Patient Engagement & Medical Devices
June 25th from 15.30 to 17.10 CET
Ground rules

• Please mute yourself during this webinar.

• If you want to ask a question, you can either ask through the Q&A box or by raising your hand.

• Our agenda is quite robust and we might need to select the questions to be answered to ensure all speakers have their statement.

• Enjoy!
Speakers

- Veerle Aertsen, EUPATI Fellow, YOPD Research Advocate and DBS Patient Expert
- Inga Drossart, Patient Engagement Officer (European Society of Cardiology)
- Oliver Bisazza, Director Regulations & Industrial Policy (MedTech Europe)
- Paul Piscoi, Scientific Policy Officer, European Commission (DG Grow)
- Prof. Alan Fraser, Chairman Regulatory Affairs Committee (European Society of Cardiology)
- Dr Tamás Bereczky, Training Coordinator (EUPATI) – moderator
Agenda

15.30 – 15.35 - Introduction to the PEOF and session by Tamás Bereczky

15.35 – 16.00 - Statements from panellists
• Paul Piscoi - summary of regulatory framework and benefits for patients
• Oliver Bisazza - medical regulation framework
• Inga Drossart - experience as a patient facing challenges with medical devices – life examples

16.00 – 16.15 - Q&A

16.15 – 16.35 - Statements from panellists
• Veerle Aertsen - experience as a patient living a medical device – dissemination and good practices
• Prof. Alan Fraser - professional and academic viewpoint on patient engagement within medical devices

• 16.35 – 17.00 – Q&A
• 17.00 – 17.10 – Takeaway messages
Patient Engagement Open Forum (PEOF)

- Patient Engagement Open Forum is a series of virtual events (in 2020) where we will work together, in a multi-stakeholder context, to turn patient engagement from an aspiration into reality.

- The Forum aims to provide a holistic perspective of patient engagement, the landscape and actors, and foster collaboration and co-creation while breaking down fragmentation that are often present in patient engagement work.
Patient Engagement Open Forum 2020 (PEOF)

**June 25th**
PEOF2020 opening plenary (PARADIGM, PFMD and EUPATI)

*Parallel sessions:*
- Patient Engagement tools session #1 (consultation organised by PARADIGM)
- Patient engagement within MedTech (panel organised by EUPATI)
- Patient experience in regulatory processes (workshop organised by PFMD)

**June 26th**

*Parallel sessions:*
- How to engage patients in the early phases? (workshop organised by PFMD)
- Patient engagement in co-creating plain language summaries (workshop organised by PFMD)

**July 9th**

*Parallel sessions:*
- Patient Engagement tools session #2 (consultation organised by PARADIGM)
- Flash presentations
  1. Sustainability roadmap for the patient engagement ecosystem
  2. Patient engagement agreements explained
  3. Patient engagement in medicines R&D in the CEE region
- Motherhood should not be a fight – better safety information on medicines use during pregnancy and breastfeeding, with patients for patients. (Workshop organised by IMI-Conception)

**September 10th**

*Plenary session*
- PARADIGM Patient Engagement Toolbox (webinar organised by PARADIGM)
- Patient Engagement Monitoring and Evaluation Framework (workshop organised by PARADIGM)

**September 24th**

*Parallel sessions:*
- How PE can foster access through improved affordability? (webinar organised by EUPATI)
- Patient engagement in clinical trial phase and in the regulatory submission phase (workshop organised by PFMD – to be confirmed at a later date)
- From diagnosis to treatment and beyond: personalised medicine – what’s in it for patients and how to make it available to patients who could benefit from it? (workshop supported by PFMD)

**October 15th**

*Parallel sessions:*
- Patient Engagement and Quality by Design: Co-Developing an Implementation Roadmap for Clinical Trials (organised by CTTI)
- Good Lay Summary Practice, communicating trial results to the general public – How patient engagement can work (organised by EFPIA and EFSCP)

**November 23rd**

*Plenary session:*
- PEOF2020 conclusion session

**November 5th**

*Theme: Regulatory*
Introduction to the session

Multi-stakeholder panel expert will discuss

- Regulation of medical devices
- Role of patients in the regulatory environment
- Examples on patient engagement within medical devices.

