Let the data flow – wie Real World Daten automatisiert vom Arzt zum Sponsor klinischer Studien fließen

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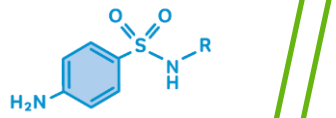
innovate.collaborate.act.

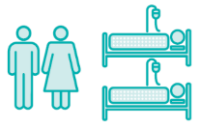
Vom Molekül zum Medikament: Der lange Weg der Arzneimittelforschung

1 *Wirkstoff-entdeckung*



2 *Vorklinik*

3 *Klinische Prüfungen*



4 *Zulassung*

5 *Nach Zulassung*

6 *Nutzenbewertung*

Von circa

4 Mio.

Prüfsubstanzen werden **10.000** weiter getestet und optimiert

< 250 Prüfsubstanzen

< 5 Prüfsubstanzen

1 Arzneimittel durch die Zulassungs-behörden zugelassen

Alle

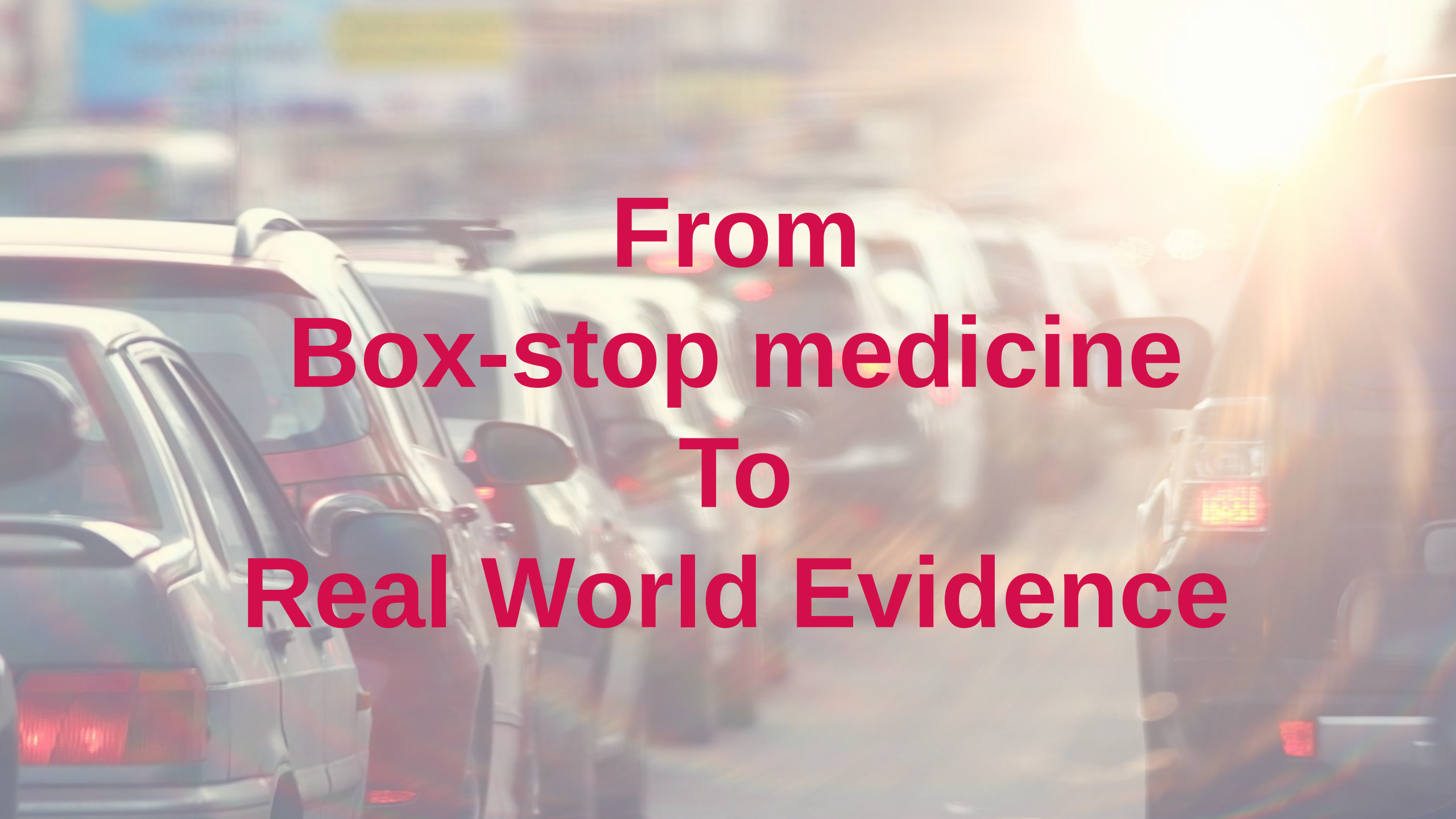
Zugelassenen Medikamente

Sammeln von Gesundheitsdaten im Praxisalltag , für eine **laufende** Nutzen-Risiko-Analyse

0 Jahre | 3 | 6 | 9 | 12 | 15

Artificial set-up
Defined protocol
Inclusion & Exclusion criteria
Comparative
Randomized
Blinded

Efficacy, Safety, Quality


From
Box-stop medicine
To
Real World Evidence

Real World Data

electronic health records (EHRs),

claims and billing data,

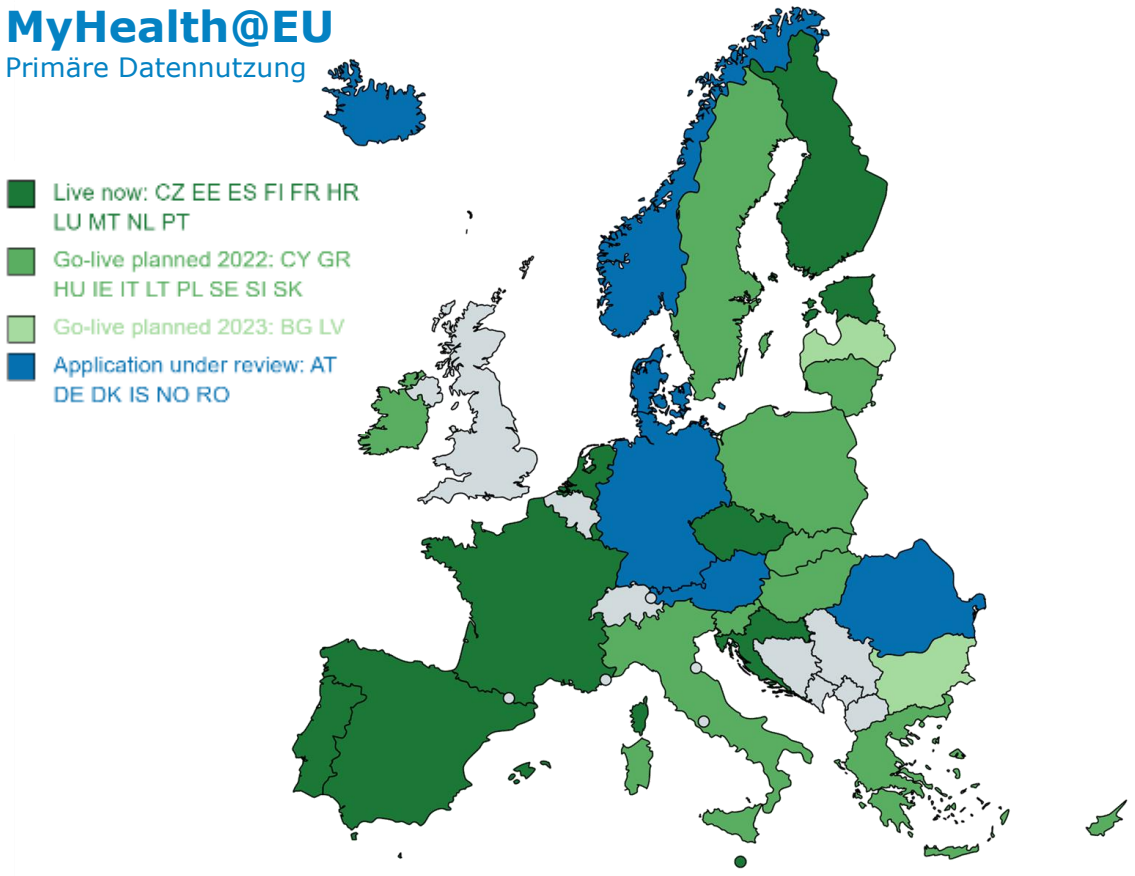
data from product and disease registries,

