Dutch National Cancer Data Node (NCDN-NL)

2025-12-08

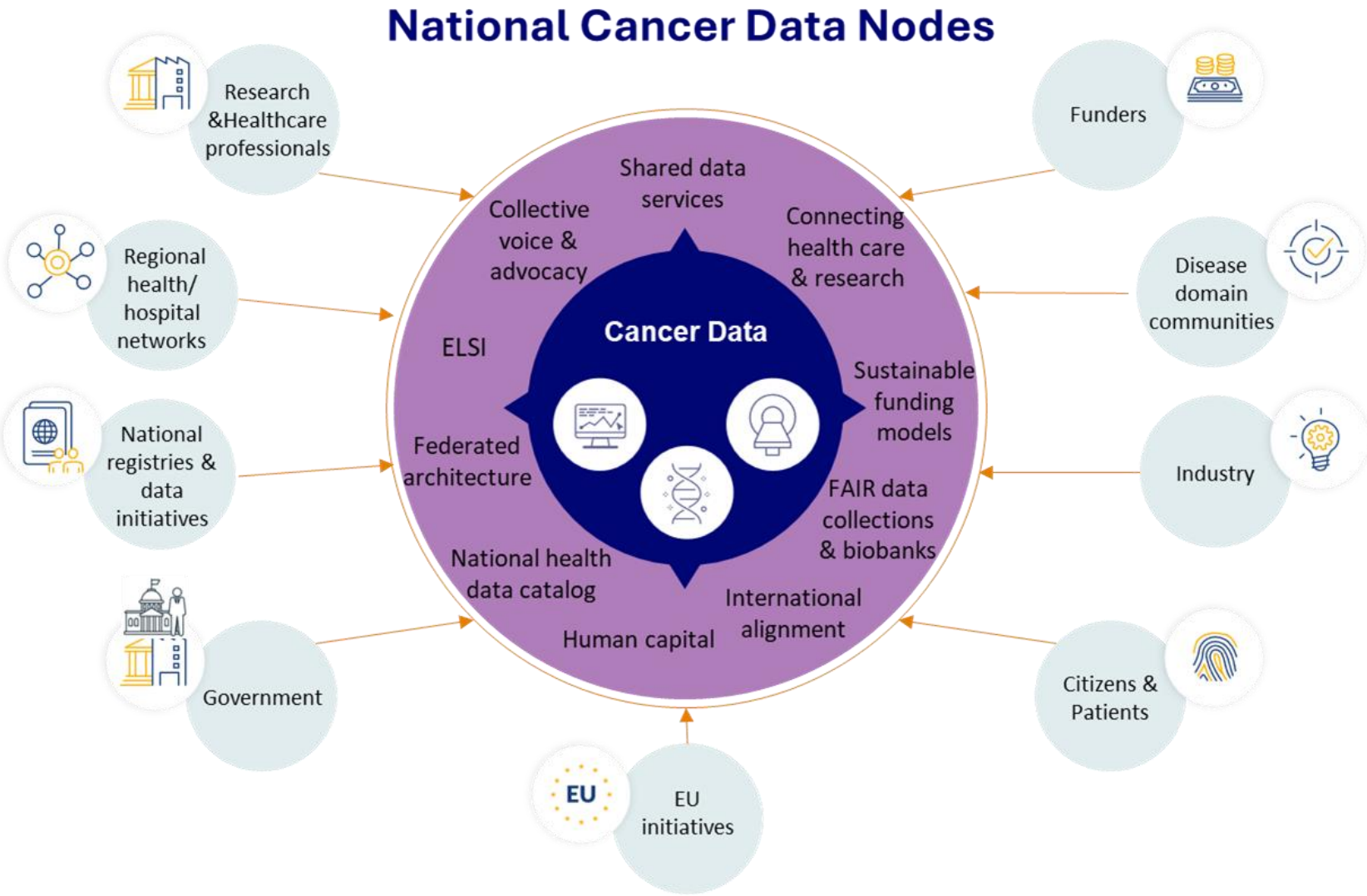
CANDLE

Funded by the European Union

The CANDLE project receives funding from the European Union's Horizon Europe programme, project number 101214368.

health RI
enabling data driven health & life sciences

A warm welcome to the whole system in this room



EOSC4Cancer and Node meetings

2021-11-02 (Heidag)

2022

2023-09-17

2024-04-12

2024-July-September
CANDLE proposal prep

Node WGs established

2024-10-18

CANDLE granted

2024-12-17

(9:46am CET)

Node meetings, WG meetings &CANDLE kick off

2025-01-31

2025-06-17

2025-06-24

2025-July-Dec

(Common data model, data linkage, cBioportal symposium, share genomic data, EOSC-ESFRI-EHDS)

2025-12-08

NCDN-NL=EU best practices acknowledged by EC and MS

2025-11-27~28

- eCancer thematic working group meeting with 25 MS and three DGs: (EHDS blueprint DC, bring EU initiative together on national level)
- Cyprus EU presidency event, 2026-04-23, NCDN roadshow
- EC cancer mission projects support 2026-09-29~10-01

NETHERLANDS CANCER INSTITUTE
ANTONI VAN LEEUWENHOEK

Symposium: cBioPortal - Making cancer data accessible for all

Tuesday 11 November 2025
09:00 - 17:00
Netherlands Cancer Institute
Symposium

health RI
enabling data driven health

Go together: go faster and further

Guiding principles

- EHDS blueprint and realization of functions of NCDNs
- ‘Whole system in the room’ =user-driven
- *Productize* functions tailored for users’ needs

EU opportunities

- CANDLE
- ECHoS collaboration
- EUnetCCC
- JA-PCM
- New EU funding opportunities

Events

- Cyprus Presidencial event
- EU-funded project NCDN supports
- CANDLE related events
- NCDN meetings, WGs

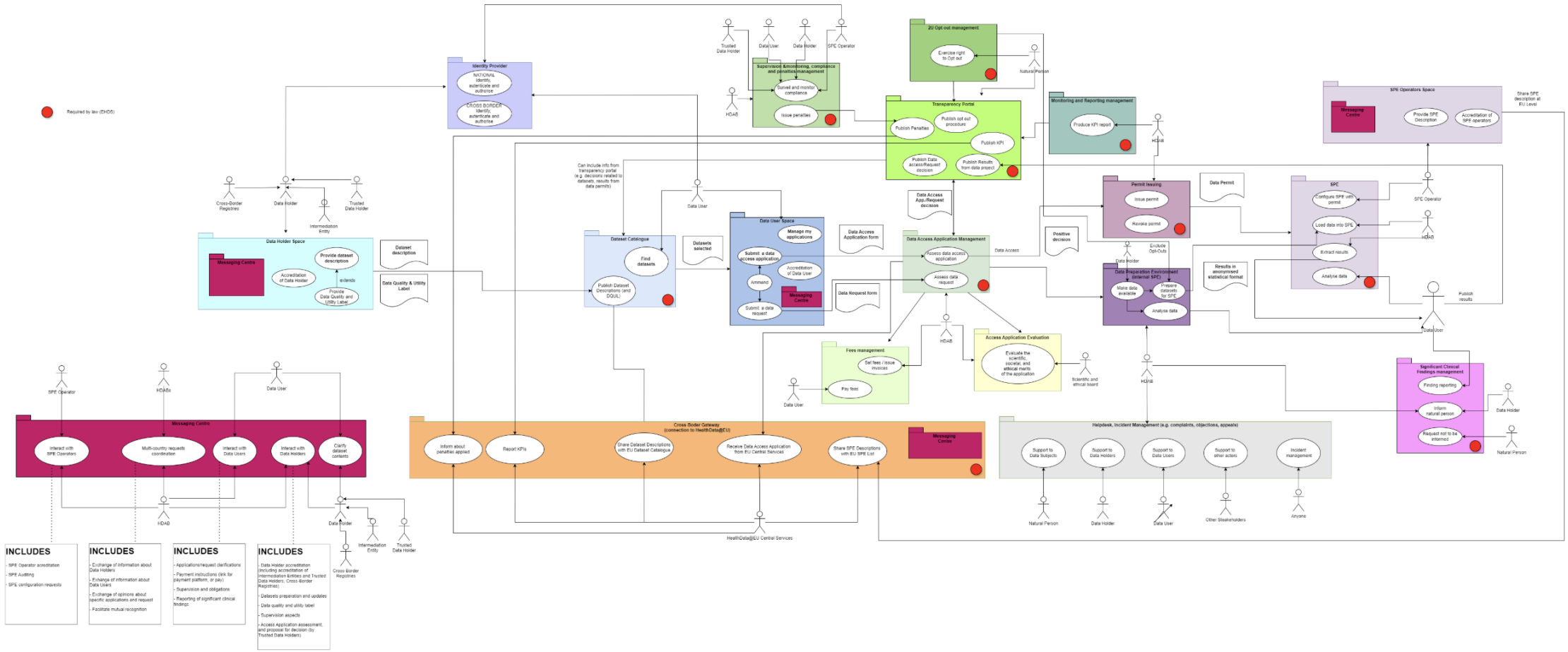
CANDLE

NCDN-NL

National Cancer Data Nodes

National Cancer Data Nodes (NCDNs) are federated hubs, responsible for standardising and harmonising data procedures within their country/region, and providing the digital tools for research collaboration – all aligned with national EHDS roles. These nodes will link to the UNCAN.eu platform (built by UNCAN-Connect). They are crucial to consider national conditions when building a European cancer data infrastructure. During the project, CANDLE will further conceptualise the nodes and their users.

Backbone


Identity Provider
Supervision &monitoring, compliance and penalties management
2U Opt out management
Transparency Portal
Monitoring and Reporting management
SPE Operators Space
Permit issuing
SPE
Data Holder Space
Dataset Catalogue
Data User Space
Data Access Application Management
Data Preparation Environment (internal SPE)
Fees management
Access Application Evaluation
Significant Clinical Findings management
Messaging Centre
Cross Border Gateway (connection to HealthData@EU)
Helpdesk, Incident Management (e.g. complaints, objections, appeals)
HealthData@EU Central Services
INCLUDES
INCLUDES
INCLUDES
INCLUDES

THEDAS2 consultation and comitology from Health-RI and ENCR

Gerrit Meijer (Health-RI)

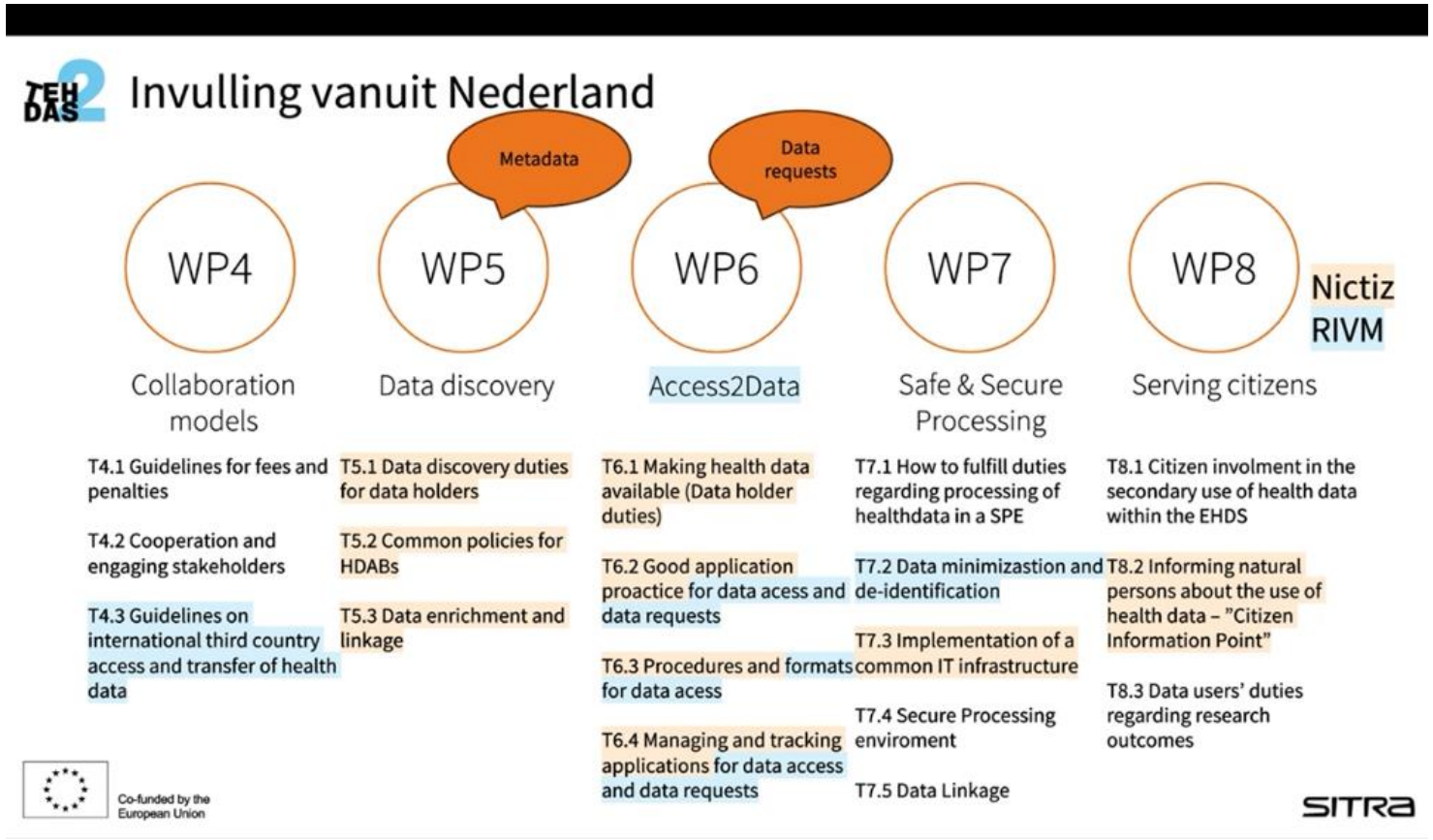
and Mattijs Sloep (ENCR representative)

health RI
enabling data driven health & life sciences


2025
March 2027
2029
March 2031
on to other
ries of data
al images,
y results and
charge reports)
Wij tellen af tot de EHDS
3
JAREN
109
DAGEN
2
UREN
34
MINUTEN
4
SECONDEN
March
Entry into
of the EHDS
start of the transition phase
2027
of certain categories of health data
(patient records,
electronic prescriptions
and dispensing)
2031

TEHDAS2 basis voor uitvoeringshandelingen EHDS

- Europees project
- 30 Europese landen
- NL: Nictiz & RIVM, Health-RI nauw betrokken
- Doel: EC adviseren over guidelines (niet verplichtend) en technische specificaties (wel verplichtend) voor secondair gebruik van gezondheidsdata



Comitologieproces

Implementing Acts under the EHDS

- Lidstaten en Europese Commissie overleggen over lagere wetgeveing EHDS (uitvoeringshandelingen):
- Nederland heeft maar 3-4% van de stemmen in Europa en sluit daarom bondjes met landen (Duitsland, Estland, Finland oa.), Nederland heeft keuzes gemaakt op welke onderwerpen (extra) ingezet wordt (in vet)
- Elke uitvoeringshandeling 3x in vergadering (totale doorloop 4 – 10 mnd)
  - 1e vergadering: discussiestuk EC
    - Initiële standpuntbepaling
    - Herijking obv discussiestuk
    - Schriftelijk commentaar
  - 2e vergadering: non-paper EC
    - Herijking obv non-paper
    - Schriftelijk commentaar
  - 3e vergadering: stemming
- Nederlandse inbreng voorbereid door “Tafel Europa” van VWS: VWS DICIO, NICTIZ, RIVM, NEN, ZIN, IGJ en Health-RI

Health-RI goed betrokken in hele proces

- Sneak-preview van TEHDAS2 guidelines, voordat deze gepubliceerd worden
- Leveren van input bij publieke consultaties
- Motiveren van netwerk om actieve input te leveren bij publieke consultatie
- Gesprekken met RIVM en NICTIZ naar aanleiding van NL input
- Participatie in diverse TEHDAS2 workshops
- Participatie in “Tafel Europa” VWS voor comitologie
- NL specifiek: juridische sessies

ENCR - the European Network of Cancer Registries

Matthijs Sloep - Tehdas2 public consultations

European Commission

The ENCR Network

ENCR Recommendations 2024

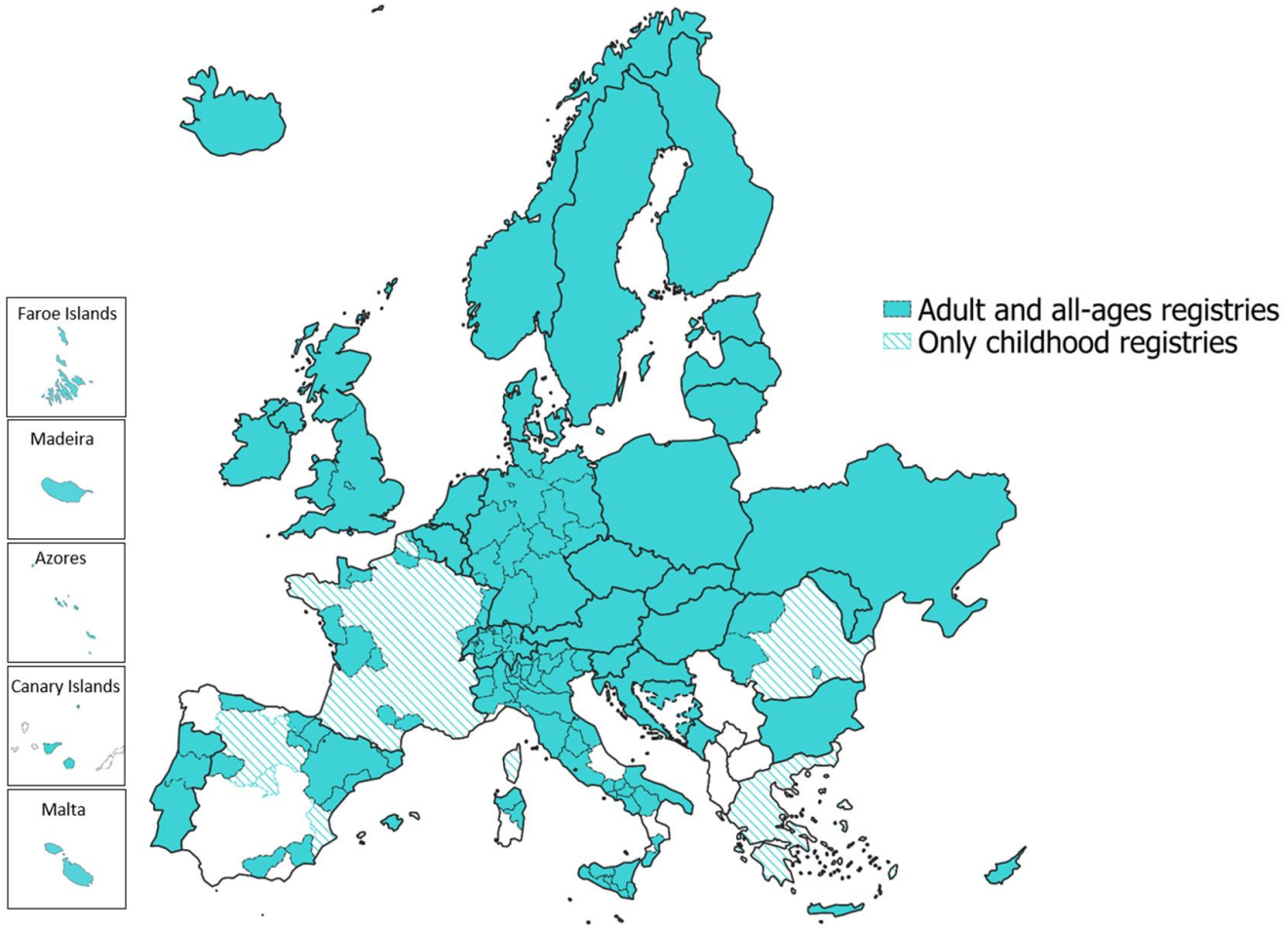
Recommendations for coding tumours of the central nervous system (CNS)

ENCR Recommendations 2025

Recording Recurrence, Progression and Transformation Episodes

ENCR Recommendations 2025

Treatment Data Recording (phase I)



CancerWatch Joint action

JA CancerWatch

Improving Quality and Timeliness of Cancer Registry Data feeding into the European Cancer Information System

EC contribution: € 13.000.000

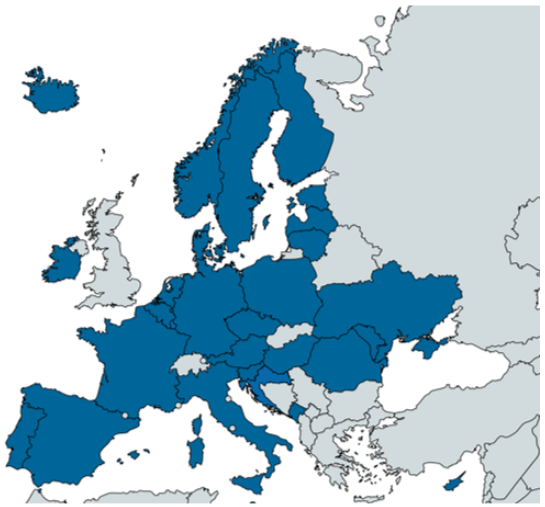
Duration: Sept 2025 – Aug 2028 (36 months)

Project Lead: Norwegian Institute of Public Health

Number of beneficiaries: 92

Who are the beneficiaries: Cancer Registries, Public Health Organizations, Ministries of Health, Cancer Centers.

IARC and JRC partake in the project



CancerWatch

European Network of Cancer Registries

European Commission

Tehdas2 - Second public consultation

01.12.2025

Second public consultation on guidelines for effective secondary use of health data across Europe concludes

Between 30 September and 30 November 2025, TEHDAS2 invited stakeholders from across Europe to provide feedback on eleven draft guidelines and technical specifications that will shape the implementation of the European Health Data Space (EHDS). The consultation period has now closed, with all feedback gathered for review.

- 1. DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON FEES RELATED TO THE EHDS REGULATION (Click to view)
- 2. DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON PENALTIES FOR NON-COMPLIANCE RELATED TO THE EHDS REGULATION (Click to view)
- 3. DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON MINIMUM CATEGORIES AND LIMITATIONS ON THE REUSE OF HEALTH DATA (Click to view)
- 4. DRAFT GUIDELINE FOR DATA HOLDERS ON MAKING PERSONAL AND NON-PERSONAL ELECTRONIC HEALTH DATA AVAILABLE FOR REUSE (Click to view)
- 5. DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON THE PROCEDURES AND FORMATS FOR DATA ACCESS (Click to view)
- 6. DATA ACCESS APPLICATION MANAGEMENT SYSTEM (DAAMS) – DRAFT TECHNICAL SPECIFICATION FOR HEALTH DATA ACCESS BODIES (Click to view)
- 7. DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON DATA MINIMISATION, PSEUDONYMISATION, ANONYMISATION AND SYNTHETIC DATA (Click to view)
- 8. DRAFT TECHNICAL SPECIFICATION FOR HEALTH DATA ACCESS BODIES ON THE IMPLEMENTATION OF THE COMMON IT INFRASTRUCTURE (Click to view)
- 9. DRAFT TECHNICAL SPECIFICATION FOR HEALTH DATA ACCESS BODIES ON THE IMPLEMENTATION OF SECURE PROCESSING ENVIRONMENTS (Click to view)
- 10. DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON IMPLEMENTING OPT-OUT FROM THE SECONDARY USE OF HEALTH DATA (Click to view)
- 11. 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 (Click to view)

Tehdas2 - Second public consultation

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2. DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON PENALTIES FOR NON-COMPLIANCE RELATED TO THE EHDS REGULATION (Click to view)

3. DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON MINIMUM CATEGORIES AND LIMITATIONS ON THE REUSE OF HEALTH DATA (Click to view)

- Expand billable tasks
- No. Patients
- Different pricing, invoices
- Cross boarder requests
- Ethical framework

Tehdas2 - Second public consultation

4. DRAFT GUIDELINE FOR DATA HOLDERS ON MAKING PERSONAL AND NON-PERSONAL ELECTRONIC HEALTH DATA AVAILABLE FOR REUSE (Click to view)

5. DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON THE PROCEDURES AND FORMATS FOR DATA ACCESS (Click to view)

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7. DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON DATA MINIMISATION, PSEUDONYMISATION, ANONYMISATION AND SYNTHETIC DATA (Click to view)

- Guidance
- Fast track
- Reidentification
- Small data holders

Tehdas2 - Second public consultation

- **8. DRAFT TECHNICAL SPECIFICATION FOR HEALTH DATA ACCESS BODIES ON THE IMPLEMENTATION OF THE COMMON IT INFRASTRUCTURE (Click to view)**
- **9. DRAFT TECHNICAL SPECIFICATION FOR HEALTH DATA ACCESS BODIES ON THE IMPLEMENTATION OF SECURE PROCESSING ENVIRONMENTS (Click to view)**
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- CDM guidance
- EHDS/GDPR
- Opt out bias
- Significant findings

First public consultation results

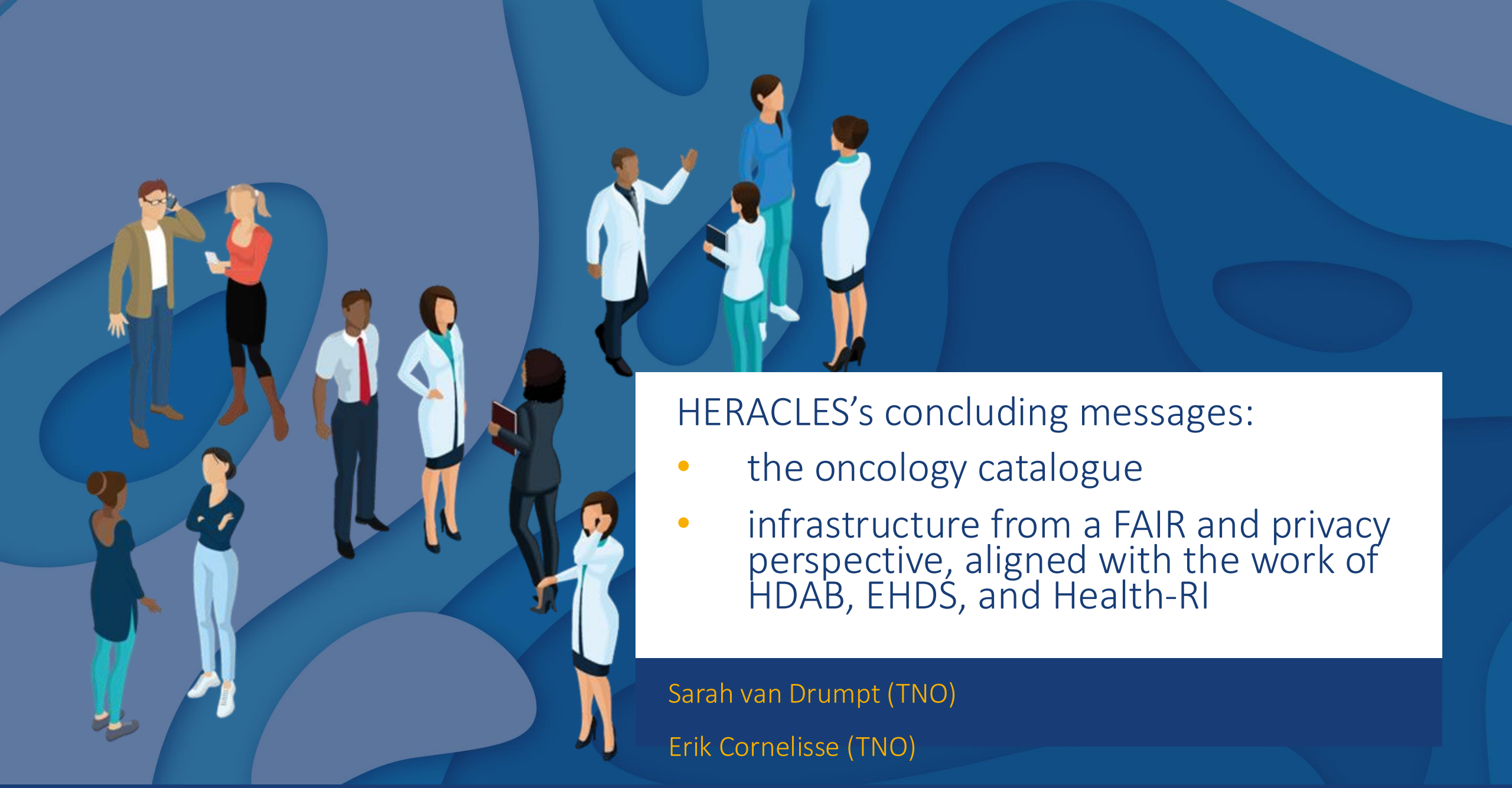
Project Public consultations News Events Get involved **Results**

Results

TEHDAS2 is developing guidelines and technical specifications to enable seamless use of health data across Europe under the upcoming European Health Data Space (EHDS). The results of this work are organised by target groups and shared here.

European Network of Cancer Registries

European Commission



HERACLES's concluding messages:

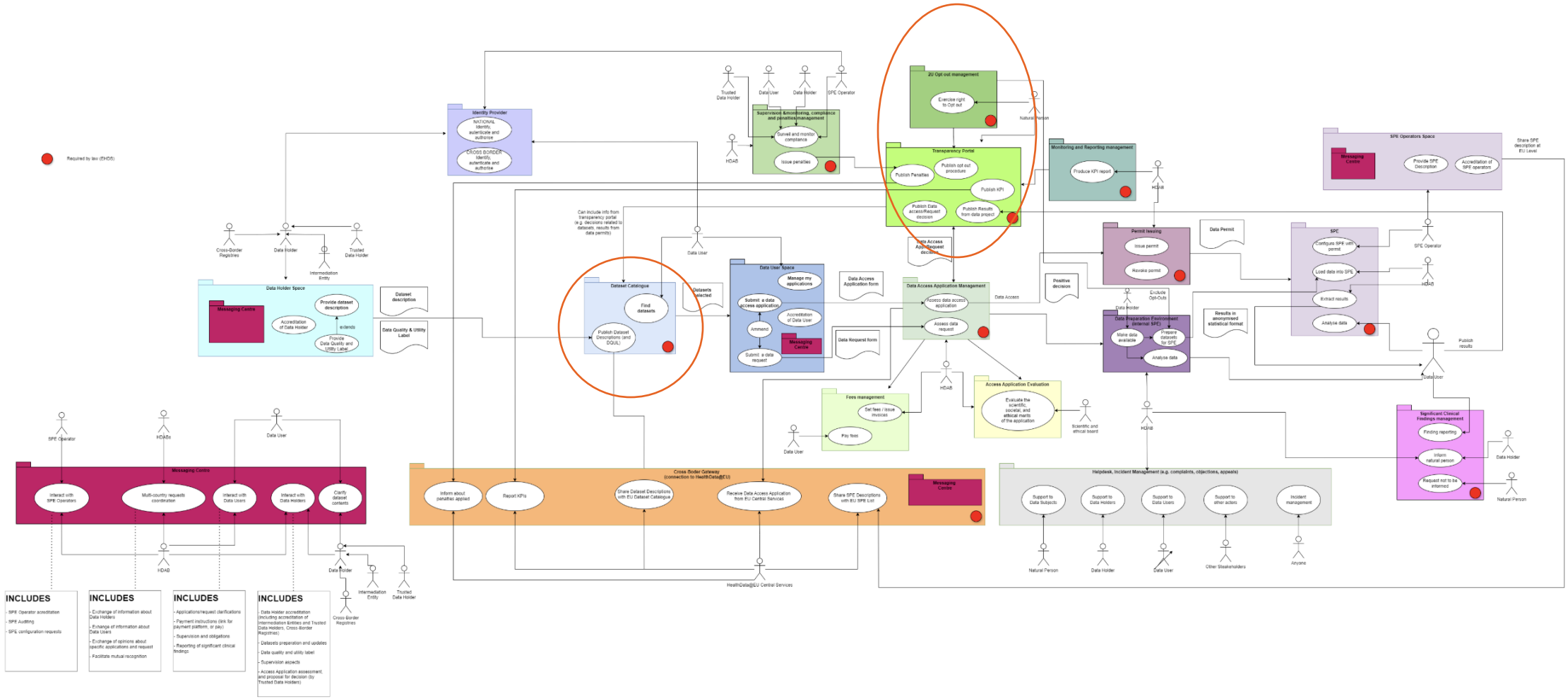
- the oncology catalogue
- infrastructure from a FAIR and privacy perspective, aligned with the work of HDAB, EHDS, and Health-RI

Sarah van Drumpt (TNO)

Erik Cornelisse (TNO)

health RI
enabling data driven health & life sciences

Backbone


Identity Provider
Supervision &monitoring, compliance and penalties management
2D Opt out management
Transparency Portal
Monitoring and Reporting management
SPE Operators Space
Permit issuing
SPE
Data Holder Space
Dataset Catalogue
Data User Space
Data Access Application Management
Data Preparation Environment (internal SPE)
Fees management
Access Application Evaluation
Significant Clinical Findings management
Messaging Centre
Cross Border Gateway (connection to HealthData@EU)
Helpdesk, Incident Management (e.g. complaints, objections, appeals)
HealthData@EU Central Services
INCLUDES
INCLUDES
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INCLUDES

HERACLES

A privacy preserving dataspace for cancer research

HERACLES and Dataspaces

Objective and content

This presentation introduces the HERACLES project and explains how it relates to European and National initiatives.

Table of content:

- General introduction to HERACLES and its purpose
- The scope and description of the HERACLES infrastructure
- The architecture and how data space standards are applied
- How the HERACLES infrastructure can contribute to Health-RI & HDAB


iKNL
integraal
kankercentrum
Nederland


TNO
innovation
for life


PHARMO


LINKSIGHT


Radboudumc
university medical center


almende
ORGANIZING NETWORKS


HERACLES


UMCG


SURF


AstraZeneca


lijf
Netwerk voor vrouwen
met gynaecologische kanker


CZ


Roche


janssen


Health~Holland


Holland.

Introduction on why HERACLES

Complication

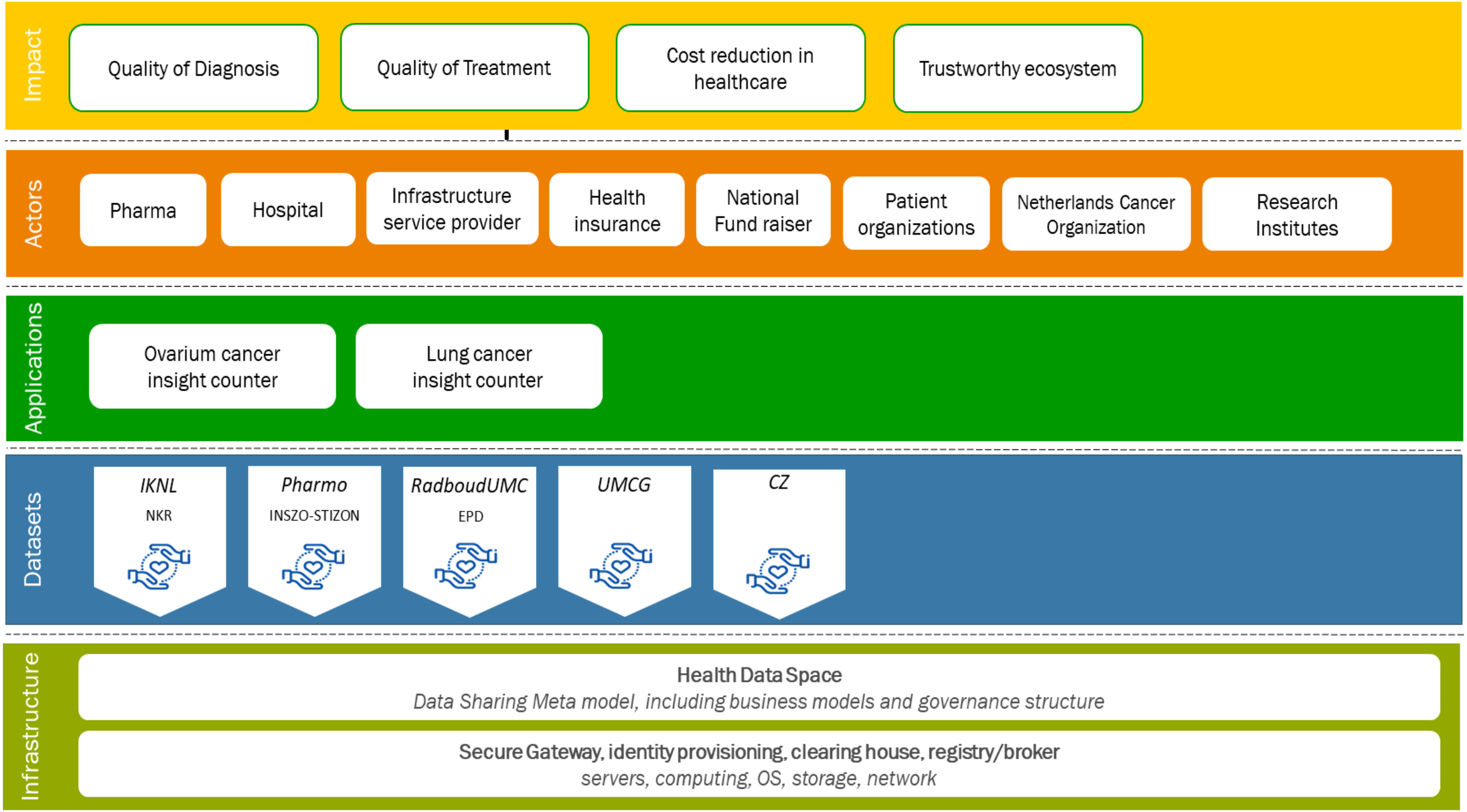
- Health related data is fragmented across various systems in different formats and cannot always be used in a privacy-friendly way and without medical confidentiality concerns, hence hindering data use for innovation, research and policy making.

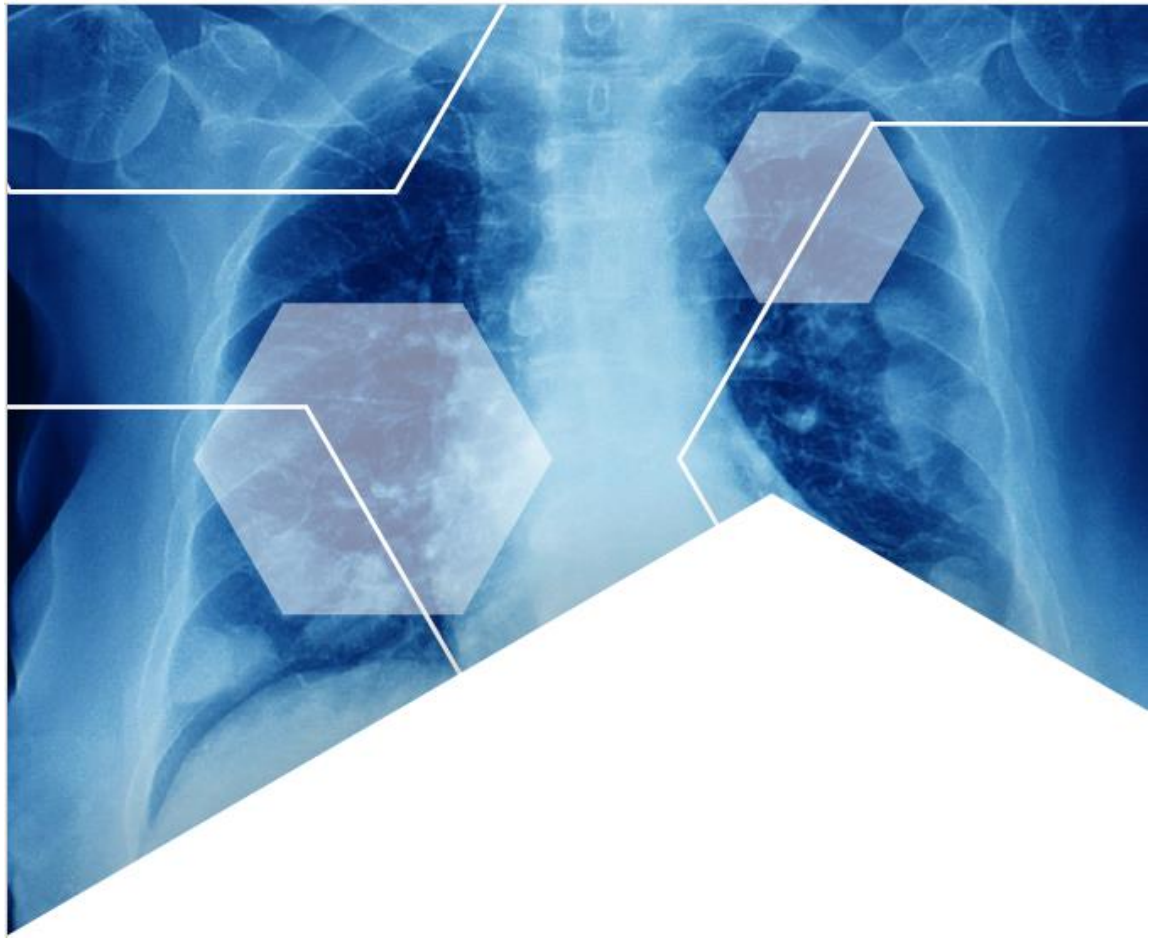
Question

- How to come to a 'learning health system' based on privacy-friendly use of data, where insights gained directly or through scientific research contribute to improving healthcare?

Answer

- The answer lies in a combination of governance and supporting technology where sensitive data stored at different sources are used for science, innovation and policy-making without compromising privacy.


Impact
Quality of Diagnosis
Quality of Treatment
Cost reduction in healthcare
Trustworthy ecosystem
Actors
Pharma
Hospital
Infrastructure service provider
Health insurance
National Fund raiser
Patient organizations
Netherlands Cancer Organization
Research Institutes
Applications
Ovarium cancer insight counter
Lung cancer insight counter
Datasets
IKNL
NKR
Pharmo
INSZO-STIZON
RadboudUMC
EPD
UMCG
CZ
Infrastructure
Health Data Space
Data Sharing Meta model, including business models and governance structure
Secure Gateway, identity provisioning, clearing house, registry/broker
servers, computing, OS, storage, network



Van mythe naar realiteit

de hobbelige weg naar een lerend gezondheidssysteem

Lessen van het HERACLES project uit de praktijk

HERACLES

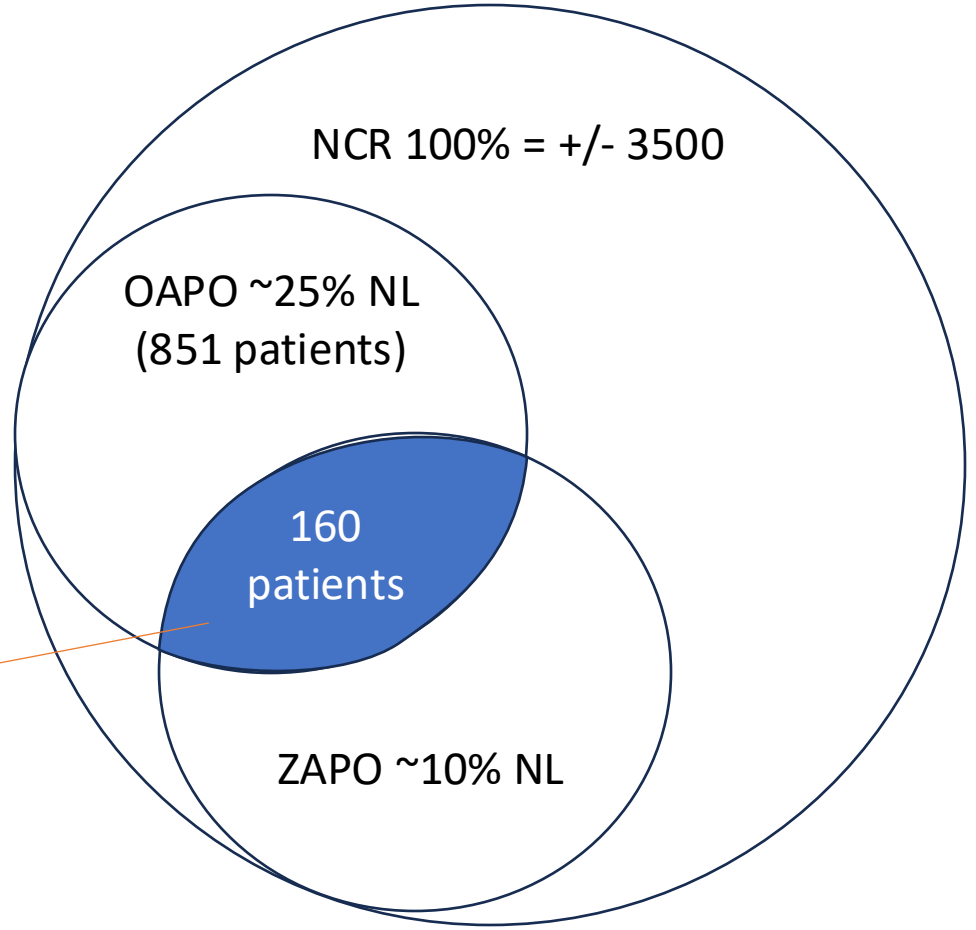
Results

- Number of patients:
- NCR – OAPO 851 patients
- NCR – OAPO – ZAPO 160 patients
- NCR – OAPO – ZAPO: inclusion criteria 96 patients

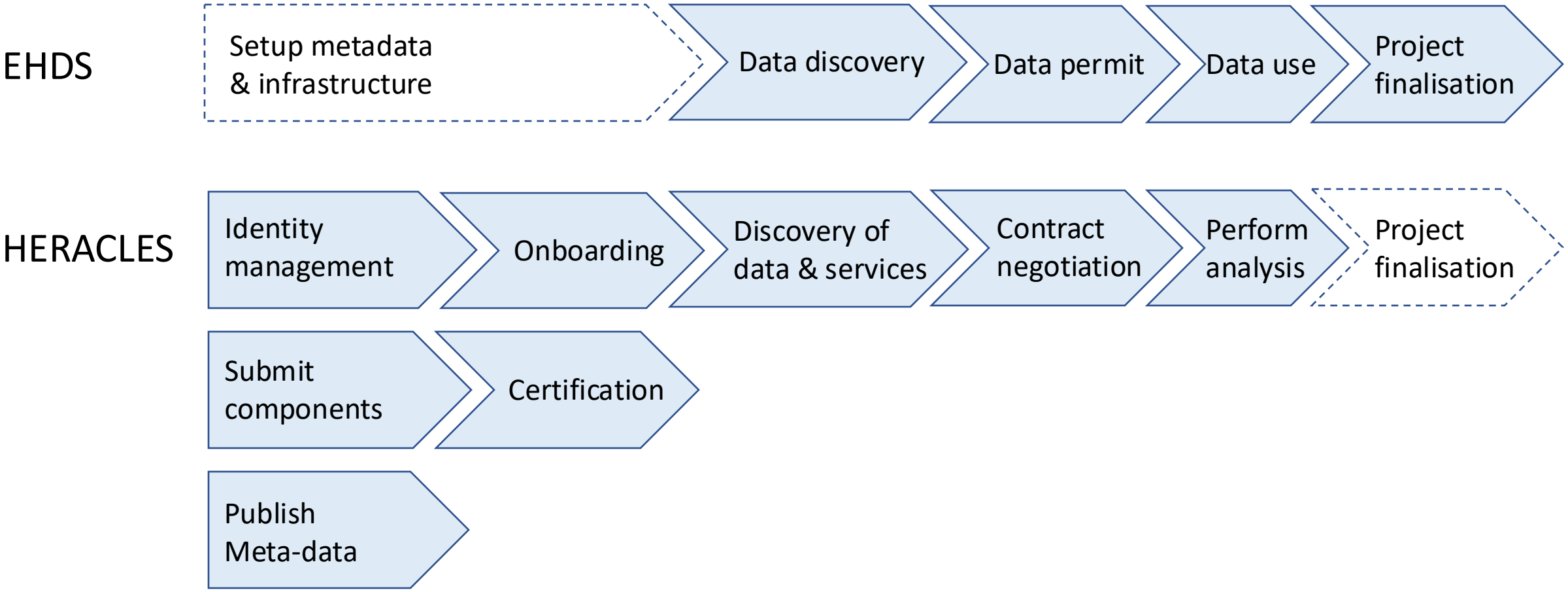
- Additionally: 36 patients with no anti-cancer treatment (from Pharmo data)

15 no treatment

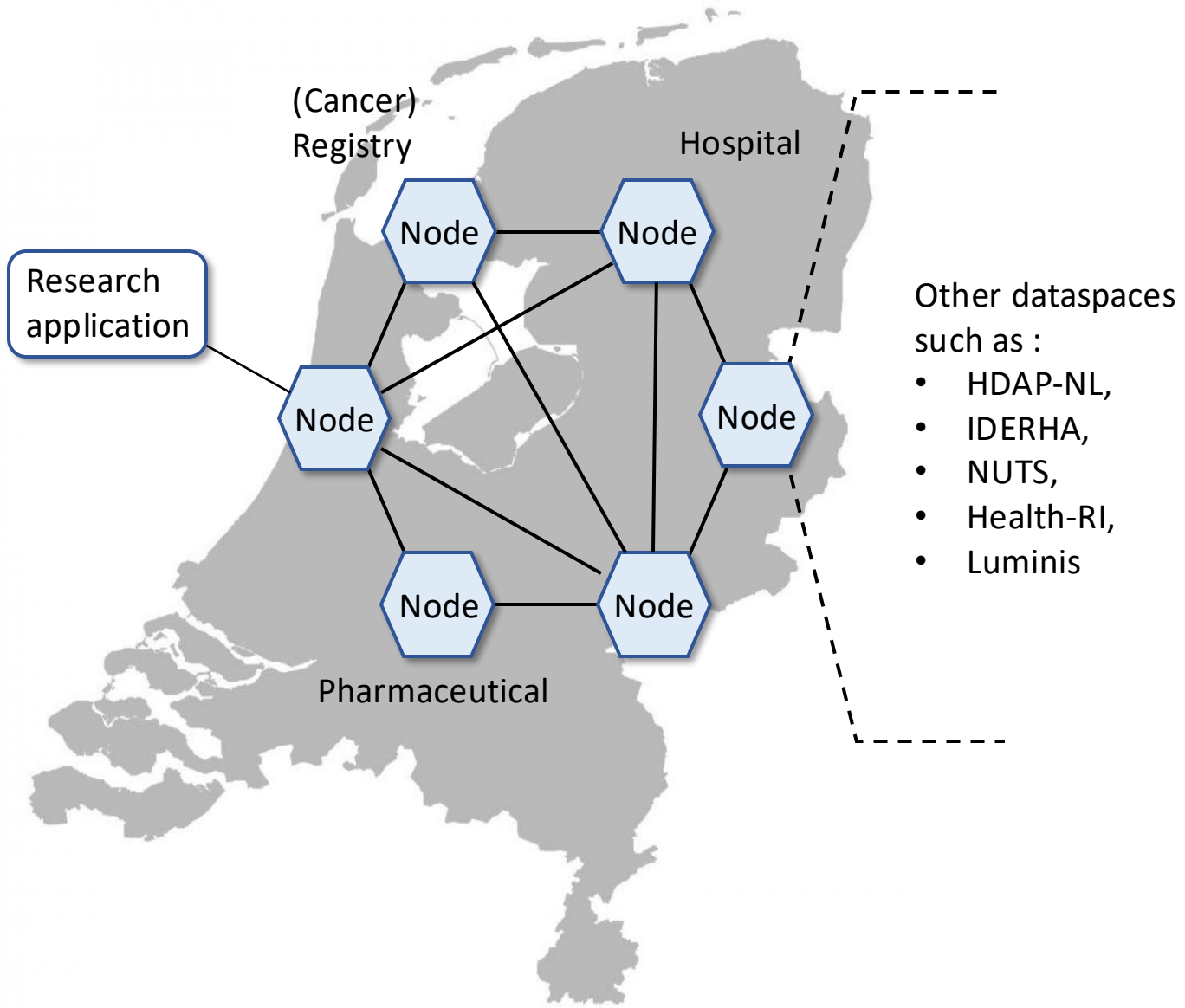
21 treatment registered NCR



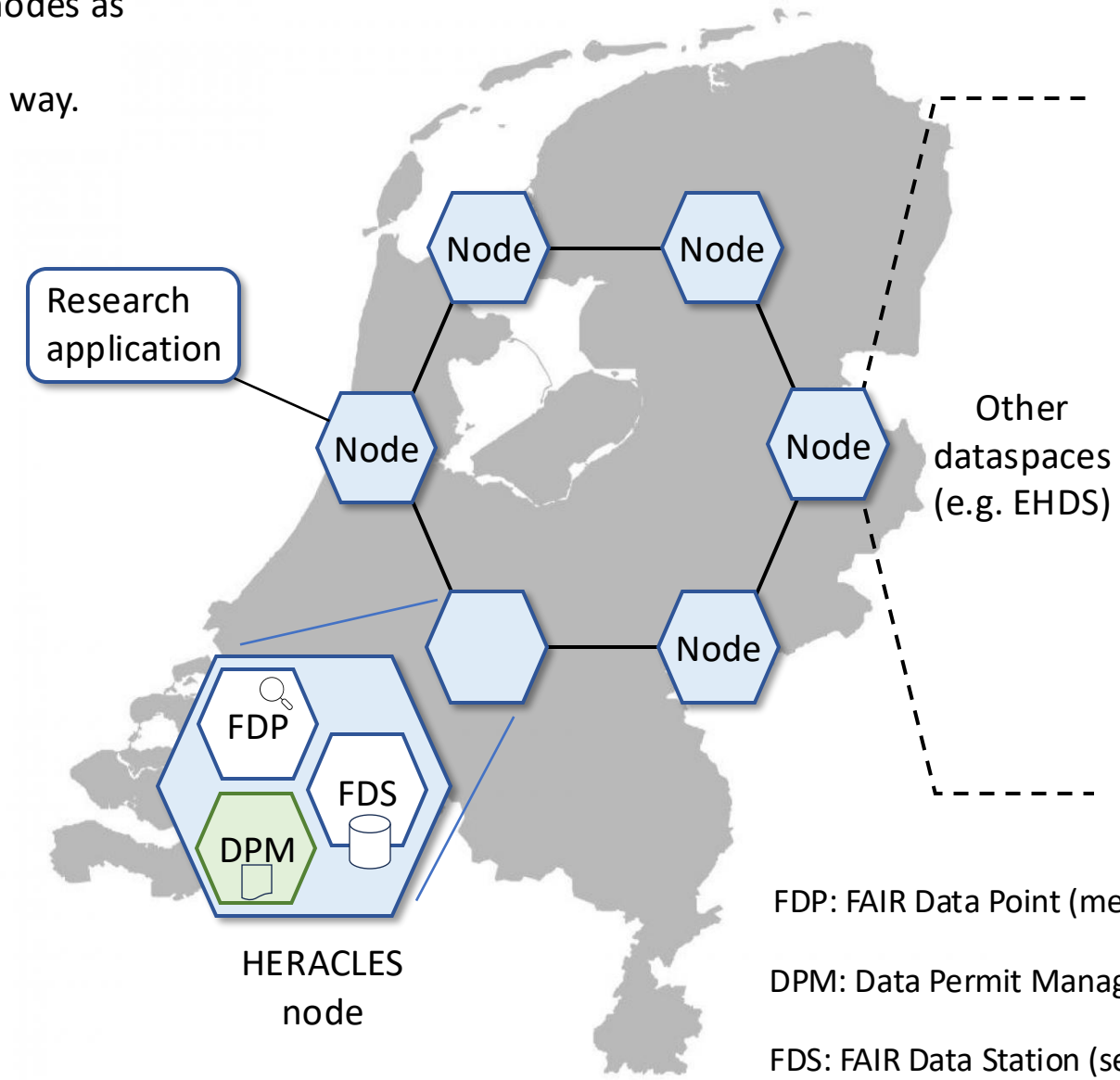
High level infrastructure process flow



HERACLES


(Cancer)
Registry
Hospital
Node
Node
Research
application
Node
Node
Node
Node
Pharmaceutical
Other dataspaces
such as :
• HDAP-NL,
• IDERHA,
• NUTS,
• Health-RI,
• Luminis

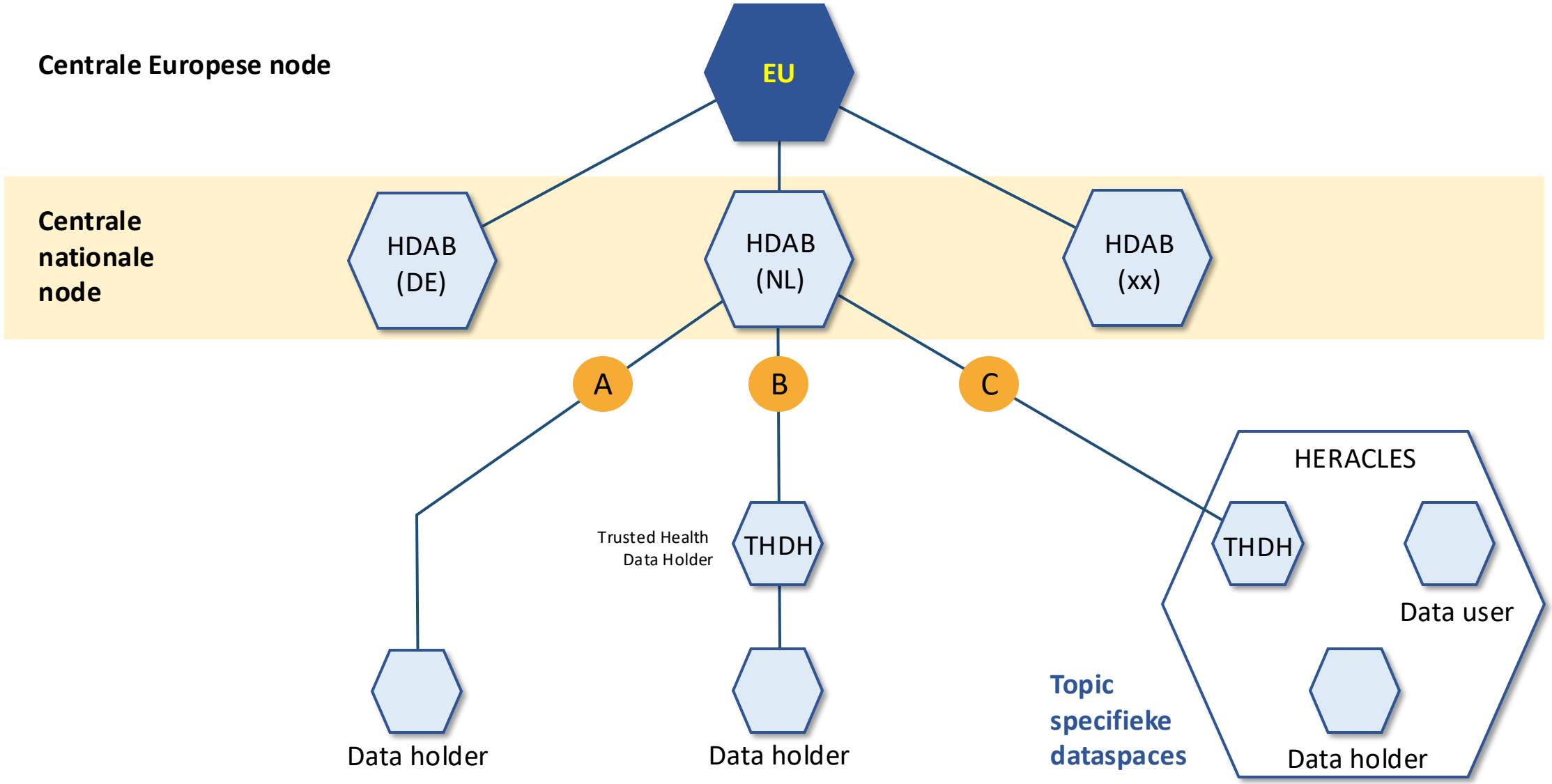
Components operate across nodes as a federation of systems in a harmonized and standardized way.



FDP: FAIR Data Point (metadata catalogue)

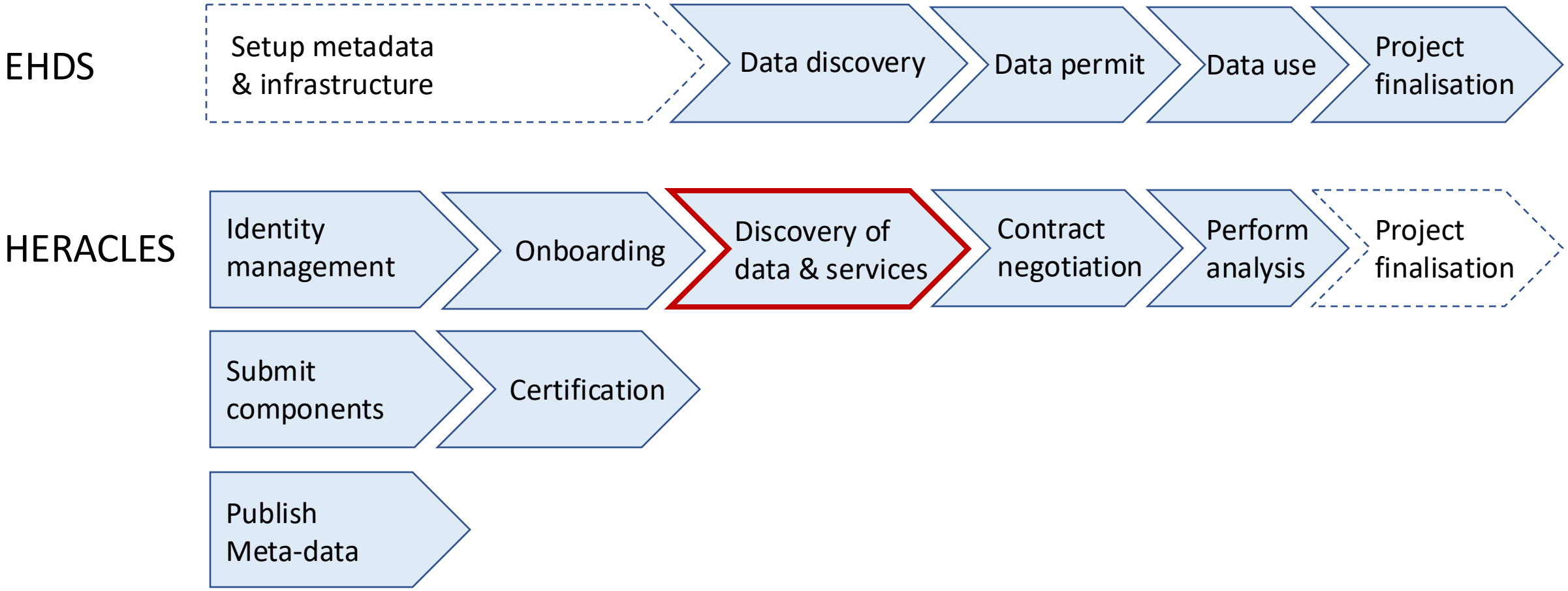
DPM: Data Permit Management (grant or reject access)

FDS: FAIR Data Station (secure processing environment)


Centrale Europese node
EU
Centrale nationale node
HDAB (DE)
HDAB (NL)
HDAB (xx)
A
B
C
Trusted Health Data Holder
THDH
HERACLES
THDH
Data user
Data holder
Data holder
Data holder
Topic specifieke dataspaces

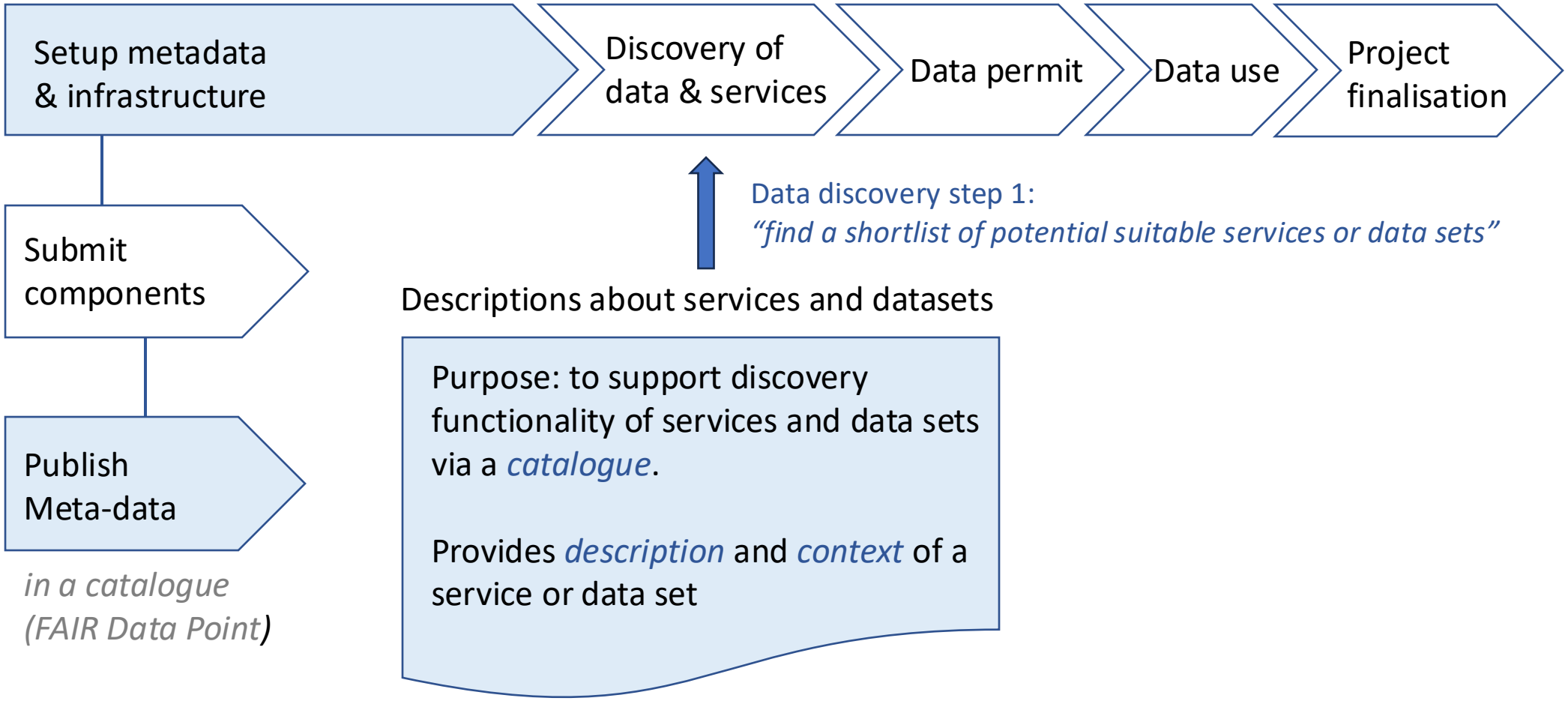
High level infrastructure process flow

Compliant to EHDS



High level infrastructure process flow

Create & publish service and data descriptions (step 0)



High level infrastructure process flow

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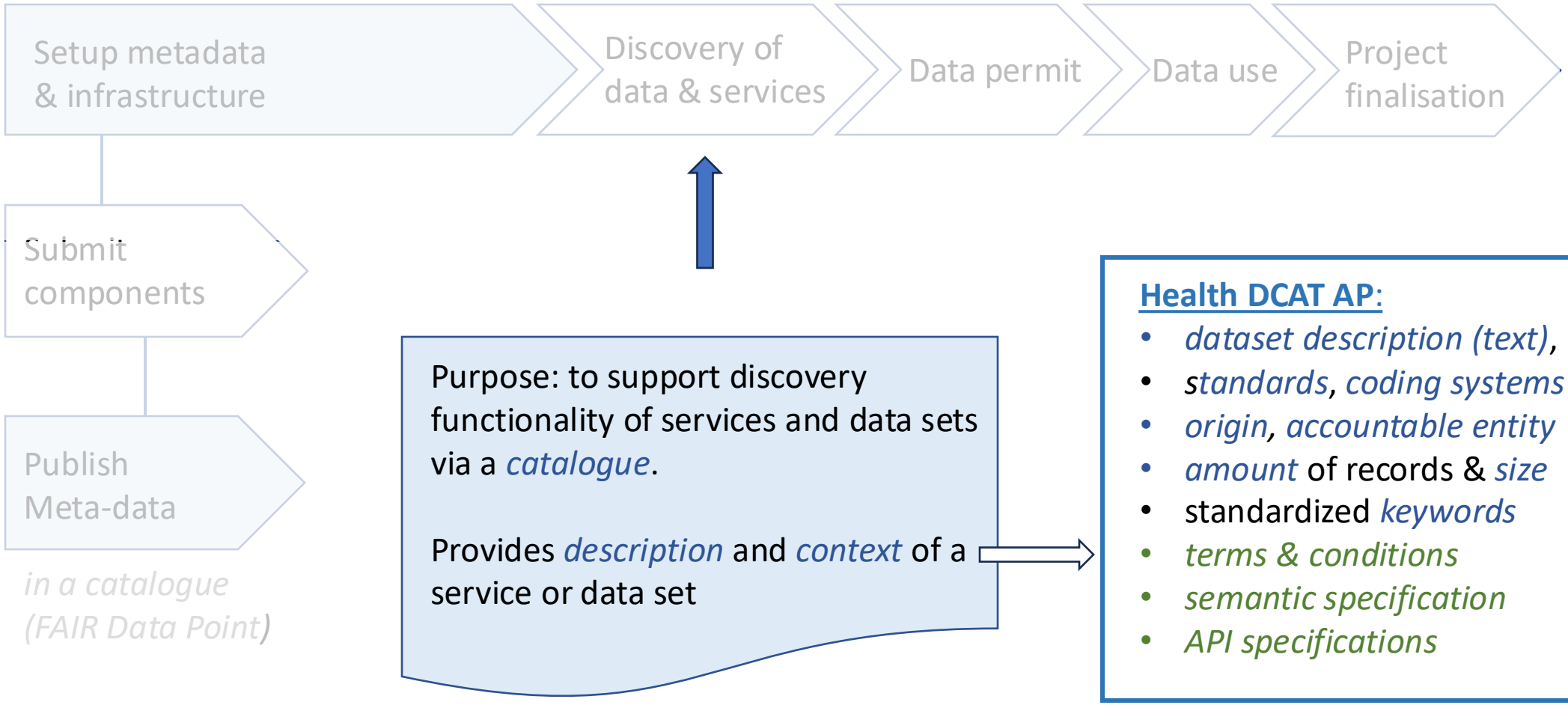

Discovery of data & services

Find suitable data & services via a FAIR Data Point (FDP)

Step 1 – *"find a shortlist of potential suitable services and data sets"*

Step 2 - *"functional verification to determine which services and data are suitable based on information about the data"*

Step 3 - *"define (sub)dataset request and test compliancy against terms and conditions, and also check technical feasibility.*

Data set attributes:

- *dataset description (text)*,
- *standards*, *coding systems*
- *origin*, *accountable entity*
- *amount* of records & *size*
- standardized *keywords*

Data attribute/reference:

- *Semantic/methodological specification (incl. units, measurement platform)*
- *quality per attribute:*
  - *% of missings*
  - *% of outliers ?*
  - *amount + std. deviation*

Data services (pre-train):

- *Provide sample data*
- *Overview of data distributions*

Compliancy references:

- *terms & conditions (policies)*
- *semantic specification*
- *API specifications*
- *Resource specifications*

Compliancy (query) services:

- *Request "amount" information about specific selection of the dataset*

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- ***Context -> QUANTUM label***

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Fair Data Point

HOME

- Fair Data Point
- Browse
- Search

Catalog

Pharmo

Pharmo connector

Datasets

Treatment of primary and recurrent ovarian cancer ★★★☆☆ DCAT Dataset

Dataset for studying the patient journey of epithelial ovarian cancer (EOC) patients, focusing on systemic therapies, treatment patterns, predictive factors, and identification of recurrence/progression. Based on linked data from the Netherlands Cancer Registry (NCR) and the PHARMO Data Network, including pharmacy, laboratory, and hospital data.

