Agenda

15:00-15:10	**Introduction and summary of EPF work on the CBHC Directive** *- Kaisa Immonen, EPF Director of Policy*
15:10-15:50	**The Evaluation of the Directive on patients' rights in cross-border healthcare: Have patients' rights improved a decade on? Overview of the evaluation consultative process.** *- Caroline Hager, Team Leader Cross-Border Healthcare &Tobacco Control, DG Sante, European Commission* **Focus on: European Reference Networks in the context of the Cross-Border Healthcare Directive evaluation** *- Martin Dorazil, Deputy Head of Unit, Digital Health & health & European Reference Networks, DG Sante, European Commission*
15:50-16:30	**Discussion on patients experiences with cross-border healthcare & Conclusions** *- Moderated by: Kaisa Immonen, EPF Director of Policy*

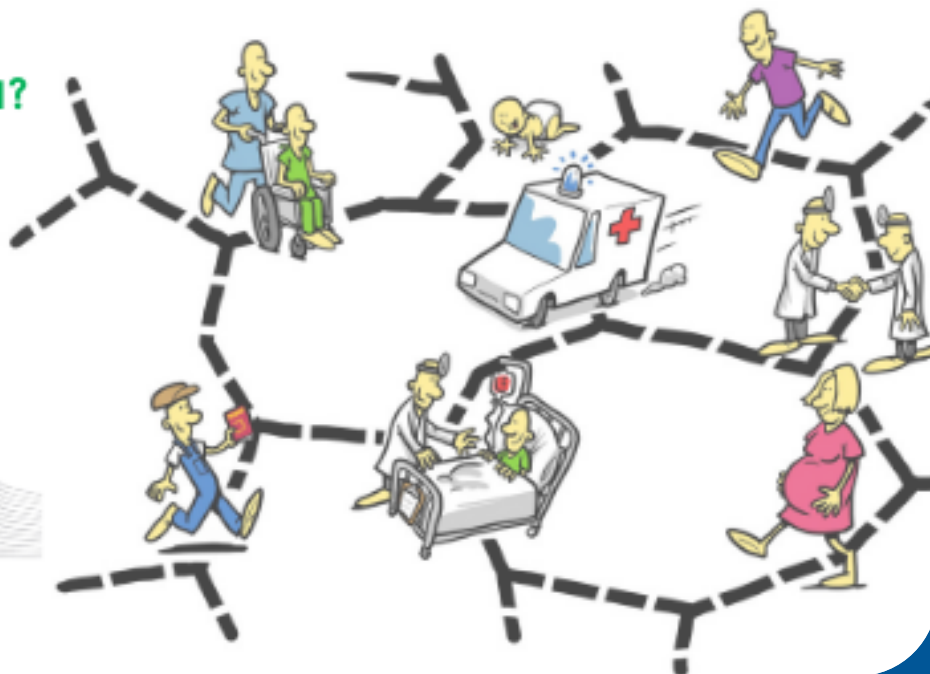# Cross-Border Healthcare: Introduction

Kaisa Immonen, EPF Director of Policy

Joint EC-EPF Webinar - Evaluating the Cross-Border Healthcare Directive: have patients' rights improved a decade on?
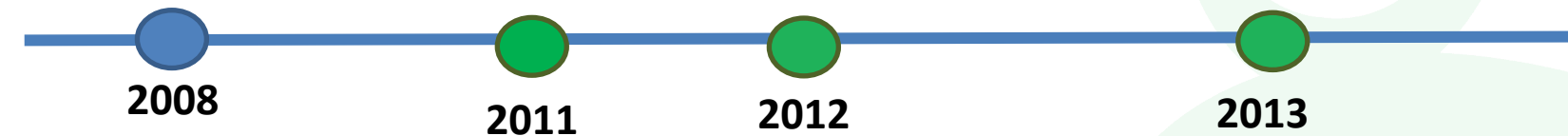23 March 2021

@eupatientsforum

EPF engaged on cross-border healthcare

EPF European Patients Forum

Long engagement with the Directive during "legislative journey", work with EU Institutions and stakeholders

EPF Guide & Recommendations

2013-2014 Series of regional seminars

2008   **2011**   **2012**   **2013**

2015 – 6 national mini-workshops

2 July 2015 – Conference in Brussels

Q3 2017 – Conference with patient organisations

2015   **2016**   **2017**   **2018**
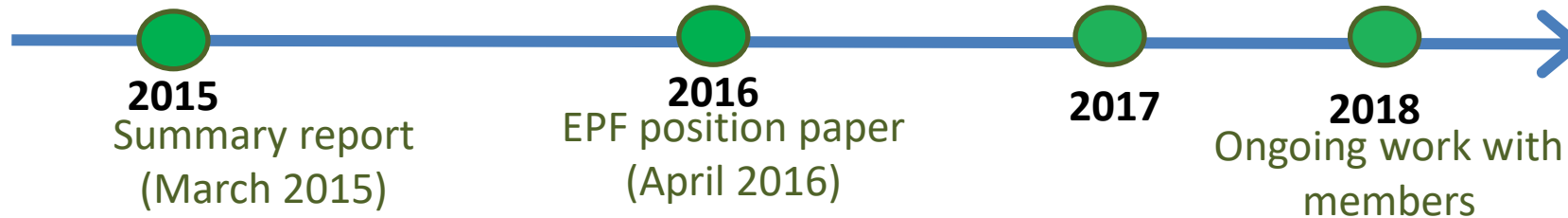
Summary report (March 2015)

