EUROPEAN COMMISSION
DIRECTORATE GENERAL FOR RESEARCH & INNOVATION

Directorate F - Health
F.1 - Horizontal aspects

Results from the European Commission public consultation about plans for a Public Private Partnership in life sciences research and innovation under Horizon 2020

30 January 2013

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1. EXECUTIVE SUMMARY AND KEY MESSAGES

The complexity of the challenge for life science research and innovation including pharmaceutical research and innovation has further increased in the past several years.

Based on the success of the Innovative Medicines Initiative (IMI), the European Commission is now exploring whether under Horizon 2020 a renewed PPP should be launched.

As part of this process a public consultation was conducted between 11 July and 4 October 2012.

The analysis of the data is presented in this document. The number of respondents, 134, is satisfactory, considering the specificity of the questions. A quantitative statistical analysis of the answers is not possible but the following considerations may be drawn:

- Respondents knew about IMI, since 74 declared to be familiar and 42 to be very familiar. The information from this questionnaire is therefore meaningful because the majority of respondents were knowledgeable of IMI ('familiar' and 'very familiar' 87%) and 29% of respondents had applied for IMI funding.
- Many of the comments indicated under the open questions related to specific research areas that are already part of the current IMI or of other initiatives on-going within the Health Directorate of DG RTD.
- In relation to PPP governance and administrative issues, a lighter approach appears as being the preferred one, consistent with the recommendation of Sherpas' report, available at http://ec.europa.eu/research/jti/pdf/jti-sherpas-report-2010_en.pdf.
- Among the various single comments, the following – from an SME – appears very relevant *"PPP offer an opportunity to translate research into products and to close the gap between academic and industrial research"*. This shows the complexity of the field, which a new PPP may address.
- In relation to improving the European industry, the respondents expressed high positive impact under the various sub-questions (related to timing): a period of ten years was considered the most appropriate (93% of respondents).

2. BACKGROUND INFORMATION AND METHODOLOGY

The on-line questionnaire for a Public-Private Partnership (PPP) in life sciences research and innovation under Horizon 2020 (the next framework programme for the period 2014-2020) was launched on 11 July 2012 and was closed on 4 October 2012. It was available at the website:

http://ec.europa.eu/research/consultations/life_science_h2020/questionnaire.pdf

All citizens and organisations were invited to submit their views and opinions. Contributions have particularly been sought from companies, organisations and researchers active in life sciences research and innovation. In addition to being published on the 'Your voice in Europe' website and the dissemination this generates, the information about the public consultation was widely disseminated. Some examples are: informing the national contact points for the Seventh Framework Programme for Research and Technology Development (FP7) Health programme, highlighting the on-going public consultation at a series of dedicated stakeholder meetings that took place during September 2012, publishing it on the IMI website and the IMI social media channels, contacting IMI project participants and sending information to a large list of stakeholder contacts of the Health Directorate of the Research and Innovation DG of the European Commission.

The consultation aimed to gather key views relating to the possible launch of a renewed PPP in the life sciences research area under the *Health, demographic change and wellbeing* challenge of Horizon 2020.

For this purpose, a comprehensive set of questions was drawn up to identify the current key challenges in life sciences innovation, the added value and potential impact of addressing these challenges via a PPP Joint Undertaking (JU) under Horizon 2020. The consultation also included questions addressing possible legal structures based on the options available under Horizon 2020 and recommendations from a high-level expert group. Respondents were moreover queried about lessons learned from the IMI JU, the world's largest PPP in life sciences, and its achievements to date.

In total 134 respondents answered the questions, but some differences about the two groups of closed and open questions should be highlighted.

For closed questions the lowest number of respondents was 102, with an average number of 126. This average does not take into account the answers about respondent's profiles, for which 134 replies were provided.

For open questions the number of answers was generally lower, as indicated in the report under the individual answers. The lowest number of respondents was 51. When 2 or more answers were provided by the same organisation, all questions have been included as different ones. This happened mainly for big organisations, e.g. CNRS or INSERM.

In relation to organisations (see chapter 3) the data have been analysed according to the group category specified by the respondents. Based on the answers provided, Commission services took the following actions:

- The category ‘Academia’ was not originally provided as an option, but representatives of Academia were extracted from the data in the post analysis; this was used to stratify the answers to some questions;
- Large companies were asked whether they were members of EFPIA (European Federation of Pharmaceutical Industries and Associations). Business organisations in the biomedical area were asked to which area they did belong. Business organisations responding that they worked in the ‘pharma’ area were all members of EFPIA also. We have received 13 answers from members of EFPIA, representing 9.7% of the replies.
- Inconsistencies have been corrected for the analysis, e.g. one anonymous respondent declared not to have applied for IMI funding but to have received funds from IMI.

Annex 1 provides graphics for all the answers analysed. Every time this occurs, a reference is made within the text. All the percentages have been calculated on the overall number of answers provided for each question (< or = 134).

The results are presented following the order of the on-line questionnaire, which was composed of 11 sections (chapters 3 - 13).

A number of limitations and uncertainties have to be taken into account.

The total answers (134), although relatively high for such a specific consultation, did not always allow organising a stratified set of answers.

The graphics inserted in the text have been selected when they appeared to be relevant, e.g. high prevalence of positive or negative answers towards the opposite. For an overview on all answers, graphics are provided in Annex 1.

The questions have been in some instance very specific, and some respondents indicated this. Respondents had the possibility to use open questions (6 out of 44) to address issues not covered by closed questions and a considerable number of respondents used this opportunity.

3. INFORMATION ABOUT RESPONDENTS' PROFILE

Questions A.1 to A.9

The distribution of respondents across EC countries is represented in the graphics below, with six EU countries - Belgium, France, Germany, Portugal, Spain and United Kingdom - that provided 66% of all answers. In terms of EU-27, 19 had at least one reply, while under "Other" (non EU-27) several replies were from Associated Countries, e.g. Switzerland and Norway.

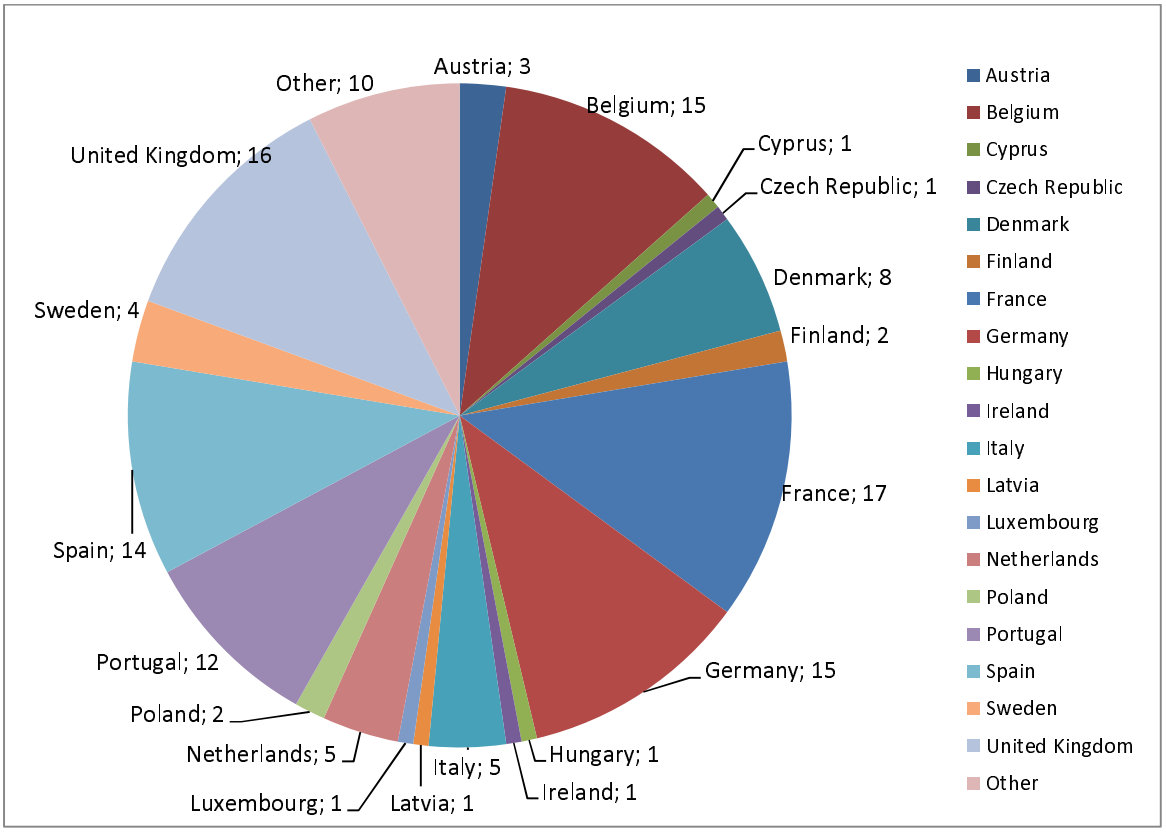


Figure 1: Country distribution of respondents (Q A.3)

In terms of organisation type, the following options were possible: Large business, Small and Medium Enterprise (SME), Business organisation in the biomedical area, Member State administration, Regional/local administration, Non-Governmental Organisation (NGO), Individual citizen and Other.

The number of respondents to Other was 37 (28%), and out of these 20 did belong to Academic organisations. As for the other 17, they were from different types of organisations such as research centres, networks of organisations, patients organisations etc.

Overall 29 respondents identified themselves as individual citizens (22%). Some of the respondents (14) were from Academic organisations.

NGOs, such as Foundations and Alliances, had the same number of respondents, 29.

Large business organisations and business organisations in the biomedical area were 19 in total, representing 14% of all organisations, while SMEs were towards the end of the scale, being 11 (8%) of the respondents.

Respondents from Member State administrations and regional/local administrations were 9 (7 and 2 respectively).

Finally, as explained in chapter 2, the new category Academia was created based on the received replies. This category takes into account respondents from various categories – Other, individual citizen, NGO – and it comprises 40 respondents, representing 30% of all replies.

Only 7 respondents (5%) declared that they did not want their contribution to be published. Their replies to open questions are therefore never mentioned in this report, but the answers are contained in the number of replies/percentages mentioned.

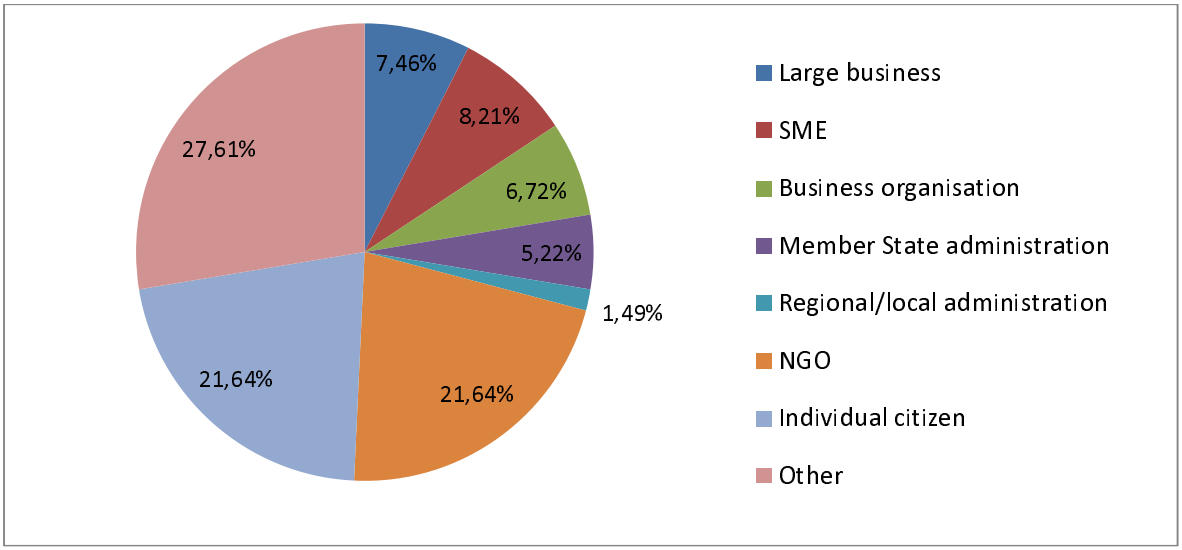


Figure 2a: Distribution by respondents' organisations (Q A.4)

The figure below presents the distribution by organisations type, with the inclusion of the new category Academia.

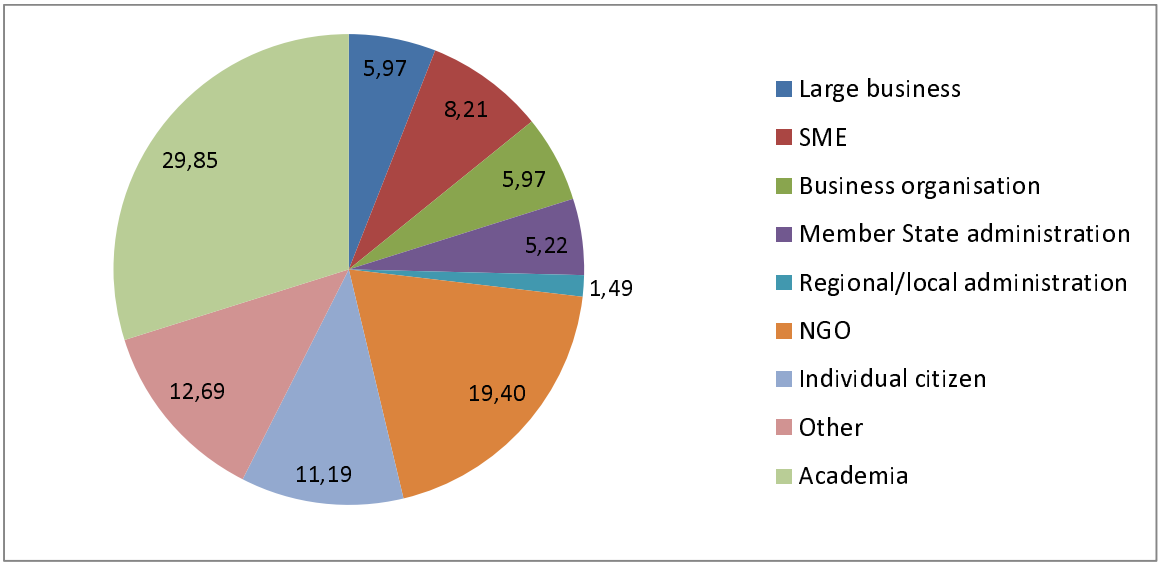


Figure 2b: Distribution by respondents' organisations with Academia (Q A.4)

The responses to some questions have been stratified using these categories.

An important observation is that respondents knew about IMI, since 74 declared to be 'familiar' and 42 to be 'very familiar'. These answers combined represent 87% of all answers. This result indicates that the knowledge of IMI was likely a driver for respondents to the rest of the survey.

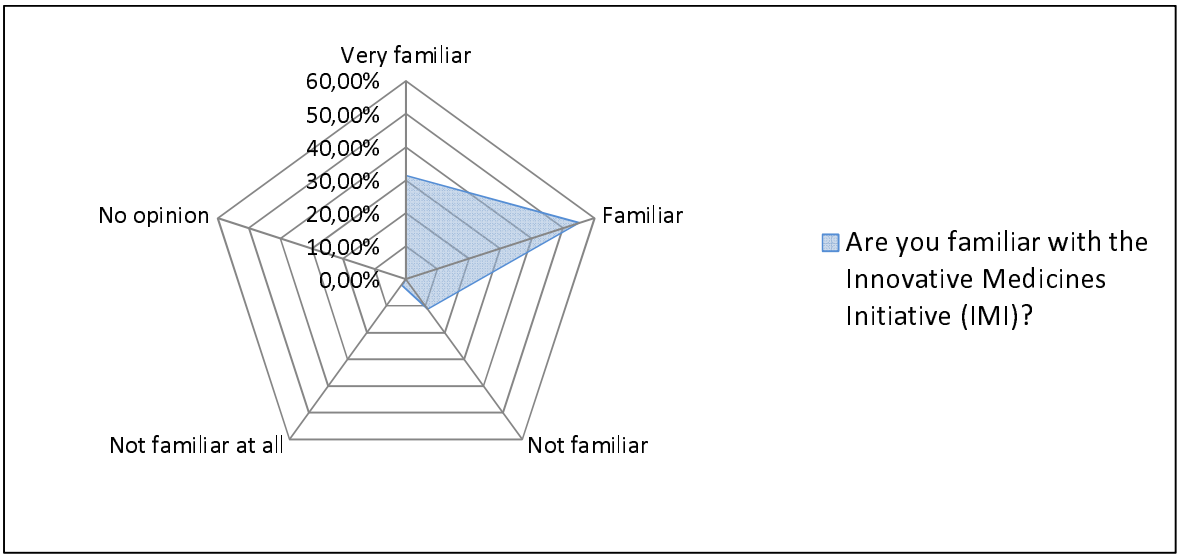


Figure 3: Degree of knowledge about IMI (Q A.7)

4. RELEVANCE OF THE LIFE SCIENCE SECTOR FOR SCIENCE AND ECONOMY

Questions B.1-B.2

This section had only two questions on the relevance of life science industry for societal challenges, such as ageing population (B.1) and European economy (B.2).

The answer to these questions is straightforward: 108 respondents think that life science industry is very relevant for addressing societal challenges, while 24 think this is relevant. All together these replies represent 98% of total respondents.

The answer to the question of the relevance of life science industry for the European economy is in line with the previous one: 105 respondents declare that this is very relevant, while 29 say that this is relevant.

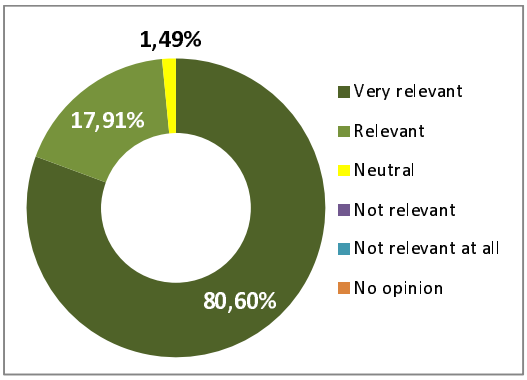


Figure 4a: Relevance of life science industry for societal challenges (Q B.1)

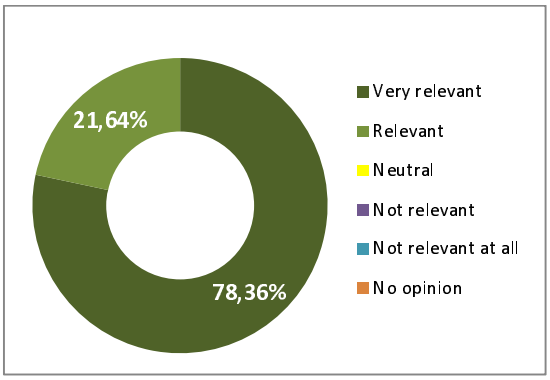


Figure 4b: Relevance of life science industry for European economy (Q B.2)

The importance of life science industry is therefore considered 'very relevant' or 'relevant' when dealing with societal and economic issues.

5. IDENTIFICATION OF THE PROBLEMS

Questions C.1-C.4

By comparing the answers to the first question of this section "How important are, in your view, the following problems for life science research to address societal challenges", the majority of respondents declared that most of the sub-questions were relevant. The two sub-questions for which there was a prevalence of "very important" are below.

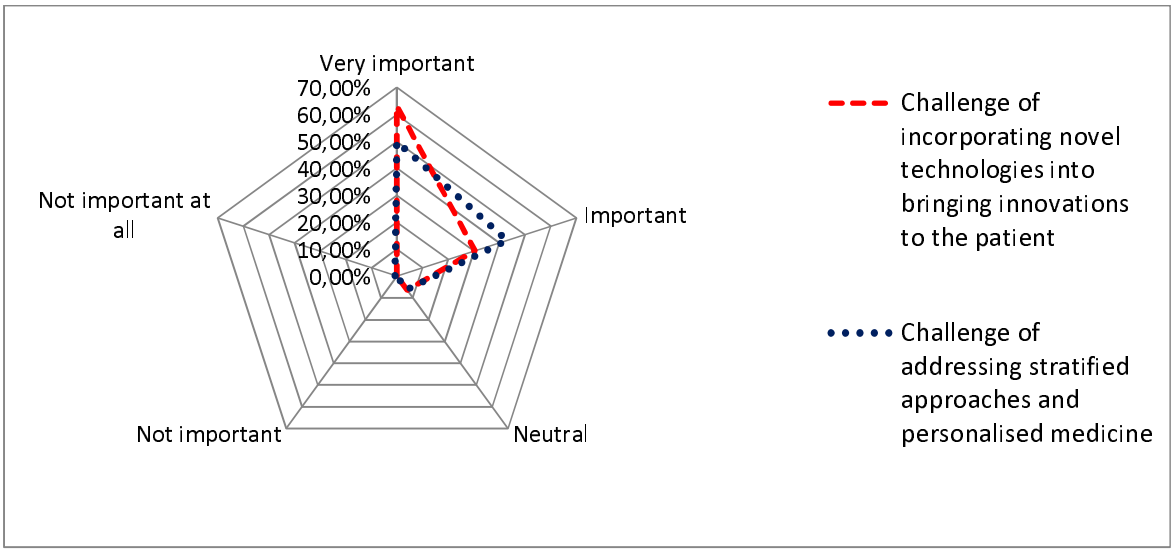


Figure 5: Importance of specific problems for life science research to address societal challenges (Q C.1)

A possible hypothesis to explain these answers is that addressing stratified and personalised medicine, and incorporating novel technologies into bringing innovations to patients, encompasses most of the grand societal challenge (treatment, diagnostic, prevention, care and health systems).

An overview for all the eight possible answers is available in Annex 1, under Question C.1.

The figure below provides the same information for Question C.1.8 "Challenges to incorporate novel technologies into bringing innovations to the patients" with answers stratified by organisation type (from 'very important' to 'neutral' since other answers were not provided). What is noticeable in this case is that 'very important' and 'important' represent 90% of all answers, while for SMEs there is the highest prevalence of 'very important' answers (82%).

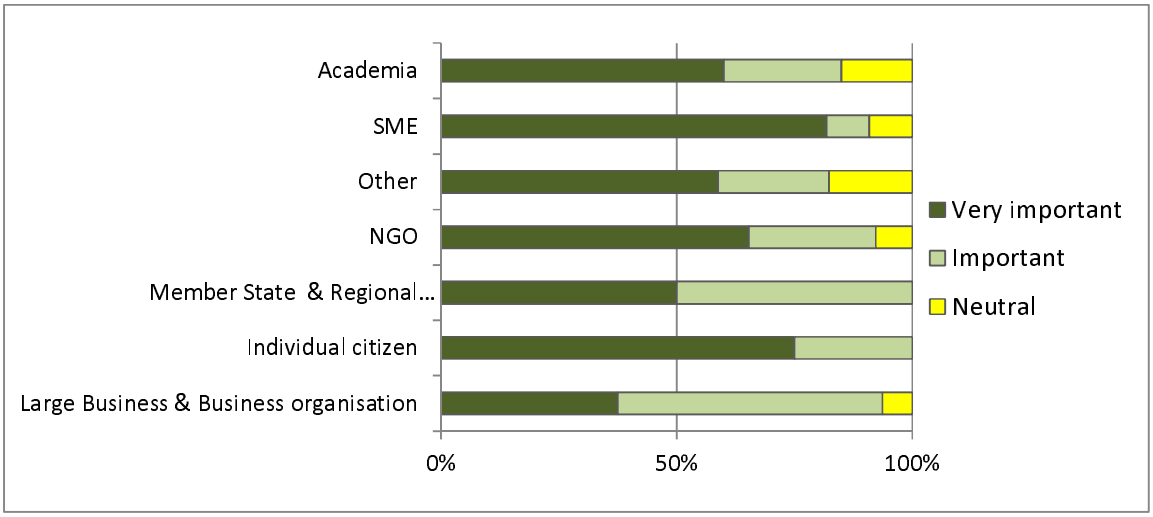


Figure 6: Importance of specific problems for life science research to address societal challenges (Q C.1.8) by organisation type

At the open question - C.2 - on "other problems for life science research to address societal challenges", the 69 replies are diverse. While some respondents specified the need of research in specific areas, e.g. infectious diseases, brain or chronic diseases**,** others underlined more general issues such as the fragmentation of national healthcare policies or the need to have clinical trials carried out not only by industries. Among the various answers, three organisations underlined the need for a partnership among large business, SMEs and public research organisations, which often remains an obstacle to do research in response of societal challenges. On the SME side, the following comment appears relevant *"Financing of SME driven research and development in Life Sciences is very difficult in Europe. PPP offer an opportunity to translate research into products and to close the gap between academic and industrial research"*.

The third question of this section (C.3) is "In your view, what are the main obstacles to bringing results of life science research to the market and to patients in Europe?".

The answers are again diverse. For example the 'lack of qualified research personnel' is considered important by 33% of respondents, while 27% considers this not important. Two issues may be highlighted: the lack of cooperation between publicly/privately funded research (88% of 'very important' and 'important') and the challenging regulatory environment.

