

REACHING REVENUE MILESTONES

AND OVERCOMING PAIN POINTS

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As the clinical research industry continues to evolve, research sites are constantly looking for ways to obtain a competitive edge over other sites in the industry while also continuing to grow financially and reach their revenue goals. It is inevitable that sites climbing the revenue ladder will encounter various pain points. When this happens, a strategic plan needs to be developed and implemented quickly in order to overcome these obstacles. By gaining a better understanding of what to expect at each milestone through the various pillars of growth considered for sites – business line/infrastructure, staffing, accounting/finance, business development, patient recruitment, and technology - sites will be able to troubleshoot and resolve any issues before they even arise. In order to reach the next level, understanding these potential pain points is crucial.

MILESTONE ONE

Jack of all trades
REVENUE GOAL: \$0 - \$500,000



During milestone one, a research site is still in the startup phase and is likely in the process of setting up for success. This phase is all about learning and ensuring that all potential opportunities are being maximized. Hiring the right people is critical in the early stages and is often based on trust, work ethic, and identifying champions of each therapeutic area. However, sites should be sure to set the bar high and lead by example. Creating an open environment that encourages idea sharing will ignite inspiration. Since staff is limited during this phase, it is important for sites to make sure that all of those on board are able to successfully jump into any aspect of site operations, whether support is needed in business development, recruitment, regulatory affairs, etc. From here sites will be able to determine who has potential as a

leader and who is most valuable to site operations. At this point, a basic structure should be put into place that includes physician compensation, staff job duties, accounting, taxes, etc. Hiring an outreach representative is critical in managing patient recruitment. However, site management should be sure to be clear when communicating expectations to staff by setting specific outreach goals paired with a commission structure for visits seen and patient calls – this serves as a motivating incentive. Many sites make the mistake of waiting too long before they implement dedicated screeners when they should be keeping an eye on labor costs and hold off on starting multiple locations.

Financially, research sites should begin to set up a firm revenue cycle management foundation by utilizing key research organization metrics. A business development strategy that focuses on a few key indications that are almost guaranteed to perform well to meet enrollment goals should follow. Focusing on the future of study pipelines is critical! Sites should implement a CTMS platform and establish standard operating procedures around technology usage, and treat this new CTMS/technology as the ‘home base’ where everything can be tracked and monitored. The longer a site waits to start using a CTMS, the more they are missing.

KEY TAKEAWAYS:

- 👤 Mold and mentor staff for growth.
- 💰 Finance is all about time management.
- 🎯 Focus on only a few therapeutic areas – less is more.
- 💻 Implement a CTMS platform early.

MILESTONE TWO

Process is key




REVENUE GOAL: \$500,000 - \$1,000,000

Milestone two is all about setting the stage for future growth and putting processes in place. This is typically a formative year for a research site, when key positions are identified and the framework for growing departments is solidified. Sites also gain a better understanding of what indications to focus resources on during this time. Hiring a hybrid site manager/study coordinator is a strategic move many sites make to ensure that day-to-day operations run smoothly. At the same time, they usually begin to think about hiring a patient recruitment specialist. It sometimes proves to be a challenge to increase screening volume while maintaining quality, but outsourcing commonly helps alleviate this pain point. Sites that establish KPIs for operational and financial aspects of operations will motivate staff to meet and exceed goals.

Sites may also focus on perfecting their pipeline at this stage and thereby gain a better understanding of what studies they should or should not take. The first year will have presented lessons learned and left sites with a newfound ability to identify and establish key partnerships, collaborations, and/or speaking opportunities. In regards to technology, sites should ensure all processes are automated and that staff is utilizing all technologies accordingly, while maintaining compliance. While this is an inevitable cost, investing in technology is necessary at this stage for success.



KEY TAKEAWAYS:

-  Define staff role – many will wear multiple hats and be encouraged to step up.
-  Implement a full-time patient recruitment specialist who can reach out to patients.
-  Outsource business development to support work flow.

