Expedited Review Mechanism and Timeline in Taiwan

Section Chief, Division of
Medicinal Products, Taiwan
Food and Drug Administration

Sep. 21, 2017

衛生福利部
食品藥物管理署
Food and Drug Administration

Outlines

01 Introduction of TFDA

02 IND Application and Approval Process

03 NDA Application and Approval Process

04 Future Prospects

Establishment of TFDA

2013

2013.07.23 TFDA Elevation (食品藥物管理署)

The *Ministry of Health and Welfare (MOHW)* was restructured from the Department of Health (DOH).

2010

2010.01.01 TFDA Inauguration (食品藥物管理局)

Integration of 4 bureaus:

- *Food Safety (食品處)*
- *Pharmaceutical Affairs (藥政處)*
- *Food & Drug Analysis (食品藥物檢驗局)*
- *Controlled Drugs (管制藥品管理局)*

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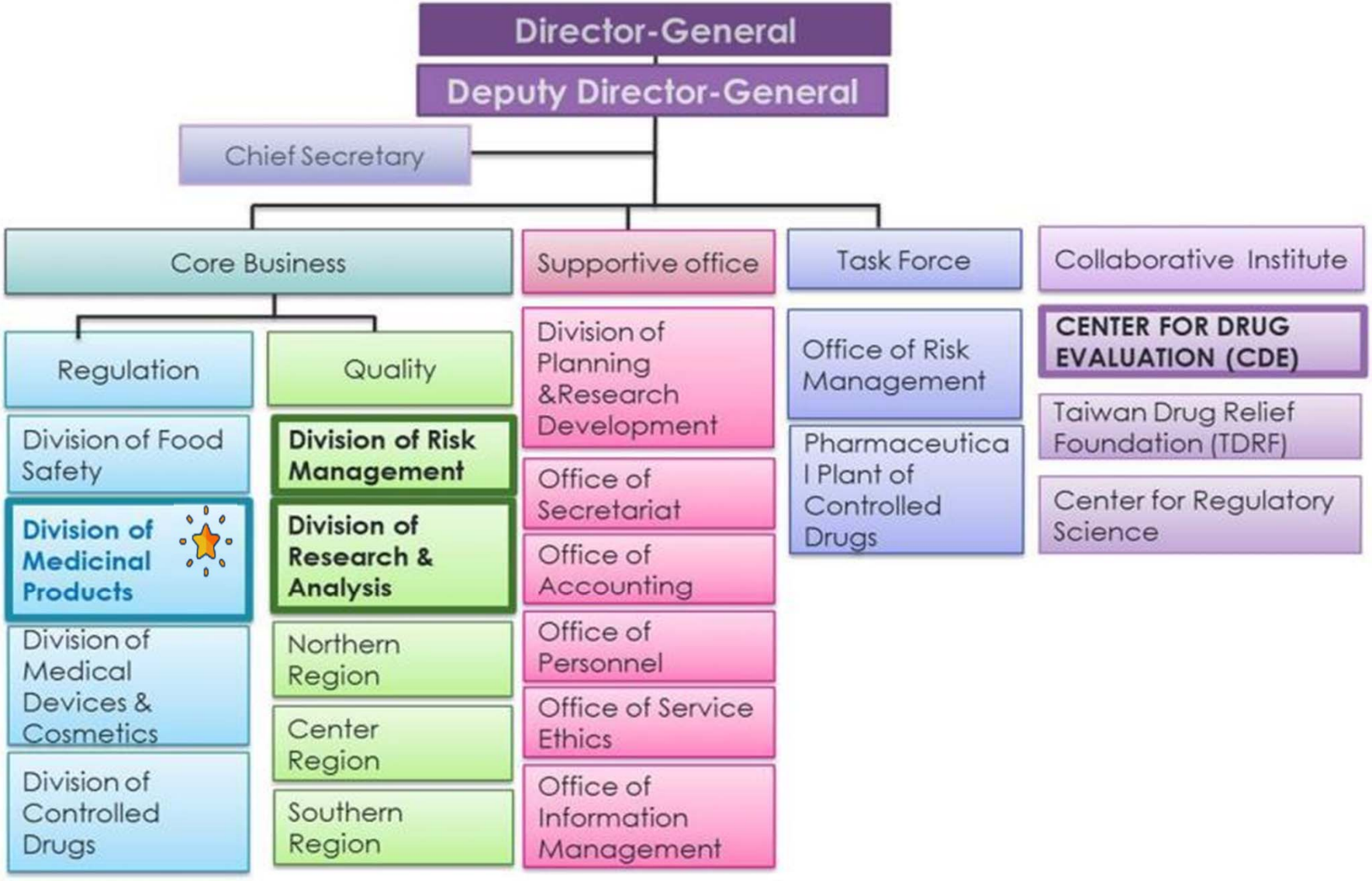
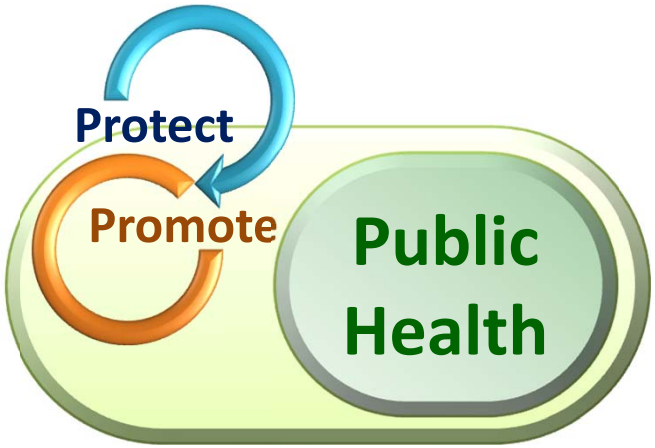
TFDA Organization Chart



Mission of Regulatory Agents

Protect

Assure Quality, Safety, Efficacy of Medicinal Products



Promote

Facilitate the Development of Innovative Medicine and Speed Drug Accessibility

Profession | Service | Quality | Innovation

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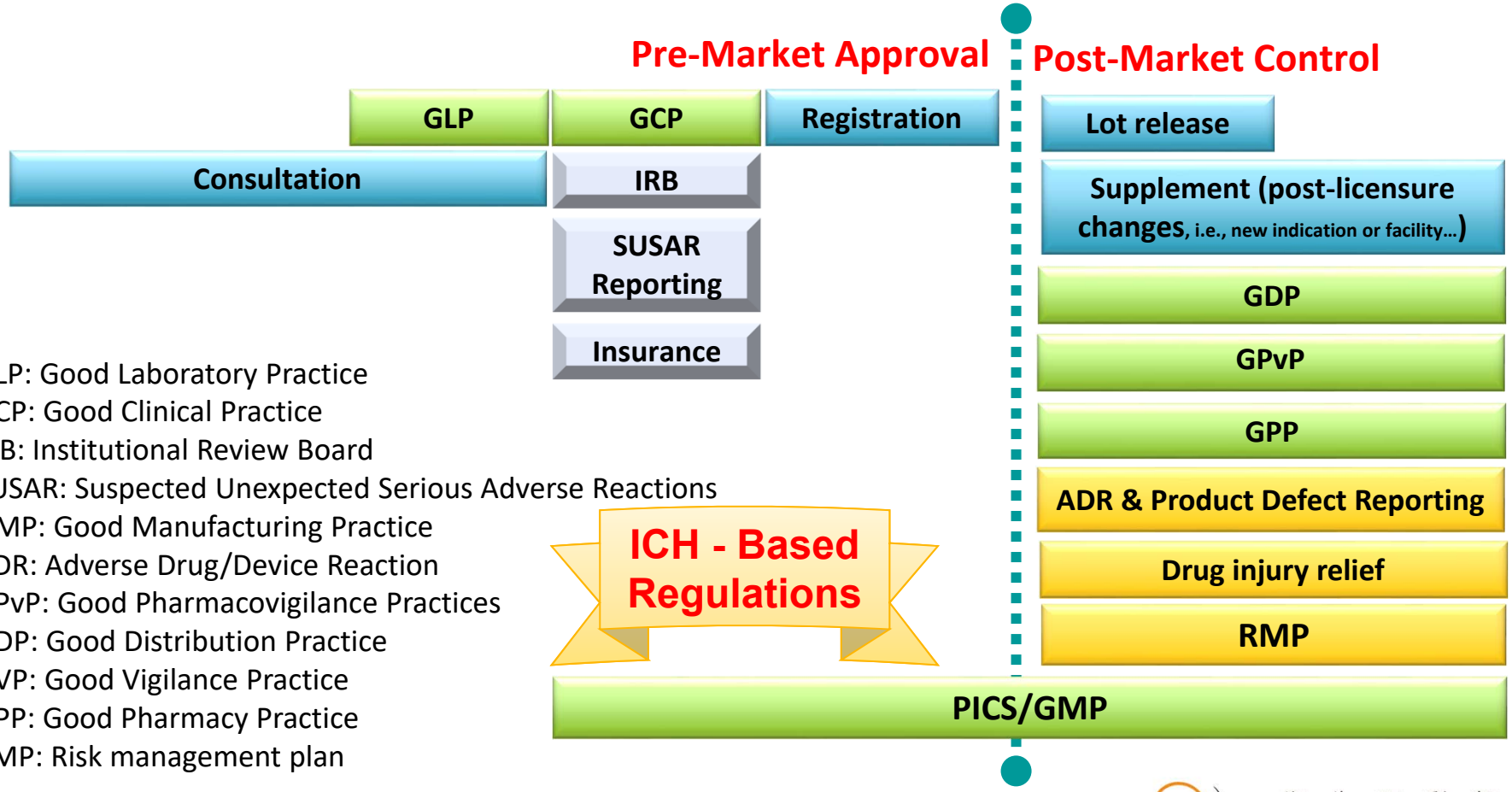
Life Cycle Management



