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Meeting with EMA: cooperation in the field of ERNs

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The road to European Reference Networks (ERNs)



Imagine if the best specialists from across Europe could join their efforts to tackle complex or rare medical conditions that require highly specialized healthcare and a concentration of knowledge and resources.



**THE
POWER
OF AN
IDEA**



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Chapter IV Cooperation between MS Article 12 European Reference Networks

Networks of healthcare providers aiming at **improving quality, and safety and access to highly specialised healthcare**

Patients affected by rare or low prevalence and complex diseases

Added value at EU level

Multidisciplinary approach
(different specialities/areas of knowledge)

Need of cooperation:

- Scarcity knowledge
- Need education
- Complexity / high cost
- Effectiveness in the use of resources

"The knowledge travels, not the patient"



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Common ERN objectives

To ensure that ERNs are operational

To improve access to clinical advice, diagnosis, treatment and follow-up of patients

To optimise patient outcomes by combining expertise

To promote education and training

To reinforce clinical research

To ensure access to high quality healthcare services

To guarantee that knowledge is spread outside the ERN

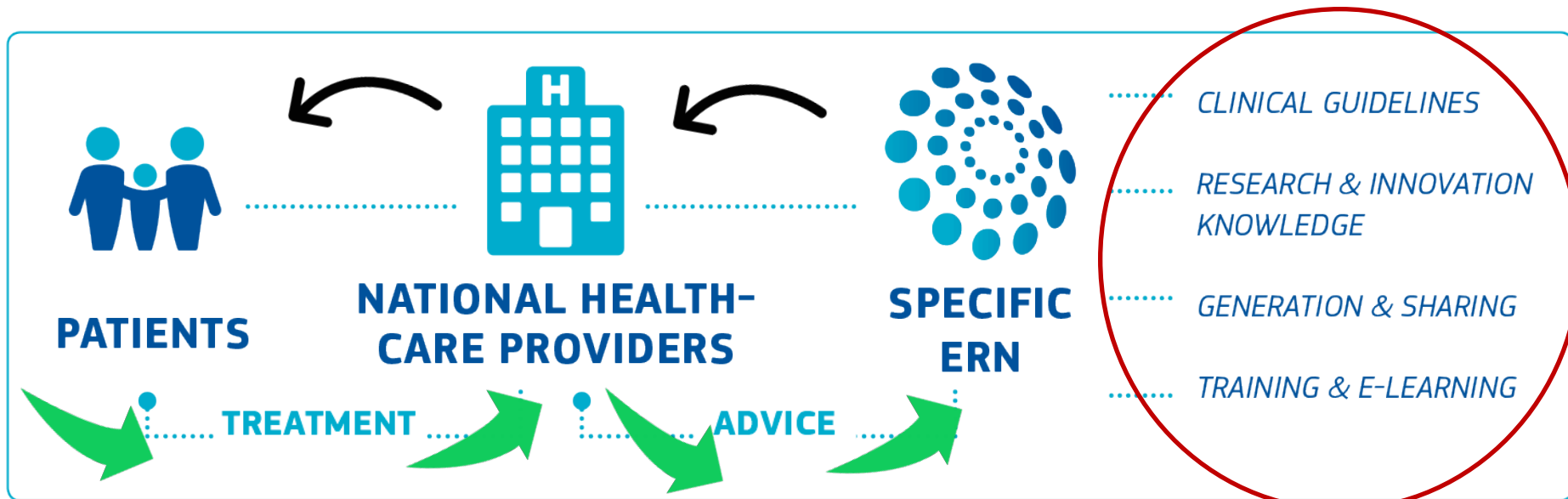
Share. Care. Cure.



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**Clinical
virtual care**

**Remote monitoring &
follow-up**

**Remote guidance and
diagnosis**

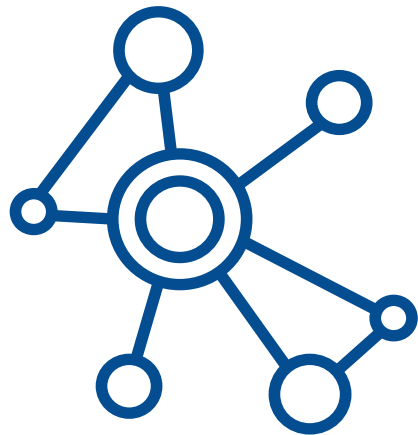
Outcome call 2016



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24



Networks

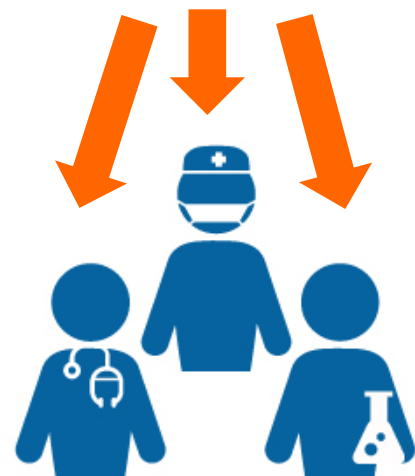
26 COUNTRIES



> 300
HOSPITALS

Full
Member

Affiliated
partner
(late 2017 ?)



