CAREER IN CLINICAL RESEARCH

What you should know about Career in Clinical Research, but could not find a proper guide / mentor…

Umakanta Sahoo, MBA, PhD
Chiltern International, Mumbai
03 June 2006
Why A Career in Clinical Research

- Sunrise Industry, Booming Market
- Huge Demand & Supply Gap, Easy Entry
- White Collared, Knowledge Intensive Job vis-à-vis Boring Sales/Marketing/Production Jobs & Unstable and Uncertain Clinical Practice
- Good Career Prospects
- Quickies (quick money, growth on the ladder)
- National & International Travel, Cross-cultural Exposure
- Increased Contacts, Marketability
- Understanding of Drugs, Diseases & Management
- I Love Research, Documentation, Paper Work
Overview

Clinical Research Environment
  The Process
  The Market
  The Players
  The Experience
  The Regulations
  The Environment
  Human Resources

Career Pathways

Career Models / Pipelines

Career Development Plans
  Professional Skill-sets
  Education & Training

Compensation, Growth & Career Prospects

Courses, Books & Periodicals
Clinical Trial (Research)

A systematic study of pharmaceutical products on human subjects – (whether patients or non-patient volunteers) – in order to discover or verify the clinical, pharmacological (including pharmacodynamics/pharmacokinetics), and/or adverse effects, with the object of determining their safety and/or efficacy.
Types of Clinical Research

**Investigator Initiated**
(your idea; know-how; study design)
1. Federal Agency (NIH, ....)
2. Contract research (Big/Small Pharma/Med Device Co, ...)
3. Collaborative research (another institution)

**Sponsor Initiated**
(their ideas; drug/device/biologic; protocol)
1. Clinical trials (Phase I, II, III, IV)
2. Contracted professional services
3. Consulting services - tests & evaluations
Clinical Trial Process

Develop Clinical Trial Plans

- Write Protocol
- Order CTMs
- Develop CRF
- Prepare IB
- Prepare Regulatory Dossier

Protocol Review & Approval

- Screen Potential Investigators
- Pre-Initiation Visits
- Select Investigators

Negotiate Budget, Identify Study Team Obtain GCP Documents, CVs, Normal Values Investigator Meeting

Make Regulatory Submission

- EC Submission

Approval

Initiation
Clinical Trial Process

Initiation Visit
- Review
  - Protocol & IB
  - CRF
  - TMF
  - Tests, Procedure
  - IP Storage etc.
  - SAE Reporting
  - Consent
  - Randomization
  - GCP Trg.
  - CTM Supplies

Monitoring Visit
- Protocol Adherence
  - SDV
  - AE / SAE
  - IP Accountability
  - Completeness
  - Filing Essential Docs
  - QA Audits
  - Third Party Audits

II Ind Scrub (In-house)

Study Status Reporting
- Database Lock

Close-out Visit
- Final Payment Archival
- Drug Retrieval / Accountability
- Closeout Report

Analysis Final Report
- IND
- GPP

CRFs – DM

DCF – DM

Data Entry
Clinical Research Partnerships

**Sponsors**
- Regulatory Approval
- Publications
- Enhanced Healthcare
- Sales & Profits

**CROs/SMOs/Monitors**
- Fee for Service
- Expand research capability
- Work satisfaction

**Investigators**
- Fee for Service
- Expand research capability
- Academic interest/recognition
- Publications
- Training & special services
- Patient care alternatives

**Patients**
- Improved care
- Decreased expenses
- New therapies
- Contribute to science
McKinsey has estimated the 2010 market size would be much higher than estimated above $1.5 – 2.0 billion by 2010.
India - Advantage

- **Speed**: Fast Recruitment
- **Cost**: 30-50% less – US / EU
- **Patient Pool**: Vast pool of treatment naïve patients
- **Language**: English speaking Investigators
- **Regulatory**: Regulatory facilitation of parallel phase studies
## The Players

