Regulatory Perspective on ICH

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Guideline Formulation and Regulators

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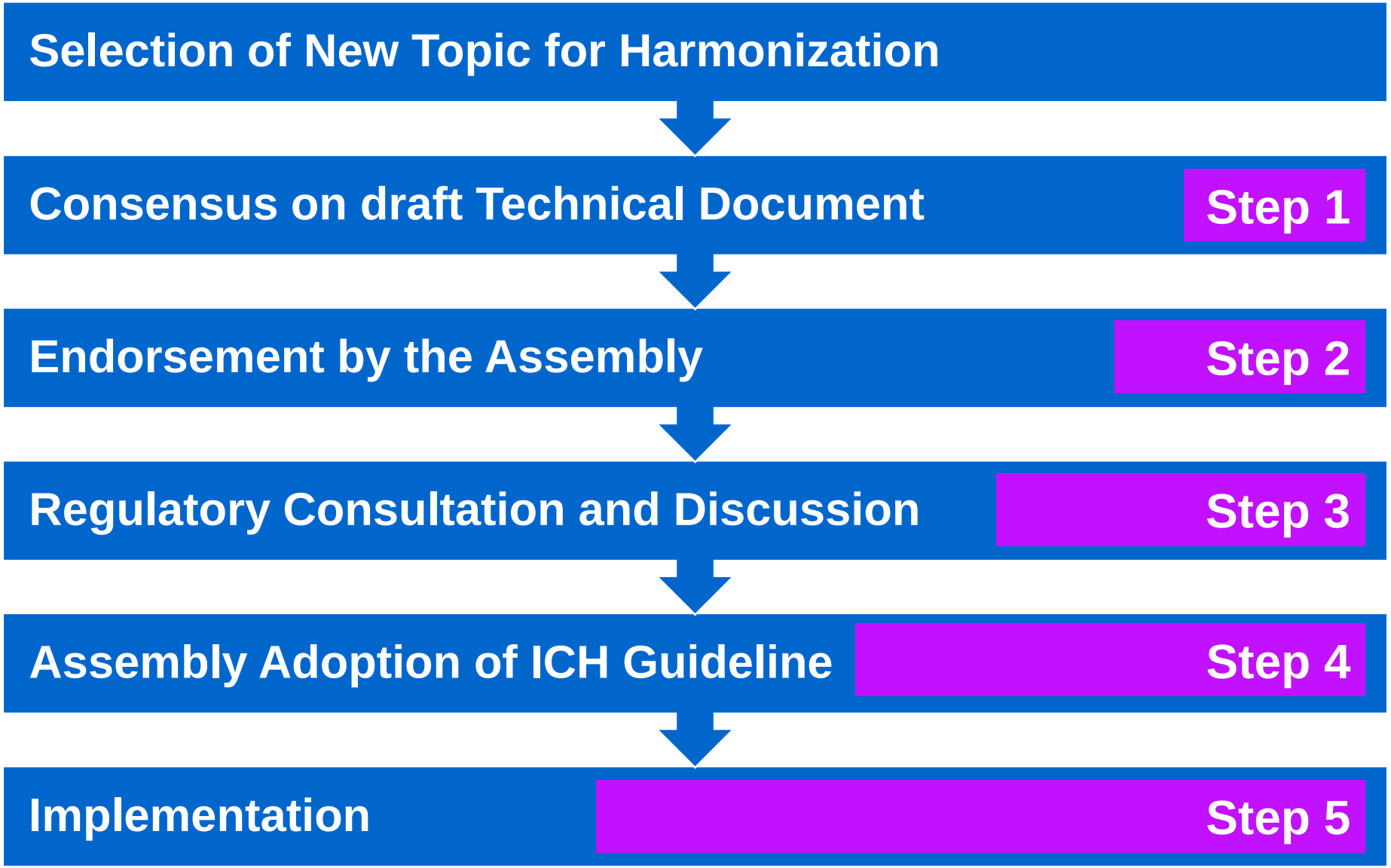
ICH Harmonization Process



