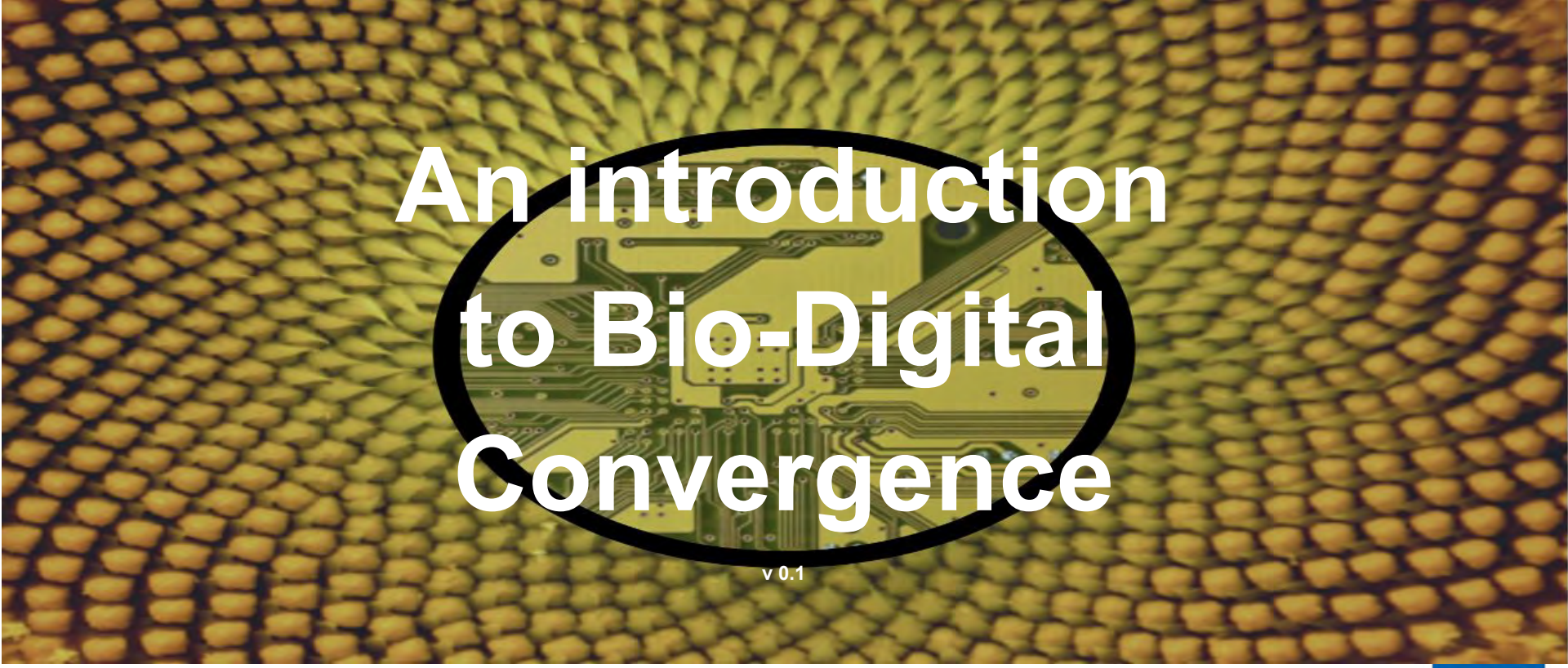
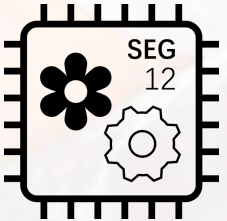


François Coallier,PhD, P.Eng.
IEC SEG 12
Convener

IEC SEG 12 Webinar
Bio-Digital Convergence
Standardization

International
Electrotechnical
Commission

BioDigital Convergence



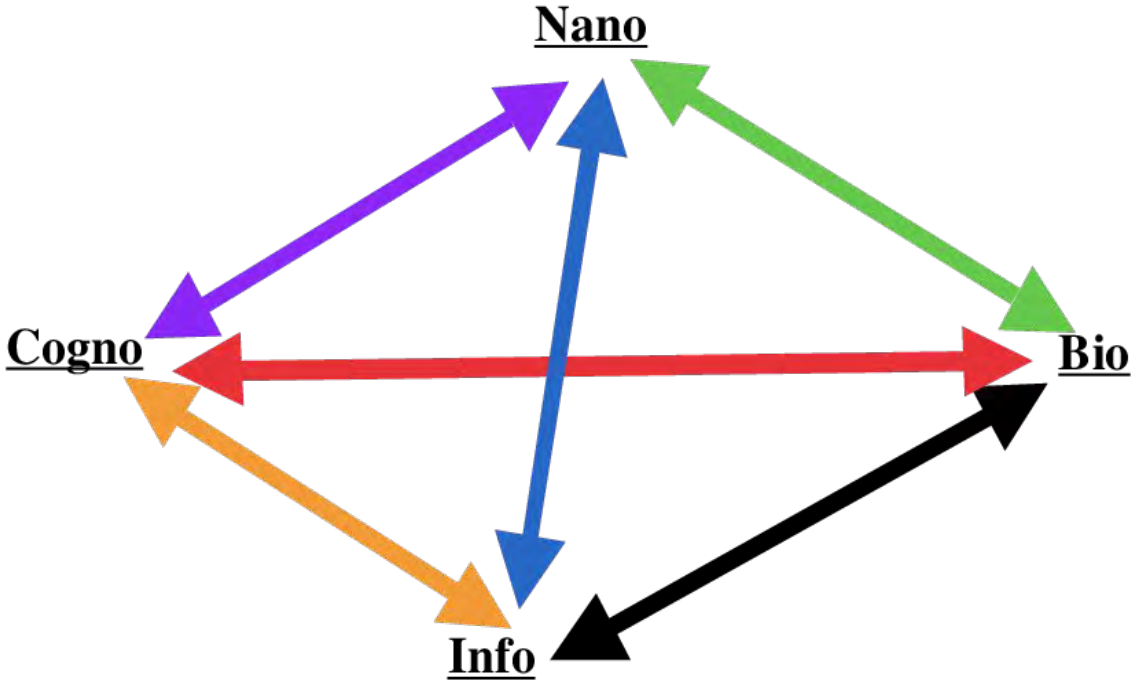
convergence of engineering, nanotechnology, biotechnology, information technology and cognitive science

Note 1 to entry: convergence means the creative union of sciences, technologies, engineering and peoples, focused on mutual benefit; this is a process requiring increasing integration across traditionally separate disciplines, areas of relevance, and across multiple levels of abstraction and organization.

[SOURCE: Modified from: *M. C. Roco, W. S. Bainbridge, B. Tonn, and G. Whitesides, Eds., Convergence of Knowledge, Technology and Society: Beyond Convergence of Nano-Bio-Info-Cognitive Technologies. Cham: Springer International Publishing, 2013. doi: 10.1007/978-3-319-02204-8.*]

BioDigital Convergence -

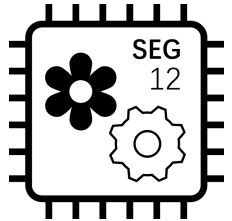
a ~20 years old concept!

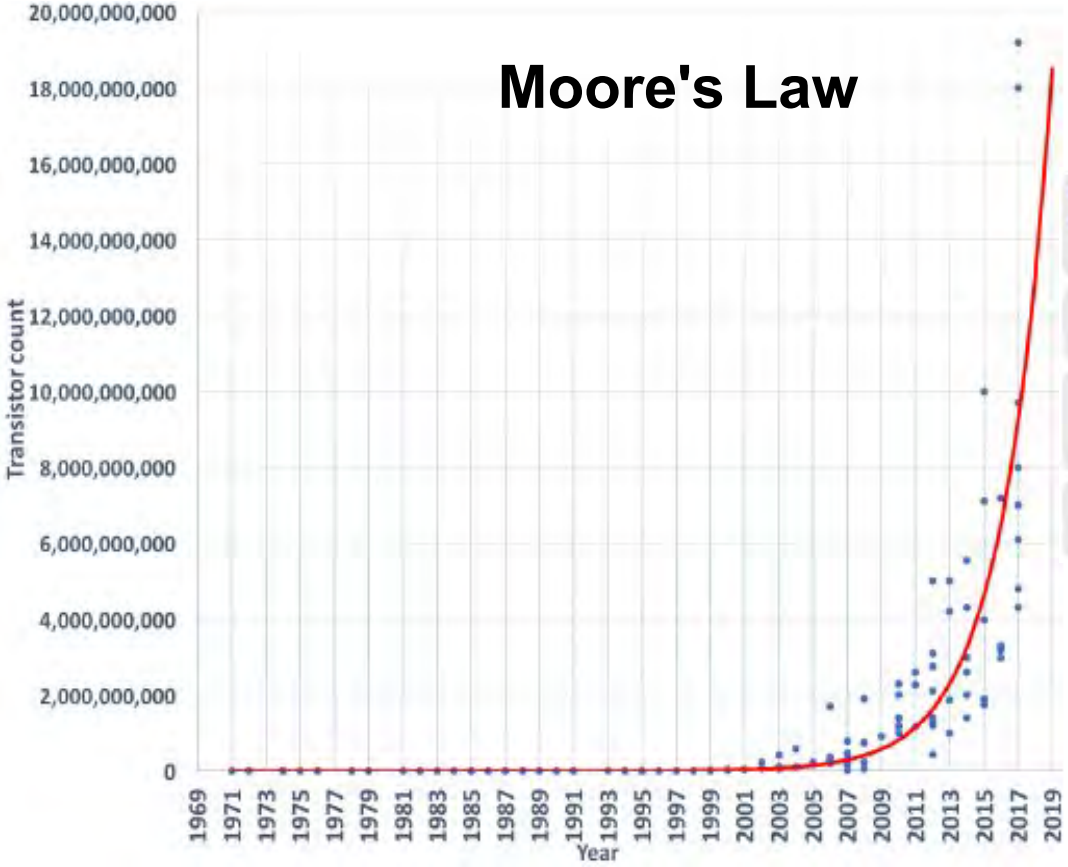


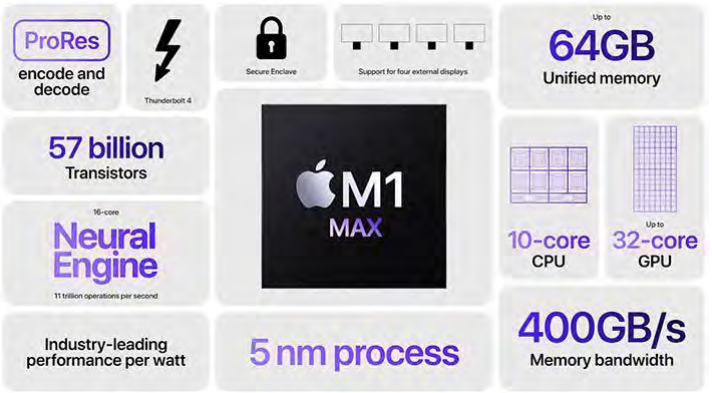
In the context of BioDigital convergence,
'The phrase "convergent technologies" refers to the synergistic combination of four major "NBIC"(Nano-Bio-Info-Cogno) provinces of science and technology, each of which is currently progressing at a rapid rate: (a) nanoscience and nanotechnology; (b) biotechnology and biomedicine, including genetic engineering; (c) information technology, including advanced computing and communications;and, (d) cognitive science, including cognitive neuroscience.' [1

[1] Roco, Mihail & Bainbridge, William **(2003)**. Converging Technologies for Improving Human Performance.
https://www.researchgate.net/publication/252444145_Converging_Technologies_for_Improving_Human_Performance
Also in DOI：10.1007/978-94-017-0359-8

IT has changed a lot in the last 20 years

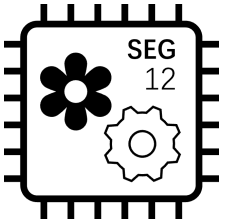






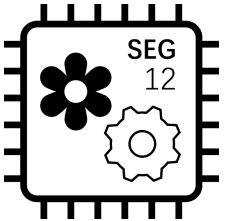
https://hothardware.com/news/apple-debuts-m1-pro-max

https://bjc.edc.org/bjc-r/cur/programming/6-computers/2-history-impact/2-moore.html?topic=nyc_bjc%2F6-how-computers-work.topic&course=bjc4nyc.html&novideo&noassignment



A systems engineering view of BioDigital Convergence

Reverse Engineering (e.g. Science)



How digital technologies are turbocharging the reverse engineering *(deep understanding)* of biological systems (and systems of systems)

Oldest fossil cell:

~3.4 * 10^9 years ago?

Oldest fossil cell with nucleus:

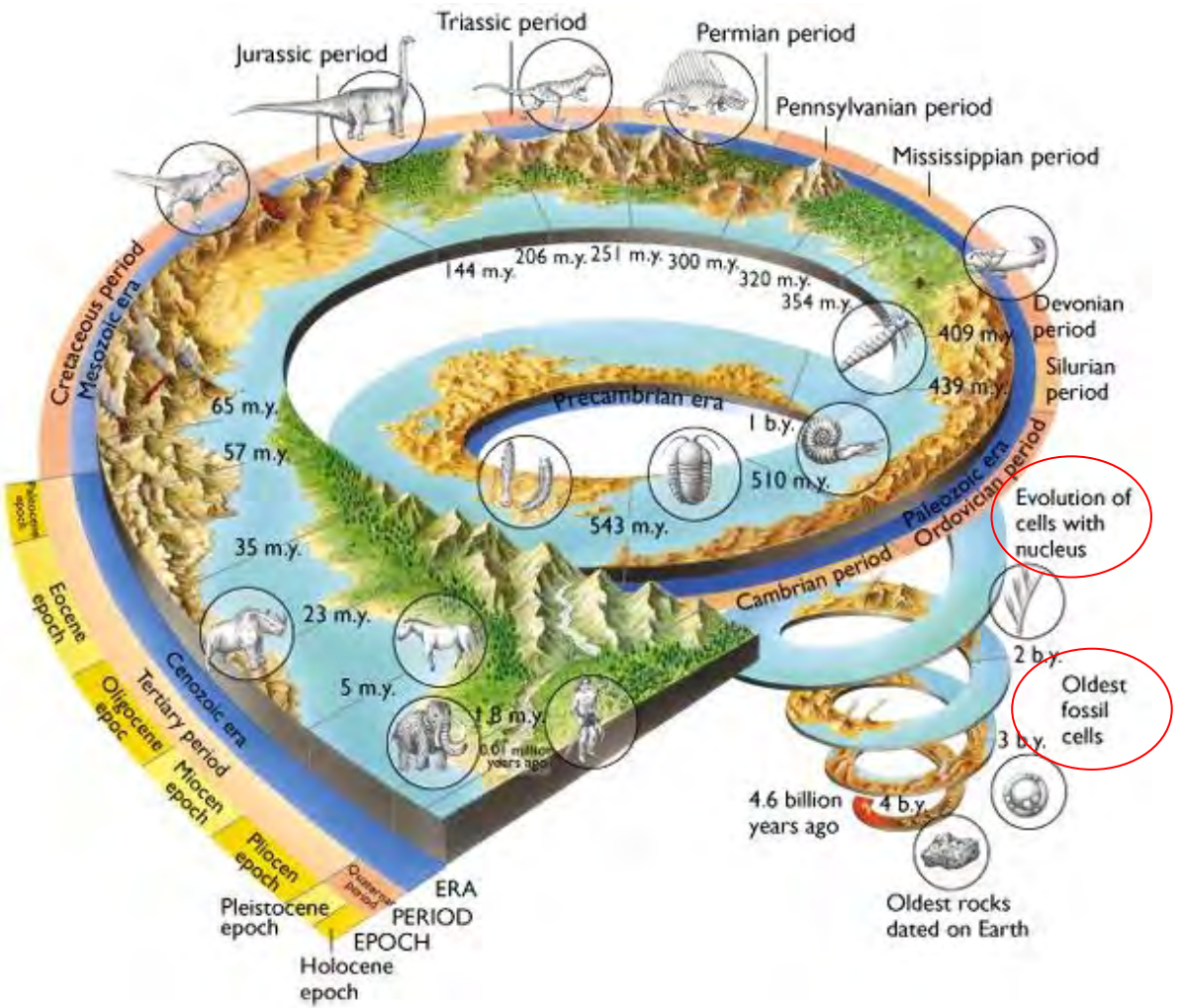
~1.5 * 10^9 years ago (or more?)

Oldest fossil multicellular organism:

~10^9 years ago

Oldest animal:

~0,57*10^9 years ago



Timeline of life evolution on earth

https://academictips.org/blogs/timeline-of-life-evolution-on-earth/

Reverse Engineering of Life

Living Systems:

Descriptive:

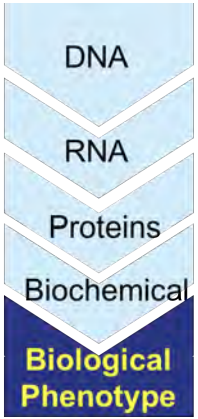
- **Genomics**
- **Transcriptomics**
- **Proteomics**
- **Metabolomics**
- **Epigenetics**
- **Microbiomics**

Systems integration

- **Physiology**

‘Life-cyle’

- **Epigenetics**
- **Developmental biology**
- **Evolution**



Genomics

Transcriptomics

Proteomics

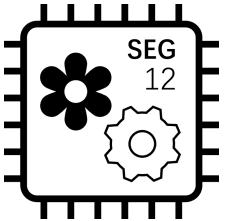
Metabolomics

https://en.wikipedia.org/wiki/Metabolomics

Environment and biologic system of systems:

- **Exposomics**
- **Ecosystems**
- **Ecosystem Evolution**
- **Gaia**

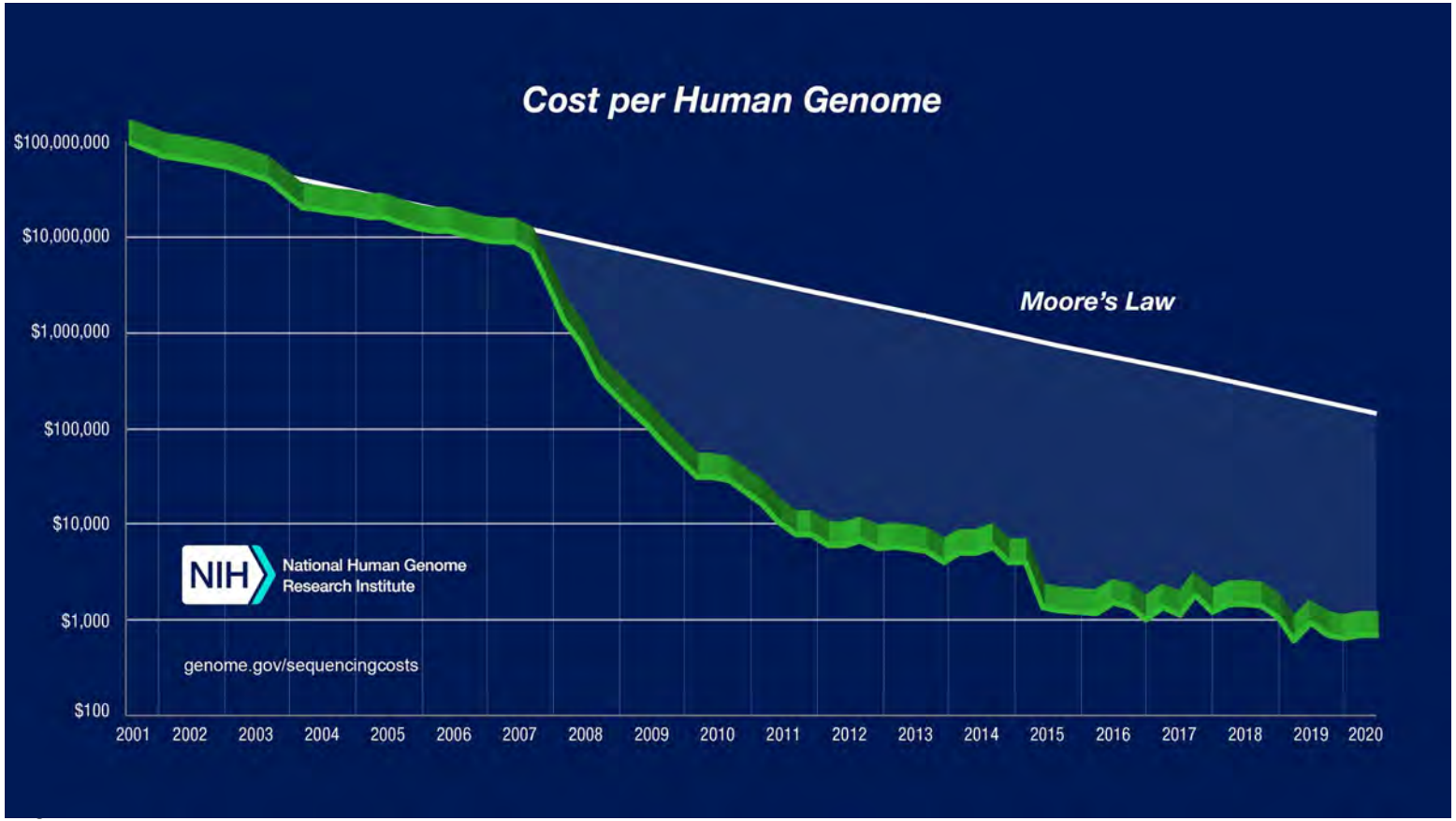
How much information?



For a human

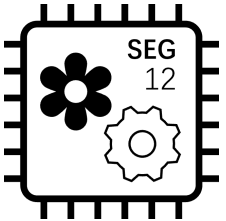
- Genome: ~3x10^9 base pairs, ~700 MB of very complex programming - need a cellular factory to 'decode' and additional 'instructions' to 'execute' ~22 000 genes
  - + *mitochondrial DNA (~17 000 base pairs)*
- Proteome: ~20 000 proteins (encoded in about 1% of the human genome)
- Metabolome: ~+110 000 molecules
- Microbiome: ~+316 000 000 genes.

