

To Explant or Not to Explant:

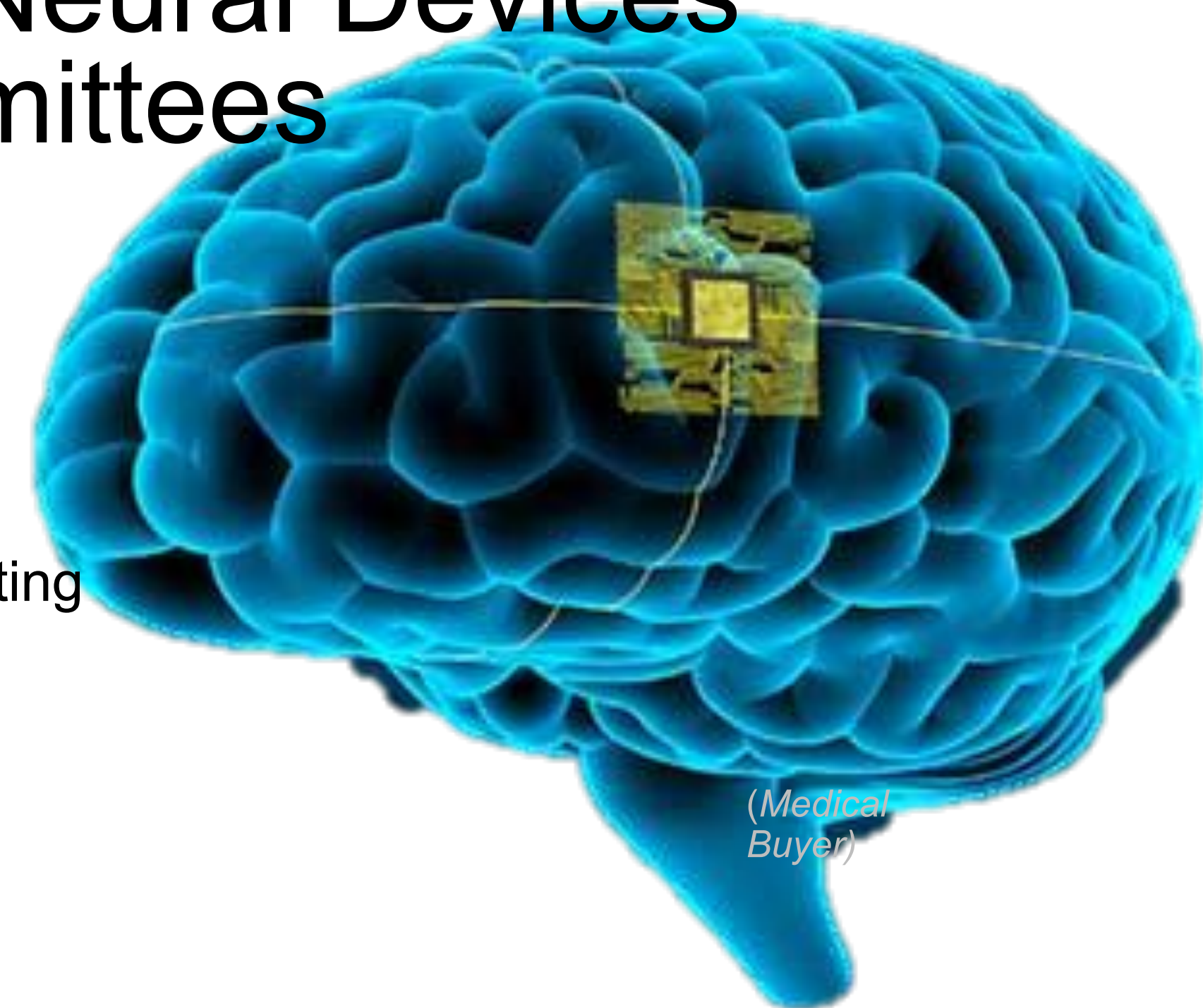
Deliberations on the Explantation of Neural Devices
within Research Ethics Committees

Katherine Bassil, PhD

2024 International Neuroethics Society Annual Meeting
15 April 2024



International
Neuroethics
Society



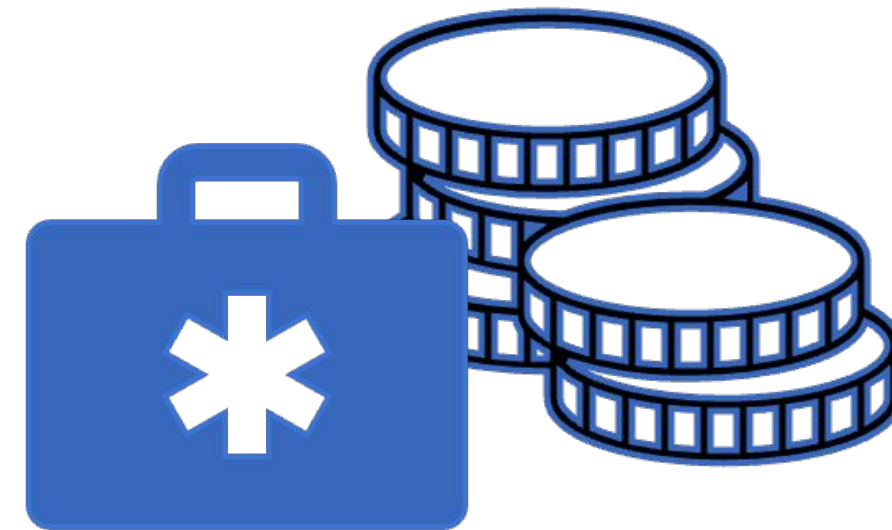
*(Medical
Buyer)*

Background

Neural Implants



Promising therapeutic intervention for neurological and psychiatric disorders



Several reasons for *explantation* (medical, financial, psychological, etc.)



