
TAXONOMY AND TEMPLATES FOR **ERN** DOCUMENTS

Mariana Dates, Optimity Advisors
4th ERN Conference, PS 7
22 November 2018

CONFLICT OF INTEREST DISCLOSURE

I have no actual or potential conflict of interest in relation to this program/presentation.

AGENDA

- 01 PROJECT INTENTION & OBJECTIVES**
- 02 LITERATURE REVIEW & CONSULTATION PROCESS**
- 03 MAPPING OF DOCUMENTS PUBLISHED BY ERNS**
- 04 STAKEHOLDER MAP**
- 05 TYPES OF DOCUMENTS**
- 06 EMERGING LIST OF DOCUMENTS**
- 07 PRELIMINARY FINDINGS**

European Reference Networks

(ERNs) are virtual networks involving healthcare providers across Europe. They aim to tackle complex or rare diseases and conditions that require highly specialised treatment and a concentration of knowledge and resources.

-
- ERNs will have access to data of millions of patients with rare diseases, and to thousands of experts, leading to the creation of information and technical documents.
 - Ensuring access to the new knowledge generated by ERNS is key to disseminate the achievement of the ERNs.
 - The development of a standardised list of documents, templates, repositories and a taxonomy will support the success of ERNs.

PROJECT OBJECTIVES

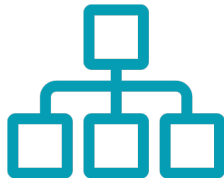
01



Identify the types of **technical & informative documents** that the ERNs may produce



