

EU Big Data Stakeholder Forum

Stakeholder perspective - Academia

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Priorities

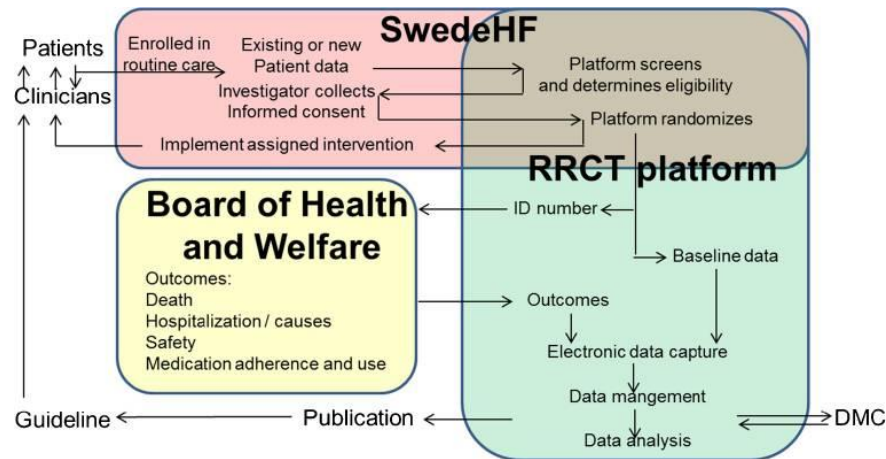
- **To improve health outcomes and healthcare systems by delivering optimal therapies to all EU patients**
 - Right patient selection
 - Treatment optimization (sequence, combination, ...)
 - Optimal use of limited health care resources
- **To reinforce academic health research and innovation**
 - in collaboration with pharma/biotechs
 - BUT ALSO independently of any market interests
- **Harmonisation of systems and guidance, at the supra national level within EU is key**
 - national disparities slow down Big Data research within EU compared to unified regions such as USA

Opportunities Drug development phase

To identify patients eligible for trials

Registry based Randomized Trials

e.g. SWEDEHEART
INFINITY trial



Lund et al. Curr Heart Fail Rep (2017) 14:59–70

Federated real-time registry at EU level could leverage the potential to run such trials at broader scale

