Introduction of Harmonization By Doing (HBD) 2003-2017

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DUKE UNIVERSITY MEDICAL CENTER

Duke Clinical Research Institute

September 2003

TCT 2003: 15th Annual Transcatheter Cardiovascular Therapeutics

September 15 - 19, 2003; Washington, DC

David Feigal MD
Director, CDRH 1999-2004

The Maureen and Mike Mansfield Foundation

Promoting Understanding and Cooperation in U.S.-Asia Relations since 1983

Program Overview

The Mansfield Fellowship Program—named after Mike Mansfield, former U.S. Ambassador to Japan, Senate Majority Leader, U.S. Senator and U.S. Congressman from Montana—is a first-of-its-kind program for both the United States and Japan. The two-year Fellowships enable U.S. federal government employees to develop an in-depth understanding of Japan, learn how its government works, and establish relationships with their counterparts in the government of Japan as well as in the business, professional and academic communities.

December 2003

FDA U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Department of Health and Human Services

FDA Home Page | CDRH Home Page | Search | A-Z Index

FDA > CDRH > International Issues > Japan - U.S. "Harmonization By Doing" HBD Pilot Program Initiative

Questions?

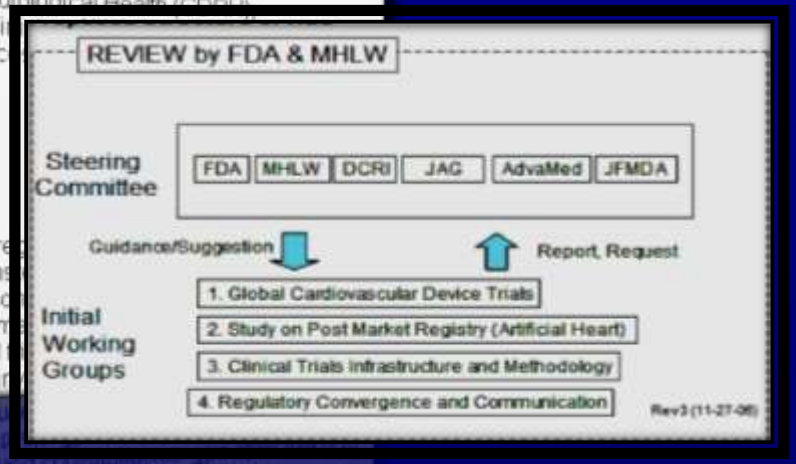
Japan - U.S. "Harmonization By Doing" HBD Pilot Program Initiative

"Harmonization by Doing," commonly known as HBD, is an international effort to develop global clinical trials and address regulatory barriers that may be impediments to timely device approvals. This process is a cooperative effort to move both Japan and the U.S. toward international regulatory harmonization. Participants in this process include:

- U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH)
- Japan 's Pharmaceutical and Food Safety Bureau (PFSB) of the Mi
(MHLW) and its review agency, the Pharmaceutical and Medical Devic
- Duke Clinical Research Institute (DCRI),
- Japanese academic community, and
- Japanese and U.S. medical device industry.

What is the HBD initiative?

The HBD initiative is a pilot project launched in December 2003 that seeks re
and MHLW-PMDA premarket review of device cardiovascular technology. Ins
to harmonization, HBD will utilize parallel development, application submissio
device projects by FDA and MHLW-PMDA in conjunction with the above-nam
eliminate redundancies, added costs, and time delays inherent in sequential
to create guidance and discuss policy but to develop common protocols for in



2003-2004: Japan MHLW launches PMDA

Pharmaceuticals and Medical Devices Agency, Japan

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April 2004: PMDA Adopts Early Consultation

- Early discussion of clinical trial science & strategy
- Potential to coordinate with pre-IDE discussions in USA

U.S. Department of Health & Human Services www.hhs.gov

U.S. Food and Drug Administration A-Z Index Search go

Home | Food | Drugs | Medi

June 2009: The "Collaborative Scheme" for parallel medical device development

Medical Devices

Home > Medical Devices > Devic

Device Advice: Device Regulation and Guidance

International Information (Medical Devices)

- Important New Changes to Canadian Regulatory Quality Systems Requirements
- Japan - U.S. "Harmonization By Doing" HBD Pilot Program Initiative
- Contacts

Japan - U.S. "Harmonization By Doing" HBD Pilot Program Initiative

ANNOUNCEMENT (June 23, 2009): U.S. – Japan Pilot Program Regarding Medical Device Collaborative Consultation and Review of Premarketing Applications

Japan MHLW/PMDA and U.S. FDA announced this week the launch of a bilateral pilot program on collaborative consultation and review of new cardiovascular devices. The goal of the pilot program is to advance both the speed and quality of clinical/statistical consultations and the regulatory review process for potential earlier market access and improved public health benefit. This collaboration would permit the scientific review staff of both MHLW/PMDA and FDA to discuss the contents of an individual submission in order to gain valuable regulatory information pertaining to device development and clinical trial design.

The Collaborative Scheme is one of several focused topics that will be discussed at the upcoming Japan-US Harmonization By Doing (HBD) West 2009 Meeting, July 16-17 at the FDA White Oak Campus.

- FDA announcement (English)
- MHLW announcement (*tsuchi*) (Japanese)

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/InternationalInformation/ucm053067.htm

HBD: 15 Years & Beyond

Identifying & Transforming Barriers to Device Innovation

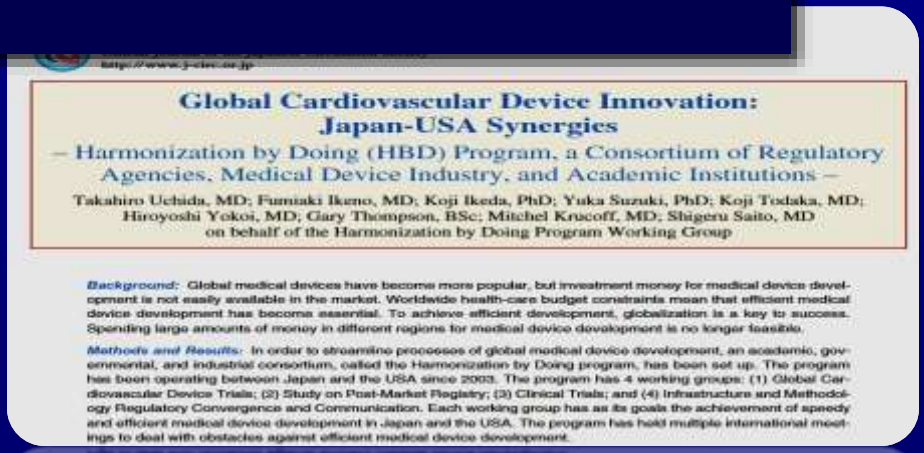
- Pre-competitive collaboration, trust & good will
- International regulatory convergence
- Research infrastructure efficiencies
- Structured data elements & definitions
- Stakeholder education & engagement
- Pilot “POC” projects

Medical Device Innovation:
Prospective Solutions for an Ecosystem in Crisis

Adding a Professional Society Perspective

Mitchell W. Krucoff, MD,* Ralph G. Brindis, MD, MPH,† Patricia K. Hodgson, BA,*
Michael J. Mack, MD,‡ David R. Holmes, Jr, MD§

Durham, North Carolina; San Francisco, California; Dallas, Texas; and Rochester, Minnesota



Global Cardiovascular Device Innovation: Japan-USA Synergies

– Harmonization by Doing (HBD) Program, a Consortium of Regulatory Agencies, Medical Device Industry, and Academic Institutions –

Takahiro Uchida, MD; Fumiaki Ikeno, MD; Koji Ikeda, PhD; Yuka Suzuki, PhD; Koji Todaka, MD; Hiroyoshi Yokoi, MD; Gary Thompson, BSc; Mitchel Krucoff, MD; Shigeru Saito, MD
on behalf of the Harmonization by Doing Program Working Group

Background: Global medical devices have become more popular, but investment money for medical device development is not easily available in the market. Worldwide health-care budget constraints mean that efficient medical device development has become essential. To achieve efficient development, globalization is a key to success. Spending large amounts of money in different regions for medical device development is no longer feasible.

