Patient Engagement open forum Into Reality

Patient Engagement & Medical Devices

June 25th from 15.30 to 17.10 CET

PARADIGM
Patients Active in Research and Dialogues for an Improved Generation of Medicines

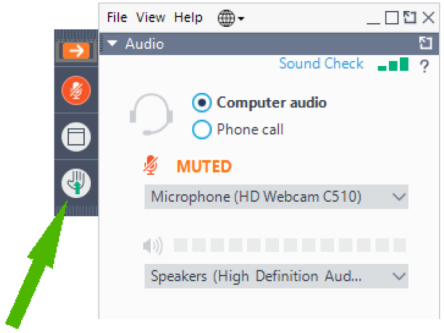
EUPATI
European Patients' Academy on Therapeutic Innovation

PATIENT FOCUSED MEDICINES DEVELOPMENT

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!

Q&A



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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.

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Patient Engagement Open Forum 2020 (PEOF) - link

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)
- National Health Council Patient Engagement Fair-Market Value Calculator Toolbox (organised by NHC)

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 or/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 EFGCP)

November 5th

THEME: Regulatory

November 23rd

Plenary session:

- PEOF2020 conclusion session

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

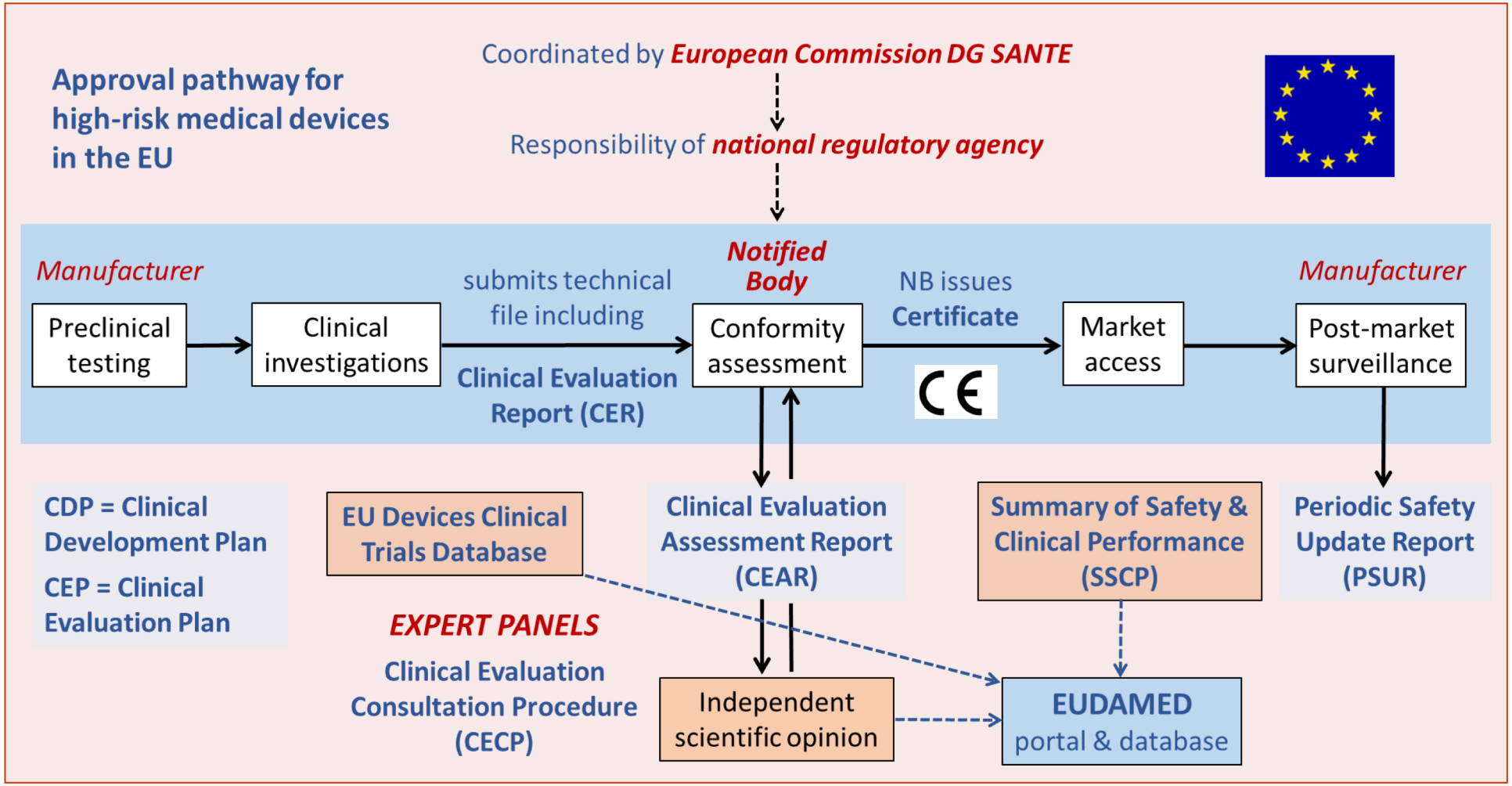
Regulation on medical devices

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



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

https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en

https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed_en

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

CE marking legislation

New Regulation

(May 2017) = 175 pages

Medical Regulation Framework

IVDR/MDR = A Modernised, Strengthened System

Patient Engagement open forum Into Reality

- Clinical Evidence
- Notified Bodies
- IVD Overhaul
- Transparency

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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

