European perspectives on the use of "Big Data" in health care research

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Liverpool Women's

Declaration of interests

- My employers have received funds for clinical studies from: Roche, Chiesi, Johnson & Johnson, Pfizer, EC FP7, NIHR, BLISS, MRC, AMR
- My employers receive funds for consultancy from Chiesi, BMS, Novartis, Shire, Janssen, Grunenthal
- Lead for International Liaison, National Institute for Health Research, Children's Theme
- Co-Coordinator, Global Research in Paediatrics (GRiP)
- Chair, European Network for Paediatric Research at the European Medicines Agency
- Co-Director, International Neonatal Consortium

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Overview

- The energy and enthusiasm for European work on big data in health care research depends on a context that provides opportunities and imposes constraints

- The nature of Europe and the respect for individual privacy inherent in European and national legislation mean that "direct" exchange of data may be difficult but "indirect" exchange is possible

- The situation is changing and the paediatric community will benefit from consistent contact points

Topics

- European context

  - What's possible, what's not possible, why?

- Approaches

  - International actions

  - Industry

  - Academic

- Maturity of the approaches

- Implications

European context

Bulgarian: Обединен в многообразието
Croatian: Ujedinjeni u različitosti
Czech: Jednotná v rozmanitosti
Danish: Forenet i mangfoldighed
Dutch: In verscheidenheid verenigd
English: United in diversity
Estonian: Ühinenud mitmekesisuses
Finnish: Moninaisuudessaan yhtenäinen
French: Unie dans la diversité
German: In Vielfalt geeint
Greek: Ενωμένοι στην πολυμορφία

Hungarian: Egység a sokféleségben
Irish: Ní ceart go cur le chéile
Italian: Unita nella diversità
Latvian: Vienota dažādībā
Lithuanian: Suvienijusi įvairovę
Maltese: Magħquda fid-diversità
Polish: Zjednoczona w różnorodności
Portuguese: Unida na diversidade
Romanian: Uniţi în diversitate
Slovak: Zjednotení v rozmanitosti
Slovene: Združena v raznolikosti
Spanish: Unida en la diversidad
Swedish: Förenade i mångfalden

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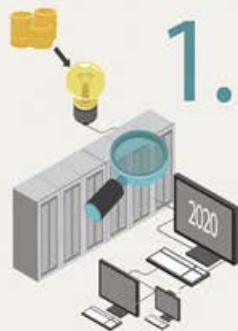Liverpool Women's

European context

- Some law

  – Regulation

  – Directive

  – National law based on shared principles

- Some shared practice

  – European Union

  – Council of Europe

  – Free-standing actions in the context of EU actions

4 STEPS TO LEVERAGE THE POTENTIAL OF BIG DATA

1. INVESTING IN IDEAS

Search for **game-shifting** ideas

Public Private Partnership

Research in **Horizon2020**

2. INFRASTRUCTURE FOR A DATA-DRIVEN ECONOMY

Network of data processing facilities

Invest in the **GÉANT** network

Supercomputing **centres of excellence**

Build big data mobile internet through **5G PPP**

Telecoms Single Market for broadband investment

3. DEVELOP BUILDING BLOCKS

Guidelines on standard licences, datasets & charging

One-stop-shop to open data across the EU

Mapping big data standards

Open data **incubator for SMEs**

Training for data professionals

Data market **monitoring** tool

4. TRUST AND SECURITY

EU **Data protection** rules

Guidelines on secure data storage

Consultations on :
- Policy options after **Trusted Cloud** Europe report
- Data ownership & liability of data provision
- User-controlled cloud-based technologies

European Commission

https://ec.europa.eu/digital-single-market/en/policies/big-data

Relevant EU activities :

- The Building a European Data Economy Communication and accompanying Staff Working Document, adopted in January 2017.
- The EU strategy on the data-driven economy, adopted in July 2014.
- Funding research and innovation activities in the field of "Big Data" and "Open Data". More on current research funding opportunities.
- Data technologies standards are considered as one of the five priority areas under the Digitising European Industry initiative.
- The communication "Connectivity for a European Gigabit Society" recognises connectivity as an essential enabler of the data economy.
- The policy on Open Data, in particular:
  - Legislation on re-use of public sector information, such as the PSI Directive (Directive 2003/98/EC), the national implementing rules as well as rules on re-use of the Commission's own data;
  - Non-legislative measures supporting the opening up of public sector information;
  - Open Data Portals.

