

SHARE AND PROTECT OUR HEALTH DATA!

Rare disease patients' preferences
on data sharing and protection

January 2020



30 MILLION
people are living with a rare disease
in Europe and 300 million worldwide



NO CURE
for the vast majority of diseases and
few treatments available

Sharing health data to advance scientific research and improve clinical benefits are of particular importance in the **field of rare diseases** where knowledge and expertise are limited and **patient populations are geographically dispersed**.

Understanding what patients want and need from rare disease research and data sharing is **important to ensure their participation and engagement in the process**, and to ensure that these wishes and needs are embedded within research and healthcare delivery design.

WITHIN THIS REPORT YOU WILL FIND:

1



Key results from research conducted by EURORDIS, outlining rare disease patients' preferences with regards to data sharing

2



Seven recommendations designed to inform and support stakeholders involved in data sharing initiatives

3



Research and recommendations methodology

1 WHY SHARE HEALTH RELATED DATA?

Rare disease patients, regardless of the severity of their disease and their socio-demographic profile are clearly willing to share their data:

To foster research on their disease...

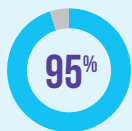
97% would be ready to share their data to better understand the mechanisms and causes of their disease

97% to develop new treatments for their disease

97% to improve diagnosis of their disease

or to improve their healthcare

95% to receive additional specialist advice on their care



are also willing to share their data to improve research on diseases other than theirs.

“ We are only 6 families in [country] affected by this. If we don't offer our database, I think it's impossible for someone to help us, to know much about us”

Rare disease patient

“ It is difficult to get the diagnosis. Doctors don't know about my disease because it is very rare. We need to share all the information about this disease – how it is manifested, how it progresses, all the experience the patients and doctors have”

Rare disease patient

“ I agree to share my data if the rare disease community gets benefit from it”

Rare disease patient

Rare disease patients seem more inclined to share their data than the general population:

depending on the study, between 37% and 80% of the general population declare that they would be ready to share their health data¹.



If given the opportunity, would you be willing to make your/the person you care for health information available for the purpose of:

The main incentives for patients to participate in such initiatives is the possibility to discuss and learn information about the disease and the project.



1 69% The possibility to learn more information about their disease



2 66% The possibility to discuss and ask questions directly to professionals involved in the project



3 62% The possibility to be informed on the results of the project



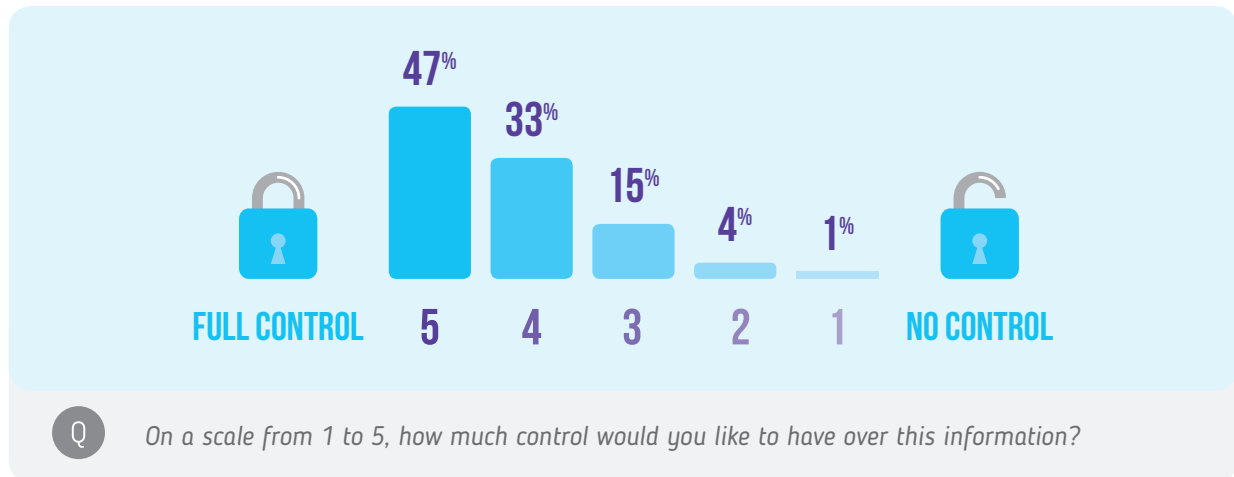
From the list below, what are the three main options that would encourage you to participate in a project involving the sharing of your/the person you care for health information?

