

EHDS – Be prepared for public consultations in TEHDAS2:
**Draft guideline for Health Data Access Bodies on data minimisation,
pseudonymisation, anonymisation and synthetic data**

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Pia Brinkmann, Bundesinstitut für Arzneimittel und
Medizinprodukte BfArM
September 17th, 2025 | 8 a.m. to 9 a.m.

online workshop series | September 15th to October 1st, 2025

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<https://tehdas.eu/public-consultations/>

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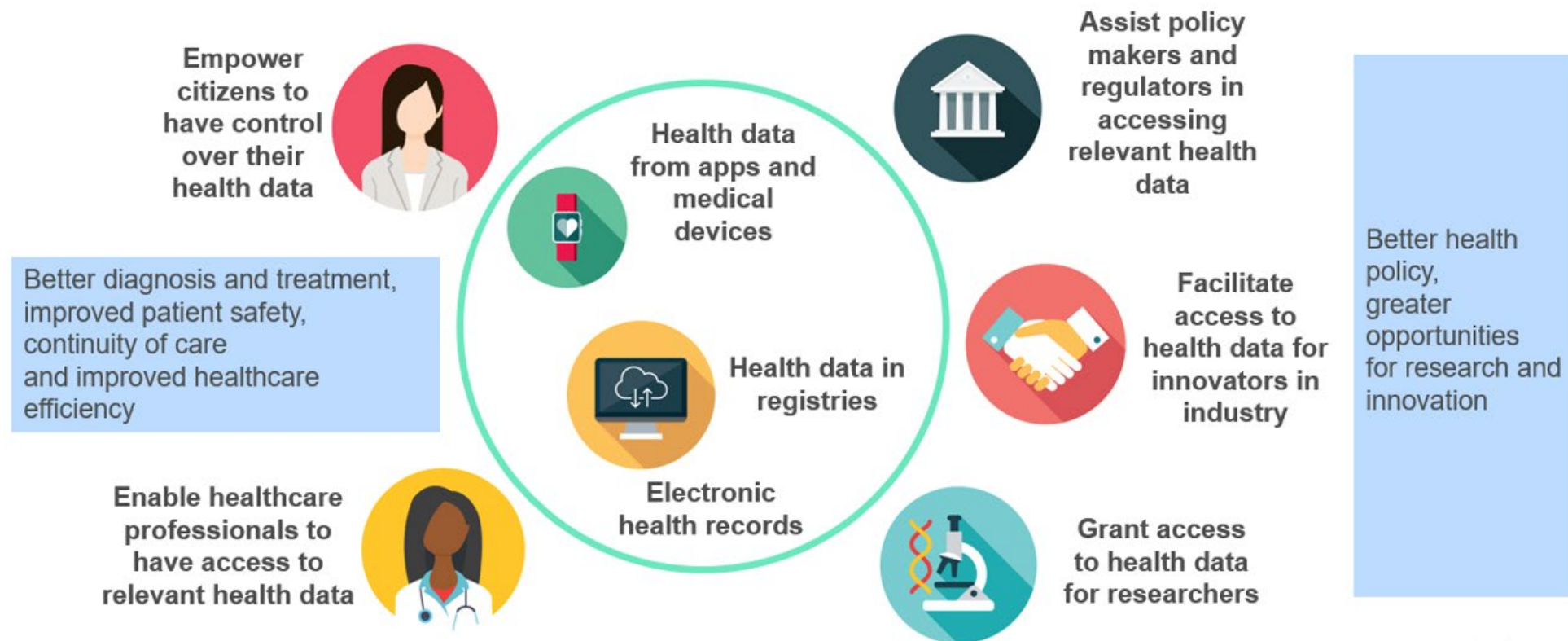
1. EHDS and TEHDAS2 in a nutshell
2. TEHDAS2 Documents for public consultation on September 30th, 2025
3. Presenting today's document:
Draft guideline for Health Data Access Bodies on data minimisation, pseudonymisation, anonymisation and synthetic data
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1. EHDS and TEHDAS2 in a nutshell

European Health Data Space (EHDS) – AIMS FROM User perspectives

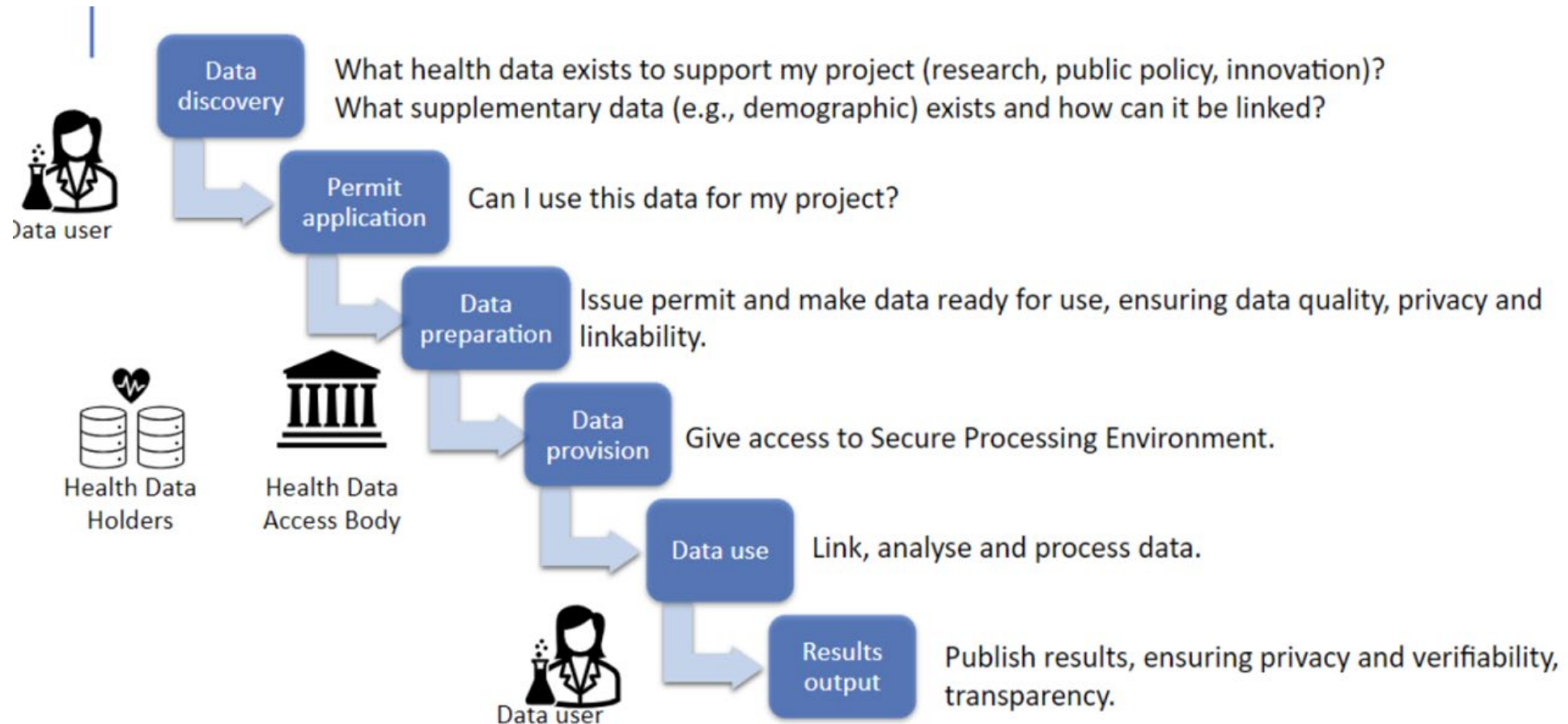
Primary use (routine care)

Secondary use



1. EHDS and TEHDAS2 in a nutshell

EHDS2: Secondary Use of Electronic Health Data



- ▶ Das Europäische Parlament hat am 24. April 2024 die legislativen Grundlagen zur Schaffung eines **Europäischen Gesundheitsdatenraums (EHDS)** gelegt.
- ▶ Sprachjuristische Endfassung, vom ER am 21.01.2025 verabschiedet.
- ▶ Die EHDS-Verordnung wurde am 5. März 2025 im Amtsblatt der EU veröffentlicht **und trat 20 Tage später, am 25. März 2025, in Kraft.**
- ▶ Die Vorschriften der EHDS-Verordnung werden schrittweise angewendet: teilweise nach zwei Jahren, teilweise nach vier, sechs oder zehn Jahren nach Inkrafttreten. Direkt rechtswirksam in allen EU-Mitgliedstaaten, so auch in Deutschland.
- ▶ **MyHealth@EU (EHDS I)** regelt **elektronische grenzüberschreitende Gesundheitsdienste** in der EU (und die hierfür notwendigen Voraussetzungen).
- ▶ Im Rahmen von **HealthData@EU (EHDS II)** soll das Potenzial der **(Sekundär-)Nutzung von vorhandenen Gesundheitsdaten für Forschung und Innovation** in anonymisierter oder pseudonymisierter Form im öffentlichen Interesse erschlossen werden.
- ▶ ➔ Detailierung durch **Durchsetzungsrechtsakte (Implementing Acts)** bis 26. März 2027



