

Wir brauchen eine bessere Dateninfrastruktur für Versorgung und Forschung



Dateninfrastruktur

Ein Baustein gegen COVID-19

Zur Bekämpfung der SARS-CoV-2-Pandemie fehlte es nicht nur an brauchbaren „guten“ Daten. Erforderlich für die künftige Prävention ist auch die Sicherstellung von interdisziplinärem Input sowie ein Austausch wissenschaftlicher Expertise und praktischer Erfahrung.

Amke Caliebe, Gerd Antes, Friedhelm Leverkus, Michael Krawczak

Die Corona-Krise ist auch eine „**Missing-Data**“-Krise. Sie hat schmerzhaft gezeigt, dass Deutschland über **zu wenig Infrastruktur** verfügt, um während einer Pandemie wichtige Daten zum Test- und Infektionsgeschehen und zur Wirksamkeit von Eindämmungs- und Therapiemaßnahmen zu akquirieren und zeitnah verfügbar zu machen.



Quellen:

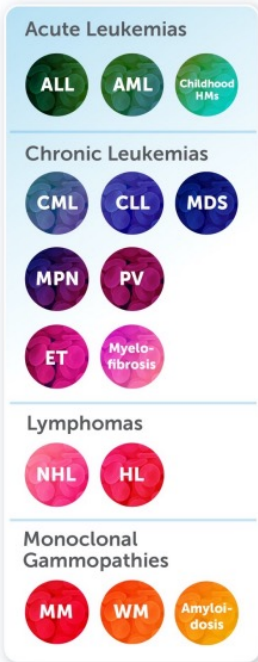
- GMS | 22. Jahrestagung des Deutschen Netzwerks Evidenzbasierte Medizin e. V. | 'Good enough'? – Evaluating evidence generation for treatment recommendations on pharmaceutical therapies during the COVID-19 pandemic (egms.de)
- Dateninfrastruktur: Ein Baustein gegen COVID-19 (aerzteblatt.de)

The HARMONY Big Data Platform

Transforming High Quality Data into Meaningful evidence for Blood Cancer.
A powerful and innovative approach to create high volumes of unique data.



FOCUS BLOOD CANCERS

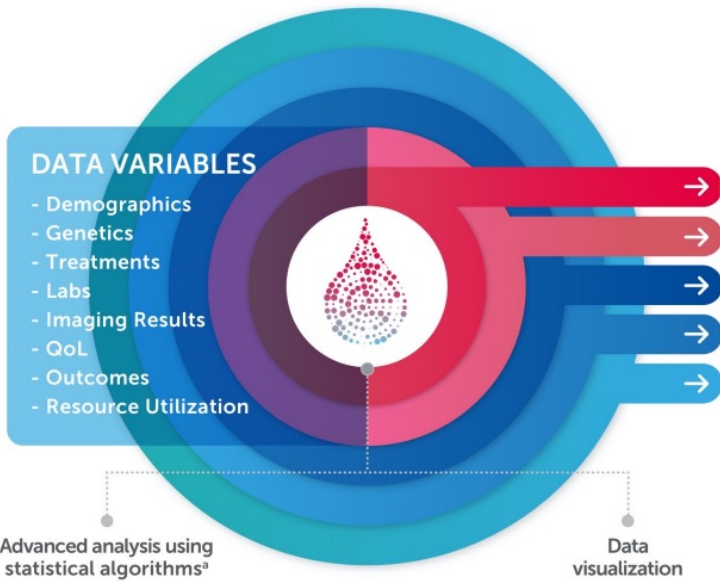


DATA PROVIDERS Partners and Associated members

- DATA SOURCES
- Hospitals
 - Interventional and non-interventional trials
 - Biobanks
 - Pharma

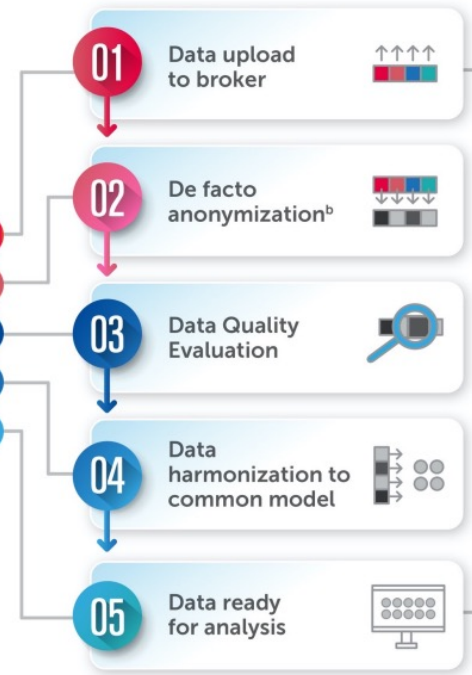
FULL PROJECT RESEARCH

HARMONY BIG DATA PLATFORM DATA PROCESSING



^a Only data essential to the analysis are accessible (to a limited group of users during a specific time span)
^b Data anonymization process is ISO 27001 certified

