REUSING HEALTH DATA FOR RESEARCH – THE PATIENT PERSPECTIVE

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#Access2030

“A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE”

EPF European Patients Forum

Outline

1. Introducing EPF
2. Meaningful Patient involvement, Patients' expectations of digital health care, Patients perspectives and concerns on reusing health data for research
3. New EU Regulation on the protection of personal data
4. EPF's activities to date
5. Next steps for EPF
6. Concluding points

About EPF

- European Patients’ Forum
    - Independent & non-governmental
    - Umbrella organisation
    - Active since 2003
    - EU patients’ voice

- Our members
    - 74 patients’ groups
    - EU disease specific organisations & National patient coalitions

EPF funding sources

Funding sources

European Commission – 80% of operating budget + co-funding of projects (PHP, FP7, CIP, IMI-JU)

Unrestricted grants from commercial sector – 19% of operating budget + project portfolio co-funding

Membership fees – 1.4% – annual fee structure ranging from 100-1000€ based on organisation's annual turnover

Principles of Transparency and Good Governance

Commitment to diversity of funding – not relying on any one source:

Transparency and independence in all aspects of our work: Code of Ethics and Framework for working with funding partners

Full details of EPF's funding available at our website: http://www.eu-patient.eu/About-EPF/Transparency/

Full details of financials and donors are available in EPF's annual reports: http://www.eu-patient.eu/globalassets/library/annualreports/epf_annual_report_2016.pdf

EPF is a registered NGO on the European Commission's Transparency Registry

Mission and vision

Our Vision!

“All patients with chronic conditions in Europe have **equal** access to **high quality**, **patient-centred** health and related care.”

Our Mission!

“To be the collective, influential patient voice in European health and related policies and a driving force to advance patient empowerment and patient access in Europe.”

Our Strategic Goals

Health Literacy

Healthcare Access and Quality

Patient involvement

Patient Empowerment

Sustainable Patients' Organisations

Non-discrimination

Evolution of EPF activities 2003-2017

Strengthening Patients’ voice in the EU

2003-2007

Influencing **policy developments** at EU-level

From 2008

EPF partnering in **EU projects** to gather evidence-based knowledge

2012 – present

Capacity Building and targeted activities for patient leaders, e.g. EUPATI

Evolution from 1 to 3 “pillars”

Strengthening policy impact

Patient Involvement

Patients expectations of digital health care

Patients’ perspectives and concerns on the reuse of health data

EPF's Role to date – Patient Involvement and Patient Empowerment

There is an **increasing drive** to improve collection, sharing and use of patients' data in order to achieve **better**, more **sustainable** healthcare and **advance health research**. The only way to do this in a meaningful and valuable way is **together with patients**.

EPF's remit:

Patients living with **chronic or long term conditions**

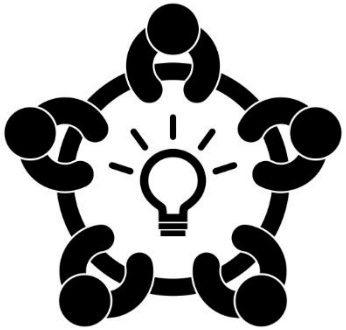
Our focus: towards the application of technology that supports the **management of chronic diseases** for patients and **ethical secondary use of health data to advance health research**

Source: PatientPartner FP7 Project (2010)