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Union

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Access to European Union law

<https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32025R0327&qid=1741704307107>



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Document 32025R0327

Verordnung (EU) 2025/327 des Europäischen Parlaments und des Rates vom 11. Februar 2025 über den europäischen Gesundheitsdatenraum sowie zur Änderung der Richtlinie 2011/24/EU und der Verordnung (EU) 2024/2847 (Text von Bedeutung für den EWR)

PE/76/2024/REV/1

AbL. L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj> (BG, ES, CS, DA, DE, ET, EL, EN, FR, GA, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV)

In force

ELI: <http://data.europa.eu/eli/reg/2025/327/oj>

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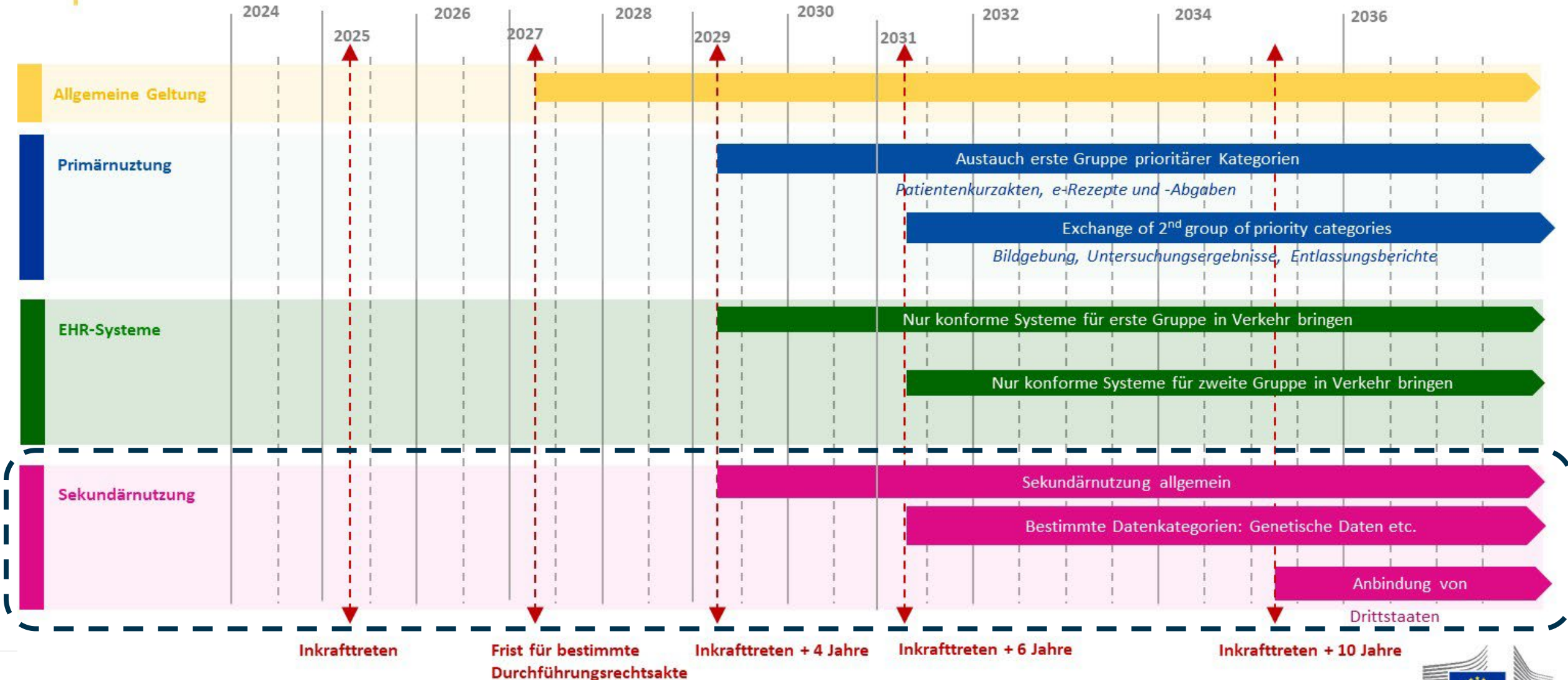
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EHDS – Inkrafttreten und Geltung



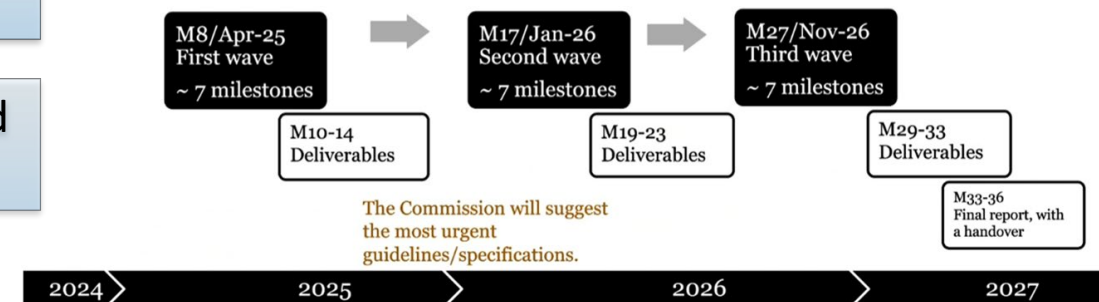
1. TEHDAS2 in a nutshell

TEHDAS2 in a nutshell

- 1 A joint action with clear scope, timeline and budget
- 2 Structured in independent work packages but common working methods
- 3 Aims for harmonised implementation of EHDS – secondary use of health data
- 4 Produces tangible results in the form of guidelines and technical specifications
- 5 High emphasis also on external communication and interlinks with other projects

für Deutschland: **BMG, BfArM, gematik, TMF**

- ▶ TEHDAS2 bereitet die Durchsetzungsrechtsakte der EU zum EHDS II durch **Guidelines** vor.
- ▶ (Für EHDS I entsprechend: xt-EHR)
- ▶ in 3 „Wellen“ (1. bereits erfolgt)
- ▶ Die Guidelines werden vor Verabschiedung und Annahme durch die EU öffentlich zur Kommentierung gestellt. Beginn: 30. Sept. 2025 (2 Monate)



2. TEHDAS2 Guidelines



Upcoming public consultations

SEP-OCT 2025

TOPIC: Processes to manage permits or data pseudonymisation

Documents scheduled for public consultation(Click to view)

1. Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance regulated to the EHDS regulation
2. Draft guideline for Health Data Access Bodies on minimum categories and limitations on the reuse of health data
3. Draft guideline for data holders on making personal and non-personal electronic health data available for reuse
4. Draft guideline for Health Data Access Bodies on the procedures and formats for data access
5. Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies
6. Draft technical specification for Health Data Access Bodies on data minimisation and de-identification
7. Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure
8. Draft technical specification for Health Data Access Bodies on the implementation of secure processing environments
9. Draft guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data
10. Draft guideline for Health Data Access Bodies on implementing the obligation of notifying the natural person on a significant finding from the secondary use of health data

<https://tehdas.eu/>



MAY-JUN 2026

TOPIC: Collaboration with third countries, data enrichment and informing citizens

Documents scheduled for public consultation(Click to view)

1. Draft guideline for Health Data Access Bodies on collaboration with other parties
2. Draft guideline for Health Data Access Bodies on international and third country access and transfer of electronic health data
3. Draft guideline for Health Data Access Bodies on enrichment of health datasets
4. Draft guideline for Health Data Access Bodies on linkage of health datasets
5. Draft guideline for Health Data Access Bodies on informing natural persons about the use of health data – “Citizen Information Point”
6. Draft guideline for data users on handling research outcomes

2. TEHDAS2 Participate in the public consultations



TEHDAS2 develops guidelines and technical specifications to enable seamless secondary use of electronic health data across Europe under the European Health Data Space (EHDS).