Cost per genome data - August 2020

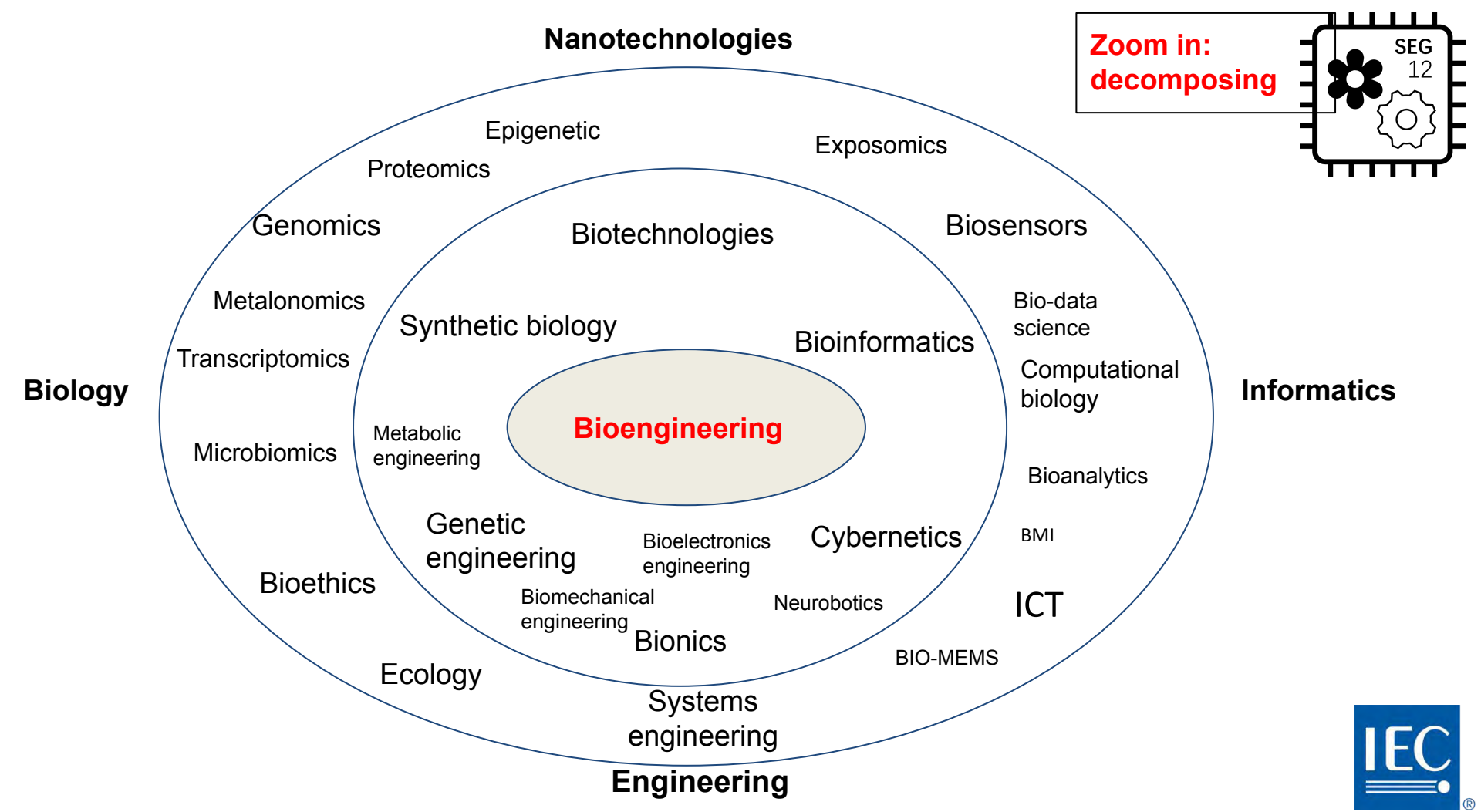


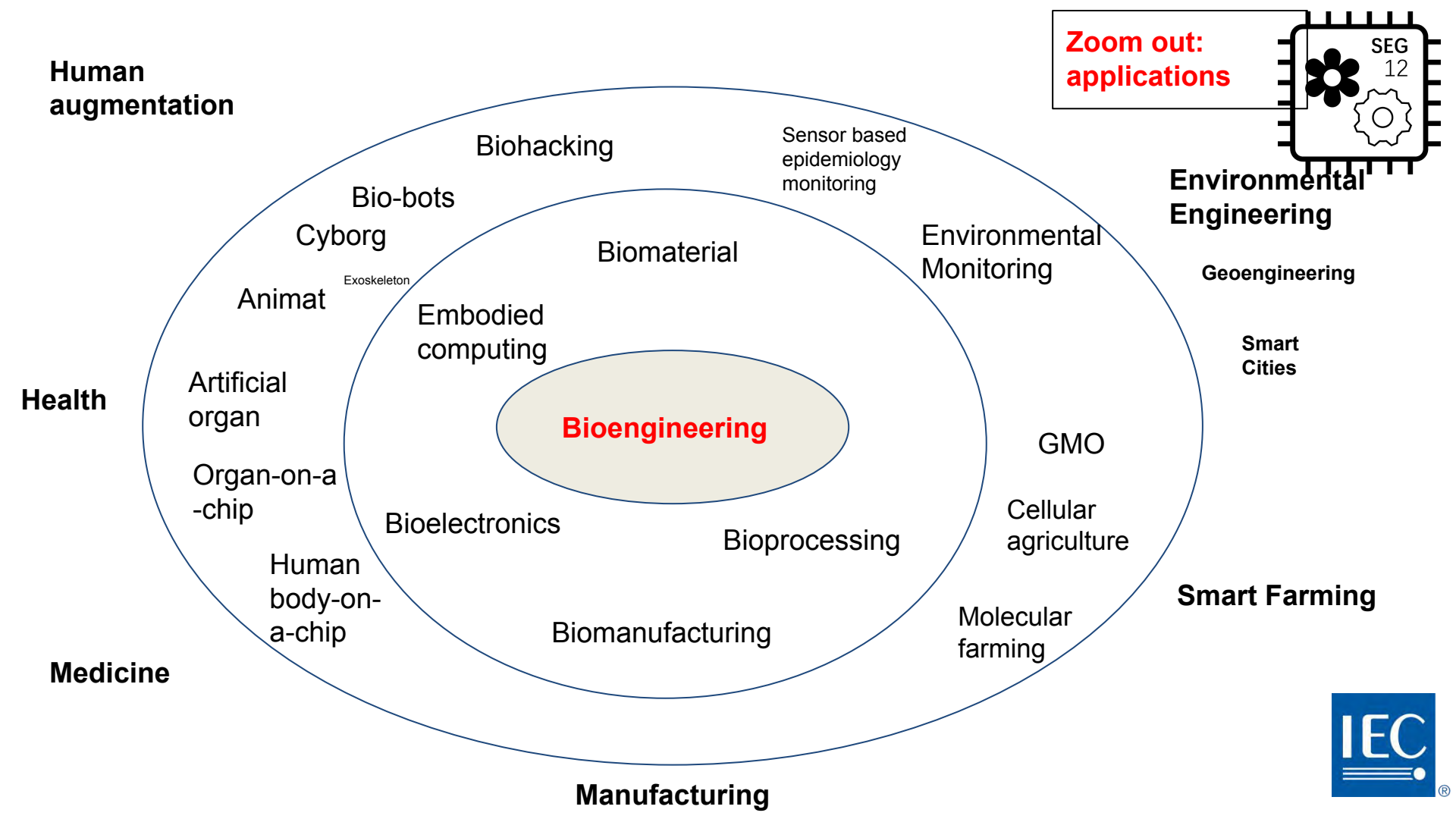
https://www.genome.gov/about-genomics/fact-sheets/DNA-Sequencing-Costs-Data

Forward Engineering



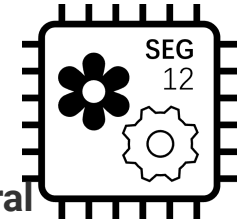
How digital technologies are turbocharging the engineering of biological systems and systems of systems *(enabling bioengineering)*


Nanotechnologies
Zoom in: decomposing
SEG 12
Epigenetic
Exposomics
Proteomics
Genomics
Biotechnologies
Biosensors
Metalonomics
Bio-data science
Synthetic biology
Bioinformatics
Transcriptomics
Biology
Computational biology
Informatics
Bioengineering
Metabolic engineering
Microbiomics
Bioanalytics
Genetic engineering
Bioelectronics engineering
Cybernetics
BMI
Bioethics
Biomechanical engineering
Neurobotics
ICT
Bionics
BIO-MEMS
Ecology
Systems engineering
Engineering


Zoom out: applications
SEG 12
Human augmentation
Biohacking
Sensor based epidemiology monitoring
Environmental Engineering
Bio-bots
Cyborg
Biomaterial
Environmental Monitoring
Geoengineering
Exoskeleton
Animat
Embodied computing
Smart Cities
Health
Artificial organ
Bioengineering
GMO
Organ-on-a-chip
Bioelectronics
Cellular agriculture
Bioprocessing
Human body-on-a-chip
Smart Farming
Biomanufacturing
Molecular farming
Medicine
Manufacturing
IEC

https://www.iec.ch/standards-development/systems-approach

IEC Standardization Evaluation Group (SEG)



The purpose of the standardization evaluation group is to assess systems including several technologies, that are normally covered by the work of more than one technical committee (TC). SEGs are set up both to evaluate new technology areas and to look at existing systems and technologies.

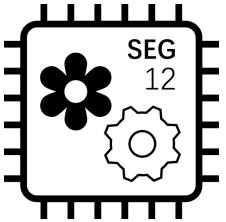
SEGs are mandated to:

- define a system and its scope
- identify all impacted stakeholders
- pinpoint relevant technical committees, existing standards and gaps
- propose architectures and roadmaps

The SEG will publish the results of its work so that it can be viewed by all interested parties. SEGs invite the involvement of many experts, including those who do not yet participate in IEC work.

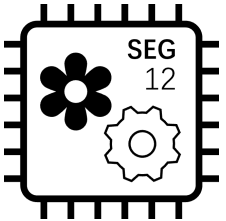
SEGs don't coordinate the technical work between different TCs, this is the role of the Systems Committee (SyC), see column on the right.

IEC/SEG 12 - Scope

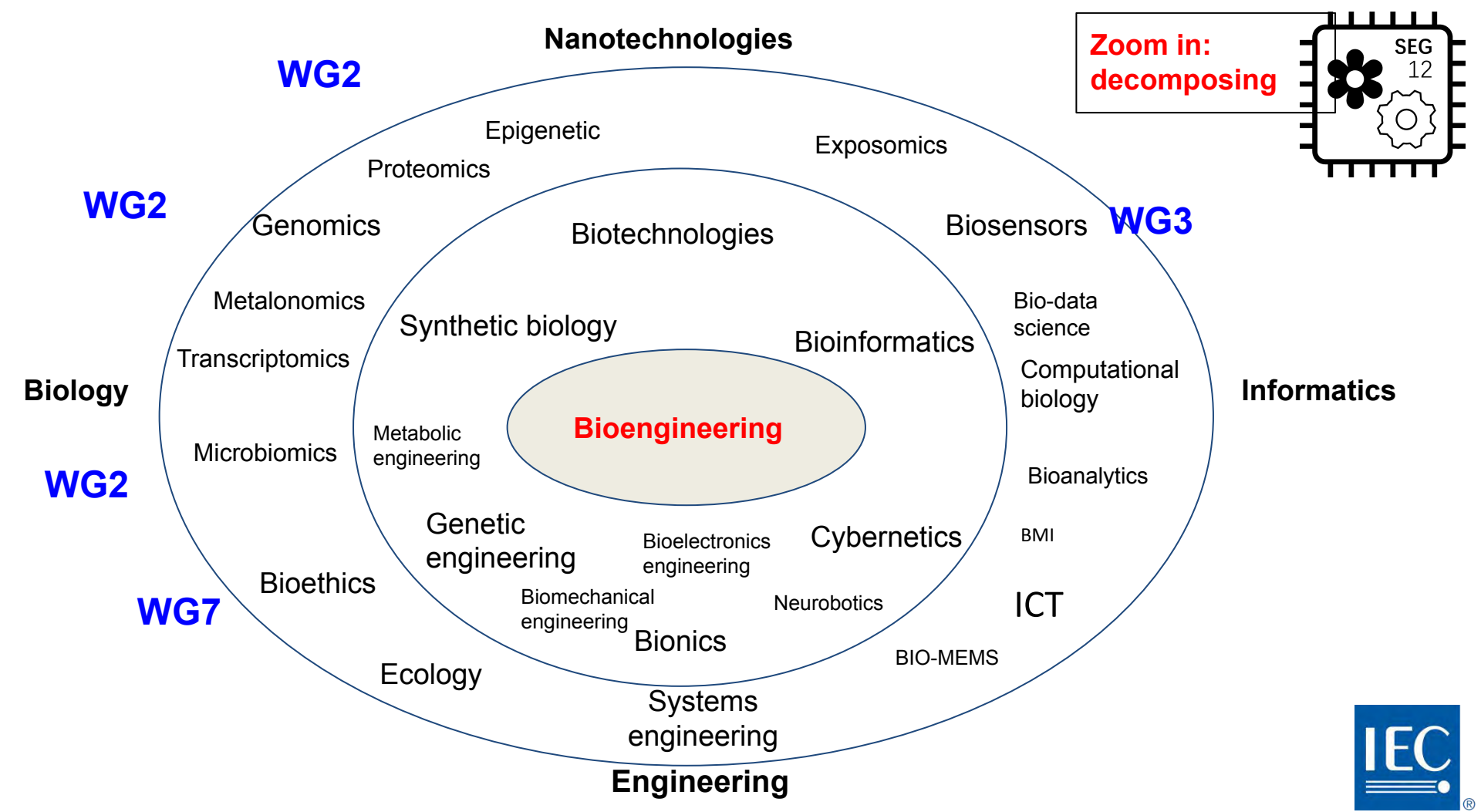


- Investigate current research and technology activities, identify critical challenges, and propose a roadmap for standardization in the area of bio-digital convergence. Ensure close cooperation with and encourage participation from MSB.
- Engage with TC/SC/SyCs including JTC 1 and ISO, as well as with other market and policy relevant organizations, on existing standards and on the need for future standards related to bio-digital convergence.
- Formulate recommendations to SMB as appropriate.

SEG 12 Structure



- WG1 - Communications, Synthesis and Edition of Report
- WG2 - Reverse Engineering of Living Systems
- WG3 - Life systems and Bioengineering
- WG4 - Human Augmentation Technologies
- WG5 - Agricultural Bioengineering
- WG6 - Environmental Bioengineering
- WG7 - Biodigital Social, Risks and Ethical Aspects
- AG8 - Convener Advisory Group


Nanotechnologies
WG2
Epigenetic
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Genomics
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Biosensors
WG3
Metalonomics
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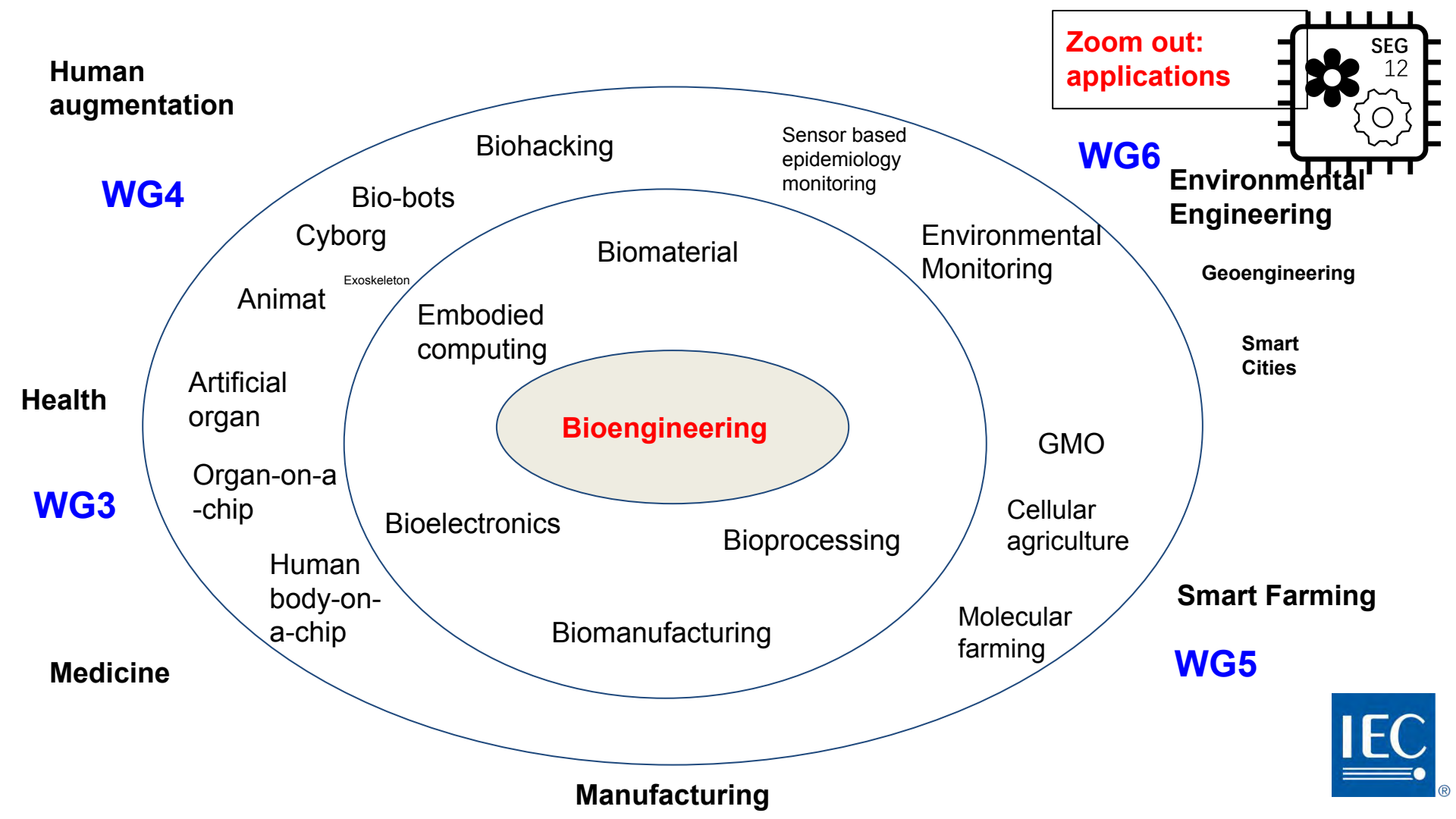
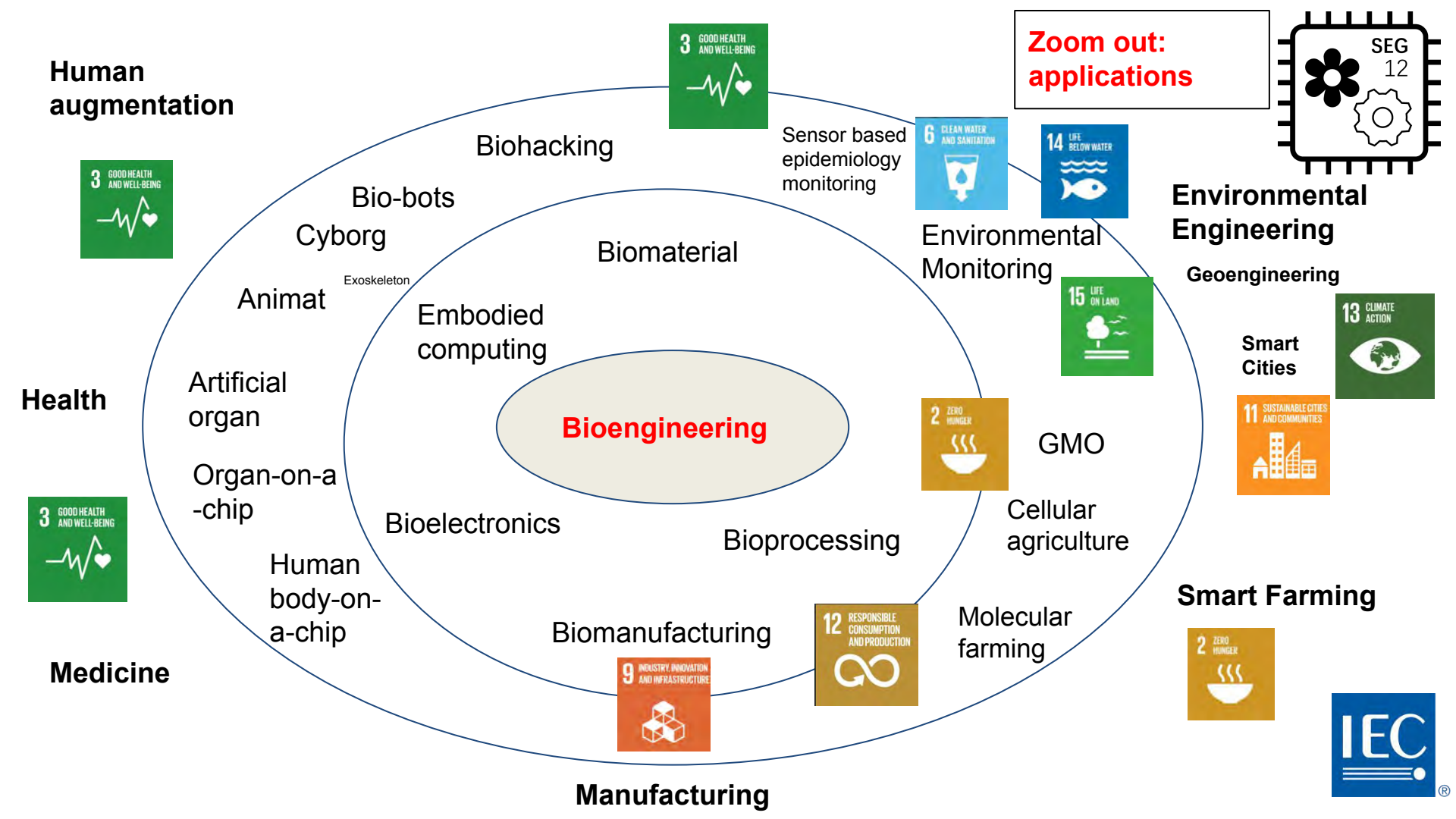
Microbiomics
Bioanalytics
WG2
Genetic engineering
Bioelectronics engineering
Cybernetics
BMI
Bioethics
WG7
Biomechanical engineering
Neurobotics
ICT
Bionics
BIO-MEMS
Ecology
Systems engineering
Engineering
Zoom in: decomposing
SEG 12


Zoom out: applications
SEG 12
Human augmentation
WG4
Biohacking
Sensor based epidemiology monitoring
WG6
Environmental Engineering
Bio-bots
Cyborg
Exoskeleton
Animat
Biomaterial
Environmental Monitoring
Geoengineering
Embodied computing
Smart Cities
Health
Artificial organ
Bioengineering
GMO
WG3
Organ-on-a-chip
Bioelectronics
Bioprocessing
Cellular agriculture
Human body-on-a-chip
Biomanufacturing
Molecular farming
Smart Farming
Medicine
WG5
Manufacturing
IEC


Human augmentation
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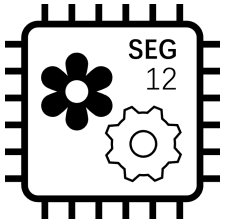
Bioprocessing
Biomanufacturing
Sensor based epidemiology monitoring
Environmental Monitoring
GMO
Cellular agriculture
Molecular farming
3 GOOD HEALTH AND WELL-BEING
6 CLEAN WATER AND SANITATION
14 LIFE BELOW WATER
15 LIFE ON LAND
13 CLIMATE ACTION
11 SUSTAINABLE CITIES AND COMMUNITIES
2 ZERO HUNGER
12 RESPONSIBLE CONSUMPTION AND PRODUCTION
9 INDUSTRY, INNOVATION AND INFRASTRUCTURE
IEC

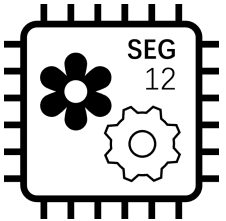
A SEG is a ‘Time boxed’ project



- Fixed delivery date (18-24 months)
- Will document known areas that were not explored or explored adequately
- Recommend how to pursue the work

https://www.projectsmart.co.uk/recommended-reads/time-boxing-strategies-to-help-you-get-things-done-in-your-project.php

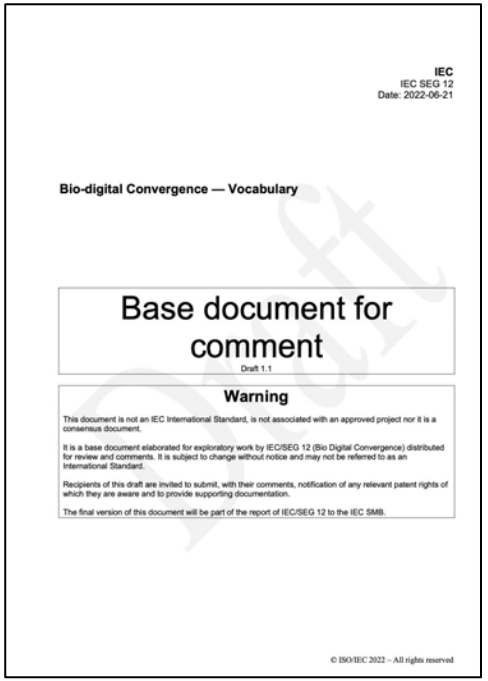
STATUS



- Work is progressing as planned
- Current deliverables:
  - Draft terminology/vocabulary
  - 2 day Webinar in early December 2022
- Planned deliverables (june 2023)
  - SMB report
  - ‘Green’ paper

Vocabulary / Glossary

- Base document for future work
- Cover bioengineering as well as relevant engineering and IT terms
- Current version: 1.4
  - 51 bioengineering terms
  - 34 engineering and IT terms
- Future version will be expanded to include terms and concepts identified by the WGs



IEC
IEC SEG 12
Date: 2022-06-21

Bio-digital Convergence — Vocabulary

Base document for comment

Draft 1.1

Warning

This document is not an IEC International Standard, is not associated with an approved project nor it is a consensus document.

