

# A BRIEF INTRODUCTION TO OPEN SCIENCE

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# Sputnik V: What's the problem?

## EMA starts rolling review of the Sputnik V COVID-19 vaccine

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News 04/03/2021

EMA's human medicines committee (CHMP) has started a rolling review of Sputnik V (Gam-COVID-Vac), a COVID-19 vaccine<sup>1</sup> developed by Russia's Gamaleya National Centre of Epidemiology and Microbiology. The EU applicant for this medicine is R-Pharm Germany GmbH.

The CHMP's decision to start the rolling review is based on results from laboratory studies and clinical studies in adults. These studies indicate that Sputnik V triggers the production of antibodies and immune cells that target the SARS-CoV-2 coronavirus and may help protect against COVID-19.

EMA will evaluate data as they become available to decide if the benefits outweigh the risks. The rolling review

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The CHMP's decision to start the review is based on the data submitted in adults. These studies in children and adolescents target the SARS-CoV-2 coronavirus.

EMA will evaluate data as

CORRESPONDENCE | [VOLUME 397, ISSUE 10288, P1881-1883, MAY 22, 2021](#)

## Data discrepancies and substandard reporting of interim data of Sputnik V phase 3 trial

[Enrico M Bucci](#) [✉](#) • [Johannes Berkhof](#) • [André Gillibert](#) • [Gowri Gopalakrishna](#) • [Raffaele A Calogero](#) • [Lex M Bouter](#) • et al. [Show all authors](#)

Published: May 12, 2021 • DOI: [https://doi.org/10.1016/S0140-6736\(21\)00899-0](https://doi.org/10.1016/S0140-6736(21)00899-0)

Several experts<sup>3, 4</sup> found problematic data in the published phase 1/2 results.<sup>2</sup> We have made multiple independent requests for access to the raw dataset, but these were never answered. Despite publicly denying some problems, formal corrections were made

<https://www.ema.europa.eu/en/news/ema-starts-rolling-review-sputnik-v-covid-19-vaccine>

[https://doi.org/10.1016/S0140-6736\(21\)00899-0](https://doi.org/10.1016/S0140-6736(21)00899-0)

# Sputnik V: What's the problem?

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EMA will evaluate data as it becomes available.

CORRESPONDENCE | VOLUME 397, ISSUE 1028

## Data discrepancies and lack of access to data of Sputnik V phase 3 trial

Enrico M Bucci  • Johannes Berkhof • et al. [Show all authors](#)

Published: May 12, 2021 • DOI: [https://doi.org/10.1016/S0140-6736\(21\)00899-0](https://doi.org/10.1016/S0140-6736(21)00899-0)

Several experts<sup>3, 4</sup> found problematic data in the phase 3 trial, but these were never made available to the public.

FIRST OPINION

## Is the Sputnik V vaccine too good to be true? Without the data, it's hard to know

By Jonathan Cushing May 26, 2021

[Reprints](#)



The current debate over the Sputnik V data is possible only because Gamaleya published its data analysis in The Lancet. But as the saying goes, you don't know what you don't know, and this will remain true for as long as the raw data for Sputnik V — and the numerous other Covid-19 vaccine clinical trials with no published data analysis — remain hidden.

The only way for concerns over Sputnik V and other vaccines to be quelled is for the developers to publish full clinical study reports along with the raw data. Not only will this build confidence in Covid-19 vaccine, but it will pave the way for other developers to follow suit.

<https://www.ema.europa.eu/en/news/ema-starts-rolling-review-sputnik-v-covid-19-vaccine>

[https://doi.org/10.1016/S0140-6736\(21\)00899-0](https://doi.org/10.1016/S0140-6736(21)00899-0)

<https://www.statnews.com/2021/05/26/data-needed-know-if-sputnik-v-vaccine-too-good-to-be-true/>

# Why is missing data a problem?

One of the prime ministers in Germany stated: There was a lack of verifiable documents needed to approve Sputnik V. The developers need to submit these documents. We cannot take the risk to approve a vaccine that is not documented in a scientifically verifiable way.





# Doubts! A medical problem?

## GLOBAL IMPACT DISASTER MANAGEMENT

Our exposure and vulnerability to extreme events - including both natural and human-induced hazards - continue to increase. Worldwide the impact of disasters is rapidly growing. At ITC, experts work to integrate hazard assessment and disaster risk management into strategic planning and sustainable development.

[Find out more](#)

## GLOBAL IMPACT GEO HEALTH

The topic of geo-health concerns the convergence of concepts and knowledge, tools and techniques developed in the health and the geographics domain. ITC brings in the necessary bio-medical expertise and link this effectively to spatio-temporal techniques and the latest developments in big data and data science.

[Find out more](#)



## GLOBAL IMPACT SMART CITIES



## SUSTAINABLE DEVELOPMENT GOALS



policies and land management practices remains a primary cause of inequity and poverty.

