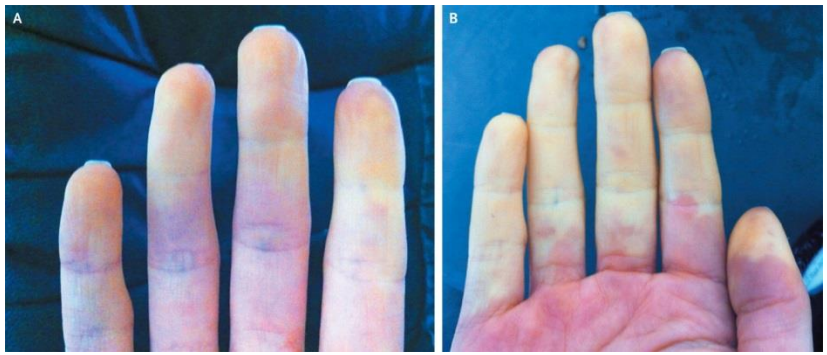
VIVERE CON IL GILS
CONVIVERE CON LA SCLERODERMIA

Brescia, 16 luglio 2018

Ilaria Galetti, vicepresidente GILS
ePAG in ERN ReCONNET

La Sclerodermia/Sclerosi Sistemica

- Malattia autoimmune
- Primo sintomo: Fenomeno di Raynaud
- Cute: durezza, teleangectasie, ulcere trofiche
- Apparato gastrointestinale: bocca, esofago, stomaco e intestino
- Cuore e reni
- Polmoni, PAH
- Donne-Uomini: 5-1



Io e la SSc

- Convivo con la SSc da oltre 22 anni
- Diagnosi precoce VEDOSS
- Paura
- Cambiamenti
- Incontro con il GILS
- Gruppo di persone e, soprattutto, gruppo di amiche

Gruppo Italiano Lotta alla Sclerodermia

- Bilancio certificato
- Informazione (Giornalino, pubblicità
- Formazione
- Progetti (Psicologhe, un Medico risponde)
- Ricerca scientifica di base e traslazionale
- Convegno nazionale (XXV 2019)
- Federazioni e reti, nazionali e internazionali

SclerøNet al servizio del paziente

- Il paziente al centro
- Patologia sistemica che necessita di approccio multidisciplinare
- GILS ha trovato le eccellenze nelle eccellenze
- Continuo monitoraggio

SclerоNet l'organizzazione

- Costituzione di agende prioritarie esclusivamente dedicate ai pazienti seguiti in rete nei centri di ScleroNet
- Riduzione dei tempi d'attesa per accedere a tali servizi
- Incontri mensili dei 4 centri al fine di avere un feedback dell'attività con discussione dei casi complessi
- Miglioramento dei percorsi diagnostici e terapeutici attraverso la condivisione di dati e studi clinici

ScleroNet chi ne fa parte

- I pazienti
- Immunologi e Reumatologi
- Cardiologi
- Dermatologi
- Chirurghi plastici
- Maxillofacciali
- Dentisti
- Ginecologi

FESCA, la Federazione Europea

- GILS è socio fondatore di FESCA
- WSD: World Scleroderma Day, insieme a Canada e Stati Uniti
- WSG: World Scleroderma Congress (Praga 2020)

