EMA
EUROPEAN MEDICINES AGENCY

Early engagement fostering innovation (Industry and EU network surveys)

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Background

To comply with the Framework for interaction between the EMA and Industry stakeholders by monitoring and reporting on industry stakeholder's interaction through dedicated surveys.

PURPOSE

*Aims to **formalise** and **structure** our interaction with industry stakeholder groups.*

SCOPE

*Framework covers **interaction** between Agency and industry associations.*

IMPLEMENTATION

***Monitoring** and **reporting** on the interaction.*

Key principles

- Facilitate & streamline communication
- Structured interaction
- Accountability
- Transparency
- Broad representation of the industry

Early engagement meetings fostering innovation survey

Obtain feedback on EMA early engagement activities fostering innovation, technology research and development from industry stakeholders and EU Network Experts.

Innovation Task Force Briefing Meetings (ITF BM)	**Portfolio and Technology Meetings (PTM)**	**Small-, Medium- Sized Enterprises briefing meetings (SMEs)**	**Quality Innovation Group (QIG) (Listen & Learn (LL) focus group and 1:1 meetings)**
early dialogue with applicants on innovative aspects in medicines development.	dialogue on issues impacting product portfolios; capture new/disruptive technology; anticipate scientific/regulatory expertise needs.	early dialogue with multidisciplinary team to discuss regulatory strategy for human or veterinary product development; advice on available procedures, guidance and incentives.	support to the development and registration of innovative technologies and products, by clarifying the regulatory requirements

Early engagement meetings fostering innovation survey

Targeted stakeholders

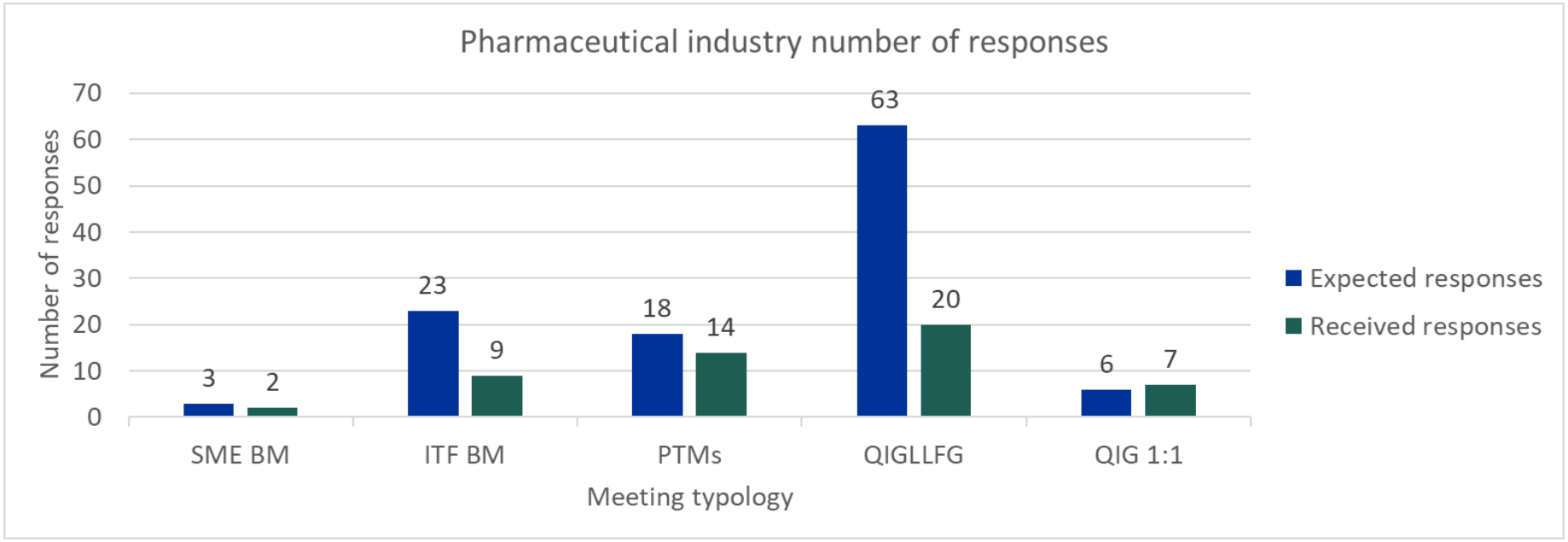
- Pharmaceutical companies who attended one of more of the meeting in scope from 1st January 2024 to 15th December 2024 (one consolidated response per company)
- EU network experts who supported one or more meeting in scope from 1st January 2024 to 15th December 2024 (only QIG and ITF meetings, 1 feedback for each meeting). –not covered in this presentation-

