Stakeholder consultation on updated list of enabling tools

Fields marked with * are mandatory.

Data protection disclaimer

In this survey EMA does not collect or process personal data. Therefore, please make sure that you do not reveal your identity or include other personal data in the free text answers. The survey is designed to collect the answers only in an aggregate and anonymous format. The responses will only be evaluated and the results shared in an aggregate way.

For the collection of data in this Survey EMA relies on the EU Survey external system. For more information on how EU Survey processes personal data, please see: https://ec.europa.eu/eusurvey/home/privacystatement

The EU Survey external system uses:

- Session "cookies" in order to ensure communication between the client and the server. Therefore, user's browser must be configured to accept "cookies". The cookies disappear once the session has been terminated.
- Local storage to save copies of the inputs of a participant to a survey in order to have a backup if the server is not available during submission or the user's computer is switched off accidentally or any other cause.

The local storage contains the IDs of the questions and the draft answers.

- IP of every connection is saved for security reasons for every server request.
- Once a participant has submitted one's answers successfully to the server or has successfully saved a draft on the server, the data is removed from the local storage."

Survey

As part of EMA's horizon scanning and foresight activities, applicants to EMA procedures are asked to highlight the enabling tools* applied in their development programs. This information is requested either when registering a Research Product Identifier (RPI) in IRIS (an EMA platform for submitting applications electronically), or when applying to an Innovation Task Force (ITF) meeting. A revised list of enabling tools has been released for public consultation until 30 November 2024.

Enabling tools are defined as novel technologies that have the potential to enable innovation in the context of medicines development. They can refer to a novel therapeutic approach, a novel category of medicinal product or a technology or methodology integrated in the pre-clinical, clinical or CMC dossier of a medicine.

*** 1. Respondent's affiliation:**

EFPIA

*** 2. Profile of respondent:**

- ○ Small and medium-sized enterprise (SME)
- ○ Large company
- ○ Academia
- ◉ Non-for-Profit organisation
- ○ EU-funded consortium
- ○ EU body or agency
- ○ International organisation: WHO, OECD
- ○ Other

*** 3. Are the categories and terms in the revised list clear, well defined and mutually exclusive?**

- ○ Yes
- ◉ No

Please elaborate:

The list is comprehensive; however, it could include technologies that could also be combined (please refer to additional suggestion below).

4. Do you consider that the revised list sufficiently captures enabling tools used in pharmaceutical developments?

Please note that this list is not meant to be exhaustive and granular but should capture major technologies.

- ○ Yes
- ◉ No

Please provide the enabling tool(s) and technologies you think should be included in the list:

- In vitro 3D disease response modeling (in vitro modelling could also be combined with other tools such as AI, or predictive modelling, including adaptive or learning modelling based on data),
- Regulatory Sandbox.
- Cloud-Based Review/Cloud-Based Regulatory tools.
- Already mentioned “Artificial intelligence applied to pre-clinical data and/or clinical data” could benefit from adding “and/or PV data” -> Artificial intelligence applied to pre-clinical data and/or clinical data and/or PV data”.
- Already mentioned "Artificial intelligence applied to regulatory compliance" could benefit from adding “and regulatory process/tools” -> "Artificial intelligence applied to regulatory compliance and regulatory process /tools" .

Contact

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