



An action by FRT
FONDATION RENÉ TOURAINE

With the support of the
EADV

ERN-Skin

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Scientific Committee of the Fondation René Touraine



What is an ERN?



European
Reference
Networks



An initiative of



«Imagine ...

- *if the best specialists*

- *from all over Europe*

- *could be brought together*

- *to tackle common problems*

- *that require highly specialised healthcare and a concentration of knowledge and resources»*



**European
Reference
Networks**

Initiatives

Legal background

- Directive 2011/24/EU on patients' rights in cross-border healthcare
- **Commission delegated decision** 2014/286/EU **and annex** listing the criteria and conditions that healthcare providers and the ERNs should fulfil
- **Commission implementing decision** 2014/287/EU and **annex** containing criteria for establishing and evaluating ERNs, including the exchange and dissemination of information about the ERNs

Establishment of an ERN

- At least 10 healthcare providers (HCP)
- From at least 8 different Member States
- **Each healthcare provider must be endorsed by its respective Member State**
- All Members of a Network must have **in common the expertise in a certain field**, or certain treatment(s) offered or in diseases or health conditions
- Each HCP must fulfill general and specific criteria defined by the EC and the ERN

Assessment of an ERN

- To ensure that it fulfils all the criteria for Networks and its Members as provided in the **Commission Delegated Decision**:
 - the network proposals are currently **technically assessed**
 - by an **independent assessment body**

Approval of an ERN

- Based on the technical assessment
- **The Board of Member State will decide the approval of the Networks and membership proposals (by the end of 2016-2017)**
- ERNs are approved for a 5 year period

Very restrictive conditions for application

- One application by speciality/thematic network to avoid fragmentation, overlapping and too limited scope of the network proposals
- Only open to expert centers from EU Member States + Iceland, Lichtenstein, Norway with a written statement from their respective national authorities certifying that their participation is in accordance with their MS national legislation

Key role of Patient Groups

- To enable the full engagement of patient groups through democratic representation, support and quality contribution,
- Eurordis has organized **Policy Action Groups** based on the “ERN disease grouping”
- One is organized specifically on **rare & complex skin disorders**

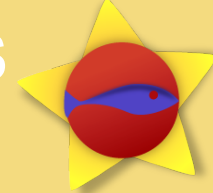
ERN-Skin

A long journey...





ENODERMATOSES and rare Skin disorders NETWORK (FRT)



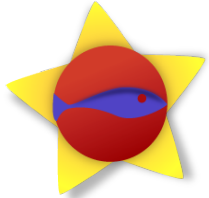
- **Definition:** the European and international network on rare genetic skin diseases for professionals and patients
- **Date of creation:** 2003
- **Geographical Coverage:** 30 European, Mediterranean and Middle-Eastern countries
- **Number of partner teams:** 52
- **Goal: to** improve health care and social support for genodermatoses patients by promoting a patient-based approach
- **Source of funding:** Fondation René Touraine, European Union, European Academy of Dermatology and Venereology, Corporate Donations, Private Donations

Since 2008,
the Fondation René Touraine
Genodermatoses & Rare Skin
Disorders Network
has been identified by
the European Commission as a
pilot project
for European Reference Network
for Rare Diseases

