Collaborative Approaches

ICMRA pilot on collaborative Assessment of Post-Approval Change: applicant's experience

CASSS Europe, October 18th 2023

Sylvie Meillerais

Director Global CMC Policy - MSD

Considerations ahead

Opportunities

Consolidated LoQs and single outcome

Streamlined PACs management and supply

Enhance PACMP understanding across all ICMRA members

Challenges

Identify programme in scope (vaccines excl.)

Submission: no single platform

Review: compiled vs consolidated LoQs

Decision: time and divergent outcome

Implementation / step-2

MSD

Pilot Application

Scope of the PACMP

- Biologic DS process change with subsequent site change

1 month from application to acceptance in the pilot

Participating & Observing Agencies (5+2)

- Participating: FDA, EMA, PMDA, HC (Swissmedic)
- FDA lead Agency
- Observing: ANVISA (HSA)

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Progress to date

Approach taken

- Streamline M1 requirements
- Common language/EN
- Calendar: follow EMA (set timeline)
- ‘Submission’ to Observers with cover letter

Learnings & Next steps

Proposals

- ✓ ICMRA WG communication
- Single submission platform
- Observer: list of interested ICMRA Agencies & Reliance
- Confidentiality Agreement in place

More to come…

- Submission planned Nov./Dec.
- Review
- Outcome & Step-2 change

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Summary

Unique initiative with tremendous Agencies efforts

Pursue Pilot learnings & experience sharing, including towards

Reliance by other Agencies

From pilot to practice, conditions?

Scope extension: products, PACs beyond PACMP?

Towards 1 Q Dossier, 1 Review and 1 Outcome?

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Thank you and Questions

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