Methods and Results: In order to streamline processes of global medical device development, an academic, governmental, and industrial consortium, called the Harmonization by Doing program, has been set up. The program has been operating between Japan and the USA since 2003. The program has 4 working groups: (1) Global Cardiovascular Device Trials; (2) Study on Post-Market Registry; (3) Clinical Trials; and (4) Infrastructure and Methodology Regulatory Convergence and Communication. Each working group has as its goals the achievement of speedy and efficient medical device development in Japan and the USA. The program has held multiple international meetings to deal with obstacles against efficient medical device development.

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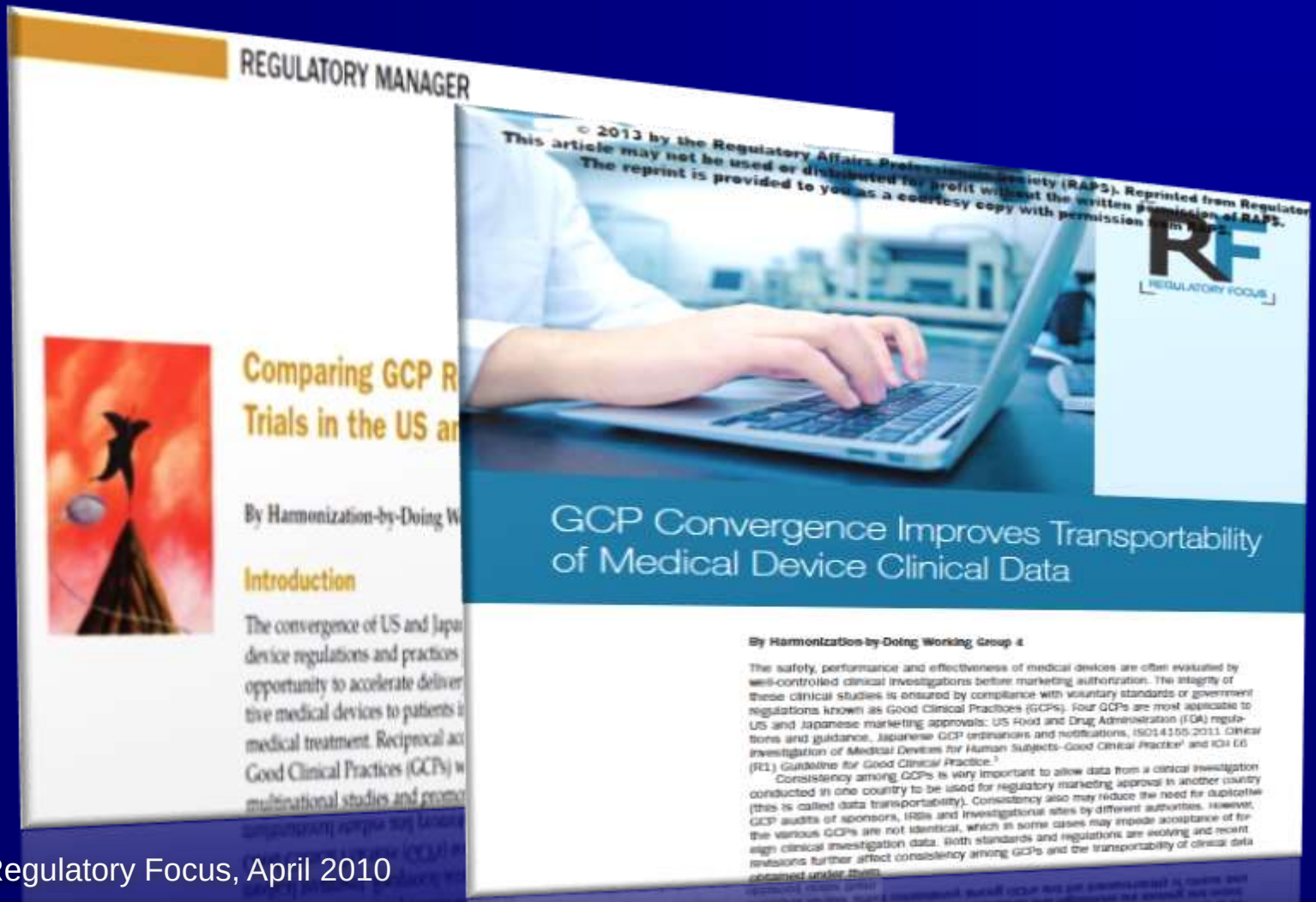
Krucoff MW et al, J Am Coll Cardiol Intv 2012;5:790–6)
Uchida T et al, Circulation Journal 2013

