

ICMRA Collaborative Hybrid Inspection Pilot (CHIP)

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CHIP Main Points

- A collaborative hybrid inspection is a joint inspection by two authorities with one lead authority on site and one authority participating remotely.
- Goal of the CHIP was to enable a CMC submission that would undergo a single hybrid inspection that would be accepted by participating authorities.
- Scope limited to pre-approval inspections and to selected products (e.g. PRIME & Breakthrough). Aim to increase manufacturing capacity and supply.

CHIP - Proposals Accepted and Regulatory Authorities

Applicant	Lead 'Onsite' Authority	Remote Authority	Observers
Roche	Swissmedic	FDA	EMA and Health Canada
Gilead*	FDA	Health Canada	PMDA, Swissmedic, MHRA, MoH Israel, EMA, HPRA

Overall Summary

- 3 collaborative hybrid inspections completed without technical difficulties
- Survey of participants was positive with view that the collaborative hybrid approach did not add regulatory burden and can benefit patients and industry
- Good operational outcomes and good communication and interaction between authorities and with the manufacturer and sponsor
- But a collaborative hybrid inspection required a significant increase in workload compared to a normal inspection

CHIP Achievements

➤ **Positive and productive collaborations with supporting tools developed**

- Regulators - Joint Inspection Protocol w/ agreed timetable for inspections
- Sponsors & Facilities – Industry Expectations Guidance and timely communication and response to deficiencies.
- Sponsors achieved approvals w/ sites securing CGMP Compliance Status.

➤ **Lead and Remote Regulatory Authorities aligned on inspection procedure and findings**

- Agreement on deficiencies, significance and post-inspection activities.
- Harmonized approach towards unfavourable compliance status in participating regions with no supply from facility pending resolution. Achieved in different ways.

➤ **Continuous communication among the RAs**

- Use of IT platform to securely share information between participating inspectorates before, during and post inspection.

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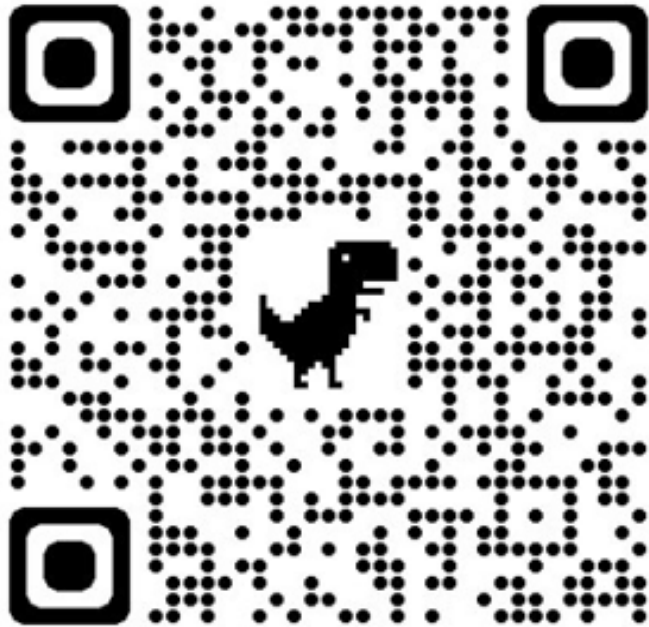
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Collaborative Pilots: [ICMRA PQKMS Website](#)



Scan the QR code using your phone for all information needed concerning the collaborative pilots



ACKNOWLEDGEMENTS – ICMRA PAC Sub-Working Group



Larry Lee
FDA



Brendan Cuddy
EMA



Evangelos Kotzagiorgis
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Theresa Mullin
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Thank you

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