BIG DATA PLATFORM ANALYTICS



CURRENT AND UPCOMING PROJECTS

- Project Research publications
- New Research Projects
- Harmonization of Outcomes
- Guidelines
- Speed up drug development
- Increase application of omics data in clinical practice
- Additional safety signals
- Patient journey and disease knowledge

EUROPEAN HEALTH DATA SPACE

#EUDigitalHealth

OBJECTIVES

- ✓ Empower individuals through better digital access to their personal health data; support free movement by ensuring that health data follow people;
- ✓ Unleash the data economy by fostering a genuine single market for digital health services and products;
- ✓ Set up strict rules for the use of individual's non-identifiable health data for research, innovation, policy-making and regulatory activities.



GROWTH POTENTIAL OF THE HEALTH DATA ECONOMY



- Coordination centre
- Advisory board
- Timelines



The European Medicines Agency (EMA) is establishing a coordination centre to provide timely and reliable evidence on the use, safety and effectiveness of medicines for human use, including vaccines, from real world healthcare databases across the European Union (EU).

This capability is called the **Data Analysis and Real World Interrogation Network (DARWIN EU®)**.

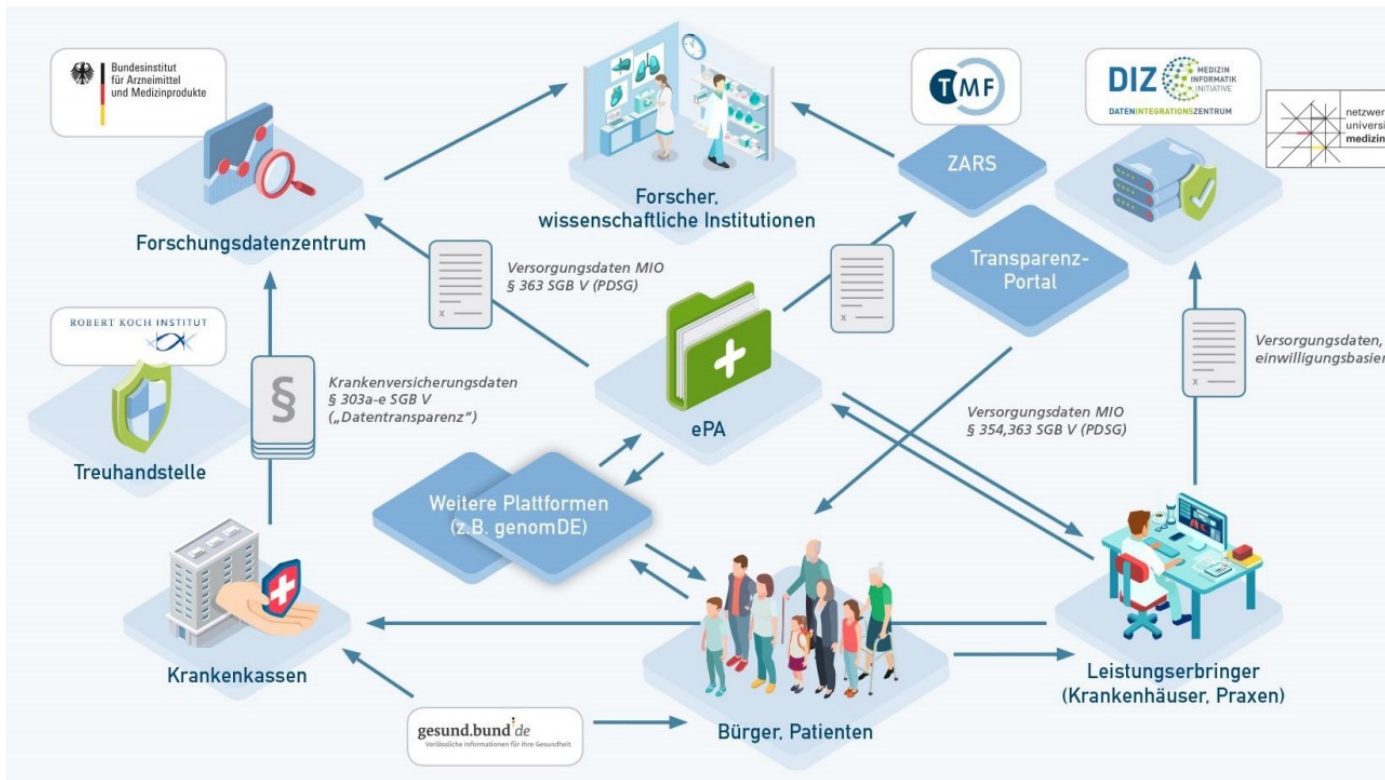
DARWIN EU will deliver **real-world evidence** from across Europe on diseases, populations and the uses and performance of medicines.

