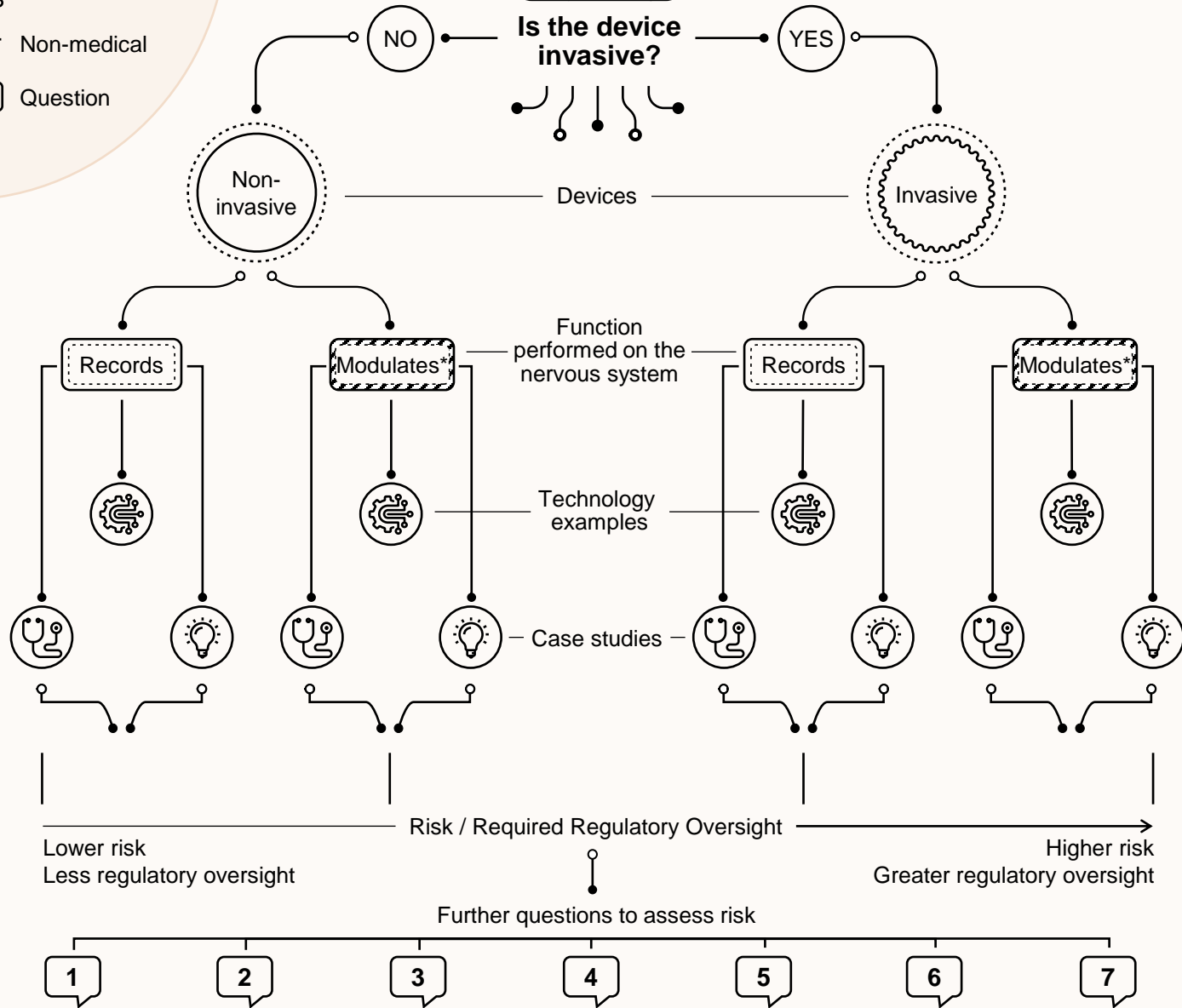
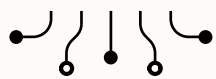


- Technology
- Medical
- Non-medical
- Question



Is the device
invasive?



*(could also record)

Neurotechnology Taxonomy

Welcome to the RHC Neurotechnology Taxonomy

The suggested taxonomy is a guide, designed to help you think about the sorts of uses to which neurotechnology is put and the risks posed by each kind of application, their potential benefits, and, therefore, the potential level of regulatory oversight required.

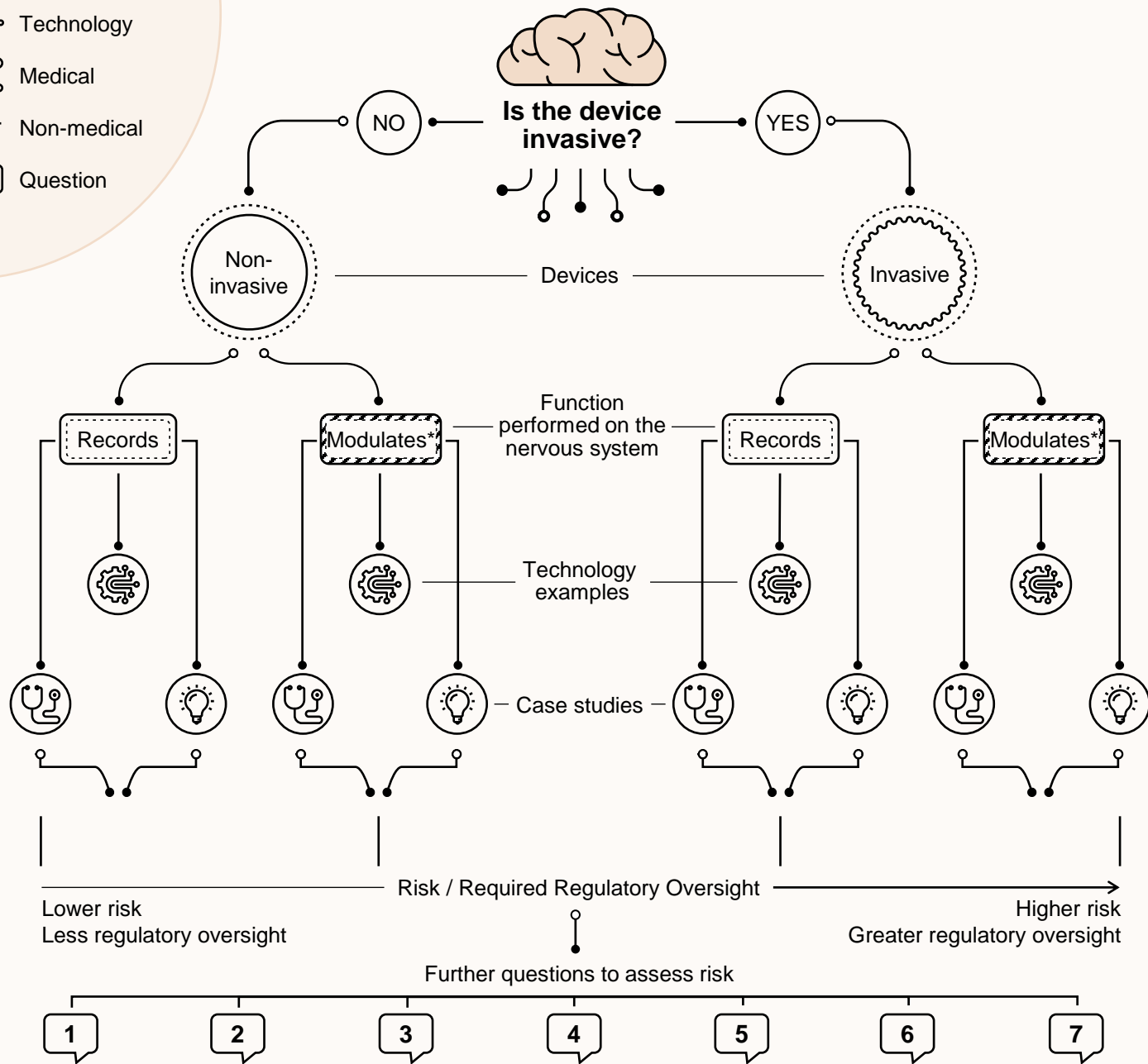
i Neurotechnologies:

Devices that can be placed inside, on, or in close proximity to the human body and used for different purposes, including medical and non-medical, to directly record and/or modulate the activity of the nervous system.

By clicking on the different icons, you will first be asked whether the device is invasive or not, and then whether it can be used to directly modulate neural activity or not. Your answer to these questions will help estimate the associated level of risk and unveil medical and non-medical case studies as well as additional information that will appear in this box.



- Technology
- Medical
- Non-medical
- Question



*(could also record)

Neurotechnology Taxonomy

Welcome to the RHC Neurotechnology Taxonomy

Even though the taxonomy suggests a general correlation between the identified categories and their associated level of risk, the correlation is not intended to be highly granular and should not be thought of as replacing individual product risk assessments. To mitigate this, 7 additional questions have been included at the bottom of the taxonomy to probe other factors that could determine the risk profile of the device.

The taxonomy also does not intend to capture every single device (now and in the future) and should be understood as a living entity that is updated as new neurotechnologies are developed. The boundaries between the different regulatory categories, and their risk profiles, can therefore be somewhat blurred in practice.

For further explanation and additional information please see the RHC report on neurotechnology regulation published alongside this taxonomy.



- Technology
- Medical
- Non-medical
- Question



Is the device
invasive?

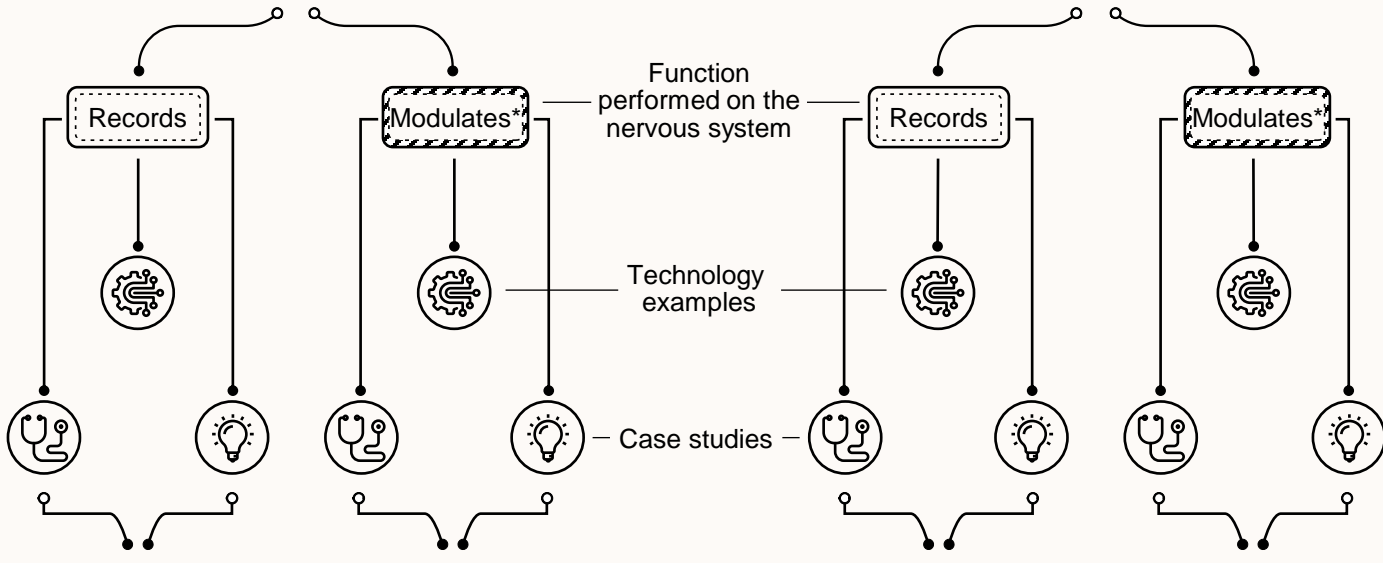
NO

YES

Non-invasive

Invasive

Devices



Risk / Required Regulatory Oversight

Lower risk
Less regulatory oversight

Higher risk
Greater regulatory oversight

Further questions to assess risk

- 1
- 2
- 3
- 4
- 5
- 6
- 7

*(could also record)

Neurotechnology Taxonomy

Non-invasive

i Non-invasive:

Includes wearables and also external devices, such as scanners.

