

出國報告（出國類別：其他）

參加 2014 年藥物資訊協會（Drug
Information Association）

第 50 屆年會出國報告

服務機關：衛生福利部

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派赴國家：美國

出國期間：103 年 6 月 14～20 日

報告日期：103 年 9 月

公務出國報告提要

參加美國藥物資訊協會(DIA)2014年第五十屆年會出國報告

頁數 19 含附件：是否

出國計畫主辦機關/聯絡人/電話

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出國類別：1 考察2 進修3 研究4 實習5 其他

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摘要

2014年藥物資訊協會第50屆年會(2014 Drug Information Association 50th Annual Meeting)於6月15日至19日在美國聖地牙哥 Convention center舉行，為全球政府法規單位與藥物發展廠商服務交流之最大會議，提供歐美及世界各國製藥產、官、學、研界之資訊交流及教育與訓練的平台，吸引超過8,000人來自80多國家參加，本年度活動包括研討會、展示攤位及壁報。大會演講共計400多場次，依議題內容共分成23大類(tracks)，並有超過550個展覽商展出。

台灣代表團結合食品藥物管理署、財團法人醫藥品查驗中心、科技發展組、中醫藥司、卓越臨床試驗與研究中心包括國立臺灣大學附設醫院、台北醫學大學、中國醫藥大學附設醫院及知名藥廠代表包括台灣禮來公司、台灣諾華股份有限公司、台灣第一三共股份有限公司及台灣中外製藥股份有限公司等共同參與，共主持3場專題研討會、發表6場演講、1篇壁報及1個展示攤位，並辦理台灣之夜活動。宣傳台灣藥政革新的方向與措施及台灣生技製藥產業環境和法規現況，並展現台灣執行臨床試驗優勢和成效，與國際交流互動，本次活動成果豐碩。

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壹、簡介及目的

藥物資訊協會 (Drug Information Association, DIA) 為一個中立的、非營利、全球性、專業的協會，會員約 18,000 人包括從事於藥物研發 (discovery, development)、藥物生命週期管理 (life cycle management of pharmaceuticals)、醫療器材及相關產品，此協會的使命在促進創新，提高全球健康和福祉。

2014年藥物資訊協會第50屆年會 (2014 Drug Information Association 50th Annual Meeting)於6月15日至20日在美國聖地牙哥Convention center舉行，為全球政府法規單位與藥物發展廠商服務交流之最大會議，提供歐美及世界各國製藥產、官、學、研界之資訊交流及教育與訓練的平台，吸引超過8,500人來自80多國家參加，本年度活動包括研討會、展示攤位及壁報；大會演講共計400多場次，1000位講座，依議題內容共分成23大類(tracks)，並有超過450個展覽商展出。

台灣代表團結合食品藥物管理署、財團法人醫藥品查驗中心、科技發展組、中醫藥司、卓越臨床試驗與研究中心包括國立臺灣大學附設醫院、台北醫學大學、中國醫藥大學附設醫院及知名藥廠代表包括台灣禮來公司、台灣諾華股份有限公司、台灣第一三共股份有限公司及台灣中外製藥股份有限公司等共同參與，共主持3場專題研討會、發表6場演講、1篇壁報及1個展示攤位，並辦理台灣之夜活動。

台灣代表團於會場解說國內生技製藥產、官、學、研環境和法規現況，與國際交流互動，並宣傳台灣食品藥物管理署成立後，藥政革新的方向與措施，並展現台灣執行臨床試驗優勢和成效，本次活動成果豐碩。並期能吸引國際大藥廠到台投資臨床研發中心及藥物研發，以促進台灣生技產業之競爭力，進而帶動國內相關產業發展。除此之外，並藉由此年會學習藥物研發過程及法規新知。

貳、過程

一、行程簡介

6/14 (出發至美國目的地):

抵達洛杉磯機場，轉搭接駁巴士至聖地牙哥下榻飯店。

6/15 (會展攤位佈置):

協助財團法人醫藥品查驗中心同仁架設台灣展場布置。

6/16 (會展、研討會議):

