Mini Case Study:

Accelerating Post Approval Changes

Co-facilitators:

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Expectations and ground rules

- Mini cases are not lectures but a learning opportunity for attendees
- Co-facilitators are here to guide the discussion
- No scribes or notes: emphasis on knowledge sharing and open-ended learning

Our mini case explores how industry and regulators have proposed ways to address current challenges associated with PACs and if this has translated into accelerating their implementation

- Please stay relevant and focused on the predefined discussion topics (same found in the session abstract)
- Raise your hand if you want to speak, the co-facilitators will indicate when it's your turn
- Each intervention by a participant is expected to have no more than 2 minutes
- Refrain from interrupting colleagues
- Please be mindful of the use of excessive technical jargon

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Discussion topics

- What regulatory mechanisms did your organization successfully use to accelerate the review of post-approval changes? Can you share real-life experiences on how to promote successful engagement between companies and Health Authorities to accelerate the approval of a (non-emergency) PAC?

- How can a company best prepare a submission to maximize the likelihood of a fast review (robust data package, global content)?

- For EU- or US-follow on markets, was your company able to leverage EU/US approval for faster review or perhaps waivers that would allow distribution of the product in the follow-on country prior to approval? What type of documentation was provided?

- PACMP approach is currently used in US and EU. Were you able to leverage PACMP Step1 / Step 2 approvals to accelerate review time in countries other than US/EU?

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