

Day in the life of a Global Trial Manager

WHITEPAPER

Before LSAC

8:00 - 9:00 am

I have my regular 1:1 with my portfolio lead and he tells me that there is a meeting later today where the TA lead wants to get a detailed estimate on number of sites, countries and protocol feasibility for a new indication/study. He needs the information by 2pm and Dr. X from the clinical team will be working with me on this. I asked for more time and he said he found out about that study that morning, so it's late breaking news. I told him that I had lot of meetings that day. He interrupted me and said he understands my concerns but he has no choice.

9:00 - 9:30 am

I leave his office and call Dr. X, we start discussing the study and he informs me that he also heard about that study this morning and hasn't gathered his thoughts either. I tell him that I will come to his office as soon as I can and then we will work on this together. I tell my admin to push out my meetings because of this urgent request.

After LSAC

8:00 - 9:00 am

I have my regular 1:1 with my portfolio lead and he tells me that there is a meeting later today where the TA lead wants to get a detailed estimate on number of sites, countries and protocol feasibility for a new indication/study. He needs the information by 2pm and Dr. X from the clinical team will be working with me on this. I told him that should be possible and would send over the information, hopefully a lot earlier than that.

9:00 - 9:30 am

I leave his office and call Dr. X, we start discussing the study and he informs me that he also heard about that study this morning and hasn't gathered his thoughts either. I tell him that I will come to his office as soon as I can and then we will work on this together. I tell my admin to move my 10am meeting to the following day but leave my rest of the meetings as planned.

Before LSAC

9:30 to 1:30 pm

In Dr. X's office, we start to think about how to even tackle this problem. We decide to divide and conquer. I start looking at historical trials from CTMS, while he starts pulling historical protocols, I/E criteria, etc. Very soon, we find ourselves with an avalanche of data and lots of spreadsheets with different calculations for several different scenarios. We both are exasperated with trying to keep our different scenarios straight. During this time, there is a lot of tension between us as I tell him that adding more MRI scans makes the study more complex and will hurt the study, to which he challenges me back and asks in what quantifiable ways. I can explain only in empirical terms to which he says that as an ops person it is my job to deal with such things. Also, we can't agree on where the sites would be placed and their expected performance. He wants to load the study with sites that have KOLs while I want to be very pragmatic, but without knowing whether these KOLs have real patients versus what they tell us, there is no way for both of us to know what is reality. Anyway, after 4+ hours, we both agree that we have done our best and go with information we have and our gut feel.

After LSAC

9:30 to 1:30 pm

I go to Dr. X's office and we quickly go through CTMS to identify some historical studies and pick 2 studies. Dr. X pulls out those 2 protocols while I log into LSAC. We start simulating the protocol's inclusion and exclusion criteria in LSAC and we are able to get a quick view into the enrollment funnel and how each I/E criteria would affect enrollment. Dr. X, as usual, wants to add more MRIs scans and I challenge him by pulling up the complexity index and the impact it will have on protocol execution. He is impressed with what the tool can show and we simulate different scenarios of the protocol design while balancing operational efficiency. Once we are happy with the design, we move over to the next part of the LSAC platform where it creates a heat map of countries and sites where these patients exist along with their historical performance and predictions on how the sites would perform, the treating clinics which could be referral centers, etc. I look at Dr. X and we are happy with where we are at in terms of design, number of countries and sites needed and the RoR backed by data for the same. I take a quick look at the watch and it is almost 11am. I tell Dr. X that I have to go and will keep him posted on the outcome. He thanks me for the partnership and we proceed with the rest of the day. I finish my 11-12 noon meeting a bit early and hope to catch my portfolio lead to review the data. As I step into my portfolio lead's office, he indicates that he has a lunch appointment and he will see me at 1:30 as planned. I acknowledge it and proceed to have lunch with my regular lunch buddies.

Before LSAC

1:30 to 2:00 pm

I meet with my portfolio lead and walk him through the data. He is frustrated that there is not a clear set of options backed by data for my recommendations. I tell him that without a tool (other than Excel) this is the best we have. He is not too happy with my answer but we don't have the time to debate this. He leaves his office with a bunch of printouts and spreadsheets on his laptop.

4:00 -5:00 pm

My portfolio lead calls me to his office and he says that neither he nor the R&D leaders came out with realistic clarity on the design of the study, and what would it take to get the study done? They want to meet again and go over the details this time and the meeting is 2 days from now. I don't know what more analysis I can do and how many more spreadsheets I can look at. He just said to me we have to get this done, no more excuses. I left his office in frustration that all my work was not appreciated and dreaded going through all the data all over again the next day.

After LSAC

1:30 to 2:00 pm

I meet with my portfolio lead and walk him through the data on the slide deck while I toggle back and forth with the LSAC to show him why we took certain decisions and made the assumptions. He is very satisfied with the approach we took and the data/assumptions behind those decisions. He asks me to send the information over to him, which I do right away, wish him luck and then proceed to the rest of my meetings.

4:00 -5:00 pm

My portfolio lead pops into my office and asks if I have a few minutes as he wants to debrief me. I ask him for a few minutes as I am finishing up a critical e-mail and will be in his office in 2 minutes. He agrees. I finish my e-mail and then go over to his office. He tells me that the meeting went very well and the committee was impressed with the options and data provided and that the study is likely to come up for funding request later that week and the data I provided will be used for that. He thanks me again for my work. I am proud of the work Dr. X and I did at such short notice and leave for home that day, satisfied that my work is making an impact.