→ The next wave of public consultations will be in **Sept-Oct 2025**

2. TEHDAS2 Documents for public consultation on September 30th, 2025



2nd Wave: Processes to manage permits or data pseudonymisation | SEP-OKT 2025

MS/D	Description
4.1	Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation
5.2	Draft guideline for Health Data Access Bodies on minimum categories and limitations on the reuse of health data
6.1	Draft guideline for data holders on making personal and non-personal electronic health data available for reuse
6.3	Draft guideline for Health Data Access Bodies on the procedures and formats for data access
6.4	Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies
7.2	Guideline for Health Data Access Bodies on data minimisation, pseudonymisation, anonymisation and synthetic data
7.3	Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure
7.4	Draft technical specification for Health Data Access Bodies on the implementation of secure processing environments
8.1	Draft guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data
8.1	Draft guideline for Health Data Access Bodies on implementing the obligation of notifying the natural person on a significant finding from the secondary use of health data

2. TEHDAS2 Online-Workshop-Serie 15.09.-01.10.2025

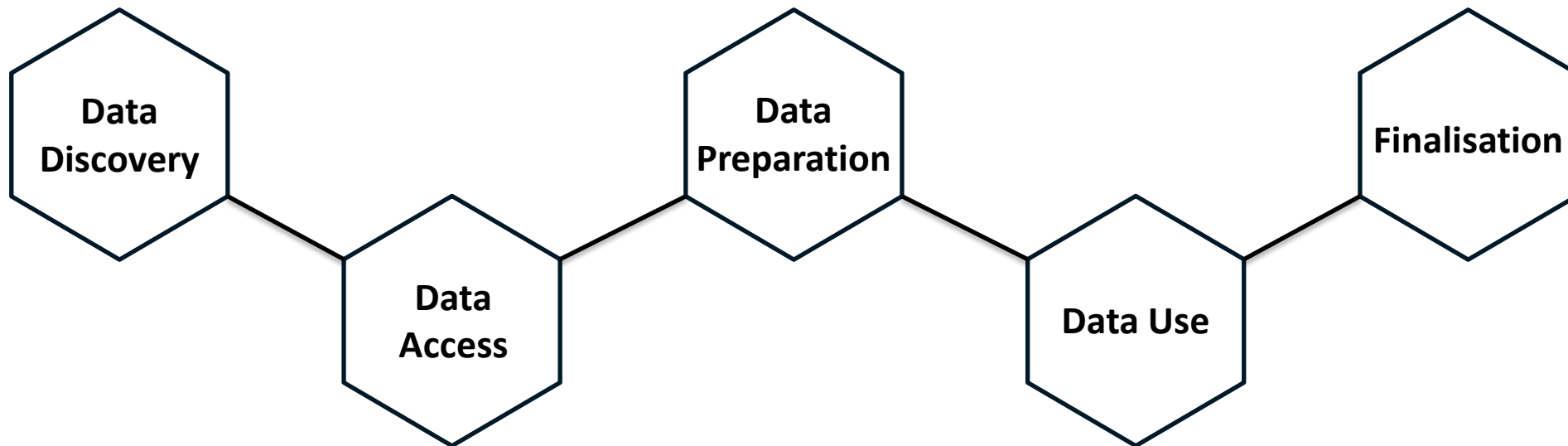


Date	Workshop
Sep 15th, 2025	5.2 Draft guideline for Health Data Access Bodies on minimum categories and limitations on the reuse of health data, <i>Dr. Anna Niemeyer (TMF e. V., Germany)</i>
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Sep 18th, 2025	6.1: Draft guideline for data holders on making personal and non-personal electronic health data available for reuse, <i>Marije van Melle (Nictiz, Netherlands)</i>
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Sep 25th, 2025	6.4: Draft Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies, <i>Dr. Ana Mužinić, Ph.D (Bundesinstitut für Arzneimittel und Medizinprodukte BfArM, Germany)</i>
Sep 26th, 2025	7.3: Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure, <i>Amélie Schäfer (Health Data Hub, France)</i>
Sep 29th, 2025	7.4: Draft technical specification for Health Data Access Bodies on the implementation of secure processing environments, <i>Heikki Lehväslaihi (CSC - IT Center for Science, Finland)</i>
Sep 30th, 2025	8.1.2: Draft guideline for Health Data Access Bodies on implementing the obligation of notifying the natural person on a significant finding from the secondary use of health data, <i>Dr. Gergely Mikešy (Semmelweis University Health Services Management Training Centre, Hungary)</i>
Oct 1st, 2025	4.1: Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation, <i>Pia Brinkmann (Bundesinstitut für Arzneimittel und Medizinprodukte BfArM, Germany)</i>

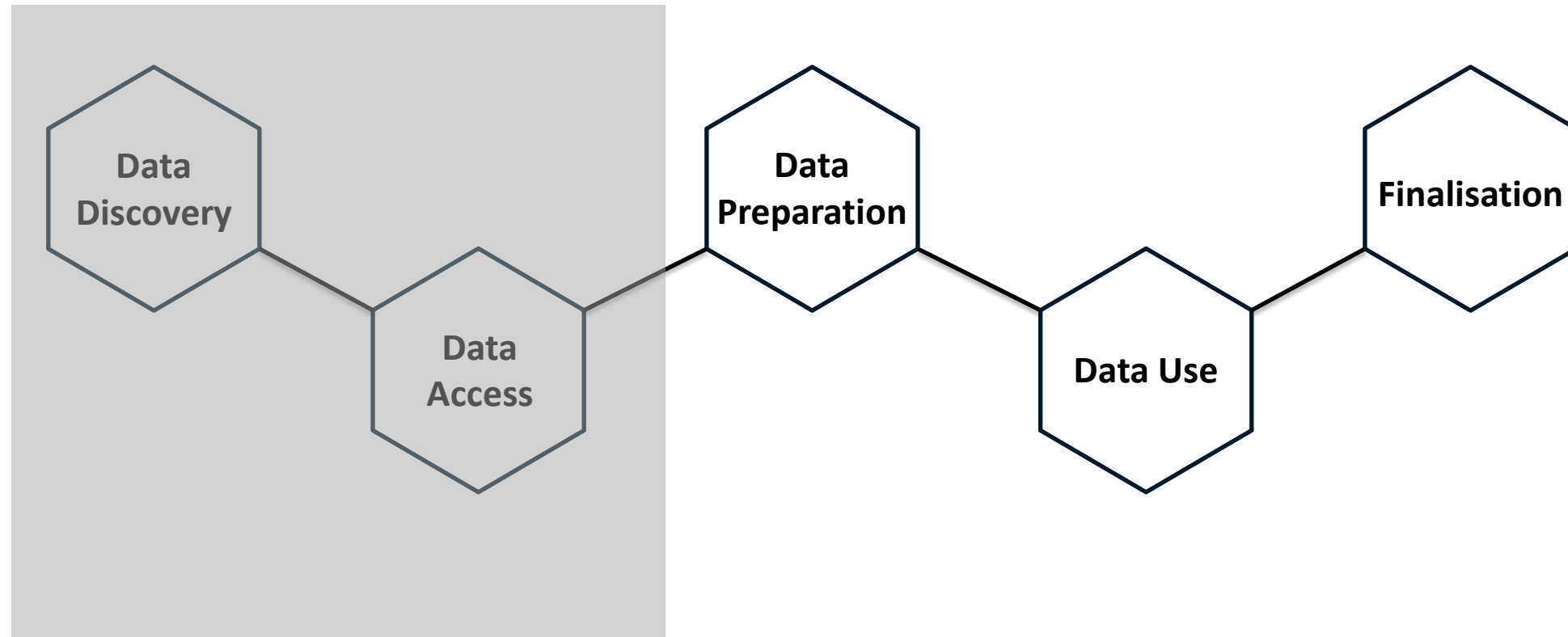
Mehr Information & Anmeldung: <https://www.tmf-ev.de/news/ehds-oeffentliche-konsultationen-starten-im-herbst>

3. Presenting today's document: **Draft Guideline on data minimisation, pseudonymisation, anonymisation and synthetic data (7.2)**

3.1



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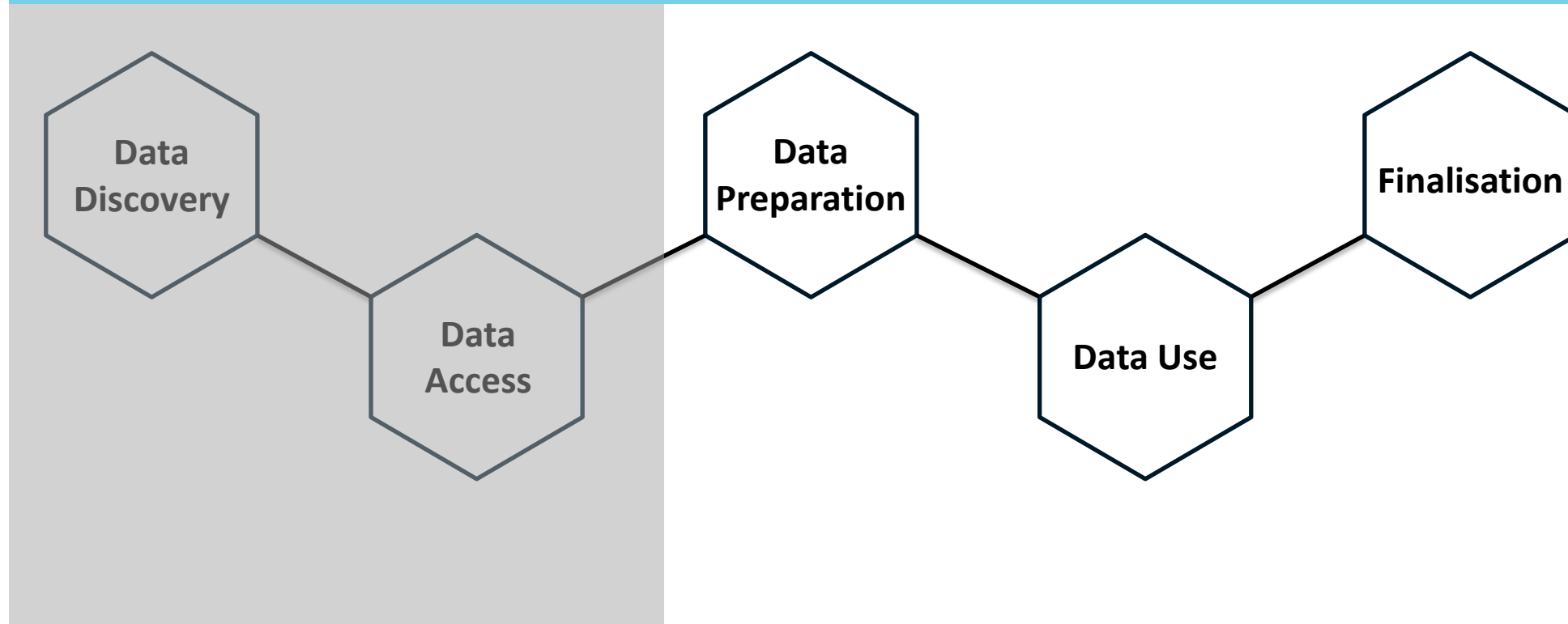


