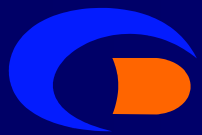
Global Development in Chinese Taipei



Oct. 13, 2006

Herng-Der Chern, M.D., Ph.D.
Executive Director
Center for Drug Evaluation, Chinese Taipei

Pharmaceutical Market of Asia

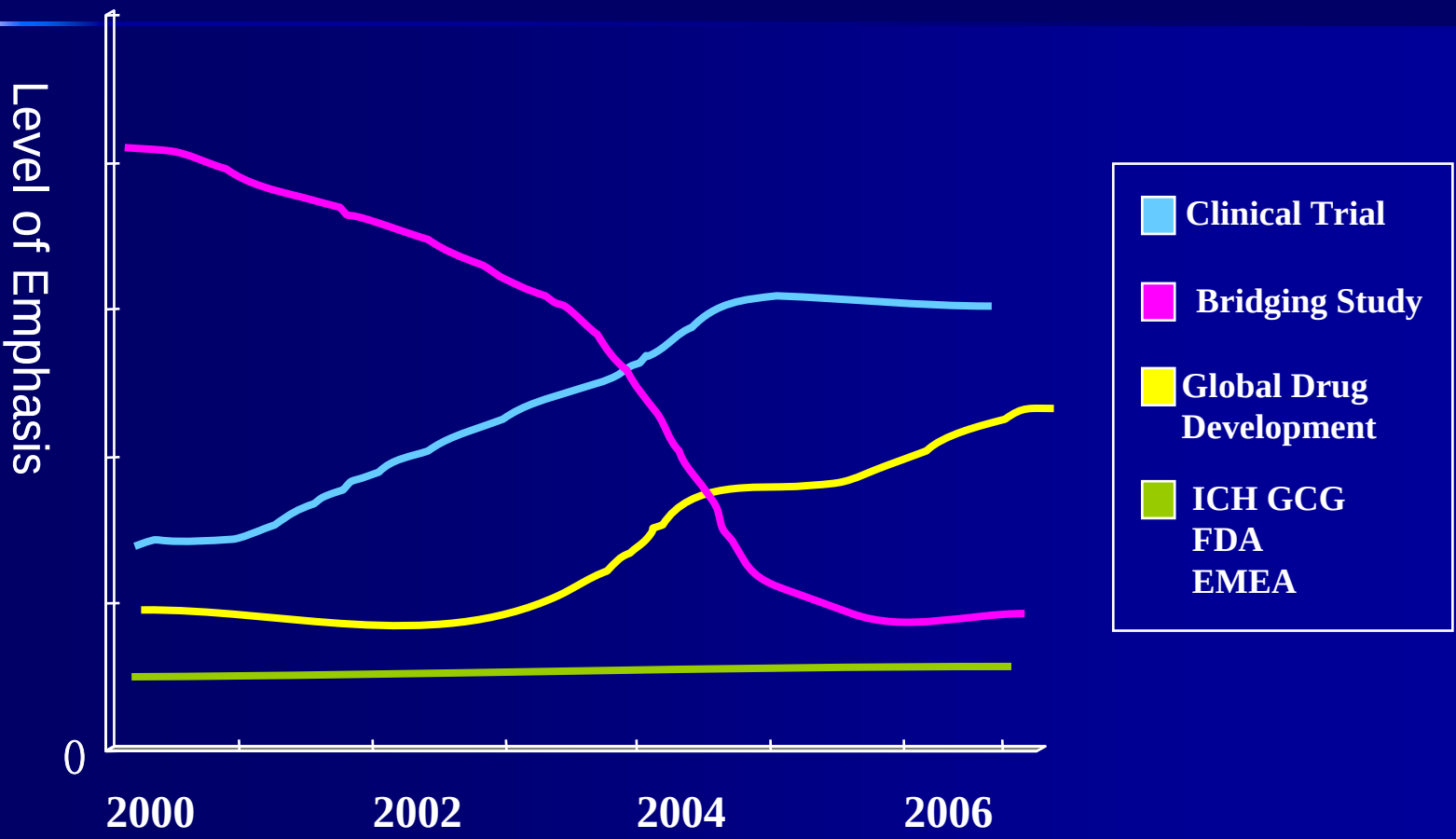
	Market Size (Million USD)	Expenditure per Capita (USD)	Population (Million)
Japan	58,000	453.4	127.9
China*	29,811	22.9	1,285.2
Korea	5,800	121.7	47.6
India	4,600	4.2	1,087.1
Chinese Taipei	2,564	112.0	22.9
Indonesia	2,250	9.3	241.9
Thailand	1,320	20.2	65.4
Hong Kong	850	123.2	6.9
Vietnam	718	8.6	83.5
Malaysia	665	25.9	25.7
Singapore	550	125.0	4.4