Further information / links / call to action

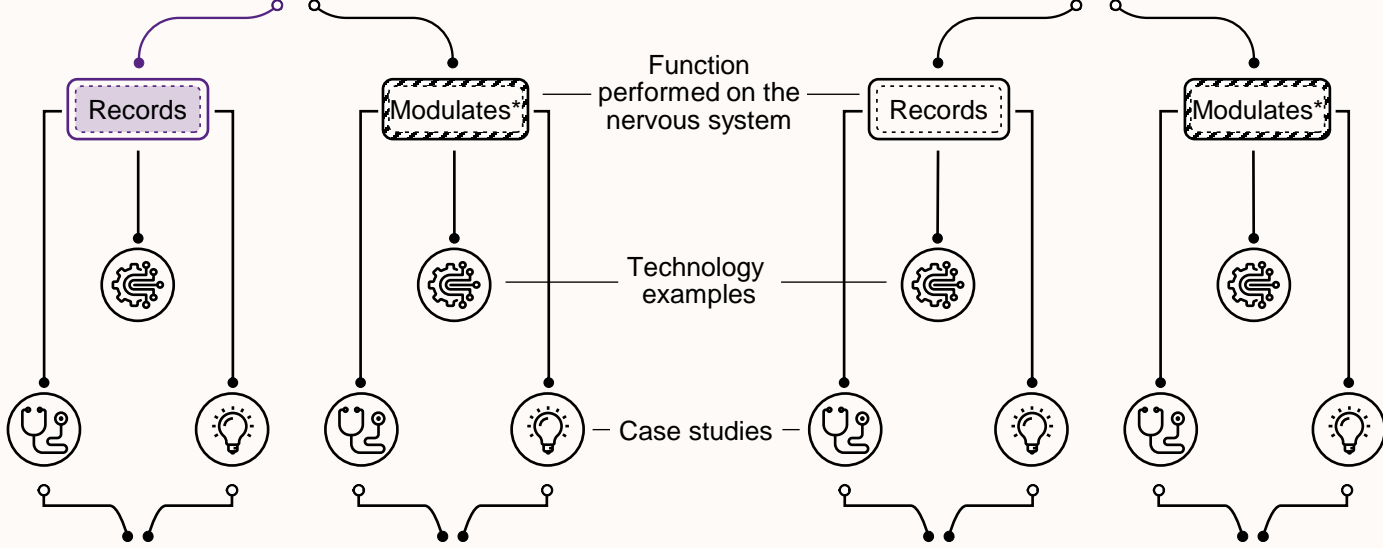
- Technology
- Medical
- Non-medical
- Question



Is the device
invasive?



Devices



Function
performed on the
nervous system

Technology
examples

Case studies



Further questions to assess risk



*(could also record)

Neurotechnology Taxonomy

Non-invasive Records

i Neurorecording:

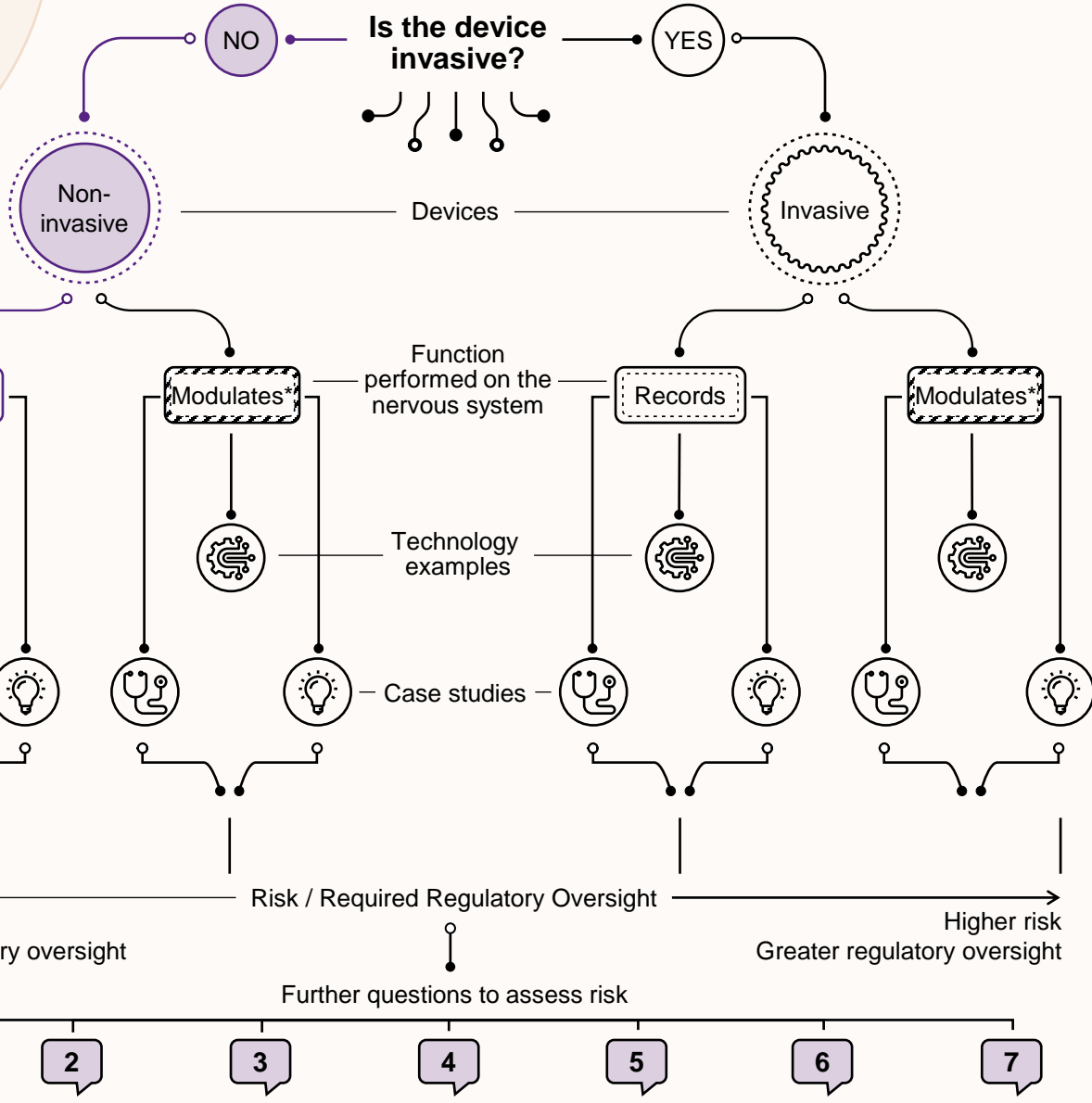
The direct collection, measurement, processing and/or analysis of neurodata to deliver insights into the nervous system and/or interact with another device.

[Click on the icons to unveil additional information on Technology examples and Case studies for this category](#)

- Technology
- Medical
- Non-medical
- Question



Is the device
invasive?



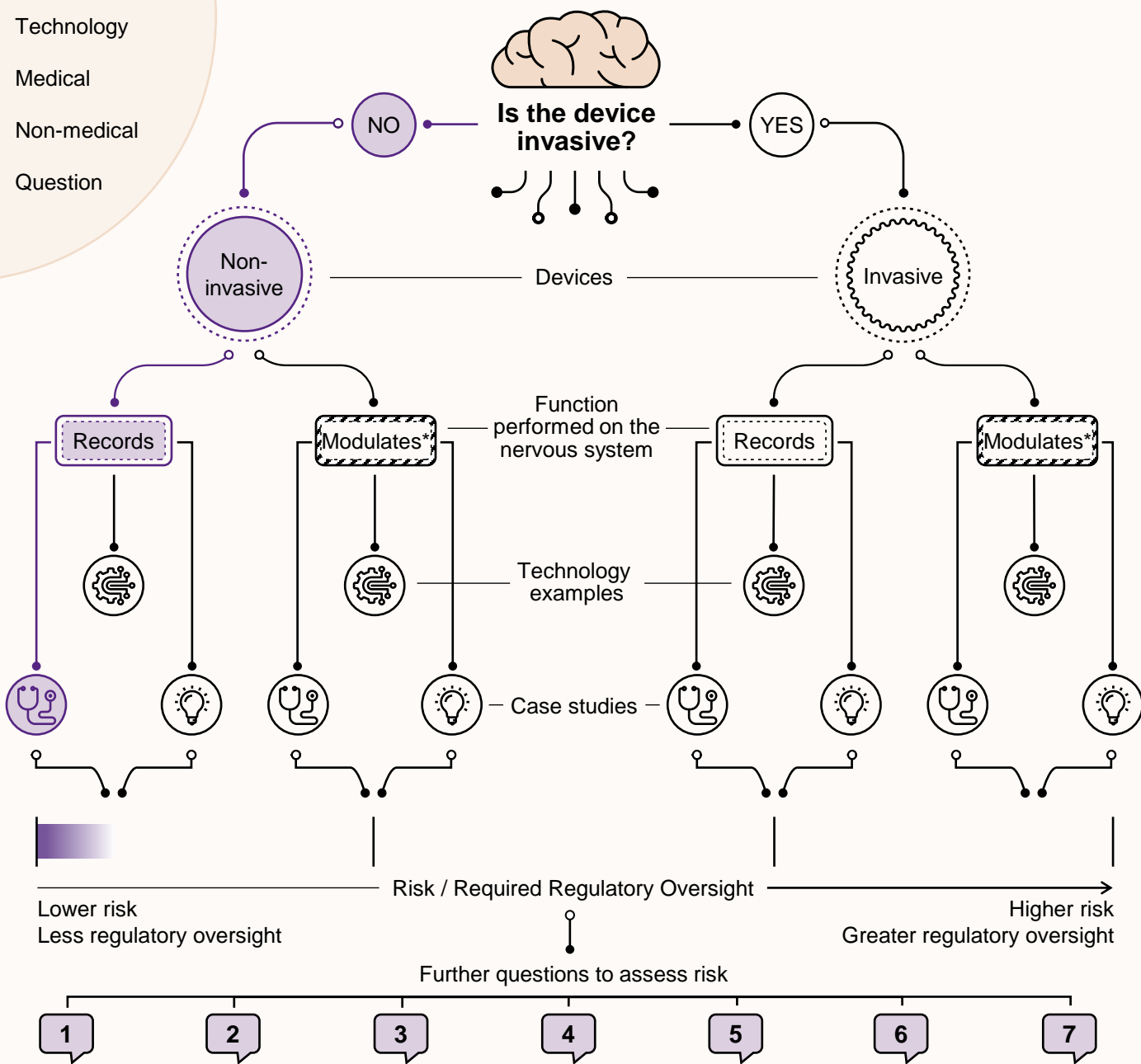
Neurotechnology Taxonomy

Non-invasive – Records Technology examples

- [EGG – electroencephalography](#)
- [MRI – Magnetic resonance imaging](#)
- [fMRI – Functional magnetic resonance imaging](#)
- [MEG – Magnetoencephalography](#)
- [fNIRS – Functional near-infrared spectroscopy](#)

