COST Action CHARME (CA15110)

Harmonising standardisation strategies to increase efficiency and competitiveness of European Life Science Research https://www.cost-charme.eu/

Domenica D'Elia

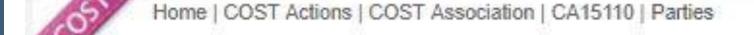
WG4: Development of a strategic dissemination plan

NETTAB 2018 - October 22-24, 2018, Italy





CHARME Lifespan



CA COST Action CA15110

Parties

Action details

MoU	042/15	
CSO Approval date	30/10/2015	
Start of Action	21/03/2016	
End of Action	20/03/2020	

https://www.cost-charme.eu/home





AIM & primary objectives

CHARME aims to **bridge and combine** the fragmented areas of various moves in the development of new norms and standards to achieve a breakthrough in standardisation efforts in life sciences research

CHARME is working to **identify needs and gaps**, teaming up with other initiatives and organisations to avoid duplication and overlap of standardisation activities

CHARME final goal is to **develop** a common, **coordinated, long-term strategy**, by active involvement of all stakeholders (from research, industry and policy), to successfully assimilate standards into the daily work-flow of Life Science Research





CHARME's pan-European network unites experts from all areas of scientific research and strategic development (academia, industry, policy, legal, ethical, etc.), joining their expertise to address needs and challenges along the value chain for life sciences across Europe.

The leverage of the COST Action CHARME relates to four pillars:

- > the creation of a network of all relevant stakeholder groups involved in standardisation, to exchange and harmonise activities;
- > the development of a cross-cutting education and training strategy to raise awareness and facilitate the implementation of standards and SOPs;
- > strengthening of innovation creation and technology transfer;
- > strategy development to urge the implementation of standards and SOPs.





Where do we come from?



CHARME is based on the work and outcomes of different European Initiatives (among others)



















The COST Action CA15110 is supported by the EU Framework Programme Horizon 2020



Why CHARME?







Science 2.0

Science 1.0

Science 2.0

Current model Emerging model

Research done privately; then submitted to journals; then peerreviewed by gatekeepers in major journals; published

Research data shared during discovery stages; ideas shared; scientists collaborate; then findings are disseminated online

Scientific literature behind paywalls online

Scientific discoveries free online

Credit established by journal name or journal impact factor.

Credit established by citation count, number of views or downloads.

Data is private until publication

Data is shared before publication

Papers generally protected by copyright

Many different licenses possible: copyright, public domain, Creative Commons 3.0, etc.

Publishers raise funds by charging for access to content

Publishers seek alternative funding models

Journal article summaries available online after publication

Share methods, data, findings via blogs, social networking sites, wikis, computer networking, Internet, video journals





Life Sciences

Harmonisation and interfacing on the level of data formats and structures, descriptors and metadata represent just one side of the coin





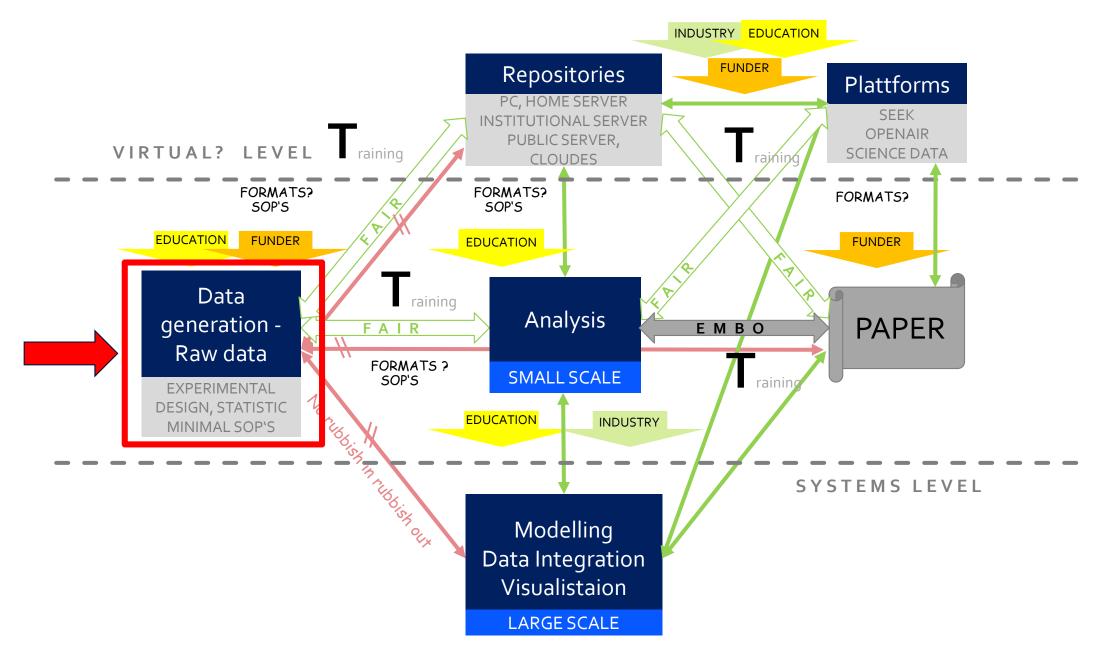
Life Sciences

...what about quality of data?