1. 協助臺灣展覽現場相關工作。
2. 參訪諾華製藥集團(Genomics Institute of the Novartis Research Foundation (GNF))

6/17 (會展、研討會議):

1. 協助臺灣展覽現場相關工作。
2. 參加研討會議課程
3. 參加 Taiwan Night 法規科學專家學者聯誼餐會。

6/18 (會展結束、Taiwan Night 法規科學專家學者聯誼餐會):

1. 協助臺灣展覽現場相關工作，結束展覽現場。
2. 受臺灣 CDE 之邀請參加 Taiwan Night 法規科學專家學者聯誼餐會。

6/19-20 (返台):

由聖地牙哥轉搭接駁巴士至洛杉磯機場，返回臺北。

二、內容

財團法人醫藥品查驗中心接受衛生福利部食品藥物管理署委託辦理，負責組團規劃設計，參展主題為「Taiwan FDA-Better Regulation, Better Life」，台灣代表團之活動包括：展示攤位、受邀擔任研討會主持人與講員、發表論文壁報、參加研討

會及舉辦台灣之夜，另主辦單位醫藥品查驗中心亦安排參訪Genomics Institute of the Novartis Research Foundation (GNF)，本次活動成果豐碩。

(一) 展示攤位

本屆參展主題為「Taiwan FDA-Better Regulation, Better Life」並宣傳「Clinical Trial Centers of excellence in Taiwan」，展現台灣執行臨床試驗優勢與成效，展示攤位之號碼為 1536，緊鄰韓國 KoNECT 之攤位及日本 PMDA 之攤位。於展場中介紹台灣生技製藥產業環境和法規現況，並回復參訪者有關國內臨床試驗與研究中心相關問題，使各國參訪者了解台灣臨床試驗與研究之卓越成效及法規之進步。在展場攤位有台灣臨床試驗中心、臺灣臨床試驗合作聯盟文宣(臺灣臨床試驗合作聯盟 (Taiwan Clinical Trial Center, TCTC) 係為「生技醫藥國家型科技計畫」(簡稱 NRPB) 下的組織，已陸續成立 12 個特定疾病臨床試驗聯盟，協調整合國內各醫學中心的醫療資源，以單一窗口的服務模式，吸引推動國內、外藥廠於台灣執行符合國際規格的臨床試驗，並積極提升 IRB 審查效率，建立公用版之三方合約範本。)、財團法人醫藥品查驗中心簡介、台灣生技整合育成中心文宣等相關資料，供至攤位參訪者索取。另備有具有傳統文化特色之小禮品包括粽子鑰匙圈、馬年燈籠等，贈與至攤位之參訪者，深受喜愛與好評。



