

Challenges and Opportunities in International Standards Development

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Content

Short introduction of SIS, CEN and ISO

Brief overview of the standards development process

How standards support innovation – one example

The role of researchers, universities, and companies in standard development.

Audience interaction



Swedish Institute for Standards

- Nonprofit organization
- 1,161 members
- Over 4,500 Swedish experts from appr. 1,600 companies participate in our national and international standardisation work
- 80% of our revenue comes from Swedish private enterprises
- Members of CEN and ISO
- Co-operate with 165 countries
- The World Trade Organization, WTO:s, rules apply
- International standardisation has been going on for 100 years



166 member countries

100 000 experts

About 21 500 published standards

3 900 Committees (TC/SC/WG)

Reaches 97 % of the world's population



34 member countries

50 000 experts

About 16 000 published standards

2 105 Committees (TC/SC/WG)

Reaches 600 million people



1 600 participating organisations (ca 1 100 medlemmar)

5 000 experts

> 8 000 published standards

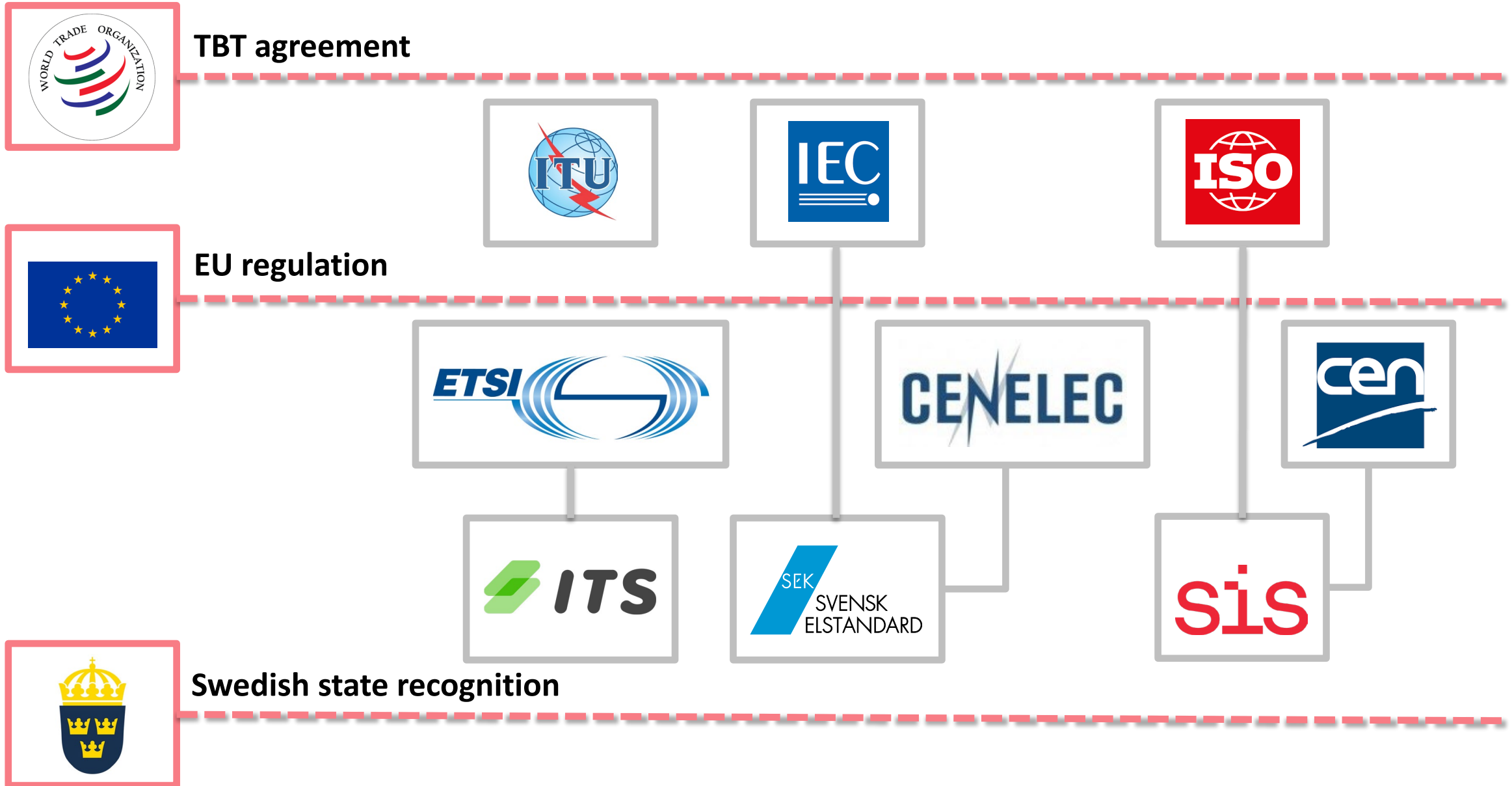
Ca 500 Committees (TK/TC/SC/WG)

