Career opportunities in Clinical Research

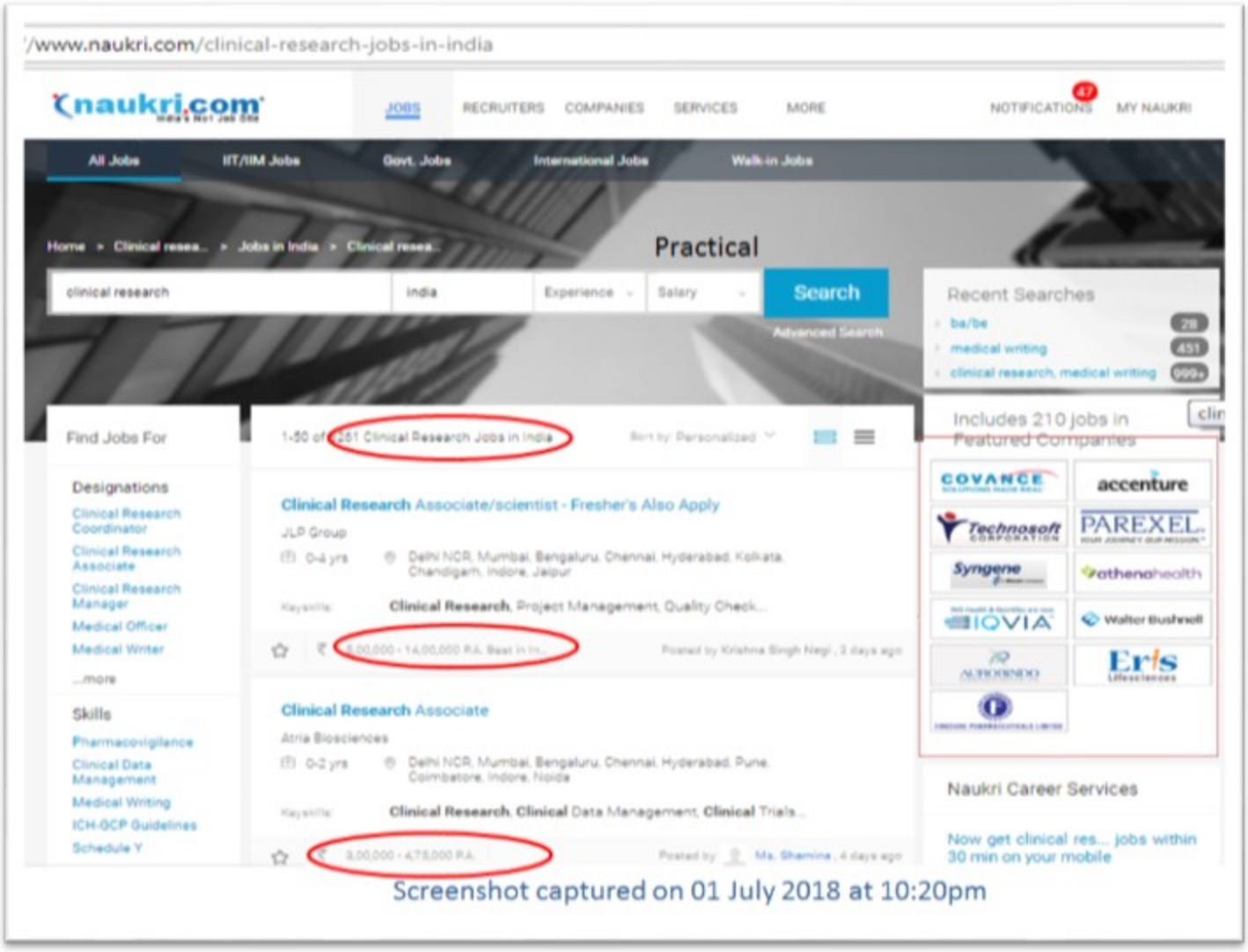
Module 13 Topic 5

Clinical Research

- Clinical research is a relatively new business and profession in India.
- There are several different career paths in clinical research.
  From administrative positions to technical, a wide range of Clinical Research jobs exist.
- Let's examine the different types of Clinical Research jobs in the India today.