圖一、2013 DIA 參展攤位位置



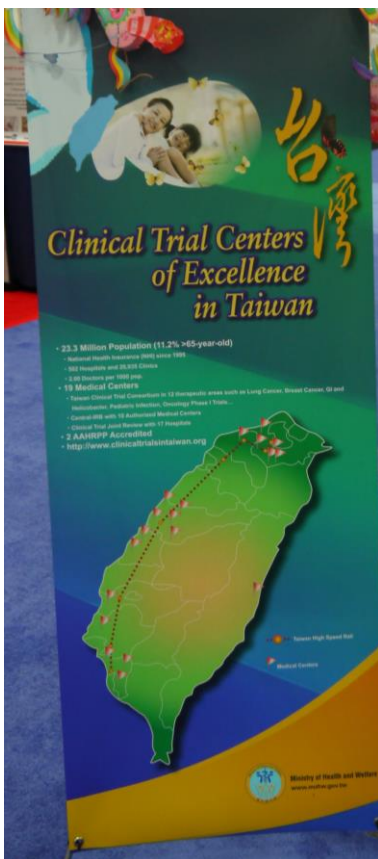
圖二、2013 DIA 台灣攤位布置



圖三、2013 DIA 台灣攤位與葉署長、高執行長及台灣業界代表合影



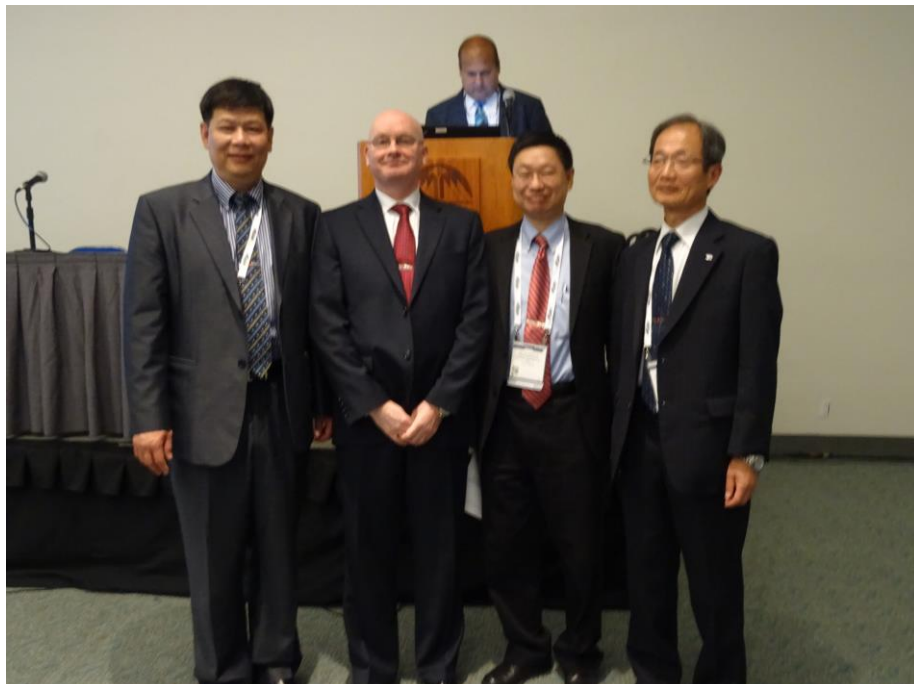
圖四、2013 DIA 向來攤位參觀者說明



(二) 主持研討會和演講及壁報

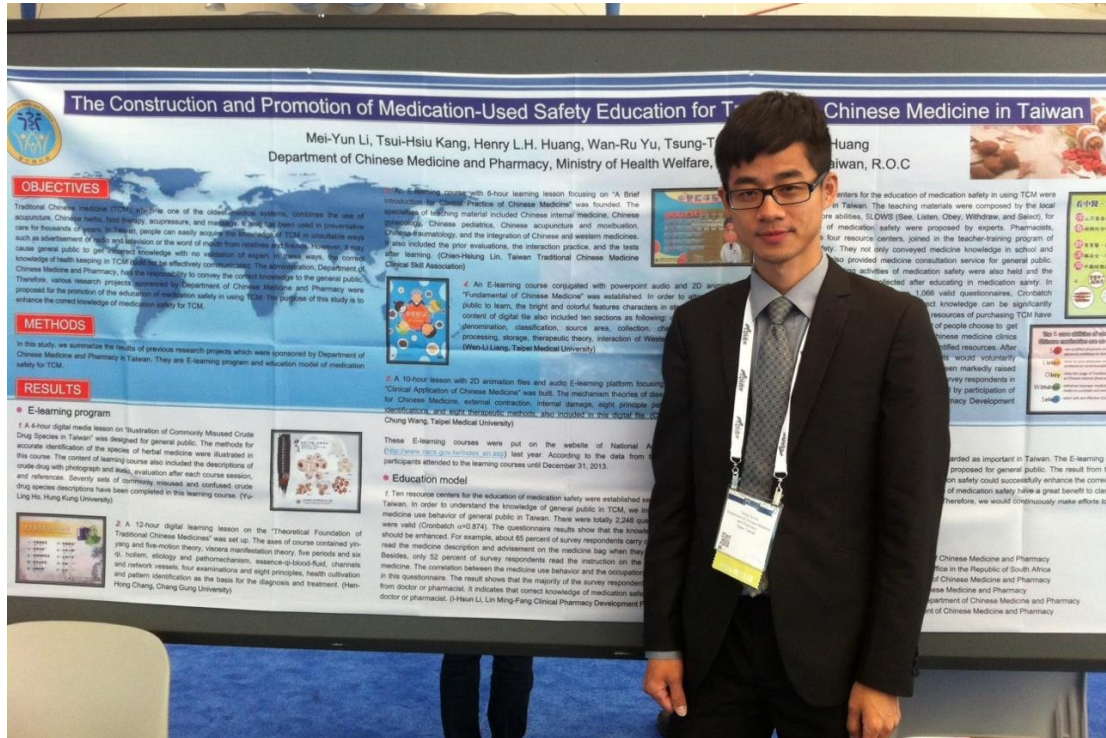
在專題演講部分，大會邀請行政院科技會報辦公室代主任林治華博士、食品藥物管理署葉明功署長及醫藥品查驗中心高純秀執行長擔任專題研討會主持人及專題講員。演講題目分別如下：

