Reproducibility of scientific results in the EU

Scoping Report

December 2020
Reproducibility of scientific results in the EU: scoping report

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Manuscript completed in November 2020.

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Reproducibility of scientific results in the EU

*Scoping report*

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EXECUTIVE SUMMARY

This report scopes the issue of the reproducibility of scientific results, based on a field review and on an expert seminar on the opportunity of policy action in Europe. As such, it aims to increase the European Commission’s understanding of the lack of reproducibility in Europe, and help design a suitable response in the context of EU Research & Innovation. The report identifies the key emerging issues in reproducibility; it is informed by clearly marked expert opinion (in italics), as it emerged from the scoping seminar. Concrete recommendations of possible action by the European Commission are featured in separate ‘Action Boxes’.

Overall the report introduces the concept of reproducibility as a continuum of practices. It is posited that the reproducibility of results has value both as a mechanism to ensure good science based on truthful claims, and as a driver of further discovery and innovation. The sections includes a working definition that is conducive for policy making and thus delimits the scope of the subject.

Then the report reviews recent claims regarding the increasing lack of reproducibility in modern science, dubbed by some a ‘crisis of reproducibility’. It explores the main traits and underlying causes of the lack of reproducibility, including bias, poor experimental design and statistics, issues with scientific reporting, research culture, career-related factors and economics.

Finally, the report reviews recent activities by scientists, research funders and publishers that aim to mitigate the lack of reproducibility; and it catalogues a range of possible remedies to the lack of reproducibility as they are found in the literature. The report provides concrete advice for policy action that may increase reproducibility in three key areas of the EU Research & Innovation, specifically guidelines; the research grant system; and training and careers.

The report is the result of an expert scoping seminar on reproducibility, held in Brussels on 23 January 2020. The original scoping paper for discussion and the notes from the seminar were merged and edited to increase its accessibility. Verbatim excerpts from the seminar notes are presented in italics and are indented. The interested reader will find the two original documents and additional information at https://europa.eu/!Qf87QU. The list of participants is found in Annex 2. We are very grateful to the experts for their time, commitment and concrete contribution.
DEFINITIONS AND SCOPE

The reproducibility of scientific results has become today a proxy term for many desirable attributes of science, including good quality, reliability and efficiency.¹ In a rather general sense, reproducibility refers to the possibility for scientists, and by extension for the scientific community at large, to obtain the same results as the originators of some specific scientific findings.² As is natural, there are various and competing definitions of what it means to replicate, reproduce and re-use the results of a specific study.

- The Commission needs to identify clearly the area of intervention on reproducibility; to do so, it should build an ‘incremental model’ of reproducibility based on a working definition that helps policy intervention. It should not adjudicate between definitions, nor establish a new definition.

In this report, and for the aims of policy action, we consider reproducibility as a continuum based on three main research processes: reproduction, replication, and re-use. We use the term ‘reproduction’ (and reproducibility *stricto sensu*) to refer to the re-enactment of a study by a third party, using the original set-up, data and methodology of analysis (e.g. for certification). We use ‘replication’ for more general re-enactment of the results, using the same analytical method, but on different datasets (e.g. for comparison). And we use ‘re-use’ for the more loose possibility to re-use the results beyond the original research context, both inside and outside the original scientific discipline (e.g. also for innovation, for transfer, for transdisciplinary research).

- A reproducibility continuum is based on three main research processes: reproduction, replication, and re-use. All three processes rest on the availability of data and methods from the original study. Policy intervention to increase reproducibility should focus on reproduction and replication; and wider open science policies would assist with re-use.

![Diagram of reproducible and replicable research results](https://www.nature.com/articles/s41562-016-0021)

![Diagram of reproducible and replicable research results](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5778115/)

![Diagram of reproducible and replicable research results](https://www.nature.com/articles/s41562-016-0021)

Figure 1. Reproducible and replicable research results³

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¹ [https://www.nature.com/articles/s41562-016-0021](https://www.nature.com/articles/s41562-016-0021)
² [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5778115/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5778115/)
³ This image was created by [Scriberia](https://www.scriberia.com) for The Turing Way community (DOI: 10.5281/zenodo.332807) and is used under a [Creative Commons Attribution 4.0 International](https://creativecommons.org/licenses/by/4.0/) license.
As such, reproducibility is a specific instance of re-use of previous results, and one that enables further re-uses; indeed the possibility to reproduce, replicate and re-use depends directly on the practical availability of the data and of the methods and protocols that were produced in the original research.

- **There are overlaps and spill over effects in both directions of the continuum, and in general over the quality of research data management, therefore also on research practices in consortia (e.g. internal triangulation) and in individual labs.**

More in general, policy intervention on reproducibility should have two broad aims. First, to guarantee that scientific results are verifiable, and ultimately valid. Second, that results benefit the scientific community beyond the executors of a study.

- **Policy action should target primarily the benefits for the scientific community, and secondarily the robustness and reliability of the study per se (though of course the two are related). While the latter is as important as the former, scientific communities are best placed to address it.**

Therefore, policy action on reproducibility may be most effective when it addresses a set of issues limited to reproducibility as strictly defined above, with the aim to maximise the benefits for the science and innovation system.

The principle of transparency, which is admittedly wider than reproducibility, is particularly well suited to depict intuitively the practices that make research results benefit a larger audience than the executors. Transparency of the research management process helps the reporting of the practices and methods that are then not necessarily documented in the publication of results, and in the best case may also help document, report and then publish negative results – an elusive but highly valuable asset of the research process. There is great epistemic value in negative results, both for guidance and for proofing future studies. Transparency is especially needed for research conducted across different sites and institutions, that rely heavily on materials, expensive machinery and complex protocols to generate data, exposed to unforeseen circumstances and with large staff turnover, among other things. In general, transparency reduces the need for trust, also when dealing with results that are not de facto reproducible, where this is harder due to the object or nature of the inquiry (e.g. original artefacts in archaeology, ethnography, astronomy events), or cases where provisions that limit open access and other open science practices.