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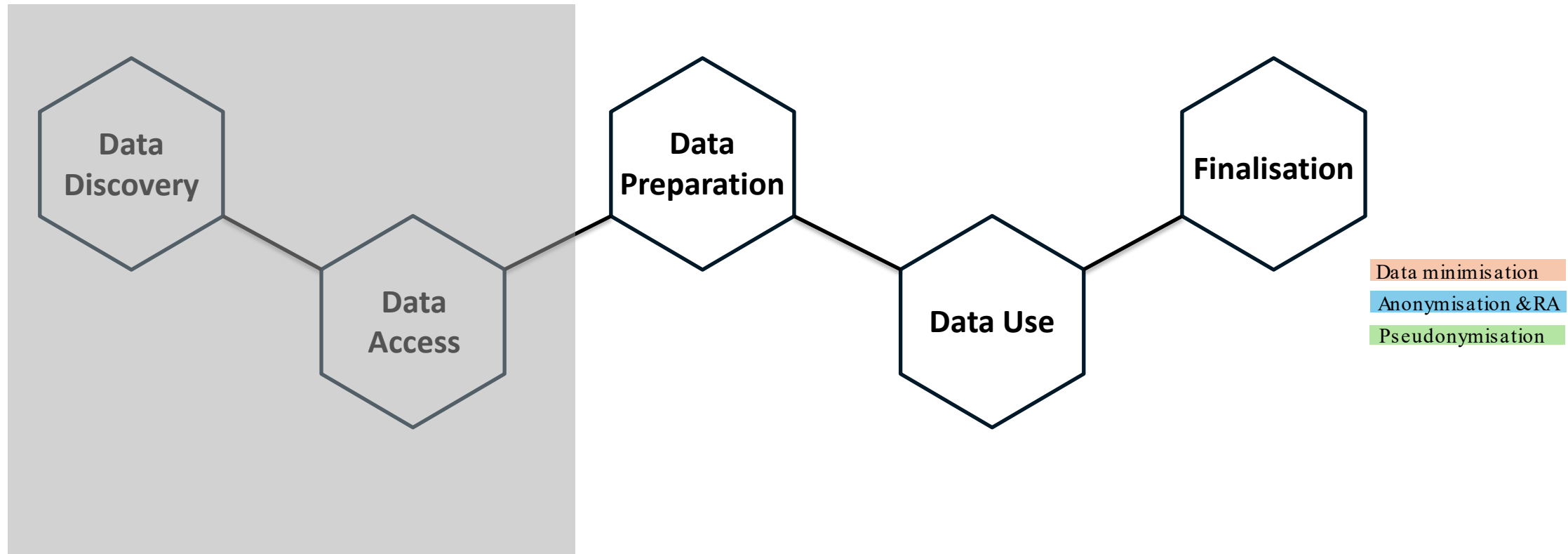
Data user – Gesundheitsdatennutzer (Art. 2(u), EHDS)

Data holder (DH) – Gesundheitsdateninhaber (Art. 2(t), EHDS)

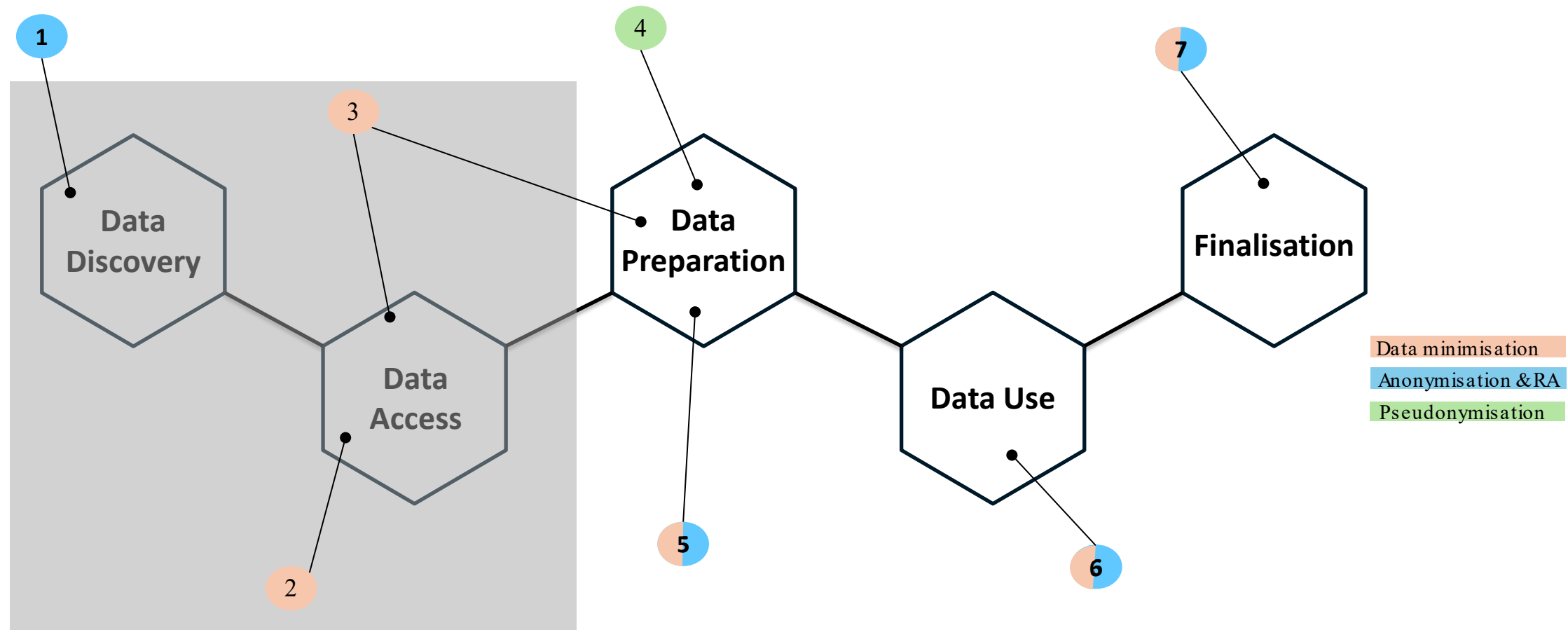
Health data access body (HDAB) – Zugangsstellen für Gesundheitsdaten (Art. 58, EHDS)



