PHARPOINT RESEARCH

ULTIMATE GUIDE TO SUCCESS

Dermatology Clinical Trials

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About the Authors

This whitepaper was produced by the team at PharPoint Research, a full-service contract research organization (CRO) that has supported over 1,000 clinical trials since 2007.

As a company, PharPoint has supported 40+ dermatology studies, including providing support for a successful ANDA with the FDA's Dermatology division.

PharPoint's clinical operations team members have experience supporting dermatology studies including skin infectious, chronic dermatological diseases, aesthetic dermatology, and rare indications. Their dermatology experience includes a wide range of populations, including studies that involve adults, pediatrics, pregnant persons, and immuno-comprompised patient populations.

Strategic Site Selection

With objective analysis and insight, Sponsors can make informed decisions on which sites to select for a more powerful, effective, and efficient clinical trial.

Identify Sites with Quantitative and Qualitative Analytics

With thorough site feasibility processes, sponsors can increase speed to first patient in and maximize enrollment potential.

According to Pharma Intelligence Informa, two-thirds of all clinical trial sites are unable to meet enrollment goals. Half of all sites recruit one or zero patients. Even for trials that are able to meet recruitment goals, 86% experience delays, with actual enrollment timelines typically 2x their planned estimates (averaging 8 months to initiate a trial from site identification to first patient in).

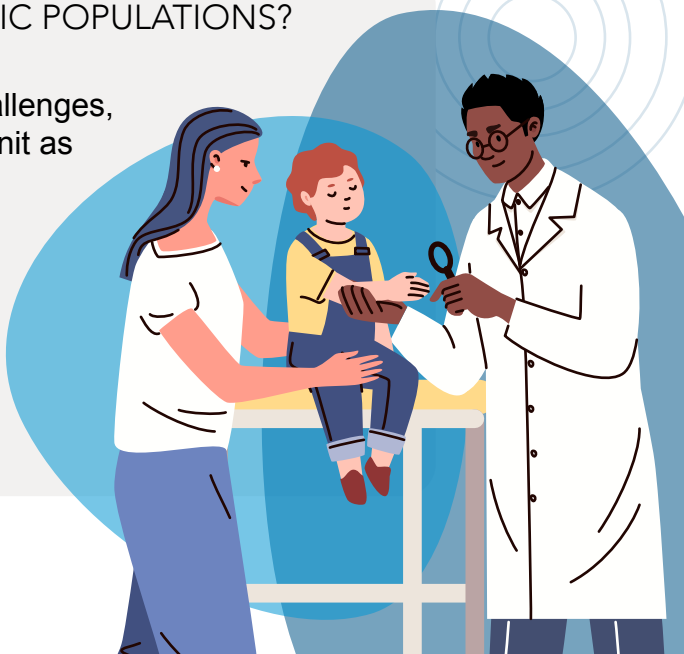
When identifying sites, look at both the therapeutic alignment of a site and investigators expertise along with their track record with similar studies. Identified sites should then be assessed to determine a best-fit for your study.

- Does the site have access to your patient population?
- Does the site have resource capacity?
- Does the site have your study-specific capabilities?
- Does the site have a clean audit history?

DOES YOUR STUDY INCLUDE PEDIATRIC POPULATIONS?

Pediatric studies have their own unique challenges, and the study team must enroll the family unit as opposed to just the patient.

One of the biggest challenges for pediatric studies, regardless of indication, is making sure site appropriately consent the parent or guardian. If a guardian is involved, additional documentation is required.



Site Characteristics

What characteristics make from an excellent site for dermatology study?

In our team's experience, prioritizing sites that have dermatologists as opposed to general practitioners may be helpful in certain cases. However, if your IP require specialty storage (e.g., a certain freezer), be aware that dermatology offices may not have the necessary equipment. This information should be gleaned during the site selection process.

Additionally, as the use of photography is common in dermatology studies, it may be important to evaluate a site's photography experience during the site selection process.

Study Conduct

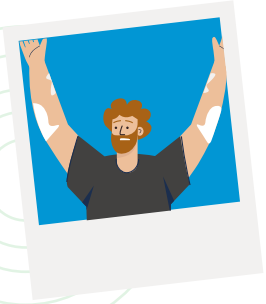
Avoid surprises by partnering closely with vendors and study partners and putting yourself in the shoes of a study subject.

