

GALDERMA

EST. 1981

U.S. Medical Grants Portal Requestor User Guide

Investigator-Initiated Studies

September 2020

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Introduction

Galderma recognizes the importance of supporting Investigator-Initiated Studies (IISs) that have the potential to improve patient outcomes, can advance medical and scientific knowledge about our products, as well as generate promising medical advancements. Results of such research may lead to greater understanding of our therapies and their potential applications, improved patient care, and new ideas for further research.

We accept unsolicited requests for research grants from academic and community-based clinician-scientists who are interested in conducting their own IISs. Support is awarded based on the scientific merit of the study, investigator qualifications, study budget, alignment with Galderma objectives, and site feasibility as reviewed through a formal evaluation process.

The purpose of this guide is to:

- Introduce users to the Galderma U.S. Medical Grants Portal
- Demonstrate how to submit a Research Grant Request
- Provide end-to-end navigation from submission through approval and close-out of an Investigator-Initiated Study

Getting Started



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[Home](#) [Request For Proposals](#) [Investigator-Initiated Studies](#) [Independent Medical Education](#) [Resident Training](#) [Site Preparation](#)

CREATE AN ACCOUNT

ALREADY HAVE AN ACCOUNT?

MEDICAL GRANTS PORTAL

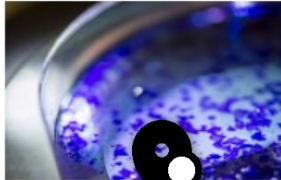
We recognize the importance of supporting activities that enhance and develop the knowledge, skill set, and proficiency of healthcare professionals to address patients' needs. We do this through a variety of mechanisms, including the provision of medical grants for the activities shown below.

REQUEST FOR PROPOSALS



LEARN MORE AND SUBMIT A REQUEST

INVESTIGATOR-INITIATED STUDIES



LEARN MORE AND SUBMIT A REQUEST

INDEPENDENT MEDICAL EDUCATION



LEARN MORE AND SUBMIT A REQUEST

RESIDENT TRAINING



LEARN MORE AND SUBMIT A REQUEST

The US Medical Grants Portal can be accessed at usmedicalgrants.galderma.com

Returning users may login by clicking **Already have an account?**

First-time users will need to **Create Account** in order to login to the system and submit a new request.

Click here to learn more about our process, the requirements, and to submit a new request with an existing account.

Creating a New Account


To create a new account, select **Create Account** from the portal homepage. Enter your information below and click **Create Account**.

CREATE NEW ACCOUNT

Please fill out the necessary information below to create an account for this Portal.

<input type="text" value="First Name*"/>	<input type="text" value="Last Name*"/>
<input type="text" value="Email Address*"/>	<input type="text" value="e.g. +99 999 999999"/>
<input type="text" value="Country*"/>	
<input type="password" value="Password"/>	
<input type="password" value="Re-type Password"/>	

If you are associated to an Institution, type in the field below and select from the popup.



Institution Name

- Enter the name of your institution into the search bar. If your institution has previously been registered, it will appear in the pop-up drop-down selection.
- If your institution is not found, you will be required to add this as a new institution after account creation.



Enter the code shown:

Creating a New Account

1. Upon clicking **Create Account**, you will receive the following validation message.
2. You will need to select either your phone number or email address to send the validation code to and click Send Validation Code.
3. Please navigate to your email or phone to locate this notification and type the code here.
4. Once your account has been validated, you may now login with your credentials.



1

Validate your Account

To help us verify your identity, a validation code will be sent to you.

☒ Phone Number (Code will be sent via SMS. Message & data rates may apply.)

☐ Email Address (Code will be sent via email. If you don't see the email in your inbox, please check your spam folder.)

Enter code here

3

2

Validate Account

Send Validation Code

Adding an Institution

Upon logging in, if your institution did not appear in the search during account creation, you will be instructed to update this information under your user profile.

1. Click **Edit Profile**
2. Click **Quick Add Institution (+)**
3. Enter the name of your academic institution, select your state, then click **Save**.
4. Select **Update Profile** to complete the setup.

! *This information is required in order to submit a grant request



Add a Photo

EDIT PROFILE

Please provide us with your contact and profile information as requested below. When typing your Institution, if the name does not appear in the popup, please select "Quick Add Institution (+)" and enter your information to save to your profile. You may return to this page at any time to update your profile or contact information as needed. (*) are all Required Fields.

* John * Doe

Prefix Suffix Title / Position

* United States

* 1234 Address

* City * 123456

* 1234567890

* Organization

Web Address

Quick Add Institution (+)

Change Password

Quick Add

Name: Name required

Type: Academic Institutions

Country: United States

Save Cancel

4

UPDATE PROFILE

Forgot Password



Home

Request For Proposals

Investigator-Initiated Studies

Independent Medical Education

Resident Training

Site FAQs

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CREATE AN ACCOUNT

ALREADY HAVE AN ACCOUNT?

1

1. If you have forgotten your password click **Already have an account?** from the homepage.
2. This will take you to the login page where you can select the **Forgot Password?** hyperlink to reset the password to your account.

PORTAL LOGIN

Email Address

Email Address is required.

Password

Password is required.

[Forgot Password?](#)

LOGIN

2

Click **Forgot Password** to receive an email with directions to reset your password.



Homepage Navigation

Once you are logged in, you will be automatically redirected to the portal homepage where you will have the following options:

1. **My Submissions:** Click here to view all of your current and past submissions.
2. **Edit Profile:** Click here to edit details within your profile and to add your institution.
3. **Site FAQ:** Click here to view Frequently Asked Questions regarding portal applications.
4. **Learn More and Submit a Request:** Click here to redirect to the Medical Education Activities Landing Page where you will find details regarding the types of support, process, requirements and policies & guidelines. You will also click here to submit a new request.