Expected outcomes

- Leverage knowledge and information on the current landscape of medical devices and how patients are or can be involved.
- Translate the proceedings into educational materials to be hosted in the EUPATI Toolbox and/or e-learning platform.
- Facilitate dialogue across stakeholders.
Summary of regulatory framework and benefits for patients

Paul Piscoi, Scientific Policy Officer, European Commission (DG Grow)
Summary of Regulatory Framework and Benefits for Patients
Revision of the EU Medical Devices Legislation

Directive 90/385/EEC on active implantable medical devices
Directive 93/42/EEC on medical devices

Regulation on medical devices

Directive 98/79/EC on in vitro diagnostic medical devices

Regulation on in vitro diagnostic medical devices
Summary of Regulatory Framework and Benefits for Patients
Approval pathway for high-risk medical devices in the EU

Coordinated by European Commission DG SANTE

Approval pathway for high-risk medical devices in the EU

Manufacturer
- Preclinical testing
- Clinical investigations

Notified Body
- submits technical file including Clinical Evaluation Report (CER)
- Conformity assessment
- NB issues Certificate

Manufacturer
- Market access
- Post-market surveillance

CDP = Clinical Development Plan
CEP = Clinical Evaluation Plan

EU Devices Clinical Trials Database

Clinical Evaluation Assessment Report (CEAR)

Summary of Safety & Clinical Performance (SSCP)

Periodic Safety Update Report (PSUR)

EXPERT PANELS
- Clinical Evaluation Consultation Procedure (CECP)

Independent scientific opinion

EUDAMED portal & database
Summary of Regulatory Framework and Benefits for Patients

Novelties & Benefits for Patients

Overall increased regulatory scrutiny

- Enhanced requirements for clinical evidence, use of equivalence, post-market surveillance, post-market clinical follow-up, vigilance and market surveillance.
- Extension of coverage for potential liability.

Transparency and access to information

- Summary of Safety and Clinical Performance
- Implant cards
- Clinical Investigations Report and Summary
- Field Safety Corrective Actions and Field Safety Notices
- More detailed IFUs and labelling
- Devices and their certificates

Online resources

Medical regulation framework

What’s ‘new’ the new EU Medical Device and IVD Regulations?

Oliver Bisazza, Director of Regulations & Industrial Policy, MedTech Europe
Medical Regulation Framework

EU Medical Devices Regulation (MDR): More Details, New Requirements

Former Directives
(from 1990s) = 95 pages

CE marking legislation

New Regulation
(May 2017) = 175 pages
Medical Regulation Framework
IVDR/MDR = A Modernised, Strengthened System

- Clinical Evidence
- Notified Bodies
- IVD Overhaul
- Transparency
Medical Regulation Framework
Why This Overhaul Was Needed?

To **modernise** the legislation, e.g.:

- Clarify which products are medical devices and their level of risk,
- Introduce cybersecurity requirements for software/IT infrastructure,
- Facilitate traceability of devices circulating on the EU market.

To **increase trust** in the EU regulatory system, e.g.:

- Increase transparency and public information about devices on the market.

To **strengthen** the **Notified Body** system, i.e.:

- Raise the bar for organisations claiming competence to audit/certify bodies.
- “Get rid of the bad apples” following past experiences with the subpar performance of certain Notified Bodies.
Medical Regulation Framework

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**INDUSTRY SUPPORTS ALL THIS (and is investing heavily to comply!)**
Experience as a patient facing challenges with medical devices

Inga Drossart, Patient Engagement Officer, European Society of Cardiology
Patients’ Perspective
Example 1: ESC Position Paper on Participatory Co-Design in Digital Health

• Medical devices can include apps, wearables and other digital health technologies.

• Traditionally, such technologies have been developed for consumers/patients without their input at the earliest stages of development. This results in tools which are not adopted, soon abandoned, or which fail to engage patients.