1: Attitudes towards data sharing. YouGov. 2018. https://docs.google.com/spreadsheets/d/1_-ntuc7IZEeXxLdvaFsfqrugjNFQUPT17B377G0XnQo/edit#gid=2093652055 and https://ec.europa.eu/health/sites/health/files/ehealth/docs/2018_ehealth_infographic_en.pdf

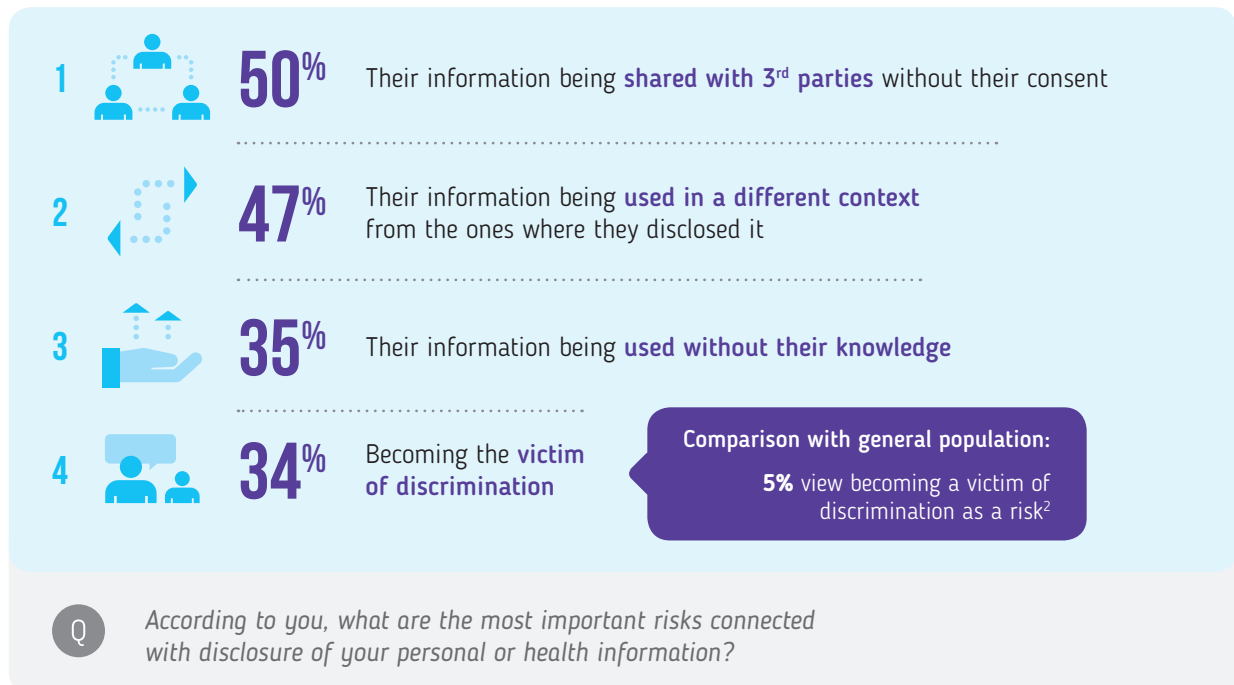
2 DATA SHARING: RISK AND LEVEL OF CONTROL

Rare disease patients want to have control over the data they are sharing.

