

# Community Building & Outreach: From grassroots to common standards

**Martin Golebiewski**

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# The need for standardisation

**Example:** Great Baltimore fire of 1904



Individual fire hydrants depending on region  
with 600 variations of hose couplings  
→ Need for standards



# What exactly is a *standard*?

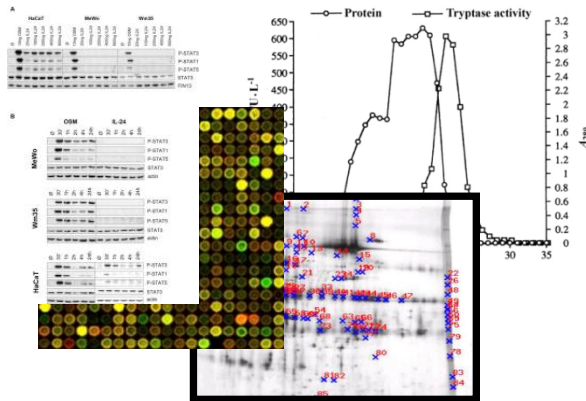
## **Definition:**

A document established by consensus and approved by a recognized body that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context

Source: ISO/IEC Guide 2

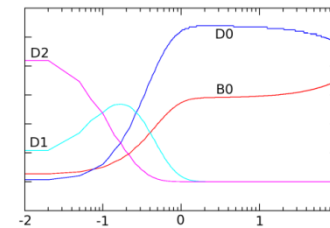
# Systems Biology Workflows

Experimental Data



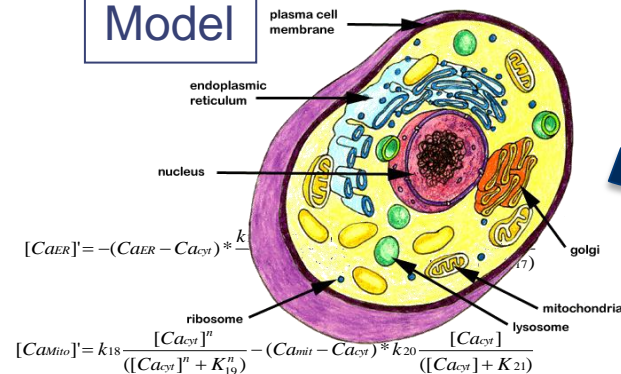
hypothesize  
& verify

Simulation

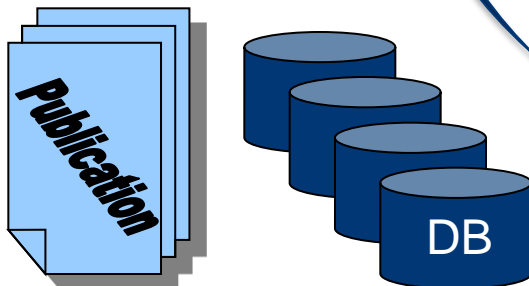


simulate

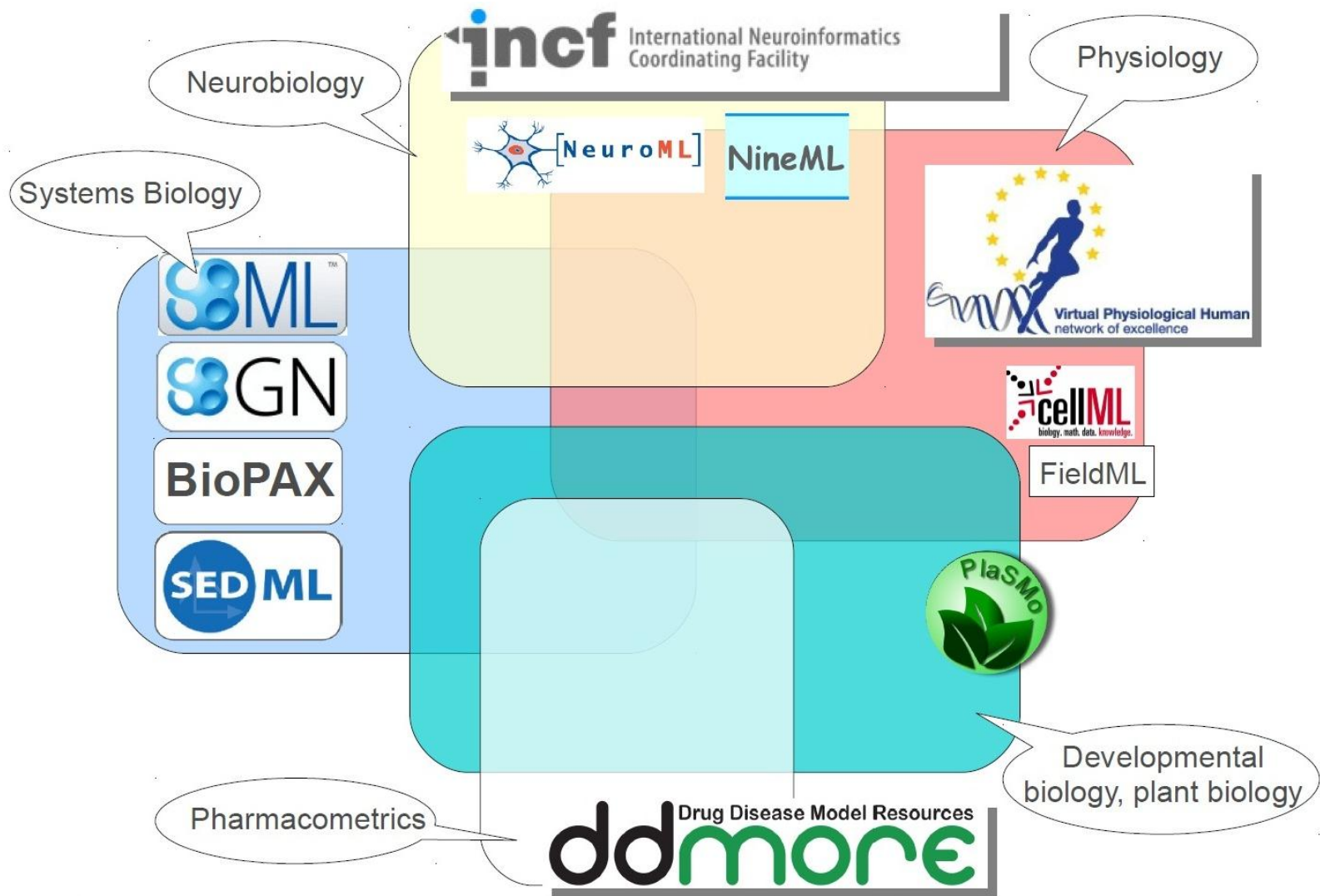
Model



integrate



# Exchange Format Standards for Biological Models

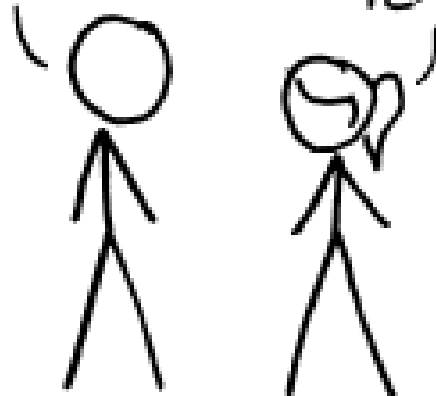


## So many standards...

HOW STANDARDS PROLIFERATE:  
(SEE: A/C CHARGERS, CHARACTER ENCODINGS, INSTANT MESSAGING, ETC.)

SITUATION:  
THERE ARE  
14 COMPETING  
STANDARDS.

14?! RIDICULOUS!  
WE NEED TO DEVELOP  
ONE UNIVERSAL STANDARD  
THAT COVERS EVERYONE'S  
USE CASES.



SOON:

SITUATION:  
THERE ARE  
15 COMPETING  
STANDARDS.



# Building a Bridge



- **Research Communities**

Develop community standards and apply



- **Industries**

Need standards to integrate research data



- **Standardisation Bodies**

Help to define and promote standards



# NormSys – Project Aims and Tasks

- **Identification** of existing community standards
- **Classification** of standards based on their possible scope of application
- **Registry** for modelling standards in systems biology: Matrix of key features and scope of application
- **Certification strategy** for selected standards
- **Evaluation of standardisation options** for standards
- **Community building**: Research, industries, startups, standardisation bodies:
- **Transfer** from grass-roots **to normative standards**: National (DIN) / European (CEN) / International (ISO)



# NormSys – Project Partners



- **HITS**  
Scientific coordination, implementation of registry and certification



- **University of Potsdam**  
(Plant Genomics and Systems Biology)  
Represents the academic requirements, community building



- **LifeGlimmer GmbH** (Berlin)  
Represents the industrial requirements

Supported by:

