



Heidelberg Institute for
Theoretical Studies



COMBINE and ISO/TC 276 Biotechnology: From Grassroots Community Standards to ISO Standards

Martin Golebiewski

Convenor of ISO/TC 276 Biotechnology WG5
'Data Processing and Integration',
HITS gGmbH (Heidelberg, Germany)

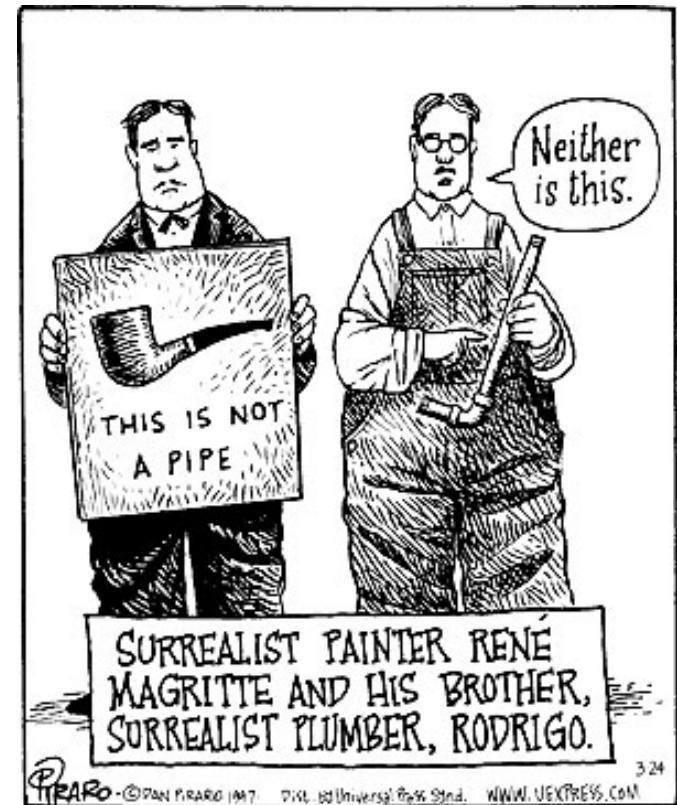


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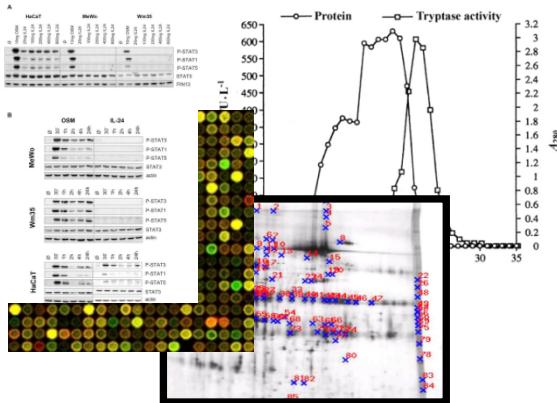
Why do we need standards in the life sciences ?

Standardized Data Representation & Consistent Metadata Description (Data Describing the Data)



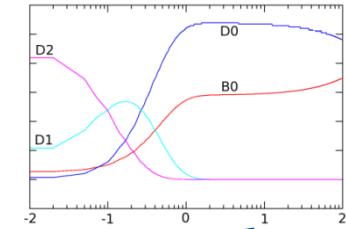
Data Integration: Systems Biology Workflows

Experimental Data

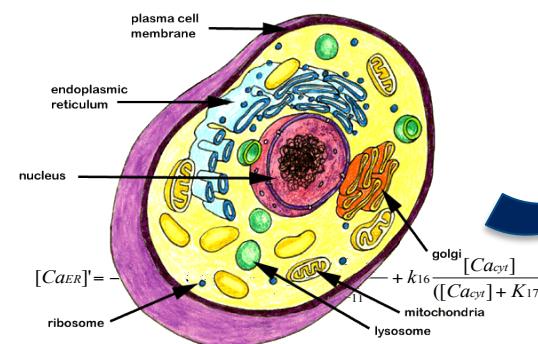


hypothesize
& verify

Simulation



collect &
integrate



Model



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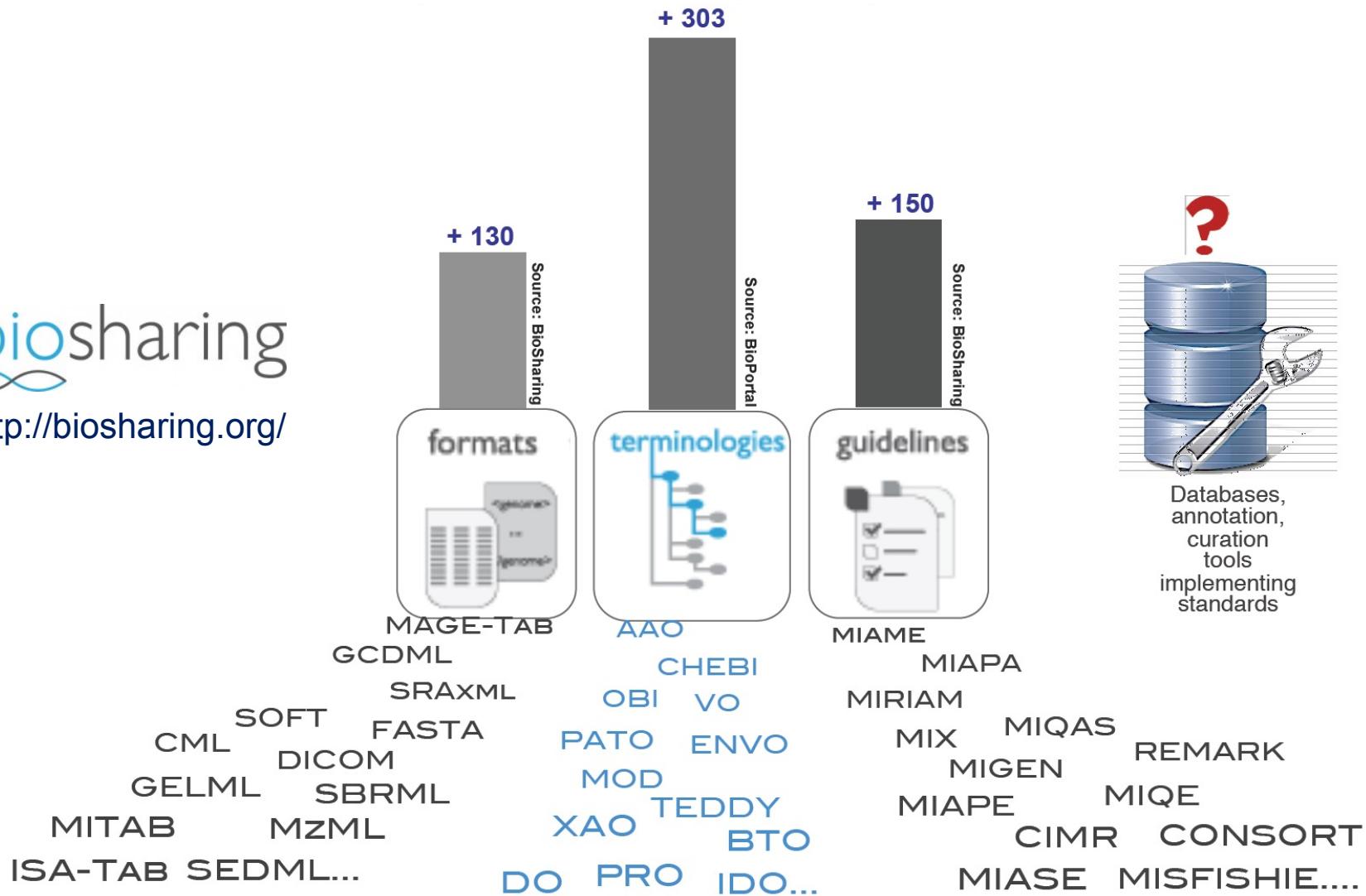
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Community (de-facto) Standards in Life Sciences



