

A Week in the Life: EAP Project Manager



From early project start-up and continued Sponsor engagement, to data collection and resupply coordination, see how a WEP PM expertly and thoughtfully orchestrates cross-functional teams so that complex access programs run smoothly for every site and patient.



By Palmer Watson
EAP Project Manager

Monday

I spend the bulk of my day working on startup activities for a new Post-Trial Access (PTA) Program that is in the very early stages. We have had both the internal and external kick-off meetings (KOMs) already, so me and my WEP project team members are off to the races! I will be working closely with them on this project, and I have had a great first initial meeting with the Sponsor team – who seem enthusiastic about working with us and is excited to get going.

I start the day with a call with one of our Senior Managers of Regulatory Affairs to align on the work she is doing specifically for the BfArM application in Germany. She provides me with an update on her progress, based on discussions we had had the week before, and she answers a few questions I have on some project specific details that could affect the submission.



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Between my calls, I spend time working on the Project Management Plan (PMP). I author all the project-specific details, based off of the Statement of Work (SOW) and Quality Technical Agreement (QTA), as well as information learned from internal calls and communication back and forth with my WEP functional leads. I also spend some time building out the project timelines for key program tasks, including finalizing documentation, mapping out supply chain pathways as well as processes for enrolling and activating sites. These timelines will be continuously referred back to throughout the duration of the program to keep us on track. I will send both the PMP and the project timelines document over to the Sponsor team for their review, input, and sign off.

I also have my weekly internal group call with the full WEP cross-functional team supporting me with this program – this includes Medical Affairs, Regulatory, Quality, and Supply Chain. The Business Development (BD) rep who led the sales process, as well as our Director of Project Start-Up and eTMF Management, are also included in this weekly call, to ensure a seamless and collaborative hand-off and ongoing alignment between Account Management and Operational teams.

Tuesday

I start my day preparing for our weekly external call with the PTA Sponsor team. This call includes members from several departments on the Sponsor side, including Clinical Operations, Regulatory Affairs, PV, Supply Chain, Legal, etc. From WEP, I lead the call each week and provide updates on all elements of the program, highlighting our progress and answering any questions. I also have my supporting project specialist join, as well as members of the cross-functional WEP team supporting me with this project.

After the call, I connect one-to-one with my project specialist, who is relatively new to the WEP team and is still finding her feet.

I take the time to download with her after each Sponsor call to make sure she understands everything that was discussed and is clear on next steps and expectations. She usually has a lot of questions for me, which I like, as this tests my own knowledge and understanding of our processes and operational tasks and keeps me on my toes. It also allows me to develop my leadership skills, which I appreciate. If we need further clarification on anything from the cross-functional team members, we loop them in, and it ends up being pretty educational for me also. I like that, at WEP, every day can be a school day!

After these two calls, I take some time to type up my meeting minutes to send to the PTA Sponsor, and then I turn my attention to some work that needs to be done for the other project I am managing. This program is an Expanded Access Program (EAP) for a rare disease drug, and it has been running for over four years. Most of the work that needs to be done is around managing resupply requests, as and when they come in from treating physicians. These requests come directly to me via email, and I work closely with our Supply Chain and Warehousing teams to process them and coordinate delivery. We have stock available at all three of our warehouse locations for this program – the US, the UK, and Ireland – which allows us to efficiently manage resupply efforts globally.

Wednesday

In the morning, I am back to working on the PMP for the PTA Program. We had some input from the Sponsor on the weekly external call around labelling requirements and responsibilities, so I make the necessary updates to the document. It is a collaborative document that lives on our SharePoint, so my project specialist can see any updates in real-time, and I leave comments for her throughout, explaining why certain changes have been made.

Then, I have an internal call to prepare for a recurring meeting with my EAP client.

The call includes our Director of Quality and our Director of Supply Chain Operations. We connect to discuss revisions that will need to be made to the project QTA, as a result of our warehouse move to a new location. The EAP Sponsor team is aware of this change and will be expecting some updates on the call later that day.

