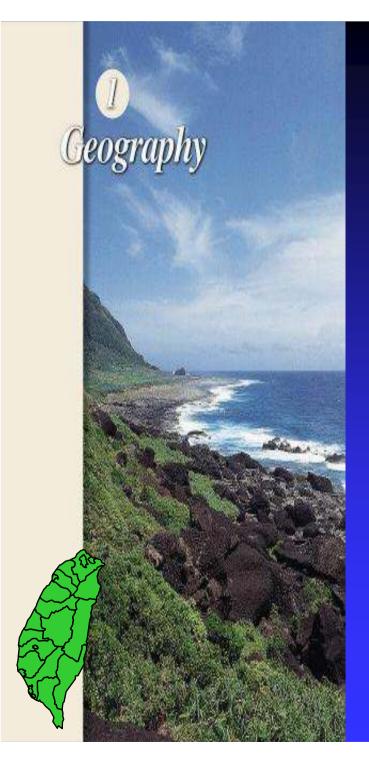
# Infrastructure of Clinical Trial in Taiwan

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## **Background Information**

- Population23 million
- Area36,006 m²
- GNPUS\$16,309
- Medical Cluster19 Medical Center114 Regional Hospital

#### **Current Status of Biotechnology Development in Taiwan**

Industry	Biotechnology	Pharmaceu- tical	Medical Device	Total
Revenue*	1.21	1.95	1.84	5
Number of manufacturers	253	419	484	1,156
Size of work force (number)	8,090	14,995	15,000	38,085
Export value*	0.48	0.36	0.84	1.68
Import value*	0.50	1.80	1.23	3.54
Domestic sales vs. export	60:40	82:18	54:46	66:34
Domestic market Demand*	1.23	3.39	2.23	6.86

<sup>\*</sup>Units: US \$ billion
Biotechnology and Pharmaceutical Industries Program Office (BPIPO), MOEA, Taiwan, 2006

## **Topics**

- Commitment and Strategy to Promote and Protect the Public Health
- GCRC and Center of Excellence
- International Harmonization

## Top Down Policy Making

Strategy to Promote the Biotech Industry 1995

R&D, IP Protection, Technology Transfer, Regulation for Premarket Review, Tax Incentive



### Strategic Review Board Annual Meeting Since 1997

Investment Environment, CRO, SMO, National Research Funding Program for Medical Product (Drug, Device, Biologics, Chinese Herbal Medicine)

## **Establishment of New Institution**

#### **JIRB**

- Authorized by hospital IRBs to review clinical protocols
- One stop for all (multi-center trials)
- Average review time calendar 32 days

## **Establishment of New Institution**

## CDE

- Full time professionals
- Based on regulatory science
- Consultation
- Critical Path Program

## **Regulatory Environment**

Implement ICH E6 for Conducting Clinical Trial

ICH: The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

 Data Exclusivity Protection for New Chemical Entity

## 14 Government Funded General Clinical Research Center

- Chang Gung Memorial Hospital Linkou Branch 長庚紀念醫院林口總院
- Buddhist Tzu Chi General Hospital 佛教慈濟綜合醫院
- Koo Foundation Sun Yat-Sen Cancer Center 奉公亮基金會和信治癌中心
- Taichung Veterans General Hospital 台中榮民總醫院
- Mackay Memorial Hospital 馬偕紀念醫院
- Changhua Christian Hospital 彰化基督教醫院
- Jianan Mental Hospital 衛生署嘉南療養院
- Yuli Hospital 衛生署玉里醫院
- Bali Psychiatric Center 衛生署八里療養院
- Taipei Medical University Hospital 臺北醫學大學附設醫院
- Chung Shan Medical University Hospital 中山醫學大學附設醫院
- China Medical University Hospital 中國醫藥大學附設醫院
- Chung-Ho Memorial Hospital, Kaohsiung Medical University 高醫中和醫院
- Chi Mei Medical Center 奇美醫院

## Biomedical Technology Island Program 2005-2009

**Infrastructure for Clinical Trial** 

Clinical Research Cooperation Network

Platform for Information Sharing

Data Processing Center for Multi-Center Trial

**Core Laboratory** 

Participation of International Trial

National Clinical
Trial Center (Center of Excellence

National Taiwan
University Hospital

Tri-Service General Hospital (Cancer)

Taipei Municipal Wan-Fang Hospital (Stroke & Brain Injury)

National Cheng Kung University Hospital (Oncology) Training Course and Professional Scholarship

GCP and Protocol Training Program

Scholarship for Physician, Study Nurse and Statistician

**Accreditation Project** 

Strengthen the Translational Research

Biomarker

**Animal Model** 

**Diagnostic Kits** 

Pharmacogenomics

Therapeutic Product and Vaccine

#### **FERCAP Recognition**

(The Forum for Ethical Review Committees in Asia and the Western Pacific Region)

#### 2005

- Changhua Christian Hospital 彰化基督教醫院
- Joint Institutional Review Board (JIRB)

#### 2006

- Chang Gung Memorial Hospital Linkou Branch 長庚紀念醫院林口總院
- National Taiwan University Hospital 台灣大學附設醫院
- Taipei Veterans General Hospital 台北榮民總醫院
- Tri-Service General Hospital 三軍總醫院

#### **2007 Under Preparation**

- National Cheng Kung University Hospital 成功大學附設醫院
- Chi Mei Medical Center 奇美醫院
- Chung-Ho Memorial Hospital, Kaohsiung Medical University 高醫中和醫院



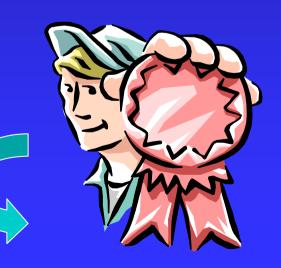
Translational Research Core Laboratory

CRO/SMO
GCRC/Center of Excellence
JIRB/FERCAP Recognition

Network of Clinical Trial CT Training Program Professional Scholarship







## **Harmonization Activities of DOH**

- Host APEC Network of Pharmaceutical Regulatory Science: every 2 years
- Participate ICH for drug regulation
- Participate GHTF and AHWP meetings for medical devices regulation



# Asian Harmonization Working Party on Medical Device Regulation

Website: www.asiahwp.org

## Host APEC Network on Pharmaceutical Regulatory Science Every Other Year Since 2000



Welcome to Taipei Nov. 27-28, 2007