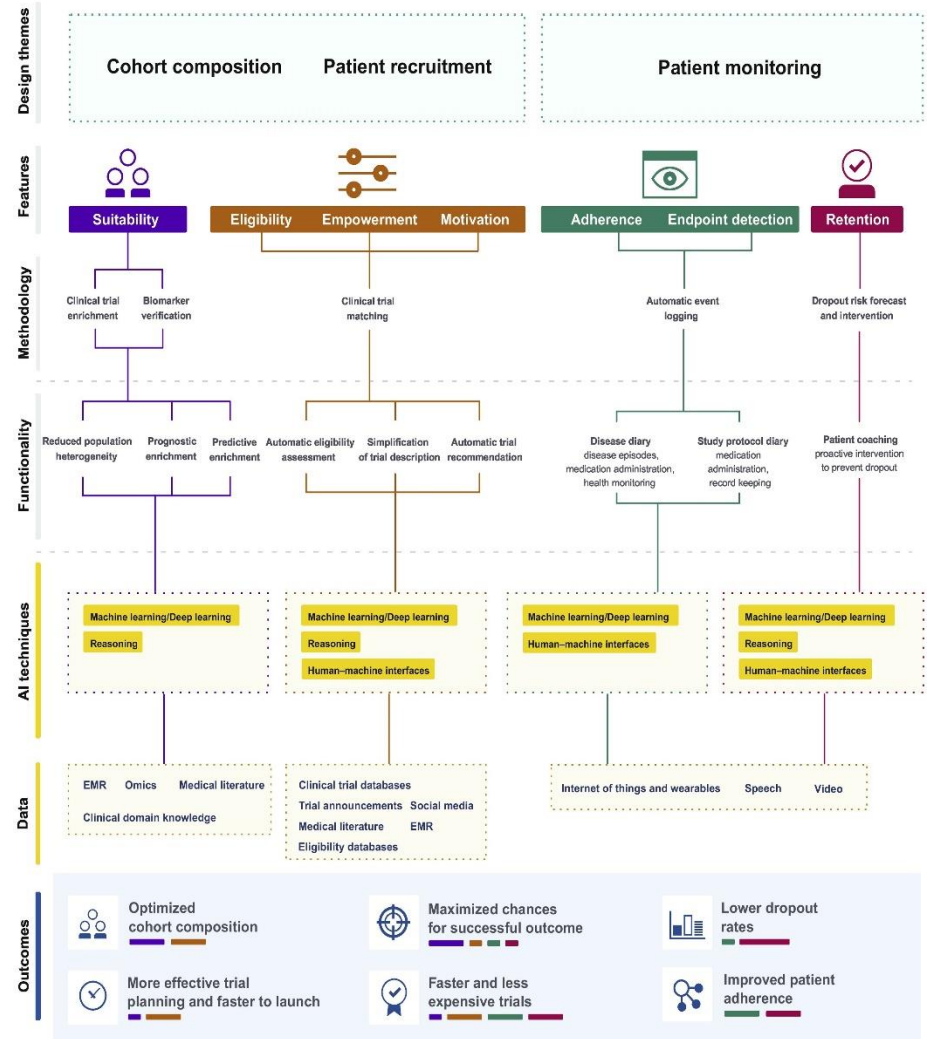
Opportunities Drug development phase

Foster new research and innovation **AI & machine learning**

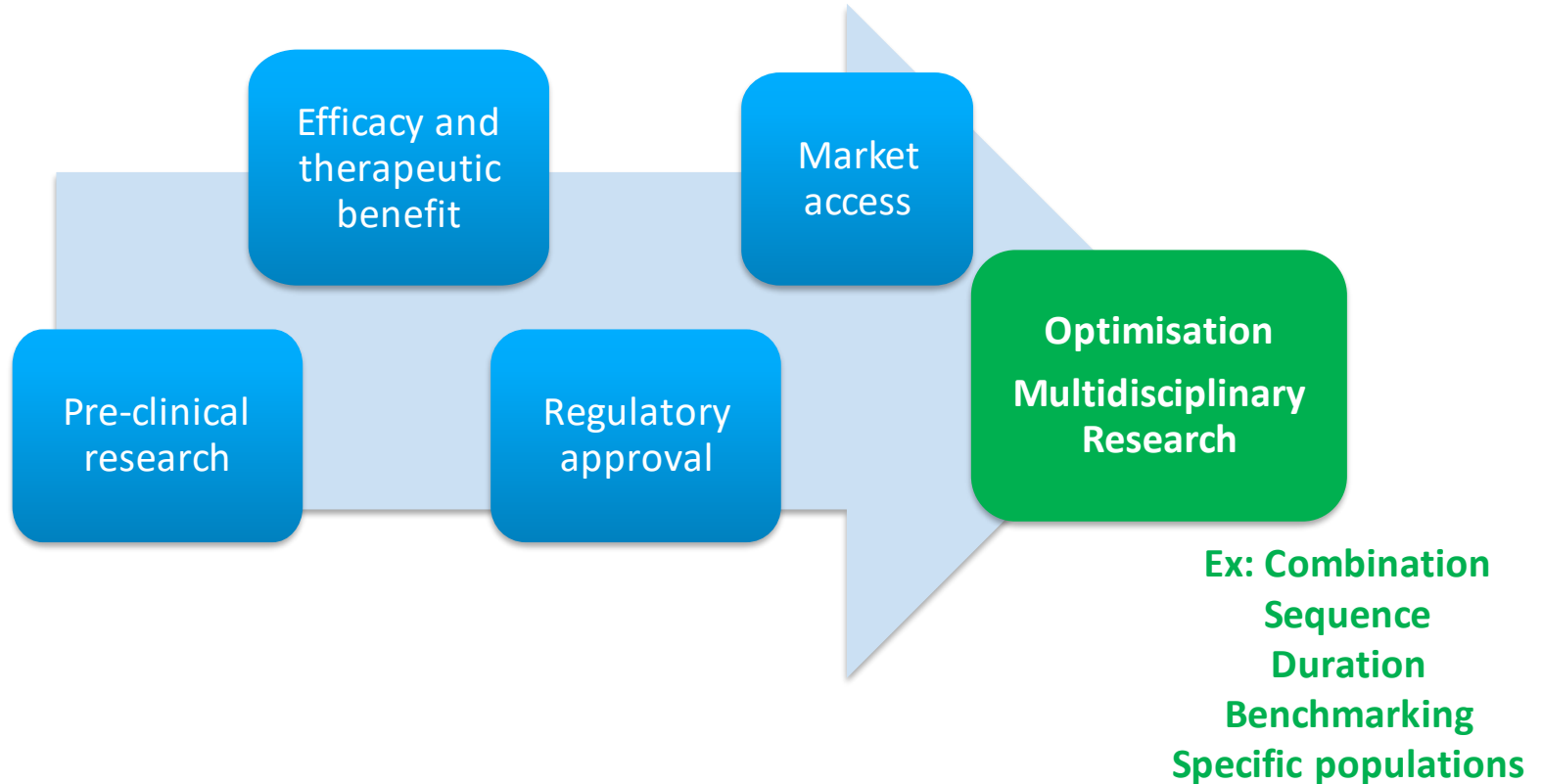
- Optimize patient selection
- Continuous real-world evaluation and updating of AI models