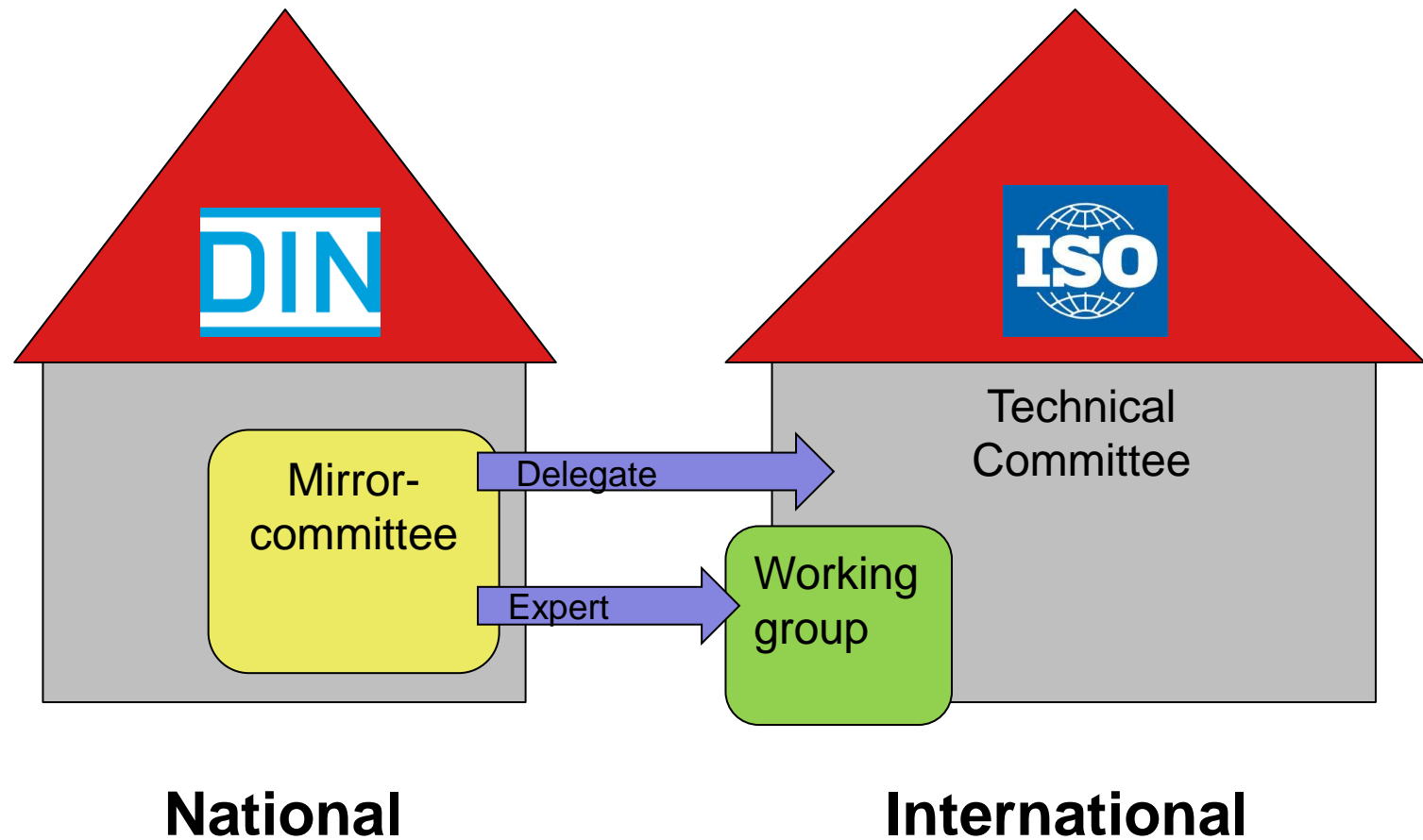


Federal Ministry  
for Economic Affairs  
and Energy

# Standardisation Organizations



# Standardisation Organisations: How do they work?



# Development of an international standard





## Traditional Role of Standards (ISO, etc.)

- Source of technical know-how (state of the art)
- Trade facilitation and technology transfer
- Complementing legislation in the health, safety and environmental sectors

→ **DIN ISO Standard**



## Valued-added role for research and innovation

- Standards as the starting point for innovation
  - Speeding up innovation by providing the required knowledge base
- Develop specifications as a **precursor** for international (ISO) standards

→ **DIN SPEC**

# Norms (Standards) vs. Specifications

## ➤ Norm (Standard)

- ✓ High level of acceptance
- ✓ Great economic benefits
- ✓ Reflects current state of technology
- ✓ But: tedious and bureaucratic normalization process

