ELSI and data protection for rare diseases data

Annalisa Landi

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Annalisa Landi

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PharmD, II level post-graduate Master in Regulatory Sciences "G.Benzi" at University of Pavia, internship trainee at Leiden University Medical Center in the FAIR team.

Involved in scientific, ethical and regulatory activities particularly related to clinical studies, data protection and confidentiality, plan and management of patient registries and medicine databases management, health data and accessibilities issues, gender equality and inclusiveness. Collaboration in several national and international projects dealing with ethics in biomedical research.

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AGENDA

- *ELSI definition & relevance*
- *Health data value*
- *Benefit and challenges of data use for research*
- *Rare Diseases data use for research*
- *ELSI related to the management of RD data*
- *Focus on rare inherited haemoglobinopathies*
- *Focus on protection of RD data & AI*
- *Benzi Foundation experience*
- *Take home messages*

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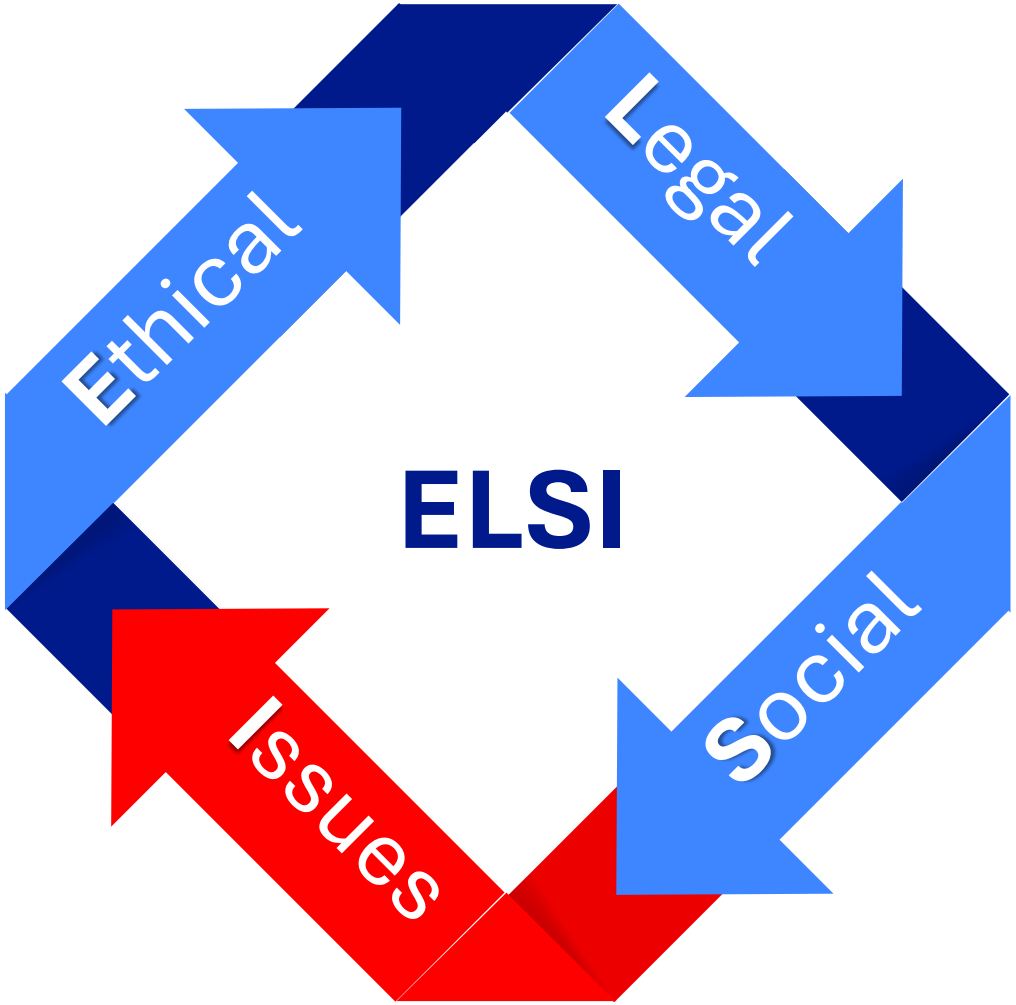
ELSI definition



- *It includes **all non-technical issues** that arise when developing emerging science and technologies and implementing them in society*

- *Originally focused on **genomics**, now applied across several fields such as **healthcare** and **Artificial Intelligence (AI)***

What is ELSI ? | Research Center on Ethical, Legal and Social Issues, Osaka University
(PDF) Ethical, Legal, and Social Issues

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ELSI relevance

- *To protect patient rights: informed consent, privacy, fairness*
- *To address equity and access to healthcare*
- *To guide healthcare policy and legal frameworks*
- *To ensure responsible innovation in AI and genetic medicine*

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Health data value

Health data constitutes a **significant resource** *and makes economic and ethical sense to use this data as much as possible to improve population health and the effectiveness and the efficiency of health care systems*[1]

Health data are a ***real value for scientific research*** *and nowadays there is an urgent need to reconcile the benefits of data sharing with privacy rights and constraints and ethical and legal requirements*[2]

1. Secondary Analysis of Health Data to Generate Health Care Quality Information. Potential, Barriers and Best Practices in Data Linkage. Organisation for Economic Co-operation and Development, OECD DELSA/HEA/HCQ(2011)11
2. Landi, A, Thompson, M, Giannuzzi, V, Bonifazi, F, Labastida, I, da Silva Santos, LOB, Roos, M. 2020. The "A" of FAIR—as open as possible, as closed as necessary. Data Intell. 2(1–2):47–55.

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Healthcare Data Vector Art, Icons, and Graphics for Free Download

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Health data types

Clinical Practice

- *Electronic Health Records (EHRs)*
- *Screening initiatives*
- *Prescriptions*
- *Data related to biological samples*
- *Patient-reported outcomes (PROs)*
- *Real world data (RWD)*

Clinical studies

- *Data related to biological samples*
- *Patient-reported outcomes (PROs)*
- *Interventional data*
- *Adverse events reporting*
- *Real world data (RWD)*

Patient registries

- *Patient-reported outcome (PROs)*
- *Real world data (RWD)*
- *Demographic and Clinical Data*

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Health information technology for patient medical history tiny person concept – VectorMine

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Benefits of data use for research

Increases the knowledge of the disease/condition & the impact of the research

Reproduce research, encourages the validation of hypothesis & reinforces open scientific enquiries

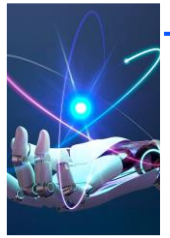
Allows new discoveries and findings

Promotes personalised treatments

Avoids unnecessary repetition of studies, accelerates medicines development & reduces costs

Improves the quality of life of patients

Allows the analysis on a large amount of data



Promotes the development and validation of artificial intelligence models to predict new interventions efficacy

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https://it.freepik.com/

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Benefits of data use for research

The coolest thing to do with your data will be thought of by someone else

Rufus Pollock, Cambridge University and Open Knowledge Foundation, 2008

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Adapted from Data sharing: How, what and why? | PPT

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Benefits of data use for research: secondary use of data

Secondary use of data

refers to the ***use of data for a different purpose*** *than the one for which it was originally collected*

EMA https://www.ema.europa.eu/en/about-us/how-we-work/big-data#hma/ema-big-data-steering-group-section; Bahr A et Al. Code of practice on secondary use of medical data in European scientific research projects. International Data Privacy Law, Volume 5, Issue 4, 1 November 2015, Pages 279–291; EMA presentation

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Health information technology for patient medical history tiny person concept – VectorMine

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Benefits of data use for research: secondary use of data

*The **secondary use of data***

may involve

***Data Access** or **Data Sharing**!*

***TO NOTE:** The term **"secondary use"** is different from the term **"further processing"** included in the GDPR since "further processing" refers not only to the secondary use of data but also to a different data processing activity (e.g., data sharing) made on the data collected for the same primary purpose*

Support Centre for Data Sharing (SCDS)

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+185.100 Medical Research Illustrazioni stock, grafiche vettoriali royalty-free e clip art - iStock | Health, Research laboratory, Medical lab