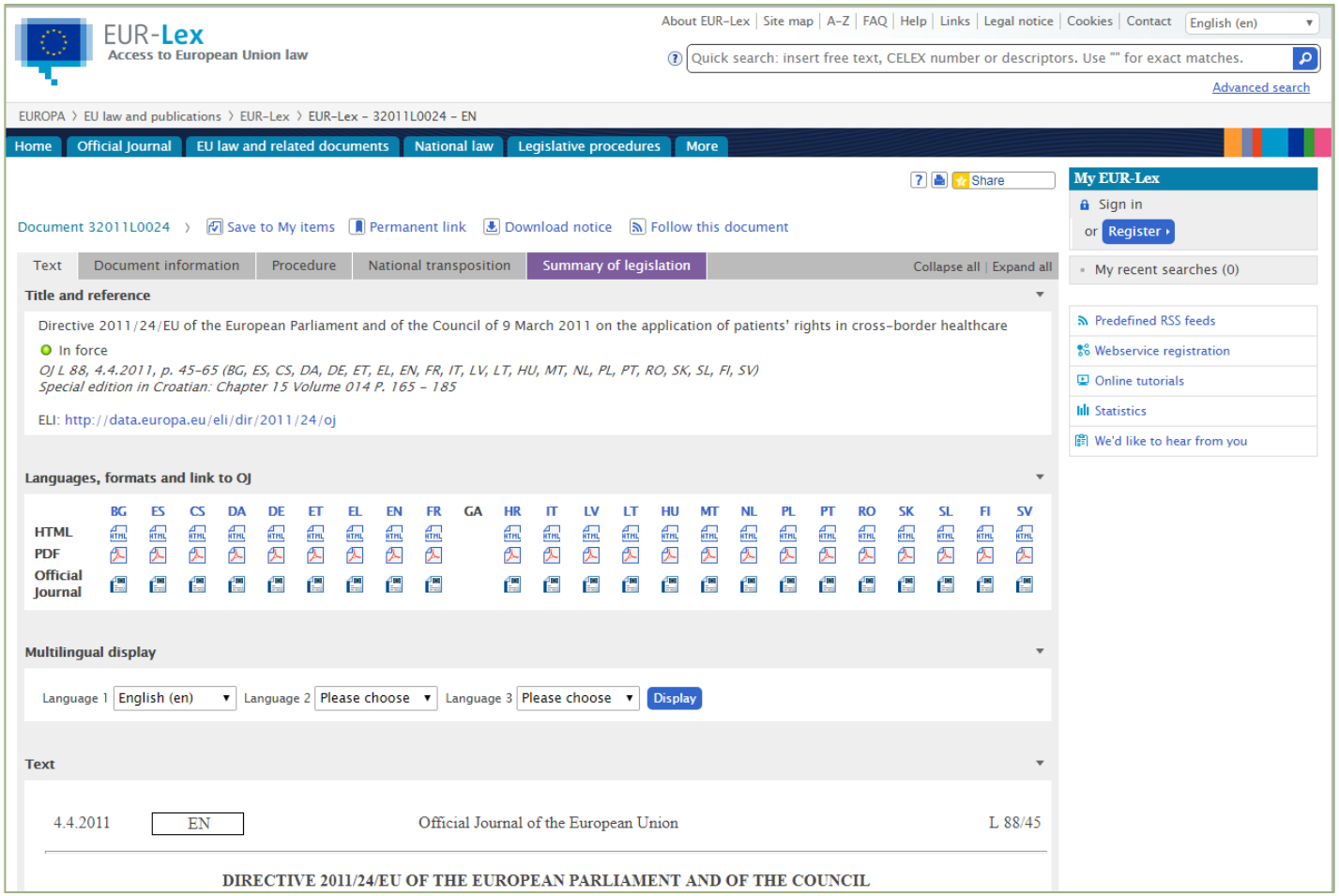
FESCA IVZW
Federation of European Scleroderma Associations

LOTTA ALLA SCLERODERMIA GILS ONLUS

EURORDIS - ISS

- Summer School sui Clinical Trials
- Winter School: advanced
- Pharmacovigilance
- EULAR Health Economics
- ISS Summer School on Registries
- EMA 2018

