PRECLINICAL TRIALS.EU

Netherlands Heart Institute

Preclinicaltrials.eu & data sharing

Ottawa's webinar, 3rd October 2022
Julia Menon, Daily Director of Preclinicaltrials.eu

Introduction

- Daily director preclinicaltrials.eu
- Research fellow ZonMw
- PROSPERO administrator
- Systematic reviews section editor Laboratory Animals
- Board member Young TPI

Conflict of interest

- I declare no conflict of interest

Outline

I-Problems in animal research

II-Preregistation: what is it?

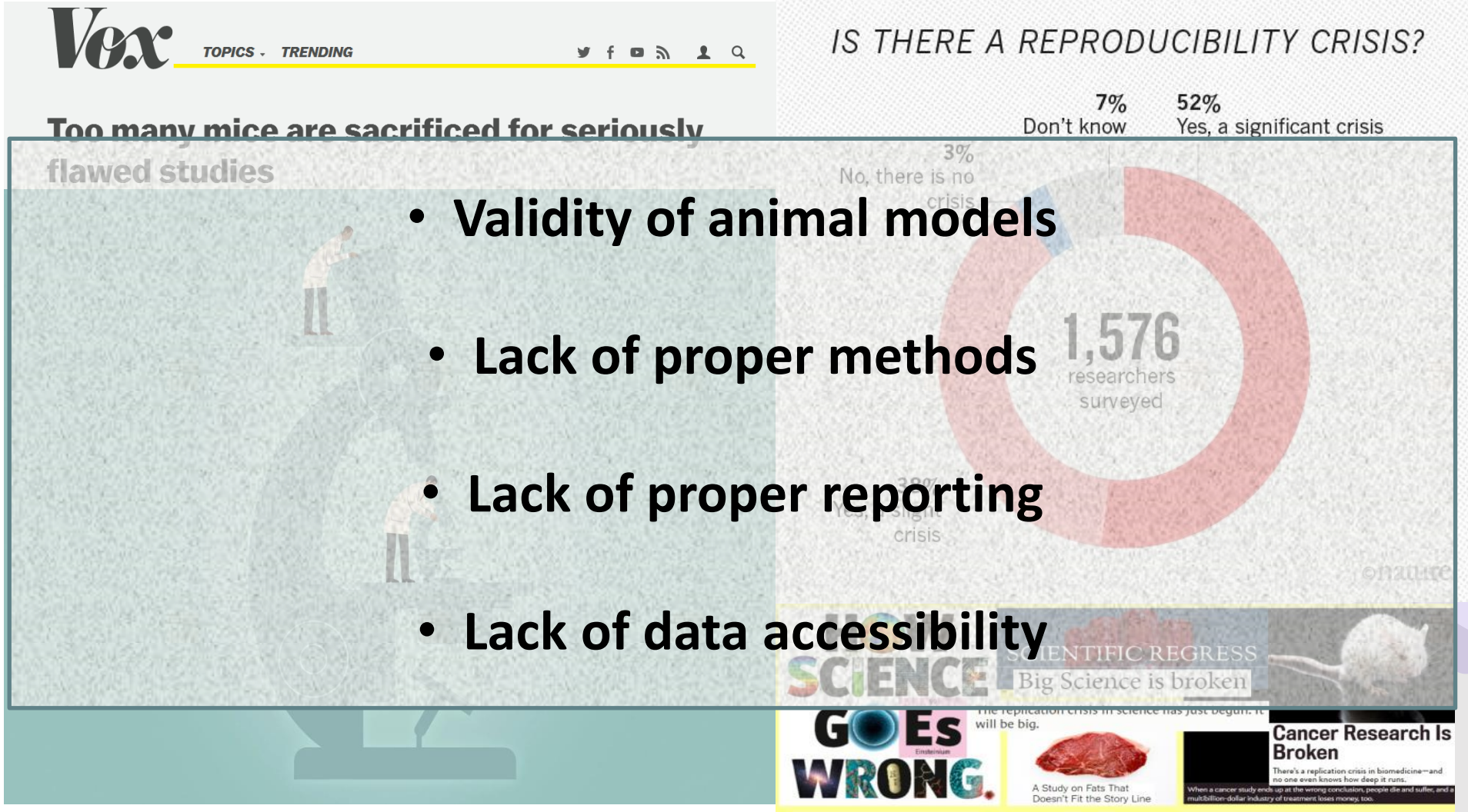
III-Preregistation benefits

& Preclinicaltrials.eu

Problems in animal research

How can we improve?

Problems in animal research

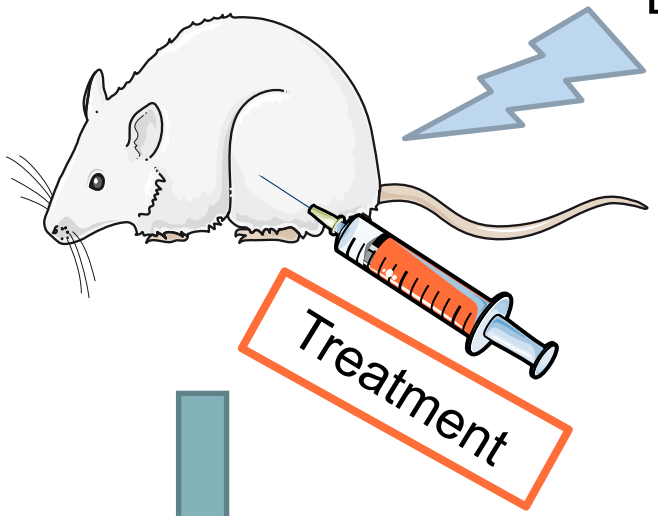


- Validity of animal models
- Lack of proper methods
- Lack of proper reporting
- Lack of data accessibility

