Data
Saves
Lives

Toolkit

Data Saves Lives

Part One:

Health data 101: understand and communicate about the power of health data

Part Two:

AI: from science fiction to science fact

Data Saves Lives

Part One:

Health data 101: understand and communicate about the power of health data

Part **One:**

Health data 101: understand and communicate about the power of health data

INTRODUCING YOUR DATA SAVES LIVES TOOLKIT

Help us to spread the word about how **Data Saves Lives**

How to use the Data Saves Lives toolkit

Health data sharing is a complex area and one that is evolving at an extraordinary pace. The process has been accelerated by the introduction of new digital ways of storing, exchanging and analysing data. Incredibly, more scientific data has been generated in the past five years than in the entire history of mankind! The advent of artificial intelligence (AI) is also set to revolutionise the way in which we use health data and this will create exciting opportunities, as well as a number of challenges.

It is no exaggeration to say that the wealth of health data has already transformed public health in some areas and has phenomenal potential. It could be used to help prevent illness, improve treatments and access to them, as well as reducing unnecessary deaths. Adding AI into the mix offers the prospect of improving medical image analysis, developing personalised treatment plans and allowing remote monitoring of patients via wearable technology. There are numerous examples of real-life situations in which this is already happening.

This is just the start and the possibilities are infinite. However, to truly harness the power of health data, it needs to be shared and used effectively. At **Data Saves Lives**, it is our mission to make this a reality.

In the last 5 years, more scientific data has been generated than in the entire history of mankind

The role of patient groups and health advocates

The aim of **Data Saves Lives** is to spread the word about the benefits of responsible health data sharing and to improve health data literacy among patient communities. This is particularly relevant now that AI is being deployed in a whole range of healthcare settings. Understandably, patients and consumers may have questions about the use of health data in AI tools and it is time to discuss some of the potential implications in an informed way. **Could you help us to spread the word?**

Patient groups and advocates play a vital role in communicating messages about health data and the use of AI in healthcare, but levels of knowledge and engagement vary. Some of you are already well-informed about the subject and feel confident discussing these topics with your members or community. Perhaps you are already involved with health data initiatives such as surveys or databases? You may even have taken part in the development of an AI-based healthcare tool. Others may be less familiar with these topics and could have concerns around privacy and security.

This is where the **Data Saves Lives** toolkit comes in! It has been developed to support you in opening a positive dialogue with your members around the topics of health data sharing and AI in healthcare – what they are, how to address concerns around security and privacy and ways of making health data more accessible and engaging. This toolkit has been designed to equip you with the information and resources you need to engage with your community and with other stakeholders in a productive and confident way. It will also support you if you are considering launching your own health data initiatives.

Part **One** focuses on the value of health data and Big Data

- It explains how sharing data can significantly improve healthcare

- It provides tips on communicating effectively with your community and ways of bringing the topic of health data to life

- It also offers guidance on the use of digital health tools and provides a risk assessment tool for those considering engaging with health data initiatives

- Other valuable resources include a template for a webinar on health data and a survey that can be used to assess patient and carer confidence in health data-sharing

Part **Two** focuses on AI in healthcare

- It explains how AI is already embedded into many areas of healthcare

- It provides general communication tips and template statements that can be used in a range of materials to help simplify the complex topic of AI

- It highlights the different stakeholders and provides outlines of potential content for presentations to each stakeholder group

- You will also find template questions that can be used if you are considering involvement with a developer, as well as template survey questions for use with clinicians to gauge attitudes towards AI

Finally, the toolkit provides guidance on how to secure funding for EU projects and also advice for anyone who is considering setting up a national version of **Data Saves Lives**

This comprehensive toolkit provides a wealth of useful information and ready-to-use tools that will help to ensure that your community will be part of the conversation around health data and AI in healthcare. We hope you will find it helpful.

What is Data Saves Lives?

It is a multi-stakeholder initiative led by the **European Patients' Forum (EPF)** and the **European Institute for Innovation through Health Data (i-HD)**. Our aim is to raise wider patient and public awareness about the importance of health data, improve understanding of responsible health data sharing, and establish a trusted environment for dialogue on this issue.

What is health data?

Health data refers to any data describing a person's health, their healthcare or anything affecting any health issues or diseases they may have. It can be collected by healthcare organisations and professionals, about individuals ("personal health data") or populations ("population health data"). There are many different types of personal health data, including electronic health records (EHR), national databases of prescriptions and lab tests, tracking from mobile apps and wearable smart devices and clinical trial databases. Health data is personal and private. It can contain sensitive information and must be protected.

What is 'Big Data'?

In a healthcare setting, the term 'Big data' is used to describe the extensive healthcare databases (like electronic health record systems) or networks of interconnected healthcare databases coming from multiple healthcare organisations. These databases contain health data from hundreds, thousands or even millions of individuals. Big data can be used to identify specific or unusual patterns of a health condition, to investigate the impact of different treatments or to discover rare-side-effects or long-term health outcomes.

Why is health data so valuable?

The public health landscape is changing at a rapid pace. Populations are growing and people are living for longer but healthcare budgets are not being increased in line with this rising demand. There is an urgent need for more effective, less costly and smarter medicines. Harnessing the power of health data can help us to achieve this and has already led to some significant advances.

Big Data: real-life advances

Published findings derived from Big Data include:
- Validating more than 200 biomarkers (identifying factors) predicting the risk of health disease
- Comparing approximately 8,000 treatment outcomes for leukaemia by age and unearthing a major unmet treatment need
- Analysing more than 700 million records to develop new algorithms to classify cancer risk

How is health data shared?

Data is originally collected by different organisations, for different purposes, most commonly to support the health and care to individuals. These organisations hold patient data in order to ensure that patients continue to receive the best possible care. It is generally accepted by most health systems, and by most patients, that an organisation like a hospital will examine its own collection of patient data in order to identify ways that it can improve the quality, timeliness and safety of care that its teams deliver.

However, this data can be aggregated at a larger population level, for a wider range of learning and improved healthcare for patients across a wide range of settings. This may be within a country or across many countries. Assuming individuals have provided their consent for their data to be shared beyond the original purposes for which it was collected, it can be shared via various means. From a smart device to a central computer database, from one database to another, even in physical form (although digitisation of data has greatly aided its shareability).

Data Saving Lives: cervical cancer

Analysis of the data generated by routine cervical screening of women across Europe revealed the link between HPV and cervical cancer and the need for regular screening. This has the potential to prevent illness and save lives. **Read this and other case studies** at **www.datasaveslives.eu**

How does sharing data improve healthcare?

Sharing data can benefit all sectors of the healthcare community. Patient care is more efficient and co-ordinated, and patients can take a more active role in understanding and managing their own health. Healthcare providers can design better diagnostic and care pathways and use resources more efficiently. In addition, the potential for medical research is enormous, allowing faster development of new treatments.

Data Saving Lives: Alzheimer's Disease

Clinical data was re-used from 1,000 people who had participated in research studies in Europe, to try and develop a test to detect those at risk of developing Alzheimer's Disease. Existing samples and data allowed the research to be performed quickly and at a lower cost, versus setting up a new study, which would have been a lengthy and very expensive process. The initiative was successful and a test has been developed that has the potential to identify those at the earliest stages of the disease, for whom research is likely to reveal the most effective new treatments. **Read this and other case studies** at **www.datasaveslives.eu**

How can Data Saves Lives support patient groups and health advocates to communicate about health data successfully?

The **Data Saves Lives** website (www.datasaveslives.eu) sshares relevant information and examples concerning the use of health data and how to generate easy-to-use materials about the basic concepts of data sharing, the data journey and the safeguards in place.

The website also includes case histories, news updates and a blog with contributions from key individuals involved in the area of responsible health data sharing. It also provides an overview of health data privacy rules and regulations.

At **Data Saves Lives**, we do not solely rely on our website to achieve our mission of raising awareness of the issues around sharing health data: we also have a strong social media presence; including platforms such as Twitter, Instagram and Facebook.

Could you develop your own health data project?

The short answer is likely to be 'yes'! This toolkit has been designed with template materials and guidance to help you consider possible next steps. You could even conduct a survey among members on attitudes towards data sharing. There may even be sources of EU funding to help make your project a reality. We include further information on this in section 10 of Part 2 of this Toolkit. Your community could make an important contribution to improving public health.

In summary, why should you support Data Saves Lives?

