

## NDA Submission Success

For any small drug development company, submitting an New Drug Application (NDA) is a very big deal. The success rate of taking a drug from Phase I through to U.S. FDA Approval is 9.6%, but if you can get to the point of submitting an NDA, the success rate jumps to 85.3%!

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This means when you're ready to submit your NDA, you'll want to do it as quickly, accurately, and efficiently as possible. That performance will largely be determined by how well the team building the NDA understands what has to be done, the interdependencies between those activities and milestones, and the timing of when they will have to do their part.

Achaogen, a late-stage biopharmaceutical company based in South San Francisco, had never submitted an NDA. While they have veteran resources on the team who had been through the submittal process before, it was a first for their team. They learned quickly what would (and wouldn't) work, to ensure everyone was on the same page, and that positive and productive collaboration was occurring on a regular basis to help move the ball toward the goal.

### If it doesn't work, change it

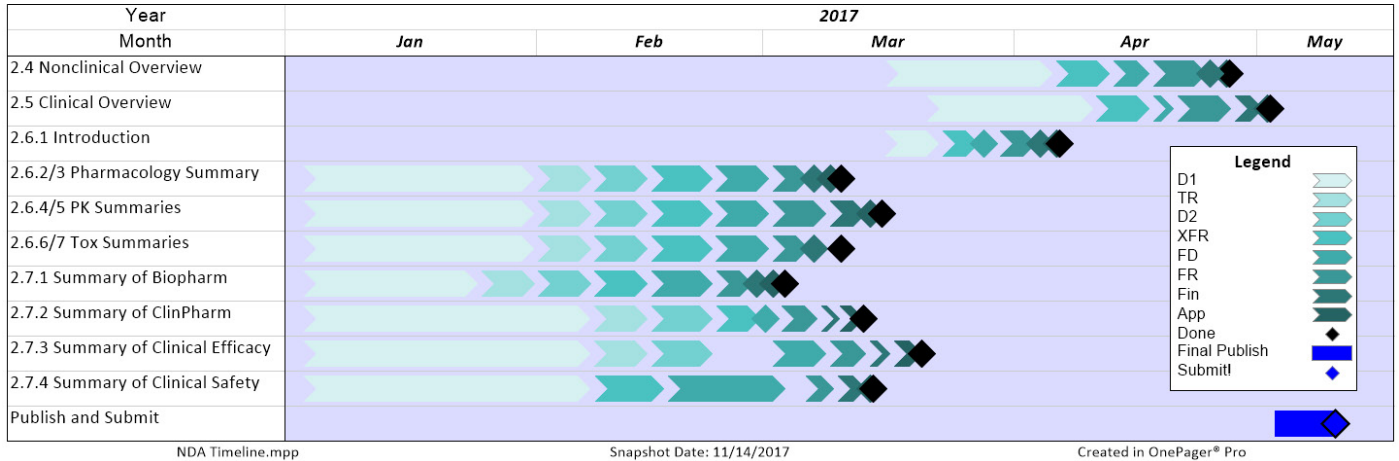
Director of Project Management, Joe Stalder drove the effort who said, “We started out with something very different in terms of reporting. Sharing the entire Project file using Project Online was just too overwhelming. It was hard for everyone to look at the aggregate and grasp meaning for them as individual contributors.”

In attempt to remedy that, each day a new plan would be published, and an automated email would be generated to all individuals by Project Online's Task Manager feature, letting them know what had changed to the items they were assigned. Even if it was a slight single-day change, a resource might get a notification about how that single-day modified their entire set of tasks. Eventually the team members agreed it wasn't helpful.

Once Achaogen went to OnePager, they received feedback from various functions that were involved with drafting the NDA that they could finally see and grasp what they had to do and when.

A daily standup meeting was initiated where they would review the plan in OnePager and get everyone aligned about what was being done, and what was coming up. People could plan around the summary because it made resourcing move visible. You could see what sections were being written by which authors, and who was overbooked.

## NDA Submission Timeline



Achaogen leadership was also very pleased with the ability to see the overall plan at the 30,000 foot-level in a clear and concise way. The CEO co-led the daily stand up and that allowed him to quickly remove any roadblocks or provide decisions that the team needed resolved in order to continue forward progress.

That level of visibility also demanded accuracy and accountability on the part of the team. “It put everyone’s work front and center, every day,” said Stalder, “so anyone who had something to do got it done quickly and kept their data in the plan accurate.”

As Achaogen looks toward production following potential approval, Stalder has plans for a Lessons Learned meeting in an attempt for the company to benefit further from the experience in the form of best practices. Future NDAs, however, will likely use the same visual and timeline structure that were created this time around, given the improvements stated by the team when they were introduced.

### ABOUT ONEPAGER

Developed and sold by Colorado-based Chronicle Graphics, OnePager is the timeline presentation software solution that empowers project managers to turn project files and spreadsheets into beautiful summary graphics in seconds. No matter the size of a project or the application used to create the original plan, OnePager turns real data into concise, instantly understandable visual project plans, suitable for PowerPoint presentations, emails, web pages, wall charts and more. Want to be a project management superhero? OnePager makes it possible. Click here to start your free 15-day trial today.