It is a base document elaborated for exploratory work by IEC/SEG 12 (Bio Digital Convergence) distributed for review and comments. It is subject to change without notice and may not be referred to as an International Standard.

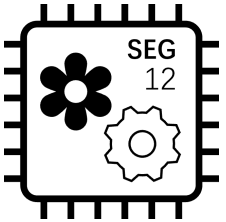
Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

The final version of this document will be part of the report of IEC/SEG 12 to the IEC SMB.

‘Green’ Paper (technology report)

- Freely available IEC technology report
- Will cover all technical areas and ethical and social issues
- Will include vocabulary /glossary

About this Webinar

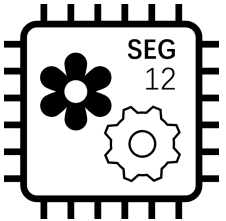


- The objectives are to present a summary of the work accomplished to date by SEG 12 in assessing standardization opportunities in this area and solicit feedback and contributions.
- The presented material, webinar recording and Q&A will be published on the IEC Academy website
- People interested in participating in SEG 12 can register at: https://www.iec.ch/ords/f?p=103:186:617330298393206:::FSP_ORG_ID,FSP_LANG_ID:27561,


Thank you!

Annex: SEG 12 Working Groups Scope

WG 1 - Communications, Synthesis and Edition of Report



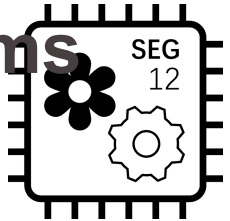
Convener: Dr. François Coallier

Membership: IEC Officer, Conveners of WGs,..

Scope:

- **Communications**
- **Synthesis**
- **‘Horizontal’/cross domains issues and technologies**
- **Edition of reports to SMB**

WG 2 - Reverse Engineering of Living Systems



Conveners: Dr. Yong Zhang and Dr. Zhiwei Cao

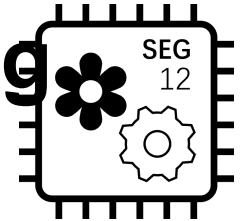
Scope:

BioDigital standardization opportunities for supporting the reverse-engineering of living systems and systems of systems. This includes genomics, transcriptomics, proteomics, metabolomics, informatics, microbiomic, neurosciences, synthetics, …

SDO's:

- **ISO/TC 215/SC1 Genomics Informatics**
- **HUPO Proteomics Standards Initiative (PSI)**
- **Metabolomics Society**
- **EU COordination of Standards in MetabOlomicS (COSMOS)**
- **ISO/IEC JTC 1/SC42 Artificial Intelligence**
- **fairsharing.org**
- **…..**

WG 3 - Life systems and bio-engineering



Conveners: Dr. Joerg Geiger and Dr. William Wasswa

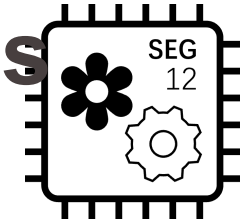
Scope:

BioDigital standardization opportunities in life systems and bio-engineering. This includes biosensors, biometrics, bio-foundries, bioprocessing, biofuels, drug discovery and engineering, synthetic biological circuit, metabolic engineering, genetic engineering, artificial life, Organ-on-Chip (OoC), artificial organs,...

SDO's:

- **ISO/TC 229 Nanotechnologies**
- **JTC1/WG12 3D Printing and Scanning**
- **JTC 1/SC 37 Biometrics**
- **IEC/TC 65/SC65B Measurement and control devices**
- **ISO/TC 276 Biotechnology**
- **European Organ-on-Chip Society (EUROoCS)**
- **CEN/CENELEC Organ on Chip Focus Group**
- **...**

WG 4 - Augmentation technologies



Conveners: Ms. Yuntao Yu and Dr. Philip Troyk

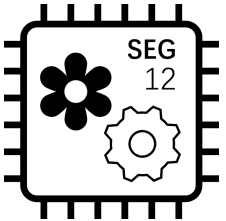
Scope:

BioDigital standardization opportunities in the area of human augmentation. This includes brain-machine interfaces, digital hardware enhancement, ubiquitous and continual monitoring, enhanced strength, enhanced sensing, embodied computing, ambient intelligence and biohacking.

SDO's:

See https://mapping.iec.ch/#/maps/113

WG 5 - Agricultural Bioengineering



Convener: Dr. Raymond Shillito

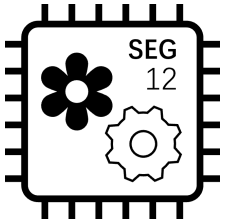
Scope:

BioDigital standardization opportunities in the Bioengineering of agricultural systems and systems of systems, including forestry, aquaculture, livestock farming, cellular agriculture and molecular pharming. This includes internet of things applications (such as precision agriculture), embodied computing for animals, genetic engineering of food as well as the following UN sustainable development goal: zero hunger.

SDO's:

- **ISO Strategic Advisory Group (SAG) on Smart Farming**
- **ISAAA International Service for the Acquisition of Agri-biotech Applications**
- **JTC 1/SC41 Internet of things and digital twin**
- **ISO/TC34/SC16 Horizontal methods for molecular biomarker analysis**
- **ISO/TC34/SC17 Management System for Food Safety**
- **ISO/TC 234 Fisheries and aquaculture**
- **ISO/TC 23/SC 19 Agricultural electronics**
- **ISO/TC 276 Biotechnology****
- **CEN/TC 275 Food analysis - Horizontals methods****
- **...**

WG 6 - Environmental Bioengineering



Conveners: Mr. Ricky Spencer and Dr. François Coallier

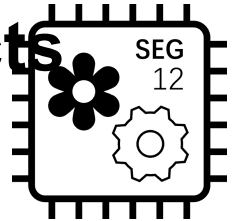
Scope:

BioDigital standardization opportunities in the area of environmental systems of systems. This includes geoengineering, sustainability and the following UN sustainable development goals: climate action, life below water and life on land.

SDO's:

- **JTC 1/SC41 Internet of things and digital twin (WG7 Maritime, underwater IoT and Digital Twin applications)**
- **ISO/TC207 Environmental Management**
- **ISO/TC 331 Biodiversity**
- **...**

WG 7 - BioDigital Social, Risk & Ethical Aspects



Convener: Ms. Andrea Romaoli

Scope:

Social, ethical, risks, resilience, safety management issues pertinent to BioDigital convergence to be considered in an international standardization context. Include data governance and related issues.

SDO's:

- **IEC SyC Active Assisted Living**
- **IEEE P2049.4 Human Augmentation: Methodologies and Processes for Ethical Considerations**
- **...**

WG 2 Reverse Engineering of Living Systems

Standardization opportunities to support the reverse engineering of living systems

Convenors: Dr. Yong ZHANG, and Dr. Zhiwei CAO

2022.12.06

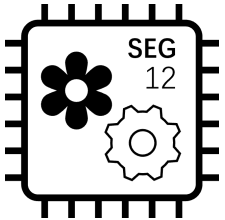
International Electrotechnical Commission

IEC/SEG 12 Bio-Digital Convergence
WG 2 Reverse Engineering of Living Systems

- **Convenor: Dr. Yong Zhang; Co-Convenor: Dr. Zhiwei Cao**

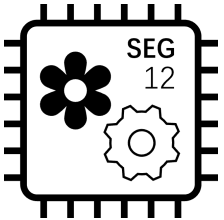
- **Members (as of 27th Nov, 2022)**
  - **23 memebers**
  - **From 7 countries: Brazil, China, Ireland, Germany, Switzerland, UK, USA**
  - **Participations from national bodies or from ISO/IEC partners.**

WG 2 Reverse Engineering of Living Systems Scope



- BioDigital standardization opportunities for supporting the reverse-engineering of living systems and systems of systems.
- This includes genomics, transcriptomics, proteomics, metabolomics, informatics, microbiomic, neurosciences, synthetics, etc.

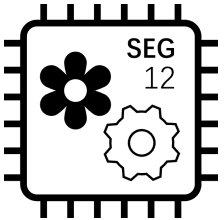
Challenges and Great Opportunities



- State-of-art technologies in "reverse-engineering of living systems and systems of systems". Three Key Topics selected in WG 2: OMICS, Synthetics, Neurosciences.

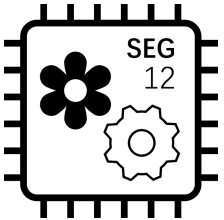
- Concepts revolution:
  - from Biology/Biotechnology to Bio-digital convergence (IEC/SEG 12)
- Lack of standards:
  - fundamental mechanisms, theory, instruments, data, tools, etc. (related to OMICS, Synthetics, and Neurosciences).
- Engineering perspective:
  - framework, instruments, pipelines, procedures, reverse-engineering, data relevant, systems relevant, etc.
- Explosive growing:
  - The industries, academics, engineers have been widely used the technologies.
  - Many major breakthroughs were using/based on those technologies.
- Extensive activities:
  - More and more experts, SDOs are involved into relevant activities for standards development.

Who needs Standardization?



- Industrial partners (Large companies, and small companies)
  - Billions USD projects, Future Applications, etc.
- Academic researchers
  - Fundamental researches for theory, tools, design, new living systems, etc.
- Governments, and regulatory authorities
  - Better and efficient supports to those industrial directions, etc.
  - Potential risk for man-kind, environments, etc.
- Business Development Entities (Organizations)
  - Participating the revolution, accelerate own business or activities
- Users/individuals, who use and are benefited from those technologies
  - Better understanding for the technologies
  - Power and knowledge for self-protections

Current Progress in WG 2



- Analysis of user cases and gaps analysis.
- Assign leaders for leading developments of three selected topics
- Analysis of standardization requirements and gaps
- Overview map for: 1) OMICS, 2) Synthetics, 3) Neurosciences.
  - to support and guide further discussion and developments

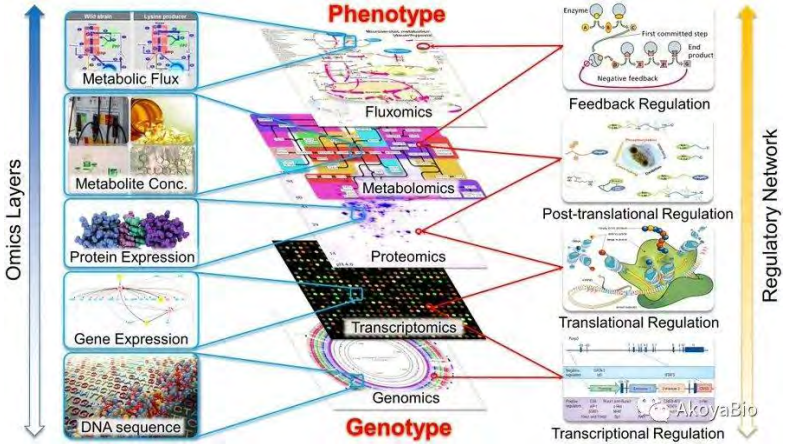
- Analyze current SDOs, and standards
- Prepare action items and recommendations

1. Omics (Genomics, Transcriptomics, Proteomics, Metabolomics, etc.)

SEG 12

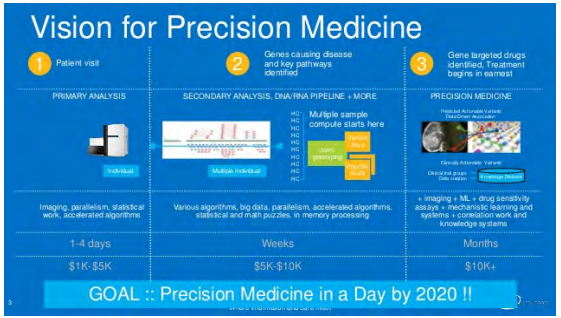
Definition

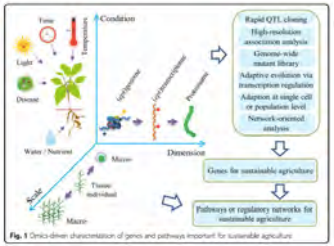
Omics refers to a field of study in biology ending in -omics, such as genomics, transcriptomics, proteomics, metabolomics or epi-genomics, etc.
One of Key characteristics is Big Data.

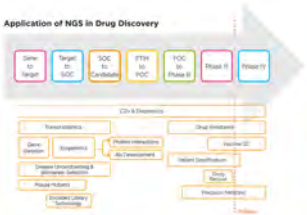


Omics Layers and Connections from genotype to phenotype.

Instruments for OMICS



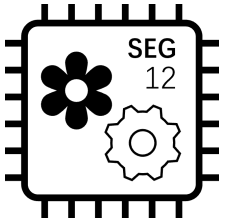




Applications (PM, Agri, Drug, etc) of OMICS

By Dr. Yong ZHANG

1. OMICS (2)



Standards efforts

- **ISO/TC 276 Biotechnology**

ISO 20397-1:2022 Biotechnology — Massively parallel sequencing — Part 1: Nucleic acid and library preparation
ISO 20397-2:2021 Biotechnology — Massively parallel sequencing — Part 2: Quality evaluation of sequencing data
ISO AWI 20397-3 Biotechnology — Massively parallel sequencing — Part 3: General requirements and guidance for metagenomics
ISO/DTS 24420 Biotechnology — Massively parallel DNA sequencing — General requirements for data processing of shotgun metagenomics

- **ISO/IEC JTC 1/SC 29 Coding f audio, picture, multimedia**

ISO/IEC 23092 Series: Information technology — Genomic information representation (Part 1- Part 6)

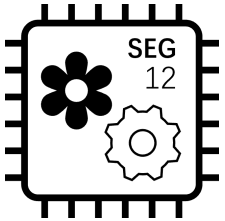
- **ISO/TC 34/SC 16 Horizontal methods for molecular biomarker analysis**

ISO 16578:2022 Molecular biomarker analysis — Requirements for microarray detection of specific nucleic acid sequences

- **ISO/TC 34/SC 9 Microbiology**

***ISO 23418:2022* Microbiology of the food chain — Whole genome sequencing for typing and genomic characterization of bacteria — General requirements and guidance**

1. OMICS (3)



Standards efforts

- **ISO/TC 215/SC 1 Genomics Informatics**

ISO 4454:2022 Genomics informatics — Phenopackets: A format for phenotypic data exchange
ISO/TS 22692:2020 Genomics informatics— Quality control metrics for DNA sequencing
ISO/TS 22693:2021 Genomics informatics — Structured clinical gene fusion report in electronic health records
ISO 25720:2009 Health informatics — Genomic Sequence Variation Markup Language (GSVML)
ISO 21393:2021 Genomics informatics — Omics Markup Language (OML)
ISO/CD TR 21394.2 Genomics informatics — Whole Genomics Sequence Markup Language (WGML)
ISO/CD TS 23357 Genomics Informatics - Clinical genomics data sharing specification for next generation sequencing

- **CEN/TC 140 In vitro diagnostic systems**

CEN/TC 140 In vitro diagnostic Next Generation Sequencing (NGS) workflows — Part 1: Human DNA examination
CEN/TC 140 In vitro diagnostic Next Generation Sequencing (NGS) workflows — Part 2: Human RNA examination

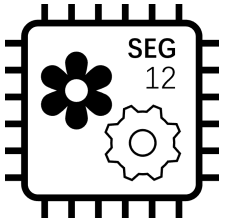
- **EU-STANDS4PM**

Standards for in silico models in personalized medicine: Data sources, in silico models, data access & governance, awareness

- **GA4GH**

Clin/Pheno (Phenopackets V2): ISO 4454:2022 (ISO/TC 215/SC 1)
Cloud; Data security; Discover; Genomic Knowledge; Large Sclae Genomics; Regulatory & Ethics; Resource and Tools;

1. OMICS (4)

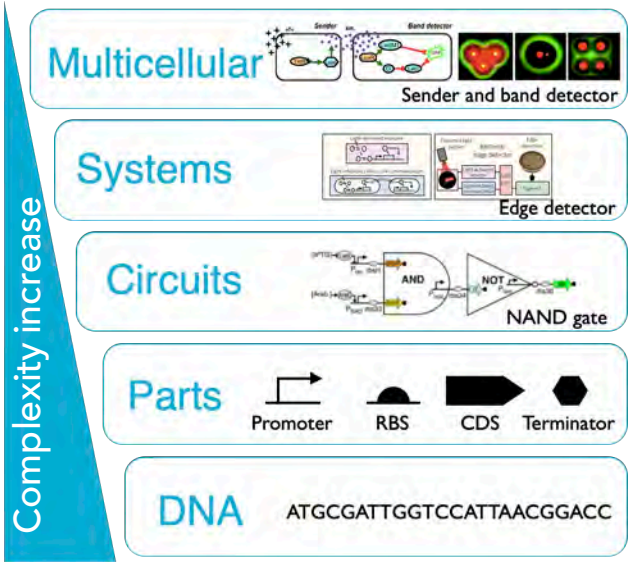


	Key Subjects	Key Factors	Standardization potentials
Instruments	Mechanism, Hardware, Software, Advantages/Disadvantages	Quality, Parameters, Data, Key algorithms	Mature ISO/TC 276, ISO/TC 215
Methods	Sample preparation, Sample quality, Protocols, Bioinformatics, Analysis, etc	Quality of Sample, Quality of Data, Requirements, etc.	Mature (ISO/TC 276, TC 212, TC 215, ISO/TC 34/SC 9/WG 25, CEN/TC 140/WG 3, etc.)
Applications	*Precision Medicine,* *Drug development,* *Agriculture,* *etc.*	Pipeline Structures, Requirements, Analysis process, database, etc.	Mature (ISO/TC 276, TC 212, TC 215, ISO/TC 34/SC 9/WG 25, CEN/TC 140/WG 3, etc.)

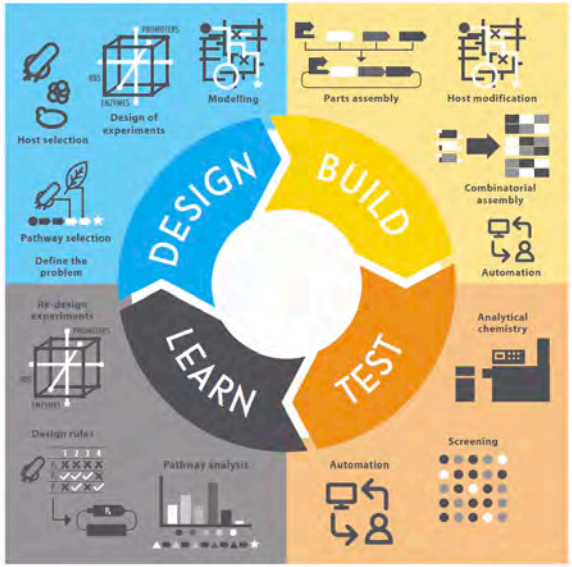
2. Synthetic Biology (1)

Definition

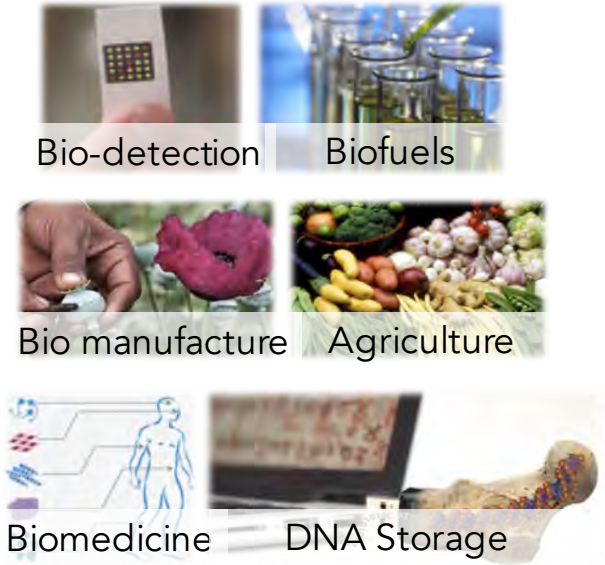
A new emerging multidisciplinary field that seeks to create new biological parts, devices, and systems, or to redesign existing systems for useful purposes and applications.