80% said they wanted to keep full (47%) or near to full (33%) control. Being in favour of sharing data and calling for more control are not contradictory, they are clearly stated as two parallel requirements.



According to rare disease patients, the main risks associated with data sharing are:

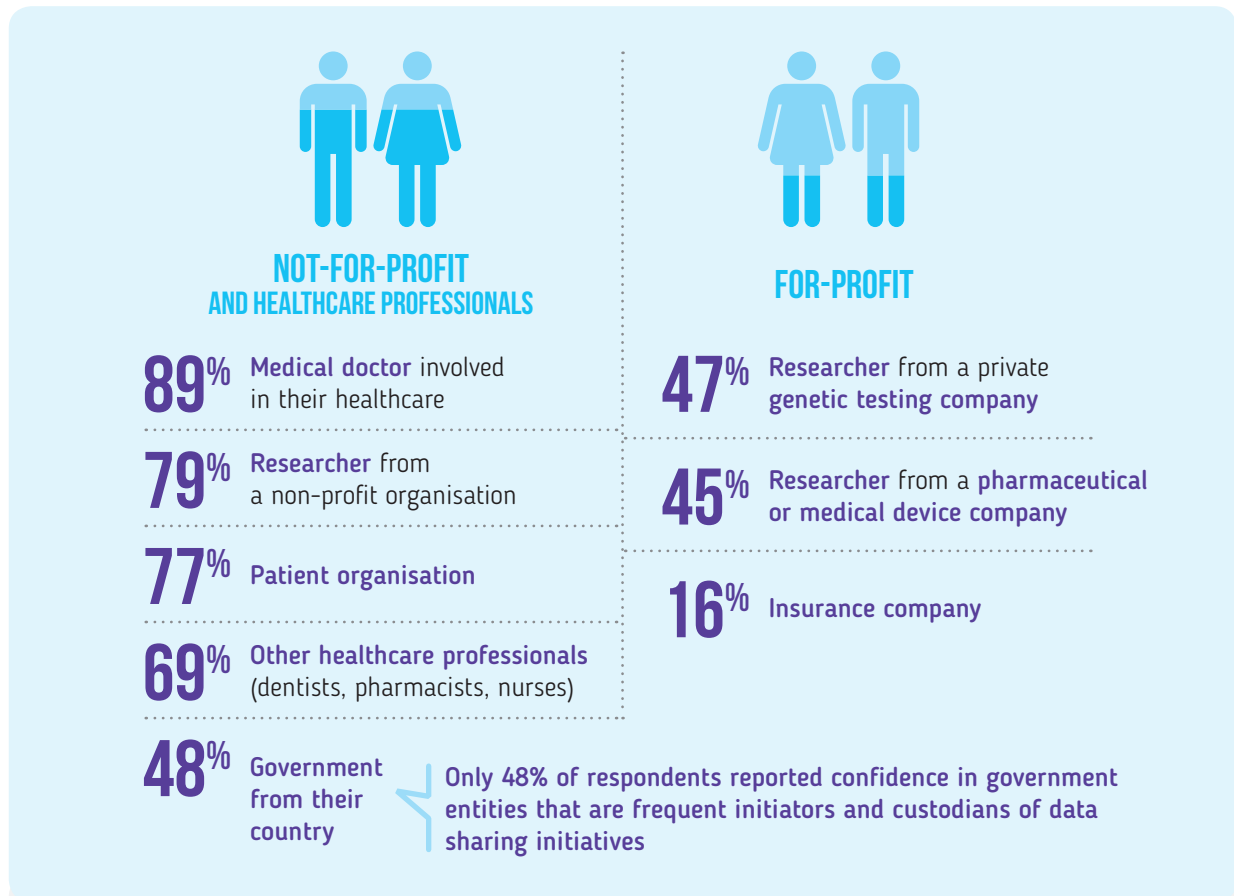


2: European Commission: Data Protection Report. Special Eurobarometer 431; 2015 https://ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_431_sum_en.pdf