To increase reproducibility, the following elements are of specific importance:

- **the integrity of datasets;**

- **the availability of data and the transparency of data collection methods (what was not reported, what was not used, why);**

- **the coherence of the approach (pre-registration of method/protocol);**
• the analysis plan and the methodology and tools of analysis;

• and verification (both to validate and to check for mistakes in data, methods, code and results).

Figure 2. Full documentation of the research process increases reproducibility

For policy making it is important to note that when a paper is published, it is too late to intervene efficiently regarding the first four elements; notwithstanding, there are currently insufficient redress mechanisms for verification and for proven cases of malpractice.

• Best practices in the reproducibility continuum start far before publication of scientific results to make them ‘reasonably available’.

The concept of ‘pre-producibility’ is sometimes used to describe a set of measures that aim to ensure accountability and quality at the earliest possible stage. The ‘pre’ phase is crucial for the success of policy action to increase reproducibility. The ‘pre’ includes documenting the scientific process at the earliest stage of research before results, including by pre-prints, pre-registration, data management plans (DMPs), journal and funder guidelines, dedicated grant support, investment in human resources (reproducibility experts, statistics training, expert evaluators), computational reproducibility practices, and universal technical tools (e.g. persistent identifiers).

Each of these and other possible early actions on reproducibility ultimately aim to offset the efforts and costs incurred by research performers and to increase

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4 Image by Karthik Ram for a talk at Rstudio::Conf in 2019 https://ram.berkeley.edu/talks/rstudio2019/. It is used under a Creative Commons CC-BY license.
the benefits for research users. Without, however, placing an excessive burden on researchers.

- Not all parts of the research process need to be or will be perfectly accounted for; even ex-ante mechanisms such as study pre-registration can only ensure integrity but not complete accountability. There are limits to prescription even in the best case scenario: while one can describe the scientific process accurately and completely, circumstances do change during studies and make it impractical to report every single change.

Reproducibility and the underlying principle of transparency do not always overlap with ‘open access’ and ‘open data’ (and conversely, ‘open access’ and ‘open data’ do not guarantee reproducibility); it thus complements ‘openness’ as this word is meant in ‘open access’ and in ‘open science’ policy. In some cases, results may be fully transparent and perfectly reproducible (e.g. via certification), but their availability may be justifiably limited or embargoed (e.g. results close to market, privacy). It is appropriate to focus on reproducibility and transparency where innovation may come from ‘closed’ data and methods, as long as they can be replicated, taken up and further developed. Moreover, while open data and methods are in general better than the alternative, transparency offers tools to ‘optimise’ research results sharing, a concept that has long been used to uphold proprietary data. Costs increase when too much data is shared – costs of storage and curation, IP issues, noise-to-signal ratio, lack of findability. Conversely, and more worryingly, there may be cases where perfectly open results are not reproducible due to lack of documenting some part of the scientific process. In this sense, work to increase reproducibility conveys the idea that methodological rigour and transparency do (and must) go hand in hand with greater openness, with research assessment and with career progression.

Finally, ‘research integrity’ is also closely related to reproducibility. Many of the underlying topics to reproducibility are often discussed under research integrity in academia, and funders and policy-makers use research integrity to frame reproducibility in science policy. ‘Research integrity’ refers to the process of good research management practices and to the truthfulness of results, which is also the focus of reproducibility, as well as to the behaviour of individual scientists and to the ethical principles of science and society. In other words, reproducibility is a well-defined complement of integrity, and it may be a clearer policy target for the issues discussed above.

Possible actions

1. Clearly define reproducibility as a continuum of practices, and focus specifically on reproduction and replication of scientific results;
2. Focus action on activities and processes before the publication of

5 https://www.nature.com/articles/s41567-018-0342-2
IS THERE A CRISIS?

There is vigorous debate in academia on whether there is an actual crisis of reproducibility in contemporary science.⁶ There are claims that a significant proportion of research results are not reproducible, and reports that data underlying publications is simply not there. Low reproducibility appears to be more prevalent in some disciplines such as medicine and psychology⁷ than in others, as a recent survey confirms.⁸ However, there is a growing awareness of the problem in many disciplines, testified by scoping studies and seminal surveys of the incidence of the issue.⁹ Variations in the rates of reproducibility may be linked to differences across disciplines, for instance in the complexity of experimental design, in the statistical methods used, in the culture of transparency, and in the data sharing and replication practices. Therefore, lack of reproducibility may have both reasons that are endogenous to the research process: the complexity, specificities and constraints of specific research designs;¹⁰ and human-related reasons, malicious and accidental, in relation to specific truth claims.¹¹ Some scholars have reached the dramatic conclusions from the in-depth analysis of the vagaries of the research process that 85% of funded research in health is actually wasted.¹² While this view is extreme, it seems related to a far more accepted observation on the growing mismatch between increasing funding and decreasing productivity of science as measured by standard methods.¹³

- While the lack of reproducibility is a serious problem, it is not to the extent of a crisis. The problem is endemic to the research process and cannot be solved at once, as scientists constantly strive to find explanations that fit both old and new results. Policy-makers need to set expectations at the right level: today, researchers who adopt good practice in reproducibility are working a double-shift (see below, Economics). From the perspective of scientists, a greater crisis in science is when citizens and funders stop

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⁶ https://www.pnas.org/content/115/11/2628
⁷ https://doi.org/10.1038/ejhg.2010.26; https://doi.org/10.1126/science.aac4716
⁸ https://www.nature.com/news/1-500-scientists-lift-the-lid-on-reproducibility-1.19970
https://www.altmetric.com/details/8229975/news
¹⁰ https://sciencebasedmedicine.org/is-there-a-reproducibility-crisis-in-biomedical-science-no-but-there-is-a-reproducibility-problem/
¹² https://www.bmj.com/content/363/bmj.k4645
¹³ https://www.e-elgar.com/shop/international-handbook-on-responsible-innovation, Ch. 2.
believing in the capacity of science to address societal needs and in the need for the state to support it. The crisis narrative around reproducibility does not assist policy makers.

Whether or not one agrees that there is a crisis, or that it is worth talking about one, reproducibility has become an unavoidable policy topic for two reasons.

