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# Industry stakeholders and EU network experts surveys on early engagement fostering innovation

Final report: 01 January 2024-15 December 2024

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# 1. Executive summary

Innovation and competitiveness are one of the key strategic goals of the European Medicines Agencies Network Strategy (EMANS) to 2025 and its revised 2028 update given the opportunities it brings in terms of making available new treatments to patients. In line with this vision, the strategic objectives of the EMANS aim to ensure support to innovators, promote the integration of science and technology and foster collaborative evidence generation for all decision makers.

The pace of scientific and technological development is increasing and is expected to accelerate with the integration of digital tools into drug research, development and manufacturing.

The EMA is committed to foster innovation in the pharmaceutical sector to ensure availability of innovative medicines to European citizens and animals. In this context, several advice mechanisms are available in support of innovative medicines and associated technology developments such as:

- Innovation Task Force briefing meetings (ITF BMs)
- Portfolio and technology meetings (PTMs)
- Quality Innovation Group (QIG) meetings (Listen and learn focus group and 1:1 meetings)
- Small and medium-sized enterprises briefing meetings (SMEs BMs)

Each of the above early engagement support forum is an opportunity for the pharmaceutical company to approach the regulatory environment and initiate a dialogue with the view to future marketing authorisation application submission.

To ensure the effectiveness of these initiatives, and in line with the requirements of the Framework for interaction between the European Medicines Agency and industry stakeholders, two surveys were conducted from 1st January 2024 to 31st of December 2024:

1. Stakeholders survey on early engagement fostering innovation: the questionnaire was targeted to pharmaceutical companies having attended one or more of the above meetings.
2. Network survey on early engagement fostering innovation: the questionnaire was targeted to all the European Medicines Regulatory Network (EMRN) experts having attended the ITF BM and or the QIG meetings.

Both surveys aimed to gather the feedback on the level of support received in relation to the meeting request process, the meeting content discussions, the meeting output, the overall engagement/communication experienced. Proposal of opportunities for improvement were also welcomed.

It should be noted that, although several reminders were sent, the response rate obtained from both Industry stakeholders and EU network experts remained low (44% from Industry stakeholders; 24% from the EU network experts).

Nevertheless, from the evaluation made with the feedback received, it can be concluded that:

- Industry stakeholders value the opportunity to engage with regulators at an early stage of product/new technology development. They expressed general satisfaction with the timing and clarity of the meeting request processes, the information made publicly available and/or subsequently provided by the support teams, the overall meeting experience and the outcomes achieved. However, opportunities for improvement were suggested in the areas of guidance and support, timing of meeting planning, discussion and engagement, and team expertise composition.

- Similar feedback was provided by the EU network experts, who also indicate a general satisfaction with the meetings experience. In this case, the experts have highlighted the need to improve planning and expert selection allowing sufficient time for resource allocation and expert briefings. Also, in this case opportunities for improvement were suggested in improving guidance/support and expert team composition.

It can be concluded that, overall, the feedback received indicates a positive satisfaction of both industry stakeholders and the EU network with the available mechanisms for early engagement in support of innovation, with some suggestions to further improve the overall experience.

# 2. Background

The EMAN commitment to innovation is outlined in the current strategy to 2025 and will remain one of the key network priorities in its strategy update to 2028; it is being supported with dedicated early engagement forum, which provide an important opportunity for industry stakeholders to approach the European regulatory environment and initiate a dialogue with relevant EU network experts.

In order to establish the effectiveness of the available mechanisms and determine potential improvement needs, two surveys were launched in line with monitoring activities outlined in the Framework for interaction between the European Medicines Agency and industry stakeholder.

# 3. Objectives, scope and methodology

## *3.1. Objectives*

The overall objective of the exercise was to obtain the feedback from the industry stakeholders and, where applicable, from the EU network experts on the overall experience with the EMA early engagement meetings fostering innovation, technology research and development.

Therefore, two different surveys were conducted:

1. Industry stakeholders survey on early engagement fostering innovation.
2. EU Network survey on early engagement fostering innovation.

## *3.2. Scope*

The scope of the survey targeting human and veterinary medicines industry stakeholders included the following meetings:

- Innovation Task Force Briefing Meetings (ITF BM)
- Portfolio and Technology Meetings (PTM)
- Quality Innovation Group (QIG) (Listen and learn focus group meetings and/or 1:1 meetings)
- Small-, Medium- Sized Enterprises briefing meetings (SMEs BMs)

Given the fact that EU network experts participate only to some of the above meetings, the scope of the second survey included:

- Innovation Task Force Briefing Meetings (ITF BM)
- Quality Innovation Group (QIG) (Listen and learn focus group (LLFG) meetings and/or 1:1 meetings) were included in the 2nd survey.

For 2024 the following meetings with Industry stakeholders have taken place:

- Innovation Task Force Briefing Meetings (ITF BM): 23 meetings.
- Portfolio and Technology Meetings (PTM): 18 meetings.
- Quality Innovation Group (QIG) (Listen and learn focus group meetings and/or 1:1 meetings): 2 LLFG meetings, and 7 1:1 meetings.
- Small and Medium- Sized Enterprises briefing meetings (SMEs BMs): 3 meetings.

It is noted that the QIG and ITF initiatives also include the participation of academia stakeholders. Given the scope of the above-mentioned framework of interaction, academia was excluded from the current analysis. Nevertheless, relevant offices were given the opportunity to adapt, as needed, the surveys also to this stakeholder and to perform a separate exercise in parallel, as applicable.

## *3.3. Methodology*

The exercise was coordinated by Industry Liaison (Public and Stakeholders Engagement Department) with the support of the relevant responsible offices: Innovation and Development Accelerator (TRS-INO), the SME Office (TRS-SME) and the Pharmaceutical Quality (H-QS-QUA).

The EU survey system was used as management tool to collect the feedback in an anonymous way.

Six main aspects were surveyed for each meeting in scope:

- Stakeholders profile: aiming at collecting information on the type of product/technology discussed as well as the profile of the associated company or EU network expert.
- Meeting request/process: this part collected information on how the applicant/EU network expert became aware of the meeting and its process for the request/preparatory phase.
- Meeting content: this section gathered feedback on the meeting scope, timing and the given feedback.
- Meeting output/deliverable: gathered feedback on the usefulness of the advice received and potential impact to regulatory strategy/submission timelines.
- Engagement and communication: gathered feedback on the experience related to EMA engagement and communication.
- Opportunities for improvement: the last session gave to the respondent an opportunity to make any suggestion for improvement.

Both surveys combined the following response formats:

- Dichotomous scale (Yes/No answers).
- 4-points rating scale (e.g. 1 Extremely easy; 2 Very easy; 3 Easy, Not easy (please specify)).
- Multiple choice and multiple response.
- Free text (maximum 500 characters).

The surveys were sent every 15$^{th}$ of the month to those companies contact points and EU Network experts that attended any of the meeting in scope during the previous month. Reminders were also sent to improve the response rate.

Each company contact point was asked to provide a consolidated feedback on the specific meeting attended while each EU network expert was asked to provide a feedback for each meeting attended.

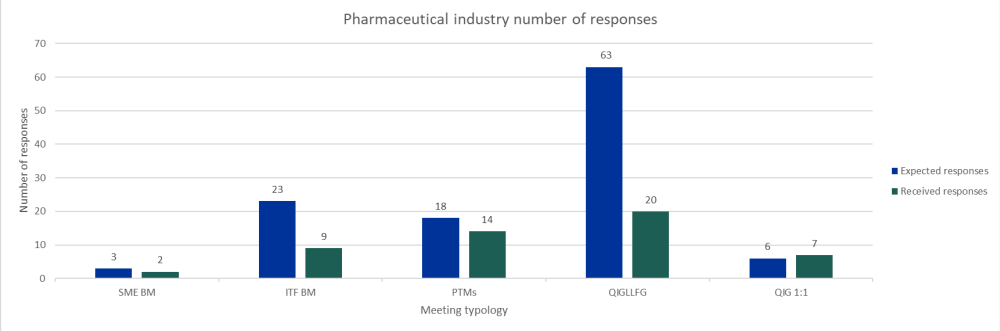
# 4. Industry stakeholders survey on early engagement fostering innovation

It should be noted that the survey run from 1st January 2024 to 31st December 2024 and that a preliminary analysis was done covering the period from 1st January to 7th August 2024 and presented at the 12th Industry stakeholder platform on research and development support meeting.

## *4.1. Overall interim survey response rate*

The survey was sent to 114 pharmaceutical companies contact points. Although several reminders were sent, a response was received from 50 individuals (response rate: 44%). Companies were asked to submit consolidated feedback, however, in some instances, more than one response was provided for the same meeting attended as it can be seen in figure 1 for the QIG 1:1 meeting (6 meetings and 7 responses received). In addition, it should be noted that for the two QIG LLFG meetings, the survey was sent to all Industry attendees asking each affiliation to provide one consolidated response (a total of 63 organisations). Therefore, also in this case it cannot be excluded that more than one feedback was provided from the same organisation.

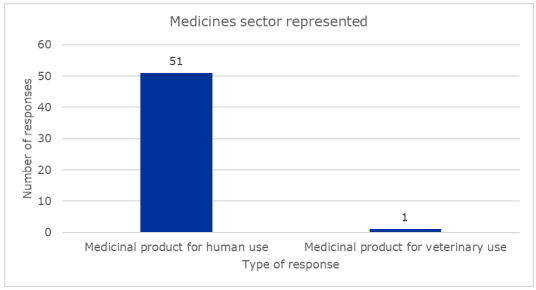
**Figure 1.** Pharmaceutical companies' number of responses per typology of meeting attended

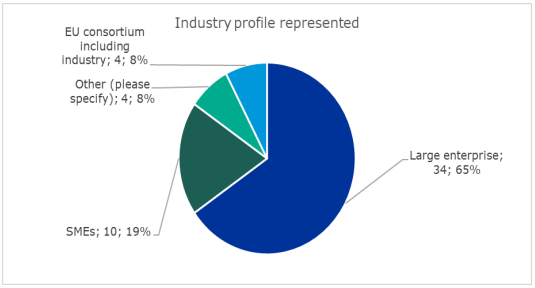



## *4.2. Industry stakeholders' profile*

Most responders represented medicinal products for humans use (51) and only 1 represented medicinal products for veterinary use. "Large enterprises" was the industry profile most represented (65%). This was followed by "Small-medium sized enterprise (SMEs)" (19%), "EU consortium including industry" (8%) and other organisations providing academia support and training (8%).

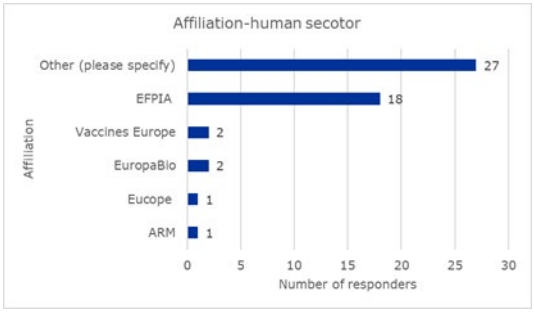
**Figure 2.** Industry stakeholders' sector and profile




The feedback received was received by individual companies as well as companies affiliated to organisations representing the human sector or the veterinarian sector (1 instance only).

**Figure 3.** Companies' affiliation (refer to the glossary for the acronyms)



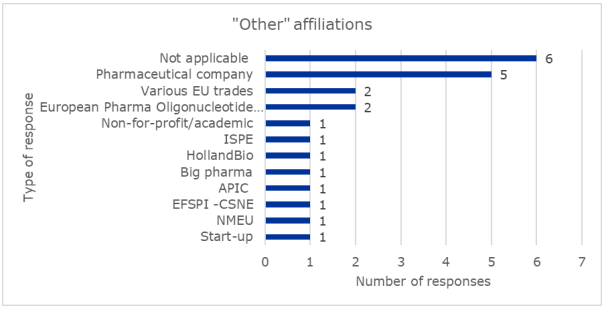
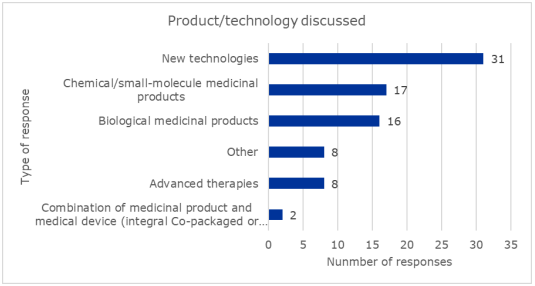




Figure 4 outlines the typology of product or technology for which early engagement support was requested. Each company had the possibility to select more than one option. It can be noted that most companies approached the EMA in order to discuss the approach to "New technologies" (31), "Chemical/small molecule medicinal products" (17) and "Biological medicinal products" (16).

