ECRIN participation in H2020 clinical trial applications

1 - The H2020 “Health, demographic change and wellbeing” work programme

The 2014-2015 H2020 “Health, demographic change and wellbeing” work programme includes calls for multinational clinical trials. Most of these calls are two-step calls (with a first deadline on March 11th for 2014), some are single-step (with a deadline on April 15th for 2014). For clinical trials, the budget is in the range of 4-6M€, and about 10 to 12 projects will be funded for each call. Of particular interest are the calls:

- PHC 13 (for 2014) on new treatments (proof of concept trials, also repurposing trials, but not comparative effectiveness trials) for chronic non-communicable diseases.
- PHC 14 (for 2015, but the product should obtain an orphan designation from EMA) on new therapies for rare diseases (from small molecules to biotherapy), covering innovative treatments and also repurposing trials, but not comparative effectiveness trials. Should be in line with the IRDiRC (http://www.irdirc.org) objectives.
- PHC 15 (for 2014 and 2015): clinical research on regenerative medicine.
- PHC 17 (for 2014): comparative effectiveness research of existing healthcare interventions in the elderly. This may includes clinical trials (but also observational studies, database analyses, meta analyses).
- PHC 22 (for 2015) Promoting mental wellbeing in the ageing population; this call may include clinical trials.

Other calls may have an interest, for example

- PHC-23 (2014) and -24 (2015) on health care, prevention and personalised medicines

2 – ECRIN, the Infrastructure supporting multinational, investigator-driven trials in Europe

ECRIN (European Clinical Research Infrastructure Network, www.ecrin.org) is a distributed infrastructure supporting multinational clinical trials in Europe. ECRIN was funded by the European Commission, FP7, as an infrastructure programme, and is now a sustainable organisation with an «ERIC» legal statute, supported by its Member countries. As access to patients and medical expertise is a critical factor in the conduct of high quality clinical trials, ECRIN is designed to facilitate multinational trials in spite of the fragmentation and poor interoperability of national clinical trial legislations, of health systems, of competent authorities and ethics committees, of national research infrastructures, of tools and procedures used, of training, of funding and of language.

In individual countries, clinical research centres or clinical trial units are able to manage national trials, but face major difficulties in the management of international trial. By connecting and coordinating these national
competence centres, ECRIN makes it possible to conduct multinational trials in Europe, independent of the health industry and of its service providers. ECRIN therefore provides, at not-for-profit cost, operational support in the conduct of multinational trials whose protocol is accepted by the ECRIN Scientific Board: information and consulting before protocol finalisation then, after protocol review, operational services supporting the management of the trial in multiple countries (including data management, monitoring, pharmacovigilance, ethical and regulatory submissions).

3 – What could be the contribution of ECRIN to H2020 clinical trial application

ECRIN may contribute to an H2020 clinical trial application through:

- Information during the preparation of the project (investigation centres, regulatory and ethical requirements, insurance, cost evaluation, etc)
- Consulting, particularly on protocol development and application strategy
- Acting as a partner in the consortium, with typically an involvement in two work packages (this of course flexible)
  - an early and short (3-4 month) work package on protocol finalisation, including methodological support if relevant, and protocol assessment by the ECRIN scientific board. As the H2020 project selection is not based on the full protocol, this ensures that the final protocol is ethically, medically and scientifically sound. This may be viewed as a security by funding bodies.
  - and a work package on management of the multinational trial, including coordinated services to the sponsor, particularly the regulatory and ethical submissions, pharmacovigilance, on site monitoring, and data management.

Please contact the ECRIN European Correspondent in your country (c.schmid@scto.ch), and/or for specific areas the European ECRIN hub on rare diseases (virginie.hivert@inserm.fr), on medical device (Sunya.Lee.Antoine@uni-wh.de), or on nutrition (yvonne.masson@clermont.inra.fr).