First, there is growing recognition of the need to address inefficiencies of the research process, to avoid useless and costly repetition, to maximise return on investment in R&D&I, to prevent the propagation of mistakes, and to facilitate the translation of results into innovations. These objectives can be pursued by increasing the openness and the transparency of all steps of the research process, to increase the likelihood that R&I results will be valid therefore reliable and reusable. Replication does not start where discovery ends but must be intertwined with it – when results are published it is too late. In relation to the ‘I’ in R&I, it was noted that ‘innovation points out paths that are possible while replication points out paths that are likely; progress relies on both’. ¹⁴

Second, there is a perceived deliberateness, or at least carelessness, in scientific production due to competitive pressures. A growing proportion of scientists are perceived as – willingly or unwittingly – bending some of the basic premises of the scientific method to produce ‘fast science’ or even ‘make believe science’ – facts and theories that are declared true but are dubious or even false. This rests more on the structure of incentives of science-making, embedded in culture and practice, than on deliberate attempts to ‘cheat’. The need for results to be reproducible, and the tangible steps needed to make them so, may help results be trustworthy and keep scientists honest.

Indeed, good science matters to people however arcane as they may find it. In the recent past, the issue of ‘false science’ has polarised public opinion on a number of hot political subjects, such as vaccines, fracking and lately COVID-19. There is a known, large gap between scientists’ understanding of what is true in science, and desirable as a result, and people’s understanding. Even in disciplines where there is near consensus among scientists and practitioners (e.g. the anthropogenic cause of climate change; the lack of a causal relationship between vaccines and autism), citizens may and do often think differently. This hiatus widens for frontier research, which is harder to communicate and which is not intuitively understandable – for instance artificial intelligence and rare diseases – and/or presenting serious ethical issues, e.g. genome hacking and human cell cloning. As the latest events around the COVID-19 pandemic demonstrate, this hiatus in perceptions is very large for science that have direct and significant consequences for people’s immediate health, everyday life, and on people’s life chances in the long run.

A similar gap between scientists and lay people also exists in the perception of the scientific process: whereby scientists may consider a certain degree of opacity and control over the research process as acceptable or even appropriate, the public and the press often take a more radical view, as was the

¹⁴ https://science.sciencemag.org/content/349/6251/aac4716
case of ‘Climategate’ in 2009. In other words, the lack of reproducibility may be perceived to be a lesser evil in science, as long as it is balanced by early discovery of truth and persistence on truth once it is discovered. Roughly this is rendered by the distinction between trustworthiness of research results, crucial for scientists; and the issues of trust in science, and more specifically of trust in expert judgement (recently decreasing), that drives public opinion. For lay people, ‘good science’ is intrinsically linked to trust in scientists and in those funding and directing public science, ultimately politicians.

- Lack of reproducibility has a negative impact on public trust in the conclusions of science. Trust and confidence are important for science, but have different meanings for scientists, citizens and policy-makers. In general, the uncertainty that is intrinsic in the scientific process may be perceived as lack of truthfulness by citizens. In some areas, like cancer research, people are willing to grant scientists a wide margin of discretion. But on other issues, such as vaccines, framing a discourse based on ‘crisis’ may put science in jeopardy for the wrong set of reasons: it may do nothing to improve the situation in the laboratories, but foster negative perceptions of science.

Policy-makers and politicians have always been keen to avoid the public perception that public funding may in fact be used to produce ‘bad science’ – that is to arrive at false results. But recently, there has been a marked shift in the understanding of the need for open science as a means to increase ‘return on investment’ on public expenditure in science. It is now accepted by scientists and policy-makers that the benefits of a specific scientific finding do not stop at the door of the lab. There is evidence that low reproducibility entails an economic loss, estimated at 28 billion USD per year for clinical trials only.

This agenda has been pursued by the EU under the banner of Open Science and FAIR data (Findable, Accessible, Interoperable and Reusable), a set of old and new practices aimed at enhancing the scientific process. Indeed, large-scale European scientific infrastructures have argued that funders should prioritise FAIR and reproducible (+R) data and provide incentives accordingly. Indeed, scientific results can be further exploited by re-use, by the creation of innovative products, for evidence-based policy making for translational and further multidisciplinary research. This policy agenda widens the objectives of reproducibility to include re-use, return on investment, reduction of ‘waste’ and socio-economic efficiency in science. Equally, concerning scientific practice itself, there is increased emphasis on the benefits of the pre-publication of results, of responsible research and innovation, of co-creation and of pre-normative approaches. Today, reproducibility has become a wider and more

15 https://www.nature.com/articles/468345a
16 https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0216125
18 https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002165
salient issue for policy-makers and for scientific communities than before, \(^{20}\) when it was a practical preoccupation of the scientist alone.

- **Reproducibility should not be framed as a crisis, rather as an ‘ideal’. Policy-makers should promote ‘ideal’ approaches for increasing quality, reliability and accurateness of research, rather than trying to prevent a ‘crisis’ of non-reproducibility as a fetish. As the lack of reproducibility hampers the productivity of research, we need actions that increase the expected impact.**

Finally, there are national differences, differences at scale (e.g. small universities struggle more) and different communities are at different stages of progress toward reproducibility.

- **Today’s situation in discrete fields may be placed on a scale ranging from 0 to 3 where: 0. Many scientific results cannot be reproduced; 1. Results are reproducible; 2. Results are replicable; 3. There is no bias in the research. As a result, general solutions based on ‘open science’ for those who can afford it may not work in all settings. While the literature portrays health research in general as most problematic, private sector health research is doing better on reproducibility, due to the prevalence of enforceable rules for prepublication, protocols and guidelines; private sector research is indeed regulated. Therefore, in principle tools exists in the health sector that can be examined for other settings.**

Research needs to be reproducible to have positive spill-over effects to the periphery of the research and innovation system, in turn requiring investment in methodologies, research management training and research management facilities in countries that are less R&I intensive.

### Possible actions

5. Frame reproducibility as an *ideal*, not as a *crisis*;
6. Develop policies that support communities at different levels of maturity, not only advanced disciplines or countries;
7. Invest all across the R&I ecosystem (including via Partnerships, in Widening and in the ERA), not just in the ‘excellence’ part.

