SAFE CT
Safety assessment cooperation and facilitated conduct of clinical trials

Co-funded by the European Union

Safety Assessment Cooperation and Facilitated Conduct of Clinical Trials (SAFE CT)

Background

Safety assessment in clinical trials plays a crucial role in respecting patient rights and wellbeing and also obtaining high quality data on safety of medicines. The new clinical trial regulation (CTR) No. 536/2014 was created to maximize efficiency and quality in the process of assessing clinical trial applications but also assessing safety after a trial is approved. The CTR introduced the concept of safety cooperation and worksharing among Member States (MS) to maximize efficiency and quality in the process of assessing safety data after a trial is approved. In line with article 44 of the CTR, the commission together with MSs developed Implementing regulation (IR) that describes in detail the safety assessment cooperation and worksharing The CTR and IR came into force on 31 Jan 2022.

Introduction to JA-12 Safety assessment cooperation and facilitated conduct of clinical trials (SAFE CT)

Financial support to provide additional resources and expertise necessary to implement these new concepts will be provided under Joint Action 12 of the *EU4Health, a programme implemented by HaDEA (EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY*.. The main objective of this Joint Action is to build competence and expertise needed for the clinical trials safety assessment cooperation. Other key objectives included the development of a training process for safety assessors, support mentorship programme and the development of a framework for sustainable procedures in safety assessment in clinical trials for the future. With Croatia as project coordinator there are 22 member states participating in the JA. The project is currently in grant agreement preparation phase and will run for 36 months (with a retrospective start date starting 01/05/2022 – 01/04/2025). The project will receive 80% funding from the Commission with the remaining 20% of costs contributed by all beneficiaries.

The project consists of 5 work packages

- WP1 Coordination (led by Croatia) includes the management and administration of the Joint Action. WP1 will establish guidelines, templates and routines for financial and administrative management and will coordinate communication with all partners and EC.

- WP2 Dissemination (led by Ireland) includes creation of a dissemination plan to ensure that stakeholders (Member states, National Competent Authorities, Ethics Committees) are

informed about opportunities (capacity support and training) with the aim to encourage active participation.

- WP3 Evaluation (led by France) will follow the progress of all WP's and identify the relevant key indicators to follow during the JA. In-depth intermediate and end of project reports will ensure the monitoring and quality of the JA deployment during the 3 years.

- WP4 Sustainability (led by Germany) will set up a training curriculum on pharmacovigilance in clinical trials and establish a network of regulatory experts in pharmacovigilance in clinical trials. This WP will improve procedures on cooperation in safety assessment in clinical trials in EU/EEA

- WP5 Capacity building (co-led by Sweden and Belgium). This WP will support recruitment of an additional assessor in the participating MSs, facilitate training through establishment of a mentorship programme and facilitate exchange of experience and knowledge.

Further updates on the progress of the project will be provided on this website.