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Reliance Pathway in Singapore

- Presenter: Sannie Chong, 5 minutes
- ❑ Abridged: Relies on 1 approval of competent authority (180 working days; 90 days < (shorter than) full route)
- ❑ Verification:
 - **NDA**: Relies on 2 *Reference Agencies' approval and 1 assessment report (60 working days; 210 days < full route)
 - **Variations**: Relies on 1 *Reference Agency's approval letter (90 working days, 30 days < standard route)
- ✓ Focus and learn to evaluate critical areas through the Ref Ag's assessment report
- ✓ Acquire knowledge and competency to independently review and arrive at sound regulatory decision based on ICH requirements
- ✓ Beef up post-marketing products' surveillance and monitoring
- ✓ Eliminate outdated "legacy" e.g. CPP – remove burden and optimize manpower
- ✓ Creates an regulatory infrastructure that enables R&D and MNCs investment to flourish, fulfilling its role as a biomedical hub in Asia
- ✓ Singapore-Australia on GMP MRA, and work-sharing with Australia, Switzerland & Canada (ACSS). Singapore becomes a full ICH member in 2017

* US FDA, EMA, Australia TGA, Health Canada and UK MHRA

Reliance: The role for global convergence

- Asia Pacific Economic Cooperation (APEC): Japan, China, USA, S Korea, Australia, N Zealand, Thailand, Indonesia, Vietnam, Malaysia, Russia, Hong Kong, Philippines, Singapore, Brunei, Chile, Mexico, Taiwan, Peru, PPNG and Canada
- Regulatory Harmonization Steering Committee (RHSC): 2020 convergence
- 2018 APEC Ministerial Chair: “We affirm our goal to advance convergence on regulatory approval procedures for medical products. We welcome identification of performance indicators (PIs) and look forward to tracking these indicators across all member economies.”
- PIs are developed. See paper published at AAPS Open: <https://doi.org/10.1186/s41120-018-0024-2>
- PIs includes implementation of reliance pathway. PI progress on reliance is tracked for 2008 and 2018. The PI tracking will be reported to Ministers and Heads of Health Agencies at the APEC’s High Level Dialogue in August 2019