2021 EPF Congress

Digital *transformation* of healthcare

the added value of patient partnerships

Summary report

Key statistics – EPF Congress 2021

152 AVG. NUMBER OF PARTICIPANTS PER SESSION

#3

#3 TWITTER TRENDING TOPIC IN BELGIUM

470

REGISTRANTS

350K

VIDEO VIEWS

12

ADVISORY BOARD MEMBERS

50

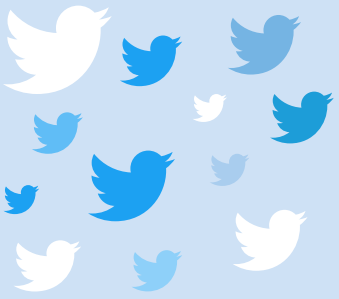
SPEAKERS

4

VIRTUAL DAYS

14

PROGRAMME COMMITTEE MEMBERS



4.6M

TWITTER IMPRESSIONS

DAY ONE: 26 OCTOBER 2021

Grand opening of EPF Congress 2021

Watch the session video here

Co-hosts **Tjasa Zajc**, podcaster at the Faces of Digital Health, and **Ivett Jakab**, President of the EPF Youth Group, welcomed participants to the virtual EPF Congress 2021. Over the next four days, Tjasa and Ivett introduced each session, highlighted key themes throughout the Congress and encouraged audience engagement and discussion during the various keynote speeches, panel discussions, concerts, and exhibition booths.

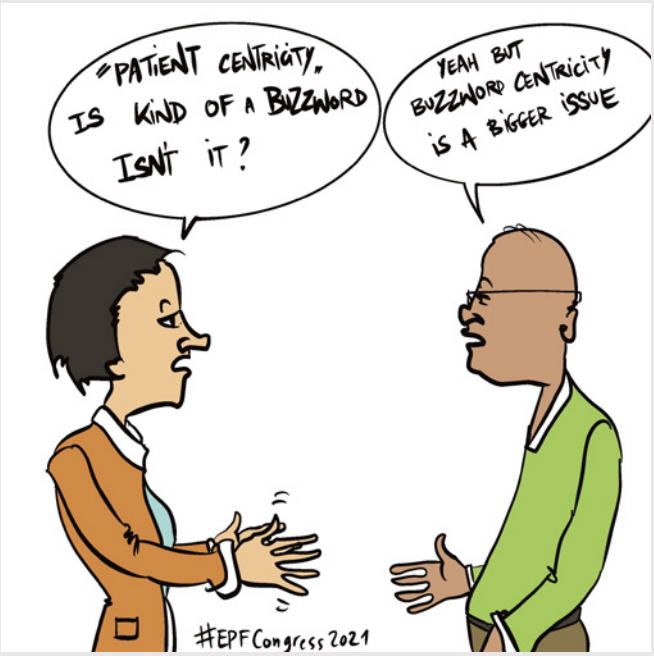
Ivett Jakab

Marco Greco, EPF President, welcomed everyone with an opening speech that introduced the topic of healthcare digital transformation and encouraged active participation and engagement throughout the four-day programme and beyond.

Tjasa Zajc

Both Congress co-hosts are patients themselves, and the recent digital transformation of healthcare has had a huge impact on the convenience of their care and life since their initial diagnoses. Healthcare exists for patients and yet the voices of patients are not heard or included as often as they should be. The Congress promised to include perspectives from patients throughout, and Tjasa and Ivett encouraged participants to share their experiences, connect and grow together.

Marco Greco



DAY ONE: PLENARY SESSION

Watch the session video here

The digitalisation of health and care systems in light of COVID-19: what way forward and which role for patients?

The Grand Opening gave way to the first plenary session, dedicated to the digitalisation of health and care systems in light of COVID-19. Exploring the way forward for digitalisation and the role of patients, the session began with a statement from **Dr Hans Kluge**, Regional Director for Europe at the World Health Organization (WHO):

Hans Kluge

> **"If there is a single overarching goal in our work ahead, it is to put patients at the centre of digital transformation."**
>
> *– Dr Hans Kluge, WHO Europe*

Dr Kluge went on to herald COVID-19 as the long-awaited wake-up call that forced the healthcare industry to overcome the long-standing structural and cultural barriers to adopting digital technologies overnight. As investment in digital infrastructures and systems increases, Dr Kluge stressed the importance of ensuring that these technologies increase universal health coverage, enable the industry to better prepare for and respond to health emergencies, and empower individuals and communities to improve their health and wellbeing.

The second part of the plenary focused on digital health from the patient perspective, encouraging us to work together to create a better future for healthcare. **Dana Lewis**, Founder of OpenAPS, gave the keynote presentation. Ms Lewis advocated for the need to build financial structures for new models of digital health outside of hospital encounters and carry forward the new developments arising from the COVID-19 era, (such as telehealth and virtual visits). It is also important to help patients avoid falling into the 'patient syndrome trap', the disconnect between what Healthcare Professionals (HCPs) think patients know and what patients actually know because, in reality, patient knowledge is frequently under-estimated. To achieve this, there needs to involve patients with diverse perspectives to participate at an individual, community or system level, and use resources to support relationships between patients and research partners.

Dana Lewis

> **"Patients are falling through the cracks of new technologies because of the systems in place."**
>
> *– Dana M. Lewis, #OpenAPS*

The themes discussed during Ms Lewis' keynote speech were further elaborated on during a discussion moderated by **Tjasa Zajc**, Congress co-host, where panellists reflected on the key learnings from COVID-19 in terms of what we can use going forward, what worked, and what did not. To start the panel discussion, **Clayton Hamilton**, Regional Advisor,

Clayton Hamilton

Digital Health Flagship at the World Health Organization (WHO) Regional Office, reflected on the WHO's key lessons from the COVID-19 pandemic: Digital technologies are only capable of serving populations when they are included in the solution design process. Overall, our lack of ability to access and use health data was likely the greatest shortcoming of our pandemic response.

