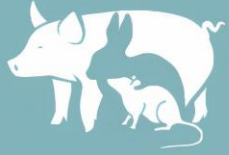


PRECLINICAL
TRIALS.EU



Samenwerkende
GezondheidsFondsen

SGF



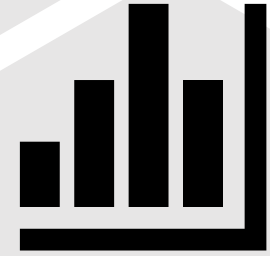
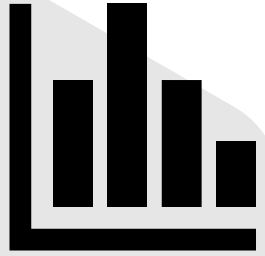
Pre-registration of animal studies at Preclinicaltrials.eu



04.12.2025

Julia Menon: Julia.menon@heart-institute.nl

Poll



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



Poll n°2

Before today, have you heard about
Preclinicaltrials.eu?

- A) Yes
- B) No



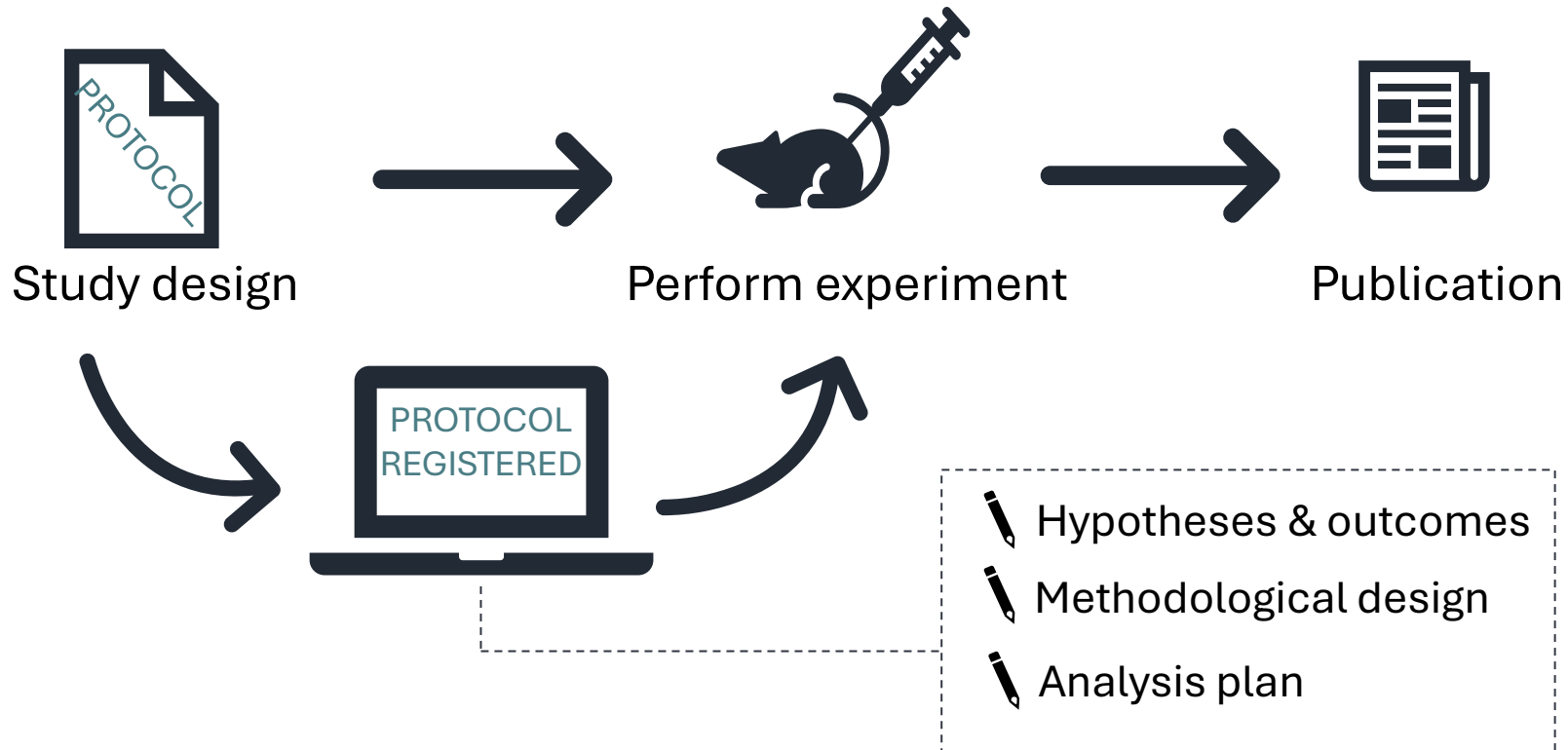
Preregistration of animal studies





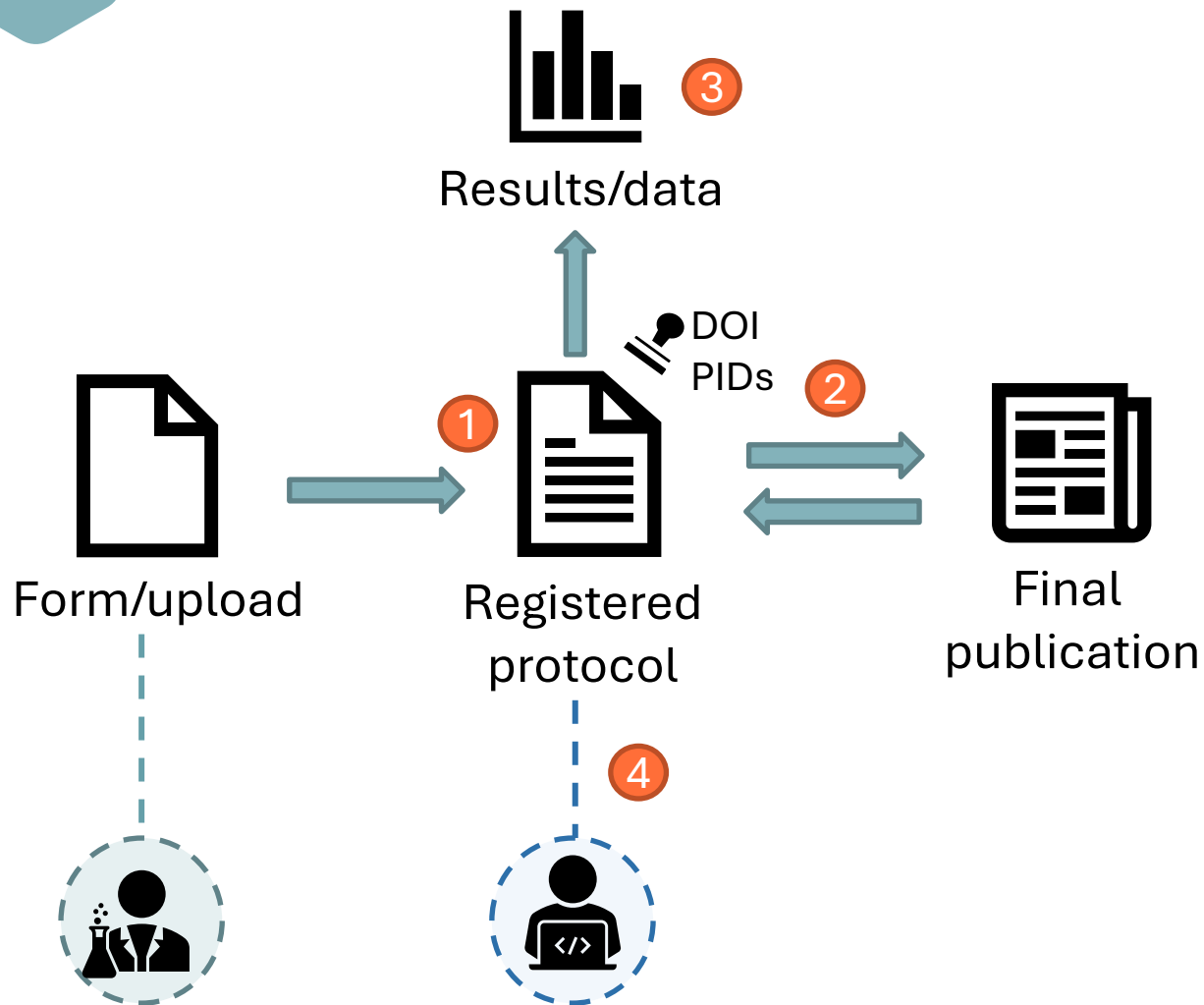
Preregistration

- **Preregistration** is the act of **pre-specifying a study protocol before** conducting the experiments.