CRI Duke Clinical Research Institute

HBD

Global regulatory convergence

Regulatory Convergence:
Ethics, Methods and Science of Human Studies



Regulatory Focus, April 2010

Regulatory Focus, January 2013

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HBD

Research infrastructure efficiencies

Advancing Research Infrastructure:
Study processes – time lines

- ✓ Protocol development
- ✓ Study design
- ✓ Site selection

- ✓ Steering Committee
- ✓ DSMC
- ✓ Safety Desk
- ✓ CEC

- ✓ Site start-up
- ✓ Training
- ✓Investigator and Coordinator Meeting

- ✓ Site Queries
- ✓ Monitoring

Database lock

- ✓ Operations Team
- ✓ Study Documents

- ✓ Contracting

- ✓ First Patient in
- ✓ Randomization
- ✓ CEC
- ✓Safety Reporting

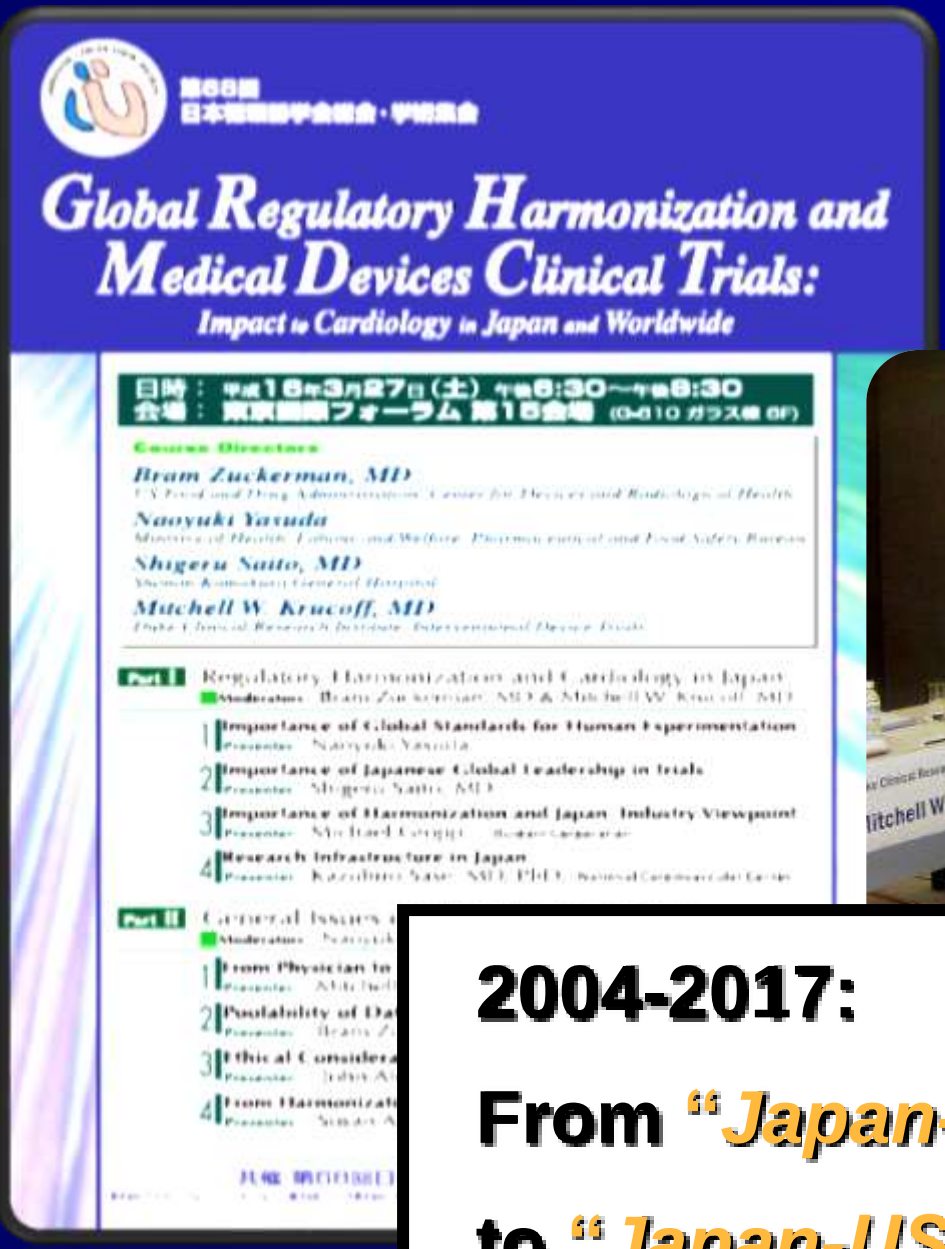
- ✓ Last Patient in

HBD Site Visits *March 2004*: Shonan Kamakura

HBD

Stakeholder education & engagement

Japan Circulatory Society
March 2004
Tokyo, Japan



2004-2017:

From "*Japan-USA Barriers*"

to "*Japan-USA Synergies*"

…, CIT, …PS, …ned, …CR

Duke Clinical Research Institute
DUKE UNIVERSITY MEDICAL CENTER

December 2004: Kamakura Public Forum

Attention to the Patient's Perspective

Medical Technology Leadership Forum
Washington D.C.
April 2005

Hiroshi Yamamoto
MHLW

Dan Schultz
U.S. FDA

Mitch Krucoff
Duke/DCRI

DUKE UNIVERSITY MEDICAL CENTER

CRI
Duke Clinical Research Institute

October 2007

Tomiko Tawaragi

MHLW

October 2011

IMDRF

International Medical Device Regulators Forum

About IMDRF

The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011, as a forum to discuss future directions in medical device regulatory harmonization. It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF). The Forum will accelerate international medical device regulatory harmonization and convergence.

IMDRF contacts

Chair:
Dr Larry Kelly
Group Coordinator
Monitoring and Compliance Group
Therapeutic Goods Administration
Australia
Email: imdrf.chair@tga.gov.au

Secretariat:
Email: imdrf.secretariat@tga.gov.au

In October 2011, representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, European Union, Japan and the United States, as well as the World Health Organization (WHO) met in Ottawa to address the establishment and operation of this new Forum.

A copy of the outcome statement from this meeting is available on the Therapeutic Goods Administration website.

http://www.imdrf.org/

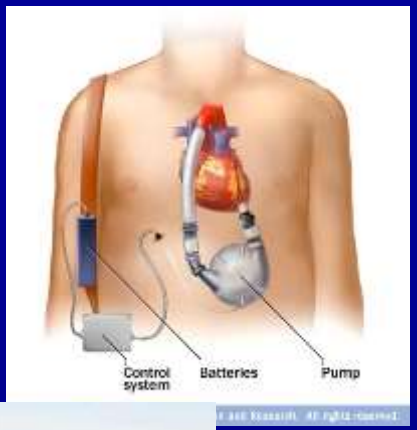
HB *Doing*

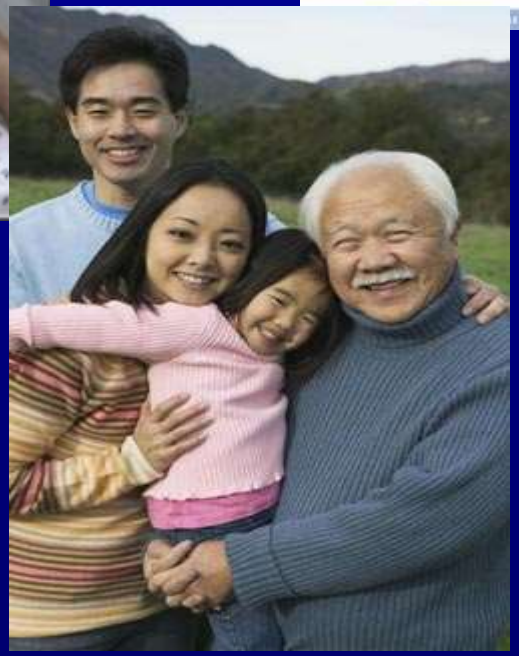
Pilot "POC" Projects:

Novel Informative Data-structure

"Harmonization By Data"

Linking Post-Market Surveillance: LVADS





JACC
JOURNAL of the AMERICAN COLLEGE of CARDIOLOGY

J Am Coll Cardiol, 2010; 56:738-740, doi:10.1016/j.jacc.2010.05.021

INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support): A New Paradigm for Translating Registry Data Into Clinical Practice

Marissa A. Miller, Karen Ulisney, and J. Timothy Baldwin

JMACS

Peripheral Academic Research Consortium (PARC)

Face to Face Workshops
FDA Headquarters, White Oak, Maryland

February 2012 & 2013

Duke Clinical Research Institute

CARDIOVASCULAR RESEARCH FOUNDATION
A Passion for Innovation

ISCTR

CARDIALYSIS
Clinical Research Management & Core Laboratories

HCRI
HARVARD CLINICAL RESEARCH INSTITUTE

THE PRESENT AND FUTURE

STATE-OF-THE-ART REVIEW

Evaluation and Treatment of Patients With Lower Extremity Peripheral Artery Disease

Consensus Definitions From Peripheral Academic Research Consortium (PARC)

Manesh R. Patel, MD,* Michael S. Conte, MD,† Donald E. Cutlip, MD,‡§ Nabil Dib, MD,‖ Patrick Geraghty, MD,¶ William Gray, MD,#** William R. Hiatt, MD,†† Mami Ho, MD, PhD,‡‡ Koji Ikeda, PhD,§§ Fumiaki Ikeno, MD,‖‖ Michael R. Jaff, DO,¶¶ W. Schuyler Jones, MD,* Masayuki Kawahara, MD,† Robert A. Lookstein, MD,## Roxana Mehran, MD,# ## Sanjay Misra, MD,*** Lars Norgren, MD,††† Jeffrey W. Olin, MD,## Thomas J. Povsic, MD, PhD,* Kenneth Rosenfield, MD,††† John Rundback, MD,§§§ Fadi Shamoun, MD,‖‖‖ James Tcheng, MD,* Thomas T. Tsai, MD,¶¶¶ Yuka Suzuki, PhD,### Pascal Vranckx, MD,**** Bret N. Wiechmann, MD,†††† Christopher J. White, MD,‡‡‡‡ Hiroyoshi Yokoi, MD,§§§§ Mitchell W. Krucoff, MD*

ABSTRACT

The lack of consistent definitions and nomenclature across clinical trials of novel devices, drugs, or biologics poses a significant barrier to accrual of knowledge in and across peripheral artery disease therapies and technologies. Recognizing this problem, the Peripheral Academic Research Consortium, together with the U.S. Food and Drug Administration