Along the pipeline of acquisition of data to (re)use. Future needs - today's requirements



Open Science

 Quality Managment and Standardisation in context with Open Science (OS) efforts





Actual Problem of Life Science Research

> 50% of the research data are **not**

re-usable or accessible





Vines et al., Curr Biol. 2014 Jan 6;24(1):94-97. doi: 10.1016/j.cub.2013.11.014.

The availability of research data declines rapidly with article age

- We examined the availability of data from 516 studies between 2 and 22 years old
- The odds of a data set being reported as extant fell by 17% per year
- Broken e-mails and obsolete storage devices were the main obstacles to data sharing

Policies mandating data archiving at publication are clearly needed





Actual Problem of Life Science Research

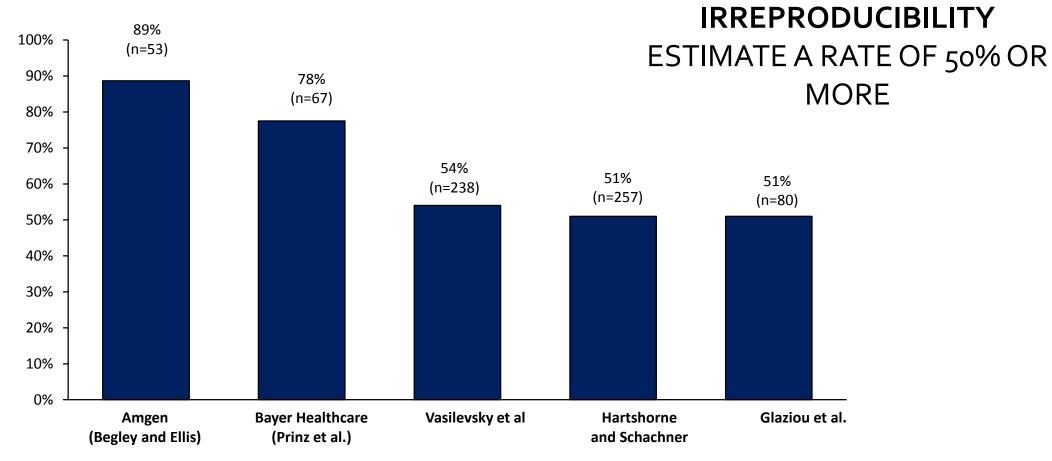
• Is accessibility the only problem we have to face

.....or there is more?





Results from ten-year retrospective analysis of experiments performed prospectively.





<u>Quality Management in Scientific Research: Challenging Irreproducibility of Scientific Results</u>

<u>By Antonella Lanati – May 2018</u>

STUDIES LOOKING AT THE

PREVALENCE OF

Extensive survey of scientists across academia and industry

By The Global Biological Standards Institute (GBSI)

The causes

- 1. Variability in biological reagents
- 2. Improper study design (lack of proper controls)
- 3. Biased data analysis and interpretation of results
- 4. Inadequate documentation and reporting of protocols
-AND
- 5. pressure to publish
- 6. lack of funding to replicate experiments thoroughly
- 7. selective reporting, excluding negative results
- 8. insufficient peer review