**Access to DARWIN data
+
federated learning**

AI for clinical trial design: from methodology to improved outcomes



Opportunities After market access



**The full benefit to population through patient-centric care
will be achieved **ONLY IF**
DARWIN includes or is federated with data of patients
treated with non IND interventions in trials or in clinical practice**

Opportunities

Secondary use of data

- If made accessible to academia a federated DARWIN DB offers opportunities for researchers to make new discoveries and fill the gap where randomized evidence to guide treatment is lacking.



Global "Big data fit for purpose" quality standards

EU-wide secure system that enables patient tracking and linkage of datasets, whilst being GDPR compliant and respectful of patients rights and preferences

Risks

- **Establish an EU framework for data quality and representativeness.** Develop guidelines, a strengthened process for data qualification through Scientific Advice, and promote across Member States the uptake of electronic health records, registries, genomics data, and secure data availability.

Increased costs to hospitals

- Cost of adoption and usage of high quality EHR systems
- Cost of integration and maintenance into federated learning systems requires investments to comply with data structure, annotation and report protocol
- **Risk of representation in the RWE accredited datasets of only those (high volume) treatment clinics who can afford such systems**

Risks

National variations in implementation of guidance on data qualification, data standards, meta-data and datasharing

Another layer of administration & costs?

Open Access

Original Research

 **ESMO** *Open*
Cancer Horizons



Safeguarding the future of independent, academic clinical cancer research in Europe for the benefit of patients

Anastassia Negrouk,¹ Denis Lacombe,² Fatima Cardoso,³ Franck Morin,⁴
Eva Carrasco,⁵ Joan Maurel,⁶ Rudolf Maibach,⁷ Enrique Aranda,⁸ Richard Marais,⁹
Rolf A Stahel¹⁰

HemaSphere
Powered by EHA



HemaTopics
OPEN ACCESS

Reducing Bureaucracy in Clinical Research: A Call for Action

By John Gribben¹, Elizabeth Macintyre², Pieter Sonneveld³, Jeanette Doorduijn³, Christian Gisselbrecht⁴, Ulrich Jäger⁵, Steven Le Gouill⁶, Simon Rule⁷, Martin Dreyling⁸

Correspondence: Martin Dreyling (e-mail: Martin.Dreyling@med.uni-muenchen.de).

Risk of further deterring the randomized evidence

By leveraging the use of
RWD to support
accelerated access, PRIME
and conditional
authorisations

- Absence of RCT
- Long term effects not observable in RCTs due to early release of results

Risks

The NEW ENGLAND JOURNAL of MEDICINE

SOUNDING BOARD

The Magic of Randomization versus the Myth of Real-World Evidence

Rory Collins, F.R.S., Louise Bowman, M.D., F.R.C.P., Martin Landray, Ph.D., F.R.C.P.,
and Richard Peto, F.R.S.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Repurposed Antiviral Drugs for Covid-19 — Interim WHO Solidarity Trial Results

WHO Solidarity Trial Consortium*

Area for collaboration/engagement

TFDA

TRUSTWORTHY FEDERATED
DATA ANALYTICS PROJECT



CISPA
HELMHOLTZ CENTER FOR
INFORMATION SECURITY

dkfz.