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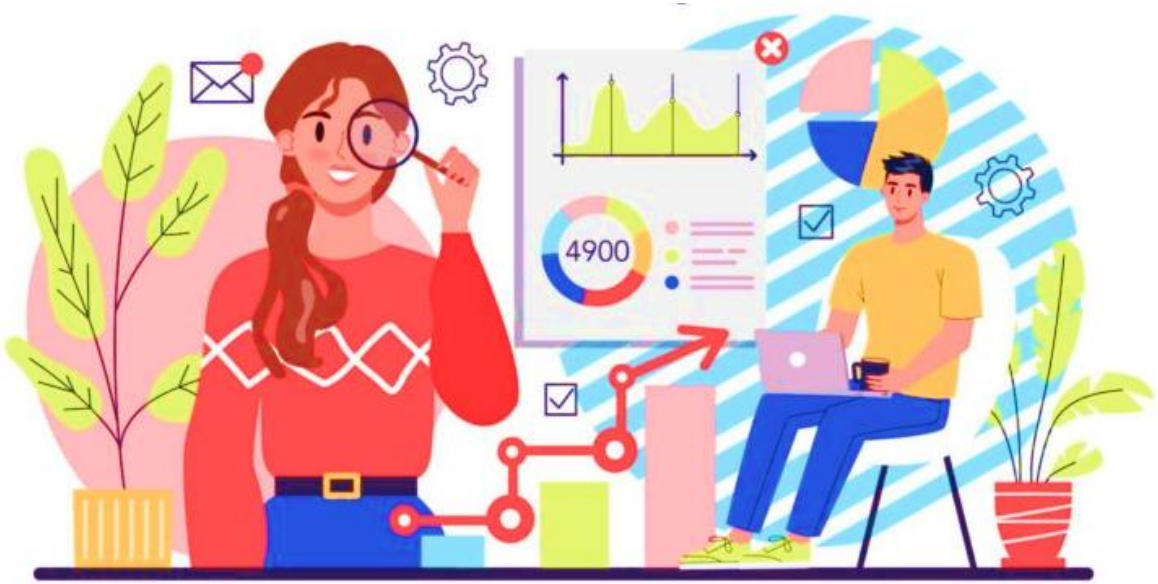
Challenges of data use for research

- ✓ *Ethical, legal, and social issues*
- ✓ *Data protection specific considerations*
- ✓ *Technical issues*
- ✓ *Data quality issues*
- ✓ *Lack of recognition or financial return/ social rewards for data owners*



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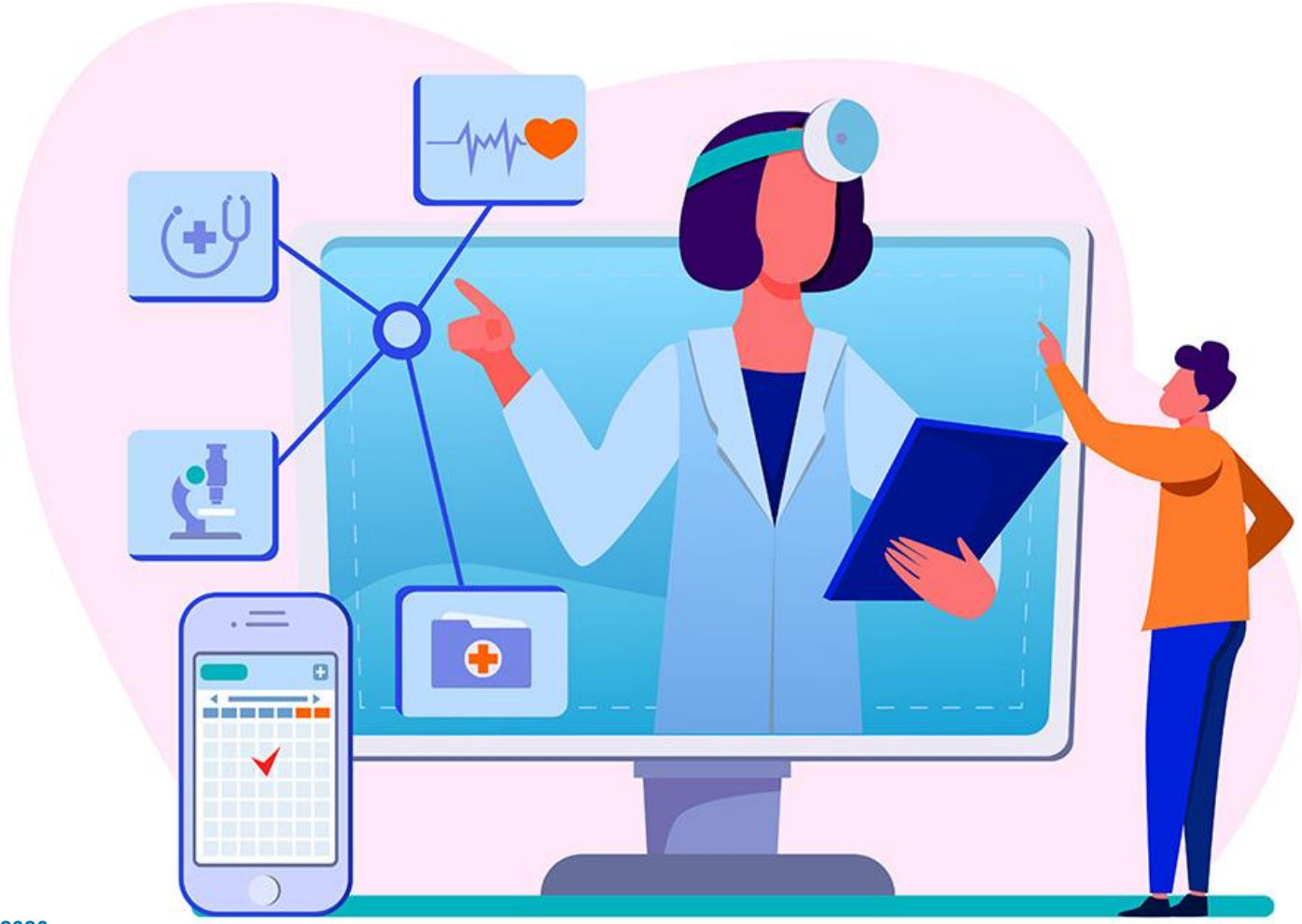
Health data represent a significant resource for research, especially for Rare Diseases!

The need to balance the benefits of data sharing/access and the related risks is urgent...



Landi, A, Thompson, M, Giannuzzi, V, Bonifazi, F, Labastida, I, da Silva Santos, LOB, Roos, M. 2020. The "A" of FAIR—as open as possible, as closed as necessary. Data Intell. 2(1–2):47–55.

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O que é Telemedicina e como funciona? - Clínica de Dermatologia em São Bernardo do Campo

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Rare Diseases data use for research

*"**Rare disease patients**, regardless of the severity of their disease and their socio-demographic profile, are clearly supportive of data sharing to foster research and improve healthcare. However, rare disease patients' willingness to share their data does come with specific requirements in order to respect their privacy, choices and needs for information regarding the use of their data"*

Research | Open access | Published: 12 July 2019

Share and protect our health data: an evidence based approach to rare disease patients' perspectives on data sharing and data protection - quantitative survey and recommendations

Sandra Courbier, Rebecca Dimond & Virginie Bros-Facer

Orphanet Journal of Rare Diseases **14**, Article number: 175 (2019) | Cite this article

15k Accesses | **79** Citations | **76** Altmetric | Metrics

LINK

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Rare Diseases data use for research

Few patients, few data, heterogeneous and complex, scattered and fragmented

Major benefits

- *Collection of a larger amount of geographically dispersed data*
- *Exchanges and interactions between expert centres in rare diseases worldwide*
- *A valid alternative to clinical trials that are not always feasible due to the low number of patients*

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https://www.istockphoto.com/it/vettoriale/set-di-personaggi-delle-lampadine-dei-cartoni-animati-idea-lampadina-con-gm1269479883-372800727

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Rare Diseases data use for research

Few patients, few data, heterogeneous and complex, scattered and fragmented

Major challenges

- *Increased risk of identification*
- *Vulnerable populations involved*
- *Processing of genetic data, with the potential risk of incidental findings*

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https://www.istockphoto.com/it/vettoriale/set-di-personaggi-delle-lampadine-dei-cartoni-animati-idea-lampadina-con-gm1269479883-372800727