<table>
<thead>
<tr>
<th>Category</th>
<th>Companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical</td>
<td>Pfizer, Eli Lilly, Novartis, Dr Reddy’s, Ranbaxy, Sanofi Aventis, Astra Zeneca, Dabur, Torrent, Zydis, Altana, Sun, Merck, GSK, Wyeth, Credence, Lupin, Galderma</td>
</tr>
<tr>
<td>Biotech Companies</td>
<td>Biocon, Shanta Biotec, Bharat Serums, Panacea, Wipro, Haffkine Bio-Pharmaceuticals, Krebs Biochemicals, Bio-Rad Labs, Indian Immunological</td>
</tr>
<tr>
<td>Discovery /Chemistry/Toxicology CRO</td>
<td>Chembiotec, DnO, Rallis, Avra, Indian Institute of Toxicology, Intox, Syngene/Biocon, Aurigene/Dr Reddy’s, Medreich, Rubicon, Natco, Bilcare</td>
</tr>
<tr>
<td>Clinical CRO (Global)</td>
<td>Quintiles, Chiltern, PPD, Covance, Pharmanet, Parexel, ICON, Kendle, Pharm Olam, IGate, PRA International</td>
</tr>
<tr>
<td>Clinical CRO (Local)</td>
<td>SIRO, Synchron, ClinInvent, Clingene, ClinWorld, ClinRx, Clintec, PharmaIntel, ACT/Suven, Reliance, Apothecaries, Clinquest</td>
</tr>
<tr>
<td>BABE CRO</td>
<td>Synchron, Lambda, Lotus Lab, Vimta Lab, Jubilant, LG Lifescience, Phoenix, Oxygen, TDM, CliniSearch, Ace Biomed, Bioassay, Reliance, PERD Centre</td>
</tr>
<tr>
<td>SMO</td>
<td>Neeman Medical, Odyssey Research, Accunova, Quintiles</td>
</tr>
<tr>
<td>Data Management CRO</td>
<td>Quintiles, Synchron, Cognizant, SIRO, Accenture, DnO, ClinInvent, TCS, IBM, HCL, Infosys, Persistent Technologies, Sristek</td>
</tr>
<tr>
<td>Central Laboratory</td>
<td>Specialty Ranbaxy, Clinigene, Metropolis, Max Healthcare, Dr Lal’s Pathlab</td>
</tr>
<tr>
<td>CR Training Institutes</td>
<td>ACE, Catalyst, ICR, Kundnani College, SIES College of Management, Kriger, Bioinformatics Institute</td>
</tr>
</tbody>
</table>
Clinical Trial Experience

- Infection
- Oncology
- Psychiatry
- Cardiology
- Endocrinology
- Gastroenterology
- Orthopaedic
- Ophthalmology
- Paediatrics
- Respiratory
- Dermatology
- Haematology
Regulations & Guidelines

- Drugs & Cosmetics Act
  - Schedule Y
- Indian GCP Guidelines
  - Clinical Trial Permission
  - Import License
  - Export License
- BA BE Guidelines
- Medical Devices Guidelines
- ICMR Guidelines for Medical Ethics
- ICH GCP Guidelines
- USFDA
- EU Directives
The Environment

Friendly Environment

Progressive Professional Development

Flat Structure / Team Approach

Flexibility – Flexi Timing
  – Flexi-work, Part Time, Full Time
  – Office Based, Home Based

Personality Development (Attitude, Knowledge, Skill)

Customer Orientation – Quality, Satisfaction, Repeat Business

Volatility, Attrition
People Involved in Trials in USA

- Sponsor Staff: 78000
- CRO Staff: 44000
- Investigator: 50000
- Other Site Staff: 35000

Source: CenterWatch 2001
Demand Supply Gap: 2010 - India

- Other Site Staff: Demand 4000, Supply 400
- Investigator: Demand 2000, Supply 300
- CRO Staff: Demand 6000, Supply 1000
- Sponsor Staff: Demand 1000, Supply 200

