cliantha® research

DERMATOLOGY CLINICAL STUDY COST DRIVERS.

Skin conditions are among the most common health problems in the United States and one in three people are affected at any given time, which is more common than obesity, cancer, and hypertension (Bickers et al., 2006). Results from clinical trials have significantly improved the outcomes and quality of life of patients with dermatologic conditions. Hundreds of clinical trials are currently underway or in the planning stages for various skin conditions like psoriasis and atopic dermatitis as well as rare skin diseases.

Partnering with a CRO that has recorded experience in successfully managing dermatology trials can help in:

1. **Optimising resources**
2. **Creating a patient-focused protocol**
3. **Providing access to an established network of investigators and sites identifying and facilitating faster recruitment**
4. **Retaining the right population of patients**
5. **Promoting adherence to the clinical trial protocol thus facilitate generation of reliable, high-quality data, and finally**
6. **Achieving regulatory approval as soon as possible**

Understanding the primary cost drivers for dermatology clinical studies can be exhausting. Based on our extensive clinical trial experience, we have identified keys cost drivers that can be encountered during the study process and can facilitate outsourcing decision from financial perspective.

Cost Drivers	Low Risk	Medium Risk	High Risk
Study Phase		✔	
Timelines and Milestones			
Key Dates			✔
Timeline Impact			✔
Project Management			
Geography	✔		
Subjects			✔
Site visit per subject		✔	
Scope of services			✔
Projected % of patient population			✔
Patient Involvement			✔
Complexity of Study		✔	
External Vendor			✔
Patient Recrtuiment and Advertising			
Protocol Factors			✔
Planned Number Of Clinical Visit			✔
Projected Screen Failure Rate		✔	
Indication Factors			
Seasoning/time of year			✔
Prevelance of Indication			✔
Number of competing studies		✔	
Data Management CRF Count			
Data Listings			✔
Data Review Cycles			✔
Monitoring Visit			✔
Remote Review Time			✔
Query Resolution			✔
Programming and Biostats			✔
EDC Hosting Cost			✔
EDC			
Complexity of CRF		✔	
Associated edit checks		✔	
Page/Data volume		✔	
Data import/export volumes		✔	
Analysis Numbers		✔	
Other Factors - Protocol Amendments , IM			
Availability of new safety information		✔	
Request from reg agencies to amend the study, changes in study strategy, protocol design flaws, difficulties recruiting study volunteers	✔		
Audio Conference vs Web based	✔		
Interactive Investigator Training	✔		

Cliantha Research has an impeccable track record of over 17 years and is a leading provider of Dermatology Clinical Research Services.

Experience in managing Dermatology studies for US FDA, EMA and DCGI Submission includes:

Molecule	Formulation	Indication	Type of Study	Regulatory	Location	No. of sites	Total Sample Size	Recruitment duration in weeks
Clindamycin Benzoyl Peroxide	Gel	Acne Vulgaris	Clinical End Point_BE	NA	India	10	60	16 weeks
Clindamycin Benzoyl Peroxide	Gel	Acne Vulgaris	Clinical End Point_BE	USFDA	India and US	13 + 13	850	36 weeks
Permethrine	Cream	Scabies	PK-BE	USFDA	India	10	154	20 weeks
Permethrine	Cream	Scabies	PK-BE	USFDA	India	10	154	20 weeks
Permethrine	Spray	Scabies	PK-BE	DCGI	India	2	18	4 weeks
Clindamycin Benzoyl Peroxide	Gel	Acne Vulgaris	Clinical End Point_BE	EU	India	20	530	14 weeks
Clindamycin Benzoyl Peroxide	Gel	Acne Vulgaris	Clinical End Point_BE	USFDA	India	20	910	20 weeks
Adapalene Benzoyl Peroxide	Gel	Acne Vulgaris	PK-BE	USFDA	India	20	650	20 weeks
Mupirocin	Cream	Secondary infected traumatic skin lesions	PK-BE	USFDA	India	25	990	51 weeks
Dimethyl Fumarate	Tablet	Psoriasis	PK-BE	EU	India	20	300	19 weeks
Ketoconazole	Cream	Tinea pedis	PK-BE	USFDA	India	25	794	46 weeks
Ketoconazole	Shampoo	Tinea versicolor	PK-BE	USFDA	India	14	425	26 weeks
Tretinoin	Cream	Acne Vulgaris	Clinical End Point	USFDA	India	20	715	15 weeks
Tretinoin	Cream	Acne Vulgaris	Clinical End Point	USFDA	India	18	570	15 weeks
Roflumilast	Cream	Atopic Dermatitis	Clinical End Point	USFDA	India	20	525	21 weeks
Ammonium Lactate	Cream	Ichthyosis Vulgaris	Clinical End Point	USFDA	India	20	390	17 weeks
Ammonium Lactate	Lotion	Ichthyosis Vulgaris	Clinical End Point	USFDA	India	20	390	17 weeks

RESEARCH DELIVERED WITH INTEGRITY

Cliantha Research, a full-service Clinical Research Organization (CRO), is a leading provider of Clinical research services, based in Ahmedabad, India. Cliantha's mission is Science with Integrity. Cliantha has seventeen years of impeccable regulatory history with USFDA, WHO, MHRA, Health Canada, AGES, AEMPS, MCC, MOH, ANSM, MOPH, ANVISA, CAP, and NABL.

Cliantha Research is headquartered in India with facilities in Ahmedabad, Noida and Vadodara. Cliantha has a presence in USA (facilities in Florida and Project Management in New Jersey), Canada (facilities in Mississauga, Winnipeg and Scarborough) and Portugal (Project management).

In seventeen years, Cliantha has accumulated expertise in Early Phase (BA/BE), First in Man, Late Phase (various therapeutic areas), Respiratory, Tobacco Research, Dermatology, Consumer Research, Analytical lab, Diagnostic Central lab, IVRT, IVPT, Biometrics, Environmental Exposure Chambers and Medical Services.

OUR STRENGTH

01
OUR ENSHRINED VALUES:
SCIENCE & INTEGRITY

02
17 YEARS
OF EXCELLENCE IN RESEARCH

03
3 CONTINENTS**, 4** COUNTRIES
AND **9** OFFICES

04
1000+
PROFESSIONALS

05
IMPECCABLE REGULATORY
TRACK RECORD

06
ROBUST
E-LEARNING SYSTEM

Should you need assistance in planning your next dermatology study, Cliantha is at your service.

Contact us at **info@cliantha.com** or visit us **www.cliantha.com** to know more.