

Developing the appropriate regulatory strategy for a patient-centric, therapy-agnostic app

A biopharma company engaged Magnolia to assess both the regulatory process as well as the likelihood of uptake of a therapy-agnostic phone app to support the patient journey for a rare pulmonary disease. Providing self-administered features that could help assess risk of disease progression was seen as a key benefit to patients. Regulatory and the company's compliance policies were ongoing commitments and requirements.



Evaluating Organizational Readiness:

Magnolia reviewed:

- The intended use statement, intended users, and product requirements developed by the originator of the app
- The existing review and approval policies, to determine the cross-functional governance bodies needed to assess the app, and the responsibilities that each function should have

Our assessment determined that new policies, procedures, and guidelines required for digital therapeutics were substantially different than those for traditional medical devices



Evaluating App Classification:

Magnolia:

- Reviewed recently released patient-centric apps to assess features and any regulatory determinations
- Mapped out a process for the company to determine whether the mobile app would be considered a medical device subject to enforcement discretion, a regulated medical device, or not a medical device at all



Actions, Outcomes

Magnolia assisted the company with multiple rounds of patient feedback to determine whether the feature set was indeed what patients would find useful. In addition to this, **Magnolia**:

- Mapped out system architecture for how data would be stored (local or cloud) and how to set up data storage for potential analysis in the future
- Analyzed feedback from HCPs, allowing team to understand whether prognostic risk features provided by the app would be useful for HCP discussions in patient consultations
- Determined drivers for patient and HCP engagement, including the need for the app to provide patients "hope"
- Determined potential road blocks to patient and HCP engagement, including how patient-generated data could be intertwined with more traditional HCP clinical parameters

Successful launch of the app resulted in a more empowered patient and caregiver community, met an unmet patient need, and helped to define a road map for future digital therapeutics for the client