

EUROPEAN HEALTH DATA SPACE

# Health data holder obligations under the EHDS

Understanding health data holder  
responsibilities for secondary use.



THE GOVERNMENT  
OF THE GRAND DUCHY OF LUXEMBOURG  
Ministry for Digitalisation

Government commission for data sovereignty

Supported by  LNDS



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# Scope

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Key elements.

01

## **Are you an EHDS health data holder?**

The conditions to qualify and the exemptions from obligations.

02

## **Which data is in scope?**

The covered categories, and the scope check applied in practice.

03

## **What must you do?**

Five main duties for secondary use, from metadata descriptions to protecting IP and trade secrets.

Not covered here: data quality labels and precise penalties.

## PART ONE

# Who is an EHDS health data holder?

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The EHDS sets obligations for health data holders.  
Qualification is a three-step test.



01

# Is the entity active in the healthcare or care sectors?

Qualification starts with the activities of the entity.

The definition covers both public and private actors in health and care, such as:

**Public  
administrations**



**Social security  
bodies**



**Reimbursement  
services**



**Hospitals and  
care providers**



**Research  
organisations**



**Health product  
and service  
companies**



**Wellness  
application  
companies**



**Courts and other  
justice system entities  
are not considered  
health data holders**

# Is the entity exempt from obligations?

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## EXEMPT CATEGORIES

— **Natural persons**  
(e.g., individual researchers)

— **Micro-enterprises**

Exempt unless national law says otherwise.

### MICRO-ENTERPRISE?

Under the EU SME definition (2003/361/EC):

- employs fewer than 10 persons
- and has either annual turnover or an annual balance-sheet total  $\leq$  €2 million euro

# Does the entity control the data it holds?

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Qualification depends on whether the entity holds personal or non-personal electronic health data.

**Pathway 1 · Personal data**

**Pathway 2 · Non-personal data**

At least one pathway must apply.

# Personal electronic health data

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An entity qualifies as an EHDS health data holder if the law gives it the right, or requires it, to process personal electronic health data for one or more EHDS listed purposes, and it decides how and why.

**A**

## A legal right or obligation to process

Processing is understood broadly — acting on the data: collecting, recording, storing, accessing, consulting, using, sharing, changing or deleting it.

**B**

## For an EHDS listed purpose

Healthcare or care

Public health

Reimbursement

Research

Innovation

Policymaking

Official statistics

Patient safety

Regulatory purposes

**C**

## Responsible for the how and the why

On its own,  
or together with another entity.

So as a ***controller***  
or a ***joint controller***.

## PATHWAY 2 OF 2

# Non-personal electronic health data

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Data that has never related to an identifiable data subject, or that was anonymised.

An entity qualifies as an EHDS health data holder when it controls how that data is shared through a product or service — the ability to make it available through control of the technical design of a product and related services.

Registering

Providing

Restricting access

Exchanging

## STEPPING BACK

To qualify as an EHDS health data holder, at least one of the two pathways must apply.

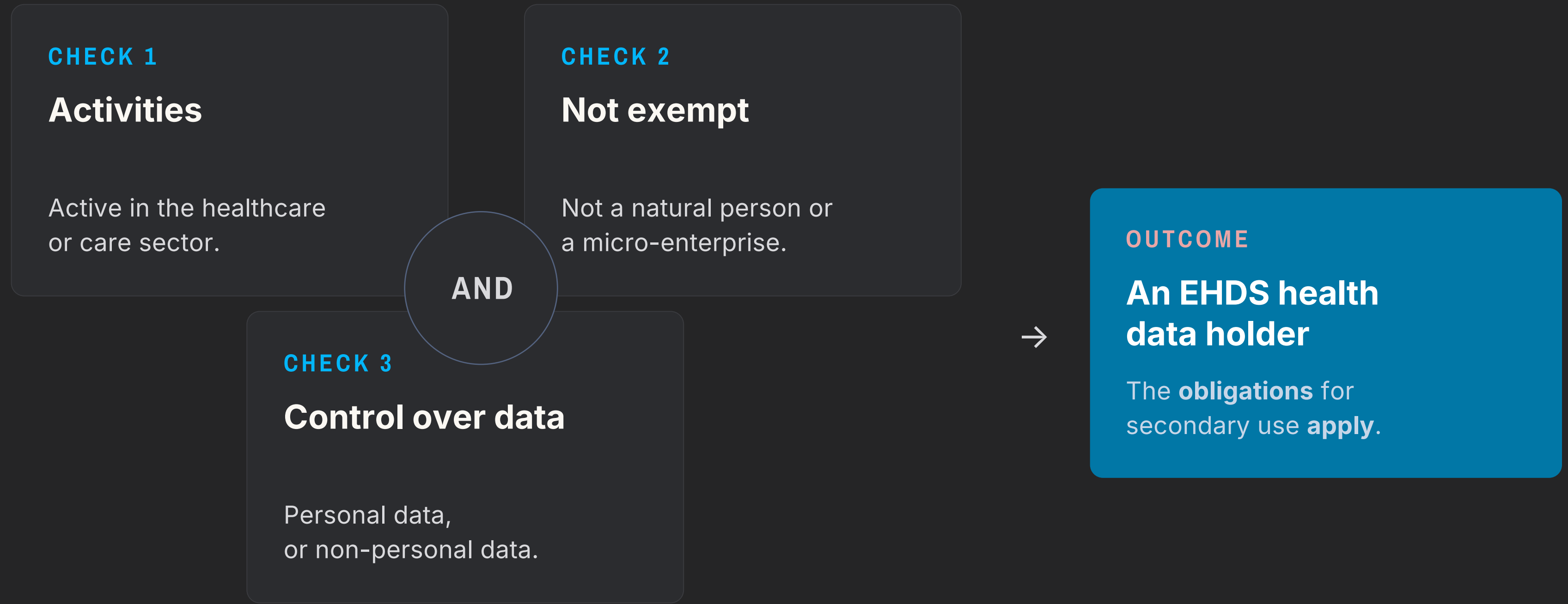
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**Personal data** — right or duty to process