We exist to spread the word about health data sharing. Now, more than ever, it is a fundamental cornerstone of effective healthcare. Our aim is to equip you with the information you need to have a positive dialogue with your members/community on important subjects around data sharing, including:

- Understanding the basic principles of health data, why it is important and the potential benefits of data sharing
- Tackling misconceptions about data sharing
- Raising awareness of privacy issues and the need to ensure that data protection is respected
- Making informed choices about health data sharing when participating in clinical research
- Guidelines on using digital health data tools

**Encouraging an informed, open discussion about sharing health data is in everyone's interest.
We will all benefit – from individuals to healthcare systems and global populations.**

Data Saving Lives: COVID-19

The COVID-19 pandemic has highlighted some of the vital applications for health data sharing. Advances in how we collect and process health data helped national and global research communities to respond to the virus more effectively. There has been an unprecedented amount of global collaboration but there is still a need to improve patient literacy about data sharing and the use of data. **Read more** at **www.datasaveslives.eu**

EXPLAINING HOW DATA SAVES LIVES

For many people, health data sharing is not an easy concept to grasp. First, they may have no clear understanding of what data sharing is or why it is important. How does it happen and why? Is it a good thing?

Second, health data is inevitably all about numbers and statistics. Few people find this topic particularly stimulating – many people simply switch off when confronted with 'dry' facts and figures. How can we people interested in this topic and encourage them to engage?

This toolkit explains how to breathe life into data and how to illustrate the value and potential of health data sharing.

How can sharing health data benefit different communities?

Benefits to patients

- Access to personalised data can lead to more efficient and personalised care
- Greater insight into own health, making patients more health literate and offering the potential to adapt lifestyle and interact with healthcare professionals more positively
- Providing data to scientific research speeds up the development of new medical treatments

Benefits to healthcare systems

- Potential to identify at-risk individuals or populations, and speed up diagnosis
- Earlier identification of pathways in disease transmission
- Ability to predict outcomes more accurately and improve the quality and safety of treatments and care

Benefits to healthcare providers

- Ability to design better diagnostic, therapeutic and care pathways and thereby improve patient outcomes and experience
- Insights for improved planning and more efficient use of resources
- Option to participate in more clinical research
- Provides reassurance as recommendations based on more data
- Decreases bureaucracy, where data is made more freely available to base decisions and guidelines on

Benefits to medical research

- Ability to identify people who may benefit from participation in medical research
- Potential to develop new diagnostics and treatments
- Providing data to accelerate regulatory approval of new diagnostics and treatments

How can we make the topic of health data more accessible?

Many people have probably never really thought about what happens to their health data and how it could be used for the common good. They may find it difficult to appreciate how one person's data could possibly have any impact on public health. **Data Saves Lives** aims to spread the word about the value of *sharing* health data and how powerful this accumulated data can be. It is already transforming healthcare in some areas.

People often find it difficult to relate to statistics. In fact, they can be pretty meaningless unless they are placed in context. In order to encourage people to engage with this topic, we need to bring the subject to life and show how it works in the real world. When statistics are used, it is helpful to illustrate what this means in reality, e.g. 'this new treatment protocol is estimated to have identified x number of at risk patients' or 'x people took part in a recent study – that is equivalent to the population of x'.

Case studies are extremely valuable in this respect as they illustrate the human impact and provide tangible examples of the benefits of sharing health data. They help to capture the imagination about the huge potential of this subject.

Below is an example of a case study and we have included other examples in our toolkit materials.

Data Saving Lives: colon cancer

Challenge: cancer of the colon (bowel) is the second most common cancer with more than 470,000 Europeans being diagnosed every year. Routine screening is available in some countries but around half of those who qualify do not take up the offer. The challenge was to increase uptake of screening

How health data was used: Anonymous patient data from two independent sources (Maccabi Health services in Israel and the UK Health Improvement Network (THIN)) was analysed to develop a new algorithm (computer program) to calculate the risk of people aged over 50 of having colon cancer

The result: The computer program is now available as part of a colorectal cancer screening system in the UK and Israel, allowing clinicians to encourage patients at greater risk of colorectal cancer to come forward for screening.

ENGAGING WITH DIGITAL HEALTH TOOLS – CHECK BEFORE YOU CLICK

As individuals, there are many ways in which personal health data can be collected, even when we are not being actively monitored in a medical setting.

In the past, our health data was largely confined to medical records stored personally or in a family doctor's practice or hospital. Today, while some European countries still rely on paper records, digital health devices are part of everyday life. Many people wear a **smartwatch or fitness tracker**. These personal wearable devices can be used to monitor our sleep patterns, track levels of activity or calorie consumption or record pulse rate. Patients with certain health conditions may use **sensors to monitor vital signs** such as blood sugar or heart rate. Even if we do not own fitness trackers, many of us **download apps** to help manage our health. We may contribute to online patient groups or take part in online health-based surveys. Often, we make use of digital health tools without giving data protection a second thought.

This section of the **Data Saves Lives** toolkit highlights some of the issues associated with the use of digital health tools, providing advice on how to protect sensitive health data. It will support you in answering questions your members may have in this area.

What are the different types of digital health tools?

Digital health tools use computer platforms, software, apps and sensors to measure different health parameters (e.g. activity levels or sleep patterns) and collect health data about these parameters. They include:

- Smart watches
- Fitness trackers
- Mobile health trackers, e.g. to monitor heart rate
- Biosensors to monitor specific health functions, such as blood glucose levels
- Health-based apps
- Online health-based surveys

The impact of **COVID-19** on medical care

During the COVID-19 pandemic, the number of face-to-face medical consultations declined sharply and increasing numbers of people turned to apps to access support on related topics such as mental health and weight loss. Many healthcare providers also started providing remote consultations, using teleconferencing and digital health tools to help them care for patients.

Can we trust digital health tools?

Digital health tools have transformed the way people engage with their own health, allowing them to play a greater role in their own well-being. These tools make it far easier to manage some conditions and can alert healthcare professionals to potential problems at an early stage.

However, it is important to remember that all of these activities generate data about our health and well-being, some of which can be of a sensitive nature. Digital health tools increase our 'digital footprint' – the traces of information that record where we've been. And some of these tools routinely share our data with third parties, sometimes without our knowledge or adequately informed consent. Before signing up to a digital health tool, it is vital to find out what will happen to your personal data and to check whether it will be shared.

Attitudes towards sharing health data

73% of EU citizens want to share health data on the precondition that data is secure and only accessible by authorised parties.

Some 42 % of the respondents fully agree or agree that a lack trust in services providers prevents them from using digital services. The proportion of the respondents who held this view was the highest in Germany (48 %) and the lowest in the Netherlands (38 %).

How can your community feel more confident using digital health tools?

Hospital and medical records are legally protected in terms of privacy, but this protection does not currently extend to other forms of digital data. For example, when a person signs up to a clinical trial, they are specifically told how the data will be used and are asked to sign a consent form.

In the case of an app, for example, information regarding data protection may be buried deep in a lengthy set of Terms and Conditions that is hard to navigate and even more difficult to understand. How many of us click the box signifying we have read and agreed to the Terms and Conditions without even glancing at the information?

As in so many aspects of life, knowledge is power. Encourage your members to ask a few key questions before signing up to an app or setting up a new fitness tracker. Most online tools will have a Privacy Policy in their Terms and Conditions that sets out how and why data will be used and how it will be protected. It is good practice to check this before proceeding.

Key questions to consider

- What personal data will be held? Will it be identifiable or anonymised? Remember that even if data is anonymised, it can sometimes be linked up with other information to form a more detailed profile
- Where and how will the data be stored?
- How will the data be protected?
- How will the data be analysed and used?
- Who will have access to the data? Will it be shared with third parties?
- Will any of the data be sold to third parties?
- Is there a possibility to opt-out of (i.e. restrict) certain aspects of data sharing?
- In the case of online support groups, who is hosting the site and what is their commitment to data policy? Who will see the information shared?
- Does the company commit to notify users if there is a data breach?
- Can I access my personal data, or ask for it to be deleted or corrected?

What is the role of the GDPR?

The General Data Protection Regulation (GDPR) is a 2018 EU law on data protection and privacy, which includes the transfer of personal data in and outside the EU. This means that the personal data of EU citizens is legally protected, and people must be told how their data will be used, for what purposes and how it will be protected.

It is perhaps not surprising that with concerns about privacy and data breaches hitting the headlines from time to time, some people are hesitant about engaging with digital health tools. Trust can certainly be an issue for some people.

It is all a question of balance. Digital health tools are here to stay. They are accessible, easy to use and most offer benefits in terms of convenience and patient empowerment. To ensure they are used safely, we need to improve patient literacy and equip consumers with the information they need to make informed choices about digital health tools. In many cases, a few simple checks can be sufficient to reduce fears and ensure that consumers engage with these tools in a safe and confident manner.

How can we identify trustworthy and useful apps?

Some patient-led organisations have already reviewed apps for patient communities. For example, MyHealthApps, which was developed in collaboration with patient organisations and launched in 2013, is maintained by PatientView. The website curates hundreds of health apps tried and recommended by patient and health consumer groups worldwide.

