GALDERMA

EST. 1981

U.S. Medical Grants Portal Requestor User Guide

Investigator-Initiated Studies

September 2020

Table of Contents

Introduction

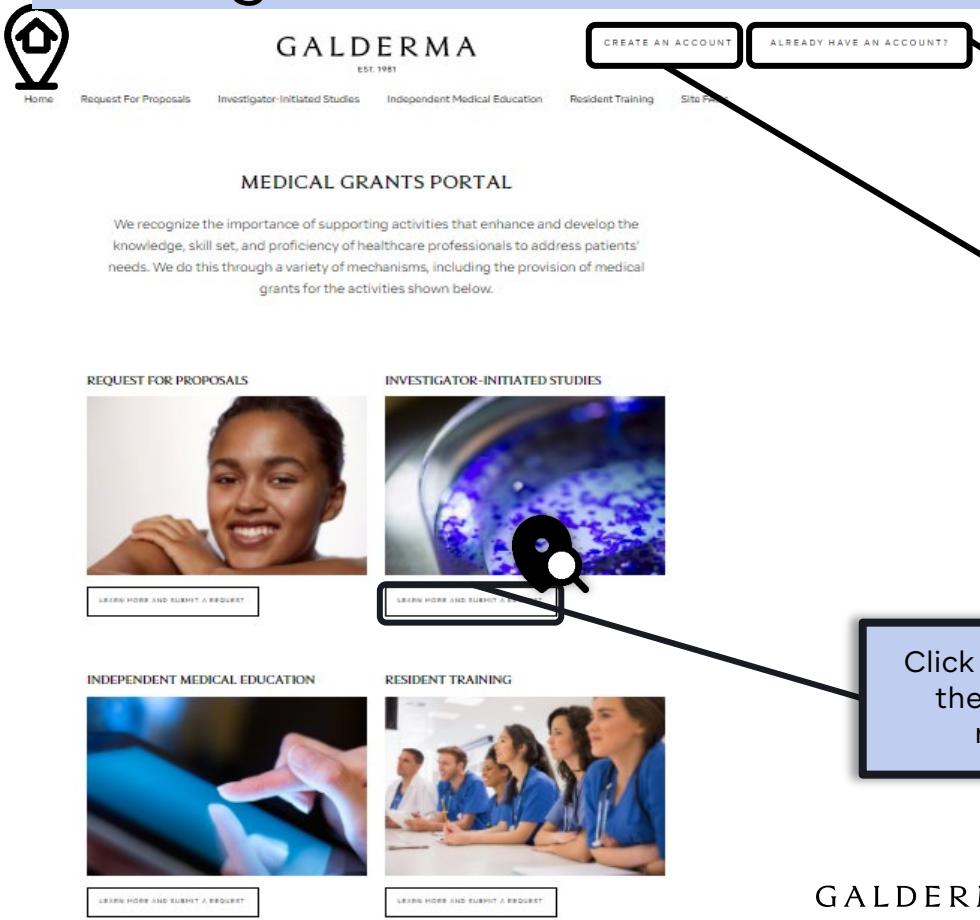
Galderma recognizes the importance of supporting Investigator-Initiated Studies (IISs) that have the potential to improve patient outcomes, can advance medical and scientific knowledge about our products, as well as generate promising medical advancements. Results of such research may lead to greater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