The screenshot displays the Medical Grants Portal homepage. At the top, a navigation bar includes links for Home, My Submissions (callout 1), Request For Proposals, Investigator-Initiated Studies, Independent Medical Education, Resident Training, Site FAQs (callout 3), and Edit Profile (callout 2). The main heading is "MEDICAL GRANTS PORTAL". Below this, a paragraph states: "We recognize the importance of supporting activities that enhance and develop the knowledge, skill set, and proficiency of healthcare professionals to address patients' needs. We do this through a variety of mechanisms, including the provision of medical grants for the activities shown below." The page features four main sections, each with a representative image and a "LEARN MORE AND SUBMIT A REQUEST" button: "REQUEST FOR PROPOSALS" (image of a smiling woman, callout 1), "INVESTIGATOR-INITIATED STUDIES" (image of a petri dish with blue cells, callout 4), "INDEPENDENT MEDICAL EDUCATION" (image of hands interacting with a digital screen), and "RESIDENT TRAINING" (image of healthcare professionals in blue scrubs sitting at a table).

Investigator-Initiated Studies Landing Page



INVESTIGATOR-INITIATED STUDIES

The tabs at the top of the [Investigator-Initiated Studies Landing Page](#) contain additional information on

- Areas of Interest
- Types of Support
- Process
- Requirements
- Updates & Reconciliations
- Policies & Guidelines

From the *Home* tab is where you will start a new request for support.

A screenshot of the Galderma Investigator-Initiated Studies Landing Page. At the top, there is a navigation bar with four tabs: HOME, AREAS OF INTEREST, HOW TO APPLY, and POLICIES & GUIDELINES. Below the tabs, the main content area contains several paragraphs of text. The first paragraph states: "Galderma recognizes the importance of supporting Investigator-Initiated Studies (IISs) that lead to a greater understanding of our therapies and their potential applications, improved patient care, and new ideas for further research." The second paragraph states: "We accept unsolicited requests for research grants from academic and community-based clinician-scientists who are interested in conducting their own IIS. The application process consists of a two-phase formal evaluation involving a preliminary concept proposal submission that, if accepted, is followed by a more detailed full proposal (protocol) submission." The third paragraph states: "Support is awarded based upon scientific merit, as well as alignment with our research areas of interest and availability of resources. We may provide research grants in the form of funding, and/or study product; however, we are not the study sponsor and will not assume any sponsor obligations." The fourth paragraph states: "All sponsor/investigators who are awarded support must agree to publish the study results regardless of study outcome and provide Galderma with ongoing study updates and closeout and reconciliation reports. Please review the sections below to ensure that you are willing to meet these requirements prior to requesting support." Below the text, there is a list of sections with expandable arrows: REQUIREMENTS OF THE SPONSOR INVESTIGATOR, ONGOING STUDY UPDATES, CLOSEOUT & RECONCILIATION REPORTS, CLINICAL STUDY REPORT, and PUBLICATION. At the bottom left, there is a blue star icon with a white house symbol. At the bottom right, there is a button labeled "SUBMIT A REQUEST".

Click **Submit a Request** to begin a new submission.

Creating a Submission

CREATE A SUBMISSION

Please create a Title for your Submission. Please remember that the Title can NOT be changed once created.

1

IIS Grant Request - Sample

CREATE NEW

1. When starting a new request, you will be asked to create a title for your submission. Please note that this title cannot be changed once the submission is created. Please enter a title for your IIS and click **Create New**.
2. You will then be redirected to your Concept Proposal Form where you will see the following header information.

IIS GRANT REQUEST - SAMPLE

2

External Status: No External Status

Submitted Date: NOT SUBMITTED

Submission ID: 1693

Group: IIS

Last Modified On Portal:

Concept Proposal Form

1. Click the **+** to enter the Contact Information for the Study Sponsor, Investigator(s), and Study Coordinator. Click **Submit** to save the information for each study contact.
2. Select the Therapeutic Area(s) of Interest.
3. Select the Study Type.
4. Select the Study Setting(s).
5. Enter the Number of Sites that will be participating in the study.

*These fields are required for submission

Please click **Save** to save your progress often.

The system does not automatically save your form. You may come back at a later date to complete your form, if needed.

CONCEPT PROPOSAL

Overview and General Details

***Contact Info**
Please provide contact information for your Sponsor, Primary Investigator, and Study Coordinator; as well as any other Sub-Investigators that may be involved.

Title	First Name	Last Name	Phone	Email	Address	City	State	Zip	License Number
+									

Page 1 of 0

No records to view

***Therapeutic Area of Interest**
Please select all that apply

- ☐ Acne
- ☐ Consumer Skin Care
- ☐ Eczema
- ☐ Fillers
- ☐ Melasma
- ☐ Neuromodulators
- ☐ Psoriasis
- ☐ Rosacea
- ☐ Other

***Study Type**

☐ Interventional ☐ In Vitro ☐ Outcomes Research
☐ Observational ☐ In Vivo ☐ Other

***Study Setting**
Please select all that apply

- ☐ Hospital
- ☐ Laboratory
- ☐ Office/Clinic
- ☐ Research Facility
- ☐ Other

***Number of Sites**

1

2

3

4

5

Add New

Title (*)

First Name (*)

Last Name (*)

Phone (*)

Email (*)

Address (*)

City (*)

State (*)

Zip (*)

License Number If Applicable (*) required

Submit Cancel

Concept Proposal Form

Background and Rationale

*Scientific Background and Study Rationale

1

Study Objectives and Endpoints

2

*Primary Objective

*Secondary Objective(s)

*Primary Endpoint

*Secondary Endpoint

Study Design & Schema

*Study Design and Methodology

*Number of Subjects

*Rationale for Number of Subjects

3

4

5

1. Enter the Scientific Background and Study Rationale.
2. Enter the Study Objectives and Endpoints:
 - Primary Objective
 - Secondary Objectives
 - Primary Endpoint
 - Secondary Endpoints
3. Enter the Study Design and Methodology.
4. Enter the Number of Subjects.
5. Enter the Rationale for Number of Subjects.

