

Information to Principal Investigators

You have agreed to receive mentoring, a service of Work Package 19 of the EJP RD program. The aim of the mentoring is to increase the impact and patient benefit of the excellent science funded in EJP RD. With this mentoring support, applicants will receive project-specific feedback from a panel of drug development, biomarker validation, methodological and regulatory experts tasked with optimizing the translational feasibility of the study. There are no costs or obligations to you.

The mentoring consists of the following steps:

Prior to mentoring

1. *Confidentiality – Letter of Engagement*
To frame our interactions and to cover confidentiality, we ask all applicants to fill in a Letter of Engagement (LoE). In the LoE you may check boxes for the 3-4 areas of most pressing need for mentoring, or you are free to suggest other areas if you do not find the desired option. In the event your mentor does not live inside EU we need your consent to share your personal data (contact details) with our expert advisors outside the EU according to Article 49. 1. (a) of GDPR (General Data Protection Regulation) on international transfers of personal data. Please check for this in the LoE document.
2. *Suggest available times for mentoring*
We would kindly ask you to suggest several timeslots where you are available for mentoring in the same email as you return the LoE. Keep in mind that the mentors have busy schedules and the more options you provide, the more helpful for our planning

Mentoring

3. *Initial teleconference*
After we receive a signed LoE we will together plan an initial teleconference (30 min) to further discuss the identified areas in which you may need support or have questions.
4. *Introduction to selected mentors*
Based on your work plan, and after the first call we will identify technical experts with matching expertise from within our pool of EATRIS collaborators and introduce them to you with links for your acceptance. All our experts have signed a mentoring agreement to cover confidentiality as well as a non-conflict of interest document.
5. *Preparing for the mentoring calls*
To help the mentors give more specific feedback you are kindly asked to send us specific questions you may have, and provide additional technical data where this might help to the discussions.
6. *Scheduling the mentoring meetings*
We next will schedule the mentoring meetings based on your and the mentor's availabilities. We ask you to quickly respond to our meeting invitations to help set up of these meetings efficiently. Keep in mind we have numerous meetings to schedule and need your cooperation for a seamless process. Also please include the contact information of the partners that are relevant to each mentoring topic for us to add in the meeting invitation and/or forward the meeting invitation to whom you would like to join.



7. *Mentoring*

The mentoring session is an interactive process with open discussions. Due to time concerns, some of the mentors will provide a written feedback only. You may however respond with additional questions to their written reports. After the initial round of mentoring, you will be expected to provide short updates to your mentors, which can be done electronically or in person, to be agreed between you and your mentors. At any time, you can contact them for questions or troubleshooting issues that may arise in the course of your project. At all times, please keep the innovation coordinator assigned to you in cc.

After mentoring:

8. *Notes*

We write notes during the mentoring session and will send them out shortly after our meeting to yourself and the mentor. You are all free to add comments or supporting information or forward additional questions after reviewing the notes.

9. *Final report*

After all mentoring meetings, a summary Mentoring reports as above will be provided - and if relevant - links to the following supporting documents and resources:

- a. Preclinical animal study – biostatistics
- b. Ethical assessment component in EU funded research proposals
- c. Orphan drug development handbook
- d. EATRIS regulatory database
- e. EATRIS resource library (list useful for the translational assessment of proposals)
- f. Target product profile template
- g. Reverse planning template
- g. Project development plan
- h. Stakeholder analysis mapping

10. *Survey*

After the mentoring, you will receive a survey with the option to provide comments that will help us further develop and improve the mentoring service. We kindly ask you to fill it out and return at your earliest convenience.

11. *Continued mentoring*

If your first mentoring experience was during grant proposal preparation, and in the happy event that you are selected to receive funding, you are offered the option to continue receiving mentoring throughout the project. Details such as frequency and topics will be agreed individually.



CONTACT

To find out more or register for the service, please email Anita Kavlie (anitakavlie@eatris.eu) or visit <https://eatris.eu/services/expert-mentoring-service-rare-disease-researchers/>

