it before and shut down. The system has been given millions of pictures of cats and dogs so that its ability to differentiate between them is fine-tuned. The system has been trained under well-defined conditions, but it’s impossible to model



**90% of the world's data has been generated in only the past two years.**

for everything. What happens if it comes across a cat wearing a bow tie? It shows that if one part of a picture is changed, the outcomes can be very different. This could be a ‘bug’ (or a bow-tie-wearing cat) that does not meet the trained environment and system function and puts in a safety constraint to avoid failures. If applied to more serious applications, then thorough testing can determine probabilities and shut down the system to prevent more catastrophic decisions or failures.”

### Trust your data

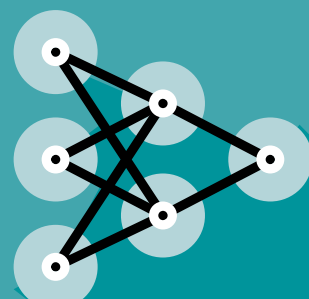
With use of AI in potentially sensitive areas such as healthcare, surveillance and banking, there remains the risk that human bias affects the data used. Dr Besold acknowledges this. “There is bias in AI, but we can agree on a standard definition to address this bias. Regulators may accept that a 5/10 bias is acceptable for soap dispensers but certainly not when it comes to self-driving cars.”

In the medical field, he says, government and society need to decide if we are OK in a validated world. Are we OK with using data that’s mostly from the first world, for the first world, in the first world? Do regulators accept that the data can only be applied to these people or insist that it has to work for everyone in the world but will be statistically less accurate?



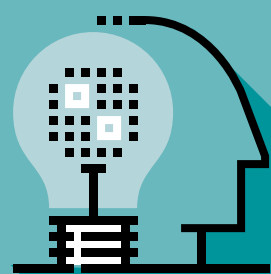
# WHAT IS AI?

## ARTIFICIAL INTELLIGENCE AT A GLANCE



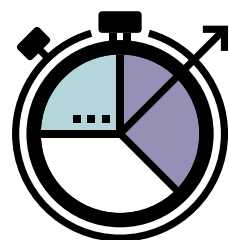
### DEFINITION

AI is the simulation of human intelligence processes through algorithms built into a dynamic data-driven environment.



### BENEFITS

AI is capable of doing very precise jobs very fast, which generates huge time and cost savings.



### ACTION

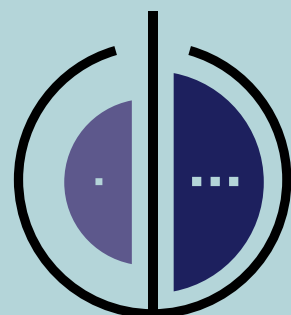
AI uses machine learning to analyse this data in real time at a speed and volume no human ever could.



### TYPES OF AI

There are two broad categories of artificial intelligence :

**Narrow AI** carries out specific tasks and is what we see around us in computers today.



**General AI** aims to create cognitive capacities and likely won't exist in our lifetime.

### IN CHARGE

ISO/IEC JTC 1/SC 42, *Artificial intelligence*, has already published 3 standards relating to big data and has 13 other projects in development.



### UN SDG 9

AI contributes to Sustainable Development Goal 9 on industry, innovation and infrastructure.



“Look at organ transplants. AI could potentially have access to all available medical records across the world and apply an enormous range of measures to determine which person gets to the top of the list, ensuring less rejection of transplanted organs and much better medical outcomes. However, if you are on a transplant list and realize that other people are receiving organs ahead of you, are you willing to accept the data used to make that decision?”

Trustworthiness is vital. The committee and researchers in the field need to look at how other fields such as medical and automotive apply measures and earn this trust by government and wider society.

Emerging machine learning is starting to look at the more pressing needs of the developing world, according to Wo Chang. “In Africa, access to energy is a big problem in rural areas. With a large uptake of smartphones there, apps are being developed that can diagnose basic medical problems in remote clinics, provide preliminary data such as weather forecasts, soil quality and agricultural tips.”

### Fears and phobias

Despite these advances, much of the general public fears AI as a scary development, imagining robots becoming Schwarzenegger-like “terminators” replacing human beings. “This won't happen in my lifetime,” Ray Walshe says. “Don't get me wrong, AI is a game changer and is capable of doing very precise jobs very fast. This is impressive and generates huge cost savings, but it's known as 'narrow intelligence'. The human brain is capable of doing that 'narrow' task but also thousands of other 'broader' and more complex tasks.” Robotics is one of the most exciting areas for AI development, but the myth that machines will be capable of artificial general intelligence like “Terminator” will not happen in the foreseeable future.

“AI is still more of a promise than an achieved feat,” agrees Dr Besold. “The research side is progressing faster than the application side. Robotic arms in factories can only do what they are programmed for and there's no 'intelligence' in this. If a change is needed, such as working on the other side of the car, it requires a change in programming that involves a human being.”

Dr Besold says that AI developers need to engage more with society to provide transparency, and Chang sees that standards developed by the committee to address system robustness, data quality and boundaries will increase trust and the ability to interact with a variety of data repositories.

Emerging machine learning is starting to look at the more pressing needs of the developing world.







For more information on subcommittee SC 42, *Artificial intelligence*, visit [www.iso.org/committee/6794475.html](http://www.iso.org/committee/6794475.html).

All three committee members see jobs changing rather than disappearing. AI will perform more manual work and routine tasks such as standard contracts and documents, giving people more time to concentrate on skills involving empathy, “bedside manner” in medical treatment, ethical matters and lateral thinking. Opportunities for re-education and to work on more challenging and interesting situations will arise.

“How ironic if increased use of AI in workplaces resulted in reviving union movements,” Dr Besold says. “If you’re at a school or hospital, then using AI for logistics or declarative knowledge such as facts, dates and figures may result in less staff time per week. Do governments and employers fire some staff or do they negotiate a shorter

work week for a more balanced life? This is where consensus is needed: what’s the biggest benefit to society?”

### **New horizons**

Future trends and benefits for AI will see more hands-free applications according to Wo Chang. “Wearing smart glasses will enable users to look at something like a broken washing machine and get information on what is wrong, where the problem is located and how to fix it. For tourism, you’ll be able to look at a building and find out the history, function and services it still provides while you are standing in front of it.”

Smart glasses aside, Chang has loftier hopes. “When government and businesses keep

The research side is progressing faster than the application side.

their citizens and customers at the forefront and learn how to leverage the best of AI and their people, it will be a bright future indeed.”

Ray Walshe has a personal interest in seeing how AI can be used to help in reaching the objectives outlined in the United Nations Sustainable Development Goals, a universal call to action to ensure peace and prosperity for mankind. “How can AI be used to help alleviate poverty worldwide, hunger and malnutrition, for better water and sanitation, equal opportunities in education, work and gender, and to accelerate development in developing nations? These are major challenges that require disruptive and game-changing technologies and expert collaboration on a global scale.”

We need to do more than put cat ears on friends’ social media selfies, Dr Besold says. “My hope for the future is that actual applications of AI will result in more effort being put into logistics that help in the field of medicine, agriculture, climate change and scientific discovery – important applications that will benefit society.”

Seems like the ISO/IEC JTC 1/SC 42 subcommittee for artificial intelligence will be busy. ■



Can artificial intelligence make the world a better place?

# WHAT AI CAN DO FOR YOU

TRANSPORTATION



SMART WEATHER FORECASTING



DISASTER RESPONSE



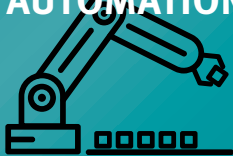
FARMING



SMART HOMES



ENHANCED AUTOMATION



HEALTHCARE



SMART CITIES



STRENGTHENED ECONOMY





# Debunking the myths of AI

Artificial intelligence is the science of building computers that can solve problems the way humans do. But there is more to it than that. *ISOfocus* sat down with Wael William Diab, Chair of ISO/IEC JTC 1/SC 42 to find out what the new technology is really about.

Artificial intelligence (AI) is the new buzzword in today's world. Some AI-based services are relatively minor such as film recommendations on a Netflix-like platform. Others, however, have expanded into areas with far greater human impact like healthcare, smart mobility or enhanced automation. Artificial intelligence is the simulation of human intelligence processes through the creation of algorithms built into a dynamic computing and data-driven environment. In simple terms, AI is trying to make computers think and act like humans.

Although people tend to think of AI as autonomous systems, in practice, it is an umbrella term for a collection of technologies that are enabling a form of intelligence in machines. This includes machine-learning and analytical capabilities that mimic the brain's ability to recognize patterns in data and learn. AI makes it possible to identify patterns and detect anomalies in the data that smart sensors and devices generate to make accurate predictions. For enterprises, this means a reduction in unplanned downtime, increased operating efficiency, enhanced risk management, as well as the development of new products and services. In short, AI represents an entire "ecosystem", from collecting and sourcing data to deriving insights and implementing actions.

Created under the auspices of ISO/IEC JTC 1, the information technology arm of ISO and the International Electrotechnical Commission (IEC), subcommittee SC 42, *Artificial intelligence*, is the only standards body looking at AI holistically. *ISOfocus* asked Wael William Diab, Chair of SC 42, to tell us more about the game-changing technology and what it can do for us.

Photo : Alex Knight/Unsplash





A robot-equipped ambulance brings relief to patients on their way to hospital.

Wael William Diab, Chair of ISO/IEC JTC 1/SC 42, Artificial intelligence.

**ISOfocus : How widespread is artificial intelligence becoming? How is AI today different than it was three decades ago?**

**Wael William Diab:** Traditionally, AI had been focused on large-scale problems that were either too complex to solve with traditional compute methods or occurred in specialized emerging areas. This is no longer the case. Today, AI is enabling the digital transformation that will have a revolutionary impact on how we live, work and play. The IDC, premier global provider of IT market intelligence, estimates that by 2019, 40 % of digital transformation initiatives will be using AI services, and by 2021, 75 % of enterprise applications will use AI.

Of note is that AI is not a single technology, but a collection of hardware and software technologies and broad application domains. Stakeholders are numerous and

diverse, bringing a holistic approach to the deployment of AI systems, driven by a business angle centred on customer needs, segments, services, products and regulatory requirements, and other non-business interests including the well-being of individuals and society at large. This is a complete turnaround from what used to be a specialized and research-driven area to one that is set for wide adoption.

**What are common uses and/or applications for AI?**

Within our lifetimes, AI will become a ubiquitous technology with endless applications across virtually every vertical. Examples include :

- AI expert systems that help healthcare professionals make better decisions for patients, with proper trustworthiness measures designed into the system

In simple terms,  
AI is trying to make  
computers think and  
act like humans.

- AI deployment in smart manufacturing where it drives higher efficiencies by allowing robots to work alongside humans with the proper safety measures designed into the system
- AI deployment in the financial ecosystem, enabling applications that range from asset management, which takes into account factors such as the client’s risk, to fraud detection that reduces false positives
- Emerging applications in the area of consumers, retail, digital assistants and expert systems such as smart grids, marketing intelligence tools, intelligent transportation systems, robotics and enterprise, to name a few

By using techniques like machine learning, big data, analytics and edge intelligence, AI systems provide “insights” into the application that would not be attainable otherwise. While the level of automation may vary across deployments, these insights are at the core of AI intelligence.