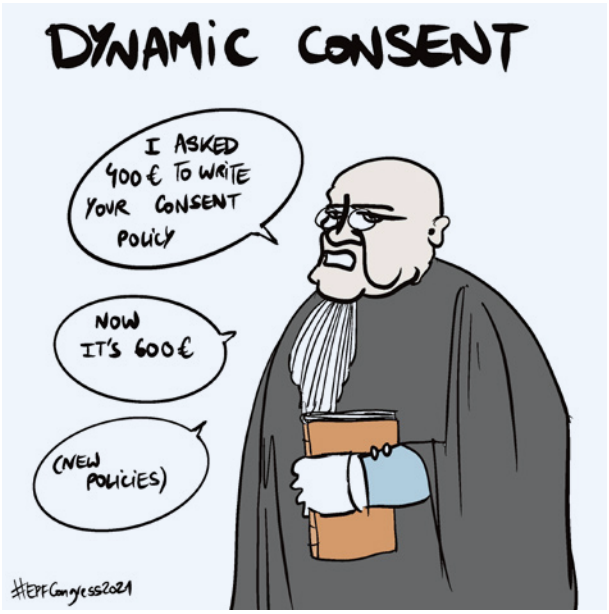
Michelangelo Canzoneri

Turning to what the pharmaceutical industry learned about technological development and adoption, **Michelangelo Canzoneri**, Global Head of Digital and Data Healthcare at Merck, believes that the pandemic has led to a deeper understanding of the overall healthcare ecosystem. The industry is moving towards precision medicine and patients are increasingly expecting personalised treatment plans. To unlock the potential of digital health and meet patients' expectations, the effective interrogation of a wealth of data is needed.

The COVID-19 pandemic accelerated the adoption of digital healthcare technologies, both from the perspective of patients and how the health system engaged individuals. However, there remains a large gap in patient trust and acceptance for data and digital technologies, and Mr Hamilton believes we need to rethink the governance, accountability, and assessment frameworks to ensure they are appropriate to new technologies.

> **"Designing with and for people and making sure we have systems in place to prevent human biases from blocking the technology from reaching people is really important."**
> *– Clayton Hamilton, WHO Europe*

This was echoed by Mr Canzoneri, who spoke about his experience in developing digital ecosystems benefitting patients by listening and engaging with them.



DAY ONE: SPECIAL SESSION

Patients' health data sharing: perspectives, risks and key concepts

Watch the session video here

Dipak Kalra, President of The European Institute for Innovation through Health Data, opened the session by stressing the challenges of balancing the need for better use of health data to accelerate new research to improve public policies and health strategies with the rising public demand for greater data protection and transparency.

Dipak Kalra

"We need to find a middle ground; a sensible way of making good use of health data whilst upholding the protection of individuals."
– Dipak Kalra, European Institute for Innovation through Health Data

Patrik Puljić, a young people's representative from the European Multiple Sclerosis Platform (EMSP), shared his perspective as a patient. Patient attitudes towards data sharing vary significantly between countries. He argues that to improve patients' trust and willingness to share data, there is an urgent need to educate patients on the value of health data in research and achieve clearer, more succinct communication during the consent process. **Petra Wilson**, Health Connect Partners, suggested that while healthcare systems have the right legal and policy framework in place, it lacks the supporting policies and practical guidance required to educate stakeholders about using health data effectively while protecting patient privacy. In particular, the existing framework requires greater detail so that the idea of consent can be made workable for healthcare research to avoid consent fatigue.

Patrik Puljić

Petra Wilson

The panel also heard from **Kees van Bochove**, Founder of The Hyve, an organisation involved in numerous projects, including the European Health Data & Evidence Network (EHDEN), to support medical evidence generation at scale. Instead of building large central collections of data, the EHDEN project uses federated architectures to enable patient data to remain at its source (i.e., a hospital or GP practice) and was able to perform critical research at the start of the COVID-19 pandemic to answer fundamental questions about the coronavirus, publish peer-reviewed research and change clinical practice behaviour at high speed.

Kees van Bochove

Turning to the panel again, Professor Kalra asked whether these federated architectures were an attractive solution to the consent challenges discussed earlier in the session. Ms Wilson believes that federated architectures worked well for extensive datasets. However, smaller datasets, such as those for rare diseases, posed a greater risk to patients' privacy. To overcome this issue and build patient trust in the approach, the healthcare industry needs to effectively communicate the value of query-driven research via federated architectures in providing better, faster, and safer healthcare for patient communities. Mr Puljić agreed; to build patient trust, healthcare systems must demonstrate the value of sharing data and communicate clearly during the consent process.

DAY ONE: SPECIAL SESSION

Watch the session video here

Our health in our hands: the role of mobile health (and digital therapeutics) to improve patients' control of their healthcare

Lyudmil Ninov

Lyudmil Ninov, Senior Programme Officer at the EPF, began the session by introducing the speakers and asking the Congress participants a question: "do you regularly use mHealth applications?", to which 38 percent answered "yes" and 46 percent answered "no".

The panellists began by presenting opening statements. First to present was **Petra Hoogendorn**, Strategic digital transformation of health and care entrepreneur at the Leiden University Medical Center. She began by introducing what she considers a 'gold-standard' randomised controlled trial (RCT) showing that if a patient undergoing routine cancer treatment used an app to monitor their symptoms on a weekly basis, they lived five months longer with a greater quality of life and fewer hospitalisations. There are many great apps available, such as the ones used in the cancer trial, but they need to be recognisable to ensure they become part of clinical guidelines, care pathways and care contracts.

In his opening statement, **Antanas Montvila**, Vice President at the European Junior Doctors Association, raised three key issues from an HCP perspective: **(1) A lack of digital health training for HCPs in Europe to use mHealth apps; (2) Fragmented standards – some European countries are more advanced than others and great inequalities exist in data protection and governance and (3) A lack of innovation in healthcare delivery due to poor industry investment.** He concluded by emphasising the need to be more ambitious and look to change the system at large.

Dr Montvila gave way to **Angel Martin**, Senior Director of Digital Health & Taxation Advocacy EMEA at Johnson & Johnson, for the final opening remarks. Mr Martin highlighted that mHealth has the potential to empower people in the ownership of their own health and, in turn, achieve more personalised care and enhance the patient's experience through their journey. Secondly, **mHealth can provide better insights into patients' health condition, which can also advance healthcare research and help the industry move towards value-based healthcare.**

Mr Ninov moved the discussion forward by asking the speakers why they thought that 46 percent of the Congress audience hasn't used any mHealth app. Turning to the challenges of rapidly developing digital healthcare technology, a common theme emerged among the panellist's as they all stressed the **importance of developing greater digital health literacy across stakeholders, from HCPs and patients to the computer and data scientists building mHealth apps.**

> **"There are many apps supporting patients to get ready and fit for surgery, and it is scientifically proven that we see better outcomes following surgery and that these patients are more engaged and interact better with HCPs."**
> *– Petra Hoogendorn, Leiden University Medical Center*

Before closing the session, the panellists shared their key take home messages: Mr Martin stressed the need for digital health and mHealth to be integrated into an ecosystem involving collaboration and cooperation. Dr Montvila emphasised that mHealth apps have the potential to effect long-lasting change to the healthcare system but the process requires collaboration with patients at the centre. Ms Hoogendorn concluded by saying that **patient advocacy will be crucial in making mHealth apps part of care pathways, clinical guidelines, and clinical contracts**.