Threats to internal

Selection Bias | **Performance bias** | **Detection bias**

Experimental group



Bias = system

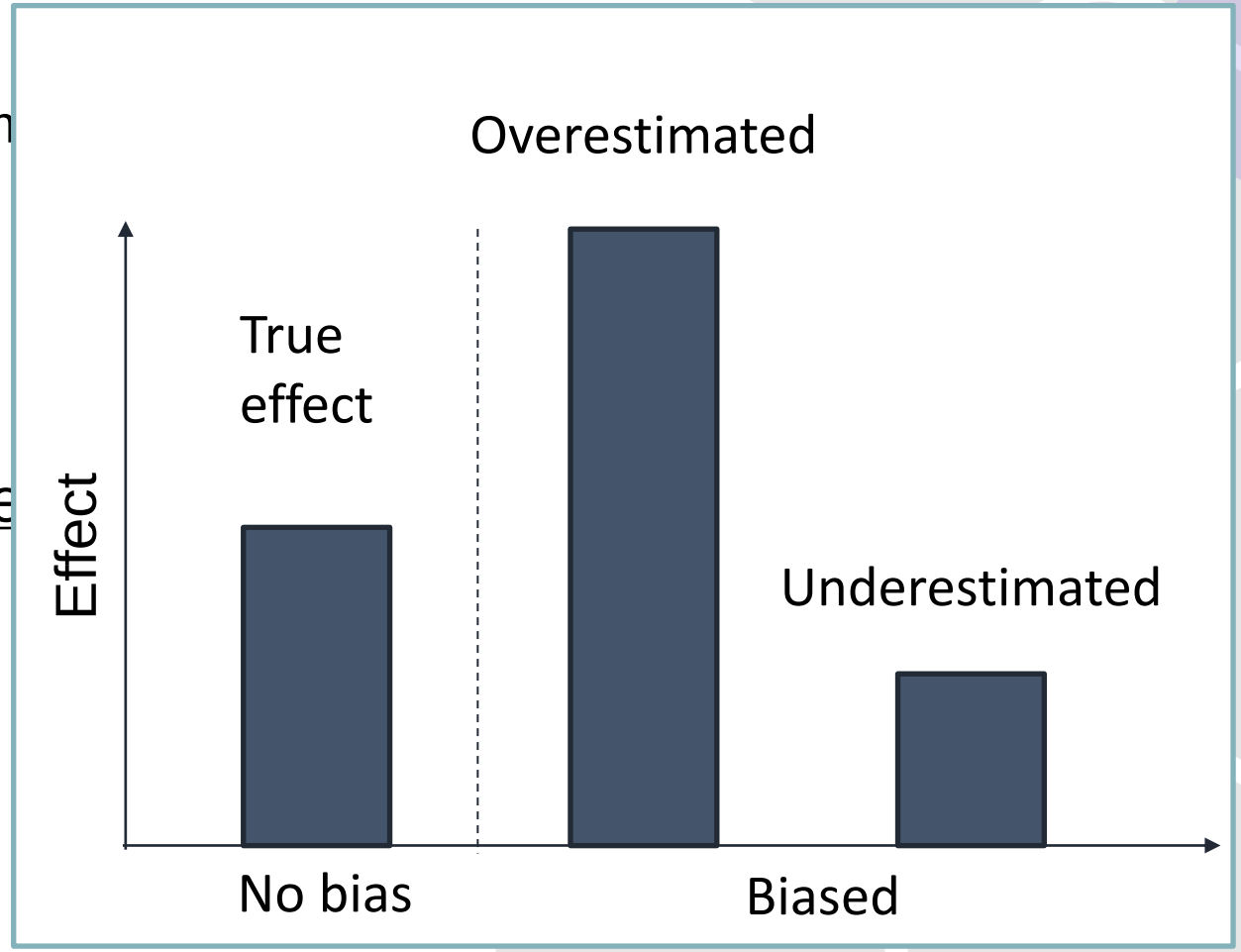
VS

Differe

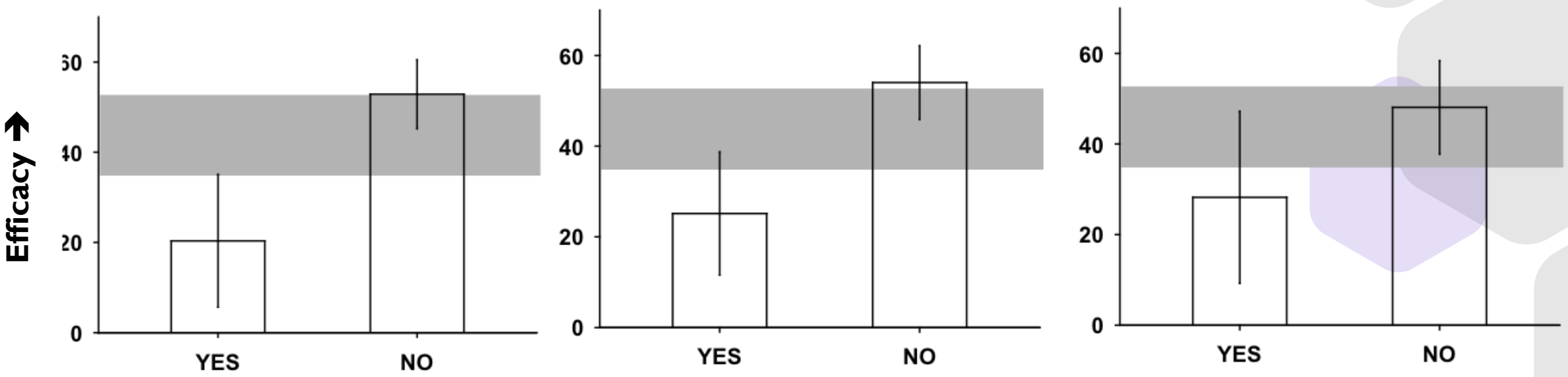
Noise
External factors

Results

Unreliable results



Threats to internal validity



Randomisation

Blinded conduct of experiment

Blinded assessment of outcome

Macleod et al., Stroke, 2004

Selective outcomes reporting & publication bias

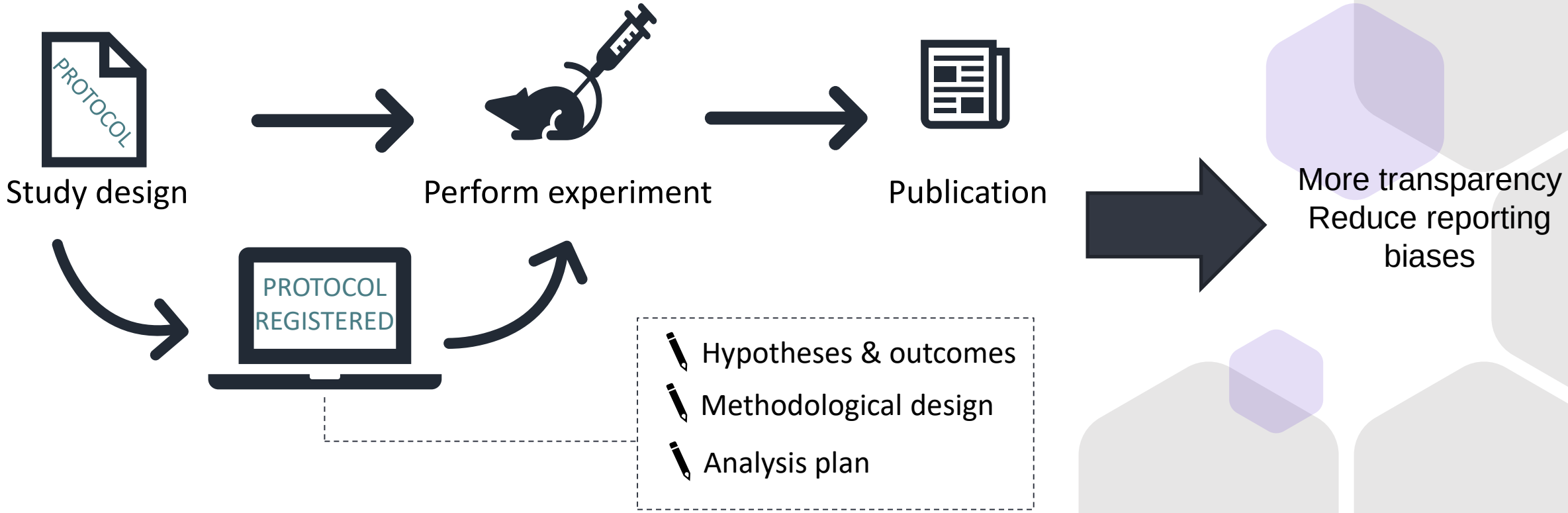
- Higher chances for positive/significant results to be published.
- Difference in likelihood to publish between studies due to study characteristics or results.
- Prevent to have a full (realistic) overview of evidence.

Preregistration of animal studies

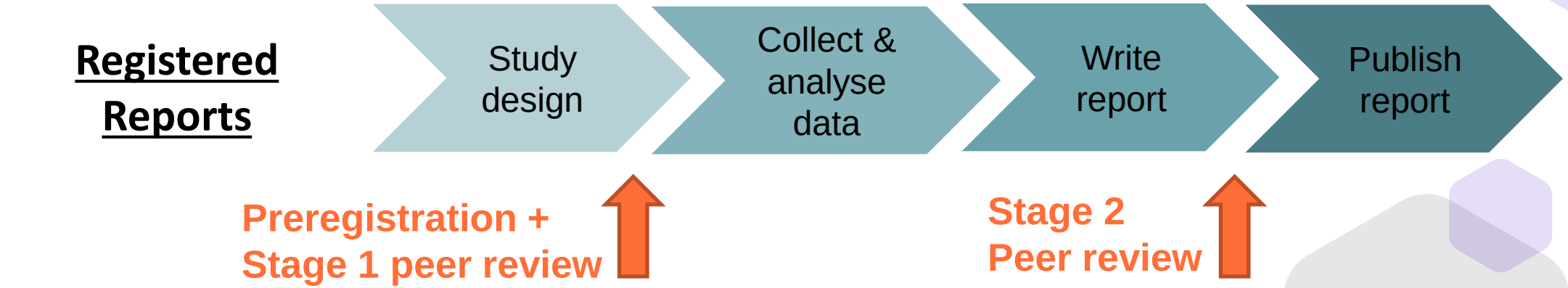
What is it?

