Contributing an intervention to IMI-EPAD – IP Safeguards

Main IMI-EPAD Objectives. The IMI-EPAD project draws on existing national and regional registers of people at risk of developing Alzheimer's dementia to create a single, pan-European EPAD register of around 24,000 people. Of these, the 6,000 deemed to be at greatest risk of Alzheimer's dementia will be invited to join an EPAD cohort of at risk subjects. This group will undergo standardized tests and follow-up. Finally, the project will select around 1,500 people from this EPAD cohort to take part in early stage 'adaptive' proof of concept clinical trials of drugs designed to prevent Alzheimer's dementia. More background information on the objectives of the IMI-EPAD project can be found on http://ep-ad.org .

It is the last part of the objectives (the proof of concept clinical trials) which required the participants in the IMI-EPAD project to tackle and agree on some complex issues created by the organization of a clinical trial within a public-private partnership consortium project. The main goal was to balance the interests of contributors of interventions and the variety of other EPAD partners, at the same time considering the IMI framework.

IP Safeguards for Intervention Contribution. The EPAD Project Agreement offers various safeguards, all within the boundaries IMI legal framework, to allow the entry of valuable interventions for the proof of concept part of EPAD ("**EPAD Trial**"). These can be summarized as follows:

- Any output (including but not limited to data and intellectual property rights) directly relating to an intervention or arising from the EPAD Trial with respect to the use of an intervention such as an investigational medicinal product ("**Intervention Foreground**"[1]) are owned by the contributor of such intervention. In case other participants in EPAD have generated such Intervention Foreground, it will be assigned free of charge to the contributor. Intervention owners are free to decide how to exploit their Intervention Foreground, subject to the next paragraph.
- **Access rights to Intervention Foreground** need to be granted under IMI rules for **Research use purposes** to EPAD participants and third parties. Access to Intervention Foreground can take place in principle only after certain milestones have been achieved (e.g. release of the relevant clinical trial report for research use by EPAD participants) and is subject to the party exercising its access rights to grant back to the intervention contributor a cost free license on any results arising from such research use which relate to the intervention.
- **Publication of Foreground**: The contributor of the intervention is responsible for any publication of Intervention Foreground and can per IMI rules take into account its legitimate interests (such as the need for intellectual property protection) in deciding on the timing and extent of the publication.
- Certain types of possible output which do not fall within the objectives of EPAD (e.g. discovery of new clinical uses, manufacturing methods, structure and dosing of the intervention) are considered "**Sideground**" which are also owned by the intervention owner and on which, in accordance with IMI rules, it does not need to grant the aforementioned research use access rights.
- The ownership of the intervention itself as well as pre-existing intellectual property related to it and used in the Project ("**Background**") is not affected. Access rights to such pre-existing intellectual property need to be granted under IMI rules "in case necessary for research use of Foreground". In accordance with the IMI rules, (i) such access rights are not free but need to be negotiated between the contributor and the requesting participant; and (ii) a participant can list pre-existing contractual or legal restrictions to which such access is subject. In addition, access rights by third parties (not participating in EPAD) to Background can be excluded by making a request to the IMI.

[1] Referred to as "IMP Foreground" in the EPAD Project Agreement

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