*(could also record)

- Technology
- Medical
- Non-medical
- Question



*(could also record)

Neurotechnology Taxonomy

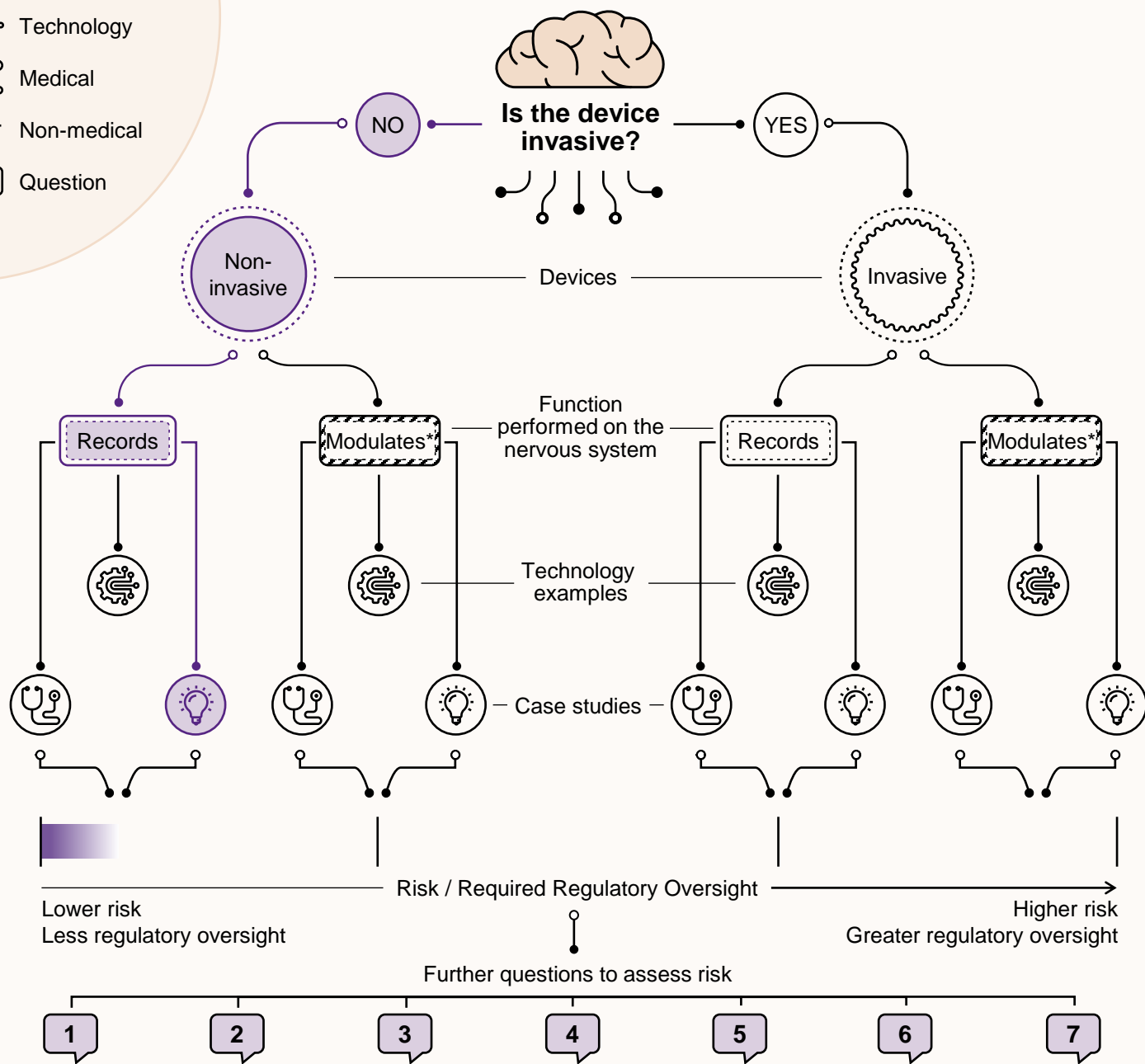
Non-invasive – Records Medical Case study

Neurorecording wearables (medical):

[Cumulus Neuroscience](https://cumulusneuro.com/) claims to be developing a home-usable EEG headset paired with tablet-based functional assessments for the identification of biomarkers to support clinical trials in neurodegenerative and neuropsychiatric disease.

<https://cumulusneuro.com/>

- Technology
- Medical
- Non-medical
- Question



*(could also record)

Neurotechnology Taxonomy

Non-invasive – Records Non-medical Case study

Neurorecording wearables (non-medical):

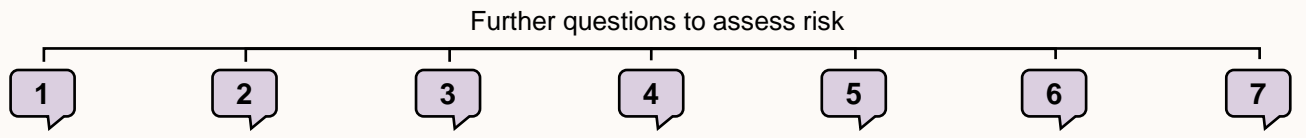
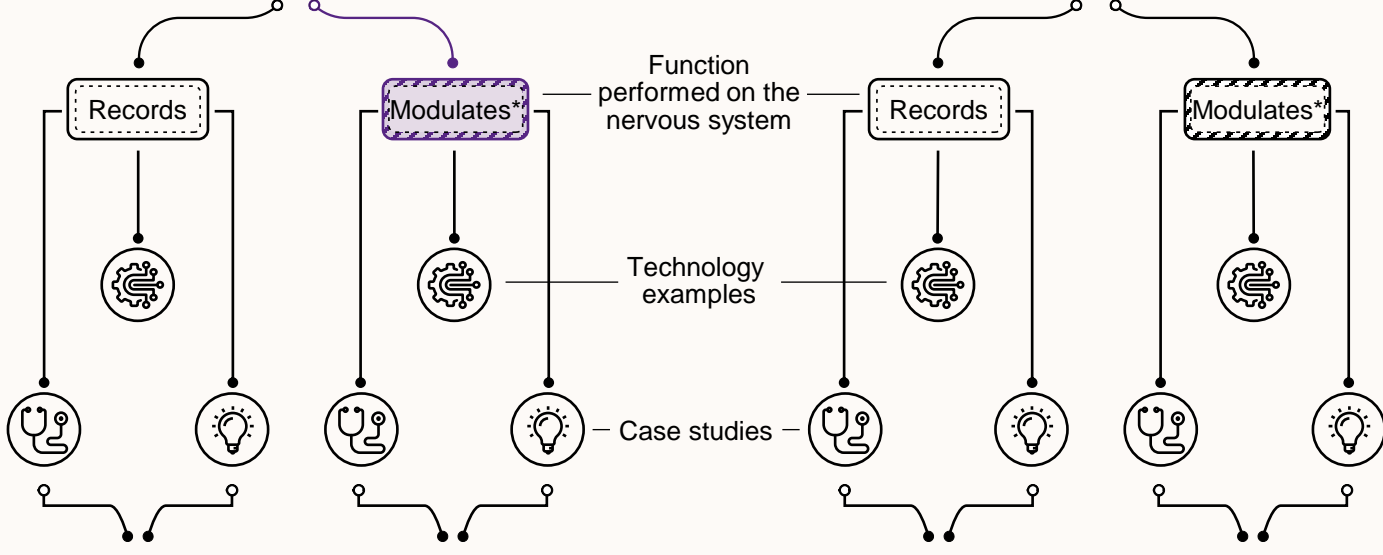
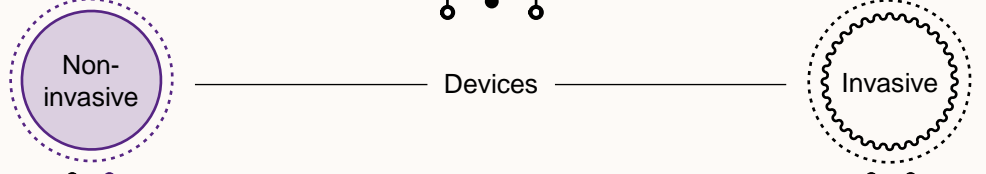
[Kernel's](#) Flow headsets aim to support functional neuroimaging (recording changes in brain blood oxygenation as a proxy for neural activity). They do this by using time-domain functional, near-infrared spectroscopy (TD-fNIRS) imaging technology intended for use in a wide range of applications such as meditation, gaming, learning and performance.

<https://www.kernel.com/>

- Technology
- Medical
- Non-medical
- Question



Is the device
invasive?



*(could also record)

Neurotechnology Taxonomy

Non-invasive Modulates

i Neuromodulation:

The alteration of neural activity through the provision of energy (electric, magnetic, etc.) directly to a target area.

[Click on the icons to unveil additional information on Technology examples and Case studies for this category](#)

- Technology
- Medical
- Non-medical
- Question



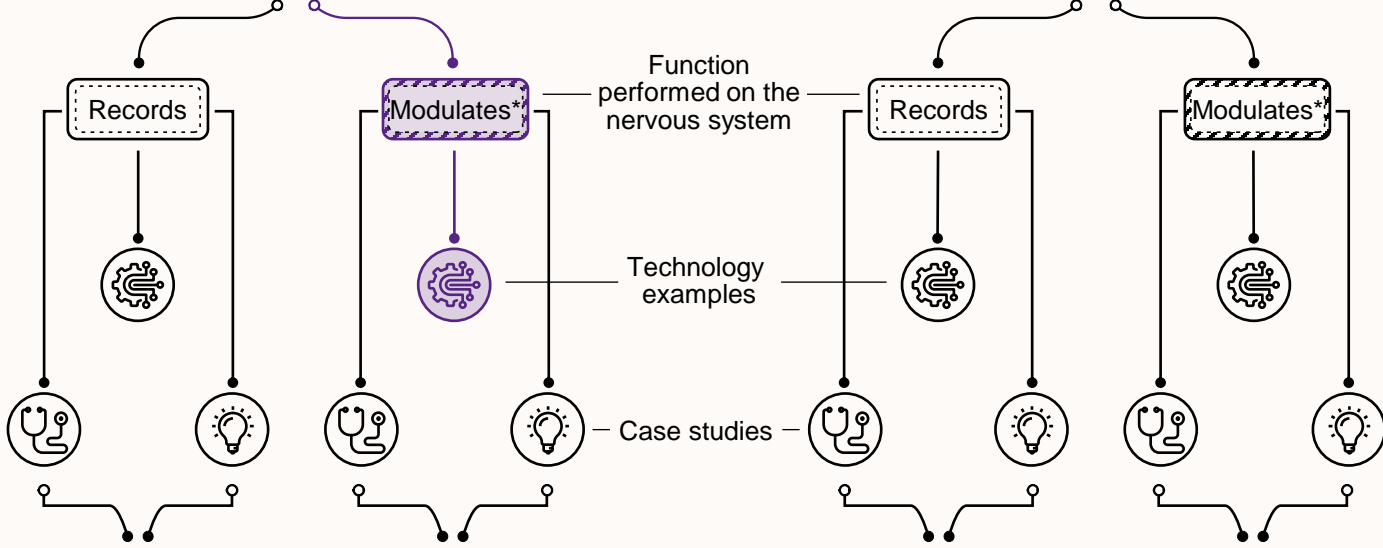
Is the device invasive?