Preregistration

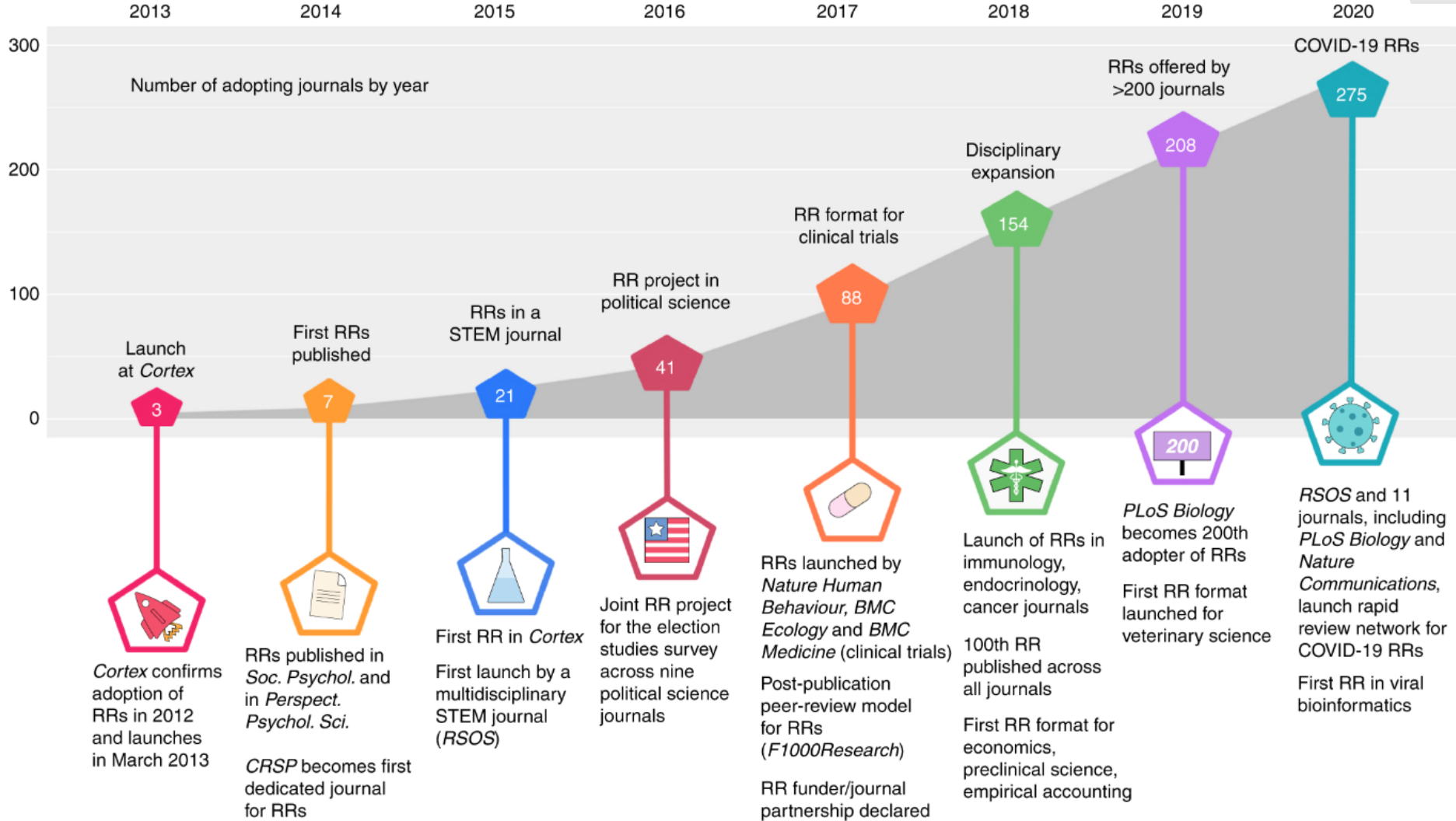
- **Preregistration** is the act of **registering research protocols before** conducting the experiments.



Registered Reports



Evolution of the registered reports



Chambers & Tzavella, 2021

“Simple” preregistration vs Registered reports

Preregistration		Registered reports
Fast and easy	VS	Longer process, less accessible
Can be flexible		Stricter
Accessible to all		Accessible only after publication
Does not ensure publication		In principle acceptance

Clinicaltrials.gov and clinical registries

Largest clinical registry
~ 410,000 records from 220 countries

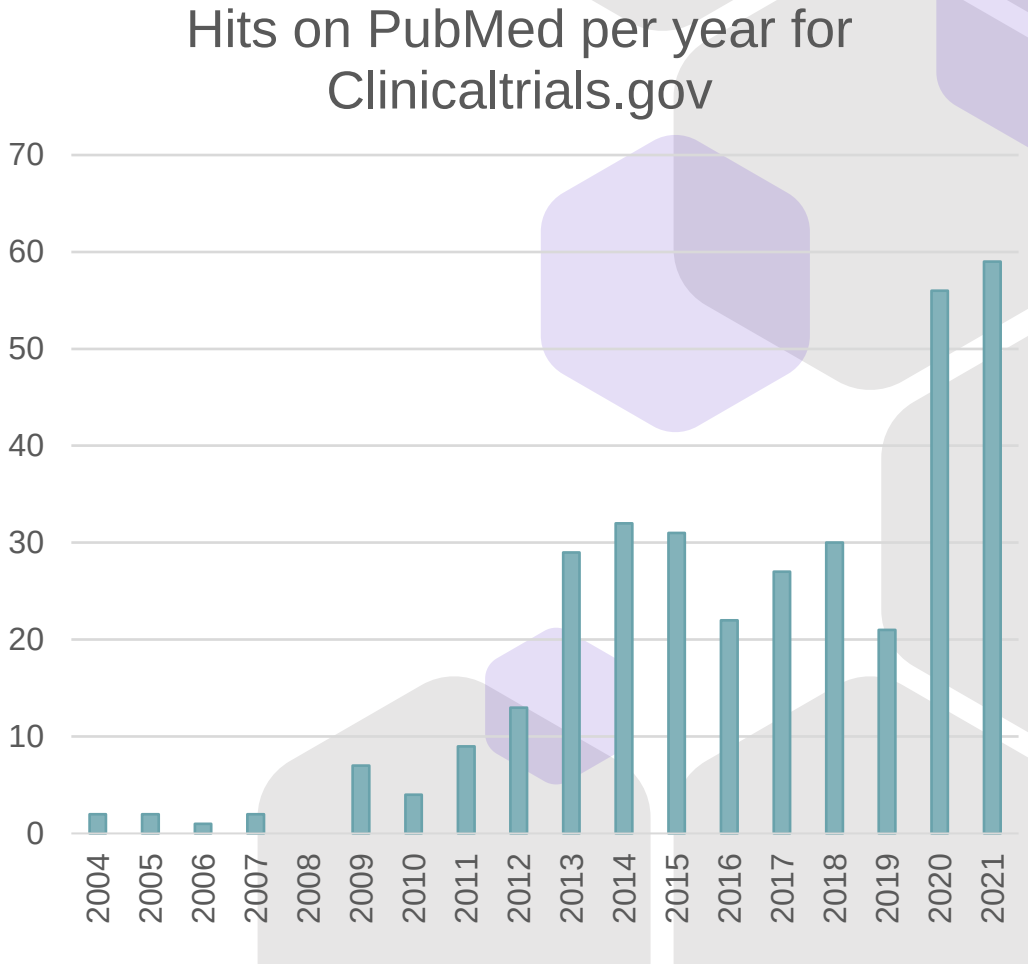
1997: FDA act requests a registry

2000: Clinicaltrials.gov is online

2005: International Committee of Medical Journal Editors (ICMJE) required preregistration

2008-2009: reporting outcomes and adverse effects

International Clinical Trials Registry Platform (ICTRP) from WHO
- Clinicaltrials.gov
- EU clinical trial register
- Netherlands National trial register
- ISRCTN.org
- …



(Pre)registration of animal studies

- Only 2 registries tailored to animal studies:
  - Preclinicaltrials.eu (*Dutch; held by the Netherlands Heart Institute*) -2018
  - Animal Study Registry (*German; held by the German Centre for the Protection of Laboratory Animals*) - 2019

