

# 藥師在臨床研究機構 (CRO) 之職涯發展

陳乃嘉 Clinical Research Associate



# Work experience

▀ - BSc. Pharmacy, Kaohsiung Medical University (2013)

Sep 2013

Sep 2015

Sep 2017



**Project Specialist**



**Clinical Research Associate**



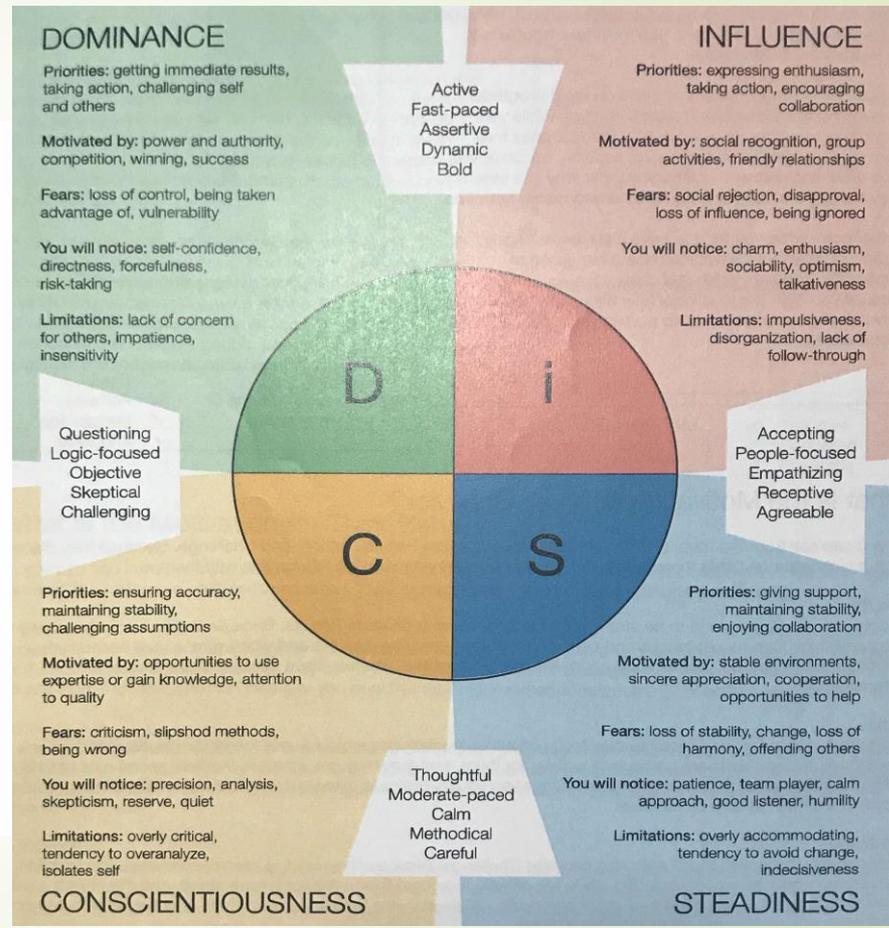
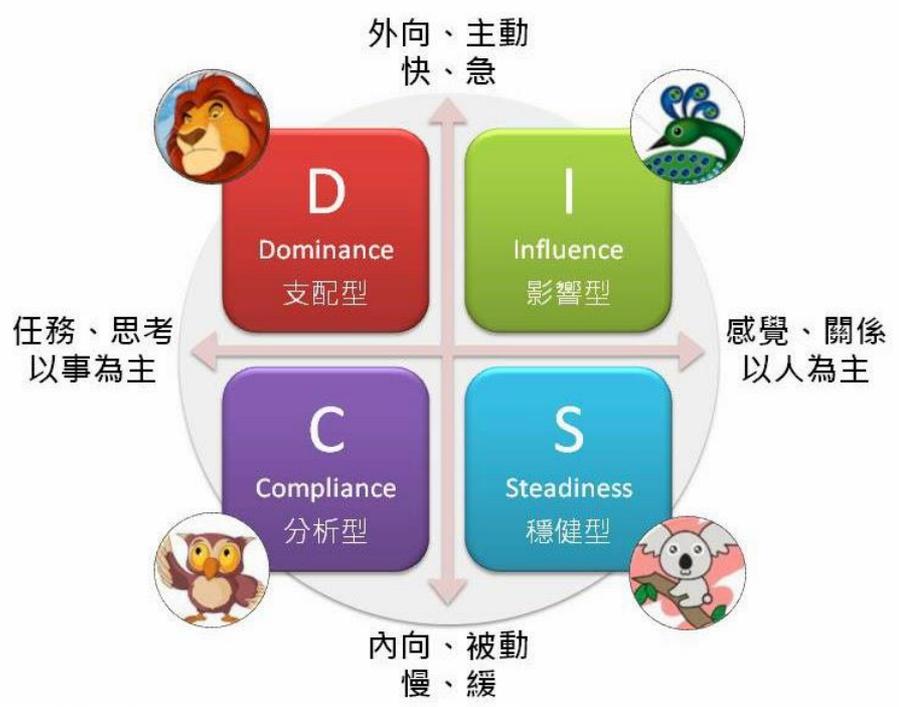
# 職涯轉換



## 為甚麼選擇當CRA?

- 喜歡與人接觸，一起解決問題
- 明確的任務目標，可專心完成
- 工作內容較非利益導向
- 運用到相關藥學、臨床知識，並且學習新藥物相關資訊
- 跨部門合作，有助未來職涯規劃發展