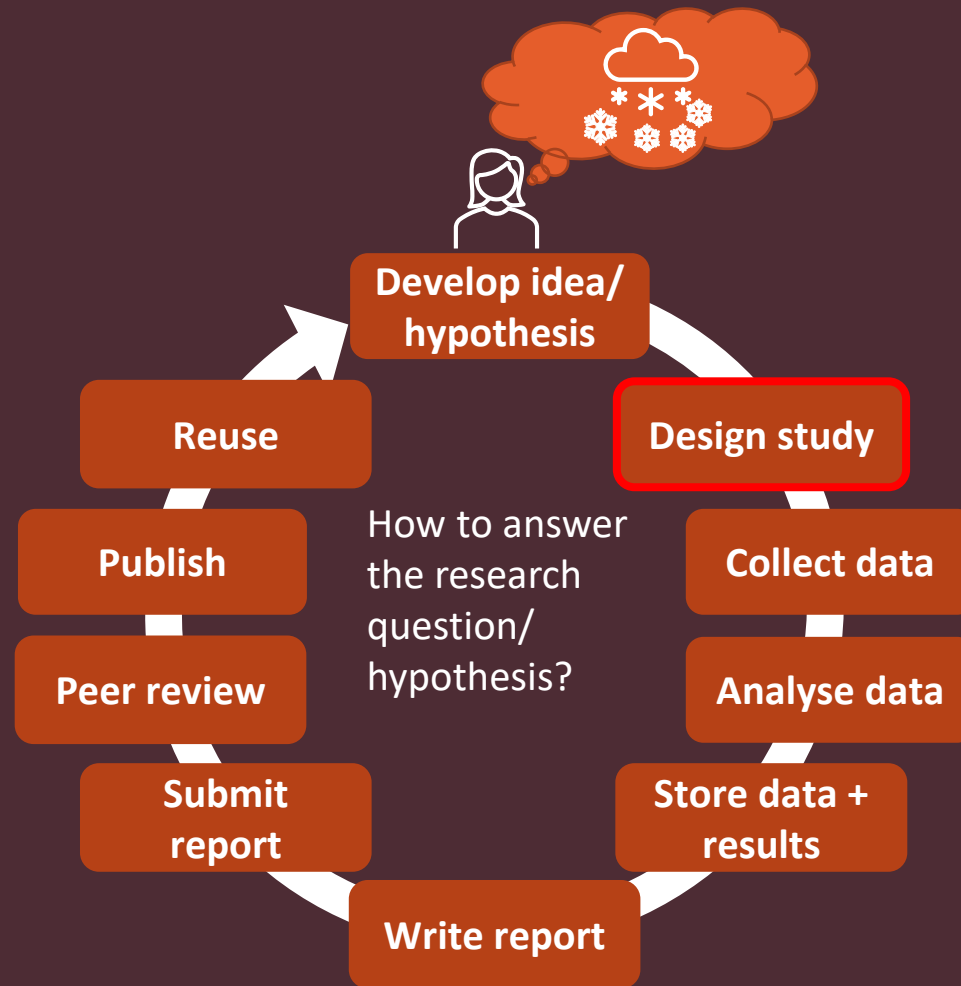
[Find out more](#)