Rough Estimated Figure
Career Pathways

• Pharmaceutical Companies
• Clinical CROs (Contract Research Organizations)
• BA/BE Centers
• SMOs (Site Management Organizations)
• AROs (Academic Research Organizations)
• Data Management CROs
• IT Companies in Healthcare / Clinical Domain
• EDC Service Providers
• Central Laboratories
• Packaging & Labeling & Contract Manufacturers
• Investigator & Site Staff
• Training Centers
Functions in Career Pathways

- Project Management
- Site Management
- Quality Assurance
- Pharmacovigilance
- Pharmacy / Distribution
- Phase I Unit
- Central Laboratory & Vendor Services
- Contract Staffing
- Data Management
- Bio-statistics & Medical Writing
Career in CROs / Pharma / Biotech Companies

Clinical Trial Assistant (CTA)
Clinical Research Associate (CRA)
Senior CRA
Clinical Team Leader
Project Manager
Senior Project Manager
Manager Medical & Regulatory
Manager – Safety / Patents
Manager Quality Assurance
Medical Director
Associate Director – Clinical
Associate Director – Projects
Director – Business Development
Director / Head (Clinical Operations)
General Manger / CEO / President

Phase I / II / III / IV Trial
Project Management
Drug Development Planning
Monitoring
Source Data Verification
Safety Reporting
Regulatory Approval
QA Audits
Business Development
Career in SMO / ARO

Clinical Research Coordinators (CRC) / Study Coordinators
Principal Investigators / Co-Investigators
Medical Monitors
Project Manager / Senior Project Manager
Manager Medical & Regulatory Manager Quality Assurance
Manager – Business Development
Medical Director
Associate Director – Clinical
Associate Director – Projects
Director / Head (Clinical Operations)
General Manager / CEO / President

Investigator Support

Recruitment
Patient Follow up
CRF Filling
Drug Accountability
Patient Consent
Patient Safety
Data Quality
Career in Clinical Data Management

- Data Entry Operator
- Data Validation Executive
- QA Executive
- Data Manager
- QA Manager
- Statistical Programmer
- Statistician
- Data Reviewer
- Data Base Designer
- Medical Writer
- Head – Data Management

- Data Base Design
- Data Entry
- Data Validation
- Data Review
- Statistical Programming
- Medical Writing
Career in BABE Centers

Clinical Research Associate (CRA)
Project Manager
Manager Medical & Regulatory
Manager – Safety / Patents
Manager Quality Assurance
Physicians
Laboratory Technicians / Head(s)
Statisticians
Principal Investigator
Medical Writer
Medical Director
Attendants / Volunteer
Business Development Manager
Director / Head / CEO

Bioanalytical Study
Bioequivalence Study
Volunteer Selection
Bioanalysis
QA Audits
Biostatistics
Pharmacy
Report Writing
Career in IT Companies & EDC Service Providers on Clinical Domain

Domain Consultant
Oracle Programmer
Data Reviewer
Data Base Designer
SAS / Statistical Programmer
Project Manager
Validation Executive / Manager
QA Executive / Manager
Statistician
EDC Trainers
Business Development
Head – Healthcare / Life sciences

Software Solution Design
Programming
Training
Implementation
Validation
## Career in Training Institutes

<table>
<thead>
<tr>
<th>Lecturer / Trainer</th>
<th>Training Fresh Talents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Associate Professor / Professor</td>
<td>Train The Trainer</td>
</tr>
<tr>
<td>– Clinical Trial Management</td>
<td>Train The Professionals</td>
</tr>
<tr>
<td>– Data Management</td>
<td></td>
</tr>
<tr>
<td>– Bio-Statistics</td>
<td></td>
</tr>
<tr>
<td>– GCP, Regulation</td>
<td></td>
</tr>
<tr>
<td>– Project Management</td>
<td></td>
</tr>
<tr>
<td>– Project Finance</td>
<td></td>
</tr>
<tr>
<td>– Logistics</td>
<td></td>
</tr>
<tr>
<td>Training Coordinators</td>
<td></td>
</tr>
<tr>
<td>Training Director</td>
<td></td>
</tr>
</tbody>
</table>
**Career Pipelines**

