

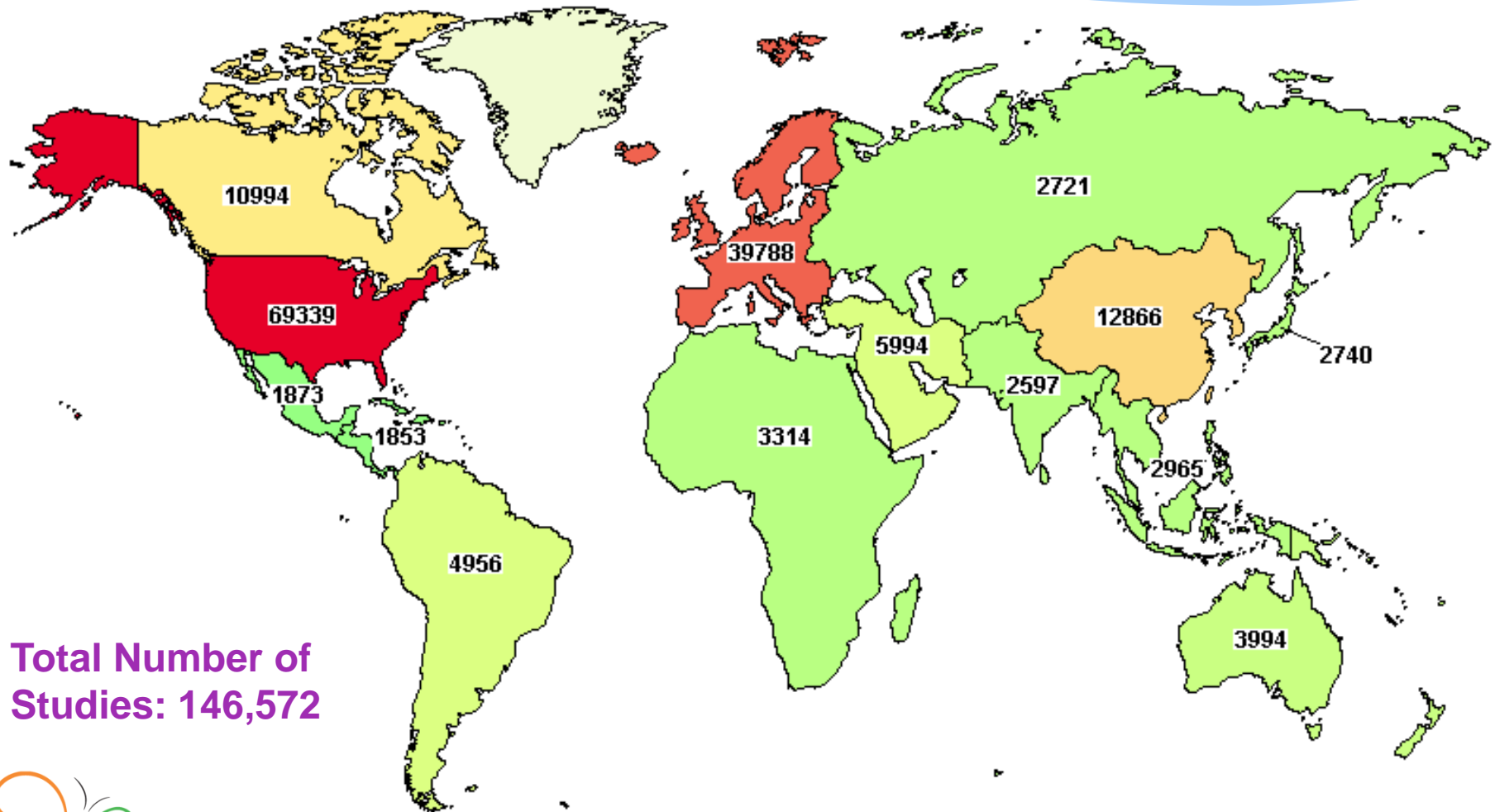
Regional Multi-Center Studies in Asia for Optimizing Drug Development ROI and Accelerating Product Registration in Taiwan

Insights Sharing

Jaw-Jou Kang, Ph.D.