DAY TWO: SPECIAL SESSION

Patients and healthcare professionals: a partnership for and through digital health

Watch the session video here

Nick Guldemond, Professor at Sechenov First Moscow State Medical University, moderated the first panel session of the day focusing on the partnership between patients and HCPs in digital health, highlighting that although the COVID-19 pandemic had accelerated the uptake of digital health, its impact is yet to be realised in healthcare systems.

Annabel Seebohm, Secretary General of the Standing Committee of European Doctors, (CPME) began the discussion by sharing elements of the *Consensus Framework on the Digital Transformation of Healthcare* (co-signed by CPME, PGEU, EFN, CED and EPF). She outlined the framework's four key recommendations for quality patient care: (1) Guarantee **high levels of data protection**; (2) **Safeguard patient autonomy and confidentiality** when sharing health data; (3) Protect **patients' safety and rights in the delivery of online medicines** and (4) Limit potential commercial influence on telehealth.

Annabel Seebohm

Danielle Drachmann, Executive Director of Ketotic Hypoglycemia International, then emphasised that taking action is key to tackling the 'digital gap', improving health literacy amongst HCPs, developing a telehealth quality label, and introducing skills training into the medical curriculum. Ms Drachmann handed over to **Chloé Lebbos**, Vice President of European Affairs at the European Pharmaceutical Students' Association, who discussed the **scarcity of e-health training in the student curriculum** resulting in up to 75% of medical students lacking the necessary e-health knowledge and skills. She also highlighted that these students are not unaware of the need for digital literacy, as they actively express the desire to learn more to help those patients who are unable to attend face-to-face consultations.

Danielle Drachmann

Chloé Lebbos

Mr Guldemond began the *panel discussion* by asking about the roll-out of the framework that Ms Seebohm mentioned earlier in the session. In response, Ms Seebohm stated a clear need to focus on digital competencies, but within a core curriculum that covers every step of a HCP's career and is adaptable to different specialities. There was agreement among the panel about Ms Seebohm's idea of having **digital champions at a local, regional and national level who could contribute to the integration of digital skills learning into the curricula.**

> **"Skills, training and testing are needed before investing. Overall, we need a hands-on learning experience at the regional and national levels to ensure greater uptake and collaboration between patients and healthcare professionals."**
> *– Danielle Drachmann, Ketotic Hypoglycemia International*

To foster a learning environment for the development of digital solutions, panellists discussed embedding digital solutions in the workflow, promoting greater oversight of IT developers' work within the healthcare industry, promoting more student representatives as change leaders, empowering IT developers to better understand their end-users, and capitalising on the ecosystem and social context.

DAY TWO: SPECIAL SESSION

Accessing digital health: from reimbursement to the digital divide

Watch the session video here

Neil Bertelsen, Past Chair of the HTAi Patient and Citizen Involvement Interest Group, began the session by welcoming the speakers and panel members and introducing the topic of digital health access. In a keynote presentation **Corrina Hartrampf**, Senior Policy Officer at the International Association of Mutual Benefit Societies (AIM), focused on the insurance community's outlook on digital health solutions.

Corrina Hartrampf

Neil Bertelsen

"Prevention is better than cure, and health apps can do a lot to keep patients healthy, save costs and improve the lives of patients."
– Corrina Hartrampf, AIM International

Outlining the many opportunities of digital solutions in healthcare, particularly teleconsultations, Ms Hartrampf highlighted how these technologies could significantly save costs, reduce patient waiting and travel time and provide flexible services to patients. While the recent steep uptake in teleconsultations is a temporary measure in response to COVID-19, they will likely remain an integral part of patient care. However, to move forward in this 'blended' approach to healthcare, we need to **build greater patient trust in healthcare technologies, and digital health skills need to be integrated into mHealth plans to ensure accessibility and care for all**.

"When you look at the Digital Economy and Society Index (DESI), it shows that 4 out of 10 adults and every third person who works in Europe lack basic digital skills."

Ana Toledo-Chávarri

The second part of the session featured a discussion with panel members who provided their diverse perspectives on how digital health solutions could be assessed and paid for by our health systems and how involvement from the patient community can strengthen decision making. The panel first heard from **Ana Toledo-Chávarri**, Coordinator of the Patient Involvement Strategy at the Spanish Network of Agencies for Assessing National Health System Technologies and Performance, who discussed how **existing HTA frameworks don't allow for important considerations such as whether digital solutions are accessible and available for all who would need them**. So, **we need to rethink how we assess new technologies**, ask questions that go beyond a technology's safety and efficacy, and gather stakeholder input on the organisational and technical issues that affect patient access.

Bleddyn Rees

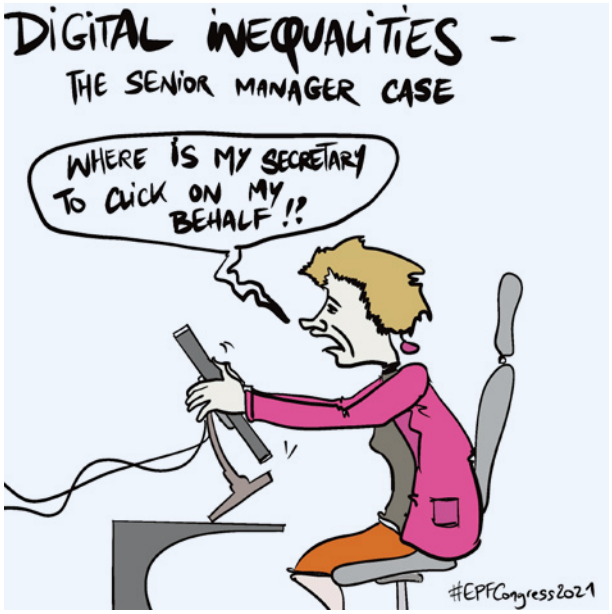
Next to share their thoughts was **Bleddyn Rees**, Founding Director of the European Connected Health Alliance, who emphasised how all aspects of best practices should be transferred between borders, including failures and lessons learned. Mr Rees highlighted that digital health is remedial, meaning there should be no distinction as health is just digital. He pointed

out **digital skills and education for staff, patients and carers are a priority,** and we should learn from other sectors but overall we must distinguish between ICT systems and the physical health system (e.g., buildings and treatment pathways) as these can constrain digital tools. Most importantly, he concluded that **we need to keep a sense of trust and perspective**; it's not about tools and equipment it's about healthcare services for people that improve outcomes, efficiency, quality of life and wellness.