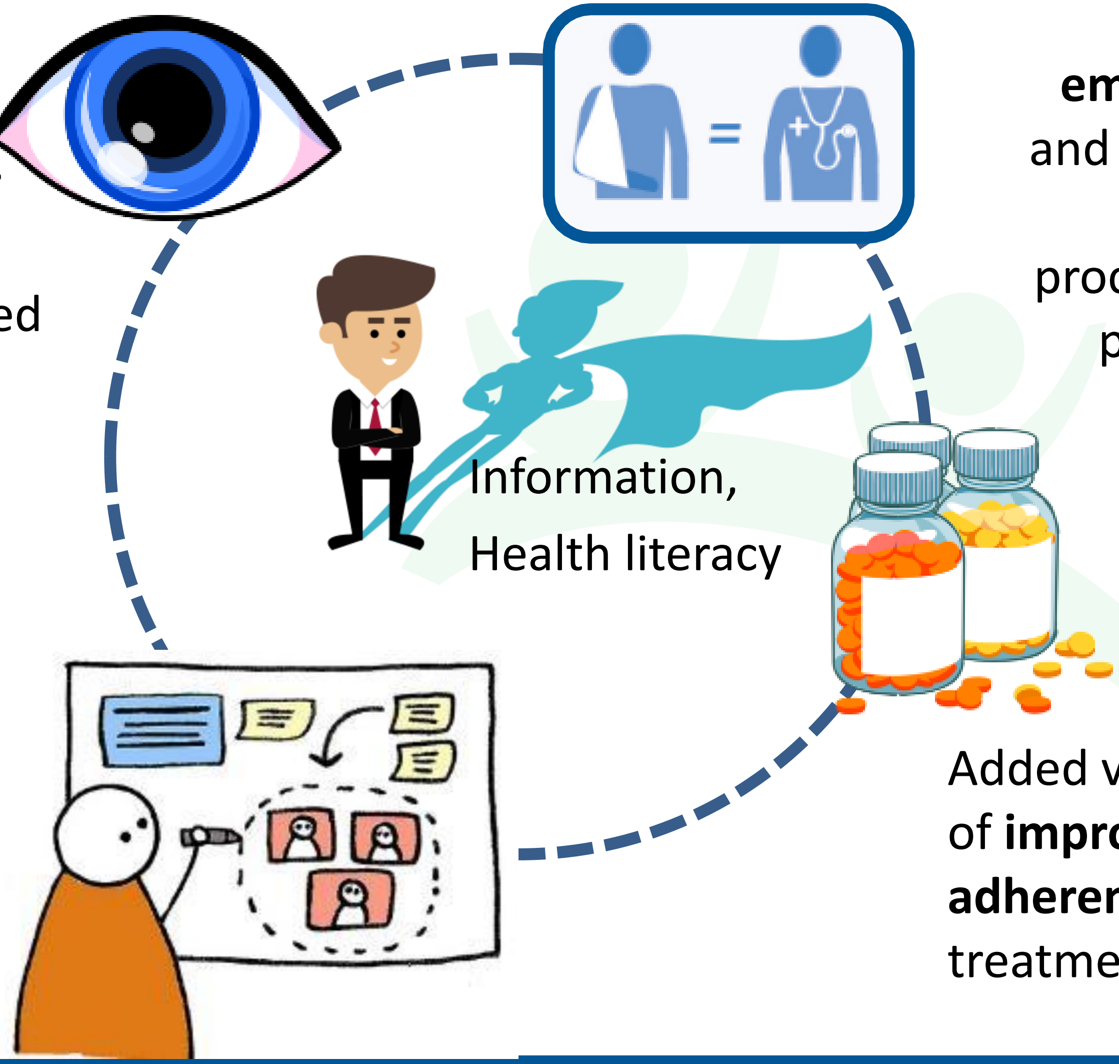
Clinical Research

Our data, our privacy, our health: Patient involvement

- Patient participation in decisions regarding health and genetic data is a matter of good governance
- Involvement at policy and programme level on questions of privacy in healthcare and health research
- Empowering patients as owner of their health and genetic data to make decisions about their personal information



Patients’ expectations of digital health care



Facilitates chronic disease management, **self-management**

And leads to improved **quality of life**

Patient empowerment and involvement in the care process as equal partners with HCPs

Information,

Health literacy

Patient centred care as opposed to disease centred and **better integration** of healthcare

Added value in terms of **improved adherence** to treatment

Data reuse for health research (1)

Patients – generally **comfortable** and **willing** to the secure sharing of their anonymized health data and recognise that this is of **vital importance to advance health research**, help other patients and ultimately benefit society

- Identify **solutions to unmet needs** (e.g. rare diseases)
- To improve **quality of care** and **quality of life** or **improved therapy**
- Patients learning from their own data - **self-management, empowerment**
- To help peers and future generations - general community and **peer support**
- Have already **experienced** the benefit of research, through therapy or management of their disease
- **Trusted environment** – healthcare and research setting

Data reuse for health research (2)

That being said, **Patients** have **privacy (anonymization)** and **data security concerns**

- **Unauthorised disclosure** of personal health or genetic information could **negatively impact** on a patient’s personal and professional life, this is why **informed consent** and **transparency** on the use made of data is essential.

