

## Questions & Answers on the AMR Accelerator in support of potential applicants

*Note: This document may be updated if further questions on the AMR Accelerator arise. Applicants should therefore check the [IMI2 – Call 15](#) or [IMI2 – Call 16](#) web pages regularly for new versions.*

*Last update: 23 July 2018*

### **Q: Are there any special provisions on the handling of data and/or samples?**

*A: The sharing of data and/or samples from clinical trials will be undertaken in accordance with the generating beneficiaries' standard procedures, including in relation to data privacy and data governance, and applicable legislation.*

### **Q: Are there any special provisions regarding the IP regime under Pillars A, B and C?**

*A: Under these topics, the applicant consortia may research and develop pre-existing product candidates and/or compounds owned by one of the beneficiaries participating in the proposal. By performing such activities, results (including shared clinical data) generated relating to the pre-existing product candidates and/or compounds tested will be owned by the generating beneficiary(ies).*

*The consortium should recognise the requirements of Article 26.2 of the IMI2 JU Model Grant Agreement in respect of jointly generated results. All beneficiaries should be aware that when negotiating the consortium agreement, each beneficiary may propose all possible safeguarding provisions in respect of the rights to results generated from their pre-existing product candidates and/or compounds.*

*For instance, in the consortium agreement, it may be agreed by the relevant beneficiaries that, when requested by one of the beneficiaries (e.g. an EFPIA partner) that is the owner of a pre-existing product candidate and/or compound, the ownership of results (including clinical results), generated by any other beneficiary, relating to the pre-existing product candidate and/or compound – when and only where not jointly owned according to Article 26.2 of the IMI2 JU Model Grant Agreement – will be transferred under the terms of the consortium agreement to the owner of the pre-existing product candidate and/or compound. The contractual arrangements may state that, e.g., such a transfer would be at no cost, if so requested by the owner of the pre-existing product candidate and/or compound.*

### **Q: Are there any specific expectations/recommendations as regards the consortium agreement in Pillar C?**

*A: Specific expectations for Consortium Agreements in Pillar C: It is expected that consortium agreements will lay out mutually agreeable and beneficial terms regarding, for example, intellectual property, decision making (as outlined in the topic text, including escalation procedures), termination conditions, possible payments from one partner to another for meeting a specific major milestone (e.g. candidate selection), and research and exploitation plans beyond the scope of the PBN.*

**Q: IMI2 JU Call 16 for Pillar C foresees the mandatory participation of EFPIA companies in the applicant consortia. How can these companies be identified by potential applicants?**

*A: All EFPIA companies can in principle participate under this Call. However particular interest has been expressed by GSK, Janssen, and Evotec. Contacts for the Call 16 topics are:*

*Janssen - [RnDG3O@its.jnj.com](mailto:RnDG3O@its.jnj.com)*

*GSK - [AMR\\_Accelerator@gsk.com](mailto:AMR_Accelerator@gsk.com)*

*Evotec - [michael.mourez@evotec.com](mailto:michael.mourez@evotec.com).*

**Q: Under Pillar B (Tuberculosis drug development network) how many molecules are expected to be provided from EFPIA and Associated partners at the start of the project? – Question added 23/07/2018**

*A: At the time of Call launch, it is estimated that between 15 to 20 molecules have the potential to enter the portfolio platform. These molecules would be either advanced leads, preclinical candidates and potentially some ready to enter into good laboratory practice toxicity studies or even first into human studies.*