Federal Institute
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and Medical Devices

Session 1 -
View from European Medicines Regulatory Network

Prof. Karl Broich

EU Medicines Network & Strategy to 2020

- HMA network: > 50 national competent authorities from EU/EEA - close cooperation - complementary approaches - common mission:
  - securing efficient and effective operation of both the European Medicines Regulatory System and the Network
  - ensuring that available resources are sufficient to support the work of the network
  - ensuring that the Network is aware of and responds appropriately to the challenges it faces due to the ever-changing nature of the environment in which it operates
- Close cooperation between EMA and HMA - common strategy to 2020 outlining
  - common challenges and opportunities
  - setting out joint key priorities & a high-level roadmap to achieve these

HMA - Multi Annual Work Plan (MAWP)

- After finalisation of the joint HMA/EMA strategy, the HMA developed a MAWP to bring the joint overarching strategy into operation on the HMA level with the involvement of all NCAs.
- 11 Priorities, e.g. **Innovation** & access to new medicines, Availability of good quality appropriately authorized medicines, Responding to public and animal health emergencies, Competence development programme,…
- Mid-term review 2018
- Discussion started for building up common strategy to 2025

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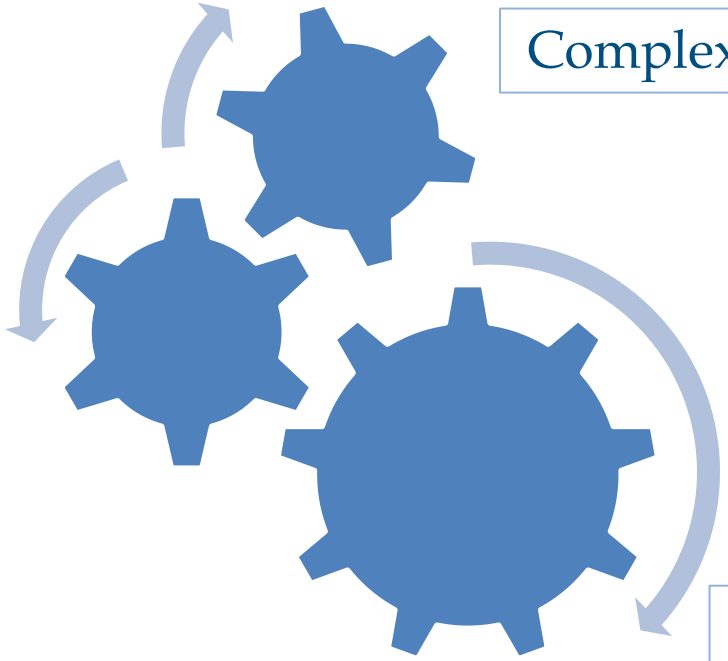
Challenges and opportunities for the EU Medicines network



Complex Lifecycle Management

Big Data, Real World, eHealth...