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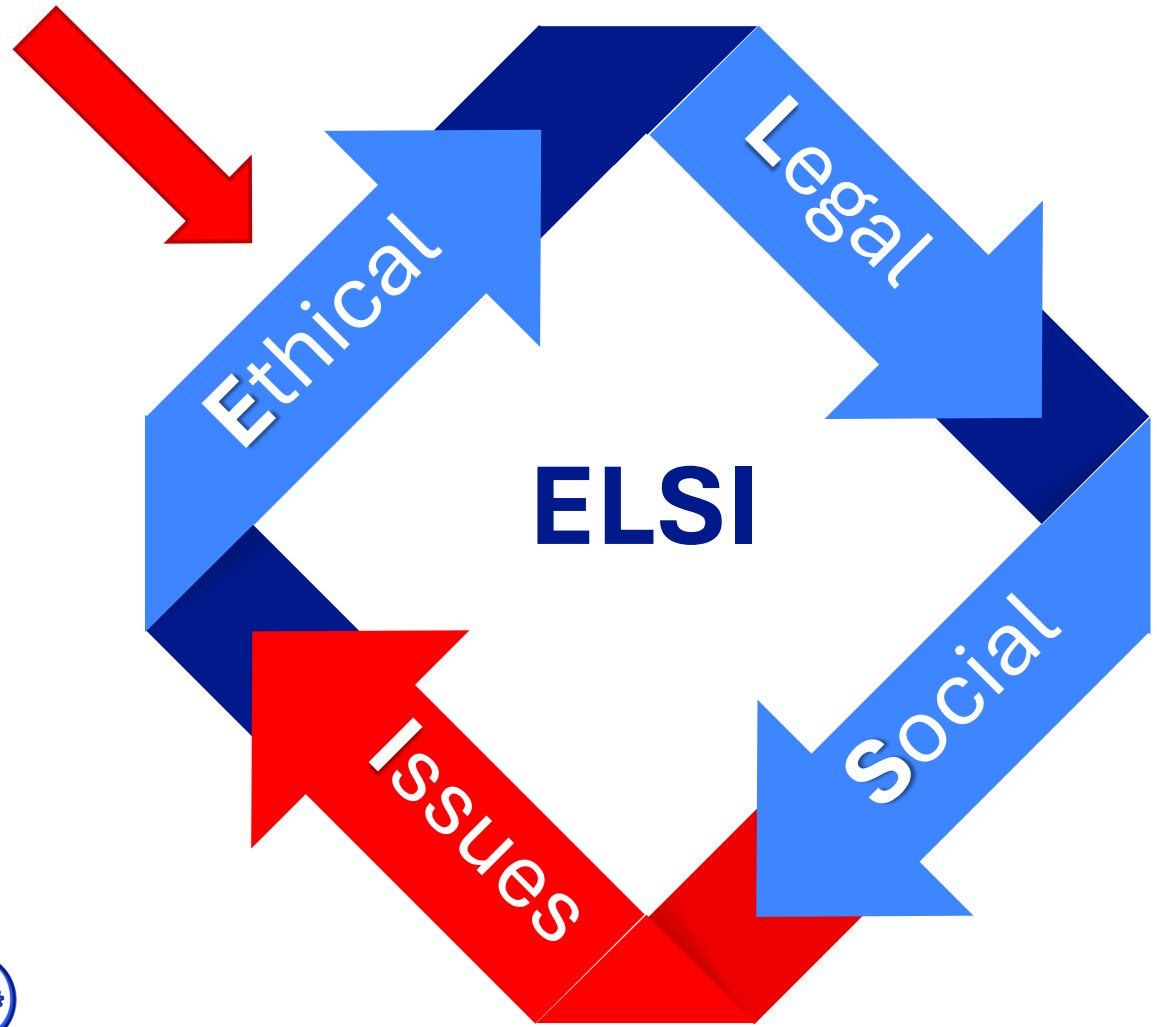
ELSI related to the management of RD data



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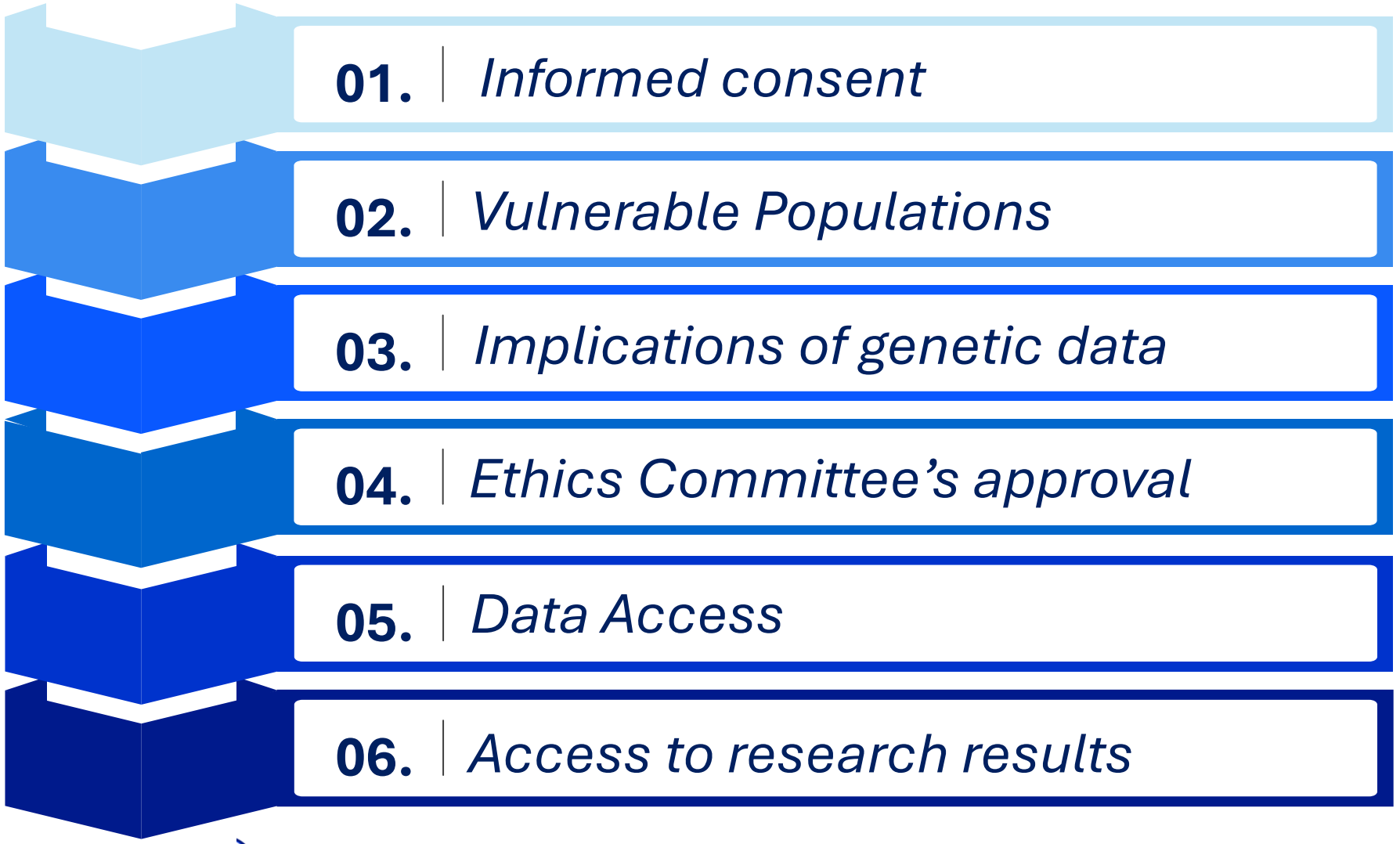
Ethical Issues