> 900
HEALTHCARE UNITS

Health and
Food Safety



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(24)



BOND ERN	Bone Diseases	EuroBloodNet	Onco-Hematological Diseases
CRANIO	Craniofacial anomalies and ENT disorders	EUROGEN	Urogenital Diseases
Endo-ERN	Endocrine Conditions	EURO-NMD	Neuromuscular Diseases
EpiCARE	Rare and Complex Epilepsies	GUARD-HEART	Diseases of the Heart
ERKNet	Kidney Diseases	ITHACA	Congenital Malformations and Intellectual Disability
ERN GENTURIS	Genetic Tumour Risk Syndromes	MetabERN	Hereditary metabolic diseases
ERN-EYE	Eye Diseases	PaedCan-ERN	Paediatric Cancer
ERNICA	inherited and congenital anomalies	RARE-LIVER	Hepatological Diseases
ERN-LUNG	Respiratory Diseases	ReCONNET	Connective Tissue and Musculoskeletal Diseases
ERN-RND	Neurological Diseases	RITA	Immunodeficiency, AutoInflammatory and Auto Immune Diseases
ERN-Skin	Skin Disorders	TRANSPLANT-CHILD	Transplantation in Children
EURACAN	Solid Adult Cancers	VASCERN	Multisystemic Vascular Diseases



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Research, innovation & knowledge generation

Key Elements of ERNs

- A framework for structured cooperation to maximise cross-country expertise through joint research projects and clinical trials
- ERN provide an opportunity to build top level translational and basic research around shared strategies
- Dissemination of research results, education & training activities





PATIENT CARE
Patient clinical unmet needs
(treatment/diagnosis)



RESEARCH
Research question/gap
Prospective/translational research
Clinical trials

Patient Data

- Population Cohorts/Concentration of cases
- Secured Databases
- Clinical/Imaging/ Biological Data
- Genetics, Molecular Pathology
- IT Solutions / Communication between HCP

- *common elements , principles and requisites*

Phases of the ERN life cycle



2011-14

Legislation and initial planning

Directive
Implementing decisions
Awareness and communication

2015-16

Implementation: (Approval stage)

Design and development
Assessment tools
Call for ERN
Assessment of Network proposals
Approval of ERNs

2017-18

Implementation: (deployment stage)

Establishment
Initial organizational phase
Functioning (initial actions and services)
Partial service production

2019-20

Consolidation

Full service production
Continuous monitoring
Performance indicators and initial outcome assessment

2021

Evaluation and update

project cycle re-initiation



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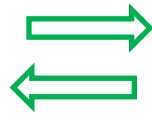
Actors involved in the ERN implementation



ERNs' Coordinators



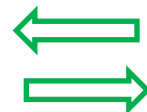
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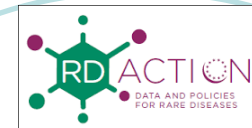
ERNs
BoMS



National
Healthcare
System



Commission expert group on rare diseases



Patients
organisations



Professional /
scientific
organisations



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Health and
Food Safety



ERN Board of MS

➤ Affiliated partners



➤ ERN & Industry



➤ ERN IT platform



➤ ERN monitoring and assessment system (June 2017)



➤ Link national networks/highly specialised centres to ERNs



➤ Support to Network coordinators and members of the ERN





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ERN Coordinators Group (ERN-CG)

Network of the Networks body

- *Set up 8.10 March*
- *Meetings: 26-27 April; 20 June; 30 October*

Governance model

Priorities & work plan 2017-18

- **Transversal & technical issues**
- **Crosslink**
- **Set-up working groups , goals and deliverables**



ERN's IT Platform and tools (under development)



CLINICAL
Online patient
management

July
2017

Web/video conferencing , Virtual clinical meetings

Exchange of Images (Radiology), diagnostic tests & pictures (genetics, pathology etc., (PACS)