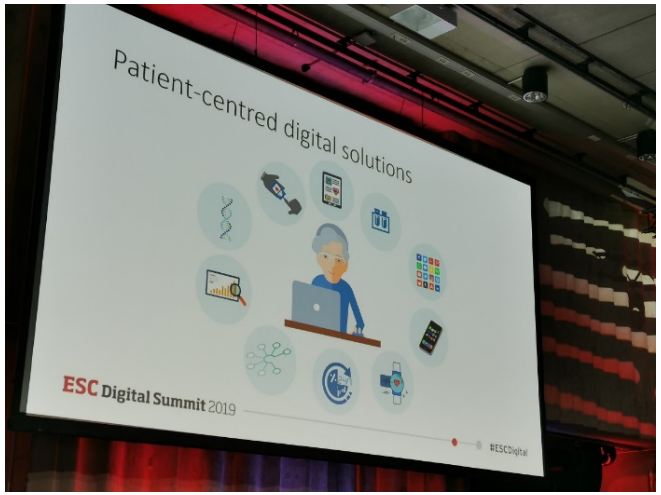
Patients' Perspective

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?
- …

Patients' Perspective

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

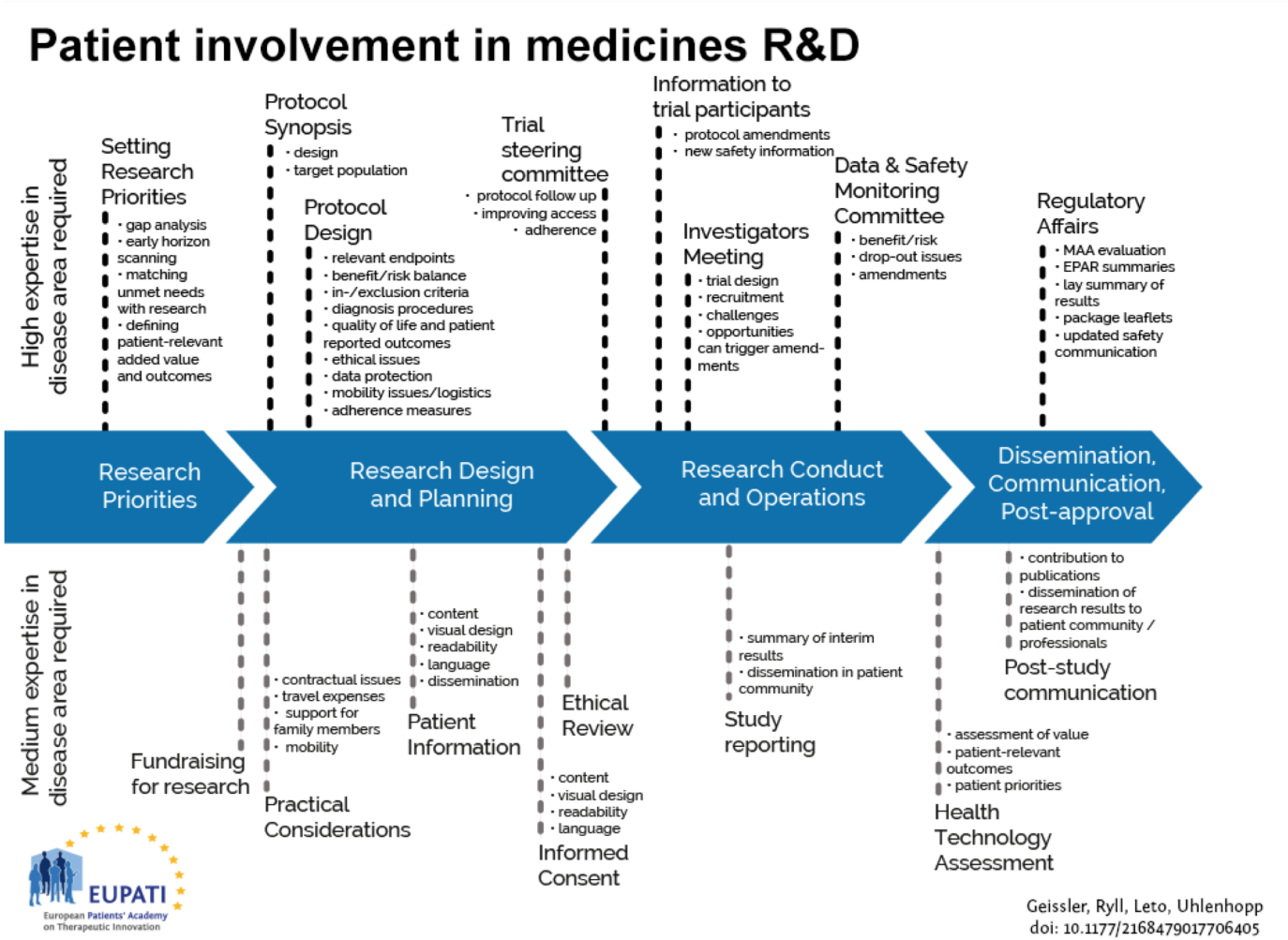
- Highly technological devices and complex regulatory framework = expert knowledge might be needed
- 'Representativeness' of the patients involved?
- Requires to accommodate to patients' needs in the process (logistics, etc.)