For the responses where "Other" was selected, the following scope was indicated:

- Experimental platform
- New endpoints
- Policy/regulatory science
- Precision medicines
- Real world evidence

**Figure 4.** Typology of product/technology discussed during the meeting



## *4.3. Innovation Task Force Briefing Meetings (ITF BM)*

ITF BMs were established in 2005 with the aim of providing to developers a forum for early dialogue on innovative medicines.

Information on ITF BMs is available on the EMA corporate webpage "Supporting innovation" where general details on ITF BM scope, supporting step-by-step guidance (Applying for an innovation task force briefing meeting version 1, version 2), ITF BM request form and Briefing Document are available.

It should be noted that all published information was updated on the 13th of March 2024. Nevertheless, the content of the guidance and template was not changed.

The survey was sent to 23 pharmaceutical companies who attended the ITF BM during the period analysed. Out of these, 9 responses were received (response rate: 39 %). Note that 7 ITF meetings with industry stakeholders were excluded from the survey (4 were omitted by mistake and 3 were omitted because they did not involve EU network experts).

### 4.3.1. ITF BM request process

The majority of responders identified the possibility to ask for ITF BM meetings through "EMA staff/meetings" (4), their "Industry colleagues" (4) or through "Conference" (3). "Internet search" and consultation of the "EMA website" were not the most rated source of information.

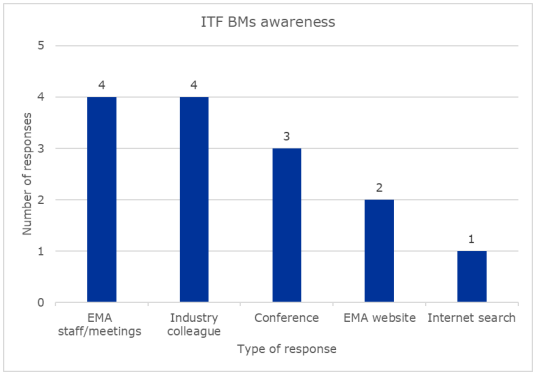
The step-by-step guidance was "Very clear" by 5 out of 9 responders. When "Not clear" was selected (1), the complexity of the process and lack of clarity/support were flagged.

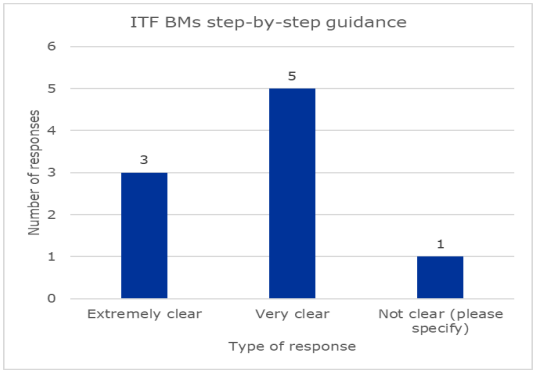
Similar positive opinions can be identified for the clarity of the ITF BMs request form and Briefing Document. Also, in the case of the request form, when "Not clear" was selected (1), the complexity of the process and lack of clarity/support were flagged.

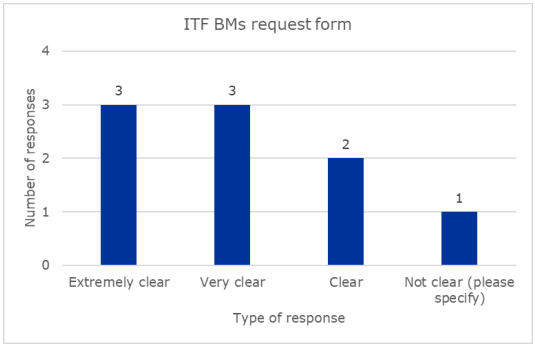
The time taken to set up the meeting was considered "Very adequate" (5/9) by most responders who were also were satisfied with the instructions received to prepare for the meeting (9/9).

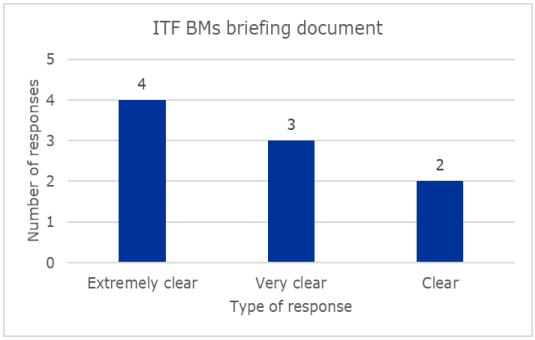
The registration through the IRIS platform was rated "Easy" by the majority of the responders (6/9). When IRIS registration process was described as "Not easy" (1), the responder clarified that the process appeared complex and there was a lack of adequate guidance for external users.

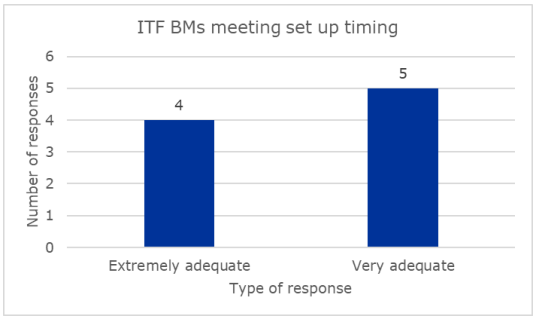
**Figure 5.** ITF BMs request process

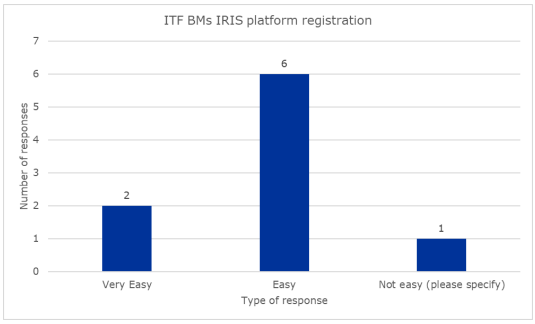



## 4.3.2. ITF BM content

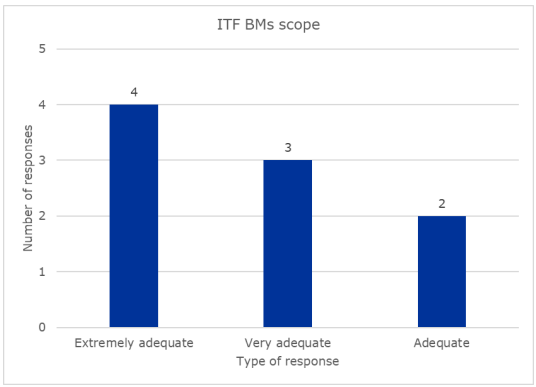
The content of the meeting was evaluated in terms of:

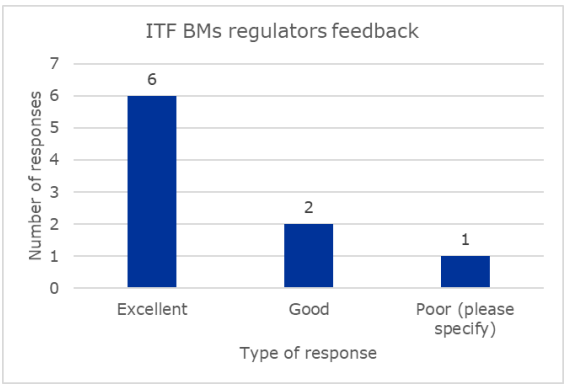
- ITF BM scope (i.e. facilitating informal exchange of information and guidance in the development process, complementing and reinforcing existing formal procedures);
- expert team representativeness and feedback received;
- allocated time for presentation and discussion.

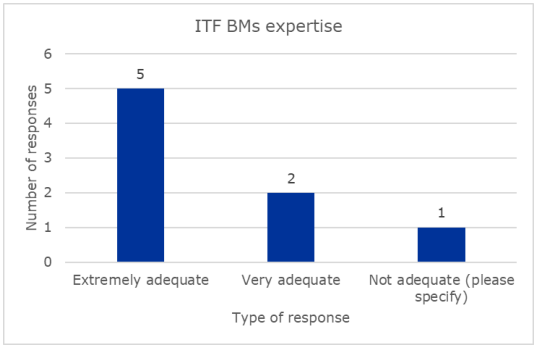
From the results reported in Figure 6, responders considered "Extremely adequate" the scope of the meeting, and the majority was pleased with the level of expertise and with the feedback received. Lack of interaction, difficulties in having discussion with the experts who, in some cases, did not introduce themselves, was reported in one case.

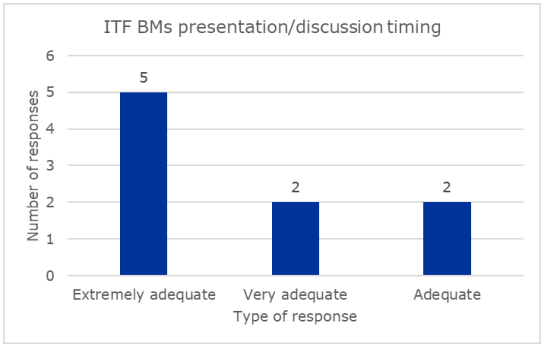
Generally, the timing allocated for the presentation and discussions was rated "Extremely adequate".

**Figure 6.** ITF BMs content




### 4.3.3. ITF BM output/deliverable

The output of the meeting was evaluated in terms of:

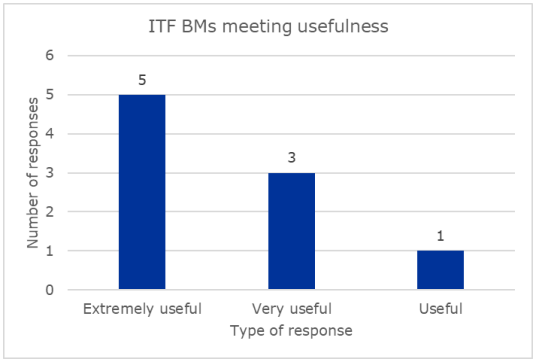
- meeting usefulness and impact to company's strategy;
- post meeting IRIS platform process.

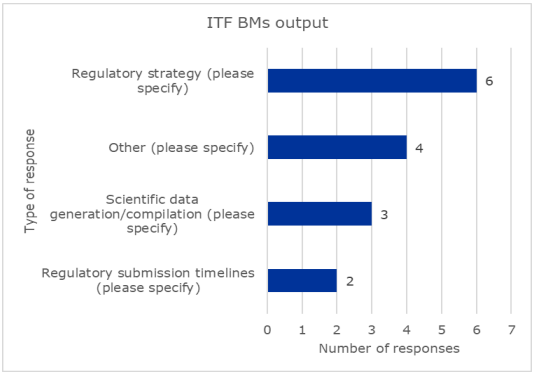
The majority of companies considered "Extremely useful" the meeting experience which resulted for the majority of responses (6) in a change to the regulatory strategy and in gaining more clarity/awareness of the data required in support of the regulatory and technical strategies.

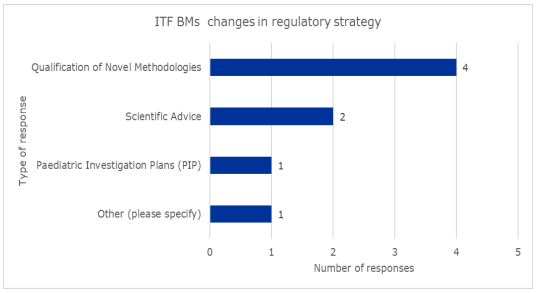
Where "Other" was selected (1), it was specified that the ITF BM gave better understanding on the regulatory and technical strategy.