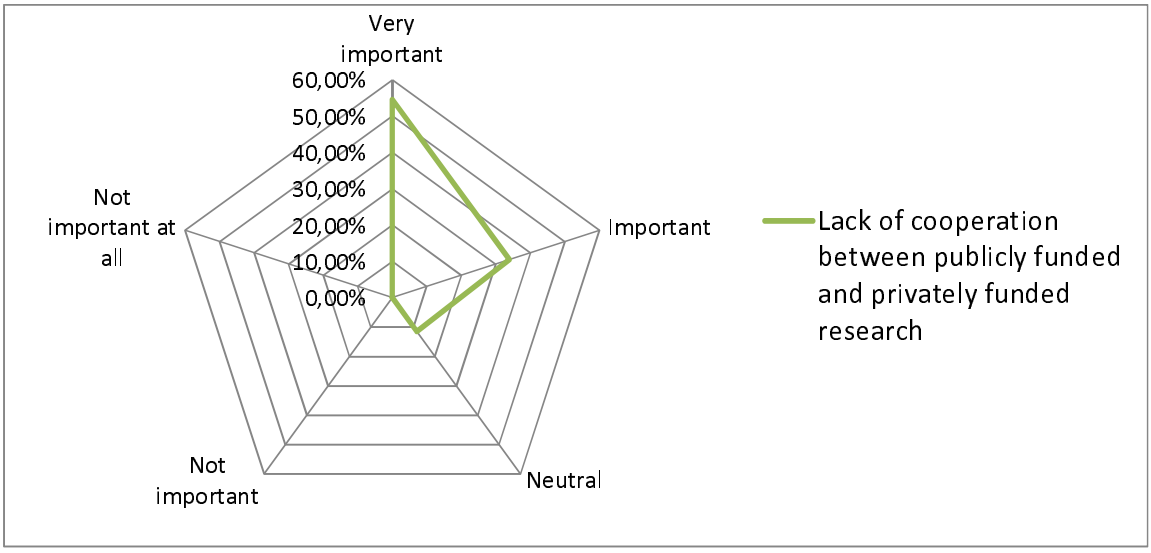


Figure 7a: Main obstacles to bring life science results to the market and to patients (Q C.3.3)

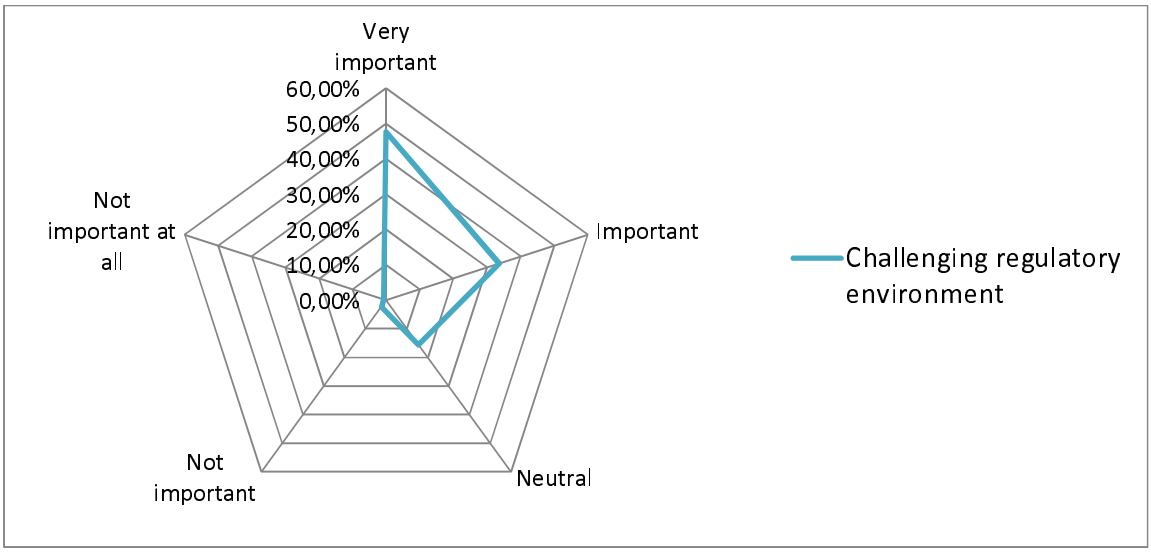


Figure 7b: Main obstacles to bring life science results to the market and to patients (Q C.3.8)

An overview of all the eight possible answers is available in Annex 1, under Question C.3.

The open question C.4 was "Do you see other important obstacles to bringing results of life science research to the market and to patients in Europe?" The 70 answers underline different types of obstacles. Several respondents declared for example that processes in the funding programmes are not designed to allow for successful translation. One German SME answered *"Cooperation with the pharmaceutical industry in early stages of research is poorly developed. Academic research usually does not attract the interest of big industry. Innovative SMEs, which enhance the academic research to a market-relevant stage, fill this gap. PPP should focus more on this enhancement."* A British SME admitted the *"lack of full economic support for SME's"*. Another interesting obstacle presented by a Danish Professor is *"the downturn of pharmaceutical*

Industry research, due in large part to the transfer of funds to marketing efforts, in a sense converting the challenge to find new drugs to old diseases to an effort to find new diseases for old drugs." CNRS found that a major obstacle is *"the lack of investment of pharmaceutical companies in Europe."* According to a Czech public administration *"the biggest obstacle is the lack of communication between researchers, clinicians and industry."* Some answers compared Europe to US. For instance one individual citizen commented that the main obstacle is *"Europe being more conservative about trying out new approaches and innovations as opposed to USA for example"*, while an anonymous respondent declared that an obstacle is due to the different requirements from the European Medicines Agency and the Food and Drug Administration for the same compound. Some industries underlined the cost containment including pressure on prices being a major obstacle.

6. EUROPEAN ADDED VALUE

Questions D.1-D.5

This chapter addresses the issue of the EU providing its support to industry.

The first three questions (D.1-D.3) refer to three possible options: a) if industry alone (no government support) can address relevant problems; b) if regions or individual countries should help industry; c) if the EU needs to step up and help industry.

The graphic below shows a general agreement with the (c) option (EU to step in), while options (a) and (b) are considered equally unacceptable. Among respondents, SMEs replied only with 'strongly agree' or 'agree' to (c) option.

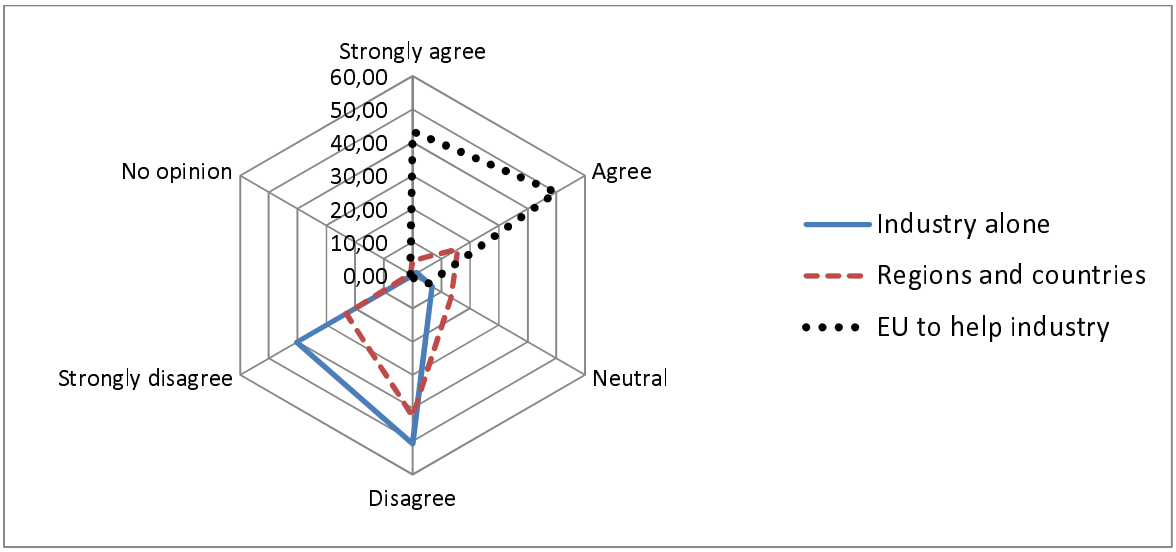


Figure 8: Entities that should address relevant problems for European added value (Q D.1-D.3)

A more detailed question (D.4) is related to question D.3 and it says "If you believe that the EU needs to step in, what should be the purpose and added value?" Apart from the suggestion on greater competition, all the hypotheses seem to be equally important, with the one on cross-sector/interdisciplinary being prevalent (higher number respondents selected 'very important'). The figure below is a summary of the three options, for which a majority of respondents declared one of the options to be 'very important'.

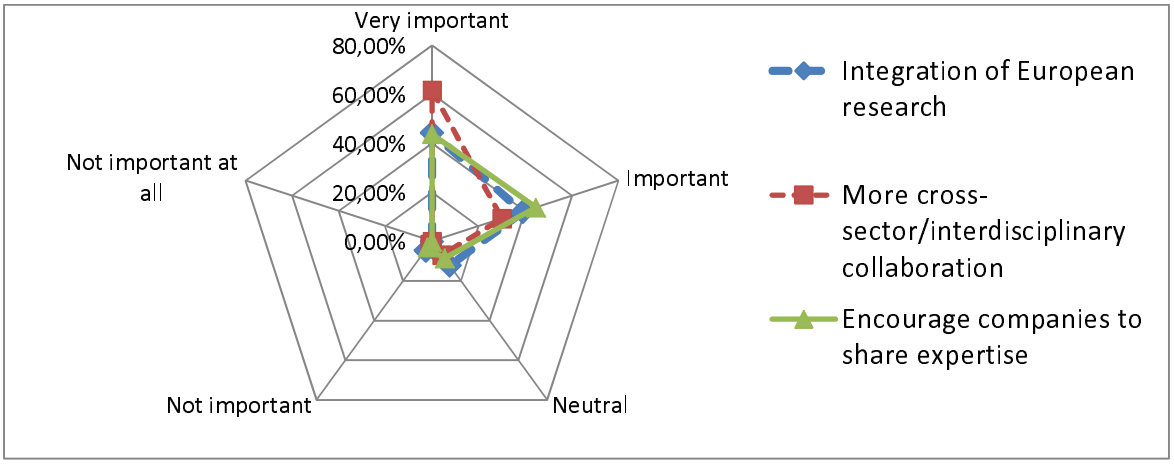


Figure 9: Purpose and added value for EU to help industry (Q D.4)

An overview of the eight possible answers is available in Annex 1, under Question D.4.

Question D.5 was an open question: "Other element of European added value you consider relevant?" Not all the 56 answers were about the European added value; several of them underlined for instance the cooperation between industry and academia. One Austrian research centre in particular claimed that *"cooperation between industry and academic research should be supported using flexible, target oriented models of support"*. A joint response from international entities added that by *"supporting innovative, collaborative research models, excellence can be promoted and taxpayers' money can be saved"*. A European platform commented on the value of *"de-risk research in Europe by complementing industrial research efforts with appropriate funding mechanisms"*. A respondent emphasised that *"without EU funding, collaborations across multiple countries are nearly impossible to support, especially at the scale needed to address the problems"*. Among the respondents, one British company said that an added value would be *"tax incentives for R&D that encourage collaboration and interaction between research and business (…) to enable academia and industry to work together in the early stages of commercial development"*. Some answers related to training and mobility. A European research centre mentioned the *"mutual recognition of R&D training to improve mobility of qualified professionals across borders"*. An Irish organisation declared that a missing element is to *"assist with networking and mobility of researchers and healthcare professionals to ensure that quality of care/research is more homogeneous across Europe. It is also important to ensure that smaller countries are not left behind in health research and access to latest discoveries and methodologies."*

Several comments dealt with development and access to new products for patients. An anonymous respondent claimed for a *"stronger involvement in risk-sharing funding mechanisms to bring therapies and diagnostics from laboratory to patient"*. A group of product development partnerships answered that *"the EU should take a stronger leadership role in supporting research to ensure that European and global public health needs are addressed, and access to resulting products ensured"*. A medical foundation highlighted the *"improved accessibility to the new products"*.

7. OBJECTIVES

Questions E.1-E.6

This chapter refers to the areas/priorities that deserve more attention and funding in Europe. Six questions were provided, of which two were open questions.

The first question refers to the agreement with the World Health Organisation (WHO) on the burden of chronic diseases. The following introduction explains the context:

"The WHO report *Priority Medicines for Europe and the World* (available at http://whqlibdoc.who.int/hq/2004/WHO_EDM_PAR_2004.7.pdf) 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? 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". The graphic below shows a general agreement ('strongly agree' plus 'agree') with an overall value of 78%.

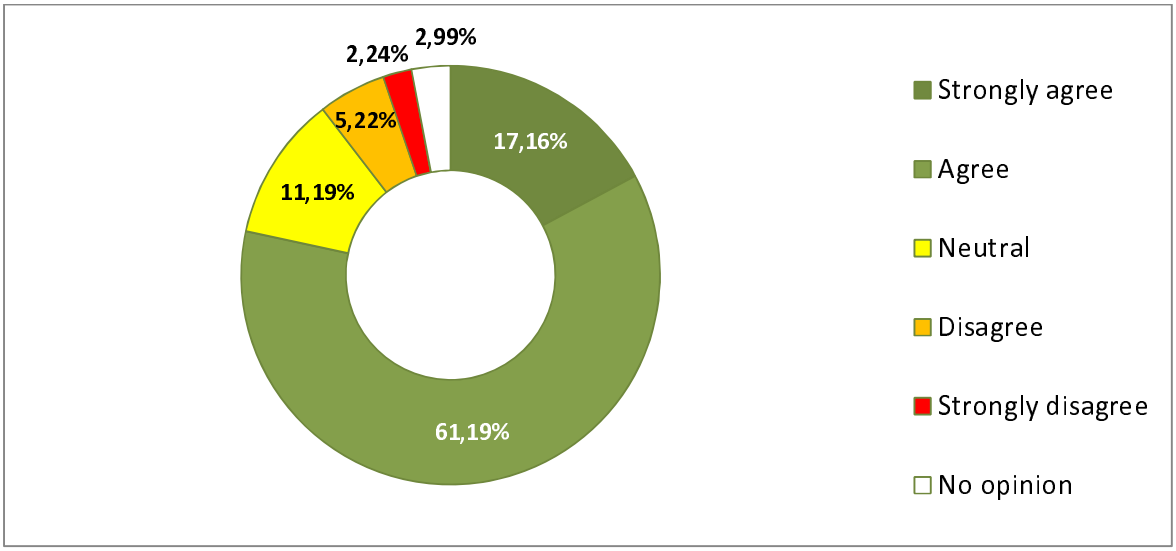


Figure 10: Agreement on the list of priority diseases of the WHO report (Q E.1)

The following question – Question E.2 "Should the Public-Private Partnership (PPP) focus on biopharmaceutical research?" – produced a balanced result, with 50% being favourable to the focus, and 44% not being favourable. Considering the replies to the following questions E3 and E4, where a number of areas to be included beyond biopharmaceutical research in a narrow sense received considerable support (see below), answers to question E2 need to be carefully interpreted.

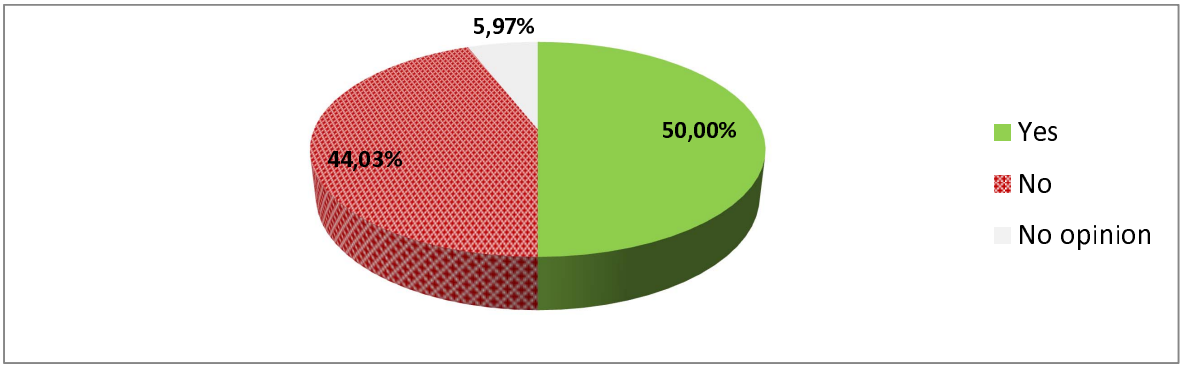


Figure 11: PPP in life science research to be focused on biopharmaceutical research (Q E.2)

The third question (E.3) provides examples in which the PPP could broaden its activities, and there is clear evidence that Diagnostics and Biomedical Imaging being the ones where the prevalence of 'very important' and 'important' is higher. The graphic below provides such evidence for these two areas.

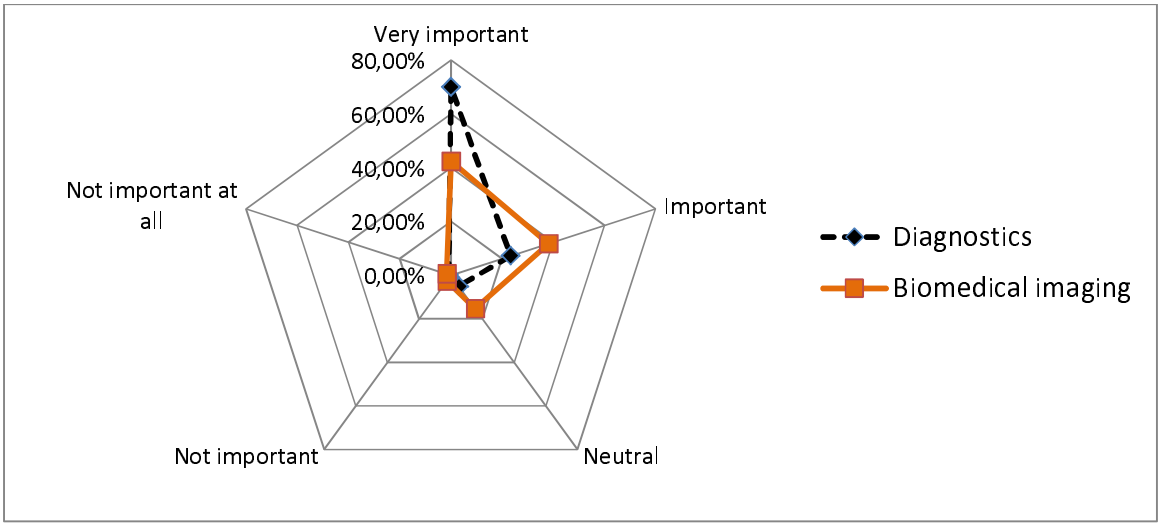


Figure 12: Important areas to be included in PPP (Q E.3.1 and E.3.3)

An overview of the four possible answers is available in Annex 1, under Question E.3.

E.4 was an open question "Do you consider other areas not yet mentioned as important to be included?" and 74 answers were received. It is worth pointing out that some areas are already covered by the current IMI.

Respondents provided answers covering different areas such as infectious diseases, metabolic diseases, mental health research, and problems affecting specific organs or tissues. Quite many answers underlined the importance of nanomedicine. In particular, a German regional network declared that *"nanomedicine, as a bridge between pharmaceutical, diagnostic, imaging and regenerative medicine area, providing new and innovative technologies to medical applications, needs to be included. Nanomedicine is seen to strongly contribute to targeted and thus*

individualised medicine". Several respondents, such as EuropaBio underlined the importance of personalised medicine. The European Public Health Alliance (EPHA) wrote that *"a balanced approach is needed to fund chronic, poverty related, rare diseases, as well as injury prevention. Data is needed for the evolution of obesity; Chronic Obstructive Pulmonary, injuries, and musculo-skeletal disorders"*.

The fifth question (E.5) provides examples in which the PPP could focus its activities. Two areas have the highest rate of 'very important' and 'important' answers (above 88%). The graphic below presents values almost overlapping.

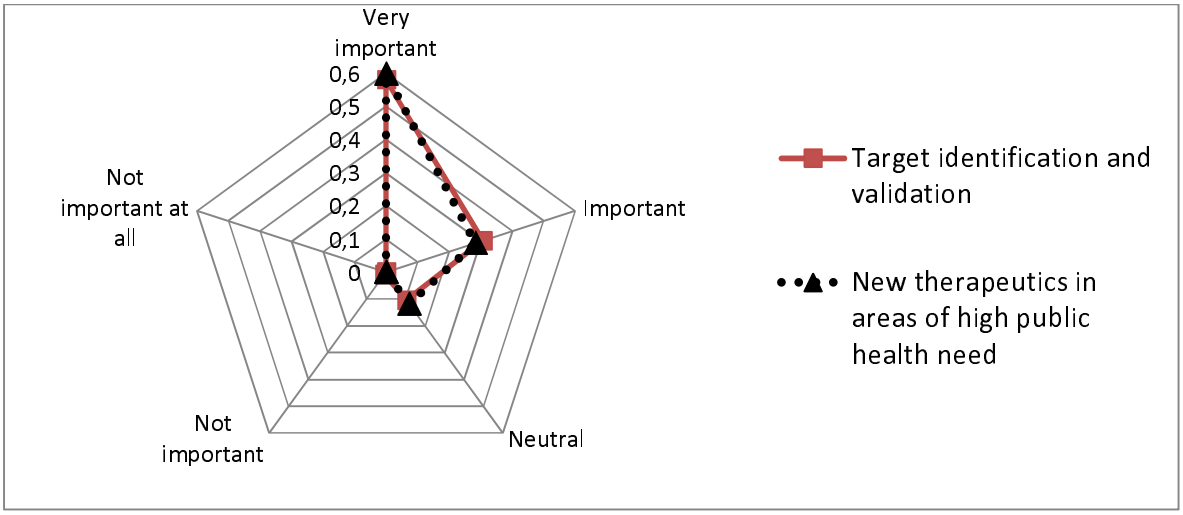


Figure 13a: Importance of specific objectives for a PPP in life sciences in Horizon 2020 (Q E.5.2 and E.5.5)

The priority for vaccines is relatively lower, taking into account the prevalence of 'neutral' among respondents, yet also for this a clear majority is in favour of including these areas and the percentage of negative responses is very low.

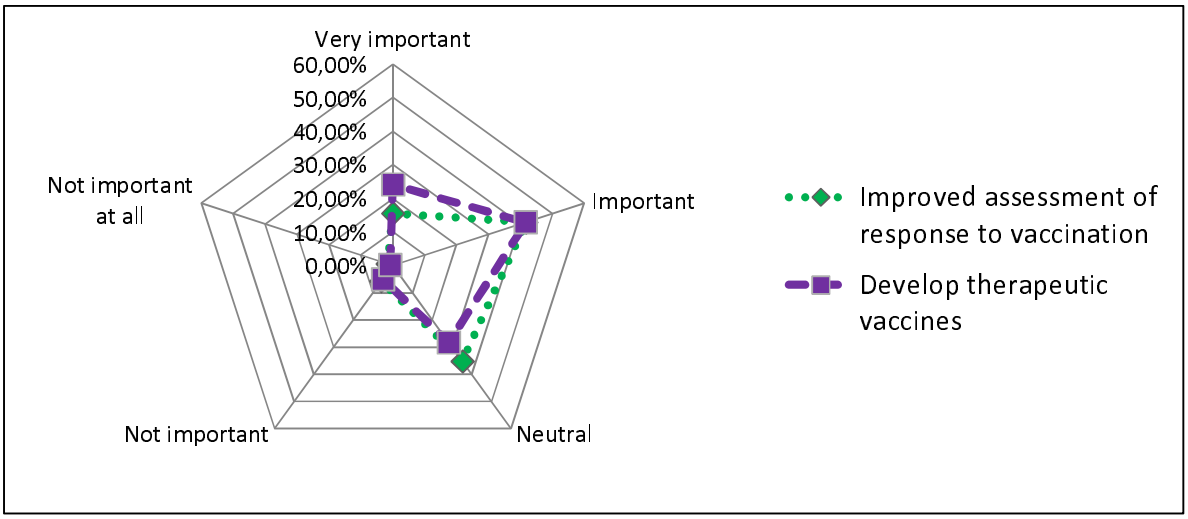


Figure 13b: Importance of specific objectives for a PPP in life sciences in Horizon 2020 (Q E.5.8 and E.5.9)

An overview for the ten different answers is available in Annex 1, under Question E.5.

E.6 was an open question "Other objectives you consider relevant for a PPP in life sciences under Horizon 2020?" and 51 respondents provided an answer to it.

The European Patients' Forum declared that there should be *"increased transparency about research and (positive/negative) results of research projects, e.g. open-access publication of data of publicly funded research, and provision of patient-friendly information about results of life science research, so it can also be leveraged by patient organisations"*. A Professor from INSERM mentioned specifically *"translational research, Phases I/II clinical trials, development of candidates vaccines, correlates of protection"*. The Group of Product Development Partnership responded that *"in addition to development of new therapeutics in areas of particularly high public health needs in Europe and globally, the PPP should also address preventive tools, and diagnostics. It should also support global technology transfer between different actors"*. A Spanish Foundation underlined the importance of some specific research areas, in particular *"research in paediatric population, rare diseases, mental health and infectious diseases"*. TOPRA, an organisation for regulatory affairs, underlined the need for *"tools for efficient clinical research conduct and design; better understanding of regulation (training) and development of a regulatory framework to match scientific advances"*.

8. OPTIONS

Question F.1

In this chapter respondents were given the possibility to choose among various options of partnership, including the establishment of a new PPP.

Among the five options, the only one that emerges with a prevalence of 'very much preferred' plus 'preferred' is the one on expanded scope and simplified implementation, while for the four other questions, the respondents expressed diverse answers.

