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RD REGISTRY DATA WAREHOUSE

JA2015 - GPSD [705038]

START DATE: 01/04/2018

END DATE: 30/11/2021

DURATION: 36 month(s)

CURRENT STATUS: Finalised

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

PROGRAMME PRIORITY: -

CALL: Rare diseases - support for New Registries

TOPIC: Rare Disease Registries

EC CONTRIBUTION: 401904.83 EUR

KEYWORDS: Disease Specific Registry, Ern, Ern Registry, Interoperability, Meta Data Repository, Population Registry, Rare Disease, Registry, Registry Of Registries

Project abstract

Patient registries and databases are key instruments to support clinical research in the field of rare diseases, to improve patient care and aide healthcare planning. The effort needed to gather registry data is enormous and yet worthwhile since they are the basis for the observation of the natural course of a disease, for planning and for doing feasibility checks of clinical trials. A widely unknown number of RD registries existed, still exist or are in the process of being set up. So far, data exchange is a problem, not foreseen in most registries and cross-border interoperability is not provided. The small number of patients affected by rare diseases make registries even more important than in the normal population or in common diseases as they enable cross-border gathering of data to achieve sufficient sample size for any purpose in clinical research and or public health issues.

Patient and care team members of ERN-LUNG have deduced that the excellent pre-existing registries within ERN-LUNG could give a strong basis for a NEW Registry Warehouse enabling full data exchange and cross-border interoperability. This Rare Disease (RD) REGISTRY DATA WAREHOUSE will be a combination of existing registries, new registries or new registry elements that are brought together with full interoperability. To develop this RD REGISTRY DATA WAREHOUSE we build upon our experience with registries established and coordinated by the applicants (starting with CF, PCD and non-CF BE), existing software solutions (Open Source registry framework OSSE) developed and/or used for RD registries by the applicants and leadership in defining minimum data sets and compliance to data quality standards such as EUCERD Recommendations on RD registries, a project led by the coordinator. This RD REGISTRY DATA WAREHOUSE will not only improve data management and research in rare lung diseases, but will serve as a blueprint to connect patient registries and databases linked to other rare diseases.

Work package

Work Package 1: Coordination of the project

Start month: 1

End month: 36

Work Package Leader: UNIKLINIK FFM

Project management

Leader: KGU. Participants: All partners.

The management consists of the integrative management, which is the consolidated management of different processes (costs, resources, communication, content and delay, risks, purchase, legal aspects, degree of excellence, access to RD REGISTRY DATA WAREHOUSE services).

This includes managing the interfaces and interactions between processes, activities, WP and partners, and managing and implementing any modifications that might occur. This task thus comprises scheduling of meetings of all participating groups, communication with attendees, provision of agendas, minutes and collection of feedback and the management of the overall project progress via technical and financial reporting, and progress meetings. 6-month progress reports will be transferred from each WP leader [using the technical and financial information provided by each partner] to the Coordinator. The coordinator will then consolidate an overall report covering all WPs.

Two milestone reports will be produced in addition to the periodic reports mentioned above: the mid-term assessment report and the final report, prepared by the coordinator. The coordinator will manage the preparation and dissemination of the project reports using information provided by partners with the support of the Project Coordination Team. The Coordinator will also ensure communication with the EC, by transferring the reports and informing the EC of any major issues/modifications of the work plan.

The RD REGISTRY DATA WAREHOUSE Project Coordination Team will monitor the schedule, the budget, the resource allocation and the risk management of the project. This mainly deals with defining with the project requirements, communicating information of specific tasks for time, budget, resources, effort by time and participant, expected end date, expected deliverables and risk adjustments.

T1: Project management (KGU)

Work Package 2: Dissemination of the project

Start month: 1

End month: 36

Work Package Leader: UNIKLINIK FFM

T1: Stakeholder analysis within ERN-LUNG M12

Confirm main target groups (patients, HCPs, public authorities)

Build understanding of target groups' knowledge of diseases covered and of existence of registries in specific rare respiratory diseases (identify online communities, conduct interviews through ERN-LUNG Patient Board) e.g. through a survey

T2: Dissemination plan M6

Build awareness of rare respiratory diseases and of the objectives of this project
Two main objectives of the dissemination plan: ensure target groups know about the registries and how to use them; share information about findings stemming from the registries to amplify its recognition and continuously increase its use and impact on research and clinical practice
Align with ERN-LUNG dissemination plan

T3: Ensuring successful use of new registries M 12 and ongoing

Develop collaterals (e.g. a video) explaining how the registries work and interact with each other
Develop information on applicable data regulation rules
Create and share guidelines through ERN-LUNG (Core Networks and Patient Board) on how to use the registries (data entry, data access, publication, etc.)
Participate at congresses/ fora/ patient events where registries can be presented to involve HCPs and patients beyond ERN-LUNG

T4: Securing long-term interest in the registries M12 and ongoing

Publication in scientific journals
Patient survey and questionnaire on evolution of knowledge pre- and post-registry launch
Create partnerships with public authorities and pharma companies to facilitate registry development and merge registry info with ERN-LUNG info (e.g. on one website/ online platform) to create a one-stop-shop for patients and HCPs

T5: Development of accompanying documents M6 and ongoing (clinical partners, KGU)

data protection concept, patient consent form, etc.