# The research process in a nutshell



# The research process in a nutshell





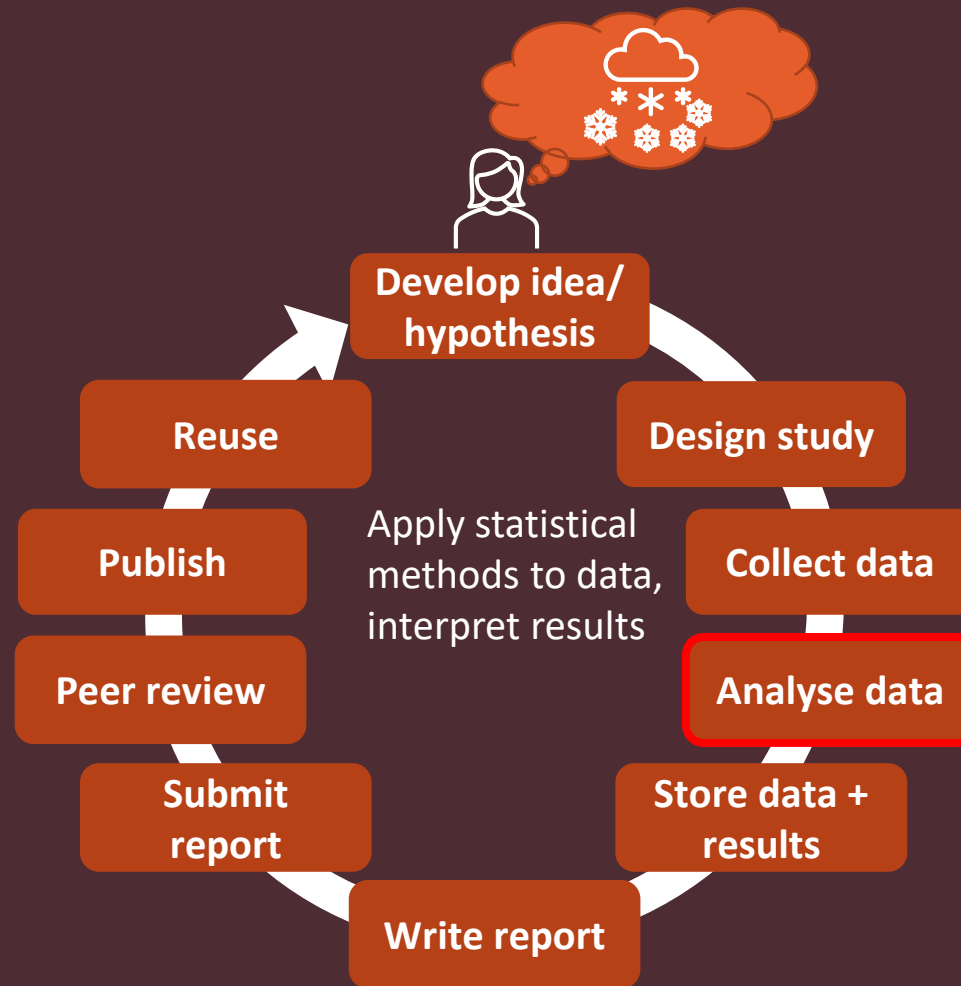
# The research process in a nutshell



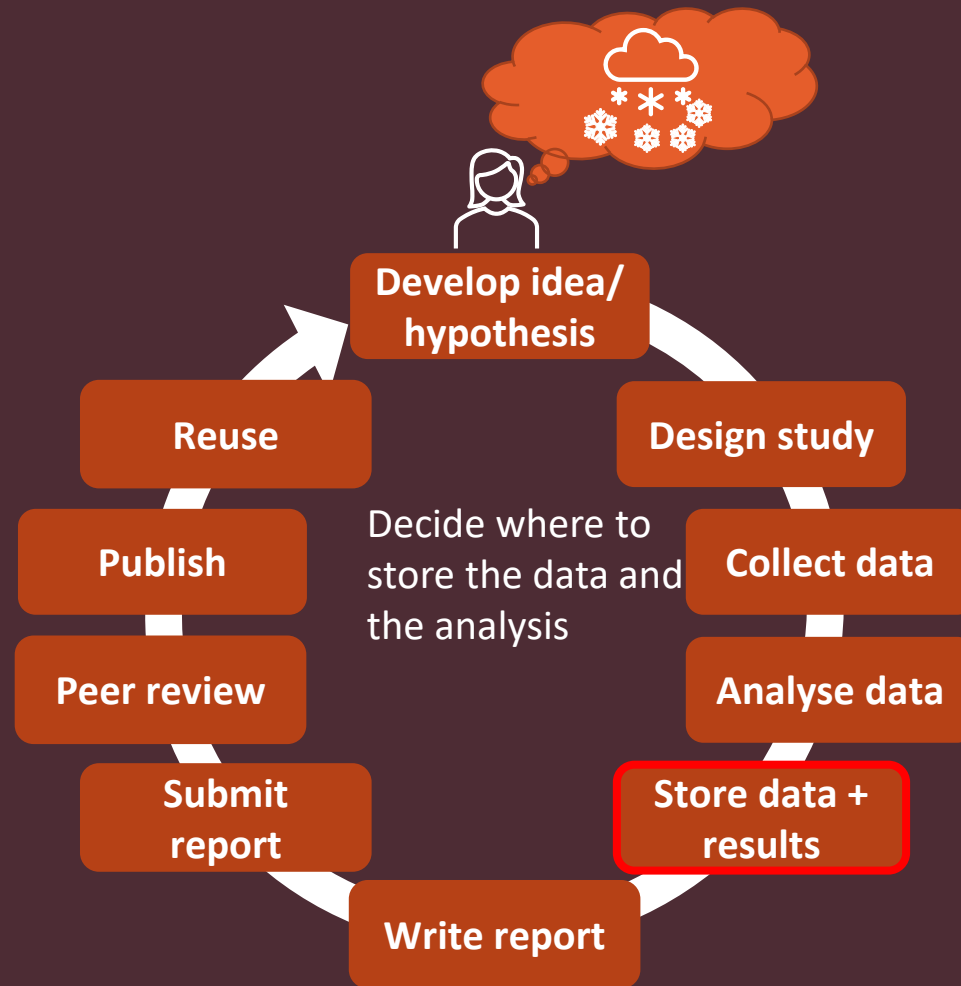
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# The research process in a nutshell



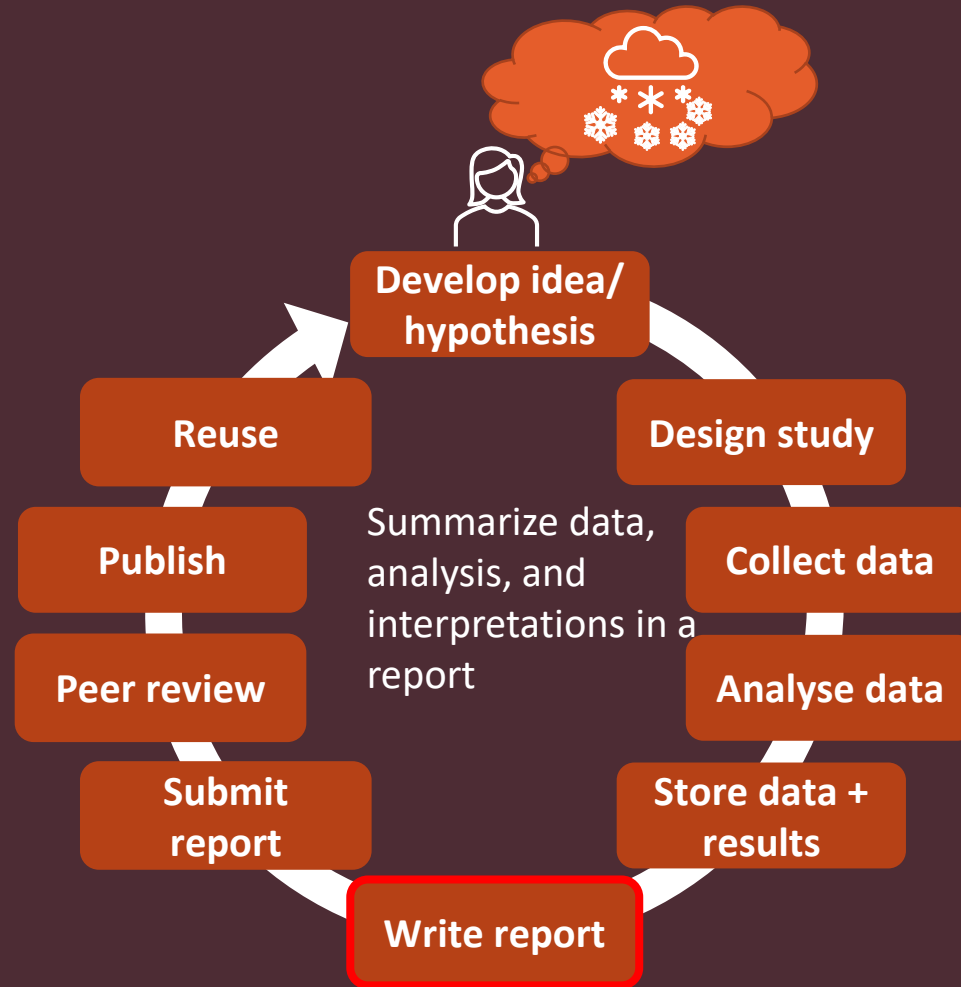
# The research process in a nutshell



# The research process in a nutshell



From: <http://gph.is/1xhfQug>



# The research process in a nutshell





# The research process in a nutshell



# The research process in a nutshell



<http://gph.is/1vc34Xb>



# The research process in a nutshell



# The research process in a nutshell



# Why is missing data a problem?

01

It is difficult to find errors in the analysis

02

Reviewers cannot verify but need to trust the results

03

Analysis is not fully understandable

04

Materials are not reusable (not sustainable)



# What is Open Science?

**Open Access:** Users gain full, immediate, unrestricted access to scientific publications.

**Open Data:** Data is accessible in accordance with good data governance.

**Open Software/Code/Methods**  
accessible under an open license.

**OS Infrastructure:** Digital I. needed to support OS (e.g. platforms/repositories) should be non-profit.

**Open Peer Review:** Transparent peer review and publicly available reviews.

**Open Education:** Learning materials should be freely and openly accessible, re-usable, and redistributable.

**Open Engagement of Societal Actors:** Involve people outside science (“Citizen and participatory science”).

**Openness and Diversity of Knowledge:** Recognize richness of diverse knowledge systems, holders, and producers.

# Open Science is about giving value to the entire research process



# Same same but different

		Data	
		Same	Different
Analysis	Same	Reproducible	Replicable
	Different	Robust	Generalisable

The Turing Way: <https://the-turing-way.netlify.app/reproducible-research/overview/overview-definitions.html>

# Benefits of Open Science

More  
citations

New colla-  
borations

Media  
attention

Funding  
opportunities

POINT OF VIEW

## How open science helps researchers succeed

**Abstract** Open access, open data, open source and other open scholarship practices are growing in popularity and necessity. However, widespread adoption of these practices has not yet been achieved. One reason is that researchers are uncertain about how sharing their work will affect their careers. We review literature demonstrating that open research is associated with increases in citations, media attention, potential collaborators, job opportunities and funding opportunities. These findings are evidence that open research practices bring significant benefits to researchers relative to more traditional closed practices.

