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PRO-MaP
Promoting Reusable and Open Methods and Protocols

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Methods Are Frequently Lost

Looking for protocol in 1997 paper: "as described in (x) et al '96". Finds '96 paper: "as described in (x) '87." Finds '87 paper: Paywall.

2017: “Devices were fabricated as previously described [ref 8]”

[ref 8] 2015: “Devices were fabricated as previously described [ref 4]”

[ref 4] 2013: “Devices were fabricated as previously described [ref 2]”

[ref 2] 2009: “Devices were fabricated with conventional methods”
The European Union Reference Laboratory for alternatives to animal testing

- Research
- Validation
- Dissemination
- Promotion
Promoting of non-guideline methods
Methods & Protocols in Peer Review Publications

working with the community
1. Majority of publications do not value the methods section enough
Neutrinos not faster than light

Half of top cancer studies fail high-profile reproducibility effort

Barriers to reproducing preclinical results included unhelpful author communication, but critics argue that one-time replication attempts don’t tell the whole story.

Plan to replicate 50 high-impact cancer papers shrinks to just 18

By Jocelyn Kaiser | Jul. 31, 2018, 5:45 PM
2% of experiments with open data

70% of experiments required asking for key reagents

69% of experiments needing a key reagent original authors were willing to share

0% of protocols completely described

32% of experiments the original authors were not helpful (or unresponsive)

41% of experiments the original authors were very helpful
‘open access’ and ‘open data’ do not guarantee reproducibility
WHY sharing Protocols and Methods?

- Transparency
- Advance in Science
- Transferability of Science
- Reproducibility is CORE to science
- Translation of Science (impact citizens)
1. Majority of publications do not value the methods section enough

2. (Part of the) Community is aware of this and some initiatives trying to tackle it!
Community Work

Phase 0:
Workshop with Key representatives

Publishers  Funders  Researchers  Platform Managers
A call for transparent reporting to optimize the predictive value of preclinical research


The US National Institute of Neurological Disorders and Stroke convened major stakeholders in June 2012 to discuss how to improve the methodological reporting of animal studies in grant applications and publications. The main workshop recommendation is that at a minimum studies should report on sample-size estimation, whether and how animals were randomized, whether investigators were blind to the treatment, and the handling of data. We recognize that achieving a meaningful improvement in the quality of reporting will require a concerted effort by investigators, reviewers, funding agencies and journal editors. Requiring better reporting of animal studies will raise awareness of the importance of rigorous study design to accelerate scientific progress.
Methods Matter for Open & Reproducible Research

**IF Cookies == Data**

**Analysis of**

Size / Thickness / Texture / Flavour etc.

**Can *ONLY* be interpreted in the context of the method tweaks**

- too much flour / incorrect ingredient
- amount of butter / bake time etc.)

*Kindly provided by Emma Ganley*
Cell Press launched STAR Protocols in 2019 to fulfill this need

Author perspective

As an author, I want to...
• Be accurate in my reporting
• Showcase my technical expertise
• Get credit for my work
• Update my protocol as needed

Benefits to authors
• Increase the reach and use of the original research article
• Gain another publication in an open access, indexed and peer reviewed journal
• Author template simplifies the process of converting lab protocols to a STAR Protocol
• Innovative, timely peer review and publication process
• Quick turnaround time (50 days from submission to accept)
• Improve lab record keeping to preserve institutional knowledge
• Contribute to open science and help encourage reproducibility

User perspective

As a user, I want to...
• Find and choose the right method
• Reproduce a method step-by-step
• Troubleshoot
• Get expert advice

Kindly provided by Elisa De Ranieri
Study reporting checklist, based on GIVIMP

Used GIVIMP guidance and SciRap tool to establish the following reporting checklist:

### Apparatus, materials and reagents

1. The **apparatus was described**.
2. The **limit of detection or limit of quantitation** of the apparatus was indicated.
3. The **materials and reagents** were described.
4. The **culture dimensions** were described (mm² or ml).
5. The **use of animal-derived materials or reagents** (e.g. Trypsin, antibodies, collagen, Matrigel etc.) was described.
6. The **use of fully animal-free materials and reagents** was described.

### Data collection and analysis

1. The **experimental design** and relevant acceptance criteria were described.
2. The **experimental layout**, e.g. plate layout was described.
3. The **time points for data collection** were stated.
4. It was stated that the effect of the test item on **cytotoxicity** was measured.
5. **Other observations that may impact the results** (e.g. autofluorescence, absorbance by the test system) are reported.
6. Details on **calculation of results** were given.
7. All **results** were clearly presented, including negative and failed runs.
8. The **statistical methods & software** used were described.
9. A clear description on how to interpret read outs and criteria for decision-making were given. OR Evaluation/data interpretation criteria were given.