→ Changes to the current health care system

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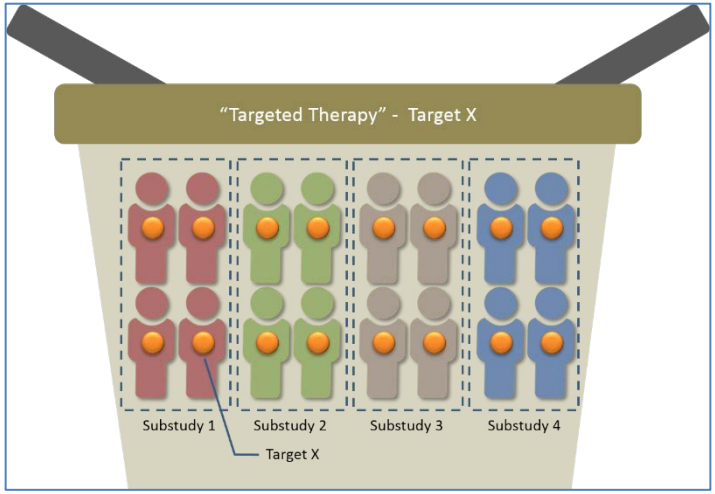
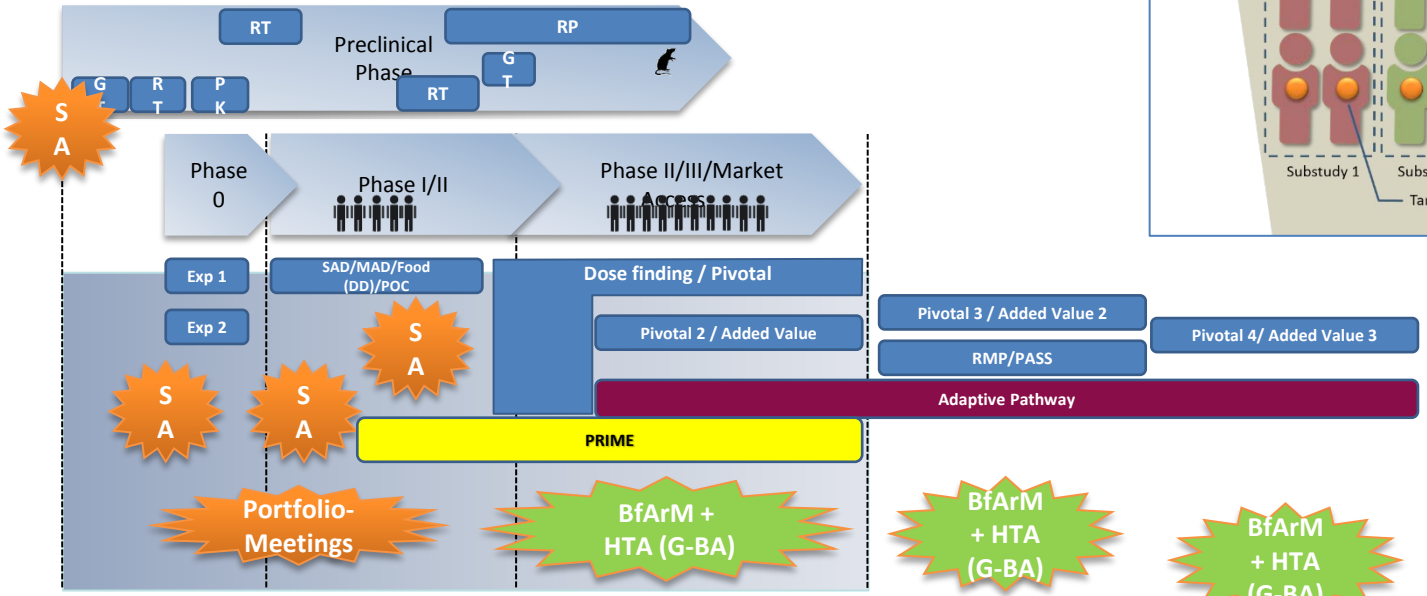
Complex Lifecycle-Management





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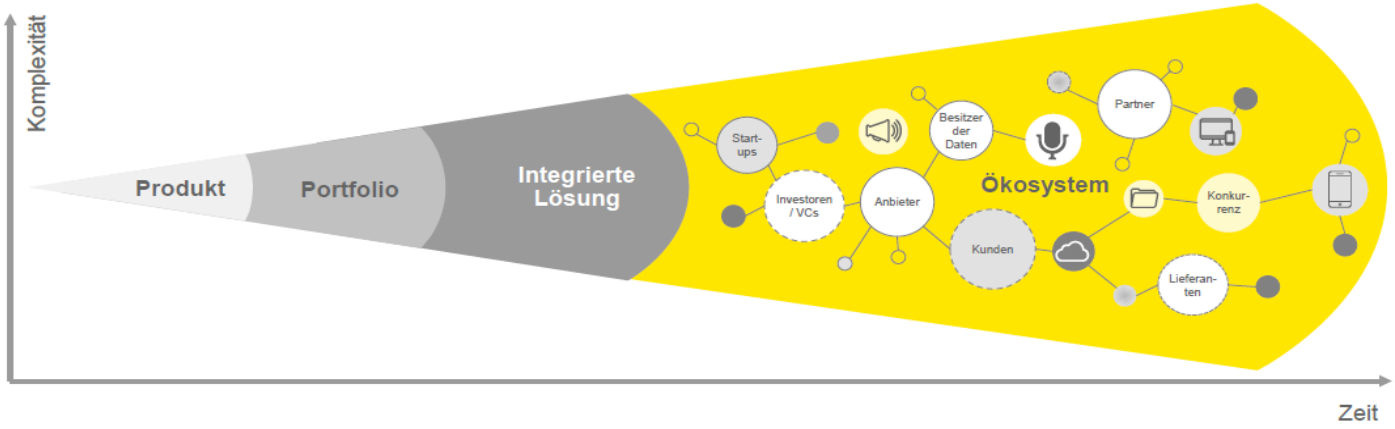
2 - Increasing complexity in the health care system