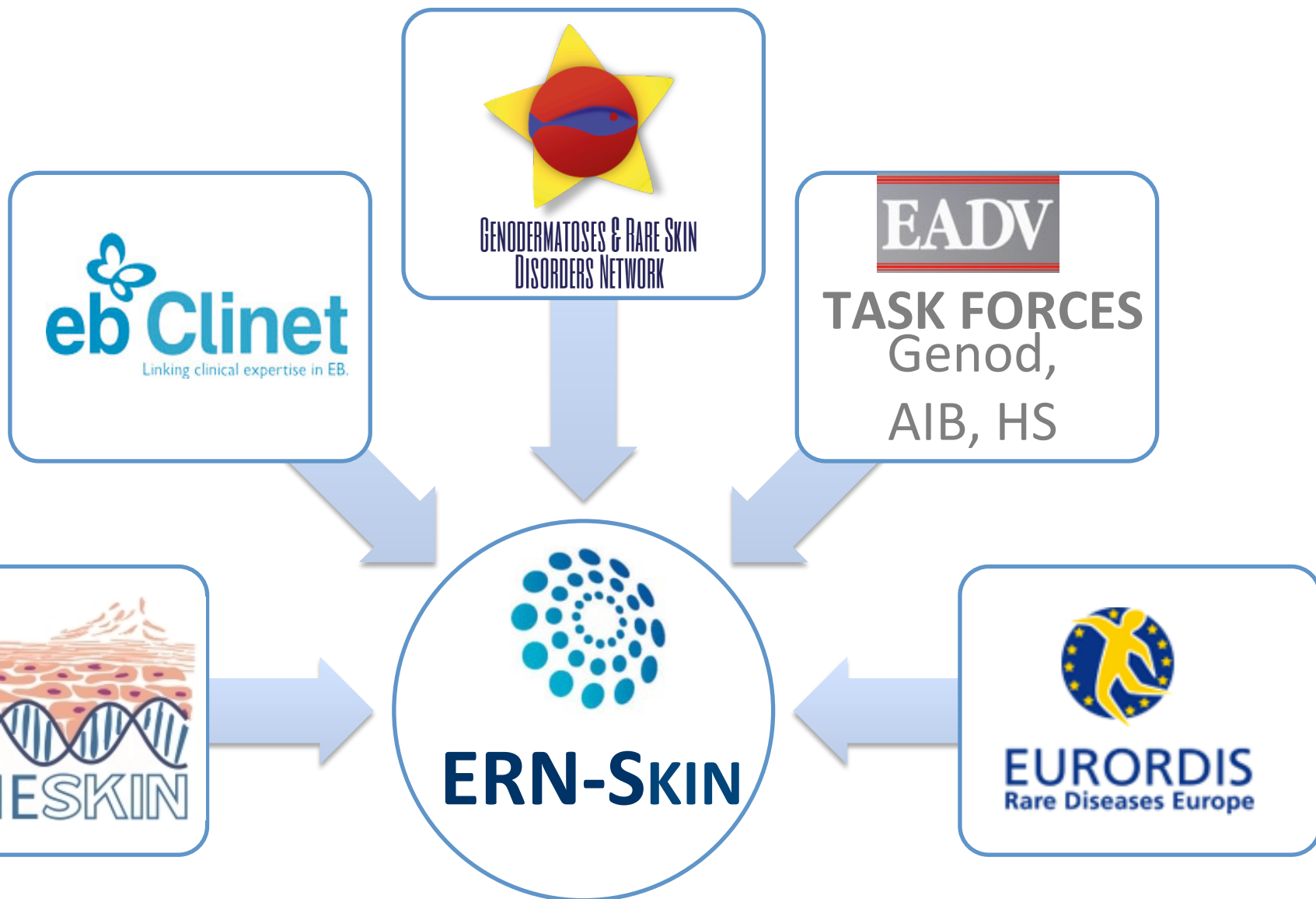
GENODERMATOSES & RARE SKIN DISORDERS NETWORK



A COOPERATIVE APPROACH



- The Network develops an **inclusive approach** to involve in the network experts and centers taking care of patients
- The Network works in close **collaboration with other networks** such as Geneskin and EB-Clinet as well as patient groups and alliances, Eurordis and also rare diseases structure as Orphanet, and EADV Task forces



RARE AND UNDIAGNOSED SKIN DISORDERS



ERN-Skin Partners



Inclusive approach: letter to the 51 representatives in the Board of Member States on European Reference Networks to identify teams willing to join the proposal for **an ERN-skin and complex or unexplained skin disorders**

Health care providers had **to fulfill** general and specific criteria defined by the EC and the ERN

HCP had to be endorsed by its own Member state

ERN-SKIN

56 EXPERT CENTRES
FROM 18 COUNTRIES

INCLUDING 30
EXPERT CENTERS
FOR EB PATIENTS
IN 17 COUNTRIES



**The network application
and all partners
passed the first eligibility check
(*August 2016*)**

**(after evaluation by the the Board of
Member State checking all the
documents)**

Many expert centers could not join for administrative issues

- In some member states, national rules were not yet in place to endorse expert centers
- The call was not open to non EU countries such as Switzerland

Cooperation with these expert centers

- Expert Centers in non EU Member States:
 - Participation to the ERN-activities
 - Sharing information
- Expert Centers in EU Member States + EEA countries can join an approved ERN anytime over the 5 years if they
 - are endorsed by their national authorities
 - fulfill criteria defined by the EC and the ERN-Skin