DOI: [10.7554/eLife.16800.001](https://doi.org/10.7554/eLife.16800.001)

ERIN C MCKIERNAN\*, PHILIP E BOURNE, C TITUS BROWN, STUART BUCK, AMYE KENALL, JENNIFER LIN, DAMON MCDOUGALL, BRIAN A NOSEK, KARTHIK RAM, COURTNEY K SODERBERG, JEFFREY R SPIES, KAITLIN THANAY, ANDREW UPDEGROVE, KARA H WOO AND TAL YARKONI

# Benefits of Open Science

More citations

Serve society

New collaborations

Media attention

Funding opportunities

POINT OF VIEW

HOME | ABOUT

Search

bioRxiv  
THE PREPRINT SERVER FOR BIOLOGY

bioRxiv is receiving many new papers on coronavirus SARS-CoV-2. A reminder: these are preliminary reports that have not undergone peer review. They should not be used to guide practice/health-related behavior, or be reported in news media as established information.

New Results [Comments \(6\)](#)

**Open Science Saves Lives: Lessons from the COVID-19 Pandemic**

[Lonni Besançon](#), [Nathan Peiffer-Smadja](#), [Corentin Segalas](#), [Haoting Jiang](#), [Paola Masuzzo](#), [Cooper Smout](#), [Eric Billy](#), [Maxime Deforet](#), [Clémence Leyrat](#)

doi: <https://doi.org/10.1101/2020.08.13.249847>

This article is a preprint and has not been certified by peer review [what does this mean?].

[Abstract](#) [Full Text](#) [Info/History](#) [Metrics](#) [Preview PDF](#)

**Abstract**

In the last decade Open Science principles have been successfully advocated for and are being slowly adopted in different research communities. In response to the COVID-19 pandemic many publishers and researchers have sped up their adoption of Open Science practices, sometimes embracing them fully and sometimes partially or in a sub-optimal manner. In this article, we express concerns about the violation of

McKiernan et al. eLife 2016;5:e16800. DOI: 10.7554/eLife.16800

Besançon et al., bioRxiv, 2020 doi: 10.1101/2020.08.13.249847



# Benefits of Open Science

More citations

Serve society

New collaborations

Media attention

Funding opportunities

Receive formal recognition



McKiernan et al. eLife 2016;5:e16800. DOI: 10.7554/eLife.16800

Besançon et al., bioRxiv, 2020 doi: 10.1101/2020.08.13.249847

Shaping 2030: <https://www.utwente.nl/en/organisation/about/shaping2030/>

# Benefits of Open Science

New collaborations

Media attention

Funding opportunities

More citations

Serve society

Receive formal recognition

Job opportunities

POINT OF VIEW

HOME | ABOUT

SCHÖNBRODT  
Psych.

Abstract: Engaging in open science practices increases knowledge as a common good, and ensures the reproducibility, verifiability and credibility of research. But some have the fear that on an individual strategic level (in particular from an early career perspective) engaging in research transparency could reduce a researcher's chance to get a tenured position in academia.


PD Dr. Dipl.-Psych.

### Changing hiring practices towards research transparency: The first open science statement in a professorship advertisement

January 6, 2016

Engaging in open science practices increases knowledge as a common good, and ensures the reproducibility, verifiability and credibility of research. But some have the fear that on an individual strategic level (in particular from an early career perspective) engaging in research transparency could reduce a researcher's chance to get a tenured position in academia.

University hiring decisions often are driven (amongst other criteria) by publication quantity and journal prestige: "Several universities base promotion decisions on threshold *h*-index values and on the number of articles in 'high-impact' journals" (Hicks, Wouters, Waltman, de Rijcke, & Rafols, 2015), and Nosek, Spies, & Motyl (2012) mention