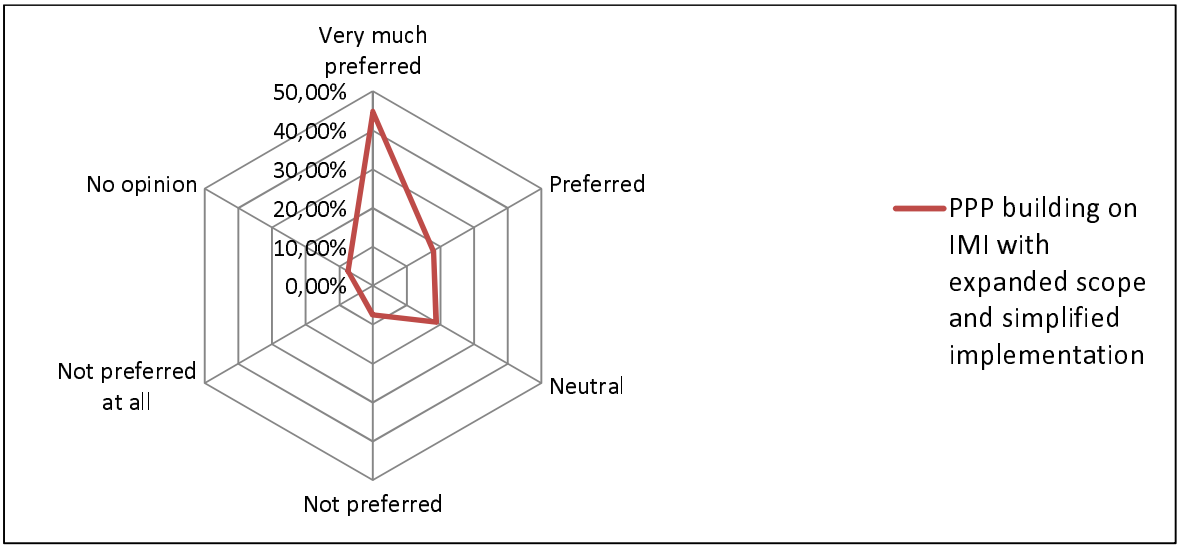


Figure 14: Options to continue after the Innovative Medicines Initiative (Q F.1.4)

An overview of the five possible answers is available in Annex 1, under Question F.1.

The graphic below presents the same information, but with stratification by type of respondent. The business organisations in the biomedical field and the large business are the ones with the highest prevalence of positive replies towards the option of building the new PPP on IMI with expanded scope (93% of replies with 'very much preferred' and 'preferred').

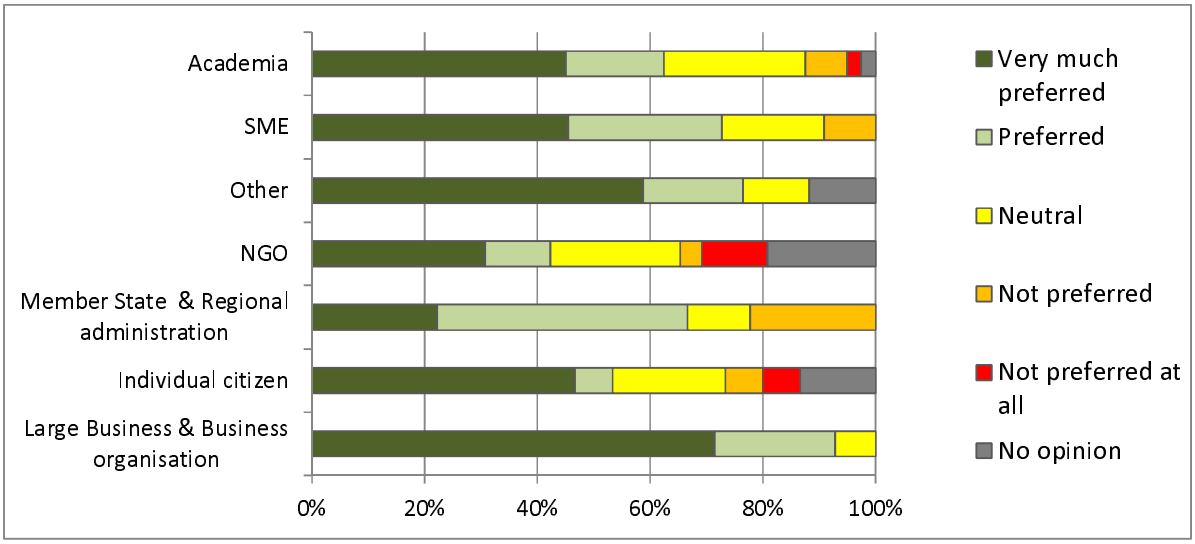


Figure 15: Options to continue after the Innovative Medicines Initiative (Q F.1.4) by organisation type

9. IMPACTS

Questions G.1-G.3

The impact was evaluated at three different levels: competitiveness of European industry, SMEs and social/environmental impacts.

In relation to improving the European industry (Question G.1), the respondents expressed high positive impact under the various sub-questions (related to timing). A period of ten years (medium term) was considered the most appropriate. This is reflected in the graph below.

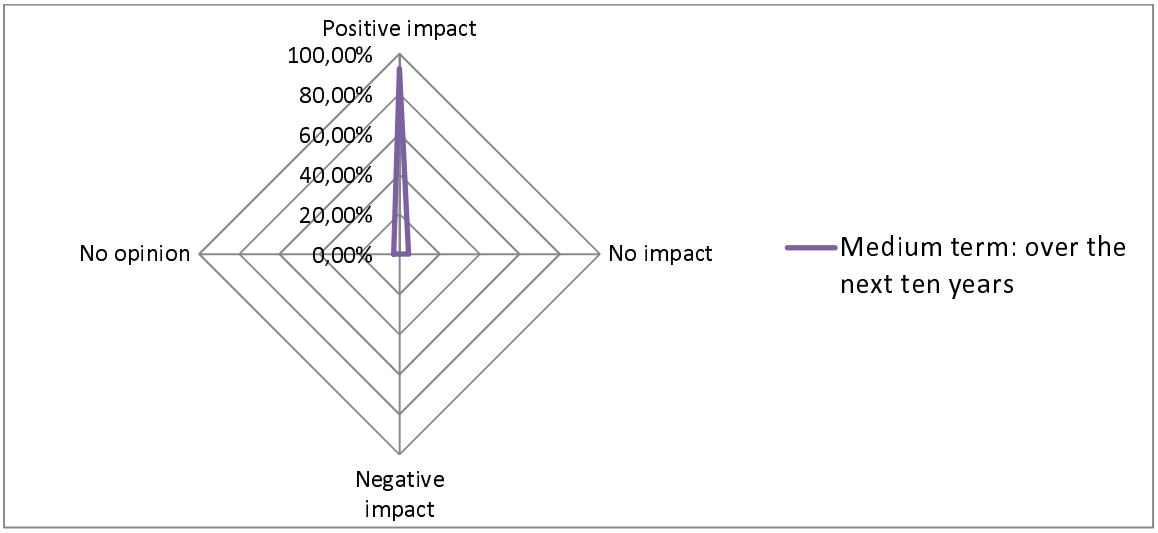


Figure 16: Period for PPP to have an impact on Europe's life science industry competitiveness (Q G.1.3)

An overview of the four possible answers is available in Annex 1, under Question G.1.

As for the impact on SMEs (Question G.2), there is not much difference between the two types of industries suggested, and overall the impact is positive.

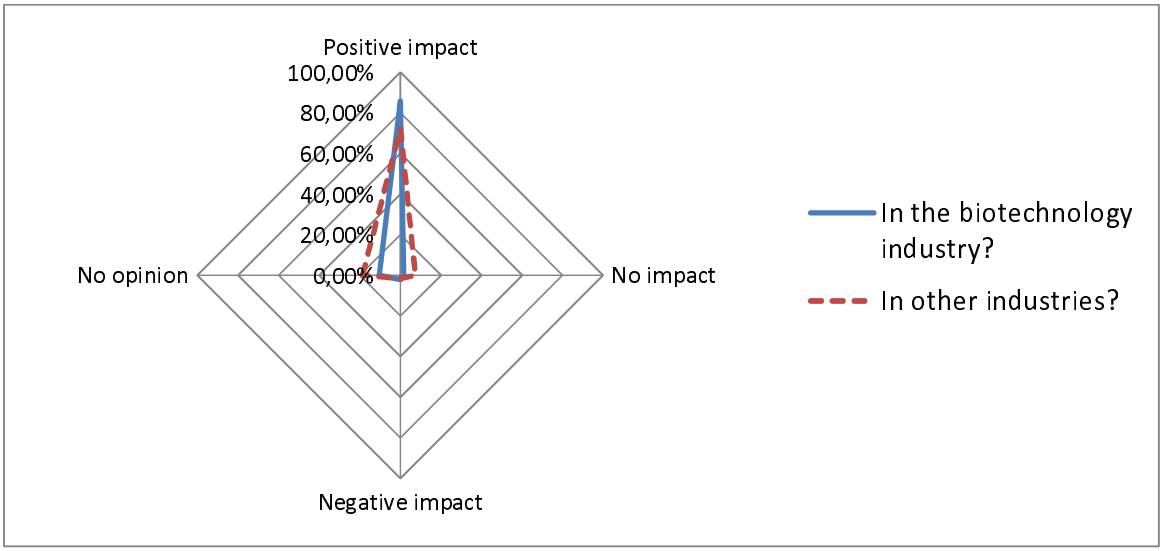


Figure 17: Potential impact of PPP on SMEs (Q G.2)

The question on the social and environmental impacts (Question G.3) shows a high degree of positive impact for some of the issues indicated. In particular, jobs, public health, and education and mobility of research workers have shares of positive impact higher than 85%. The area in which the PPP has lower impact is the environment (only 28% positive impact), and this may be due to the life science research area of the PPP. The graphic below shows jobs (the one with highest impact) comparing it to potential impact on health care costs.

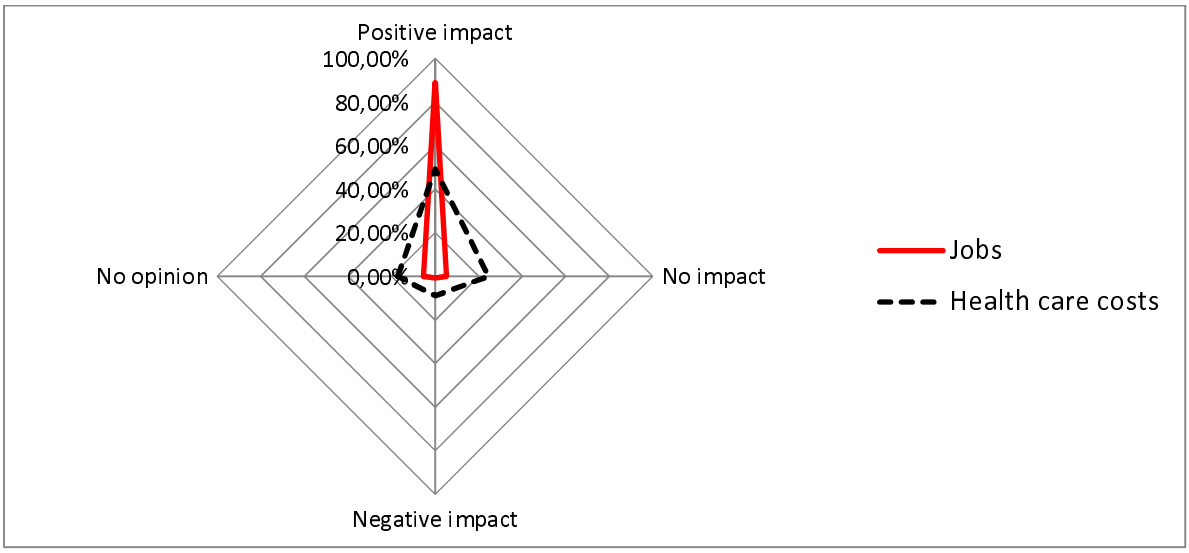


Figure 18: Areas for PPP to have potential social or environmental impacts (Q G.3.1 and G.3.4)

An overview of the eight possible answers is available in Annex 1, under Question G.3.

10. ACHIEVEMENTS OF THE ON-GOING INNOVATIVE MEDICINES INITIATIVE (IMI)

Questions H.1-H.2

This chapter asking questions about IMI is made of two questions. In both questions, at least 127 out of 134 respondents provided an opinion. Respondents were mainly 'familiar' or 'very familiar' with IMI.

In question H.1 the answers go in different directions (from 'strongly agree' to 'strongly disagree'), with a rather large number of responses on 'neutral'. Nevertheless, with the exception of the specific question H.1.6 "Has IMI effectively engaged with SMEs in relevant sectors?" where the same amount of respondents (approximately 20%) agreed and disagreed, for all other possible answers there is a relative majority agreeing or strongly agreeing with the proposed possible answers. The issue on which there is clear prevalence of similar answers is the one on the possibility for IMI to bring together relevant stakeholders, for which 'strongly agree' and 'agree' account for 68% of total answers.

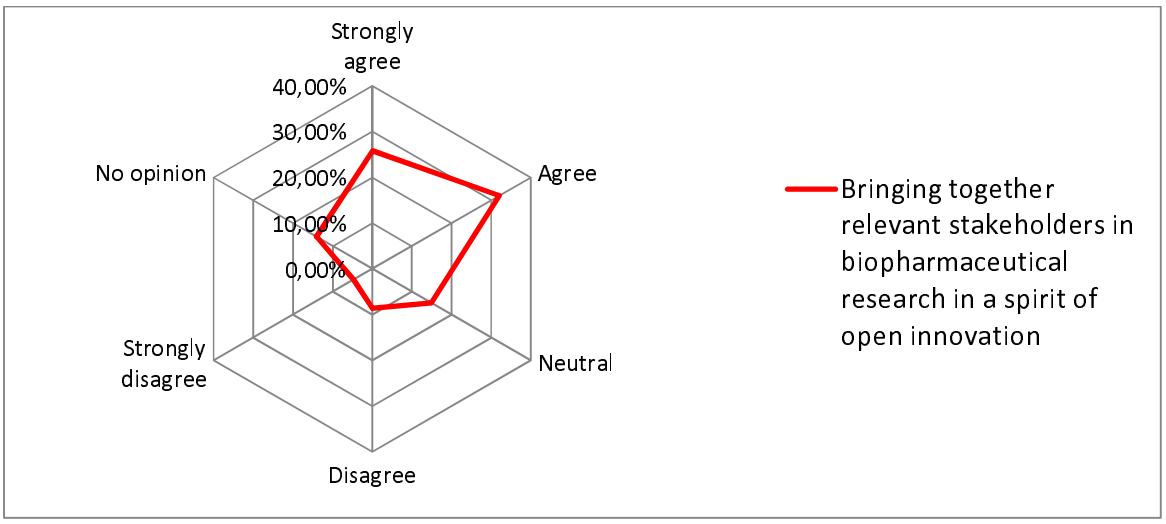


Figure 19: Areas in which IMI succeeded (Q H.1.3)

An overview of the six possible answers is available in Annex 1, under Question H.1.

The graphics below provide a deeper analysis, linking this specific question H.1.3 to the knowledge with IMI and to those respondents who got funds from IMI.

When linking question H.1.3 to question A.7 (Are you familiar with IMI?) the 'very familiar' respondents had mainly 'strongly agree' and 'agree' type of answers, while the familiar respondents, although more numerous, had more scattered replies. The 'non familiar' respondents gave very few replies, mainly in the area of 'no opinion'.

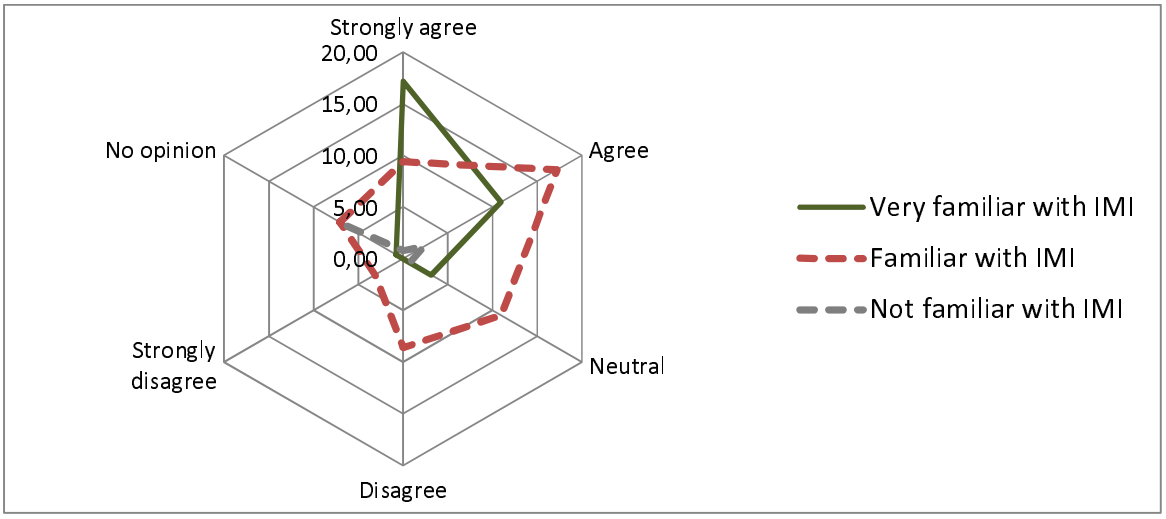


Figure 20: Link between familiarity to IMI (Q A.7) and share of agreement to Q H.1.3

In relation to the 39 respondents who said yes to question A.8 (Have you applied for funding from IMI?), there is clear majority expressing agreement with the answer H.1.3 (71% of 'strongly agree' plus 'agree').

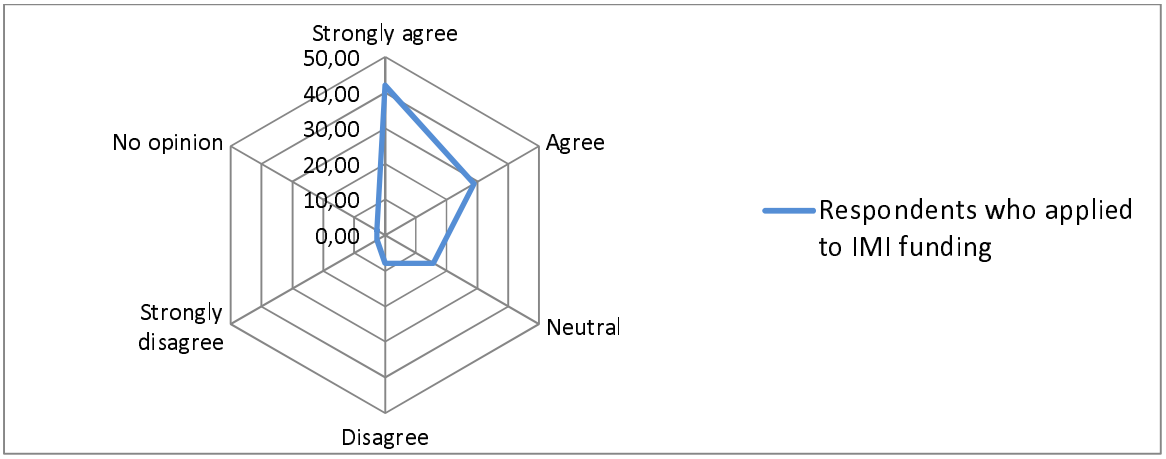


Figure 21: Link between respondents who applied to IMI (Q A.8) and share of agreement to Q H.1.3

In relation to the question if IMI projects have produced scientific successes (Question H.2), there is a high prevalence of 'no opinion', and this may be understandable given the relatively short life of IMI projects. On the other hand it has to be noted that 'strongly agree' and 'agree' (58%) prevail on 'disagree' and 'strongly disagree' (8%).

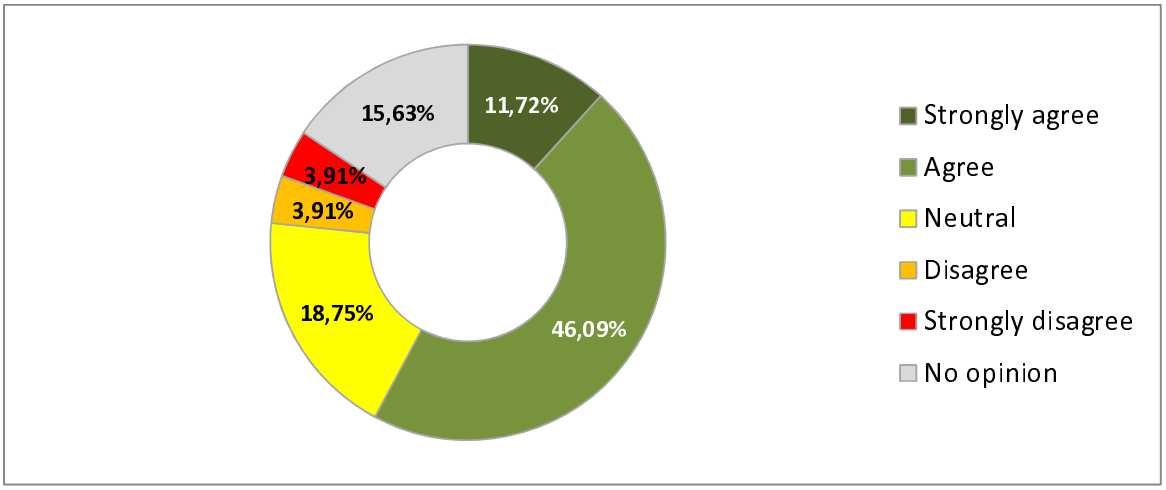


Figure 21: IMI projects have produced scientific successes (Q H.2)

11. LESSONS LEARNED FROM THE ON-GOING INNOVATIVE MEDICINES INITIATIVE

In relation to this chapter, it has to be pointed out that the separate consultation of lessons learned for IMI participants represents direct feedback, while responses from other respondents to this public consultation represent a perception of the IMI programme.

This chapter consisted of two parts, listed below.

11.1. Involvement of SMEs and large industry

Questions I.A.1-3

This chapter intends to get answers on the involvement of SMEs and industry, but also on the contribution of private companies.

The first two questions (Questions I.A.1 and I.A.2) are on whether the PPP in life science under Horizon 2020 should ensure a better involvement of SMEs or large industry. The answers provided are not straightforward, but certainly highlight higher expectation of greater involvement of SMEs as compared with large industry. SME respondents were, as expected, quite favourable, with 8 out of 11 respondents declaring to 'strongly agree' and 2 to 'agree' to a better involvement of SMEs in a new PPP.

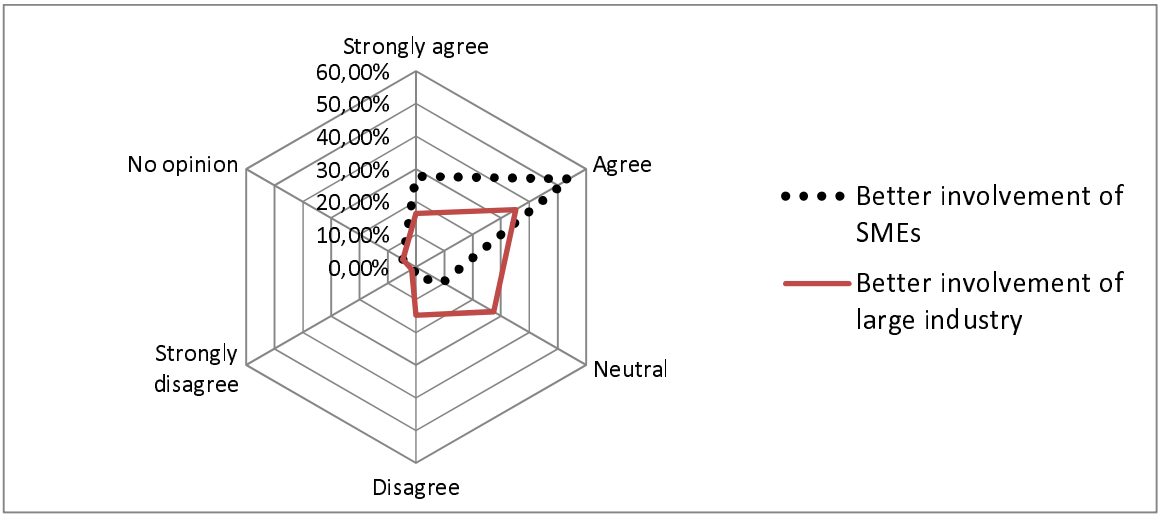


Figure 22: What a PPP in life science research should ensure (Q I.A.1 and I.A.2)

There is strong agreement (Question I.A.3) on the way industry should contribute to the partnership, with 90% of respondents agreeing on a mixed in-kind and cash contribution.

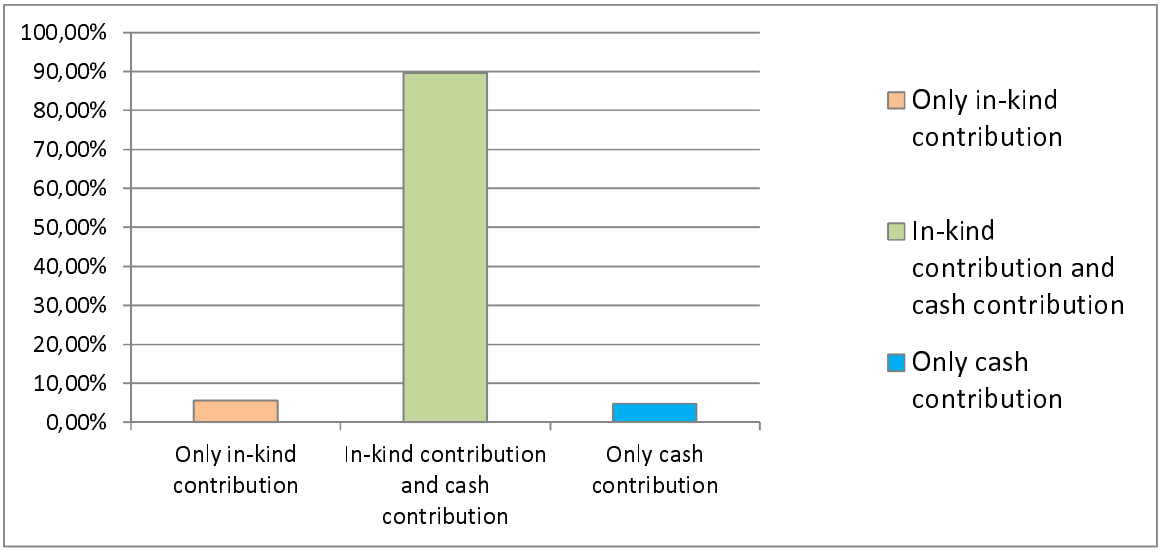


Figure 23: Preferred contribution of industry to life science PPP (Q I.A.3)

11.2. Evaluation of proposals at IMI and selection of Expressions of interest

Questions I.B.1-4

The Question I.B.1 is about the way IMI has been carrying out the evaluation of proposals. On the issue of transparency the situation is not very clear, with all the possible answers from 'strongly agree' to 'strongly disagree'.