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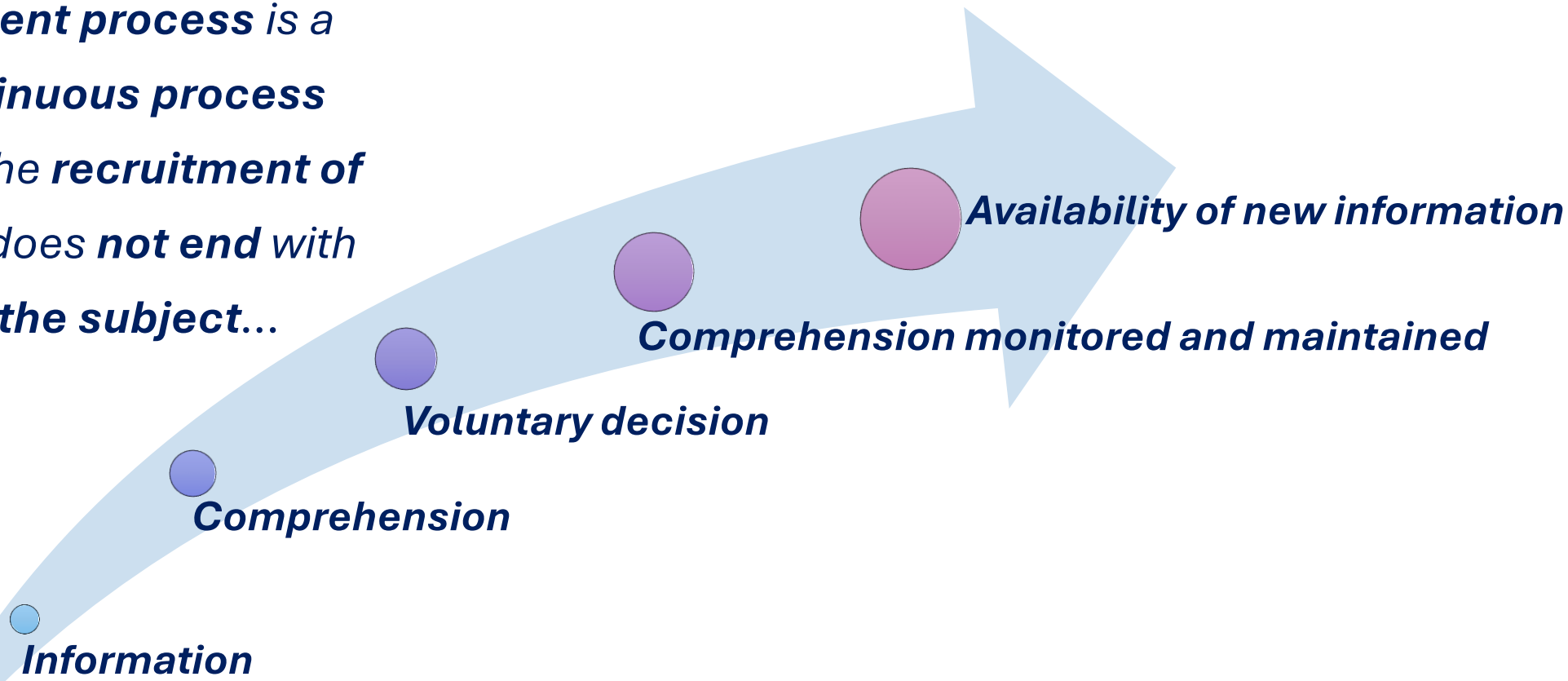
E01. Informed consent

*The **informed consent process** is a **dynamic** and **continuous process** which begins when the **recruitment of subjects** starts **but** does **not end** with the **signature of the subject**...*



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E01. Informed consent

FEATURES

- *Freely given*
- *Informed*
- *Clear and comprehensive*
- *Transparent*
- *Explicit*
- *Easy to withdrawn*

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E02. Vulnerable populations

Rare diseases research often involves small or particularly ***vulnerable populations*** *(e.g., minors; individuals with intellectual disabilities), who are not able to give their consent*

The ***risks*** *to participants must be carefully considered compared to the* ***potential benefits*** *of the research*

https://www.istockphoto.com/it/search/2/image?mediatype=illustration&phrase=vulnerable+people

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E02. Vulnerable populations

PAEDIATRIC POPULATION

- ***Parents/Legal designated representatives*** *must provide authorisation to the research*
- ***Informed assent*** *should be obtained from minor participants*
- ***Age-appropriate information*** *should be adapted to the language skills and understanding of the minor*
- *The use of* ***visual strategies*** *is encouraged (drawings, pictures, cartoons), but also other media and formats may be used*
- ***Cultural differences*** *should be considered*

https://www.shutterstock.com/it/search/cartoon-children-doctor?page=2

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E03. Implications of genetic data

72% of Rare Diseases are genetic and discoveries about one patient can have implications for his/her family

Consent for genetic testing *separated from the consent for the main research*

Information of expected or possible unexpected results *should be provided*

An ***incidental findings policy*** *should be agreed*

Possible implications for ***family members***

Genetic counselling *should be foreseen*

Findings should be fed back ***when they are of immediate clinical relevance from a preventive, diagnostic and therapeutic level, and for reproductive choices***

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E04. Ethics Committee's approval

*The need for the **Ethics Committee's approval** according to the national and local applicable provisions **must be checked before starting the research**!*

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E05. Data Access

Access to data might be regulated by accessibility conditions and restrictions..

*"A Data Access Committee represents an institutional safeguard charged with applying rules meant to ensure an **ethically** permissible balance between data protection and accessibility"*

*The **purpose** is to assess if the **proposed use of the data** is...*

- ✓ *within the bounds of the **data's permitted uses***
- ✓ *in line with the **data user's qualifications***
- ✓ *in compliance with the **applicable laws, regulations and practices**!*

https://it.freepik.com/

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E06. Access to research results

INCREASE TRANSPARENCY

Clear and comprehensive

***research results** should*

be provided to study

participants!

BUILD TRUST

https://www.imprendinews.it/2014/08/19/obiettivi-positivi/

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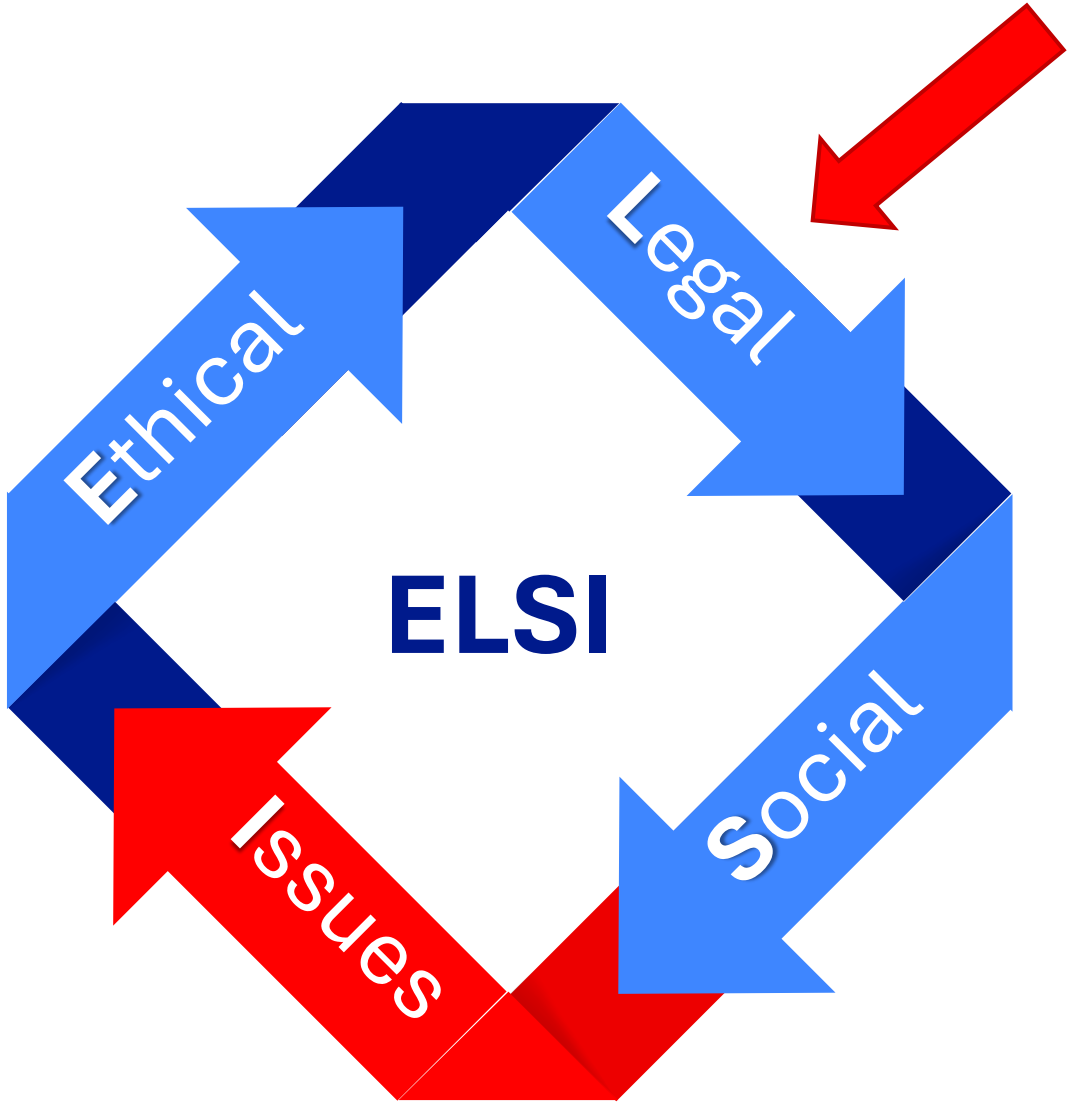
ELSI related to the management of RD data