<http://biosharing.org/>



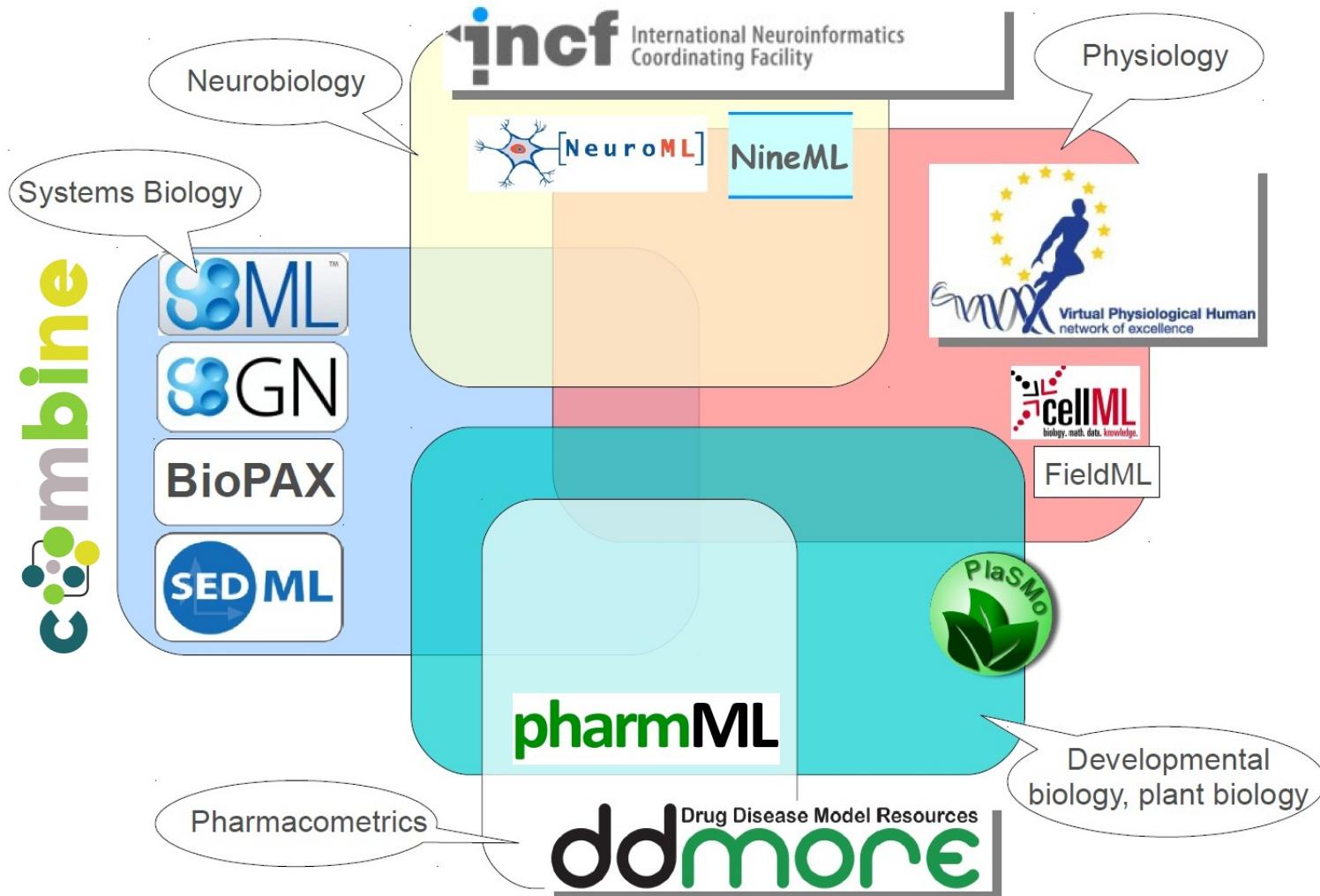
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Source: Susanna-Assunta Sansone (University of Oxford, UK)



Standard Modelling Formats in Different Fields



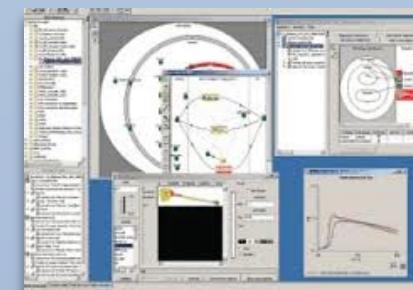
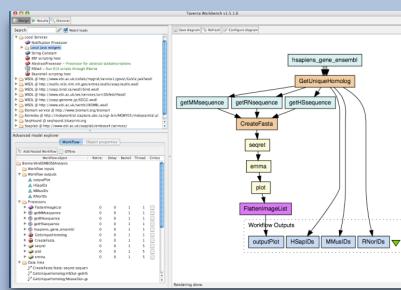
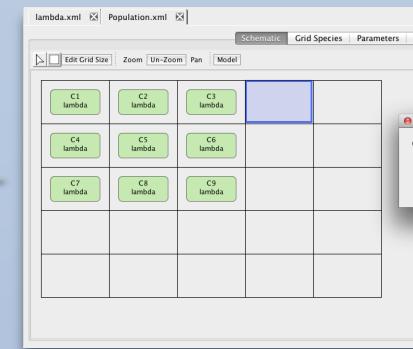
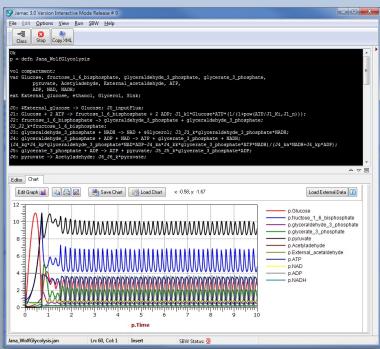
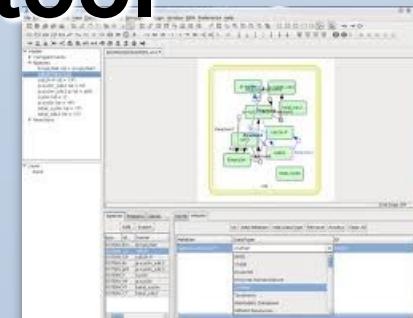
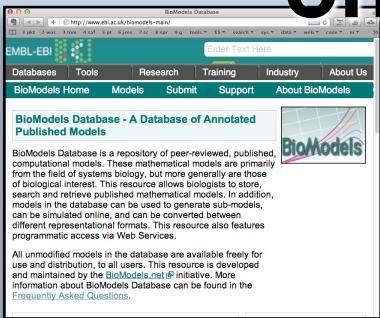
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Source: Nicolas Le Novère (Babraham Institute, Cambridge, UK)



Modelers often need to use more than one software tool



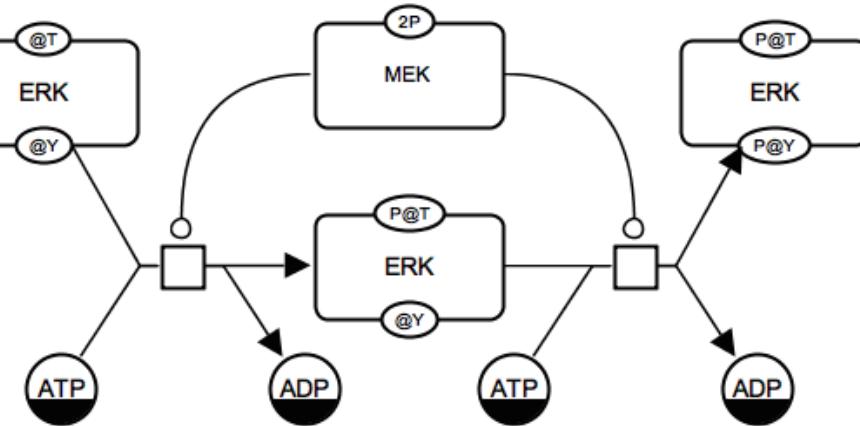
SBML = format for exchanging biological process models between software systems