**Why was ISO/IEC JTC 1/SC 42 created? What need/void was it expected to fill?**

While AI is not a new discipline, the rapid advancement in technology capability, coupled with demands for transformative services supported by the digitalization of applications, has emphasized the need for enabling technologies like AI and big data. This requires looking at the entire environment in which these technologies will be deployed, including its integration with operational technologies (OT), and addressing challenges with the technology from the onset.

This ecosystem approach allows us to build frameworks and horizontal deliverables that link non-technical requirements to the technical standardization. Prior to SC 42, this was both needed and absent. Finally, as technologies such as AI become more universal, there is a need to connect the non-technical requirements to interoperability standards, open-source implementations and proprietary innovations. Top of mind are regulatory aspects, societal or business requirements, issues with trustworthiness, ethics, governance, security, privacy, transparency and controllability.

Tasked with providing guidance to application areas of AI, SC 42 has been building an ecosystem through liaisons with application committees, technically complementary organizations and a variety of communities. The net result has been to act quickly to provide International Standards that remove barriers to adoption while proactively addressing technology concerns with AI from the onset through an inclusive consensus process that pools a diversity of opinions and stakeholders.



**How important are International Standards for AI? What are the benefits of the standards ISO/IEC JTC 1/SC 42 is developing – to industry, to consumers, to society as a whole?**

The importance of International Standards cannot be overstated. While we may not always be conscious or appreciative of them, they are routinely present in our everyday lives, supporting innovations that we have come to expect and rely on. For example, JTC 1 is responsible for JPEG/MPEG standardization on image compression formats, which is one of the foundations of our modern-day digital lives.

In a world that is rapidly being reshaped by the promise of digital transformation, we are seeing a convergence of IT and operational technology (OT). It is therefore no surprise that the users and producers of such technology have come to expect harmonization across geographies. International standardization, such as that carried out by ISO, does exactly that. Without it, not only would adoption of transformative technologies be stifled, but innovation and requirements would suffer from a lack of broad input. The market and stakeholders have weighed in that technologies such as AI are here for the long term, and ISO has recognized this through SC 42.



**By 2019, 40 %  
of digital  
transformation  
initiatives  
will be using  
AI services.**



**What does the current SC 42 programme look like? What are some of the future challenges? What would you recommend to those interested or skeptical of AI standards development?**

SC 42 has transformed its ecosystem approach into a comprehensive work programme that looks at AI and big data through key areas including technical, business, societal and ethical considerations. For example, use cases from different vertical application domains allow the distillation of technical requirements that will form the basis of future standards projects. These in turn serve to provide guidance to other ISO and IEC committees looking at AI applications. Our deliverables take a horizontal view that enables wide-scale adoption of AI across verticals while, at the same time, addressing the requirements, concerns and challenges of its deployment.

The expectations for AI and big data are many and varied, but the path SC 42 is on, while not devoid of obstacles, will in my opinion be successful in achieving them. Nonetheless, the challenge remains to bring in both supporting and dissenting opinions, all the while evolving our work programme to accommodate those diverging views. That's why we welcome your participation and contribution to SC 42, whatever perspective you come from, to help develop a comprehensive programme around AI and big data standardization. I hope this article inspires you to follow our work, and perhaps even join our committee, as we embark on this exciting journey. The best is yet to come! ■

The importance  
of International Standards  
cannot be overstated.



# The AI and big data ecosystems

As the focal point for standardization on artificial intelligence (AI), ISO/IEC JTC 1/SC 42 is producing a series of standards and best practices for the use of AI on an international scale. The subcommittee is broken down into five working groups (WG), each with a specific goal.

## FOUNDATIONAL STANDARDS (SC 42/WG 1)

This working group is developing standards that provide a **framework for AI**, using machine learning and a common terminology for AI concepts to ensure that all users, producers, innovators and regulators involved in artificial intelligence are using the same language. The group's projects are also looking at the standards for AI life cycle.

## GOVERNANCE OF AI (SC 42/JWG\* 1)

Working in collaboration with ISO/IEC JTC 1/SC 40, which specializes in IT governance issues, this working group will **identify key questions and their answers for organization boards and executives looking to deploy AI**. While SC 42 has the lead on administering this project, the equal partnership brings in experts from the AI and IT governance world.

\* Joint working group

## BIG DATA (SC 42/WG 2)

This sector has garnered a lot of interest from industry. The revolutionary idea is to **focus on data characteristics** rather than the compute system in isolation as this may be a better predictor of computational systems and their ecosystem. **The working group is focusing on horizontal projects such as overview and vocabulary as well as big data reference architecture**. In addition, it has initiated work looking at the business process management for big data analytics.

## TRUSTWORTHINESS (SC 42/WG 3)

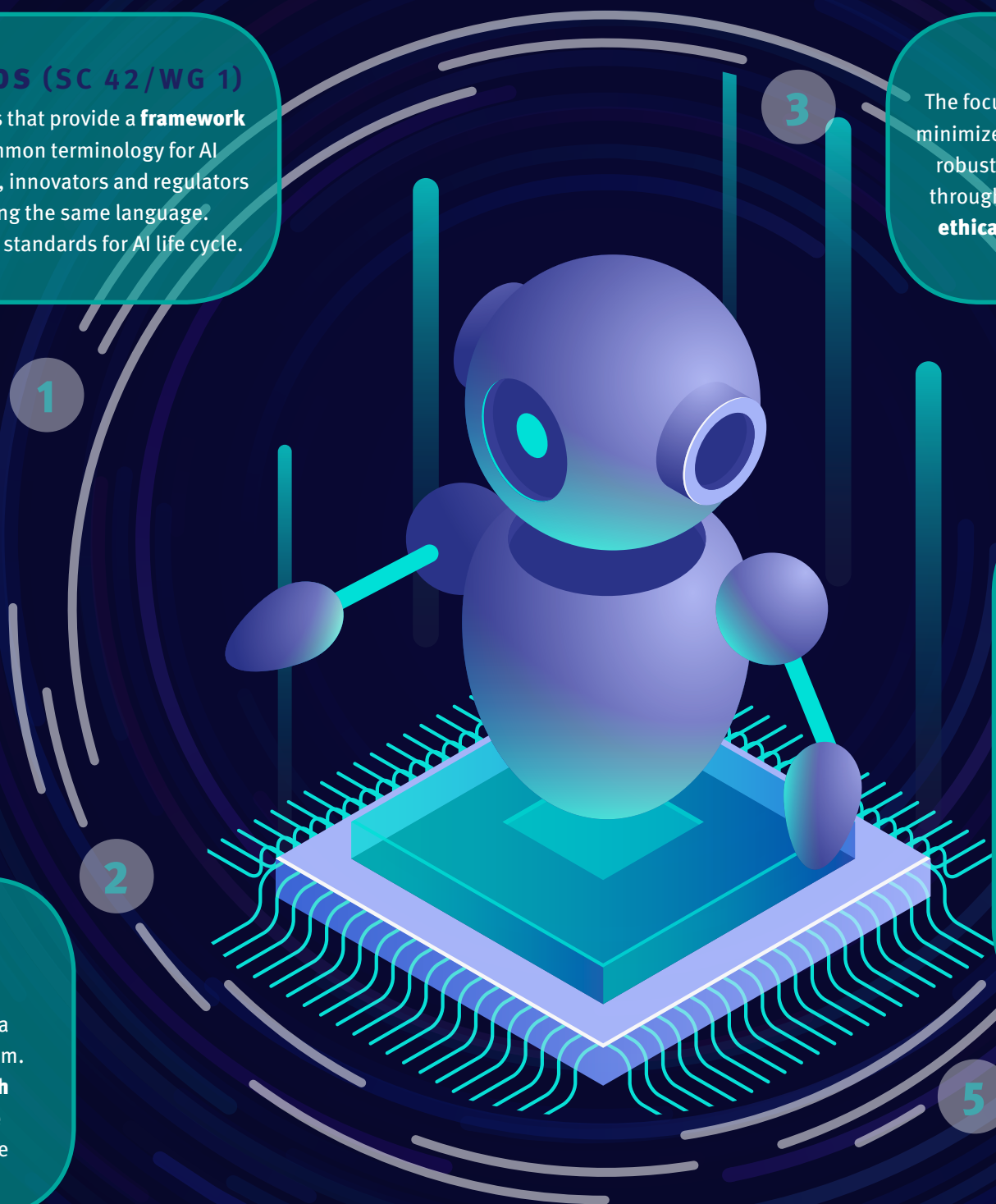
The focus is on **exploring ways to establish trust in AI systems** while assessing methods to minimize threats and risks. This includes identifying issues such as the transparency, bias and robustness of AI systems and investigating how these issues can be addressed technically through risk assessment standards. This working group is also **collecting requirements for ethical and societal considerations for AI systems** and mapping them to the trustworthy solutions being developed.

## USE CASES AND APPLICATIONS (SC 42/WG 4)

Tasked with collecting use cases from across vertical domains and providing guidance to application areas, this working group not only **designs the questions and interprets the data to understand what a requirement means** from a technical perspective, it also works to **enable AI in emerging applications that are at the backbone of the digital transformation**.

## COMPUTATIONAL APPROACHES AND CHARACTERISTICS (SC 42/WG 5)

Learning models and computational techniques are at the heart of AI systems. This working group is **looking at different technologies, such as machine-learning algorithms and specialized AI systems, to understand their underlying architecture and characteristics**. It will also study current industry processes to help define the best practices that will become standardized.







# HOW TO UNLOCK *the AI promise*

by Robert Bartram

Artificial intelligence (AI) technologies and their applications continue to grow and evolve. AI technologies are now being deployed across almost every industry and sector, including transportation, healthcare, defence, finance and manufacturing. But what exactly are these technologies? How prevalent are they? And with AI developing so rapidly, how will International Standards respond to these challenges?

Given that AI data is at the intersection of many different fields, it is hugely important that a common framework is developed.

As artificial intelligence (AI) becomes increasingly ubiquitous in various industry sectors, establishing a common terminology for AI and examining its various applications is more important than ever. In the international standardization arena, much work is being undertaken by ISO/IEC's joint technical committee JTC 1<sup>1)</sup>, *Information technology*, subcommittee SC 42, *Artificial intelligence*, to establish a precise and workable definition of AI. Through its working group WG 4, SC 42 is looking at various use cases and applications. The Convenor of SC 42/WG 4 is Dr Fumihiro Maruyama, Senior Expert on AI at Fujitsu Laboratories.

Currently, there are a total of 70 use cases that the working group is examining. Health, for example, is a fascinating area to explore. Dr Maruyama himself describes one use case in which a program undertakes a “knowledge graph” of ten billion pieces of information from existing research papers and databases in the medical field. The application then attempts to form a path representing the likely development from a given gene mutation to the disease that deep learning has predicted from the mutation.

1) ISO/IEC JTC 1 is the joint technical committee formed by ISO and its sister organization, the International Electrotechnical Commission (IEC), to serve as a focal point of standardization in information technology.



It is precisely because  
AI technologies are  
developing so quickly  
that International Standards  
are so needed.



### Solutions for health

Dr Radouane Oudrhiri is Chief Data Scientist at Eagle Genomics, whose work involves research undertaken “in silico” – that is, using primarily computer or data-driven innovation. One area of focus is on microbiome, which comprises all of the genetic material of micro-organisms (bacteria, viruses and fungi) within an entire collection, such as the human gut, mouth or skin. Microbiomes aren’t just limited to humans and other animals: oceans, soils and rivers all host microbiome communities that impact entire ecosystems. Microbiome data is very complex as it is hyper-dimensional and compositional. Dr Oudrhiri’s colleagues analyse microbiome data using AI and machine-learning computational tools for spotting associations that humans simply cannot. This radically improves productivity and enables revolutionary discoveries. It identifies new, sustainable ingredients and therapeutic targets and informs safer, more efficient industry practices.