ERN-Skin

OBJECTIVES

ORGANISATION

EXPECTED OUTCOMES





ERN-SKIN

Sub Thematic groups

DISEASES APPROACH

- The aim is to cover **all rare, complex and undiagnosed skin diseases in children and adults requiring a highly specialized healthcare and multidisciplinary approach**
- **Inclusive and stepwise approach** based on existing and mature networks and taskforces
- Multi-year **disease expansion plan**

12 SUB THEMATIC GROUPS

**Epidermolysis
Bullosa**



**Ichthyosis &
Palmoplantar
Keratoderma**

**Ectodermal
Dysplasia**
including Skin
Fragility Disorders &
X-linked cutaneous
disorders

**Monogenic
Connective Tissue
Disorders**

**Cutaneous Mosaic
Disorders**

Nevi & Nevoid Skin
Disorders & Complex
Vascular Malformations
& Vascular Tumours

**Cutaneous
diseases related
to DNA Repair
Disorders**

**Autoimmune
bullous diseases
and severe
cutaneous drug
reactions**

**Hidradenitis
suppurativa
PAPA, PAPASH,
PASH, PASS,
SAPHO,
Behcet, Degos**

Photosensitivity

*Non bullous complex
autoimmune/
inflammatory
cutaneous diseases*

*Premature Skin
Ageing*

*Rare cutaneous
proliferation in
children and adults*

Subthematic groups to be included in the ERN-Skin expansion plan

ERN-SKIN: Sub thematic groups

The Rational

- Misdiagnosis** (poor skin knowledge among HCP)
- Ignorance regarding the management** of skin symptoms
inflammation, skin barrier alteration, malnutrition, sepsis, pain
- Lack of training of paramedical** teams for the management of
a severe involvement o the skin
- Poor recognition** of the skin alteration **as a handicap**
- Poor social integration** of patients
- Life-threatening diseases**, skin carcinogenesis due to
inflammation (chronic wounds...), immunosuppression or
genetic predisposition, secondary effect of therapeutic
attempts
- The cost of treatments

ERN-SKIN: Sub thematic groups

The Rational

-The complex pathophysiologic mechanisms of the different sub thematic groups often match each other: the better understanding of some skin diseases will be a key to have a better understanding of the others, providing a better knowledge on the skin biology

(example: collagen VII anomalies in hereditary EB/collagen VII autoantibodies in acquired EB)

-Each sub thematic group needs a multidisciplinary approach objective to develop a collaborative approach with other ERNs

Sub Thematic groups

DISEASES APPROACH

HIGH-LEVEL PATIENT MANAGEMENT

- Diagnosis
- Treatment
- Follow-up
- Management
- Best practice
- Multidisciplinary advice
- Clinical guidelines
- Cross-border patient pathways
- Empower patients

*Each sub
Thematic
group is led
by a leader
team*

2 coordinators

Specific road map
Specific outcomes
Specific criteria

RESEARCH

- Identify and fill research gaps
- Develop collaborative research
- Epidemiological surveillance
- Share Registries
- Rare skin diseases burden
- Deep phenotyping

Epidermolysis Bullosa



HIGH-LEVEL PATIENT MANAGEMENT

Coordinators: M. Jonkman (NL), J. Mellerio (UK)

Core Group: A. Diem (AT), C. Bodemer (FR), D. Kiritsi (DE), M. El-Hachem (IT), R. de Lucas (ES)

RESEARCH

Coordinators: L. Bruckner-Tuderman (DE), I. Leigh (UK), G. Zambruno (IT)

Core Group:
M. Pasmooji (NL), D. Castiglia (IT), A. Nystroem (DE), M. J. Escamez Tolarado (ES), B. Mayer (HU), E. O'Toole (UK)