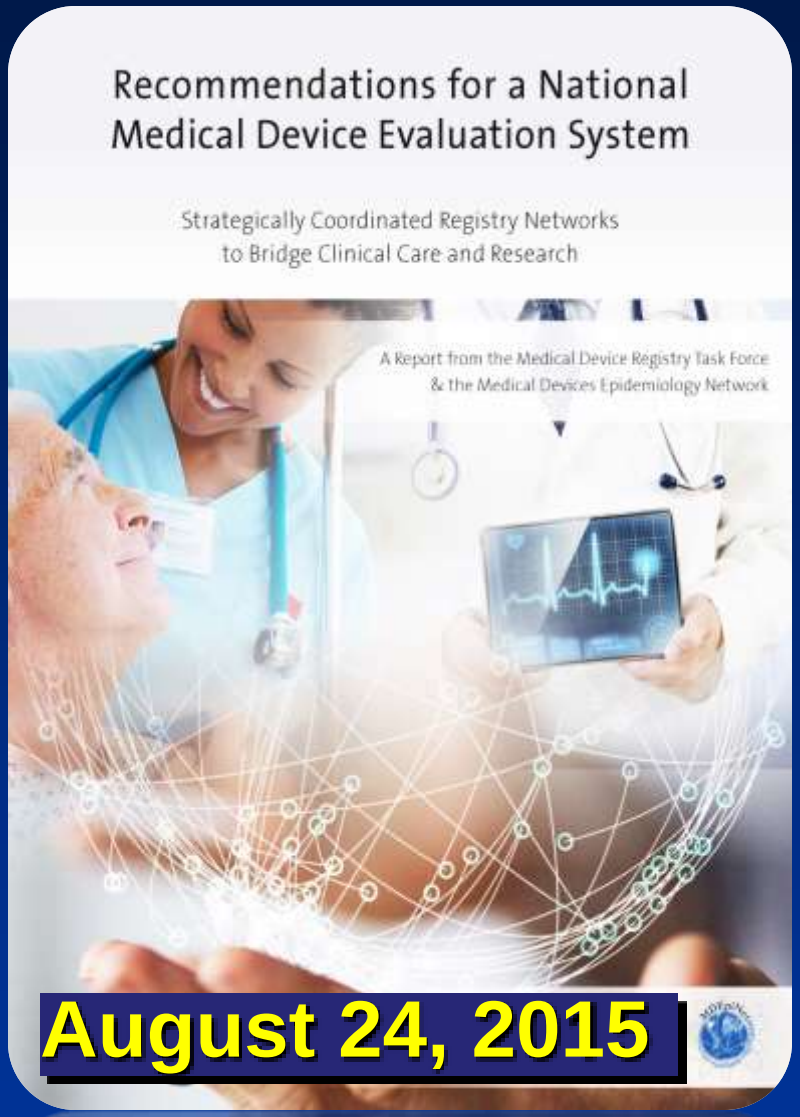
UCSF

Patel MR et al, JACC 2015: 65:931-41

Integrated Definitions & Registries:
Harmonization By Data

https://www.ncdr.com/TVT/Home/Default.aspx

Real World Evidence Structure, Quality & Capture



BRIDGING UNMET CLINICAL CARE AND CLINICAL RESEARCH NEEDS WITH STRATEGICALLY COORDINATED REGISTRY NETWORKS

Report from the National Medical Device Registry Task Force & The Medical Devices Epidemiology Network

Mitchell W. Krucoff, Sharon Lise Normand, Fred Edwards, Theodore Lystig, Eve Ross, Elise Berliner, Kristi Mitchell, James Tcheng, David Blaser, Ralph Brindis, Jack Cronenwett, Pamela Gavin, Linda Harrington, Amy Helwig, Kevin Larsen, William Maloney, Matthew McMahon, Bray Patrick-Lake, John Rumsfeld, Julia Skapik, Art Sedrakyan, Danica Marinac-Dabic


VIEWPOINT

Bridging Unmet Medical Device Ecosystem Needs With Strategically Coordinated Registries Networks

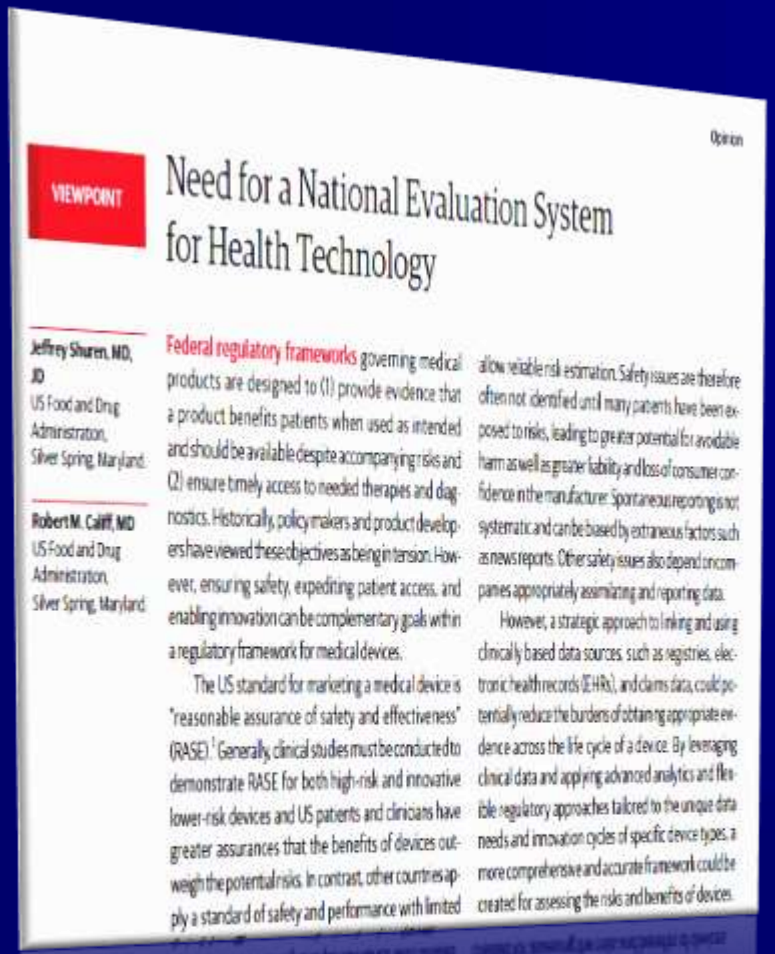
www.mdepinet.org

Duke Clinical Research Institute
DUKE UNIVERSITY MEDICAL CENTER

Krucoff MW, Normand SL et al, JAMA 2015

NEST: The Vision

Real World Evidence of Device Benefit/Risk, Safety



Opinion

VIEWPOINT

Need for a National Evaluation System for Health Technology

Jeffrey Shuren, MD, JD
US Food and Drug Administration, Silver Spring, Maryland

Robert M. Califf, MD
US Food and Drug Administration, Silver Spring, Maryland

Federal regulatory frameworks governing medical products are designed to (1) provide evidence that a product benefits patients when used as intended and should be available despite accompanying risks and (2) ensure timely access to needed therapies and diagnostics. Historically, policy makers and product developers have viewed these objectives as being in tension. However, ensuring safety, expediting patient access, and enabling innovation can be complementary goals within a regulatory framework for medical devices.

The US standard for marketing a medical device is "reasonable assurance of safety and effectiveness" (RASE).[1] Generally, clinical studies must be conducted to demonstrate RASE for both high-risk and innovative lower-risk devices and US patients and clinicians have greater assurances that the benefits of devices outweigh the potential risks. In contrast, other countries apply a standard of safety and performance with limited allow reliable risk estimation. Safety issues are therefore often not identified until many patients have been exposed to risks, leading to greater potential for avoidable harm as well as greater liability and loss of consumer confidence in the manufacturer. Spontaneous reporting is not systematic and can be biased by extraneous factors such as news reports. Other safety issues also depend on companies appropriately assimilating and reporting data.

However, a strategic approach to linking and using clinically based data sources, such as registries, electronic health records (EHRs), and claims data, could potentially reduce the burdens of obtaining appropriate evidence across the life cycle of a device. By leveraging clinical data and applying advanced analytics and flexible regulatory approaches tailored to the unique data needs and innovation cycles of specific device types, a more comprehensive and accurate framework could be created for assessing the risks and benefits of devices.

