Standardisation to enhance the scientific credibility
of alternative methods

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COST webinar

2nd December 2021

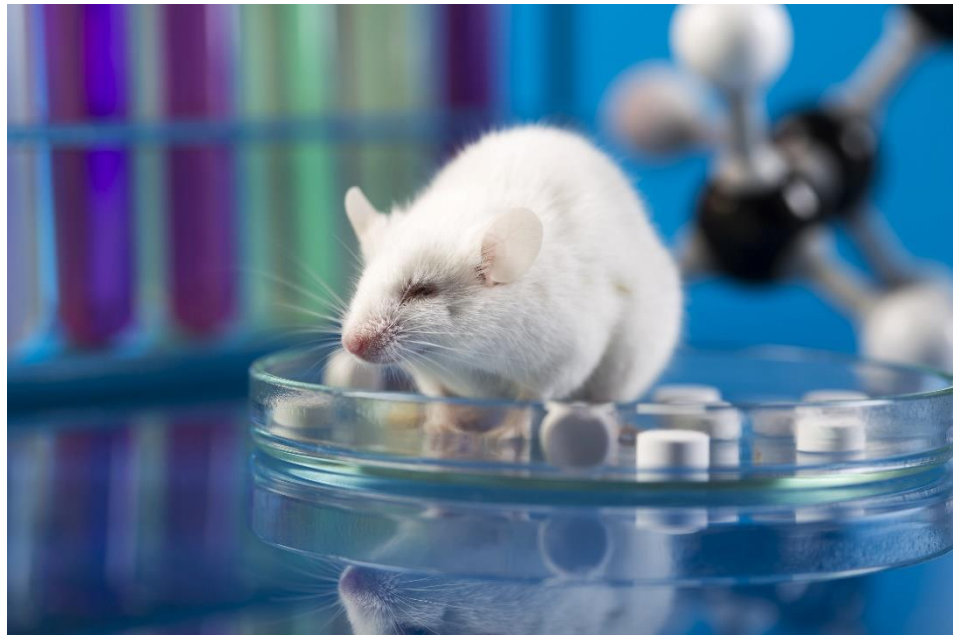
Joint Research Centre

JRC Mission

As the science and knowledge service of the European Commission our mission is to support EU policies with independent evidence throughout the whole policy cycle.

The European Union Reference Laboratory for alternatives to animal testing

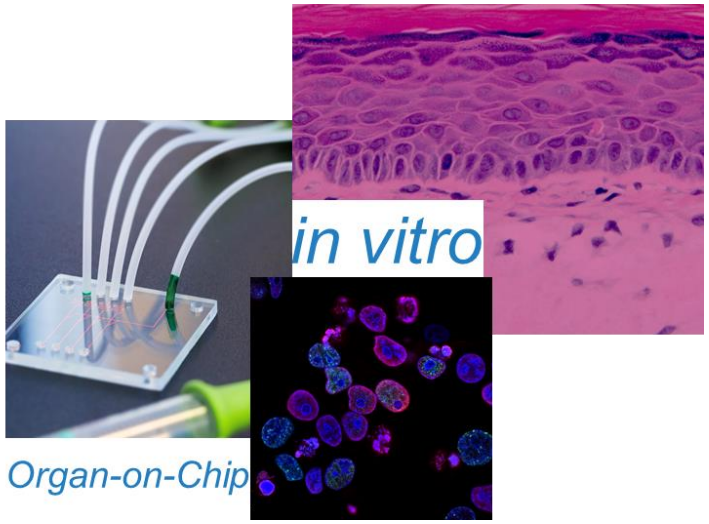
- Research
- Validation
- Dissemination
- Promotion



