Gerrit Meijer

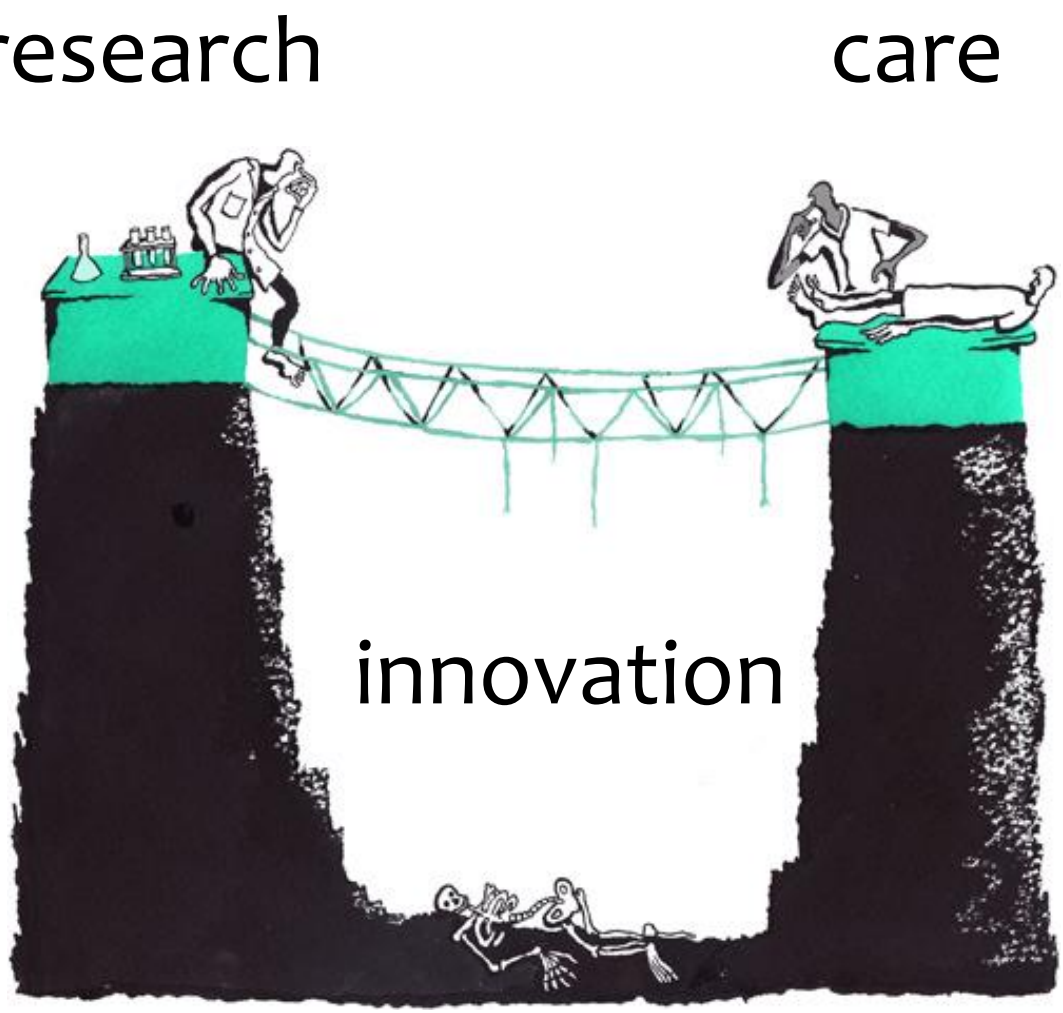
Netherlands Cancer Institute Amsterdam, University Medical Center Utrecht

Health-RI voor effectieve personalised medicine research

health RI research infrastructure

SELL THE PROBLEM YOU SOLVE, NOT THE PRODUCT.

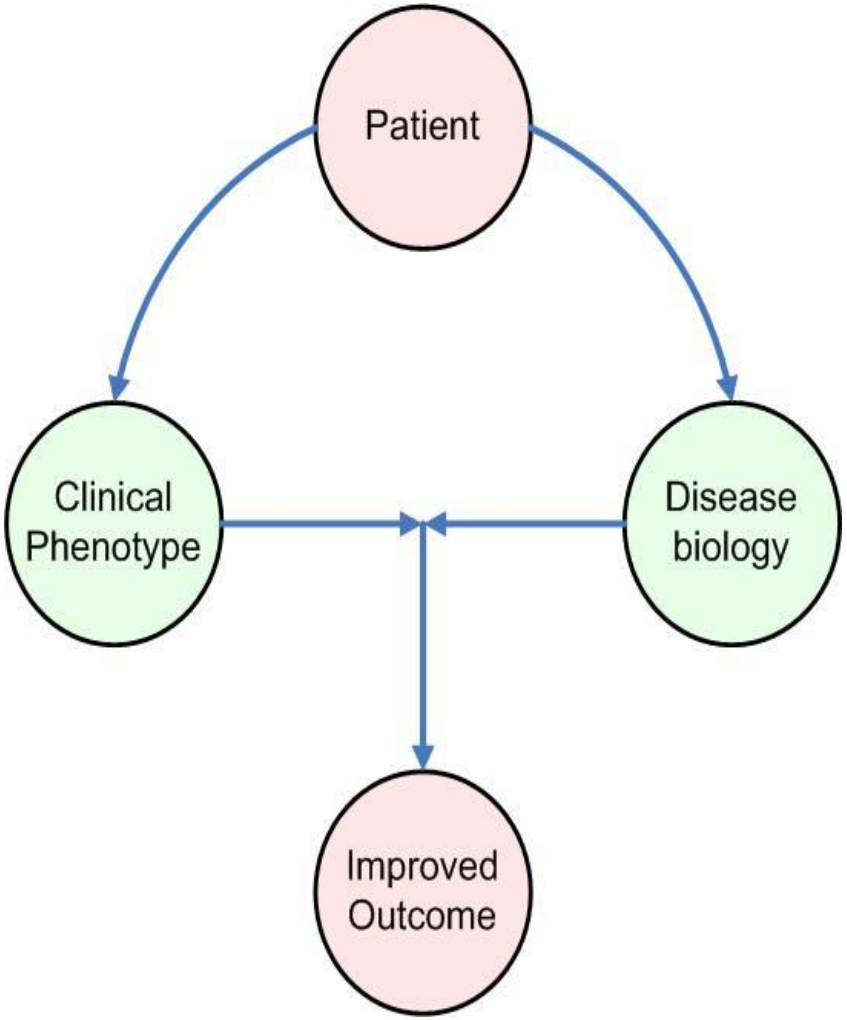
Why Health-RI?



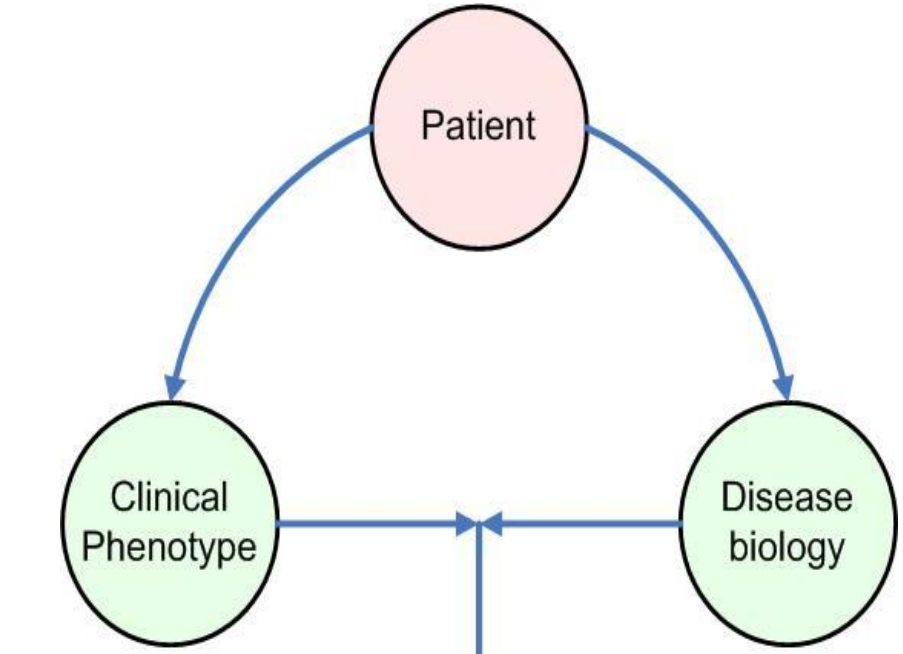
If want better treatment for patients, then we must:

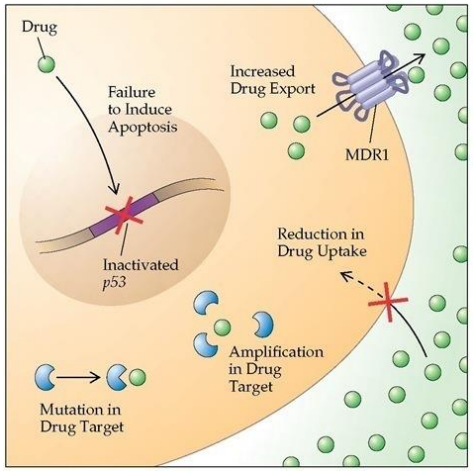
- change clinical & public health practices
- change guidelines
- generate high-level evidence
- conduct research providing such evidence
- this requires an *excellent research infrastructure*

