Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

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22nd Asian Harmonization Working Party Annual Meeting

MAKE IN INDIA

MAKE IN INDIA

4-8 December, 2017 I New Delhi

Ministry of Health & Family Welfare
Government of India

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Medical Device Clinical Trial Landscape in APAC

Presented by **Mie Ohama**
Medtronic
Sr. Clinical Quality Manager Gr. China & APAC
Corporate Clinical Quality & Compliance

AGENDA

1. Introduction
2. Overview of medical device clinical trial landscape in APAC.
3. New and changing clinical regulations
4. Summary
5. Q & A



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MEDTRONIC
GLOBAL LEADER IN MEDICAL TECHNOLOGY

84,000+	~160	$29,7B	$2B	2,000+	2 Lives every second
Number of employees	Number of countries Medtronic operates in	FY17 global sales	Research and development spend	Number of employees involved in clinical study activities	Improved by Medtronic

**Information reflects Medtronic fiscal year 2017 data* http://www.medtronic.com/us-en/about/facts-stats.html

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MEDTRONIC STRATEGY
FOCUS ON GLOBALIZATION

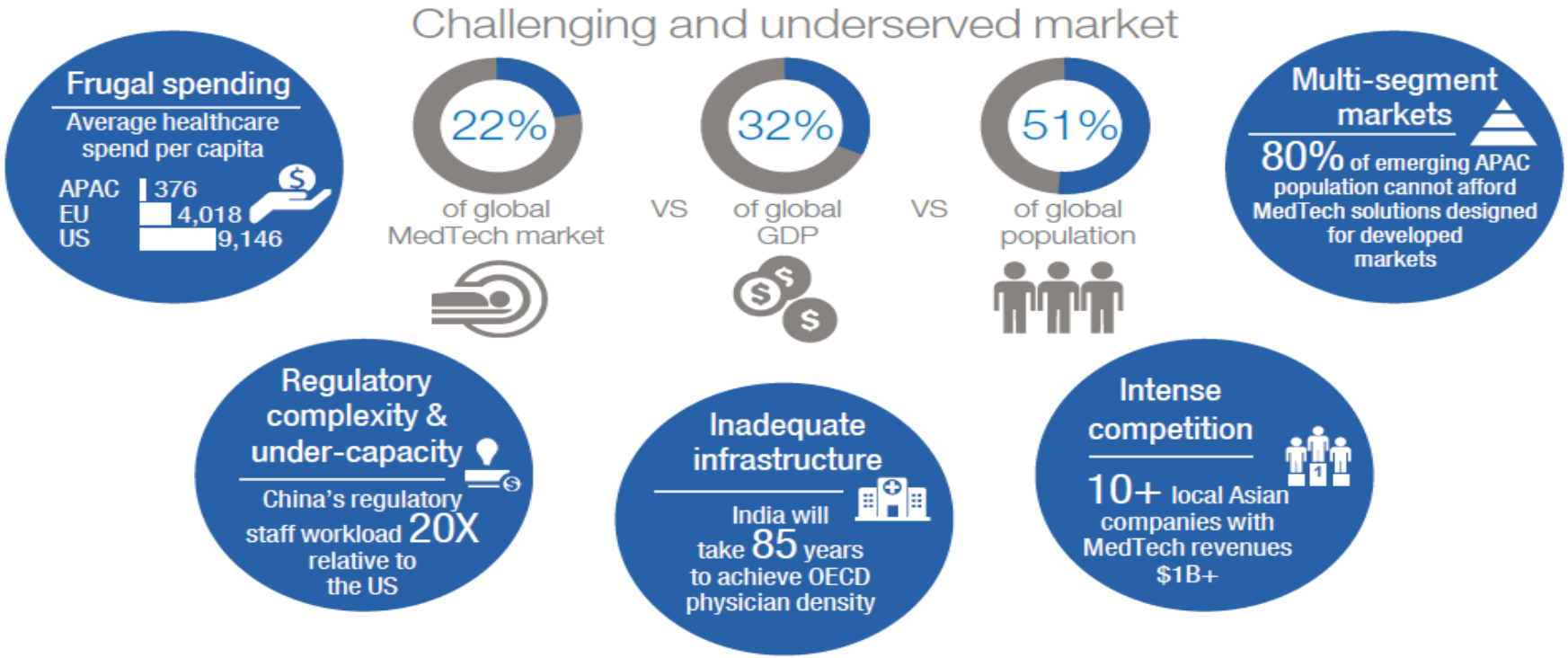
Universal Healthcare Needs	Medtronic Strategies
IMPROVE CLINICAL OUTCOMES	THERAPY INNOVATION
EXPAND ACCESS	GLOBALIZATION
OPTIMIZE COST AND EFFICIENCY	ECONOMIC VALUE