**Non-personal data** — control of the sharing

# Putting the checks together

All conditions must apply — then the question moves from the entity to its datasets.



**NEXT** Which of the datasets held fall inside EHDS scope?

PART TWO

# Which data is in scope?

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The EHDS covers a wide range of electronic health data for secondary use.

02

# Covered data categories

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Examples of data categories that may fall within scope for secondary use.

*The list is illustrative and not exhaustive. Other health data may exist and require separate assessment.*



## Electronic health records

Clinical records held in electronic form.



## Healthcare and administrative data

Activity, claims and reimbursement data.



## Genetic and genomic data

Including omics data.



## Medical devices and wellness applications

Device- or app-generated data.



## Health registries

Disease and population registries.



## Research and clinical studies

Study data and results.



## Biobanks

Data associated with stored samples.



## EXISTING ELECTRONIC DATA

Organisations do not have to digitise paper files nor create new data just for secondary use.

# The scope check in practice

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Map the datasets held, then answer three questions for each one.

**01**

**What data does the organisation hold?**

Inventory first.  
Must cover datasets, not systems.

**02**

**Is that data electronic?**

The duties attach to data already held in electronic form.

**03**

**Does it fall in a covered category?**

If yes, the dataset is in scope.

## PART THREE

# The five main obligations

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Together, they ensure health data can be discovered, assessed, and made available in a timely and safeguarded way.



03

# Five main duties for secondary use

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Discoverable, accurate, correctly routed, delivered on time, and safeguarded.

**01**

## **Metadata description**

Describe in-scope datasets in a machine-readable standard.

**02**

## **Accuracy over time**

Review at least once a year and keep records up to date.

**03**

## **Make data available**

Classify the data, then route the request correctly.

**04**

## **Timely delivery**

Provide the data within the given timeframes

**05**

## **Protecting IP and trade secrets**

Flag elements covered by specific rights, and justify.

DUTIES 1 AND 2

# Describe the dataset, then keep it accurate

Structured metadata in a machine-readable, interoperable standard such as HealthDCAT-AP. These records feed the National Health Dataset Catalogue used for secondary-use access.

|                                           |                                                  |
|-------------------------------------------|--------------------------------------------------|
| ● ● ● HealthDCAT-AP – dataset description |                                                  |
| SOURCE                                    | Where the data comes from, and who holds it      |
| SCOPE                                     | Population, period and coverage of the dataset   |
| MAIN CHARACTERISTICS                      | Variables, formats and provenance                |
| ACCESS CONDITIONS                         | How the health data may be requested and re-used |

