

Congratulations on becoming selected for the second round of interviews for Director of Clinical Trials on an exciting new project at Merck & Company.

We appreciate your continued interest in a position in the Division of Clinical Development at Merck Pharmaceuticals. As a member of this team, you will be part of an exciting effort to determine the effectiveness of a new antidepressant medication. At Merck, we are fully committed to improving health through the ethical and safe development of new medications. As covered

in your initial interview, the answers you give in this process are confidential. You are also bound by the non-disclosure agreement you signed during the initial interview process. Please answer all of the questions to your best ability. We look forward to seeing you during the final interview process.

Applicant name:

Application date: July 27, 2010

Position: Director of Clinical Trials

Salary range: \$105,000-130,000 (plus benefits)

Please check if you would not wish your answers to be used to assess learning outcomes

Ethics

At Merck, ethics are our first priority. We are looking for scientists, managers, administrators, and workers who share this priority.

Give your thoughts, in a paragraph, on the important factors to consider when designing an *ethical* study in order to test a new drug.

Ethics is one of the main things between staying in business and having some major problems with the law and many people. Making ethics one of your top priorities is a good way to show that you care about the people around your business, and the ones in it. Without good ethics on your company you can lose your good people and your good work environment. Ethics is one of the main thing in keeping a good work environment, and a good work ethic.

Ethics is something that will give your company a good reputation to the outside world so that you can get more participants for studies to come. Without morality in your studies you would have many people questioning your work and what you are trying to do. And with people questioning your work you have less and less participants in your studies which can make them less valid to the people that use your results.

Maintaining great ethics is one of the easiest ways to maintain a growing company and its great products. Having programs in your company to teach and keep good ethics is a great way to keep a positive vibe around the people of your company. A good vibe around the people of the company makes it a great work environment, and a better product. Ethics is the basis of a growing company in a poor economy.

Ethics

Think of a situation in which you have had to think about ethics in research design. What did you learn from the experience?

A research design that I can recall that I have thought about ethics on is the Milgrams experiment that we have talked about in this class. In the Milgrams design they would have a person asking questions to a participants that were hooked up to a shocking apparatus that when they would miss a question they were asked to shock them. Each question that they missed they were asked to turn up the voltage of the shock. But something that the person that was giving the shock didn't know was that the person wasn't being shocked wasn't being shocked. So the person that was shocking would think that they were hurting the participant, but really they weren't.

The ethical dilemma in this design is that you had people that were directing the experiment basically forcing the people that were doing the shocking till they would break, and stop doing the

experiment. This raises moral issues with some people about making the participant feel uncomfortable about hurting another human being, even though they don't know that they aren't.

Something that this experimental design has taught me about ethics is that it is best to use ethics in your designs to make sure that you can make all of your participants happy, as well as all the people that you effect with your research and results. It isn't moral to make people feel uncomfortable about hurting other people, and many other things. Ethics isn't something that you can take lightly, because they can get you and your company in lots of trouble, and in bad graces with the people that you wish to be your participants.

Study Design

We are currently about to start a Phase 3 human clinical trial in order to test the effectiveness of our newly developed antidepressant, *Serenique* (elevevor).

As Director of Clinical trials, you will work with your team to design and oversee the research studies for this exciting new depression treatment. Describe, in general, how you will go about this. Please give specific information on important research methodology considerations for this study.

Testing this new drug could make a great medical and psychological breakthrough, and I want to make sure that it is done right to get the best results. Testing medicine can have a lot of liability if not conducted in the right manner. To start the procedure I would go through a team meeting that I would make sure that all of my team is clear with what our goals are in testing this drug and that we all know what kind of risk can go along with it.

When setting up my design for the experiment I would start out by selecting people that have depression so that we can see what the effect of our new drug is on people with depression. I would want to make sure that my groups of people are very diverse so that I can get a good reading on what our medication is doing to them. So I would have a random sample of people in five groups, so that we can test multiple factors so that we can let people know what kinds of things that can counter act or be bad to take with our new medicine. We could test factors like pregnancy, smoking, overweight, and age to get the best results possible.

I would make sure that during the testing time that all of my team is aware what is going on so that they can help the whole team come up with good results on the medicine. I would make sure that we have a checks process so that we don't have any missing information that is withheld from anyone on our team. We would also have meetings for everyone to share what is going on with their groups of people so that we can see trends and make the best results out of this design.

Study Design

You are in the second round of interviews because of your research methodology experience.

Describe a time in the past when you have conducted your own research. What problems did you encounter and what did you learn?