https://ec.europa.eu/digital-single-market/en/policies/big-data

Digital Single Market

The Digital Single Market strategy aims to open up digital opportunities for people and business and enhance Europe's position as a world leader in the digital economy

Shaping the Digital Single Market

Boosting European digital industry

Building a European data economy

Improving connectivity and access

Investing on network and technologies

Advancing in digital science and infrastructures

Supporting media and digital culture

Creating a digital society

Strengthening trust and security

https://ec.europa.eu/digital-single-market/

Since May 2015, EU decision-maker have achieved the following:

As of **15 June 2017**, **mobile roaming charges will finally be abolished** in the EU.

34% of Europeans travel abroad at least once a year. In 2014, about half of Europeans would not use mobile internet abroad because it was too costly.

As of **May 2018**, a new single set of EU rules on **data protection and privacy** in electronic communications.

This will allow people to take back control of their personal data and set clear limits on the use of their data.

As of **2020**, EU Member States will for the first time coordinate their use of the **high-quality band 700 MHz**.

This will enable 5G networks and bring new services such as connected cars, remote health care, smart cities or video streaming on the move and across borders.

As of **early 2018**, citizens will be able to **enjoy their online films, sports broadcasts, music, video games, and e-book subscriptions when travelling** in the EU.

68% of online digital content providers block users in another Member State. 60% of young Europeans say cross-border portability is important for taking up a subscription.

As of **May 2018**, the EU will be equipped with its first ever **common cybersecurity law** to help keep network and information systems safe in all Member States.

The EU also supports the competitiveness of its cyber-security industry through a public-private partnership expected to generate €1.8 billion of investment by 2020 to help develop devices to defend against cyber-attacks.

If EU governments follow the Commission **e-government action plan,** they could save up to €5 billion per year as of **2020**.

The action plan seeks to simplify the life of citizens and businesses by ensuring public registers are connected and by accelerating the transition to e-procurement and e-signatures.

https://ec.europa.eu/digital-single-market/en/shaping-digital-single-market

European Commission > Strategy > Digital Single Market > News >

Digital Single Market

CONSULTATION | 20 JULY 2017 TO 12 OCTOBER 2017

Public Consultation on Health and Care in the Digital Single Market

Introduction

The purpose of this consultation is to define the need and scope of policy measures that will promote digital innovation in improving people's health, and address systemic challenges to health and care systems. Those measures must be aligned with legislation on the protection of personal data, patient rights and electronic identification.The consultation collects views on:

- Cross-border access to and management of personal health data;

- A joint European exploitation of resources (digital infrastructure, data capacity), to accelerate research and to advance prevention, treatment and personalised medicine;

- Measures for widespread uptake of digital innovation, supporting citizen feedback and interaction between patients and health care providers.

Building blocks of supportive health data ecosystems

1. Collaboration and coordination (interdependencies in value capture)

2. Public acceptability and engagement with health data

3. Data protection regulation and models of data access and use

4. Data quality, interoperability and other technical considerations

5. Workforce capacity

Understanding value in health data ecosystems

A review of current evidence and ways forward

by Sonja Marjanovic, Ioana Ghiga, Miaoqing Yang, Anna Knack

https://www.rand.org/pubs/research_reports/RR1972.html

The World Health Organization (WHO) European Health Information Initiative (EHII)

- is bringing together partners to work on harmonising health indicators and developing an integrated Health Information System for the European Region

TRANSFoRm project (2010–2015)

- used integrated EHR from Europe's family doctors with the aim of developing a core, integrated computational infrastructure
- aimed to promote interoperability between different clinical systems across different countries

The EHR4C initiative (2011-2016)

- collaboration between 35 academic and pharmaceutical companies, & 11 hospital sites in France, Germany, Poland, Switzerland and the UK
- established techniques to analyse anonymised data;provide information to identify eligible patients for trials, assess a trial's feasibility; locate the most relevant hospital sites