EPF position paper (April 2016)

Ongoing work with members

Patients' organisations

75

OUR MEMBERS

National level
Non–disease specific

EU level
Disease specific
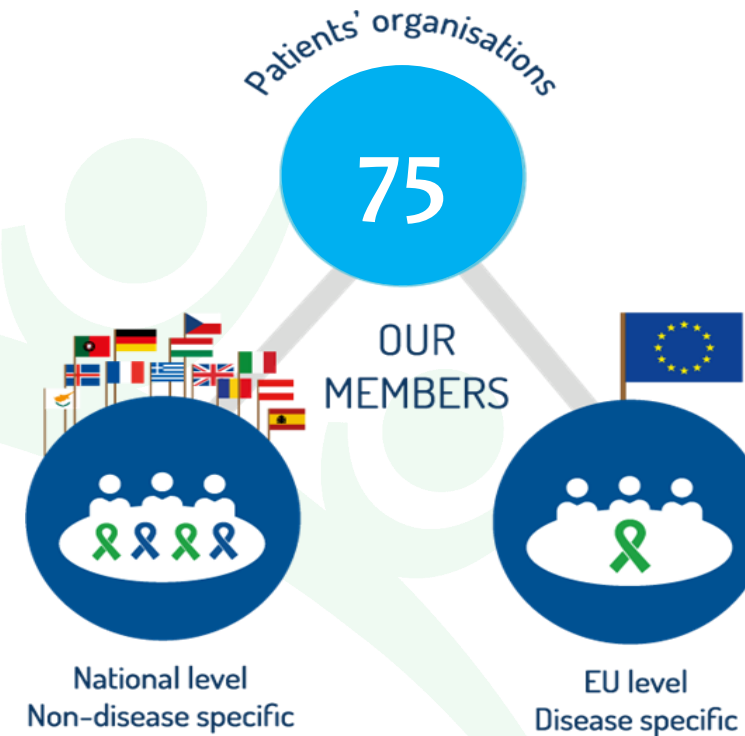
EPF's regional conferences 2013-2014

- EPF organised a series of conference with patient communities and NCPs
- Summary report → patient journey & (information) needs
- Willingness to engage, practical reality lagged
- NCPs wanted feedback from patients (e.g. if information received was useful, did the patient succeed in getting treatment)
- Concerns expressed:
  - Were NCPs adequately resourced to provide the *assistance* (information+) patients need? (1 person vs. 60?)
  - Would they be able to evolve from "gatekeeper" towards "gateway" role?

EU collaboration & engagement with patient organisations can benefit NCPs → benchmarking, sharing best practices
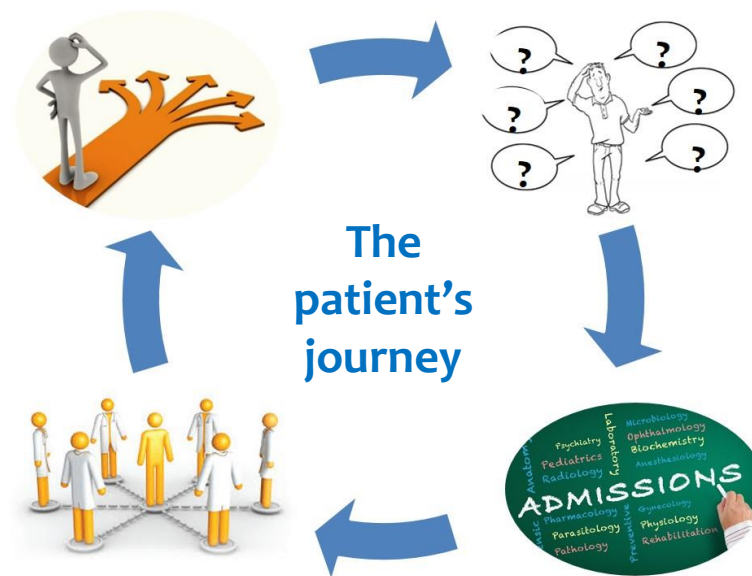
- EPF Roundtable 2017

❝ A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE ❞

EPF checklist & recommendations for NCPs

Patients lacked info on:

→ Their rights

→ Complaint process

→ Dispute settlement

→ Time to process things

The patient's journey

Patients asked for:

→ Practical step-by-step guides & checklists

→ Harmonised procedures & forms

- The NCP is able to offer informed assistance regarding rare diseases and specialised treatments.
- The NCP works with other stakeholders to identify and implement solutions to mitigate patients' financial difficulties regarding upfront payment, thus upholding the principle of equity of access based on needs, not means.

Accessibility and visibility

- The NCP is highly visible, easy to find and to contact, ideally with a name that is easy to recognise.
- The NCP communicates using simple language that all patients can understand.
- The NCP provides information in foreign languages, at least English and relevant minority languages as well as ideally the language(s) of the most common cross-border flows.
- The NCP is accessible in real-life situations, not just via its website or only during office hours.
- The NCP can be accessed via multiple channels – website, email, free telephone line, 24-hour emergency hotline, as well as physical premises with barrier-free access for personal consultations.
- In member states with significantly large rural or dispersed populations there are regional contact points in addition to the central NCP.