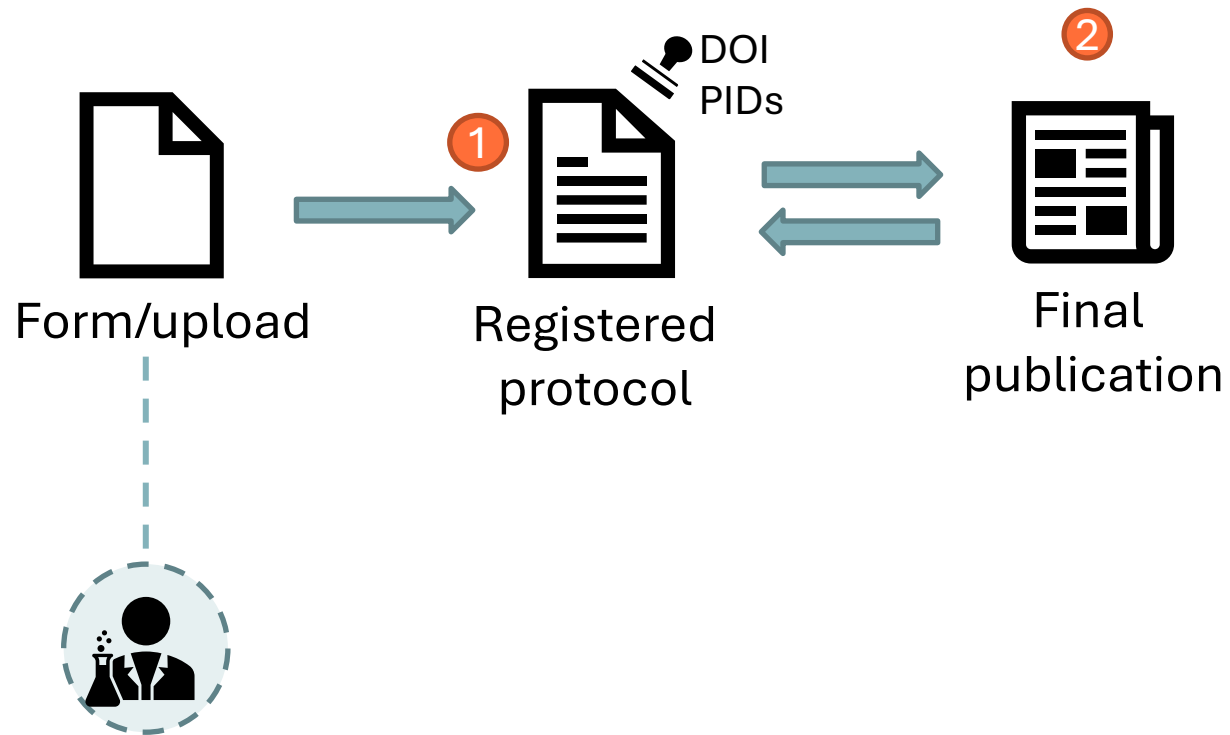
The benefits for science



- 1 Increase transparency
- 2 Promote robust study design
- 2 Reduce reporting bias & QRPs
- 3 Reduce publication bias
- Avoid duplication of animal studies
- 4 Help reproducibility



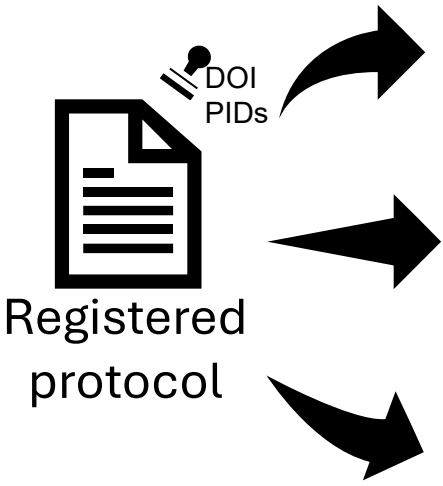
The benefit for researchers



- 1  Helps you to plan your experiments thoroughly
- 1  Identifier & embargo protect your ideas
-  Raises awareness for common mistakes
-  Facilitates reporting according to guidelines
- 2  Proves your commitment to OS practices/help publish



Who benefits from preregistration?



