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, IMI2 – Call 16 or IMI2 – Call 20 web pages regularly for new versions.

Last update: 15 November 2019

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

A: The sharing of data and/or samples from clinical trials will be undertaken in accordance with the applicable legislation and the rules and procedures of the generating beneficiaries (more specifically EFPIA's policy on transparency of clinical trial data (see https://www.efpia.eu/news-events/the-efpia-view/blog-articles/29112017-efpia-phrma-principles-successfully-enable-responsible-clinical-trial-data-sharing/), in relation to data privacy and data governance.

Q: Are there any restriction to the therapy areas investigated in Pillar B Call 20 Topic 3 (United4TB) - Question added October 2019

A: For the avoidance of doubt, the UNITE4TB Consortium and Action as described in this Call Topic, is not having as objective, nor is it intending to investigate (i) the discovery of new clinical uses, dosage regimens or therapeutic indications of an investigational medicinal product (IMP) outside of TB, (ii) manufacturing methods for such IMPs, including any starting materials and intermediates, insofar as they are not solely related to TB, physical properties, forms, formulations, route of administration, dosing regimens, structure, and characteristics of the IMPs. None of accidental or specific findings related thereto are to be considered as findings made towards the Action Objectives.

Q: Are there any special provisions regarding the IP regime under Pillars A B and C (updated October 2019)

A: Under these Call Topics, the applicant consortia may research and develop pre-existing product candidates (NCE) (or compounds) owned by one of the beneficiaries participating in the proposal. By performing such activities, clinical results that are generated from the NCE (or compounds) tested will be owned by the generating beneficiary(ies). However, these results may be improvements (or directly related) to the NCE. 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 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 (i.e. background of the project), the ownership of results (including clinical results), generated by any other beneficiary, relating to the pre-existing background – 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. Such contractual arrangements may state that, e.g., such transfer would be at no cost, if so requested by the owner of the pre-existing product.

Q: **Are there any restrictions on data management within Pillar B, Call 20 Topic 3 (United4TB) – Question added October 2019**

A: A significant part of data generated in the funded action may be exploited in the development and, on the long term, market launch of new therapeutics against tubercular infections (validating targets, confirming lead compound candidates, developing and testing new drug regimens, further clinical trials). In particular, such data may have a significant commercial value since important subset of the data will be needed for filing regulatory documents. Consequently, preliminary sharing data outside of the consortium could hinder the exploitation of the project results and hence the overall objectives of the AMR Accelerator (bringing new TB/NTM drugs on the market). Thus, the selected consortium should propose a strategy for access to data, which would be compatible with the protection of its commercial value. Such a strategy should be presented in the funded action Data Management Plan (DMP).