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Executive Summary

Patient input in research projects and in the handling of their data is now being seen as important or essential. This trend is reflected in major pharmaceutical companies who see patient input as increasingly important for regulatory approval of new treatments. In eTRIKS the major intersection with patient input has been identified as understanding the value of data and how this understanding impacts on decisions around data use. This is itself is an area of growing interest as collected data continues to grow exponentially and the methods of data collection become more diverse.

Across Europe health researchers are collecting more and more information about diseases and treatments and how they impact individual patients. Often these data are stored in incompatible, inaccessible systems that make it difficult or even impossible to reuse the information to improve patient outcomes. The challenges to using the data to their full value may be both practical and ethical.

eTRIKS is looking to inform medical researchers about the value of data and to provide practical advice on making data more valuable through ethical sharing. To do this, eTRIKS is reaching out to the patient community to gain insight and support that will help us reach the full potential that European medical research data has to offer. Patient's views on this topic will help further development of educational material, for the practical purpose of peer-to-peer learning, so that the general understanding of the importance of data and its reuse becomes more widespread.

One on one teleconferences with patients and patient representatives have been and will continue to be organised to discuss the value of data and its reuse. These discussions will also provide the opportunity for patients to outline their concerns around the management of medical research data, and highlight any key gaps in the patients understanding of the value of data and its reuse. The outcomes of the discussions will form the basis of a summary provided to EFPIA members and the development of a Play Decide discussion game. The discussion game will be specifically designed to broaden the scope of patient awareness of the value of data and its reuse, and the issues that affect it.

Face to face workshops are being convened with patient groups and data experts to conduct Play Decide sessions, so that patients will get direct access to the people who are involved in managing medical research data. The outcomes of the workshops will be recorded and integrated on a live decision portal, which will help develop a broader European picture of the key concerns and wishes of patients.

The broader European picture will be used to generate a framework for the development of informational and educational material on the value of data. This information will be used to engage the broader patient community through peer-to-peer learning.

The educational material will take the form of a one-page information sheet describing the value of data and a collection of information produced within the Play Decide discussion game. This work will be conducted in conjunction with the eTRIKS Ethics and Security work package, work package 7. The information sheet, will be an explanation of how patient data can be used and reused, and will focus on information identified as current gaps in societies knowledge. It is expected that this sheet could be supplement to patient consent forms.

Background

eTRIKS is a pivotal project funded by the Innovative Medicines Initiative (IMI JU) that focuses on knowledge management support for a broad spectrum of national and international medical research projects. Our focus is to help translational researchers improve the efficiency of translating quality data into quality patient treatment, by providing a platform that enables efficient **Integration, Staging and Exploration** of clinical and research data.

There is an increasing level of interest in the re-use of medical research data. There is an appreciation that there is a fair amount of redundancy in the medical research data that is collected. The problem is that many scientific questions require large datasets. However, most studies are limited in scope and scale. So, in recent years researchers and bioinformaticians have been seeking ways to make use of existing data assets and minimize the need to conduct studies anew to have enough data to answer important questions.

The challenge is that this requires the re-use of research data that was collected for a different purpose. This raises questions about data privacy and data protection. When being enrolled in a study patients typically complete a consent form that describes what the collected data will be used for. It is clear for researchers that there is value in the re-use of medical research data. It is not so clear if the general public and research study participants have the same level of appreciation of the value of data and would therefore favour being protective of their privacy in regards to medical research data re-use.

Inputs and Outputs from related deliverables

eTRIKS have produced guidelines and recommendations on the adoption of data standards and the use and re-use of data in research. In light of this work a number of challenges have been highlighted, both at a technical level and at a community level. One of which is societies level of understanding around the value of medical research data and its reuse.

Relevant milestones and deliverables cited in eTRIKS Description of Work

M3.3 Standards Proposal (The Standards Starter Pack)

D3.5 Manual of guidelines and recommendations for adoption of standards in eTRIKS v3

D7.4 Guidance for reuse of biomedical data in research.

The cited milestone and deliverables have enabled supported projects to integrate their medical research data, and to further inform the translational research community on what they can and cannot do with the data they have. However, this is an ever-evolving field with a number of technical and legislative issues that block efficient data sharing. The issues include:

- Poor adoption of standards
- Data privacy regulations
- Organisational policies
- A general lack of appreciation by experts that data has value beyond its original use.

These issues are barriers that limit the value society gets from medical research data. A more aligned and educated community will be better equipped to deal with these issues.

Patient Input Plan

Purpose of the plan

Main purpose:

- To contribute to societies growing understanding of the value of data and its reuse.
- To obtain deep and meaningful patient engagement

We will bring together experts in medical research, translational research, data and patients to discuss the issues affecting the value of data, and to identify the gaps in understanding. The output of the interactions will be used to widen understanding of data and its reuse, through a World Wide Web portal, and by developing educational material that will be disseminated through vectors such as clinical trial consent forms.

In order to effectively engage the different stakeholders an multi-stakeholder discussion approach will be employed, aligned to clear outputs informing on perceptions and challenges in understanding the value of data.

Objectives

- To engage with patients with a view of understanding the gaps in their knowledge on the subject matter and identify the issues that concern them.
- To engage with EFPIA members to gauge their views on key issues concerning data reuse.
- Set up workshops to broaden the scope of input from patients and experts cross borders, disease domains and demography.
- Based on workshop outcomes, design educational material on the use and reuse of medical research data.
- To generate an information sheet focused on the value of data, which could be supplement to patient consent forms.

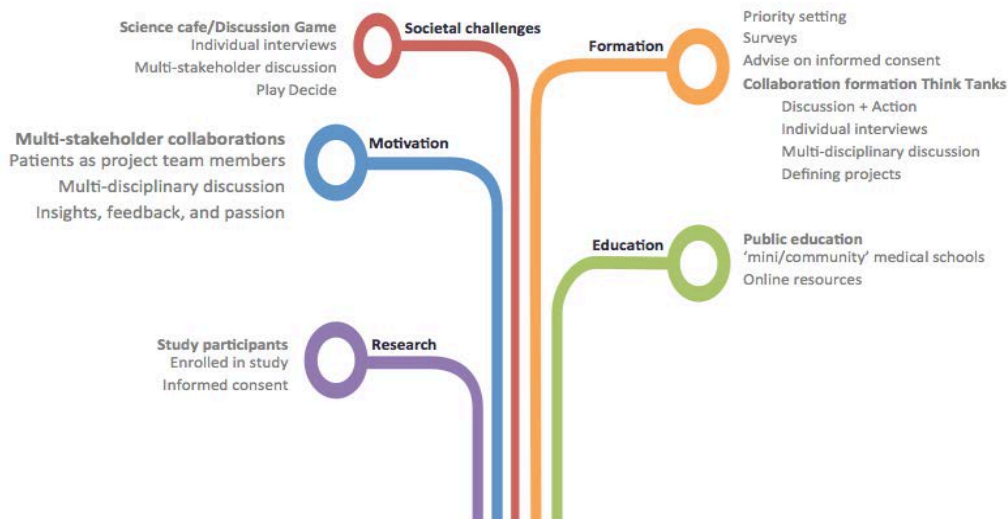
The patient involvement plan is intended to do more than only reach out to patients. It put's patients at the core of the effort to communicate about and understand the value of data.

We can see the degree with which patients may be involved in an innovation project in figure 1, 'Levels of patient Involvement'. This figure, developed by BioSci Consulting, shows how patients can be involved at multiple levels and by implication, at different depths, in the work of a project.

