

Making personalized medicine research productive

Gerrit Meijer

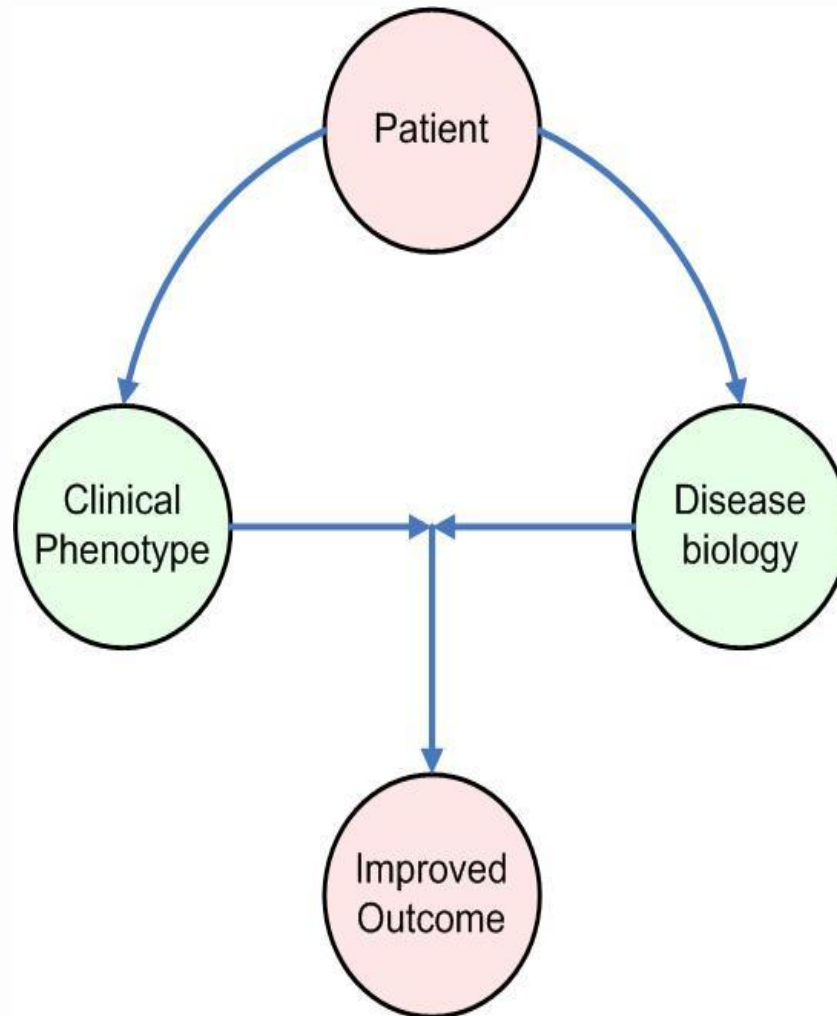
Department of Pathology

NETHERLANDS
CANCER
INSTITUTE

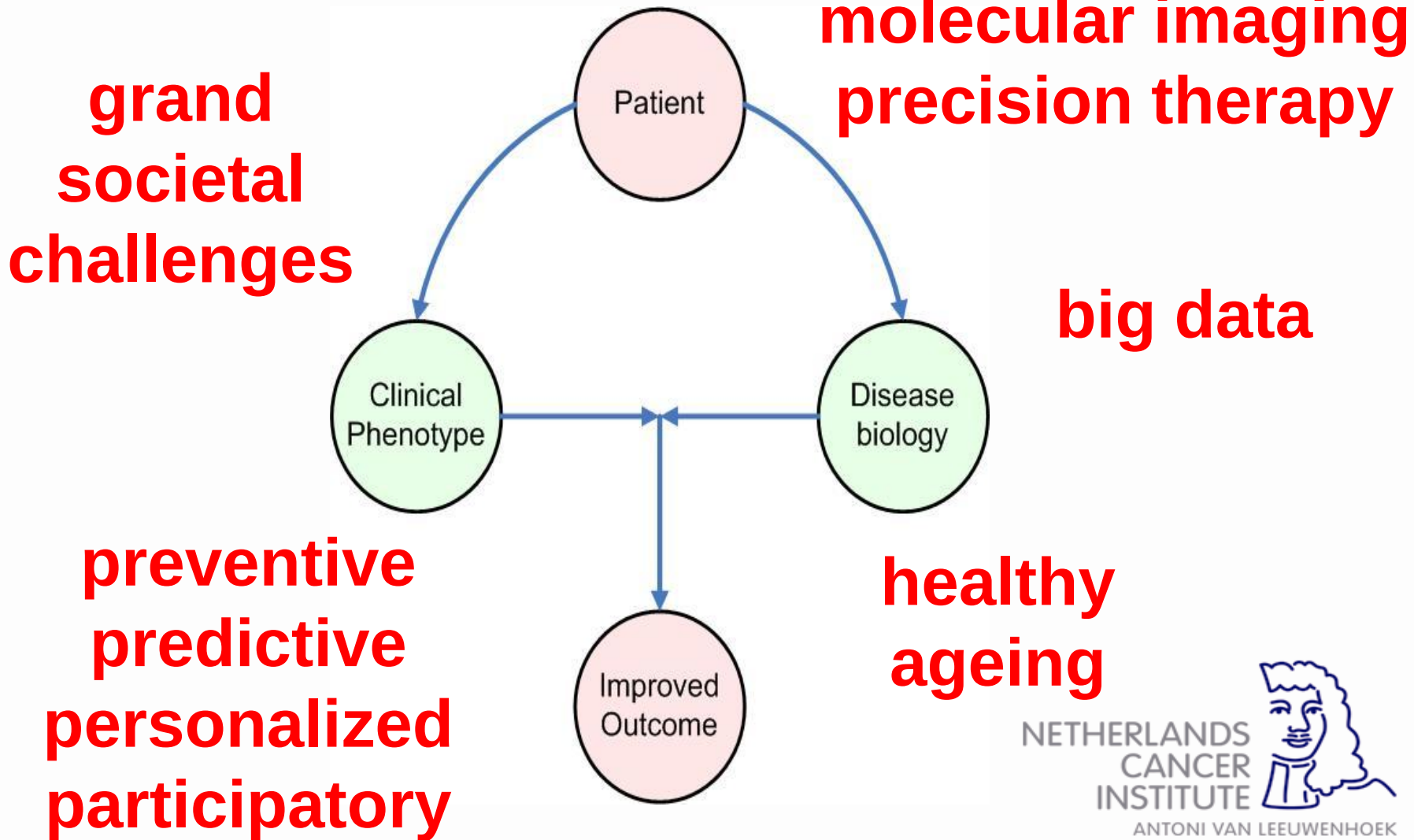
ANTONI VAN LEEUWENHOEK

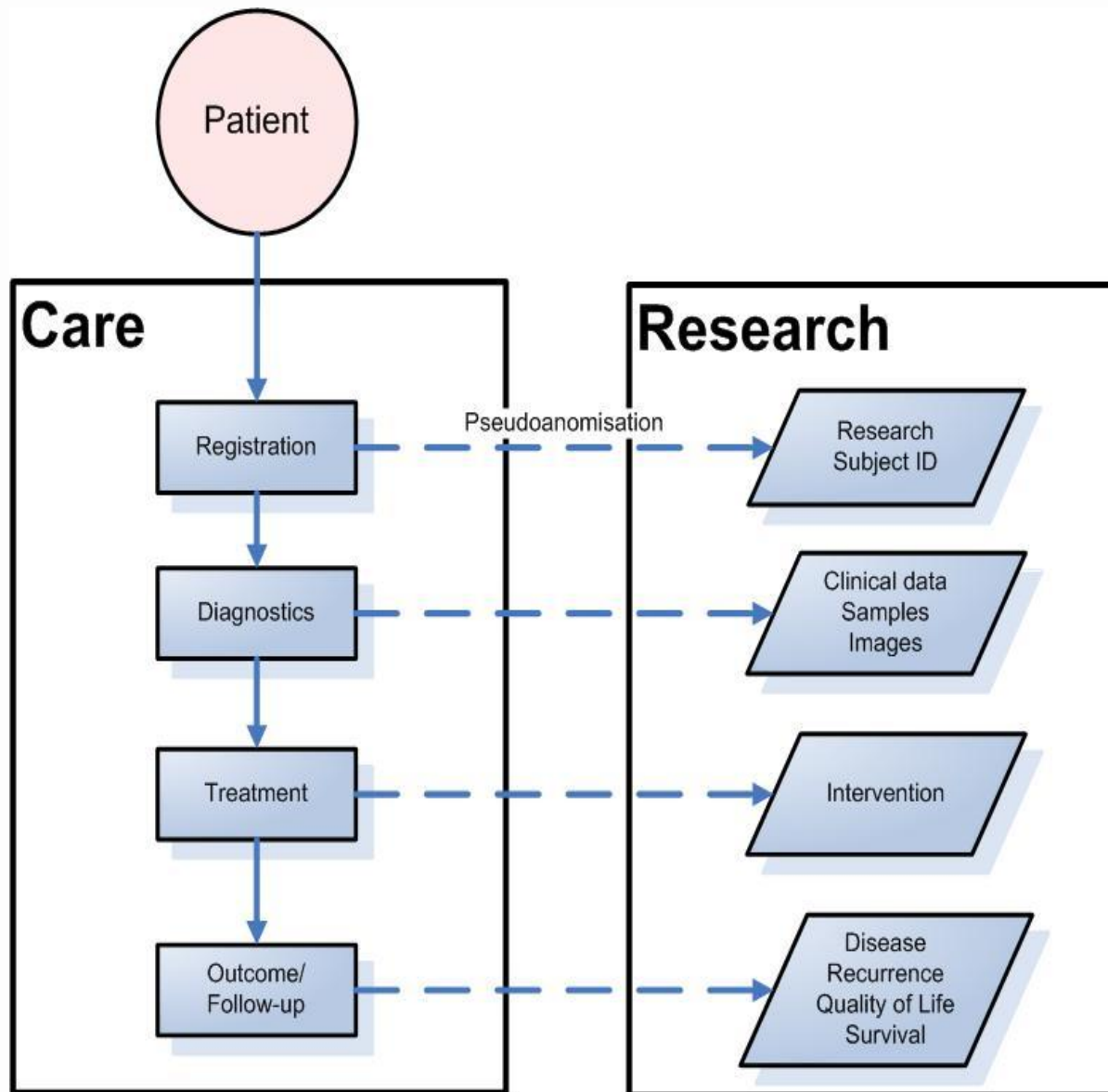


Personalized medicine generic concept



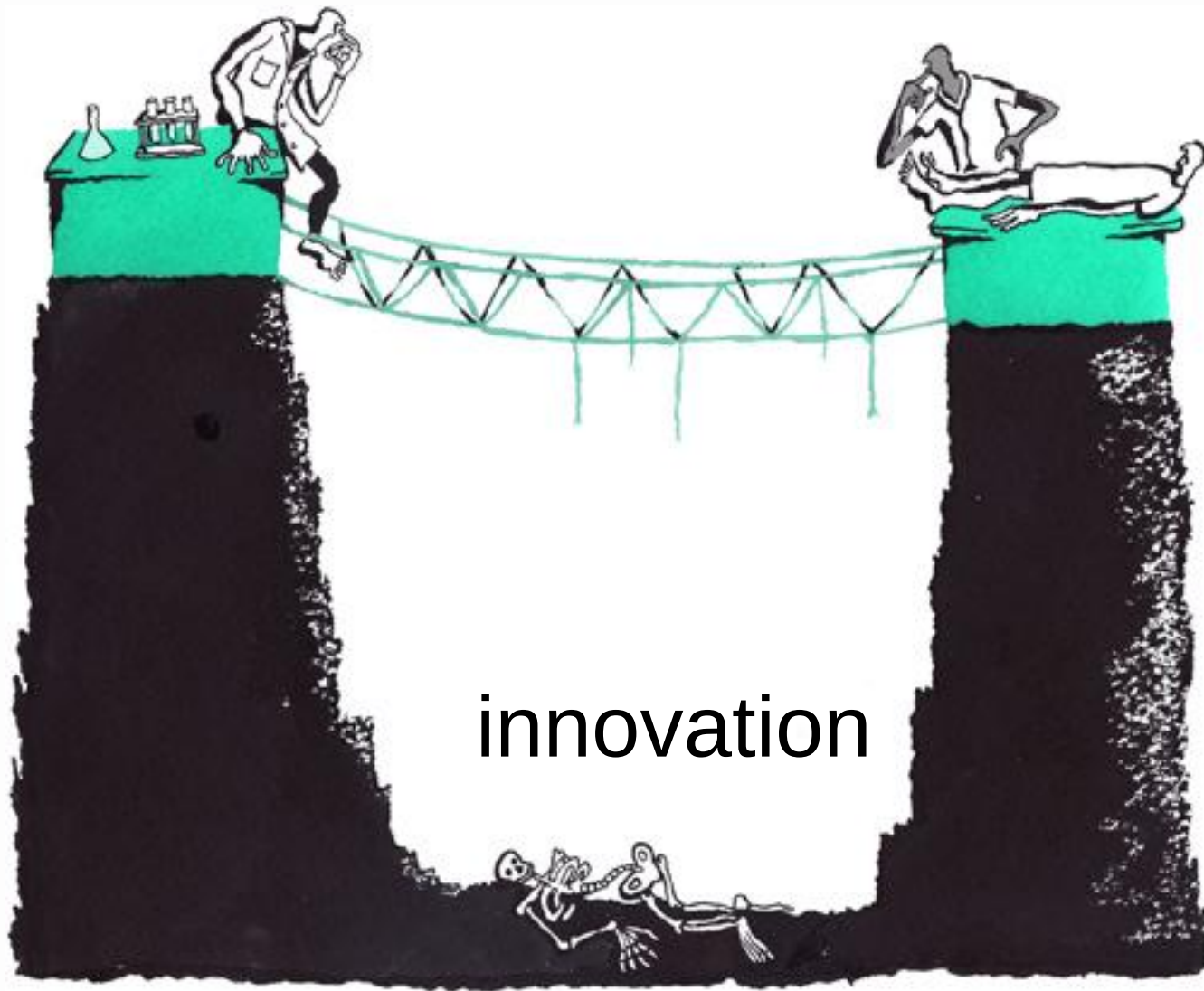
Personalized medicine





research

care



EU General Data Protection Regulation = showstopper for Health Innovation



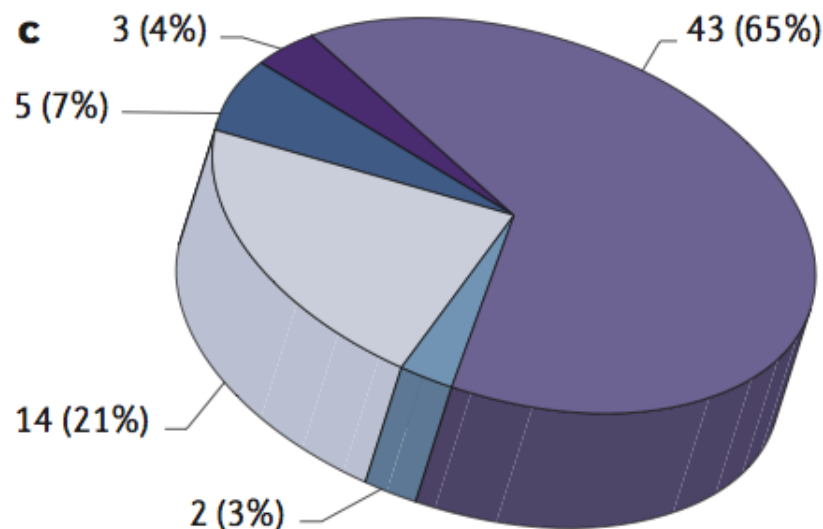
Personalized Medicine
Health Innovation
Precision Medicine

<http://datasaveslives.eu>

Believe it or not: how much can we rely on published data on potential drug targets?

Florian Prinz, Thomas Schlange and Khusru Asadullah

NATURE REVIEWS | DRUG DISCOVERY



- Inconsistencies
- Not applicable
- Literature data are in line with in-house data
- Main data set was reproducible
- Some results were reproducible

THE WALL STREET JOURNAL.

FRIDAY, DECEMBER 2, 2011 - VOL. CCLVIII NO. 130

WSJ.com

*** \$2.00

Scientists' Elusive Goal: Reproducing Study Results

BY GAUTAM NAIK

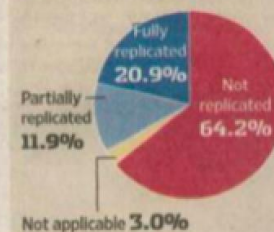
Two years ago, a group of Boston researchers published a study describing how they had destroyed cancer tumors by targeting a protein called STK33. Scientists at biotechnology firm Amgen Inc. quickly pounced on the idea and assigned two dozen researchers to try to repeat the experiment with a goal of turning the findings into a drug.

It proved to be a waste of time and money. After six months of intensive lab work, Amgen found it couldn't replicate the results and scrapped the project.

"I was disappointed but not surprised," says Glenn Begley, vice president of research at Amgen of Thousand Oaks, Calif.

No Cure

When Bayer tried to replicate results of 67 studies published in academic journals, nearly two-thirds failed.



Source: Nature Reviews Drug Discovery

"More often than not, we are unable to reproduce findings" published by researchers in journals.

This is one of medicine's dirty secrets: Most results, including those that appear in top-flight peer-reviewed journals, cannot be reproduced.

"It's a very serious and disturbing issue because it obviously misleads people" who implicitly trust findings published in a respected peer-reviewed journal, says Bruce Alberts, editor of Science. On Friday, the U.S. journal is devoting a large chunk of its Dec. 2 issue to the problem of scientific replication.

Reproducibility is the foundation of all modern research, the standard by which scientific claims are evaluated. In the U.S. alone, biomedical research is a \$100-billion-year enterprise. So when published medical findings

Please turn to page A16

NIH plans to enhance reproducibility

Francis S. Collins and **Lawrence A. Tabak** discuss initiatives that the US National Institutes of Health is exploring to restore the self-correcting nature of preclinical research.