The NCP website:

✓ is easy to find through Google
✓ is easy to navigate
✓ has content that is informative and clearly structured
✓ includes visual tools where appropriate, such as infographics and video
✓ includes real patients' stories and testimonies
✓ includes FAQs, guides and checklists
✓ includes a simple mechanism for patients to submit applications
✓ has an interactive feedback facility
✓ links to other relevant websites, such as the national health authorities, health providers and patient organisations.

Operation

- The NCP has transparent procedures and clear timelines.
- The NCP process provides for individualised guidance with case managers.

Patients have specific access issues

Patients' rationale for seeking care abroad is based on "need" as much as "choice"

 = = ?
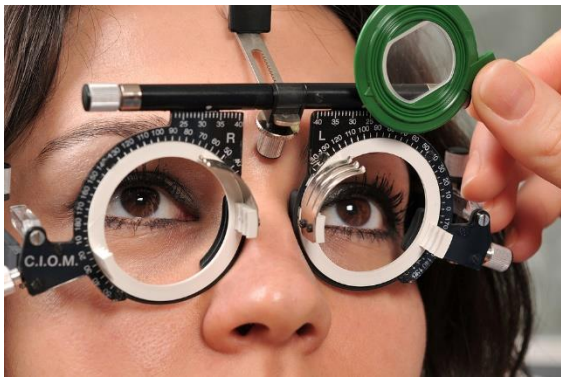
Some questions

- What are the drivers of patients' choice to seek CB healthcare? Country of birth? Family? Quality? Lack of access nationally?

- How many patients do not even try to seek CB healthcare? Why? Preference? Lack of information? Barriers by the member state?

- Can data disaggregate between "one-time" healthcare users and people w/ chronic conditions?

- Are patients being informed about possibilities under the Regulation if Directive is not adequate?

- Are Member States using both Reg and Dir effectively – political will to make treatment more accessible?

- How does all this reflect the health inequalities across the EU?
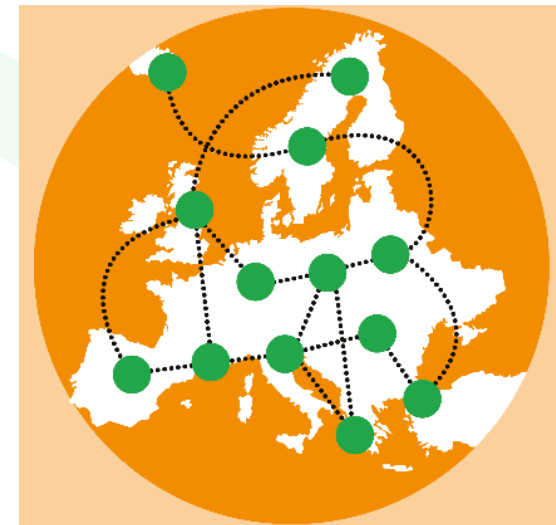
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"A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE"

EPF — European Patients Forum

EVALUATION OF PATIENT RIGHTS' in CROSS-BORDER HEALTHCARE

Caroline Hager
Team Leader
Cross-Border Healthcare Directive
DG Health & Food Safety
European Commission

EU legal framework for cross-border healthcare

➢ Coordination of social security schemes (Regulation 883/2004)

➢ Directive on patients' rights in cross-border healthcare (Directive 2011/24/EU)

Cross-border Healthcare Directive

CJEU jurisprudence 1997 – 2006
- Healthcare is a **service;**
- Patients can **choose** healthcare provider abroad;
- Level of **reimbursement** up to cost of treatment at home;
- **Prior authorisation** is acceptable;

Harmonized minimum patients' rights

Kohll and Decker (1998); Ferlini (2000); Geraets-Smits and Peerbooms (2001); Vanbraekel (2001); Inizan (2003); Müller Fauré and Van Riet (2003); Leichtle (2004); Watts (2006); Stamatelaki (2007); Elchinov (2010); Petru (2014)