### MAIN PITFALLS AND DRIVERS

Both arguments presented above, respectively the framing of reproducibility as verifiability (science, regardless of intentions, can be checked) and reusability (science, when open and transparent, can be built upon), build necessarily on certain characteristics that define a sound research process. Reproducibility concerns the full spectrum of the research process: the design, the methods, the results, the interpretation of results and their dissemination.

Failure at any of these main junctions undermines the validity of research. These failures have been well illustrated as follows (Figure 4).

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22 Munafò, M., Nosek, B., Bishop, D. et al. A manifesto for reproducible science. Nat Hum Behav 1, 0021 (2017). [https://doi.org/10.1038/s41562-016-0021](https://doi.org/10.1038/s41562-016-0021). The figure is covered by a [Creative Commons Attribution 4.0 International License](https://creativecommons.org/licenses/by/4.0/) and no changes were made.
Despite the abundance of literature on and guidelines for a good research process, and increasing guidance directly on reproducibility, the scientific process is rife with pitfalls. There have been attempts to look specifically at where, when and why research becomes irreproducible. In essence, it is argued that false positive results, which are strongly associated with the lack of reproducibility, may be the intended and unintended consequence of scientists’ efforts to obtain positive results rapidly and with the least possible effort. The literature helps identify many such pitfalls.

- **Cognitive biases**
- **Poor experimental design**
- **Small, limited studies, with low selection rate and small effect size**
- **Original findings obtained with low statistical power / low statistical significance / poor statistical analysis**
- **Insufficient oversight and mentoring by lab senior staff**
- **Lack of knowledge sharing inside research teams**
- **Lack of data-related skills**
- **Original findings not robust enough because not replicated enough in lab publishing work**
- **Lack of independent testing**
- **Lack of standard equipment and materials**
- **Lack of standardisation: greater flexibility in designs, definitions, outcomes, and analytical modes**
- **Selective and incomplete reporting of results, outcomes and data**

23 https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124
24 The list has been compiled from various sources, starting from https://www.nature.com/magazine-assets/d41586-018-04590-7/15675426 and then integrated appropriately.
25 https://www.nature.com/articles/530027a
26 See 23.
27 https://www.nature.com/articles/530027a and see 23. https://www.nature.com/articles/s41562-016-0021
29 https://science.sciencemag.org/content/349/6251/aac4716
30 See 23.
31 https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002165
32 See 23.
• Protocols, computer code or reagent information insufficient or not available from original lab\textsuperscript{33}

• Raw data is unavailable

• \textit{Pressure to publish immature research}\textsuperscript{34}

• Mistakes or inadequate expertise in reproduction efforts

• Methods need particular technical expertise that is difficult for others to replicate

• \textit{Insufficient peer review of published research, no peer review of data}

• Impossibility to cite data directly as a research result

• \textit{Lack of recognition for data-related work (e.g. data manipulation, data stewardship and data software skills)}

• Hype around a specific scientific field

• \textit{Lack of time and motivation to replicate in \textquoteleftcompetitive science\textquoteright\textsuperscript{35}}

• \textit{Large time devoted to high-impact publication}

• Financial, political and other interests in the results, either biasing or directly interfering with the research process

• Fraud

There is wide agreement in the literature that a good part of these pitfalls, underlined above, are rooted in current practices governing the career advancement of researchers, the publication of scientific results, the allocation of grants and recognitions, and overall a culture of research that primes competition over collaboration.

As it emerges from the literature, there are cultural and economic drivers for the lack of reproducibility, and it will take time and resources to address them.

• \textit{Too much focus on traditional canons of researcher productivity in modern science is a main cause of the problem: the pressure to publish often and to publish in bulk (e.g. salami slicing of studies) play a part in the rush to publish results without making them reproducible. Inertia of old practices is also slowing down reproducibility.}

\textsuperscript{33} https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002165

\textsuperscript{34} See 23.

\textsuperscript{35} https://www.e-elgar.com/shop/international-handbook-on-responsible-innovation, Ch.2.
Research culture and inertia in academic practice clearly play a part in turning risks into bad practice. Additionally, there is evidence of emerging generational dynamics regarding reproducibility.

- While senior grant applicants are still following an old logic, juniors are more invested in good data management. It is necessary to act at the earliest possible stage, in graduate school (MSc), to ensure that old hoarding practices do not propagate to new generations of scientists. Competition to publish at PhD level makes young researchers vulnerable: they will pressurise themselves to conform to the current race to the bottom. There is a need for rewards for good practice from an early career stage to guide PhD and young scholars to share data, findings, methods, to engage with the public, to focus on real impact vs. the impact factor.

Training in statistics, data management and intellectual property rights (IPR) are critical, and career and cultural rewards are needed. Indeed, young scholars face a greater pressure to obtain positive results, and not to be seen as having ‘failed’ when achieving no positive results or new breakthroughs in spite of good research, than scholars with an established standing.

- Given the current fetishisation of publication in ‘top journals’, there is a need for broader action than to address the impact factors of the biggest journals, especially for young scholars.

There is a concurrent need to change behaviours of older researchers, who are both users of, competitors to and judges of young scholars’ research performance. Senior panels are still judging from the old criteria even when this is not required (linked to inertia), sometimes because they lack the competences required by reproducibility.

- Research institutions, as employers, and funders, as sponsors, have an important role in changing such practices. Some funders, like the Wellcome Trust, have led the way on research integrity and start requiring a change in both attitudes and practices.

The cost of reproducibility

As reproducibility is a relatively new topic, there is limited understanding of its economics. At the bottom line, reproducibility requires producers of scientific results to make an extra effort and incur a cost for sharing data, methods and code. Scientists are known to be somewhat reluctant to share codes and methodologies because it is time consuming, it is not usually paid for by the funder nor supported by the home research institution (it may be seen as giving competing institutions an advantage) and it does not carry a premium. Journals have limited resources to support it directly (beyond issuing guidelines), and they charge either producers or users for the materials and procedures supporting reproducibility. This is more so the case for smaller journals and/or journals with a lower readership. Curation via dedicated repositories also carries a cost.
Funders need to fund and incentivise reproducibility to assist the efforts of results producers for the benefit of users by shifting costs from producers via intermediaries; by ensuring that there are incentives for re-use of the results, rather than continuous re-doing; by supporting basic infrastructures for the preservation and sharing of underlying data and method, among other actions.