EU Smart Open Services for European Patients (epSOS) Pilot Project

- aimed to create cross-border Data Exchange by Building An ICT Infrastructure To allow different European healthcare systems to access patient health information

The usage of guidelines such as the Continua guidelines

- reference standards and specifications to ensure interoperability of health IT solutions. This is currently employed in Denmark

The EMIF project (ongoing)

- building a catalogue of data that aims to provide researchers a single point of access for searching aggregated data across different sources and countries, from consented users
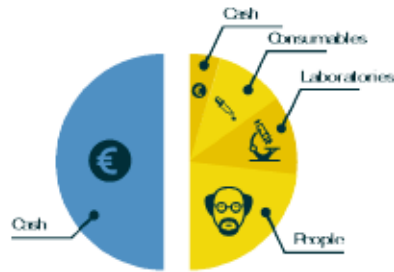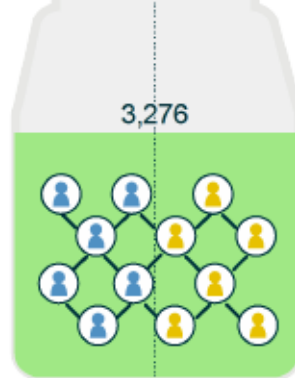
The public contribution

1,638 Billion €

The private Industry in-kind contribution

1,638 Billion €

Cash
Consumables
Laboratories
People
Cash

1.
1,638
From H2020

2.
1,425
EFPIA direct and indirect members

213
Other sectors

CASH for grants for PUBLIC PARTNERS

innovative medicines initiative

3.
Public Partners + Private Partners = in IMI2 consortia

3,276

What are the results ?

Improve outcomes & safety

Improve R&D

Speed up patient access

3,276 Billion €
2014 - 2024

The Big Data for Better Outcomes programme at a glance

http://bd4bo.eu/index.php/about-the-programme/about-bd4bo/

"Big data for better outcomes"

Goal: Support the evolution towards outcomes-focused and sustainable healthcare systems, exploiting the opportunities offered by big and deep data sources

COORDINATION AND SUPPORT ACTION (CSA)

EUROPEAN DISTRIBUTED DATA NETWORK

1 Design sets of standard outcomes and demonstrate value

2 Increase access to high quality outcomes data

3 Use data to improve value of HC delivery

4 Increase patient engagement through digital solutions

ROADS: ALZHEIMER'S DISEASE – CALL OPEN FOR APPLICATIONS

HEMATOLOGIC MALIGNANCIES – CALL OPEN FOR APPLICATIONS

CARDIOVASCULAR

MULTIPLE SCLEROSIS

MULTI-DISEASE / MULTI-MORBID PATIENTS

RARE CANCERS

Coordination and operational topics

Themes / Enablers

Disease-specific topics

IMI Big Data projects (examples)

Personalized care

ADAPTSMART

Get Real

ddmore
Drug Disease Model Resources

PROTECT

WEB-RADR

RADAR: Remote access RWD

Open PHACTS
eTOX

eTRIKS

ADVANCE

EHR4CR

EMIF

EPAD

PRO active

| Analysis | Quality and access | Defi-nition |

Targeted drug research and development

Faster and cheaper clinical trials

Faster approval and uptake

Improved value in HC delivery

Topic 4: Creation of a pan-European paediatric clinical trials network

Topic details

Topic code IMI2-2016-10-04

Action type Research and Innovation Action (RIA)

Submission & evaluation process 2 Stages

Work package 5: Data coordinating centre and data quality standards

The goals of this work package are to:

a) establish procedures and systems/tools to monitor performance metrics in all network trials at the sites, national hubs, and in the central network organisation;

b) promote shared definitions of terminology enabling uniform process for collection and storage of clinical data;

c) contribute to common eCRF definitions (e.g. common paediatric data dictionary);

d) contribute to common program/process to allow electronic storage and archiving of study related documentation.