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

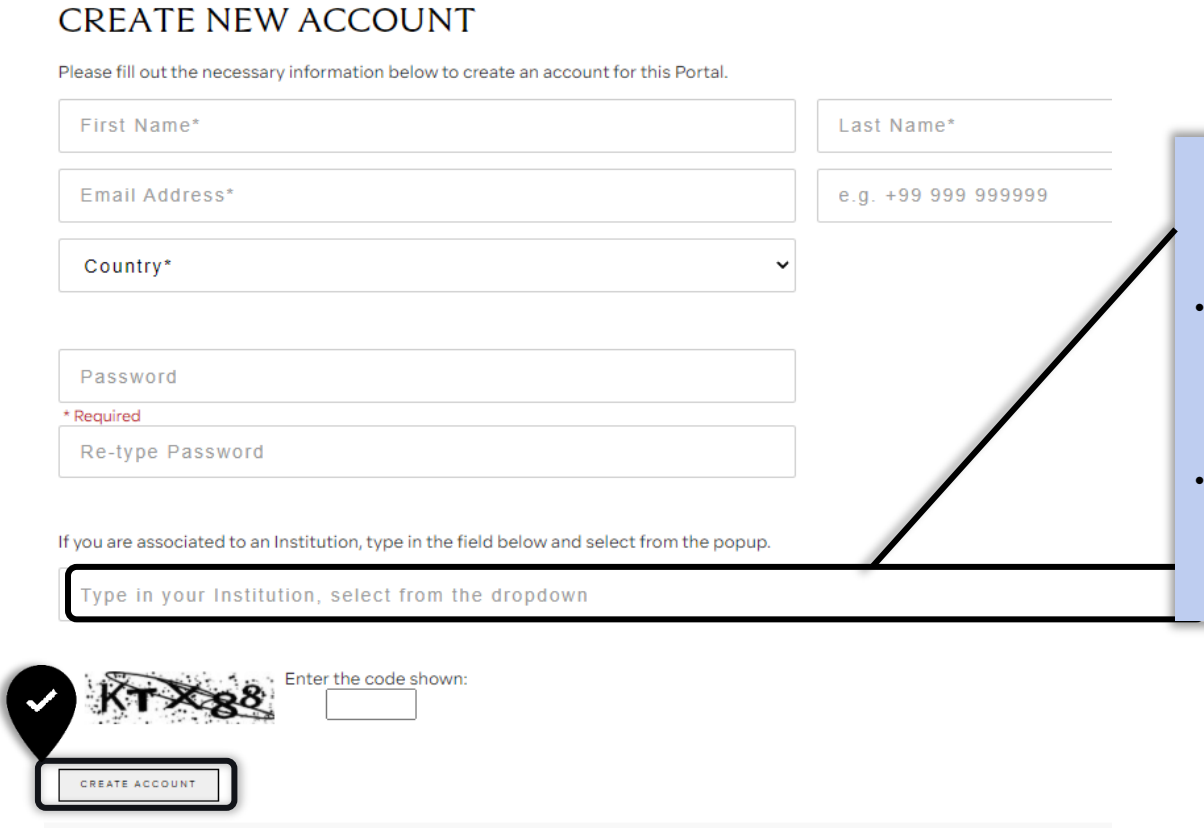
Returning users may login by clicking **Already have an account?**

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**.



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.

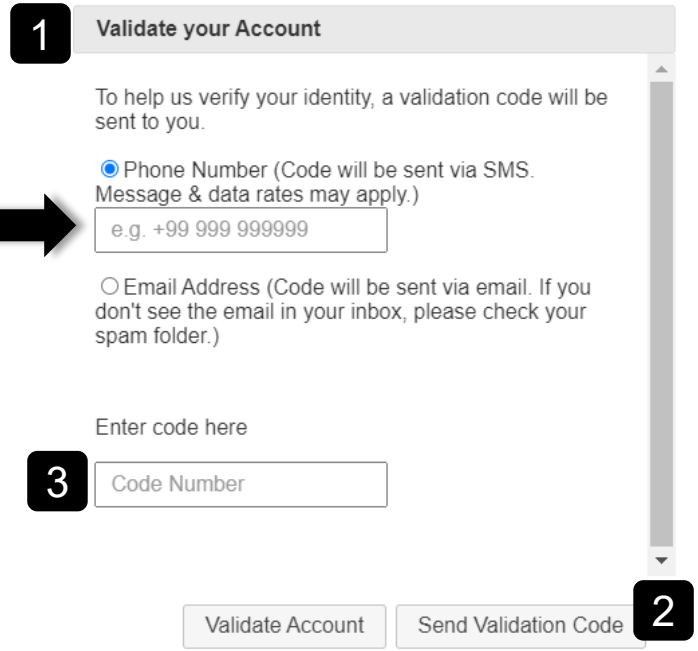
Creating a New Account

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.