Directive 2011/24/EU



Directive 2011/24/EU

Directive of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare

ERNs – European Reference Networks

ERN – European Reference Networks

24 ERNs

Oltre 300 HCPs

25 MS (Norvegia inclusa)

Ogni ERN ha un Coordinatore

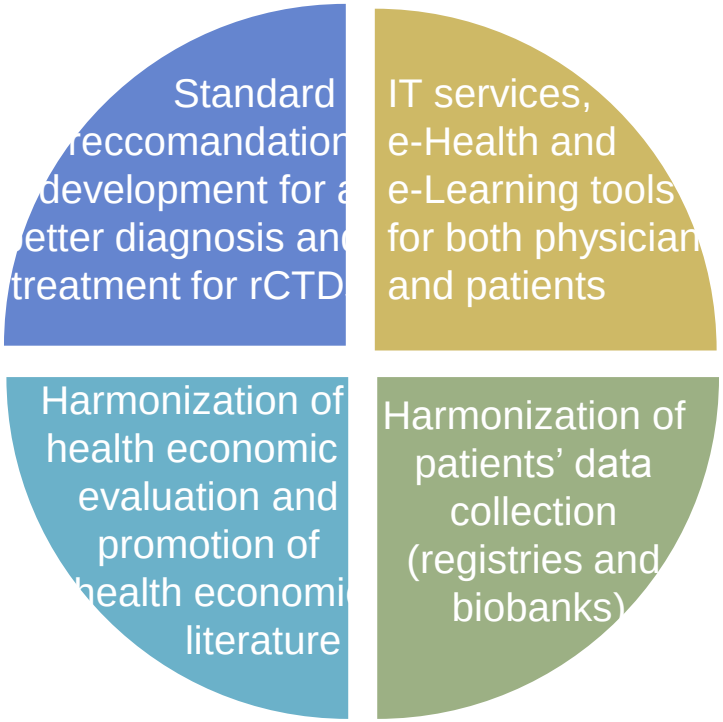
ReCONNET (prof Marta Mosca)

Il Coordinatore dei Coordinatori è il prof Maurizio Scarpa (MetabERN)

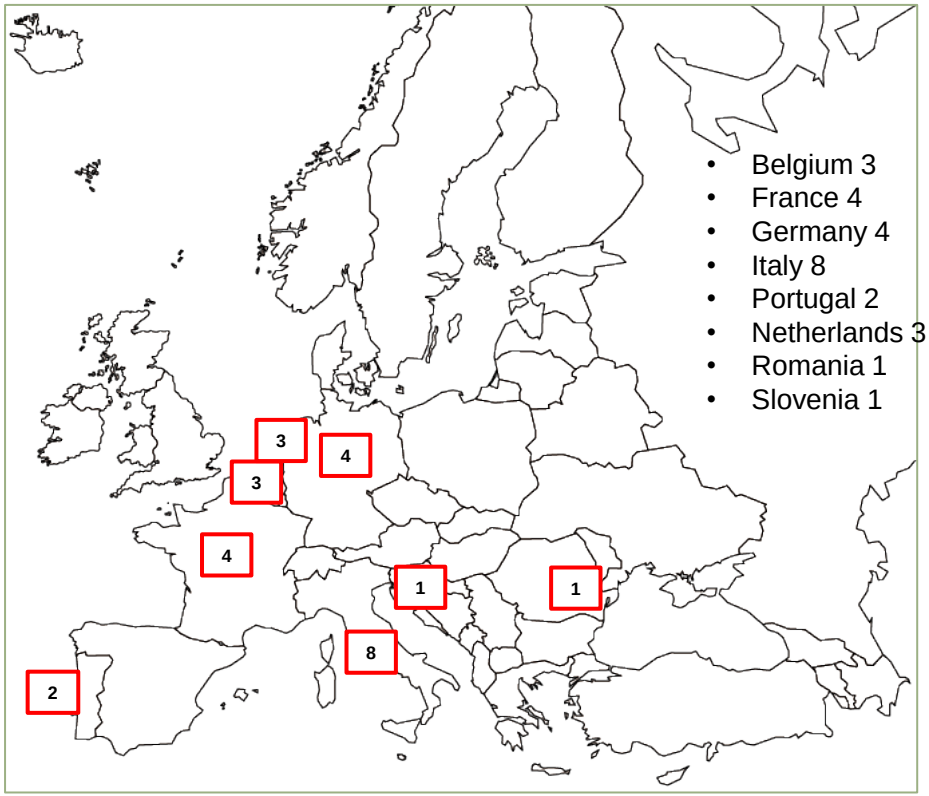
24 ERN approvati

- ERN BOND
- ERN CRANIO
- Endo-ERN
- ERN EpiCARE
- ERKNet
- ERN-RND
- ERNICA
- ERN LUNG
- ERN Skin
- ERN EURACAN
- ERN EuroBloodNet
- ERN eUROGEN
- ERN EURO-NMD
- ERN EYE
- ERN GENTURIS
- ERN GUARD-HEART
- ERN ITHACA
- MetabERN
- ERN PaedCan
- ERN RARE-LIVER
- **ERN ReCONNET**
- ERN RITA
- ERN TRANSPLANT-CHILD
- VASCERN