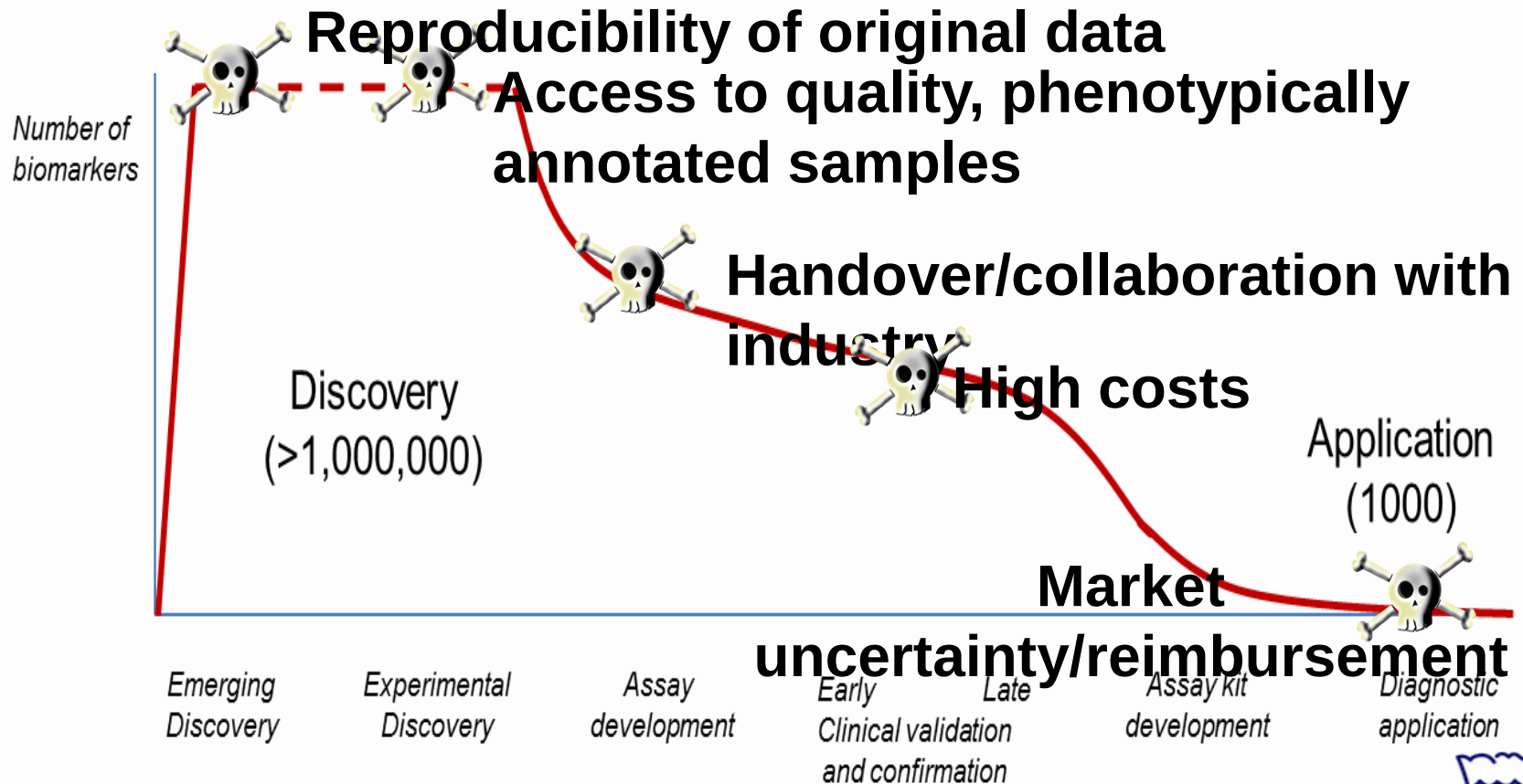
Biomarker Discovery

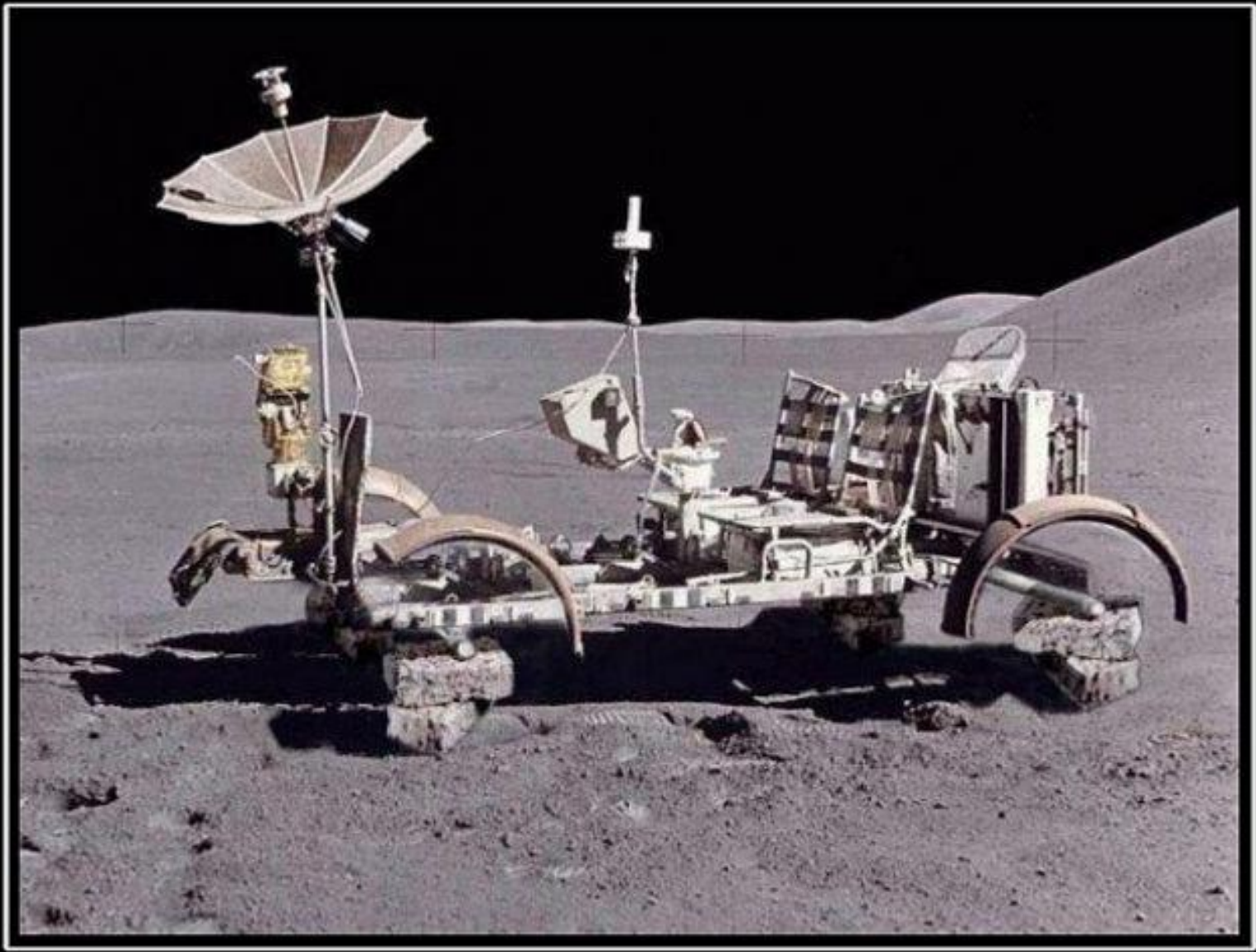


December 2011

“An empirical assessment of 18 published papers of microarray studies showed that independent analysts could perfectly reproduce the results of only two of the studies...”

Biomarker development pipeline





Houston, we have a problem

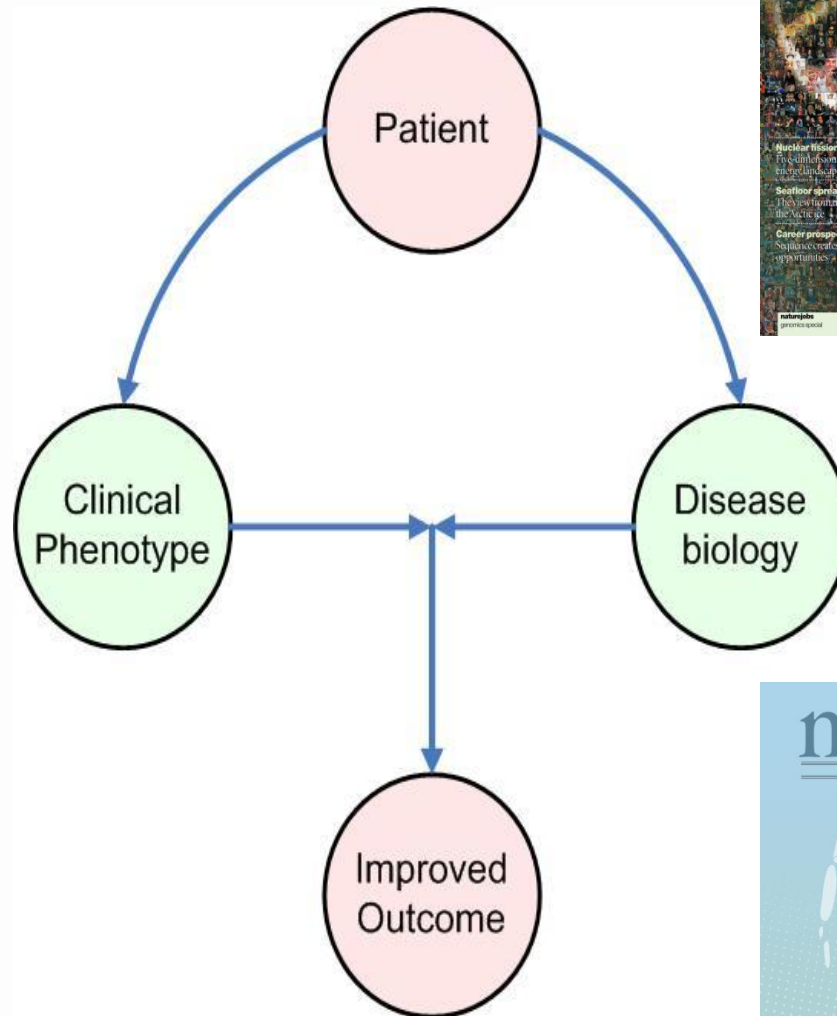
Mission of biomedical research



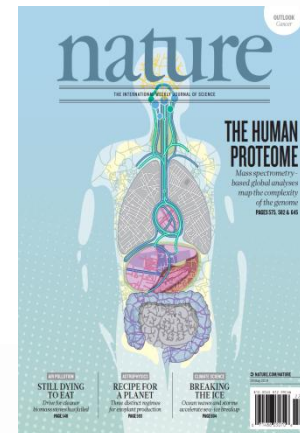
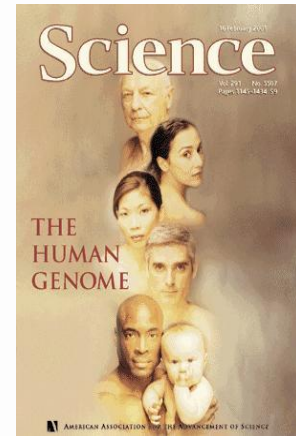
**Create better outcomes
for patients tomorrow
than we have today!**

- If we want to change outcome for patients, we need to change medical practice.
- If we want to change medical practice, we need to change guidelines.
- If we want to change guidelines, we need to generate evidence.
- If we want to generate that evidence, we need the right tools!

Personalized medicine



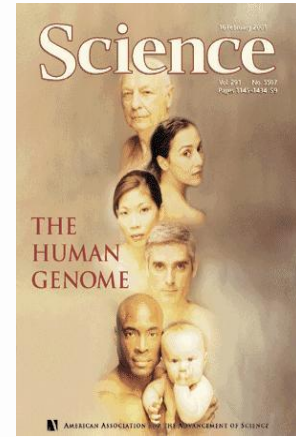
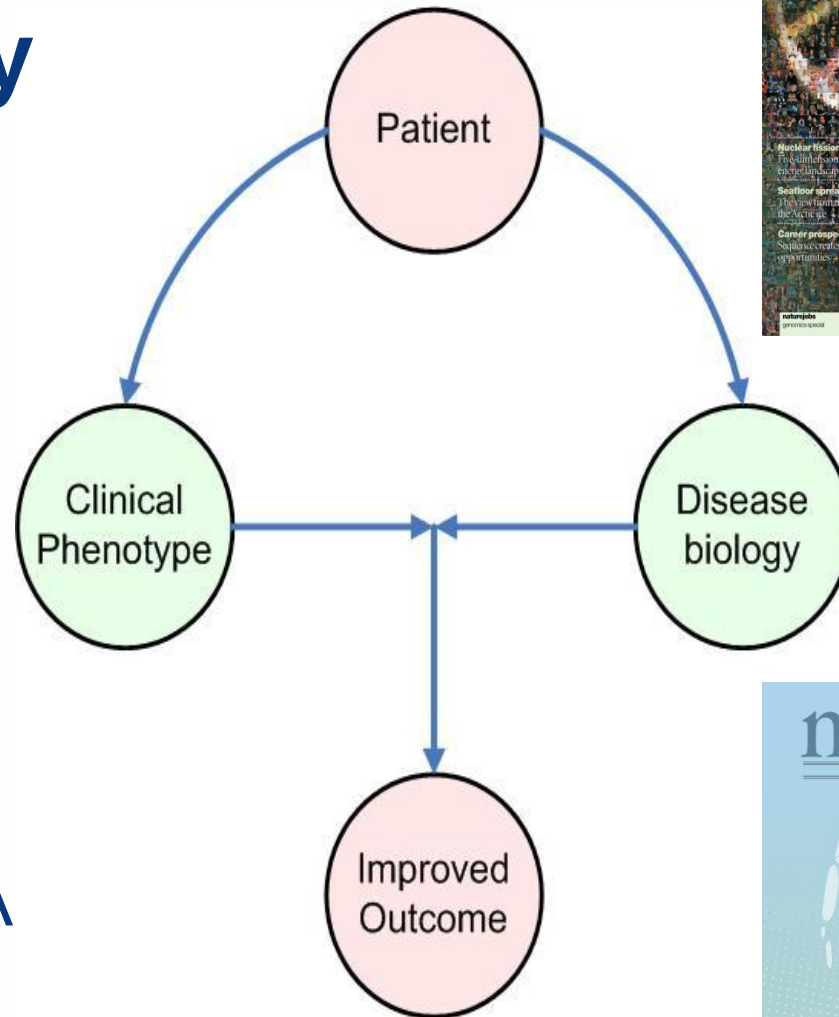
the omics
revolution