- General registry, e.g. Open Science Framework (*American; held by the Center for Open Science*) - 20

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BfR Bundesinstitut für Risikobewertung

OSF

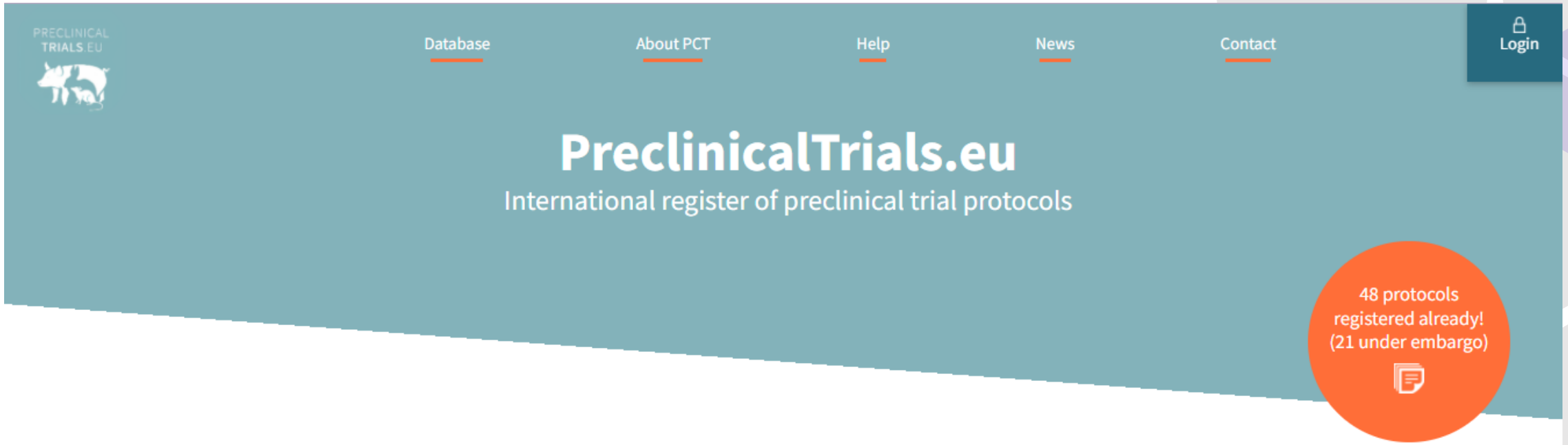
Poll n°1

Have you ever preregistered a protocol before?

A) Yes
B) No, but I thought about it
C) No, because I don’t know how to do it
D) No

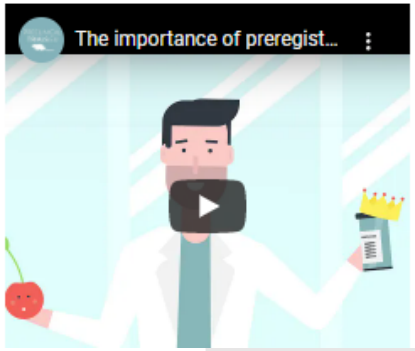
Preregistration benefits & Preclinicaltrials.eu

Preclinicaltrials.eu

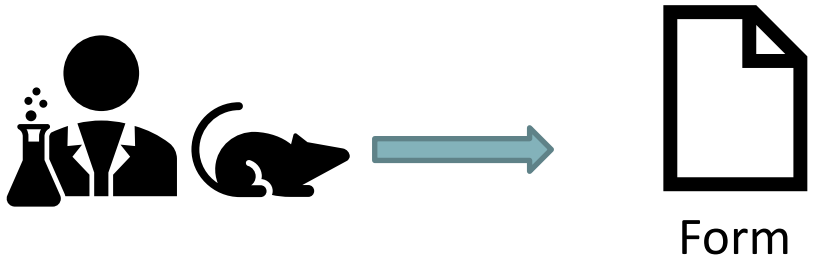


Preclinicaltrials aims to provide a comprehensive listing ofpreclinical animal study protocols. Preferably registered atinception in order to increase transparency, help avoid duplication,and reduce the risk of reporting bias by enabling comparison of thecompleted study with what was planned in the protocol. Registration of your study requires you to create an account that is:

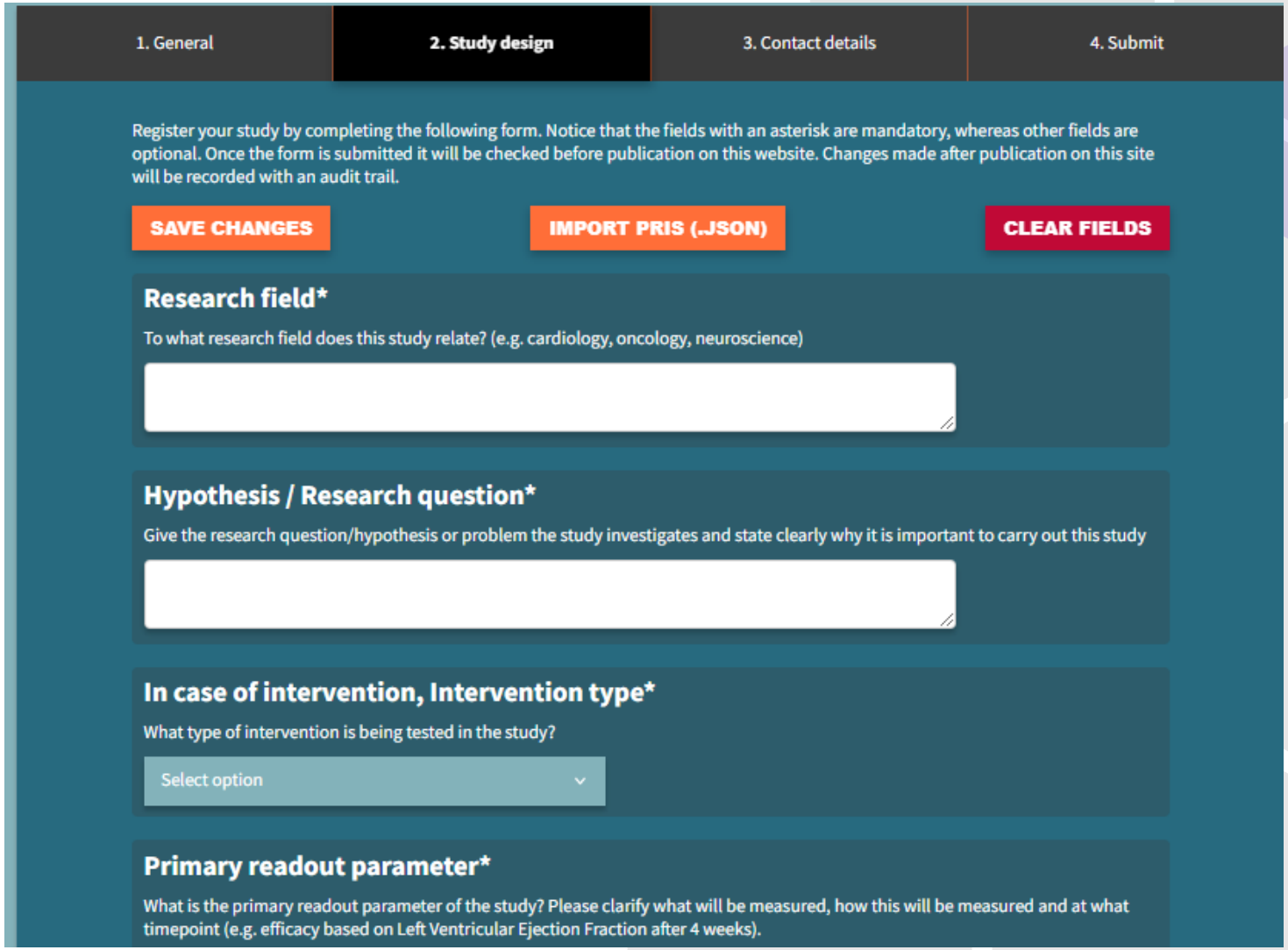
- Anonymous
- Free of charge



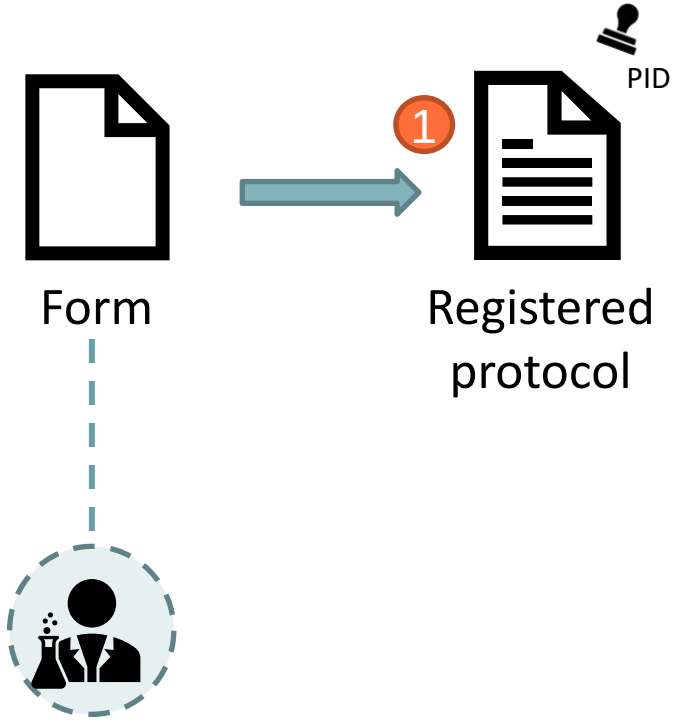
Benefits of preregistration



- Form focuses on experimental design
- Compliant with ARRIVE essential 10



Benefits of preregistration



1

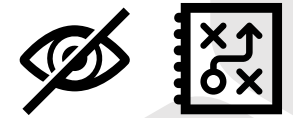
- Increase transparency
- Promote robust study design & reporting

Stamp icon was created by DinosoftLab from Noun Project

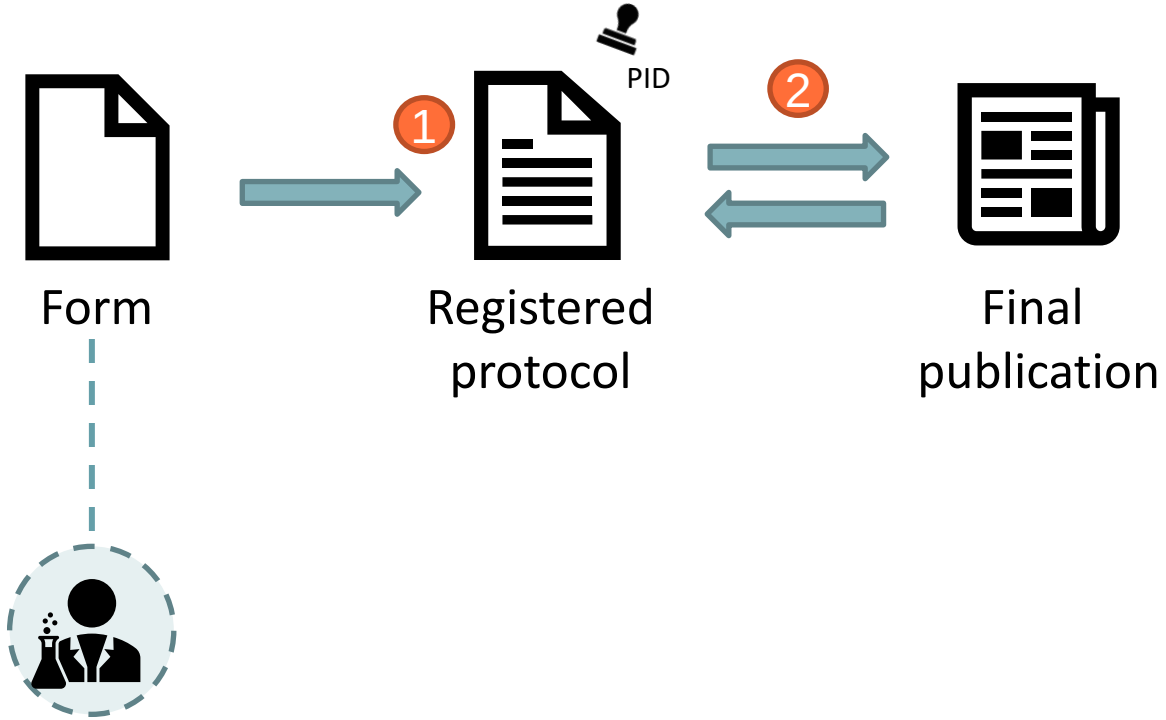
Benefits of preregistration

- Increase transparency
  - All study protocols and their content are available online
  - Provide a persistent identifier

- Promote robust study design
  - Demand information on blinding, randomisation, sample size calculation



Benefits of preregistration



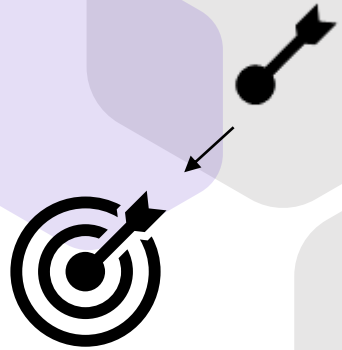
1 Increase transparency

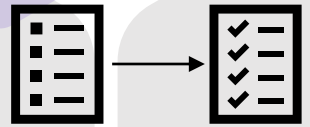
1 Promote robust study design & reporting

