Open science and research integrity

Silvia Bottaro

European Commission, Directorate-General for Research & Innovation, Unit A.4 ‘Open Science’

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What is Open Science?

“Open science” means an approach to the scientific process based on open cooperative work, tools and diffusing knowledge

(Horizon Europe Regulation and Model Grant Agreement)

• Open science has the potential to increase

  • Quality & efficiency of R&I, if all the produced results are shared, made reusable, and if their reproducibility is improved

  • Creativity, through collective intelligence and cross-disciplinary research that does not require laborious data wrangling

  • Trust in the science system, by engaging both researchers & citizens
The Council:

- Considers research integrity as the foundation of high quality research and as a prerequisite for achieving excellence in research and innovation in Europe and beyond. […]

- Acknowledges the increase in scientific output and dissemination worldwide and, in such context, highlights the importance of good practice through all stages of the research and innovation cycle;

- Recognises the importance of open science as a mechanism for reinforcing research integrity, while, at the same time, research integrity contributes to open science
## Recommendations from the Open Science Policy Platform (OSPP) – Research Integrity

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**REC 1**

*All research organisations must have a research integrity policy, including promotion of good research practices, clear procedures for dealing with allegations of research misconduct and a description of possible sanctions for proven cases of misconduct. This policy must be enforced and adequately staffed and financed to investigate any allegation pertinent to their staff. The processes for dealing with such issues should be public, transparent and prominently displayed. Outcomes should be published where the allegations are upheld, taking into account the sensitivity of the issues involved.*

**REC 2**

*All published research outputs should be reported according to recognised community standards where they exist. For any research project, researchers should define conditions by which their work can be replicated or otherwise verified by others.*

**REC 3**

*All researchers must receive regular training and accreditation on research integrity pertaining to Open Science, including the ethical, legal and social implications of their research practices. Funders (including the EC through FP9) must ensure that there is adequate training given to the researchers they fund, either through the researcher’s institution, or provided via other means.*

**REC 4**

*Publishers, data platform and infrastructure providers must agree a standardised set of minimum quality control checks on outputs and openly display the results. The task of undertaking these independent checks needs to be adequately funded. Outputs that pass these checks should be recognised and rewarded in research and researcher evaluation systems, such as FP9.*
The reproducibility ‘crisis’ (zoom in health R&I)

• Close to €300 billion/year for Health R&I (worldwide)
• A large share of the research investment may be wasted: potentially as much as 85%, according to Chalmers & Glasziou 2009, Lancet; Macleod 2014, Lancet

Unusable research reports
- Methods and codes unavailable;
  Inadequate information on medical interventions in trials; etc.

Scientific question not pertinent
- Not relevant to clinicians, carers and patients; Lack of awareness of already existing evidences; etc.

Biased reporting of results
- Selective reporting; Data reported not made comparable with other studies; Conflicts of interest; Fraud; etc.

Poor study design, conduct and analysis
- Low statistical power; Not replicated enough; Not enough collaborative efforts; Poor training and mentoring of researchers; etc.

Results not fully accessible
- “Disappointing” results less likely to be promptly published (or at all); Trials not registered; etc.
➢ Open access to outputs tools or instruments needed to validate research conclusions

➢ Early and open sharing of research through pre-registration, registered reports, data deposition in repositories etc.

Reforming the current research assessment system is crucial for a wider uptake of open science practices.

➢ Research data/output management in line with FAIR

Open Science in Horizon Europe (1/2)

- **Mandatory open science practices (art. 17 of the MGA)**

  - **Publications**: Immediate open access to peer-reviewed publications via a trusted repository, under open licenses

  - **Research Data**: Research data management in line with FAIR (including data management plans) mandatory for all projects generating or reusing data (no exceptions); open access ‘as open as possible as closed as necessary’

  - **Reproducibility of research**: information for validation of publications and for validation and reuse of data required; access for validation of publications must be provided (while legitimate interests safeguarded)
Open Science in Horizon Europe (2/2)

- **Recommended open science practices (incentivised through evaluation)**
  - Early and open sharing of research (Preregistration, registered reports, preprints, etc.)
  - Open access to research outputs other than publications and data (e.g. software, models, algorithms, workflows etc.) through deposition in trusted repositories
  - Participation in open peer-review
  - Involving all relevant knowledge actors (Involvement of citizens, civil society and end-users in co-creation of R&I agendas and content)
  - …
Evaluation of proposals and Open Science

“Excellence” criterion (methodology)

• Evaluation of the quality of relevant open science practices

• E.g. 1 page to describe Open Science practices + max 1 page to describe research data/output management [RIA, IA]

“Quality and efficiency of implementation” criterion (capacity of participants and consortium as a whole + list of achievements)

• Explain expertise on Open Science

• List publications, software, data, etc, relevant to the project with qualitative assessment and, where available, persistent identifiers

Publications are expected to be open access; datasets are expected to be FAIR and ‘as open as possible, as closed as necessary’. Significance of publications to be evaluated on the basis of proposers’ qualitative assessment and not per Journal Impact Factor
Is this consistent with rules on ethics and research integrity?

• Art. 14 MGA - The beneficiaries must respect the fundamental principle of research integrity - as set out in the ALLEA European Code of Conduct for Research Integrity. This implies compliance with the following principles:

  • reliability in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources
  • honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way
  • respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment;
  • accountability for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts and means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices including ensuring, where possible, openness, reproducibility and traceability and refrain from the research integrity violations described in the Code.
The Ethics Appraisal ensures that all research activities carried out under Horizon Europe are conducted in compliance with fundamental ethical principles. Proposers are requested conduct an Ethics Self-assessment.

**Areas covered:**
- Human Embryonic Stem Cells and Human Embryos
- Human participants
- Human cells / tissues
- Personal data
- Animals
- Non-EU countries
- Environment & Health and Safety
- Artificial Intelligence – NEW!
- Other ethics issues
Thank you