- **More real world**
- **Less unique effort & cost**
- **More value across ecosystem:**
  - ***Regulatory decisions***
  - ***Best practice guidelines***
  - ***Payer decisions***
  - ***Patient information***
- **Learning model:**
  - Use/re-use structure solutions
  - Linked architecture
- **International application**

JAMA Published online July 11, 2016

MDEpiNet PPP PASSION CV Registries

Program Launch
October 2014

Predictable And SuStainable Implementation Of National CardioVascular Registries:

- Coronary
- Valves
- ICD/CRT
- Peripheral/Endo

Registry Assessment of Peripheral Interventional Devices (RAPID)

Jack L. Cronenwett, M.D.
Dartmouth-Hitchcock Medical Center
Lebanon, New Hampshire

RAPID Partners

- 3 Major U.S. Societies / Registries
  - American College of Cardiology (ACC)
    - National Cardiovascular Disease Registry (NCDR)
  - Society of Interventional Radiology (SIR)
    - National Interventional Radiology Quality Registry (NIRQR)
  - Society for Vascular Surgery (SVS)
    - Vascular Quality Initiative (VQI)
- 5 International Partners
  - Japan's Pharmaceuticals and Medical Devices Agency (PMDA)
  - Global Medical Device Nomenclature Agency (GMDNA)
  - Australian Vascular Audit
  - German Vascular Society
  - Northern German Association for Vascular Medicine

RAPID Partners

- 7 U.S. Agencies
  - FDA (CDRH pre- and post-market, and CDER)
  - Agency for Healthcare Research and Quality (AHRQ)
  - Centers for Medicare and Medicaid Services (CMS)
  - Department of Defense (DOD) Healthcare Resources
  - Office of the National Coordinator (ONC)
  - National Heart, Lung and Blood Institute (NHLBI)
  - National Library of Medicine (NLM)
- 6 EHR / Registry / Clinical Research Companies
  - Epic
  - M2S
  - MedStreaming
  - Healthjump
  - Boston Biomedical Assoc.
  - Novella Clinical, Quintiles

RAPID Partners

- 12 Device Manufacturers
  - Abbott
  - Aortic Medical Inc.
  - Avinger
  - Boston Scientific
  - Cardiovascular Systems Inc
  - Cook Medical
  - CR Bard
  - Medtronic
  - Spectranetics Corp
  - Terumo
  - Volcano Corp/Phillips Health Technology
  - WL Gore

Data Elements

Data Element Label	Data Element Definition	Value set	Definitions of the elements of the value set	Reference source
CONDITION - MODIFIED RUTHERFORD CLASSIFICATION				
Modified Rutherford Category	Categorical description of the symptoms associated with the obstruction of the lumen of the peripheral arteries (NCI C78533).	0	Asymptomatic: documented peripheral arterial disease, without symptoms of claudication or ischemic pain	Adapted from VQI PVI registry, Rutherford J Vasc Surg 1997;26:517-38, ACC/AHA PAD Data Standards Circulation 2012;125:395-467, and PARC J Am Coll Cardiol 2015.
		1	Mild claudication: ischemic limb muscle pain that does not limit walking, or limits walking only after >2 blocks (>600 feet, or 2 football fields)	
		2	Moderate claudication: ischemic limb muscle pain that limits walking to 1-2 blocks (300-600 feet, or 1-2 football fields)	
		3	Severe claudication: ischemic limb muscle pain that limits walking to <1 block (<300 feet, or 1 football field)	
		4	Ischemic rest pain: pain in the distal foot at rest felt to be due to limited arterial perfusion	
		5	Minor tissue loss: nonhealing ischemic ulcer(s) on distal leg, or focal gangrene with diffuse pedal ischemia	
		6	Major tissue loss: ischemic gangrene extending above TM level, functional foot no longer salvageable without extensive revascularization efforts	

HB *Doing*

Pilot "POC" Projects:

Clinical Trials

2005: Endeavor Japan (Medtronic)

The clinical evaluation of the Endeavor zotarolimus-eluting coronary stent in Japanese patients with de novo native coronary artery lesions: primary results and 3-year follow-up of the Endeavor Japan study☆☆☆

Shigeru Saito ✉, Ross Prpic, Jeffery J. Popma, John Alexander, Mitchell W. Krucoff, on behalf of the ENDEAVOR Japan Investigators

Cardiovascular Revascularization Medicine
Volume 12, Issue 5, Pages 273–279, September–October, 2011

- Identical inclusion/exclusion
- Identical endpoints
- Identical core laboratories
- Enhanced poolability
- Enhanced interpretability

2007: SPIRIT III Japan (Abbott Vascular): *Enhanced poolability & interpretability*

JIC JOURNAL OF INVASIVE CARDIOLOGY

Mid-Term Results of Everolimus-Eluting Stent in a Japanese Population Compared With a US Randomized Cohort: SPIRIT III Japan Registry With Harmonization by Doing

Wednesday, 08/29/12 | 9993 reads

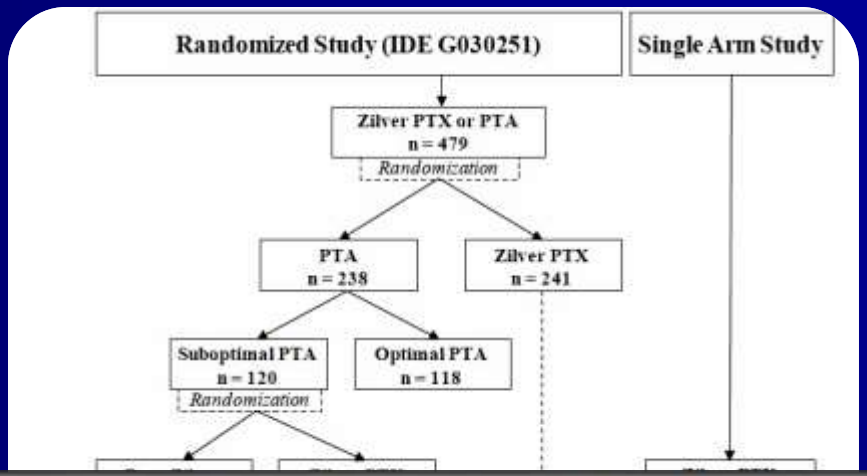
Author(s):

Shigeru Saito, MD[1], Shigeru Nakamura, MD[2], Kenshi Fujii, MD[3], Masato Nakamura, MD[4], Takaaki Isshiki, MD[5], Haruo Hirayama, MD[6], Tadashi Kikuchi, MD, PhD[7], Hiroshi Fujita, MD[8], Hiroshi Nonogi, MD, PhD[9], Kazuaki Mitsudo, MD[10], Takeshi Kimura, MD[11], Keiichi Igarashi, MD[12], Kumiko Saito, MS, MPH[13], Alexandra J. Lansky, MD[14], Gregg W. Stone, MD[14], Yasuhiro Honda, MD[15], Katsuhisa Waseda, MD, PhD[16], Peter J. Fitzgerald, MD, PhD[15], Krishnankutty Sudhir, MD, PhD[16]

Issue Number:
Volume 24 - Issue 9 - September 2012

- *Concomitant enrollment*
- Identical inclusion/exclusion
- Identical endpoints
- Identical core laboratories

2009: Zilver PTX (Cook Medical)
Single protocol global RCT



Zilver® PTX® Drug-Eluting Peripheral Stent - P100022

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Zilver® PTX Drug-Eluting Peripheral Stent
PMA Applicant: Cook, Inc.
Address: 750 Daniels Way, P.O. Box 489, Bloomington, IN 47402-0489
Approval Date: November 14, 2012
Approval Letter: http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100022a.pdf

COAST Study (CSI)

Diamondback 360® Coronary OAS Micro Crown

- To evaluate the performance of the Coronary OAS Micro Crown in treating *de novo*, severely calcified coronary lesions
  - Prospective, single-arm, multi-center Investigational Device Exemption (IDE) study conducted in Japan and the USA
  - Harmonization by Doing (regulatory collaboration between Japan and the USA)