Patients' privacy concerns

- Fear of discrimination on the grounds of health/genetics: **in the field of employment, insurances -** The consequences of data falling into the wrong hands could threaten livelihoods, confidence, dignity and relationships. Importance of informed consent and anonymised data.
- **Ownership** of data e.g. clinical trials – Who's data is it?
- Concerned of **security mechanisms** (links to interoperability of systems and software) that will be put in place to ensure safe sharing
- Concern for **respect of the law** and **professional secrecy**
- Patients' fundamental right to protection of their data is vital in diverse contexts: healthcare, eHealth, cross-border care, clinical trials,…

➢ New technologies offer opportunities to collect, use and share health data more efficiently

… but set new challenges for privacy and data security

EU Policy

General Data Protection Regulation

EU General Data Protection Regulation (GDPR)

The General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679): regulation by which the European Parliament, the Council of the European Union and the European Commission intend to **strengthen and unify data protection** for all individuals within the EU

- **May 2016:** Data Protection Regulation was officially **adopted** after four years of debates between the EU institutions
- **May 2018**: it will be directly ***applicable*** in all Member States

EPF and the GDPR

- **EPF**: engaged in the GDPR debate to work on solutions around **informed consent** and **anonymization**, actively advocating for a **balanced approach** to protect patients' privacy while ensuring patient's data can be shared for healthcare and research purposes since the publication of the proposal for a regulation in 2012

- **Regulation and why it matters to patients:** provides progressive rules that give more rights to citizens and by extension to patients to be **informed** on the **processing** of their data, to object to the processing, to rectify their data, to access the information being processed or to be better informed about the **use made** of their personal data, and gives clearer responsibilities to people and entities using personal data

- **EPF guide to the GDPR**: outlines what this new legislation means for patients and how patients' organisations can contribute to ensuring that patients' rights to privacy, data sharing, and accessing their health data are implemented optimally.

EPF’s activities to date

What EPF is doing

1 **Gathering patients' views and building patient group's capacity**

2 Raising awareness: EPF's Campaign on Patient Empowerment 2015-2016 and Access 2017

3 Influencing the legislative process

4 Projects: AdaptSmart, EUPATI, Get Real (IAPO), (IMI)

EPF’s Work so far

- **Position Statement** on the EC’s proposal for a General Data Protection Regulation – December 2012
- **Position Statement** on **informed consent in clinical trials** – May 2016
- Guide for patients’ organisations – **The new EU Regulation on the protection of personal data: what does it mean for patients?** – Autumn 2016
- **eHealth Position Paper** – December 2016
- 2017: **Briefing on big data** - aim of ensuring the capacity of patient communities to provide meaningful input to policy discussions in this highly technical area
- 2017-2018: **Patient survey** on electronic health records and data sharing

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Meaningful Patient Involvement

- Need to acquire thorough understanding of **patients' needs and perspectives**, with patients at the centre of digital health and care design
- Ensure that the digitalisation of health and social policies and systems is accompanied by strategies for **strengthening health literacy and patient empowerment**

Patient-centred digital technologies: <u>privacy by default </u>and <u>accessibility (including affordability)</u> and <u>design for all</u>

Empowering Patients and Health Literacy

Navigating the health "maze" is challenging …

… even more so if you have low health literacy

(EPF CBHC paper)

"Patient empowerment is *a process* that helps patients gain control over their lives, increasing their *capacity to act* on issues that *they themselves* define as important

… a process through which patients *individually and collectively* are able to express their needs, present their concerns, devise strategies for involvement in decision-making, and take action to meet those needs."