Direct benefits



Researchers



Colleagues & peers



Reviewers

Semi-direct benefits



Journals



Funders



Research institutes

Indirect benefits




Animals



Society



Preregistration is mandatory in clinical research

 U.S. National Library of Medicine

ClinicalTrials.gov

[Find Studies](#) ▾ [About Studies](#) ▾ [Submit Studies](#) ▾ [Resources](#) ▾ [About Site](#) ▾

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore **276,190** research studies in all **50** states and in **204** countries.

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks and potential benefits](#).

Find a study (all fields optional)

Status

- Recruiting and not yet recruiting studies
- All studies

Condition or disease (For example: breast cancer)

X

Other terms (For example: NCT number, drug name, investigator name)

X

Country

X

Search

[Advanced Search](#)

[Help](#) | [Studies by Topic](#) | [Studies on Map](#) | [Glossary](#)

Patients and Families

Search for actively recruiting studies that you may be able to participate in or learn about new interventions/treatments that are being considered.

[Learn more](#)

Researchers

Search the database to stay up to date on developments in your field, find collaborators, and identify unmet needs.

[Learn more](#)

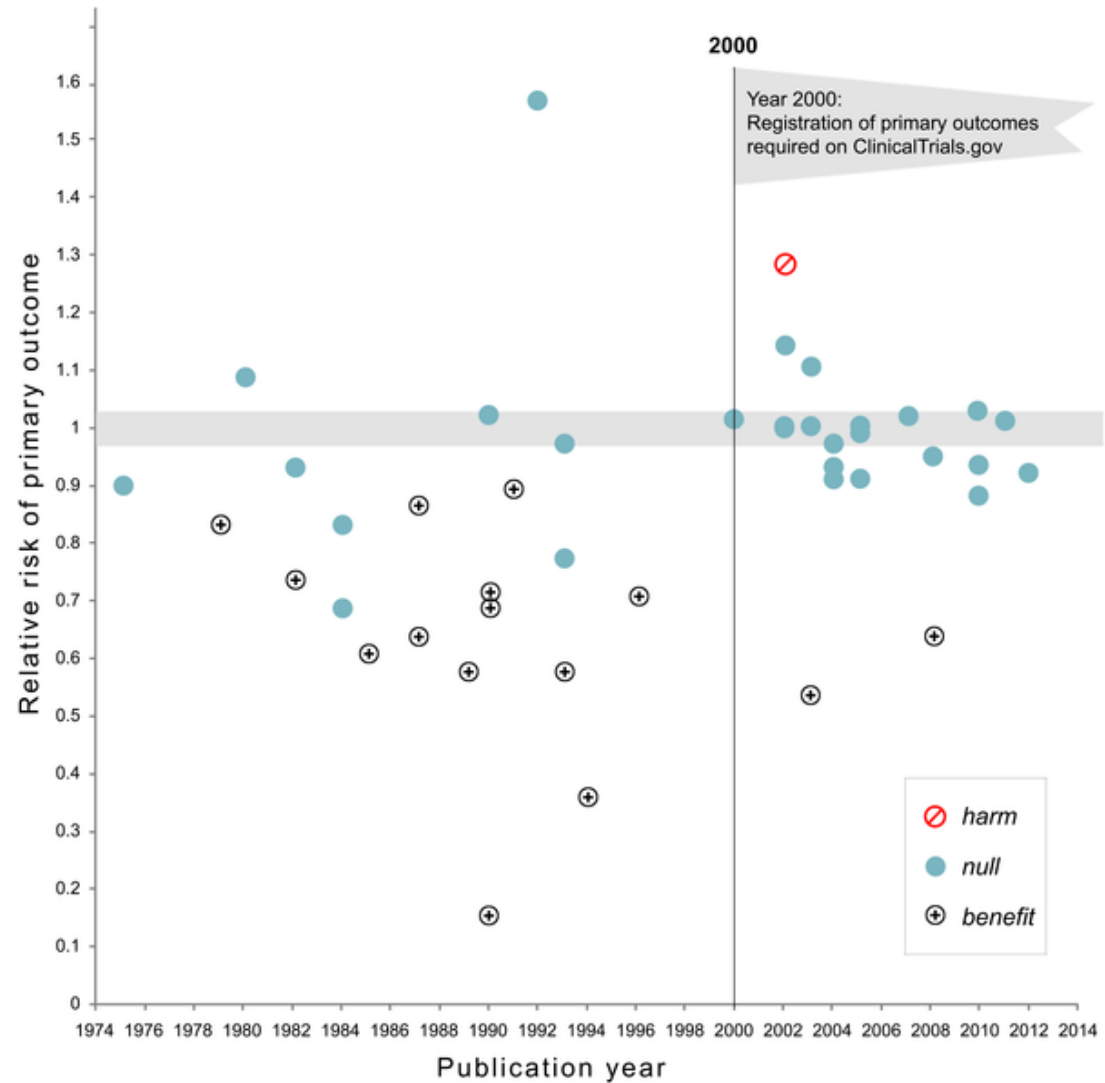
Study Record Managers

Learn about registering studies and about submitting their results after study completion.

[Learn more](#)



Preregistration increases the display of null results





Preregistration of animal studies

- ◆ General registry, e.g. Open Science Framework (*American; held by the Center for Open Science*)
- ◆ Two registers for animal studies:
 - ◇ Preclinicaltrials.eu (*Dutch; held by the Netherlands Heart Institute*) (2018)
 - ◇ animalstudyregistry.org (*German; held by the German Centre for the Protection of Laboratory Animals*) (2019)



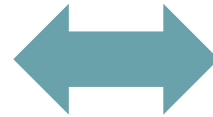


What is the effect of preregistration on quality?

Paper with a
preregistered protocol

Similar paper from the
same journal without
preregistration

Similar paper from the
same authors
without preregistration



or



Collaboration:

- Same journal/authors
- Same publication date (+/- 2 years)
- Experimental studies
- Same or similar species
- Similar fields
- Similar techniques





What is the effect of preregistration on quality?

- ARRIVE guidelines essential 10
- Transparency statements
- Scored as:
 - Complete = 2 points
 - Unclear/Incomplete = 1 point
 - No information = 0 point

Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10
2	2	1	0	1	1	1	2	0	0



$$\frac{\text{Score}}{\text{Max score}} = \text{score } 0-1$$

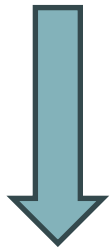


0.8-1	Excellent
0.6-0.79	Good
0.4-0.59	Average
0.2-0.39	Mediocre
0-0.19	Poor

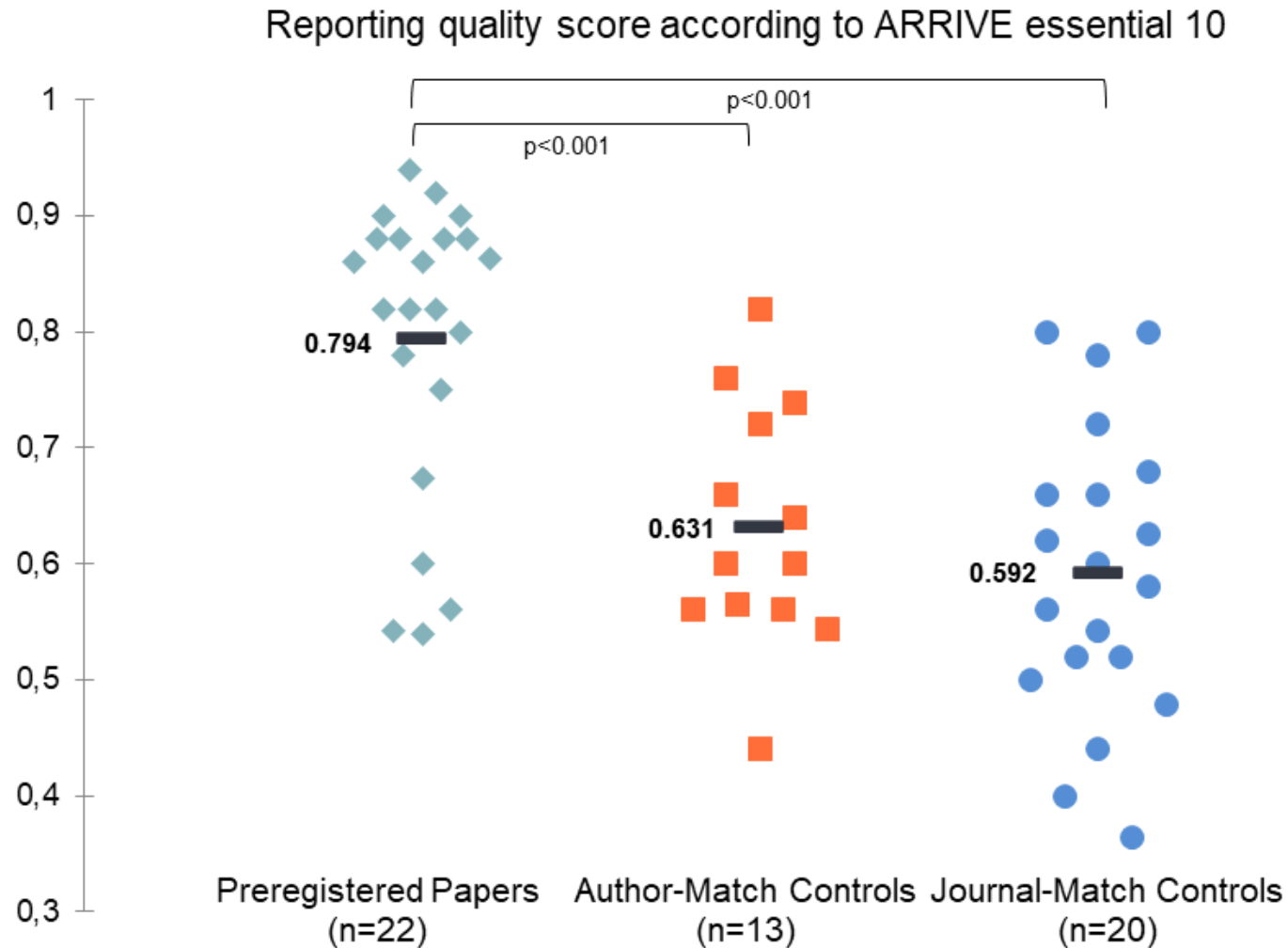


What is the effect of preregistration on quality?

Arrive essential 10



- 0.8-1 Excellent
- 0.6-0.79 Good
- 0.4-0.59 Average
- 0.2-0.39 Mediocre
- 0-0.19 Poor





Where to preregister?

Preclinicaltrials.eu as an example



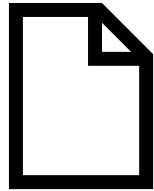
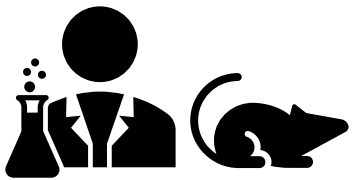
Preclinicaltrials.eu

- Started since 2018
- Funded by the Dutch Ministry of Agriculture & SGF + hosted at Utrecht University
- Free & anonymous registration
- Accept all type of research & all animal \neq only preclinical

The screenshot shows the website's header with navigation links: Database, About PCT, Help, News, Contact, and a Login button. The main title is 'PreclinicalTrials.eu' with the subtitle 'International register of preclinical trial protocols'. A prominent orange circle on the right states '151 protocols registered already! (26 under embargo)'. Below this, a text block explains the site's purpose: 'Preclinicaltrials aims to provide a comprehensive listing of preclinical animal study protocols. Preferably registered at inception in order to increase transparency, help avoid duplication, and reduce the risk of reporting bias by enabling comparison of the completed study with what was planned in the protocol. Registration of your study requires you to create an account that is:'. This is followed by a bulleted list: 'Anonymous', 'Free of charge', and 'Has an optional embargo period'. To the right of the text is a video player thumbnail titled 'The importance of preregist...' showing a scientist with a red apple and a clipboard. At the bottom, a paragraph states: 'This register is web-based, open to all types of animal studies and freely accessible and searchable to all with a preclinicaltrials.eu account. The registration form is designed by experts in preclinical animal studies and preclinical evidence synthesis. Please join us and create a user account, this will provide access to the database and enables you to register your preclinical trial. Contact us at info@preclinicaltrials.eu'.



