Call for expression of interest to recruit an Ethics Advisor to the European Joint Programme on Rare Diseases

BACKGROUND:

The European Joint Programme on Rare Diseases brings over 130 institutions from 35 countries: 27 EU Member States (Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Croatia, Ireland, Italy, Netherlands, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Spain, Sweden, Slovakia, Slovenia, United Kingdom), 7 associated (Armenia, Georgia, Israel, Norway, Serbia, Switzerland, Turkey) and Canada, to create a comprehensive, sustainable ecosystem allowing a virtuous circle between research, care and medical innovation.

The European Joint Programme on RD (EJP RD) has two major objectives:

1. To improve the integration, the efficacy, the production and the social impact of research on RD through the development, demonstration and promotion of Europe/world-wide sharing of research and clinical data, materials, processes, knowledge and know-how;
2. To implement and further develop an efficient model of financial support for all types of research on RD (fundamental, clinical, epidemiological, social, economic, health service) coupled with accelerated exploitation of research results for benefit of patients.

Taking into account the size of the EJP RD project and the complexity of the ethical/regulatory questions that may arise, the European Commission requested that the EJP RD consortium nominates an independent Ethics Advisor.

The Advisor will be in charge to verify the application of EU ethical/legal/regulatory framework within the EJP RD project, as well (with the support of WP4) of the projects that will be financed within and by the EJP RD. A dedicated work package (WP 21) with 15 deliverables was created.

The WP4 (coordinated by the Foundation GIANNI BENZI) is focusing on all ethical, regulatory, legal and IP support aspects. This WP will support the EJP RD partners and the Ethics Advisor in all activities related to the ethical and regulatory domains.

The **Ethics Advisor** is directly attached to the coordinator of the project and the Executive Committee of the EJP RD. He/she facilitates the dialogue with the European Commission (for all ethical/regulatory aspects). The Ethics Advisor ensures that the consortium applies and respects all ethical, regulatory and legal norms within all activities run under the EJP RD project.

To that end:

• He/she participates in conference calls/meetings of the Executive Committee to be informed, discuss and to react in advance the initiatives/actions are being

implemented. The ExCom meets via conference call every 2 months and physically once a year (at the start of July);
• If deemed necessary, he/she is available for consultation to discuss the activities foreseen in WP4 and participates in the conference calls/meetings of WP4;
• He/she participates in the meetings of the Advisory Regulatory Ethics Board (AREB) (once a year; meeting precedes the ExCom meeting)
• He/she expresses opinion/advice on controversial questions in order to find the most suitable solution according to ethical and legal frameworks;
• He/she writes the annual report on the activities, detailing the undertaken choices (based on the ethical/legal framework);
• He/she initiates/participates in the governing measures to ensure their conformity with ethical and legal frameworks of the EU/Horizon 2020;
In summary, the participation of the expert will be exercised through the participation in conference calls/meeting, in decision-making processes, via punctual advice on specific aspects related to the EJP RD activities. The work of the Advisor will be summarized in the annual report.

FIELD OF EXPERTISE:
The EJP RD is looking for an expert able to guide the programme on the following ethical/regulatory/legal question related to the EJP RD activities:

1. Use of animals in pre-clinical research (application of 3R rules, justification of the use of primates, etc.)
2. Research on (or including) vulnerable populations (children, participants outside of EU), the criteria of inclusion, consents/information provided, authorization for clinical trials, evaluation of benefit/risk, etc.
3. Data and confidentiality protection (of collected data, their use, share and secondary use of personal data within research projects) in the context of the GDPR and other relevant regulations
4. Use of genetic test and outcoming data for research (and especially from vulnerable populations)
5. Collection and exchange of human samples and associated data
6. "Dual use" of research (bioterrorism applications, etc.)
7. Application of the Clinical Trials Regulation/Protection of data under legal and ethical context of Council of Europe for EU and non-EU countries

APPLICATION PROCEDURE:
We invite individuals to apply as Ethics Advisor to the European Joint Programme on Rare Diseases by sending an email to coordination@ejprarediseases.org with the following information:
- CV of the applicant
- Motivation letter in which you detail in particular how you envisage your role in the EJP RD.

Deadline for applications: September 1st 2019

CONTRACTUAL MODALITIES:

A consultancy contract will be formalized, specifying the number of hours/activities, which will constitute the basis for the work of expert until December 2023 (end of the EJP RD contract). Some additional activities may be included based on the yearly requirements. All additional activities will be listed in the Addendum.

On the basis of the contract, the expert will deliver honorary bills on a monthly basis. The VAT application/exoneration should be verified in advance of the signature of the contract.

The amount will be established based on the number of hours of work required and adaptation according to hour or fee proposed by the expert. For the participation in face-to-face meetings of the EJP RD, a daily fee will be applied. The travel and accommodation costs will be covered by the EJP RD project (and will follow the rules applied by the coordinating institution INSERM, France).

In the context of the contract, the expert will be bound by the professional confidentiality agreement and will act with impartiality