Delving deeper into Mr Rees's point about patient co-design, **Paola Kruger**, Patient Advocate at EUPATI, agrees that **digital solutions should be developed with patients and that this may solve some of the technology assessment problems raised previously**. Digital devices offer the opportunity to collect a wide variety of patient data to assess the value of digital solutions and provide the wider picture of a patient's experience with a product.

Paola Kruger

> **"When we talk systems, we must distinguish between ICT and the physical health systems because they can constrain digital tools."**
> *– Bleddyn Rees, ECHAlliance*



DAY TWO: PLENARY SESSION

Discussing health data between access, control and ownership

Watch the session video here

Co-led with thebmj

Henry Scowcroft

Henry Scowcroft, BMJ Patient Editor, opened the final session of Day Two by taking a look at patients' access, control and ownership of their health data. He began by emphasising the importance of the topic at the BMJ as part of its Patient and Public Partnership strategy that began in 2014.

Maria Hägglund

In an opening keynote presentation, **Maria Hägglund**, Senior Lecturer at the Uppsala MedTech Science & Innovation Centre, provided an overview of the global progress towards providing patients with access, ownership and control of their full Electronic Health Records (EHR). She acknowledged that patient access is increasing in prevalence across Europe, while showcasing examples of platforms that can be seen internationally, such as Australia's MyHealth Records and India's unified health interface platform and regionally, with Toronto's Universal Health network. Ms Hägglund concluded by highlighting that **the more data we gather, the more interesting it becomes to researchers, industry, and other third parties.**

Tessa Richards

Mr Scowcroft welcomed three panel members – **Tessa Richards**, Senior Editor at the BMJ, **Angela Coulter**, Freelance Researcher, and **Emma Doble**, Patient Editor at the BMJ – for the ensuing discussion and invited them to set the scene with a series of short presentations. In a brief overview of the benefits of access to personal health records, Ms Richards began by citing patient advocates from more than 40 years ago, who described patients as the least used resource in the healthcare system. As **countries struggle with enabling patients access to their records, they encounter technological, organisational, governance and cultural barriers.** Ms Richards used the UK as a good example of the challenging nature of these issues, describing how the **lack of intra-operability** between primary and secondary care prevents the notes from hospitals from being shared with general practitioners and vice versa.

> **"Access has also helped improve health literacy by providing patients with a powerful incentive to learn about their own health data, place it in the context of generic health data and then act on it."**
> *– Maria Hagglund, Uppsala MedTech Science & Innovation Centre*

Ms Coulter then discussed the issue of patient control regarding who gets access to their data and how this can be achieved. She began by emphasising the **challenges facing patients, such as an inability to see all of their data, slow responses from data custodians, an increased risk of data misuse and a lack of transparency and standards**.

Ms Coulter gave way to Ms Doble, who explored the changing nature of patient data and why **it is important to define ownership of self-tracking data,** using her personal experience with type 1 diabetes as an example. The availability and access to data around disease management have changed phenomenally in the last five years, enabling a dynamic power shift in the relationship with her doctors, who now ask Ms

Doble for information. Discussing the importance of defining ownership of self-tracking data, Ms Doble explained **the need to have autonomy and power over her body and the data it creates, privacy and data protection, and access both for herself and for granting to others**.

Angela Coulter

> **"True ownership is almost impossible, informed consent of data usage is complex, and there are ethical challenges to using the data to aid health research."**
> *– Emma Doble, BMJ*

Mr Scowcroft welcomed them to the panel discussion. This part of the session began with Mr Scowcroft sharing the results of a poll started that earlier in the session, in which delegates were asked about their top priority regarding health data. **The right to determine which third parties have access to and use of patient data was voted the most important issue**. In response to a question about her experience of how this is controlled, Ms Hägglund emphasised the **broad variation across systems and the 'bluntness' of tools designed to control access.** For example, in Sweden, it is possible to block access to third parties, but that could have a detrimental impact on care. Cultural sensitivities around trust play an important role in this situation. Ms Coulter stressed the importance of what we have learned in terms of using patient data from the COVID-19 pandemic. In the final few minutes, Ms Richards picked up on the theme of **trust,** advocating the **involvement of patients in the co-development and evaluation of mechanisms for sharing data.**

Emma Doble

DAY THREE: SPECIAL SESSION

Improving medicine innovation through better use of health data – big data and real-world evidence

Watch the session video here

Kaisa Immonen, Director of Policy at EPF, began the first session highlighting that, although randomised controlled trials (RCTs) remain the 'gold-standard of evidence generation', they have several limitations in design, interpretation and ability to be extrapolated. As such, there is a growing need to understand the effects of healthcare interventions in real-world clinical practice; data which could be harnessed to better support medicines innovation and provide added value to patients and society. This real-world data (RWD) may be sourced from observational studies, patient reported outcomes surveys, electronic health records (EHR), claims databases and patient registries.

Kaisa Immonen

Ms Immonen then introduced the panel speakers one-by-one to present their opening remarks. First to present was **Dimitrios Athanasiou**, Board Member of EPF, the World Duchenne Organization and United Parent Projects Muscular Dystrophy (UPPMD). These **challenges associated with RCTs create uncertainty around the use of the data**, but Mr Athanasiou argues that uncertainty is in the DNA of drug development and regulation. For patients, uncertainty is life. To progress in an ethical and efficient way, he called for **a framework that clearly states stakeholder roles and includes a plan for the harmonisation of stakeholder efforts in defining the data they seek, for what purpose, and who has access**.

Dimitrios Athanasiou

Ms Immonen then introduced **Martina von Meyenn**, Medical RWD Chapter Lead at F. Hoffmann La-Roche, who discussed the specific ways RWD is being used to improve patient care. In clinical decision making, small patient populations, such as those with rare diseases, often do not have the breadth of data required to generate sound insights while access to data is also often limited. Further, a **lack of agreement on what is considered 'clinically relevant data'** leads to the generation of low quality data and non-linear treatment journeys, involving multiple treatment settings and locations, all of which confound the collation of follow-up data.

Martina von Meyenn

> **"Patient records are unlikely to travel with you, so the patient journey is not always linear when it comes to patient data."**
>
> *– Martina von Meyenn, Roche*

In conclusion, Ms von Meyenn highlighted there is significant interest from policy makers, regulators, payers, and industry, which creates unique opportunities for the involvement of patients and patient groups.