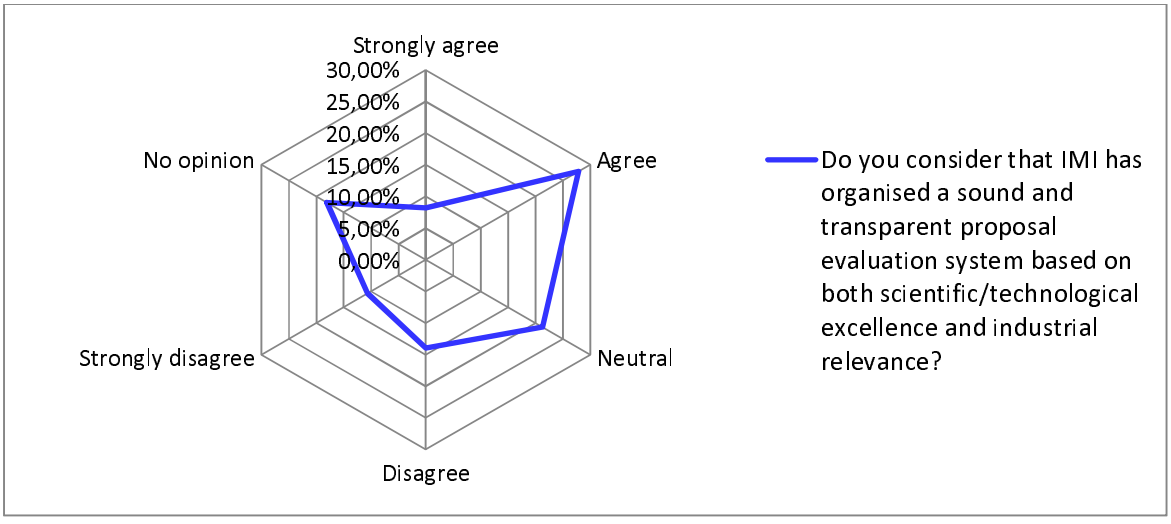


Figure 24: Opinion on the organisation of IMI proposal evaluations (Q I.B.1)

The three last questions (I.B.2-I.B.4) of this chapter refer also to the methodology used under IMI. The first of this group is about the appropriateness of the two-stage approach, the second on the possibility to merge two or more highly ranked proposals and the third on the option to have

various consortia starting in parallel, but decide after one or two years on the one to bring forward. According to the respondents, the clear-cut situation is the one referring to the possibility to merge two or more highly-ranked consortia, while the two other options have very similar values of 'yes' versus 'no'.

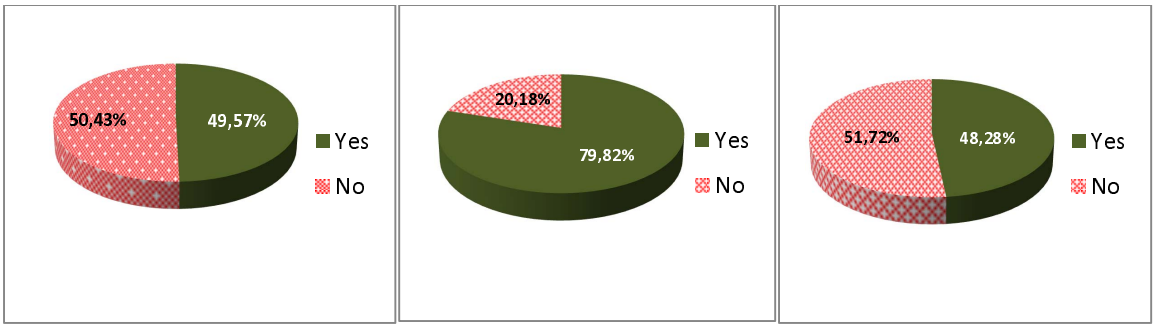


Figure 25: Opinion on use of 2-stage evaluation (left), possibility to merge proposals (centre) and possibility to stop a consortium after 1-2 years (right) (Q I.B.2-B.4)

12. ADMINISTRATIVE/LEGAL SET-UP OF A PPP UNDER HORIZON 2020

Questions J.1-J.4

This chapter is quite specific since it implies the knowledge of the Sherpa's report. This report of the JTI Sherpa's Group was set up to take stock of the first experience with setting-up Joint Technology Initiatives (JTIs) under FP7.

The questions are therefore very specific and related to the implementation of IMI. The percentage of respondents is around 76%.

Question J.1 is about an opinion on the legal structure of IMI, which enjoys the same rights and obligation of an EU Institution. The answer does not provide a clear direction, but probably indicates the limited knowledge of the specific issue. Nevertheless, the higher percentage of answers is 'positive' (39%)

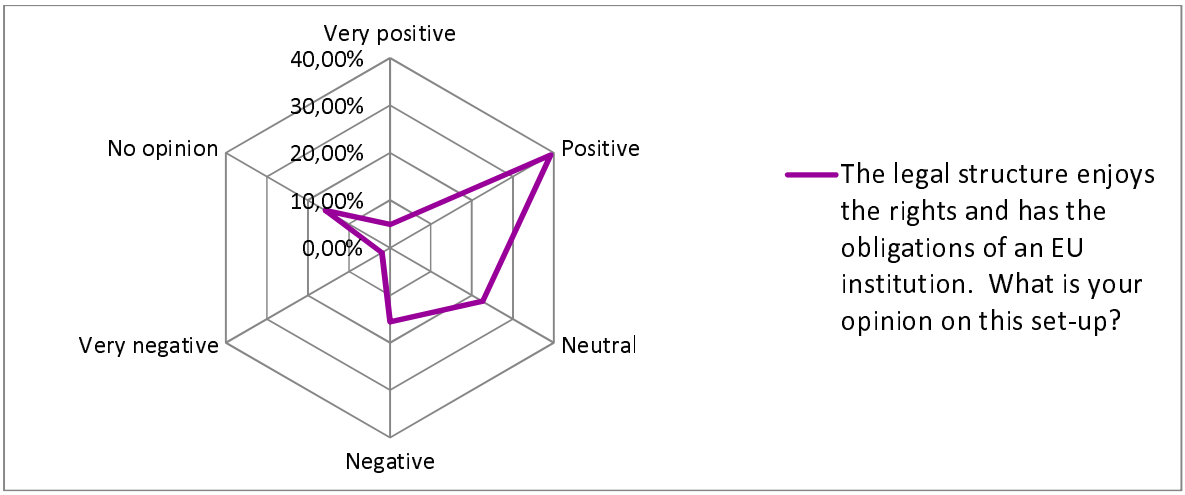


Figure 26: Opinion on the current administrative/legal set-up of IMI (Q J.1)

The type of answer is confirmed on the next question (Question J.2), which presents three different cases. The answers, although quite scattered, show that the proposal of a dedicated legal structure but with a lighter approach is the favourite one (higher number of 'preferred' and 'very much preferred' answers).

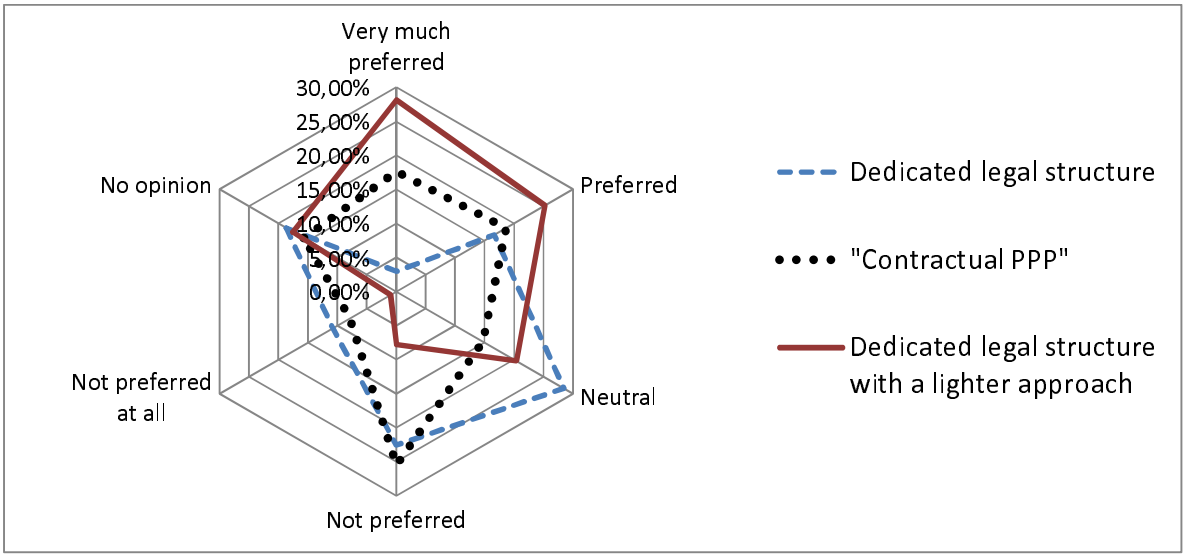


Figure 27: Preferred option for the new PPP (Q J.2)

The answer is however clearer on the third question (Question J.3), which is if a JTI might support also activities that do not qualify as R&D (e.g. education and training or infrastructure). The answers 'agree' and 'strongly agree' cumulate in this case to 65%.

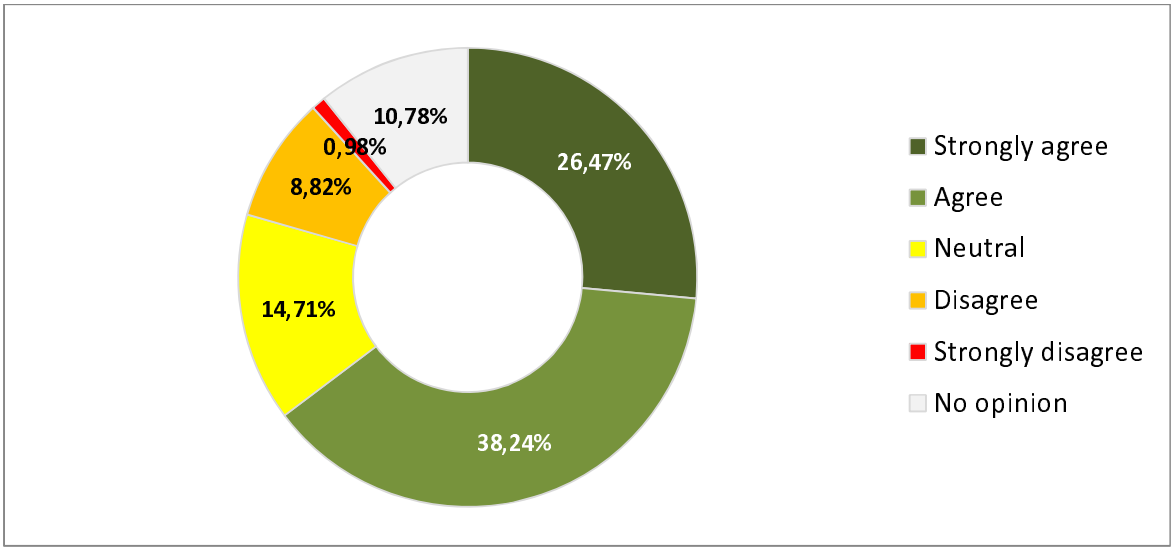


Figure 28: Opinion of activities such as education and training for the new PPP (Q J.3)

The final answer in this chapter (Question J.4) is about the possibility to accept financial contributions from other sources, such as funding agencies (public or private). The overall appreciation is positive with 'agree' and 'strongly agree' accounting a total of 75%.

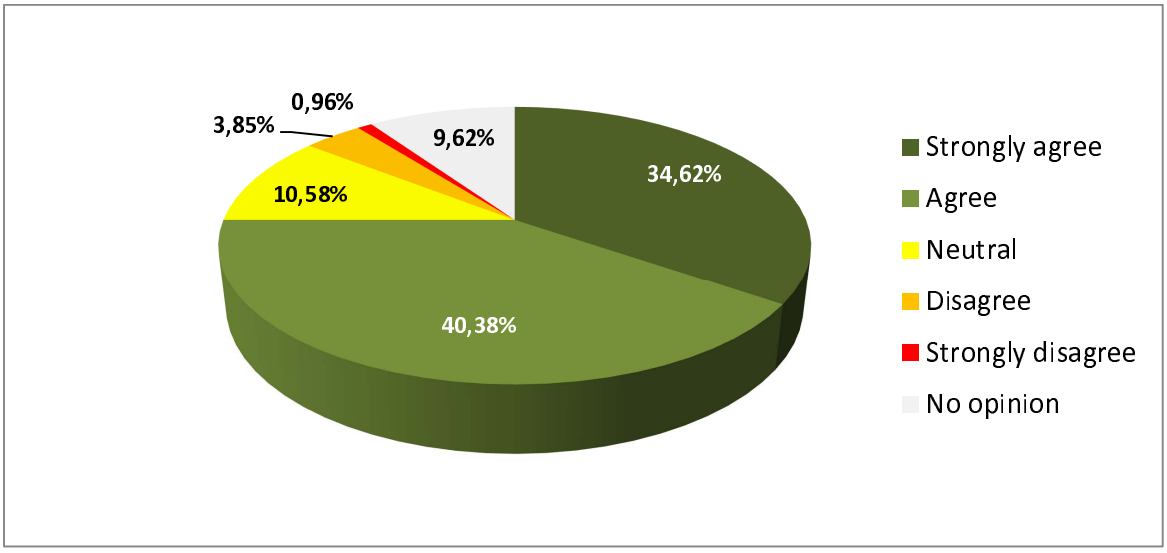


Figure 29: Opinion for JTI to accept financial contribution from any reputable source (Q J.4)

13. OVERALL

The final open question K.1 was "Do you have further comments?" to which 55 respondents provided a feedback.

The answers provided were mainly on what should be improved, or included, in a new PPP, and covered a wide array of aspects, including:

- PPP governance and administrative issues;
- Nature of the partnership;
- Strategic research agenda (SRA), and suggestions on diseases/challenges, as well as on technology/tools focus;
- Specific comments around SME involvement.

Regarding governance, structure and related issues, most of the respondents praised for a lighter and more flexible structure. ETP Nanomedicine, for instance, replied that *"it will be fundamental to establish a flexible structure for the forthcoming PPP in order to allow for the inclusion of newly arising topics in the lifetime of the PPP and the framework programme"*. Another answer in this direction was from the European Patients' Forum *"current IMI rules do not reflect flexibility required in today's working models. The lack of eligibility of VAT in IMI even for NGOs unable to redeem VAT turns out to be a major financial issue for patient organisations engaging in IMI projects"*. The opinion of TI Pharma, a Dutch PPP in biopharmaceutical research, is that, *"governance structures should be set-up based on the partners involved, the identified results and the timeframe allocated. "One-size-fits-all" is clearly not the best way forward and thus an overarching PPP mechanism that allows for flexibility – especially with regard to administrative procedures – is needed"*.

Concerning the nature of the PPP, a British SME answered that *"IMI is too big pharma driven and hence new approaches are not embraced. The European pharma industry model is broken and IMI does not seem to be making any impact on fixing the problems. Open research collaborations are required between academia, pharma/biotech, government and independent organisations where the best approaches to address a problem are welded together to produce a coherent and innovative research programme"*. EORTC commented that *"the independence of IMI from pharma should be reinforced"*.

Several respondents emphasised areas (disease, technology, etc.) that should be included in the new PPP. The European Society of Radiology claims that *"currently IMI is focused on the development of pharmaceuticals and vaccines and does not cover the area of imaging, for which a PPP approach would be much needed in Europe. (…) New disease targets should be approached by network collaboration where imaging (new imaging devices/new imaging biomarkers/molecular imaging) will allow a fast, repeatable and accurate non-invasive evaluation. Collaboration between industry and academia would be extremely beneficial for advancing the field"*. BioMed Alliance *"emphasised the need to move away from disease-specific approach. Patient is central. This is the point of departure for personalised medicines"*. Some

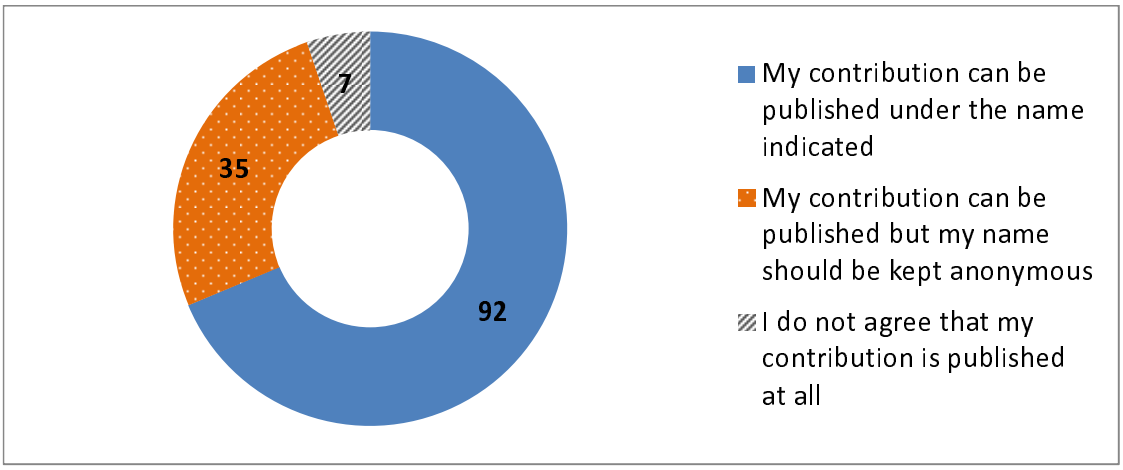
organisations expressed concern for the risk of no funding available to support product development efforts on poverty-related and neglected diseases.

Several aspects were frequently mentioned when the answers considered the involvement of SMEs. EuropaBio said that *"it is important to streamline, simplify and make the future system more flexible and more SMEs friendly: SMEs have limited access to research funding due to the fact that the current system is too bureaucratic and too complex"*. INSERM's and CNRS' response was that *"a reflection is to be conducted between EFPIA members, the European Commission (EC) and Member States on points where adjustments are necessary such as the definition process of scientific and technological priorities, the implementation modalities, the projects selection procedure, the interactive tools which will permit SMEs to participate to IMI, and the EC financing to SMEs to build up their proposal"*. One of the comments of a German SME was "*In relation to the participation of SMEs, a big problem is the omission of companies that no longer meet the criteria for SMEs, but are also not among the EFPIA companies. These companies could partner theoretically in IMI projects, however, the incentive is relatively low, as there is no funding option (such as SMEs), but also no possibility of participation (such as for EFPIA companies). Here a change would be desirable to allow either a promotion or a right of co determination for these companies.*"

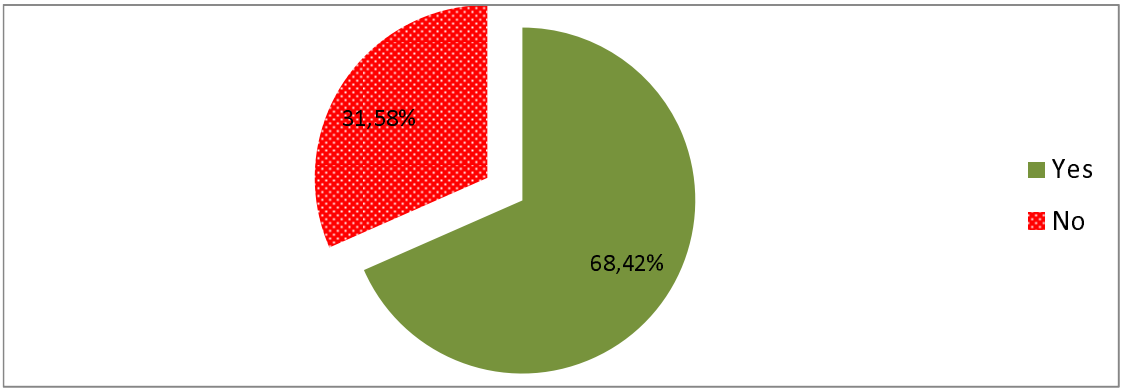
Finally, other respondents used this section to reinforce the value of PPP with due changes. The answer from a researcher at INSERM was that *"the setup of a stronger PPP in life sciences is mandatory for the medium term survival of the EU biotech industry"*.

14. ANNEX 1: GRAPHICS

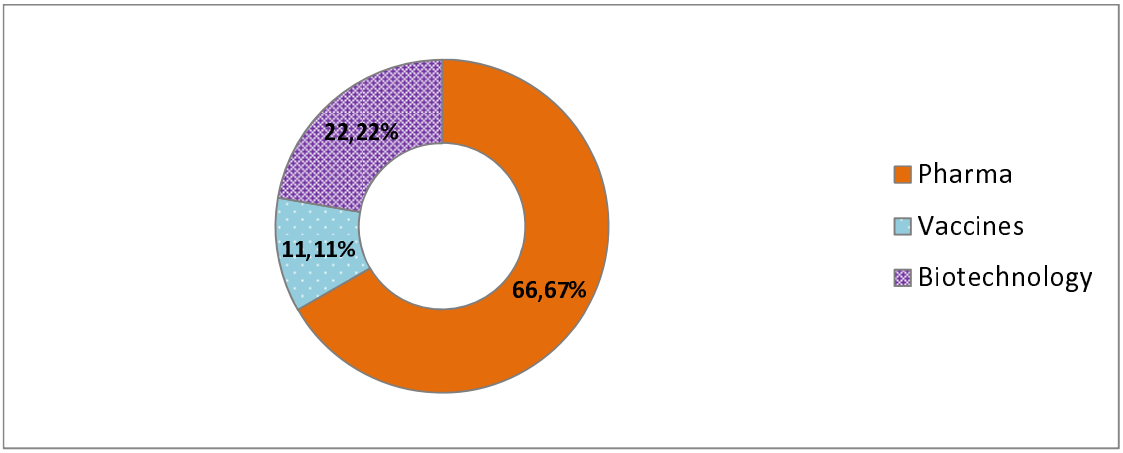
Question A.2: "Do you agree to your contribution being published under your name"?



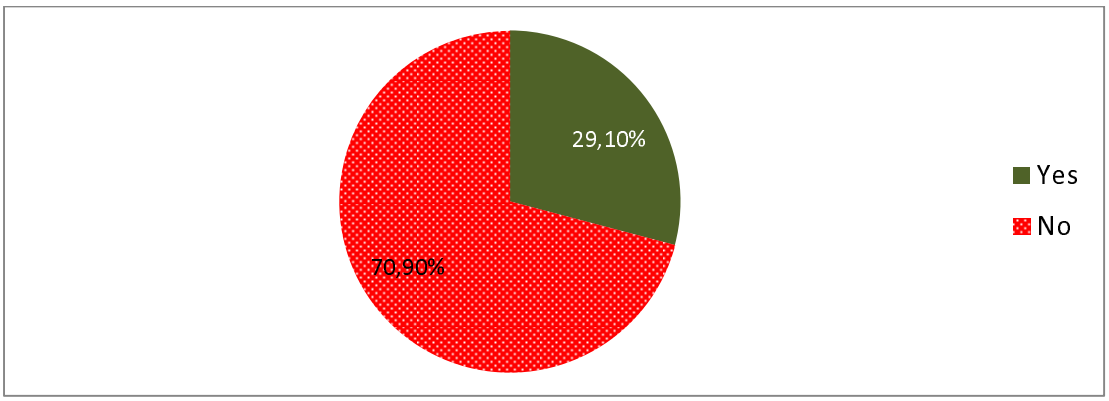
Question A.5 "Member of EFPIA" (this Question applied only to respondents belonging to Large business)



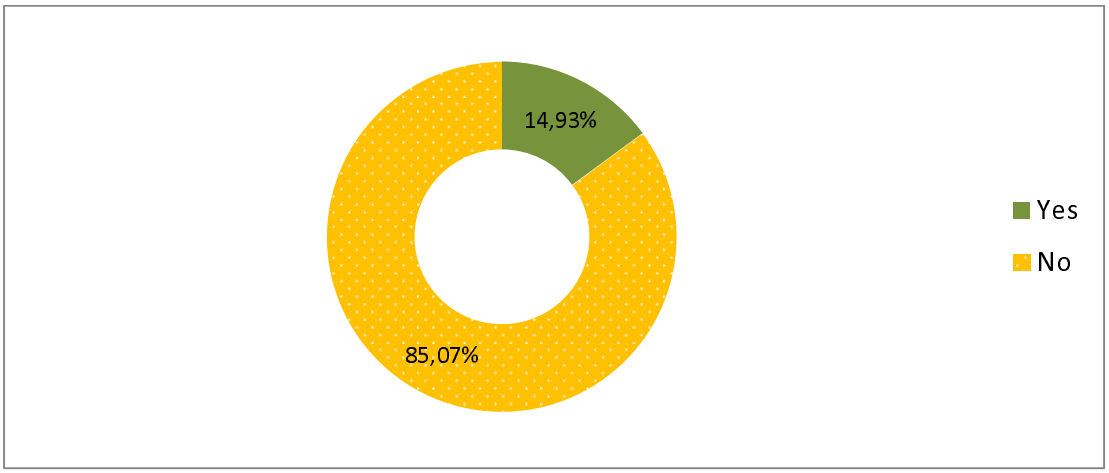
Question A.6 Business area of Business Organisations in the biomedical area



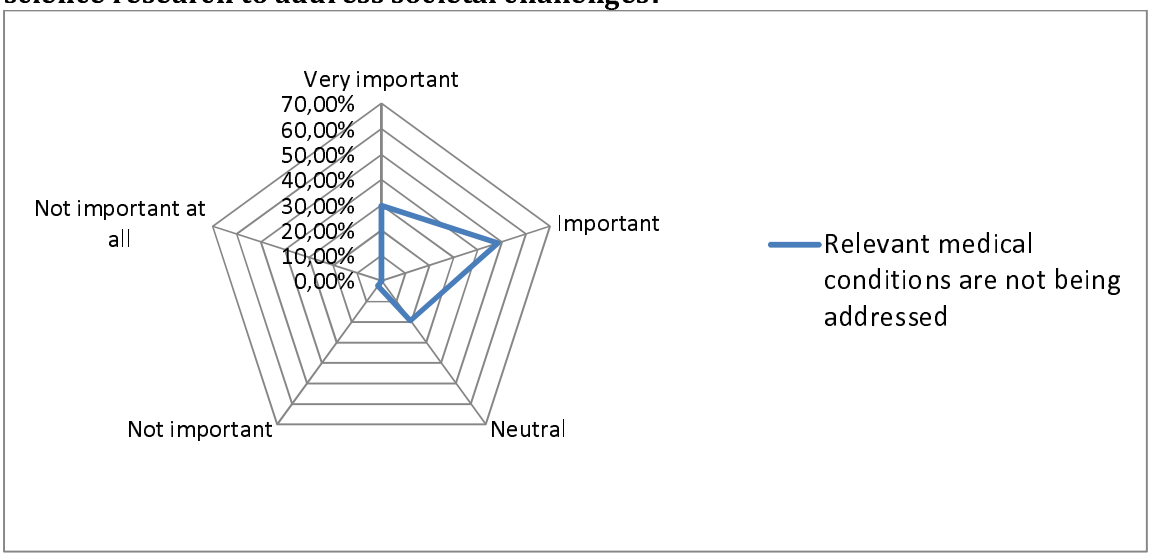
Question A.8 "Have you applied for funding from IMI?"