Lung Cancer Early Diagnosis Prediction Model Dataset DCAT Dataset

Dataset for developing a prediction model to identify individuals at risk of Small Cell Lung Cancer (SCLC) and Non-Small Cell Lung Cancer (NSCLC) based on clinical and patient characteristics from general practitioner records. Aimed at enabling earlier diagnosis and improving treatment outcomes through timely referral.

Conforms to

Catalog Shapes

Modified

26-09-2025

Issued

26-09-2025

License

Publisher

did:web:pharmo.heracles.dataspac.es

Catalog identifier

https://pharmo.heracles.dataspac.es/fdp/api/catalog/4c35f92a-89e3-40ac-82b4-28d8c588fb6a#identifier

TSG Fair Data Point

HOME

- Fair Data Point
- Browse
- Search

Distributions

TSG Federated Learning Data Plane — DCAT Distribution

Protocol: tsg:FL

Table structure

Patientmatrix — 852 records

Columns

patient_id
Type: string
Description: Unique patient ID (PHARMO)

key_nkr_spec
Type: string
Description: Patient key number specific to this request

key_eid
Type: string
Description: Tumor key number

startfu
Type: date
Description: Start data collection of specific patient

endfu
Type: date
Description: Day-month-year end of follow-up in the PHARMO Data Network (death, end of study period [31-12-2021], or end of follow-up in PHARMO)

CED
Type: date
Description: Cohort entry date (i.e., first diagnosis of EOC)

oapo_avail
Type: integer
Description: Availability of out-patient pharmacy data (1=Yes)

zapo_avail
Type: integer
Description: Availability of in-patient pharmacy data (1=Yes)

kln_avail
Type: integer
Description: Availability of clinical laboratory data (1=Yes)

hosp_avail
Type: integer
Description: Availability of hospital data (1=Yes)

Keywords

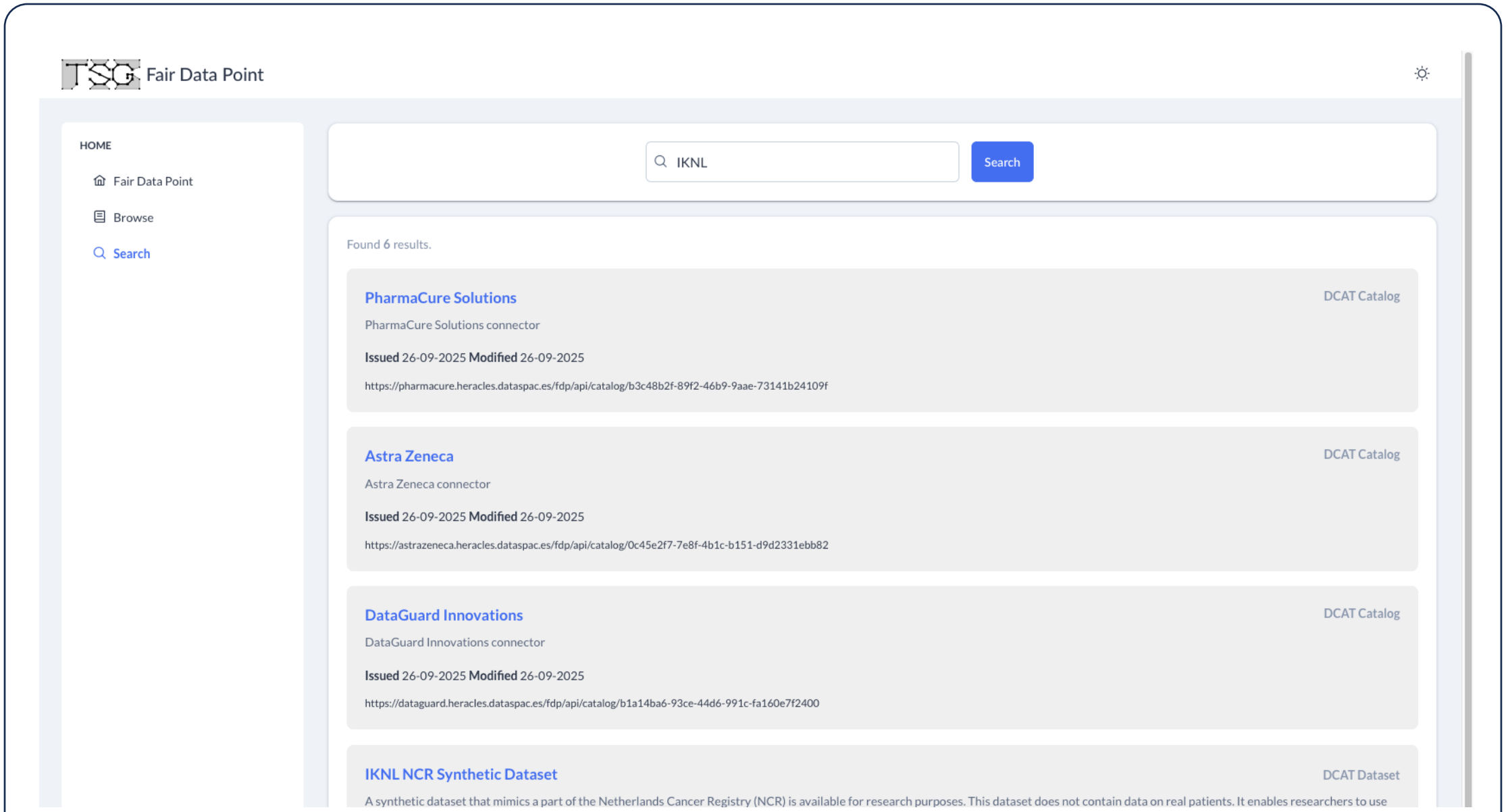
Coding System
- SNOMED CT
- ICD-10 ID
- WCIA
- ATC code

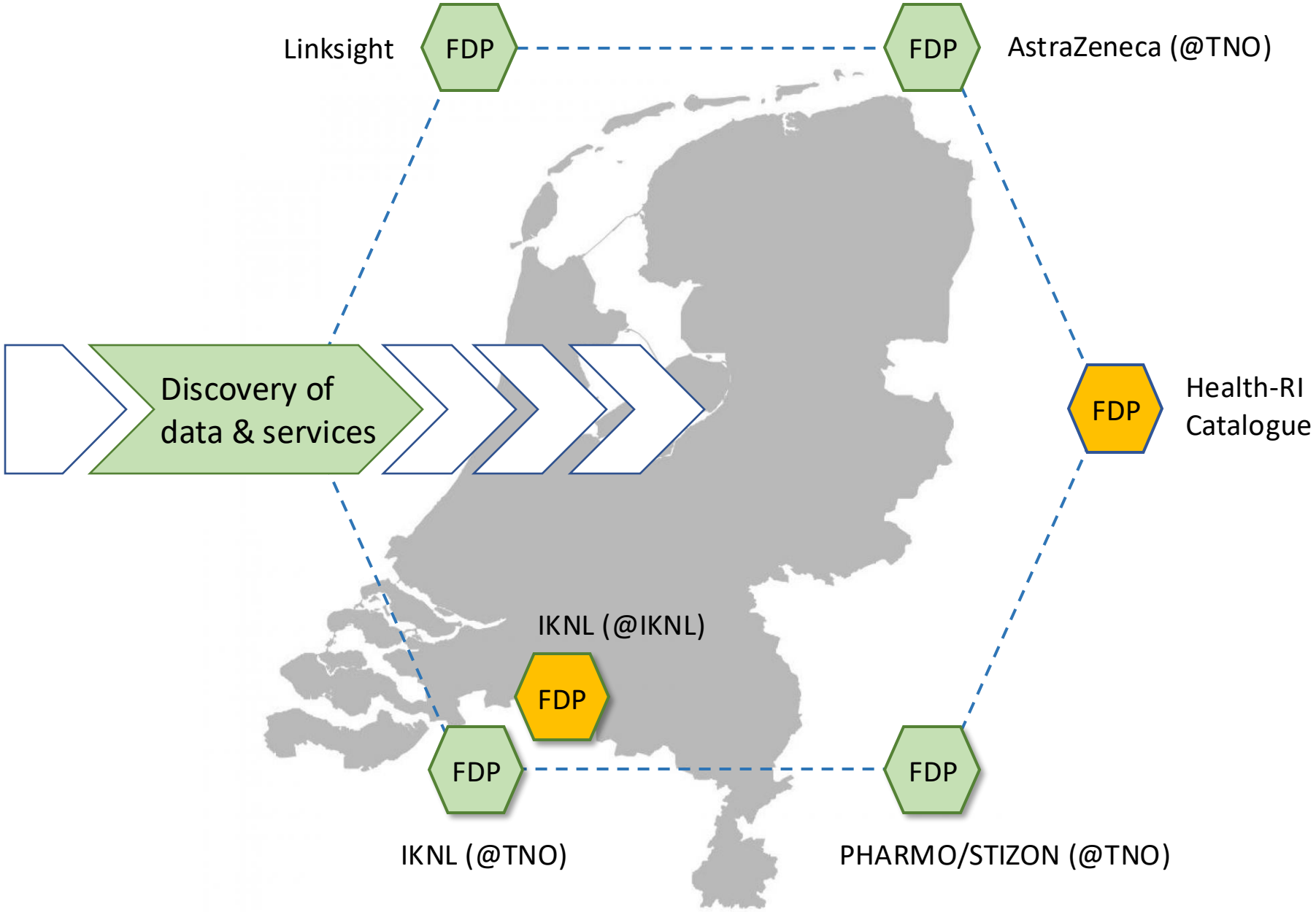
Health Theme
- cancer
- ovarian cancer

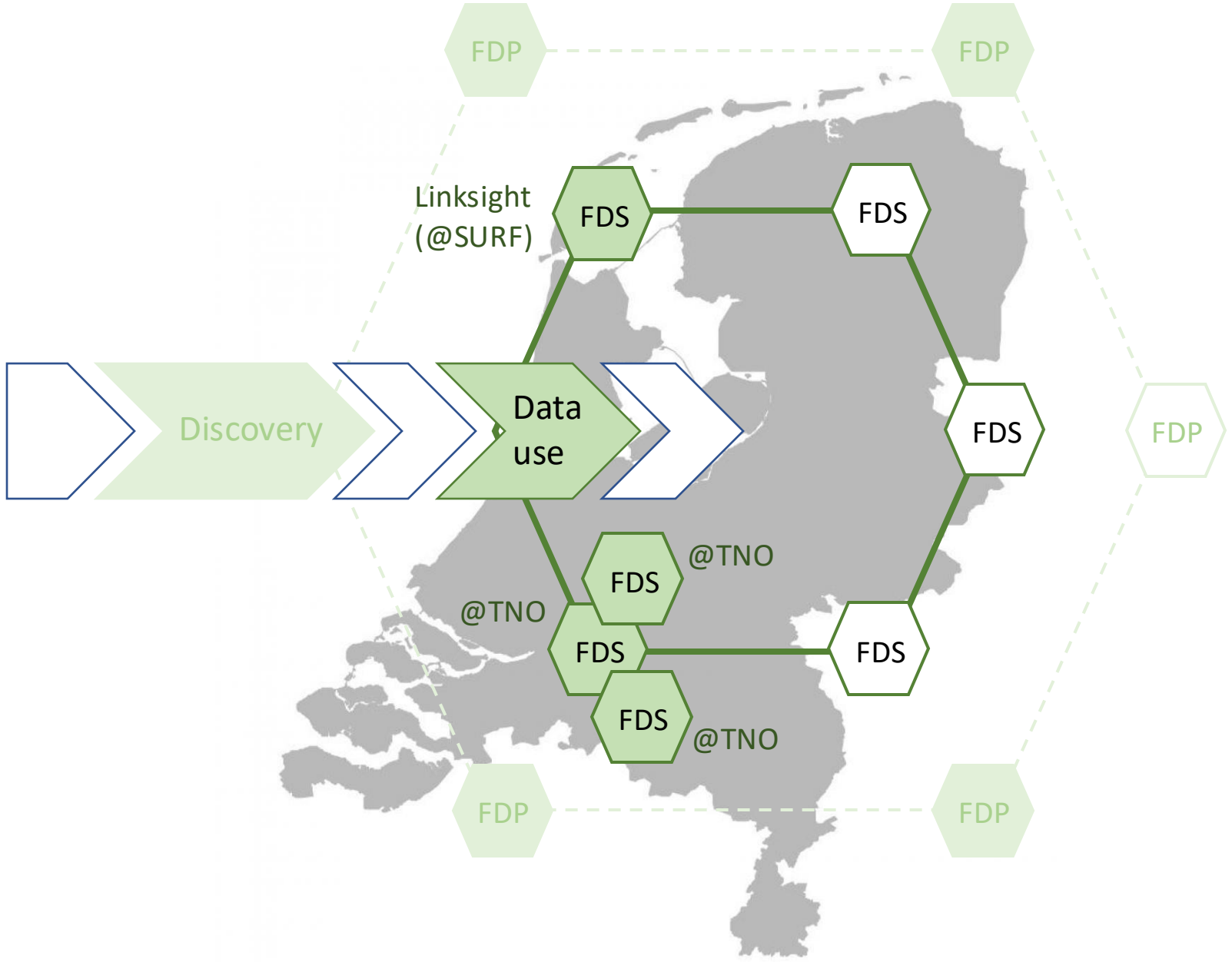
Number of Records
138224

Number of Unique Individuals
851

Quality Certificate
- Quantum label (pdf)

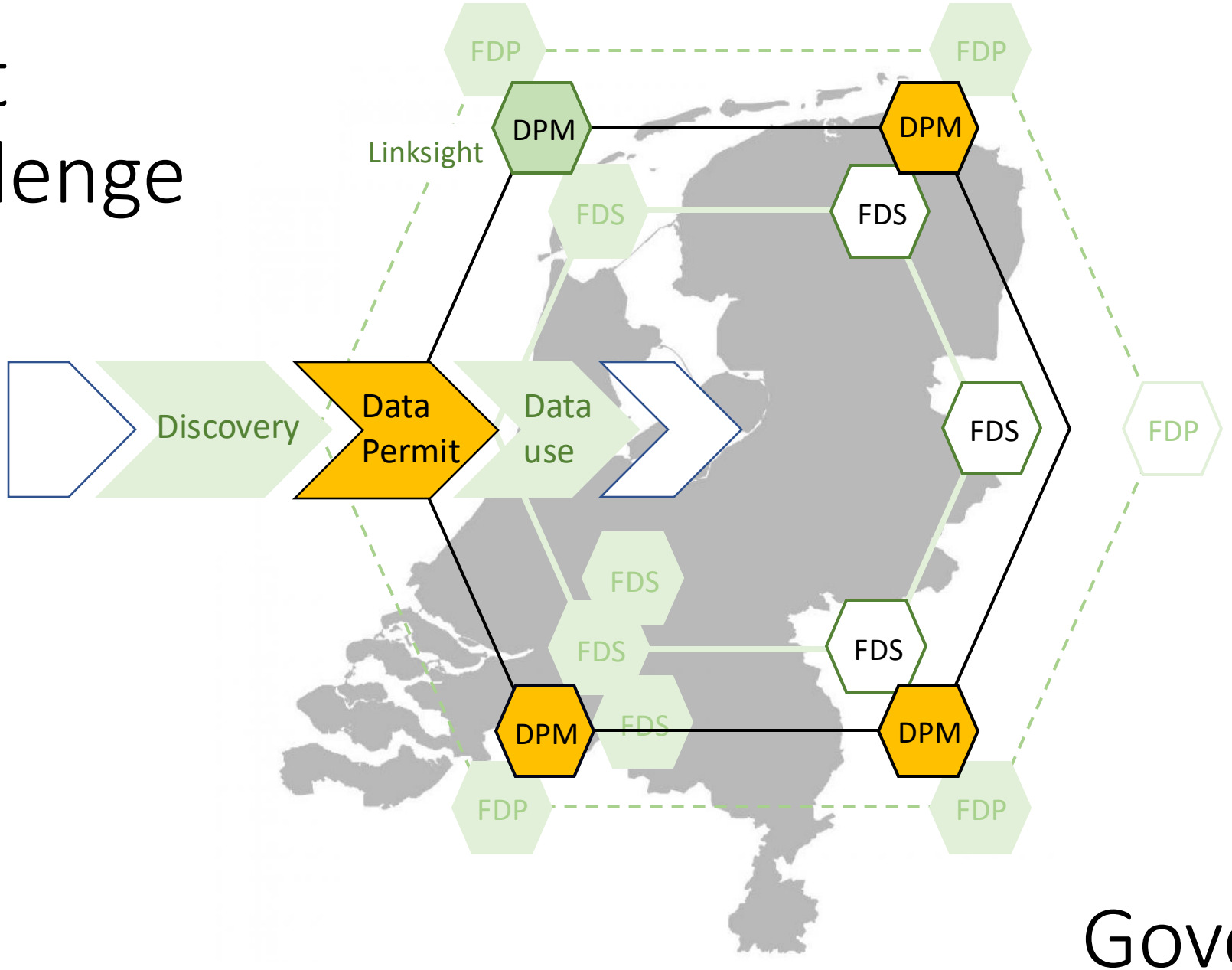

TSG Fair Data Point
HOME
Fair Data Point
Browse
Search
IKNL
Search
Found 6 results.
PharmaCure Solutions
DCAT Catalog
PharmaCure Solutions connector
Issued 26-09-2025 Modified 26-09-2025
https://pharmacure.heracles.dataspac.es/fdp/api/catalog/b3c48b2f-89f2-46b9-9aae-73141b24109f
Astra Zeneca
DCAT Catalog
Astra Zeneca connector
Issued 26-09-2025 Modified 26-09-2025
https://astrazeneca.heracles.dataspac.es/fdp/api/catalog/0c45e2f7-7e8f-4b1c-b151-d9d2331ebb82
DataGuard Innovations
DCAT Catalog
DataGuard Innovations connector
Issued 26-09-2025 Modified 26-09-2025
https://dataguard.heracles.dataspac.es/fdp/api/catalog/b1a14ba6-93ce-44d6-991c-fa160e7f2400
IKNL NCR Synthetic Dataset
DCAT Dataset
A synthetic dataset that mimics a part of the Netherlands Cancer Registry (NCR) is available for research purposes. This dataset does not contain data on real patients. It enables researchers to use


Linksight
FDP
FDP
AstraZeneca (@TNO)
Discovery of
data & services
FDP
Health-RI
Catalogue
IKNL (@IKNL)
FDP
FDP
FDP
IKNL (@TNO)
PHARMO/STIZON (@TNO)


FDP
FDP
Linksight
(@SURF)
FDS
FDS
Discovery
Data
use
FDS
FDP
@TNO
FDS
@TNO
FDS
FDS
FDS
@TNO
FDP
FDP

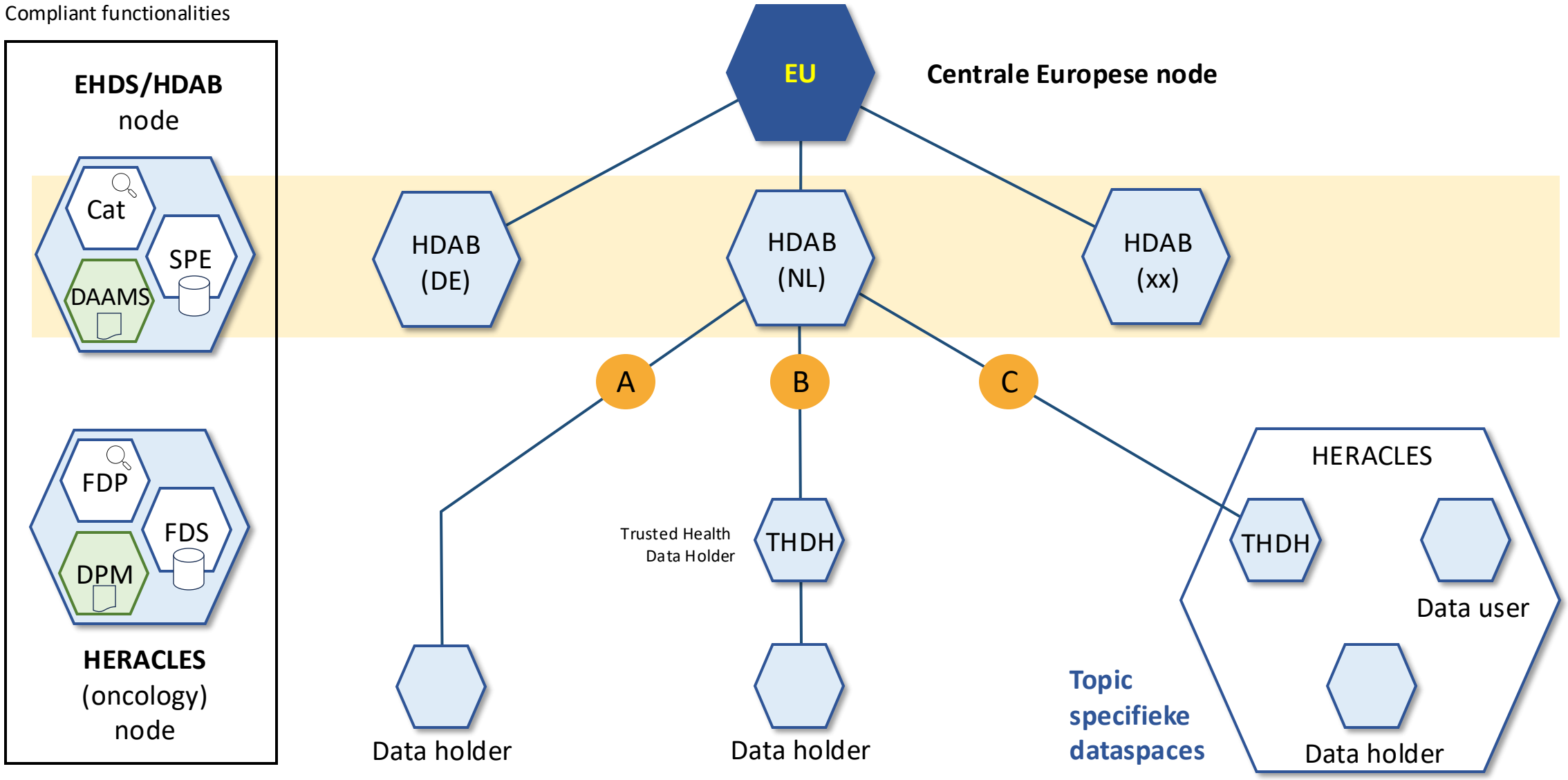
PET

Next challenge



Governance

Compliant functionalities



Summary

From a technical infrastructure point of view, HERACLES:

- Proposed a technical architecture based on EU standards to support the implementation of **EHDS** – including the use of Health DCAT AP and QUANTUM label.
- Demonstrated which/how software components can be implemented according to the proposed architecture - FDPs, FDSs with MPC and SPEs
- Is still sharing knowledge and experiences with **THEDAS2**, **Health-RI** and **HDAP-NL** to accelerated the development of a national (self-learning and improving) data sharing infrastructure and to avoid reinventing the wheel.

Contact

+31 6 15 67 48 72

Erik.Cornelisse@tno.nl

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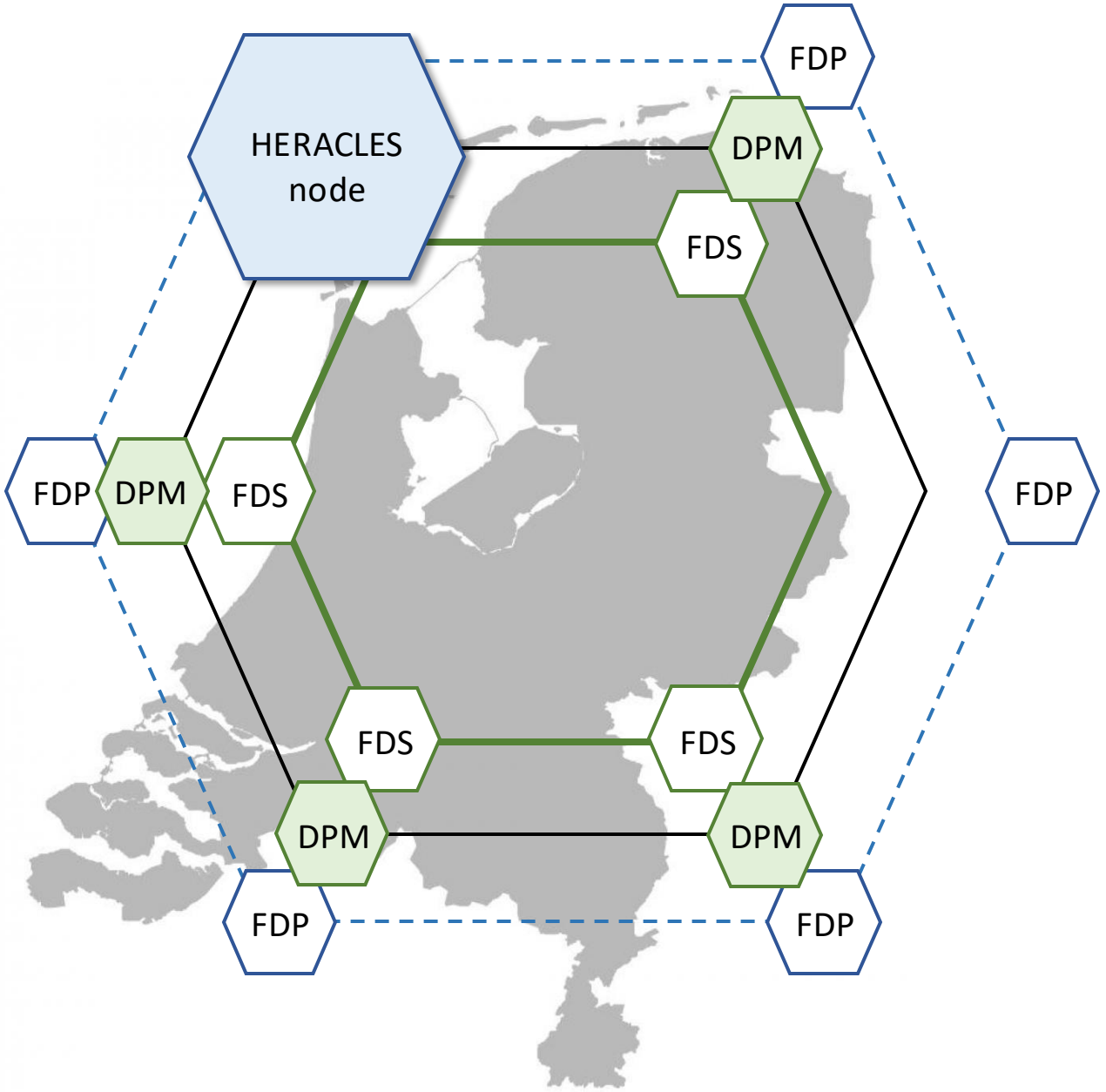
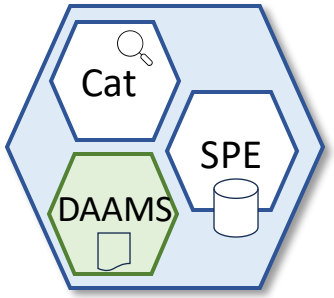
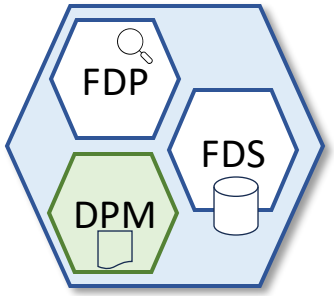

HERACLES
node
FDP
DPM
FDS
FDP
DPM
FDS
FDP
FDS
FDS
DPM
DPM
FDP
FDP

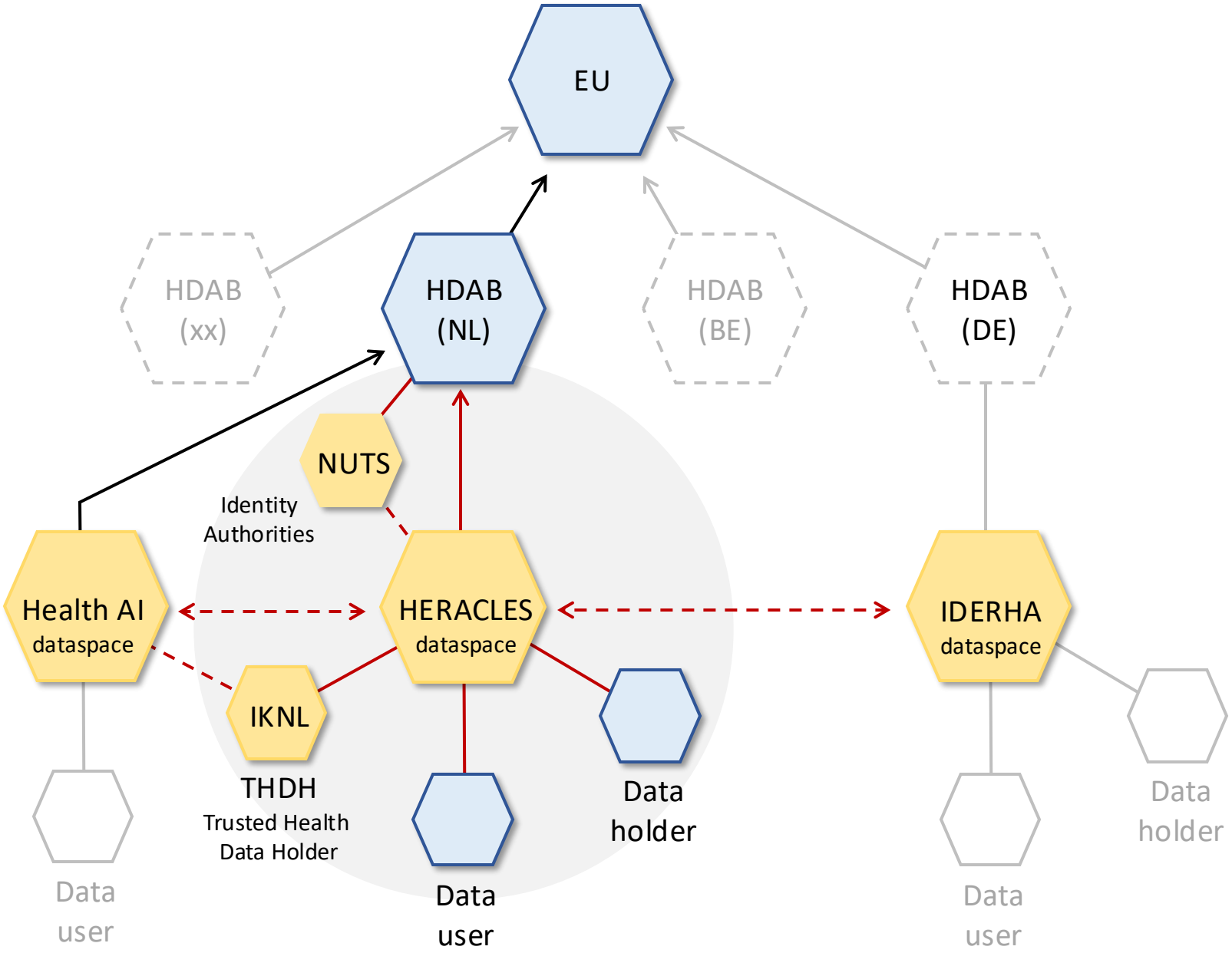
EHDS/HDAB
node



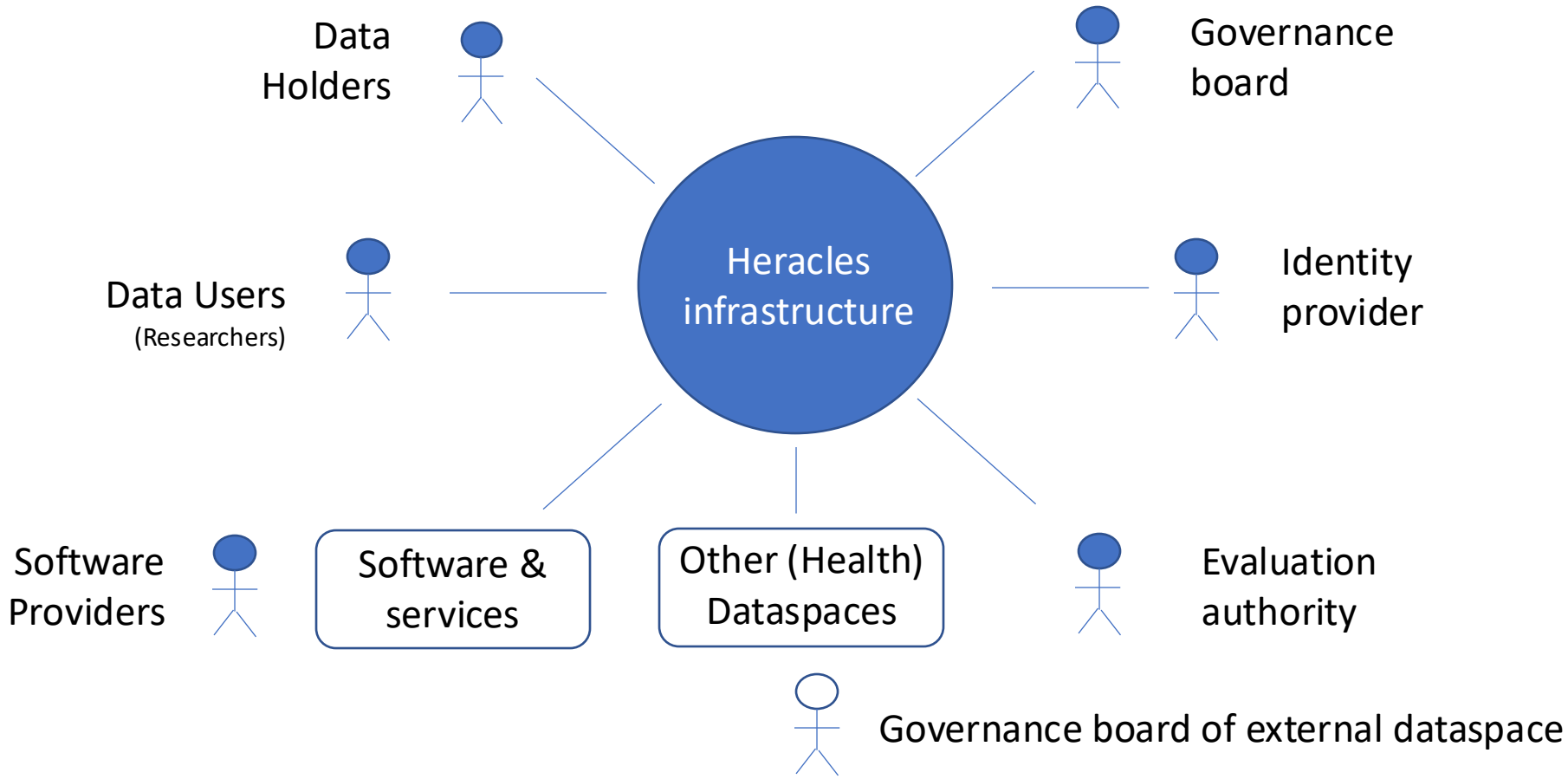


HERACLES
(oncology)
node

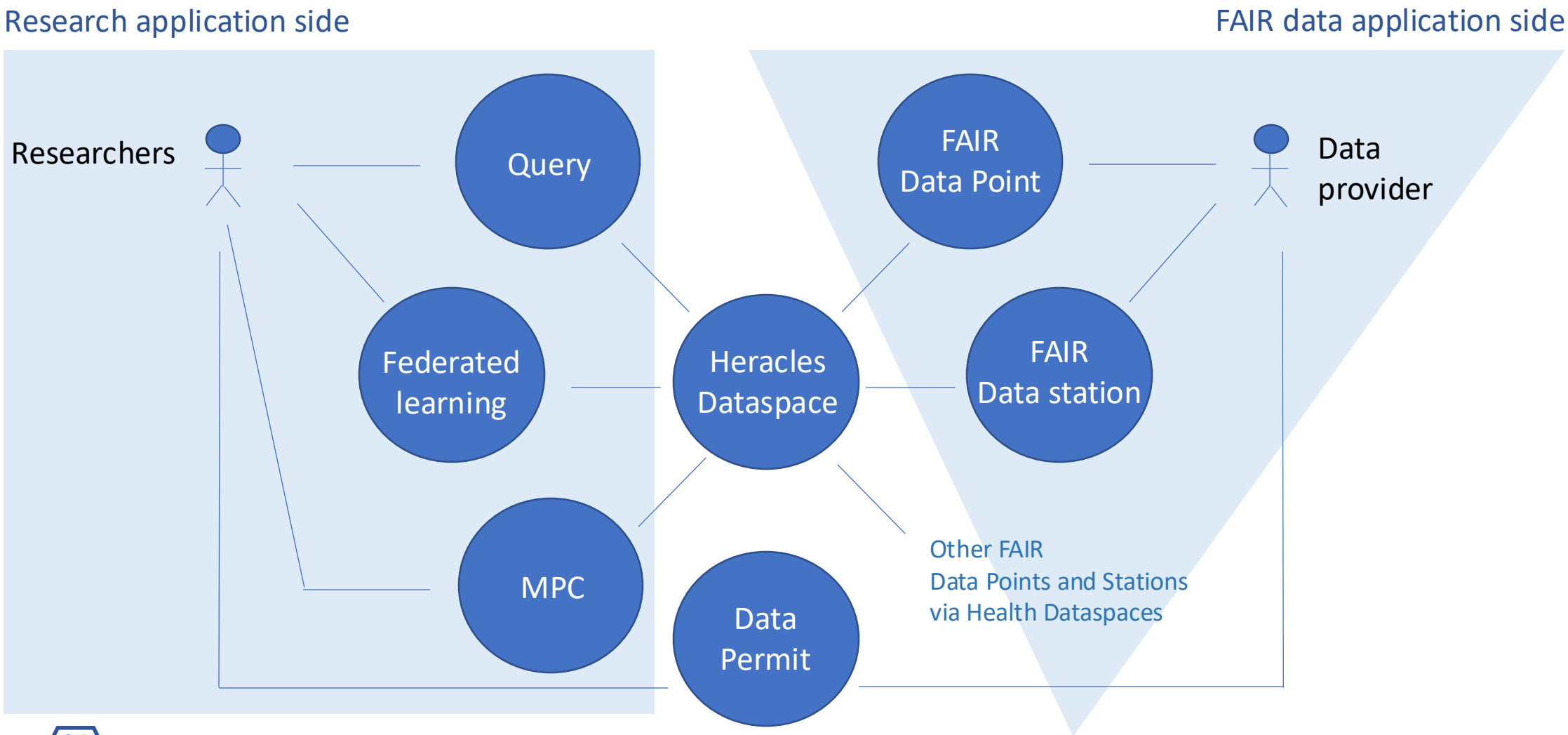
Compliant functionalities



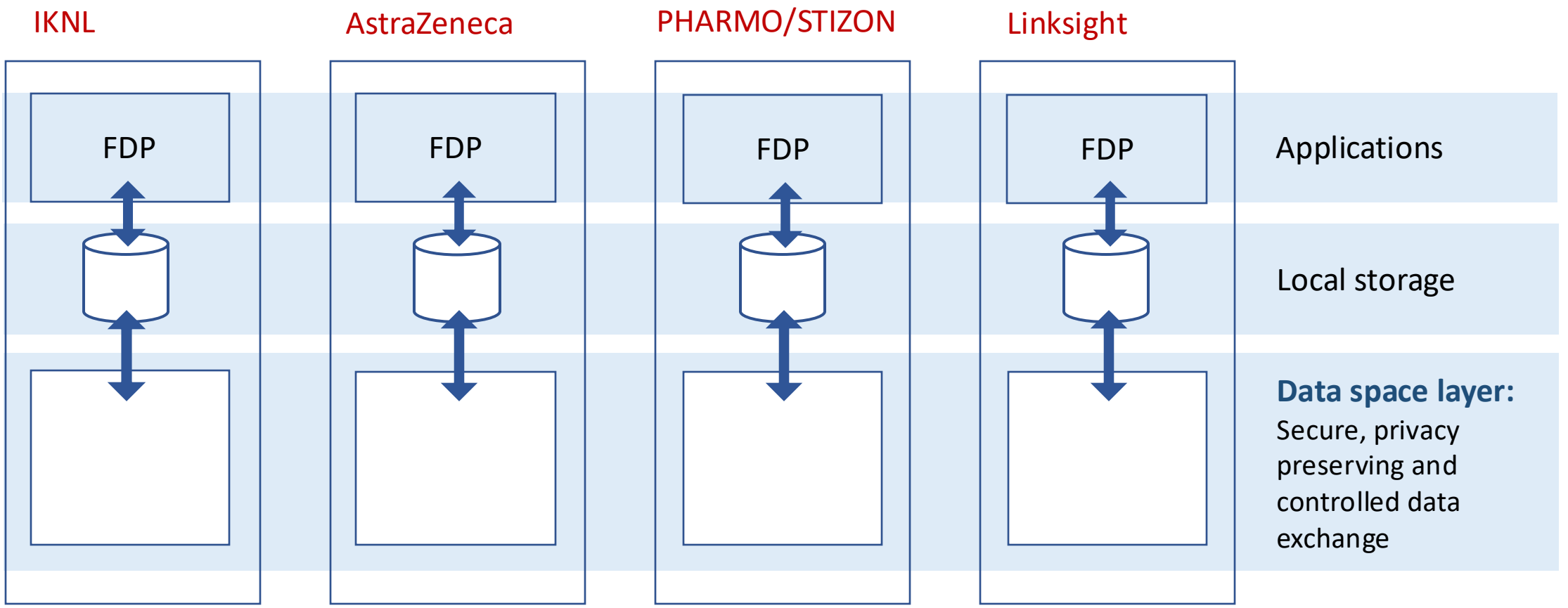
HERACLES infrastructure context diagram



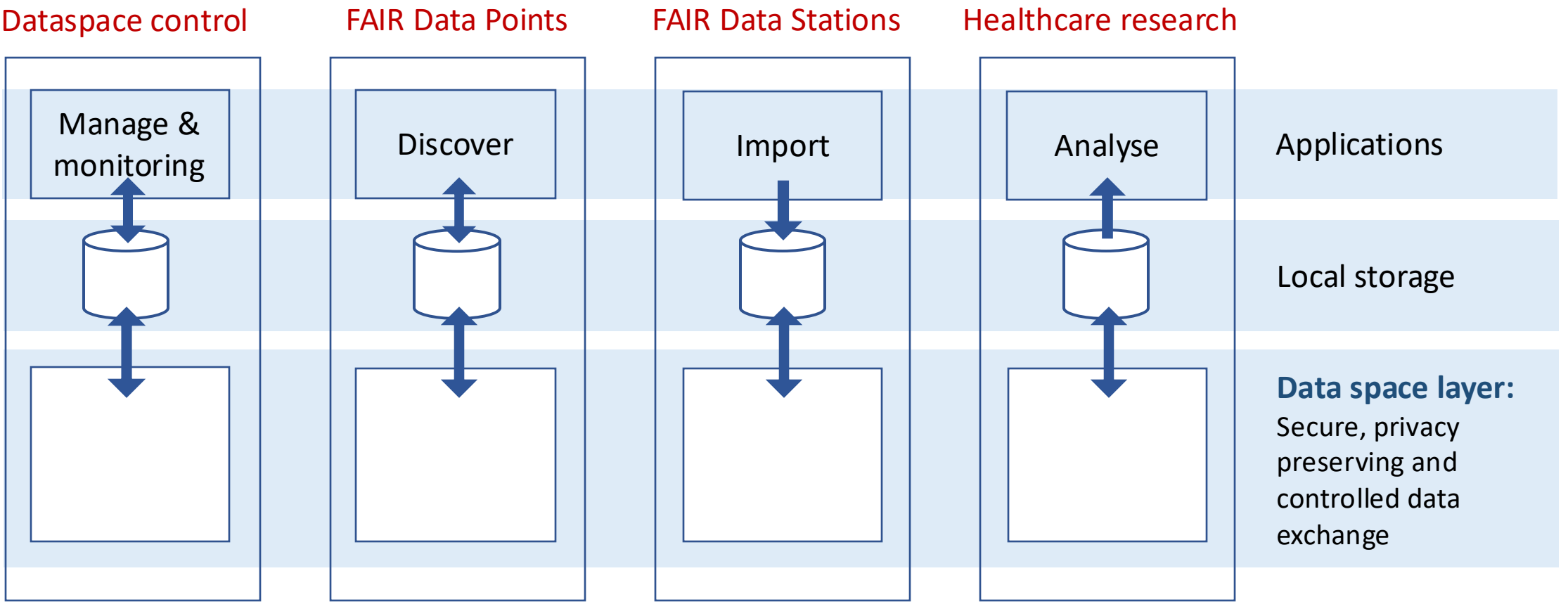
HERACLES infrastructure decomposition



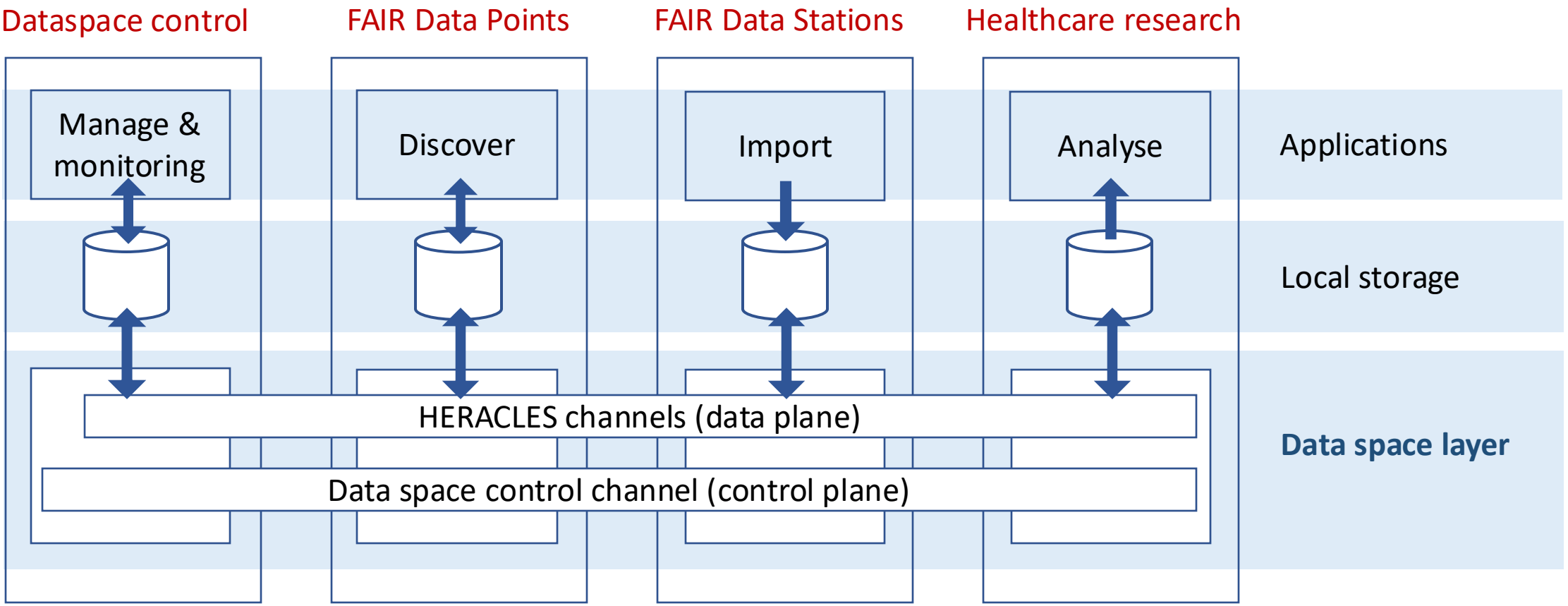
Federated Catalogue (FAIR Data Point)



Four types of services

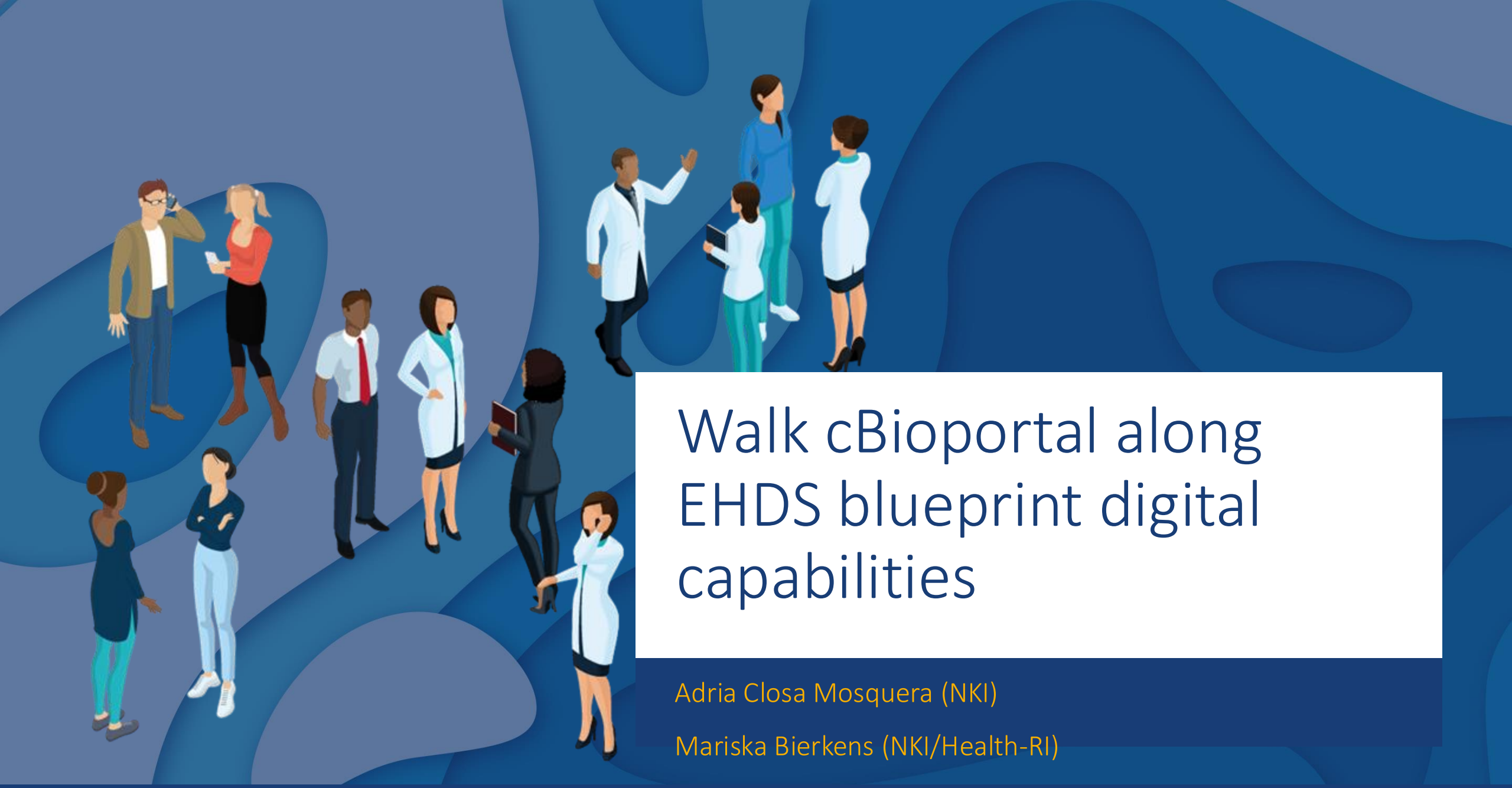


Connected by standards (DSP, DCP, DCAT, VC …)



Coffee break

10:45-11:00



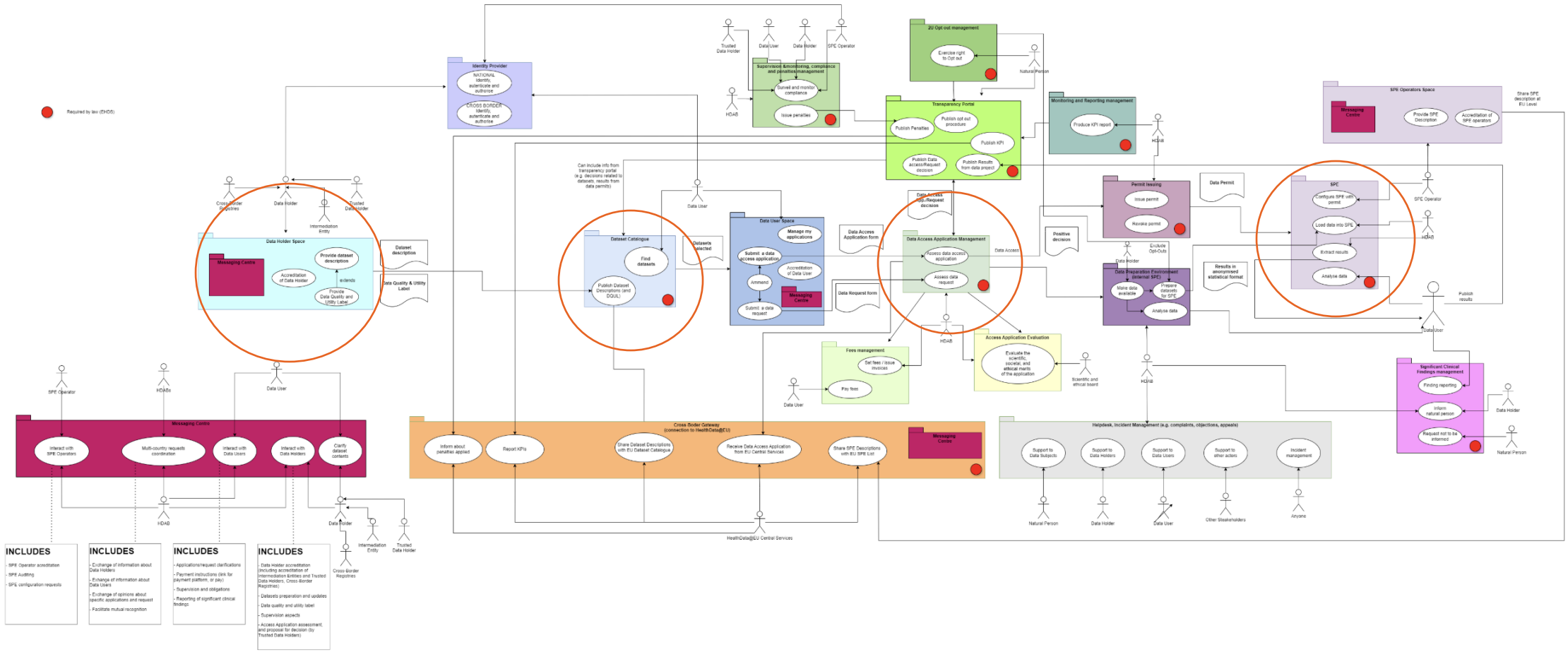
Walk cBioportal along EHDS blueprint digital capabilities

Adria Closa Mosquera (NKI)

Mariska Bierkens (NKI/Health-RI)

health RI
enabling data driven health & life sciences

Backbone


Identity Provider
Supervision &monitoring, compliance and penalties management
20 Opt out management
Transparency Portal
Monitoring and Reporting management
SPE Operators Space
Data Holder Space
Dataset Catalogue
Data User Space
Data Access Application Management
Permit issuing
SPE
Data Preparation Environment (internal SPE)
Fees management
Access Application Evaluation
Significant Clinical Findings management
Messaging Centre
Cross Border Gateway (connection to HealthData@EU)
Helpdesk, Incident Management (e.g. complaints, objections, appeals)
HealthData@EU Central Services
INCLUDES
INCLUDES
INCLUDES
INCLUDES

NETHERLANDS CANCER INSTITUTE
ANTONI VAN LEEUWENHOEK

One Portal, One Standard: Transforming Translational Research Data for an EHDS-Future with cBioPortal

Empowering clinical research with efficient data management workflows.

Adria Closa, PhD
Bioinformatician & Data Steward
Department of Pathology
The Translational Gastrointestional Oncology group
The Netherlands Cancer Institute
Email: a.c.mosquera@nki.nl

08 December 2025

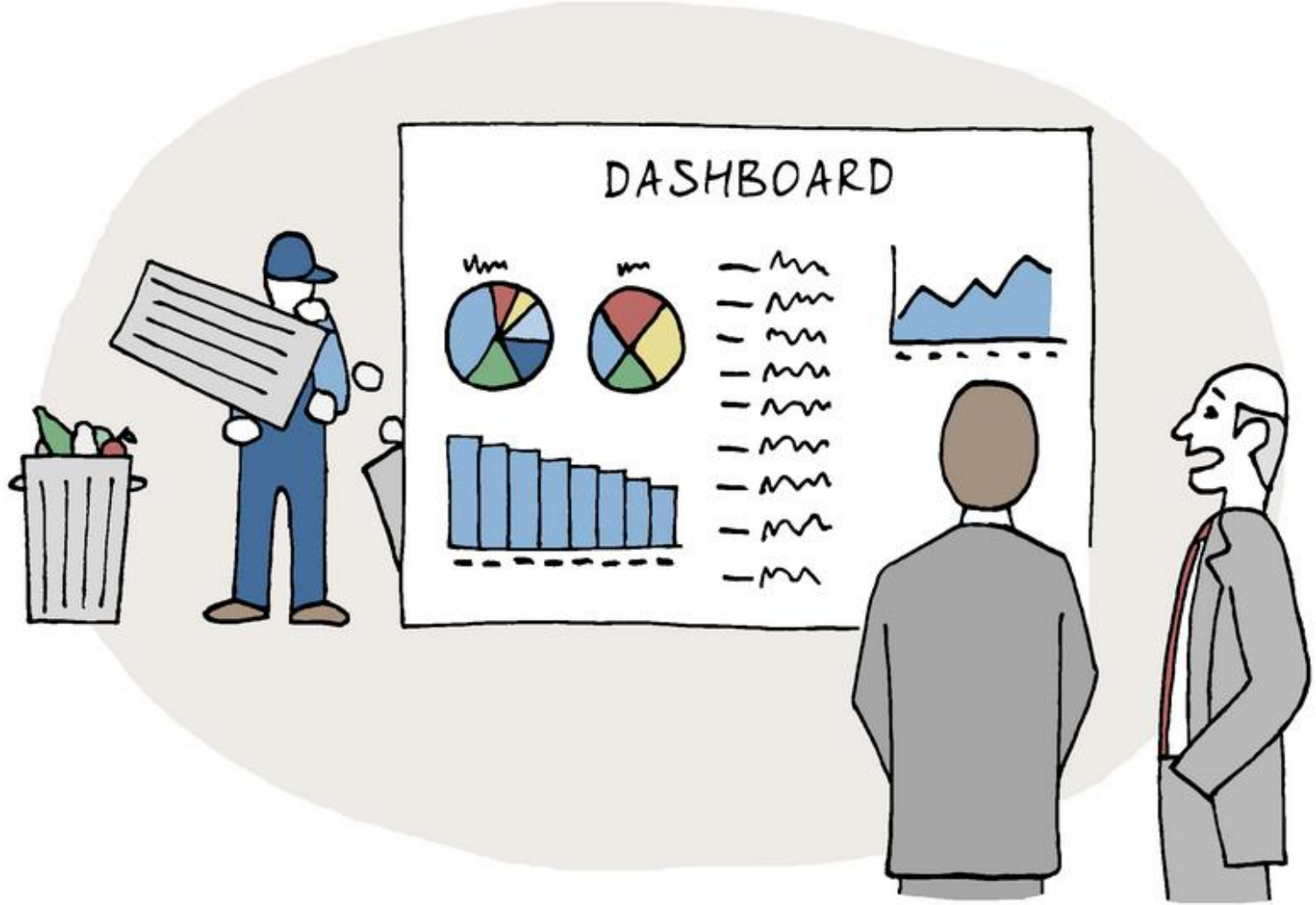
Biology degree (2007-2011)
Master Advance Genetics (2011-2012)
Autonomous University of Barcelona (UAB)
Catalonia

PhD in Medicine (2012-2017)
University of Barcelona (UB)
Catalan Institute of Oncology (ICO-IDIBELL)
Catalonia

Bioinformatician (2016-2017)
Post-doctoral researcher (2017-2019)
Barcelona Biomedical Research Park (PRBB)
Catalonia

Post-doctoral researcher (2019-2023)
John Curtin School of Medical Research (JCSMR)
Australia

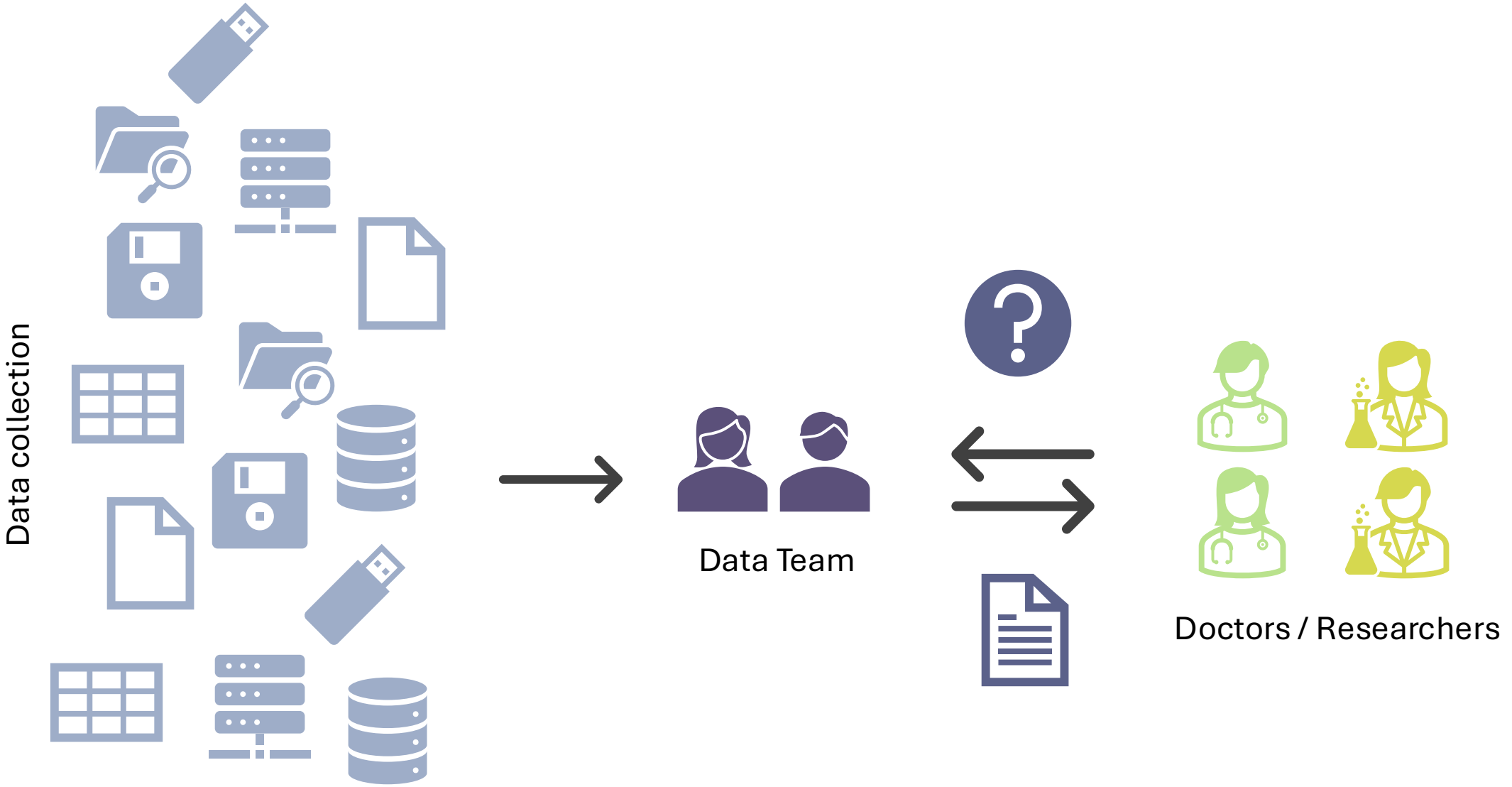
Bioinformatician / data steward (2023-Present)
Netherlands Cancer Institute (NKI)
The Netherlands



DO WE TRUST THIS DATA?

Dataedo /cartoon

Piotr@Dataedo



*"The **main goal of a data management team** is to make sure that data across the organization is **reliable, accessible, secure, and usable** so the researchers can make informed decisions and generate value."*

TGO DATA MANAGEMENT JOURNEY

Data collection

- What to collect?
- Where to collect?
- How to collect?
- How often?