Within the eTRIKS project patients are being motivated to be involved in the multi-stakeholder project, they are central to the discussion game and education material development and are part of the formation process for this deliverable and were involved in earlier stages of the project development as well. As eTRIKS provides services to other, mainly IMI, projects who collect patient data, the patients and patient reporesentatives involved in eTRIKS are considered to reporesent the patient data providing population. Of course, individual study trial participants may not be reached out to in broader initiatives due to confidentiality issues, but may be broadly communicated to via project sites.

Levels of patient involvement

Innovating toward meaningful engagement



©BioSci Consulting

Figure 1: Levels of patient involvement (BioSci Consulting)

Structure of the patient input plan

1. Conference calls with patients and patient representatives.
2. Discussion with EFPIA members.
3. Development of structured multi-stakeholder workshops.
4. Play Decide multi-stakeholder discussion workshops with patients and data experts.
5. Development of educational material and one page consent form supplement.
6. Dissemination of educational material.

The concept pipeline for the process of engaging multiple stakeholders to form one voice (if not opinion), developed by BioSci Consulting is seen in figure 2 below. This describes the stepwise approach to engagement, allowing space for forming the scope of the need and opinions before moving to developing the discussion game to engage further partners bringing in a wider circle of input, leading to consensus approaches found in synergies which can then be translated into documentation.

This broad approach is expanded upon in the 6 steps outlined above and which are further detailed in the sections below.



Figure 2: Pipeline process for stakeholder engagement (BioSci Consulting)

Conference calls

To organise and conduct conference calls with patients and patient representatives to garner their views and insights. The scope of the patient cohort should cross disease fields, national borders and demography to gain a wide distribution of perspectives.

- Patients and patient's representatives will be identified and invited to discuss the value of data and its reuse. Invitations will be provided through intermediaries such as the IMI and Patient organisations (Appendix1), as well as directly contacting patients already known to eTRIKS members, through previously run projects.
- During the conference calls the attendees will be asked questions (Appendix 2) to identify any gaps in their understanding around the value of data and its reuse.
- When the conference calls are finished, a high level summary and gap analysis of the conference calls outcomes will be conducted, Appendix 3.
- The patients will be asked whether they would be interested in taking part in a Face-to-Face meeting or workshop focused on developing educational material for the purpose of peer-to-peer education. Other members of the community will be identified as prospective attendees.
- A conference call with eTRIKS WP6 members will be conducted to discuss a proposed face to face meeting agenda based on the outcomes of the discussions had with patients. Agenda to be circulated for review and finalisation.

A set of standard questions has been developed to guide the conference calls. The answers will be summarised for each patient interviewed:

- Have you participated in a research study, can you say which?

2. What do you understand by the word data?
3. What do you know of the value of data?
4. How do you feel about sharing data?
5. Do you expect your data to be shared between one or several projects?
6. What do you think happened to your data? and why do you think that?
7. What does data security mean to you?
8. What is pseudonymized data?
9. Are you familiar with the relationship between Data Value and Data Security?
10. Where have you seen information about your data, and where would you look for it?
11. Do you have any questions around data and its value?
12. Do you think this idea is worthwhile?
13. Would you be interested in a face-to-face meeting to generate educational material for the wider patient community?
14. Can you recommend a patient or patient representative that would be interested in discussing the value of data and data sharing.

Face to face Play Decide multi-stakeholder discussion workshops

This face to Face meeting will include all stakeholders, principally patients, patient representatives, data experts, clinicians and researchers.

eTRIKS is looking to inform medical researchers about the value of data and to provide practical advice on making data more valuable through ethical sharing. To do this we want to bring together patients, bioinformaticians, translational researchers and software developers, to gain a broader insight into the value of data, data sharing and data reuse. This face to face meeting will be a workshop with patient representatives to be attended by a broad range of experts involved in data management, software development, analytics and eTRIKS supported projects. The workshop will be framed by a Play Decide game developed by eTRIKS members, to help facilitate discussions.

- a. Based on the conference calls outcomes analysis a Play Decide game will be developed to efficiently inform workshop participants of the subject matter and help frame discussions, Appendix 4.
- b. eTRIKS patient input platform (PIP) workshops will be convened and eTRIKS members will participate in workshops organised by patient community members.
- c. Outcomes of the workshops will be uploaded onto a web portal. The outcomes of all workshops will be integrated so that a European wide view on the value of data and its reuse can be formed.

Figure 3, below, shows the template for the Play Decide game, which is accompanied by various cards (Story card, Info Card etc) the place for which can be seen in this template. This board is placed centrally within the discussion group, while cards are distributed (appendix 4) which provide different perspectives, information and material for a discussion facilitated by project members with appropriate experience.

<p>The Value of Data</p> <p>Across Europe health researchers are collecting more and more information about diseases and treatments and how they impact individual patients. Often data is stored in incompatible, inaccessible systems that make it difficult or even impossible to reuse the information to improve patient outcomes. The challenges to using the data to their full value may be both practical and ethical.</p> <p>Datasets that are in a standardised format that makes combining them with other datasets are more valuable. They are more valuable because they can be reused as part of studies. By combining datasets researchers aim to answer scientific questions which are not possible to answer with smaller individual datasets. Poor adoption of standards, data privacy regulations, organisational policies, and a general lack of appreciation that data has value beyond its original use are all barriers that limit the value society gets from medical research data.</p> <p>On what areas do you think there needs to be more effort to build awareness?</p> <ol style="list-style-type: none"> 1. The value of being able to reuse datasets. 2. Understanding how data is shared. 3. The degree to which personal data can be de-identified 4. Why standards are not being used 5. Other points of interest <p>Aims of the game</p> <ul style="list-style-type: none"> - Clarify what your opinions are - Work towards a shared group vision - Let your voice be heard in Europe - Enjoy discussing! 	<p>Story Card</p>	<p>Info Card</p>	<p>Info Card</p>	<p>Initial Thoughts</p> <p>Write down your initial thoughts, use white cards to add issues</p>
	<p>Guidelines</p> <p>You have a right to a voice: speak your truth, but not the whole truth, don't go on and on.</p> <p>Value your life learning.</p> <p>Respect other people. Allow them to finish before you speak.</p> <p>Delight in diversity. Welcome surprise or confusion as a sign that you've let in new thoughts or feelings.</p> <p>Look for common ground. 'but' emphasises difference; 'and' emphasises similarity.</p>	<p>Three stages</p> <div> <p>1. Information Clarify your personal view on the subject, reading and selecting the cards which you feel are most important for you. Place your cards on the placemat and then read them about to the other players.</p> <p>± 30 MIN.</p> </div> <div> <p>2. Discussion Together with the other players, start discussing and identify one or more larger themes that you all feel relevant. Everyone gets a chance to speak. Put your cards on the table to provide your arguments for each theme.</p> <p>± 30 MIN.</p> </div> <div> <p>3. Shared group response Reflect on the theme(s) that the group has identified and the cards that sustain the arguments. As a group, can you reach a positive consensus on a policy position that reflects the group's view? You can formulate a new common policy, if you wish.</p> <p>± 20 MIN.</p> </div>	<p>Issue Card</p>	<p>Issue Card</p>
<p>... plus one</p> <p>4. Action Go to www.playdecide.eu to: - Submit the results of your group to the Decide database; - See how other European countries think about this issue; - Read more about this subject; - Download a game kit to play with your friends or colleagues; - Learn how you can make a difference after playing Decide.</p>				

Figure 3: Play Decide multi-stakeholder discussion game board

The benefits of running a discussion game have been identified as providing a:

- ▶ Neutral true dialogue
- ▶ Faster way to get useful stakeholder input
- ▶ Improved understanding of stakeholder perspectives
- ▶ Direct impact on decision makers

The expected outputs from the discussion game are:

- ▶ Content for educational material
- ▶ Influencing policy makers
- ▶ Understanding of what affects adherence
- ▶ Team/collaboration formation
- ▶ User input for product design
- ▶ Messaging for promotional efforts

Gap analysis

Based on the expert and patient interviews and the multi-stakeholder discussion game, a gap analysis will be undertaken in order to understand the gaps in patient understanding and the gaps in data and medical researcher's knowledge in understanding patients.