Concept Proposal Form

Study Duration

1

***Planned Number of Study Visits**

2

***Estimated Duration of Enrollment for All Subjects (first subject in to last subject in)**

3

***Duration of Treatment for One Subject**

4

***Duration of Follow-up for One Subject**

5

***Main Inclusion Criteria**

6

***Main Exclusion Criteria**

7

8

Please provide a REALISTIC estimate of the time it will take to fully recruit all subjects.

Ethics and Regulatory Process

***Name of Institutional Review Board/Independent Ethics Committee**

***Do you believe this study will require an IND/IDE application submission to the FDA?**

Please note that the Investigator is responsible for the submission and maintenance of all IND/IDE applications.

☐ Yes ☐ No

1. Enter the Planned Number of Study Visits
2. Enter the Estimated Duration of Enrollment for All Subjects (first subject in to last subject in).
3. Enter the Duration of Treatment for One Subject.
4. Enter the Duration of Follow-up for One Subject
5. Enter the Main Inclusion Criteria
6. Enter the Main Exclusion Criteria
7. Enter the Name of Institutional Review Board/Independent Ethics Committee.
8. Indicate if you believe this study will require an IND/IDE application submission to the FDA.

Concept Proposal Form

Support Requested

***Type of Support Requested**
Please select all that apply

☒ Financial
☐ Product

***Amount of Financial Support Requested**

***Are you requesting any type of additional support from a third party?**
☒ Yes ☐ No

***Please Specify**

***Has the third party support been secured?**
☒ Yes ☐ No

Support Requested

Depending on the **Type of Support Requested**, field requirements will change. The following information is required if **financial support** is requested.

1. Enter the Amount of Financial Support Requested.
2. Indicate if you requesting any type of additional support from a third party.
3. If "Yes," please specify these details.
4. Indicate if the third party support been secured or if the status of this support is pending.

i

An itemized budget document is not required at the concept phase, however it is highly suggested.

Concept Proposal Form

Support Requested

***Type of Support Requested**
Please select all that apply

☐ Financial
☒ Product

***Galderma Product(s) Requested**

Product Name	Quantity
<div><div>+</div><div></div><div></div></div>	

Page 1 of 0 10 No records to view

If any Cetaphil® or Differin® Over-the-counter product is selected, please indicate which specific product(s) you're requesting.

2

***Are you requesting placebo or vehicle product for this study?** 3
☒ Yes ☐ No

*** Please Specify** 4

Add New

Product Name (*) 1

Quantity (*)

(*) required

Support Requested

The following information is required if **product support** is requested.

1. Click the + and select the product you are requesting from the drop-down list provided. Enter the quantity and click **Submit**.
2. If you are requesting Cetaphil® or Differin® OTC, please enter the specific product name here.
3. Indicate if you requesting any placebo or vehicle product for this study.
4. If yes, please specify (i.e., are you requesting placebo/vehicle from Galderma or a third party? What type? Are there certain packaging requirements? Etc.)

Concept Proposal Form

1. Once you have filled out the form in its entirety, click **Save** at the bottom of the form.
2. You will see the following confirmation banner on your screen once your submission has been saved. Please note, your request has not been submitted when you click **Save**.

Please note that you are required to upload the following documents before submitting this form:

- CVs for all Investigators and Study Coordinator
- Medical Licenses' for all Investigators

Please upload these documents under the "Files" tab

These documents are required for Concept Proposal Submission

1

Save

Submit

2

Saved

This request has been saved but not submitted. Please come back to complete at a later time.

IIS Grant Request

External Status: No External Status

Submitted Date: **NOT SUBMITTED**

Submission ID: 1013

Group: IIS



Please note, your request has not been submitted when you click **Save**.

3

Submission Form

Files

Emails

Please fill out the form below and select the Save button to save your progress. When you have completed this form in its entirety and uploaded all required documents in the Files tab, you may then select the Submit button.

Save

Submit

You will need to upload CVs for study coordinators and investigators and medical licenses' for all investigators under the **Files** tab before submitting the Concept Proposal form.

3. Click on the **Files** tab to upload these required documents.

Concept Proposal Files

Files

The *Files* tab lists all of the required documents for submission of a Concept and a Full Proposal. This is also where all of your documents will be housed throughout the lifecycle of your grant.

1. To upload a document, click **Select file(s) to upload...**
2. Locate the file(s) on your computer, click on the file(s) to select, and click **Open** to upload the file(s) to your submission.

Submission Form

Files

Emails

FILES

Please upload the following required documents for your Concept Proposal and Full Proposal here.

Concept Proposal

- CVs for all Investigators and Study Coordinator
- Medical Licenses for all Investigators

Full Proposal

- Study Protocol
- Itemized Budget

Clinical Study Report

- Galderma IIS Clinical Study Report Template
- Galderma IIS Clinical Study Report Guidance


Please select the appropriate File Type v

Once all documents are uploaded, please

1

Select file(s) to upload...

No files.

 To upload multiple documents at one time, hold down the ctrl key and click on each of the file names on your computer.

Open

PORTAL > Test Documents > PDF > IIS Grant Request

Organize

New folder

Quick access

OneDrive - NESTLE

This PC

Network

Name	Date modified	Type	Size
Investigator CV	12/10/201...	Chrome H...	32 KB
Investigator Medical License	12/10/201...	Chrome H...	32 KB
Study Coordinator CV	12/10/201...	Chrome H...	32 KB

File name: "Investigator CV" "Investigator Medical License" "Study Coordinator CV"

All Files

2

Open

Cancel

Concept Proposal Files

6

Submission Form

Files

Emails

FILES

Please upload the following required documents for your Concept Proposal and Full Proposal here.