patient-generated data including in home-use settings,

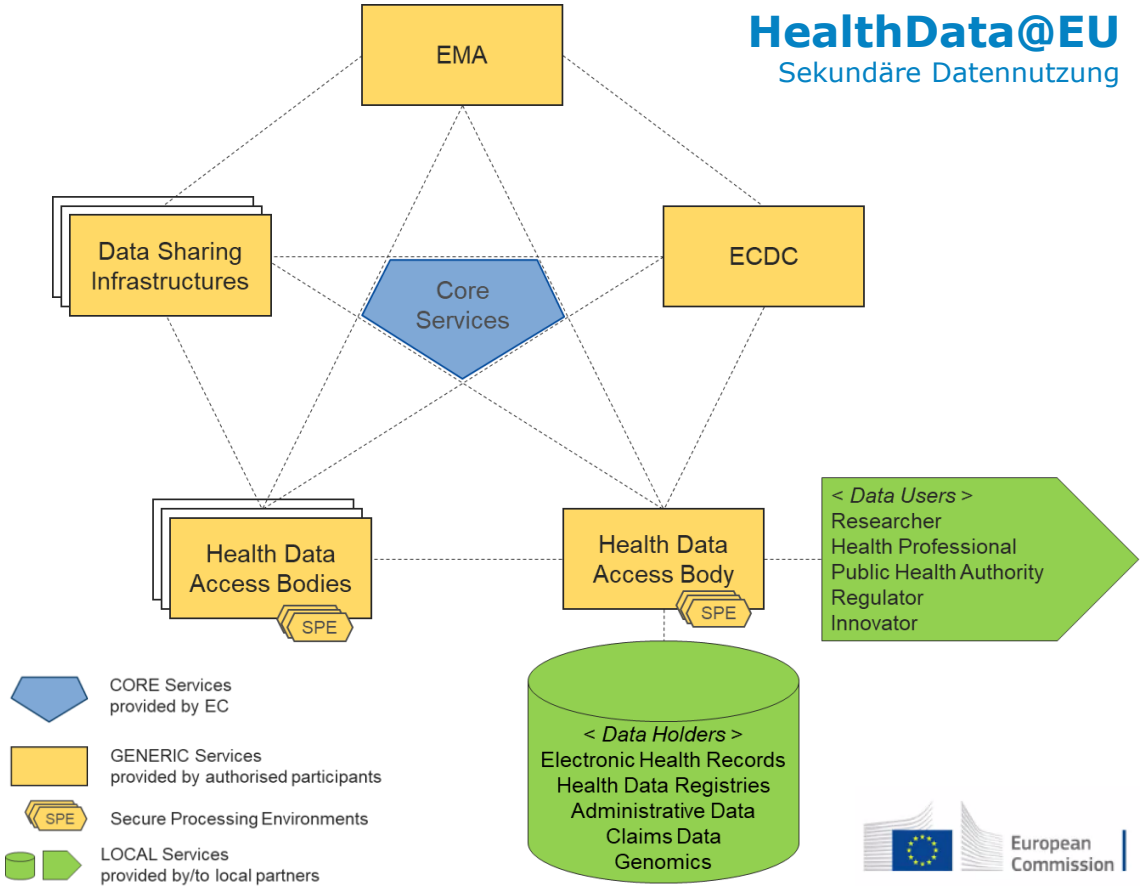
data gathered from other sources that can inform on health status, such as mobile devices

Für die EU-weite (=grenzüberschreitende) Datennutzung müssen neue digitale Infrastrukturen geschaffen werden

MyHealth@EU
Primäre Datennutzung



HealthData@EU
Sekundäre Datennutzung



European Commission

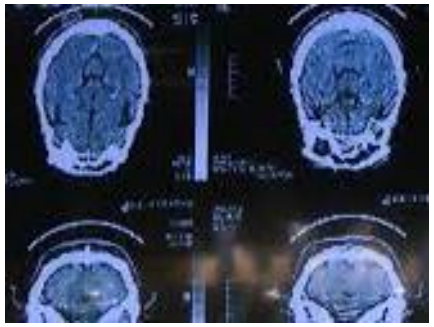
vfa. Die forschenden Pharma-Unternehmen

P-Medicine and D-Tools

1. **Preventive medicine** is the practice of promoting preventive health care to improve patient well-being. The goal is to ultimately prevent disease, disability, and death.