This will look to see the level of knowledge and understanding on the value of data, the views on data sharing, the understanding of what happens to patient data on one side and the needs, expectations and objectives of patients in sharing their data on the other side.

Development of educational material

- a. Based on the outcomes of the PIP workshops, specific points will be focussed on for the development of educational and other informational materials. These points will be considered the most vital made by patients and experts together.
- b. eTRIKS WP6 and WP7 members will work together to form the educational materials so that they are framed in a way that is aligned to European legislation.

Dissemination of educational material

Educational material will be made available on or to:

- eTRIKS.org website (Appendix 5)
- Patient organisations
- Through supported projects
- Through multi media outlets

Who in eTRIKS will be involved?

Leads: Scott Wagers, Anthony Rowe

Contributors: Trevor Garrett (WP6), Chris Marshall (WP6), Scott Wagers (WP6), Neil Fitch (WP7), Anthony Rowe (WP6).

Early Outcomes

Appendix 6

Play Decide website – The eTRIKS made version of the Play Decide game has been uploaded onto the official Play Decide website for access to all who are interested in the game.

Appendix 7

Two Play Decide games have been arranged and conducted.

1. Melanoma Patient Network Europe – Annual Meeting, Leuven, March 18th 2016
2. Lorentz center conference - translating data to health. Amsterdam, March 21st – 24th

The value of medical research data and its reuse. The participants were asked on what areas do they think there needs to be more effort to build awareness?

Areas identified through patient teleconferences and gap analysis:

1. Understanding how data is shared
2. The value of being able to reuse datasets
3. The degree to which personal data can be de-identified
4. Why standards are not being used

Time frame for input and exploitation

Task	2015					2016							
	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul
To organize and conduct TCs with patients and patient representatives to garner views and insights.													
Preliminary patient/patient representatives TCs													
Summary outcome report based on TC discussions													
TC with WP6 to discuss FtF Agenda in alignment with WP2 and WP4													
Multimedia marketing													
Face to Face meeting with patients, patient representatives and researchers.													
Location of meeting determined and booked													
Invite and agenda to be sent to prospective community members													
Administrative management of FtF													
FtF Event													
Development of educational material.													
Executive summary of the FtF event drafted and agreed													
Members of eTRIKS and other volunteers assigned tasks to develop the educational material cited in the plan.													
Dissemination of educational material													
Website													
Patient organisations													
Supported projects													
Multi-Media													

List of abbreviations

FtF – Face to Face

TC – Teleconference

PIP – Patient Input Plan

Appendix 1

The call for patients to interact with eTRIKS

Title: How can patients help make sure research data is used to its maximum potential?

Description:

The IMI and EFPIA funded eTRIKS project is reaching out to the patient community to gain insight and support that will help us meet the full potential that European medical data has to offer. Patient's views will be used to develop educational material, for the practical purpose of peer-to-peer learning, so that general understanding of the importance of data and its reuse becomes more widespread.

Required participation: A 30 minute teleconference with individuals to establish views on the value and sharing of data; in addition to an optional one day face to face meeting planned for April 2016.

Opening date: August 1st 2015

Closing date: December 31st 2015

Contact email: trevorgarrett@biosciconsulting.com

Assign a category: Clinical Trial, Research Data, Ethics

Assign a provider: Innovative Medicines Initiative and EFPIA

Detailed Description

Across Europe health researchers are collecting more and more information about diseases and treatments and how they impact individual patients. Often data is stored in incompatible, inaccessible systems that make it difficult or even impossible to reuse the information to improve patient outcomes. The challenges to using the data to their full value may be both practical and ethical.

eTRIKS is a pivotal project funded by the Innovative Medicines Initiative (IMI JU) that focuses on knowledge management support for a broad spectrum of national and international medical research projects. Our focus is to help translational researchers improve the efficiency of translating quality data into quality patient treatment, by providing a platform that enables efficient **Integration, Staging and Exploration** of clinical and research data.

eTRIKS is looking to inform medical researchers about the value of data and to provide practical advice on making data more valuable through ethical sharing. To do this we want to bring together patients, eTRIKS expertise and supported project representatives, to gain insight into the value of data and data reuse. The output of the plan will be educational material that will be used to widen understanding of data and its reuse.

Overview

1. **Interviews by teleconference.** TC interviews with patients and patient representatives will be conducted to gain views and insights. The scope of the patient cohort, should cross disease fields and national borders, to gain a wide distribution of perspectives.
2. **Face to Face meeting** in April 2016 with patients, patient representatives and researchers. This will be a full day meeting with patient representatives to be attended by a broad range

of experts involved in data management, software development, analytics and eTRIKS supported projects. The objective will be to plan the development of educational material on the need to share and reuse data.

3. **The development of educational material.** Members of eTRIKS and other volunteers will be assigned tasks to develop the educational material decided upon during the face to face meeting in April.
4. **Dissemination of educational material.** This will be done through the IMI, patient organisations, supported projects and through multimedia outlets.

Appendix 2

Patients engaged and Questionnaire

Patients

Nine patients and patient representatives were interviewed, eight were female and one was male.

Five countries represented included: United Kingdom, Netherlands, Cyprus, Portugal and Sweden.

Six disease domains were of interest to the patients and they include: Asthma, Charcot-Marie-Tooth disease, Rheumatoid Arthritis, Lipoprotein lipase deficiency and Melanoma.