Non-invasive

Invasive

Devices



Function performed on the nervous system

Technology examples

Case studies



Further questions to assess risk

- 1
- 2
- 3
- 4
- 5
- 6
- 7

*(could also record)

Neurotechnology Taxonomy

Non-invasive – Modulates Technology examples

[tDCS- Transcranial direct-current stimulation](#)

[tACS – Transcranial alternating-current stimulation](#)

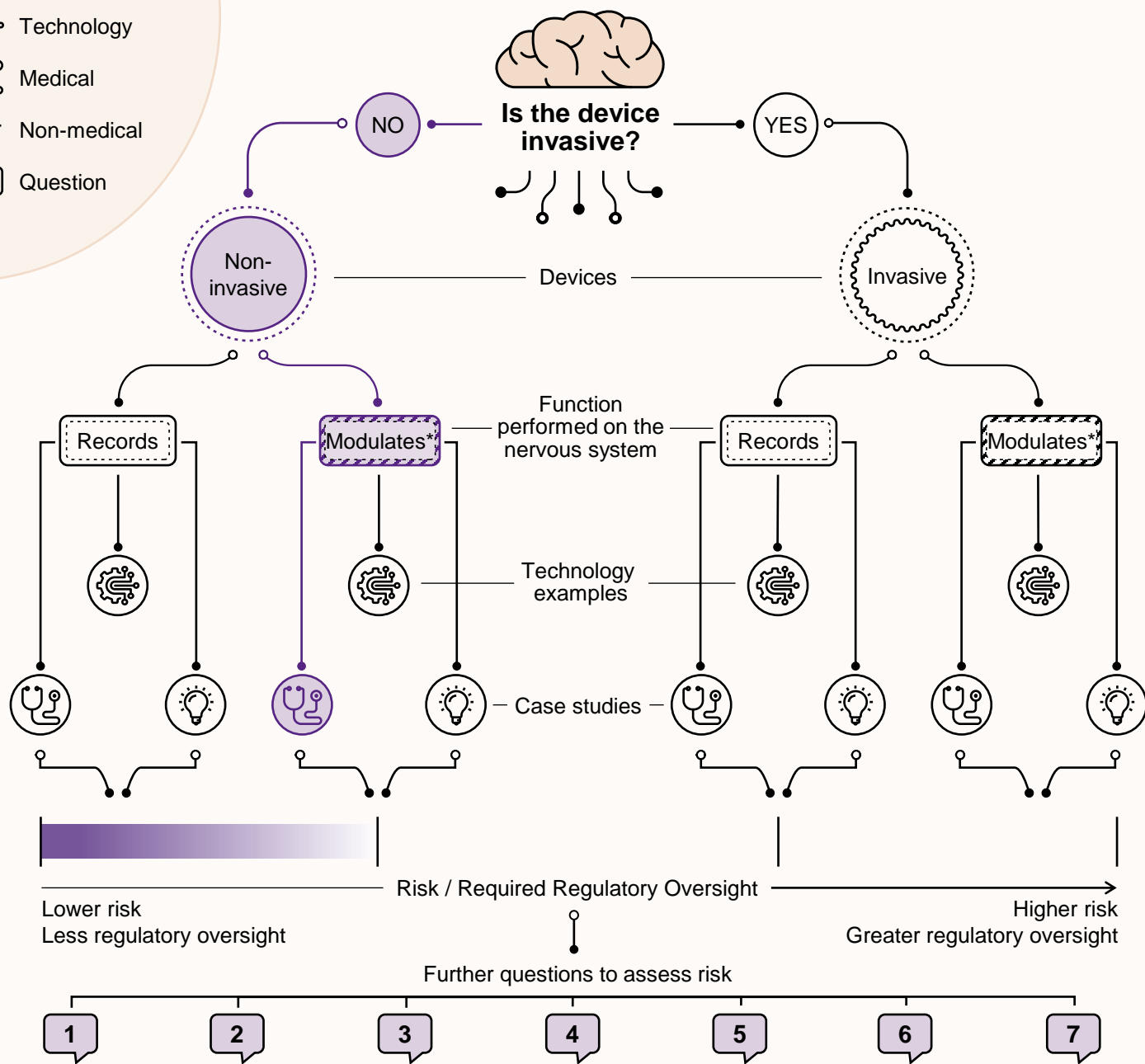
[TMS – Transcranial magnetic stimulation](#)

[PEMF - Pulsed electromagnetic field](#)

[ECT – Electroconvulsive therapy](#)

[MST – Magnetic seizure therapy](#)

- Technology
- Medical
- Non-medical
- Question



*(could also record)

Neurotechnology Taxonomy

Non-invasive – Modulates Medical Case study

Neuromodulating wearables (medical):

[Flow Neuroscience](https://www.flowneuroscience.com/) claims to have developed a headset that delivers electrical stimulation to the dorsolateral prefrontal cortex of the brain's frontal lobe to allow at-home treatment for depression. As part of the treatment, patients are asked to use the device for 30 mins each day; 5 times per week for the first 3 weeks and 2 times a week from then onwards. They are also given advice on developing better eating habits, exercise routines and meditation practices, etc.

<https://www.flowneuroscience.com/>

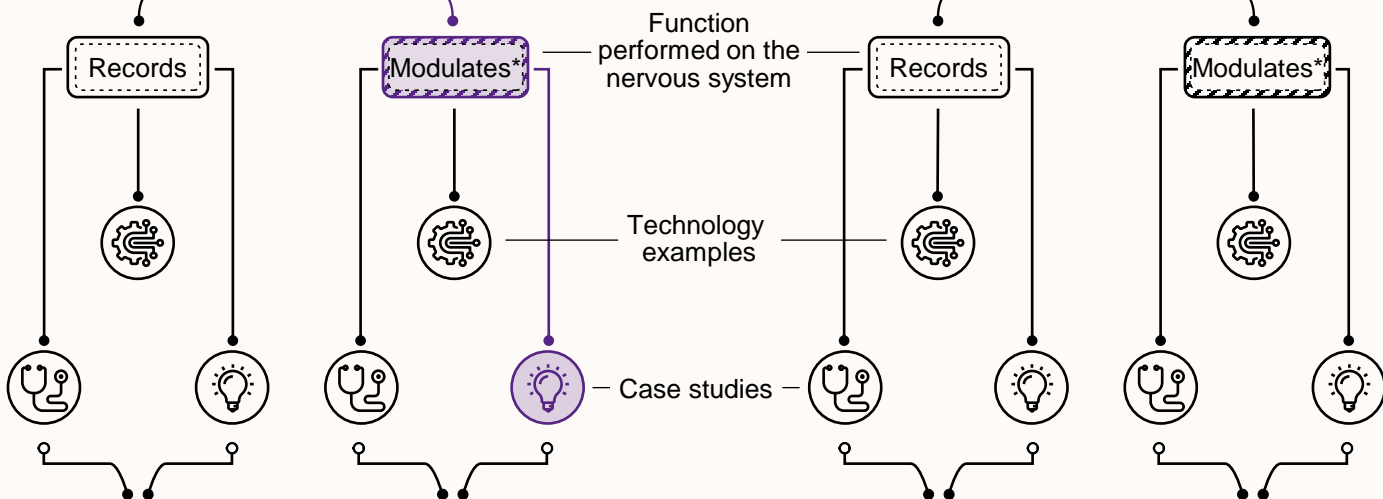
- Technology
- Medical
- Non-medical
- Question



Is the device
invasive?



Devices



Function
performed on the
nervous system

Technology
examples

Case studies



Further questions to assess risk



*(could also record)

Neurotechnology Taxonomy

Non-invasive – Modulates Non-medical Case study

Neuromodulating wearables (non-medical):

[Omnipemf](https://omnipemf.com/) markets headsets that use pulsed electromagnetic field (PEMF) technology to expose the brain to electromagnetic waves and claims that these can help with meditation, sleep, relaxation, focus, and improved physical wellbeing.

<https://omnipemf.com/>

- Technology
- Medical
- Non-medical
- Question



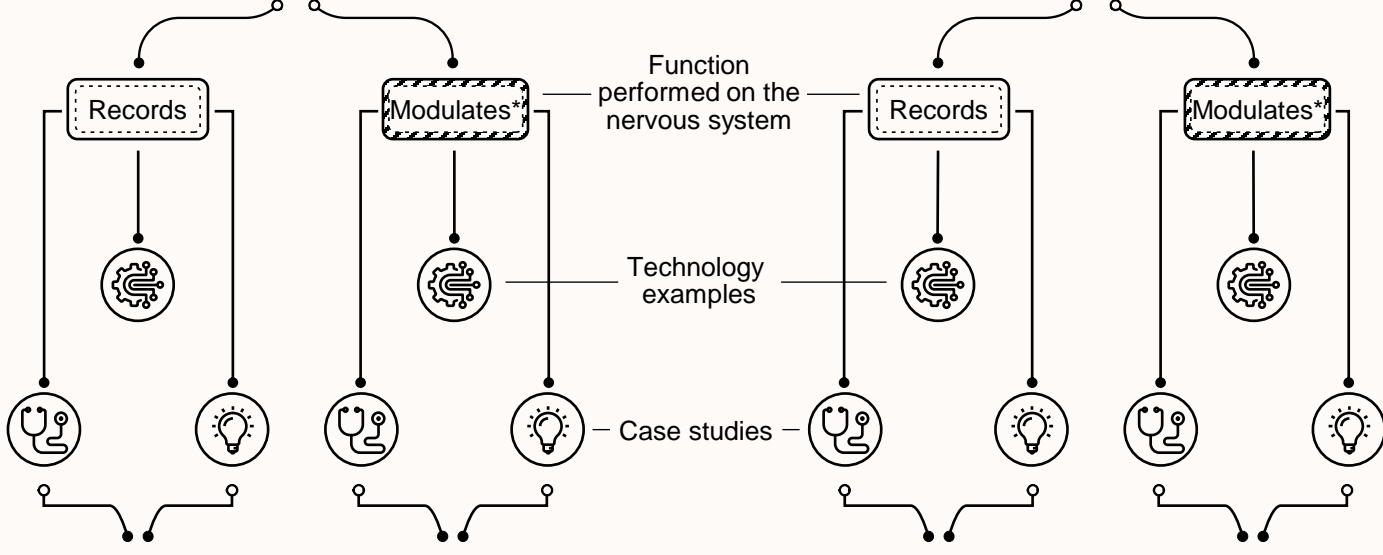
Is the device
invasive?



