



Innovative Medicines Initiative

IMI 9th Call for proposals Questions & Answers

Topic: Driving re-investment in R&D and responsible use of antibiotics (ND4BB topic 4)

Question: Is the architecture of the proposal flexible and can it be adapted, i.e. can another work package be added?

Answer: It is important to address all of the objectives of the topic. Minor changes in the proposed architecture of the project, such as the addition of a work package, are within the flexibilities that applicants have, as long as it is well explained how this helps in fully addressing the objectives of the project.

New! Question: It seems that Part A is intended to further strengthen the clinical network from Call 6, and Part B is basically co-funding the clinical trials for Aztreonam-Avibactam, is this correct? It seems surprising since AZ is already developing Ceftazidime-Avibactam. And in theory, MDs are allowed to prescribe any combination of antibiotics, so they could just add Aztreonam to that mix, leading to the question if this is really a very much needed combination at all? Of course, a marketed combination will have the advantage of having fine-tuned the dosing etc., but will that be enough?

Answer: To ensure efficacy, aztreonam-avibactam (ATM-AVI) needs to be studied as a product distinct from ceftazidime-avibactam (CAZ-AVI). Efficacy of each combination is dependent on achieving (a) optimal dosing of the beta-lactam partner (ATM, CAZ) as well as (b) correctly matched pharmacokinetics (PK) of the beta-lactamase inhibitor (AVI).

Thus, these products are co-formulated to guarantee synchronous administration and hence matched pharmacokinetics (PK) and thus pharmacodynamics (PD) with each dose. Differences in optimal dosing frequency mean that adding ATM to CAZ-AVI (or vice versa) would lead to either under- or over-dosing of one component.

In summary, these are distinct products and require distinct development pathways both to support regulatory approval and so that adequate guidance can be given to prescribers on dose adjustments, drug interactions, and safety profiles. This approach has been reviewed and agreed in detail with FDA, EMA, and multiple external PK-PD consultants.

Topic: Clinical development of antibacterial agents for Gram-negative antibiotic resistant pathogens (ND4BB topic 5)

Question: Are compounds like antibacterial peptides, proteins and bacteriophages considered?

Answer: These particular antibacterial agents are not part of the current Topic 5 as described in the current Call 9 text. However it is anticipated that the ND4BB programme will further expand with future calls that may consider these other type of compounds

Question: Can partners from previous calls (6th and 8th Calls for proposals) apply?





Answer: Yes, partners from previous Calls are able to apply. They will have to be part of the applicant consortium and be able to demonstrate that they have the capacity and capability to undertake the work outlined in the 9th Call text.

In addition, as specified in the Call 9 Topic 5 text, applicants should be able to fulfil, within the indicated timeframe, the patient recruitment, and for work packages 4 and 5, preferentially the site should have no other clinical studies that may compete for the target patient groups.

More questions?

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