Forum Health Data & Digitalisation

26/09/2025

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ASSOCIATION GÉNÉRALE DE L'INDUSTRIE DU MÉDICAMENT
ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

WELCOME

Caroline Ven, CEO, pharma.be

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ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

AGENDA

10h	welcome Caroline Ven
10:15-10:45	Evidence generation with real world data in Belgium: lessons learned (Katoo Muylle & Bart Verheyden, Astrazeneca)
10:45-11:15	MOOD: Major Opportunity On Depression (David Smeets & Elke Peeters, Johnson & Johnson)
11:15-11:45	coffee break
11:45-12:15	Dr. EPD: the power of medical text (Bram De Caluwé, AZ Klina)
12:15-12:45	Learnings from RWD/E pilots in Belgium to support decision-making (Ingrid Maes, innovigate)
12:45-13:45	lunch
13:45-14:15	The societal cost of breast cancer: Using real-world data to assess the short- and long-term impact of diagnosis in Belgium (Eva kimpe & prof Koen Putman, VUB)
14:15-14:45	INVENTS - pharma-academia collaboration and data sharing via the French Health Data Hub - the Roche perspective (David Pau and Claire Castagne, Roche)
14:45-15:15	Integration through the telemedicine platform in practice (Tim Bogaert, Byteflies)
15:30-16:30	closing & drinks

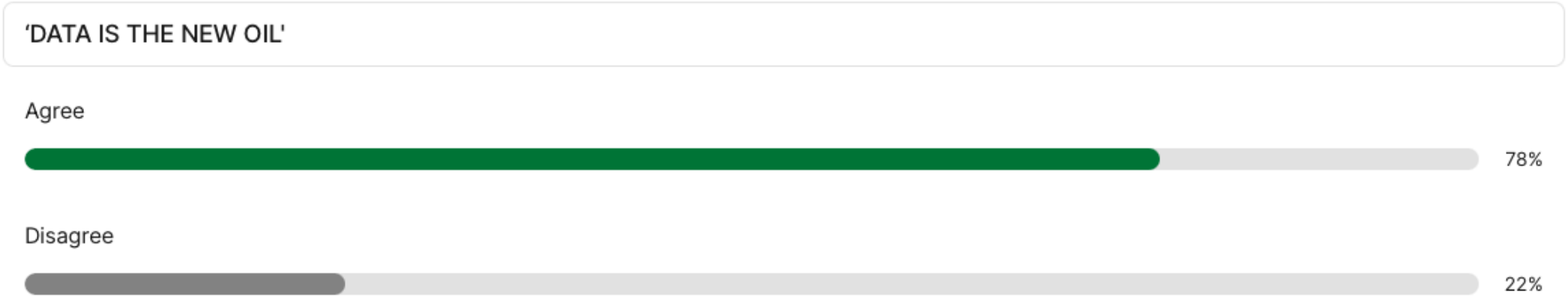
Evidence Generation with Real World Data in Belgium: Lessons Learned

Bart Verheyden & Katoo Muylle

NS ID BE-3987-Revision date 10/2025-LB
Local code: 1958

‘DATA IS THE NEW OIL'

67 votes



Data is the new oil?

Highly valuable resource

Driver for (economic) growth

Processing needed to bring value

…

Ownership

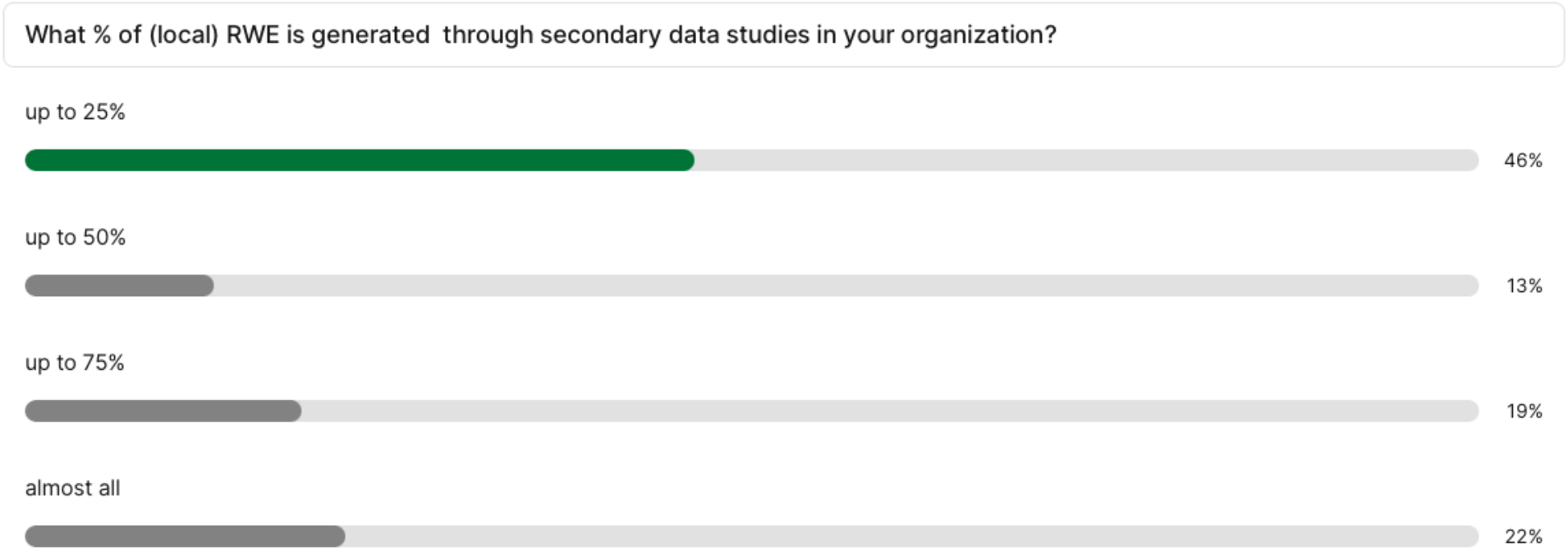
Infinite resource

Unlimited re-use (FAIR)

…

What % of (local) RWE is generated through secondary data studies in your organization?

54 votes



Shift from primary data collection towards secondary data studies for local RWE generation

2020

>75% primary

CRO
Observational, prospective
Dozens of patients
Mostly single-center
CRF-based, centralized

Timelines ↓
Impact ↑
Cost-efficiency ↑

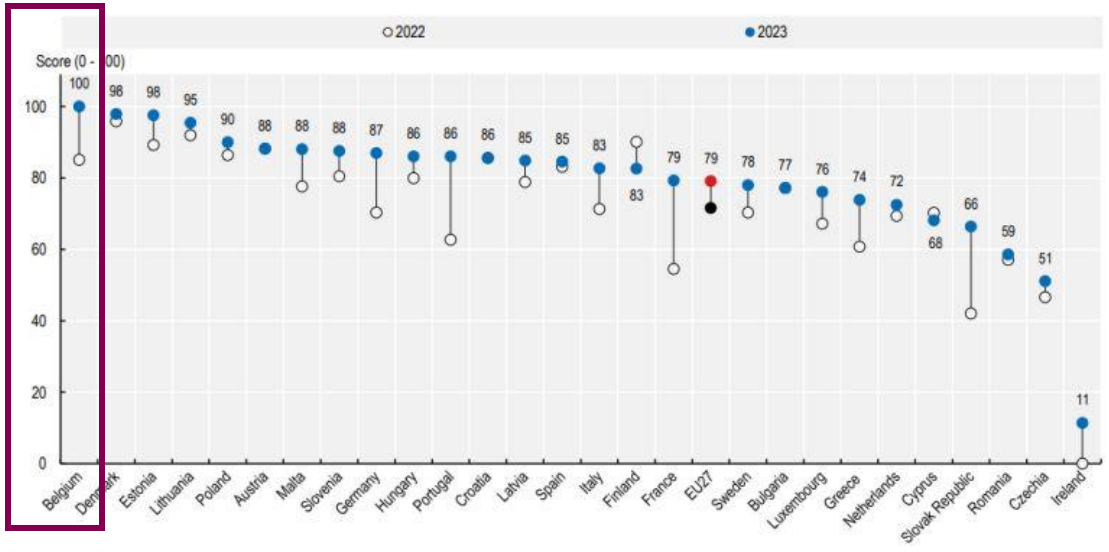
2025

>75% secondary

Data-partnerships
Retrospective, 2nd data
Thousands of patients
Mostly multi-center
OMOP-based, federated

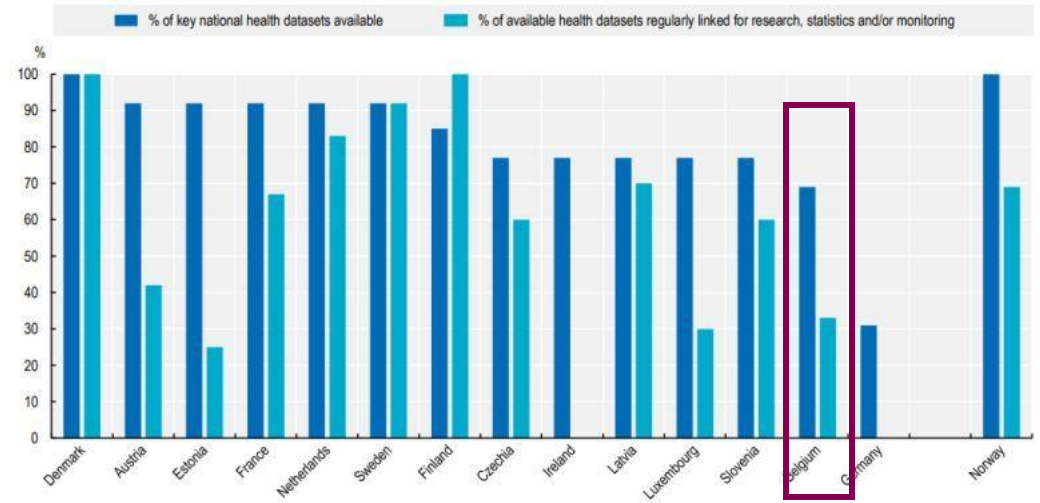
BE is frontrunner in health-data digitalization, but the full potential for real-world research is not yet reached

Figure 8.11. Access to electronic health records, 2022 and 2023



Source: European Commission (2024[1]), *Digital Economy and Society Index (DESI)*.

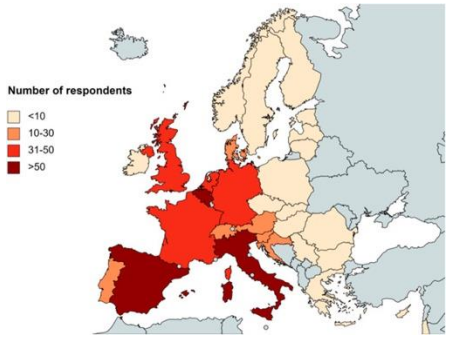
Figure 8.12. Percentage of key national health datasets available and regularly linked for monitoring and research, 2019-20

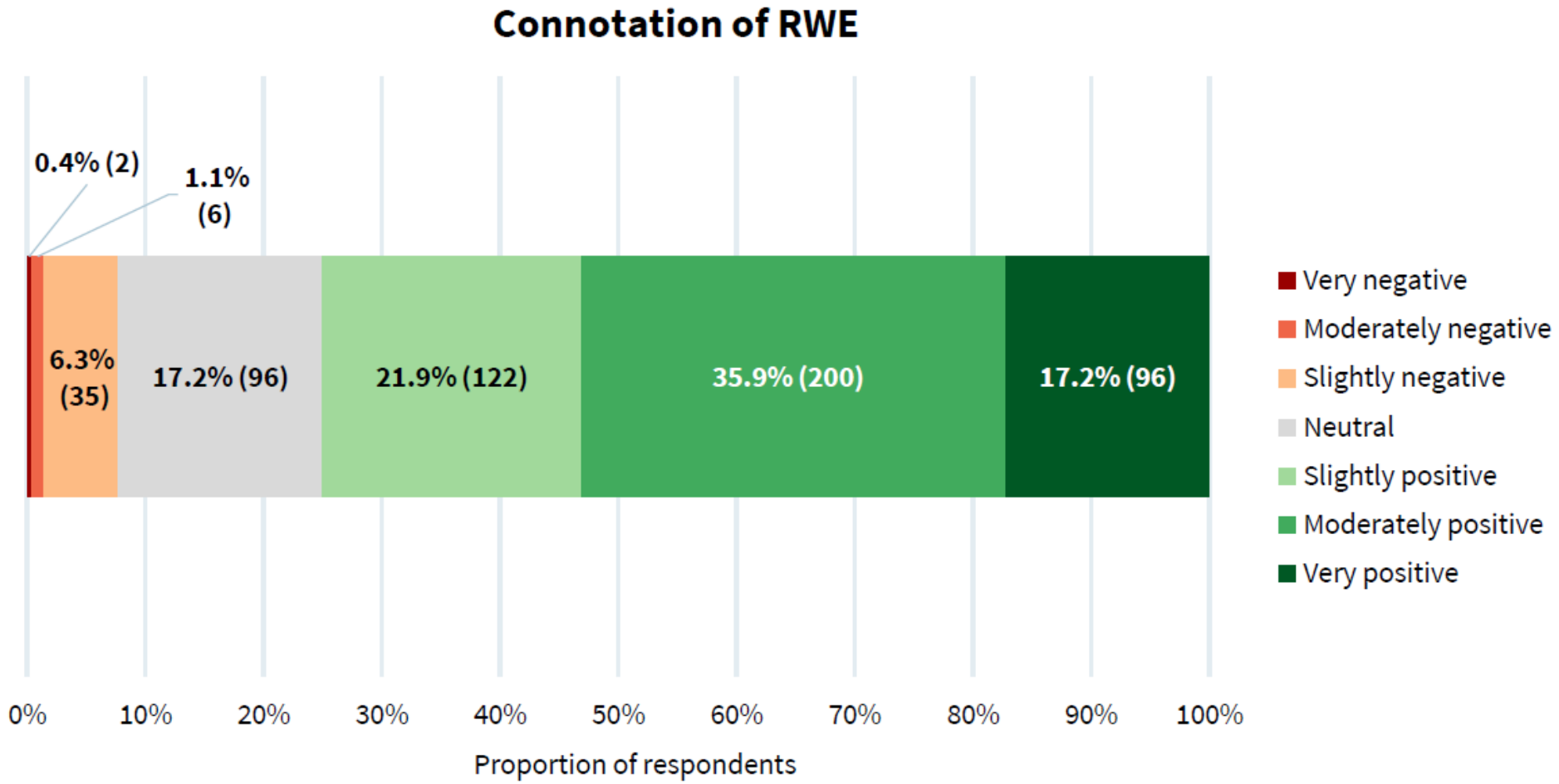


Source: Oderkirk (2021[4]), *Survey results: National health data infrastructure and governance*, https://doi.org/10.1787/55d24b5d-en.

Source: Health at a Glance, Europe 2025 (OECD - (Organisation for Economic Co-operation and Development)

Over 70% of cancer clinicians have positive opinions about RWE

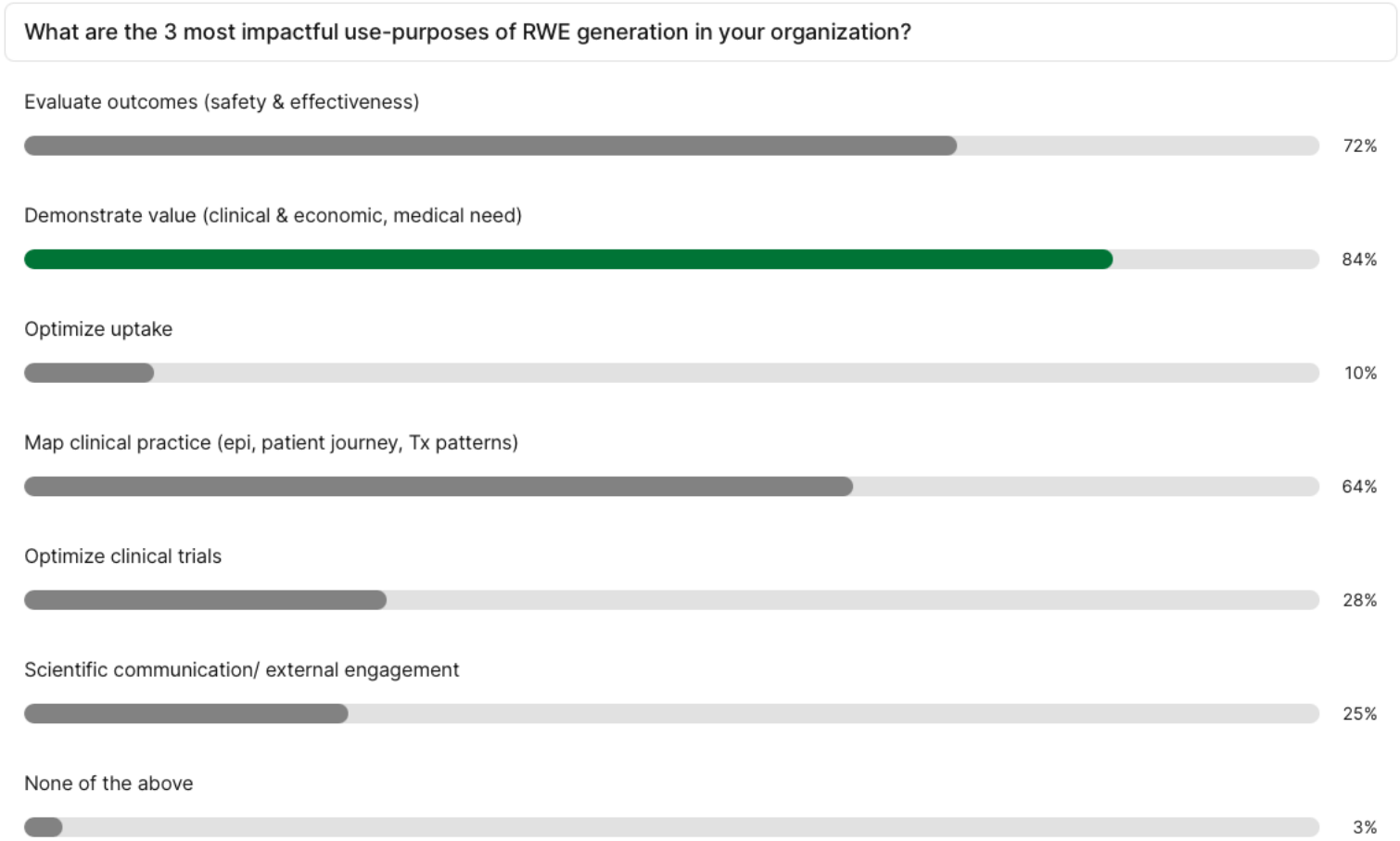




R. Saesens et al. How do cancer clinicians perceive real-world data and the evidence derived therefrom? Findings from an international survey of the European Organisation for Research and Treatment of Cancer. Front Pharmacol. 2022 Aug 24:13:969778

What are the 3 most impactful use-purposes of RWE generation in your organization?

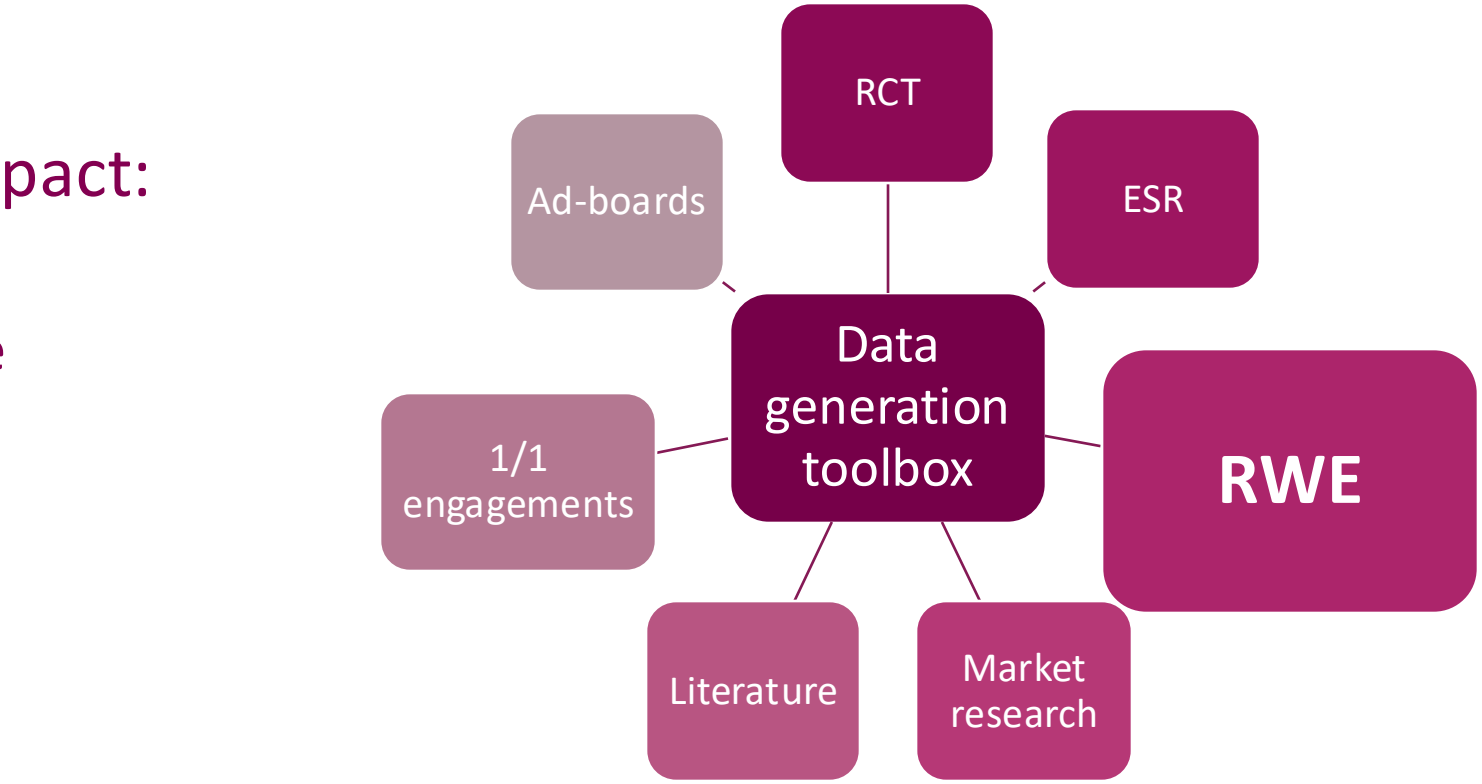
61 votes



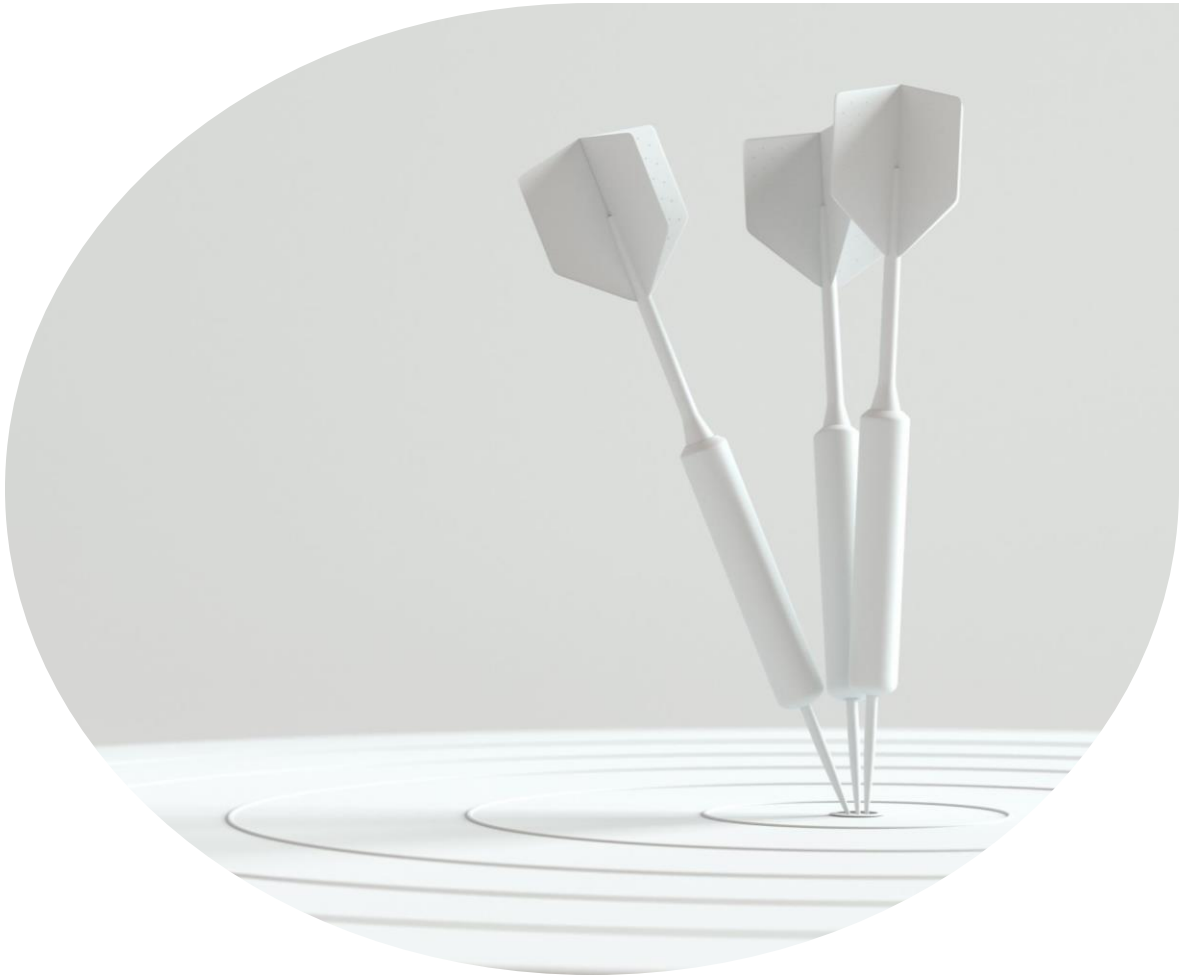
RWE impact does not depend on the use-purpose but rather on how (fit-for-purpose) it is integrated in strategic planning

Factors determining impact:

- Evidence gap
- Product life cycle phase
- Treatment landscape
- …



Our mission



Plan, generate and communicate fit-for-purpose local real-world evidence, complementary to the existing body of evidence and insights, aimed to maximize the impact of our therapies for all eligible patients

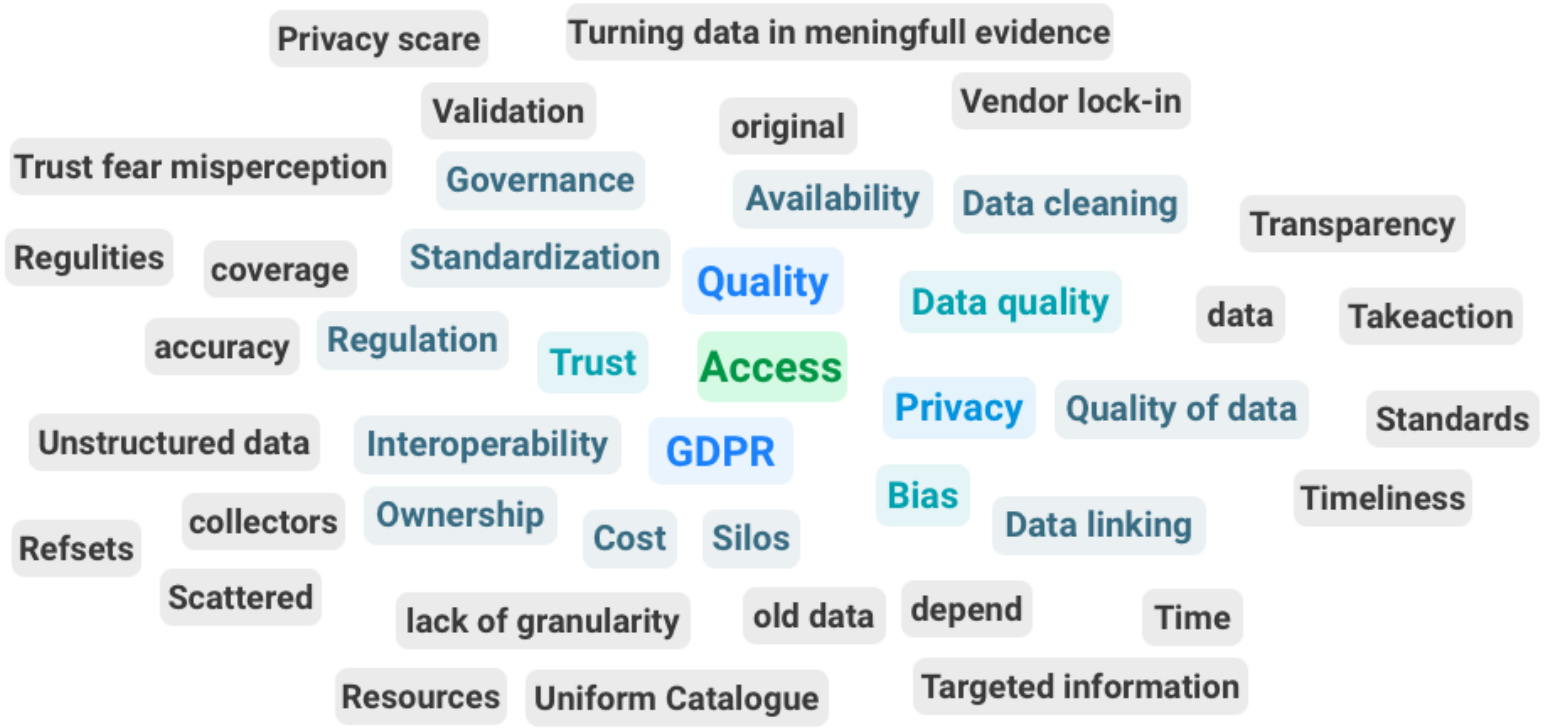
Key-challenges & lessons learned from secondary data studies

Slido: What are your key challenges for RWE generation with secondary data studies?

61 votes

What are key challenges with the secondary use of health data for RWE generation?