Research Ethics Committees (RECs) play a *role* in explantation decisions

Problem

Neural Implants

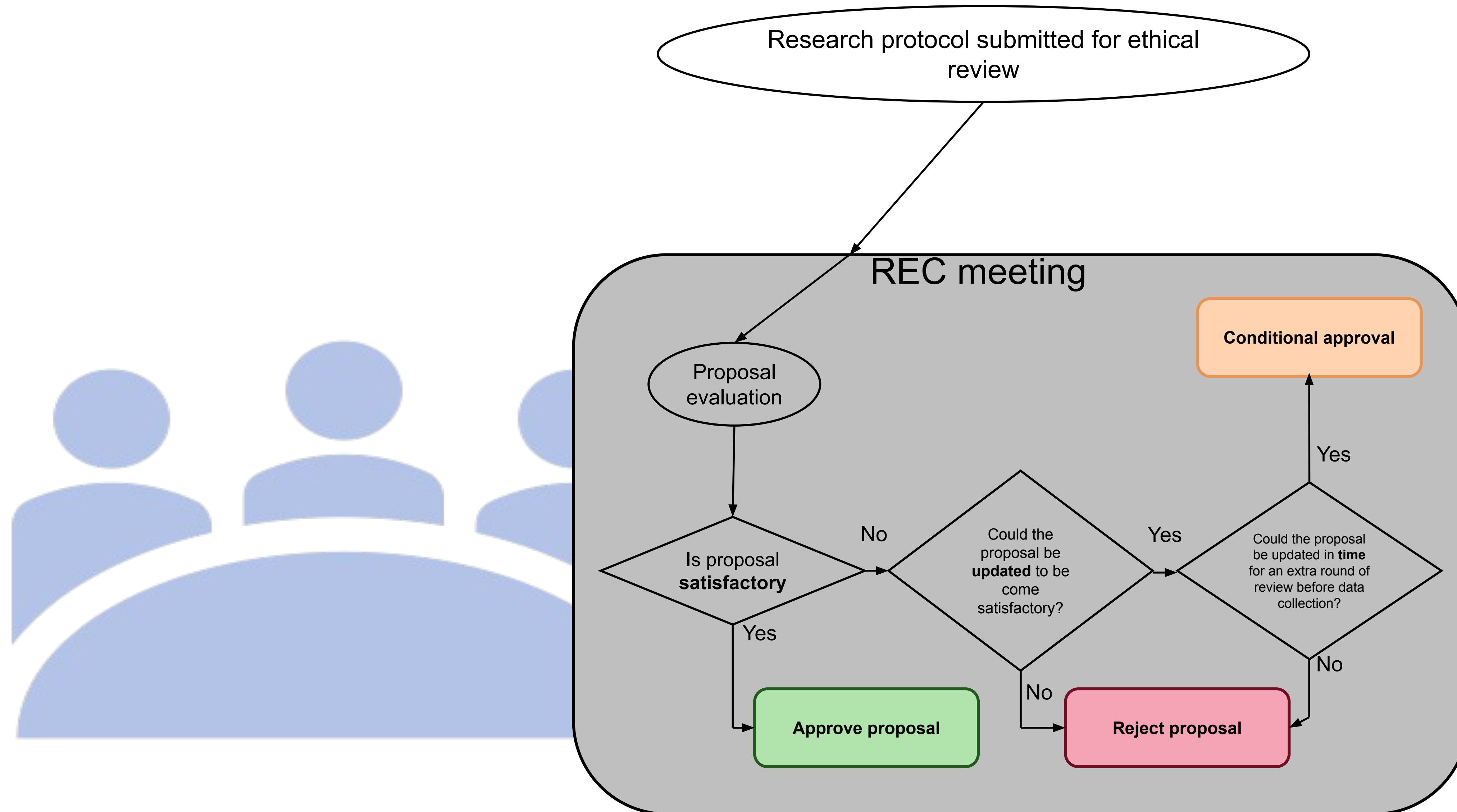


In the Netherlands, REC requirements on device removal at the end of a trial are *conflicting*

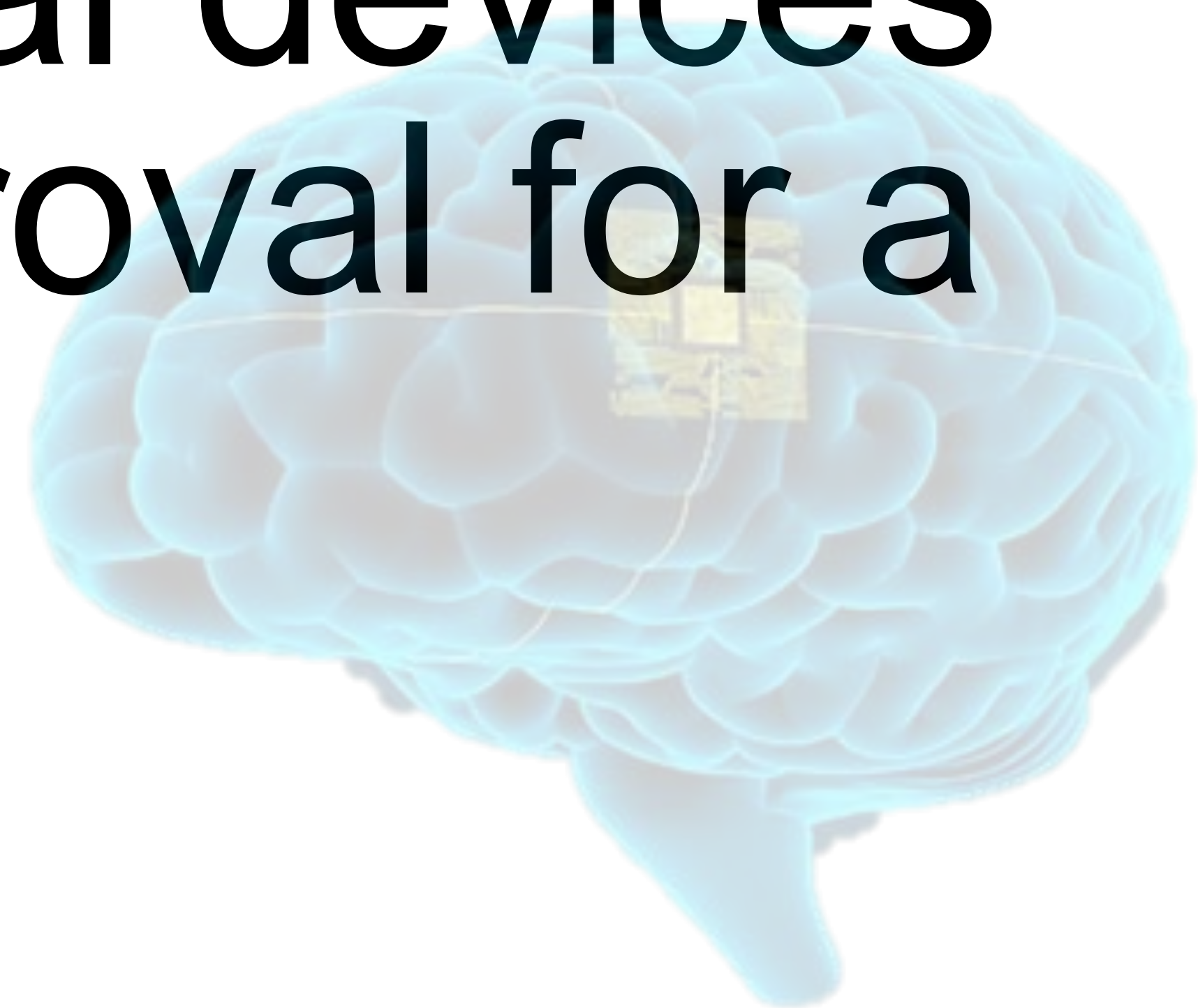


Arbitrary decision may lead to more *negative* experiences for study participants

REC Review Process in the Netherlands



Do Dutch RECs assess the **explantation** of neural devices before granting approval for a study?



Methods

The screenshot shows the CCMO Register search page. At the top left is the CCMO logo and the text 'Centrale Commissie Mensgebonden Onderzoek'. Below this is a navigation bar with links: 'Sluiten', 'Printen', 'Documentatie (NL)', 'Documentation (EN)', 'FAQ (NL)', 'FAQ (EN)', and 'CCMO'. The main content area is titled 'CCMO Register' and contains several search filters: 'Taal / Language' with radio buttons for 'Nederlands / Dutch' (selected) and 'Engels / English'; 'Methode' with radio buttons for 'Trefwoord' (selected), 'Dossiernummer ToetsingOnline', 'EudraCT nummer', and 'Uitgebreid'; a 'Trefwoord' text input field; and a 'Query' text input field.