GLP: Good Laboratory Practice
GCP: Good Clinical Practice
IRB: Institutional Review Board
SUSAR: Suspected Unexpected Serious Adverse Reactions
GMP: Good Manufacturing Practice
ADR: Adverse Drug/Device Reaction
GPvP: Good Pharmacovigilance Practices
GDP: Good Distribution Practice
GVP: Good Vigilance Practice
GPP: Good Pharmacy Practice
RMP: Risk management plan

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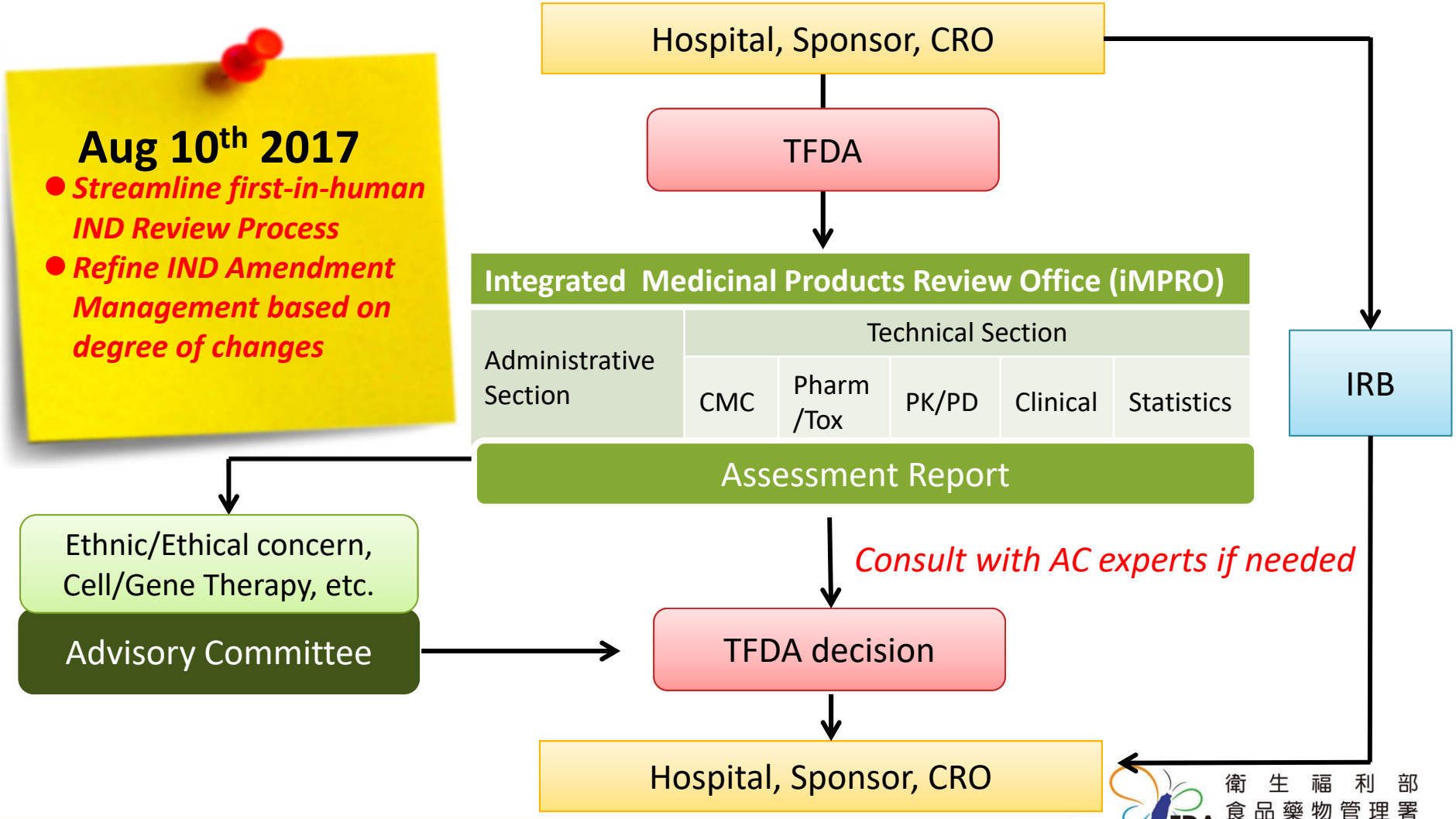
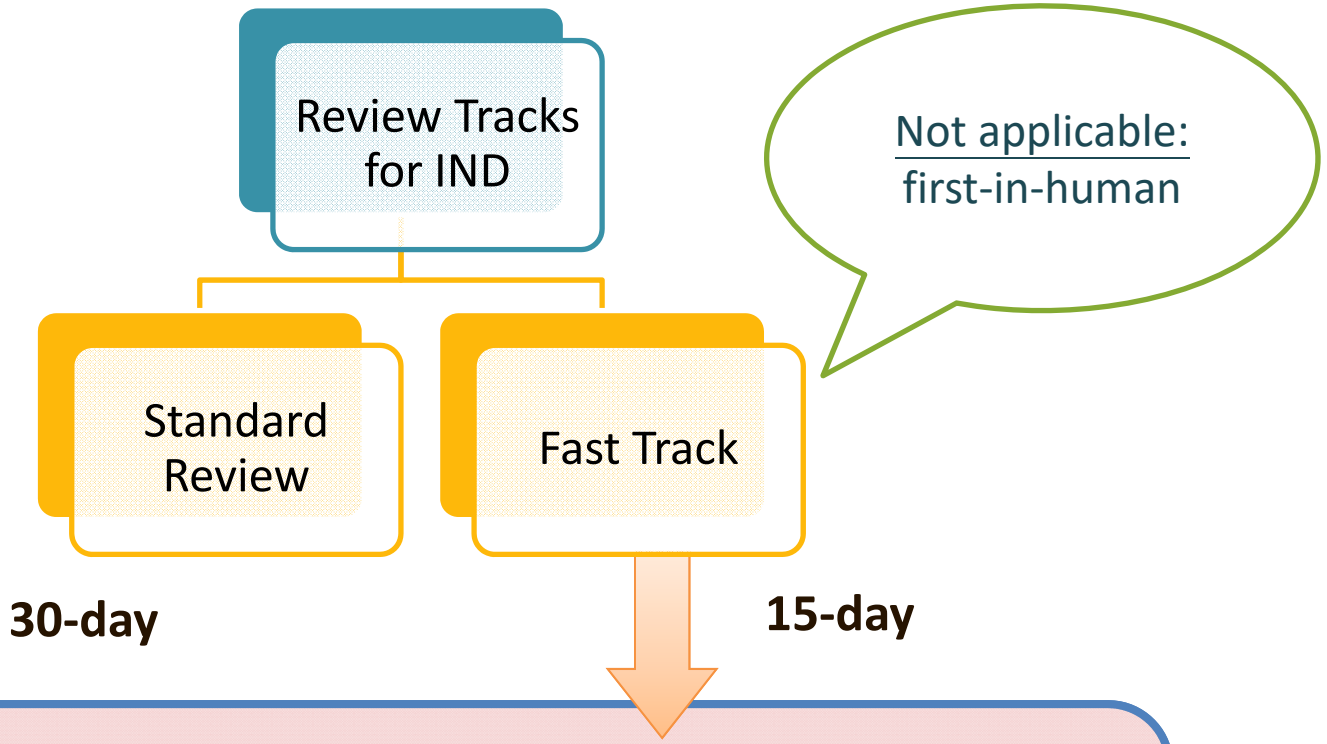
Review Process for Clinical Trial (IND) Applications

A standard review process: 30 calendar days



Enhance IND Review Efficacy-Fast Tract Review for Pharmaceutical Product



Applicable for:

1. IND with the Same **US FDA-Approved** IND Number (July, 2004)
2. Multinational multicenter trials **simultaneously conducted in one of the 10 medically advanced countries**; Taiwan's medical center hospital also involved (Aug, 2010)