AI technologies have been used to analyse human tumours for some time now, but as Prof. Frank Rudzicz, the Canada representative for SC 42, Director of AI at Surgical Safety Technologies Inc., and Associate Professor of Computer Science at the University of Toronto, points out in an interview for this article, this is just one application of several. For instance, an application has been deployed recently to identify early-onset dementia in more elderly patients. Residents at care facilities, normally assessed by a doctor once every six months for 15 minutes, have instead been issued with a computer tablet and asked to respond verbally to a series of questions. The program then alerts the medical team if anything seems awry, such as a change in the patient’s voice patterns, or if they seem unable to spot obvious relationships in an image of a family group.

Dr Oudrhiri has also been working with a company that has developed an AI solution, initially designed to make shoes smarter by collecting biomechanical metrics, measuring



aspects such as shoe usage and sporting performance. It works via a chip inserted into the sole. The application has been so successful that advances in technology will soon allow it to be used for the detection of the likelihood of developing diseases – such as Parkinson’s – just by analysing the way in which an individual walks.

### The AI of everything

Health, of course, is not the only field that the work of SC 42 will impact. Dr Maruyama also cites the example of an AI program that uses ultrasonic waves for inspecting wind turbines. The program flags up any portions of the turbines that may have defects, clearing the way for its human inspection experts to make an informed choice about any subsequent course of action. Crucially,

as the program is undertaking the initial inspection, time is freed up for human experts to inspect more turbines.

Intelligent transportation systems (ITS) is another sector that already relies heavily on AI. Dr Mahmood Hikmet, Head of Research and Development at Ohmio Automotion, a company that focuses on ITS, points to lidar technology, which measures distance to an object by the use of laser light rather than sound or radio frequency. If several of these laser lights are stacked on top of one another and spun round at top speed, the result is a three-dimensional “point cloud” showing how far away a given object might be. All of this takes place at “tens or hundreds of times a second”. It’s an application that can be used in driverless cars, with the capability even to distinguish between different blades of grass.



Dr Hikmet also highlights crowd-counting AI for driverless cars, a predictive analysis application drawn from data on the infrastructure side of ITS (as opposed to the cars themselves). This involves cameras that monitor people walking back and forth, tracking them throughout an entire shot, whilst predicting their likely “route” as they interact with others. This data is then picked up by the car and used to prevent any possible collisions.

### Behaviour training for machine learning

YOLO – You Only Look Once – is object-recognition technology that separates to the tiniest degree the different aspects of disparate objects. It has obvious applications in safety and security contexts. Behavioural cloning is another field of AI, in which a machine is obliged to learn a series of tasks through reinforcement training. It’s “a way of punishing and rewarding a neural network for doing things right or wrong,” Dr Hikmet explains. The network ends up learning from the reward or punishment signals it receives from the human user as to how it is supposed to “behave”.

Health, for example,  
is a fascinating area  
to explore.



Venture capital is key to certain aspects of Dr Oudrhiri’s work. One exciting area of research seeks to digitize and systematize nothing less than “the entire entrepreneurship process”. By gathering data throughout the venture life cycle, identifying innovation challenges and categorizing information, the platform provides predictive models on a company’s performance, growth potential and valuation. A risk profile is therefore established, assisting in the selection process and the entire start-up evolution. Until now, information of this kind has been collected through human responses to surveys. These are more aggregate in nature, do not lend themselves to easily-built predictive models, or often lead to unwittingly biased conclusions. After all, it is only natural that company owners will want their projects to succeed.

These examples are as ingenious as they are effective. And yet the vast majority of us are unlikely to have heard of these specific AI technologies, still less to have an awareness of their impact. Current AI solutions are often developed in silos and built for very specialized applications; their true power will be properly realized when they are considered in a holistic framework, such as the horizontal frameworks SC 42 is developing.

### A role for standards

For this and other reasons, International Standards are now under development. Dr Oudrhiri suggests that standards are needed to “cut through the hype” so that fears and objections to AI can be either taken on board or simply rebutted as groundless. Radical ideas for AI applications are often promoted with great fanfare in the media and other public forums – for better or worse – yet, as Dr Maruyama points out, many, if not most of these ideas never get past the Proof of Concept (PoC) phase.

Consumers do need to be protected – from physical harm, certainly, but also from companies that use the phrase “artificial intelligence” as a way of promoting a product simply to spike its share price. And given that AI data is at the intersection of many different fields – software engineering, neuroscience, decision making – it is hugely important that a common framework is developed, so that consumers, producers and regulators can speak a common language.

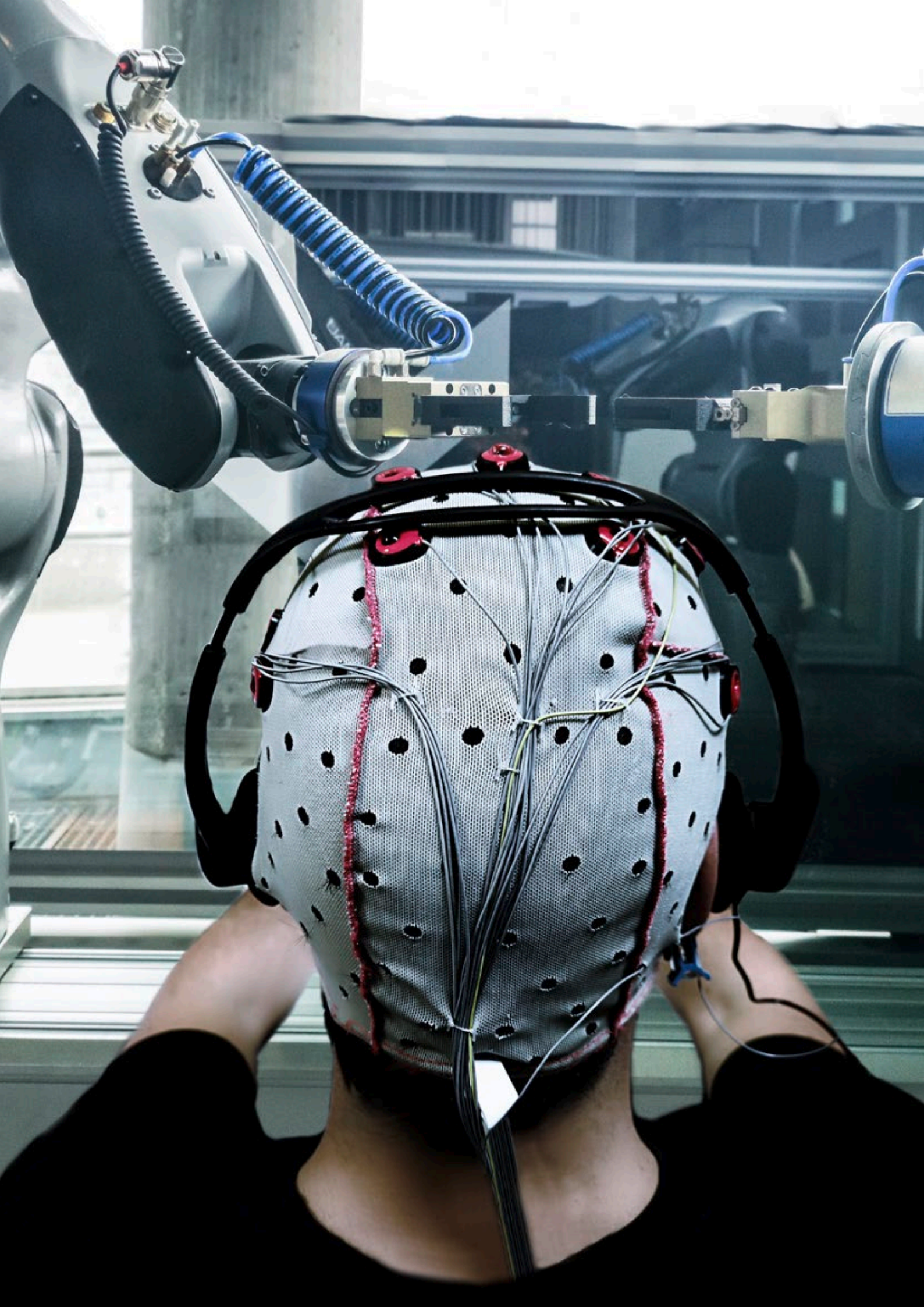
This is not as ridiculous or unlikely as it first sounds. Experts talk of “AI winters” in which previous generations of AI technology peaked, only to fall away because of misplaced experimentation and consequent withdrawal of funding. The same could possibly happen again and undo much of the progress in today’s world.

### State of the practice

It is precisely because AI technologies are developing so quickly that International Standards are so needed. In the words of Dr Oudrhiri, they should focus on the “state of the practice, not the art”. SC 42 has already produced draft technical reports, with standards under development. The subcommittee is working with technical committee ISO/TC 69, *Applications of statistical methods*, on mapping both terminologies and concepts within the machine-learning world, between statistics, software engineering, AI, data science, and operational research. An entire working group – SC 42/WG 3 – is looking solely at trustworthiness.

Dr Maruyama believes the best approach to developing International Standards is to converge around a limited number of alternatives, and to “focus on where technology is already stable”. A common language and criteria are being created to get beyond the PoC stage. Another area of focus is describing the process and life cycle for developing AI applications. They will also help capture the broad requirements of consumer needs, which must include the ethical and societal considerations in use cases and applications. A third area focuses on model validation. This is highly technical and statistical in nature, but will one day ensure that programs and machines will do what they are supposed to be doing. ■





# It's all about trust

*by Clare Naden*

Artificial intelligence (AI) has the potential to aid progress in everything from the medical sphere to saving our planet, yet as the technology becomes ever more complex, questions of trust arise. Increased regulation has helped to rebuild this trust, but grey areas remain. How can we ensure AI is trustworthy without impeding its progress?

Using our personal data without authorization to spam us with products to buy is one thing, but quite another is when it is used in an attempt to manipulate politics. This was best demonstrated in the Cambridge Analytica affair, where millions of Facebook profiles of US voters were harvested to build a software system that could target them

with personalized political advertising. The dangers of this were well recognized by the US consumer regulator that slammed Facebook with a USD 5 billion fine, but the trust in how organizations use our data was rattled, to say the least. The scandal also exposed the power, and dangers, of badly used artificial intelligence (AI).



Malicious use,  
personal data leaks  
and cybersecurity  
are key threats to  
our trustworthiness.

But AI is here to stay. Used well, it can help to improve our lives and solve some of the world's toughest issues. It enables humans and machines to work collaboratively, with the potential to enhance the capabilities of humans and technology beyond what we can even imagine. For organizations, this can mean increased productivity, reduced costs, improved speed to market and better customer relations, amongst other things. This is reflected in a Forbes Insights survey titled "On Your Marks: Business Leaders Prepare For Arms Race In Artificial Intelligence", which revealed that 99% of executives in technical positions said their organizations were going to increase AI spending in the coming year.