1. Search by technology type

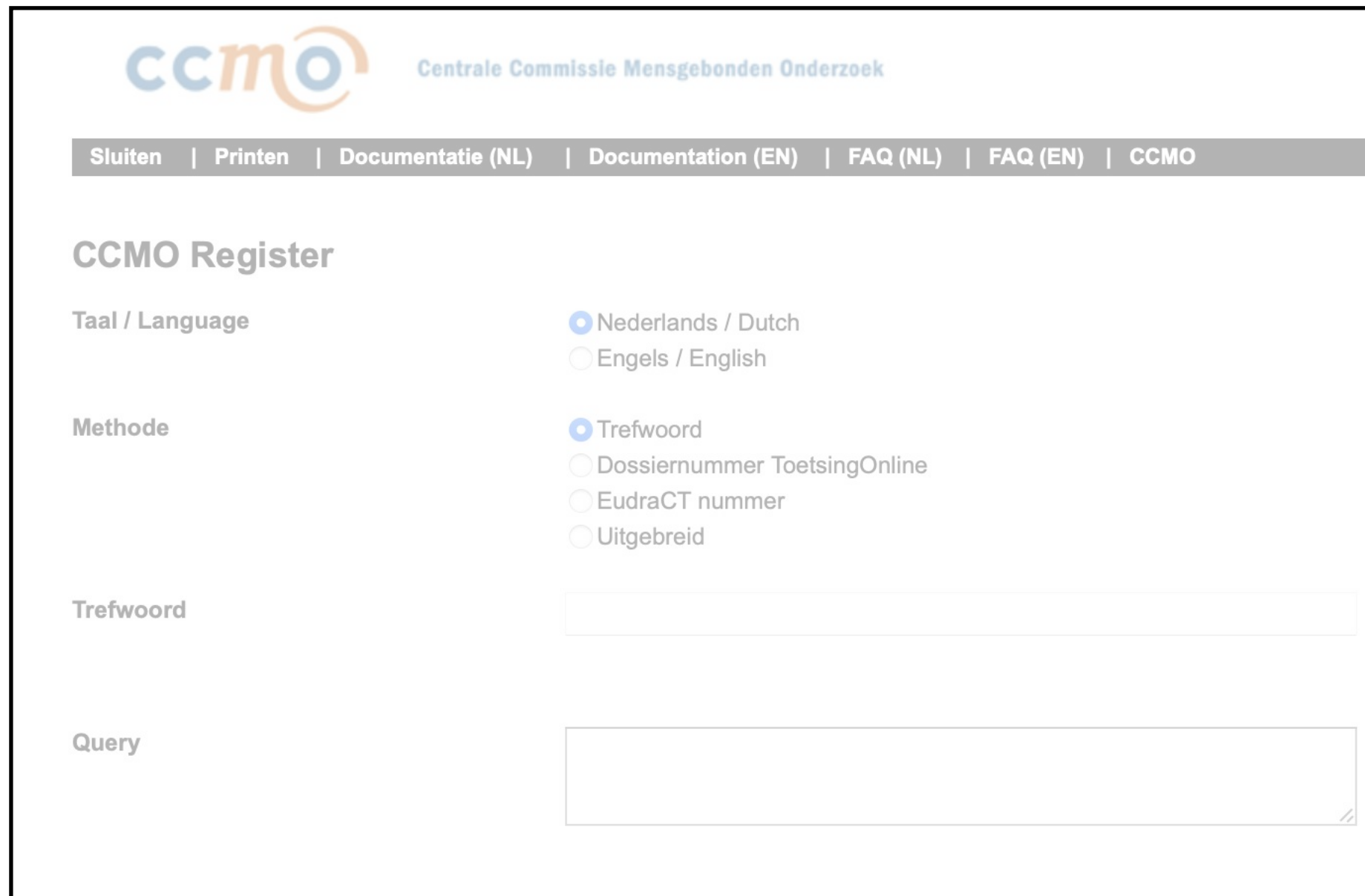


2. Selected protocols

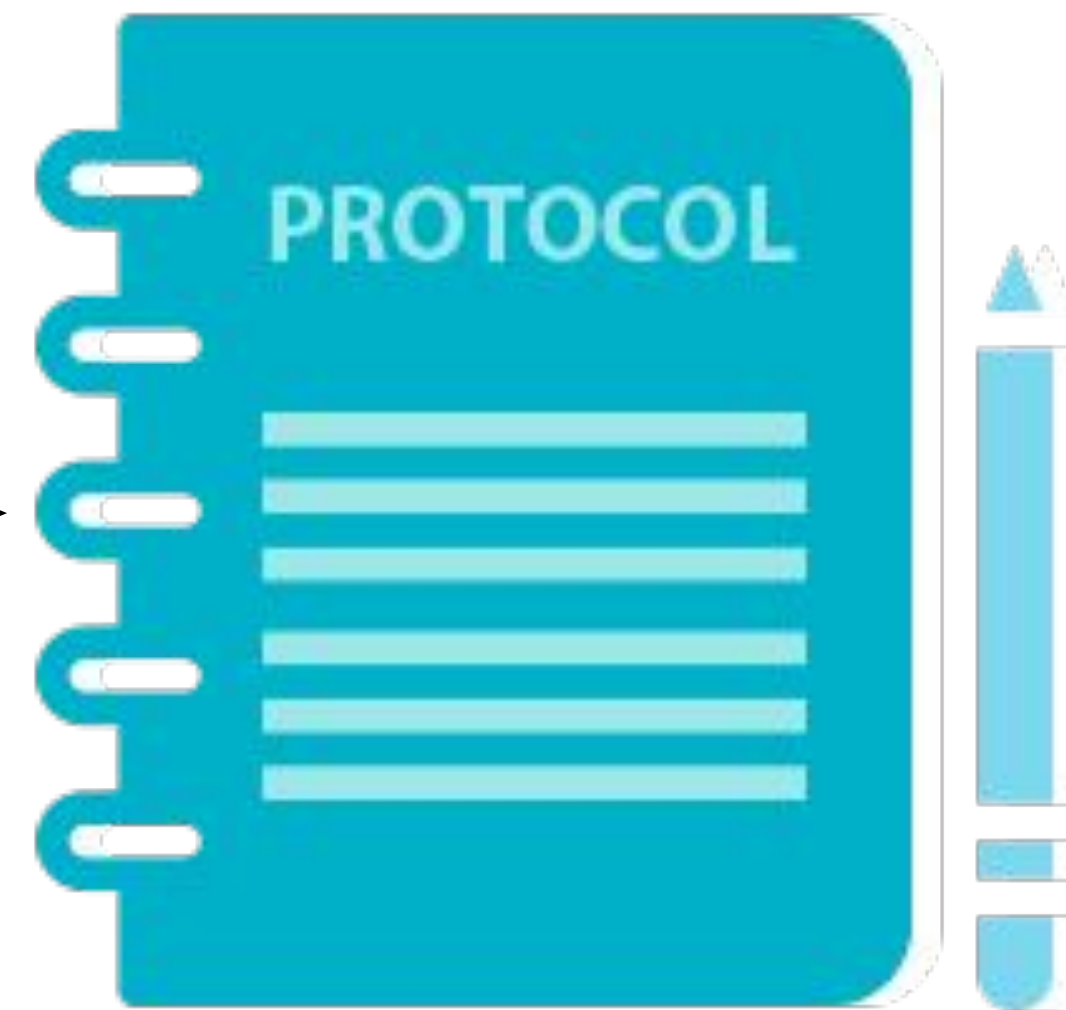
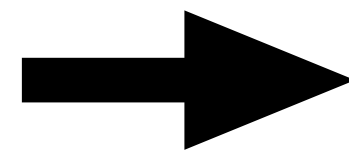