3 HOW MUCH DO PATIENTS TRUST POTENTIAL USERS OF DATA?

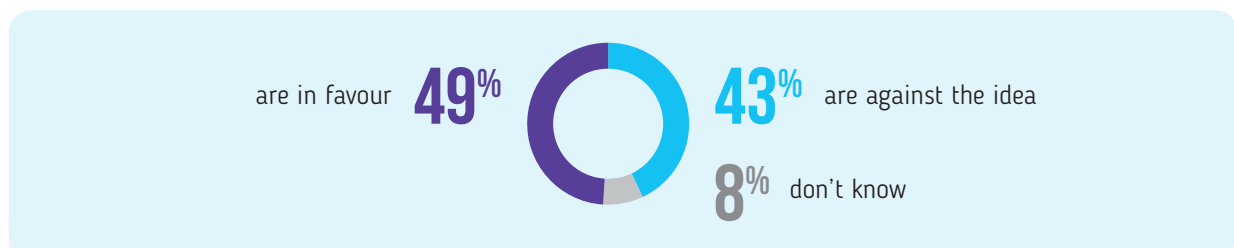
Rare disease patients show a higher level of confidence in not-for-profit stakeholders.

Respondents were asked whether they trust various authorities and types of organisations to handle and use their health information carefully. Patient trust in not-for-profit stakeholders is considerably higher than trust in for-profit stakeholders.



People involved in the project can belong to different types of organisations. How much confidence do you have in each of them to handle and use your health information carefully?

Opinions are fragmented on whether responsibility for deciding with whom information is shared, how and why, could be delegated to an ethics committee.



Would you allow an ethics committee to decide on your behalf with whom your information will be shared, how and why?

4 HOW BEST TO COMMUNICATE WITH RARE DISEASE PATIENTS?

Participants were asked to express their preferences regarding the types of information they would like to receive and how they would like to receive it.

The top three most important pieces of information patients would like to receive about a data sharing initiative are:



- 1 **80%** Details on how the project could be **beneficial** for their disease or other diseases
- 2 **51%** Brief **summary of the key information** necessary to understand the main aspects of the project
- 3 **49%** Information about the **data management rules** (eg. how access to health information will be granted or is there an ethical review?)



What are the three main pieces of information about the project that would be important for you to receive?

Email and face-to-face discussion are the favoured ways of receiving information.



93% Email



86% Face-to-face discussion with professionals involved in the project



85%

A dedicated **website**



67%

Attending **conferences**



56%

A **mobile app**



Would you like to be informed about the outcome of the project through each of the following means?

The ideal frequency to be informed for the majority of the respondents is once a month.

55%
ONCE A MONTH



Once a week
21%

Once a year
12%

Several times a week
6%

Don't know
6%



How often would you like to be informed about the outcome of the project?

5 RECOMMENDATIONS FOR DATA SHARING INITIATIVES

The following recommendations have been derived from the surveys and consultations.

Policy makers should:

RECOMMENDATION **1**
ENSURE IMPLEMENTATION OF APPROPRIATE LEGISLATION



Ensure implementation of appropriate legislation at European and national levels and pursue efforts to foster cultural, technological and infrastructural changes to further develop international data sharing initiatives in health and research for rare diseases.

Already existing initiatives in this area include:

- The work undertaken by the European Reference Networks to establish a dedicated data-sharing platform enabling information exchange and mutual learning to improve rare disease patients' diagnosis and care, while also contributing to the development of research and innovation.
- The signature by several EU countries of a declaration whereby their governments commit to cooperate to deliver cross-border access to genomic information. This declaration has the potential to maximise use of health care resources and advance the development of personalised medicine especially in the rare disease field³.