* 42% from Traditional Chinese Medicine

(2004, Rabobank International)

APEC Network under ISTWG, since 1999

Theme and Topics



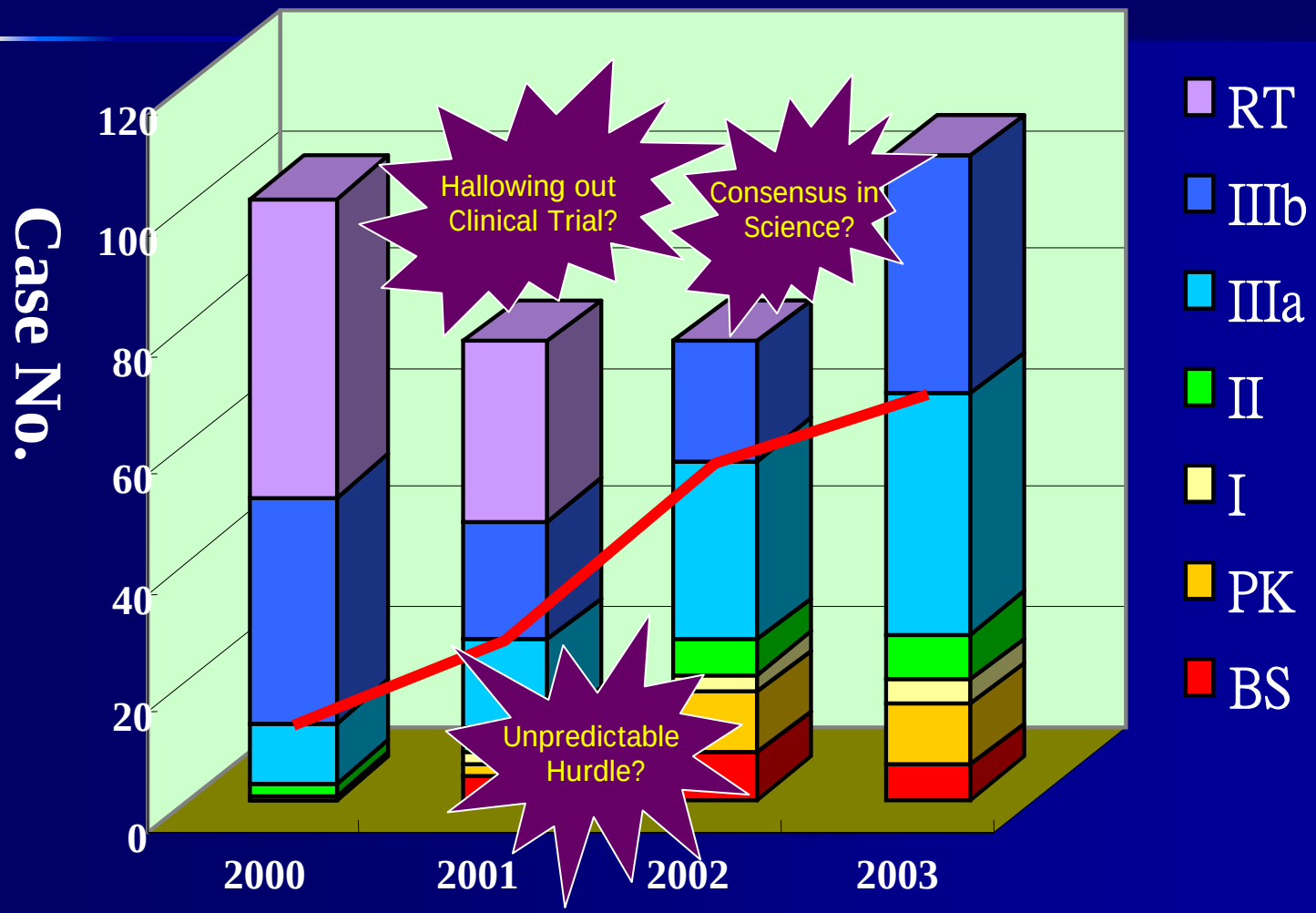
Theme of APEC Tokyo Meeting 2006

"Global simultaneous development and introduction of innovative drugs"