2. **Predictive medicine** is a branch of medicine that aims to identify patients at risk of developing a disease, thereby enabling either prevention or early treatment of that disease.

3. **Precision medicine** looks at the genetics, environment, and lifestyle of a person in order to select treatment that could work best for them.



Diagnostic

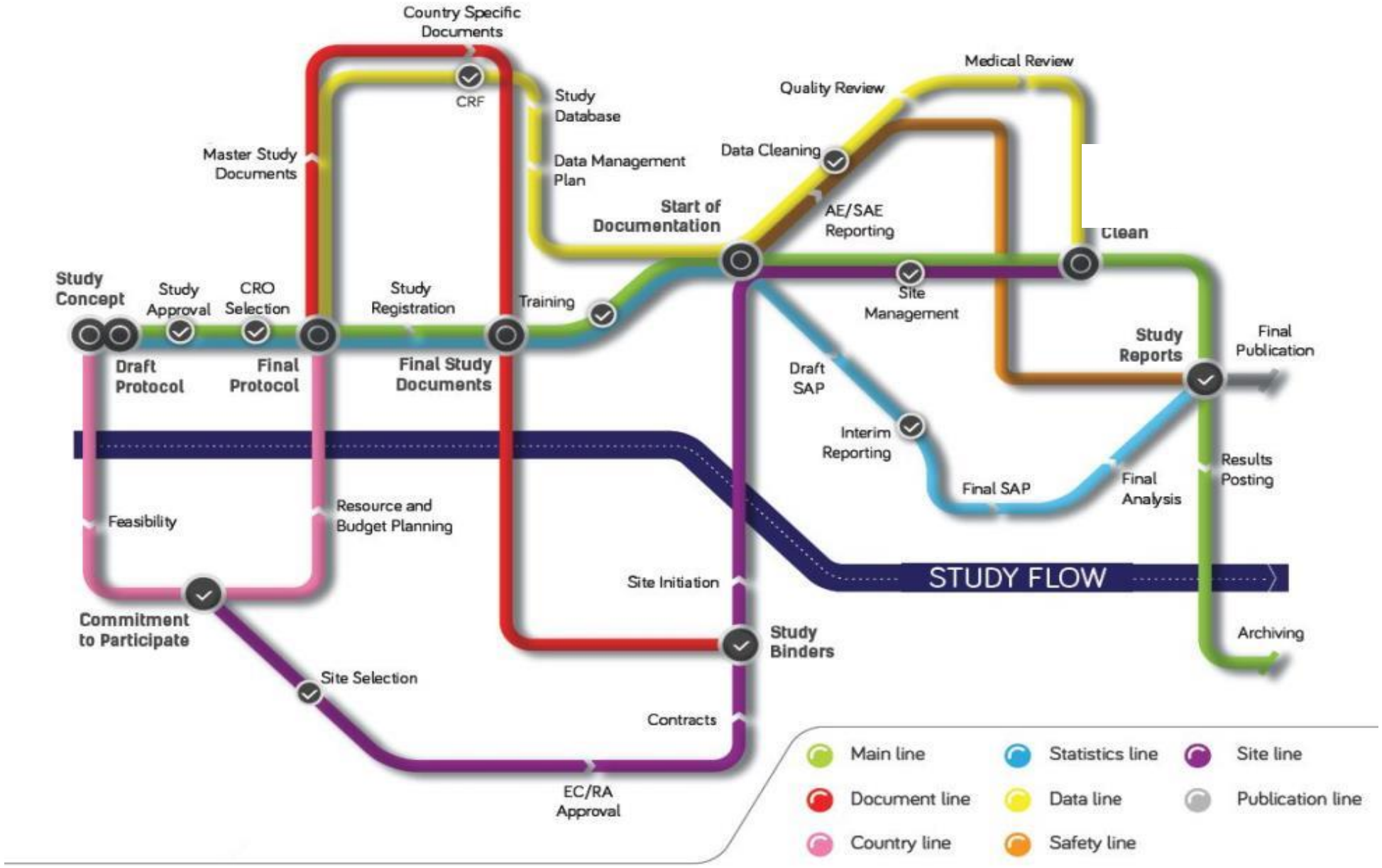
Drugs

Devices

Data

1 https://www.acpm.org/about-acpm/what-is-preventive-medicine/
2 https://www.nature.com/subjects/predictive-medicine#:~:text=Definition,future%20disposition%20to%20a%20disease.
3 https://medlineplus.gov/genetics/understanding/precisionmedicine/definition/

NIS PROCESS MAP



I have a dream,

52 Ethikkommissionen

17 Datenschutzbehörden

2 Bundesoberbehörden

Eine Studie
Eine Ethik
Eine DP-Behörde
Eine Genehmigung

Gold standard of clinical study data capturing is manual data input

Copying data from EHR into EDC systems manually

Copy paste mistakes, waste of time for site staff and the necessity to review the entries during source data verfication visits

Quality Review visits ensuring source data verification are time and cost intensive

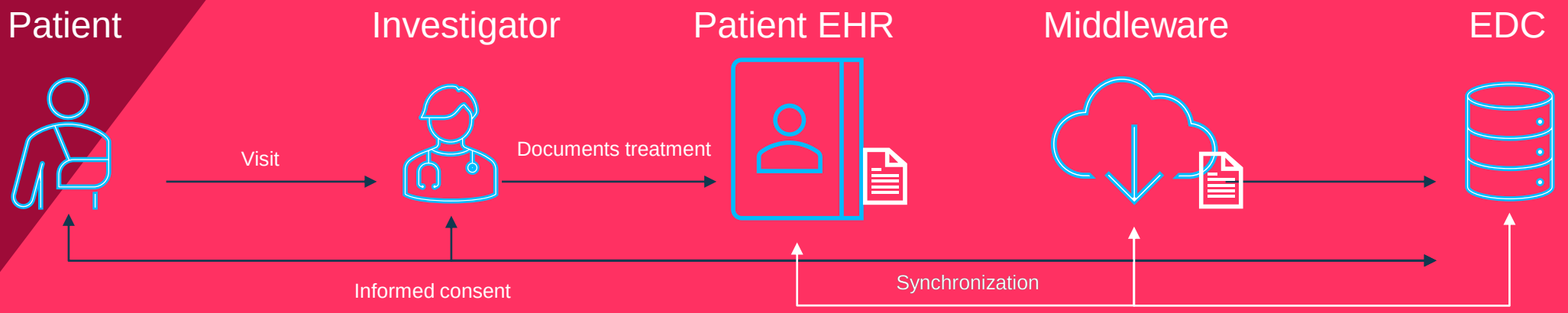
Investigators are paid for time spent of documentation

I have another dream,

that pseudonymized health data flow automatically from point of care to clinical research database to authorities

Let the data flow
Automatic Data Transfer in Clinical Studies (EHR2EDC)

FINE-Real Study a non-interventional study providing insights in a routine clinical setting



- Lab values
- Diagnoses
- Medication (start, stop, dose, frequency)
- Personal data (age, year of birth, weight, height, gender)

1) Mueller et al. 2023 Journal of Medical Internet Research - Automated Electronic Health Record to Electronic Data Capture Transfer in Clinical Studies in the German Health Care System: Feasibility Study and Gap Analysis

Beyond the idea of EHR2EDC there are multiple challenges for implementation

- **Prospective study design**
- **EHR not interoperable with EDC**
- **Variability of systems and lack of web connectivity**
- **Regulatory requirements (ICD, 21 CFR part 11, CDISC)**

Changing the status quo - benefits for investigators, sponsors and regulators

Addresses feasibility, connectivity, and compatibility

100%

compliance with the **GDPR** due to patient consent

Prospective primary data collection

1x1

high quality of the collected data

Reduce costs and improve study planning

15.000€

Savings per Patient due to 87,500 h in a 3.5 million-Data point study

Germany is moving forward in Digital Health – Political Framework

- GDNG enabling secondary use of health data
- Patients empowered to donate data to research data center (FDZ)
- ePA to EDC