100 patients enrolled

USA	74 patients 12 sites
Japan	26 patients 5 sites

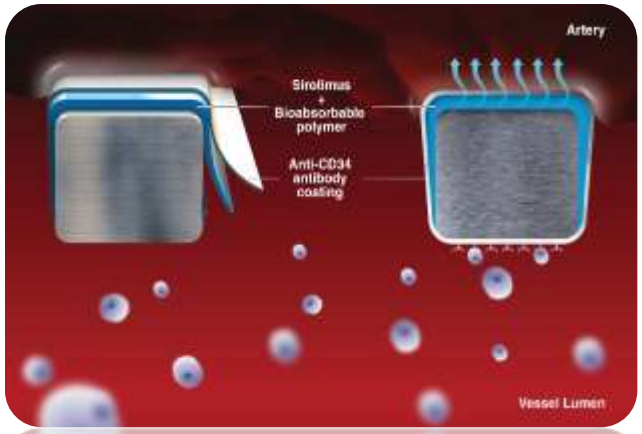
1-year follow-up completed* (93/100)

*6 subjects died and 1 subject lost to follow-up

Harmonized Assessment by Randomized Multicenter Study of OrbusNEich's COMBO StEnt

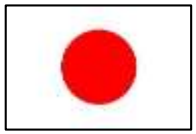
Japan-USA *HARMONEE: Primary Report*

Of A Randomized Trial of a Bioabsorbable Polymer-Based DES With A Luminal CD34+ Antibody Coating vs A Durable Polymer-Based DES in Patients With Coronary Artery Disease



The COMBO Plus Dual Therapy Stent

Enrollment & Follow-Up: ITT population



33 sites
439 pts (77%)

572 patients randomized

17 sites
133 pts (23%)

287 COMBO

285 EES

3 (1.0%) non-protocol stent

2 (0.7%) withdrew or lost to FU

2 (0.7%) non-protocol stent

6 (2.1%) withdrew or lost to FU

285 (99.3%) 1 year clinical FU

279 (97.9%) 1 year clinical FU

271 (95.1%) 1 year angio FU

261 (91.6%) 1 year FFR

262 (93.9%) 1 year angio FU

256 (91.8%) 1 year FFR

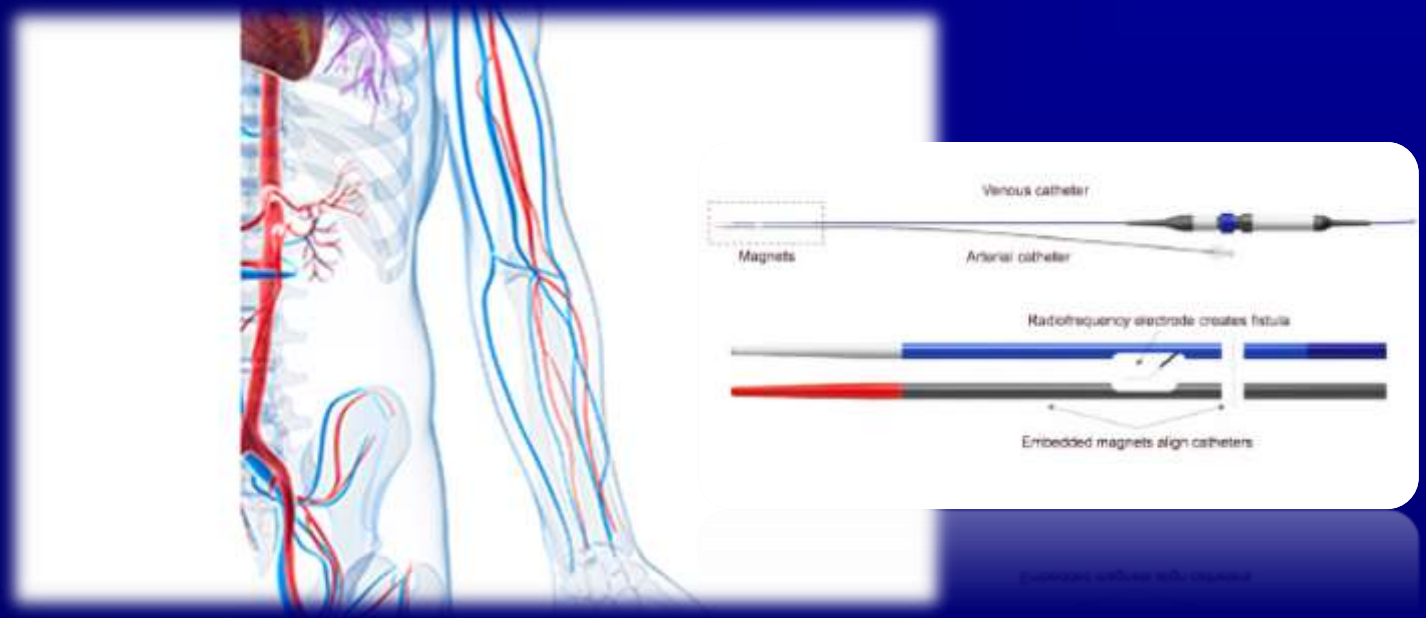
Cohort A&B 1 year OCT FU (n=70)

65 (92.9%)

Cohort A&B 1 year OCT FU (n=70)

63 (90.0%)

TVA medical



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Duke Clinical Research Institute

HB *Doing*

Pilot "POC" Projects:

New Directions

Early Feasibility Studies: Can We Do Together?

Investigational Devi
(IDEs) for Early
Medical Device Cli
Including Certain F
(FIH) Stu

Guidance for Indus
and Drug Adminis

Document issued on: Octob

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm279103.pdf

Based on our experiences of EFS in Japan and discussions in HBD activity, we'd like to build up the successful framework of EFS and make the environment to perform it better in Japan.