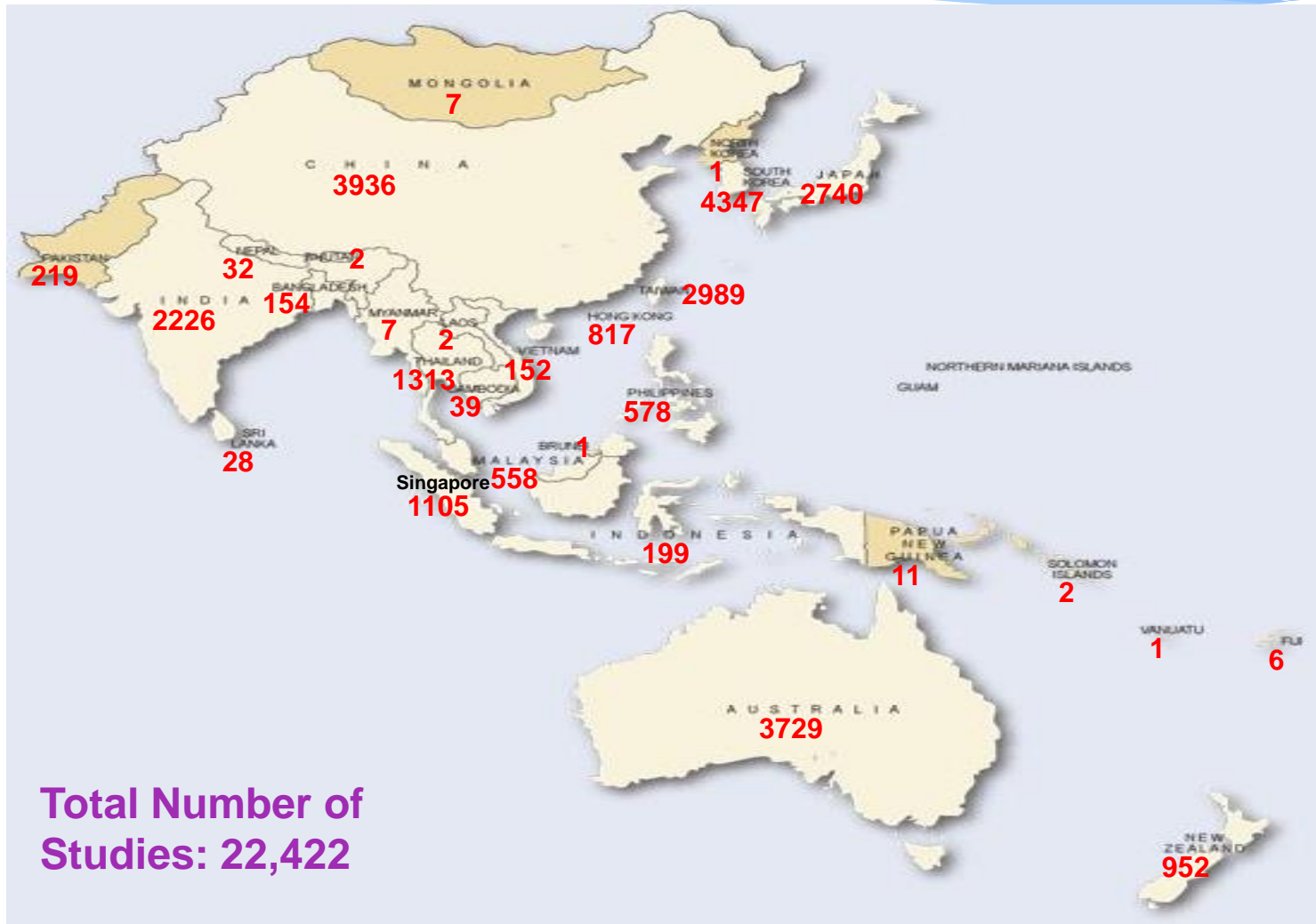
Commissioner, Taiwan FDA
Department of Health, Taiwan
July 17th , 2013