Concept Proposal

- CVs for all Investigators and Study Coordinator
- Medical Licenses for all Investigators

Full Proposal

- Study Protocol
- Itemized Budget

Clinical Study Report

- Galderma IIS Clinical Study Report Template
- Galderma IIS Clinical Study Report Guidelines

Please select the appropriate File Type when uploading.

Once all documents are uploaded, please submit your request.

Select file(s) to upload...

- ✕ Investigator CV.pdf
- ✕ Investigator Medical License.pdf
- ✕ Study Coordinator CV.pdf

--None--

Adverse Event Reconciliation

Study Updates

Draft Manuscript

Payment Request Form

Check Request

Amendments

Budget Reconciliation

ClinicalTrials.gov

CV

Full Proposal Approval Letter

IND/IDE Documentation

Invoices

IRB Approval Letter

IRB Approved Protocol

Itemized Budget

Clinical Trial Agreement (CTA)

Medical License

Product Reconciliation

Publication

--None--

2

3

4

Save Files

When you are done uploading and selecting the options for each file, click this button to save your files and go back to the listing.

Files Uploaded

3 file(s) were uploaded with the options you selected.

5



1. Your documents will now appear in this section and will require a File Type selection.
2. Click on the ▼ to select the corresponding File Type from the drop-down list provided.
3. The list will refresh after each File Type selection is made so please make sure that each document has a File Type selected.
4. When you have uploaded all of your documents click **Save Files**.
5. You will see the following "Files Uploaded" confirmation banner on your screen once your files have been saved.
6. Click on the *Submission Form* tab to navigate back to your Concept Proposal form to submit your request to Galderma for review.

Submitting a Concept

Submission Form

Files

Emails

Please fill out the form below and select the Save button to save your progress. When you have completed this form in its entirety and uploaded all required documents in the Files tab, you may then select the Submit button.

Save

Submit

1

CONCEPT PROPOSAL

1. Once you have uploaded all of the required documents and completed the Concept Proposal form, click **Submit** to submit your request to Galderma for review.

IIS Grant Request

External Status: **Submitted**

Submitted Date: **8/25/2020**

Submission ID: **1013**

Group: **IIS**

2

✓ SUBMITTED

2. You will see the following confirmation banner on your screen once your Concept Proposal has been submitted.

The External Status is now changed to **Submitted**.

Submitting a Concept

Changes After Submission

Once your Concept Proposal has been submitted, no changes can be made. However, if Galderma requires clarification due to an incomplete submission or has questions about your Concept, a **"Request for Additional Information"** will be issued.

Request for Additional Information

A **"Request for Additional Information"** will be sent to you by email should additional information be needed in order for Galderma to make a determination regarding approval of your Concept. If the additional information provided is insufficient or not received in a timely manner, the request may be denied.

Review Process

Once your Concept Proposal has been submitted it will proceed through an internal review process. Submissions will be evaluated on the following:

- Scientific Merit
- Investigator Qualifications
- Study Budget
- Alignment with Galderma Objectives
- Site & Investigator Feasibility

Timing for Processing and Review

Review times vary. Typically, the Concept Proposal review process takes a minimum of 12 weeks. Additional processing time may also be needed around company and national holidays. Please note that your request may be declined due to insufficient processing time.

Emails: Concept Proposal Received


Submission Form

Files

Emails

EMAILS

From	Subject	Created ▼
No-ReplyGalderma@idea-Point.com	IIS Concept Proposal Received by Galderma 1013	8/25/2020 12:05:00 AM



Thank you for submitting your Investigator-Initiated Study (IIS) Concept Proposal, "IIS Grant Request"


All requests for IIS research grants are vetted by an internal committee. Should your Concept Proposal be of interest, a follow-up request for a Full Proposal will be issued by email through the Medical Grants Portal.


We thank you for your interest in conducting an IIS with support from Galderma.

Sincerely,
Galderma Medical Grants

usmedicalgrants@galderma.com

You will receive the following automated confirmation of receipt email upon submission of your Concept Proposal.





You can find all of your portal notifications under the *Emails* tab should you need to reference them at any time.

Emails: Concept Proposal Approved


Submission Form

Files

Emails

Emails

From	Subject	Created ▼
No-ReplyGalderma@idea-Point.com	Galderma IIS Concept Proposal Approved: Submission #1013	8/25/2020 12:24:00 AM



Thank you for submitting your Investigator-Initiated Study (IIS) Concept Proposal. Your submission has been reviewed by our committee and we are pleased to inform you that your Concept Proposal has been approved.

This is an initial approval and indicates that Galderma is interested in your study, but does not guarantee or imply final approval of your IIS. If you are interested in continuing the process to request support for your IIS, please log into the Medical Grants Portal and submit a Full Proposal along with all required information and documents, including your study protocol. Before doing this, we recommend reviewing the requirements listed on the Medical Grants Portal, including the requirement to submit the study results for publication within 6 months of study completion, to ensure that you are willing and able to comply with them all.

You may use the following link to submit your Full Proposal: [View](#)

We thank you for your interest in conducting an IIS with support from Galderma and look forward to receiving your Full Proposal.

Sincerely,
Galderma Medical Grants

usmedicalgrants@galderma.com

If your Concept Proposal is of interest to Galderma, you will receive a follow-up request for a **Full Proposal** submission.

A notification email will be sent to your email address on file.




My Submissions

If your Concept Proposal is of interest to Galderma, the status of your submission will be changed to **Concept Approved**.

Your submission will now be located under the *In Process / Editable* tab.