Regulators' Role in Harmonization Process

	Regulators & Industry Members	Regulators only
Pre Step1	✓ Proposal by Members/Observer ✓ Agreement by Assembly to initiate ✓ Rapporteur from Reg. or Ind. member	✓ When there is no consensus, Regulators can adopt Concept Paper ✓ Regulatory Chair to WG
Step 1	WG consensus on draft tech. doc.	—
Step 2	2a (whole Assembly endorse technical document)	2b (Regulatory Assembly members endorse Draft Guideline) ✓ Rapporteur from Reg. member
Step 3	Consensus in WG	Public Consultation by Regulators
Step 4	—	Final Document adopted by Regulatory Assembly members
Step 5	—	Implementation by Regulatory members

Implementation of Guidelines

1. Eligibility for a Regulatory Member
   - Implementation of Q1, Q7, E6 (Tier 1)
2. Implementation of ICH GLs (Rules of Procedure for Assembly 1.1.3)
   1. All ICH Regulators should implement all ICH Guidelines.
   2. Priority on Tier 2 GLs (E2A, E2B, E2D, M4, M1) and then others (Tier 3)
   3. In nation/region's implementation, no requirements should be added or omitted from ICH Gls.
   4. Assembly monitors and discusses Regulatory Members' Gl implementation.

Step 5: Implementation

ICH harmonisation for better health

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Q S E M

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Quality Guidelines / ICH Guidelines / Work Products /

Harmonisation achievements in the Quality area include pivotal milestones such as the conduct of stability studies, defining relevant thresholds for impurities testing and a more flexible approach to pharmaceutical quality based on Good Manufacturing Practice (GMP) risk management.

Zip with all ICH Quality Guidelines in word format

Q1A - Q1F Stability

Code	Document Title	Previously coded
Q1A(R2)	**Stability Testing of New Drug Substances and Products**	Q1A

Description : This Guideline has been revised a second time and has reached *Step 4* of the ICH process in February 2003.

This Guideline provides recommendations on stability testing protocols including temperature, humidity and trial duration for climatic Zone I and II. Furthermore, the revised document takes into account the requirements for stability testing in Climatic Zones III and IV in order to minimise the different storage conditions for submission of a global dossier.

Finalised Guideline: February 2003

Q1A(R2)

Implementation : *Step 5*

EC	:	Adopted by CPMP, March 2003, issued as CPMP/ICH/2736/99
MHLW/PMDA	:	Adopted 3 June 2003, PFSB/ELD Notification No. 0603001
FDA	:	Published in the Federal Register, 21 November 2003, Vol. 68, No. 225, p. 65717-18
Health Canada	:	Implemented 25 September 2003, File #: 03-118437-914
Swissmedic	:	Please refer to the press release on Swissmedic's website for information on implementation

