



Innovative Medicines Initiative

IMI indicative Call topic

Development of drug-drug combinations

All information regarding future IMI Call topics is indicative and subject to change. Final information about the IMI's future Calls will be communicated after approval by the IMI Governing Board.

Background

Patients, healthcare professionals, the pharmaceutical enterprise and society as a whole could potentially benefit, to a greater extent than today, from combination products in which two or more drugs are combined and co-formulated in a single dosage form. Drug-drug combinations could:

- lead to simplified treatment regimen for the patients;
- enhance treatment adherence thus rendering improved clinical effectiveness;
- reduce collective societal health care costs through the resultant improved patient outcomes.

Need for public-private collaborative research

While the science could evolve based on individual actor's merit, expediting the advancement of science in the drug-drug combination field would require concerted efforts and commitments from several stakeholders, most notably academic institutions and the pharmaceutical industry. Other stakeholders involved in assessing patient related outcomes and/or representing payers could also be envisaged being part of such an initiative.

Overall objectives

The overall objectives are threefold:

1. to foster a creative interaction between academia and pharmaceutical companies stimulating innovation in the field of drug-drug combination products;
2. to advance basic research and science on drug-drug combinations enabling a faster, more efficient, and less expensive development process thus delivering value to patients and society by earlier access to novel and effective therapies;
3. to advance the understanding of the underlying health economic aspects considering reimbursement models and understanding pricing and reimbursement bodies' requirements.

Suggested Key Deliverables

The IMI Drug Combination Consortium should produce three tangible outcomes. These are:

1. Development Options - This should furnish a discussion on how to develop drug-drug combinations in a favourable way from a time and cost perspective. It should analyse critical success factors and identify serious pit falls that need to be considered during the drug development phase.
2. A White Paper - This entails a review of current literature, including regulatory guidance and legislation, on drug-drug combinations. The survey should identify gaps in requirements and science related to what is needed by regulators, payers, patients, healthcare professionals, and the development process pertaining to drug combinations. The result(s) should be made visible by publications in peer reviewed journals.
3. Advancing the Science - Fostering a collaborative atmosphere between pharmaceutical companies and academic institutions stimulating and advancing basic research on drug-drug combinations