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

Systems Biology Graphical Notation: SBGN

Process Description

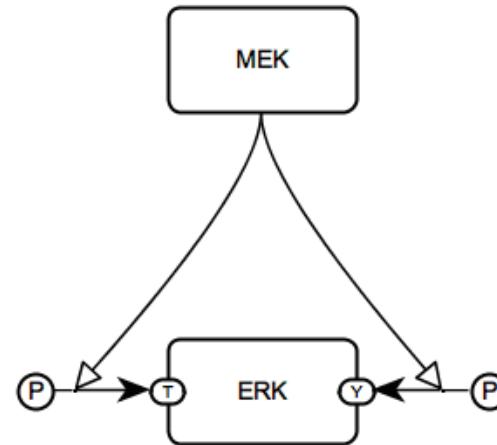
maps



- ▶ Unambiguous
- ▶ Mechanistic
- ▶ Sequential
- ▶ Combinatorial explosion

Entity Relationships

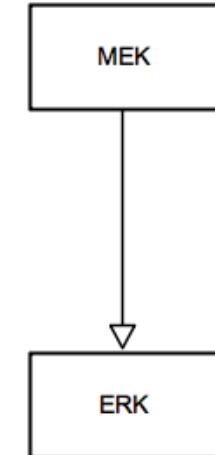
maps



- ▶ Unambiguous
- ▶ Mechanistic
- ▶ Non-Sequential

Activity Flow

maps



- ▶ Ambiguous
- ▶ Conceptual
- ▶ Sequential

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, Kawaiji 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)

Supported by:



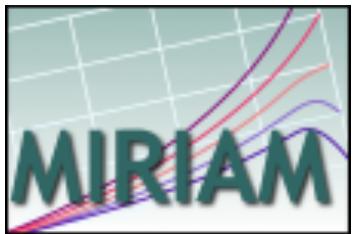
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<http://www.sbgn.org>



Reporting Guidelines: e.g. Models



Minimum Information Requested In the Annotation of biochemical Models

Reporting guidelines (Checklists) for the annotation and curation of quantitative biochemical models

www.ebi.ac.uk/miriam

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Nature Publishing Group <http://www.nature.com/naturebiotechnology>

PERSPECTIVE

Minimum information requested in the annotation of biochemical models (MIRIAM)

Nicolas Le Novère^{1,15}, Andrew Finney^{1,15}, Michael Hucka², Upinder S Bhalla⁴, Fabien Campagné⁵, Julio Collado-Varela⁶, Edmund J Crampin⁷, Matt Hulstein⁷, Béatrice Kippp⁸, Pedro Meadés⁹, Poul Nielsen⁷, Herbert Sauro¹⁰, Bruce Shapiro¹¹, Jacky L Snoep¹², Hugh D Spence¹³ & Barry L Wanner¹⁴

During the genomic era we have witnessed a vast increase in availability of large amounts of quantitative data. This is motivating a shift in the focus of molecular and cellular research from qualitative descriptions of biological interactions towards the quantification of such interactions and their dynamics. One of the limits of systems biology is the use of quantitative models (see Box 1 for definition), as a mechanism for capturing precise hypotheses and making predictions^{1,2}. Many specialized models exist that attempt to explain aspects of the cellular machinery. However, as has happened with other types of biological information, such as sequence, macromolecular structure or

Box 1 Glossary

Some terms are used in a very specific way throughout the article. We provide here a precise definition of each one.

Curated model. A formal model of a biological system, based on the mathematical description of its molecular and cellular components, and the interactions between those components.

Encoded model. A mathematical model written in a formal machine-readable language, such that it can be systematically parsed and employed by simulation and analysis software without further human translation.

MIRIAM-compliant model. A model that passes all the tests and fulfills all the conditions listed in MIRIAM.

Reference description. A unique document that describes, or references as the description of the model, the structure of the model, the numerical values necessary to instantiate a simulation from the model, or to perform a mathematical analysis of the model, and the results one expects from such a simulation or analysis.

Review process. The process by which the compliance of an encoded model with MIRIAM is achieved and/or verified. The curation process may encompass some or all of the following tasks: encoding of the model, verification of the reference correspondence and annotation of the model.

Reference correspondence. The fact that the structure of a model and the results of a simulation or an analysis match the information present in the reference description.

Published online 6 December 2005; doi:10.1038/nbt1154

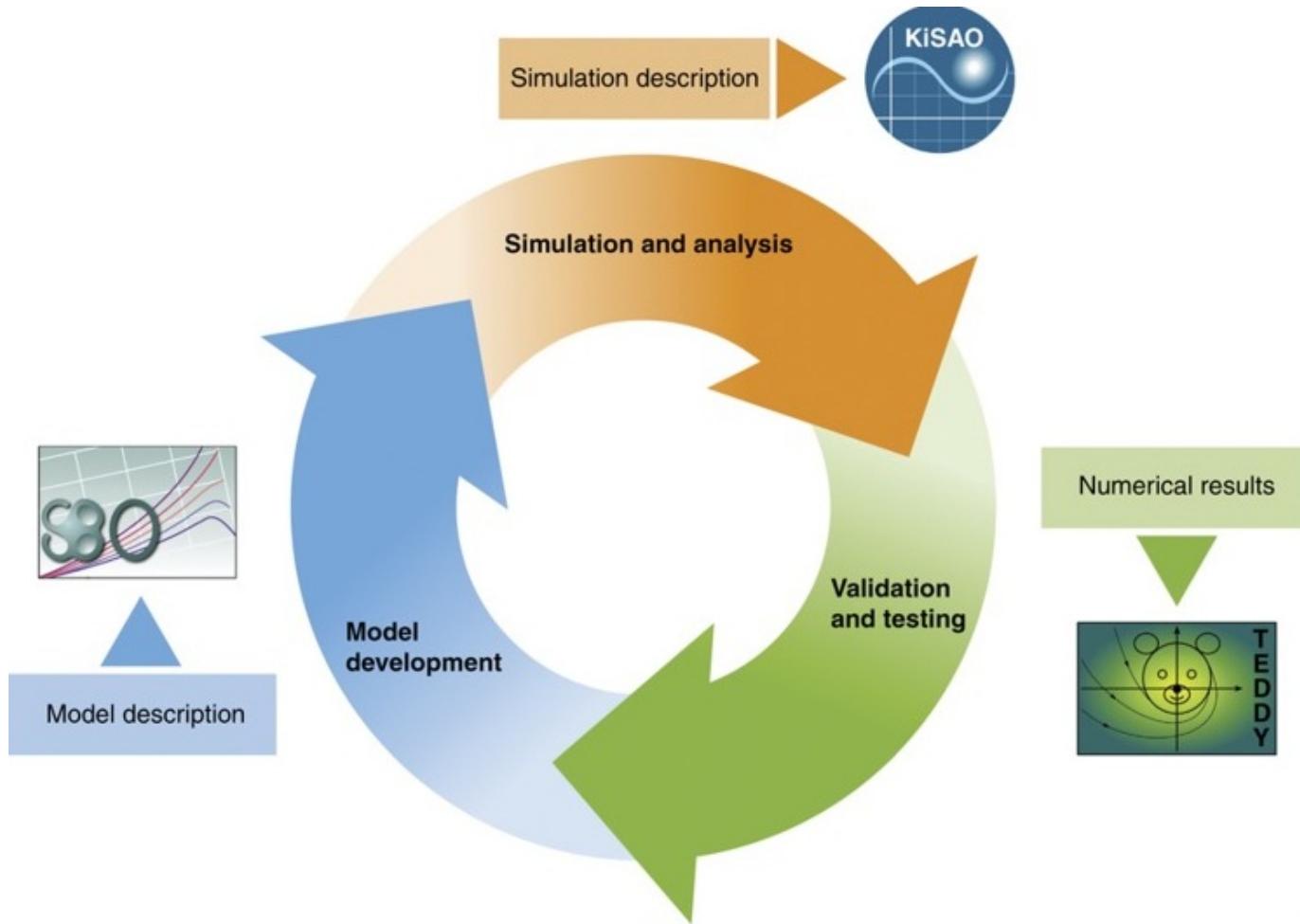
NATURE BIOTECHNOLOGY VOLUME 23 NUMBER 12 DECEMBER 2005