As a patient group or individual advocate, you might consider inviting known app developers or industry partners working in your disease area to involve you in the design process of a digital tool. This could help ensure that any new app in your disease area is truly useful for affected patients and their families and importantly, that you understand how data will be collected and used.

Data Saves Lives

CONVEYING YOUR MESSAGE: COMMUNICATING EFFECTIVELY WITH YOUR COMMUNITY

When you communicate with your community are you confident that you are conveying your message well? Well-written materials have the power to inform, clear up misconceptions and stimulate action. Poorly targeted items rarely hit the spot and are likely to be ignored, deleted or thrown in the bin.

We know that many of you feel comfortable developing online or printed materials and have already established a positive dialogue with your members. However, others may be less confident and therefore **Data Saves Lives** has produced this factsheet with general guidance on how to make materials accessible and appropriate for your audience.

First things first

Before you begin writing, consider the following points:

- Are you absolutely clear **why you are producing this item** and what you want to say? What is the intended outcome, and who is your intended audience? Are you aiming to encourage people to take a specific action?
- Identify your **key messages** and map out a rough plan of sections and what will be included. The content should flow naturally, leading readers through a logical sequence
- What is the most appropriate **format** for your members? An online booklet, factsheet or email? A printed item that can be mailed out? A recorded interview or an animation that can be uploaded to your website? Each of these formats has its own advantages and disadvantages
- How much **detail** do your members need? What is their current level of understanding?

The most important rule is to ensure that the item you are producing is appropriate for your audience – the right format, the right level of detail and the right content.

General language and tone

- Use **everyday language**. Written text does not have to be more complex or formal than the spoken word. Use the same language you would use if you were talking to someone. On the other hand, an occasional colourful expression or unusual turn of phrase can incite interest
- Generally speaking, the simpler the words, the clearer the message
- **Avoid jargon** and explain any technical terms
- If you use an abbreviation (shortening) of a title or organisation, state it in full the first time you use it with the acronym in brackets – e.g. General Data Protection Regulation (GDPR)
- Use the **active voice** with personal pronouns – 'we', 'you'. Speak directly to your audience, e.g. 'check the Privacy statement on your app' rather than 'the privacy policy of your app should be checked'
- Use an **informal, supportive tone** to encourage engagement and involvement, e.g. 'Together we can …', We can help you to …' People do not enjoy being told to do something
- Keep **punctuation** simple
- Always **check spelling and grammar**
- Consider whether terms might be stigmatising, discriminatory or negative about populations or groups

Layout

- Text is much easier to digest in **short blocks**. Use short paragraphs with 1-2 points in each
- Divide text into sections with **headings and sub-headings** to make it easier to find specific information
- Use **bullet-points** if you have a list of points to make
- Use **call-outs** to highlight key facts. An example is shown below:

> **"According to Mental Health Europe, 1 in 4 people will experience a mental health problem in any given year"**

- Vary the format. Use graphics where appropriate to illustrate points
- Avoid using too many colours or different fonts that may distract from the content
- Using a question and answer format can sometimes work well to cover a number of different points
- Avoid long lists of statistics and where you use them, keep them as simple as possible, i.e. 'almost a third of people' is more accessible than '31% of people'

Highlighting key information in boxes can help it to stand out

Content

- Clearly state what the item you are producing is intended to do. Explain what will be covered in the introduction and then go on to expand
- Do not be tempted to include too much information in one document. You can provide links to more detailed information elsewhere
- Ensure that the level of detail is appropriate for your audience
- Check key facts and if relevant, provide a source reference
- Vary the content if possible. Blend text with graphics, quotes from experts
- Try to end with a **call to action** that is relevant to the content of the item – a prompt to respond in some way or to take a specific action, e.g. 'Why not check the Terms and Conditions on your fitness tracker?' or 'Think about talking to your doctor about taking part in a clinical trial
- If you are printing items, do not include information that may quickly date, e.g. contact details of specific people within your organisation or details of legislation that is likely to change in the near future. It is better to direct people to your website which can be updated more regularly

The section on Explaining how Data Saves Lives includes information on how to bring health data to life.

SUPPORTING HEALTH DATA INITIATIVES:
SHOULD YOU ENGAGE?
A RISK ASSESSMENT TOOL FROM DATA SAVES LIVES

As a patient group or individual advocate, you may occasionally be approached by third parties to support or be involved in a health data initiative or initiatives. This is entirely natural – after all, your members or network can offer valuable 'real-life' insights into living with specific diseases and can suggest how improvements could be made in healthcare delivery.

These third parties could be public or private institutions. They could include pharmaceutical companies, healthcare facilities, clinicians, government bodies, academic institutions, commercial technical companies (e.g. app developers) healthcare organisations, research institutions or other patient groups.

Taking part in such initiatives could have a number of advantages.

- It could help to raise your profile or allow you to develop a positive relationship with an influential third party
- It could increase knowledge about the area you are involved in or facilitate access to support or care for your members

However, before you sign on the dotted line, it is important to be fully aware of what you are committing to. How will this venture impact your community and your organisation's reputation? Are there any potential risks or disadvantages?

This tool from **Data Saves Lives** provides a risk assessment framework so that you can assess the pros and cons of any potential project and, if you decide to proceed, allow you to engage in a more confident and informed way.

What are the opportunities for engaging in health data initiatives?

The possibilities range from simple sharing of information among your members to close involvement in the development of a new digital health tool. Examples include:

- Sharing an online survey with members and encouraging them to participate
- Supporting the development of a new patient registry or greater involvement in an existing one
- Promoting an app among your members and encouraging uptake
- Involving your members in the development or assessment of a new health app
- Sharing or selling data from an existing database of members

The value of involving patient communities in digital healthcare design

According to research, patient needs are not always taken into account during the design of digital health tools such as apps and usage is often lower than expected: typical medical or fitness apps have a 90-day retention rate of just 27–30%. To create relevant, usable and effective digital health, it is critical to increase patients' involvement in the design of technological tools.[1]

Before you commit to any project, it is important to ask some **key questions** first to ensure that you have a clear understanding of what is being proposed. These will not all be relevant to each type of initiative but they provide a starting point for discussions.

The basics

- Exactly what does the project involve – what is its aim and what are the expected outcomes?
- Precisely what are you being asked to do? Has it been set out in detail and do you understand what is being asked of you?
- Is there any financial remuneration and if so, is this at an appropriate level? Fair market value (FMV) may differ from country to country. How and when will payment be made?
- How much of your time will the project involve? Do you have the capacity to devote this time to the exercise? Will you need to be involved personally?
- Who will be your point of contact?
- Will you be updated as the project progresses?
- What is the timescale?
- How will your organisation benefit from involvement? Will the project provide relevant data and will this be shared with you? Will it empower your members in any way or lead to the development of a tool that could be beneficial to them?

How will this exercise reflect on you and your organisation?

- Will your involvement be made public? How will this be done?
- Will this have a positive impact on your profile, for example by positioning your organisation as forward-thinking or innovative?
- Could there be any downsides, e.g. perceived influence from third parties that could affect independence/credibility?
- Will you have the option to see any materials relating to the project you are involved in before they are published?
- Who will have the copyright to the material?

"Many companies have developed new ways to incorporate patient insights and to collaborate with patients and patient organisations in a transparent and ethical way. This has led to better trials, better engagement, better communication throughout the entire life cycle of medicines – and ultimately better patient outcomes"
European Federation of Pharmaceutical Industries and Associations[2]

Safeguarding privacy

- If your members are being asked to contribute data, how will this data be used? Will it be shared with third parties?
- Will the data be anonymised?
- Will you have access to the full set of data?
- If you are considering sharing or selling member data, has this been made clear to members in your Privacy Policy? Could this impact their trust in your organisation?

Before you go ahead

If you decide to proceed with a health data initiative with a third party, there are a few final points to consider.

- How much information do you need to provide to your members?
- Do you need to make a more public declaration? For example, if you are working with a pharmaceutical company it is important to be transparent about this, particularly if you are receiving payment of any kind

If the third party you are engaging with is not able to answer your questions fully or you feel uncomfortable with any aspect that is being asked of you, it may be wiser not to proceed or to take some time to consider your options. Do not feel pressured into taking part. The potential benefits of involvement in a joint health data initiative are significant, but there are certainly downsides to consider.

Below is a table which you can use to record your thoughts on a project and keep them for future reference.