All stakeholders involved in data-sharing initiatives, including funders, sponsors, clinicians and researchers, healthcare authorities and professionals, patient organisations and non-profit organisations should:

RECOMMENDATION **2**
IMPLEMENT ROBUST STANDARDS AND SAFEGUARDS



Implement robust standards to ensure secure, ethical and responsible data sharing whilst putting in place safeguards around data protection.

- Ethical and responsible data sharing should be enabled through widespread implementation of the IRDiRC recognised resource, the international charter of principles for sharing biospecimens and data which provides guidance for effective legally and ethically grounded data sharing.
- Furthermore, several ongoing initiatives are testing the use of blockchain technology, which has proved an efficient tool to protect personal data⁴.

3: EU countries will cooperate in linking genomic databases across borders. <https://ec.europa.eu/digital-single-market/en/news/eu-countries-will-cooperate-linking-genomic-databases-across-borders>.

4: Zyskind G, Nathan O, Pentland A. Decentralizing privacy: using Blockchain to protect personal data. *Journal of Information Security and Cryptography (Enigma)*; 2015.

RECOMMENDATION **3**
INCLUDE TRUSTED REPRESENTATIVES



Data sharing initiatives should include representatives from trusted advocacy organisations, i.e. patient organisations and non-profit organisations, as well as clinicians and healthcare professionals.

RECOMMENDATION **4**
PROMOTE DYNAMIC SYSTEMS



Promote the development of, and implement, dynamic systems enabling:

- the possibility to express different attitudes and preferences
- access to updated information on research outcomes to increase patient participation in research and stimulate data sharing whilst respecting patients' preferences.

Definition: Dynamic systems enable patients to tailor preferences about whom they share their data with, for which purpose and to change their preferences reliably at any time. They use information technology to facilitate a more explicit and accessible opportunity to opt in and out of a project. Electronic systems also provide opportunities for informing patients of the results of research to which their data has contributed.

RECOMMENDATION **5**
DEDICATE FINANCE TO EDUCATIONAL RESOURCES



Dedicate financial resources to enable the development of, and facilitate access to, relevant educational resources to enable informed choices for patients to share or not to share their health related data.

RECOMMENDATION **6**
DEDICATE FINANCE TO INFORM PATIENTS



Ensure that adequate financial resources are allocated to inform patients on the purpose and outcomes of data sharing initiatives in which they participate.

RECOMMENDATION **7**
EMPHASISE POTENTIAL HEALTH BENEFITS OF STUDIES



Emphasise potential health benefits of research studies and healthcare initiatives on future generations and other disease areas, as an incentive for wider participation in data sharing initiatives.

For more information on the results of the survey and the recommendations, see the article published in the Orphanet Journal of Rare Diseases :

[Share and protect our health data: an evidence based approach to rare disease patients' perspectives on data sharing and data protection](#) or contact rare.barometer@eurordis.org.

6 RESEARCH AND RECOMMENDATIONS

METHODOLOGY

EURORDIS-Rare Diseases Europe has organised and participated in a number of consultations with rare disease patients and carers in order to reach a comprehensive understanding of rare disease patients' needs and expectations regarding data sharing.

Patient and carer views and perspectives were collected via the following methods:



A FINAL LARGE SCALE QUANTITATIVE SURVEY
conducted by Rare Barometer

| | | |
|--|----------------------------|--|
| <p>2013 respondents</p> | <p>23 languages</p> | <p>March to May 2018</p> |
| <p>TARGET POPULATION: patients living with a rare disease or family members (parents and close relatives) over 16 years old</p> | | <p>66 countries and 664 diseases represented</p> |

THANK YOU to all people living with a rare disease who participated in the survey and discussion groups and to Rare Barometer partners!

5: McCormack P et al: 'You should at least ask'. The expectations, hopes and fears of rare disease patients on large-scale data and biomaterial sharing for genomics research. European Journal of Human Genetics 2016, 24(10):1403-1408