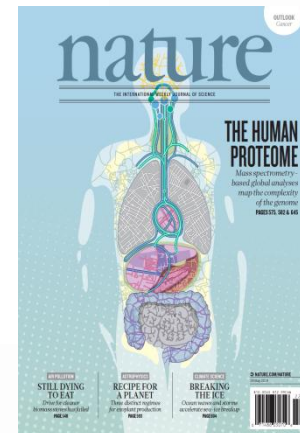
Personalized medicine

the unsexy problem

samples
images
data
process & QA



the omics revolution

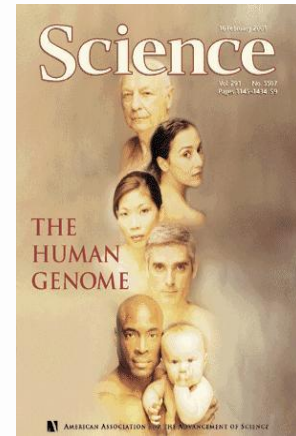
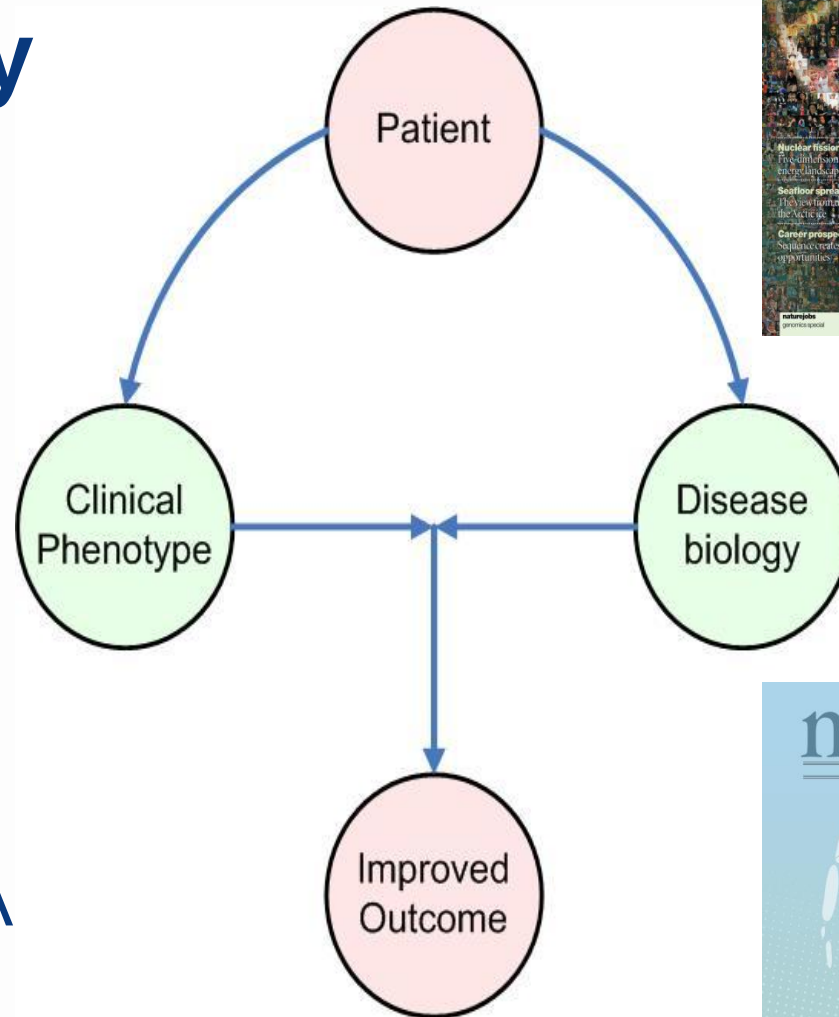


Personalized medicine

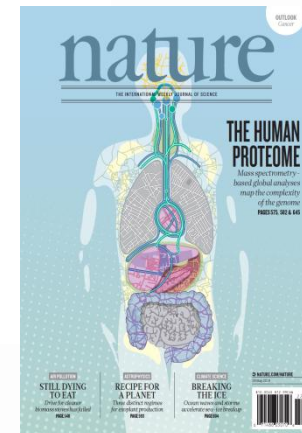
the unsexy problem

samples
BBMRI
images
BBMRI
data

process & QA



the omics revolution



Managing resources for the future of biomedical research

Home Nieuws Agenda Publicaties Projecten Biobankcatalogus Contact Over BBMRI-NL

Wat is BBMRI-NL

Partners

Organisatie

Internationaal

Vacatures

Contact

Begrippen

Over BBMRI-NL

BBMRI-NL is het Nederlandse samenwerkingsverband dat de Nederlandse biobanken faciliteert de onderlinge samenwerking door het ontwikkelen van een gemeenschappelijke infrastructuur. Verder faciliteert BBMRI-NL [datamanagement](#) en de onderlinge samenwerking tussen biobanken is op het gebied van (chronische) ziekten, in het bijzonder op het gebied van de Nederlandse bevolking. BBMRI-NL is een initiatief van onder andere de Centra en andere kennisinstellingen. BBMRI-NL is een onderdeel van de Europese Biobanking and Biomolecular Resource Infrastructure (EBI) gefinancierd door de Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO).

National infrastructure for
- collection
- management
- access
of
- samples
- images
- data
for scientific research

BBMRI-ERIC Members



Personalized medicine

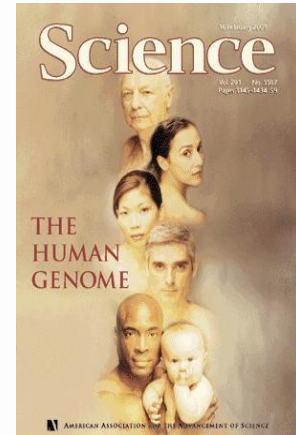
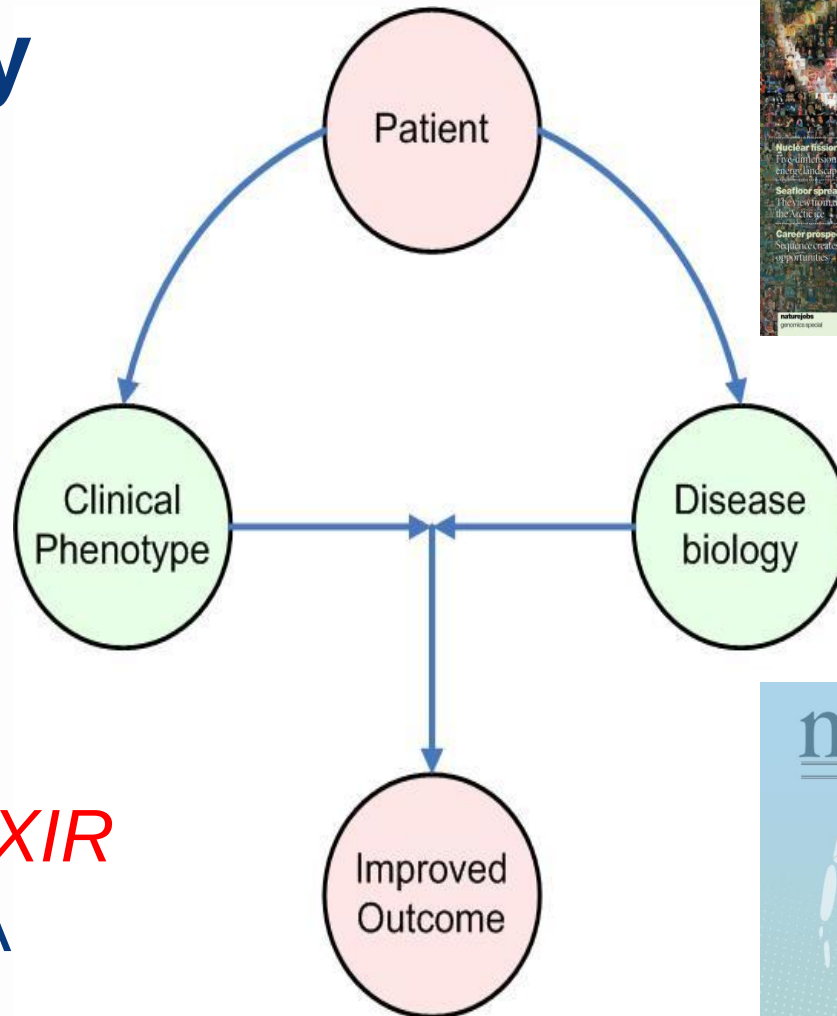
the unsexy problem