This will enable EMA and national competent authorities in the the European medicines regulatory network to use these data whenever needed throughout the lifecycle of a medicinal product.

DARWIN EU will support regulatory decision-making by:

- establishing and expanding a **catalogue of observational data sources** for use in medicines regulation;
- providing a source of high-quality, validated real world data on the uses, safety and efficacy of medicines;
- addressing specific questions by carrying out high-quality, **non-interventional studies**, including developing scientific protocols, interrogating relevant data sources and interpreting and report study results.

Forschungsdatenzentrum



**Ähnliche Datenräume in Europa:
Frankreich, Italien,
Finnland, Portugal,
Niederlande, UK**

- Antragsberechtigte Organisationen**
- Akademische Forschung
 - Öffentliche Forschungseinrichtungen
 - Öffentlich-Private Partnerschaften
 - Industrielle Forschung

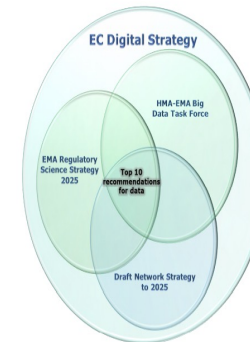


Quelle:
→ BfArM – Startseite- TMF Präsentation

FRAMEWORK FOR FDA'S
**REAL-WORLD
EVIDENCE
PROGRAM**

December 2018
www.fda.gov

Mandate: EMA and Network strategies both include DARWIN



Big Data Task Force – Priority number 1:

Deliver a sustainable platform to access and analyse healthcare data from across the EU (Data Analysis Real World Interrogation Network (DARWIN))

[Making best use of big data for public health: publication of the Big Data Steering Group workplan for 2020-21](#)

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Classified as internal/staff & contractors by the European Medicines Agency

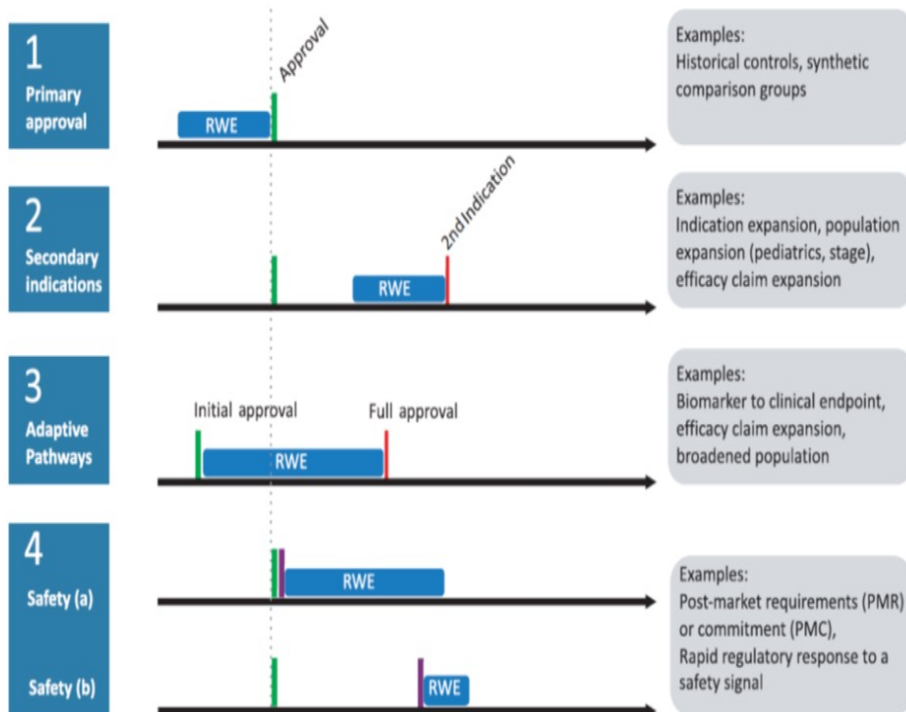
Real-World Evidence in EU Medicines Regulation: Enabling Use and Establishing Value