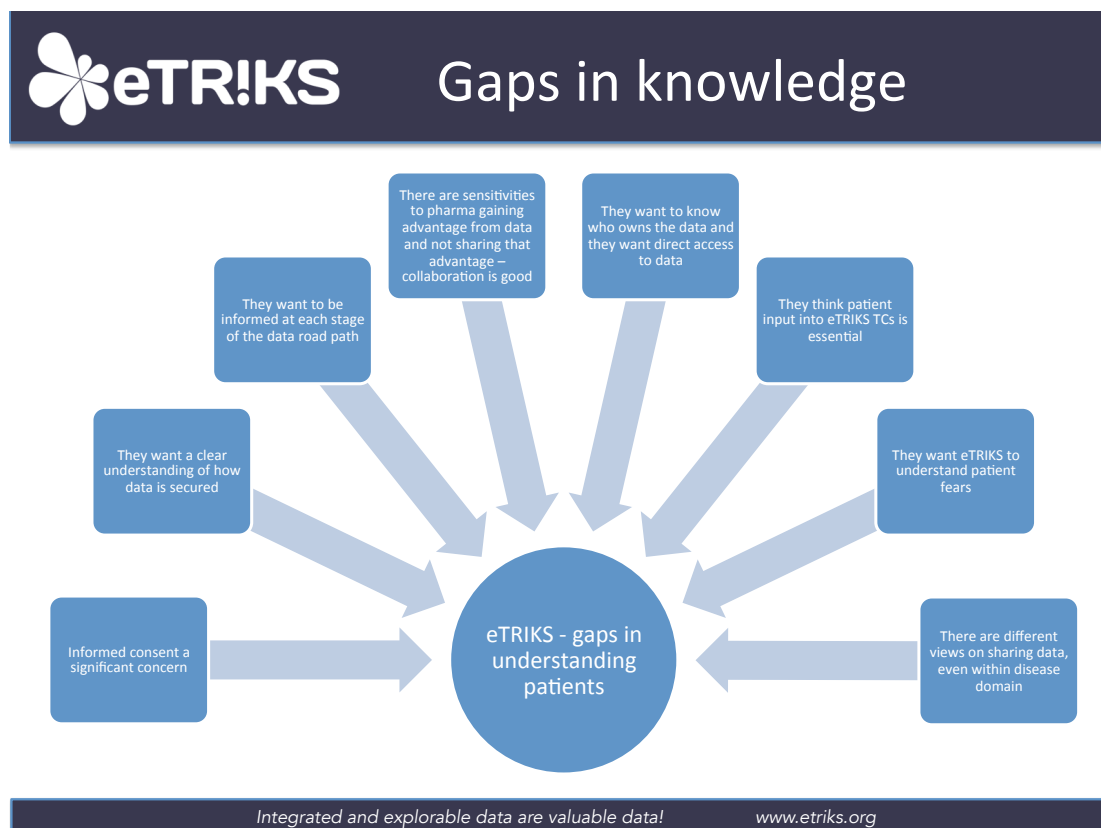
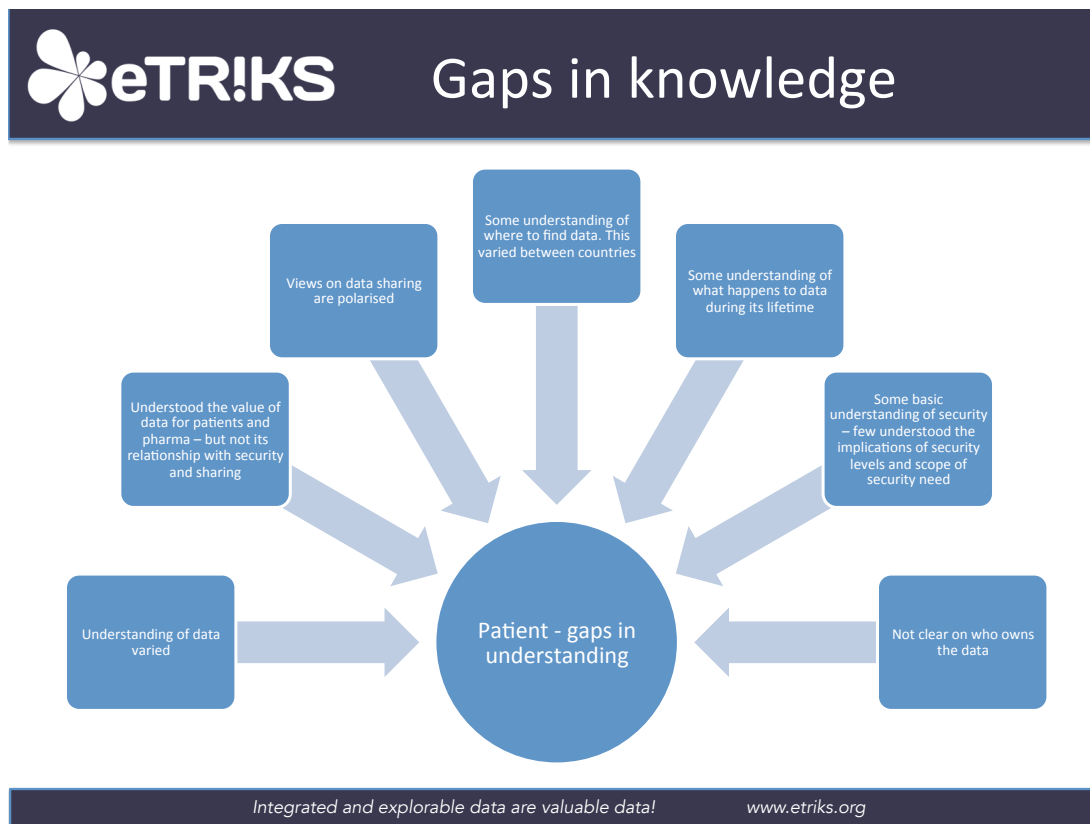
Some patients had previously participated in medical research projects. Understanding of subject matter varied significantly, between the interviewees.

Questionnaire

15. Have you participated in a research study, can you say which?
16. What do you understand by the word data?
17. What do you know of the value of data?
18. How do you feel about sharing data?
19. Do you expect your data to be shared between one or several projects?
20. What do you think happened to your data? and why do you think that?
21. What does data security mean to you?
22. What is pseudonymized data?
23. Are you familiar with the relationship between Data Value and Data Security?
24. Where have you seen information about your data, and where would you look for it?
25. Do you have any questions around data and its value?
26. Do you think this idea is worthwhile?
27. Would you be interested in a face-to-face meeting to generate educational material for the wider patient community?
28. Can you recommend a patient or patient representative that would be interested in discussing the value of data and data sharing.

Appendix 3

Gap Analysis



Appendix 4

Play Decide Game Overview

Play Decide is a discussion game that focuses on the key issues pertinent to the group that plays. It encourages a spread of actors to try and understand alternative views and aims to align those views.

The Play Decide board outlines the framework of the discussion and provides a series of positions, which the group can ultimately agree with, or disagree. Players scan the cards provided (Information, Issue and User Story – see below) and identify the ones most interesting to them.

The information cards efficiently describe a broad range of technical points of the subject matter, allowing the group to be quickly informed on matters critical to the discussion. Even without prior knowledge, members will be able to effectively contribute to the discussion.

Once discussion points of interest are identified, the group discusses. After the discussion, the group's views on the position points (outlined on the board) are decided. The decisions are then uploaded onto a web portal to be integrated with the views of many other discussion groups.

The Value of Data and its Reuse Play Decide Game

Across Europe health researchers are collecting more and more information about diseases and treatments and how they impact individual patients. Often data is stored in incompatible, inaccessible systems that make it difficult or even impossible to reuse the information to improve patient outcomes. The challenges to using the data to their full value may be both practical and ethical.

Datasets that are in a standardised format that makes combining them with other datasets are more valuable. They are more valuable because they can be reused as part of studies. By combining datasets researchers aim to answer scientific questions which are not possible to answer with smaller individual datasets. Poor adoption of standards, data privacy regulations, organisational policies, and a general lack of appreciation that data has value beyond its original use are all barriers that limit the value society gets from medical research data.

On what areas do you think there needs to be more effort to build awareness?

1. The value of being able to reuse datasets.
2. Understanding how data is shared.
3. The degree to which personal data can be de-identified
4. Why standards are not being used.
5. Other points of interest

Aims of the game

- Clarify what your opinions are

- Work towards a shared group vision
- Let your voice be heard in Europe

Information Cards

Info Card 1	Info Card 2	Info Card 3
What is special about medical research data?	What is medical research Data?	What happens to medical research data?
Medical research data can be compiled, standardized and integrated with a wide range of data drawn from multiple projects from a variety of disease domains. This data when researched enables a more refined understanding of the mechanisms of disease and provides a strong basis for the development of treatments that target phenotypes, as opposed to symptoms of disease.	<p>Data acquired during clinical trials. Data can be presented in many forms depending on the technology used for sample analysis and protocols followed for delivery.</p> <p>There are different levels of data:</p> <p>Level 1 – Raw data Level 2 – Processed Data (standardised, curated, normalised) Level 3 – Modified data through analysis and validated Level 4 – Integrated datasets</p>	Data is standardized and stored in databases designed to host data securely. Data can be accessed for processing and or study. Data can be anonymised so that there is no chance of identifying patients. Data is analysed using statistical and analytical methods. Trends and markers that indicate disease and the underlying cause of disease are found within the data, and used to develop future diagnostics, patient care and medicine.
Info Card 4	Info Card 5	Info Card 6
The six steps used to protect patient data	Patient consent	Who produces medical research data?
<ol style="list-style-type: none"> 1. Know what assets you need to protect. 2. Know what the threats are to your assets. 3. Assess probability and impact of the threats being enacted. 4. Identify the appropriate counter measures to prevent threats from being realised. 5. Implement the measures. 6. Continue monitoring. 	<p>This is the means by which a patient chooses to accept the conditions of a clinical research trial. The trial coordinators provide the recruit with every piece of information pertaining to the trial that a recruit would reasonably expect to be informed on.</p> <p>Patient consent can be added as well as taken away. If asked, patients can provide further consent.</p>	Partners and affiliates that are registered, recognised and conducting research authorized research. These normally include pharmaceuticals, academic institutes, hospitals, CROs and some small to medium enterprises.