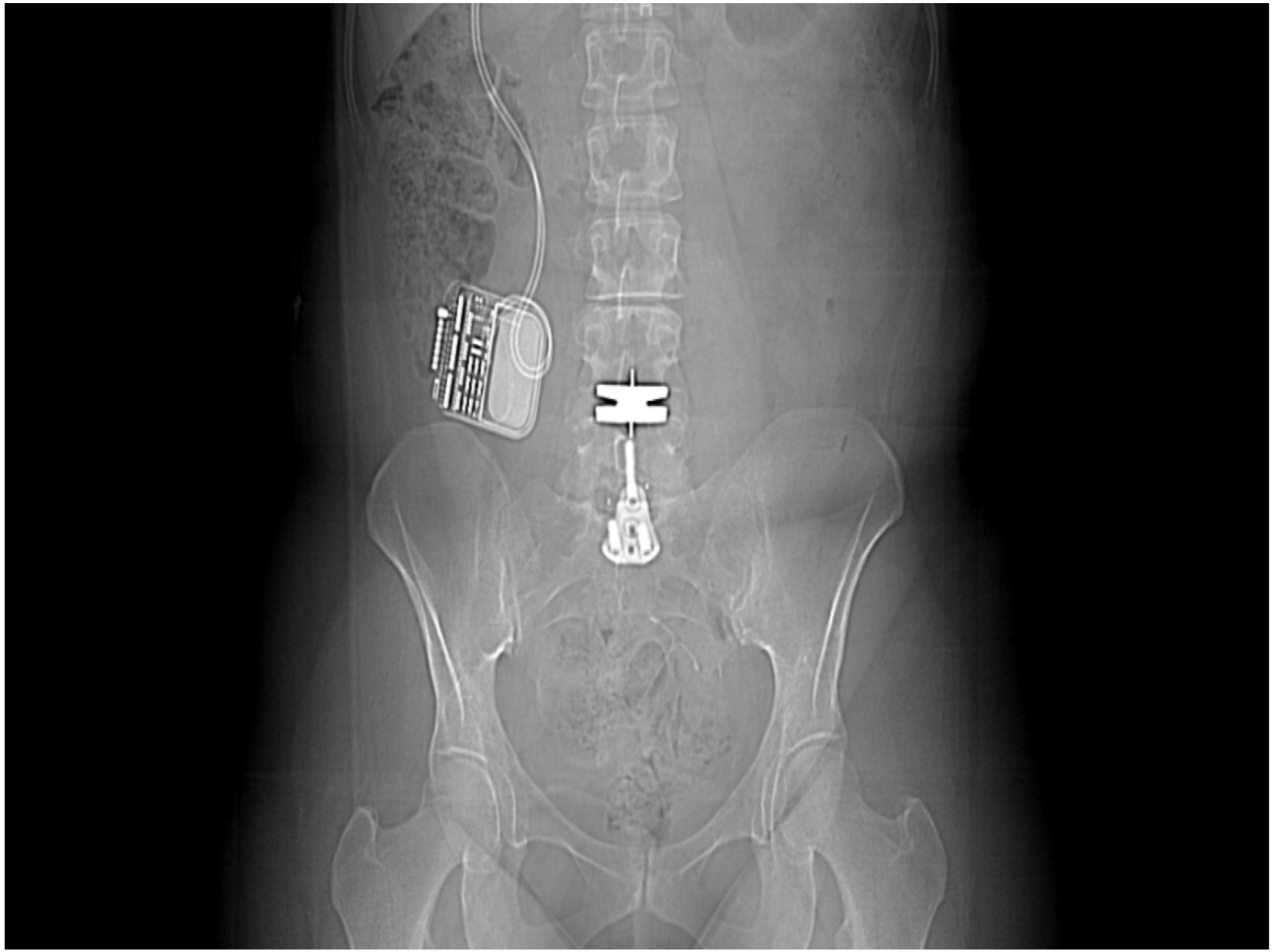
Questions and… Answers!

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

1

2

Credit: Dominique Hamerlijnck

Medtronic

TÉLÉCOMMANDE PATIENT

37642

Manuel d'utilisation de la thérapie DBS™ de Medtronic®
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Activa® SC Modèle 37602 / Activa® SC Modèle 37603

PATIENTEN-PROGRAMMIERGERÄT

Bedienungsanleitung für die Medtronic® DBS™-Therapie
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CLINICAL/SCIENTIFIC NOTES

Beware of deep water after subthalamic deep brain stimulation

Daniel Waldvogel, MD, Heide Baumann-Vogel, MD, Lennart Stieglitz, MD, Ruth Hänggi-Schickli, MSc, and Christian R. Baumann, MD

Neurology® 2020;94:39-41. doi:10.1212/WNL.0000000000008664

Correspondence
Dr. Waldvogel
d.waldvogel@bluewin.ch

MORE ONLINE

Video

We report the worrisome 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 lost 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, macroelectrode 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 69-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 confident after DBS because of his good motor outcomes, he literally jumped into the lake, where he would have drowned if he had not been rescued by a family member.

Case 4

This 59-year-old woman with PD with 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 61-year-old woman with PD with motor fluctuations had a lifesaving diploma and used to participate in swimming competitions crossing Lake Zurich. She was satisfied with the overall outcome of STN-DBS, having achieved good motor control without fluctuations. However, postsurgery, 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 switching off 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 (D.W., H.B.-V., C.R.B.) and Department of Neurosurgery (L.S.), University Hospital Zurich, University of Zurich; and Practice for Neurorehabilitation (R.H.-S.), Zurich, Switzerland.