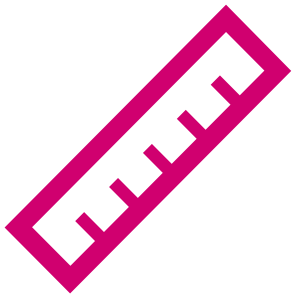
Review answers 90 >



Key challenges for evidence generation with RWD

Collaboration model

Data quality

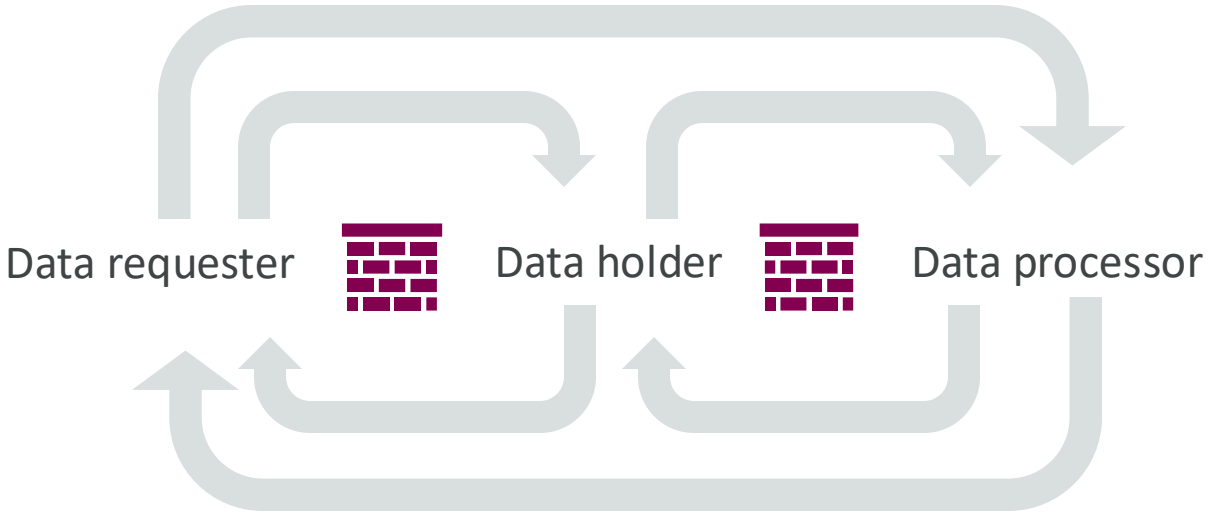


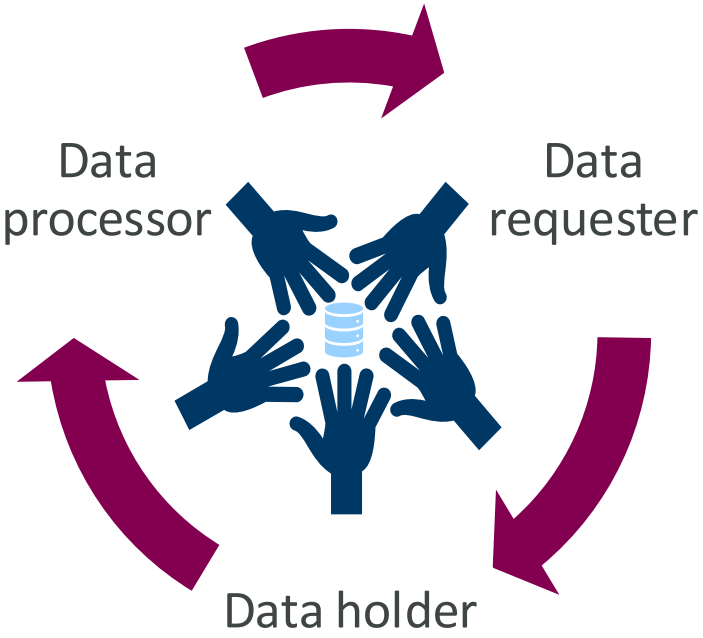
Scalability

Collaboration model

Moving towards an efficient collaboration model

From transactional relationship towards **trusted data partnership**





Working in silos
Unclear roles and responsibilities
Long approval timelines
Misinterpretation

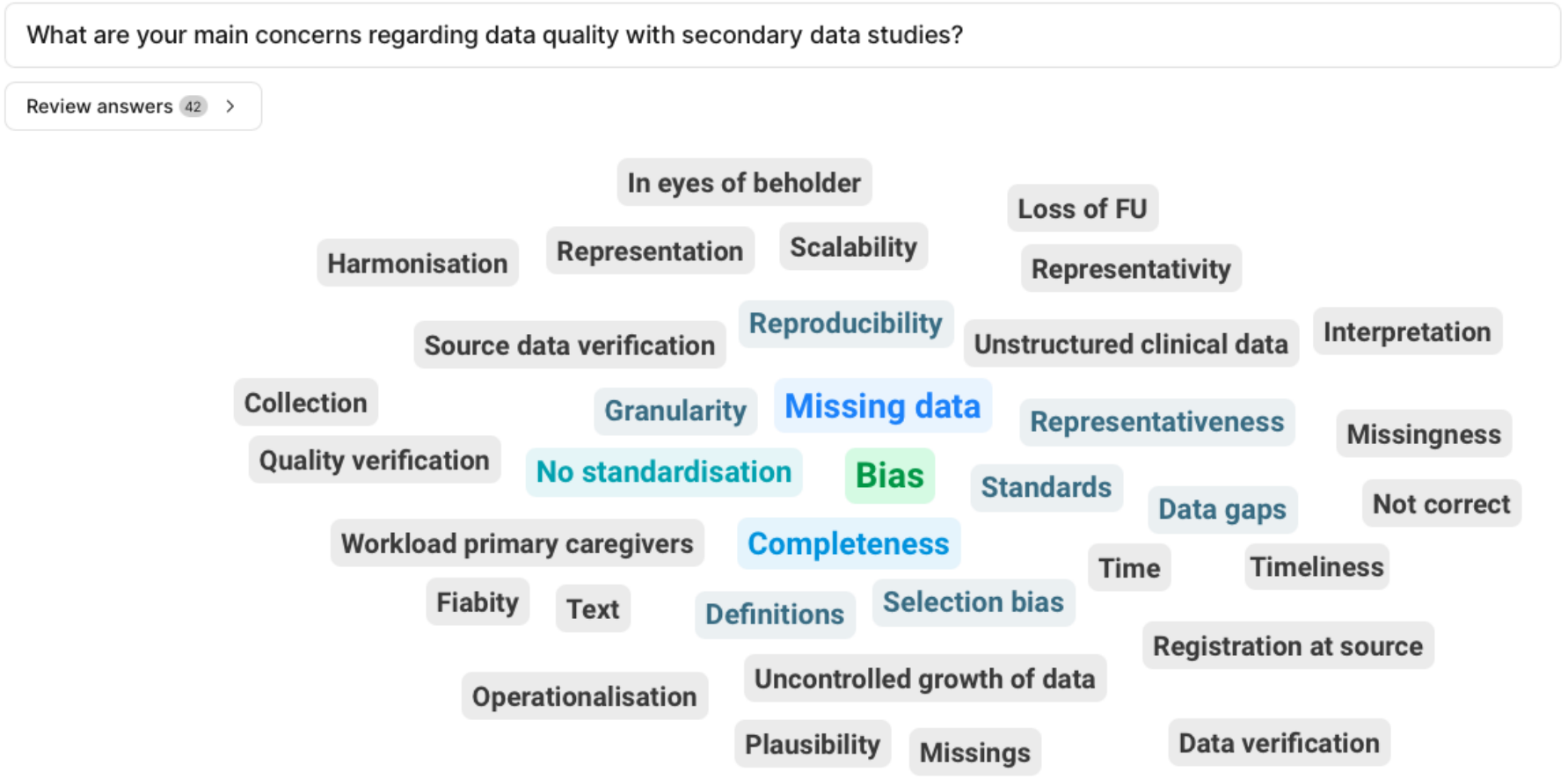
Exchange of expertise
Clear governance structure for RWD studies
Shorter timelines
Better data quality

EHDS as enabler

Data quality

Slido: What are your main concerns regarding data quality with secondary data studies?

44 votes



Data quality depends on the purpose

Fit-for-purpose data quality

Availability ≠ Access ≠ Quality

Progression is documented…

…in the clinical notes…

…mostly

Access to clinical notes?

NLP needed to unlock unstructured data?

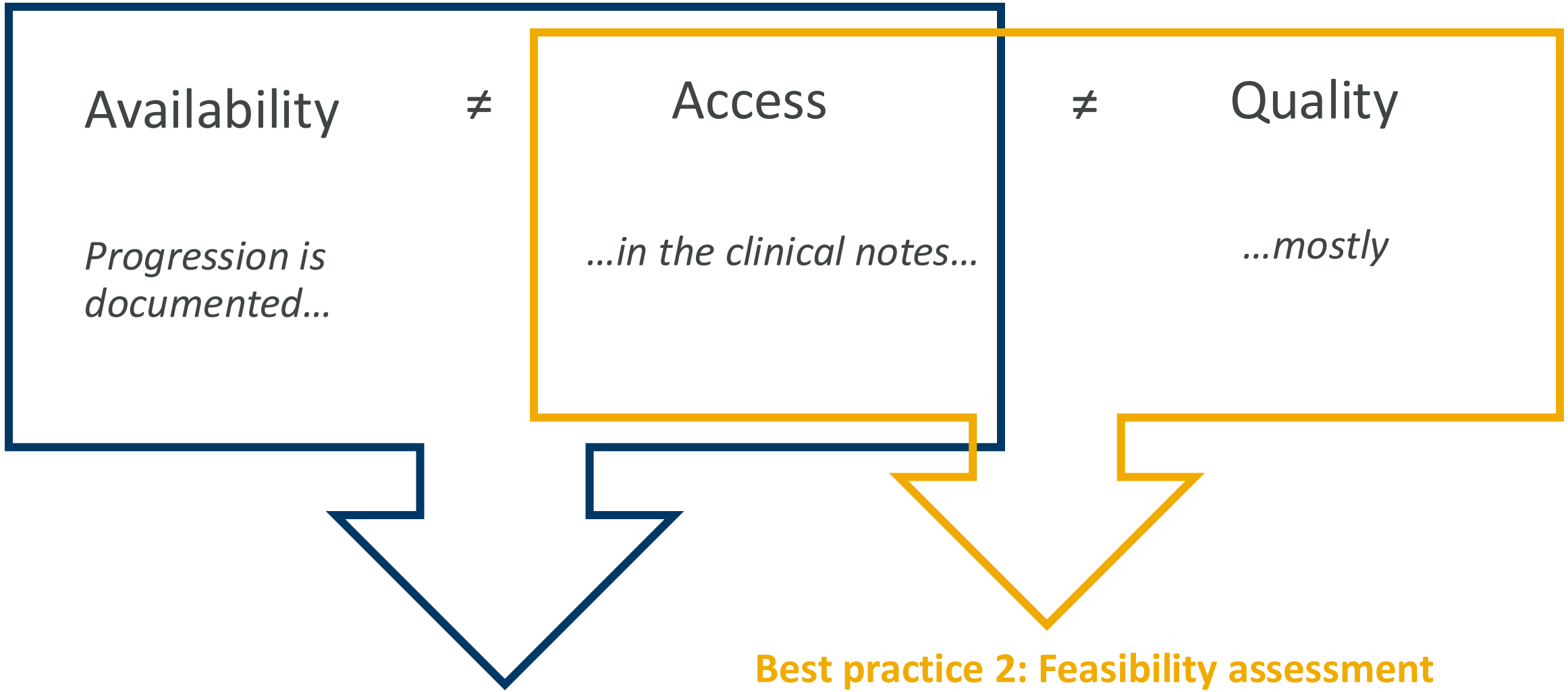
Completeness?

Consistency?

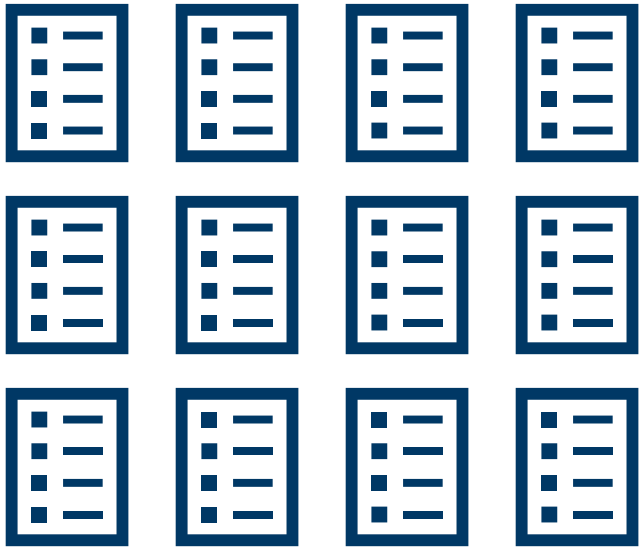
Accuracy?

…?

Fit-for-purpose data quality



Step 1.Data catalog



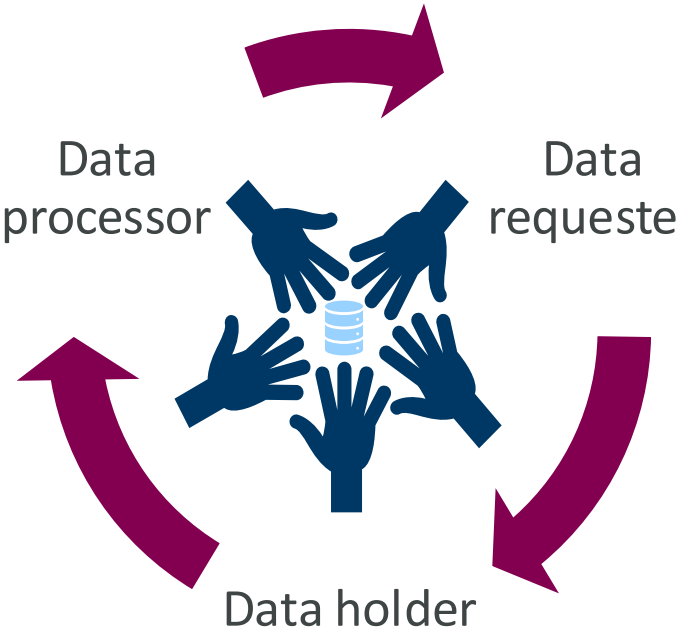
A data catalog is a library of datasets describing key metadata elements helping you to make **a first assessment whether a certain dataset is suitable for your purpose**

Step 2. Feasibility based on data dictionary

A data dictionary is already a study-specific document that contains operationalized data definitions, i.e., the technical translation of the research question(s) that gives you an **answer to fit-for-purpose data quality**

Expert validation to close the fit-for-purpose quality loop requires specific expertise

Technical validation and quality control



Validation of research objectives

Technical **and** medical validation

Link to data origins and clinical practice

Scalability

How to improve scalability

Availability ≠ Access ≠ Quality

Progression is documented…

…in the clinical notes…

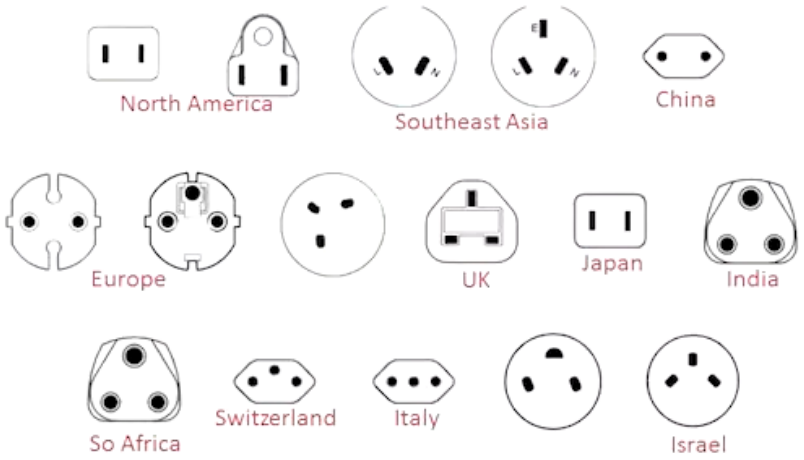
…mostly

Increase data availability and data access in more centers

1. OMOP common data model
2. Unlocking unstructured data

OMOP Common Data Model

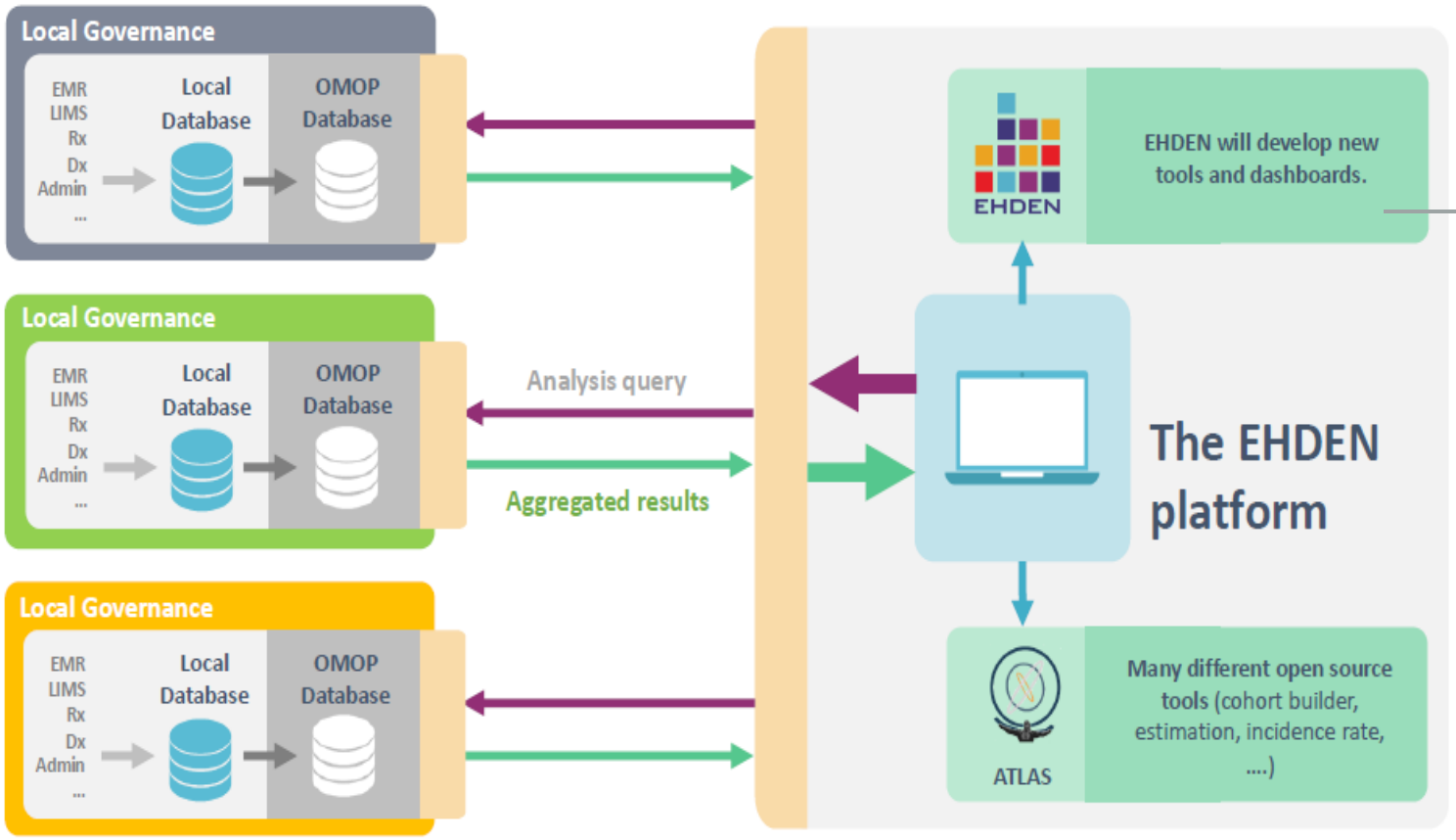
A CDM is a tool to help organize data from diverse data sources and settings into a common structure, format and terminology independent from a particular study to allow efficient data re-use



Data harmonization
(OMOPing)

https://ohdsi.github.io/TheBookOfOhdsi/

OMOP Common Data Model

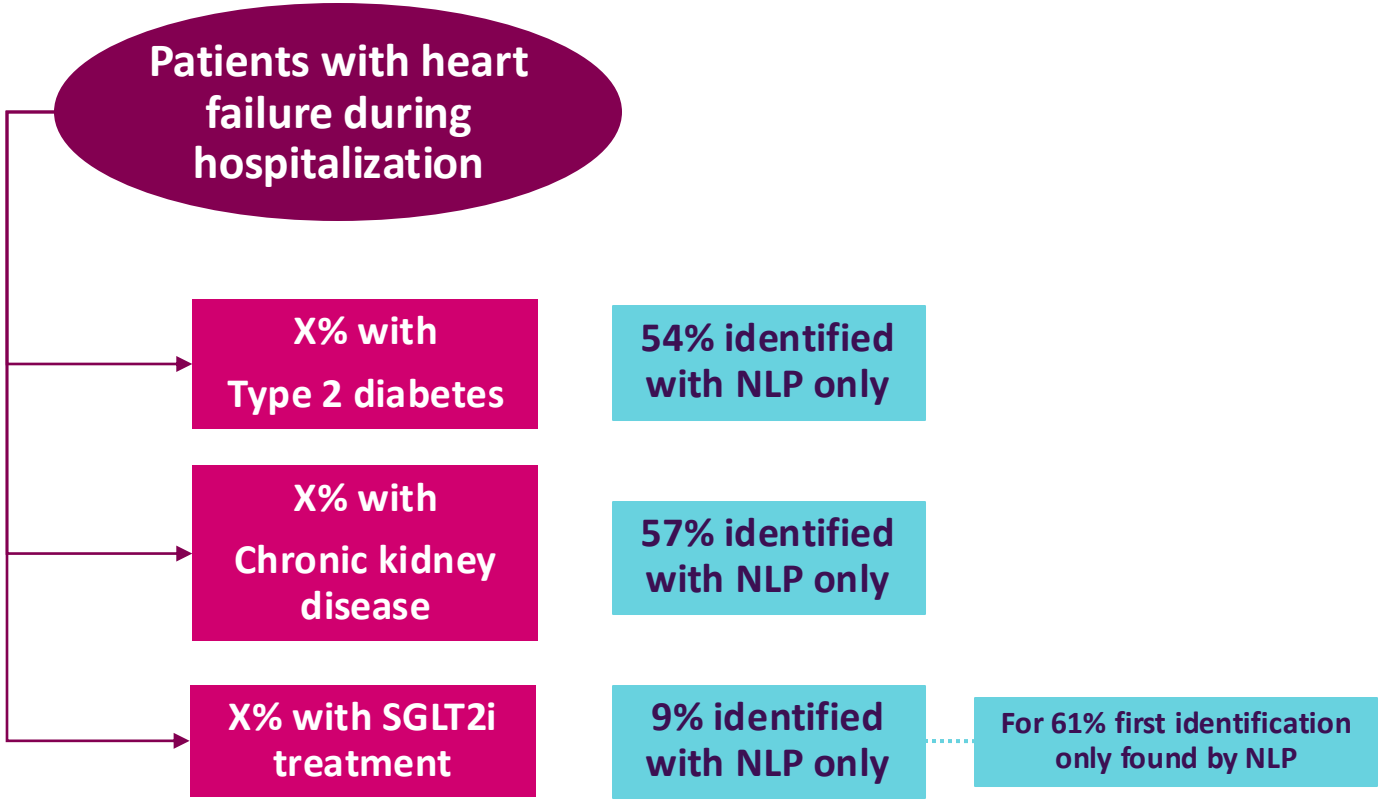


Remote (federated) analytics: collaboration while privacy preserving

Same standardized and validated open-source analytical tools can be reused leading to reliable RWE

https://ohdsi.github.io/TheBookOfOhdsi/

Unlocking unstructured data via natural language processing (NLP)



Without NLP technology, at least 50% of the patients in the subgroups would not have been identified

This raises questions about known versus unknown unknowns regarding data availability and access, reinforcing the importance of a thorough feasibility

Conclusions

1. Growing role for secondary use of data for RWE generation
2. Impact of RWE depends on level of integration in broader data strategy
3. With EHDS as enabler we can expect
   - More data partnerships & collaborations
   - Better fit-for-purpose data quality
   - Accelerated adoption of technology to scale

Thank you

Mood: Major Opportunity on Depression

David Smeets, Digital Health and Data Policy Manager, Johnson & Johnson

Elke Peeters, Medical Advisor Neuroscience, Johnson & Johnson

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MOOD project:

Major Opportunity On Depression

FORUM HEALTH DATA & DIGITALISATION
September 26th, 2025
Dr. Elke Peeters, Medical Advisor Neuroscience JNJ
David Smeets, Digital Health & Data Policy Manager

LYNXCARE
obasi partner in healthcare
Universitair Ziekenhuis Brussel
PSYCHIATRISCH CENTRUM ARIADNE
MARIA MIDDELARES

AGENDA

1. Introduction
2. Partners and Setup
3. MOOD Cohort
4. Next Step and Q&A

Introduction

MOOD Project: AI supported data collection

Scientific publications

Clinical study

INNOVATION

AI supported data collection and visualisation

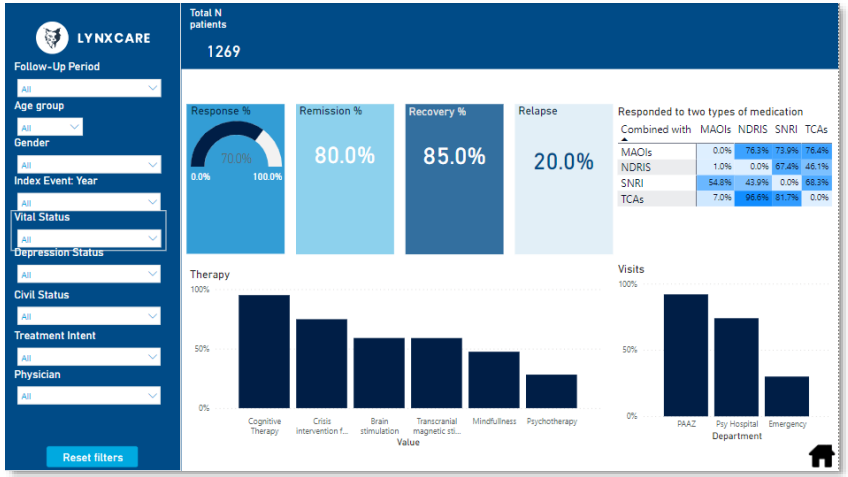
COLLECT

Structured Data

Unstructured Data: AI - NLP

ANALYZE/
VALIDATE

VISUALIZE

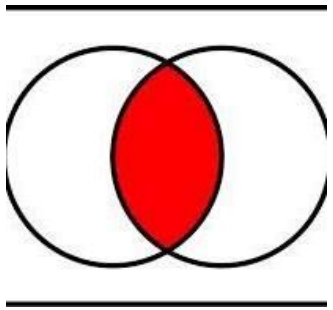


 AI: artificial intelligence; NLP: natural language processing

MOOD Project: AI supported data collection

Psychiatry service/Hospital:

- Systematisation of experience -> care optimisation
- Compare to benchmarks over other participating centers
- Use in research/publication
- Taking a head start in data collection and AI



Win - Win

Patient:

- Benefits from care optimization via
  experience based guidelines
  patient profiles to support treatment decisions
  quick advance in knowledge on new therapies

Pharmaceutical Company:

- Learnings on implementation new therapy -> optimisation
- Useful data for market access negotiations
- Define unmet needs for future research

Structural real-world evidence data network in psychiatry = collaboration on improving health care and learning from each other

MOOD project : research objective

Research objective

a) To better understand and visualize **the characteristics of patients** with treatment resistant depression **(TRD)** and their **treatment pathways,** in hospitals.

b) To gain more insights in the **real-world use of novel therapies (in casu: Esketamine (esk) nasal spray** in the **TRD population),** using the following data points:

- Dosing
- Frequency
- Treatment duration
- Efficacy
- Side effects
- Changes in other antidepressant therapy or neuromodulation
- Psychiatric Emergency Room referral after index event
- Hospitalization on psychiatric ward and length of stay

Partners and Setup

PSYCHIATRISCH CENTRUM ARIADNE

Dr. Bernagie
Dr. Lievens
Dr. De Bruecker

Universitair Ziekenhuis Brussel

Dr. Zeeuws
Prof. Vanderbruggen

MARIA MIDDELARES

Dr. Claeys

obasi
partner in healthcare

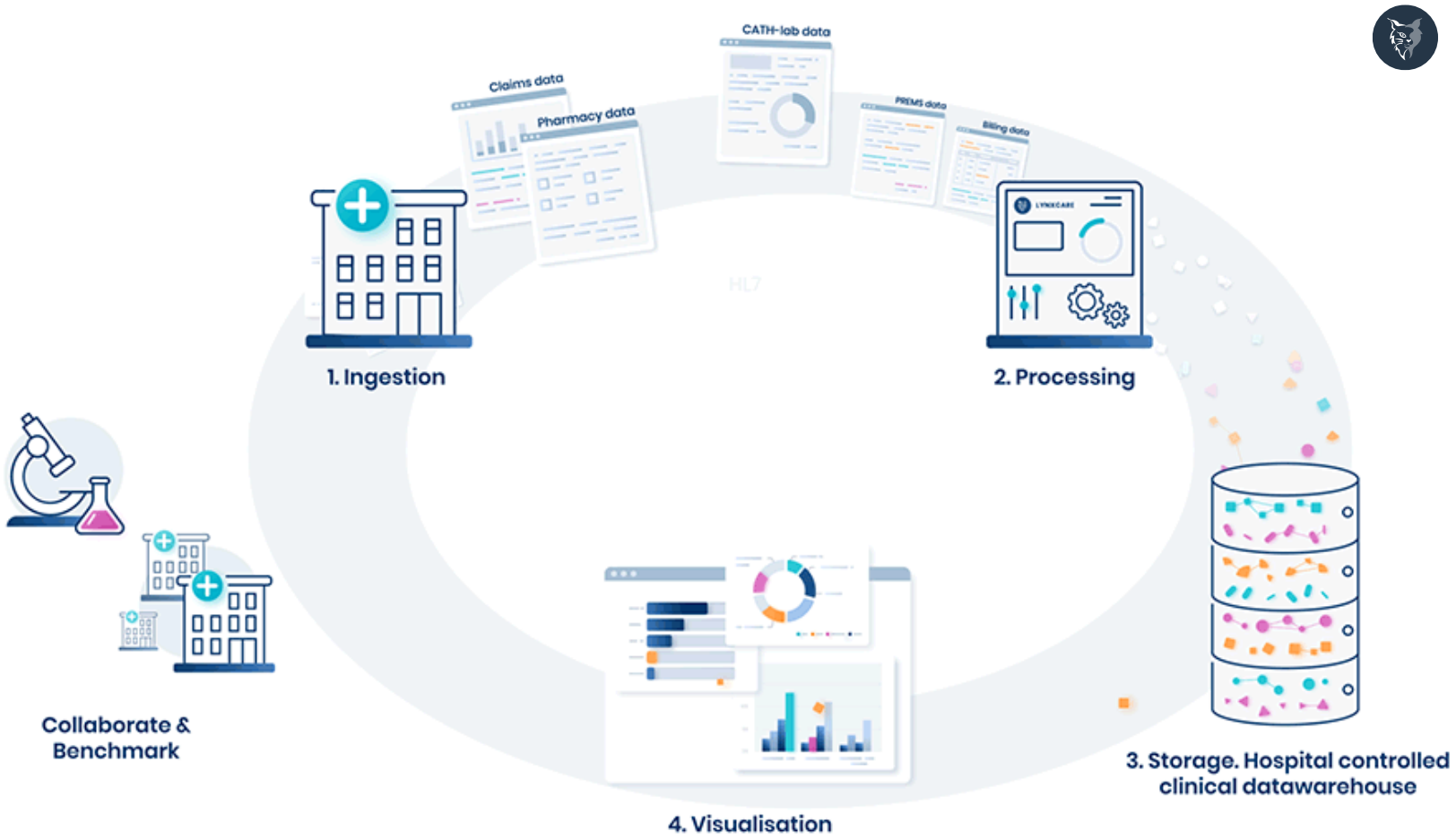
Support and facilitation

Serves many psychiatric centers in Flanders and is also active in Wallonia

LYNXCARE

Approach

From data to meaningful insights



OMOP

PowerBI

Key for the project

SPEED
Access & Freshness

Fast access to clinical data together with Obasi **Near-real-time** data

BREADTH & DEPTH
Granularity

High number of **variables** and **endpoints** with high level of completeness because of **disease-specific NLP.**

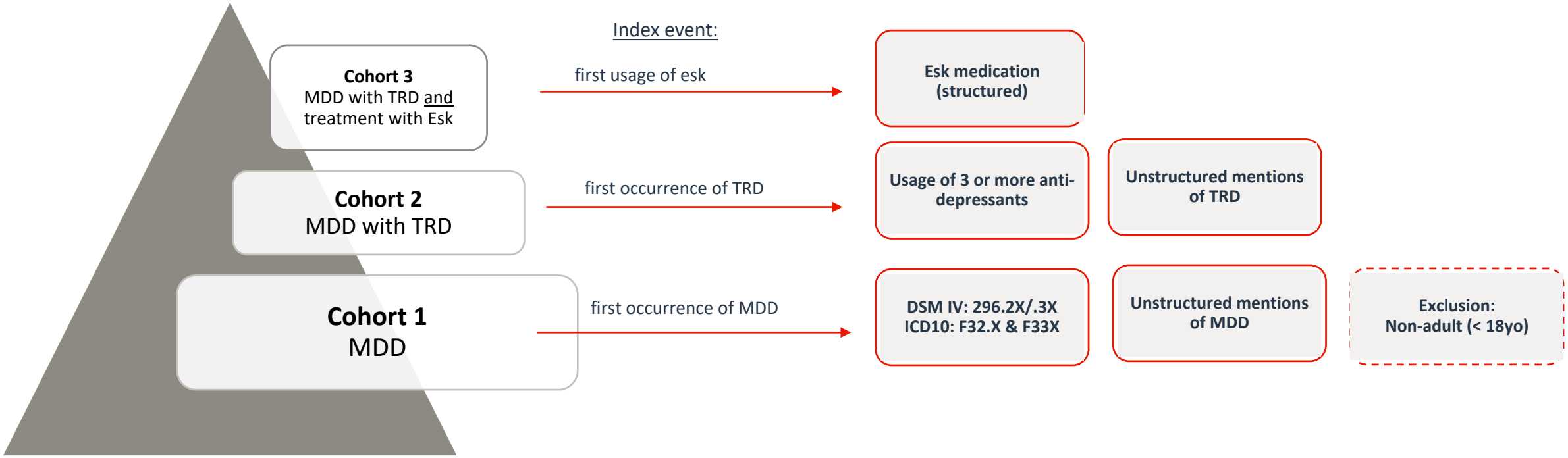
QUALITY
90% accuracy

Regulatory-grade clinical data with exceptional **granularity** and externally **validated**.