EURL ECVAM

Duties set out in Directive 2010/63/EU

THE MODERN SAFETY ASSESSMENT TOOLBOX

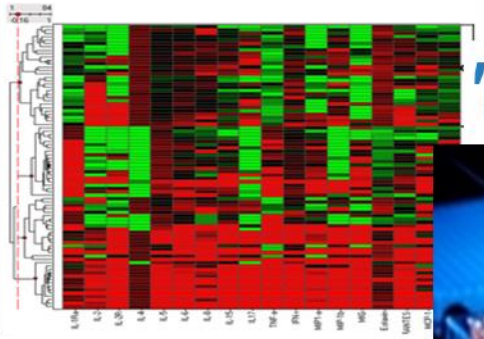


in vitro

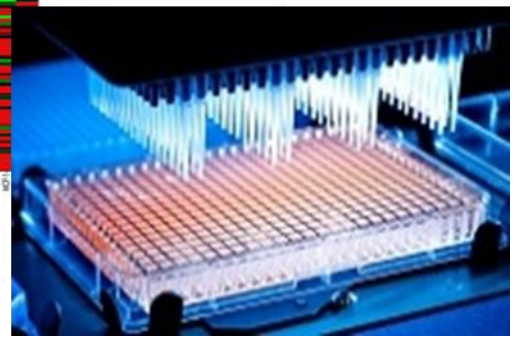
Organ-on-Chip