Non-invasive

Invasive

Devices



Function performed on the nervous system

Technology examples

Case studies

Risk / Required Regulatory Oversight

Lower risk
Less regulatory oversight

Higher risk
Greater regulatory oversight

Further questions to assess risk

- 1
- 2
- 3
- 4
- 5
- 6
- 7

*(could also record)

Neurotechnology Taxonomy

Invasive

i Invasive:

A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

- Technology
- Medical
- Non-medical
- Question



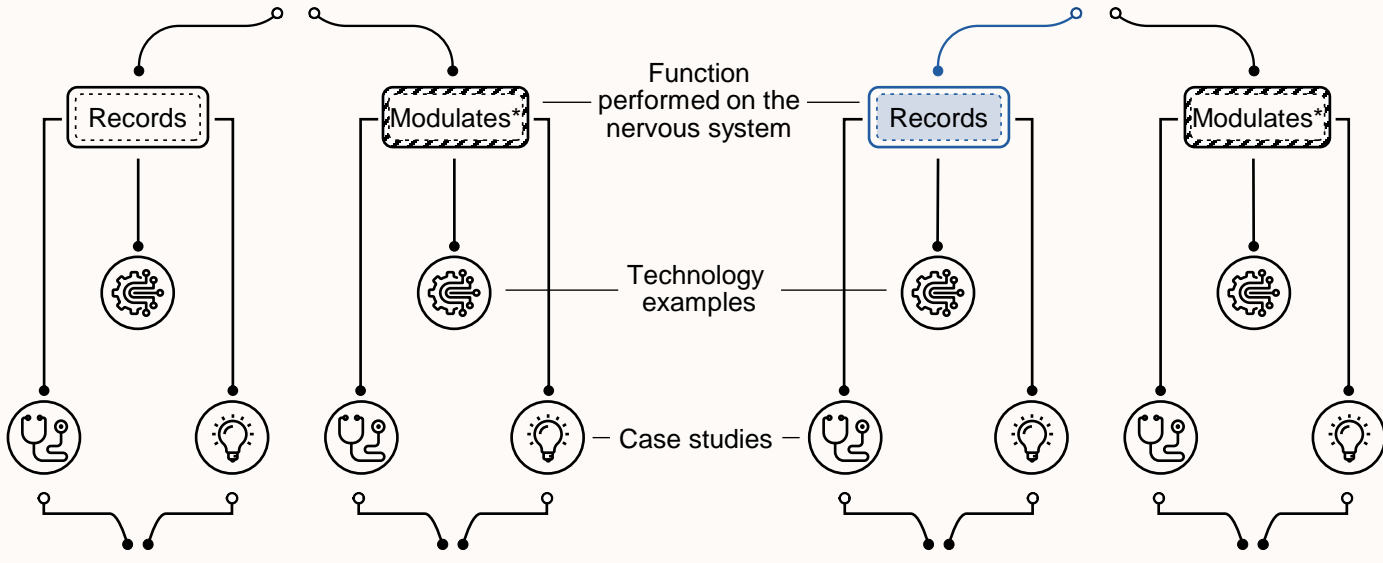
Is the device
invasive?



Non-invasive

Invasive

Devices



Function
performed on the
nervous system

Technology
examples

Case studies



Lower risk
Less regulatory oversight

Risk / Required Regulatory Oversight

Higher risk
Greater regulatory oversight

Further questions to assess risk



*(could also record)

Neurotechnology Taxonomy

Invasive Records

i Neurorecording:

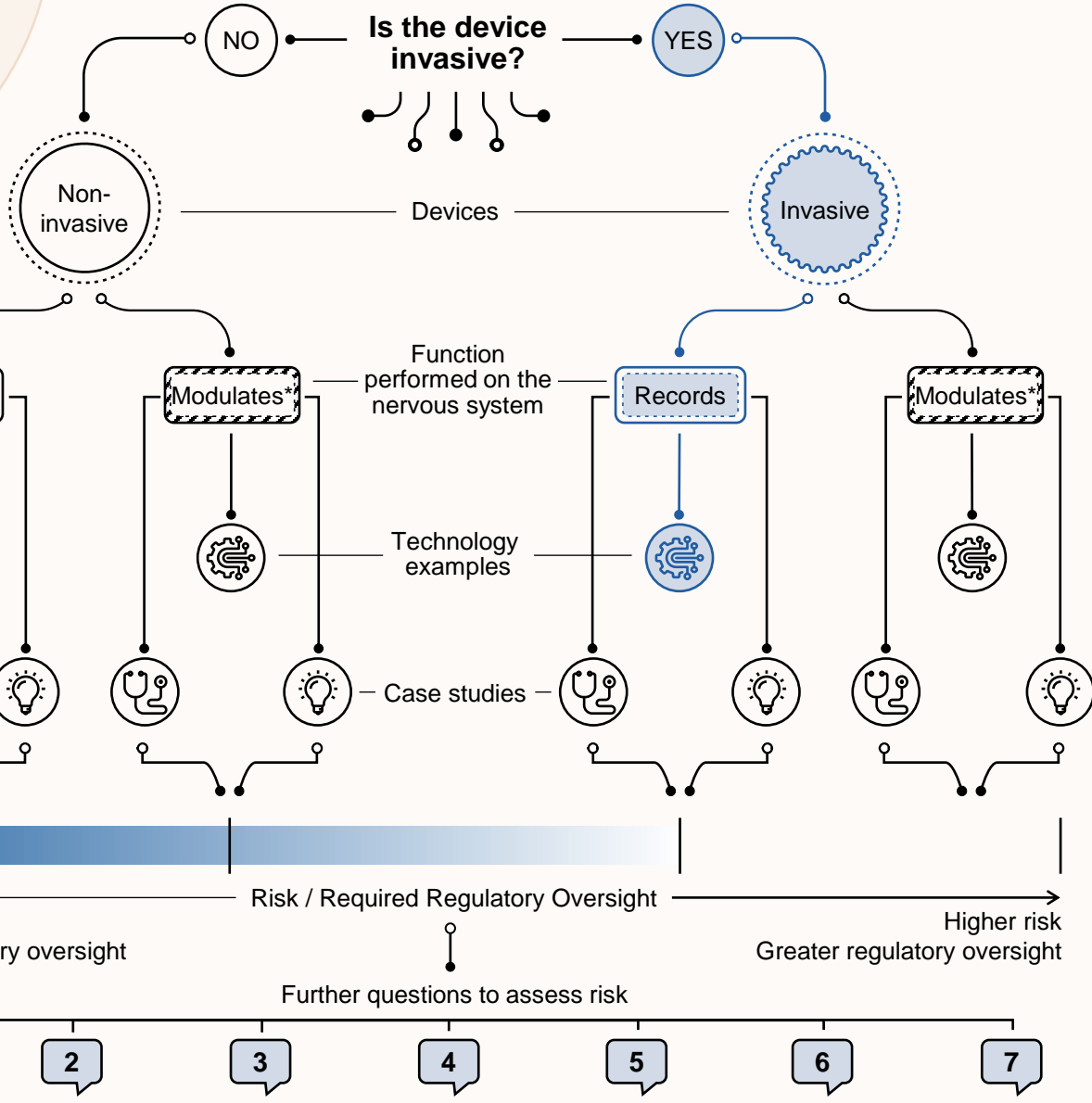
The direct collection, measurement, processing and/or analysis of neurodata to deliver insights into the nervous system and/or interact with another device.

[Click on the icons to unveil additional information on Technology examples and Case studies for this category](#)

- Technology
- Medical
- Non-medical
- Question



Is the device
invasive?



Neurotechnology Taxonomy

Invasive – Records Technology examples

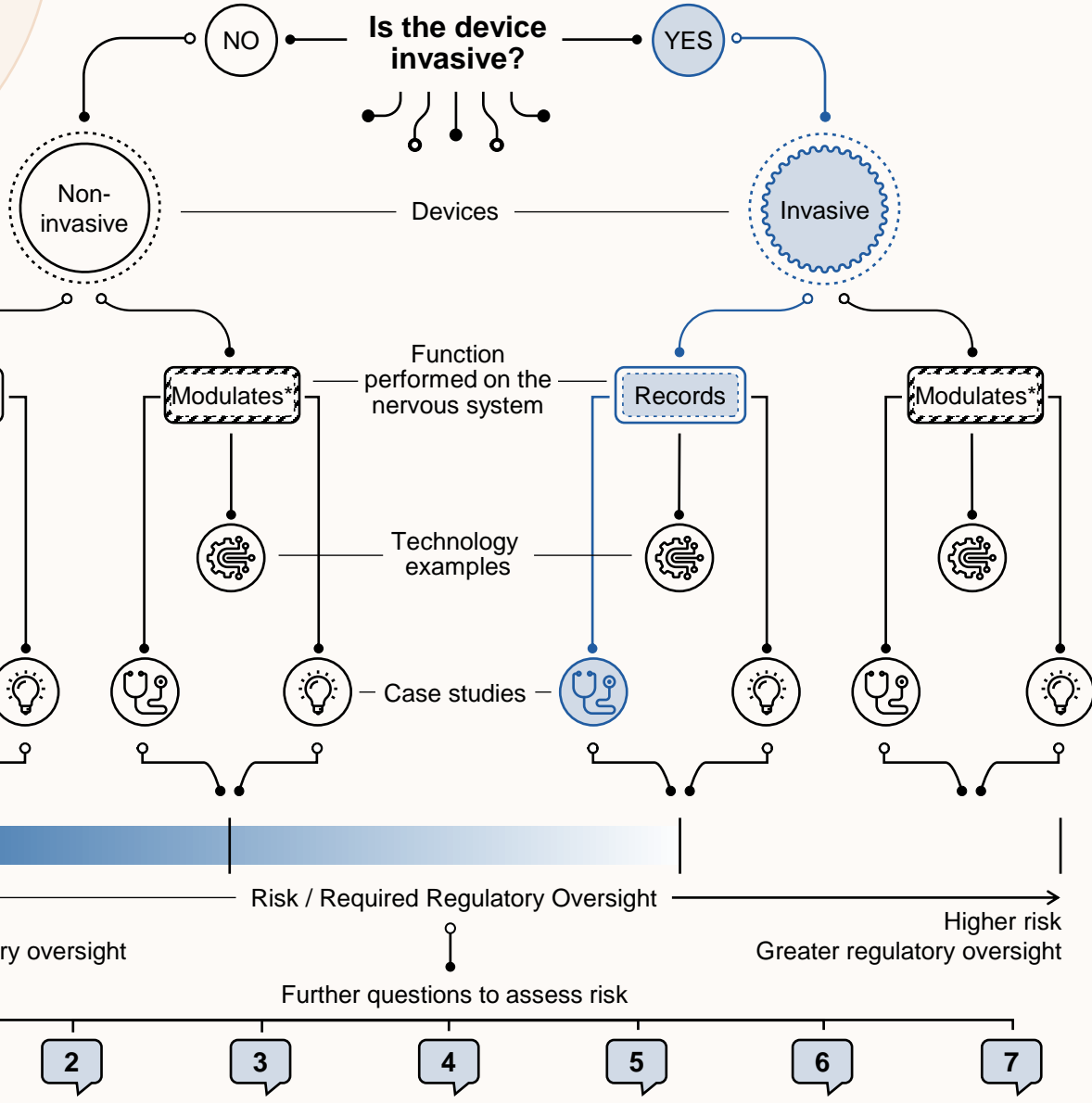
iEEG – Intracranial electroencephalography, also known as **Electrocorticography (ECoG)**

*(could also record)

- Technology
- Medical
- Non-medical
- Question



Is the device
invasive?