MOOD cohort

MOOD project: the cohort

Selection criteria



Please note: The summary reports of patients were used to extract the unstructured data. Not the detailed reports.

MDD = major depressive disorder, TRD = treatment-resistant depression, CGI = clinical global impression scale and Esk = esketamine

a) To better understand and visualize the characteristics of patients with treatment resistant depression (TRD) and their treatment pathways

Study variables and interest	Analytics
Demographics, medication and medical history • Age, sex • Medical history • Psychiatric history • MDD diagnosis • Age at diagnosis (Date index event – DoB) • Treatment overview	Any mention of these datapoints before index event and at index event. Index event = MDD. Before = broad (all data available) Any mention of e.g., HF
MDD severity (MDD severity classifications were mild, moderate, severe, and unclassified (MDD without a severity classification).	▪ Value of [Datapoint] MADRS ▪ Closest mention to the index event will be used to define "severity". ▪ Include DSM/ICD10 coding or descriptive mention of severity
Use of psychotherapy	Any mention before index event and at index event
Use of neuromodulation	Any mention before index event and at index event

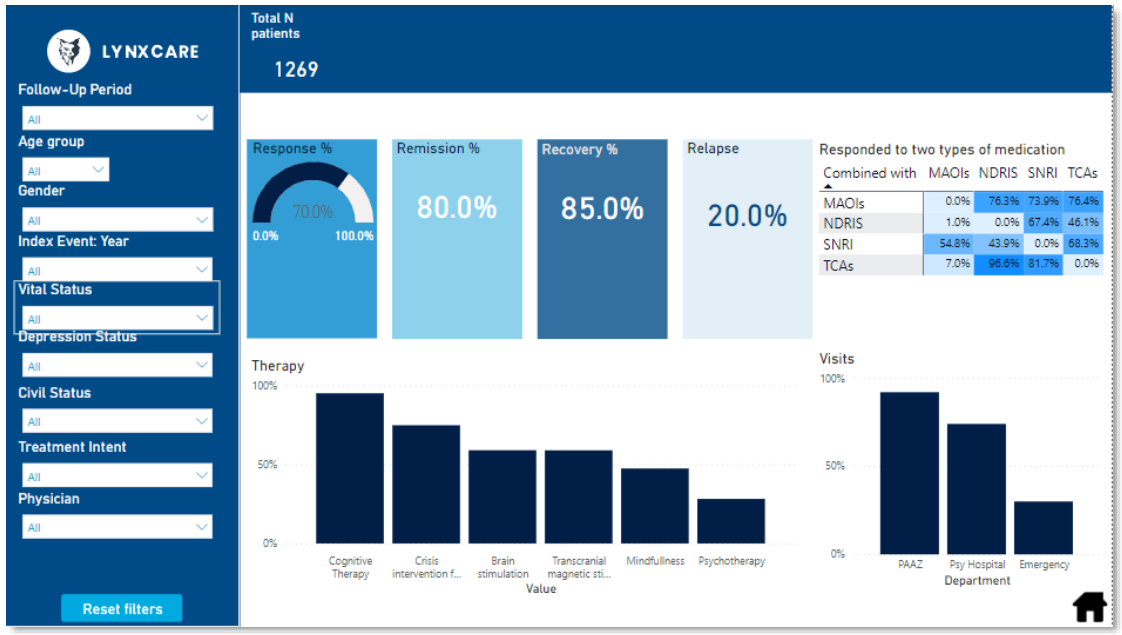
Example	MDD with TRD	MDD with TRD **and** Esk
MDD diagnosis	N (%)	N (%)
Psychotherapy	N (%)	N (%)

b) More insights in the real-world use of esketamine nasal spray in the TRD population on the other hand with following data points

Study variable	Analytics and data source
Dosing	Structured data (based on medication prescription + administration (sept 2021))
Frequency	Structured data (based on medication prescription + administration (sept 2021))
Duration of treatment	Structured data, based on first and last administration => mention of “esketamine”. Registration system of hospital (EPD) indicates administration
Efficacy	No response Response Remission Recovery Relapse
Long term safety profile (>6): Side effects	Number of datapoints after index event i.e., start of Esk
Psychiatric Emergency Room referral after index event	Structured data (ADT) after index event i.e., start of Esk
Hospitalization on psychiatric ward and length of stay	Structured data (ADT) after index event i.e., start of Esk
Changes in other antidepressant therapy or neuromodulation	Number of datapoints retrieved before and after index event i.e., start Esk

Clinical Dashboard and Report

Clinical Dashboard



Janssen Report

- To better understand and visualize the characteristics of patients with **treatment resistant depression (TRD)** in hospitals and their treatment pathways.
- More insights in the **real-world use of esk nasal spray** in the **TRD population** on the other hand with following data points:
  - Dosing
  - Frequency
  - Treatment duration
  - Efficacy
  - Side effects
  - Changes in other antidepressant therapy or neuromodulation during Esketamine nasal spray therapy
- **Secondary aim: Accuracy, value and time investment**

Example outputs

Dashboard + Report

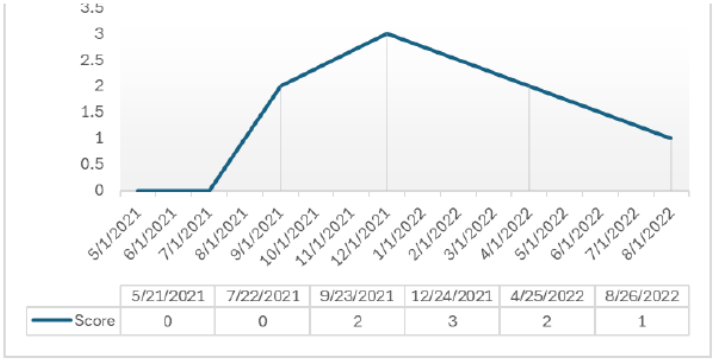
Table 8. Medical histories for Major Depressive Disorder (MDD), Treatment Resistant Depression (TRD), and esketamine (Esk) cohorts.

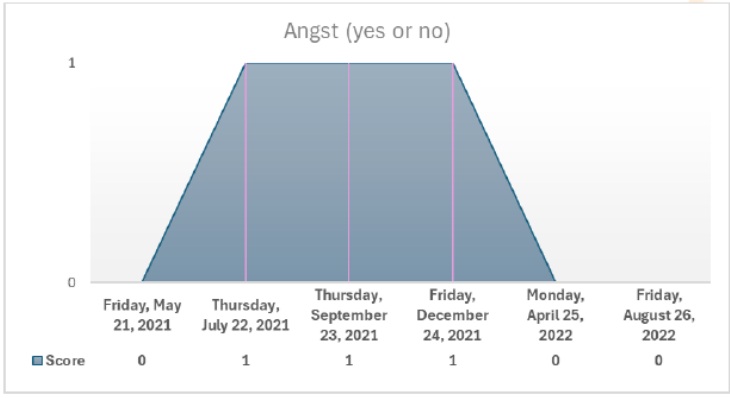
	MDD	no-TRD	TRD overall	Esk
Anaemia				
Auto immune disease				
Cancer				
Cardiac arrythmia				
Central Nervous System Diseases				
COPD				
CVS/Fibromyalgia				
Dementia				
Diabetes				
Heart diseases				
HIV				
Hypercholesterolemia				
Hypertension				
Infection				
Kidney disease				
Liver disease				
Obesity				
Parkinson's				
Rheumatoid Arthritis				
Stomach disease				
Stroke/cerebrovascular accident				
Thyroid disease				

Dashboard = dynamic
Clinical added value: example

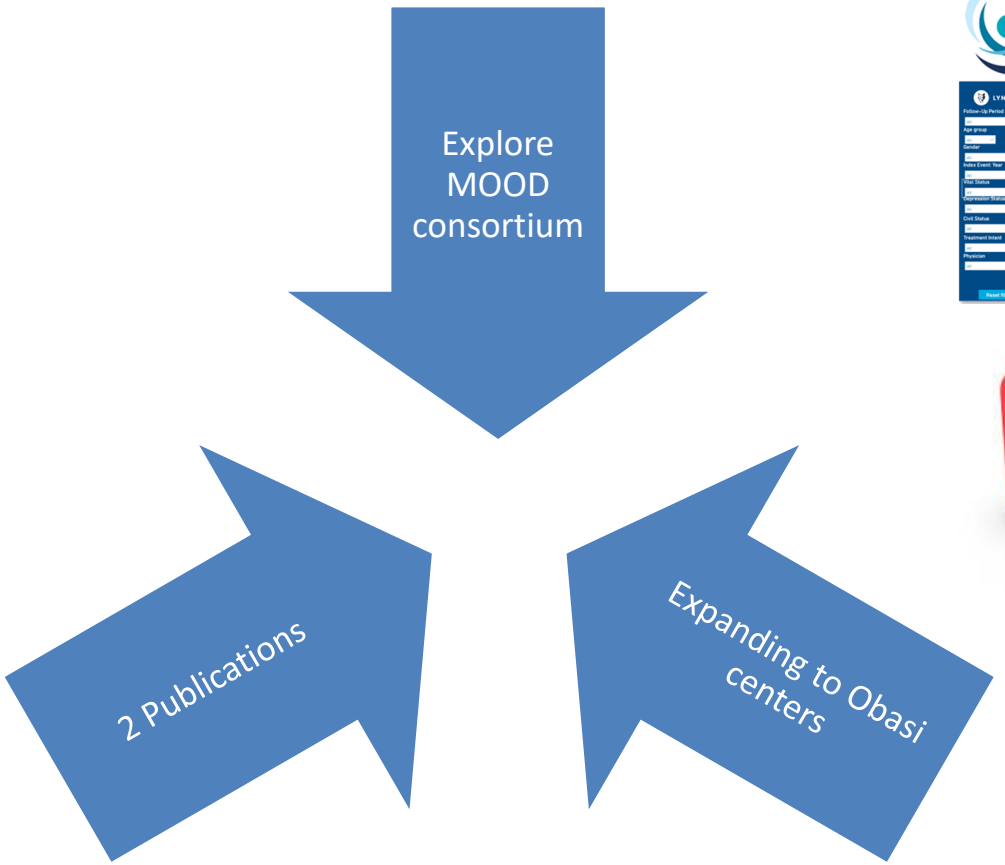
1. **Anhedonie**
2. Somberheid
3. **Gewichtsverandering**
4. **Slaapproblemen**
5. Agitatie of vertraging
6. **Angst**
7. Schuld/schaamte
8. Verminderde concentratie/vermoeidheid
9. **Suïcidaliteit**/zwarte gedachten

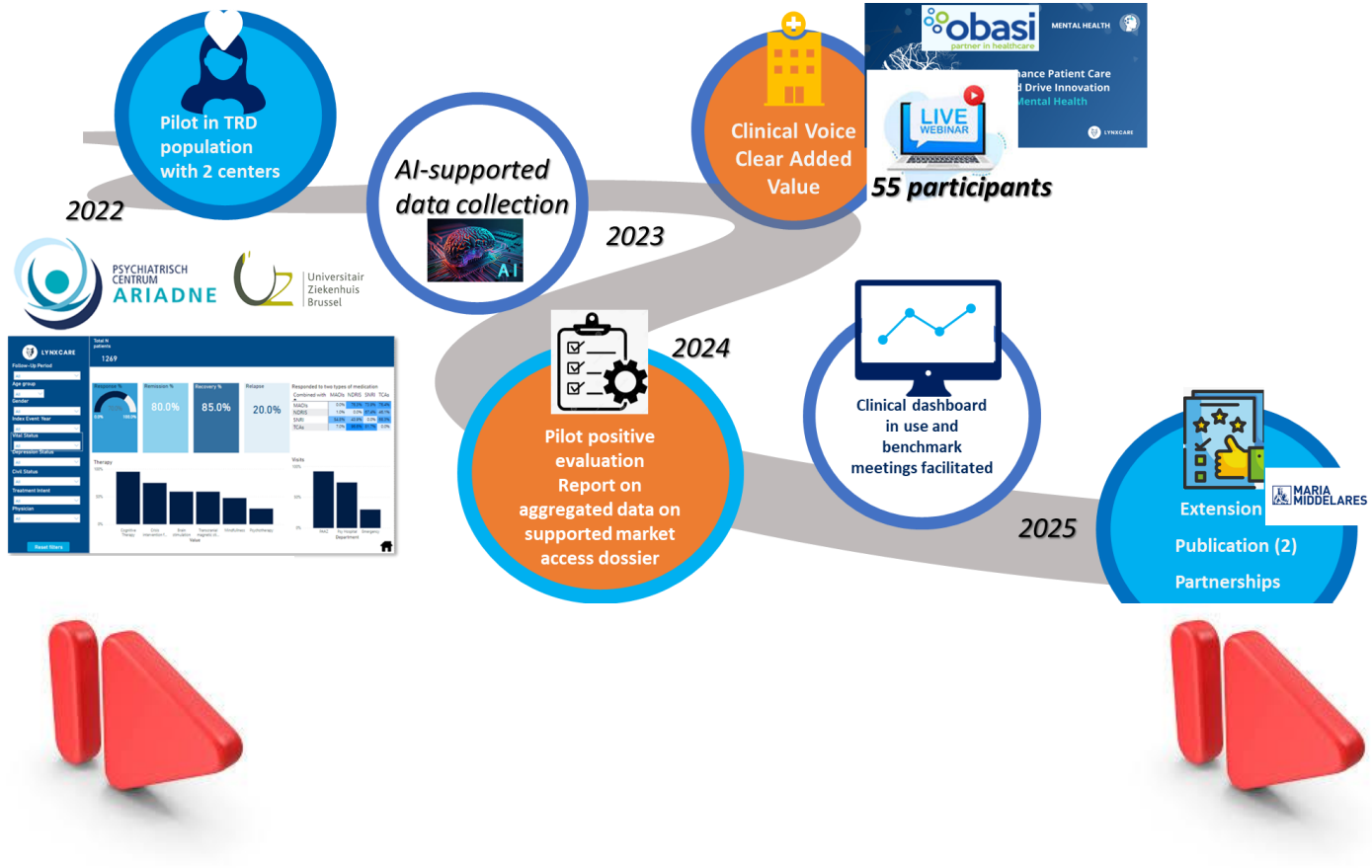
Evolution over time, at what level?
- Binary: present or not
- Scoring: 0-5 (structured reporting required)





Next Steps


Explore MOOD consortium
2 Publications
Expanding to Obasi centers


Pilot in TRD population with 2 centers
2022
AI-supported data collection
2023
Clinical Voice Clear Added Value
obasi
MENTAL HEALTH
LIVE WEBINAR
55 participants
PSYCHIATRISCH CENTRUM ARIADNE
Universitair Ziekenhuis Brussel
LYNXCARE
1269
80.0%
85.0%
20.0%
2024
Pilot positive evaluation Report on aggregated data on supported market access dossier
Clinical dashboard in use and benchmark meetings facilitated
2025
Extension
Publication (2)
Partnerships
MARIA MIDDELARES

Q&A

Time for a little break

30 min.

AGENDA

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13:45-14:15	The societal cost of breast cancer: Using real-world data to assess the short- and long-term impact of diagnosis in Belgium (Eva kimpe & prof Koen Putman, VUB)
14:15-14:45	INVENTS - pharma-academia collaboration and data sharing via the French Health Data Hub - the Roche perspective (David Pau and Claire Castagne, Roche)
14:45-15:15	Integration through the telemedicine platform in practice (Tim Bogaert, Byteflies)
15:30-16:30	closing & drinks

Dr. Epd: The Power of Medical Text

Bram De Caluwé, Head of the Data Department, AZ Klina

pharma.be
ASSOCIATION GÉNÉRALE DE L'INDUSTRIE DU MÉDICAMENT
ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

Dr. EPD

The Power of Medical Text

Bram De Caluwé

Forum Health Data & Digitalisation

26/09/2025

What do the fans of West-Ham United F.C. have in common with AI?

AZ Klina
voluit voor zorg

de Correspondent

Maurits Martijn, Correspondent Beter internet, geeft je een maandlidmaatschap op De Correspondent cadeau

Start een gratis maand ›

28.08.25 Analyse 7-9 min

De realiteit zit de beloofde AI-revolutie nog wel even in de weg

Maurits Martijn
Correspondent Beter internet

DeMorgen.

neren vanaf undefined,undefined per | Log in

IN HET NIEUWS | BETER LEVEN | MENINGEN | POLITIEK | TV & CULTUUR | TECH & WETENSCHAP | SPORT | PUZZELS

Achtergrond AI

Is de AI-revolutie een bubbel die elk moment kan barsten? ‘Sommige beleggers zullen hier serieus hun vingers aan branden’

CEO van OpenAI Sam Altman. AFP

Meest recent Podcast Opinie De Helpdesk

De Standaard

© NurPhoto via Getty Images

TECHNOCRAAT DOMINIQUE DECKMYN

Sam Altman praat beter niet te veel over AI-bubbels

Sam Altman die zélf zegt dat we in een AI-bubbel zitten, dat was niet zo verstandig. AI is het natuurlijk ook gewoon de waarheid.

Dominique Deckmyn

Luisteren | Delen

22 augustus 2025 om 23:59

Focus knack

Knack Club & Voordelen Shop

Inie Factcheck Onderwijs Sport Magazine Vid

© Illustratie: Elizabeth Sanduvete

Deel dit artikel:

Elisa Huistaert · Lotte Lambrecht

13-09-2025, 10:00 · 9 min leestijd

THE NEW YORKER 100

The Latest News Books & Culture Fiction & Poetry Humor & Cartoons Magazine Puzzles & Games Video Po

THE FINANCIAL PAGE

IS THE A.I. BOOM TURNING INTO AN A.I. BUBBLE?

As the stock prices of Big Tech companies continue to rise and eye-popping I.P.O.s reëmerge, echoes of the dot-com era are getting louder.

By John Cassidy
August 11, 2025

Forbes

EDITORS' PICK | INNOVATION › AI

Is The AI Bubble Bursting? Lessons From The Dot-Com Era

By Paulo Carvão, Contributor. © Paulo Carvão is a Senior Fellow at Harvard

Published Aug 21, 2025, 04:40pm EDT, Updated Aug 22, 2025, 04:19pm EDT

Share Save Comment 4

Artificial intelligence — are we in a bubble?
GETTY

Dr. EPD

The Power of Medical Text

Bram De Caluwé

Forum Health Data
& Digitalisation

26/09/2025

Dr. EPD

The Power of Medical Text

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& Digitalisation

26/09/2025

MEDICAL TEXT

- Patient journey: Granular information on diagnosis, treatment and environment
- Common clinical practice
- Historically available

- Langu
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- A

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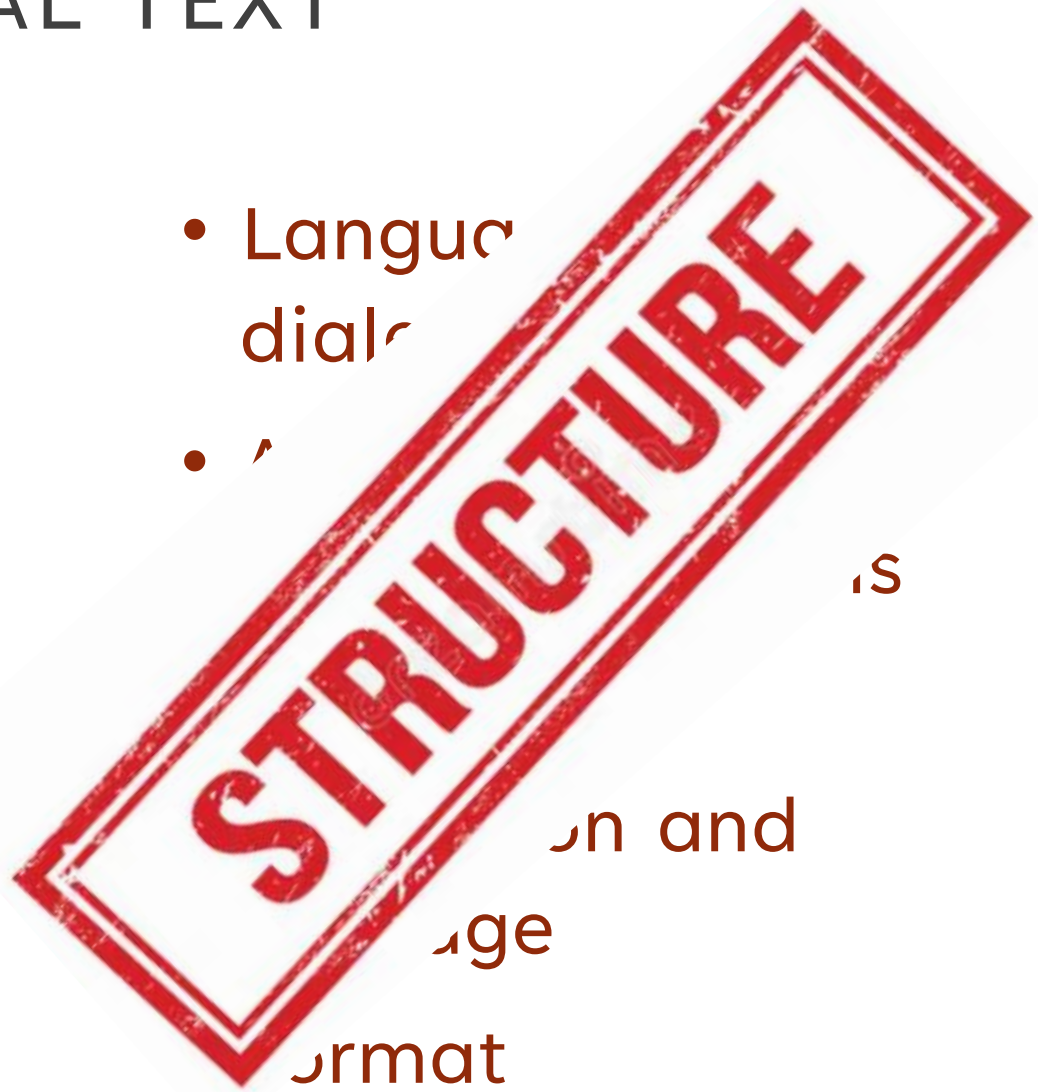

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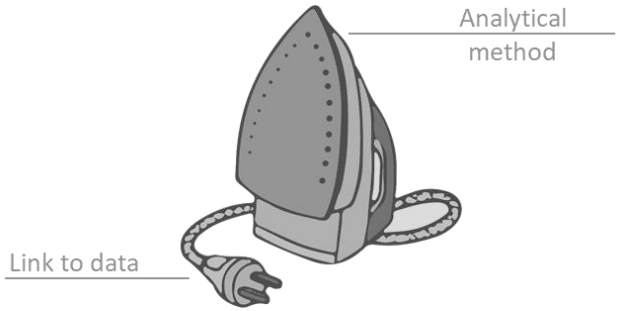
NLP > OMOP

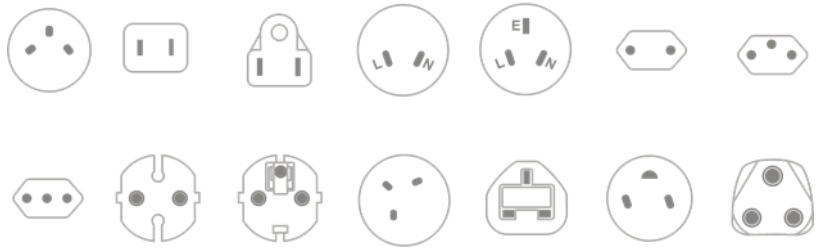
Structured data silos

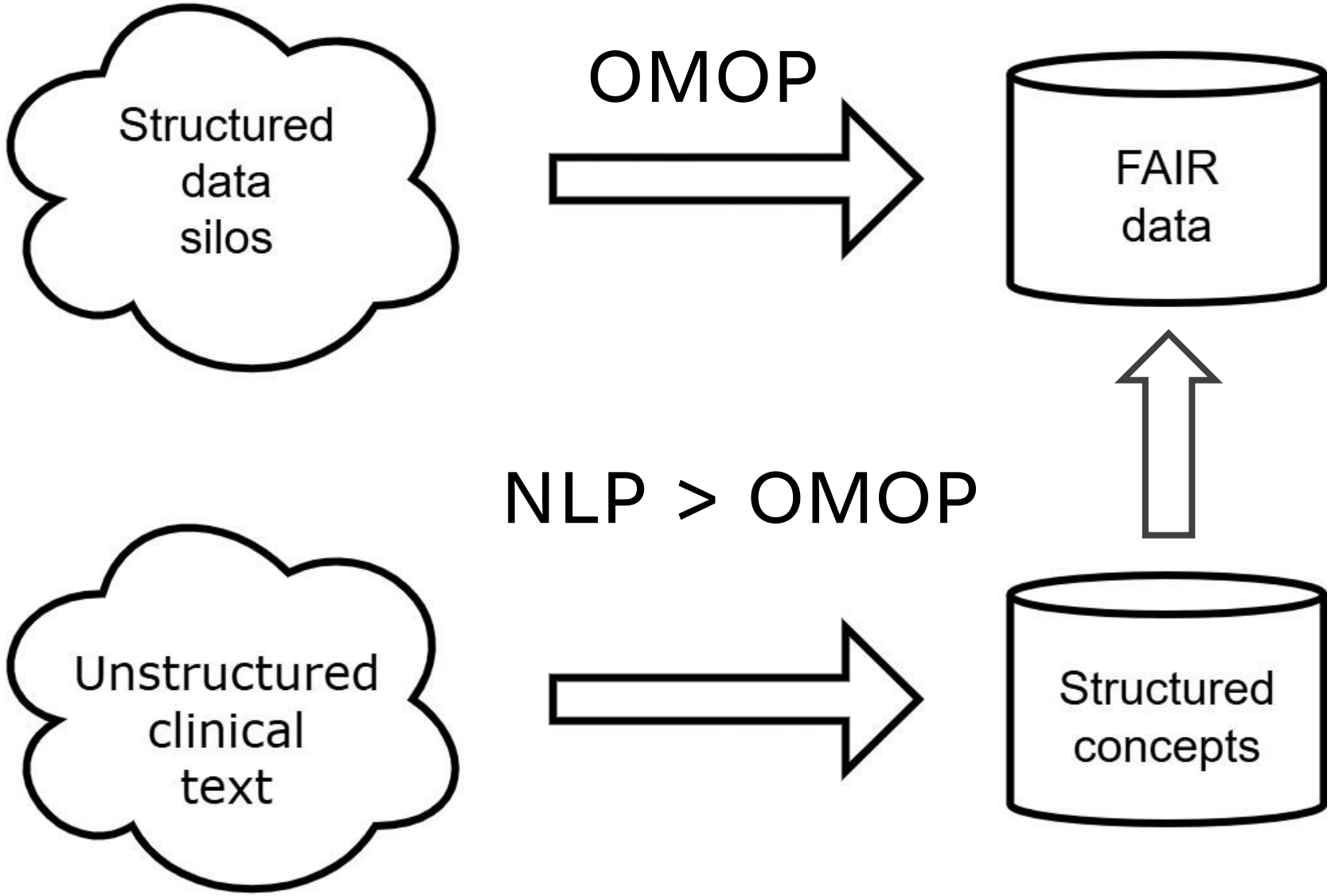
OMOP

FAIR data



The data…

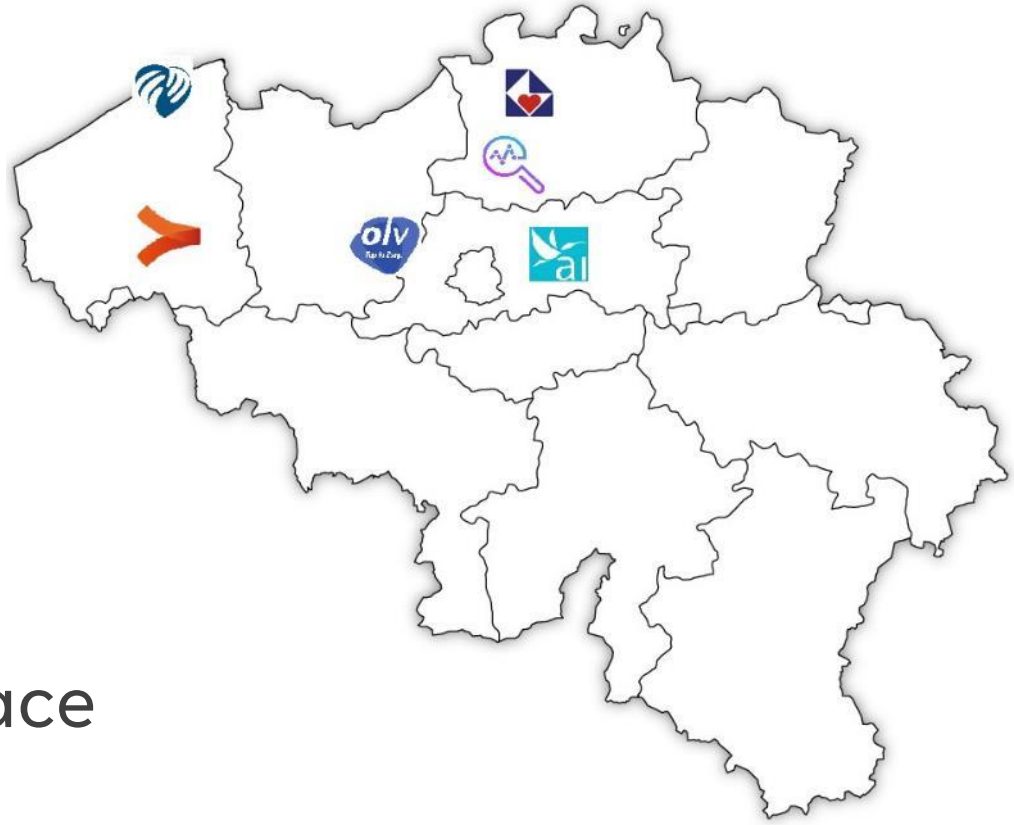




AZ Klina
voluit voor zorg

Health
Food Chain Safety
Environment

- Unstructured data
  > Snomed CT
  > OMOP
- Data capabilities April 2023
- 4 hospitals
  2 private partners
  - Generic solution
  - EPD-independent
  - Easy to use – Simple interface
- Open source publication



PROBLEMS TO SOLVE

- Privacy
- Absence of historical coding > training data
- Limiting the search
- Interaction with the model
- Lack of Snomed knowledge
- Integration into OMOP CDM

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voluit voor zorg

PROBLEMS TO SOLVE

- **Privacy**
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- Integration into OMOP CDM