Our Mission:

To contribute to human welfare by application of biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that **alleviate pain, restore health, and extend life.**

The Asian Century

REALITIES FACING MEDTECH INDUSTRIES IN GR. CHINA & APAC



▪ *Note 1 :McKinsey & Company report 'MedTech in Asia Committing at scale to raise standards of care for patients December 2015'*

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ASIA PACIFIC THE RISE OF A SUPER REGION

3.7 BILLION PEOPLE

51% of WORLD'S POPULATION

LIVES IN APAC

TOP 3 DISEASE

HEART DISEASE | CANCER | DIABETES

DID YOU KNOW?

1.1B people

50+ years of age by 2025

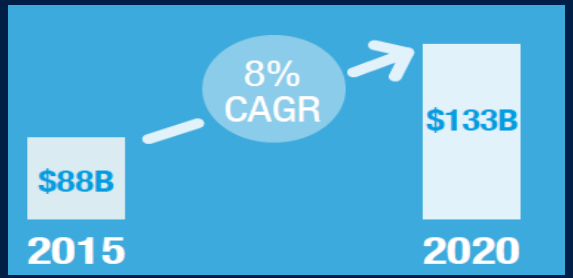
65M babies

born each year (equivalent to UK population)

2B people

in consuming class by 2025 (~50% of whole APAC)

ASIA PACIFIC MEDTECH MARKET, $B



▪ *Note1 :McKinsey & Company report 'MedTech in Asia Committing at scale to raise standards of care for patients December 2015'*

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FOCUS ON THE ASIA PACIFIC REGION

Medtronic finishes acquiring China Kanghui

Updated: 2012-11-19 16:18
By Liu Jie (chinadaily.com.cn)

Comments() Print Mail Large Medium Small

Medical equipment company Medtronic Inc has completed its $755 n
Jiangsu-based China Kanghui Holdings, a Chinese provider of ortho

Chris O'Connell, executive vice-president and president of Medtronic
Group, said that China is one of the fastest-growing medical device n
scale opportunities.

"Medtronic will establish a bigger and more direct local presence. Ka
broad product portfolio, a strong l
operation, a vast China distributio

Kanghui brings a strong product p
reconstruction.

Medtronic teaming up with China's LifeTech to develop cardiovascular products

July 28, 2014 | By Emily Wasserman

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Medtronic ($MDT) is teaming up with LifeTech Scientific to manufacture and distribute cardiac devices for China's growing cardiovascular market.

Under the terms of the agreement, Lifetech will develop pacemaker and cardiac leads at its Shenzhen facility and Medtronic will provide technological support and training. The Minnesota device giant could also partner with

Medtronic CEO Omar Ishrak

August 6, 2014 UPDATED 8/8/2014

Medtronic enters hemodialysis field, builds factory in China

By NINA YING SUN

SHARE

China Medical

Medtronic Inc. has just broken ground to build its first production line for hemodialysis systems, hoping to serve the global market from its new production base in Chengdu, China.

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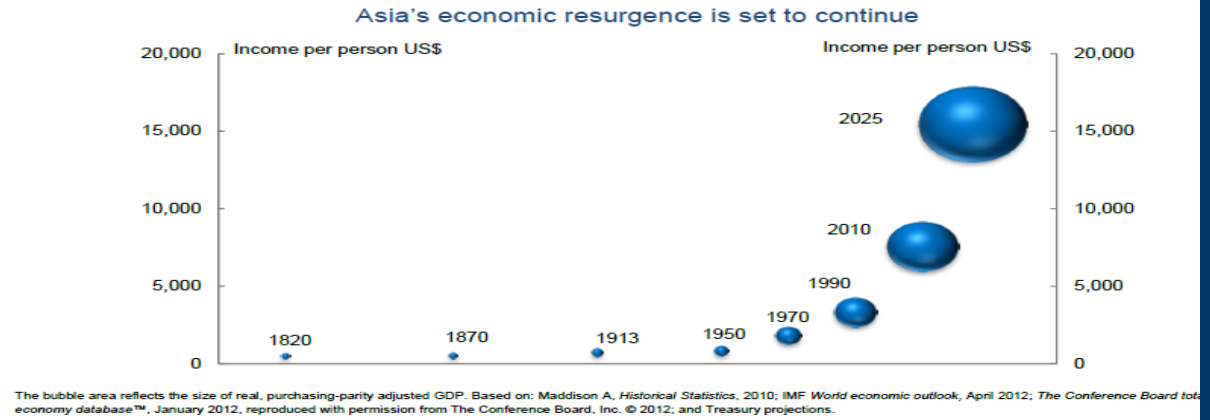
OPPORTUNITY TO SHAPE ENVIRONMENT FOR CLINICAL RESEARCH