Project details	
Level of confidence on scale of 1–5*	
Comments/further action needed	
Additional comments/final decision	

*Confidence level

1. Not satisfied with answers to questions/insufficient information to make an informed decision
2. Some areas of interest but significant additional information/reassurance required
3. Promising proposal but additional information/clarification required
4. Largely satisfied with proposal, clarification on final points appreciated
5. Fully satisfied with proposal: willing to proceed

References
1. Patient Engagement and the Design of Digital Health - Birnbaum - 2015 - Academic Emergency Medicine - Wiley Online Library
2. working-together-with-patient-groups-23102017.pdf (efpia.eu)

DATA SAVES LIVES
TEMPLATE WEBINAR AGENDA
AN 'INTRODUCTION TO HEALTH DATA'

One of the ways the team at Data Saves Lives has found success in raising awareness of and communicating about health data issues is by holding public webinars with its communities and their wider networks.

If you are a patient group that is interested in running your own online webinar with a panel to provide an introduction to health data for your members, you may find this 90-minute agenda template a helpful starting point for your plans.

The European Patients' Forum (EPF) and the European Institute for Innovation through Health Data (i~HD), which have been leading the Data Saves Lives initiative to date, are both useful groups to contact for guidance on potential expert speakers to feature in your webinar. You can access previous webinar recordings from Data Saves Lives via our YouTube channel.

Webinar **objectives**
Following the webinar/workshop, attendees should be able to:

- **Better understand the benefits** of health data sharing for patients, healthcare systems, healthcare providers and medical research

- **Better understand the principles** behind data and privacy protection and how data protection measures should be implemented for health data sharing

- **Be more confident** in making informed choices about the use of their personal information

Timing	Agenda	Lead
5 mins	**Introduction and housekeeping**	Host
10 mins	**What is electronic health data? And who benefits from health data sharing and how?**	Expert speaker
10 mins	**What data protection measures are needed to protect the privacy of individuals when sharing health data?**	Data privacy expert speaker
10 mins	**Keynote presentation on a patient organisation-led health data project, focusing on benefits of their health data sharing initiative, how they implemented data protection measures and how they overcame any barriers around these**	Patient organisation representative
50 mins	**Open forum discussion** *Example facilitator questions (to be posed to the expert panel or to the audience):* • Are there any other benefits to health data sharing that have not been discussed so far on this webinar? Or are there benefits which you think need to be discussed in greater depth? • How do you think patient groups can best communicate the benefits of health data sharing? • Implementing data security measures can be seen as cumbersome, very technical and requiring a lot of time. How would you respond to this? • Are there any existing practical resources that would help to overcome perceived challenges of implementing required data protection measures?	Host / independent facilitator
5 mins	**Round up**	Host

DATA SAVES LIVES **TEMPLATE SURVEY** TO UNDERSTAND PATIENT AND CARER CONFIDENCE IN HEALTH DATA-SHARING

As a starting point to help you better understand the knowledge and beliefs around health data sharing of your community, **Data Saves Lives** has developed this easily adaptable survey template that you can tailor to suit your needs.

Online survey platforms, such as SurveyMonkey® and Google Forms®, provide a secure and accessible way of surveying your members or network and are intuitive to set up. These platforms can be accessed by non-paying account holders and allow users to upload and share surveys, with a limit of 10 free questions on SurveyMonkey®. They also both provide supplementary analytics and statistics of the results after the survey has been completed and are an extremely useful tool for patient groups or individuals with limited resources.

We recommend if you share a survey like this with your members or network, that you include a description of what electronic health data is as an introduction, to provide context. You can use the description from the introductory section to this toolkit.

Example survey questions

1. On a scale from 1–5, to what extent do you agree with the statements below?
   (**1** = completely disagree, **3** = neither disagree nor agree, **5** = completely agree)

☐ I feel comfortable sharing my health data if I know it is contributing towards wider-societal benefit

☐ I feel confident that there are safeguards in place that will protect my health data and ensure that it is not exploited for commercial gain

☐ I understand what happens to my health data once it has been shared and who controls it

☐ I feel confident that by sharing my health data, my information will make a positive impact in the field of medical research and clinical trials

☐ By donating my health data, I feel confident that my privacy and anonymity (should I choose to remain anonymous) is protected

☐ I understand what my given consent implies when I agree to provide health data and the 'limitations' of this consent, such as in instances where I should choose to withdraw it

☐ I believe that by donating my health data, I may suffer adverse consequences as a result e.g. it could affect my health insurance, or my employment options

☐ I fully trust that healthcare regulatory bodies and corporations will use my data to benefit society at large

☐ I am concerned about sharing my personal health data (and those separate from my condition(s) – such as age, ethnicity & sexual orientation) in case it is made publicly accessible

2. Which individuals or organisations do you feel most comfortable sharing your health data with? Tick all that apply

☐ My healthcare team

☐ Hospitals

☐ Universities

☐ Drug companies

☐ Charities

☐ Patient groups

☐ Mobile phone apps

☐ Digital health tools

☐ Online forums

☐ Social media platforms

☐ Medical devices

☐ Other [Open text]

3. Which individuals or organisations do you feel least comfortable sharing your health data with? Tick all that apply

☐ My healthcare team

☐ Hospitals

☐ Universities

☐ Drug companies

☐ Charities

☐ Patient groups

☐ Mobile phone apps

☐ Digital health tools

☐ Online forums

☐ Social media platforms

☐ Medical devices

☐ Other [Open text]

4. Please explain your responses to questions 2 & 3. [Open text]

5. What concerns might you have regarding your health data use? [Open text]

6. In your opinion, what could patient groups and data collectors do to address these concerns and increase your trust in health data-sharing initiatives? [Open text]

7. If you are interested in learning more about health data, which methods of communication would you find most helpful from us? Tick all that apply

☐ An online webinar

☐ A discussion session at our annual meeting

☐ A factsheet

☐ More information on our website

☐ Regular updates on research initiatives

8. Please confirm if you are:

☐ A patient

☐ A carer

☐ Other [Open text]

☐ Prefer not to say

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10 THINGS YOU MAY NOT KNOW ABOUT HEALTH DATA

Fact sheet to share with your networks

1. **The first electronic health record (EHR) was created in 1969.**[1]
   Before the worldwide phenomenon that is computer technology became widely known and used, Dr Lawrence Weed developed the first rudimentary EHR system, called the Problem-Oriented Medical Information System. Although revolutionary at the time, it would take some time before the EHR was adopted by nearly all hospitals throughout the UK.

2. **80% of health data is 'unstructured'** – stored in its native or raw form, in hundreds of formats such as lab results, images and medical transcripts.[2]

3. **In 2020, it is estimated that the digital universe reached 40 zettabytes of data** – that is equal to 5,200 gigabytes (GB) of data for every person in the world.[3] Considering most modern smartphones hold 64 GB of data – that is the equivalent of 81 full phones for every person in the world!

4. **The use of Big Data analytics** (massive volumes of information created by digital technology that collect patient records) **could reduce pharmaceutical R&D costs by as much as $70 billion.**[4]

   Data analytics lower administrative costs to the hospital and reduces the cost to the patient. Statistical data shows that administration currently contributes to 25% of healthcare costs, as humans are required to perform administrative tasks.

5. **Health data can help to facilitate medical diagnoses.**[5]
   Electronic health records can help healthcare professionals make informed clinical decisions, making all prescribed medicine, lab test reports and the medical history of a patient accessible through a single screen. This can help these professionals see the full picture of a patient's condition, allowing them to give more accurate diagnoses and better care.

6. **Health data sharing can help make health systems more responsive and sustainable.**[6] Digital health technologies can improve access to health services, reduce costs, improve quality of care and make health systems more efficient, while allowing patients to care for themselves. For example, remote monitoring devices like smart watches can help people to better manage their own health, thereby reducing the burden on health systems and increasing their sustainability.

7. **Digital health data can help to reduce inequalities in health.**[7] Digital healthcare can offer remote medical services, serving people who live in isolated areas by providing access to medical services that may not otherwise be available or affordable. Digital health systems can promote health literacy by educating the public on how to maintain healthy habits, thus promoting healthy behaviours and providing access to support networks for patients, helping to reduce health inequalities throughout the world.

8. **The quantity of health data has grown at an explosive rate of 878% since 2016** and is continuing to grow exponentially, according to statistics compiled from Dell EMC.[8]

9. **Digital health data can reveal information about health factors outside of those measured in a clinical setting**, such as data concerning diet and happiness levels.[9] This data can help to fill the gaps in current research and provide valuable information outside that gathered in clinical trials, thus improving the quality of research.

10. **Health data collection can help to monitor your stress levels.**[10] Some smart watches come with an electrodermal activity (EDA) sensor that measures electrical activity in the skin, which can be used to compute your stress levels. Apps can also be used to encourage regular deep breathing and meditation that can decrease stress levels and improve the quality of your sleep.