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Legal Issues

01. | *Data protection*

02. | *Legal bases for data processing*

03. | *Respect of the participants' rights*

04. | *Intellectual property & data ownership*

05. | *Regulatory compliance*

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L01. Data protection

Compliance with the applicable ***Data Protection Regulations*** ***(e.g., European General Data Protection Regulation, GDPR)*** *must be ensured!*

Within **international projects** and **collaborations**, data processing activities must comply with the legal frameworks regarding cross-border data flows/access

https://it.freepik.com/

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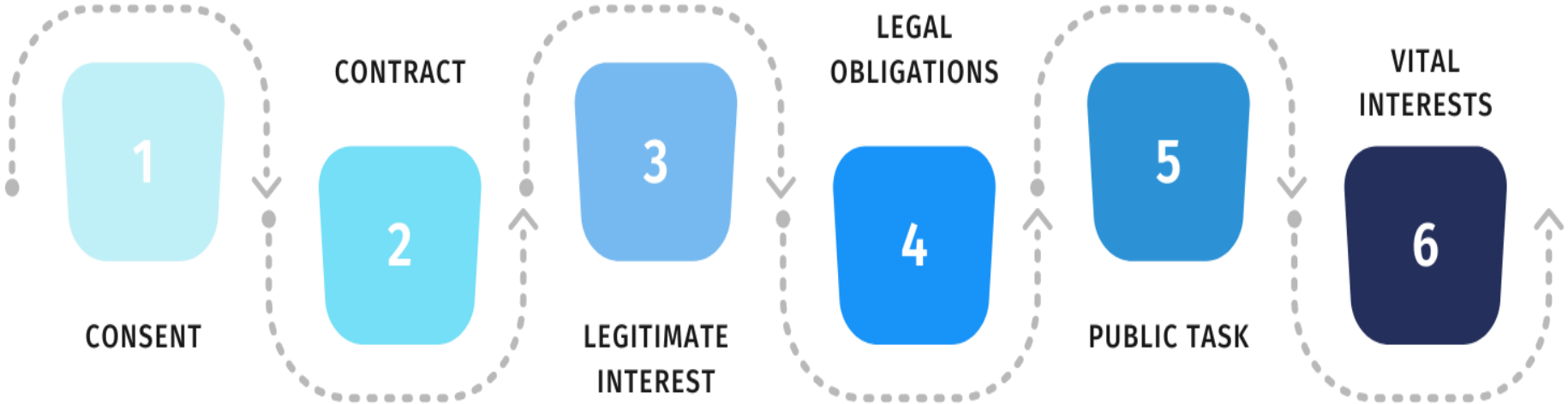
L02. Legal bases for data processing

Informed consent *is only one of the* ***legal bases for data processing*** *according to the* ***EU GDPR....***



https://dataprivacymanager.net/processing-personal-data-of-employees/

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L03. Respect of the participants' rights

The right to be informed	*The right of access*	*The right to rectification*	*The right to object to processing*
The right to restrict processing	*The right to data portability*	*The right to be forgotten*	*Rights in relation to automated decision making and profiling*

https://kidshelpline.com.au/teens/issues/all-about-respect

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L04. Intellectual property & data ownership

*Clarification on the **ownership** of the data, research findings and any products that may be generated by the research must be provided!*

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L05. Regulatory compliance

Researchers may need to obtain approval from relevant ***Regulatory Authorities*** *(e.g., the European Medicines Agency (EMA))*

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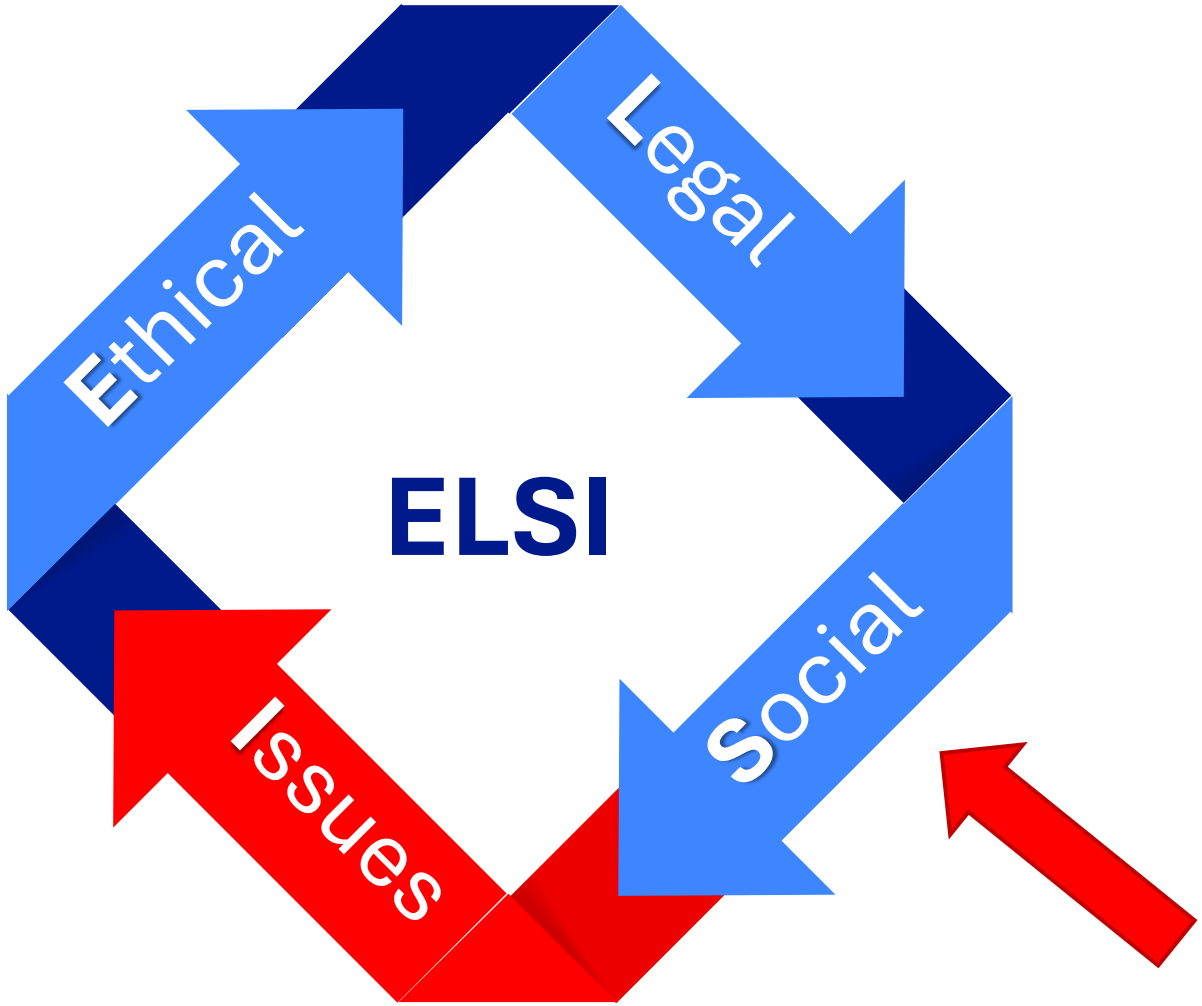
ELSI related to the management of RD data



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Social Issues

01. | *Access to treatment and care*

02. | *Discrimination and stigmatisation*

03. | *Autonomy and informed consent*

04. | *Equity and justice*

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Social Issues

01. Access to treatment and care	02. Discrimination and stigmatisation	03. Autonomy and informed consent	04. Equity and justice
• *Availability of new treatments and findings for all patients*	• *Emotional, social, and psychological implications of the findings related to the patients and their families should be considered*	• *Participants must voluntarily agree to participate in the research*	• *Inclusive participation in the research*

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Focus on rare inherited haemoglobinopathies

Racism and implicit bias *within and outside the health care system*

Stigmatization *due to cultural beliefs and lack of understanding of the disease*

Complex interplay *between socioeconomic, psychological, and biological factors (e.g. pain experiences in SCD)*