Work Package 3: Evaluation of the project

Start month: 1

End month: 36

Work Package Leader: UNIKLINIK FFM

T1: Evaluation strategy

Liaise with ERN-LUNG

Evaluation methodology

T2: Internal evaluation

Monitoring criteria to ensure partners deliver against objectives (quality control)

Reporting mechanism to flag potential implementation issues

Annual implementation report

Final report

T3: External evaluation

Structured surveys at various steps with external audiences (HCPs and patients) to ensure project meets their needs

End-of project evaluation to identify impact of project outcomes and identify options for continuity of registries

Publication of results

Work Package 4: ERN-LUNG specific registry (ERN-LUNG REGISTRY)

Start month: 1

End month: 36

Work Package Leader: UNIKLINIK FFM

In WP4 a new registry for the ERN-LUNG will be planned and realized. For realization, a stepwise process has been chosen. For that the work is split in according tasks:

T1: Definition of data elements (clinical partners)

T2: Analysis of the technical requirements (KGU)

T3: Installation and preliminary configuration of the OSSE-registry (KGU)

T4: End-user test (clin. experts) of the ERN-LUNG REGISTRY (clinical partners)

T5: Final configuration of the ERN-LUNG REGISTRY (KGU) T6: Maintenance and technical adaptations (KGU)

Work Package 5: Rare Lung Diseases Population Registry (ERN-LUNG POPULATION REGISTRY)

Start month: 1

End month: 36

Work Package Leader: UNIKLINIK FFM

In WP5 the new population registry for the ERN-LUNG (ERN-LUNG POPULATION REGISTRY)will be planned and realized. As an entry point for the patients, the ERN Patient Portal will be designed and implemented. For realization, a stepwise process has been chosen. For that the work is split into tasks:

T1: Definition of data elements for the POPULATION REGISTRY (clinical partners)

T2: Analysis of the requirements: pop. registry & patient portal (KGU)

T3: Installation and preliminary configuration of the OSSE-registry (KGU)

T4: Concept and development of the patient portal (KGU)

T5: End-user test (patients) of the POPULATION REGISTRY (KGU, clin. partners)

T6: Final configuration of the POPULATION REGISTRY (KGU)

T7: Maintenance and technical adaptations (KGU)

Work Package 6: Interoperability across disease specific registries

Start month: 1

End month: 36

Work Package Leader: UNIKLINIK FFM

In WP6, primarily the content-related interoperability of the participating registries will be addressed by defining a comprehensive 'common data set' (CDS) for ERN-LUNG. This will be integrated into the existing registries for further entries. The registries CF, NCFBE, and PCD will be connected with the help of the OSSE-bridgehead approach. If the existing registries are not able to be connected, they will (only within the context of the RD REGISTRY DATA WAREHOUSE) be replaced by OSSE-Registries and the data transferred (ETL). A data mapping to the Metadata Repository is necessary.

T1: Definition of a CDS for ERN-LUNG (clinical partners)

T2: Integration of CDS in registries (CF, NCFBE, PCD) (clinical partners)

T3: Technical analysis of the existing registries (KGU)

T4: Connecting the existing registries via OSSE-Bridgeheads (KGU)

Work Package 7: Extending the Metadata Repository to support Registry Data Schemes (Registry & Metadata Repository (RMDR))

Start month: 1

End month: 36

Work Package Leader: UNIKLINIK FFM

In WP7 the ERN central Registry & Metadata Repository (RMDR)) will be planned and set up. By that, the basis for a high degree of interoperability for collaboration is given. In a first version, the OSSE-MDR is used for general use. The functionality of storing and providing the additional data scheme information of the registries will be added in a second version.