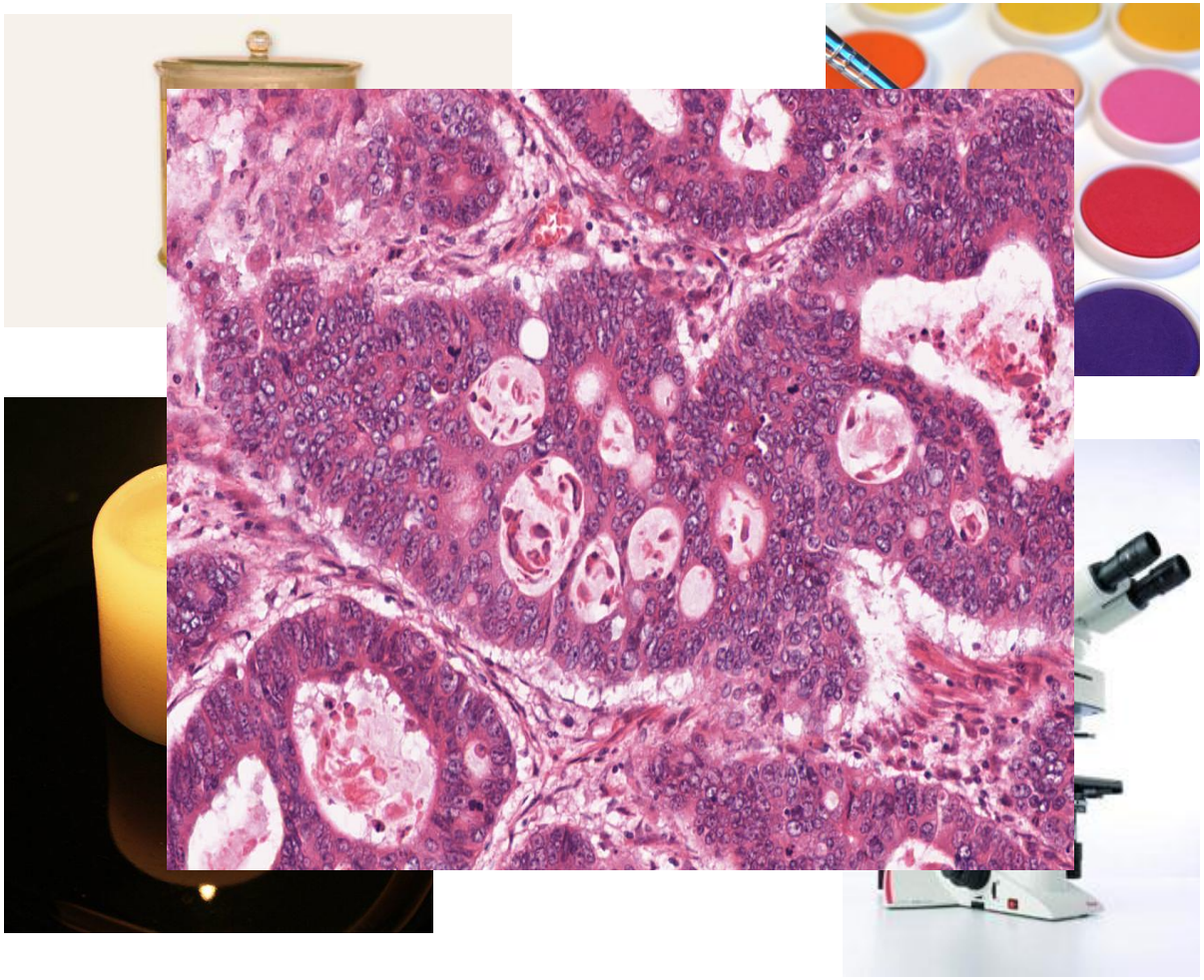
Personalized medicine & health



Personalized medicine: drugs







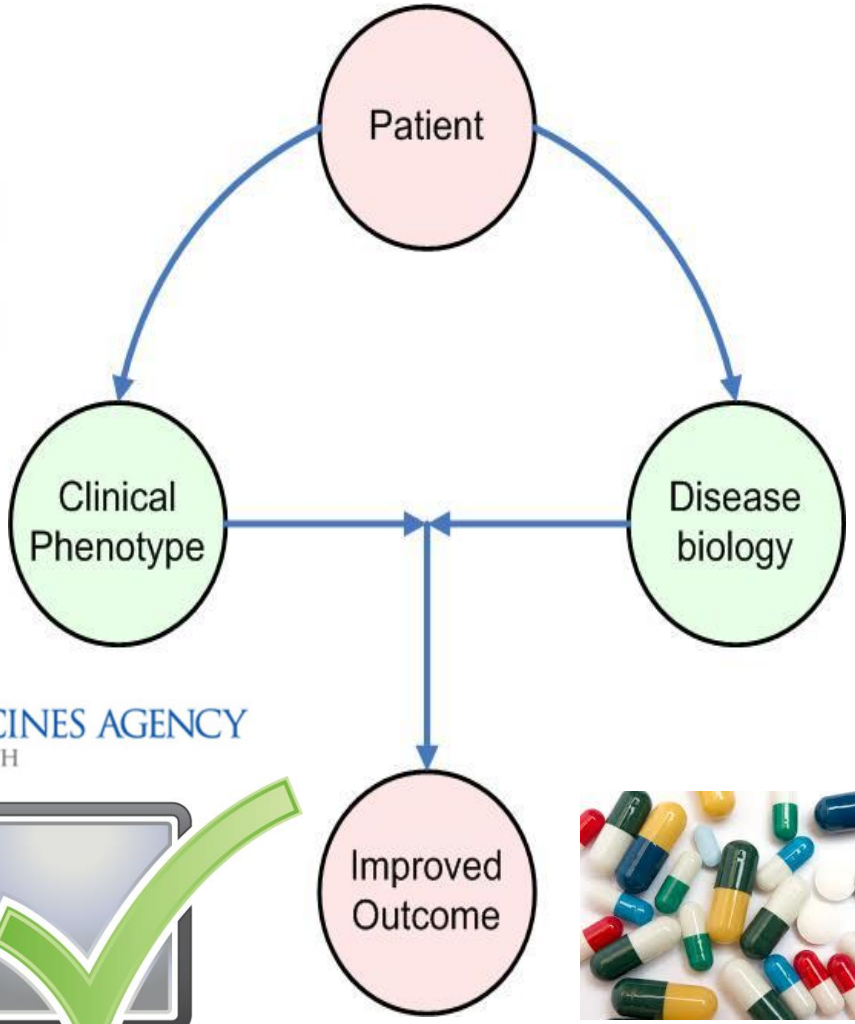
Personalized medicine: drugs

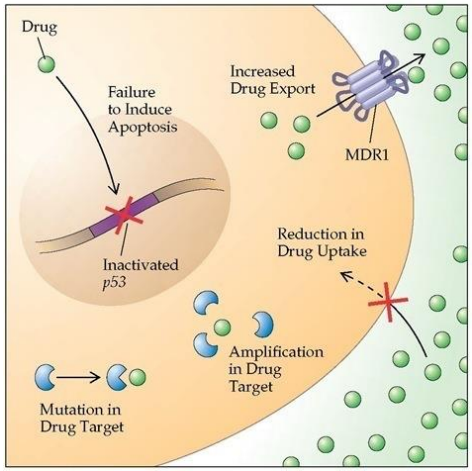
GCP

Good Clinical Practice

FDA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

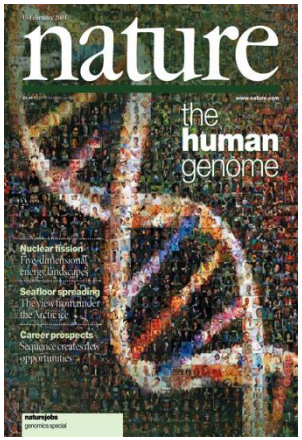


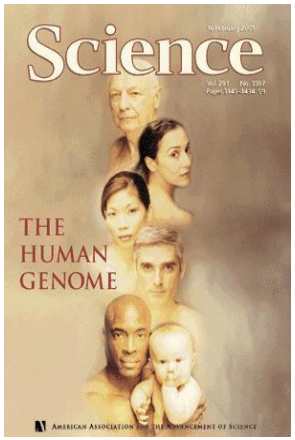


CROs

etc.

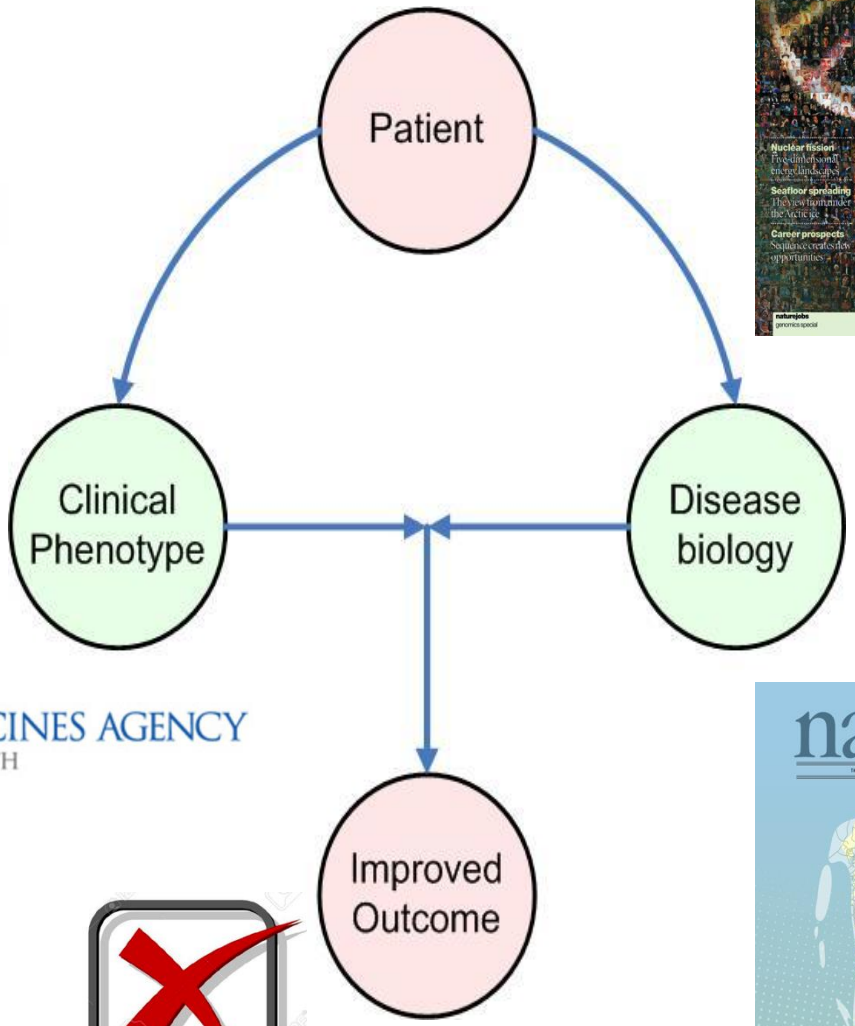
Personalized medicine: biomarkers





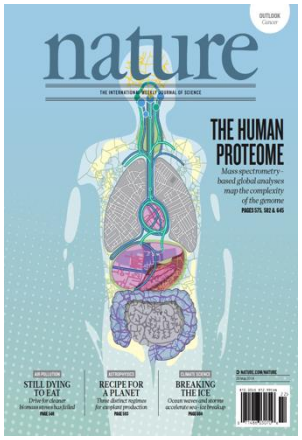
GCP

Good Clinical Practice



the omics revolution

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



CROs

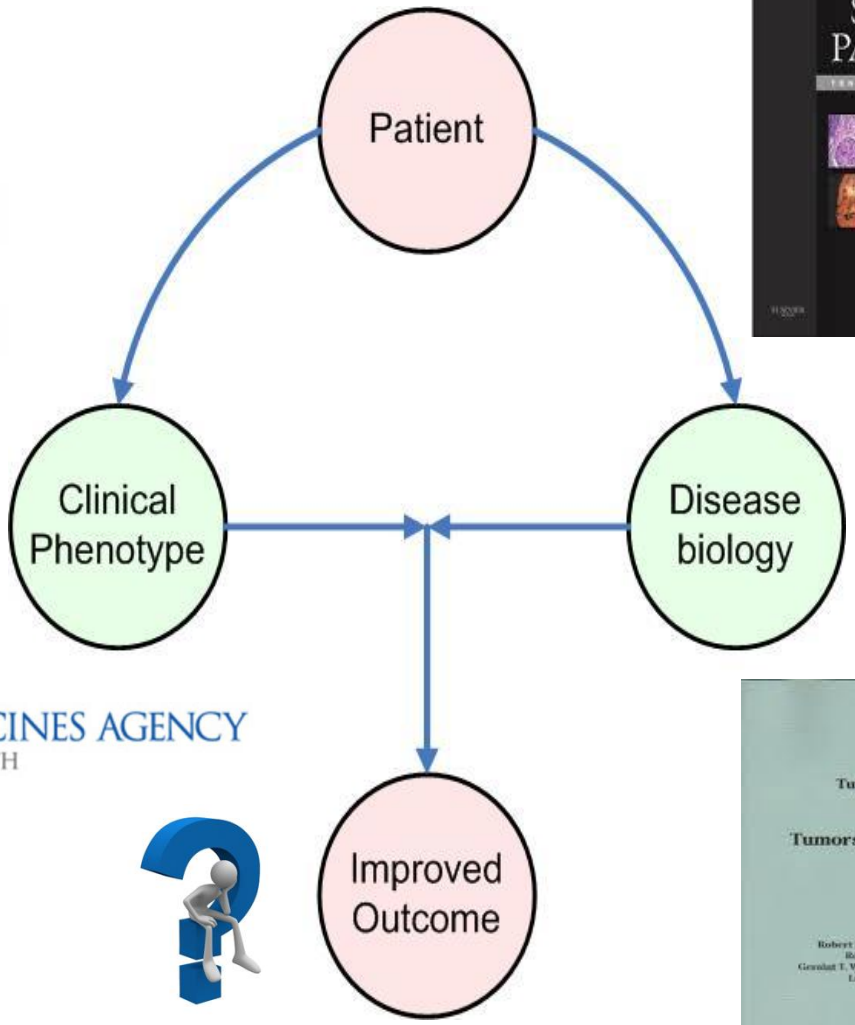
etc.

Personalized medicine: pathology

GCP

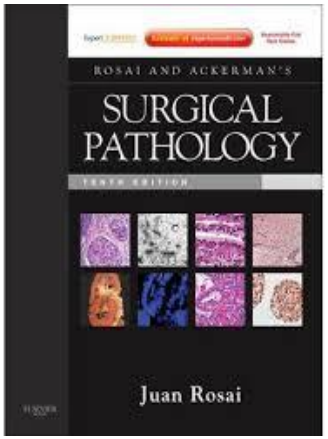
Good Practice

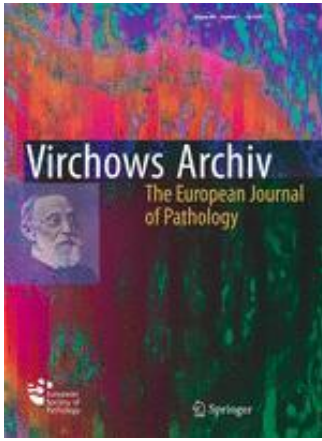
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

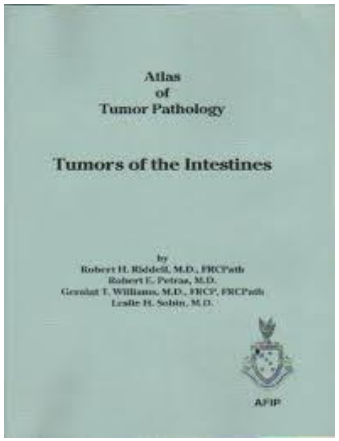


CROs

etc.







How can big data change science?

