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David F Kong

Duke Clinical Research Institute, USA
Duke University, USA

Harmonization By Doing: Looking to the next decade

The US-Japan Medical Device Harmonization By Doing (HBD) program has enabled the US FDA, Japan PMDA, international regulators, academia, and industry to develop practical standards for global clinical trials. This has facilitated development of novel cardiovascular devices and helped overcome regulatory barriers that have historically delayed timely medical device approvals in both countries. The collaborative activity is expanding its scope to create additional synergies in global medical device development, particularly for early feasibility studies, non-cardiovascular therapeutic areas and pediatric medical device applications. Encouraging single global clinical trial protocols will facilitate device evaluation in both the US and Asia by improving the timeliness and cost-effective generation of more informative clinical datasets for pre-market, and potentially post market evaluation. This will reduce the data requirements for device development programs by reducing redundant data collection. For example, the Japanese Registry for Mechanically Assisted Circulatory Support (J-MACS) registry and the US Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) registry, both collect and analyze clinical and laboratory data from patients receiving mechanical circulatory support devices for end-stage heart failure. The complementary datasets in these registries provide valuable information for improving the treatment of advanced heart failure patients in both countries. Clinical trial programs, such as the HARMONEE (NCT02073565) and COAST (NCT02132611) trials, represent a new approach to evaluating efficacy and safety in a global environment. Future directions will extend these initiatives and their benefits to additional countries and facilitate patient access to new medical device technology worldwide.

Biography

David F Kong is an Associate Professor of Medicine at Duke University Medical Center and Co-Director of the Cardiovascular Devices Unit at the Duke Clinical Research Institute. An Interventional Cardiologist at Duke Hospital and a Faculty Member in the Duke Center for Healthcare Informatics, he specializes in cardiovascular informatics research and integration of evidence from cardiovascular clinical trials. He has completed his graduation in magna cum laude from Harvard University, where he also received a Master's degree in Organismic and Evolutionary Biology. He has received his Medical degree from the Johns Hopkins University School of Medicine and was a Resident on the Osler Medical Service at the Johns Hopkins Hospital. He has completed his Fellowships in Cardiovascular Disease and Interventional Cardiovascular Medicine at Duke University before joining the Duke Faculty. He is board certified in Internal Medicine, Cardiology and Interventional Cardiology. He is a Certified Diver Medic, Master Diver and Dive Medical Examiner and has been elected Fellow of the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions.

dkong@acpub.duke.edu

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