Clinical Research (contd)

- Clinical research trials require a variety of different people working together to execute a proper trial.
- Doctors and scientists often oversee clinical research trials to help cure different types of diseases and conditions, and test pharmaceuticals and treatments.



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What are the growth prospects and pay-scales?

- Initially, start off as a Clinical Research Coordinator/ Clinical Research Associate/ Pharma Co vigilance associate (PVA)/ Research Associate (RA) and earn around Rs 10,000-Rs 20,000/month.
- After acquiring an experience of 2 years, they go on to the next level of becoming a Senior Clinical Research Associate/PVA/RA earning something around Rs 25,000 – Rs 40,000 per month.

What are the growth prospects and pay-scales?

- With an experience of three years, they proceed to the next level i.e. Project Manager/Team leader/Quality Assurance (QA) associate. At this stage, they earn around Rs 35,000 to Rs 65,000/month.

https://www.shiksha.com/medicine-health-sciences/paramedical/articles/career-as-a-clinical-research-associate-blogId-5494

What are the growth prospects and pay-scales?

- The next stage is that of a Manager – Clinical operation/QA/PVA/RA which requires an experience of 5-7 years. As a manager clinical operation, individuals can earn something between Rs 80,000-Rs 1,00,000/month
- Lastly, individuals end up acquiring the position of a Director or Vice-President with an experience of 7-10 years. At this level, the pay scale goes up to Rs 3,00,000/month

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Stakeholder of Clinical Research

Clinical Research Associate (CRA)	Senior Business Development Associate
/Field Monitor/	Business Development Assistant
Clinical Monitor or Trial Monitor	Senior QA Specialist
Data Manager	QA Specialist
Clinical Research Scientist	Manager of Patient Recruitment
Biostatistician	Patient Recruitment Specialist
Clinical Quality Assurance Auditor (CQA)	Administrator Clinical Systems Info
Clinical Safety Analyst	Senior CRA
Medical Writer	Manager Clinical Development
Regulatory Coordinator	Director
Senior Regulatory Associate	Senior Manager
Regulatory Specialist	Senior Vice President
CTMS Associate	Vice President

Clinical Research Associate (CRA)/ Field Monitor/ Clinical Monitor or Trial Monitor

- A CRA monitors and supervises individuals administering clinical trials.
  - Sponsors, those who pay for and request the trial, often will hire CRAs to help with the administrative needs of a clinical trial.
- CRAs may travel from trial to trial.
- Duties:
  - Reviewing case reports,
  - Ensures filing of data,
  - Performs investigational product accountability and all necessary items are properly documented.
  - Sometimes contract employees or direct hires, CRAs assist with the research of pharmaceuticals, biologics and devices.
  - CRAs monitor investigators to ensure Good Clinical Practices and protocol are in order.

Clinical Research Coordinator (CRC), Research Nurses or Site Managers

- CRCs are responsible for directing clinical trials alongside Principal Investigators (PI) or Clinical Research Associates (CRAs) using good clinical practice (GCP).
- As a Clinical Research Coordinator individuals are under the immediate direction of the investigator.
- CRCs often stay locally and monitor trials helping to prepare the site, recruit, screen and enroll patients.