Go to Neurology.org/N for full disclosures. 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 responsable

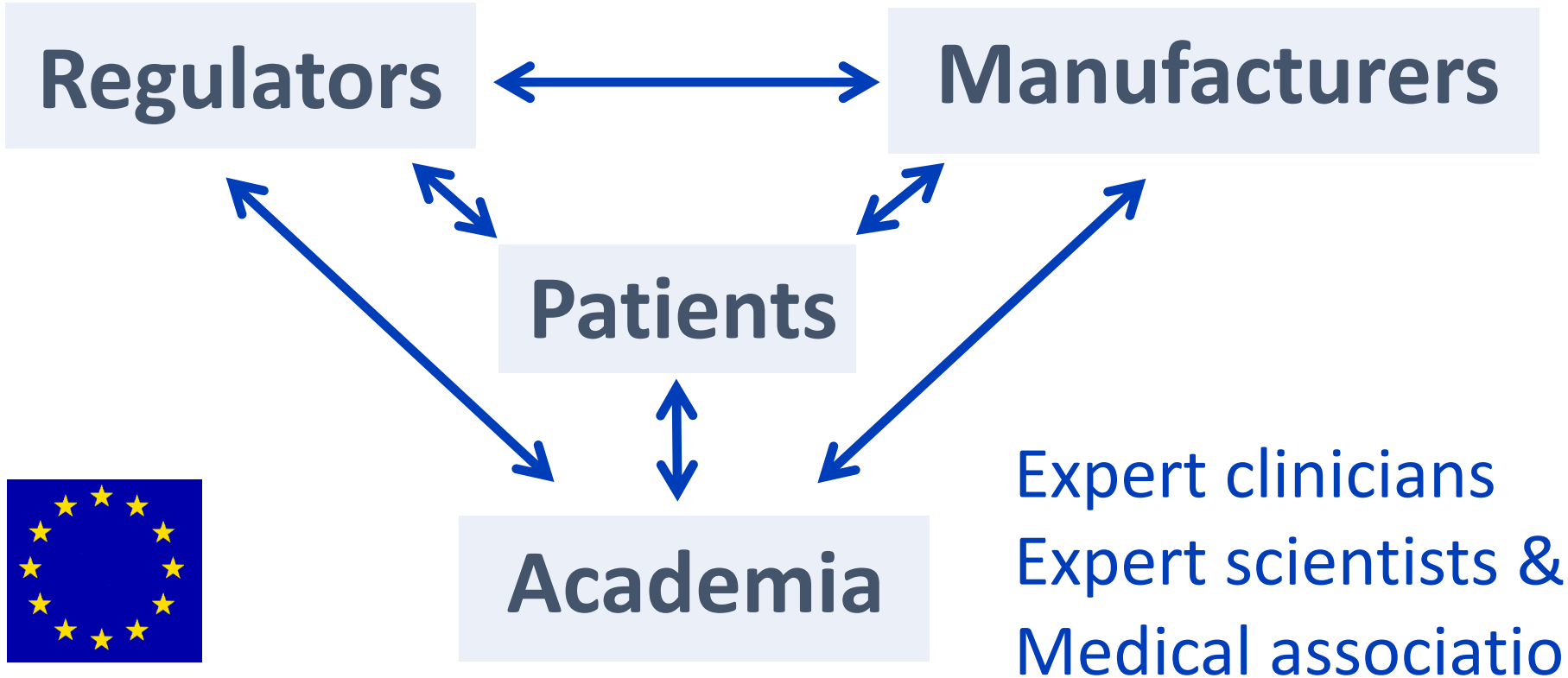
- *Caroline Pauwels Rector VUB*

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

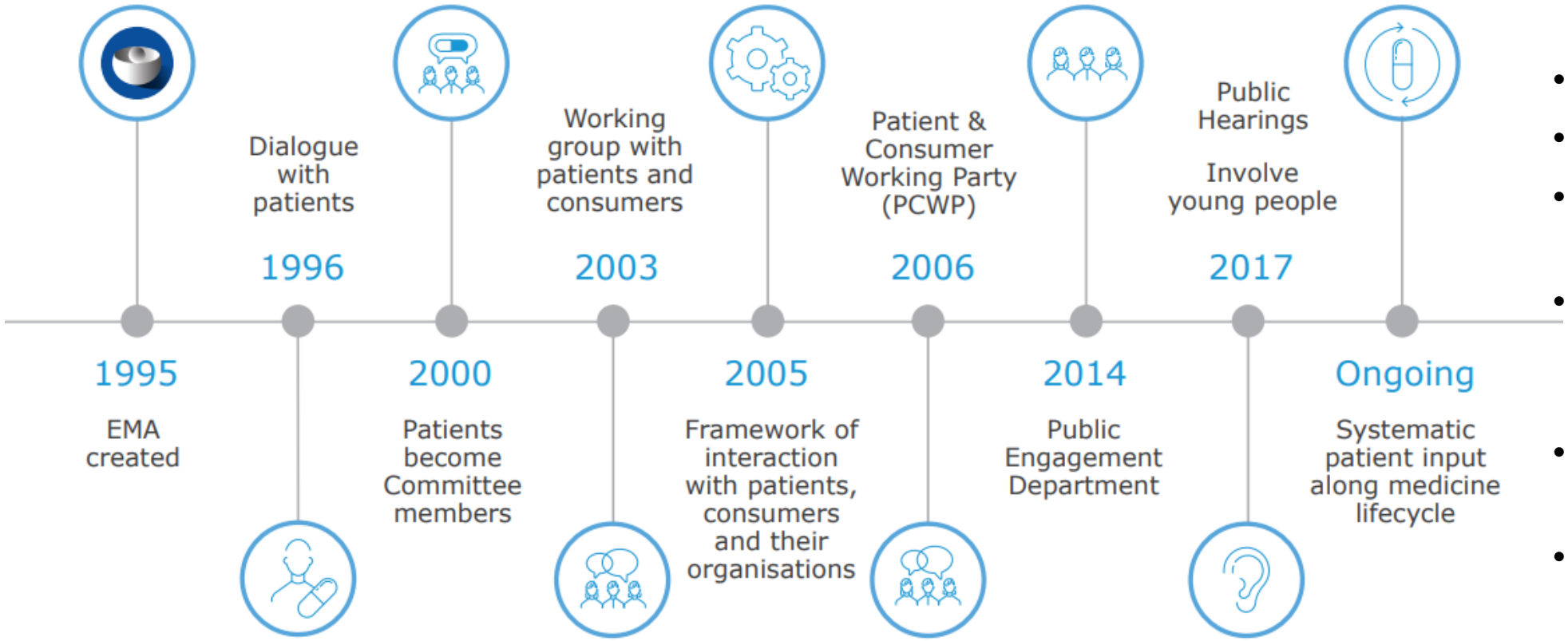
An effective regulatory environment



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

https://www.ema.europa.eu/en/partners-networks/patients-consumers

Professional and academic viewpoint

Patient Engagement open forum Into Reality

Opinion prepared on behalf of the BioMed Alliance concerning