Abstraction of Synthetic Biology in different scales



Classical iterative "DBTL" cycles of Synthetic Biology



Emerging Applications of Synthetic Biology

By Dr. Yue SHEN

2. Synthetic Biology (2)

Standards efforts

ISO Foresight Trend 2022-Science-Synthetic Biology

- **ISO/TC 276 Biotechnology**

  ISO 5058-1:2021 Biotechnology-Genome editing-Part 1: Vocabulary
  ISO 20688-1:2020 Biotechnology- Nucleic acid synthesis Part 1: Requirements for the production and quality control of synthesized oligonucleotides
  ISO/CD 20688-2 Biotechnology — Nucleic acid synthesis — Part 2: General definitions and requirements for the production and quality control of synthesized gene fragment, gene, and genome

- **ISO/TC 34/SC 16 Horizontal methods for molecular biomarker analysis**

  ISO 16578:2022 Molecular biomarker analysis — Requirements for microarray detection of specific nucleic acid sequences

2. Synthetic Biology (3)

Standards efforts

Other related Organizations & Standards

ASTM E3072-22A

- Standard Terminology for Industrial Biotechnology and Synthetic Biology

Chinese Institute of Electronics（CIE）

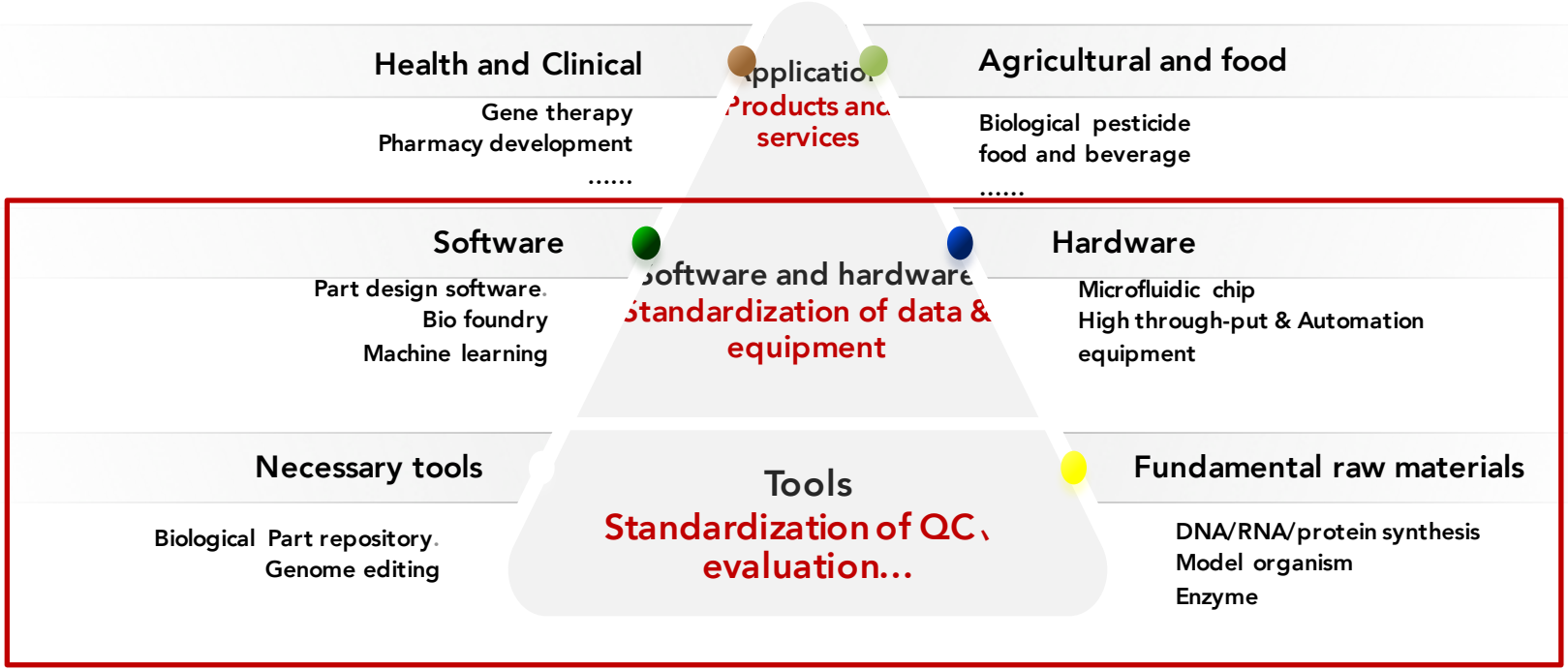
- Technical specification for the coding system in DNA-based information storage

BioRoboost

- Whitebook <Standardisation in Synthetic Biology: A White Book>
  - Technical Core: Metrology, Classis, Yeast, Other eukaryotic systems
  - Social Concerns: Biosafety, Biosecurity, etc.

2. Synthetic Biology (4)

Standards needed



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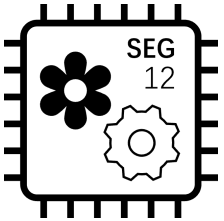
2. Synthetic Biology (5)



	Key factors	Methodologies/Sources	Standardization potentials
DESIGN	Part repository		
	In silico design tools	Computer aided tools	At early stage
	Data mining	Databases	Mature
BUILD	Nucleic acids (DNA/RNA)	Nucleic acids/genome synthesis	Mature (ISO/TC 276/WG 3)
	Peptides	Peptide synthesis	
	Amino acids	Protein engineering/design	
	Proteins		
TEST & APPLY	*In vitro* (cloning, assembly)	PCR/ligation	
	In vivo (prokaryotes, eukaryotes)	Homologous recombination	
	Measurements (Omics, functions)	Sequencing, LC/MS, FCM	Mature
	Screenings & Automations	Colony picking, liquid handling	

IEC®

By Dr. Yue SHEN

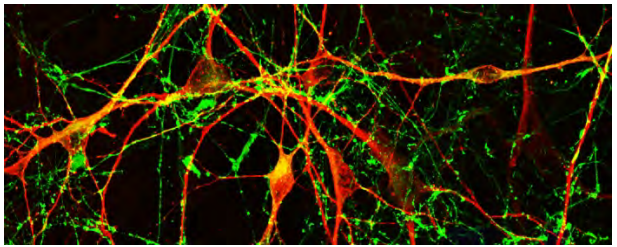
3. Neuroscience (1)

Exploring the Field

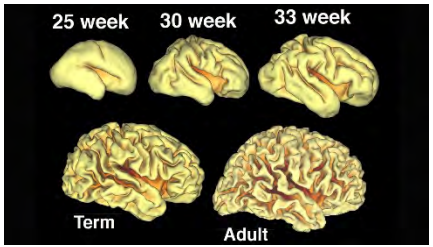
Neuroscience is the study of the nervous system, including the brain, spinal cord, and nerves

- Understand the brain and how it functions
- Understand neurological & psychiatric disorders, discover methods to prevent or cure them
- Simulate and even create a brain or brain-like machines/algorithms – AI / Brain organoids

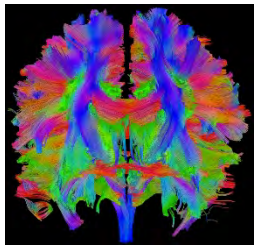
Molecular & Cellular Neuroscience



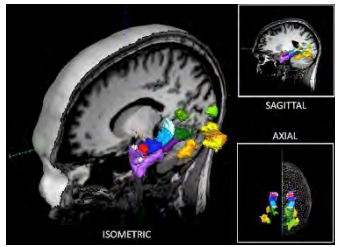
Development Neuroscience



Computational Neuroscience



Cognitive Neuroscience



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3. Neuroscience (2)

Subjects & Fields

Fundamental Research
- Cellular Neuroscience
- Molecular Neuroscience
- …

Neural Engineering
- Neural Imaging
- Neural Informatics
- …

Behavioral & Clinical
- Cognitive Neuroscience
- Affective Neuroscience
- …

Microscopic
Bottom-up

Bridging & Tools

Macroscopic/System
Top-down

Standardization Opportunities

- **Data:** ISO 20691:2022 Biotechnology — Requirements for data formatting and description in the life sciences
- **Devices:** IEC 63077:2019 Good refurbishment practices for medical imaging equipment

By Dr. Jiangbo PU

3. Neuroscience (3)

Standardization Gaps

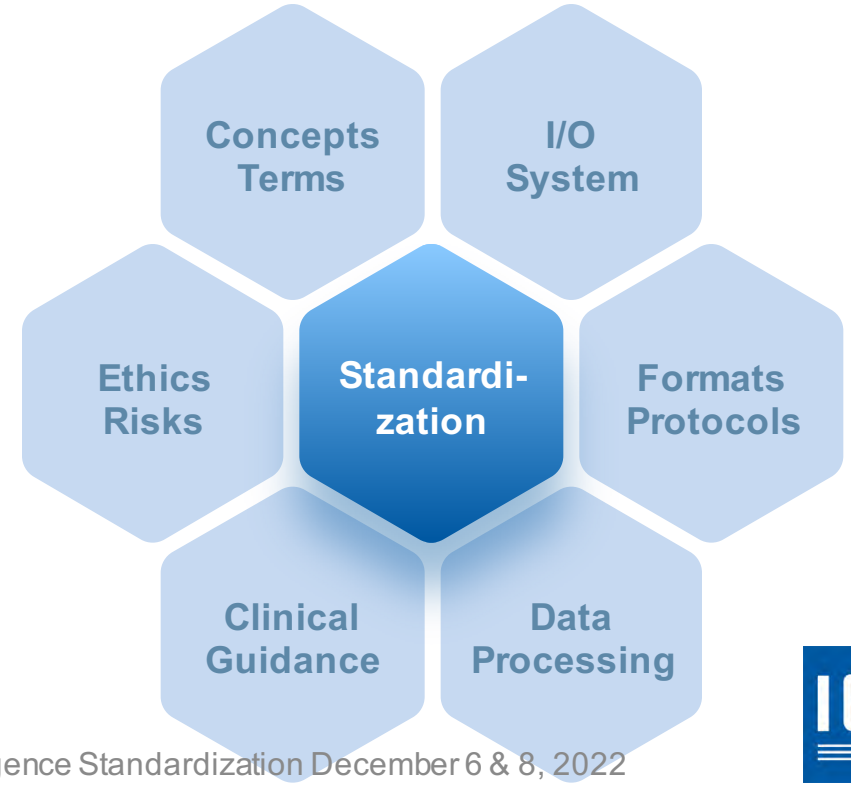
Clinical Neuroscience
- Clinical Guidance / Ethics / Risk Management

Computational Neuroscience
- Models / Data Formats / Algorithms / Databases

Neuroengineering
- Brain-computer Interface / Neurostimulation / Brain Implants

Neuroimaging
- Imaging Hardware (electrical/optical/magnetic/ultra sonic) / Algorithms / Data Formats

Neuroinformatics
- Data Formats / Databases / Algorithms / Interfaces



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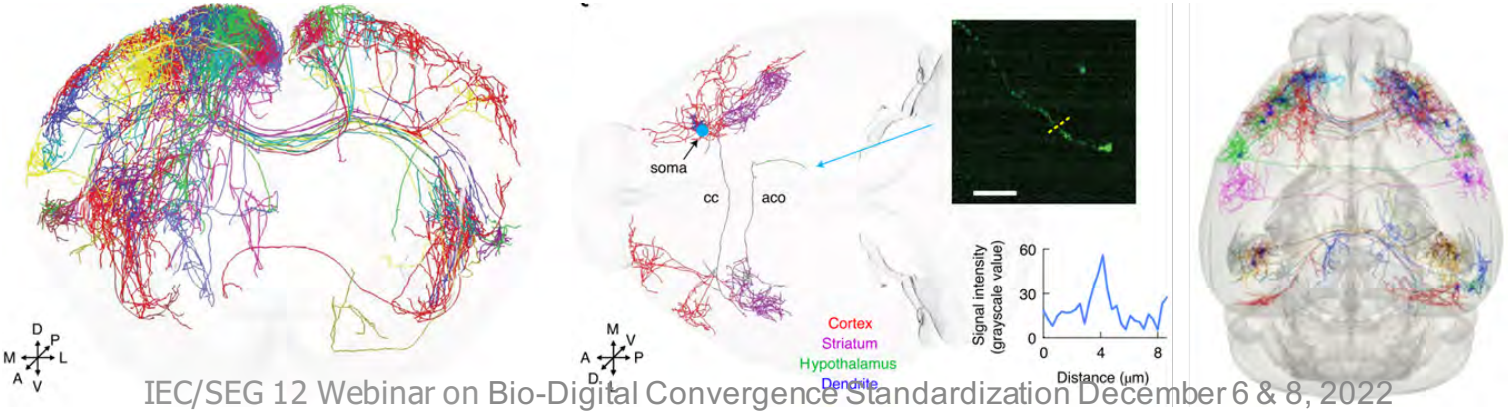
3. Neuroscience (4)

An Example: Sample Preparation for 3D Optical Imaging in the Neural System

Background

- Dissection fine structures as dendritic and axonal morphology of single neuron in brain-wide neural circuits is important.
- Light microscopy has potential to dissect the organization in the whole tissue with mesoscopic resolution.
- However, two gaps need to be solved:
  - To prepare homogeneous samples that maintain the real structure information
  - To have unified standards for the data from different sources for comparison together.



By Dr. Jiangbo PU

3. Neuroscience (5)

An Example: Sample Preparation for 3D Optical Imaging in the Neural System

Existing International Standards

Keywords: Sample preparation, 3D imaging, Biotechnology

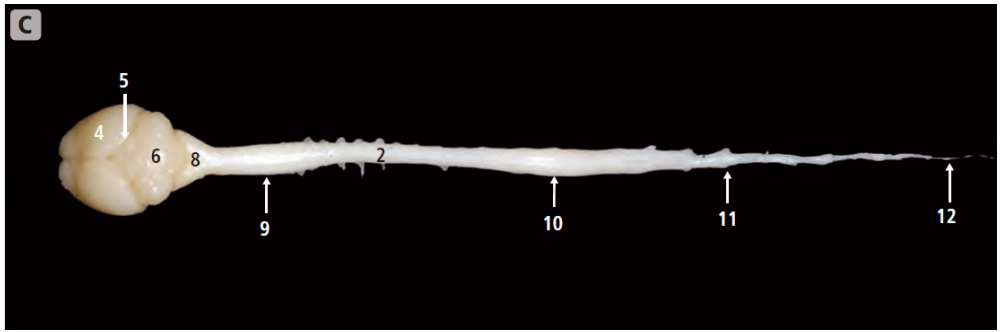
No matching standards in ISO OBP

Keywords: Sample preparation, 3D imaging, Biotechnology

No matching standards

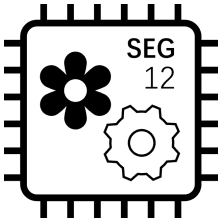
Standardization Needs

- Huge increase in demand of 3D optical imaging
- Focusing on three-dimensional organization of biological structures and the pathological processes, especially as neurodegenerative diseases.
  - **Tissue:** Brain, spinal cord or other tissue
  - **Animal Model:** Mouse, rat, ferret, tree shrew, monkey, post-mortem human tissues
  - **Methods:** Histological staining, transgenic/viral tools fluorescent labeling



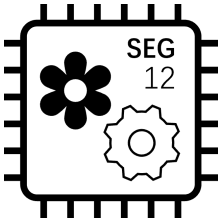
By Dr. Jiangbo PU

Standards Development Organizations (1)



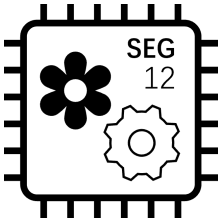
- ISO/TC 276 Biotechnology
- ISO/TC 215 Health informatics
- ISO/TC 215/SC 1 Genomics Informatics
- ISO/TC 34/SC 9 Food Product/Microbiology
- ISO/TC 34/SC 16 Food Product/ Horizontal methods for molecular biomarker analysis
- ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems
- ISO/IEC/ JTC 1/SC 42 Artificial Intelligence
- ISO/IEC/ JTC1/SC 29/WG 8 MPEG (standards for genome compression and storage)
- CEN/TC 140/WG 3 - QUALITY MANAGEMENT IN THE MEDICAL LABORATORY
- …

Standards Development Organizations (2)



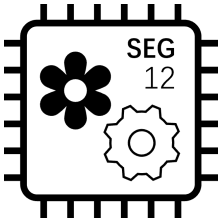
- HUPU Proteomics Standards Initiative (PSI)
- Metabolomics Society
- EU Coordination of Standards in MetabOlomicS (COSMOS)
- Fairsharing.org
- GA4GH (The Global Alliance for Genomics Health)
- EU-STANDS4PM (standards for in silico models for personalised medicine)
- Instand-NGS4P (integrated and standardized NGS workflows for personalised therapy)
- BioRoboost (to enhance biosafety and risk assessment in synthetic biology standards)
- …

Standards (published) (examples)



- ISO 5058-1:2021 Biotechnology — Genome editing — Part 1: Vocabulary
- ISO 20397-1:2022 Biotechnology — Massively parallel sequencing — Part 1: Nucleic acid and library preparation
- ISO 20397-2:2021Biotechnology — Massively parallel sequencing — Part 2: Quality evaluation of sequencing data
- ISO 20688-1:2020 Biotechnology — Nucleic acid synthesis — Part 1: Requirements for the production and quality control of synthesized oligonucleotides
- ISO 21710:2020 Biotechnology — Specification on data management and publication in microbial resource centers
- ISO 20691:2022 Biotechnology — Requirements for data formatting and description in the life sciences

Standards (under development) (examples)



- ISO/AWI TS 9491-1 Biotechnology — Recommendations and requirements for predictive computational models in personalized medicine research — Part 1: Guidelines for constructing, verifying and validating models
- ISO/AWI 20397-3 Biotechnology — Massively parallel sequencing — Part 3: General requirements and guidance for metagenomics
- ISO/CD 20688-2 Biotechnology — Nucleic acid synthesis — Part 2: General definitions and requirements for the production and quality control of synthesized gene fragment, gene, and genome
- ISO/DTS 24420 Biotechnology — Massively parallel DNA sequencing — General requirements for data processing of shotgun metagenomics

Future Plan

- Invite more experts join us
- Continually discuss and draft the report
  - Identify user cases, analysis gaps
  - Analyze standardization requirements and gaps
  - Analyze standardization status and activities
- Discuss about action items and recommendations for three topics (including potential standard proposals)

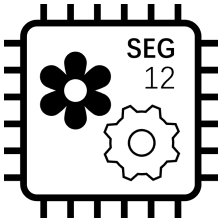
- Host more online meeting for discussion, or start new topics

Action Items

- **Action Items:**
  - **Set up task groups, etc**
  - **Propose standardization roadmaps for selected topics**
  - **Prepare for new standards or proposals to IEC/SEG 12, or IEC/ISO**
  - **Work to meet IEC/ISO goals and requirements**

- **Prepare reports or analysis manuscripts for publication**

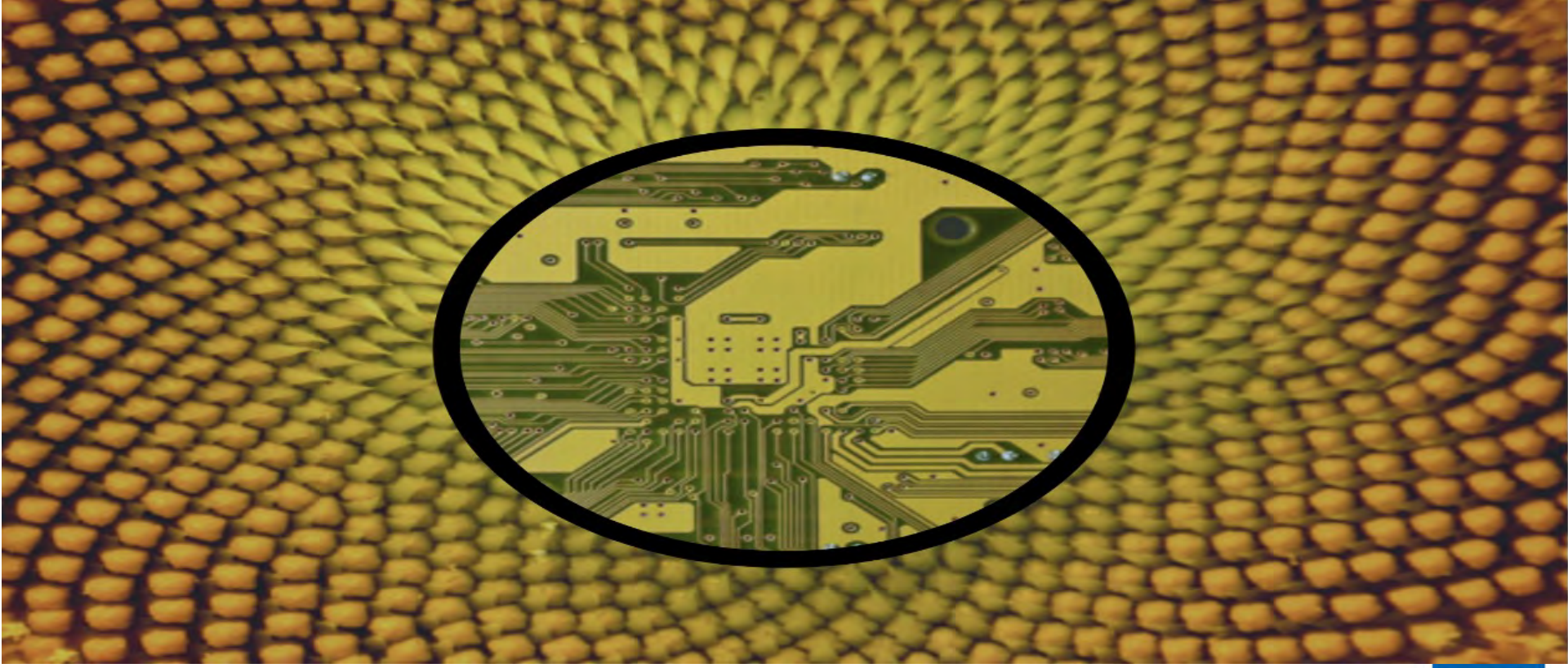
Future developments of standardization in WG 2 Reverse Engineering of Living Systems



- **Basic technologies:**
  - **OMICS, such as sequencing**
  - **Synthetic, such as design, synthesis, evaluation, etc.**
  - **Neurosciences, such as …**
- **Reverse-Engineering:**
  - **How to reverse engineering the living systems**
- **Data:**
  - **Big Data (PB, TB level)**
  - **Data format, data integration, data processing, data interoperability, ownership, security, block chain, etc.**
- **Systems:**
  - **What is the systems, how do you define a systems, design it and transform it.**
- **Living Systems:**
  - **Living Systems …**
- **Interface between Living Systems and "Life Systems and Bio-engineering "(WG 3)**
  - **Interface between , and as bridge, to link, to connect …**
- **...**

Thanks a lot,
Welcome to join IEC/SEG 12/WG 2.