• Position Paper aims to give recommendations for the use of co-design in digital health.
Patients’ Perspective

Example 2: Remote monitoring of cardiac implanted electronic devices – legal requirements and ethical principles (to be published July 2020)

Informed consent to RM should enable patients to understand:

• How does it work?
• Where does my data go?
• Who’s got access to my data?
• What are my rights?
• …
As a **patient** living with **two implanted medical devices** (pacemaker, lumbar-disc prosthesis), what kind of **personal challenges** have I faced?
Patients’ Perspective
Engaging patients in medical devices R&D

**BENEFITS**

- Provides opportunities for mutual learning and effective collaborations
- Allows to better understand the benefits most important to patients and what risks patients may or may not be willing to tolerate.
- Allows to develop patient centred design of medical devices = higher acceptance/adherence by patients

**CHALLENGES**

- Highly technological devices and complex regulatory framework = expert knowledge might be needed
- ‘Representativeness’ of the patients involved?
- Requires to accommodate to patients’ needs in the process (logistics, etc.)
Questions and... Answers!
Experience as a patient living a medical devices – dissemination and good practices

Veerle Aertsen, EUPATI Fellow, YOPD Research Advocate and DBS Patient Expert
Meaningful patient involvement in R&D
Return on engagement: example 1 asthma spacers

Credit: Dominique Hamerlijnck
TÉLÉCOMMANDE PATIENT
Manuel d'utilisation de la thérapie DBSTM de Medtronic®
Activa® PC Modèle 37601 / Activa® RC Modèle 37612
Activa® SC Modèle 37602 / Activa® SC Modèle 37603

PATIENTEN-PROGRAMMIERGERÄT
Bedienungsanleitung für die Medtronic® DBSTM-Therapie
Activa® PC Modell 37601 / Activa® RC Modell 37612
Activa® SC Modell 37602 / Activa® SC Modell 37603

PATIENTENPROGRAMMIERAPPARAAT
Medtronic® Gebruikershandleiding
DBSTM-therapie
Activa® PC Model 37601 / Activa® RC Model 37612
Activa® SC Model 37602 / Activa® SC Model 37603
Beware of deep water after subthalamic deep brain stimulation

Daniele Walioglu, MD, Heide Baumann-Vogel, MD, Lenart Steglich, MD, Ruth Hänggi Schmidli, MSc, and Christian R. Baumann, MD


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We report the worsening complaint of 9 patients receiving deep brain stimulation of the subthalamic nucleus (STN-DBS) for Parkinson disease (PD), who lost their ability to swim after surgery. All patients had been proficient swimmers even after their PD diagnosis but found their swimming skills deteriorated after deep brain stimulation (DBS) (video 1).

All patients reported being highly satisfied with the overall outcome of DBS, with very good motor outcomes (table) and stable neuropsychological functions. However, they were frustrated by their loss ability to coordinate limb movements for swimming, be it for breaststroke, backstroke, or crawl. On systematic assessments 6 months after DBS and compared with pre-DBS conditions, neither neuropsychological functions nor gait was markedly changed in these patients. Routine intraoperative microelectrode recordings, microelectrode test stimulation, and postoperative imaging confirmed correct position of the active electrode contacts in the dorsolateral portion of the STN. Three cases are highlighted to illustrate the problem.

Case 1

This 49-year-old man with PD experienced troubling motor fluctuations and was treated with STN-DBS. He owned a house right at the lakeside and was an experienced and proficient swimmer. Feeling convinced after DBS because of his good motor outcome, he literally jumped into the lake, where he would have drowned if he had not been rescued by a family member.

Case 4

This 39-year-old woman with PD and motor fluctuations was an accomplished swimmer who had participated in countless competitions. Even after being diagnosed with PD, she enjoyed swimming regularly up to the time of surgery. Despite good control of motor symptoms after DBS, she was no longer able to swim. She regularly practiced swimming with her physiotherapist, but never came close to her previous level.

Case 5

This 65-year-old woman with PD and motor fluctuations had a lifelong swimming and used to participate in swimming competitions covering Lake Zurich. She was satisfied with the overall outcome of STN-DBS, having achieved good motor control without fluctuations. However, postoperatively, she could only swim for about a quarter of a kilometer and complained that her posture was "awkward" when trying to swim.

