Questionnaire for public consultation in the context of the Impact Assessment on plans for a public-private partnership (PPP) in life sciences research and innovation under Horizon 2020

Information about respondent profile	
Please enter your organisation's name or your personal name (for individuals), address and e-mail address. -open reply-(compulsory)	
Society of Biology Charles Darwin House, 12 Roger Street, London, WC1N 2JU policy@societyofbiology.org	
Received contributions together with the identity of the contributor may be published on the Commission's website. Do you agree to your contribution being published under your name? -single choice reply-(compulsory)	My contribution can be published under the name indicated
Please enter your current country of residence or where your organisation is based. -single choice reply-(compulsory)	United Kingdom
Who do you represent? -single choice reply-(compulsory)	Non-governmental organisation (NGO)
Are you familiar with the Innovative Medicines Initiative (IMI)? -single choice reply-(compulsory)	Not familiar
Have you applied for funding from IMI? -single choice reply-(compulsory)	No
Have your received funding from IMI? -single choice reply-(compulsory)	No
Relevance of the life science sector for science and economy	
In your view, how relevant is the life science industry sector for addressing societal challenges such as the ageing population? -single choice reply-(compulsory)	Very relevant
In your view, how relevant is the life science industry sector for the European economy? -single choice reply-(compulsory)	Very relevant
Identification of the problems	
Relevant medical conditions are not being addressed -single choice reply-(optional)	Important
Lack of predictability of pre-clinical toxicology -single choice reply-(optional)	Important
Difficulty to detect clinical toxicology early -single choice reply-(optional)	Important
Lack of predictability of pre-clinical efficacy -single choice reply-(optional)	Important
Difficulty to get indications on efficacy in early clinical testing -single choice reply-(optional)	Important
Challenge of clinical trial designs -single choice reply-(optional)	Important

Challenge of addressing stratified approaches and personalised medicine -single choice reply-(optional)	Important
Challenge of incorporating novel technologies into bringing innovations to the patient -single choice reply-(optional)	Important
Other problems for life science research in addressing societal challenges? -open reply-(optional)	
Research tends to focus on targets where chemical tools are already available. Difficulty of bringing together expertise in whole organism biology and clinical pharmacology. Increasing scientific complexity. Reduced focus on neuroscience.	
Lack of public R&D funding -single choice reply-(optional)	Important
Lack of private R&D funding -single choice reply-(optional)	Important
Lack of cooperation between publicly funded and privately funded research -single choice reply-(optional)	Important
Lack of cooperation between different industry sectors -single choice reply-(optional)	
Lack of competitiveness of European life science research -single choice reply-(optional)	
Lack of qualified research personnel -single choice reply-(optional)	
Lack of coordination between Member State and EU level -single choice reply-(optional)	
Challenging regulatory environment -single choice reply-(optional)	Important
Do you see other important obstactles to bringing results of life science research to the market and to patients in Europe? -open reply-(optional)	
Lack of funds as companies fall off patent cliff. Lack of connectivity between investors & researchers working in different stages of drug discovery & development. Environment of risk-aversion to early stage development; necessity of investment & skills in business development for proof of concept.	

European added value

Is industry alone, without government support, able to address the relevant problems? -single choice reply-(compulsory)	Strongly disagree
In your view, can regions or individual countries alone help industry address these problems? -single choice reply-(compulsory)	No opinion
Do you agree that the EU needs to step up and help industry address these problems? -single choice reply-(compulsory)	Agree
Greater competition for project funding -single choice reply-(optional)	Neutral
Integration of European research -single choice reply-(optional)	Neutral

More cross border collaboration -single choice reply-(optional)	Neutral
More cross-sector/interdisciplinary collaboration -single choice reply-(optional)	Important
Quicker adoption of standards -single choice reply-(optional)	Important
Allowing leverage of external pools of knowledge -single choice reply-(optional)	Neutral
Better availability of research results -single choice reply-(optional)	Neutral
Encourage companies to share expertise -single choice reply-(optional)	Important

Other element of European added value you consider relevant? -open reply-(optional)

Provision of sustainable funding under Horizon 2020, in areas of unmet medical need. Facilitating bridging of expertise-investment gap. Knowledge transfer.