Lastly, the Congress heard from **Peter Arlett**, Head of Data Analytics and Methods Taskforce at the EMA, who shared the EU regulator's perspective on RWD in medicines innovation. Given the opportunities and challenges presented by RWD, Mr Arlett shared key recommendations

Peter Arlett

from the HMA-EMA Joint Big Data Taskforce and explained how it is actively engaging with patients across all of the EMA's workstreams to collaborate on patient reported outcomes and data privacy as well as working with patient organisations as researchers and data holders.

In citing the COVID-19 pandemic as an example, Mr Arlett highlighted how **RWD** can have a major, positive impact on public health. From the EMA's perspective, **regulatory decisions will increasingly include a hybrid of clinical trial data and RWD**, and the best way to achieve this is by adopting a collaborative role with all stakeholders at every stage.

> **"With real-world evidence, we want to make sure we have patients at the table at every step of the way."**
> *– Peter Arlett, European Medicines Agency (EMA)*

DAY THREE: SPECIAL SESSION

Artificial Intelligence in Healthcare

Watch the session video here

In a special session looking at Artificial Intelligence (AI) in healthcare, **Anca Petre**, CEO of 23 Consulting, moderated a panel discussion on the challenges and opportunities of AI in health. Setting the context for the discussion before introducing the panellists, Anca begins by explaining what AI is before sharing some of the many examples of how we use AI during our day-to-day.

Anca Petre

"Although movies depict AI as these terrifying robots ready to take over the world, the reality is completely different. For instance, we use AI when we ask Siri or Alexa a question."
– Anca Petre, 23 Consulting

Rintje Agricola

Digging deeper into the exciting applications of AI in healthcare, the panel first heard from **Rintje Agricola**, Orthopaedic Surgeon at Anna Ziekenhuis Hospital, who shared some of the AI projects he's a part of. In his research work, AI is used with computer fission to recognise disease patterns from images such as radiographs and prediction modelling, estimating the chances of disease in a given population. In clinics, AI is used for digital history-taking, whereby patients can answer a set of questions at home before their first consultation, and to track patients' post-surgery to analyse and benchmark how well they are progressing.

"With automated history taking, we don't have to ask repetitive questions about what kind of medications they're taking, what their medical history is etc... The quality of consultations is higher."
– Rintje Agricola, Anna Ziekenhuis Hospital

Speaking from his perspective as a patient and as the Founder of the Estonian Inflammatory Bowel Disease Society, the discussion turned to **Janek Kapper**. Janek highlighted the important role that doctors must play in providing and explaining the results or predictions from AI, the human element that is integral in comforting patients and preventing unnecessary concern. Further, **patients want to be informed as to whether their doctors are using AI or predictive algorithms to analyse their data so they can ensure that their inputs or answers are of high quality.**

Janek Kapper

Elaborating on the role doctors should play between machines and patients, **Sameer Pujari**, Vice Chair of the WHO ITU Focus Group on AI, stated that AI is not intended to replace humans, it should act as an enabler in the healthcare space. The WHO's recent 'Ethics and Governance of Artificial Intelligence for Health' guidance focuses on the key principles and recommendations to ensure AI works to the equitable and ethical public benefit of all countries and sectors. Touching on Ms Petre's point about public fear around AI, Mr Pujari recommends **wider education on the real-use cases and applications of AI technology.**

Sameer Pujari

Dr Agricola has also witnessed fear from doctors that AI could replace their jobs and are afraid to use it. However, this fear may be overcome once patients and doctors see the benefits for themselves and that **AI doesn't replace human connection between a doctor and patient, it simply improves the experience.**

DAY THREE: PLENARY SESSION

Patients as co-designers and co-innovators: between theory and practice

Watch the session video here

Co-led with

Funded by the European Union

In the final panel discussion of the day, **Nicola Bedlington** moderated a live pitch and roll session looking at patients as co-designers and co-innovators. She introduced the session by talking about the learnings from the EPF Congress 2019 and the development of the new Innovative Health Initiative (IMI), which is helping to create an EU-wide health research and innovation ecosystem. She then handed over to **Jaume Puig** and **Dr Esther Murphy** to pitch their ideas around meeting the challenge of digital innovation in specific patient groups.

Jaume Puig

Nicola Bedlington

> **"People with intellectual disabilities are being left behind in our digital revolution, which is having a detrimental impact on their health, wellbeing and inclusion."**
> *– Dr Esther Murphy, Trinity College Dublin*

Mr Puig, co-founder and CEO of Biel Glasses began his presentation by talking about his son Biel, who was born with low vision. After being told by doctors that there was no medical solution to help his son navigate through daily life without falls and injuries, Mr Puig founded Biel Glasses to create advanced and affordable solutions to adapt the world to the eyes of those with low vision. From the very beginning, Biel Glasses has placed the patient at the heart of everything it does, working with low vision patients and patient organisations throughout the product design and clinical trial process. Companies such as Mr Puig's offer value through their personal knowledge of the problem that their product is trying to solve, aiming to fill the gap that exists between a patient's needs and the health systems offering.

Dr Murphy introduced herself as the Activity Lead for the EIT Health funded, pan-European interdisciplinary digital skills education project, Digi-ID, co-created with and for people with intellectual disabilities (ID), their families and health professionals.

Dr Esther Murphy

Beginning her Digi-ID co-creation story, Dr Murphy highlighted the many challenges of digital inclusion and low usage of digital technologies amongst people with ID and their supporters. At the heart of the project is a Citizen Advisory Panel (CAP), comprising seven people with ID who have a passion for technology to inform and shape decision-making and design. Through a co-creation process with people with ID throughout all phases of innovation, **the Digi-ID programme has harnessed crucial patient insights to feed into their design and technology development work.** Dr Murphy was joined by Mei Lin Yap, one of the Digi-ID CAP members, who shared examples of the Digi-ID prototype design before and after co-creation focus group sessions to demonstrate the meaningful design changes implemented in response to CAP feedback to make the product even more accessible for people with ID.

Nicola Bedlington kicked off the panel discussion by welcoming **Jan-Philipp Beck**, CEO EIT Health, and asking him to share the organisation's strategy and approach to patient engagement. He

> **"For most people, technology makes life easier. For us [people with intellectual disabilities], it makes life possible."**
> *– Mei Lin Yap, Digi-ID*

Jan-Philipp Beck

began by saying that **patient engagement is about understanding health – it is about people.** EIT Health strives to ensure that patients are meaningfully involved throughout the whole healthcare innovation pathway. EIT Health does this in two ways: firstly, by involving patients and citizens early in the co-design and co-creation approach and secondly, by providing the framework within which co-creation can take place, for example, with education and entrepreneurship programmes.