Once we are aligned, I jump onto the client call. As this EAP is longstanding and is well into the maintenance phase, it is a relatively small group that joins. It usually only includes two people from the Sponsor team – the Director of EAP and a representative from the Quality team. I go over the changes to the QTA and then provide an update on the current sites and patients, as well as the status of a new site we are currently in the process of enrolling. I then walk the team through the inventory at each of our warehouse locations and expected shipments going out in the next month. This program involves data collection, so our Data Management (DM) lead also joins the call to give the Sponsor and update on REDCap Cloud data entry.

After the call, I have a quick catch up with the DM lead, as the Sponsor requested some specific information to be sent over to them after the call, and I want to make sure he fully understands the ask and has everything he needs to get going. We align on timelines, and I put this in my email to the Sponsor, with my meeting notes, so the Sponsor team is kept in the loop. It is important to us to provide consistent and transparent communication and ensure complete alignment with Sponsor teams as programs progress.

I also reach out to our Senior Manager of Regulatory Affairs, as well as the BD rep that was involved in the sales process for this specific program, to schedule a call for tomorrow to discuss an important regulatory milestone for the EAP. The Sponsor informed me on the call that they have officially received FDA approval for one of their indications, so I want to connect internally to discuss what this will mean for the EAP and efficiently action any next steps.

Thursday

This is my favorite day of the week, as I work from the office, rather than from my home. We have offices local to me in Cary, NC, and each week, we have team members from all departments who come in to spend some time together in person. This week it also happens to be our monthly Global EAP Project Management meeting. This meeting is held each month by our VP, Project Management for EAPs and our Director, Project Management for EAPs.

The meeting usually starts with an icebreaker and a review and quick celebration of any employment anniversaries. We then go over any important updates or changes to our processes and/or tools that we use in project management. Some of these will be relevant to all of our access programs while others will only affect certain ones. We then have a session dedicated to lessons learned, in which someone from the team presents on a topic of their choosing, that is relevant to the work they are doing within their project, and then provides tips and tricks that would be helpful for anyone else experiencing something similar. We end by going over any project wins – this week, I inform the team of the FDA approval for one of the indications for my EAP drug. Before we finish, the floor is opened for any questions.

I always leave the monthly Global EAP Project Management meeting feeling re-energized and committed to the work I am doing here at WEP. I really appreciate having such wonderful teammates around me, who I can learn from and be inspired by, and I feel lucky to have senior members of the Project Management team who are enthusiastic, approachable, and dedicated to the group's continued success.

I finish the day with the call I set up yesterday with our Senior Manager of Regulatory Affairs and the BD rep for my EAP.

This group has been aware of the upcoming FDA approval, so the call is intended to realign and action some next steps that we had agreed upon previously. At WEP, we are committed to supporting our Sponsors across the full product lifecycle. So, each regulatory milestone offers a chance for our team to reassess if and where value can be potentially added, based on the Sponsor's unique development and commercialization goals.

Friday

Fridays usually involve a mixture of follow-up work and continuation of tasks started during the week. I like to start the day by touching base with all the internal team members I have spoken with throughout the week, to get an update on their activities. I keep a project tracker for both of my access programs, so I spend some time reviewing who is doing what for each one and sending out some messages on Microsoft Teams asking for updates.

I have been asked to help with planning for one of our upcoming social events, so I have a call with our Social Committee in the afternoon. At WEP, we have quarterly social events, both in the US and the UK, and these usually involve some kind of educational component from one of the functional teams. For the next one, the project team working on my EAP will give an update on the work we are doing so we can help celebrate and raise awareness for World Mitochondrial Disease Awareness Week. Our EAP provides access to a much-needed medicine for patients who suffer from genetically confirmed rare diseases with known mitochondrial dysfunction. We decide we are going to present a few slides and then do a quiz, so I spend the rest of the afternoon getting started on that.

Before I log off, I update both project trackers for the week and set myself reminders for important tasks that need to be carried out next week. See you on Monday!