

Providing program management support in the lead-up to NDA submission and launch

A development-stage biopharma company engaged Magnolia to help put in place an overarching launch road map for a drug that had just received positive phase 3 data. The company was ramping up hiring across different functions and realized that there was a need for internal cohesion and alignment in order to achieve a successful NDA submission and launch.



Evaluating Organizational Readiness:

Magnolia reviewed:

- Current state of awareness of the plans and actions of other internal stakeholders, the impact of those actions on other departments, and the level of communication needed to allow for cross-functional alignment on milestones and deliverables
- Processes in place in the lead-up to NDA submission, to create a “winning label”, and subsequently ramp up for launch

Our assessment determined that each individual function, such as Medical Affairs, Commercial, and Market Access, knew what was needed within their area of expertise, but they were lacking a coordinated, cohesive strategy to allow for a successful submission and launch.



Actions, Outcomes

Magnolia assisted the company with firstly prioritizing what steps in the launch planning needed cross-functional input and alignment, and then implementing these changes as the company ramped up staffing:

- Worked with Marketing group to develop a lifecycle plan for the asset, with input from Product Development and Medical Affairs, to provide awareness to new employees regarding future development plans
- Developed a RACI matrix, with input from Marketing, PR and Advocacy, Managed Markets, Trade, Medical Affairs, and Sales, that provided cross-functional awareness and ownership for all key deliverables
- Mapped out postlaunch activities, such as patient assistance programs, to assist the company with new organizational areas of growth

Activities outlined above resulted in product launch being on time and within budget, ensuring patients had access to a new therapy.