Figure 3: the indicative position of ESFRI RIs relative to the different levels of organisation in the Health domain.
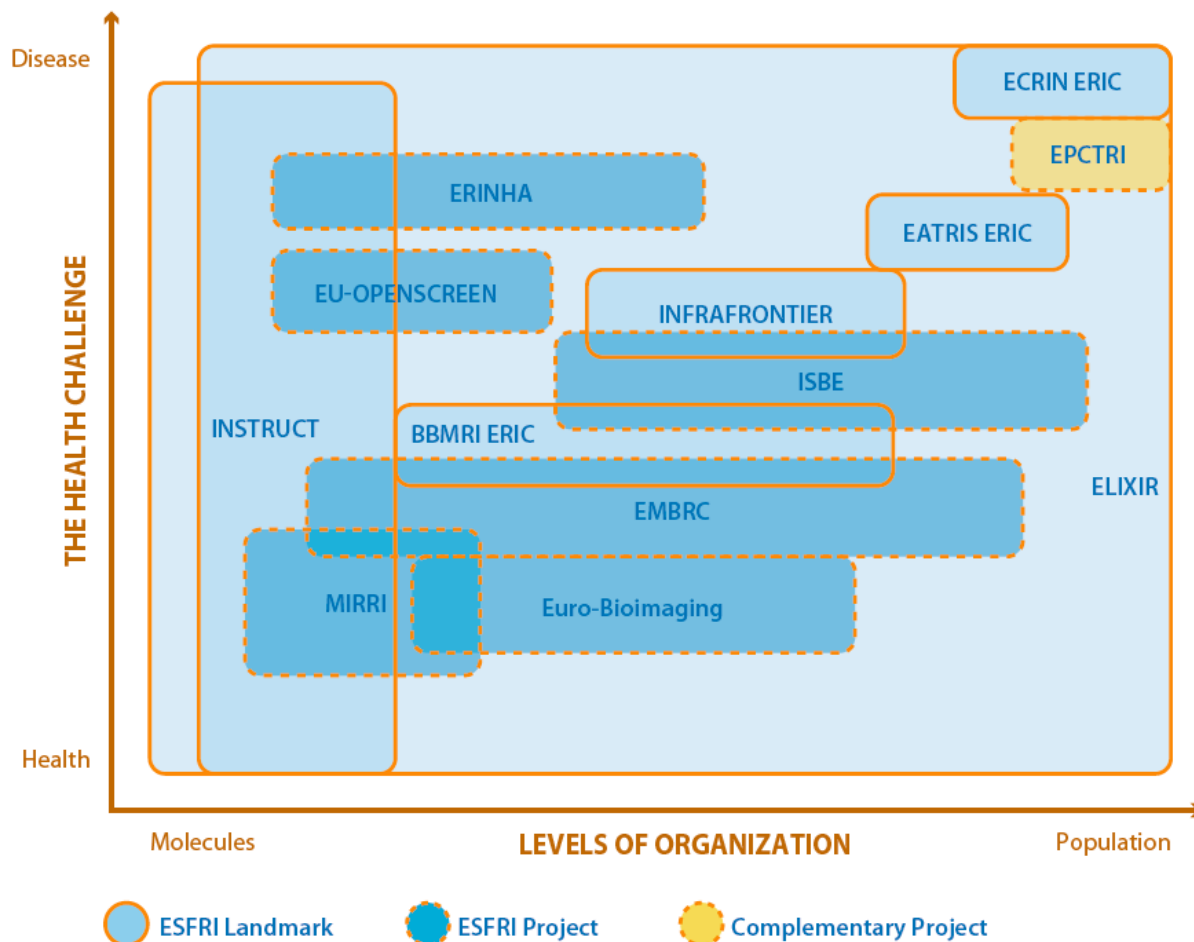
Existing infrastructures such as the ESFRI Landmarks ECRIN, BBMRI, EATRIS and others could connect in a "meta---structure" aiming at providing a full pipeline for drug development.