Consequences for investigators, sponsors & EHR provider

- No double documentation is necessary
- Prospective Research would be implemented into everyday life
- Industry is aligning on standard data kit for research based on FHIR
- No interoperability without standards
- Involving authorities to align on standards, processes and data

adesso
AICURA MEDICAL
AstraZeneca
.B.A.
BAYER
BDI
bdr.
bitko
Boehringer Ingelheim
BPI Bundesverband der Pharmazeutischen Industrie e.V.
BRAINLAB
c&
managing
das lab
Deloitte.
DIG IN HEALTH
Fraunh
GESUNDHEITS-FOREN
inovex
IQVIA
janssen
kjur
Medtronic
MSD
Roch
ROTE LISTE
T-Systems
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zvei
electr
ideas

“Data-driven innovation in today's healthcare system requires the creation of an all-win situation, which is almost impossible under the current conditions.”

That's why we need to change the conditions.

sphinX will be a game changer in the data-driven healthcare sector

Why

Innovation is central for everyone.

It enables patients to live better and longer and companies to achieve financial success.

However, data-driven innovation is severely hampered by various factors such as data quality, data access, data protection and regulations.

It is necessary to break new ground.

What

sphinX pursues a multi-stakeholder approach.

As a data space, it creates an opportunity to develop common data standards and connect participants dynamically.

For a variety of use cases along the value chain.

From B2B to B2C to B2C2C.

How

Let's tackle the challenges together.

In a trustworthy, collaborative data environment.

Simple and compliant. From data owner to innovator.

For all of us.

sphinX: Defragmentation of the healthcare system

sphinX is a new, collaborative data space for all stakeholders in the healthcare sector and enables targeted new connections and access. Broad agreement on standards will form the basis for data-driven innovation in 1:n instead of 1:1 use cases along the entire value chain.

As a new infrastructure, sphinX facilitates the establishment of various use cases (B2B and B2C)

Research & Development

- Discovery Concept
- (Pre-)Clinical Engineering
- Clinical Validation
- Authorization
- Market Access
- HCP Interaction
- Market Launch

Supply chain & Delivery

- Inbound Logistics
- Production & Tracking
- Inventory Management
- Outbound Logistics & Distribution

HCP / Patient Interactions

- Prevention
- HCP Awareness
- Diagnosis
- Prescription & Treatment
- Monitoring

Product Use & Support

- Product Use
- Monitoring & RWE
- End of Life Cycle Management

sphinx

Further ideas on how sphinX could improve data-driven innovation and thus patient care

Digit. twins / Synth. control arms
Optimisation of study protocols, identification of patients and improved study execution

Pharmacies service portal
Centralisation of access management for pharmacies and data exchange standards, similar to the boarding pass principle in the aerospace sector

Drug-drug interaction warning system
Central system for monitoring and alerting patients and/or HCPs with potential drug-drug interactions

Central Register of Rare Diseases
Central base for rare disease patients and synthetization to enable research on little patient data

Supply chain management
(Semi-)automated, standardised data exchange between wholesalers and BfArM, with monitoring algorithms in case of bottlenecks

Connection point new innovation
Agreement on central standard interfaces in HIS/PVS systems in order to be able to quickly integrate new innovations into the treatment process

Research Data Hub+
Standardised, interoperable, GDPR-compliant care data for proprietary and academic research, e.g. laboratory values, image data, etc.

Digital supply chain / Industry 4.0
Complete description of the supply chain and digitalisation of all processes and documents including standardised CO_2 footprint calculation

Centralised remote patient monitoring
Centre for remote patient monitoring to transfer suitable treatments to patients' homes and increase patient convenience

Master data management sphinX
Master data management of sphinX participants, for integration into automated systems (similar to Catena-X)

Standardised consent management & data donation portal
Standardisation of patient-determined consent management and the possibility of research donation

Central Patient Support Portal
Links to information and services of the respective pharmaceutical companies for patients with corresponding medication via packaging QR codes

... and many other use cases

1) Project is also being discussed in the vfa

Health for all
Hunger for none

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