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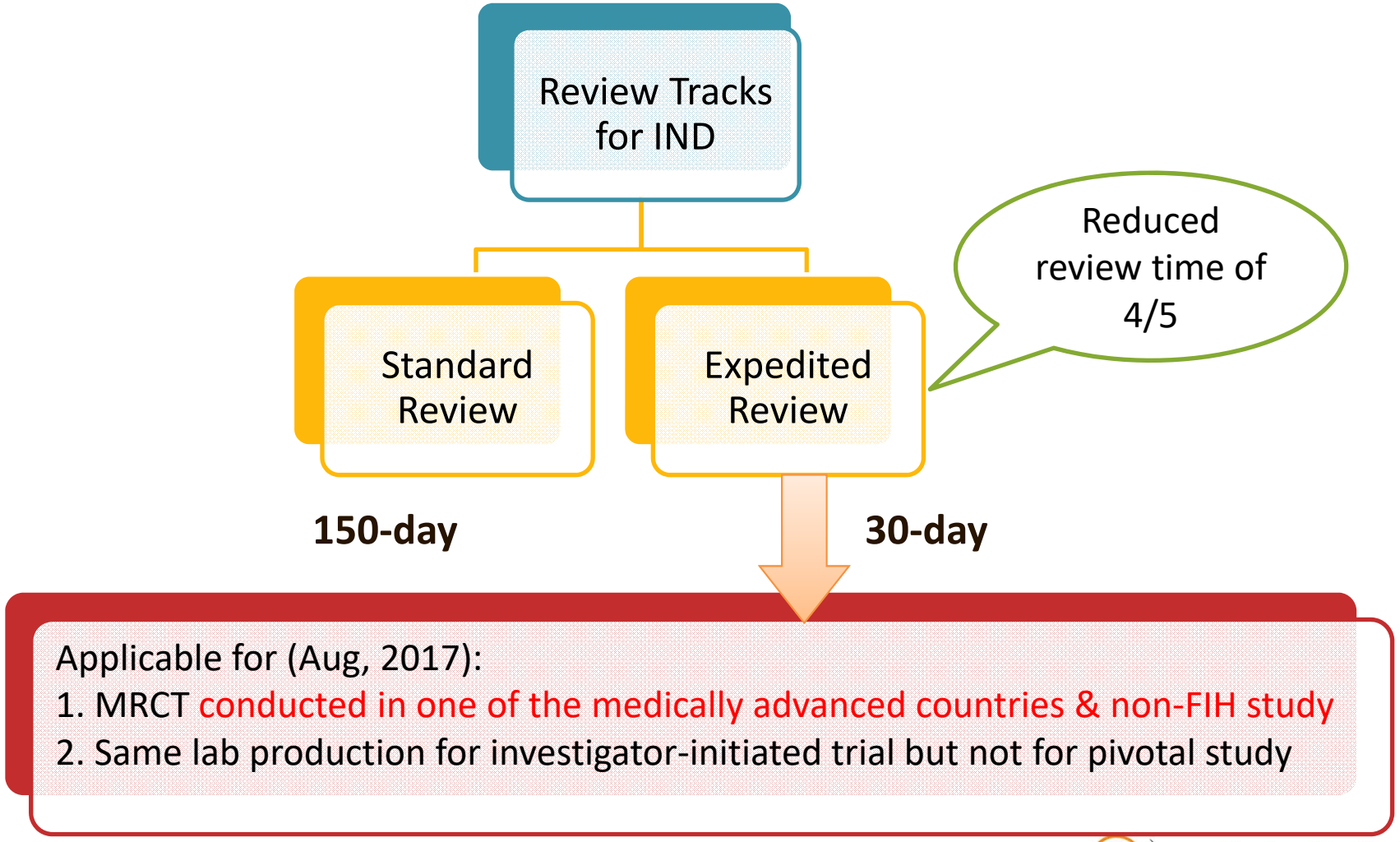
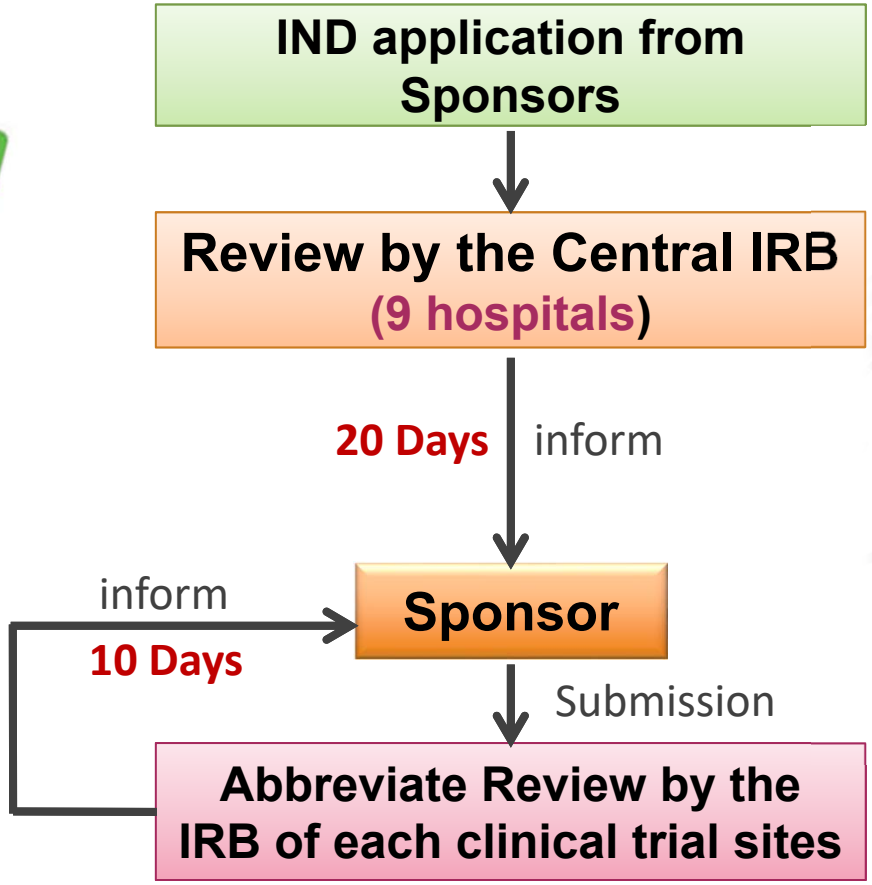
Enhance IND Review Efficacy- Expedited Review for Cell/Gene Therapy



Enhance IND Review Efficiency- central IRB system

To control IRB review time and synchronize the trial schedule in multiple sites.