Japan’s Clinical Trials and ICH Guidelines

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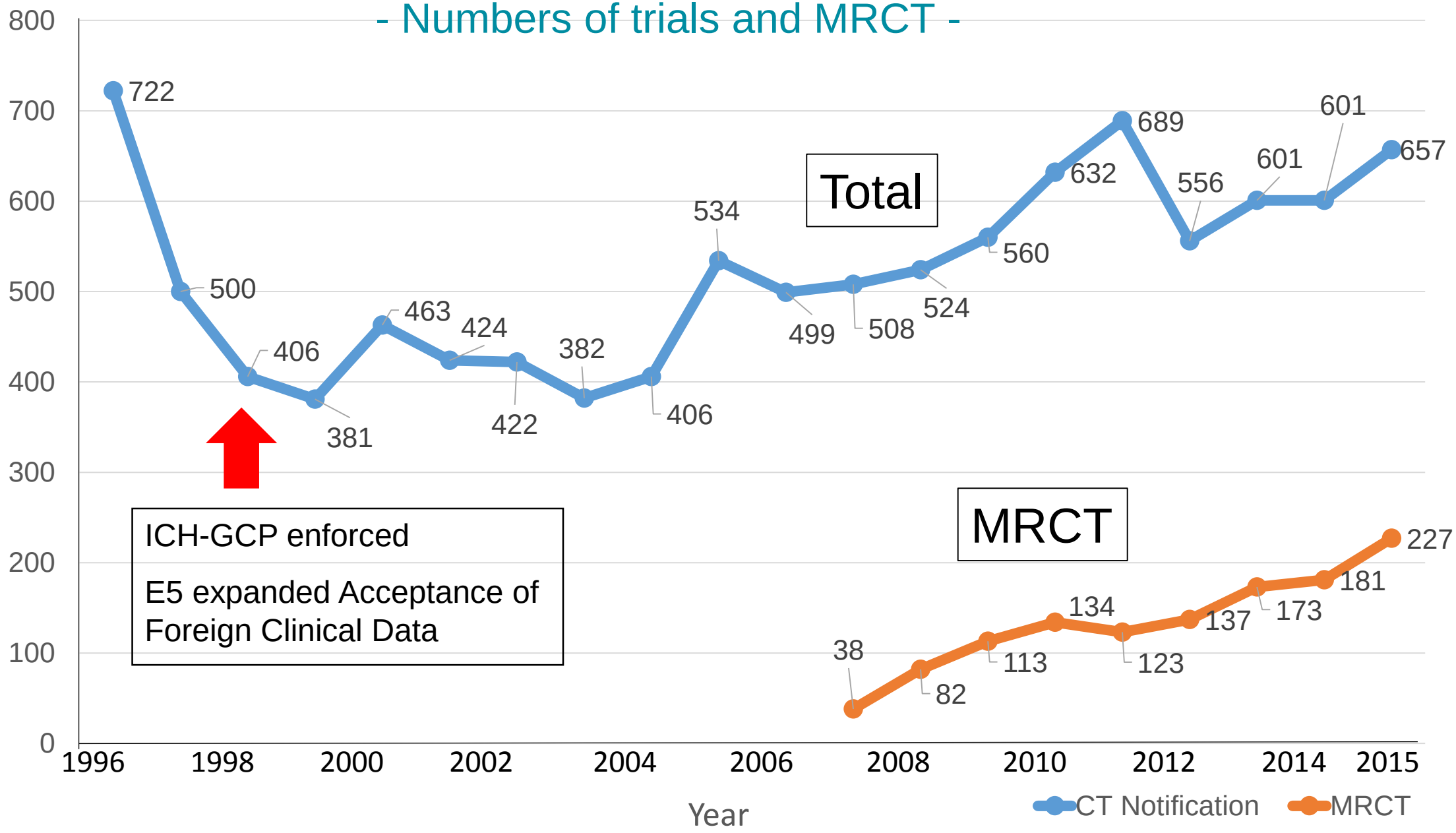
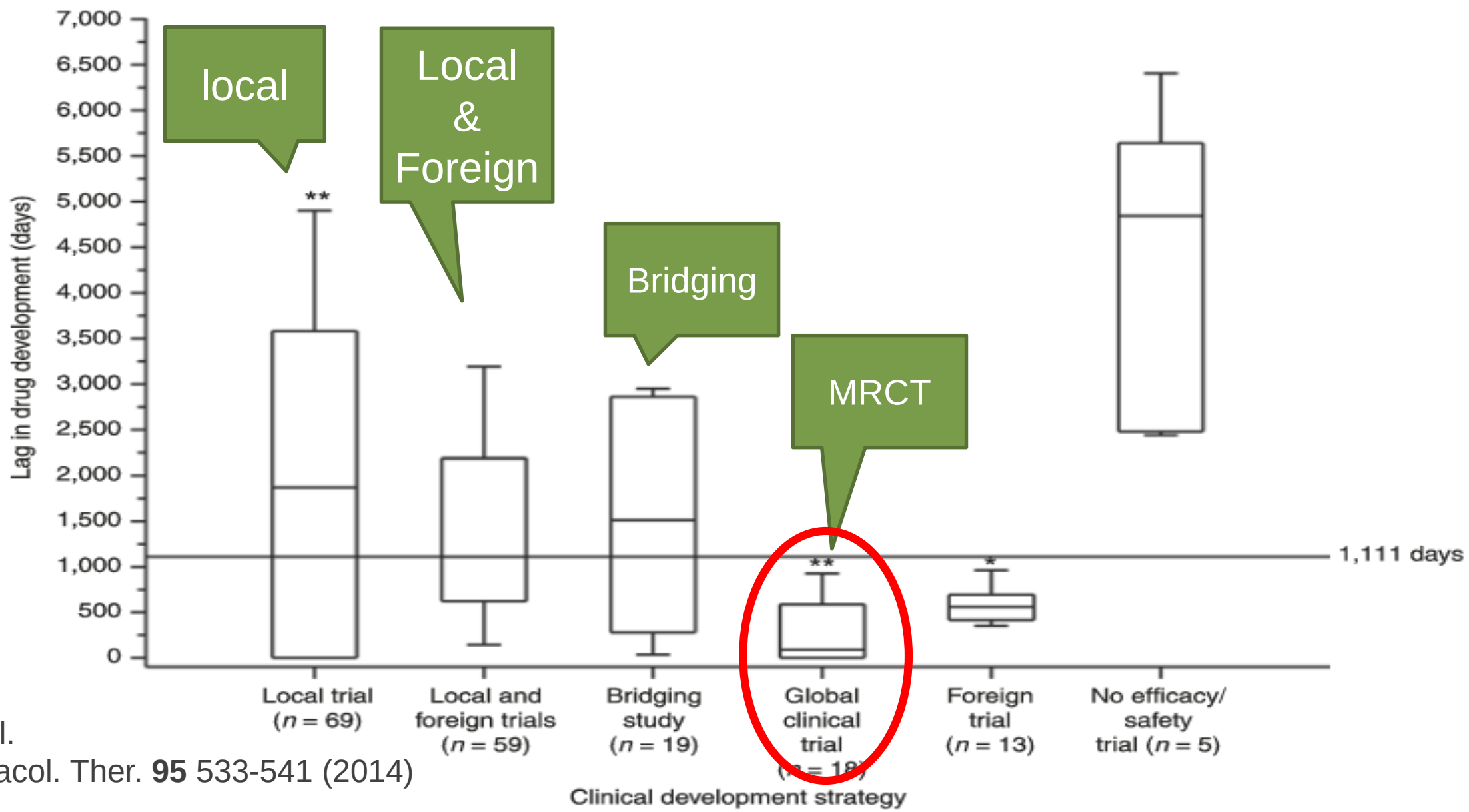
CT Notification