Info Card 7	Info Card 8	Info Card 9
Personal identifiers	Data reuse	Data confidentiality and Integrity
<p>These are pieces of information associated to data that can be used to identify an individual.</p> <p>These markers uniquely identify an individual either directly, for example, by name, address or phone number; Or indirectly by combining several of them for example; date of birth and zip code in small or middle size cities.</p> <p>Genetics is a recent addition to the list of identifiers.</p>	<p>Processing already existing research data for a purpose not originally planned for. For example, health data collected to conduct a clinical trial on a given intervention, which are subsequently used to compare the results of another intervention, or a study by another company.</p>	<p>There are two aspects to health data that should be considered when assessing threat; data confidentiality and data integrity. Understanding the value and sensitivity of your data is a step towards mitigation of any potential threat. Relating threat to the potential fallout in the event of a breach should provide sufficient drive for any data owner to ensure the security of their health data.</p>
Info Card 10	Info Card 11	Info Card 12
Data types and standards	Data Security	Data Hosting
<p>These are broad and varied and are currently a source of rich discussion. Standardised data can be easily shared and integrated with other data types. This enables a far richer opportunity for study and greater opportunities to discover important markers of disease and subsequently treatment.</p>	<p>Data must be protected. The host system needs to be secure, both technically and operationally. The process to access and make changes to data must be well controlled. Data security entails anonymisation at different levels, and the confidence in the applications used to analyse the data have also to be validated for use. Threat analysis needs to be conducted so that when protecting the data, all forms of possible disruption are considered.</p>	<p>Data hosting is conducted using databases that can manage very large amounts of information. The hardware used must have back up facilities in times of unexpected problems. For example power cuts and surges and accidental deletions. The processes to enable access to data must be very stringent.</p>

Info Card 13	Info Card 14	Info Card 15
Who has access to and analyses medical research data?	Applications of data	The value of data
Only those that are cited in the consent form as having access to the data can work on the data. There are two basic categories of actors that should have access. The owners of the data, ie those who produce the data and associated partners. In addition, those who manage the process of curating and securing the data also have access, but normally to a lesser extent.	The fundamental application of medical research data is to enable translational researchers to develop new treatments for patients and diagnostics for GPs, consultants, and Medical laboratories.	The value of data increases with greater adaptability. If recognized data standards are employed the ability to integrate the data with other sets increases. There is a correlation between data integration and value. There is also a relationship between value and security. The greater opportunity to share, the more interest in its use will be provoked. Increased security reduces chances of sharing the data, which decreases the value of the data.
Info Card 16	Info Card 17	Info Card 18
Retrospective research	Data sharing	Who has medical research data?
Retrospective research refers to work in which the study participants are not directly approached by a representative of the project, and in which data needed for the research project have already been collected for either another scientific research project or for healthcare.	The consent form lists what can be done with the datasets once acquired. This includes the sharing rights of the project. The more researchers that have access to data, the more opportunities there are to discover something useful from the data. To share the data, the data must be in a state conducive to integration.	Medical research data is normally held securely in larger companies such as the European Federation of Pharmaceutical Industries and associations members (EFPIA), organisations including the European Medical Association, and some universities.

Info Card 19	Info Card 20	Info Card 21
Data Standards	European research	Who owns medical research data?
Before you conduct an analysis of data, you must first ensure a certain level of data quality through standardization and curation, so that new datasets can be meaningfully integrated with all other available data. Aligned data enables high quality: data storage, access, extraction, sharing and analysis. It is this type of data management that provides a greater opportunity for discovery.	<p>Calls are periodically released at the European level for interested consortiums to submit proposals for research into various disease domains. The Innovative Medicines Initiative is one such funder.</p> <p>Data transfer between countries in Europe is stalled by many restrictions, but anonymised data is much less restricted than identifiable data. A lot of the issues around data sharing go away when you can't identify individual patients.</p>	The organisations that produce the data generally own the data. Ultimately the owners are responsible for the data too.
Info Card 22	Info Card 23	Info Card 24
What does the future of medical research data look like?	Data analysis plans	Cross Project agreements
<p>Fully standardized and Integratable.</p> <p>There is a call for turning medical data public, to provide as much access to it as possible.</p> <p>Continuous monitoring.</p> <p>Genetic data of the future will be much more informative than it is now.</p>	<p>Data analysis plans are programs that describe the uses of the data produced within a medical research project.</p> <p>Observational study – The plans foster the use of standards, and lay out how the data can be rendered integratable so that the projects can get the most out of the data.</p> <p>Interventional Study – DAPs describe what the project partners are allowed to do with the data. This is part of the project approval process.</p>	<p>These are agreements between projects that enable the transfer and access to data, enabling data treatment, storage and greater opportunities for analysis.</p> <p>The legal agreements used to enable data sharing include:</p> <ol style="list-style-type: none"> 1. CDA – Confidential Disclosure Agreement 2. MTA – Material Transfer Agreement

Issue Cards

Issue Card 1	Issue Card 2	Issue Card 3
Impact of medical research data	Incomplete understanding of data management	Patient requirements
Impact of data is related to its integratability, which enables greater sharing. The more sharable datasets are, the greater impact on research studies they will have. Greater impact increases the value of the data.	Translational research is an evolving field, which is relatively new to many researchers. When planning a medical research project, quite often the provision for data management is overlooked, or underestimated. The importance of standardizing data is not universally accepted, and there is very often misinterpretation of the legislation governing what can and cannot be done with data, in all its forms.	<p>Patients can be stratified according to their priorities. Priorities include:</p> <ul style="list-style-type: none"> Data privacy vs Open data Patient engagement Disease domains Quick results Greater insight Quality of existing treatments
Issue Card 4	Issue Card 5	Issue Card 6
Loss of data	Patient engagement	New forms of data analysis
<p>Can this be made impossible? If so, does this affect data security and privacy?</p> <p>How much effort should be made to guarantee preservation of data?</p>	<p>What was possible at the beginning of the study project may be very different a year down the line. New technologies, progress, unexpected blockers, partner movement and change of focus all affect the direction that a project takes.</p> <p>It is critical to have patients involved in discussions that impact projects, so that their insight can help guide the course the project takes, and ensure that patient perspectives are seriously considered.</p>	<p>With the advent of translational research, new statistical and topographical tools have been developed that enable new ways to interpret data. These tools integrate old data with new, providing new possibilities to develop a treatment for a given condition or disease. On the one hand we have a very exciting new way to develop medicines, but on the other hand we cannot ignore patients privacy and go and reuse data without first due consideration.</p>