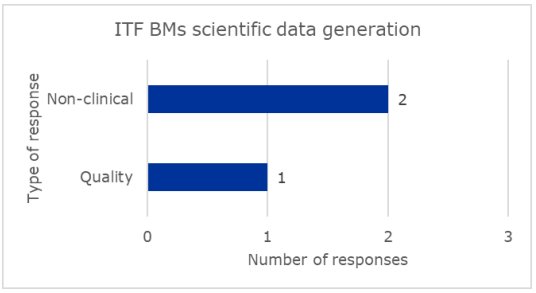
Many of the survey responders rated the post meeting process on the IRIS platform as "Extremely easy" (5/9).

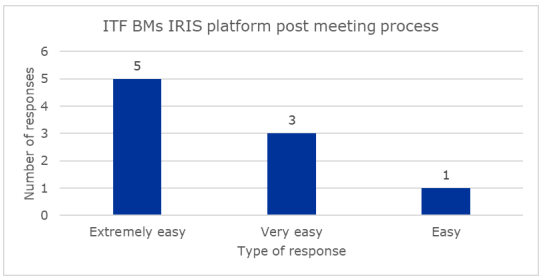
**Figure 7.** ITF BMs output/deliverable



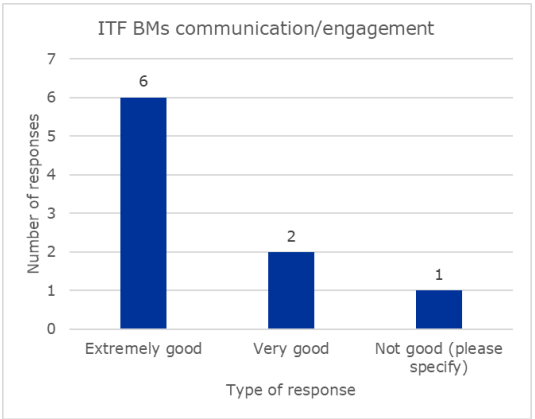




## 4.3.4. ITF BMs communication and engagement

The overall satisfaction of the communication and engagement experienced was rated as "Extremely good" (6/9). When "Not good" was selected (1), details were provided on the lack of adequate engagement with the experts.

**Figure 8.** ITF BMs communication and engagement

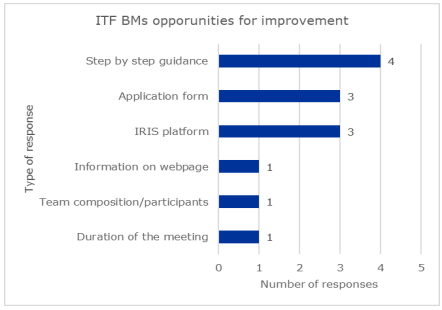


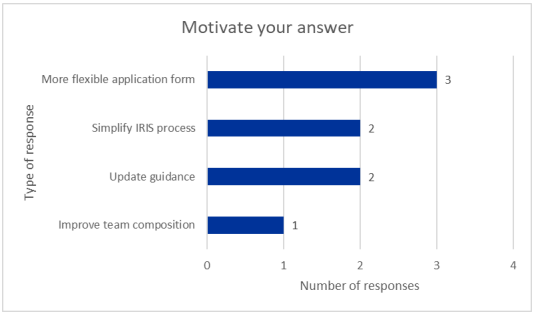
### 4.3.5. ITF BMs opportunities for improvement

The last part of the survey allowed companies to suggest opportunities for improvement.

Most of the feedback received, indicated the need to update the step-by-step guidance, to improve the application form in order to increase usability for other products; improvements to the IRIS platform, described as "confusing process". In all cases the useful support of the ITF team was flagged.

**Figure 9.** ITF BMs opportunities for improvement




### 4.3.6. Conclusions and recommendations on ITF BMs

The majority of responders expressed general satisfaction with the meeting request process, with the timing and the organisational aspects. The information available on the website, the guidance and the templates were rated positively with some suggestions for improvements made on providing updated and clearer information and improve the flexibility of the request form.

The content and outcome of meetings were also rated positively. Remarks were made in promoting more engagement and discussions with the experts. All responders confirmed that the ITF BM has an impact on their regulatory strategy and/or submission timelines and also increased companies' awareness of regulatory aspects. Positive ratings were also given to the ITF team support and their engagement and communication.

Improvements were suggested to the application form, IRIS platform, step-by-step guidance and published information.

#### *4.3.6.1. Recommendations*

Based on the feedback received the following recommendations are made to the ITF team for further reflection:

1. Evaluate need of updating published information, guidance and templates.

## *4.4. Portfolio and Technology Meetings (PTM)*

The Portfolio and Technology Meetings (PTMs) were established by EMA in 2003 as "Business Pipeline meetings".
In October 2023 the process was revamped and renamed as "Portfolio and Technology Meetings (PTM)" in order to enhance transparency and extend the scope to a wider industry audience.

Information on PTM is available on the EMA corporate webpage "Supporting innovation".

The aim of the PTM is discuss with pharmaceutical companies with large medicinal products portfolio any issues impacting the progress of product portfolios and assist successful development; to capture innovative and disruptive technologies and to anticipate the scientific and regulatory expertise needed to assess future applications.

Further to the revamp, 29 applications were received for 2024 and, out of these, EMA will proceed in having 18 PTMs with 16 companies during the course of the year.

For the concerned period for this interim report, the survey was therefore sent to 18 pharmaceutical companies and a response was received from 14 of them.

### 4.4.1. PTMs request process

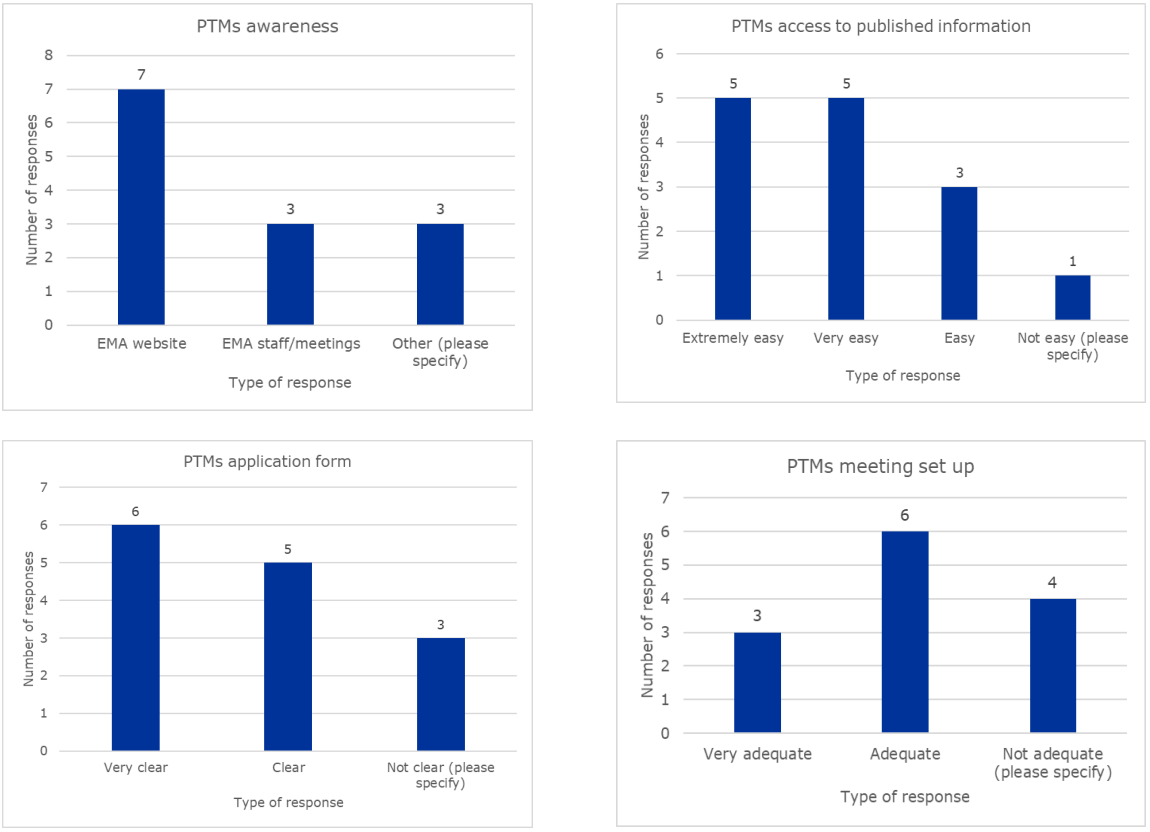
Responders became aware of the opportunity to engage in a PTM either through "EMA website" (7) or interaction with "EMA staff". When "Other" was selected the previous experience and EMA direct approach were indicated. The access to relevant published information was considered generally "Extremely easy" and "Very easy".

The Application form although considered generally "Very clear" by 6 out of 14 companies, was also flagged as "Not clear" by 3 respondents given the presence of too many sections requesting detailed information and the lack of flexibility for the therapeutic area mandatory field.

The meeting set up process was generally considered "Adequate" (6/14). Where "Not adequate" was indicated (4/14), the need to allow more time for the company to familiarise with the request process and its template, and to have the list of questions in advance to better prepare for the actual meeting was reported. Additionally, the need to shorten the waiting time between meeting request and meeting set up was flagged. Proposals to improve scheduling timing and provide list of questions in advance were made.

The preparatory instructions were considered satisfactory by all responders (14/14).

**Figure 10.** PTMs meeting request process




## 4.4.2. PTMs content

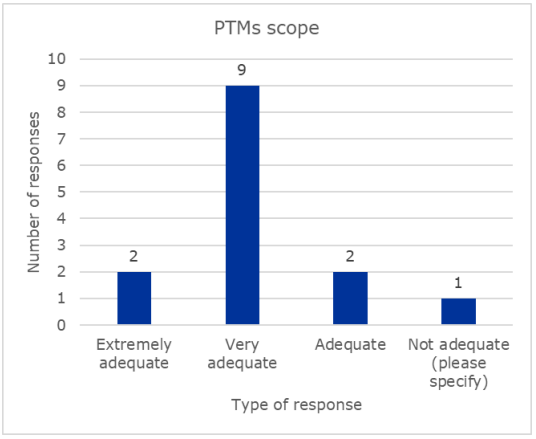
PTM content was evaluated in terms of:

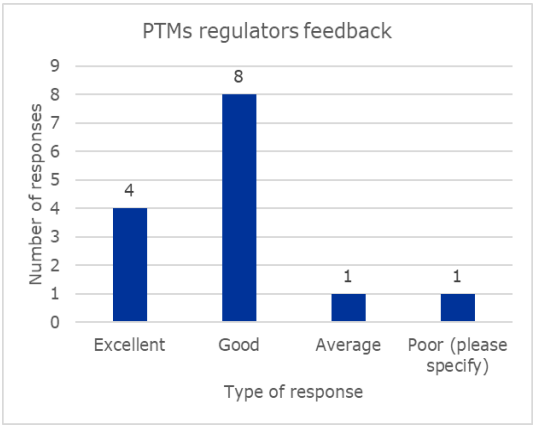
- PTM scope (i.e., identify any issues impacting the progress of product portfolios; capture new and disruptive technology already in use; anticipate the scientific and regulatory expertise needed to assess future applications);
- expert team representativeness and feedback received;
- allocated time for presentation and discussion.

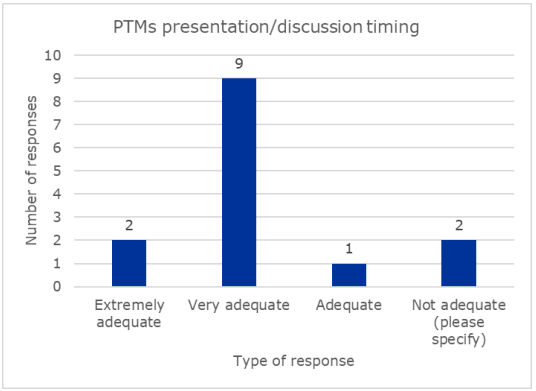
The scope of the meeting was generally considered "Very adequate". The need to include policy/regulatory topics into the discussions was flagged by 1 responder. The majority of responders (8/14) rated as "Good" the quality of the feedback received from regulators. Where "Not good" was selected (1/14), it was indicated the desire to receive more informal advice even if it is understood that the is a need to follow up formally via the scientific advice procedure.