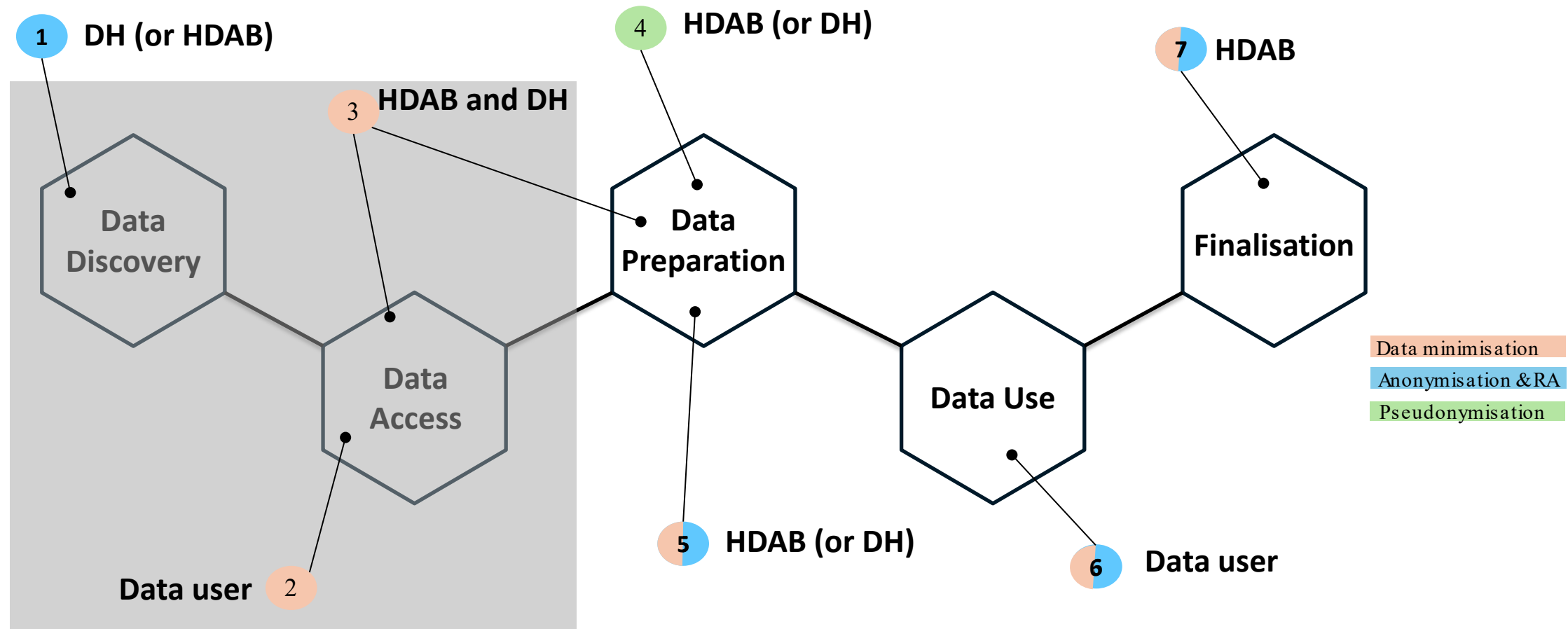
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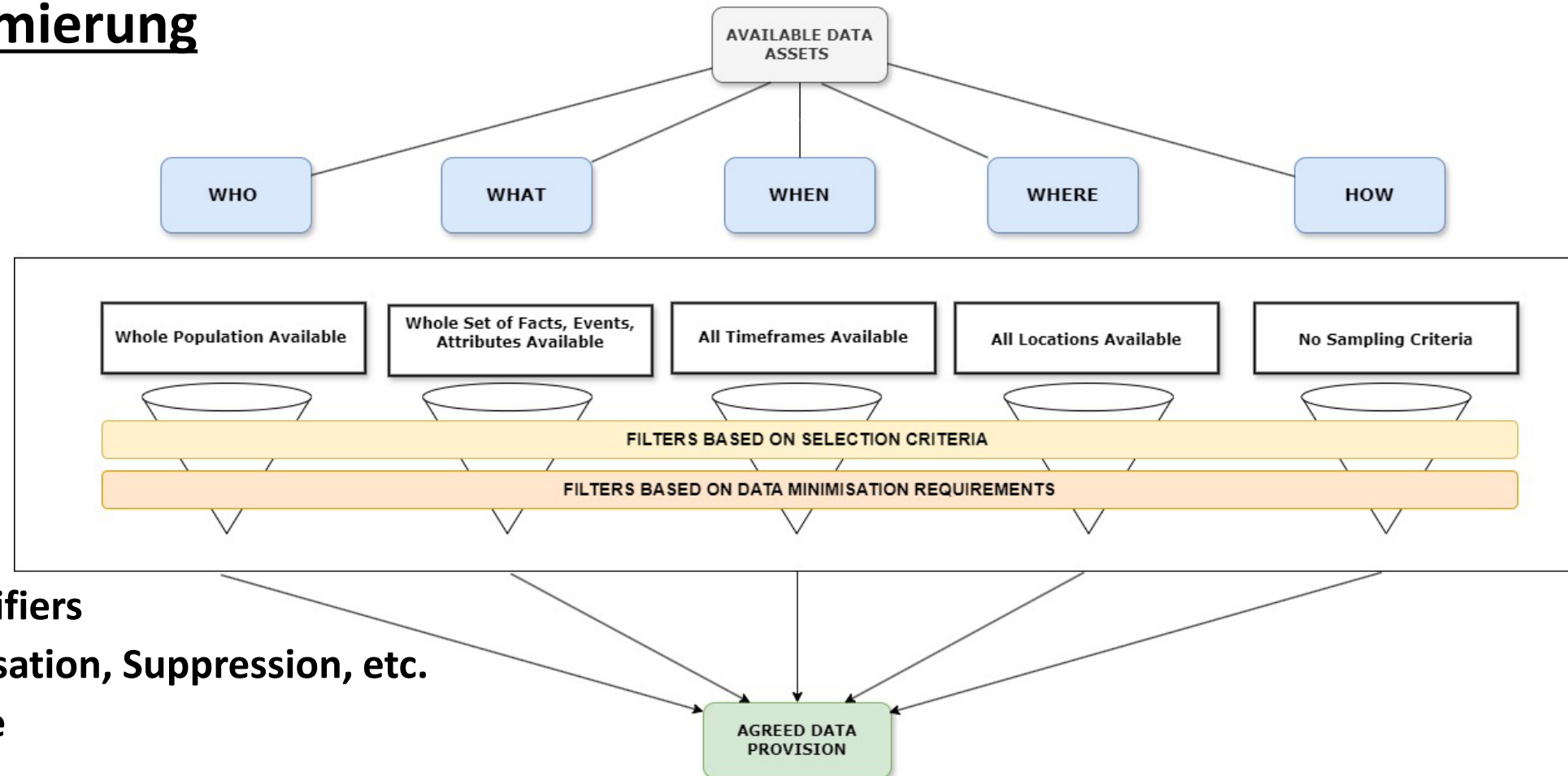


Datenminimierung

- GDPR (Art. 5(1)(c))
- Data minimisation and purpose limitation (Art. 66, EHDS)
 - Anonymised data – if sufficiently justified = pseudonymised data
 - information necessary to reverse the pseudonymisation shall be available only to the health data access body or an entity that acts as a trusted third party in accordance with national law

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Datenminimierung

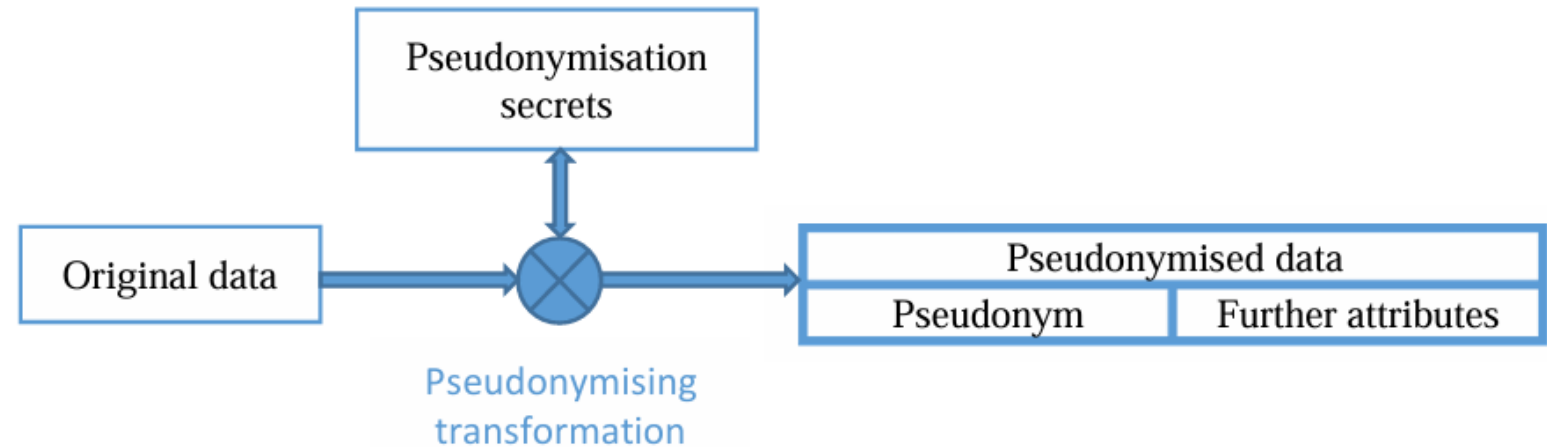


- **Quasi-identifiers**
 - Generalisation, Suppression, etc.
- **Data linkage**

3. Presenting today's document: **Draft Guideline on data minimisation, pseudonymisation, anonymisation and synthetic data (7.2)**

Pseudonymisierung

- EDPB Guideline 01/2025



- Data discovery – hasPersonalData
- Data access – utility & identifiers
- Data preparation – adequacy of the process
- Data linkage
- Pseudonymisation techniques:
 - Lookup tables/Cryptographical functions
 - = reversible!