Exchange of clinical information and patient data

Communication
and
collaboration

March
2017

Management /governance tools

Communication/conferencing tools



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Funding/support



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THE THIRD HEALTH PROGRAMME 2014-2020
FUNDING HEALTH INITIATIVES



EUROPEAN UNION
STRUCTURAL FUNDS



Erasmus+

Health and
Food Safety



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EMA and ERNs: cooperation based on mutual benefits



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Common areas of interest / action

- *Approval of new drugs for the benefit of patients*
- *Strong innovation dimension*
- *Knowledge generation (Clinical guidelines, evidence etc..)*
- *Low prevalence and complex diseases (Orphan drugs)*
- *Advanced therapies: Genetic origin of diseases:*
- *Scientific and expert advise*
- *Interaction between research, clinical care and healthcare provision organisation*



Capacities of the ERNs

- *Sustainable and robust structure*
- *Scientific and clinical expertise ("best in class")*
- *Data collection capacity (IT clinical platform)*
- *Commercial & non commercial clinical trials*

- *Long term follow up*
- *EU cohorts of patients*
- *Post-commercial studies:*
 - ✓ *Off label use of medicines*
 - ✓ *Repurposing*
 - ✓ *Compassionate use*
- *Patient safety / adverse events analysis and reporting*



Common challenges

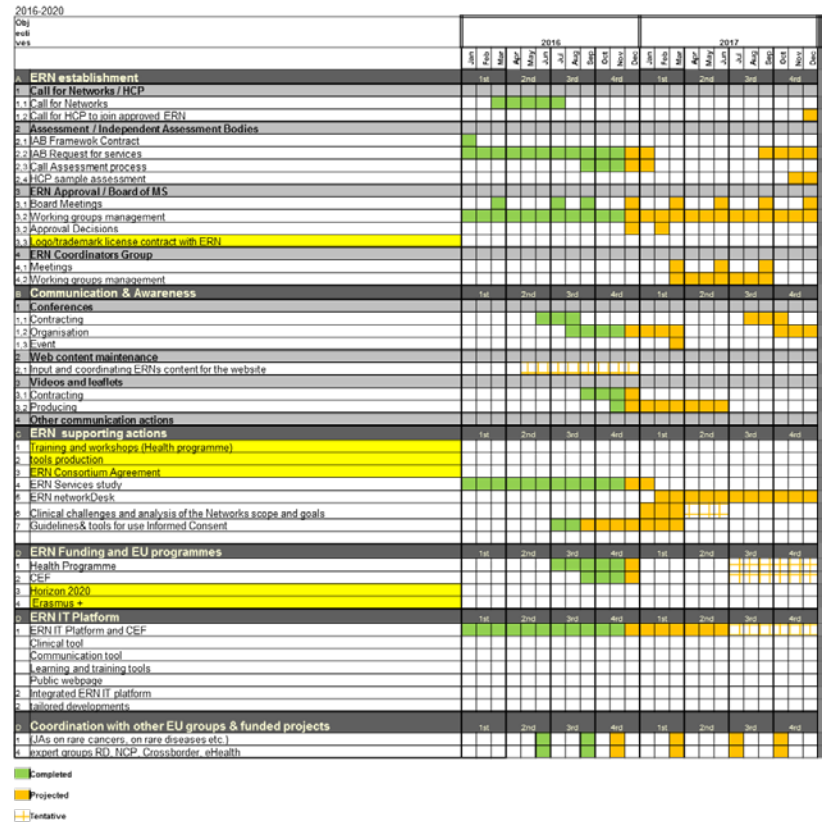
- Ethical concerns
- Data management/protection/ownership
- Information to patients
- Patient registries strategy
- Standards in clinical practice and clinical guidelines development



5 year planning

- Integration of policies
- Funding
- Tools
- Member States role
- Network outcomes

European Reference Networks: Project implementation



Challenges



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General Framework

- ✓ Definition of the legal status of ERNs
- ✓ Referral of patients (Social Security and CBHC Directive)
- ✓ ERNs & national healthcare systems
- ✓ Integration
- ✓ Liability & Data protection
- ✓ ERN IT solutions
- ✓ Coordination relevant funding streams
- ✓ UK HCPs in a post-Brexit scenario
- ✓ Sustainability of ERNs and opportunities for continued funding post-2022

Specific tasks of ERNs

- ✓ ERN management (coordinators)
- ✓ Clinical virtual care
- ✓ Coordination within the Network
- ✓ Knowledge generation & dissemination
- ✓ Development of patient pathways & shared clinical guidelines
- ✓ ERN crosslink
- ✓ Clinical outcomes
- ✓ Research leadership



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**Thank you for
your attention**

Further

information: http://ec.europa.eu/health/ern/toolkit_en

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

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