Yong Zhang (yongzhangcn@foxmail.com)
Zhiwei Cao (zwcao@fudan.edu.cn)



WG 3 Living systems standardization

Joerg GEIGER (convenor)

IEC SEG 12 Webinar
Bio-Digital Convergence Standardization

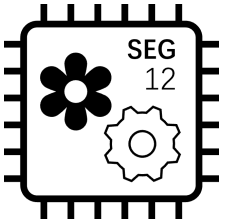
International Electrotechnical Commission

SEG 12

Living systems standardization

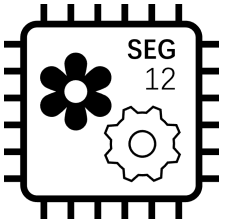
IEC
International Electrotechnical Commission

WG 3 – Facts



- 32 members from ISO, national and international SDOs, industry, academia
- Covering: agriculture, health, biotechnology
- cn, kr, us, ug, ca, uk, de, ie, eu
- Convenors: William WASSWA (ug) and Joerg GEIGER(de)

Scope

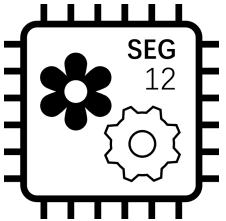


- **BioDigital standardization opportunities in life systems and bio-engineering.**
- **including (but not limited to):**
  biosensors, biometrics, bio-foundries, bio-processing, biofuels, drug discovery and engineering, synthetic biological circuit, metabolic engineering, genetic engineering, artificial life, Organ-on-Chip (OoC), artificial organs

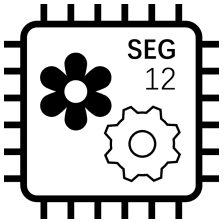
Topics

- Biosensors
- Human Digital Twins
- Synthetic Biology
- Artificial Organs & Organoids
- CAR-T Cells
- CRISPR Technology
- Data Quality

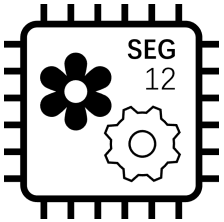
Presentations



- Task Group 1: “Biosensors – Bio-Electronic Nose"
  - Dr. Tai Hyun Park
- Task Group 2: "Human Digital Twins"
  - Dr. Claudia Cotca and Dr. Martin Golebiewski and
- Task Group 3: "Synthetic Biology"
  - Dr. Yue Shen
- Task Group 4: "Artificial Organs & Organoids"
  - Dr. Jiangbo Pu
- Further Standardization Opportunities
  - CAR-T, CRISPR, Data Quality



Biosensors

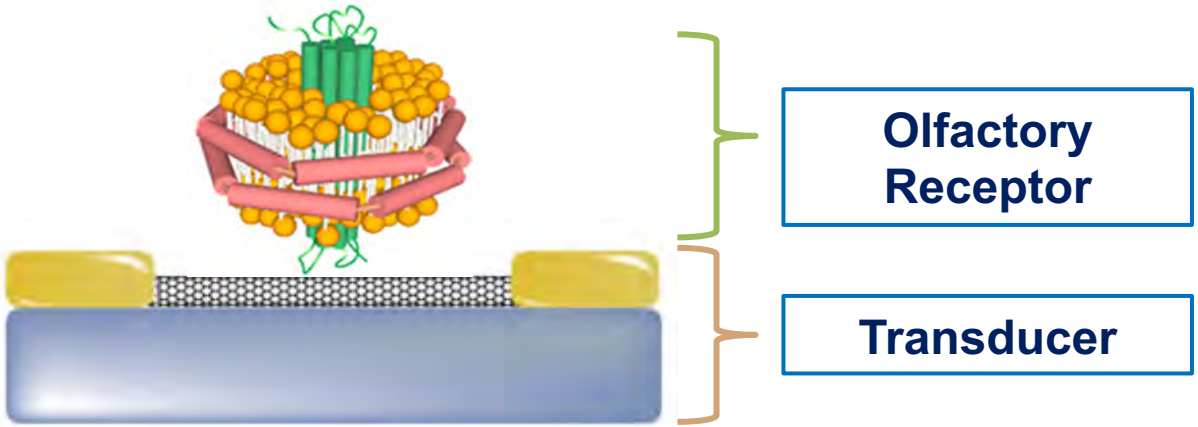


Biosensors
– Bio-Electronic Nose

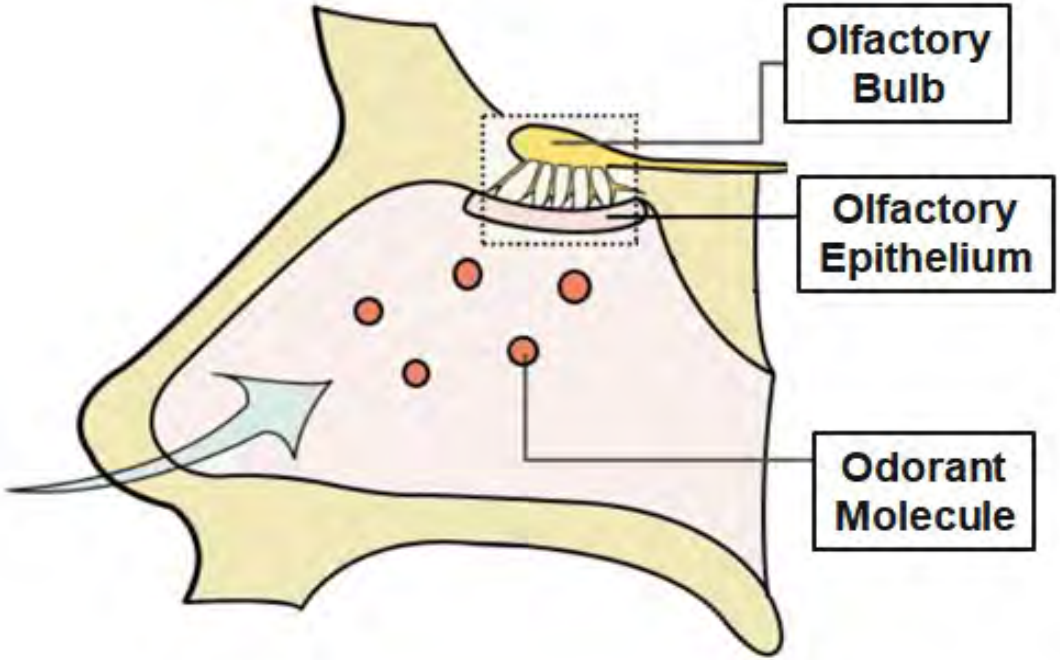
Tai Hyun Park
School of Chemical and Biological Engineering
Seoul National University

Bio-Electronic Nose

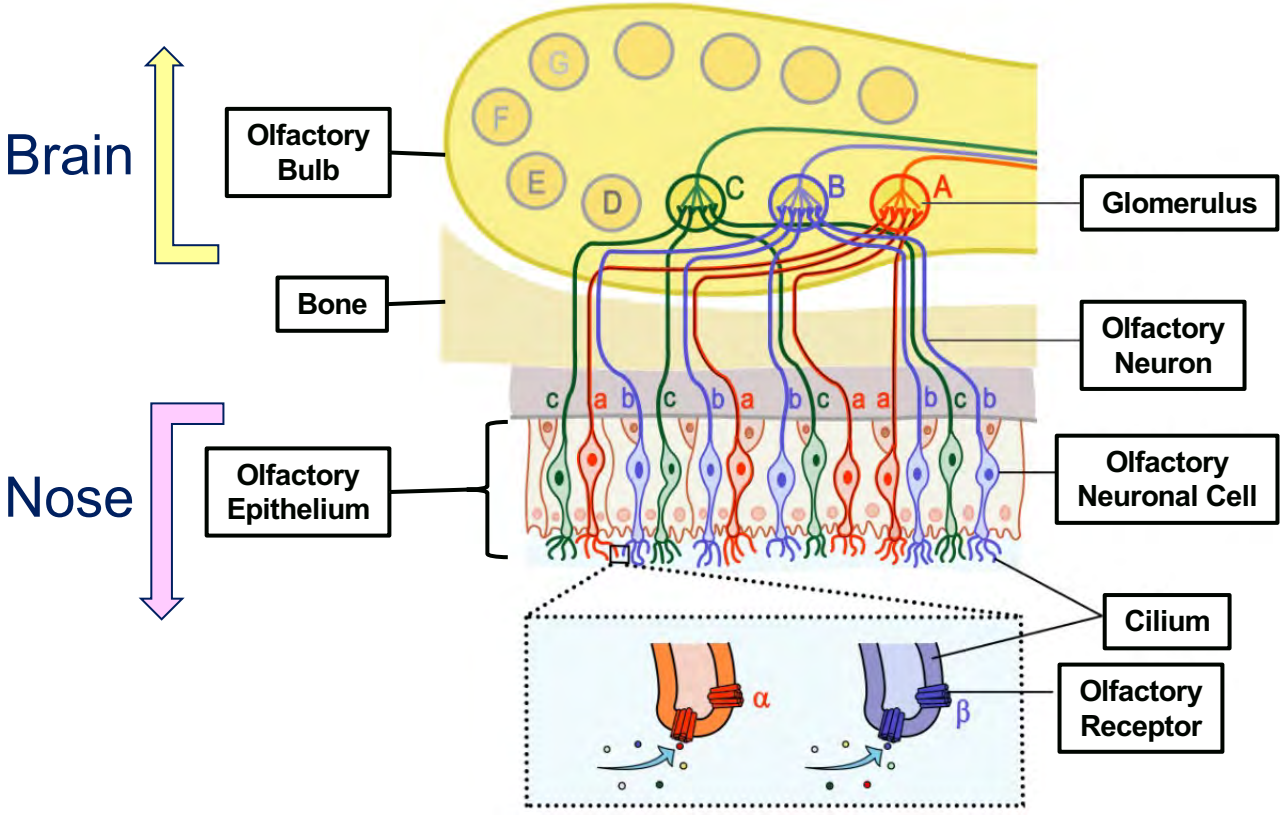
- Concept
  - Olfactory Receptor **(Biological sensing element)**
  - Transducer **(Generation of electrical signal)**



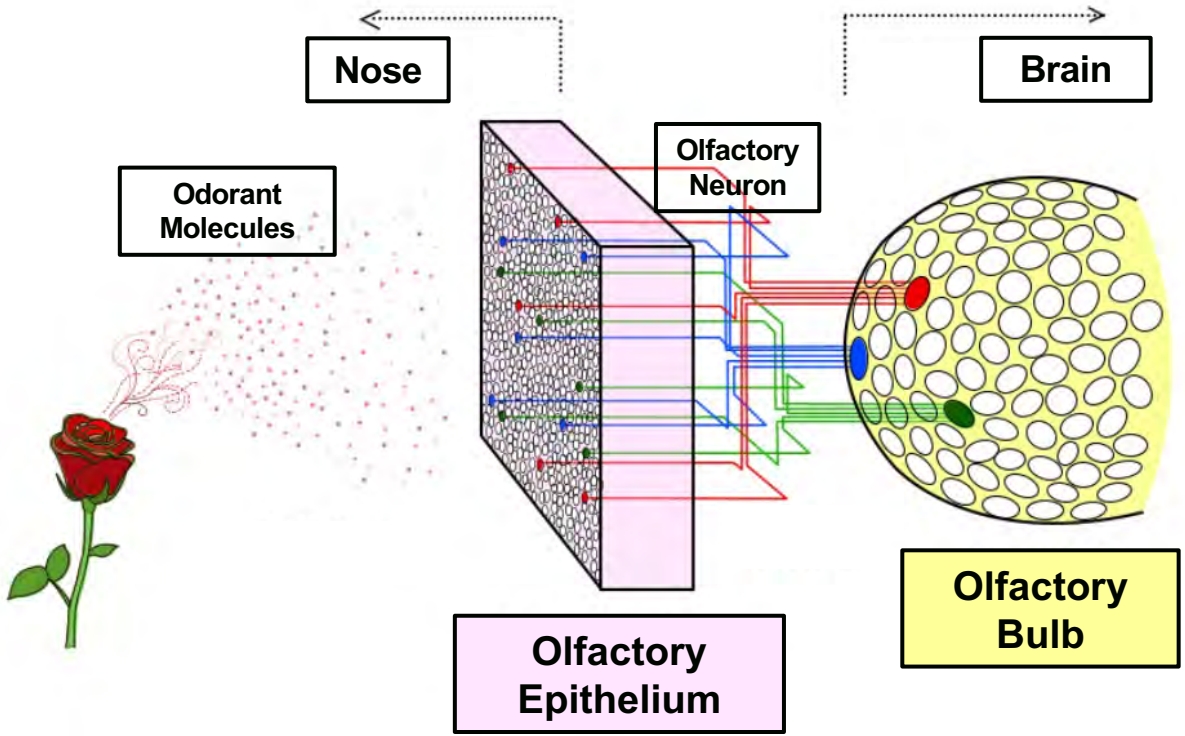
Human Olfactory System



Human Olfactory System

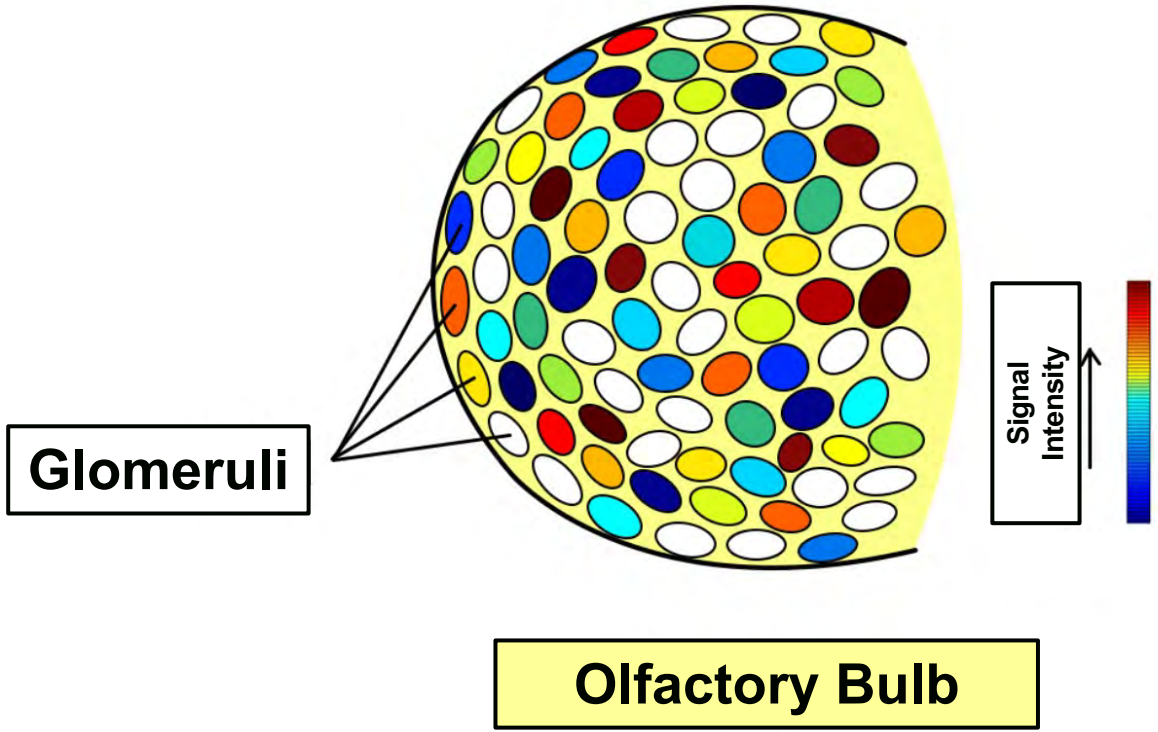


Generation of Combinatorial Pattern

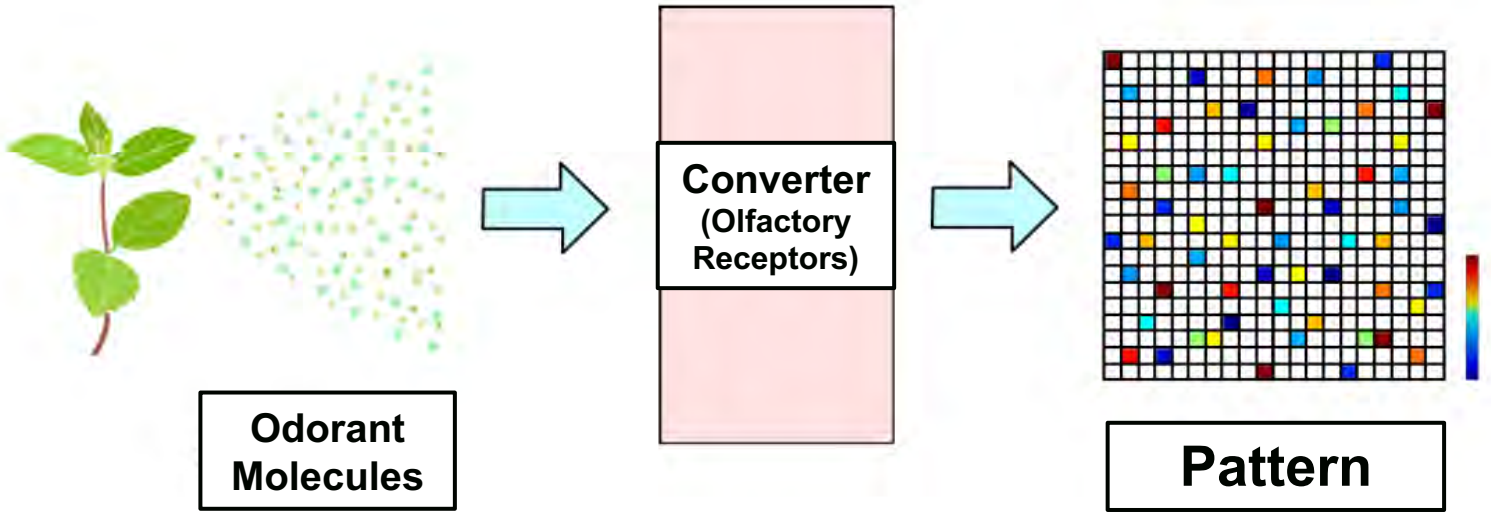


Smell Information:

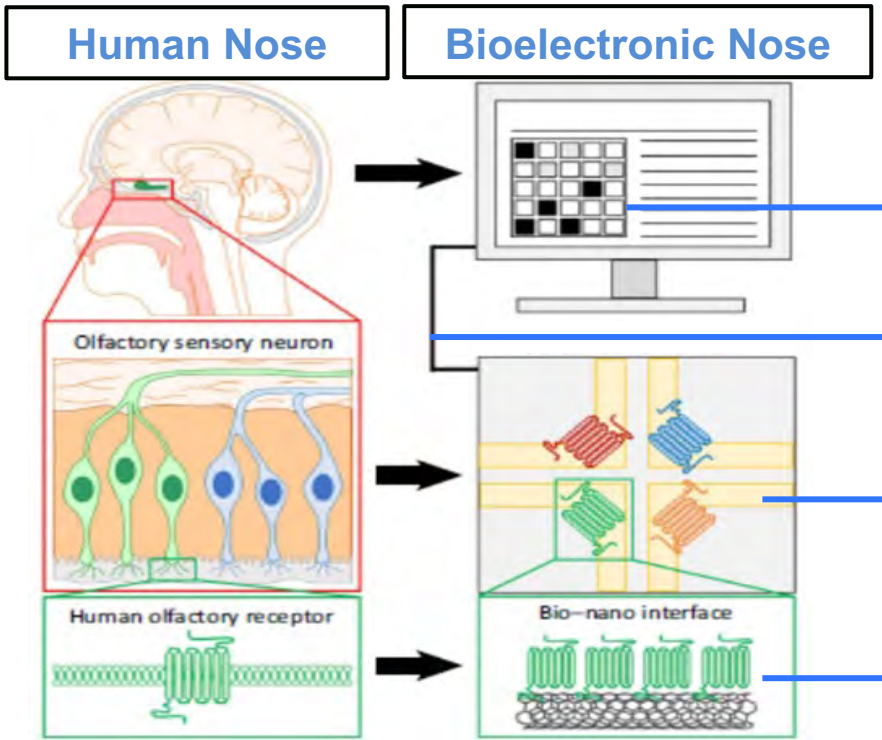
Combinatorial Pattern Projected on Olfactory Bulb



The pattern is made by the binding between odorants and olfactory receptors



Potential Standardization Targets



Pattern Analysis
- Analytics
- AI

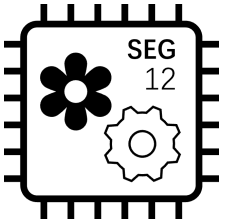
Signal Processing
- Electronics
- Computer Sci

Transducer
- Electronics

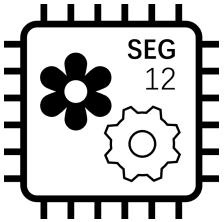
Receptor
- Biotechnology

Son *et al.*, *Trends in Biotechnol.*, 35, 301 (2017)

Applications

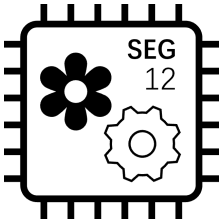


- **Health**
  - diagnostics, wearables
- **Food quality**
  - freshness, spoilage
- **Public safety**
  - virus, toxicant, explosive, drug, etc.
- **Environmental monitoring and assessment**
  - air pollution, water quality



Thank you!

