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Building a Clinical Research Program

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SCALE's CEO and Co-Founder, **Roy Bejarano**, recently had the opportunity to speak with Founder and CEO, at Iron Horse Research, **Chad Eriksen, MS, CCRC** about best practices for implementing a clinical research program into a physician platform.

Previously, Chad held leadership and advisory positions at a variety of organizations within the clinical research industry, including Iron Horse Research, GuideStar Clinical Trials Management, Ochsner Health System, Pennington Biomedical Research Center and the ACT Center (A Comprehensive Tobacco Treatment Center). He is also a panel member for the Ochsner Clinic Foundation Institutional Review Board (IRB).

Chad is the President of the Southeast Louisiana Association of Clinical Research Professionals (ACRP) Chapter. He is a Certified Clinical Research Coordinator and earned his BA from the University of Alabama and MS from Louisiana State University.

Chad has worked as a clinical research coordinator, working on complex therapeutic trials in academic medical settings, responsible for study protocols, enrolling, and consenting patients. At GuideStar, Chad worked for three years at a management company focused on providing clinical research management services to over forty physician platforms and academic institutions. As a Director, Chad provided the full range of administrative support services, including negotiating clinical trial agreement (CTA) contracts, regulatory submissions, and financial compliance. At Ironhorse, Chad formed his own company in order to provide physician practices that have very little, if any, research exposure and who need added expertise to expand their research divisions.

Getting Started with a Clinical Research Program

What are the more suitable clinical specialties for the formation of a platform research division and what are less suitable specialties, and why?

There really isn't a bad clinical research specialty. Some require more strategic and creative thinking to make them work. Others require more money, staff, resources, etc. However, if you have a well-developed program with the right team on board, the sky's the limit regardless of therapeutic indication. If an organization dedicates themselves to focusing on the fundamentals, they will undoubtedly find success.

With that being said, there are specific areas which are currently expanding their R&D efforts at a faster rate:

- **Gastroenterology** is a particularly hot area for clinical research right now. Specifically, IBD clinical trials have flooded the market. Pharmaceutical companies are desperately looking for new clinicians and patient populations to help fulfill their enrollment goals for these IBD trials. In addition to IBD, with Hepatitis C essentially being cured, the next frontier for liver disease is NASH, as there is currently nothing approved on the market to address this disease.
- **Neurology** is a great area worth exploring as there are a multitude of companies working towards addressing the issues associated with the aging population including

Alzheimer's Disease, Dementia, Stroke and Sleep Disorders. Another area of focus in Neurology is on addressing the ongoing opioid epidemic. As such, we're seeing an increase in the number of opioid-free pain management trials.

- **Psychiatry**, Depression, Dementia, Bipolar Disorder, Schizophrenia, Obsessive-Compulsive Disorder are the more common psychiatry-based clinical trials being seen right now. Additionally, many of these trials have a strong Neurology component (and vice versa) so the potential for collaboration between a Neurology and Psychiatry clinic is a strong possibility and further opportunity for growth.
- **Dermatology** is a great therapeutic area for clinical trials, although it does tend to be a fairly competitive area. However, there are currently a myriad of atopic dermatitis trials available, which makes this an area worth pursuing. These atopic dermatitis protocols can vary widely, thus a clinic would be able to run several AD trials in tandem.

Areas that tend to be more difficult to break into include more common ailments such as hypertension, diabetes, flu, vaccines, etc. Trials for these areas are not as prevalent as they once were because improved medications are now available to manage these conditions. When these trials do become available, they are extremely competitive because they tend to be less complex to operate – fewer visits, easier inclusion/exclusion criteria, more subjects to enroll, etc. Every site wants this type of trial.

The trend in clinical research tends to follow the same trend in medicine, where more specific diseases are now being targeted. As a result, specialists are required to handle these types of trials as they'll have the patient population to meet enrollment goals and experience in these very specific disease areas to be able to properly implement the protocol requirements.

Platforms of all shapes and sizes can have a successful research program.

I have worked with single physician practices who have developed very successful research programs by investing in the appropriate resources, developing efficient processes and fully understanding the requirements of running clinical trials. However, I have also seen very large, multi-provider organizations lose a tremendous amount of money because they didn't take the time to develop a sustainable clinical research infrastructure from the beginning.

Describe what a typical clinical research business unit should look like in a provider platform organization.

There is not a one-size-fits-all structure for clinical research sites. Do not let anyone convince you otherwise. The structure of a research program should be determined by the site's goals, infrastructure, physician engagement, etc.

I am a strong proponent of research being integrated into the existing practice. While the administrative duties of clinical trials (i.e. trial budges/contracts, business development, marketing, financial management, etc.) can be successfully outsourced, the clinical research coordinator (CRC) should be employed by the physician practice. The relationship between the CRC and the PI/site is paramount to the success of a research program.