Signe Ratso

Ms Bedlington then welcomed **Signe Ratso**, European Commission DG RTD Deputy DG for Open Innovation, to the panel and asked how the EU Commission sees patient involvement in research and development in digital health. In response, **Ms Ratso emphasised that the Commission already has a strong track record in supporting patient involvement**, for example, the EU joint programme on rare diseases (EJ PRD) is a large consortium involving 140 partners working closely with patients to empower their full involvement in research. There is also PARADIGM, with its patient engagement toolbox. Ms Ratso went to describe one of the most recent initiatives, the EU Cancer Mission, which set an ambitious goal of uniting countries to improve the lives of the three million plus people affected by cancer by 2030.

In response to a question about what can be done to facilitate patient innovation, Mr Puig highlighted the dilemma he faces each day – one where **innovators struggle to leverage the potential that living with a condition** or caring **for someone who lives with a condition offers to the design of innovative health solutions.** Ms Bedlington picked up on this point, highlighting the importance of **enabling patents to bring their expertise and knowledge whilst managing other challenges**, before moving on to ask Dr Murphy to describe how her project has moved beyond patient co-creation. Dr Murphy responded by saying that their work in helping citizens become educators has been described as a project within a project. They have advocated for action on the lack of employment opportunities for people with intellectual or physical disability with the mantra – nothing about us without us – a move towards the space where patients are recompensed at a fair market value for their knowledge, experience and expertise.

Mei Lin Yap

For a long time, discussion has focused on the risk of involving patients in developing healthcare solutions but now, there is a shift towards recognition of the **risks associated with not involving patients from both a business and human perspective.** Mr Beck expanded on this point, saying that **by focusing on the output and outcomes that really matter to patients, the success and potential of solutions are increased and waste is reduced**. His suggestion to address the issue of the lack of available time to scale-up and commercialise patient innovations is to look at building capable teams and bringing in people with the expertise to address specific aspects of the project. When asked why patient innovation is so important to society, Mr Puig highlighted that **patients can detect the gaps in care created by current solutions, particular in relation to quality of life, and can therefore lead initiatives to meet these unmet needs**.

As the discussion concluded, Ms Bedlington asked each panellist to share what they felt was a key take-home message. For Mr Beck, it was exploration of how the challenge of creating solution and scale up of ideas can be more transparent to help patients see what others are working on. Dr Murphy built on the point about transparency with emphasis on the need to make all these wonderful projects accessible to patents so that they can connect and engage in projects that are meaningful to them. Ms Ratso called for everyone to be engaged and to look at ways to prioritise that engagement and provide the relevant information needed by patients. Mr Puig recognised that, despite institutional and stakeholders' intentions to prioritise patient innovation, there was a lot of work still to be done but this Discussion represents a good start to future collaboration.

DAY FOUR: SPECIAL SESSION

The road to patient empowerment – data and digital health literacy

Watch the session video here

Developed with Data Saves Lives

Birgit Bauer

Jessica Pacey

Jessica Pacey, CEO of 67health and communications representative from the Data Saves Lives (DSL) team, opened up the session by introducing the ground-breaking movement of digital health data literacy and its transformative potential to improve health outcomes and patient lives for the better. Following a detailed introductory video on the power of health data, the first speaker, social media and digital health expert **Birgit Bauer**, then opened up the session with an informative presentation on the DSL toolkit. This valuable information resource was designed to equip patient communities with the skills to become health data literate, providing them with the tools to discuss health data with their communities.

Ms Bauer then handed over to health literacy trailblazer and globally renowned expert **Kristine Sørensen**, who explored how empowering individuals through health literacy could be the key to unlocking a better life. However, these outcomes are dependent on the individual's position on certain social gradients like their socioeconomic status, that reflect inequity in society. Those with low health literacy have less resources and thus, a lower health status. Health literacy could help to bridge these inequalities.

Kristine Sørensen

Angela Bradshaw

On behalf of Alzheimer's Europe, Project Officer **Angela Bradshaw** kickstarted the insightful panel discussion, exploring how **digital health initiatives must be shaped around the idea of 'nothing about us without us', prioritising patient voices and interests.** Health literacy is central to patient empowerment, allowing them to be meaningfully involved in their care whilst helping them to better understand their diagnoses and make informed decisions. For Ms Bradshaw, a one-size-fits-all approach cannot be applied when designing health data initiatives due to varying levels of health literacy.

As Head of Division of new technology and health data use at the German Ministry of Health, **Nick Schneider** pointed out that **the greatest barrier prohibiting patients from accessing digital health literacy is the regulatory environment.** The European Health Data Space (EHDS) could present a solution to this, bringing together patients and regulators from across the continent. However, there must be an efficient health data infrastructure that promotes patient interests.

> **"Health literacy is not an end in itself, it is a means to better quality of life."**
> *– Kristine Sørensen, Global Health Literacy Academy*

Nick Schneider

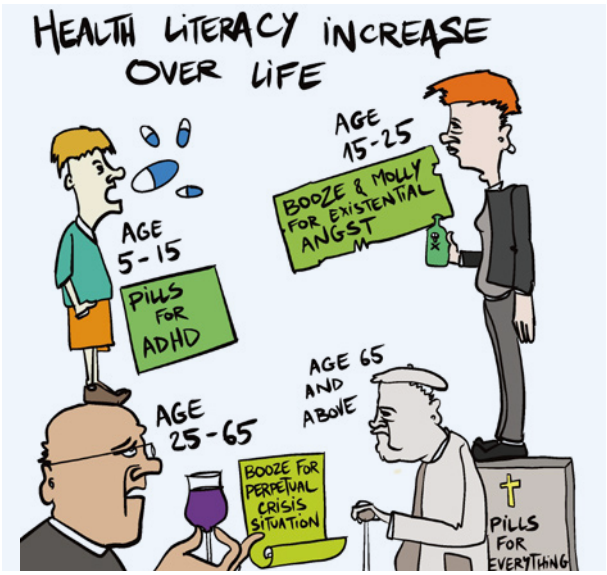
For Ms Sørensen, **the last 18 months have highlighted the value of technology, but**

also revealed crucial inequalities in access to services. In addressing these inequalities, **Aleš Bourek**, gynaecologist and Head of Centre for Healthcare at Masaryk University, stressed that **healthcare professionals must facilitate dialogue about health data literacy with their patients**. He contends that it is their job to translate information in a way that empowers patients to make informed decisions.