- Think Globally, Act Locally

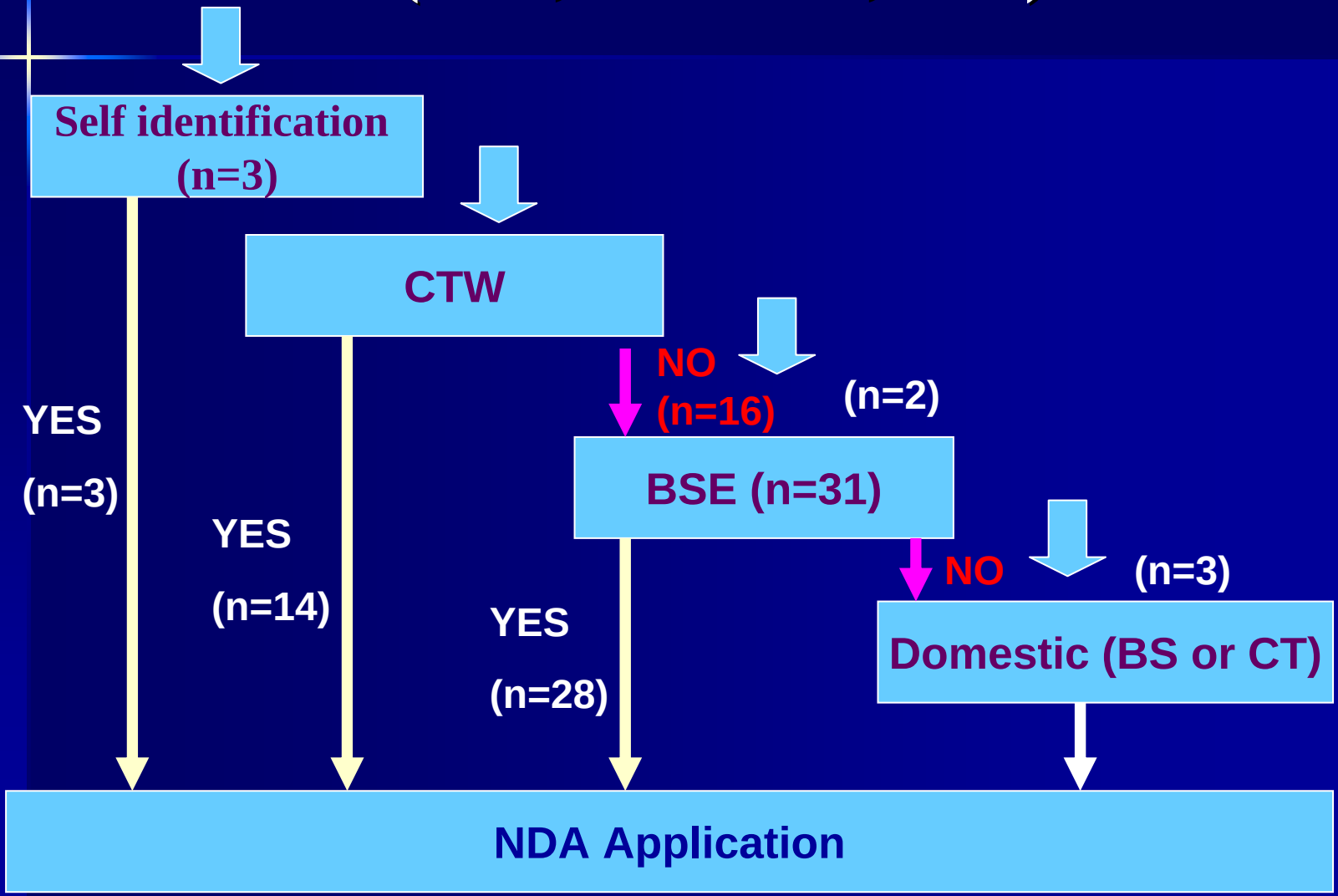
Prediction of Clinical Trial Pattern

(2001 Taipei APEC Network of Pharmaceutical Regulatory Science)



Ethnic Sensitivity in NDA Application

(n=55, 2005~2006, June)



ICH E5 Q & A (R1)
June 2, 2006

"A multi-regional ***trial*** for the purpose of ***bridging*** could be conducted in the context of a ***global development*** program designed for near simultaneous world-wide ***registration***."

- Japan Accepting Asian Data

IND Approval (2003-2005)

Early stage (phase I, II) Protocol increase but phase III predominant, 70% multi-national trials, 35% with FDA IND no.