Scientific bodies under the new EU medical device legislative framework

(European Commission Joint Research Centre, Draft technical report, July 2018)

10 September 2018

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**."

ESC European Society of Cardiology

BioMed Alliance

https://www.biomedeurope.org/images/pdf/news/Biomed_Alliance_Response_to_JRC_Consultation_10_Sep_2018.pdf

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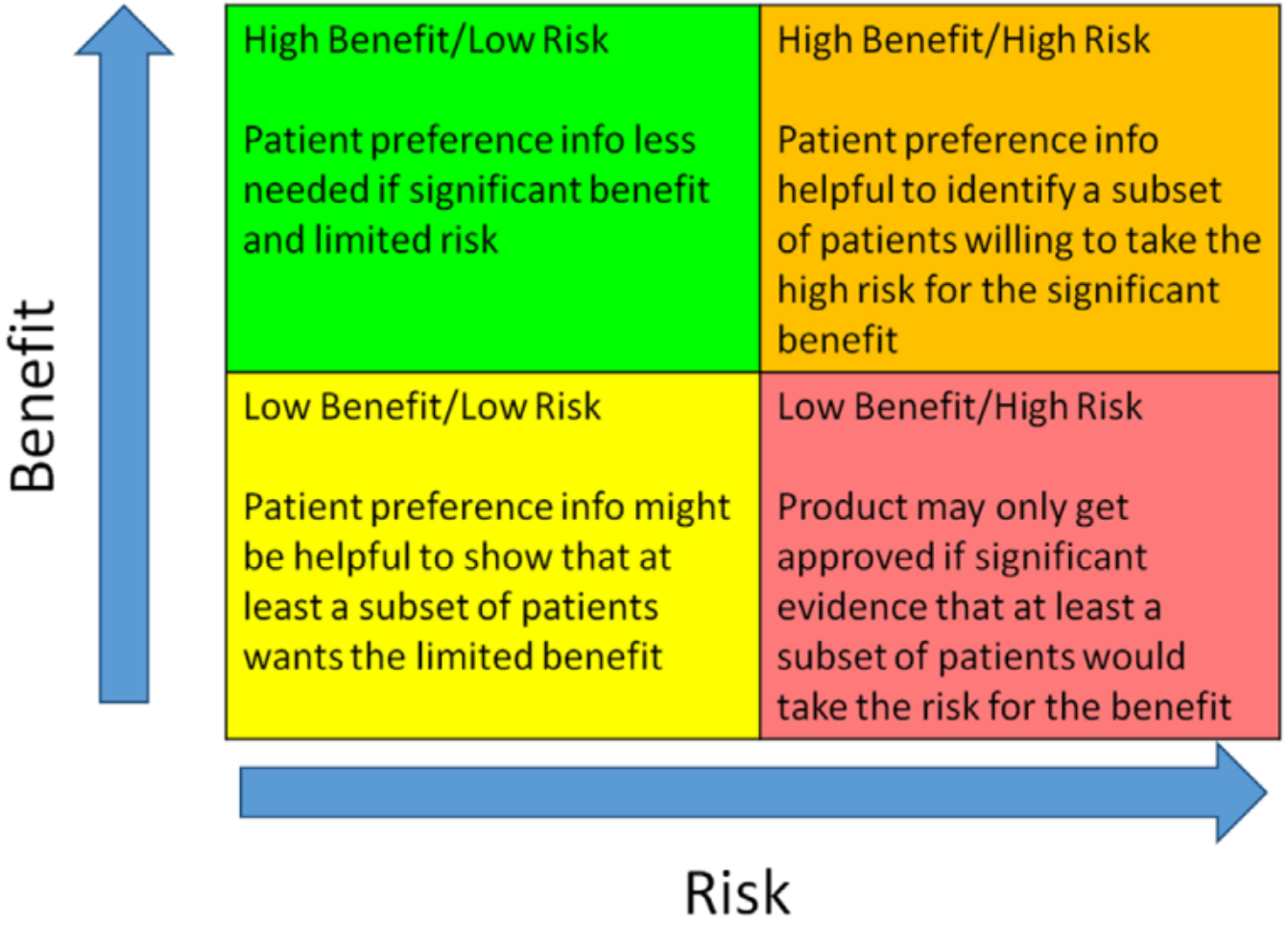
Professional and academic viewpoint

Framework for incorporating patient preferences into regulatory assessment of medical technologies