3. Identified RECs

Methods

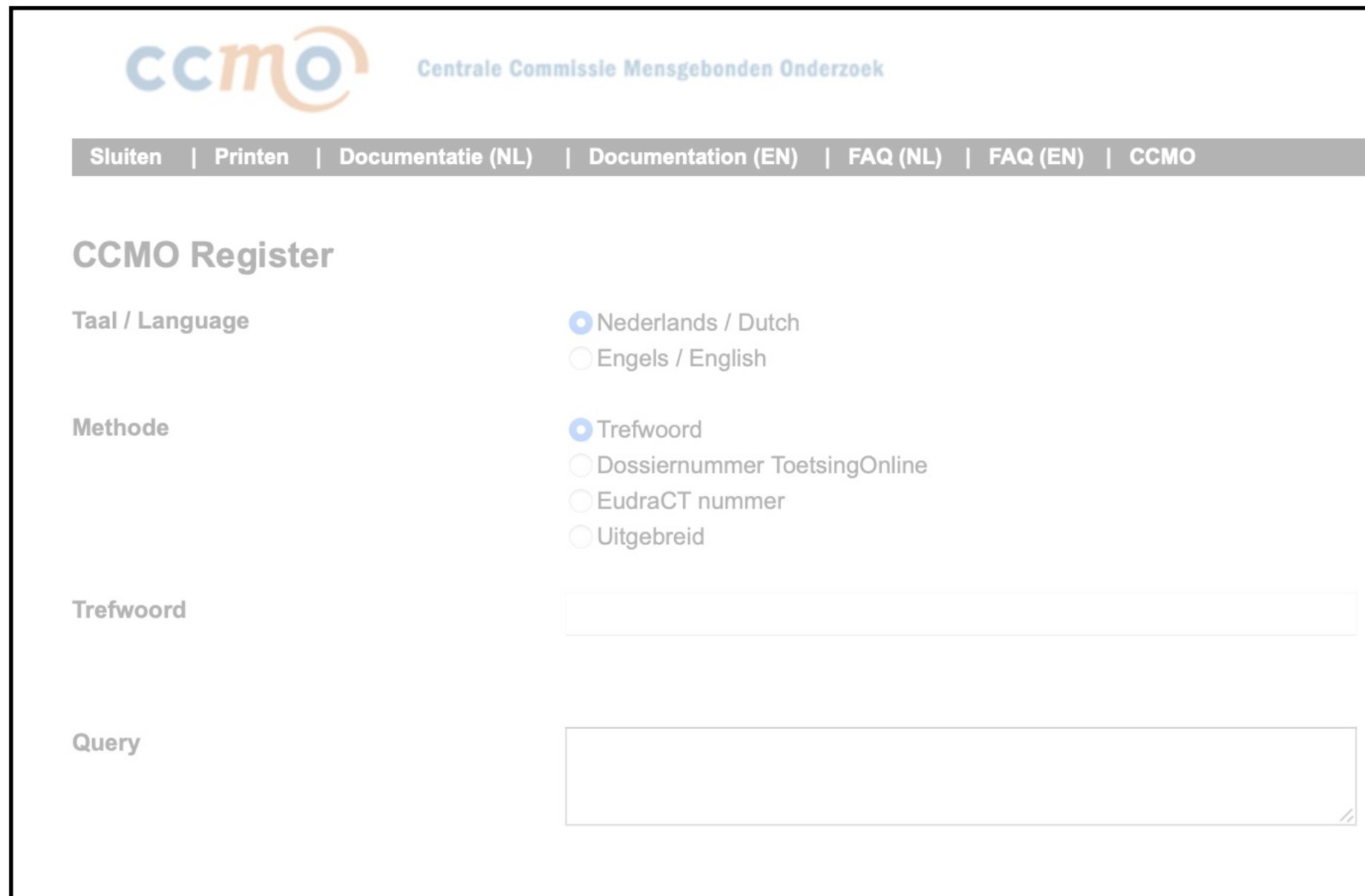


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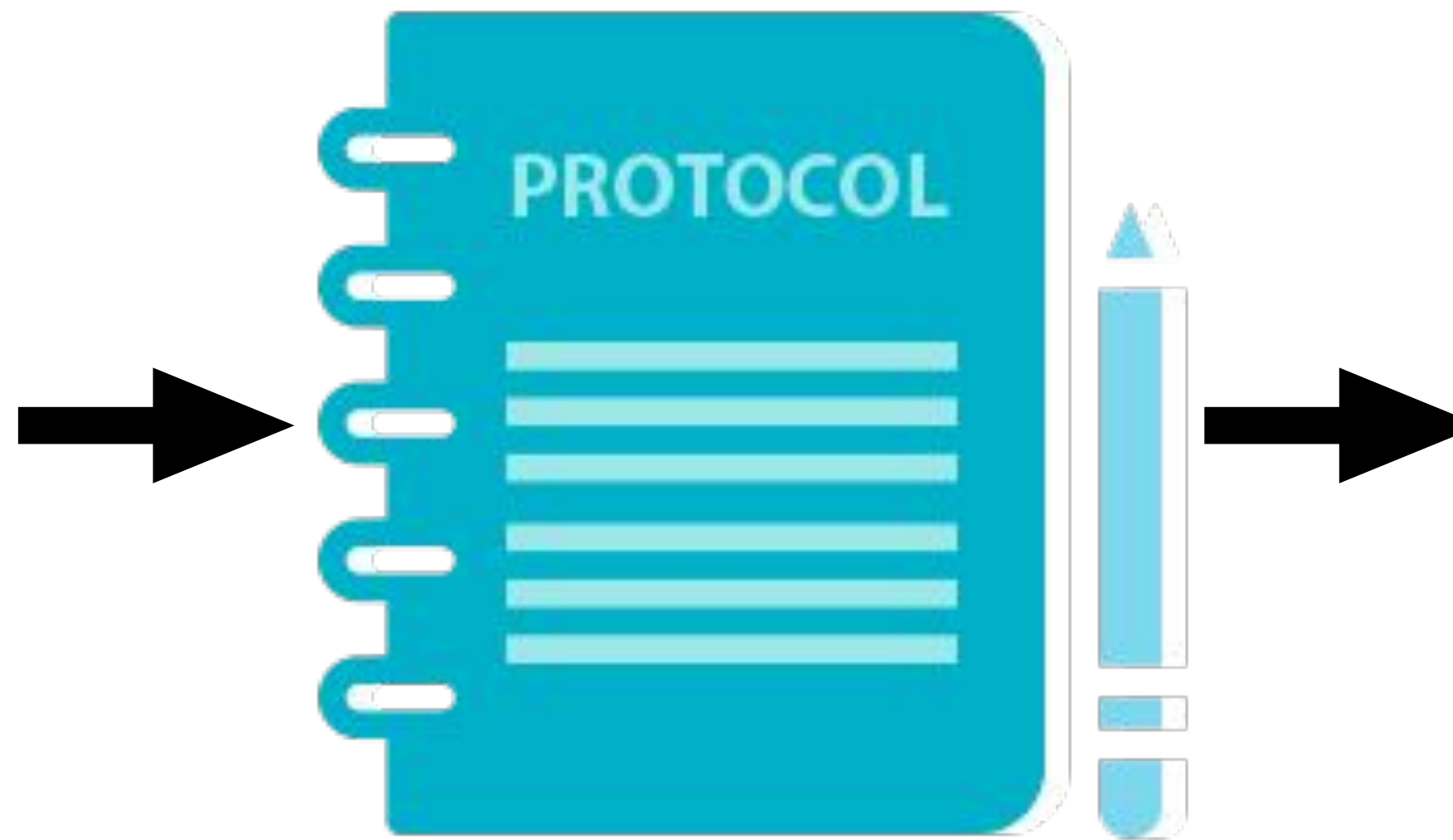


