Request for early interaction on innovative developments

Innovation Task Force Briefing Meeting (ITF BM) request form

To apply for an ITF briefing meeting, please complete this form and send it (as a Word document) to the email addresses indicated below.

* [ITFsecretariat@ema.europa.eu](mailto:itfsecretariat@ema.europa.eu) (human medicines)
* [ITFvet@ema.europa.eu](mailto:ITFvet@ema.europa.eu) (veterinary medicines)

You may use Eudralink to send the form. Eudralink provides an encrypted transmission to protect your confidential information. (First, create an [EMA account (Self-Register)](https://register.ema.europa.eu/identityiq/home.html). Then, request a EudraLink account via the [EMA ServiceNow](https://support.ema.europa.eu/esc?id=sc_cat_item&table=sc_cat_item&sys_id=2e75fc678709c110da9d873e8bbb35e1)).

Please email us if you have further questions.

Disclaimer

The views expressed in these meetings are the opinions of the participants and may not reflect the opinion of the EMA scientific committees. Therefore, the answers provided should not be interpreted as regulatory guidance or review recommendations for an application, but as a preliminary set of scientific and regulatory considerations of the information presented.

Should aspects of the subject matter discussed herein become part of a formal data submission, application, or supplement, it is at the full discretion of the appropriate working party, evaluation team or scientific committee to completely and independently assess the product(s) in question.

# Data protection notice

By following this process, you are providing your consent to the processing of your personal data (e.g. name, email address), which will be processed by EMA in accordance with Regulation (EU) 2018/1725.

You can access EMA’s data protection notice for the organisation of meetings and events here: <https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-privacy-statement-organisation-meetings-events_en.pdf>

You are reminded that recording this meeting is strictly prohibited.

**Please confirm that you have read and understood the data protection notice and you consent to the processing of your personal data.**

|  |  |  |
| --- | --- | --- |
| **Application details** | | |
| Application date: | Click or tap to enter a date. | |
| Organisation name: | Click or tap here to enter text. | |
| Contact person name: | Click or tap here to enter text. | |
| Contact e-mail: | Click or tap here to enter text. | |
| Contact telephone: | Click or tap here to enter text. | |
| Applicant type[[1]](#footnote-1)[[2]](#footnote-2): | Choose an item. | |
|  | Click or tap here to enter text. | |
| Human or veterinary: | Choose an item. | |
| **Innovative development** | | |
| Please select: | Choose an item. | |
|  | Click or tap here to enter text. | |
| **Stage of development** | | |
| Please select: | Choose an item. | |
|  | Click or tap here to enter text. | |
| **Product / Technology / Development method** | | |
| Name / identifier: | Click or tap here to enter text. | |
| Product / technology / method / methodology description:  *(max. 100 words)* | Click or tap here to enter text. | |
| Mode of action  *(max. 100 words)* | Click or tap here to enter text. | |
| Intended use  *(max. 100 words)* | Click or tap here to enter text. | |
| UPI/RPI number  *(if previously assigned)* | Click or tap here to enter text. | |
| Previous / parallel contact with other **EMA departments** on this product / technology / method / methodology (e.g. ITF, QIG, Scientific Advice, Qualification, etc.) | Click or tap here to enter text. | |
| Previous / parallel contact with **other regulators** on this product / technology / method / methodology (e.g. National Competent Authority, FDA, etc.) | Click or tap here to enter text. | |
| Do you know of a similar substance / product / technology / development method currently under review, or already approved or marketed?  If yes, please provide details: | No, not aware of similar substance / product / technology / development method  Yes, similar substance / product / technology / development method. Name: Click or tap here to enter text.  Under review / reviewed by Click or tap here to enter text.  Approved by Click or tap here to enter text.  Marketed in Click or tap here to enter text. | |
| Patent(s): | Choose an item. | |
|  | If yes, provide patent number: Click or tap here to enter text. | |
| Funding: | Choose an item. | |
|  | If yes, please indicate source(s):Choose an item. | |
|  | Please provide details/stage of funding:  Click or tap here to enter text. | |
| (Min 1, Max 3) | **Therapeutic area(s) of concern** | |
| 1 | Choose an item. | |
| 2 | Choose an item. | |
| 3 | Choose an item. | |
| **Enabling technology** | **Enabling tools** | |
| Directly product-related | Nanotechnologies | |
| Synthetic biology | |
| Genetically modified organism(s) | |
| Development-related: clinical | Novel biomarkers, omics | |
| Medicines for tropical diseases | |
| Biodefense/biowarfare | |
| Associated medical devices | Biomaterials | |
| Matrixes | |
| Other associated medical device | |
| Advanced manufacturing | Printing | |
| Bedside/point of care manufacturing | |
| Mobile/portable manufacturing | |
| Distributed manufacturing | |
| Transgenic technologies | |
| 3D printing | |
| Other ingredients | Novel/uncommon excipient | |
| Adjuvant | |
| Pharmacological chaperone | |
| Bioenhancer | |
| Smart materials in active substance(s) | Photodynamic product | |
| Other smart/advanced material | |
| Delivery methods | Targeted release to specific site(s) | |
| Controlled-release technologies | |
| New/uncommon pharm. form or route of admin. | |
| Genome editing | Genome editing - deletion | |
| Genome editing - replacement | |
| Genome editing - regulation | |
| Human cell-based | Human cell based in vitro models | |
| Human stem cell in vitro models | |
| Non-clinical development: other | Organoids | |
| Avatar, nude and humanised mice | |
| Physiologically based pharmacokinetics | |
| Other in silico models | |
| Methodology of clinical trials | Extrapolation proposed | |
| Platform/Umbrella/Basket trials | |
| Novel endpoints | |
| Bayesian designs | |
| Adaptive designs | |
| Digital healthcare | Monitoring devices/sensors/systems | |
| Closed loop systems | |
| E/m-health | |
| Novel data sources | Big data analysis | |
| Real world data analysis | |
| Other innovation aspect, enabling or disrupting technology | Click or tap here to enter text. | |
| Click or tap here to enter text. | |
| Click or tap here to enter text. | |
| **Proposed topics for discussion at the meeting** (maximum 8 topics)  Include any topics to be discussed; including scientific, regulatory, general, and other | | |
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| **Additional information you wish to share** | | |
| Click or tap here to enter text. | | |
| **Are you planning any other EMA procedures in the future?**  (click the links for details on procedures) | | |
| [Small and Medium Enterprise (SME) status](https://www.ema.europa.eu/en/human-regulatory/overview/supporting-smes/applying-sme-status) | | Choose an item. |
| [ATMP Certification SMEs](https://www.ema.europa.eu/en/human-regulatory/research-development/advanced-therapies/advanced-therapy-development/certification-procedures-micro-small-medium-sized-enterprises-smes) | | Choose an item. |
| [Scientific recommendation on advanced therapy (ATMP) classification](https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/advanced-therapies/advanced-therapy-classification) | | Choose an item. |
| [Orphan medicinal product designation](https://www.ema.europa.eu/en/human-regulatory/overview/orphan-designation-overview) | | Choose an item. |
| [Paediatric applications](https://www.ema.europa.eu/en/human-regulatory/overview/paediatric-medicines-overview) | | Choose an item. |
| [Scientific advice / Protocol assistance](https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistance) | | Choose an item. |
| [Qualification of novel methodologies](https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistance/qualification-novel-methodologies-medicine-development) | | Choose an item. |
| [Veterinary limited markets[[3]](#footnote-3)](https://www.ema.europa.eu/en/veterinary-regulatory/research-development/veterinary-limited-markets/limited-markets-guidance-under-veterinary-medicinal-products-regulation) | | Choose an item. |
| [HTA / parallel Scientific Advice](https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistance/parallel-consultation-regulators-health-technology-assessment-bodies) | | Choose an item. |
| [MAA for this specific interaction](https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation) | | Choose an item. |