Distribution of Clinical Trials Conducted Globally

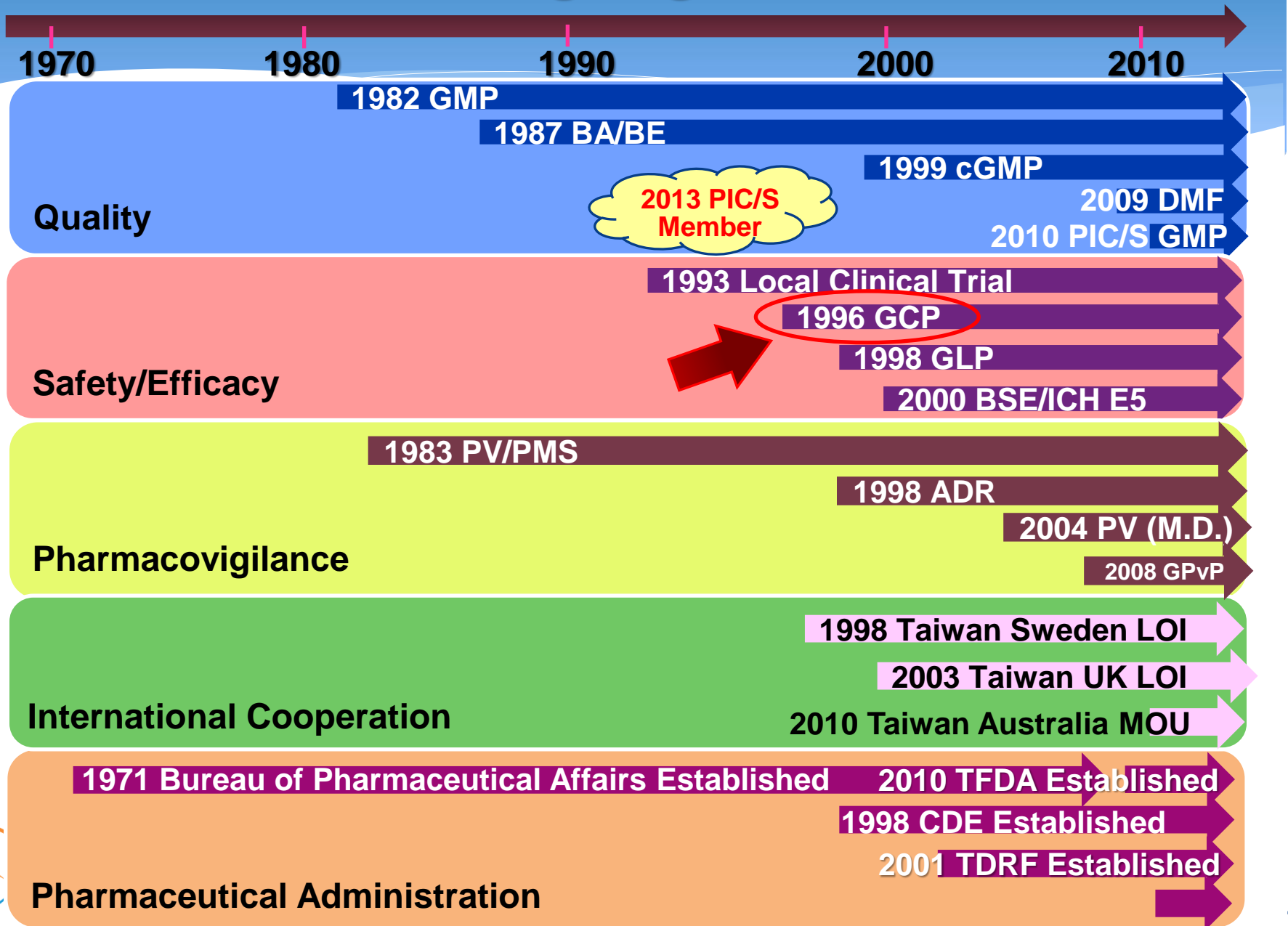


Total Number of
Studies: 146,572

Distribution of Clinical Trials Conducted in Asia Pacific Region



Milestone of Drug Regulation in Taiwan



Establishment of a Modern Clinical Trial Environment in Taiwan

- * **Goal**

- * Establishment of infrastructure for clinical trial conduction to Meet International Standard
- * Introduce Early Phase Multi-National, Multi-Center Trial, Concurrently with Global Drug Development
- * Strengthen Quality of Clinical Trial

- **Government Funding Research Centers :**

- * Grant \$22 million (2011)
- * Good Clinical Research Center, GCRC(12);Center of Excellence(5); Cancer Center of Excellence(8)

- * **Qualified Clinical Trial Sites for IND :** 131 Teaching Hospitals

- * **Training for Clinical Trial Professionals**

- * Include All Trial-Related Persons in Medical Care Institutions, CROs, and Sponsors
- * Require 30 Hours in 6 Years of Human Related Training for PIs

- * **Inspection**

- * Enhance IRB Quality
- * Establish a Clinical Trial GCP Inspection System in Line with International Standard
- * Intensify Inspection of CROs
- * Encourage Voluntary Non-Clinical Studies GLP Inspection

Clinical Research Centers in Taiwan

• Chung Gung Medical Hospital*#

• National Health Research Institute#

• China Medical University Hospital*#
• Taichung Veterans General Hospital+
• Chung Shan Medical University Hospital+

• Changhua Christian Hospital+

• Jainan Mental Hospital, DOH+

• National Cheng Kung University Hospital*#
• Chi Mei Medical Center+

• Kaohsiung Medical University Hospital#+
• Kaohsiung Municipal Kai-Syuan Psychiatric Hospital+

• National Taiwan University Hospital*#
• Wanfang Hospital*
• Taipei Veterans General Hospital#
• Taipei Medical University Hospital#+
• Mackay Memorial Hospital+
• Koo Foundation Sun Yat-Sen Cancer Center+
• Bali Psychiatric Center, DOH+

• Yuli Hospital+

• **Qualified Clinical Trial Sites for IND: 131 Teaching Hospitals**
• **Government Funding Research Centers: Grant \$22 million (2011)**

Type of Clinical Research Centers	No.
Excellent Center*	5
Excellent Center of Oncology#	8
General Clinical Research Center+	12

MOU between Taiwan Center of Excellence and International Pharmaceutical Company

Taipei Veterans General Hospital

- 2009 Sanofi Aventis
- 2010 GSK
- 2011 Norvatis

China Medical University Hospital

- 2010 Norvatis

Chung Gung Medical Hospital

- 2010 Norvatis, MSD
- 2011 Norvatis

National Taiwan University Hospital

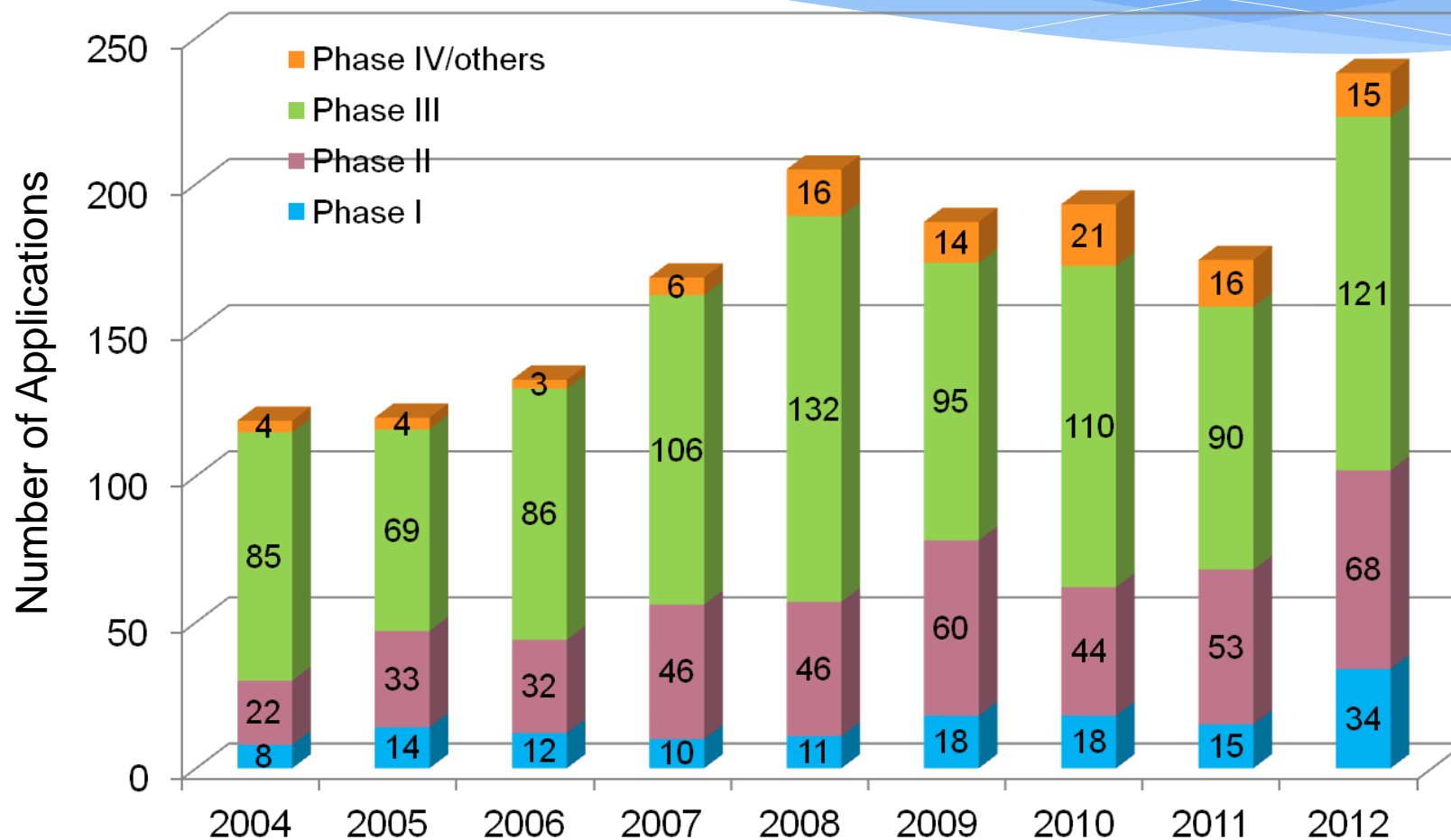
- 2007 GSK
- 2009 Norvatis, Boehringer Ingelheim
- 2012 Pfizer
Bayer
MSD