Data Cleaning

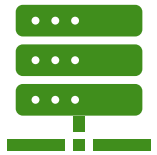
- Data needs to be cross validated
- Multiple sources = multiple errors
- Human error cleaning

Data Integration

- Data coming from multiple sources include different types of data and need to be integrated

Data Model/Storage

- Data needs to be converted on a machine-readable structure to improve scalability and efficiency (SQL/OMOP)



Data distribution

- Data must be distributed in a research ready format to be useful for research (cBioPortal)

TGO DATA MAP

Collection

Care
- HiX
- LMS
- Slide Score
- TRIMIS
- MolPA / DNA DB

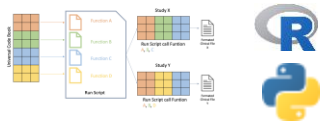
Reserach
- Labguru
- ART-CFMPB
- CASTOR
- XNAT
- LDOT
- HMF

Registries
- PALGA
- IKNL-NKR

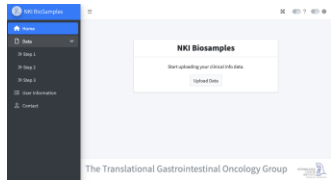
TGO

Integrate

Data formatting



TGO Biosamples App



TGO studies

RHPC

Bioinformatics Pipelines Workflow

Seq, annot, Aligment, VC

Freeman (DATA)

Virchow (HPC)

Morgan (HPC)

I&A AVL
- C2
- Res

SurfDrive
- Users
- Share

Rsync+ cron Backup

RAW DATA

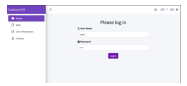
EUROPEAN GENOME-PHENOME ARCHIVE

VM – AVL cBioPortal

ANTONI VAN LEEUWENHOEK NEDERLANDS KANKER INSTITUUT

cBioPortal FOR CANCER GENOMICS

SQL DB



MySQL

HEALTH-RI cBioPortal

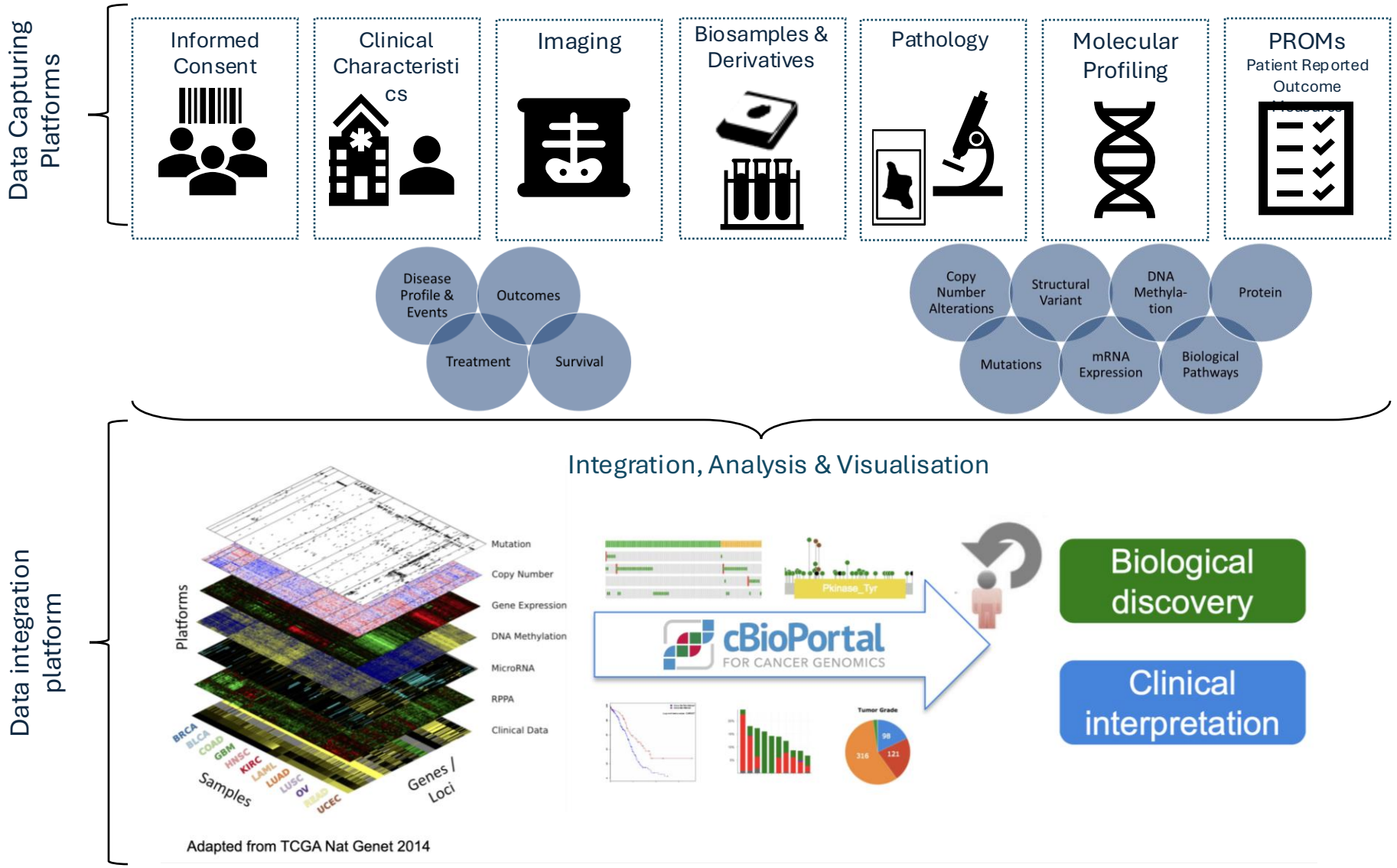
ftp ETL

Acc sBox Pro

cBioPortal FOR CANCER GENOMICS

health RI enabling data driven health

Cancer data in cBioPortal

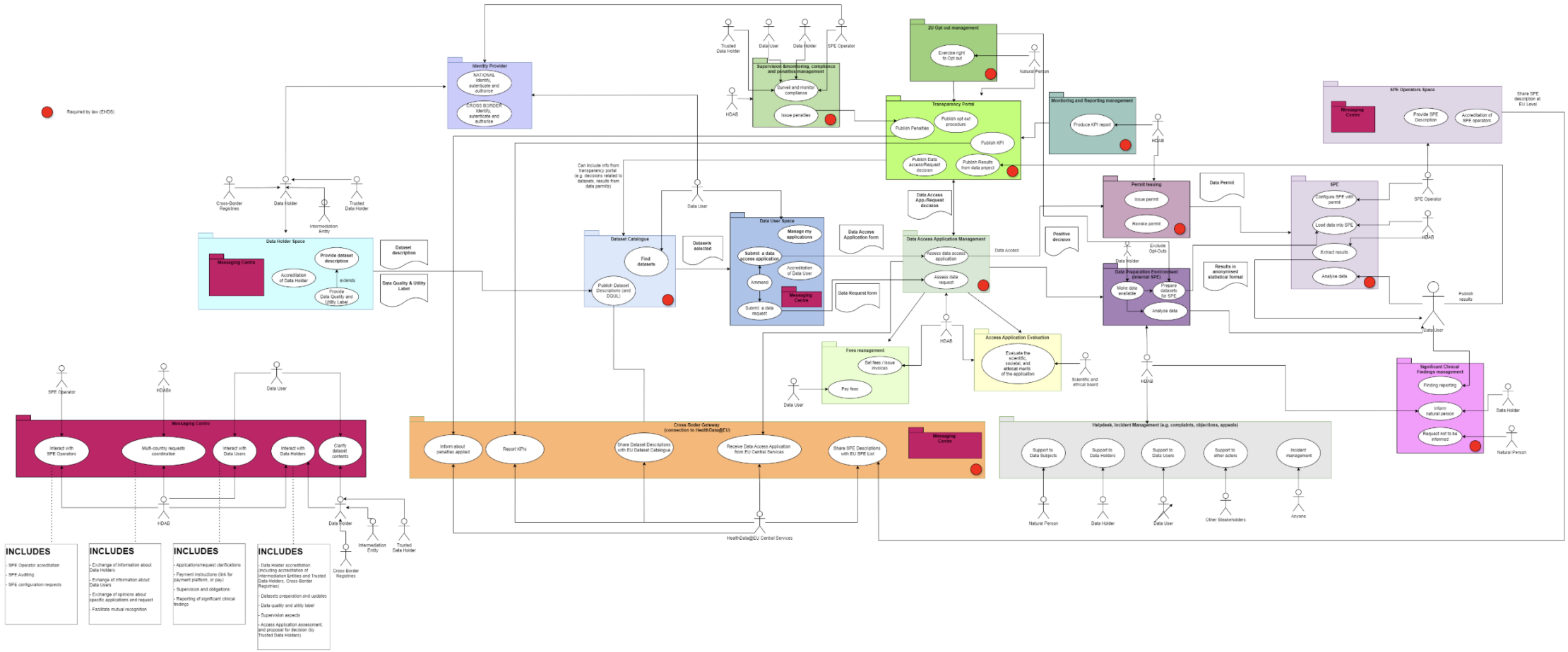


Cerami et al. *Cancer Discovery* 2012
Gao et al. *Science Signaling* 2013

- Make complex cancer genomic data accessible and interpretable for cancer biologists and clinicians

EHDS digital business capabilities (DBC) blueprint

Where does cBioPortal fit in this DBC in the Netherlands?



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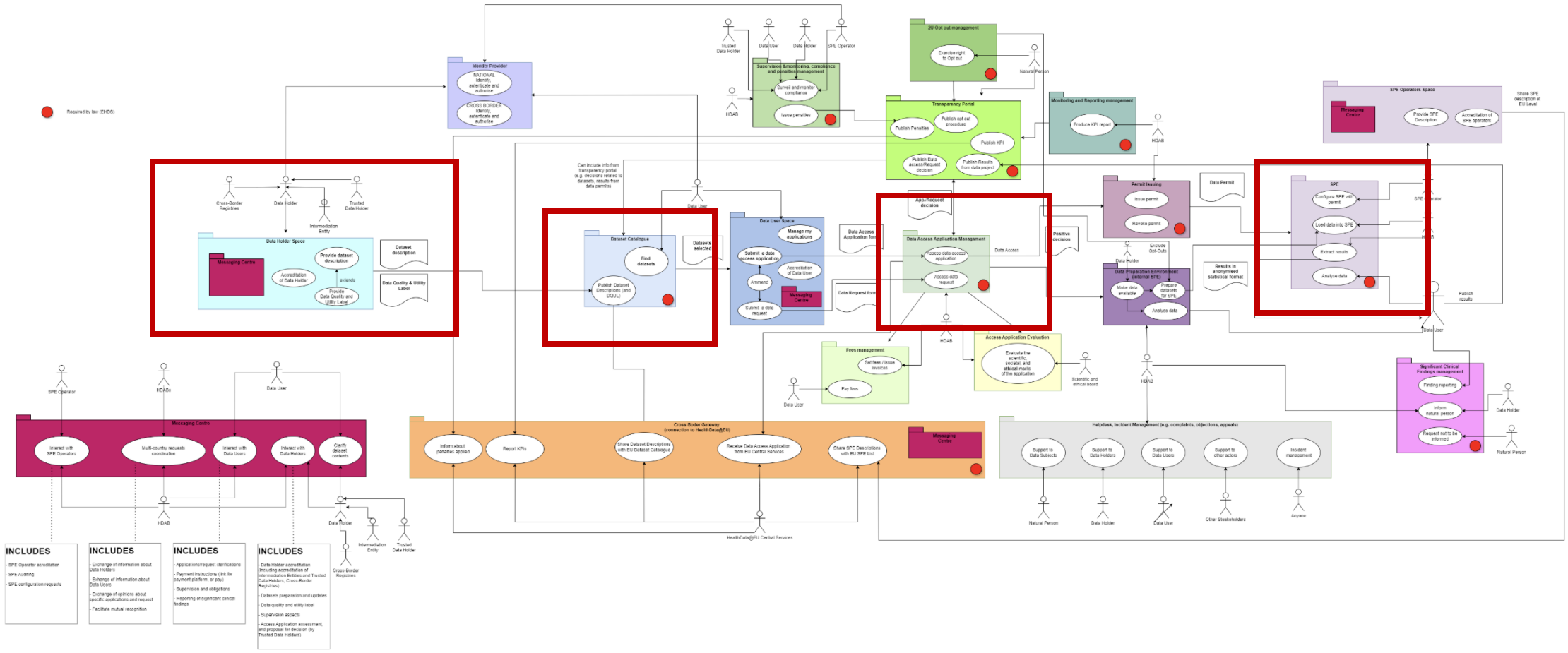
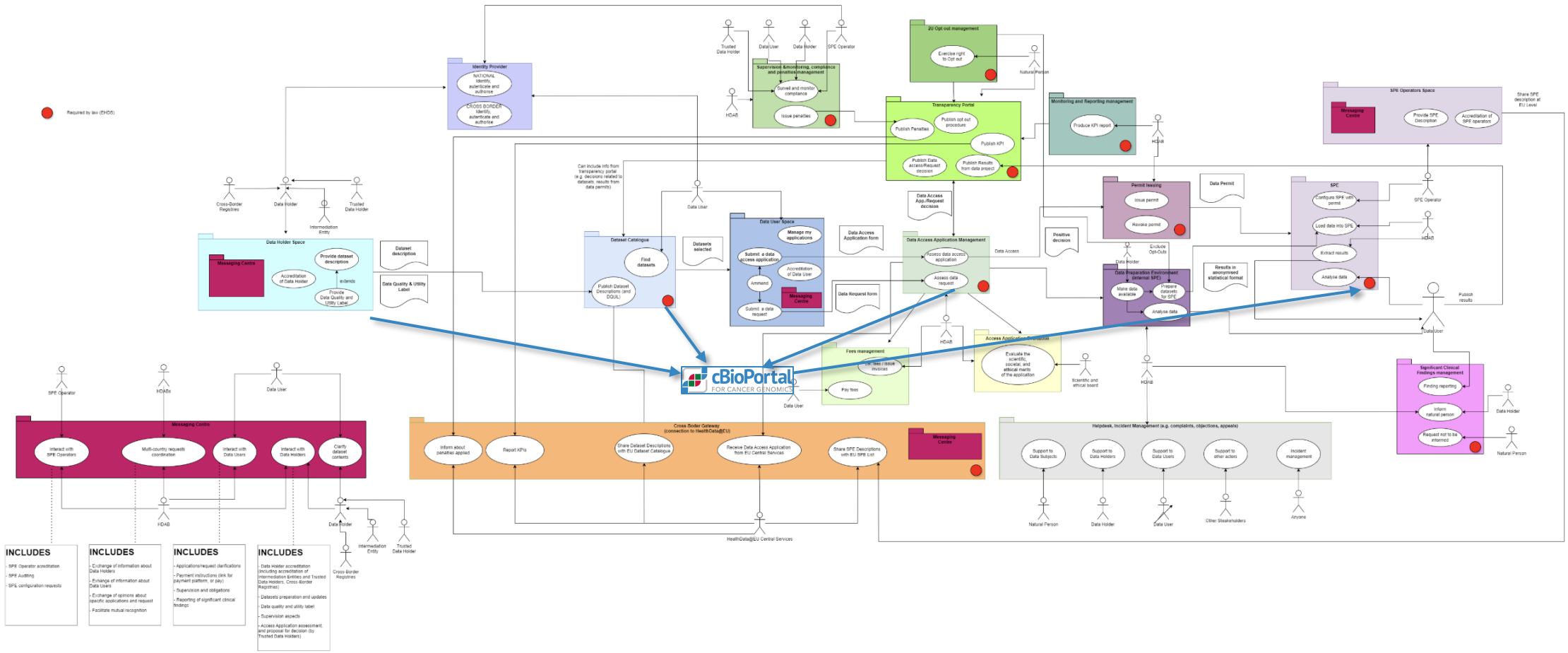


EHDS digital business capabilities (DBC) blueprint

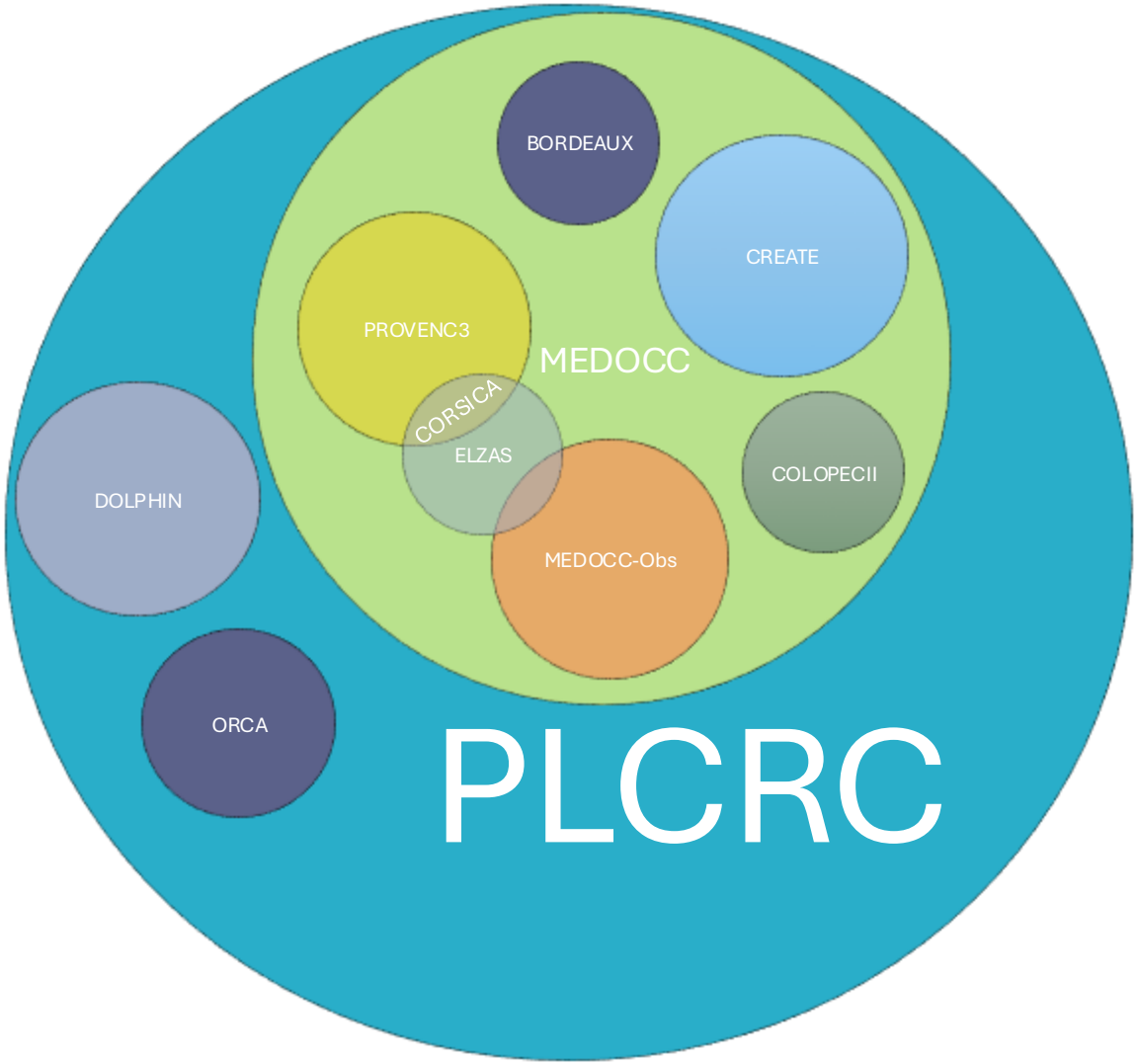
Where does cBioPortal fit in this DBC in the Netherlands?

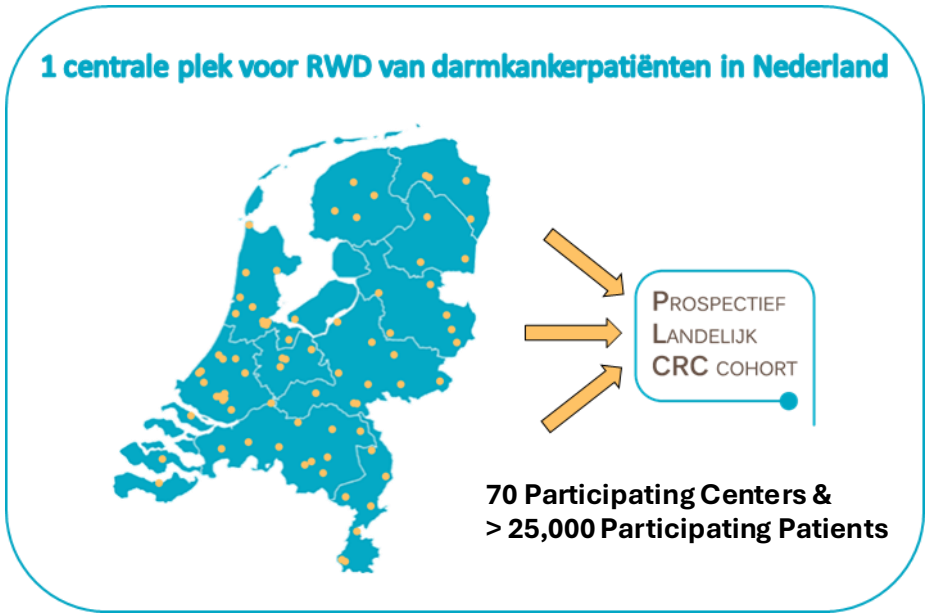


NETHERLANDS CANCER INSTITUTE
ANTONI VAN LEEUWENHOEK

Real use case: mapping the PLCRC data workflow to the EHDS blueprint

PROSPECTIEF
LANDELIJK
CRC COHORT





What is PLCRC?

The Prospective National CRC cohort (PLCRC) provides an infrastructure for collecting clinical data, patient-reported outcomes and storing body material such as blood and tumor tissue from patients with small intestine, colon, rectal and anus cancer. This happens after obtaining the patient's consent.

Main goal?

The goal of the cohort is to facilitate scientific research to improve the prognosis and quality of life of (future) patients.

NKI biobank infrastructure is used to collect and store blood and tissue samples from donors that are part of the different sub-studies inside the PLCRC umbrella.

Executive board PLCR members:

- Prof. Dr. Miriam Koopman, internist oncologist, UMCU
- Dr. Robert Jan Kwakman, internist oncologist, UMCU
- Dr. Anna van Tetering, program manager PLCRC
- Dr Frederieke van der Baan, project leader PLCRC

PLCRC needs and requirements for study monitoring

Weekly monitoring of blood collections and tissues for MEDOCC and CrEATE patients.

Global statistics of inclusion and status of patients, blood and tissue availability and tumor stage distribution.

Structured and clean ready data for data analysis and research.

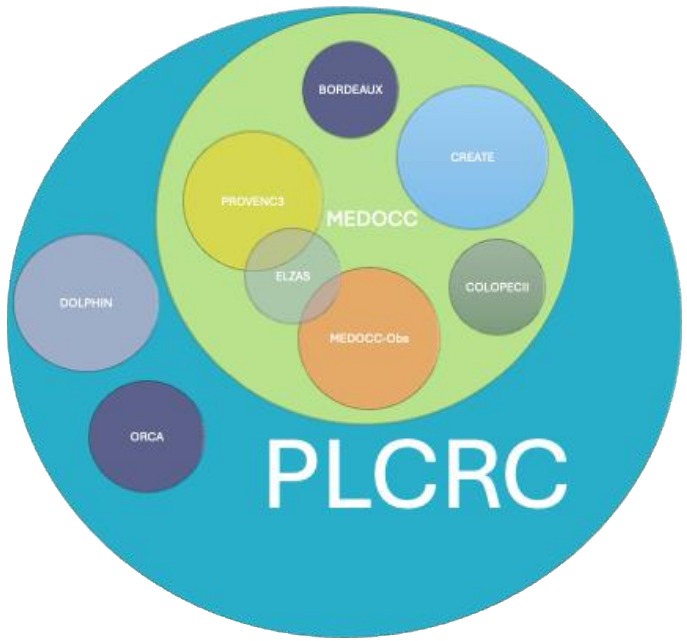
An approach to communicating study data to clinicians and partners involved in the MEDOCC during the weekly UMCU meetings.

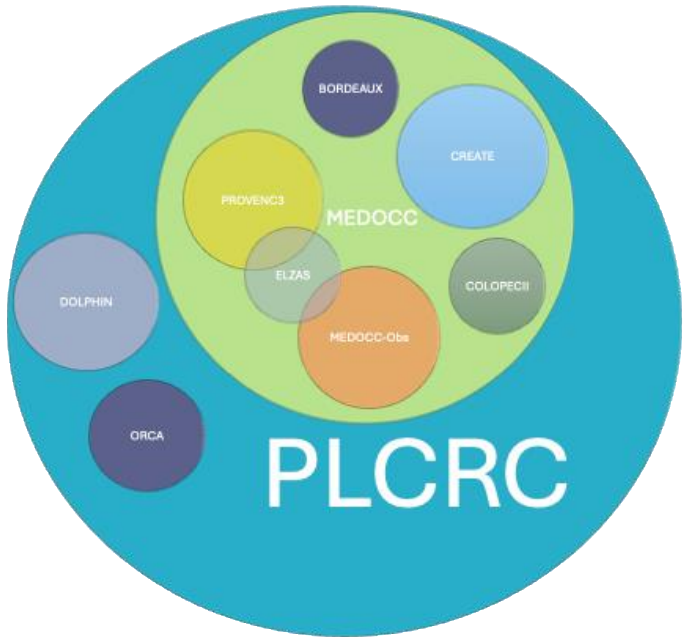
Prediction of the next blood collection moment per patient to be able to prepare the next appointment request.

Can we make all PLCRC studies available in cBioPortal at national level?

cBioPortal FOR CANCER GENOMICS

health RI
enabling data driven health


BORDEAUX
CREATE
PROVENC3
MEDOCC
ELZAS
COLOPECII
DOLPHIN
MEDOCC-Obs
ORCA
PLCRC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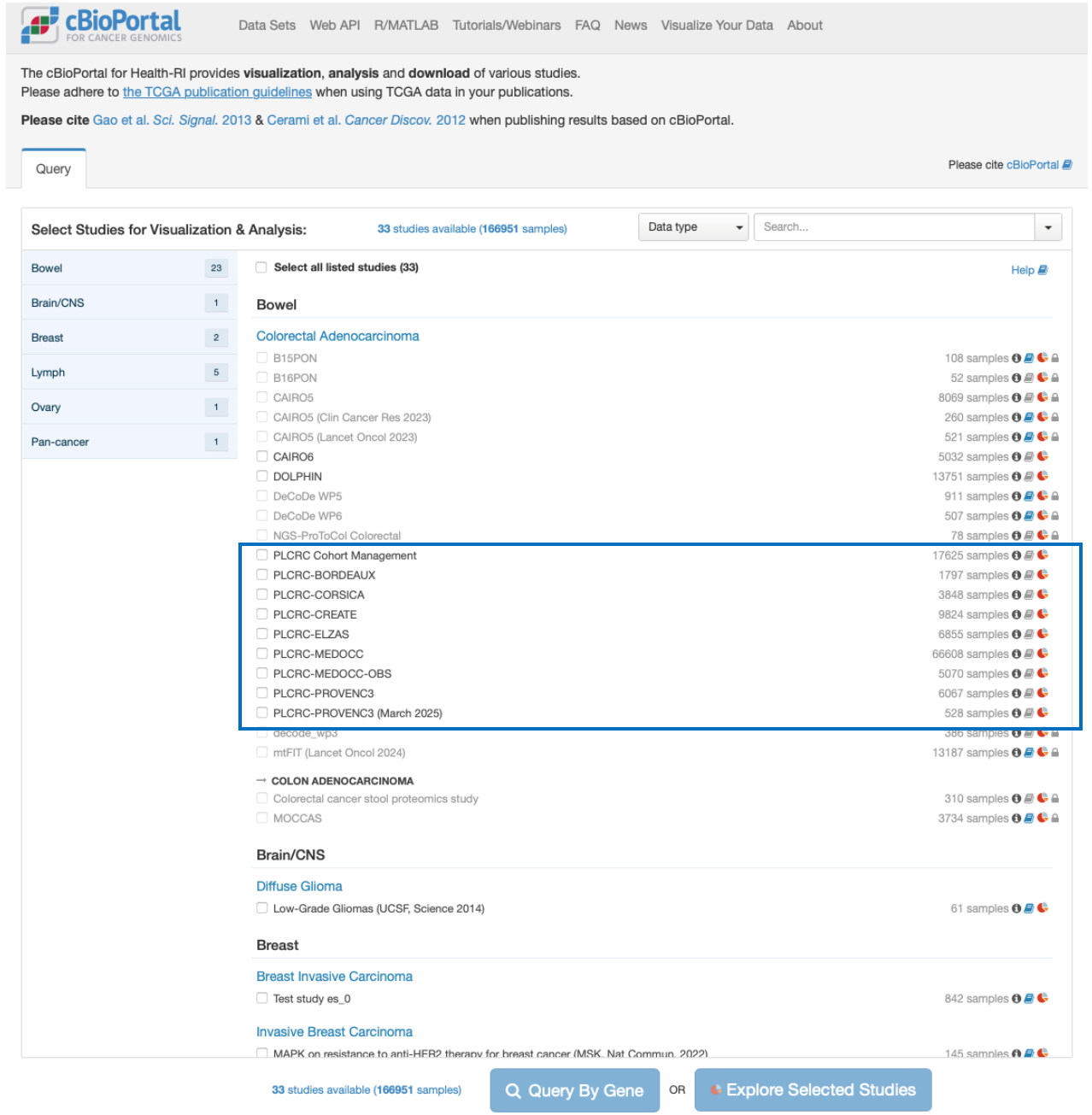
MEDOCC
ELZAS
COLOPECII
DOLPHIN
MEDOCC-Obs
ORCA
PLCRC


cBioPortal FOR CANCER GENOMICS
Data Sets
Web API
R/MATLAB
Tutorials/Webinars
FAQ
News
Visualize Your Data
About
The cBioPortal for Health-RI provides visualization, analysis and download of various studies.
Please adhere to the TCGA publication guidelines when using TCGA data in your publications.
Please cite Gao et al. Sci. Signal. 2013 & Cerami et al. Cancer Discov. 2012 when publishing results based on cBioPortal.
Query
Please cite cBioPortal
Select Studies for Visualization & Analysis:
33 studies available (166951 samples)
Data type
Search...
Bowel 23
Brain/CNS 1
Breast 2
Lymph 5
Ovary 1
Pan-cancer 1
Select all listed studies (33)
Help
Bowel
Colorectal Adenocarcinoma
B15PON 108 samples
B16PON 52 samples
CAIRO5 8069 samples
CAIRO5 (Clin Cancer Res 2023) 260 samples
CAIRO5 (Lancet Oncol 2023) 521 samples
CAIRO6 5032 samples
DOLPHIN 13751 samples
DeCoDe WP5 911 samples
DeCoDe WP6 507 samples
NGS-ProToCol Colorectal 78 samples
PLCRC Cohort Management 17625 samples
PLCRC-BORDEAUX 1797 samples
PLCRC-CORSICA 3848 samples
PLCRC-CREATE 9824 samples
PLCRC-ELZAS 6855 samples
PLCRC-MEDOCC 66608 samples
PLCRC-MEDOCC-OBS 5070 samples
PLCRC-PROVENC3 6067 samples
PLCRC-PROVENC3 (March 2025) 528 samples
mtFIT (Lancet Oncol 2024) 13187 samples
COLON ADENOCARCINOMA
Colorectal cancer stool proteomics study 310 samples
MOCCAS 3734 samples
Brain/CNS
Diffuse Glioma
Low-Grade Gliomas (UCSF, Science 2014) 61 samples
Breast
Breast Invasive Carcinoma
Test study es_0 842 samples
Invasive Breast Carcinoma
33 studies available (166951 samples)
Query By Gene
OR
Explore Selected Studies


cBioPortal
Data Sets Web API R/MATLAB Tutorials/Webinars FAQ News Visualize Your Data About
Logged in as a.c.mosquera@nki.nl
PLCRC-MEDOCC
PLCRC (Prospective Dutch ColoRectal Cancer cohort, www.PLCRC.nl) is a nationwide infrastructure initiative to facilitate colorectal cancer research, with participation of over 50 hospitals that are open for patient accrual. PLCRC-MEDOCC (Molecular Early Detection of Colon Cancer) is a substudy of PLCRC, in which a.o. blood samples are being collected from patients with localized (stage I, II, III) disease, for various translational research studies. The main purpose of this cBioPortal study request is to obtain an overview of PLCRC-MEDOCC patient accrual and longitudinal blood sample collection. Last update 28-02-25
Click gene symbols below or
Query
Summary
Clinical Data
Selected: 4,231 patients | 61,852 samples
Custom Selection
Charts
Groups
angioinvasion
braf_status
cancer_hist
cancer_site_code
differ_grade
dx_basis
fu_complete
fu_last_status
intest_perf
Cancer Studies
rmeta_num
sample_status
sample_type
stage_cat
age_dx
asa_status
stage_m
stage_n
stage_system
stage_t
status
txsx_source
sample_moment_ch...
txsx1_loc
txsx1_type
txsx1_radical
txsx1_emerg
txsx1_tech
msi_ostat
lymph_invasion
cancer_hist_code
cea_post
multifocal
recur_meta
rmeta_lung
rmeta_lv_status
rmeta_lymph
rmeta_other
cea_pre
days_collect_arrive
line1_num
rmeta_other2
rmeta_perit
txsx2_code
txsx2_loc
line2_num
meta_num
prv_tr_num
txsx2_type
txsx2_radical
txsx2_tech
txsx2_emerg
ras_status
prv_tr_genit
rmeta_lv_num
prv_tr_skin
prv_tr_brst
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txsx_num
ln_exam
Number of Samples Per Patient
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prv_tr_hemat
prv_tr_gi
prv_tr_other
prv_tr_urin
prv_tr_resp
prv_tr_endocr
prv_tr_mskst
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stage_m_pa
status_medocc
who_perform_status
line3_num
status_plcrc
ic_blood
ic_dna_results
ic_fut_res
ic_survey
ic_tissue
stage_medocc
status_create
meta_liver_num
study_arm
blocknumber
protocol
ic_version
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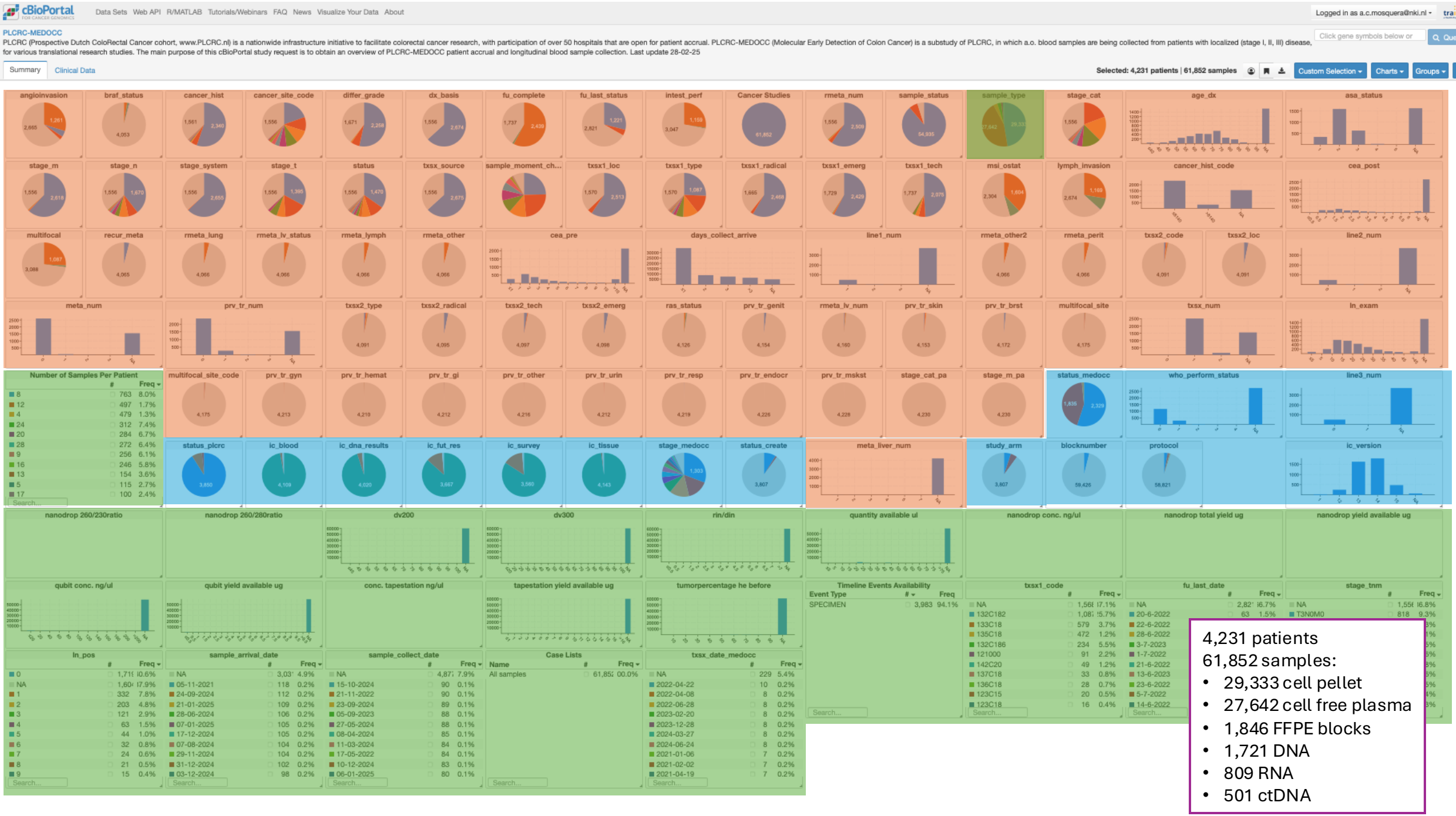
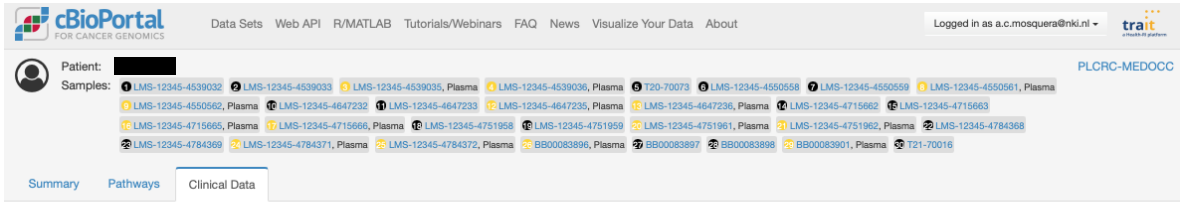
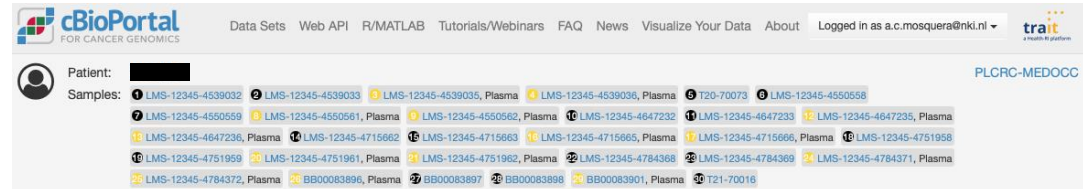
nanodrop 260/280ratio
dv200
dv300
rin/din
quantity available ul
nanodrop conc. ng/ul
nanodrop total yield ug
nanodrop yield available ug
qubit conc. ng/ul
qubit yield available ug
conc. tapestation ng/ul
tapestation yield available ug
tumorpercentage he before
Timeline Events Availability
txsx1_code
fu_last_date
stage_tnm
ln_pos
sample_arrival_date
sample_collect_date
Case Lists
txsx_date_medocc
Search...


cBioPortal
Data Sets Web API R/MATLAB Tutorials/Webinars FAQ News Visualize Your Data About
Logged in as a.c.mosquera@nki.nl
PLCRC-MEDOCC
PLCRC (Prospective Dutch ColoRectal Cancer cohort, www.PLCRC.nl) is a nationwide infrastructure initiative to facilitate colorectal cancer research, with participation of over 50 hospitals that are open for patient accrual. PLCRC-MEDOCC (Molecular Early Detection of Colon Cancer) is a substudy of PLCRC, in which a.o. blood samples are being collected from patients with localized (stage I, II, III) disease, for various translational research studies. The main purpose of this cBioPortal study request is to obtain an overview of PLCRC-MEDOCC patient accrual and longitudinal blood sample collection. Last update 28-02-25
Summary
Clinical Data
Selected: 4,231 patients | 61,852 samples
Custom Selection
Charts
Groups
Query
IKNL-NKR
LDOT
ART-CFMPB
4,231 patients
61,852 samples:
• 29,333 cell pellet
• 27,642 cell free plasma
• 1,846 FFPE blocks
• 1,721 DNA
• 809 RNA
• 501 ctDNA



Patient

Attribute	Value
age_dx	57
angioinvasion	No
asa_status	2
cancer_hist	Adenocarcinoma, NOS
cancer_hist_code	8140
cancer_site_code	C187
cea_post	0.5
cea_pre	0.5
differ_grade	Moderately Differentiated
dx_basis	Histology of Primary Tumor
fu_complete	No
ic_blood	Yes
ic_dna_results	Yes
ic_fut_res	Yes
ic_survey	Yes
ic_tissue	Yes
ic_version	13
intest_perf	No
ln_exam	15
ln_pos	0
lymph_invasion	No
meta_num	0
msi_ostat	No
multifocal	No
prv_tr_num	0
rmeta_num	0
stage_cat	2a
stage_m	M0
stage_medocc	T3N0M0
stage_n	N0
stage_system	Pathology
stage_t	T3
stage_tnm	T3N0M0
status	Included
status_create	Included
status_medocc	Included
status_plcrc	Included
study_arm	Intervention
txsx_date_medocc	2020-08-17
txsx_num	1
txsx_source	NKR Dec 2023
txsx1_code	133C18
txsx1_emerg	No, elective
txsx1_loc	Organ
txsx1_radical	Microscopically radical resection
txsx1_tech	Conventional scopic
txsx1_type	Sigmoid resection
Number of Samples Per Patient	30



Samples

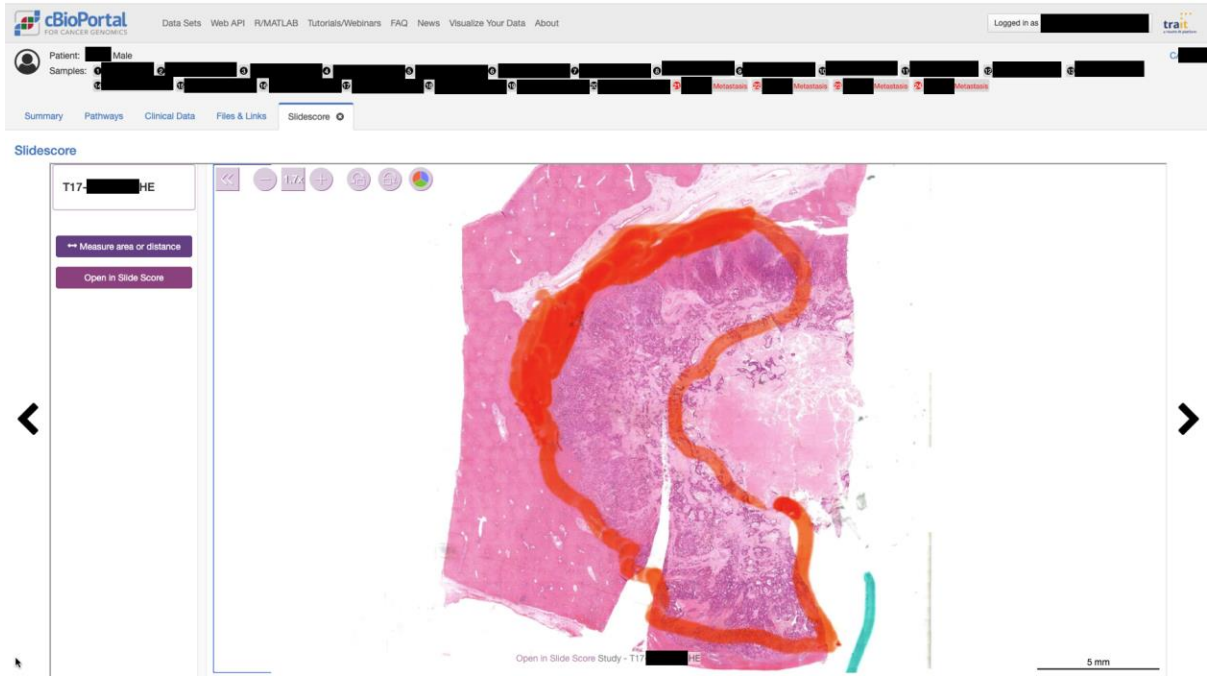
Attribute	LMS-12345-4784369	LMS-12345-4784371	LMS-12345-4550562	LMS-12345-4550558	LMS-12345-4539033	LMS-12345-4784372	LMS-12345-4715663	LMS-12345-4539035	LMS-12345-4647236	LMS-12345-4784368	BB00083896	LMS-12345-4539032	LMS-12345-4751959	LMS-12345-4715662	LMS-12345-4647233
days_collect_arrive	1	1	2	2	4	1	1	4	1	1	1	4	2	1	1
sample_arrival_date	01-03-2022	01-03-2022	04-09-2020	04-09-2020	17-08-2020	01-03-2022	23-07-2021	17-08-2020	24-02-2021	01-03-2022	07-03-2023	17-08-2020	10-11-2021	23-07-2021	24-02-2021
sample_collect_date	28-02-2022	28-02-2022	02-09-2020	02-09-2020	13-08-2020	28-02-2022	22-07-2021	13-08-2020	23-02-2021	28-02-2022	06-03-2023	13-08-2020	08-11-2021	22-07-2021	23-02-2021
sample_moment_checked	T5FU18m	T5FU18m	T2Post	T2Post	T1Pre	T5FU18m	T4FU12m	T1Pre	T3FU6m	T5FU18m	T7FU3y	T1Pre	T4FU12m_O	T4FU12m	T3FU6m
sample_status	Available	Available	Used	Available	Available	Available	Available	Available	Available	Available	Available	Available	Available	Available	Availabl
sample_type	Cell Pellet	Cell-free Plasma	Cell-free Plasma	Cell Pellet	Cell Pellet	Cell-free Plasma	Cell Pellet	Cell-free Plasma	Cell-free Plasma	Cell Pellet	Cell-free Plasma	Cell Pellet	Cell Pellet	Cell Pellet	Cell Pellet

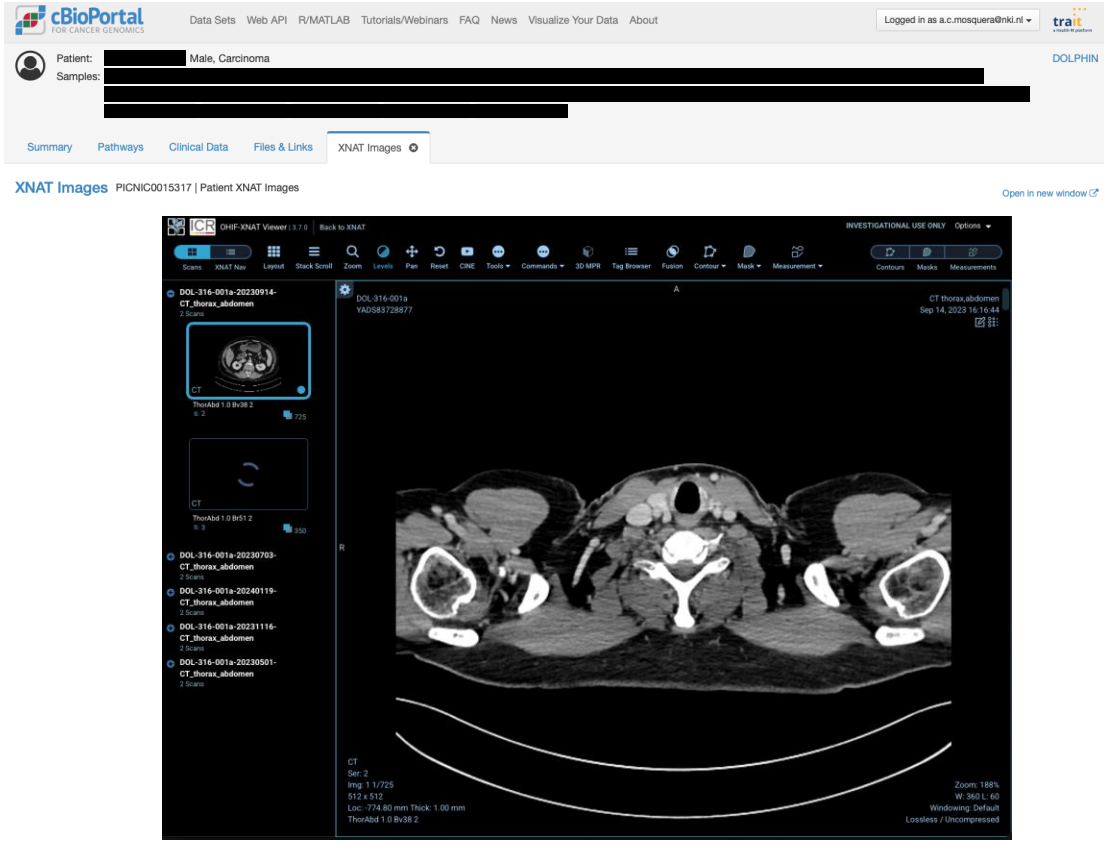
Timeline Data

Specimen

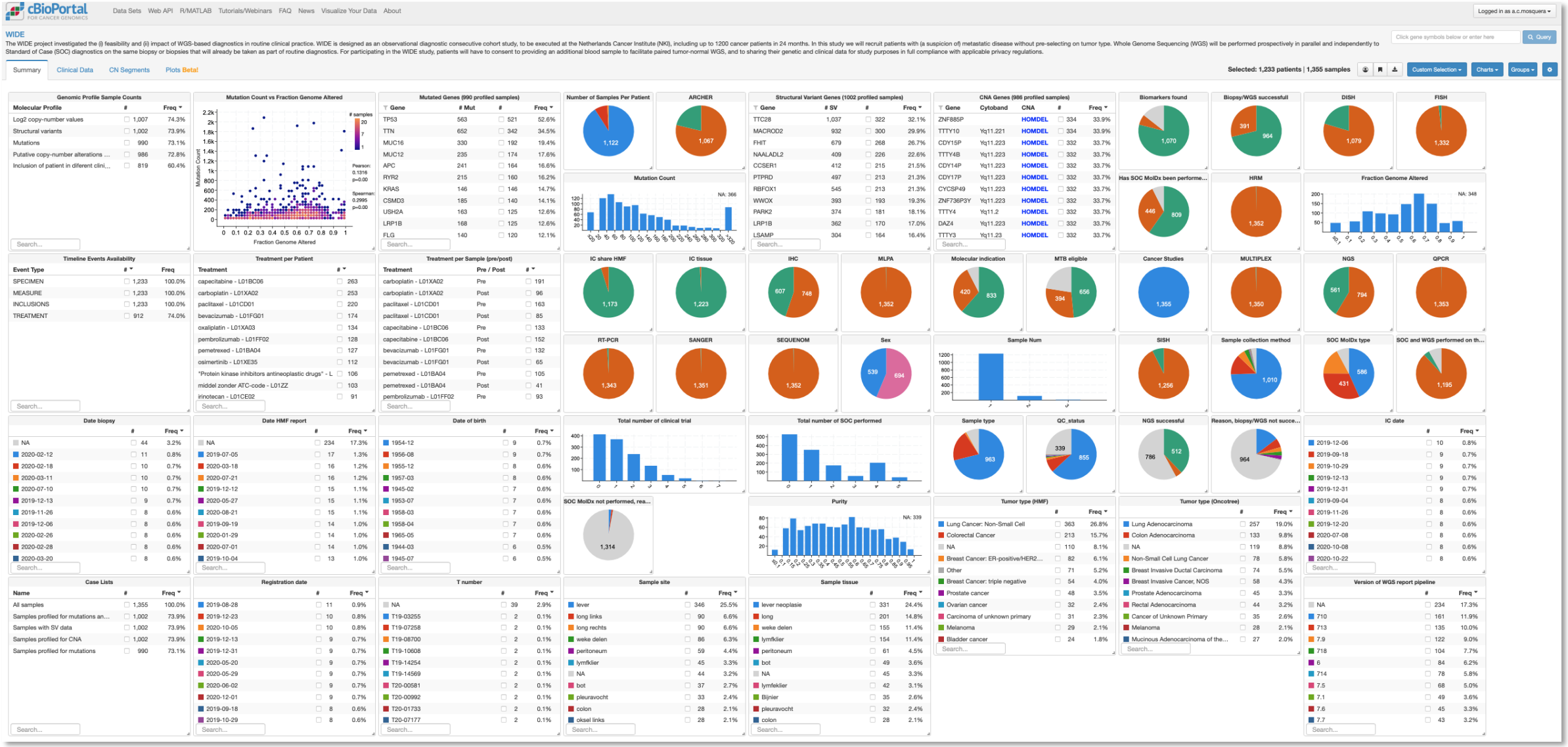
START_DATE	STOP_DATE	EVENT_TYPE	SPECIMEN_TYPE	SAMPLE_ARRIVAL_DATE	SAMPLE_TYPE	SAMPLE_ID
0		SPECIMEN	Blood	17-08-2020	Cell-free Plasma	LMS-12345-4539036
0		SPECIMEN	Blood	17-08-2020	Cell Pellet	LMS-12345-4539032
0		SPECIMEN	Blood	17-08-2020	Cell-free Plasma	LMS-12345-4539035
0		SPECIMEN	Blood	17-08-2020	Cell Pellet	LMS-12345-4539033
4		SPECIMEN	Tissue	21-08-2020	FFPE block	T20-70073
18		SPECIMEN	Blood	04-09-2020	Cell-free Plasma	LMS-12345-4550561
18		SPECIMEN	Blood	04-09-2020	Cell Pellet	LMS-12345-4550558
18		SPECIMEN	Blood	04-09-2020	Cell-free Plasma	LMS-12345-4550562
18		SPECIMEN	Blood	04-09-2020	Cell Pellet	LMS-12345-4550559
191		SPECIMEN	Blood	24-02-2021	Cell-free Plasma	LMS-12345-4647236
191		SPECIMEN	Blood	24-02-2021	Cell Pellet	LMS-12345-4647233
191		SPECIMEN	Blood	24-02-2021	Cell-free Plasma	LMS-12345-4647235
191		SPECIMEN	Blood	24-02-2021	Cell Pellet	LMS-12345-4647232
340		SPECIMEN	Blood	23-07-2021	Cell Pellet	LMS-12345-4715662
340		SPECIMEN	Blood	23-07-2021	Cell Pellet	LMS-12345-4715663
340		SPECIMEN	Blood	23-07-2021	Cell-free Plasma	LMS-12345-4715666
340		SPECIMEN	Blood	23-07-2021	Cell-free Plasma	LMS-12345-4715665
450		SPECIMEN	Blood	10-11-2021	Cell Pellet	LMS-12345-4751959
450		SPECIMEN	Blood	10-11-2021	Cell-free Plasma	LMS-12345-4751961
450		SPECIMEN	Blood	10-11-2021	Cell-free Plasma	LMS-12345-4751962
450		SPECIMEN	Blood	10-11-2021	Cell Pellet	LMS-12345-4751958
561		SPECIMEN	Blood	01-03-2022	Cell Pellet	LMS-12345-4784369
561		SPECIMEN	Blood	01-03-2022	Cell-free Plasma	LMS-12345-4784371
561		SPECIMEN	Blood	01-03-2022	Cell Pellet	LMS-12345-4784368
561		SPECIMEN	Blood	01-03-2022	Cell-free Plasma	LMS-12345-4784372
932		SPECIMEN	Blood	07-03-2023	Cell Pellet	BB00083897
932		SPECIMEN	Blood	07-03-2023	Cell-free Plasma	BB00083896
932		SPECIMEN	Blood	07-03-2023	Cell Pellet	BB00083898
932		SPECIMEN	Blood	07-03-2023	Cell-free Plasma	BB00083901

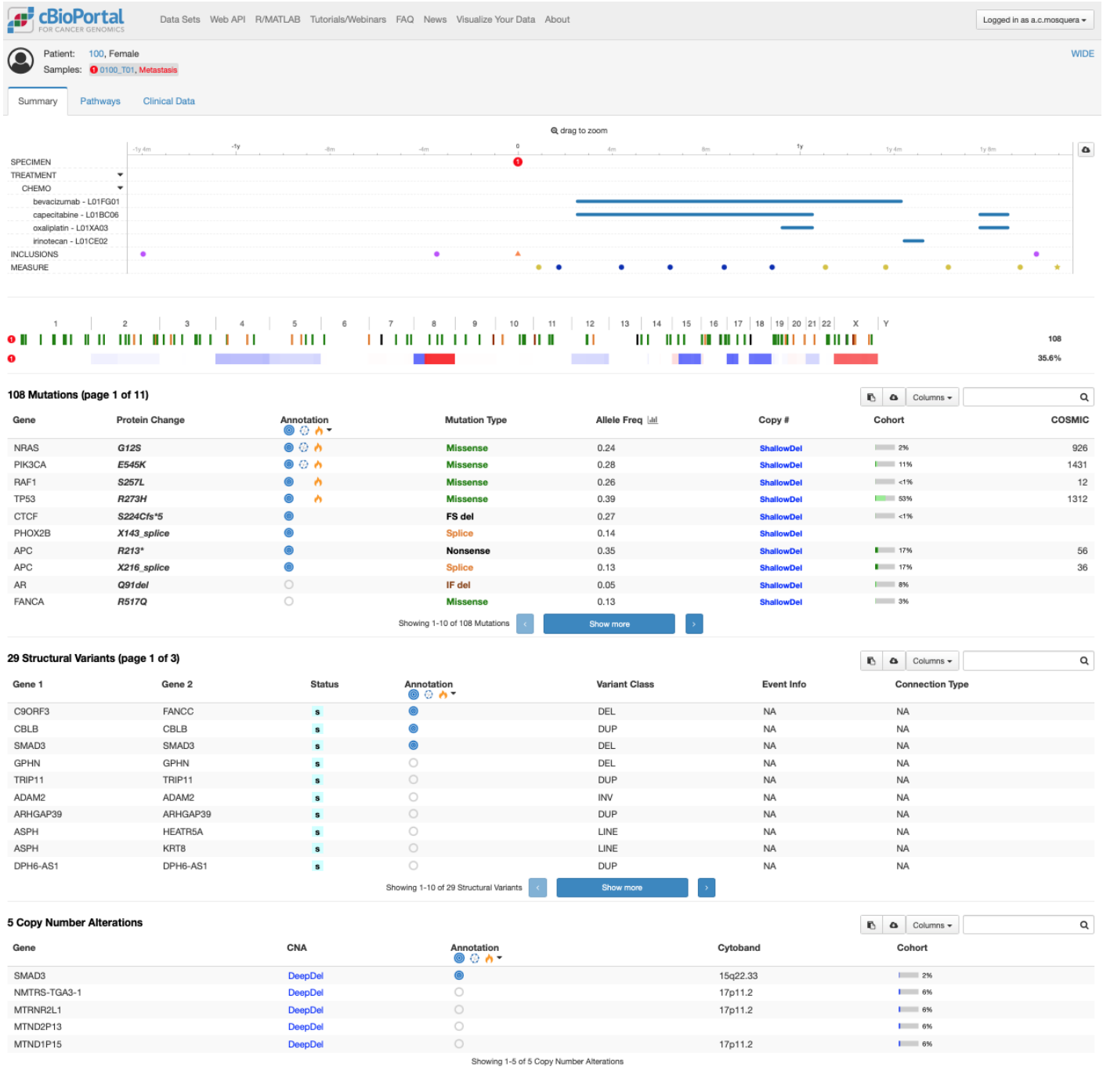
Slidescore and XNAT





WIDE: Integration of ALEA data + sequencing data from HMF in NKI cBioPortal





Patient timeline:
- Specimen collection
- Treatments received by the patient during study
- Inclusions in clinical trials
- Different tumor measurements

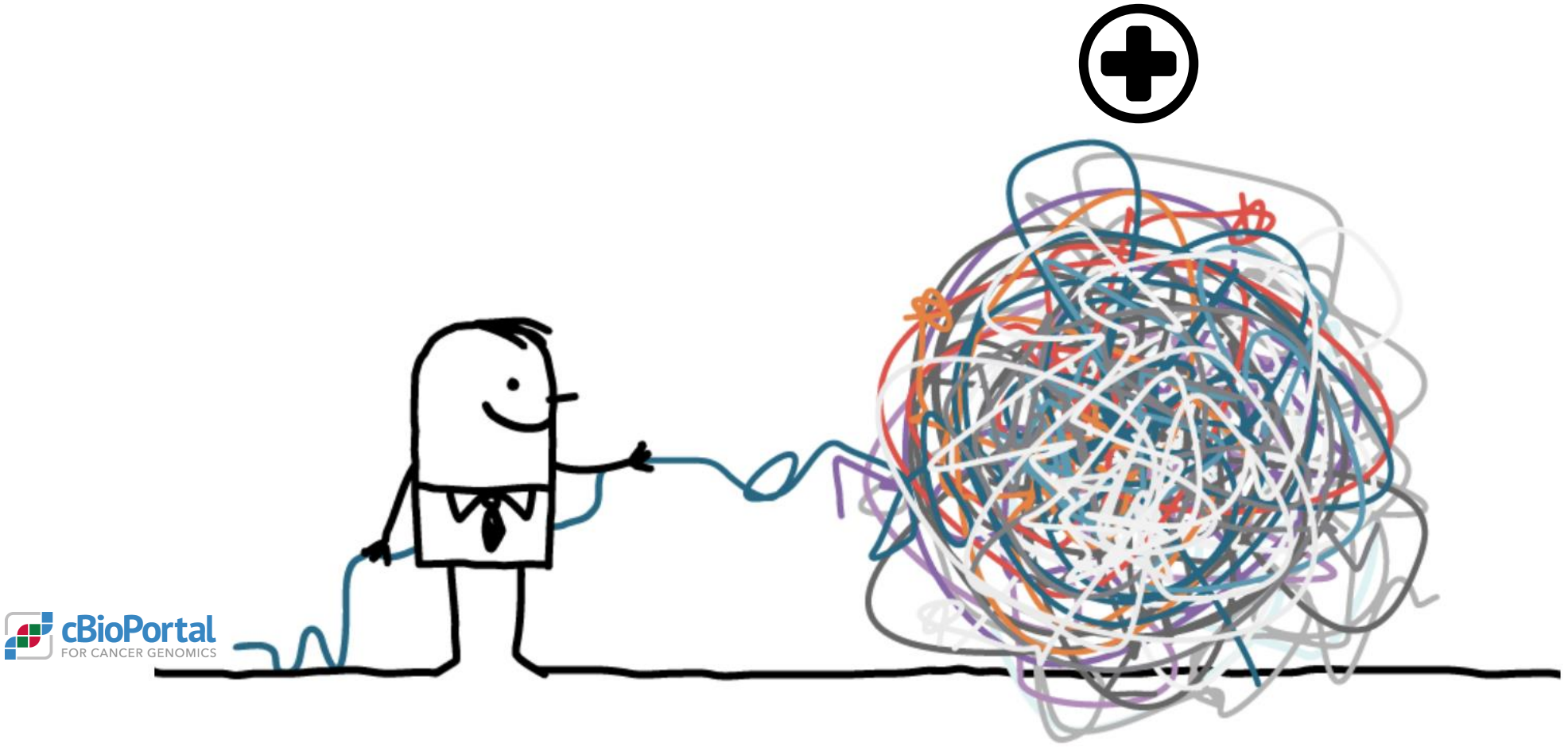
Mutation data
Segmented copy number

Annotated mutation data linked to multiple reference data bases (OncoKB, My Caner Genome, Cancer Hotspots)

Structural Variants (DUP, DEL, INV, etc)

Copy Number Alterations

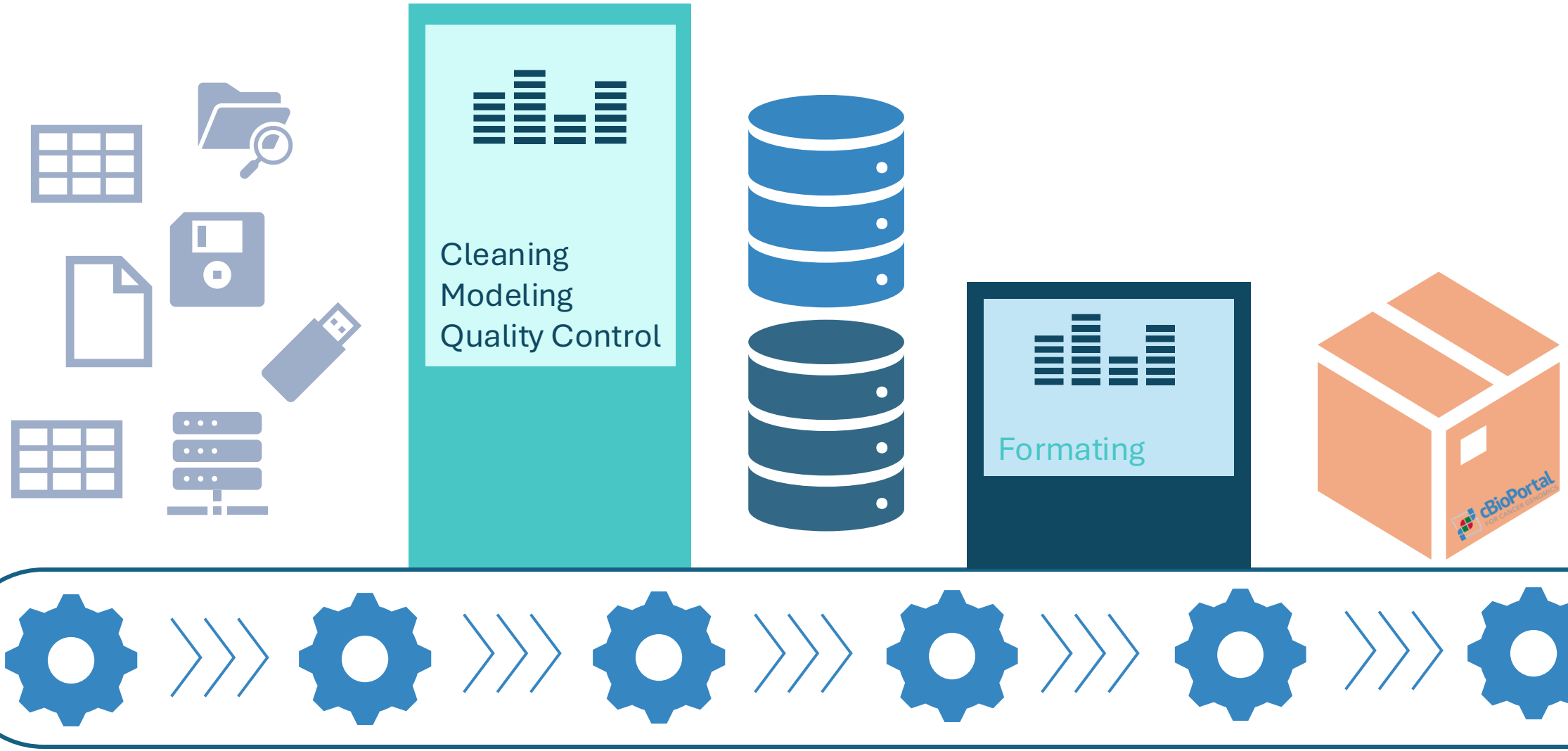
From unstructured data to cBioPortal?



cBioPortal
FOR CANCER GENOMICS

[N.I. par Dreamstime]

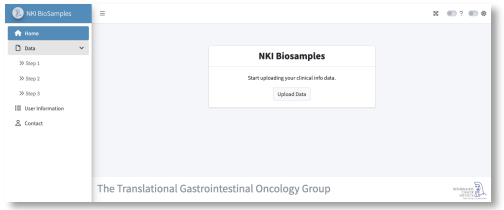
Data modeling and standardization allows automatization



TGO data workflows summary

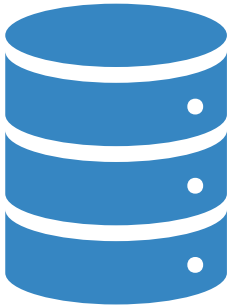
- External vs internal patients
- Blood samples
- Tissue samples
- Isolations (blood/tissue)
- Seq data
- Molecular data
- Clinical data
- Informed consent
- Imaging data

TGO Biosamples App



- Detection errors registration biomaterial and patient data.
- Integrates biomaterial info, collections time points, IC and minimal set of clinical variables.
- Allows active longitudinal follow up of patients per study.
- Dashboard to explore the data.

- Centralized all data in a db.
- Combine Biosample app output with IKNL-NKR clinical data and molecular data.

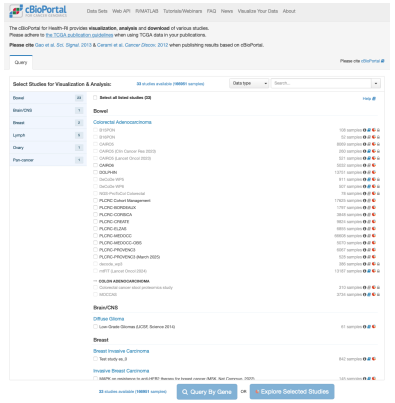


MySQL

cBPFG

- The cBioPortal File Generator extracts data form the SQL database to generate cBio files ready to import data to cBioPortal

- Data is shared with researchers and doctors in cBioPortal to easily explore de data in a user-friendly environment



cBioPortal FOR CANCER GENOMICS

Collecting data	Cleaning/Curation	Data modeling	Data formatting	Data Distribution

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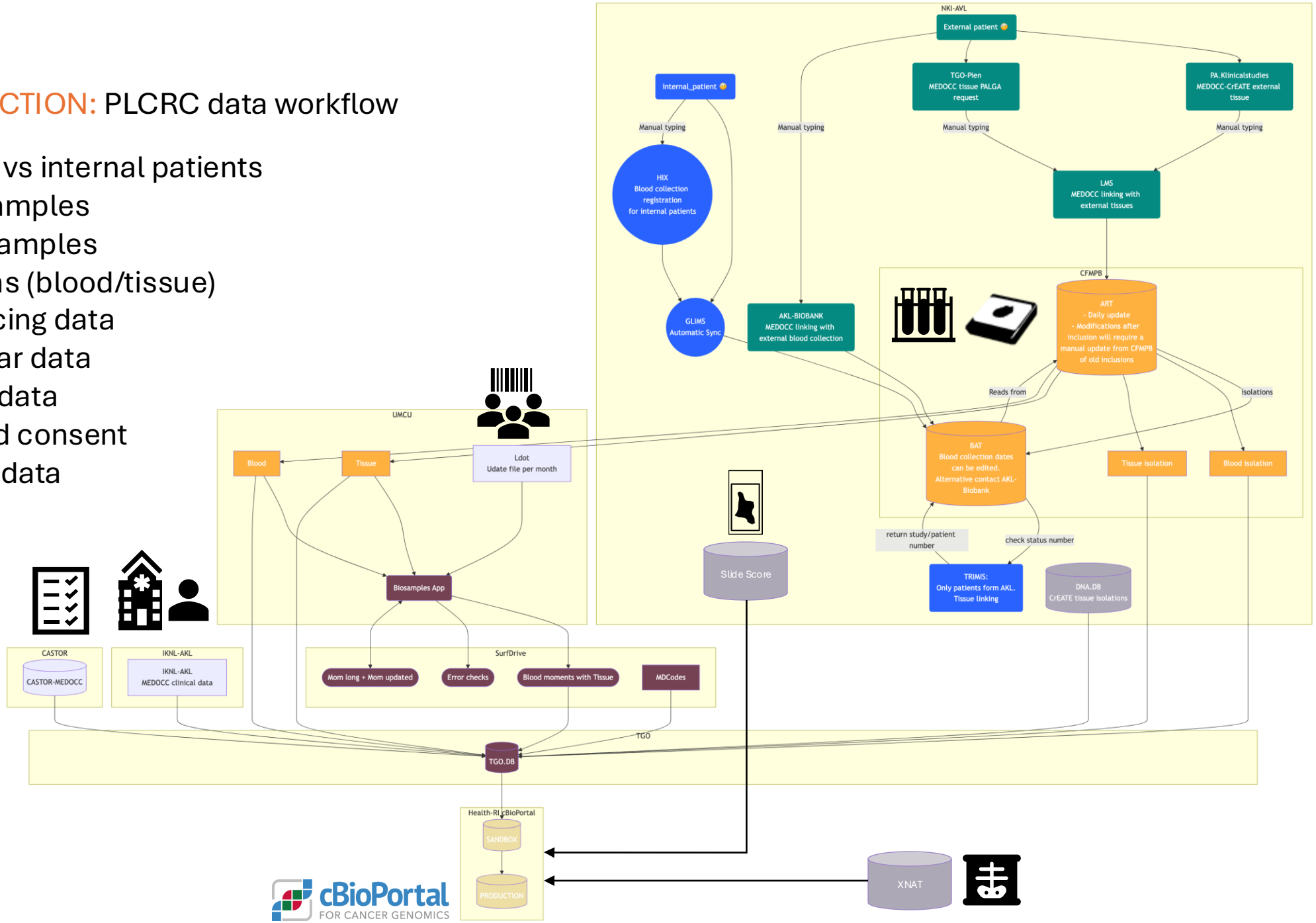
DATA COLLECTION

It’s a challenging maze

DATA COLLECTION: PLCRC data workflow

- External vs internal patients
- Blood samples
- Tissue samples
- Isolations (blood/tissue)
- Sequencing data
- Molecular data
- Clinical data
- Informed consent
- Imaging data



Challenges:

- Care data is **not structured for research** use.
  - Example: different file formats, lack of standardization, Dutch vs English, etc.
- Data is **fragmented** (information is spread in multiple EDC systems and files).
  - Example: data comes from a lot of different places, some data overlaps but does not match, complementary data needs to be integrated, different ids depending on the origin of the data, etc.
- Data is **not monitored i**n the different capture systems and **no validation** rules inside EDC systems (accumulation of **human errors**).