Annex

We invite you to consider topics identified in the context of the Regulatory Science Strategy (RSS) to 2025. Please see relevant examples in the table below.

|  |
| --- |
| Catalysing the integration of science and technology in medicines’ development |
| Support developments in precision medicine, biomarkers and ‘omics |
| Support translation of advanced therapy medicinal products (ATMPs) into patient treatments |
| Development and integration of medical devices, in vitro diagnostics and borderline products |
| Implementation of novel manufacturing technologies |
| Development and integration of medical devices, in vitro diagnostics and borderline products |
| Nanotechnology and new materials in pharmaceuticals and combination products: Scientific and regulatory implications |
| Driving collaborative evidence generation – improving the scientific quality of evaluations |
| Integration of non-clinical models and 3Rs principles |
| Innovation in clinical trials |
| Considerations about the regulatory framework for emerging clinical data generation and addressing specific needs |
| Special populations initiatives |
| Integration and consideration of digital technology and artificial intelligence in decision making, manufacturing and product development |
| Advancing patient-centred access to medicines in partnership with healthcare systems |
| Patient relevance in evidence generation |
| Use of high-quality real-world data (RWD) |
| Novel approaches to deal with big data |
| Product information in electronic format (ePI) |
| Biosimilar development |
| Addressing emerging health threats and availability/therapeutic challenges |
| Approaches to health threats |
| Development of new antibacterial agents and their alternatives |
| Addressing supply chain problems |
| Innovative approaches to the development and post-authorisation monitoring of vaccines |
| Development and implementation of repurposing frameworks |
| Enabling and leveraging research and innovation in regulatory science |
| Partnerships with academic/research centres to undertake research in strategic areas of regulatory science |

1. [Support to SMEs | European Medicines Agency (europa.eu)](https://www.ema.europa.eu/en/human-regulatory/overview/support-smes#sme-status-section) [↑](#footnote-ref-1)
2. <https://www.ema.europa.eu/en/partners-networks/academia> [↑](#footnote-ref-2)
3. Veterinary only [↑](#footnote-ref-3)