Three patients (cases 3–5) tried outofhopping DBS for swimming. All found their ability to swim came back immediately, with improved coordination of the limbs. However, PD motor symptoms deteriorated rapidly; therefore, all decided to switch stimulation on again as soon as possible.

From the Department of Neurology, UZH, N.H.S., C.R.B.S., and Department of Neurosurgery, UZH, University Hospital Zurich, Zurich, Switzerland, and the Parkinson Center for Neuro-rehabilitation, UZH, Zurich, Switzerland.
This manuscript is a preliminary version of the article. Funding information and disclosures deemed relevant by the authors, if any, are provided at the end of the article.
It is not because something is technologically possible
That therefore it is
• socially desirable
• Legally permissable
• Economically viable
• And ethically responsible

• Caroline Pauwels Rector VUB
Professional and academic viewpoint on patient engagement within medical devices

Prof Alan Fraser, Chairman Regulatory Affairs Committee (European Society of Cardiology) and Chairman of Task Force on Regulatory Affairs (Biomedical Alliance in Europe)
Professional and academic viewpoint
An effective regulatory environment

Regulators → Manufacturers

Patients
Academia

Expert clinicians
Expert scientists & engineers
Medical associations
Patients
Professional and academic viewpoint
EMA interaction with patients and consumers

- Management Board
- Scientific committees
- Disease-specific consultations
- Reviewing written information on medicines
- Preparation of guidelines
- Conferences and workshops

Composition and size of expert panels

“Panels meeting to fulfil these tasks should include a wide range of experts.”

“Members of the public/patients/users should be included.”

Professional and academic viewpoint
Framework for incorporating patient preferences into regulatory assessment of medical technologies

Professional and academic viewpoint
Wearable devices for ambulatory cardiac monitoring

Ambulatory Monitoring Capabilities
- ECG
- Heart Rate
- Arrhythmia
- Blood Pressure
- Cardio-Respiratory Fitness
- Stress
- Respiratory Rate
- Temperature
- Oxygen Saturation
- Ischemia
- Apnea

Devices for Ambulatory Monitoring
- Wristwatches
- Smartphones
- Patches
- Headbands
- Eye-glasses
- Necklaces

Sana F et al, JACC 2020; 75: 1582–92
Professional and academic viewpoint
Implantable devices for cardiac monitoring and treatment

Remote monitoring of cardiac implanted electronic devices – legal requirements and ethical principles

ESC REGULATORY AFFAIRS / EHRA JOINT TASK FORCE REPORT


- EU General Data Protection Regulation
- Cybersecurity of remote monitoring
- Informed consent
- Patients included in Task Force

Nielsen JC et al, Europace 2020 (in press)
Professional and academic viewpoint

Aggregating real-world data using a patient-centered health-data-sharing platform

Dhruva SS et al, NPJ Digit Med. 2020 Apr 20;3:60

Patient Reported Outcome Measures (PROMs)
Short, post-procedure, mobile-friendly questionnaire emailed twice weekly for 10 total times immediately post-procedure
Longer, disease-specific, questionnaires emailed at baseline, 1, 4, and 8 weeks post-procedure
Email reminder instituted during study

Electronic Health Record Data
- Encounters
- Encounter location
- Encounter diagnoses
- Labs and lab results

Imaging tests
- Medications
- Procedures
- Problem List

Pharmacy Data
- Prescription names
- Prescription source
- Formulations and dosages
- National Drug Code (NDC)
- Start and end date
- Number of refills available
- Prescriber

Personal Digital Device Data
- Activity, including ambulation and sleep (Fitbit™)
- Weight (Withings Body Scale)
- Single Lead ECG (Kardia Mobile)
Professional and academic viewpoint
How European patients can contribute to the evaluation of medical devices?