- Digitalisation
- Real World Data/
- „Big Data“



Pharma 1.0	Pharma 2.0	Pharma 3.0	Pharma 4.0
▸ Blockbuster Modell	▸ Portfolio an Produkten in mehreren therapeutischen Bereichen ▸ Fokus auf Geschäftseinheiten und Kostenreduzierung	▸ Engere Vernetzung von Patienten, Ärzten, Kostenträgern ▸ Fokus auf verbesserte Resultate (health outcomes)	▸ Die Digitalisierung disruptiert das traditionelle Geschäftsmodell und Wettbewerbsumfeld ▸ Agile Startups, Technologieunternehmen und andere sektorfremde Dienstleister (z.B. Health IT) drängen in den Markt

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https://www.ey.com/Publication/vwLUAssets/ey-die-groessten-pharmafirmen-weltweit-analyse-der-wichtigsten-finanzkennzahlen/$FILE/ey-die-groessten-pharmafirmen-weltweit-analyse-der-wichtigsten-finanzkennzahlen.pdf

Ongoing Ideas in the European Network

Clinical Pharmacology & Therapeutics

State of the Art | Full Access

Data rich, information poor; can we use electronic health records to create a learning healthcare system for pharmaceuticals?

eorg Eichler, Brigitte Bloechl-Daum, Karl Broich, Paul Alexander Kyrle,
derkirk, Guido Rasi, Rui Santos Ivo, Ad Schuurman, ... See all authors

blished: 04 September 2018 | https://doi.org/10.1002/cpt.1226

Judicious use of Real World Data (RWD) is expected to make all steps in the development and utilisation of pharmaceuticals more effective and efficient, including research and development, regulatory decision making, health technology assessment, pricing and reimbursement decisions and treatment. A 'learning healthcare system' based on electronic health records and other routinely collected data will be required to harness the full potential of RWD to complement evidence based on randomised controlled trials.

We here describe and illustrate with examples the growing demand for a learning healthcare system; we contrast the exigencies of an efficient pharmaceutical ecosystem in the future with current deficiencies highlighted in recently published OECD reports; and we reflect on the steps necessary to enable the transition from healthcare data to actionable information.

A coordinated effort from all stakeholders and international co-operation will be required to increase the speed of implementation of the learning healthcare system, to everybody's benefit.

learning healthcare system that harnesses RWD?

al paradigm, assessment of the benefits and harms of any new drug takes place
rch-settings. Data are generated prospectively, i.e. according to pre-planned and
tudies require pre-authorisation, and patients are asked to actively enrol in a
terms of research methodology, the (double-blind) RCT became the standard for
cacy to support marketing authorisations, HTA, reimbursement decisions and
nt decisions.

n collaboration with academia and industry, already make use of RWD in
processes. These aim to broaden the funnel of incoming data, primarily for the monitoring of drug safety and, in particular, for the assessment of rare and/or late-onset safety issues 4 5 6. Pre-planned and vetted study protocols (e.g. by regulators in the framework of scientific advice) have now become standard also for many RWD studies. While these initiatives have been largely successful for the purpose of monitoring safety, we argue that scientific developments –

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Structure of Research and Cooperations at the BfArM

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DZNE German Center for Neurodegenerative Diseases within the Helmholtz Association