Japan's Modernization of Clinical Trials

- Numbers of trials and MRCT -



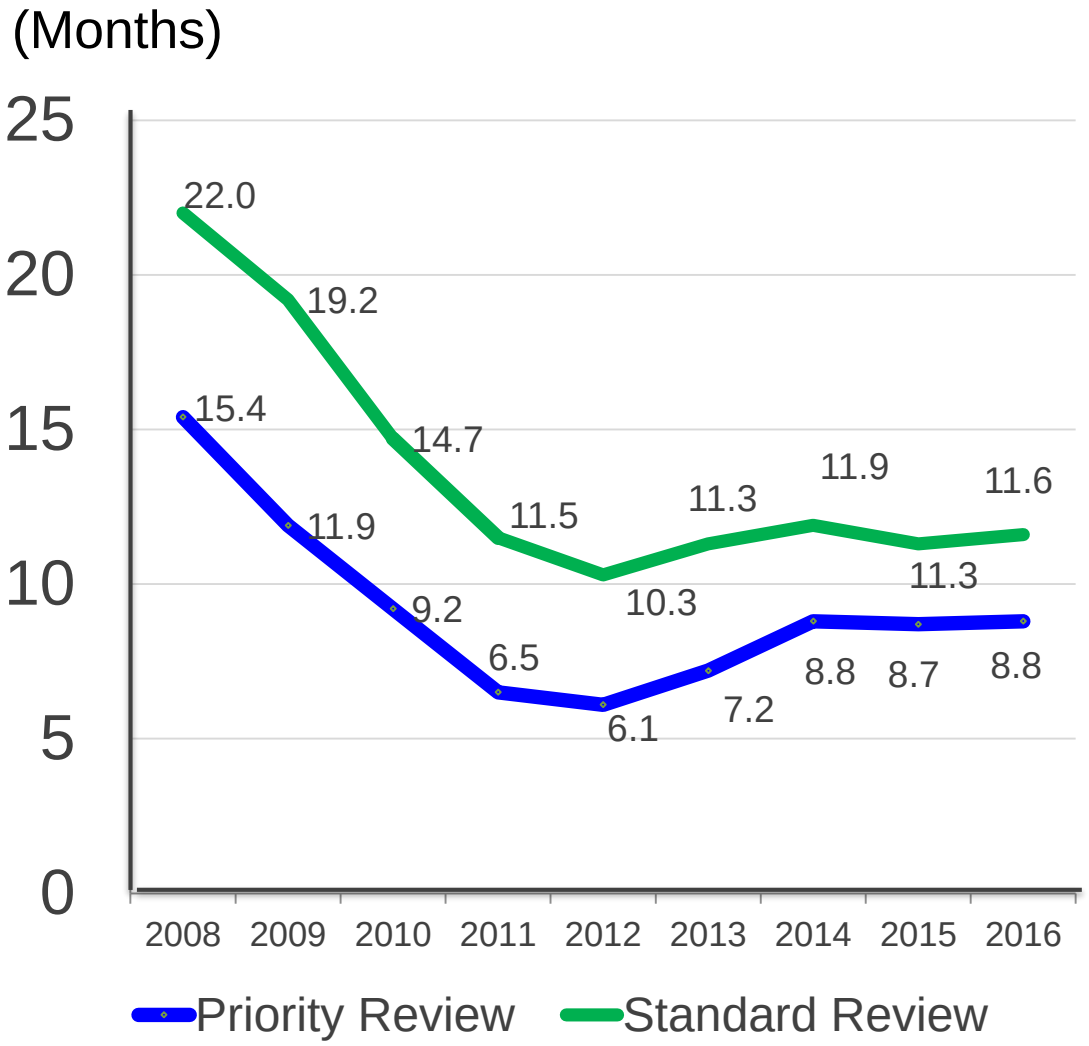
MRCT and US/Japan Development Lag for Drugs Approved in Japan (2007-2012)