02



Develop a complete **taxonomy** these documents



03



Develop the **templates** for these documents



04



Develop a **repository model** for the templates

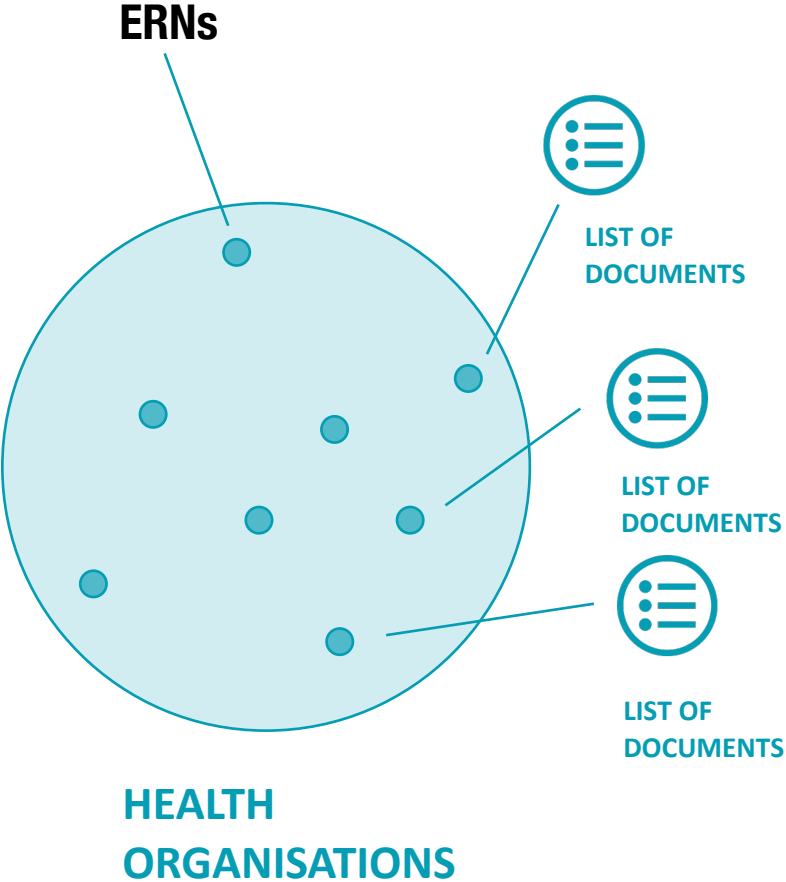
05



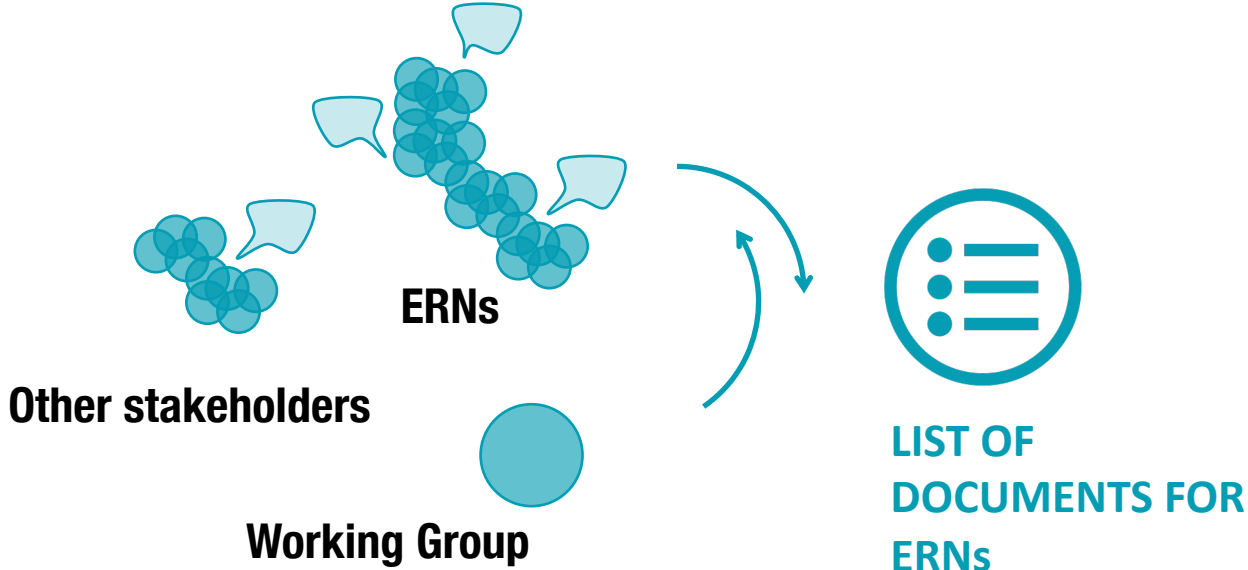
Develop a **repository model** for the technical & Informative **documents**

LITERATURE REVIEW & CONSULTATION PROCESS

01 We examined organisations within ERNs remit & assessed the documents they produce



02 We are co-creating the list of documents that ERNs are currently producing and are aiming to produce



MAPPING OF ERN PUBLICATIONS (1/2)

CLINICAL DECISION SUPPORT DOCUMENTS

Clinical Practice Guidelines	EURACAN	PaedCan	VASCERN	ReCONNET	Endo-ERN		
Clinical Practice Recommendations	ERKNET	EuroBloodNet	ReCONNET	CRANIO	VASCERN		
Guidelines	EURACAN	EURO-NMD	CRANIO	ReCONNET	ERKNET	ERN-RND	VASCERN
Consensus Reports/Statements	ERKNET	Endo-ERN	ReCONNET	EURO-NMD			
Patient Pathways	VASCERN	ReCONNET					
Outcome Measures	VASCERN						
Case Reports	ERKNET	Transplant Child	ReCONNET				
Operating Procedures & Protocols	EURO-NMD						
Quality of Care Standards	Endo-ERN						
Definition Criteria	Endo-ERN						
Evidence Reports	ERN-RND						
Clinical Scale Ratings	ERN-RND						
PowerPoint for Condition Recognition	CRANIO						

MAPPING OF ERN PUBLICATIONS (2/2)

INFORMATIVE DOCUMENTS

Patients' stories	ITHACA										
Do's and Don'ts Factsheets for diseases	VASCERN										
Leaflets / Flyers for Patients	VASCERN	MetabERN	ReCONNET	Endo-ERN	Transplant Child	ERKNET					
Newsletters	Endo-ERN	GENTURIS	GUARD-Heart	Transplant Child	EYE	EURO-NMD	PaedCan	EURACAN	ReCONNET		
	ERNICA	ITHACA									
Brochures	EYE	MetabERN	EURO-NMD	GUARD-Heart	ReCONNET	Transplant Child					
ERN Factsheet	GENTURIS										