	2003		2004		2005	
	P	S	P	S	P	S
Phase I	6	**13**	8	**12**	14	**26**
Phase II	23	**56**	22	**57**	33	**78**
Phase III	87	**278**	85	**237**	69	**242**
Phase IV	4	**12**	4	**10**	4	**5**
Total	120	**359**	119	**316**	120	**351**

P: Protocol, S: Sites

International Third Party Accreditation

- SIDCER : IRB (3 approved, including JIRB)
- ACRP : PI & CRA (test in Chinese Taipei twice a year)
- AAHRP : Clinical Trial Site (planning)

Clinical Trial Network in Chinese Taipei

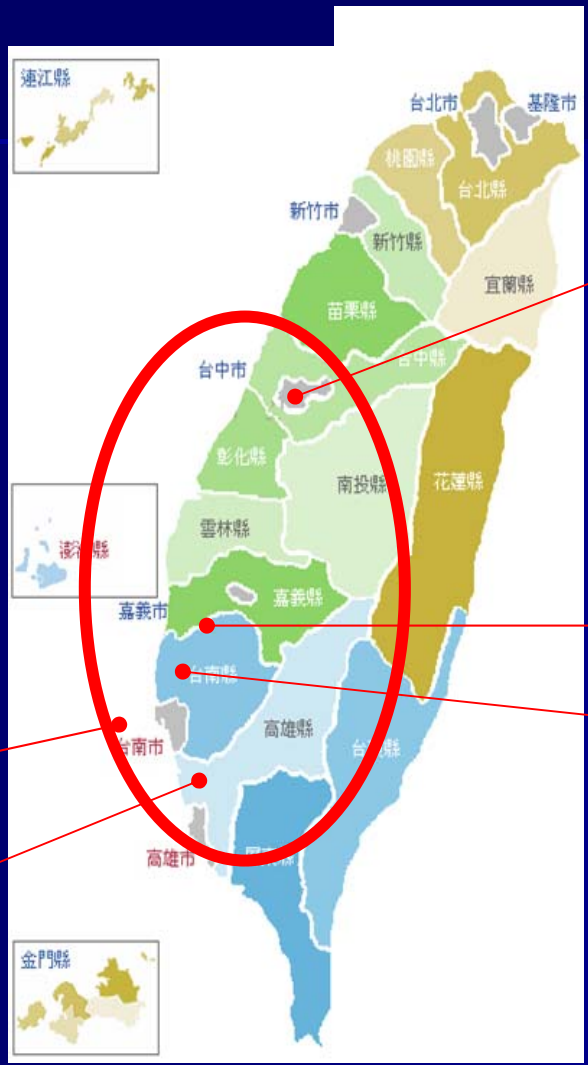
(http://www.cde.org.tw/ct_taiwan/index.htm)

- Search by : sponsor, site, phase, indication, recruiting status

(all with contact person available)