QSAR

Adverse Outcome Pathways

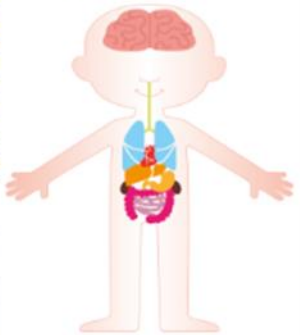


'omics



High Throughput

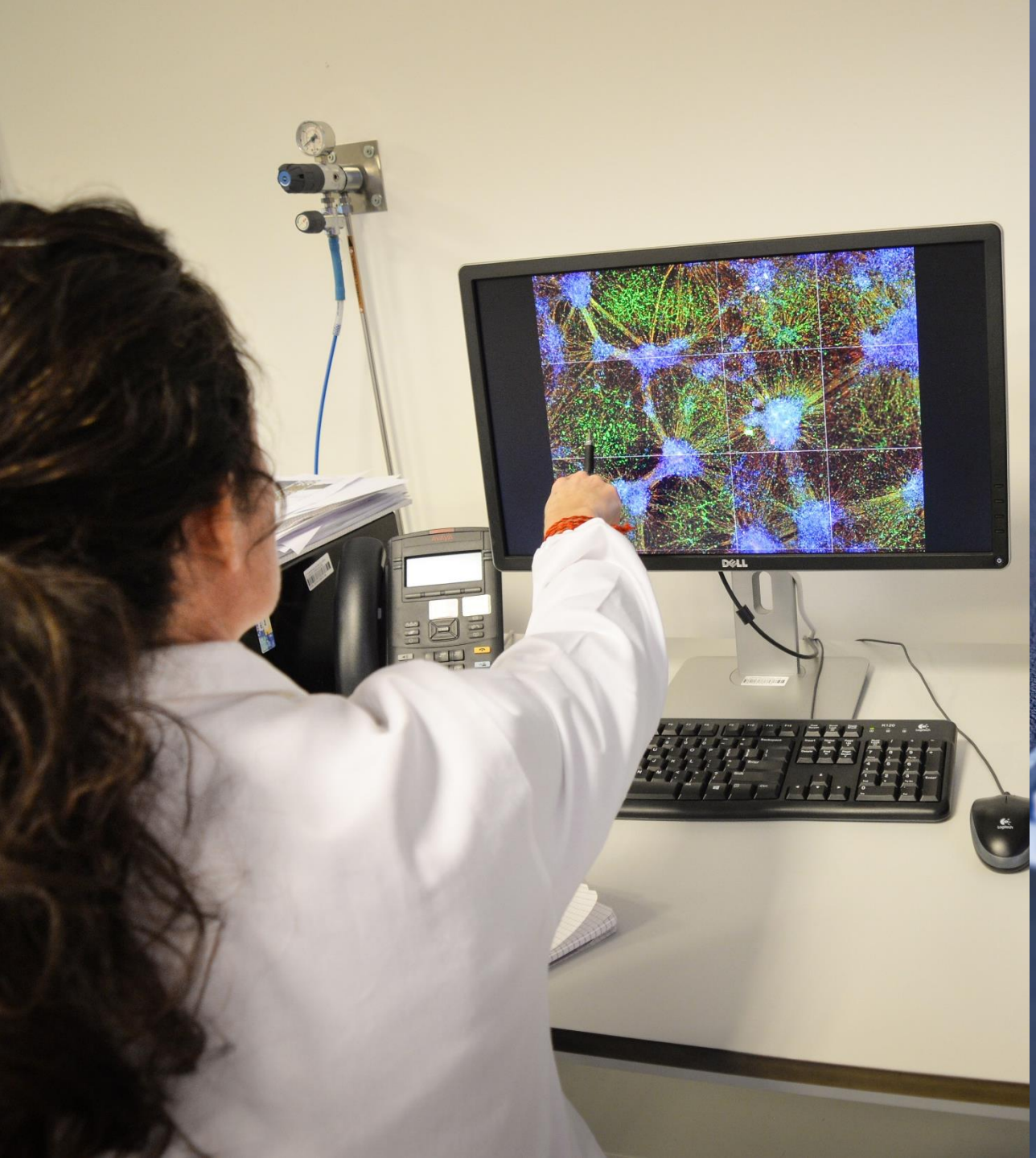
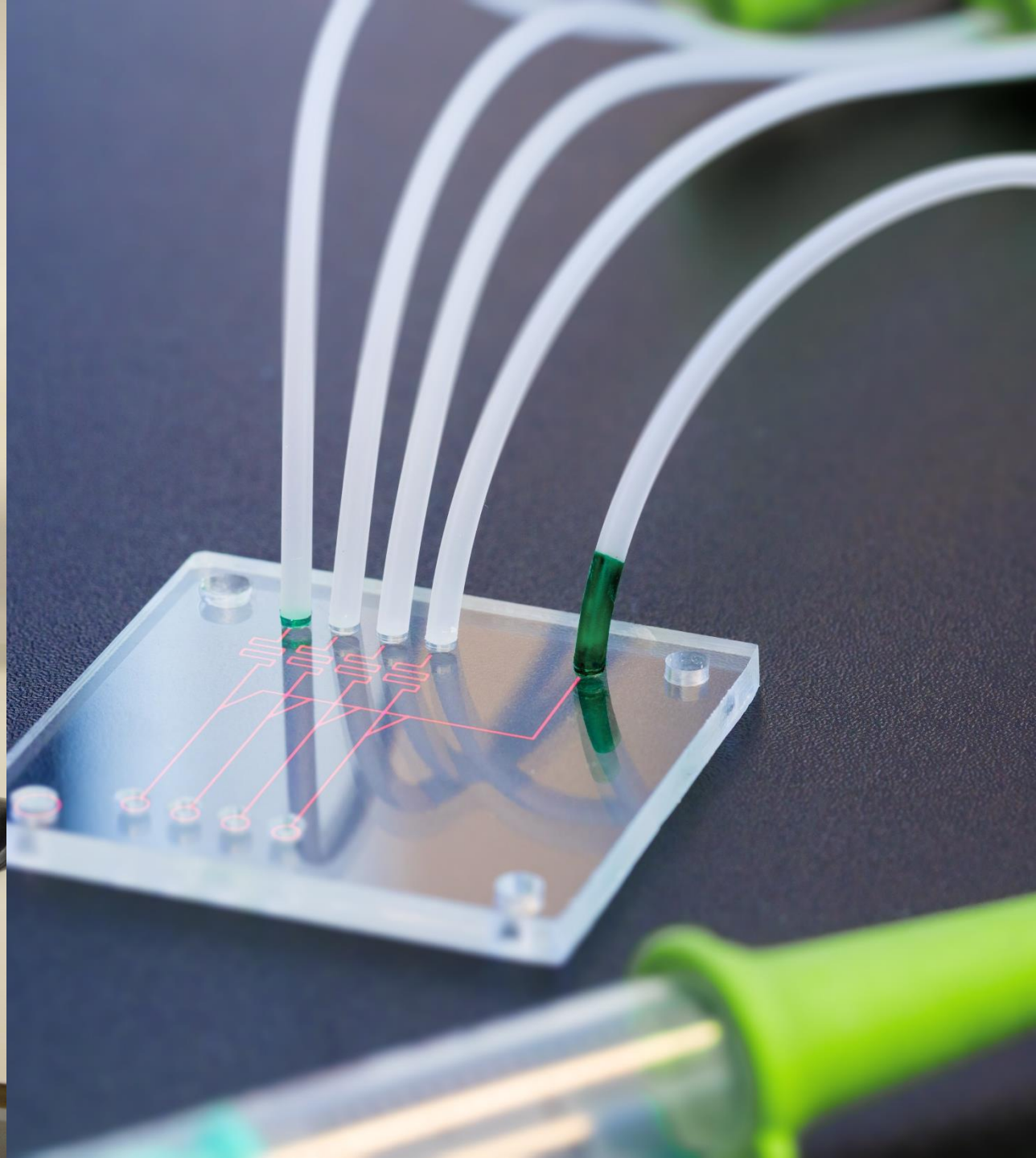
in silico