2 Reduce reporting bias & malpractice

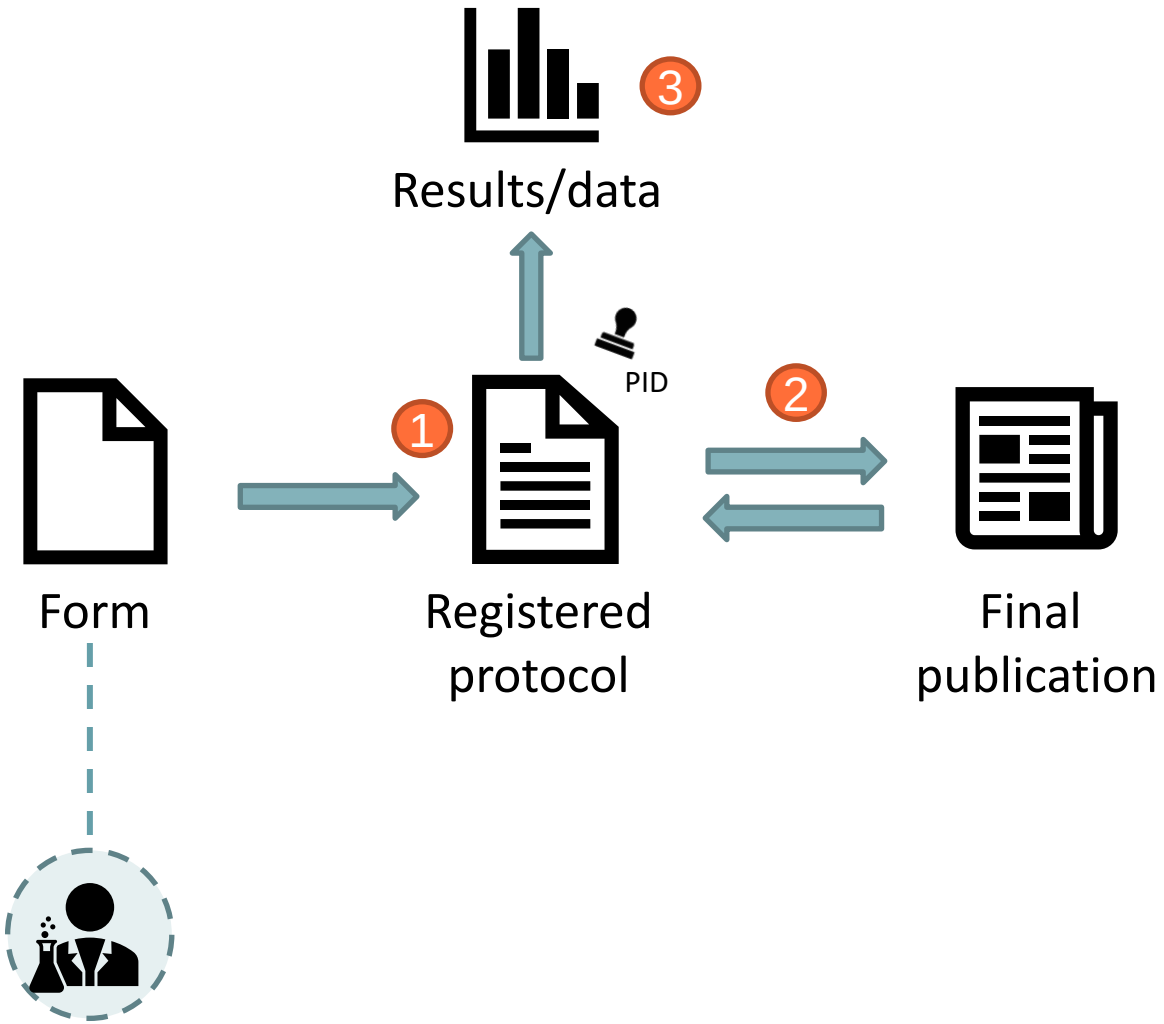
Benefits of preregistration

- Decrease reporting bias
  - Selective outcomes reporting
- Decrease malpractice
  - Prevent HARKing
  - Prevent P-hacking
- Increase reliability





Benefits of preregistration



- Increase transparency
- 1 Promote robust study design & reporting
- 2 Reduce reporting bias & malpractice
- 3 Reduce publication bias

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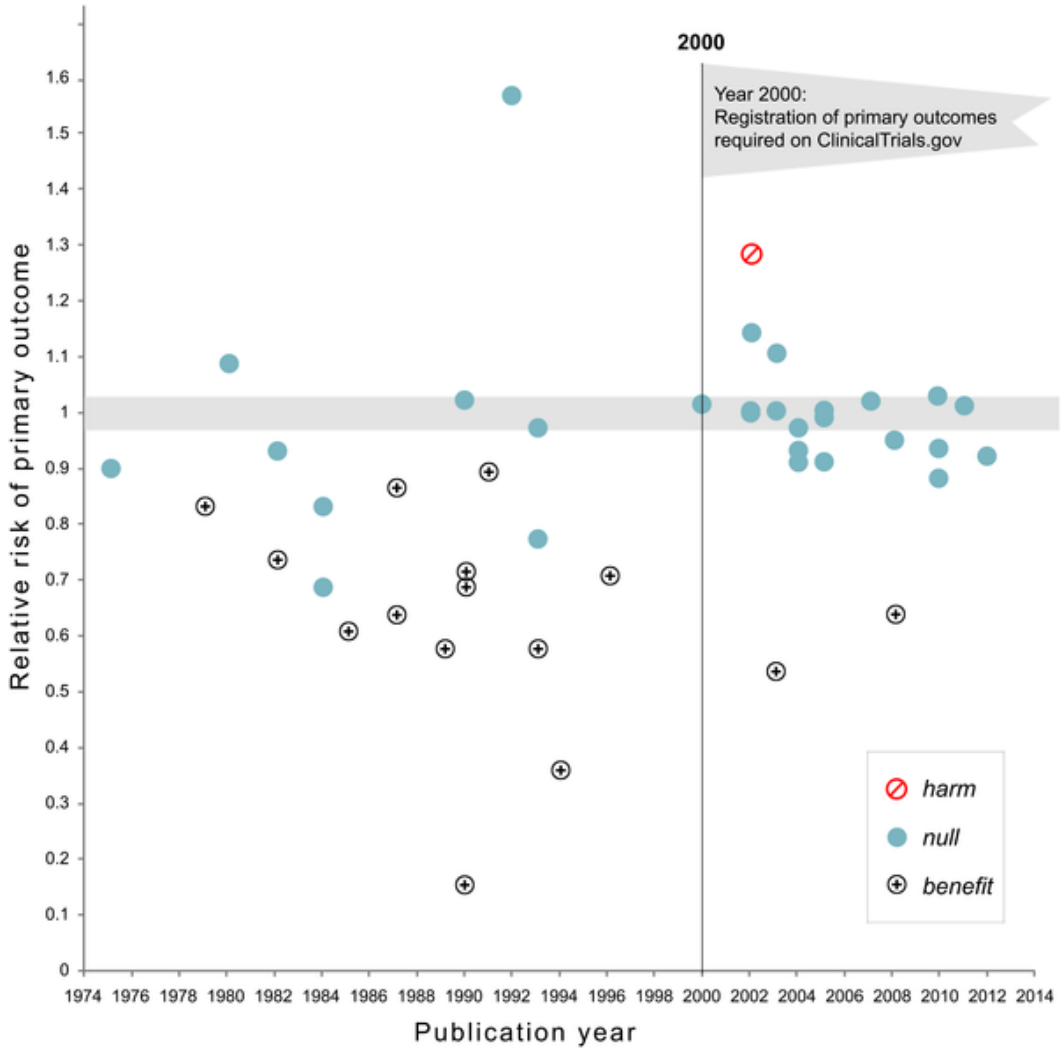
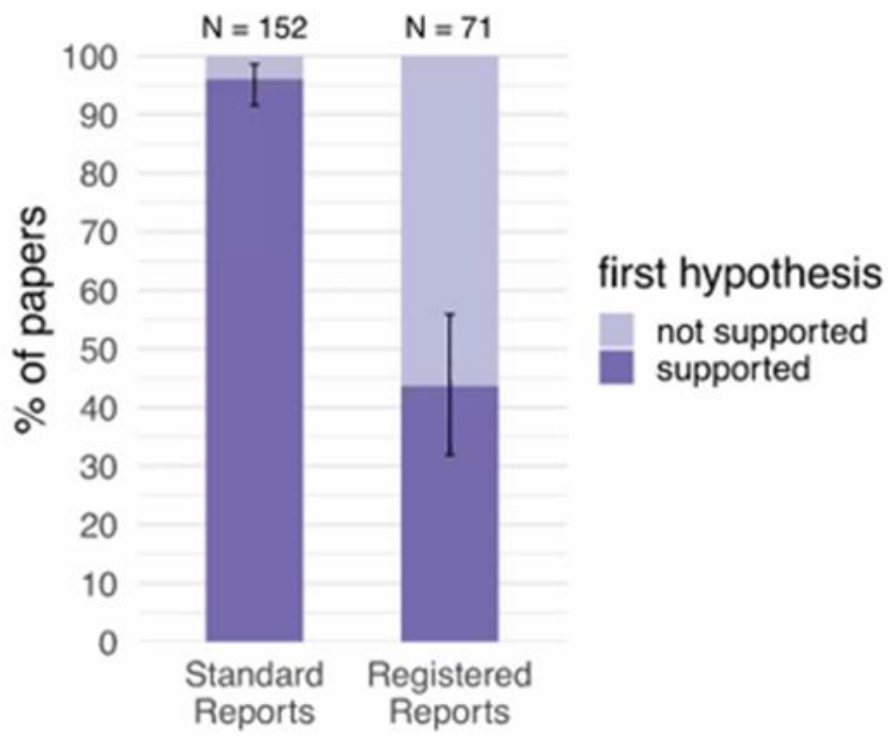
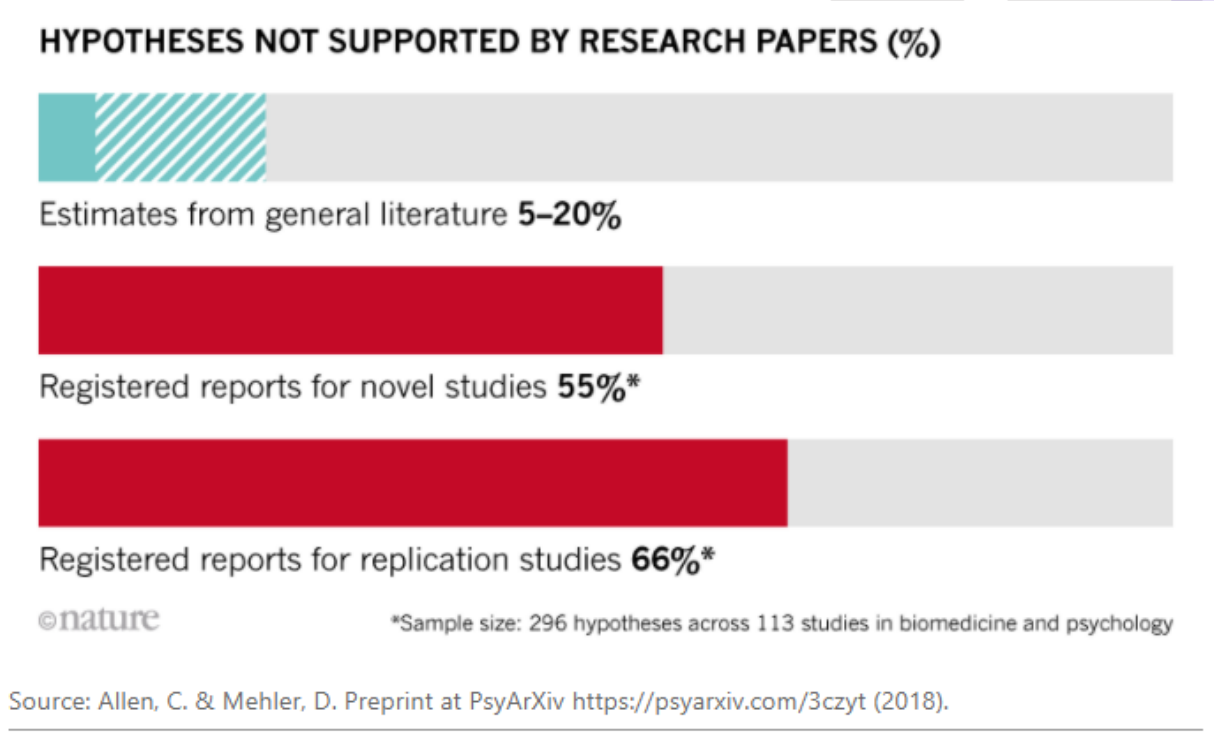
Benefits of preregistration



