



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on Opening Procedures at EMA to Non-EU authorities (OPEN) framework

ISG meeting – 21 November 2024

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- July 2023: OPEN expanded to **Anti-Microbiol Resistance (ARM), PRIME, high unmet need, and public health emergencies products** - [Questions and Answers on the 'OPEN' Framework](#).
- July 2023 to June 2024: **Four** products reviewed under OPEN
- July 2024: At request of industry applicants can ask for their product to be part of the OPEN pathway – tick box in **Letter of Intent** submission
- **Engagement from OPEN partners** remains strong, and some partners considering aligning timetables with EMA for these procedures

→ **However, no applications** submitted by industry for OPEN since option given to choose to use the framework

* Application to be reviewed under the OPEN framework: 0

Opening procedures at EMA to non-EU authorities (OPEN) initiative ✕

-- Please Select --

* OPEN partners expected:

EMA encourage the opportunity to use OPEN framework and to identify OPEN partners early, and plan for regulatory submission alignment

- **Questions to industry:**
 - 1 - What are the barriers?
 - 2 - Do you need any other specific information on the OPEN framework to include it in your regulatory filing strategies?
 - 3 - Are there challenges in terms of alignment synchronisation ?
 - 4 - Do you have competing collaborative frameworks?
 - 5 - Other reasons?
- We will come back at the ISG in March 2025, and helpful if you could survey your members.



Further reading:

[Questions and Answers on the 'OPEN' Framework](#) [One-year review of the OPEN pilot and recommendations \(europa.eu\)](#)

Any questions?