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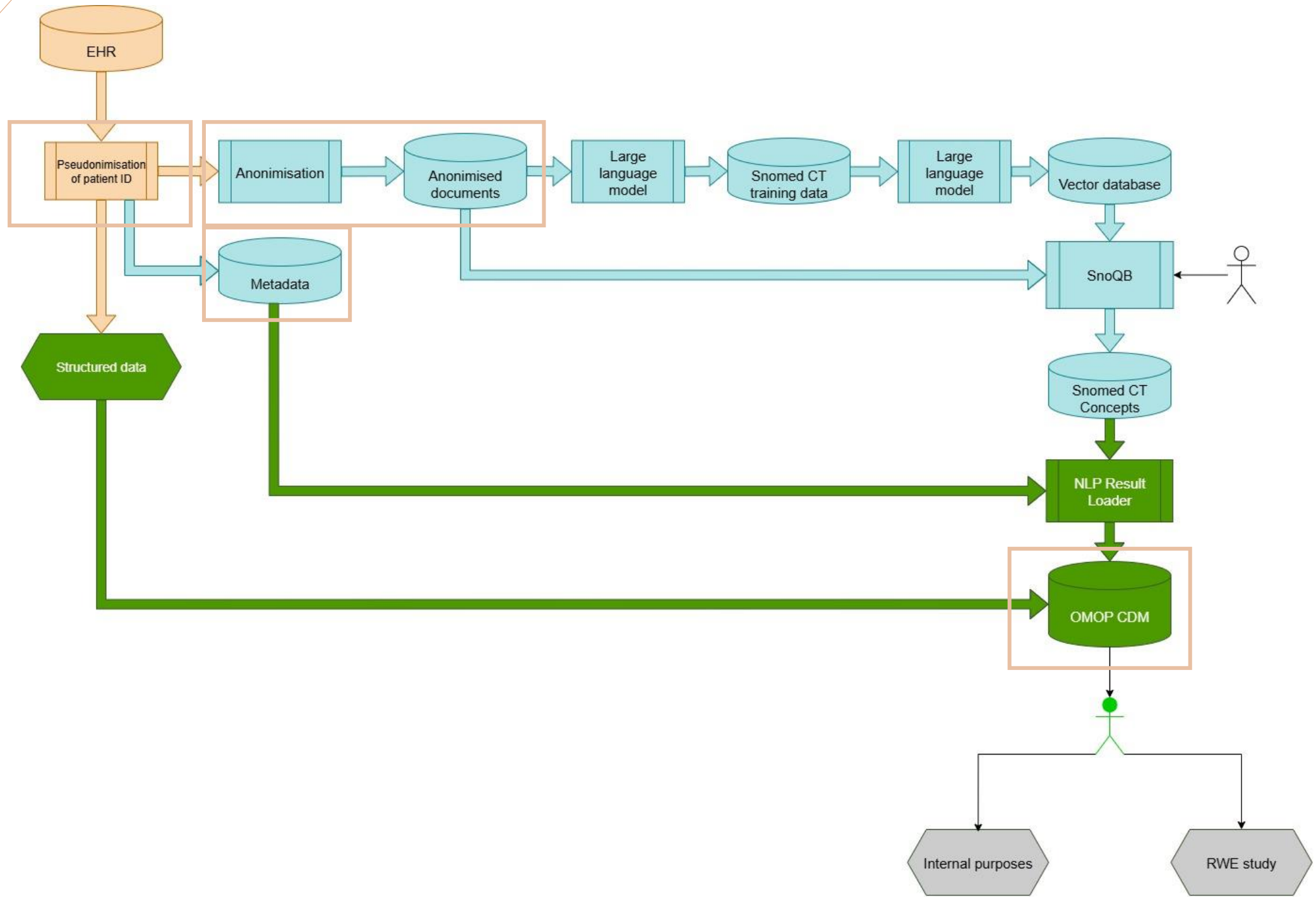

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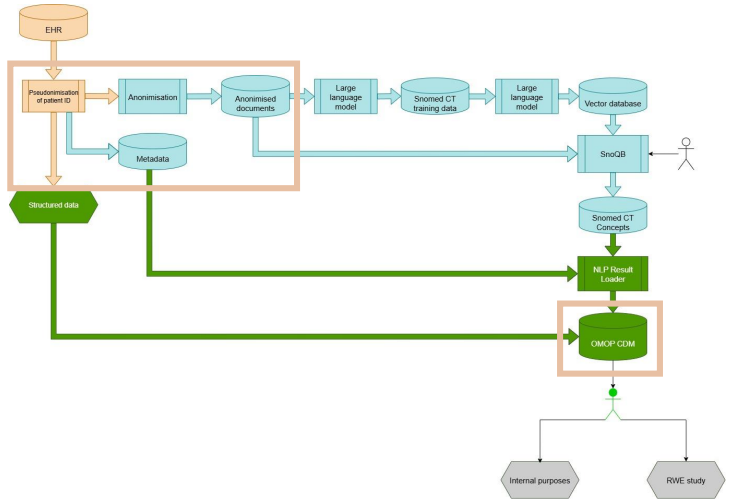
PRIVACY



PSEUDONIMISATION OF PATIENT ID

SPLIT TEXT AND METADATA

ANONIMISATION

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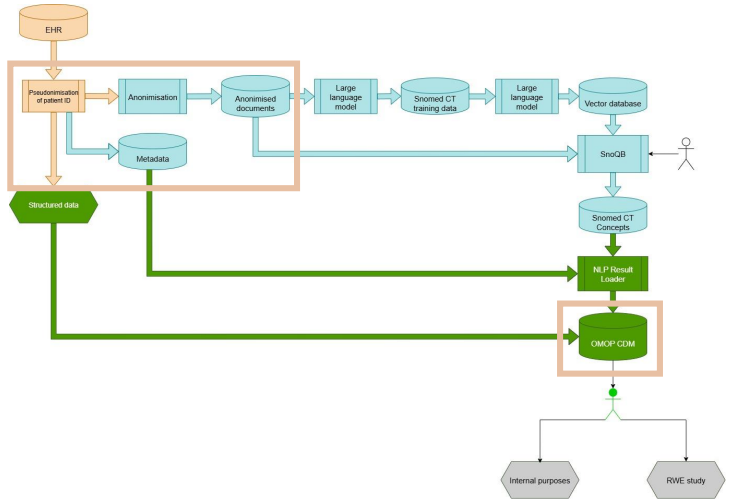
Vervolg brief <PATIENT>, \u00b0 07-10-1943 van 08-07-2024 Verslag Eerste Multidisciplinair Oncologisch Consult: (eerste MOC) \tNaam patiënt: <PATIENT>\tGeboortedatum: 7/10/1943\tWonende: <LOCATIE-1>, <LOCATIE-2>\tMutualiteit: \t- CM MIDDEN-VLAANDEREN(Laatst gekende in HiX)\t \t\t\t\t MOC-datum en Betrokken geneesheren: MOC-datum: 3/07/2024 Aanvragende geneesheer: <PERSOON-1> ,1-<ID-1>-69-340,Gynaecologie Verslag: 1. Initiële probleemstelling: <LEEFTIJD-1>-jarige patiënte met zelf gepalpeerde massa LINKS. M/E toont massa links van 35x45mm centraal op 12u met echografisch correlaat met alle kenmerken van maligniteit. Op 26/06 werd een punctie uitgevoerd dewelke een ILA toont, pleiomorf type, ER/PR 8/8, HER2 negatief. CA 15.3 44 kU/l. Staging volgt nog. 2. Overzicht van de medische gegevens: THP rechts Totale schouderprothese Anatomopathologie: 26/06 punctie Borstpunctie links op 12 u: - invasief lobulair adenocarcinoom, pleiomorf type. Resultaat ER (CNB): positief (>10%). 91 \u00e0 100% kleurt sterk aan. Allred score: 8. Resultaat PR (CNB): positief (>10%). 91 \u00e0 100% kleurt sterk aan. Allred score: 8. Resultaat HER2-IHC (CNB): HER 2 negatief (score 1+). - 2 % stromale TIL's (tumor infiltrerende lymfocyten) - diagnosecategorie: B5. Radiologie: 26/06 M/E - RX mammografie bevestigt de aanwezigheid van een spiculaire massa links centraal op 12 uur, mammografisch met een diameter van \u00b135 x 45mm., echografisch correlerend met een hypo-echogeen RIP met een diameter van ongeveer 30 mm: 'alle kenmerken van maligniteit'. - Geen vergrote lymfeklieren links axillair. - Geen afwijkingen ter hoogte van de rechterborst. - Gezien de patiënt weinig mobiel is wordt onmiddellijk een punctie procedure uitgevoerd en geen MR-mammografie: 3x core punctiebiopsie na verdoving via mediaal. Het resultaat wordt u bezorgd. BI-RADS 5. Nucleaire geneeskunde: CA 15.3 44 . 3. Diagnose: Primaire tumorlokalisatie: C50.8 - Bovenkant borst cT2, cN0, Lateraliteit: links 4. Prognose: afhankelijk van verdere evolutie 5. Concreet behandelingsplan op korte termijn met motivatie, rekening houdend met medische maar ook psychische en sociale argumenten: Herbespreking na staging: CT thorax abdomen en botscan. 6. Concreet behandelingsplan op langere termijn met motivatie, rekening houdend met medische maar ook psychische en sociale argumenten: vzw <ZIEKENHUIS-1> - <LOCATIE-3>, <LOCATIE-4> - <URL-1> vzw <ZIEKENHUIS-1> - <LOCATIE-3>, <LOCATIE-4>- <URL-1>\, "generated_patient_nummer": 688497

PRIVACY



PSEUDONIMISATION OF PATIENT ID

SPLIT TEXT AND METADATA

ANONIMISATION

OMOP CDM

AZ Klina
voluit voor zorg

PROBLEMS TO SOLVE

- Privacy
- **Absence of historical coding > training data**
- Limiting the search
- Interaction with the model
- Lack of Snomed knowledge
- Integration into OMOP CDM

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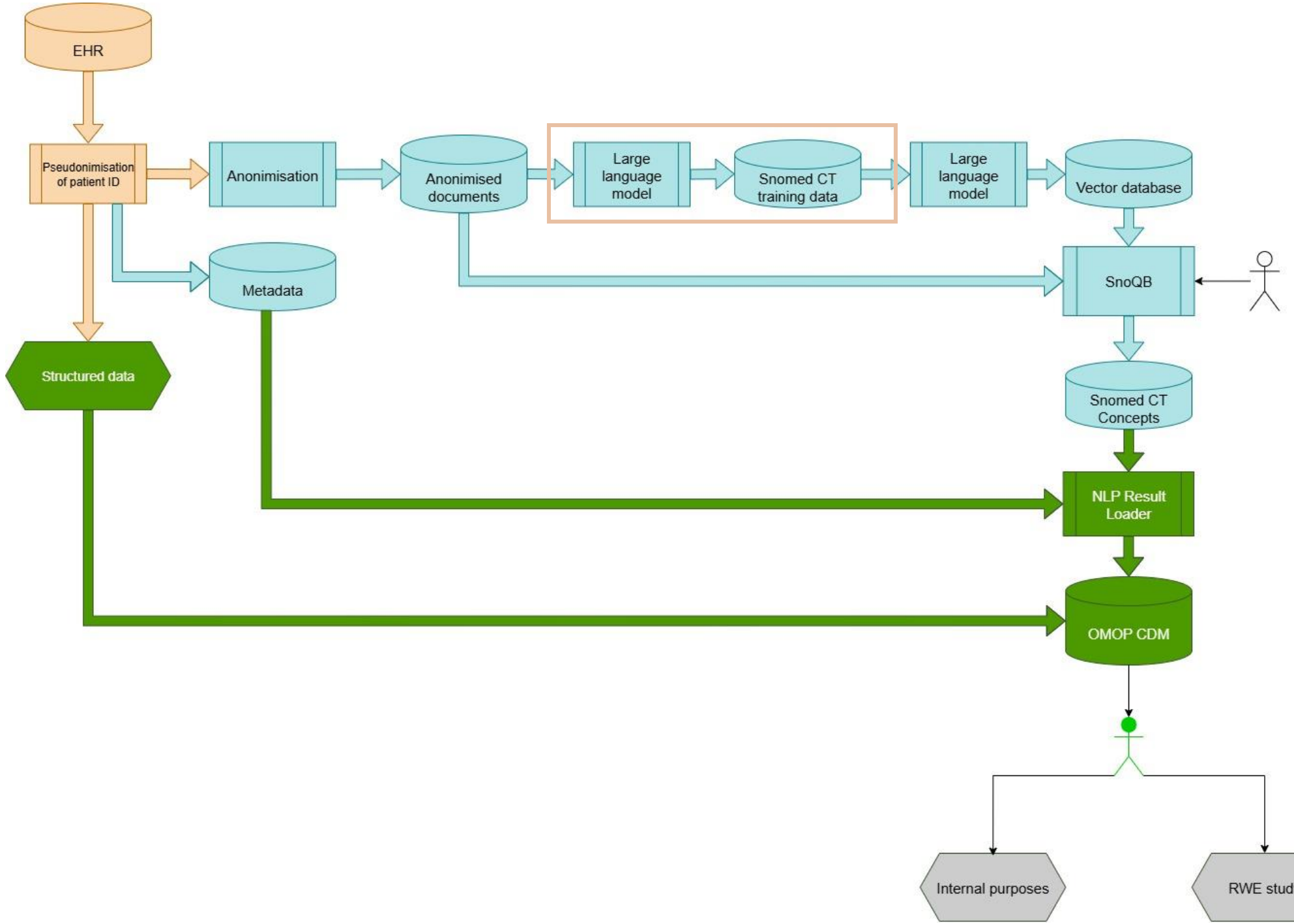
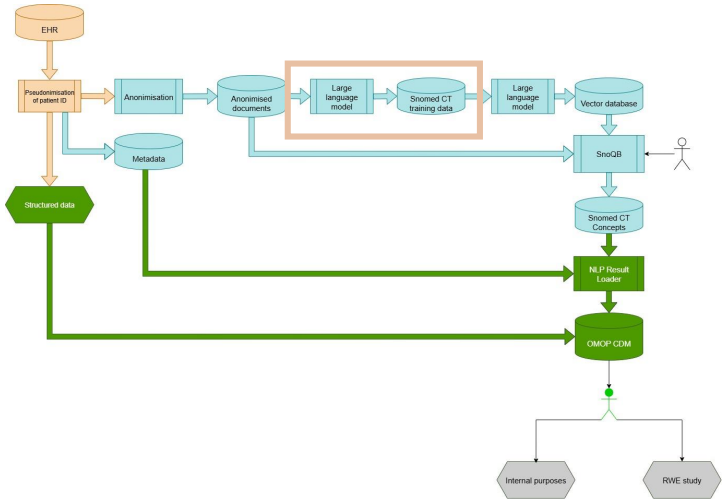
voluit voor zorg


EHR
Pseudonimisation of patient ID
Anonimisation
Anonimised documents
Large language model
Snomed CT training data
Large language model
Vector database
Metadata
SnoQB
Structured data
Snomed CT Concepts
NLP Result Loader
OMOP CDM
Internal purposes
RWE study