- **Number of FTEs**
  - Start with 1 clinical research coordinator who is a rock star. Successful CRCs have a unique skillset and personality. Seek help to identify your ideal candidate.
  - Increase staff as volume of trials and subject enrollment increases.
  - Secondary hires can have less experience and then be trained by the current team in place.
- **Org Structure/Hierarchy**
  - Ideally, the original CRC will develop into a manager/ director role as the volume of trials/patients increases.
  - As the program continues to grow, consider having dedicated staff for admin, business development/ marketing, regulatory, etc.
- **Daily Activities**
  - The goal should be to have your clinical research coordinators focus on what they do best – enroll research subjects. CRCs can easily get bogged down in the administrative work required for each trial. Make every effort to free your CRCs of these administrative burdens so they can focus on recruiting and enrolling research patients to the trials. Your site is paid by the number of subjects enrolled and the number of visits they complete on each trial – your CRCs should focus on these revenue generating activities.
  - Administrative duties can be handled by either the site's admin staff or outsourced to a professional research organization.
- **Access to Equipment**
  - A site should own their own research equipment. Most practices already own the majority of required equipment, i.e. sphygmomanometer, scale, thermometers, phlebotomy supplies, exam table, etc.
  - Trial-specific equipment can be purchased inexpensively – centrifuge, refrigerator, freezer, temperature monitoring supplies.
  - All equipment to be used during clinical trials must be calibrated yearly and the records should be maintained for reference.
  - If the sponsor requires specific equipment (-80 freezer or EKG machine), consider negotiating for this equipment or rent the equipment from a local medical supply company. Be sure to negotiate these fees into your trial budget.

- **Strategic Partnerships**
  - While there is a myriad of vendors, organizations & networks throughout the clinical trial landscape, keep your partnerships simple!
  - The relationship between the site and sponsor or their representative (CRO) is critical to the success of a site. The significance of this relationship often gets overlooked. There is a high turnover rate on the industry side of CTs, so the person you are working with today may be employed by a trial you are trying to get awarded tomorrow. The PI and site staff should be engaged with their pharmaceutical partner, answering emails in a timely manner and being available for phone calls and schedule office visits.
  - Another important partnership is the one with the patients on the trials. These are people who are volunteering to take an experimental medication and trust that the physician has their best interest in mind. By establishing a relationship based on respect, research subjects are far more likely to attend all required visits, which is a serious problem within the industry. Additionally, if treated professionally and respectfully, a research subject is more likely to become an advocate for not only you, but also for clinical research trials.

What are the difficulties/timelines/costs/expectations associated with building a research unit from scratch?

The most common challenges for a new site include:

- **Underestimating the time it takes.** It's reasonable to expect a 6 to 9-month startup as landing the first trial can take time since you are having to convince sponsors/Contract Research Organization(s) to choose your site for participation despite your lack of experience. Obviously, there is variance depending on a number of circumstances – experience of PI, therapeutic area, etc.
- **Personnel needed.** The greatest challenge is finding an experienced clinical research coordinator (CRC) who possesses not only the right skill set but also the right attitude for building a program. The CRC will make or break a new program. I can't overemphasize this point enough.
- **Infrastructure needed.** Do you have the office space for a CRC, do you have an available exam room, space for storing supplies, cabinets that lock (drug storage), etc.

Measuring the Success of a Clinical Research Program

What are the KPIs associated with measuring performance in a research unit? Include normal financial performance and a description of a healthy research revenue model.

At the most basic level, a site has to have active trials and enroll subjects to be successful – this should be the basis for all other metrics.

Common KPIs can be categorized by Operations, Subject Recruitment, Business Development & Financials.

Examples include total monthly trial revenue & receivables, total number of active trials (enrolling subjects), number of protocol deviations, number of subjects screened & randomized, number of trials in the pipeline, contract/budget TAT, time open to first patient enrolled, timely data entry, etc.

What are the additional synergies/benefits associated with a strong research unit?

There are a tremendous amount of benefits to having a strong clinical research program:

1. Opportunity to provide cutting edge therapeutic options to your patients and community.
2. New stream of revenue.
3. New payor source that is not tied to 3rd party payers.
4. Improved patient care – research subjects receive outstanding care on clinical trials. Trials are dictated by a protocol which specifies how often a patient must visit their study team/physician, which is typically for more frequently than standard of care. Research subjects also have a team of professionals (their local study team AND an external group) monitoring their ongoing status on the trial. Research patients have direct access to their study team and can contact them 24/7 to report any concerns or changes.
5. Increase ancillary service volume.
6. Downstream revenue from research subjects who become patients of the clinic once the trial ends – patients who participate in a trial will often transfer their care to the trial physician because they have received such excellent care.
7. Patient recruitment – Sponsors (pharmaceutical companies) often provide a recruit budget for their trials, which is a great way to not only promote your enrolling clinical trial, but it's also an easy way to promote your practice. Fifty people might call or walk through your door inquiring about the trial and not one may qualify – BUT you just had 50 people get exposed to your practice who may have never known about you otherwise.
8. Enhance your image & reputation.
9. Recruit new physicians to your practice.
10. Reduce patient leakage and increase patient keepage.
11. Continuity of care. If they don't have to leave a practice to participate in a study they are better off because they do not have broken/disjointed care.

