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EU-Innovation Network Workplan 2023

Contents

1. Introduction

This 2023 EU-Innovation Network Workplan is intended to assist in the delivery of strategic goals related to the mandate of the EU-Innovation Network (EU-IN) that are described in the European Medicines Agencies Network Strategy to 2025 and EMA's Regulatory Science Strategy to 2025. The workplan also considers relevant actions described in the multi-annual work plans associated with these strategies.

The workplan carries forward relevant activities from previous years but also proposes a renewed focus on specific topics aimed at supporting innovation as reflected in section 2 of the work programme. It also takes into account other relevant initiatives such as Accelerating Clinical Trials in the EU (ACT EU) and the joint action on capacity building within the EU medicines regulatory network with a view to supporting these initiatives and avoiding duplication.

2. Support for Innovation

2.1. Promote involvement of CAs in science and regulatory projects

- **Objectives**

  a) Harmonisation of efforts to advance regulatory science.

  b) Promoting R&D, manufacturing and clinical trials.

  c) Promoting CAs involvement in projects of regulatory relevance.

- **Deliverables**

  1. Complete the mapping of current involvement of CAs in externally funded projects.

     Timeline: Q1 2023

  2. Share best practices and experiences in relation to involvement in such projects.

     Timeline: Q2-Q3 2023

  3. Raise awareness of future opportunities by raising awareness and facilitating discussions in relation to work programmes / funding calls.

     Timeline: Ongoing

2.2. Fostering collaboration with academia

- **Objectives**

  a) Foster expertise-exchange between regulators and academia.

  b) Enable access to the best expertise across Europe (in collaboration with the EMA Academia liaison office).

- **Deliverables**

  1. Stakeholder meeting with representatives from academic researchers and research centres, technology transfer offices and funders to facilitate knowledge and information exchange and highlight EU-IN initiatives targeted at academia.

     Timeline: Q4 2023

2. Engage with academic researchers with a view to addressing regulatory science research needs (RSRN).

   Timeline: Ongoing

3. Promote and progress the implementation of the recommendations from STARS in conjunction with other relevant groups and external stakeholders.

   Timeline: Ongoing

2.3. Promote the translation of innovation from bench to bedside

- **Objective**

  a) Engage with external stakeholders to identify the most promising innovative developments.

  b) Explore opportunities to further promote the translation of innovative developments from bench to bedside.

- **Deliverables**

1. Workshop with pharma and med-tech development incubators on Innovative Medicines with disruptive potential.

   Timeline: Q4 2023

2. Share best practice in relation to innovation and support to innovators.

   Timeline: Ongoing

2.4. Promote collaboration and integration across the network

- **Objective**

  a) Ensure alignment with other groups and avoid duplication.

- **Deliverables**

1. Contribute to ACT EU PA2 (with focus on supports for academic sponsors), PA7 (scientific advice including SNSA) and PA10 (training curriculum).

   Timeline: Ongoing

2. Participate in the INNO group and explore opportunities for further collaboration with other groups, e.g. collaborate with QIG, CTCG on topics of common interest (e.g. borderline classification, horizon scanning).

   Timeline: Ongoing

3. Support the development of the work package on innovation within the EU4Health joint action on capacity building.

   Timeline: Ongoing

4. Participate in the Big Data Steering Group and share information in relation to significant updates and developments e.g. in relation to DARWIN or training initiatives.

   Timeline: Ongoing

3. Ongoing initiatives

3.1. BLCG

- **Objective**

  a) Enable scientific and regulatory sound feedback to innovative complex medicine developers with regards to the classification of their products and consequently applicable legal/regulatory framework and its requirements for evidence generation.

- **Deliverables**

  1. Continue providing a forum and organise regular meetings for informal discussions between competent authorities in relation to the classification of innovative borderline products and approaches to the regulation of such products.

     Timeline: Q1-4 2023

  2. Continue exploring a mechanism for interaction with the established classification processes within other relevant frameworks, e.g. BTC, medical devices.

     Timeline: Q1-4 2023

  3. Continue to monitor and discuss legal cases and support the implementation of new legislative proposals.

     Timeline: Q1-4 2023

3.2. SNSA

- **Objective**

  a) Support and promote the SNSA pilot in phase II as an optimized best-practice model with a multi-purpose approach and continue developing the format towards implementation of a an efficient, harmonised and sustainable scientific advice concept within the EMRN to meet the needs of different stakeholders.

- **Deliverables**

  1. Improve guidance and tools/templates with NCAs to optimize and facilitate the procedural handling and evaluation of SNSA requests under pilot phase 2.

     Timeline: Ongoing

  2. Implement an internal and external communication and dissemination strategy to improve participation from NCAs and uptake of SNSA by the external stakeholders in pilot phase 2.

     Timeline: Ongoing

  3. Continue interaction with ACT-EU (PA7), CTCG and SAWP to optimise support of clinical-trial related scientific-regulatory advice and explore new models for consolidated SA processes.

     Timeline: Ongoing

  4. Optimise the coordination of SNSA procedures and explore the feasibility of a platform for NCAs to share SA-related data and documents.

     Timeline: Ongoing

5. Prepare interim evaluation of the SNSA pilot phase 2 with a view to reporting to HMA in early 2024.

   Timeline: Q4 2023

3.3. Repurposing

- **Objectives**

  a) To support not-for-profit organisations performing clinical research involving repurposing.

  b) To complete the repurposing pilot and evaluate its effectiveness.

- **Deliverables**

  1. Assess the pilot project using the agreed Key Performance Indicators (KPIs).

     Timeline: Q2 2023

  2. Committee Pharmaceutical report with the results of the pilot.

     Timeline: Q4 2023/Q1 2024

3.4. Horizon scanning

- **Objectives**

  a) Ensure a consistent EU network approach to horizon scanning.

  b) Progress implementation of recommendations arising from horizon scanning activities.

- **Deliverables**

  1. Finalise and publish horizon scanning reports on prioritised topics.

     Timeline: Q4 2023

  2. Progress the implementation of recommendations from previous reports, e.g. workshop on gene editing and work with others to implement recommendations from the faecal microbiota transplantation report.

     Timeline: Q1 2023 (workshop) and ongoing

  3. Increase engagement with external stakeholders and ensure coherence with other horizon scanning initiatives, e.g. ICMRA.

     Timeline: Ongoing