n=78 research protocols

Methods



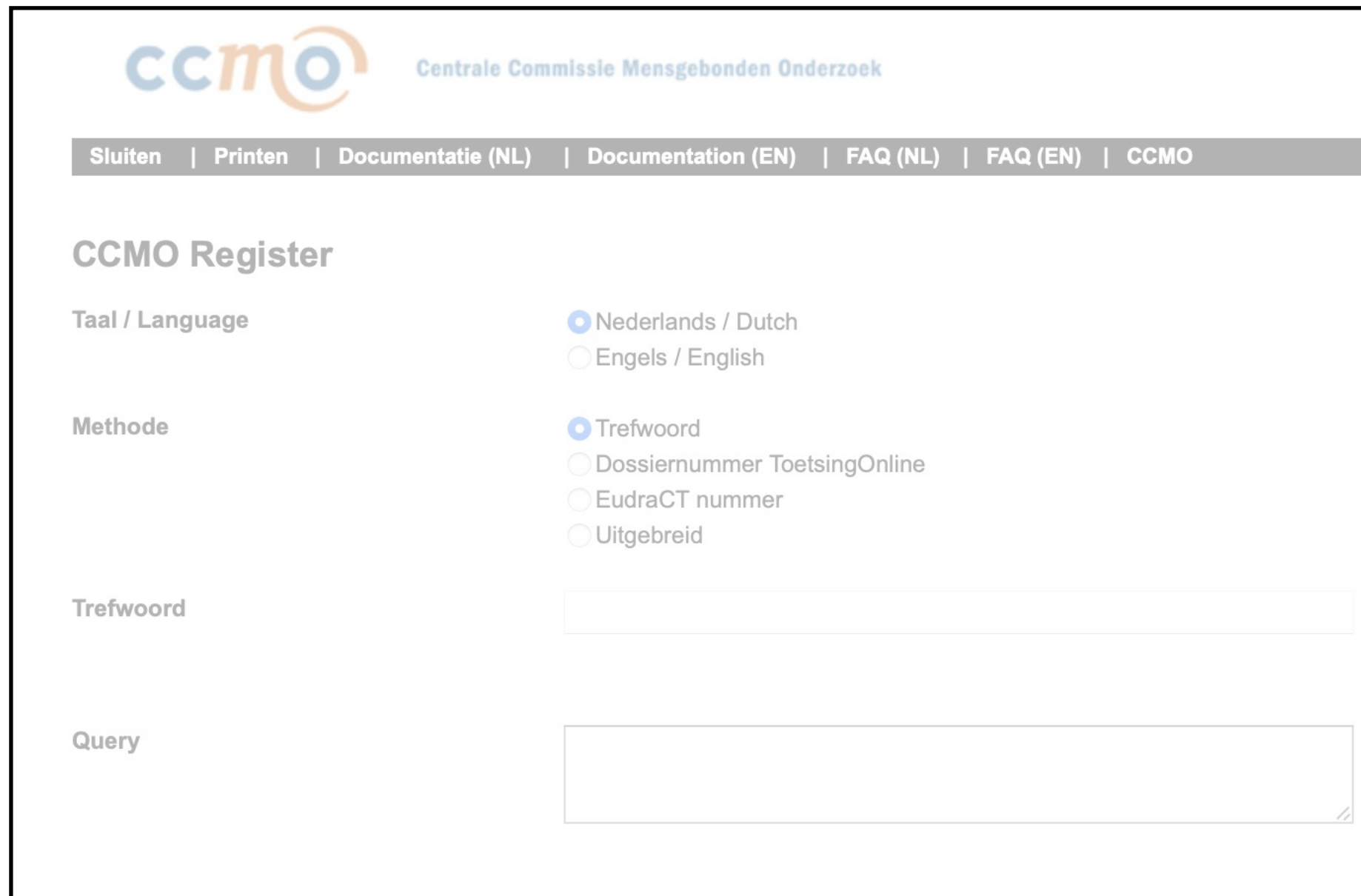
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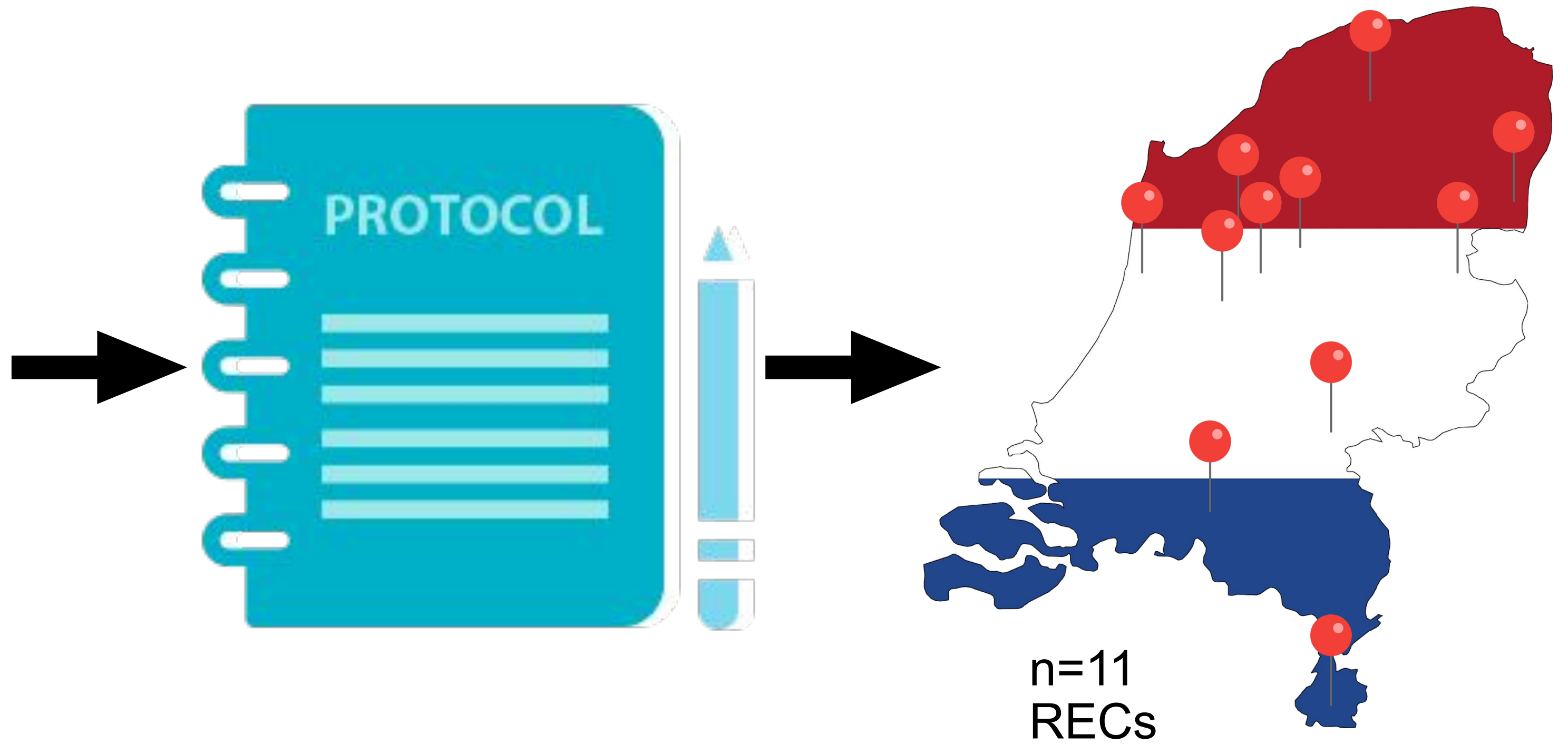
n=78 research protocols

- n=29 Neurostimulator
- n=29 Deep Brain Stimulation (DBS)
- n=26 Spinal Cord Stimulation (SCS)
- n=3 Vagal Nerve Stimulation (VNS)
- n=2 Brain-Computer Interface (BCI)

Methods



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Methods

ccmo Centrale Commissie Mensgebonden Onderzoek

Sluiten | Printen | Documentatie (NL) | Documentation (EN) | FAQ (NL) | FAQ (EN) | CCMO