TRAINING DATA



21.441 DOCUMENTS

2.289.835
TRAINING BLOCKS

LLM MATCH
SNOMED CT

SECOND
INTERATION LLM

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```
  "llm_input": "<ID-1> <ID-2> <ID-3> (<ID-4>)\n Datum afname: 14/07/2022\n Patient naam: <PATIENT>\n Patient geboortedatum: <ID-5>\n \n DEFINITIEF PROTOCOL\n \n Aard van het te onderzoeken weefsel : \n Lipoom rechter knie\n \n Klinische inlichtingen :\n Lipoom\n  \n Macroscopisch onderzoek :\n Aantal fragmenten: 5. Totaal gewicht 0.5 g. Afmetingen grootste fragment: 1 x 0.5 x 0.5 cm. Een kapsel is aanwezig. Het weefsel is homogeen geel op snede. Volledig ingebed in B1.\n \n Microscopisch onderzoek :\n Dwarse doorsnede doorheen een fragment bestaande uit meerdere lobuli mature vetcellen van elkaar gescheiden door dunne bindweefselsepta.\n Er is geen abnormaal aantal vaatjes. \n\n\nBesluit:\nResectie subcutaan vetgezwel rechter knie: goedaardig: lipoom.\n \n \n <PERSOON-1>\n ELEKTRONISCH GEVALIDEERD DOOR <PERSOON-1> op 15/07/2022 12:01.Kopie aan: <PERSOON-2>, <PERSOON-3>\n ",
  "llm_extraction_output": [
    {
      "description": "Lipoom rechter knie",
      "evidence": "Aard van het te onderzoeken weefsel : \nLipoom rechter knie",
      "meta": {
        "status": "confirmed",
        "section": "antecedents",
        "type": "condition"
      },
      "matches": [
        {
          "cid": "1080671000119108",
          "score": 0.8896484375,
          "defn": "lipoom van rechter onderste ledemaat",
          "select": true,
          "SCT_DEF": "Lipoma of right lower limb (disorder)",
          "ce_score": 0.9937599301338196
        },
        {
          "cid": "189003009",
          "score": 0.87841796875,
          "defn": "lipoom van knie en fossa poplitea",
          "select": true,
          "SCT_DEF": "Lipoma of knee and popliteal area (disorder)",
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        {
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          "score": 0.8564453125,
          "defn": "hypertrophy of fat pad of right knee",
          "ce_score": 0.00039955743704922497
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          "score": 0.8271484375,
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        {
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          "ce_score": 0.12762409448623657
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        {
          "cid": "301873005",
          "score": 0.8115234375,
          "defn": "lipoom van membrum inferius",
          "ce_score": 0.9760422706604004
```

PROBLEMS TO SOLVE

- Privacy
- Absence of historical coding > training data
- **Limiting the search**
- **Interaction with the model**
- **Lack of Snomed knowledge**
- Integration into OMOP CDM

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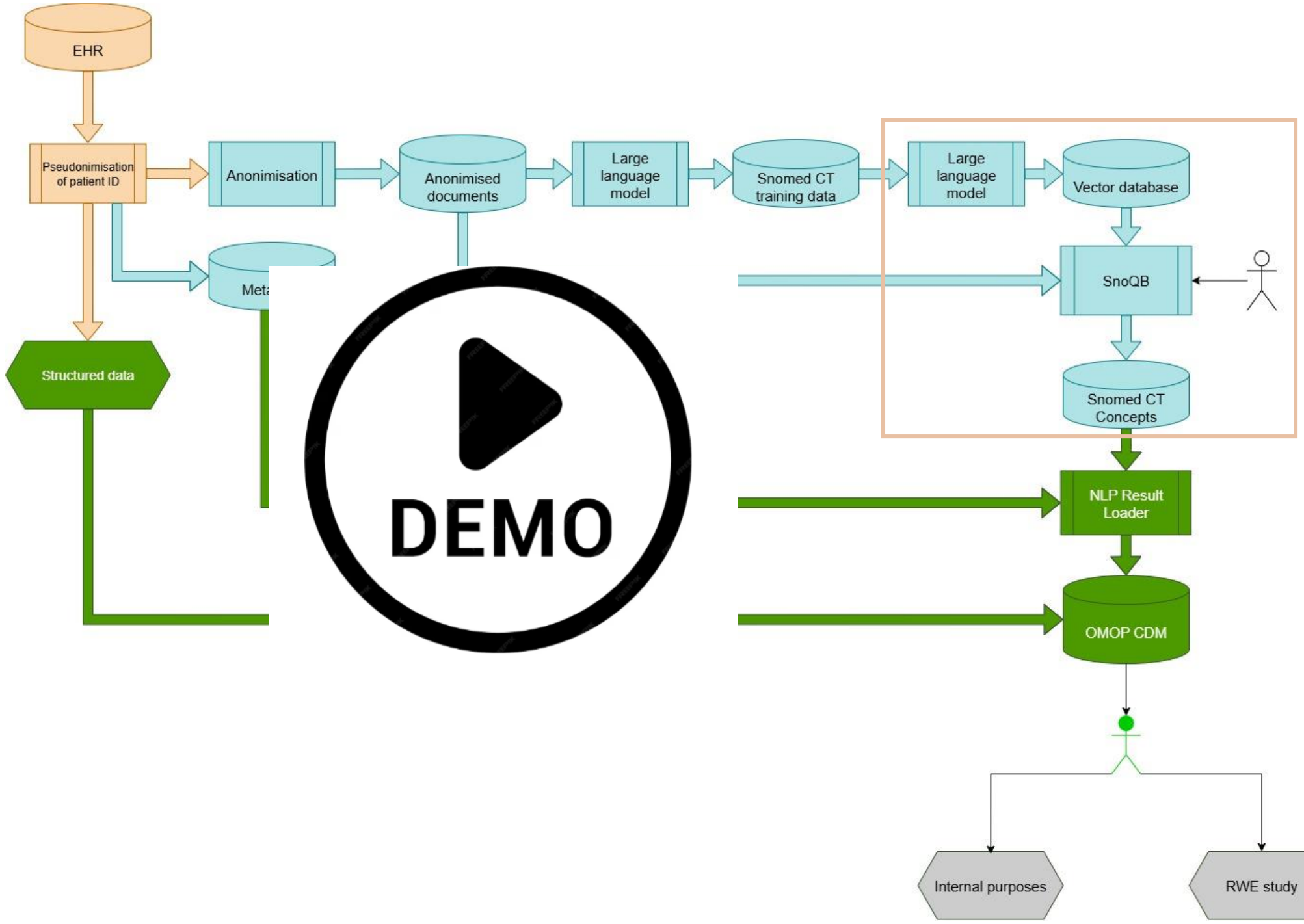
EHR
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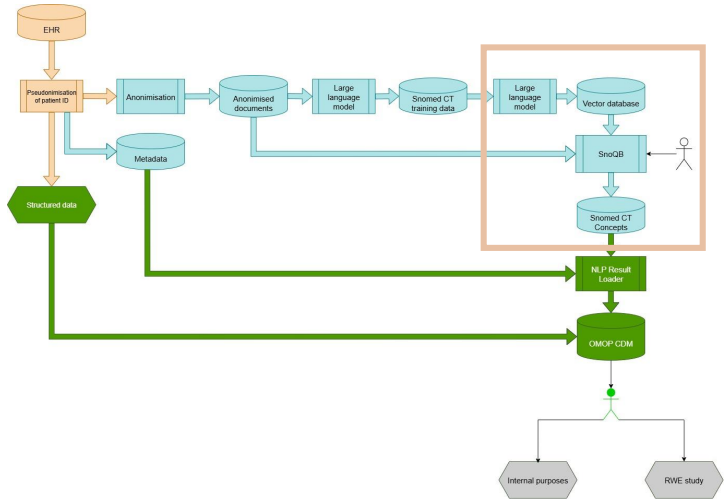
Vector database
SnoQB
Snomed CT Concepts
Structured data
NLP Result Loader
OMOP CDM
DEMO
Internal purposes
RWE study

SNOQB



- Interaction with the model
- Limiting the search volume
- Knowledge of Snomed CT
- Post-processing negation
  - Search for negative terms
  - Match in sentence
  - Delete from snippet and re-run
- *Post-processing family history*

The patient shows no signs of diabetes
*The patient shows no **signs of diabetes***
*The patient shows no **signs of diabetes***
*The patient shows **no signs of diabetes***
*The patient shows ~~**no signs of diabetes**~~*
The patient shows

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PROBLEMS TO SOLVE

- Privacy
- Absence of historical coding > training data
- Limiting the search
- Interaction with the model
- Lack of Snomed knowledge
- **Integration into OMOP CDM**

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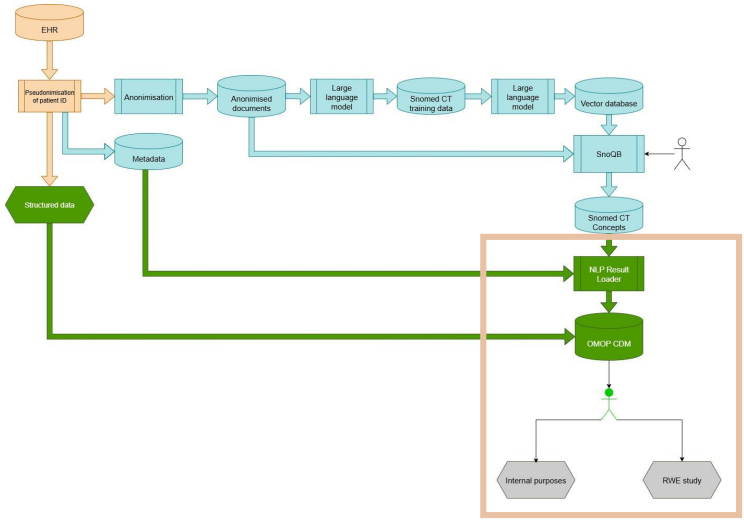
OMOP CDM



- Output
  - Snomed CT term
  - Patient ID (de-pseudonimised)
  - Document ID (de-pseudonimised)
  - Date
  - Flag for NLP
  - Negation
  - *Family history*

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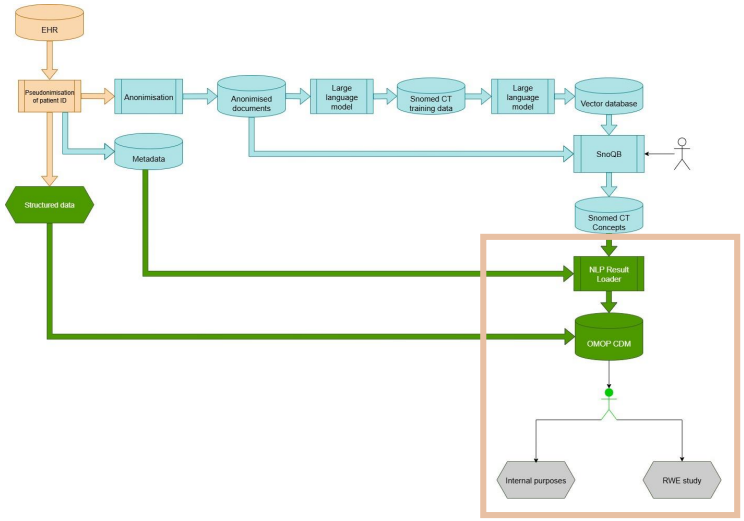
OMOP CDM



- Structured data flow + NLP > OMOP flow
  - Federated analysis
  - Federated learning
- Post-operative infection after knee prosthesis placement

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(SIDE)BENEFITS

- Community
- Reusable technology
- Trust and experience
- In-house interest

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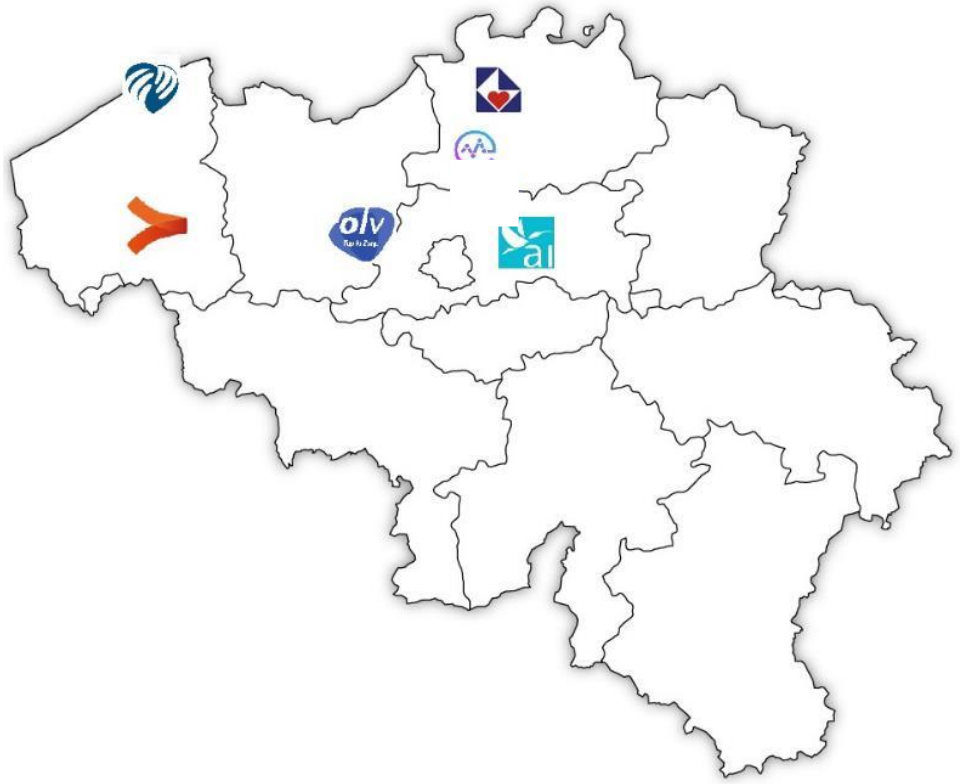
SUBSEQUENT PROJECTS

PROZA

Health
Food Chain Safety
Environment

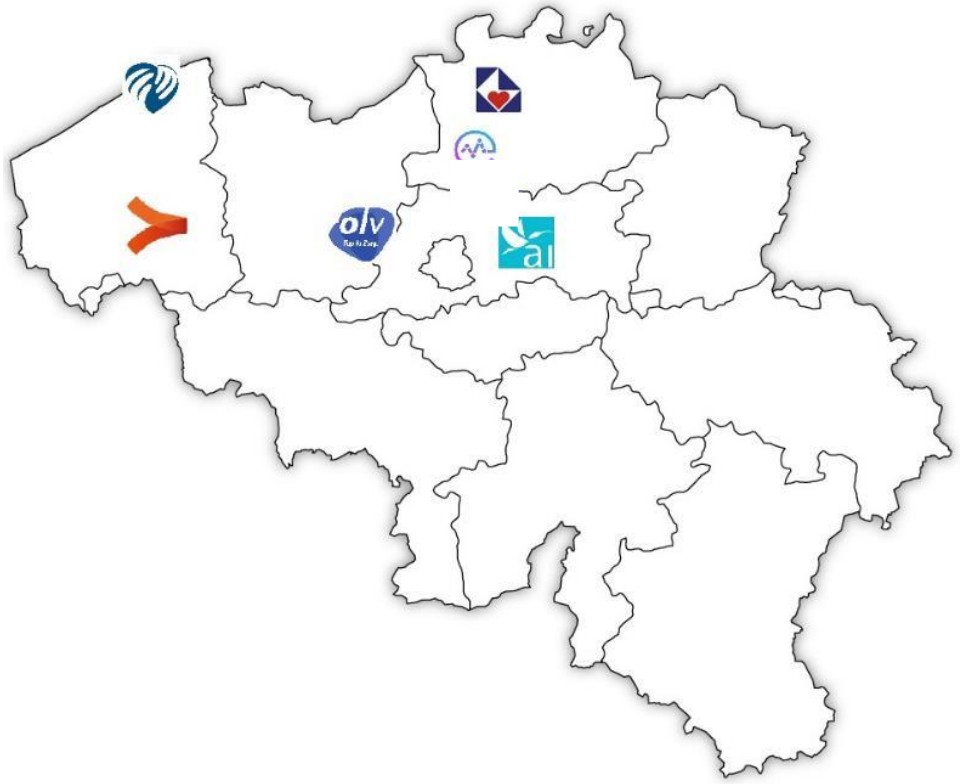
- Innovation call - July 2024
- AZ Oostende + partners
- *Project Risicofactoren Osteoporose Zoekapplicatie via AI*
- *Osteoporosis*
  - *Large population at risk*
  - *Non-invase dexa scan*
  - *Dietary supplements*
  - *Preventing fractures*



PROZA

Health
Food Chain Safety
Environment

- Automated file screening
- NLP > OMOP AI models
- 27 risk factors
- launch and report in EPD
- MDR
  - Simple search?
  - In-house exemption
  - Retrospective validation
- Other diseases



NLP > OMOP CONNECT

Health
Food Chain Safety
Environment

- Crossover call – October 2025
- Tech transfer
- Partners
  - ZAS
  - UZ Gent
  - Jan Yperman
  - Noorderhart
  - No private partners

- 2029
- Snomed CT
- Pro-active coding
- **Medical history**

Sean Tandoy

AZ Klina
voluit voor zorg

Triage

Grouper on Snomed CT

Registries

Diagnosing

Structuring of COZO

Patient selection for studies

AIm for the stars

start in the mud

THANK YOU

Bram De Caluwé

03/650.53.07

bram.de.caluwe@klina.be

pharma.be

pharma.be Forum Health data & digitisation

Learnings from RWD/E pilots in Belgium to support better decisions and better research

September 26th

Ingrid Maes

INOVIGATE
achieving outcomes

There is a huge influx of promising innovations for cancer and other diseases in the coming years to benefit patients, but they pose specific challenges

How can we balance innovation and future preparedness of our healthcare (eco)system?

Outline

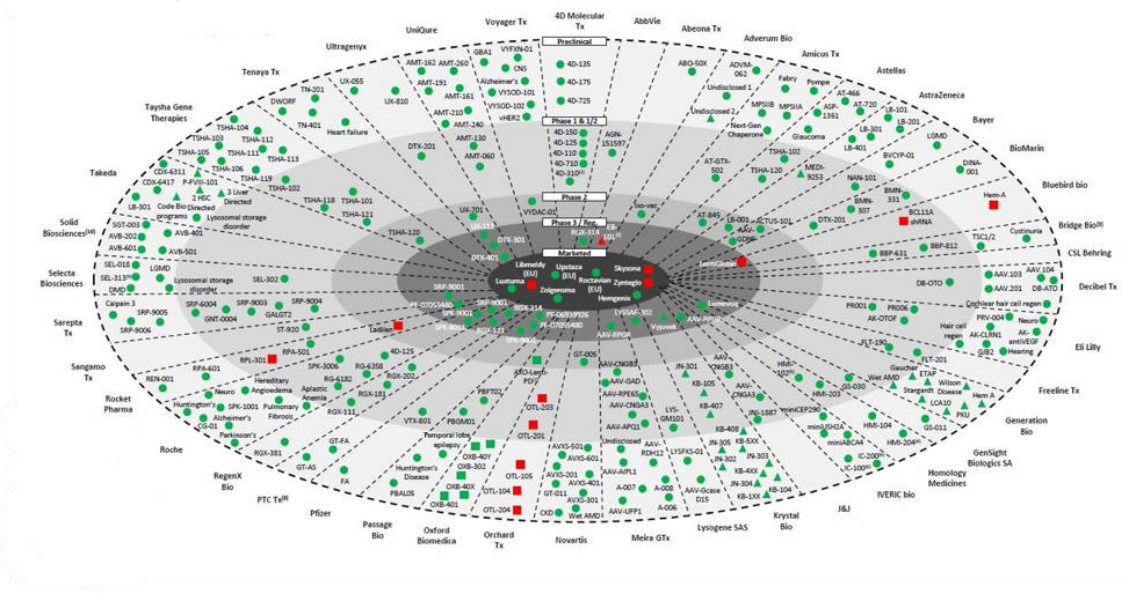
1. The challenges
2. RWD pilots & key learnings
3. Vision for the future

1 The challenges

There is an unprecedented wave of innovations that promise to revolutionise healthcare but have many uncertainties

Many transformative innovations are coming our way…

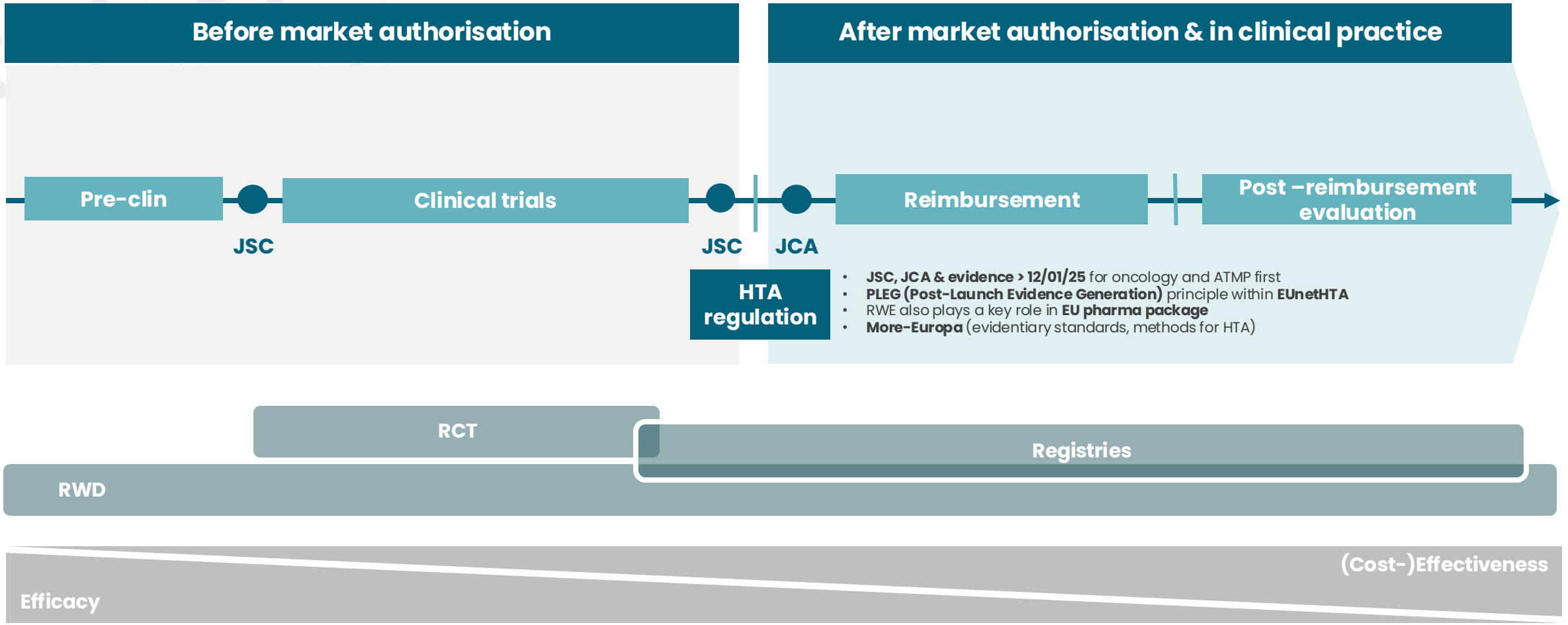
ATMPs in various clinical trial phases



… but require careful consideration of funding and societal issues to ensure they benefit society

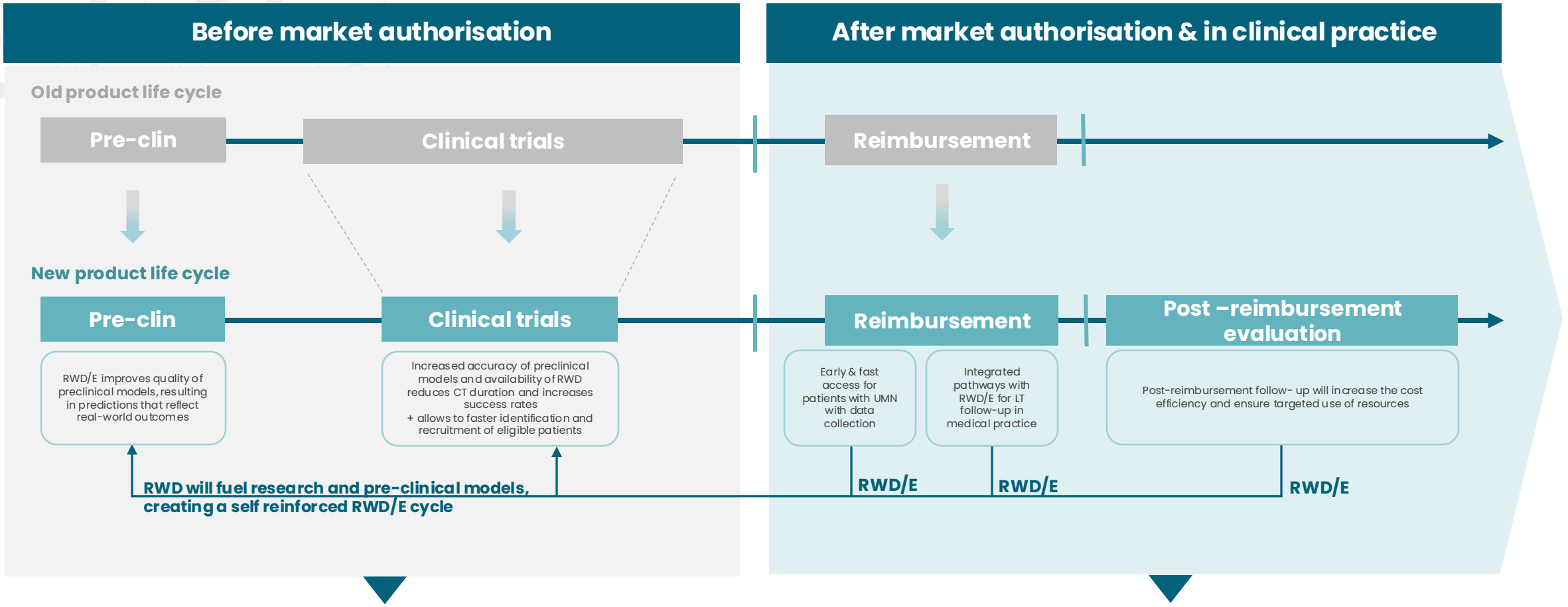
Source: Andrew Pannu

New initiatives focus on evidence generation across the lifecycle to address uncertainties

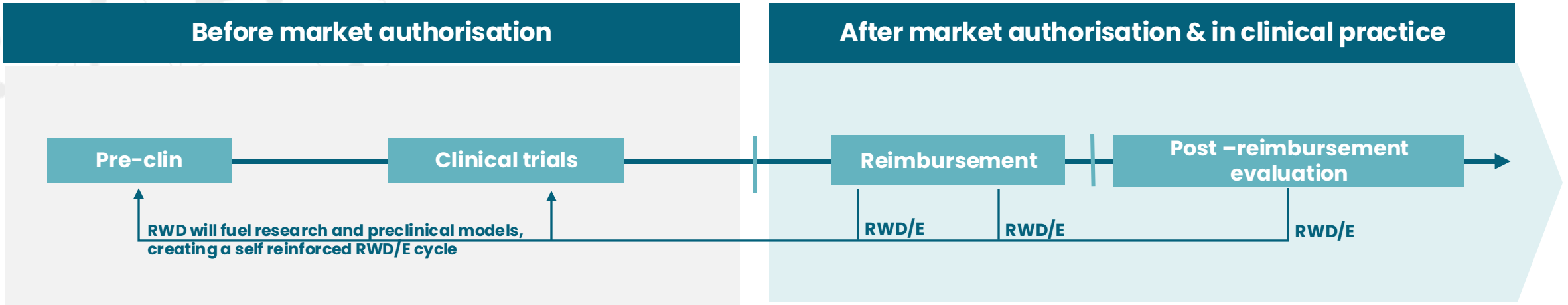


JSC= Joint Scientific Consultation
JCA = Joint Clinical Assessments

RWD and RWE is reshaping the life cycle, leading to both better research and better decisions



However, there are multiple challenges to be addressed to collect RWD to address the uncertainties



Challenges :

- Lack of infrastructure for RWD
- Starting data collection on time
- Long-term follow-up
- Alignment between EU and BE

- Defining necessary RWD for reimbursement
- RWD access
- Setting up necessary infrastructure and contractual agreements in time
- Evaluation of the generated evidence

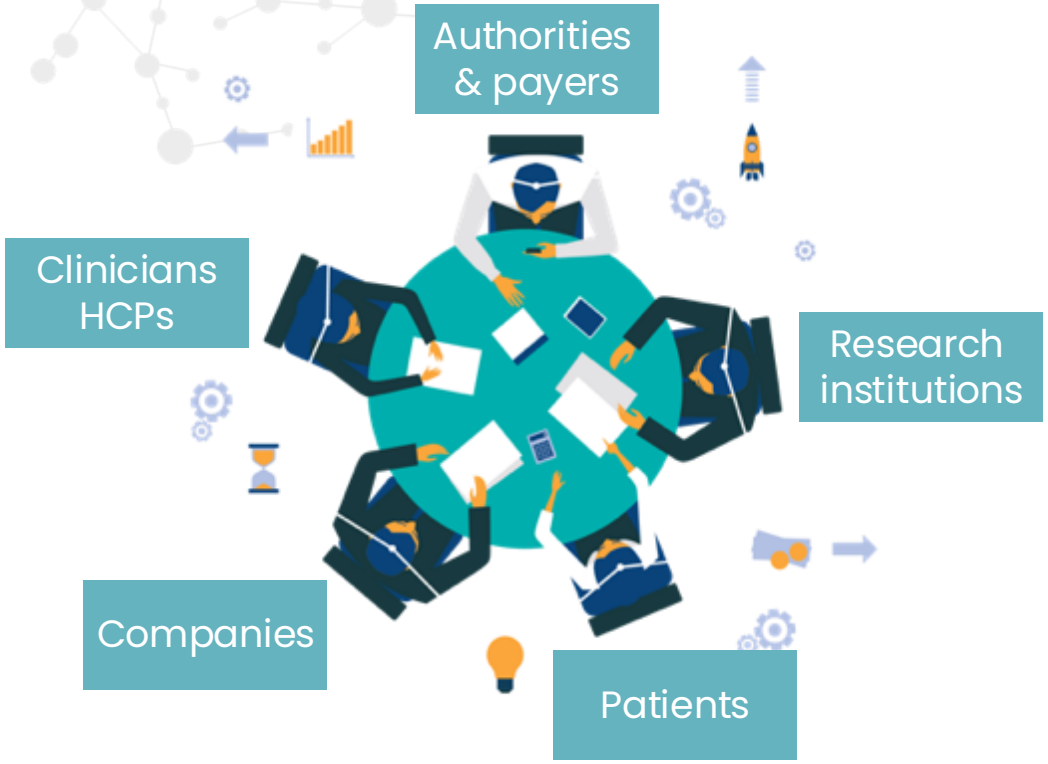
- Collecting RWD/E is costly and requires a lot of effort
- Missing formal structure for early payer advise on RWD/E requirements and consensual advise on evidence generation method

JSC= Joint Scientific Consultation
JCA = Joint Clinical Assessments

2 RWD/E pilots – Key learnings

Solving these challenges is a shared responsibility of all stakeholders

Multi-stakeholder dialogue is required to develop solutions for supportive RWD/E collection to address the uncertainties of innovative therapies for reimbursement



- …. In full transparency
- … Mutually understand challenges and interests
- … Collaboratively seek win-win solutions

Over the past years we have developed solutions for RWD/E in multi-stakeholder dialog

The pathway to a modern, sustainable and future prepared (eco-)system for innovative therapies

Initiated top down, with bottom-up involvement of all stakeholders

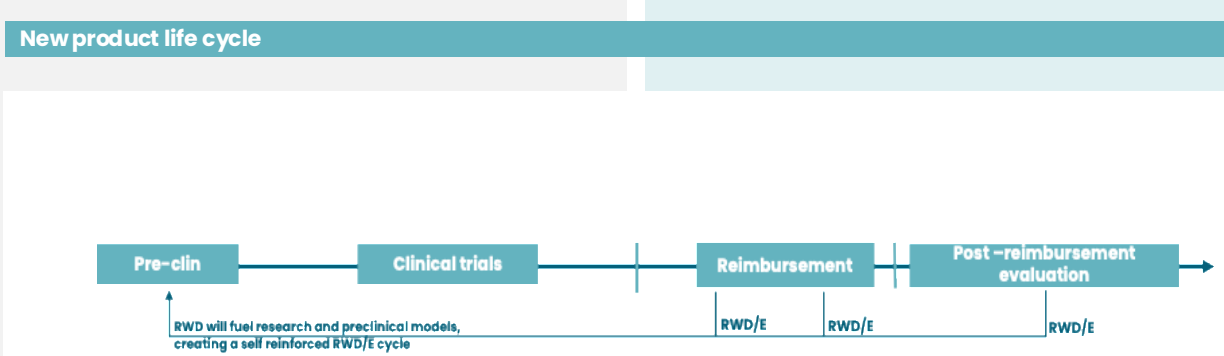
Each has built on conclusions and solutions of previous dialogs, continuously building towards a structural solution, beyond ad hoc and point solutions