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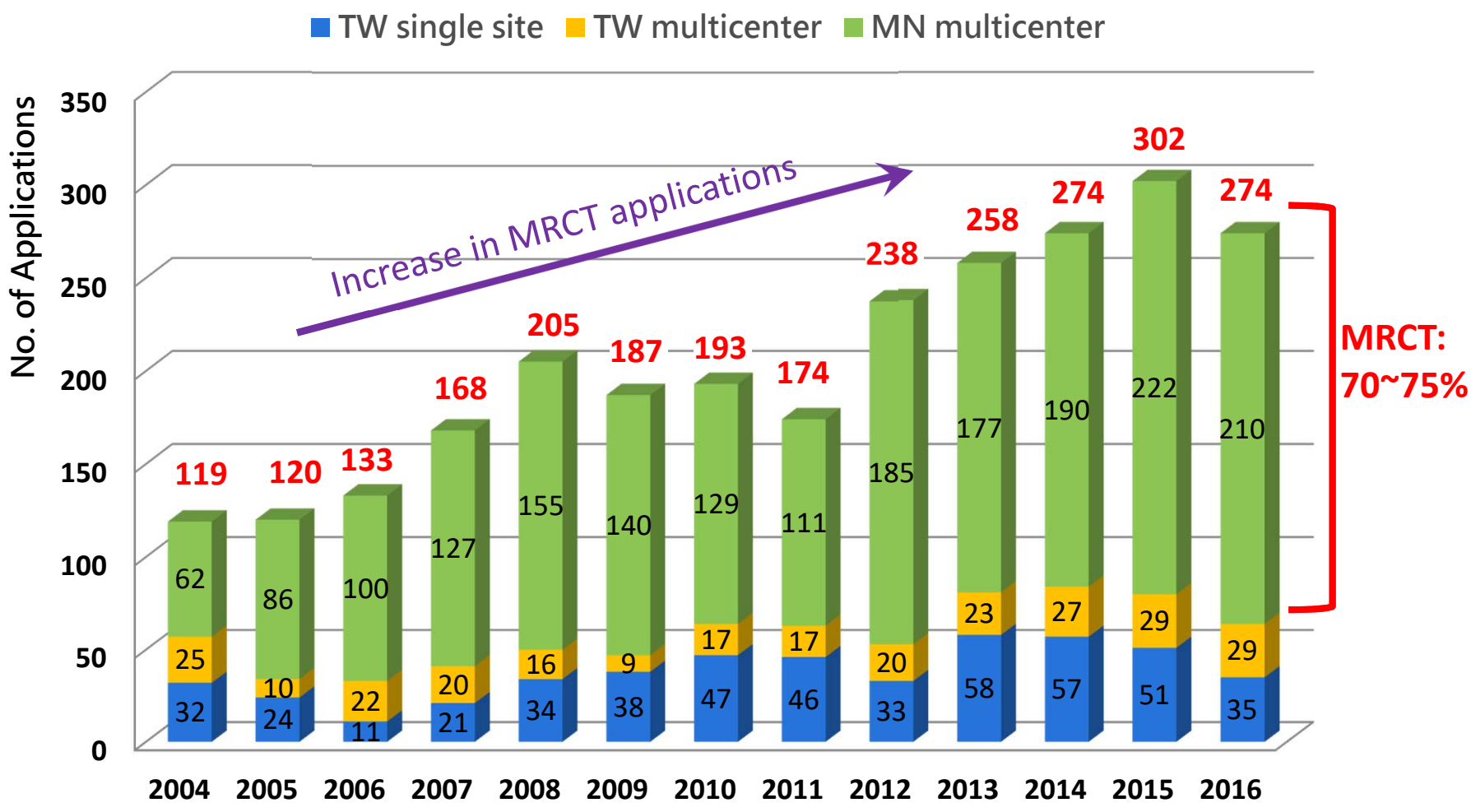
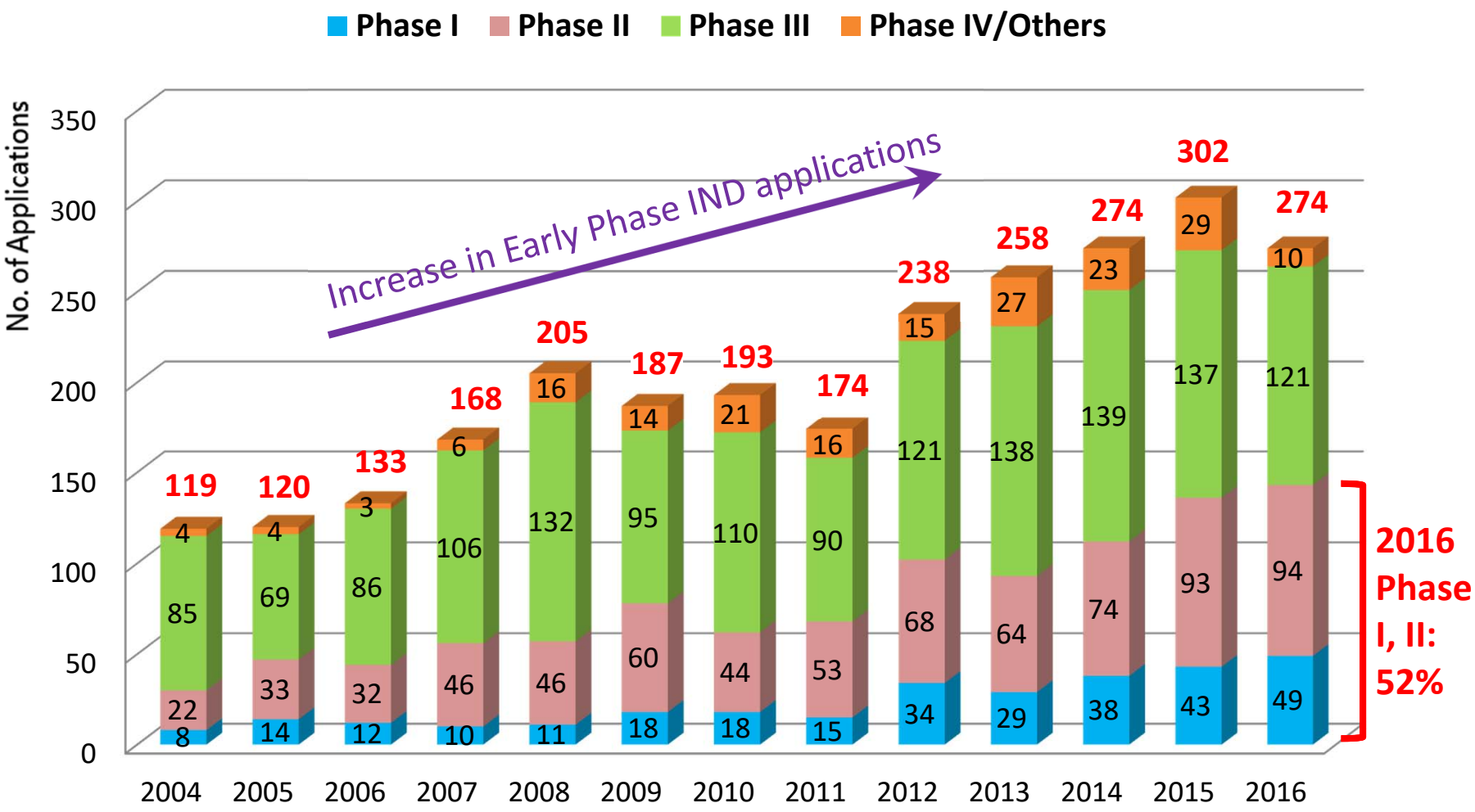
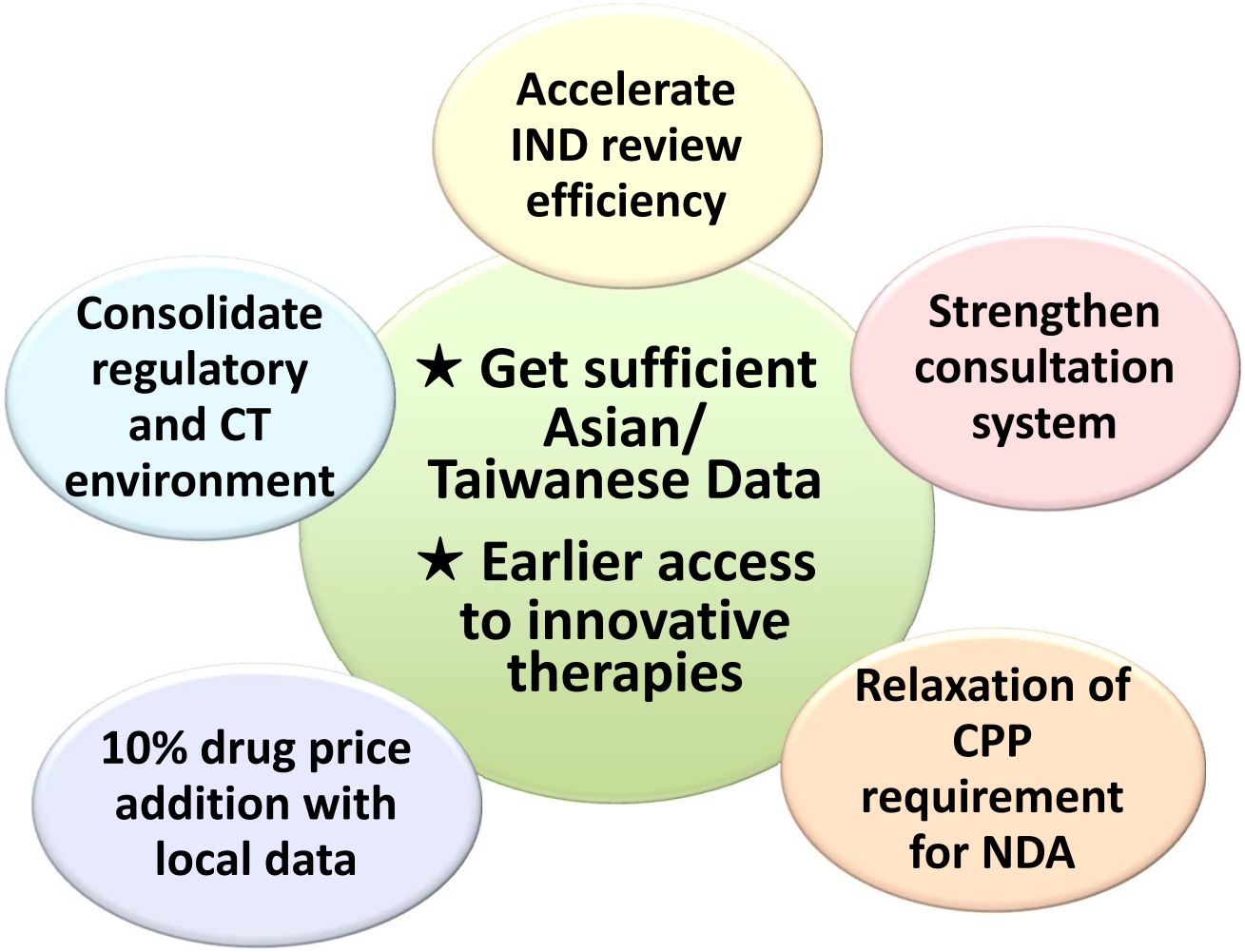
IND Applications in Taiwan by Local/MRCT Type



IND Applications in Taiwan by Study Phases



Strategies to encourage Multi-Regional Clinical Trials (MRCT) and Early Phase Trials in Taiwan