1206

Nature Biotech. 23(12), Dec. 2005

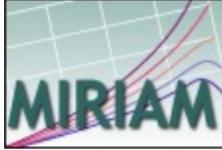
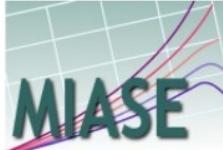
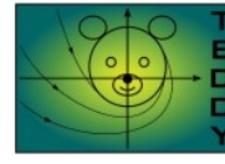


Terminologies, Ontologies and Controlled Vocabulary



Courtot M, Juty N, Knüpfer C, Waltemath D, Zhukova A, Dräger A, Dumontier M, Finney A, Golebiewski M, Hastings J, Hoops S, Keating S, Kell DB, Kerrien S, Lawson J, Lister A, Lu J, Machne R, Mendes P, Pocock M, Rodriguez N, Villeger A, Wilkinson DJ, Wimalaratne S, Laibe C, Hucka M, Le Novère N:
Controlled vocabularies and semantics in systems biology. *Mol Syst Biol.* 2011 Oct 25;7:543

Community Modelling Standards in Systems Biology

	Model descriptions	Simulations and analysis	results
Minimal requirements			
Data-models	  		NuML
Terminologies			

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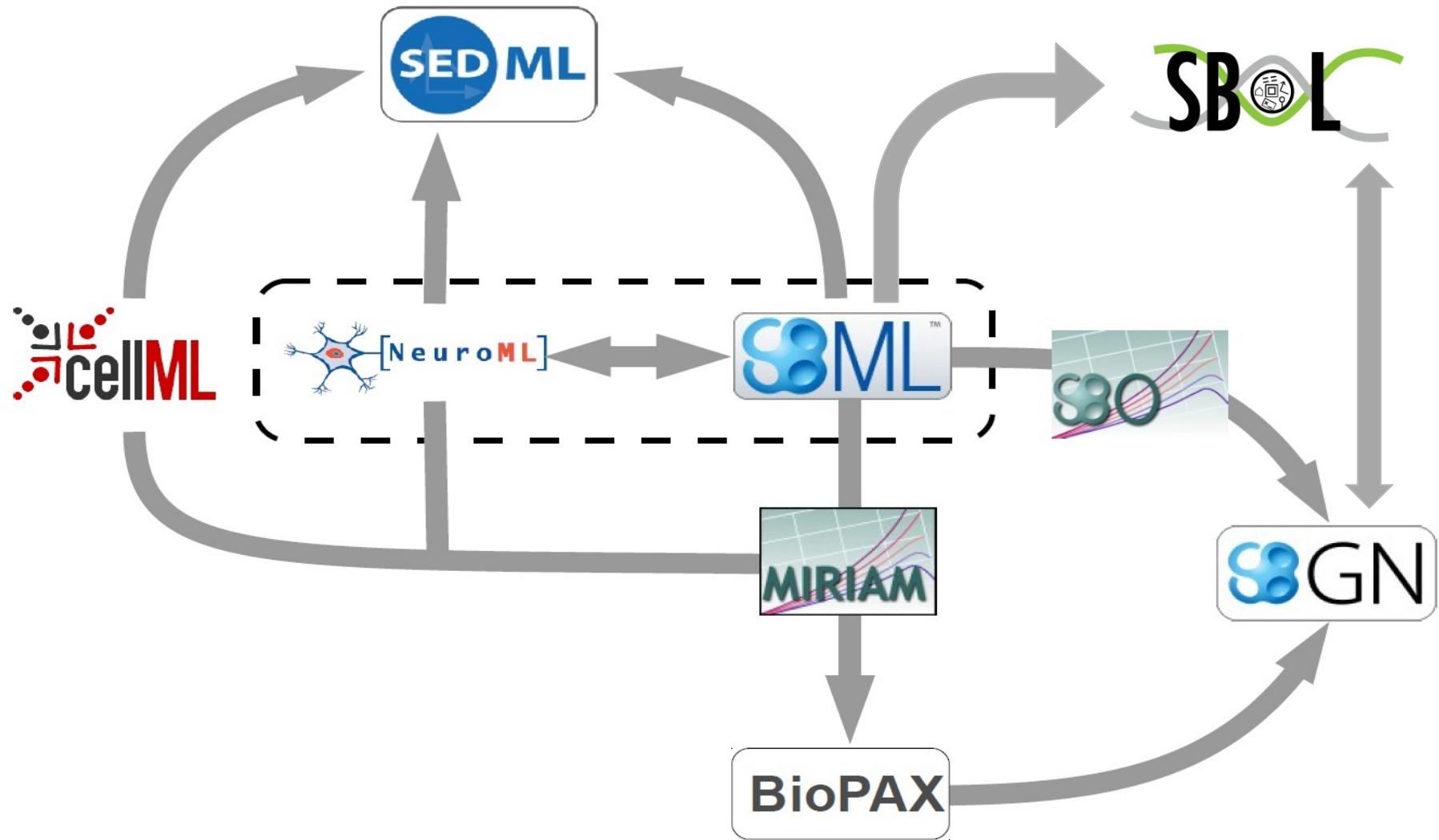


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Source: Nicolas Le Novère (Babraham Institute, Cambridge, UK)



Interfacing and Interoperability of Modelling Standards



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combine

 **HITS**

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.

Coordination of Standard Development in Systems Biology



<http://co.mbine.org/>

The “WorldWide Web consortium” of modelling in biology

***Interoperable Standards
For modelling in biology***

Hucka M, Nickerson DP, Bader GD, Bergmann FT, Cooper J, Demir E, Garny A, Golebiewski M, Myers CJ, Schreiber F, Waltemath D, Le Novère N:

Promoting Coordinated Development of Community-Based Information Standards for Modeling in Biology: The COMBINE Initiative

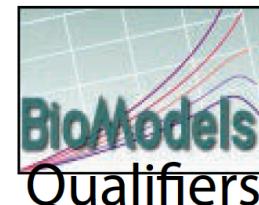
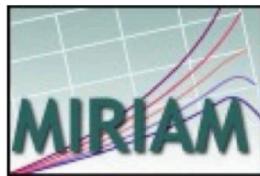
Front Bioeng Biotechnol. (2015) 3:19. doi: 10.3389/fbioe.2015.00019