## ➤ Specification (Standard)

- ✓ Quickly available because full consensus is not required
- ✓ Effective and flexible diffusion of innovations
- ✓ First step towards international (ISO) standardization



# What's happening in Biotech?



DIN

## An Excerpt

### International

**ISO/TC 276**      ***Biotechnology*** (established and managed by DIN)

ISO/TC 34/SC 16 *Methods for Molecular Biomarker Analysis*

ISO/TC 194      *Biological Evaluation of Medical Devices*

ISO/TC 272      *Forensic Sciences*

### Europe

CEN/TC 275/WG 11 *Genetically Modified Foodstuffs*

CEN/TC 316      *Medical Products Utilizing Cells, Tissues, and Derivatives*

CEN/TC 411      *Bio-Based Products*

### US

ASTM E 48      *Biotechnology*

ASTM E 55.04 *General Biopharmaceutical Standards*

ASTM E 55.90 *Manufacture of Pharmaceutical Products*



# Biotechnology Committees at DIN and ISO

**NA 057 Normenausschuss Lebensmittel und landwirtschaftliche Produkte (NAL)**

Deutsche Version | [Contact](#) | [Shopping Basket](#) | [Livelihood](#)



**Develop Standards**

**Buy Standards**

**Use Standards**

- Standards issued by standards committee
- Specifications issued by standards committee
- Projects of the standards committee
- National Committees
- European Committees
- International Committees
- About us

[Home](#) > **NA 057-06-02 AA**

## NA 057-06-02 AA Biotechnology



Standards of the Committee



Projects of the Committee

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**Livelihood NA 057-06-02 AA**

Contact

**M. Sc.  
Katharina Lippert**

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Free access to  
**DIN-TERMinology Portal**

### Subordinate Committees NA 057-06-02 AA

Committee ID	Name
NA 057-06-02-01 AK	Terminology
NA 057-06-02-02 AK	Biobanks/Bioresources
NA 057-06-02-03 AK	Analytical methods
NA 057-06-02-04 AK	Bioprocesses
NA 057-06-02-05 AK	Dataprocessing and Integration

### Mirrored Committees of NA 057-06-02 AA

Committee ID	Name
ISO/TC 276/TG 1 Secretariat : DIN	Term and definition
ISO/TC 276/TG 2 Secretariat : DIN	Biobanks and bioresources
ISO/TC 276/TG 3 Secretariat : DIN	Analytical methods
ISO/TC 276/TG 4 Secretariat : DIN	Bioprocessing

# ISO/TC Biotechnology

DIN

## ISO/TC 276 - Biotechnology



→ 20 participating countries

→ 13 observing countries

● Secretariat  
Germany (DIN)

### ● Participating Countries (20)

Austria (AS)  
Belgium (NBN)  
Canada (SCC)  
China (SAC)  
Denmark (DS)  
Finland (SFS)  
France (AFNOR)  
Germany (DIN)  
Iran, Islamic Republic of (IRI)  
Japan (JISC)  
Korea, Republic of (KATS)  
Luxembourg (LNAS)  
Netherlands (NEN)  
Nigeria (SON)  
Spain (AENOR)  
Sri Lanka (SLSI)  
Sweden (SIS)  
Tanzania, United Republic of (TBS)  
United Kingdom (BSI)  
United States (ANSI)

### ● Observing Countries (13)

Argentina (IRAM)  
Australia (SA)  
Czech Republic (UNMZ)  
Ecuador (NEN)  
Estonia (EVS)  
Hungary (MSZT)  
Ireland (NSAI)  
Israel (SII)  
Italy (UNI)  
Lithuania (LST)  
Norway (SN)  
Poland (PKN)  
Switzerland (SNV)

# How we want to proceed?

How to coordinate the different COMBINE standards?

How to certify support of standards provided by tools?

What form of organisation for COMBINE?

How to organize the governance?

How to publish the standards?

How to convince the communities to apply standards?

## How to coordinate COMBINE standards??

→ See previous session

## How to certify support of standards provided by tools?

→ See previous session

# What form of organisation for COMBINE?

- Voluntary association
- Society
- Trust
- Means of communication?

## How to organize the governance?

- 1 delegate from each standard/user community  
(current organization structure)
- Elected board  
(voting across the whole COMBINE community)
- How to organize the contact between COMBINE coordinators and the editors of the standards?

# How to publish the standards?

- Journals
- Through standardization bodies (e.g. ISO)
- Independently organized by each standard?
- Concerted actions?



# How to increase the acceptance?