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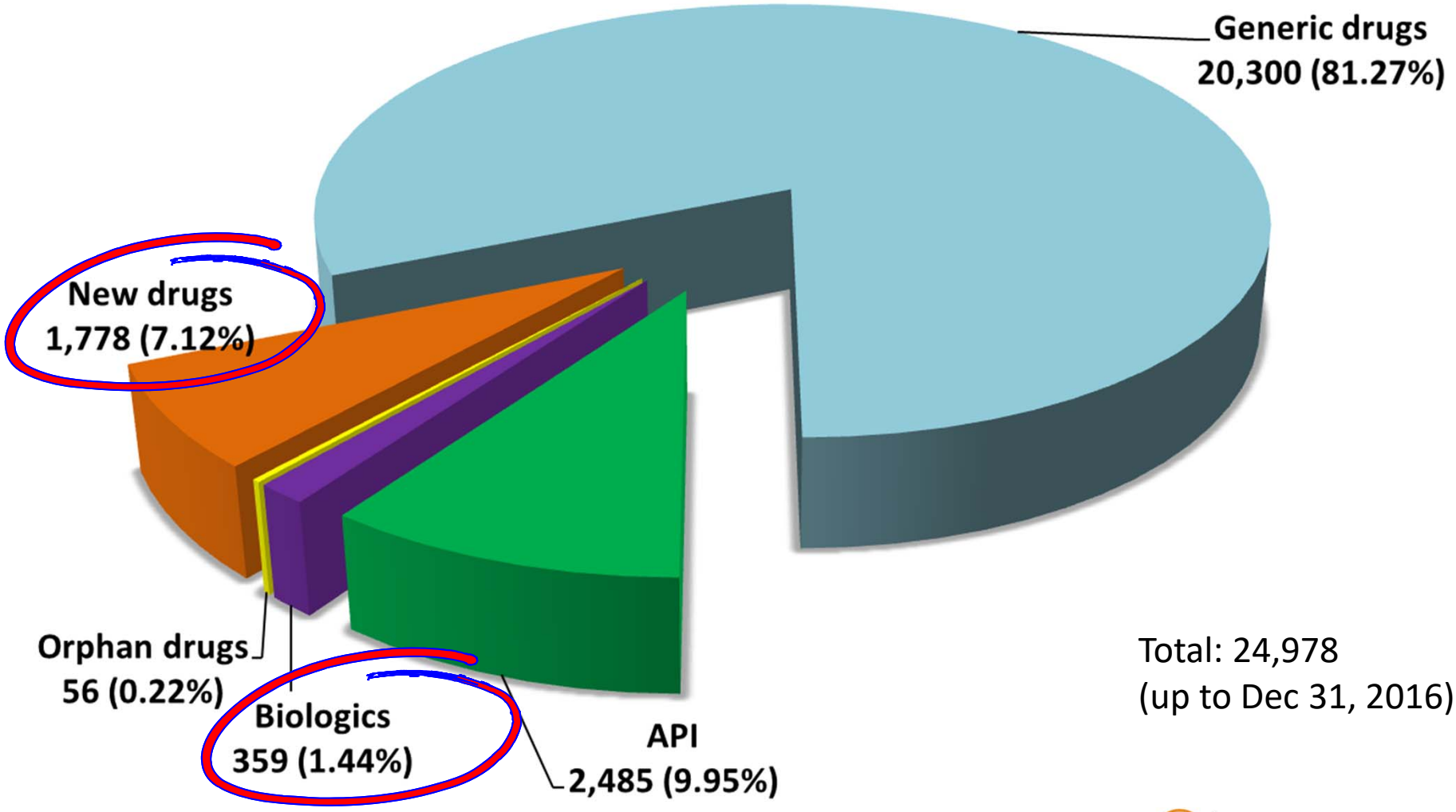
Statistics on Pharmaceutical Licenses in Taiwan



Total: 24,978
(up to Dec 31, 2016)

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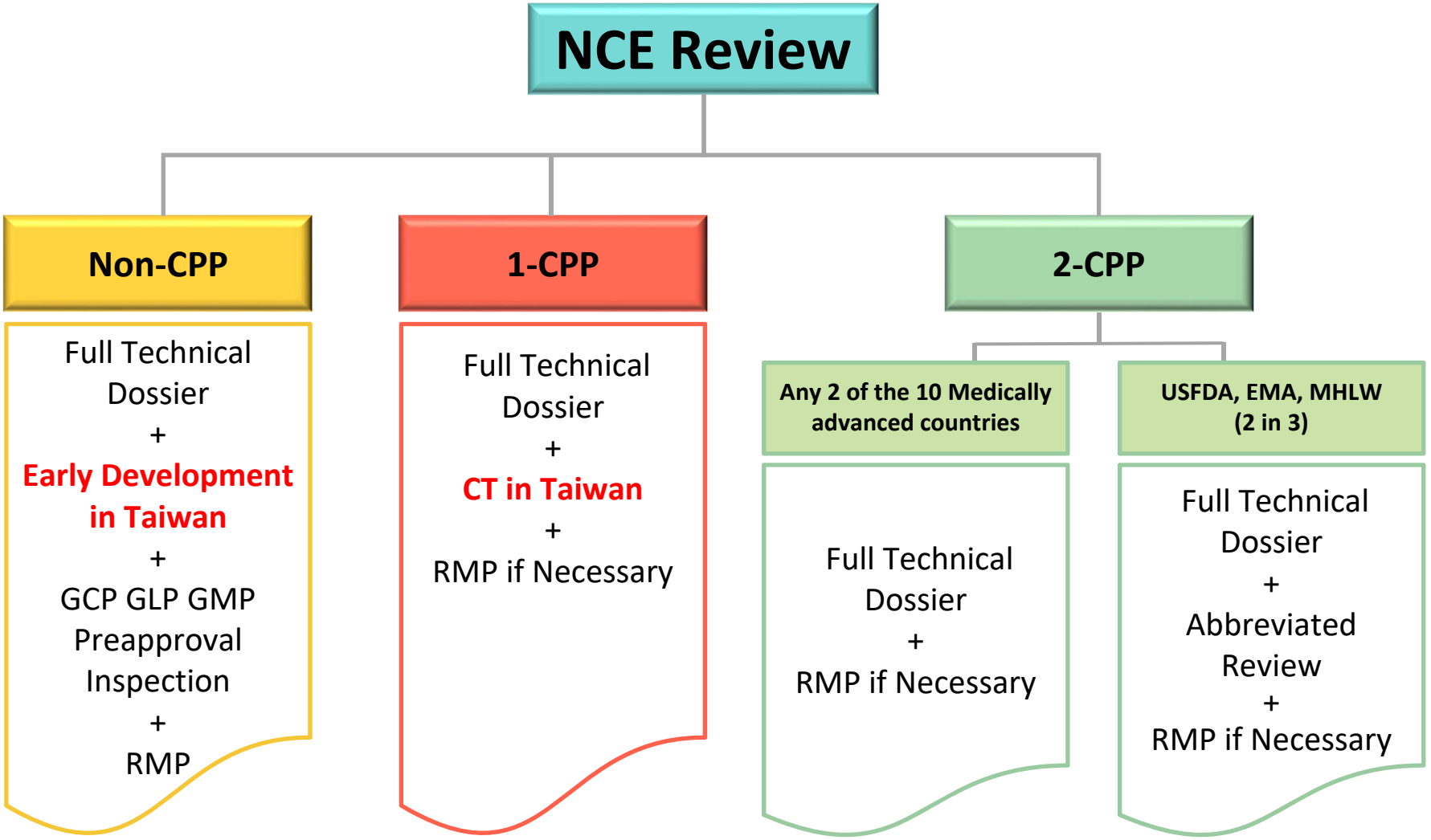
Rationalization of CPP Requirements



CPP: Certification of Pharmaceutical Products
RMP: Risk Management Plan

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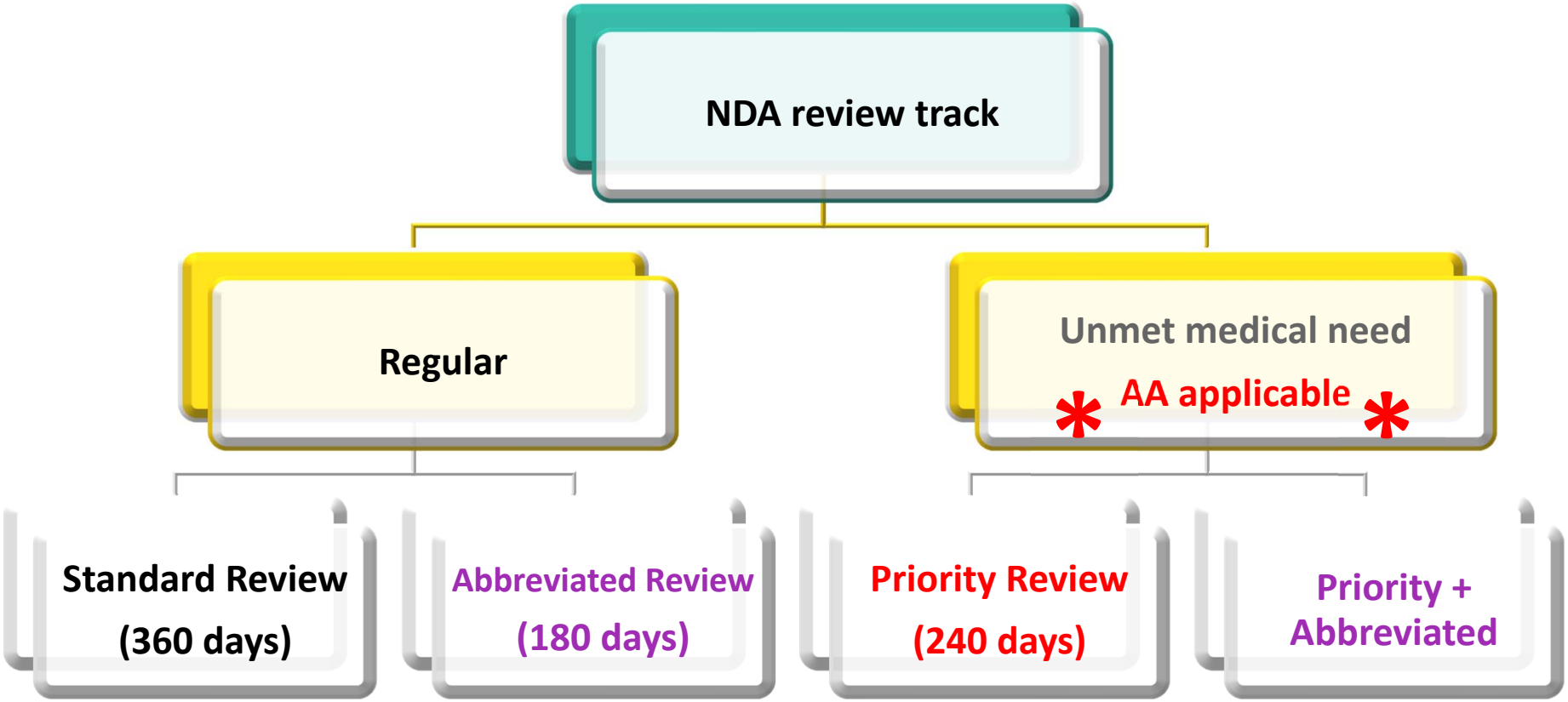
Expedited Program of NDA