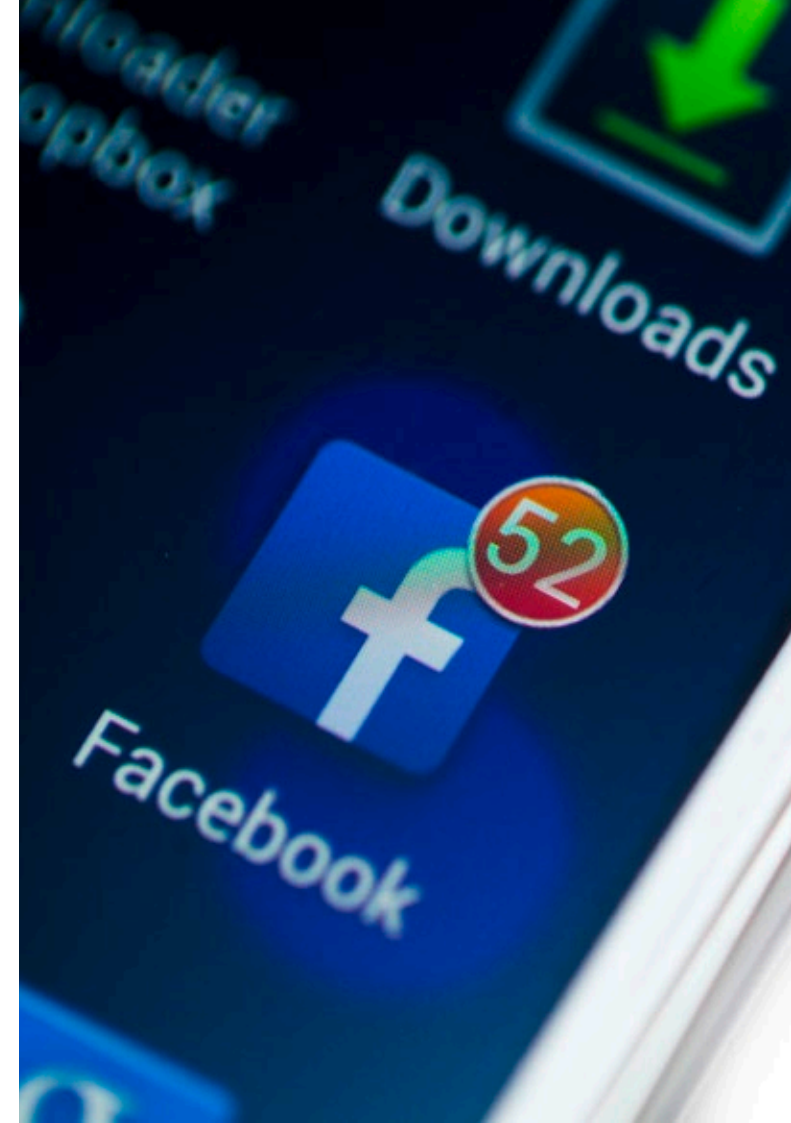
The technology is developing at lightning speed, raising as many questions about safety and security as the benefits it promises to deliver. If the point is to outperform humans on decisions and estimations such as predicting disease outbreaks or steering trains, how can we be sure we have control?

### In AI we trust?

Leading industry experts believe that ensuring trustworthiness from the outset is one of the essential aspects to widespread adoption of this technology. With this in mind, ISO and the International Electrotechnical Commission (IEC) set up joint technical committee ISO/IEC JTC 1, *Information technology*, subcommittee SC 42, *Artificial intelligence*, to serve as a focal point for AI standardization. Among its many mandates, the group of experts is investigating different approaches to establish trust in AI systems.

Convenor of the trustworthiness working group within SC 42, Dr David Filip, research fellow at the ADAPT Centre in Trinity College Dublin, a dynamic research institute for digital technology, sums it up: "When software began 'eating the world', trustworthiness of software started coming to the forefront. Now that AI is eating the software, it is no big surprise that AI needs to be trustworthy."

"However," he analyses, "my impression is that people fear AI for the wrong reasons. They fear doomsday caused by some malicious artificial entity... A far bigger issue,



**The US consumer regulator slammed Facebook with a USD 5 billion fine.**

I feel, is that the lack of transparency will allow a deep-learning system to make a decision that should be checked by a human but isn't."

Naturally, the level of harm depends on the way in which AI is used. A poorly designed tool that recommends music or restaurants to users will obviously cause less harm than an algorithm that helps to diagnose cancer. There is also the danger of using data to manipulate outcomes, such as in the Cambridge Analytica case.

### Threats to trustworthiness

According to the Organisation for Economic Co-operation and Development (OECD), a collaborative international government body dedicated to furthering economic progress and world trade, malicious use of AI is expected to increase as it becomes less expensive and more accessible<sup>1)</sup>. Malicious use, personal data leaks and cybersecurity are key threats to our trustworthiness.

A self-driving car, for example, that is involved in an accident could be hacked and information related to liability meddled with. A system that aggregates patient data and uses it to recommend treatments or make diagnoses could suffer errors or bugs that result in disastrous outcomes.

1) OECD, *Artificial intelligence in society*. Paris: OECD Publishing, 2019.





Other risks include the effects of data or algorithmic bias, a phenomenon that occurs when an algorithm produces results that are systematically compromised due to erroneous assumptions in the machine-learning process. When influenced by racist, prejudiced or other subjective behaviour, this can have a profound influence on everything, from what you see in your social media feed to the profiling of criminals in policy systems, or the processing of immigration claims.

AI systems that require access to personal information also pose risks to privacy. In healthcare, for example, AI has the potential to help advance new treatments by using patient data and medical records in certain ways. But this creates the possibility that data will be misused. Privacy laws reduce that risk but also limit the technology. It is clear that if AI systems are robust, secure and transparent, the eventuality of this happening is

removed and their potential can flourish so we can fully reap the benefits.

### What is being done

The industry is very aware of the need for trustworthiness and many technologies have been developed, and are steadily evolving, such as differential privacy, which introduces bits of randomness into aggregated data in order to reduce the risk of re-identification and preserve the contributions of individual users. Other examples include cryptographic tools such as homomorphic encryption and multiparty computation, which allows machine-learning algorithms to analyse data that is still encrypted, and thus secure. Or using a trusted execution environment, which is a technology to protect and verify the execution of legitimate software.

Standards  
for AI should  
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language.

The European Union (EU) formed a High-Level Expert Group on Artificial Intelligence (AI HLEG) to support the implementation of Europe's strategy on artificial intelligence, which includes ethical, legal and social dimensions. Earlier this year, it published Policy and Investment Recommendations for Trustworthy Artificial Intelligence that set out the group's vision for a regulatory and financial framework for trustworthy AI.

On an international scale, the Partnership on AI to Benefit People and Society is dedicated to advancing the public understanding of AI and formulating best practices for future technologies. Bringing together diverse global voices, it works to "address such areas as fairness and inclusivity, explanation and transparency, security and privacy, values and ethics, collaboration between people and AI systems, interoperability of systems, and of the trustworthiness, reliability, containment, safety and robustness of the technology", thus providing support opportunities for AI researchers and other key stakeholders.

"We are a co-founder of the Partnership on AI," says Olivier Colas, Senior Director International Standards at Microsoft, who also plays an active role in SC 42, "and we've forged industry partnerships with both Amazon and Facebook to make AI more accessible to everyone." He asserts that "as AI systems become more mainstream, we as a society have a shared responsibility to create trusted AI systems and need to work together to reach a consensus about what principles and values should govern AI development and use. The engineering practices that can be codified in International Standards should support these principles and values". Microsoft, he says, has set up an internal advisory committee to help ensure its products adhere to these principles and takes part in industry-wide discussions on international standardization.

### The standards factor

Standards, then, are the key. Dr Filip explains why: "We can never guarantee user trust, but with standardization we can analyse all the aspects of trustworthiness, such as transparency, robustness, resilience, privacy, security and so on, and recommend best practices that make AI systems behave in the intended and beneficial way."

Standards help build partnerships between industry and policy makers by fostering a common language and solutions that resolve both regulatory privacy issues and the technology required to support that, without stifling innovation. Colas believes standards will play an important role in coding engineering best practice to support how AI is being developed and used. They will also complement emerging policies, laws and regulations around AI.







“International Standards have been successfully used to codify risk assessment and risk management for decades. The ISO/IEC 27000 series on information security management is a great example of such an approach for cybersecurity and privacy,” he says. It helps organizations manage the security of their assets, such as financial information, intellectual property, employee details or information entrusted by third parties. “What’s more, AI is a complex technology,” observes Colas. “Standards for AI should provide tools for transparency and a common language ; then they can define the risks, with ways to manage them.”

### The time is now

The ISO/IEC JTC 1/SC 42 work programme outlines several topics for AI, many of which are currently under development in its working group WG 3, *Trustworthiness*. Projects include a number of normative documents directly aimed at helping stakeholders in the AI industry build trust into

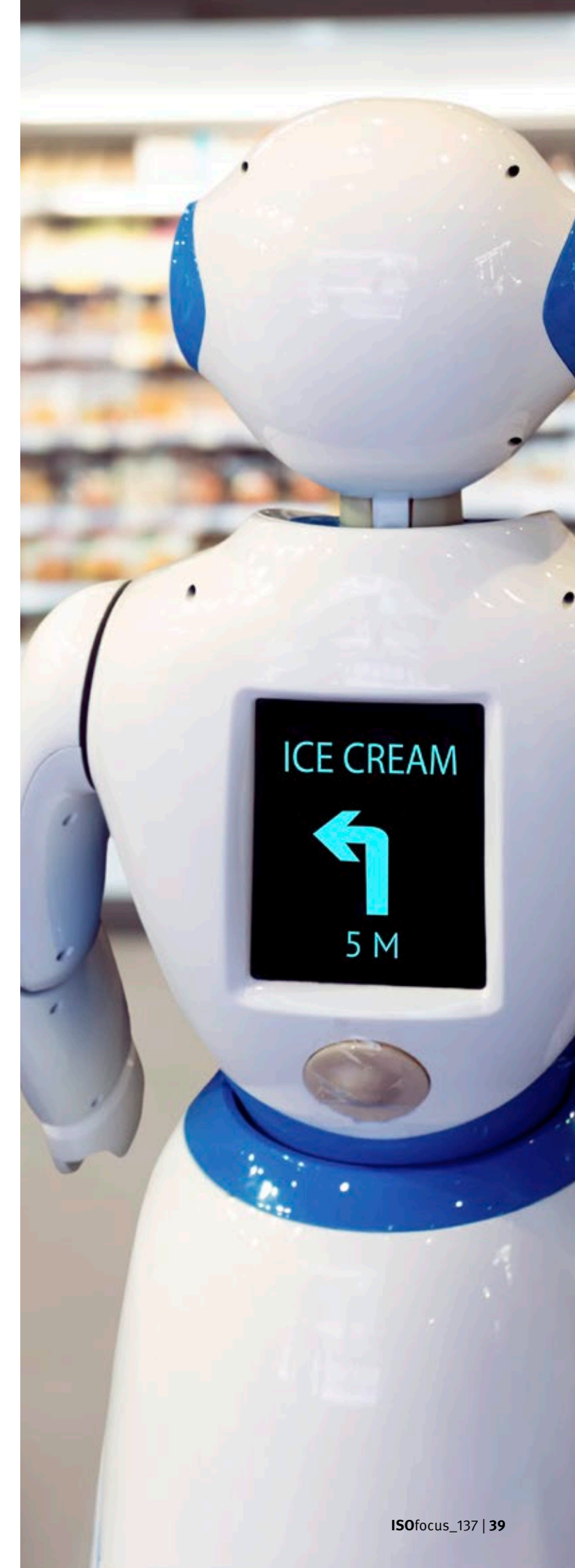
their systems. One example is future technical report ISO/IEC TR 24028, *Information technology – Artificial intelligence (AI) – Overview of trustworthiness in artificial intelligence*, which analyses the factors that may contribute to the erosion of trust in AI systems and details possible ways of improving it. The document covers all stakeholders and AI vulnerabilities such as threats to security, privacy, unpredictability, system hardware faults and much more.

