



Strengthening partnerships and processes for clinical trial excellence in medical devices

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INTRODUCTION

Before my focus in Medical Devices

- MPH (Boston University)
- Dana-Farber-Harvard Cancer Center

Med Device Experience (2003-current)

Boston
Scientific

KYPHON

Alydia
HEALTH

Medtronic

BENVENUE
MEDICAL

ORGANON

INTUITIVE

SI-BONE®

novocuff





AGENDA

- Identification of investigators aligned with study goals, required expertise, and regulatory expectations
- Building relationships at clinical sites
- Effective training for investigators and site staff
- Optimizing the informed consent process

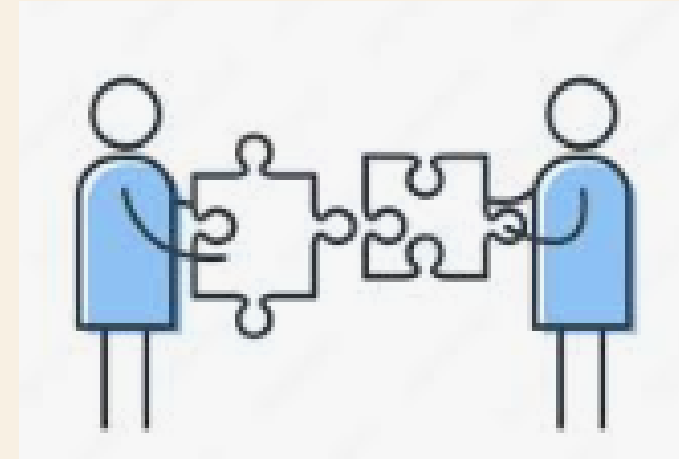


CHOOSING SITES AND STUDY LEADERSHIP

- Qualification with an early focus on effective communication

CONSIDERATIONS TO MAKE IN SELECTION OF SITES

- Geography-based decisions
- Known friends vs. new introductions
- WHO are your leaders... are they your “whole” future customer? Do they have research support / infrastructure?
- Concentrated connections at Society Mtgs
- Plan your process
 - Early introductions vs in-depth meetings
 - Plan your elevator pitch and your on-site qualifications carefully
 - Avoid wasting time and resources by addressing challenges first
- Number & type of Sites to involve can vary greatly by Study



EVALUATING EXPERTISE

Typical early identification

1. Initial list (hopefully some KOLs in your space included)
2. "Friends and family" plus research publications
3. Many short intro calls following (or pre-NDA)
4. Develop forms / process

With an onsite visit, encourage participation of key partners in the early meetings

In-depth qualification

1. Once "enough" information is gathered (sometimes multiple points of contact)
2. Set up qualification (ideally onsite)
 - Site, PI, tour
 - Documentation

Note to your team: Connect regularly to ensure process is working and the "right" site list and leadership is taking form



SETTING EXPECTATIONS

Priorities in early presentations

- Present the problem and the device as a potential solution
- Does that leader perceive they have that problem and desire your solution?
- Show you have done your homework
- Describe anticipated challenges and open posture to solutions

As you get further along...

- Lean into the requirements of the project as much as possible
- Get to a “no” early
- Show that decision to move forward is a mutual decision with work to be done on both sides
- Discuss the ideal DNA of a study leader openly
- Discuss team requirements and communication expectations openly
- Discuss background / experience / regulatory experience / device research experience
- ... will anything be done here for the first time?





BUILDING SITE RELATIONSHIPS

It's the people...

A LONG-TERM RELATIONSHIP

Foundation

1. Trust
2. Thought-partners
3. Clear communication
4. Accurate information
5. Community-building



Tools

1. Study logo, "brand"
2. In-person engagement, "live at your sites", pick up the phone, reply quickly to emailed questions / requests
3. Regular calls (Research Management, Investigator, Study Team)
4. Newsletters
5. Toolkits (randomization kit, recruitment toolkit, etc.)
6. Holiday or thank you notes, recognition

AVOID THESE PITFALLS

"She's just not that into you."

Behavior	Result	Instead
Late to reply to emails or return a call	Loss of momentum and slow progress	Be responsive! Bring your energy.
Too much talking... not enough listening	Sites go silent and don't offer their good ideas / solutions	Give a structure to the conversation but ensure healthy, balanced engagement
Defensive posture when faced with challenges	Lose the respect of your partners	Face those challenges head-on and side-by-side
Use of wrong language, persistently	Disconnection and lack of interest	Lean in to learning and then implement changes in your language with intention / admit you are learning
Avoidance of hard conversations	Non-compliance / festering problems	See what's working, what isn't... start hard conversations early when they are not as hard



BE FLEXIBLE... WHAT WORKS FOR SOME DOES NOT WORK FOR ALL

- Be ready for team changes / transitions by refreshing your training program and being ready with reminders
- If someone is facing a struggle (low enrollment, low retention, compliance issues, slow to enter data or respond to queries) partner with them and create space to hear the struggle in their voice...
- Encourage site-to-site communication to share challenges, solutions, successes to further enhance the Study Community
- Budget for study meetings (Kick-off, study training, casual gatherings)
- Openly ask (early at Site Qualification!) for communication preferences and try to abide by them!