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Part Two:

AI: from science fiction to science fact

Part **Two:**
AI: from science fiction to science fact

AI: FROM **SCIENCE FICTION** TO SCIENCE **FACT**

Introduction

Many people still think of Artificial Intelligence (AI) as being futuristic – something that belongs in a science fiction film. In reality, AI is already here and is firmly rooted in everyday life. Think of weather apps, digital assistants and chatbots, online banking and wearable devices such as fitness trackers so many of us use. All of these are examples of AI technology.

» **FACT: Alan Turing, British mathematician and WWII code-breaker is widely credited as being one of the first people to come up with the idea of machines that 'think'. He created the *Turing test*, also known as the imitation game, which is still used as a benchmark to determine a machine's ability to 'think' like a human.** **«**

AI has shown great potential in the field of healthcare. It is already transforming many aspects of the way we diagnose diseases, develop medicines, treat patients and monitor our own health. AI technology is developing at astonishing speed. It is likely that it will revolutionise other areas of healthcare over the coming years. We have barely begun to scratch the surface …

AI can be used to carry out some tasks normally performed by humans – but more rapidly, accurately and often at a lower cost. AI technology is already supporting radiologists in spotting malignant tumours, and guiding researchers in how to construct cohorts for costly clinical trials.

Some fear that AI will eventually replace healthcare professionals, but this is highly unlikely. AI has limitations and will never be able to consider the whole and holistic context of a patient or show emotion. What it can do is help reduce the chance of human error and free up the time of healthcare professionals so that they can focus on what they do best – spending time with patients.

What is the relationship between health data and AI?

There is a strong link between big data (large volume of data, different types of data and high speeds of data transmissions) and AI. AI tools need large volumes of data in order to operate and this inevitably raises issues of privacy and security, especially within the context of healthcare. Work is underway to develop appropriate regulations and a robust framework that is designed to protect the interests of all parties and to safeguard the security and privacy of patient data used in AI technology. (See Section 03 for further details).

As is often the case with anything new, some people are hesitant about embracing AI technology. Often this is due to misinformation or misunderstanding and this toolkit aims to dispel some of the myths surrounding the subject.

Why should you engage with AI?

Currently, there is limited involvement of clinicians and citizens in the design of AI healthcare tools – particularly in the initial stages of development. This means that some AI technology could potentially not meet the needs of the patients it has been designed for.

We believe this situation needs to change. We would like to see closer cooperation between AI developers and patient communities.

Developers working on apps and AI tools are usually experts in technology rather than healthcare. They may lack true insight into the needs of patients. Your communities are ideally placed to provide this real-life perspective. With your support, we can help to improve the quality and relevance of AI tools and develop AI technology that truly meets the needs of your members.

This section of the toolkit aims to give a simple explanation of what AI is and to highlight its potential benefits for the patient community, as well as some of the potential drawbacks. It will equip you with the information you need to talk confidently about the topic and to engage with the AI community in a constructive way.

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WHAT IS AI AND HOW COULD IT BENEFIT PATIENT COMMUNITIES?

Let's take a brief look at what AI is, what it can and can't do, and how it offers exciting opportunities but also some potential downsides.

AI is a branch of computer science. It involves many different technologies working together to enable machines to sense, understand, act and 'learn' with human-like levels of intelligence.

FACT: AI is not new – the phrase 'artificial intelligence' was first used by computer scientist John McCarthy in 1956!

What it can do

- AI is assistive technology – it can help a healthcare professional reach a decision about a patient's diagnosis or treatment
- AI can improve productivity by analysing huge amounts of data quickly and accurately
- It can predict care needs
- AI can generate game-changing research
- It can reduce the risk of human error in certain settings

What it can't do

- AI cannot fully replace humans but it can support them
- It cannot generate original ideas or strategies (although content generation is original)
- AI cannot solve everything: some problems are too vague, ambiguous, or subjective for AI to handle or they require human judgment, intuition, or creativity
- It can't offer unique human skills such as emotion

Potential benefits

- Improving diagnostics by developing more sophisticated screening and diagnostic models
- Advancing treatment – helping to develop more targeted, personalised medicines and treatment plans
- Improving patient engagement
- Supporting administrative tasks freeing up healthcare professionals
- Improving prediction of disease outbreaks

Potential drawbacks

- Potential biases that could disadvantage some people
- Privacy and security issues
- Potential harm due to AI errors
- Misuse of medical AI tools and vulnerability to hacking
- Accountability issues – it could be difficult to know how AI technology has reached a decision
- Obstacles to implementation in real-world healthcare – lack of training or infrastructure

Potential healthcare applications	**Potential healthcare applications**
• Outbreak prediction	• Drug discovery
• Diagnosis of diseases	• Electronic health records (e.g. for data analysis and insights and clinical decision-making)
• Medical image analysis	• Medical robots
• Clinical trials (e.g. automating patient recruitment and data collection)	• Personalised medicine
• Optimisation of appointment scheduling	

Why is there potential bias?

AI can 'learn' from data and make predictions or recommendations based on patterns and probabilities, but it cannot guarantee that the data source is of good quality, accurate, complete, or representative. This means that AI can inherit or amplify the biases of the data sources, the algorithms, or the human designers. The AI developers can mitigate some biases by using more diverse and inclusive data sets, methods, and teams, but it is almost impossible to eliminate them completely.

KEY REGULATIONS/ GUIDELINES

"Our future is a race between the growing power of technology and the wisdom with which we use it. Let's make sure that wisdom wins."
Professor Stephen Hawking, 2015

AI technology is advancing at lightning speed and regulating such a fast-moving area is challenging. There is an urgent need to develop appropriate regulations to ensure that there is a strong framework to protect the interests of all parties and to increase trust.

FACT: Citizens of the US and Europe remain cautious about AI and how it is implemented. In a recent survey by the Centre for the Governance of AI, 91% of respondents agree that AI 'requires careful management'.
[Source: Preliminary Survey Results: US and European Publics Overwhelmingly and Increasingly Agree That AI Needs to Be Managed Carefully | GovAI Blog (governance.ai)]

Here are some of the key guidelines existing and in development, that are relevant to the development of AI technology.

The 2017/745 Medical Devices Regulation (MDR) and 2017/746 In vitro Diagnostic Medical Devices (IVDR) regulation

AI Regulations on medical devices produced by the EU co-legislators, the European Parliament and the Council of the European Union aim to ensure a high level of protection of health for patients and users by setting high standards of quality and safety for such devices.

Currently, medical devices that use AI technology are covered by these regulations. However, in 2017, when the Medical Devices regulations were agreed upon, AI healthcare technologies were still at the very early stage of development and the regulatory framework did not anticipate some of the aspects related to AI.

Ethics guidelines for Trustworthy AI

In 2019, the European Commission published the guidelines that set out requirements that AI systems should meet in order to be deemed trustworthy. According to the Guidelines, trustworthy AI should be: lawful, ethical and robust. The requirements cover 7 key areas:

- Human agency and oversight
- Technical robustness and safety
- Privacy and data governance
- Transparency
- Diversity
- Societal and environmental well-being
- Accountability

Ethics and governance of artificial intelligence for health

The 2021 WHO Guidance identifies the ethical challenges and risks with the use of artificial intelligence in health and sets out six consensus principles to ensure AI works to the public benefit of all countries. It also contains a set of recommendations that can ensure the governance of artificial intelligence for health maximizes the promise of the technology and holds all stakeholders – in the public and private sector – accountable and responsive to the healthcare workers who will rely on these technologies and the communities and individuals whose health will be affected by its use.

Artificial intelligence in healthcare: Applications, risks, and ethical and societal impacts

This study carried out by the European Parliament Think Tank provides an overview of how AI can benefit future healthcare, for example by increasing the efficiency of clinicians, improving medical diagnosis and treatment, optimising the allocation of human and technical resources. The report also highlights the main clinical, social and ethical risks posed by AI in healthcare: potential errors and patient harm; risk of bias and increased health inequalities; lack of transparency and trust; and vulnerability to hacking and data privacy breaches. The study proposes mitigation measures and policy options to minimise these risks and maximise the benefits of medical AI. These include multi-stakeholder engagement through the AI production lifetime; increased transparency and traceability; in-depth clinical validation of AI tools, and AI training and education for both clinicians and citizens.

The EU proposal on the regulatory framework for AI

The European Commission is proposing the first-ever legal framework on AI. The regulatory proposal aims to provide AI developers, deployers and users with clear requirements and obligations regarding specific uses of AI. The aim is to ensure that when an AI system goes 'live', safeguards are in place to ensure it complies with regulations and that action can be taken if this is not the case.

The Regulatory Framework will define 4 risk categories: minimal, limited, high and unacceptable. The negotiations are still underway, but the current positions suggest that all medical devices will most probably fall into the high-risk category which will be subject to specific stringent legal requirements.

The AI Act is designed to be future-proof, allowing rules to adapt to technological change.

The regulatory framework is expected to come into effect in 2025.

