Thu. Jul 5, 2018

第2会場

JSPCCS-AHA Joint Symposium

JSPCCS-AHA Joint Symposium （ I-AHAJS）
HBD-children in JAPAN

座長:安河内 聰（長野県立こども病院 循環器小児科）
座長:Nicole G. Ibrahim（U.S. Food and Drug Administration, USA）
8:40 AM - 11:50 AM 第2会場 (301)

[I-AHAJS-Session01] What We Can Do Now to Foward Development of Pediatric Medical Device?

[I-AHAJS-01] Introduction of HBD-children
○杉山 央 （東京女子医科大学心臓病センター 循環器小児科）

[I-AHAJS-02] Activity in US
○Nicole G. Ibrahim （U.S. Food and Drug Administration, USA）

[I-AHAJS-03] Activity in Japan
○田中 大祐 （厚生労働省 医薬・生活衛生局）

[I-AHAJS-04] Request to the regulatory from the industry
○日本ライフライン株式会社

[I-AHAJS-Discussion01] Importance of international harmonization
How to use existing data to facilitate development
Incentive to motivate industries
高橋 彩来[1], Richard Ringel[2], Frank Ing[3], 杉山 央[4], Nicole G. Ibrahim[5], 田中 大祐[6], 日本ライフライン株式会社 （1.医薬品医療機器総合機構, 2.Johns Hopkins Hospital, USA, 3.Los Angeles Children’s Hospital, USA, 4.東京女子医科大学心臓病センター 循環器小児科, 5.U.S. Food and Drug Administration, USA, 6.厚生労働省 医薬・生活衛生局）

[I-AHAJS-Session02] Clinical Evaluation to Develop Pediatric Medical Device

[I-AHAJS-05] Coarctation Of the Aorta Stent Trials: What can we learn from the COAST/COAST II studies?
○Richard Ringel （Johns Hopkins School of Medicine）

[I-AHAJS-06] Clinical evaluation of Genesis XD stent for PMA approval
○Frank Ing （Los Angeles Children's Hospital, USA）

[I-AHAJS-07] Doctor oriented clinical trial of CP stent for pulmonary stenosis
○富田 英 （昭和大学病院　小児循環器・成人先天性心疾患センター）

[I-AHAJS-08] Clinical Evaluation for Approval of Pediatric Medical Devices; from Regulatory Stand of View
○中村 泰子 （医薬品医療機器総合機構）

[I-AHAJS-09] Clinical Evaluation for Approval of Pediatric Medical Devices; from Regulatory Stand of View
○TBA

[I-AHAJS-Discussion02] Pre- and post-market clinical evaluation of pediatric medical devices, special focus on its feasibility
How to set and how to evaluate the primary and the secondary end point to develop these devices ?
杉山 央[1], 日本ライフライン株式会社, 方 眞美[2], Richard Ringel[3], Frank Ing[4], 富田 英[5], 中村 泰子[6] （1.東京女子医科大学心臓病センター 循環器小児科, 2.医薬品医療機器総合機構, 3.Johns Hopkins School of Medicine, 4.Los Angeles Children's Hospital, USA, 5.昭和大学病院　小児循環器・成人先天性心疾患センター, 6.医薬品医療機器総合機構）

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[I-AHAJS-Discussion02] Pre- and post-market clinical evaluation of pediatric medical devices, special focus on its feasibility
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[I-AHAJS-01] Introduction of HBD-children

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[I-AHAJS-02] Activity in US

○Nicole G. Ibrahim （U.S. Food and Drug Administration, USA）

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[I-AHAJS-03] Activity in Japan

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[I-AHAJS-05] Coarctation Of the Aorta Stent Trials: What can we learn from the COAST/COAST II studies?

○Richard Ringel （Johns Hopkins School of Medicine）

Obtaining FDA approval for a new medical device in the USA can be a challenging task even for large corporations. For an academic clinician navigating these challenges can be overwhelming. This experience and the lessons learned from the COAST and COAST II pivotal FDA trials will be discussed. Specifically the use of Objective Performance Criteria and Severity of Illness Scores will be discussed. Also reviewed will be the lessons learned from the trial design.

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