Preclinicaltrials.eu



PCT form

- Form focuses on experimental design
- Compliant with ARRIVE essential 10
- Write according to the details demanded

1. General **2. Study design** 3. Contact details 4. Submit

Register your study by completing the following form. Notice that the fields with an asterisk are mandatory, whereas other fields are optional. Once the form is submitted it will be checked before publication on this website. Changes made after publication on this site will be recorded with an audit trail.

SAVE CHANGES **IMPORT PRIS (.JSON)** **CLEAR FIELDS**

Research field*
To what research field does this study relate? (e.g. cardiology, oncology, neuroscience)

Hypothesis / Research question*
Give the research question/hypothesis or problem the study investigates and state clearly why it is important to carry out this study

In case of intervention, Intervention type*
What type of intervention is being tested in the study?

Select option ▾

Primary readout parameter*
What is the primary readout parameter of the study? Please clarify what will be measured, how this will be measured and at what timepoint (e.g. efficacy based on Left Ventricular Ejection Fraction after 4 weeks).

Submit for publication

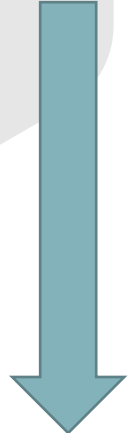


Review



Registered on Preclinicaltrials.eu w/ or w/out embargo

Request minor changes:
• Information missing
• Information misplaced



Sent back to authors via e-mail



2nd review



To note:
✎ No ethical review/peer-review
 ✎ For a full review, registered report would be better
✎ Amendments allowed
✎ Embargo 1 year and +
✎ Only access by admin

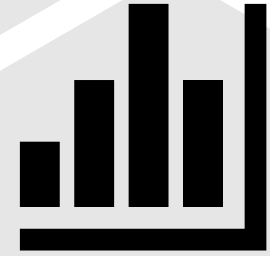
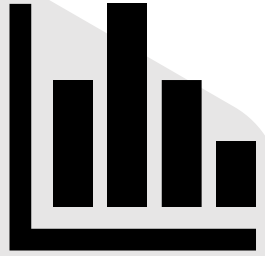


What do you need to preregister

1. An internet connection
2. A study protocol (preferably finished)
→ Follow the detail demanded to be accepted faster
3. An account to [Preclinicaltrials.eu](https://preclinicaltrials.eu)
4. A little bit of time



Poll n°3



Poll n°3

What is your first impression
about preregistration?





Concerns about preregistration

I don't have time for this

What if my methodology changes?

What about the cost?

I don't know where to start


What about eligibility?

I'm scared my data or private information get stolen






Cost & eligibility

A line-art illustration of a male scientist with short dark hair, wearing a white lab coat over a teal shirt and teal trousers. He has his arms crossed and is looking towards the right.

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


A line-art illustration of a person with long dark hair, wearing a teal sweater and white trousers. They are standing with their hands clasped in front of them, looking towards the left.

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


Allow registration at all stages



Lack of time



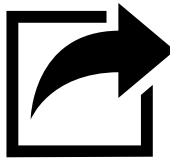
I don't have time for this!
This is too much effort



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



Short form – similar to
ethical procedure



Fast export
Guiding documents



Security and intellectual property

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

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



1 year embargo, renewable



Anonymous




Account required




Blinding allowed



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



Key points to remember

- Preregistration is the act of pre-specifying a research protocol before the start of the study
- Preregistration can:
 - Improve transparency, quality and data sharing
 - Decrease research waste
- Limited number of platforms to preregister, Preclinicaltrials.eu: fast and secure platform, respect researchers' needs





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?

Contact me at: Julia.menon@heart-institute.nl