Ho M et al, Value Health. 2016; 19: 746–50

MDIC MEDICAL DEVICE INNOVATION CONSORTIUM

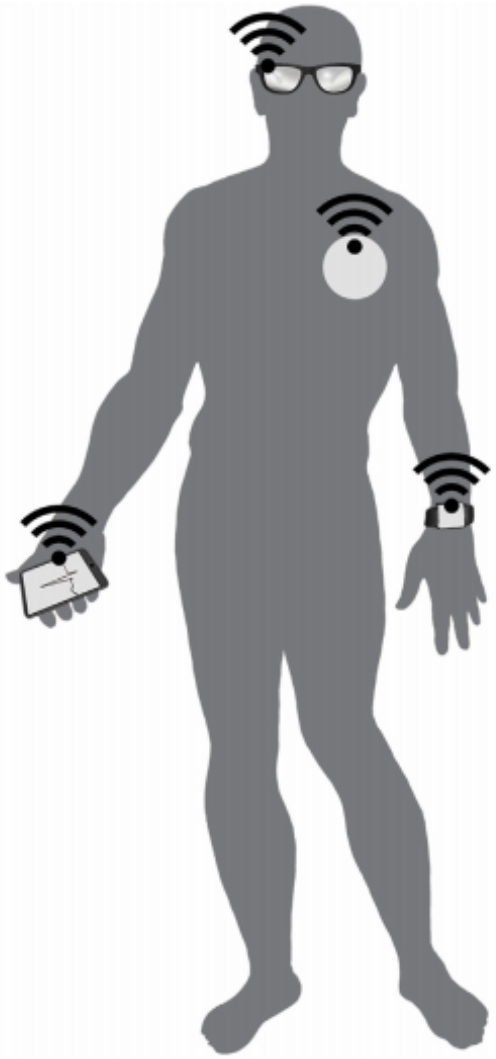
Patient Centered Benefit-Risk Steering Committee

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



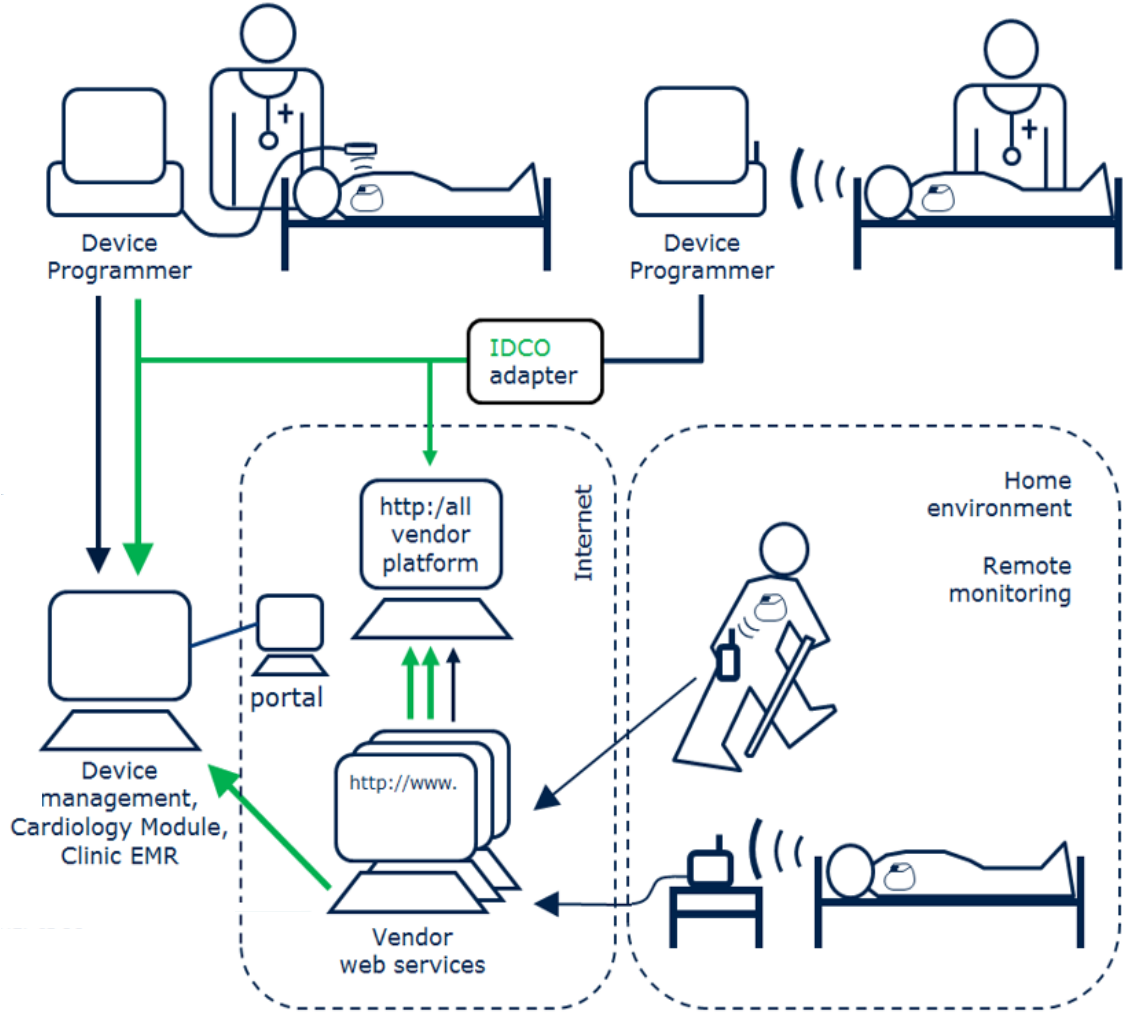
Devices for Ambulatory Monitoring

- 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



Nielsen JC et al, Europace 2020 (in press)