Therefore, there is a clear need for broad action to support reproducibility, to reward good practice and robust methods, including but clearly not only via high-impact journals. Regarding the latter, as publishers have tools to monitor compliance (see below, Guidelines) and practices to redress ‘error’, funders should work with them based on a clear and fair value proposition. Funders and journals have complementary roles: journals have international scope, they help level the playing field across boundaries; funders direct large resources and can reach across disciplines. Additionally, this collaboration may be articulated via repositories of scientific results, broadly defined; there is a need for greater collaboration among repositories (there is no level playing field today, compounded by the lack of data sharing and just the beginning of work on FAIR) and between repositories and journals.

### Possible actions

1. Tackle the root causes of the lack of reproducibility including **research assessment, culture and biases**;
2. Invest in training, guidelines and rewards for young scholars at the earliest possible stage, in graduate school (MSc, Master);
3. Encourage research institutions to **change the generational inertia** in research assessment;
4. Cover the costs related to **reproducibility** and put in place other measures to **shift the financial burden of reproducibility** from producers to intermediaries;
5. **Set incentives for the re-use** of existing results;
6. **Align efforts** on reproducibility with publishers and stakeholders.

### INSTITUTIONAL RESPONSES AND POSSIBLE REMEDIES

A variety of remedies, practical and theoretical, have been considered or implemented.

European policy-makers have been front-runners in the wider framework of ‘Open Science’. In the European Union’s Horizon 2020 funding programme, research data underlying a publication has to be made available (with possible opt-outs), in addition to the requirement to create a ‘data management plan’. In Horizon Europe there are plans for compulsory Data Management plans (DMPs) and provisions in Model Grant Agreements (MGA) for open data availability; similarly, the EU has promoted and is implementing ‘FAIR’ research data principles and has recently amended the Public Sector Information
Directive, which makes specific reference to research data as a type of publicly-funded data to be made available by Member States under certain, non-restrictive conditions.

In the US, USAID fashioned a strategy on ‘transparency’ that pivots on data, and created a Development Data Library for the large number of projects it funds. But other funders have linked reproducibility directly to evaluation. The US’s NiH and AHRQ put in place a policy, resources and training to support reproducibility, as part of their wider ‘rigour’ agenda. This includes revised guidance concerning directly the evaluation of prior research in the instructions and review criteria for career development award applications and for Research Grant Applications.

In Brazil, there is an ongoing nationwide project, the Brazilian Reproducibility Initiative, to diagnose practically the extent of the lack of reproducibility in biomedical sciences by attempting to reproduce 60-100 experiments. In European countries, efforts have ranged from innovative efforts, such as cascad, the first public laboratory for the certification of the reproducibility of scientific research, funded by the CNRS, HEC Paris, and the University of Orléans to more traditional efforts, such as the rather cautious general statement regarding reproducibility issued by the German funder DfG.

Then there is a panoply of practical resources and tools to help researchers make results reproducible. This starts, at the bottom line, with taxonomies regarding reproducibility, which are not dissimilar to scientific journal guidelines, discussed further below, and discipline-agnostic toolkits based on reviews of scientific software and technologies, produced by projects and by large organisations alike. There are discipline-oriented guidelines and resources from major funders like the NiH (health) and the NSF (education). Finally, there are pilot projects and software platforms in established and large communities, including life sciences and physics; and agnostic reproducibility platforms including services and tools.

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37 https://nexus.od.nih.gov/all/2018/07/02/rigorous-resources-for-rigorous-research/
39 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6374071/
41 https://www.dfg.de/en/research_funding/announcements_proposals/2017/info_wissenschaft_17_18/
42 https://www.fosteropenscience.eu/foster-taxonomy/reproducibility-guidelines
43 https://ropensci.github.io/reproducibility-guide/
44 https://dimewiki.worldbank.org/wiki/Reproducible_Research
45 https://www.nih.gov/research-training/rigor-reproducibility
47 https://elixir-europe.org/about-us/commissioned-services/cwl-2018
Journal publishers have also been active on reproducibility; they have produced guidelines and policies for proposers, both in large-scale, collaborative efforts, and independently of each other. Journals, currently 63 of them, have introduced ‘badges’ for good open data and reproducibility value of a paper. Specific reproducibility policies of scientific journals have been tested and found necessary but wanting in effectiveness; policies may increase data sharing but not necessarily reproducibility.

Finally, scientists themselves have taken a range of measures to tackle the problem. This includes reports by national science academies; prizes for the best reproducibility projects; events and symposia of learned societies; and dedicated conferences, working groups and workshops.

Possible remedies

The actors involved in reproducibility have produced a large body of recommendations on how to tackle one or more of the drivers, and the root causes, of the lack of reproducibility. Following, we provide a list of possible remedies, in the form of recommendations, roughly divided by subject. A large number of the remedies in the list imply and/or require the intervention of more than one actor involved in scientific research, identified above.

General remedies

- Foster a reproducibility culture by providing incentives and rewards, and invest in research integrity.

Funding practices and policies

- Set clear guidelines to encourage data sharing;

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48 REANA is a platform for reproducibility set up by CERN and NSF [http://www.reanahub.io/](http://www.reanahub.io/). Also see the review at [https://ec.europa.eu/info/sites/info/files/research_and_innovation/reana.pdf](https://ec.europa.eu/info/sites/info/files/research_and_innovation/reana.pdf)
49 CONQUAIRE is a project funded by Germany’s DFG that provides tools for replicability [https://conquaire.uni-bielefeld.de/about/](https://conquaire.uni-bielefeld.de/about/)
50 [https://cos.io/top/](https://cos.io/top/)
52 [https://cos.io/our-services/open-science-badges/](https://cos.io/our-services/open-science-badges/)
53 [https://www.pnas.org/content/115/11/2584](https://www.pnas.org/content/115/11/2584)
Expand the perception of integrity to include methodological aspects that guard against cognitive biases;

Set up schemes for certification of data reproducibility

Set specific grant requirements;

Encourage the pre-publication and competition on protocols (e.g. piloting) – e.g. in clinical trials and synchrotron experiments;

Provide dedicated funding for the reproduction/replication of studies;

Provide guidance material, checklists, etc.

