Customer Acquisition: mRNA Gene Therapy

Awareness Narrative

You have high aspirations in the fast-moving mRNA market. But goals are often high risk/high reward for you and potential patients. Everyone wants to be the first new solution to successfully pass the phases to reach commercialization.

There's a lot of expectation riding on finding a winning therapy. Whoever is funding your program wants to see a return on their investment. Regulators are stingier about new therapies outside of the COVID emergency authorizations—and they're unafraid to send a therapy back to the drawing board if you can't prove efficacy.

Your scientists are understandably focused on the science—not necessarily on getting their product to market. They need help. They might not be able to run therapy research, development, and commercialization on their own—so they either task a bunch of internal teams to manage different parts of the process, or they seek external assistance to just get to the next phase.

But in the search for the easiest, fastest, and cheapest option in each phase, they often hear a lot of false promises.

- Some vendors present an optimistic view of the development process, assuming that everything will go smoothly regardless of phase. They may be aggressive with timelines, setting unrealistic fill dates and cutting corners to meet those timelines.
- Some vendors might develop GMP-like plasmid products for immediate phase approvals, without considering future GMP product needs.
- And some vendors might offer to seek mRNA product approval prematurely, just to stay aligned with development deadlines.

The reality is that these promises are often broken, which can leave you scrambling to fix mistakes during or after a filing request.

- Releasing products prematurely creates drug safety risks, which would mean that you'd need to rectify the filing to pass regulatory muster.
- In the gaps between phases, you deal with multiple handoffs between teams and companies, creating confusion and miscommunication. This can be a big waste of time and money. Every minute matters, so wasted time is wasted opportunity to reach market viability.
- Being unrealistic about timelines can mean that you skip due diligence before seeking phase approval. Any loss of project viability means you're either retreating to prior phase work or cutting bait entirely.
- And if you aren't able to pass that phase requirement, it could hamstring your resources, reduce your funding, and cripple your reputation.

Is this truly a realistic approach to making it in the mRNA market?

Instead of trying to **solve for speed to the clinic**, and just getting the therapy to the next phase as fast as possible, you need to focus on **increasing your probability of success** when the product reaches the clinic.

Improve your odds of patient benefit

- Understand—and simplify—the entire research, development, and design process, and extend findings beyond your immediate phase.
- Plan for quality at the end of the manufacturing process when the drug is administered to the patient—and not just to meet the next phase milestone.
- And prevent unforeseen surprises from derailing your program.

And these approaches will lead to…

- Increased odds for positive patient impact without losing yield.
- More reliable, achievable timelines.
- And more return on investment.

Let’s talk about how you can improve your chances.