CCMO Register

Taal / Language

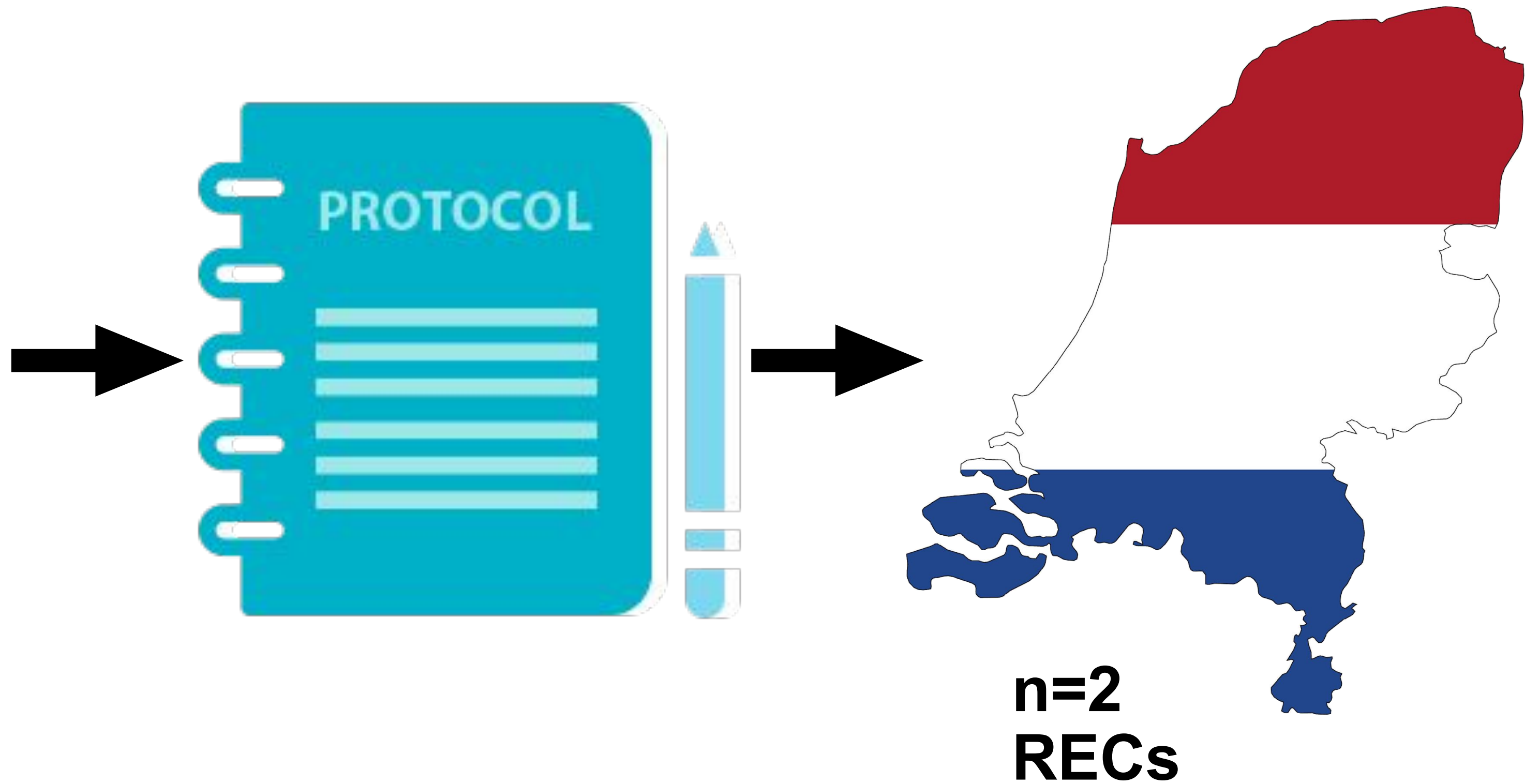
Nederlands / Dutch
 Engels / English

Methode

Trefwoord
 Dossiernummer ToetsingOnline
 EudraCT nummer
 Uitgebreid

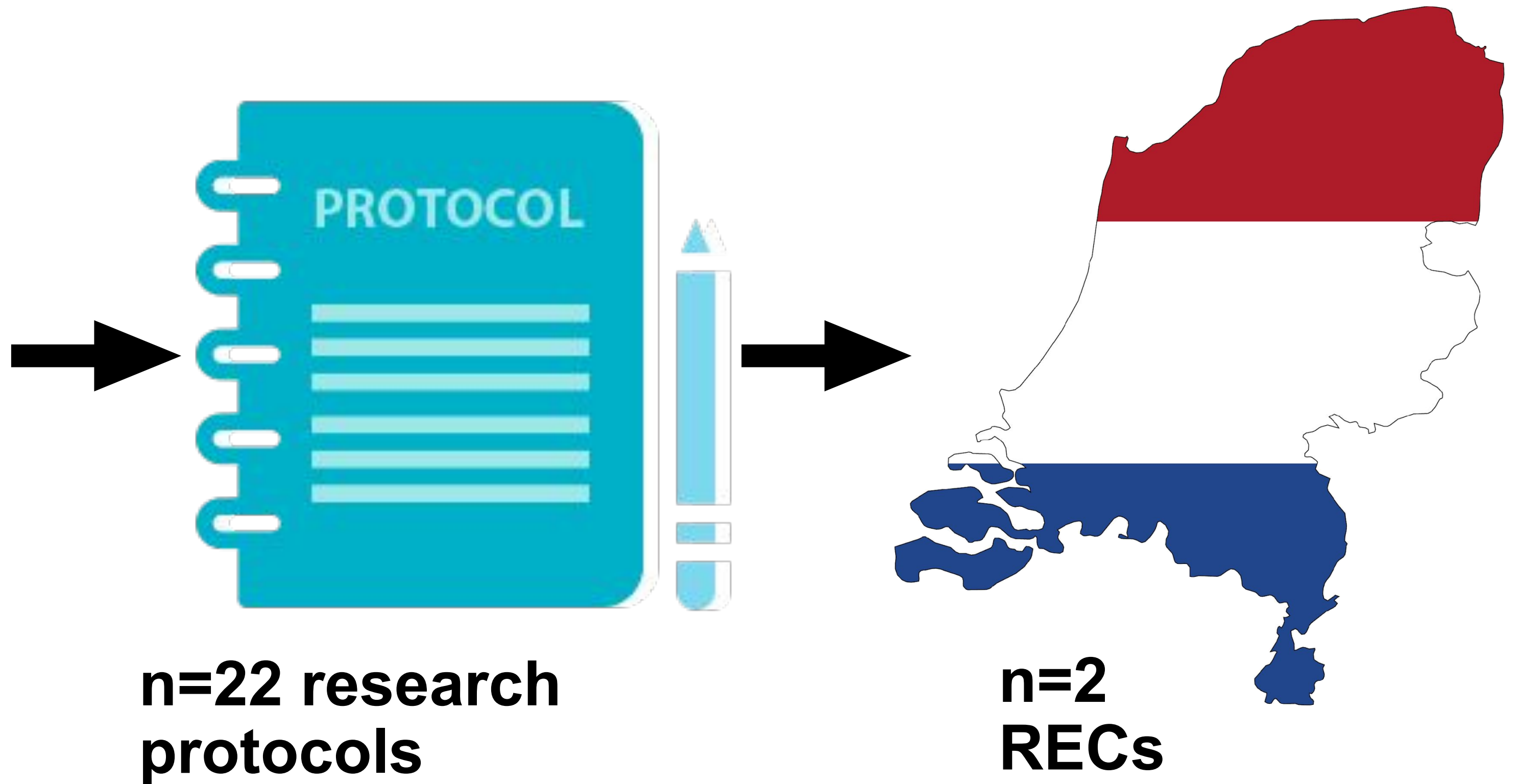
Trefwoord

Query