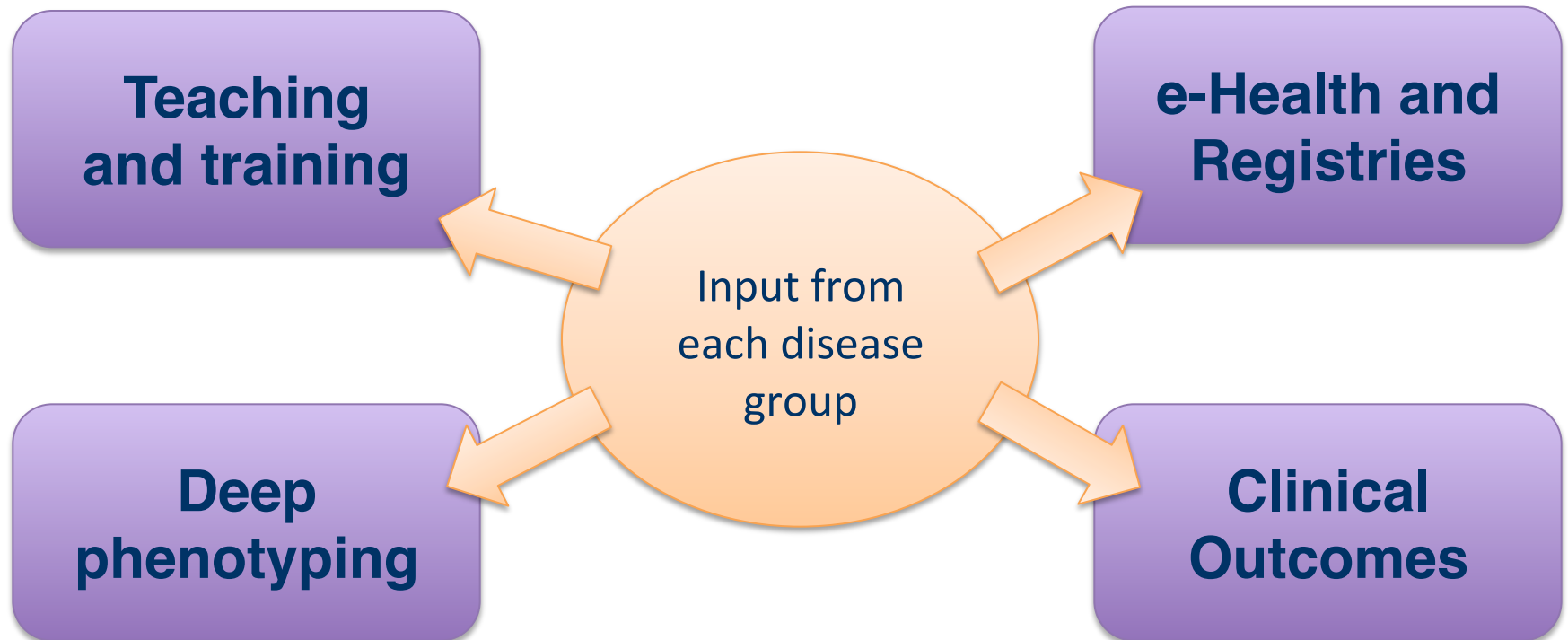
Patient Representatives

M. Jaega (Debra UK), A. Kennan (Debra Ireland), E. Makow (Debra Spain),
C. Robinson (Debra International)

TRANSVERSAL GROUPS

for a transversal and complementary approach

Create synergy

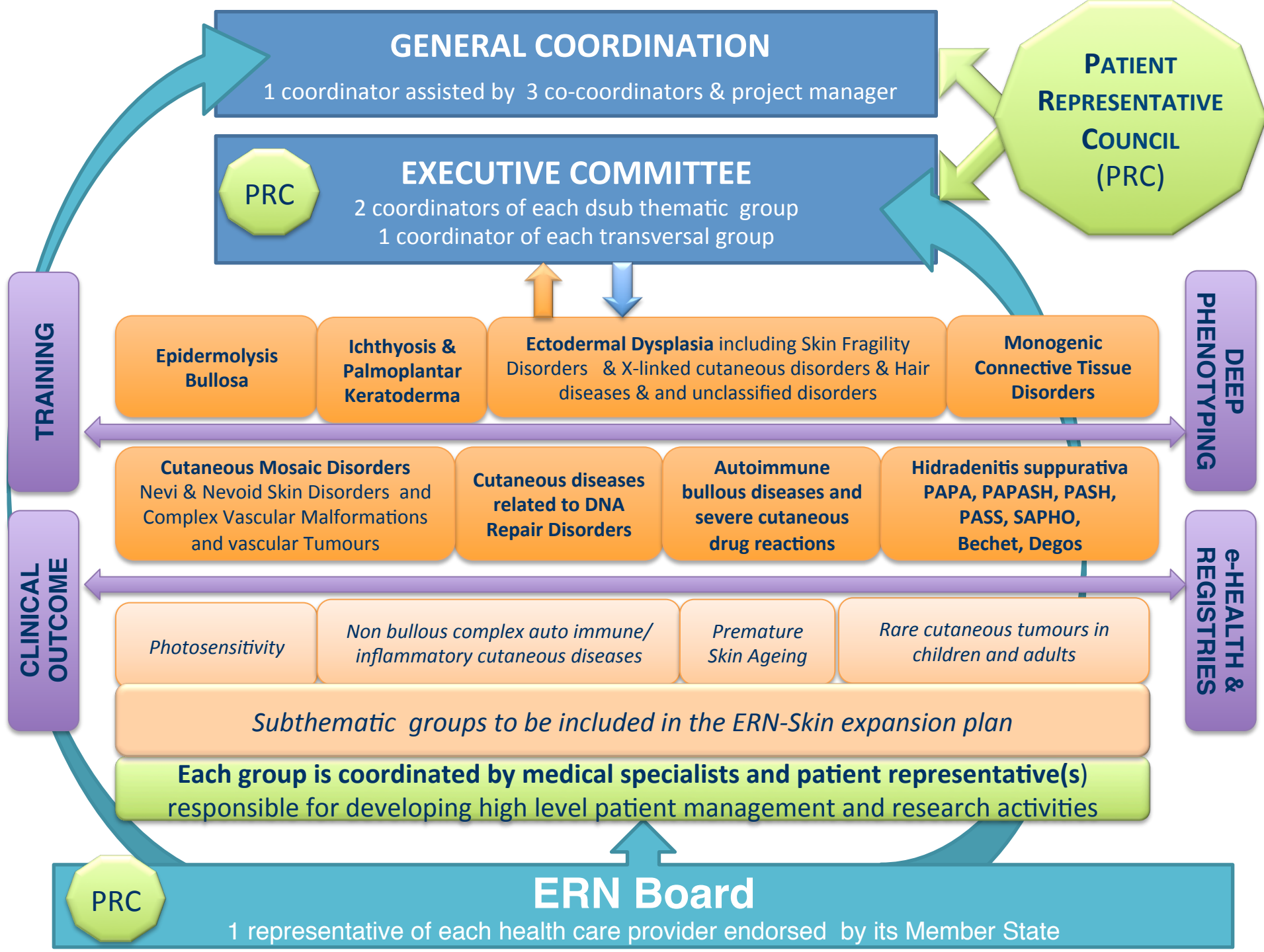


Expected Clinical Outcomes defined with patient representatives

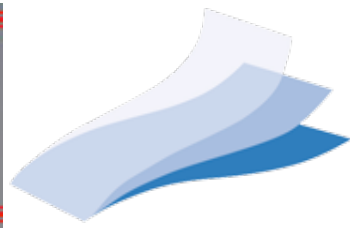
- Easy access to an expert center
- Regular training of the multidisciplinary teams
- Specific therapeutic education programs for adult, adolescent, paediatric patients
- European and national specific guidelines
- Harmonization of treatment procedure between all network partners
- Development of an individual burden score with cross-cultural adaptation
- Improvement of the patient centered care in the affiliated center
- Better visibility of the expert network in each country
- Stimulation of clinical research leading to concrete Better recognition of rare diseases by authorities
- European registries

ERN IT Platform

The EC is developing an ERN IT platform to **support networks in the diagnosis and treatment of rare or low-prevalence complex diseases or conditions across national borders in the European Union**



Official endorsement of the ERN-Skin



**European
Dermatology
Forum**



European
Society for
Pediatric
Dermatology



EURORDIS
Rare Diseases Europe

ERN tentative timeline & milestones



**March – June
2016**



**Call for
Networks**

**July-October
2016**



**Assessment
proposals**

**October -November
2016**



**Approval ERN
by Board MS**

**November 2016
– March 2017**

**Grant
evaluation**



**March
2017**

**3rd ERN Conference &
Kickoff meeting ERNs**



Health and
Consumers

European
Reference
Networks

Preliminary « mini-site »: www.ern-skin.org