International Electrotechnical Commission



Human Digital Twins

Standardization needs for Digital Human Twins

Martin Golebiewski

HITS - Heidelberg Institute for Theoretical Studies
Germany

IEC webinar on Bio-Digital Convergence Standardization

December 6 - 8 , 2022

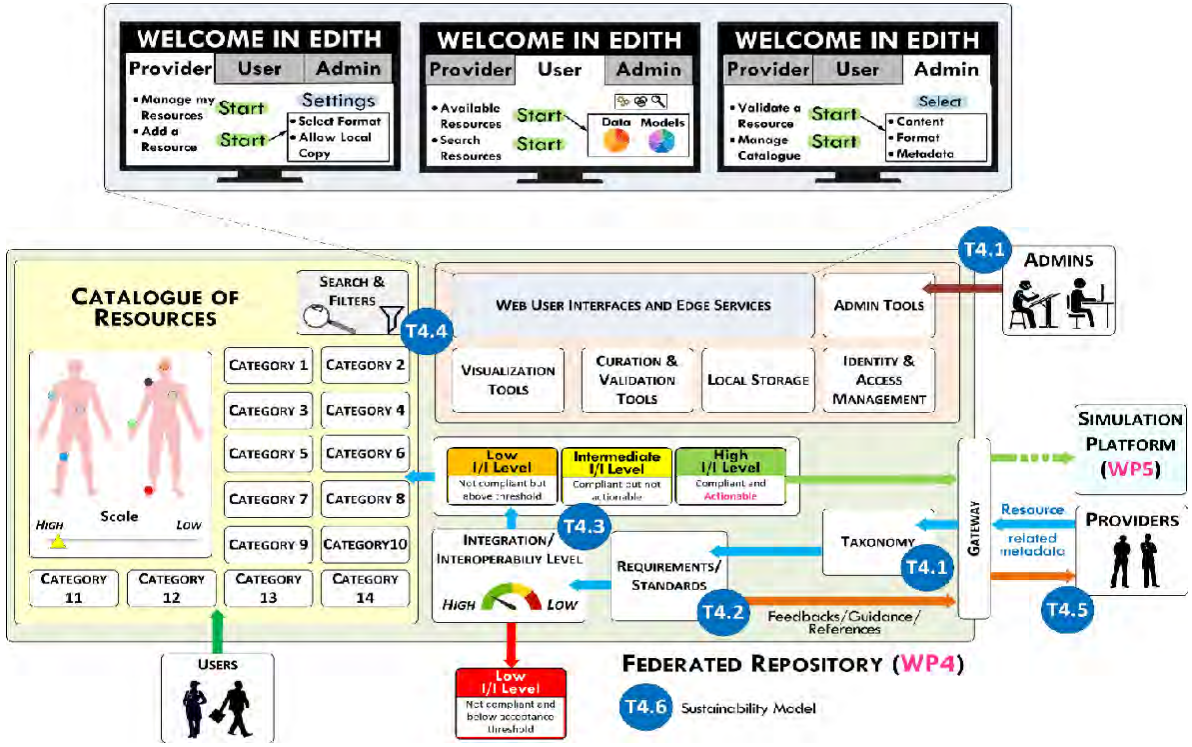
HITS

EU-STANDS4PM standards for in silico models for personalised medicine

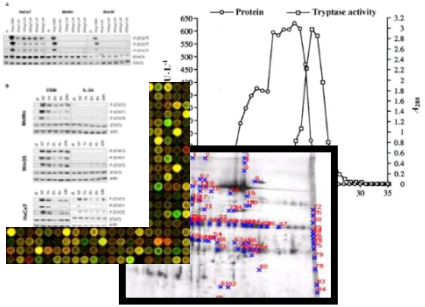
LiSyM Liver Systems Medicine

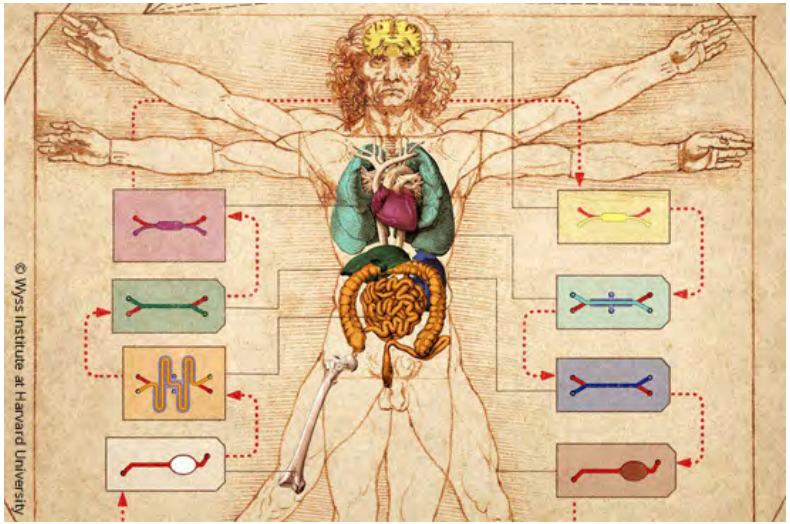
nfdi 4 health

EDITH

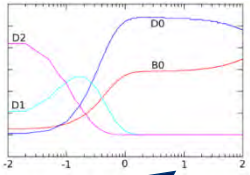

WELCOME IN EDITH
Provider User Admin
• Manage my Resources
• Add a Resource
Start
Start
Settings
• Select Format
• Allow Local Copy
WELCOME IN EDITH
Provider User Admin
• Available Resources
• Search Resources
Start
Start
Data Models
WELCOME IN EDITH
Provider User Admin
• Validate a Resource
• Manage Catalogue
Start
Start
Select
• Content
• Format
• Metadata
CATALOGUE OF RESOURCES
SEARCH & FILTERS
T4.4
CATEGORY 1
CATEGORY 2
CATEGORY 3
CATEGORY 4
CATEGORY 5
CATEGORY 6
CATEGORY 7
CATEGORY 8
CATEGORY 9
CATEGORY10
CATEGORY 11
CATEGORY 12
CATEGORY 13
CATEGORY 14
HIGH
Scale
LOW
USERS
WEB USER INTERFACES AND EDGE SERVICES
ADMIN TOOLS
VISUALIZATION TOOLS
CURATION & VALIDATION TOOLS
LOCAL STORAGE
IDENTITY & ACCESS MANAGEMENT
T4.1
ADMINS
Low I/I Level
Not compliant but above threshold
Intermediate I/I Level
Compliant but not actionable
High I/I Level
Compliant and Actionable
T4.3
INTEGRATION/ INTEROPERABILITY LEVEL
HIGH
LOW
REQUIREMENTS/ STANDARDS
T4.2
Feedbacks/Guidance/ References
TAXONOMY
T4.1
GATEWAY
SIMULATION PLATFORM (WP5)
Resource related metadata
PROVIDERS
T4.5
Low I/I Level
Not compliant and below acceptance threshold
FEDERATED REPOSITORY (WP4)
T4.6
Sustainability Model

Measured Data



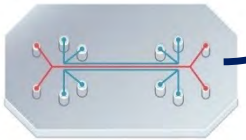


Simulation

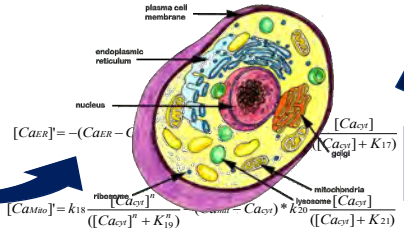


simulate

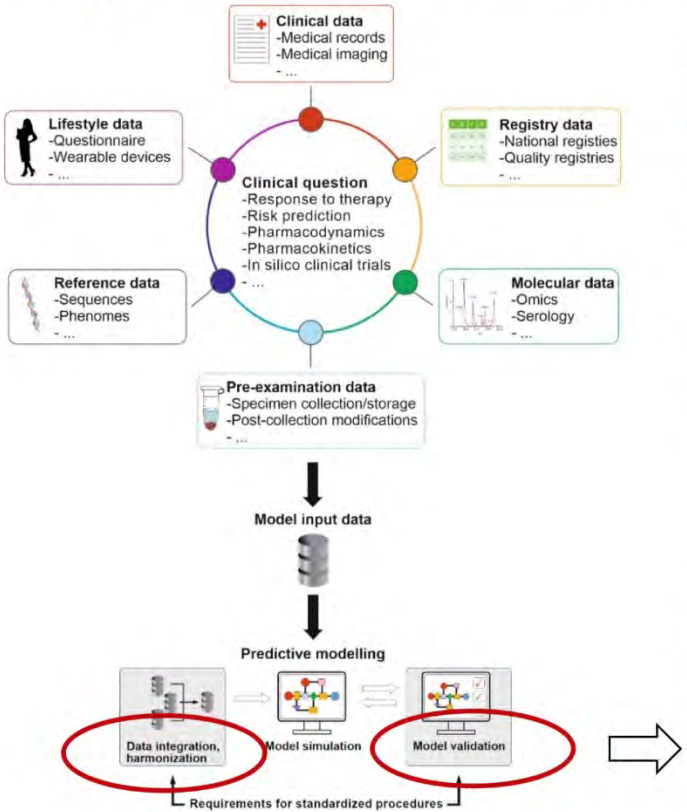
Process Data



collect & integrate



Model



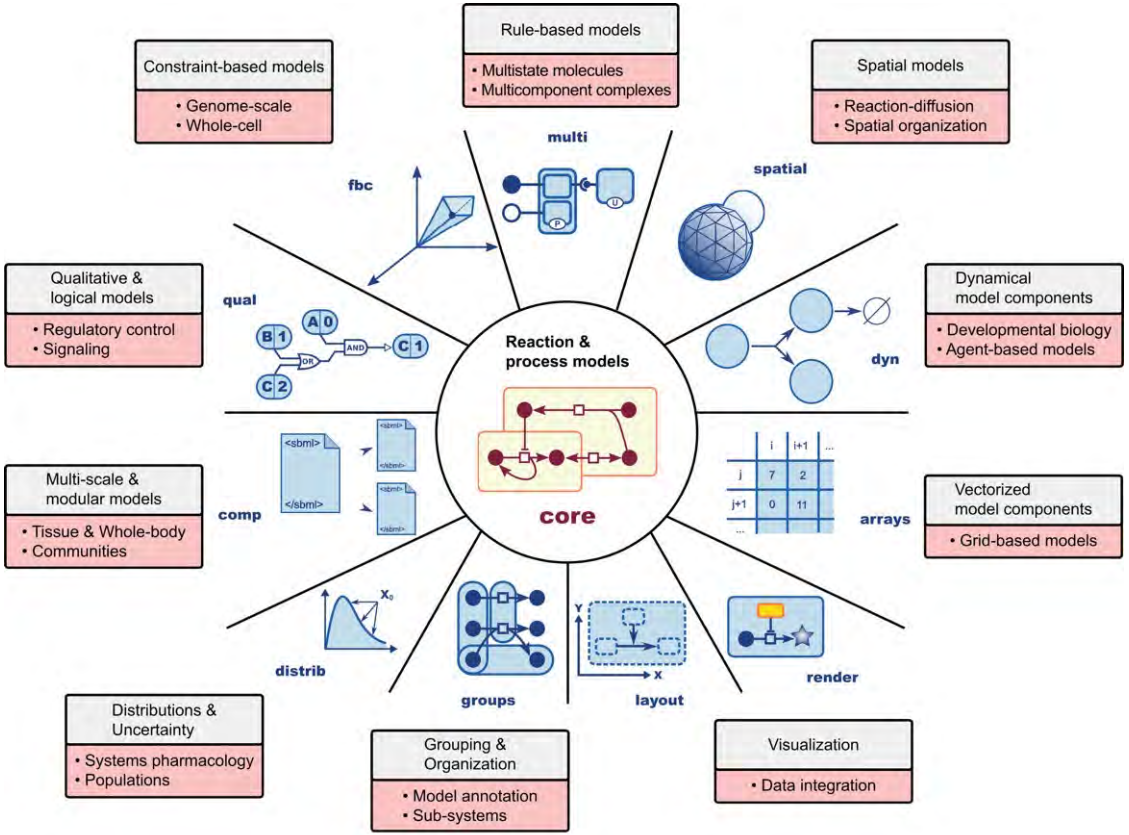
Recommendations and standards for

- ⇨ Data integration
- ⇨ Model validation
- ⇨ Legal/ethical issues (e.g. patient rights, GDPR)

e.g.

- ISO 20691:2022 Requirements for data formatting and description in the life sciences
- ISO/TS 9491 Biotechnology — Recommendations and requirements for predictive computational models in personalised medicine research — Part 1: Guidelines for constructing, verifying and validating models Part 2: Guidelines for implementing computational models in clinical integrated decision support systems
- ISO 4454:2022 Genomics informatics — Phenopackets: A format for phenotypic data exchange
- ISO 23494 series: Biotechnology — Provenance information model for biological material and data
- Community standards: e.g. COMBINE, GA4GH, etc.

e.g. Formats for Computational Models on Humans



Systems Biology Markup Language

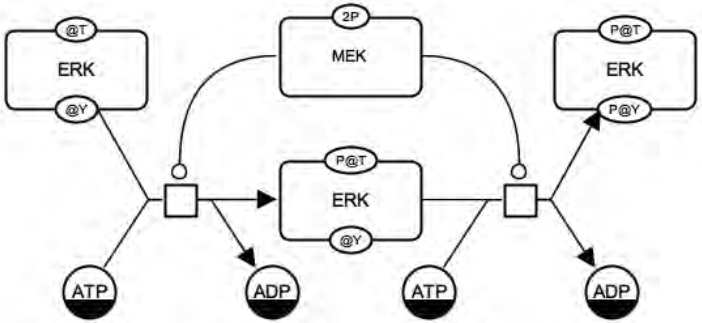
sbml.org

Hucka M, Finney A, Sauro HM, *et al.*: **The systems biology markup language (SBML): a medium for representation and exchange of biochemical network models**. Bioinformatics (2003) 19(4): 524-531

Keating, Waltemath, et al., Molecular Systems Biology (2020)

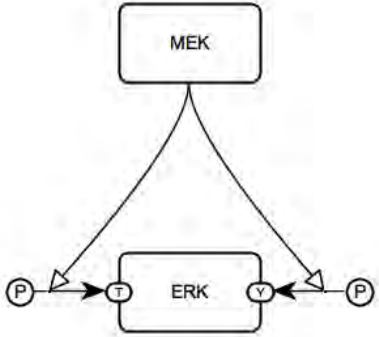
e.g. Standards for Visualization of Human Models

Process Description maps



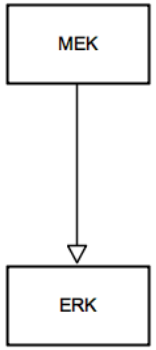
- Unambiguous
- Mechanistic
- Sequential
- Combinatorial explosion

Entity Relationships maps



- Unambiguous
- Mechanistic
- Non-Sequential

Activity Flow maps



- Ambiguous
- Conceptual
- Sequential

SBGN

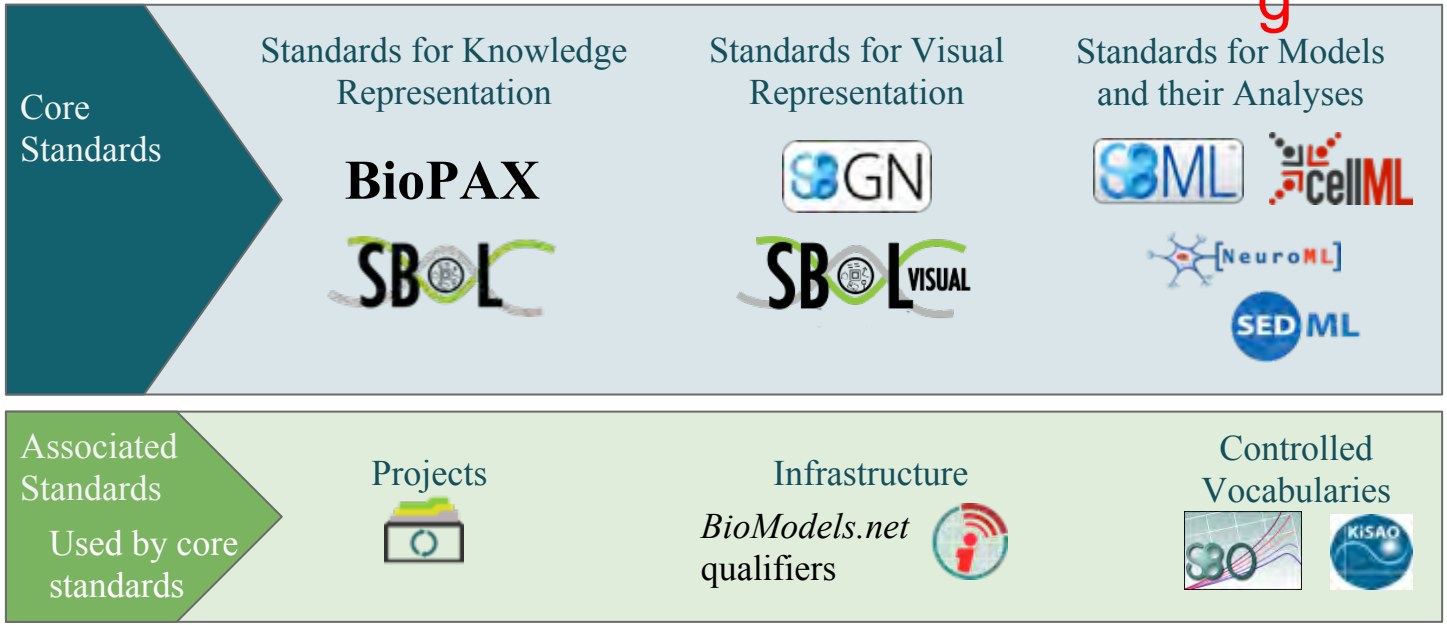
Systems Biology Graphical Notation

Le Novère N, Hucka M, Mi H, Moodie S, Schreiber F, Sorokin A, Demir E, Wegner K, Aladjem MI, Wimalaratne SM, Bergman FT, Gauges R, Ghazal P, Kawaji H, Li L, Matsuoka Y, Villéger A, Boyd SE, Calzone L, *et al.*
The Systems Biology Graphical Notation. Nature Biotechnology 27(8):735-41 (2009)

http://www.sbgn.org

combine

http://co.mbine.org



adapted from:
Schreiber F, Bader GD, Gleeson P, Golebiewski M, Hucka M, Le Novère N, Myers C, Nickerson D, Sommer B, Walthemath D: **Specifications of Standards in Systems and Synthetic Biology: Status and Developments in 2016** J Integr Bioinform. (2016) 13:289. doi: 10.2390/biecoll-jib-2016-289

Standardized and Harmonized Data Sharing: ISO 20691
Requirements for data formatting and description in the life sciences

Meta-standard for data formatting, description, reporting, integration and sharing
→ Catalogue of criteria and requirements for life science data formats and semantic data description as prerequisites for a framework of interoperable standards

Example: Great Baltimore fire of 1904

Individual fire hydrants depending on region with 600 variations of hose couplings

→ Need for a set of harmonized and interoperable data standards for DHTs

Thank you !

Martin Golebiewski

HITS - Heidelberg Institute for Theoretical Studies

Germany

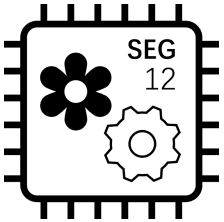
martin.golebiewski@h-its.org

HITS

EU-STANDS4PM standards for in silico models for personalised medicine

LiSyM Liver Systems Medicine

nfdi 4 health



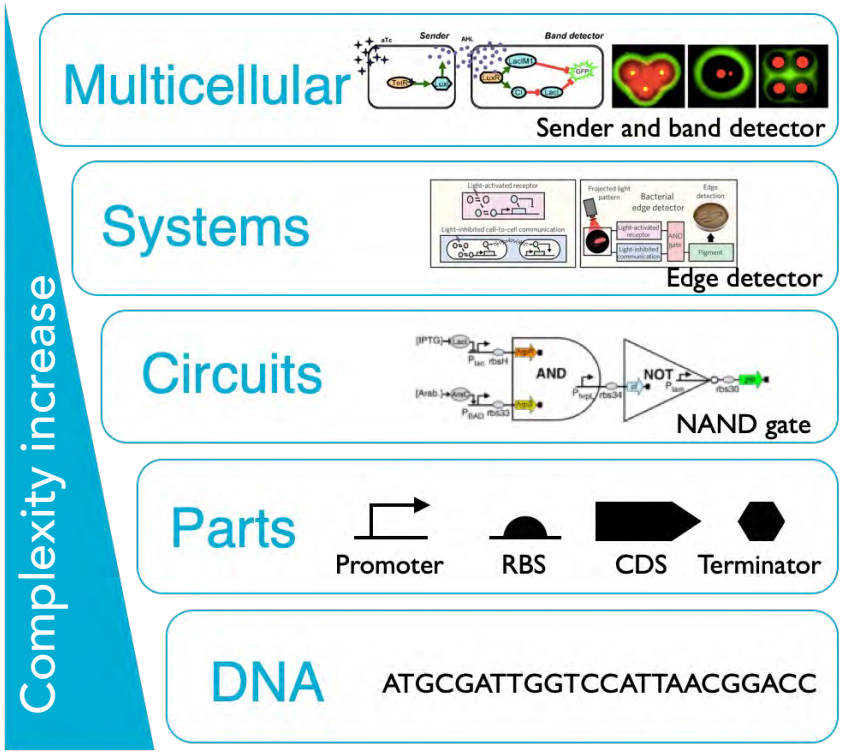
Synthetic Biology

IEC
International Electrotechnical Commission

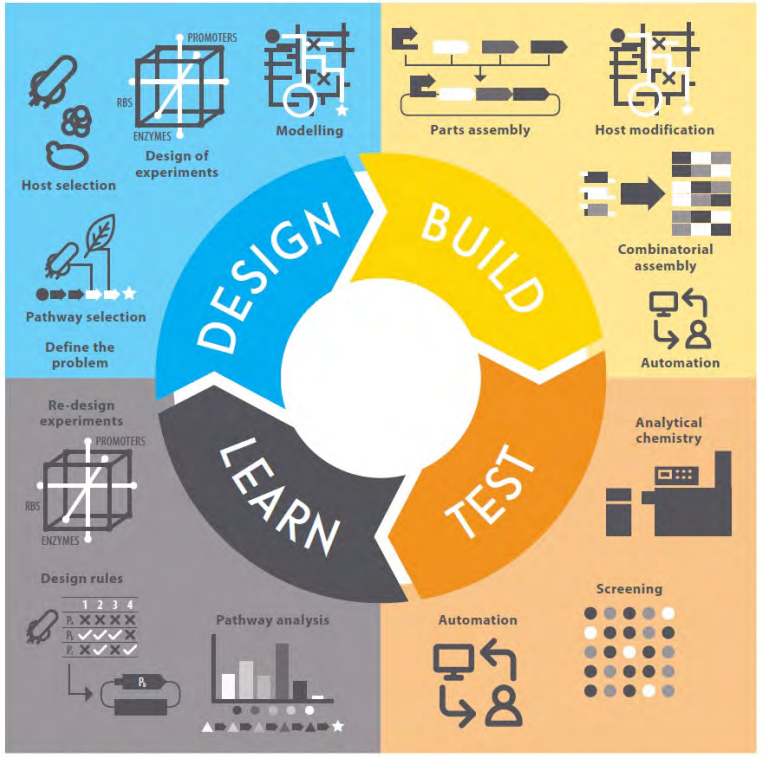
Synthetic Biology

Definition

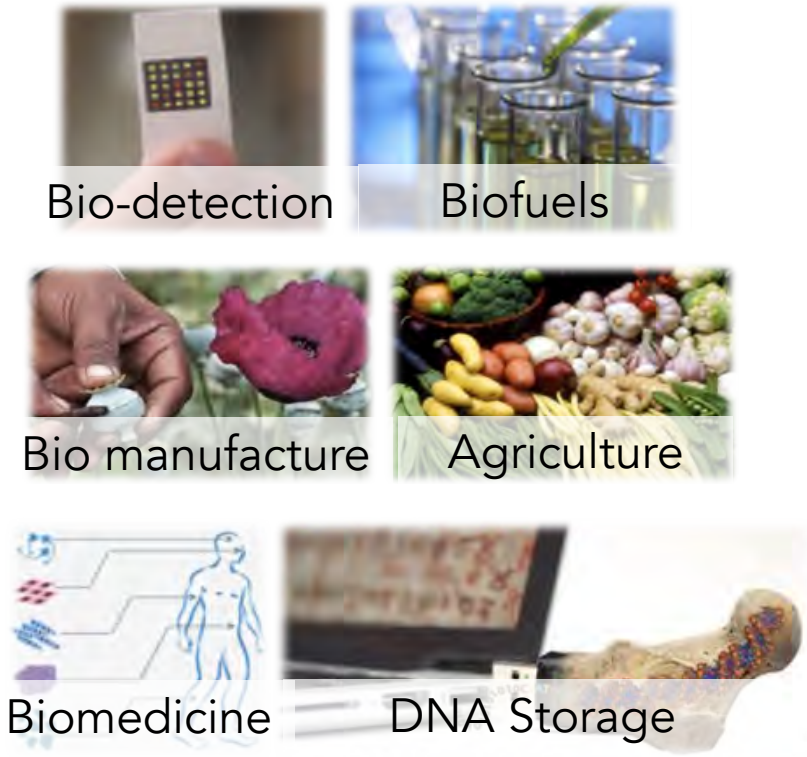
A new emerging multidisciplinary field that seeks to create new biological parts, devices, and systems, or to redesign existing systems for useful purposes and applications.