samples

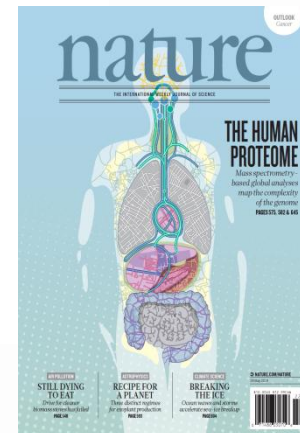
images

data

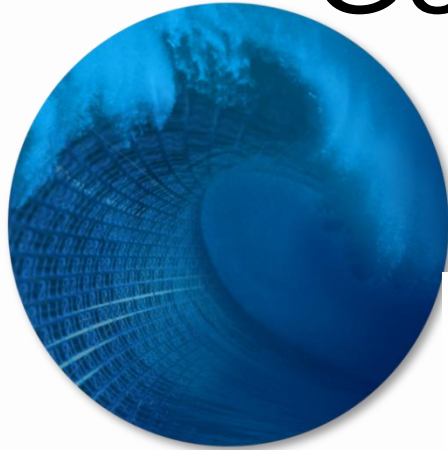
TraIT, DTL/ELIXIR
process & QA



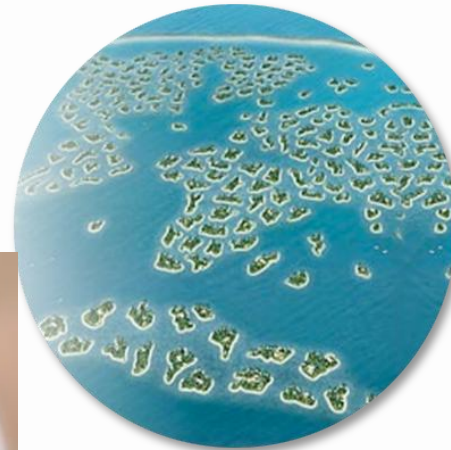
the omics revolution



Generic problems



Tsunami of Genomic
and Clinical Data



Islands of Information



Sustainability

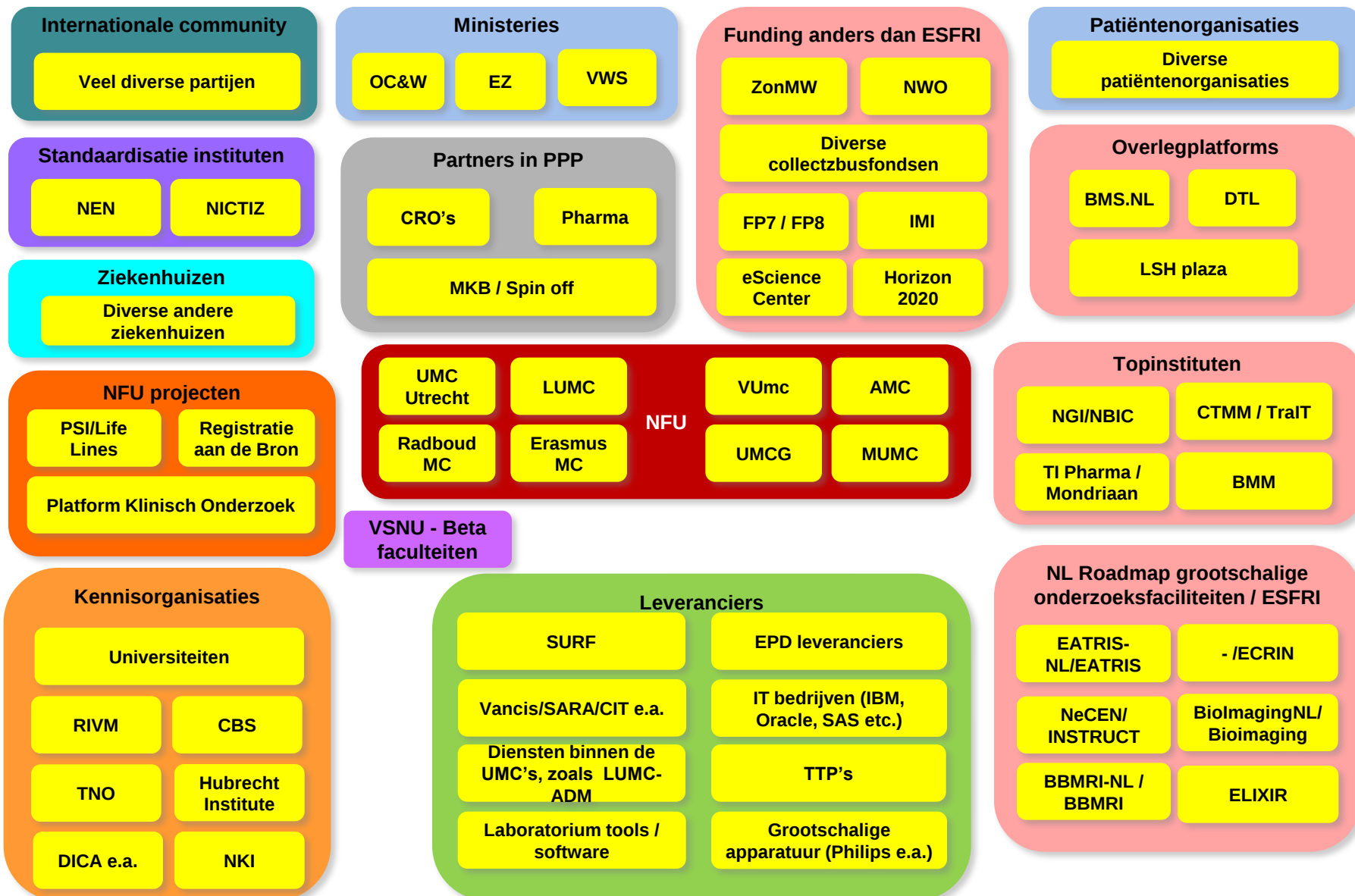


No Standard
Language

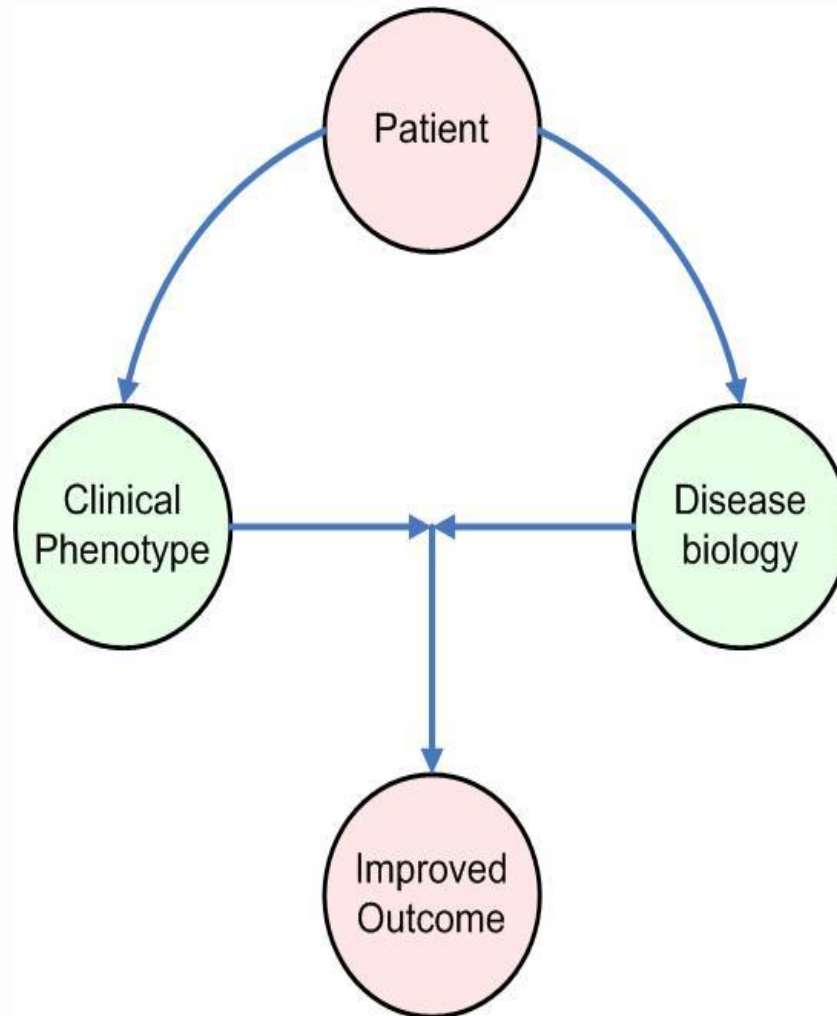


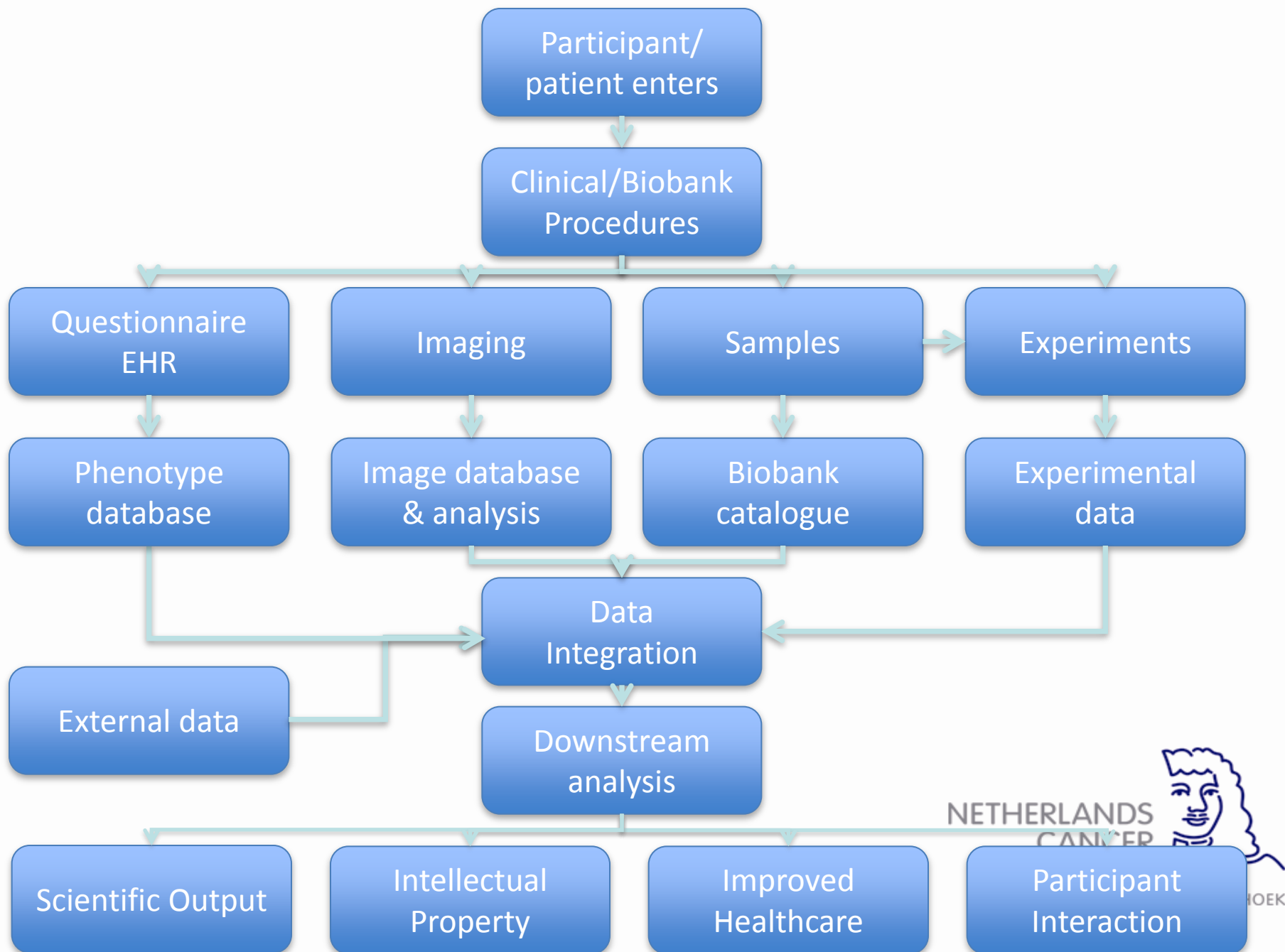
IT Systems Do Not Interoperate

Stakeholder map



Personalized medicine generic concept






[Home](#) > [TraIT tools](#)
[Contact](#)
[Site Map](#)
[Search](#)

[ABOUT TRAIT](#)
[WORK PACKAGES](#)
[TRAIT TOOLS](#)
[SERVICE DESK](#)
[NEWS](#)

LINKS

[Self Service Desk](#)
[OpenClinica](#)
[LOGIS](#)
[NBIA](#)
[XNAT](#)
[CTP](#)
[Keosys Viewer](#)
[tEPIS](#)
[Catalogue](#)
[Workflow](#)
[Phenotype Database](#)
[Galaxy](#)
[Chipster](#)
[tranSMART](#)

TraIT tools

Information on and link to the TraIT suite of tools

- For more information on each of the TraIT tools follow the links on the left.
- To go directly to the tool of interest, follow the corresponding link on the image below.

Clinical research data	Clinical imaging	Digital pathology	Biosample data	Experimental data
 	   		 	  
Data integration and analysis				
Deployment and user support				

TraIT tools

For more information on each of the TraIT tools follow the links on the left.

To go directly to the tool of interest, follow the corresponding link on the image below.