The bubble area reflects the size of real, purchasing-parity adjusted GDP. Based on: Maddison A, *Historical Statistics*, 2010; IMF *World economic outlook*, April 2012; *The Conference Board tot economy database™*, January 2012, reproduced with permission from The Conference Board, Inc. © 2012; and Treasury projections.

- *The number of clinical studies in Asia Pacific is increasing in line with economic growth.*
- *Now is the opportunity to set standards and create an environment for successful clinical research for the region.*

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MEDICAL DEVICE CLINICAL TRIAL LANDSCAPE IN APAC

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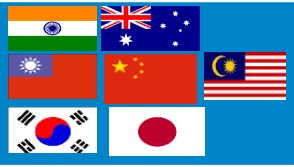
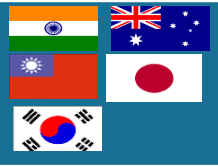
COMPLEX REGULATORY ENVIRONMENT FOR CONDUCTING CLINICAL TRIALS

Regulatory status	Premarket		Post market	
	Clinical research	Clinical Investigation	Post market release release study	Post market surveillance*
Fully Regulated				
Partially Regulated OR Regulation not enforced OR No Regulation but specific requests				
Not regulated				

Note: The terminology, "post market surveillance" is not used in the context of vigilance reporting in this slide.

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NEW AND CHANGING CLINICAL REGULATIONS IN APAC

Country			
Regulations	CFDA and NHFPC joint joint release of new GCP GCP Order No. 25	Revised Ethical Guidelines for Medical Medical and Health Research Involving Humans	Medical Device Rules Rules 2017
Study type	Premarket studies for for regulatory submission	Post market studies and and premarket studies for studies for research purposes	Any clinical trials with with regulated devices