COMBINE Standards

BioPAX



Associated Standardization Efforts



COMBINE
Archive



Related Standardization Efforts

NineML



FieldML

NuML

PSI-MI

GPML

MAMO



pharmML

Standardization efforts represented in COMBINE today

COMBINE Coordination Board



Gary D. Bader
(University of
Toronto, Canada)
BioPAX Delegate



Mike Hucka
(Caltech,
Pasadena, USA)
SBML Delegate



Chris Myers
(University of
Utah, USA)
SBOL Delegate



David Nickerson
(University of
Auckland, NZ)
CellML Delegate



Falk Schreiber
(Monash University
Melbourne, AUS)
SBGN Delegate



Dagmar Waltemath
(University of
Rostock, Germany)
SED-ML Delegate



Padraig Gleeson
(University College
London, UK)
NeuroML Delegate



**Martin
Golebiewski**
(HITS gGmbH,
Germany)



Nicolas Le Novère
(Babraham
Institute, UK)



Tasks and Actions:

- Computational Modeling in Biology Network
- Concerted meetings of standards:
HARMONY & COMBINE
- Training in application of standards (COMBINE tutorials)
- Coordinate standards development
- Develop common procedures & tools
- Provide a recognized voice

European COST Action CHARME



European research network comprising 28 European countries (networking action with ca. 150.000 € per year for 5 years, starting in March 2016):

CHARME - Harmonising standardisation strategies to increase efficiency and competitiveness of European life-science research

- Harmonizing and merging activities of different grass-roots standardization communities in the life sciences
- Community building/networking of scientific standardisation initiatives in systems biology (and beyond)
- Mediation between the scientific standardisation initiatives and the competent standardisation bodies and standards committees' activities (including input from stakeholders, e.g. standardisation bodies, policy makers, regulators, users)
- Analysis and classification of existing (or developing) community standards in the field of systems biology and computational modelling (and beyond)
- Support the positioning of Europe as a "leading partner" in international standardisation and standardisation activities in the life sciences (including input for future market applications and cooperation with private enterprises)

European COST Action CHARME



Chair of the Action: Susanne Hollmann (Germany)

Vice chair of the Action: Erik Bongcam-Rudloff (Sweden)

CHARME consist of 5 interaction Working Groups:

WG 1 Community/platform-building

WG lead: Ugur Sezerman (Turkey) / Martin Golebiewski (Germany)

WG2 Innovation transfer

WG Lead: Andreas Kremer (Luxembourg) / Ray Walshe (Ireland)

WG3 Design, implementation, and incorporation of software solutions

WG lead: Chris Evelo (Netherlands) / Witold Rudniki (Poland)

WG4 Development of a strategic dissemination

WG lead: Domenica d'Elia (Italy) / Babette Regierer (Germany)

WG5 Educational advertising

WG Lead: Kristina Gruden (Slowenia) / Markus Frohme (Germany)

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NormSys – Project Aims and Challenges

- Identification and **classification** of modelling standards
- Transfer from **grassroots** to **approved standards**
- Bring together all stakeholders
 - Standard **developers** providing the standards
 - Research **initiatives** and **industries** using and applying the standards
 - Publishers and **Journals** distributing (standardized) data and models
 - **Funders** having interest in sustainability and reuse of scientific results
 - Standardization **bodies** providing support for the standardization process
- How to **publish** and **distribute** the standards?
- How to **convince** the communities to apply standards?
- How to **certify** implementation of standards?



<http://www.normsys.org>

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Research Communities

Develop and apply *de facto* community standards in grass-roots initiatives



Industries

Need sustainable standards to certify



Standardisation Bodies



Help to distribute and promote standards



Standardisation Organizations



What is ISO?

ISO (International Organization for Standardization) is the **world's largest developer of voluntary International Standards**. International Standards give state of the art specifications for products, services and good practice, helping to make industry more efficient and effective. Developed through global consensus, they help to break down barriers to international trade.

ISO is a network of **164** national standards bodies who make up the ISO membership and represent ISO in their country.



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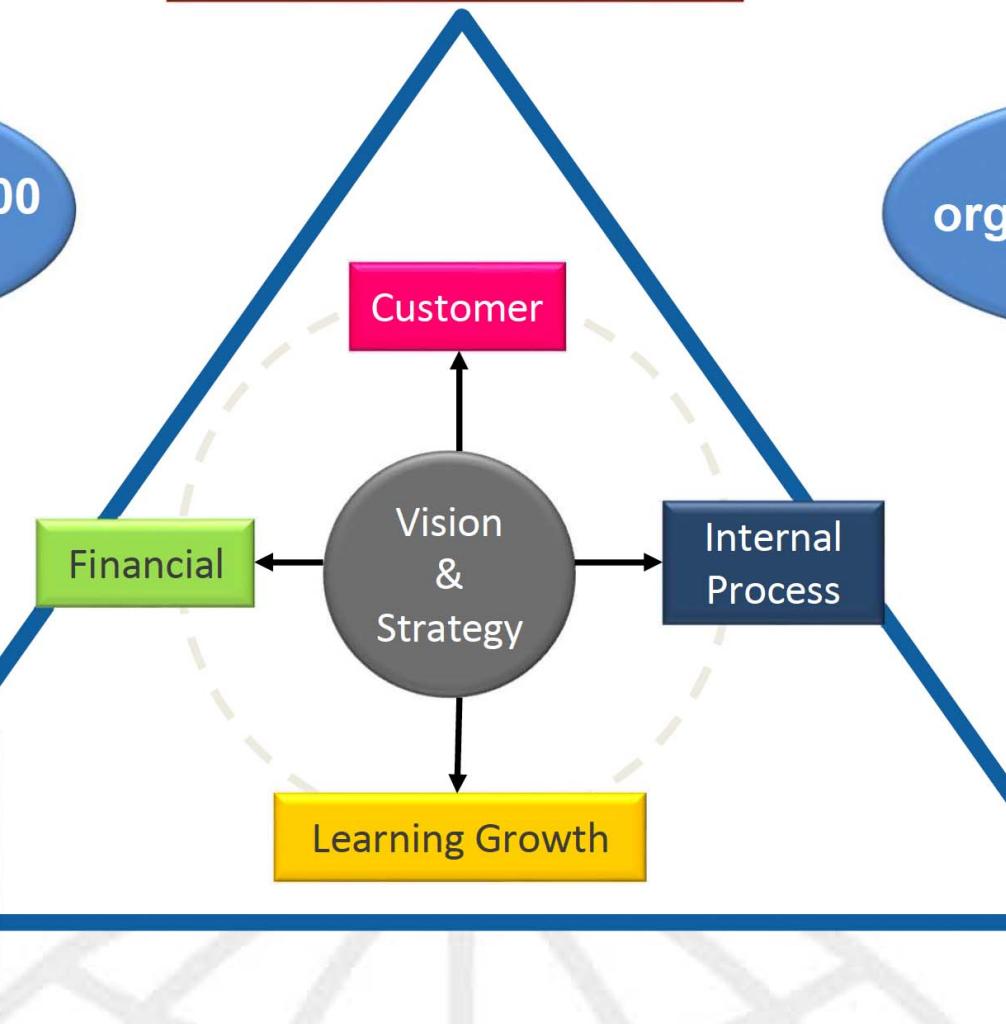
164 national members
98% of world GNI
97% of world population

Collection of 19 600
ISO Standards

1 208 standards
produced
in 2011

224 active TCs
3 354 technical
bodies
100 000 experts

Over 625
organizations in
liaison



Standardisation Organisations: How do they work?



How does ISO develop standards?