Error type	Description	Examples
ID formats	Medocc ids format is MEDOCC-XXX-XXXX or XXX-XXX	MED12300000123, MEDOCC-123-123, MED-123-123, MED-123-0123
Wrong ids	MEDOCC ids that does not exist on the study	MEDOCC-296-0020 vs MEDOCC-296-0019
IDs missing	All blood collections and tissues included on the study must have a MEDOCC id, sometimes is missing	
Intake moments incorrect	Intake moment should be registered for each blood intake. The variables to use are Na operatie, Voor operatie or Follow-up.	1954, preoperatief, preop, 2-3 weken postoperatief, 3 weken postoperatief, Eerste postoperatieve controle, MED-123-004 (postop afname), MED-123-005 (Controle-arm) postoperatief, post-op (MED-316-001), postoperatief 2-3 weken na operatie, volgt, 31-10-2024, MED-687-002 (t=6 mnd), 6 maanden postop, MED-567-151, vandaag
Incorrect dates	The arrival date of the sample to the hospital should always be the same or later than the collection date	Arrival dates happening before the collection, futuristic dates, dates from XIX century, dates does not match with the collection moment.
Decimal problems	Concentration problems how “.” or “,” are used depending on the machine.	Ng/ul concentration ranking from 1-10000 depending on the decimals used, also happening with 260/280 or 260/230 ratios.

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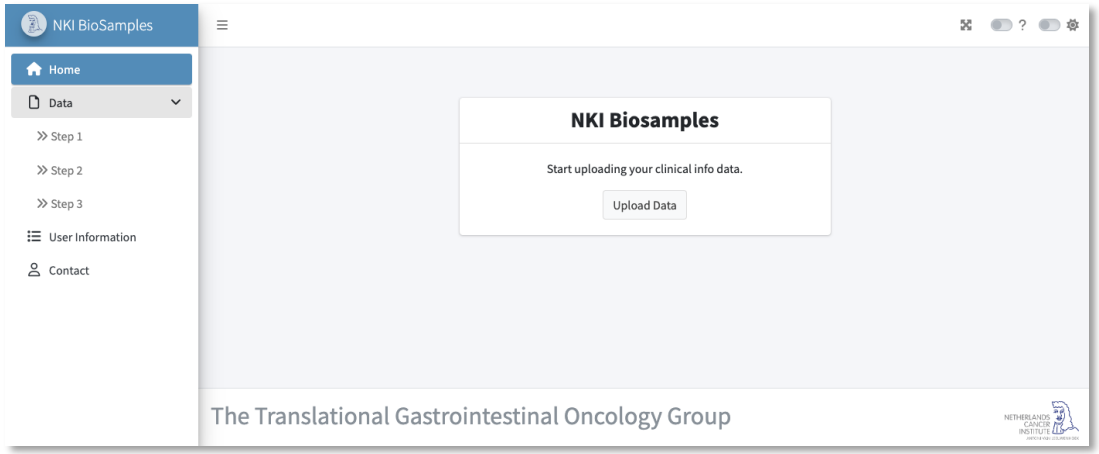
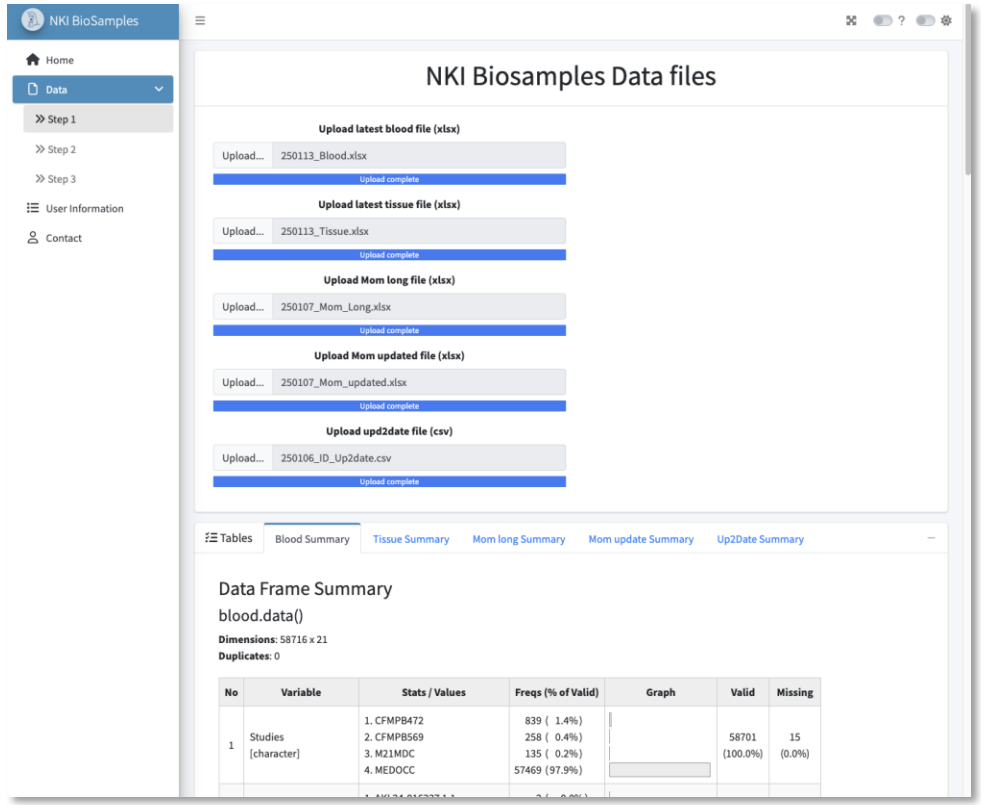
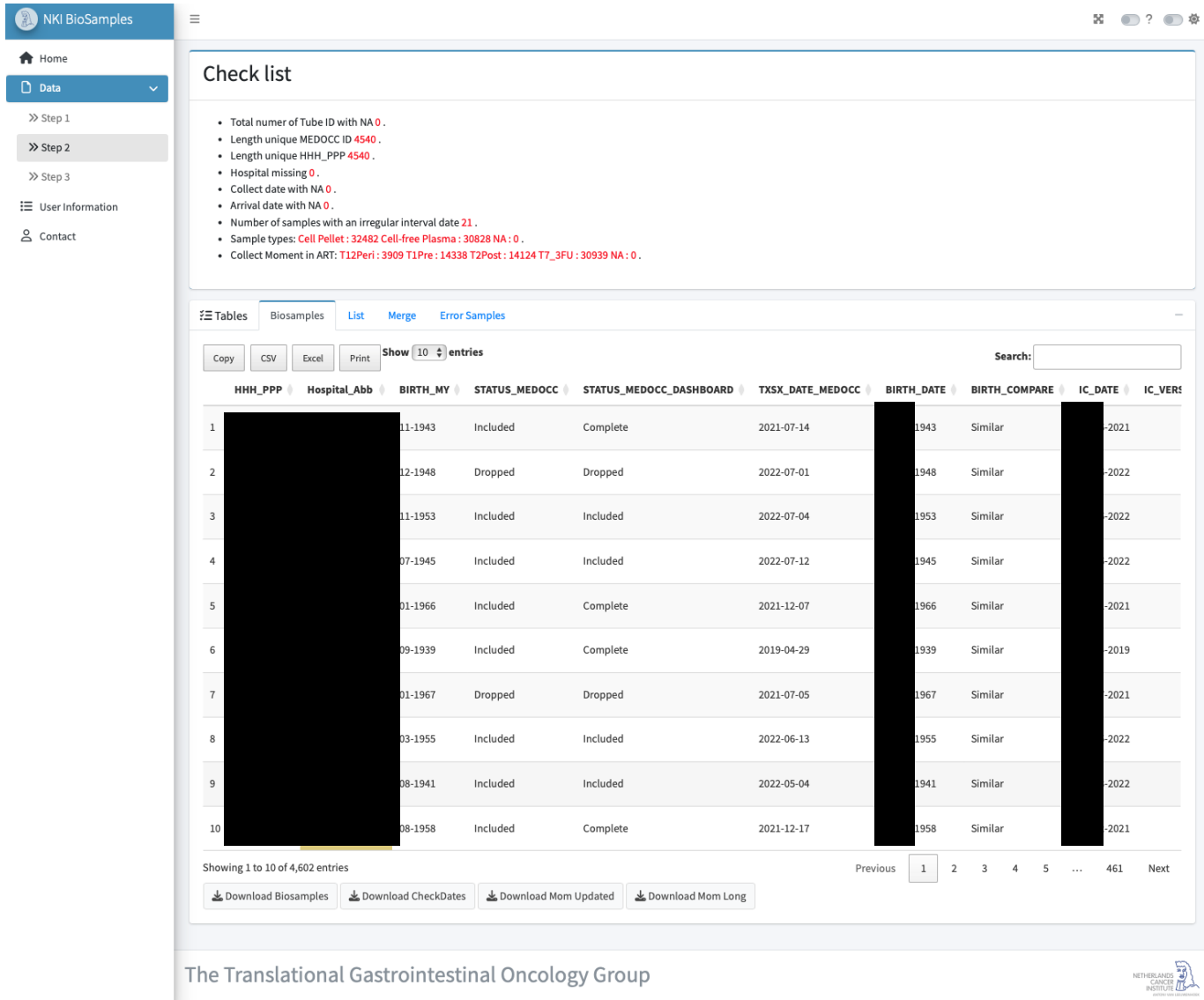
DATA CLEANING AND CURATION: TGO Biosamples App

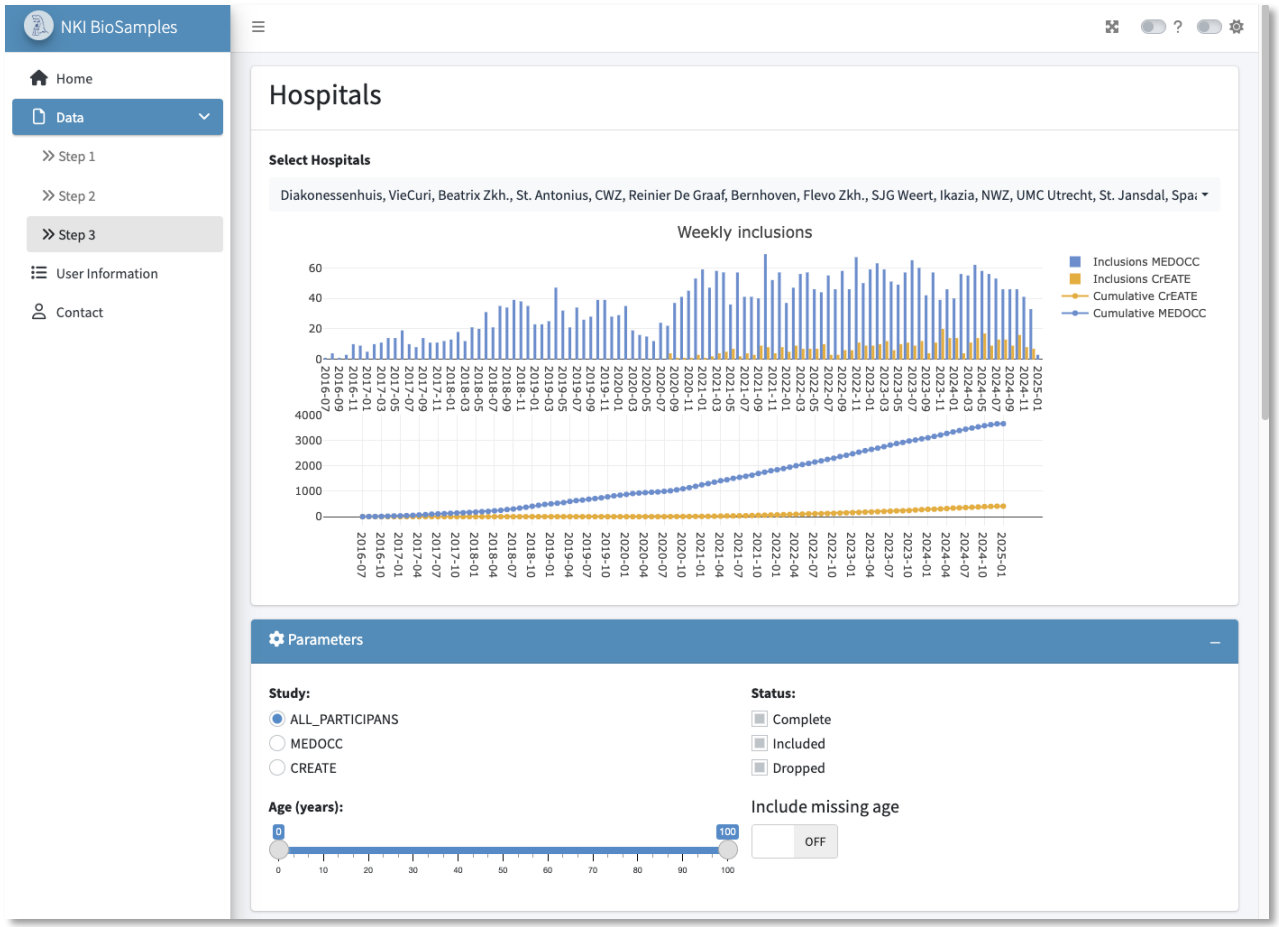
TGO Biosamples App

- Error report application
- Generate document for weekly follow up

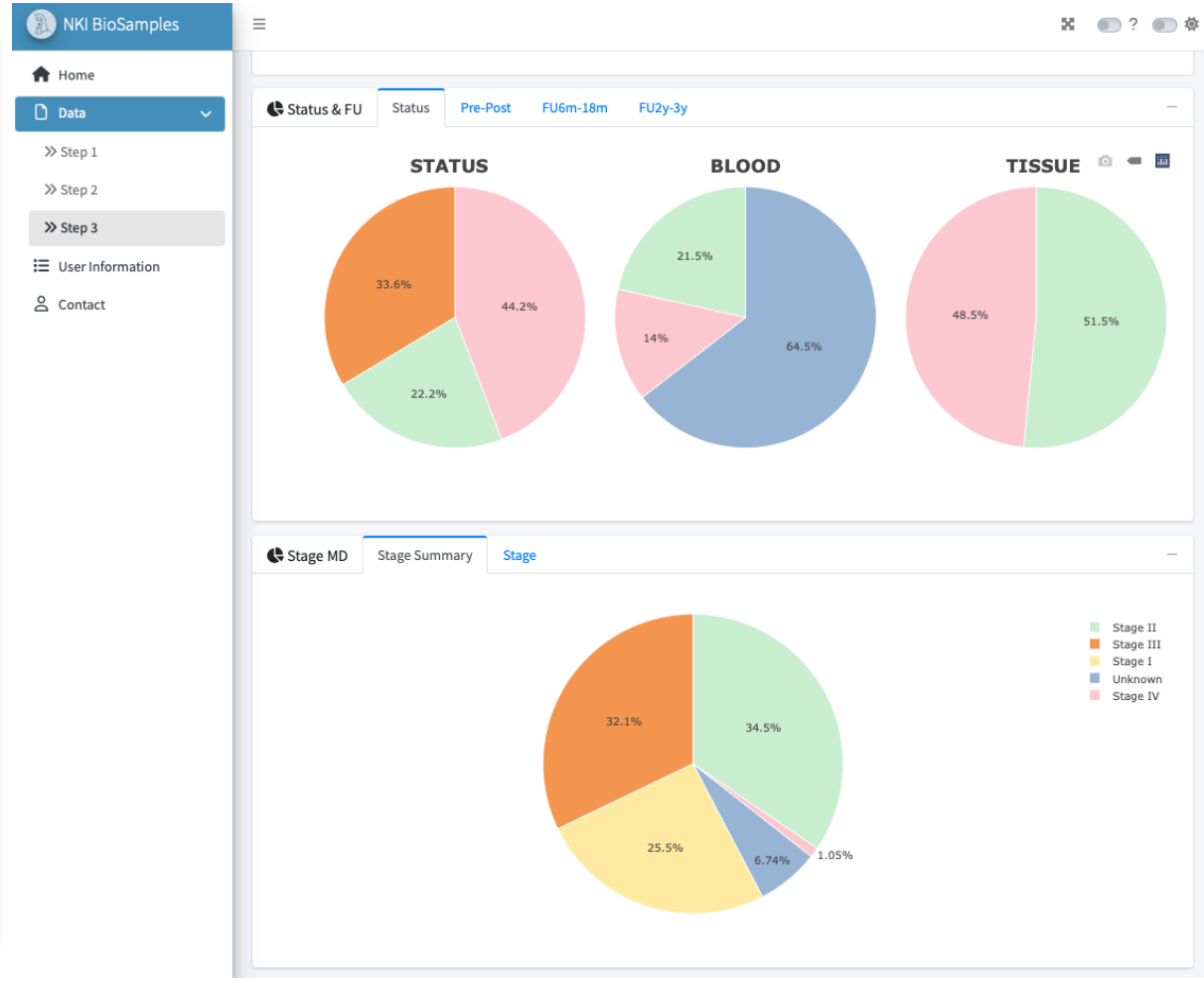








- Follow up inclusion per study
- Parameters to filter at Study, Status, Age and Hospital level



- Distribution of patient status
- Blood collection
- Tissue Collection
- Time points
- Stage Summary

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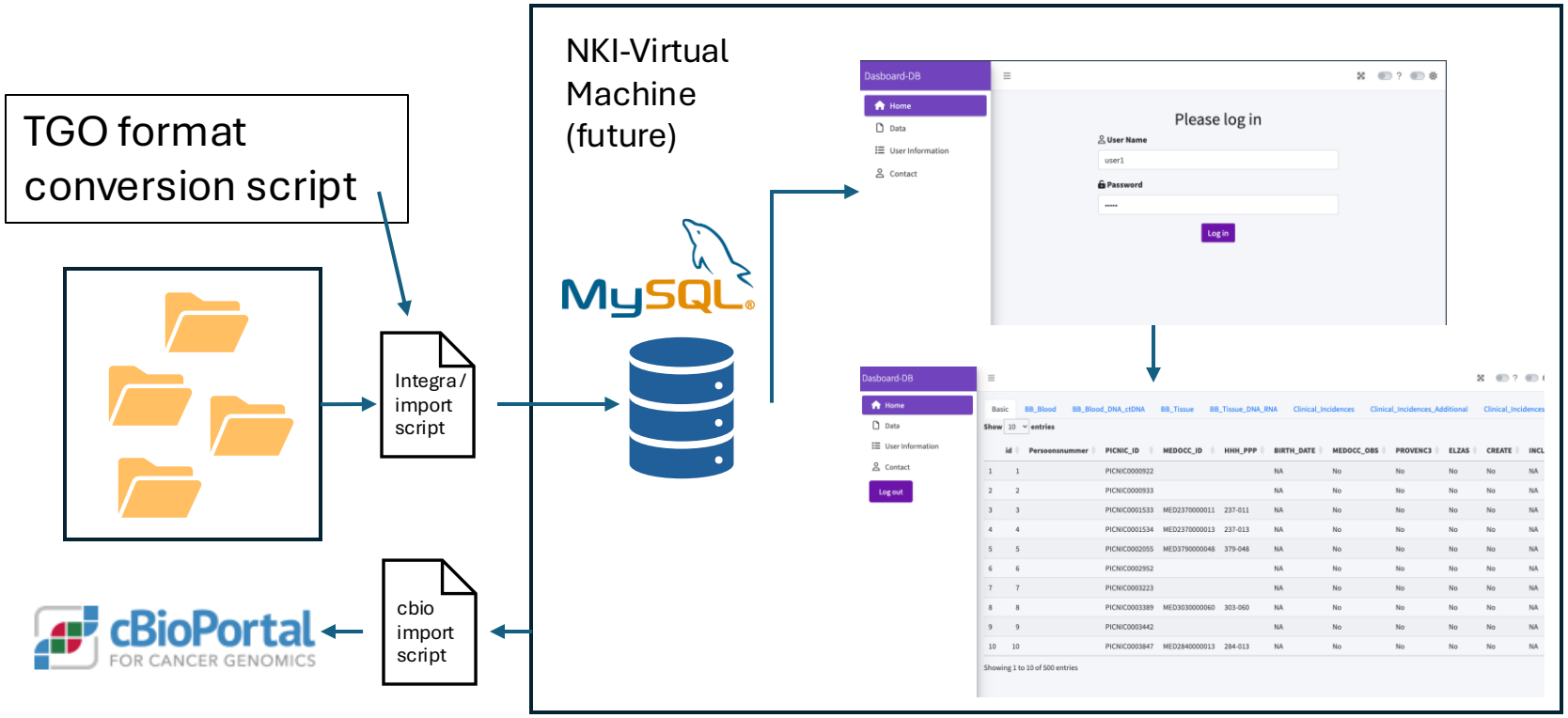
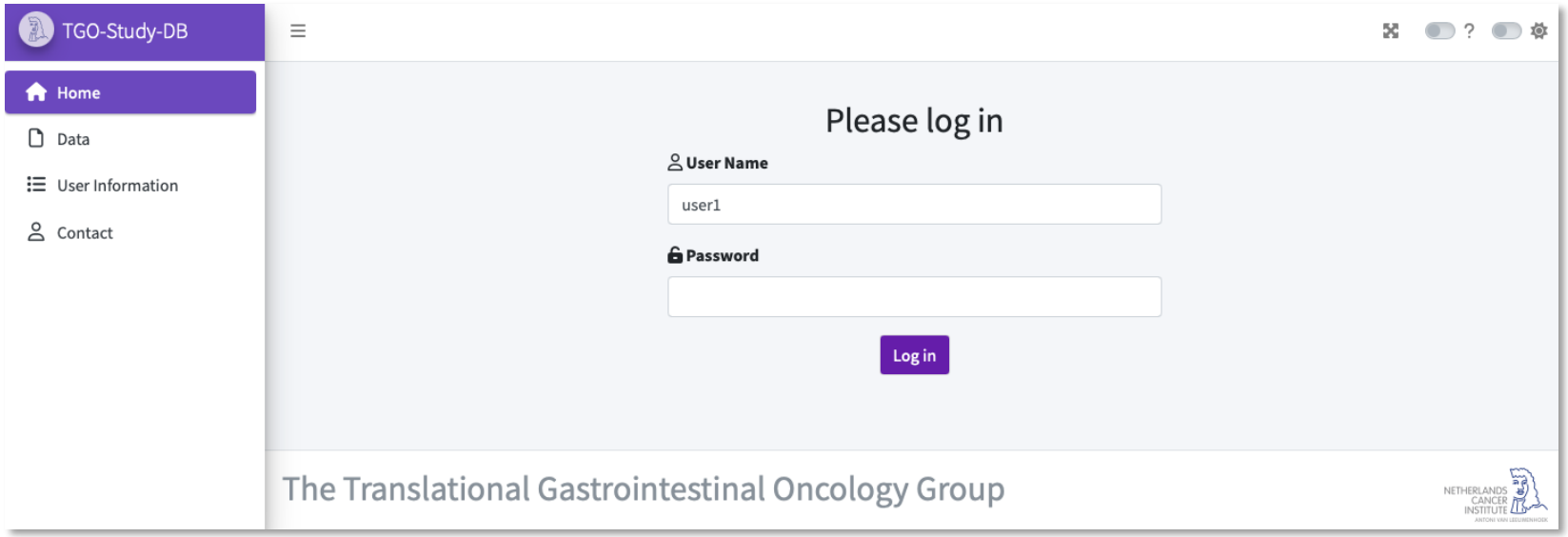
MODELING AND STORAGE:
The TGO database

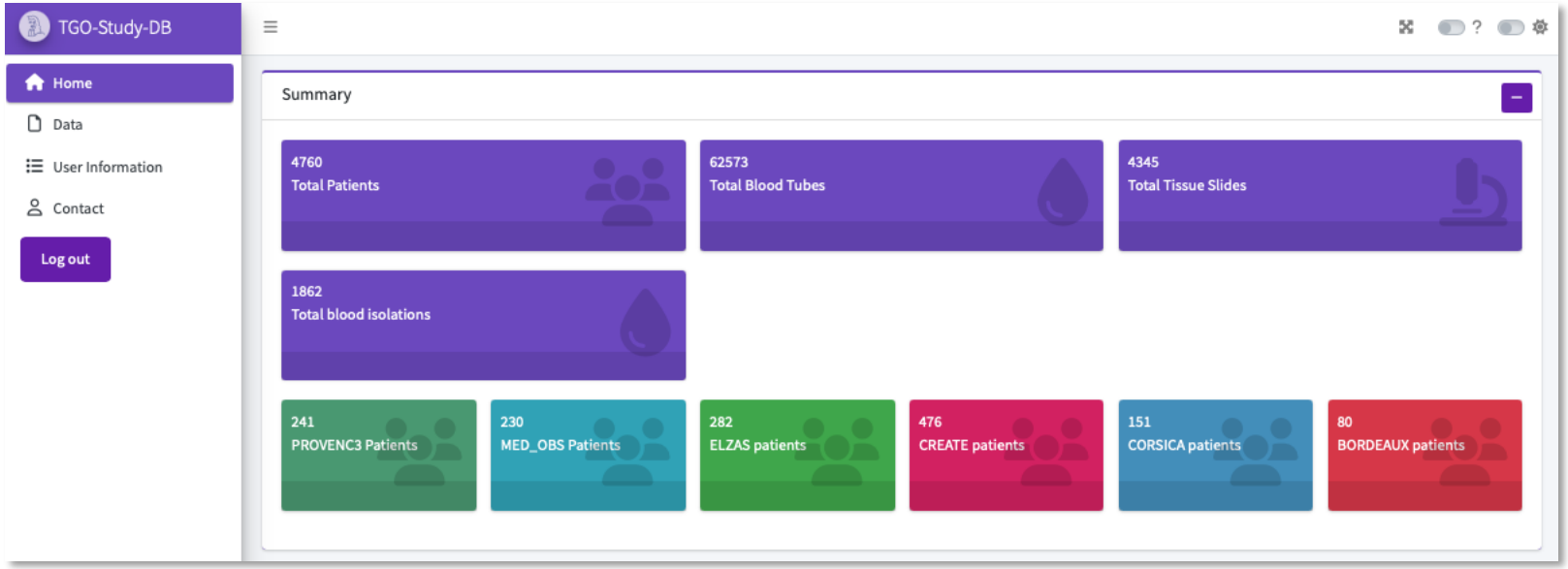
TGO-Study-DB (prototype)

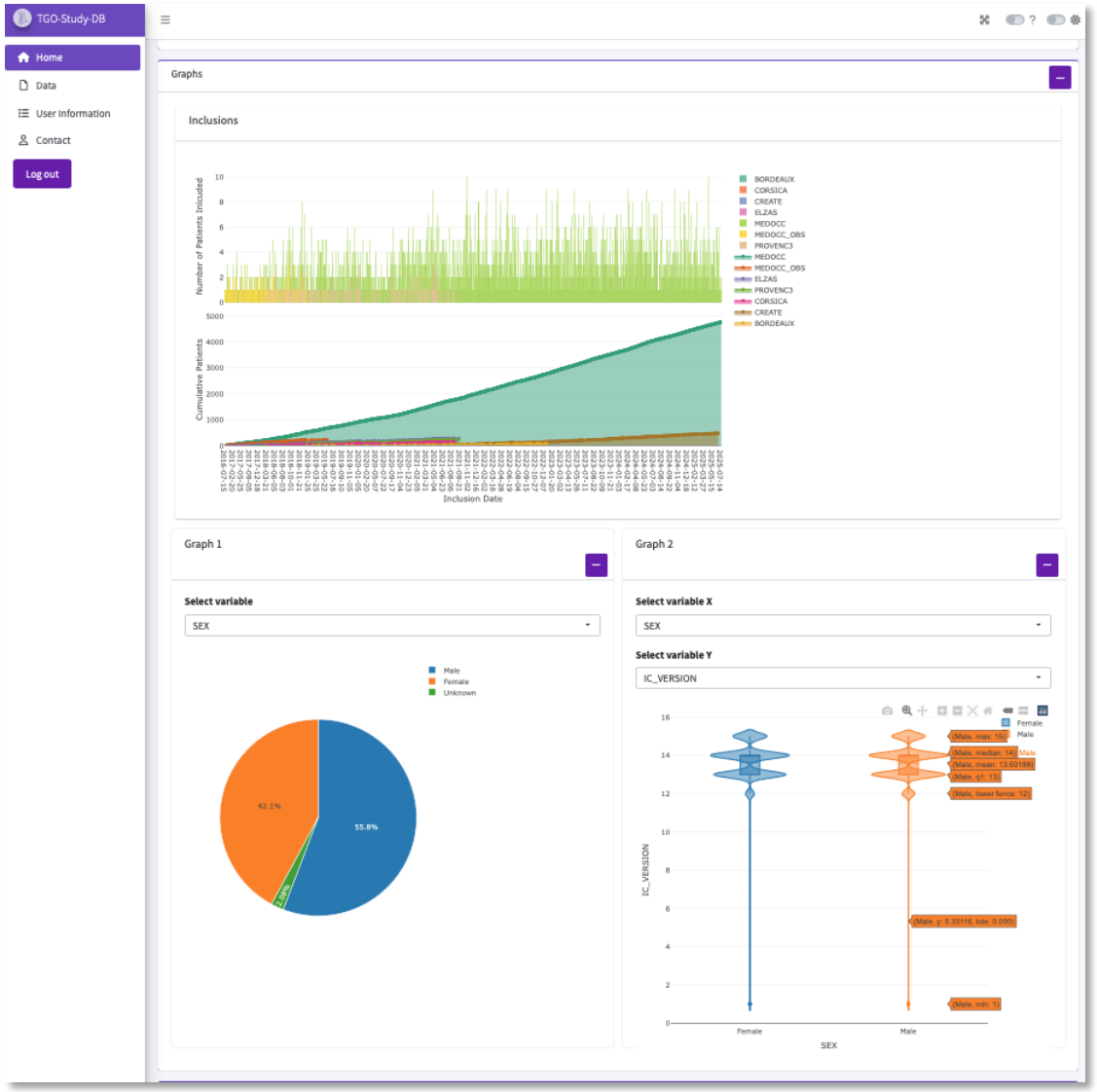




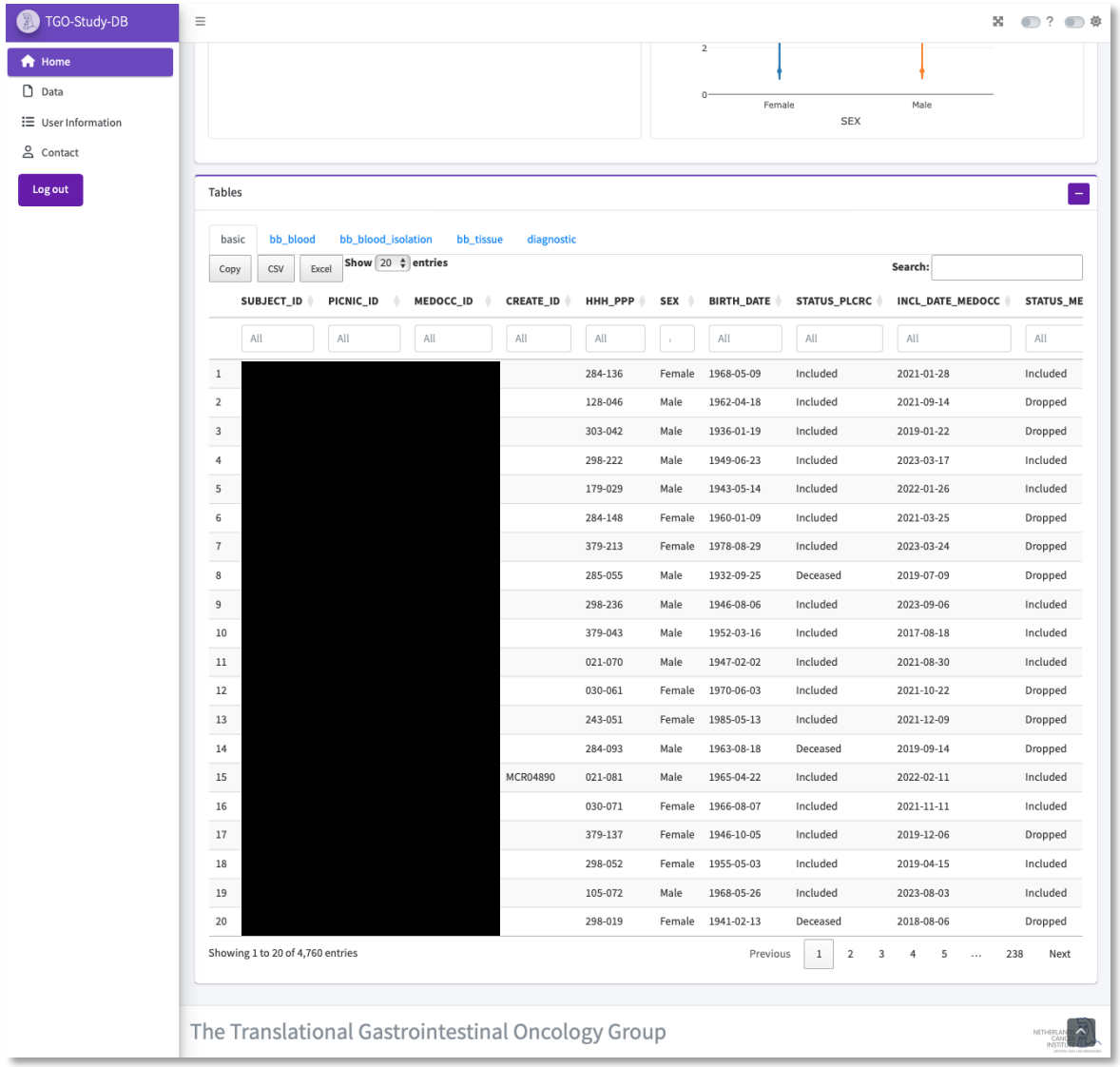
TGO-Study-DB (prototype phase)

- User management to control access
- Connected to a live MySQL database
- Summary page to give general info of the data collected in the DB





- Small dashboard to explore data.
- Inclusion graph to check the inclusion status per sub-study since the beginning of the study.
- Give tools to create graph base on variables collected on the database.



- Easy access and visualization of the data collected in the database (allow to apply filters per variable).
- Export buttons to share the data with researcher under request.

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FORMATTING AND DISTRIBUTION: cBioPortal File Generator (cBPFG)

cBioPortal File Generator (cBPFG)

Data types cBioPortal:

- Meta data
- Clinical patient
- Sample data

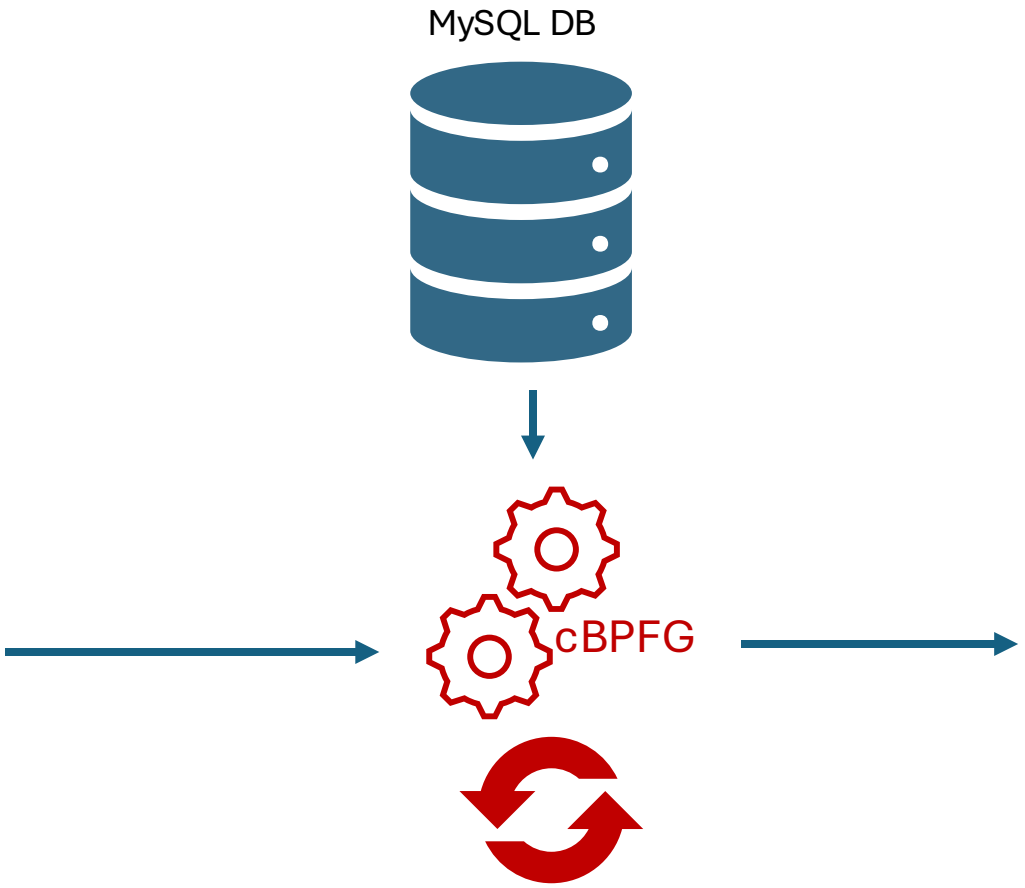
Mandatory

- Timelines
- Sequencing data
  - Mutations
  - Discrete/continuous CNV
  - SV
  - Segmented
  - Expression
  - Methylation
  - Fusion
  - Protein

Optional

- Case list

Mandatory



cBioPortal FOR CANCER GENOMICS

Study 1

Meta Data

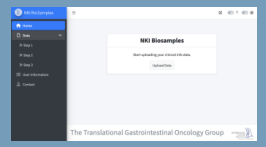
Seq Case

GitHub

PLCRC data workflow status in 2025

Data collection

TGO-BioSamples App



LDOT

NKR

castor

UMCU

Internal - Researcher

External - Researcher

HiX

LMS

TRIMIS

ART

castor

SEQ.

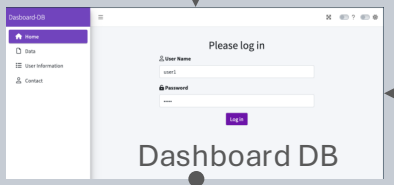
Data Cleaning/Integration/Modeling

TGO Study DB

Central, structured repository that stores and inegrates data from multiple sourcers

Data Distribution

connected to



data request

data access

data access

cBPFG

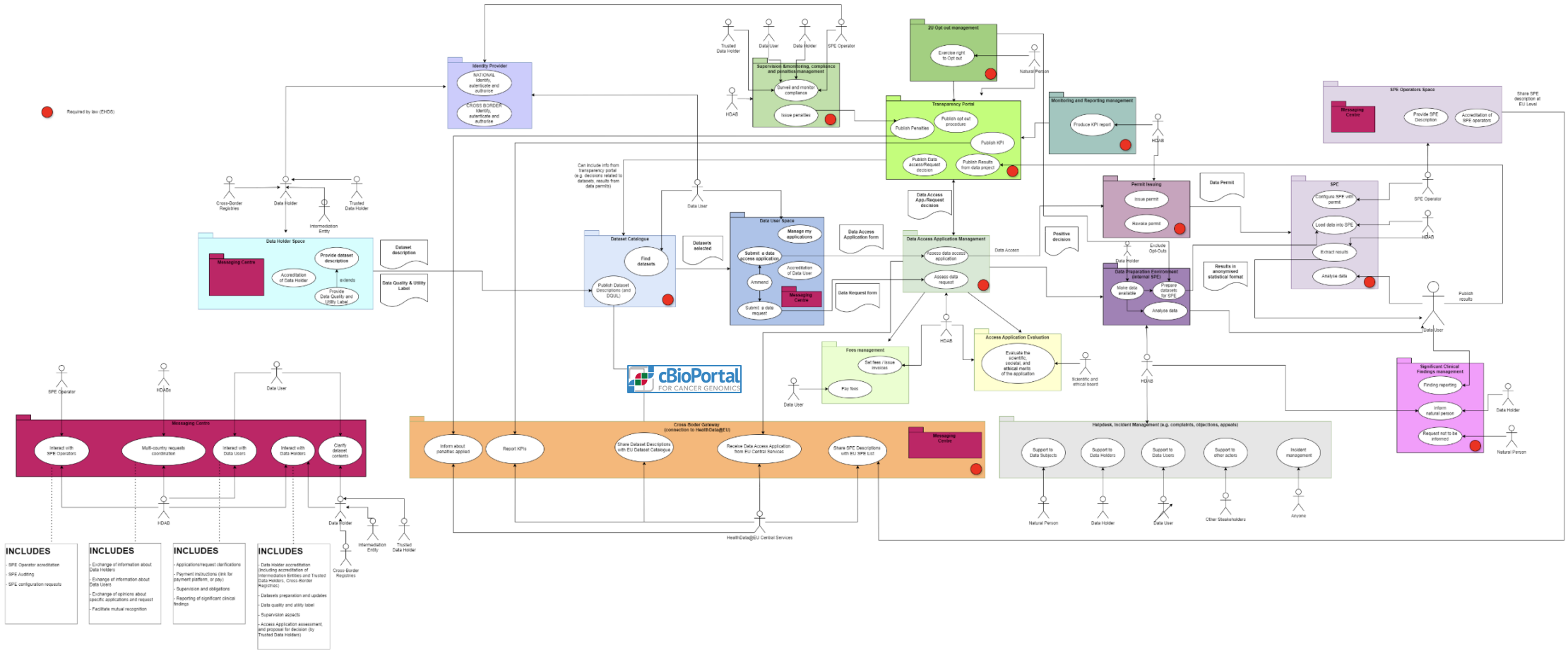
NKI-cBioPortal

HRI-cBioPortal

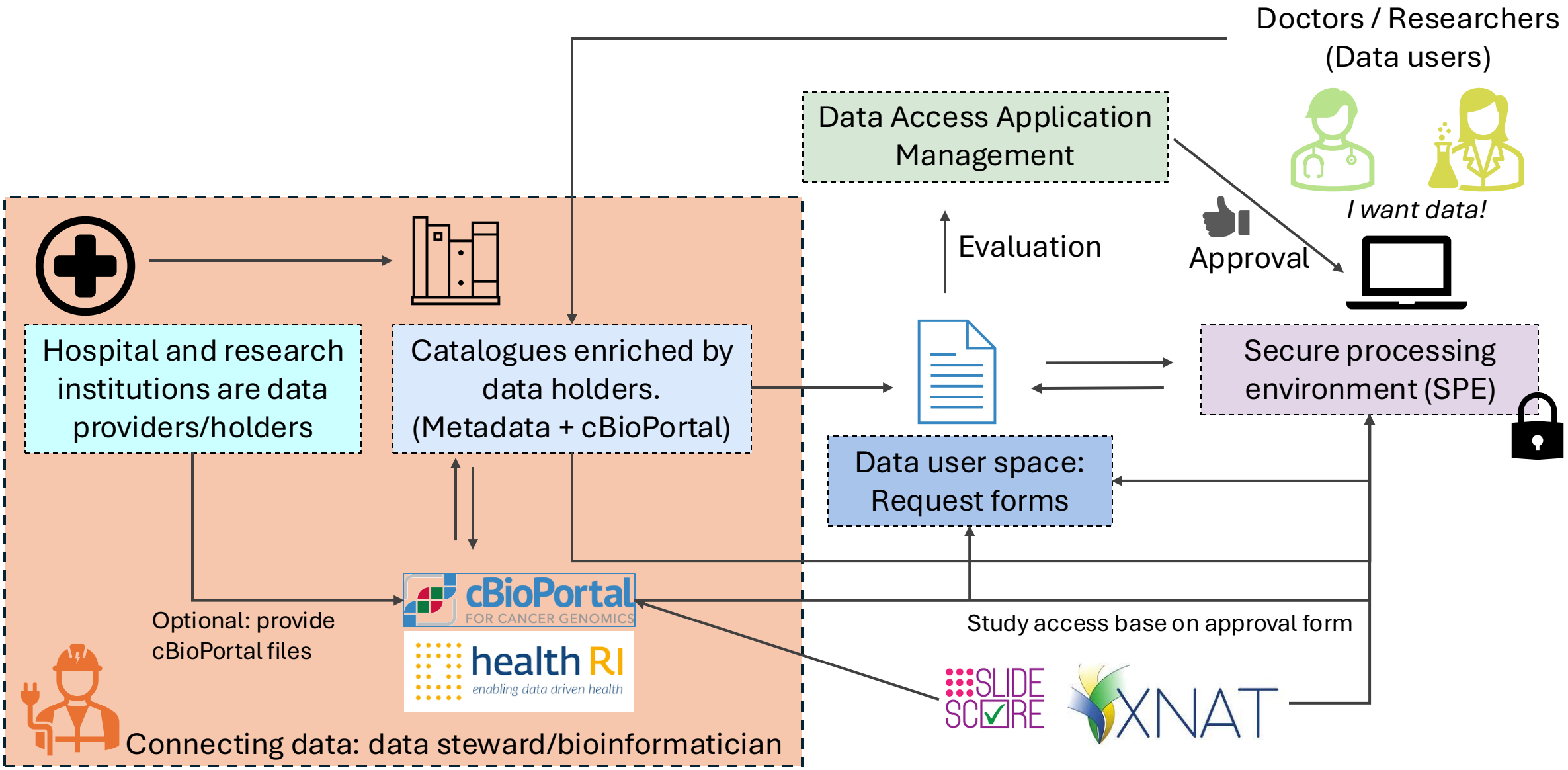
AVL-NKI

HEALTH-RI

How would the EHDS business capabilities blueprint align with the PLCRC data workflow?



Summary: Deployment of cBioPortal in the EHDS DBC blueprint



How would the EHDS business capabilities blueprint fit with the translational research data journey?

Data holder collecting study data.

Responsible to **clean** and **model** the data to provide a **good quality** datasets.

Generate cBioPortal ready files

Catalogue + cBioPortal:
cBioPortal is used as a catalogue.
PLCRC datasets are uploaded at the national Health-RI cBioPortal and researchers can request access to the datasets

Data access application management:
Health-RI are already managing any data request via forms coming from cBioPortal (TopDesk)

Secure processing environment (SPE).
cBioPortal can be accessed via browser with a user account. But easy to connect to any SPE

"PLCRC's translational research substudies demonstrate how national infrastructures (IKNL, PALGA, etc.) and the Health-RI platform can deliver FAIR, high-quality research data at scale. This blueprint is easily transferable to other studies and offers a solid foundation for the expansion of the EHDS"

Is cBioPortal a good tool for EHDS?

Pros	Cons
Central place for clinical, sample and molecular data.	Gene centric, limited functionalities for isoform or SV.
Visualization of additional data from other tools via resource linking (imaging data).	Annotation dependent on external sources, needs to be limited the access in close environments.
Can be used to explore data sets but at the same time work as a catalogue.	Expertise is needed to create the cBioPortal ready files from raw data.
Build in a variety of analysis tools, can be even connect to to external tools like Galaxy.	Automatization can be implemented but each data holder needs to model the data before or work with data steward/Bioinformatician to model the data an make it available
User friendly, no need technical skills to use the tool.	
Open-source tool witch high capacity for customization, expandability end scalability.	
Allows user management access.	

Data Team:
Mariska Bierkens
Lana Meiqari
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Iris Huitink

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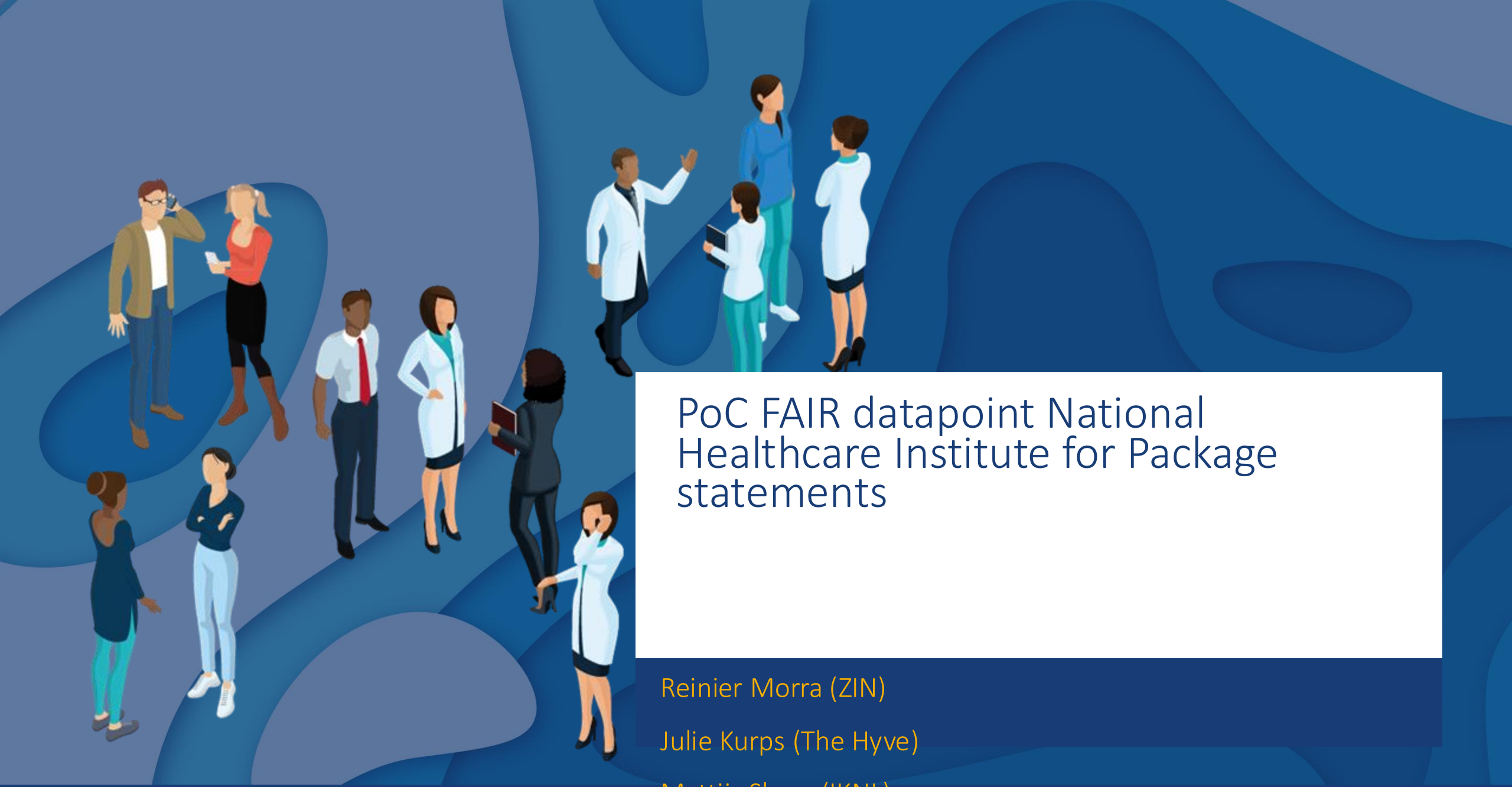
NKI-TGO-group

NETHERLANDS CANCER INSTITUTE
ANTONI VAN LEEUWENHOEK

The Translational Gastrointestinal Oncology Group (TGO)



PoC FAIR datapoint National Healthcare Institute for Package statements

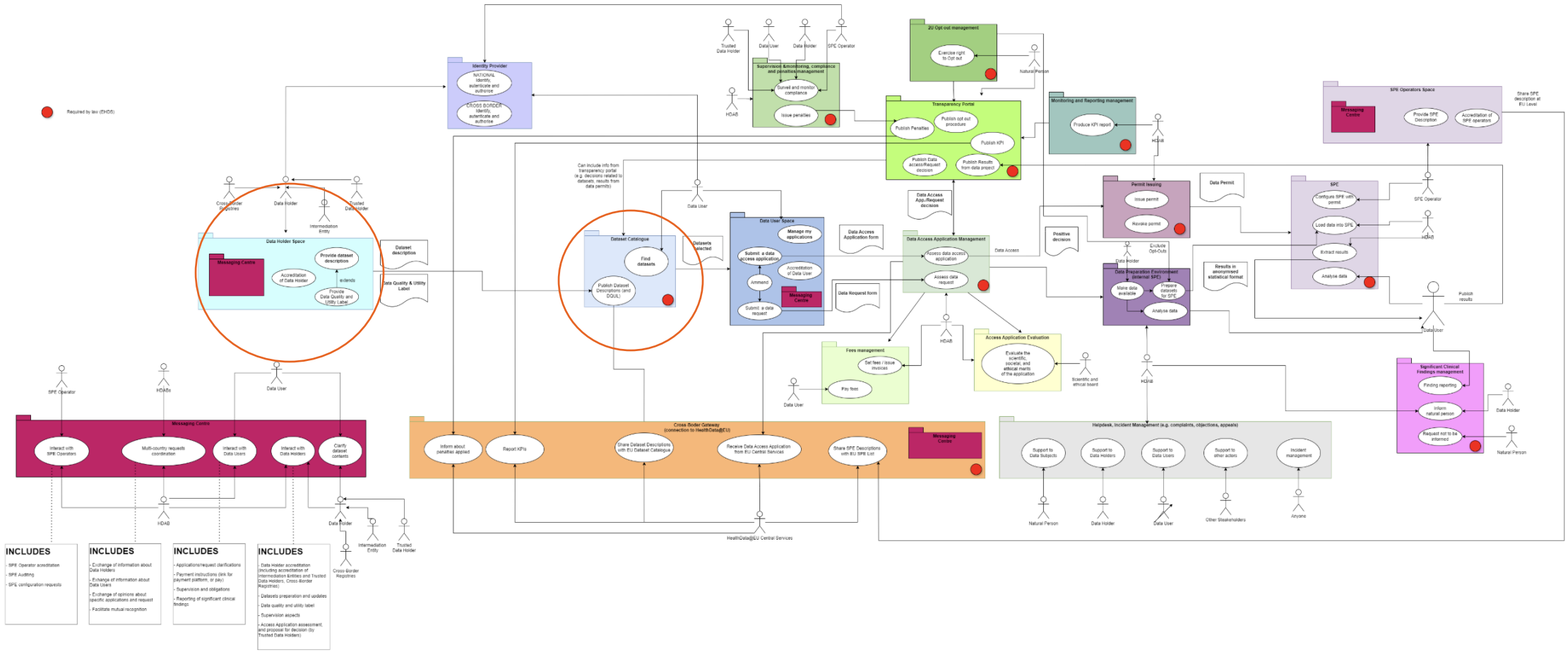
Reinier Morra (ZIN)

Julie Kurps (The Hyve)

Mattijs Sloep (IKNL)

health RI
enabling data driven health & life sciences

Backbone


Required by law (EHDS)
Identity Provider
NATIONAL
Identify, authenticate and authorise
CROSS BORDER
Identify, authenticate and authorise
Supervision &monitoring, compliance and penalties management
Surveil and monitor compliance
Issue penalties
2D Opt out management
Exercise right to Opt out
Transparency Portal
Publish Penalties
Publish opt out procedure
Publish KPI
Publish Data access/Request decision
Publish Results from data project
Monitoring and Reporting management
Produce KPI report
SPE Operators Space
Messaging Centre
Provide SPE Description
Accreditation of SPE operators
Share SPE description at EU Level
Trusted Data Holder
Data User
Data Holder
SPE Operator
HDAB
Natural Person
Cross-Border Registries
Intermediation Entity
Data Holder Space
Messaging Centre
Provide dataset description
Accreditation of Data Holder
extends
Provide Data Quality and Utility Label
Dataset description
Data Quality & Utility Label
Can include info from transparency portal (e.g. decisions related to datasets, results from data permits)
Dataset Catalogue
Find datasets
Publish Dataset Descriptions (and DQ/UL)
Datasets selected
Data User Space
Manage my applications
Submit a data access application
Accreditation of Data User
Ammend
Submit a data request
Messaging Centre
Data Access Application form
Data Request form
Data Access App./Request decision
Data Access Application Management
Assess data access application
Assess data request
Data Access
Positive decision
Permit issuing
Issue permit
Revoke permit
Data Permit
Exclude Opt-Outs
Data Preparation Environment (internal SPE)
Make data available
Prepare datasets for SPE
Analyse data
Results in anonymised statistical format
SPE
Configure SPE with permit
Load data into SPE
Extract results
Analyse data
Publish results
Fees management
Set fees / issue invoices
Pay fees
Access Application Evaluation
Evaluate the scientific, societal, and ethical merits of the application
Scientific and ethical board
Significant Clinical Findings management
Finding reporting
Inform natural person
Request not to be informed
Messaging Centre
Interact with SPE Operators
Multi-country requests coordination
Interact with Data Users
Interact with Data Holders
Clarify dataset contents
Cross Border Gateway (connection to HealthData@EU)
Inform about penalties applied
Report KPIs
Share Dataset Descriptions with EU Dataset Catalogue
Receive Data Access Application from EU Central Services
Share SPE Descriptions with EU SPE List
HealthData@EU Central Services
Helpdesk, Incident Management (e.g. complaints, objections, appeals)
Support to Data Subjects
Support to Data Holders
Support to Data Users
Support to other actors
Incident management
Other Stakeholders
Anyone
INCLUDES
- SPE Operator accreditation
- SPE Auditing
- SPE configuration requests
INCLUDES
- Exchange of information about Data Holders
- Exhange of information about Data Users
- Exchange of opinions about specific applications and request
- Facilitate mutual recognition
INCLUDES
- Applications/request clarifications
- Payment instructions (link for payment platform, or pay)
- Supervision and obligations
- Reporting of significant clinical findings
INCLUDES
- Data Holder accreditation (including accreditation of intermediation Entities and Trusted Data Holders, Cross-Border Registries)
- Datasets preparation and updates
- Data quality and utility label
- Supervision aspects
- Access Application assessment, and proposal for decision (by Trusted Data Holders)

Research project FAIR package registry

- Introductie onderzoek: Doelstelling, problem, aanpak, PoC
- Resultaten
    - Modellering
    - Infrastructuur PoC FAIR Pakketregister
    - Behoefte onderzoek op basis interviews
    - Use cases:
      - Signalering/Nieuw bewijs
      - Evalueren & Monitoren met IKNL
      - BIA Evaluatie
- Inpassing binnen het Zorginstituut en IKNL
    - Mogelijke rol/relatie met cyclisch pakketbeheer
    - Kansen en risico's
    - FDP voor data en documenten van het Zorginstituut
- Conclusies, discussie & vervolg

DISCLAIMER

Het is een onderzoeksproject.
Intern nog geen besluit genomen om het FAIR Pakketregister in productie te nemen.

Vandaag bedoeld om methodiek en lessen te delen en te horen hoe jullie toepasbaarheid zien.

Doelstelling

Context: rol van het Zorginstituut in cyclisch pakketbeheer

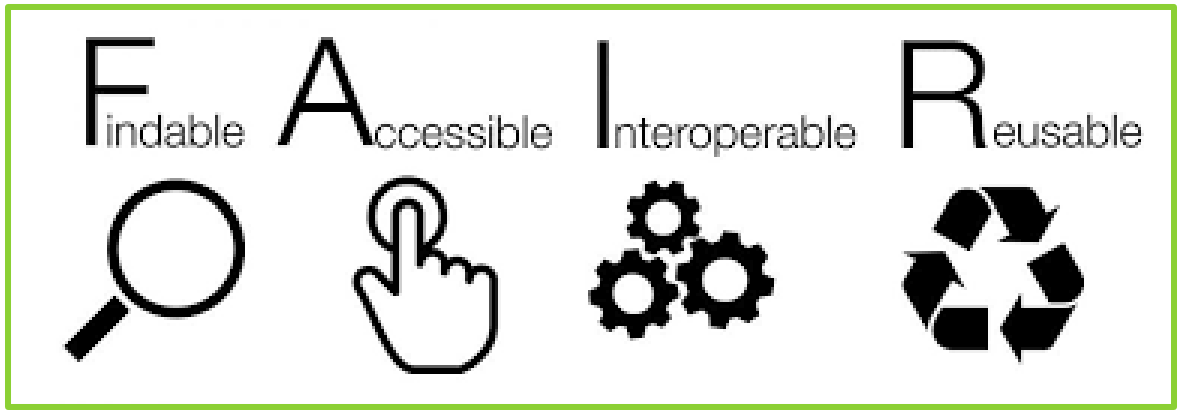
datagedreven systeem om pakketuitspraken te monitoren en te evalueren (real world data)

Pakketuitspraken stroomlijnen

om informatie beter beschikbaar maken

Focus vandaag

FAIR: machine-readable, machine-actionable



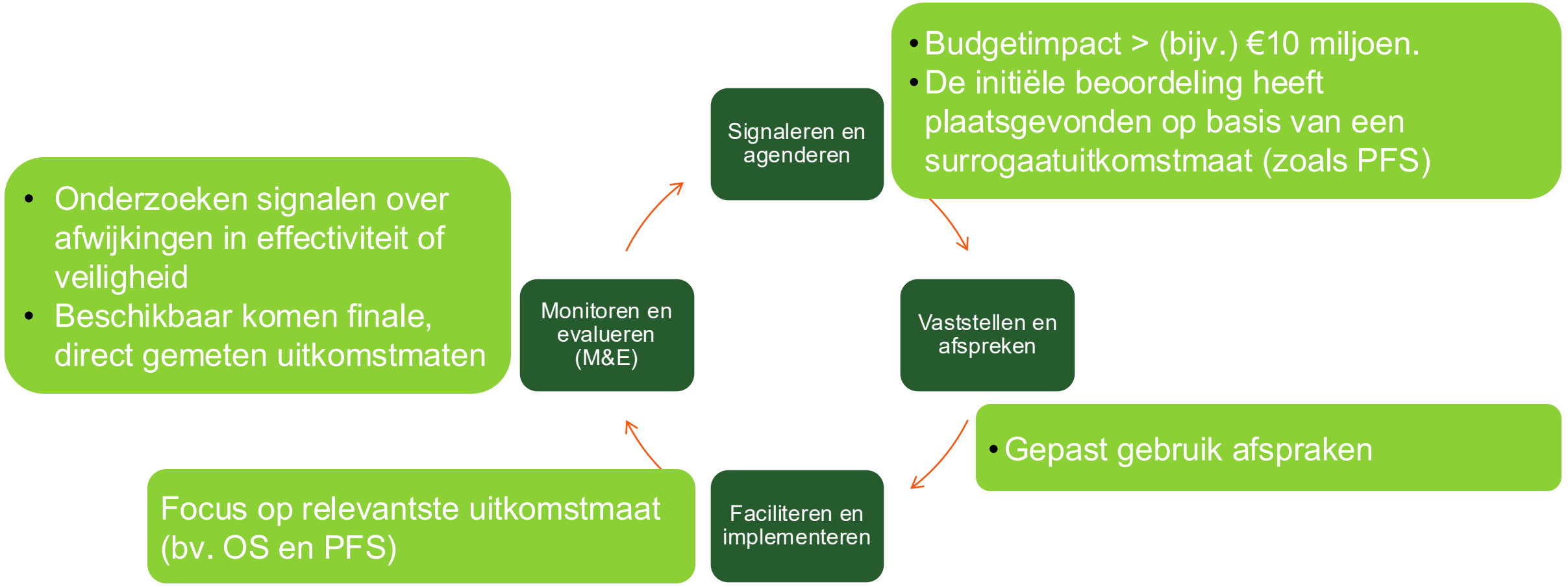
PoC: Borstkanker use cases:

- Signalering
- Real World Data (IKNL) voor een lerend zorgsysteem
- Budget-Impact-Analysis (BIA)

Focus vandaag

CONCEPT

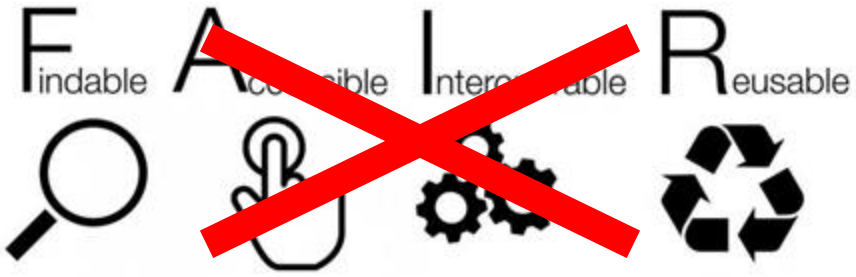
Aanzet cyclisch pakketbeheer met FAIR pakketregister: Wens voor meer monitoren en evalueren passende zorg



Het probleem

Pakketbesluiten niet FAIR

- Gepubliceerd op de website van het Zorginstituut, niet goed doorzoekbaar
- Als PDF documenten:
  - Ongestructureerde data: kan moeilijk hergebruikt of geanalyseerd worden
- Niet FAIR!



Praktijkdata beperkt beschikbaar voor M&E

- RCT niet altijd representatief voor de praktijk
- Momenteel geen / beperkte data toets of een uitspraak te monitoren en evalueren is op basis praktijk data
- Behoefte aan zowel overall survival (OS) en kwaliteit van leven (QoL) data
- Voorbeeld: PARP remmers

Modelling

The Hyve

FAIRification process

Package
Statements

Consulting experts

Identify relevant (meta)data

Datum 10 juli 2024

Betreft Pakketadvies herbeoordeling sacituzumab govitecan (Trodelvy®)

Onze referentie
2024026955

Geachte mevrouw Agema,

Zorginstituut Nederland adviseert u hierbij over de uitkomst van zijn herbeoordeling van het farmaco-economisch dossier van sacituzumab govitecan (Trodelvy®) voor de behandeling van volwassen patiënten met inoperabele of gemetastaseerde triple-negatieve borstkanker (mTNBC)[1] die twee of meer eerdere systemische therapieën hebben gekregen, waaronder één lijn taxaan-bevattende therapie en ten minste één voor gevorderde ziekte. Dit advies volgt op het eerdere, positieve vergoedingsadvies d.d. 15 juli 2022.Het Zorginstituut liet u daarin weten dat sacituzumab govitecan bij de eerdergenoemde indicatie voldeed aan de stand van de wetenschap en praktijk, en in het verzekerde pakket kon worden opgenomen indien bij prijsonderhandelingen een korting van tenminste 75% werd overeengekomen.

Concept Statements

Pakketuitspraak (PU)

- Een PU (focus van dit werk) verstaan we
  - Vanuit het Zorginstituut:
    - Standpunten (open pakket);
    - Pakketadviezen voor voornamelijk geneesmiddelen (gesloten pakket, sluis).
    - Een Zvw geschil kan een aanleiding zijn voor een advies (buiten scope)
    - Duidingen (veelal in de eerstelijns zorg) onder welk wetsdomein zorg valt zijn buiten scope.
  - Vanuit Zorgverzekeraars Nederland (buiten scope, behalve BIA-gedeelte)
    - ZN maakt o.a. gebruik van de commissie BOM als er geen PU is vanuit ZIN. Zie hier voor borstkanker de actuele adviezen.
- Behandelt een vraag voor vergoeding (='vergoedingsvraag', kan ook door ZIN geagendeerd worden) van een behandeling vanuit het basispakket
  - Geneesmiddel vergoedingssysteem (GVS) geneesmiddel, of
  - Medisch specialistisch geneesmiddel (voor Medisch Specialistische Zorg, MSZ)
  - Ook voor medisch-specialistische behandelingen (AFT pakketuitspraak) = duiding
- De vergoedingsvraag kan beantwoord worden met een standpunt en eventueel gevolgd met een pakketadvies.
  - De beantwoording van vergoedingsvraag begint met een duiding.
  - Een duiding is een toets op SWP (stand van Wetenschap en Praktijk), en eventueel andere pakketcriteria
  - SWP: Zorg voldoet aan SWP als het in voldoende mate bewezen effectief is in vergelijking met de standaardbehandeling of gebruikelijke behandeling (relatieve effectiviteit)
  - Een duiding leidt altijd tot een standpunt.
  - Aanvullend op een standpunt kan ook een pakketadvies gegeven worden.
  - Bij een pakketadvies worden (volgend op de SWP-toets -> SWP is een knock-out criterium) ook de andere pakketcriteria gewogen.
  - De 4 pakketcriteria zijn:
    - 1 noodzakelijkheid (moet je je ertegen verzekeren, en hoe hoog is de ziektelast?),
    - 2 effectiviteit (is SWP, om deze te toetsen wordt het

MR **Morra, R.**

Overzicht sluismiddelen waarover het Zorginstituut heeft geadviseerd | Zorginstituut Nederland

GM **Gothlin, M.P.**

Een duiding (beoordeling) is een proces, met een standpunt of advies als resultaat.

GM **Gothlin, M.P.**

Meestal, ook andere pakketcriteria kunnen getoetst worden.

E **eelke**

of?