MY SUBMISSIONS

Here is a collection of all your Submissions.

<div>Submitted</div> <div>In Process / Editable</div>					
Title	Current Status	Date Submitted	Editable Until	Group ↓	ID
IIS Grant Request - Sample	 <u>Concept Approved</u>	8/24/2020	10/31/2020	IIS	1693



Click on the title of your submission to begin your Full Proposal submission.

Full Proposal Form

Submission Form

Files

Emails

Please fill out the form below and select the Save button to save your progress. When you have completed this form in its entirety and uploaded all required documents in the Files tab, you may then select the Submit button.

Save

Submit

FULL PROPOSAL

*Contact Info

Please provide contact information for your Sponsor, Primary Investigator, and Study Coordinator; as well as any other Sub-Investigators that may be involved.

Title	First Name	Last Name	Phone	Email	Address	City	State
Primary Investigator	Primary	Investigator	000-000-0000	Primaryinvestigator@Address	Address	City	Alabama
Study Coordinator	Study	Coordinator	000-000-0000	coordinator@email.co	Address	City	Alabama
Sponsor	Study	Sponsor	000-000-0000	sponsor@email.com	Address	City	Alabama

+ -> <-

Page 1 of 1

*Therapeutic Area of Interest

Please select all that apply

- ☐ Acne
- ☐ Consumer Skin Care
- ☐ Eczema
- ☒ Fillers
- ☐ Melasma
- ☐ Neuromodulators

The **Concept Proposal** form has now expanded into a **Full Proposal** form.

- All of the information previously entered on the **Concept Proposal** form is shown here.
- Additional required fields have been added to the **Full Proposal** form for your completion.
- Should you need to update any of the information that you entered previously on the **Concept Proposal**, you may do so at this time, however please note that any significant changes to the original **Concept Proposal** will require formal review and may impact the approval process.

Full Proposal Form

Other Contacts

If there are any IP/Legal or Financial contacts, please enter their information as well.

Title	First Name	Last Name	Phone	Email	Address	City	State
Financial	Financial	Contact	000-000-0000	finance@email.com	Address	City	Alabama

+


Page 1 of 1


10

1

1. Click the + to enter the contact information for any other study contacts such as financial or legal contacts.

2. Click **Submit** once all required fields have been entered.

3. To edit the information, click on the row to highlight the information and then click on the pencil  icon to edit the fields, as needed.

4. To delete a row, click on the row to highlight the information and then click on the trashcan  icon to delete the row.

Add New

Title

(*)

First Name

(*)

Last Name

(*)

Phone

(*)

Email

(*)

Address

(*)

City

(*)

State

(*)

Zip

(*)

(*) required

2

Submit

Cancel

GALDERMA

26

Full Proposal Form

Study Objectives and Endpoints

1

*Primary Objective

Primary Objective

*Secondary Objective(s)

Secondary Objective(s)

Other Objectives

2

*Primary Endpoint

Primary Endpoint

*Primary Endpoint Analysis

3

*Secondary Endpoints

Secondary Endpoint

*Secondary Endpoint Analysis

4

*Safety Endpoint Analysis

Safety Endpoint Analysis

1. Update your Study Objectives and Endpoints, as needed.
2. Enter any Other Objectives, if applicable.
3. Enter your Primary Endpoint Analysis.
4. Enter your Secondary Endpoint Analysis.
5. Enter the Treatment/No Treatment Regimen.
6. Enter the Permitted/Prohibited Concomitant Medications.

Study Treatments

*Treatment/No Treatment Regimen

5

Permitted/Prohibited Concomitant Medications

6

Full Proposal Form

Study Visit Description and Procedures

Please describe all procedures and treatments required at each visit, broken out by visit. Please identify the purpose of the visit and state permissible time windows for each. If this information is included in your Protocol, which is a required attachment to your submission, you may skip this section.

Study visit	Study day	Visit window	Window duration	Information collected
1	0	3	day(s)	Assessments
2	7	3	day(s)	Assessments Treatment Photos Diary AEs

Page 1 of 1 10

View 1 - 2 of 2

1

Add New

Study visit

Study day

Visit window

Window duration

Information collected

+ or -

(*) required

Submit

Cancel

2

Create a schedule of study visits and procedures by entering information into the Study Visit Description and Procedures section.

1. Click the **+** to create a new row for each study visit. Enter the study visit name, day, visit window, window duration, and information collected such as all procedures and treatments completed.
2. Click **Submit** to save the information.

If you have a detailed schedule of visits and procedures chart or flowchart diagram in your study protocol that you will be uploading as an attachment, this section may be skipped. However, please make sure that this information is detailed as required.

GALDERMA

Full Proposal Form

Safety Definitions, Reporting, and Monitoring

*Adverse Events of Interest

1

*Procedure for Recording and Reporting Adverse Events

2

Statistical Plan, Size and Calculations

*Statistical Plan Description

3

*Determination of Sample Size/Power Calculation

4

Data Management Plan

*Data Management Plan

5

Study Monitoring

*Study Monitoring Plan

6

Ethical and Regulatory Considerations

*Ethical and Regulatory Considerations

7

Premature Termination of the Study or Close-Out of a Site

*Describe Procedures for Premature Termination of the Study or Close-Out of a Site

8

1. Enter the Adverse Events of Interest.
2. Enter the Procedure for Recording and Reporting Adverse Events.
3. Enter the Statistical Plan Description.
4. Enter the Determination of Sample Size/Power Calculation.
5. Enter the Data Management Plan.

6. Enter the Study Monitoring Plan.

7. Enter the Ethical and Regulatory Considerations.

8. Describe the Procedures for Premature Termination of the Study or Close-Out of a Site.

Full Proposal Form

Support Requested

1

*Type of Support Requested

Please select all that apply

- ☒ Financial
☒ Product

* Amount of Financial Support Requested

25,000

Download this [Budget Template](#) and upload this on the Files Tab.