McKiernan et al. eLife 2016;5:e16800. DOI: 10.7554/eLife.16800

Besançon et al., bioRxiv, 2020 doi: 10.1101/2020.08.13.249847

Shaping 2030: <https://www.utwente.nl/en/organisation/about/shaping2030/>

Job calls: <https://www.nicebread.de/open-science-hiring-practices/>

# Open Science for scientists only?

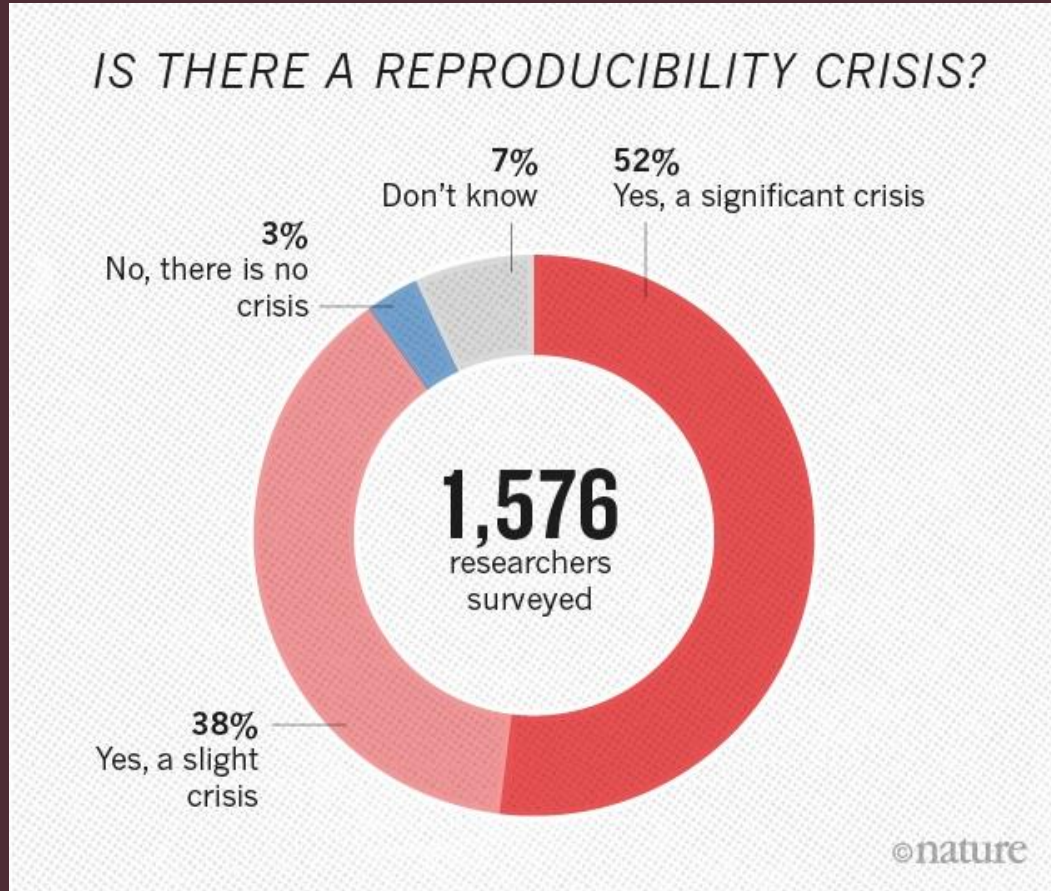
Open Science skills are also relevant in industry

- Data management
- Creating sharable and reusable data
- Software skills (versioning of code)
  - Companies can see your work

Recommendations:

- Keep your workspace clean (file names , folder structure etc.)
- Learn a versioning software (e.g., [git](#))
- Learn a scripting language (e.g., [Python](#), [R](#))

# The state of Open Science



~~Open Data~~

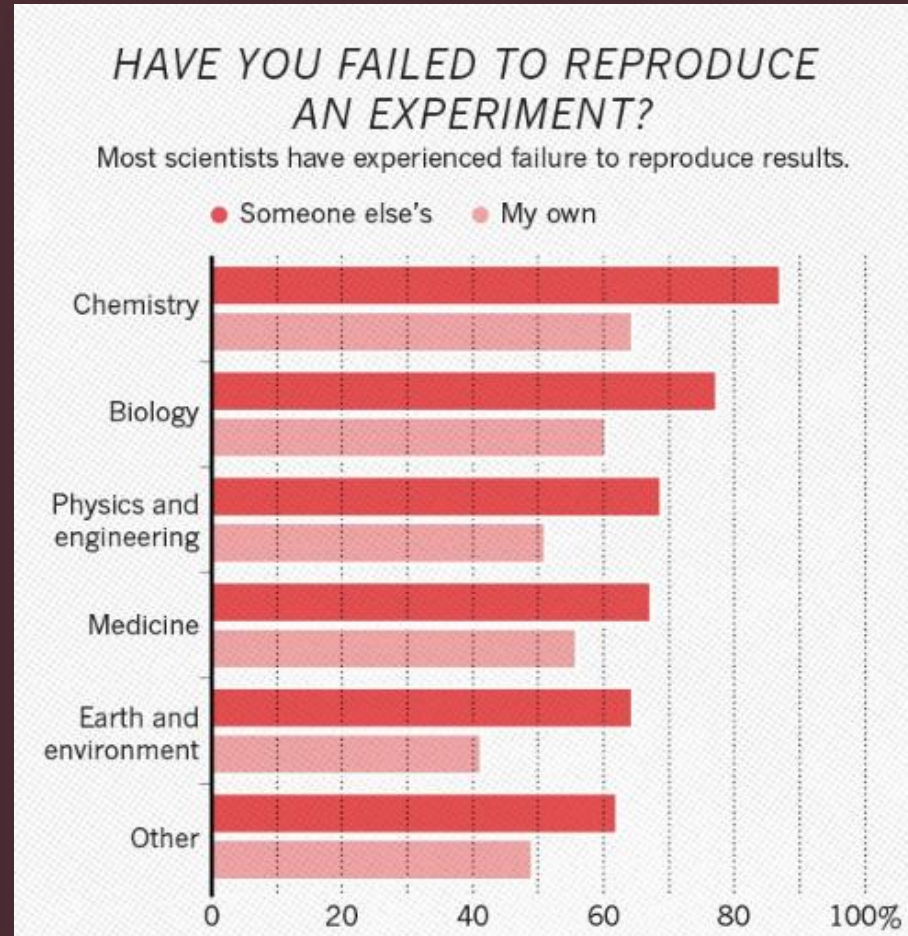
~~Open Code~~



From: <https://gph.is/g/4DAnQjB>



# The state of Open Science



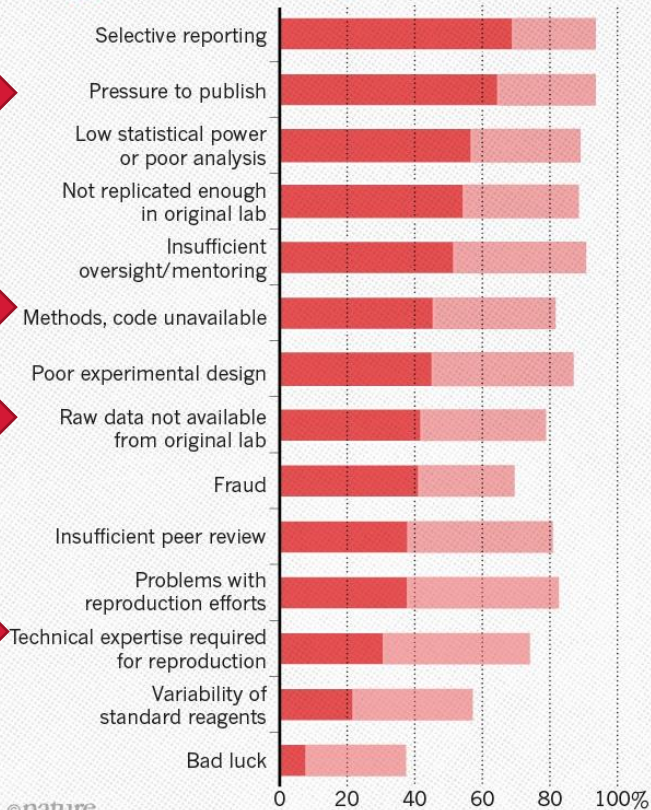


# The state of Open Science

## WHAT FACTORS CONTRIBUTE TO IRREPRODUCIBLE RESEARCH?

Many top-rated factors relate to intense competition and time pressure.