CHINA ORDER NO. 25

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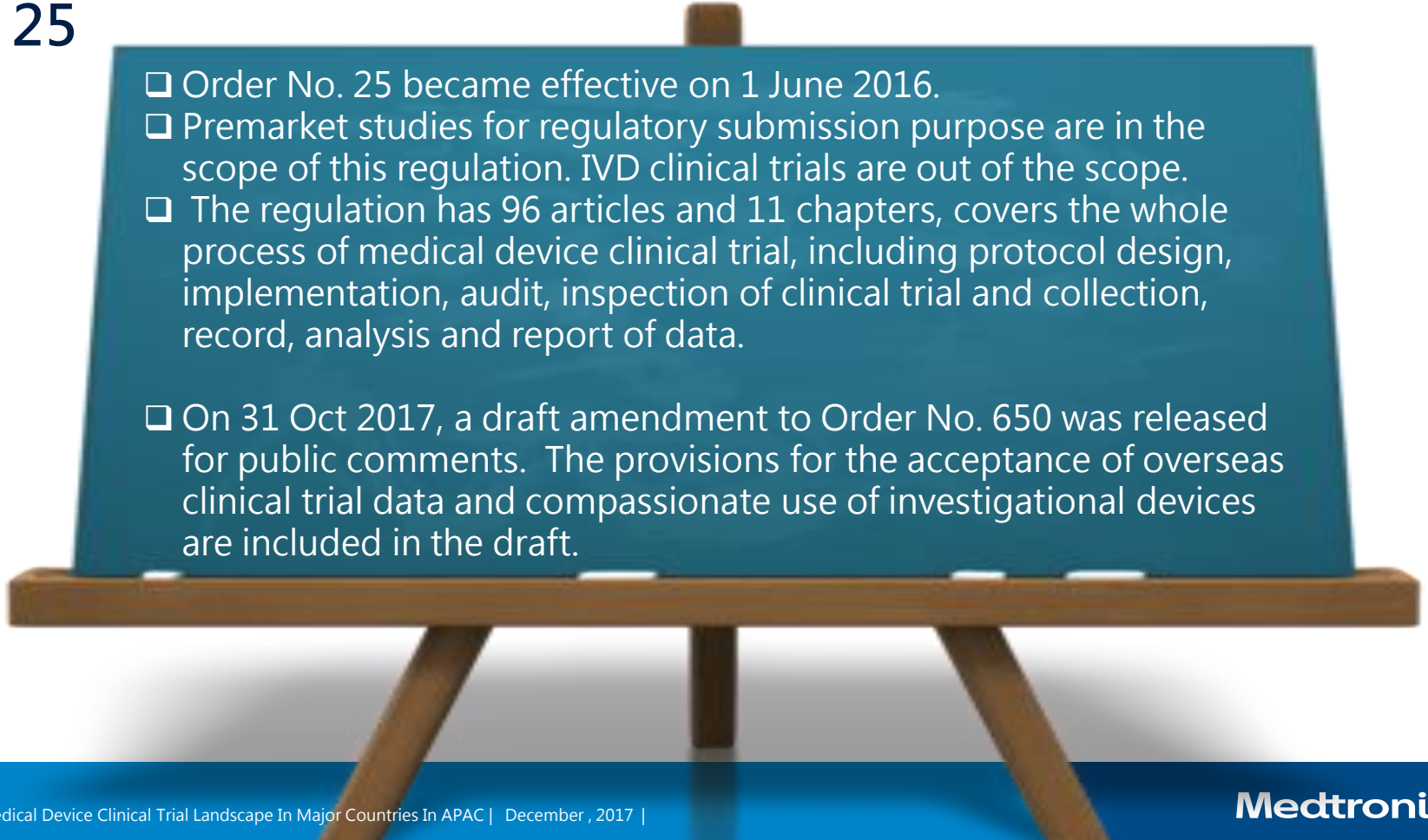
CFDA AND NHFPC JOINT RELEASE OF NEW GCP ORDER NO. 25



- Order No. 25 became effective on 1 June 2016.
- Premarket studies for regulatory submission purpose are in the scope of this regulation. IVD clinical trials are out of the scope.
- The regulation has 96 articles and 11 chapters, covers the whole process of medical device clinical trial, including protocol design, implementation, audit, inspection of clinical trial and collection, record, analysis and report of data.

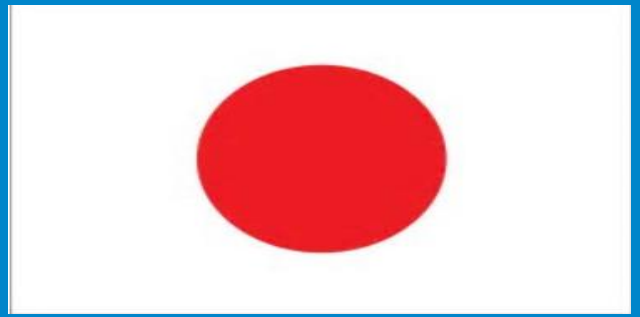
- On 31 Oct 2017, a draft amendment to Order No. 650 was released for public comments. The provisions for the acceptance of overseas clinical trial data and compassionate use of investigational devices are included in the draft.

THE LEADING INSTITUTION IS RESPONSIBLE FOR DATA MANAGEMENT & STATISTICAL ANALYSIS ACTIVITIES UNDER ORDER NO. 25.