3

* Are you requesting any type of additional support from a third party?

☐ Yes ☒ No

* Galderma product(s) requested

Product Name	Quantity
Restylane® Kysse 1 mL syringe	50

+ ✎ 🗑 Page 1 of 1 10 View 1 - 1 of 1

If any Cetaphil® or Differin® Over-the-counter product is selected, please indicate which specific product(s) you're requesting.

* Are you requesting placebo or vehicle product for this study?

☐ Yes ☒ No

Will any non-Galderma products be used in this study?

2

1. Update the Support Requested section, if needed.
2. Indicate if any non-Galderma product will be used in the study.



A detailed itemized budget is required for a Full Proposal submission. A Budget Template is provided for convenience, but you may use an alternative template if preferred.

3. Should you elect to use the Galderma Template, click on the hyperlink to download the excel spreadsheet for completion.

Full Proposal Form

The screenshot shows a web form titled "Publication/Presentation Plan". It features a large text input field with a "1" callout. Below the field is a note about required uploads: "Study Protocol" and "Itemized Budget". Further down, there are "Save" and "Submit" buttons with a "2" callout. At the bottom, there is a "Back To Top" button with a "3" callout.

Publication/Presentation Plan

***Publication/Presentation Plan**

1

Please note that you are required to upload the following documents before submitting this form:

- Study Protocol
- Itemized Budget

Please upload these documents under the "Files" tab

2 Save Submit

3 Back To Top

1. Enter your Publication/Presentation Plan.
2. Click **Save** to save your Full Proposal Form.
3. Click **Back to Top** to navigate back to the top of the submission form where you can easily access the *Files* tab to upload your required documents before submitting your Full Proposal to Galderma for review.

Full Proposal Files

Submission Form **Files** Emails Post-Activity Reconciliation Action Items

FILES

Please upload the following required documents for your Concept Proposal and Full Proposal here.

Concept Proposal

- CVs for all Investigators and Study Coordinator
- Medical Licenses' for all Investigators

Full Proposal

- Study Protocol
- Itemized Budget**

Please select the appropriate File type for each document.

Once all documents are uploaded, click the Submit button to submit your request.

1 Select file(s) to upload...

2

Name	Date modified	Type	Size
IIS Itemized Budget	12/10/201...	Chrome H...	32 KB
IIS Protocol	12/10/201...	Chrome H...	32 KB
Investigator CV	12/10/201...	Chrome H...	32 KB
Investigator Medical License	12/10/201...	Chrome H...	32 KB
Study Coordinator CV	12/10/201...	Chrome H...	32 KB

File name: "IIS Protocol" "IIS Itemized Budget" All Files Open Cancel

1. Upload your Study Protocol and Itemized Budget. Click **Select file(s) to upload...**
2. Locate the file(s) on your computer, click on the file(s) to select, and click **Open** to upload the file(s) to your submission.



To upload multiple documents at one time, hold down the ctrl key and click on each of the file names on your computer.

Full Proposal Files

6 Submission Form | **Files** | Emails | Post-Activity Reconciliation | Action Items

FILES

Please upload the following required documents for your Full Proposal and Full Proposal here.

Concept Proposal

- CVs for all Investigators and Study Coordinators
- Medical Licenses for all Investigators

Full Proposal

- Study Protocol
- Itemized Budget

Please select the appropriate File Type for each document. If the correct file types are not uploaded, you will not be able to submit your request.

Once all documents are uploaded, please click the Submit button under the Submission Form tab.

Select file(s) to upload...

1 IIS Itemized Budget.pdf
IIS Protocol.pdf

2

- Budget Reconciliation
- ClinicalTrials.gov Form
- CV
- Full Proposal Approval Letter
- IND/IDE Documentation
- Invoices
- IRB Approval Letter
- IRB Approved Protocol
- Itemized Budget
- Letter of Agreement (LOA)
- Medical License
- Product Reconciliation
- Publication
- Request for More Information
- Right of Reference Letter
- Schedule of Visits/Procedures
- Study Flow Chart
- Study Protocol**
- Study Report
- Supporting Documents

3 Study Protocol

4 Save Files

When you are done uploading and selecting the options for each file, click this button to save your files and go back to the listing.

Name	Uploaded ▼	File Type	File SubType	Size
Study Coordinator CV.pdf	8/28/2020 4:57:25 AM CV	31.43 KB		
Investigator Medical License.pdf	8/24/2020 7:56:50 PM Medical License	31.43 KB		

5 Files Uploaded
2 file(s) were uploaded with the options you selected.

Your documents will now appear in this section and will require a File Type selection.

Click on the ▼ to select the corresponding File Type from the drop-down list provided.

The list will refresh after each File Type selection is made so please make sure that each document has a File Type selected.

When you are done uploading all of your documents click **Save Files**.

You will see the following "Files Uploaded" confirmation banner on your screen once your files has been saved.

Click on the *Submission Form* tab to navigate back to your Full Proposal form to submit your request to Galderma for review.

Submitting a Full Proposal

Submission Form

Files

Emails

Please fill out the form below and select the Save button to save your progress. When you have completed this form in its entirety and uploaded all required documents in the Files tab, you may then select the Submit button.

Save

Submit

1

FULL PROPOSAL

1. Once you have uploaded all of the required documents and completed the Full Proposal form, click **Submit** to submit your request to Galderma for review.

IIS Grant Request

External Status: **Submitted**

Submitted Date: 8/25/2020

Submission ID: 1013

Group: IIS

2. You will see the following confirmation banner on your screen once your Full Proposal has been submitted.

The External Status is now changed to **Submitted**.