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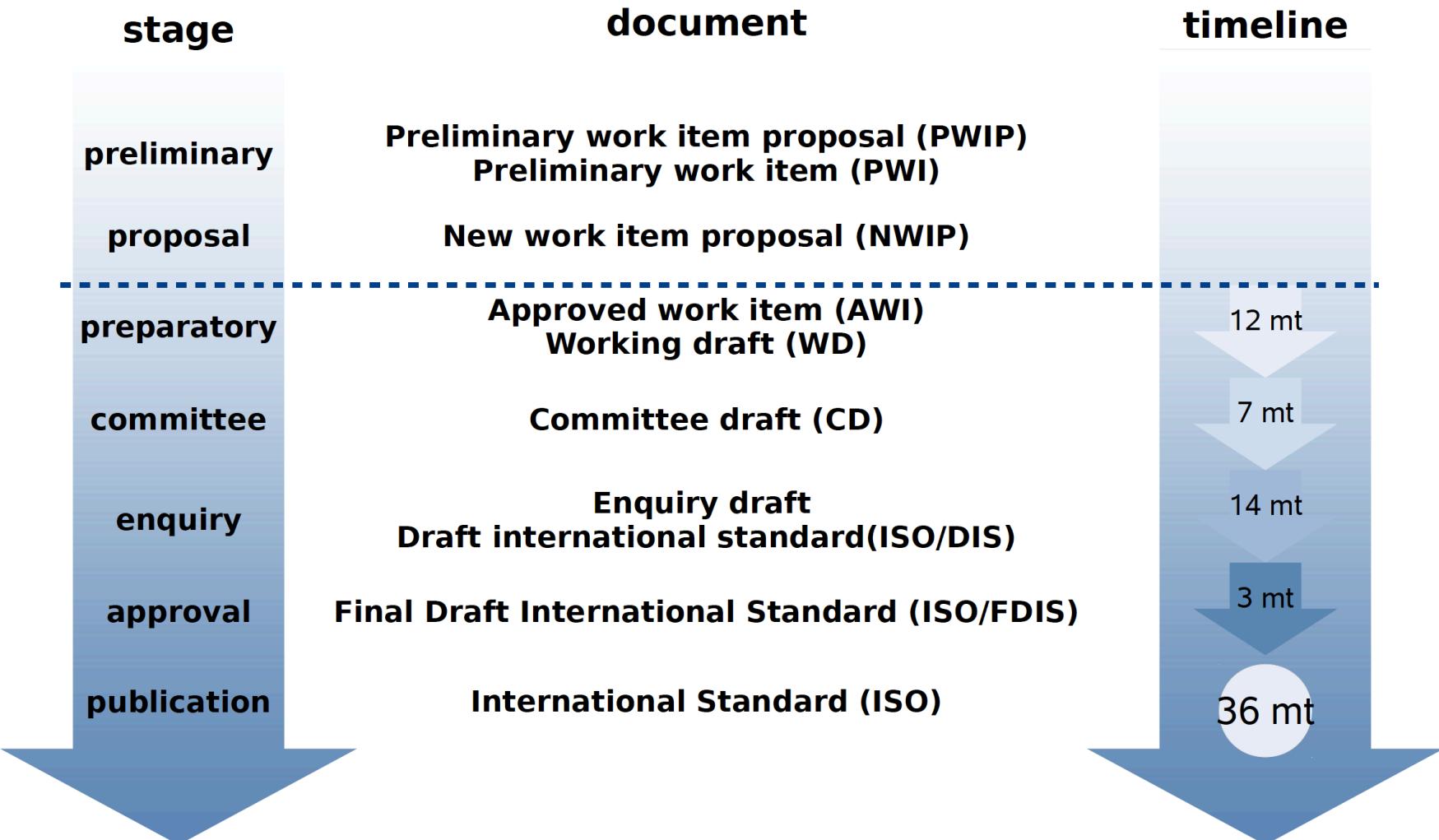
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ISO Project Stages



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ISO Document Types

IS: International standard

- normative document
- developed according to consensus procedures
- approved by the ISO membership and members of the responsible committee
- developed through the preparatory and/or committee stages until consensus is reached in the committee
- submitted to all ISO member bodies for a three-month vote as a draft International Standard (DIS) and is approved if twothirds of the P-members vote affirmatively and not more than a quarter of all votes cast are negative

TS: Technical specification

- normative document representing consensus within an ISO committee
- subject in question still under development or no agreement to publish an IS
- acceptance requires approval by two-thirds of the P-members

TR: technical report

- adopted by simple majority
- informative document containing information of a different kind from that normally published in a normative document (e.g. references and explanations)

ISO/TC 276 - Biotechnology

Scope:

Standardization in the field of biotechnology processes that includes the following topics:

- Terms and definitions
- Biobanks and bioresources
- Analytical methods
- Bioprocessing
- Data processing including annotation, analysis, validation, comparability and integration
- Metrology.

<http://www.iso.org/>

Participating Countries (25)

Argentina (IRAM)

Australia (SA)

Austria (ASI)

Belgium (NBN)

Brazil (ABNT)

Canada (SCC)

China (SAC)

Denmark (DS)

Finland (SFS)

France (AFNOR)

Germany (DIN)

Iran, Islamic Republic of (ISIRI)

Ireland (NSAI)

Israel (SII)

Italy (UNI)

Japan (JISC)

Korea, Republic of (KATS)

Luxembourg (ILNAS)

Nigeria (SON)

Portugal (IPQ)

Sri Lanka (SLSI)

Sweden (SIS)

Tanzania, United Republic of (TBS)

United Kingdom (BSI)

United States (ANSI)

Observing Countries (14)

Colombia (ICONTEC)

Czech Republic (UNMZ)

Ecuador (INEN)

Estonia (EVS)

Hungary (MSZT)

India (BIS)

Lithuania (LST)

Mexico (DGN)

Mongolia (MASM)

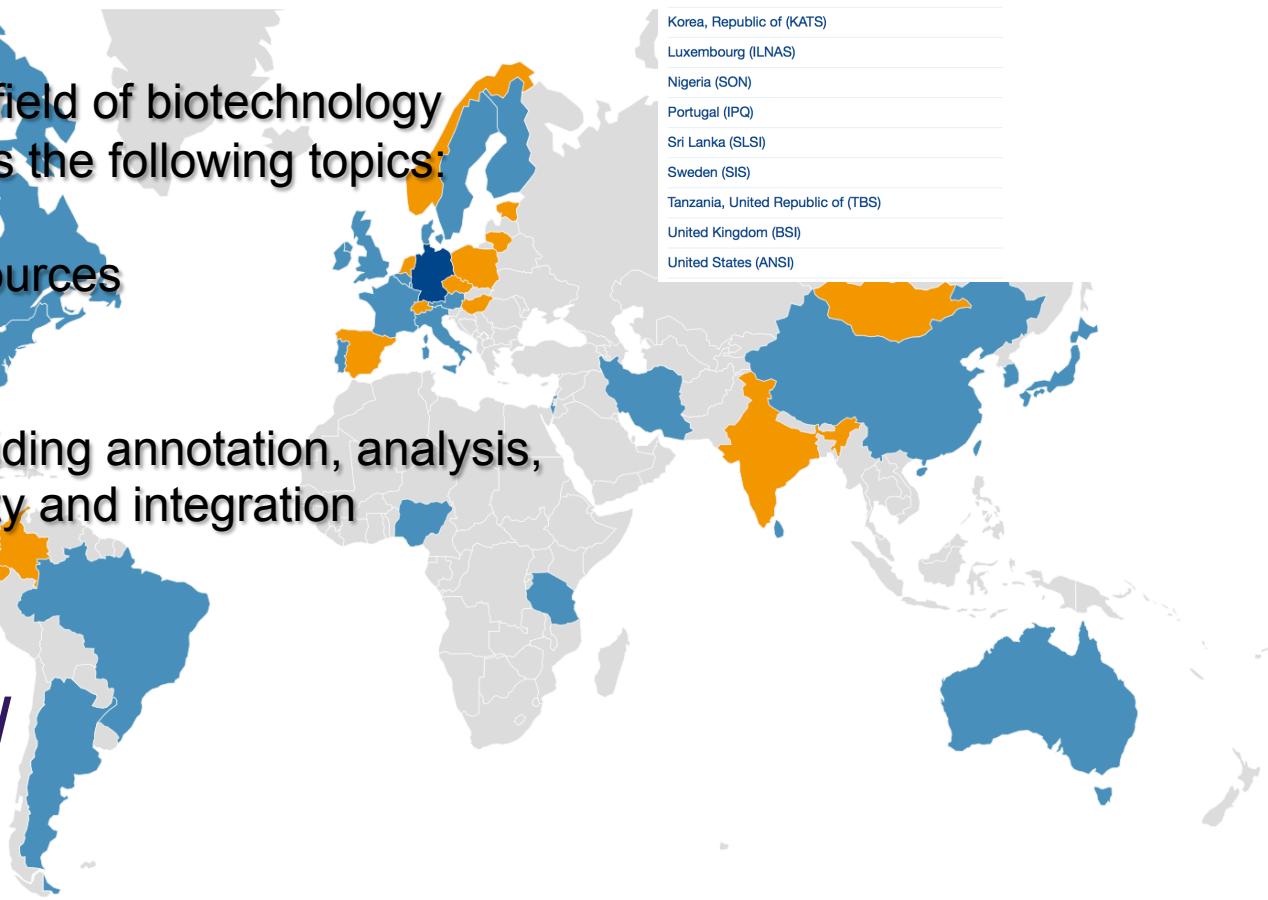
Netherlands (NEN)