MR **Morra, R.**

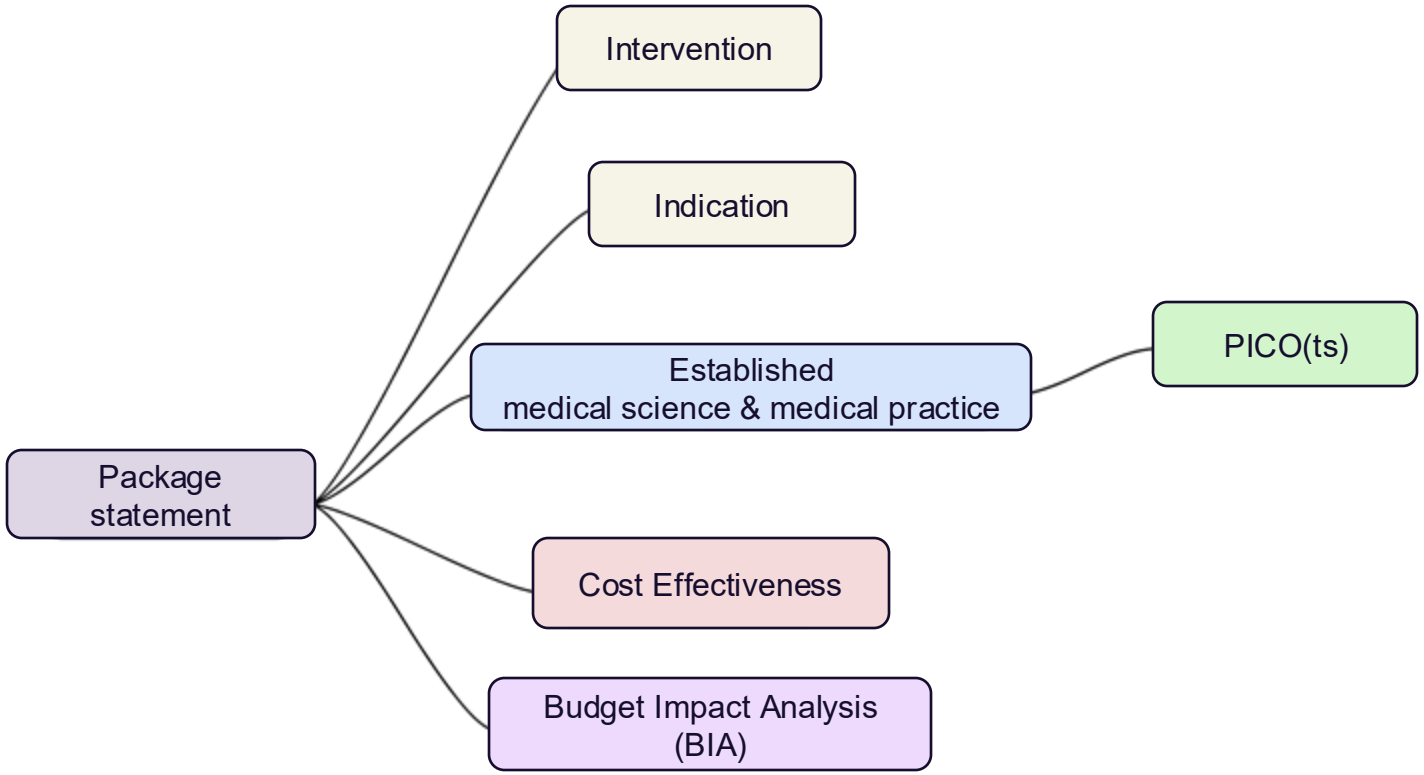
Een advies over een sluisgeneesmiddel van het Zorginstituut gaat altijd samen met een advies over een mogelijke prijsonderhandeling en afspraken over

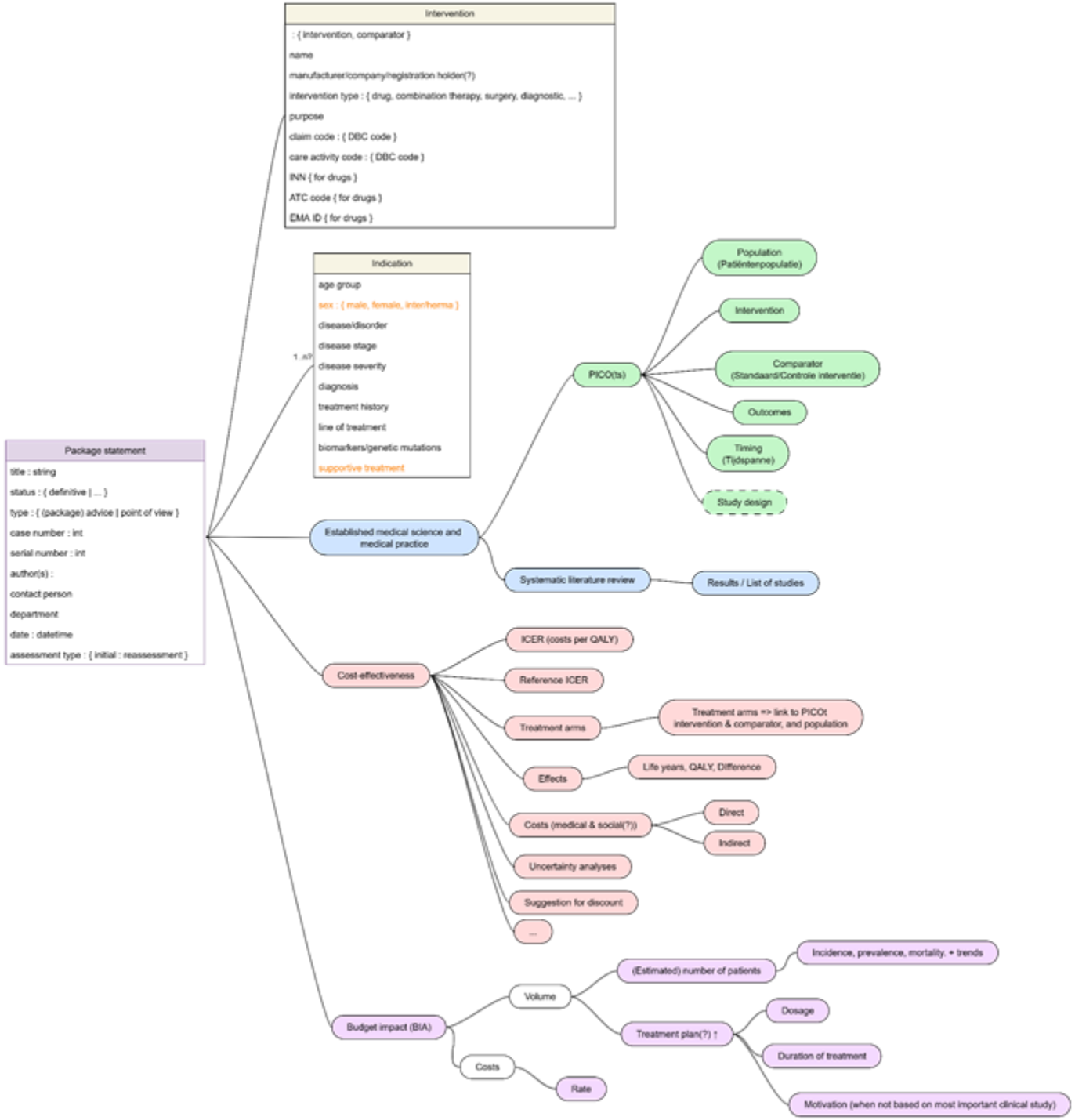
See more

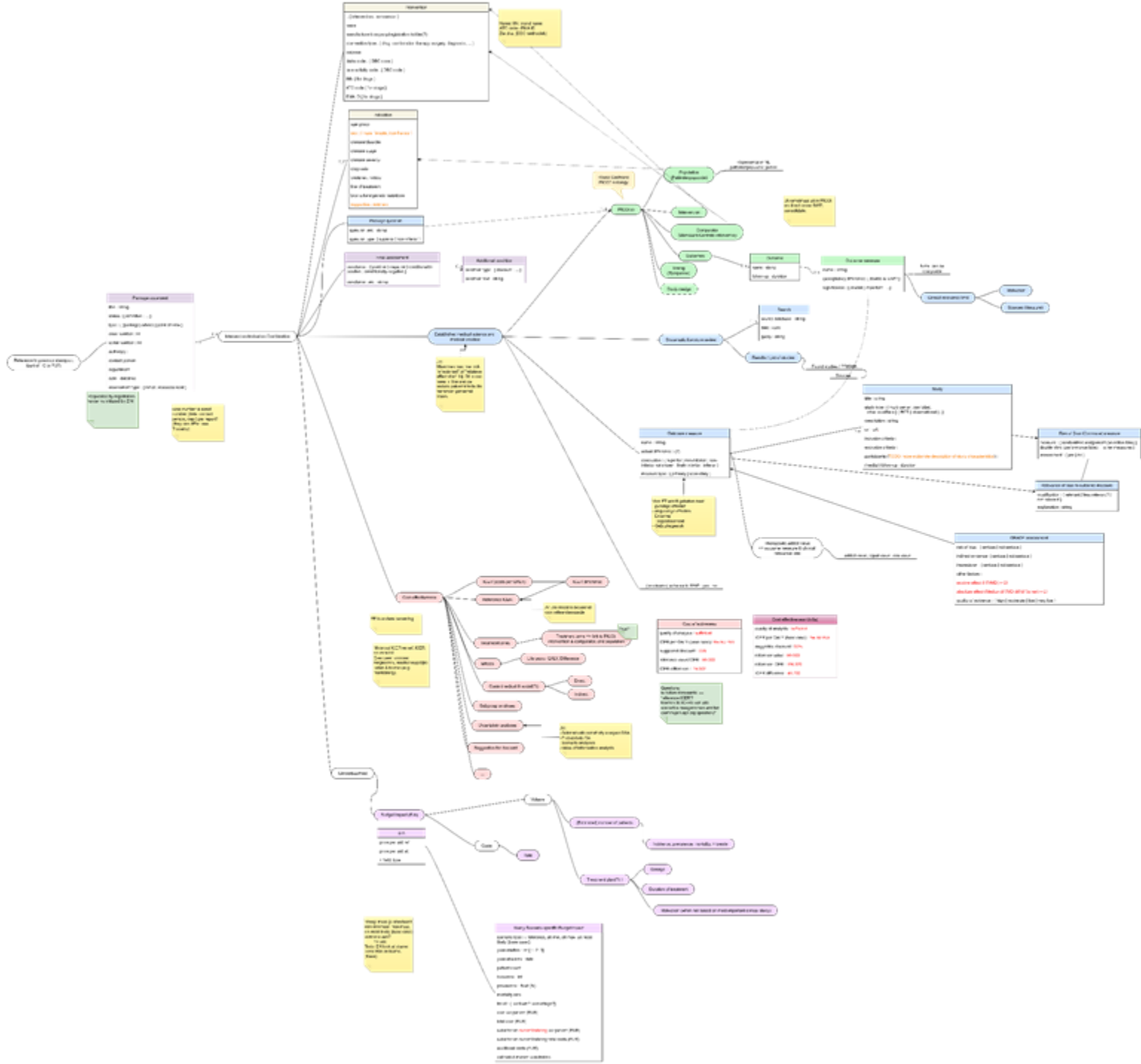
GM **Gothlin, M.P.**

Is het zorg zoals de beroepsuitoefenaars plegen te bieden?

✓ Resolved


Intervention
Indication
Established
medical science & medical practice
PICO(ts)
Package
statement
Cost Effectiveness
Budget Impact Analysis
(BIA)

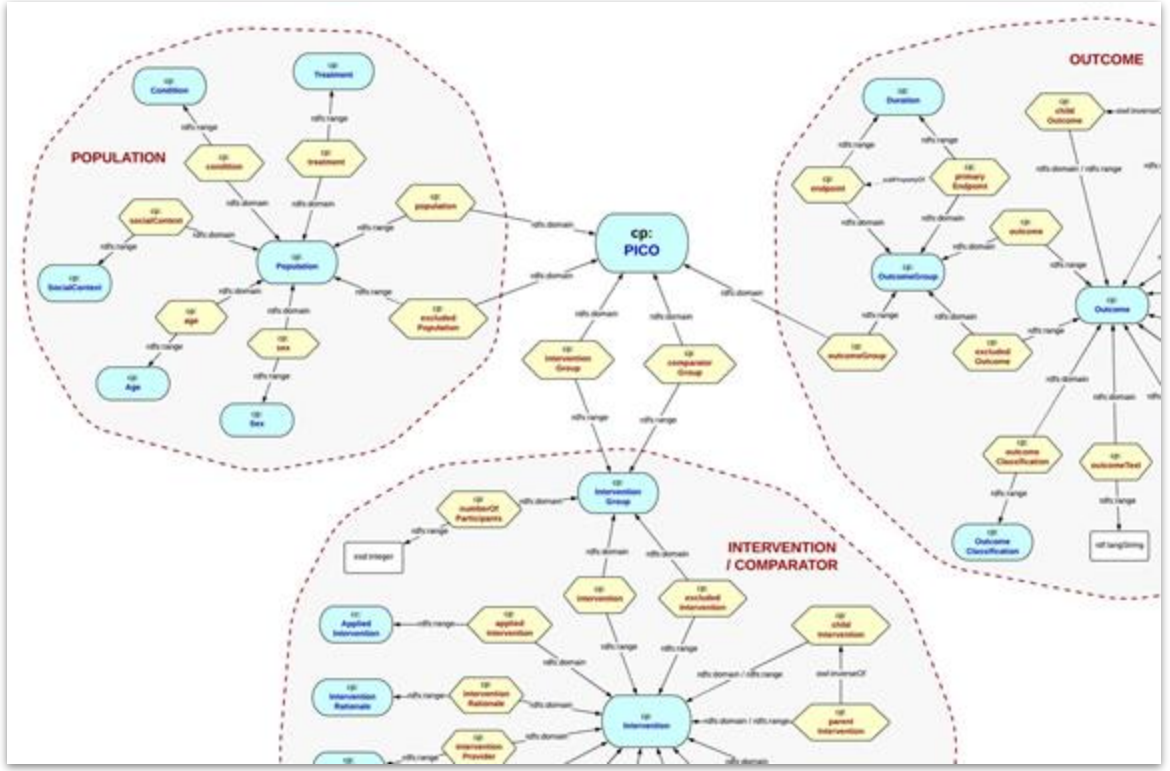

Intervention
: { intervention, comparator }
name
manufacturer/company/registration holder(?)
intervention type : { drug, combination therapy, surgery, diagnostic, ... }
purpose
claim code : { DBC code }
care activity code : { DBC code }
INN { for drugs }
ATC code { for drugs }
EMA ID { for drugs }
Indication
age group
sex : { male, female, inter/herma }
disease/disorder
disease stage
disease severity
diagnosis
treatment history
line of treatment
biomarkers/genetic mutations
supportive treatment
1..n?
Package statement
title : string
status : { definitive | ... }
type : { (package) advice | point of view }
case number : int
serial number : int
author(s) :
contact person
department
date : datetime
assessment type : { initial : reassessment }
Established medical science and medical practice
PICO(ts)
Population (Patiëntenpopulatie)
Intervention
Comparator (Standaard/Controle interventie)
Outcomes
Timing (Tijdspanne)
Study design
Systematic literature review
Results / List of studies
Cost-effectiveness
ICER (costs per QALY)
Reference ICER
Treatment arms
Treatment arms => link to PICOt intervention & comparator, and population
Effects
Life years, QALY, Difference
Costs (medical & social(?))
Direct
Indirect
Uncertainty analyses
Suggestion for discount
...
Budget impact (BIA)
Volume
(Estimated) number of patients
Incidence, prevalence, mortality, + trends
Treatment plan(?) ↑
Dosage
Duration of treatment
Motivation (when not based on most important clinical study)
Costs
Rate



Re-use of existing standards

- Explore ontologies and vocabularies to represent (parts of) the information in the package statements

- Examples:
  - Cochrane PICO ontology
  - Ontology of biomedical investigations for study data
  - DataQube ontology for data sets



(Example: PICO ontology)

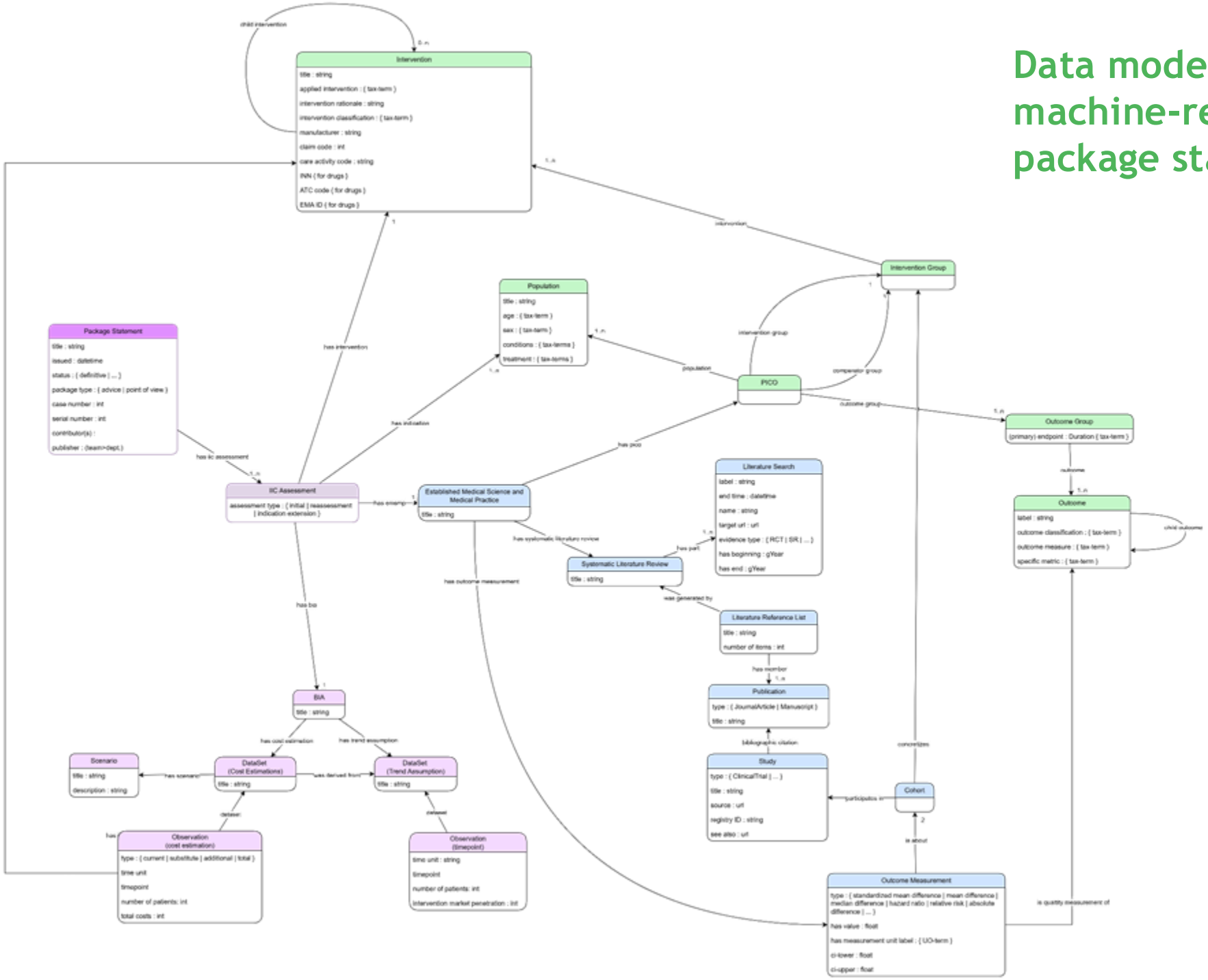
Keuze proces ontologiën – hergebruik waar mogelijk

Onderdeel	Overweging	Keuze	Afgevallen
Interventie, Indicatie, en de PICO	1. Dekt de lading 2. Semantische representatie i.t.t. OMOP en SDTM 3. Gerenommeerd instituut 4. Eenvoud in gebruik voor zoekvragen i.t.t. ERGO	Cochrane PICOts + eigenschappen voor de use cases, zoals bijvoorbeeld prijs en codes voor de interventie	• OMOP (Observational Medical Outcomes Partnership) • SDTM (Study Data Tabulation Model) • Eligibility Rule Grammar and Ontology (ERGO)
Taxonomie	1. Aansluiting op de Cochrane PICO ontologie 2. beschikbaar is als Linked Data met verwijzingen naar andere vocabulaires, zoals MedDRA en UMLS (die weer verwijzingen hebben naar o.a. SNOMED-CT) 3. Meer van de benodigde termen bevatte dan bijvoorbeeld SNOMED-CT	Applicatie-specifieke taxonomy op basis termen Cochrane Core vocabulaire + de extra benodigde termen	Eligibility Rule Grammar and Ontology (ERGO)
Literatuur-onderzoek	Geen 1 omvatte ontologie die de informatie over het literatuuronderzoek kan weergeven, zoals zoekopdracht en resultaten (als lijst weten-schappelijke artikelen die verwijzen naar studies)	Documenten: Provenance ontologie (PROV-O) Activiteiten en uitkomsten: Schema.org Literatuurreferenties: FABiO	BIBO (Bibliographic Ontology) [Had ook gekund]

Keuze proces ontologiën – hergebruik waar mogelijk

Onderdeel	Overweging	Keuze	Afgevallen
Uitkomstmaten en Studie	• Inzet STATO omdat verschil nodig tussen de uitkomstmaat uit de PICO ontologie en de waarde van een uitkomst zoals gerapporteerd in een specifieke studie of in meta-analysen in de context van een pakketuitspraak. • Voor het definiëren van studies en relevante groepen zijn klassen uit OBI gebruikt omdat dit een veelgebruikte en up-to-date ontologie is.	• STATO ontologie (statistics ontology) met verwijzing naar de onderzochtte 'kwaliteit', d.w.z. de PICO uitkomstmaat. • Ontology of Biomedical Investigations (OBI)	• Ontology of Clinical Research (OCRe)
Budget Impact Analyse (BIA)	Geen geschikte ontologieën gevonden.	Zelf ontwikkeld met Data Qube vocabulaire, dat weer gebaseerd is op het Statistical Data and Metadata Exchange (SDMX) informatiemodel	-
Overig	Properties die 2x voorkomen: 1. uit een externe ontologie met een te restrictief domein en bereik 2. Ander domein / bereik	Properties met dezelfde naam, maar andere namespace, zijn gedefinieerd.	-

Data model / Schema machine-readable package statements



to illustrate:
matching data points with the ontologe

Demo

- Coupling with the national health data catalog

- FDP

The Hyve

Infrastructure PoC FAIR Packet statement registy

PoC Components

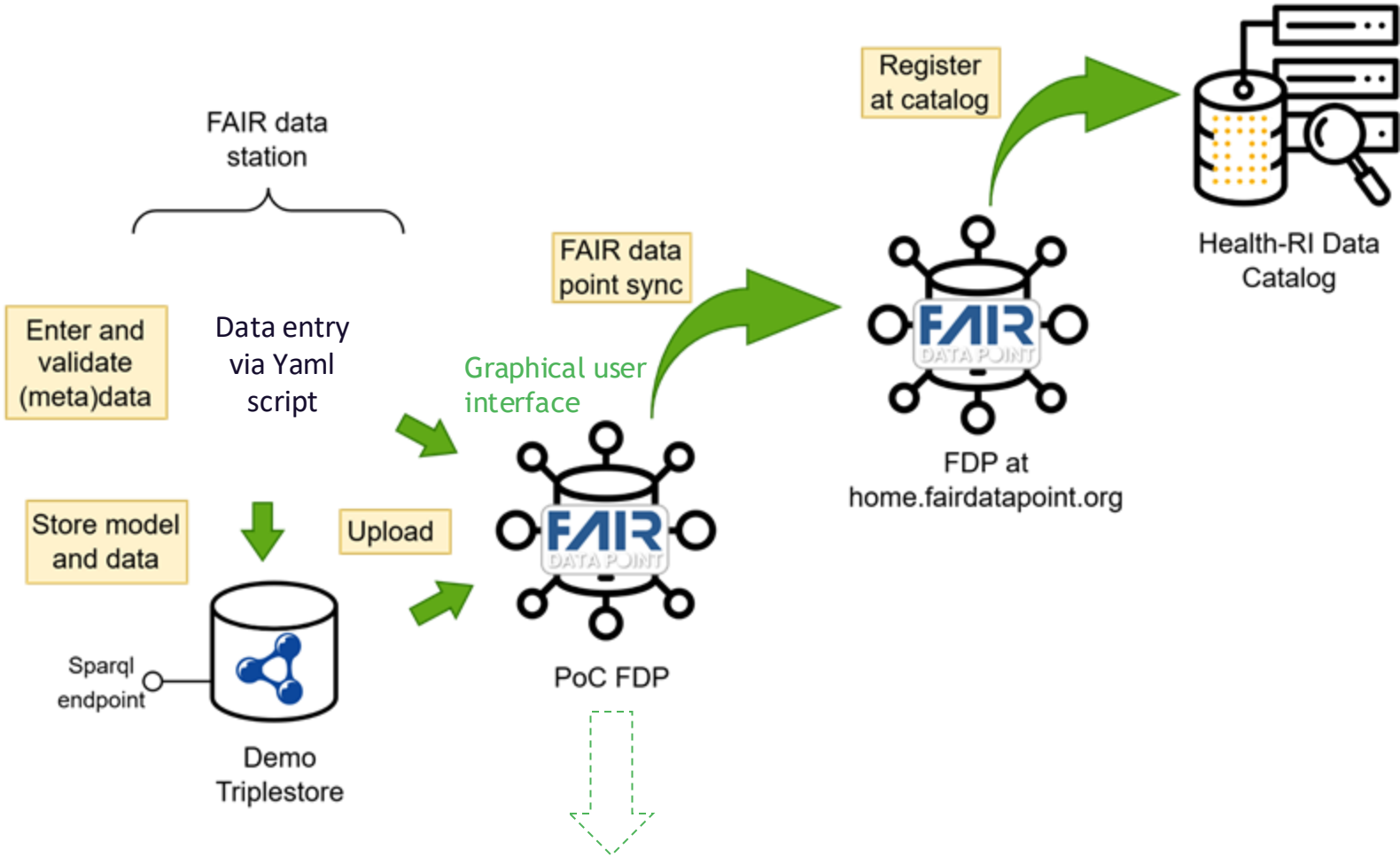
1) Queryable model of 3 package statements in breast cancer domain
2) FAIR data station (triplestore with Sparql endpoint) met data and semantic model
3) FAIR data point in which the package statements are registered with relevant metadata
4) Entry in Health-RI national health data catalog
5) PURL's on basis of w3id.org

Next steps:

6) Create entry form and templates

> currently data entry via scripts from YAML files, which have been manually created

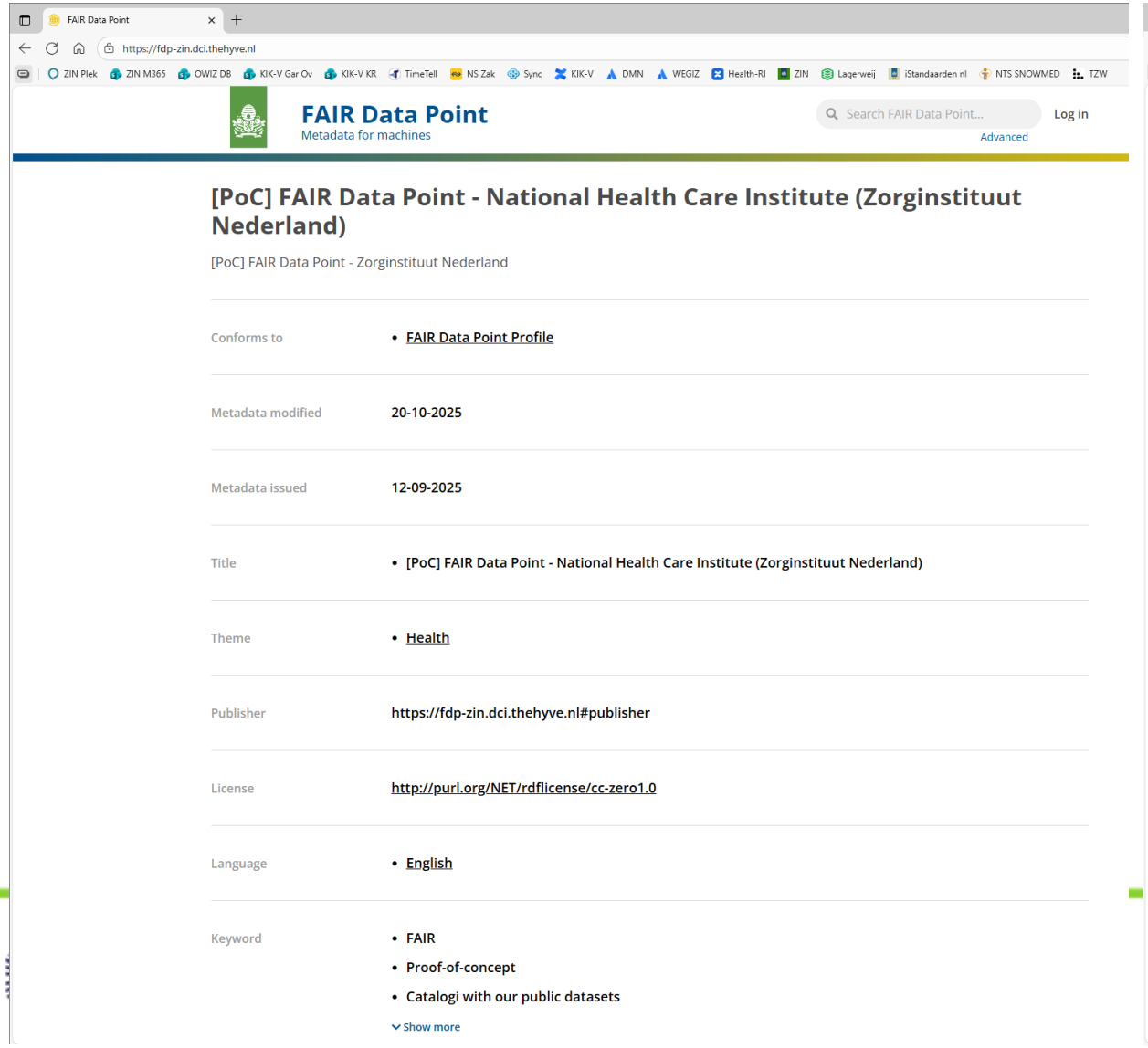
7) Publication on open-overheid en open.minVWS

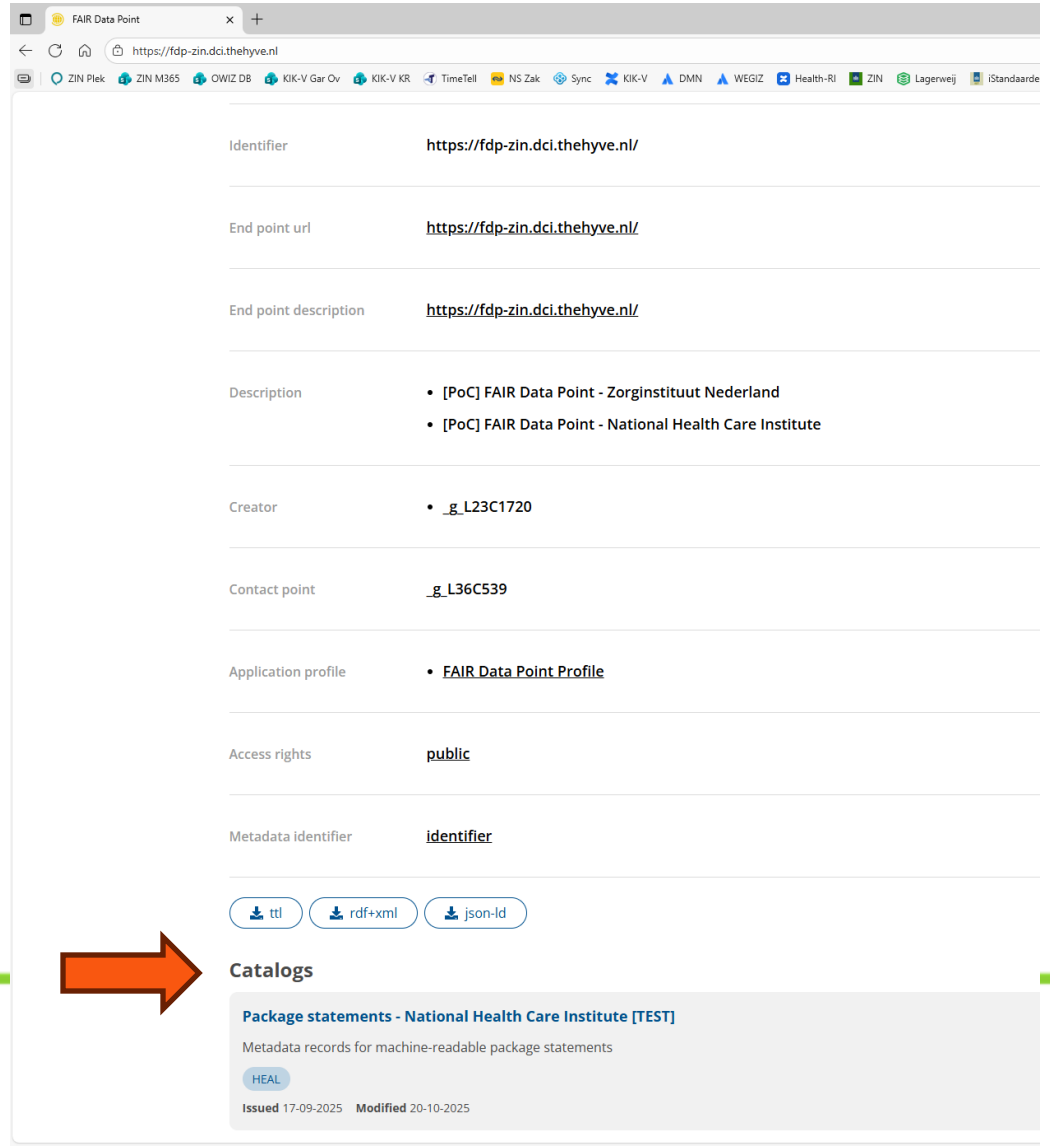


https://www.open-overheid.nl/
https://open.minvws.nl/

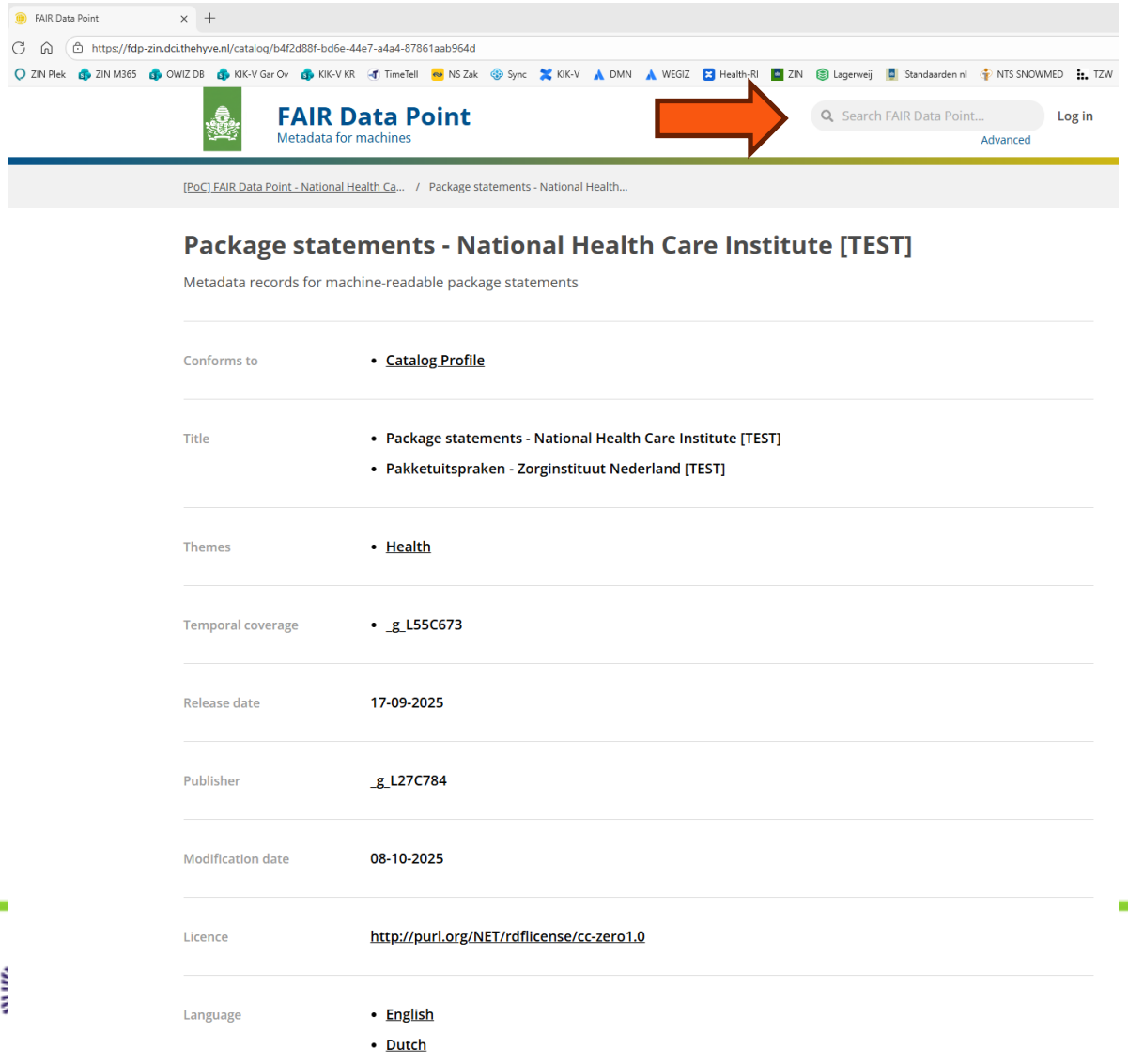
PURL's:
- Link to the FDP: https://w3id.org/zinl/fdp
- The FAIR Package Registry ontology: https://w3id.org/zinl/fpr-o
- The taxonomy (part Cochrane & part new terminology): https://w3id.org/zinl/fpr-tax
- Examples from 3 package statements: https://w3id.org/zinl/package-statements/aft

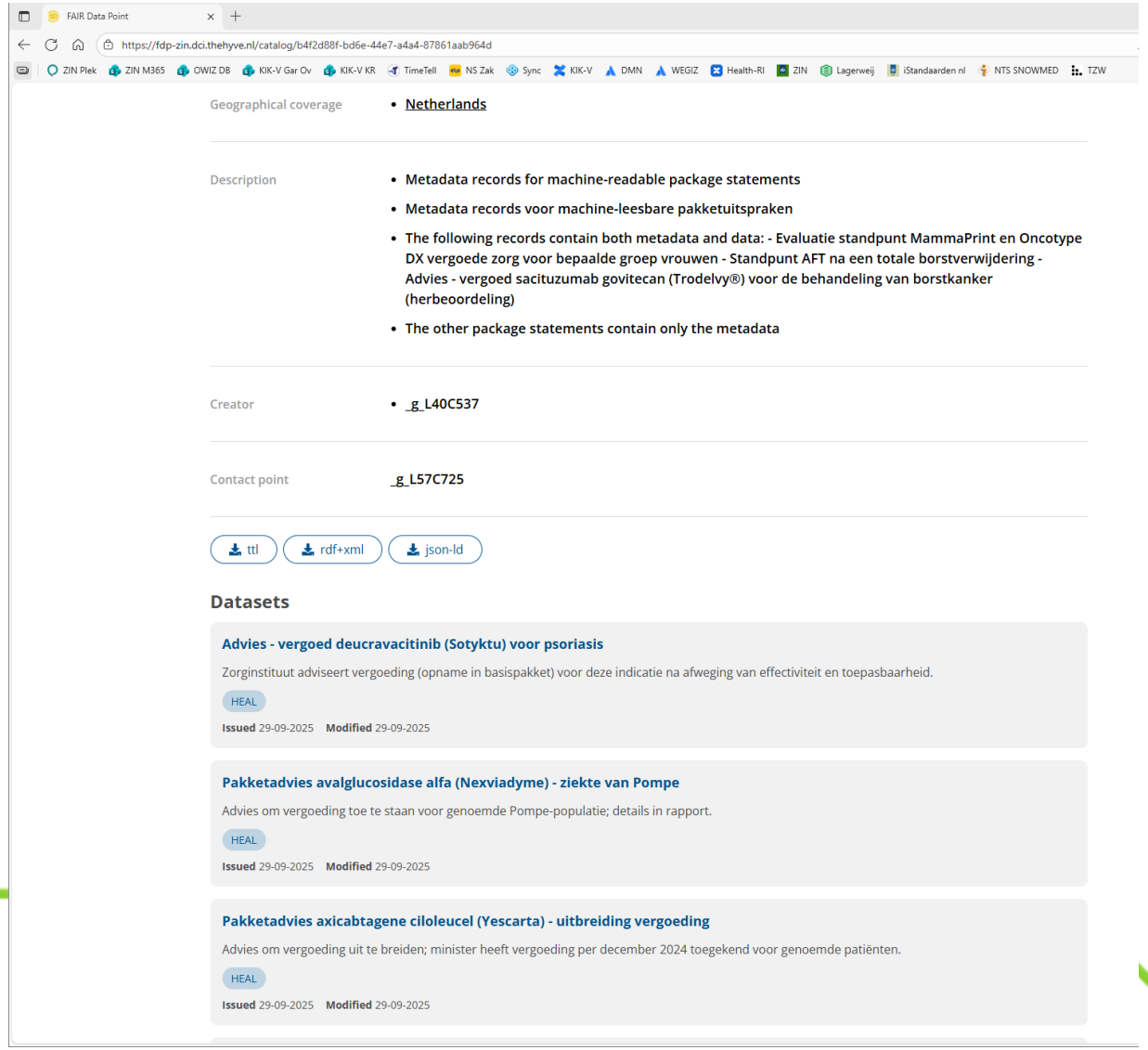
FDP Homepage Zorginstituut met metadata en link naar datacatalogi Zorginstituut



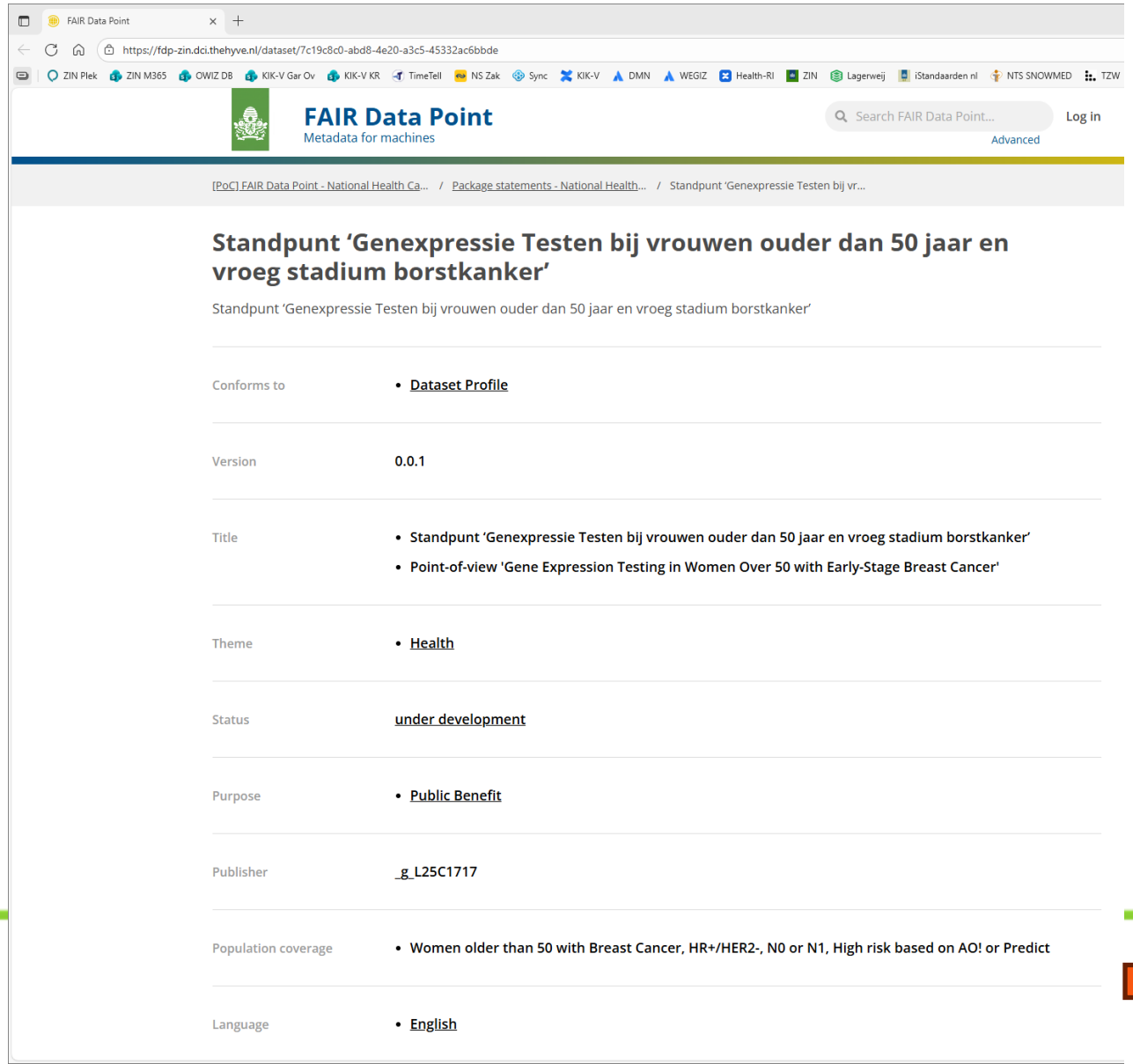


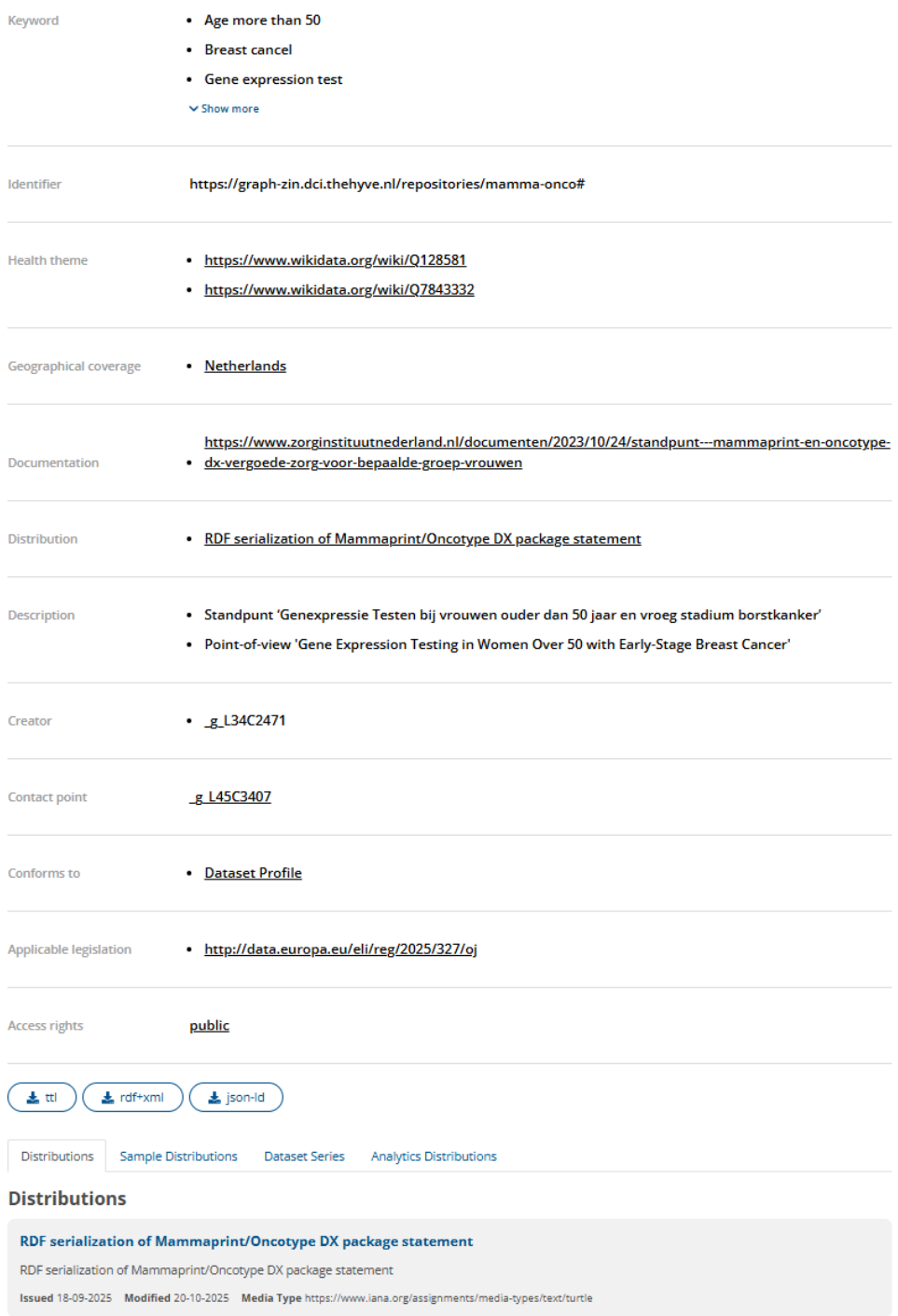
FDP “Homepage” catalogus
FAIR Pakketregister met zoekcriteria



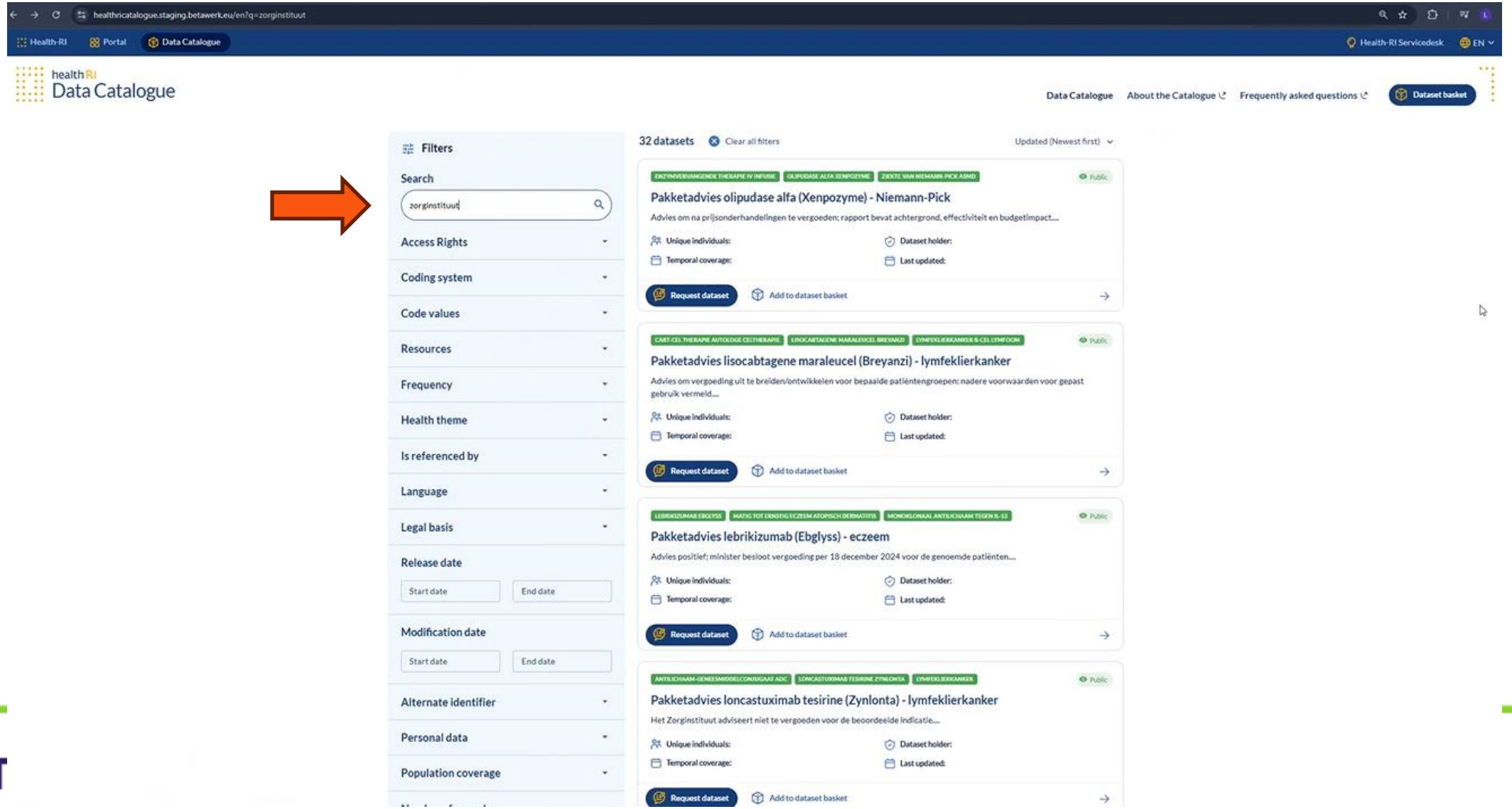


FDP Pagina PU met rdf data

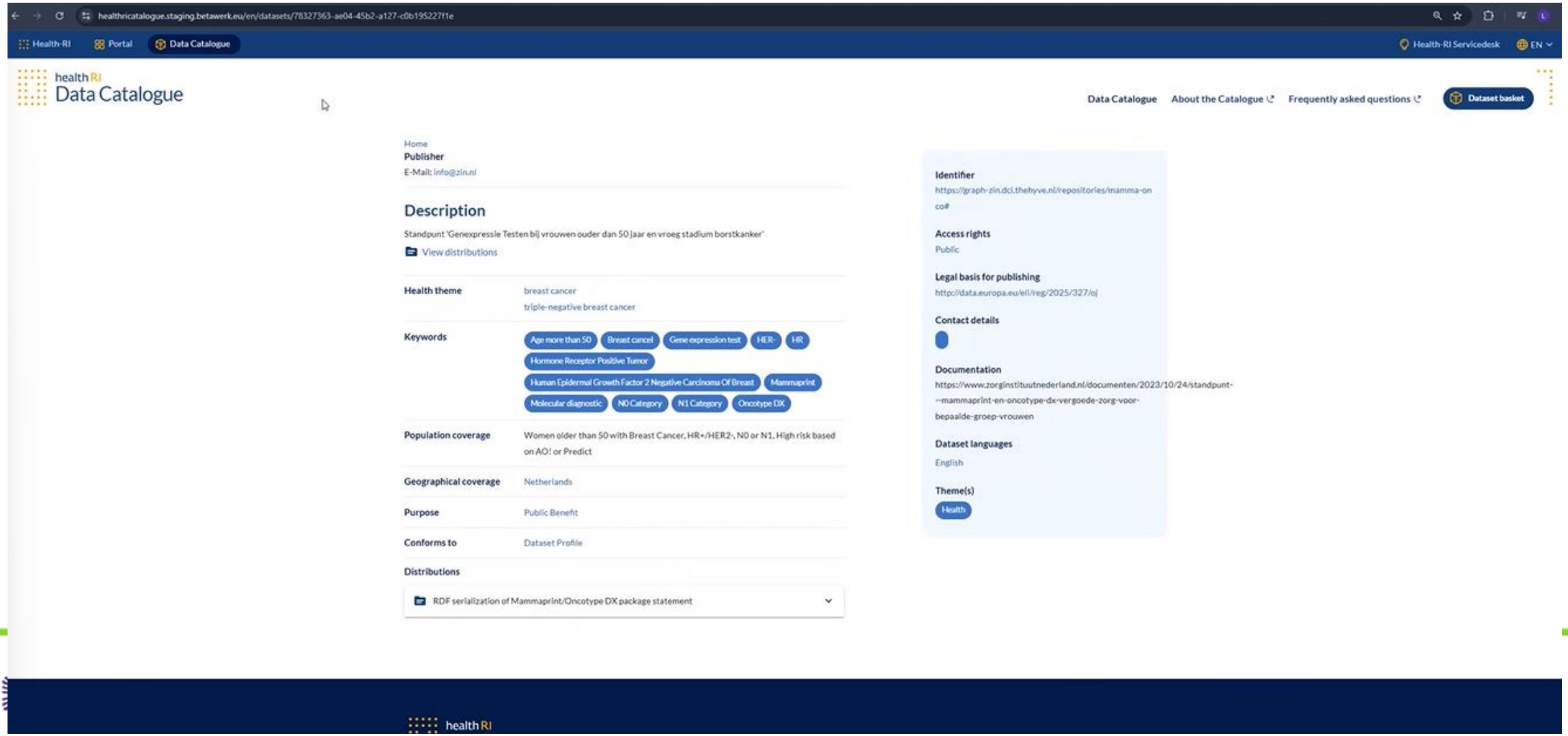




Data gepubliceerd in Health-RI Datacatalogus (acceptatie omgeving)



PU in Health-RI Datacatalogus (acceptatie omgeving) voorbeeld



Behoefte onderzoek op basis interviews

The Hyve

Resultaten Interviews

Internal and external stakeholders

Wishlist:

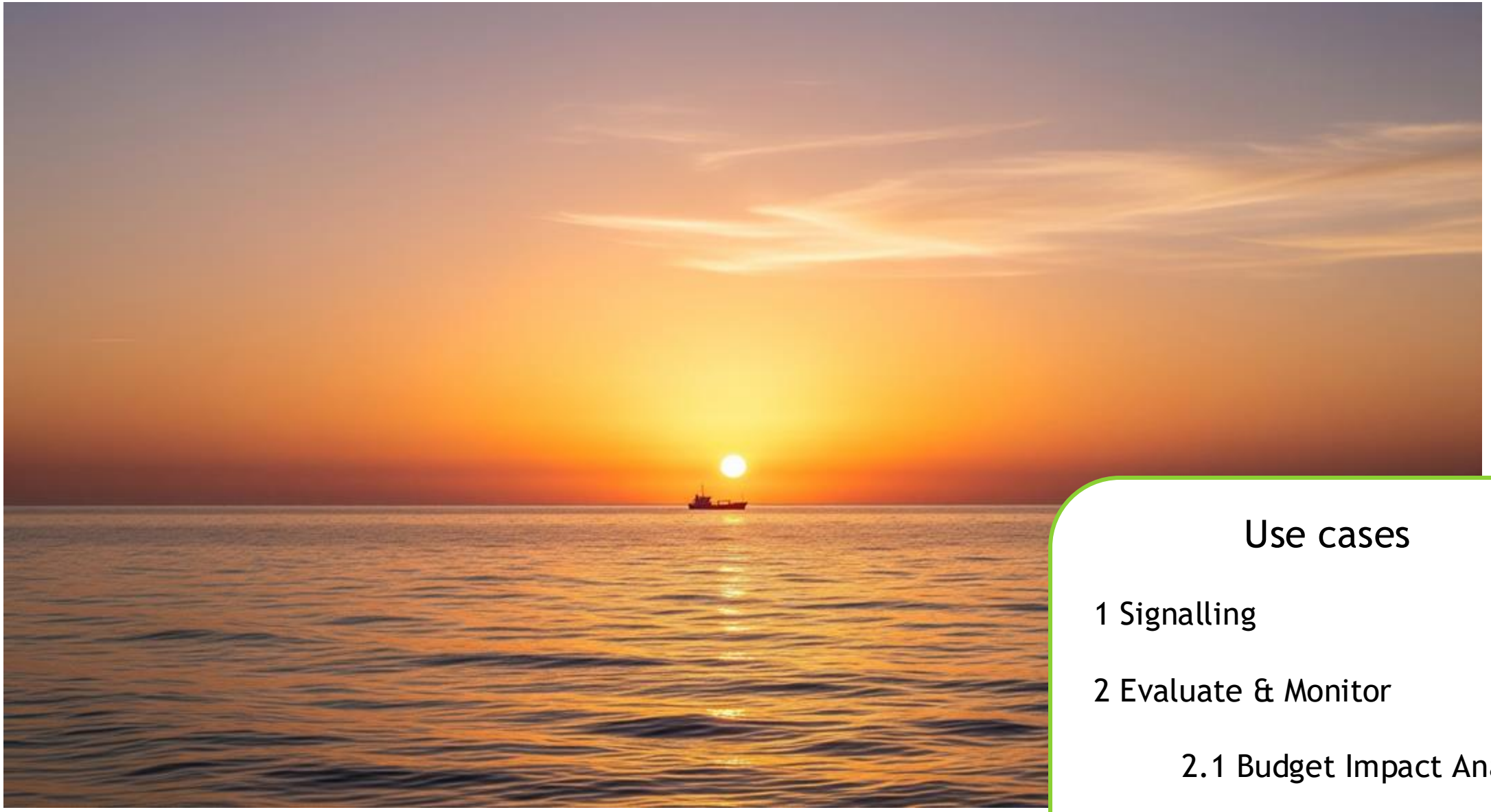
- FAIR data to query as first step of process automation
  - focus on **findability and search**
  - focus on **machine-readability**

- Coupling with RWD

- Future outlook
  - Which data will we need to evaluate new statements

Use cases

The Hyve



Use cases

1 Signalling

2 Evaluate & Monitor

- 2.1 Budget Impact Analysis
- 2.2 Real-World Data – IKNL

Signalling
- What's on the horizon? -

Is there new evidence that prompts us to reevaluate?