These publications are available on our website

We have worked on the solutions to overcome the RWD/E challenges to support better research and better decisions

Better data for better research

Better data for better decisions



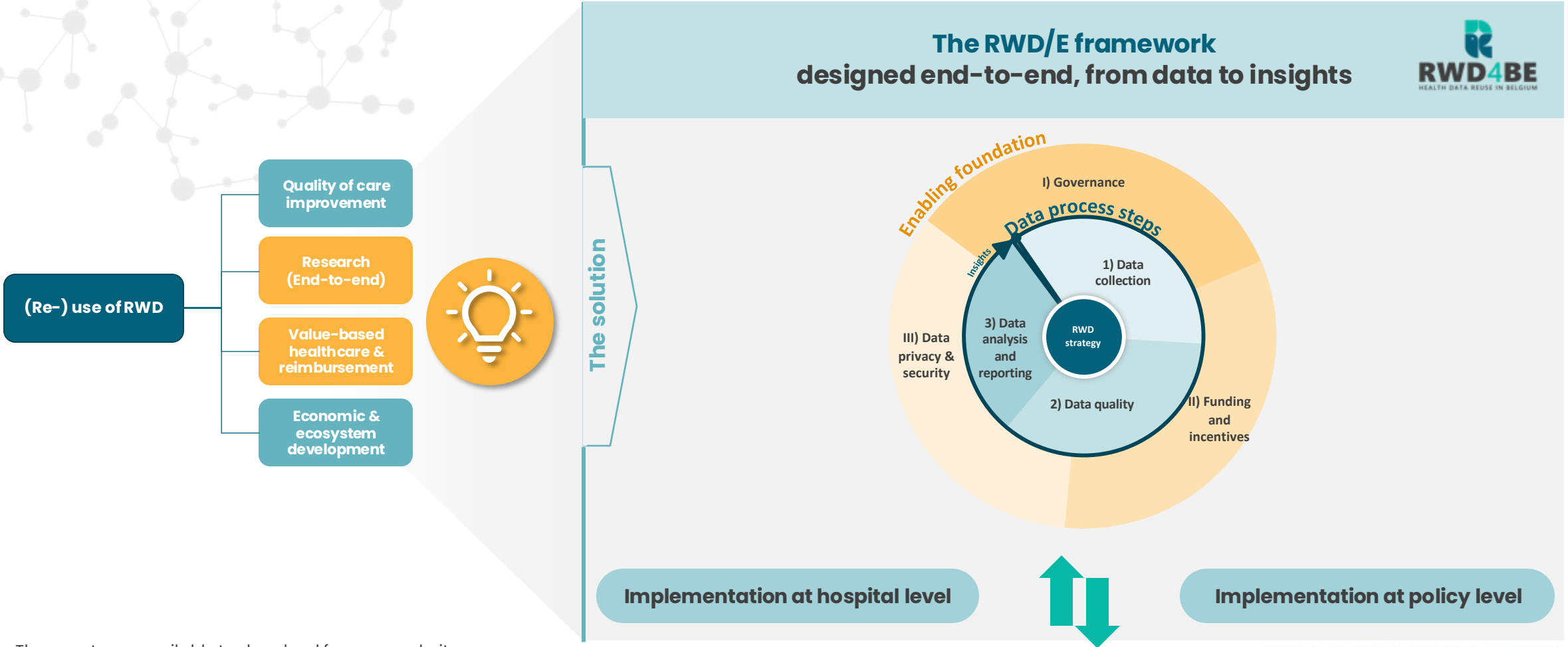
Solution building blocks:

- Reimbursement roadmap with integrated RWD collection
- RWD4BE initiative
- RWD collection collaboration agreement
- Automated RWD collection & registration
- Evidence Platform
- 2 Pilots: oncology and rare diseases

Integration of RWE generation in the reimbursement roadmap to address uncertainties of breakthrough therapies

	What?	How?	Who?
1 Horizon scanning	Identify high impact products and unmet medical need disease areas	Horizon scanning with yearly updated UMN list	RIZIV + clinicians and patients' input
2 Request for early dialogue to Evidence Platform	Assessment of clinical development plan and uncertainties & potential need for additional evidence (CT and RWE)	Set-up BE **Evidence platform to hold early dialog with** with ref centres/ KOLs, patient rep, HTA, industry & data experts	RIZIV, companies initiatie Evidence Platform
3 Evidence Platform meeting	**Agree on RWE generation plan** + potential early access scheme for high medical need	Organize meeting with industry, clinicians, patient org, data experts (data & RWD infrastructure)	RIZIV + companies + clinicians + patient organisations
4 Management of the enabling foundation (governance, conventions)	Management of the execution of the RWD collection and RWE generation plan (access model)	**Apply RWD governance framework** + agree on multidisciplinary disease conventions	BHDA - Multistakeholder board
5 Set-up of data collection and analysis	Data collection and analysis based on FAIR principles, incl. stakeholder responsibilities	Set-up **RWD Collection Collaboration agreement** Reference centres take the lead in data collection & analysis, pool the knowledge	Reference centra + BHDA+ BCR/ScienSano
6 Critical assessment of RWE and implementation in MEA/OBA	Evidence generation & assessment over time	Critical assessment of RWE and implementation in OBAs by RIZIV	CTG

RWD4BE framework to support data to insights for research and reimbursement decisions

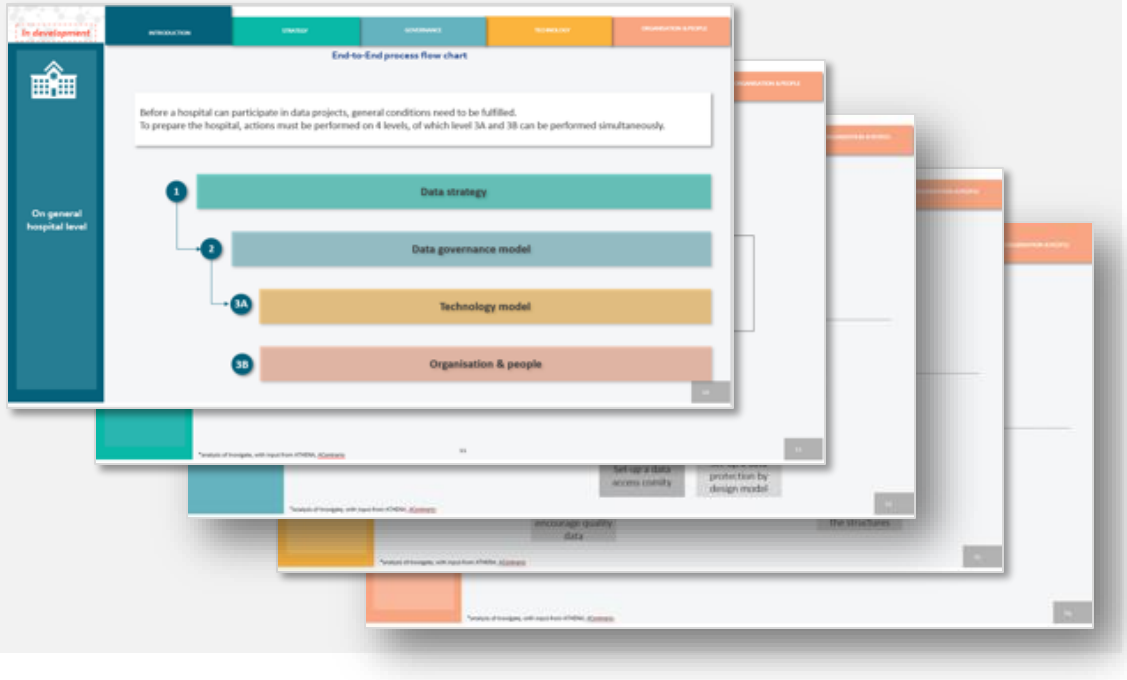


The reports are available to download from our website

Resulting in the RWD preparedness playbook, a guide for hospitals and research entities to be RWD re-use ready

Playbook

A foundational guide to be ready for RWD re-use by ensuring RWD collection practices are standardised and aligned



Hospital exchange visits

Several hospital visits took place to exchange experience and share knowledge

5 May '23
OLV Aalst

15 June '23
Az Maria Middelares Gent

16 November '23
AZ Groeninge Kortrijk

17 April '24
CHU Liège

To operationalise the RWD4BE framework, 2 pioneering pilots in oncology and in rare diseases serve as blueprints for general roll-out

Rare diseases

Gene therapies (GTx) for **Duchenne Muscular Dystrophy** and **Haemophilia**

Holding early dialogs to:

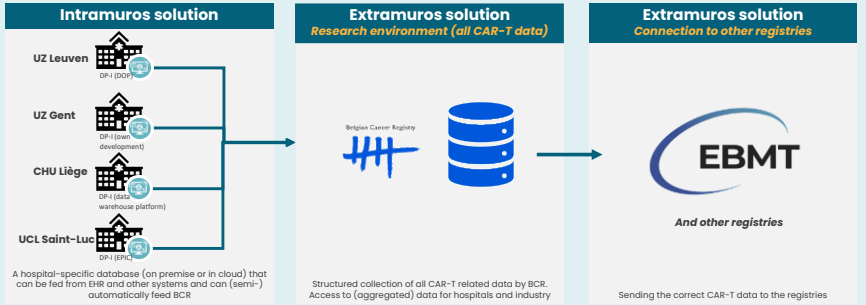
- **agree on evidence needs,**
- **RWD collection requirements,**
- **setting-up an RWD Collection Collaboration Agreement** between all parties,

to support **early access and reimbursement models**

Oncology

CAR-T therapies for **multiple myeloma** and **lymphoma**

Automated data registration of treatment data to lower administrative burden and to make the data available for both reimbursement and research

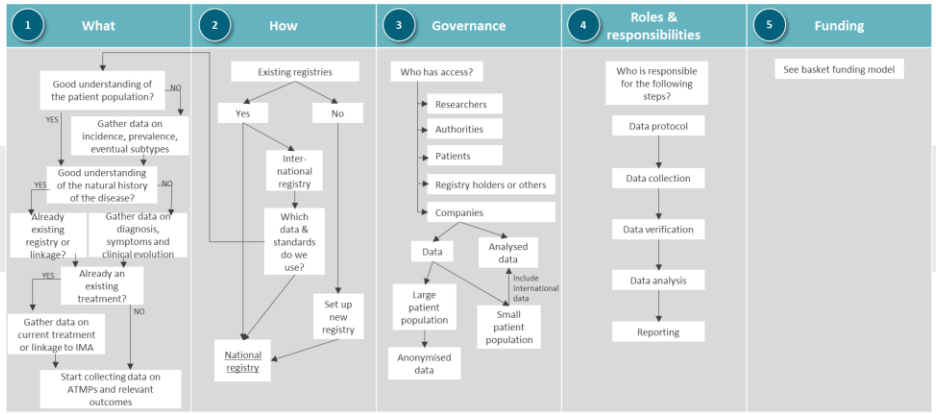


Automated RWD collection & registration

Resulting in a decision tree to facilitate structured dialog and set-up fast multi-partite contracting for

Start early multi-stakeholder dialog on evidence needs and RWD requirements

Decision tree to conduct a structured dialog to decide and set-up



RWD collection collaboration agreement

§
§
§

§
§
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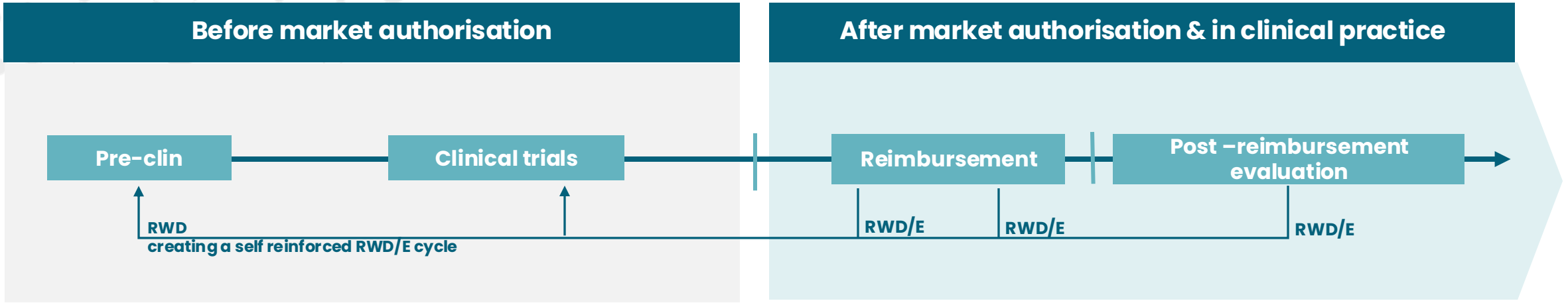
§
§

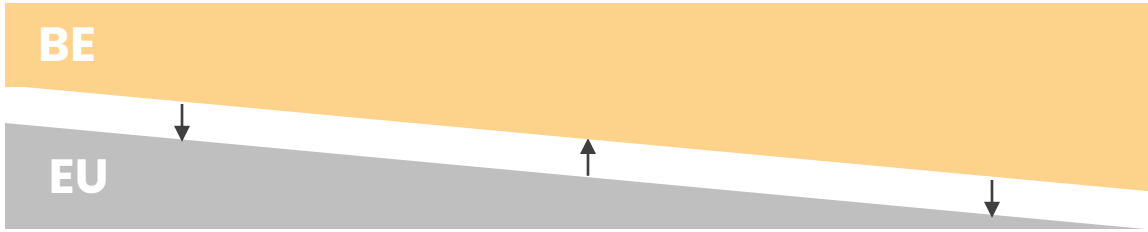
§
§

Per disease:
multi-partite agreement
on RWD/E generation

To discuss and agree on the RWD needs, how to collect RWD, governance, funding and roles & responsibilities to address uncertainties

For structural dialogs, the Evidence Platform will provide advise on evidence generation plans, in support of HTA, MEAs



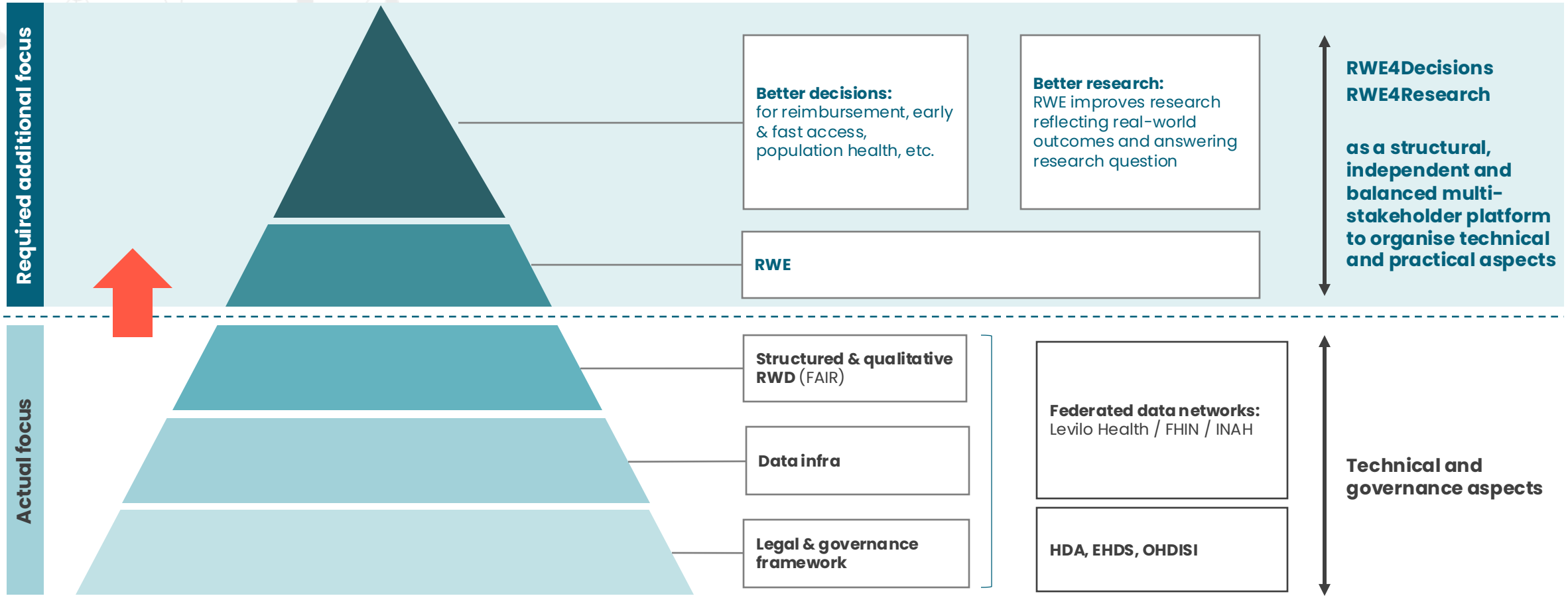


Evidence platform

- **Provides guidance on the evidence generation plan**
- **Evaluates evidence generation method**

3 Vision for the future

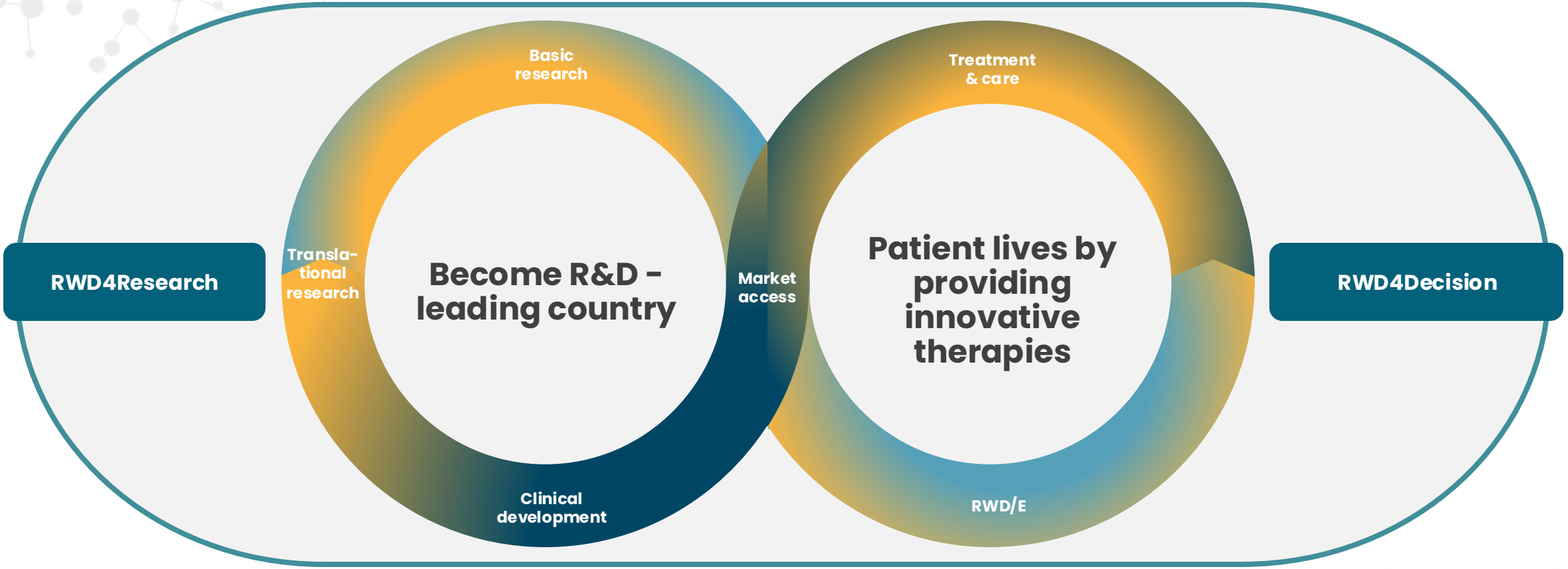
We need now to shift focus from governance and technical aspects to RWD for better decisions and research



Why is this important?
RWD/E will support the integration of the innovation and healthcare value chains to benefits for all

From
innovation...

...to outcomes



Collaborative solution-seeking initiatives via a multi-stakeholder dialog is key for solving challenges and **develop reusable building blocks**

The pilots and resulting solution serve as a **blueprint for other applications**

Let’s take this next step

Vision for the future

Ingrid Maes - Ingrid.maes@inovigate.com

Time for lunch break

Until 13:45

AGENDA

10h	welcome Caroline Ven
10:15-10:45	Evidence generation with real world data in Belgium: lessons learned (Katoo Muylle & Bart Verheyden, Astrazeneca)
10:45-11:15	MOOD: Major Opportunity On Depression (David Smeets & Elke Peeters, Johnson & Johnson)
11:15-11:45	coffee break
11:45-12:15	Dr. EPD: the power of medical text (Bram De Caluwé, AZ Klina)
12:15-12:45	Learnings from RWD/E pilots in Belgium to support decision-making (Ingrid Maes, innovigate)
12:45-13:45	**lunch**
13:45-14:15	The societal cost of breast cancer: Using real-world data to assess the short- and long-term impact of diagnosis in Belgium (Eva kimpe & prof Koen Putman, VUB)
14:15-14:45	INVENTS - pharma-academia collaboration and data sharing via the French Health Data Hub - the Roche perspective (David Pau and Claire Castagne, Roche)
14:45-15:15	Integration through the telemedicine platform in practice (Tim Bogaert, Byteflies)
15:30-16:30	closing & drinks

The Societal Cost of Breast Cancer: Using Real World Data to Assess The Short and Long Term Impact of Diagnosis in Belgium

Eva Kimpe, PhD Researcher and Teaching Assistant, Department of Public Health, VUB

Prof. Koen Putman,Head of i-CHER and Dean of the Faculty Medicines & Pharmacy, VUB

pharma.be
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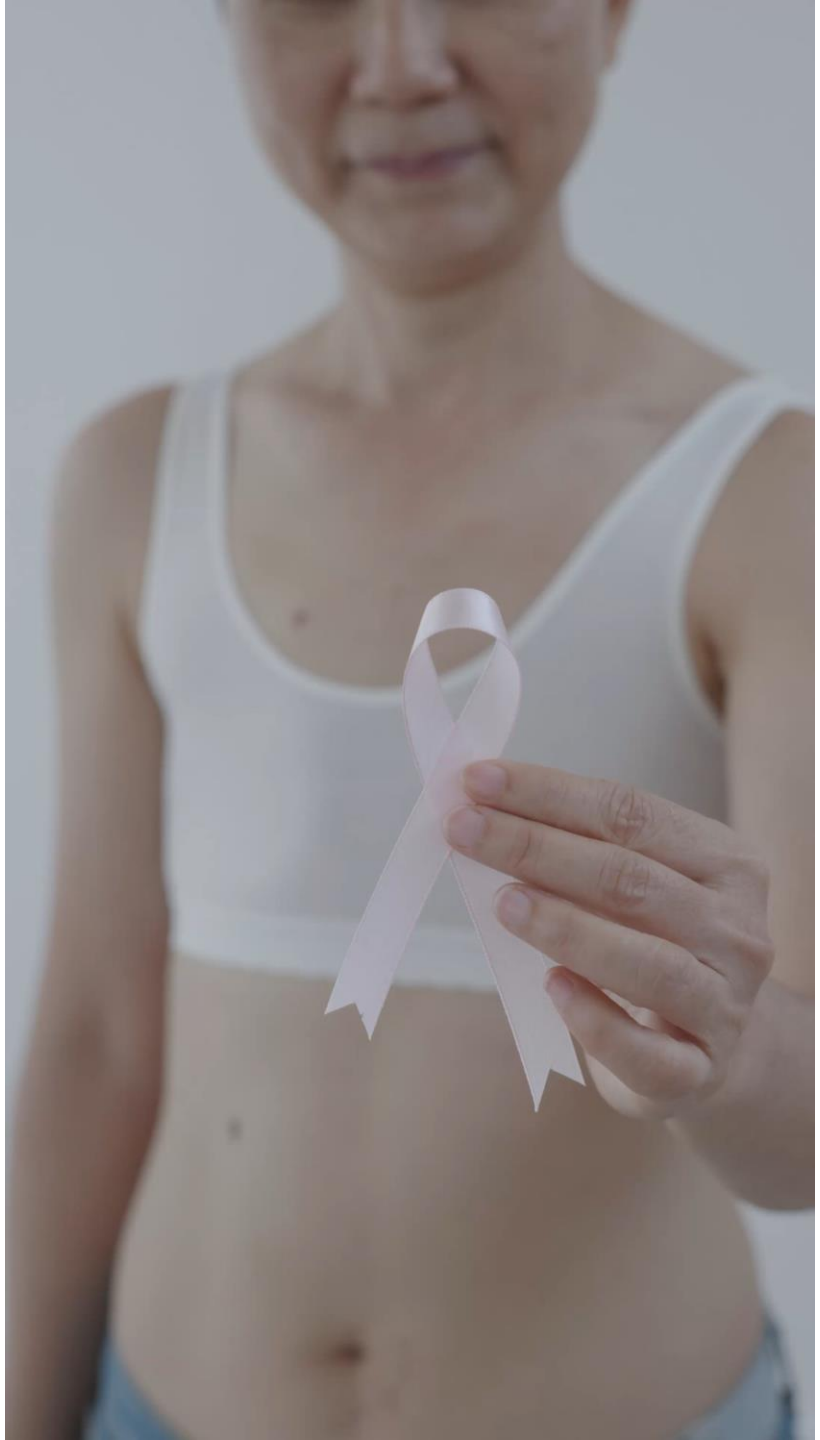
ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

Breast cancer



Heart attack

2010

2025

Clinical trials
Limited follow-up and exclusion criteria

Real-world data
Longer follow-up and entire patient population

VRIJE UNIVERSITEIT BRUSSEL

I-CHER INTERUNIVERSITY CENTRE FOR HEALTH ECONOMICS RESEARCH

UNIVERSITEIT GENT VUB

The societal cost of breast cancer

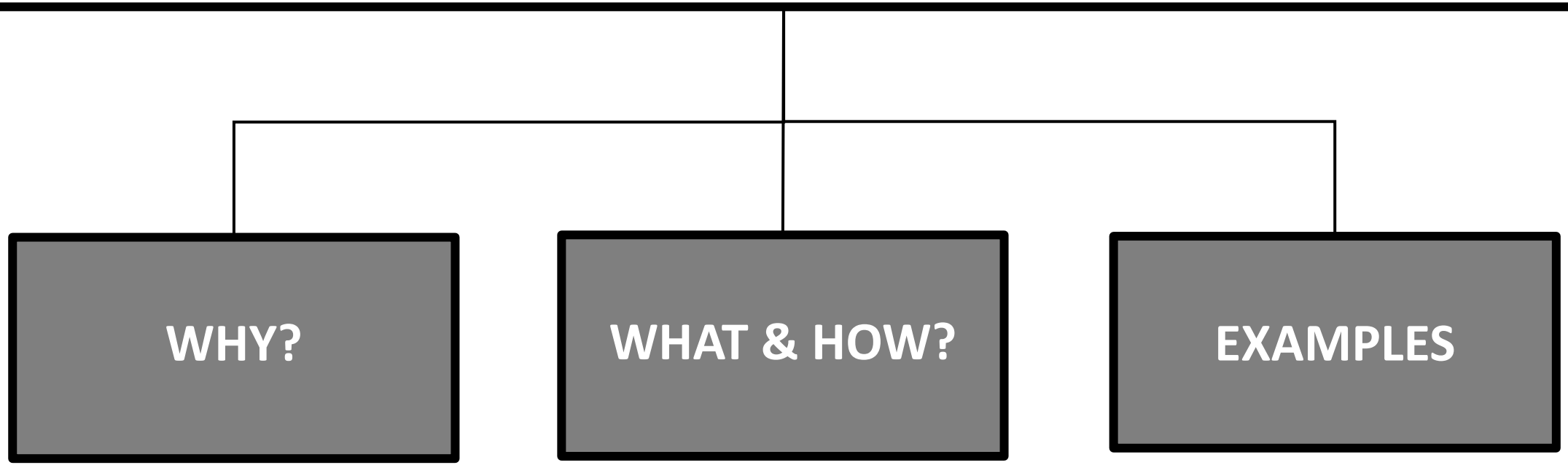
USING REAL-WORLD DATA TO ASSESS THE SHORT- AND LONG-TERM IMPACT OF DIAGNOSIS IN BELGIUM

Eva Kimpe

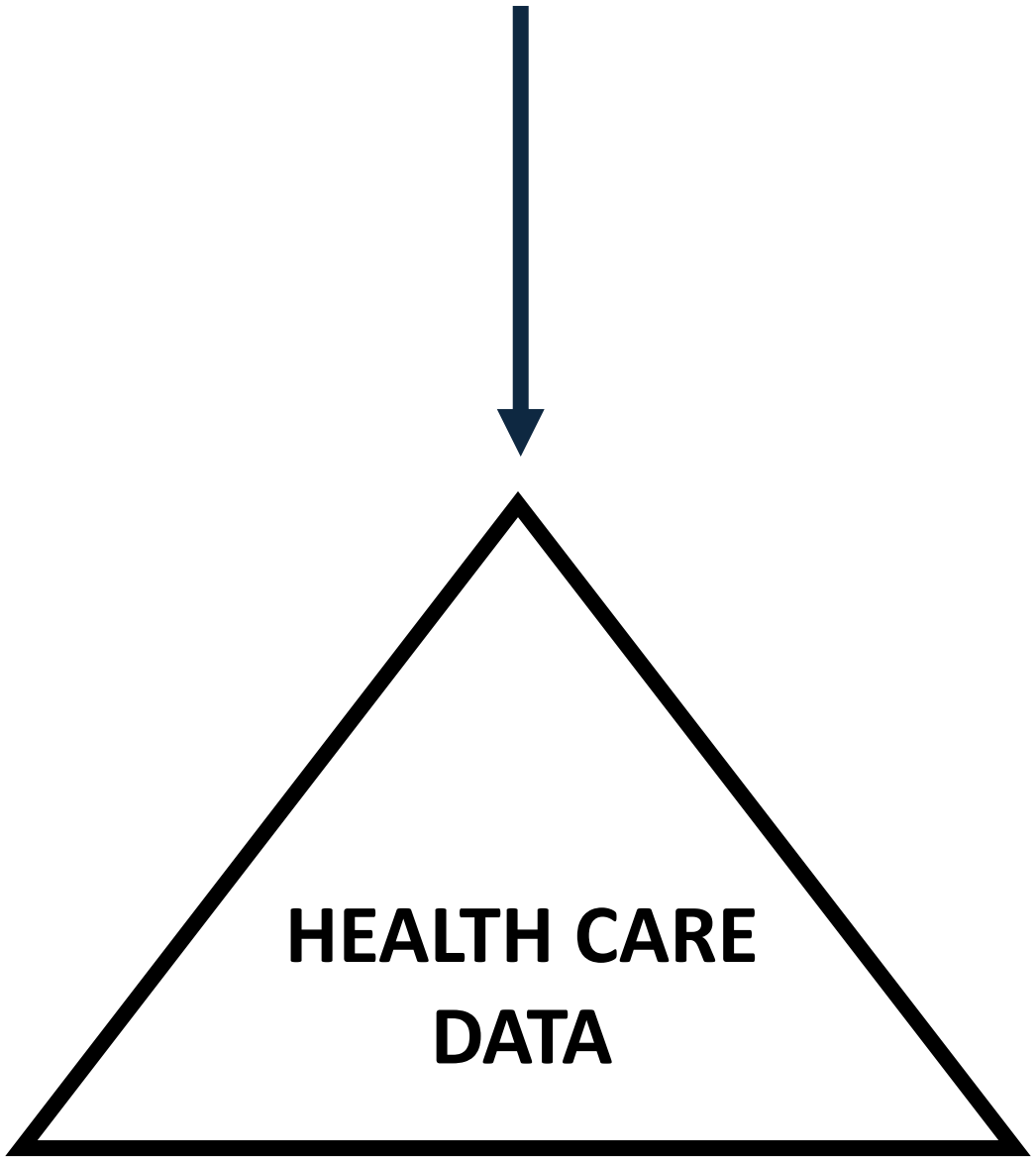
Supervisors: Prof. Dr. Koen Putman

Prof. Dr. Mark De Ridder

The use of real-world data in health economics outcomes research



Digitalization



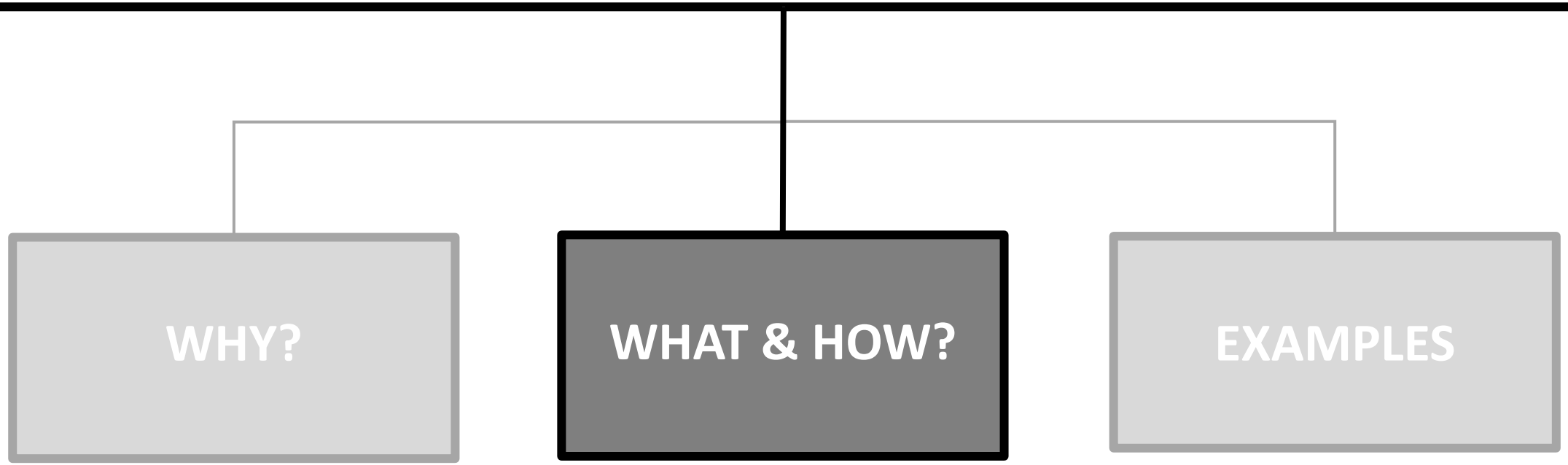
Real-world data is informative alongside RCTs

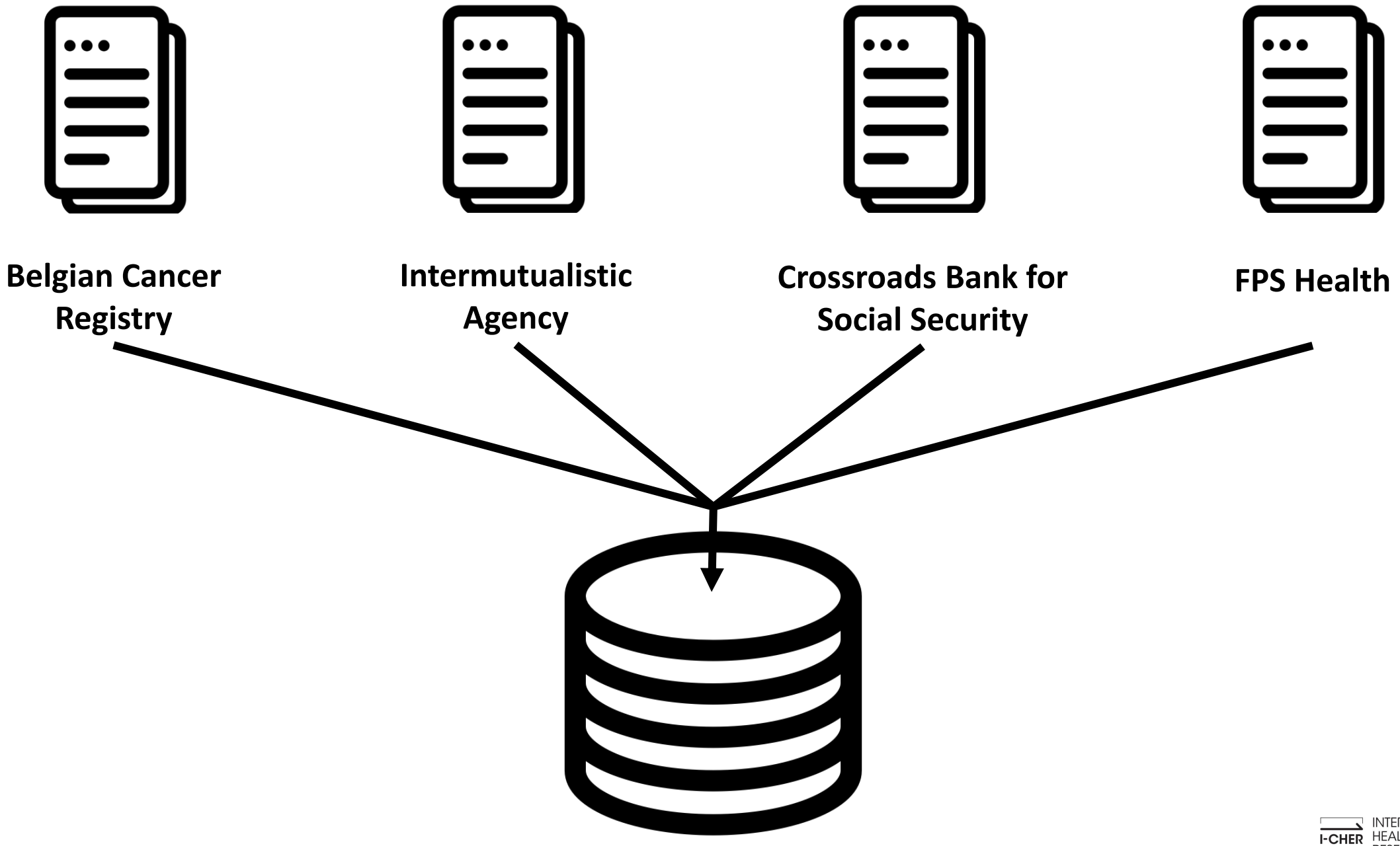
Clinical

Economic

Patient-reported outcomes

The use of real-world data in health economics outcomes research




Belgian Cancer Registry
Intermutualistic Agency
Crossroads Bank for Social Security
FPS Health

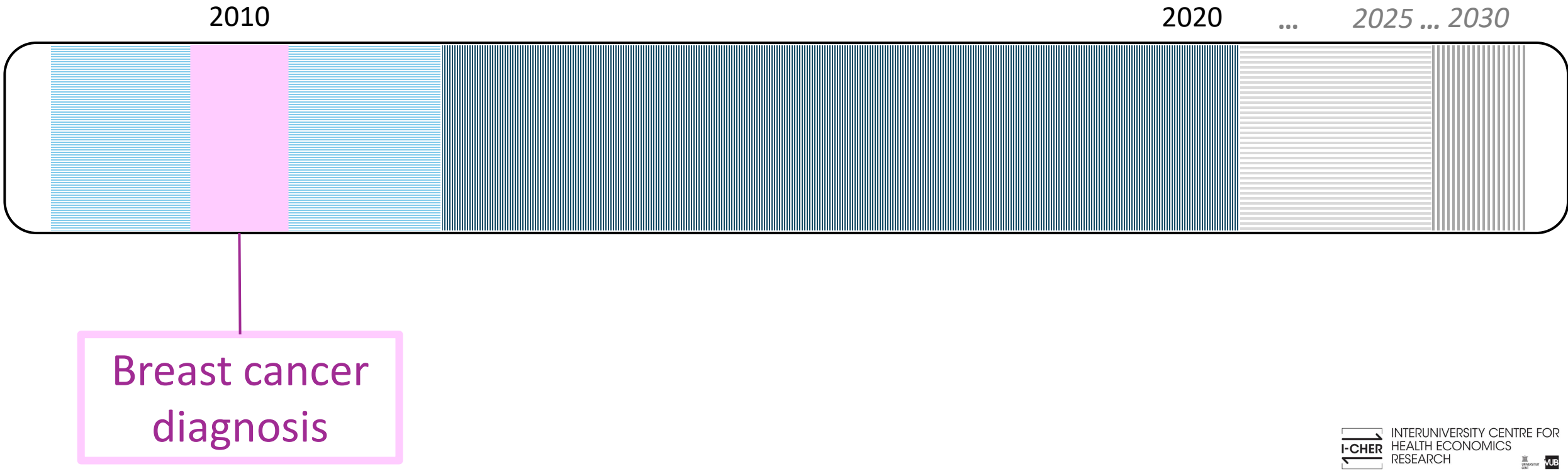
Healthcare cost of breast cancer treatment

Cardiovascular diseases and lung cancer in breast cancer survivors

Strategies to reduce burden of disease in breast cancer

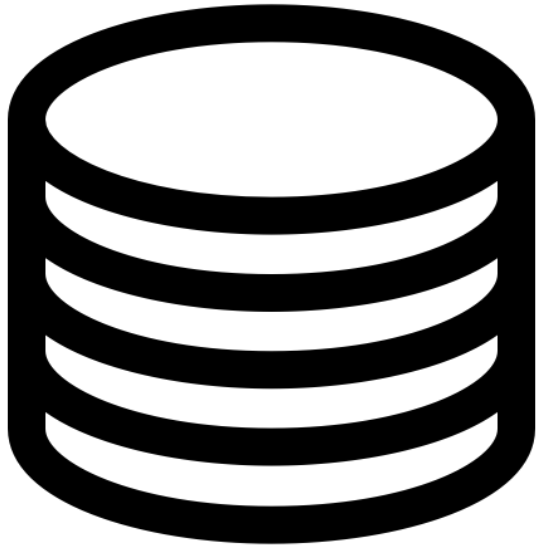
- Women
- Breast cancer diagnosis
- 2010
- *N* = 11,054

- Patient-level: IVC-CSI approval
- Multiple data provisions



Patient and tumour characteristics

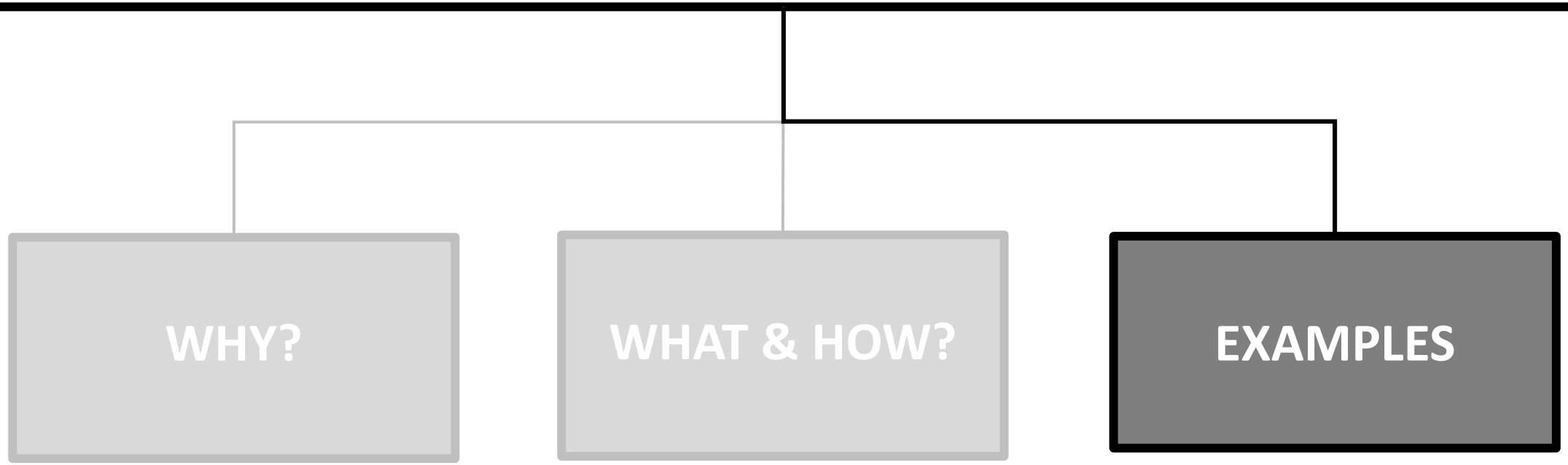
Socio-economic factors



Hospitalizations

Healthcare utilization and costs

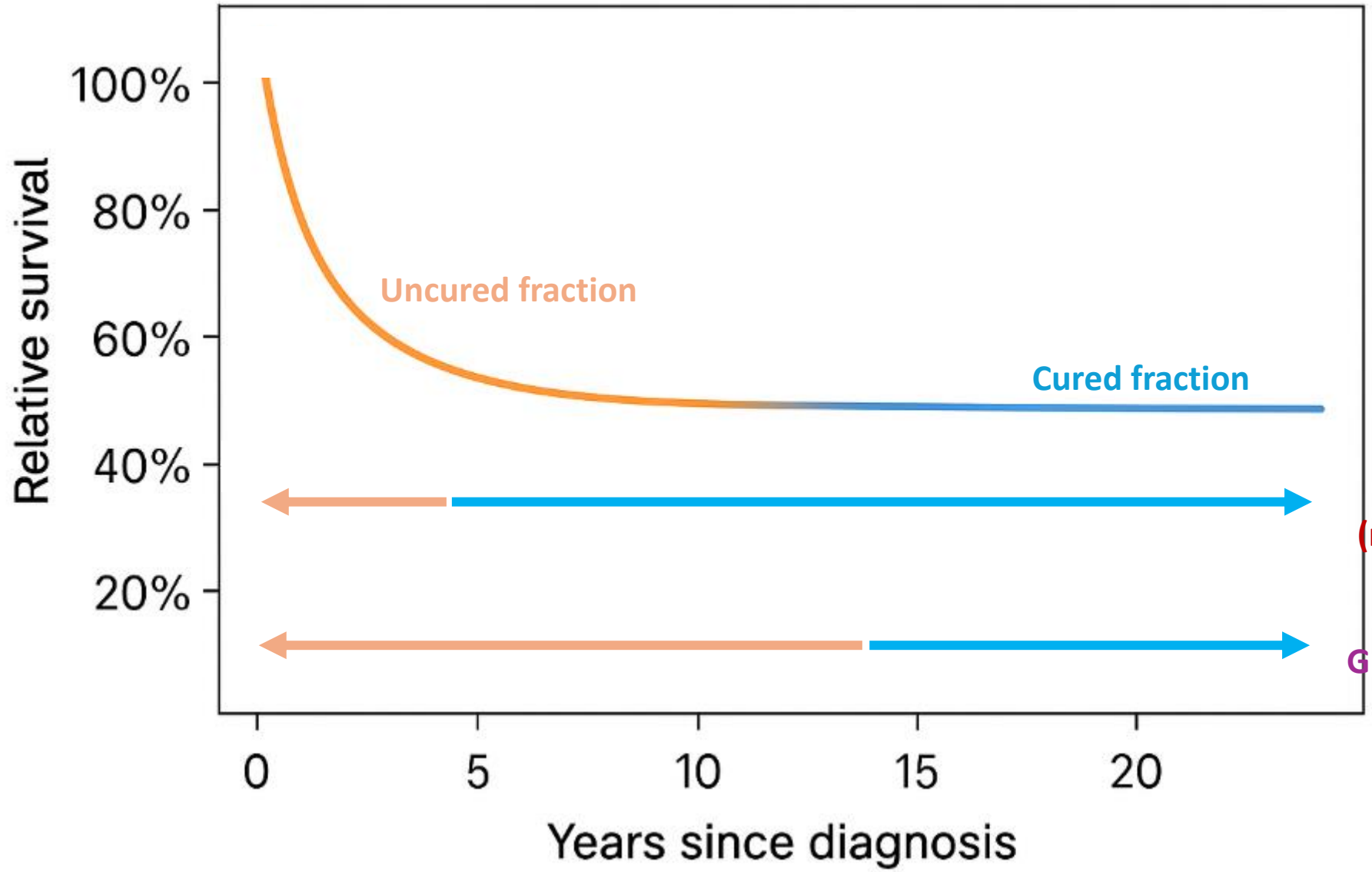
The use of real-world data in health economics outcomes research



Cancer survival is associated with various clinical-related factors, socio-economic determinants, healthcare utilization and drug use

- Rich data linkage (3 data providers)
- Long-term follow-up (10 year)
- Area-level proxies vs. patient-level data