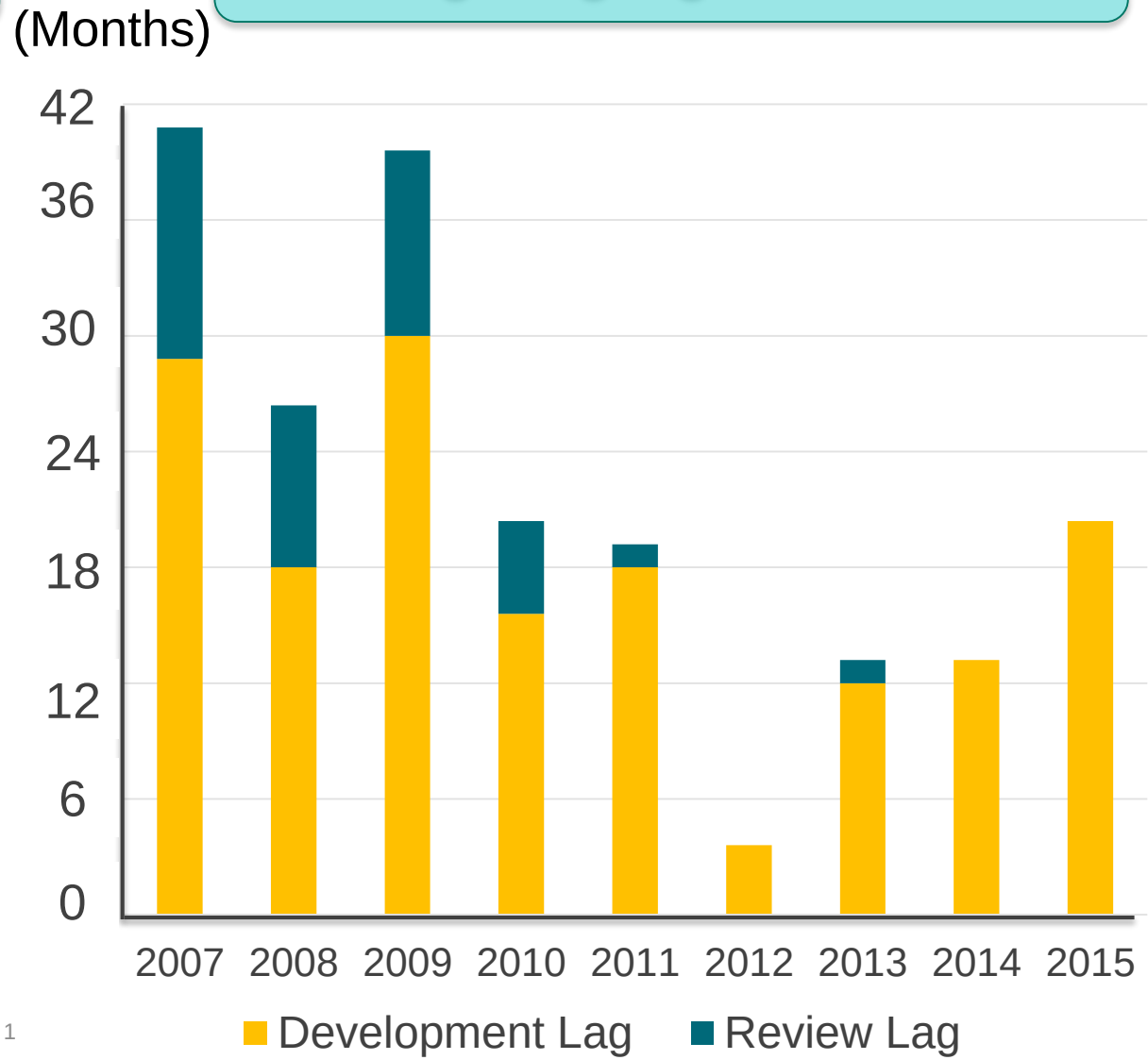
T. Ueno et al.
Clin. Pharmacol. Ther. **95** 533-541 (2014)