Chung Gung Medical Hospital

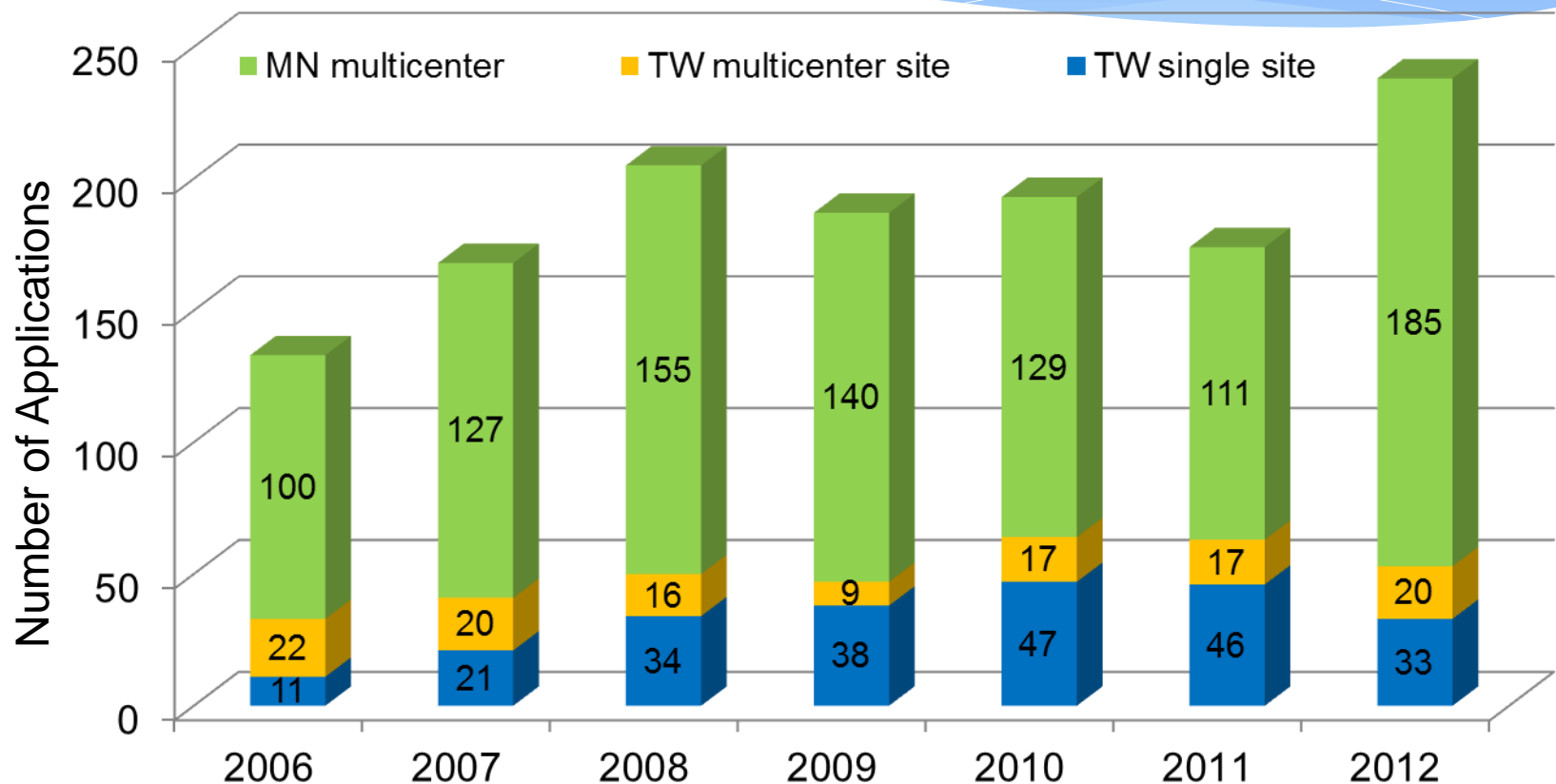
- 2010 Norvatis
- 2012 GSK
- 2013 MSD



IND Applications in Taiwan (by Phase)



IND Applications in Taiwan (by Site)



