CAREER PATHS IN R&D AND PHARMA INDUSTRY

CRA

Ιωάννης ΡΟΥΣΣΟΣ BSc, MSc MedPhys

REQUIREMENTS TO BECOME A CRA

1. **Educational Requirements**
   a. A Bachelors Degree is a must, preferably in life sciences.
   b. If education not related to Life science, be prepared or extra training courses.
   c. A MDPhD is not enough if you lack experience.
2. **Qualifications**
   a. Monitoring Experience, if not you have to invest (money or time).
   b. Enter Training Courses and after 6-12 months you become CRA.
   c. Start as CTA or CRC to get highly valued experience.
3. **CRA Training Courses**
   a. Basic GCP course.
   b. Add for extra value (Advanced GCP, Time Management, Stress Management, GDP, GLP, ……. e.t.c.
4. **Experience**

RESPONSIBILITIES

Presenting trial protocols to a steering committee

Train investigators in data collection forms, known as CRFs or e-CRFs.

Coordinating with the ethics committee, which safeguards the rights, safety and wellbeing of all trial subjects

Managing regulatory authority applications and approvals that oversee the research and marketing of new and existing drugs.

Identifying and assessing the suitability of facilities to be used as the clinical trial site.

Identifying/selecting an investigator who will be responsible for the conduct of the trial at the trial site.

Liaising with doctors/consultants or investigators on conducting the trial.

Ensuring each site/center has the trial materials, including the trial drug /investigational medicinal product.

Training the site staff to trial-specific industry standards.

Monitoring the trial throughout its duration, which involves visiting the trial sites on a regular basis.

Verifying that data entered on to the CRFs is consistent with patient clinical notes, known as source data/document verification (SDV).

Collecting completed CRFs from hospitals and general practices.

Writing visit reports and filing and collating trial documentation and reports.

Ensuring all unused trial supplies are accounted for.

Closing down trial sites on completion of the trial.

Archiving study documentation and correspondence.

And, and ,and, and …….

SKILLS

- Good excellent organizational skill.
- The ability to motivate others.
- The ability to multi-task and think on your feet.
- Accuracy, numeracy and an eye for detail.
- Excellent communication skills (both written and oral) and the ability to build effective relationships with trial site/center staff and colleagues.
- IT and administrative skills - the job involves a lot of documentation and recording of information through computerized processes such as:
  - ✓ CTMS (Clinical Trial Management Systems).
  - ✓ EDC (Electronic Data Capture).
  - ✓ e-TMF (Trial Master File).
  - ✓ e-CRF

WORKING HOURS – SALARY

- Working conditions vary between companies, although the hours are usually Monday to Friday in full-time basis.
- You should expect to work some evenings, although weekend or shift work is uncommon (?).
- The job can involve a lot of travelling, especially if working in a field-based role. You may be out of the office three or four days a week, possibly including overnight stays.
- Short term contracts of 6 to 12 months with a company are common, meaning you may work more like a contractor than a permanent employee.
- Part-time work is possible, as they are career breaks.
- Salaries vary from company to company.
- Income figures are intended as a guide only.
- Additional benefits, such as a car allowance and bonus are offered in some cases(?).

CAREER PROSPECTS

Junior CRA Working as CTA or in-house CRA, organizing and archiving documents and correspondence.

CRA level I Working on pre-trial procedures, setting up and organizing clinical trial sites (with some supervision), archiving documents and correspondence.

CRA level II Selecting investigators, coordinating ethics committee and regulatory authority applications, supervising trial supplies, monitoring and attending investigator meetings.

CRA level III Any of the above tasks plus supervising, training and mentoring junior staff, project management of a whole trial.

Senior CRA Any of the above tasks plus supervising, training and mentoring junior staff, project management of one or more trials possibly on an international scale, protocol development and design of case report forms (CRFs).

CTM Any of the above tasks plus supervising, training and mentoring the staff of the Clinical Operations.

CPM Project Managers must be certified now days.

FUTURE CHANGES IN R&D AND PHARMA INDUSTRY

MINIZE THE COST (~2.5 Billion$ to develop a new drug)

For the field of CRA means less compensation in all expenditure:

1. **CENTRALIZED Procedures to avoid same work for every country and/or site.**
2. **Decrease Site Visits, RISK BASED MONITORING.**
3. **OUTSOURCING to use resources when is needed.**
4. **STANDARDIZATION of Hospital Databases to accept direct recording of SD.**
5. **CENTRALIZED recording of AE, SAE, Pharmacovigilance.**
6. **Decrease R&D ASSETS and HUMAN RESOURCES.**
7. **New Philosophy, COLLECT DATA on source AUTOMATICALLY SAVED in international hospital networks to avoid investigator data entering/recording (no need of SDV).**

CAREER PATHS IN R&D AND PHARMA INDUSTRY

THE CRA

17 June 2017