<table>
<thead>
<tr>
<th>Fresh – 2 Years Experience</th>
<th>2-5 Years Experience</th>
<th>5-15 Years Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pipeline 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRA, CRC, Study Coordinator</td>
<td>Medical Advisor, Regulatory Affairs Manager, Medical Monitor, Medical Writer, Safety Officer</td>
<td>Medical Director, Head (Clinical Operations), Consultants</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pipeline 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRA, Senior CRA, Data Entry Operator, Data Validation Executive, QA Executive, Pharmacy Executive</td>
<td>Clinical Team Leader, Project Manager, Manager (Clinical Operations), QA Manager, Data Manager, Clinical Study Manager, Clinical Development Manager, Regulatory Manager, Project Manager</td>
<td>Head (Operations), Associate Director (Clinical Operations), Head (Projects), General Manager, CEO</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pipeline 3</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Base Designer, Statistical programmer, Data Validation / QC Executive</td>
<td>Data Manager, Statistician, SAS Programmer, QC Manager</td>
<td>Head Data Management, Biostatistician</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pipeline 4</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts/HR Executive, Business Development Executive</td>
<td>Manager Business Development, Manager (Clinical Trial Supplies, Manager (Accounts), Manager (HR), Manager (Training)</td>
<td>Head (HR), Director – Business Development, Head (Logistics), Head (Finance), Head (Training &amp; Development)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pipeline 5</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study Coordinator</td>
<td>Study Coordinator, Co-Investigator, Principal Investigator</td>
<td>Principal Investigator Consultant</td>
</tr>
</tbody>
</table>

**Note**: Experience levels refer to the required years of experience for each role.
Selection Process

**Written Test**
- English
- Medical Terminologies
- Essay writing, on career path

**Presentation**
- To assess communication
  (speaking, language, confidence)

**Personal Interview**
- Clarity of thoughts, career goal
- Priorities, interests
- Attitude
- Computer skills
- Knowledge of clinical research / GCP / Regulations
- Understanding of the job profile
- Communication skill
Knowledge

Basic knowledge

- Drug Development Process
- Clinical Trial Design & Statistics
- Adverse Events & Toxicology
- Regulatory & Ethics (GCP, GMP, GLP)
- Pharmacy, Pharmacokinetics, Pharmacology
- Disease, Diagnosis, Drugs
- Information Technology, Computing Skills
Skill

- Interpersonal Skills – People Management
- Communication Skills –
  - Written, Verbal, Presentation
- Time Management
- Leadership & Teamwork
- Diplomacy & Conflict Management
- Business Acumen
- Decision Making & Crisis Management
- Planning Skills
- Financial Management
CRO Staffing Models

- Home Based
- Regional Based
- Office Based
  - Sponsor office Based
  - CRO Office Based
## Cost Effectiveness

<table>
<thead>
<tr>
<th>Position</th>
<th>2001 Annual Gross Salary* US$</th>
<th>India, 2005 Annual Gross Salary US$</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTA</td>
<td>36000</td>
<td>3600</td>
<td>10%</td>
</tr>
<tr>
<td>CRA</td>
<td>52000</td>
<td>5555</td>
<td>11%</td>
</tr>
<tr>
<td>Senior CRA</td>
<td>68000</td>
<td>7750</td>
<td>11%</td>
</tr>
<tr>
<td>Regional CRA</td>
<td>65000</td>
<td>7750</td>
<td>12%</td>
</tr>
<tr>
<td>Project Manager</td>
<td>74000</td>
<td>17500</td>
<td>24%</td>
</tr>
<tr>
<td>Regulatory Affairs</td>
<td>73000</td>
<td>17500</td>
<td>24%</td>
</tr>
</tbody>
</table>