biokinetics

Technology Readiness Level


STANDARD

CHARACTERISE

- Provide a complete **description** of the system
- Describe and verify the expected **performance**

COMPARE

with data from other *in vivo, in vitro, in silico* methods

- Use the same parameters and units of measure

COMMUNICATE

- Ensure **reporting** according to specific templates
- Facilitate **understanding** with stakeholders

Lab on a Chip

ROYAL SOCIETY OF CHEMISTRY

PERSPECTIVE

Standardisation needs for organ on chip devices†

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Monica Piergiovanni, * Sofia B. Leite, Raffaella Corvi and Maurice Whelan

Organ on chip (OoC) devices represent the cutting edge of biotechnologies, combining advanced cell and tissue culture with microengineering. OoC is accelerating innovation in the life sciences and has the potential to revolutionise many fields including biomedical research, drug development and chemical risk assessment. In order to gain acceptance by end-users of OoC based methods and the data derived from them, and to establish OoC approaches as credible alternatives to animal testing, OoC devices need to go through an extensive qualification process. In this context, standardisation can play a key role in ensuring proper characterisation of individual devices, benchmarking against appropriate reference elements and aiding efficient communication among stakeholders. The development of standards for OoC will address several important issues such as basic terminology, device classification, and technical and biological performance. An analysis of technical and biological aspects related to OoC is presented here to identify standardisation areas specific for OoC, focusing on needs and opportunities. About 90 standards are already available from related fields including microtechnologies, medical devices and *in vitro* cell culture, laying the basis for future work in the OoC domain. Finally, two priority areas for OoC are identified that could be addressed with standards, namely, characterisation of small molecule absorption and measurement of microfluidic parameters.