Kick Off Meeting

Kick-off meetings set the foundation for study success, bringing together all key team members and any involved third-party vendors.

Expectations and study goals should be set during the kick-off meeting, including communication flow, timelines, and responsibilities.

Supporting Study Recruitment



Address Potential Patient Pain Points

Will photography be an obstacle for your patient?

While photography is helpful to measure progress (especially for indications like eczema), it's important to put yourself in a patient's position. Will subjects be comfortable with having their photos taken? If, for example, patients must consent to being photographed in their undergarments, this may be an added enrollment barrier. Sponsors may instead choose to limit photography areas to specific parts.

Using eDiaries? Consider a "BYOD" Approach

eDiaries are a helpful tool for many dermatology studies and are often easier than the traditional paper diaries. If your study is utilizing eDiaries, consider allowing a "BYOD" (Bring your Own Device) approach. By allowing subjects to download an app as opposed to using a provisioned device, they won't have to carry around a second device.

Prompt Query Resolution

Ensure your sites coordinators, data management (DM) team, and CRAs have an excellent working relationship so queries can be raised and resolved promptly.

It's no secret - site coordinators are incredibly busy, and typically are working on multiple studies at once. Your data management team should prioritize prompt query generation, as study dedication can be contagious. Remember: if DM takes weeks to raise a query, it's likely your site coordinators will not feel the need to prioritize timely resolution, either.

Positive working relationships between a study's DM lead and CRA can also be helpful in faster query resolution, as study team members can pick up the phone at a moment's notice to quickly resolve any misunderstandings or questions.

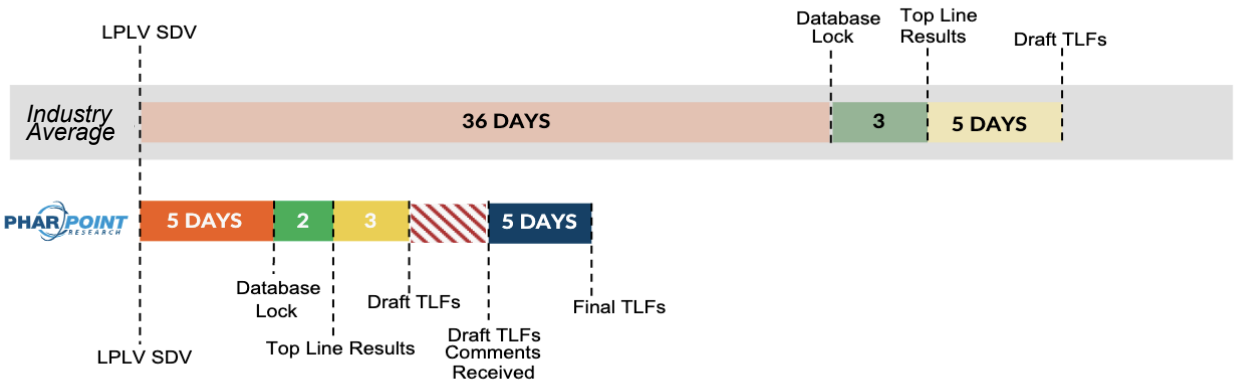
Get Results Faster

After study conduct completes, how soon should you expect results for your study?

Plan for a Faster Database Lock

When it comes to faster database lock, planning is everything.
At PharPoint, we use a variety of tools, including comprehensive data management plans, a well-designed database, input from cross-functional stakeholders, and meaningfully written edit checks to allow for cleaner, faster data. Our team uses ongoing data cleaning, keeping studies top of mind and addressing issues and queries on an ongoing basis. We regularly interact with stakeholders, and ensure data issues are addressed with sites while that site is still engaged.

Evaluating Standard Biometrics Timelines



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ABOUT PHARPOINT

PharPoint Research is an award-winning and client-focused contract research organization (CRO) that offers Phase 1 through Phase 4 clinical trial support to clients of all sizes. Founded in 2007, PharPoint's team has participated in over 1,000 clinical trials with a high business repeat rate.

Our services include:

- Site Feasibility
- Clinical Operations
- Medical Monitoring
- Project Management
- Data Management
- Biostatistics
- Statistical Programming
- DMC Support
- Medical Writing
- Study Rescue