- (1) Regulatory and GCP Quality Trends in Emerging Markets-Regulatory Perspective.(林治華博士)
- (2) Recent Trend of Pharmaceutical Regulations in Taiwan.(葉明功署長)
- (3) Facilitate the Accessibility via Asia-Pacific Collaboration Network of Clinical Trials for Orphan Drugs.(林治華博士)
- (4) Novel Development and Licensing Models: The Implications for HTAs and Payers.(高純秀執行長)
- (5) Recent Advancement of the Pharmaceutical Inspection Cooperation Scheme and Good Manufacturing Practices in the Asian Pacific Region - TFDA Point of View. (葉明功署長)
- (6) CMC Regulatory Pathways in the Emerging Markets-Perspective from Taiwan. (高純秀執行長)
- (7) Evolution and Recent Reformation of Regulatory Framework of Medical Devices in Asia pacific. (林治華博士)



圖五、2013 DIA 演講後葉署長、林博士與其他演講者合影

在壁報部分，大會接受衛生福利部中醫藥司發表之論文壁報：「中醫藥衛生教育及數位學習成果」。



圖六、2013 DIA 中醫藥司發表壁報與報告者中醫藥司吳宗達博士

(三) 研討會

大會演講共計400多場次，依議題內容共分成23大類(tracks)，包括

- Clinical Operations
- Project/Portfolio Management and Strategic Planning
- Innovative Partnering Models and Outsourcing Strategies
- Nonclinical and Translational Development/Early Phase Clinical Development
- Regulation of Product Advertising and Marketing in an Ever-changing World
- Processes and Technologies for Clinical Research
- Regulatory Affairs and Submissions

- Medical Devices, In Vitro Diagnostics, and Combination Products
- Public Policy/ Health Care Compliance/ Law
- Innovative Approaches to Ensuring Compliance with Good Clinical Practice (GCP) and Quality Assurance (QA)
- Pharmaceutical Quality Statistics
- Health Economics and Outcomes (HEO)/Comparative Effectiveness Research (CER)/Health Technology Assessment (HTA)
- Clinical Safety and Pharmacovigilance
- Statistical Science and Quantitative Thinking
- Professional Development
- Rare/Orphan Diseases
- Global Regulatory
- Communities Showcase
- Executive Program
- Late Breaker
- White Paper Showcase
- Innovation Theater

(三)參訪 Genomics Institute of the Novartis Research Foundation (GNF)

本次主辦單位特別安排在 6 月 16 日中午，經由台灣諾華股份有限公司醫藥學術部藥事法規處莊處長與美國 Novartis 的 GNF 連繫後，安排參訪行程。本次參訪行程主要有：

- (1) GNF 簡介
- (2) 主題介紹：Novartis and Global Health: The Malaria.
- (3) 主題介紹：Novartis and Innovation: The Future of Cell Therapies.
- (4) 實驗室導覽