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

ESC REGULATORY AFFAIRS / EHRA JOINT TASK FORCE REPORT

Jens Cosedis Nielsen[1] Josef Kautzner[2], Ruben Casado-Arroyo[3], Haran Burri[4], Stefaan Callens[5], Martin R Cowie[6], Kenneth Dickstein[7], Inga Drossart[8], Ginger Geneste[9], Zekeriya Erkin[9], Fabien Hyafil[10], Alexander Kraus[11], Valentina Kutyifa[12], Eduard Marin[13], Christian Schulze[14], David Slotwiner[15], Kenneth Stein[16], Stefano Zanero[17], Hein Heidbuchel[18] and Alan G Fraser[19]

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

Professional and academic viewpoint

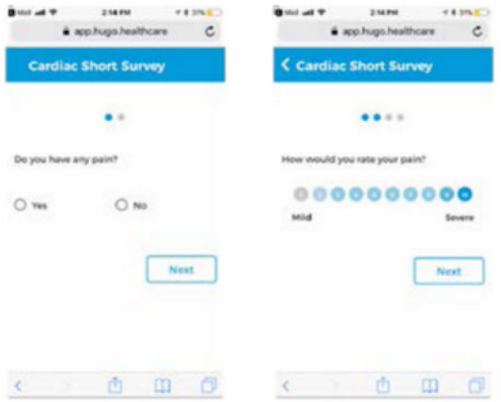
Aggregating real-world data using a patient-centered health-data-sharing platform

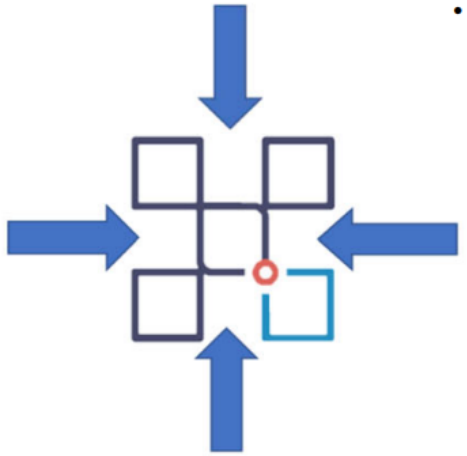
Patient Reported Outcome Measures (PROMs)