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Focus on rare inherited haemoglobinopathies

Example - Use of Hydroxyurea in children

Health Provider

- *Lack of expertise in hydroxyurea use*
- *Concerns about safety profile during pregnancy and lactation*
- *Fear of male infertility*
- *Fear of blame in case of adverse outcomes*
- *Patient compliance*
- *Drug availability and cost*
- *Absence of appropriate paediatric formulation*
- *Lack of time and resources to explain the risks and benefits*

Health Facility

- *Availability and cost of laboratory monitoring*
- *Lack of formal guideline for use in children*
- *Ineffective follow-up*
- *Lack of adequate clinician and experience with hydroxyurea*

Patient/Family

- *Lack of awareness of SCD and hydroxyurea*
- *Patient compliance*
- *Doubts about the effectiveness of hydroxyurea*
- *Need of frequent follow-up*
- *Drug costs and availability*
- *Fear of carcinogenic and teratogenic potential*
- *Fear of increased risk of infections*

Adaped from
Barriers to utilization of hydroxyurea for children with SCD. | Download Scientific Diagram

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Focus on protection of RD data & AI

*Personal and special categories of data (e.g., health and genetic data) must be **kept confidential***

***Access to data** shall be provided only to authorised people*

***Data breaches and loss** must be prevented by implementing ad-hoc safeguards measures (e.g., secure storage)*

*The **data minimisation principle** should be followed thus collecting only the data that is necessary for the purposes of the research*

***De-identification measures** (e.g. pseudonymisation) shall be put in place to reduce the risk of re-identification of participants*

*Information related to the **retention period** and to what will be done with the data after the end of this period must be provided*

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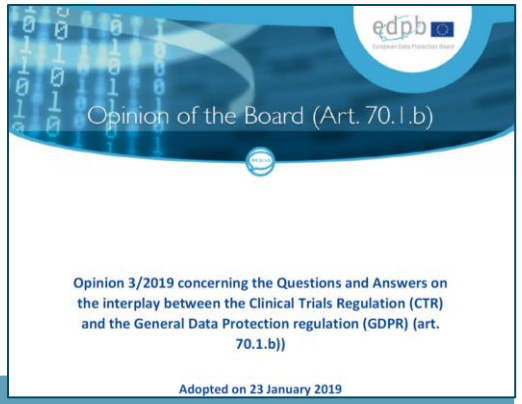
Focus on protection of RD data & AI

*Besides the consent to the research, participants **must** provide the researcher with the consent to the processing of their personal data...*



The lack of consent to data processing may compromise the participation in the study!

Information to be provided to the data subject when processing personal data (GDPR, Articles 13-14)

- ✓ ***TYPE OF DATA PROCESSED***
- ✓ ***THE PURPOSES/FUTURE PURPOSES OF THE PROCESSING***
- ✓ ***THE DURATION OF DATA STORAGE OR THE CRITERIA TO DETERMINE IT***
- ✓ ***ANY TRANSFER OF PERSONAL DATA TO A THIRD COUNTRY AND THE APPROPRIATE SAFEGUARD MEASURES***
- ✓ ***ANY AUTOMATED DECISION-MAKING***
- ✓ ***THE RESPONSIBLE FIGURES FOR DATA PROCESSING***
- ✓ ***THE MAIN RIGHTS OF THE SUBJECT***

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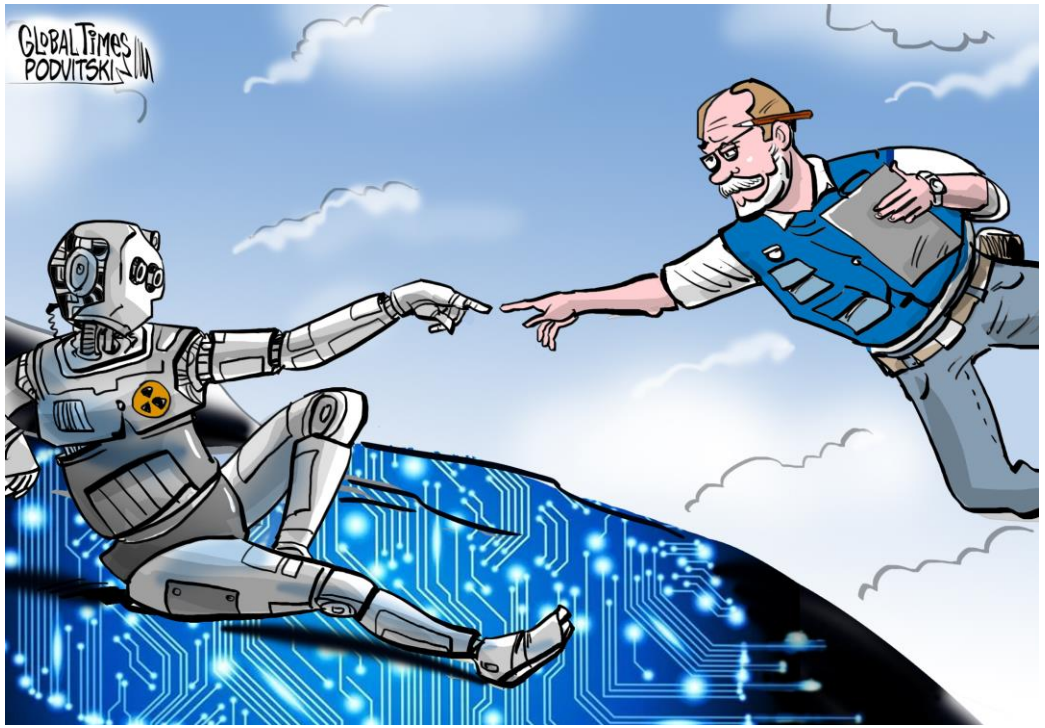
Focus on protection of RD data & AI

*If **AI systems** are used in the context of research with RD data, additional ELSI should be considered…*

- ***Ethics Guidelines for Trustworthy AI*** *(EU standards) should be followed*
- ***Trustworthiness*** *and* ***compliance*** *must be ensured*
- ***Potential AI risks*** *must be identified and mitigated*



https://www.globaltimes.cn/page/202304/1289965.shtml

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Focus on protection of RD data & AI

Requirements for Trustworthy AI

- ✓ *Human oversight*
- ✓ *Technical robustness and safety*
- ✓ *Privacy and data governance*
- ✓ *Transparency*
- ✓ *Accountability*
- ✓ *Societal and environmental well-being*
- ✓ *Diversity, non discrimination and fairness*

Ensuring AI aligns with ethical principles:

- ✓ ***Human autonomy*** → *AI should not undermine decision-making.*
- ✓ ***Harm prevention*** → *Strong data governance.*
- ✓ ***Fairness & transparency*** → *Avoid bias, ensure explainability*

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Based on ALTAI Framework

https://www.vectorstock.com/royalty-free-vector/ai-technology-robot-cartoon-vector-48526588

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Focus on protection of RD data & AI

Responsibility and implementation

Key AI governance actions:

- ✓ ***Training & awareness*** → *Educate stakeholders on Trustworthy AI*
- ✓ ***Clear accountability*** → *Processes to review AI decisions and seek redress*
- ✓ ***AI traceability*** → *Ensure proper testing, validation and monitoring*

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https://specialistudio.corriere.it/grupposandonato/al-cuore-della-tecnologia-quando-linnovazione-entra-in-sala-operatoria/

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European initiatives for the use of health data

European Commission

- ***European Health Data Space (EHDS) Regulation***

European Medicines Agency

- ***Data Analysis and Real-World Interrogation Network (DARWIN EU®)***

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Benzi Foundation experience

FONDAZIONE PER LA RICERCA FARMACOLOGICA GIANNI BENZI ONLUS

*The Benzi Foundation is a **not-for-profit scientific research organisation** with a focus on **rare disease patients and children**.*

It was founded in 2007, inspired by the work of Professor Gianni Benzi, a respected scientist and one of the first regulatory expert who joined the European agency for medicines.

The Foundation works to make sure that innovative and safe medicines become part of the European pharmaceutical system.

*The **key areas of work** include:*

- ETHICS AND REGULATORY SCIENCE
- RESEARCH METHODOLOGY
- DATA SCIENCE AND INFORMATION TECHNOLOGY

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Benzi Foundation experience

Research and Innovation

We play a key role to develop a European ecosystem of research, global data sharing and collaborations finally promoting prevention, diagnosis, and treatment for rare diseases.

