

Collaborative Approaches

ICMRA pilot on collaborative

Assessment of Post-Approval

Change: applicant's experience

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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

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)

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

✓ ICMRA WG communication

Single submission platform

Observer: list of interested ICMRA Agencies & Reliance

Confidentiality Agreement in place



More to come...

Submission planned Nov./Dec.

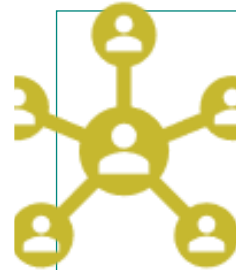
Review

Outcome & Step-2 change

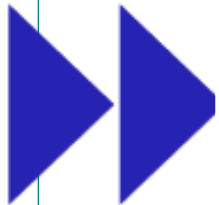
Summary



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?

Thank you and Questions