ERN: Mission and Vision Statement

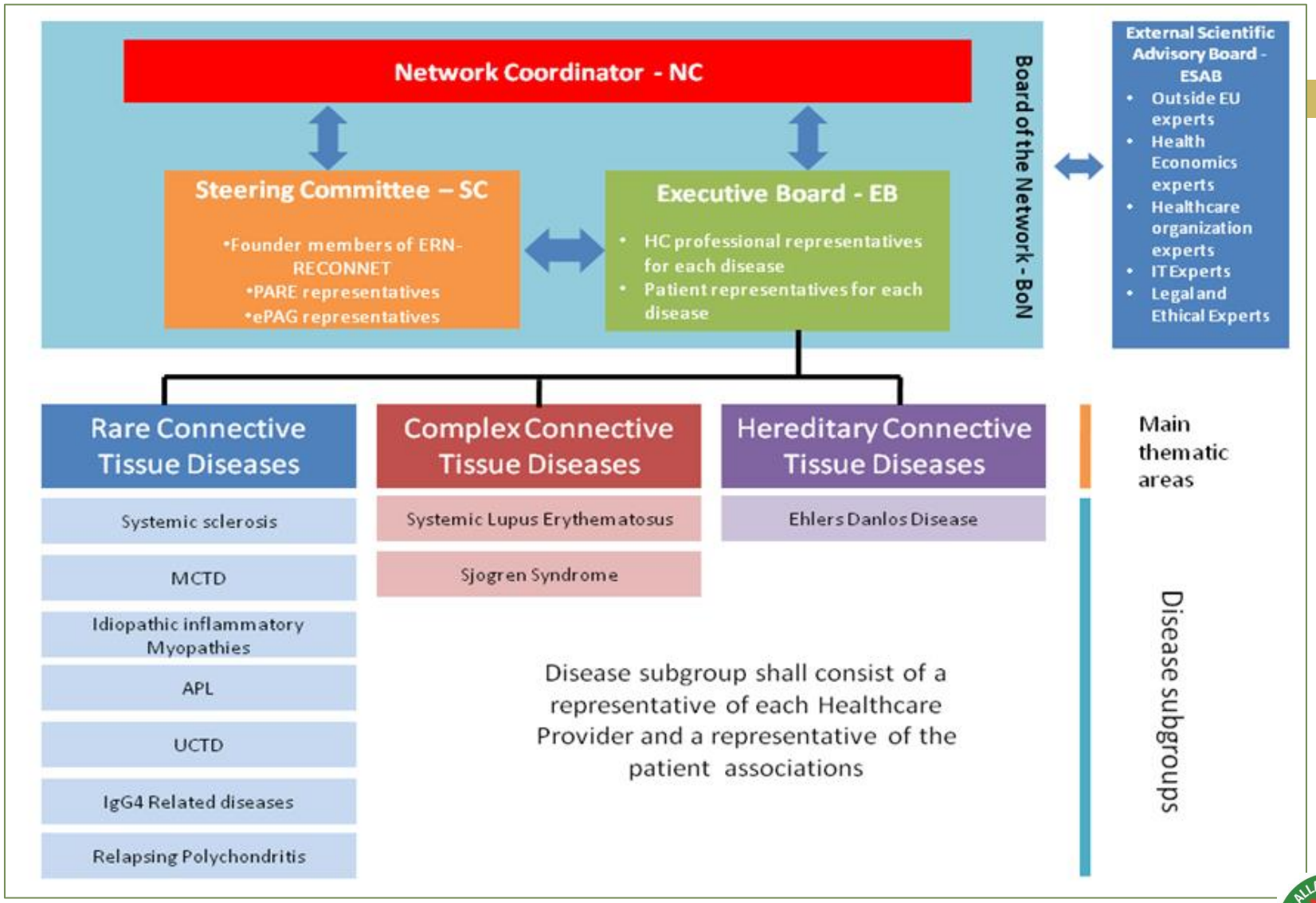


ERN ReCONNET (26 HCPs)