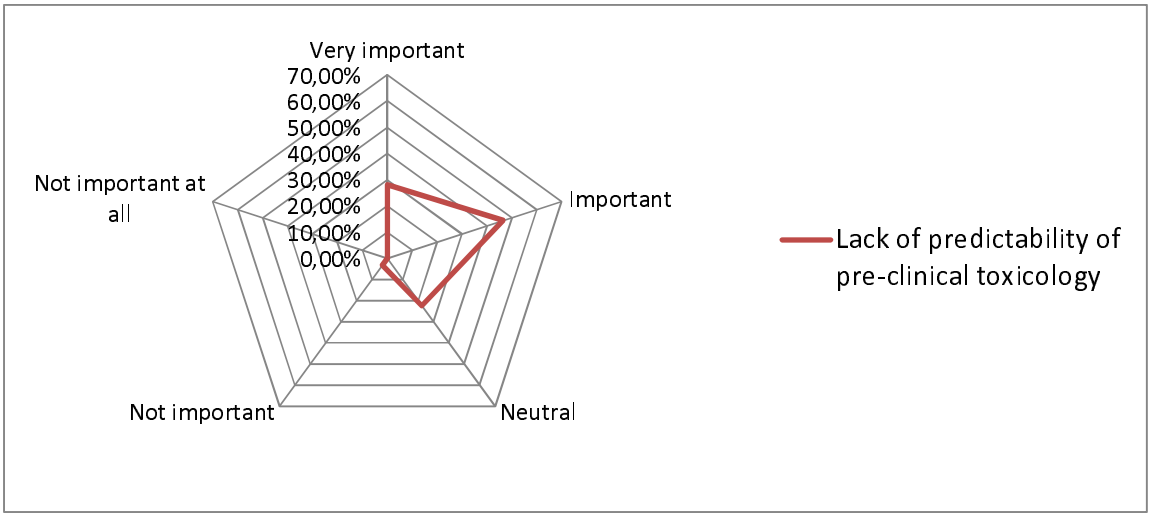


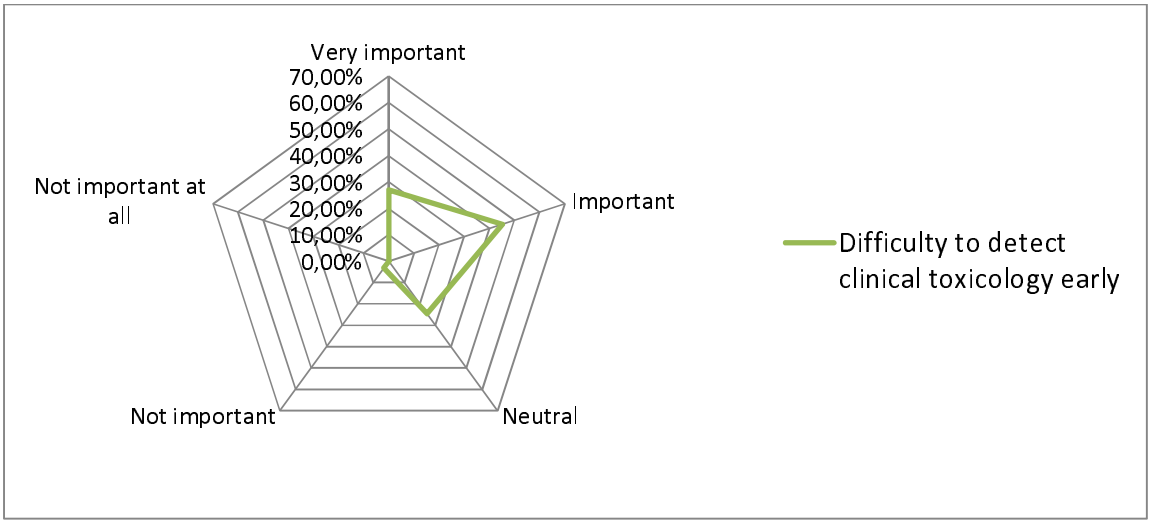
Question A.9 "Have you received funding from IMI?"



Question C.1.: "How important are, in your view, the following problems for life science research to address societal challenges?"







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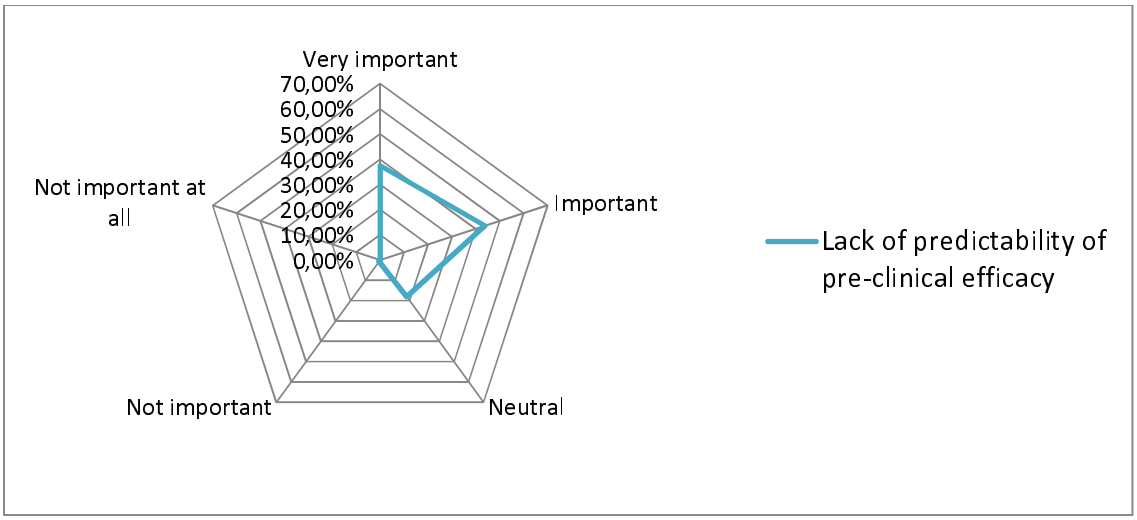

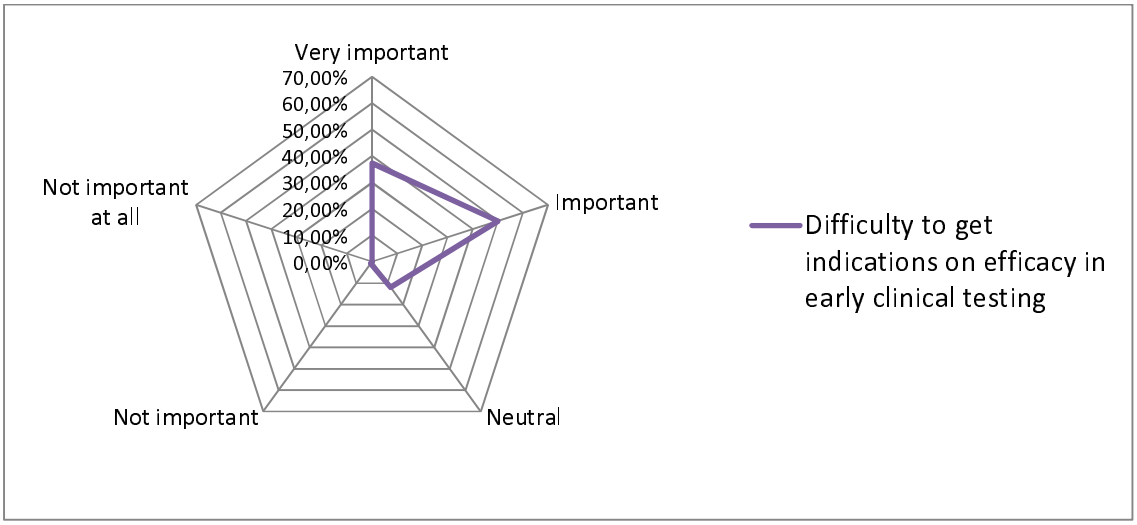

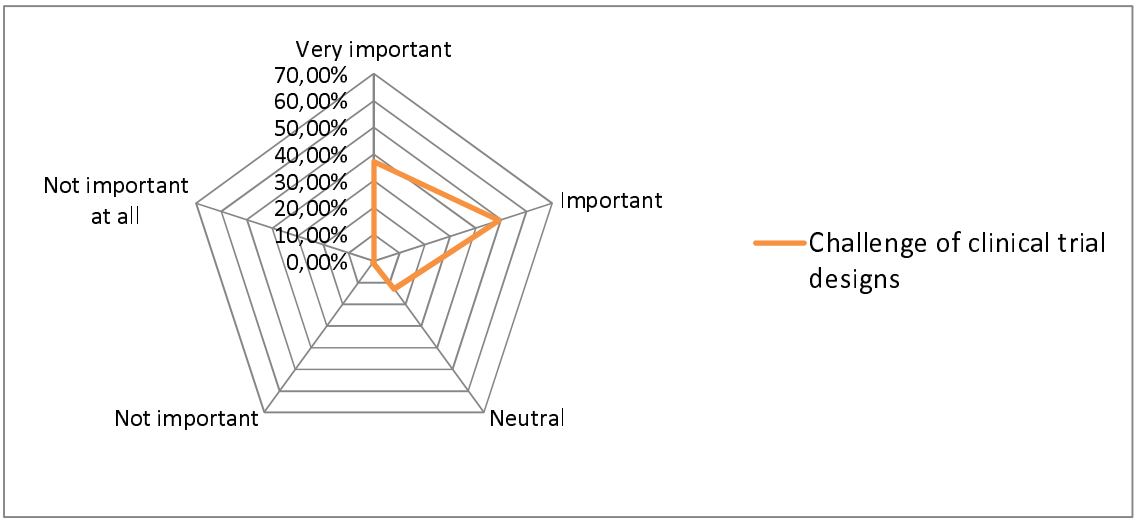

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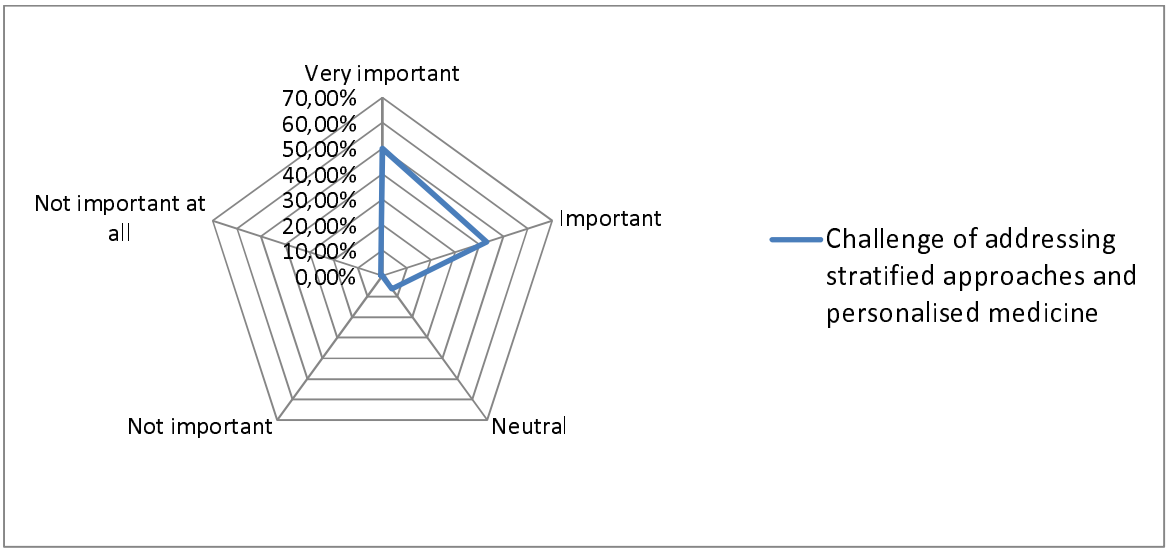
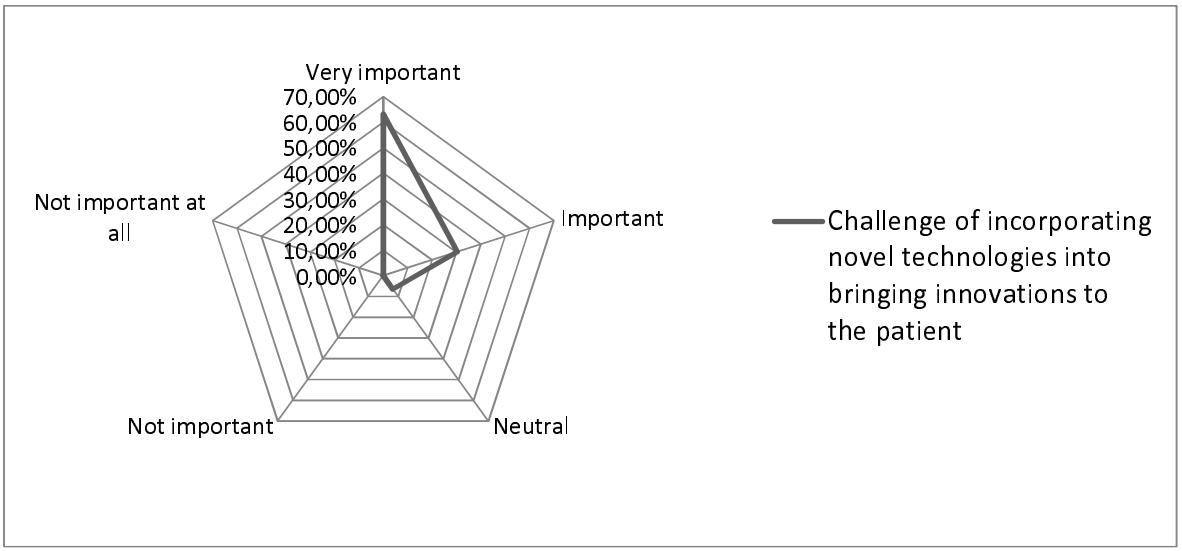
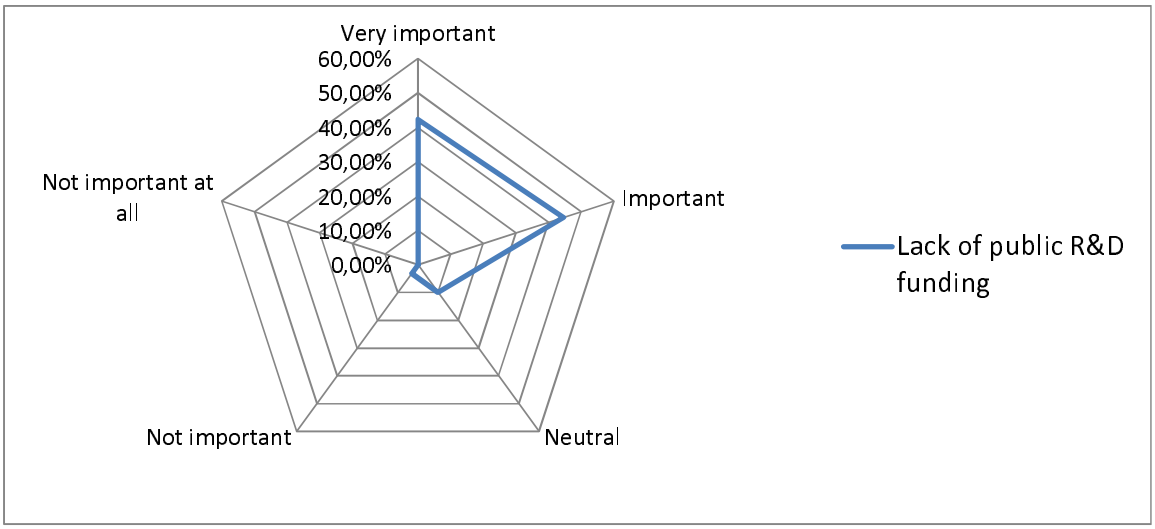
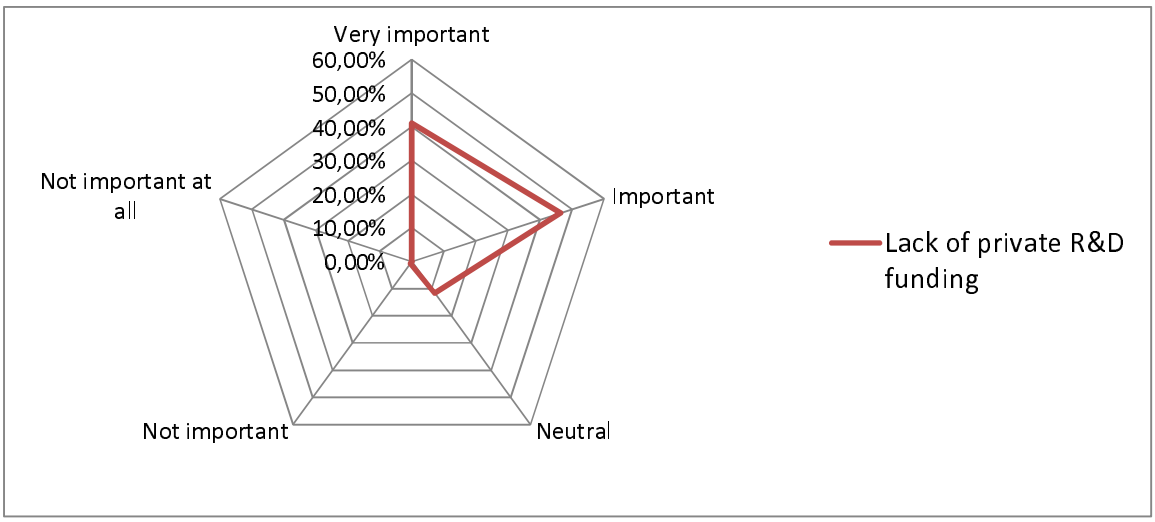
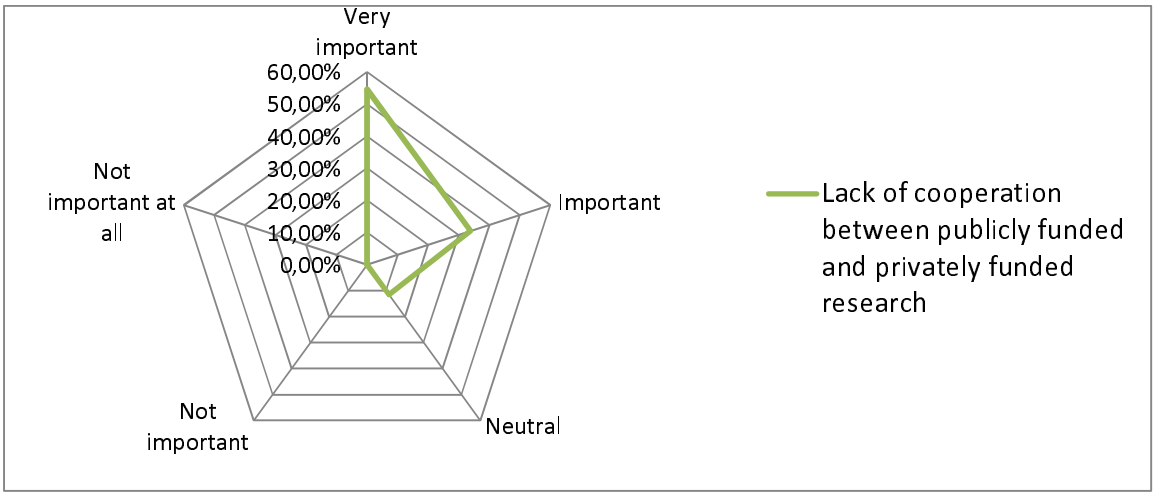




Question C.3 "In your view, what are the main obstacles to bringing results of life science research to the market and to the patients in Europe"







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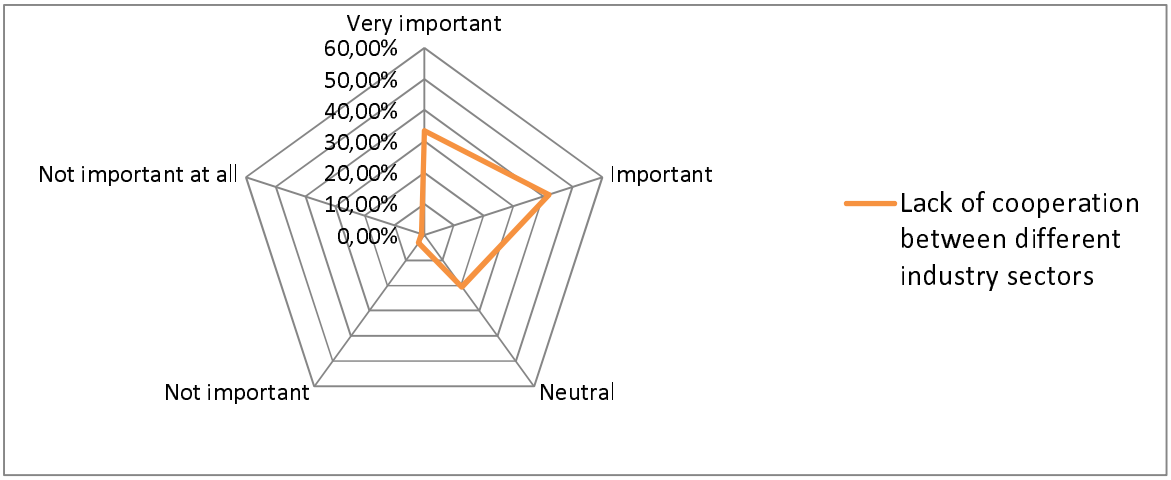

