



PRODUCT PROGRAM MANAGEMENT

Asset Program Management of a Novel Gene Therapy Product

THE NEED

An innovative start-up, C> company, is advancing a rAAV gene therapy for a debilitating genetic disease affecting both neurological and cardiac functions, required program management of their new, pre-clinical gene therapy program. The therapeutic candidate was in early concept stage and required a development strategy and execution plan to advance the program to IND-enabling pre-clinical studies.

THE APPROACH

- Primecore customized their best practice approach to product management to meet the needs of the client; in this case the program required clear roles and responsibilities, program governance, Level 1 and 2 schedules, deliverables list, and a strong asset team to guide the program.
- Primecore established the client's team providing the overall asset program manager, the CMC program manager, scheduler, and SMEs in analytical development and clinical operations.
- A program strategy and schedule were prepared outlining the timelines, cross-functional interdependencies, potential bottlenecks, and risks.
- A project management structure was implemented, enabling the program to be governed, managed, and monitored to achieve the key program objectives with a clear communication and escalation plan.
- Primecore hosted and facilitated a series of strategy workshops to quickly capture current thinking and help develop the product strategy, identify risks, and align on go forward execution plan.

THE SOLUTION

The combined Primecore and client team successfully managed the program from plasmid selection to IND-enabling tox studies.

- Primecore's SMEs were able to work in the areas of greatest need and then shifted as priorities changed.
- Implementing an Asset Management team with clear accountabilities helped drive results and hold the team accountable to the schedule and deliverables.
- The best practice methodology of 1) Strategize 2) Plan 3) Execute was adopted as the clients standard along with the document requirements and templates.



THE RESULTS

- *The program was initially a back-up to the lead candidate but eventually the timelines of the two programs were equivalent, giving the Client the option to choose their preferred candidate for IND submission.*
- *Primecore quickly added value for the client by deploying best practice program management to a dynamic start-up environment; the methodology enabled good and timely decision making to expedite the program and meet their stated goals; it also focused resources on the right tasks and the right time.*
- *The Executive team received program updates that reflected realistic timelines and risks as well as timely escalated actions. The program had a high level of transparency that allowed for clear governance.*