DEUTSCHES
KREBSFORSCHUNGSZENTRUM
IN DER HELMHOLTZ-GEMEINSCHAFT

Academia's experience in federated learning

Joint Imaging Platform

The strategic initiative "Joint Imaging Platform" establishes a distributed IT infrastructure for image analysis and machine learning at all DKTK sites. It will facilitate pooling of analysis methods that can be applied in an automated and standardized manner to patient data of the different centers. This will allow unprecedented cohort sizes in cross-center evaluations as well as faster transfer of analytical methods from research to evaluation on clinical data. The underlying infrastructure facilitates applications like federated learning across multiple clinical centers.

Interreg
Euregio Meuse-Rhine
European Regional Development Fund

Euradiomics

The Euregional network for Distributed Deep Learning from radiology imaging to improve decision making in oncology for doctors and patients

Oncoradiomics SA, CHU de Liège, RWTH Aachen Universität - Lehrstuhl für Bildverarbeitung, Health Innovation Ventures, Maastricht University dept. Precision Medicine, LOC Hasselt, Dosevue NV, Uhaselt

www.euradiomics.com

Contents lists available at ScienceDirect

Clinical and Translational Radiation Oncology
journal homepage: www.elsevier.com/locate/ctro

Infrastructure and distributed learning methodology privacy-preserving multi-centric rapid learning he

M. Deist^{a,b,1,*}, A. Jochems^{a,b,1}, Johan van Soest^{a,b}, Georgi Michael Eble^c, Paul Bulens^d, Philippe Coucke^e, Wim Dries^f, Arthur Jochems^{a,b,1}, Timo M. Deist^{a,b,1}, Johan van Soest^{a,b}, Michael Eble^c, Paul Bulens^d, Philippe Coucke^e, Wim Dries^f, Philippe Lambin^{a,b,1}, Andre Dekker^{a,1}

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pm
precision medicine

Contents lists available at ScienceDirect

Radiotherapy and Oncology
journal homepage: www.thegreenjournal.com

Distributed learning

Distributed learning: Developing a predictive model based on data from multiple hospitals without data leaving the hospital – A real life proof of concept

Arthur Jochems^{a,b,1}, Timo M. Deist^{a,b,1}, Johan van Soest^{a,b}, Michael Eble^c, Paul Bulens^d, Philippe Coucke^e, Wim Dries^f, Philippe Lambin^{a,b,1}, Andre Dekker^{a,1}

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Radiotherapy and Oncology
CrossMark

Radboud umc

Maastricht University

Area for collaboration/engagement

Working with cancer registries and with data linkage



> J Comp Eff Res. 2017 Sep;6(6):485-490. doi: 10.2217/ce-2017-0044. Epub 2017 Aug 31.

Practical implications of using real-world evidence (RWE) in comparative effectiveness research: learnings from IMI-GetReal

Amr Makady ^{1 2}, Heather Stegenga ³, Antonio Ciaglia ⁴, Thomas Pa Debray ^{5 6}, Michael Lees ⁷, Michael Happich ⁸, Bettina Ryll ^{9 10}, Keith Abrams ¹¹, Rob Thwaites ¹², Sarah Garner ³, Páll Jonsson ³, Wim Goettsch ^{1 2}

Affiliations + expand

PMID: 28857631 DOI: [10.2217/ce-2017-0044](https://doi.org/10.2217/ce-2017-0044)



The future of cancer therapy

> Br J Haematol. 2017 Jan;176(1):65-75. doi: 10.1111/bjh.14379. Epub 2016 Oct 21.

