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Info Kinetics, Korean univ sign MoU for medtech trial

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Singapore: Info Kinetics and Clinical Trial Center for Medical Devices of Yeungnam University Hospital, South Korea, signed a memorandum of understanding (MoU) to establish co-operation and collaboration in medical device testing and clinical trials, including in-vitro biocompatibility testing according to ISO 10993, toxicology studies, leaching studies and medical devices clinical trials according to ISO 14155.

This MoU provides a platform for technical collaboration for compliance with Organization for Economic Co-operation and Development (OECD)'s good laboratory practice (GLP). It will also provide opportunities for technical internship placement between the two institutes. In addition, both parties will collaborate as bidding partners in a global trial proposal. Furthermore, this collaboration will also lay the foundation for the first fully-structured medical device clinical trials center in the Northern Corridor Economic Region (Koridor Utara).

Professor Sang-Ho Anh, director, clinical trial center of medical devices, Yeungnam University Hospital, South Korea, said that, "Although South Korea has been an OECD member country since 1995, there are very few OECD GLP laboratories, especially for medical device testing. The best strength offered by Info Kinetics is their six years of OECD GLP accreditation status."

The companies with significant manufacturing facilities in Koridor Utara include Ambu, Bard, B Braun, Covidien, Symmetry Medical, St Jude Medical, Teleflex and a home-grown company Vigilenz.

Dato' Redza Rafiq, chief executive, Northern Corridor Implementation Authority (NCIA), said that, "The collaboration in clinical trial and in-vitro biocompatibility testing will be able to support various entry point projects (EPPs) for 'Healthcare and Medical Devices' under 'Healthcare National Key Economic Area' (NKEA) announced last year. The seven EPPs launched in 2011 are expected to bring in some $5.57 billion (RM 17.1 billion) in revenue and a gross national income of $3.71 billion (RM 11.4 billion), as well as creating 86,000 employment opportunities by the year 2020."

Mr Hitendra Joshi, chairman, Association of Malaysian Medical Industries, said that, "The collaboration is a timely initiative and in line with AMMI Strategy 2015 to promote R&D, innovation and shared services for the growth of the medical devices industry in Malaysia."

The collaboration in the MoU was initiated by Professor Ahn and Dr Lee Toong Chow, MD, Info Kinetics and was witnessed by Dato' Redza Rafiq. Also present during the signing of the MoU were Dr Mary Quah, CEO, LohGuanLye Specialists Center and Mr Hitendra Joshi.