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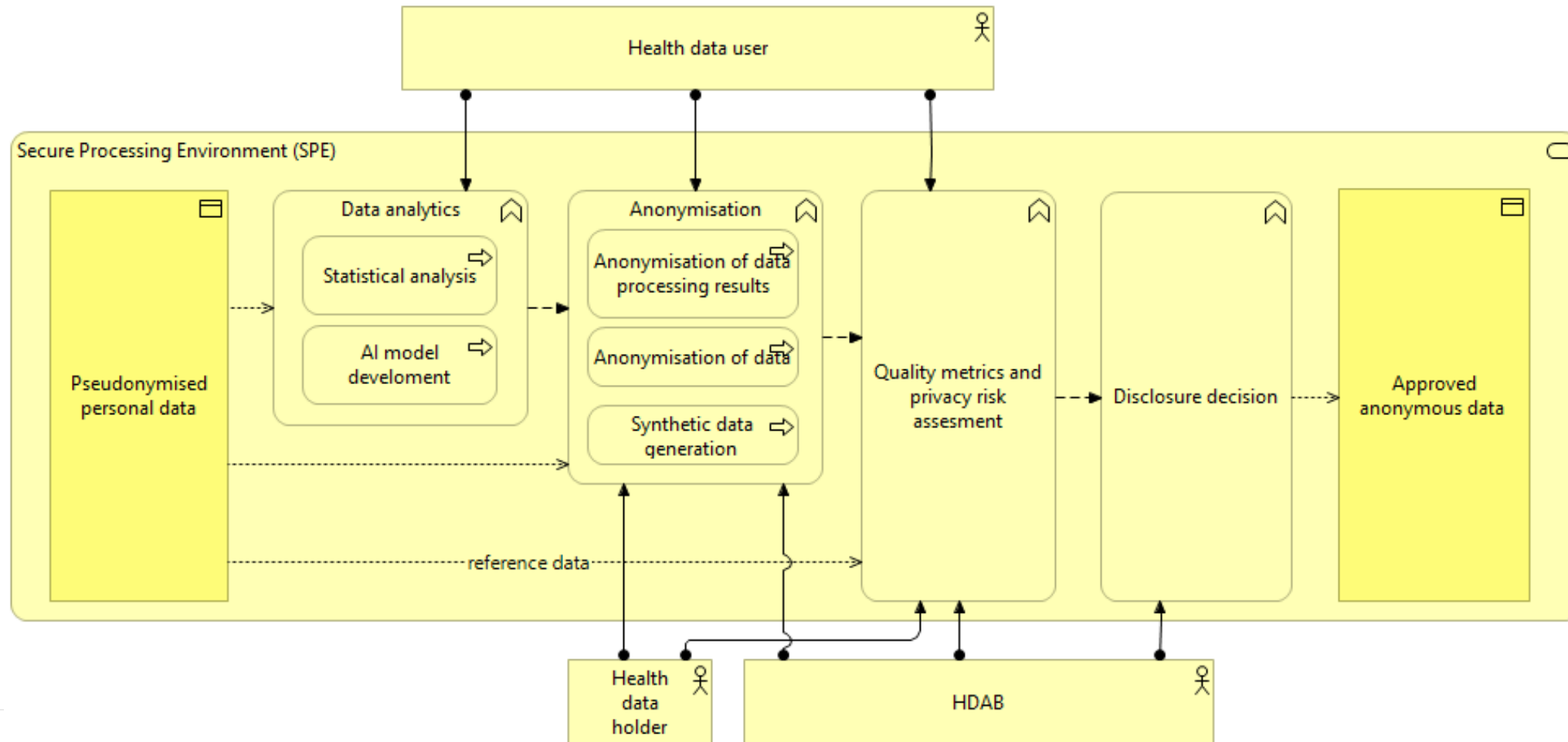


Anonymisierung & synthetic data generation

- **Protect personal data**
- **Anonymisation → modifies personal data**
- **Synthetic data → creates new data, (possibly) based on personal data**
- **Shared goal → adequate guidance to determine whether data are sufficiently anonymised**
- **Responsibilities are shared between HDAB and data user!**

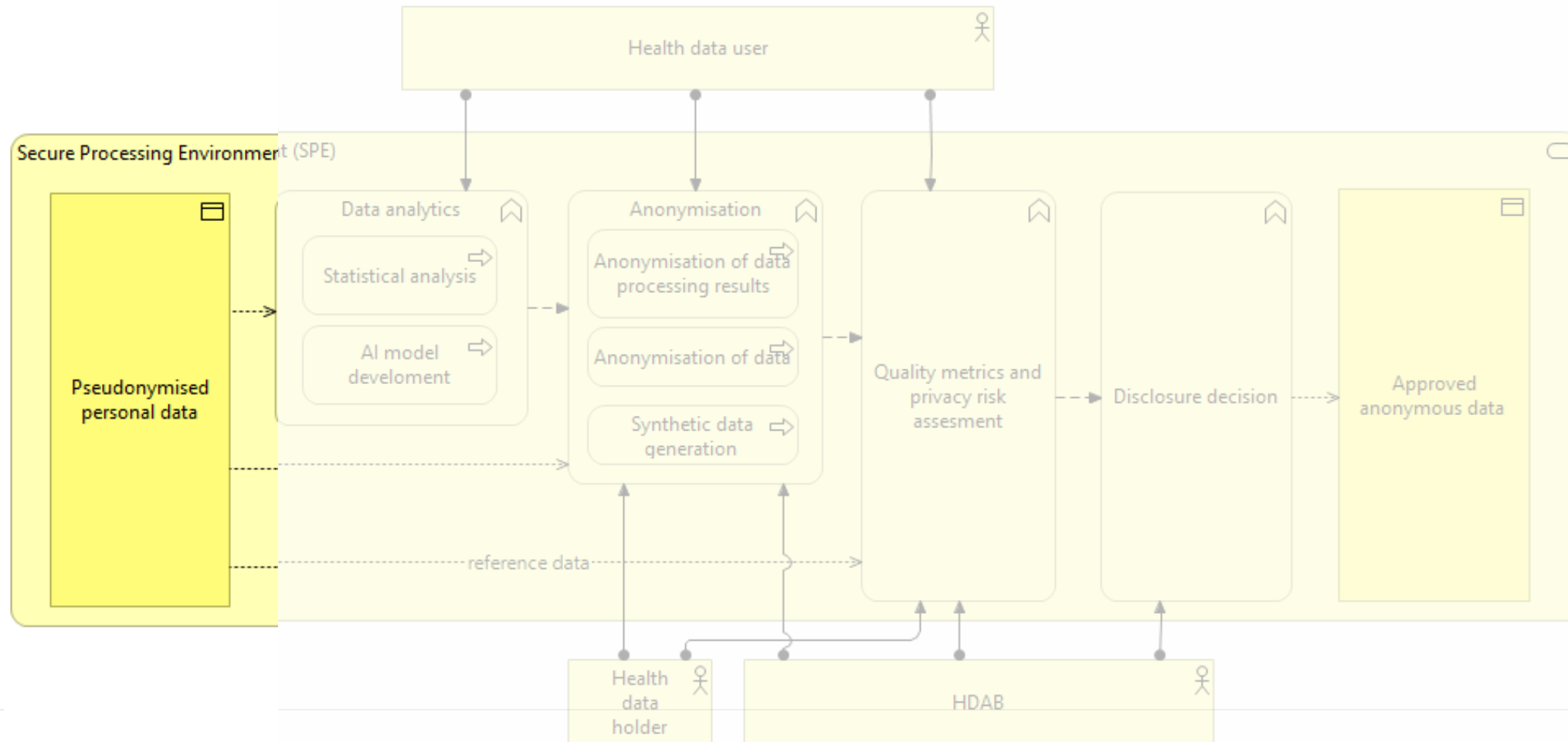
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Anonymisierung & synthetic data generation