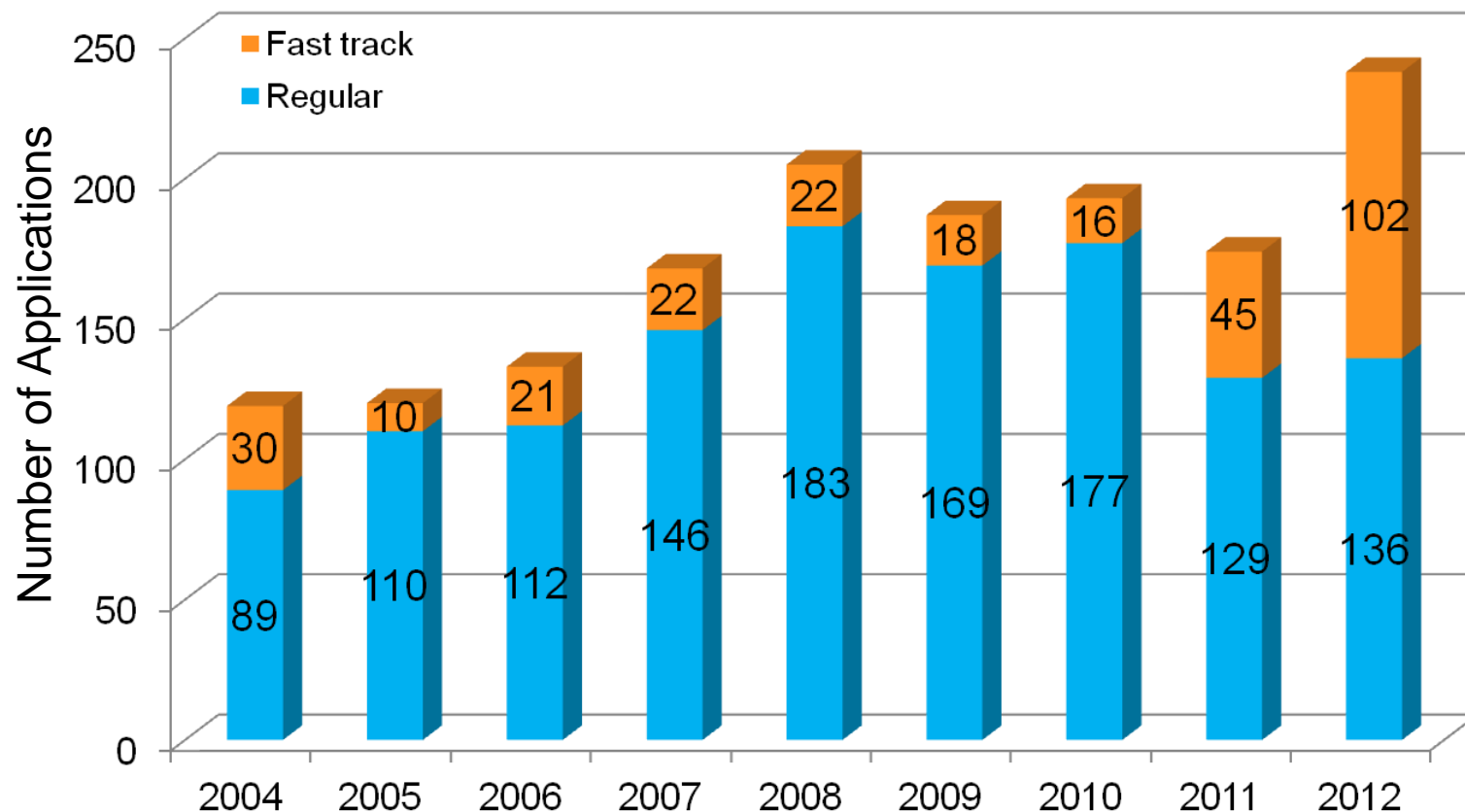
Increase of Multi-National Clinical Trials in Taiwan