The image displays a grid of TraIT tools organized into five main categories, each represented by a light blue box. The tools are as follows:

- Clinical research data:**
 - OpenClinica (highlighted with a red box)
 - logis
- Clinical imaging:**
 - NBIA
 - XNAT
 - KEOSYS MEDICAL IMAGING
 - 100 YEARS RSNA Radiological Society of North America
- Digital pathology:**
 - tEPIS
- Biosample data:**
 - workflow
 - catalogue
- Experimental data:**
 - Phenotype database
 - Galaxy
 - Chipster

Below these categories are two additional tool categories:

- Data integration and analysis:**
 - transSMART v1.2
- Deployment and user support:**
 - TCPdesk Service Management Simplified

LINKS

[Open Clinica](#)
[About OpenClinica](#)
[Why TraIT OpenClinica?](#)
[Our OpenClinica services](#)
[Setting up OpenClinica](#)
 [Preparation phase](#)
 [Execution phase](#)
 [Completion phase](#)
[OpenClinica training](#)
[Rule Designer](#)
[Frequently Asked Questions](#)

[LOGIS](#)
[NBIA](#)
[XNAT](#)
[CTP](#)
[Keosys Viewer](#)
[tEPIS](#)
[Catalogue](#)
[Workflow](#)
[Phenotype Database](#)
[Galaxy](#)
[Chipster](#)
[tranSMART](#)
[Self Service Desk](#)

Setting up OpenClinica

Steps to get a study up and running in OpenClinica

PREPARATION



EXECUTION



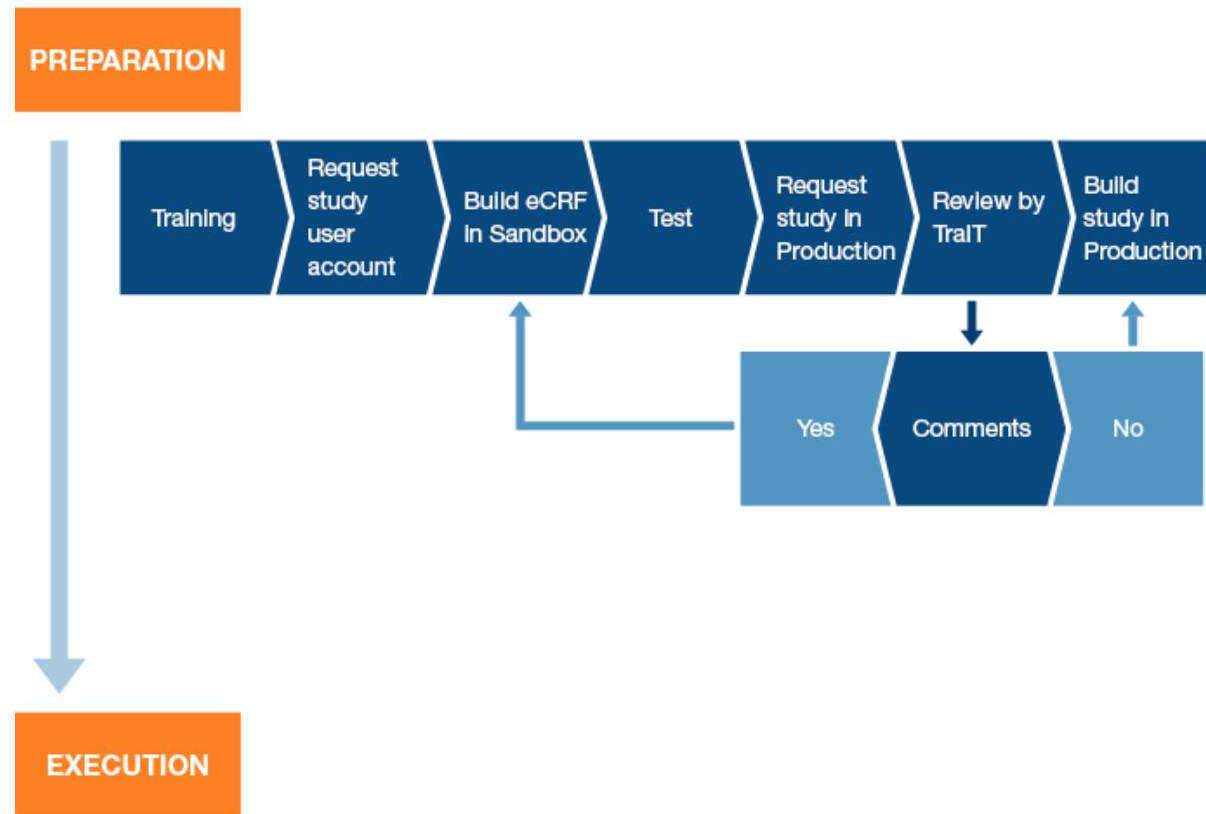
COMPLETION

LINKS

- Open Clinica
 - About OpenClinica
 - Why TraIT OpenClinica?
 - Our OpenClinica services
 - Setting up OpenClinica
 - Preparation phase
 - Training
 - Request study and user account
 - Build Study in Sandbox
 - Test Study
 - Request study on OpenClinica.nl
 - Review by TraIT
 - Build study in final environment
 - Execution phase
 - Completion phase
- OpenClinica training
- Rule Designer
- Frequently Asked Questions
- LOGIS
- NBIA
- XNAT
- CTP
- Keosys Viewer
- tEPIS
- Catalogue

Preparation phase

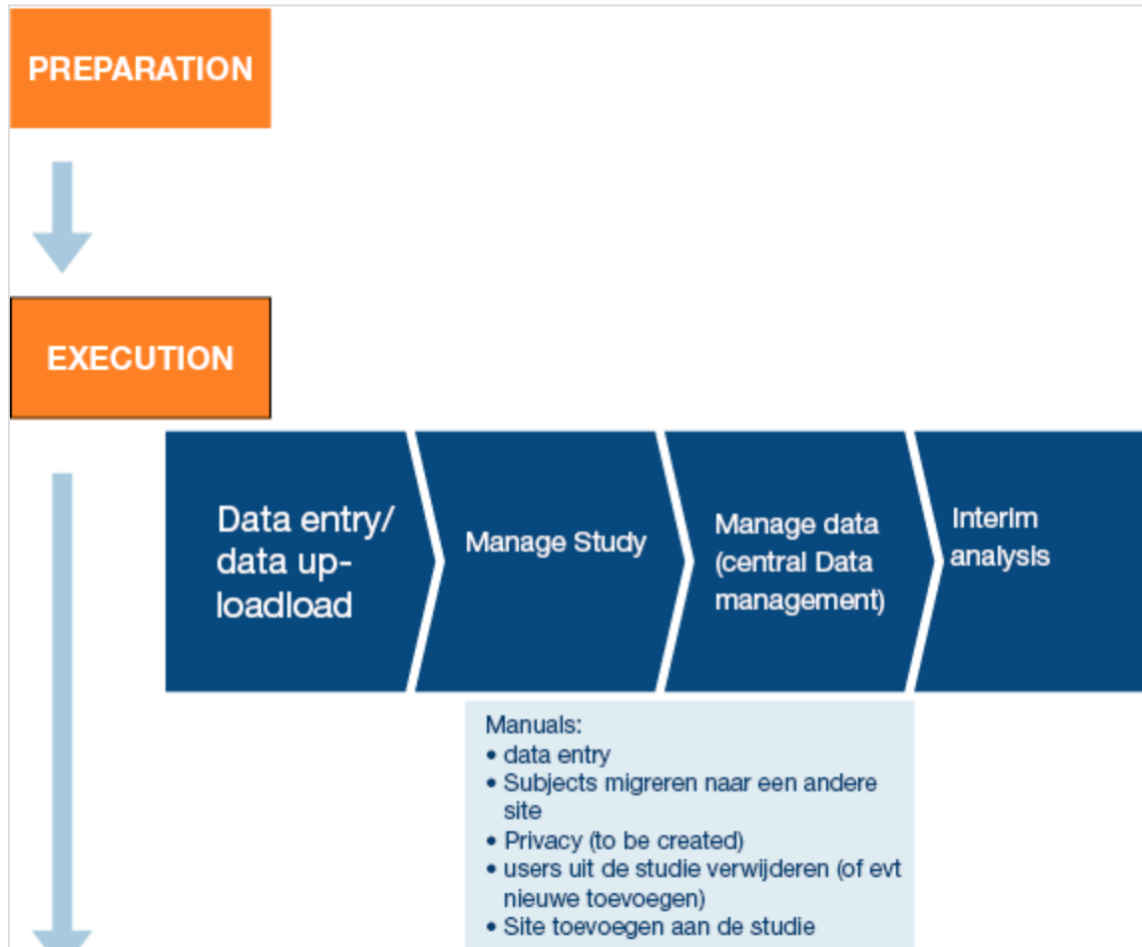
Steps to get a study up and running in OpenClinica



LINKS

[Open Clinica](#)
[About OpenClinica](#)
[Why TraIT OpenClinica?](#)
[Our OpenClinica services](#)
[Setting up OpenClinica](#)
[Preparation phase](#)
[Execution phase](#)
[Data entry/data upload](#)
[Manage Study](#)
[Central data management](#)
[interim analysis](#)
[Completion phase](#)
[OpenClinica training](#)
[Rule Designer](#)
[Frequently Asked Questions](#)
[LOGIS](#)
[NBIA](#)
[XNAT](#)
[CTP](#)
[Keosys Viewer](#)
[tEPIS](#)
[Catalogue](#)
[Workflow](#)
[Phenotype Database](#)
[Galaxy](#)
[Chipster](#)
[tranSMART](#)

Execution phase



LINKS

Open Clinica

[About OpenClinica](#)[Why TraIT OpenClinica?](#)[Our OpenClinica services](#)[Setting up OpenClinica](#)[Preparation phase](#)[Execution phase](#)[Completion phase](#)[Data cleaning](#)[Data Frozen](#)[Data Locked](#)[Data extraction
\(export/import\)](#)[Data storage](#)[OpenClinica training](#)[Rule Designer](#)[Frequently Asked Questions](#)

LOGIS

[NBIA](#)[XNAT](#)[CTP](#)[Keosys Viewer](#)[tEPIS](#)[Catalogue](#)[Workflow](#)[Phenotype Database](#)[Galaxy](#)[Chipster](#)

Completion phase

COMPLETION

Data
Cleaning

Data
Frozen

Data
Locked

Data
Extraction
(export/Import)

Data
Storage

Manual status
study on 'Frozen'
or 'Locked'

Manual SPSS

TraIT tools

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To go directly to the tool of interest, follow the corresponding link on the image below.