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AI AT WORK: FROM PREVENTION TO REHABILITATION

AI is already integrated into a whole range of elements of healthcare and there is huge potential for it to play a role in a wide variety of other areas. Currently, AI tools can be grouped into four key areas: **clinical practice, biomedical research, public health and health administration.** Let's look at each of these in a little more detail.

Clinical practice	Biomedical research
AI TOOLS IN HEALTHCARE	
Public health	Health administration
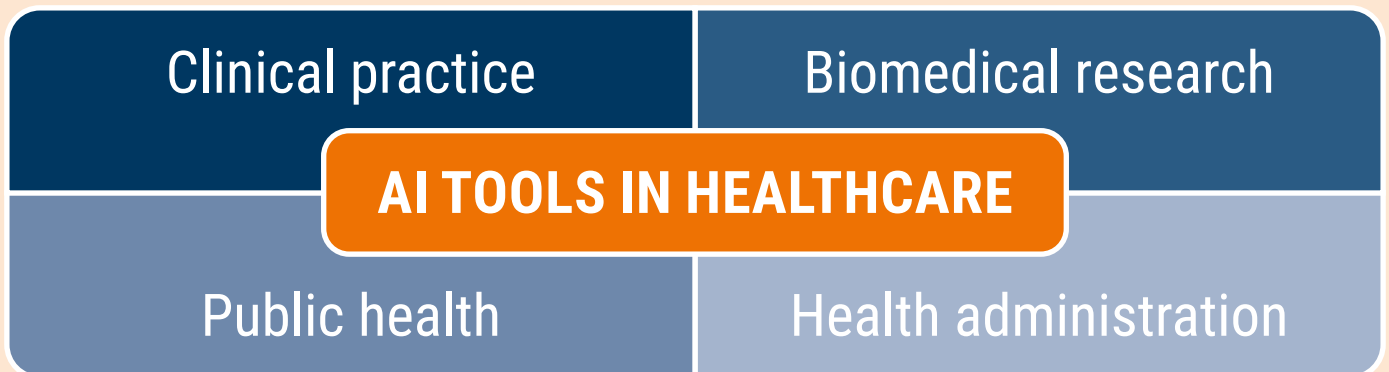
Clinical practice:

AI can provide support in a variety of areas, by speeding up the analysis of data, improving administrative systems, or supporting the decision-making process in terms of diagnosis and treatment. AI already plays a key role in the following areas:

- **Radiology:** analysis of X-ray images or scans – AI can detect clinically relevant features in imaging data that the human eye cannot perceive

- **Pathology:** analysis of images to support a diagnosis

- **Surgery:** use of robots to provide precise and minimally invasive surgery

AI **IN ACTION**

Analysis of CT scans in patients with suspected coronary heart disease

AI technology called HeartFlow is being used in the NHS in the UK and in many other healthcare settings. It analyses CT scans of patients who are suspected of having coronary heart disease. It creates a personalised 3D model of the heart that shows blood flow and highlights any blockages. HeartFlow is less costly and invasive than standard procedures such as angiograms.

[Source: https://www.heartflow.com/heartflow-ffrct-analysis/article/our-technology-core/]

AI **IN ACTION**

Diagnosis of skin cancer

A number of different forms of AI technology are available to assist in the diagnosis of melanoma and research has shown that a form of AI can actually out-perform experienced dermatologists at detecting skin cancer. Researchers in Germany, the USA and France 'trained' AI technology by showing it more than 100,000 images of malignant melanomas, as well as benign moles. They compared its performance with that of 58 international dermatologists and found that the AI technology missed fewer melanomas and misdiagnosed fewer benign moles less as being malignant. It is not envisaged that AI will replace dermatologists in the diagnosis of skin cancer but that it will act as a supportive tool.

[Source: https://www.esmo.org/]

Biomedical research

AI is already widely used in clinical research and is helping to streamline the process of drug discovery. Key areas include:

- **Clinical research:** analysing large volumes of data
- **Drug discovery:** identifying potential candidates for drug development, significantly reducing traditional timescales
  - Some technology companies are now using AI to design experiments to discover new drugs and potential treatments.
    [source: https://www.exscientia.ai/our-mission]
- **Clinical trials:** ensuring patient diversity, improving retention rates patient selection and recruitment, randomising patients signed up for trials
  - Some tech companies are leveraging AI to improve clinical trials. For example, 'digital twins' (identical data sets) of patients can be created in clinical trials to design more efficient, ethical and reliable clinical studies
    [source: https://www.unlearn.ai/about]
- **Personalised medicine:** developing treatment plans based on individual patient data or personalised treatment such as immunotherapy

Public health

AI can support public health by analysing data more efficiently and facilitating the development of wearable technology to monitor health. Areas where AI is already being employed include:

- **Prevention:** AI can identify, track and monitor emerging health threats so that appropriate action can be taken
- **Global health:** identifying risks via accurate forecasting
- **Health facilities:** use of virtual wards, where patients can be assessed at home via remote monitoring tools
- **Resource allocation:** targeting treatment more effectively, improving efficiency and reducing costs

AI **IN ACTION**

Forecasting a patient's risk of **stroke** recurrence

A research team based at the Vall D'Hebron University in Barcelona has presented a study demonstrating how AI can be employed to accurately predict a patient's risk of stroke recurrence. AI technology was used to review non-modifiable risk factors (e.g. age and ethnicity) and modifiable factors such as body weight, smoking, blood pressure and physical activity levels. The technology was able to provide accurate and personalised risk profiles for patients at three months and one year.

[Source: https://www.healtheuropa.com/potential-risk-of-stroke-recurrence-predicted-with-artificial-intelligence/110697/]

AI **IN ACTION**

Assessing pain in people with **dementia** who cannot self-report

PainChek is a CE-marked pain assessment tool in the form of an App on personal mobile devices. It takes a 3-second video of a person's face and applies AI to identify facial micro-expressions indicative of pain. This information is combined with other pain indicators recorded by a carer to generate an overall pain score. Originally developed in Australia, PainChek is now used in many care homes in the UK.

[Source: https://transform.england.nhs.uk/ai-lab/explore-all-resources/understand-ai/assessing-pain-people-dementia-who-cannot-self-report/]

AI **IN ACTION**

The role of AI in **COVID-19** treatment decisions

The use of an AI tool aiding personalised COVID-19 treatment decisions has been shown to lead to a 50% reduction in COVID-19 mortality rates. The tool was developed by researchers at Hospital Clinic Barcelona-IDIBAPS. It is capable of analysing, in real time, more than a trillion anonymised data points of patients, identifying clinical patterns and suggesting personalised treatments. The tool was able to predict, with 90% accuracy, the trajectory of the disease in individual patients to allow for timely and appropriate treatment.

[Source: https://www.healtheuropa.com/artificial-intelligence-covid-19-mortality-reduction/102053/]

Health administration

AI can support the healthcare administrative burden by streamlining a number of processes, including:

- Clinical coding
- Scheduling of appointments
- Patient flow management
- Healthcare audits

AI **IN ACTION**

Using AI to predict demand for hospital beds coming from A&E

Bed allocation in hospitals is a complex, constantly-changing matter. An artificial intelligence tool developed by researchers at University College Hospital in London is being used to predict how many patients coming through the emergency department will need to be admitted into the hospital, helping planners manage demand on beds. The AI technology assesses each patient's probability of being admitted to hospital from the emergency department, based on a range of data including age, how the patient arrived in hospital, test results and number of consultations.

[Source: https://www.ucl.ac.uk/news/2022/sep/ai-predicts-demand-hospital-beds-coming-ae#:~:text=An%20artificial%20intelligence%20tool%20developed,planners%20manage%20demand%20on%20beds]

COMMUNICATING ABOUT AI IN HEALTHCARE

Getting to know **the stakeholders**

Every type of stakeholder involved in the development and uptake of AI will have a different perspective, with their own specific priorities and viewpoint. Below we look at the key stakeholders and some of their drivers and perspectives.

DEVELOPERS

- Key driver is likely to be the success/viability of the AI tool rather than how it will benefit patients
- Likely to have technical rather than clinical expertise
- They may have minimal understanding of the disease area for which they are developing AI technology and low awareness of the true needs of patients
- They may place greater emphasis on 'tech' elements of an AI tool rather than usability and accessibility factors that make it easy to use – this can affect adoption of the technology
- They may lack insight into factors affecting the uptake of the tool, such as training of users
- They may be less or entirely unaware of the ethical implications of their products

Opportunities for engagement

- Emphasise that you can offer valuable insight into the needs of patients via the lived experience of your community and that you can help to identify where there are gaps that AI technology could fill
- Offer advice on practical aspects of AI technology that are likely to improve usability and increase uptake
- Suggest that your community could be involved at the development stage, for example by taking part in advisory or focus groups, and in testing early versions of AI technology
- Explain that your community can offer 'real life' feedback on the AI technology and the important ethical values that might be at stake
- Offer guidance on training materials for patients
- Offer to act as a point of contact for information on the new technology and how it is being used

HEALTHCARE PROFESSIONALS

- Key driver is likely to be how AI can improve efficiencies and benefit HCPs and patients
- Key questions/concerns are likely to be:
    - What are the benefits to me and/or my patients? Cost?
    - How well will the technology integrate with existing systems?
    - What resources will be needed to implement the technology?
    - Will my staff be offered appropriate training?
    - Will this impact on the relationship I have with my patients?
    - Am I responsible and accountable for possible unforeseen and undetectable mistakes of the AI-system?
    - Will using AI technology disrupt current care pathways?

