argument is made to take advantage of an opportunity for additional studies which could lower the future risk of a bad formulation during clinical trials, the team may allocate extra investment and time.

For instance, if a team observes particulates at low concentrations during short-term studies, the team may invest extra time and resources in a more rigorous screening of the formulation. This may avoid future delays during clinical trials due to an unstable or dangerous formulation.

Considerations of device technologies can begin with the improved clarification of whether a product will be in a lyophilized or liquid formulation. If no device exists, device development can also take place at this time. Device development tends to have a long timeline and can run in parallel with drug development. The goal is for the device to be ready in time for phase II or phase III trials, at the latest. If not ready, regulatory issues or even launch delay can occur. This occurred to MannKind when they proposed a late switch in inhaled delivery devices during phase III trials.

Early Clinical

As the product enters clinical trials, the team will acquire valuable information on likely dose, volumes, and schedule. Frequent dose or higher volume products may benefit from a higher concentration formulation to improve patient convenience and competitiveness.

With the improved likelihood of success, the product development team should prepare a commercial formulation that can be brought through late stage clinical trials to the market. Since phase I and IIa trials can be very short, depending on the indication, teams should prepare accordingly.

Late Clinical and Launch

Formulation teams should have a commercial product in the course of a long-term stability study during phase III trials, which can last from 6 months to 5 years depending on the indication.

Reconstitution systems, delivery devices, kits, and other product presentations should ideally be part of any phase III trial, where quality-of-life data can be captured. These data will be used at launch by marketing to demonstrate the ease of use and cost of delivery. Government and private payers have increasingly required such data to set access, reimbursement, and pricing.

Packaging requirements may differ in various geographical locations due to local regulations, differences in volumes due to weight, or local clinical practices. The formulation and packaging team need to anticipate these hurdles in preparation for an effective launch.