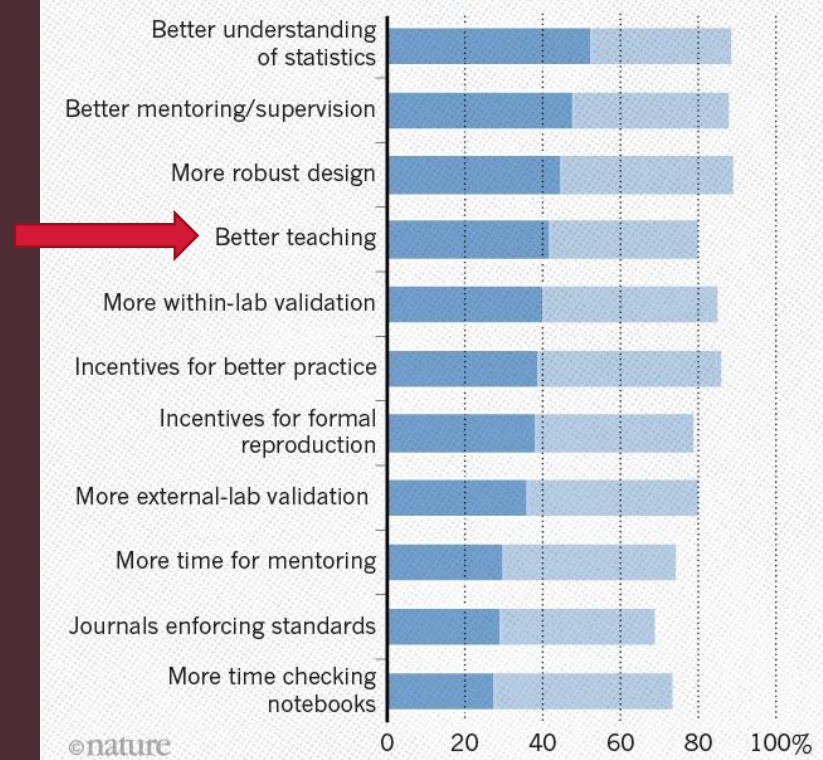
● Always/often contribute ● Sometimes contribute



## WHAT FACTORS COULD BOOST REPRODUCIBILITY?

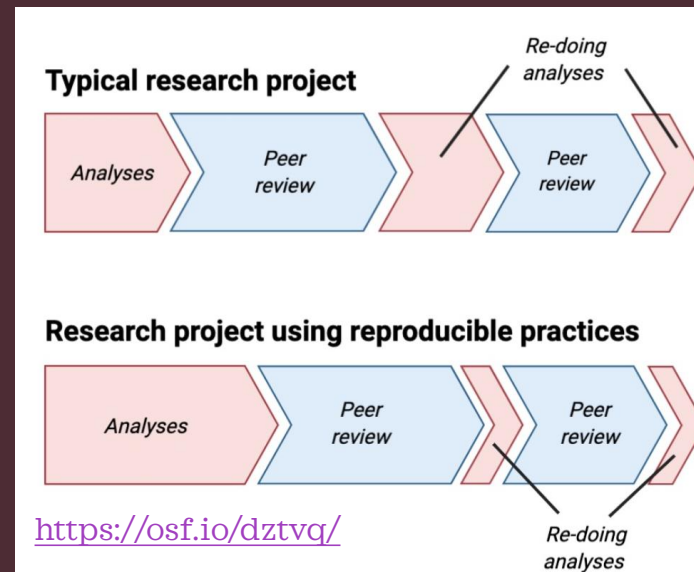
Respondents were positive about most proposed improvements but emphasized training in particular.

● Very likely ● Likely



# The state of Open Science

- Losing competitive advantages – publish materials after paper acceptance, use embargoes
- Prepare source code and data – make it reusable to increase your impact
- Proprietary software – use open source software and scripting languages (R, Python)
- Not yet relevant – this will change!
  - How many papers published?
  - In which journals?
  - How many citations?