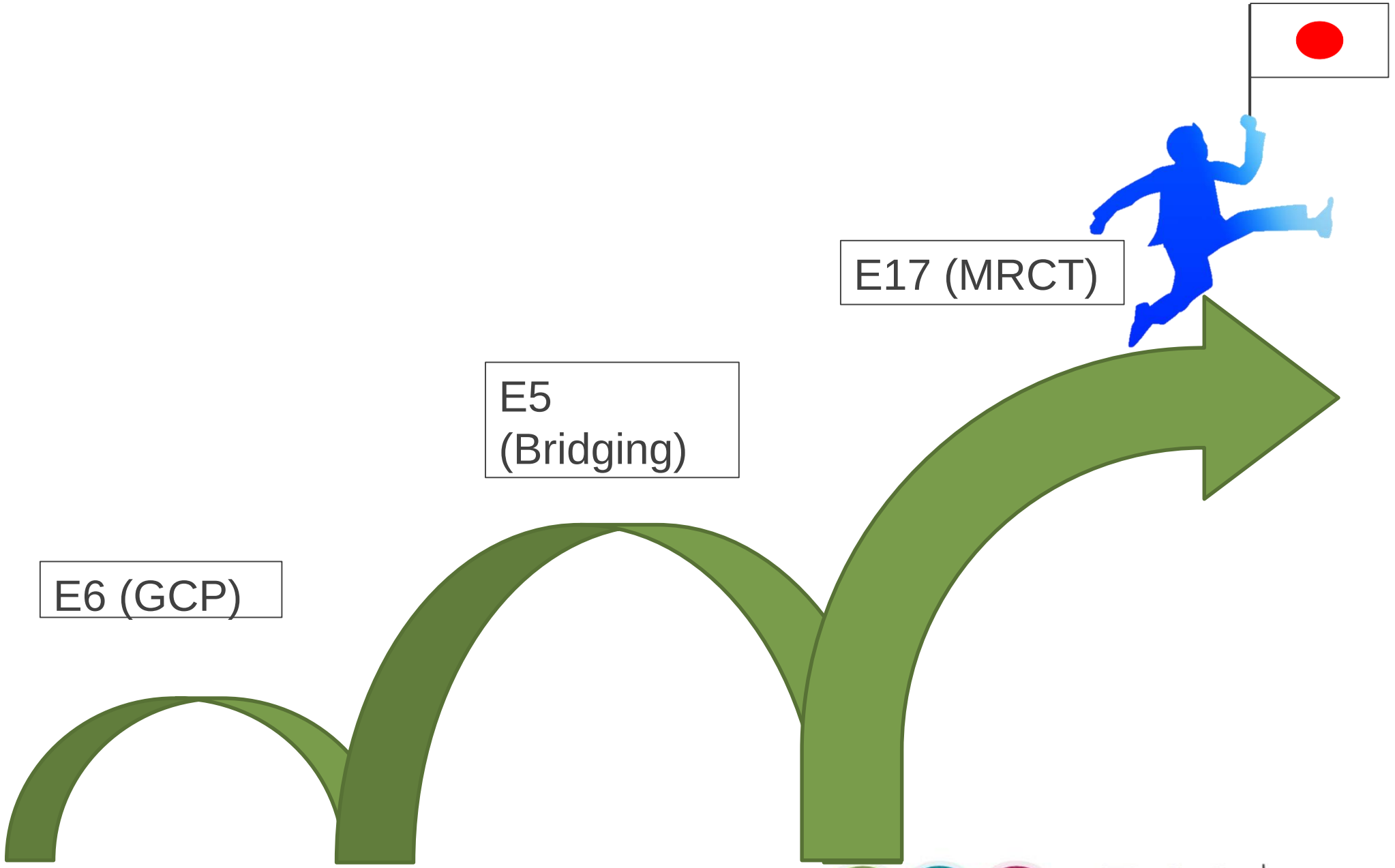
Review Time and Drug Lag in Japan

Review Time (Median) for New Drugs



Drug Lag against U.S.





Rapporteurs for WGs (EWG/IWGs active as of Mar. 2017)

Member	WG with its Rapporteur	
MHLW/PMDA	E2B, E11, E17, M2*, M8, M10, S3A	**7**
FDA	E18, S9, Q3C, Q3D, M2*, M7	6
EC/EMA	S5, E9, M2*, M9, Q11	5
JPMA		0
PhRMA	Q12, S1, S11, E14/S7B	4
EFPIA	M1	1
Health Canada		0
Swissmedic		0
Total		23

* ”Co-Rapporteurs” are nominated for M2 WG.

“Rapporteur” leads the scientific discussion in WGs.

Use of ICH Guidelines in ASEAN

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Regulatory convergence and promotion of work sharing in ASEAN

Sharing Our Progress

Tharnkamol Chanprapaph, Ph.D
Chief, Premarketing Control Division
Bureau of Drug Control, Thai FDA

9th Asia Regulatory Conference, Tokyo, Japan 7 April 2016

ACTR Efficacy and ACTR Safety

- ICH Efficacy/Safety Guidelines were adopted according to criteria for adoption of ICH Efficacy/Safety GL for ASEAN
  - Finalization from ICH (step 5) and implemented in all 3 regions
  - Usefulness (for evaluation of efficacy/safety)
  - Relevance and importance (environment, region, country)
  - Readiness (human resources, infrastructure, legislation)
  - Impact of implementation (to the existing regulatory system)

ACTR: ASEAN Common Technical Requirements

PMDA Asia Training Center's Programs

MRCT/GCP Inspection Workshop
APEC Pilot CoE Program, Jan. 23-26, 2017

32 participants from 14 Economies

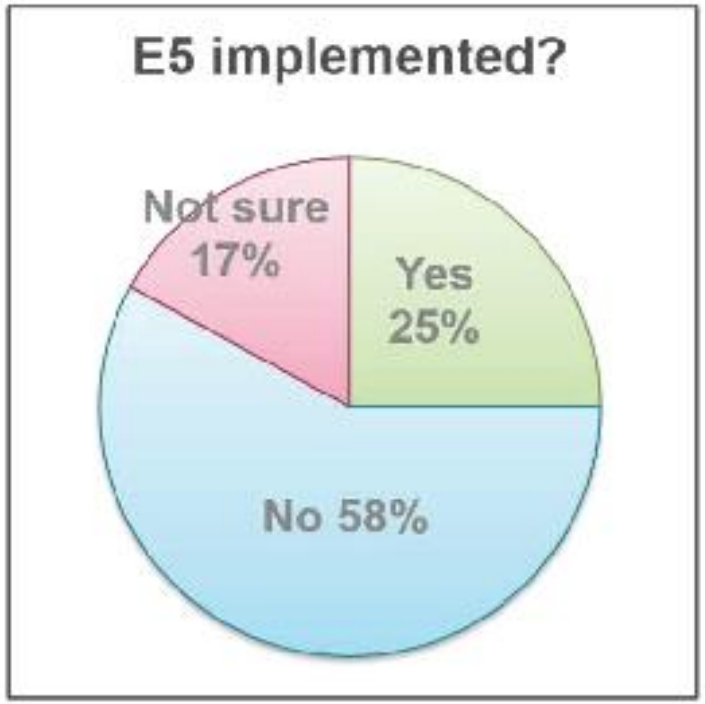
Malaysia, Philippines, Chinese Taipei, Indonesia, Peru, Brazil, Myanmar, Sri Lanka, Tanzania, Thailand, China, Mexico, Nepal, Papua New Guinea