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



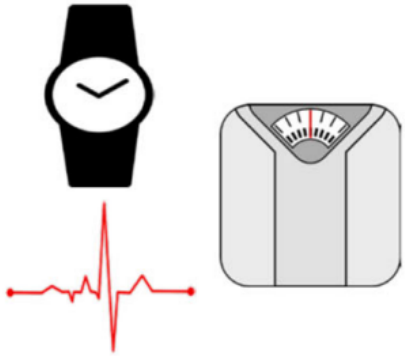


Electronic Health Record Data

- 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



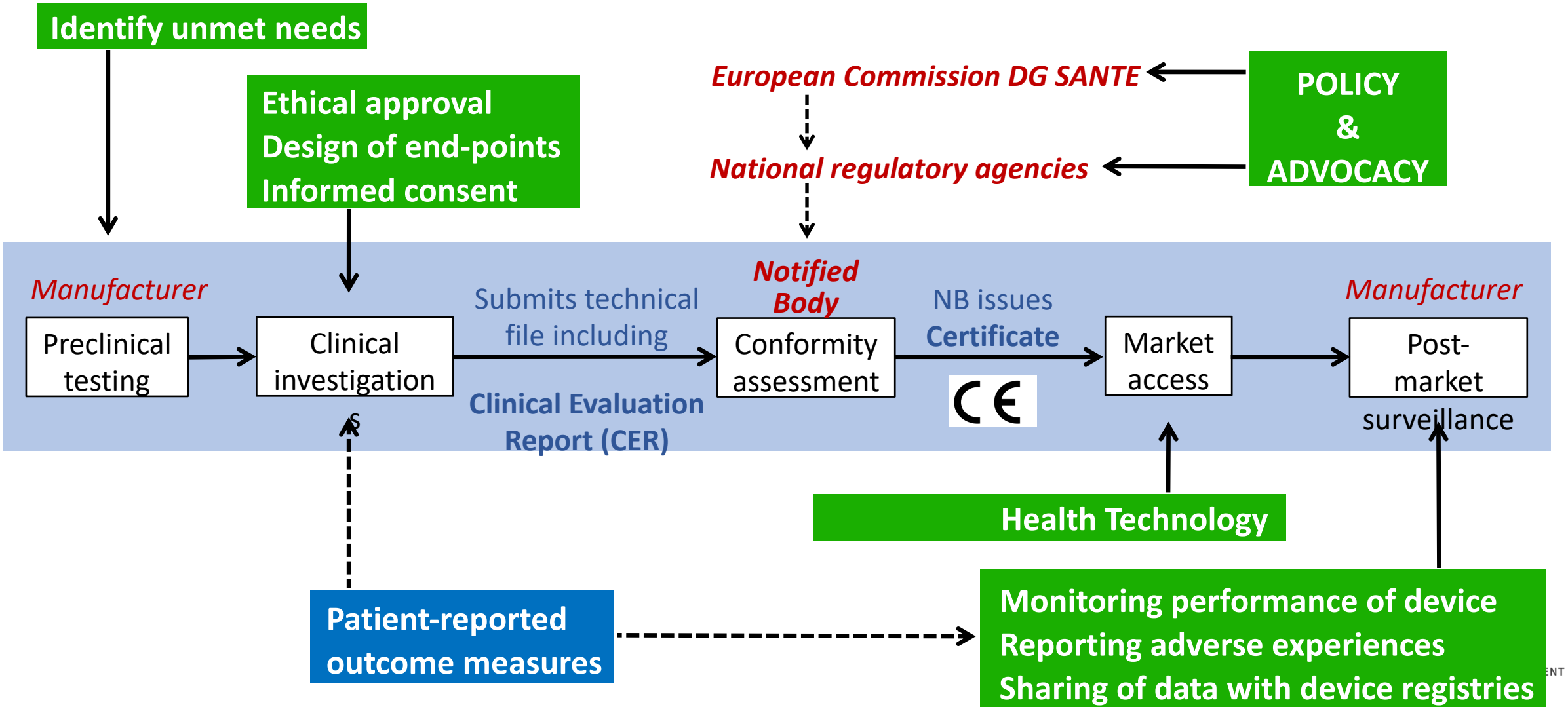
Personal Digital Device Data

- Activity, including ambulation and sleep (Fitbit™)
- Weight (Withings Body Scale)
- Single Lead ECG (Kardia Mobile)

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

Professional and academic viewpoint

How European patients can contribute to the evaluation of medical devices?



Questions and… Answers!

Takeaway messages
What's next?

Tamás Bereczky, Training Coordinator, EUPATI

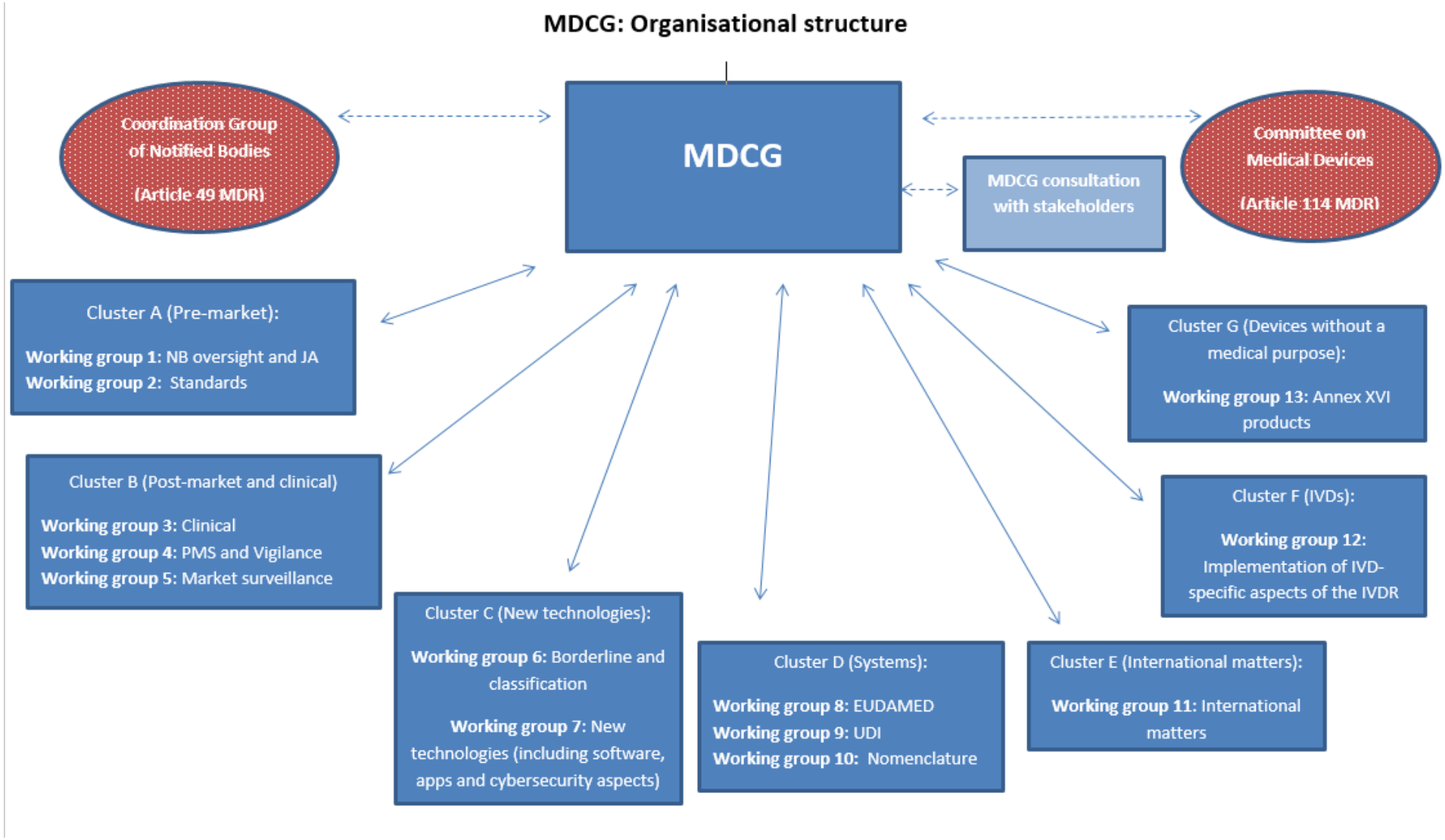
Thank you!

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

Clinical Evidence

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

Notified Bodies

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' exertise 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

Medical Regulation Framework (Oliver Bisazza)

IVDR/MDR = A Modernised, Strengthened System

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, equiating to an 8-fold increase compared to the past

IVD Overhaul

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

Transparency

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.

Patient Engagement open forum Into Reality

Let's work together to spread the word!

#PEOF2020

@imi-paradigm

@eupatients

@PFMDwithPatient

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