L *(Order No. 25 Article Article 29 VI)*	S *(ISO 14155: 20118.2.2 a, 6.8.2)*	S *(Korea GCP section section Clinical Trial Trial Sponsor A 2)*	S *(Chinese Taipei GCP GCP article 57)*	S *(India GCP 3.1.5)*	S *(CPMP/ICH/135/95 5 annotated with TGA TGA comment section*	S *(Japan GCP guidance guidance Chapter 2 2 section 2-1. 1)*

- L= Leading institution, S = Sponsor

JAPAN



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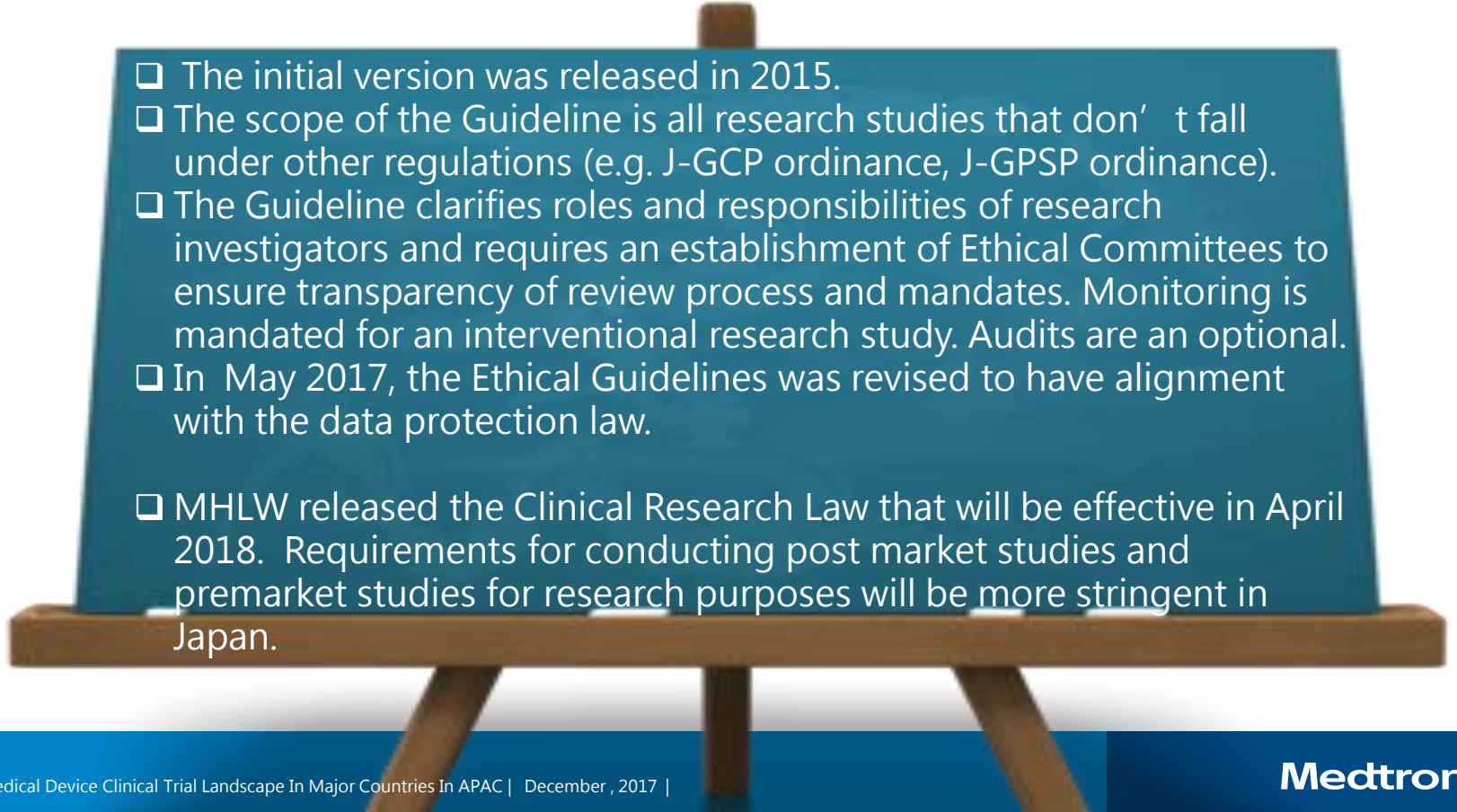
REVISED ETHICAL GUIDELINES FOR MEDICAL AND HEALTH RESEARCH INVOLVING HUMANS



- The initial version was released in 2015.
- The scope of the Guideline is all research studies that don' t fall under other regulations (e.g. J-GCP ordinance, J-GPSP ordinance).
- The Guideline clarifies roles and responsibilities of research investigators and requires an establishment of Ethical Committees to ensure transparency of review process and mandates. Monitoring is mandated for an interventional research study. Audits are an optional.
- In May 2017, the Ethical Guidelines was revised to have alignment with the data protection law.

