European Reference Networks

European Commission

Conclusion and Next Steps from Workshop "How ERNs can Provide Added Value in the Area of Clinical Research"

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Conflict of interest disclosure

I have no actual or potential conflict of interest in relation to this program/presentation

Topic 1/Transversal Action Points: ***What sorts of activities under the heading of 'clinical research' will ERNs engage in, and what are the advantages of the ERN structure?***

- ✓ To get more clear picture from the results of the survey
- ✓ To organise further annual meetings with EMA and continue to define how ERNs will conduct clinical research
- ✓ To explore robust ways to interact with Companies, as well as how to avoid a Conflict of Interest (Research WG/Ethics WG)
- ✓ To continue to advocate for dedicated grant opportunities to enable the ERNs to perform certain types of research (Research WG)

- ✓ To create a checklist of the research to which ERNs could contribute to
- ✓ Face-to-face meeting with key representatives from the biomedical ESFRI Infrastructures to improve understanding of how each could benefit the ERNs and vice versa (Research WG)
- ✓ To implement IDEAL, ASTERISK, and InSPiRE deliverables and to share with Coordinators any existing summaries
- ✓ To elucidate the IRDiRC TF plans and steps on clinical research Networks and outline ERNs engagement

Topic 2 Action Points: What opportunities exist under current EMA structures and resources presented on Day 1, and how might ERNs engage with these?

- ✓ Interested ERNs should consider joining the EMA's Stakeholder Database in order to receive information relevant to their Thematic Grouping
- ✓ Research WG/each ERN representative should explore with the EMA how the process of expert consultation might work in practice
- ✓ ERNs should be invited to present at meetings of the PCWP and HCPWP and opportunities for strategic ERN representation in those bodies should be explored
- ✓ The WG on Research (or other body) could explore and shortlist topics for cross-ERN scientific solutions in the pre-competitive space to be evaluated by EMA for qualification
- ✓ EMA offered a dedicated contact point to follow up on ERNs enquires – Networks should make use of this contact as and when relevant, but all ERN members should approach this single named contact for any Agency-related business, henceforth

Topic 3 Action Points: Identifying concrete roles and recommended practices to involve patients in the various types of ERN-related Clinical Research

- ✓ To establish a TaskForce/Working Group to implement strategies to remove barriers and facilitate full engagement of patients and families, with a goal to replicating some of these practices within ERNs
- ✓ To deliver training in some of the content of programmes (e.g. EURORDIS Summer School) –via the EJP Pillar 3
- ✓ To develop a cross-ERN training event tailored to researchers on how to involve patients in research activities
- ✓ To explore more concretely how ERNs can develop and collect more appropriate health, clinical and QoL-related Outcomes (including PROs), and under which circumstances

Topic 4 Action Points: How can ERNs generate/link/exchange data to support the planning and execution of clinical trials and studies?

- ✓ To organise a large workshop, involving ERN representatives, to help Europe's RD registry stakeholders shape and progress with strategic, complementary plans concerning RD registration

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Contact persons:

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Thank you for your attention!

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