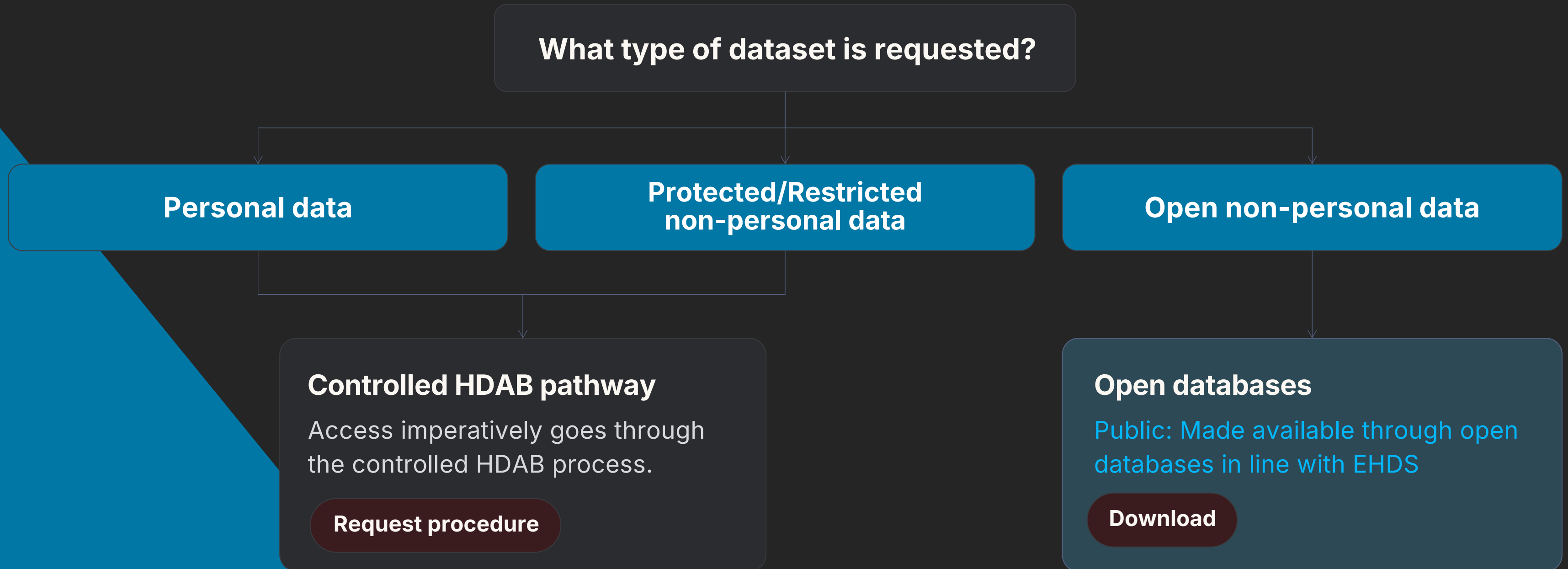
DUTY 2

1× reviewed at least once a year, and kept up to date

PLUS, WHERE APPLICABLE

Any additional mandatory fields required by applicable EHDS specifications and national implementation rules (Commission Implementing Regulation (EU) 2026/2098).

# Making data available



#### DUTY 4

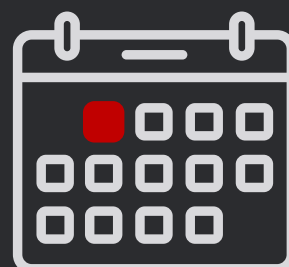
## Timely delivery

3 months

Requested health data should be provided within three months of the request by the CGSD to transfer the data after the permit has been issued or the request approved.

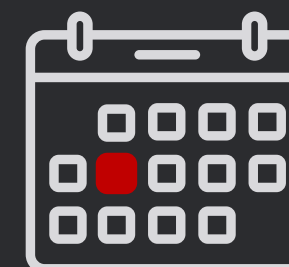
Month 1

Extraction



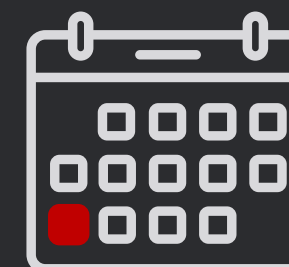
Month 2

Quality checks



Month 3

Secure transfer



### Extension of the timeframe

Possible when it is justified and documented.

**Plan extraction, quality checks and secure transfer early, not at the deadline.**

## DUTY 5

# Safeguarding rights

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### RIGHTS THAT MAY APPLY

**Intellectual property rights**

**Trade secrets**

**Regulatory data protection and marketing protection for medicinal products**

### WHAT THE HEALTH DATA HOLDER MUST DO

**01 Identify which elements are protected**

**02 Specify which rights apply**

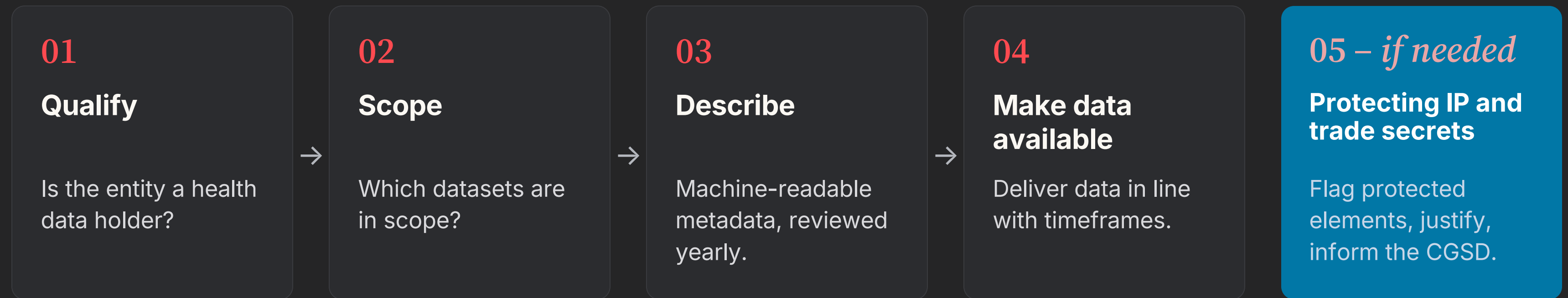
**03 Justify why protection is needed**

### INFORM THE CGSD

In the initial dataset description, or when making the data available following an approved data permit or request for anonymised statistics.

# Process summary

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**THE PRACTICAL RULE** **Classify · Document · Communicate · Update**

# Questions?

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Related training on EHDS secondary use:

What is the EHDS?

What is the HDAB?

What secondary use makes possible

What is an SPE?

Discovering datasets



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