Information to patients

Cooperation between Member States

A EUROPEAN PRESCRIPTION of MEDICAL PRODUCTS

DIRECTIVE 2011/24

ENCOURAGE MEMBER STATES TO DISCUSS PROBLEMS & CHALLENGES

A NATIONAL CONTACT POINT

PATIENTS CAN BE REIMBURSED FOR CARE ABROAD

A LEGAL FRAMEWORK FOR COOPERATION

Photo credit: https://drawnalism.com

Options for Cross-border treatment

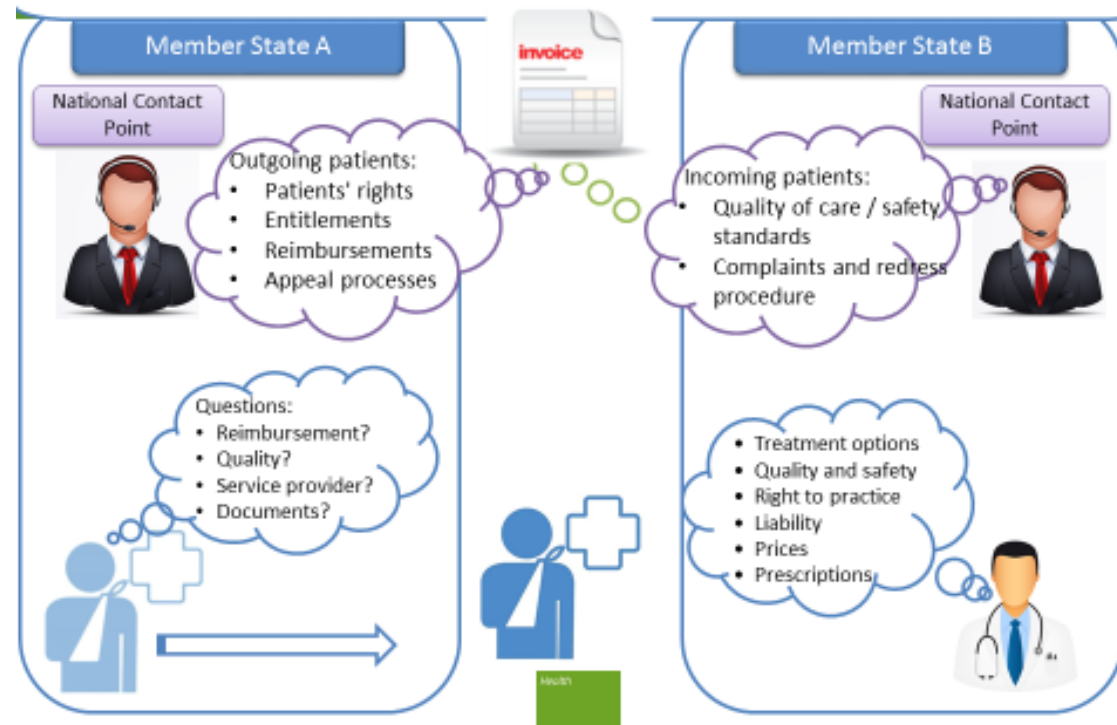|	Prior authorisation	Providers	Reimbursement
Regulation ❑ Necessary treatment ❑ Planned treatment	NO YES	Public providers	Between health insurers (except co-payment)
Directive	NO, but YES in case of hospital treatment , highly specialised & cost intensive	Public/Private providers	Patients up-front payment Max until the tariffs of home MS
ERNs	▪ No direct access to ERNs; patient referral only ▪ Virtual panel consultations covered by providers; ▪ In case of cross-border treatment: Regulation or Directive rules are applicable;		

Information to patients

- ❑ **National Contact Points**

- ❑ **Healthcare providers**

Information to patients and NCPs

Member State A

National Contact Point

Outgoing patients:
- Patients' rights
- Entitlements
- Reimbursements
- Appeal processes

Questions:
- Reimbursement?
- Quality?
- Service provider?
- Documents?

invoice

Member State B

National Contact Point

Incoming patients:
- Quality of care / safety standards
- Complaints and redress procedure

- Treatment options
- Quality and safety
- Right to practice
- Liability
- Prices
- Prescriptions

Health and Food Safety

Manual for Patients
available in all EU languages

MANUAL FOR PATIENTS

Patient's right to accessing healthcare in any EU/EEA* country*
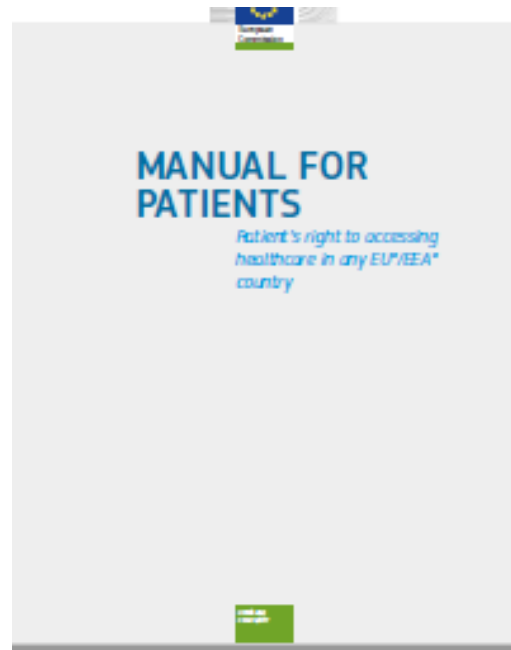
Health and
Food Safety

- Patients' rights - choice of public or private healthcare in another EU country subject to conditions of insurance body. 200 000 patients pa

- European cooperation – considerable efforts
  - Digitilisation in healthcare – e-prescriptions, European health data space
  - EU actions in the area of rare and low prevalence complex diseases, European Reference Networks

Key figures on patient mobility

- **Regulations coordinating social security systems**
  - Necessary (unplanned) healthcare:
    - ±2 million cases/year
  - Planned healthcare:
    - ±55,000 PA/year

- **Directive 2011/24/EU**
  - CB healthcare without prior authorisation:
    - ±200,000 reimbursement/year
  - CB healthcare with prior authorisation:
    - ±3500 PA/year

  → 0.004% of the EU-wide annual healthcare budget

- Bilateral agreements for cross-border healthcare & cross-border contracts between providers and payer – No data

