My Career Path as a Clinical Research Coordinator

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July 1, 2015

RUTGERS
Robert Wood Johnson Medical School

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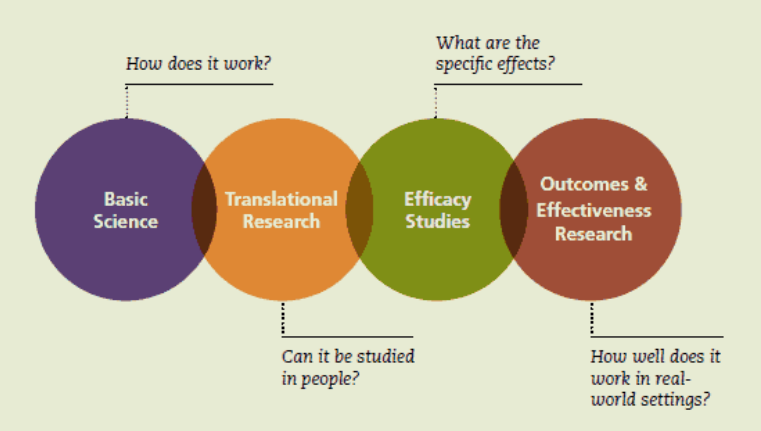
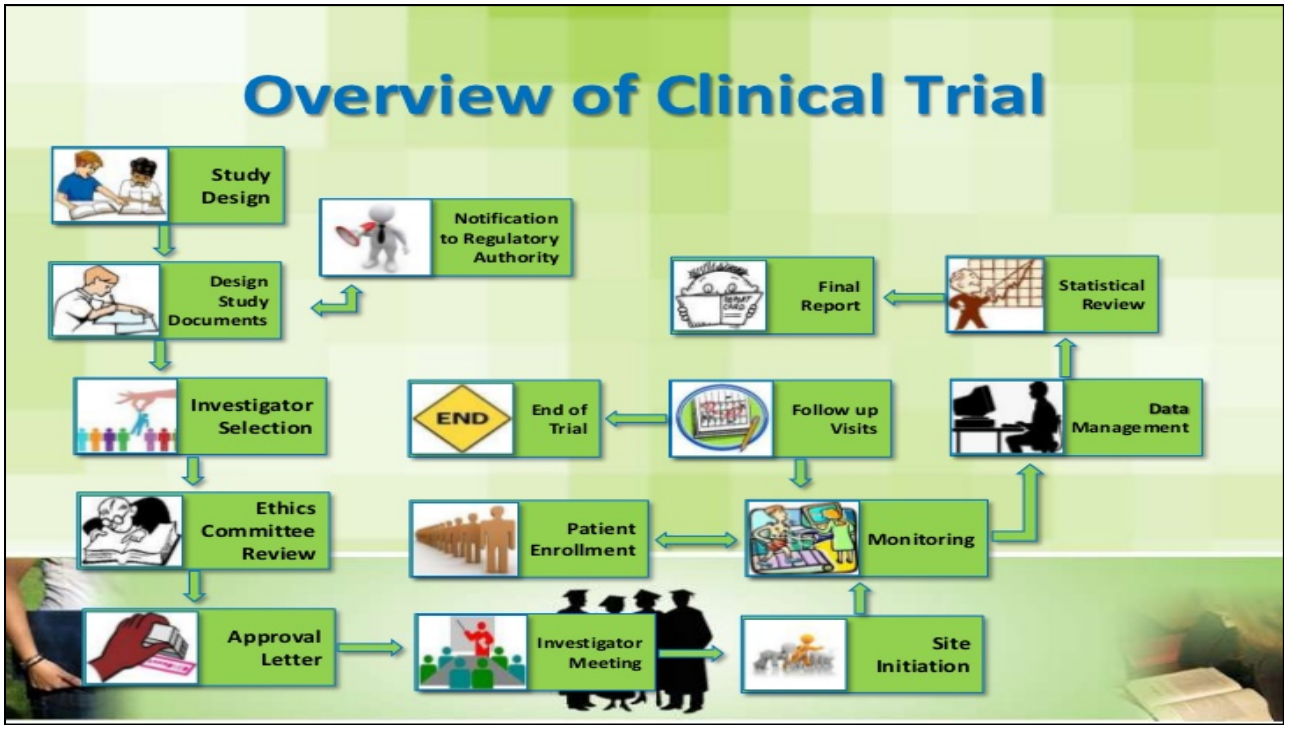
Transition from Basic Research to Clinical Trials





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Who we are and what we do

- AlcheraBio is a leading veterinary clinical contract research organization (CRO) and animal health consultancy. We work primarily with conducting clinical trials in companion animals.
- AlcheraBio is a subsidiary of Argenta, a global formulations R&D and manufacturing company headquartered in New Zealand.
- AlcheraBio is a comprehensive resource supporting many facets of the animal health industry.
- AlcheraBio has provided a variety of services for animal health companies, biotechnology and life sciences companies, and investors since our inception in April 2001.

