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# The ERN-RND Rare Neurological Disease Registry

JA2015 - GPSD [705038]

START DATE: 01/04/2020

END DATE: 31/03/2023

DURATION: 36 month(s)

CURRENT STATUS: Ongoing

PROGRAMME TITLE: 3rd Health Programme (2014-2020)

PROGRAMME PRIORITY: -

CALL: Call for Proposals for Projects 2019

TOPIC: Rare disease registries for the European Reference Networks (Heading 2.1 of the AWP 2019)

EC CONTRIBUTION: 400000 EUR

KEYWORDS: European Reference Network, Patient Registry, Rare Neurological Diseases

## Project abstract

The ERN-RND Registry project aims to establish a demographic platform for collection of relevant core patient information. This will be accomplished by the construction and implementation of a single data base encompassing all rare neurological diseases in pediatric and adult patients (the ERN-RND Registry), which will collect information according to the "Set of common data elements for Rare Diseases Registration". The members of ERN-RND provide healthcare to more than 35,000 patients with rare neurological diseases. The proposed ERN-RND Registry will target patients, who suffer from the following rare neurological diseases and conditions: Ataxia and HSP, Leukodystrophies, Frontotemporal Dementia, Dystonia, Paroxysmal Disorders & NBIA, Atypical Parkinsonism and Huntington's Disease & Chorea. The ERN-RND registry project will pursue three main objectives: 1. The ERN-RND core Registry will be developed using the RedCap database platform that is being operated at University Hospital Tübingen, Hertie Institute for Clinical Brain Research. 2. The second main objective of the project will be to link the central ERN-RND registry with existing hospital databases and disease- or treatment-specific registries. 3. The third objective is the implementation of a continuous monitoring system to follow center performance in terms of care quality and patient outcomes.

# Work package

## Work Package 1: Coordination of the project

Start month: 1

End month: 36

Work Package Leader: UKT

T1. Coordinate and monitor the overall project progress. The task comprises the development and implementation of management procedures for the coordination of the project. The work comprises the establishment of the project management manual giving the main decision-making rules and the main procedures for a good operation of the project. UK-TÜ will carry out the daily management of the project. Furthermore, the task comprises the management, technical and financial reporting of the project's advancement.

T2. Communicate to ERN-RND partners. An external-facing website and internal intranet will be developed and linked with the ERN-RND web-site to ensure visibility and impact of the project. Furthermore, the communication infrastructure of ERN-RND will be used.

T3. Management of the funding. UK-TÜ will be managing the funding of the project. One main subtask will be to prepare the subcontracts with the ERN-RND centres.

## Work Package 2: Dissemination

Start month: 1

End month: 36

Work Package Leader: UKT

T1 Develop dissemination plan. A dissemination plan that takes into account dissemination target groups, objectives, channels and time lines will be developed.

T2 Implement the dissemination plan towards ERN-RND. We will carry out the target group and channel specific dissemination activities as planned in the dissemination plan.

T3 Implement the dissemination plan towards external stakeholders. We will carry out the target group and channel specific dissemination activities as planned in the dissemination plan.

## Work Package 3: Evaluation

Start month: 1

End month: 36

Work Package Leader: UKT

T1 Evaluation of the deliverables and milestones, indicators as well as output and impact.

Evaluation will be done by every six month through monitoring deliverables and milestones and indicators. This will be done by using an update report by the project manager in the first instance and then a joint assessment exercise with the project coordinator.

## Work Package 4: ERN-RND Core Registry

Start month: 1

End month: 36

Work Package Leader: UKT

T1 Registry Development: The ERN-RND Registry will be developed using the RedCap database platform that is being operated at University Hospital Tübingen, Hertie Institute for Clinical Brain Research.

T2 Pilot Testing: After programming, the registry will undergo a 3-month phase of intense iterative pilot testing. At least 6 clinicians at 3 ERN-RND HCPs will be asked to serve as test users by submitting data and improvements will be implemented according to the experience collected thereby.

T3 Implementing Quality Assurance Measures: Data plausibility checks will be implemented.

T4 Assuring data Privacy and Protection: All patient data will be stored in a pseudonymised fashion. Patient data will not be collected on individual basis but through a secure bulk upload procedure on an annual basis. Each HCP sends the collected data as an encrypted CSV-file to the UK TÜ cloud. Access to the data base will be provided to all HCPs contributing to the registry. To this end an encrypted file with the full data set of the ERN-RND registry will be deposited at the UK-TÜ cloud. Access to this encrypted file will be restricted to HCPs that successfully uploaded their data for the respective year and solved all queries of the plausibility check.

T5 Documentation: A Registry Manual will be produced.