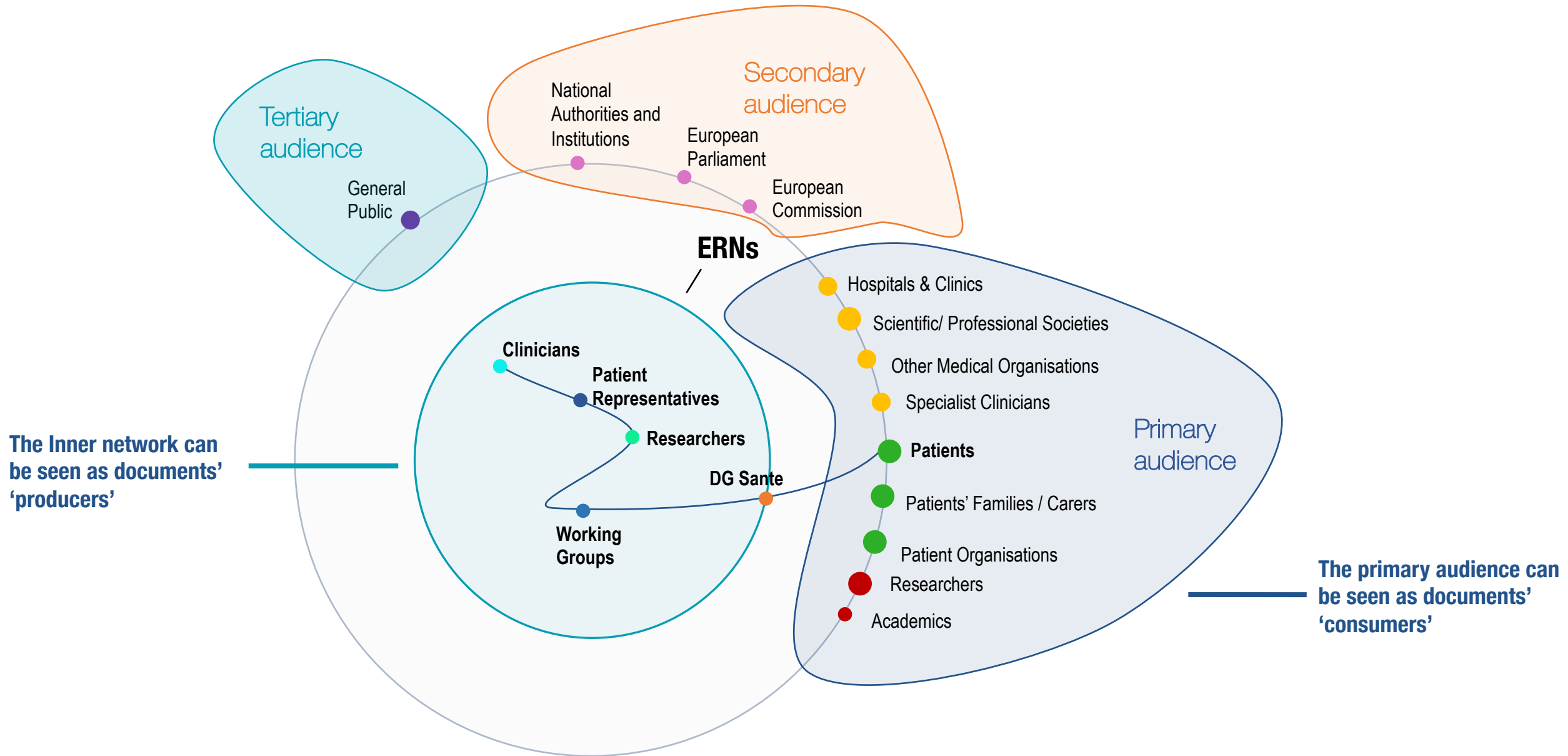
REPORTING DOCUMENTS

Activity/Meeting Reports	EYE	MetabERN	ReCONNET	ITHACA			
Satisfaction Surveys / Surveys	EYE	LUNG					

EXTERNAL PUBLICATIONS

Scientific Articles	Endo-ERN	GENTURIS	LUNG	Transplant Child	ERKNET	CRANIO	ReCONNET
---------------------	----------	----------	------	------------------	--------	--------	----------

STAKEHOLDER MAP



TYPES OF DOCUMENTS

CLINICAL DECISION SUPPORT

- Documents that directly support clinicians in delivering high quality and effective care.



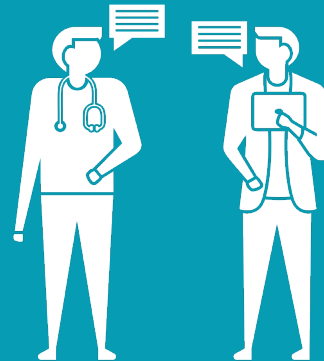
INFORMATIVE

- Publications providing information on a specific topic or condition
- Aim at educating and supporting patients and clinicians.