Here's how medical research traditionally works:

1 Come up with a question or hypothesis.

2 Design an experiment to test it. Wait for new data to come in.

3 Form your conclusion.

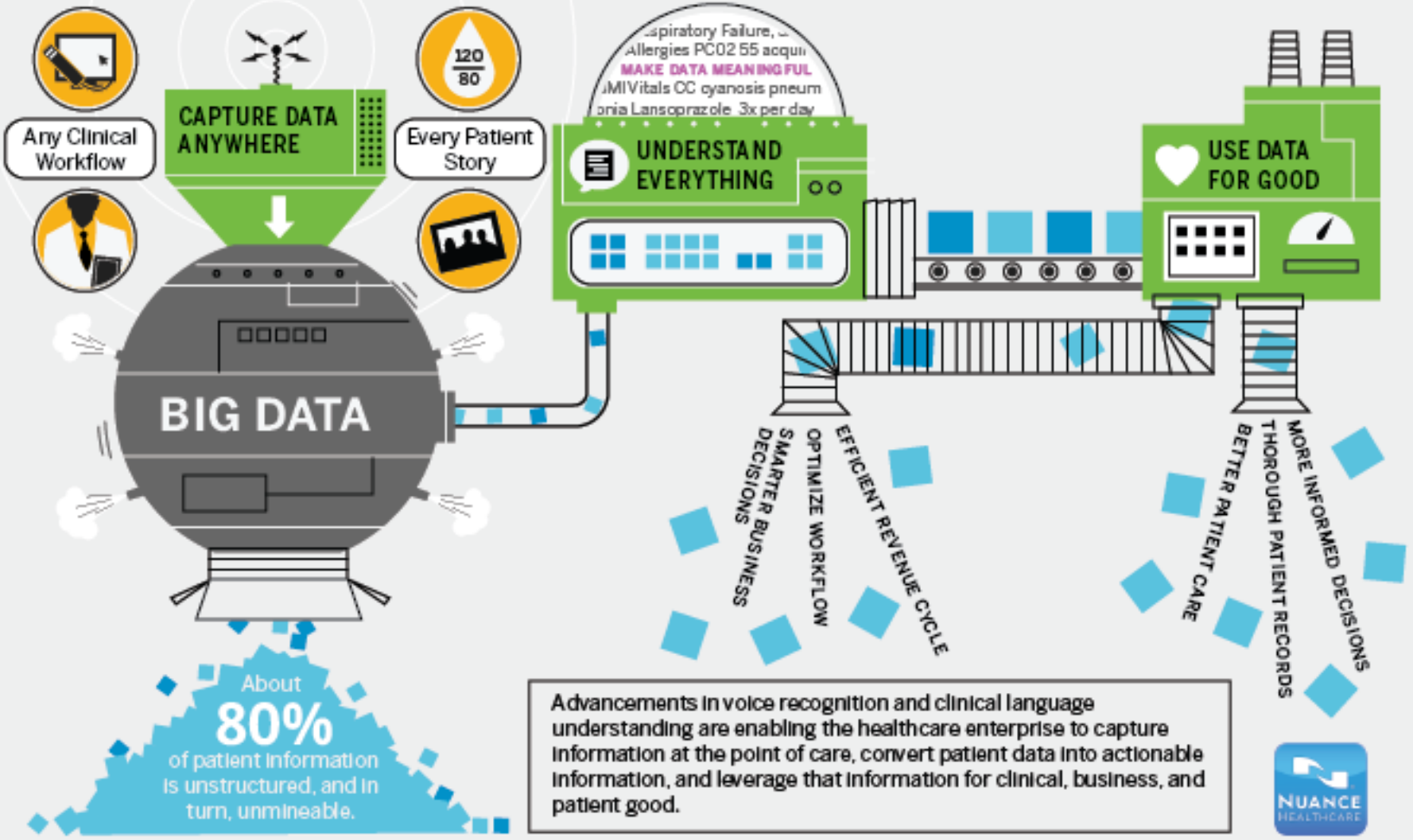
Big data changes step 2

Online, searchable databases provide instant answers, speeding up research.

HEALTHCARE'S DATA CONUNDRUM

FROM DISPARATE DATA TO MEANINGFUL INFORMATION

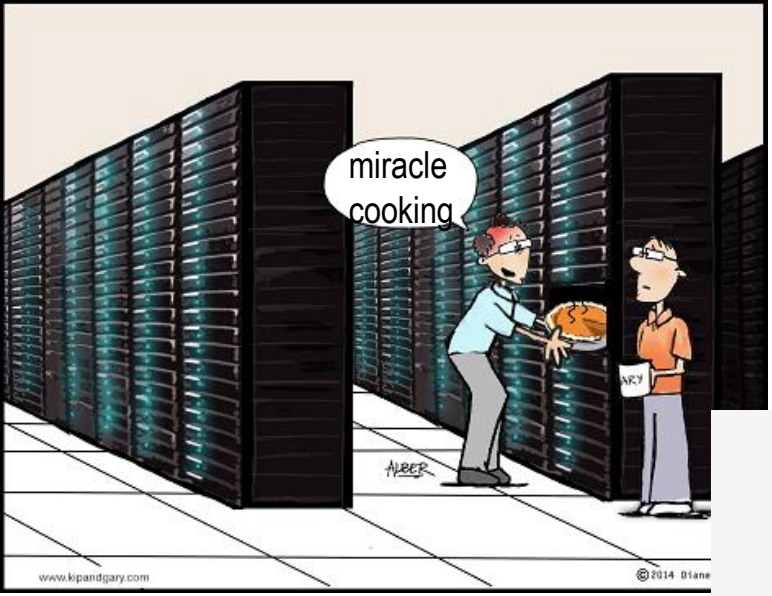
We can empower healthcare organizations, providers and payers to unify the capture, analysis, and use of data to drive smarter care and business.

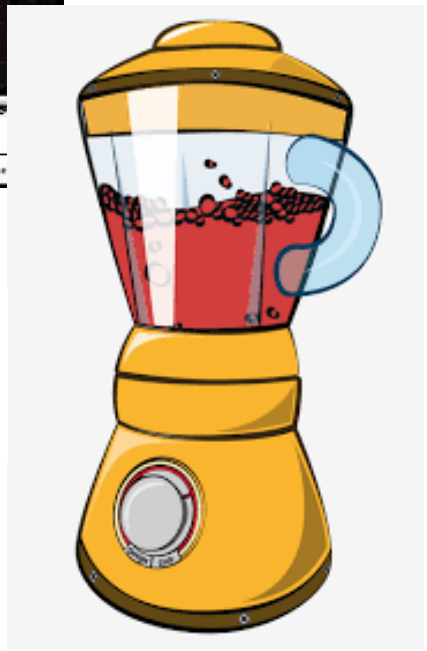


Advancements in voice recognition and clinical language understanding are enabling the healthcare enterprise to capture information at the point of care, convert patient data into actionable information, and leverage that information for clinical, business, and patient good.

NUANCE HEALTHCARE

www.nuance.com/for-healthcare





IBM Watson

Google Nederland

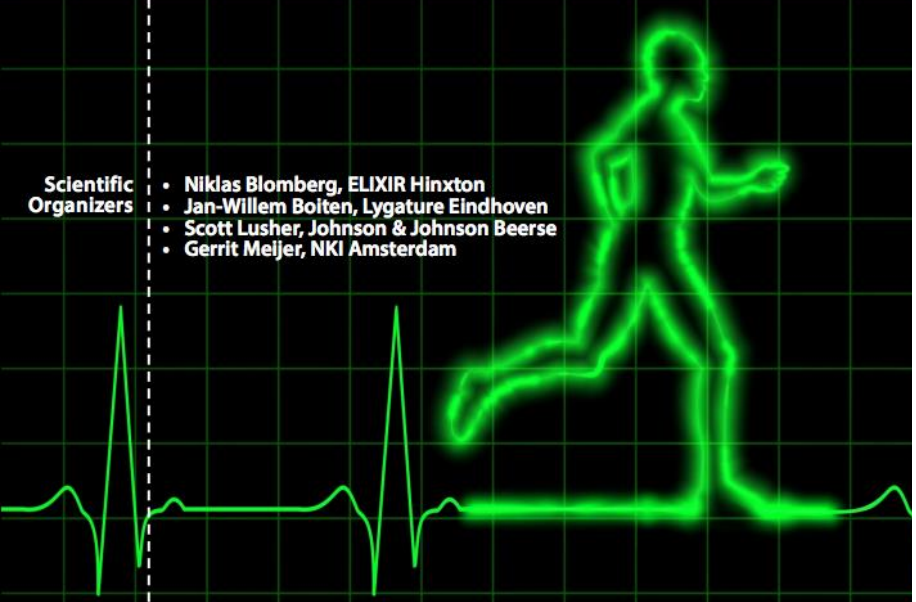
AlphaGo

Lorentz center

netherlands eScience center

Translating Data to Health

Workshop: 21 – 25 March 2016, Leiden, the Netherlands



Scientific Organizers

- Niklas Blomberg, ELIXIR Hinxton
- Jan-Willem Boiten, Lygature Eindhoven
- Scott Lusher, Johnson & Johnson Beerse
- Gerrit Meijer, NKI Amsterdam

Topics

- One Patient - One Petabyte
- Rethinking Data-Driven Translational Research
- Crossing the Research-Clinical Care Line
- Social & Regulatory Aspects
- FAIR Data Sharing

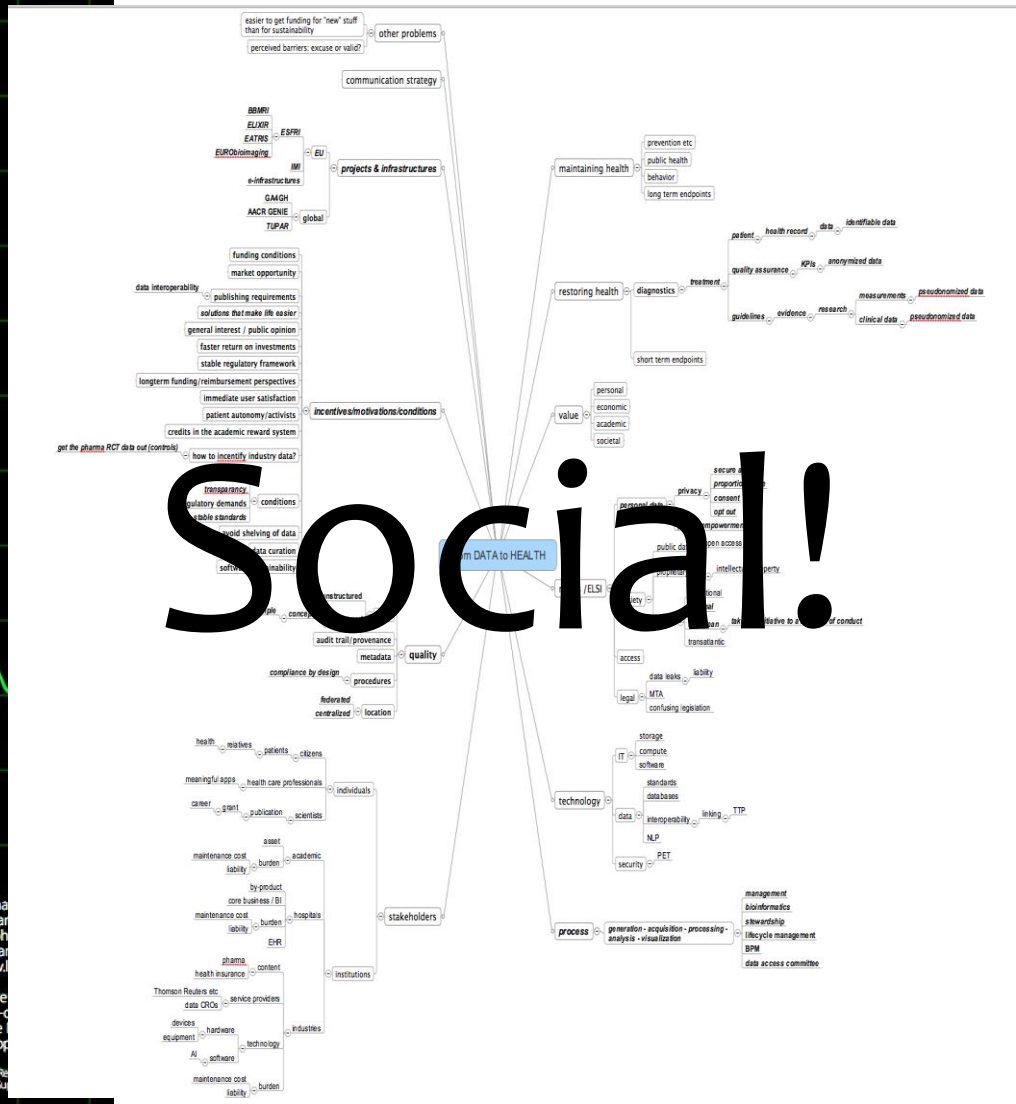
The Lorentz Center is an interna
the sciences. Its aim is to orga
for scientists in an atmosph
collaborative work, discussions a
For registration see: www.l

This workshop is part of the
program, stimulating multi-
data-intensive research in the
developing and app

Background image: One patient - One petabyte: Re
translational research. Poster design: Su

Universiteit Leiden The Netherlands · FOM · STW · NWO · elixir · trait a cbmm project · netherlands eScience center · Lorentz center

w w w . l o r e n t z c e n t e r . n l



The underlying problem…

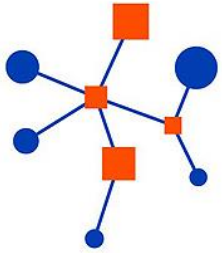
FRAGMENTATION of…

- data
- sample collections
- image collections
- regulations
- software tools
- research initiatives
- funding
- expertise
- etc.