# The Open Science Movement

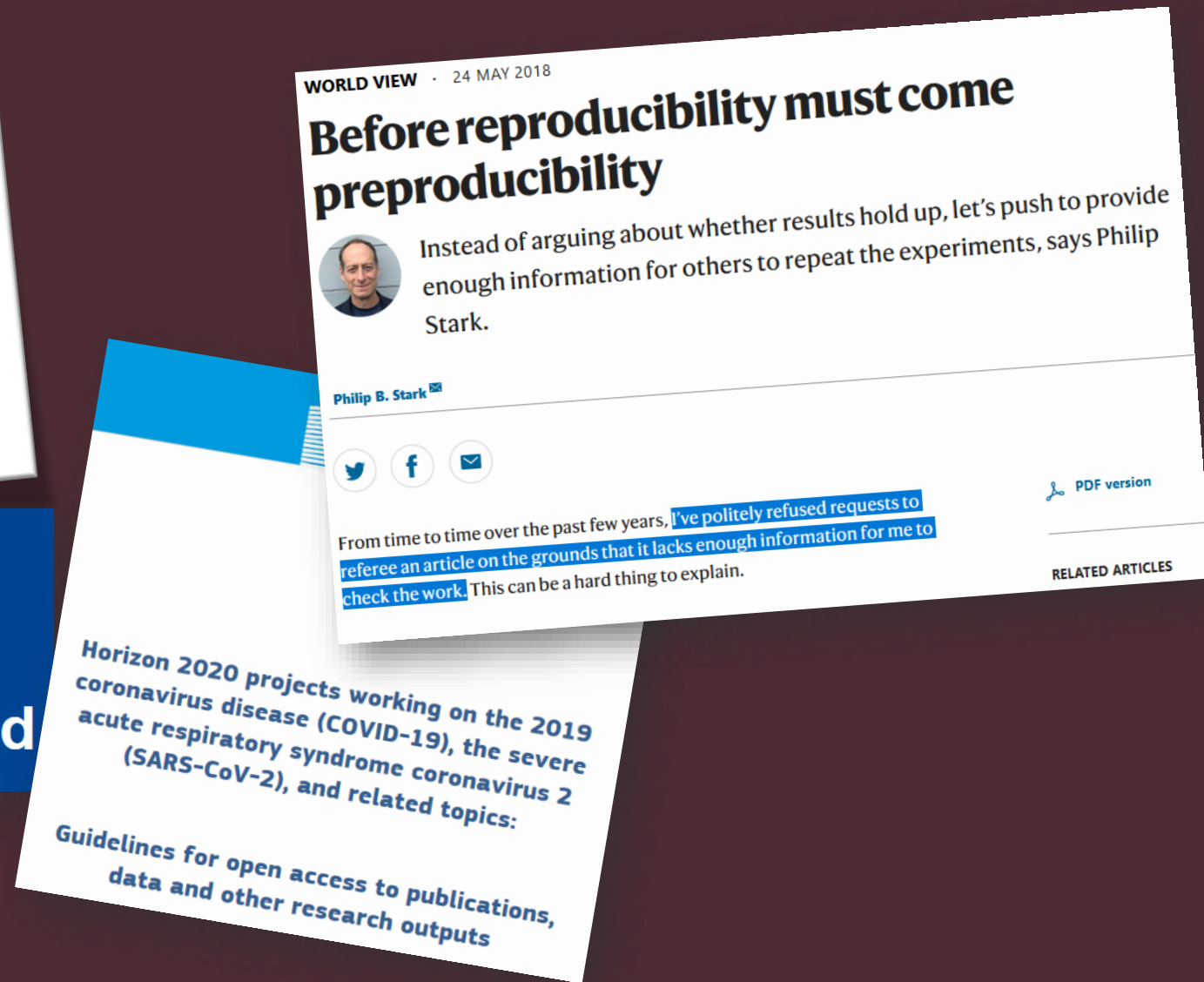


Shaping Europe's digital future

POLICY

## European Open Science Cloud

UNESCO: <https://unesdoc.unesco.org/ark:/48223/pf0000374409.page=10>  
EOSC: <https://ec.europa.eu/digital-single-market/en/european-open-science-cloud>  
Article: <https://www.nature.com/articles/d41586-018-05256-0>  
H2020: [https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/oa-pilot/h2020-guidelines-oa-covid-19\\_en.pdf](https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/oa-pilot/h2020-guidelines-oa-covid-19_en.pdf)



# Open Science Communities

- Bottom-up communities to learn, share, and discuss Open Science practices
- Make Open Science more visible and accessible
- Organize events, seminars, and workshops
- Facilitate knowledge exchange amongst peers
- Support member initiatives focussed on Open Science
- Connect with international Open Science Communities
- Open to everyone who would like to
  - Ask questions
  - Look for support
  - Share (positive and negative) experiences
  - Acquire skills to make research more open