Neurotechnology Taxonomy

Invasive – Records Medical Case study

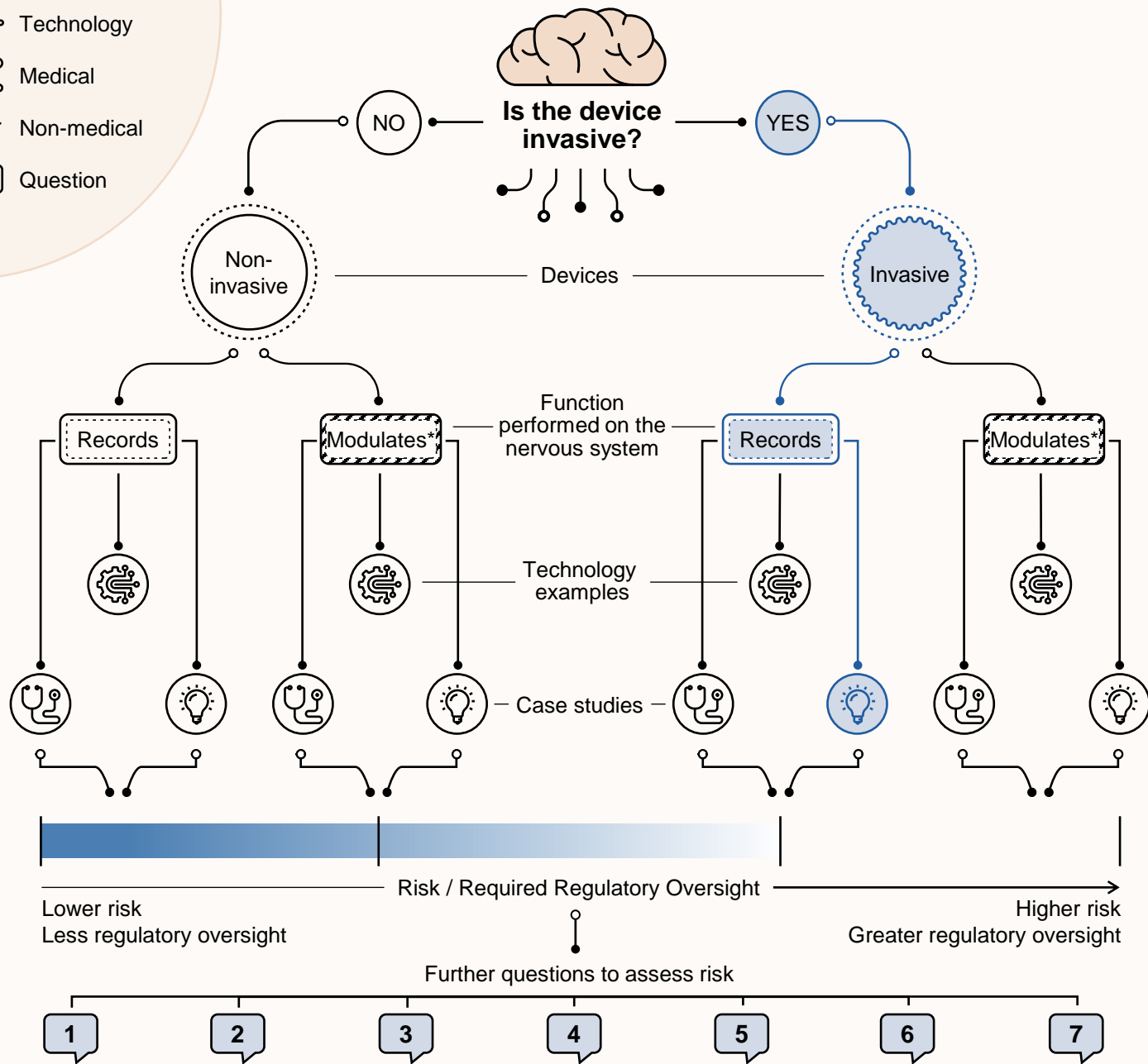
Neurorecording implant (medical):

[Braingate](https://www.braingate.org/) uses intra-cortical microelectrode arrays with the aim of supporting early detection of epileptic seizures, and recording from patients with tetraplegia with a view to allowing them to control a computer cursor and other assistive devices with their thoughts.

<https://www.braingate.org/>

*(could also record)

- Technology
- Medical
- Non-medical
- Question



*(could also record)

Neurotechnology Taxonomy

Invasive – Records Non-medical Case study

Neurorecording implant (non-medical):

[Neuralink](https://neuralink.com/) claims it is developing implants that will record electrical signals in the brain to help people with paralysis regain their independence and provide new kinds of neural information that could help treat a wide range of neurological disorders. However, the company's ambitions do not end there and cross over to the non-medical space. In 2021, Neuralink famously shared a video of a monkey playing the game Pong with its mind. Neuralink hopes its devices will “eventually expand how we interact with each other, with the world, and with ourselves”.

<https://neuralink.com/>

- Technology
- Medical
- Non-medical
- Question



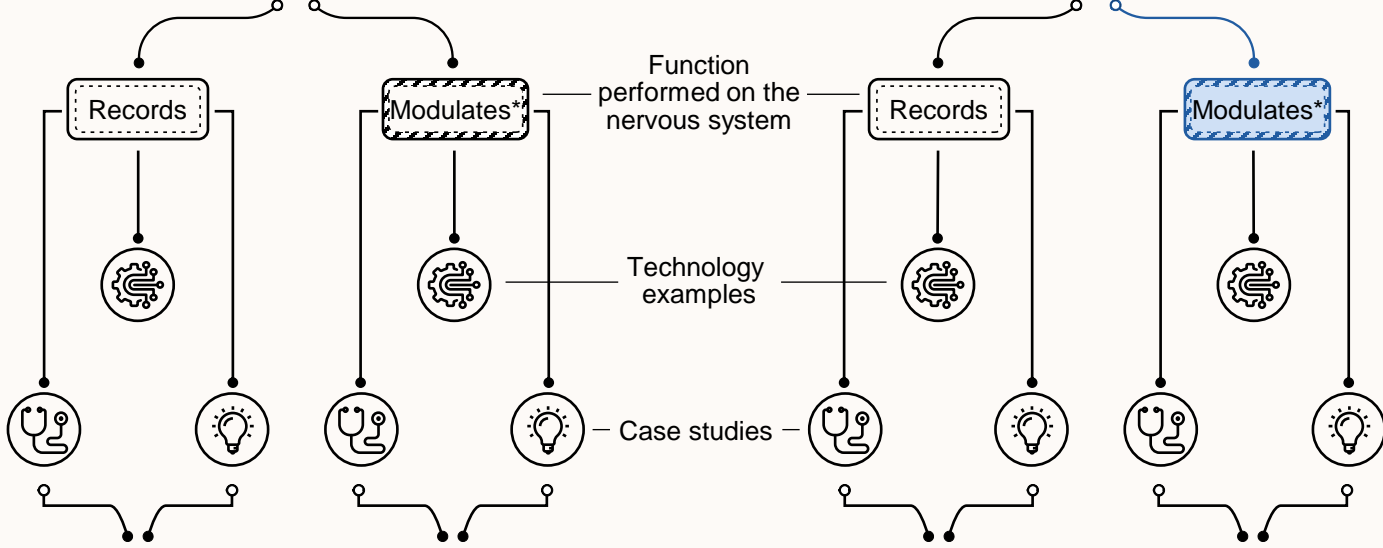
Is the device
invasive?



Non-invasive

Invasive

Devices



Lower risk
Less regulatory oversight

Risk / Required Regulatory Oversight

Higher risk
Greater regulatory oversight

Further questions to assess risk



*(could also record)

Neurotechnology Taxonomy

Invasive Modulates

i Neuromodulation:

The alteration of neural activity through the provision of energy (electric, magnetic, etc.) directly to a target area.

[Click on the icons to unveil additional information on Technology examples and Case studies for this category](#)

- Technology
- Medical
- Non-medical
- Question



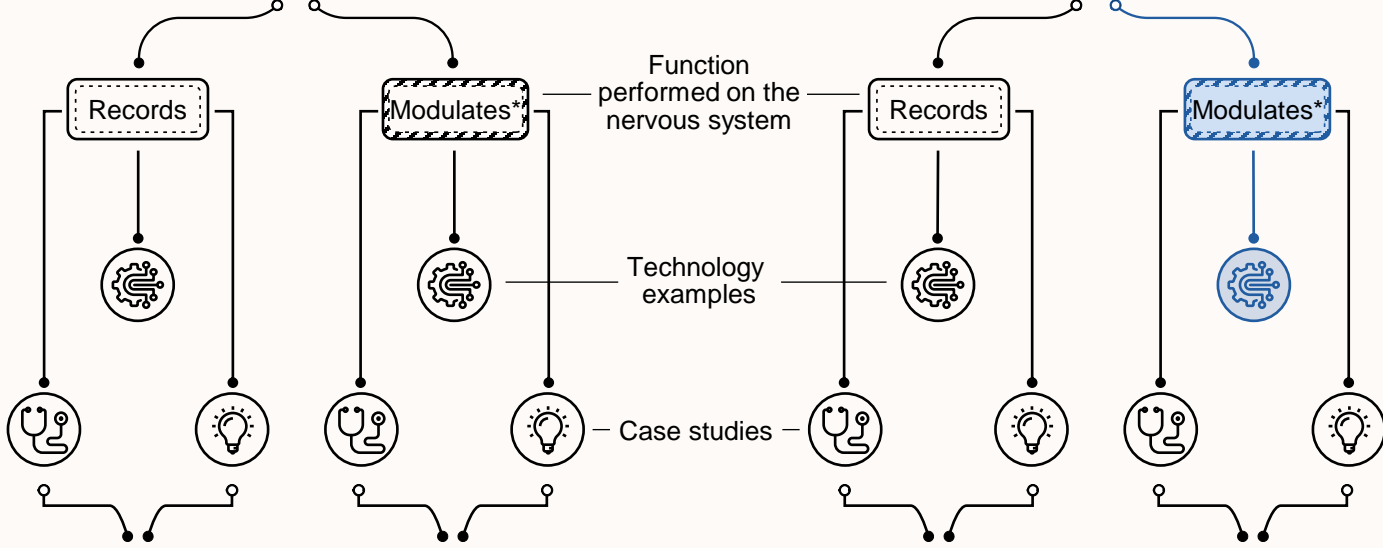
Is the device
invasive?