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

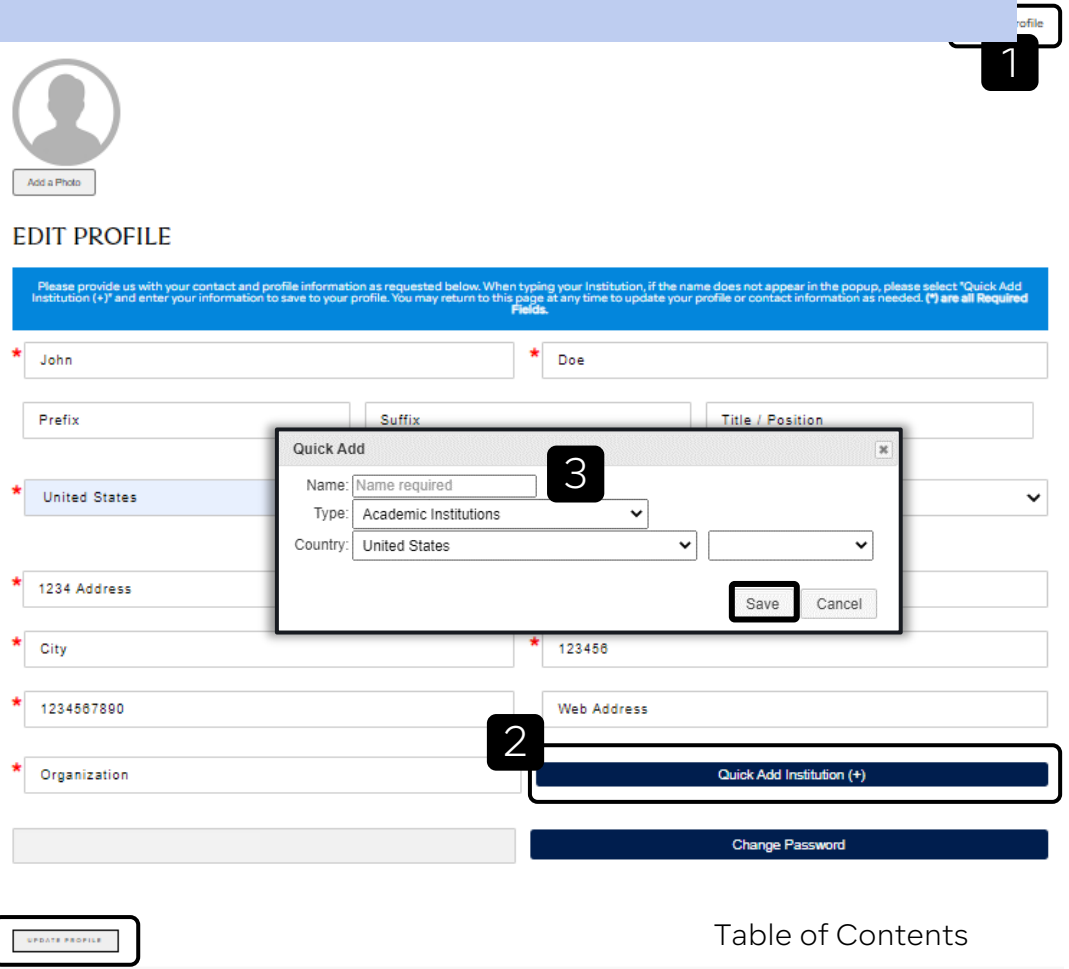
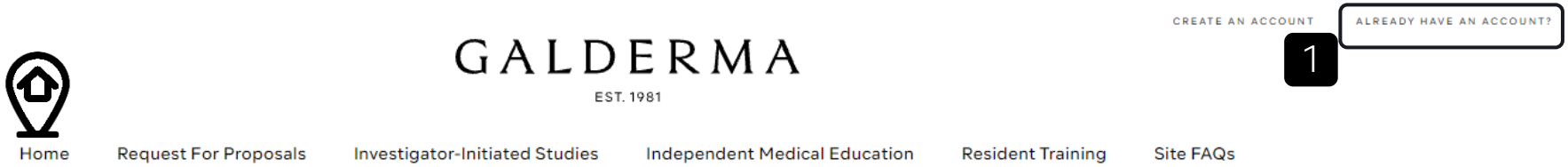
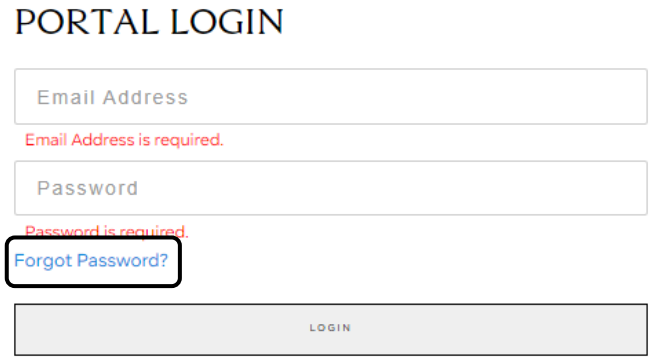


Table of Contents

Forgot Password



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.