EU

ESFRI European Strategy Forum on Research Infrastructures

health RI research infrastructure



BBMRI
Biobanking and Biomolecular Resources Research Infrastructure

EU INF

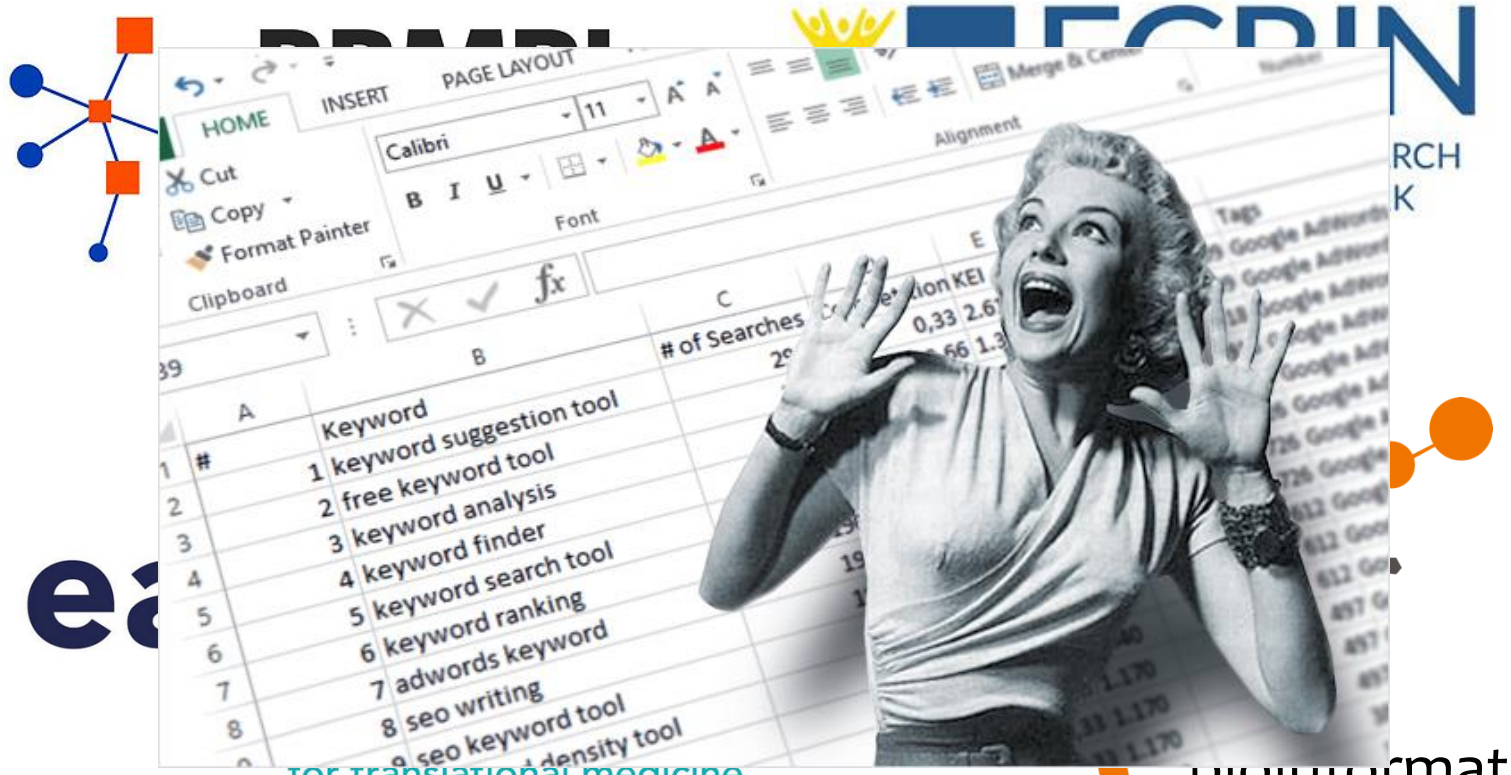
DCRF
Dutch Clinical Research Foundation

IN
EARCH
ORK

eatris
European infrastructure for translational medicine

elixir
bioinformatics

researchers want hassle free research...



.... and patients want fast innovation

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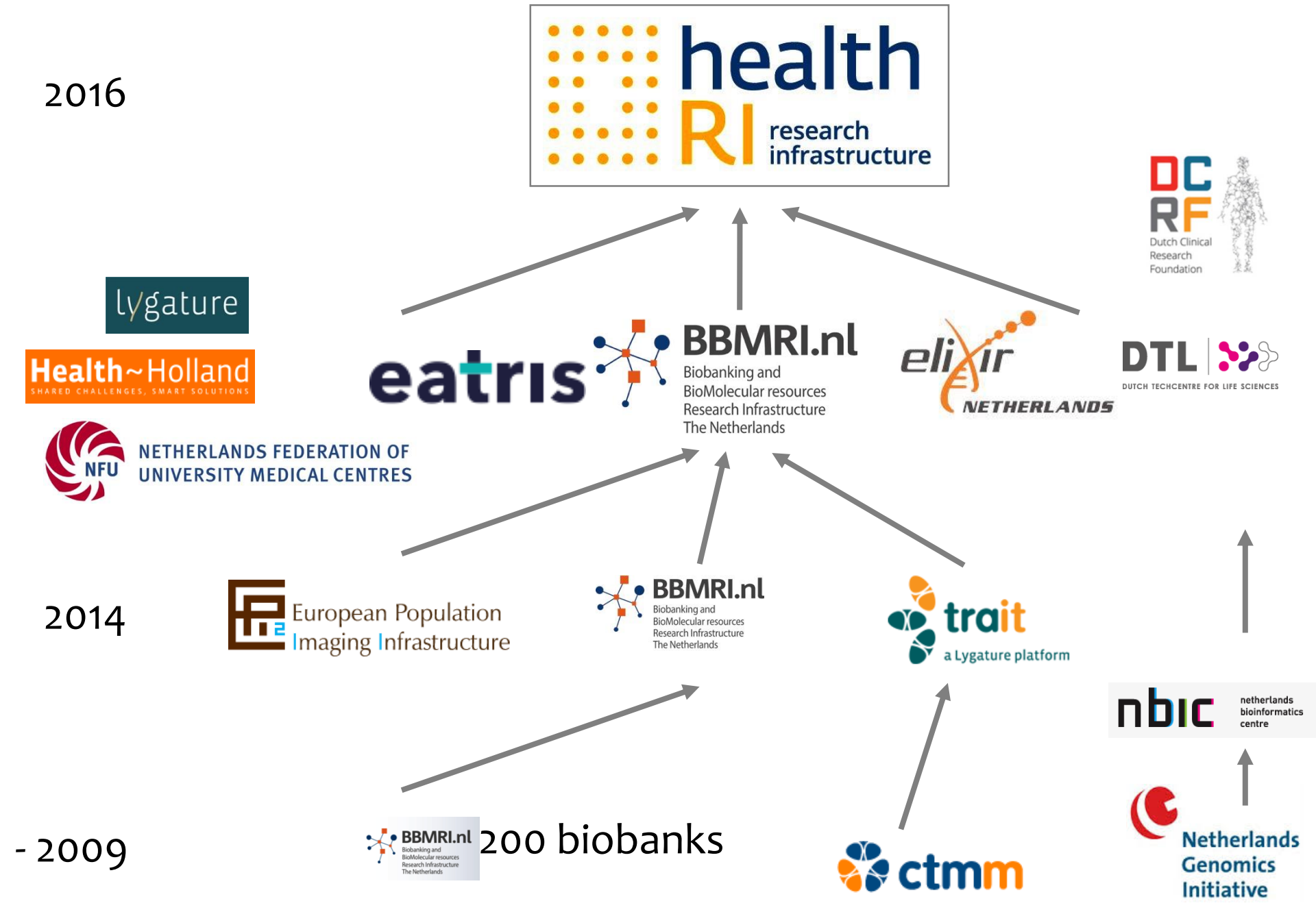

2016
health RI research infrastructure
DCRF Dutch Clinical Research Foundation
lygature
Health~Holland SHARED CHALLENGES, SMART SOLUTIONS
eatris
BBMRI.nl Biobanking and BioMolecular resources Research Infrastructure The Netherlands
elixir NETHERLANDS
DTL DUTCH TECHCENTRE FOR LIFE SCIENCES
NFU NETHERLANDS FEDERATION OF UNIVERSITY MEDICAL CENTRES
2014
European Population Imaging Infrastructure
BBMRI.nl Biobanking and BioMolecular resources Research Infrastructure The Netherlands
trait a Lygature platform
nbic netherlands bioinformatics centre
- 2009
BBMRI.nl 200 biobanks
ctmm
Netherlands Genomics Initiative

Link naar het filmpje:
https://www.bbmri.nl/health_ri/1563/

Internet of Personalized Medicine&Health Data&Things

health RI research infrastructure

Biobanks, cohorts

Wearables

Clinical records

MRI center

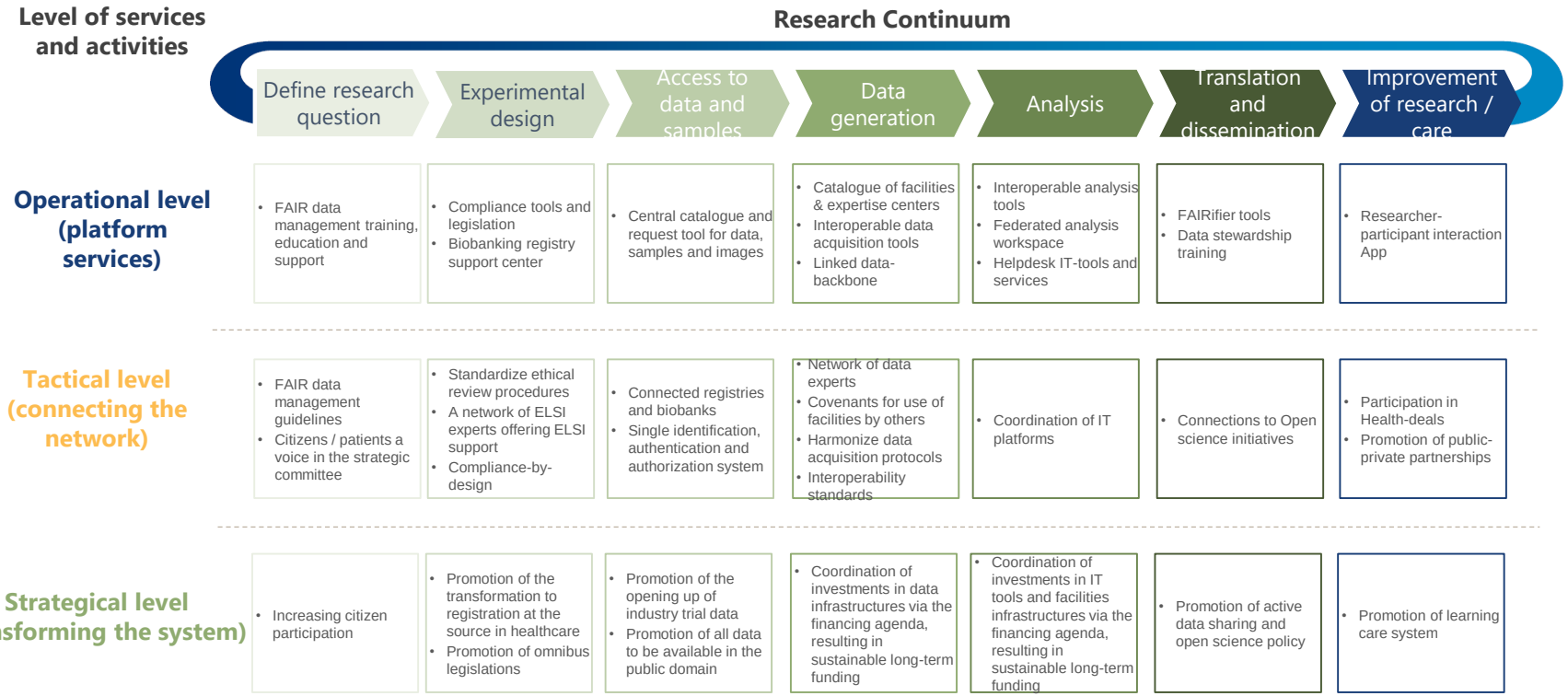
Research laboratory

Microscopy facility

Twitter data

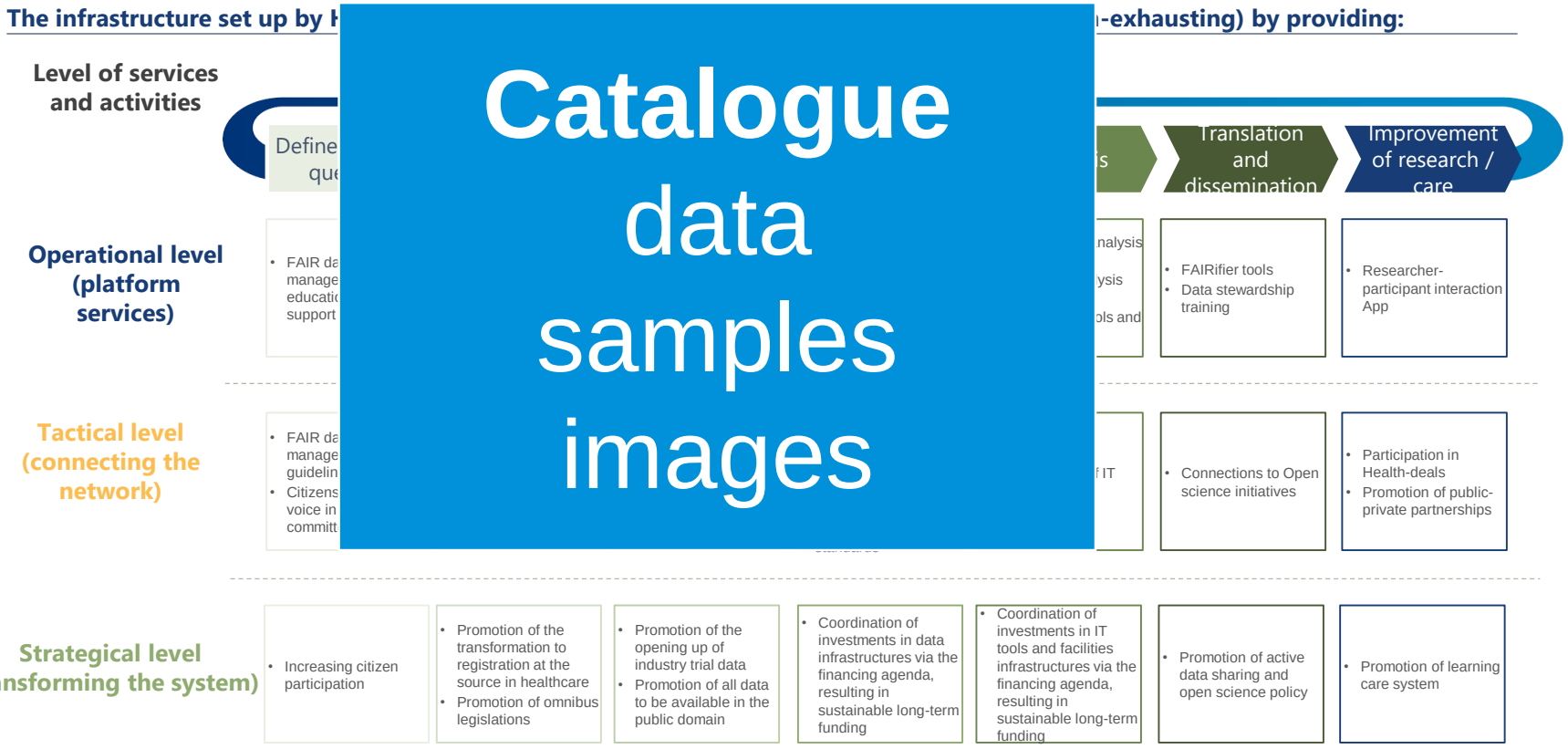
Health-RI services and activities lead to an infrastructure that facilitates the research process