Career and promotion

Make rewards less focused on sheer number of high-impact publications, and more focused on methodological rigour, sharing of results, quality of reports, impact of research;

Review and tweak research and researcher’s assessment to valorise data re-use;

Create career incentives (credit and recognition) for data-management;

Evaluate positively registered reports (acceptance pre-research based on research question and methods proposed to answer them);

Training and careers

Provide accredited training on integrity, basic statistics principles/methods, publication process, reproducibility culture, etc.;

Provide training for peer-review panel chairs;

Foster specific career tracks (specialised data stewards).

Design and methods

Incorporate best reproducibility practices early in the research design;

Endorse compliance with established methodological guidelines;

Reinforce standardised study design, protocols, etc.;

Foster the use of better statistics, value of samples, methodologies

Pre-registration of protocols, analysis plans, etc.;
• Sharing of data, protocols, materials, software, codes, and other tools underlying publications; Transparency of analysis and modelling;

• Providing a reporting checklist to ensure detail of methods and sufficient data is presented.

Publication

• Support full OA publication;

• Publishing checklists and guidelines by publishers, to be used before publication;

• More opportunities and mechanisms to present/publish negative results;

• More recognition of peer review (with e.g. more time for it);

• Provide a publishing platform for all experimental outputs;

• Establish a quality assurance system for Open Access journals, to avoid predatory journals and non-peer-reviewed / low quality journals.

Open data

• Enable liberal and fair re-use of project data;

• Encourage peer-review of data;

• Extend the concept of ‘open’: open data, open protocols, open software, open research tools, open computational workflows, ...;

• Capture structured information about the research data analysis and document workflows, both computational and lab-based;

• Support the production of dedicated software and workflows that enable reproducibility.

Systemic incentives

• Finance meta reviews and systematic checks on reproducibility of funded research;

• Fund meta-research to improve the research process;

• Establish and maintain quality data infrastructures (curation, archiving, etc.);

• Establish reporting systems for witnessed malpractice;
• Conduct audits to ensure maintenance of record keeping and good research practice;

• Require compulsory ex-ante disclosure of conflict of interest;

• Make undeclared conflict of interest sanctionable, e.g. no access to grants, other resources and publication.

KEY AREAS OF INTERVENTION IN THE EU R&I SYSTEM

Three key areas of priority intervention emerged from the discussion of remedies in the context of EU research and innovation system, respectively guidelines, training and careers and the grant system.59

1 Guidelines

There is empirical evidence that reproducibility principles and publishers’ guidelines may foster compliance. This does not happen automatically. A common culture of result-sharing is difficult to build; even in cohesive teams in the best conditions there may be diverging approaches regarding whether to follow internal or external guidelines, which ones and how to comply with them in practice. Additionally, as there are sets of competing guidelines, their alignment across fields is needed. Finally, guidelines only work if at least a critical mass of the community follows them. There is a need for ‘multipliers’ for guidelines and principles inside communities of practice to foster the contagion of good practices.

A distinction should then be made between principles and guidelines. While both aim to provide guidance to make a study reproducible, they serve different purposes. Principles are general in nature; to be effective, they need to be aligned with specific requirements regarding e.g. data peer-review, pre-prints, pre-registration of study design, badges and seals for good data management. Top-down, abstract sets of principles are unlikely to work as intended.

Guidelines for reproducibility are more specific tools used today by some publishers and funders to require compliance with certain research management criteria. Guidelines work best when they are in a clear format, close to the onset of the study and clearly linked to acceptable outcomes (e.g. for a grant or a publication); they need to be few and short and include clear and concrete requirements: mandatory checklists are more efficient than general guidelines. There is a need for common guidelines for journals, that are modular, allow for different levels of implementation and allow communities to start moving. Apart from fostering compliance, guidelines signal to communities that data can actually be reproduced.

Specific guidelines are useful not only to orient the choice of methodologies and analysis, but also to guide statistical reporting. Reporting guidelines have more

59 As this section is based almost integrally on the seminar notes, text is not marked in *italics*. 
power than pre-registration of a study’s protocol for professionals involved in meta-reviews and for large-scale reproducibility drives. To be effective and to raise the profile of reporting, guidelines should be promoted/required by large funders or, ideally, commonly by various funders (in part to avoid dumping). In general, funders have three main roles regarding checklists: motivation, means and monitoring (three Ms).

Journals are increasingly moving towards guidelines for reproducibility. However, responsible publishing is resource intensive: checks even before peer-review are costly and need to be done manually by researchers on request of journals; journals do not have in-house skills, time and resources to police their guidelines. Therefore, there is a need to mainstream guidelines at institutional level and to anchor them at pre-publication, possibly already at grant application, to reduce the cost for publishers (who can deal with more standardised supporting evidence).

On the other hand, there is a need for automatic machine systems to perform these checks and produce an approximate ‘reproducibility score’ in steps (e.g. 20%, 40%, 60%) for guidance. Some current open science systems are engineered to perform similar tasks - e.g. cascad certifies that journal articles can be reproduced before or after submission;\(^60\) REANA\(^61\) can back-cast in the future on what will be computationally reproducible; SciScore\(^62\) provides an assessment for reproducibility at review stage; a COS project run for Darpa SCORE aims to do roughly the same for the publication pipeline.\(^63\) Much more innovative work is needed on the automation of reproducibility assessment and compliance check at different stages of the whole research pipeline.

Compliance with reproducibility guidelines is also an important area of work. Compliance needs to be monitored, to signal a change in adherence to the rules of the game; however, policing compliance after publication may be very costly and ultimately unfeasible. While the practice of retraction is appropriate, to foster compliance it needs to be stipulated from the beginning to decrease incidence; the existing inertia in connection with the pressure to publish works against systematic correction of dubious results. Several questions emerge with an ex-post approach: what can ‘compliance controllers’ do when they find a non-conformity? When should journals step in to address the issue, and with what practical consequences? Is the ultimate solution the retraction of individual journal articles?