Ghent University Hospital – Vanessa Smith
Ghent University Hospital – Francisca Malfait
Clinique Universitaires Saint-Luc – Frederic Houssiau
University Hospital of Lille – Eric Hachulla
University Hospital of Strasbourg – Thierry Martin
Assistance Publique Hopitaux de Paris – Zahir Amoura
Cochin Hospital – Luc Mouthon
Charité - University Medicine Berlin – Gerd Burmester
University Medical Centre Dusseldorf – Matthias Schneider
Kerckoff Klinik gGmbH – Ulf Mueller Ladner
University of Cologne – Thomas Krieg
Azienda Ospedaliero Universitaria Careggi Firenze – Marco Matucci Cerinic
Azienda Ospedaliero Universitaria Pisana - Marta Mosca
Spedali civili di Brescia – Angela Tincani
Policlinico San Matteo di Pavia – Carlomaurizio Montecucco
Azienda Ospedaliera Universitaria San Martino Genova – Maurizio Cutolo
Azienda Ospedaliera di Padova - Andrea Doria
San Camillo Forlanini – Marco Castori
IRCCS Ca' Granda Ospedale Maggiore Policlinico Milano – Lorenzo Beretta
Erasmus MC Rotterdam – PM Van Hagen
University Medical Center Utrecht – Jaap van Laar
Leids Universitair medisch Centrum – Jeska de Vries-Bouwstra
Centro Hospitalar Lisboa Norte – Joao Fonseca
Hospital Curry Cabral, Centro Hospitalar de Lisboa Central - Francisca Fontes
Spitalul Clinic Judetean de Urgenta Cluj – Simona Rednic
University medical Centre Ljubljana – Tadej Avcin

ReCONNET Governance



ePAGs in ERN ReCONNET

Senior Coordinator
Juergen Grunert

Junior Coordinator
Ilaria Galetti

ReCONNET ePAGs Reps

Ana Vieira
Sjögren

Alain Cornet
SLE

Ilaria Galetti
SSc

Charissa
Frank
EDS

In pazienti in ReCONNET

- Si assicurano che le cure siano patient-centred e rispettino i diritti e le scelte dei pazienti
- Danno il loro advice sulla trasparenza della qualità di cure, degli standard di sicurezza, dei clinical outcomes e delle opzioni di trattamento
- Si assicurano che tutti gli aspetti etici siano tenuti nella massima considerazione e che vengano da tutti rispettati
- Contribuiscono allo sviluppo e alla dissemination delle informazioni, della policy, delle buone pratiche e delle linee guida

Inoltre i pazienti…

…avranno un ruolo nella review della performance dell' ERN:

- ✓ Rivedendo l'appropriatezza degli indicatori di qualità, i tempi di accesso alla diagnosi e ai trattamenti
- ✓ Fornendo la "patient perspective" sulla applicazione delle "personal data rules", il rispetto del consenso informato e confermato e la gestione delle lamentele
- ✓ Contribuendo alla ricerca (COS, PROMs)
- ✓ Identificando i centri ospedalieri che faranno parte degli ERN, sia come full member, sia come affiliated partners

Share, Care, Cure

- Per le malattie rare care and cure coincidono spesso con la ricerca
- Maggio 2018 incontro all'EMA
- 10 ePAG hanno partecipato a un incontro per capire se c'è la possibilità di portare la ricerca all'interno degli ERN

ReCONNET WPs workplan di 5 anni

WP Number	WP Title	Start month	End month
1	Coordination and Management	1	60
2	Evaluation	1	60
3	Development of standard clinical guidelines and practice	1	36
4	Adaptation and definition of the contents of the central ERN IT platform and environment	6	54
5	Economic and organizational issues	7	60
6	Communication and Dissemination	1	60
7	Networking and sustainability of the ERN	7	60
8	Education	13	60
9	Ethical and legal issues, and privacy	18	60
10	Data integration and sharing	13	60

WP3 – DEVELOPMENT OF STANDARD CLINICAL GUIDELINES AND PRACTICE

Tasks	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12
Task 3.1 - Deep revision of the existing guidelines and practice for rCTDs												
Task 3.1.1 Review of the literature and screening of websites and documents of scientific Societies												
Task 3.1.2 Survey among HCPs members to map current practice												
Task 3.1.3 Design and conducting of a survey among patients, authorities, healthcare providers, etc.												