2



SUBMITTED

Submitting a Full Proposal

Submission Form

Files


Emails

You will receive the following confirmation of receipt email upon submission of your Full Proposal.

✓

EMAILS

From	Subject	Created ▼
no-reply@idea-point.com	IIS Full Proposal Received 1013	9/1/2020 4:17:00 AM



Thank you for submitting your Investigator-Initiated Study (IIS) Full Proposal, "IIS Grant Request."

All requests for IIS research grants are vetted by an internal committee. Support is awarded based on the scientific merit of each submitted proposal, investigator qualifications, study budget, alignment with company objectives, and site feasibility. Should your Full Proposal be of interest, you will be notified by email through the Medical Grants Portal of next steps and requirements for obtaining support.

We thank you for your interest in conducting an IIS with support from Galderma.

Sincerely,
Galderma Medical Grants

usmedicalgrants@galderma.com

GALDERMA

Full Proposal Approval

Submission Form

Files

Emails

3

EMAILS

If your Full Proposal is of interest to Galderma, a notification email will be sent to your email address on file.


1

From

no-reply@idea-point.com

Subject

Galderma IIS Full Proposal Approved 1013



Thank you for submitting your Investigator-Initiated Study (IIS) Full Proposal, "IIS Grant Request." Your request for support has been reviewed by our committee and we are pleased to inform you that your Full Proposal has been approved.

At this time, please log into the Medical Grants Portal and navigate to the tab of your submission where you will find a draft Letter of Agreement (LOA) uploaded here for your review. Please note that final approval of your IIS is contingent upon obtaining a fully executed LOA. Support from Galderma is contingent upon compliance with the terms and conditions of the LOA, and submission of all required documentation.

The Study may not begin (i.e., product will not be shipped, subjects may not be enrolled, etc.) until the following documents are executed and filed on the Portal:

- 1) Fully Executed LOA
- 2) Final IRB-approved Study Protocol
- 3) IRB/IEC Approval Letter
- 4) Clinicaltrials.gov NCT Identifier (proof of registration)
- 5) IND/IDE Application Submission Determination (if applicable)
- 6) Sub W-9

If you have any questions about your approval, or the requirements to move forward in this process, please send all inquiries to usmedicalgrants@galderma.com

We thank you for your interest in conducting an IIS with support from Galderma. We look forward to working with you on your IIS.

Best regards,
Galderma Medical Grants

2

1. If the Full Proposal is approved, you will receive an approval notification to your email address on file containing instructions regarding the next steps of the process including obtaining a fully executed Letter of Agreement (LOA).
2. The following documents are required to be on file prior to study start.
3. Click on the *Files* tab to download the draft LOA for your review and completion and to upload your required documents.

Letter of Agreement

Submission Form

Files

Emails

FILES

Please upload the following required documents for your submission:

Concept Proposal

- CVs for all Investigators and Study Coordinator
- Medical Licenses for all Investigators

Full Proposal

- Study Protocol
- Itemized Budget

Please select the appropriate File Type when uploading:

Once all documents are uploaded, please submit your request by selecting the Submit button under the Submission Form tab.

Select file(s) to upload...

Name	Uploaded	File Type	File SubType	Size
IIS Draft Letter of Agreement (LOA) for Review.docx	9/1/2020 3:43:15 PM	Letter of Agreement (LOA)	Galderma Document	101 KB
IIS Protocol.pdf	8/29/2020 1:32:48 PM	Study Protocol		31.43 KB
IIS Itemized Budget.pdf	8/29/2020 1:32:45 PM	Itemized Budget		31.43 KB

- Click on the **Files** tab to access your draft Letter of Agreement (LOA).
- Click on the file link to download LOA.
- Review the document in its entirety.
 - Track any changes in a Microsoft Word redlined version.
 - Complete any missing information.
 - Complete the Milestone Schedule in Exhibit A.
 - Complete the Study Contacts information in Exhibit B.
- Email the updated LOA back to Galderma for review and full execution at usmedicalgrants@galderma.com.

Investigator-Initiated Study Grant Agreement

Galderma Laboratories, L.P. ("Company") and **[insert name and address of Sponsor]** ("Sponsor") and **[insert name and address of Primary Investigator]** ("Investigator") enter into this Investigator-Initiated Study Grant Agreement (the "Agreement") on this **XX** day of **[month]**, **20XX** (the "Effective Date").

Investigator Responsibilities

Once a LOA is executed and Galderma receives all required documentation, Galderma provides support for the study and the study may start.

Investigators are required to:

- Register the study on www.clinicaltrials.gov, as well as, provide status updates and post-study results, (for trials involving human subjects);
- Immediately notify Galderma of any protocol amendments submitted to the IRB/IEC;
- Notify the FDA, IRB, and Galderma of any severe adverse event possibly related to a study product for any study within 24 hours of receiving notification of such an event;
- Submit frequent progress reports to Galderma regarding study status;
- Submit all study close-out documentation to Galderma within 90 days of study completion:
 - Clinical Study Report
 - Budget Reconciliation
 - Product Reconciliation
 - Adverse Event Reconciliation
- Submit the results of the study for publication within six (6) months of study completion, whether or not the results are favorable to Galderma or any Galderma Product; and
- Comply with all terms, conditions, and requirements of the LOA.

Action Items

Submission Form

Files

Emails

Action Items

ACTION ITEMS

You are required to provide study updates and documentation regarding the identified areas below.

- [Document Upload Checklist](#)

This section lists all of the required documents as needed prior to subject enrollment.

- [Milestones](#)

This section lists all of the Milestone Payments and allows you to track planned and actual dates regarding Milestone completion, and payment execution.

- [Product Shipment](#)

This section allows you to submit requests for product as well as track previous shipments.

- [Subject Enrollment](#)

This section allows you to provide updates regarding subject enrollment.