DZIF German Center for Infection Research

Scientific Advisory Board

Key Research Areas

Regulation

universitätbonn

Centre for Translational Medicine

Pharmacogenetics Personalized Medicine

Pharmaco-epidemiology

Medical Devices Safety

Research Department

Trainee Programmes

Advanced Training, Scientific Symposiums

Integration

Licensing

Pharmacovigilance

Medical Devices/ Borderline Products/ eHealth

Ad Hoc Research Areas

Internal Research Council

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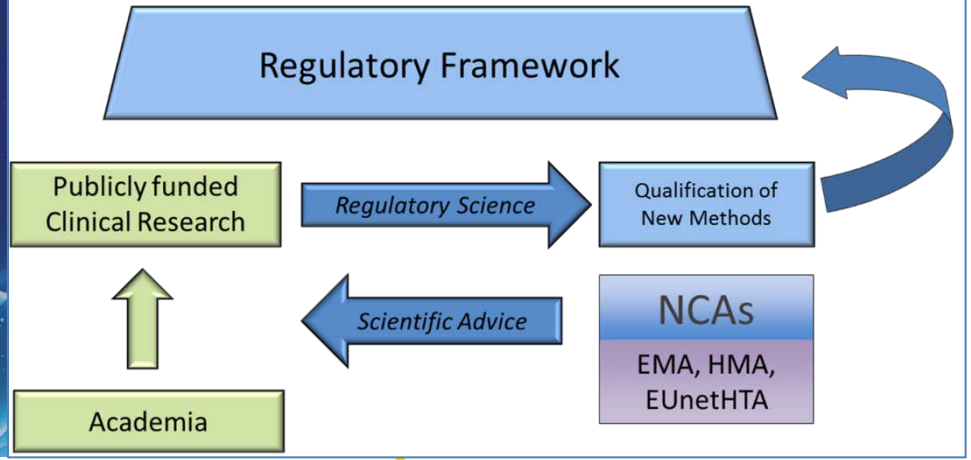
Center for Translational Medicine (CTM)
Partnership of Research Facilities

Coordination and Support Action (CSA): Strengthening training of academia in regulatory sciences and supporting regulatory scientific advice (STARS)



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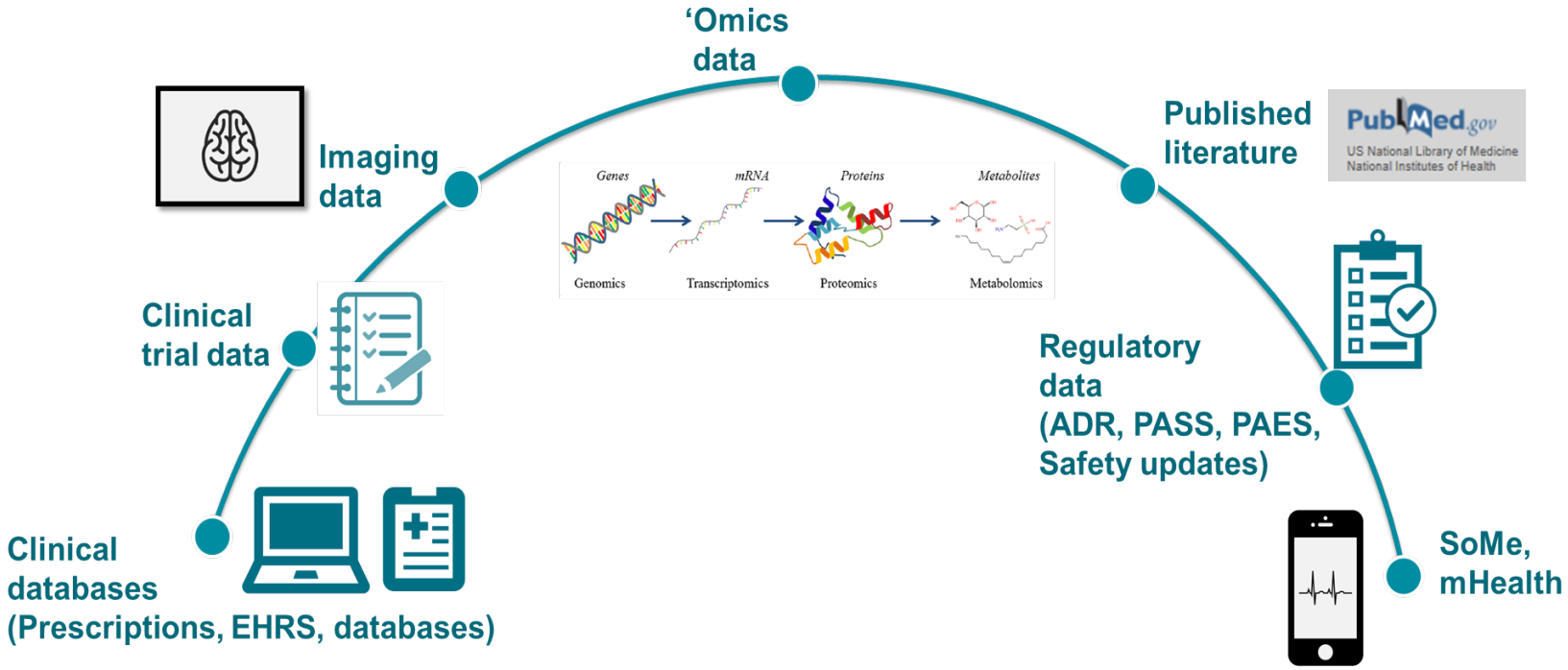
Regulatory Sciences: Which Data for What?