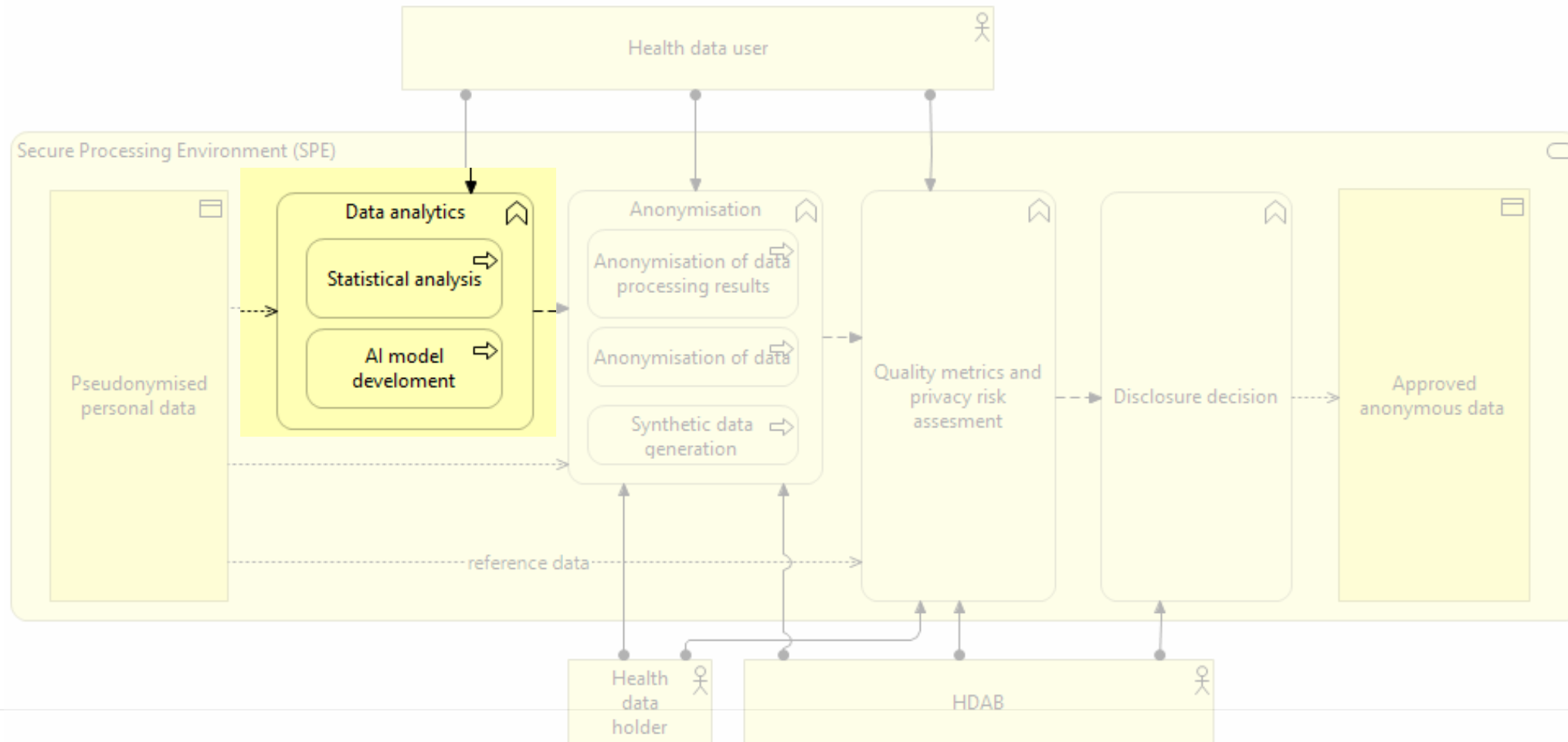
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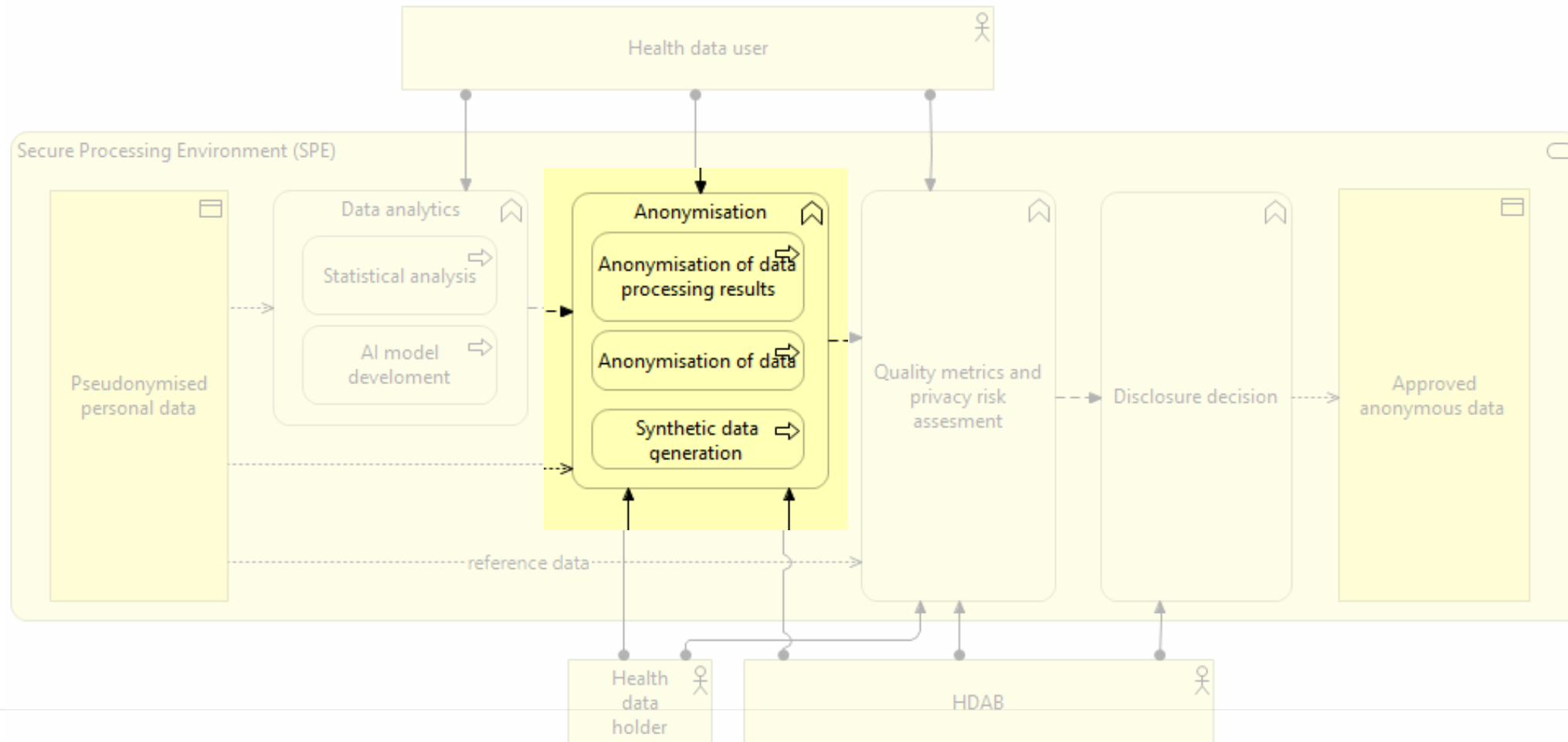
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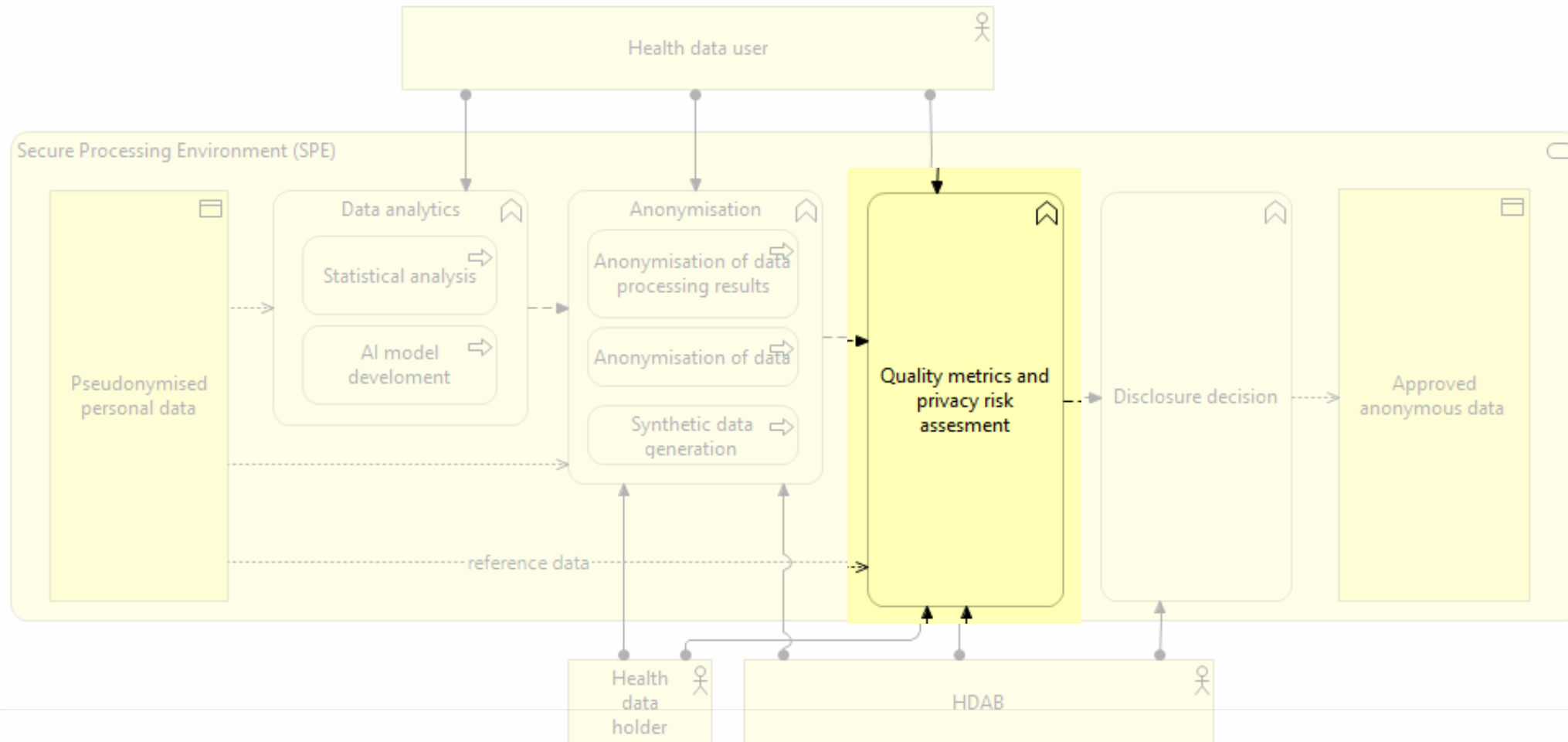
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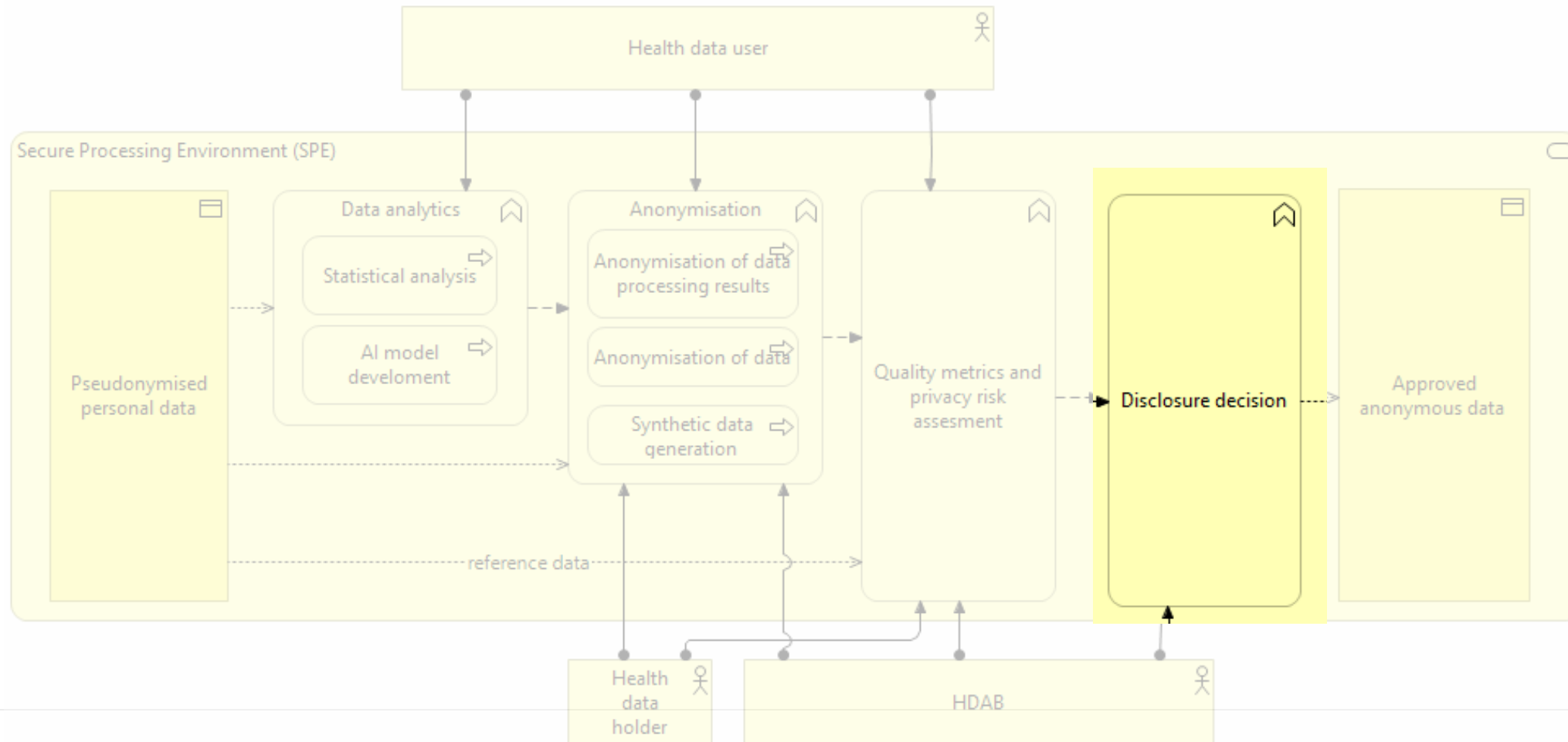
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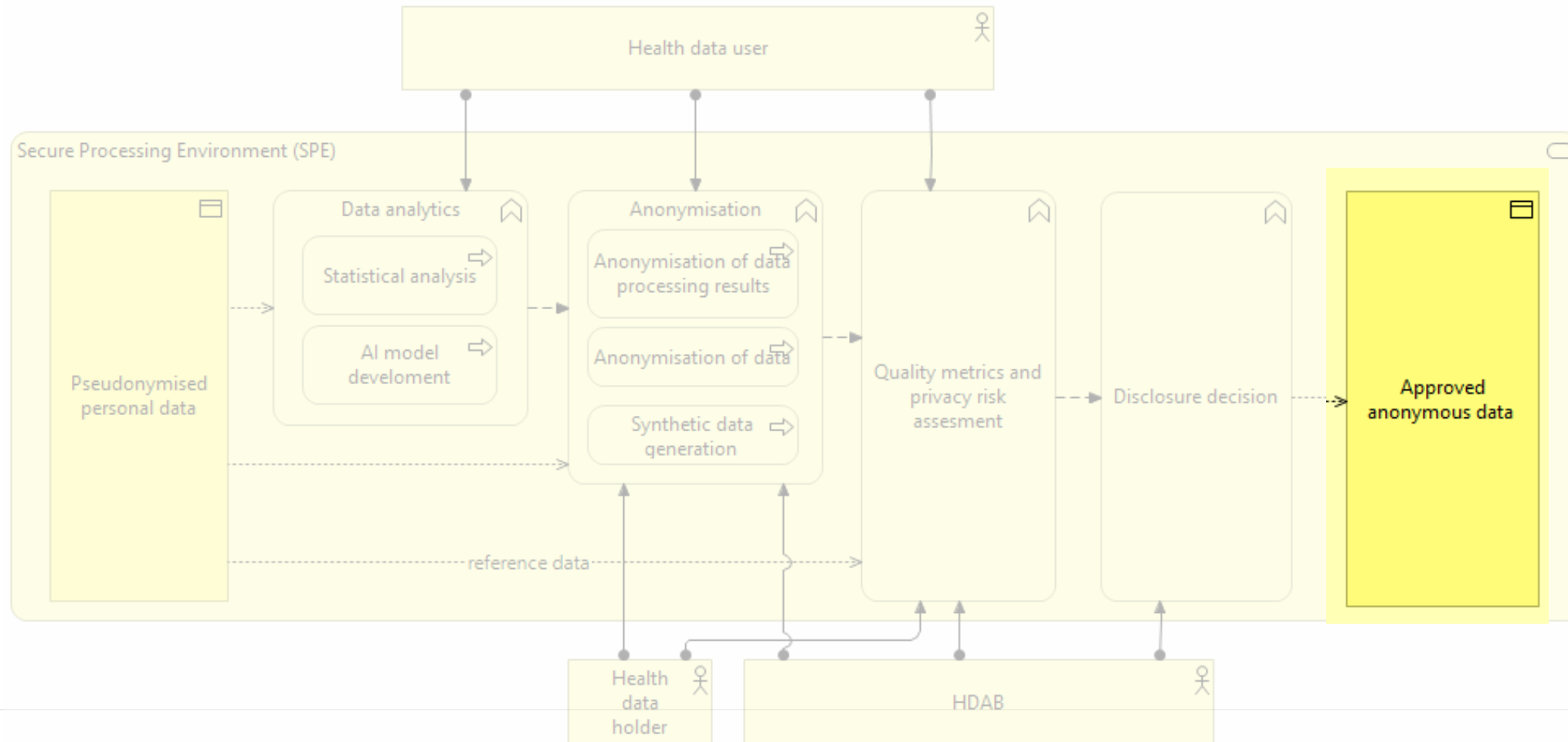
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3.3 Critical points – public consultation questions

- Does the guideline clarify when and by whom **data minimisation** should be performed throughout the data lifecycle (data collection, application assessment, data processing and result export)?
- How practical are the recommendations for identifying and managing direct and **indirect/quasi-identifiers** in line with **data minimisation** principles, particularly regarding the trade-off between reducing privacy risks and maintaining data utility?
- Does the guideline provide adequate detail and recommendations on the practical implementation of **pseudonymisation transformations**?
- Does the guideline adequately describe how **anonymisation and synthetic data generation** can be applied within the EHDS?

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3.4 Who should comment?

- **HDABs**
- **Data user**
- **Data holder**
- **Data protection officers**
- **Anyone interested**

4. Q&A



5. Save the date: Next workshops



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More information & registration: <https://www.tmf-ev.de/news/ehds-oeffentliche-konsultationen-starten-im-herbst>

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