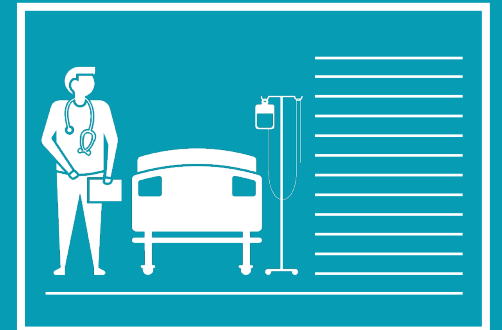
REPORTING ERN ACTIVITIES

- Internal documents that support the ERN activities, administrative and financial reports
- Published reports on the strategic direction of the networks, annual reports of activities, etc.



EXTERNAL

- Mainly publications in scientific and medical journals.



EMERGING LIST OF DOCUMENTS (1/2)

CLINICAL DECISION SUPPORT DOCUMENTS

- CLINICAL PRACTICE GUIDELINES
- CLINICAL PRACTICE RECOMMENDATIONS
- CONSENSUS STATEMENTS
- GUIDELINE SCOPE
- EVIDENCE SUMMARY AND GRADING TEMPLATE
- EXPERT POSITION PAPERS
- OUTCOME DISEASE SPECIFIC INDICATORS
- QUALITY STANDARDS AND INDICATORS
- PATIENT REGISTRIES
- STATE OF THE ART ON CPGs
- PATIENT PATHWAYS / "DIAGNOSTIC, MONITORING AND THERAPEUTIC PATHWAYS" / CLINICAL PATHWAYS
- CHECKLIST OF BASIC CORE SET OF VARIABLES FOR THE MANAGEMENT OF DISEASES
- MINIMUM DATASET FOR COLLECTION OF DATA ACROSS EU

EXTERNAL

- SCIENTIFIC PUBLICATIONS IN ACADEMIC JOURNALS
- CONFERENCE POSTERS

EMERGING LIST OF DOCUMENTS (2/2)

INFORMATIVE DOCUMENTS

- VERSION FOR PATIENTS OF CLINICAL PRACTICE GUIDELINES OR RECOMMENDATIONS
- PATIENT JOURNEYS
- PATIENT INFORMATION BOOKLETS
- DO'S AND DON'TS FACTSHEETS
- INFORMATION ON THE DISEASES (BROCHURES AND LEAFLETS)
- REFERRAL PATHWAY FOR GPs AND OTHER CLINICIANS
- INFOGRAPHICS
- EDUCATION AND TRAINING MATERIALS
- PILLS OF KNOWLEDGE VIDEOS

REPORTING ERN ACTIVITIES

- QUESTIONNAIRES / SURVEYS / INVENTORIES
- TERMS OF REFERENCES
- STRATEGY PLANS / PROGRAMMES (COMMUNICATION AND EDUCATION)
- POLICY PAPERS
- ePAG POSTER
- LEAFLETS AND BROCHURES ABOUT ERN; ERN ADDED VALUE FLYER
- PRESENTATIONS
- NEWSLETTERS
- MINUTES OF MEETING
- DELIVERABLE, TECHNICAL, FINANCIAL REPORTS
- MONITORING TEMPLATES

PRELIMINARY FINDINGS

- It is assumed by ERN representatives that these documents will be available online.
- As a general rule, it is assumed by ERN representatives that patients and healthcare professionals are the main audience.
- Most ERN representatives have indicated that they understand that there will be a single approach to develop consensus statements and guidelines.
- Guidelines and consensus statements would be differentiated by level of evidence to support the recommendations within them.
- Depending on the level and strength of evidence, the document would be classified as a Network Consensus Statement, or as a Clinical Guideline.
- It has been suggested that ERN follow the criteria defined in the Orphacode and used by Orphanet when referring to rare diseases in their publications.

THANK YOU FOR YOUR TIME

CONTACT US

Mariana Dates

mariana.dates@optimityadvisors.com

Nikolas Reschen

nikolas.reschen@optimityadvisors.com

Micol Tedeschi

micol.tedeschi@optimityadvisors.com

Optimity Advisors

<http://optimityadvisors.com/>

ANNEXES

ABOUT OPTIMITY ADVISORS

We take a **design-thinking approach** and apply **multidisciplinary skills** to our projects. We work collaboratively combining expertise in **public policy, healthcare, research & analysis, design & creativity, and technology** to drive change.

Our **public policy** team has expertise in working in the intersect between policy and technology for EU institutions. We have worked in the areas of cyber-security for DG CNECT, interoperability of justice and home affairs systems for the European Parliament, digital tools for company law for DG JUST and, are undertaking a study for DG CNECT to raise awareness on the use of algorithms in decision making.