New Review Track for IND



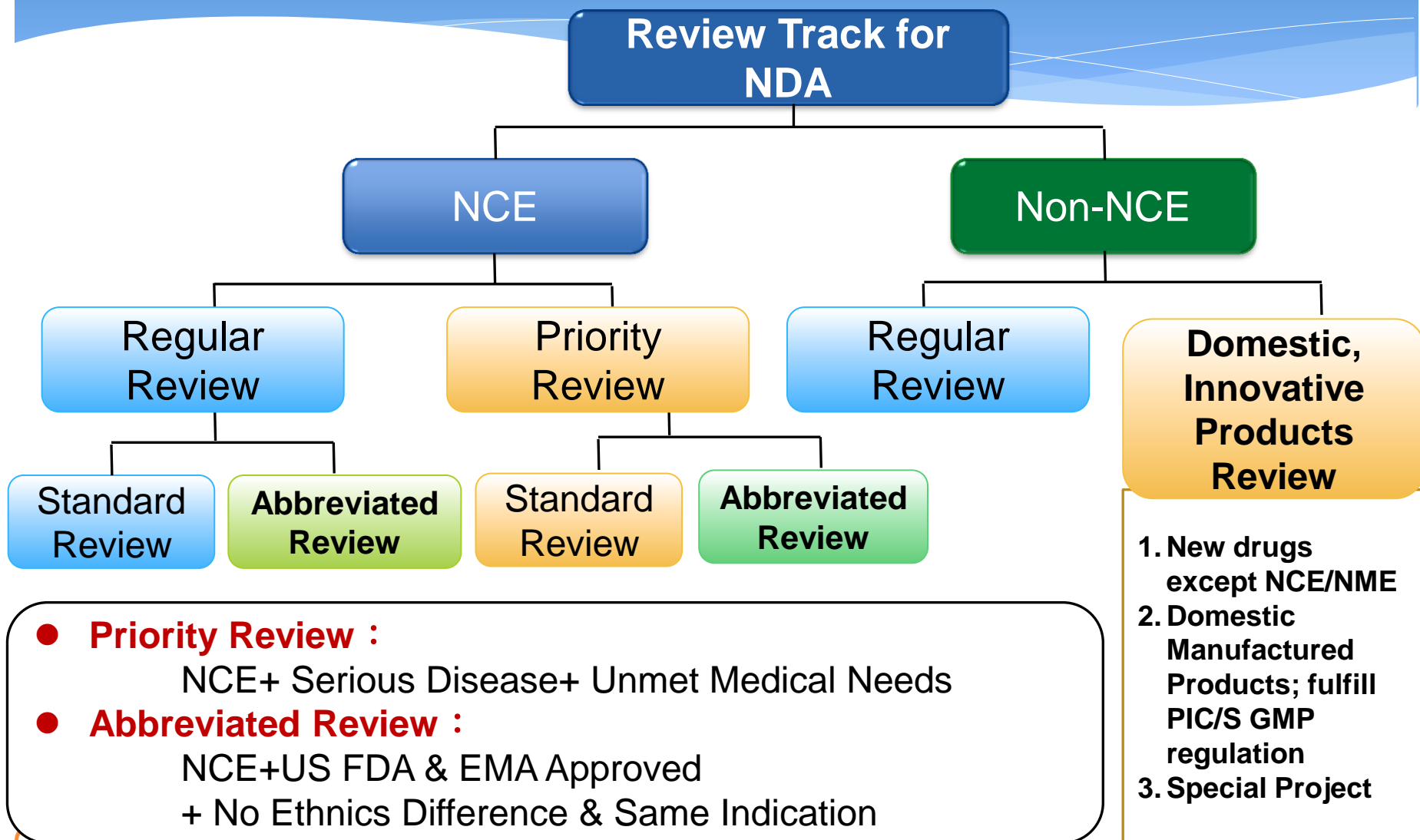
- 
1. IND with the Same **US FDA-Approved** IND Number
 2. Multinational multicenter trials **simultaneously conducted in one of the medically advanced countries**; Taiwan's medical center hospital also involved