Opportunities for engagement

- Emphasise that you can offer insight into how the new AI technology might benefit your members and why there is a need for it
- Offer to act as an interface between healthcare professionals and your community
- Offer to act as a point of contact for patients who need additional information on the new technology

PATIENT COMMUNITIES

- Key driver is likely to be whether the technology will have a positive impact on the patient communities
- Key questions are likely to be:
    - Will the technology benefit me?
    - Will I have less opportunity for face-to-face contact with my doctor?
    - Will my privacy be safeguarded? And if so, how?
    - How will my data be used?
    - Will the AI technology be biased and could this affect me negatively?

Opportunities for engagement

- Act as a point of liaison between patients and the AI technology developer – forwarding questions from users and sharing patient feedback
- Offer to act as a point of contact for patients who need additional information on the new technology
- Ensure that you have the information you need to deal with enquiries about privacy and security

Data Saves Lives

TELLING THE STORY OF **AI**

AI is a complex, often controversial topic. Many people have misconceptions about how the technology is being used in healthcare or concerns about what may happen in the future. You can contribute positively by providing clear, balanced information in a way that is accessible to your community. Some of you will feel confident about doing this but others may be less relaxed about tackling the subject. This factsheet provides general guidance on how to talk about complex subject matters along with some useful statements on AI that can be incorporated into any materials you produce.

Please also refer to section 04 of part 1 of this toolkit, which has additional information on communicating effectively with your community.

GENERAL TIPS ON COMMUNICATING COMPLEX SUBJECTS

- Use clear everyday language

- You will inevitably need to use some technical terminology when talking about AI, but explain any terms in simple language

- If you are producing something with a lot of technical terms, it can be useful to include a glossary (list of terms with short explanations) at the end of the item. There is an example of a glossary in section 12 of this toolkit

- Don't try to communicate too much at once – it is better to give an overview of the key points of a subject with links to sources of further information

- Good layout is important – use short paragraphs and break text up with graphics, quotes, fact boxes and images where possible

- Many people are not wholly familiar with the subject of AI. If possible, include examples of how AI is already being used in healthcare – there are some examples in section 04 of this document

Template statements that can be used when communicating about AI in healthcare

What is AI?

- AI is a branch of computer science. It involves many different technologies that can work together to enable machines to sense, interpret, act and 'learn' with human-like intelligence
- Weather apps, digital assistants, online banking and wearable devices such as fitness trackers are all examples of AI technology in common use
- AI is already being used in numerous healthcare settings. AI tools can be grouped into four key areas: clinical practice, biomedical research, public health and health administration

AI in healthcare

AI has the potential to transform healthcare. There are already a number of research studies suggesting that AI can perform as well as or better than humans at key healthcare tasks, such as diagnosing disease. Today, algorithms are already supporting radiologists at spotting malignant tumours, and guiding researchers in how to construct cohorts for costly clinical trials
[Source: Future Healthcare Journal https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6616181/]

- AI is not designed to fully replace medical professionals. It is assistive technology that is designed to support them, allowing them to use their time more profitably. In theory, freeing clinicians from routine or time-consuming tasks will allow them to spend more face-to-face time with patients
- AI cannot offer uniquely human skills such as emotion
- AI is already transforming healthcare in a number of ways. Key areas include:
  - improving diagnostics by allowing faster and more sophisticated screening and diagnostic models
  - advancing treatment by streamlining the process of drug discovery and helping to develop personalised treatment plans
  - improving patient well-being and engagement through the use of wearable or remote devices that allow patients to be monitored away from the clinical setting
  - supporting the design and recruitment of patients into clinical trials

The ethics of AI

- AI is relatively new technology and it is important to ensure that adequate legislation is in place
- There are concerns over data privacy and data protection
- There are concerns over potential biases that could lead to unreliable results or disadvantage some people
- Transparency is another area of potential concern. AI technology is based on algorithms and in some cases, it could be difficult to know how a decision regarding patient diagnosis or treatment has been reached
- Establishing a clear line of accountability is crucial. This entails defining responsibilities in case of errors and outlining available options for redress

The need for transparency in AI

- In the past, healthcare decisions were taken almost exclusively by humans. The use of AI technology to make or assist such decisions raises issues of accountability, transparency, permission and privacy
- It is important for all stakeholders to clearly understand how an AI system works and how it makes decisions and processes data. This will help to build trust in AI and will ensure that AI systems are fair and ethical
- AI developers should clearly explain the processes involved in decision-making so that it is clear how a decision was reached. This will help to reduce the risk of potential bias
- All stakeholders need to be open and transparent about how personal data will be used and what type of procedures are in place to safeguard privacy and security. Moreover, any applicable consent mechanisms need to be fully respected.
- Specific regulations are being drawn up to help ensure that AI technology is transparent, trustworthy and explainable

How your community can be part of the conversation around AI in healthcare

- AI developers are skilled in technology but some lack medical expertise or insight into the disease area for which they are developing AI technology. Therefore, it is important for the patient community to be involved from the initial concept stages and throughout the development process
- Patient communities can provide real life expertise on what it is like to live with a specific condition and highlight the areas in which AI technology could be useful. They can also provide valuable feedback during testing phases of development
- Co-operating with AI developers can increase the likelihood of developing tools that are relevant, user-friendly and fulfil a useful function
- Engaging with AI developers will help to build trust in the new technology

HOW TO COMMUNICATE
WITH DIFFERENT AUDIENCES

Below we have developed a series of outline content for presentations on AI that can be adapted to suit different audiences.

FOR YOUR COMMUNITY

SLIDE 1: **About your organisation**	• When you were founded and by whom • Introduction to team members • Membership details • Geographical location
SLIDE 2: **Aims**	• Aims and objectives of group • Why the group was founded
SLIDE 3: **Support**	• Services/materials provided by your group (helpline, patient materials, forums, webinars etc.)
SLIDE 4: **Successes**	• Details of any key initiatives and how they have improved the situation for your community
SLIDE 5: **Current benefits of AI for your community**	• Examples of AI how technology is already improving the lives of your community
SLIDE 6: **Potential areas of AI development**	• Examples of circumstances where appropriate AI technology could improve the lives of your community
SLIDE 7: **Safeguards**	• Importance of robust systems to safeguard privacy and security • Examples of systems already in place
SLIDE 8: **Why should your community engage with AI?**	• Importance of involving patients in the early stages of AI technology development • Potential to develop more targeted and personalised tools and to improve numerous stages of the healthcare journey
SLIDE 9: **How you can get involved**	• Ways in which your community can get involved, either in the development of AI tools or their testing

FOR POTENTIAL FUNDERS/INVESTORS

SLIDE 1: **About your organisation**	• When you were founded and by whom • Introduction to team members • Membership details • Geographical location
SLIDE 2: **Aims**	• Aims and objectives of group • Why the group was founded
SLIDE 3: **Support**	• Services/materials provided by your group (helpline, patient materials, forums, webinars etc.)
SLIDE 4: **Successes**	• Details of any key initiatives and how they have improved the situation for your community
SLIDE 5: **Current benefits of AI for your community**	• Examples of AI how technology is already improving the lives of your community
SLIDE 6: **How could AI tools/ funding support your community?**	• Current challenges facing your community • Examples of circumstances where appropriate AI technology could improve the lives of your community
SLIDE 7: **Why should we work together?**	• Importance of involving patients in the early stages of AI technology development • Potential to develop more targeted and personalised tools that truly meet patient needs • Increases likelihood of good uptake of AI tools
SLIDE 8: **How could we work together?**	• Stages at which your community could become involved – initial concept, development, testing and assessment, training of clinicians, ongoing feedback

TEMPLATE QUESTIONS
FOR DEVELOPERS

Before considering any involvement with an AI developer, it is vital to understand what is being proposed – what the technology aims to do, how it could impact on your patient community and exactly what is being asked of you.