## Work Package 5: Integration with existing disease-specific registries/data bases

Start month: 4

End month: 36

Work Package Leader: UKT

T1 Linking the central ERN-RND registry with existing hospital databases and disease- or treatment-specific registries: We have already been collecting information from the ERN-RND centres' hospital information systems on the availability and extractability of the required data. Based on this information we will role out the registry in the ERN-RND centres through a staged process. Variable mapping will be performed and a data transmission manual will be created for each centre. The data transmission manual will be the basis for data completeness and consistency checks of the data exports

T2 Meeting regulatory requirements: The regulatory requirements for data transmission to the ERN-RND Registry will be assessed by review of the centres informed consent documents and ethics committee approvals. Wherever necessary, amendments to informed consent documents will be obtained.

T3 Data collection: based on the data submission readiness of the ERN-RND centres we will collect data from the ERN-RND centres

## Work Package 6: Network-wide performance and outcome monitoring

Start month: 13

End month: 36

Work Package Leader: UKT

T1: Identification of key performance and outcome indicators. The ERN-RND disease groups will revisit the issue of key Quality and Outcome Indicators

T2 Inclusion of identified Key Indicators in the registry database: a statistics and benchmarking module will be programmed. For example the rate of undiagnosed patients per disease group will be used as an indicator. Statistics will be provided not only for an individual center but also for all patients within each disease group category.

T3 Analysis of key performance and outcome indicators: analysis will be done annually.

## COORDINATOR



Universitaetsklinikum Tuebingen (UKT)

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72076 Tuebingen

Germany

WEBSITE: <http://www.med.uni-tuebingen.de>

## PARTNERS

No partners related to the current project

## Layman version of the final report

UKT

The ERN-RND Rare Neurological Disease Registry (ERN-RND Registry)

Expected on: 31/03/2023

Layman version of the final report

## Evaluation report 2

UKT

The ERN-RND Rare Neurological Disease Registry (ERN-RND Registry)

Expected on: 31/03/2022

Evaluation report 2 produced Justification for confidential status: Contains sensitive information on submitted patient data.

## Evaluation report 3

UKT

The ERN-RND Rare Neurological Disease Registry (ERN-RND Registry)

Expected on: 31/03/2023

Evaluation report 3 produced Justification for confidential status: Contains sensitive information on submitted patient data.

## Mapping report for all ERN-RND centres

UKT

The ERN-RND Rare Neurological Disease Registry (ERN-RND Registry)

Expected on: 30/06/2022

Mapping report for all ERN-RND centres finalised Justification for confidential status: Contains sensitive information on submitted patient data.

## Analysis report for key performance and outcome indicators

UKT

The ERN-RND Rare Neurological Disease Registry (ERN-RND Registry)

Expected on: 31/03/2023

Analysis report for key performance and outcome indicators produced



## Registry Manual

UKT

The ERN-RND Rare Neurological Disease Registry (ERN-RND Registry)

Published on: 06/02/2022

Registry Manual produced

## Evaluation report 1

UKT

The ERN-RND Rare Neurological Disease Registry (ERN-RND Registry)

Published on: 03/02/2022

Evaluation report 1 produced Justification for confidential status: Contains sensitive information on submitted patient data.

## ERN-RND Registry developed

UKT

The ERN-RND Rare Neurological Disease Registry (ERN-RND Registry)

Published on: 03/02/2022

ERN-RND Registry developed using the RedCap database platform

## Privacy and Protection measures consented

UKT

The ERN-RND Rare Neurological Disease Registry (ERN-RND Registry)

Published on: 03/02/2022

Privacy and Protection measures consented

## Key performance and outcome indicators

UKT

The ERN-RND Rare Neurological Disease Registry (ERN-RND Registry)

Published on: 03/02/2022

Key performance and outcome indicators determined

## Project manual

UKT

The ERN-RND Rare Neurological Disease Registry (ERN-RND Registry)

Published on: 09/02/2021

Project manual available

## Project risk management plan

UKT

The ERN-RND Rare Neurological Disease Registry (ERN-RND Registry)

Published on: 09/02/2021

Project risk management plan approved

## Dissemination plan

UKT

The ERN-RND Rare Neurological Disease Registry (ERN-RND Registry)

Published on: 09/02/2021

Dissemination plan generated

## Data plausibility checks implemented

UKT

The ERN-RND Rare Neurological Disease Registry (ERN-RND Registry)

Published on: 09/02/2021

Data plausibility checks implemented for collection of data

## Leaflet

UKT

The ERN-RND Rare Neurological Disease Registry (ERN-RND Registry)

Published on: 09/02/2021

Leaflet

## Website

UKT

The ERN-RND Rare Neurological Disease Registry (ERN-RND Registry)

Published on: 09/02/2021

Website