The infrastructure set up by Health-RI facilitates the different steps in the research process (non-exhausting) by providing:



The Health-RI platform offers researchers solutions on demand for each step of the research process.
By simultaneously operating on tactical and strategic level, Health-RI connects the needs of researchers and other stakeholders (funders, society, etc.) transforming the total personalized medicine & health research system.

Health-RI services and activities lead to an infrastructure that facilitates the research process



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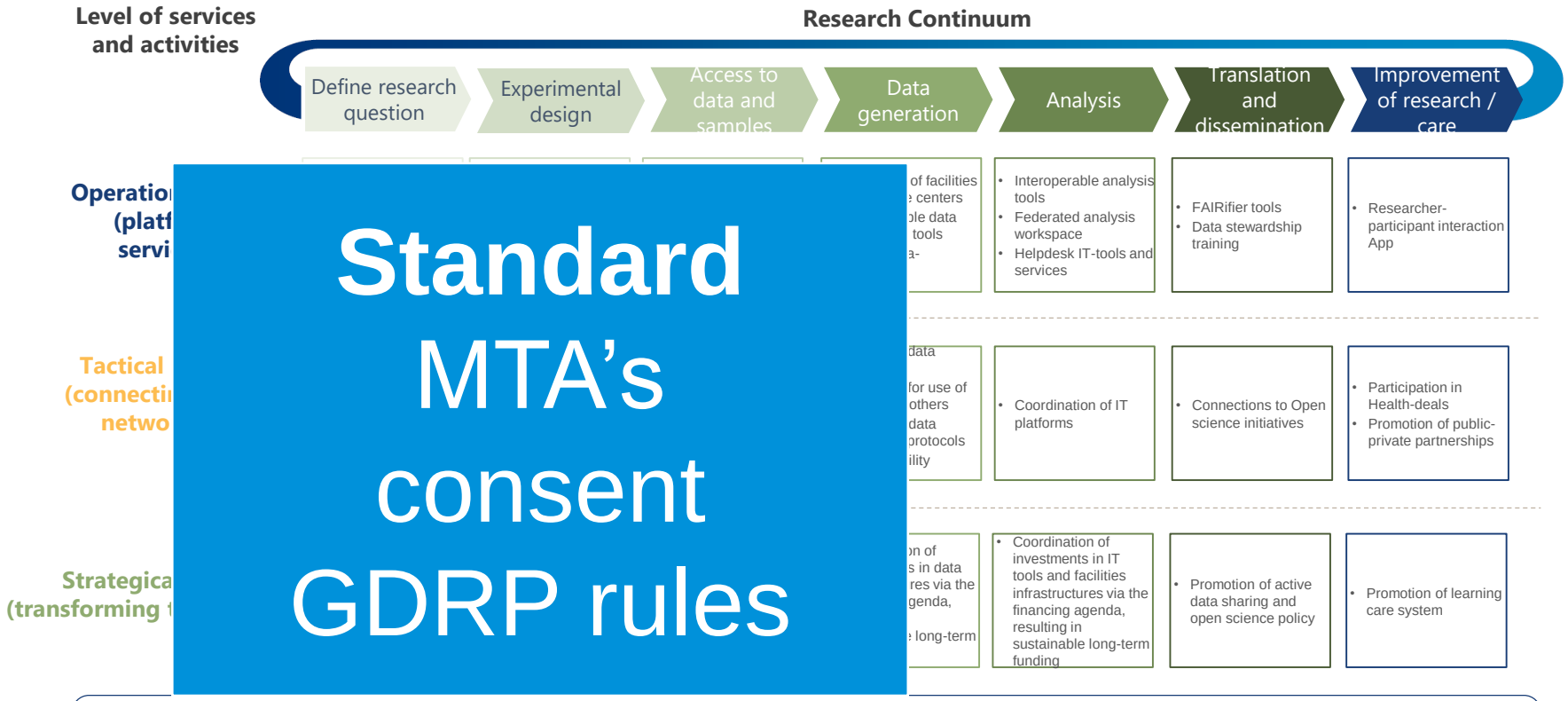

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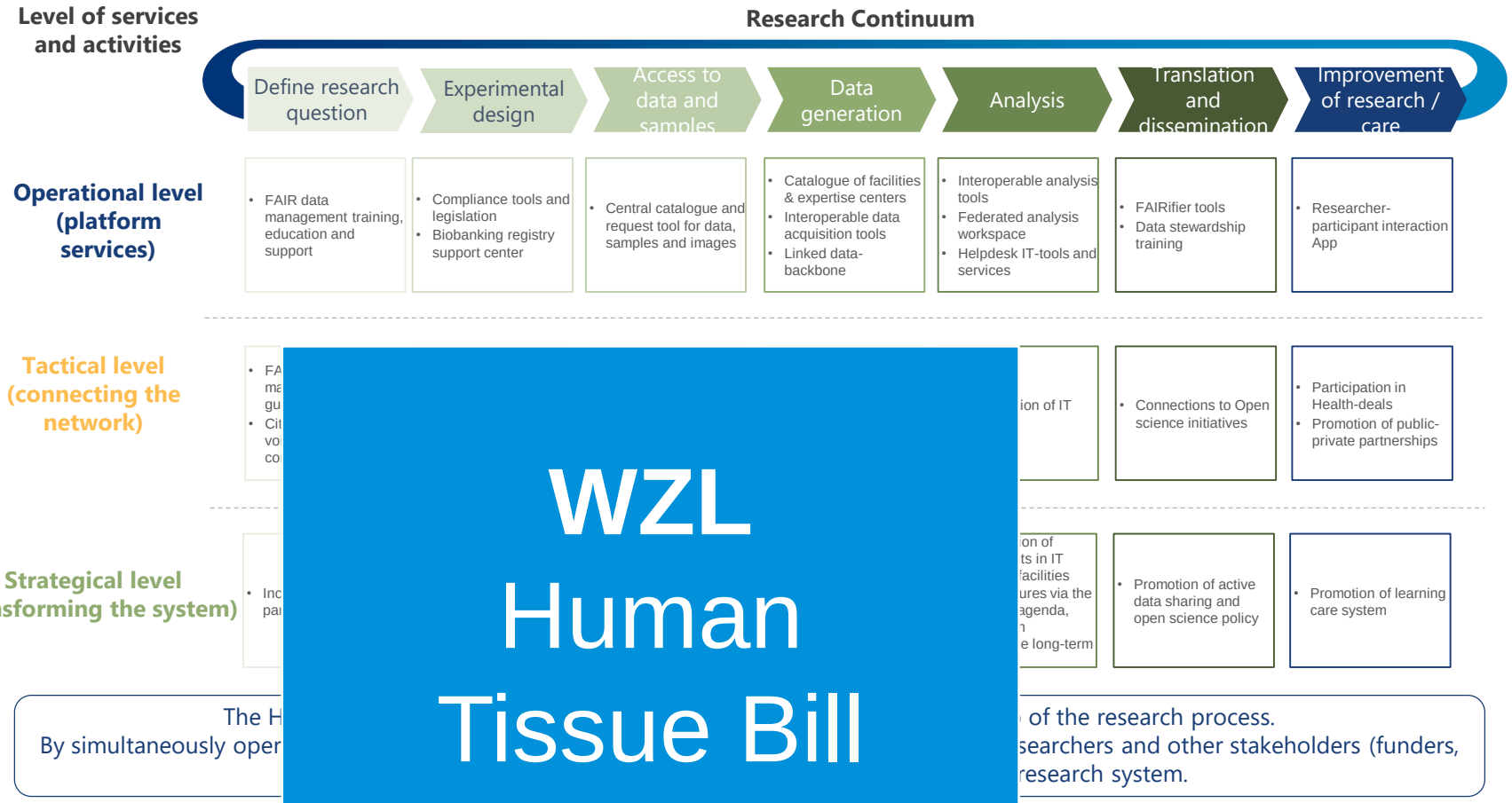

of the research process.
searchers and other stakeholders (funders,
research system.

Health-RI services and activities lead to an infrastructure that facilitates the research process

ELSI service desk

The infrastructu **process (non-exhausting) by providing:**

Level of servic and activitie **nuum**

Analysis | Translation and dissemination | Improvement of research / care

Operational le (platform services)

- Interoperable analysis tools
- Federated analysis workspace
- Helpdesk IT-tools and services
- FAIRifier tools
- Data stewardship training
- Researcher-participant interaction App

Tactical level (connecting th network)

- voice in the strategic committee
- Compliance-by-design
- authentication and authorization system
- acquisition protocols
- Interoperability standards
- Coordination of IT platforms
- Connections to Open science initiatives
- Participation in Health-deals
- Promotion of public-private partnerships

Strategical level (transforming the system)

- Increasing citizen participation
- Promotion of the transformation to registration at the source in healthcare
- Promotion of omnibus legislations
- Promotion of the opening up of industry trial data
- Promotion of all data to be available in the public domain
- Coordination of investments in data infrastructures via the financing agenda, resulting in sustainable long-term funding
- Coordination of investments in IT tools and facilities infrastructures via the financing agenda, resulting in sustainable long-term funding
- Promotion of active data sharing and open science policy
- Promotion of learning care system

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Health-RI services and activities lead to an infrastructure that facilitates the research process

The infrastructure set up by Health-RI facilitates the diffe

"Office 365" for personalized medicine research

Level of services and activities	Define research question	Experimental design	…	…ovement …search / …are
Operational level (platform services)	• FAIR data management training, education and support	• Compliance tools and legislation • Biobanking registry support center	• Cer… req… san…	…her- …nt interaction
Tactical level (connecting the network)	• FAIR data management guidelines • Citizens / patients a voice in the strategic committee	• Standardize ethical review procedures • A network of ELSI experts offering ELSI support • Compliance-by-design	• Cor… and • Sing… auth… auth…	…tion in …eals …n of public- …artnerships
Strategical level (transforming the system)	• Increasing citizen participation	• Promotion of the transformation to registration at the source in healthcare • Promotion of omnibus legislations	• Promotion of the opening up of industry trial data • Promotion of all data to be available in the public domain	• Coordination of investments in data infrastructures via the financing agenda, resulting in sustainable long-term funding • Coordination of investments in IT tools and facilities infrastructures via the financing agenda, resulting in sustainable long-term funding • Promotion of active data sharing and open science policy • Promotion of learning care system