Please also refer to <u>section 05</u> of the toolkit
Supporting Health data initiatives: should you engage? **which includes relevant information on engaging in digital healthcare design.**

Product/technology

In terms of the technology itself, make sure you understand what the tool is intended to do, how it will work and how you will be involved. Potential questions include:

- **What** problem are you trying to solve and how will AI support this? How will this new technology offer advantages over current technology?
- **How** will the technology work on a practical basis and what results do you anticipate?
- **What** stage of development has the project reached? Are you being involved in the development of a new AI tool or are you being asked to test an existing AI tool?
- **What** input do you expect from us? How much time is likely to be incurred?
- **Will** you provide adequate training/support materials for patients and/or healthcare professionals to ensure that the AI technology can be used successfully?
- **(For fully developed tools) Does** the product meet regulatory standards? Is it safe?
- **(For fully developed tools) Was** the AI-system trained on a dataset representing my patient group?
- **(For fully developed tools) Does** the product/technology perform in line with the manufacturer's claims and what evidence is available to support this?

Security and privacy

Security is a particular concern with newer tools that have not been tried and tested. Again, make sure you understand how patient data will be collected, stored and used. Potential questions include:

- **How** will you comply with individual rights requests?
- **How** will you mitigate security risks?
- **How** will you ensure transparency?
- **Where** will patient data go and will it be shared with any other parties?
- **Are** you the controller, joint controller or processor of the data?

If the AI developer you are engaging with is not able to answer your questions fully or you feel uncomfortable with any aspect that is being asked of you, it may be wiser not to proceed or to take some time to consider your options. Do not feel pressurised into going ahead.

Data
Saves
Lives

GATHERING **INSIGHTS**

It is helpful to understand how AI is currently being used in your patient communities.

As a starting point, we have prepared a short survey to share with practising clinicians in your disease area. This can be adapted to take account of local infrastructure.

- **How** is AI currently being used in the treatment pathway, from screening and diagnosis to ongoing management?

- **What** is your attitude to using AI – do you feel comfortable, neutral or uncomfortable about using AI in the treatment pathway?

- **How** would you rate the current accuracy of the AI?

- **Have** you experienced any issues using AI technology? If so, what are they?

- **Are** your patients aware that AI is being used in their treatment pathway? If yes, how do they feel about it?

- **Do** you believe that AI helps to eliminate human bias from decision-making?

- **How** does AI influence decision-making?

- **Are** patients aware of the use of AI in their treatment decision-making?

- **How** have patients responded to the use of AI technology? Please give examples of positive and negative responses if relevant

- **Are** there aspects of your clinical practice where you believe AI technology would be beneficial? If so, what are they?

- **Are** there any other therapy areas that you plan to use AI for?

TIPS FOR FINDING **FUNDING OPPORTUNITIES**

The question of how to secure EU project funding in today's fiercely competitive market is a common one. It's important to recognise that the process of securing funding isn't always a straightforward path. It calls for meticulous planning, relationship building, and above all, a healthy dose of patience.

In the following section, we provide ten practical tips on how to find, approach and ultimately secure funding:

1. **Plan ahead:** Before contacting potential funders, ensure you have your project concept note and budget ready. This will help you establish a clear strategy, define goals, outline a communication plan and identify necessary tools.

2. **Align on missions:** Look for funders whose mission aligns with yours. Prioritise those who are key stakeholders and partners, as you never want to compromise your reputation for funding!

3. **Stay informed:** If you cannot find suitable opportunities online, sign up to the newsletter of the target funders, as that is often where they publish funding opportunities, particularly in the not-for-profit sector

4. **Diversify funding sources:** Strive for funding diversity from various sources like not-for-profit entities, for-profit organizations, private donors, and public sectors

5. **Build sustainable partnerships:** Seek long-term, sustainable and transparent funding partnerships

6. **Play the long game:** Prioritise establishing a genuine relationship before discussing funding matters

7. **Leverage networks:** Delve into your existing network and their contacts to identify potential funders

8. **Initiate Contact:** Reach out to funders to arrange a meeting where you can introduce your organisation. This initial step will lay the foundation for a future relationship and potential funding opportunities

9. **Apply early:** Submit funding applications well in advance of your project's start date. This ensures compliance with funders' budget deadlines and allows for any necessary preparations. Depending on the organisation, submitting your application a quarter before the activity starts might be prudent due to potential compliance delays

10. **Honour commitments:** Be aware and respectful of reporting and contractual requirements. Remember that funders need to demonstrate value to their stakeholders too!

LOCALISING
DATA SAVES LIVES

Are you interested in setting up a national version of Data Saves Lives to raise awareness of the value of responsible health data sharing in your country? The idea might be daunting but in fact, it has already been successfully done in Germany and we are aware of other countries who are actively considering the possibility. This section explains what a local version of Data Saves Lives looks like in practice and outlines some of the considerations.

Re-use and recycle!

We understand that resources are limited so it makes sense to maximise the use of existing materials – there is no need to re-invent the wheel! Think about:

- **Using the #DataSavesLives hashtag –** this is free for anyone to use
- **Translating** some or all of the materials from the Data Saves Lives website, adapting them to your own country where relevant
- **Using the visuals** from our website for continued brand awareness
- **Taking inspiration from our communication channels –** consider using social media or organising webinars or training workshops

Data Saves Lives Germany

Launched at the end of 2022, Data Saves Lives Germany is the first local variant of the initiative. It is headed up by patient expert Birgit Bauer, who has been part of the advisory group for Data Saves Lives from the outset. It offers:

- **A fully translated website**
- **Local blogs in German**
- **A dedicated hub to access translated information and materials**
- **Dedicated Data Saves Lives DE social media channels, including Twitter**

Funding has been gained from the German Ministry of Health and from industry sponsors.

Key considerations

Before you embark on a localised version of Data Saves Lives, it can be helpful to consider a few key questions:

- **Why** do we need a local version – what benefits will it bring?
- **Is** there an appetite to keep local momentum around DSL alive through regular activities and communications?
- **What** specific elements would be useful?
- **How** can it be made relevant to your local community?
- **What** financial resources will be needed?
- **Will** additional funding be needed?
- **Who** will head up the project?
- **Do** you have the capacity to undertake this project – will you need to involve other people?
- **How** much time will the project involve?

Step by step guide

1. **Define** your goals and get in touch - contact the Data Saves Lives Secretariat to request the logo and data files
2. **Choose** which materials to translate
3. **Decide** whether or not you want to clone the website – the website is created on Wordpress and is easy to replicate
4. **Once** you have developed the relevant resources, you're good to go. Start communicating!

Timescale: allow approximately 6–8 weeks to launch the website, from the time you start the translation process.

We are also happy to share our experiences of setting up the Data Saves Lives project so if you have any questions, get in touch!

KEY TERMINOLOGY

Below is a glossary of key terms in the subject of AI.

AI	AI is the use of digital technology to mimic human intelligence to 'learn' how to perform a given task by analysing big data (See also **Machine Learning** and **Deep Learning**). AI helps computers to identify patterns, make predictions, solve problems and even learn from their own mistakes
Algorithm	A process or set of instructions that can be used by a human or a computer to solve a problem or perform an activity
Big data	In the healthcare setting, Big Data is used to describe the extensive healthcare databases (like electronic health record systems) or networks of interconnected healthcare databases (called 'linked' databases) coming from multiple organisations. See also **The Three Vs**
Consent	To give permission for something to happen or agreement to do something. This can be given verbally or in writing. Usually, medical staff do not need your permission to record information about a patient as it is important for their care (**implied consent**). If a patient's confidential information is used for purposes beyond their individual care, their **explicit consent** will be needed. However, under GDPR, certain exceptions exist for using health data for specific secondary purposes, such as research, where patient consent might not be required.
Deep Learning	A subset of **Machine Learning** that uses large **Neural Networks** and big data to better solve complex problems. It creates an adaptive system to allow computers to 'learn' from their mistakes
EHDS	**European Health Data Space:** an EU initiative designed to offer patients access to their own health data in electronic format immediately and at no cost, with the ability to share data with health professionals within the EU and cross-border (primary use) & facilitate the use of such data for research and innovation purposes
Federated data	Federated datasets allow data to stay in the place they are produced to avoid unsafe transferral to other areas
FAIRified data	**FAIRification** is based on the concept of data being Findable, Accessible, **Interoperable** and Reusable to allow data to be used in a **Federated** manner
Homomorphic encryption	An encryption technology designed to enhance privacy
Interoperability	Issuing information in a common format so it can be easily exchanged and made use of
Machine learning	A subset of AI that involves machines 'learning' from patterns of data or previous tasks and improving their performance
Neural network	A type of machine learning process that uses interconnected nodes to teach computers to process data in a way that is inspired by the human brain
The Three Vs (in the context of big data)	**Volume, velocity and variety:** these are seen as a way to define and measure big data and to understand how it differs from 'old-fashioned' data