ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

ECRIN-ERIC
Management Office

ECRIN-ON-BOARD (updated version October 2015)

ECRIN (www.ecrin.org) launches in 2015 a campaign to provide early support to multinational clinical research projects preparing a Horizon 2020 (H2020) application for the SC1 2016 call. This "ECRIN-on-board" initiative requires principal investigators to send a draft synopsis of the proposed clinical study by November 1st 2015.

Based on this synopsis, ECRIN will provide free support to the development of the project through:

1. Independent methodological consulting during protocol development, and independent review of the full protocol before H2020 application (optional) in cases with an existing full protocol at the end of January

2. Consulting on logistical and operational aspects of the clinical trial with focus on the international nature: regulatory and ethical aspects, insurance, contracting, monitoring strategy, costs, risk and mitigation, trial oversight boards, site identification and selection

3. Advice on structural aspects of H2020 application: work package architecture, impact, management, governance and consortium, (however ECRIN will not draft the application)

This 2015 pilot initiative will be restricted to ECRIN-ERIC Member or Observer Countries.

Based on previous experience, we expect two different applicant scenarios:

1. **Investigators with a clinical study concept and ideas on establishing the consortium**
   Principal investigators are welcome to send a simple study synopsis summarising the basic idea of the investigation (medical need), the overall concept of the consortium including a selection of major subprojects, the patient population envisaged for the clinical study and estimated of number of participants, the number of countries involved and a simple outline of the study design (consort diagram). This should be sent before November 1st, 2015 to the ECRIN European Correspondent. This information will be handled in the strictest confidentiality.
   By November 15th, after endorsement of the synopsis by ECRIN, a methodologist from the ECRIN Scientific Board will be assigned to each study. The methodologist will assess the synopsis and will provide recommendations by mid January 2016. In parallel, consulting on operational and logistical aspects, as well as advice on the H2020 application will be given for free by the European Correspondents and the ECRIN Core Team.

2. **Investigators with an existing protocol e.g., a proposal previously submitted to a public call or a proposal that has been prepared well in advance of the timeline** (in this case, the outline of the clinical trial should be in alignment with the attached template)
   These investigators are asked to submit their full proposal no later than January 15th 2016. The proposals will be reviewed by the ECRIN Core Team and the Scientific Board by the end of February. This gives investigators another 6 weeks to modify their projects before submission to the H2020 portal (deadline: April 14th 2016).