European Cross-Border Cooperation on Health: Theory and Practice
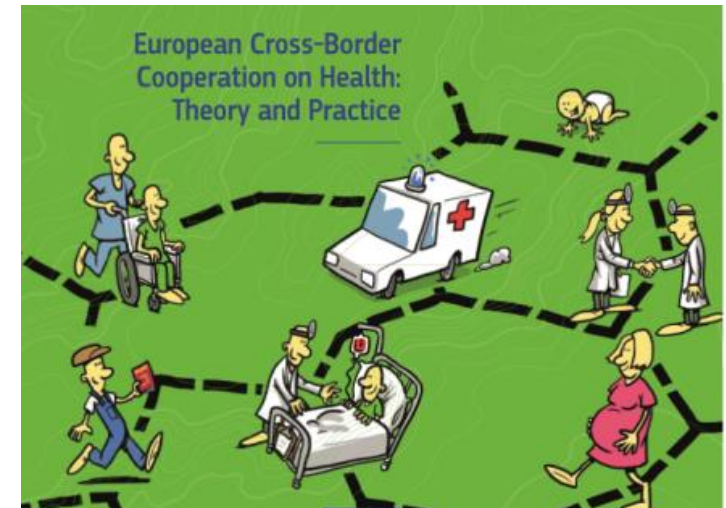
Reports on implementation

Conclusions

➢ **Complex systems of reimbursement**

➢ **Over-use of prior authorisation for planned treatment**

➢ **Administrative obstacles**

➢ **Improve information to patients**

EU actions to support better implementation
➢ Sharing experience
➢ Good practice workshops
➢ Non-binding guidance : Manual for Patients, NCP Toolbox
➢ EU studies

European Commission

EUROPEAN COURT OF AUDITORS
Guardians of the EU finances

European Committee of the Regions

European Parliament

Evaluation scope

- responsibilities of the Member State of treatment,
- responsibilities of the Member State where the patient is insured provision of information to patients by the National Contact Points on cross-border healthcare,
- administrative procedures for cross-border healthcare,
- recognition of prescriptions issued in other Member States,
- mutual assistance and cooperation in healthcare in the border regions
- development of the European reference networks and cooperation in rare diseases.

Out of evaluation scope

- Provisions on <u>e-health</u>: will be evaluated separately as part of the preparatory work on the legislative proposal for the creation of a <u>European Health Data Space</u> to be adopted in 2021.

- Cooperation in <u>health technology assessment</u> is a proposal for a Regulation under negotiation (therefore also outside the scope of this evaluation).

Health

Evaluation questions

- to what extent have the Directive's objectives been met?

- to what extent is the Directive relevant for meeting patient needs in cross-border healthcare?

- how effectively and efficiently does the Directive operate in practice?

- what administrative burdens and barriers do patients still face when seeking healthcare in another Member State and reimbursement thereafter?
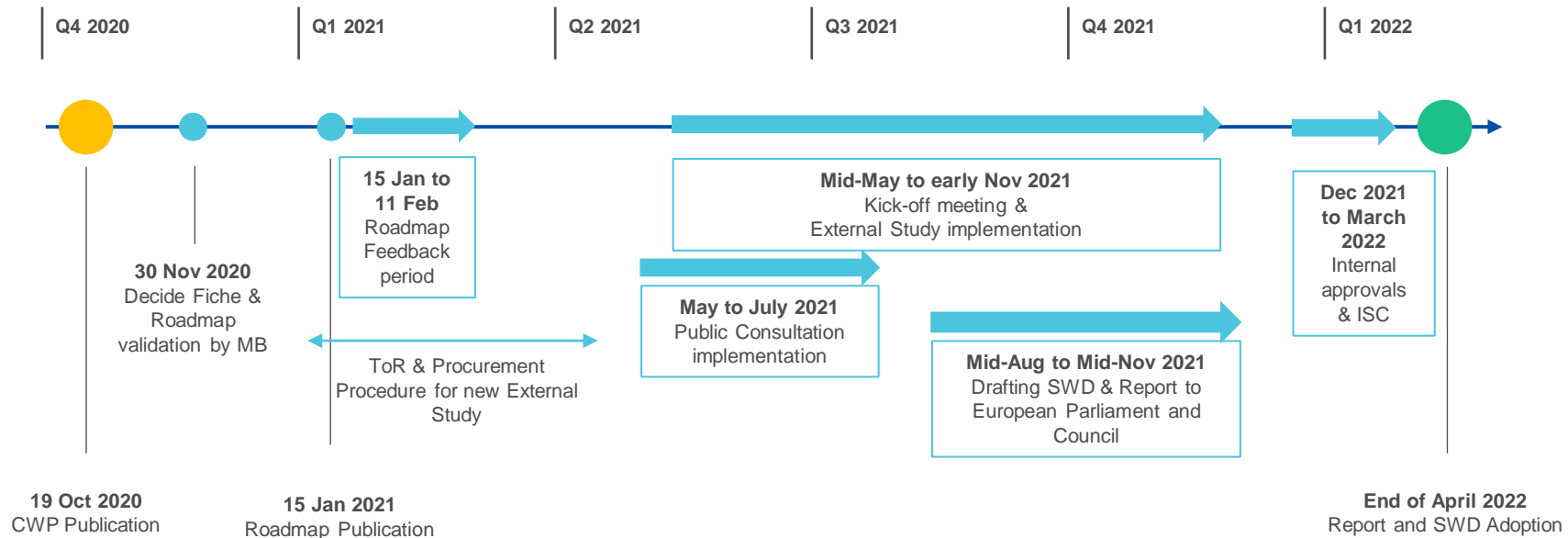
Consultation Strategy

