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Improving Patient Health and Safety

Case Study: Drug Development Program Management

A biotech company focused on immuno-oncology needed expertise not only in drug development program management, but with NDA and MAA filing experience as well. ProPharma provided a consultant with twenty years of experience in drug development who also had immuno-oncology and filing experience. The hands-on program manager collaborated with the development team to develop a cross-functional plan through filing. The development program manager met with stakeholders in clinical, non-clinical, CMC, regulatory, commercial, etc., along with the CRO and CDMOs, to develop an agreed-upon strategy and plan to obtain approval for their lead product. The program manager developed one page timeline reports for not only the product, but the whole portfolio as well. The consultant worked closely with the physician project leader, the regulatory lead and other team members to update the target product profile (TPP) for all products in the portfolio.

The initial timeline for the immuno-oncology filing had no CMC activities in the filing plan. As the development program manager reviewed the plan with the team, it became clear how the filing would be managed and who would be responsible for the necessary actions. As the filing approached, the development program manager implemented a process for weekly reviews for the reports in the electronic common technical document (eCTD). The consultant also implemented an Issues, Decisions, and Risk Log, along with a tactical and big picture timeline to ensure the team remained in alignment with the plan. Executives received a weekly list of report reviews required for the week, which allowed visibility into time management. The executive review and approvals were typically the rate limiting step for the submission of the NDA, so the program manager worked closely with the executives to book their calendars in order to complete this work.

As a result of the consultant's effort, the NDA was successfully submitted on time. There was less confusion about the development plan due to the cross-functional discussions and the communication of the integrated development plan. Vendors had visibility into the timelines as well, so it was clear which major milestones they needed to align with. Since it was the first NDA filing for the company, the development program manager's efforts to install a structure around the filing months in advance minimized the churn and stress during the compilation of the documents for the eCTD.