IND Applications in Taiwan

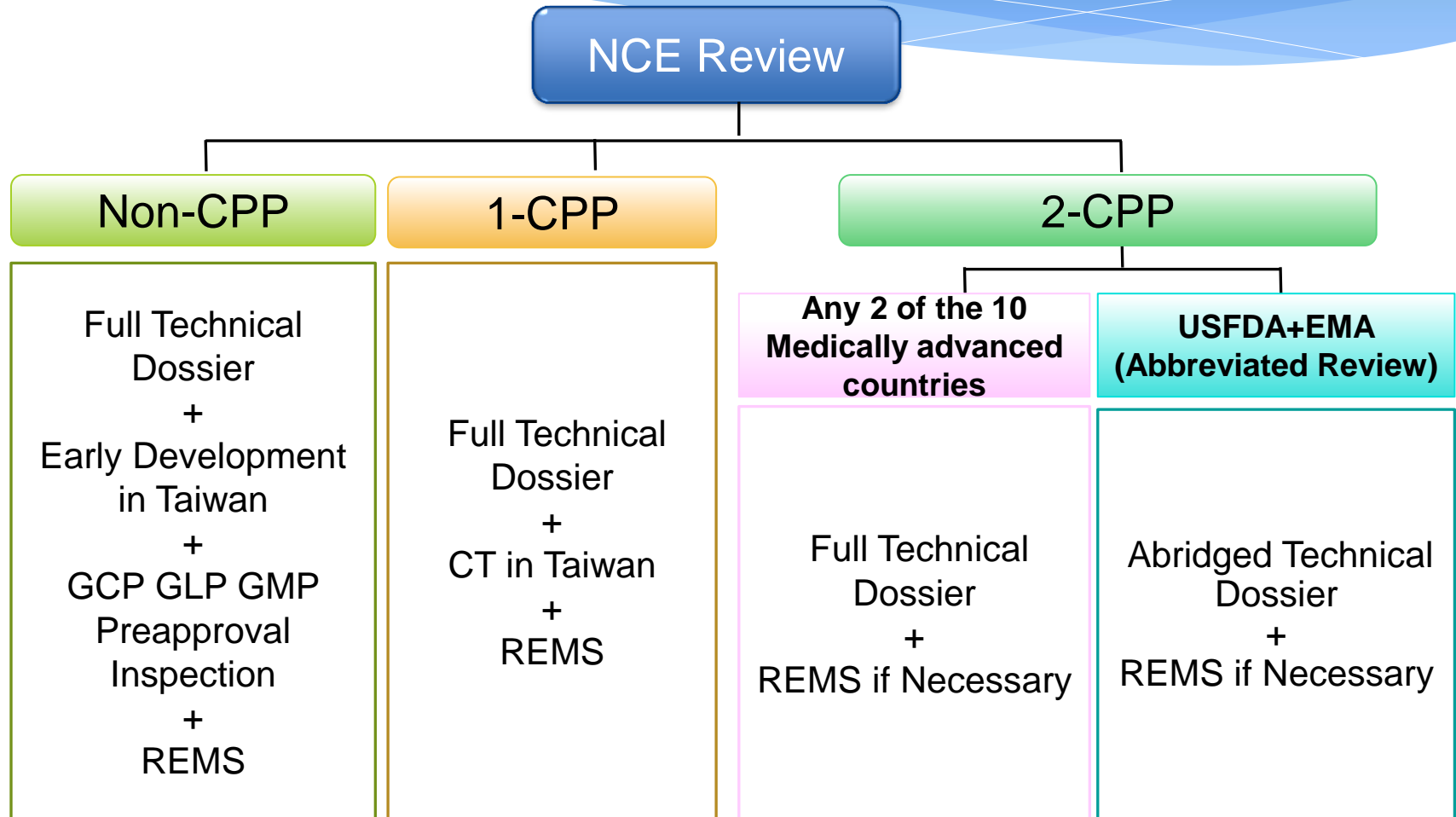


Increase of IND Applications conforming Fast Track Reviewing Process

New Review Track for NDA



Relaxation of CPP Requirements

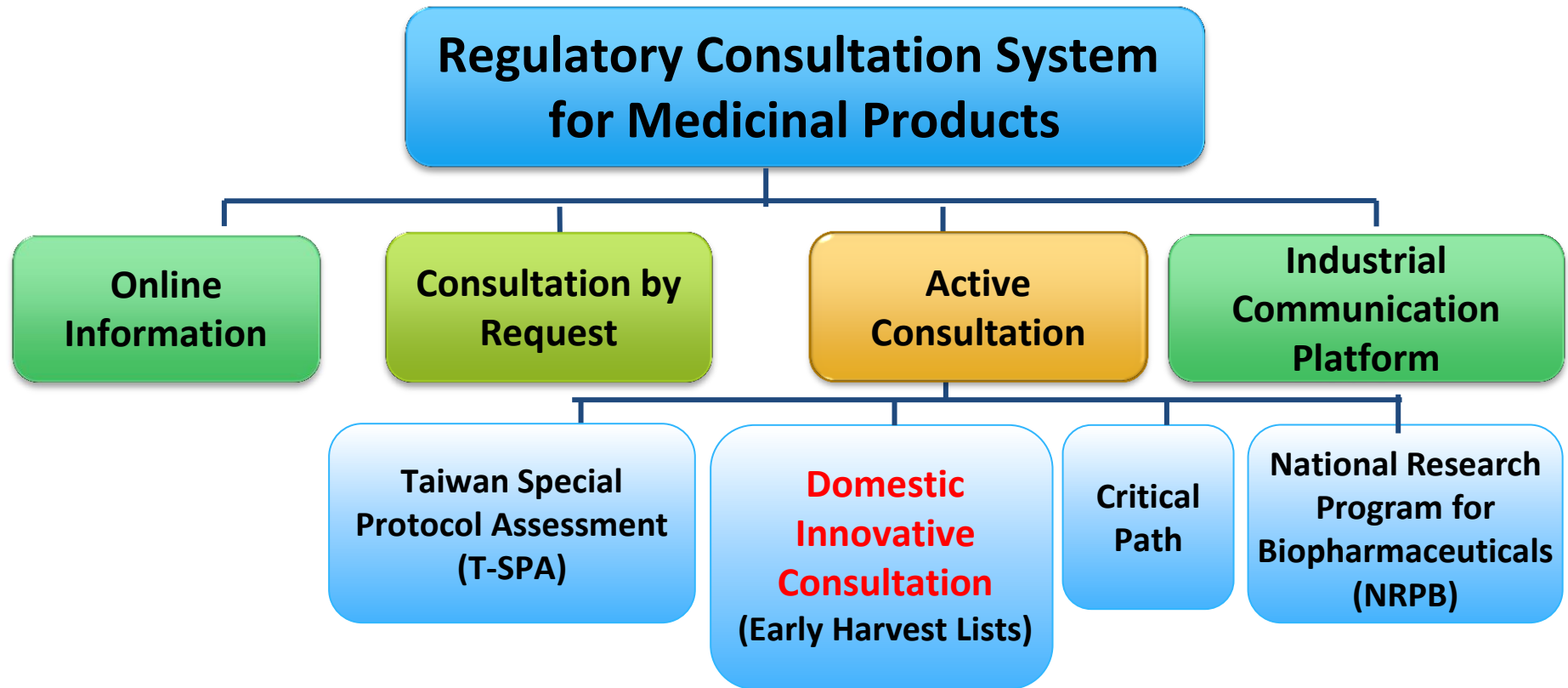


CPP: Certification of Pharmaceutical Products

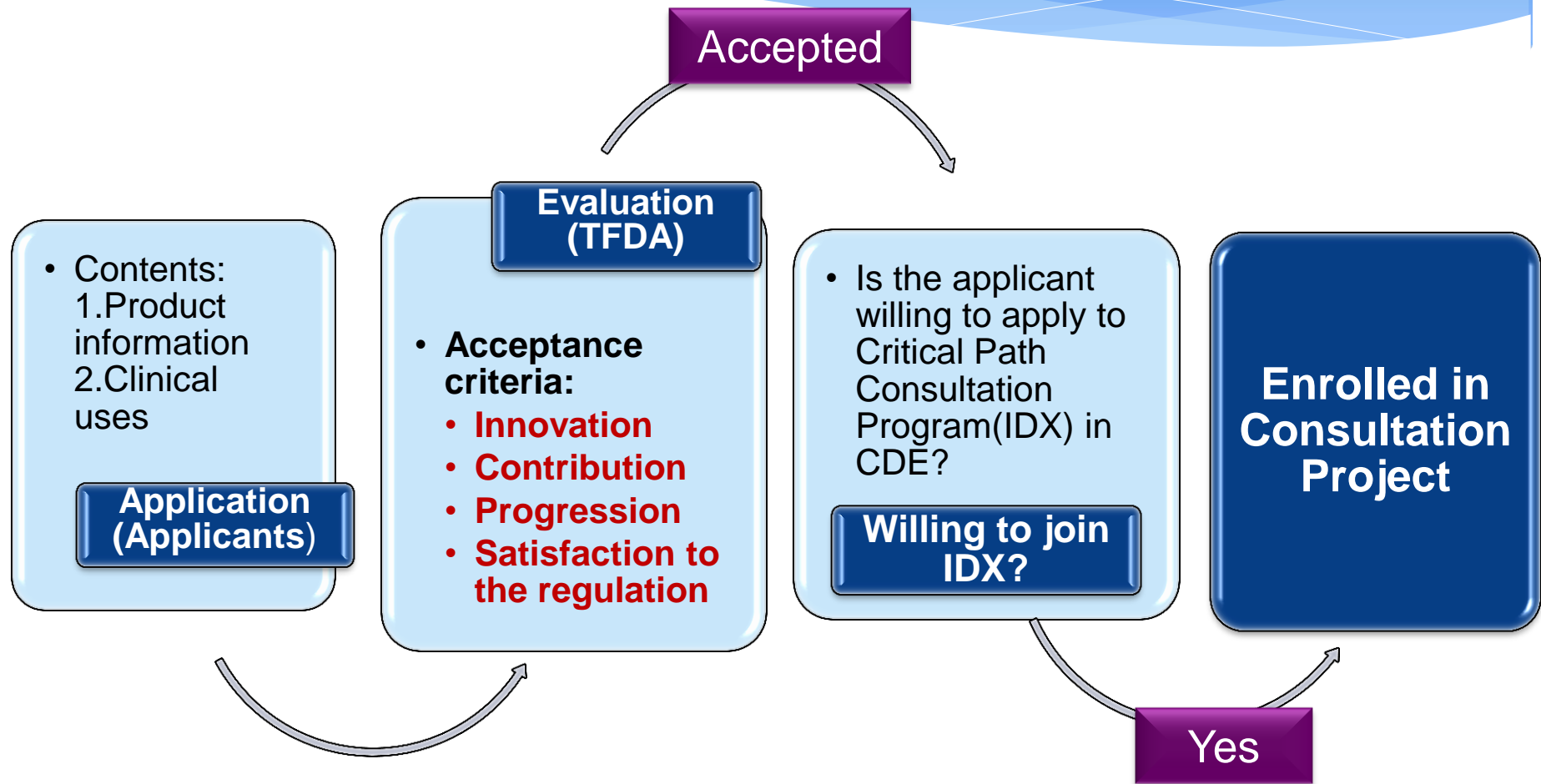
New Drug Approval

- * **First Approved in the world (2013)**
 - * Afatinib (BIBW 2992)
 - * New Chemical Entity (Non-CPP)
 - * Target therapy drug for advanced non-small cell lung cancer
 - * a selective, irreversible ErbB family blocker for the treatment of patients with locally advanced or metastatic NSCLC with EGFR mutation
 - * Multinational Trial lead by Taiwan Investigator