Data Manager

- The data managers are the architects of the systems that produce data
- Since there is a great deal of data involved in a clinical trial, the data manager has to be incredibly thorough, strategic and analytical
- Before the clinical trial even starts, the data manager would review the protocol for the trial and create instructions for the people on the trial who are responsible for implementing the protocol

Data Manager (contd)

- The data manager would also make sure that all of the data makes sense, and that it is maintained in the database
- A Data Manager prepares protocols, reviews regulations, and otherwise helps the Senior Manager to keep the trial on track
- The Data Manager is in charge of study information, documentation and the monitoring of all research study staff

Clinical Research Scientist

- The role of primary scientist conducting clinical research trials requires years of experience working on clinical trials, conducting scientific tests and monitoring
- Individuals must be familiar with regulatory framework, submission process, assessments and more
- Travel is occasional with this position, but may be required depending on the company and sponsor of trials

Biostatistician

- When the product of the trial and data starts to become compiled, the biostatistician's job begins
- In order for the Food and Drug Administration to approve a product, the product's data must meet certain criteria
- The biostatistician would set up the parameters for data collection. They would also analyze all of the trial data and come up with a report containing the results

Biostatistician (contd)

- The person who holds this job would need to be honest and ethical. Some statistics have been known to be tweaked a bit to suit the needs of the pharmaceutical company
- The person who holds this job you would need to have ethics and morals and then stick to them

Clinical Quality Assurance Auditor (CQA)

- It is the responsibility of the clinical quality assurance auditor to inspect the documents and processes of the clinical trial to make sure that they comply with certain guidelines, known as the good clinical practice (GCP)
- The clinical quality assurance auditor also needs to make sure that the trial is adhering to the standard operating procedures (SOP)
- The standards, guidelines, and the rules of clinical trials are changing often
- It is up to the clinical assurance auditor to stay up to date on the rules and regulations and make sure that they are being followed

Clinical Safety Analyst

- The job of the clinical safety analyst on a clinical trial is a very important one
- It is their job to monitor, code, organize, and track the adverse events that happen during the trial
- The person who holds this job would need to be empathetic and have excellent people skills, as they would be acting as an advocate for the patients

Clinical Safety Analyst (contd)

- Not only would they be responsible for tracking the negative results during the trial, they would need to make sure that each patient in the trial is receiving the medical care that they need
- This person would also need to report the negative events to the Food and Drug Administration
- Most of the people who hold this position are nurses, however, people who hold other degrees can land this position as long as they have at least 2 to 4 years' experience working in the clinical field

Medical Writer

- Every finding in the clinical trial would need to be written up and published
- Medical writers can be hired by the people running the clinical trials, and also by pharmaceutical companies, hospitals, government agencies, and marketing companies
- The reports written by medical writers would be read by other pharmaceutical companies, hospitals, physicians, and even the public

Medical Writer (contd)

- A clinical trial is made up of more than just the doctors and the participants
- In order for a trial to be successful, many people are necessary who have many responsibilities. Some of these jobs are entry level and there are some jobs that participants need to work towards

Research Assistant

- During a clinical trial, a Research Assistant works with the trial sponsor to ensure that patient progress is closely followed, that the recruitment of patients has produced a random sample, that adverse results are properly recorded, and all other patient information is properly documented
- The Research Assistant sees to many other administrative duties such as updating and maintaining databases, data entry and distributing trial related supplies

Regulatory Coordinator

- A Regulatory Coordinator is responsible for making sure that regulations are followed
- This professional ensures strict adherence to all codes of ethics, monitors procedures and then reports findings to the appropriate regulatory agencies
- A Regulatory Coordinator must be familiar with all regulations to ensure compliance

Senior Regulatory Associate

- The Senior Regulatory Associate is primarily concerned with making sure that documentation is in order and regulations are followed so that paperwork for the trial can be submitted to the FDA for approval
- Senior Regulatory Associates oversee Regulatory Specialists

Regulatory Specialist

- A Regulatory Specialist helps with regulatory documentation and submission, ensures adherence to Standard Operating Procedures and otherwise assists the regulatory team with all compliance matters

CTMS Manager

- A Clinical Trial Management System (CTMS) manager oversees the program that is keeping a trial organized
- This manager is responsible for making sure that all elements of the trial are properly scheduled, performed and recorded, ensuring documentation of costs and risks related to the trial
- The CTMS Manager is supported by a CTMS Associate