In research there are many things that you can make a mistake on or even miss. In research you have to be very organized in what you are doing, and have a team that are helping you to be very organized as well. Organization and a system of research can help eliminate mistakes and miss things that can be vital to your work. I also have found that it is great to have a team around you that you can get along with and have the same mindset that you do, so that you can get the best results as possible.

When you are working with other people you have to take in to account everyone's opinions and not overlook things that you don't like. You have to take in to account the opinion of the people that you testing on, because those are the opinions that make up the majority of your results. Without these opinions you would have no experiment. But you also have to give close attention to the people that you are working with because they are the trained people that have educated opinions that you should have surrounded yourself with.

Some things that I learned from the experimental designs that I have seen is that you have to have people that support what you are doing, and have the people around you to help you get the results you want. Without the support of people from the outside, you might be doing something that might be immoral to others. Something else I have learned that makes your research go much smother is giving attention to all opinions that you have been given by the people that are around you as well as your participants.

Study Design

Explain in what ways science may be limited for studies testing the effectiveness of antidepressant medications.

Some of the ways that science is limited to testing antidepressant medicine is that there are many people with the depression but they don't always want to be part of studies, or try new medicines. People that are depressed are not always going to want to go try new medicines; they are just going to want to use the options out there that are proven to work, to get over their symptoms now. Some people might just have beliefs that they don't want to test medicine on human subjects, so they do not want to participate in these studies.

Also in the medicine world they are always hurting to get funding for all the medicines that they keep testing. So since depression isn't one of the biggest killers right now they don't get as much funding as would some cancer centers to test for solutions. Sometimes you have to compensate people for their time and their body as a test subject on your medicine. So funding and lack of willing people might be some limitations to testing new antidepressants.

The Merck Team

Though you are applying to be a member of the Division of Clinical Development, members of this division often work with members of the Division of Marketing and Advertising. Merck & Co., Inc. expects *Serenique* (levexor) will compete with the antidepressant *Pristiq* (desvenlafaxine) made by Wyeth Pharmaceuticals. We would like you to review their television and internet advertisements for this product prior to answering the following questions. (Trademark requirements prohibit us from providing links to their advertisements.)

Please identify any claims of fact made for *Pristiq* and the basis AND the validity of those claims.

ALSO please provide additional explanations for why their claims of effectiveness might not be true or why the claims may be questionable. Your answer may continue on the next page.

I think that one of the biggest claims that they are making in their ad is that the suicide effects that might come with the drug, are more self based, than medicine effected. I think that they have made this claim so that when people think about or do kill themselves while on the drug they aren't liable for what happened. Making this claim is a little bias on their part just because it sounds like they have no proof of this effecting patient. So the validity of this claim isn't very good, it is just more of a way to save them if an event like this was to occur. In these new medicines I feel that there are so many risks involved with them that you have to be careful of what you take. With all these conditions that they tell you to be careful of what you take it with, it makes me think that they might not know a whole lot about their drug. Plus when you do take the drug you have another list of things that you have to worry about. The symptoms that might occur with it when you do take the drug, like nausea, dizziness, headache, and diarrhea. I don't feel that you should have to worry about that many different kinds of sicknesses, when taking something that is supposed to help you out. I feel that with drugs like this you need to know what effects people, so that you don't have to fill a page about how this might make you sick in other ways.

With medical claims that they make with all of these new medicines, is that most of the problems may not happen to you but it is just there so that the company is not liable for their product when you take it. So most of the claims that the companies make with their drugs they do not have to be true, or proven by their researchers, but are put on there for legal issues. Most of the drugs out there today are acceptable to take, but there are also the ones out there that are not.

The Merck Team *(continued)*

Other information

In this section please supply us with any information you feel may help us with your application. For example, you may describe what you feel you have learned about research methodology in your course work or in other activities. You may also tell us how understanding research is important for everyday life. We would also like to know how you feel our consumers may or may not understand research and how that affects how we develop and market our life improving pharmaceuticals.

I think that in the new modern research that we are doing there is a lot of liability that can occur with the work you can be doing. I think that you have to be very organized, and be very knowledgeable in what you are doing, or it can be detrimental to you and your company. So you have to think about everything at all times to make sure that you are moral about everything you do so that you can keep good standings in the world as a pharmaceuticals company. Other things that can help you grow as a company is to have a good set of donors or even have support groups that can bring you funding for your research. You also need to keep in good standings with population or people that you are trying to make medicines for.

Being a pharmaceuticals company you have to keep the people that you are marketing to confident in your products, and keeping their trust in you. In a pharmaceutical company I think that it is good to have a wide variety of medicines that treat all kinds of illnesses. With all the questions that people have with the medicine that people are creating, you have to be loyal to your customers, and always trying to make new ones. Making more people confident in your product will make growth and expansion a lot easier.