SC 42 takes a horizontal approach by working closely with as many people as possible across industry, government and related technical committees, so as to build on what already exists rather than duplicating it. This includes ISO/TC 262, *Risk management*, whose standard ISO 31000 on risk assessment serves as a basis for the development of ISO/IEC 23894, *Information technology – Artificial intelligence – Risk management*. The new guidelines will help organizations better assess typical risks and threats to their AI systems and effectively integrate risk management for AI into their processes.

Early consideration of trustworthiness in standardization is essential for ensuring the successful role of artificial intelligence in society.

The standard will be joined by other important technical reports on the assessment of the robustness of neural networks (ISO/IEC TR 24029-1) and the bias in AI systems and AI-aided decision making (ISO/IEC TR 24027). All of these will complement the future ISO/IEC TR 24368, designed to tackle the ethical and societal concerns thrown up by AI (see article [page 40](#)).

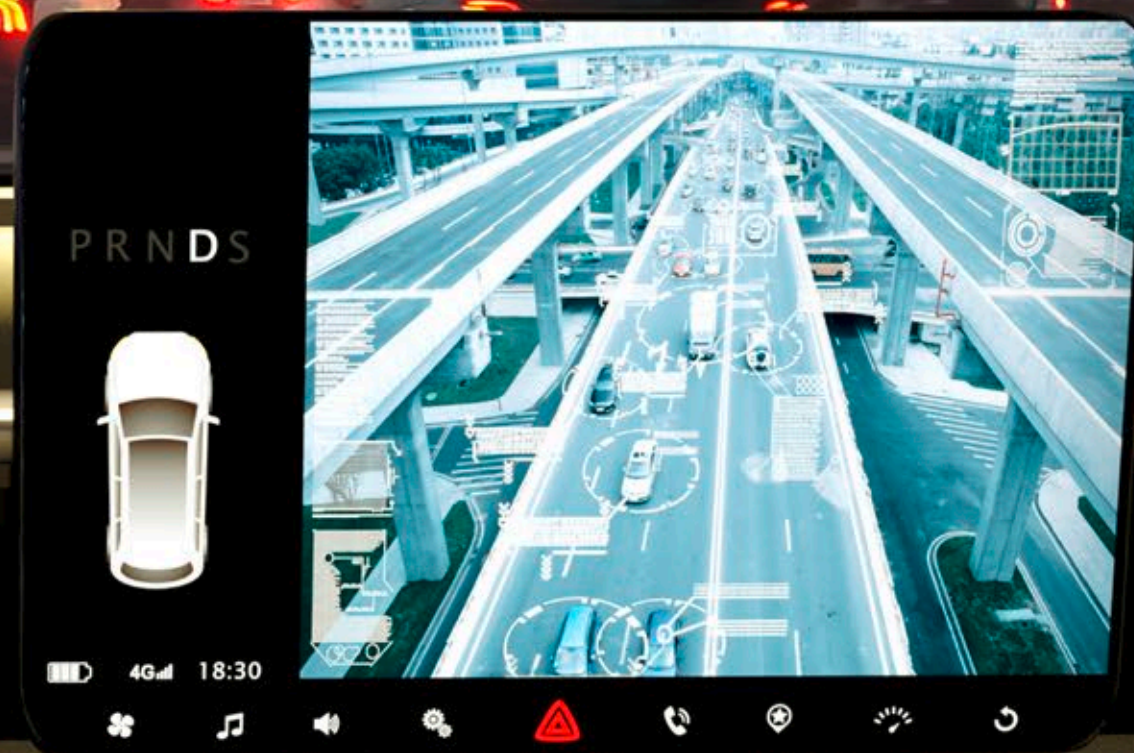
Early consideration of trustworthiness in standardization is essential for ensuring the successful role of artificial intelligence in society. “Humans need trust to survive in every sense,” remarks Dr Filip. This includes trust in technology and infrastructure to be safe and reliable. “We rely on our politicians to put laws and systems in place that protect us, and we rely on the good of humans around us to function in everyday society. Now, we need to be able to trust software and digital technology in all its forms. Standards provide us with a way of achieving that.” ■





# To ethicize or not to ethicize...

Ethical decision making isn't just another form of problem solving. As artificial intelligence (AI) grows in capability and influence, experts are treading uncharted territory to develop the International Standards for ethical AI, addressing its challenges from the onset.



**A**s algorithms become more sophisticated and autonomous, there is a risk that they begin to make important decisions on our behalf. The technology is already capable of automating decisions, such as medical diagnostics or smart manufacturing, that would normally be done by human beings. When it comes to artificial intelligence, automotive technology is ahead of the curve. Autonomous cars are a popular research domain in AI. Big names such as Google, Uber and Tesla have been investigating how to make cars learn to drive correctly using deep reinforcement learning, i.e. learning by trial and error. But self-learning machines are vulnerable to failure, bringing ethical considerations to the fore. This challenges the conventional conception of moral responsibility: Who is responsible? And who holds the key to best practice? In the absence of a global standard on AI, how do we bring more awareness about such issues? ISO and the International Electrotechnical Commission (IEC) have launched a range of work items through their joint technical subcommittee ISO/IEC JTC 1/SC 42, *Artificial intelligence*. Here, Mikael Hjalmarsen of SIS, ISO's member for Sweden, a leading expert in SC 42, explains how International Standards will help create an ethical foundation for building and using AI systems in the future.



**ISOfocus:** Techniques such as AI promise to be very transformative. Why are ethical and societal problems necessary considerations for AI?

**Mikael Hjalmarsen:** AI uses technologies that enable information to be collected and processed in new ways and more automatically. Nowadays, the capacity to handle a lot more data than in the past has increased – a potential that is prone to have ethical and societal consequences. It is when the data is managed in the hidden layers of an AI network, such as a neural or machine-learning implementation, that ethical and societal issues – which need not always be negative! – have to be considered. That is to say, the decisions and considerations that were previously handled outside the systems now have to be dealt with *within* the systems. It may also be that an AI application, no matter how

“self-learning” it is, has preconceived biases that were inadvertently added when we developed and built the system.

It is imperative that we understand the ethical and societal considerations of the technology so that we can develop trustworthy systems that include assurances of transparency, explainability, bias mitigation, traceability, and so forth, as these are key to accelerating AI adoption and acceptance in the future. International Standards could play a role in identifying these ethical issues and provide the necessary framework to address them.

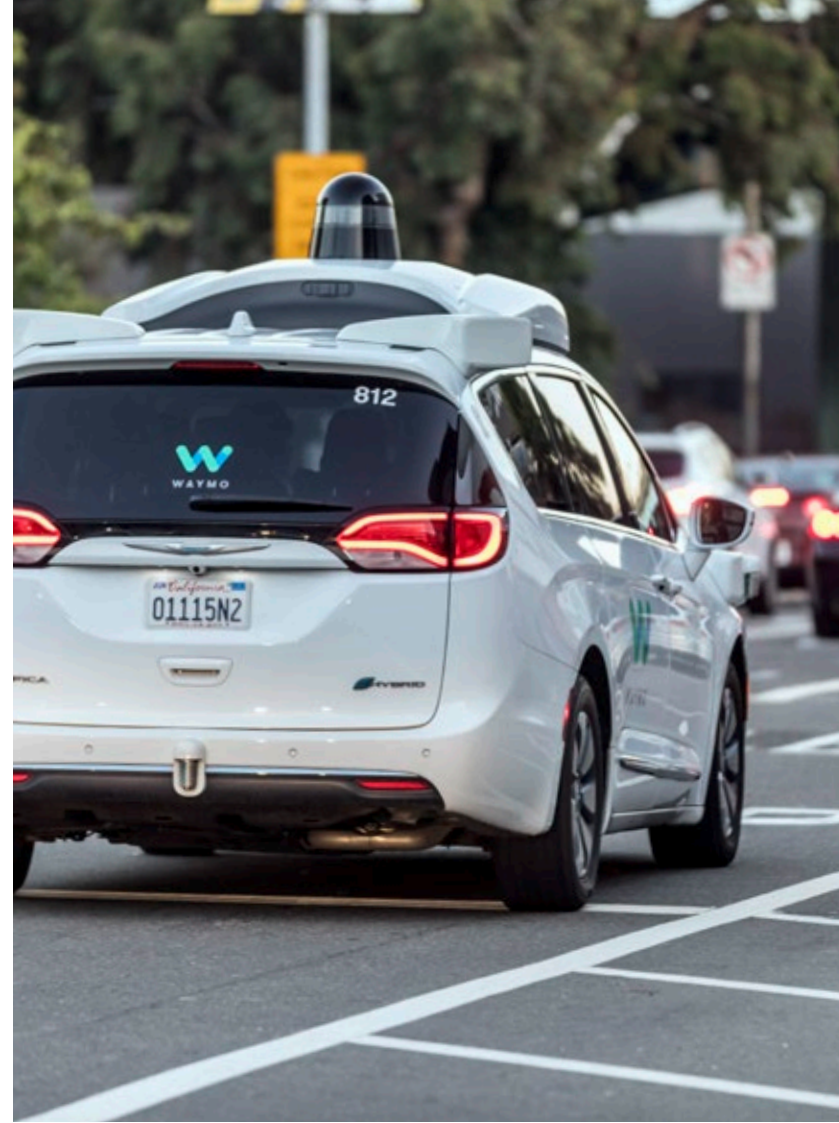
**What are the biggest challenges facing AI ethics and societal issues? What are some of the consensus areas?**

AI presents new and unique challenges to ethics. The main challenge is that systems leveraging AI can be implemented by many different users in



Photo: SIS

**Mikael Hjalmarsen** of SIS, ISO’s member for Sweden, is a leading expert in subcommittee ISO/IEC JTC 1/SC 42, Artificial intelligence.



Waymo began as the Google Self-Driving Car Project in 2009.



Robot helps keep Singapore’s Changi Airport spick and span.

International Standards could play a role in identifying these ethical issues and provide the necessary framework to address them.

different ways across various application verticals – from healthcare to mobility – with completely different requirements, and sometimes with market and regional differences as well. An AI technology becomes a “black box” that can answer questions... But can it tell you why one option is better than another? Can it provide alternatives? Then, there are the different policies, directives and environmental aspects to consider, for example those governing how data can and should be collected and used.

Another challenge is ensuring that aspects such as accountability, responsibility, trust, traceability and human values are handled equally (in the same way) so that they gain wide acceptance, even though we are not talking about creating value systems. An illustration of this might be that in one application domain it is permitted to capture and evaluate a given set of data while in another domain it is forbidden. For instance, a financial platform would be keen to avoid unintended bias rather than “AI eavesdropping” while healthcare would likely put the emphasis on transparency of the types of data captured. The system needs to be able to manage these differences.





AI presents new and  
unique challenges  
to ethics.