- **Consultation on roadmap -** 15 Jan – 11 Feb 2021
  - **big thank you to patient organisations' feedback**

- **Public consultation** May – July 2021

- **Targeted consultation activities** (including workshops, interviews and/or questionnaires) tailored to particular stakeholder groups, including:

- National/regional authorities, National Contact Points for cross-border healthcare, health insurance providers, healthcare providers, **patient organisations (including organisations representing patients with rare or low prevalence and complex diseases), patient ombudsmen**, audit bodies, trade unions, members of the European Reference Network (ERN) Board of the Member States and ERN coordinators.

Health

Patients Rights – have they improved a decade on?

- Patient awareness and patient experience

- Information for patients: doctors, insurers, National Contact Points

- Prior approval for healthcare – which treatments covered?

- Administrative barriers – what are they?

- Reimbursement of Costs – complex? delays?

- Follow-up care back home

European Commission

Health

Key steps for the CBHC Directive Evaluation

Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022

15 Jan to 11 Feb
Roadmap Feedback period

Mid-May to early Nov 2021
Kick-off meeting &
External Study implementation

Dec 2021 to March 2022
Internal approvals & ISC

30 Nov 2020
Decide Fiche & Roadmap validation by MB

ToR & Procurement Procedure for new External Study

May to July 2021
Public Consultation implementation

Mid-Aug to Mid-Nov 2021
Drafting SWD & Report to European Parliament and Council

19 Oct 2020
CWP Publication

15 Jan 2021
Roadmap Publication

End of April 2022
Report and SWD Adoption

European Commission

What are ERNs and what do they do?

PATIENTS — NATIONAL HEALTH-CARE PROVIDERS — SPECIFIC ERN

TREATMENT · ADVICE

CLINICAL GUIDELINES · RESEARCH & INNOVATION KNOWLEDGE · GENERATING & SHARING EVIDENCE · TRAINING & E-LEARNING

Share. Care. Cure.
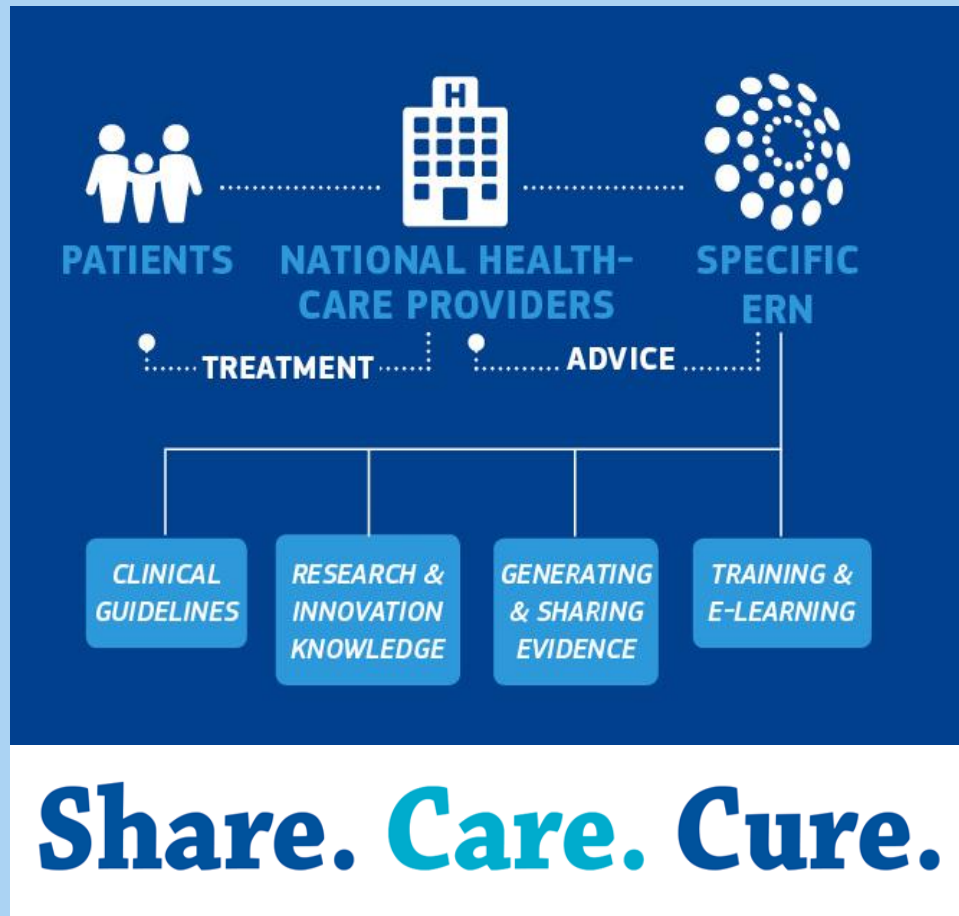
- ✓ Virtual remote consultations and clinical data on patient cases
- ✓ Advise and exchange of expertise (diagnosis & treatment)
- ✓ Knowledge Generation
- ✓ Research on rare diseases
- ✓ Education & professional training

