



"EURLSREG"

EUROPEAN CENTRAL RESTLESS LEGS PATIENT
REGISTRY - PILOT

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EXECUTIVE SUMMARY

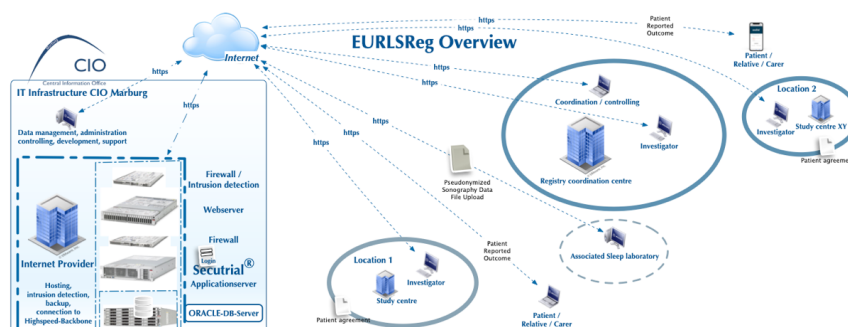
OBJECTIVE

This document describes in short the basic initial concept for a European Central Restless Legs Patient Registry.

GOALS

After preliminary thoughts in 2020 and earlier, concrete plans for a “European Central Restless Legs (RLS) Patient Registry” started at the beginning of 2021 by Joke Jarsma (EARLS, EFNA), Yves Dauvilliers (EURLSSG, University of Montpellier), F, Sören Berg (RLS-Förbundet, SWE) and Wolfgang Oertel (EFNA, University of Marburg, D). It was agreed on three initial goals

1. Provide data for physicians to better understand RLS (e.g. evaluation and monitoring of patient safety, evaluation of effectiveness in the care routine, economic evaluation)
2. Involve patients by having them entering data themselves (e.g. current state, medication log, adverse events, visit date calendar)
3. Support of clinical/medical research by providing a common, secure, standardised (minimal data set) and reliable central platform for study data



SOLUTION (CONCEPT)

Main backbone shall be a standards-compliant minimal data set for all patient's data entered.

It will be implemented within an IT-platform for secure web-based data entry and -access - usable by all registered participants AND moreover by login-enabled patients.

According to nowadays standards the data entry system can be used with any modern web browser on a computer, tablet or smartphone. The system provides additional secure interfaces and import-/export-features. Anonymized datasets can be exchanged with other medical research data platforms. It is compliant to major regulatories like 21 CFR Part 111, GxP, DSGVO.

This backbone will be provided by CIO Marburg GmbH on their own servers in a high-security data center in Germany running an ORACLE database server and the Java-based web-application-package secuTrial®. More on CIO Marburg GmbH in an own chapter.





RESULTING INITIAL IMPLEMENTATION TASKS - ...ALREADY STARTED

Customizing of the secuTrial®-system to setup and run the EURLSReg for enabling internet-based multi-centric and multi-lingual data entry into a central study database. Initially two study centres are planned for a "pilot"-registry (incl. Institute for Neurosciences, Montpellier, FRANCE, lead by Prof. Yves Dauvilliers). Three languages (F, UK and D) will be supported initially.

The set of implemented data entry forms include demographics, lifestyle habits, RLS-specific and concomitant medication, side effects, vital signs, comorbidity, sleep behavior as well as disease-/sleep-specific questionnaires (RLS Severity scale, IRLS-6 Severity scale, ISI) and global ones (BDI, EQ-5D) for patient reported outcomes entered into the registry by the individual patients themselves.

More European centres and additional features will be added after the pilot phase.

PROJECTED INITIAL COSTS (2022FF)

Approx. 75.000 € for initial setup and customizing of the pilot incl. hosting and licenses for the first year.

Year 2ff: 10.000 €/yr for hosting, licenses and basic user support PLUS additional costs for coordination, data management, further development and initiating of structures for internal study cooperation and communication.





CIO MARBURG GMBH

is part of the non-profit Competence Network Parkinson's Disease and develops and provides IT solutions to support medical research with secuTrial®. CIO Marburg provides these research systems hosted on its own servers in a high-security data centre in Germany.

CIO Marburg has been in existence for more than 20 years and during this time has implemented more than 60 medical databases for multi- and monocentric, national and international medical study projects and patient registries; 17 of these for the Parkinson's Competence Network, the German Parkinson Study Group and their associations.

One of the largest projects that the CIO Marburg is currently responsible for, is the IT-platform of the Competence Network Multiple Sclerosis (www.kompetenznetz-multiplesklerose.de) with consent registry, 3 patient cohorts, 7 clinical studies, documentation of decentralised biomaterial collections and image management for more than 4600 patients. The KKNMS also uses the IT platform to re-import research results for further use of these data in the network (e.g. genotypes, MRI volumes).

Another current major project is the European Management Platform for Childhood Interstitial Lung Diseases "ChILD EU" (www.childeu.net) used by almost 400 participants from over 20 European countries.

In addition to medical registries and cohorts, clinical studies and application observations, image and biomaterial management, the range of services offered by CIO Marburg GmbH also includes evaluation and creation of data protection concepts.





PROJECT CONTACTS

CONCEPT, TECHNICAL IMPLEMENTATION, ADMINISTRATION, HOSTING

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