Aleš Bourek

For Ms Sørensen, health literacy builds over a lifetime. **Public education must turn towards health literacy so that new generations can gain the competencies to act in an informed way.** Mr Schneider reiterated this notion, underscoring the importance of having a navigation route or map for the European Health Data Space. Mr Bourek furthers this idea, reiterating that we can design our own personalised data repositories rather than centralised one. What is needed is a transparent and effective code of conduct. Building on this, Ms Bradshaw reiterated that **trust** is an essential component to this equation. We must remember **the human dimension to health data literacy, continuing to centre our work around promoting patient outcomes**.

> **"Data sharing is still stuck at the national regulatory systems, and I think that the European Health Data Space is actually the silver lining of this situation. The COVID-19 pandemic has become a catalyst to demonstrate how relevant it is to virtually share data."**
> *– Nick Schneider, German Ministry of Health*



DAY FOUR: SPECIAL SESSION

Safer digital health: how to ensure it at European level

Watch the session video here

Valentina Strammiello, Head of Programmes at the EPF, welcomed a multidisciplinary panel to discuss the regulation and safety of digital health solutions by emphasising the broad operational areas of the Medical Devices Regulations (MDR) and In-Vitro Diagnostic Regulations (IVDR) of 2017. She welcomed **Rosanna Tarricone**, Associate Dean at the SDA Bocconi School of Management, to set the scene. Ms Tarricone began by sharing figures to demonstrate the exponential growth in mobile health (mHealth) applications in response to the COVID-19 pandemic and initiatives such as the EU Next Generation. Even prior to the pandemic in 2019, the worldwide market size of mHealth applications was $52.6 billion and estimated to grow to over $300 billion by 2025. While mHealth apps have the potential to empower patients to self-manage their health and allow healthcare services delivery to become more efficient and financially sustainable in the long term, the impact of mHealth apps on health outcomes for chronic diseases remains unclear.

Valentina Strammiello

Rosanna Tarricone

Rosanna discussed the new EU regulation of medical devices implemented on 26th May 2021 and the new regulation for health technology assessments (HTAs) to be introduced by the end of 2021, highlighting the impact on digital health. Overall, the mHealth industry is facing increasing demand for greater evidential requirements, which is only expected to grow following the new EU HTA regulation approval. A circular process covering the various stages of a product's entire lifecycle is needed to generate evidence in support of market authorisation, coverage, reimbursement and purchasing decisions.

> **"The new HTA regulation is an opportunity to make regulation and assessment part of a greater innovation chain, starting from early prototyping through to product commercialisation."**
>
> *– Rosanna Tarricone, SDA Bocconi*

Valentina Strammiello opened the panel discussion with a question about the current safety measures in place. In response, **Oliver Bisazza** of MedTech Europe, highlighted that **safety considerations should not be confined to digital health and mHealth apps as there are also exciting innovations taking place in hospitals**. Within this broader landscape, the medical device regulations introduced in 2017 ensure that all criteria must be met before the device reaches the market. However, a significant development in enhancing device safety has been in the use of post-marketing surveillance, where developers have to actively seek feedback from users and all device manuals must contain guidance for users to provide that feedback.

Oliver Bisazza

Papatya Alkan-Genca, Board Member of the International Federation for Spina Bifida and Hydrocephalus responded to a question about the safety issues by highlighting three key concerns. Firstly, the orthopaedic and neurological problems caused by spina bifida, alongside hydrocephalus, present on a wide spectrum therefore there cannot be a 'one size fits all' approach to digital health solutions. Similarly, users have **different socio-technological backgrounds which impacts on their ability to use these solutions**.

Papatya Alkan-Genca

Flora Giorgio

In response to the question about how the medical device regulatory framework will improve health technology assessment, **Flora Giorgio**, Deputy Head of Unit, DG SANTE, European Commission, advised that it has already started to enhance the body of evidence and provide reassurance. The change to HTA regulation will contribute to the methodologies for assessment of medical devices, further strengthening the evidence and building confidence for payers and decision makers. Ms Giorgio emphasised that this is a first step in the right direction but echoed Mr Bisazza's comments on the importance of post-marketing surveillance.

A question about how safety data collection in the post-marketing space would inform the HTA prompted discussion about the importance of avoiding duplication of work. Mr Bisazza was keen for the HTA to focus purely on assessment and comparison of clinical effectiveness, emphasising that safety is a regulatory issue and has sat within the remit of MDR and IVDR for the last ten years and has provided the most substantial safety assessments in the world. He did emphasise, however, that there was no room for complacency.

Ms Giorgio emphasizes that the HTA would not be re-assessing safety but would compare it across the devices so that both frameworks can support and enable the update of mobile technology in healthcare. Ms Tarricone echoed these comments, emphasizing that the assessment of health technology should be seen as a continual process. A key point to consider is that in digital health, the lifecycle is much shorter than for traditional medical devices so it would be beneficial for both processes to be clear about what evidence is needed for developers.

> **"Making all the data available and transparent relies on a European database. We are still a few years off that unfortunately but we are working on it in earnest."**
> *– Flora Giorgio, DG SANTE*

Ms Alkan-Genca's key takeaway from the discussion was focused on this point: that **patient and their organisations represent an untapped potential**, they should be part of the process in every single way. Ms Giorgio was keen to emphasise that **digital apps offer great opportunities for the future and ensuring that the comparative evidence available to everybody, we can hopefully increase uptake and improve their contribution to patient care**. Finally, Mr Bisazza highlighted that, like all health technology, digital health innovations present opportunities on the one hand and a need to manage the uncertainties on the other. **Regulation is one way to manage this and Europe is very well-regulated but we now need to make sure we are consistent and clear in what we do**.

DAY FOUR: PLENARY SESSION

Shaping a European health data space with and for patients

Watch the session video here

Petra Wilson

Petra Wilson, of Health Connect Partners, moderated the final plenary discussion of the day. As a potential key milestone for health data and digital health policy at EU level, this final session looked at the state of play of EHDS development and discussed how to shape it in partnership with patients, particularly building on the key learnings from the EPF Congress debates.

Ioana Maria Gligor

Ioana Maria Gligor, Head of Unit at Sante.B3, Digital Health and European Reference Networks, began by outlining the **role of the EHDS, which consists of not only wanting to improve the access to health data for individuals, but also aims to support healthcare delivery, health research, innovation, and health policy through the re-use of data.** The European Commission is looking at how it can support cross-border use of data and innovation by focusing on legal frameworks, quality of data and infrastructure, and capacity-building and digitisation.