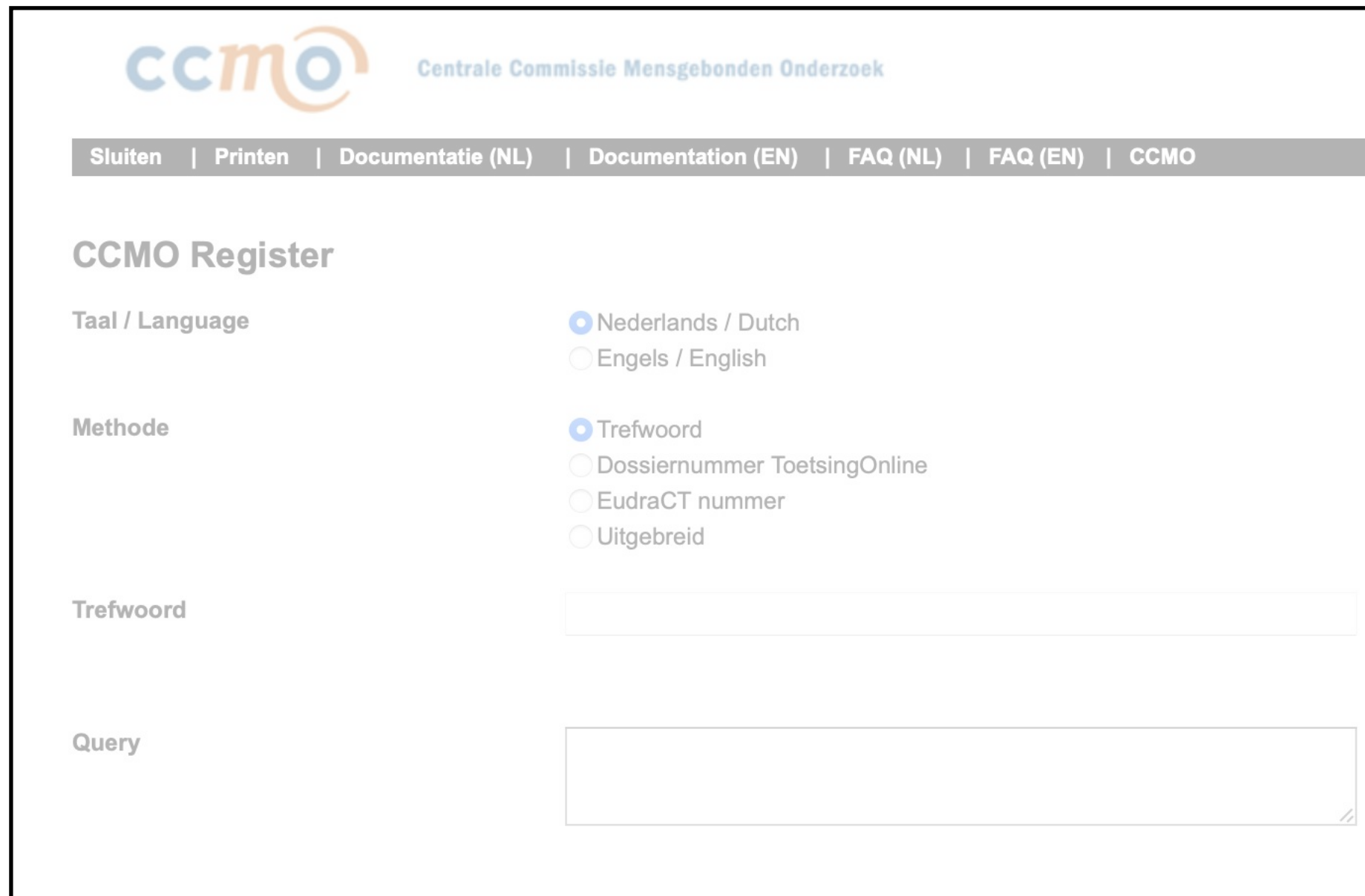


Methods

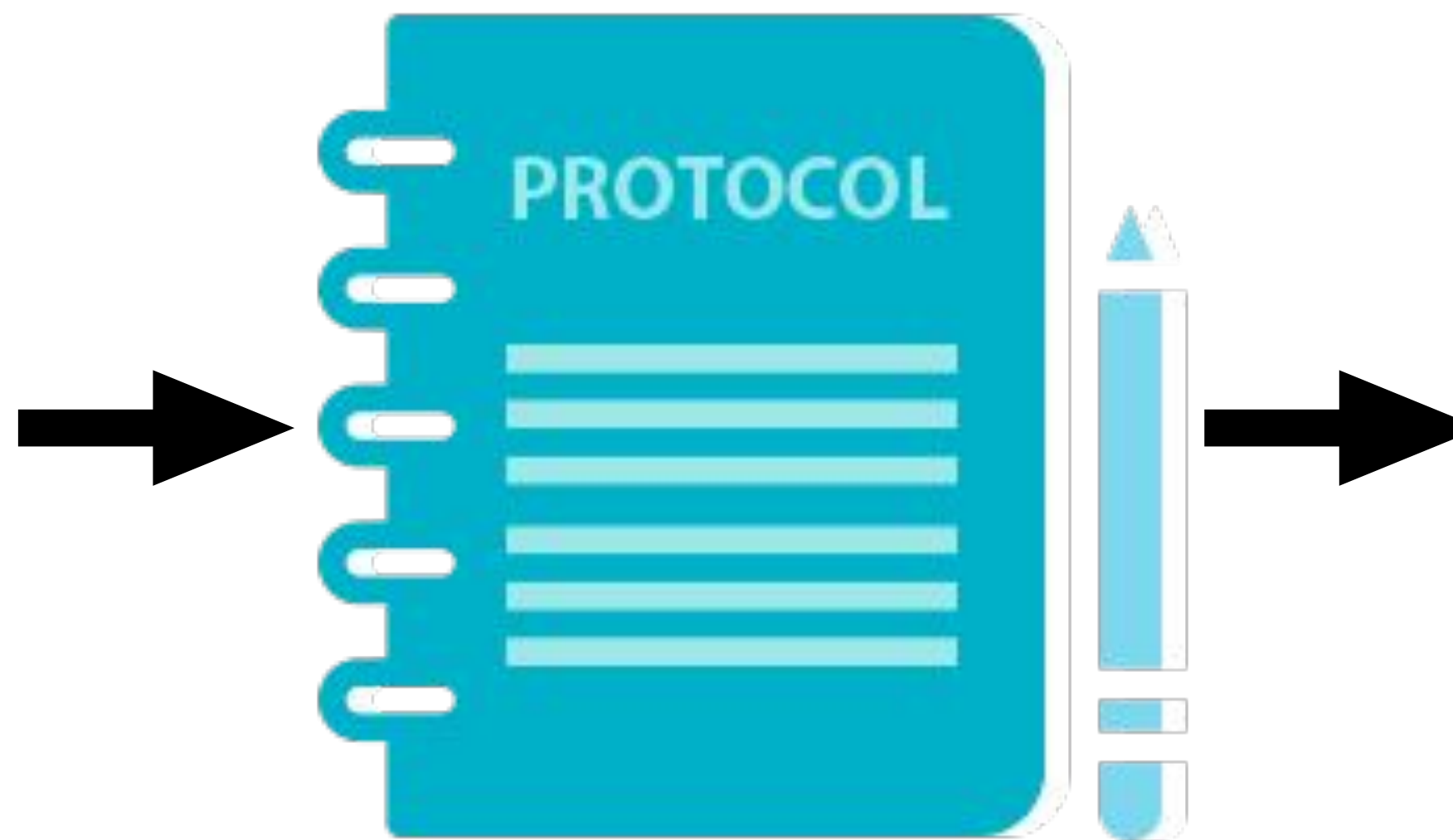
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Methods



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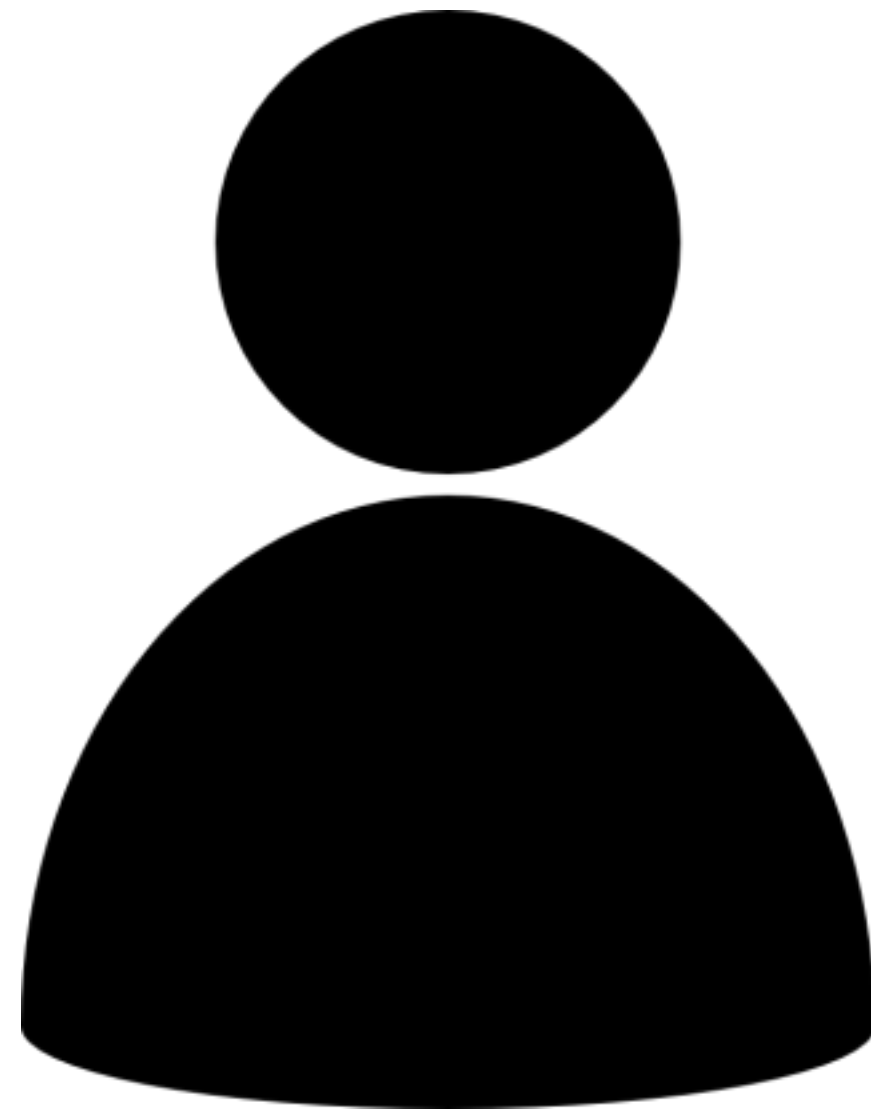