EFS in Japan: PMDA View

Sara Takahashi

Reviewer

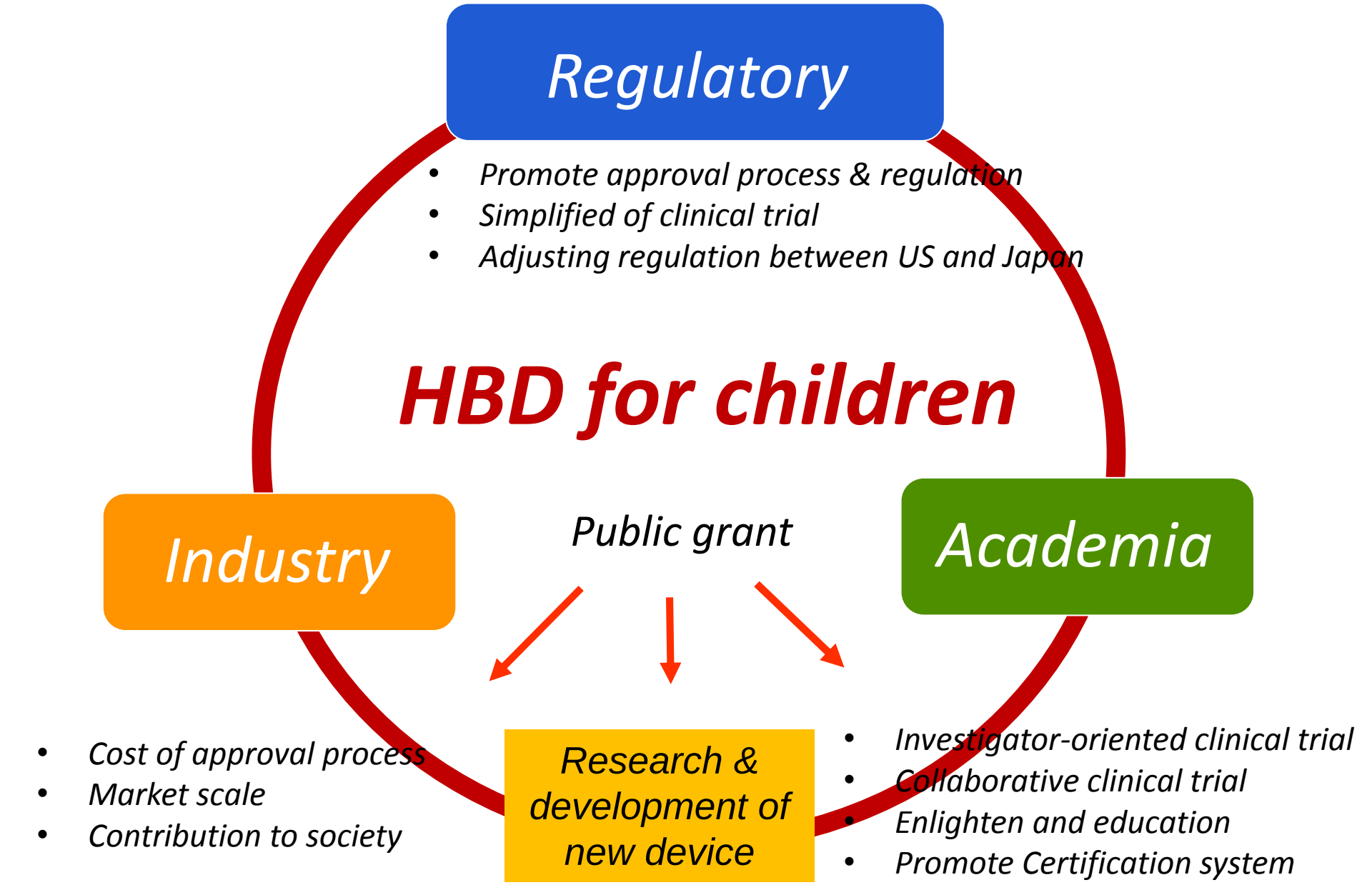
Office of Medical Devices III

Pharmaceuticals and Medical Devices Agency (PMDA), Japan

HBD-for-Children
Progress and Challenges

Satoshi Yasukochi, MD
Nagano Children's Hospital
JSPCCS vice-president

December 7th, 2017
National Center for Global Health and Medicine (NCGM)


Regulatory
Promote approval process & regulation
Simplified of clinical trial
Adjusting regulation between US and Japan
HBD for children
Industry
Public grant
Academia
Cost of approval process
Market scale
Contribution to society
Research & development of new device
Investigator-oriented clinical trial
Collaborative clinical trial
Enlighten and education
Promote Certification system

HBD-Children Work Report & schedule

Kick-Off Meeting At PMDA

Session of HBD-C At CRT 2017 In Wqshington On 2/20/2017

Chaired by Yasukochi S (JSPCCS)and Ibrahim N (FDA)
Ing F, Ringel R, (US)
Sugiyama H (JSPCCS)

Session of HBD-C At TCT2017 In Denver On 10/30/2017

Chaired by Yasukochi S (JSPCCS)and Ibrahim N (FDA)
Ing F, Ringel R, (US)
Tomita H (JSPCCS)

Dec 8 HBD East 2017 Think Tank Meeting

Mar 3-6 CRT 2018 In Washington DC

HBD session

July 5-7 JSPCCS 2018 in Yokohama, Japan

Tentative nominee

- HBD session for HBD-for-children
- Nicole Ibrahim (FDA)
- Frank Ing (US academia)
- Richard Ringel (US academia)
- Tom Forbes (US academia)

Sep 5-8 PICS 2018 in Las Vegas Or Sep 23-25 TCT2017 In San Diego

Introduction and achievement of HBD-for-Children

Yasuko Nakamura

Reviewer, Office of Medical Devices III

Pharmaceuticals and Medical Devices Agency (PMDA)

An established scheme ⬅ HBD

- Development of pediatric medical device tends to delay in the U.S. and Japan but there are **high needs** in clinical institutions.
- Regulatory authorities have to resolve problems in the U.S. and Japan.

HBD has made a great contribution to promote innovative medical device development for ADULT !

We will find problems of development of pediatric medical devices in the U.S. and Japan and propose solutions *by Doing*.

POC candidate

	Covered CP Stent	Medtronic Melody Transcatheter Pulmonary Valve	AMPLATZER muscular VSD occluder
industry	NuMED	Medtronic	ST.JUDE MEDICAL
			

HBD East: Tokyo 2008

Remember, Luke Skywalker:

“Don’t try…
Do!”

Harmonization By Doing

Thank you!