位於聖地牙哥的 GNF 是 Novartis 主要的 9 個研究機構的其中一個(其他分別位於 Emeryville, CA, USA; Cambridge, MA, USA; East Hanover, NJ, USA; Horsham, UK; Basel, Switzerland; Siena, Italy; Shanghai, China; Singapore)，其主要任務為藥物研發、解決生醫問題，例如：腫瘤學、傳染疾病、免疫學、代謝疾病等等。

此次參觀 GNF 實驗室，主要參觀 Novartis 研發之自動化機器手臂，可以設定程式後，要混和哪些試劑及劑量、要震盪多久、溫度控制等等，皆可快速及無時間限制的完成所需作業，工程師只需將程式設定好後，定時查看數據即可，對於需要大量分析資料的研究而言，確實是快速且便利許多。



圖七、2013 參訪 GNF 合影

(四) 台灣之夜活動

台灣之夜在富臨海鮮酒家舉辦，邀請澳、加、大陸、法、日、韓、英、美之藥政法規專家學者出席聯誼餐會，共計 100 餘位各國嘉賓及僑界代表熱情與會，包括駐洛杉磯辦事處副處長周慶龍，藥物資訊協會相關人員等，藉由晚宴與各國醫藥界人士互相交流並建立關係。

駐洛杉磯辦事處副處長周慶龍於致詞時，除歡迎台灣代表團外，並表示非常樂見這樣的醫藥外交，可以增進和先進國家的交流，讓台灣的醫藥生技產業能夠增加跟國際合作的機會，來提升這個產業，成為台灣下一個明星產業。

醫藥品查驗中心高純琇執行長致詞時表示很高興來到聖地牙哥，本次年會台灣代表團包含產、官、學、研界皆積極參與各項活動，宣揚台灣生技醫藥產業之成果與發展，並了解各國生物科技製藥產業的法規規範，相互交流。

晚宴上除了精緻佳餚外，主辦單位並精心安排許多表演，包括演唱中英文歌曲、表演充滿民俗風情的國樂演奏、與嘉賓共同演唱英文歌曲，晚宴在歡樂的笑聲與溫馨的氣氛中圓滿成功落幕，此次活動深獲各國友人好評，亦有助於提高台灣醫藥生技產業的國際能見度。



圖八、2013 Taiwan night 與各國人士合影

參、心得與建議

- 一、此次年會參加之成員藉此機會交流藥物臨床試驗及法規管理的經驗。本次活動透過參展、演講、台灣之夜，呈現台灣活力，提升台灣國際能見度。建議應積極持續參與國際相關會議或展覽，與國外相關領域的人士互相交流，以提升我國專業素質與國際觀，並增加我國之國際能見度。建議台灣藥廠研發管理人士參與此 DIA 年會，以了解藥物臨床試驗及法規之國際脈動，對藥廠本身之研發營運將大有助益，並增加交流，促進與國際大藥廠合作機會，提升我國醫藥產業之發展。
- 二、至攤位詢問者多對於台灣食品藥物管理署(TFDA)執行之業務以及與美國食品藥物管理署間之差異及臨床試驗目前在台灣執行之環境有興趣，但因 TFDA 並無製作相關文宣及顧攤同仁，所以無法精確的回應問題。建議 TFDA 可製作相關英文文宣，以便於國際間宣傳 TFDA。
- 三、本次大會於展場中發現有許多印度的臨床試驗人員來台灣的攤位詢問許多有關台灣臨床試驗的問題，包含新申請案之審查速度、如何與國內臨床試驗中心接洽等、目前臨床試驗在台執行成果以及相關法規問題，代表印度正積極推動國內臨床試驗產業，本國之臨床試驗除要積極趕上中、韓、日外，印度這一新興起的國家亦要注意。
- 四、另，此次展覽所見，有幾點建議可作為本組「推動臨床試驗創新及競爭力計畫」之參考。
 - (1) 我國卓越臨床試驗的成果缺少「整合型」對外行銷文宣，本年度雖有提供以各家卓越臨床中心製作之成果文宣，但以台灣整體臨床試驗之成果亮點文宣，對於吸引國外廠商來台之誘因似乎不太足夠。