EUROPEAN JOINT PROGRAMME RARE DISEASES

ERDERA
European Rare Diseases Research Alliance

Through innovative methodology tool based on clinical data and in-silico models, we contribute to improve a regulatory-sounded development of paediatric and orphan medicines.

ERAMET

invents

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FONDAZIONE PER LA RICERCA FARMACOLOGICA GIANNI BENZI ONLUS

We contribute to improve the development of innovative medical devices for children affected by rare diseases.

OrphaDev4Kids

We are involved in a national project which aims to integrate biosamples and data from biobanks, registries, and health records through modelling and networking.

better

Advancing in the field of rare haemoglobinopathies

ARISE

INHERENT
International Hemoglobinopathy Research Network

HemaFAIR

HELIOS

Focusing on haemoglobinopathies, we work together in international networks, projects and initiatives to drive research forward.

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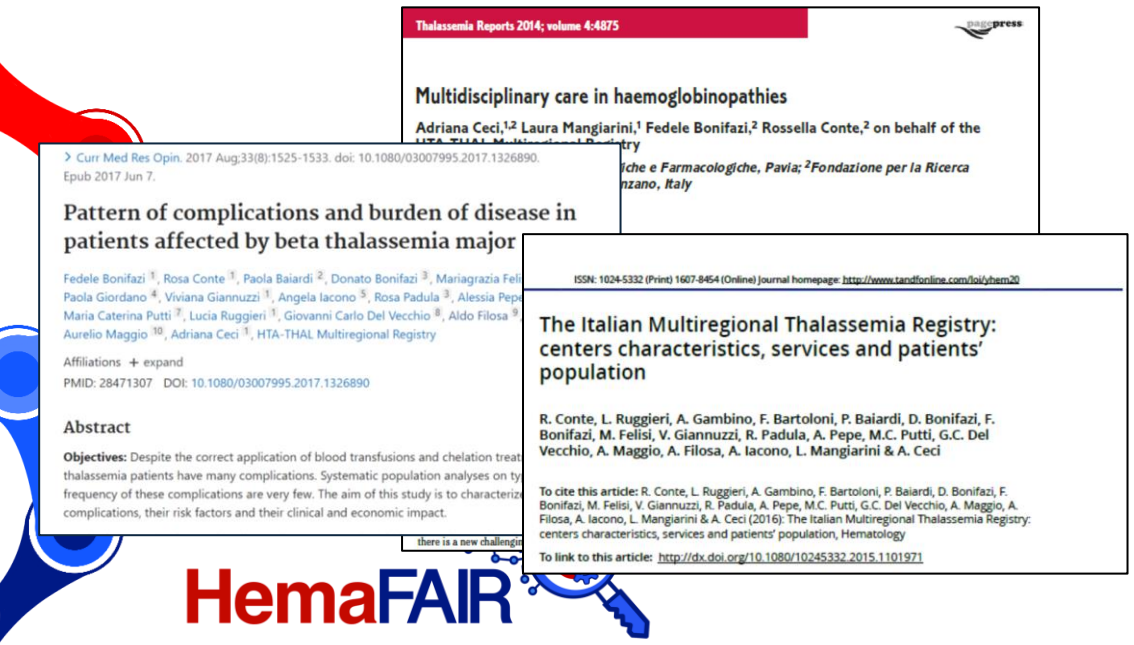
Benzi Foundation - HTA-Thal experience

Italian Multiregional Thalassaemia *registry including epidemiological, clinical, diagnostic and therapeutic data on about* ***2.000 thalassaemia patients*** *and technology assessment data on methods to evaluate iron overload useful for planning of services in a cost-efficacious way*



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Funded by the Italian Health Ministry and by Fondazione 'Leonardo Giambrone'

Voluntary managed by FGB after the end of the public funds period

Collaboration with other data collection initiatives aimed to create a common source of electronic data system

Including a map of the existing Italian thalassaemia centres with details on services and tools available at each participating centre

Useful instrument to conduct analyses and follow-up on the disease outcomes and emerging issues

FONDAZIONE PER LA RICERCA FARMACOLOGICA GIANNI BENZI ONLUS

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Benzi Foundation - c4c experience

conect 4children
COLLABORATIVE NETWORK FOR EUROPEAN CLINICAL TRIALS FOR CHILDREN

Desk research on existing CTs data-sharing repositories/platforms containing paediatric data

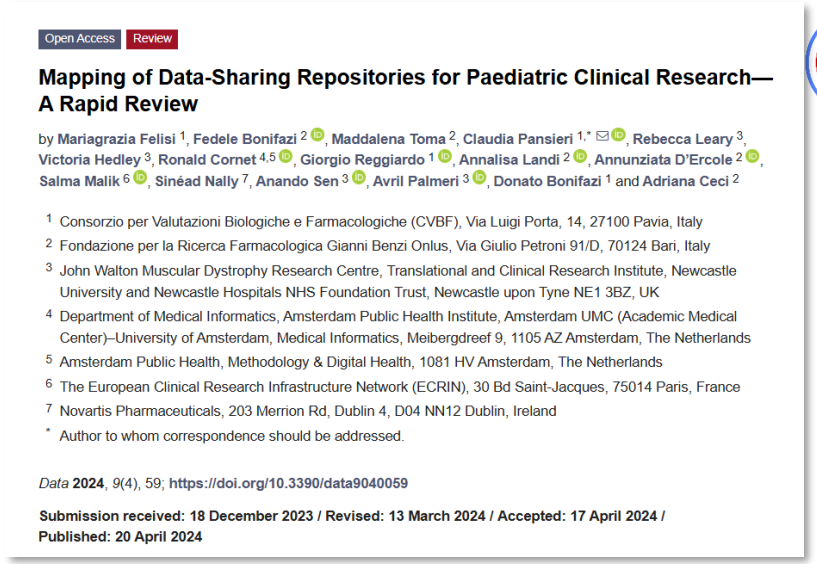
Collection of the repositories/platforms' main features

Analysis of the collected information

Assessment of the suitability for sharing paediatric data through a set of indicators

Surveys & Interviews with the representatives of the repositories/platforms

- *To identify existing initiatives that have developed electronic archiving programs or repositories, to store, share and reuse data from (paediatric) clinical trials (CTs) and to describe their features and impact on paediatric research*



Open Access Review

Mapping of Data-Sharing Repositories for Paediatric Clinical Research—A Rapid Review

by Mariagrazia Felisi [1], Fedele Bonifazi [2], Maddalena Toma [2], Claudia Pansieri [1,*], Rebecca Leary [3], Victoria Hedley [3], Ronald Cornet [4,5], Giorgio Reggiardo [1], Annalisa Landi [2], Annunziata D'Ercole [2], Salma Malik [6], Sinéad Nally [7], Anando Sen [3], Avril Palmeri [3], Donato Bonifazi [1] and Adriana Ceci [2]

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Perspective

Sharing Data and Transferring Samples Within Pediatric Clinical Studies: How to Overcome Challenges and Make Them a Science Opportunity

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Abstract: EPIICAL (Early treated Perinatally HIV-Infected individuals: Improving Children's Actual Life) is a consortium of European and non-European research-driven organizations inter-connected with the aim of establishing a clinical and experimental platform for the early identification of novel therapeutic strategies for the pediatric Human Immunodeficiency Virus (HIV). Within the EPIICAL project, several pediatric clinical studies were conducted, requiring the collection and transfer of biological samples and associated data across boundaries within and outside Europe. To ensure compliance with the applicable rules on pediatric data and sample transfer and to support the efforts of academic partners, which may not always have the necessary expertise and resources in place for designing, managing and conducting multi-national studies, the consortium established a dedicated expert Working Group. This group has guided the consortium since the start of the project through the complexities of the ethical and regulatory aspects of international clinical studies. The group provided support in the design and preparation of the prospective and retrospective multi-center and multi-national pediatric studies with a focus on the clinical study protocols, informed consent and assent forms. In particular, well-structured informed consent and assent templates were developed, and data sharing and material transfer agreements were set up to regulate the transfer of samples among partners and sites. We considered that such support and the implementation of ad hoc agreements could provide effective practical solutions for addressing ethical and regulatory hurdles related to sharing data and transferring samples in international pediatric clinical research.