Methodology

Set of questions sent monthly asking feedback on the experience with:

- Meeting request process
- Meeting content
- Meeting output/deliverable
- Engagement and communication
- Opportunities for improvement

Industry response rate



44% response rate

- Each meeting was dedicated to 1 specific company with exception of the QIG LLFG when more Industry stakeholders attend.

Feedback on meetings request, content, output and communication

ITF BM

- Satisfactory request process.
- Positive feedback on meeting content (scope/time/discussion).
- More clarity gained in terms of regulatory requirements and strategy.
- Positive feedback on ITF team support.

PTM BM

- Satisfactory request process but timing improvement flagged.
- Positive feedback on meeting content (scope/discussion).
- More clarity gained in terms of regulatory requirements and strategy.
- Positive feedback on PTM team support.

SME BM

- Satisfactory request process but clarification on guidance flagged.
- Positive feedback on meeting content (scope/time/expertise).
- More clarity gained in terms of regulatory requirements and strategy.
- Positive feedback on SMEs team support.

QIG (LLFG/1:1)

- Satisfactory request process.
- Positive feedback on meeting content (scope/time/expertise). For QIG 1:1 scope expansion suggested.
- Satisfaction with the support to innovation. More clarity gained in terms of regulatory requirements and strategy.
- Positive feedback on QIG team support.

Opportunities for improvement/recommendations

ITF BM

Top 3 suggestions: update or provide clarity on step-by-step guidance, application form, IRIS platform.

Recommendation:

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

PTM BM

Top 3 suggestions: ensure clarity on team composition/roles; improve timelines and application from.

Recommendations:

- Evaluate need of updating published information, guidance and application form.
- Evaluate enhancing company preparedness before the meeting.

SME BM

Main suggestion: update published information.

Recommendation:

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

QIG (LLFG/1:1)

Top 3 suggestions: more transparent topic selection, improve timelines and published information.

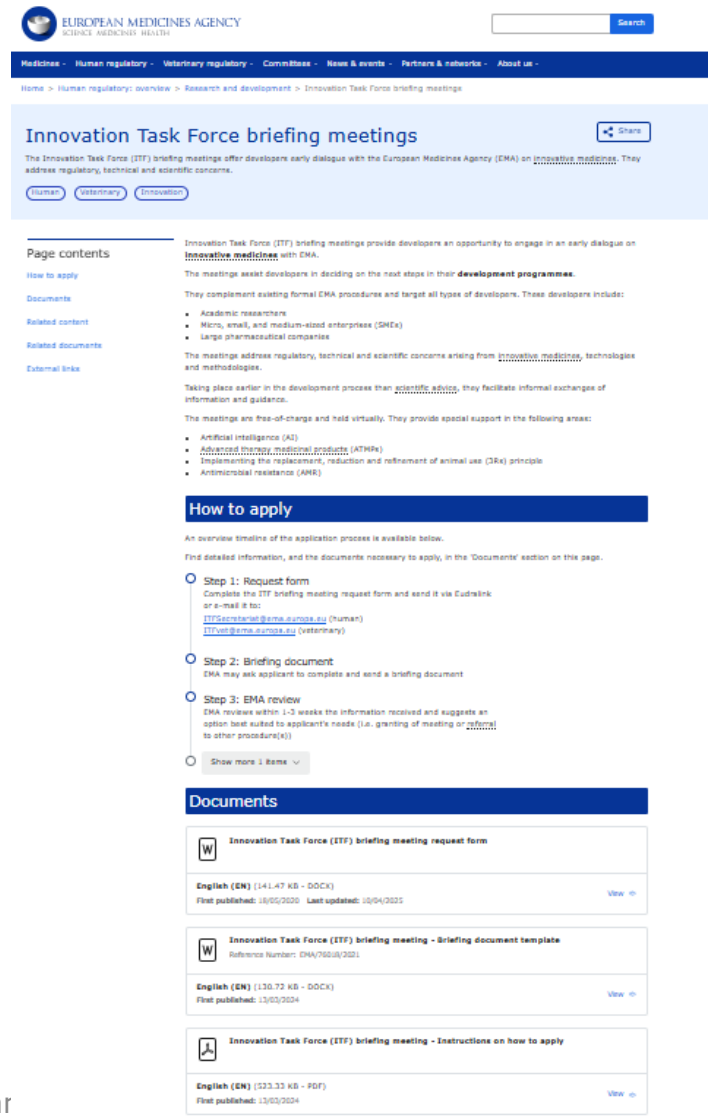
Recommendations:

- Improve timelines for pre-meeting and post-meeting steps.
- Increase transparency on topic selection. (LLFG)
- Clarify interlinks with other relevant groups.
- Provide supporting activities following 1:1 meetings.
- Consider publication of additional guidance.

Overview of recommendations implementation

ITF BM

Evaluate need of updating published information, guidance and templates.

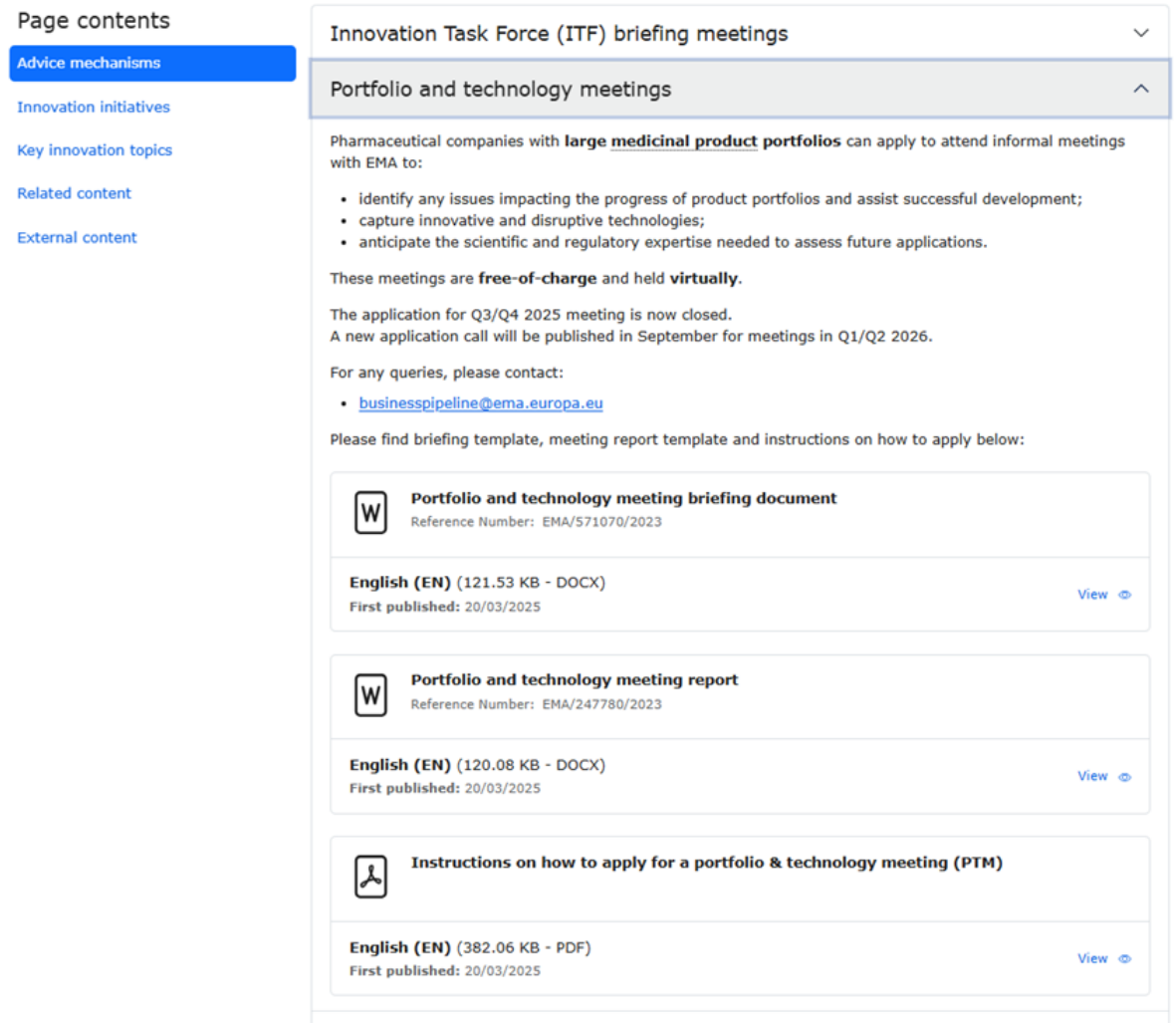


- Creation dedicated ITF webpage with updated guidance
- Guidance documents and templates update to enhance process clarity
- EMA corporate website update to enhance clarity and access to information

Overview of recommendations implementation

PTM BM

- Evaluate need of updating published information, guidance and application form.
- Evaluate enhancing company preparedness before the meeting.



Overview of recommendations implementation

SME BM

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

Support to SMEs | European Medicines Agency (EMA)

- contact the SME office for **questions** about regulations, administrative requirements or procedures: by phone +31(0)88 781 8787 or email.
- request a **briefing meeting** to:
  - engage in an early dialogue with a multidisciplinary EMA team;
  - discuss a regulatory strategy for a human or veterinary product development;
  - find out about available procedures, guidance and incentives

SME briefing meetings (BM)

SME BM

- Simple process: Tailored to the specific development needs.
- Low resource requirement: Minimal document preparation. Typically involves a PowerPoint presentation and the SME's questions & views on how to proceed.
- Minutes provided by the SME and validated by EMA participants
- Free of charge

How to request an SME BM:

- **Email**: Send a request to sme@ema.europa.eu
- **Phone**: Call the SME helpline at +31(0)88 781 8787
- **No forms required**

How the SME office processes the request:

1. Initial contact:

1. The SME office contacts the company & schedule a call to gather more information on the request.

2. Triage:

1. Determine if an SME BM is the best way to address the request.
2. Consider other early engagement tools if appropriate.

3. Preparation support:

1. Assist the SME in preparing for the BM to ensure the relevant background is provided and the questions are clear.
2. Identify topics that need further guidance.

Overview of recommendations implementation

QIG (LLFG; 1:1)

- Improve timelines for pre-meeting and post-meeting steps.
- Increase transparency on topic selection. (LLFG)
- Clarify interlinks with other relevant groups.
- Provide supporting activities following 1:1 meetings.
- Consider publication of additional guidance.

- Improve timelines for pre-meeting and post-meeting steps. Consider publication of additional guidance.
  - QIG will consider to include more information in the next the revision of the web page
- Increase transparency on topic selection. (LLFG)
  - QIG Interested parties invited to share their priority areas with QIG on an annual basis (WP preparation).
  - QIG main working areas published on the web page and IPs are informed about the topic for next year LLFG(s)
  - Workplan published
  - QIG will consider to include more information on LLFG(s) in the next the revision of the web page
- Clarify interlinks with other relevant groups.
  - QIG Mandate (published): QIG is an OEG within the quality domain and collaborates with the Biologics Working Party (BWP), the Quality Working Party (QWP) and the GDMP Inspectors Working Group (IWG).
- Provide supporting activities following 1:1 meetings.
  - QIG offers the possibility for follow-up 1:1 meetings for further discussion
  - Contact: QIG@ema.europa.eu

Overall conclusions

- The feedback received from both industry stakeholders and the EU network experts is confirming the great value of the early engagement mechanism available at the EMA in support to innovation.
- Observations were made on the following areas:
  - clarify/update published guidance to boost awareness and ensure preparedness.
  - streamline timelines and organisational aspects.
  - ensure more dialogue with relevant experts during the meetings.
- Published on the following corporate webpages: Pharmaceutical industry and Supporting innovation.

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Thank you

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