Automated, periodic search request to identify new data/new studies/new publications for:

- Individual package statements
- Specific PICOs
- Final outcome measure available instead of surrogate outcome measure

Package statement, Published on 01-01-2020

FDP/FDS

Initial or last search

- Date search
- Sources
- Search query
- Results

Automated repetition of search on sources with search query & results

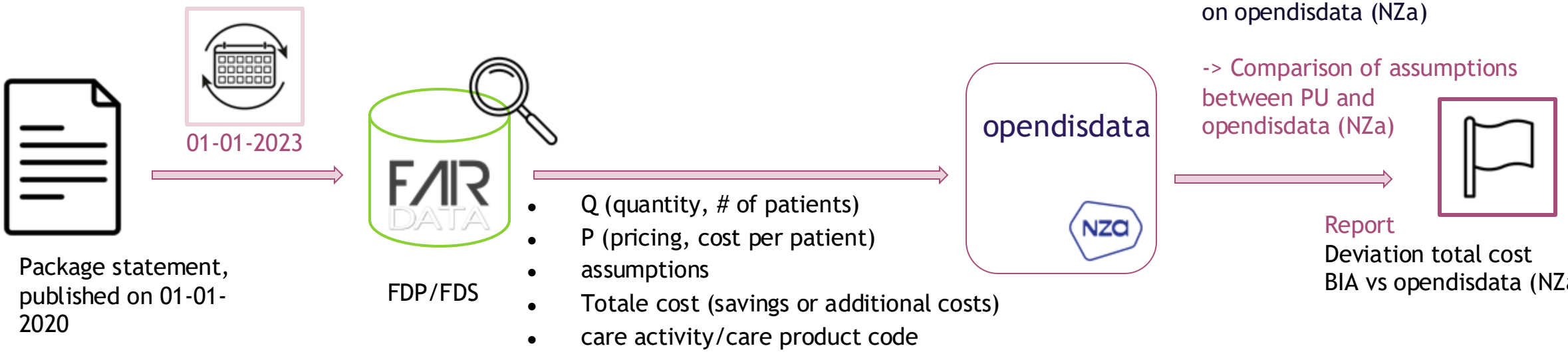
Report
New publications
New studies

Evaluate & Monitor: Budget Impact Analysis - What's on the horizon? -

Cyclic package management
Evaluate assumptions and estimates in BIA part of the package statement

- Automated
- Periodically
- Leveraging e.g., opendisdata (NZa)

Application - fact check leveraging opendisdata

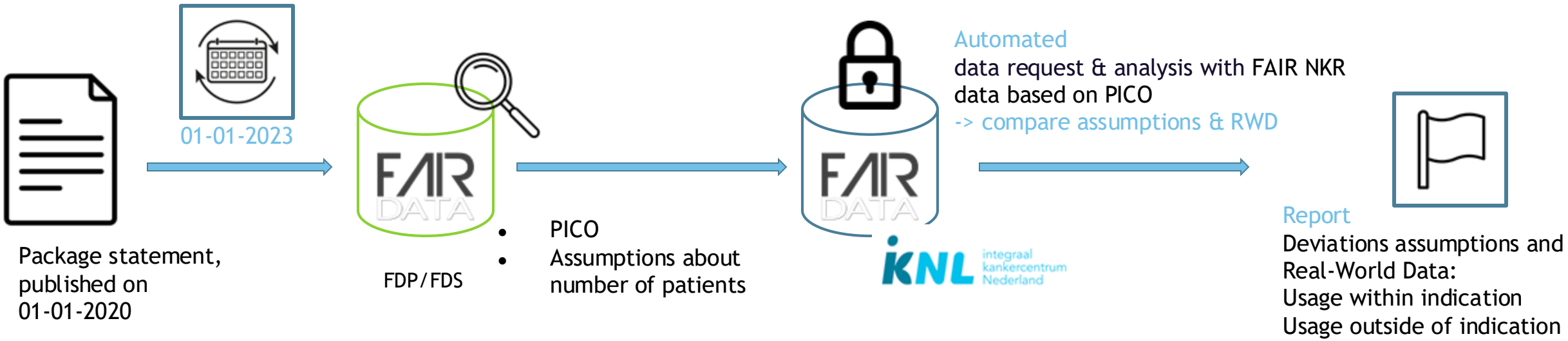


Evaluate & Monitor: RWD
- What's on the horizon? -

Cyclic package management

1) Evaluate assumptions and estimates about indications and number of patients
   - Automated
   - Periodically
   - Leveraging RWD (NKR data)
2) Data availability check (PARP blockers)

Application - RWD fact check leveraging NKR data



Evaluate & Monitor: RWD
- Status Quo -

Package statement, published on 01-01-2020

No automated trigger

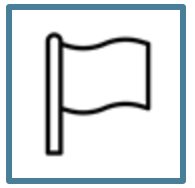
Generic data requests

FDP/FDS

- PICO
- Assumptions about number of patients

IKNL intern:
Identify and analyze relevant data in NKR data

Report
Deviations assumptions andReal-World Data:
Usage within indication
Usage outside of indication



Externe parties:
data request via the IKNL data catalogus

FAIR Package statement

Intervention

title : Chemotherapie op basis van MammaPrint uitslag

applied intervention : { Genetic test advised Chemotherapy }

intervention rationale : Pas chemotherapie toe naar aanleiding van hoge risicoschatting MammaPrint

intervention classification : { Screening (?) }

Population

title : Vrouwen ouder dan 50 met borstkanker, HR+/HER2-, N0, hoog risico op basis van AO! of Predict

age : { Age more than 50 years }

sex : { Female }

conditions : { Breast cancer, Estrogen Receptor Positive Tumor, Progesterone Receptor Positive Tumor, Human Epidermal Growth Factor 2 Negative Carcinoma Of Breast, N0 Category, High risk based on AO! or Predict }

treatment : { Surgery }

DataSet (Trend Assumption)

title : Geschatte trend voor MammaPrint en/of Oncotype DX

dataset

Observation (timepoint)

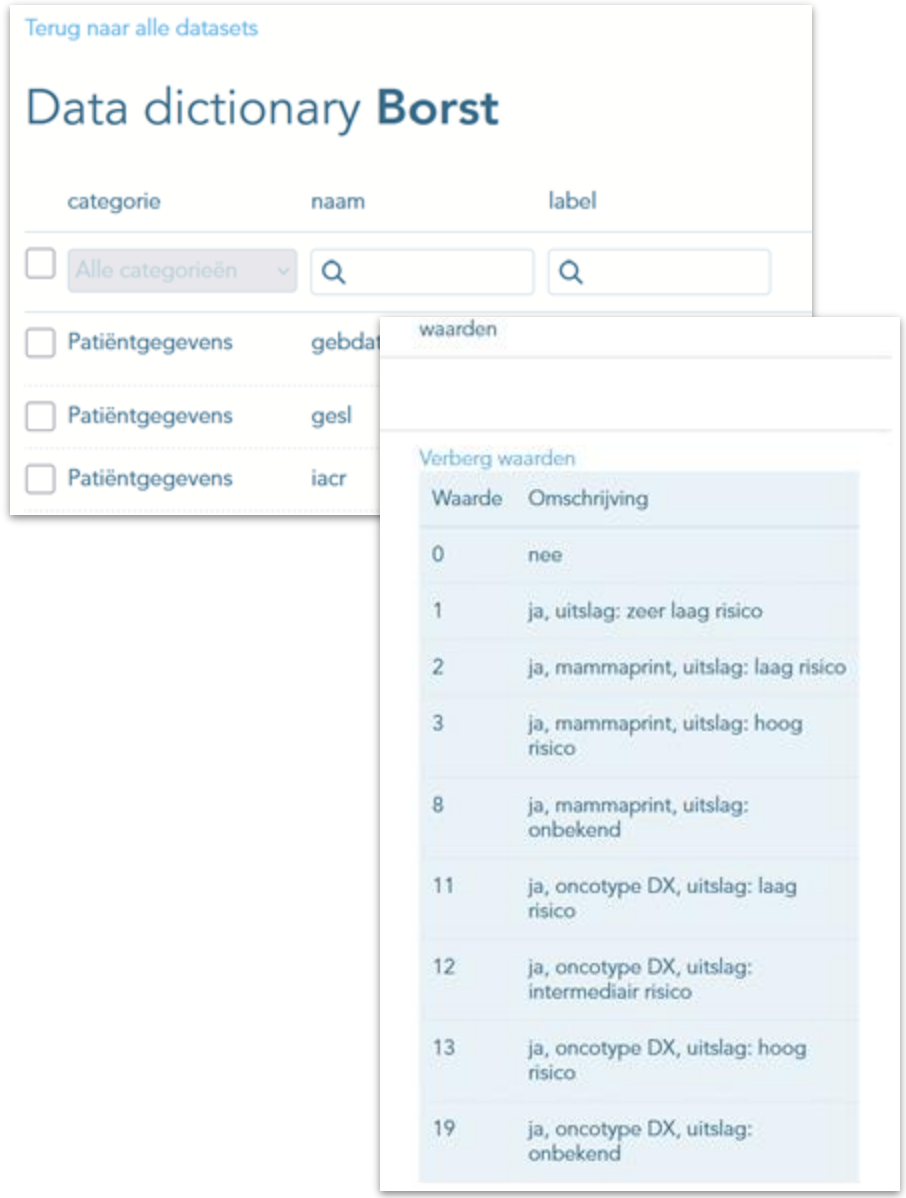
time unit : N/A

timepoint: default

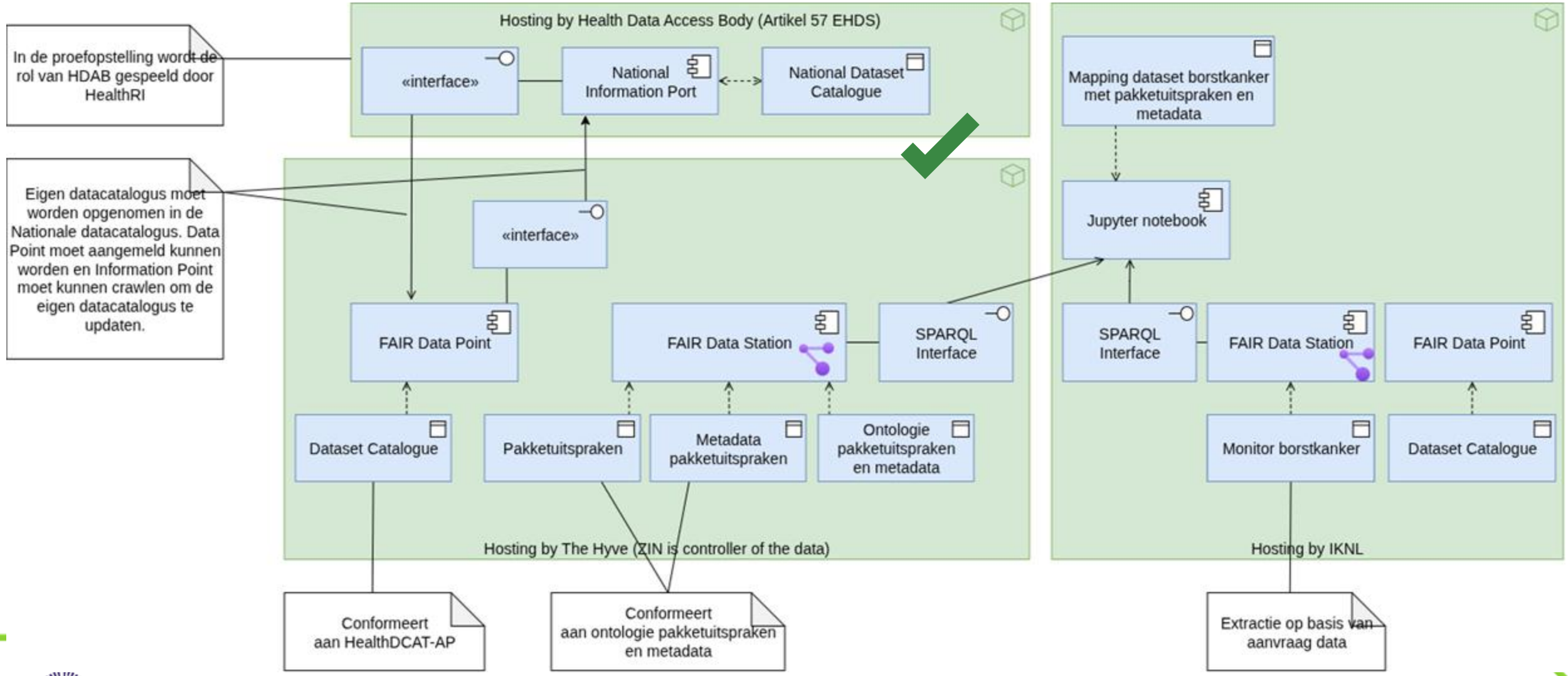
number of patients: 808

intervention market penetration : 1.0

IKNL Real-world data



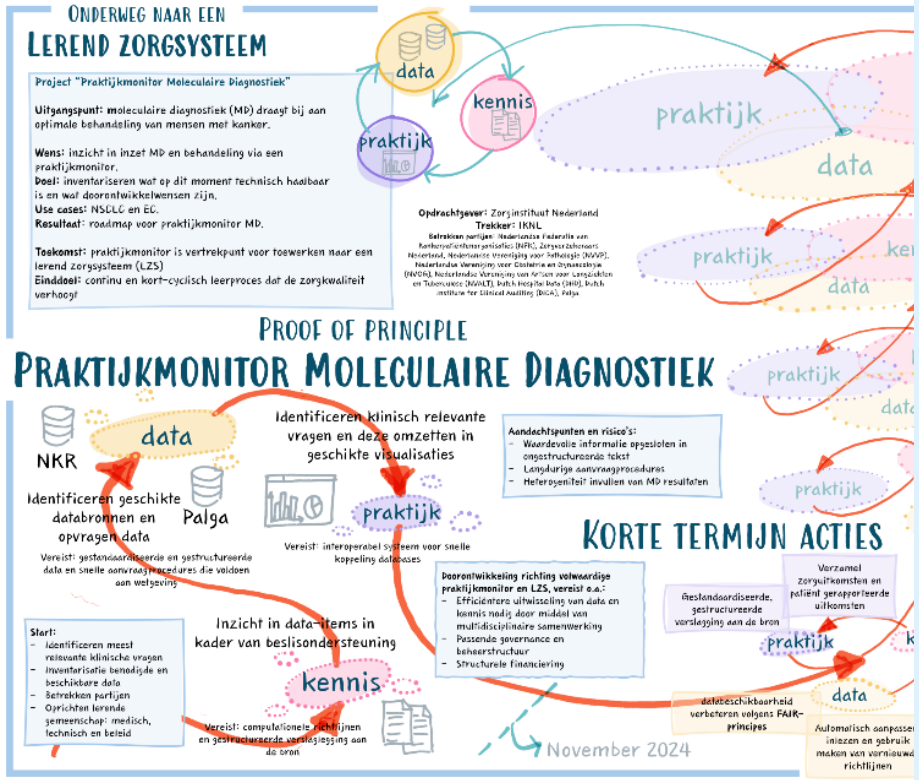
Evaluate & Monitor: RWD
- What's on the horizon? -



The Hyve

Reflectie IKNL

- **Roadmap lerende zorgsysteem**



Oncologieuptodate

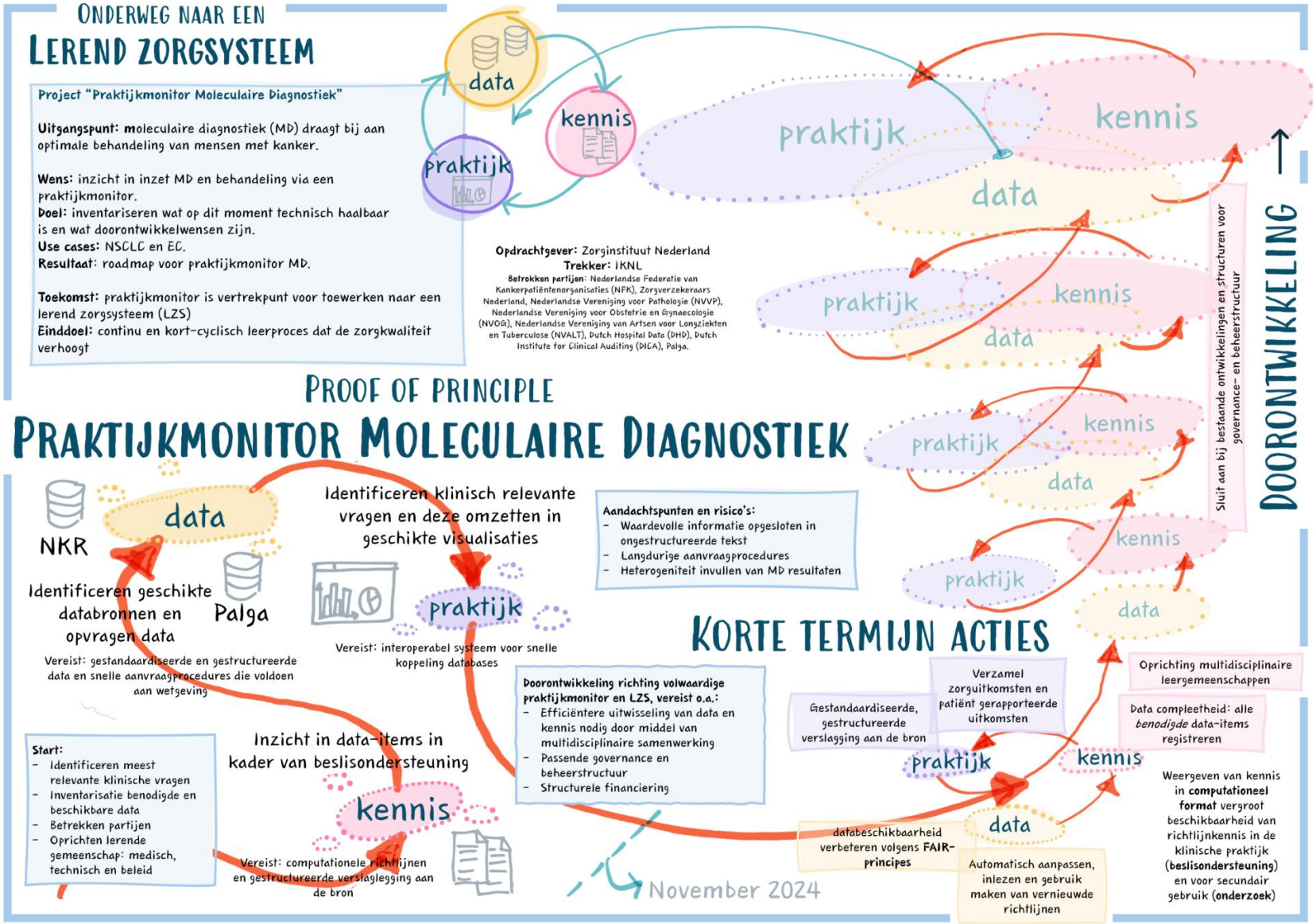
beteren

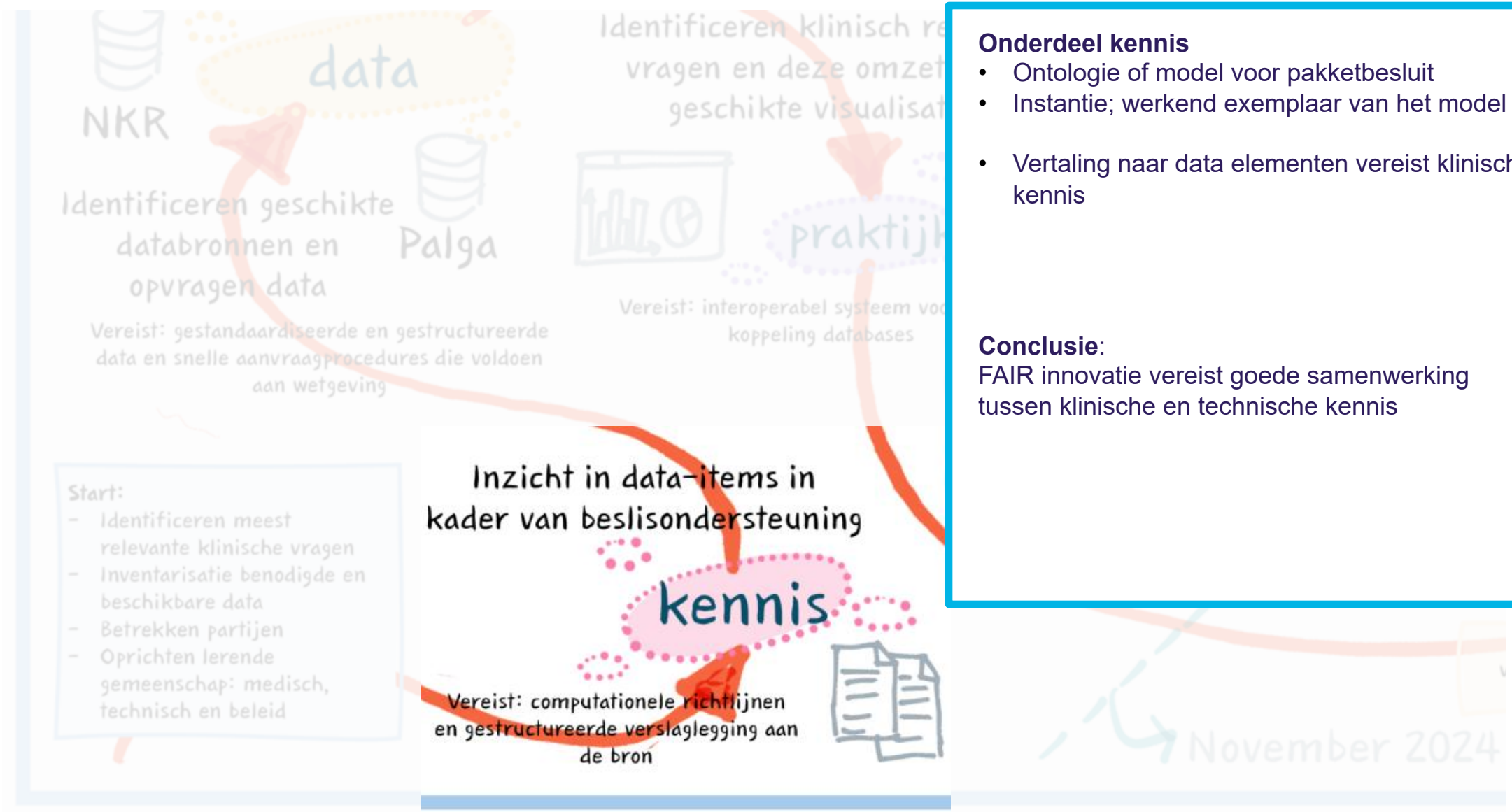
msen (foto: © Bert Roos)

de landelijke moleculaire-pathologie-
len, maar ondanks geprotocolleerde
gging blijkt het toch niet zo mak-
zijn om alle benodigde data te ver-
."

IKNL

Roadmap lerend zorgsysteem



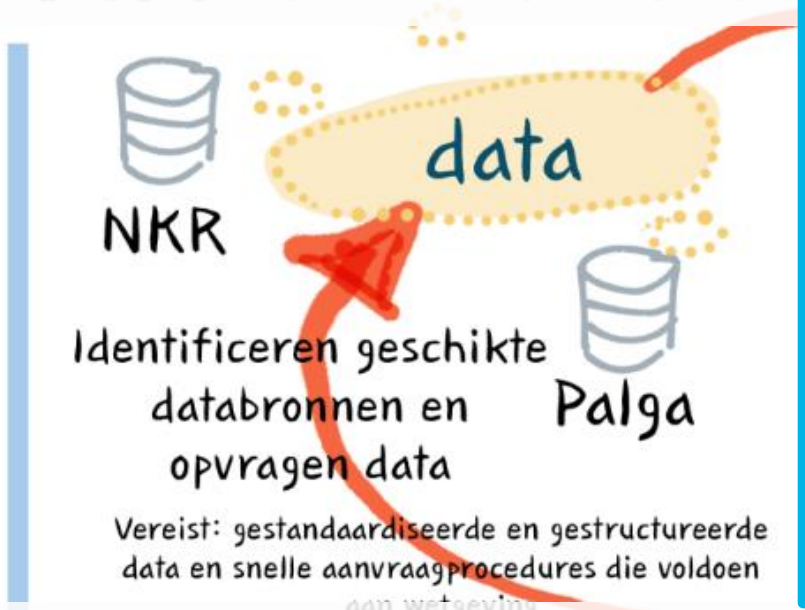


Onderdeel kennis
- Ontologie of model voor pakketbesluit
- Instantie; werkend exemplaar van het model

- Vertaling naar data elementen vereist klinische kennis

Conclusie:
FAIR innovatie vereist goede samenwerking tussen klinische en technische kennis

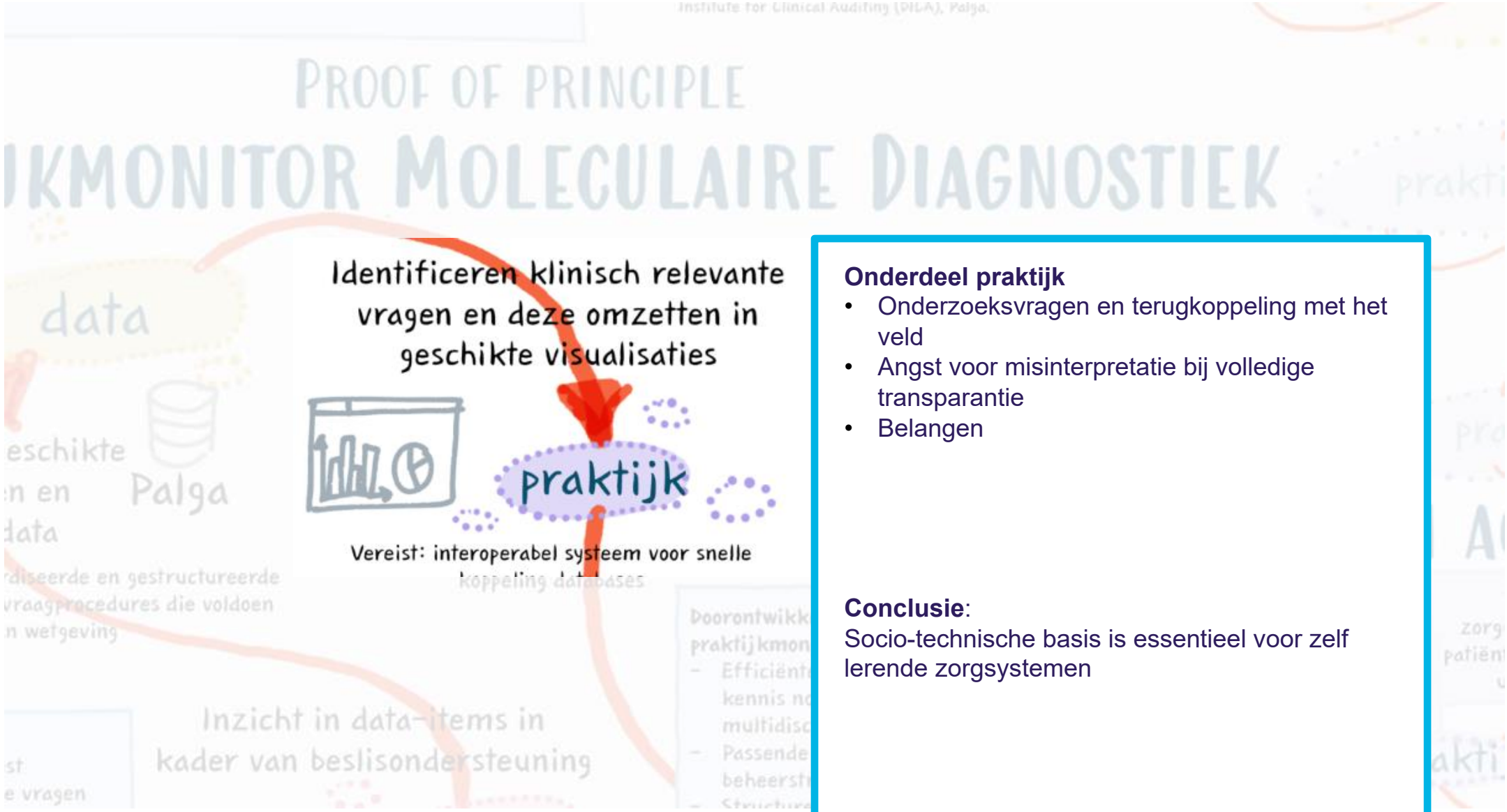
Roadmap lerend zorgsysteem



Onderdeel data

- Niet alle relevante data items zijn beschikbaar
- Wens voor FAIR by design voor cyclische pakketbeheer
- Stel eisen aan RWD

Conclusie:
Cyclisch pakketbeheer vereist voorbereiding o.a. door een datatoets voor uitbrengen pakketbesluit waar wens voor evalueren en monitoren bestaat



Onderdeel praktijk

- Onderzoeksvragen en terugkoppeling met het veld
- Angst voor misinterpretatie bij volledige transparantie
- Belangen

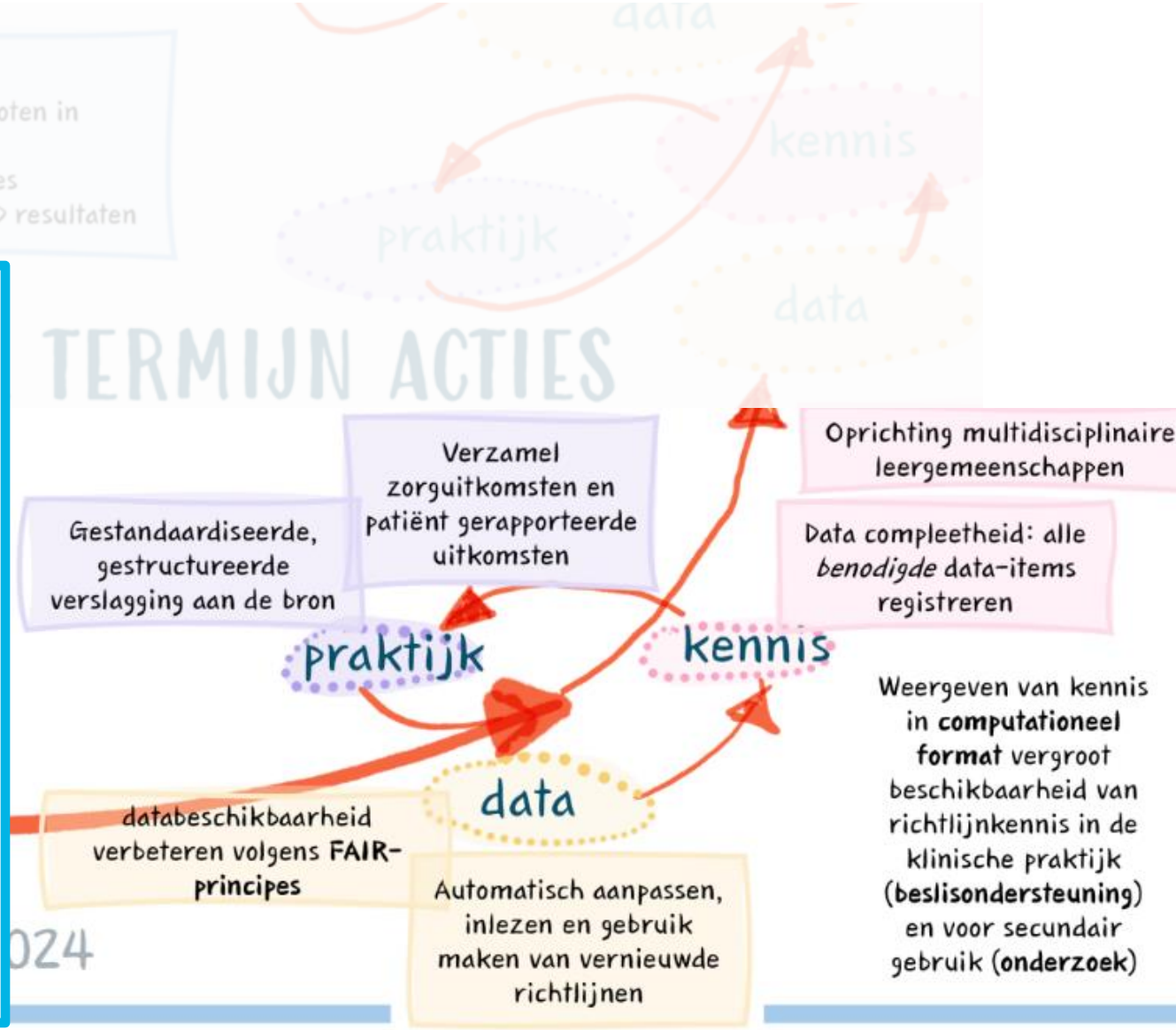
Conclusie:
Socio-technische basis is essentieel voor zelf lerende zorgsystemen

Roadmap lerend zorgsysteem

Algemeen

- Aanvragen en verzamelen van data post hoc kost veel tijd.

Conclusie:
Niet technische onderdelen van dit project zijn grootste vertragende factoren

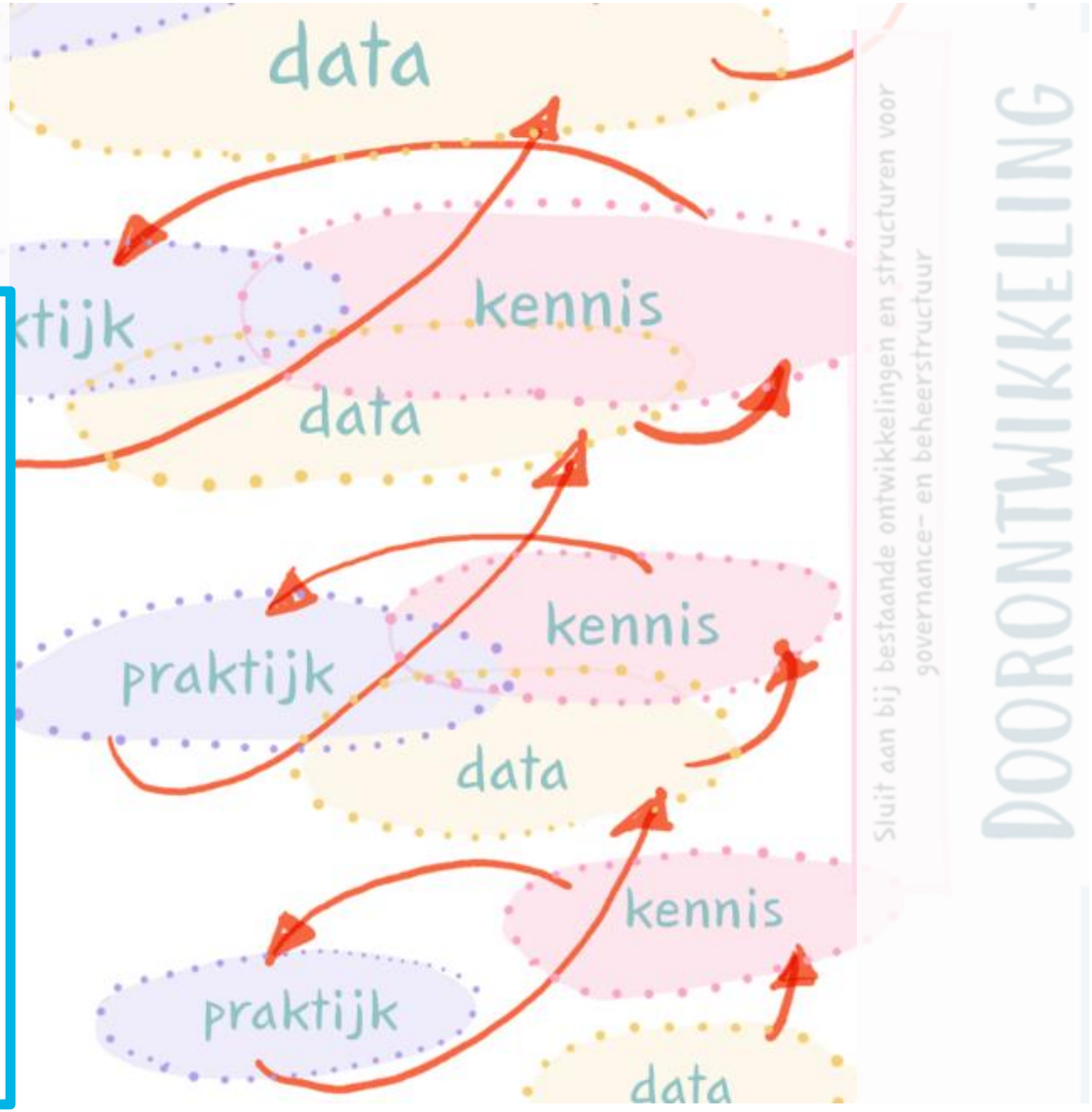


Roadmap lerend zorgsysteem

Relevantie voor IKNL en lerend zorgsysteem

- Iteraties zijn ultieme resultaat en doel
- FAIR Pakketregister met machineleesbare pakketbesluiten zijn heel relevant voor IKNL
- Veel kansen tot verdere samenwerking en borging in relevante initiatieven (OncoNext, dure geneesmiddelen, kwaliteitsregistraties etc.)

Conclusie:
Zelf lerende zorgsystemen zijn relevant en veel mogelijkheden tot opvolging.



Inpassing binnen het Zorginstituut en IKNL

DISCLAIMER

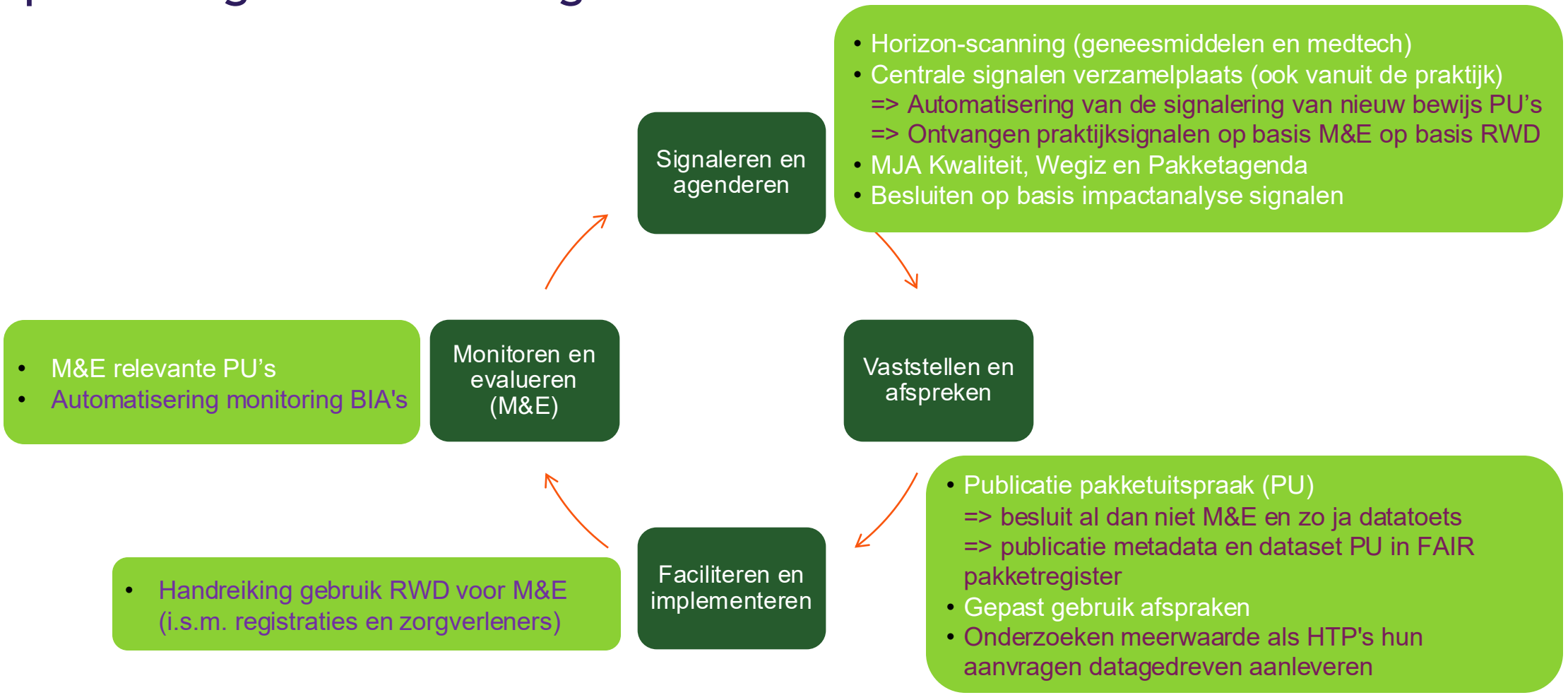
Het is een onderzoeksproject.
Intern nog geen besluit genomen om het FAIR Pakketregister in productie te nemen.

Vandaag bedoeld om methodiek en lessen te delen en te horen hoe jullie toepasbaarheid zien.

The Hyve

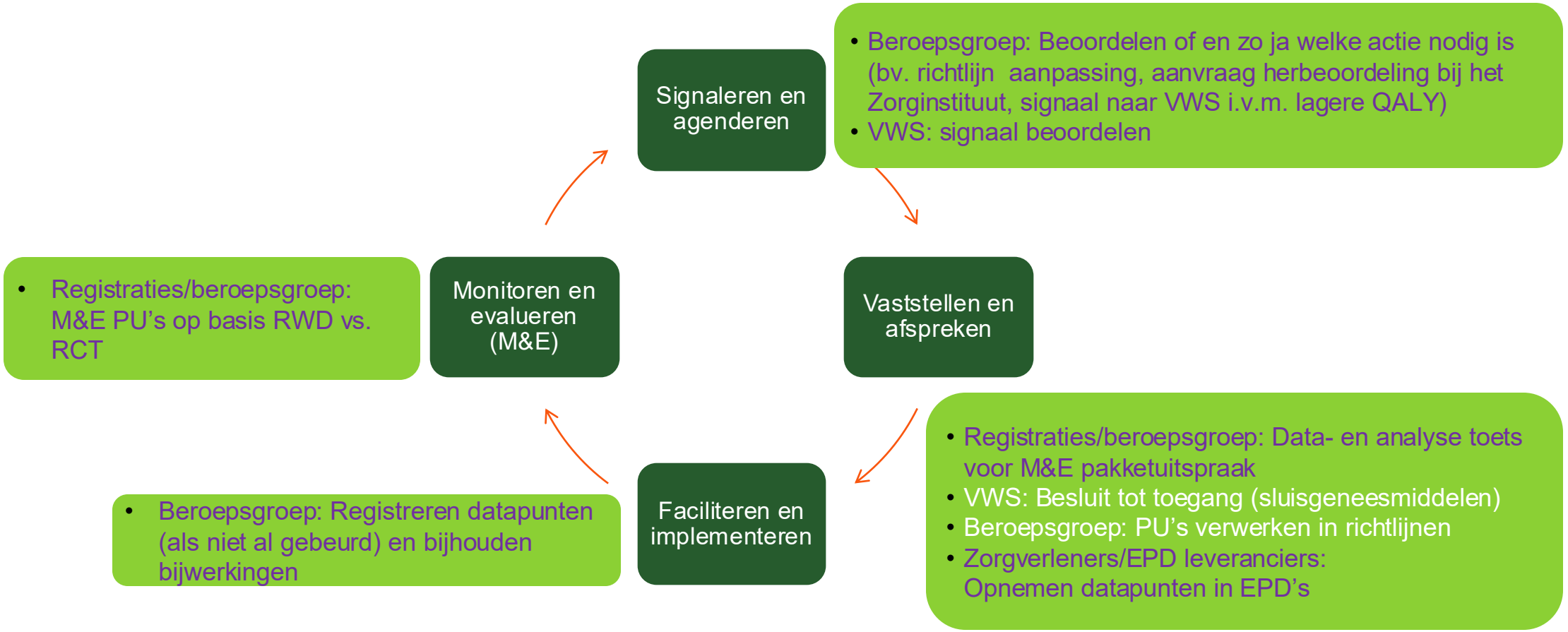
CONCEPT

Aanzet cyclisch pakketbeheer met FAIR pakketregister – Rol Zorginstituut



CONCEPT

Aanzet cyclisch pakketbeheer met FAIR pakketregister – Rol VWS & veldpartijen



Kansen en risico's van een FAIR pakketregister

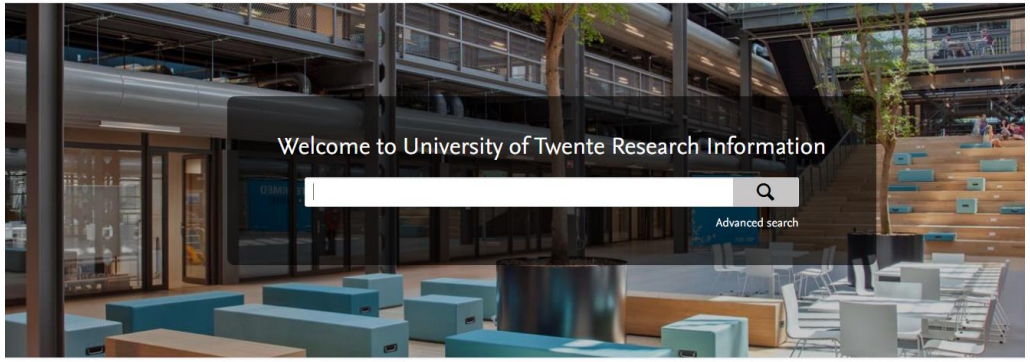
Stakeholder	Kans	Bedreiging	Nog verkennen
Zorginstituut - Inhoud	• Automatisering signalering • Automatisering BIA herberekening • Sneller signalen uit het veld door data toets vooraf en automatsering E&M door registraties	• HTP heeft makkelijker toegang tot alle uitspraken om daar analyses op te doen t.b.v. rechtzaken	• Hoe proces gaat lopen • Onderzoeken meerwaarde als HTP's hun aanvragen datagedreven aanleveren
Zorginstituut – Data	• Evalueren en monitoren op basis RWD • FAIR publicatie onze data en documenten (gewenst vanuit EHDS, WOO)		• Hoe proces gaat lopen - ook (de inspanning) op data vlak • Relatie met OMOP en Pharmaceutical ResearchProtocol (Vulcan UDP) v1.0.0-ballot
VWS	• Inzicht in effectiviteit op basis RWD ter beoordeling of prijsarrangement (nog) passend is • Transparantie over pakketbesluiten naar burger		
IKNL – Inhoud	• Inzicht in effectiviteit bij geëxcludeerde subpopulaties • RWD validatie van effectiviteit studies	• Methodologische risico's - Mis-interpretatie van resultaten (e.g. regios, ziekenhuizen)	• Wenselijkheid en haalbaarheid van verzamelen relevante variabelen • Juridische basis
IKNL - Data	• NKR data gebruik voor HTA en lerende zorgsystemen voor snellere impact • Koppelen van registratie data met relevante bronnen	• NKR is een onafhankelijke bron, geen kwaliteitsregistratie of beleidsinstrument	• Relatie met OMOP CDM en andere standaarden • Synergie met EHDS en FAIR initiatieven
Zorgverleners / aanbieders	• Snel informatie vinden over vergoede behandelingen • Snel inzicht over effectiviteit bij onderbelichte subpopulaties	• Mis-interpretatie van behandelkeuzes gebaseerd op klinische kennis en ervaring	• Proces, implementatie van data in FDP in EPDs • Koppelen aan (machineleesbare) richtlijnen
Health technology providers (HTP)	• Datagedreven aanleveren aanvragen • Beter overzicht op alle uitspraken		

Mogelijkheden: "Bibliotheek" gebaseerd op FDP

https://research.utwente.nl/en/

ZIN M365 · TimeTell · NS Zak · Sync · KIK-V · DMN · WEGIZ · Health-RI · ZIN · Lagerwij · iStandaarden nl · NTS SNOWMED · TZW · Babyconnect · Google · Gmail

UNIVERSITY OF TWENTE. | RESEARCH INFORMATION



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- SDG 3 - Good Health and Well-being (6426)
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- SDG 7 - Affordable and Clean Energy (4061)
- SDG 11 - Sustainable Cities and Communities (2990)
- SDG 13 - Climate Action (1935)

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Type
- Article (69622)
- Conference contribution (31641)
- Chapter (13061)
- Report (10032)
- Poster (9729)

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Open access
- Show OA content (59126)

Language
- English (108123)
- Undefined (52963)
- Dutch (8253)
- German (593)
- Spanish (155)

Show more ›

Publication Year
- 2025 (2919)

2026

Abstracting Conceptual Models as a Weakening Process

Romanenko, E., Kutz, O., Calvanese, D. & Guizzardi, G., 2026, *Logic, Language, Information, and Computation: 31st International Workshop, WoLLIC 2025, Porto, Portugal, July 14–17, 2025, Proceedings.* Kozen, D. & de Queiroz, R. (eds.). Springer, p. 141-157 17 p. (Lecture Notes in Computer Science; vol. 15942).

Research output: Chapter in Book/Report/Conference proceeding › Conference contribution › Academic › peer-review

Conceptual Model · Ontology · Formal Semantics · Basic Transformation · Description Logics

AI-Powered API for Brain Tumour Classification: A Deep Learning Approach to Accessible Medical Imaging

Rangelov, D., Miltchev, R. & Genchev, E., 8 Sept 2026, *Flexible Query Answering Systems: 16th International Conference, FQAS 2025, Burgas, Bulgaria, September 11–13, 2025, Proceedings.* De Tré, G., Sotirov, S., Kacprzyk, J., Psaila, G., Smits, G., Andreasen, T., Bordogna, G. & Legind Larsen, H. (eds.). Cham: Springer, p. 53–65 13 p. (Lecture Notes in Computer Science; vol. 16119).

Research output: Chapter in Book/Report/Conference proceeding › Conference contribution › Academic › peer-review

Medical Imaging · Learning Approach · Deep Learning Method · Artificial Intelligence · YOLO

Anticipating uncertainty in infrastructure LCC, LCA, and S-LCA: A systematic, context-aware early identification framework

Vargas-Farias, A., Santos, J., Stipanovic, I. & Hartmann, A., Mar 2026, In: Environmental impact assessment review. 117, 21 p., 108175.

Research output: Contribution to journal › Article › Academic › peer-review

Open Access · File

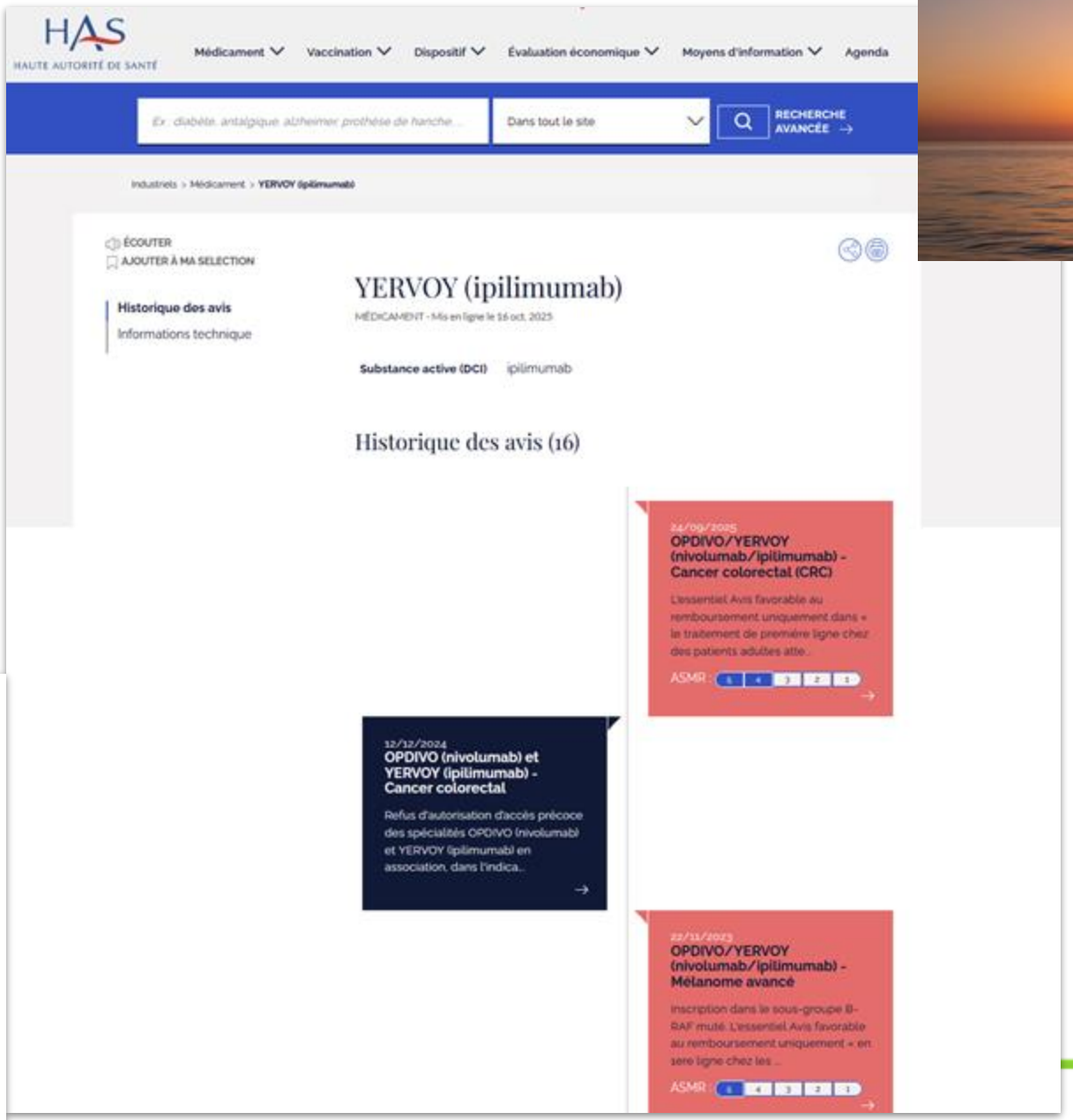
Asset Management · Life Cycle Assessment · Social Life Cycle Assessment · Life Cycle · Life Cycle Costing

9 Downloads (Pure)

AutoSV-Annotator: Integrating Deductive and Automatic Software Verification

Armborst, L., Beyer, D., Huisman, M. & Lingsch-Rosenfeld, M., 2026. *Formal Methods for Industrial Critical Systems -*

Mogelijkheden:
Tijdlijn van gerelateerde pakketbesluiten gebaseerd op FDP



https://www.has-sante.fr/jcms/pprd_2983154/fr/yervoy-ipilimumab

Conclusies, discussie & vervolg

The Hyve

Geslaagde 1e stap op weg naar automatisering van datagedreven cyclisch pakketbeheer dat naar meer smaakt

- Technisch & informatiekundig geslaagd.
- Enthousiasme voor het concept zowel bij het Zorginstituut als IKNL en zowel vanuit de inhoud als de informatiekundigen
- De volgende stap is adoptiebesluit door het Zorginstituut in samenspraak met VWS en veldpartijen

* Op basis ZonMw score model op basis FAIR Data Maturity Model. Specification and Guidelines.
Gegeven dat het een PoC is, voldoet het FDP nog niet aan documentatie eis en metadata beschikbaar houden na verwijderen van data.
Volgens de F-UJI - Automated FAIR Data Assessment Tool 53%.

Stap 1 op weg naar geautomatiseerd cyclisch pakketbeheer

- We hebben 3 pakketuitspraken ‘100%’ FAIR gemaakt*!
  - Machine-leesbaar
  - Volgens standaarden
  - Gepubliseerd volgens FAIR principes
- Bewezen hoe het zou kunnen werken (use cases)

- Kennismodelering: rijke expressie met zowel meerdere onderlinge relaties en op meerdere plekken structuur varianten (o.a. BIA) (en soms uitzonderingen)
- De menselijke evaluatie is lastig te standaardiseren
- Vrij uitgebreid datamodel waardoor opstellen yaml file met de data makkelijkers is dan inrichten entry forms voor de verschillende varianten
- Data beschikbaar op FAIR manier

* Op basis ZonMw score model op basis FAIR Data Maturity Model. Specification and Guidelines.
Gegeven dat het een PoC is, voldoet het FDP nog niet aan documentatie eis en metadata beschikbaar houden na verwijderen van data.
Volgens de F-UJI - Automated FAIR Data Assessment Tool 53%.

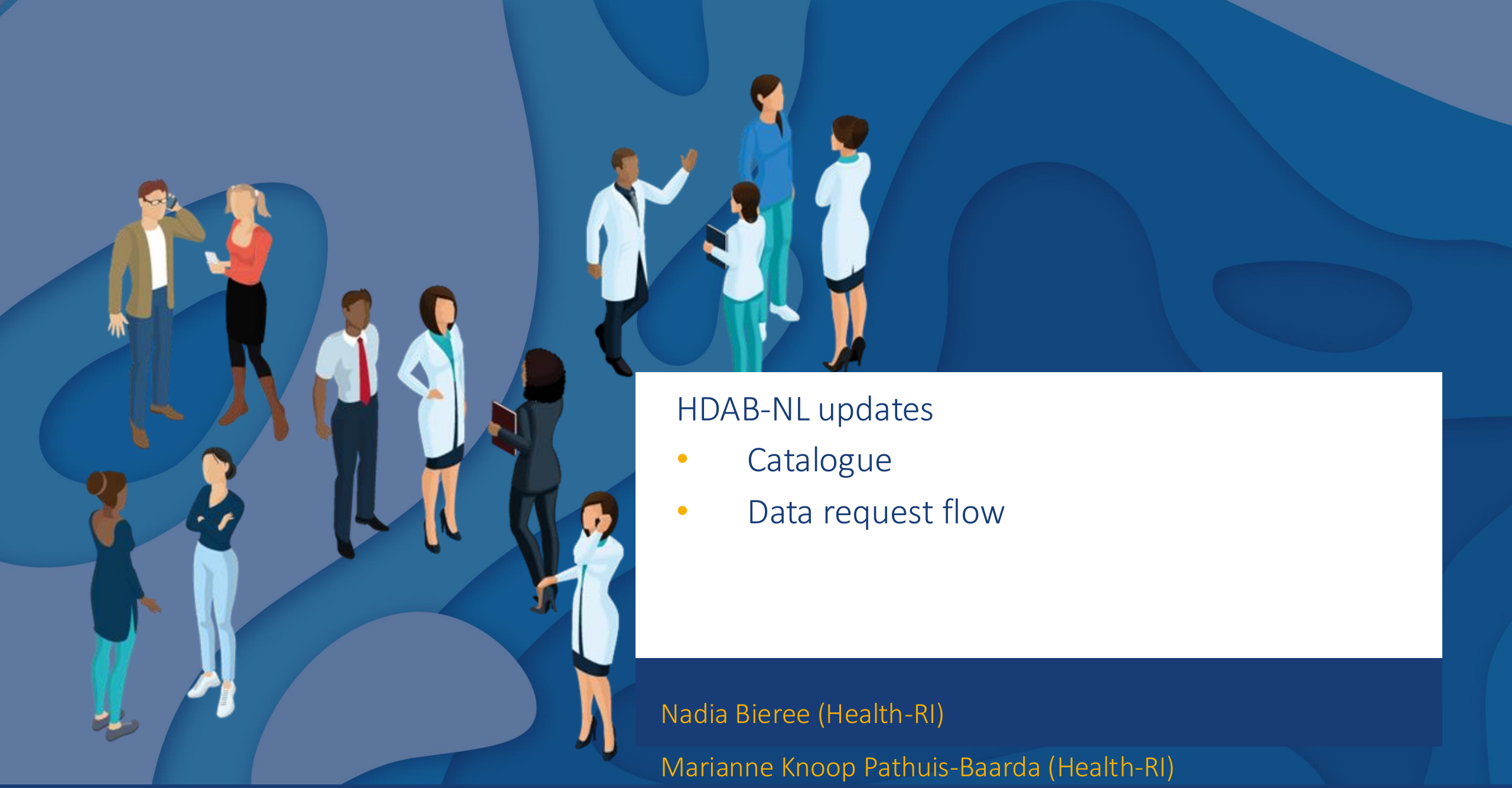
Vervolgstappen

- Besluit of we hiermee verder gaan, zo ja:
  - Oude besluiten met basis metadata publiceren (deel 2024 gedaan, ander deel onderweg)
  - Bekijken welke besluiten zinvol zijn om deels of volledig uit te werken tbv signalering, evalueren en monitoring, herbeoordeling
  - Evaluatie in hoeverre AI ingezet kan worden bij het coderen van de (oude) pakketbesluiten
  - Inschatting benodigde inzet en maken projectplan
- Kijken of het aansluit bij
  - Home - Pharmaceutical Research Protocol (Vulcan UDP) v1.0.0-ballot
    We kunnen vragen voor de initiele beoordelingen of HTP's op basis hiervan aanleveren.
    Dan ontvangen we de studies ook als data
  - Internationale samenwerking met HTA bodies
  - Pakketuitspraken van zorgverzekeraars
- Publicatie

The Hyve

Enabling open science

12:30-13:00



HDAB-NL updates

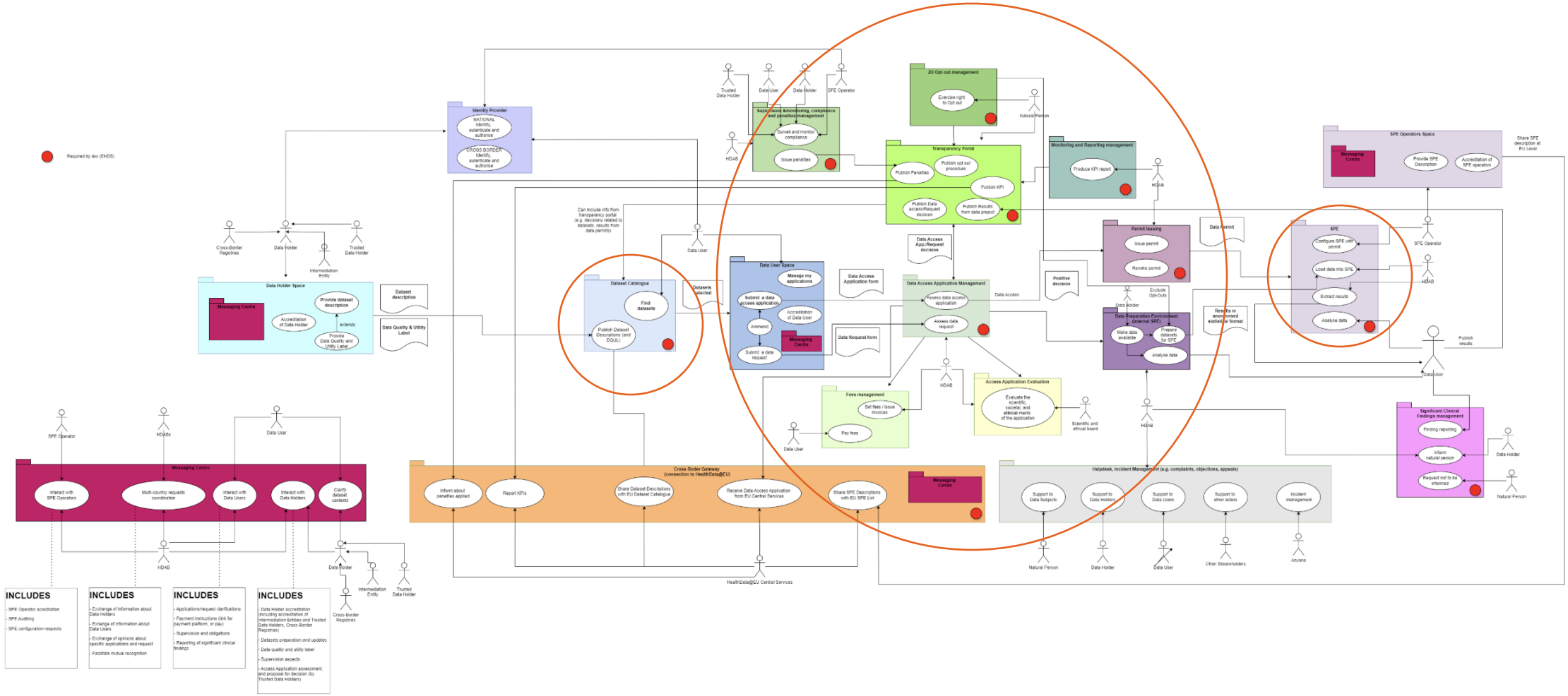
- Catalogue
- Data request flow

Nadia Bieree (Health-RI)

Marianne Knoop Pathuis-Baarda (Health-RI)

health RI
enabling data driven health & life sciences

Backbone


Required by law (EHDS)
Identity Provider
NATIONAL Identify, authenticate and authorise
CROSS BORDER Identify, authenticate and authorise
Supervision &monitoring, compliance and penalties management
Surveil and monitor compliance
Issue penalties
2U Opt out management
Exercise right to Opt out
Transparency Portal
Publish Penalties
Publish opt out procedure
Publish KPI
Publish Data access/Request decision
Publish Results from data project
Monitoring and Reporting management
Produce KPI report
SPE Operators Space
Messaging Centre
Provide SPE Description
Accreditation of SPE operators
Share SPE description at EU Level
Trusted Data Holder
Data User
Data Holder
SPE Operator
HDAB
Natural Person
Cross-Border Registries
Intermediation Entity
Data Holder Space
Provide dataset description
Accreditation of Data Holder
extends
Provide Data Quality and Utility Label
Dataset description
Data Quality & Utility Label
Can include info from transparency portal (e.g. decisions related to datasets, results from data permits)
Dataset Catalogue
Find datasets
Publish Dataset Descriptions (and DQ/U)
Datasets selected
Data User Space
Manage my applications
Submit a data access application
Accreditation of Data User
Ammend
Submit a data request
Messaging Centre
Data Access Application form
Data Request form
Data Access App./Request decision
Data Access Application Management
Assess data access application
Assess data request
Data Access
Positive decision
Permit issuing
Issue permit
Revoke permit
Data Permit
Exclude Opt-Outs
Data Preparation Environment (internal SPE)
Make data available
Prepare datasets for SPE
Analyse data
Results in anonymised statistical format
SPE
Configure SPE with permit
Load data into SPE
Extract results
Analyse data
Publish results
Fees management
Set fees / issue invoices
Pay fees
Access Application Evaluation
Evaluate the scientific, societal, and ethical merits of the application
Scientific and ethical board
Significant Clinical Findings management
Finding reporting
Inform natural person
Request not to be informed
Messaging Centre
Interact with SPE Operators
Multi-country requests coordination
Interact with Data Users
Interact with Data Holders
Clarify dataset contents
Cross Border Gateway (connection to HealthData@EU)
Inform about penalties applied
Report KPIs
Share Dataset Descriptions with EU Dataset Catalogue
Receive Data Access Application from EU Central Services
Share SPE Descriptions with EU SPE List
HealthData@EU Central Services
Helpdesk, Incident Management (e.g. complaints, objections, appeals)
Support to Data Subjects
Support to Data Holders
Support to Data Users
Support to other actors
Incident management
Other Stakeholders
Anyone
INCLUDES
- SPE Operator accreditation
- SPE Auditing
- SPE configuration requests
INCLUDES
- Exchange of information about Data Holders
- Exhange of information about Data Users
- Exchange of opinions about specific applications and request
- Facilitate mutual recognition
INCLUDES
- Applications/request clarifications
- Payment instructions (link for payment platform, or pay)
- Supervision and obligations
- Reporting of significant clinical findings
INCLUDES
- Data Holder accreditation (including accreditation of intermediation Entities and Trusted Data Holders, Cross-Border Registries)
- Datasets preparation and updates
- Data quality and utility label
- Supervision aspects
- Access Application assessment, and proposal for decision (by Trusted Data Holders)

HDAB-NL & Catalogue

Marianne Knoop Pathuis - Baarda

Senior Productmanager for the Catalogue at Health-RI

Lead Work Package 6 – Catalogue in HDAB-NL Direct Grant project

Marianne.knoop@health-ri.nl

Our direct grant work packages in 3 phases

1) De uiteindelijke vorm van operationalisatie is nog nader te bepalen

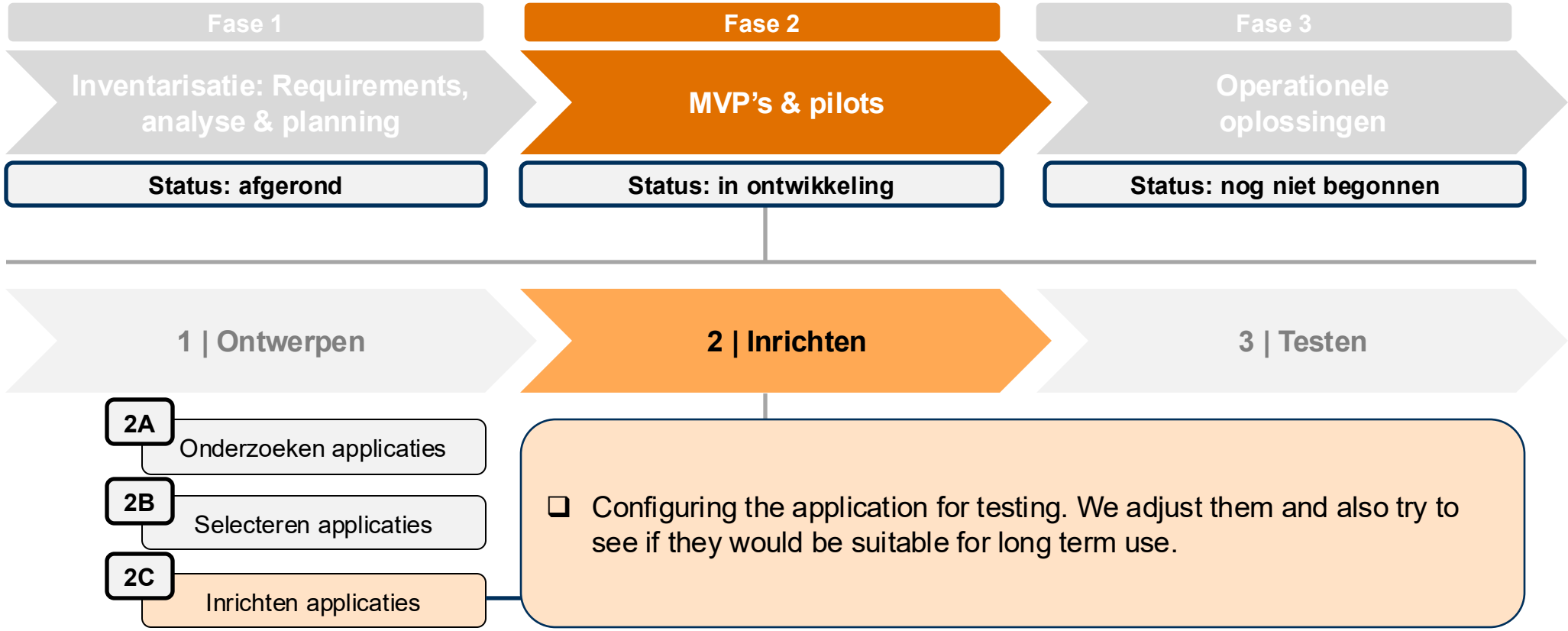
Applications Minimal Viable Products

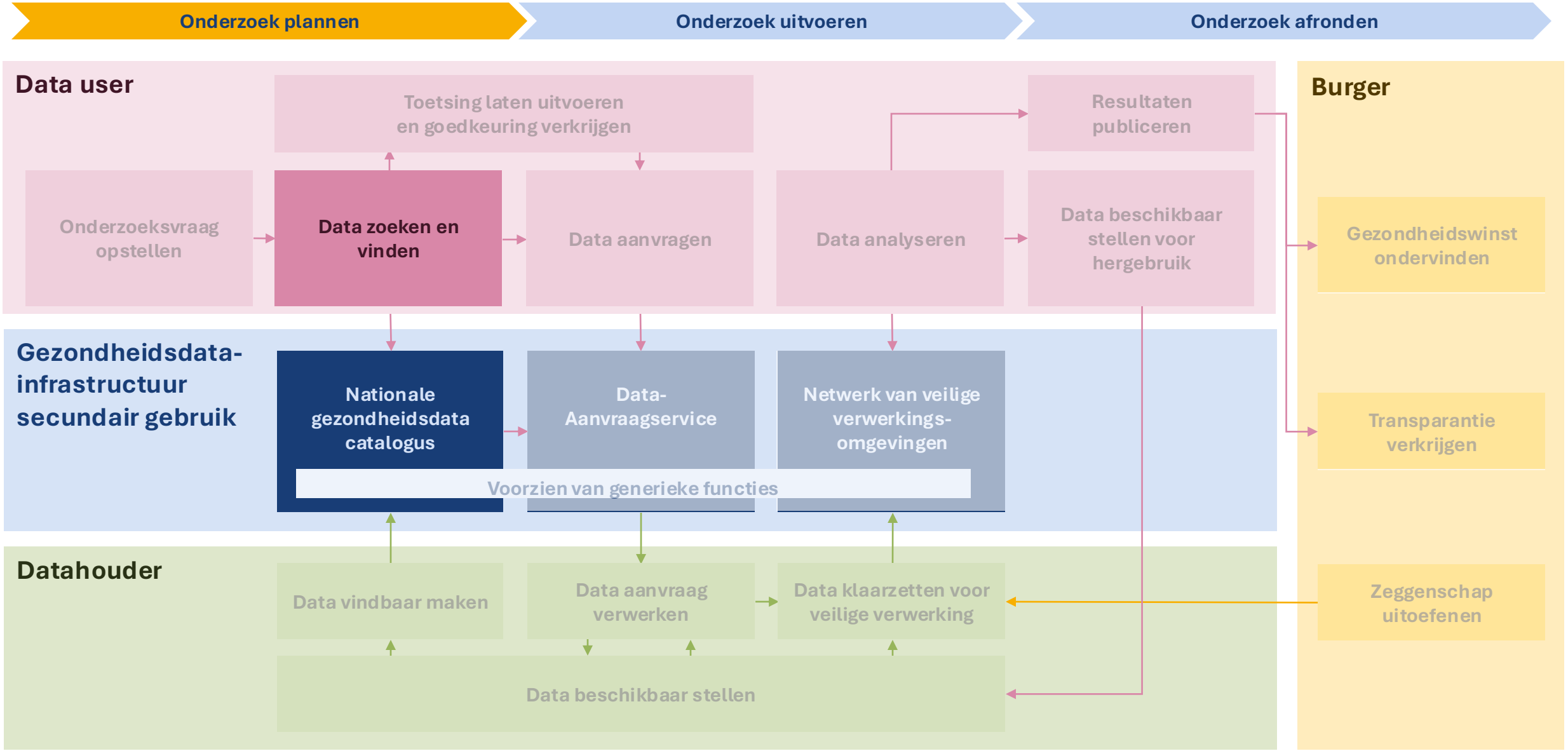
Data Request Service - for a first version of a Data Access Application Management System (DAAMS), the system that can process data requests and data access (permit) requests.

National Health Data Catalogue - For the first version of the national dataset catalogue.

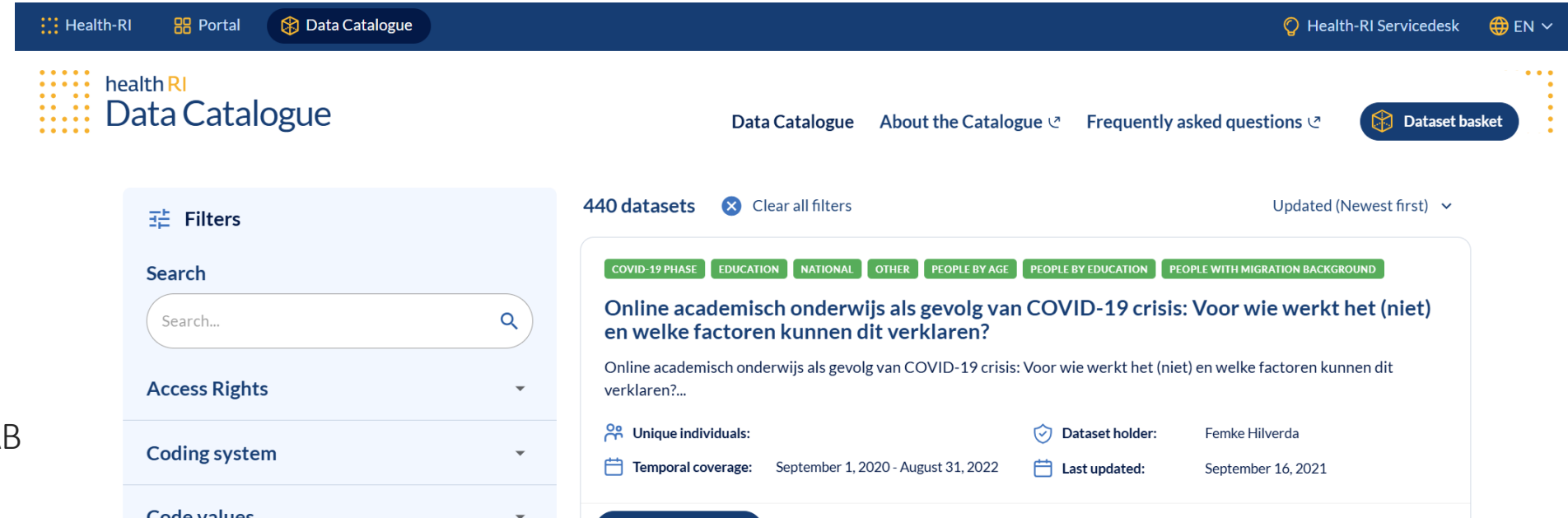
Microdata environment - for a fist version of the Secure Processing Environment (SPE), also testing other SPE's (o.a..anDREa, SURF SANE)

In the configuration phase we have researched and chosen applications. Now they are being configured for testing.