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AlcheraBio services include:

•Veterinary clinical contract research, including pivotal and post-marketing studies

•Regulatory affairs (FDA CVM, USDA, EPA), including GMP manufacturing regulations

•Data management, including SAS programming

•Quality Assurance services (GLP and GCP)

•Project planning and management

•Marketing and related services

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Some of the companies we work with:

- Eli Lilly and Company/Janssen Pharmaceutical NV
- Pfizer Inc./King Pharmaceuticals Inc.
- Aratana Therapeutics Inc./RaQualia Pharma Inc.
- Vétoquinol
- Boehringer Ingelheim
- NexVet
- Hill's Pet

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My Life as a Clinical Research Coordinator At AlcheraBio LLC

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Daily Activities

- Responsible for multiple-site veterinary clinical studies conducted under FDA regulatory conditions (GCP).
- Conduct Investigator and site selection at veterinary clinics.
- Conduct pre-study site evaluations.
- Coordinate the creation and assembly of study materials.
- Conduct site setup and training.
- Monitor sites to ensure compliance with the protocol, applicable regulatory and guidance documents, and SOP's.
- Setup and maintain Central File.
- Process incoming study forms and notebooks.
- Ensure project organization, review patient recruitment and enrollment and tracking of data.
- Facilitate clarifications and data query resolutions.

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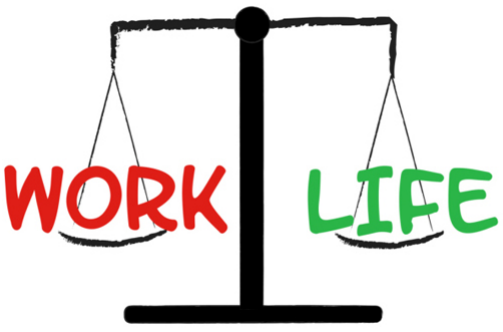
Current Projects

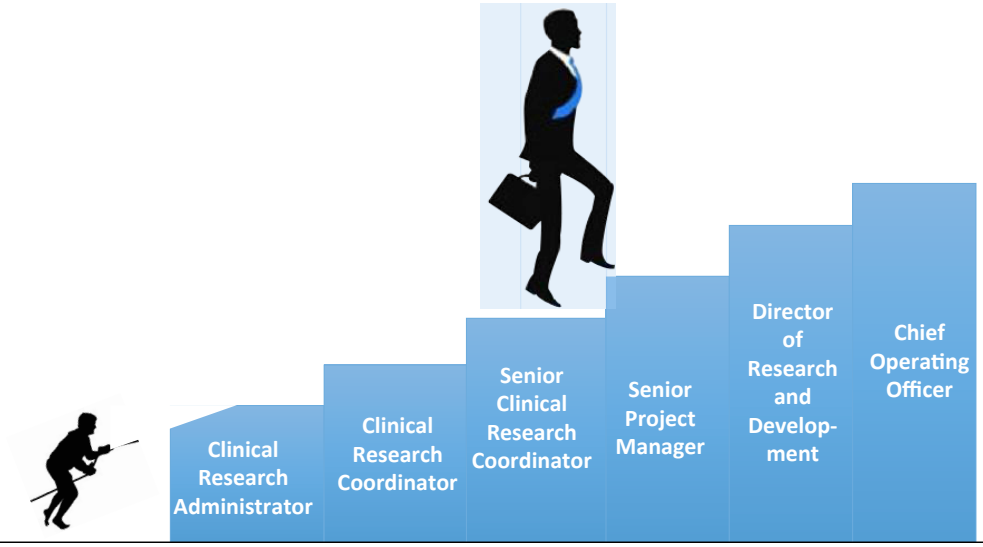
- Post Surgical Pain Management
- Osteoarthritis Pain Management
- Appetite Stimulant Study
- Skin Infection Study

Life and Work Balance

- Office
- Traveling
- Work from home



Clinical Research Career Path



Title Descriptions

- Clinical Research Coordinator

  - Ensure the protocol is being followed and clinical trial being conducted accordingly to GCP at each clinical site.

- Clinical Research Project Manager

  - Responsible for the successful completion of assigned projects conducted within the allocated timeframe and budget.

  - Ensure scientific excellence and regulatory compliance, high levels of personnel / team performance.

- Director of Research and Development

  - Leading development programs for novel from designing pre-development studies to directing pivotal licensing studies.

  - Working with marketed products to expand label claims or conduct post-marketing studies

Careers in Clinical Research

- Multinational Companies
  - Small molecule
  - Biotherapeutics
  - Medical Devices
- Small Biotech Companies
- Contract Research Organizations (CRO)

Advice

- Networking

- Keep an open mind