Issue Card 7	Issue Card 8	Issue Card 9
Data privacy loss	Data Protection	Lack of public information
<p>The Patient - Patient personal data may no longer be private. Could be used for things that the patient does not agree with. Control is lost.</p> <p>The researcher - If patient privacy is lost, the consequences could include loss of patient trust in the idea of researchers using data responsibly. Wider news of a breach of privacy would compromise the researcher and associated company considerably.</p>	<p>Data holders need to understand the nature of the risks and safeguards put into place concerning data protection.</p> <p>There is a huge body of data users uninformed about EU legislation, albeit not specifically binding itself, national law does hold groups accountable.</p> <p>EU directives must be adopted by national law, but can be interpreted differently in different countries.</p>	<p>Should the public be informed of what is done in medical research projects? Do they have a right to know?</p>
Issue Card 10	Issue Card 11	Issue Card 12
Data standards	International law governing data	Data legacy and reuse
<p>Standardizing health data is socially, technically, economically and politically very challenging. However, non-standardised data runs the very real risk of becoming old and forgotten.</p> <p>Perhaps 10% of the world's health data is standardized, but this figure could be optimistic. There are data standards already available and recommended, for example the multiple suites of clinical trial standards recommended by CDISC.</p>	<p>In 2015, a new EU regulation stipulates that new users of medical research data will have to gain patient permission, unless there is a specific exclusion to the regulation permitted. Exclusion to the regulation will need to be applied for.</p> <p>Regulations are often adjusted each passing year. Staying abreast of data protection legislation is a significant challenge. To help, official publications are frequently released to explain the changes.</p>	<p>Data that is anonymised can be reused without permission given the appropriate authority.</p> <p>However, the reuse of pseudo-anonymised data needs to be considered very carefully, as quite often patient consent forms do not stipulate the reuse of data. This means that prospective new users of health data do not necessarily have direct permission to analyse already used data.</p> <p>New techniques can erode the anonymity of legacy data and samples.</p>

Issue Card 13	Issue Card 14	Issue Card 15
Patient confidence	Data compliance guidelines	Legal agreements for data sharing
<p>Patients confidence is lost if they believe that studies are not adhering to good compliance of corporate policy, national law and international regulation into data protection.</p>	<p>The greater the stringency on compliance, the less a researcher can do with the data. In other words, highly protected data affects utility of data.</p> <p>This can be helped by being well informed on the new advances in data regulations and in the methods being used to threaten data security.</p> <p>How should the scales be set between utility and security?</p>	<p>Agreements are complex legal documents that enable different projects to share data.</p> <p>Project partners have legal teams to review the documents. This takes time, and can be stalled for a number of reasons. This prevents swift access to data, and ultimately development of new insights into disease.</p>
Issue Card 16	Issue Card 17	Issue Card 18
Exploitation and misuse of medical research data	Under utilization of medical research data	Data Integrity
<p>Does data actually get misused? If so, is the fallout that bad?</p>	<p>Under utilization of data is not reliant on the want of trying. It's related to the difficulty in sharing and reusing.</p> <p>Landscape Blockers – Data is often unaligned and un-integratable and so difficult to share.</p> <p>Technical Blockers –Technology today is largely modular, it's the breadth of available technology that has become the blocker.</p> <p>Mind blockers - Institutions fearing the costs but not fully appreciating the benefits of sharing.</p>	<p>Researchers use data to yield new insights into disease. To do this, they need to be certain that the data they have is exactly what they think it is. Researchers need to be certain that their conclusions are true to the original data generated. This ensures research validity and integrity. The corporate world is very interested in this, as integrity is vital to success. This is a pillar of confidence all data stakeholders should hold.</p>

Issue Card 19	Issue Card 20	Issue Card 21
Are the risks related to data understated?	Who gets affected when management of data goes wrong?	Patient samples
The risks are often understated, but the mitigation plans are available. The pressure on researchers, exploitation by insurance companies and banks, and data theft are all real issues that are considered when assessing risk.	Ultimately the patient suffers. Pharmaceuticals lose out financially, academic institutes lose out on quality publications, and small to medium enterprises lose out on the very positive outreach that can come from success.	Who has right of access, and who decides on access? Quality samples, storage and transport can be a bottleneck in medical research. This relates to training of staff, costs and national and international laws.
Issue Card 22	Issue Card 23	Issue Card 24
Data security 1	Data security 2	Continuous health monitoring
As well as the technical IT strategies of firewalls, data provenance, passwords, intrusion alerts and the adoption of security updates, bioinformatician strategies to protect data also include pseudo-anonymisation (encrypted data with existing access key) and complete anonymisation of data (encrypted data with identifiers removed and with no access key available). Each of these bioinformatician measures has advantages and disadvantages.	Pseudo-anonymised data can through special keys be re-associated to the patient. This reduces data protection (slightly), but is particularly useful if the data can be used in some way to benefit the patient directly. Once the data has been completely anonymised it is not possible to relate the data to its source, increasing the level of patient protection but preventing the patient from getting	There are two possible approaches: 1. Health care led – Health providers say you need to wear this device. 2. Voluntary – People wear by choice. Does this matter?
Issue Card 25		
Data Anonymisation		
Many patients require that their medical research data be anonymised, but is data anonymisation possible in today's internet age? There is a growing belief that data anonymisation is in fact impossible.		

Story Cards

Story Card 1	Story Card 2	Story Card 3
Translational Researcher	The Activist	Project Coordinator
I take data, study it and try to provide a clear path for the development of high quality treatment based on it. High quality data includes data that I can re-use. This means that the data I have can be integrated with any new datasets that I receive so that new insights can be identified. I worry that I cannot find a way forward through the data.	I don't trust everything that is being done within medical research. I would like to see that what's being done, is done in a transparent way. If this is not the case I may take steps to make sure it happens.	People need to know about the project I run. They need to know it is being run well and I need to know that the project is moving forward. I want to see updates, good practice and good progress.
Story Card 4	Story Card 5	Story Card 6
Project Participant (Patient)	Relative to the Project Participant	Data Curator
I want to see my data used well. I want to make sure that what I have consented to is what is happening. I also want to know that if I don't benefit from the data, at least others will. I want to have an impact on future treatment.	I want to be certain that everything that happens to my relative's data is done efficiently, and with the best of intentions. I want to see my relative helped. I want to know about any possible impacts on me and other relatives.	Librarian for data. I am concerned about semantics and naming conventions. I spend a lot of time in front of a computer preparing data for entry into databases. I am interested in interfaces used for entering data and tools that enable automated loading. I'm concerned about the data provenance.

Story Card 7	Story Card 8	Story Card 9
The Project Funder	Data Manager	Academic Professor
Where and how will the money be most effectively used? What are the priorities? What diseases and initiatives need the most attention? How can I best improve the success of research? Who do I need to know? What's the most up to date information. Lots of people are hounding me. I need to make the right decisions.	I have worked a few years for a Clinical Research Organisation. I see a lot of effort in cleaning databases. "There will always be manual work". I see a lot of value in standards as they will limit the amount of data that is not comparable and minimize the transformational work. I spend most of my time querying people on incorrect data.	What drives me is the idea I can make a difference. My work can benefit many positively. What ever I do must translate into publications. That means I have an interest in success and good quality output.
Story Card 10	Story Card 11	Story Card 12
Software Developer	Pharmaceutical Manager	Insurer
I write software for data managers, bioinformaticians, analysts and others, to enable them to manage and analyse data as effectively as possible.	I am concerned about public health and that the company I work for is successful. This means I may compete with other pharmaceutical for the same data.	I want access to data so I can accurately foretell my liabilities. The more data the better, I want to analyse them statistically and individually, so that I can understand how far away from the norm my clients are.