For this project we have combined our 25-year expertise in **healthcare**; our world-renown experts in the field of **Taxonomy, Information Management and Digital Asset Management**; our team of in-house **graphic designers** and creative thinkers who will co-design the user-friendly deliverables for the ERNs; and our team of **technology experts** and **software developers** with extensive experience supporting public sector organisations in the development of databases and reporting applications.



PROJECT TIMELINE

CURRENT STATE

FUTURE STATE

PHASES & OUTCOMES

PROJECT INITIATION

Kick-off Meeting, familiarisation interviews, refining the methodological approach, preparation of Inception Report

ZOOM OUT

LITERATURE REVIEW

Collection of documents, review and assessment, identification of critical components and best practice, recommendations

CONSULTATION WITH ERN COORDINATORS AND REPRESENTATIVES

One-to-one interviews, and other consultations online and/or face to face

LIST OF DOCUMENTS

List of technical, informative and other documents, defined and classified (emerging taxonomy)

COMPLETE DOCUMENTATION LIST

ZOOM IN

TAXONOMY, TEMPLATES & REPOSITORIES FOR TEMPLATES AND DOCUMENTS

Consultation in online collaborative environment with coordinators, rapid prototyping, online working sessions, use of personas to identify needs of target users

COMPLETE TAXONOMY

REPORTING TASKS

Consultation in online collaborative environment with coordinators, rapid prototyping, online working sessions, use of personas to identify needs of target users

REPORTING OUTCOMES

Draft final report, final report review call

DISCOVERY PHASE /
BY END OF DECEMBER

DESIGN & DEVELOPMENT PHASE /
FROM JANUARY 2019

OBJECTIVES

Define the current and future state of ERNs IM system;
Define success factors;
Define the target user groups/personas;
Identify ERNS current information and content;
Identifying technology, security and data protection;
Identifying brand and design requirements.

Define target information architecture, content structure, navigation and interactions of the ERNs IM systems;
Defining target visual design for the documents ;
Define target technology and data sources, integrations, security, identity management;
Defining a solution for the taxonomy and the repositories that is compatible with the ERNs existing systems;
Execute appropriate handover activities;
Execute DG SANTE reporting requirements.

TECHNICAL DOCUMENTS

DOCUMENT	DEFINITION	CONSUMERS
CPG - (two formats: i) at-a-glance, easy to read summary and ii) full document)	“Clinical practice guidelines (CPGs) are statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefit and harms of alternative care options" (The Institute of Medicine) Their aim is to advise clinicians on best practice. The structure of these documents should be based on AGREE II and GRADE methodology	Clinicians
Guideline Scope (CPG supporting document)	Template that captures the guideline scope that would be used to conduct a literature review including: i) targeted patient population; ii) intervention and comparator; iii) clinical question and outcomes for the guideline; iv) methodology to rate / rank the priority of the clinical questions and outcomes researched	Clinicians
Evidence summary and grading template (CPG support document)	When competing an evidence based review the evidence needs to be organised for the clinical leads and patients to grade the evidence in terms of strength and relevance	Clinicians
State of the art on CPGs	Publication of a supplement on the state of the art of CPGs	Public
Checklist of basic core set of variables for the management of diseases	A checklist to be used for the management of rare diseases	Clinicians
Patient Journeys	Document providing guidance on how care is organised in the MS involved in the network. Patients are therefore more informed of the process before making an informed choice on the healthcare they receive. The aim is to map the natural history of a single condition and the patient’s needs and recommended care and treatment at all points of their life journey. (infographic of the patient life journey as well as table with detailed information that sits behind each of the summary sections in the visual overview)	Patients
Consensus Statements	Clinical recommendations / consensus between experts with regard to the clinical diagnosis, treatment, outcome measures and follow-up of the rare disease	Clinicians
Expert Position Statement	Expert statement on a clinical question	Clinicians
Patient Pathways / "Diagnostic, monitoring and therapeutic pathways" / Clinical Pathways	Document that aims to improve the care and management of patients with a rare disease. They include the “red flags” that may lead to suspicion on the disease, how to reach a definite diagnosis and the management and follow-up recommendations. They are a very important tool used in defining the best patient care and will be further validated and updated when needed. Three levels of granularity: (i) high level pathway summary; (ii) detailed clinical pathways; (iii) integrated care pathway (MTD document that details the handovers in care and treatment)	Clinicians, Patients, Policy makers, health economics experts
Minimum dataset for collection of data across EU	A set of data required for the collection of rCTDs data in EU	Clinicians, data managers
Quality Standards and Indicators	List of quality indicators for the assessment of healthcare	Clinicians
Clinical Outcomes for specific diseases	A common format to present disease specific outcomes profiled, during annual meetings. Format should enable outcomes to be interchangeable between different networks, and profiles by case mix at annual meetings or peer-review	Network Members