MILESTONE THREE

Grow without fear

REVENUE GOAL: \$1,000,000 - \$1,500,000




As a site approaches the 50-study threshold in milestone three, it is important to keep in mind that this success will also attract the attention of the FDA. Audit preparations should begin, and all processes should be established, along with a QA department. As staff continues to grow, site management should work to develop and foster a culture where all voices are heard, ideas are valued, and employees are encouraged to run with those ideas without fear. The most viable solutions come from those who are actually doing the work – not from leadership or management.

Financially, it is critical for sites to ensure that their teams are using forecasted costing tools to help monitor the budget from all levels.

Continuing to strategize more efficient ways to project revenues and cost as expense budgets grow is extremely beneficial. At this milestone, when a site is more established and has earned credibility in the industry, it is likely that they will be able to bring in high level attention, such as translational medicine partnerships and physician publications. In order to support the increase in studies, it is imperative for sites to secure the right person on their teams to support patient recruitment efforts. Advertising is a strategic tactic during this milestone, so having a team that can set and meet goals is a huge opportunity for growth.

As part of the strategic planning, it is important for sites to diversify the revenue stream through multi-specialty studies and infrastructure. This stage is the time to evaluate the site operation processes for standardization, which helps justify an increase in charges for services, leading to higher compensation.

KEY TAKEAWAYS:

-  Expect departments to flow together and overlap.
-  Develop a staff/team culture.
-  Begin transitioning from cash to accrual.



MILESTONE FOUR

Brilliant at the basics

REVENUE GOAL: \$1,500,000 - \$3,000,000









Adding and optimizing teams to help build the organizational chart are key in milestone four. While fear may be a major pain point, delegating tasks and putting trust in site staff is necessary for continued growth. Sites should establish and implement a solid recurring training plan for the team based on developed standard operating procedures and strive to be “brilliant at the basics.” Building a team-oriented culture with a focus on celebrating the ‘wins’ and recognizing the team when the basics are working is a necessary element of continued success. Sites with multiple locations must work to ensure that the support staff are not fragmenting the operation.



During this milestone sites should be focused on determining how to reduce costs while growing – this includes monitoring KPIs to ensure successful month’s end close-outs. If finance tasks are not already outsourced at this stage, sites often make the strategic move of hiring a CPA. At this point, when the infrastructure has grown and new investments in growth are being made, sites should focus on the opportunities that have developed and can bring more patients into enrolling studies. A growing research site should prioritize mastering their established therapeutic areas while exploring new ones with caution. Since they are operationally solid at this stage, starting conversations to establish long term master agreements with sponsors, hospitals, and health systems, as well as ancillaries that have key capabilities you have been utilizing, is a smart move.

In regards to patient recruitment, sites should have the right balance of in-house staff and outsourced support. An enrollment team may be used to work across all site locations, where the site staff (CRC, PI) has a central point of contact to assist in patient identification, screening, recruitment and retention. A site should also have one person who oversees and works with other personnel. If the volume rises to over 400 patients screened per month, an outsourced service is typically implemented, as this volume does not observe economies of scale points. In terms of technology, a site will likely have a full integration across multiple platforms with a dedicated IT staff member at this time. The technology platform should have the ability to help manage staff, forecast revenue, and generate reports (both financial and operational). Investigate technology enhancements and partnerships that will enable sites to access viable ‘big data’ that support their mission, such as claims data or population health trends that could help further grow the business. During this phase, sites will also work to reduce manual processes and continue to think strategically about moving towards automation, where possible.

KEY TAKEAWAYS:

-  Value strong leadership.
-  Focus on therapeutic diversity.
-  Set up for stability and open additional locations.
-  Don't forget the fundamentals.
-  Allow accounting departments room to become more sophisticated.
-  Learn how to be profitable doing the same study at more than one site.
-  Balance outsourced support.
-  Embrace technology beyond a CTMS platform.

Reaching each revenue milestone in the site implementation process will automatically result in various pain points. The key to continued success is being able to recognize these obstacles and in turn, overcome them. By having a better understanding of what to expect, a site will be set up for success and will likely exceed KPI and revenue goals.