Where/Who are some of the platforms that have developed the strongest research units to date?

You know, no one does it perfectly. We have worked for and with some of the "top" research sites in the country and even they have opportunities for improvement. Research is highly scrutinized, and a very litigious space where the rules are definitely not black and white and no situation is ever the same.

St. Jude, Duke, MD Anderson, UT Southwestern Medical Center, Rush, Northwestern are all ones we have personally worked with and found their processes to be on point.

The Risks of Implementing a Clinical Research Program

Why are so many research units under-developed across the provider landscape?

All too often, research sites fail to treat their research program as a separate service line just like they would any other service line. Clinical research must be run like any other business to be successful.

Expectations are not aligned. Many practices believe clinical trials are a way to make a quick buck but are then completely caught off guard with the amount of work that is involved in conducting clinical trials. There is a phenomenon in our industry called the "PI one-and-done Syndrome". This is where PIs are convinced that running clinical trials are "easy" but then don't realize the amount of effort and infrastructure involved. They don't know how to properly negotiate a clinical trial budget and end up losing a tremendous amount of money because they didn't know how to properly account for all trial expenses. These physicians will conduct one trial and, based on their experience during the trial, will never pursue clinical research again. This is a very serious concern in our industry as we are desperate for new physicians to carry the torch.

Sites that fail do not provide the appropriate resources and tools needed for success. One example is when new sites try to borrow one of their own employees (who has no experience in clinical trials) to run a trial. Now this employee is going to be unsuccessful with both of their job responsibilities, get disgruntled, do bad research and leave the practice – leaving the physician in a lurch on 2 fronts – their research and their daily duties.

Clinical trials should be fully integrated into the practice. The research team should be eating lunch with the receptionist and getting invited to the MA's baby shower. Clinical trials should be considered a therapeutic option for all patients who enter the clinic. The only way to make this happen is to have the research program integrated into the practice.

What are the risks associated with a research unit – items to keep an eye on?

Regulatory and financial compliance.

- **Regulatory Compliance:** The PI needs to fully understand their role and the expectations for being a PI. They have to provide adequate oversight and ensure patient safety and data integrity are maintained throughout the life of a trial
- **Financial Compliance:** It's imperative to have a system in place to ensure double billing (aka Medicare fraud) does not occur. A site cannot bill a third-party payer for a procedure that is part of a trial AND that gets paid for by the pharmaceutical company.

There needs to be someone who understands the intricacies of clinical research finances. This person needs to not only understand financials, but they also must understand the trial budget, payment terms, invoiceables, etc. A significant amount of money often goes uncollected by sites simply because they don't have a process in place to ensure all trial-related fees are recovered. This goes back to why sites are unsuccessful.

Teamwork Makes the Dream Work

What else would you like to cover? Changing regulatory landscape? Compliance issues?

Like every other industry, technology is changing the clinical research landscape at a rapid pace. Without question, technology plays a tremendous role in the future of clinical trials. With that being said, the success of a site still comes down to very simple metrics – trials and subjects. A site can have all the technology and toys available, but if they aren't enrolling subjects and providing clean data, they aren't going to continue to get new trials awarded to their site and will ultimately have to shut their program down. At the end of the day, sites still must master the fundamentals to be successful. I am constantly amazed how often this simple concept gets overlooked.

Why is SCALE an ideal partner to help your platform develop its research division?

SCALE bring a unique combination of industry acumen and experience to the table. We have been in their shoes – having rolled up our sleeves and worked in the trenches as clinical research coordinators – consenting patients, answering queries, submitting to the IRB, working with CRO/Sponsors to solve recruitment issues, etc. – but also have worked with major hospital and health systems to identify and help solve significant concerns and issues. We want our lessons learned to be your bullets dodged. We want you to be successful. We take the philosophy of coaches. A coach is on your team and he/she has a vested interest in your success. If you fail, they fail and if you win, they win. People and companies are often not self-aware. They don't know what they don't know. We don't always see our opportunities for improvement. We need a champion who is looking out for our own good. Iron Horse wants to be your coach. We want to grow with you at every step of the game.

We work closely with our clients to understand their goals and then develop and implement a strategic plan that best fits their needs.

Our goal, when we work with sites, is to establish/revitalize their research program so that they are left with a model that is a gold standard in research—strong, consistent, reliable, durable, trustworthy, and able to scale up and down to ride the ebb and flow of research.

Special thanks to Chad Eriksen for his insights and our Executive for their participation in this discussion.