CTMS Associate

- A Clinical Trial Management System Associate is responsible for assisting the CTMS Manager in all duties
- This associate updates the CTMS program when amendments are made and helps to uphold accuracy in reports

Senior Business Development Associate

- The Senior Business Development Associate works largely with clients and prospective clients in an effort to bring attention to and generate interest in medications or devices being tested through clinical research
- This person prepares and presents study proposals, timelines and budgets to clients

Business Development Assistant

- A business development assistant is responsible for supporting the project's Senior Business Development Associate in all duties
- This might include the development and maintenance of client relationships, assist with proposal development and presentation, prepare and distribute information to necessary team members and clients

Senior QA Specialist

- A Senior Quality Assurance Specialist is in charge of all good practice compliance, including clinical, laboratory and manufacturing practices
- This specialist reviews and approves documentation, training and auditing
- A Senior Quality Assurance Specialist compiles and submits all quality reports to governing agencies

QA Specialist

- A Quality Assurance Specialist assists the Senior QA Specialist in all duties
- This QA Specialist ensures proper documentation and filing of that paperwork, appropriate staff training in all good practice standards, and participates in study auditing

Manager of Patient Recruitment

- The Manager of Patient Recruitment oversees the recruitment of volunteers to participate in a clinical study
- This professional ensures that the volunteer demographic is diverse and that proper protocol is followed in the recruitment process
- The Manager of Patient Recruitment is also responsible for volunteer retention

Patient Recruitment Specialist

- A Patient Recruitment Specialist is responsible for finding and then screening volunteers to participate in a clinical study
- This specialist interviews patients to assesses their trial experiences and results
- A Patient Recruitment Specialist obtains consent and maintains strict patient confidentiality

Administrator Clinical Systems Info

- An Administrator of Clinical Systems Information is responsible for the operation of the facility wherein a trial is performed
- This Administrator of Clinical System information oversees the computer programs used during a trial at a specific location and determines which information system is best suited to the trial
- This specialist also maintains functionality of computer systems

Senior CRA

- A Senior Clinical Research Associate is involved in designing and carrying out clinical research trials
- This professional monitors all aspects of the study and communicates with sponsors, ensuring that all involved professionals are updated on trial progress
- A Senior Clinical Research Associate is responsible for budget proposals and payments
- This professional also assumes the responsibility of directing questions to the proper department

Manager Clinical Development

- The Manager of Clinical Development leads a team in the performance of clinical trials
- This specialist writes and oversees reports and forms related to the study and creates strategies for trial, procedure and medicine development

Director

- The Director of a clinical trial oversees the entire study
- This professional develops guidelines, procedures and budgets, making sure that all staff is on task and the study is running as it should
- The Director of a clinical trial monitors and reviews all department staff and all procedures, answering to upper management
- There might be a variety of directors for a variety of departments, depending on the specific clinical study

Senior Manager

- In a clinical trial, the Senior Manager manages the entire clinical study program
- This professional helps to prepare all documentation necessary for the trial, fields questions and attends inspections and audits from regulatory entities
- The Senior Manager of a clinical trial reviews all files and ensures that all documentation is correct and current
- There might be multiple Senior Managers in a clinical trial, overseeing different departments

Vice President

- The Vice President of a clinical trial is responsible for writing protocols, developing study plans and making sure study goals (including schedule and budget) are reached. In this leadership role, the Vice President will sometimes act as the study's spokesperson during interaction with governing agencies. Depending on the trial, there could be multiple VPs over different facets of the study

Senior Vice President

- A Senior Vice President of a clinical trial is the person to whom the Vice President reports
- As the senior member of the study, this professional oversees the entire administration of the trial; monitoring, reviewing and approving staff, budgets, protocol and strategy
- A Senior Vice President is also responsible for all communications with investors
- There may be more than one SVP; depending on the management needs of the trial

- The positions discussed till now in clinical research are general positions and subject to change as per the organizational structures
- However the career options in clinical research are endless

References

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