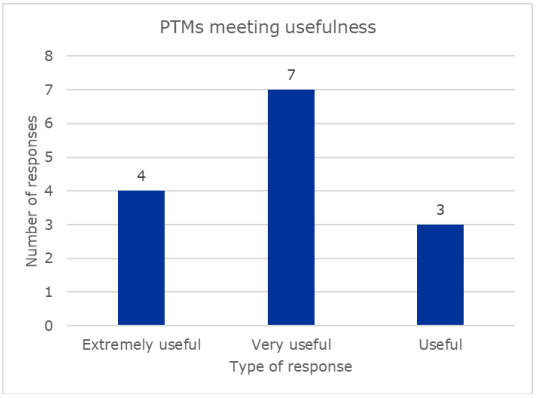
The overall time provided for the presentation and discussions was also considered satisfactory with exception of 2 responders asking to ensure adequate timing for discussion all topics. All responders considered the PTM a useful experience.

**Figure 11.** PTMs content



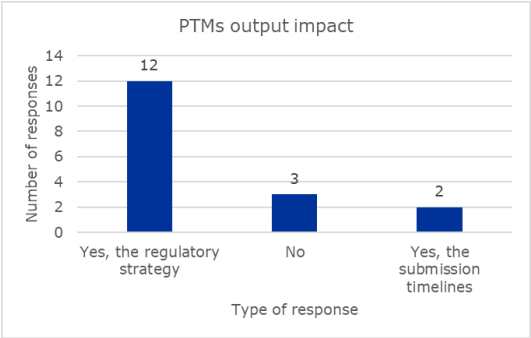

### 4.4.3. PTM output/deliverable

The output of the meeting was evaluated in terms of:

- meeting usefulness;
- impact to company's strategy.

The majority of responders indicated that the meeting had an impact on the regulatory strategy and/or on the submission timelines. The open feedback and insights gained were appreciated especially the clarity received on the regulatory strategy and on the position of the EMA and other agencies. In some instances, the need to receive a less high-level feedback was flagged.

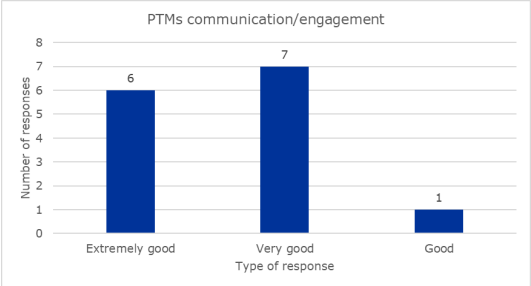
**Figure 12.** PTMs output/deliverable




## 4.4.4. PTMs communication and engagement

The overall level of communication and engagement experienced was considered "Extremely good" to "Very good" by the majority of responders.

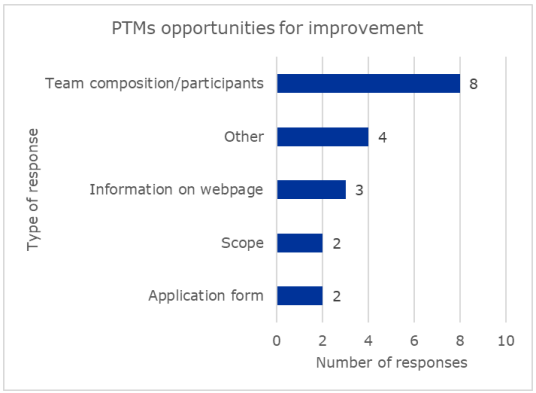
**Figure 13.** PTMs communication/engagement




## 4.4.5. PTMs' opportunities for improvement

Ensure clarity, composition and roles of the EU network expert attending the meeting was flagged as an opportunity for improvement along with improvement of published information, application form and timelines for submitting briefing document and prepare for the meeting.

**Figure 14.** PTMs opportunities for improvement




### 4.4.6. Conclusions and recommendations on PTMs

PTMs experience was generally considered useful by the responding companies who valued the feedback received from regulators. Generally positive feedback was received on the meeting request process and organisational aspects. Improvements to the application form, published information (i.e. more details on the timelines and guidance to companies) were flagged.

Overall, the engagement and communication processes were considered to be very good and the PTMs resulted in an impact to regulatory submissions and timelines.

The need to allow more preparatory time for companies not familiar with the process was flagged. At this regard, receiving the list of experts and the list of questions in advance was suggested.

#### *4.4.6.1. Recommendations*

Based on the feedback received, the following recommendations are made to the PTM team for further reflection:

1. Evaluate need of updating published information, guidance and application form.
2. Evaluate how to enhance company preparedness before the meeting (list of experts; list of questions).

## *4.5. Quality Innovation Group (QIG)*

The QIG organises listen and learn focus group (LLFG) meetings and dedicated 1:1 meetings with stakeholders. A dedicated webpage is available on the EMA corporate website outlining the activities of the group.

During the period analysed 2 QIG Listen and Learn Focus Group (LLFG) were hosted. The survey was sent to 63 Industry stakeholders who participated to these events. The response rate is currently 32% (20/63).

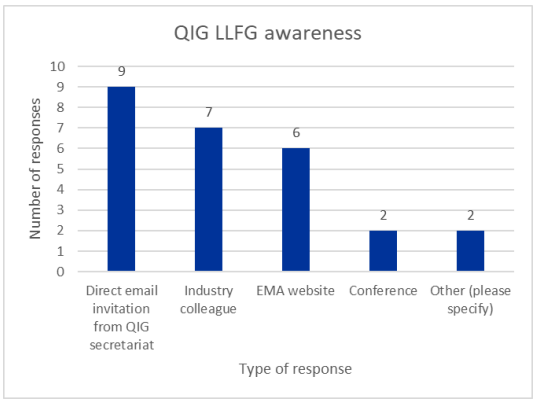
In terms of the QIG 1:1 meetings with specific stakeholders, 6 meetings were hosted. In this case the response rate was 117% given the fact that 7 responses were received.

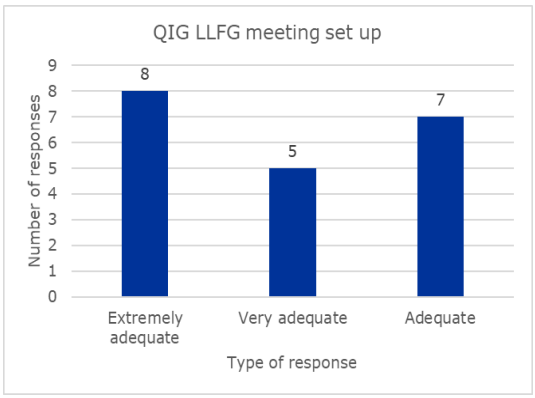
### 4.5.1. QIG LLFG request process

Most respondents became aware of the QIG LLFG through QIG secretariat direct invitation (9/19) or through their colleagues (7/19). The "EMA website" and "Conferences" are a less prominent source of information. When "Other" was selected (2), it was indicated previous collaboration in other work or via the trade organisation.

Generally, the timing to set up the meeting was considered "Extremely adequate" (8/19).

**Figure 15.** QIG LLFG Meeting request process



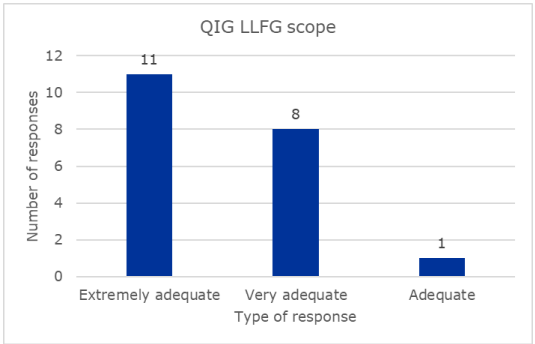

## 4.5.2. QIG LLFG content

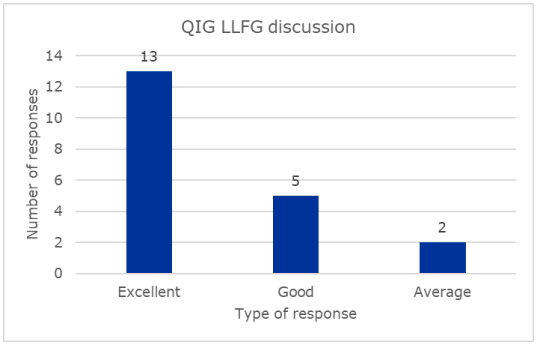
The content of the meeting was evaluated in terms of:

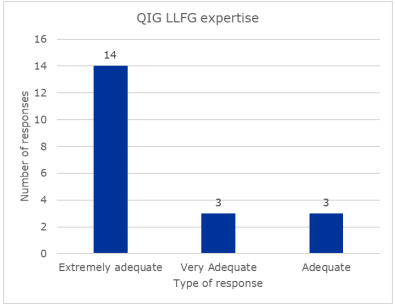
- QIG LLFG scope (i.e. hear about the regulatory challenges developers face in relation to innovative products, processes, control strategies and facilities, and to identify potential solutions);
- expert team representativeness and engagement experienced;
- allocated time for presentation and discussion.

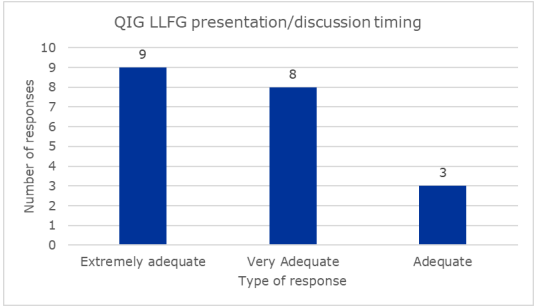
As showed in figure 16, responders were satisfied with the scope, level and timing of the discussions and expertise represented.

**Figure 16.** QIG LLFG meeting content



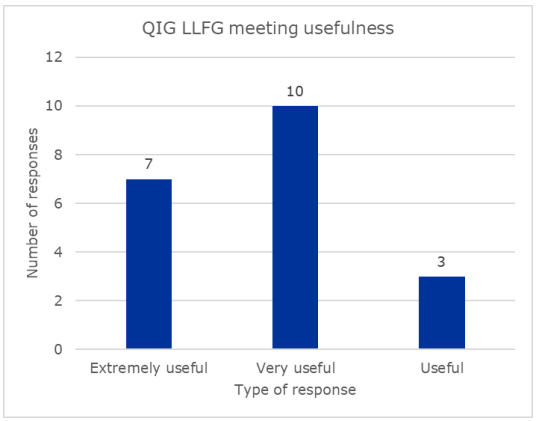
### 4.5.3. QIG LLFG output/deliverable

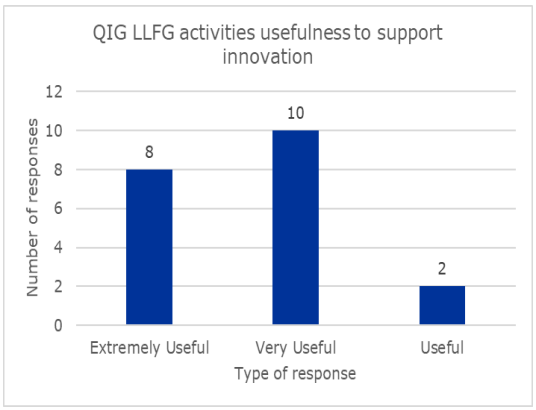
The output/deliverable of the meeting was evaluated based on:

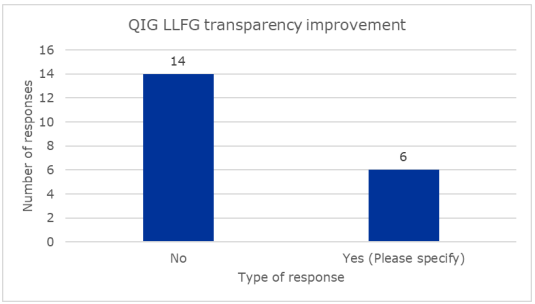
- meeting usefulness;
- meeting report publication.