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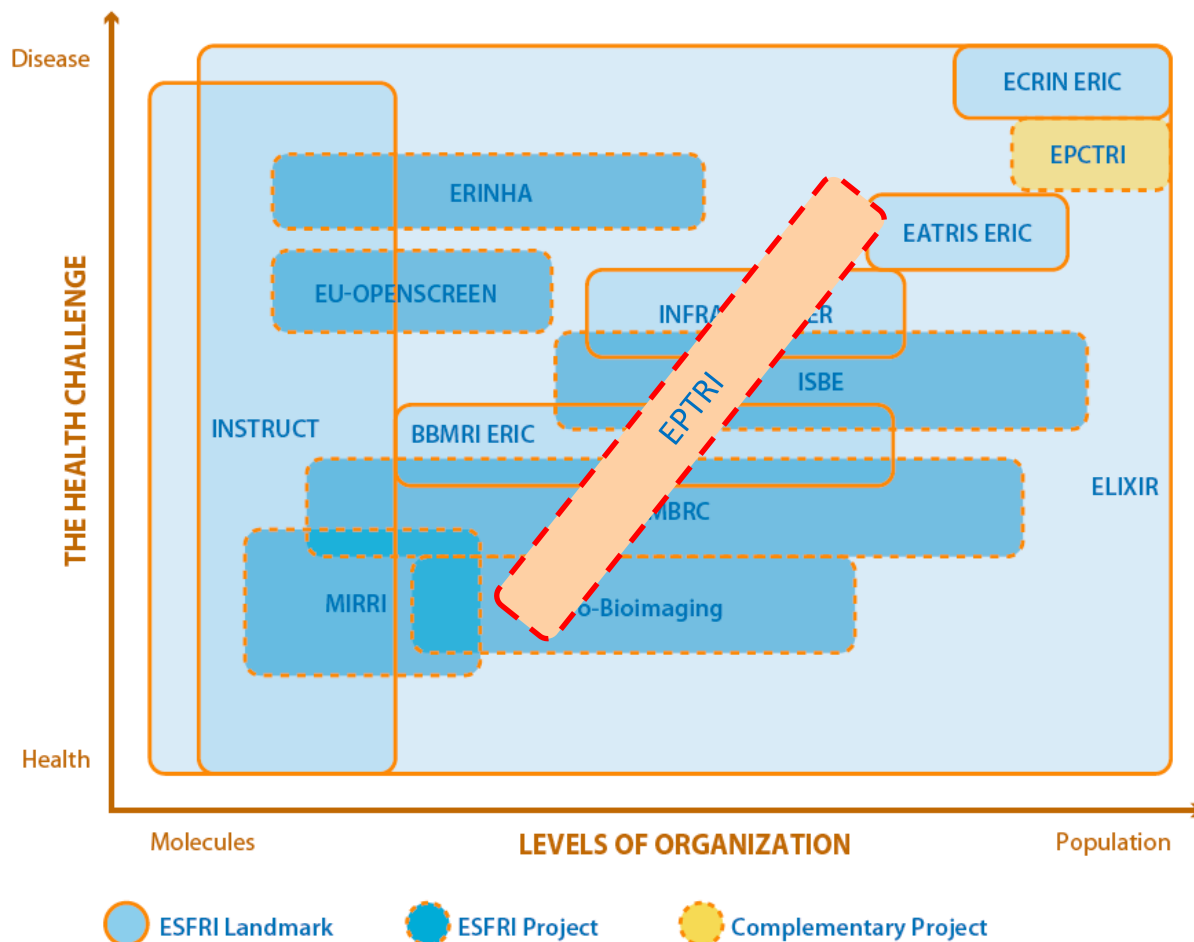
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Other actions:

https://eupid.eu/#/home

European law

- The General Data Protection Regulation comes into force in 2018

    - Immediately applicable across all EU countries

    - Some aspects need enabling legislation and actions at national level

- This puts individuals and their rights at the centre of data protection

- It aims to facilitate research, subject to:

    - Clear justifications

    - Protection of individuals

    - Institutional / corporate responsibilities

Assessment of Maturity

Good intentions

Complexity / organized fragmentation

Current status:

- Scoping

- Consultations

- Pilots

- Limited generalisability of principles or action

Conclusion

We need contact points:

- ENCEPP

encepp_secretariat@ema.europa.eu

- EnprEMA

enprema@ema.europa.eu

- Global Paediatric Research Networks
  - In Europe, the network under development by IMI2