Day in the Life of a **Portfolio Lead**

WHITEPAPER

Before LSAC

8 - 8:30 am

I get a call from TA head about an urgent meeting that has been scheduled in the afternoon with senior R&D leadership to review the portfolio for Drug X, specifically focused on operational readiness to file the NDA by end of the year. I ask her why there was no heads up and am told, just get ready. With 10 studies in different stages of start-up, conduct and DBL, and with many of them outsourced, I start to panic.

9 - 9:30 am

I reach the office and immediately call each of my trial managers; some pick-up my call, 2 are on vacation and others are in meetings. For the ones I can reach, I explain to them that I need all the relevant information and metrics by 12 noon so I can review and get ready for the 1pm meeting. The ones I spoke to said it would be nearly impossible to get me all that information in 2 hours as they have other fires they need to put out and the information is in many places and it will take them lot of time to get me the information that I need. I tell them that this is the most urgent need of the day and hence they have to drop everything and focus on this. For the ones that are on vacation, I decide to take it on myself to find the information. I tell my admin to cancel all my meetings for the day.

After LSAC

8 - 8:30 am

I get a call from TA head about an urgent meeting that has been scheduled with senior R&D leadership in the afternoon to review the portfolio for Drug X, specifically focused on operational readiness to file the NDA by end of the year. I tell her, sure I will be ready by then.

9 - 9:30 am

I get a cup of coffee and call each of my trial managers to inform them of this meeting and I call or text them only if I need something or have a question. I realize that 2 of my trial managers are on vacation for that week and I think, wonder where they are vacationing. I log into the LSAC, and with sophisticated filters and functionalities, I do a quick assessment of status of all the 10 studies and use the Create Power point feature of the platform to start creating slides of key dashboards. I have some questions to my trial managers for which they quickly respond via Skype messenger and feel that I am ready for the meeting. I send the slide deck over to my TA head for his review and comments.

Before LSAC

9:30 to 12 noon

I log into CRO's portal, the information is dated 4 weeks ago and it is static. I can see that Europe is delayed in site activation but I can't find out why. So, I call the CRO trial manager and she doesn't have an answer right away. I call my EU-region lead and he tells me that he will have to call all the country heads to get me the information. He indicates that these requests are now becoming common and it takes him lot of time to collect this information. In the meantime, I check-in on the other trial managers and they seem to be struggling. In frustration, I log into CRO portals for their studies, now I am simultaneously looking into 3 different CRO portals to get the information in addition to accessing internal systems to get the relevant information on query rates, etc. I finally ask all my trial managers to meet me at 12 noon.

12:00 - 1:00 pm

We go over the information that the trial managers have collected so far. A lot of information in budget spend, reasons explaining start-up delays, rates of patients discontinuations etc., is missing. Worse off, some the information and conclusions I came to are not the same for what the trial managers came up with. We debated a lot, agreed to disagree and we were left with multiple versions of the truth. I was left with the big question on what do I report back to the committee. I decided that I was going to do my best with what I have and hope for the best.

After LSAC

9:30 to 12 noon

I proceed with rest of the meetings on my calendar as planned. I keep checking my e-mails to see if my TA head has some comments on the deck. As expected, he has. So I quickly log back into LSAC and check on questions, find the answers and quickly send it over to him. He indicates that we are in good shape, see you in the board room at 1pm.

12:00 - 1:00 pm

I have my lunch meeting with my mentor and she guides on various ways I can continue to enhance my skills and get exposure to senior leaders in the company. I tell her that at 1pm, I am presenting to the senior R&D leaders and she says that this is exactly the time for me to shine and make a lasting impression and wishes me luck.

Before LSAC

1:00 -5:00 pm

I am co-leading the presentation and discussion with my TA head (he looks at me with deep sense of frustration as if asking "Why didn't you run any of the information by me before we entered the board room)" on the review of Drug X and the questions, start flying on from the senior R&D leaders. I try my best to answer the questions such as when do we think recruitment will be finished, why are 3 studies behind on recruitment, what are base, best and worse case scenarios on when should we expect database locks for pivotal registrational studies, etc., I mumble through almost all of them, take best guesses, go with my gut, etc. My concerns are realized when there is mutual frustration on lack of accurate information, blame on operations, CRO, etc., and the filing (not to mention my credibility) is at risk. I leave the meeting with a deep sense of frustration of not having been given enough time, saddled with legacy systems (or lack thereof), data sitting in silos, inability to quickly interrogate the data, and several versions of the truth. I feel immensely frustrated with the situation and am disappointed in myself and my team. I dread similar call-ups in the future.

After LSAC

1:00 -5:00 pm

I am co-leading the presentation and discussion with my TA head who wishes us luck and we immediately start our presentation. The questions start flying in and I toggle effortlessly between the slide deck and the LSAC and answer all the questions. The committee is very satisfied with where we are, the risks for meeting the NDA timelines and our plans to mitigate them. We are congratulated by the committee for our command of the project. We finish a bit ahead of schedule. I go back to my office and provide the debrief to my trial managers and convey the congratulations and appreciation from the senior R&D leaders as well. They are glad that everything went well and we are on track. I then go back to my office and check on my e-mails and then leave for home for the day, continuing to be believe that I am in a privileged position to fulfill my life's mission of bringing innovating medicines to patients in need.