Play Decide Board


<p>The Value of Data</p> <p>Across Europe health researchers are collecting more and more information about diseases and treatments and how they impact individual patients. Often data is stored in incompatible, inaccessible systems that make it difficult or even impossible to reuse the information to improve patient outcomes. The challenges to using the data to their full value may be both practical and ethical.</p> <p>Datasets that are in a standardised format that makes combining them with other datasets are more valuable. They are more valuable because they can be reused as part of studies. By combining datasets researchers aim to answer scientific questions which are not possible to answer with smaller individual datasets. Poor adoption of standards, data privacy regulations, organisational policies, and a general lack of appreciation that data has value beyond its original use are all barriers that limit the value society gets from medical research data.</p> <p>On what areas do you think there needs to be more effort to build awareness?</p> <ol style="list-style-type: none"> 1. The value of being able to reuse datasets. 2. Understanding how data is shared. 3. The degree to which personal data can be de-identified. 4. Why standards are not being used. 5. Other points of interest. <p>Aims of the game</p> <ul style="list-style-type: none"> - Clarify what your opinions are - Work towards a shared group vision - Let your voice be heard in Europe - Enjoy discussing! 	<p>Story Card</p>	<p>Info Card</p>	<p>Info Card</p>	<p>Initial Thoughts</p> <p>Write down your initial thoughts, use White cards to add issues.</p> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
	<p>Issue Card</p>	<p>Issue Card</p>	<p>Challenge Card</p>	

<p>Guidelines</p> <p>You have a right to a voice: speak your truth. But not the whole truth: don't go on and on.</p> <p>Value your life learning.</p> <p>Respect other people. Allow them to finish before you speak.</p> <p>Delight in diversity. Welcome surprise or confusion as a sign that you've led in new thoughts or feelings.</p> <p>Look for common ground. "Our" emphasises difference, "and" emphasises similarity.</p>	<p>Three stages</p> <div> <p>1. Information Clarify your personal view on the subject, reading and selecting the cards which you feel are most important for you. Place your cards on the placemat and then read them about to the other players.</p> <p>■ 30 MIN.</p> </div> <div> <p>2. Discussion Together with the other players, start discussing and identify one or more larger themes that you all feel relevant. Everyone gets a chance to speak. Put your cards on the table to provide your arguments for each theme.</p> <p>■ 30 MIN.</p> </div> <div> <p>3. Shared group response Reflect on the theme(s) that the group has identified and the cards that sustain the arguments. As a group, can you reach a positive consensus on a policy position that reflects the group's view? You can formulate a new common policy, if you wish.</p> <p>■ 20 MIN.</p> </div>	<p>... plus one</p> <p>4. Action Go to www.playdecide.eu to:</p> <ul style="list-style-type: none"> - Submit the results of your group to the Decide database; - See how other European countries think about this issue; - Read more about this subject; - Download a game kit to play with your friends or colleagues; - Learn how you can make a difference after playing Decide.
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Appendix 5

The eTRIKS Patient Input Platform Website

This website contains all the information necessary for the play decide game to be conducted.



HomeThe ProjectCase StudiesBlogServices PortaleTRIKS LabsPress Releases

Reduce the effort needed to integrate, explore and preserve your data

We provide advice, open source platforms and training to translational research projects.

eTRIKS is an IMI project that is funded to support other projects. If you know of a project that eTRIKS could support [contact us here](#).

Join our community and get free resources from eTRIKS including a **data management plan guide**.

First Name *

Email *

JOIN NOW!

eTRIKS Code of Practice on Secondary Use of Medical Research Data

Get a copy of the Code of Practice here


New eTRIKS LAB established - The Patient Input Platform

Widening understanding of the value and reuse of medical research data amongst patients

Enter the Patient Input Platform here


Portfolio of Resources

eTRIKS Training



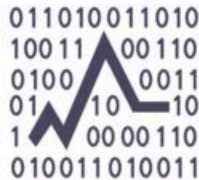
Training on the use of the eTRIKS platform to all supported partners.

Standards starter pack




Data harmonisation begins with standards.

eTRIKS Public Platform



Explore public datasets and see the eTRIKS platform in action.

Code of practice



Uncertain about what you can and cannot do with medical research data?

32

Welcome to eTRIKS Labs!

Current Developments



ETRIKS Harmonisation Services



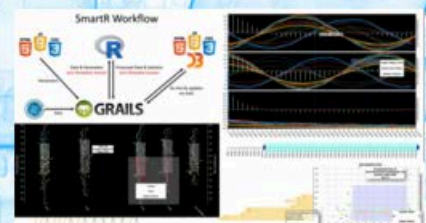
SNF



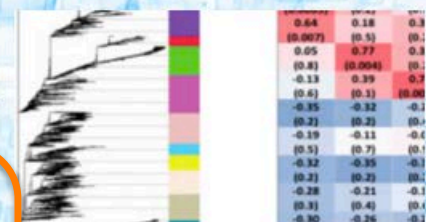
Disease Knowledge Base



Patient Input Platform



SmartR



WGCNA

Patient Input Platform

The Value of Data and its Reuse - Developing Educational Material

Across Europe health researchers are collecting more and more information about diseases and treatments and how they impact individual patients. Often data is stored in incompatible, inaccessible systems that make it difficult or even impossible to reuse the information to improve patient outcomes. The challenges to using the data to their full value may be both practical and ethical.

Sharable, or standardised integratable data, is valuable data. In this form data is compatible with all other standardised forms of data, which subsequently enables broader and richer analysis. The challenges that stop data becoming integrateable are the non-adoption of data standards, national legislation and organisational policy and a lack of understanding of the importance to share data.

eTRIKS is looking to inform medical researchers about the value of data and to provide practical advice on making data more valuable through ethical sharing. To do this we want to bring together patients, bioinformaticians, translational researchers and software developers, to gain a broader insight into the value of data, data sharing and data reuse.



Patients, meet
the data experts

Discuss the
issues

Find the gaps in
understanding

Contribute to the growing understanding of the value of data

We will use a play decide game to bring together experts in medical research and patients to discuss the issues affecting the value of data, and to identify the gaps in understanding. The output of the discussions will be used to widen understanding of data and its reuse, through a World Wide Web portal, and by developing educational material that will be disseminated through vectors such as clinical trial consent forms.

Play Decide

Play Decide is a discussion game that focuses on the key issues pertinent to the group that plays. It encourages a spread of actors to try and understand alternative views and aims to align those views.

The Play Decide board outlines the framework of the discussion and provides a series of positions, which the group can ultimately agree with, or disagree. Players scan the cards provided (Information, Issue and User Story) and identify the ones most interesting to them.

The information cards efficiently describe a broad range of technical points of the subject matter, allowing the group to be quickly informed on matters critical to the discussion. Even without prior knowledge, members will be able to effectively contribute to the discussion.

Once discussion points of interest are identified, the group discusses. After the discussion, the group's views on the position points (outlined on the board) are decided. The decisions are then uploaded onto a web portal to be integrated with the views of many other discussion groups.

Review the discussion board here

Play Decide Board

Read the information cards for quick understanding of the subject matter

Information Cards

Review the issues

Issue Cards

Understand the actors

Story Cards

Contact Us


For further information about the patient input platform, please contact scottwagers@biosciconsulting.com or trevorgarrett@biosciconsulting.com

Acknowledgement


Authors would like to acknowledge [Play Decide](#) for open access to their game framework and resources. We would also like to acknowledge the patients and patient representatives that helped shape the content of our play decide game.

Appendix 6

Play Decide Website

Log out My account About

[Play](#) [Get involved](#) [View the results](#) [Share your results](#)



PlayDecide is a discussion game to talk in a simple and effective way about controversial issues.