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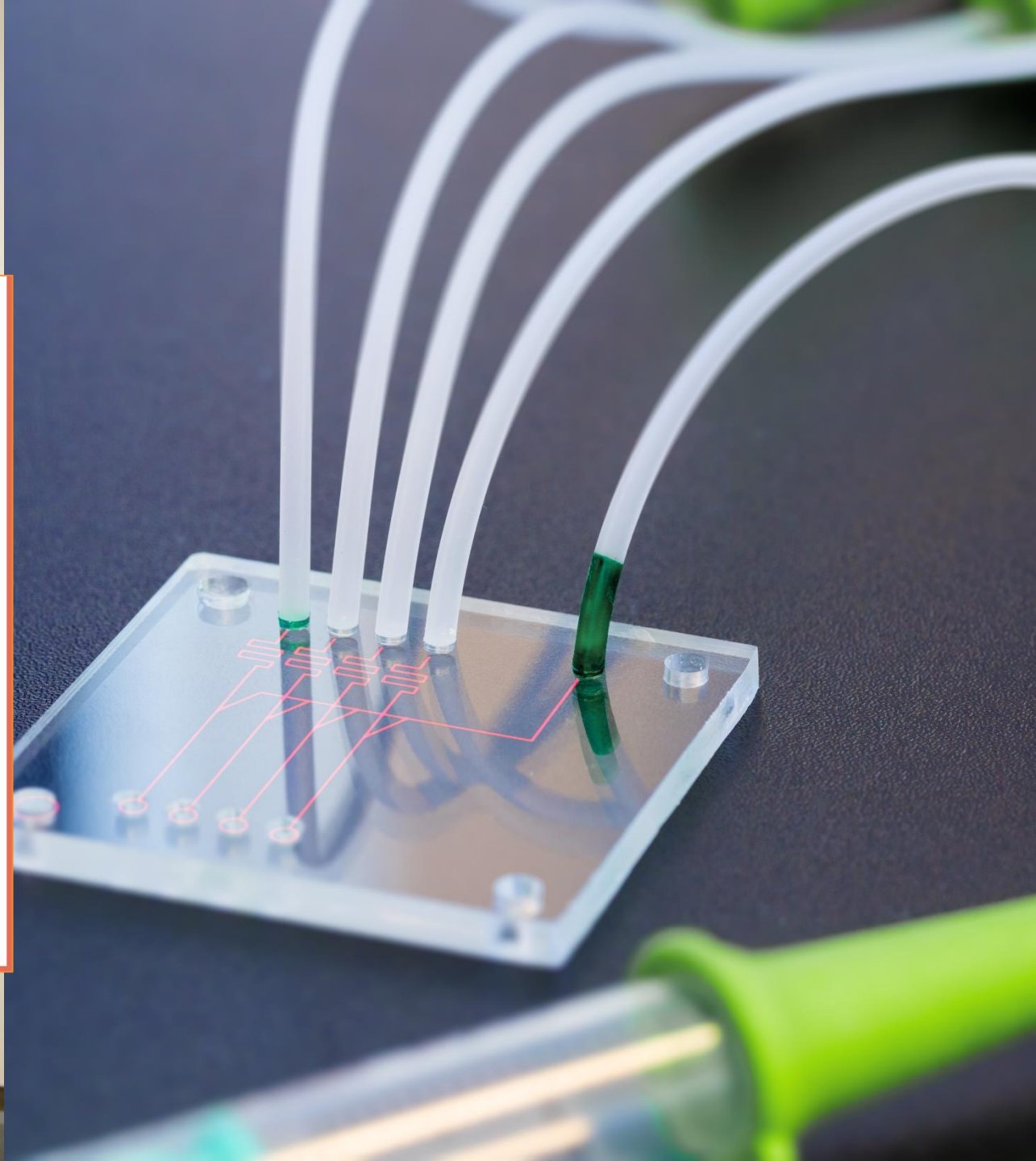

28-29 April 2021

Organ-on-chip

Putting Science into Standards

#Standards4OoC

CEN CENELEC

European Commission

Demonstrate technological and biological relevance, increase OoCs implementation by the pharma/chemical industry and provide basis for regulatory acceptance.

Validation

*The process by which the **reliability** and **relevance** of a particular approach, method, process or assessment is established for a defined purpose.*

From OECD Guidance Document 34

Validation

Reliability *is defined as the extent that a* ***test method*** *can be performed* ***reproducibly*** *within and between laboratories over time, when performed using the same protocol.*

From OECD Guidance Document 34

Validation

Relevance *is defined as the extent to which the test correctly measures or predicts the* ***biological effect of interest***.

From OECD Guidance Document 34

Why validation?