- Invasive breast cancer (*N* = 9,982)
- 22 independent variables
- Mixture cure model → designed for long-term survival



GROUP A (reference odds = 1)

GROUP B (odds < 1)

	OR (95% C.I.)	*P-value*
Age	0.919 (0.918-0.919)	<0.001
Treatment (tx.)		
Surgery followed by adjuvant radiotherapy and systemic tx.	Ref.	
Surgery followed by adjuvant radiotherapy	1.073 (0.951-1.212)	0.254
Surgery alone	0.695 (0.620-0.780)	<0.001
Surgery followed by adjuvant systemic tx.	0.639 (0.611-0.668)	<0.001
No treatment	0.301 (0.264-0.343)	<0.001
Neo-adjuvant tx. followed by surgery with/without adjuvant tx.	0.289 (0.277-0.302)	<0.001
Primary systemic tx. and/or radiotherapy	0.025 (0.022-0.027	<0.001
Beneficiary to increased reimbursement		
No	Ref.	
Yes	0.522 (0.511-0.534)	<0.001
Unknown	0.280 (0.242-0.324)	<0.001

Long-term survival is associated with

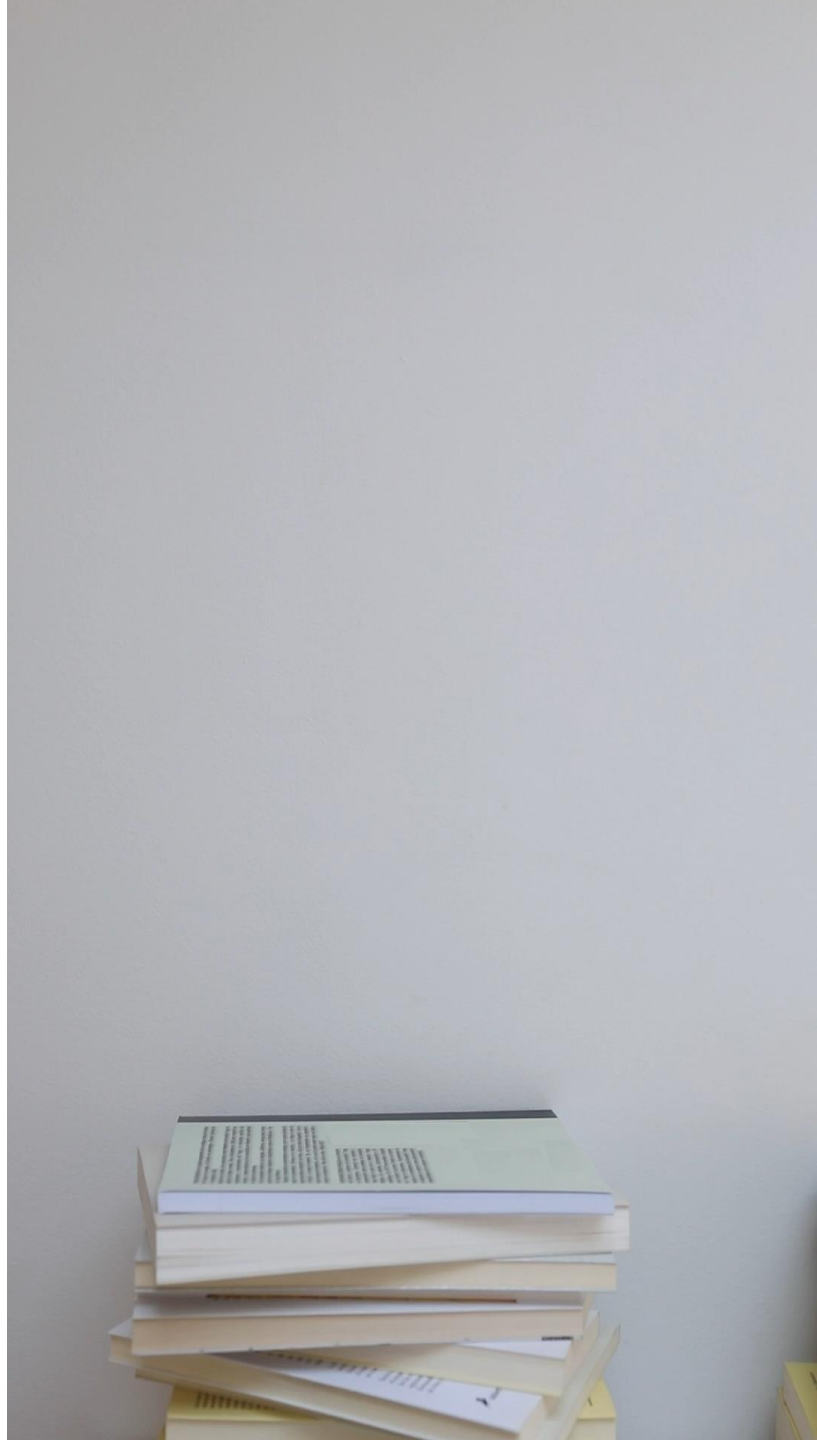
- Age
- Breast cancer treatment
- Entitlement to increased reimbursement

For healthcare policy-makers

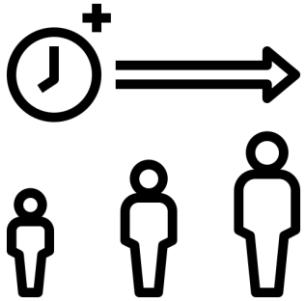
Tailor breast cancer screening programmes to women at risk of socio-economic deprivation

For academia

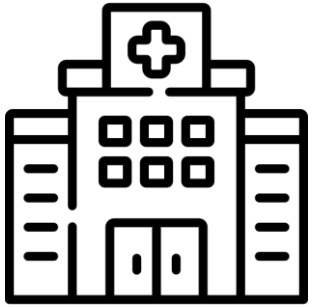
Advance understanding of the use and interpretation of cure models



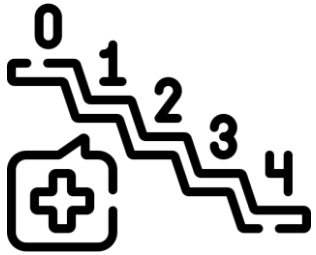
People with cancer encounter higher healthcare costs compared to the general population



Age

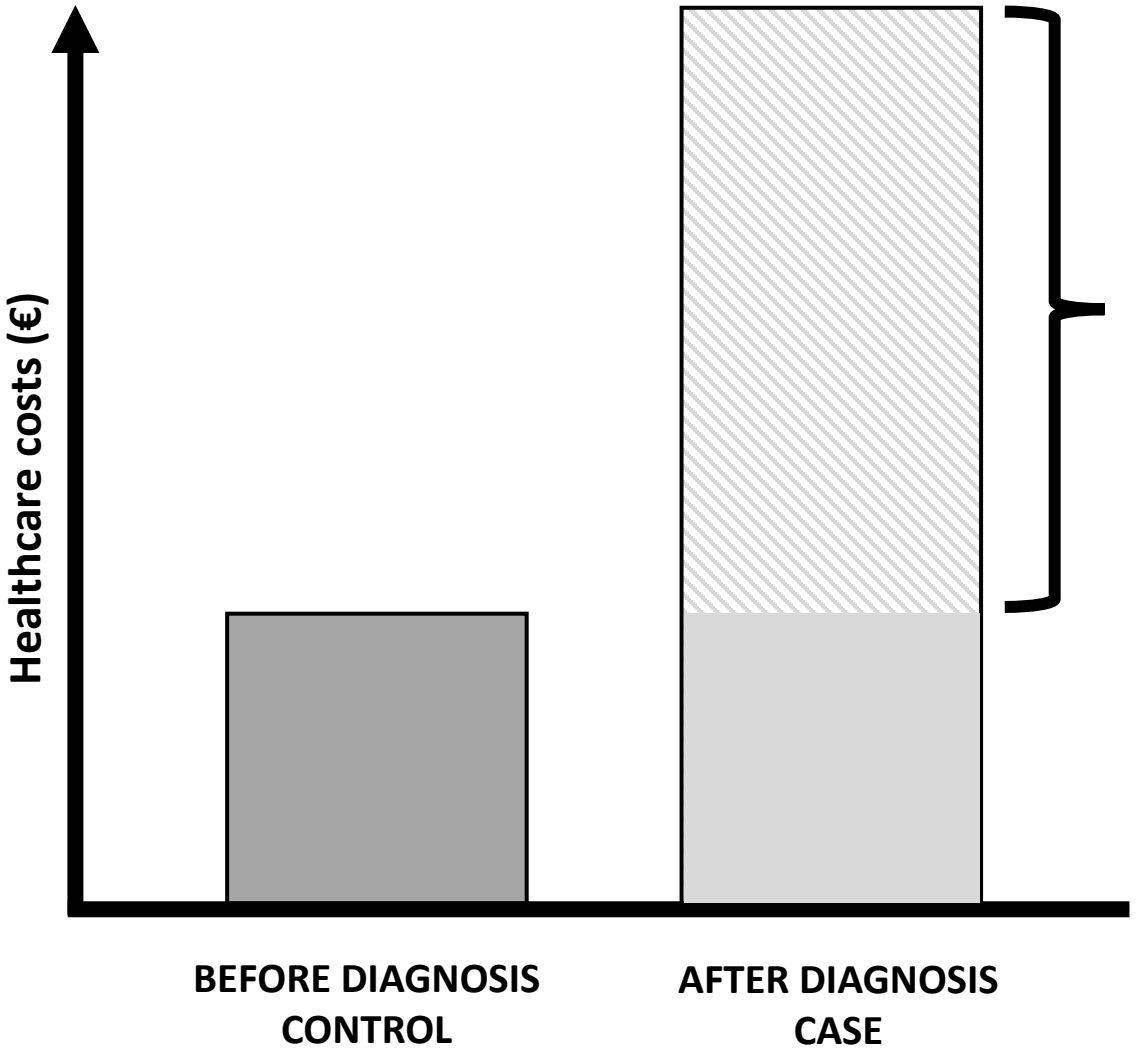


Cost type



Stage

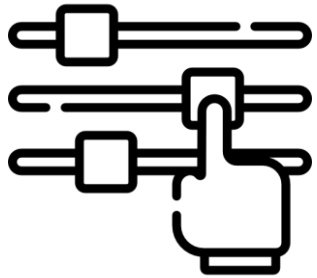
Income



Attributable cost

Case-crossover
Case-control

What is the attributable cost of breast cancer at a specific point in time after diagnosis?

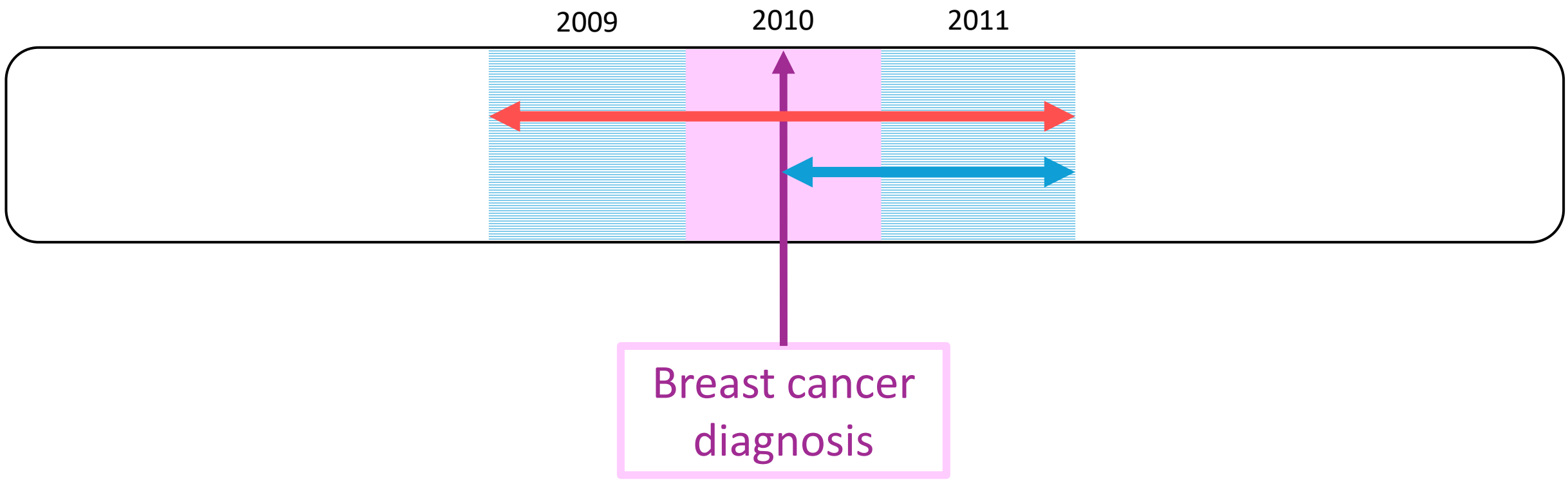


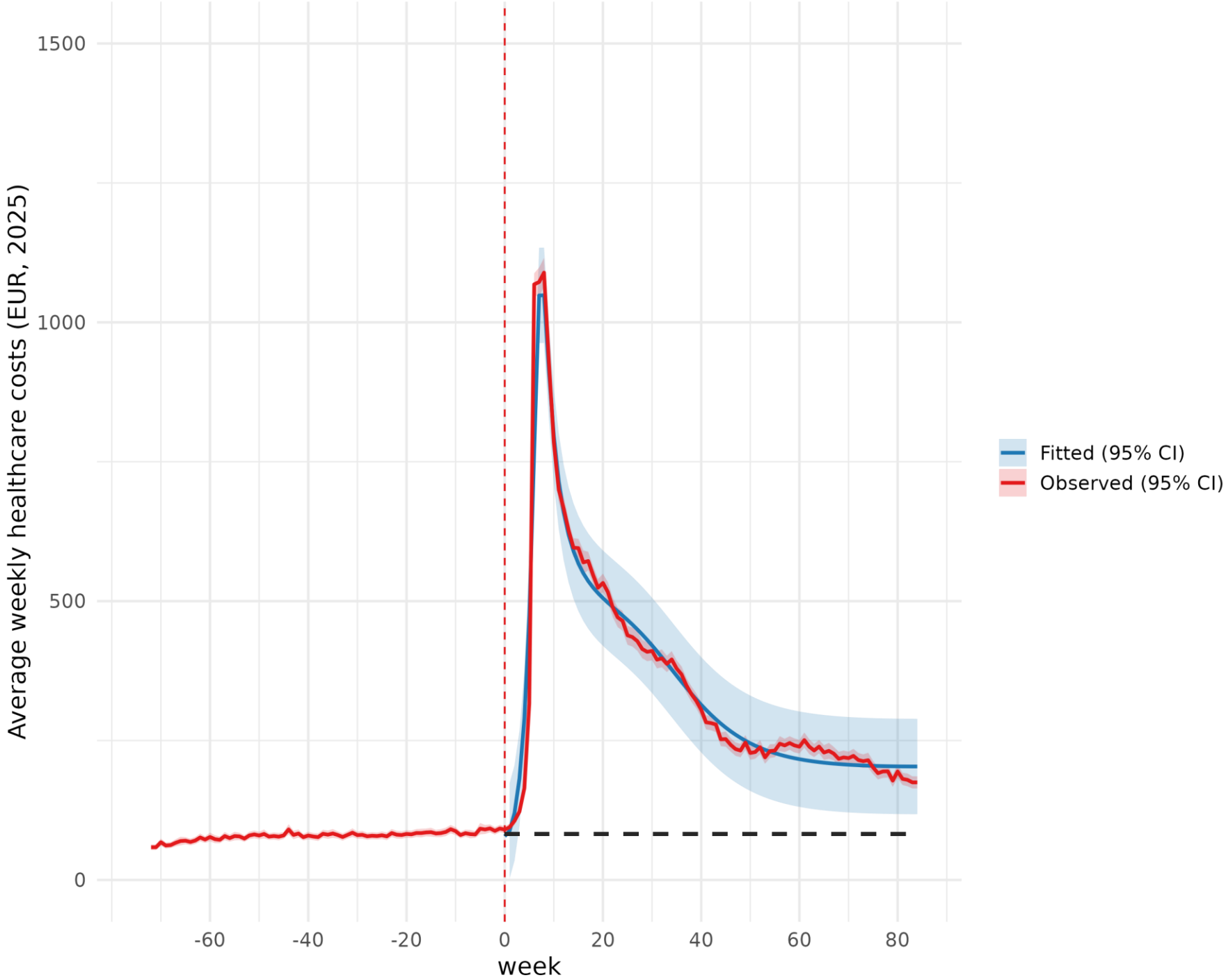
Variables

Cost patterns

Analytical window: 3 years

- Unadjusted observed costs
- Fitted time series model




1500
1000
500
0
Average weekly healthcare costs (EUR, 2025)
-60
-40
-20
0
20
40
60
80
week
Fitted (95% CI)
Observed (95% CI)

What is the added value of real-world data in health economics outcomes research?

- Context-specific
- Inclusive
- Patient-level
- Long-term follow-up

SCORA
~ Societal cost of radiation-induced morbidities in cancer survivors
Focus: **BREAST CANCER**

SENSATION
~ Societal costs and employment in persistent spinal pain syndrome type II patients after spinal cord stimulation
Focus: **CHRONIC PAIN**

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REBRAIN
~ Research on the impact of traumatic brain injuries
Focus: **TRAUMATIC BRAIN INJURIES**

HEARTWISE
~ The health economic analysis of return to work and the societal cost of cardiovascular diseases
Focus: **CARDIOVASCULAR DISEASES**

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Invents – Pharma-Academia Collaboration and Data Sharing via The French Health Data Hub – The Roche Perspective

Markus Elze, People and Product Leader, Roche

pharma.be
ASSOCIATION GÉNÉRALE DE L'INDUSTRIE DU MÉDICAMENT
ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

INVENTS: pharma-academia collaboration and data sharing via the French Health Data Hub - the Roche perspective

September 26th 2025
Forum Health Data & Digitalisation

David Pau, Claire Castagne, Camille Bachot, Jane Marshall, Svetlana Le Ralle, Markus Elze
Anne-Sophie Jannot, Geoffrey Rateau, Lise Vansteenkiste, Vincent Damotte, Marina Savelieva, Karen Sinclair, Sarah Zohar

Disclaimer: *this presentation are Roche views and are not supported by HDH*

INVENTS has received funding from the European Union's Horizon Europe Research and Innovation program under grant agreement 101136365.

Funded by the Swiss State Secretariat for Education, Research and Innovation (SERI).

Funded by the UKRI Innovative UK under their Horizon Europe Guarantee scheme.

The EU call HORIZON-HLTH-2023-IND-6.04

Modelling and simulation to address regulatory needs in the development of orphan and paediatric medicines

- Call linked to EMA's "**Regulatory Science Strategy to 2025**"
- **Expected outcomes**:
  - Developers and regulators have access to **robust modelling and simulation tools** to accelerate the effective development of orphan and/or paediatric medicinal products.
  - Developers and regulators use accurate simulation tools to **improve the statistical robustness in clinical trials intended for small populations and guide cost-effective clinical trials designs**.
  - Regulators have access to accurate **in-silico tools for assessing real world data (RWD) and patient reported outcomes** for optimizing the clinical endpoints in clinical trials for small populations.
  - **Regulators develop guidance** for a **robust extrapolation framework for the safety and efficacy** prediction during the regulatory assessment of orphan and/or paediatric medicinal products.
- Project is planned for 5 years with a budget of 8 million €

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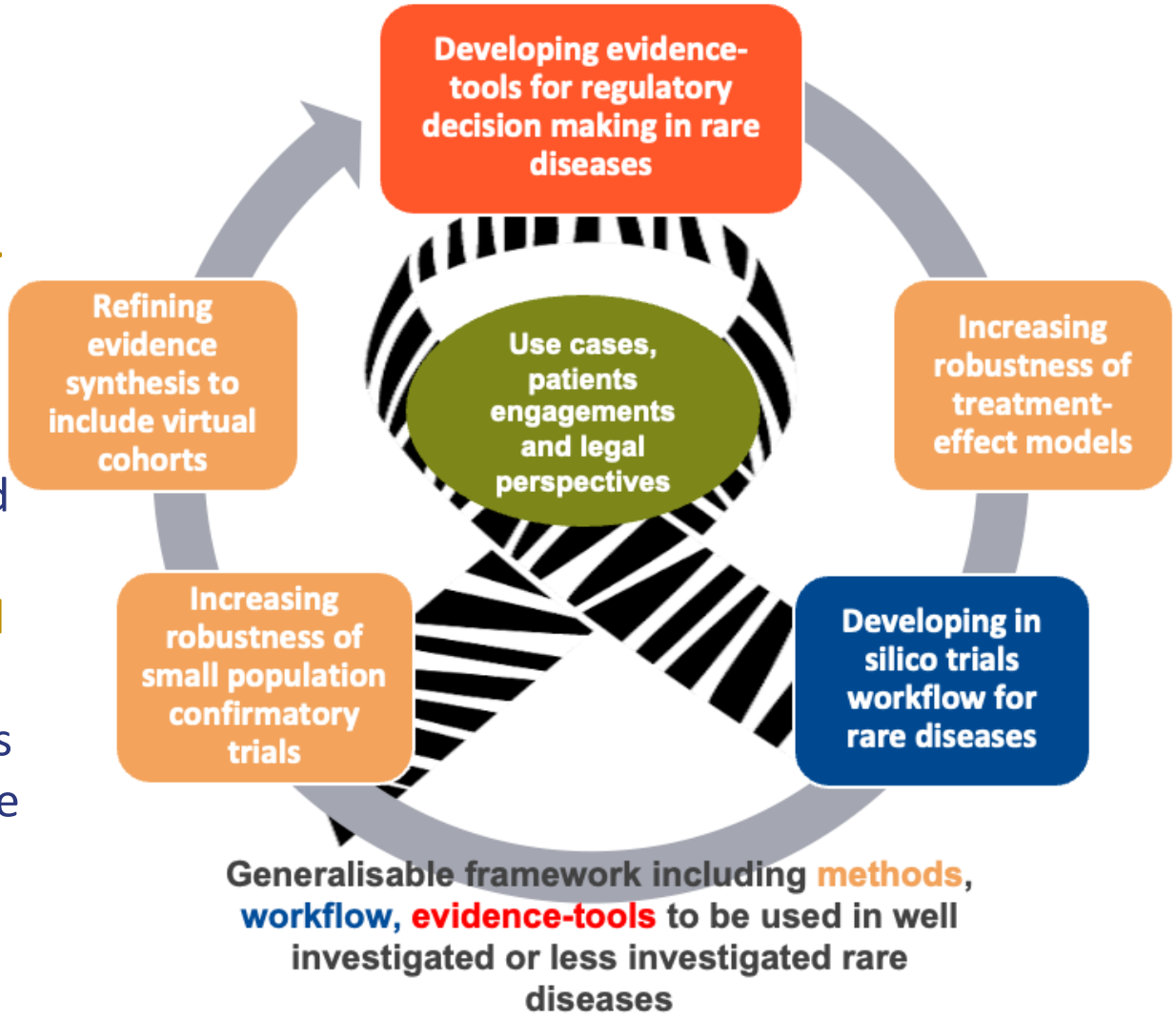
Objective of the INVENTS consortium

To provide clinical trial stakeholders, trialists and regulators with a **generalisable framework encompassing methods, workflows and evidence-tools to improve the level of evidence in regulatory decision making in rare diseases**.

This will be achieved through the development and validation of **improved extrapolation models, simulation and in silico trials, model based clinical trial design and evidence synthesis methods**, all based on robust and mature computational models and qualified on extensive data from representative selected use cases.



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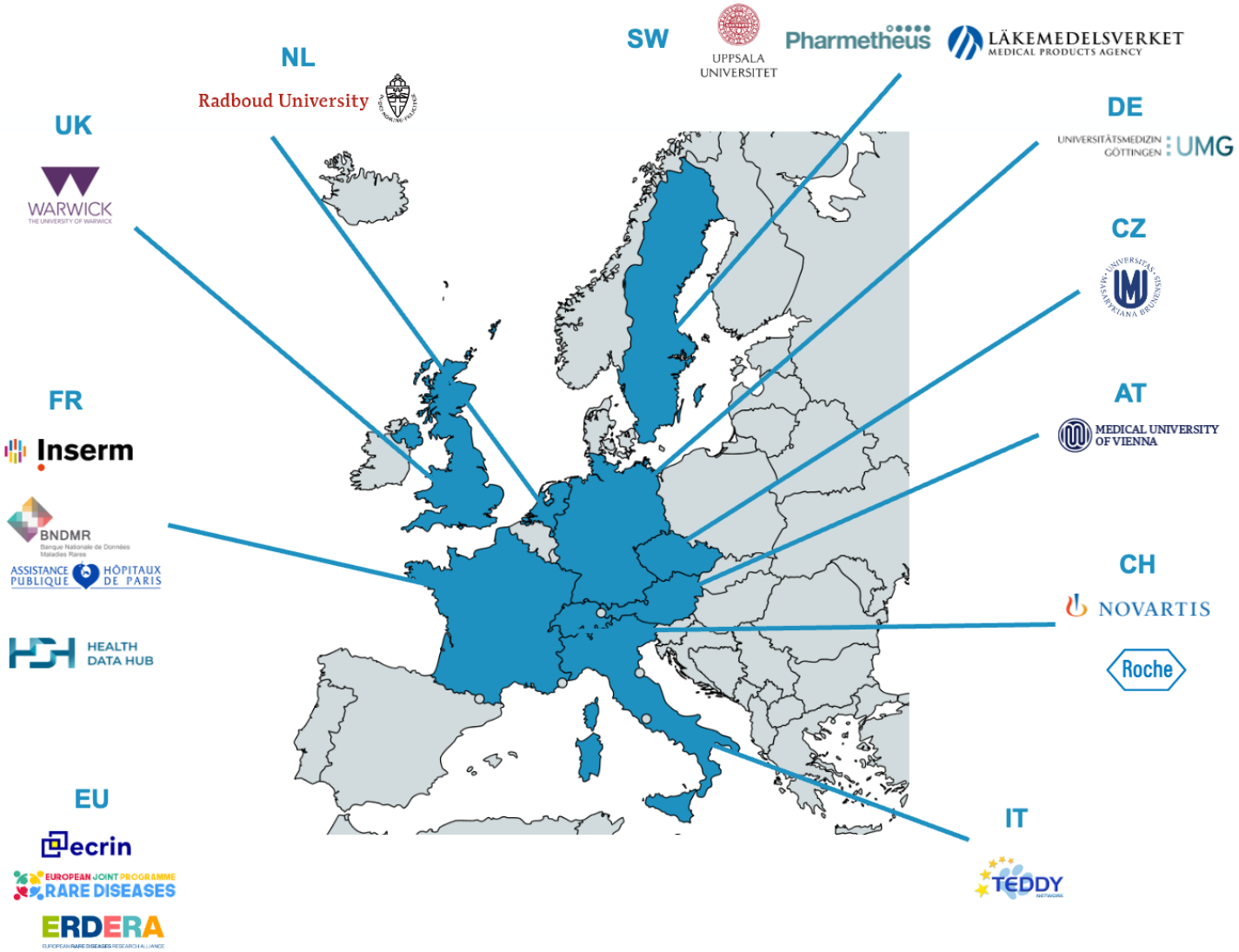
INVENTS as a pan-European partnership



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Health Data Hub
French public interest group to securely host patient data

HEALTH DATA HUB

- Make available pseudonymized patient data as well as analytical tools for researchers
- Supports data controllers in bringing data to the platform, including necessary ethics and privacy permissions, pseudonymization process, data documentation, and data use
- Strict controls to ensure the patient privacy and to enable patients to exercise their data rights
- Strategic partner throughout the project from ideation to final results and data deletion

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Funded by the Swiss State Secretariat for Education, Research and Innovation (SERI).

Funded by the UKRI Innovative UK under their Horizon Europe Guarantee scheme.

Key Roche data sharing challenges

- Secondary data use rules vary between countries – some are incompatible (e.g. China)
- Risk-based de-identification – remove key identifiers (e.g. ethnicity, site), move to relative dates
- GDPR compliance (anonymization or pseudonymization ?)
- Data protection laws are not always easily actionable (and different people have different interpretation)
- Study ICFs are older, so need to be manually assessed for compliance with current law
- Ethics and privacy approvals are mandatory
- Patients need to be informed about data use, but no ability to contact patients directly
- HDH is a wonderful platform, but comes with rules and processes for security and data ingestion

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Timeline of the Roche data sharing – getting the grant

- September 2022: initial contact between INSERM and Roche to discuss a possible project
- Winter: preliminary internal approvals for patient privacy, intellectual property, and resources
- January 2023: commitment letter signed
- April 2023: grant proposal submitted – successful in August
- Summer 2023: define which studies to share and gain approval from the molecule team
- November 2023: grant agreement signed
- January 2024: project start
- April 2024: 1 million in funding from the Swiss SERI for data anonymisation and PhD students
- May 2024: consortium agreement signed

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER
State Secretariat for Education, Research and Innovation SERI

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Funded by the UKRI Innovative UK under their Horizon Europe Guarantee scheme.

Timeline of the Roche data sharing – approvals

- January 2024: data anonymization process started, specs defined in summer 2024, initial programming in fall, then additional privacy review of results for paediatric and rare diseases
- March 2024: review of country ICFs for all studies