### Test item treatment

1. The **test item concentrations/dose levels** were stated.
2. Biological fluid characterisation was described (quantification of proteins and cells/tissue present).
3. Binding to biological fluid material was described.
4. Binding to culture material was described.
5. Test system number, density, dimension, quantity used during treatment was described.
6. The **duration of treatment** was stated.
7. The **number of replicates per concentration/dose** was stated.
8. The **number of times the experiment was repeated** (independent biological runs) was stated.

### Funding and competing interests

1. The **funding sources** for the study were stated.
2. Any competing interests were disclosed or it was explicitly stated that the authors did not have any competing interests.
3. Information on the **overall availability of the IPR protected components**, including whether they are commercially available or require a Material Transfer Agreement or other licensing agreements, was given.
Importance in Peer-review
WORKSHOP OUTCOMES
OR WHERE DO WE STAND NOW
Ideally...

Methods and Protocols that are Detailed, Clear, Complete, Transferable, Reusable, Dynamic, Transparent, Reliable, Reproducible and Open
Recommendations to Key Groups

1. Increasing awareness
2. **HOW** to achieve good methods and protocols reporting
3. Developing better means and tools to share and publish protocols
4. Increasing funding and Investing in education on good reporting
RECOMMENDATIONS

for

Researchers & their Institutions

- Embed in the culture
- Use of protocols
- Relevant guidelines
- Method section linked to dynamic protocols
- Training
- Reward: CV, Prizes, awards...
- Embed on PhD thesis structure
RECOMMENDATIONS
for
Editors & Publishers

✓ Promote access to detailed protocols
✓ Ensure and allow enough detail – no word limit or copyright, include material reference
✓ Structured methods
✓ Link to protocols that are versioned, fork and not duplicate or supplementary
✗ Shortcut citations
✓ Update guides for authors and reviewers accordingly
RECOMMENDATIONS for Funding Agencies

- Support open protocols
- Request availability of study protocols
- Reward good practices
- Focus on Early Career researchers
- Fund dedicated actions and development of tools
- Fund training
WHY IS THIS RELEVANT FOR Non-ANIMAL METHODS?
Methods in the Regulatory arena

Regulatory Testing for Endocrine Disruptors; Need for Validated Methods and Integrated Approaches

Elise Grignard*, Kelly de Jesus and Philippe Hubert
PEPPER, Paris, France

Another aspect to take into account when considering the revision of the information requirements is the need of methods able to fulfil the three aspects of the criteria for the identification of EDs, as laid out in the Pesticides and Biocides Regulations, i.e., the

Identifying methods with a potential for validation and use in regulatory-relevant ED characterisation is a tricky issue for many reasons. For example, the published literature is mainly presenting toxicological properties of substances, and rarely describes methods in an extensive or transparent way. A list of data collection on methods was compiled by a group developing a case
Animal methods better covered for transparency

- Ethics
- Mandate by funding entities
- Guidelines enforced by journals
- Compulsory training
- More scrutinized at the facilities

Important to invest in the same type standards for non-animal methods
Commitment and Actions Document
Working in separate working groups

Workshop
Identification of the problem and possible actions.

Engaging with Key players
Open the document to consultation/feedback from others.

Final document and implementation of the actions
The document open to all and further engagement.
Improve Reporting of Protocols and Methods to

Increase Transparency
Increase Reproducibility
Increase trust in methods & data
Advance in Science
Acknowledgments

PRO-MaPs
Bernd PULVERER
Tracey WEISSGERBER
Annamaria CARUSI
Pierre DECEUNINCK
David PAMIES
Jean-Francois DECHAMP

Pre-workshop Consultations:
Sandra CALDEIRA, EC-JRC
Georgina HARRIS, Frontiers in Physiology
Thiago CARVALHO, Cold Spring Harbour
Laure-Alix CLERBAUX, EC-JRC
Evangelos DASKALOPOULOS, EC-JRC
Francesca PISTOLATTO, EC-JRC
Ivana CAMPIS, EC-JRC

Emma GANLEY
Andy COLLINGS
Bronwen DEKKER
Caroline SHAMU
David SADLER
Ellsa De RANIERI
Fanglian HE
Ingrid LANGEZAAL

James MORRIS
Marcel LAFLAMME
Marco STRACCIA
Matthew BROOKE
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Vivian SIEGEL
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