Introduction of Harmonization By Doing (HBD) 2003-2017

Mitchell W. Krucoff MD, FACC, FSCAI, FAHA

Professor of Medicine / Cardiology

Duke University Medical Center

Director, Cardiovascular Devices Unit

Director, MDEpiNet Coordinating Center

Duke Clinical Research Institute

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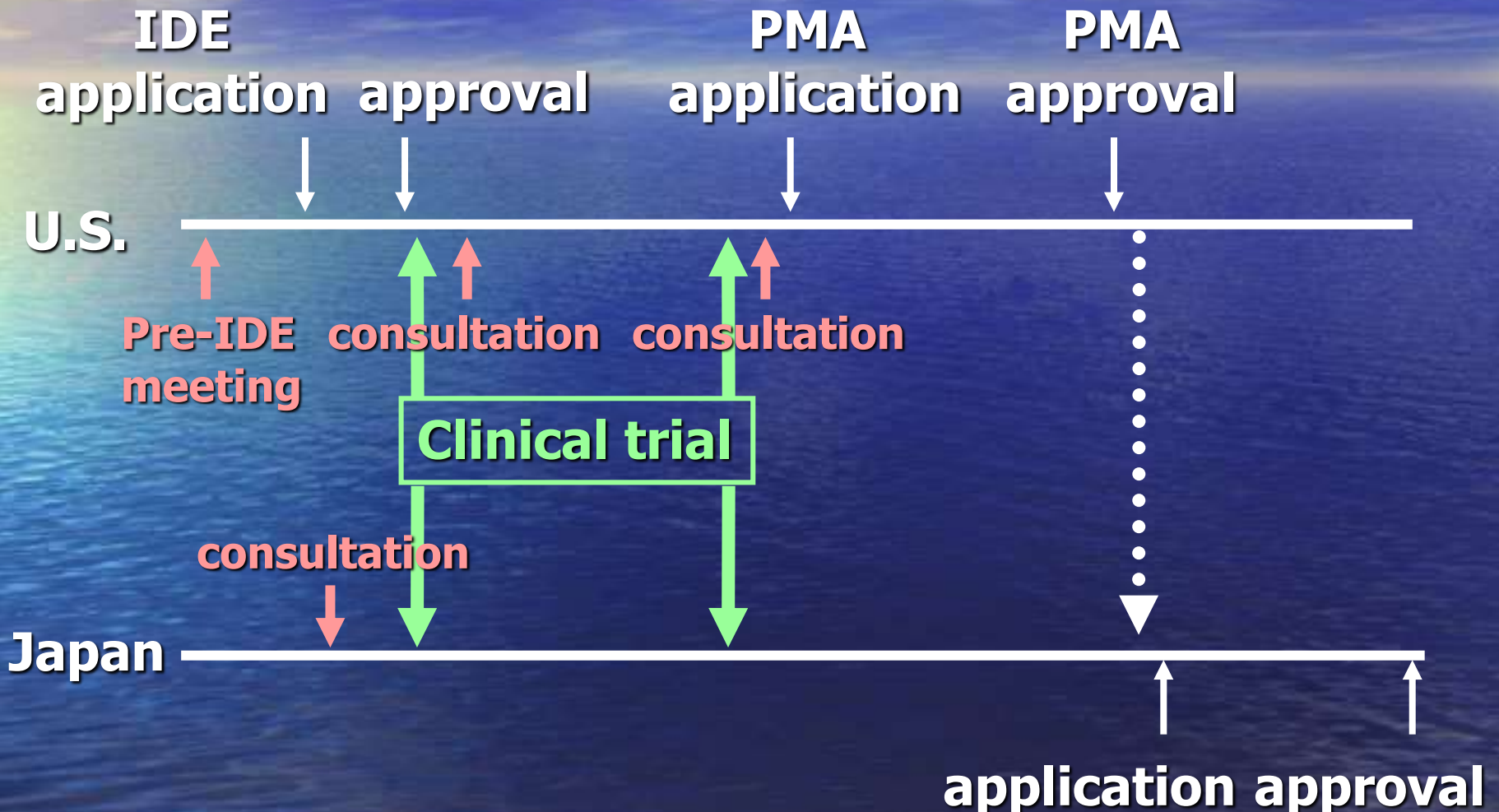
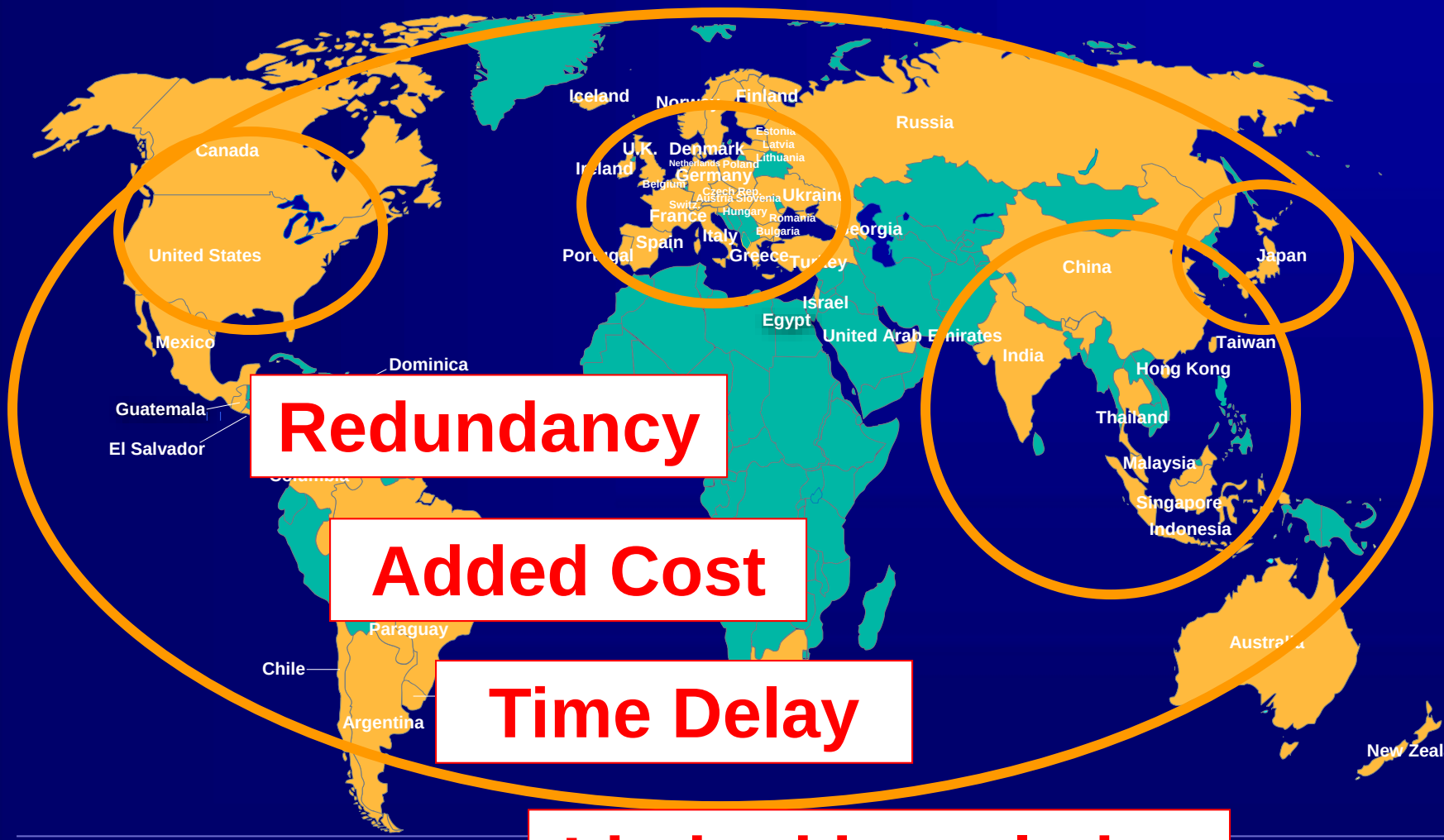
DUKE UNIVERSITY MEDICAL CENTER

Duke Clinical Research Institute

Flow to the approval



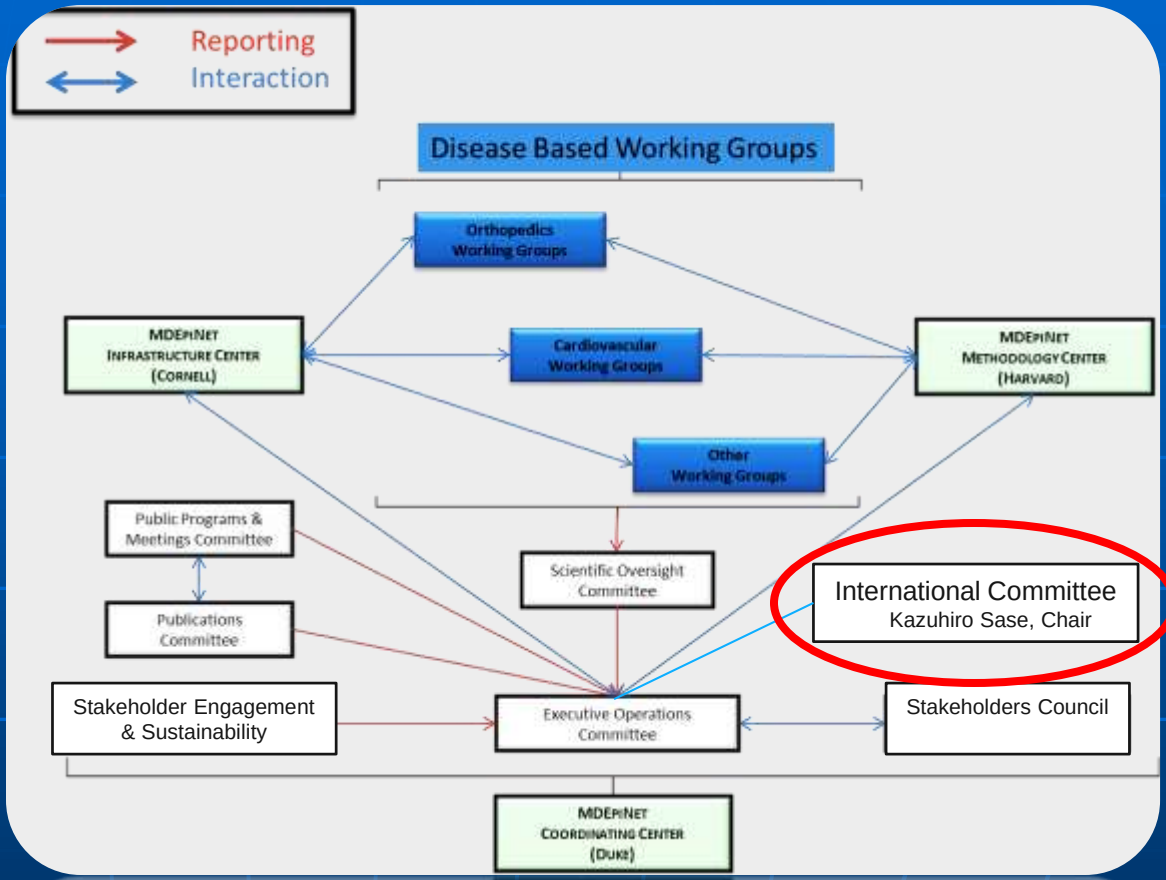
Global Clinical Evaluation



2012: MDEpiNet PPP

http://www.fda.gov/MedicalDevices/ScienceandResearch/EpidemiologyMedicalDevices/MedicalDeviceEpidemiologyNetworkMDEpiNet/default.htm

…to develop and maintain national and international scientific infrastructure and…methodological approaches…to overcome and eliminate discontinuities in evaluation and surveillance that currently exist within the TPLC…



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