- MHLW released the Clinical Research Law that will be effective in April 2018. Requirements for conducting post market studies and premarket studies for research purposes will be more stringent in Japan.

TO ENSURE RELIABILITY OF CLINICAL STUDY RESULTS, THE PRINCIPLE INVESTIGATOR IS REQUIRED TO MANAGE CONFLICTS OF INTERESTS.

STATUS OF CONFLICTS OF INTERESTS

(Revised Ethical Guideline Chapter VIII, Part18 (1)

- Investigators and site representatives shall report to the PI on the status of conflicts of interests related to the research.

TRANSPARENCY OF CONFLICTS OF INTERESTS

(Revised Ethical Guideline Chapter VIII, Part18 (2) (3)

INDIA MDR

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INDIA MEDICAL DEVICE RULES 2017

- The new rules will be effective on January 1, 2018.
- The clinical regulations are applicable for clinical research with regulated devices, specifically pre-market and post market interventional clinical studies.
- Medical management and compensation requirements are more stringent comparing to other countries.
- Clinical investigation is not required for class A devices, and the devices that are not innovative and have comparable devices in the India market, and if the specific conditions are met.
  - If MD is approved in UK (not EU), USA, Australia, Canada or Japan and has been marketed since last 2 years
  - If there is no evidence of difference in the behavior and performance in Indian population
  - If Applicant will conduct Phase IV Clinical Investigation (PMS) as per approved protocol by Competent Licensing Authority.

UNIQUE REQUIREMENTS UNDER INDIA MDR

PIVOTAL CLINICAL TRIALS IN INDIA

(India MDR Chapter VII section 51 (3))

- Investigational medical devices developed and studied in country other than India except investigational medical device classified under class A,

AUDIO-VIDEO RECORDING OF INFORMED CONSENT PROCESS

(India MDR Seventh Schedule section 2 (1) (iv)

- Involvement of vulnerable subjects;
- Innovative medical device which is not approved anywhere in the world,

ISO 14155 MEDICAL DEVICES GCP

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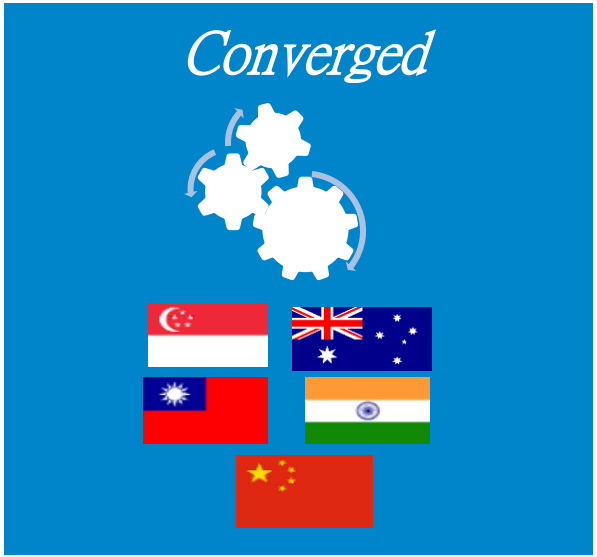
ISO 14155:2011

- ISO 14155 is the global standard for clinical trials that assess the safety or performance of medical devices for regulatory purposes.
- The standard was created to clarify worldwide the design, conduct, recording, and reporting of clinical investigations carried out in human subjects.
- The standard is currently under revision, aiming to increase the acceptance of the standard by countries that were not engaged in the development of the 2011 version.

ISO 14155:2003/ 2011
INCREASING ACCEPTANCE GLOBALLY



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SUMMARY

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SUMMARY
CLINICAL TRIAL LANDSCAPE IN ASIA PACIFIC

- ✓ *Clinical regulatory environment in APAC is complicated and continuously evolving.*
- ✓ *More clinical regulations are aligned with ISO 14155:2011. The ISO 14155 is currently under revision, aiming to increase the acceptance of the standard by countries that were not engaged in the development of the 2011 version.*
- ✓ *There is economic opportunity for the region in attracting clinical research investment from industry, however we need to ensure that the capacity and standards are in place to ensure compliant and high quality research.*
- ✓ *Open collaboration and discussion with all stakeholders is needed to adopt ISO in the region.*

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Thank you

Q&A