There is a clear need for systematic ex-ante checks on compliance to reproducibility policies of journals and funders, as far back as grant allocation, as this allows for redirection of the research efforts and have a positive end result. And the need to reward compliance with reproducibility guidelines rather than to only sanction non-compliance. A new framing is needed that is linked to

\(^{60}\) https://science.sciencemag.org/content/365/6449/127.summary; DOI 10.1126/science.aaw 2825. Project website: https://www.cascad.tech/

\(^{61}\) http://reanahub.io/

\(^{62}\) https://www.sciscore.com/

\(^{63}\) https://www.cos.io/
incentives for positive behaviours. Data checks for reproducibility, random or systematic, may be done by an embedded professional (‘data scientist’ model, see Training below) to help build economies of scope, as they link directly the ex-ante (helping before submission) and the ex-post (guidance of published evidence).

In the absence of an institutional culture of compliance, guidance and a link to research assessment, grant-seekers and would-be authors may be tempted to ‘optimise’ applications for the published principles and guidelines; the result may look like reproducible science but it is unlikely to be. Similarly, finger-pointing and ‘blaming’ may back-fire in the period preceding publication, where guidelines are most effective.

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<tr>
<th>Possible actions</th>
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<tr>
<td>14. Foster and finance ‘multipliers’ of reproducibility principles and guidelines inside specific scientific (thematic) communities;</td>
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<tr>
<td>15. Co-create ‘enforceable’ guidelines/templates/checklists for practical implementation of reproducibility (e.g. on statistical power of the project; expertise in statistical analysis; re-use of data) at grant proposal/design stage, aligned between actors and with related activities;</td>
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<tr>
<td>16. Fund thematic actions to support the development of reporting guidelines, which can then be integrated as requirements in funding topics;</td>
</tr>
<tr>
<td>17. Fund the testing and R&amp;I development of automatic systems of compliance for reproducibility before publication;</td>
</tr>
<tr>
<td>18. Support a system for checks before publication, linked to correction and positive incentives.</td>
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</table>

2 Training and careers

General training in statistics and research methods for researchers at all career stages is much needed and is proven to increase reproducibility. However, this need is not best addressed by specific action by the EU on ‘reproducibility’, but by investment on methodology and integrity training overall in the context of the European Research Area (ERA). The EC could work specifically with other funders towards common statistical reporting guidelines; on courses on ‘research integrity’ that bring in different factors of good research management; on the support to the establishment of independent offices at institutions dealing with integrity, and help as needed in case of controversy relating to data sharing, transparency, other requirements. While there are increasing avenues for arbitration and redress, both institutional and bottom-up, there is no overall arbitration mechanism.

The EU could also coordinate European action by e.g. training networks, conferences and policy advice; support and coordination activities such as

64 E.g. the project ‘Path to Integrity’ (https://www.path2integrity.eu/).
platforms for collaboration on standards and good practices where they do not exist; support Master’s and doctorate level programmes in research integrity; foster quick ‘onboarding’ of young researchers and promote knowledge sharing inside research teams; coordinate national level funders, and use policy tools to steer national initiatives in the same broad direction.

Finally, there is a need for investment in and support for the emergent professional figures who sit in-between the two fields of primary research and research data management: research software engineers (RSE), ‘data stewards’, data librarians, and integrity experts to assist scientists across all their projects, not necessarily in one specific study only.

**Possible actions**

19. Insert **reproducibility competences in statistical training** in the context of the ERA;

20. Coordinate research performing organisations to **develop and accredit thematic training modules** on: basic research principles and methods, research integrity, skills for open science, etc. at different levels including doctoral training; earlier in the career; and life-long;

21. Support the development of **research integrity officers** in research performing organisations, and network these jobs to share good practice and identify best practice;

22. Fund an ‘integrity and reproducibility training/learning platform’ that: (1) train trainers/intermediaries; (2) produce training material; (3) exchange good practice and tools; and (4) offer practical discipline-specific guidance for researchers, reviewers, institutions, funders, publishers etc.;

23. Fund (access to) a network/pool of resources (statisticians, data stewards, experts in research methodologies etc.) to assist research teams in ensuring quality and statistical significance of their datasets.

**3 Research grant systems**

Overall, the research grant system holds great potential as a lever to increase reproducibility. In general, funders’ proposal templates and guidelines to applicants may easily ask to demonstrate robustness of the methodology, significance of sample size and appropriateness of the analysis tools and methods. Grant agreements can have minimum specifications and requirements for reproducibility, as is increasingly the case for open access, IP and re-use of the results.

More specifically regarding Horizon Europe:

- **Ensure that issues related to research integrity are part of proposal evaluation**, to link funding to good research data management practices in the study;

- **Ensure that reproducibility issues are part of Data Management Plans (DMPs)**;
• **Introduce a standardised score for reproducibility** for research proposals, initially for guidance purposes;

• **Include good research management, transparent methods and reproducibility in the excellence evaluation area**, so proposers can decide how to best design work packages;\(^{65}\)

• **Make prior checks on existing results compulsory** for research proposals, as soon as supporting infrastructure (DOI, metadata, FAIR) make it feasible;

• **Include more independent reviewers** on evaluation and review panels who have methodological and data expertise for reproducibility, research integrity, research methodologies, data stewardship etc.

• **Invest in EC training of reviewers**, to enhance their career progression and so that they can leverage this back in their institution;

• **Include categories describing expertise** such as reproducibility, research integrity, open science, research data management etc. in the expert registry;

• **Revise evaluation guidelines** to reward robustness of methodologies and analysis (including statistical), and the associated budgets, re-use of data, etc. in the evaluation of proposals.

Specific extra funding may be appropriate to support intensive effort on making key research data reproducible, as quality implies extra efforts and costs. While research management costs are currently reimbursable in EU projects, this is done ex-post and not ex-ante; this risks reducing the proposed resources for good data management in favour of other parts of the ‘excellence’ pillar and overall becomes diluted. An add-on funding stream for reproducibility could be envisaged, either competitive (two-stage) or non-competitive, based on the scores of the first evaluation. For example, there are dedicated NIH grant supplements to shore up ‘rigour’ component of research proposals; in EU FPs, twinning and other schemes for additional funding could be used to bolster reproducibility. In practice, proposals that can demonstrate the capacity to generate widely reusable results may get additional funding for this activity. Using Horizon 2020 as a baseline, additional funding could be linked to ‘ERA’, to ‘Widening’ or to EOSC-related activities in FAIR (e.g. provide supplementary funding for FAIRification of datasets).