- Increase confidence on a method by demonstrating its ability to provide reproducible and relevant data
- Ensure that regulators obtain reliable and useful information on chemicals for their decision making
- Ensure sound science-based decisions are made to protect human health and the environment
- Facilitate development of globally harmonized standard methods

OECD test guidelines

The Organisation for Economic Co-operation and Development is an intergovernmental economic organisation with 38 member countries, founded in 1961 to stimulate economic progress and world trade.

The **OECD Test Guidelines (TG) for the testing of chemicals** are a collection **of internationally harmonised and agreed testing methods** used by governments, industry, research or contract laboratories and academia to assess the safety of chemicals and products.

Mutual Acceptance of Data Agreement (**MAD**)

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Chemicals

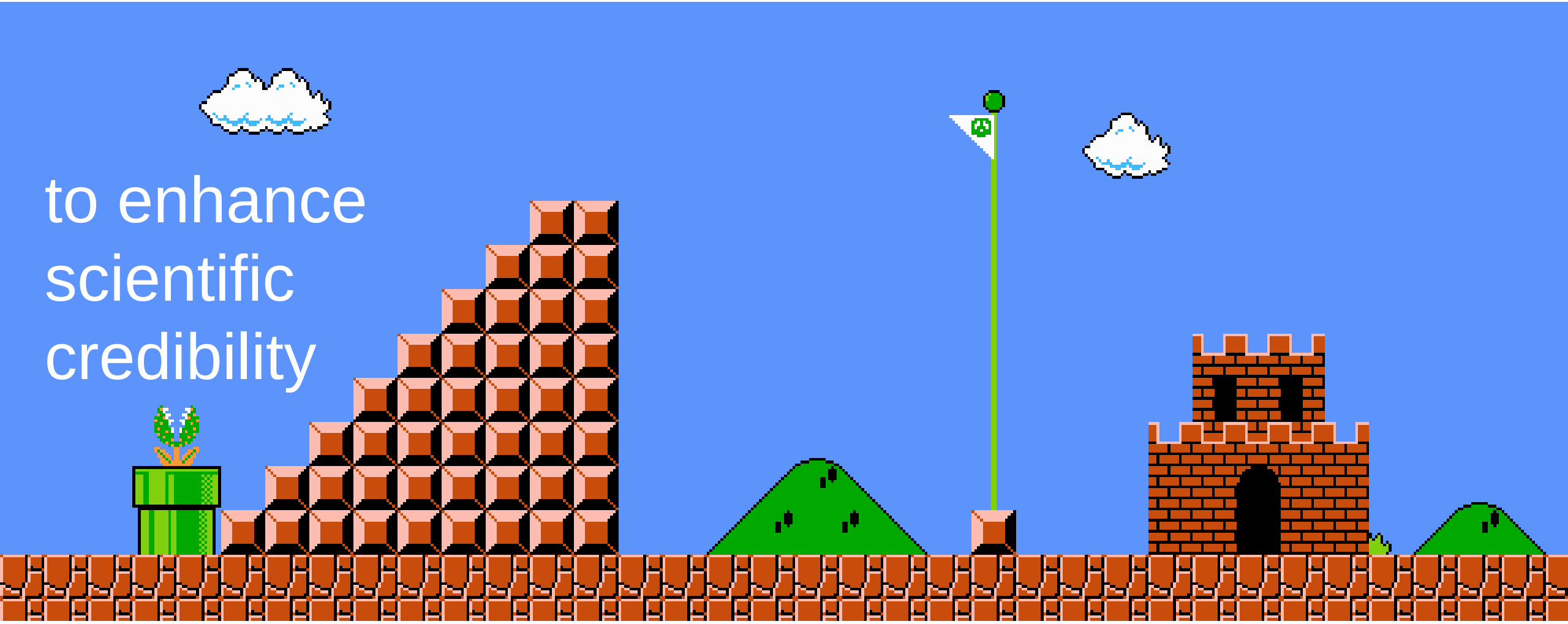
Cosmetics

Pesticides
Biocides

Drugs

Medical Devices

STANDARDISATION



Thank you

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