* Source: CenterWatch
### Clinical Profession Advantage

<table>
<thead>
<tr>
<th>Position</th>
<th>Annual Salary Rupees</th>
<th>Position in Comparable Industry</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTA / DEO (0.5-1)</td>
<td>150000-200000</td>
<td>Area Manager (2-3)</td>
</tr>
<tr>
<td>CRA / Data Coordinator (1-2)</td>
<td>200000-300000</td>
<td>Executive / RM / ZM (6-8)</td>
</tr>
<tr>
<td>Senior CRA (2-3)</td>
<td>300000-450000</td>
<td>Manager/ RM/ ZM (6-8)</td>
</tr>
<tr>
<td>Regional CRA (2-3)</td>
<td>300000-450000</td>
<td>RM/ZM/SM (6-8)</td>
</tr>
<tr>
<td>Project Manager / Data Manager (3-5)</td>
<td>450000-600000</td>
<td>RM/ZM/SM (8-10)</td>
</tr>
<tr>
<td>Regulatory Affairs (3-5)</td>
<td>600000-800000</td>
<td>ZM/SM (8-10)</td>
</tr>
<tr>
<td>Quality Assurance (3-5)</td>
<td>450000-600000</td>
<td>Executive/ Mgr (QA)</td>
</tr>
</tbody>
</table>

* Source: CenterWatch
## Training Institutions / Courses

<table>
<thead>
<tr>
<th>Institution</th>
<th>Website</th>
<th>Program Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academy of Clinical Excellence - Mumbai</td>
<td><a href="http://www.aceindia.org">www.aceindia.org</a></td>
<td>Post Graduate Diploma in Clinical research, 7-8 months, Fee ~ Rs 40,000</td>
</tr>
<tr>
<td>Institute of Clinical Research, Mumbai, Delhi, Bangalore</td>
<td><a href="http://www.icriindia.com">www.icriindia.com</a></td>
<td>Post Graduate Diploma in Clinical research, Fee ~ Rs 1,15,000 MSc. (Clinical Research) – 2 years, Approx. 3 Lakh Rupees</td>
</tr>
<tr>
<td>PEXA - Mumbai</td>
<td><a href="http://www.pexa.org">www.pexa.org</a></td>
<td>Certificate courses, 6 months, Fees ~ Rs 25000</td>
</tr>
<tr>
<td>University of Pune</td>
<td><a href="http://www.clinicpune.org">www.clinicpune.org</a></td>
<td>Certificate course in Clinical Research and Data Management – 6 months</td>
</tr>
<tr>
<td>Kriger Research</td>
<td><a href="http://www.krctraining.net">www.krctraining.net</a></td>
<td>2080 USD</td>
</tr>
<tr>
<td>SIES College of Management, Nerul</td>
<td><a href="http://www.siescoms.edu">www.siescoms.edu</a></td>
<td>1 module on clinical research as Part of PGD-Pharmaceutical Mgt</td>
</tr>
<tr>
<td>Kundnani College of Pharmacy Mumbai</td>
<td></td>
<td>Diploma, Short Term Course</td>
</tr>
</tbody>
</table>
# Certification

<table>
<thead>
<tr>
<th>Institution</th>
<th>Website</th>
<th>Requirements</th>
<th>Fees</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACRP</td>
<td><a href="http://www.acrpnnet.org/education/examrev/cracourse.html">www.acrpnnet.org/education/examrev/cracourse.html</a></td>
<td>2 years experience required.</td>
<td>100 USD</td>
</tr>
<tr>
<td>SoCRA</td>
<td><a href="http://www.socra.org">www.socra.org</a></td>
<td>2 years experience required.</td>
<td>195 USD</td>
</tr>
<tr>
<td>McMaster University</td>
<td><a href="http://www.mcmaster.ca">www.mcmaster.ca</a></td>
<td>5 years experience required.</td>
<td>60 USD</td>
</tr>
</tbody>
</table>
# Online Courses