n=22 research protocols

- n=18 Deep Brain Stimulation (DBS)
- n=2 Spinal Cord Stimulation (SCS)
- n=2 Brain-Computer Interface (BCI)

Methods

	Explanation	Post-trial access	Post-trial care and support	Psychological Harm	Roles and Responsibilities
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REC
secretaries



- Information from research protocols
 - Internal discussions
- Feedback communicated with researchers

Results

Explantation of implanted neural devices **rarely** discussed

	Explantation	Post-trial access	Post-trial care and support	Psychological Harm	Roles and Responsibilities
Discussed	6	7	9	7	14
Not Discussed	16	13	13	16	7
Not applicable	1	3	1	0	2

Results

Explantation reasons and consequences need to be clearly **communicated** with participants

	Explantation	Post-trial access	Post-trial care and support	Psychological Harm	Roles and Responsibilities
Discussed	6	7	9	7	14
Not Discussed	16	13	13	16	7
Not applicable	1	3	1	0	2

Results

Post-trial considerations of DBS devices not discussed because it is
“standard care”

	Explantation	Post-trial access	Post-trial care and support	Psychological Harm	Roles and Responsibilities
Discussed	6	7	9	7	14
Not Discussed	16	13	13	16	7
Not applicable	1	3	1	0	2

Results

Post-trial considerations of BCI devices are discussed

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Results

Post-trial considerations of BCI devices are discussed

	Explantation	Post-trial access	Post-trial care and support
Discussed	6	7	9
Not Discussed	16	13	13
Not applicable	1	3	1

- Ensure participants are aware of the safe removal of the device at the end of the trial
- Ensure post-trial access is provided according to the patient's wishes
- Provide participants with scenarios and options for them to decide what to do with the device at the end of the trial (e.g., turn off, (partial) explantation)

Results

Psychological harm is discussed in relation to **implantation** and **rarely explantation**

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Results

Psychological harm is discussed in relation to **implantation** and **rarely explantation**

	Explantation	Post-trial access	Post-trial care and support	Psychological Harm
Discussed	6	7	9	7
Not Discussed	16	13	13	16
Not applicable	1	3	1	0

No discussion on the psychological impact of explantation on:

- Well-being
- Autonomy
- Sense of self

Conclusion

Diverse evaluations of safety for different implantable neural devices, can result in modified ethical risks and require distinct technology-specific assessments.

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Diverse evaluations of safety for different implantable neural devices, can result in modified ethical risks and require distinct technology-specific assessments.

Psychological harm is mainly understood in relation to implantation of neural devices negatively impacting the experience of participants.

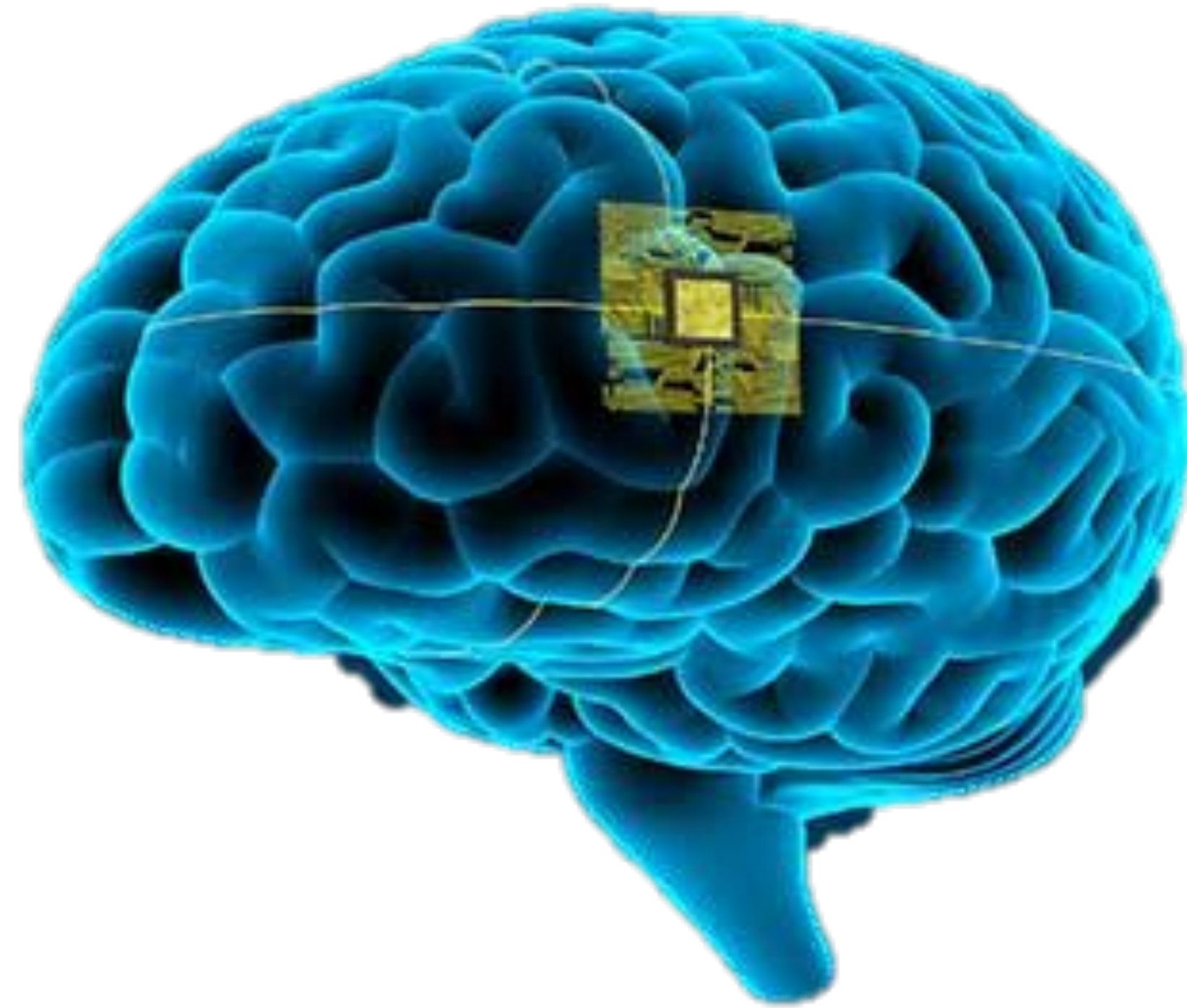
Conclusion

Diverse evaluations of safety for different implantable neural devices, can result in modified ethical risks and require distinct technology-specific assessments.

Psychological harm is mainly understood in relation to implantation of neural devices negatively impacting the experience of participants.

Discussions (or lack thereof) at the level of RECs can greatly influence the procedures of explantation for research with neural implants and ultimately the associated risks and harms for participants.

To Explant or Not to Explant?





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Society

Team

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QUESTIONS?