Click **Forgot Password** to receive an email
with directions to rest 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.

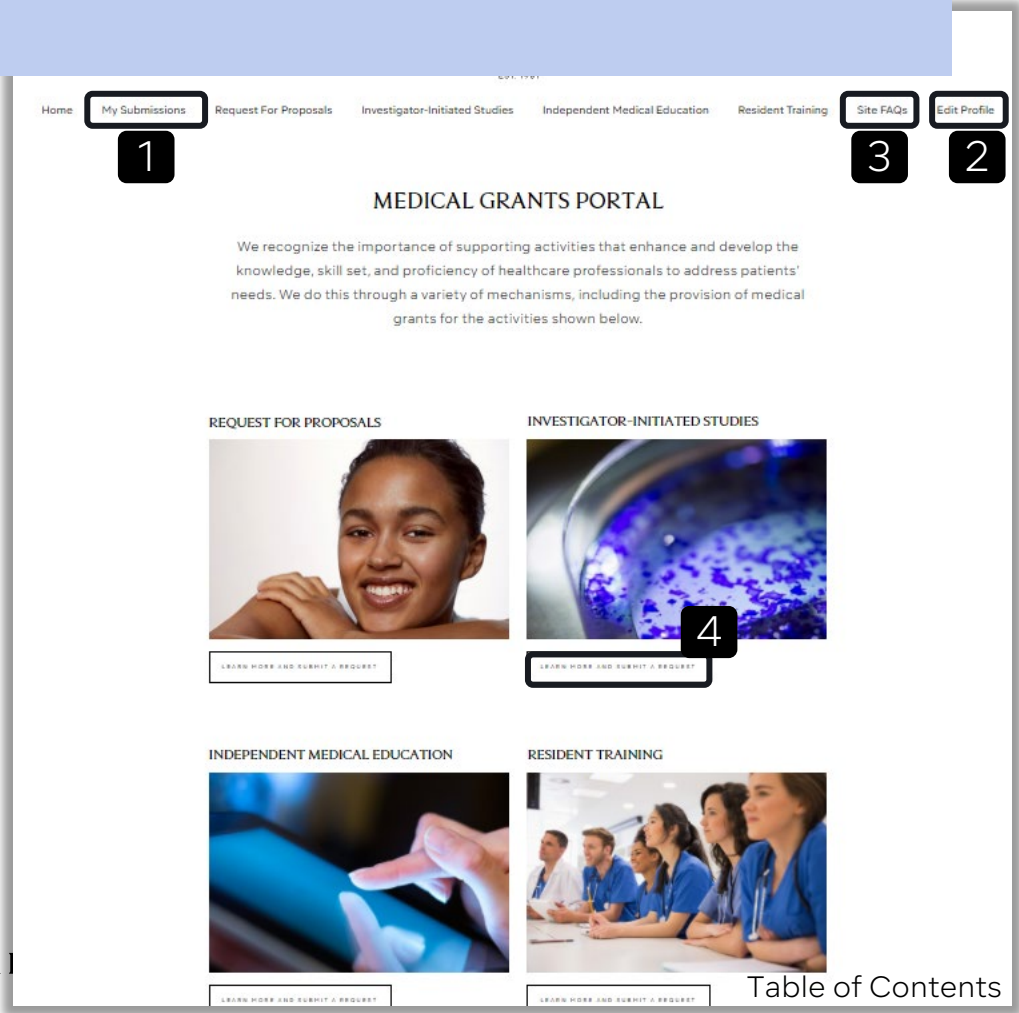


Table of Contents

Investigator-Initiated Studies Landing Page

INVESTIGATOR-INITIATED STUDIES

HOME | AREAS OF INTEREST | HOW TO APPLY | POLICIES & GUIDELINES

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.

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.

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.

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.