Kaplan RM, Irvin VL (2015) PLOS ONE 10(8): e0132382. https://doi.org/10.1371/journal.pone.0132382

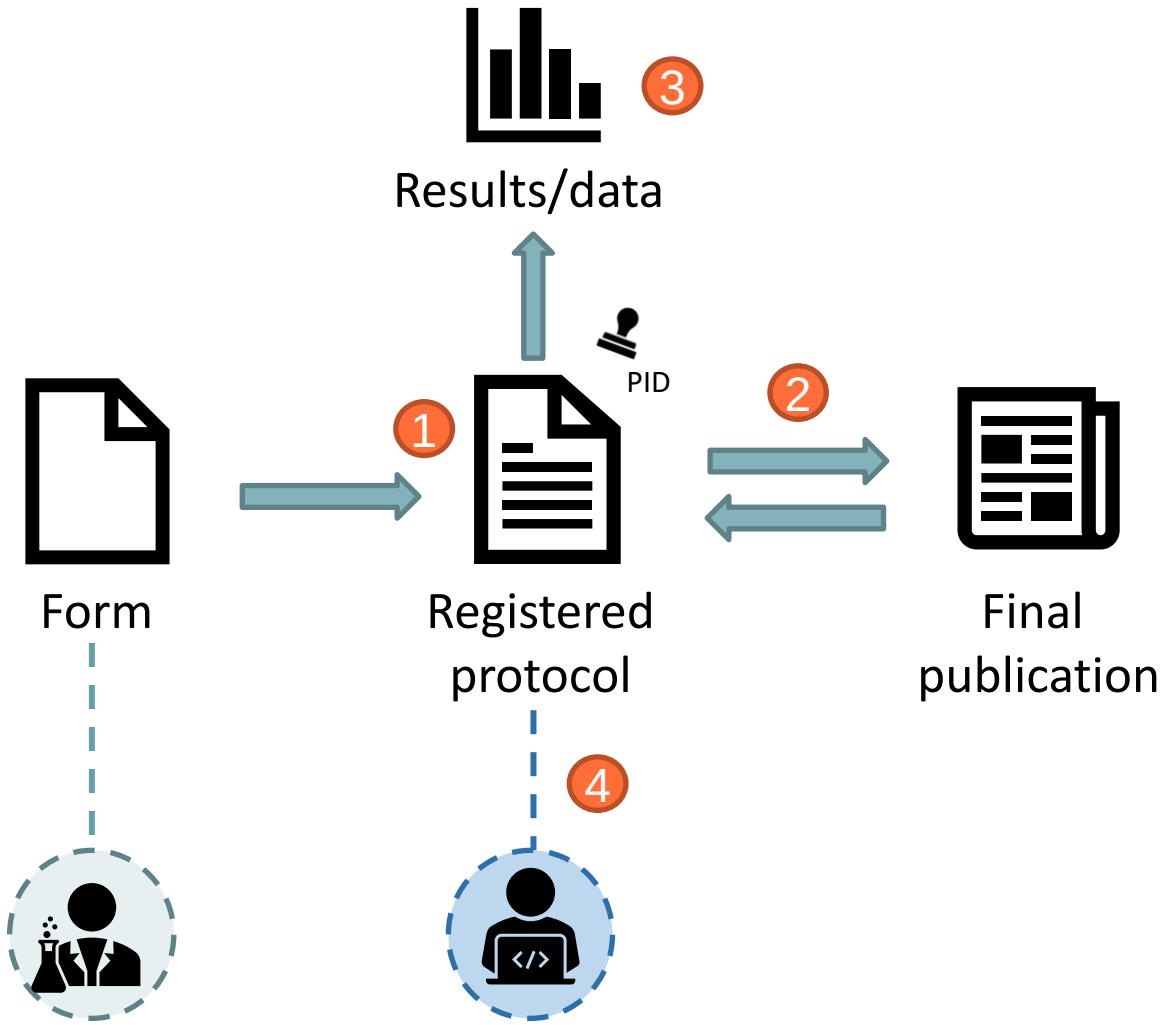
Benefits of preregistration





Scheel, A. M., Schijen, M. R., & Lakens, D. (2021). An excess of positive results: Comparing the standard Psychology literature with Registered Reports. Advances in Methods and Practices in Psychological Science, 4(2).

Benefits of preregistration



1. Increase transparency
2. Promote robust study design & reporting
3. Reduce reporting bias & malpractice
4. Reduce publication bias
5. Avoid duplication of animal studies
6. Help reproducibility

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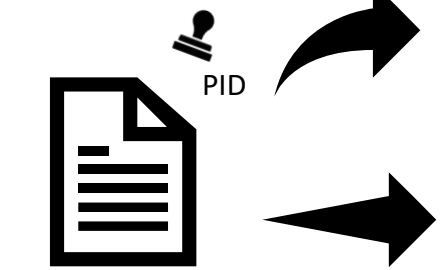
Who benefits from preregistration?



Direct benefits

- Researchers
- Colleagues & peers
- Reviewers

Semi-direct benefits

- Journals
- Funders
- Research institutes

Undirect benefits

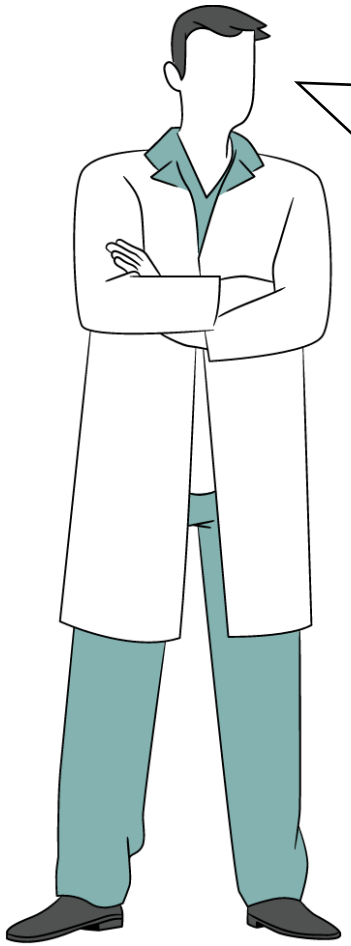
- Animals
- Society

Poll n°2

Which concerns would prevent you from preregistering?