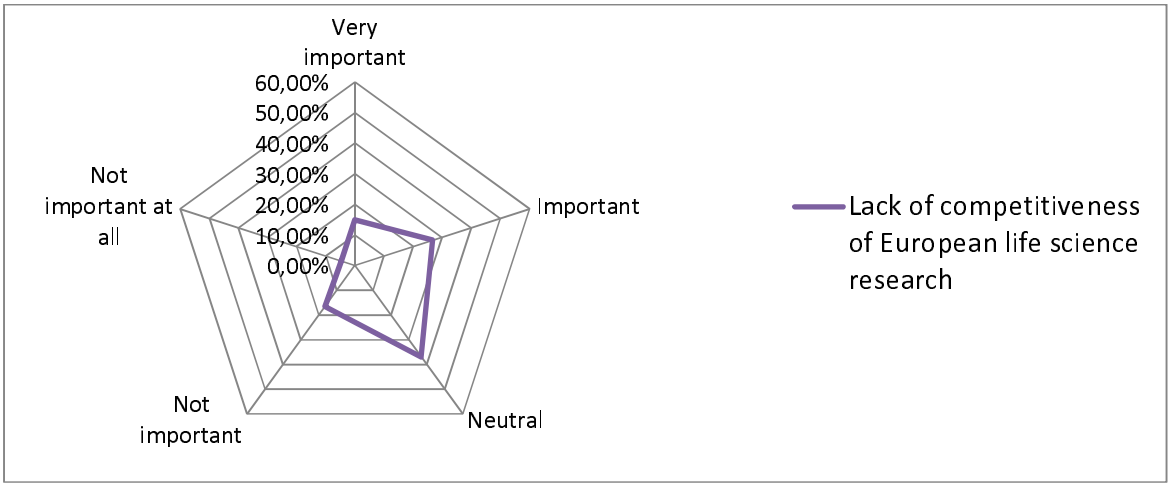

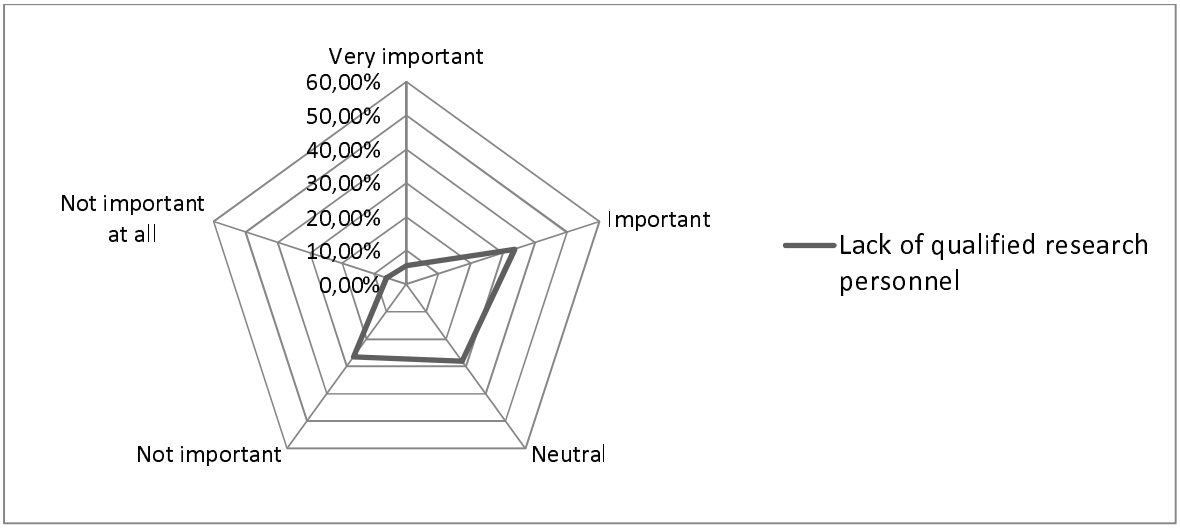

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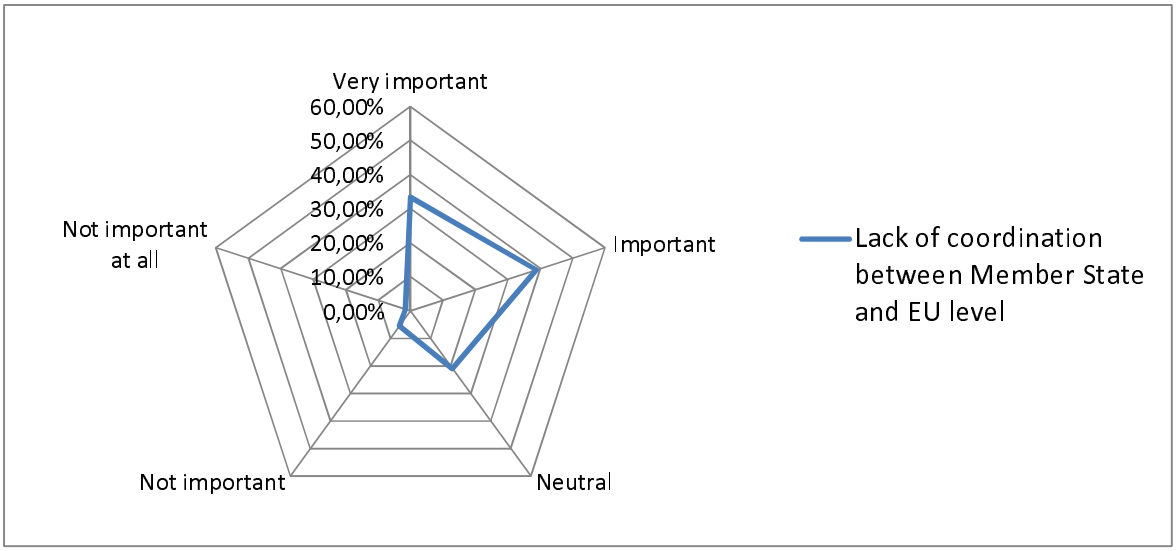
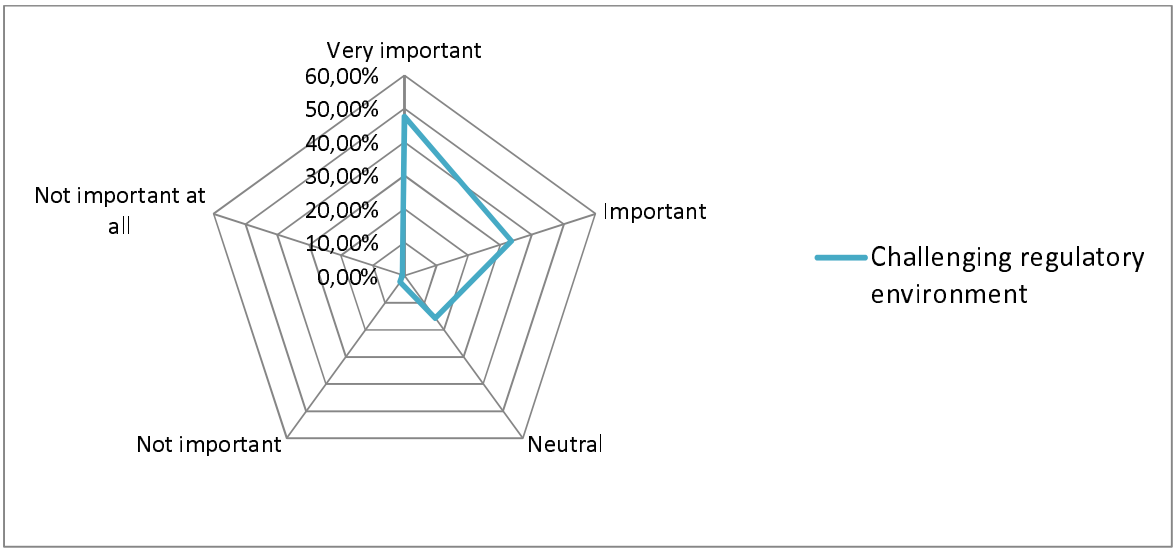
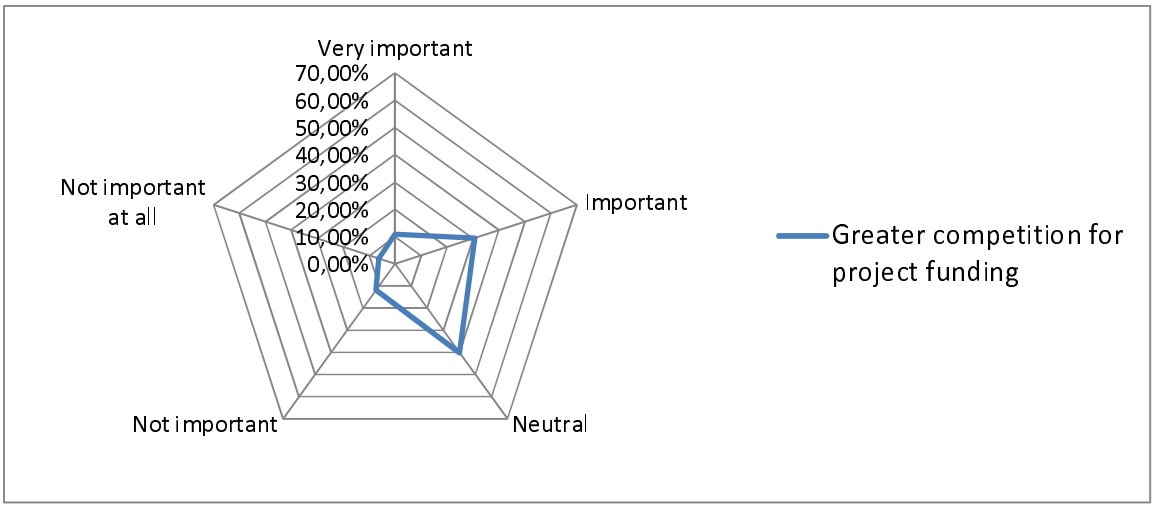
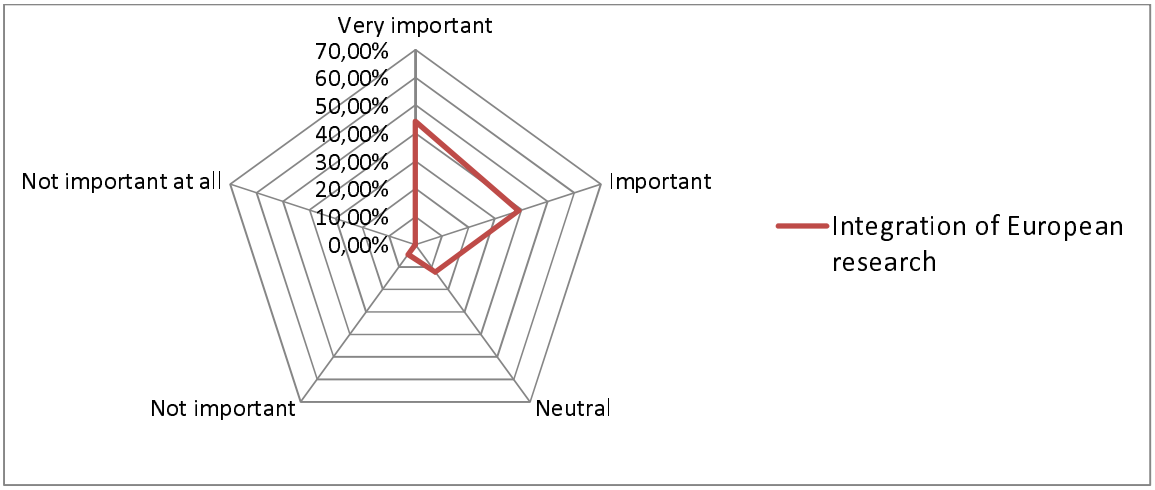
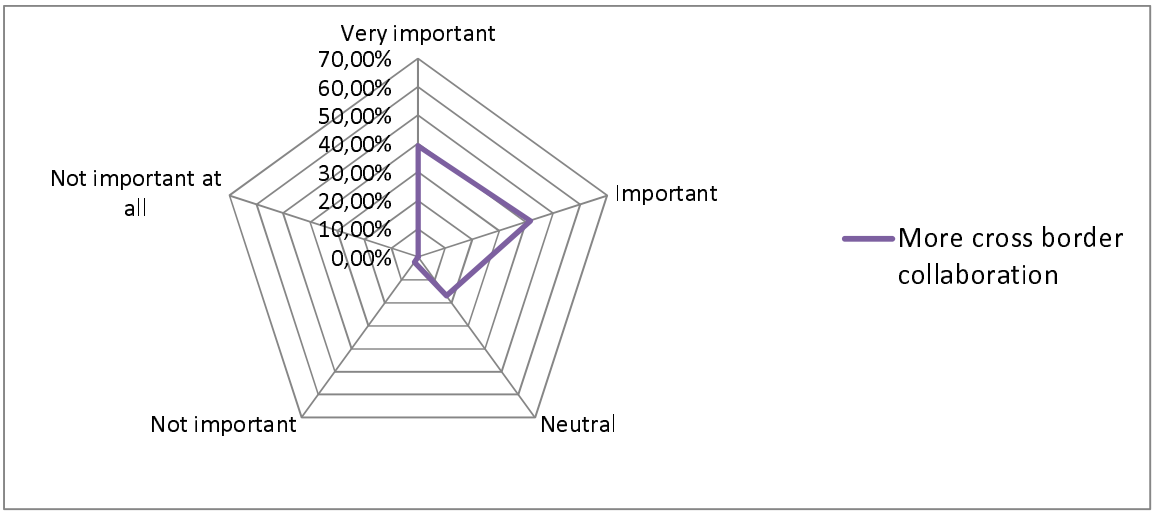




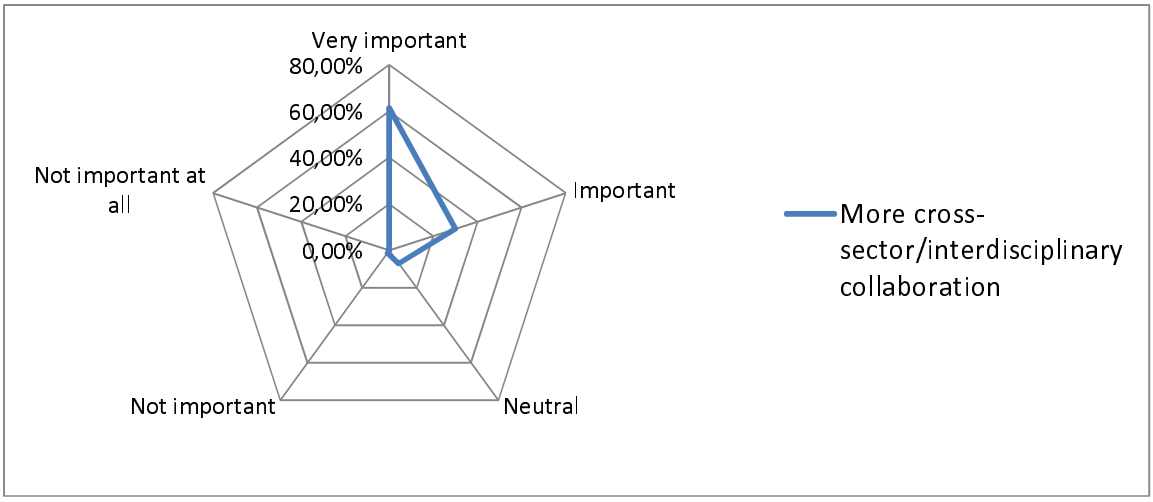
Question D.4 "If you believe that the EU needs to step in, what should be the purpose and added value of its action?"

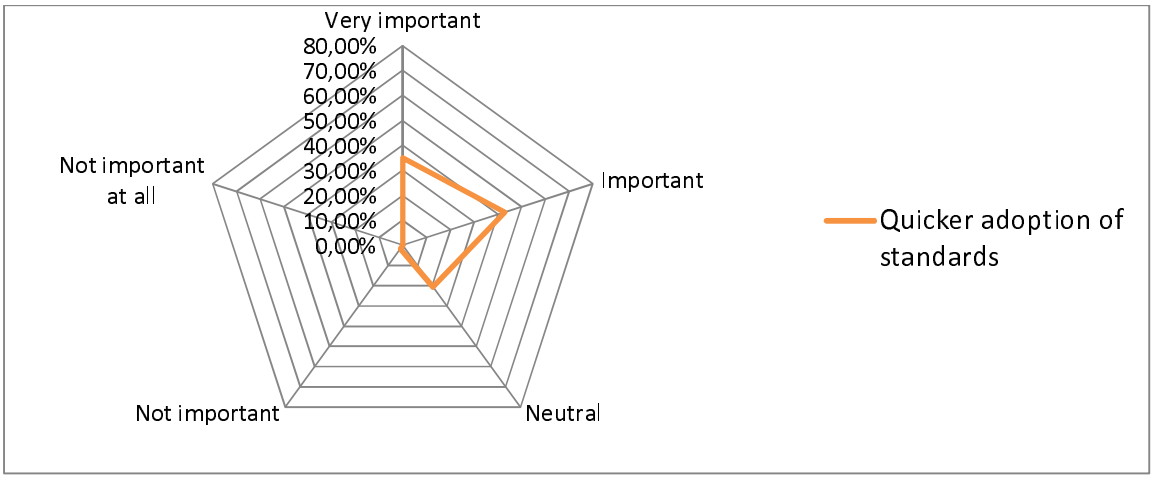


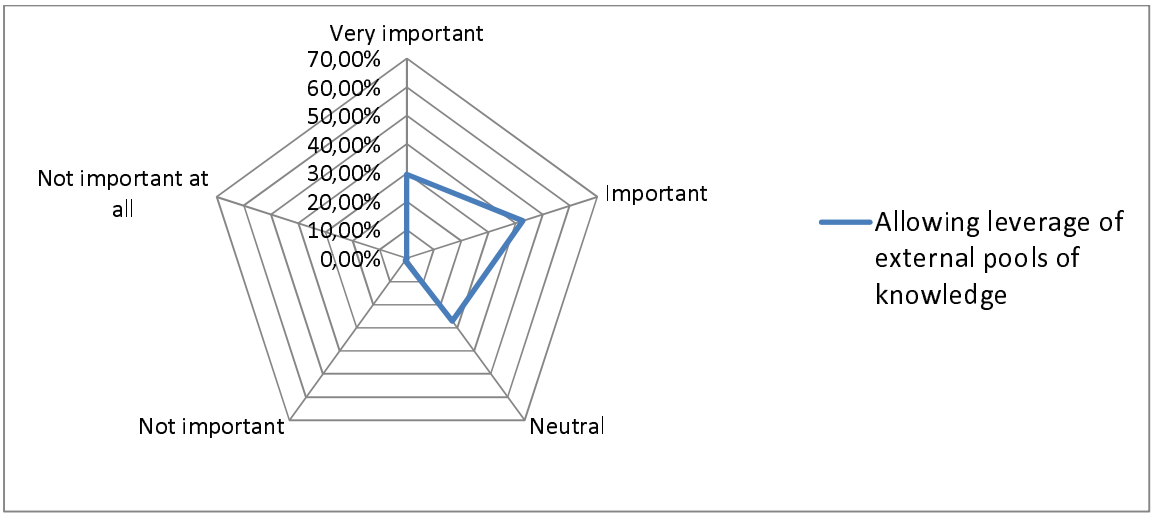




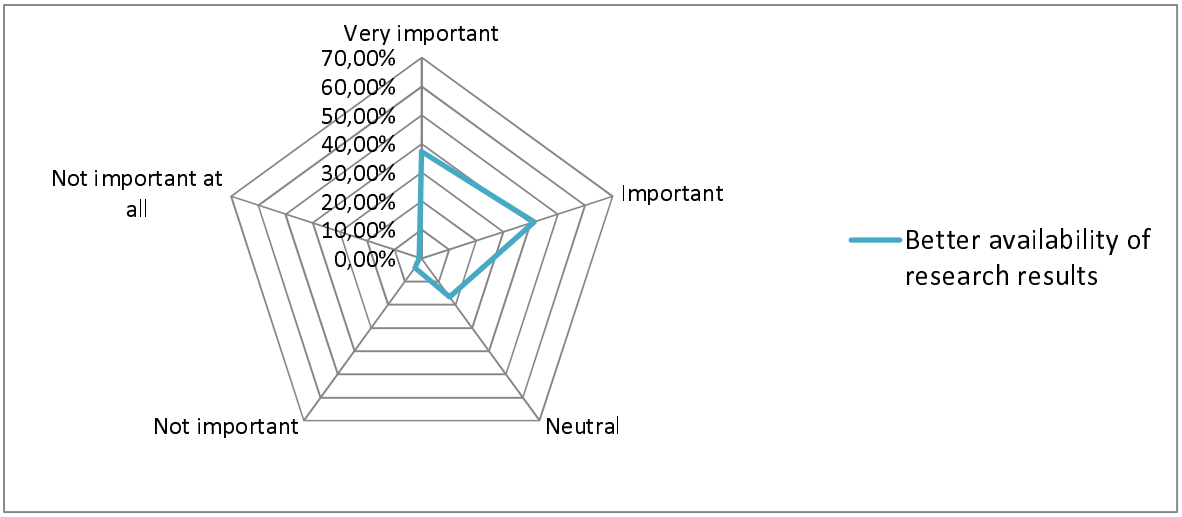
Question D.4 "If you believe that the EU needs to step in, what should be the purpose and added value of its action?"

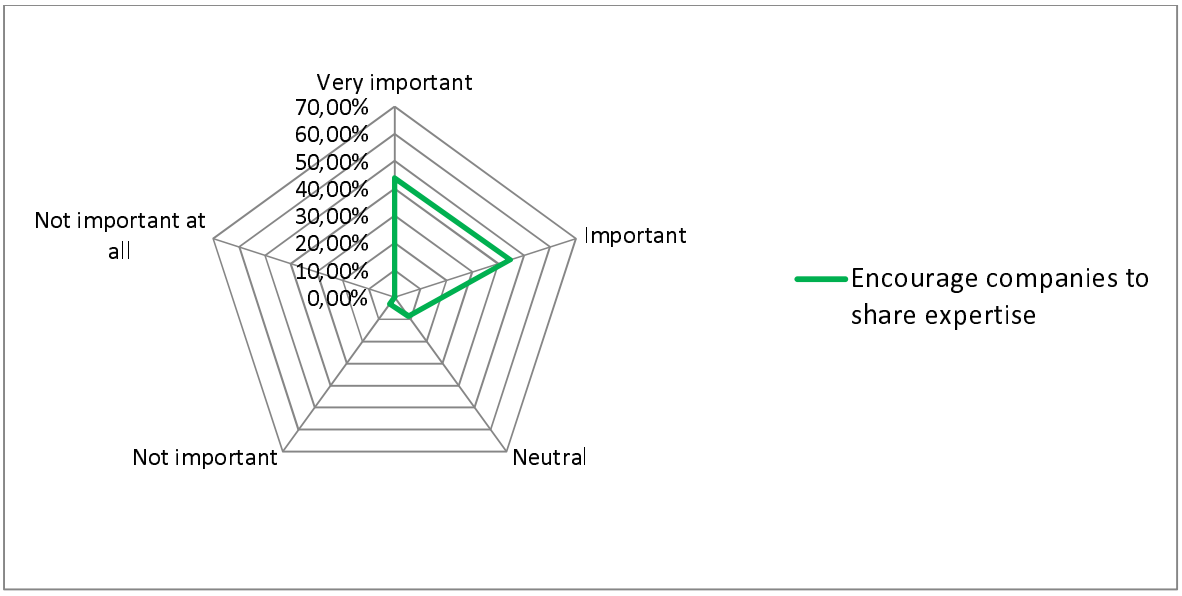




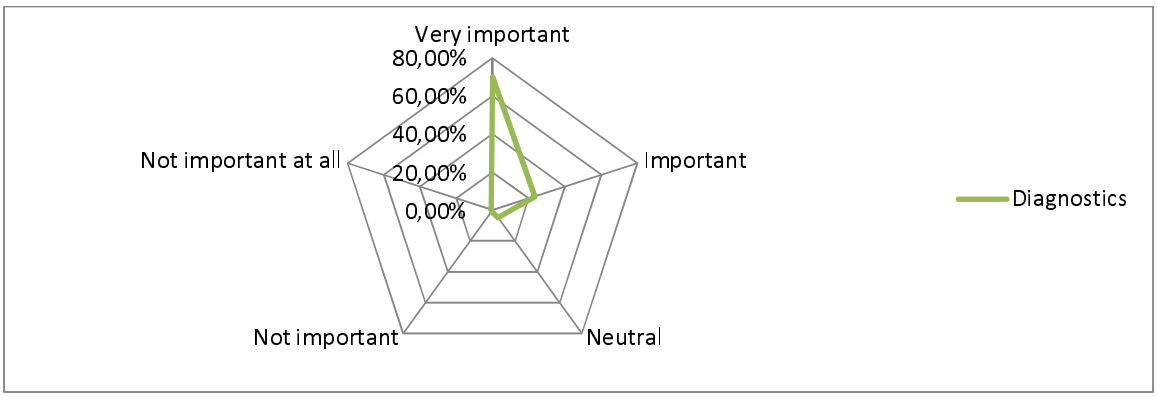


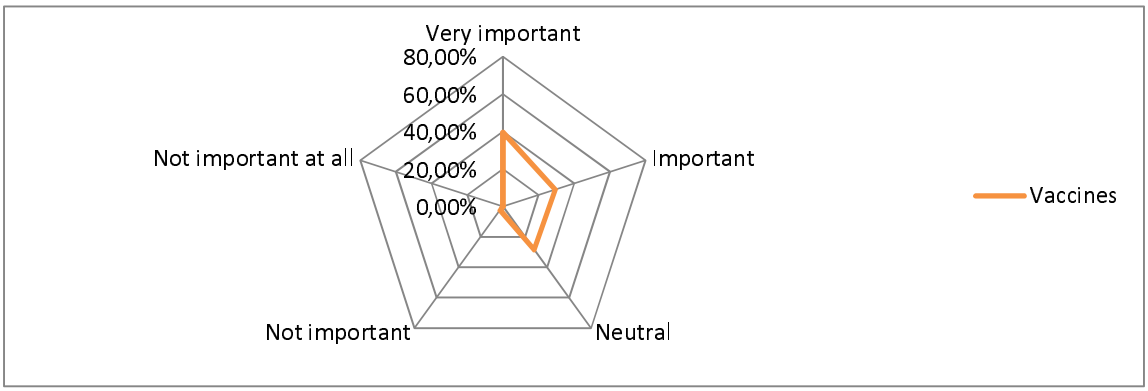
Question D.4 "If you believe that the EU needs to step in, what should be the purpose and added value of its action?"

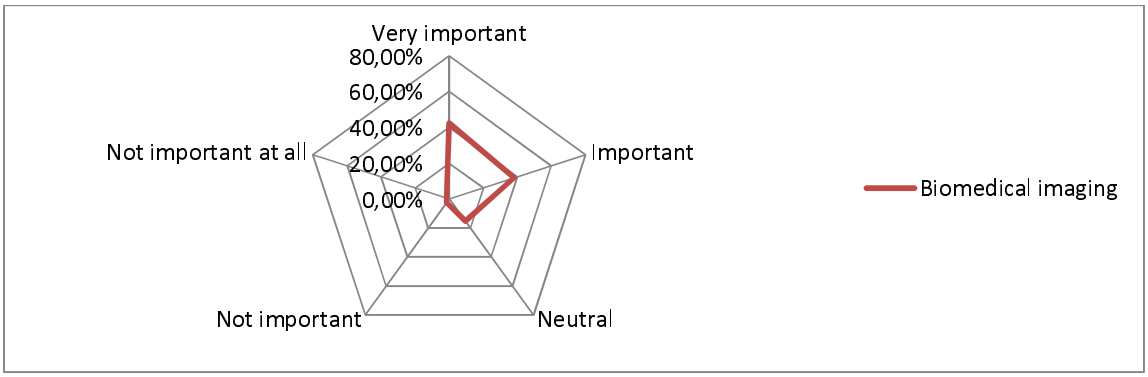


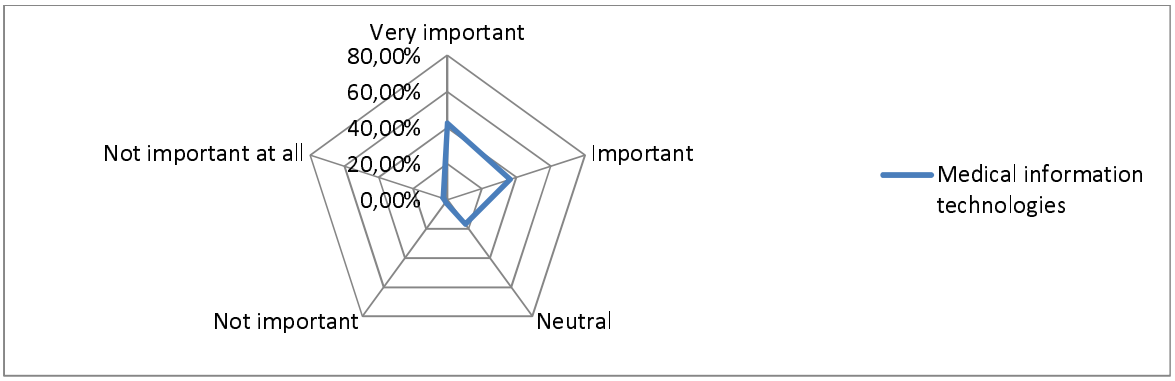


Question E.3 "Which other areas do you consider important to be included"?