- April 2024: ethics submission to CESRESS (Comité éthique et scientifique pour les recherches, les études et les évaluations dans le domaine de la santé) – approved in April

CESREES
Comité Éthique et Scientifique pour les Recherches, les Études et les Évaluations en Santé

- April 2024: approval from Roche's Global Privacy Office
- July 2024: privacy submission to CNIL (Commission nationale de l'informatique et des libertés) – approved in October

CNIL.
COMMISSION NATIONALE INFORMATIQUE & LIBERTÉS

- September 2024: new SOP on external data sharing – additional review by Pharma Data Sharing Governance Committee
- December 2024: collective information to patients published
- April 2025: data anonymization completed

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Timeline of the Roche data sharing – making available

- Throughout 2024: workshops with HDH to prepare data sharing, work on security & compliance
- January 2025: HDH platform contract signed
- February 2025: create data documentation in HDH format
- March 2025: set up secure transfer channel to HDH
- April 2025: data sent to HDH together with data documentation
- April 2025: first users onboarded to HDH
- May 2025: data sharing agreements signed, ensure data subjects can exercise their rights
- Now: multiple partners able to work with data on HDH

HEALTH DATA HUB

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Three use cases to meet different modelling objectives

1. **Rheumatoid arthritis** is a very large, well understood adult disease with multiple large studies. Useful for modelling where a lot of patients are needed or where a good mechanistic understanding of the disease is helpful. Potential extrapolation to **giant cell arteritis** to explore additional evidence needs. Substantial additional French registry / real world studies are also available.
2. **Juvenile Idiopathic Arthritis** (polyarticular, systemic) has 4 pediatric studies that offer extrapolation from adult to pediatric or between related pediatric studies.
3. **Systemic sclerosis** has 2 large randomized trials with a negative primary endpoint and a (nominally) very positive secondary endpoint. This is an interesting example of a very high-quality replicated result without alpha control, which led to a label by FDA and a rejection by EMA.

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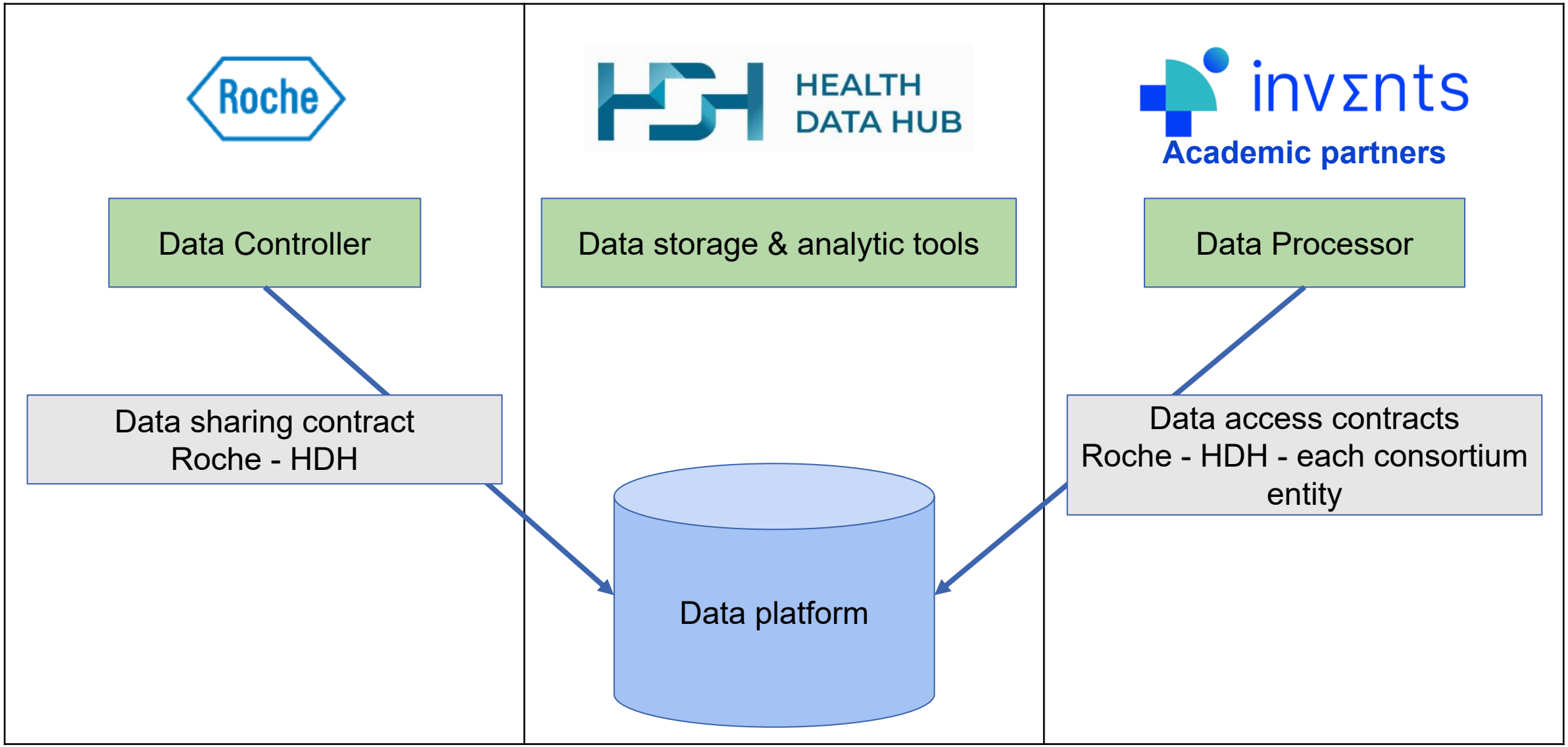
Sharing setup simplifies necessary privacy approvals



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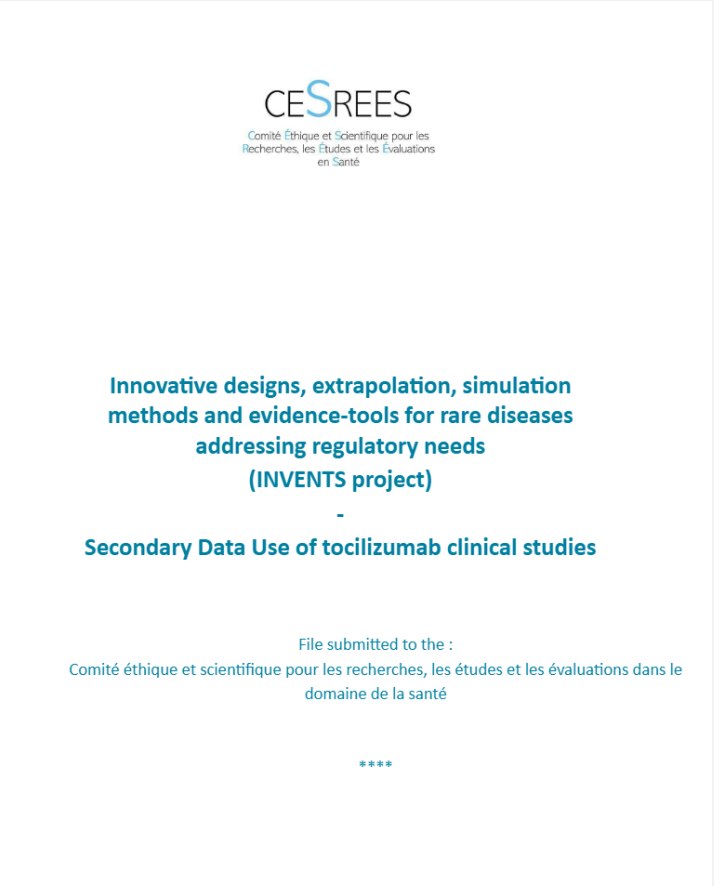
Protocol describes research objectives, methods, data protection and project roles

1. **Project participants**
2. **Objectives and aims**
3. **Methodology**
4. **Privacy, security, and confidentiality of data**

and…

- Ethics approval
- Informed consent
- Data documentation
- IT risk assessment


CESREES

Comité Éthique et Scientifique pour les Recherches, les Etudes et les Evaluations en Santé

Innovative designs, extrapolation, simulation methods and evidence-tools for rare diseases addressing regulatory needs (INVENTS project)

-

Secondary Data Use of tocilizumab clinical studies

File submitted to the :
Comité éthique et scientifique pour les recherches, les études et les évaluations dans le domaine de la santé

****

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De-identification to get privacy approval from the French National Commission on Informatics and Liberty (CNIL)

3.6. Preparation of data

Data collected from patients and their investigating physicians were originally pseudonymized and a patient number was randomly generated.

Before proceeding with the data sharing and analyses, preliminary work in 2 steps will be performed for each study:

1. Variables useful for the research will be selected and potentially identifying data will be removed, including:
    - Ethnicity information is needed for the purpose of pharmacokinetic modelling in work package 1, but will be limited to the most common ethnicities (others will be grouped as “other”) and access to ethnicity will be limited to situations where it is required for the purpose of the research
    - Patient names and initials will be removed
    - Site information will be removed
    - Country information will be removed, retaining only the geographic region (e.g. Europe)

2. Variables subject to modification are altered, including:
    - Patient number will be randomly re-allocated
    - All dates (enrolment, treatment administration, …) will be truncated (month/year) or removed

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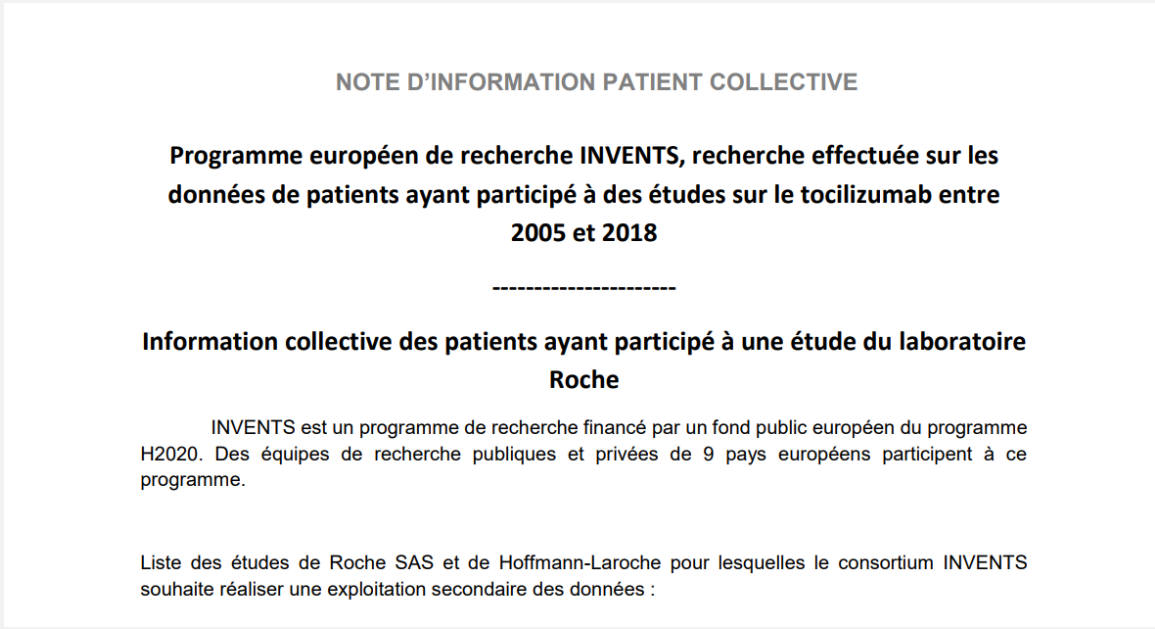
Collective information notifies study participants about research objectives and gives opportunity to opt out

1. **How is my data being used?**
2. **What is the research purpose?**
3. **How can I object?**



NOTE D'INFORMATION PATIENT COLLECTIVE

Programme européen de recherche INVENTS, recherche effectuée sur les données de patients ayant participé à des études sur le tocilizumab entre 2005 et 2018

Information collective des patients ayant participé à une étude du laboratoire Roche

INVENTS est un programme de recherche financé par un fond public européen du programme H2020. Des équipes de recherche publiques et privées de 9 pays européens participent à ce programme.

Liste des études de Roche SAS et de Hoffmann-Laroche pour lesquelles le consortium INVENTS souhaite réaliser une exploitation secondaire des données :

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Comprehensive sharing of clinical trial and RWD

Tocilizumab studies

Indication	Clinical Trials	Real world data
Rheumatoid arthritis	NCT00106548 (N=623➞442): Phase 3 NCT00106535 (N=1196➞894): Phase 3 NCT00109408 (N=673➞480); Phase 3 NCT00106522 (N=499➞458): Phase 3 NCT00106574 (N=1220➞983): Phase 3 NCT01331837 (N=3080➞2586): Phase 4 TOSCA (N=183➞183); Phase 4 TORPEDO (N=125➞125): Phase 4	Non-interventional studies: ACT SOLO (N=608➞608 ”POOL-TCZ”) SPARE-1 (N=321➞321 ”POOL-TCZ”) PEPS (N=719➞719 ”POOL-TCZ”) TANDEM (N=291➞291) DUO (N=1115➞1115)
Giant cell arteritis (rare disease)	NCT01791153 (N=251➞251): Phase 3	
Systemic sclerosis (rare disease)	NCT02453256 (N=212➞171): Phase 3 NCT01532869 (N=87➞87): Phase 2/3	
Systemic juvenile idiopathic arthritis, (paediatric)	NCT01904292 (N=51➞48): Phase 1 NCT01904279 (N=52➞50): Phase 1 NCT00642460 (N=112➞108): Phase 3 NCT00988221 (N=188➞176): Phase 3	

Total N is 10,096!

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Integration through The Telemedicine Platform in Practice

Tim Bogaert CTO, Byteflies

pharma.be
ASSOCIATION GÉNÉRALE DE L'INDUSTRIE DU MÉDICAMENT
ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

Transmural Platform

Phama.be - Sept 26

Who am I?

Byteflies

Vital Signs Measurements

HL7

Standardization

Make steps towards sustainable Healthcare

Data Interoperability

be MedTech
Medical Technologies Belgium

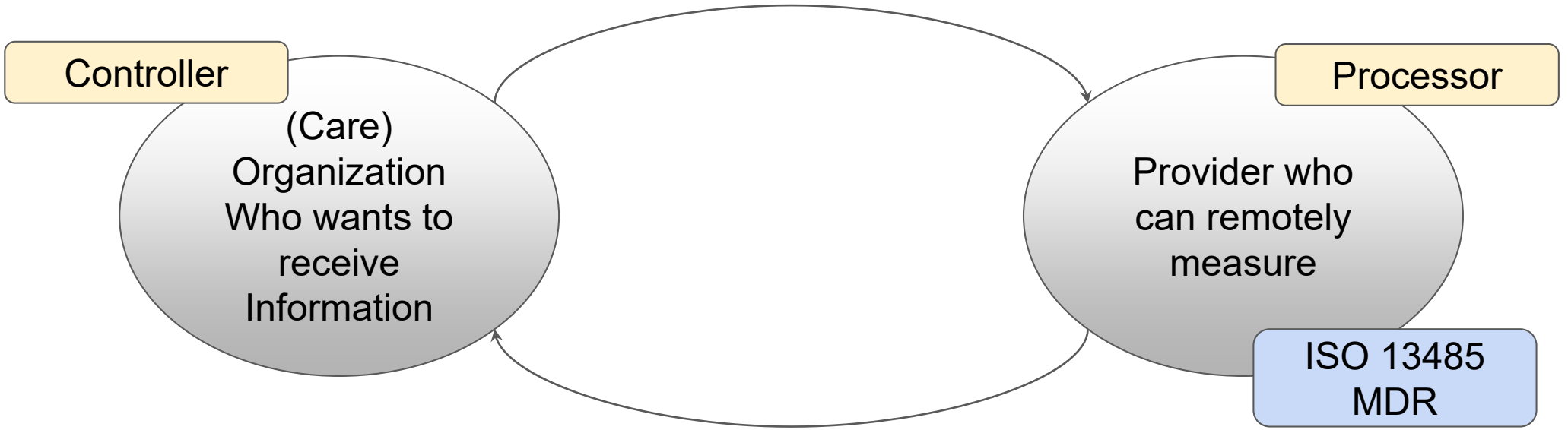
.AGORIA

e Health

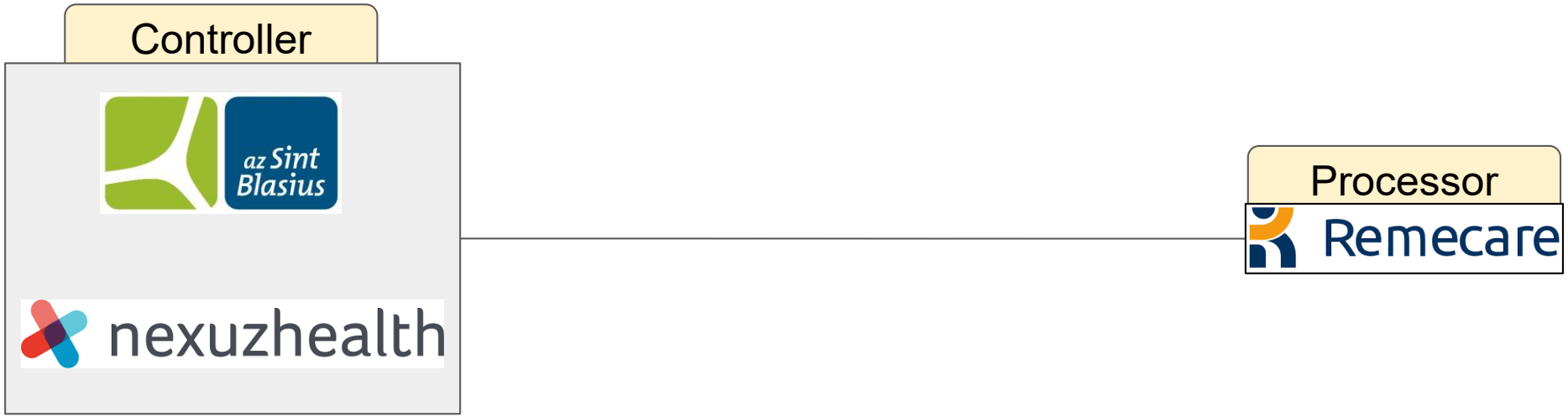
Direct Patient Impact

Brandweerzone Oost

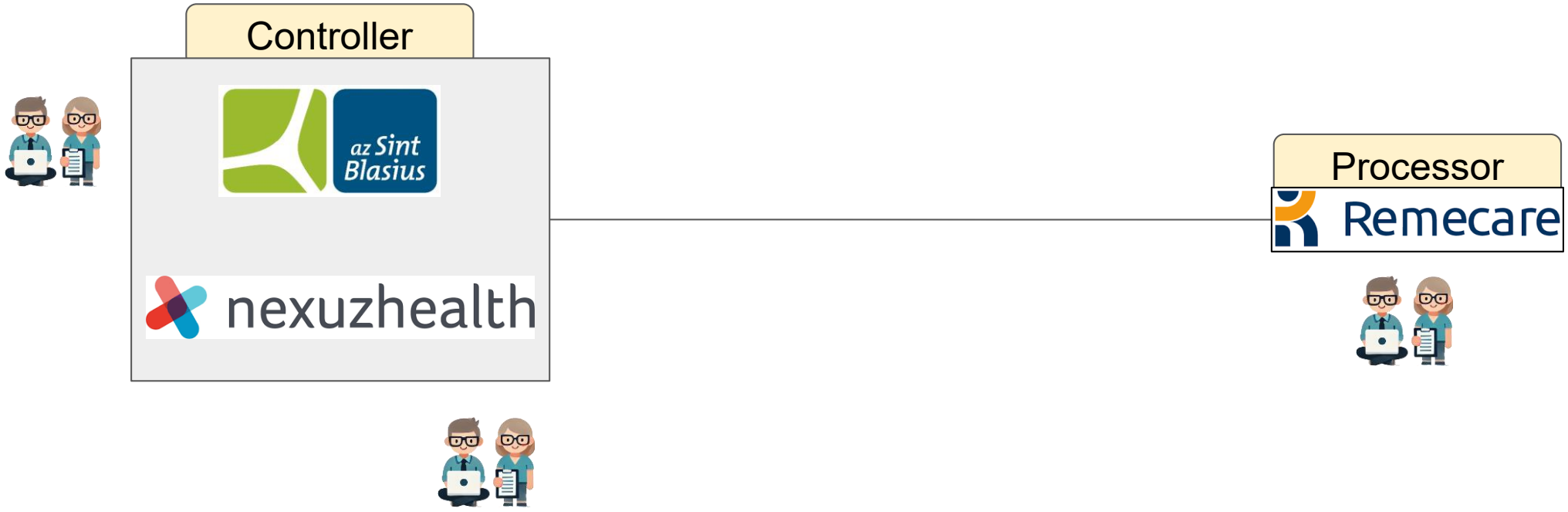
Remote Monitoring in Practice



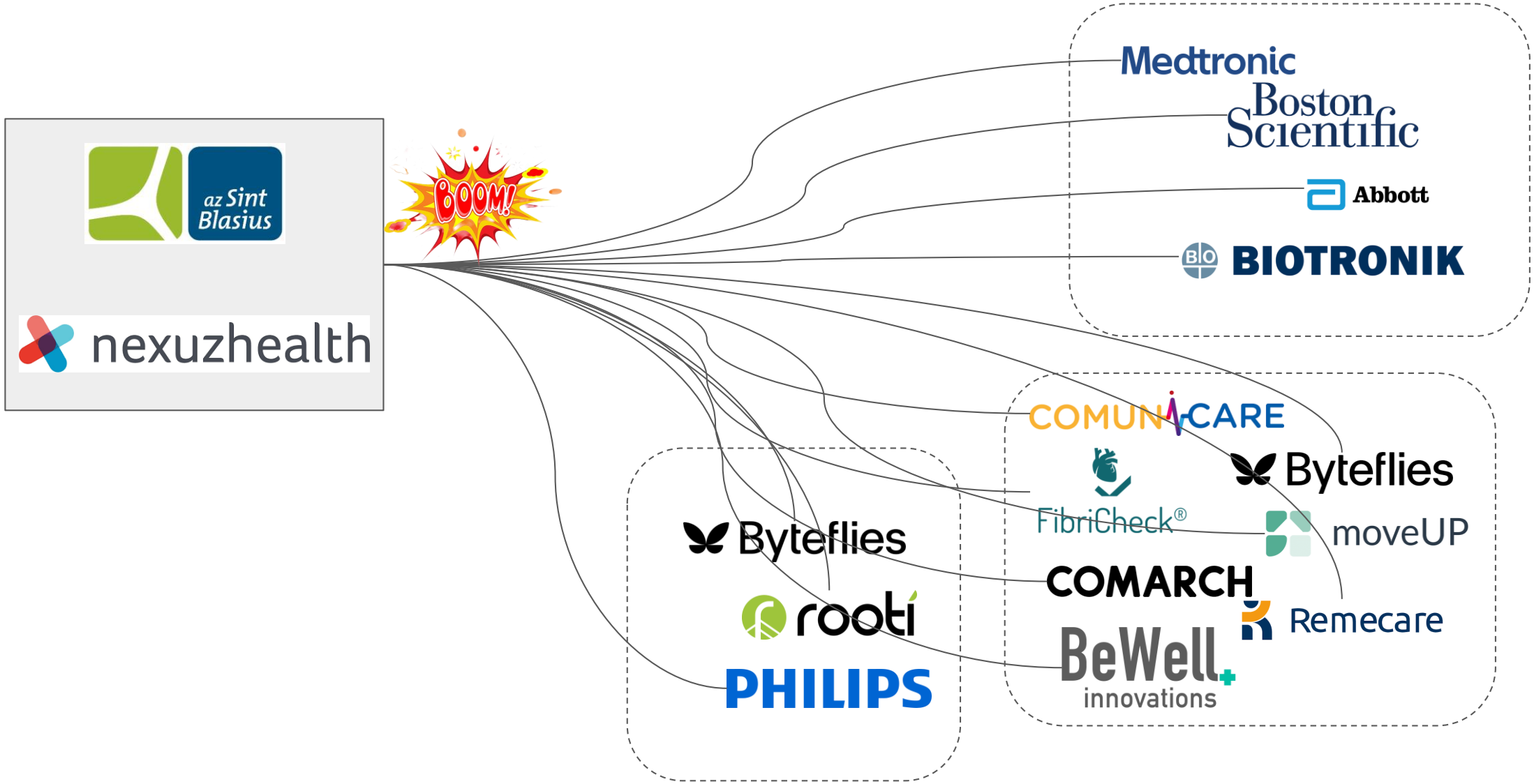
Remote Monitoring in Practice



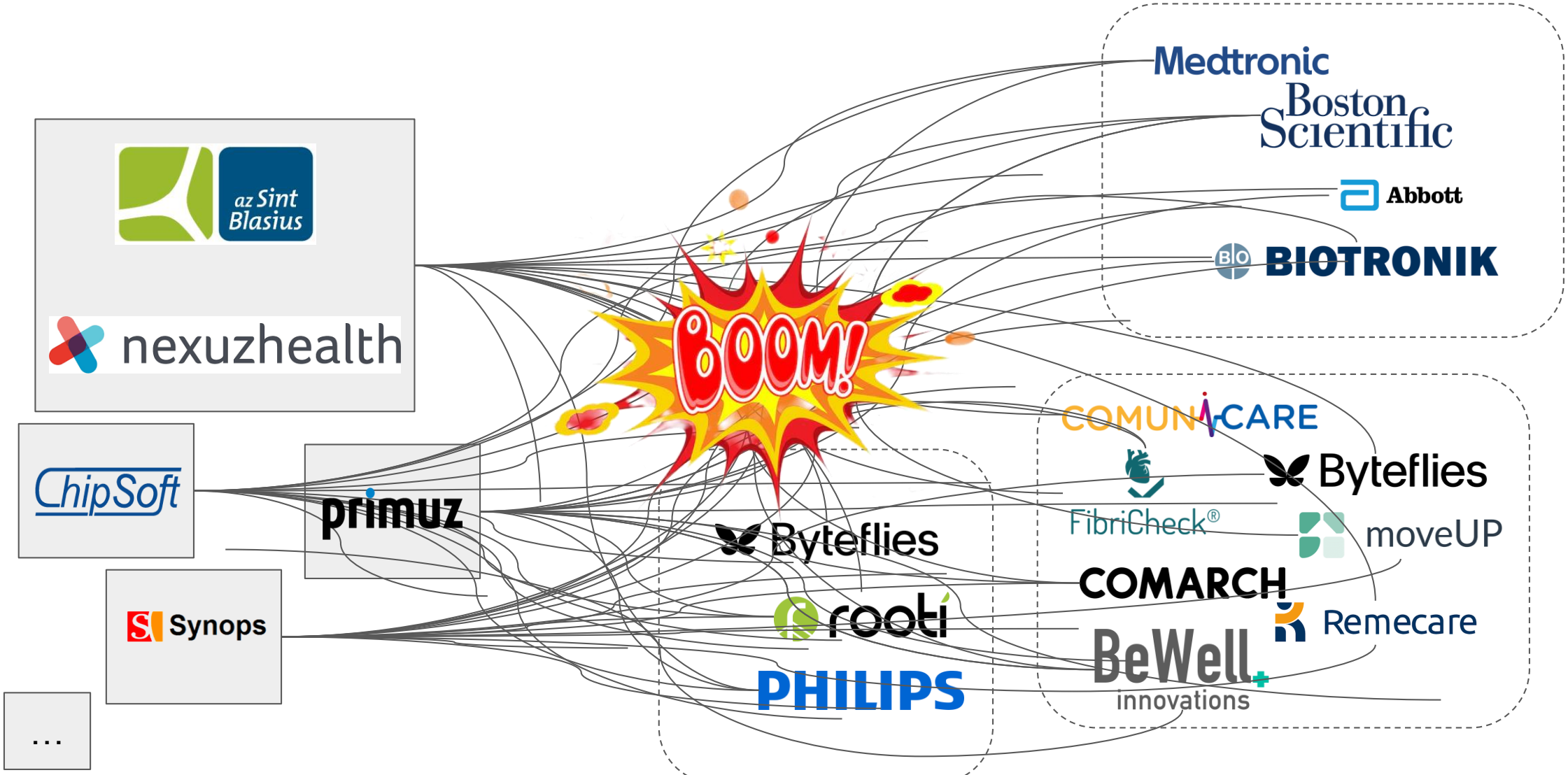
Remote Monitoring in Practice



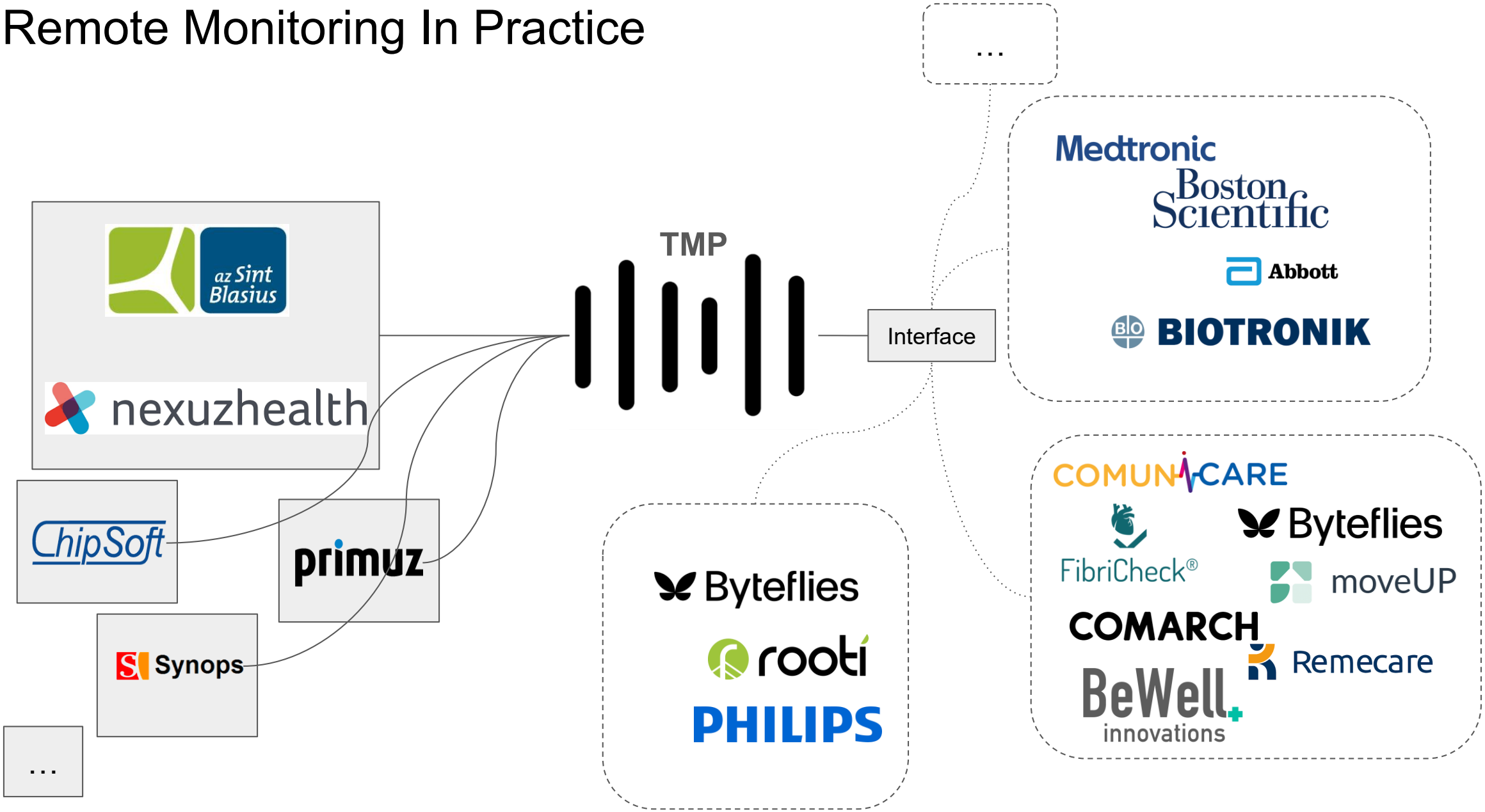
Remote Monitoring in Practice



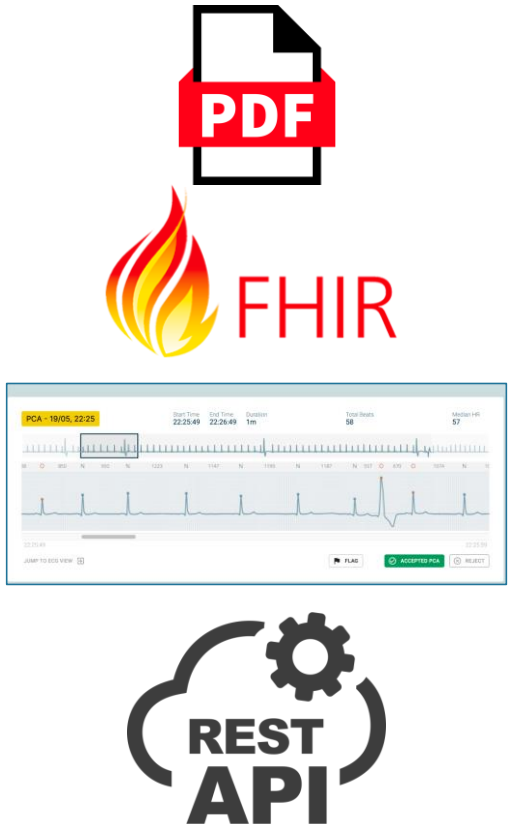
Remote Monitoring in Practice



Remote Monitoring In Practice



Layered Data Born FAIR



PDF : summary, unstructured

FHIR : structured measurements

Dashboard : full dataset, visual

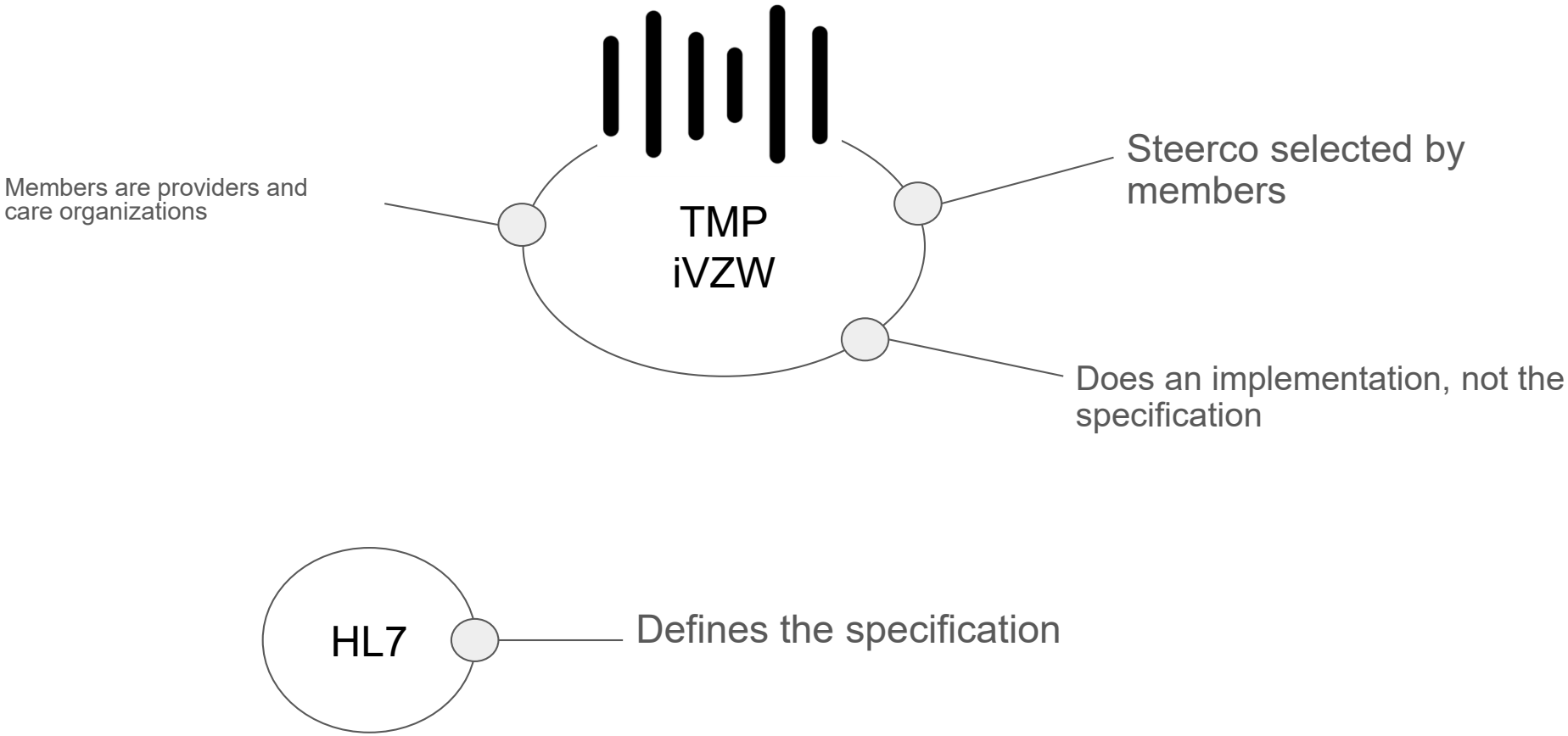
API : full dataset, structured

Findable, Accessible, Interoperable, Reusable

Unblocking Transmural Care

- One Integration connects you to a standardized data flow
- No Lock-in : new providers keep the same data flow
- Provider Transparency gets centralized
- Integrating new providers requires no effort on interoperability
- The Foundation for secondary Use

Interoperability needs neutrality



The Results

Milestones december 2025

10 hospitals

4 EHR’s

4 Providers

1000 Patients

The Results

Reality september 2025

~~Milestones december 2025~~

~~10~~ hospitals	~~4~~ EHR's	~~4~~ Providers	~~1000~~ Patients
56	**10**	**14**	**2800**

Evolve
Don’t disrupt

hospitals
EHRs
data providers
healthcare providers
carepaths
transmural landscape
governments
regions

Q?

Thank you and hope to see you next year with more RWD results!

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