Please type your answer in the chat or speak up

Cost & eligibility

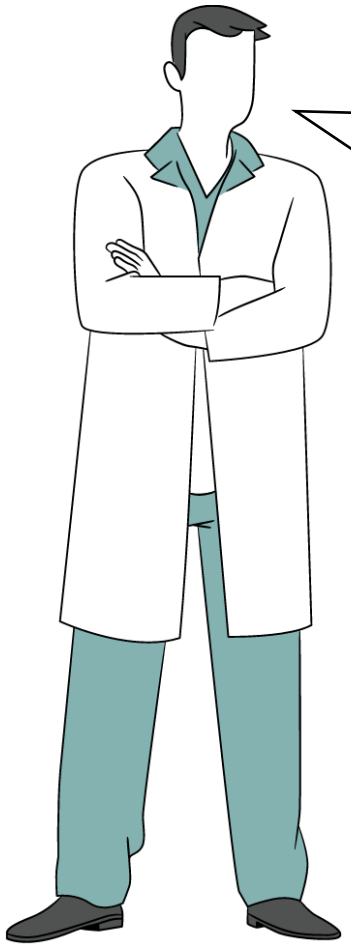


I cannot spend money on preregistration!
Besides, I'm not even sure my studies would match the registry.

No problem, this platform is **free** to use.
And they accept all studies using animals.

Allow registration at all stages

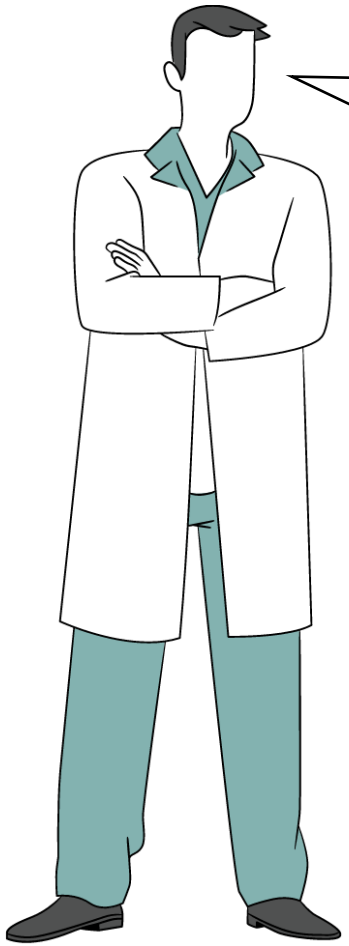
Exploratory studies



My research is purely exploratory. This platform is not for me

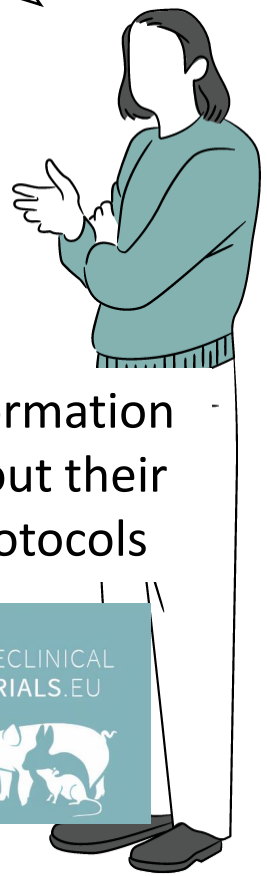
Wait, all experiments have to be properly planned, right?
Also exploratory research can fit the format. Just have a look!

Lack of time



I don’t have time for this!
This is too much effort

The time is well invested.
A well-planned study can save a lot of time later in the publication process.



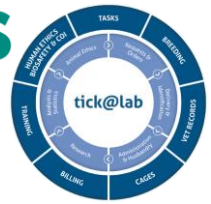
Information about their protocols

EXPORT

Information about their protocols

PRIS

iVENTION
Lab Automation



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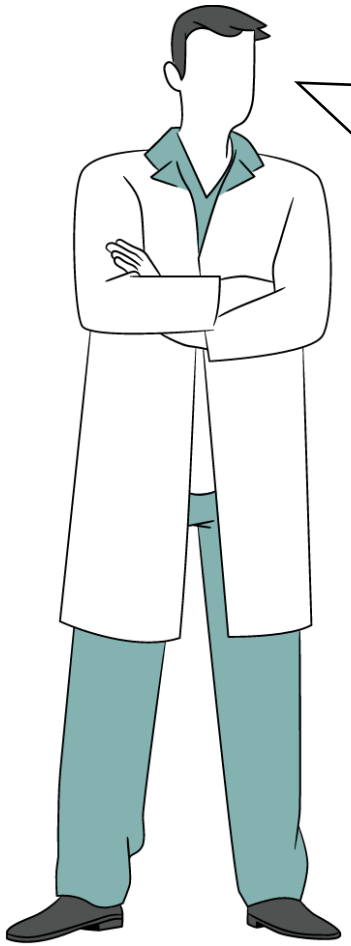
Flexibility

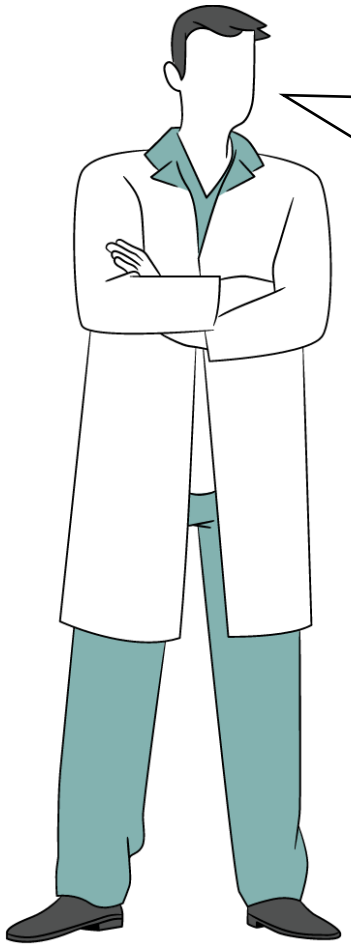


I'm concerned I will be limited in my scientific creativity!

What will happen if my methodology changes?

This platform is tailored to your research & allow flexibility.
You can amend your protocol at any time.

Security and intellectual property

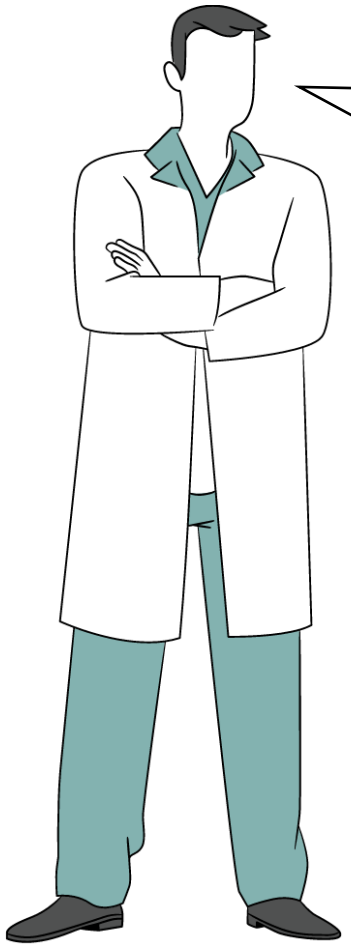


I’m afraid to get scooped or that malicious people steal my private information

No worries, you protocol can be protected by an embargo! You get to decide when to make your info public

Embargo: start with 1 year, extendable
Registration are anonymous
Only users can access protocols

Guidance



I don’t know where to start.
Preregistration seems complex

Do no worry, the process is easy.
There is plenty of guidance online!

-FAQ
-How to document
-Guidance hours

What do you need to preregister

1. An internet connection
2. A study protocol (preferably finished)
3. An account to the registry
4. A little bit of time




Contact us and check our (social) media

Info@preclinicaltrials.eu

Julia.menon@heart-institute.nl

LinkedIn Profile

Website

Twitter Account

Guidance Hours

Thank you for your attention!

Any questions?