### What types of ethical and social standards is SC 42 working on?

SC 42's working group WG 3, *Trustworthiness*, is currently busy with a newly approved project. The idea is to collect and identify the ethical and societal considerations related to AI and link back to the trustworthiness projects we are working on. These efforts will culminate in a future technical report, ISO/IEC TR 24368, which aims to highlight the specifics of ethics and societal concerns in relation to other more generic ongoing projects on trustworthiness, risk management and bias, among others. The ethics and societal aspects are examined from an ecosystem point of view, which could lead to more work being carried out in SC 42 in the future, as well as provide guidance to other ISO and IEC technical committees developing standards for domain-specific applications that use AI.

### What are some of the regulatory issues in this area and how does SC 42 plan to overcome them? One of the challenges with ethical standards is that they are often voluntary, which means some AI technology creators may not follow them. Any thoughts?

ISO, IEC and JTC 1 develop voluntary consensus standards across the board, not just on ethics. Our concern right now is that the technology is changing faster than regulators can keep up. This results in a cat-and-mouse game between the increasing use of AI in various types of systems and environments and the development of rules and legislation to control it. Since we are looking at the entire ecosystem, we have a cross-sector participation that represents the concerns of a variety of viewpoints in the field, including regulatory requirements. One illustration of this is the navigation system in your car. It is perfectly acceptable for a GPS giving directions on the best route to get from A to B to go wrong from time to time, as we will probably still reach our destination eventually. But is it OK if an AI application chooses to give a patient a more effective drug (A) with a higher risk of side effects rather than the less effective drug (B) with fewer chances of side effects? This may work well in a hospital that has patients under control and doctors on site, but may be more inconvenient, not

to mention risky, in an elderly care home. Had the drug been prescribed by a doctor, it would have been possible to ask why the more effective drug (A) was chosen, but an AI application that is only supposed to *deliver* a drug may not even be able to answer why drug (A) is more appropriate than drug (B).

International Standards, including those dealing with ethics, could serve as guidance to assist regulators in their work. For example, when building new systems that will be connected to other new or existing systems, they will increase the possibility of these being widely adopted and used. Standards, by their very nature, are developed for the long term; yet, today, the call is often for research and development, which means other types of documents may be needed on an ongoing basis. Alongside the new ethics project, a vocabulary establishing clear terms and definitions would therefore be a valuable

asset to ensure a common understanding across the various parties involved and a good starting point for developing such documents.

### When is it unethical not to use AI?

This is a difficult question because what is ethical or unethical very much depends on the context in which AI is used, which may also differ between regions. For instance, not using AI in the study of diseases could be deemed unethical since its very use might have increased the ability of finding a cure faster than if it had not been used. It is important to remember the potential of AI to help solve some of our biggest challenges, in particular when they relate to human safety. But it's a difficult judgement call. For example, is it more "ethically acceptable" when a self-driving car kills a number of individuals per year than when we humans are driving? Such is the dilemma of AI ethics. ■



Berlin tests its first driverless buses in August 2019.





# On the path to 2030

by Maria Lazarte

We operate in a world where change is a constant. This precept was at the core of all discussions at this year's ISO Week in Cape Town, as the standards community mapped out the organization's strategic directions to 2030.



Successful innovation requires not just an understanding of today's needs, but also the ability to project ourselves into future challenges. If ISO wants to remain relevant in years to come, the organization must respond to the disruptive forces that are transforming our world. This was one of the discussions at the heart of the ISO General Assembly held in Cape Town, South Africa, on 16-20 September 2019 during ISO Week 2019. The event hosted by our South African member SABS brought together ISO member bodies from around the world to discuss the future of standardization as the organization elaborates its future strategy – the ISO Strategy 2030. “Without appropriate standards, it will be impossible to address multiple challenges at a global and national level,” said Jodi Sholtz, Group Chief Operations Officer from the South African Department of Trade and Industry, as she opened the event. “Standardization provides the tools to achieve sustainable development, to counter the immediate threat posed by climate change and, amongst other things, secure gender equality and optimal healthcare.”

## Getting developing countries involved

Innovation is not a just a rich country's business. Developing countries need to get on board and actively participate in the standards development work if ISO is going to continue to deliver relevant global solutions into the future. This was the key message to come out of the annual meeting of ISO's Committee on developing country matters (DEVCO), which also took place during ISO Week 2019. “This week, we have a unique opportunity to contribute to the process of developing the ISO Strategy 2030,” said DEVCO Chair Lena Dargham. “I encourage you to use this opportunity and to contribute to this discussion. It will have a significant impact on us as developing countries, and we need to ensure our voice is heard,” she added.

## Shifting powers

There are significant changes occurring in the world today, many of which will impact developing countries in particular. For instance, we are seeing important shifts in global economic power that need to be considered when charting the future of an organization such as ISO, underlined Herman Warren, Network Director for Africa at *The Economist*.



ISO Secretary-General Sergio Mujica.

## Gender Action Plan

The ISO Week 2019 also saw the approval of ISO's first Gender Action Plan. ISO Secretary-General Sergio Mujica became an International Gender Champion in 2018 as part of a leadership network that promotes gender parity in executive management roles. ISO has already committed to an ambitious plan to be rolled out over the coming years comprising three major goals:

- Gathering data on gender representation in standardization
- Assessing the impact of standards on the United Nations' Sustainable Development Goal 5 for gender equality
- Collecting best practices in the area of gender parity

Several ISO members have also signed the UNECE Gender Responsive Standards Declaration initiated by the United Nations Economic Commission for Europe (UNECE), which affirms the pervasive role of standards in society and recognizes that their content provides opportunities for women's empowerment.





*Jodi Sholtz, Group Chief Operations Officer from the South African Department of Trade and Industry.*

ISO will have to adapt and innovate to meet future challenges.

vision and goals, and to deliver solutions to the world. More than ever, we need each other,” he said. “ISO members have long cooperated and collaborated in the creation of International Standards and solutions. This is needed even more today than ever before. Together, we can achieve much more in this time of uncertainty,” he concluded.

#### **Four disruptive forces**

The ISO Week was itself reflective of collaboration between national standards bodies and regional and partner organizations, who jointly discussed how ISO will have to adapt and innovate to meet future challenges. It was agreed that four main disruptive forces need to be taken into account when defining the ISO Strategy 2030. These comprise economic and trade uncertainty; changing societal expectations; impacts of climate change; and digital transformation.

#### **Increasing trade uncertainty**

For Jodi Sholtz, standards are crucial to securing more inclusive economic growth in an uncertain economic environment. “Globalization has brought in its train massive new production capabilities and capacity. However, it has also resulted in growing inequalities, economic concentration and economic marginalization of many developing countries. It is important that a more inclusive growth path is secured, and for that, standardization will increasingly be one of the anchors,” she said.

Looking back to 1843 when *The Economist* was first published, the global economy was dominated by the United Kingdom, Germany and France, he said. The 20<sup>th</sup> century saw the additional rise of the United States and Japan. “Now we see that the centre of economic gravity in the world is shifting east. The two largest economies today are the United States and China but, by the end of the century, we expect to see China as the largest economy, followed by the US and then India.”

Warren argued that the trade tensions we are currently witnessing linked to technology and related intellectual property may result in a bifurcation of supply chains. “This decoupling raises issues from a standards perspective, where countries and businesses might need to make a choice as to who they work with,” he said.

For Bernardo Calzadilla-Sarmiento, Director, Trade, Investment and Innovation at the United Nations Industrial Development Organization (UNIDO), “trade growth up until now has not

been sustainable and we need to work together to ensure it benefits all actors, including small communities”. “We can only be as strong as our weakest member,” agreed ISO Secretary-General Sergio Mujica.

It’s important for developing countries to participate in global value chains, echoed Trade Facilitation and Border Management specialist William Gain, from the World Bank Group, but additional policy choices and drivers around economic development are needed to ensure that benefits are sustained in the long term and shared equally.

The way forward requires global collaboration underlined Gain. “International cooperation between organizations such as ISO, the World Trade Organization (WTO) and the World Customs Organization (WCO) is critical. The global approach has to be the answer.”

The power of cohesive action was also highlighted by ISO President John Walter. “We must move forward collectively to achieve our common



From left to right: *Kate Sturgess* (event moderator), *Herman Warren* (The Economist), *William Gains* (World Bank), *Bernardo Calzadilla-Sarmiento* (UNIDO) and DEVCO Chair *Lena Dargham* discuss today’s major challenges for developing countries.





UNCTAD's **Regina Asariotis** highlighted the scope of climate change impacts.



**Prof. Bitange Ndemo** of the University of Nairobi, Kenya, explains digital transformation and its impact on business, economic development and society.

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in motion

Check out the video of  
the main highlights!



ISO President John Walter added, “the economy is obviously one of the most important drivers of change and there is an unquestionable role for us to play in restoring faith in the values of free trade and multilateralism”.

Trade expert Catherine Grant-Makokera referenced the rise of economic nationalism, increasing levels of protectionism and falling confidence in the multilateral trading system. There has been a tenfold increase in trade uncertainty in recent years, in contrast to the relative stability of the preceding two decades. “This is important because an increase in the world trade uncertainty index reduces global growth projections,” she said.

Standards remain among those issues that are incredibly important for the establishment and continuation of global value chains, she added. They are critical if trade agreements are to live to their full potential, including the African Continental Free Trade Area (AfCFTA).

### Changing societal expectations

The changing expectations of consumers and society were another disruptive force highlighted as impacting the world around us. An example of this can be seen in the sharing economy where individuals offer their personal assets, like their vehicles or apartments, to other members in the community.

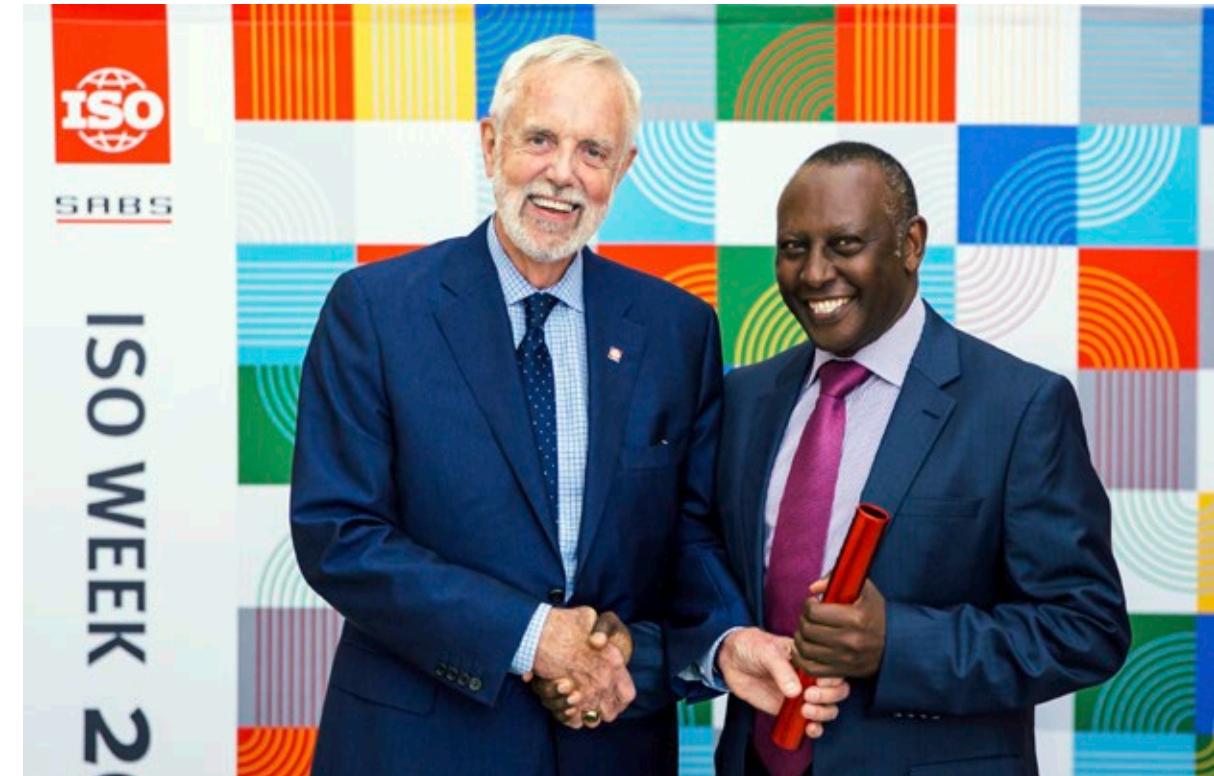
These new models bring new challenges for regulators and policy makers that standardization may go some way to solve. “Standards are desperately needed in the sharing economy,” explained Mark Atwood, founder of ride-sharing app Jrney. “Does taking extra passengers in your car on a long journey impact your insurance? Does it change anything if these extra passengers were found through an app or your personal network of friends? There are no clear answers to these questions today.”