(2) 另外，建議多於國際場合發表演講，以提升國際能見度，同時應提供及推廣單一窗口，用以吸引國際大藥廠來台執行臨床試驗及建立臨床研發中心，以提升國際競爭力。

(3) 若要推廣台灣臨床試驗可以韓國 KoNET 攤位為範本，其攤位很明確就是要推廣韓國的臨床試驗成果以及提供國外廠商接洽的管道，相較於台灣攤位就較無具體主題，來攤參觀者較無法一眼就看出是要宣傳什麼，這是台灣攤位比較弱勢的地方。

五、攤位所宣傳重點有些許零散，建議再更聚焦及製作主題式文宣。

六、未來年會可能在不同地方舉辦，建議主辦單位可連繫當地相關的藥廠，安排相關參訪活動，以增進國際間交流及增廣見聞。

肆、附件

本部卓越臨床試驗與研究計畫於DIA年會發送之宣導單張

台灣大學

National Taiwan University Hospital Clinical Trial Center

▶ Highest level of quality in clinical trials
▶ Human research protection
▶ Patient care

Our Vision and Mission @NTUH CTC

Our Accreditations @NTUH CTC

Our Process @NTUH CTC

Strengths @NTUH CTC

Our Accreditations @NTUH CTC

Year	Clinical Medicine Papers	Citations
2004-2008	3,458	16,509
2009-2013	4,989	27,636

(Source: ISI)

Clinical Trial @NTUH CTC

Phase I Trials: Sponsored (blue), PI-Initiated (orange)

Our Process @NTUH CTC

Timely contract review

Strengths @NTUH CTC

Assist NTUH in >600 clinical trials annually

Pivotal trials that support FDA/EMA/PMDA registration

Clinical Medicine Papers from NTU

Year	Clinical Medicine Papers	Citations
2004-2008	3,458	16,509
2009-2013	4,989	27,636

(Source: ISI)

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Email: ctc@ntuh.gov.tw
Website: <http://www.ntuh.gov.tw/en/NCTRC/>

台北榮民總醫院

General Clinical Research Center, Taipei Veterans General Hospital

Our Vision and Mission
Our Accreditations
Our Advancing Clinical Trial
Our Process
Our Strengths

Our vision:
To improve healthcare through developing clinical studies and medical research in Taiwan

Our mission:
To provide high-quality clinical research services to pharmaceutical, biotechnology and medical device industries
To achieve a full-service of academic research organization and to offer a complete spectrum of product development, clinical research, regional studies and regulatory services in Taiwan

Strengths @VGHICE

▶ Great patient population

- Annual outpatients >2,000,000
- Annual inpatients >10,000

▶ High quality academia

- >600 original publication annually
- >10% clinical trial publication
- 50 industrial investment

▶ Experienced investigators

- Cardiovascular disease
- Neurodegenerative disease
- Cancer treatment
- Inherited storage disorders
- Stem cell therapeutics

Advancing Clinical Trial @VGHICE 2011-2013

> 100 sponsored clinical trials annually

- Multi-center trials >70%
- National lead investigators >25%
- Steering committee members >10%

Our Process @VGHICE

Parallel track review system

- Timely IRB review by 3 IRBs
- Timely contract review

Our Accreditations @VGHICE

Contacts @Taipei Veterans General Hospital

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長庚紀念醫院



Clinical Trial Center of Chang Gung Memorial Hospital



Infrastructure of CTC in CGMH



Background

- Chang Gung Memorial Hospital, Northern region (Linkou, Taipei, Keelung, Taoyuan) has more than 6200 beds and serves more than 400,000 out-patients a month. We are still constantly striving to improve ourselves in service, teaching and research.
- In 2009 November, we established Clinical Trial Center (CTC) in CGMH to foster the growth of clinical research by means of the highest ethical and scientific standards in a practical and cost effective manner for new diagnostic and therapeutic discoveries and validation.