(Adapted from JA-PaSQ, 2012)

Being health literate empowers people

Being health literate enables people for example

- **To understand information about their health**
- **To evaluate information for its quality and trustworthiness**
- **To reflect on and explore alternative options**
- **To make more informed decisions**

- Considering patients as owners of their data and providing them with rights to transparency, informed consent, to access their own information is also important to **build the trust** and **confidence** necessary to encourage their sharing of data for research and public health.
- We are increasingly talking of the **potential of big data** and **real world evidence**, but this cannot work without ***patient empowerment***.

Empowering patients

Right of Access to one's own data:

- Key component of PE and patients' health literacy
- in EU still obstacles for patients to access their health information
- and data stored in silos rather than in interoperable systems

Right to information:

- Transparent policies in place
- Informed consent
- Information about their right as data subjects

Right to be forgotten/ to object/ to rectification

Any restriction to these rights should be limited and justified

Informed consent and Information to Patients

- **Informed consent**: *not simply a process of providing information to the patient. Neither is it about obtaining a signature on a form. From a patient's perspective, informed consent should be seen as a process a kind of "decision aid" that should enable a patient to make an enlightened decision*

- ➢ **disparities across the EU** - both in terms of the **quality** and **quantity of the information** provided to patients, and the **effectiveness** of the **informed consent process**
- ➢ **Consent** is still often regarded as a ritual or a box-ticking exercise, rather than a crucial means by which patients are able to **fully comprehend** and **evaluate the risks** and potential benefits (of taking part in a clinical trial for e.g.)

- See EPF recommendations for meaningful informed consent

What EPF is doing

1. Gathering patients’ views and building patient group’s capacity
2. Raising awareness: EPF’s Campaign on Patient Empowerment 2015-2016 and Access 2017
3. **Influencing the legislative process**
4. Projects: AdaptSmart, EUPATI, Get Real (IAPO), (IMI)

Patients campaign on Data Protection

- In March 2014 the European Parliament adopted a first reading position of the data protection regulation for stricter rules on consent for research.
- If implemented, this Regulation would have harmed health research by creating an obligation to seek specific consent when personal data was used.

=> EPF joined research and public health NGOs in the **datasaveslives campaign** to raise awareness of how research with personal data has led to tangible improvement for health and well-being and to ensure the final Regulation would allow vital research that has taken place for many years to continue, whilst keeping appropriate/ proportionate safeguards

The ‘Data Saves Lives’ Campaign

EPF European Patients Forum

The European Data in Health Research Alliance - *ensuring the Data Protection Regulation allows vital research to continue*

#DatamattersEU

www.datasaveslives.eu

What EPF is doing

1 Gathering patients' views and building patient group's capacity

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3 Influencing the legislative process

4 **Projects: AdaptSmart, EUPATI, Get Real (IAPO), (IMI)**

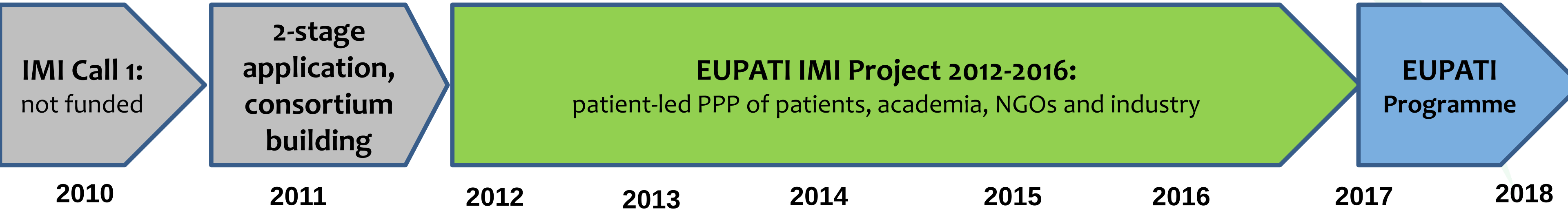
- MAPPs, broadly, are a multi-stakeholder approach to developing an “RCT-plus” to evaluating new medicines
- **MAPPs** involve a notable upstream **shift** in prospective planning and discussions on topics such as: design of the **development plan**, identifying sources of real world data (**RWD**) and how they can be best utilized in combination with registries and RCTs, budget impact estimates, reimbursement and prescribing conditions, and resource planning.