> **"To date, there are nine member states signed up to 'MyHealth@EU' and we now need to focus on the interoperability of this data."**
>
> *– Ioana Maria Gligor, DG SANTE*

At the start of the plenary, Ms Wilson asked delegates about their expectations of the EHDS via an online poll, whether their priority was free movement of electronic health records around the EU, securing safe and transparent use of data, enabling better research use of the data, or easy access and control of an individual's own health data. Although delegates felt that all these were important, **easy access and control of their own data was voted the main priority**.

Cecilia Bonefeld-Dahl

In the opening question, Ms Wilson shifted the focus to the communities represented by the panellists, by asking what want from the EHDS. **Cecilia Bonefeld-Dahl**, Director General at DIGITALEUROPE, stressed two key needs – namely a **common consent form for patients to use to access their data across the EU and harmonisation of use of that data.** There is also a need to **upskill healthcare professionals in the use of this data**, particularly in the fast-growing area of medical devices, so that the data can make a timely contribution to the care of the patient. **Elizabeth Kasilingam**, Acting Executive Director of the EPF, echoed the need to address the skills gap in healthcare but also highlighted that **patients want access and control of their data in a framework that is clear, transparent, and trustworthy**. A mechanism that encourages the meaningful involvement of patients' perspective across the whole system is also needed.

Elizabeth Kasilingam

As discussion moved on to what the communities the panel represented could bring to the EHDS. **Toni Andreu** explained that, although there is a **blurring of the border between the research and care domains**, the issue of reproducibility of data is a barrier to the translation of research findings into the care setting. He emphasised the **need to work within the four principles of**

Toni Andreu

FAIR data, namely findability, accessibility, interoperability, and reusability to maximise the capacity for research data to inform workable solutions that can be implemented in the healthcare space. Ms Bonefeld-Dahl stressed the need for renewal of national systems, highlighting that many cybersecurity issues arise from outdated systems. Industry, health authorities, the public sector, and patients need to work together to create these updated infrastructures. Ms Kasilingam picked on the patients' contribution in terms of having the right seat at the table and strategies to achieve their acceptance of health data. These included educating patients to enable them to see the impact of their data at local and policy level and building trust through ownership and collaboration. In doing this, it is important to remember that not all patient networks operate at the same level across the EU. For Mr Andreu, **developing stories of success that can be shared with patients and policy makers and using a common language framed in an honest dialogue, will help to overcome the common barriers.**

As the discussion drew to a close, Ms Wilson advised delegates that it wasn't too late to engage with the team behind the development of the EHDS. According to Ms Gligor, consultation between members states and patients will the taking place for a considerable time to come.

> **"Patients and citizens really have to be the center of the discussion. To ensure this, we must harmonize data standards, to truly enable patients to understand how their health data is going to be used."**
> *– Cecilia Bonefeld-Dahl, DIGITALEUROPE*

Closing remarks

Watch the session video here

Tjasa Zajc and Ivett Jakab shared their final thoughts as co-hosts on the Congress by highlighting some of the key takeaways from the mix of plenary, discussion and networking sessions over the four days. Ms Zajc highlighted the **top-down management of the recent pandemic as a missed opportunity for patient involvement at policy level** and that the Congress had exposed the **need for better understanding and expectations of data**, particularly that being used in AI solutions. As well as **better access and control of health data for patients,** there is also a need for someone to **take ownership of digital literacy for both patients and healthcare providers**, perhaps for the latter as part of the wider medical education curriculum. The examples of **co-creation show the power of the patient experience,** but better support is needed to address the challenge of being a patient or a carer as well as a founder. Finally, although the EHDS framework is still in its final inception phase, we are on our way to a better digital future.

> **"We need to reflect on their importance and ensure that, when we go forward five years from now, we can look back and see that we have used them properly."**
> *– Marco Greco, EPF*

Ms Jakab picked up this point by adding that the **digital transformation of healthcare requires everyone involved, from patients to policy-makers, to have an open mind and come together to talk.** The complexity of digitalisation is exciting but it raises more questions than answers. However, the earlier these questions are identified, the earlier everyone can find the answers.

In his closing address, Marco Greco, the President of the EPF, emphasised the importance of organising a truly patient-led congress on the digitalisation of healthcare. As a topic at the core of the European healthcare debate, it is essential to talk about the issues around data. **We generate data all the time and we perhaps underestimated the importance of some of these data as we dealt with the pandemic emergency**. But now we have an opportunity

to **look more broadly at the data and explore the risks and the opportunities they offer.** At the same time, we need to build understanding of the importance of the data and **accept the legal and ethical challenges in using them to generate a safer and more effective healthcare system**. Mr Greco concluded by focusing on three key words relevant to the building and regulation of that system: **education** – essential to empowering patients and stakeholders, **co-creation** – a really useful and wonderful word that may completely change digital health, and opportunity. The Congress has highlighted many key learnings opportunities.

EPF Congress 2021 Key Takeaways

1. Education is crucial and essential to empowering patients and stakeholders
2. Co-creation with patients can completely change digital health
3. Trust is essential when working with patients.

Key Comments from the audience Q&A at the EPF Congress 2021

When thinking about trust in the context of RWD, the European regulatory network is committed to leveraging RWD and doing it with patient. Patient involvement is becoming super relevant and core to everything we do from a regulatory and industry perspective. We have momentum at the policy level about patient data; it's just down to the final push, and we should do it all together.

Although we are optimistic that AI will help in the development of prediction models for diagnosis of disease and the personalisation of treatment, we also need to make the models generalisable to all populations. That can be a challenge when you are building the models using RWD from limited populations.

Digital solutions need to reflect patient needs i.e., they need to be relevant to the end-user, drive patient empowerment and be embedded in the workflow, not sitting in bureaucratic structures.

The https://patient-innovation.com/ is a platform created for patients and those who care about them to share and access useful solutions to cope with their diseases. A further site for those interested in patient co-created digital innovation suggested in the chat was the DayOne Health Hack EUPATI CH as Partner at https://www.dayone.swiss/what-we-do/dayone-events/health-hack/

Education is key to addressing the digital divide and preventing people from being left behind. We should look outside healthcare; for example, banks are incentivised to reduce fraud by training their customers in digital literacy, and they do this for free. Other organisations, for example in sport, use their expertise in sports nutrition and exercise to educate pupils in schools.

We need broader, cross-border surveys, but we need to be mindful of the cultural and trust issues. We also need to understand what we mean by data and to be cognizant of how lack of knowledge can drive fear.

Special thanks

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