Norway (SN)

Poland (PKN)

Spain (AENOR)

Switzerland (SNV)



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ISO/TC 276 Biotechnology

[About](#)[Contact details](#)[Structure](#)[Liaisons](#)[Meetings](#)[Tools](#)

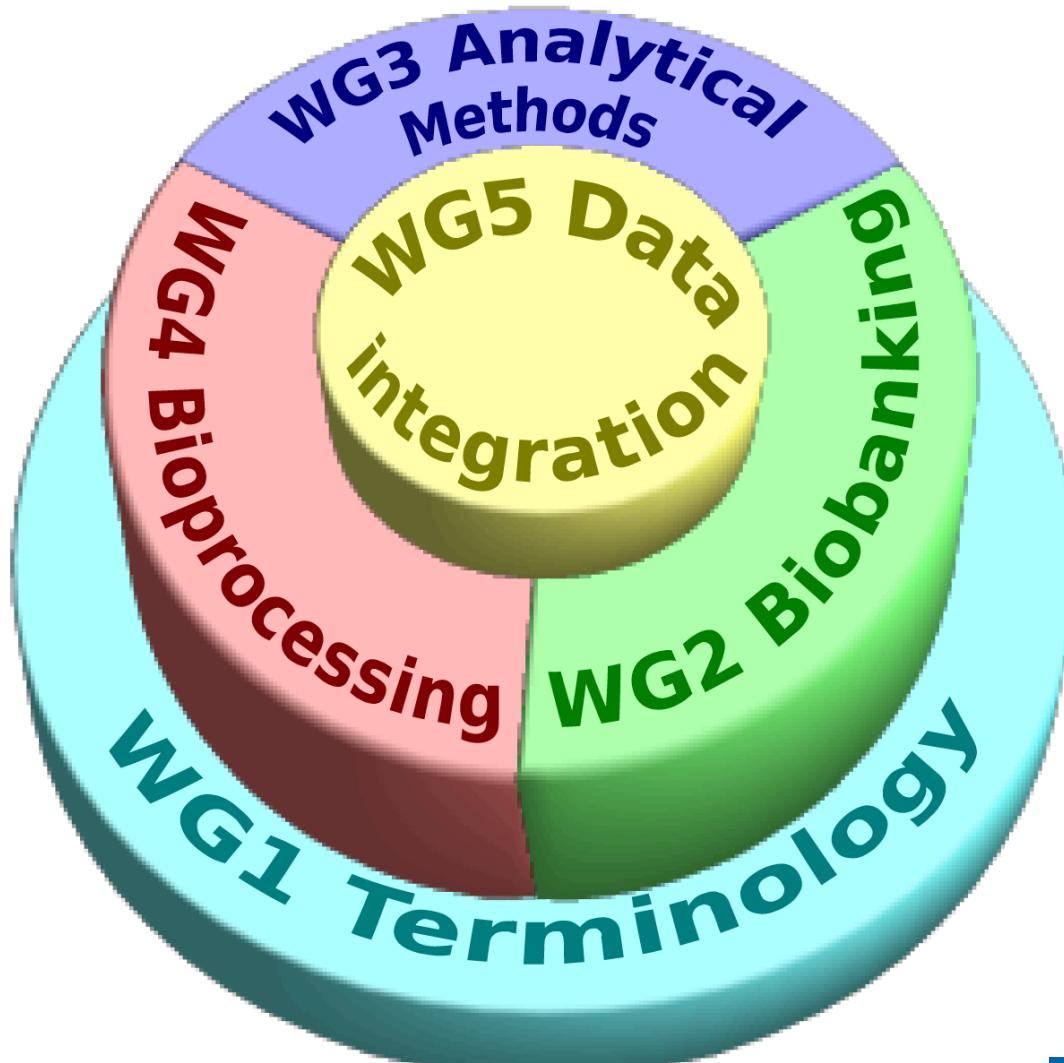
Chair: Ricardo Gent , Deutsche Industrievereinigung Biotechnologie im VCI e.V. (Germany)

Subcommittees/Working Groups:

Subcommittee/Working Group	Title
ISO/TC 276/WG 1	Terminology Convenor: Pablo Serrano, BPI e.V. (Germany)
ISO/TC 276/WG 2	Biobanks and bioresources Convenor: Georges Dagher, INSERM (France)
ISO/TC 276/WG 3	Analytical methods Convenor: Sheng Lin-Gibson, NIST (USA)
ISO/TC 276/WG 4	Bioprocessing Convenor: Tatsuo Heki, FUJIFILM (Japan)
ISO/TC 276/WG 5	Data processing and integration Convenor: Martin Golebiewski, HITS gGmbH (Germany)

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ISO/TC 276 Biotechnology - Structure



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ISO/TC 276 Biotechnology – Liaisons to ISO / CEN

Liaisons with standardization committees

- *industrial products*

- ISO/TC 229 Nanotechnologies
- CEN/TC 411 Bio-Based Products

- *information technology*

- ISO/IEC JTC 1/SC 29 Coding of audio, picture, multimedia and hypermedia information → Standardization of Genome Compression
- ISO/TC 215 Health informatics → Data Annotation

- *food products*

- ISO/TC 34/SC 5 Milk and milk products
- CEN/TC 275/WG 11 Genetically modified foodstuffs

- *technologies*

- ISO/TC 229 Nanotechnologies

ISO/TC 276 Biotechnology – Liaisons to ISO / CEN

Liaisons with standardization committees

- *laboratory*

- ISO/TC 34/SC 9 Microbiology
- ISO/TC 34/SC 16 Horizontal Methods for Molecular Biomarker Analysis
- ISO/TC 48 Laboratory equipment
- ISO/TC 184 Automation systems and integration
- ISO/TC 212 Clinical Laboratory testing and in vitro Diagnostic Test Systems

- *quality management*

- ISO/TC 176 Quality management and quality assurance

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ISO/TC 276 Biotechnology – Liaisons to ISO / CEN

Liaisons with standardization committees

- *medicine*

- ISO/TC 150/SC 7 Tissue-engineered medical products
- ISO/TC 194/SC 1 Tissue product safety
- CEN/TC 140 In vitro Diagnostic Medical Devices
- CEN/TC 316 Medical Products Utilizing Cells, Tissues

- *others*

- CEN/TC 411 Bio-Based Products

- *ISO committees*

- ISO/CASCO Committee on conformity assessment
- ISO/REMCO Committee on reference materials

