Medical Device Trials in Malaysia - New Opportunities

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InnoSignum

Declaration of Interest

I have nothing to declare

All opinions expressed are solely my own

Regulatory framework for Investigational Medical Device – Past and Present

Challenges prior gazettement of Medical Device Act

Implementation

Medical Device Act 2012

Clinical trial application processes for medical devices & opportunities

Implementation Medical Device Act 2012

Focusing of commercialization of Medical Devices. No specific provision under Act 737 on the control of clinical investigation

Medical Device (Exemption) Order 2016 exempts medical device for clinical investigation purpose from product registration and establishment license requirements under subsection 15 (1) of the Act 737

Notification to MDA. No Restriction Letter to be issued by MDA for the lawful supply of the medical device for any clinical investigation use after approval by Technical Committee.

Type of Clinical trial application processes for medical devices

Investigational Use

- the use of an unregistered medical device in a clinical investigation designed to generate clinical data on the clinical performance and safety of the device required to support the pre-market approval submission for device registration.

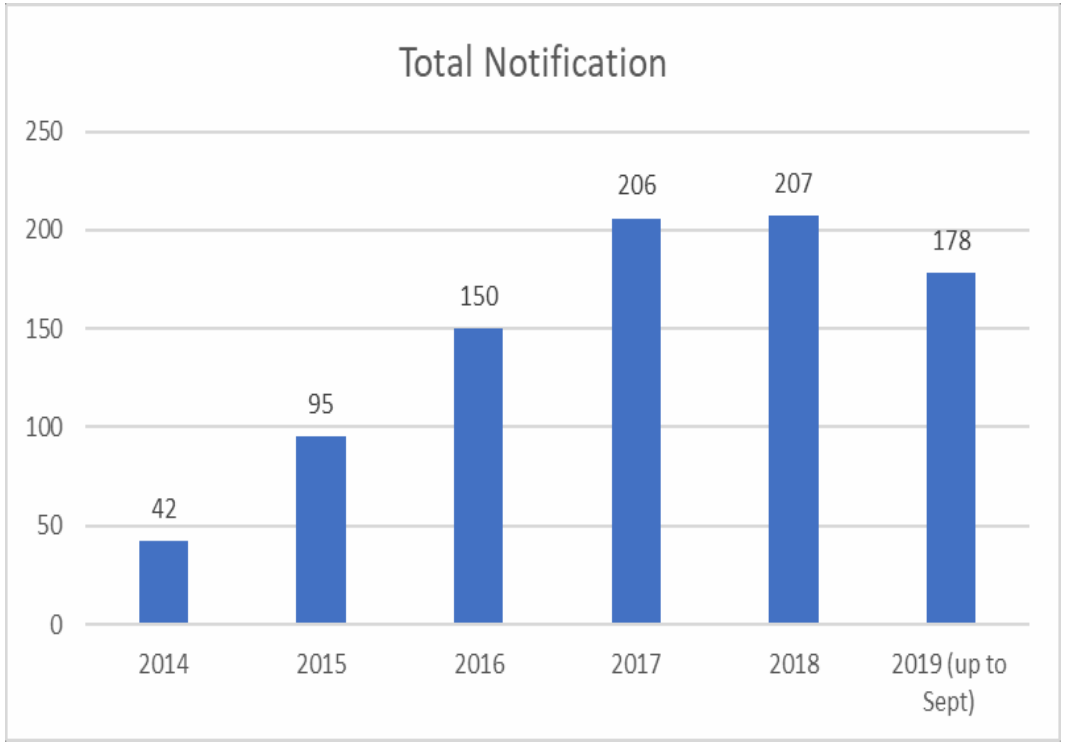
Clinical Use/ Clinical Experience

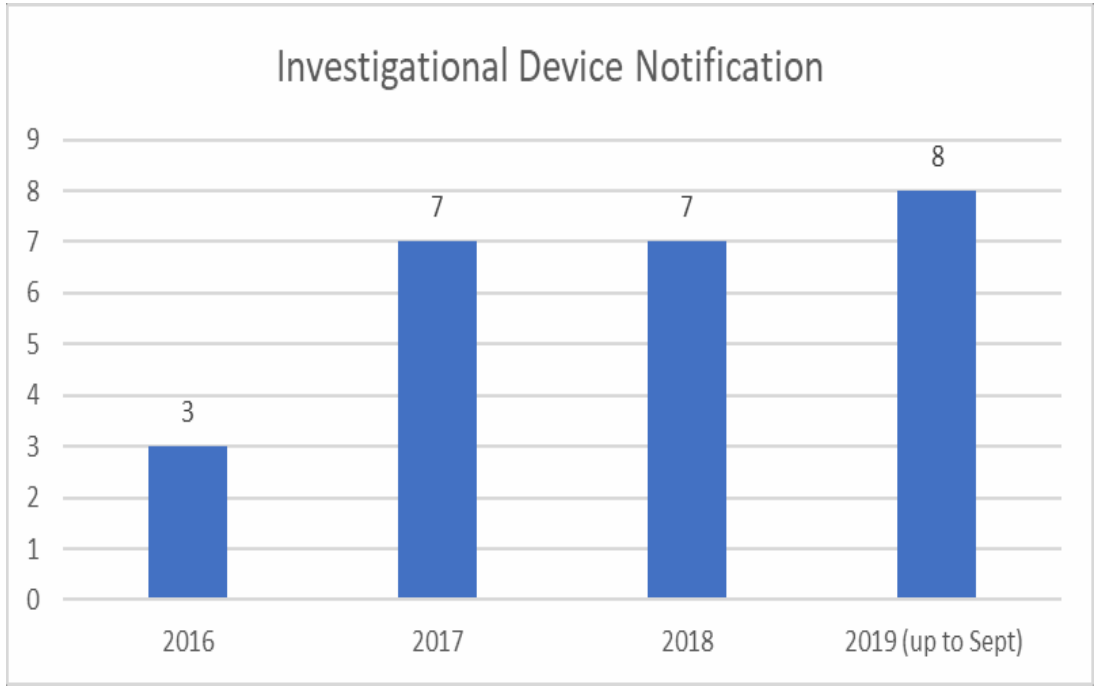
- the use of an unregistered medical device to generate clinical experience data. Clinical use is particularly useful source of clinical data for low-risk devices that are based on long standing, well-characterised technology/long standing in the market.