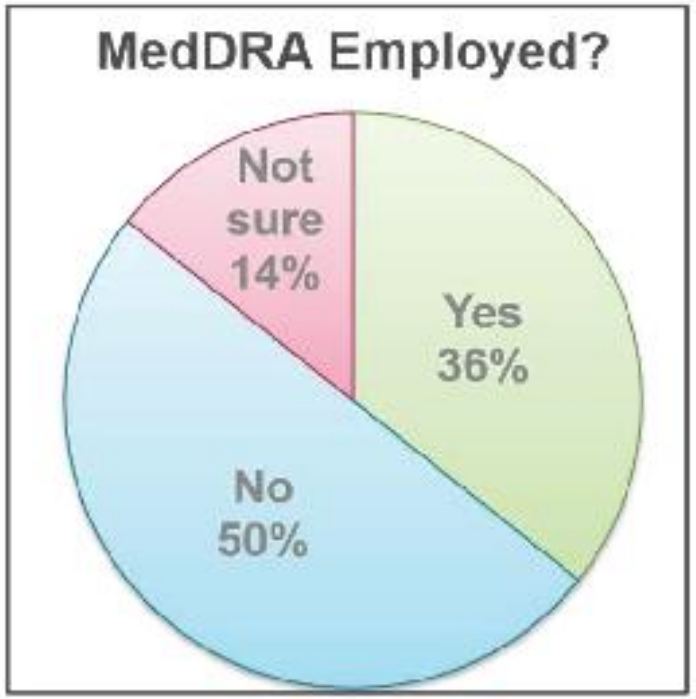
Pharmacovigilance Workshop
APEC Pilot CoE Program, Feb. 6-9, 2017

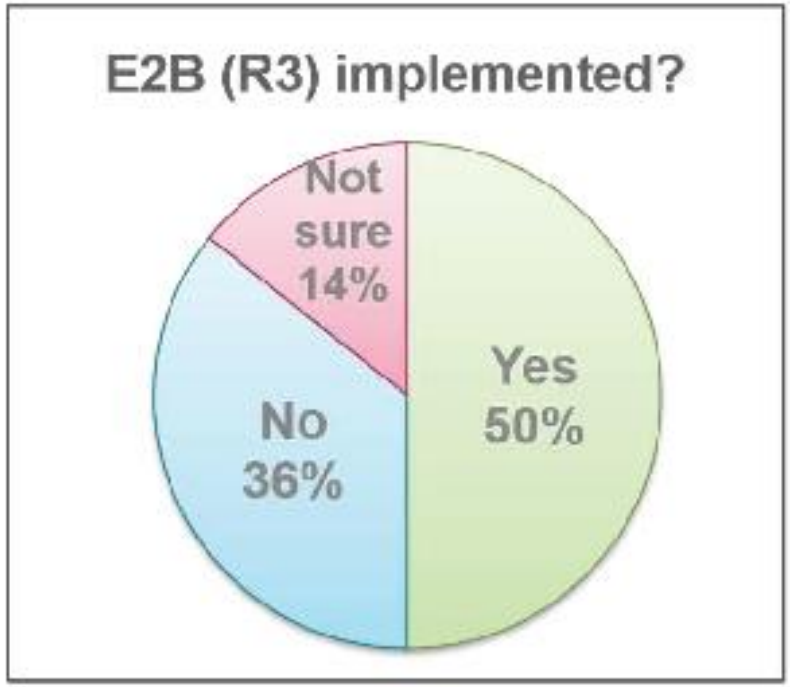
28 participants from 15 Economies

Chile, China, India, Indonesia, Korea, Malaysia, Myanmar, Nepal, Peru, Philippine, Poland, Singapore, Taiwan, Thailand

Results of the Surveys on Trainees







Thank You

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