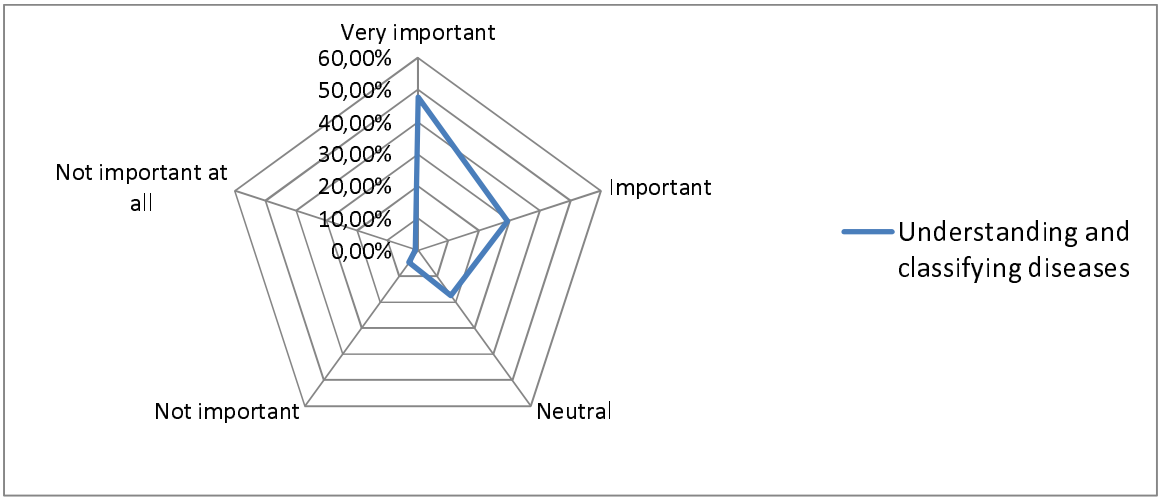


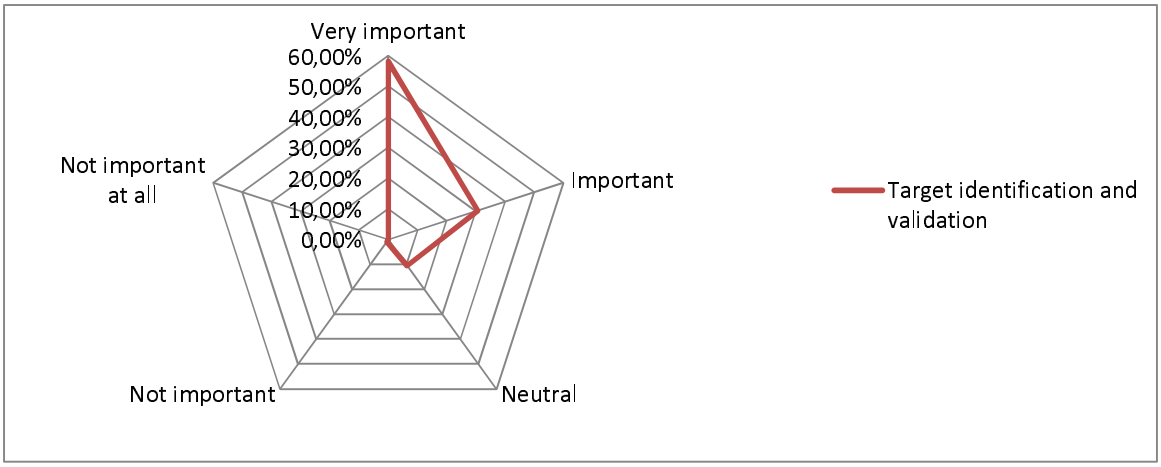


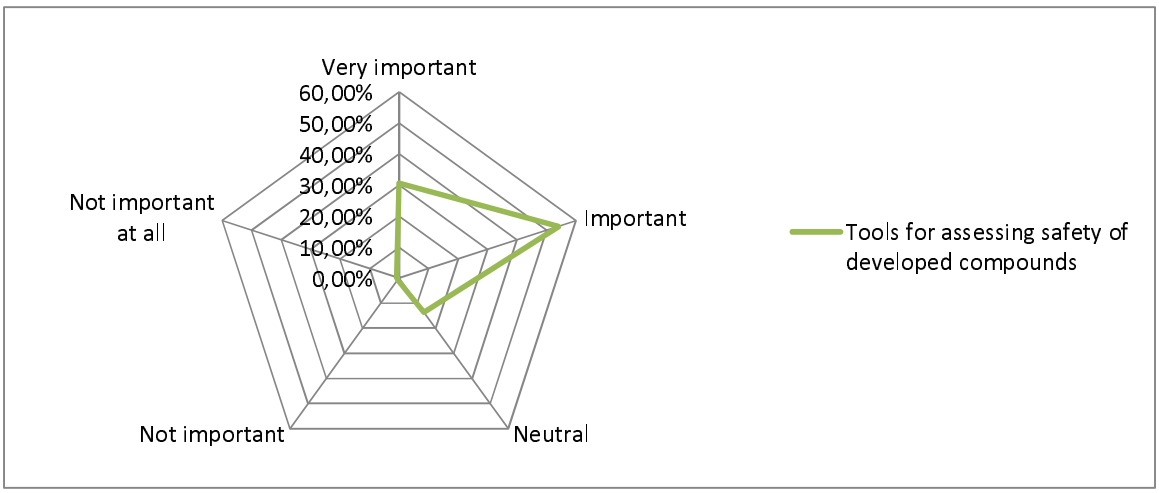




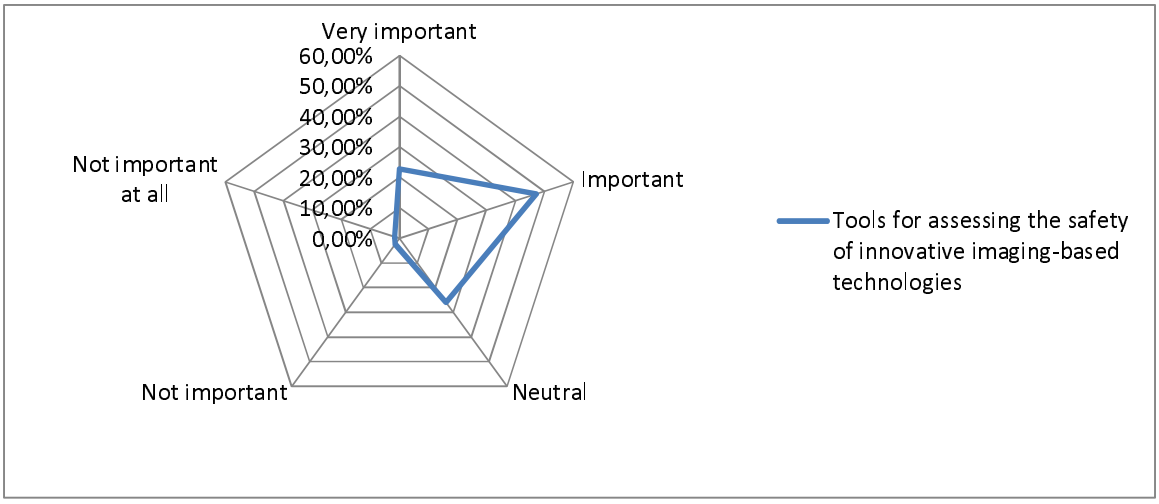
Question E.5 "Do you consider the following objectives relevant for a PPP in life sciences under Horizon 2020"?

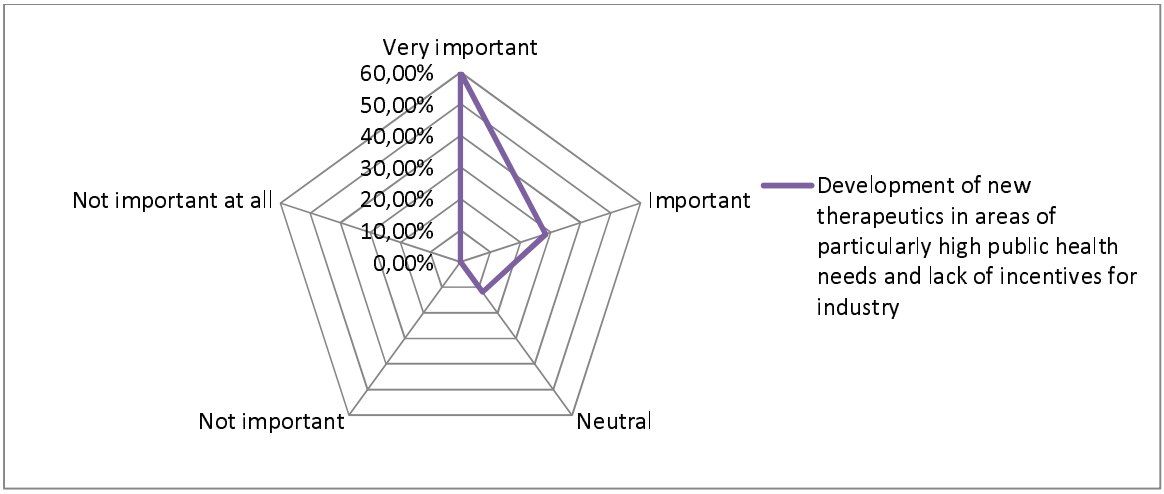


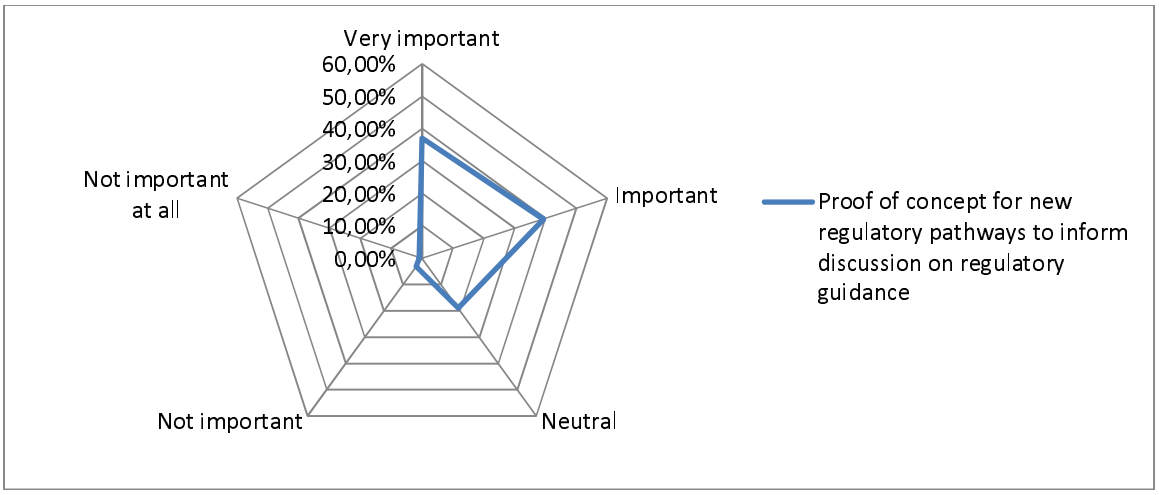




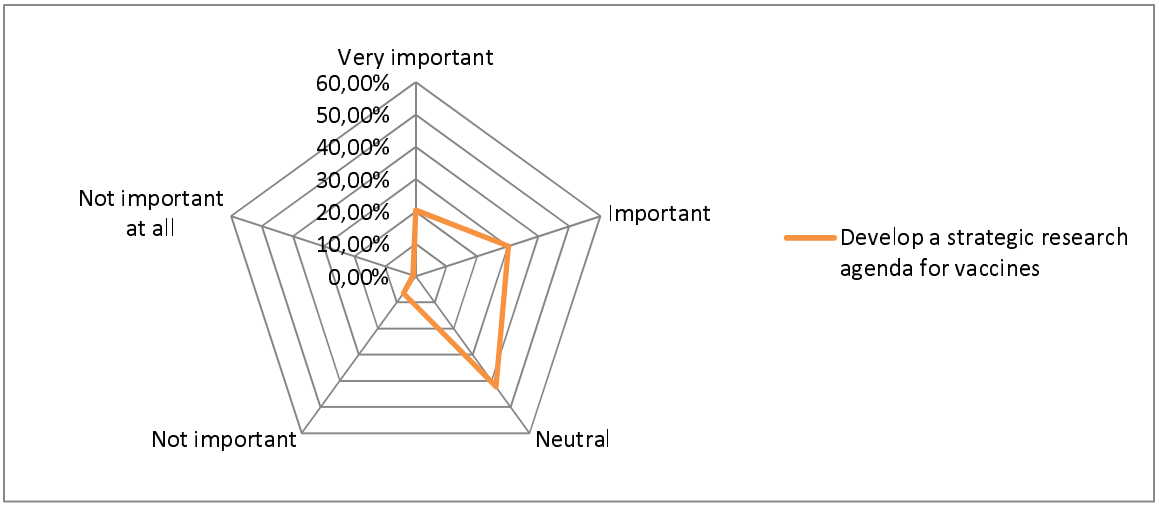
Question E.5 "Do you consider the following objectives relevant for a PPP in life sciences under Horizon 2020"?

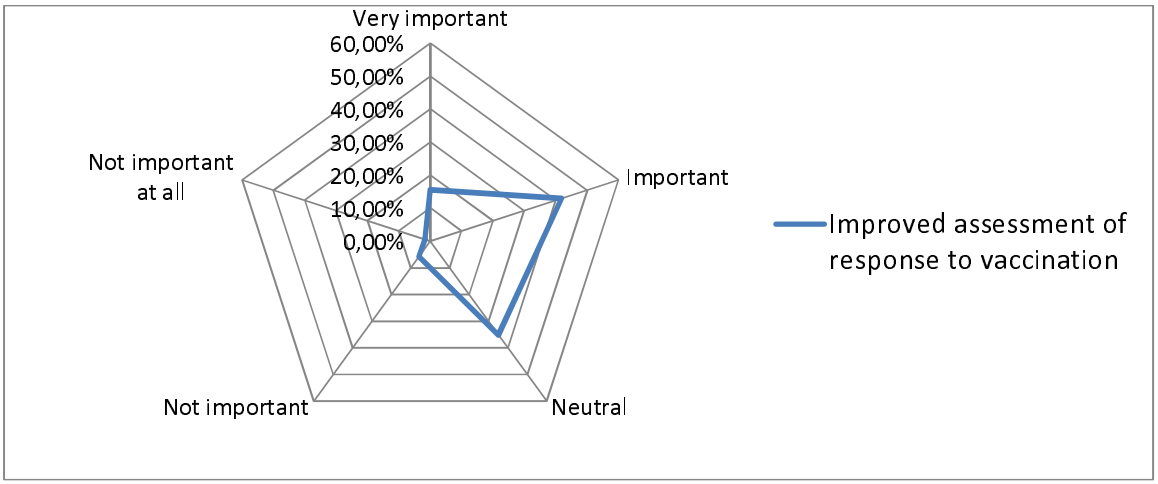


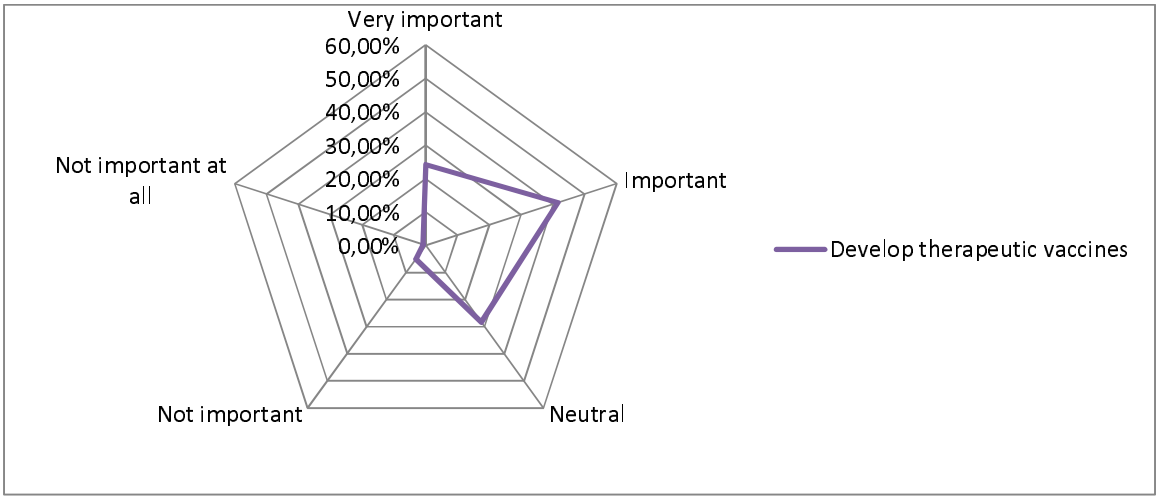




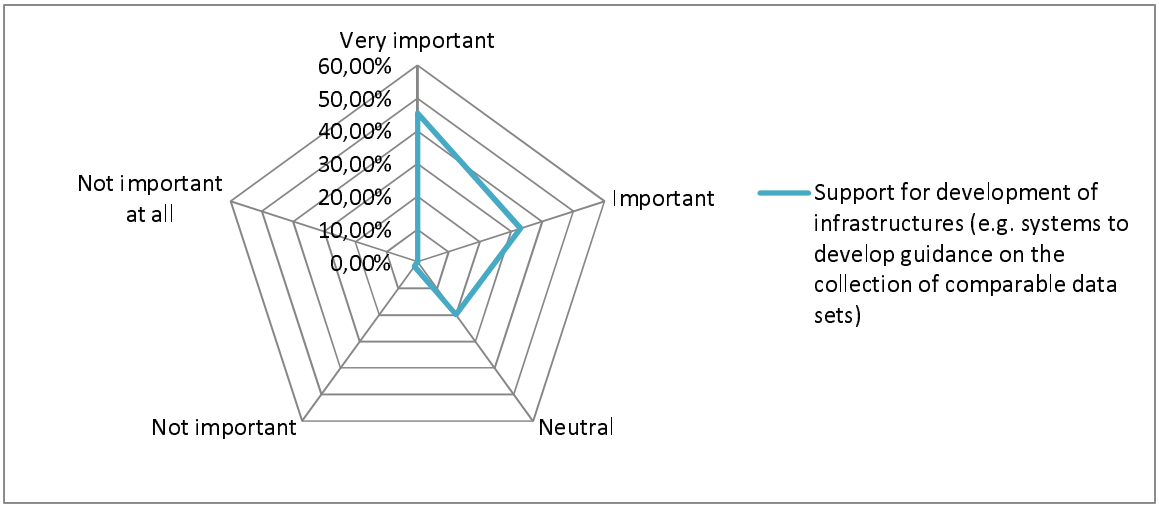
Question E.5 "Do you consider the following objectives relevant for a PPP in life sciences under Horizon 2020"?



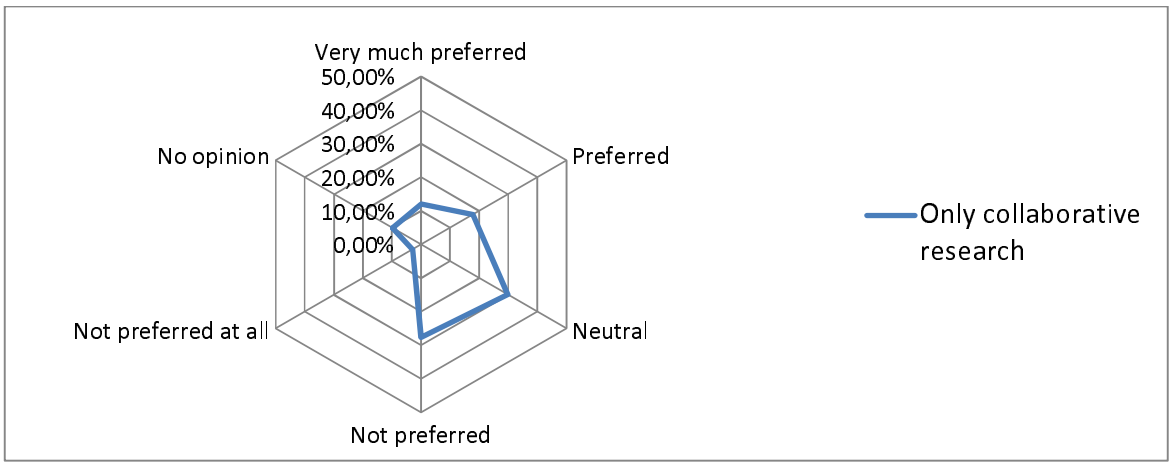


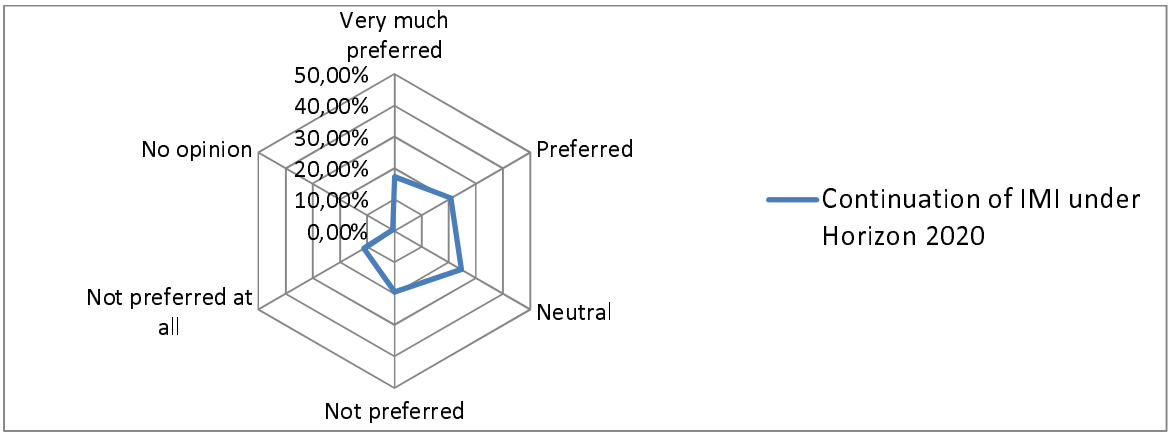


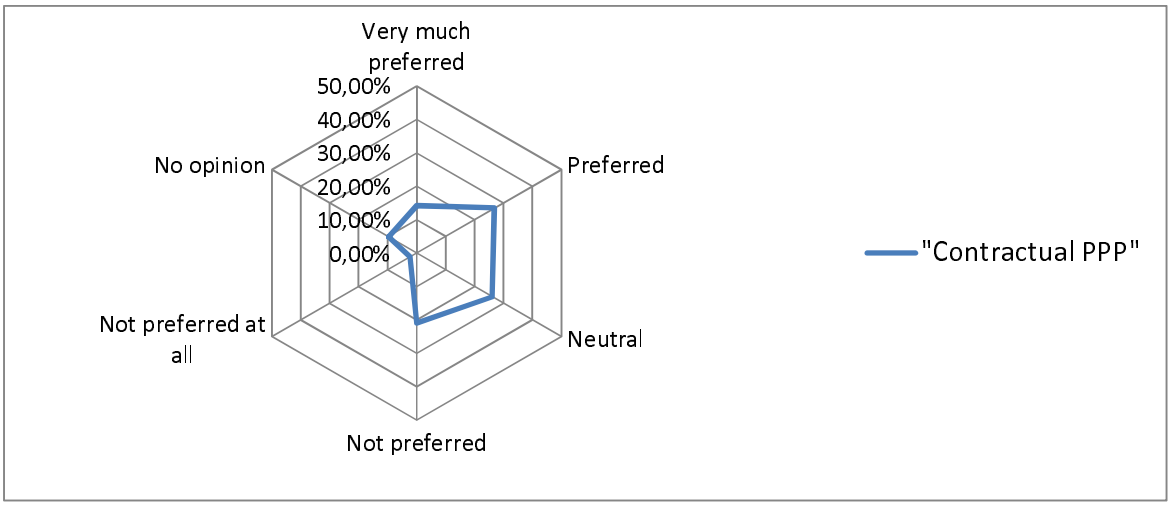
Question E.5 "Do you consider the following objectives relevant for a PPP in life sciences under Horizon 2020"?