Mission

- We strive to (1) facilitate routes of communication between industry sponsorship and CGMH investigators and (2) provide the infrastructure to perform excellent clinical trials and researches.

Collaboration Infrastructure



Parallel Committees

- Experienced Protocol Review Committee (PRC) members are available to assist young investigators and CTC faculty at any stage of their career.
- Data and Safety Monitoring Board (DSMB) is responsible for oversight the conduct of trials and the safety of data and subjects.

Facilities of CTC

- Clinical Trials Support Office (CTSO) : Project manager (PM) assist administration affairs (grant application, IRB, agreement, and budget management), Clinical research coordinators (CRC) can assist Investigators requiring resources for patient evaluations, maintaining compliance, recording data, and collecting clinical samples. Clinical research associate (CRA) will be doing randomization, monitoring, and reporting to DSMB.
- The Clinical Trial Center serves as the bridge that connect the industry and academic researchers.
- CTC maintains a physician database enabling us to place research studies around the institution.

Infrastructure of CTC

- Clinical Trial Ward (8 beds) is located at 13F of Pathology Building.
- Clinical Trial Clinic and Day Care and Therapy Unit is located at 3F of Pathology Building.
- Construction of phase I unit (11 beds) , will be finished at May 2014.

Clinical Trial Day Care and Therapy Unit




Clinical Trial Center of Chang Gung Memorial Hospital

Sample Management & Laboratory Facilities

- Sample Management
 - Sample management by LIMS system, flow as next page
- Laboratory facilities
 - The permanent CTC laboratory and Tissue Banking Unit is located at Medical Building B1. The Specimen Processing Room is located at 3F.
 - CTC Specimen Processing Room for now has one 4°C refrigerator, one -20°C freezer and one -80°C freezer for samples storage located at 3J. All freezers have continual alarmed, 24-hour temperature monitoring. All temperature logs are archived on site for up to 10 years.



Pre-Study Services

- Calculation and negotiation of internal and external budgets for the CGMH with outside sponsors.
- Communication with the funding agency for all initial study administration.
- Contract negotiation, follow-up, and passage of the CGMH administration.
- Assisting in patient recruitment and enrollment, and monitoring progress and quality assurance.

Regulatory Services

- Draft of IRB submission and consent forms.
- Protocol tracking through the IRB.
- Assist draft responses to IRB queries until committee approval.
- Collection of all regulatory documents and maintenance of regulatory binder.
- Assist preparation for IRB audits and governmental inspection.

Study Services

- Full study coordination at CGMH.
- Coordinate specimen preparation, processing, and shipping.
- Clinical space for study visits and storage of laboratory supplies.
- Regular meetings with the Investigator(s), or designated person for study updates.
- Monthly administration and reconciliation of financial statements.
- Management of contract payments and receivables.

Clinical Trial Pharmacy Unit

- Receipt and storage conditions
 - Cold chain management
 - Dedicated pharmacist receive investigational products (IPs) and store them immediately according to the sponsor's instruction (SOP)
- Notify sponsor immediately on temperature deviation (TD) or any other relevant issue concerning the quality and quarantine the affected IPs
- Emergency power supply implemented
 - 4-1111 - 24/7 central alarm system
 - Notify dedicated pharmacist via e-mail and text and 24/7 on duty pharmacist in the hospital
 - IT monitoring
 - IMC logger - annual calibration
 - Check the current temperature and the function of the logger twice a day during week days
 - Active provide monthly temperature record to sponsor
 - Notify sponsor when TD becomes aware, provide report for evaluation and quarantine the affected IPs

Clinical Trial Pharmacy Unit

- Chyong-Huey Lai, MD
Professor and Director, Clinical Trial Center
- Yung-Chang Lin, M.D.
Associate professor and Vice Director, Clinical Trial Center
- Hui-Hsin Leila Cheng
Administrative Chief, Clinical Trial Center

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台北醫學大學




Taipei Medical University Joint Clinical Research Center


A RENOWNED INTERNATIONAL CLINICAL TRIALS HUB
CENTERED IN RESPONSIVENESS, INNOVATION AND
RELEVANT OUTCOMES.