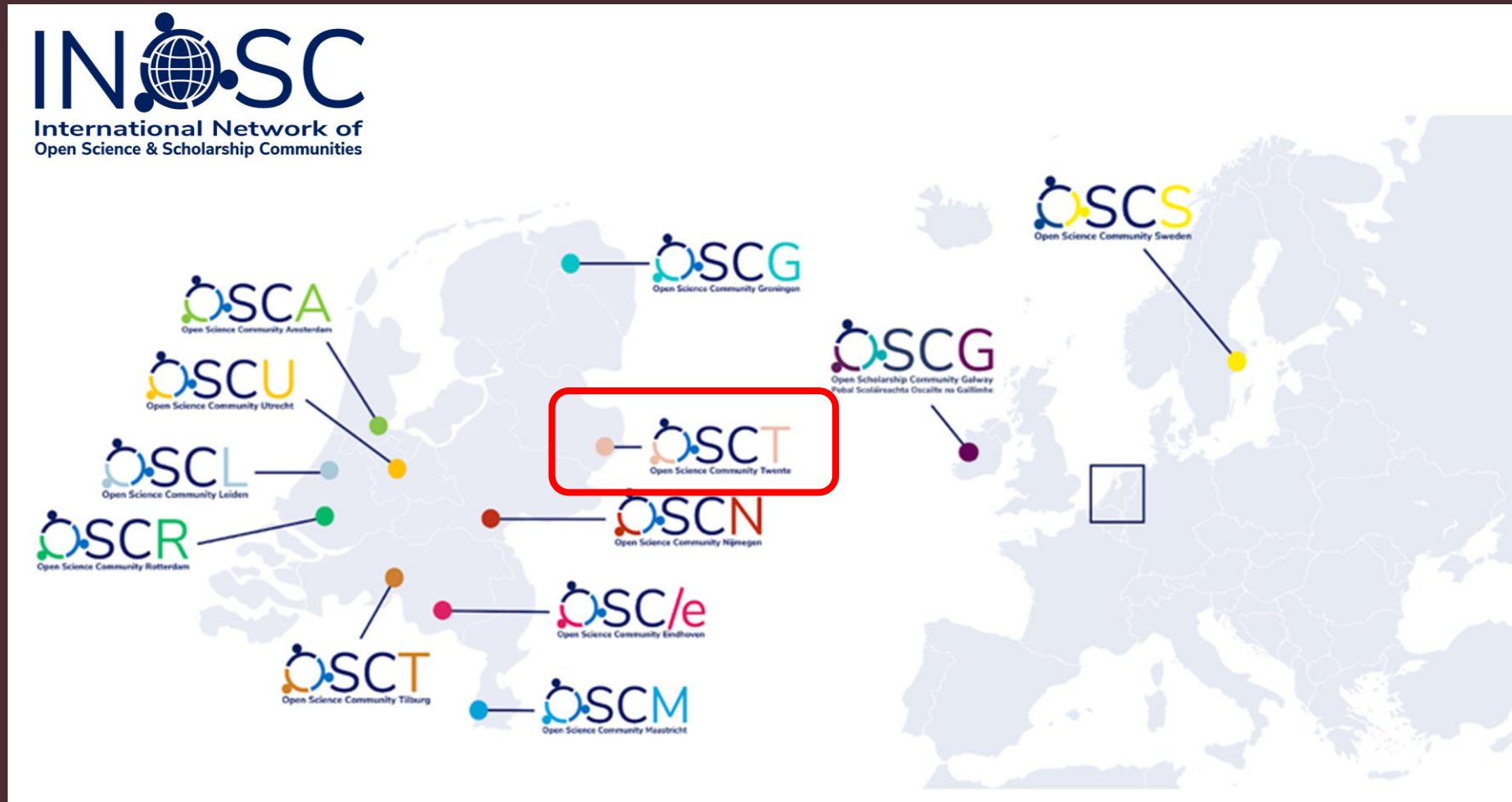
**We are not an  
expert club!**



# Open Science Communities



Twitter: @OSCTwente



# Open Science Communities <https://www.openscience-twente.com/>



The image is a collage of three overlapping elements related to Open Science Twente. On the left is a dark-themed mobile app interface for the University of Twente, showing a search bar and a list of menu items: OSCTwente, Community, Our activities, Newsletter, What is Open Science?, Events, Blog posts, Open Science Binge Watching, and Contact. In the center is a white banner for the 'JOIN OPEN SCIENCE COMMUNITY TWENTE' with the OSCTwente logo and the text 'All employees and students from the University of Twente'. On the right is a white newsletter header titled 'OSCTwente / Newsletter NEWSLETTER' with a decorative blue molecular structure. Below the newsletter header is a paragraph of text and a list of goals, followed by a large blue 'SUBSCRIBE' button.

UNIVERSITY OF TWENTE. HIGH TECH HUMAN TOUCH

OSCTwente

Community

Our activities

Newsletter

What is Open Science?

Events

Blog posts

Open Science Binge Watching

Contact

OPEN SCIENCE TWENTE

OSCTwente / Community / Join OSCT

## JOIN OPEN SCIENCE COMMUNITY TWENTE

All employees and students from the University of Twente

## OPEN SCIENCE KITCHEN

Let's be honest: The most important room in any department is the kitchen. There you get coffee or tea and meet your colleagues for quick chats about daily life and work. Open Science Kitchen is a series of regular, virtual meetings of around 60 minutes with changing topics that are free to everyone. These meet-ups hopefully help to get to know each other better and across departments. The goals are to

- provide a space to discuss topics in the context of Open Science,
- make people think about Open Science regularly, and
- present current developments people at UT and Saxion University should know about.

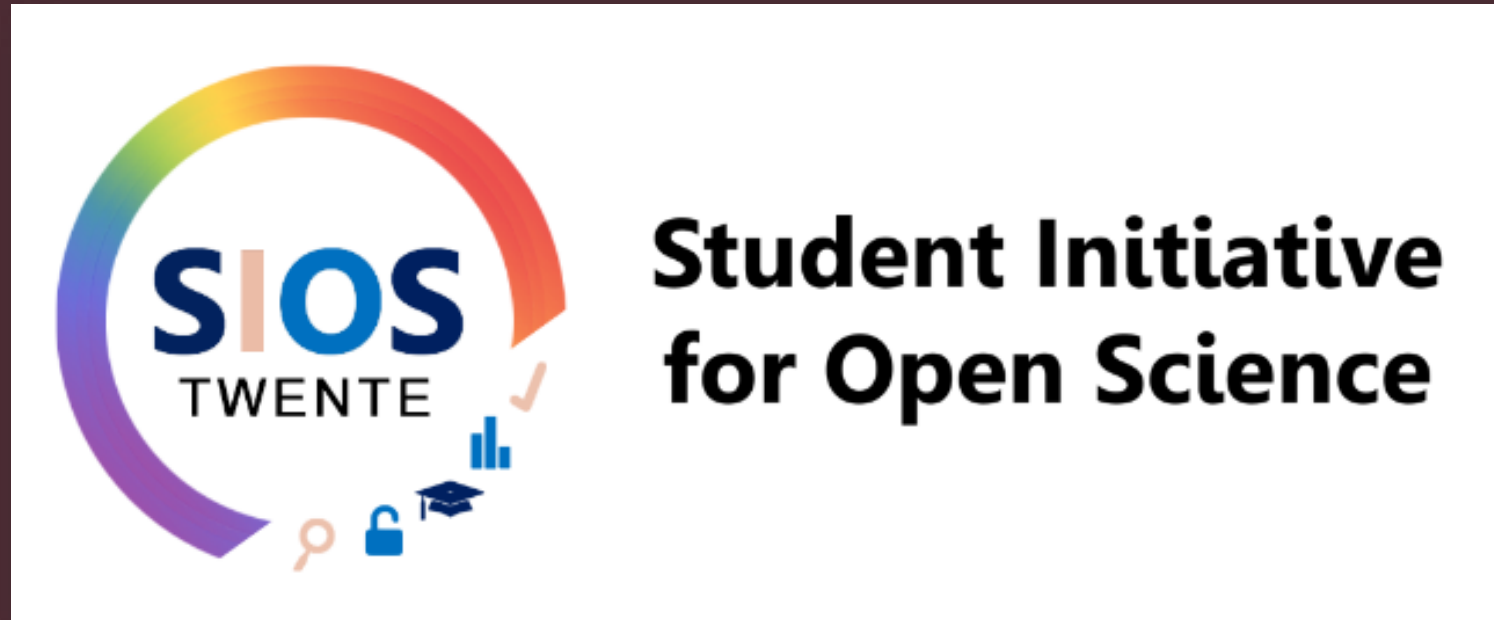
OSCTwente / Newsletter

## NEWSLETTER

Only OSCT newsletter. It provides a quick and concise summary of all news. The newsletter is created by a joined effort of the OSCT members interested in topics related to the broad and beautiful spectrum of Open Science. Have a questions, comments, or ideas regarding the newsletter, please send a [message](#).

**SUBSCRIBE**

# Open Science Communities for Scientists only?



<https://www.openscience-twente.com/sios/>