Clinical research data	Clinical imaging	Digital pathology	Biosample data	Experimental data
 	   		 	  
Data integration and analysis				
Deployment and user support				

Meldingen



Snelkoppelingen

Huidig nieuws

Openstaande meldingen

Nieuwe melding

Kennissysteem



Welkom Gerrit Meijer

17 februari 2015

Welkom op de SelfServiceDesk

Nieuwsoverzicht

Er zijn op het moment geen berichten



Nieuwe melding



Openstaande meldingen



Suggestions for Improvement



Kennissysteem



TraIT website

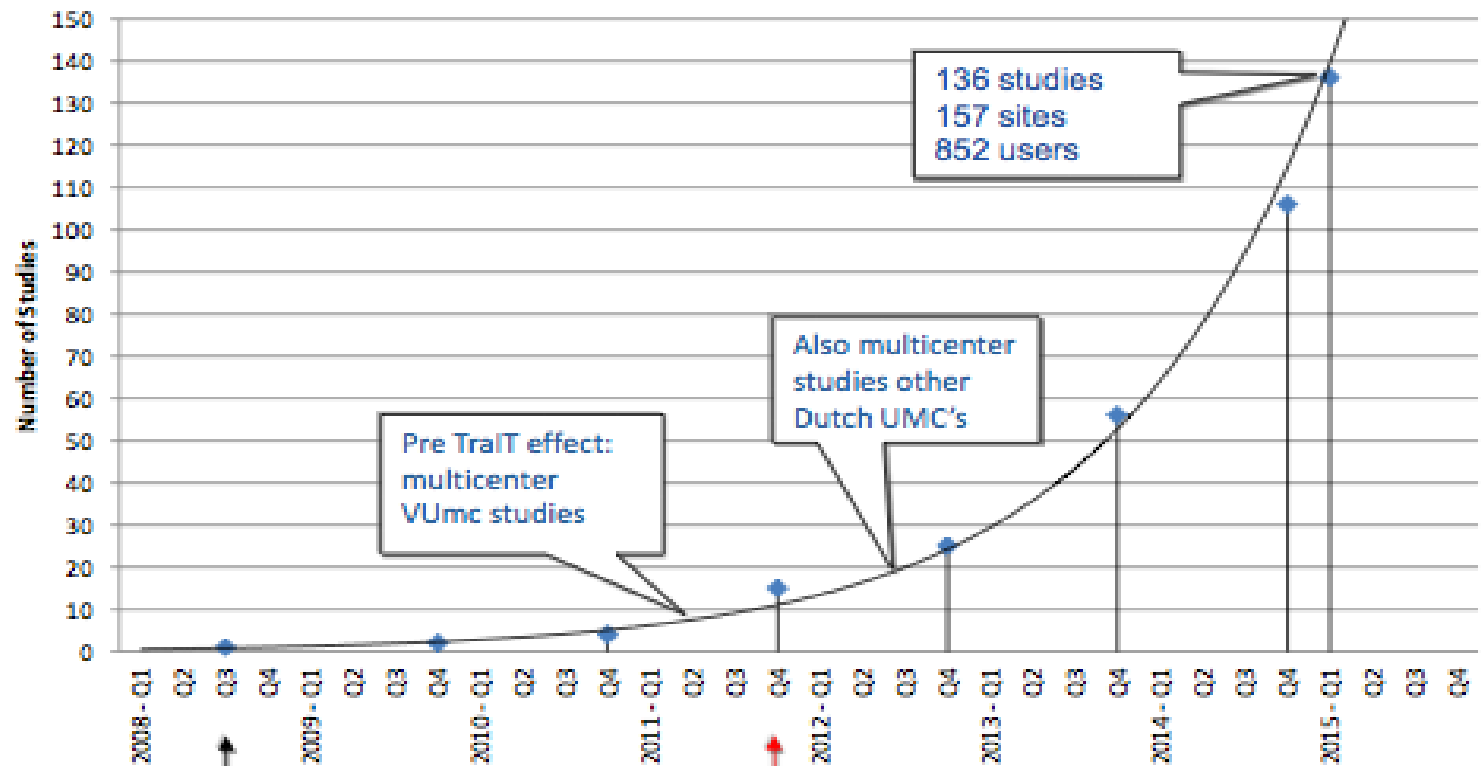
Webformulieren Clinical Research Data



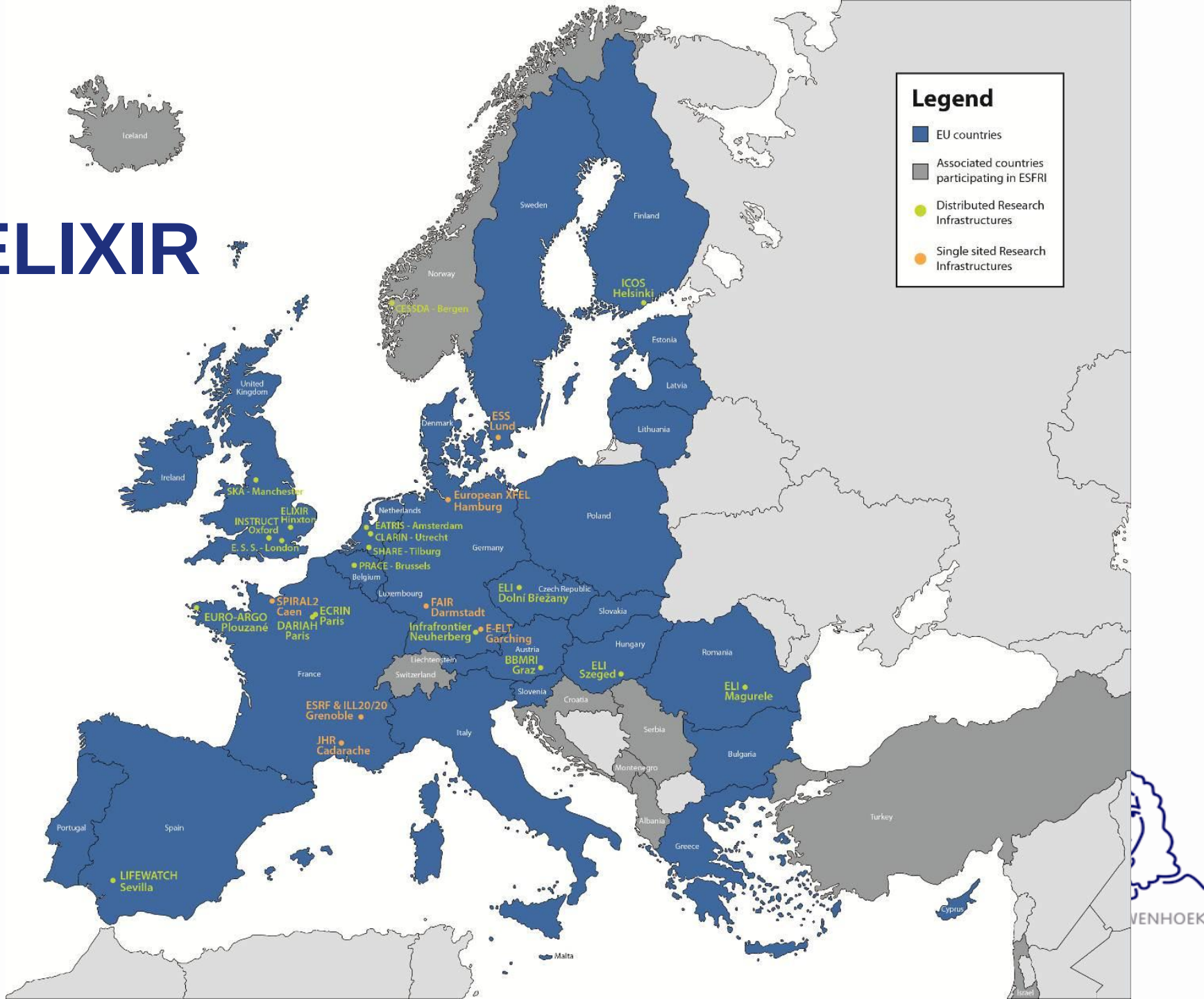
OpenClinica

Uptake of OpenClinica

Open source electronic data capture tool



ELIXIR



Personalized medicine

the unsexy problem

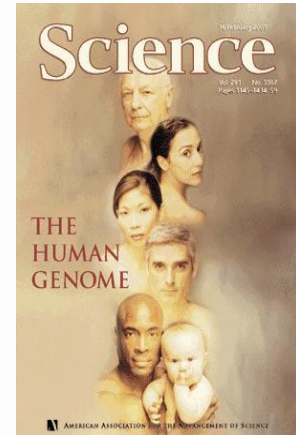
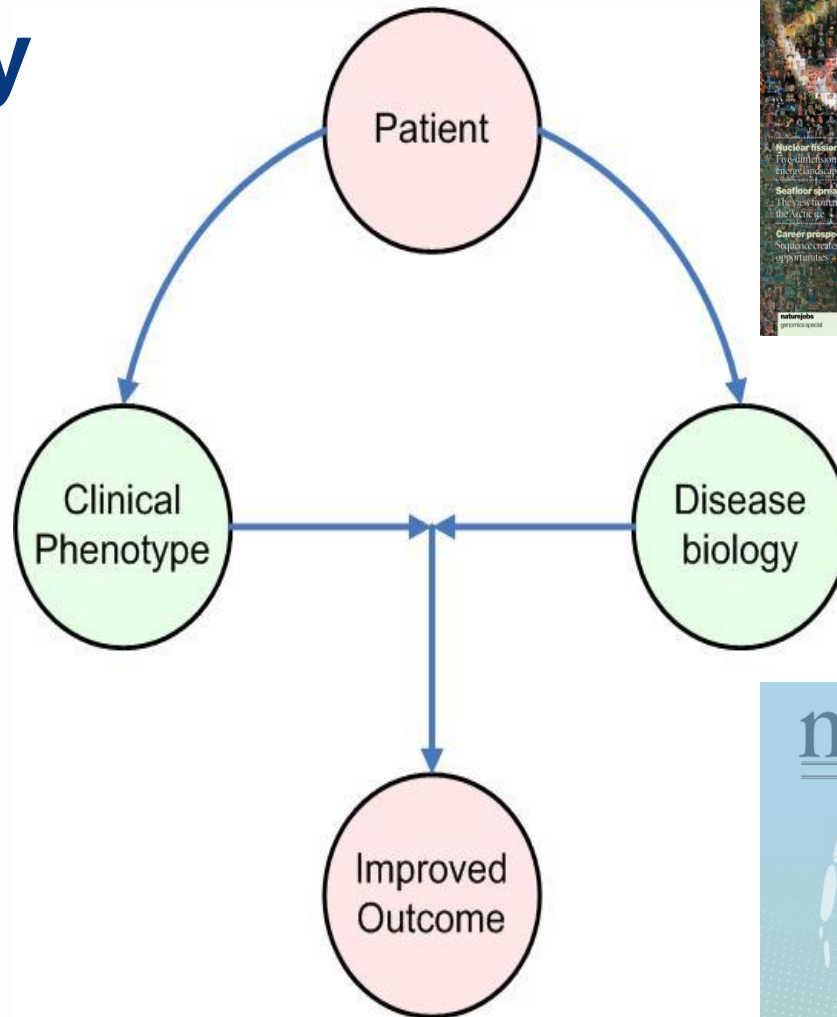
samples