- 3 Global qualified sites and investigators.
- Nationwide clinical trial consortium.
- Solid pool of Asian Chinese trial subjects.
- Standard infrastructure for cooperation in early and late clinical studies.
- Commitment to a long term quality, responsiveness and innovation.
- Open to broad cooperation with sponsors.

Taipei Medical University Joint Clinical Research Center


Early Phase Clinical Trial Ward



Our Strengths

- 3 "class A" hospitals in Taipei city (Taiwan) equipped with overall 3000 beds and 3,540,000 OPD consults patients/year.
- Over 60 beds dedicated to early clinical studies.
- Experienced clinical trial personnel (directors, project managers, coordinators, trial pharmacists, trial administrators) dedicated to respond every detail of your clinical trial needs.
- Commitment to quality and long term partnership with sponsors and investigators.

Clinical Trials @ TMU-JCRC



Written by Research Area 2012-2013


Oncology	46%
Endocrinology	20%
Cardiovascular	8%
Neurology	6%
Psychiatric	6%
Gastrointestinal Rheumatology	6%
Infectious disease	4%
Orthopedics and trauma	3%

Completion of Studies by Trial Phase 2012-2013

SA/PI/IV	35%
Phase 1	3%
Phase 2	17%
Phase 3	39%
Phase 4	5%

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中國醫藥大學附設醫院



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 Community Medicine Network for Out-Patient Clinical Trials
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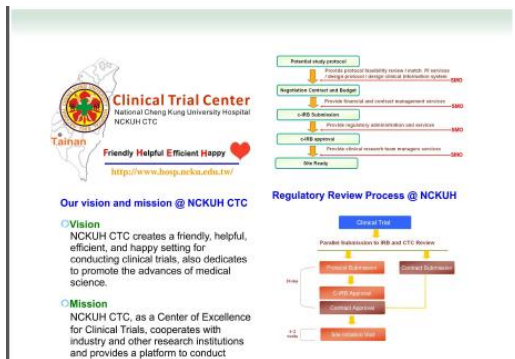
CMU Healthcare System From Medical Center, Hospitals to Clinics

Operator	2010	2011	2012
Out-patient	1,623,336	1,740,468	1,840,294
Admission	64,791	71,264	71,999
Emergency	134,070	129,070	144,000
Surgery	22,214	41,617	42,733
Delivery	1,883	2,282	3,256

World's largest TCM database with more than sixty thousands TCM compounds

1st Clinical Trial Center with In-house CRO & SMO
 Free EDC setup
 Phase I Center (44 beds)
 GTP Lab for Cell Therapy (First in Taiwan)

成功大學附設醫院



Clinical Trial Center
 National Cheng Kung University Hospital
 NCKUH CTC
 Friendly Helpful Efficient Happy
<http://www.hosp.ncku.edu.tw/>

Our vision and mission @ NCKUH CTC

Regulatory Review Process @ NCKUH

Medical Service Capacities @ NCKUH

Our SMO @ NCKUH

Our facilities @ NCKUH CTC

Pharmacy
 An independent storage space in the hospital pharmacy is well equipped for investigators to store investigational products.

Outpatient clinic for clinical trials
 Having an independent outpatient clinic that provides a private and comfortable space for trial subjects.

Ward for clinical trials
 Provides 4 beds for early phase clinical trials and 6 beds in a 24-hour running oncology ward.

Specimen handling room
 Process specimens for overseas transport and meet all the study requirements.

Data room
 Effectively preserve the trial-related documents, and carefully protect the intellectual property of each clinical trials.

Conference and monitoring room
 The room is equipped with complete video-audio communication.

Our Services @ NCKUH CTC

Clinical trial coordination

Administrative support

Human resources

Clinical Trials @ NCKUH CTC

Contacts with NCKUH CTC

2014.05