Research Supportive Use

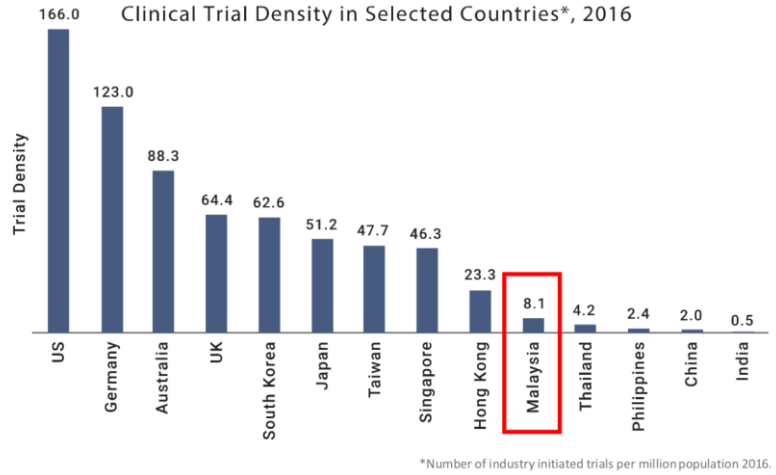
- the use of an unregistered device in the context of another health research. The device per se is not under investigation but is required to make the research feasible to be conducted in Malaysia.

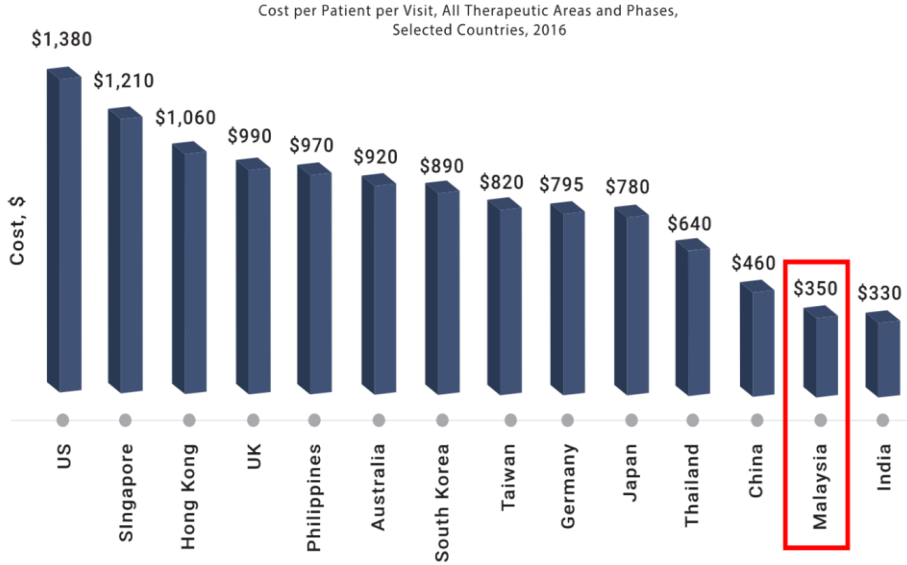
Clinical Research Notification for Medical Devices & Investigational Devices





Clinical Investigation Notification, 2019
Medical Device Authority





Frost and Sullivan Asia clinical trials whitepaper – Feb 2017

Opportunity to conduct medical devices clinical research in Malaysia

- Approval within 7 working days after technical committee review meeting
- Lower clinical trial density & relatively lower cost
- Other Improvements
  - Start-up timelines (e.g. CTA timeline)
  - Investigator accessibility and site personnel capability
  - Patient recruitment and more reliable feasibility for recruitment projection

1st Facility in Malaysia is ready to conduct First-in-Human Studies

Clinical Research Malaysia
Yesterday at 11:49 AM ·

Heartiest congratulations to CRC Sarawak General Hospital for being the 1st facility in the country to be accredited under the Phase 1 Unit Accreditation Program by NPRA! A giant leap for Malaysia indeed in our readiness to conduct First-in-Human studies.

Conclusion

- Regulatory requirement and processes are progress positively to create a more conducive environment for medical device clinical research
- Further improvements are required to facilitate consistent and faster regulatory approval timelines while ensuring patient safety


Thank You