The "New" EUPATI Programme

EPF-led, permanent programme in the PPP spirit

- **3rd EUPATI Patient Expert Training Course**
- **EUPATI Toolbox** in all languages
- **"Mini-Course Starter Kits"** and capacity building
- **Content updates** (~10 Toolbox elements updated p.a.)
- **National Platforms**
- **Evolution!**

EUPATI
European Patients' Academy on Therapeutic Innovation



IMI Call 1: not funded

2-stage application, consortium building

EUPATI IMI Project 2012-2016: patient-led PPP of patients, academia, NGOs and industry

EUPATI Programme

2010 2011 2012 2013 2014 2015 2016 2017 2018

Real-world data according to GetReal

- An **umbrella term** for data regarding the **effects of health interventions** (e.g. safety, effectiveness, resource use, etc) that are **not** collected in the context of highly-controlled **RCT's**.
- Instead, RWD can either be **primary research data** collected in a manner which reflects how interventions would be used in routine clinical practice or **secondary research data** derived from routinely collected data.
- Data collected include, but are not limited to, clinical and economic outcomes, patient-reported outcomes (PRO) and health-related quality of life (HRQoL). RWD can be obtained from many sources including patient registries, electronic medical records, and claims databases.

Next Steps for EPF

2018 onwards - Next Steps for EPF

Objective: Accessible, equitable, high quality and patient-centred healthcare

- **2018: Report** on the outcome of the **patients' survey on electronic health records and sharing of patients' data**
- **2018 -2021:** EPF **working group** on **technology in healthcare** - provide a 'real-life' patient perspective on technology solutions; focus on access, sharing and (re)use of patients' health data and ethical aspects - consisting of patients and external advisers
- **2018:** Lay-friendly **information resources on digital health** to empower patient communities
- **2019: Principles** and **positions** on **big data, health data sharing and use**, based on the outcomes of the survey on electronic health records and data sharing
- **2021: Commentary** on the European Commission's report on the **evaluation and review of the EU Data Protection Regulation**

Principles and Questions

- Health literate and Informed patient -> Empowered patient
- Patient access to health data
- Safety and Quality of data
- Protect against harm
- Harness safe and ethical secondary use of quality data and confidentiality

➢ Patient-centred data ecosystem

Reuse of data by who and for what purpose?

- Non for profit / for profit
- Quality management
- Disease registries
- Organisational learning (hospitals)
- For health research
- Pharma observational studies

Extent of anonymisation

…

Making Progress and Moving Forward

- **Patients' role** has evolved over the last decades

- informed and engaged actors, a source of expert information, participating and leading research

- **Traditional silos breaking down**
- **Forward thinking** of health professionals
- **Space for opportunity** in determining health priorities and driving the research agenda
- **Partnership and cooperation** in research

=> a new clinical research ecosystem

To conclude

- The **right balance** needs to be reached between ensuring confidentiality of data while allowing their availability and sharing for public health, healthcare and research purposes

- **Ethical** secondary use of health data and **confidentiality**

- **Interests and attitudes of patients** towards the use of their data for research across Europe is generally **favourable**

- **Together with patients and patient organisations**

THANK YOU

www.eu-patient.eu

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Further Information

- EPF Position Statement on the EC's proposal for a General Data Protection Regulation
- Position Statement on informed consent in clinical trials
- The new EU Regulation on the protection of personal data: what does it mean for patients? A guide for patients and patients' organisations
- EPF Position Paper on eHealth
- EPF Position Statement on the Patients' Rights In Cross-Border Healthcare Directive
- EPF Patient Empowerment Roadmap
- EPF Campaign on Access to Healthcare