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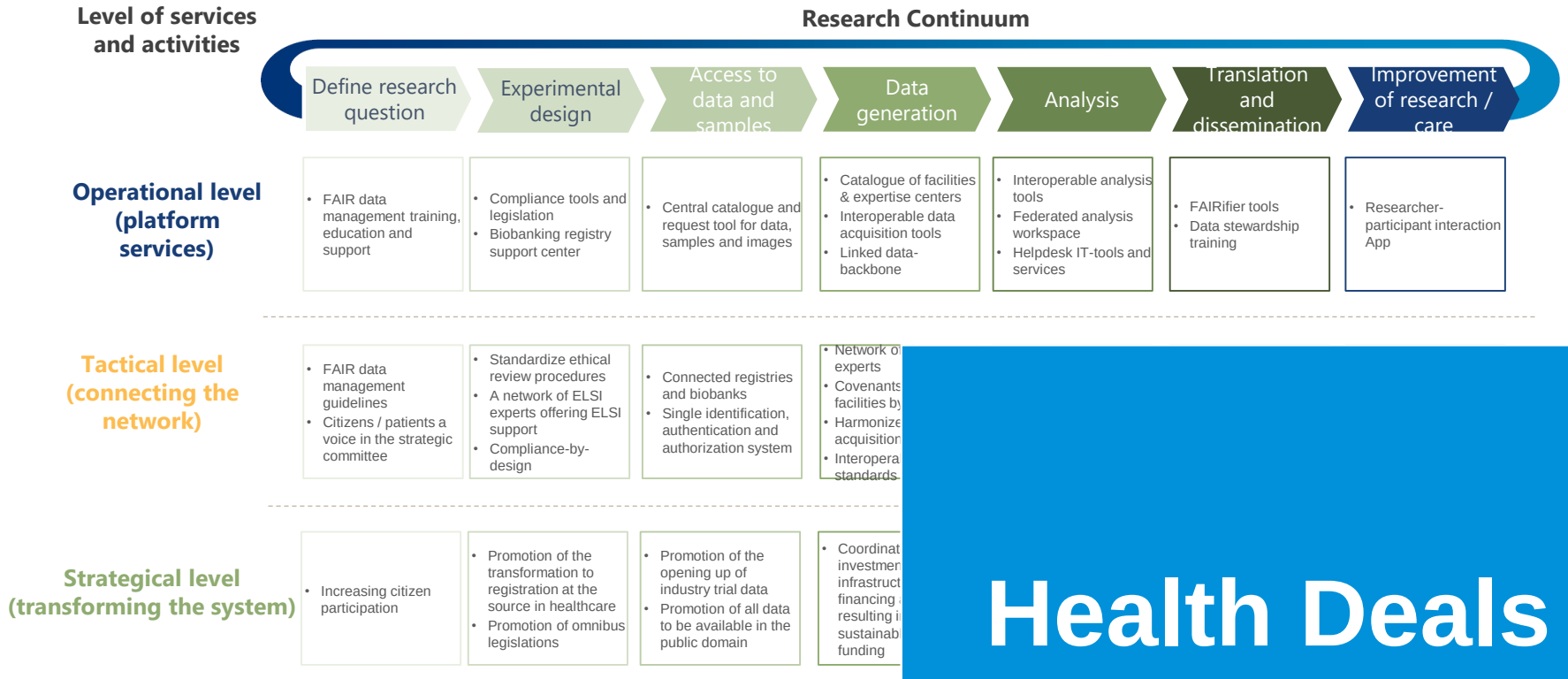

The Health-RI platform offers researchers solutions on dema
By simultaneously operating on tactical and strategic level, Health-RI connect
society, etc.) transforming the total personalized me

Health Deals

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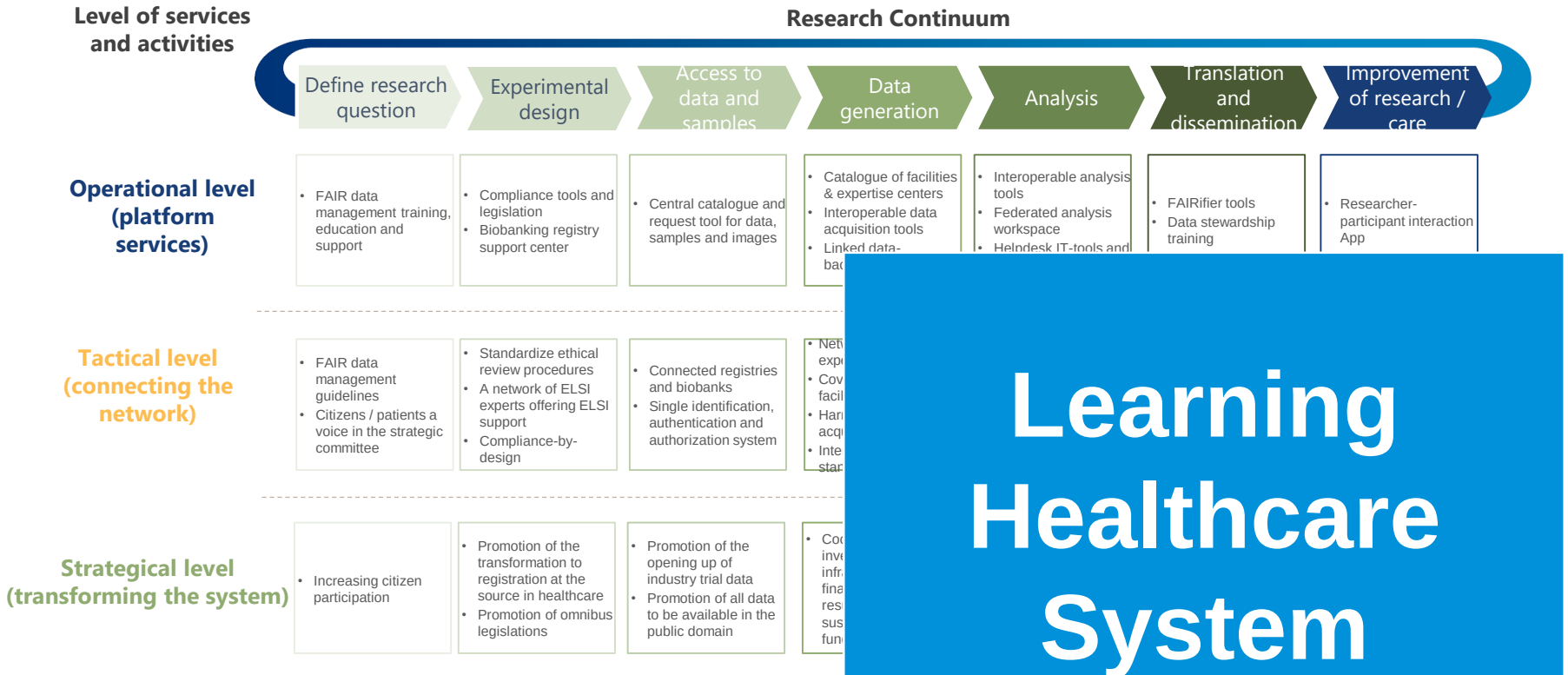

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By simultaneously operating on tactical and strategic level, Health-RI conn
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Operational shared services

Catalogue

- data
- phenotype
- omics
- wearables
- images
- samples

ELSI services

- compliance by design to regulations
- privacy
- influencing legislation
- mybiobank etc

IT services

- standardisation
- online digital research environment
- "office 365" for personalized medicine & health research
- interfacing to advanced technologies
- deep learning pipelines for image analysis
- multi-omics pipelines
- etc

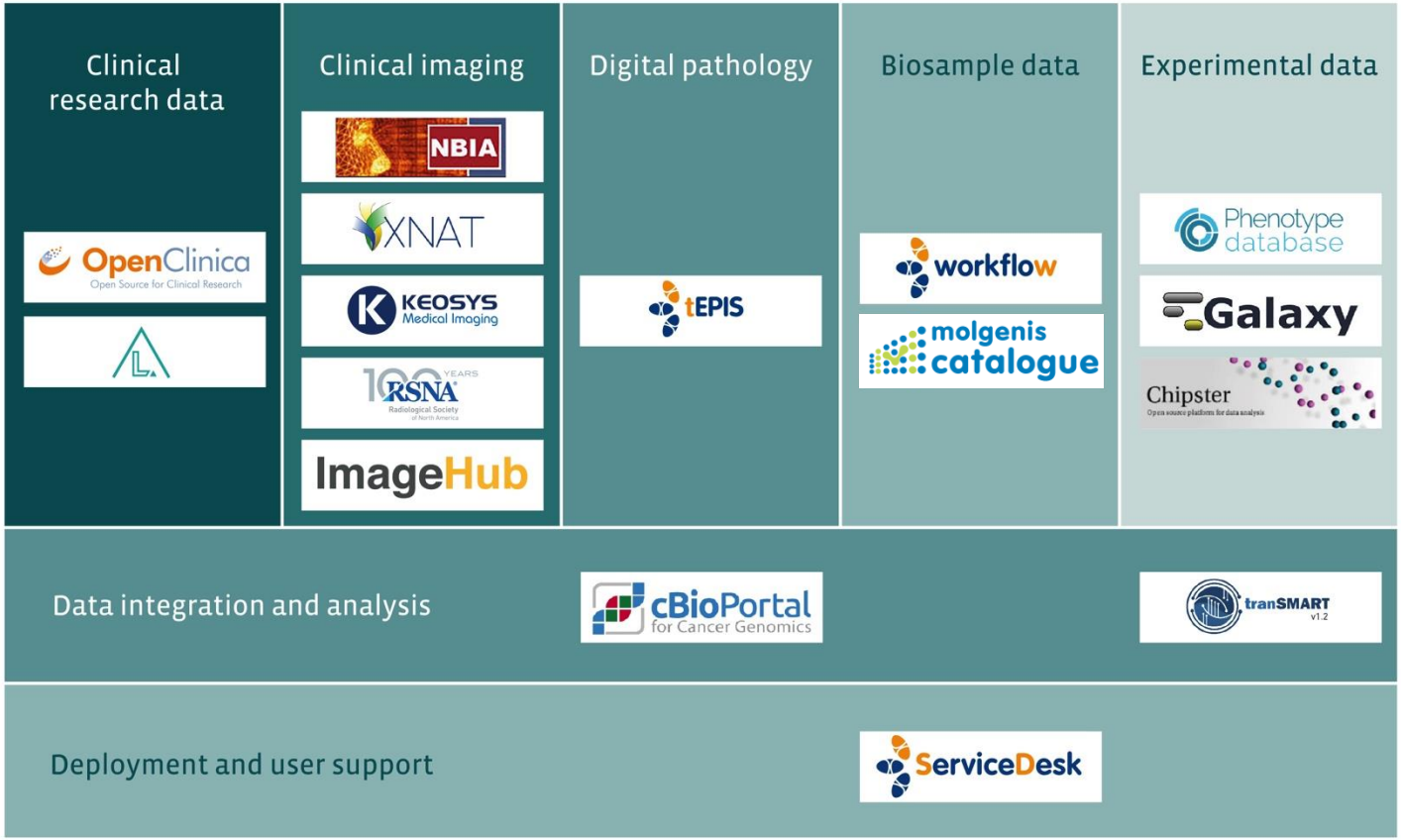
Personalized Medicine Research Process Management