ERNs: Legal basis

Article 12 of Directive 2011/24

- The Commission shall support Member States in the development of ERNs
- Member States encouraged to facilitate the development of ERNs
- Objectives of the networks
- Commission shall:
  - Adopt list of criteria and conditions that the networks and their members must fulfill
  - Develop and publish criteria for evaluating ERNs
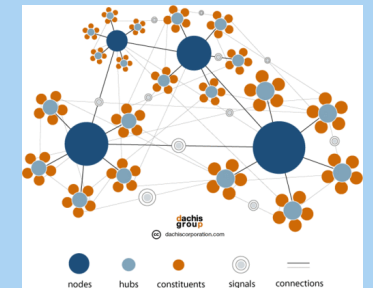 - Facilitate exchange of information and expertise

Commission Implementing Decision 2014/287/EU

- defining criteria for establishing and evaluating ERNs,
- amended in 2019 by Commission Implementing Decision (EU) 2019/1269.

Commission Delegated Decision 2014/286/EU

- defining the criteria and conditions that healthcare providers and the ERNs should fulfil

24 European Reference Networks

ERN BOND	Bone Diseases
ERN CRANIO	Craniofacial anomalies and ENT disorders
Endo-ERN	Endocrine Conditions
ERN EpiCARE	Rare and Complex Epilepsies
ERKNet	Kidney Diseases
ERN GENTURIS	Genetic Tumour Risk Syndromes
ERN-EYE	Eye Diseases
ERNICA	inherited and congenital anomalies
ERN-LUNG	Respiratory Diseases
ERN-RND	Neurological Diseases
ERN-Skin	Skin Disorders
ERN EURACAN	Solid Adult Cancers

ERN EuroBloodNet	Onco-Hematological Diseases
ERN EUROGEN	Urogenital Diseases
ERN EURO-NMD	Neuromuscular Diseases
ERN GUARD-HEART	Diseases of the Heart
ERN ITHACA	Congenital Malformations and Intellectual Disability
MetabERN	Hereditary metabolic diseases
ERN PaedCan	Paediatric Cancer
ERN RARE-LIVER	Hepatological Diseases
ERN ReCONNET	Connective Tissue and Musculoskeletal Diseases
ERN RITA	Immunodeficiency, Auto-Inflammatory and Auto Immune Diseases
ERN TRANSPLANT-CHILD	Transplantation in Children
VASCERN	Multisystemic Vascular Diseases

Key assets and achievements so far

24 ERNs

European Reference Networks

2017

› 900 HEALTHCARE UNITS

› 300 HOSPITALS

25 Countries

2019 2020

Affiliated Partners

Call for new members

Established structure

✓ Clear Legal Basis and Institutional framework

✓ 24 Networks started their clinical work with patients

✓ Strong political support (EU) and perceived as a good example of European cooperation

✓ Joint ownership (Member States authorities, patients, health professionals, hospitals, EU institutions)

✓ EU funding sources available

✓ Consolidated governance structure and networking capacity

Actions and outcomes

✓ Clinical cooperation, **patient cases** discussed virtually (CPMS)

✓ Knowledge Generation and development of **training, education and awareness** actions

✓ Implementation of **clinical practice guidelines**

✓ Important number of **scientific publications**

✓ Development of **research projects**

✓ Support for ERN patient **registries** as part of EHDS

European Commission

Enlargement of the Networks

Affiliated Partners:

- ✓ Associated National Centres and Coordination Hubs

- ✓ Designated by the MS

New Members:

- ✓ Procedures and assessment

- ✓ Specific criteria and thresholds

- ✓ Several stakeholders involved (Commission, National authorities, Hospital managers, ERN Boards, IAB, BoMS)

Call for new members
843 applications

Affiliated Partners
~250 units

26 Member States + Norway

627 Favourable ERN opinions → going to IAB for independent review

To be completed in 2021

16 MS applied for ANC (247)

4 MS applied for HUBs

Completed in 2020

European Reference Networks

European Commission

European Reference Networks

https://ec.europa.eu/health/ern_en

ERNs: Next Steps

1. Manage enlargement of the geographical scope and diseases coverage:

- ✓ Complete the ongoing enlargement (2021);
- ✓ Potential extension of diseases coverage and address overlaps
- ✓ Consolidate the system and ensure long term sustainability: financial (EU4Health Programme, Member States) and organisational (including CPMS)
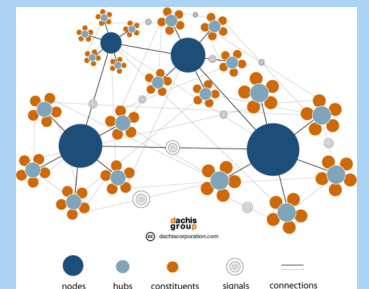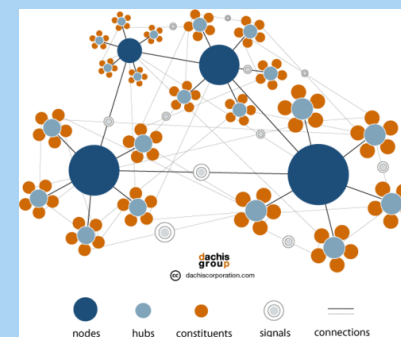
ERNs: Next Steps

2. Integrate ERNs into national healthcare systems:

✓ Joint Action on ERN integration into national healthcare systems (2021?)