Abstraction of Synthetic Biology in different scales



Classical iterative "DBTL" cycles of Synthetic Biology



Emerging Applications of Synthetic Biology

Synthetic Biology

	Key factors	Methodologies/Sources	Standardization potentials
DESIGN	Part repository	Computer aided tools	At early stage
	In silico design tools	Databases	Mature
	Data mining		
BUILD	Nucleic acids (DNA/RNA)	Nucleic acids/genome synthesis	Mature
	Peptides	Peptide synthesis	
	Amino acids	Protein engineering/design	
	Proteins		
TEST & APPLY	*In vitro* (cloning, assembly)	PCR/ligation	
	In vivo (prokaryotes, eukaryotes)	Homologous recombination	
	Measurements (Omics, functions)	Sequencing, LC/MS, FCM	Mature
	Screenings & Automations	Colony picking, liquid handling	

Synthetic Biology

Standards efforts

ISO Foresight Trend 2022-Science-Synthetic Biology

- **ISO/TC 276 Biotechnology**

  ISO 5058-1:2021 Biotechnology-Genome editing-Part 1: Vocabulary
  ISO 20688-1:2020 Biotechnology- Nucleic acid synthesis Part 1: Requirements for the production and quality control of synthesized oligonucleotides
  ISO/CD 20688-2 Biotechnology — Nucleic acid synthesis — Part 2: General definitions and requirements for the production and quality control of synthesized gene fragment, gene, and genome

- **ISO/TC 34/SC 16 Horizontal methods for molecular biomarker analysis**

  ISO 16578:2022 Molecular biomarker analysis — Requirements for microarray detection of specific nucleic acid sequences

Synthetic Biology

Standards efforts

Other related Organizations & Standards

ASTM E3072-22A

- Standard Terminology for Industrial Biotechnology and Synthetic Biology

Chinese Institute of Electronics（CIE）

- Technical specification for the coding system in DNA-based information storage

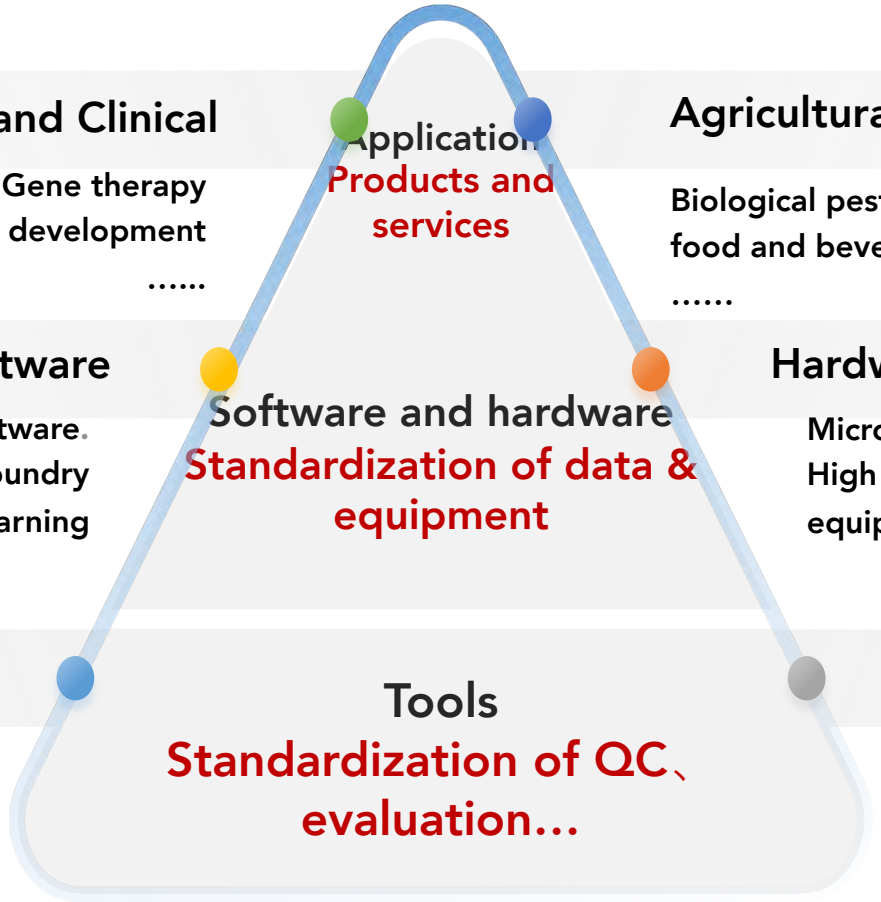
Synthetic Biology

Standards limitations

Incomplete system	No specific standard roadmap for synthetic biology
Less coverage	DNA synthesis Food and Agricultural application
No counterpart TC	Partly in ISO/TC 48&276&212&215 Partly related to ISO/IEC JTC1
Lagging behind tech	No international vocabulary & general standard Less foundation standards on part and data

Synthetic Biology

Standards needed



Health and Clinical

Gene therapy
Pharmacy development
……

Agricultural and food

Biological pesticide
food and beverage
……

Software

Part design software.
Bio foundry
Machine learning

Hardware

Microfluidic chip
High through-put & Automation equipment

Necessary tools

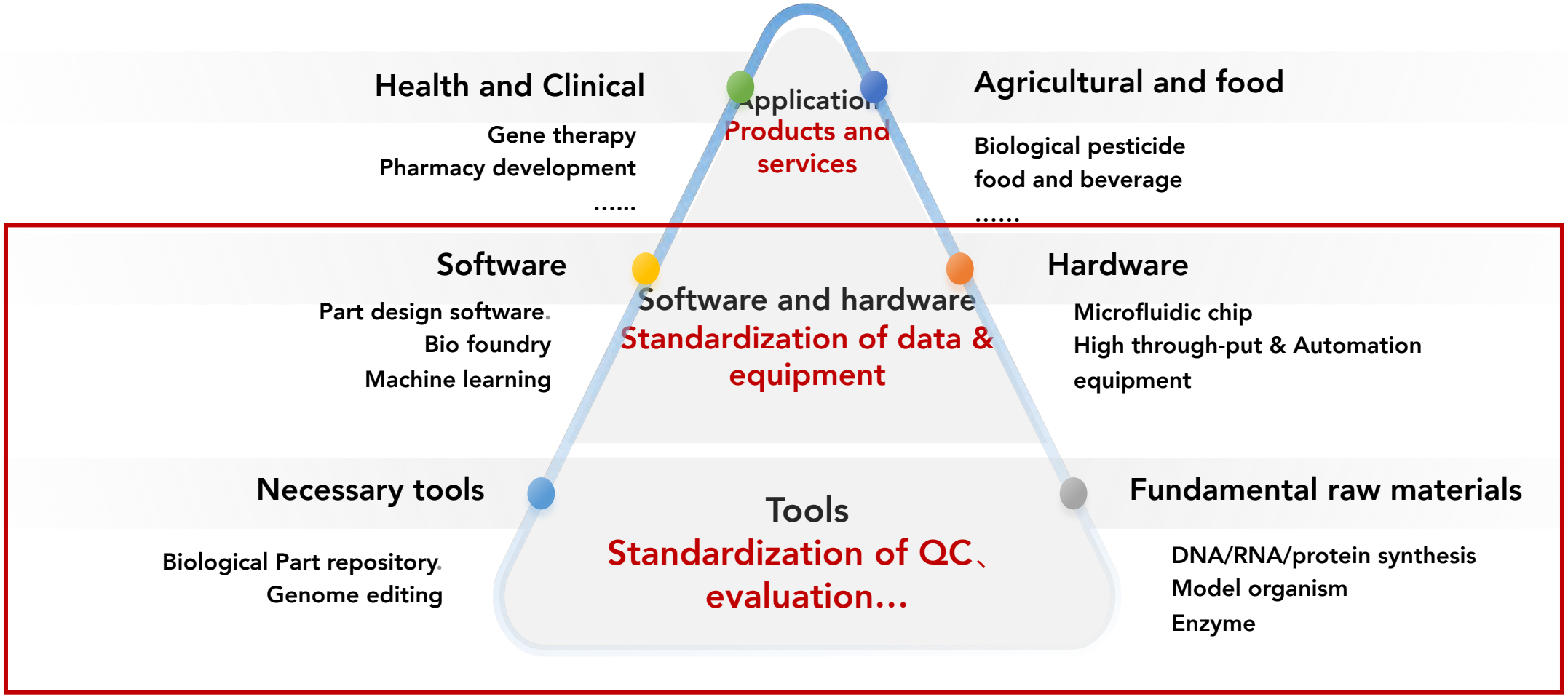
Biological Part repository.
Genome editing

Fundamental raw materials

DNA/RNA/protein synthesis
Model organism
Enzyme

Synthetic Biology

Standards needed



华大生命科学研究院
BGI·Research

THANKS

OMICS FOR ALL

Contact information

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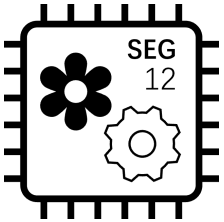
Dr. Ran WANG

Senior manager of standardization, BGI-Research

+86 136 3296 5820

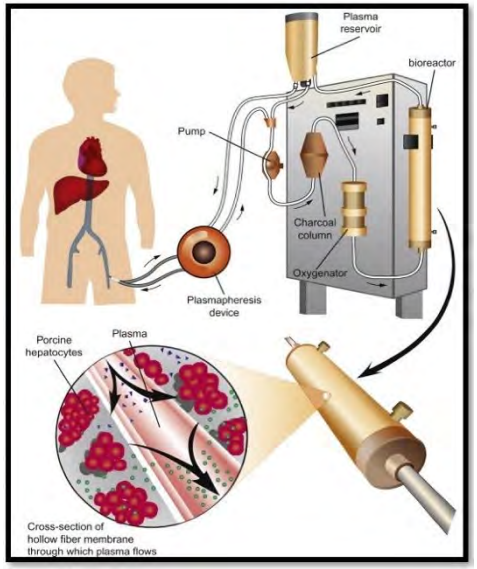
wangran1@genomics.cn



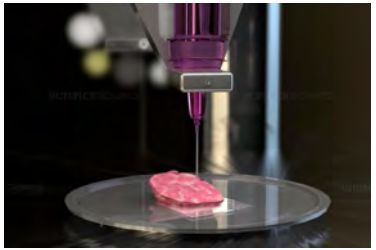
Artificial Organs & Organoids

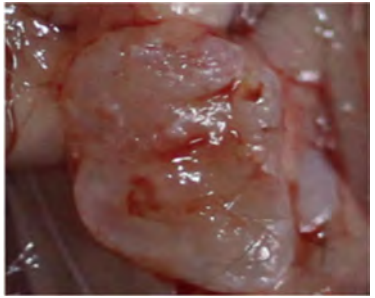
Artificial Organs & Organoids

Mechanical
Artificial Heart



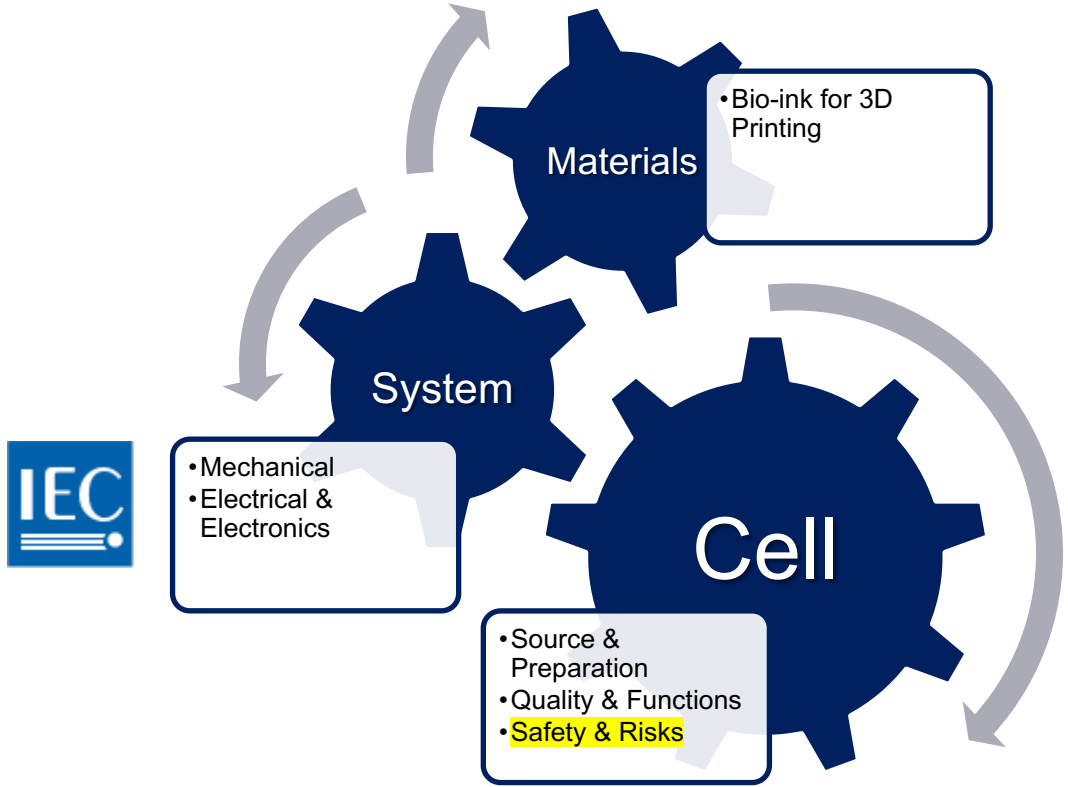
Biomechanical
Bioartificial Liver



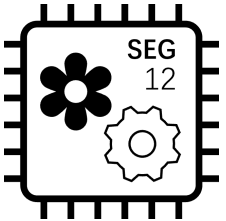


Biological
3D-printing Liver

Artificial Organs & Organoids



Artificial Organs & Organoids



- **Existing International Standardization Organizations**

ISO

Standards:

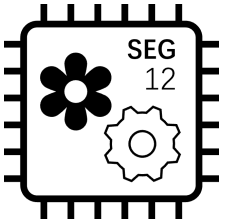
Under Development:

- ISO/CD TS 23511.2 Biotechnology — General requirements and considerations for cell line authentication
- ISO/WD TS 7833 Extraction method of nanomaterials from organs by the proteinase K digestion

Published:

- ISO 13022:2012 Medical products containing viable human cells — Application of risk management and requirements for processing practices
- And a series of standards in the scope of “Cardiovascular implants and artificial organs” (Total: 9 standards)

Artificial Organs & Organoids



Published ISO standards on the topic of Cardiovascular implants and artificial organs:

- ISO 18193:2021 Cardiovascular implants and artificial organs — Cannulae for extracorporeal circulation
- ISO 15675:2016 Cardiovascular implants and artificial organs — Cardiopulmonary bypass systems — Arterial blood line filters
- ISO 15674:2016 Cardiovascular implants and artificial organs — Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags
- ISO 7199:2016 Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)
- ISO 15676:2016 Cardiovascular implants and artificial organs — Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)
- ISO/TS 23810:2018 Cardiovascular implants and artificial organs — Checklists for use of extracorporeal circulation equipment
- ISO 15675:2016/Amd 1:2020 Cardiovascular implants and artificial organs — Cardiopulmonary bypass systems — Arterial blood line filters — Amendment 1: Connectors
- ISO 15674:2016/Amd 1:2020 Cardiovascular implants and artificial organs — Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags — Amendment 1: Connectors
- ISO 7199:2016/Amd 1:2020 Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators) — Amendment 1: Connectors

Other SDOs?

ESAO
European Society for Artificial Organs

European Society for Artificial Organs ↔ **ISO/TC 150/SC 2 Cardiovascular implants and extracorporeal systems**

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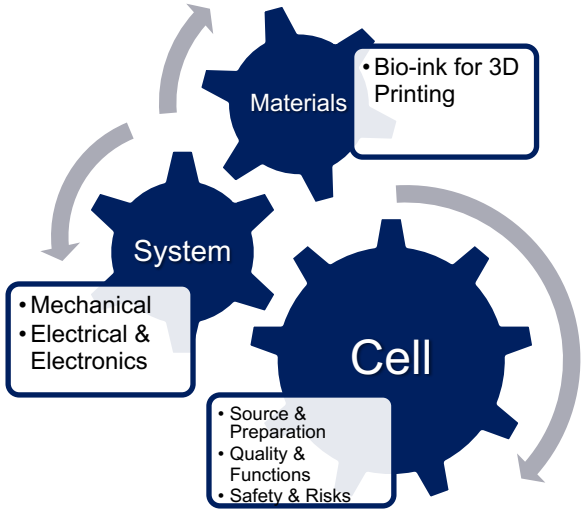
Artificial Organs & Organoids



- IEC/SEG 12 - BioDigital Convergence
- IEC/TC 62 - Electrical equipment in medical practice
- IEC/TC 77 - Electromagnetic compatibility
- IEC/TC 113 - Nanotechnology for electrotechnical products and systems

More on Electrotechnical aspects and at the System level…

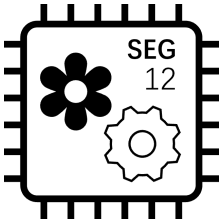
- ISO/TC 276 - Biotechnology
- ISO/TC 150 - Implants for surgery
- ISO/TC 194 - Biological and clinical evaluation of medical devices
- ISO/TC 262 - Risk management

More on Biological/Clinical aspects and towards regulations

Standardization Needs:

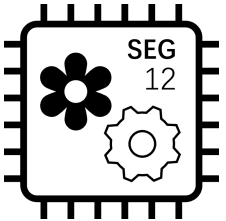
✓ **Cell/Reagents/Production/Facilities/Equipment**

✓ **Ethics/Risks/Social Impacts**



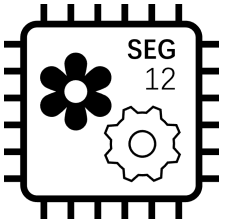
Further Topics

CAR-T cells



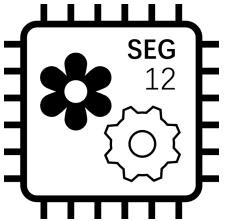
- Emerging technology with immense potential
- Currently focused on tumors (leukemia, but increasingly also solid tumors), but extending to non-malignant disease
- Standardization currently based on established guidelines, such as: GLP, GMP, GCP
- For therapeutic use national regulations apply
  - Guidelines from FDA, Health Canada, EMA
  - Accreditation for cell therapy (FACT, JACIE)
  - Drug safety and efficacy approval required for commercial CAR-T products
- Guidelines by professional societies (International Society for Cell & Gene Therapy (ISCT))

CAR-T cells



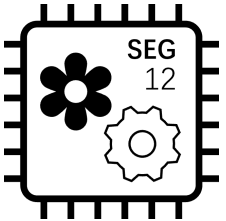
- Existing standards/standards under development
  - ISO/TC 276/WG 3 and WG 4 for cell therapeutic products
  - Published standards
    - ISO/TS 20399 series Biotechnology — Ancillary materials present during the production of cellular therapeutic products
    - ISO 21973 Biotechnology — General requirements for transportation of cells for therapeutic use
    - ISO 23033 Biotechnology — Analytical methods — General requirements and considerations for the testing and characterization of cellular therapeutic products
    - ISO/TS 23565 Biotechnology — Bioprocessing — General requirements and considerations for equipment systems used in the manufacturing of cells for therapeutic use
  - Standards under development
    - ISO/AWI 8934 Biotechnology — General considerations and requirements for cell viability analytical methods
    - ISO/DIS 20404 Biotechnology — Bioprocessing — General requirements for the design of packaging to contain cells for therapeutic use

CAR-T cells



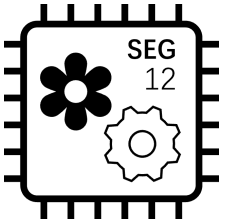
- Potential standaridzation targets
  - Pre-commercial development/pre-clinical phase not covered
  - Standardization needs notwithstanding extensive regulation
    - Safety of viral products, quality of viral vectors
    - Handling in the lab
    - Data standards
    - The Regenerative Medicine Standards Portal

CRISPR



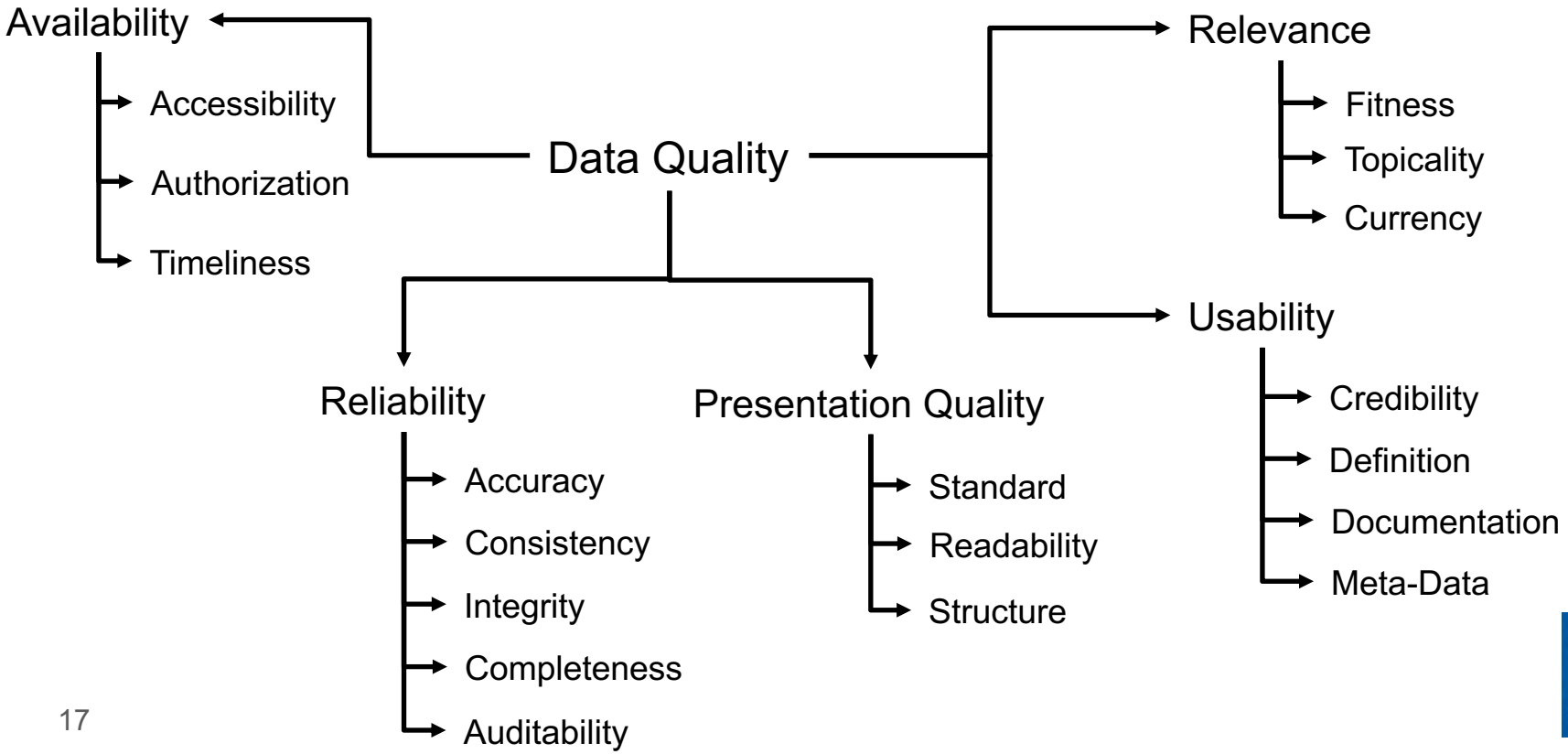
- Genetic engineering technology with (almost) unlimited application spectrum
- For all colors of biotechnology (green, white, red, blue)
- Standards
  - ISO 5058-1:2021 Biotechnology — Genome editing — Part 1: Vocabulary
  - ISO 20688 series Biotechnology — Nucleic acid synthesis
  - ISO/AWI 24480 Biotechnology — Validation of Database used for nucleotide sequence evaluation
  - The Regenerative Medicine Standards Portal

CRISPR

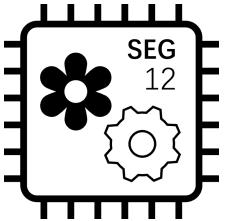


- Potential Areas to Standardize
  - Criteria for assessing product performance consistently applicable across products in the gene therapy field.
  - Identification of factors affecting product performance
  - Appropriate thresholds for performance data
  - Guidelines for sample preparation
  - Product performance test selection and requirements
  - Critical quality attributes applied both early and late in development
  - Risk-based framework for assessing comparability to support manufacturing changes

Dimensions of Data Quality

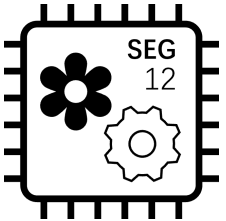


Data Quality



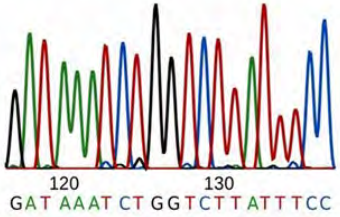
- Existing standards
  - ISO/TC 276/WG 5 Data processing and integration
    - ISO 20691 Biotechnology — Requirements for data formatting and description in the life sciences
    - ISO 23494 series: Biotechnology — Provenance information model for biological material and data
  - ISO/IEC JTC 1/SC 7 Software and systems engineering
    - ISO/IEC 25000 series
    - ISO/IEC 25012:2008 Software engineering — Software product Quality Requirements and Evaluation (SQuaRE) — Data quality model
  - ISO/IEC JTC 1/SC 42 Artificial intelligence
    - ISO/IEC CD 5259 series: Artificial intelligence — Data quality for analytics and machine learning (ML)
  - ISO/TC 184/SC 4 Industrial data
    - ISO 8000 series Data quality

Data Quality



- Standardization needs and gaps
  - Fundamental to any application
  - FAIR-principles (Findable, Accessible, Interoperable, Reusable) ensure reusability and verifiability
  - Additional quality dimensions
    - Metrological traceability
    - Comparability
    - Validity
  - Generic specifications mostly insufficient, Domain specific requirements needed


Thank you!