INFORMATIVE DOCUMENTS

DOCUMENT	DEFINITION	CONSUMERS
Patient versions of guidelines	Patient-accessible version of clinical practice guidelines to inform patients on best medical practice in an informative and accessible way	Patients
Patient information booklets	To provide accurate (diagnosis specific) information to patients	Patients, public, GPs
Do's and Don'ts Factsheets	To assist patients and the medical community in knowing the basic do's and don'ts of common and emergency situations that need to be considered in patients with rare diseases. These are recommendations made by consensus at expert level. Recommend that these factsheets are used as a guide to implement locally agreed policies.	Mainly patients and carers, but also GPs and other clinicians
(Pills of Knowledge Videos)	Short single video lessons (3-5 minutes) available on YouTube in which an expert talks about a specific topic that has been selected and validated by the Networks. They are made by either clinicians within the network or ePAG patient advocates.	Patients, public, GPs
Multidisciplinary online course	Build upon the videos, it is an online course of short expert talks for rare diseases by topic	Patients, public, GPs
List of Patients organisations and centre of expertise	List of network patients organisations and centre of expertise in EU	Patients, carers, GPs, Clinicians, public
Information on the diseases (brochures and leaflets)	Description of the disease, the treatments available, etc.	Patients, carers, GPs
Added value flyer	Information flyer explaining the added value of ERNs	Patients, Public
Referral pathway	Template for referral into the ERN for a CPMS consultation and advice; Template for the referral criteria / protocol for external publication and use in Member States and the referral pathways; Information on virtual consultation under the CPMS	National Healthcare Systems, MS, Clinicians, GPs
Infographics	Graphic description of activities of ERN	Public
Education and training material	A suitable range of templates that can be used in training and education, including slide decks, feedback questionnaires, training materials	NHS, patients, GPs

REPORTING ERN ACTIVITIES

DOCUMENT	DEFINITION	CONSUMERS
Questionnaires / Surveys / Inventories	Surveys to all network members to find out what research has been completed within their professional centre and whether or not they would like the support of the ERN and to find out what type of patient info is available (paper, digital, movies, etc) and in what language)	Network members (if it's a deliverable, then also public)
Banner	For the identification of the ERN at meetings and conferences	Public
Conference Posters	Presentation of the ERN, of activities, roadmap, survey results, etc	Clinicians, patients or public
Terms of References	Description of internal rules of each ERN to regulate itself	ERN Members
Strategy plans / programmes (communication and education)	Documents that outline the future activities planned within the ERN	Network members (if it's a deliverable, then also public)
Policy papers	Branded and formatted templates for all ERN policy and procedure documents	Public, network members
ePAG Poster	Poster that aims to inform patients and ePAG on ERN activity and scope	ePAGs, Patients, Scientific Societies, EURORDIS, Carers
Leaflets and Brochures	Information on ERN	Public
Presentations	Power point presentations describing the ERNs aims, specific objectives, activities, etc, to be used during conferences and workshops on rare diseases at EU and national level	Public, used by all network members
Newsletters	To inform network members, patients and they wider healthcare professional community of key updates / events / progress	All network members, public
Minutes of Meeting	Description of the topics discussed in a meeting/web conference.	Usually within the ERN, occasionally Public
Deliverable, technical, financial Reports	Documents that report on the results of ERN activities, documents reporting financial aspects of the project, etc.	Public, ERN stakeholders
Social Media Account	Share of information on the ERN initiatives	Public
Monitoring templates	Checklist for reporting against the 18 EC ERN indicators and a template for publishing this monitoring externally	EC, MS, network members
Position papers	On ERN opinion for the use of new innovation and technologies	National Healthcare Systems, hospitals and patients.

DOCUMENTS	DEFINITION	CONSUMERS
Scientific Publications	Research reviews and write ups of research studies published in scientific journals / part of PhD theses to: (i) inform on novel findings; (ii) contribute to best practice; (iii) stimulate future research in the field.	Clinicians, patients and the general public