# DISC 人格特質分析



# Novotech: Australia's Largest Independent CRO

- ▶ Largest full-service Australian based CRO
- ▶ Established in 1996 with head office in Sydney
- ▶ Currently 14 offices in 12 countries through-out ANZ, Asia and South Africa
  - ▶ On-the-ground operations in Australia, New Zealand, India, South Korea, Taiwan, Thailand, Malaysia and Singapore, the Philippines, Hong Kong, South Africa and China.
  - ▶ Approx. 270 full-time employees
- ▶ Managed APAC component of pivotal trials for multiple FDA, EMA registered products since 2001
- ▶ Access to over 3.4 billion people in increasingly important consumer markets
- ▶ Extensive therapeutic area experience



## ➤ **CRA in Clinical Research**

## PRECLINICAL TESTING

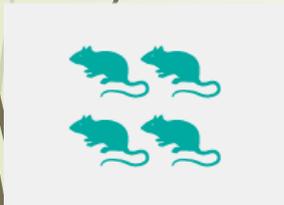
Laboratory tests



Research protocol



Animal models



## CLINICAL RESEARCH

### DOSE FINDING



Assessment of drug/therapy



### PROOF OF CONCEPT



Testing of beneficial effects



and undesirable effects



### EFFICACY & SAFETY

Comparison of new drug to placebo or standard therapy



Conducted in multiple locations throughout the world



## FINAL DATA ANALYSIS

Biostatistical analysis



Determine medically compelling and statistically significant results



## FOLLOW UP

New therapy shown to be safe and effective



Approval by medical authorities



Continuing testing

Therapy/drug is continuously tested for efficacy and safety

# Clinical Trial Process

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Phase I ~ III study;  
Phase IV study (Post-marketing)



確認臨床試驗執行是否符合  
Protocol (計畫書)、GCP、相關SOP及法規



試驗前: Submissions,  
找尋執行試驗醫院/醫師

試驗期: Monitoring

試驗收尾:  
確認所有相關資料收集  
齊全 & Well-filing

# CRA (Clinical Research Associate)

## CTA (Clinical Trial Assistant)

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Developing country/site ICF  
Documents Translation  
Vendor management  
Study materials managements  
Clinical Trial Agreement negotiation..., etc



CTA

Sponsor/CRO

Feasibility

Selection

Study Site

IRB/EC and RA approvals

Initiation

Monitoring

Close-out



CRA

Study Protocol

Patient Recruitment

New Drug Application (NDA)

Amendments

IRB/EC and RA approvals

Safety reporting

Deviations

Interim reports

Others

IRB/EC and RA approvals

# CTA Job Description

- ▶ Vendor management, liaison, payment management and tracking
- ▶ Planning and tracking of Investigator site finances and invoicing
- ▶ Responsible for site initiation, set up and maintenance of systems to track study progress, materials and documentation
- ▶ In collaboration with the study CRAs, manage the collection & tracking of essential documents centrally.
- ▶ Co-ordinate and manage distribution of study materials to clinical sites
- ▶ Responsible for tracking the transfer of study materials, data and documents
- ▶ Provide in-house support to the study CRAs & PMs
- ▶ Assist with agenda and be responsible for minute writing and distribution for project team meetings
- ▶ Lead organisation of Investigator Meetings including venue and vendor selection

# CRA Job Description

- ▶ Monitoring of investigational sites as per ICH GCP §5.18 (Monitoring) and the Clinical Monitoring Plan for each study.
- ▶ Provide written and verbal site updates (including monitoring visit reports) on study progress to the PM according to the study requirements/timelines as documented in the Clinical Monitoring Plan and Sponsor/CRO SOPs.
- ▶ Demonstrate a thorough understanding of ICH GCP, The Declaration of Helsinki, and any local guidelines as they apply to investigator, sponsor, monitor, and IEC.
- ▶ Understand the requirements of applicable local regulatory requirements, and a working knowledge of international regulations as relevant to specific clinical trials.
- ▶ In collaboration with the PM, co-ordinate the services of sub-contractors to ensure the study is adequately supported, i.e. central laboratory, drug distributors, IVRS/IWRS providers etc.
- ▶ Assist the PM with the development of protocols, CRFs, monitoring guidelines, study specific forms and local process, as per the needs of the study.

# Visits performed by CRA



- Past experience
- Enrollment capabilities
- Study team members
- Site information

- ICH GCP/ IRB& EC/ Protocol compliance
- Data review and tracking
- Documents management



# ICH GCP

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International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

- Bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration
- To achieve greater harmonisation worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner

## 藥品優良臨床試驗規範 (GCP, E6)

### Guidance for Industry: Good Clinical Practice

- 為臨床試驗設計、執行、記錄與報告之倫理與科學品質的國際標準
- 遵守此標準可確保受試者的權利、安全與福祉，使臨床試驗執行與赫爾辛基宣言的原則相符，並可保證臨床試驗數據的可信度。

## CRA的日常生活 – 出差



5:15am



6:30am



8:30am



9:30pm



看不完的病歷們 +  
與試驗團隊 “許多” 溝通協調...

## CRA的日常生活 – 進辦公室後



寫監測報告



試驗相關文件送審&  
存檔、試驗相關費  
用統整等



開會 & 訓練



接不完的電話  
與email們...

➤ 成為CRA 及後續職涯發展

## CRA所需具備的條件

### 硬實力

- 病歷閱讀 & 資料收集處理
- 語言程度
- 專案管理

### 軟實力

- 人際關係處理及溝通
- 人脈
- 細心 & 效率 間的平衡

# Career Path

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## Project Management

- Associate Project Management (APM) / Project Manager (PM)
- Clinical Operation Lead / Clinical Trial Manger

## People Management

- Clinical Trial Leader
- Clinical Research Manager

Others: Quality Assurance, Data Management, Medical Writing, Biostatistics, Pharmacovigilance..., etc.

➤ 學生時期可以做哪些準備?



Thank you