*Abbreviated Review：NCE + US FDA, EMA, MHLW approved (2 out of 3)
*AA: Accelerated approval (AA): Surrogate endpoint CT accepted

Case Sharing

MRCT + **Fast Track** = ***First Approval in the world***

AFATINIB DIMALEATE

- ✓ New Chemical Entity
- ✓ Target therapy drug for advanced non-small cell lung cancer
- ✓ Non-CPP
- ✓ Review Time: 89 days
- ✓ Approval: May 17, 2013 in TW (globally first approval)

IRINOTECAN (liposome)

- ✓ New indication & new dosage form
- ✓ Treatment of pancreatic cancer
- ✓ Non-CPP
- ✓ Review Time: 74 days
- ✓ Approval: Oct 22, 2015 in TW (globally first approval)

Domestic Innovative New Drugs

Nemonoxacin

- NCE

Flu Vaccine

- Flu vaccine with adjuvant (Virosome)

Ferric citrate

- NCE

Irinotecan liposome

- New indication & new dosage form

Methtlene blue

- Orphan drug

Phenylbutyrate

- Orphan drug

Fomepizole

- Orphan Drug

Omega-3-acid Ethyl Esters 90

- NCE

Atropine/ Pralidoxime chloride

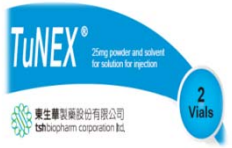
- New combination

Nalbuphine sebacate

- NCE

Flu vaccine

- 4-strain Flu vaccine



Opinercept

- Biotechnological products

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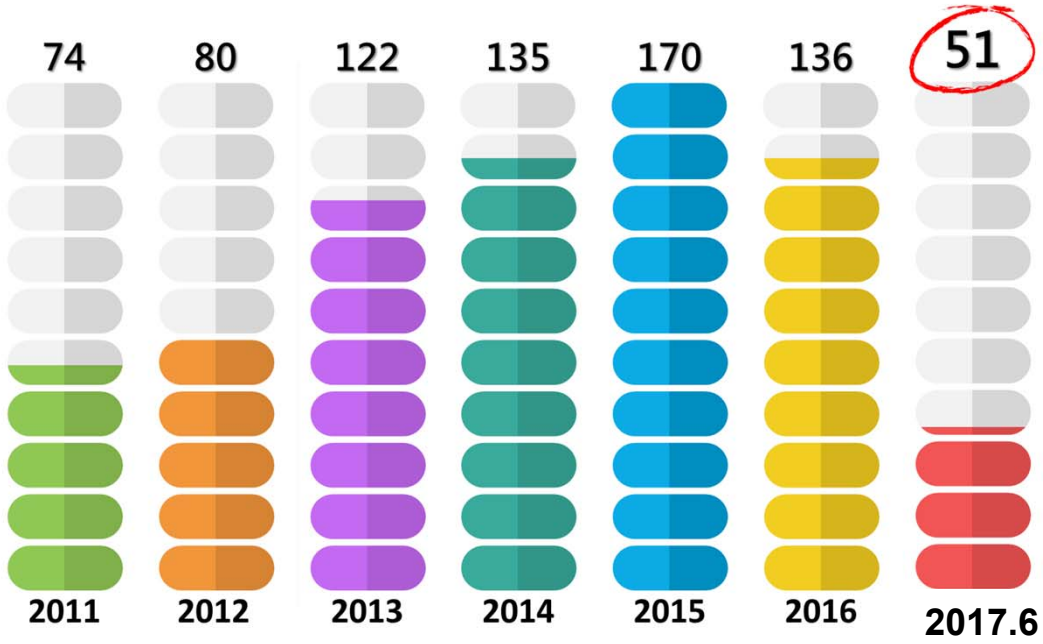
Statistics of New Drugs Approval

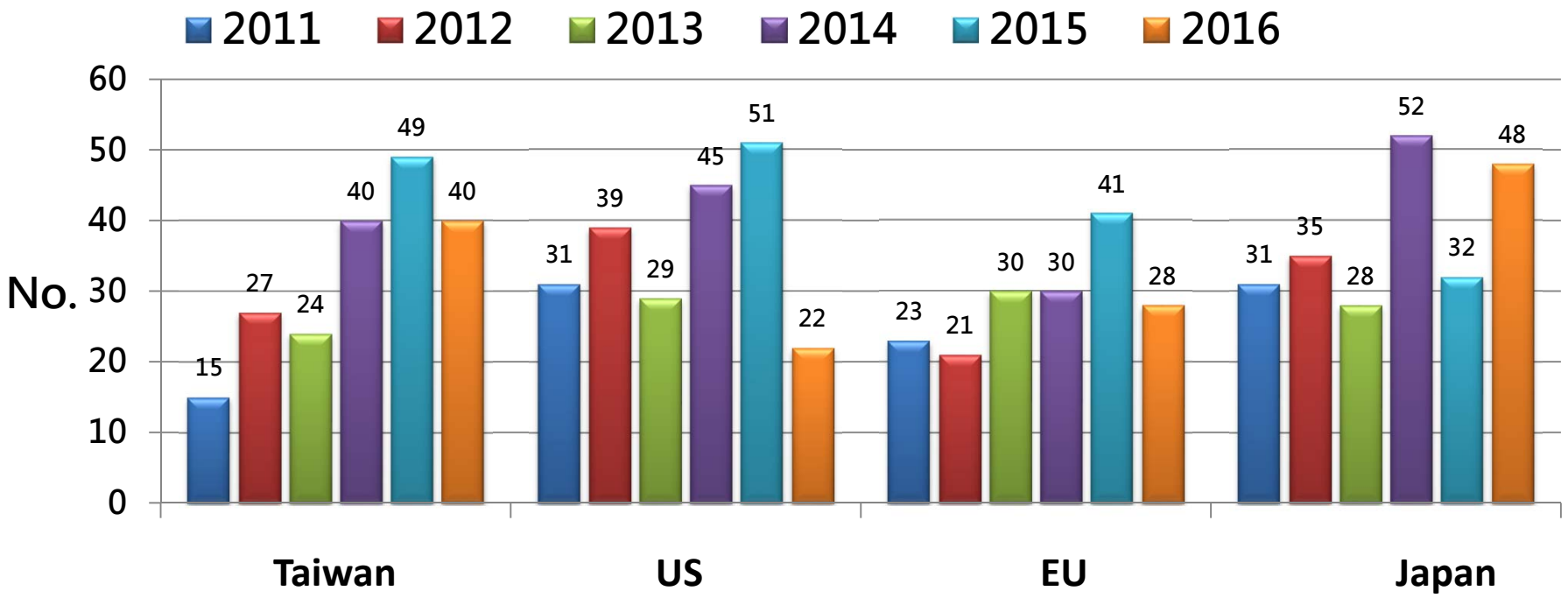
The number of approval in 2011-2017.06



Number of approvals	51											
Types	Domestic						Import					
Numbers (%)	5 (10%)						46 (90%)					
Types	Chemical			Biologics			Chemical			Biologics		
Numbers	3			2			38			8		
Numbers	New chemical entity	1	1	Vaccine	1		New chemical entity	13	32	Vaccine	0	
	New combination	0		Plasma derivative	0		New combination	14		Plasma derivative	2	
	New indication	0		Toxoid	0		New indication	5		Toxoid	0	
	New route of administration	0		Biotechnological products	1		New route of administration	0		Biotechnological products	6	
	New dosage forms	1	2				New dosage forms	0	6			
	New dosage and administration	0					New dosage and administration	3				
	New strength	1					New strength	3				

New Drugs Approval Number

The number of new active substance (NAS) approval in 2011-2016



Reference: CIRS

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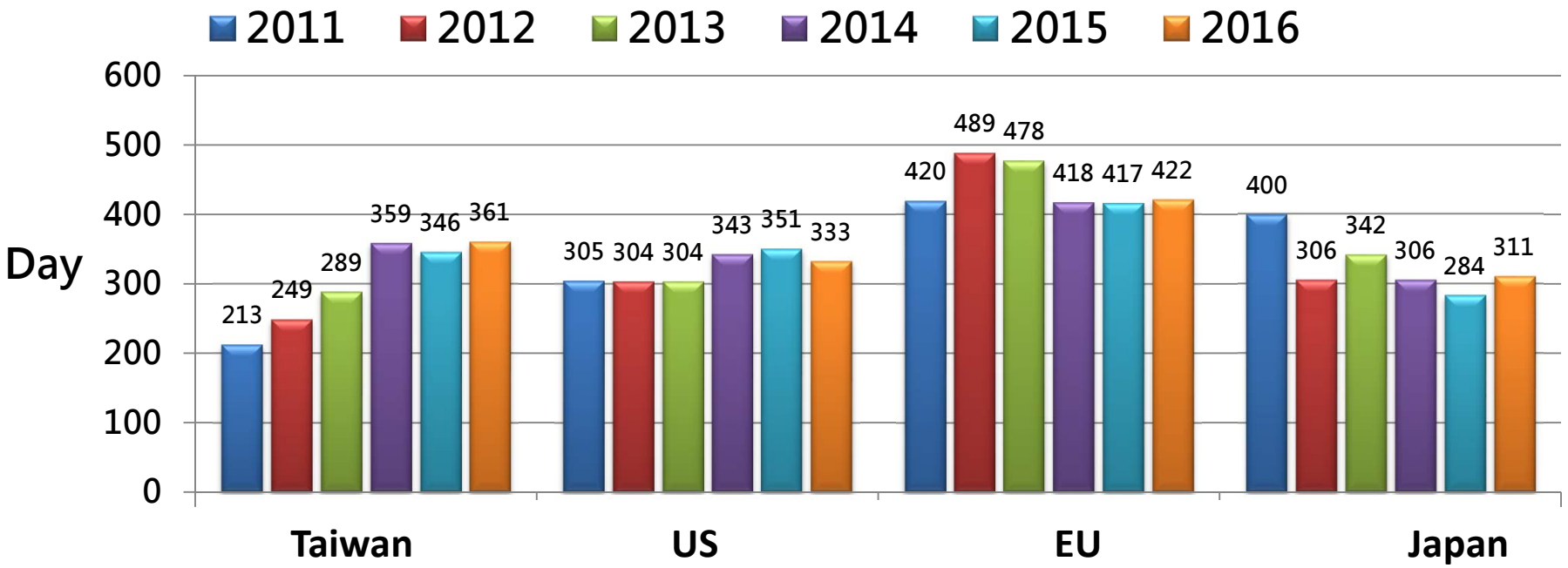
Median Approval Time for New Drugs