[More about PlayDecide](#)
[Learn how to play](#)

INSPIRING STORIES

[Democracy played out conscientiously - PlayDecide at the Peggy Guggenheim Collection in Venice](#)

By Andrea Bandelli - On 23 April 2012 the Playdecide kit on Neuroscience was used in a slightly unusual setting - an art museum. The Peggy Guggenheim Collection in Venice organized a series of 4 workshops under the title "Be Creative - four classes to reawaken adult creativity". James Bradburne, director of Palazzo Strozzi in Florence and moderator of the 4 workshops, presented this initiative...

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DECIDE

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[Download the manual](#) to learn how to create a PlayDecide kit. It describes the process to prepare and develop a kit, with several references to previous experiences and projects.

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eTRIKS - The Value of Medical Research Data and its Reuse



The Value of Data and its Reuse - Developing Educational Material

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Contribute to the growing understanding of the value of data

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Project information

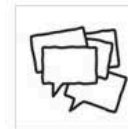
[Details](#)
[Content](#)
[Events](#)
[Results](#)

Project toolkit

[Announce event](#)
[Share results](#)
[Create decide kit](#)
[Create template](#)
[Write an inspiring story](#)

Contact

Questions, comments, thoughts? Contact the author directly.



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Appendix 7

Results of first play decide game

Melanoma Patient Network Europe – Annual Meeting, Leuven, March 18th 2016

The value of medical research data and its reuse. On what areas do you think there needs to be more effort to build awareness?

Out come of discussion *(averaged from 22 active participants)*

The Play Decide participants discussed the cited areas using the information and issues cards to support discussion. At the end of the game the participants were asked to rate the importance of each area from one to six. One being not at all important, and six being essential. The outcomes of this rating exercise were averaged between participants.

Areas

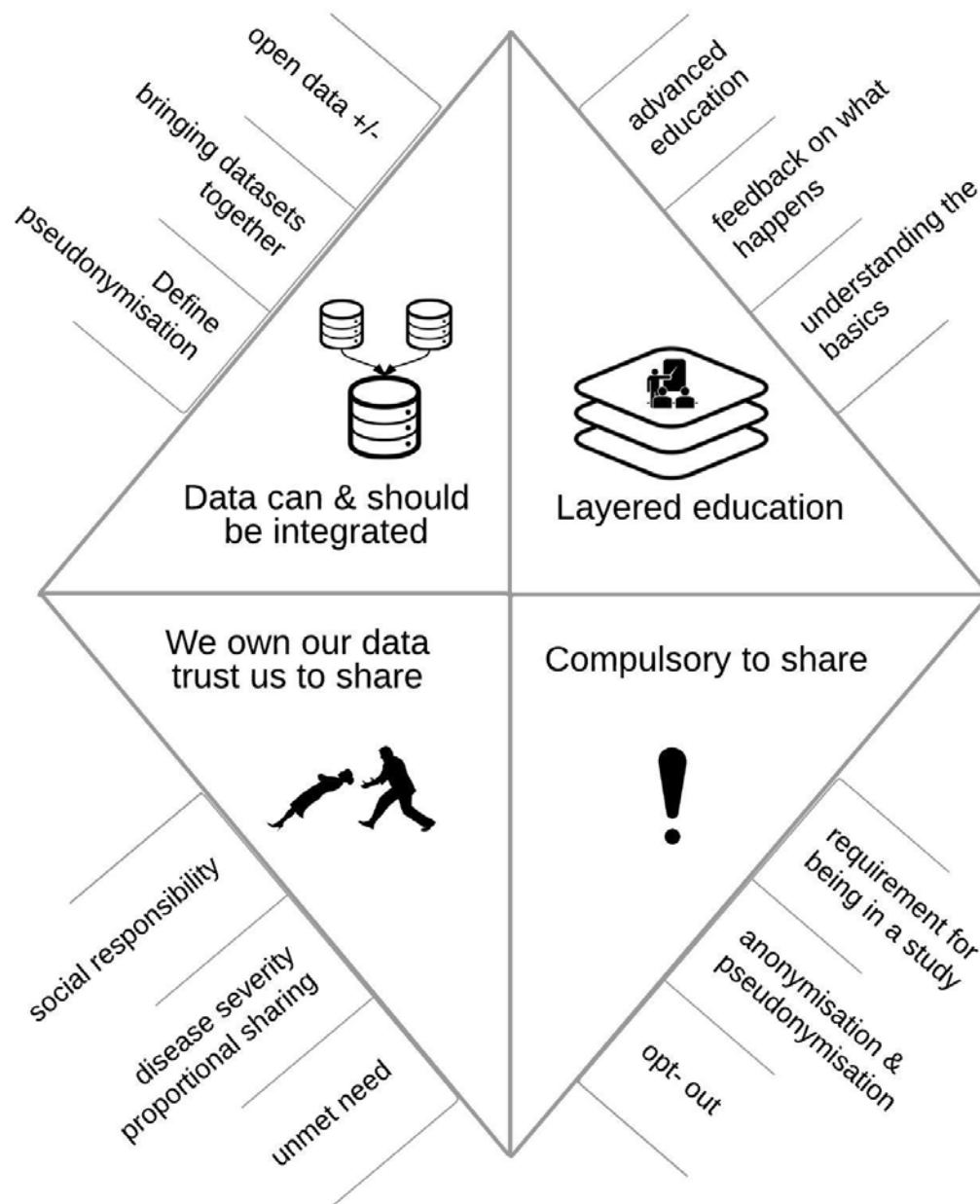
5. Understanding how data is shared
6. The value of being able to reuse datasets
7. The degree to which personal data can be de-identified
8. Why standards are not being used
9. Other points of interest

	1	2	3	4	5	6
Understanding how data was shared					✓	
The value of being able to share data					✓	
The degree of which personal data can be de-identified					✓	
Why standards are not being used				✓		
Others					✓	

Other points of interest:

- When data can be accessed/shared readily across EMR (opting out system)
- Integrity of data sets is a concern for when re-used multiple times
- Beware of consent revocation & need for re-consenting when re-using data
- Patients perspective on valuable data analysis
- Data should always be open
- Exploitation and re-use of data

- Information of the sharing of data
- 101 of data, what is data, how is it generated, how is it used, who owns/holds the data?
- Education – How is data used, Legal, data glossary, data types and harmonization.
- Value back to society, the value of freely giving away data.
- Motivation behind sharing.
- Time limits on data use? How do patients gain feedback? Stage of the disease, how can this be supported?
- Selection of cohorts in studies relating to data quality.
- Standardised sample collection and subsequent security of data starting with sample collection.
- What are the legal barriers to data sharing?
- Data confidentiality and disease stage stratification
- Compulsory submission of patient data. Opt out causes biased in a dataset and ultimately reduces the strength of datasets.
- Informed consent form
- Privacy
- Exploitation and misuse of data.
- Reuse and sharing of data crucial.
- Who has access to data?
- Open source data is key to sharing.
- Integrity of datasets after multiple use a concern
- Reconsent important for reuse.
- Monitoring progress and data
- Data management technology needs to be delivered.
- What impact can patients have concerning data sharing issues?
- Who owns the data?
- How informed do we need to be to agree to sharing?
- Patients contribution can be thwarted, as dialogue is driven by
- What of rare diseases.
- What is data, who collects it, how is it generated and how is it used?
- What is medical research?
- Patient access to data
- Openness in data analysis
- Risks involved – what are they?



Lorentz center conference - translating data to health. Leiden, March 21st – 24th

The value of medical research data and its reuse. On what areas do you think there needs to be more effort to build awareness?

Out come of discussion (4 active participants)

Areas

1. The value of being able to reuse datasets
2. Understanding how data is shared
3. The degree to which personal data can be de-identified
4. Why standards are not being used
5. Other points of interest

