Relying upon multiple sources of global, regional and country information for signal detection and safety decision making

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Disclaimer and declaration of conflict of interest

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Declaration of Conflicts of Interest

- No conflict of interest to declare

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Relying upon multiple sources of global, regional and country information for signal detection and safety decision making

1	Relying upon multiple sources of global, regional and country information for signal detection and safety decision making
2	PV reliance in the Arab world
3	Experience of a NRA with limited resources using VigiLyze

November 8

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In the beginning (2001)

postmarket	VigiBase-VigiSearch
premarket	?

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Benefits of international cooperation/reliance

- More reports -> improved signal detection
- Access to expertise & experience
- Reduce duplication of effort
- Reduce evaluation times

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Now (2021)

postmarket	VigiBase-VigiLyze ICMRA IPMST
premarket	project ORBIS Access Consortium ASEAN-JACG
RMP/PSUR	Access Consortium

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ICMRA

- International Coalition of Medicines Regulatory Authorities
- 24 member agencies and 11 associate members
- Three pharmacovigilance working groups
  - big data
  - increasing AE reporting
  - vaccines
- COVID-19 group meets twice per month

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Access Consortium

- Australia-Canada-Singapore-Switzerland-UK
- "Like-minded, medium-sized" regulatory authorities
- Focus on premarket activities
- Work sharing subgroups
  - new active substances
  - generic medicines
  - biosimilars
- COVID-19
- RMPs/PSURs/PBRERs: information sharing (not work sharing)

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IPMST

- International Post-Market Surveillance Teleconference
- Australia-USA-Canada-NZ-Singapore-Switzerland-UK
- Every two months
- Sharing of signals under investigation, mainly following local identification

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Routine use of external data for PV evaluations at TGA

- Published literature
- International labelling
  - readily available: US, Canada, AUS, UK, EMA
- VigiLyze – case numbers; countries; statistics
  - rarely request original reports
  - IPMST (medicines)
  - ICMRA (COVID-19)

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Example: vedolizumab-pancreatitis

- vedolizumab used for Crohn's and ulcerative colitis
- 4 Australian reports of pancreatitis (unlisted)
  - detected on routine statistical screening of database (PRR 5.5)
  - 2 good quality published reports
  - VigiBase IC_{025} +0.4
- Discussed with other regulators (IPMST)
  - US FDA: signal under review -> added to 6.3 Postmarketing Experience
  - other regulators: minimal / poor case reports; no review

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Local (Australian) programs

- The programs below are funded by the Australian Government Department of Foreign Affairs and Trade
- **Pacific Medicines Testing Program (PMTP) – launched March 2018**
  - Provide Pacific Island Countries access to Australian laboratory testing for medicine quality assurance
- **Indo-Pacific Regulatory Strengthening Program (RSP) – launched October 2018**
  - Strengthen the capabilities of National Regulatory Authorities to increase the availability of better quality, safer and more effective medicines/medical devices through improved regulatory practice and collaboration
- **The Australian Expert Technical Assistance Program – Regulatory Support and Safety Monitoring (AETAP-RSSM) – launched May 2021**
  - Support Pacific and Southeast Asian countries' efforts to deliver safe, effective and accessible COVID-19 immunisation programs, based on a health and regulatory systems strengthening approach and in line with best practice standards.

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Regulatory Agencies working together

- **Spectrum from Transactional <----> Partnership**
- **Carrying out regulatory work on behalf of another agency:** laboratory testing
- **Information Sharing:** unredacted evaluation reports; other review documents
- **Knowledge Transfer:** training webinars; communicating emerging safety information
- **Adapting "best practices":** development and use of evaluation templates.
- **Capacity building:** on-the-job training in a variety of regulatory functions
- **Enabling Reliance:** bilateral, product specific worksharing; multilateral approaches (ASEAN-JACG, WHO EUL)

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Barriers to cooperation / reliance

- Differing priorities
- Confidentiality

- Timezones

- RMP evaluations:
  - differing focus areas
  - differing evaluator expertise
  - differing evaluation timelines (point at which RMP is considered)

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شكرا لك على انتباهك
Merci de votre attention
Agradecimentos para sua atenção
Thank you for your attention
спасибо за Ваше внимание
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