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Keywords: pediatric clinical studies; transfer of samples; data sharing; regulatory; ethics

✓ *Insightful recommendations on how challenging* ***data and samples sharing in paediatric clinical research*** *can be transformed into science-driven opportunities → fostering collaboration and innovation within the field*

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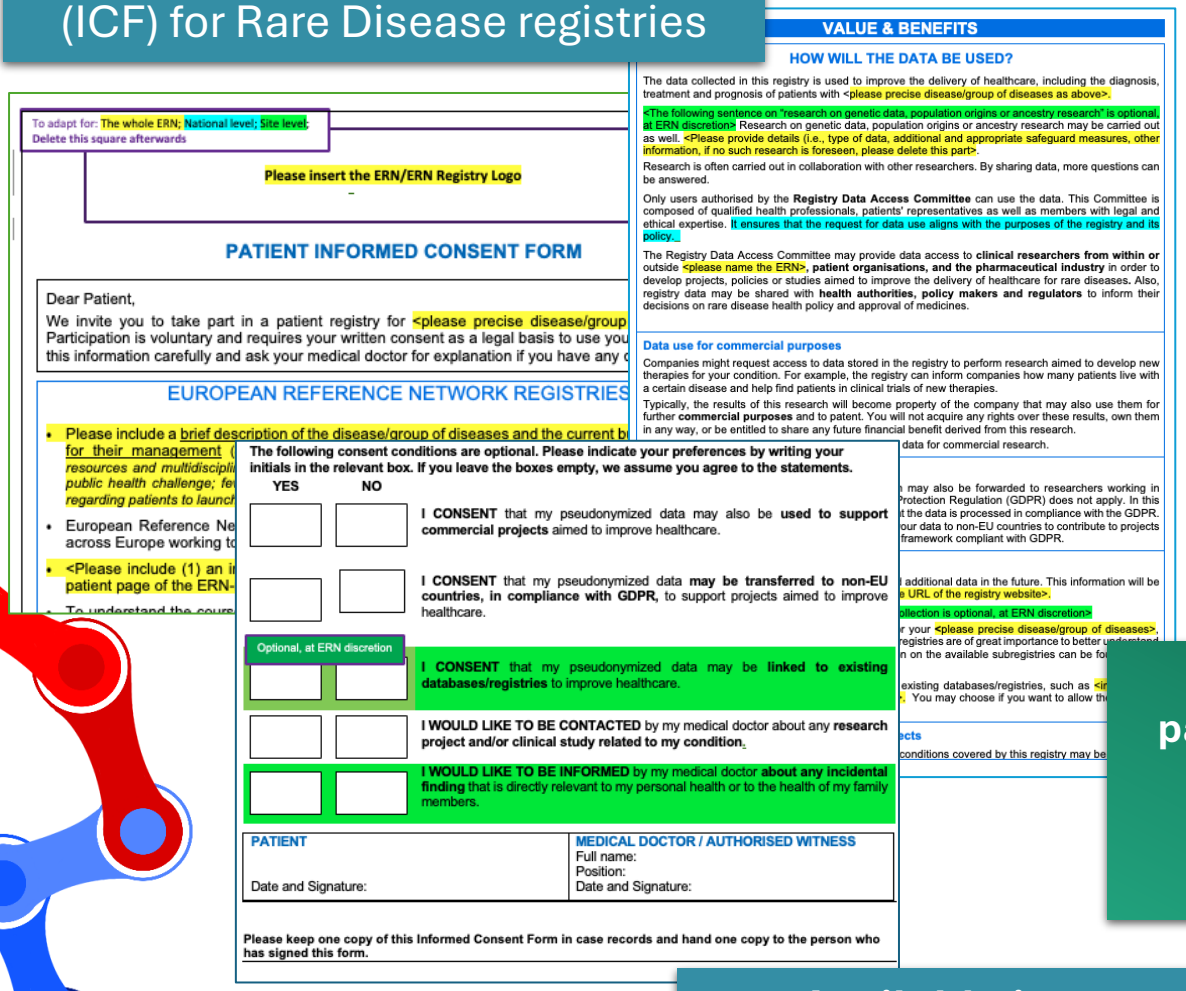
common Informed Consent Form (ICF) for Rare Disease registries


To adapt for: The whole ERN; National level; Site level;
Delete this square afterwards

Please insert the ERN/ERN Registry Logo

PATIENT INFORMED CONSENT FORM

Dear Patient,

We invite you to take part in a patient registry for <please precise disease/group

Participation is voluntary and requires your written consent as a legal basis to use you

this information carefully and ask your medical doctor for explanation if you have any

EUROPEAN REFERENCE NETWORK REGISTRIES

- Please include a brief description of the disease/group of diseases and the current b
for their management (
resources and multidisciplin
public health challenge; fe
regarding patients to launch
- European Reference Ne
across Europe working to
- <Please include (1) an i
patient page of the ERN-

VALUE & BENEFITS

HOW WILL THE DATA BE USED?

The data collected in this registry is used to improve the delivery of healthcare, including the diagnosis, treatment and prognosis of patients with <please precise disease/group of diseases as above>.

<The following sentence on "research on genetic data, population origins or ancestry research" is optional, at ERN discretion> Research on genetic data, population origins or ancestry research may be carried out as well. <Please provide details (i.e., type of data, additional and appropriate safeguard measures, other information, if no such research is foreseen, please delete this part>.

Research is often carried out in collaboration with other researchers. By sharing data, more questions can be answered.

Only users authorised by the **Registry Data Access Committee** can use the data. This Committee is composed of qualified health professionals, patients' representatives as well as members with legal and ethical expertise. It ensures that the request for data use aligns with the purposes of the registry and its policy.

The Registry Data Access Committee may provide data access to **clinical researchers from within or** outside <please name the ERN>, **patient organisations, and the pharmaceutical industry** in order to develop projects, policies or studies aimed to improve the delivery of healthcare for rare diseases. Also, registry data may be shared with **health authorities, policy makers and regulators** to inform their decisions on rare disease health policy and approval of medicines.

Data use for commercial purposes

Companies might request access to data stored in the registry to perform research aimed to develop new therapies for your condition. For example, the registry can inform companies how many patients live with a certain disease and help find patients in clinical trials of new therapies.

Typically, the results of this research will become property of the company that may also use them for further **commercial purposes** and to patent. You will not acquire any rights over these results, own them in any way, or be entitled to share any future financial benefit derived from this research.

data for commercial research.

may also be forwarded to researchers working in Protection Regulation (GDPR) does not apply. In this t the data is processed in compliance with the GDPR. our data to non-EU countries to contribute to projects framework compliant with GDPR.

additional data in the future. This information will be URL of the registry website>.

llection is optional, at ERN discretion>

r your <please precise disease/group of diseases>, registries are of great importance to better understand n on the available subregistries can be fo

existing databases/registries, such as <ir . You may choose if you want to allow th

acts

conditions covered by this registry may be

The following consent conditions are optional. Please indicate your preferences by writing your initials in the relevant box. If you leave the boxes empty, we assume you agree to the statements.

YES	NO	
		I CONSENT that my pseudonymized data may also be **used to support commercial projects** aimed to improve healthcare.
		I CONSENT that my pseudonymized data **may be transferred to non-EU countries, in compliance with GDPR,** to support projects aimed to improve healthcare.
		Optional, at ERN discretion — **I CONSENT** that my pseudonymized data may be **linked to existing databases/registries** to improve healthcare.
		I WOULD LIKE TO BE CONTACTED by my medical doctor about any **research project and/or clinical study related to my condition.**
		I WOULD LIKE TO BE INFORMED by my medical doctor **about any incidental finding** that is directly relevant to my personal health or to the health of my family members.

PATIENT	MEDICAL DOCTOR / AUTHORISED WITNESS
Date and Signature:	Full name: Position: Date and Signature:

Please keep one copy of this Informed Consent Form in case records and hand one copy to the person who has signed this form.

The Informed Consent Form template aims to foster, according to patients' preferences, the reuse of registries data for research purposes in compliance with the applicable laws and standards

Adaptation at:

- **ERN level**
- **National level**
- **Site level**

One version for **participants** and one for **parents/legally designated representatives**

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The creation of an adaptable informed consent form for research purposes to overcome national and institutional bottlenecks in ethics review: experience from rare disease registries

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LINK

Available in 26 national languages

Paediatric version is being finalised

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Take home messages

- ✓ *Health data are a real value for scientific research*
- ✓ *In the context of research with RD data, benefits and challenges are greatest*
- ✓ *Addressing ELSI is relevant mainly to protect patient rights and to guide healthcare policy and legal frameworks*
- ✓ ……

…TO BE COMPLETED WITH YOU!

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Interactive session

https://ahaslides.com/L3DB3

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