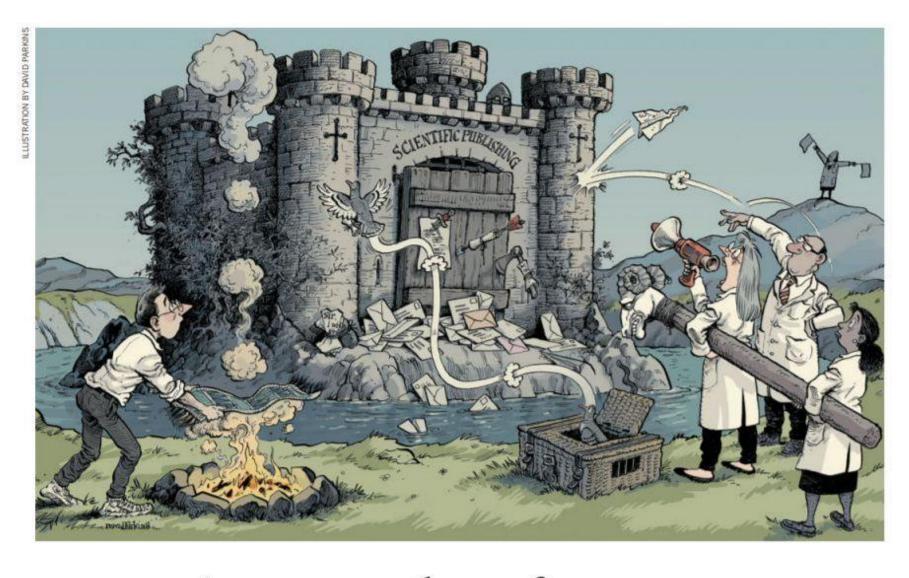


Open Science

Formal Quality Systems are Lacking in Academic Research







- Robust science needs robust corrections
- It is time to make the process less onerous.

A tragedy of errors

Mistakes in peer-reviewed papers are easy to find but hard to fix, report **David B. Allison** and colleagues.

https://www.nature.com/news/repro ducibility-a-tragedy-of-errors-1.19264

Three common errors

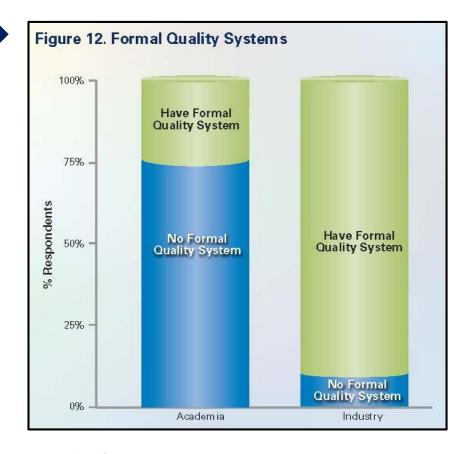
 Mistaken design or analysis of clusterrandomized trials

Miscalculation in meta-analyses

Inappropriate baseline comparisons







"Irreproducibility occurs in the absence of a unifying quality control and assurance framework"

Standards facilitate the alignment of consensus-based best practices, reduce variance, and **improve reproducibility** in research



© Leonard P. Freedman, PhD President, GBSI





Challenges in implementing SOPs in the laboratory

- Resistance from PhD students, postdocs and technicians
- It require more time for the people initiating SOPs (indicating more documentation and more quality controls), who would be the first ones?
- No incentive system (funding and/or papers)
- No convincing documents that benchmark the works with or without SOPs





How to fix this?

- Unified guidelines and standards in biological research
- global participation of the scientific community

Irreproducibility

NIH, together with **journal groups led by Nature and Science**, have conducted workshops with scientists and journal editors and drafted:

- consensus guidelines for research training
- best practices
- journal policies and reporting standards to enhance transparency and reproducibility







Science moves forward by corroboration – when researchers verify others' results. Science advances faster when people waste less time pursuing false leads. No research paper can ever be considered to be the final word, but there are too many that do not stand up to further study.

There is growing alarm about results that cannot be reproduced. Explanations include increased levels of scrutiny, complexity of experiments and statistics, and pressures on researchers. Journals, scientists, institutions and funders all have a part in tackling reproducibility. Nature has taken substantive steps to improve the transparency and robustness in what we publish, and to promote awareness within the scientific community. We hope that the articles contained in this collection will help.

https://www.nature.com/collections/prbfkwmwvz



The EU Joint Initiative on Standardisation

June 2016

Joint Initiative on Standardisation

- **Objective**: to reinforce the partnership between the European institutions and the standardisation community
- Aim: to ensure that Europe remains a global hub for standardisation
- Motivation: standards need to keep pace with the changing economy, the increasing importance of services, and the digital revolution
- Annual work programmes
- WP for 2017: services and ICT sectors as priority for future standard-setting because of their cross-cutting role in economy







What is the EC Open Research Data Pilot?

The Open Research Data Pilot of the European Commission enables open access and reuse of research data generated by Horizon 2020 projects. There are two main pillars to the Pilot: developing a Data Management Plan (DMP) and providing open access to research data, if possible.

The conditions you have to adhere to, are:

- Develop (and keep up-to-date) a Data Management Plan (DMP).
- Deposit your data in a research data repository.
- · Ensure third parties can freely access, mine, exploit, reproduce and disseminate your data.
- Provide related information and identify (or provide) the tools needed to use the raw data to validate your research.

The Pilot applies to:

- The data (and metadata) needed to validate results in scientific publications.
- Other curated and/or raw data (and metadata) that you specify in the DMP.

Data management costs are eligible for reimbursement during the duration of the project, and can be claimed under the conditions defined in the grant agreement.





> ...are do we prepared?





Needs in Standards

Needs in standards/standardisation:

- Information exchange between communities
- Involvement of different stakeholders
 (incl. publishers, funders, standardisation bodies)
- Distribution of information
- Adoption on a broad scale
- Involvement of institutions and founders
- Compliance of all actors

- EDUCATION!!!