QIG LLFG was considered "Very useful" by the majority of responders (10/19) in terms of meetings discussion and QIG activities in support to innovation on advanced manufacturing in EU and its impact at global/international level. General satisfaction with the publication of a meeting report outlining the discussions was also reported (14/19). Considerations on improving the timing for publishing the meeting report, on increasing the engagement/input with all stakeholders and in allowing post meeting activities were flagged.

**Figure 17.** QIG LLFG output/deliverable



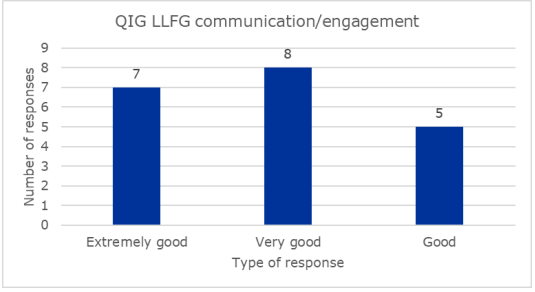




### 4.5.4. QIG LLFG communication and engagement

All responders expressed general satisfaction with the level of communication and engagement as showed in figure 18.

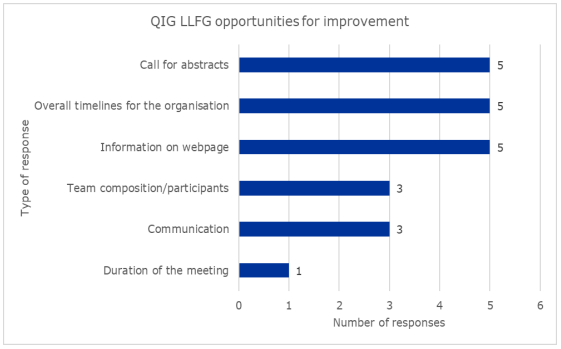
**Figure 18.** QIG LLFG communication and engagement

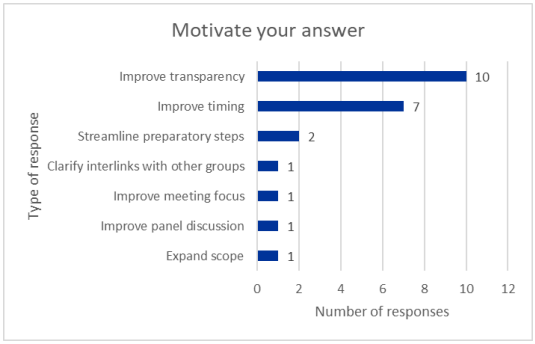


## 4.5.5. QIG LLFG opportunities for improvement

Improvement of the overall organisation timelines and of the information available online were the main suggestions made. Suggestions were made on the need to have more published information, on the need to ensure more transparency on topic selection and on interlinks of the QIG LLFG with other relevant groups.

**Figure 19.** QIG LLFG opportunities for improvement




## 4.5.6. Conclusions and recommendations for QIG LLFG

Responses were received from 19 out of 63 companies for the QIG LLFG indicated satisfaction on the available published information, on the organisational aspects and the meeting content. QIG activities in support to innovation was considered useful. Engagement and communication were also rated as very good.

Suggestions for improvement included further promotion of the meetings (possibly in person) with more focussed discussions, improved timelines for publication of the meeting report, streamline the preparatory steps and increase transparency on topic selection.

### *4.5.6.1. Recommendations*

Based on the feedback received the following recommendations are made to the QIG team for further reflection:

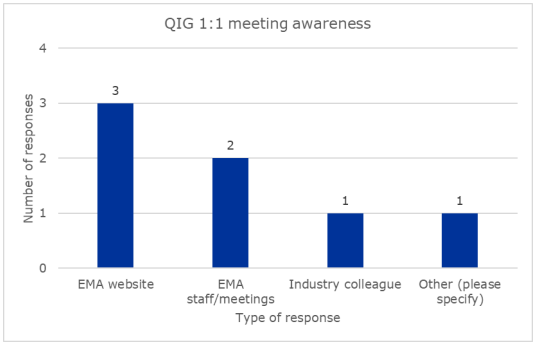
1. Evaluate how to improve timelines for pre-meeting and post-meeting steps.
2. Explore how to increase transparency on topic selection.
3. Clarify interlinks with other relevant groups.

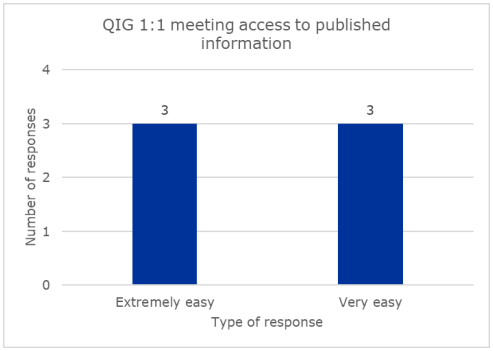
## 4.5.7. QIG 1: 1 meeting request process

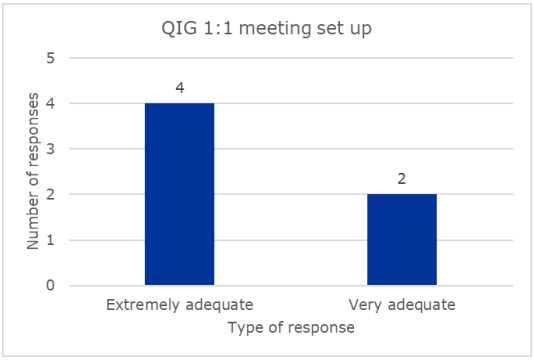
The responders became aware of the meeting mainly via the EMA website, advice given by EMA staff (also via other meetings) and industry colleagues.

All companies expressed satisfaction with the available information and the meeting set up timing and preparatory instructions.

**Figure 20.** QIG 1:1 meeting request process



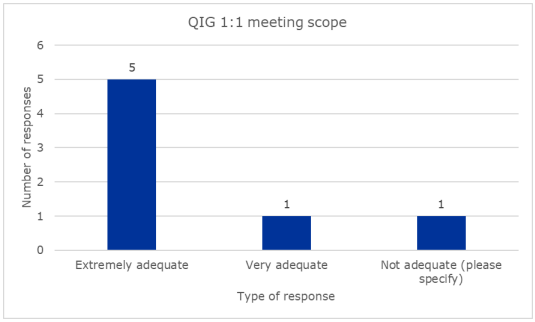

## 4.5.8. QIG 1:1 meeting content

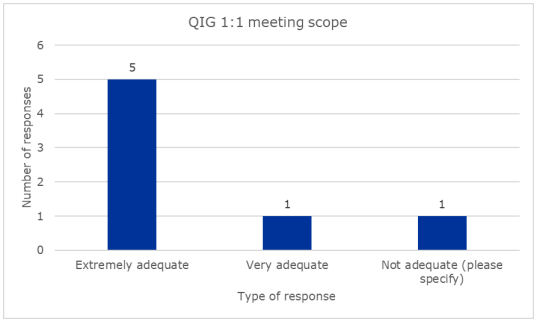
The content of the meeting was evaluated in terms of:

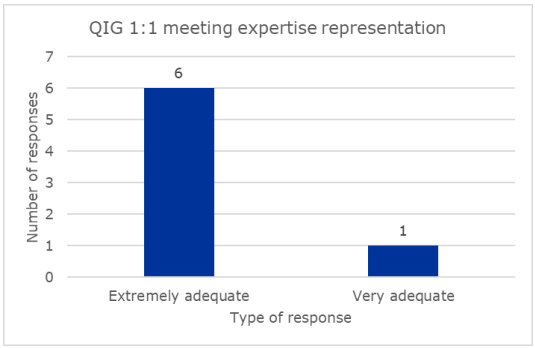
- QIG targeted interaction scope (to provide advice and discuss plans for applying for an EMA Scientific advice procedure on a topic covered by the QIG work programme/2023-2024 priority topics);
- expert team representativeness and feedback received;
- allocated time for presentation and discussion.

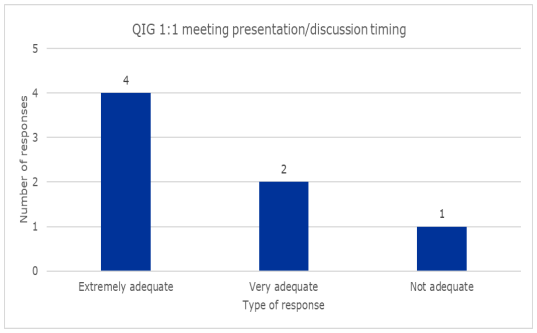
The majority of responders (5/7) considered "Extremely adequate" the scope of the meeting (i.e. to provide advice and discuss plans for applying for an EMA Scientific advice procedure on a topic covered by the QIG work programme/2023-2024 priority topics) and were generally satisfied with the interaction with regulators, the expertise represented and the feedback received and with the timing of the presentation/discussions (Figure 21). When "Not adequate" was selected, the proposal to expand the scope to other areas of innovation and include early stages of development was given.

**Figure 21.** QIG 1:1 meeting content




## 4.5.9. QIG 1:1 meeting output/deliverable

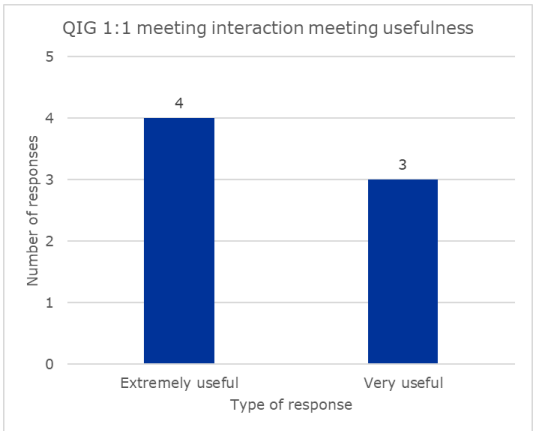
The meeting output/deliverable was evaluated in terms of:

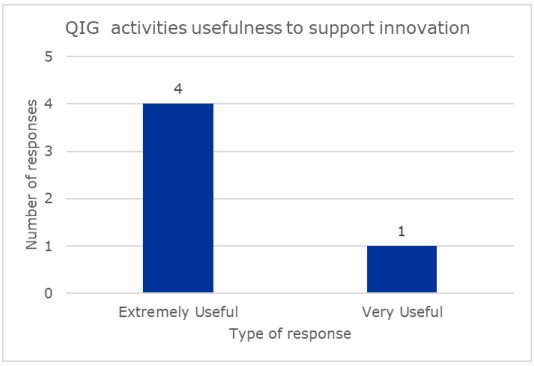
- meeting usefulness;
- impact to company's strategy.

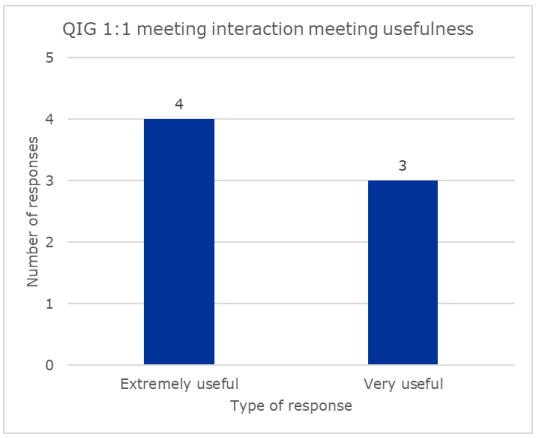
The meeting was considered "Extremely useful" by the majority of respondent companies. Similar feedback was provided for the usefulness of QIG activities in support to innovation on advanced manufacturing in EU and its impact at global/international level.