Investigator responsibilities are focused on the ***Action Items*** tab. Each of the following sections contain required tasks for the Investigator to complete.

Action Items: Document Upload Checklist

Submission Form

Files

Emails

Action Items

ACTION ITEMS

You are required to provide study updates and documentation regarding the identified areas below.

Document Upload Checklist

Document Type	Due Date	Completed	Comments	Date Submitted
Contract Execution		Yes	Fully Executed 9/30/2020	9/30/2020
FDA IND/IDE Application Determination		Yes	N/A	9/18/2020
IRB Approval Letter		Yes	IRB Approval Date 9/2/2020. Renewal Date: 9/1/2021.	9/18/2020
IRB Approved Protocol		Yes	IRB Approval Date 9/2/2020. Protocol Version 1.	9/18/2020
Clintrials.gov Registration		Yes	NCT #123456789	9/28/2020
Study Report		No	Due 90 days post study completion.	
Adverse Event Reconciliation		No		
Budget Reconciliation		No		
Product Reconciliation		No		
Draft Publication/Presentation		No	Due within 6 months of study completion.	
Submission for Publication/Presentation		No	Due within 6 months of study completion.	

The **Document Upload Checklist** tracks all the required documents as needed prior to subject enrollment as well as post study completion.

Documents should be uploaded by the study contact under the **Files** tab.

The Document Upload Checklist is managed by Galderma – you are unable to edit this information from your portal submission.

Action Items: Milestones

Submission Form

Files

Emails

Action Items

ACTION ITEMS

You are required to provide study updates and documentation regarding the identified areas below.

Milestones

This section lists all of the Milestone Payments and allows you to track planned and actual dates regarding Milestone completion, and payment execution.

Milestone Type	Amount	Planned Date	Actual Date	Invoice Date	Scheduled Payment Date	Actual Payment Date	Editable Until
Execution of Agreement	5000	10/1/2020	9/30/2020	10/2/2020	12/4/2020	12/4/2020	1/1/2022
First Subject First Visit	5000	11/2/2020					1/1/2022
Last Subject Last Visit	5000	1/29/2021					1/1/2022
Study Report Submitted	5000	5/3/2021					1/1/2022
Submission for Publication	5000	8/2/2021					1/1/2022

Study Milestones and Milestone Payments are listed under the **Milestones** section. Galderma will enter the Milestones after LOA execution.

You are required to update the Planned Date and Actual Date of Milestone completion. Highlight the row and click the pencil icon to change the Planned Date or Actual Date of Milestone completion.

Once a Milestone has been met, Galderma will submit a request for Milestone Payment execution and update the payment information once this is obtained from finance. You will receive an email notification through the portal each time a Milestone is updated.

Action Items: Product Shipment

Submission Form


Files

Emails

Action Items

ACTION ITEMS

You are required to provide study updates and documentation regarding the identified areas below.



Product Shipment

This section allows you to submit requests for product as well as track previous shipments.

Product Requested	Quantity	Shipping Address	Requested Delivery Date	Delivery Date	Tracking Number	Editable Until
+ < << >> > No records to view						

Product Requested	Quantity	Shipping Address	Requested Delivery Date	Delivery Date	Tracking Number	Editable Until
Restylane® Kysse 1 mL syringe	50	123 Main St.	9/30/2020	9/11/2020	abc12345	

The **Product Shipment** section is where you will **submit your requests for shipment of study product**.

Click the + and select the study product from the drop-down list provided. Enter the quantity needed, shipping address, and requested delivery date. Click Save to submit the product request to Galderma for review.

Galderma will receive your product request and schedule your shipment as appropriate. Tracking information will be entered here and you will receive an email notification through the portal each time a product shipment is updated.

Action Items: Subject Enrollment

Submission Form

Files

Emails

Action Items

ACTION ITEMS

You are required to provide study updates and documentation regarding the identified areas below.

Subject Enrollment

This section allows you to provide updates regarding subject enrollment.

Number of Subjects Enrolled

Out Of (Total)

Enrollment Date

1

25

9/23/2020

Add New

Number of Subjects Enrolled

Out Of (Total)

Enrollment Date

(*) required

Save

Cancel

Subject Enrollment will be tracked in this section. **You are required to provide updates on enrollment progress.**

Click the + to enter new information for the number of subjects enrolled and dates of enrollment. This is important for maintaining study timelines and anticipated Milestone completion.

Galderma will receive your product request and schedule your shipment as appropriate. Tracking information will be entered here and you will receive an email notification through the portal each time a product shipment is updated.

Study Close-out Requirements

The Investigator is contractually obligated to provide Galderma with all study closeout documentation within ninety (90) days of study completion. If Galderma does not receive the required study closeout materials, you will not be eligible to apply for future support. Additionally, for research support that includes funding, the final milestone payment is dependent on proof of submission for publication or presentation of study results within 6 months of study completion. Study closeout documents include:

- Study Report;
- Budget Reconciliation;
- Product Reconciliation;
- Adverse Event Reconciliation; and
- Evidence of Submission for Publication.

Selection and submission for publication/presentation is at the discretion of the Investigator; however, submission to a peer-reviewed journal is required to receive support from Galderma. A copy of all draft publications that report the results of Galderma supported IISs must be sent to Galderma at least thirty (30) days in advance of submission for publication to allow Galderma to conduct a courtesy review. Additionally, Galderma must receive evidence of submission for publication no later than six (6) months following completion of the study. For research support that includes funding, the final milestone payment is dependent on submission for publication or presentation of study results.

All closeout documents should be uploaded to the *Files* tab of the portal submission.

Once Galderma has received all documentation and close-out requirements have been met, the study will be marked as **Complete**.

Additional Help

For questions about the submission process, or for technical support, please contact the U.S. Medical Grants Team at:

usmedicalgrants@galderma.com