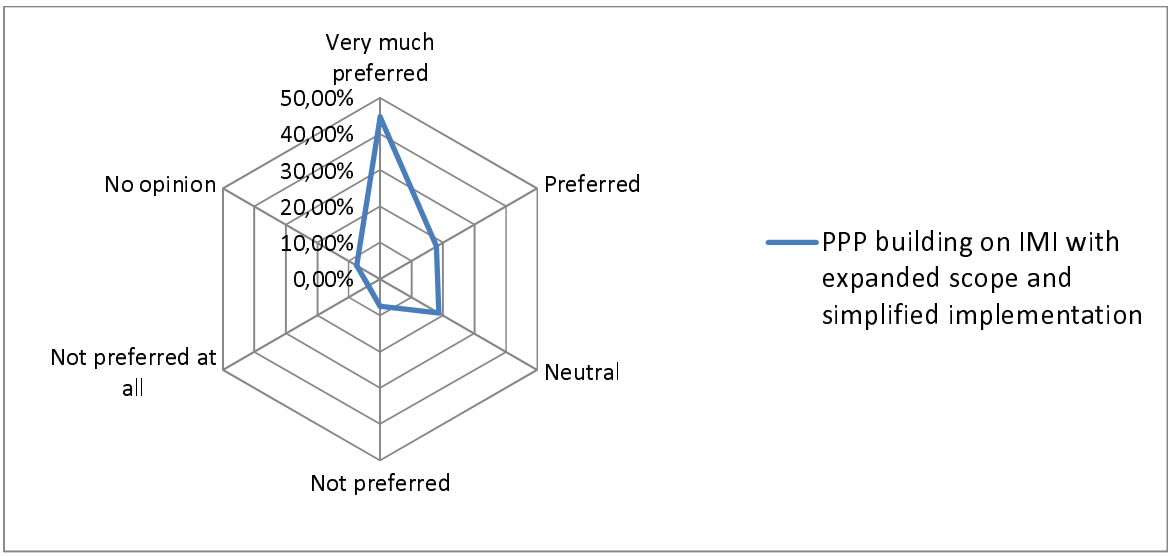
Question F.1 "Please rate the one of the following options"

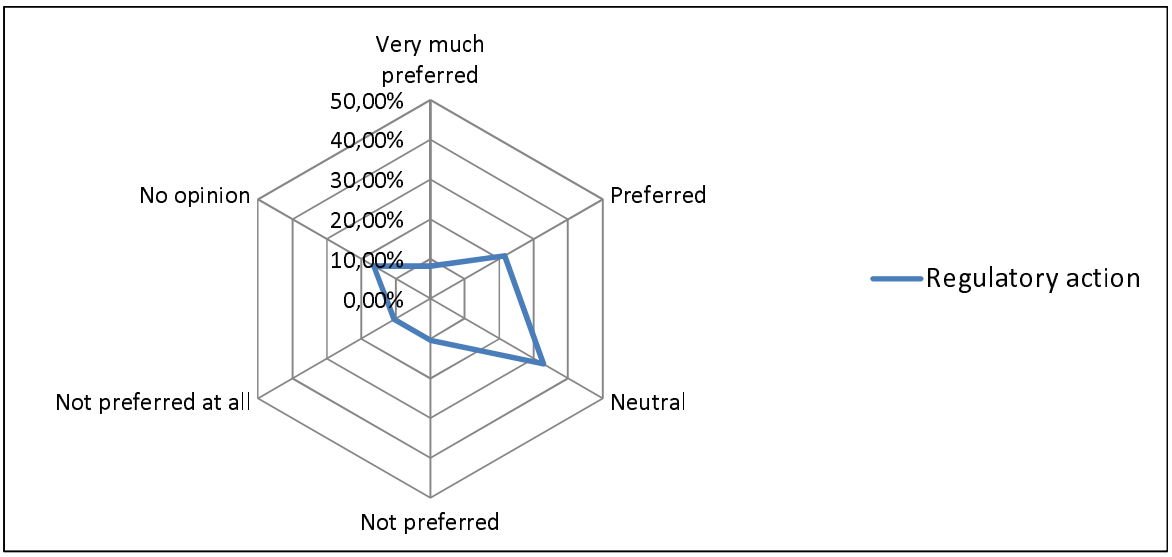




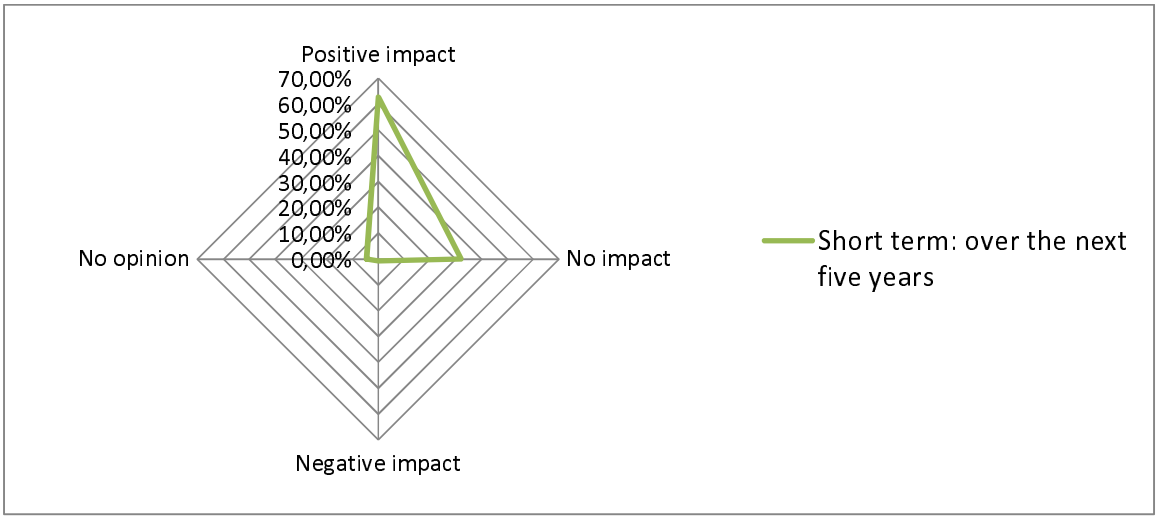


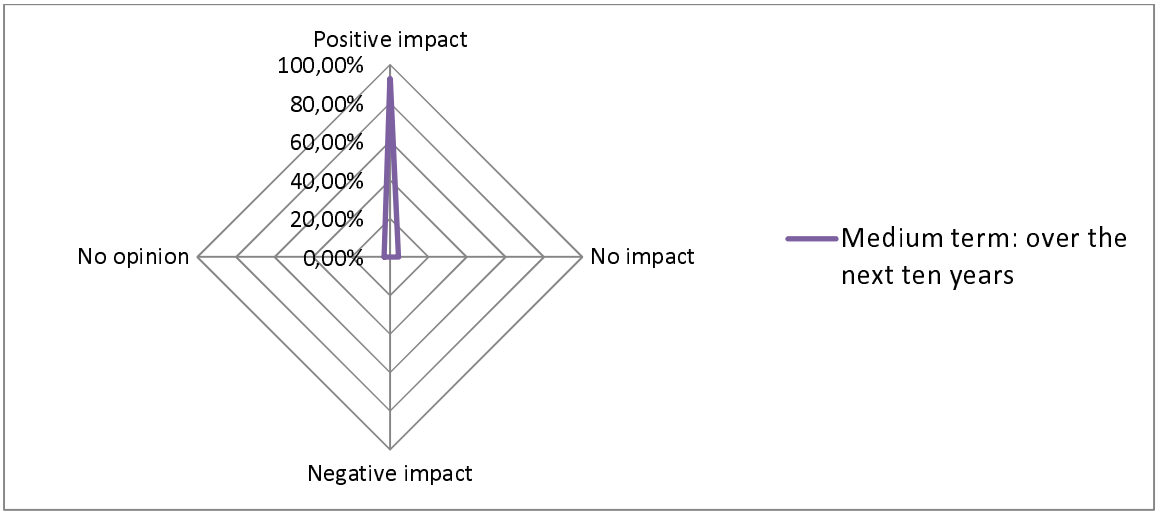
Question F.1 "Please rate the one of the following options"

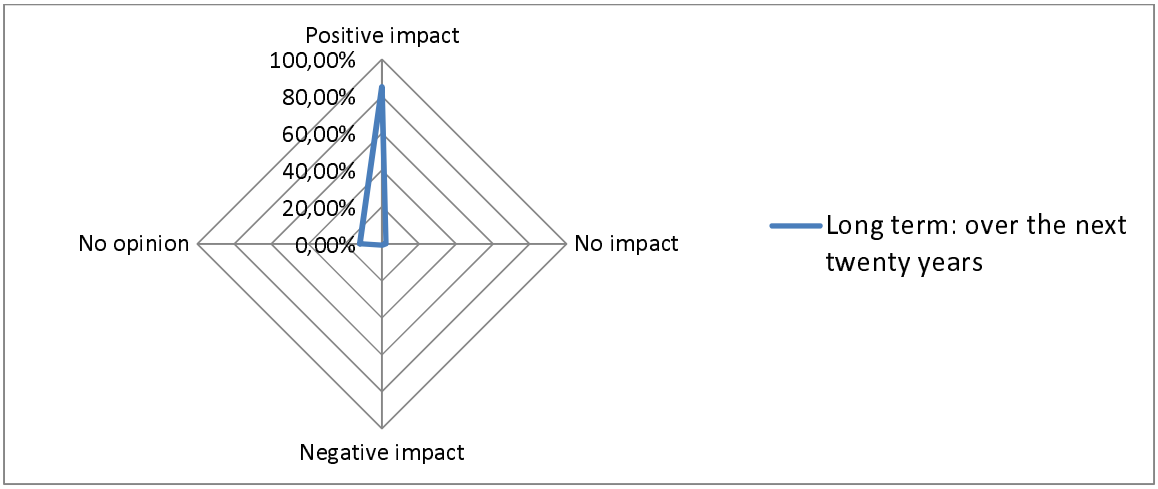




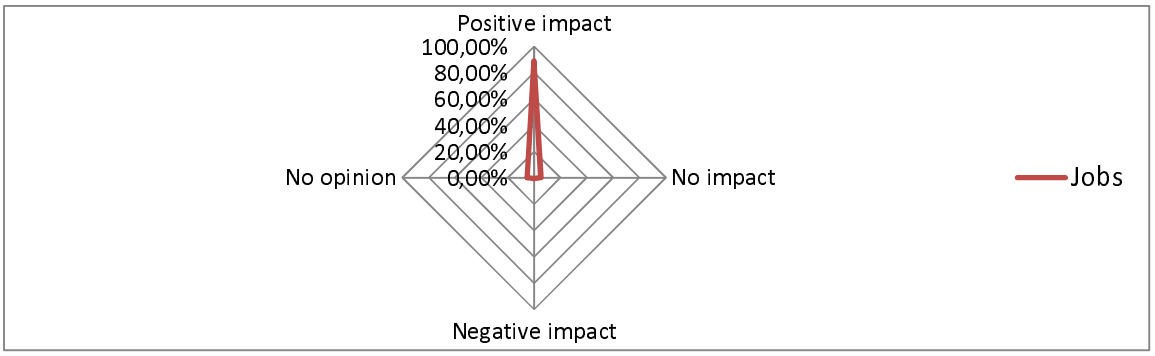
Question G.1 "Can a PPP in life science research improve the competitiveness of Europe's life science industry"?

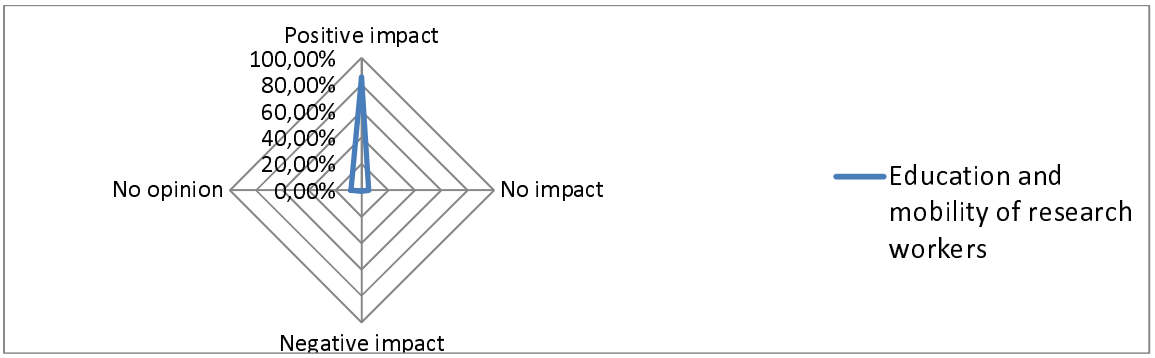


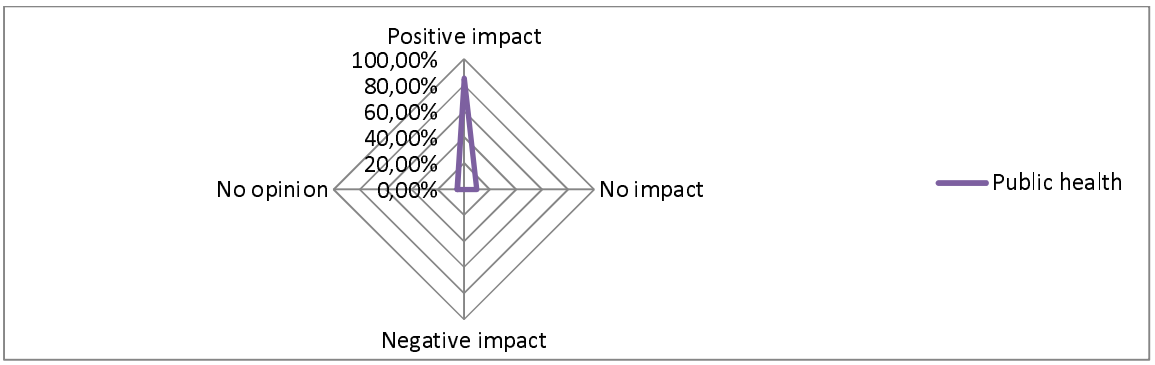


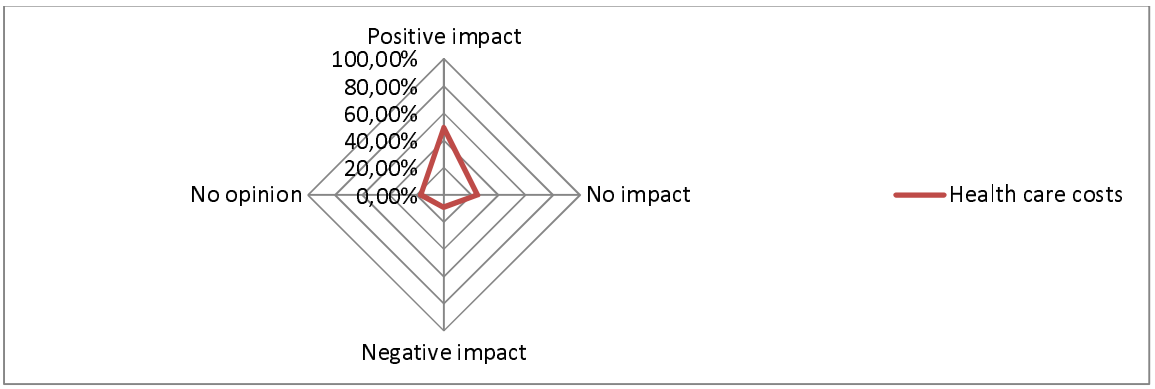


Question G.3 "Has a PPP in life science research the potential to have social impacts or environmental impacts"?









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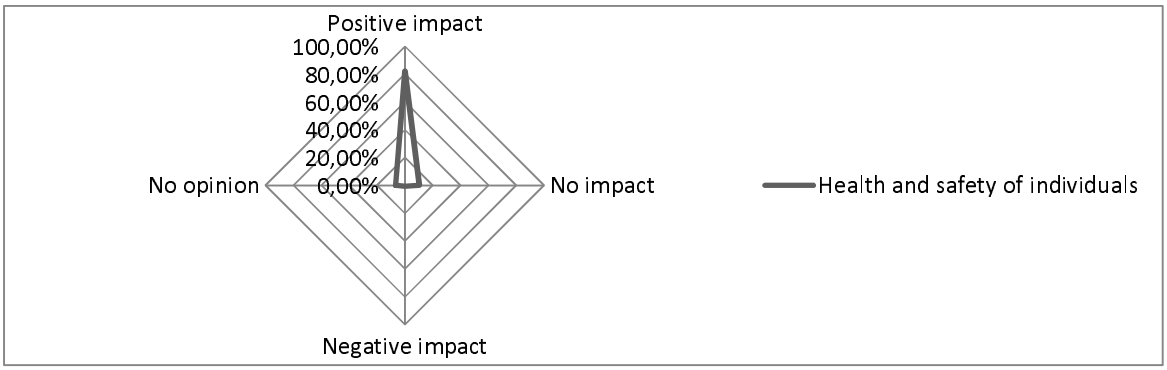
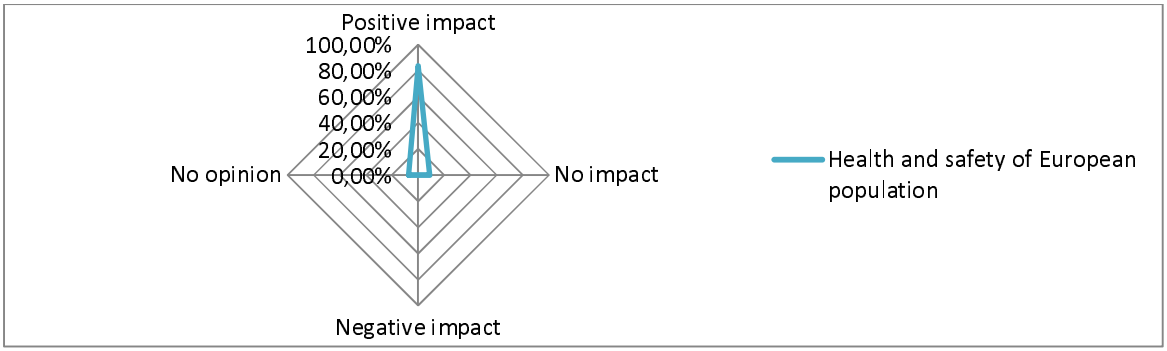
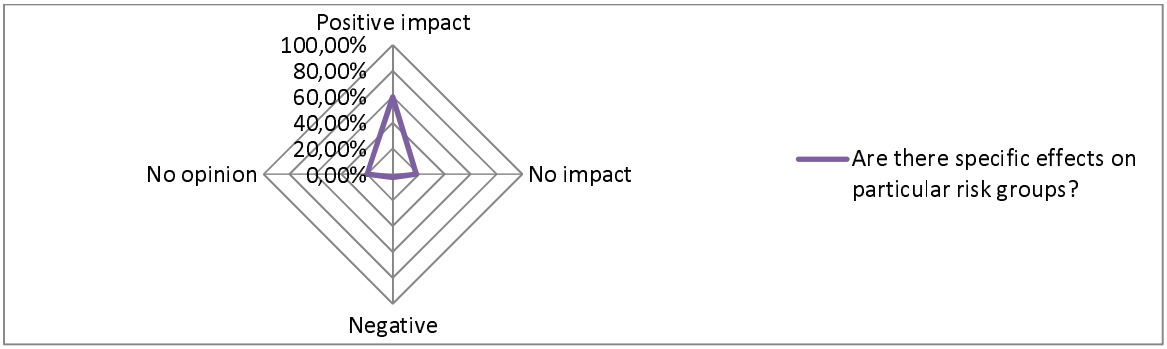
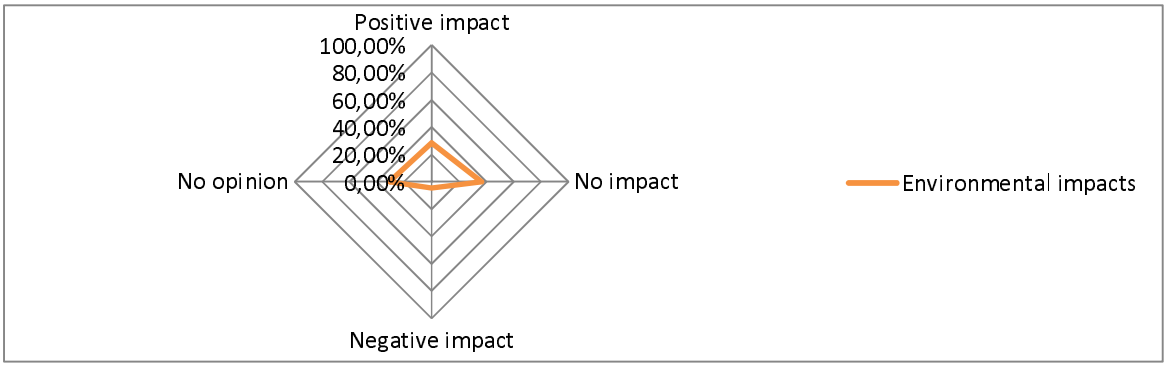
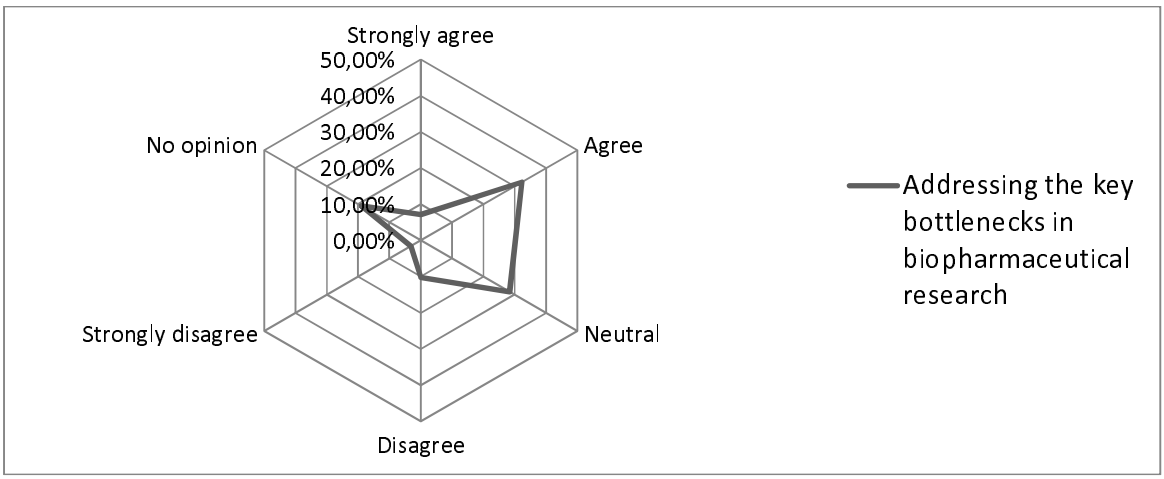


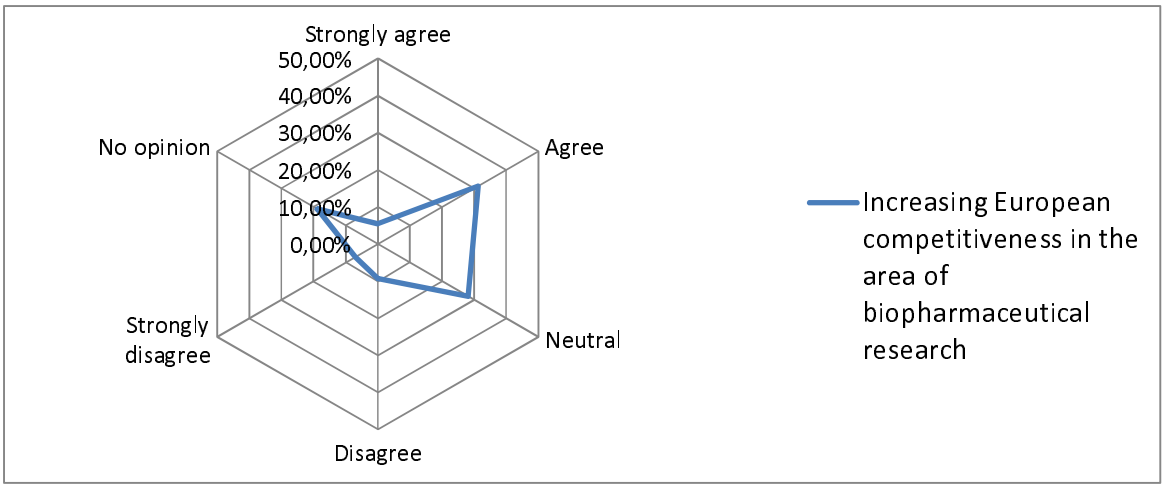


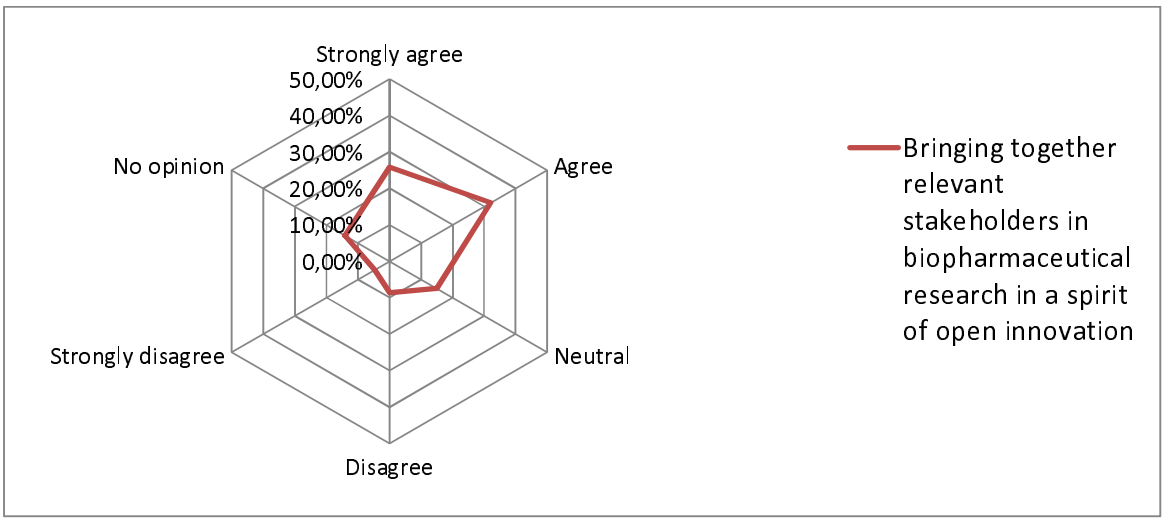




Question H.1 "Has IMI succeeded in the following"?







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