Peter Arlett^{1*}, Jesper Kjær², Karl Broich³ and Emer Cooke¹

We outline our vision that by 2025 the use of real-world evidence will have been enabled and the value will have been established across the spectrum of regulatory use cases. We are working to deliver this vision through collaboration where we leverage the best that different stakeholders can bring. This vision will support the development and use of better medicines for patients.

Evaluating the Use of Nonrandomized Real-World Data Analyses for Regulatory Decision Making

Jessica M. Franklin¹ , Robert J. Glynn¹, David Martin² and Sebastian Schneeweiss^{1*} 



Causal Inference

Die Verwendung von versorgungsnahen Daten im Zulassungsprozess wird zunehmen Und RCTs ergänzen

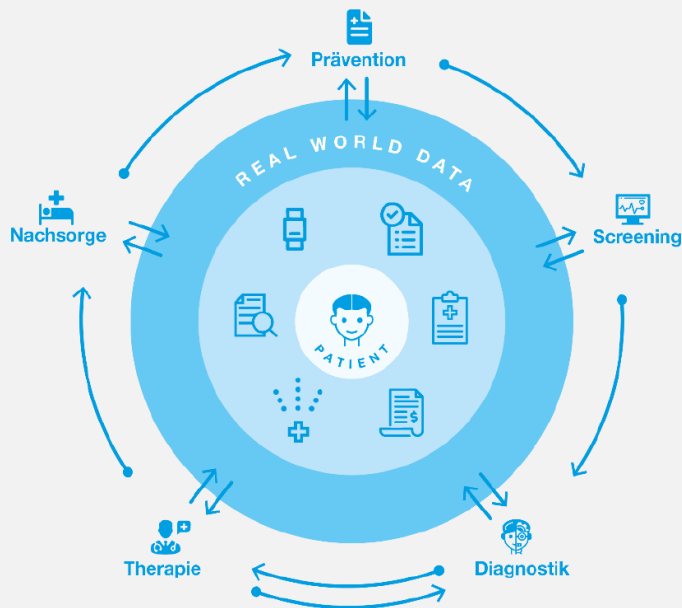
Real-world evidence (RWE) in regulatory decision making: key use cases.



Quelle:
 → Schneeweiss, S., & Glynn, R. J. (2018). Real-world data analytics fit for regulatory decision-making. American journal of law & medicine, 44(2-3), 197-217.

RWE für Forschung und Versorgung

Data Journey – Gesundheitsdaten von Prävention bis Nachsorge



Definition

Real World Data sind Gesundheitsdaten, die in der klinischen Routine bzw. im Alltag erhoben werden oder wurden.

Beispiele für Datenquellen

- Register
- elektronische Patientenakten (ePA)
- Krankenkassenabrechnungen/ Krankenkassenerhebungen
- Krankenhausinformationssysteme (KIS)
- Beobachtungsstudien
- Wearables

Nutzen von versorgungsnahen Daten z.B.:

Verbesserung der Versorgung durch Daten

- Diagnostik /Screening
- reproduzierbare und transparente Unterstützung in ihren Entscheidungsprozessen
- schnellere und einfachere Datenverfügbarkeit

Arzt und Patient können datenbasiert entscheiden

Forschung

Leitlinienentwicklung
Offene Fragestellungen
Bester Zeitpunkt Therapiebeginn
Sequenzen und Kombinationen

Hypothesengenerierung
Informationen für CT

Pharmacoepidemiology
Versorgungslücken
Burden of diseases
Inzidenz und Prävalenz Schätzungen
Behandlungsmuster
Adhärenz/Compliance
Predictive Modelling
Comparative Effectiveness und Safety
Gesundheitökonomische Analysen

Erkenntnisgewinn aus versorgungsnahen Daten: von RWD
zu RWE | SpringerLink