Reference: CIRS

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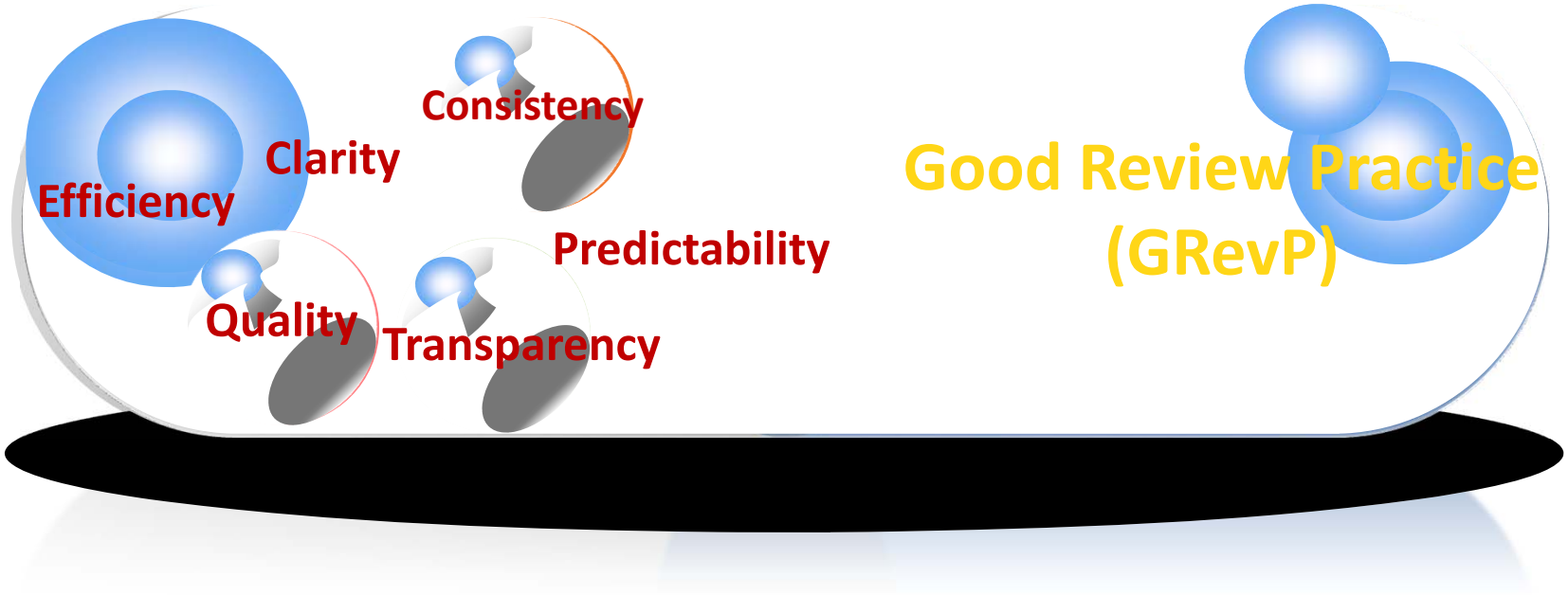
Implementation of Good Review Practice

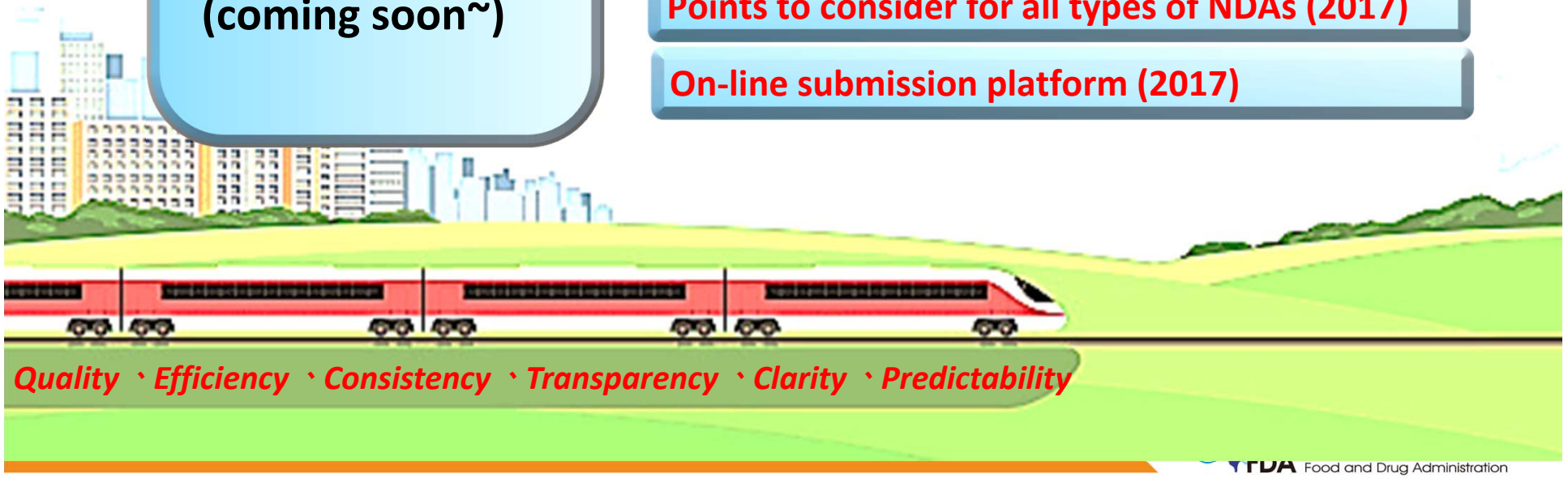


Enhancement of Review Efficiency

Pre-clinical → **Clinical** → **Marketing Approval**

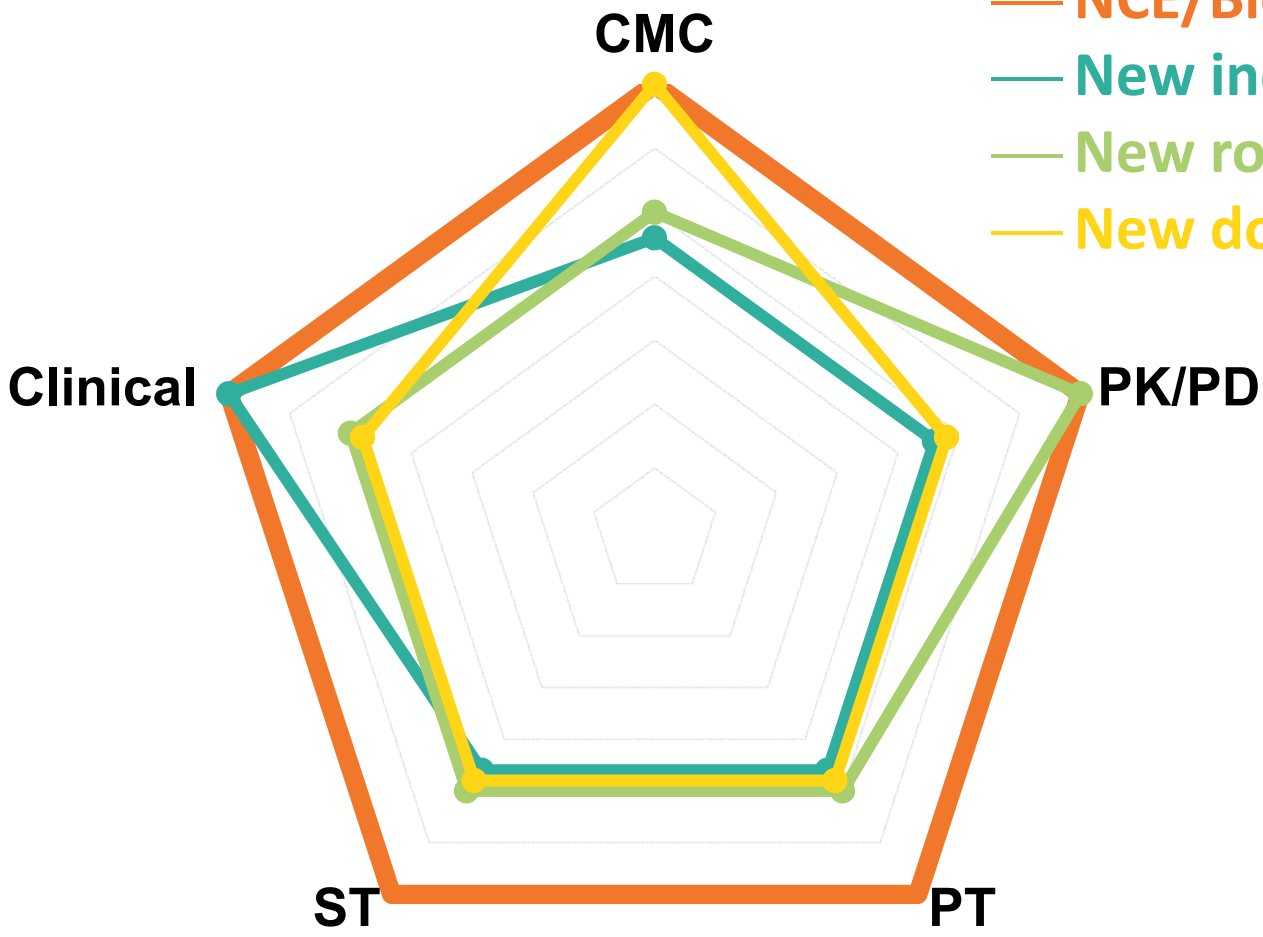
- **Consultation and Rolling Review (2016)**
- **Breaking Through Destination (coming soon~)**