Overall, it would be useful to have dedicated funding to reproduce and replicate studies; and to find innovative ways to incentivise production of new results using existing data and not only new data per se (what ‘original’ means now). Equally, there is a need for clearly spelled incentives, and possibly requirements in the future, to report ‘unsuccessful’ research and to publish negative results.

The EC could use Horizon Europe to sand-box policy innovation from its inception in 2021, to keep the current leadership in open science policy innovation. New action on reproducibility should build on existing EC action on

\(^{65}\) Partly this is already the case for Horizon Europe, e.g. the quality of the methodology is part of excellence, the ethics review, etc. (Ed.)
open access to publications and data and other research outputs and on sharing through open knowledge infrastructures (e.g. work on FAIR and on the EOSC). To increase efficiency, there is a need to identify what specific action is required and what action is in common with ‘open science’ policies. To facilitate dissemination, there is a need for networked infrastructures and basic infrastructures for data identification and traceability. PIDs could be used under the new Open Research Europe platform (ORE) and for Horizon Europe proposals and projects: for grants, for data sets, for samples, for authors. Finally, the ORE may help link requirements and publications (i.e. build in reproducibility in the platform, specify requirements). Such infrastructural investment has clear additionality and EU added-value.

There is also a need to identify what interventions are universal and touch all disciplines and what are then specific actions that will work in specific fields, based on their maturity; this could be done by leveraging an existing success story in a new domain (e.g. Foster for research integrity).

Finally, the work on reproducibility needs to be scaled up to other funders via policy making. The EC may be able to work with Science Europe (e.g. on science protocols) and other ERA stakeholders on reproducibility as part of the research assessment in Europe; and encourage the reform of the research assessment system via rewards and incentives. Horizon Europe ‘Partnerships’ may be a tool for reproducibility programming, to increase coherence and scale; data requirements in funding rules need to be consistent across funding systems, so that applications can be re-used across programmes / funders if they are excellent but below the threshold. It would also be useful to engage in a multi-stakeholder dialogue, including publishers, on rewards and responsible publishing.

**Possible actions**

24. Ensure that Horizon Europe provisions encourage and support reproducibility (see list of possible actions, above);
25. Employ and police guidelines early in the grant application phase to anchor journal practices;
26. Fund a platform for exchange of good practices and tools;
27. Consider providing additional funding where the value of reproducible data is clearly demonstrated for the project and for the scientific community;
28. Fund projects to directly reproduce research findings;
29. Recognize role models in integrity/reproducibility, also through a prize;
30. Fund meta-research on integrity and reproducibility, thematic and horizontal;
31. Provide supplementary funding e.g. for FAIRification of datasets;
32. Identify clearly the best policies and practices across disciplines by private and public funders, and coordinate European activities in the domain;
33. Coordinate policy and funding work for reproducibility with other European funders.
ANNEX 1 - QUESTIONS FOR THE SCOPING SEMINAR

The following questions guided the discussion. Questions in **bold** were prioritised.

(1) What are the **most serious consequences** of the lack of reproducibility?
   (a) Which are avoidable and which unavoidable?

(2) **Why are some disciplines most affected?**
   (a) What are the common traits of disciplines doing better?
   (b) Possible to export them?

(3) **Of the causes of the lack of reproducibility:**
   (a) Which are most urgent to tackle?
   (b) Which are easy/difficult to tackle?
   (c) Are there obvious dependencies?

(4) Are generic ‘Open science / open access’ remedies sufficient to increase reproducibility, or is specific action needed?

(5) Who is best placed to both take the lead and take action in the EU – universities, funders, academies, publishers?

(6) Are there evident differences between the EU, the US and other areas (e.g. China)?

(7) How can policy-makers help shift the cost of reproducibility (financial, time, opportunity) from producers and users of data eventually to intermediaries (funders, editors and publishers)?

(8) In the ‘toolbox’ of remedies emerging globally, which ones could work best in Europe?
   (a) Research programming / funding (e.g. in Horizon Europe: funding, open data policies, replication projects, random replication, access for verification purposes ...)
   (b) Technical solutions (e.g. platforms, repositories, workflows)
   (c) Structural solutions (e.g. careers, skills ...)
   (d) ‘Pipeline’ solutions (e.g. pre-registration, data publishing ...)

(9) Science used for policy-making: should it be reproducible by default?
## ANNEX 2 – EXPERTS ATTENDING THE SCOPING SEMINAR

<table>
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<th>Name</th>
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<tr>
<td>Lee Baker</td>
<td>Interel</td>
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<tr>
<td>Ioana Alina Cristea</td>
<td>Università degli Studi di Pavia</td>
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<td>Timothy M. Errington</td>
<td>Center for Open Science</td>
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<td>Katarzyna Jaśko</td>
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<td>Catriona J. MacCallum</td>
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<td>Vivienne Parry</td>
<td>Science writer and broadcaster</td>
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<td>Christophe Pérignon</td>
<td>HEC Paris and cascad (CNRS)</td>
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<td>Tibor Šimko</td>
<td>CERN</td>
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<tr>
<td>Catherine Winchester</td>
<td>Cancer Research UK Beatson Institute</td>
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The EU Open Data Portal (http://data.europa.eu/euodp/en) provides access to datasets from the EU. Data can be downloaded and reused for free, for both commercial and non-commercial purposes.
This report scopes the issue of the reproducibility of scientific results, based on a field review and on an expert seminar on the opportunity of policy action in Europe. The report identifies key emerging issues in reproducibility, the drivers of the lack of reproducibility in Europe and it helps design a suitable response in the context of EU Research & Innovation. The report recommends concrete action by the European Commission that may increase reproducibility, in dedicated 'Action Boxes'. The report provides advice in three key areas of EU Research & Innovation: scientific guidelines, the research grant system, and training and careers.

*Research and Innovation policy*