An ‘office’ suite

health RI research infrastructure

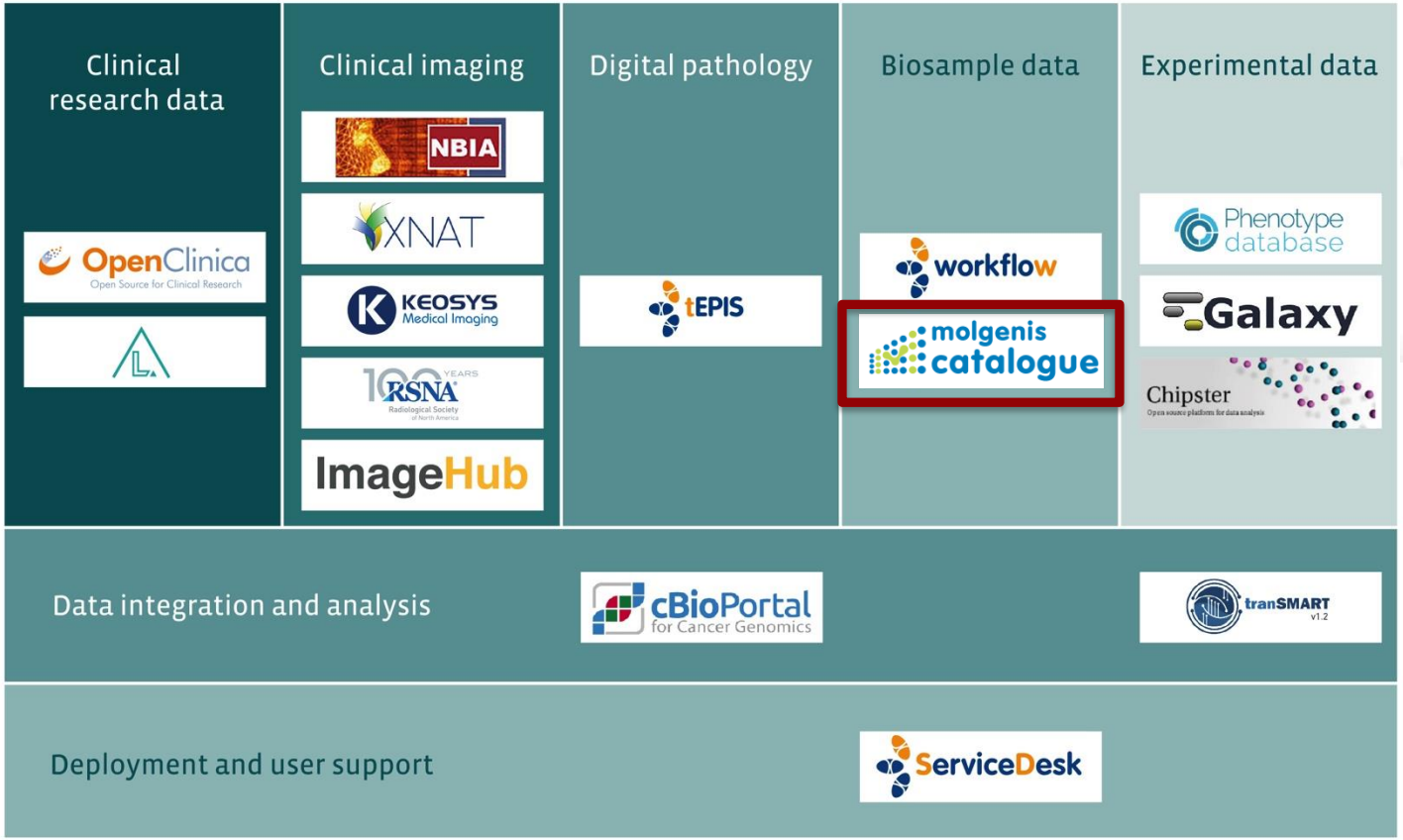
Microsoft® Office 365

“Office 365” suite for translational research



http://www.ctmm-trait.nl/trait-tools

“Office 365” suite for translational research



http://www.ctmm-trait.nl/trait-tools

rescue manual curation efforts

clinical trials

cohort studies

retrospective studies

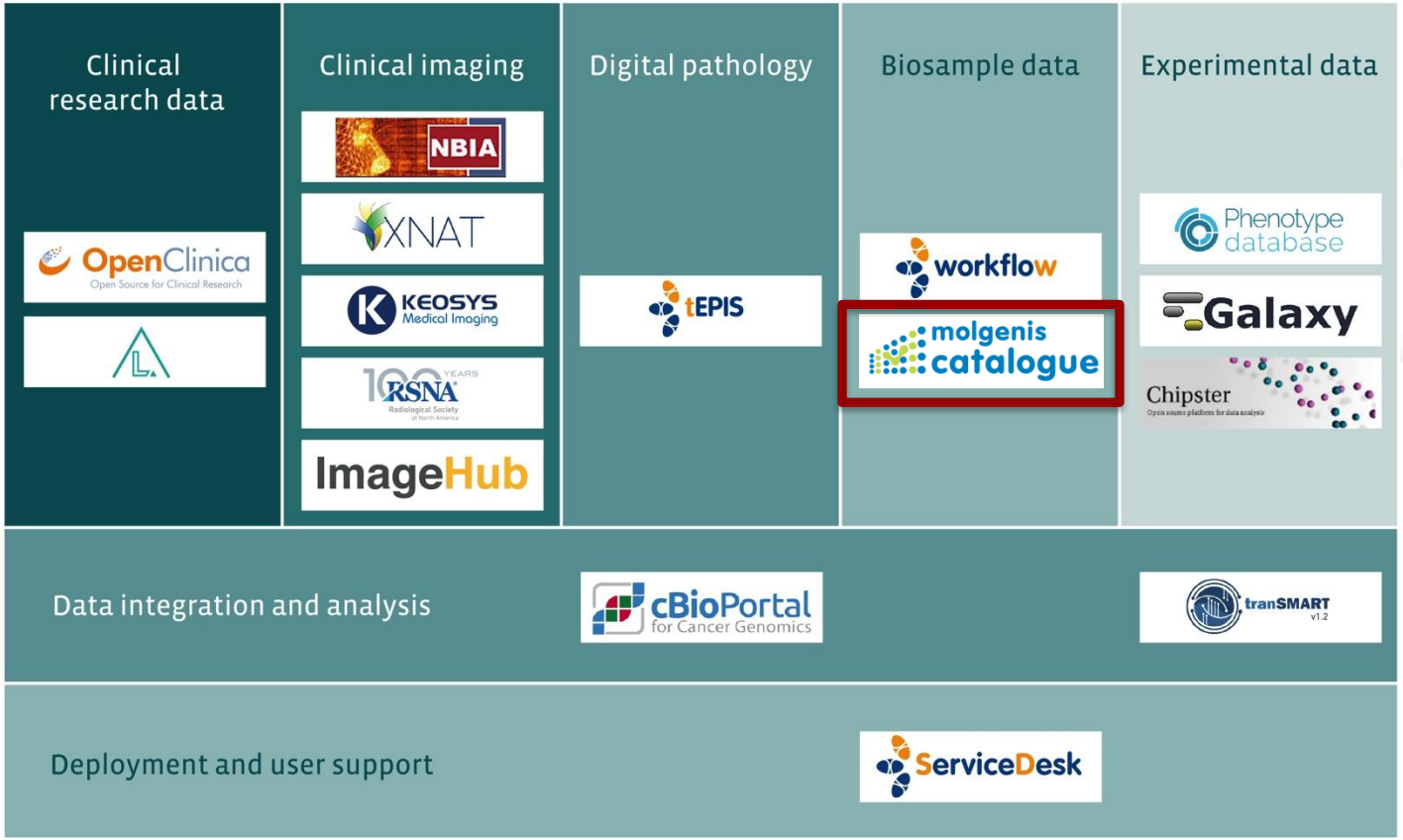
A practical example:
I would like to perform a study!

Topic: breast cancer in men (age 18-50 years)

Questions: Where do I begin?

Are there already existing datasets?

“Office 365” suite for translational research



http://www.ctmm-trait.nl/trait-tools

A practical example

FAIR: Findable

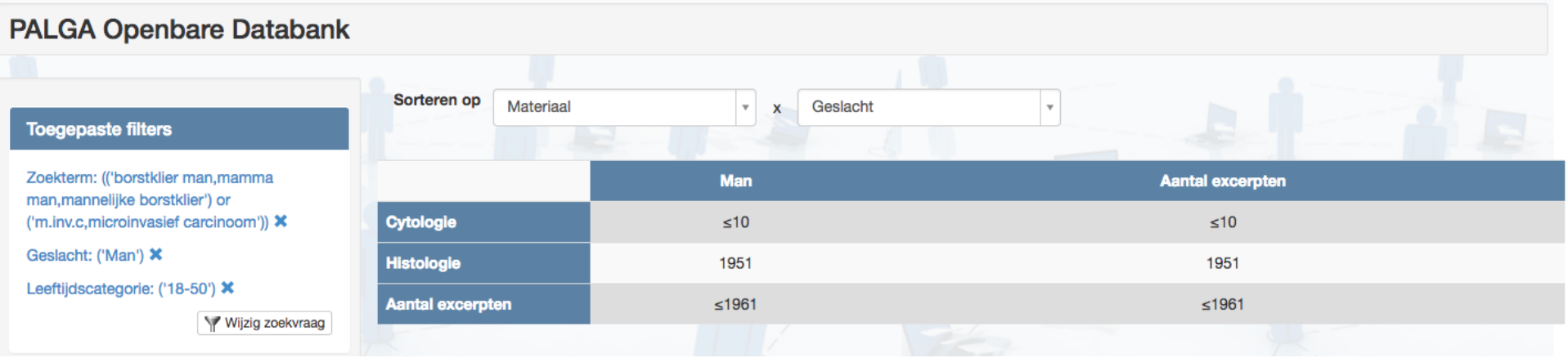
Study: breast cancer in men

Question: of how many men (age 18-50 years) is material available?

→ data, samples, treatment and follow-up

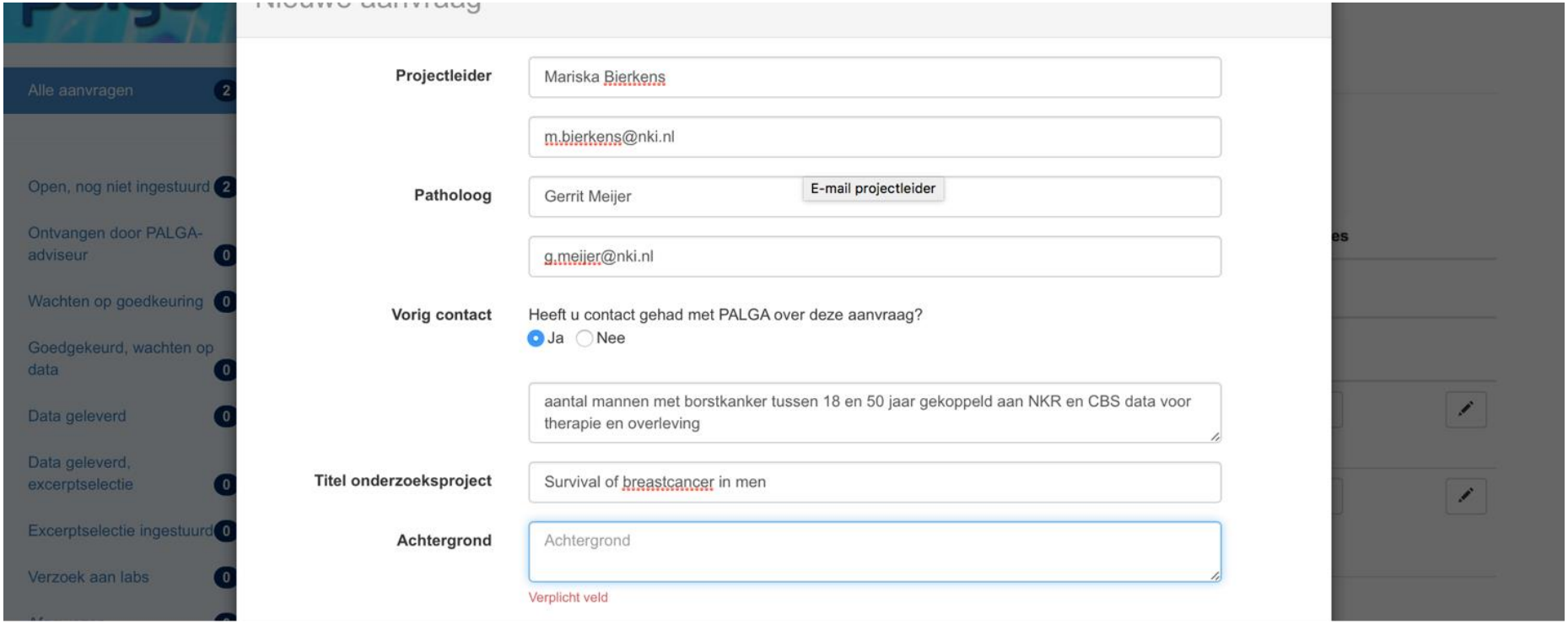
Step 1: Search and find:

- **Catalogue:**
  - National (cyto)pathological Public Archive (Palga Openbare Databank)
  - Dutch Cancer Registry (IKNL)
  - Central Bureau for Statistics (CBS) statline