- Educational information of clinical trial for general public

Site Network



Cheng-Ching Hospital

Chi Mei Foundation Hospital **(Liouying)**

Chi Mei Foundation Hospital

National Cheng Kung University Hospital

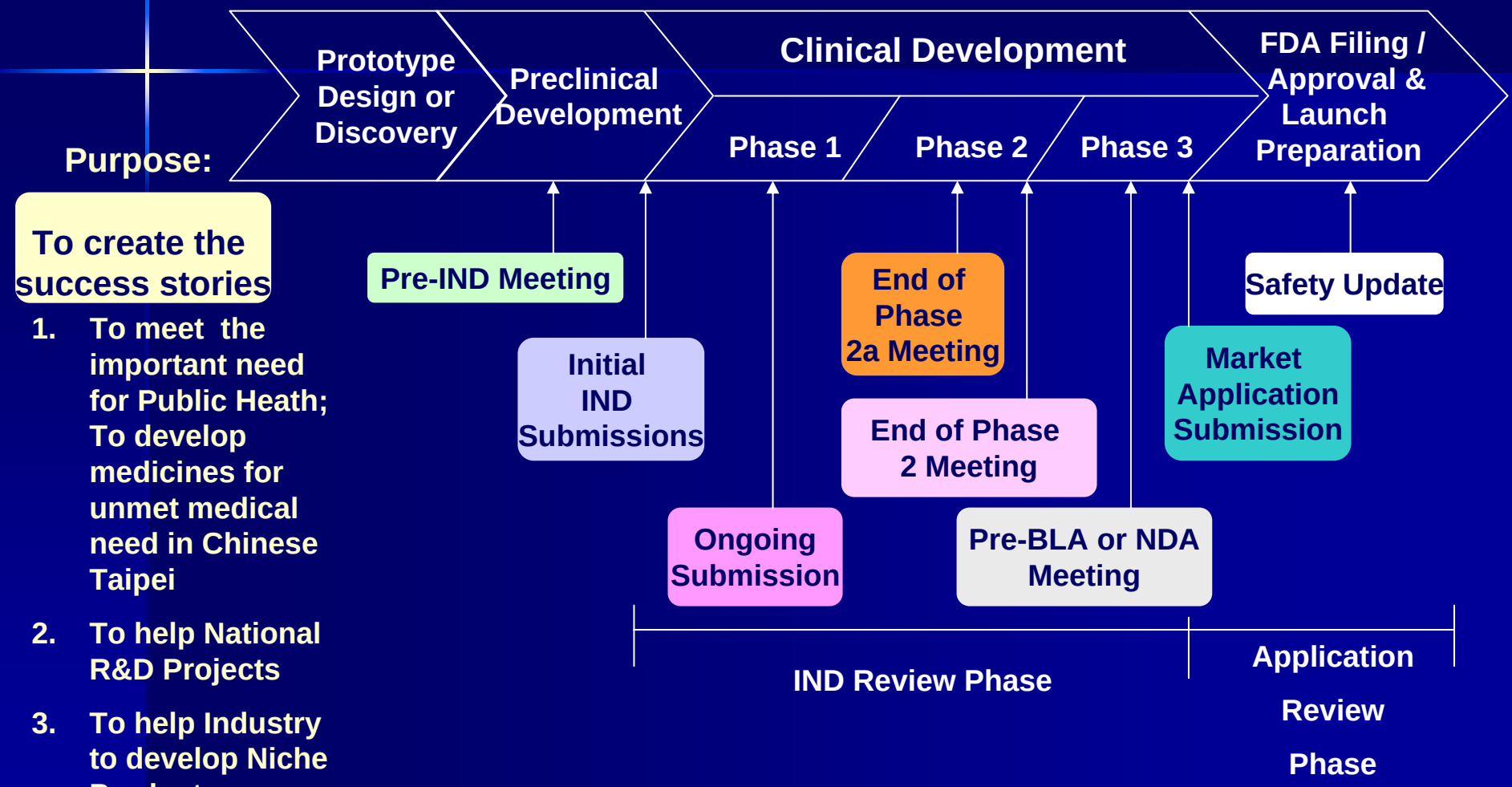
E-Da Hospital

site management organization

Chinese Taipei Biomedical Technology Island

- Clinical trials center of excellence-4 med. centers
- Critical path initiatives-CDE
- Fellowship for clinical research and regulatory science: physician, statistician, pharmacist, research nurse, reviewer
- Site management organization

Critical Path Program-Increase the Interaction of New Drug Development and Regulatory Agencies



Purpose:

To create the success stories

1. To meet the important need for Public Heath; To develop medicines for unmet medical need in Chinese Taipei
2. To help National R&D Projects
3. To help Industry to develop Niche Products

Critical Path Initiative in Chinese Taipei

11 cases selected / total 30 cases submission

Product Type	R&D status／case number			Total
	pre-IND	IND	NDA	
TCM	3	2/5	0	2/8
Chemical Drug	1	1/7	1	2/9
Biologics	4/8	1	0	4/9
Medical Devices	2/3	1/1	0	3/4
Total	7/15	4/14	1	11/30

Critical Path Initiative in Chinese Taipei

A Checking List :

- Planning Schedule, Goals, Questions to ask
- IPR evaluation report, Due Diligence report, Inventor-ship, partners. IP Estate, Freedom to Operate
- Legal Document of Technology Transfer
- R& D Team: Leader, Managers & Management Team, Technical Expert Team, Rainmakers.
- Funding mechanism, Obstacles

PURPOSE: To create successful story in Chinese Taipei

Proposal for APEC Cooperation

- APEC Network on Pharmaceutical Regulatory Science Forum website
- Joint Training Program on Regulatory Science, Exchange reviewer
- Information Sharing – “Revival of Pharmaceutical Evaluation Report Scheme”

APEC Network on Regulatory Science Forum

- APEC-Forum website (http://www.apecpharm-forum.org)
  - APEC Symposium, 2000~2005
  - News Issues & Forum
  - Country Profile
  - Links, Site Map
  - Contact Widow needed

Partnership in Harmonization (I)

Revival of PER Scheme?

- Pharmaceutical Evaluation Scheme (PER)
- A model once very well accepted before EMEA under EFTA
- Set up the standard of GRP for members
- Exchange assessment reports, CMC/CTD issues
- Training program on regulatory science

Partnership in Harmonization (II)

Revival of PER Scheme?

- Trust but verify without duplication of the whole review process- Verification of Assessment
- A platform involving regulatory agency and industries to improve regulatory affairs
- Interest from CMR, WHO, Swissmedic, TGA, Brazil, Roche, Novartis, GSK, AstraZeneca, CDE, PhRMA

Regulation, for Life

http:// www. cde.org.tw