Onderzoek plannen
Onderzoek uitvoeren
Onderzoek afronden
Data user
Toetsing laten uitvoeren en goedkeuring verkrijgen
Resultaten publiceren
Onderzoeksvraag opstellen
Data zoeken en vinden
Data aanvragen
Data analyseren
Data beschikbaar stellen voor hergebruik
Burger
Gezondheidswinst ondervinden
Gezondheidsdata-infrastructuur secundair gebruik
Nationale gezondheidsdata catalogus
Data-Aanvraagservice
Netwerk van veilige verwerkings-omgevingen
Voorzien van generieke functies
Transparantie verkrijgen
Datahouder
Data vindbaar maken
Data aanvraag verwerken
Data klaarzetten voor veilige verwerking
Zeggenschap uitoefenen
Data beschikbaar stellen

Catalogue

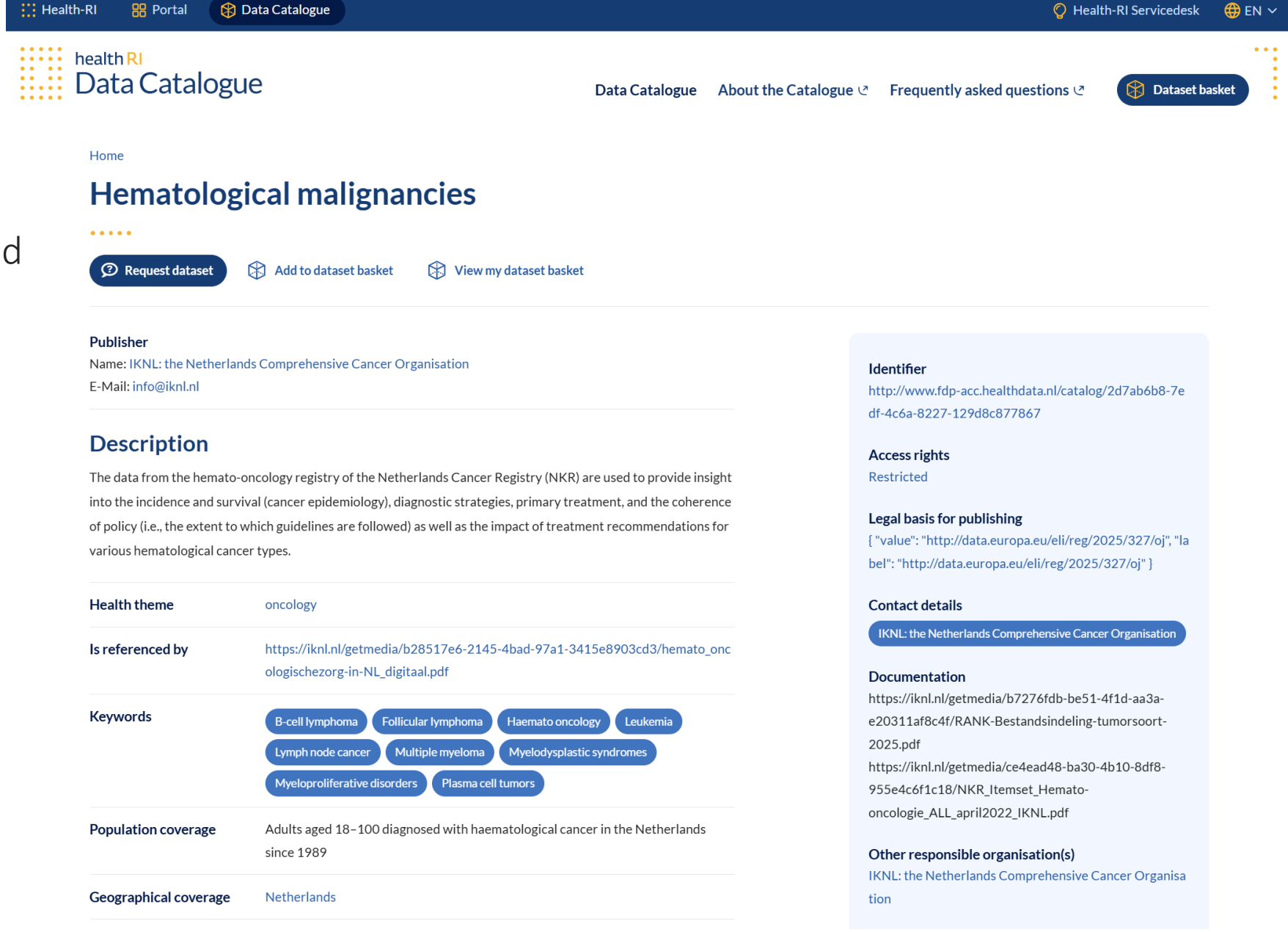


catalogus.healthdata.nl

- Considerations HDAB-NL
  - Available for pilot
  - Transferrable to HDAB
  - Modular approach
    - CKAN back-end
    - FDP
    - FE
- CKAN
  - Open source (pro and con)
  - DCAT-AP (but not fully v3)
  - GDI momentum
- HealthDCAT-AP fields added

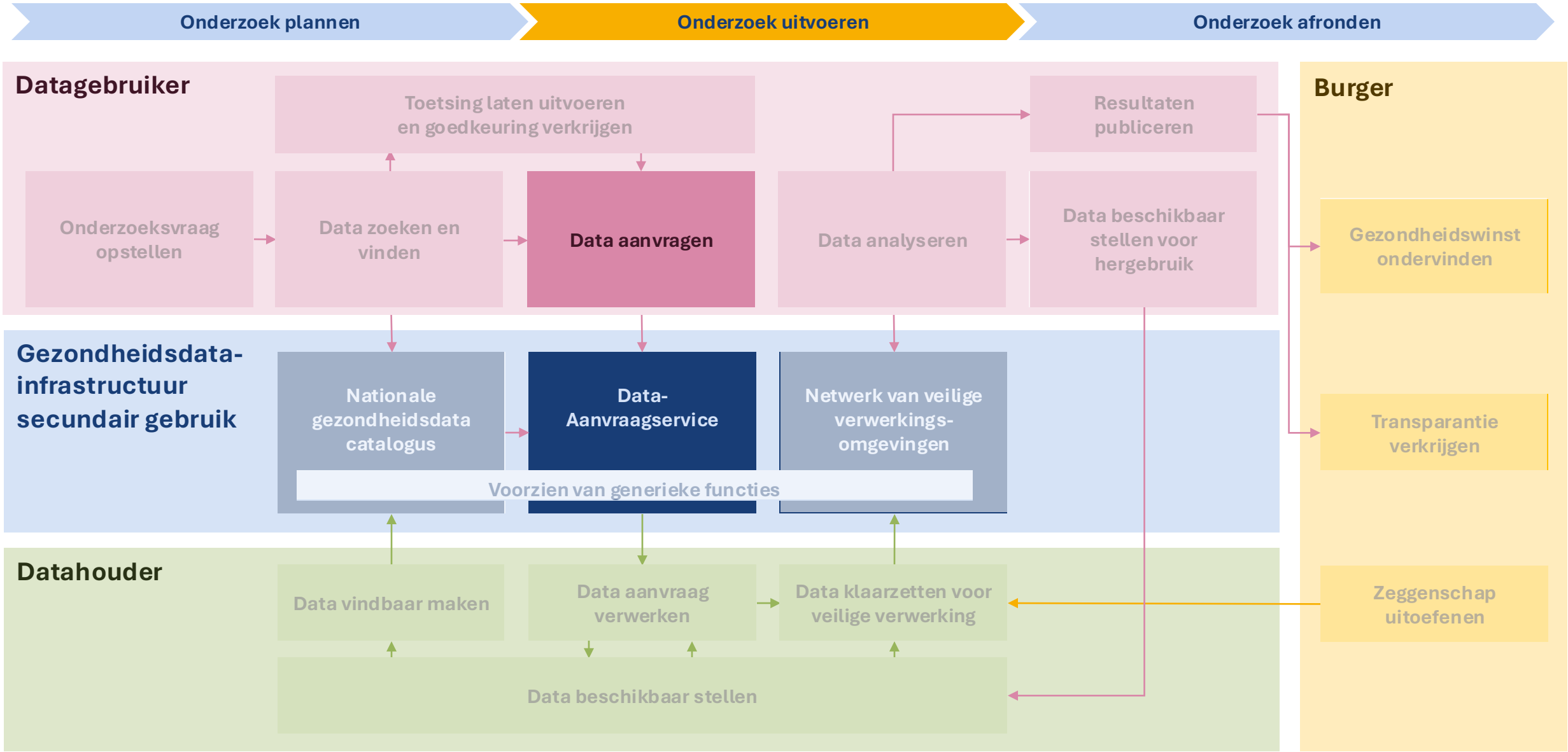
Catalogue

- Details added, filters added
- Some newer HealthDCAT fields will follow after HealthDCAT-AP stability



DAAMS

Secundair datagebruik Health-RI: het proces



DAAMS-NL Solution Approach

MVP

- The DAAMs solution will be developed as a Minimum Viable Product (MVP) to validate core functionality and gather feedback from real-world use cases before scaling to a full production system. The MVP approach enables iterative development, early stakeholder engagement, and risk mitigation through phased delivery.

Low-code

- To accelerate implementation and ensure flexibility, the MVP will be built using a low-code platform (Microsoft Dynamics). This choice supports rapid prototyping, easier maintenance, and adaptability to evolving requirements, while reducing dependency on extensive custom development.

Re-use

- The DAAMS system that is to be developed, will be based on the existing Data Request Service application developed by Health-RI, which already provides foundational capabilities for managing data access requests.

Status of Data Access or Data Request Application and automated flows

ea73c039-bfde-442c-b84e-019462099300 - Unsaved

Request · Data access

Edward Robinson
Owner

Application Business Pro...
Active for 7 days

Received | Pre-Screening | Assessment & Cost Determination | Data Permit/Request Approval | Provisioning (16 Hrs) | Active

Application | Pre-screening | Assessment | Cost determination | Data Permit/Request Approval | Related

← Checklists for HDAB employees

Form assist

Data Access Application

Date added	12-11-2025 15:37
Title	Access Application submitted from Insomnia3
Application ID	ea73c039-bfde-442c-b84e-019462099300
Application type	Data Access Application
User ID	sanne.de.vries
Application created	22-9-2025 12:30
Application modified	2025-09-22T10:30:00Z
Version	2

Timeline

Search timeline

Enter a note...

Section 6. Description of the data needed

Country ID	NL
HDAB Contacts	Health-RI data steward team
How Data From Different Sources Will Be Linked	Using pseudonymized patient identifiers across datasets.
Person Profile Data Date	22-9-2025 12:30
How the Study Cohort Is Formed	Registry-based selection
Has the study cohort been formed based on information of study participants?	Yes
Does the informed consent cover the requested registry extractions?	Yes
Consent and Information Letter Attachment	Choose File No file chosen
Confirmation That Data	Nee

JSON request received from HealthData@EU portal parsed as case

And much more! More information?

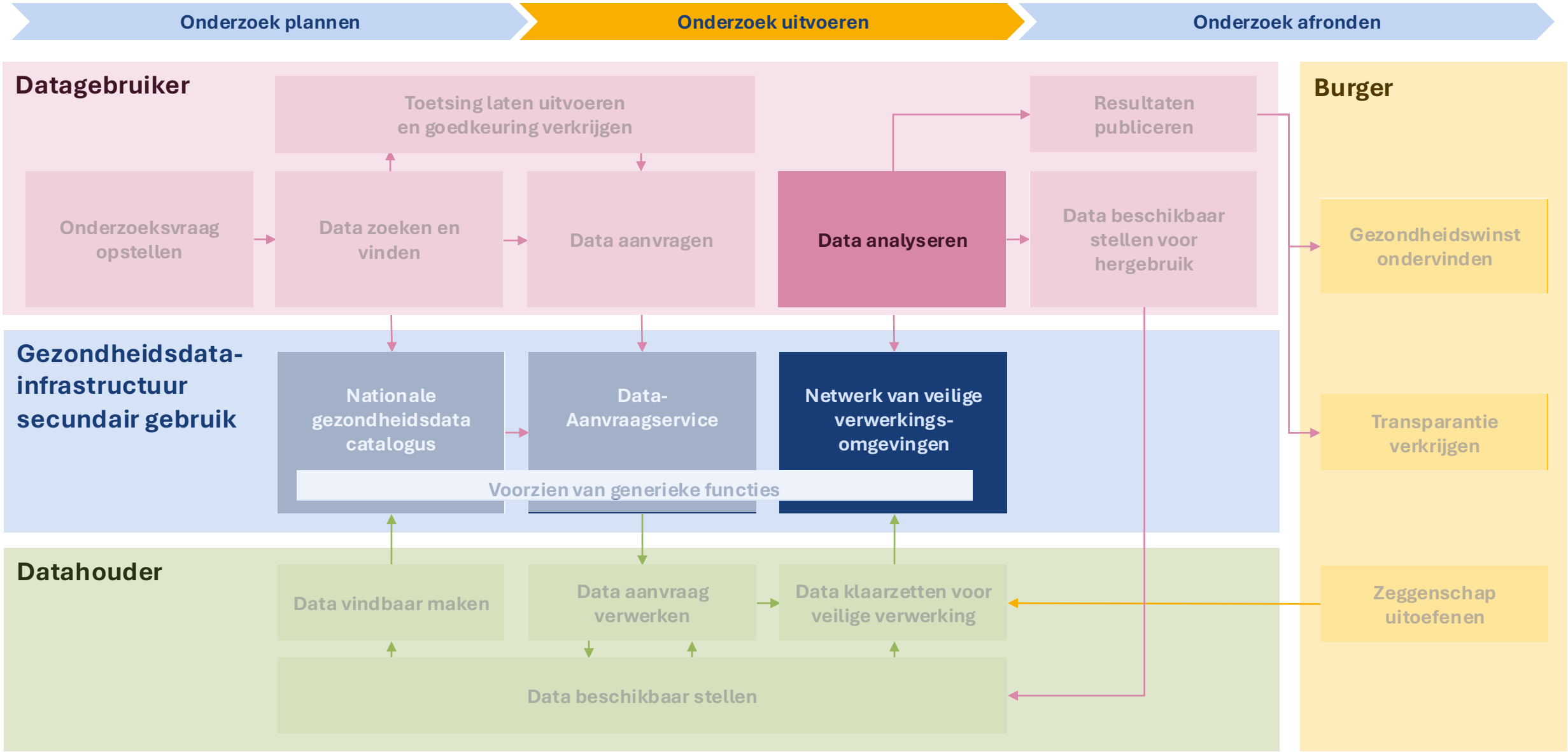
Edward Robinson
Edward.Robinson@health-ri.nl

Mind the gap

- Prior to Data permit application / data request, a series of interactions is needed between data user and data holder:
  - What is the fit-gap with the research question?
  - What (part of) the data is suitable?
  - What to fill in in the request or permit application – taking into account data minimization? (sharing the forms to both data user and data holder?)

SPE

Secundair datagebruik Health-RI: het proces



Secure Processing Environment

Testing with already available products:

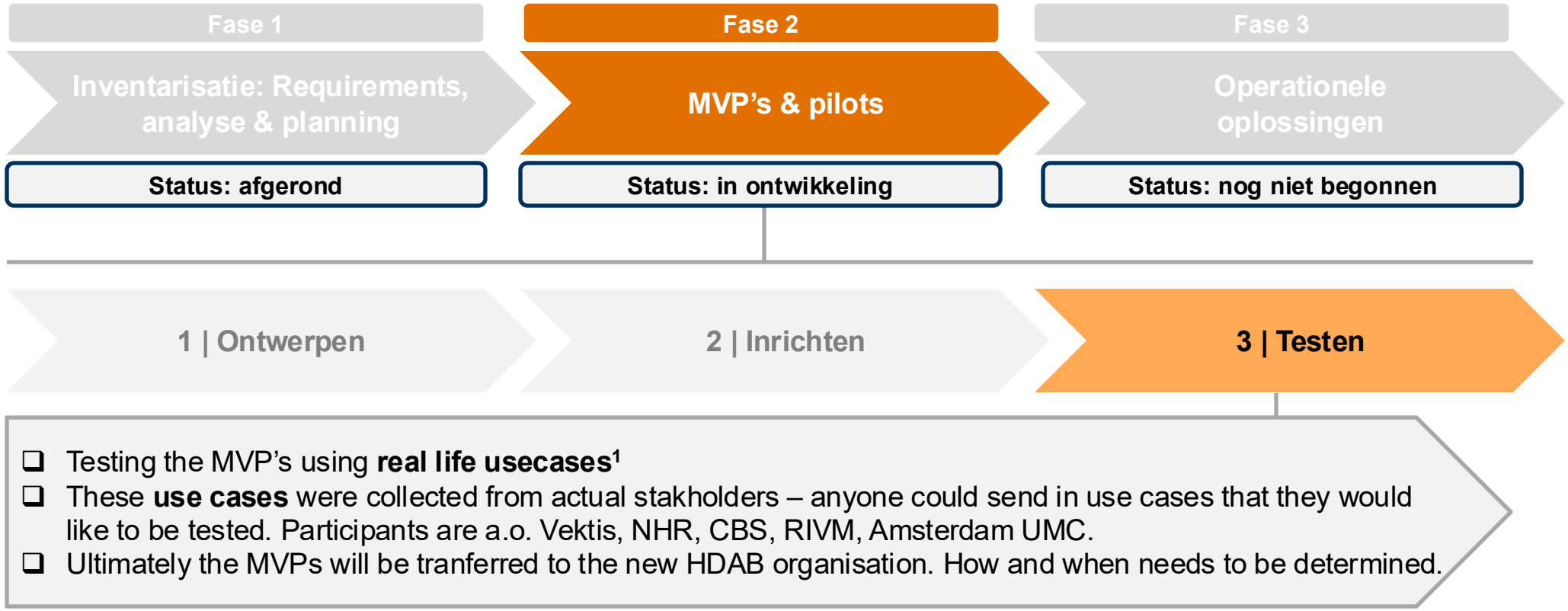
- Microdata environment (National Bureau of Statistics)
- SURF SANE
- AnDREa

In the end working towards a network of validated SPEs, nationally and internationally

To test: How will data preparation work cross-border, and with the European SPE?

Next Steps

In January and February we will test the process with 7 selected use cases, using the applications as far as they can already be connected. Mocking the interfaces where needed.



1) 'Real life usecaes' moeten overeenkomen met realistische scenario's die in de praktijk kunnen plaastvinden. Tegelijk moeten ze geschikt zijn voor het testen van een **minimal** viable product en hoeven ze niet overeen te komen met 'de meest complexe scenario's die we kunnen bedenken'

HealthData@EU

Delivery Timeline

2024 JAN	2024 JUL	2024 OCT	2025 JAN	2025 MAY	2025 SEP	2026 JAN	2026 MAY	2026 SEP	2027 JAN
Release 0	Release 1	Release 2	Release 3	Release 4	Release 5	Release 6	Release 7	Release 8	Release 9

Objective of Release 6

Release 6 will focus on enabling seamless interaction between the HealthData@EU Central Platform and Member States' Data Access Application Management Systems (DAAMS). This release will introduce key interoperability features to support application status exchange, bidirectional communication, and decision management.

Planned features

The planned features include:

- Enabling the HealthData@EU Central Platform to receive detailed DAAMS status updates via the National Contact Points (NCPs).
- Supporting message exchange between users and Health Data Access Bodies (HDABs) through the platform and NCPs.
- Allowing users to modify submitted Data Access or Data Request Applications upon HDAB request.
- Displaying final application decisions (positive or negative) transmitted by the NCP on behalf of the HDAB directly in the user's profile.
- Creating a European registry of Data Access and Data Request decisions.
- Allowing users to request amendments to a positive Data Access Decision (Data Permit).
- Allowing users to submit appeals following negative Data Access or Data Request decisions.

https://acceptance.data.health.europa.eu/healthdata-central-platform/home?locale=en

cumuluZ .org

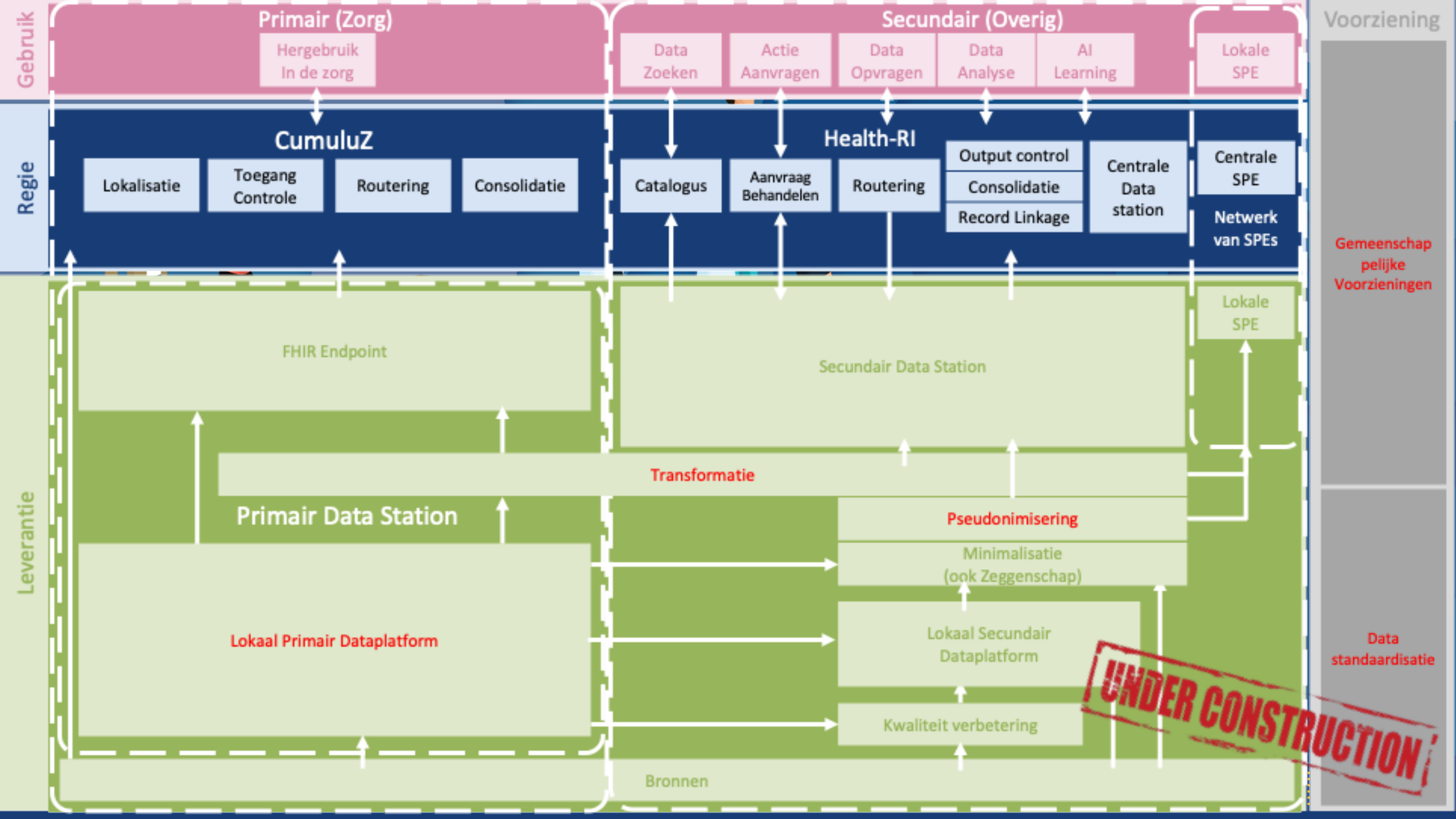
Primair

health RI

enabling data driven health & life sciences

Secundair

Landelijk Dekkend Netwerk


Gebruik
Regie
Leverantie
Voorziening
Primair (Zorg)
Hergebruik In de zorg
Secundair (Overig)
Data Zoeken
Actie Aanvragen
Data Opvragen
Data Analyse
AI Learning
Lokale SPE
CumuluZ
Lokalisatie
Toegang Controle
Routering
Consolidatie
Health-RI
Catalogus
Aanvraag Behandelen
Routering
Output control
Consolidatie
Record Linkage
Centrale Data station
Centrale SPE
Netwerk van SPEs
FHIR Endpoint
Secundair Data Station
Lokale SPE
Transformatie
Primair Data Station
Pseudonimisering
Minimalisatie (ook Zeggenschap)
Lokaal Primair Dataplatform
Lokaal Secundair Dataplatform
Kwaliteit verbetering
Bronnen
Gemeenschappelijke Voorzieningen
Data standaardisatie
UNDER CONSTRUCTION

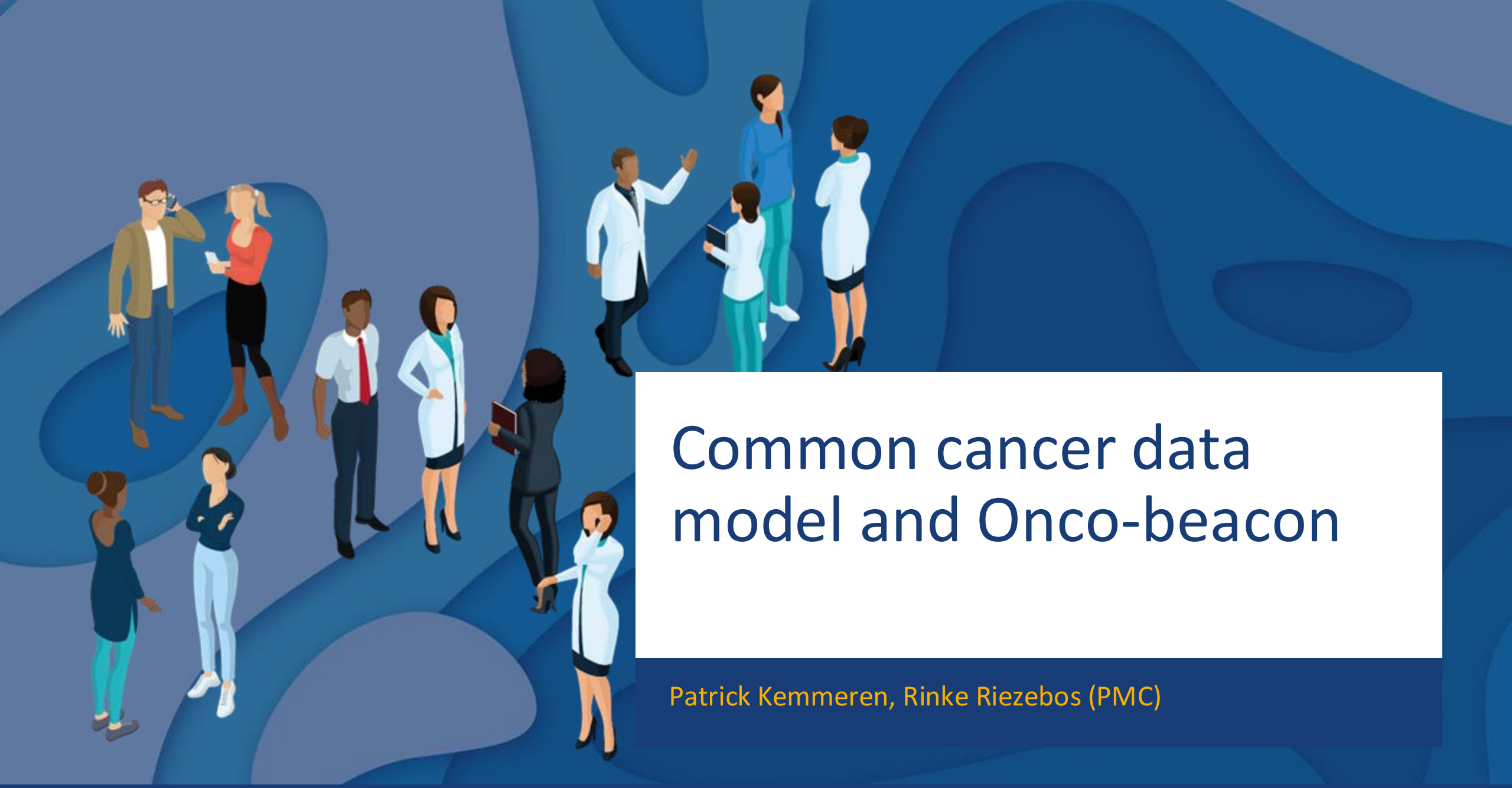
Questions?

Marianne Knoop Pathuis - Baarda

Senior Productmanager for the Catalogue at Health-RI

Lead Work Package 6 – Catalogue in HDAB-NL Direct Grant project

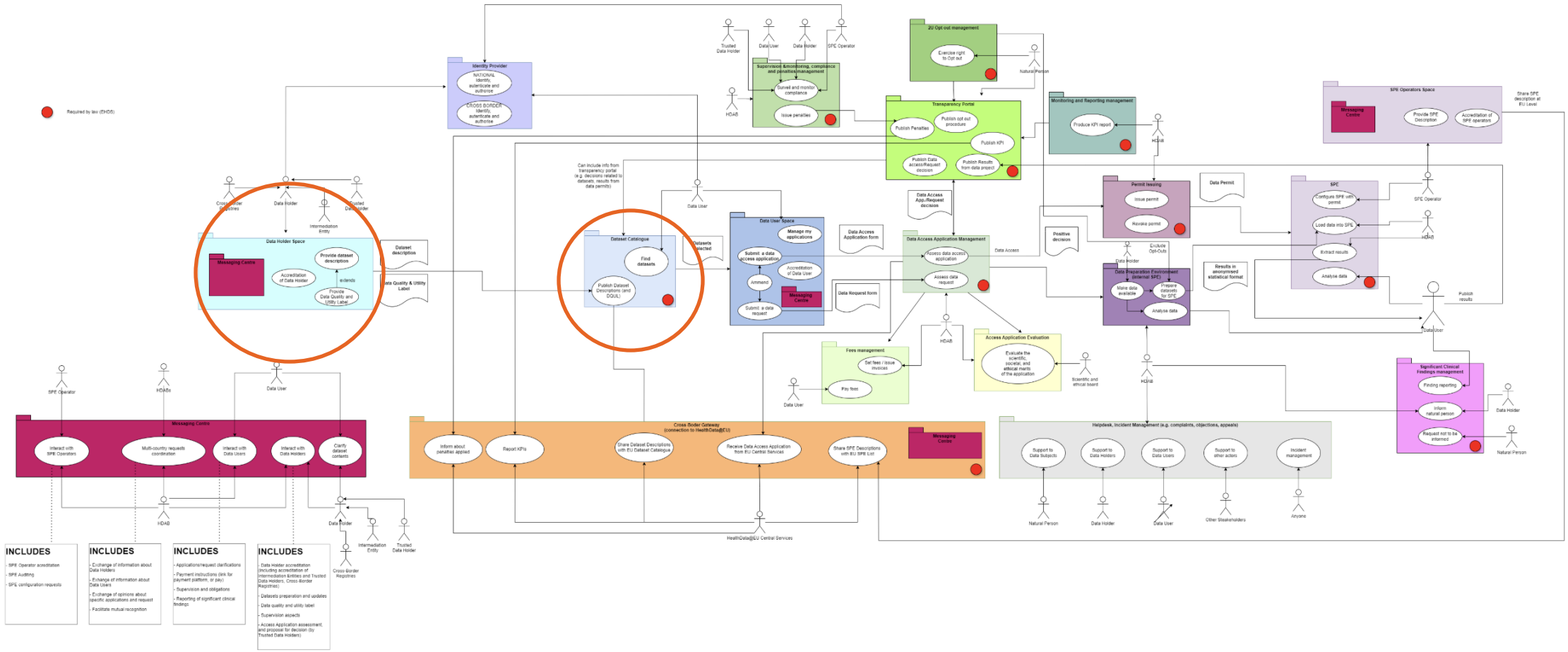
Marianne.knoop@health-ri.nl



Common cancer data model and Onco-beacon

Patrick Kemmeren, Rinke Riezebos (PMC)

Backbone


Identity Provider
Supervision &monitoring, compliance and penalties management
Transparency Portal
Monitoring and Reporting management
Permit issuing
SPE Operators Space
Data Holder Space
Dataset Catalogue
Data User Space
Data Access Application Management
Fees management
Access Application Evaluation
SPE
Data Preparation Environment (internal SPE)
Significant Clinical Findings management
Messaging Centre
Cross Border Gateway (connection to HealthData@EU)
Helpdesk, Incident Management (e.g. complaints, objections, appeals)
INCLUDES
INCLUDES
INCLUDES
INCLUDES

Overarching aim

Establish recommendations and agreements on the use of a **common ~~data~~ interoperability model** (CIM) to foster data interoperability for **secondary use** in **oncology**

Key principles

- Is focused on secondary use of oncology data
- Is an umbrella model that reuses existing internationally established models
  - openEHR, FHIR, OMOP, CDISC
- Supports single and multi patient/sample queries
- Is never going to be perfect, 80/20 rule is key
- Supports a few selected use-cases for practical usage

User stories

User stories should drive the use-cases

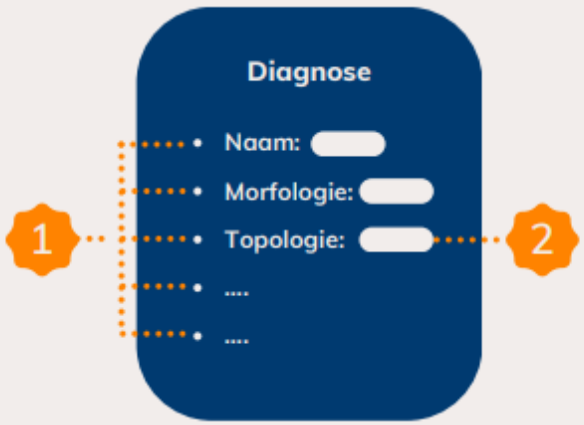
As a **clinician**, I want a data-driven tool that offers personalized treatment recommendations using clinical guidelines, patient data, trial eligibility, and outcomes from similar cases, to inform my decision for tumor board discussions.

As a **(biomedical) researcher**, I want to use sequencing data in combination with medical imaging, histopathology and clinical data to investigate which molecular and cellular characteristics relate to different cancer types, outcome and quality of life.

As an **epidemiologist**, I want ….

Standardise and communicate

We maken onderscheid tussen twee typen standaarden:



1 Modeleringstandaard
Wat leggen we vast?

Bepaalt de structuur voor vastlegging, zodat informatie consistent en overzichtelijk terug te vinden is.

2 Coderingstandaard
Hoe leggen we het vast?

Zorgt voor eenduidige vastlegging van termen, zodat dezelfde "taal" wordt gebruikt

Dit is een infographic van het volledige verslag: "registraties en standaarden in het Máxima"

1 Modeleringstandaarden

Welke en hoe passen we deze toe?

De meest gebruikte (inter)nationale modeleringstandaarden* en hoe deze worden toegepast in het Máxima.

*Preklinische standaarden worden later toegevoegd

1.1 OpenEHR

Focust zich op het vastleggen breed scala aan generieke en specialistische klinische gegevens voor langdurige opslag.

- Hoge dekking breed toepasbaar
- Consistente structuur
- Flexibel & robuust

1.2 FHIR

Richt zich op structuur voor uitwisseling en deling klinische en administratieve gegevens om interoperabiliteit te bevorderen.

- Hoge interoperabiliteit
- Gestandaardiseerde formats
- 80/20 regel voor dekking

1.3 Zibs

Richt zich op zorginformatie binnen de Nederlandse zorg, met als doel eenduidige en herbruikbare gegevensmodellen

- Nederlandse focus
- Niet volledig dekkend
- Opgenomen in de Wegiz

1.4 OMOP

Focust zich op een uniform datamodel voor het vastleggen van gegevens ten behoeve van observationele studies en onderzoeksdoeleinden.

- Gestandaardiseerd datamodel
- Ondersteunt onderzoek
- Hoge interoperabiliteit

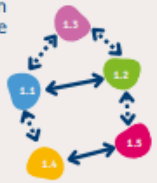
1.5 CDISC

Focust zich op het uniform vastleggen en uitwisselen van klinische studiegegevens in farmaceutisch en biomedisch onderzoek.

- Efficientie in gegevens analyse
- Regelgevende acceptatie
- Strikte structuur

Mapping is (deels) mogelijk

Sommige standaarden kun je mappen voor eenduidige en bruikbare uitwisseling van informatie.



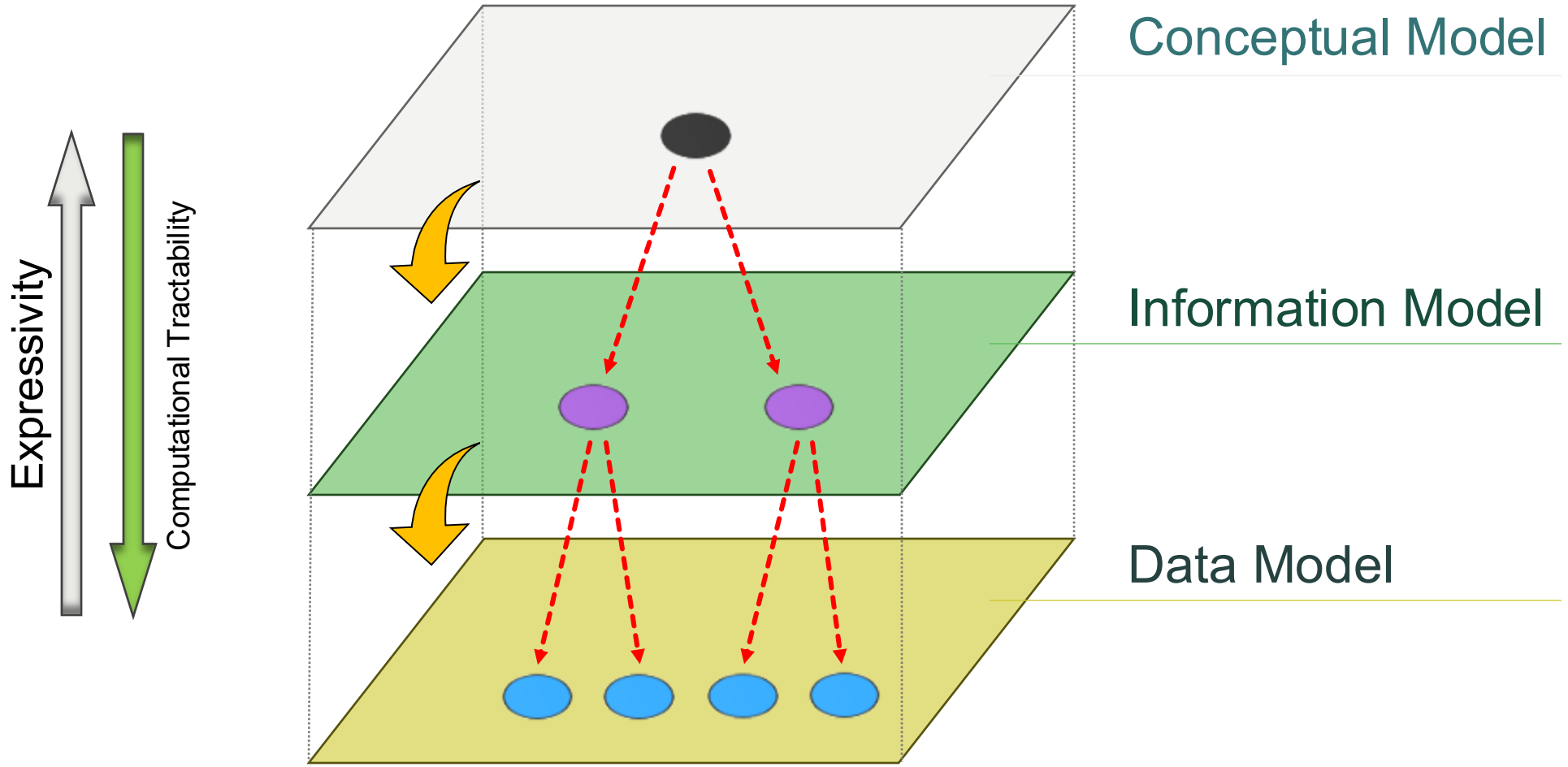
Deels
Volledig

Wat gebruiken we in het Máxima?

Afhankelijk van het doel gebruiken we één of meerdere standaarden.

- **OpenEHR:** wordt o.a. gebruikt door TDC en IDT voor structureren van klinische data en ontwikkeling van evaluatie en beslisalgoritmen
- **CDISC:** worden gebruikt voor Intended-to-File studies die o.a. ingediend worden bij FDA
- Zibs: t.b.v. VIPP 5 programma voor uitwisseling in bgz

Model-driven development



An inhouse example

Van domeinbegrip tot implementatie: 3 modelleerlagen

Elke laag bouwt voort op de vorige: het informatiemodel geeft betekenis, het logisch model vertaalt dit naar datastructuur, en het fysiek model zorgt voor opslag en vindbaarheid.

Informatie model*

Wat is de betekenis?

Doel: Alle betrokkenen dezelfde interpretatie hebben van gegevens en wat erbij hoort

Wat is het: Beschrijving van de structuur en betekenis van de informatieobjecten en terminologie in een bepaald domein.

Gemaakt door:

- Zorgverleners, domeinexperts
- klinisch informatici & informatiemanagers

Voorbeeld: wat is een diagnose, welke informatie heb je nodig?

Logisch datamodel

Hoe slaan we dit gestructureerd op?

Doel: De gegevens logisch structureren voor ontwerp en implementatie, zodat systemen/analisten ermee kunnen werken.

Wat is het: Een ontwerp van een datastructuur uitgedrukt in entiteiten, attributen, datatypes, technische sleutels, relaties en dataregels.

Gemaakt door:

- Data-architecten,
- Data analisten,
- Informatieanalisten, klinisch informatici

Voorbeeld: Hoe modelleren we "diagnose" voor in een database?

Fysiek datamodel

Hoe staat dat in de database?

Doel: De gegevens daadwerkelijk opslaan in een systeem of database, zodat ze beschikbaar zijn voor gebruik, query's en analyse.

Wat is het: De technische implementatie van het logisch datamodel, inclusief bestandsindeling, opslagformaat, indexen etc.

Gemaakt door:

- Databasebeheerders
- Developers
- Data-engineers

Voorbeeld: Hoe wordt "diagnose" precies opgeslagen in de database?

Focus van projecten: KIS — CSR

Ter info – voor nu buiten scope

*Lijkt erg op het begrip conceptueel datamodel, voor simpliciteit deze laag niet meegenomen

An inhouse example

Way forward – gekozen oplossingsrichting

Gekozen oplossingsrichting:

Centraal informatie model

Wat is de betekenis?

KIS als centraal informatie model

- **KIS wordt uitgebreid** met bouwstenen/templates benodigd preklinisch (bijv. biomaterial)
- Valideren en/of aanpassen bouwstenen met nieuwe stakeholders
- Betrekken/uitbreiden KIS team met nieuwe stakeholders

In lijn met elkaar

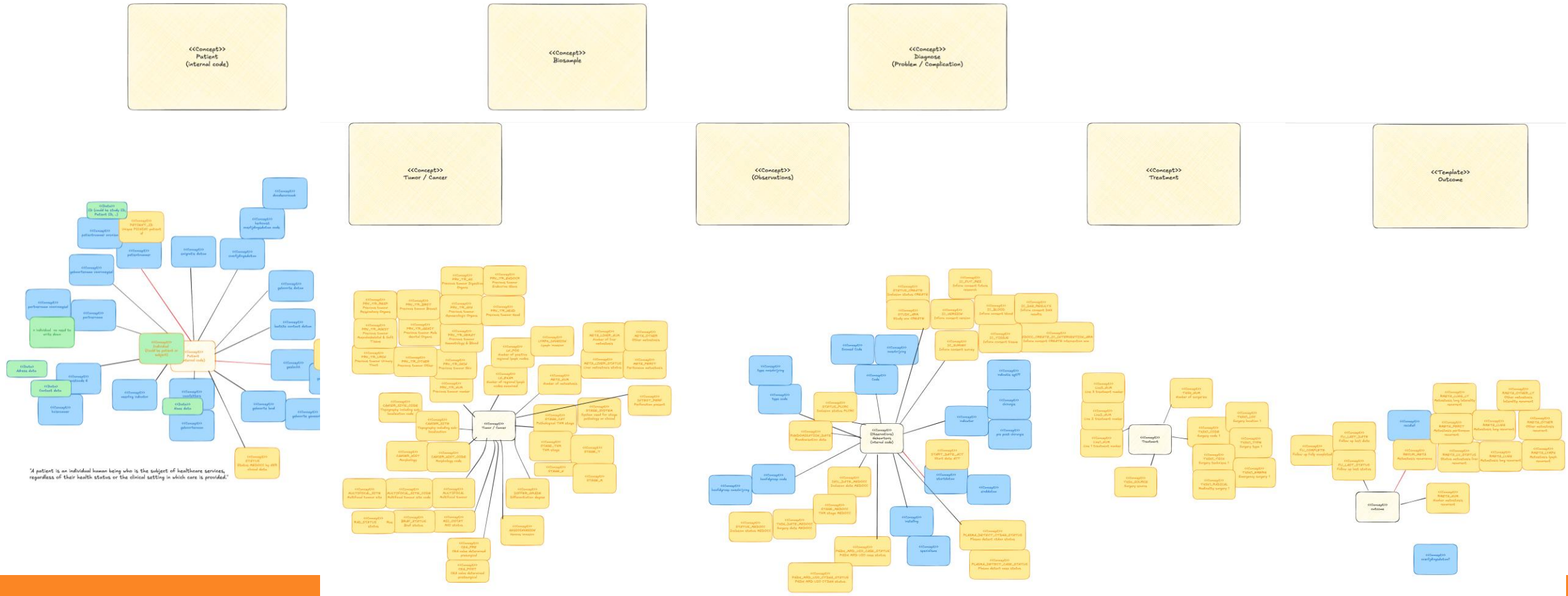
Common data model

Hoe slaan we dit gestructureerd in de database?

Pragmatisch naar één common data model (logisch)

- Eén logisch datamodel voor kinderoncologie (Máxima)
- **CSR wordt uitgebreid** met KIS als kaders voor één centraal datamodel (logisch)
- Pragmatische insteek, uitgangspunt alle entiteiten centraal. Mocht dit niet passend zijn, altijd nog de mogelijkheid om via mappingen aparte entiteiten te definiëren.

Alignment oncology core concepts



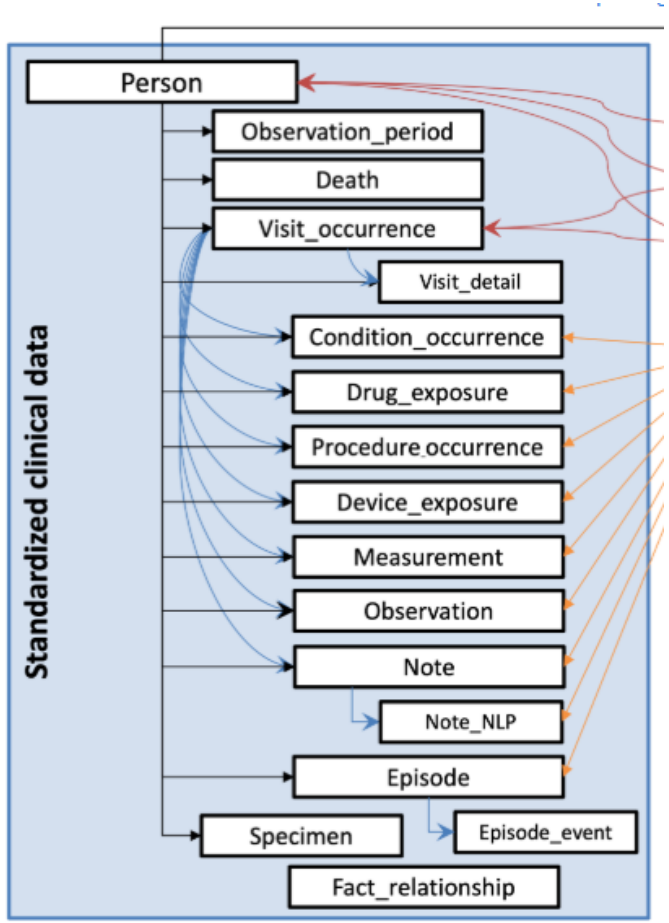
Focus on core concepts & mapping to existing standards

Highest level of classes in the data model

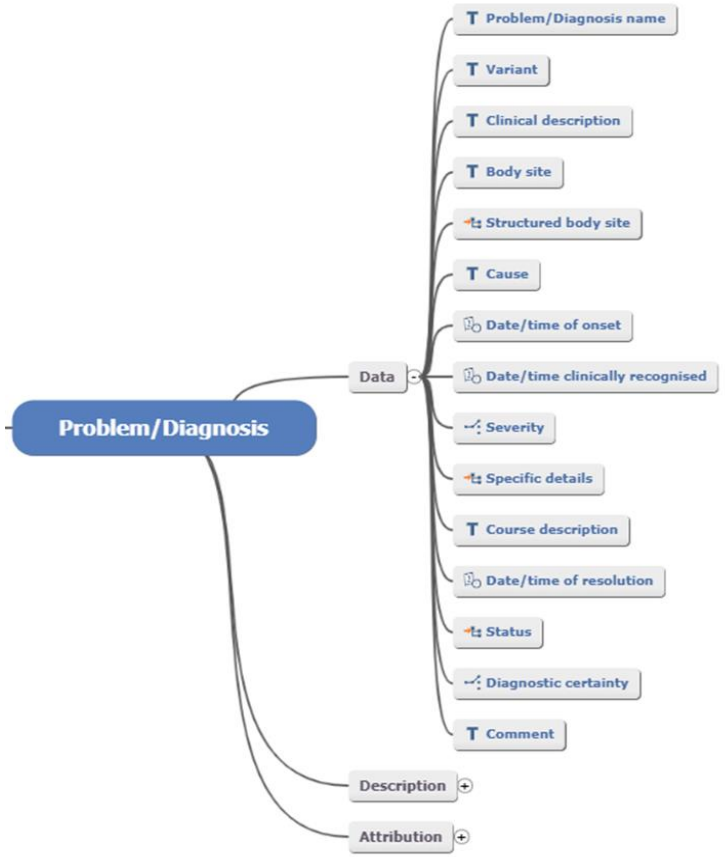
1+MG-MDC		OMOP		mCODE FHIR		AACR GENIE	
Domain	Item description	Domain	Item description	Domain	Item description	Domain	Item description
1_SUBMITTER	Information about the data submitter						
2_PATIENT	Cancer patient's personal information and demographics	PERSON	(Information about the person)	Patient Information Group	Patients demographics	Patient Demographics	Patient demopgraphics, sequencing biosample information) + Social Determinants of Health
3_SEQUENCE	Details of the DNA sequence (useful for grouping purposes based on technology and protocols and to account for technical differences and possible biases)	EPISODE	(aggregates lower-level clinical events into a higher-level abstraction representing clinically and analytically relevant disease nhases.outcomes and treatments.)	Disease Characterization Group	The mCODE Disease Characterization group includes data elements specific to the diagnosis and staging of cancer.	Cancer Diagnosis (by Dx)	Cancer diagnosis and tumour staging
4_SAMPLE	Details about the source (i.e., normal tissue, primary cancer, metastasis) of the analysed genomic material	EPISODE EVENT	(connects qualifying clinical events to the appropriate EPISODE entry.)	Health Assessment Group	The mCODE Assessment group contains information related to the patient's general health, before and during treatment.	Imaging	Type of imaging technique, disease status according to imaging
5_DISEASE_CANCER	Cancer disease description (histology, staging, and grading) to be reported for each cancer-related event	CONDITION OCCURENCE	(records of Events of a Person suggesting the presence of a disease or medical condition stated as a diagnosis, a sign, or a symptom, wnier is either observed by a Provider or reported by the patient.)	Genomics Group	mCODE includes genomics-related data elements needed to inform cancer assessment and treatment options.	Clinical Visits	Clinical visits - follow-up
6_DISEASE_COMORBIDITY	Co-occurring medical conditions other than cancer	PROCEDURE OCCURENCE	(activities or processes ordered by, or carried out by, a healthcare provider on the patient with a diagnostic or therapeutic	Cancer Treatments Group	The Treatment group includes reporting of procedures and medications used to treat a cancer patient, or relevant to that treatment. Treatments fall into three classes: medications, surgery, and radiotherapy.	Procedures	Procedure type, intent
7_TREATMENT	Therapeutical interventions for cancer and comorbidities	MEASUREMENT	(structured values, numerical or categorical, obtained through systematic and standardized examination or testing or a Person ol Person's sample - predominately lab tests with a few exceptions, like blood pressure or function tests.	Outcomes Group	Recording patient outcomes in mCODE involves disease status, tumor size, and date of death.	Treatments	Treatment types,medications, toxicities
8_TREATMENT_CANCER_SURGERY	Surgical procedures for cancer	DRUG EXPLOSURE	(drug exposure)			Labs and Biomarkers	Lab test used, results
9_TREATMENT_CANCER_CHEMOTHERAPY	Chemotherapy for cancer					Outcomes	Follow-up information, outcome data
10_TREATMENT_CANCER_RADIATION_THERAPY	Radiation therapy for cancer						
11_TREATMENT_CANCER_HORMONAL_THERAPY_AND_BIOLOGICAL_THERAPY	Hormonal therapy and biological therapy (including immunotherapy, targeted therapy,..) for cancer						
12_ENVIRONMENTAL_EXPOSURE	Exposure to environmental factors for which an association with cancer is established (or reported)						
13_BIOMARKER	Biomarkers with clinical value						

Identificeren van informatiebouwblokken

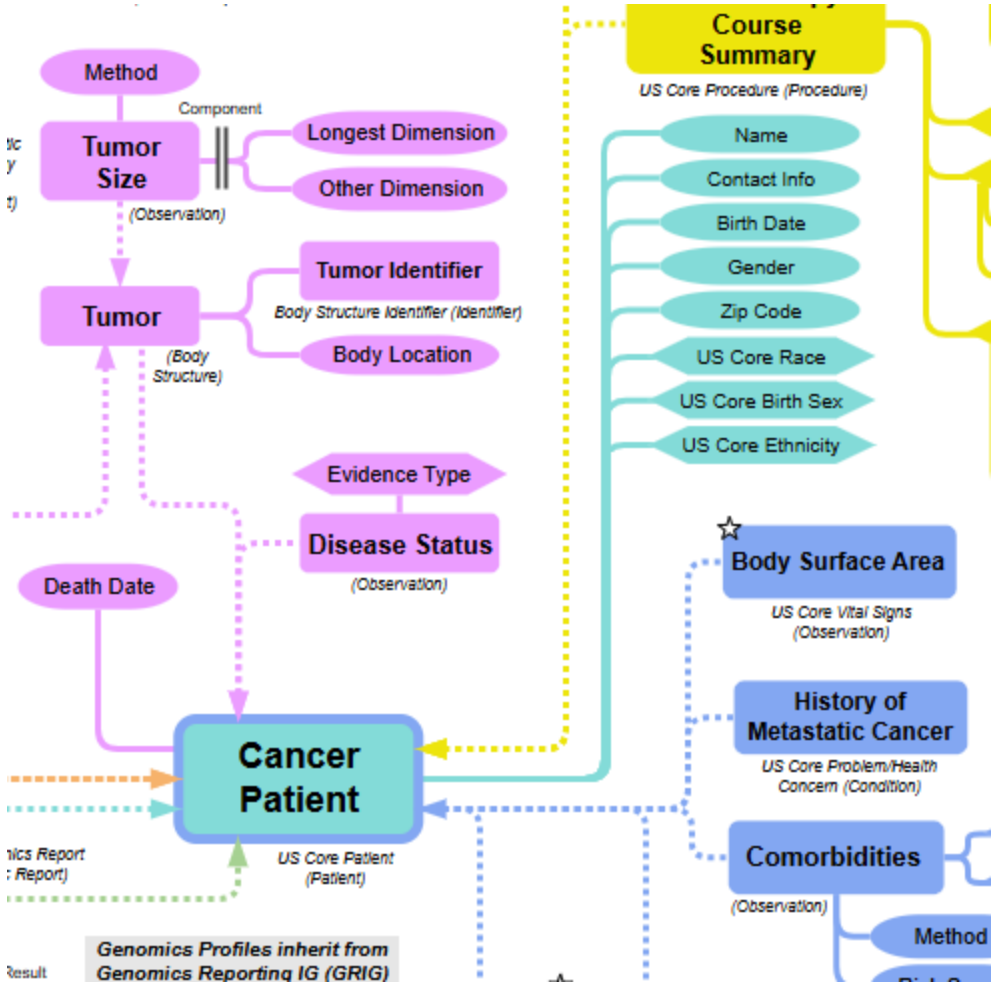
OMOP Common Data Model



openEHR



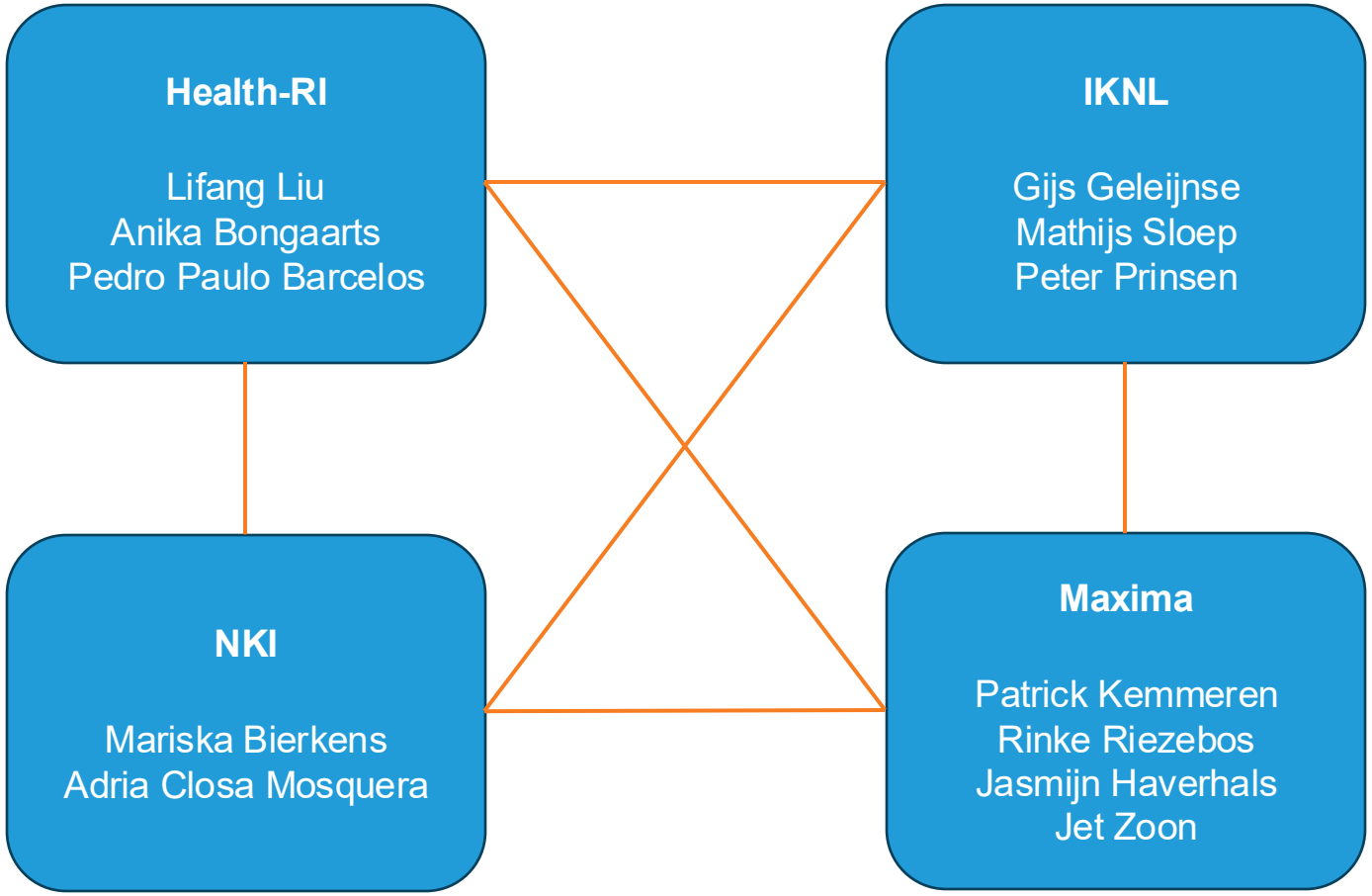
mCODE STU 4



Next steps

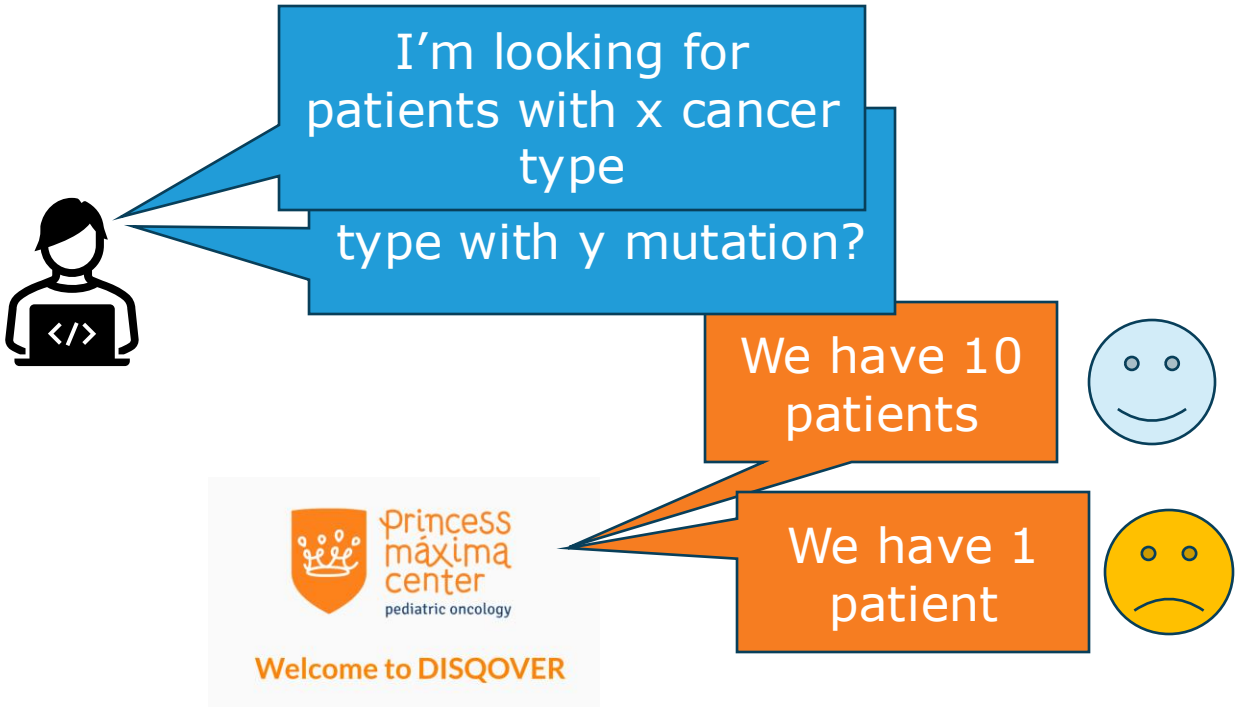
- Version 1.0 (almost) ready to be further shared
- Mapping (and overarching) to existing international standards: openEHR, HL7-FHIR, MG1+, OMOP
- Run actual use-case with NKI, IKNL & PMC

Core CIM working group



OncoBeacon: a federated catalog for integrated clinical and molecular cancer data

Hinri Kerstens



What would the answer have been if we could ask the question globally?

Federated data, the cancer use case

Cancer is a leading cause of disease related death worldwide.

- Most drugs don’t work well
  - ~30% response rate is considered good
  - molecular mechanisms are not fully understood

- We need statistical power to find new biomarkers for (non)response
  - clinical trials hampered due to the low number of (known) cases
  - data lives in silos
  - need integrated clinical and molecular data

Survival rates have increased over the past decades but are still low in particular for some very rare malignancies.

Aim: build a (inter)national (NL) beacon genomics network

Context:

- no top down national (govt) omics agenda
- grass-roots ‘data-holder’ initiative supported by GDI/Health-RI

Outcomes:

- Discover and integrate datasets
- Scalable searching
- Harmonised data structures & ontology usage

Finding federated data? Beacon

An API specification for genomic/phenoclinical data discovery while ensuring privacy, developed by GA4GH

- request/response format
- biological data format

Beacon Components

”Beaconized” dataset

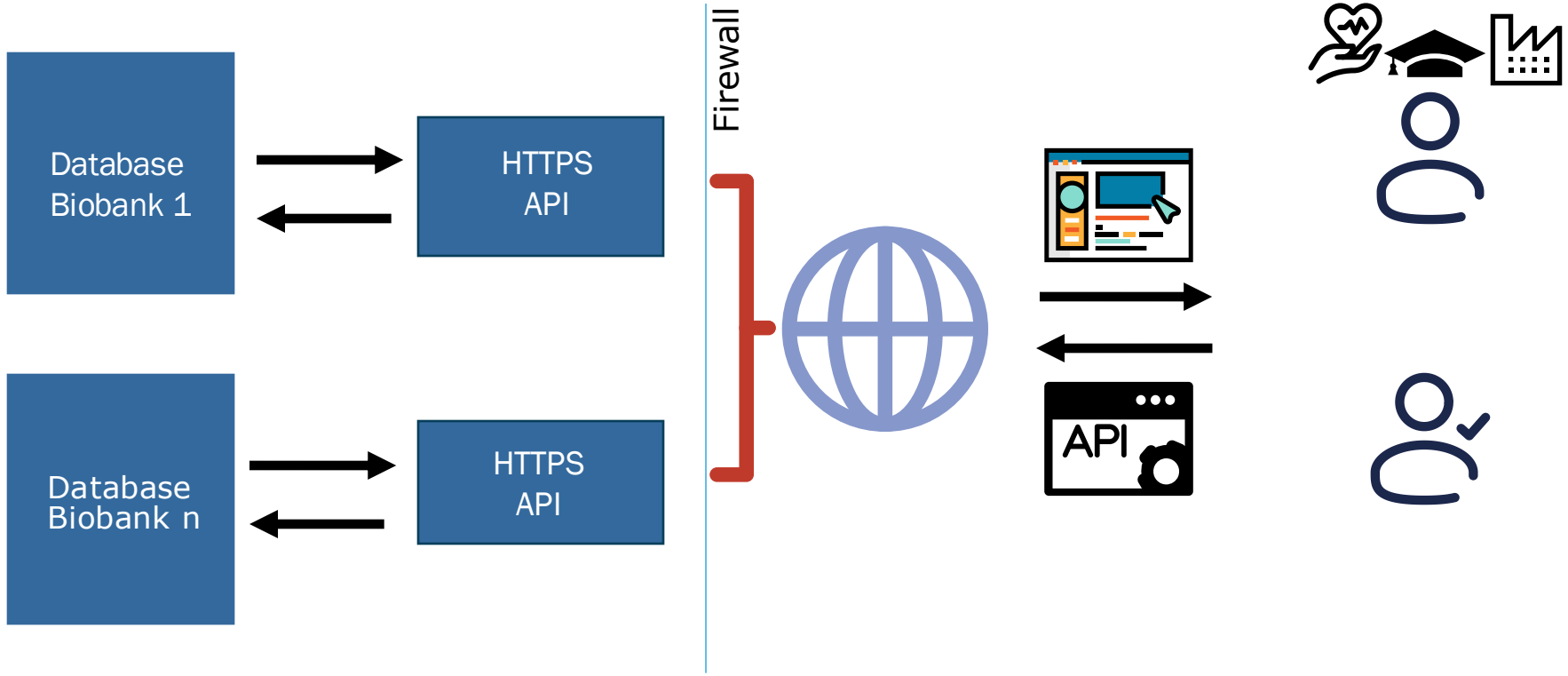
Cohorts >50 (3 required)
- Cohort metrics
- Cohort design
- …

Individuals >80 (2 required)
- Sex
- Diseases
- PhenotypicFeatures
- …

Biosamples >50 (3 required)
- Origin (tissue)
- Status (tumor/normal)
- Individual
- …

Analyses 10 (3 required)
- Pipeline
- Biosample
- …

genomicVariations >150
- Variant type
- Case level data
- Individual
- …



Database
Biolological data is structured similar to reference model

Standardized Request &response
Language agnostic
Tiered access

Beacon Network
Distributes queries aggregates results

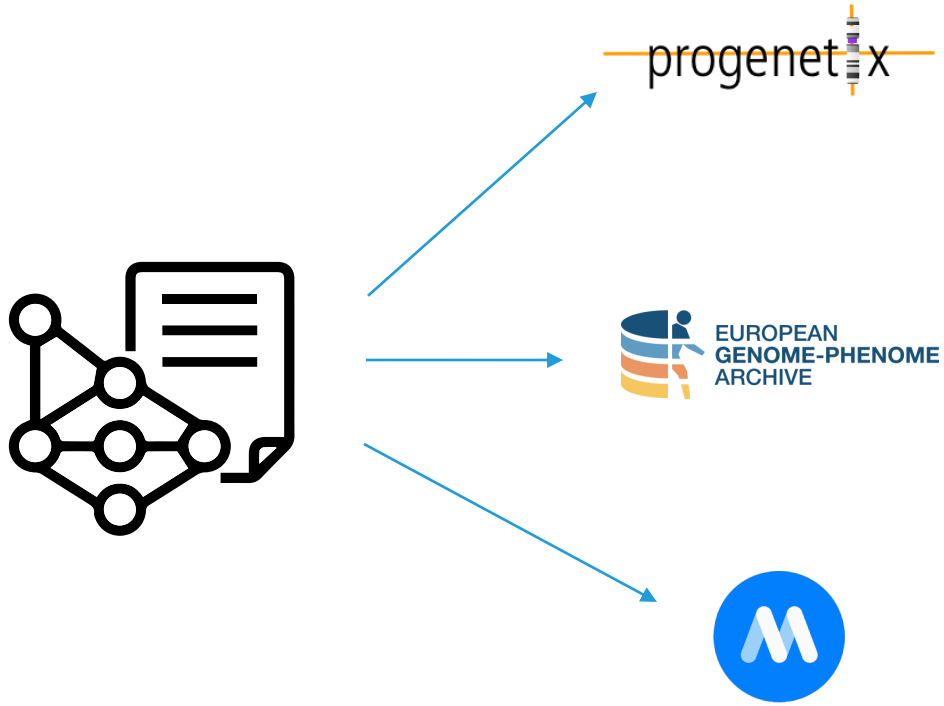
User authentication
Access granularity

One specification, multiple implementations

Preference based on technical requirements

	Progenetix	BeaconV2-pi	Molgenis
Permission granularity	Yes	Yes	Yes
Data access granularity	Experimental	Dataset level	Database level
Federated authentication	No	Yes	Yes
Coding style	Less structured	Structured, object oriented	Structured, object oriented
Code comments	Lacking	Lacking	Few
Unit Testing (framework)	Few	Yes	Yes
Logging/exception handling	Few	Yes, stepwise	Yes
Documentation	Incomplete	Near complete	Near complete
Ingestor/Beaconizer	Yes	beacon2-ri-toolsv2	No
Containerized deployment	No	Yes	Yes
Configurability	Hard	Easy	Intermediate

And to what extent platforms adhere to the specifications



Synthetic data

Beacon platforms

Standard queries at all complexity levels

EUROPEAN
GENOME-PHENOME
ARCHIVE

Not perfect
Closely matches expectations/specifications
Code lends itself to further development/improvement

The ability to map cancer genomics attributes

Feature	Progenetix	BeaconV2-pi	Molgenis
Tumor (neoplastic)	biosampleStatus	biosampleStatus	PathologicalState
ICDO morphology	icdoMorphology	histologicalDiagnosis?	IndividualsDiseases.diseaseCode
ICDO topography	icdoTopography	sampleOriginType?	sampleOriginType?
Pathological stage	pathologicalStage	pathologicalStage	
Tumor grade	tumorGrade	tumorGrade	
Primary/relapse/metastasis	tumorProgression	tumorProgression	IndividualsDiseases.stage
Cancer of unknown primary	histologicalDiagnosis.value	histologicalDiagnosis?	
Bone marrow transplant status	interventionsOrProcedures*	interventionsOrProcedures*	
Reference sample (blood,skin,..)	biosampleStatus.value	biosampleStatus?	
Age at diagnosis	interventionsOrProcedures*	interventionsOrProcedures*	IndividualsDiseases.ageAtDiagnosis**
Pre-treatments	treatments	treatments	
FFPE/FF + duration?	sampleStorage	sampleStorage	
Molecular subtype	measurements	measurements	
Mutation signature	measurements	measurements	
Homologous recombination def.	measurements	measurements	
Tumor drivers	measurements	measurements	
Tumor purity	measurements	measurements	

*includes age/time_date and intervention label/id

**not in BeaconV2 reference model

The Beacon schema

The schema used in Beacon heavily relies on the use of hierarchical ontologies.