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ISO/TC 276 Biotechnology – External Liaisons

Liaisons with organizations (cat. A)

- *ANRRC Asian Network of Research Resource Centers*
- *BBMRI-ERIC Biobanking and BioMolecular resources Research Infrastructure*
- *EDQM European directorate for the quality of medicines & healthcare*
- *ESBB European, Middle Eastern and African Society for Biobanking*
- *ICH The International Conference on Harmonization*
- *ISBER International Society for Biological and environmental repositories*

ISO/TC 276 WG5 Data Processing and Integration

Established at ISO/TC 276 plenary meeting in Shenzhen (China) on April 17, 2015
(upon request by the German delegation of ISO/TC 276 Biotechnology)

Participating:

Currently about **60 Experts** from **13 Countries** (P-Member):

Argentina (IRAM), Canada (SCC), China (SAC), France (AFNOR), Germany (DIN), Iran (ISIRI), Ireland (NSAI), Israel (SII), Japan (JISC), Luxembourg (ILNAS), Republic of Korea (KATS), United Kingdom (BSI), United States (ANSI)

Liaison:

- **BBMRI-ERIC** (Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium): Members contribute actively
- **ISO/IEC JTC 1/SC 29/WG 11 (MPEG)** has requested a strategic alliance with ISO/TC 276 WG5 to develop a „Genome Compression Standard“ together
- **ISO/TC 34/SC 9 Microbiology**: Members contribute actively

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ISO/TC 276 WG5 Data Processing and Integration

Secretariat: Germany (DIN) / Secretary: Mr. Björn Hermes

Covenor: Martin Golebiewski (HITS gGmbH, Heidelberg, Germany)

Co-Convenor: Yong Zhang (BGI Shenzhen and China National GeneBank)

Meetings:

1st Meeting: Berlin (Germany)	July 15 – 16, 2015 (22 experts, 8 countries)
Ad-hoc Online meeting (WebEx)	September 9, 2015
2nd Meeting: Tokio (Japan)	October 26 and 30, 2015
3rd Meeting: Paris (France)	February 18 – 19, 2016
4th Meeting: Washington (USA)	May 9 – 10, 2016
5th Meeting: Dublin (Ireland)	October 24 – 25, 2016
6th Meeting: Seoul (Korea)	May 8 – 13, 2017



New ISO Standard for Data Management and Publication in Microbial Resource Centers

ISO/TC 276 Biotechnology WG 5 (Data Processing and Integration) has started to work on a draft for a new ISO standard (Proposal from China):

- Requirements for the data management workflow and information structuring for in-house databases in microbial resources centers
- Standards for data collection, structuring and handling during deposition, preservation and distribution of microbes
- Criteria for the data sharing in online catalogues
- Minimum recommended information dataset for data publication

Potential users: Culture collections, Research groups and Biotechnology companies in the field of microbiology

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Standardization of Genome Compression



Heidelberg Institute for
Theoretical Studies



Research Institute Events News Press Career Contact



Call for Proposals for Genomic Information Compression and Storage

June 6, 2016

MPEG Issues Genomic Information Compression and Storage Joint Call for Proposals in Conjunction with ISO/TC 276/WG5

The introduction of high-throughput DNA sequencing has led to the generation of large quantities of genomic data and related information that have to be stored, transferred and analyzed. To handle these massive amounts of genomic data technologies are developed for their compression. These methods and underlying data formats need to be consistently standardized for their effective application to ensure interoperability between computer systems and databases. At its 115th meeting, MPEG issued a joint Call for Proposals (CfP) for Genomic Information Compression and Storage in conjunction with the working group for standardization of data processing and integration of the ISO technical committee for biotechnology standards (ISO/TC 276/WG5). The call seeks submissions of technologies that can provide efficient compression of genomic data and metadata for storage and processing applications.

Companies and organizations are invited to submit proposals in response to this Call. Responses are expected to be submitted by the 12th October, and will be evaluated during the 116th MPEG meeting of 17th – 21st October 2016. Detailed information, including how to respond to the CfP, is available as document N16320 at the 115th meeting website (<http://mpeg.chiariglione.org/meetings/115>). For any questions about the call, test conditions, required software or test sequences please contact: **Joern Ostermann**, MPEG Requirements Group Chair (ostermann@tnt.uni-hannover.de) or **Martin Golebiewski** (HITS), Convenor ISO/TC 276/WG5 (martin.golebiewski@h-its.org).

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Developing an ISO standard for applying and connecting community modelling standards

Downstream data processing and integration workflows — Minimal requirements for downstream data processing and integration workflows for interfacing and linking heterogeneous data, models and corresponding metadata

1 Scope

The standard comprises recommendations for the specific application of dedicated community standards for the formatting of processed life science data derived from the original raw data, covering technology fields such as genomics (including next-generation sequencing), transcriptomics, proteomics, metabolomics, glycomics, immunohistochemistry, image processing, synthetic biology and related fields, as well as for the formatting of resulting computer models. It also contains specific recommendations for the application of dedicated standards for the description of metadata related to the data and models and recommended workflows for the structured processing, storing, integration and dissemination of the biological computer models and their metadata.

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Developing an ISO standard for applying and connecting community modelling standards

ISO/TC 276 Biotechnology WG 5 (Data Processing and Integration) has started to work on a draft for a new ISO standard in the life sciences:

„Minimal requirements for downstream data processing and integration workflows for interfacing and linking heterogeneous data, models and corresponding metadata“ (ISO/PWI 20691)

Framework („hub“) standard making references to existing community standards:

- Criteria and requirements for life science data and model formats
- References to community formats for life science data and computer models
- References to minimal reporting guidelines for data, models and metadata
- Definition of interfacing between data sets, models and metadata
- Standards for describing workflow elements and their interplay in modelling biological systems

4 Criteria and requirements for life science data formats and model formats

4.1 Technical criteria and requirements

4.2 Semantical criteria and requirements

5 Mapping existing guidelines related to formats for processed life science data and computer models

5.1 Recommended formats for processed life science data

5.2 Recommended formats for the description of synthetic biological parts, devices and systems

5.3 Recommended formats for complex metadata (technology-independent)

5.4 Recommended formats for computer models of biological systems

5.5 Recommended formats for model simulations and their results

5.6 Recommended ubiquitous identifier scheme for biological and conceptual entities

5.7 Recommended descriptors for quality measurements for data and models

6 Minimal reporting requirements for data, models and metadata

6.1 Recommended minimum information standards (checklists)

6.2 Recommended domain specific ontologies, taxonomies and controlled vocabularies

Need for a meta-standard for standards

Example: Great Baltimore fire of 1904



Individual fire hydrants depending on region
with 600 variations of hose couplings
→ Need for a standard for general interfaces

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Reproducibility, standards and SOP in bioinformatics

Combined CHARME – EMBnet and NETTAB 2016 Workshop, October 25-26, 2016, Rome, Italy

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Reproducibility, standards and SOP in bioinformatics

Combined CHARME – EMBnet and NETTAB 2016 Workshop,
October 25-26, 2016, Rome, Italy

The Workshop '**Reproducibility, standards and SOP in bioinformatics**' is co-organised by the COST European Action **CHARME** (CA15110), **EMBnet** (The Global Bioinformatics Network) and **NETTAB** (International Workshop Series on Network Tools and Applications for Biology). It is hosted by the **ELIXIR-ITA** Node and will be held at the Italian **CNR** (National Research Council) head quarter, in Rome. The workshop will be preceded by a **GOBLET/ELIXIR-ITA** Tutorial and a **ELIXIR** Hackathon on Monday 24th and followed by the **EMBnet** Annual General Meeting on Thursday 27th and Friday 28th.

News!

NETTAB Workshops are social



COST is supported by the
EU Framework Programme Horizon 2020