Directive 2011/24/EU

Art 12.4 (III)

- These (specific) criteria and conditions shall ensure, inter alia, that European reference networks: offer a high level of expertise and have the capacity to produce good practice guidelines and to implement outcome measures and quality control;

- Patients must play a crucial role in it

Unmet needs

1. Patients' need

- None of the references selected in the domain "patients" could be withheld as being a real guideline. This highlights the fact that there is a **lack of recommendations built in favour of the patients with SSc**. Additionally, there is **a need for homogenous sanitary regulations for all patients in Europe**.

2. Specific organ involvements

- There are missing recommendations for several SSc specific complications. A contribution could be given for ulcers, gastro-intestinal tract involvement, renal involvement and management of calcinosis.

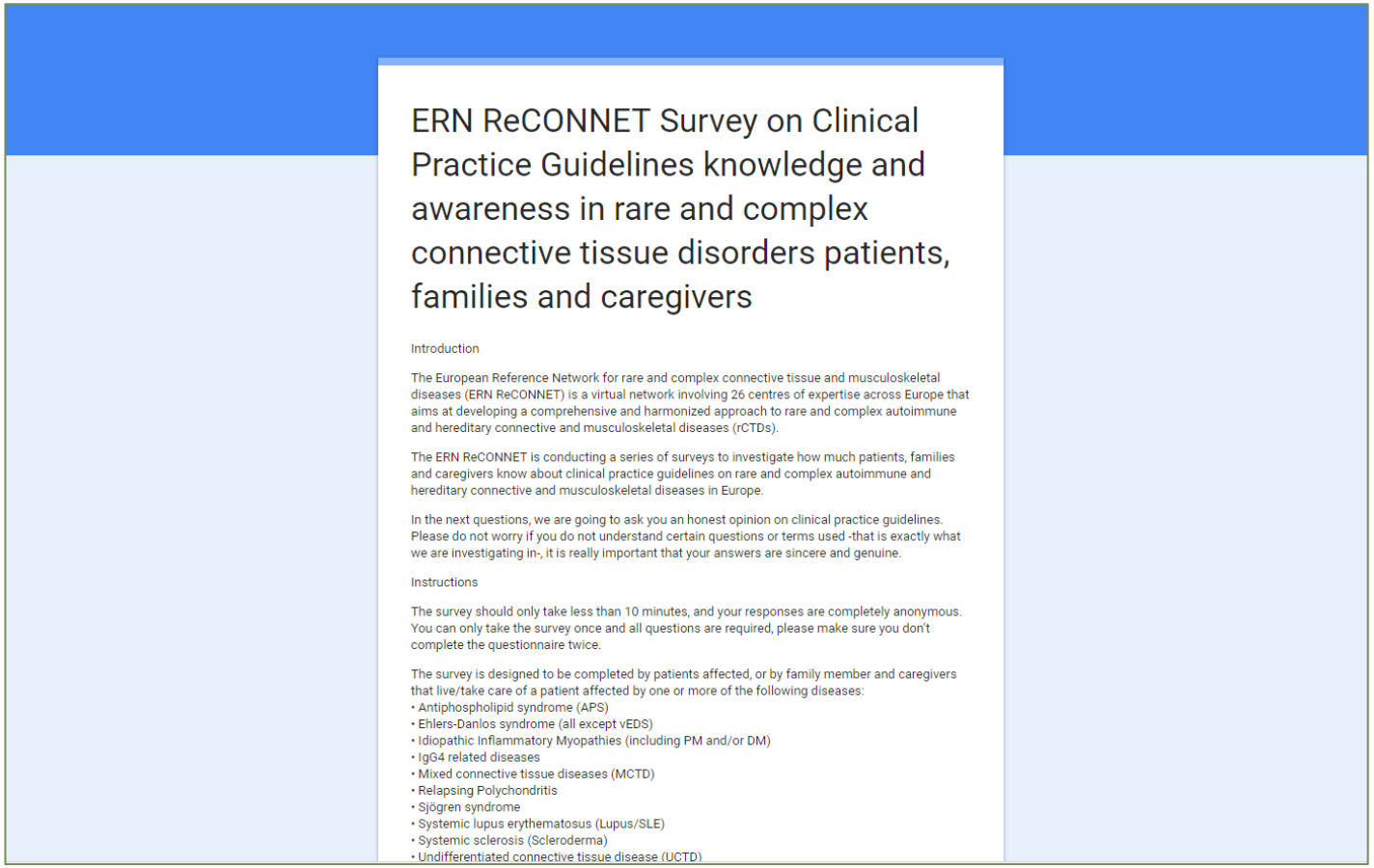
3. HSCT

- The lack of recommendations for the use of HSCT in SSc patients including detailed recommendations on the main clinical features of the SSc patient are an important unmet need to be addressed in the next future in connection with other institutional entities (EULAR, EUSTAR).

4. (Very) early diagnosis of SSc

- At present, the very early and early diagnosis still remains an unmet need. In this area, the contribution of SSc-ERN could be to raise the awareness of the physicians on the problem and foster the early referral of patients to tertiary centers. Moreover, the problem to be addressed by SSc-ERN is the use of classification criteria to diagnose SSc: this highlights the **absence of diagnostic criteria that are useful in practice**. It is also to be noted that the dispersion of capillaroscopy (teaching and interpretation) to early detect patients with Raynaud's phenomenon who will develop SSc may be steered by both ERN and EULAR **study group on microcirculation in Rheumatic diseases**.

SURVEY on CPGs



ERN ReCONNET Survey on Clinical Practice Guidelines knowledge and awareness in rare and complex connective tissue disorders patients, families and caregivers

Introduction

