Work Package 4
Clinical Trial Support

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WP4 Clinical Trial Support

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European Reference Networks

Work of the WP4 – Clinical Trial Support

Activities in this work package will be geared towards:

- Create a strong ERN overarching clinical trials network and thereby promote the EU as an attractive location to run RD clinical trials;
- Avoid unnecessary duplication of studies/resources already available at the EU level;
- Ensure that the patient voice is systematically included in clinical trial design.

Work of the WP4 – Clinical Trial Support

Objectives:

- To foster clinical trial research implementation;
- To increase awareness of activities/opportunities available from stakeholders (EJP-RD, BBMRI, EMA, C4C, IRDiRC);
- To build a solid foundation for a Patient Engagement framework on clinical trials.

Work of the WP4 – Clinical Trial Support

Objectives:

Facilitate collection, sharing and analysis of clinical research data within and between ERNs

- In collaboration with WP2, interdisciplinary expert working groups will be formed to work out harmonized data protection and access policies and foster joint data analyses across the ERN
- provide methodological and operational guidance for ERN-wide biobanking projects.

WP4 -Clinical Trial Support- Task 4.1

Objectives:

Encourage methodology sharing and increase the innovation potential of ERNs

- Better clinical trial set-up through the implementation of state-of-the-art methodology for which ERNs can be used to show proof of concept (in collaboration with EJP RD WP20).
- Increased knowledge on how to perform Europe-wide clinical trials to expedite clinical testing and realise faster market access of newly developed therapies.

WP4 -Clinical Trial Support- Task 4.2

Objectives:

To map, integrate and link ongoing activities with regards to facilitating Europe-wide multicentre clinical trials

- Theme-specific coordination and support actions, which will cover the integration and sharing of clinical trial support, such as Connection and stimulation of the Trial Hub of EJP RD (WP20) for ERNs (TH-ERN), an annual RD trial workshop, interaction with EMA and national competent authorities, connection with biobanks, and interaction with IRDIRC

WP4 -Clinical Trial Support- Task 4.3

Objectives:

Framework for patients engagement

- Ensure that the patients' voice is systematically included in every step of the clinical trial development.
- structuring the engagement of patients in clinical trial design, including the patients' views across all previosly mentioned relevant activities
- inspiring a broader patient engagement framework for the whole CSA in collaboration with WP3

WP4 -Clinical Trial Support- Deliverables

- D4.1 Procedure to provide ERN experts to EMA for expert opinion on RD (M6)
- D4.2 Report on prepared factsheets and Youtube movie (M18)
- D4.3 Report on frequency of use of the website (M24)
- D4.4 Report on unmet clinical needs in ERN-overarching diseases (M24)
- D4.5 Report on the outcome of clinical trial workshops (M39)
- D4.6 Report on achievements of ERN-EMA dialogue (M42)
- D4.7 Report on establishing foundations for Patient Engagement Framework (M48)