ALTASCIENCES

NONCLINICAL DERMAL SAFETY ASSESSMENT SUPPORT

Altasciences' team of toxicologists, veterinarians, and technicians move in unison to provide a wide range of dermal services to bring your molecule from **lead candidate selection** to **clinical proof-of-concept,** and beyond. Our team can help you develop dermal models, validate existing dermal models, and perform both GLP and non-GLP safety assessment to support 505(b)(2) and new chemical entity regulatory filings.

WHY ALTASCIENCES FOR DERMAL RESEARCH?

Dedicated Dermal Team

We have assembled a dedicated team of experts to increase the accuracy of dermal scoring, to consistently provide you with high-quality data.

Dedicated Dermal SOPs

We have implemented special dermal SOPs to minimize any potential challenges in dermal dosing and mitigate the risk of cross-contamination.

Dedicated Dermal Facilities

We have customized our vivarium to ensure the integrity of test article exposure and transfer.

Testing Capabilities

- **Dermal efficacy**
- **Pharmacokinetics**
- **Pharmacodynamics**
- **Wound healing**
- **Inflammation**
- **Dermal toxicology**
- **Irritation**
- **Sensitization**
- **Acute studies**
- **Sub-chronic studies**
- **Chronic studies**

Our team brings decades of combined experience to support multiple dermal drug development programs, from initial efficacy to clinical proof-of-concept.

We we will work with you to:

Develop dermal models

Validate pre-existing dermal models

Design and conduct dermal toxicology studies that support your regulatory filings

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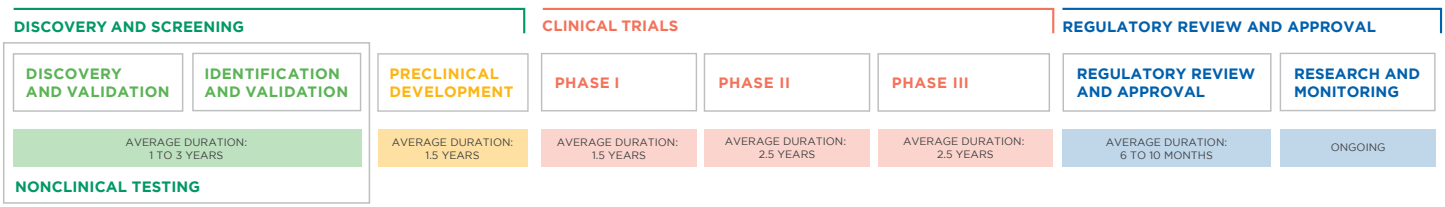
REGULATORY GUIDANCE AND SUPPORT

Our experienced scientific team helps you understand the regulatory needs of your program, and provides necessary guidance and support when it comes to submitting your applications for approval.

DRUG DEVELOPMENT TIMELINE



The Challenges of Dermal Research

Nonclinical dermal studies differ from other drug studies. The skin provides a significant point of entry for chemical agents, and *in vivo* dermal studies pose unique challenges not seen with parenteral or oral studies, such as normal anatomical variation in cutaneous morphology, and the increased risk of systemic exposure due to animal grooming. Given such challenges, no single approach, method, or species suffices for effectively evaluating dermal toxicity.

Understanding the regulatory options is crucial to your studies. At Altasciences, we will help you weigh the pros and cons of each dermal study to determine the right path for you. Making these decisions early in the process will help **decrease program costs**, **streamline** the development process, and **accelerate** timelines to obtain regulatory approval and move your compound into clinical trials.

AVAILABLE FDA PATHWAYS

The FDA offers several pathways for getting your products to market, including:

505(b)(1) New Drug Application

NDA filings can be complicated and time-consuming, costing as much as **$2.6 billion**. For drug products that have never been approved by the FDA for the condition your drug addresses, a 505(b)(1) is the most appropriate pathway.

505(b)(2) New Drug Application

For products that are not new chemical entities that would require the scrutiny of a 505(b)(1), but are also not generic equivalents, choose a 505(b)(2).

A 502(b)(2) application is the most appropriate pathway if a previously approved drug product has had substantive changes to create a wholly different drug, or “improved” product. Changes can range from dosage strength to a new route of administration, to an entirely different disease indication.

A 502(b)(2) pathway can offer unique opportunities for rapid approval at **lower cost**, and **lower risk**, due to the nature of previous drug approval.

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