Objectives

The WHO report "Priority Medicines for Europe and the World" **[1]**mentions a list of priority diseases. Is the list from this report, or from future updates of this report an adequate point of departure for the scientific research agenda for a PPP in life science research? **[1] http://whqlibdoc.who.int/hq/2004/WHO_EDM_PAR_2004.7.pdf** ; The report mentions the burden throughout the world from chronic diseases such as cardiovascular disease, diabetes, or cancer, while the burden of acute diseases in Europe is low, although they can become threats. The burden from preventable diseases is also highlighted. -single choice reply-(compulsory)	Neutral
Should the PPP in life science research be focused on biopharmaceutical research? -single choice reply-(compulsory)	No
Diagnostics -single choice reply-(optional)	Very important
Vaccines -single choice reply-(optional)	Very important
Biomedical imaging -single choice reply-(optional)	Very important
Medical information technologies -single choice reply-(optional)	Very important

Do you consider other areas not yet mentioned as important to be included? -open reply-(optional)

Early small molecule research in new pathways/ orphan diseases.

Understanding and classifying diseases -single choice reply-(optional)	Important

Target identification and validation -single choice reply-(optional)	Important
Tools for assessing safety of developed compounds -single choice reply-(optional)	Important
Tools for assessing the safety of innovative imaging-based technologies -single choice reply-(optional)	Important
Development of new therapeutics in areas of particularly high public health needs and lack of incentives for industry -single choice reply-(optional)	Very important
Proof of concept for new regulatory pathways to inform discussion on regulatory guidance -single choice reply-(optional)	Important
Develop a strategic research agenda for vaccines -single choice reply-(optional)	Important
Improved assessment of response to vaccination -single choice reply-(optional)	Important
Develop therapeutic vaccines -single choice reply-(optional)	Important
Support for development of infrastructures (e.g. systems to develop guidance on the collection of comparable data sets) -single choice reply-(optional)	Important

Other objectives you consider relevant for a PPP in life sciences under Horizon 2020? -open reply-(optional)

Support development of system allowing greater collaboration and open innovation-infrastructure Develop an initiative that improves patient selection Support the bridging of the 'valley of death' Help ensure that duplication of effort is minimised Support improvement of predictive toxicology

Options

Continuation of IMI under Horizon 2020 -single choice reply-(compulsory)	No opinion
Only collaborative research -single choice reply-(compulsory)	No opinion
"Contractual PPP" -single choice reply-(compulsory)	No opinion
PPP building on IMI with expanded scope and simplified implementation -single choice reply-(compulsory)	No opinion
Regulatory action -single choice reply-(compulsory)	No opinion

Impacts

Short term: over the next five years -single choice reply-(compulsory)	Positive impact
Medium term: over the next ten years -single choice reply-(compulsory)	Positive impact
Long term: over the next twenty years -single choice reply-(compulsory)	Positive impact

In the biotechnology industry? -single choice reply-(compulsory)	Positive impact
In other industries? -single choice reply-(compulsory)	Positive impact
Jobs -single choice reply-(compulsory)	Positive impact
Education and mobility of research workers -single choice reply-(compulsory)	Positive impact
Public health -single choice reply-(compulsory)	Positive impact
Health care costs -single choice reply-(compulsory)	Positive impact
Health and safety of individuals -single choice reply-(compulsory)	Positive impact
Health and safety of European population -single choice reply-(compulsory)	Positive impact
Are there specific effects on particular risk groups (determined by age, gender, disability, social group, mobility, regions) -single choice reply-(compulsory)	No opinion
Environmental impacts -single choice reply-(compulsory)	No opinion