images

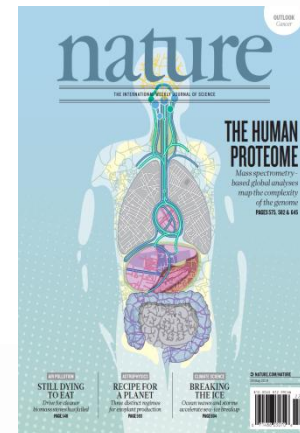
data

process&QA

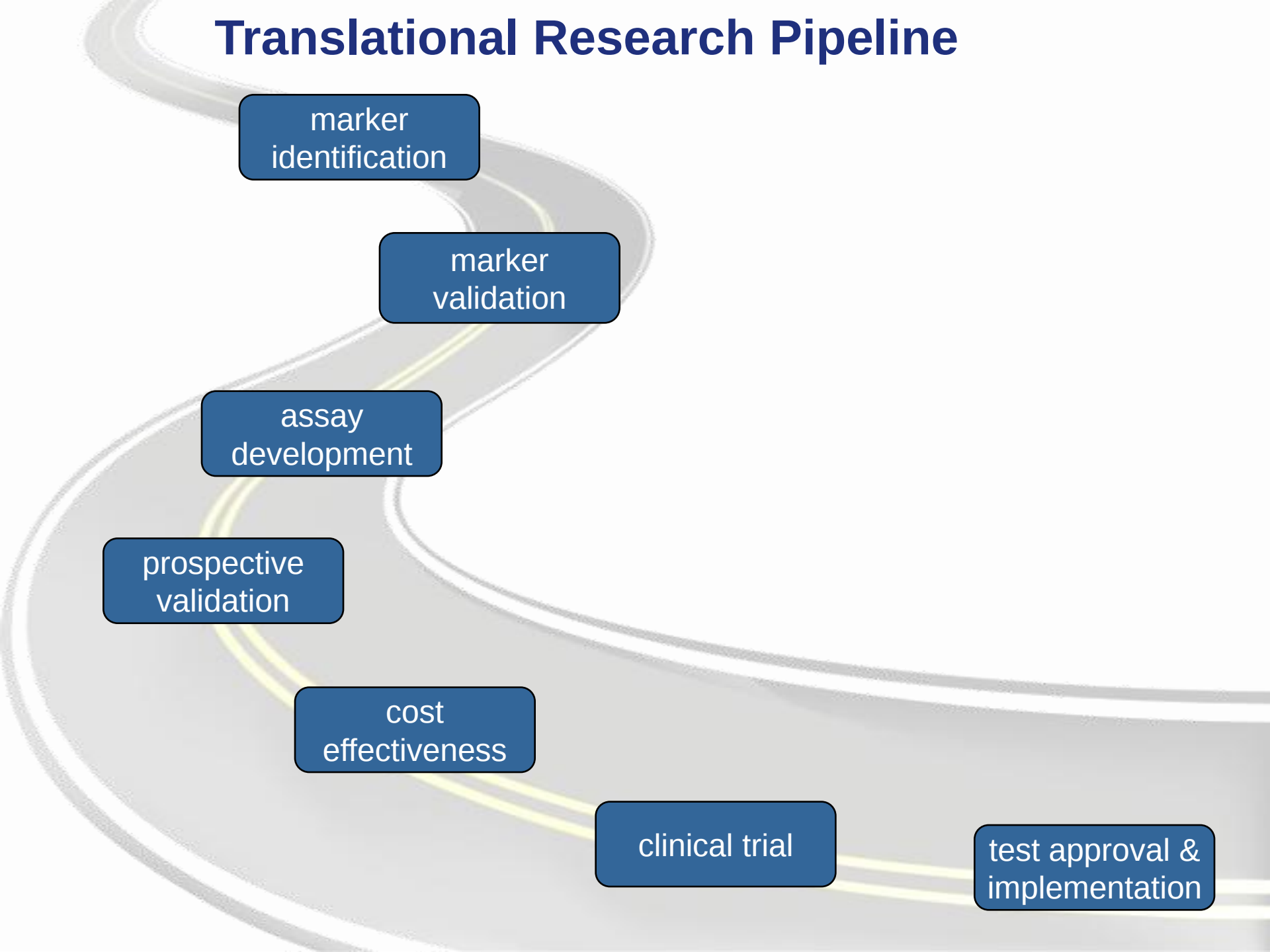
EATRIS



the omics revolution



Translational Research Pipeline



```
graph TD; A[marker identification] --> B[marker validation]; B --> C[assay development]; C --> D[prospective validation]; D --> E[cost effectiveness]; E --> F[clinical trial]; F --> G[test approval & implementation];
```

marker
identification

marker
validation

assay
development

prospective
validation

cost
effectiveness

clinical trial

test approval &
implementation

EATRIS positioning

Vision

Making translation of scientific discoveries into medical products ***more effective*** to improve human health and quality of life.

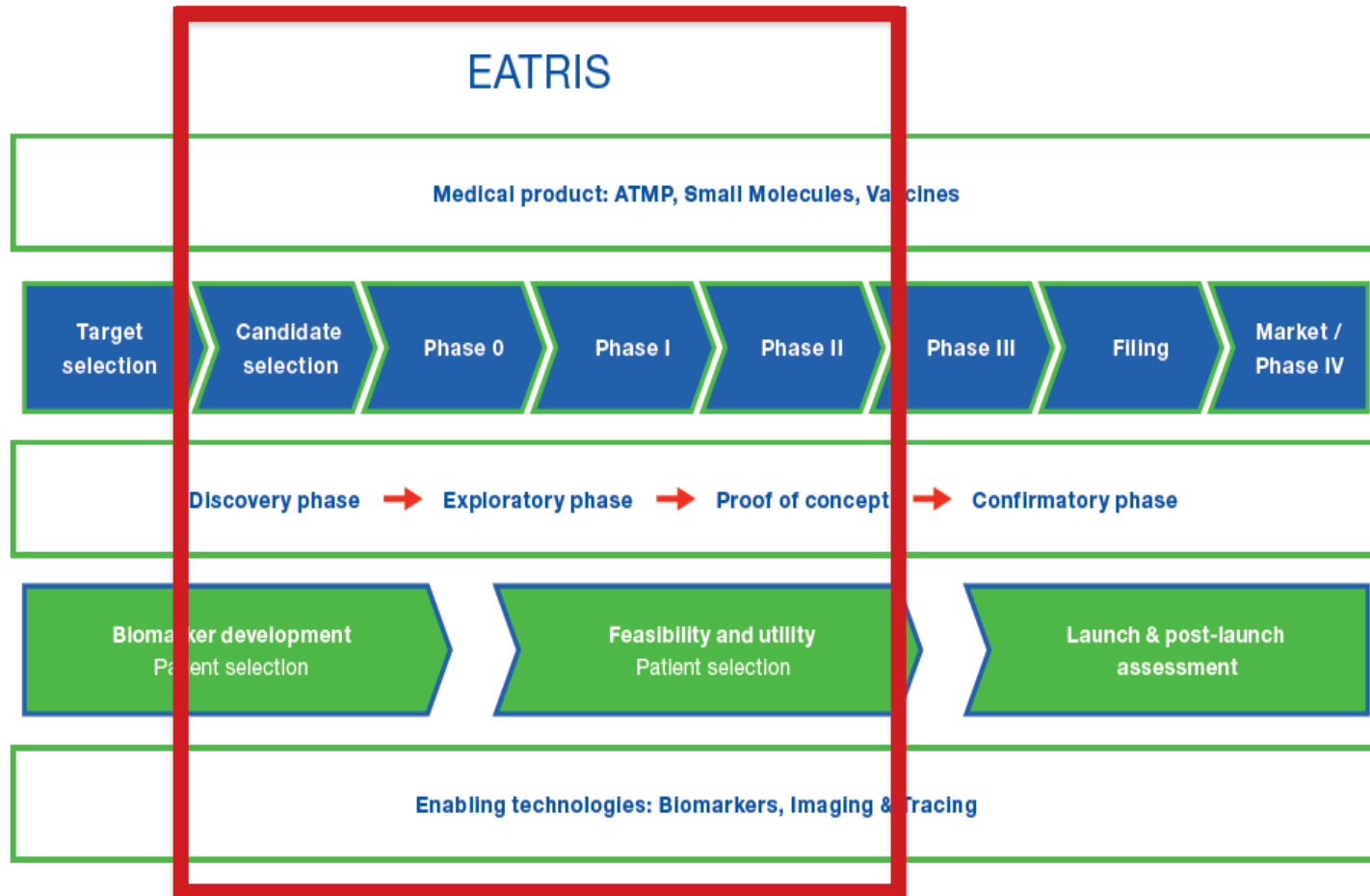
Mission

To support researchers in developing their biomedical discoveries for novel preventive, diagnostic or therapeutic products ***up to clinical proof of concept.***

**Supporting academia, funders,
SME & biotech/pharma**



EATRIS scope of operations



EATRIS members



**Participating countries
: CZ, DK, ES, FI, FR, IT,
NO, EE, NL (Host)**

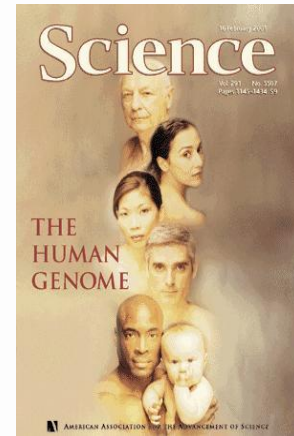
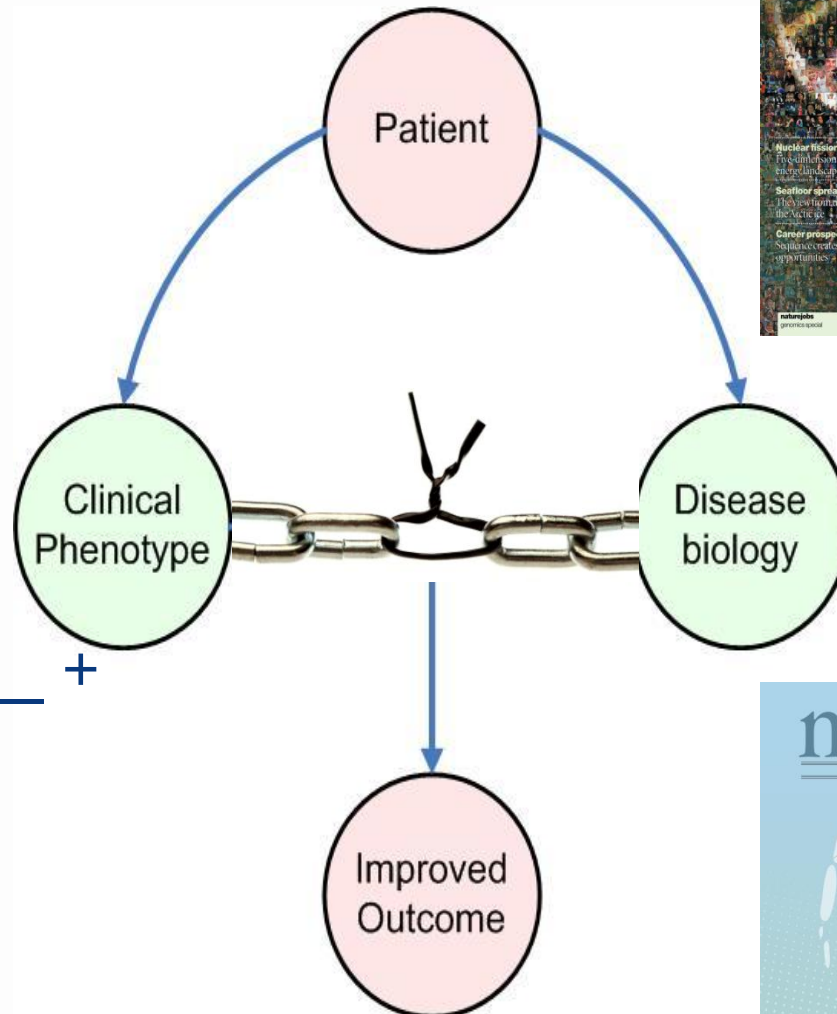
**Negotiations ongoing
with: BE, DE, PT, SI,
TR, UK, SE**

**75 Academic & non-
profit research
institutions of
excellence in
translational medicine**

The answer to the unsexy problem

BBMRI.NL
ELIXIR.NL/DTL
EATRIS.NL
CTMM TraIT
CPCT
Parelsnoer
data4lifesciences
DICA
clinical registries
other

**Personalized
Medicine
Research
Infrastructure
.NL**



the omics
revolution