Non-invasive

Invasive

Devices



Function
performed on the
nervous system

Technology
examples

Case studies



Risk / Required Regulatory Oversight

Lower risk
Less regulatory oversight

Higher risk
Greater regulatory oversight

Further questions to assess risk






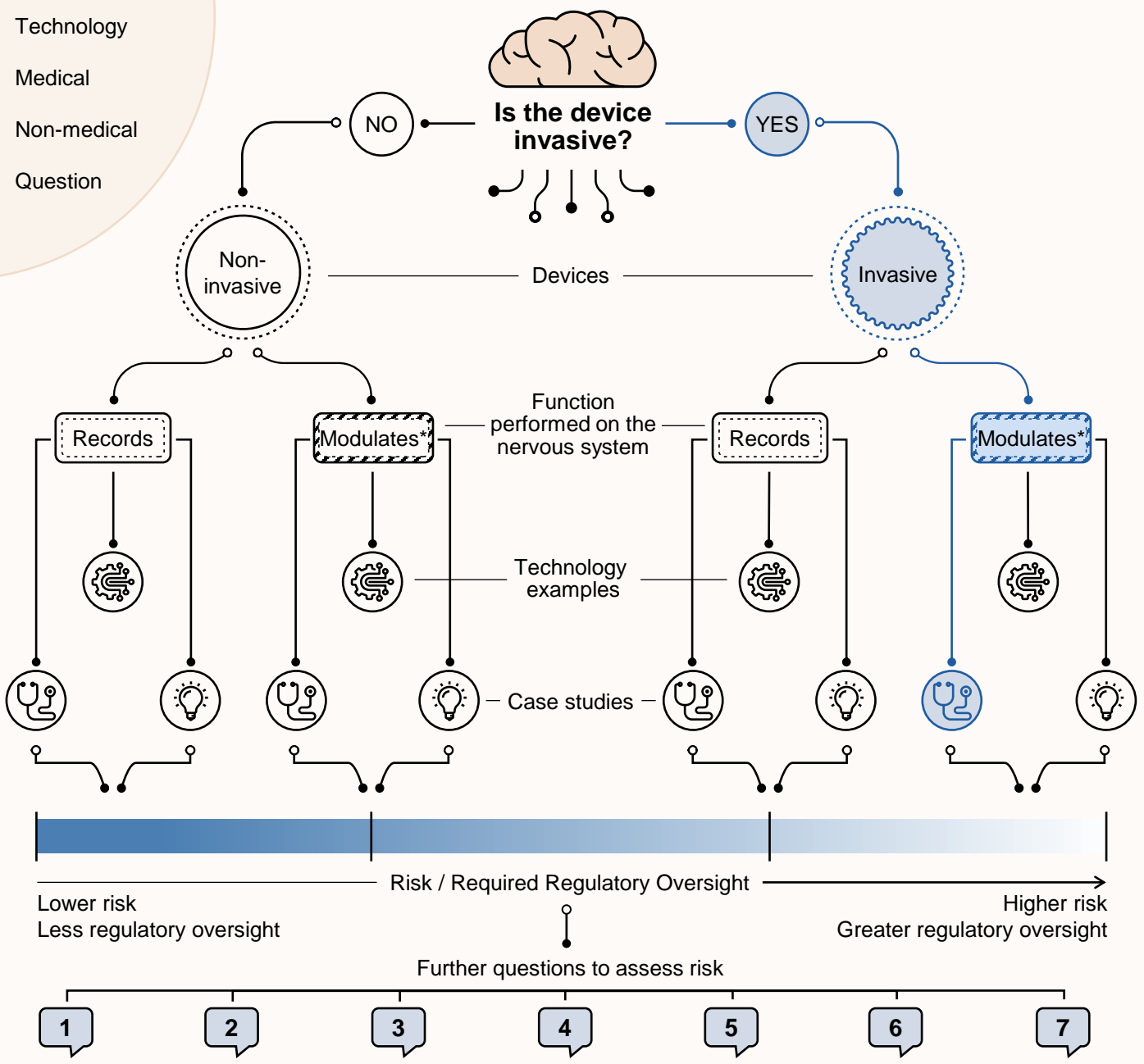
*(could also record)

Neurotechnology Taxonomy

Invasive – Modulates Technology examples

DBS – Deep brain stimulation

-  Technology
-  Medical
-  Non-medical
-  Question



*(could also record)

Neurotechnology Taxonomy

Invasive – Modulates Medical Case study

Neuromodulating implant (medical):

There are many companies that have developed devices in this space. For instance, [Bioinduction](https://bioinduction.com/) has developed a miniaturised Deep Brain Stimulator that is designed to respond to the feedback of neural signals and patient activity. Their device has already been implanted in patients with Parkinson's disease and, in the future, they hope it will treat diseases of cerebrovascular origins such as resistant hypertension, stroke, Alzheimer's disease, and vascular dementia.

<https://bioinduction.com/>

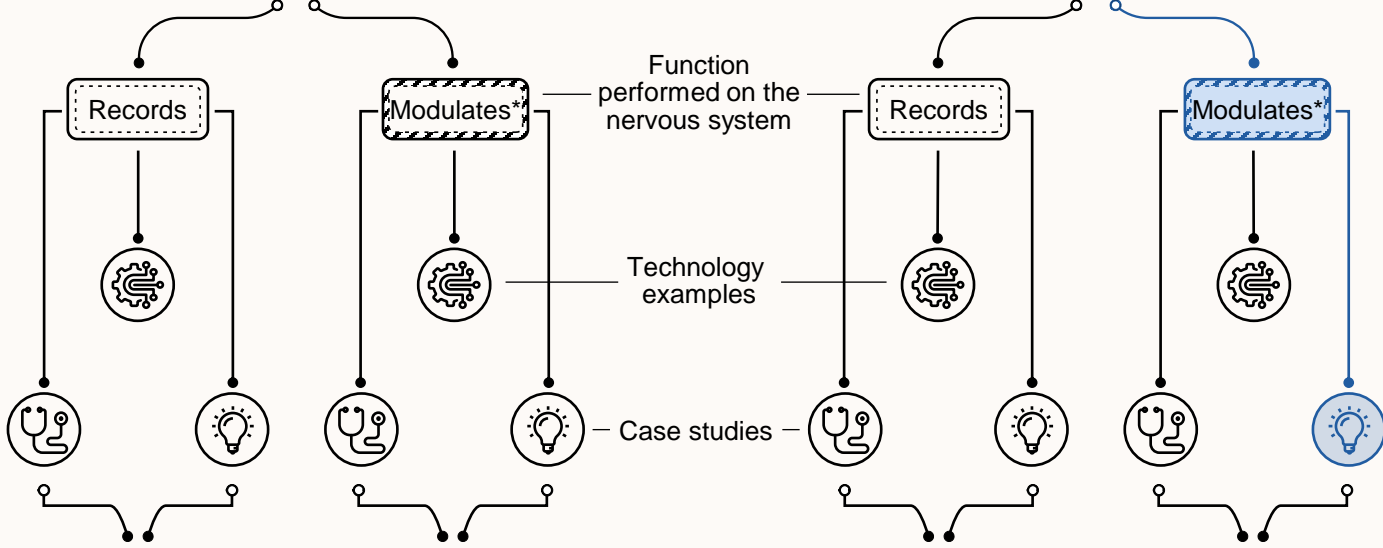
- Technology
- Medical
- Non-medical
- Question



Is the device invasive?



Devices



Function performed on the nervous system

Technology examples

Case studies



Risk / Required Regulatory Oversight

Lower risk
Less regulatory oversight

Higher risk
Greater regulatory oversight

Further questions to assess risk



*(could also record)



Neurotechnology Taxonomy

Invasive – Modulates Non-medical Case study

Neuromodulating implant (non-medical):

The council was not aware of any applications being developed in this space at the time of publication.

- Technology
- Medical
- Non-medical
- Question



Is the device
invasive?

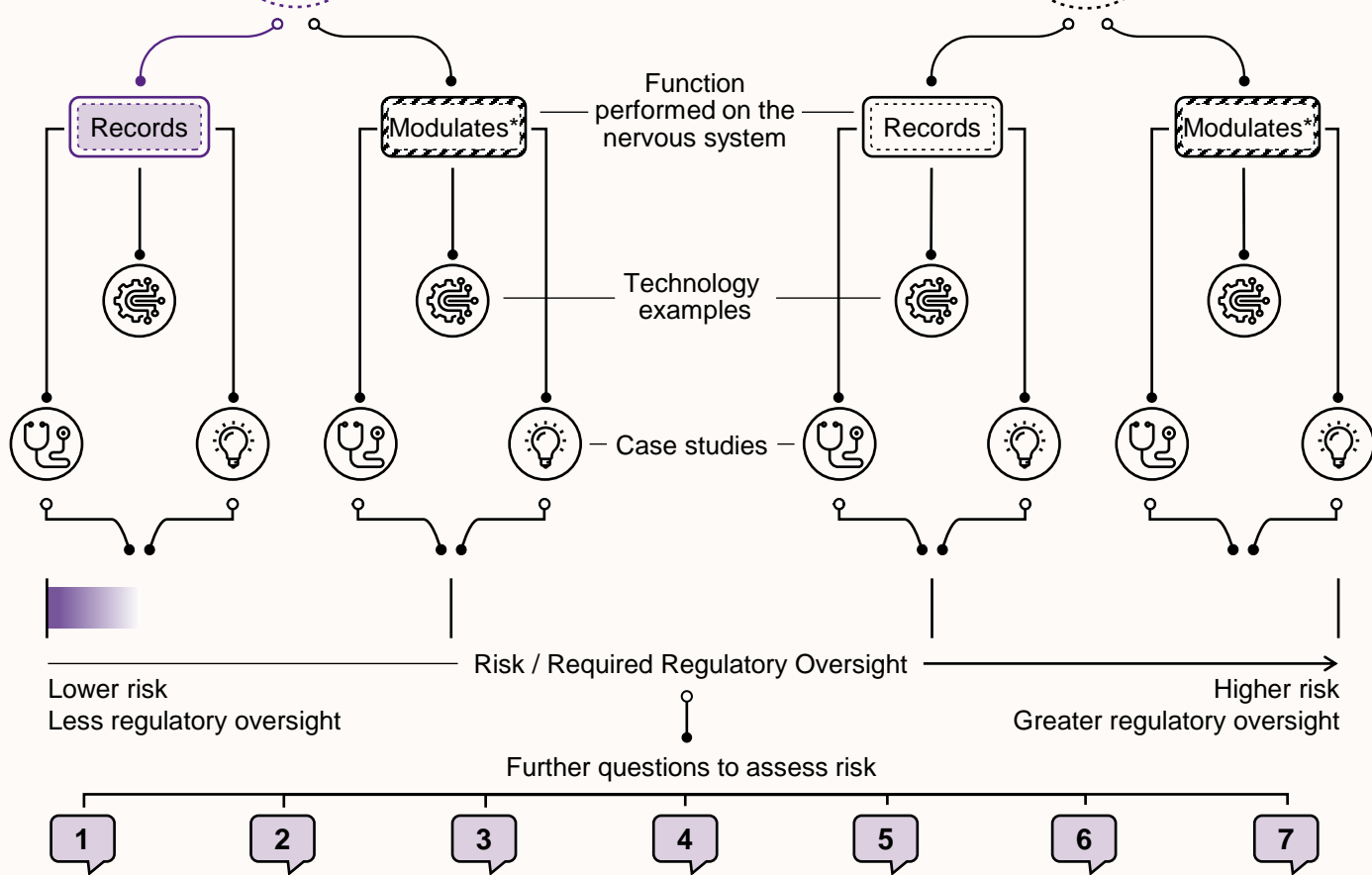
NO

YES

Non-invasive

Invasive

Devices



*(could also record)

Neurotechnology Taxonomy

Non invasive – Records

Further questions to assess risk

1. Does the device have a history of safe use?
2. Does the device optimise or enhance human performance?
3. Does the device interact with the CNS or PNS?
4. Is the use case of concern?
5. What is the device's duration of use?
6. What is the device's spatial and temporal resolution?
7. Is the impact of the device on brain function irreversible?

For more definitions click here

- Technology
- Medical
- Non-medical
- Question



Is the device
invasive?