The European Reference Network for rare and complex connective tissue and musculoskeletal diseases (ERN ReCONNET) is a virtual network involving 26 centres of expertise across Europe that aims at developing a comprehensive and harmonized approach to rare and complex autoimmune and hereditary connective and musculoskeletal diseases (rCTDs).

The ERN ReCONNET is conducting a series of surveys to investigate how much patients, families and caregivers know about clinical practice guidelines on rare and complex autoimmune and hereditary connective and musculoskeletal diseases in Europe.

In the next questions, we are going to ask you an honest opinion on clinical practice guidelines. Please do not worry if you do not understand certain questions or terms used -that is exactly what we are investigating in-, it is really important that your answers are sincere and genuine.

Instructions

The survey should only take less than 10 minutes, and your responses are completely anonymous. You can only take the survey once and all questions are required, please make sure you don't complete the questionnaire twice.

The survey is designed to be completed by patients affected, or by family member and caregivers that live/take care of a patient affected by one or more of the following diseases:
- Antiphospholipid syndrome (APS)
- Ehlers-Danlos syndrome (all except vEDS)
- Idiopathic Inflammatory Myopathies (including PM and/or DM)
- IgG4 related diseases
- Mixed connective tissue diseases (MCTD)
- Relapsing Polychondritis
- Sjögren syndrome
- Systemic lupus erythematosus (Lupus/SLE)
- Systemic sclerosis (Scleroderma)
- Undifferentiated connective tissue disease (UCTD)

2018 Working Groups

- Team Coordination and management
- AGREE ADAPTE (SSc – SLE – IIM – Sjogren)
- Implementation of existing guidelines
- Endorsement of existing guidelines (How to present CPG covering aspects pertinent to different diseases (eg steroids, vaccination…) consultation toolkit
- Patients Laymen Guidelines
- Disseminations and communication

2018 Working Groups

- Economic and Organizational issues
- IT Platform
- Education
- Ethical, legal issues and privacy (crossing other ERNs)
- Data integration and sharing (Registries)
- CPMS activities and team – NO PATIENTS
- Quality assessment activities and team
- Patients brochures, activities and team

Attorno agli ammalati bisogna essere allegri.

(Teresa di Lisieux)

Grazie

Ilaria Galetti

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