T1: Set up and initialization of a ERN-Metadata-Repository (Version 1) (KGU)

T2: Analysis of the requirements of the additional functionality (RMDR) (KGU)

T3: Planning and realization of the RMDR (Version 2) (KGU)

T4: Adaption of the OSSE-Framework for connecting the RMDR (KGU)

T5: Maintenance and technical adaptations (KGU)

Work Package 8: Interaction of the RD REGISTRY DATA WAREHOUSE with the European platform and the ERN IT-platform

Start month: 1

End month: 36

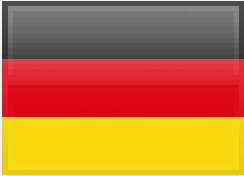
Work Package Leader: UNIKLINIK FFM

In WP8 a central ERN-wide pseudonymization service with record linkage functionality is set up. The Mainzliste OpenSource software is used as a basis. In this WP, also the interfaces to the central ERN-IT platform and with ERDR will be realized.

T1: Set up and initialization of a ERN-wide pseudonymisation service (KGU)

T2: Supporting interfaces to ERN-IT platform and ERDR (KGU)

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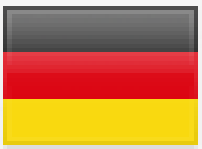
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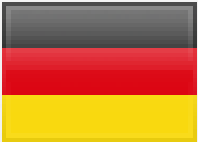
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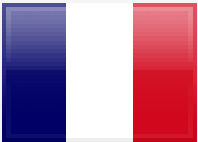
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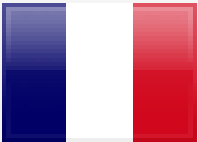
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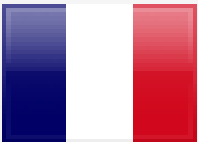
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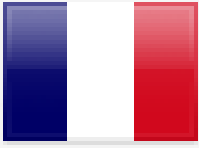
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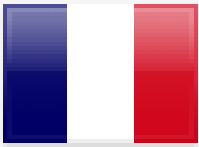
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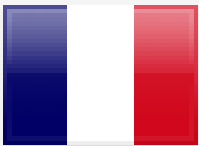
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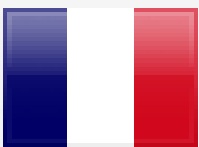
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Layman version of the final report

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

This is a short (e.g. 10 pages) version of the final report, written for the interested public as a target group.

Layman version of the final report

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

Published on: 11/05/2022

This is a short (e.g. 10 pages) version of the final report, written for the interested public as a target group.

Second interim report

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

This report describes the activities carried out, milestones and results achieved in the first half of the project. Deliverables can be attached as annexes.

Final report

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

This report describes the project implementation and the results achieved. The deliverables are annexed.

Leaflet

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

A leaflet to promote the project must be produced at the beginning

Website

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

Each project must have a dedicated web-site / web-pages. This can have a public part and another one accessible only to the applicants.

Scientific publication

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

Publication in scientific journal.

Evaluation plan

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

List of indicators and time line

Publication of users' feedback

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

Publication in scientific meeting and/or journal.

List and description of the registry elements (ERN-LUNG REGISTRY)

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

This list includes the registry's data elements the applicants agreed upon, along with descriptions and data type definitions.

User guide for the ERN-LUNG registry

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

This guide contains brief instructions for users unexperienced in working with the ERN-LUNG registry.

List and description of the registry elements (POPULATION REGISTRY)

UNIKLINIK FFM

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UNIKLINIK FFM

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This document describes the adapted API of the MDR to include the new functionality of the RMDR.

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UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

This document describes the necessary steps to connect additional disease specific registries to the ID-Management component.

Scientific publication

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

Published on: 28/04/2020

Publication in scientific journal.

Publication of users' feedback

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

Published on: 28/04/2020

Publication in scientific meeting and/or journal.

ERN-LUNG Registry

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

Published on: 28/04/2020

ERN-LUNG registry is ready and can be used

Evaluation plan

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

Published on: 10/07/2019

List of indicators and time line

List and description of the registry elements (ERN-LUNG REGISTRY)

UNIKLINIK FFM

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Published on: 10/07/2019

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RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

Published on: 10/07/2019

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Definition of extended API including additional RMDR features

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

Published on: 15/05/2019

This document describes the adapted API of the MDR to include the new functionality of the RMDR.

Dissemination plan

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

Published on: 10/04/2019

List of measures for outreach, training and research publications

Website

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

Published on: 10/04/2019

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List and description of the registry elements

(POPULATION REGISTRY)

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

Published on: 10/04/2019

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Definition and description of the CDS for ERN-LUNG

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

Published on: 10/04/2019

This list includes the data elements to be used as the CDS for ERN-LUNG, along with descriptions and data type definitions.

Leaflet

UNIKLINIK FFM

RD REGISTRY DATA WAREHOUSE (REGISTRY WAREHOUSE)

Published on: 19/07/2018

A leaflet to promote the project must be produced at the beginning