"Testing for safety and effectiveness..."

Bio-economy Career Profile

Position: Clinical Project Manager

Name: Nicola Price

Company: Xenon Pharmaceuticals, Inc.

Salary Range: $60,000 to $120,000 per year

What I do:

My job is to plan and coordinate the various activities required to perform the human clinical trials and ensure that everything is completed on time and budget.

Once a potential drug product has been tested in animals and is found to be non-toxic and efficacious, we can start testing in humans for safety and effectiveness. Clinical trials range from small studies, which may involve less than 30 healthy volunteers, to huge studies, which may involve hundreds to thousands of volunteer patients at sites around the world. Typically, we administer the new medication under close medical supervision and record and analyze any side effects.

I generate the plans and timelines, select a site (or sites) for the trial to be carried out, and work with the site and scientists to ensure they have everything they require. Before the trial can begin, I coordinate the submission of supporting documentation to the relevant government authority for its approval. When the trial is ongoing, I monitor progress and deal with any issues that may arise. Once the trial is complete, I coordinate the data analysis, authoring, review, and finalization of the clinical-study report.

What education and skills do candidates need for this position?

There are no academic qualifications that will automatically make you eligible to be a Clinical Project Manager. A Bachelor of Science degree is usually preferred, but is not essential. Many project managers have nursing degrees or diplomas because they moved from nursing into a CRA role and then into project management.

You require excellent verbal and written communication, strong organization and time-management skills, and an ability to prioritize effectively. You need to be able to interact with a wide range of people with different skills, education, and experiences. You should have a solid understanding of the different activities required to perform clinical trials and knowledge of regulatory requirements. You also need to be detail oriented while not losing sight of the overall plan.

What are the best parts of your job?

I like that the job varies. One day I might spend the entire day writing or editing a document and the next day I'll be in meetings or interacting with people, making plans, dealing with issues or answering project-related questions. It is also very rewarding to know that the drugs tested in clinical trials that I helped design and implement will be used to treat patients with severe or debilitating diseases.

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