- Identify unmet needs
- Ethical approval
- Design of end-points
- Informed consent

Manufacturer

Preclinical testing → Clinical investigation
Submits technical file including Clinical Evaluation Report (CER)

Notified Body

Conformity assessment
Conforms to CE mark

National regulatory agencies

European Commission DG SANTE

POLSICY & ADVOCACY

Post-market surveillance

Manufacturer

Market access

Patient-reported outcome measures

Monitoring performance of device
Reporting adverse experiences
Sharing of data with device registries

Health Technology

Ethical approval
Design of end-points
Informed consent

Manufacturer

Preclinical testing → Clinical investigation
Submits technical file including Clinical Evaluation Report (CER)

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POLSICY & ADVOCACY

Post-market surveillance

Manufacturer

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Reporting adverse experiences
Sharing of data with device registries

Health Technology
Questions and… Answers!
Takeaway messages
What’s next?

Tamás Bereczky, Training Coordinator, EUPATI
Thank you!

Do you want to get in touch with us?
- info@eupati.eu
- www.eupati.eu
- @eupatients
Back-up slides
Summary of Regulatory Framework and Benefits for Patients (Paul Piscoi)
Medical Regulation Framework (Oliver Bisazza)
IVDR/MDR = A Modernised, Strengthened System

1. Both Regulations place greater emphasis on clinical studies as the ideal means for demonstrating device safety and performance

2. Clinical evidence must be continually demonstrated across the device lifecycle, i.e., it is not just a ‘once-off’ pre-market exercise to check a box

3. New panels of independence clinical experts will conduct ‘scrutiny’ assessments for the highest-risk device innovations, to oversee Notified Bodies in their checks of manufacturers’ clinical evaluations
Medical Regulation Framework (Oliver Bisazza)
IVDR/MDR = A Modernised, Strengthened System

1. All Notified Bodies must be re-accredited and redesignated to continue operating under the new Regulations, to ensure they operate to the maximum levels of independence and impartiality.

2. Member States will oversee Notified Bodies’ competence with far more attention than ever before under the new Regulations, particularly with respect to Notified Bodies’ exercise in individual IVD technologies.

3. There may be (significantly) fewer Notified Bodies in the future, but those who remain ‘should’ be best-in-class and operate in a more harmonised manner.
1. If MDR is only an evolution of the prior regulatory framework, IVDR is a revolution, with significantly more detailed requirements across the board.

2. A new risk classification system for IVDs is created, plotting all tests from Class A (lowest-risk) to D (highest risk). Higher risk class = more stringent requirements.

3. Far more IVDs than ever before will need Notified Body oversight, e.g. 85% of all IVDs will need this, equating to an 8-fold increase compared to the past.
Medical Regulation Framework (Oliver Bisazza)
IVDR/MDR = A Modernised, Strengthened System

1. The new ‘EUDAMED’ database will render more information public than ever before. E.g., patients will know which devices are available in which country

2. A summary of safety and (clinical) performance will be publicly-available for the higher-risk devices, giving patients and users have a snapshot of the safety and performance evidence underpinning those devices

3. Implant cards will be provided to patients in all EU Member States, so that patients know what implant they have received and how they can stay safe with it
**Medical Regulation Framework (Oliver Bisazza)**

**What is a medical technology?**

Medical technologies are products, services or solutions used to save and improve people’s lives.

In their many forms, they are with you all the time, from prevention, to diagnosis to cure. There are three main categories of medical technologies: medical devices, in-vitro diagnostics and digital health solutions.

There are more than 500,000 medical technologies available in hospitals, community-care settings and at home.
Medical Regulation Framework (Oliver Bisazza)
The MedTech Industry in Europe

- €120 billion market
- 675,000+ employees
- 50,000+ In vitro diagnostic tests
- 500,000+ medical devices
- 32,000+ Companies of which 95% are SMEs
- #2 In filing patent applications or 8% of total number of applications in Europe
Medical Regulation Framework (Oliver Bisazza)

About MedTech Europe

• MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health.

• Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

• MedTech Europe’s purpose is to make innovative medical technology available to more people, while helping healthcare systems move towards a more sustainable path.
Let’s work together to spread the word!

#PEOF2020

@imi-paradigm
@eupatients
@PFMDwithPatient