Programma specifico: Titolo Call: Call Identifier:	FP7 Cooperation JTI Iniziativa tecnologica congiunta sui medicinali innovativi – IMI Joint Undertaking IMI-JU-9-2013
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Obiettivi	IMI-JU è un partenariato pubblico-privato paneuropeo che intende favorire il dinamismo e la competitività del settore biofarmaceutico europeo promuovendo la collaborazione tra le relative parti interessate, tra cui grandi e piccole aziende biofarmaceutiche e sanitarie, *regulatory agencies*, università e associazioni di pazienti.
Beneficiari	Qualsiasi impresa, istituzione di ricerca, università o altri enti che svolgano attività collegate con gli obiettivi dell'IMI-JU, in stati membri UE o paesi associati al 7PQ.
Attività e Priorità Scientifica	Attività comunitarie di ricerca, sviluppo tecnologico e dimostrazione. I topic coperti da questo bando sono: 1.Webae - Leveraging emerging technology for pharmacovigilance Objectives: ✓The primary goal of this partnership is to develop a technical and policy framework for mining publicly available (and licensed) web and social media content outside the control or sponsorship of pharmaceutical and biotechnology companies (i.e. independent web media) for emerging ADRs. ✓The scientific aim of the consortium is to develop methodologies and adopt data mining algorithms applicable to social media content (forums, blogs, tweets, public posting, etc.) in order to find emerging, self-reported medical insights such as adverse events associated with medicines and medical devices. Special emphasis will be put on the multi-lingual nature of the content. ✓A further objective would be to provide a working set of applications to enable direct reporting of suspected ADRs tonational competent authorities via the established, secure EudraVigilance data-processing network. The applications would be made available free of charge to all users of tablets, smartphones, and the mobile web, for all major platforms as well as social networking sites like Facebook. The evolution of the scientific and technical solutions will also inform the necessary evolution of the regulatory guidance and ultimately the practice of the pharmaceutical industry with respect to ADRs discovered in digital media. 2.Developing innovative therapeutic interventions against physical frailty and sarcopenia (ITI-PF&S) as a prototype geriatric Objectives: ✓Qualification of biomarkers and adapted clinical methodologies for the regulatory development of innovative interventions against Physical Frailty and Sarcopenia (PF&S) in at-risk Older Persons, to prevent or delay mobility disability and its consequences, is the overarching objective of this IMI project, including: - development of an operational definition of at-risk subpopulations with undisputable therapeutic need - qualification of biomarkersof muscle anabolism and catabolism and indicators of muscle function in at-risk sub-populations and their correlation with major outcomes - development of advanced therapeutic approaches in preclinical settings - implementation of innovative clinical development methodologies for testing integrated interventions for the prevention of PF&S and consequent mobility disability;

	- scientific and Regulatory Consensus of these three elements. 3.Combatting antibiotic resistance: Newdrugs4badbugs (ND4BB) - topic 4: Driving re-investment in R&D and responsible use of antibiotics. Objectives: ✓Analysis and understanding: This project should develop a vision for a new way for the public and private sectors to collaborate to ensure future generations are not faced with untreatable infections in seriously ill patients. The project needs to develop new insights and collate data to inform the vision. Required outputs need to deliver clarity and agreed approaches to address the following challenges: -Our lack of implementable commercial models that will incentivize work in this arena by providing rewards to innovators while addressing simultaneously the need for antibiotic stewardship -Our lack of a shared understanding of the responsible use of antibiotics and how this can be delivered for seriously ill patients -Our differences in perspectives on ways to set, communicate, and act on Public Health priorities -Our lack of a broad understanding of the value of antibiotics to society ✓Output ->Outcome ->Impact: Producing a vision is not sufficient: it needs to be turned into policy recommendations and implemented. This will require a significant effort from the Project. The policy recommendations need to cover both current eventualities as well as likely future trends. 4.Combatting antibiotic resistance: Newdrugs4badbugs (ND4BB) - topic 5: clinical development of antibacterial agents for gram-negative antibiotic resistant pathogens. Objectives: ✓Increase the efficiency of antibiotic R&D through analysing observational clinical and microbiological data sets and making recommendations for the development of novel antibiotic agents for MDR Gram-negative pathogens ✓Understand the clinical management and outcomes of patients with serious hospitalised infections to validate our understanding of the clinical outcomes for patients in areas of emerging and endemic antibiotic resistance. ✓Support the sustainability of ND4BB supported investigator and laboratory networks. ✓Conduct prospective clinical trials with novel trial designs to deliver safety, pharmacology, and proof of efficacy data for novel agents directed towards treatment, prevention or sequelae of infections due to priority pathogens and if possible to validate novel bacterial identification diagnostics or clinical endpoints with the aim of reducing the sizeand cost of clinical trials.
Durata del progetto	3 - 5 anni.
Presentazione della proposta in due fasi:	1. Espressione d'interesse. Almeno due entità indipendenti tra di loro e indipendenti dai membri della Federazione Europea delle Industrie e delle Associazioni Farmaceutiche (EFPIA). 2. Full proposal. I consorzi che abbiano superato la prima fase sono invitati a presentare un progetto dettagliato e a creare un partenariato con almeno altre due istituzioni membri di EFPIA. La deadline per la sottomissione della full-proposal è comunicata direttamente dalla JU ai consorzi che superano la prima fase. Criterio di valutazione: eccellenza scientifica.

Quadro di Finanziamento	Co-finanziamento. IMI-JU contribuisce ai costi eleggibili sostenuti dagli enti che partecipano ai progetti tranne le aziende EFPIA, i cui costi sono totalmente a loro carico. Stanziamento IMI-JU per il bando: € 63,12 milioni. Il contributo di IMI-JU copre: - Attività di ricerca: 75% dei costi eleggibili. - Altre attività (management & training): 100% dei costi eleggibili. - Costi indiretti: flat rate del 20% dei costi diretti, esclusi i subcontratti.
Per saperne di più:	http://www.imi.europa.eu/content/stage-1-7 http://ec.europa.eu/research/participants/portal/page/call_FP7?callIdentifier=IMI-CALL-2013-9&specificProgram=COOPERATION#wlp_call_FP7
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