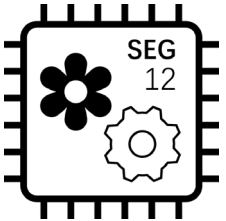
SEG 12

IEC SEG 12 WG5: Agricultural Bioengineering

IEC

International Electrotechnical Commission

IEC SEG 12 WG5
Agricultural Bioengineering



Ray Shillito,
Senior Expert
BASF

Chair ISO/TC 34/SC 16
Convenor IEC/SEG 12/WG 5

All views and opinions expressed in this presentation are those of the author, and do not necessarily reflect the official policy or position of BASF, or its affiliated companies.

Scope of WG5

- BioDigital standardization opportunities in the Bioengineering of agricultural systems and systems of systems, including forestry, aquaculture, livestock farming, cellular agriculture and molecular pharming. This includes internet of things applications (such as precision agriculture), embodied computing for animals, genetic engineering of food as well as the UN sustainable development goal SDG2: End hunger, achieve food security and improved nutrition and promote sustainable agriculture.

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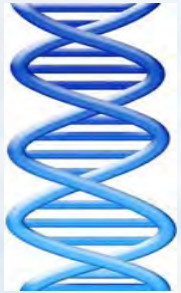
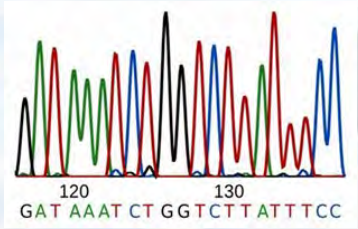
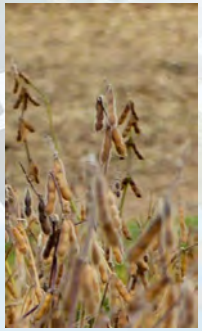
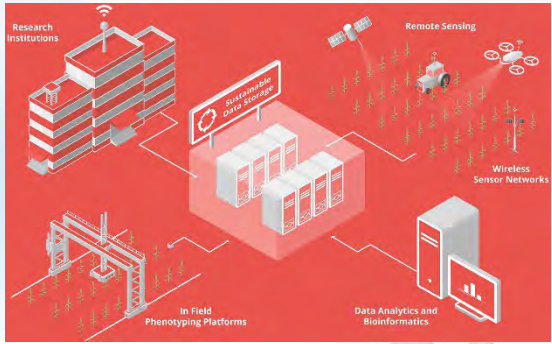
The Convergence of Bio and Digital Technologies in Agriculture









Challenges

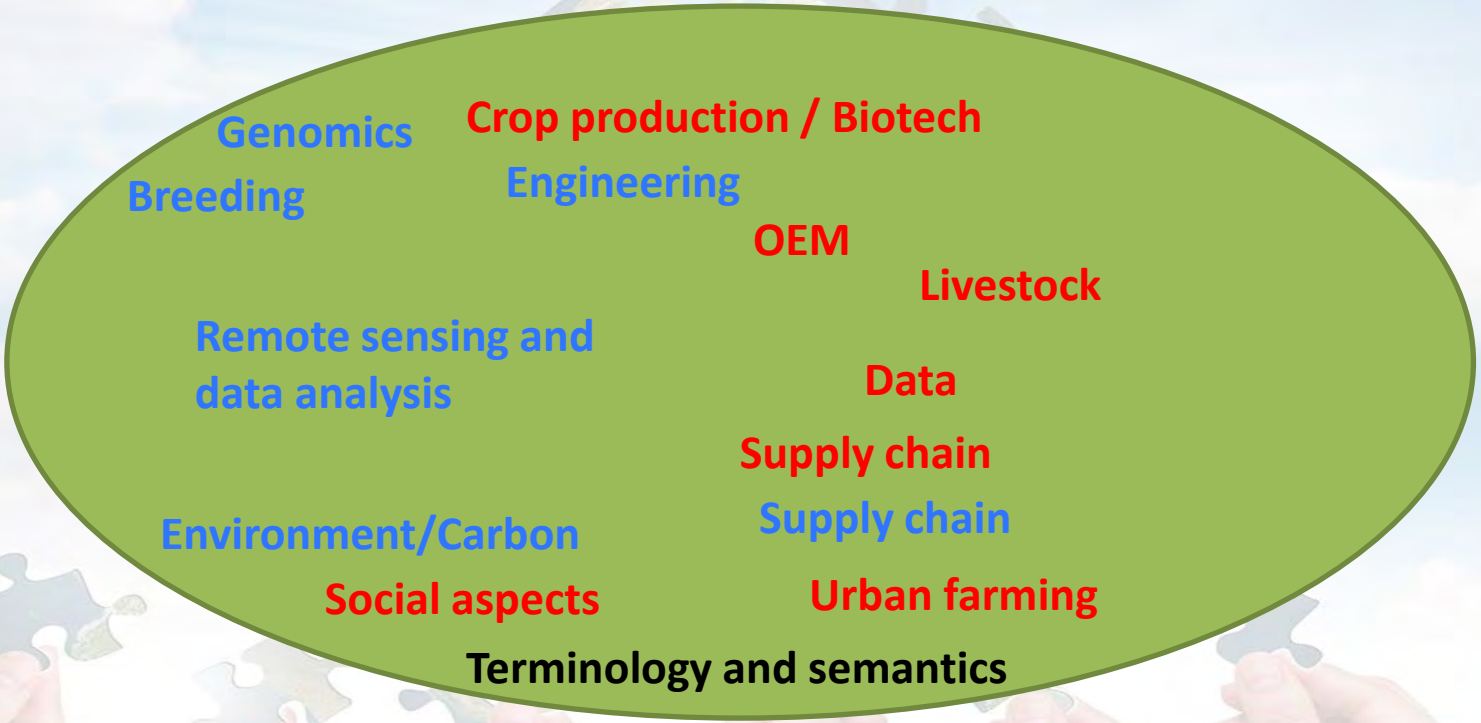
- Small number of participants with a limited range of expertise
- No success in broadening expert group
- Low attendance at meetings
- Competition from ISO Smartfarming initiative

- However, those that attended were very engaged.

What is the ISO Smart Farming Initiative

ISO/SAG SF-SG9

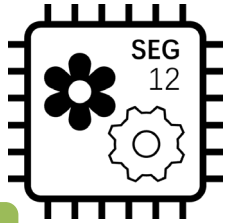
Overlap with Smartfarming



Who needs Standardization?

- Genetic Engineering and breeding of plants and animals (including fish, cellular organisms etc.)
- Digitalization of processes in cellular agriculture and molecular pharming.
- Remote sensing, acquisition of data, and integration of enormous data sets, leading to sharing for optimization of precision agriculture.
- Supply chains to achieve food security and reduce food loss
  - From seed to food, feed and fiber
- Understanding nutrition needs and how to improve nutrition
- What does sustainable agriculture actually mean? (SDG2)

Who might have relevant standards?



Codex Alimentarius

ISO

- ISO/TC 276 – Biotechnology
- ISO/TC 34/SC16 – Molecular Biomarkers (Food and agriculture)
- ISO/SAG SF-SG9 – Smartfarming
- ISO/TC 23/SC 19 – Agricultural electronics
- ISO/TC 20/SC 16 – Unmanned aircraft systems
- IWA 42:2022: Net zero guidelines – how can digitalization impact global warming?
- Sustainability Standards – cf London Declaration?

Breeding and grading standards (e.g., Cattle, Apples,)

USDA FACT (Food and Agriculture Cyberinformatics and Tools)

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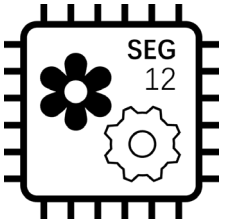
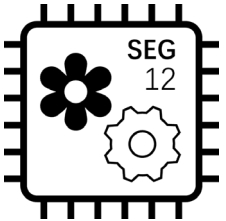
DNA sequencing and data handling



- ISO/TR 3985:2021 - Biotechnology — Data publication — Preliminary considerations and concepts
- ISO 20397-1:2022 - Biotechnology — Massively parallel sequencing — Part 1: Nucleic acid and library preparation
- ISO 20397-2:2021 - Biotechnology — Massively parallel sequencing — Part 2: Quality evaluation of sequencing data
- PWI 24480 - Biotechnology — Validation of Database used for nucleotide sequence evaluation

Standardization in Biobanking



- ISO 20387:2018 - Biotechnology — Biobanking — General requirements for biobanking
- ISO/TS 23105:2021 - Biotechnology — Biobanking — Requirements for the biobanking of plant biological material for research and development (does not cover seed)
- ISO/AWI 16677-1 - Biobanking — Biobanking genetic material for biodiversity and conservation of genetic material — Part 1: Agricultural animal species

Standardization of Analytical methods (DNA or protein)

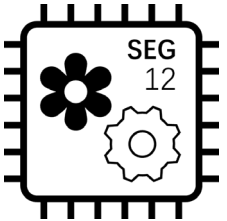
- CGX-74
- ISO 24276
- ISO 21569
- ISO 21570
- ISO 21571
- ISO 21572
- ISO/TS 16393
- ISO 22942-1
- ISO 13495
- ISO/WD 11781
- ISO 20813
- ISO 22949-1
- ISO/TS 20224
- ISO 16578
- ISO/CD 5354-1
- ISO/CD TS 5354-2
- ISO 16577
- ISO/TR 17622 and 17623

Data Communication (equipment)

- ISO/TC 23/SC 19 - Agricultural electronics
  - ISO 11783 series - Tractors and machinery for agriculture and forestry

- ISO/TC 20/SC 16 - Unmanned aircraft systems
  - ISO 21384 series - Unmanned aircraft systems
  - ISO 23629 series - UAS traffic management (UTM)
  - ISO 24356:2022 - General requirements for tethered unmanned aircraft systems

Remote sensing, acquisition of data, and integration of data sets



- Although there are standards for data exchange, there does not appear to be a general willingness to standardize data acquisition and interoperability
- On-site data acquisition using smartphone apps. Rural internet?
- ITU-T Y.2238: “However, there exist many difficulties to establish services and systems to actualize the convergence service in the agricultural field to cope with various problems such as time-varying weather changes, growth condition of farm products, and continual diseases or technical problems such as battery life and sensor malfunctions due to severe conditions.”
- ISO/SAG SF-SG9 has suggested several professional terms about smart agricultural equipment. However, it is struggling to focus on gap analysis.
- **The issues of the ownership and monetarization of data are in the way.**

Standardization in Supply Chains

Applications of knowledge graphs
for food science and industry
Min et al., 2022 https://doi.org/10.1016

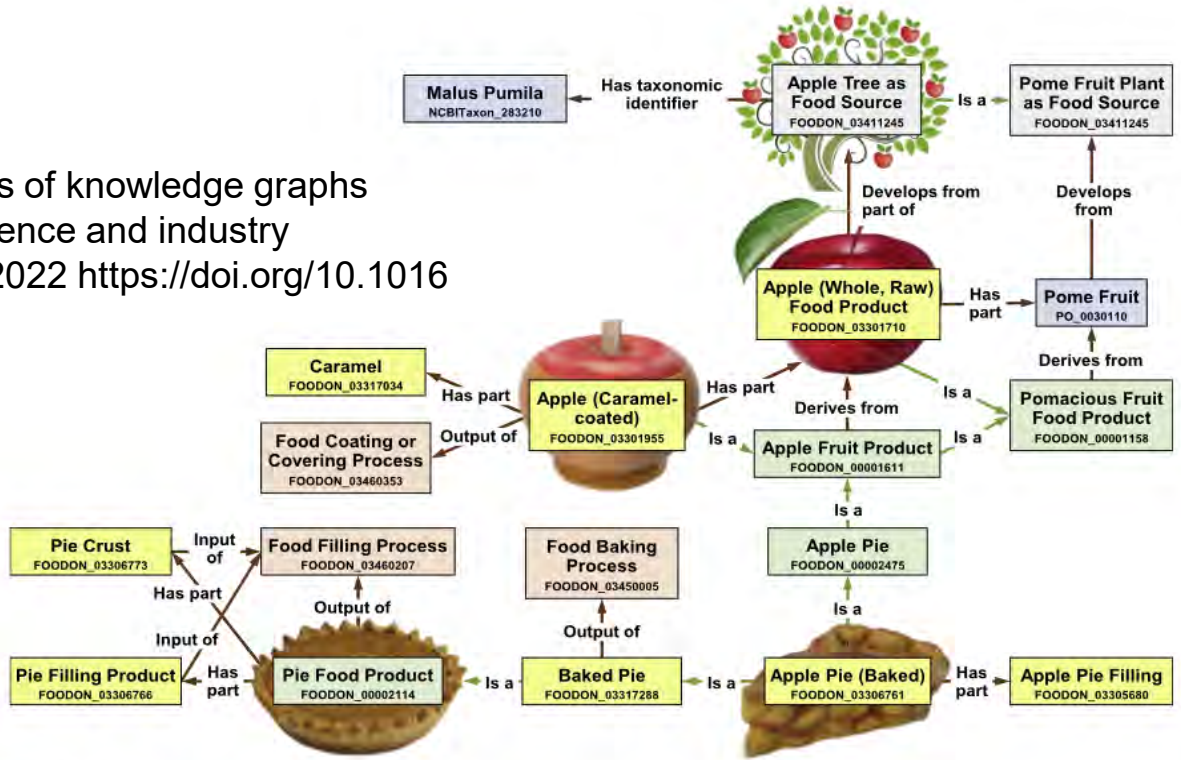
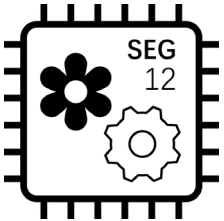


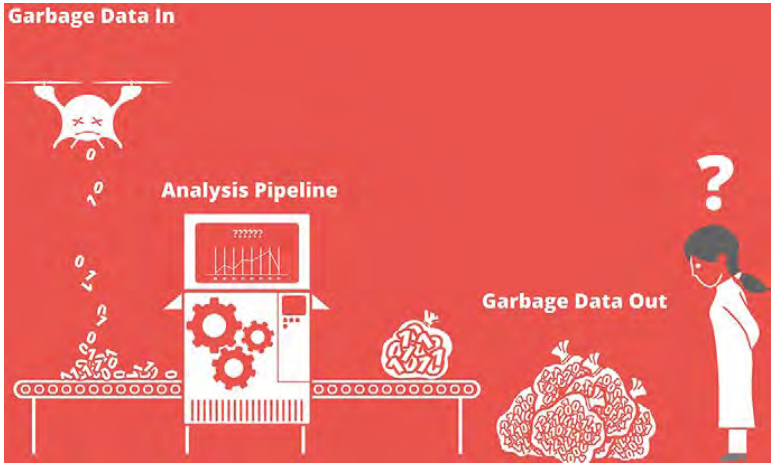
Figure 4. A simplified structure of FoodOn
In this example, the relations among food sources, products, and related food processes of apples are described. Different entities are shown in different colors according to their classes. These entities are linked by different relations with different colors according to the type of relations. [15]

Standardization in Supply Chains



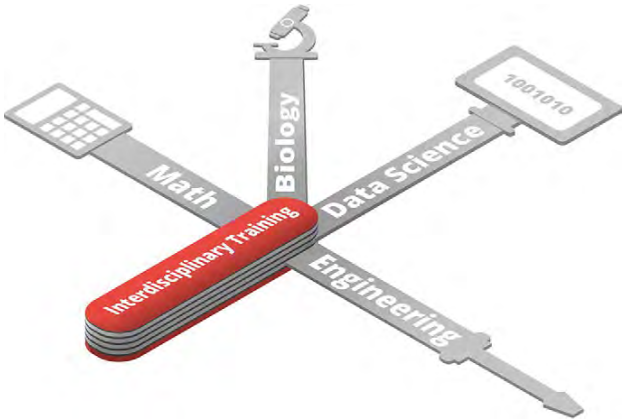
- There have been demonstrations of blockchain processes in supply chains.
- Some demonstrations (e.g. 2017 melons/Walmart/IBM) have not subsequently been heard much of publicly.
- Although some are deploying blockchain and digital twins internally, we are not aware of any wider standardization initiative.
- Lots of hype in digital twins/modeling, but actual offers of off-shelf cannot cope with complexity of supply chains
- Push for competitive advantage by users hampers standardization
- Data interconnection and data integration are difficult, so may cover certain sections
- Difficulties include the issue of the ownership of data within the blockchain, possibility for large entities to control prices etc.

Standardization – Integration of Ag. Systems



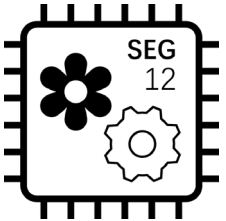
Shakoor 2019 – USDA FACT Initiative

"The most important challenge is to ensure that the plant science communities and data analytics communities know how to use these data to deliver actionable results for scientists and farmers."

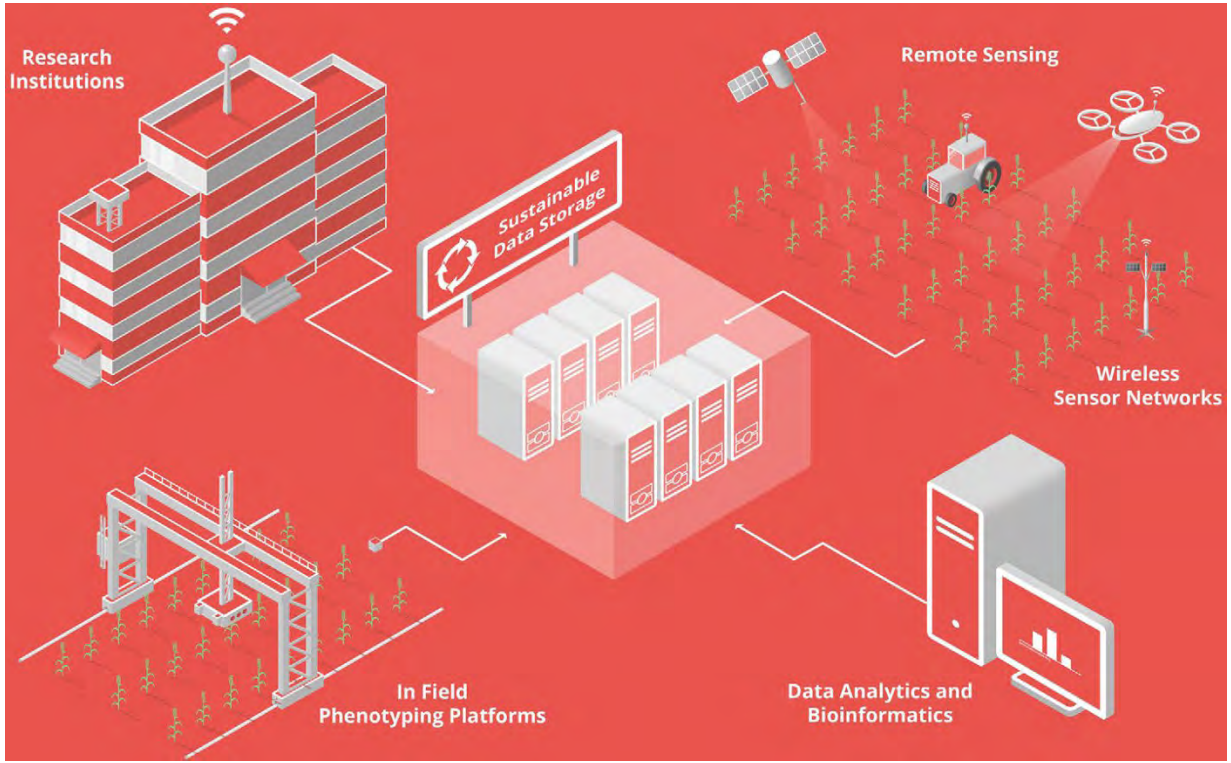


Plant Phenome J. 2: 180009 (2019) doi:10.2135/tppj2018.12.0009 (CC BY)

Future developments



- Improvements in managing and understanding huge genomic and sensor data sets
- Integration of teams of data scientists, statisticians and biologists
- Interoperability of sensor and other data and between systems for timely on-the-farm decision making
- Resolution of data ownership issues in sensing, machinery, blockchain etc.
- Blockchain technology increases transparency, but can it be used to model and improve supply chain behavior??



Thankyou Questions/Discussion?

International Electrotechnical Commission