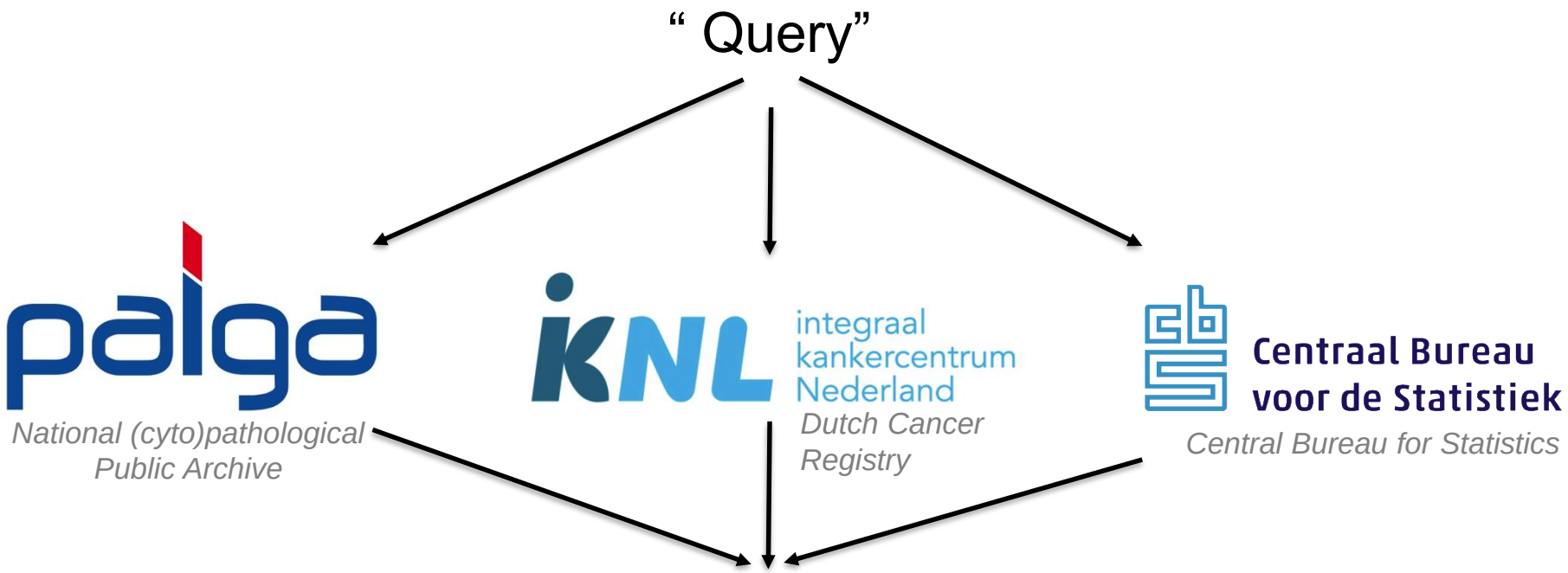
A practical example
FAIR: Accessible

Step 2: Online request portal



A practical example
FAIR: Interoperable

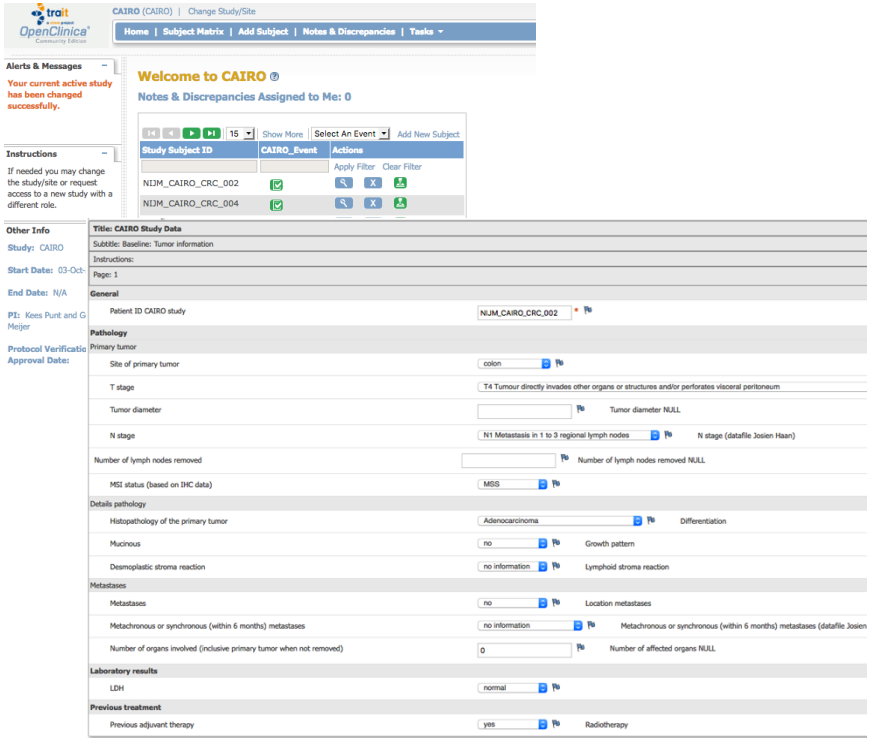
Step 3: Wait for a linked dataset

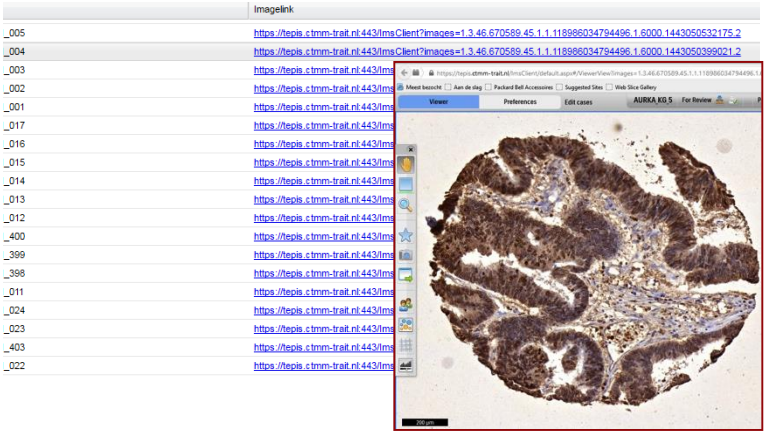


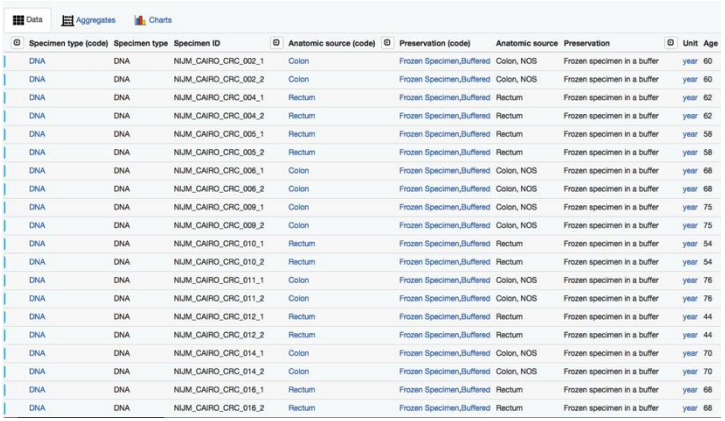
Available, pseudonymized, dataset and samples for research

A practical example

Step 4: Storage and editing of data, samples, images in Health-RI tools







A practical example
FAIR: Reusable

Step 5: Publish and share!

ClinicalTrials.gov

PubMed

Gene Expression Omnibus

EMBL-EBI PRIDE Archive

EUROPEAN GENOME-PHENOME ARCHIVE

- Clinical data
- Pathology data
- Imaging data
- Biobank data
- Experimental data

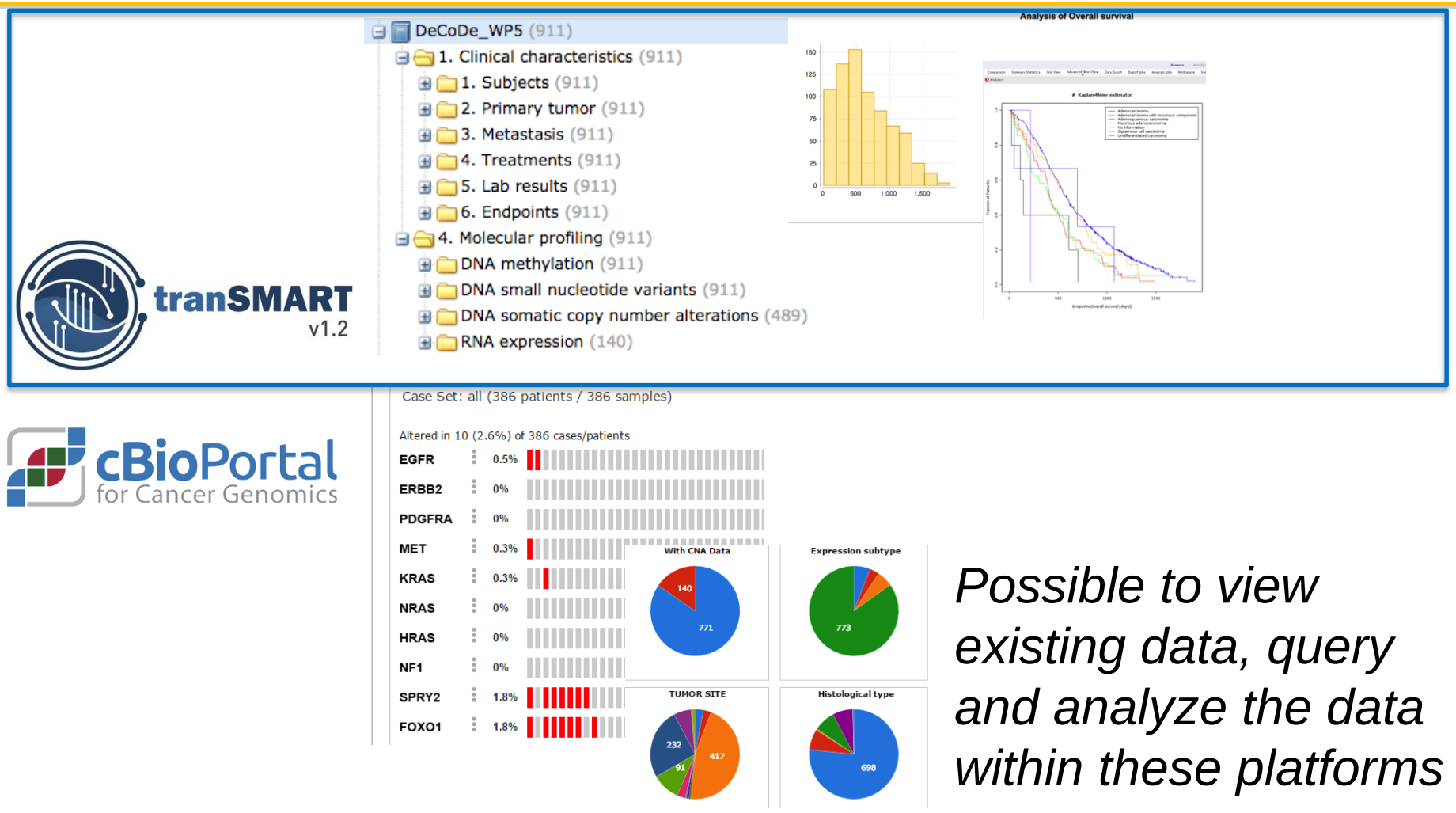
tranSMART v1.2

cBioPortal for Cancer Genomics

Also publish and share the 'final' data itself, not just conclusions

Accessible and insightful for non bio-informaticians!

‘Final’ data available for view and query within the data-integration platforms



Possible to view existing data, query and analyze the data within these platforms

Background tranSMART

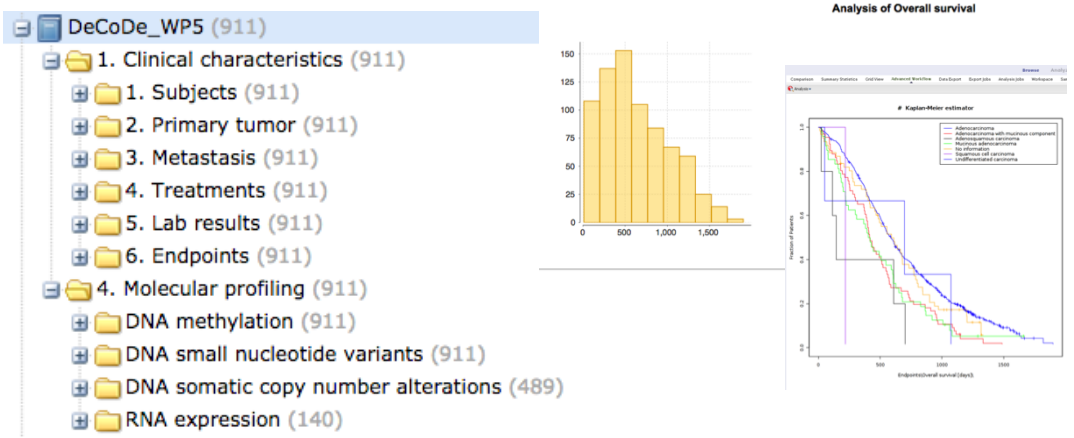
- Originally designed as a data-warehouse by Johnson & Johnson and Recombinant Data Corporation (2009), used internally for view and analysis
- Software turned open-source in 2012
  in the context of IMI ETRIKS
- tranSMART Foundation (2013), a public-private partnership, established an open source community (USA and EU collaborators)
- tranSMART Foundation & i2b2 Foundation merged in 2017

Over 50 implementations

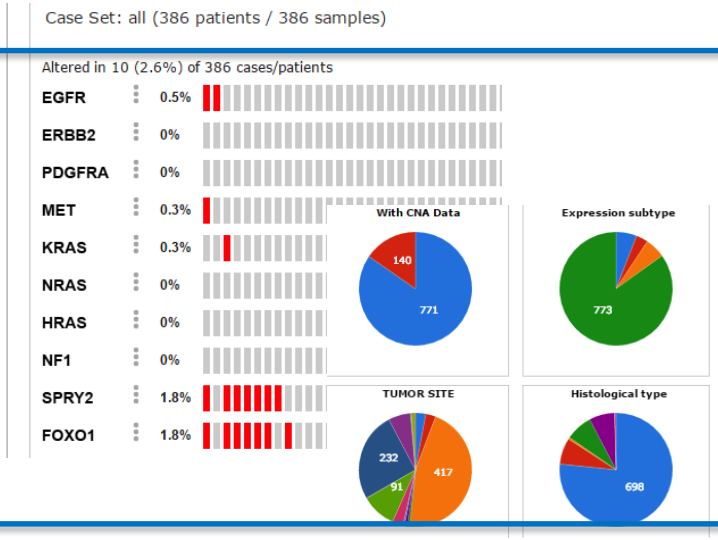
health RI research infrastructure

‘Final’ data available for view and query within the data-integration platforms

tranSMART v1.2



cBioPortal for Cancer Genomics



Possible to view existing data, query and analyze the data within these platforms

The trick: apply FAIR to best practices

- BBMRI-NL catalogue (Findable, Accessible)
- Parelsnoer PRISMA data model
- Request portal DNTP developed for PALGA
- ELSI support center BBMRI-NL & COREON
- Molgenis & tranSMART portals for downstream analysis
- cBioportal for intuitive visualisation
- Minimal data sets: Registration at the Source, involving medical assocations
- Quality assurance & process optimization: EATRIS
- Standardize ETL between large registries (NKR-oncology; NHR-cardiology, etc.)
- FAIRification expertise: DTL/ELIXIR-NL
- Digital Research Environment Data4lifesciences/ELIXIR
- Harmonized organization of institutional back offices D4LS
- Effective helpdesk for end users

Time Table

- business plan by KPMG started in spring
  - 1st stakeholder meeting june
  - 2nd version draft with project group
  - will be sent off to stakeholders 5/10
  - 2nd stakeholder meeting 12/10
  - presentation final version business plan 8/12
  - establish Health-RI organization Q2 2018

Health-RI wrap up

A) we all share the same problem

- innovation gap in PM&H research
- substandard infrastructure

B) solution is clear

- defragmentation
- standardization / FAIR
- bring users & infrastructures together

C) how to organize

- efficient & effective
- inclusive

D) how to finance

- integrated approach
- with all payers
- basic component + fee for service

That's why!

basic research > excellent science> more cure

Endorsed by stakeholders, and the people behind these

health RI research infrastructure