Beacon term (179)	***Properties***
BiosampleStatus	*id, label*

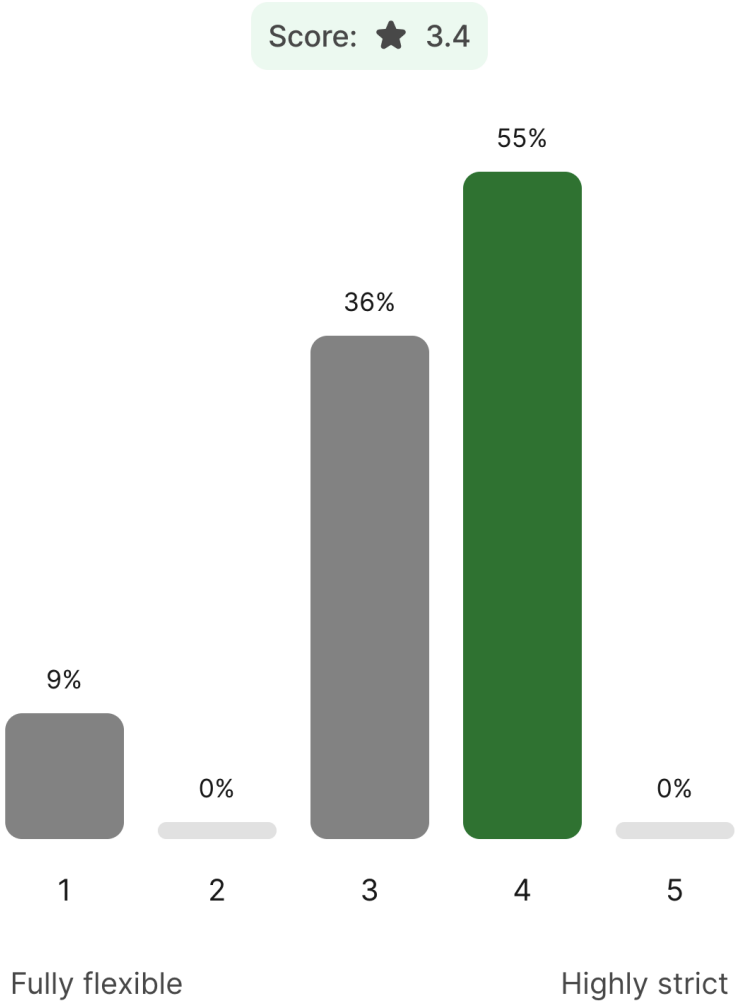
"Ontology value from Material Entity term (BFO:0000040)"


```
"id": "EFO:0009654", "label": "reference sample"
"id": "EFO:0009656", "label": "neoplastic sample"
```

Structured but ***not*** *always* ***harmonized*** data

Harmonization of cancer genomics attributes in Beacon

Should we be more flexible or stricter?



Structured and ***more harmonized*** data

Adding and harmonizing cancer data attributes

Adding to and harmonizing the (onco)Beacon schema involved three steps

- Inventory of oncology-specific data attributes not represented by Beacon terms
- Use generic concepts from the standard beacon model to describe these attributes
- Apply (require) specific ontology classes in attribute ids and values

Specific attribute	Beacon concept	Ontology classes
Tumor Mutational Burden	assayCode date (optional) measurementValue	NCIT:C181335 - Tumor Mutation Burden Assessment string NCIT:C188348 - Mutations per Megabase

Collecting data in the Princess Máxima Center

Collected information from 50 patients (59 samples) in the iTHER* studies.

- Structured and curated data sources.
- Manual extraction from pathology reports, under review.
- Automated, partially validated analysis workflows, needs review.

Current data provides an overview of what we can report; the values are not yet guaranteed to be accurate.

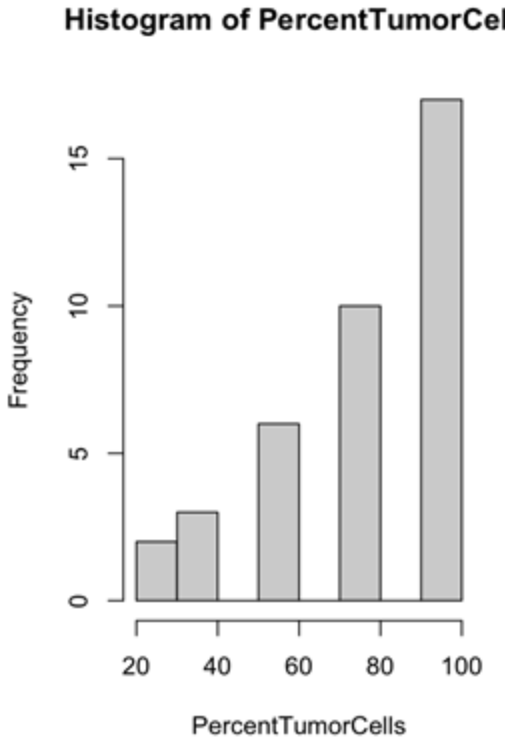
* DOI: 10.1016/j.ejca.2022.09.001: Implementation of paediatric precision oncology into clinical practice: The Individualized Therapies for Children with cancer program 'iTHER'

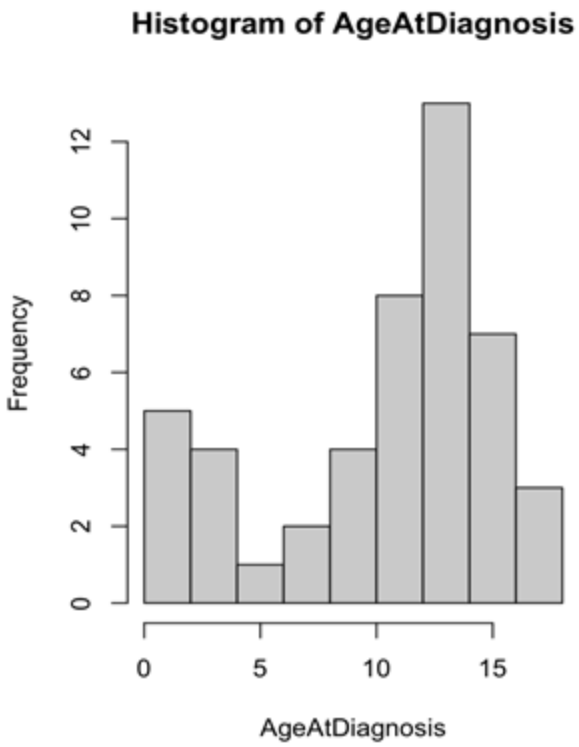
Processing data in the Princess Máxima Center

Attribute	Scope	Terms extracted (269)	Id queried	Query result
sampleStatus	biosample	✓	EFO:0009655	✓
histologicalDiagnosis	biosample	✓	ICDO3:89633	✓
sampleOriginDetail	biosample	✓	ICDO3:C402	✓
sampleOriginType	biosample	✓	OBI:0001479	✓
sampleStorage	biosample	✓	NCIT:C185338	✓
pathologicalStage	biosample	✓	NCIT:C27971	✓
tumorProgression	biosample	✓	NCIT:C84509	✓
pathologicalTnmFinding	biosample	✓ After fix in beaconV2-pi	NCIT:C48700,NCIT:C48706,NCIT:C48724	✓
Tumor Grade	biosample	✓	NCIT:C14162	✓
Tumor Purity	biosample	✓	NCIT:C159484	✓
PreoperativeChemotherapy	individual	✓	NCIT:C68770	✓

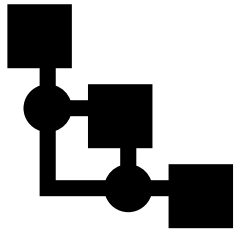
Query filtering in the Princess Máxima Center

Attribute	Scope	Query + Filtering	Result (count)	Query result
Cancer Cellularity Measurement	biosample	NCIT:C123556 > 89	59	✗
Age At Diagnosis	individual	NCIT:C156420 > P14Y	50	✗



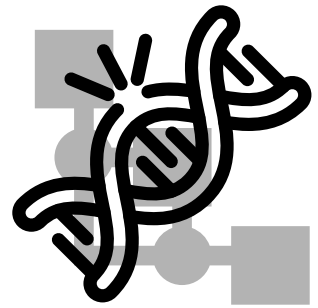


OncoBeacon adds (to) the oncological context

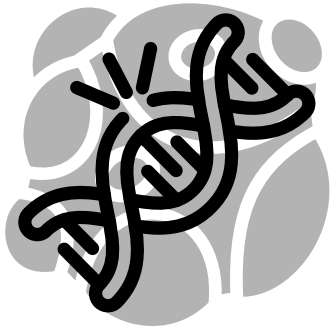


Further specification of existing attributes using ontology terms

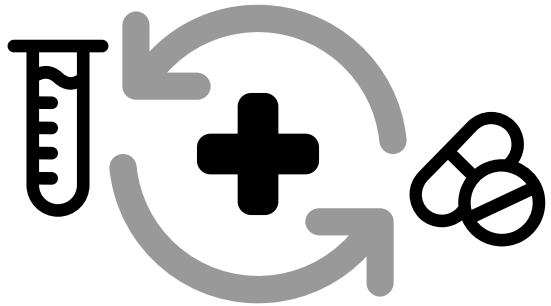
Contextual attributes that help researchers correctly interpret the genetic data



Standards for molecular subtyping



Attributes describing molecular drivers of tumor initiation and tumor genesis



Attributes placing samples in the context of the patient's treatment trajectory

Next steps

Community:

- Feedback to cancer and beacon working groups
- Cancer community to define minimal standards
- OMOP to Beacon mapper/integrator

We:

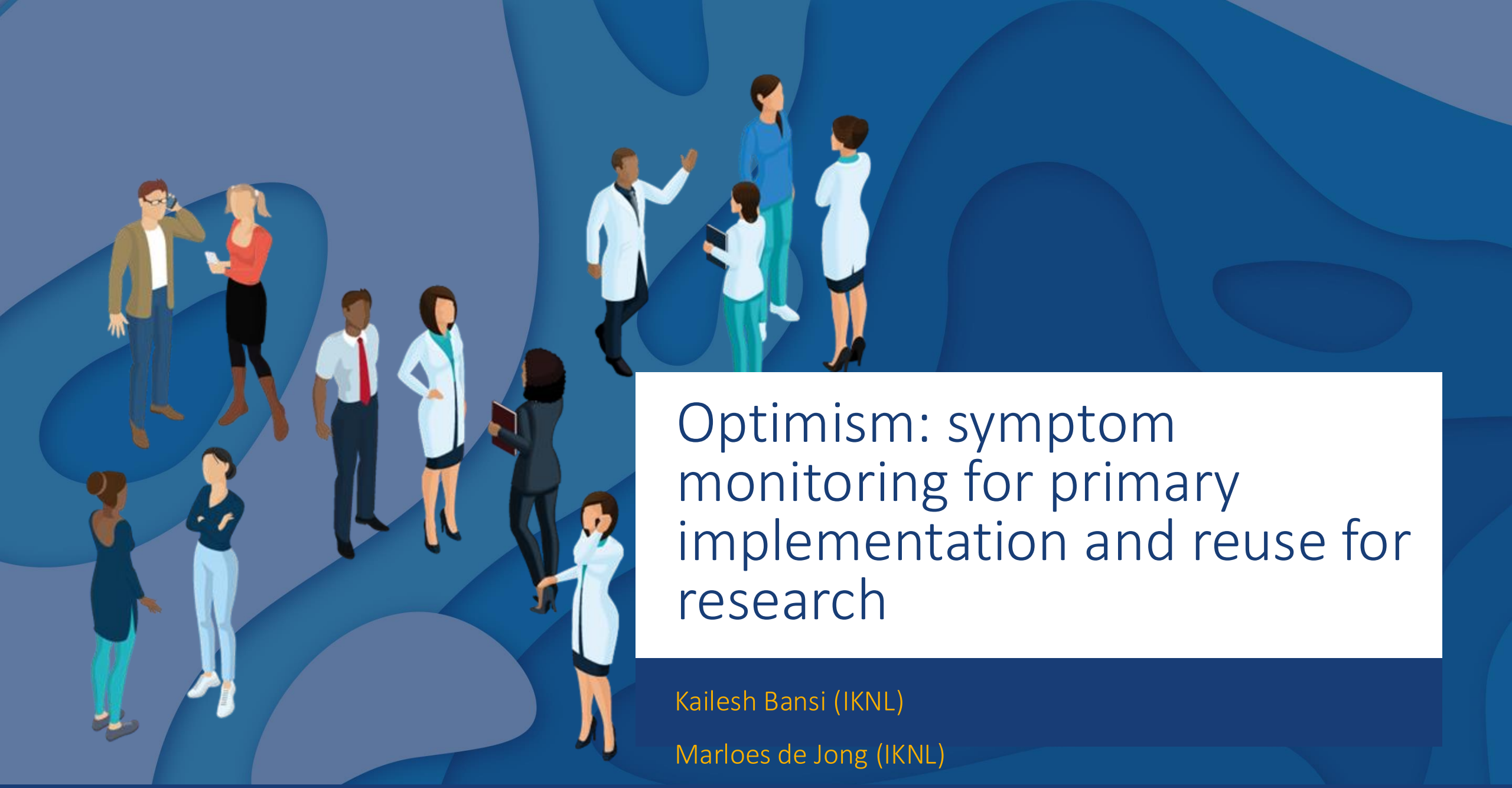
- Solve query issues
- Deploy OncoBeacons (international)
- Be transparent about the clinical to Beacon field mappings
- Test federated queries on the beacons

Acknowledgements

Patrick Kemmeren	PI, Princess Máxima Center for Pediatric Oncology
Alex Staritsky	ETL development
Marcel Santoso	Beacon platform deployment, testing, debugging
Jasper van Dalum	Cloud infrastructure development
Joep de Ligt	Lead Data, Hartwig medical Foundation
Stefan Dentro	Beacon implementation
Matthijs van Niekerk	Cloud infrastructure
Sophie Roerink	Clinical data mapping
Jordi Rambla & Michael Baudis	Beacon insights
Oriol López-Doriga	Beacon v2 Production Implementation developer

Coffee break

14:30-14:45

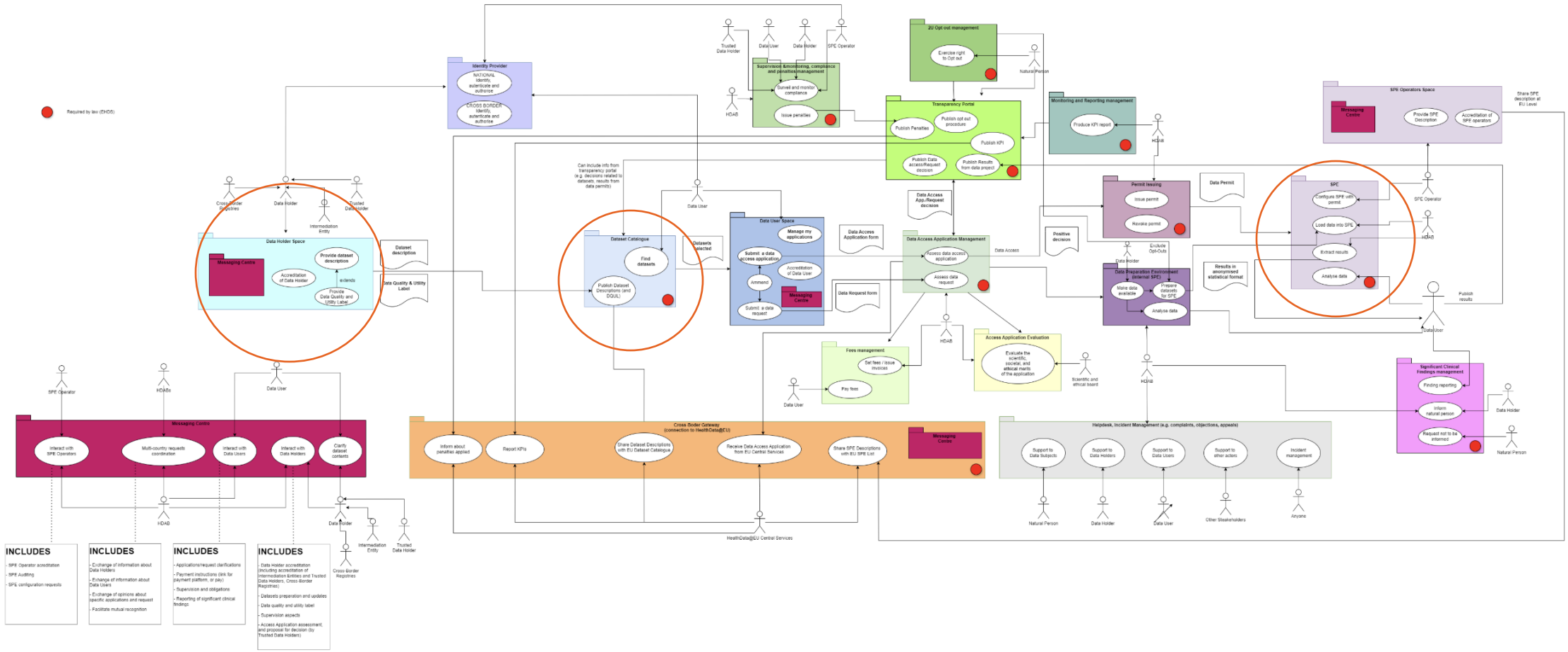


Optimism: symptom monitoring for primary implementation and reuse for research

Kailesh Bansi (IKNL)

Marloes de Jong (IKNL)

Backbone


Required by law (EHDS)
Identity Provider
NATIONAL
Identify, authenticate and authorise
CROSS BORDER
Identify, authenticate and authorise
Supervision &monitoring, compliance and penalties management
Surveil and monitor compliance
Issue penalties
2D Opt out management
Exercise right to Opt out
Transparency Portal
Publish Penalties
Publish opt out procedure
Publish KPI
Publish Data access/Request decision
Publish Results from data project
Monitoring and Reporting management
Produce KPI report
SPE Operators Space
Messaging Centre
Provide SPE Description
Accreditation of SPE operators
Share SPE description at EU Level
Trusted Data Holder
Data User
Data Holder
SPE Operator
HDAB
Natural Person
Cross-Border Registries
Intermediation Entity
Data Holder Space
Messaging Centre
Provide dataset description
Accreditation of Data Holder
extends
Provide Data Quality and Utility Label
Dataset description
Data Quality & Utility Label
Can include info from transparency portal (e.g. decisions related to datasets, results from data permits)
Dataset Catalogue
Find datasets
Publish Dataset Descriptions (and DQ/U)
Datasets selected
Data User Space
Manage my applications
Submit a data access application
Accreditation of Data User
Ammend
Messaging Centre
Submit a data request
Data Access Application form
Data Request form
Data Access App./Request decision
Data Access Application Management
Assess data access application
Assess data request
Data Access
Positive decision
Permit issuing
Issue permit
Revoke permit
Data Permit
Exclude Opt-Outs
Data Preparation Environment (internal SPE)
Make data available
Prepare datasets for SPE
Analyse data
Results in anonymised statistical format
SPE
Configure SPE with permit
Load data into SPE
Extract results
Analyse data
Publish results
Fees management
Set fees / issue invoices
Pay fees
Access Application Evaluation
Evaluate the scientific, societal, and ethical merits of the application
Scientific and ethical board
Significant Clinical Findings management
Finding reporting
Inform natural person
Request not to be informed
Messaging Centre
Interact with SPE Operators
Multi-country requests coordination
Interact with Data Users
Interact with Data Holders
Clarify dataset contents
Cross Border Gateway (connection to HealthData@EU)
Inform about penalties applied
Report KPIs
Share Dataset Descriptions with EU Dataset Catalogue
Receive Data Access Application from EU Central Services
Share SPE Descriptions with EU SPE List
HealthData@EU Central Services
Helpdesk, Incident Management (e.g. complaints, objections, appeals)
Support to Data Subjects
Support to Data Holders
Support to Data Users
Support to other actors
Incident management
Other Stakeholders
Anyone
INCLUDES
- SPE Operator accreditation
- SPE Auditing
- SPE configuration requests
INCLUDES
- Exchange of information about Data Holders
- Exhange of information about Data Users
- Exchange of opinions about specific applications and request
- Facilitate mutual recognition
INCLUDES
- Applications/request clarifications
- Payment instructions (link for payment platform, or pay)
- Supervision and obligations
- Reporting of significant clinical findings
INCLUDES
- Data Holder accreditation (including accreditation of intermediation Entities and Trusted Data Holders, Cross-Border Registries)
- Datasets preparation and updates
- Data quality and utility label
- Supervision aspects
- Access Application assessment, and proposal for decision (by Trusted Data Holders)

OPTIMISM

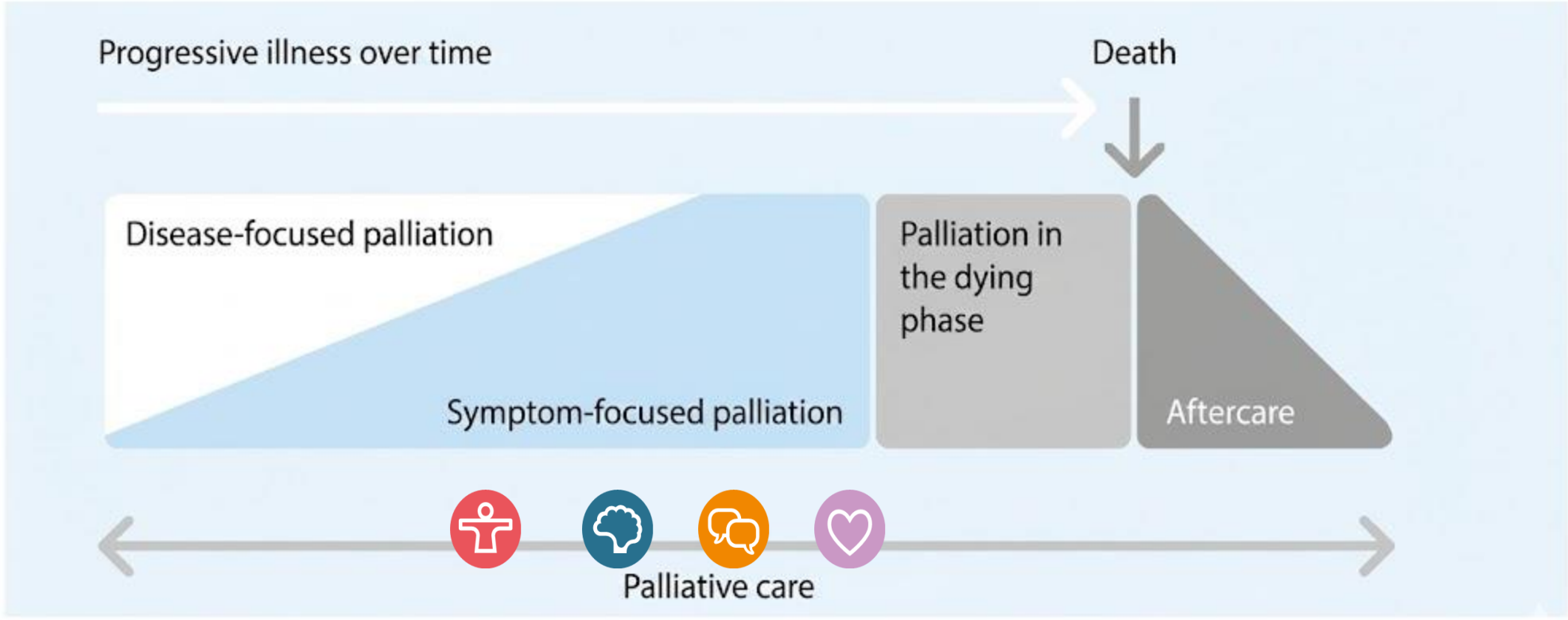
Development and implementation of structural symptom monitoring for patients with incurable cancer

Marloes de Jong, IKNL
Kailesh Bansi, IKNL

HRI Oncology node, 8 december 2025

KWF

Phases in palliative care



model by Joanne Lynn and David Adamson

4 dimensions/pillars of palliative care

Physical

- *Pain*
- *Shortness of breath*
- *Fatigue*

Psychological

- *Anxiety*
- *Frustation*
- *Depressive feelings*

Social

- *Loneliness*
- *Tensions in relations*
- *Loss of work*

Spiritual

- *Questions about meaning*
- *Existential fears*

Aim OPTIMISM

OPTIMIzation of symptom management through implementation of structural

Symptom **M**onitoring

Establish a scalable **symptom monitoring system** to improve patient and caregiver **quality of life** and facilitate **research**

System's applicability extends **beyond oncology and palliative care**

Academic hospitals / Dutch Centers of Expertise in Palliative Care & IKNL
Project duration: 60 months
Budget: € 3.957.790,-

KWF

OPTIMISM

https://www.kwf.nl/onderzoek/onderzoeksdatabase/ontwikkeling-en-implementatie-van-structurele-symptoom-monitoring-voor

KWF

Home / Onderzoek / Onderzoeksdatabase

Ontwikkeling en implementatie van structurele symptoom monitoring voor patiënten met ongeneeslijke kanker

start binnenkort

Onderzoekssamenvatting

In 2021 zijn in Nederland 45.863 mensen aan kanker overleden, wat het belang van palliatieve zorg voor een grote groep patiënten met kanker benadrukt. Patiënten met ongeneeslijke kanker ervaren vaak verschillende klachten zoals pijn, vermoeidheid, kortademigheid, obstipatie en angs gelijktijdig kunnen voorkomen. Naarmate de ziekte vordert, nemen het aantal en de erns klachten toe. Zelfs bij milde klachten kunnen deze een aanzienlijke invloed hebben op de leven en dagelijkse activiteiten van patiënten. In de dagelijkse zorg is het een uitdaging o aanwezige klachten van een patiënt goed in kaart te kunnen brengen. Daardoor is het b van klachten vaak niet optimaal.

Voorgestelde oplossing

De implementatie van symptoommonitoring kan bijdragen aan het verminderen van klachten. Symptoommonitoring houdt in dat patiënten aangeven hoe ernstig zij hun klachten ervaren, zodat zorgverleners snel kunnen ingrijpen om de klachten te verminderen. Dit heeft diverse voordelen, zoals minder last van klachten, minder bezoeken aan de spoedeisende hulp en minder ziekenhuisopnames,

Projectgegevens

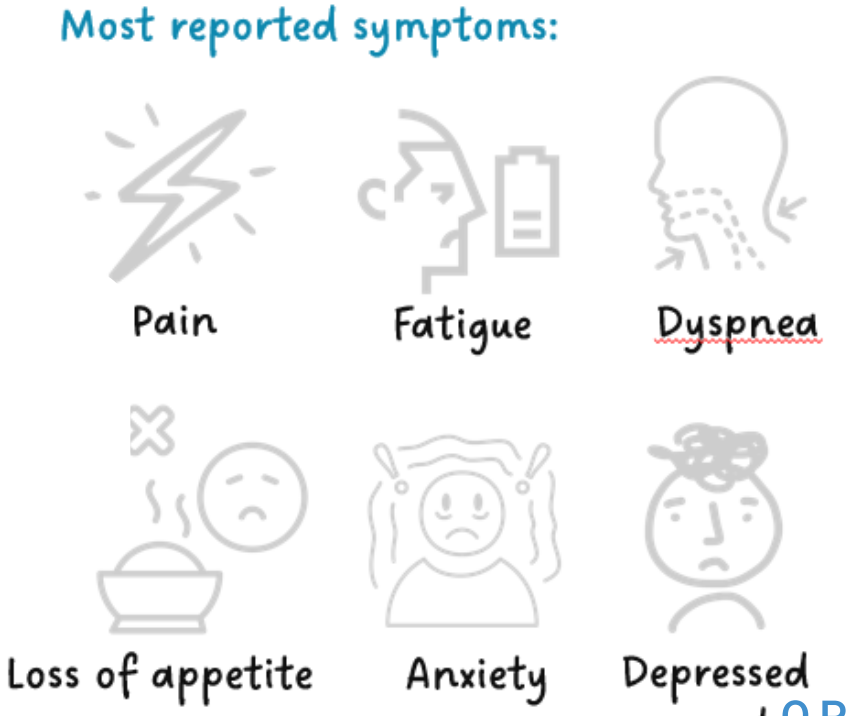
- **Projectnummer:** 15985
- **Projectleider:** prof. dr. An Reyners
- **Projectteam:** dr. Jurrian van der Werf (IKNL) - dr. Rudolf Fehrmann (University Medical Center Groningen) - dr. Everlien de Graaf (UMC Utrecht)
- **Instituut:** UMC Groningen
- **Startdatum:** 1 juli 2024
- **Kankersoort:** Algemeen (geen specifieke kankersoort)
- **Looptijd:** 60 maanden
- **Projectbudget:** € 3.957.790,-

OPTIMISM: OPTIMIzation of symptom management through implementation of structural Symptom Monitoring

OPTIMISM – why?

Patients with advanced cancer have complex care needs

- On average, 6 simultaneously occurring symptoms
- As the disease progresses, the number of symptoms and severity increase
- Significant impact on quality of life and daily activities, even at low intensity
- Challenge to properly map all present complaints!



Why symptom monitoring in palliative care?

At end of life:
average of
6 concurrent symptoms
of which
4 clinically relevant

Most reported symptoms:

Pain

Fatigue

Dyspnea

Loss of appetite

Anxiety

Depressed mood

If **not consistently assessed**, may fail to recognize or underestimate severity and impact, leading to **suboptimal care.**

+

Often assessed retrospectively, relying on **patient recall** rather than **real-time evaluation**

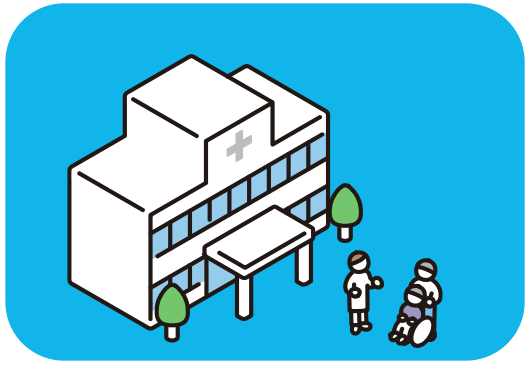
=

Challenge to **provide timely** and **effective interventions**

Possible benefits

Reduced symptom burden

Less anxiety



Fewer emergency room visits and hospital admissions

Improved quality of life

Successful example:

Ontario, Canada, with the Edmonton Symptom Assessment System (ESAS)

Illustraties: SVGRepo.com - Soco St Various Illustration Vectors

OPTIMIzation of quality of life by individualized Symptom Management: national implementation of structural symptom monitoring and realization of a research data-hub

OPTIMISM

Systematic approach

Where patients actively and structurally report symptoms (USD-4D)

Infrastructure

For (inter)national research on symptom burden and quality of life

Supported by KWF

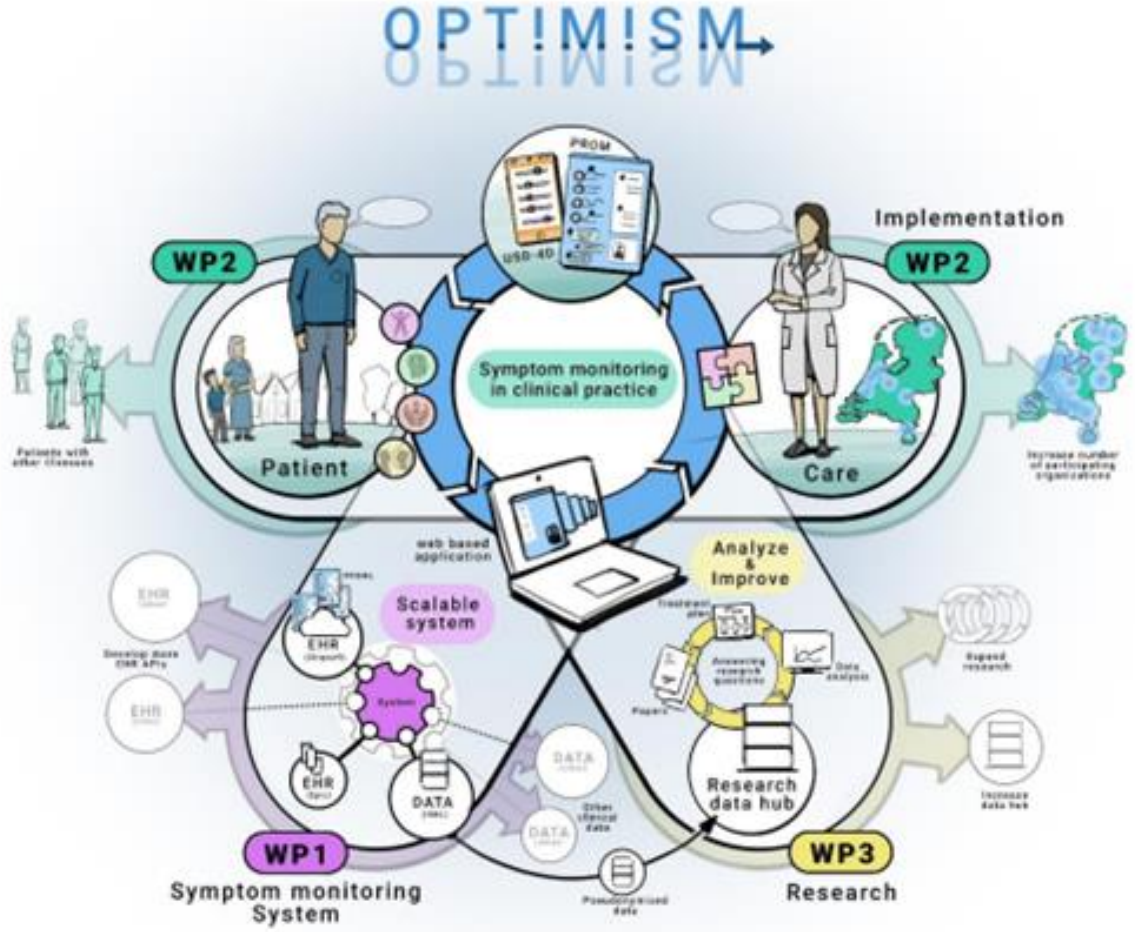
SONCOS normeringsrapport 2025

“Symptom monitoring is an integral part of palliative care, as part of proactive care planning.”

“Attention to symptom monitoring and symptom treatment on the four dimensions (physical, psychological, social, and spiritual) is in any case present for all patients with a life expectancy of <1 year.”

Preliminary inventorisation of hospitals

Plan of investigation: 3 work packages

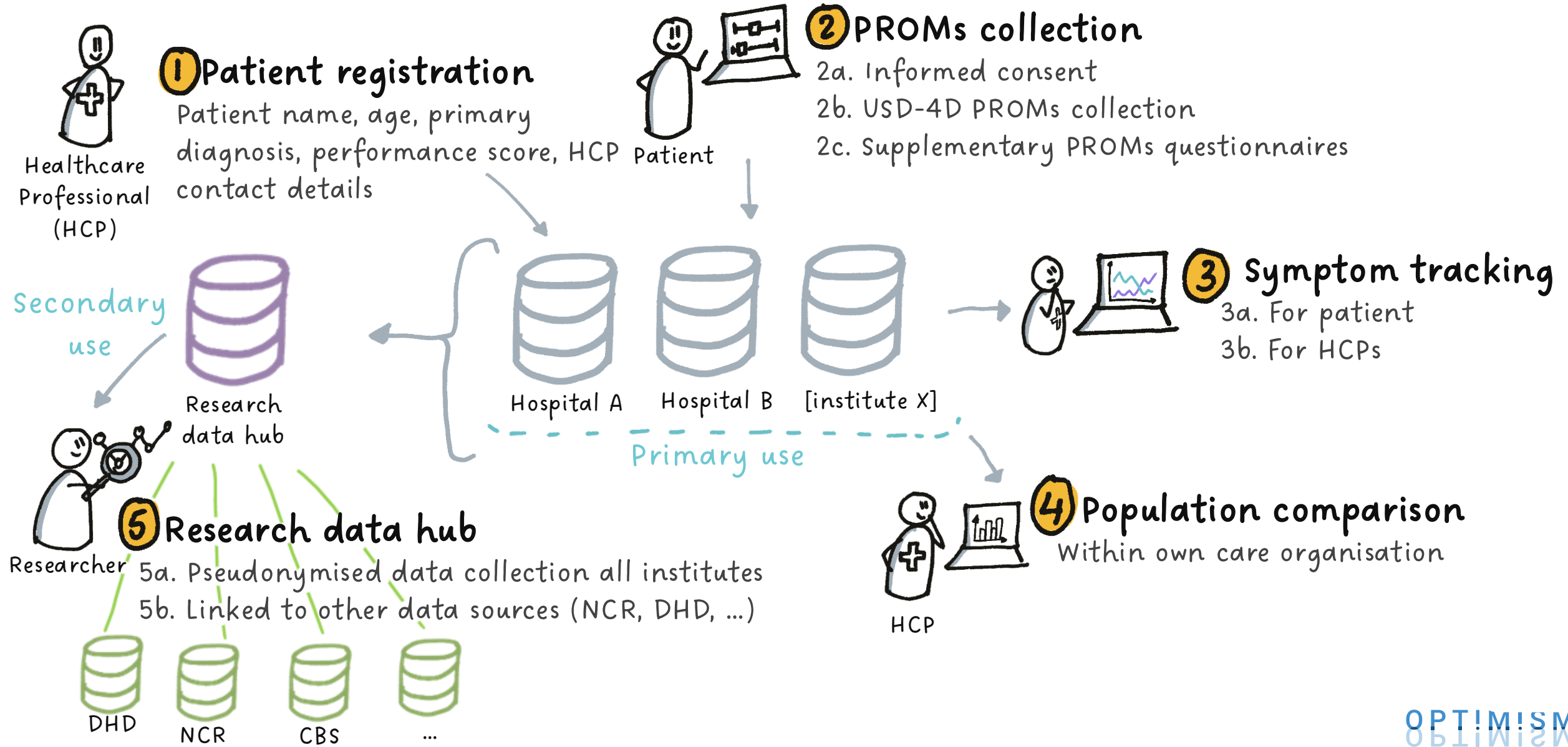


WP1 Development and deployment
- Symptom monitoring system
- Goal architecture for scalability
- Data research hub

WP2 Implementation in daily clinical oncology practice
- Starts in academic hospitals
- Additional care settings

WP3 Research on
- Implementation strategies
- Obtained symptom data

Development of the symptom monitoring system



Lessons learned from pilot implementation

- Difficulty finding entry points (implementation and data export)
- Individual approaches within hospitals and departments:
  - Continuous improvement
  - Value-driven care
  - Appropriate care
- Varying data export:
  - FHIR
  - CSV
  - XML

Researcher's need

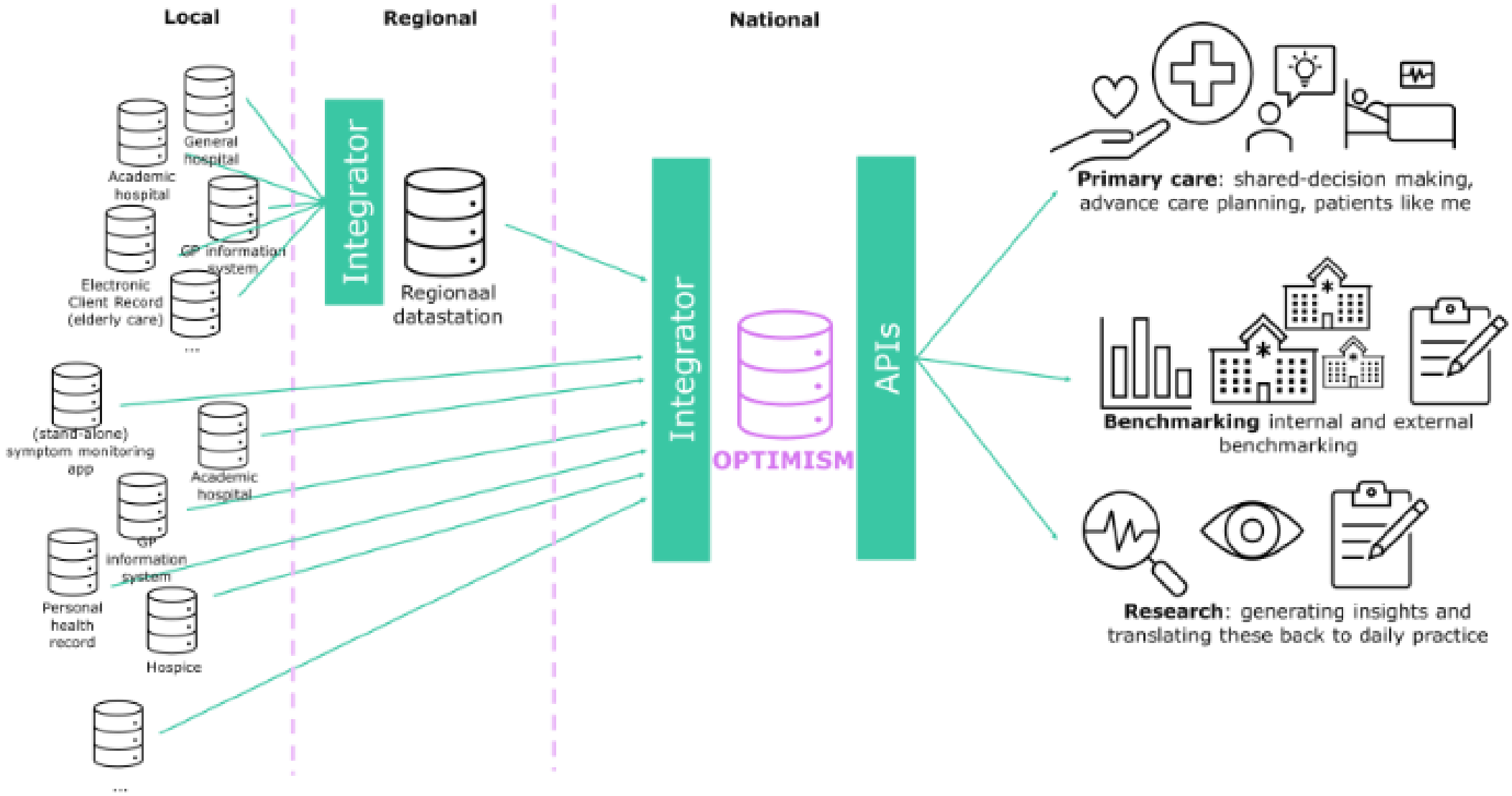
Data must be findable (currently lacking regarding symptoms)

Data must be interoperable (a lot of time spent on data harmonization)

Data must be of quality (completeness of data)

Real-world data (currently often retrospective)

Technical components



Lessons learned from pilot implementation

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  - Appropriate care
- Varying data export:
  - FHIR
  - CSV
  - XML

Optimism & Dutch Oncology Node

How would Optimism fit in an oncology node:

- Where do you see opportunities?
- How can we support datalinkage? For instance genomics
- For reuse?
- For a learning healthsystem?

OPTIMISM

- Any questions?

- E-mailadres: OPTIMISM@UMCG.nl

A mini workshop

Nederlandse Kanker Agenda: Delayed diagosis, and needs for data infrastructure

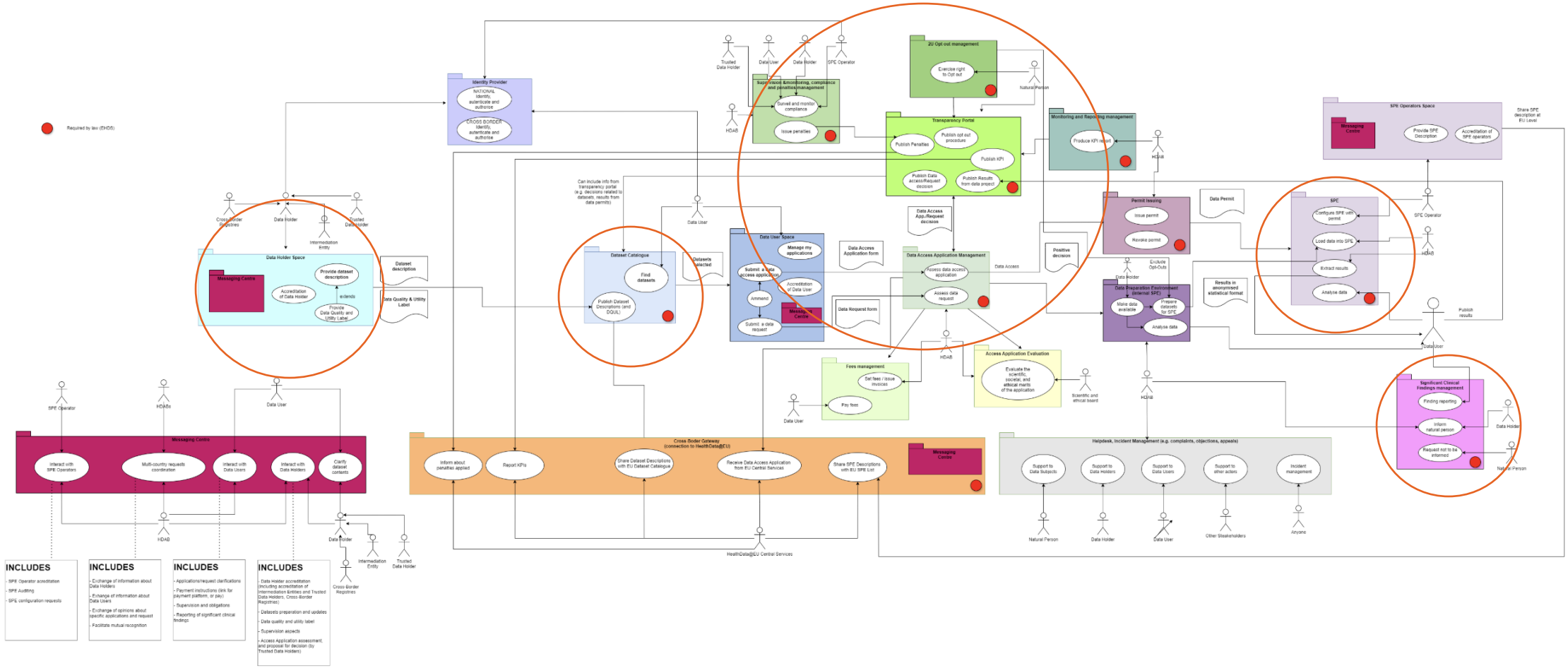
Femke Jacobs (IKNL)

Tilja van den Berg (NKC)

Warnyta Minnaard (NKC)

health RI
enabling data driven health & life sciences

Backbone


Identity Provider
Data Holder Space
Data User Space
Dataset Catalogue
Transparency Portal
Data Access Application Management
Permit Issuing
SPE Operators Space
SPE
Messaging Centre
Cross Border Gateway (connection to HealthData@EU)
Helpdesk, Incident Management (e.g. complaints, objections, appeals)
Access Application Evaluation
Fees management
Significant Clinical Findings management
INCLUDES
INCLUDES
INCLUDES
INCLUDES

NEDERLANDSE KANKER AGENDA

ACCELERATION TEAM DIAGNOSTICS

Workshop on delayed diagnosis, and needs for data infrastructure

Nederlands Kanker Collectief

One plan for the Netherlands

24
nov 2023

Netherlands Cancer Agenda (NKA)

- 20 ambitious & clear goals for 2032 which are apolitical, independent of resources/funding
- Direct and proactive approach with action plans
- Continuous monitoring and adjustment/alignment
- Endorsed by the government

Working together as the Dutch Cancer Collective

Mission – why we do what we do

Together, we reduce the impact of cancer on society.

How we work together

Connect – organisations, knowledge, disciplines, and life before, during, and after cancer

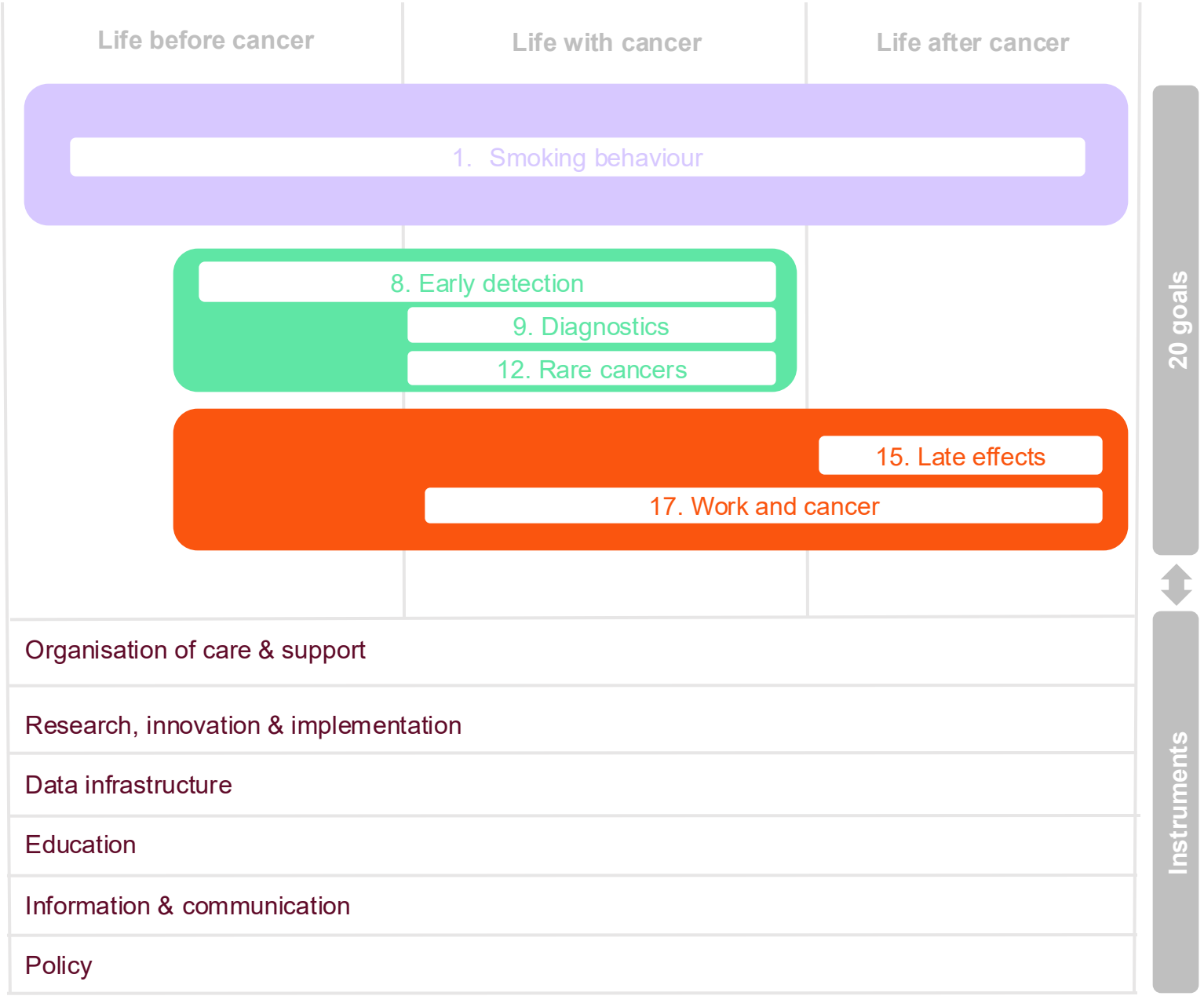
Strenghten – combining forces, embracing perspectives, creating integrated solutions

Accelerate – keeping a clear focus, removing obstacles together, move quickly

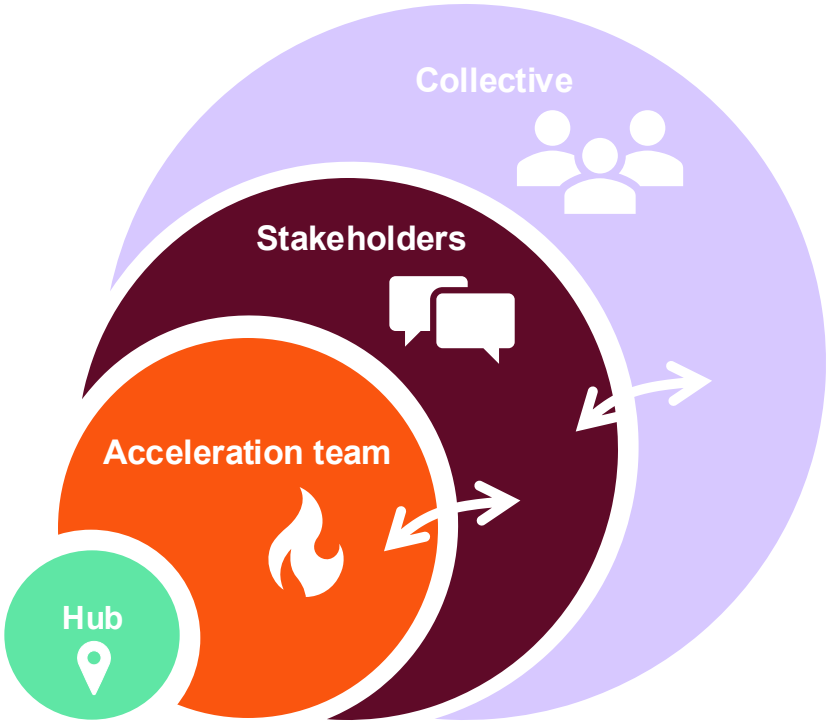
What we do

Work together on the 20 goals of the Agenda

Conceptual framework



How do we accelerate together?



Acceleration teams

Who	Experts, leaders
Focus	Content - unravelling the problem together, arriving at concrete actions and implementing them
Role	Action holder developing and implementing solutions
Input	Expertise, time and resources to realise the goal

How the hub complements

Who	Supporting project manager
Focus	Process focus - brings structure, monitors and facilitates the end goal and the process: pace, effectiveness, etc
Role	Facilitator, process supervisor and initiator
Input	Way of working, neutrality, ‘interspace’

Diagnostics

By 2032, people with cancer will have a personalised diagnosis (more) quickly with minimal burden

01.

What do we want to change?

By 2032, people with cancer will have a personalised diagnosis (more) quickly with minimal burden

We want to make the right diagnosis as soon as possible so that appropriate treatment can be started quickly. This takes into account the wishes, values and preferences of people with cancer. Currently, there are differences in outcomes and lead times of diagnostic processes between hospitals. Data on these are not available for all tumour types. The use of technology and innovations can make the diagnostic pathway more efficient. This potential is currently insufficiently exploited

The use of comprehensive molecular diagnostics has proven added value for certain patient groups, for example for Cancer of Unknown Primary (CUP) and lung cancer. This is not known for all other patient groups. There are differences in the offer of various forms of comprehensive molecular diagnostics across hospitals.

DIAGNOSTICS

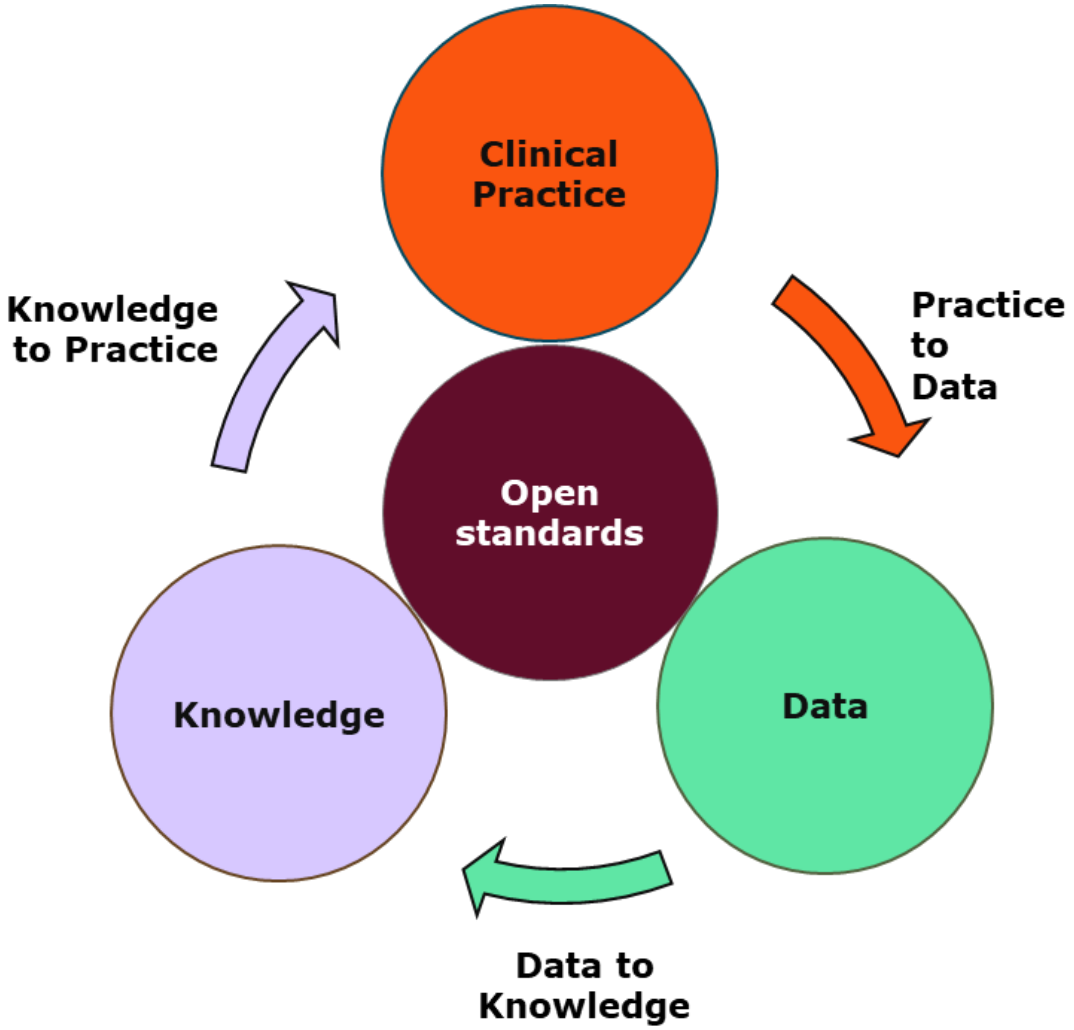
02.

ACTIVITIES FOR 2026

Activities for 2026

Activities *What will we do in 2026*	*What this contributes to*
Activity 1: Diagnostic patient journey and milestones The diagnostic process can be experienced as a black box. In this patient journey, we identify phases and critical moments to best support the person suspected of having cancer.	Lack of information, shared decision-making and point of contact
Activity 2: Coordinated, integrated and streamlined diagnostics Analysis of the opportunities to better align the various components of diagnostics, so that they take place in a coordinated, integrated and streamlined manner.	Diagnosis takes a long time
Activity 3: Bringing together initiatives for a learning health system Analysis of initiatives and stakeholders involved in developing a learning health system to identify gaps and potential for acceleration.	Data and insights are not sufficiently utilized
Activity 4: Analysis of diagnostic turnaround times Desk research and (possibly) additional data analysis of turnaround times per tumor group, stage, and/or technique to gain insight into bottlenecks and opportunities for acceleration.	Diagnosis takes a long time
Activity 5: Analysis of practice variation in diagnostics Desk research and (possibly) additional data analysis of practice variation by tumor group, stage, and/or technique in deviation from guidelines and innovations to gain insight into the scope of the problem and to assess what is desirable and undesirable, and where opportunities for improvement lie.	Inequality and inefficiency in diagnostic pathways create differences in the quality and accessibility of care

Activity 3: bringing together initiatives for a learning health system



Activity 3: bringing together initiatives for a learning health system

Goals

Define the content of a LHS

Define to which urgent/relevant questions a LHS should contribute

Identify existing initiatives

Identifying relevant Dutch initiatives (and affiliated parties) that are working on (components of) a learning health system. We are interested in initiatives that are collecting, analysing and/or standardizing data on cancer diagnostics, aiming to enable healthcare evaluation.

Support and connect existing initiatives

Use the strengths of the Dutch Cancer Collective to support, connect and improve existing initiatives

Discussion – the role of DCC

- What role do you think the Dutch Cancer Collective can play in bringing existing initiatives together?
- What support is still missing in the field?
- How can we truly help parties working on elements of a learning health system to move forward?

Discussion – learning health systems

- What role do you think the Dutch Cancer Collective can play in bringing existing initiatives together?
- What support is still missing in the field?
- How can we truly help parties working on elements of a learning health system to move forward?

- What initiatives and/or stakeholders working on learning health systems in oncology should we be aware of?
  - Focusing on the Netherlands, and perhaps international initiatives that can be an inspiration for us
- What is their scope? What questions are the systems aiming to answer?

Would you be interested to brainstorm further with us to drive this activity forward?

Questions? Want to get involved?

Reach out to us via: warnyta@nederlandskankercollectief.nl &

tilja@nederlandskankercollectief.nl

An (extended) panel discussion:

Our NCDN-NL

ALL node members

EOSC4Cancer and Node meetings

2021-11-02 (Heidag)

2022

2023-09-17

2024-04-12

2024-July-September CANDLE proposal prep

Node WGs established

2024-10-18

CANDLE granted

2024-12-17

(9:46am CET)

Node meetings, WG meetings &CANDLE kick off

2025-01-31

2025-06-17

2025-06-24

2025-July-Dec

(Common data model, data linkage, cBioportal symposium, share genomic data, EOSC-ESFRI-EHDS)

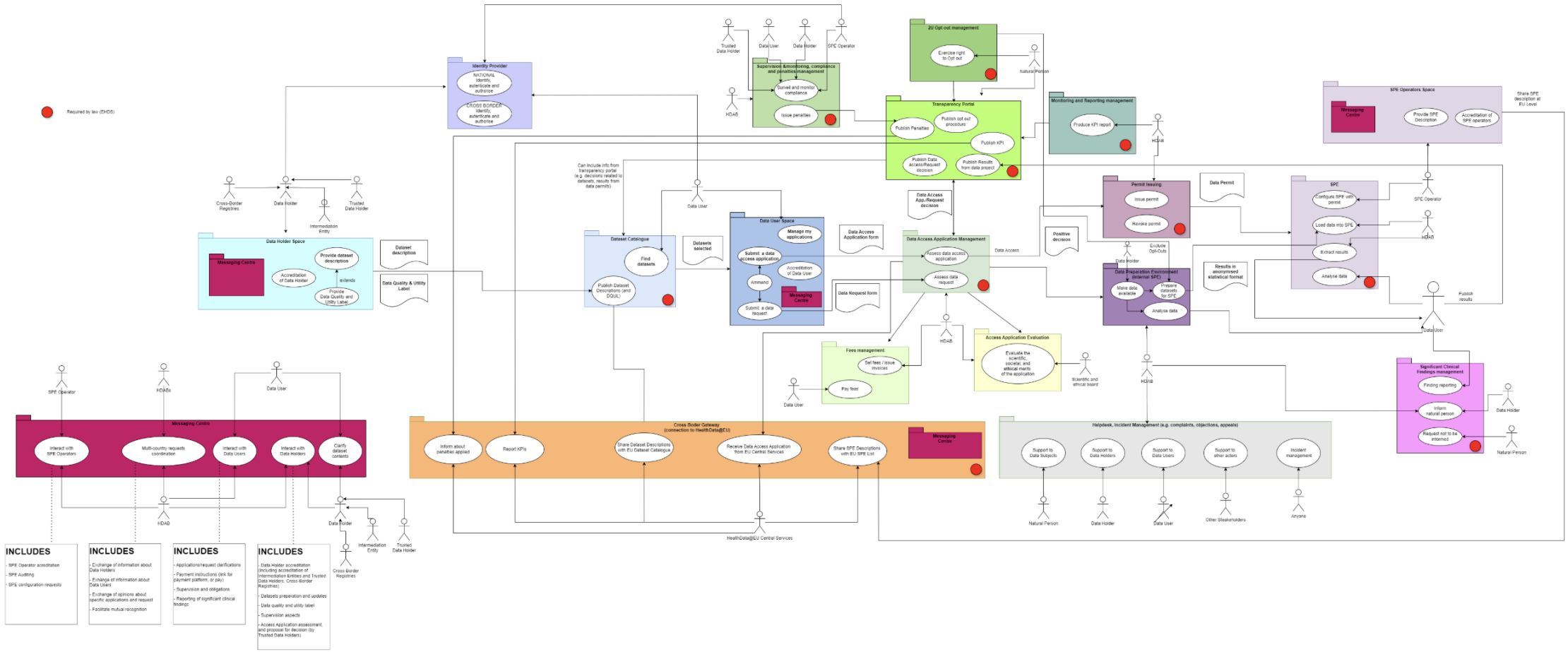
2025-12-08

NCDN-NL=EU best practices acknowledged by EC and MS

2025-11-27~28

- eCancer thematic working group meeting with 25 MS and three DGs: (EHDS blueprint DC, bring EU initiative together on national level)
- Cyprus EU presidency event, 2026-04-23, NCDN roadshow
- EC cancer mission projects support 2026-09-29~10-01

Backbone


Identity Provider
Supervision &monitoring, compliance and penalties management
2U Opt out management
Transparency Portal
Monitoring and Reporting management
SPE Operators Space
Permit issuing
SPE
Data Holder Space
Dataset Catalogue
Data User Space
Data Access Application Management
Data Preparation Environment (internal SPE)
Fees management
Access Application Evaluation
Significant Clinical Findings management
Messaging Centre
Cross Border Gateway (connection to HealthData@EU)
Helpdesk, Incident Management (e.g. complaints, objections, appeals)
HealthData@EU Central Services
INCLUDES
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INCLUDES
INCLUDES

Carla van Laer (NKC)

Patrick Kemmeren(PMC)

Joep de Ligt (HMF)

Carla Pieterman (KWF)

Joppe Tra (HRI)

Anika Bonggarts (IKNL)

Eva Meize (IKNL)

Lifang Liu (HRI)

health RI
enabling data driven health

Q1: What is your vision and expectation about the Dutch National Cancer Data Node (NCDN-NL)?

Nr of comments	What is your vision and expectation about the Dutch National Cancer Data Node (NCDN-NL)?
1	To show what is possible by bringing the right data together
2	A nation-wide data findability infrastructure for oncology data. beyond the metadata catalogus, a more advanced and robust infrastructure with oncology-specific items that can be used for exploration journeys.
3	Stimulating datadriven learning healthcare system for oncology for the whole patient pathway so. incl. prevention, palliative care and berievement care
4	The NCDN should be THE place for experts and thought leaders from data holders and other stakeholders that take a tactical and strategic approach to improve data availability, data quality and data usage in order to create faster and better insights.
6	A 'living lab' on how we can operationalize the EHDS/HDAB ambitions, and a Trusted Health Data Holder for the oncology domain
7	Work as a coordinator between EHDS and data holders giving support to them on how model and transfer data, and make data available for others.
8	I envision the NCDN-NL as a national enabling infrastructure that makes it easier, faster, and safer to use cancer data for impact: improving patient outcomes, reducing inequalities, accelerating research, and informing policy. The node should not become “another platform,” but rather a connector and simplifier across existing datasets, standards, and initiatives in alignment with European initiatives, projects & networks
9	To bring together the required infrastructure, tooling and harmonization of data for oncology research and care and act as a linking pin for international harmonization and sharing of data.

Q2: What are the priorities/priority projects in your organization in the coming year(s)? Are there any challenges and opportunities related to data? if so, what are they?

Nr of comments	What are the priorities/priority projects in your organization in the coming year(s)? Are there any challenges and opportunities related to data? if so, what are they?
1	Making the learning care system a reality, this is mostly a data standardisation and sharing problem (for now)
2	See our digital strategy, https://www.prinsesmaximacentrum.nl/storage/configurations/prinsesmaximacentrumnl/files/digitale_strategie/idt_strategie_nl.pdf And our main multi-year strategy, for example paragraph 2.3 (page 29) on data
3	Datadriven evaluation and monitoring of package decisions And broader data availability for oncology
4	For IKNL and DICA: create a well integrated portfolio of data and information products. Increase the data availability and data quality. Biggest challenges: 1. Data availability from hospitals (by far the biggest challenge) 2. Data linkage 3. Data standardization and addressing the semantic layer.
6	Help out with (technical) innovations that support sovereign, automated, verifiable and privacy preserving data analysis for secondary use. Related questions: How to make data FAIR? How to verify your computation? How to preserve privacy? How to come to an equal level playing field, with a healthy market around it (incl. public/private partners)
7	Centralise and harmonise data to be able to share data for secondary use.
8	Implementing the (action plans of) Netherlands Cancer Agenda through coordinated action across care, research, data, and lived experience.
9	Standardize and harmonize clinical, phenotypical and genomic data; develop federated query possibilities; cloud-enabled secure processing environments.

Q3: What do you see that NCDN-NL can help you?

Nr of comments	What do you see the NCDN-NL can help you?
1	Help organisations realise this is possible and needed now
2	National alignment on standards. Making sure everyone uses the same ontologies.
3	Information modelling to come to shared models to facilitate interoperability Stimulate datastatons which make cancerdata available both at healthcare providers as well as (research)institutions In co-creation :-)
4	Create a business case and urgency to improve data availability and the application of information standards in hospitals.
5	Exchange of ideas, jointly work on projects
6	Application area to test innovations
7	I hope NCDN-NL can help on model clinical/research data to make it FAIR and manage the data request via EHDS
8	The node can help by offering a unified entry point to discover and access data, shared standards and reusable agreements, and technical support for federated queries and secure analytics. It lowers operational barriers through interoperable workflows, provides structured pathways to move NKC use cases into practice, ensures trusted federated governance, and aligns the Netherlands with European data infrastructures.

Q4: How do you like to work with the node to solve challenges and maximize opportunities?

Nr of comments	How do you like to work with the node to solve challenges and maximize opportunities?
1	getting things done
2	We can contribute with expertise and experience
3	Present work, collect feedback and see how we can co-create together
4	Both in general meetings and in separate projects. Focus less on knowledge sharing and focus more on results and strategy.
6	Discuss pains, brainstorm for solutions, openness to work together on pilots
7	Deployment of a national cBioPortal instance connected to all data holders and help them to model the data in cBioPortal format. Make cBioPortal accessible via SPE environments. Provide support on modelling data to be able to use it for secondary purposes.
8	I would like to work with the node in a co-creative, iterative, and transparent way—focused on real use cases, clear governance, and early involvement of professionals and patients. Collaboration should connect to existing national initiatives, avoid duplication, and start with high-value, feasible projects that build trust. Preferred collaboration includes joint exploration of use cases (e.g. from the action plan diagnostic), short learning cycles that integrate technical and organisational alignment

Action list

(see more on the meeting agenda)

Take home message

- NCDN-NL is a community for all of us. Come, share and collaborate.
- NCDN-NL brings the Dutch consensus on standards, tools for cancer data.
- Maximize opportunities EHDS offers
- Maximize benefits from national and international expertise (e.g. NCDN-network)
- Maximize EU funding opportunities (CANDLE, EUnetCCC, JA-PCM as focal points)