Ca 10 000 customers





Regulations of the international standardization world



Different standardisation levels



Different types of standards:



Products



Services



Materials



Testing



Processes



Symbols



Terminology



Competences



Management



Methods

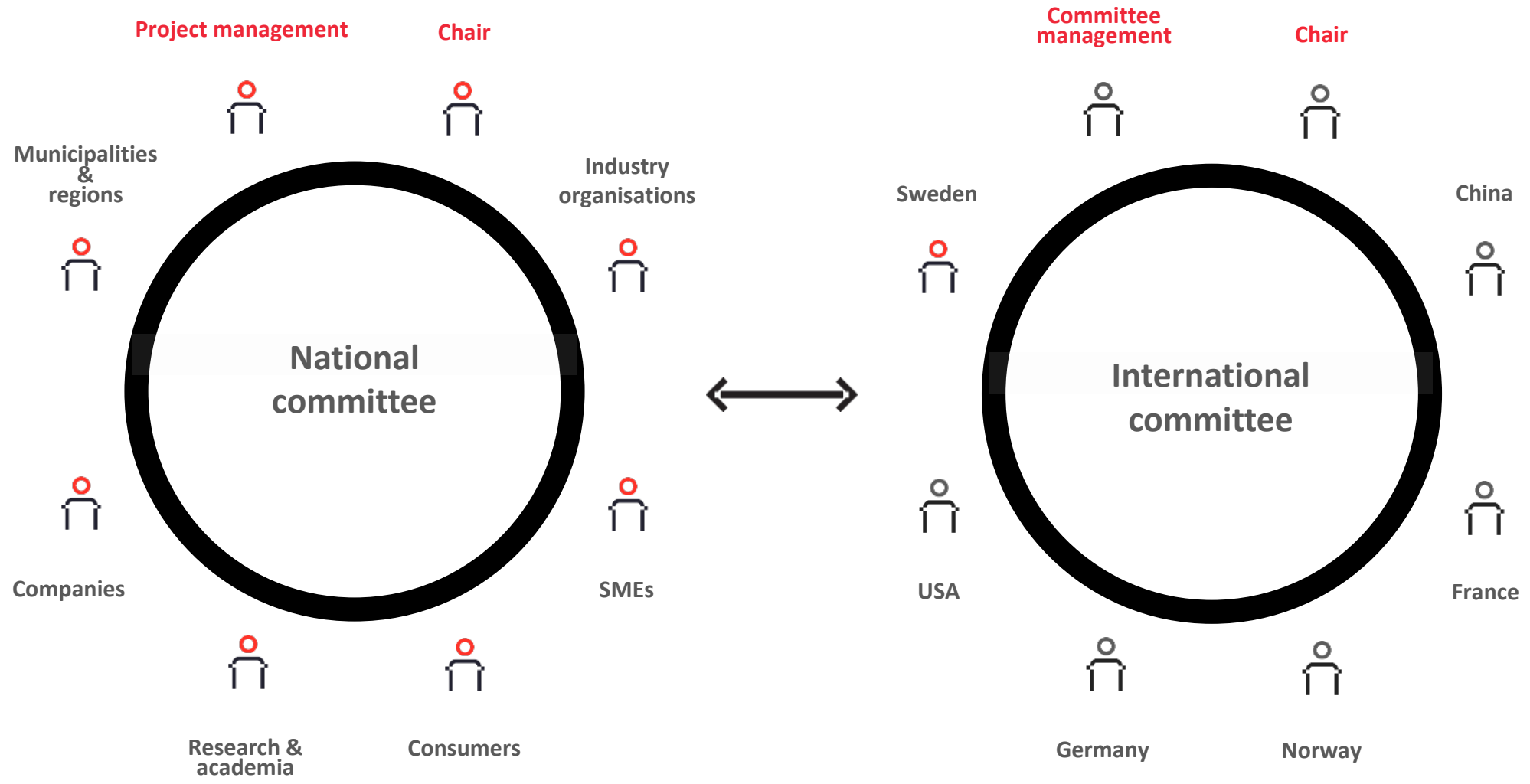


Information












Systems

Technical Committees

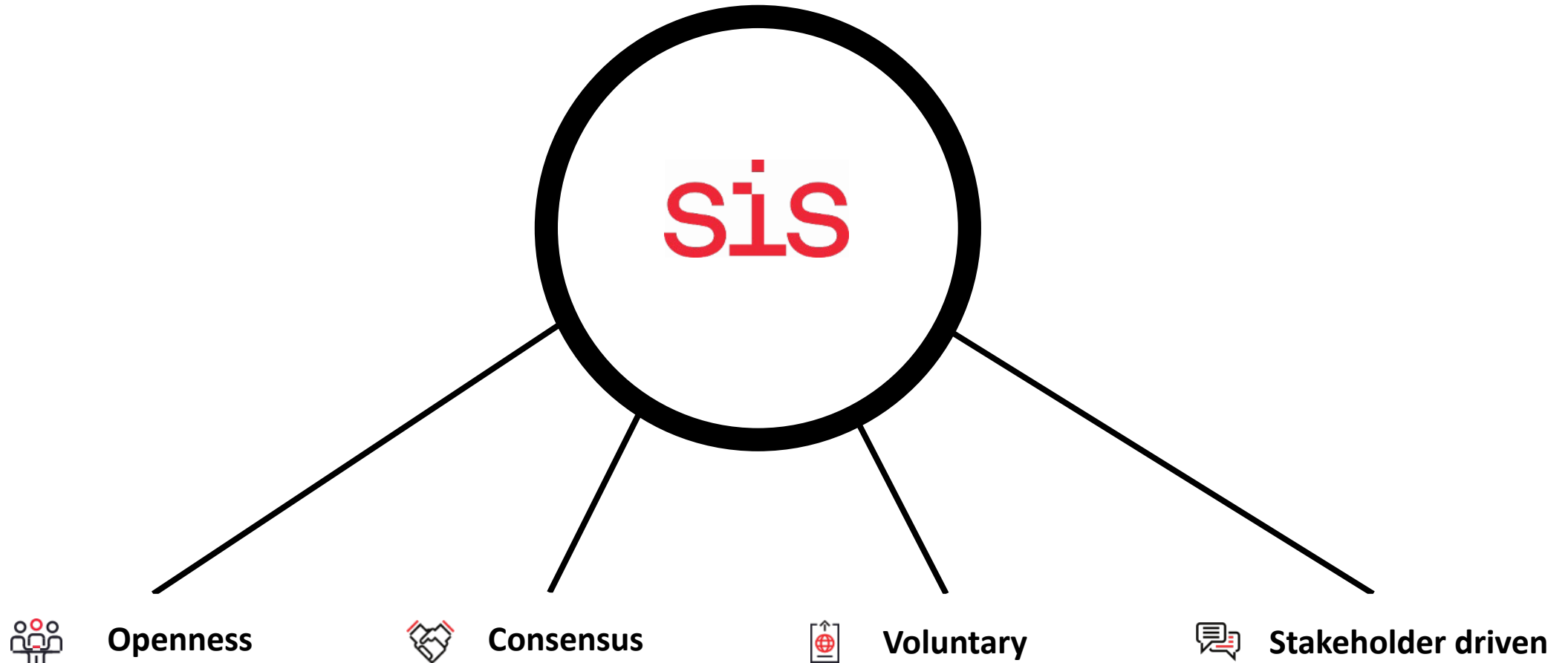


From idea to finished standard



-  1. Idea
-  2. Start-up decision
-  3. Project start
-  4. Working group drafting
-  5. Committee consensus
-  6. Enquiry
-  7. Revision of the draft
-  8. Final vote
-  9. Notification and publication

Principles of good standardisation



Innovation

ISO 56002:2019 Innovation management — Innovation management system — Guidance

Provides guidance for the establishment, implementation, maintenance, and continual improvement of an innovation management system for use in all established organizations.