✓ Implementation of the ERN BoMS 2019 Statement (Legal and governance framework at national level, Patient care pathways, Referral systems to ERNs, Awareness raising on ERNs at national level, Sustainability of the ERN model at HCP level)

✓ Effective support at hospital level
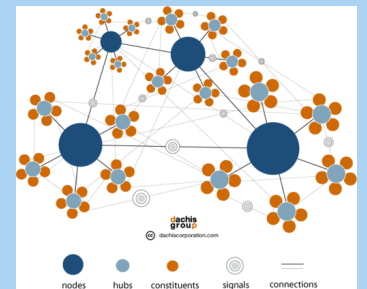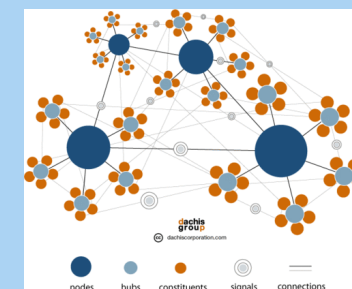
ERNs: Next Steps

3. Knowledge generation actions
- ✓ Clinical Practice Guidelines,
- ✓ ERN Virtual Academy,
- ✓ Professional mobility programme,
- ✓ Draft ERN training and education strategy

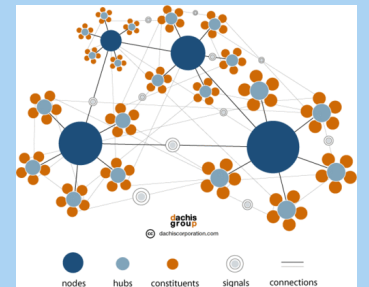# ERNs: Next Steps

4. Support ERNs' research activities:
- ✓Support set up of ERN registries,
- ✓Link the registries with European Health Data Space (EHDS)
- ✓European Joint Programme for rare diseases (EJP RD)

ERNs: Next Steps

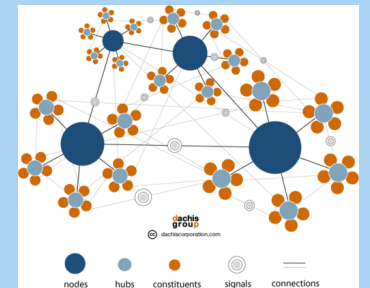**5. Demonstrate the added value of the ERNs: Evaluation and monitoring**

- ✓ Evaluation of Cross-border Healthcare Directive (2011/24/EU), including legal provisions on ERNs and rare diseases cooperation (2021-2022)

- ✓ First periodic 5-year assessment of performance of ERNs and their members (2022-2023)

- ✓ Follow up to ECA Report

ERNs: Next Steps

Evaluation:

- How effective is the directive in supporting the diagnosis and treatment of patients with rare and complex diseases through ERNs?

- How effective is the knowledge sharing on rare and complex diseases among EU healthcare professionals thanks to ERNs?

- What has been the impact of the ERNs on the research on rare and low prevalence and complex diseases?

- Are the ERNs as set out in the directive relevant for meeting the needs of patients with rare and complex diseases?

- In what ways the ERNs established by the Directive provide an added value for patients with rare and complex diseases compared to the national solutions alone?
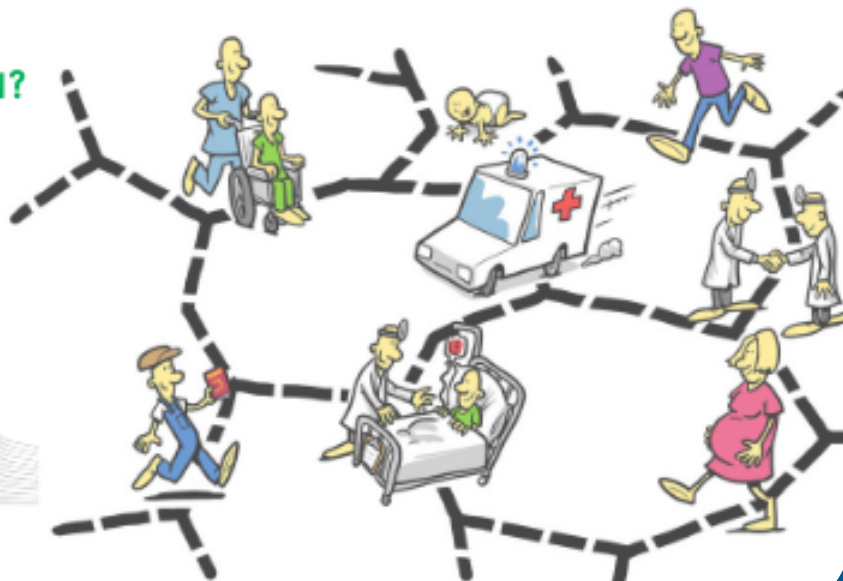
Thank you for your attention

Further information:
http://ec.europa.eu/health/ern/policy/index_en.htm

Health and Food Safety