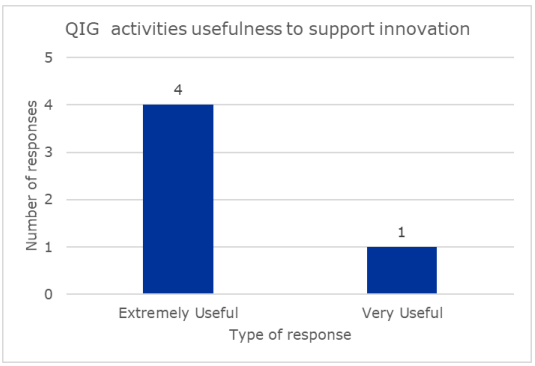
Impact to submissions timelines and regulatory strategy given the improved clarity on regulatory requirements and evaluation of alternative strategies including modelling was reported.

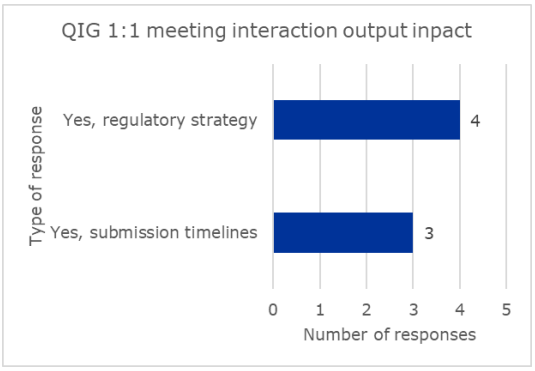
**Figure 22.** QIG 1:1 meeting output/deliverable





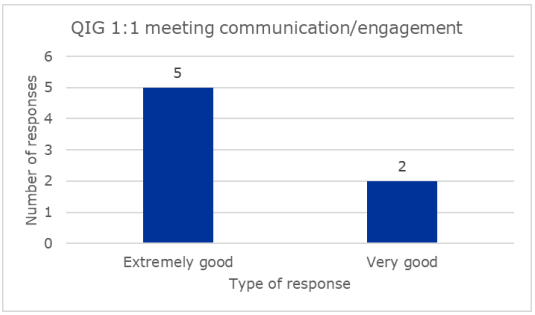




## 4.5.10. QIG 1:1 engagement and communication

The majority of responders rated the level of communication and engagement experienced as "Extremely good" (5/7).

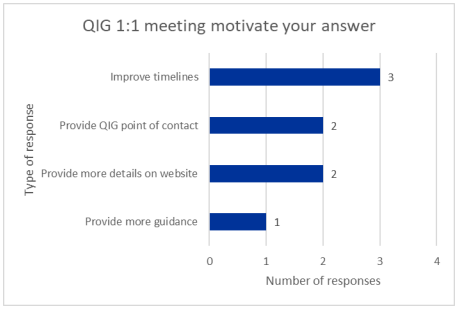
**Figure 23.** QIG 1:1 engagement and communication




## 4.5.11. QIG 1:1 meeting opportunities for improvement

Companies have suggested to provide more information on the webpage and to improve overall meeting timing. The establishment of QIG contact points for follow up and support to future marketing authorisation application and the possible participation of FDA were also flagged.

**Figure 24.** QIG 1:1 meeting opportunities for improvement


## 4.5.12. Conclusions and recommendations for QIG 1:1 meetings

Responses were received from 7 companies for the QIG 1:1 meetings and in all cases general satisfaction on the available published, meeting process, level of interaction and dialogue. QIG activities in support to innovation was considered useful and, in the case of the 1:1 meetings, the feedback received led to changes in regulatory strategies and submission timelines.

Engagement and communication were also rated as very good.

Suggestions for improvement included exploring possible dedicated QIG contact points for future MAA, inclusion of international authorities for 1:1 meetings, provide more information on the webpage.

#### *4.5.12.1. Recommendations*

Based on the feedback received the following recommendations are made to the QIG team for further reflection:

1. Explore further supporting activities following the QIG 1:1 meetings.
2. Consider publication of additional guidance.

## *4.6. Small-, Medium- Sized Enterprises briefing meetings (SMEs BMs)*

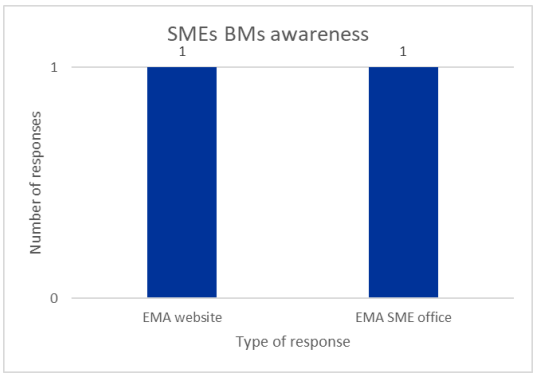
The Small-, Medium Sized Enterprises beefing meetings (SMEs BMs) is a form of support provided by EMA SME Office to SMEs. The goal of these meetings is to provide guidance and help smaller companies navigate the centralised authorisation procedure and available incentives. SMEs can engage in an early dialogue with a multidisciplinary EMA team to discuss a regulatory strategy for developing human and veterinary products.

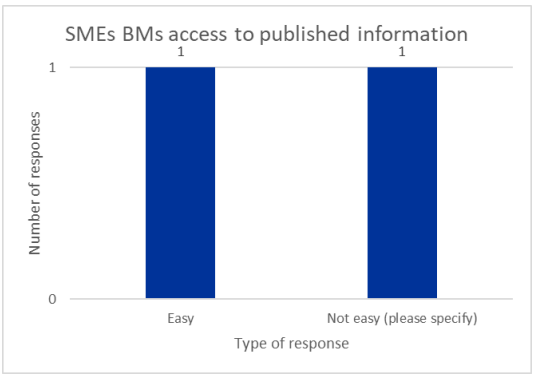
Relevant information is available on the "Support to SMEs" corporate website.

During the period analysed 3 SMEs BM was held for which 2 responses were received (67% response rate).

## 4.6.1. SMEs BMs meeting request process

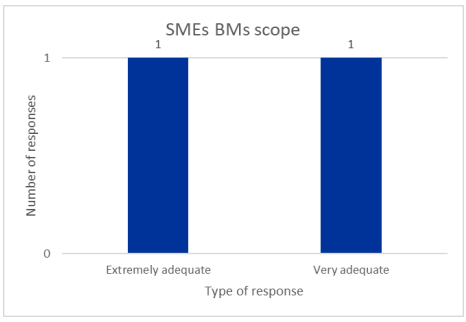
The responders became aware of the opportunity for a meeting via the EMA website or directly via the SME office. The application process was rated as "Clear" in all cases while the access relevant information from the EMA webpage for the meeting request and preparation was considered "Not easy" by 1 respondent given the lack of information available and the different instructions received. The timing for setting up the meeting was considerate "Adequate" in both cases.

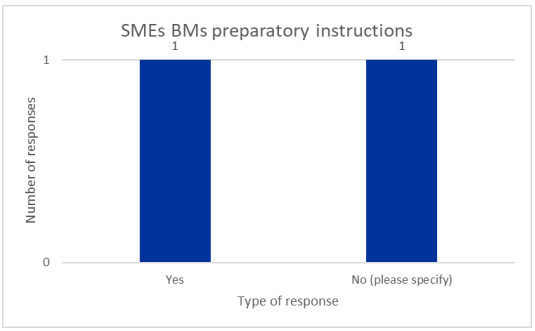



## 4.6.2. SMEs BMs content

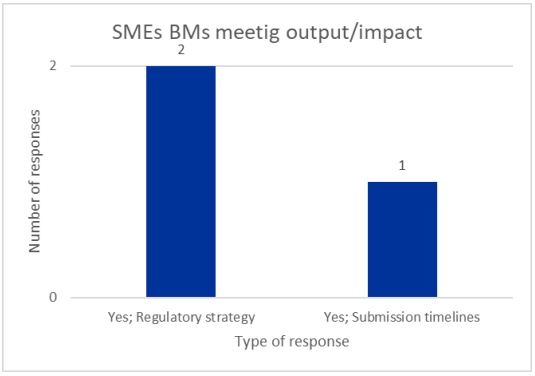
Preparatory instructions available on the website were considered helpful by 1 respondent and not considered helpful by the other who appreciated the additional guidance received from the SME office. The scope of the meeting was considered "Extremely adequate" and "Very adequate". Positive opinions were also given to the feedback received, to the expertise involved and to the timing given for presentation and discussion. The overall experience was considered positive.



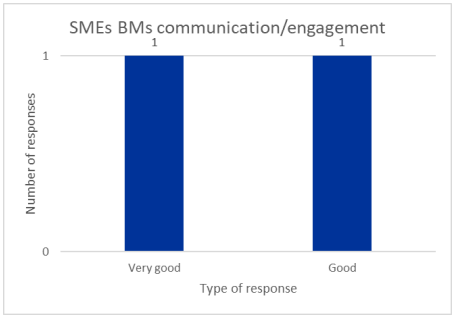

## 4.6.3. SMEs BMs output/deliverable

The meeting resulted in informing the next steps in term of regulatory strategy and/or submission timelines.



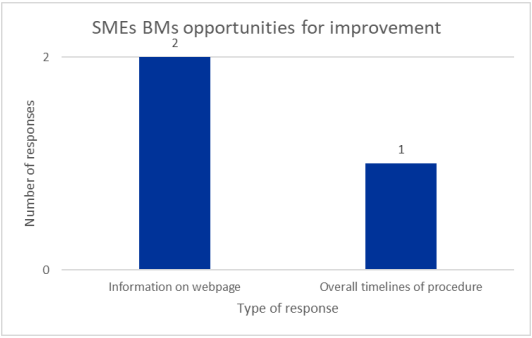
### 4.6.4. SMEs BMs communication and engagement

The interaction experience was considered positive by both companies.




### 4.6.5. SME BMs opportunities for improvement

Opportunities for improvement were suggested for the information displayed on the website. One company suggested improving information available on the website in order to outline a standard approach on how to prepare and organise the meeting.




### 4.6.6. Conclusions and recommendations for SMEs BMs

Feedback was received from 2 out of 3 companies confirming in both cases the usefulness of SMEs BMs meetings allowing SMEs interactions with regulators. Positive feedback was provided on the meeting experience and output and on the support received from the EMA team. Opportunities for improvement were flagged for the preparatory steps given some difficulties in identifying information and pre-meeting instructions on the EMA website.

### 4.6.7. Recommendations

Based on the feedback received the following recommendations are made to the SME team for further reflection:

1. Consider providing additional SME office webpage guidance on meeting preparation.

# 5. EU network survey on early engagement fostering innovation

Members from the EU network contribute to the engagement activities fostering innovation with their expertise on specific fields.

Relevant experts are informed of the upcoming ITF BM on a monthly basis and participation is on a voluntary basis. QIG activities are instead supported by an established group of EU network representatives (i.e. QIG core members).

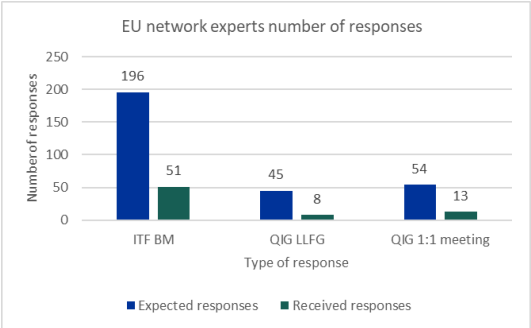
All EU experts who attended any of the meetings in scope (i.e. QIG Listen and learn focus group meetings and/or targeted company meetings and ITF BMs) were asked to provide their feedback on meeting request and preparatory phase, meeting scope, overall communication and engagement experience and suggestions for improvement.

If the expert attended more than one meeting, the completion of more than one feedback survey was requested.

## *5.1. Overall interim response rate*

During the period analysed, a total of 295 were surveyed for 30 ITF BMs (196 experts), 2 QIG LLFG meeting (45 experts) and in 6 QIG targeted interaction meetings (54). All the experts were asked to provide their feedback on each meeting attended. A response was received from 72 EU-network experts (overall response rate 24%).