It is applicable to:

- a) organizations seeking sustained success by developing and demonstrating their ability to effectively manage innovation activities to achieve the intended outcomes;
- b) users, customers, and other interested parties, seeking confidence in the innovation capabilities of an organization;
- c) organizations and interested parties seeking to improve communication through a common understanding of what constitutes an innovation management system;
- d) providers of training in, assessment of, or consultancy for, innovation management and innovation management systems;
- e) policy makers, aiming for higher effectiveness of support programs targeting the innovation capabilities and competitiveness of organizations and the development of society.

The guidance within this document is generic and intended to be applicable to:

- a) all types of organizations, regardless of type, sector, or size. The focus is on established organizations, with the understanding that both temporary organizations and start-ups can also benefit by applying these guidelines in all or in part;
 - b) all types of innovations, e.g. product, service, process, model, and method, ranging from incremental to radical;
 - c) all types of approaches, e.g. internal and open innovation, user-, market-, technology-, and design-driven innovation activities.
- It does not describe detailed activities within the organization, but rather provides guidance at a general level. It does not prescribe any requirements or specific tools or methods for innovation activities.

Innovation and standardisation, ex Organ on Chip



1. Terminology

Common definition and classification of OoC devices - fundamental to facilitate communication among developers, end-users and regulators.

2. Methodology to assess the technological performance

Common procedures for technical validation.

Consensus on **relevant parameters, acceptability ranges** and measurement methods and units.

3. Methodology for biological assessment

Considering specific purpose or context of use - **relevant biomarkers for organ function** and **reference compounds**

Paving the way for standards to support research

CEN CENELEC and the European Commission's Joint Research Center

Putting Science Into Standards workshops

CEN CENELEC Collaboration agreement aims

@ knowledge- and technology transfer
 @ research results & innovations traverse using standardisation to applications ready for market uptake

- Anticipation
- Identification of standardisation needs
- Bringing together researchers, innovators, standardisers and policy makers
- Organised by JRC, EC services, CEN-CENELEC (incl NSBs)

Organ on Chip

Putting Science into Standards
 (PSIS)

April 2021



- CEN
- EUROoCS
- SIS
- Bayer
- EC JRC
- EC DG GROW

[Open access:](#)



Workshop tracks and opportunities

LIFE SCIENCE

- Cells and Tissues
- Biomaterials and 3D printing
- Assays and Biomarkers

Make better use of guidance documents (GIVMP, GCCP)

Document experimental methods using SOPs

Stem cells - requirements needed for genetic stability and reproducibility

ENGINEERING

- Sensing and Integration
- Interoperability
- Microfluidics

Characterization of devices and components

Interoperability between devices

Metrology standards

Standard for materials characterization (e.g. absorption of compounds)

REGULATORY AND DATA MANAG.

- Good Experimental Practices
- Data acquisition and Manag.
- Characterization and Reporting

Regulators favor data-rich contexts, such as liver metabolism and cardiotoxicity

Reporting standards – facilitate regulatory uptake

Common vocabulary

Minimum information checklists for meta data

Initiation of CEN Focus Group on OoC

Now fully active

Lead: Netherlands

- ensure interaction between all relevant European stakeholders interested in potential standardization
 - liaise with the European Organ-on-Chip Society (EUROoCS) and the International Society for Stem Cell Research (ISSCR)
- map ongoing activities
- define needs and opportunities
- recommend further action to ensure that standards support the deployment of OoC in industry and help to ensure its regulatory acceptance



The role of researchers, universities, and companies in standard development.

Quantum technology with-in healthcare

SIS was contacted by a researcher from Karolinska Institute to participate in the kick off meeting for [Quantum Lifescience](#) center in Sweden. A consortium consisting of individuals/patients, academia, healthcare, and industry, from e. g. Wallenberg Center for Quantum Technology, AstraZeneca, IBM, Karolinska Institutet, SAS Institute and Swelife

Futher contacts wich the scope of thinking of standards within the innovation process

In november there will be a Nordic meeting re Quatum lifescience where the nordic standardisation organisations are invited.

Research project regarding sepsis analysis at the University of Skövde, invited SIS to participate in the reference group of the project for guidance and ideas regarding standardisation.

Thank you for the attention!

Don't hesitate to contact us

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