<table>
<thead>
<tr>
<th>Course</th>
<th>Website</th>
<th>Duration/Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH Training</td>
<td><a href="http://www.nihtraining.com">www.nihtraining.com</a></td>
<td>certificate</td>
</tr>
<tr>
<td>ClinfoSource</td>
<td><a href="http://www.clinfosource.com">www.clinfosource.com</a></td>
<td>Certificate $100 - 500</td>
</tr>
<tr>
<td>BioInformatics Institute of India</td>
<td><a href="http://www.bii.in">www.bii.in</a></td>
<td>6 months Rs 5000</td>
</tr>
<tr>
<td>Kriger Research Canada</td>
<td><a href="http://www.krctraining.net">www.krctraining.net</a></td>
<td>$1580</td>
</tr>
</tbody>
</table>
Academy for Clinical Excellence (ACE)

- Foundations of Clinical Research & GCP
- Ethics Committee – Composition and Function
- Advanced Module on Protocol Design
- GCP for Investigators
- Diploma in Clinical Research
Suggested Books / Materials for Reading

• GCP-SOP for Clinical Researchers
  Joseph Kolman

• Handbook of Clinical Research
  Julia Llyod, Ann Raven

• Monitoring Clinical Research
  Karen E. Woodlin & John C S

• Drugs & Cosmetics Act-1940
  Vijay Malik

• Methodology of Clinical Drug Trials
  Edelstein, Weinstraub

• Clinical Trials Stuart
  Pocock

• Fundamentals of Clinical Research
  Lawrence Friedman

• Which Document, Why?
  David Hutchinson
### Suggested Magazines / Journals

<table>
<thead>
<tr>
<th>Magazine/Journal</th>
<th>Cost/Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACRP Monitor</td>
<td>$12 (Annual)</td>
</tr>
<tr>
<td>Contract Pharma</td>
<td>Free, <a href="http://www.contractpharma.com">www.contractpharma.com</a></td>
</tr>
<tr>
<td>Applied Clinical Trial</td>
<td>Free, <a href="http://www.actmagazine.com">www.actmagazine.com</a></td>
</tr>
<tr>
<td>GCPj</td>
<td><a href="http://www.gcpj.com">www.gcpj.com</a></td>
</tr>
<tr>
<td>Pharmabiz Asia</td>
<td><a href="http://www.pharmabiz.com">www.pharmabiz.com</a></td>
</tr>
<tr>
<td>Express Pharma Pulse</td>
<td><a href="http://www.expresspharmapulse.com">www.expresspharmapulse.com</a></td>
</tr>
<tr>
<td>Pharmabioworld</td>
<td><a href="http://www.pharmabioworld.com">www.pharmabioworld.com</a></td>
</tr>
<tr>
<td>Biospectrum India</td>
<td><a href="http://www.biospectrumindia.com">www.biospectrumindia.com</a></td>
</tr>
</tbody>
</table>
Worth Reading – If Interested

1. Career in Clinical Research - India, ACRP Monitor, Volume 19, October 2005
5. Bioavailability and Bioequivalence Trials, A Promising Business Opportunity in India, ACRP Monitor, will be published in Jun 2006 issue
Worth Reading – If Interested

9. 2010 - Indian Clinical Research Odyssey - Pharmabiz, February, 26, 2004
10. EDC - A new mantra for clinical trials - Pharma Pulse, April, 01, 2004
11. Laboratories & Clinical Trials in India, ACRP Monitor, Summer 2004
12. Clinical Trial in India : Monitoring Issues, ACRP Monitor, Fall 2004
13. Challenge of patient recruitment and retention: Critical role of clinical research coordinator, Pharmabiz, July 08, 2004
All the best.