Achievements of the ongoing Innovative Medicines Initiative (IMI)

Addressing the key bottlenecks in biopharmaceutical research -single choice reply-(optional)	
Increasing European competitiveness in the area of biopharmaceutical research -single choice reply-(optional)	
Bringing together relevant stakeholders in biopharmaceutical research in a spirit of open innovation -single choice reply-(optional)	
Changed the business model of research in the pharmaceutical industry towards collaboration and open innovation -single choice reply-(optional)	
Is IMI visible at the international level as a European PPP in biopharmaceutical research -single choice reply-(optional)	
Effectively engaged with SMEs in relevant sectors -single choice reply-(optional)	
Do you consider that IMI projects have produced scientific successes? -single choice reply-(optional)	

Lessons learned from the ongoing Innovative Medicines Initiative

Involvement of SMEs and large industry

Do you consider that a PPP in life science research under Horizon 2020 should ensure a better involvement of SMEs	

than in IMI? -single choice reply-(optional)	
Do you consider that a PPP in life science research under Horizon 2020 should ensure a better involvement of large industry than in IMI? -single choice reply-(optional)	
The contribution of private partners to the partnership can be through paying for their own research (in-kind contribution), a cash contribution or a combination of both. The contribution of industry to the life science PPP should be: -single choice reply-(optional)	
Evaluation of proposals at IMI and selection of Expressions of Interest	
Do you consider that IMI has organised a sound and transparent proposal evaluation system based on both scientific/technological excellence and industrial relevance? -single choice reply-(optional)	
Under IMI, only the consortium having submitted the winning expression of interest at the first stage selection is invited to enter into negotiation with the pre-formed industry consortium for preparing a full project proposal. Do you consider this appropriate? -single choice reply-(optional)	
Should there have been an option for merging two or more highly-ranked consortia? -single choice reply-(optional)	
Should there have been an option for starting with several consortia and after 1-2 years decide which consortium to take forward based on results, functionality and viability of the hypothesis? -single choice reply-(optional)	
Administrative/legal set-up of a PPP under Horizon 2020	
Under FP7, the Innovative Medicines Initiative has been set up as a legal structure based on an article of the EU treaty (Article 187 of the Treaty on the Functioning of the European Union**[1]**). A dedicated budget for the initiative is defined from the outset. The legal structure enjoys the rights and has the obligations of an EU institution. For example, it needs to follow the internal staff rules of the EU and the Executive Director of IMI has to ask for discharge from the European Parliament. What is your opinion on this set-up? **[1]***Article 187* (ex Article 171 TEC): The Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes. -single choice reply-(optional)	
Dedicated legal structure -single choice reply-(optional)	
Dedicated legal structure with a lighter approach -single choice reply-(optional)	
"Contractual PPP" -single choice reply-(optional)	

A group of experts (Sherpa's group) had made further suggestions for the set-up of PPPs: It should be possible for JTIs to support to a certain extent activities which do not directly qualify as R&D, provided they contribute to the achievement of their innovation ecosystem goals. This could for example be support for education and training or infrastructure. Do you agree with this suggestion? -single choice reply-(optional)	No opinion
The Sherpa's group had also suggested that it should be possible for JTIs to accept financial contributions, for R&D and innovation actions as well as running costs, from any reputable source, including funding agencies, public or private. Do you agree with this suggestion? -single choice reply-(optional)	No opinion

Overall

Do you have further comments? -open reply-(optional)
C4. Continued: Further obstacles include: " Overcoming an environment that does not support open innovation " Global competition; commodity base shifting (BRIC, Mexico) " Not all medicines command reimbursement or are of interest to large pharmaceutical companies G1. PPP in life science research can be expected to produce a positive impact within 5 years, only if precompetitive collaboration and transparency is improved. We are concerned that many of the questions in this survey are leading and so do not invite open answers. Furthermore the format and ambiguity of the questions has prevented us from answering questions where we hold relevant opinion. We are writing separately on this matter.