PHASE 3 DERMATOLOGY CLINICAL TRIALS

– all you need to know

Patients

Protocol

Investigators

Plan

Resources

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PHASE 3 DERMATOLOGY CLINICAL TRIALS – all you need to know

Patients

When planning for a Phase 3 program it is important to think about the **patient** population you will need to access

- ***Where are they?***
- ***How many will you need?***
- ***How motivated will they be to participate in the study?***

FDA has recently issued guidance for industry on Patient-Focused Drug Development

- ***What is important to Patients?***

More than ever it is important to understand how the disease impacts the patient and how the treatment is perceived by the patient

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PHASE 3 DERMATOLOGY CLINICAL TRIALS – *all you need to know*

Protocol

A well written **protocol** is key to a successful clinical trial

- ***Endpoints*** **–**
  - By the time you are ready to plan your Phase 3 program the expected clinical benefit for patients should be clearly understood
  - It may sound obvious, but it is essential for success that clinical endpoints are aligned with the expected clinical benefits
  - Look at your Phase 2 study carefully to ensure that moving forward you have confidence that signs and/or symptoms will be evaluated at the most appropriate times

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Protocol

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- ***Endpoints*** –
  - Review FDA-approved comparators' endpoints and scales for reference
  - Review FDA websites for newly posted guidances for your indication

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- ***Visits*** **–** the timing and frequency of patient visits should minimize risk to patients while ensuring endpoint data is collected, but not over-burden the patient with frivolous visits. Depending on study needs, options like remote visits should be considered to minimize impact on patient schedules, and in-clinic visits should be scheduled with the Investigator when key in-person assessments and data is to be collected

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A well written **protocol** is key to a successful clinical trial

- ***Inclusion & Exclusion*** **–** entrance criteria should ensure subject safety and top quality data. The criteria should be considered as a whole by experts in Dermatology to ensure ideal patients are enrolled, but also from the patients' and sites' perspective to limit unnecessary recruitment challenges. Fast enrollment of ideal subjects is feasible with this planning

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PHASE 3 DERMATOLOGY CLINICAL TRIALS – *all you need to know*

Investigators

The most perfectly planned study cannot be successful without the best **Investigators**. When selecting Investigators it is important to consider many factors, not just high enrollment rates

- ***Selection of sites that are adequately staffed with knowledgeable research professionals is key to ensure qualified Investigators provide reliable, accurate data with top quality***
- ***Dermatologists, Investigators with past training and experience with Dermatology, and indication-specific physicians understand the accelerated speed at which Dermatology studies run and build their clinic to accommodate the pace while maintaining quality***

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Investigators

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- ***The number of evaluable subjects can be much reduced at a site that enrolled unqualified or marginal subjects, or did not comply with protocol requirements***
- ***Your CRO should have and use historic indication-specific Dermatology data metrics for each Investigator on both enrollment rates, but as importantly, on data quality when selecting Investigators. Leveraging this data increases the likelihood of a successful study***

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Plan

In Dermatology, there tend to be waves of clinical trials simultaneously in the same indication as multiple Investigational Products vie for market share in that indication

- ***With some planning and research, forecasts on competition for both Investigator and patient attention for participation in your Dermatology trial can be generated, and plans for navigating any forecasted enrollment challenges can be implemented from the beginning to avoid enrollment delays***

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Plan

- ***Key to Success**: Your CRO should have historical data on enrollment challenges for the indication and successful proactive strategies for resolution*
- *Ultimately the goal is to enroll quickly with patient safety the paramount focus while collecting **top quality data**, on the master track to marketing approval*

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Training is also key -

- *In Dermatology, primary endpoint assessments can be objective or subjective and require proper training for standardization. Your CRO should have proven methods for training Investigators on all assessments to minimize variability seen in Dermatology clinical trials*

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Resources

Many resources and references are available and should be utilized.

Some important Guidances for Industry Include

- E8R1 General Consideration for Clinical Studies (7/31/19)
- E19 Optimization of Safety Data Collection (6/26/19)
- Epidermolysis Bullosa: Developing Drugs for Treatment of Cutaneous Manifestations (6/28/19)
- Acne Vulgaris: Establishing Effectiveness of Drugs Intended for Treatment (5/12/18) Multiple Endpoints in Clinical Trials (1/12/17)
- Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment (10/16/13)
- Patient-Focused Drug Development: Collecting Comprehensive and Representative Input (6/2018)
- Patient-Focused Drug Development: Methods to Identify What Is Important to Patients Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders (10/2019)

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ABOUT SYMBIO

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Symbio is the only *Dermatology focused, global CRO from Formulation Development, through Clinical Trials, to Final Approval*

- *Symbio is a niche global CRO specializing in Dermatology with offices in the United States and Germany*
- *Since 2002, Symbio has conducted over 140 clinical trials, 91% of the studies in Dermatology, including over 90 Phase 3 studies 50 FDA approvals and counting*
- *Symbio's subsidiary, Dow Development Laboratories, LLC, designs, develops, tests and manufactures topical drug products, including creams, gels, ointments, pastes, solutions, and suspensions*
- *In-house **Dermatology** clinical trial expertise including **Project Management, Medical Monitoring, Medical Writing, Site Monitoring, Data Management, BioStatistics**, coupled with Dow Development Laboratories' formulation and manufacturing*

The reward for good work is more work.

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About Symbio, LLC, Dermatology CRO

- *Chad Troller has worked in Dermatology clinical trials for 20 years in roles from CRC at a Dermatology Investigative Site, CTM at a Pharmaceutical Sponsor, CCRA, Project Manager, Director, Project Management, and is currently Director, Client Services at Symbio, LLC, Dermatology CRO*

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