Tarryn Daniels from the Consumer Goods Council of South Africa emphasized that standards were needed to support the development of the sharing economy, but also the disruptive nature of these evolutions. “Those who stand to lose in the sharing economy are traditional industries that refuse to adapt and those using conventional business models that refuse to evolve,” she said.

### Urgency for sustainability

The true scope of the impacts of climate change were highlighted by Regina Asariotis of the United Nations Conference on Trade and Development (UNCTAD), using a concrete example from the field of global transportation.

“International trade depends critically on well-functioning transport links. Environmental challenges such as extreme



**John Walter**, ISO President (left), hands over a symbolic baton to **Eddy Njoroge**, ISO President-elect, who will take up the presidency in January 2020.

storms, floods, changes in temperature, humidity or precipitation and rising sea levels will have significant impacts on transportation infrastructure such as ports,” she explained, urging for better risk assessment and preparation to ensure we can successfully adapt to climate change.

### Digital transformation

Finally, the impacts of digital on all of us were also explored, with calls for the standardization community to embrace digital transformation. The event looked at what the rapid evolution and adoption of digital technologies could mean for businesses and society. For example, what does digital transformation mean for businesses? How are digital technologies changing what and how we trade? And how are digital technologies driving entrepreneurial growth and innovation?

“We must get ready for disruption, serious disruption,” warned Kenyan professor Bitange Ndemo of the University of Nairobi. Digital technologies are now widely adopted and new advancements (e.g. automation, artificial intelligence or blockchain) offer multiple opportunities for organizations, helping to boost their efficiency and

productivity, create competitive advantage and promote innovation. It is, however, important to analyse which technologies have real value and relevance, and where investments should be made.

### The road ahead

Together these four trends – economic and trade uncertainty, changing societal expectations, the urgency for sustainability and digital transformation – will shape ISO’s future priorities and objectives, agreed ISO Week participants.

“When people look for a point of orientation in a fast-spinning world, I want them to look at ISO. At a time when the rules are unclear and parameters uncertain, stability and innovation are keys to shared success,” said the ISO President.

The ISO Week 2019 was also the last General Assembly of ISO President John Walter, who was warmly thanked for his commitment to promoting ISO during his tenure. Taking up the role in January 2020 is Kenyan Eddy Njoroge who emphasized the importance of encouraging developing country participation among other priorities. ■





# Injecting standardization into patient care

by Clare Naden

Auto-injectors, hand-held injection pens, body-worn injection devices, inhalers and single-use syringes are just some of the latest solutions in healthcare aimed at keeping patients safe and getting better faster.

ISO standards are at the heart of it, helping the industry to flourish for the health and well-being of all.

**B**ruce Hanson, 68, from Orewa, New Zealand, was diagnosed with type 2 diabetes when he was 40 years old. His life immediately changed since that diagnosis and he has had to inject himself with insulin three times a day, mostly in the abdominal region, leaving bruising and sensitivity. While he had a good idea of the dosage required, he could never be entirely sure if he was receiving the correct dose. For the last 20 years, however, the syringes have been put away, the bruising has cleared up and his dosage is no longer a stab in the dark – thanks to his pen-injector. Not only is administering the injections less painful and more convenient, as the device delivers the dosage more accurately, but Bruce is expected to have a better quality of life for longer, with less risk of complications such as poor eyesight and kidney issues. Bruce is just one of millions of people reliant on regular medication who benefit from advances in technology related to the administering of medicinal products.

## Injections have come a long way

Injections are big business and more than 16 billion of them are administered around the world every year<sup>1</sup>. Things have come a long way since the 1980s when the delivery of drugs, specifically injections, was mostly done by needles and syringes. The industry has evolved since the invention of the pen-injector which opened the field to new technologies and made self-administration easier and safer. The rise of chronic diseases such as diabetes has called for more convenient methods of administering medications, such as body-worn devices, pen-injectors, auto-injectors, needle-free injectors, patches, inhalers and more. More recently, the trend has been moving towards the use of devices with larger-volume containers, prefilled devices and digitally connected systems, as treatments are increasingly transferred from hospitals to the home.

Paul Jansen, an engineer with more than 30 years' experience in the medical devices industry, is Chair of ISO technical committee ISO/TC 84, *Devices for administration of medicinal products and catheters*. These new devices, he says, allow for safer, more accurate treatment. "People often travel long distances or spend many hours in medical centres getting their treatment, which adds costs to the facility and a burden on the healthcare professionals," he explains. "At the same time, new digital health technologies and big data analytics allow healthcare companies and professionals to optimize individual therapies that are more targeted, safer and provide better outcomes for patients."

Jansen says that the number of injectable drugs approved and in development has also grown in recent years. "The number of products in development is two to three times higher than it was in 2014, and there are currently over three thousand injectable drugs being developed." However, with this new technology comes an increased focus on regulation to ensure patient safety.

## Reducing risk

This concern with safety is not surprising as administering anything into the body brings with it a risk of disease transmission – to patients as well as medical staff and ancillary personnel such as cleaners or laboratory technicians. A 2010 study sponsored by the World Health Organization (WHO) estimated that 1.7 million people were infected with hepatitis B virus (HBV), up to 315 000 with hepatitis C virus (HCV) and as many as 33 800 with HIV through an unsafe injection<sup>2</sup>. The organization has a range of programmes in place to combat this, such as the WHO Injection Safety Programme and the Safe Injection Global Network. The medical devices industry has hopped on board, developing new technologies such as the syringe with reuse prevention.

1) WHO, "Injection Safety Fact Sheet" [pdf], revised May 2016.

2) WHO, "WHO calls for worldwide use of 'smart' syringes" [press release], 23 February 2015.





From left to right: **Maria Skou**, Head of International Affairs from Danish Standards, representing Committee Manager **Bibi Nellemose**, **Paul Jansen**, Chair of ISO/TC 84, **John Walter**, ISO President, **Sauw Kook Choy**, ISO Vice-President (technical management) and **Sergio Mujica**, ISO Secretary-General.



## Excellence in standardization

Created in 1956, ISO/TC 84, *Devices for administration of medicinal products and catheters*, is one of ISO's most established technical committees. Since its conception, it has published over 30 key industry standards with many more in development. These not only help medical device manufacturers comply with regulations, they also provide a platform for new technology in the field to develop.

By providing an internationally agreed common language for systems and processes, as well as minimum safety and quality requirements, the standards establish a firm foundation on which new inventions and regulations can be based.

The hard work and achievements of ISO/TC 84 were recognized through the Lawrence D. Eicher Award for excellence and superior performance in standards development, which was presented in September 2019 at the 42<sup>nd</sup> ISO General Assembly in Cape Town, South Africa.

Announcing the award winner, ISO President John Walter praised the committee's strong focus on patient safety and building connections with all areas of the industry: "Not only does its work directly address Goal 3 of the United Nations Sustainable Development Goals for good health and well-being, it provides a valuable platform for industry, regulators and other interested partners to work together to make further advances in this field," he said.

The reuse prevention mechanism works by locking up the injection device and breaking if a second use is attempted. In 2015, the WHO launched a new policy on injection safety, calling on the international community to switch to the exclusive use of safety-engineered syringes by 2020. It issued highly detailed injection safety guidelines, which outlined a number of safety features for syringes that not only protect the recipient of the injections, but the healthcare worker who administers them as well.

The increase in the prevalence of HIV also led to ISO/TC 84 establishing a project with the Standards Association of Zimbabwe (SAZ), ISO's member for the country, in order to assist involvement of the African continent into the development of standards for safer devices. Chaired by SAZ, it resulted in the successful development of standards for sharps protection features and requirements for sharps containers.

### The technology drive

Since the development of the insulin pen-injector in the 1980s, explains Jansen, the industry has developed a range of new technologies, especially within the home care area leading to better

**More than  
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treatments, better convenience for the patients and less cost to communities. Pen-injectors have become useful for many other types of medicine, he adds, and auto-injectors have been developed for many therapies. Another recent development comes in the form of body-worn devices that can deliver high-viscosity medicine, which tends to be larger in volume, over a longer time.

ISO/TC 84 has been on top of these developments. "At the time of marketing of the first body-worn devices, the committee had already drafted requirements for the new device type – a benefit for both the industry, authorities and users," says Jansen. "Where there are new technological improvements or features, or new types of medicinal products, the committee aims to be there to adapt the standards in order to ensure patients receive the safest and most effective care."

It is clear the committee has big plans to keep ahead of the technology game, often having the relevant standards ready by the time the technology makes

it on to the market – no mean feat when standards traditionally take years to be developed.

