5 HURDLES TO OVERCOME
When Planning a Clinical Trial

Does your staff have formal training?

YES

You're off to a great start!

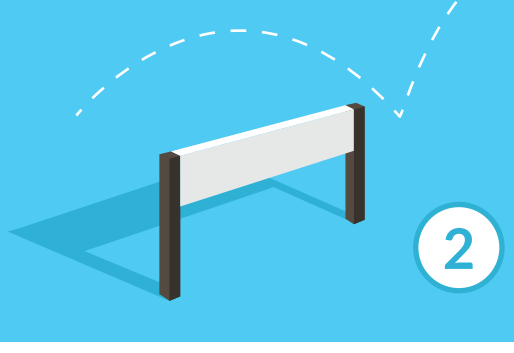
As you fine-tune your training program, here are a few important elements to remember:

- Clinical Investigational Plan
- Good clinical practice (GCP)
- Human subject protection
- FDA/ICH regulations
- Device use
- Safety management

NO

Consider hiring trained monitors or implementing training to prepare your staff for your upcoming clinical trial.

Do you have buy-in from all necessary stakeholders such as investigators, nurses, monitors, and research coordinators?



YES

It's great that you can count on these individuals to accurately and consistently report clinical trial data.

Keep them in your corner by maintaining consistent, transparent processes and a frequently updated project schedule.

NO

Turnover rates among healthcare workers are high, which could expose your study to the risk of noncompliance.

Consider hiring a project management team adept at handling the shifting of key stakeholders throughout the clinical trial process to keep "buy-in" levels high and noncompliance issues low.

Do you have an objective third party overseeing your trial?

YES

Great! You're well on your way to achieving compliance and approval.

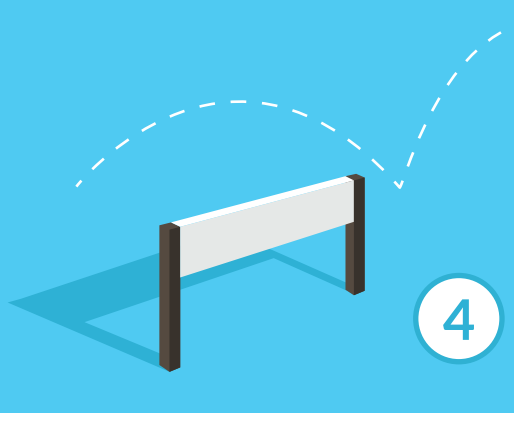
Conducting a site audit helps ensure you have all your bases covered so you can approach your next inspection with confidence.

NO

Given that there are so many moving parts in a clinical trial, those closest to it risk overlooking critical issues.

Consider adding independent oversight by utilizing third party monitoring, auditing, and/or a DSMB/CEC to give your study an added layer of patient protection and credibility.

Are you aware of the complexities of your device study and are you taking steps to mitigate risks?



YES

We have an extensive process in place for this.

Great! Be sure to revisit your process and make updates as needed. A third-party consultant can evaluate your process periodically and make recommendations.

NO

Hiring an experienced consultant for your trial can aid in identifying and proactively planning for the management of potential risks.

A good team can help you conduct a risk assessment and create processes, documents, or tools to help mitigate the identified risks.

Is your study global?

YES

We have extensive experience working on multi-national studies.

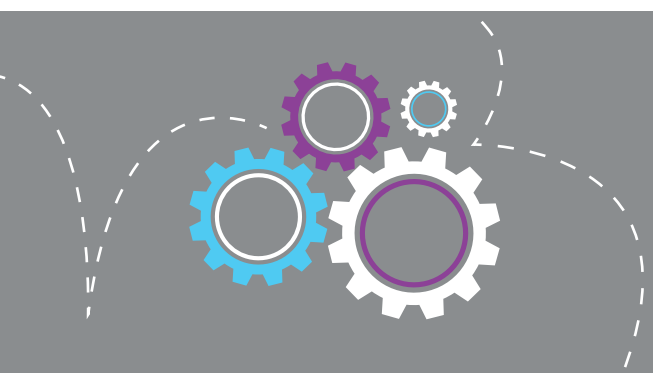
Excellent! Don't ever underestimate the importance of communication, and consider an external auditor to ensure global acceptance of clinical data.

NO

It may be helpful to seek out partners who are knowledgeable about both foreign and domestic regulations to minimize the challenges of a global study.

Familiarize yourself with the following:

- Language differences
- Cultural differences, such as work styles
- Logistical challenges due to distance, time zones, etc.
- Labeling requirements that could complicate shipping
- Different governing and regulatory bodies



Medical device trials are complex, with many moving parts. Each presents the potential for human error, which can jeopardize the integrity of your study, delay approvals and even put human subjects at risk.

imarc
WE'LL EARN YOUR APPROVAL.

22560 Lunn Road, Strongsville,
Ohio 44149
• tel 440.801.1540 • fax 440.801.1542
• info@imarcresearch.com
• imarcresearch.com

IMARC brings order to the chaos, simplifying difficult processes and ensuring compliance at every stage. Our team of clinical research experts works closely with yours to assess your current processes, advise you on best practices and ultimately, earn FDA approval.
To learn more, **contact us today**.