Just released



Keyphrases: Education, FAIR data, Interoperability, Quality Control (QC), Quality Management (QM), Standard Operating Procedures (SOPs), standardisation



curricula.

https://easychair.org/publications/preprint/1fZQ



Needs in Standards

The Major Barrier to the implementation of FAIR data principles:

Lack of experts who understand the principle and posses knowledge of the principles and relevant tools





Needs in Standards

> Insufficient and unequal education

> Barriers:

- ✓ Institutional
- ✓ Lack of local experts
- ✓ Lack of appropriate teaching material
- ✓ Lack of appropriate adaptation of curricula





Key Points

- Tools & Training on how to achieve rigorous and consistent identification is a fundamental step towards making research data FAIR
- Publishers have an obligation to ensure the integrity of the research they publish; this means that they too have a responsibility in:
 - to develop guidelines for data-management, linked to FAIR principles
 - 2. to help researchers to understand and meet their data-stewardship standards
- Repositories, platforms and tools already exist for the community

HOVEWER.....





There are still some barriers to overcome

Metadata vs. raw data:

The FAIR data principles, mainly address the metadata levels in research, whereas the quality of the source datasets themselves often remains unaddressed

High quality for samples and data:

Using Standard Operating Procedures (SOPs)

Managing data according to a Data Management Plan

Host data, SOP and standards workflows on sustainable infrastructures

Low acceptability caused by lack of education





CHARME Proposal

- Introducing certified methods and protocols in a top-down process
- Encouraging a EU-wide adoption of training of "next-generation" scientists
- Provide open access protocols, methods and tools serving as a basis for proper data management
- Encourage publishers to request authors to make the source data available for any publication they consider



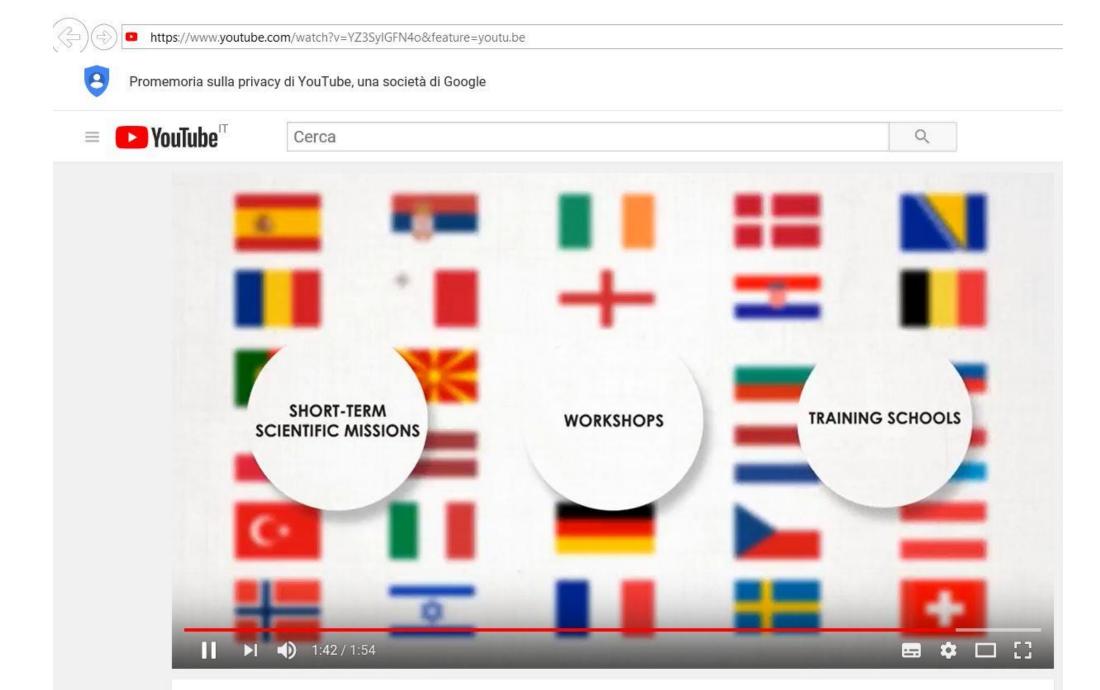


Pressing Need

Education in Data Management, Standardisation and Quality Management

- Definition of the **minimal skills** that students should acquire within their Bachelor studies and Master's programme
- Possible basic CV with flexibility to adjust to different application areas and local research strengths
- Involvement of teachers, principal investigators and lecturers to increase awareness in these groups
- Mechanisms for collaborative preparation and sharing high quality teaching materials and methods among education professionals





COST Action CHARME

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