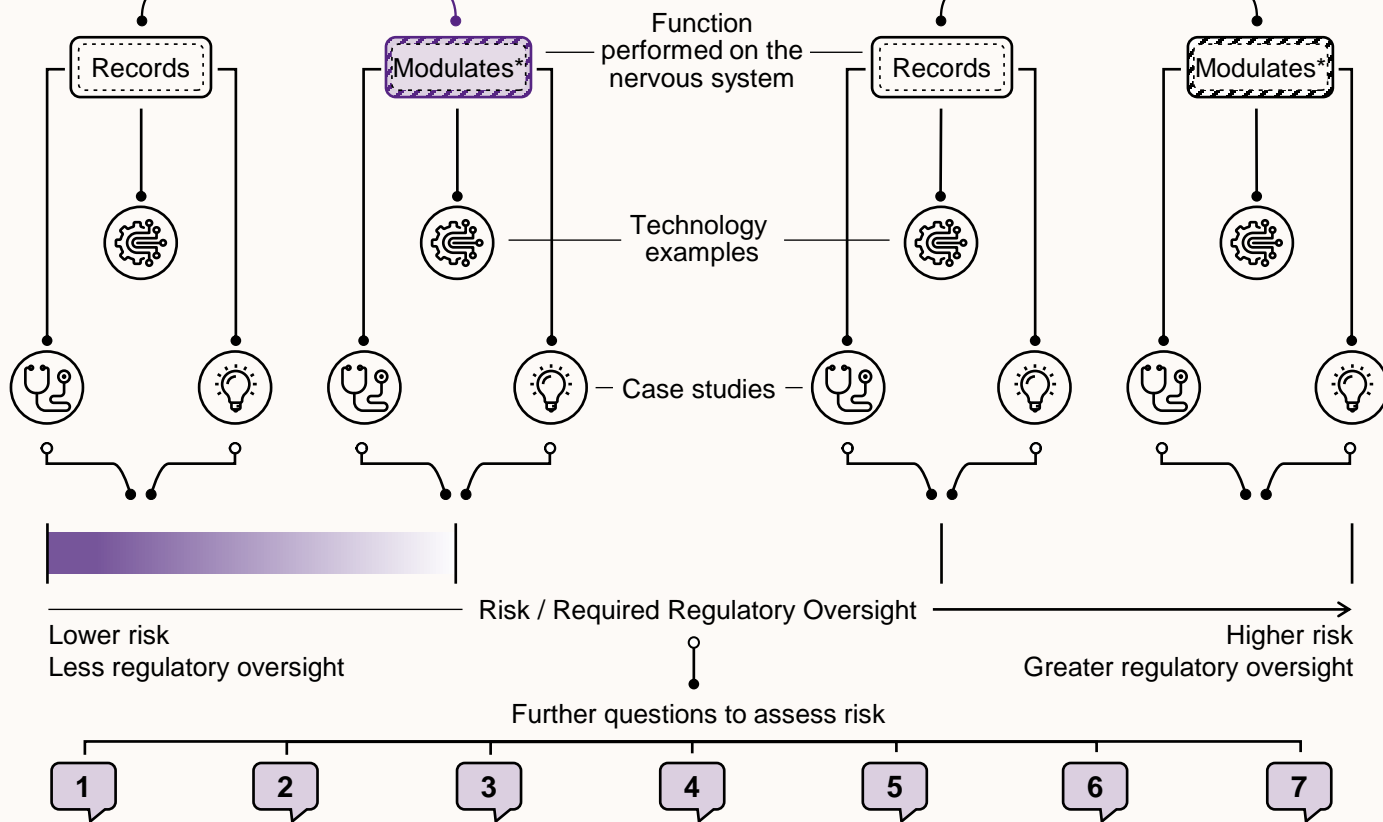
NO

YES

Non-invasive

Invasive

Devices



*(could also record)

Neurotechnology Taxonomy

Non invasive – Modulates

Further questions to assess risk

1. Does the device have a history of safe use?
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For more definitions click here

- Technology
- Medical
- Non-medical
- Question



Is the device
invasive?

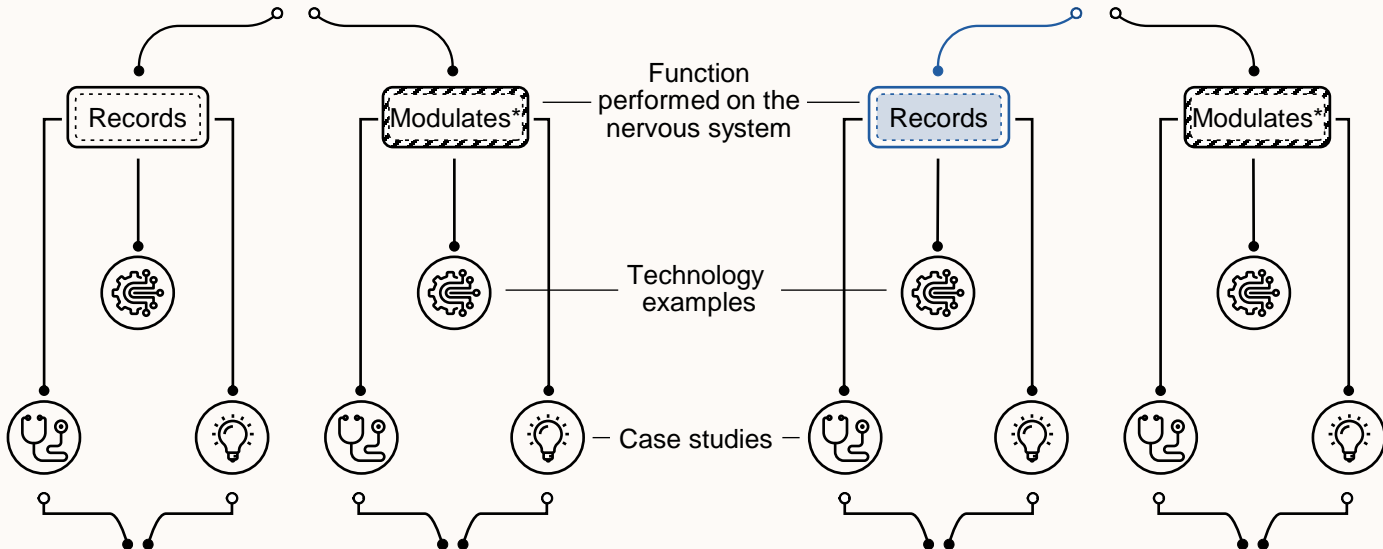
NO

YES

Non-invasive

Invasive

Devices



Function
performed on the
nervous system

Technology
examples

Case studies



Further questions to assess risk

- 1
- 2
- 3
- 4
- 5
- 6
- 7

*(could also record)

Neurotechnology Taxonomy

Invasive – Records

Further questions to assess risk

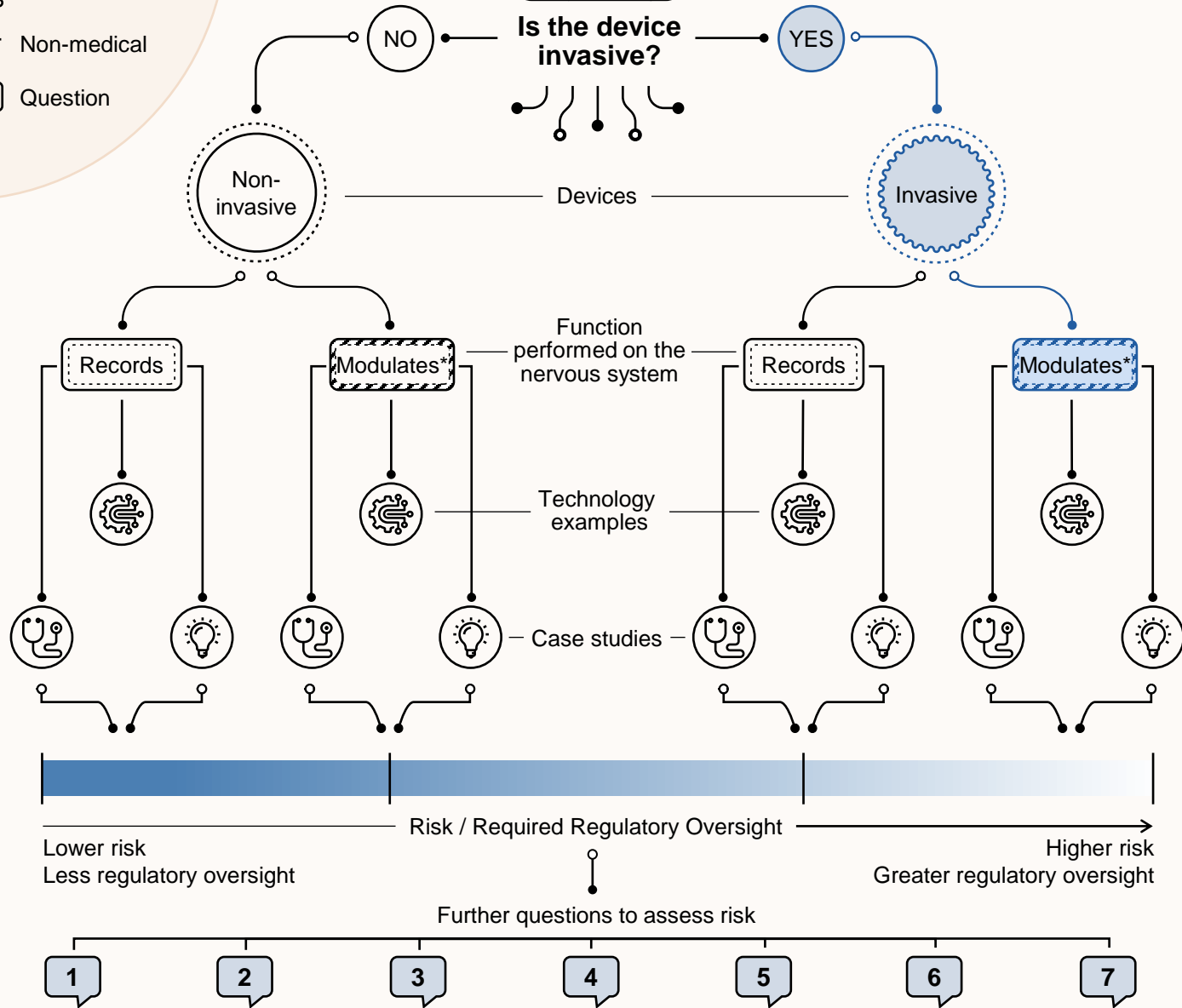
1. Does the device have a history of safe use?
2. Does the device optimise or enhance human performance?
3. Does the device interact with the CNS or PNS?
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5. What is the device's duration of use?
6. What is the device's spatial and temporal resolution?
7. Is the impact of the device on brain function irreversible?

For more definitions click here

- Technology
- Medical
- Non-medical
- Question



Is the device invasive?



Neurotechnology Taxonomy

Invasive – Modulates

Further questions to assess risk

1. Does the device have a history of safe use?
2. Does the device optimise or enhance human performance?
3. Does the device interact with the CNS or PNS?
4. Is the use case of concern?
5. What is the device's duration of use?
6. What is the device's spatial and temporal resolution?
7. Is the impact of the device on brain function irreversible?

For more definitions click here

*(could also record)

Definitions

Optimisation/Enhancement: Neurotechnologies that allow individuals to reach or exceed their biological potential. This does not include applications that restore an individual's performance to its baseline level when it has been degraded by a medical condition.

History of safe use: When the safety of the device has already been confirmed with clinical data and from experience of continued use of an equivalent device.

Duration:

- Transient - normally intended for continuous use for less than 60 minutes.
- Short term - normally intended for continuous use for no more than 30 days.
- Long term - normally intended for continuous use for more than 30 days.

Use case of concern: Neurotechnologies that require special consideration given the sensitive nature of the context in which they are used. Examples may include, but are not limited to, applications used for medical, military, employment, insurance, education, surveillance, security and judicial purposes.

Irreversible: Neurotechnologies that have a permanent impact on nervous system function.

Spatial and temporal resolution: The smallest interval (in space and/or time) at which separate neural activities can be detected or modulated.