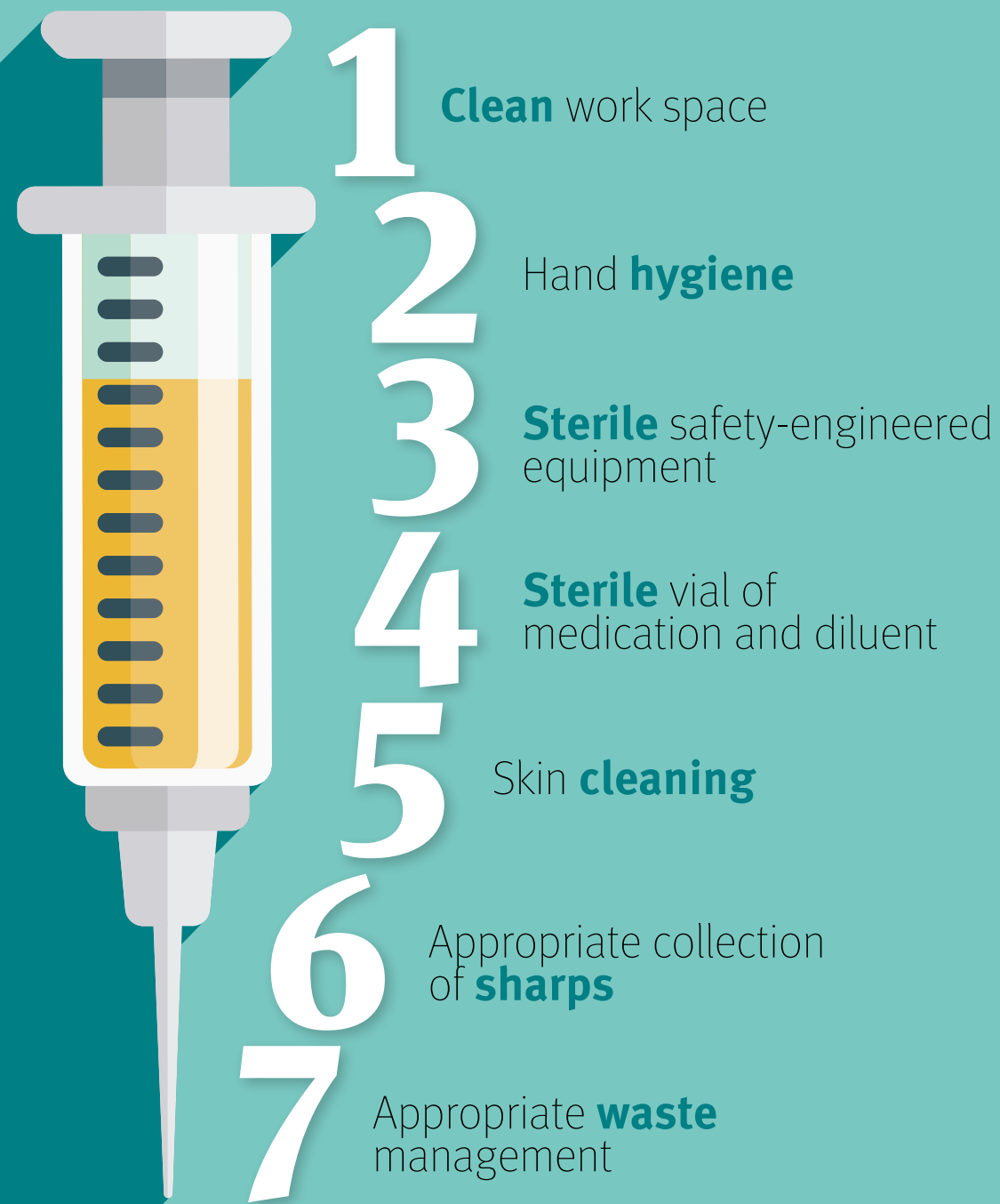
### All about patient safety

ISO/TC 84 boasts more than 30 published International Standards and documents, with 11 more in development, representing the work of experts from all over the world. The committee's mission and vision are to focus on patient safety, ensuring that the requirements of the standards are the most up-to-date possible in order to serve as a basis for the regional and national approval of injection devices worldwide. One of the keys is to draw on a large number of representatives from different authorities as well as from users or specialists bearing users' views. Participation from authorities and user groups, such as blind people and paediatrics, is fundamental for making standards that are applicable in government and fulfil patient needs.



# THE 7 STEPS OF A SAFE INJECTION

All of us, at some point in our lives, will have an injection to retain or restore good health. But sometimes injections that are intended to promote health do the opposite. This happens when they are given in an unsafe way, using the same needle or syringe to give injections to more than one person. Practices like this can lead to the transmission of life-threatening infections.



For further information, please visit: [www.who.int/infection-prevention/en](http://www.who.int/infection-prevention/en)

“This is why we appreciate the involvement of all parties when developing our standards, including health authorities such as the Food and Drug Administration (FDA), international organizations like the WHO and the United Nations International Children’s Emergency Fund (UNICEF), manufacturers of both drugs and devices, and end users such as patients and healthcare workers,” adds Jansen.

Diabetes, rheumatoid arthritis, fertility hormones and many other therapeutic areas benefit from the devices covered by the standards of ISO/TC 84. These devices include needle-based injection systems, auto-injectors, body-worn injectors, safety needle systems, primary medicinal containers and needles. The committee’s portfolio also includes a number of standards related to catheters for all kinds of treatments and used in conjunction with many other types of devices such as infusion pumps.

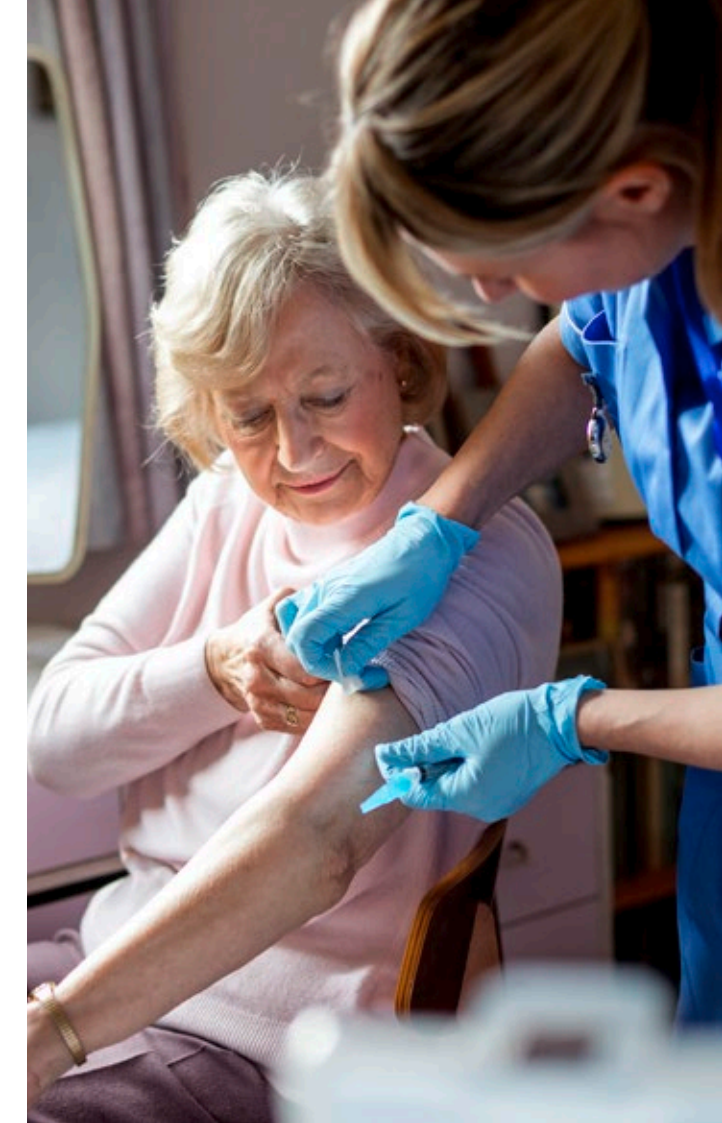
ISO/TC 84 estimates that, over the past three years, 95% of such products in the marketplace are self-declared or fully certified to ISO standards as most health authorities, manufacturers such as pharmaceutical companies and international organizations like the WHO and UNICEF require compliance with International Standards.

## Looking forward

As these technologies develop, so, it seems, does the scope of ISO/TC 84. Jansen again: “The ISO 11608 series of standards for needle-based injection systems originally covered just three components: pen-injectors, primary containers and needles. Now, they have expanded to include automated functions, electromechanical functions and body-worn delivery devices.”

To avoid any confusion or difficulty in interpreting the standards, a key project for the committee moving forward includes harmonizing existing standards to reduce complexity and to incorporate the rapid rise of electronics and software that has permeated the industry in recent years. And as standardization develops, so too does the technology, providing a win-win situation for all.

“With standards guiding and supporting the devices, by providing a common language and requirements for safety and quality, even more sophisticated technologies can emerge,” concludes Jansen. All of which will make life easier, and perhaps longer, for the likes of Bruce and millions of people around the world who rely for their care on medical devices such as these. ■



## 95% of medical products in the marketplace are self-declared or fully certified to ISO standards.



**Did you watch the latest video?**

Discover how ISO/TC 84 is keeping patients safe.



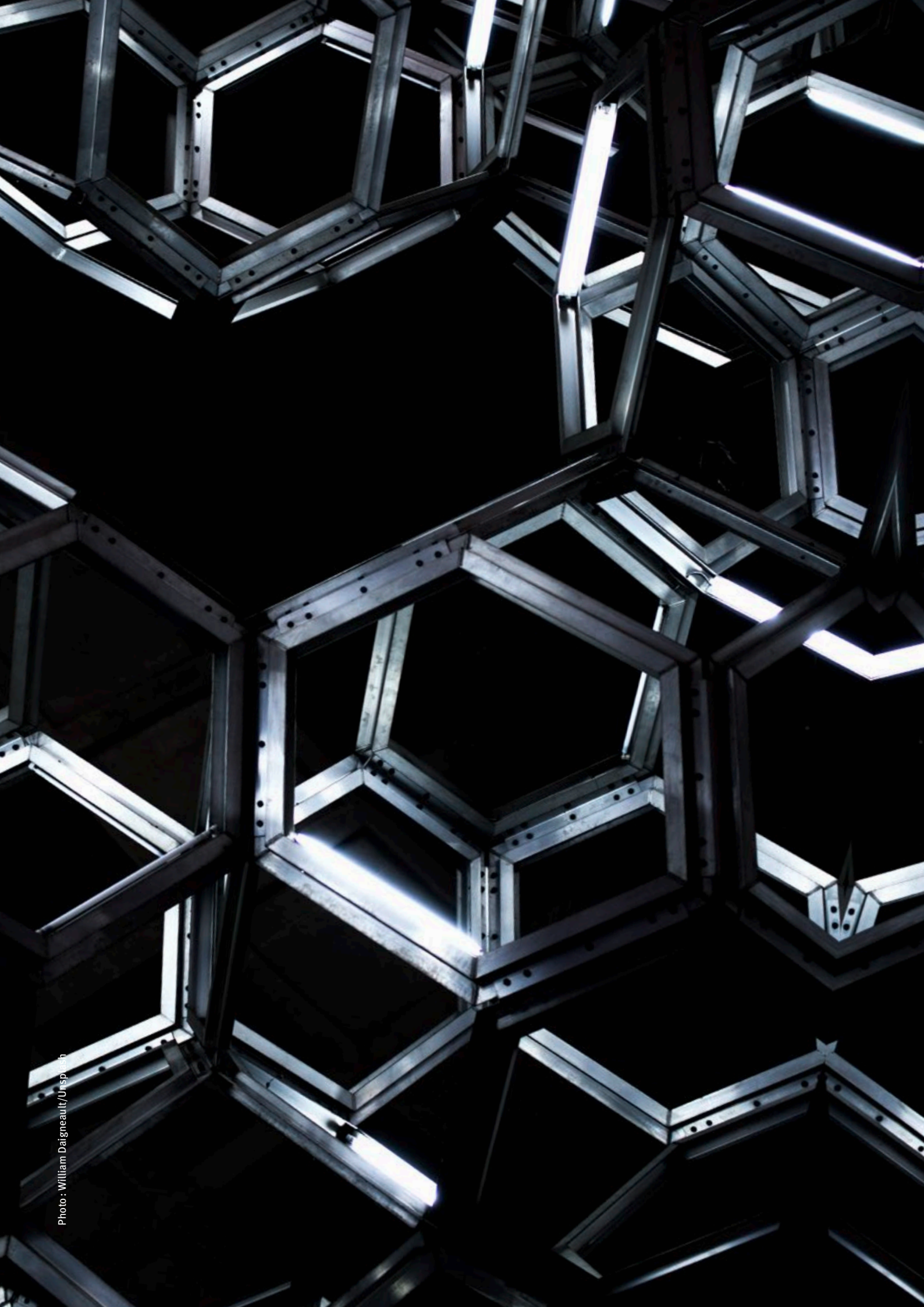


Photo : William Daigneault / Unsplash