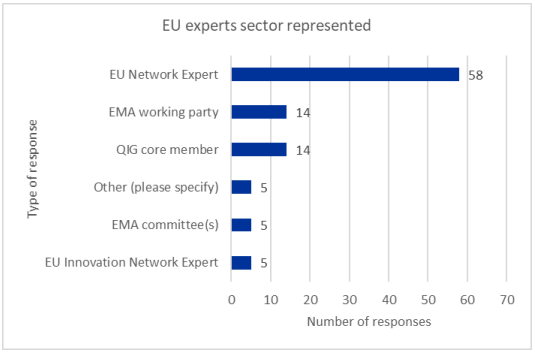
**Figure 25.** EU Network experts number of responses




## *5.2. EU-network profile*

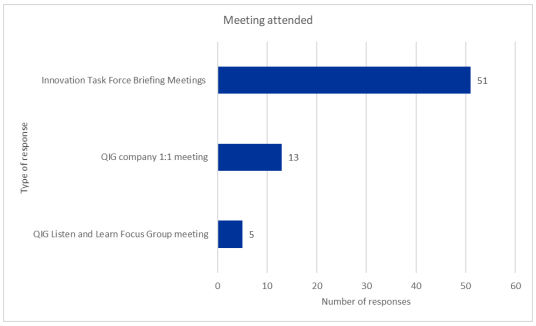
Responses were received from 58 EU network experts; in some cases, these experts were affiliated with groups such as EMA working parties, committees, QIG core members and EU Innovation task force. Where "Other" was indicated, it was specified that the expert was an assessor, an inspector or was a member of a specific group or the European Commission (EC).

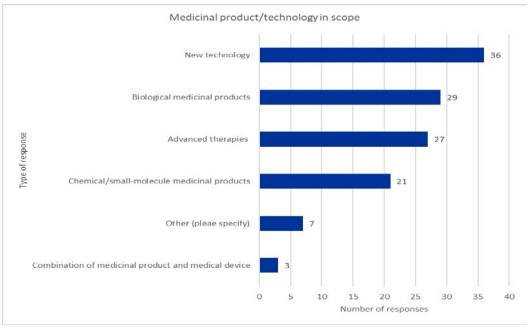
**Figure 26.** EU Network sector represented




The majority of responders attended the ITF BMs (51/72). The majority of expertise supported the discussion on "New technology" (36) followed by "Biological medicinal products" (29) and "Advanced therapies" (27). Where "Other" was selected the following areas were indicated: "veterinary", "platform technologies", "visual inspection", "quality tools", "quality management system", "artificial intelligence" and "process models".

**Figure 27.** EU Network type of meeting attended and scope




## *5.3. EU network experts supporting Innovation Task Force Briefing Meetings (ITF BMs)*

### 5.3.1. EU network experts ITF BMs request process

The EU-network experts became aware of the specific meeting through various channels linked to EMA staff activities and via EMA working party colleagues. This includes monthly call for expression of interest and monthly presentation of upcoming ITF BMs at the relevant EMA committees, EMA working parties and other groups.

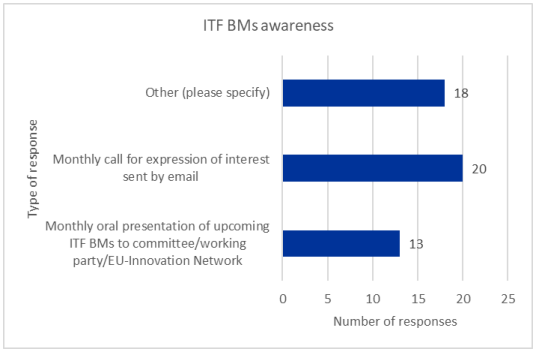
The majority of the experts (48/51) considered adequate the information provided by the company in preparation of the meeting. Where this was not considered adequate (3/51) the few opportunities to debrief colleagues or the unclarity of the information from the company were indicated as main reason.

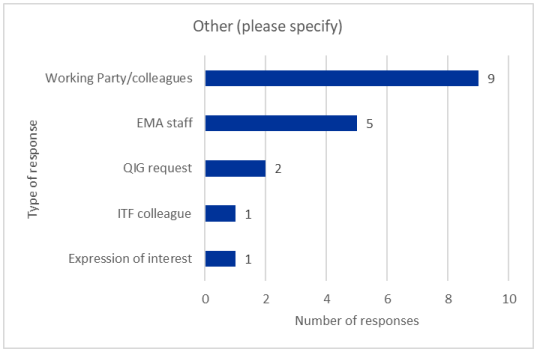
The preparatory timelines were generally rated satisfactory (49/51).

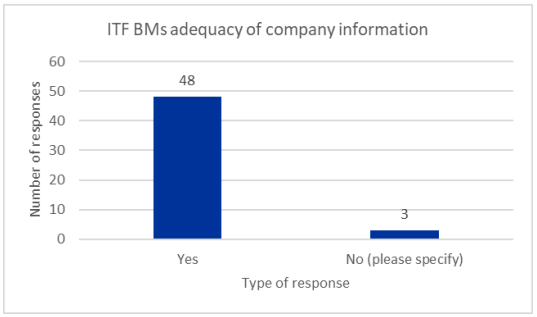
Some expert flagged the late inclusion of background documents in the meeting with lack of time to familiarise with the topic and meeting process.

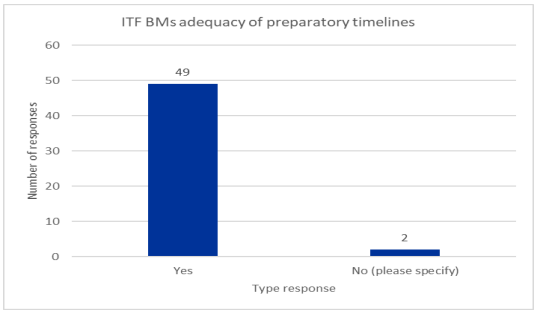
Access to information on IRIS platform and to SharePoint was rated satisfactory by the majority of the experts (41/51). Challenges were flagged by 10 responders on difficulties in accessing IRIS and lack of knowledge on IRIS process.

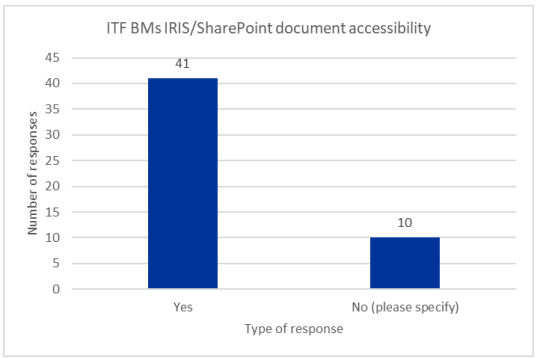
**Figure 28.** ITF BMs request process

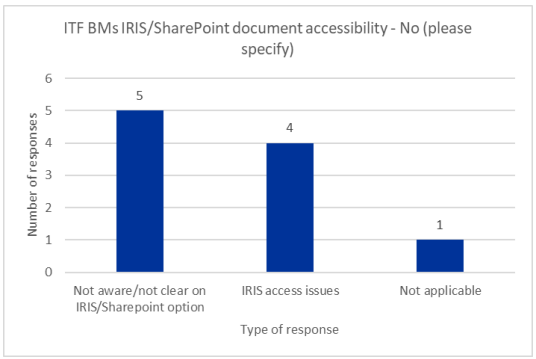


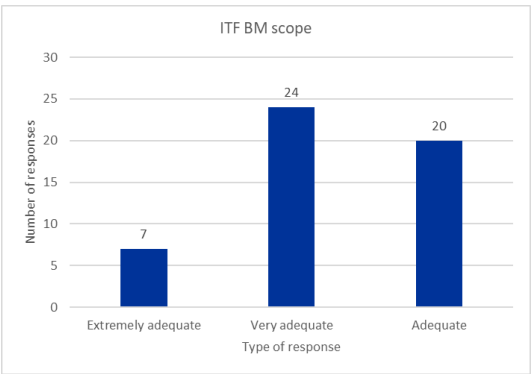




## 5.3.2. EU Network experts ITF BMs scope

The scope of ITF BM was generally rated "Very adequate" by the majority of responders (24/51).

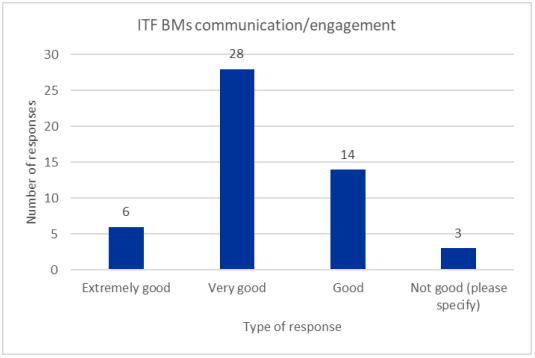
**Figure 29.** Meeting scope



### 5.3.3. EU Network experts communication and engagement

The majority of the experts (34/51) rated the communication and engagement from ITF secretariat as "extremely good" or "Very good" and 14 experts rated the communication "good". Where "Not good" was indicated, the lack of sufficient interaction with EMA and experts on meeting scope and lack of adequate expertise was flagged.

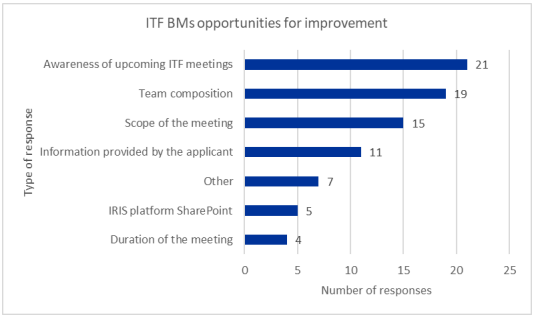
**Figure 30.** EU Network experts communication/engagement

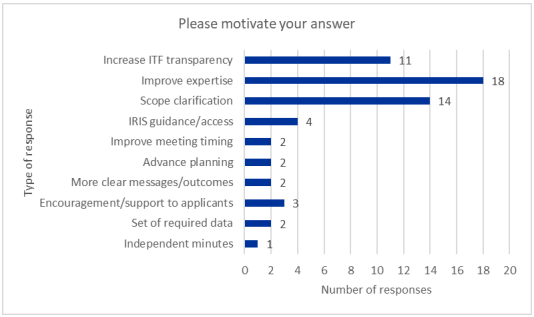



### 5.3.4. EU Network experts ITF BMs opportunities for improvement

Opportunities for improvement suggested by the EU network experts were related to raising awareness of upcoming meetings in order to facilitate resource planning and identification of the required expertise; ensuring adequate team composition based on the topic under discussion; ensure clarity on the scope of the meeting in order to meet expectations and better triage the requests to more suitable procedures (e.g. Scientific Advice).

**Figure 31.** EU Network experts ITF BMs opportunities for improvement




### 5.3.5. Conclusions and recommendations on EU Network experts supporting ITF BMs

The EU network experts were generally satisfied with the collaboration with ITF activities in terms of the level of information provided by companies and the overall communication and engagement with ITF secretariat. An important point flagged was the need to increase awareness amongst the network on upcoming meetings in order to facilitate resource planning and identification of the required expertise. The need to ensure adequate team composition based on the topic under discussion, to ensure better clarity on the scope of the meeting and provide more guidance to companies in order to improve the documentation provided were flagged as opportunities for improvement.

#### *5.3.5.1. Recommendations*

Based on the feedback received the following recommendations are made to the ITF team for further reflection:

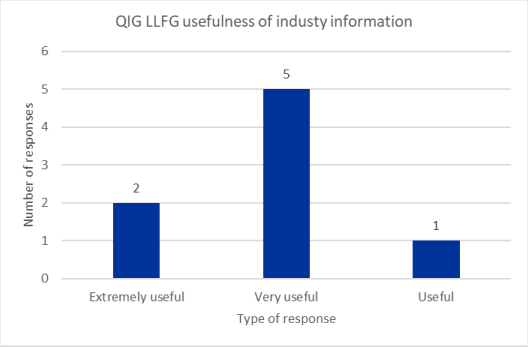
1. Evaluate how to raise awareness and adequately select EU network experts.
2. Evaluate additional guidance for companies.

## *5.4. EU Network experts supporting Quality Innovation Group (QIG) LLFG and QIG 1:1 meetings*

### 5.4.1. EU Network QIG LLFG meeting preparation

EU network experts, including also the QIG core group members, who responded to the survey, considered generally "Very useful" the information received from industry in preparation to the meeting (8/45). All of them considered adequate the preparatory guidance received from QIG secretariat.