- Review process and Timeline (2016)
- Review time for non-NCE NDA (2016)
- Refuse-to–File (2016)
- Pre-NDA meeting (2016)
- Points to consider for all types of NDAs (2017)
- On-line submission platform (2017)



Points to Consider for All Types of NDAs

Clarity



— NCE/Biologics
— New indication
— New route of administration
— New dosage forms

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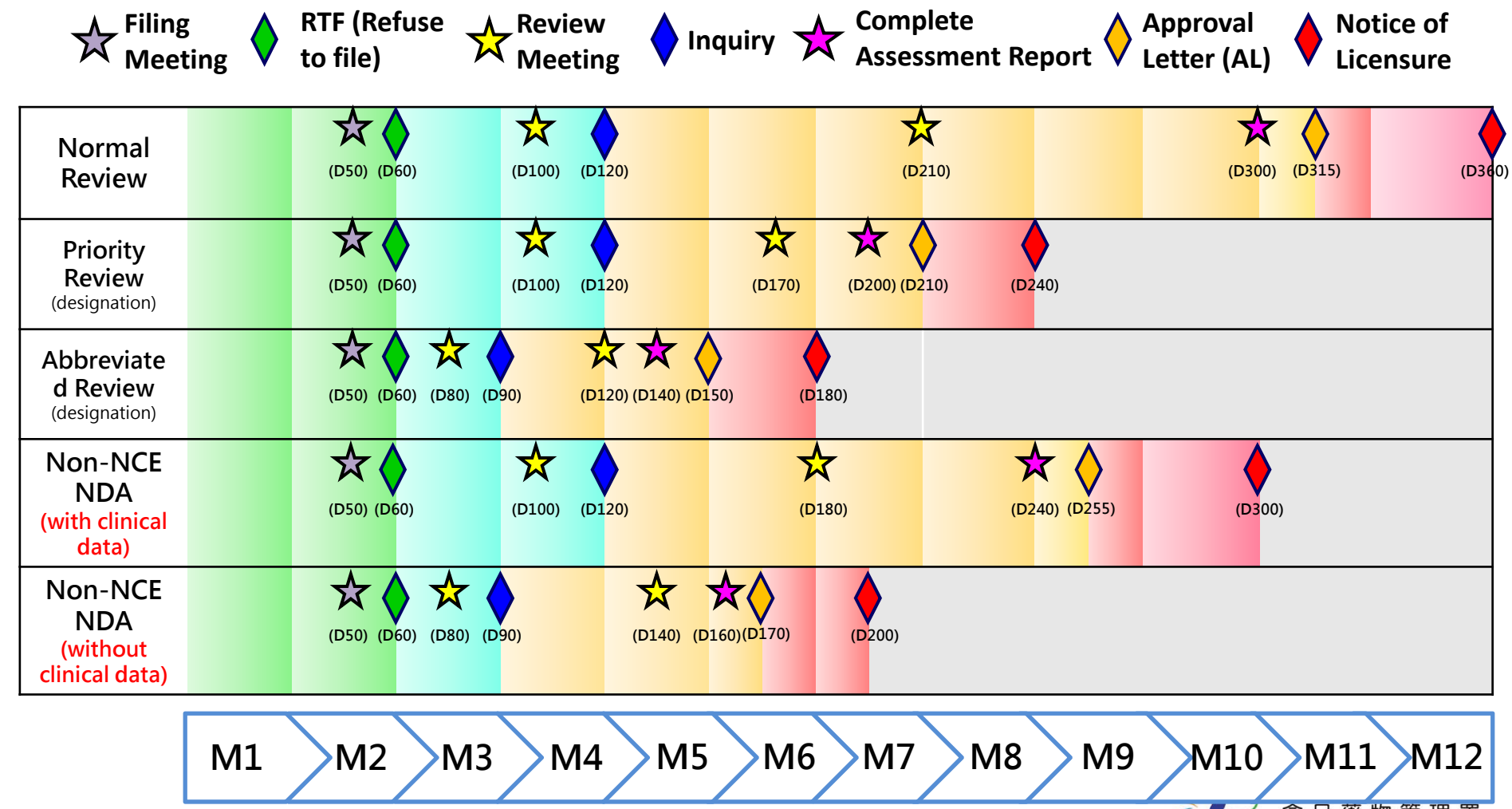
Review Timeline Management

Predictability



QA/QC Meeting

Quality

Integrated Medicinal Product Review Office

↑ Internal Control Monitoring & Auditing

↑ Resource Integration

↑ Job Integration

↑ Process Integration

Consultation System

Transparency

Consultation System

- **Online Information**
- **Consultation by Request**
- **Active Consultation**
  - **Domestic Innovative Consultation** (Early Harvest Lists)
  - **National Research Program for Biopharmaceuticals (NRPB)**
- **Industrial Communication Platform**

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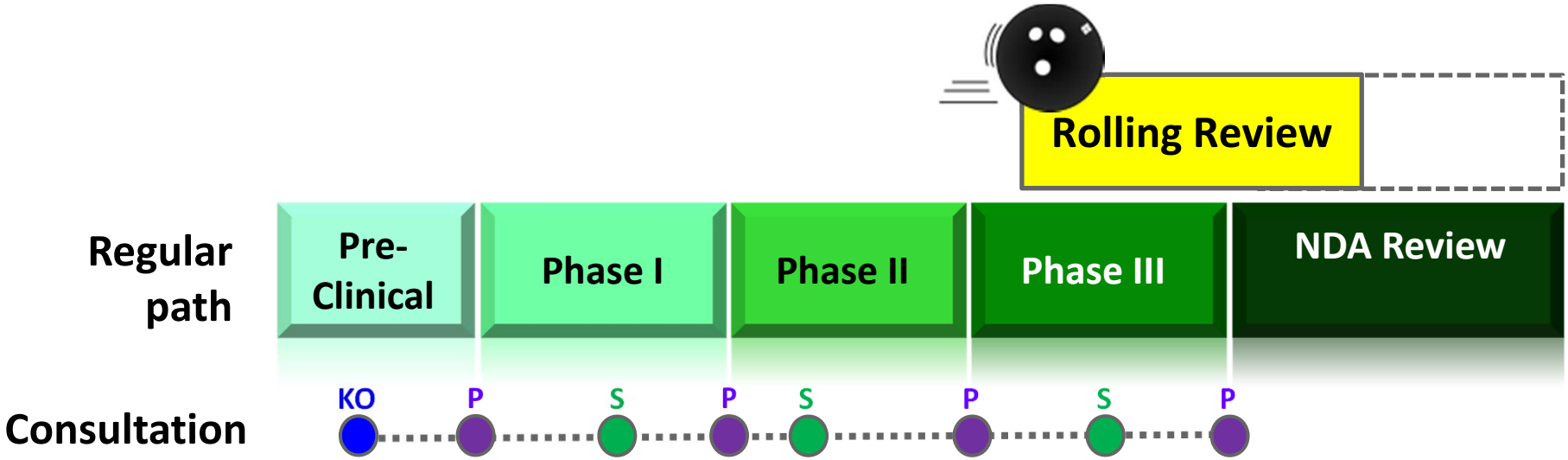
Domestic Innovative Consultation

Transparency

To facilitate medicinal products development and marketing approval

Meeting types:

- Kick-off meeting
- Sponsor meeting
- Pre-filing meeting



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ExPRESS (E Platform for Review & Submission)

The E Platform for Review & Submission (ExPRESS) is for accepting electronic submissions. The ExPRESS enables the secure submission of premarket and postmarket regulatory information for review.

Information Database

Easy to Retrieve

Paperless

Enhancing Review Efficiency

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Promoting Good Registration Management (GRM) in APEC

Roles in RHSC

- **GRM Roadmap co-champion**
- **GRM CoE hosting institution**

Promoting Good Registration Management (GRM) in APEC

2017 APEC GRM CoE Workshop

- **Date: Oct 31 to Nov 2, 2017**
- **Venue: NTUH Convention Center, Taipei**
- **Target Audience: regulators and industries**

All 21 APEC member economies are invited

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Thank You for Your Attention!

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