Survival differences between patients with Hodgkin lymphoma treated inside and outside clinical trials. A study based on the EORTC-Netherlands Cancer Registry linked data with 20 years of follow-up

Lifang Liu ¹, Francesco Giusti ¹, Michael Schaapveld ^{2 3}, Berthe Aleman ⁴, Pieterella Lugtenburg ⁵, Paul Meijnders ⁶, Martin Hutchings ⁷, Valery Lemmens ², Jan Bogaerts ¹, Otto Visser ²

Affiliations + expand

PMID: 27766636 DOI: [10.1111/bjh.14379](https://doi.org/10.1111/bjh.14379)

Area for collaboration/engagement

- Building on experience gained through Academic-Industry IMI partnerships
 - Defining data standards and ontologies
 - Testing incorporation of EHR datasets
 - Identifying the real world questions to inform clinical practice



FEDERATION

Creation of an EU-wide architecture for federated analyses of real world data

HARMONISATION
Harmonise more than 100 million
anonymised health records to the OMOP
common data model



COMMUNITY

Establish a self-sustaining open science collaboration in Europe, supporting academia, industry, regulators, payers, government, NGOs and others

OUTCOMES

Enabling outcomes-driven healthcare at a European level

EDUCATION

The establishment of an EHDEN Academy, webinars and face-to-face training sessions to train all stakeholders

Area for collaboration/engagement

- **Universities/academic research centers Methodology**
- Artificial intelligence for health data analytics, bioinformatics/genomic and clinical research expertise, pharmacology

► [BMJ](#). 2020 Mar 20;368:l6927. doi: 10.1136/bmj.l6927.

Machine learning and artificial intelligence research for patient benefit: 20 critical questions on transparency, replicability, ethics, and effectiveness

Sebastian Vollmer^{1 2}, Bilal A Mateen^{1 3 4}, Gergo Bohner^{1 2}, Franz J Király^{1 5}, Rayid Ghani⁶, Pall Jonsson⁷, Sarah Cumbers⁸, Adrian Jonas⁹, Katherine S L McAllister⁹, Puja Myles¹⁰, David Granger¹¹, Mark Birse¹¹, Richard Branson¹¹, Karel G M Moons¹², Gary S Collins¹³, John P A Ioannidis¹⁴, Chris Holmes^{15 16}, Harry Hemingway^{17 18 19}

► [F1000Res](#). 2020 Sep 9;9:1109. doi: 10.12688/f1000research.26253.2. eCollection 2020.

Adaptive platform trials using multi-arm, multi-stage protocols: getting fast answers in pandemic settings

Nurulamin M Noor¹, Sarah L Pett¹, Hanif Esmail¹, Angela M Crook¹, Claire L Vale¹, Matthew R Sydes¹, Mahesh K B Parmar¹

Affiliations + expand

PMID: 33149899 PMID: PMC7596806 DOI: 10.12688/f1000research.26253.2

[Free PMC article](#)

Digital Object Identifier 10.1109/ACCESS.2020.3029445

Blockchain for Privacy Preserving and Trustworthy Distributed Machine Learning in Multicentric Medical Imaging (C-DistriM)

FADILA ZERKA^{1,2}, VISARA UROVI³, AKSHAYAA VAIDYANATHAN^{1,2}, SAMIR BARAKAT², RALPH T. H. LEIJENAR², SEAN WALSH^{1,2}, HANIF GABRANI-JUMA², BENJAMIN MIRAGLIO², HENRY C. WOODRUFF^{1,4}, MICHEL DUMONTIER³, AND PHILIPPE LAMBIN^{1,4}

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⁴Maastricht University Medical Centre, Department of Radiology and Nuclear Medicine, 6202 AZ Maastricht, The Netherlands

► [JCO Clin Cancer Inform](#). 2020 Mar;4:184-200. doi: 10.1200/CC1.19.00047.

Systematic Review of Privacy-Preserving Distributed Machine Learning From Federated Databases in Health Care

Fadila Zerka^{1 2}, Samir Barakat^{1 2}, Sean Walsh^{1 2}, Marta Bogowicz^{1 3}, Ralph T H Leijenaar^{1 2}, Arthur Jochems¹, Benjamin Miraglio², David Townend⁴, Philippe Lambin¹

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PMID: 32134684 PMID: PMC7113079 (available on 2021-03-05) DOI: 10.1200/CC1.19.00047

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- Prof Bertrand Tombal, Université Catholique de Louvain (BE)