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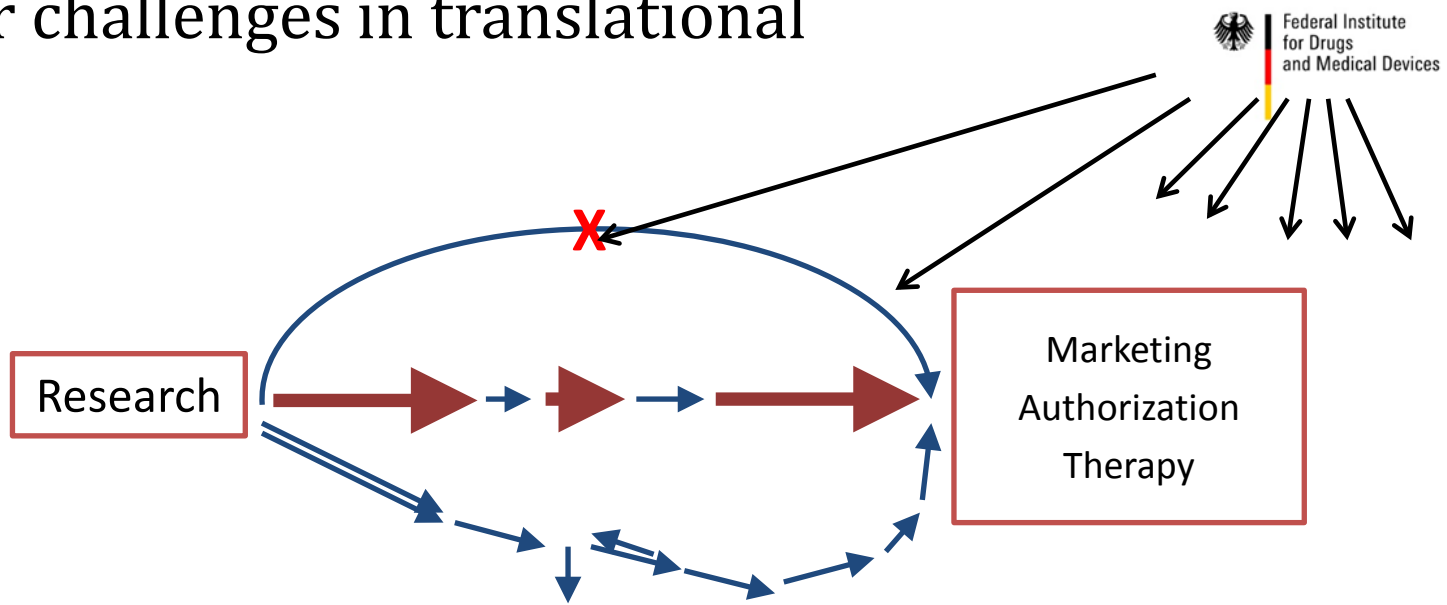
Particular challenges in translational medicine



- Very early education, communication and cooperation
- Identify key elements, systematic service and advice

→ **Shapen the chain**

Conclusions

- BfArM - as well as the entire EU regulatory network - supports Regulatory Sience by offering interaction, communication, education & advice as early as possible

- The impact of systematic approaches must be analyzed to allow further optimization

- Regulatory environments are changing

→ experiences are to be shared

→ mechanisms and incentives to promote Regulatory Science (and keep it up-to-date) must be continuously adapted to future developments

Thank you very much for your attention!

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