 - * Taiwan: 6 Medical Center, 566 subjects included

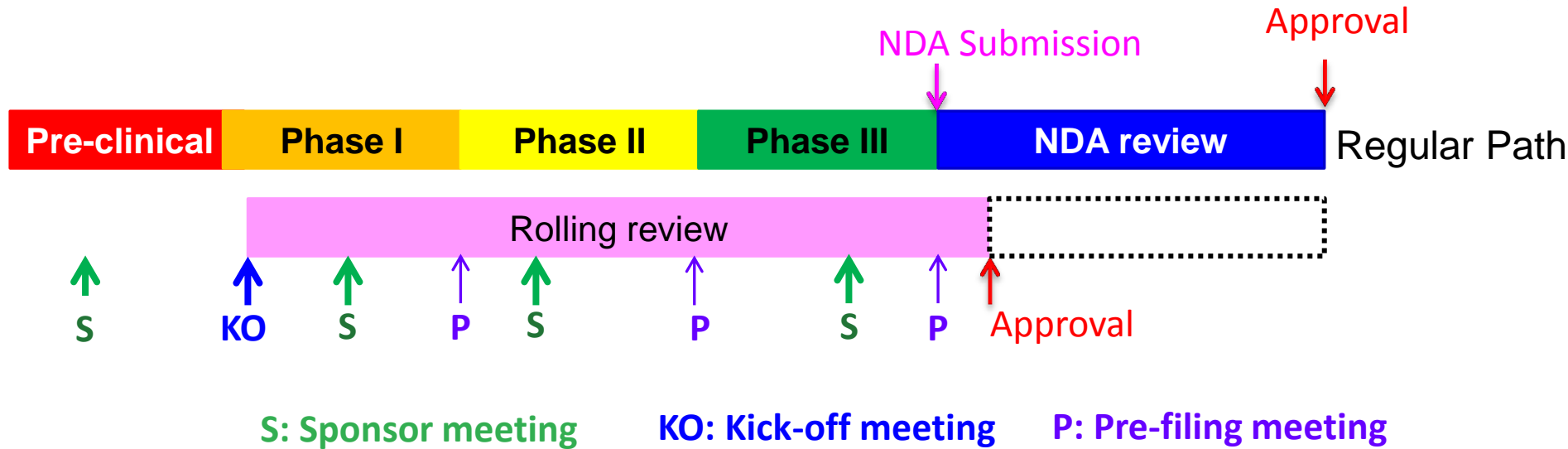
Regulatory Consultation System



Domestic Innovative Consultation Evaluation Process



Domestic Innovative Consultation



Total Cases (102.6.30)	NDA Approval	NDA Review	Phase III	Phase II	Phase I	Others
22	2	2	7	7	3	1

New Drug Approval



First Approved in the world

- * Afatinib (BIBW 2992)

First Approved Domestic Innovated Products

- * Botanical New Drug: PG2
- * Botanical/Combinational New Drug: Herbiron

Approved through Innovated Review Process

* **Priority Review:**

Dificid, Fluarix Tetra, Xgeva, Benlysta

* **Abbreviated Review:**

Edurant, Actemra

* **Domestic, Innovative Product Review:**

Nobelin XR, Linicor, Tynen, Repass, Meglide

Thank You