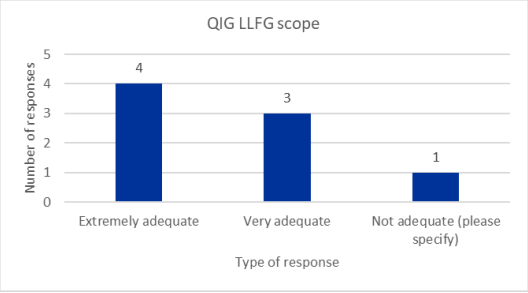
**Figure 32.** EU Network experts QIG LLFG preparation




### 5.4.2. EU network experts QIG LLFG meeting scope

The scope of the meeting was generally satisfactory by the responders. Where "Not adequate" was indicated, suggestions to broaden the meeting scope were made.

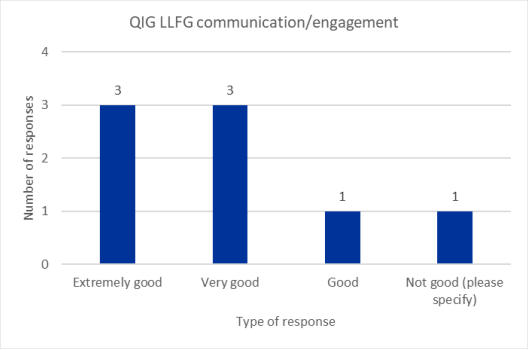
**Figure 33.** QIG LLFG meeting scope




### 5.4.3. EU Network experts QIG LLFG communication and engagement

The majority of responders rated positively the communication and engagement. Where "Not good" was indicated, the difficulties reported related to virtual engagement.

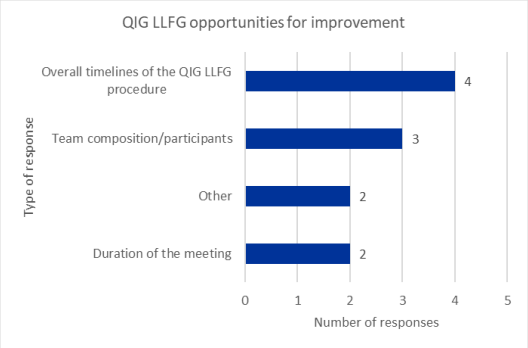
**Figure 34.** QIG LLFG communication/engagement




## 5.4.4. EU Network experts QIG LLFG opportunities for improvement

Allocation of more appropriate timelines for topics discussions and at the same time considerations on meeting duration were flagged. This feedback was also provided by Industry stakeholders. Promote participation of academics and other experts was also suggested.

**Figure 35.** QIG LLFG opportunities for improvement




## 5.4.5. Conclusions and recommendations for EU network as experts on QIG LLFG

EU network experts participating to the QIG LLFG provided positive feedback on the meeting organisation and content. QIG team engagement and communication was also rated positively. Suggestions for improvements were made in the improvement of meeting overall timelines and team composition.

### *5.4.5.1. Recommendations*

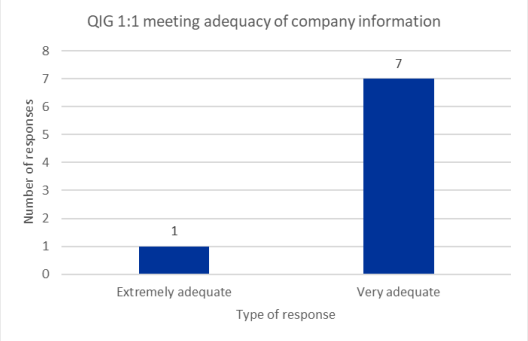
Based on the feedback received the following recommendations are made to the QIG team for further reflection:

1. Evaluate improvement of meeting timelines.
2. Evaluate improvement of team composition/participants.
3. Evaluate raising awareness on QIG LLFG meetings to SMEs and academia.

### 5.4.6. EU Network experts on QIG 1:1 meeting preparation

The majority of the EU experts, including the QIG core members, (7/8) rated "Very adequate" the information provided by the company to prepare for the meeting and all of them considered adequate the timeline provided for reviewing the information prior to the meeting.

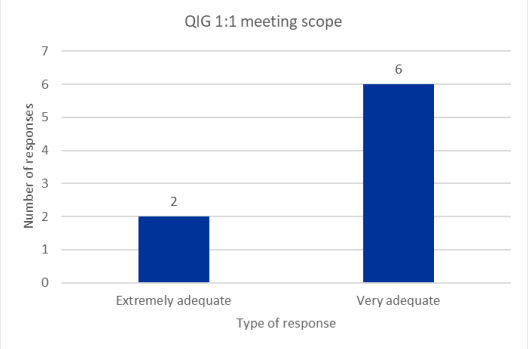
**Figure 36.** QIG 1:1 meeting preparation




### 5.4.7. EU Network experts on QIG 1:1 meeting scope

The majority of the experts (6/8) considered "Very adequate" the scope of the meeting.

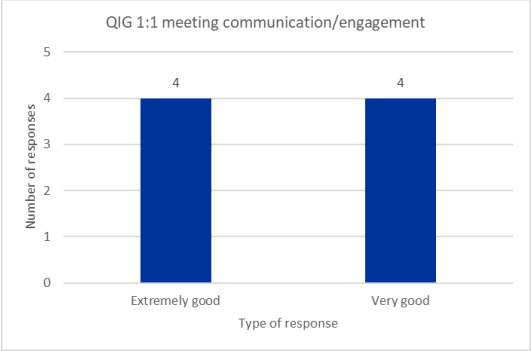
**Figure 37.** QIG 1:1 meeting scope




### 5.4.8. EU Network experts on QIG 1:1 meeting communication and engagement

The overall level of communication and engagement experienced was rated as "Extremely good" (4/8) and "Very good" (4/8).

**Figure 38.** QIG 1:1 meeting communication and engagement




## 5.4.9. EU Network experts on QIG 1:1 meeting opportunities for improvement

The majority of responders suggested improvements in team composition, meeting scope, overall timelines and provide more guidance to companies in order to meet expectations.

**Figure 39.** QIG 1:1 meeting opportunities for improvement



## 5.4.10. Conclusions and recommendations from EU network experts supporting QIG targeted interaction

EU network experts were generally satisfied with the participation to QIG 1:1 meetings in terms of meeting organisation, level of engagement and communication. The need to improve team composition and overall timelines were flagged. Additionally, the need of having more clarifications for the companies on meeting scope in order to set expectations and avoid overlaps with other procedures was raised.

### *5.4.10.1. Recommendations*

Based on the feedback received the following recommendations are made to the QIG team for further reflection:

1. Evaluate improvement of meeting timelines.
2. Evaluate improvement of team composition.
3. Evaluate increasing clarity of meetings scope.

# 6. **Overall preliminary conclusions**

The surveys to pharmaceutical companies and EU network experts aimed at gathering the feedback on several aspects of the early engagement mechanisms offered by the EMA with the support of EMRN in order to promote development and approval of innovative medicines in the EU.

The response rate obtained from both Industry stakeholders and EU network experts was low (44% from Industry stakeholders; 24% from the EU network experts). Nevertheless, the analysis conducted allowed to drawn the following conclusions and recommendations:

- Industry stakeholders feedback:
  - **ITF BMs**: generally good and impactful experience reported. Responders highlighted the benefits of such meeting in terms of acquiring more understanding of regulatory needs and aligning, as a consequence, their strategy. More clarity of published information, more streamlined process and templates and promotion of dialogue with expert team were flagged as opportunities for improvement.
  - **PTMs**: companies were generally satisfied with this type of interaction given the impact represented for the regulatory strategy and submission timelines. Increased clarity of published information and flexibility of templates, as well as enhance companies familiarisation with the process were the main point flagged.
  - **QIG LLFG**: generally positive feedback on usefulness of QIG activities and meetings was received. Responders mainly suggested to improve timelines, promote engagement during the meetings with more focussed discussions and to have more clarity on topic selections. The need to have more clarity on how the QIG interlinks with other groups was also flagged.
  - **QIG targeted interaction**: general support on QIG activities in support to innovation and satisfaction on the meeting organisational aspects, scope and level of interaction. Responders suggested to establish regular QIG contact points and provide additional guidance.
  - **SME BMs**: positive feedback on the meeting experience and usefulness for SMEs. The need to have additional clarity on published guidance for pre-meeting preparation flagged.
- **EU network experts**:
  - **ITF BMs**: EU network experts expressed general satisfaction with the collaboration on ITF BMs. Improvement on expert selection in terms of timing and expertise and better clarification of meeting scope for companies were highlighted, amongst others, as opportunities for improvement.
  - **QIG LLFG:** positive considerations on meeting experience and usefulness with suggestion to improve overall timelines, team composition and raise awareness amongst SMEs and academia.
  - **QIG targeted interaction**: general satisfaction with the meeting organisation and level of interaction. Suggestion to improve timelines, team composition/participants and to provide more guidance on meeting scope to companies.

Early support to developers, especially small entities, is considered key given the relevance of innovation for the progress of science and availability of new treatment options for EU patients and animals. The feedback received from industry stakeholders and the EU network experts is confirming the great value of these interactions in support to innovation. The observations made and the proposed recommendations will be further evaluated and implemented in the processes as required.

## *6.1. List of consolidated recommendations*

Note: some recommendations are already under implementation.

| Meeting | Recommendation |
|---|---|
| ITF BMs Industry stakeholders feedback | 1. Evaluate need of updating published information, guidance and templates. |
| ITF BMs EU network expert feedback | 2. Evaluate how to raise awareness and adequately select EU network experts. |
| | 3. Evaluate additional guidance for companies. |
| | |
| PTMs | 4. Evaluate need of updating published information, guidance and application form. |
| | 5. Evaluate how to enhance company preparedness before the meeting (list of experts; list of questions). |
| | |
| QIG LLFG Industry stakeholders feedback | 6. Evaluate how to improve timelines for pre-meeting and post-meeting steps. |
| | 7. Explore how to increase transparency on topic selection. |
| | 8. Clarify interlinks with other relevant groups. |
| QIG LLFG EU network expert feedback | 9.Evaluate improvement of meeting timelines. |
| | 10.Evaluate improvement of team composition/participants. |
| | 11. Evaluate raising awareness on QIG LLFG meetings to SMEs and academia. |
| | |
| QIG 1:1 meetings- Industry stakeholders feedback | 12. Explore further supporting activities following the QIG 1:1 meeting. |
| | 13. Consider publication of additional guidance. |
| QIG 1:1 EU network expert feedback | 14. Evaluate improvement of meeting timelines. |
| | 15. Evaluate improvement of team composition/participants. |
| | 16. Evaluate increasing clarity of meetings scope. |
| | |
| SMEs BMs | 17. Consider providing additional SME office webpage guidance on meeting preparation. |

# 7. Glossary

| | |
|---|---|
| APIC | Active Pharmaceutical Ingredients Committee |
| ARM | Alliance for Regenerative Medicines |
| CSNE | CMC Statistic Network Europe |
| EMANS | European Medicines Agency Network Strategy |
| EMRN | European Medicines Regulatory Network |
| EFPIA | European Federation of Pharmaceutical Industries and Associations |
| EFSPI | European Federation of Statisticians in the Pharmaceutical Industry |
| EUCOPE | European Confederation of Pharmaceutical Entrepreneurs |
| EuropaBio | The European Association for Bioindustries |
| H-QS-QUA | Human Division-Quality and Safety of Medicines-Pharmaceutical Quality |
| ISPE | International Society for Pharmaceutical Engineering |
| ITF BMs | Innovation Task Force Briefing Meetings |
| LLFG | Listen and learn focus group |
| NMEU | Nuclear Medicines Europe |
| PTM | Portfolio & Technology Meeting |
| QIG | Quality Innovation Group |
| SME BMs | Micro, small and medium-sized enterprises Briefing Meetings |
| TRS-INO | Regulatory Science and Innovation-Innovation and Development Accelerator |
| TRS-SME | Regulatory Science and Innovation-SME Office |