EFFECTIVE TRAINING PROGRAMS

- Listening, Planning, and Execution



LISTENING & PLANNING FOR A GREAT TRAINING PROGRAM

Questions

- Will you have a number of roles on the Study?
- How will you train to each?
- What is the time commitment?
- Will refreshers be necessary?
- Who will be your training staff? (You? CRO? CRAs? Do you need clinician trainers?)
- Can you include each group in review of training material?

Tips

- Use both didactic training and hands-on training in medical devices
- Consider best models & realistic location
- “Voice” - keep it interesting
- Use your protocol and your IFU to ensure you don’t leave anything out
- Create a training matrix
- Develop a training “playbook” and all the tools to ensure documentation is complete and consistent
- Hire people who love to educate and involve them in the development of training materials

SEAMLESS TRAINING

Schedule	Checklists	Documentation
Determine who, where, how long	Ensure entire training team has access to training program checklists	Don't document incomplete training (keep track of completion / attendance)
Find out who at the Site can keep a schedule organized	Ensure all understand the necessary preparation and their role on the day(s) of training	Consider "certificate" of completion, quiz, sign-off
Partner with the Site for shared ownership	Include snacks for training team... keep everyone fueled and happy	Take pictures... update running slideshow of pictures daily

ON THE DAY OF...

- Ensure the trainers have:
 - Good sleep / good meals
 - Respect one another; cheerful introductions of one another
 - Proper introduction to Site leadership for familiarity and connection
 - Internal recognition of long days... "the push"
- Paperwork is neat and organized
- Consider "brand"
 - Pens
 - Clipboards
 - Stickers

Sarah 9:05 PM

Amy rocked tonite's info session for UAB's nurses. These RNs (and new residents and whole investigator team!) are psyched to treat as early as possible! Go, team, go!

Image from iOS ▼





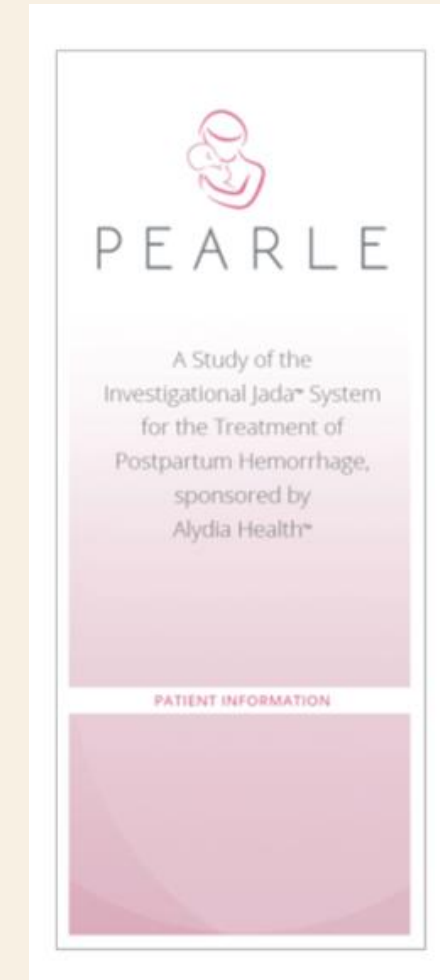
SUPPORTING THE INFORMED CONSENT PROCESS

Ways to empower sites
and patients considering clinical trials

WHEN ENROLLMENT IS A CHALLENGE

- The Story of the PEARLE Study
- Medical device for abnormal PP uterine bleeding (2017-2020)
- The numbers:
 - > 16,000 approached
 - > 7,000 consented
 - 107 enrolled

Unique challenge of diagnosis at a time when consent not possible... Needed commitment from all Sites to run a very challenging clinical trial





TOOLS FOR RECRUITMENT & INFORMED CONSENT

➤ How is the study best presented?

Is your study complex? Is it presented at a stressful time of diagnosis or during an admission where the patient is otherwise bored?

Are your study eligibility overly restrictive?

Consider specific needs for patient education or recruitment material.

Ensure your educational material is translated, as needed and ensure your illustrations or photos depict diversity.

Educational material - examples

1. Brochure
2. Well-written ICF (with illustration / picture of device)
3. Have your PIs & experienced research staff review your templates before they become final... language
4. "Demo" medical device or anatomic model
5. Study poster, ad, social media
6. Patient advocacy groups - consider study listings

ACCOUNTABILITY & OVERCOMING CHALLENGES



Good planning and tools avoid:

1. Trial taking too long to enroll
2. Trial exceeding budget or overweighted in recruitment
3. Frustration among investigators, research staff, Sponsor/CRO
4. High drop-out rate
5. "Dud" site experiences with no / low enrollment
6. Overall, team burnout



FINAL TIPS & TAKEAWAYS

Start out on the right foot with your site recruitment and qualification process

- Plan how you will gather information about Sites, Leaders early and then execute consistently

Respect your partnerships and invest in long-term relationships

- Regularly return to relationship-building brainstorming


Training is key to successful operations

- Incorporate learnings to develop a strong program and avoid non-compliance and inefficiency

Focus on empowering your sites to empower their patients

- The door to enrollment is your well-prepared Sites





"They may forget your name, but they will never forget how you made them feel." - Maya Angelou

THANK YOU

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