REQUIREMENTS OF THE SPONSOR INVESTIGATOR +

ONGOING STUDY UPDATES +

CLOSEOUT & RECONCILIATION REPORTS +

CLINICAL STUDY REPORT +

PUBLICATION +

SUBMIT A REQUEST

The tabs at the top of the Investigator-Initiated Studies Landing Page contain additional information on

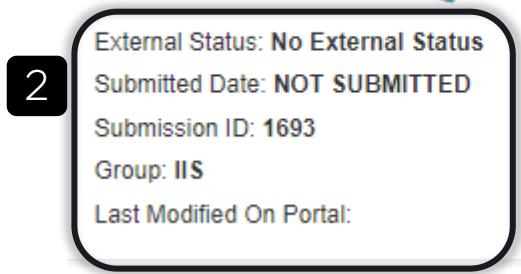
- Areas of Interest
- Types of Support
- Process
- Requirements
- Updates & Reconciliations
- Policies & Guidelines

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

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

Creating a Submission

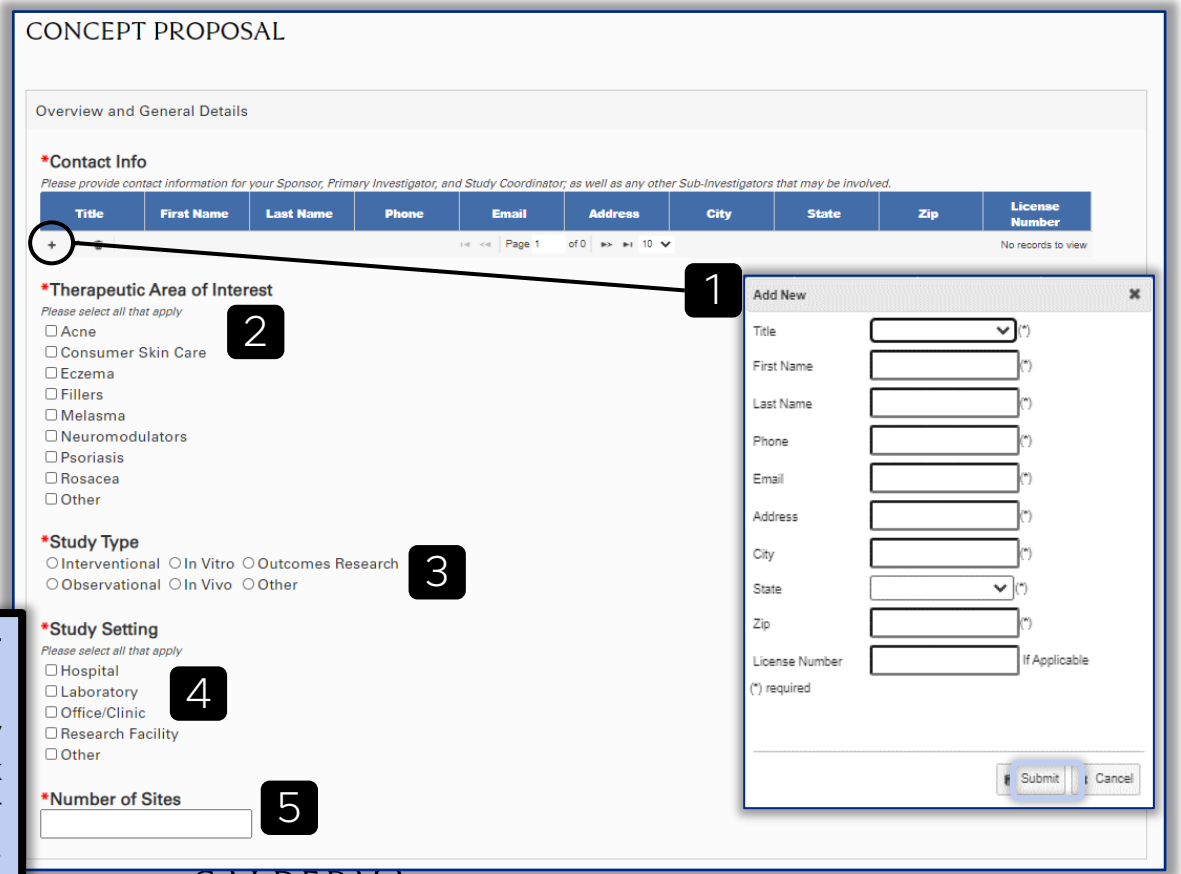
1. When starting a new request, you will be asked to create a title for your submission. Please note that this title cannot be changed once the submission is created. Please enter a title for your IIS and click **Create New.**
2. You will then be redirected to your Concept Proposal Form where you will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



Concept Proposal Form

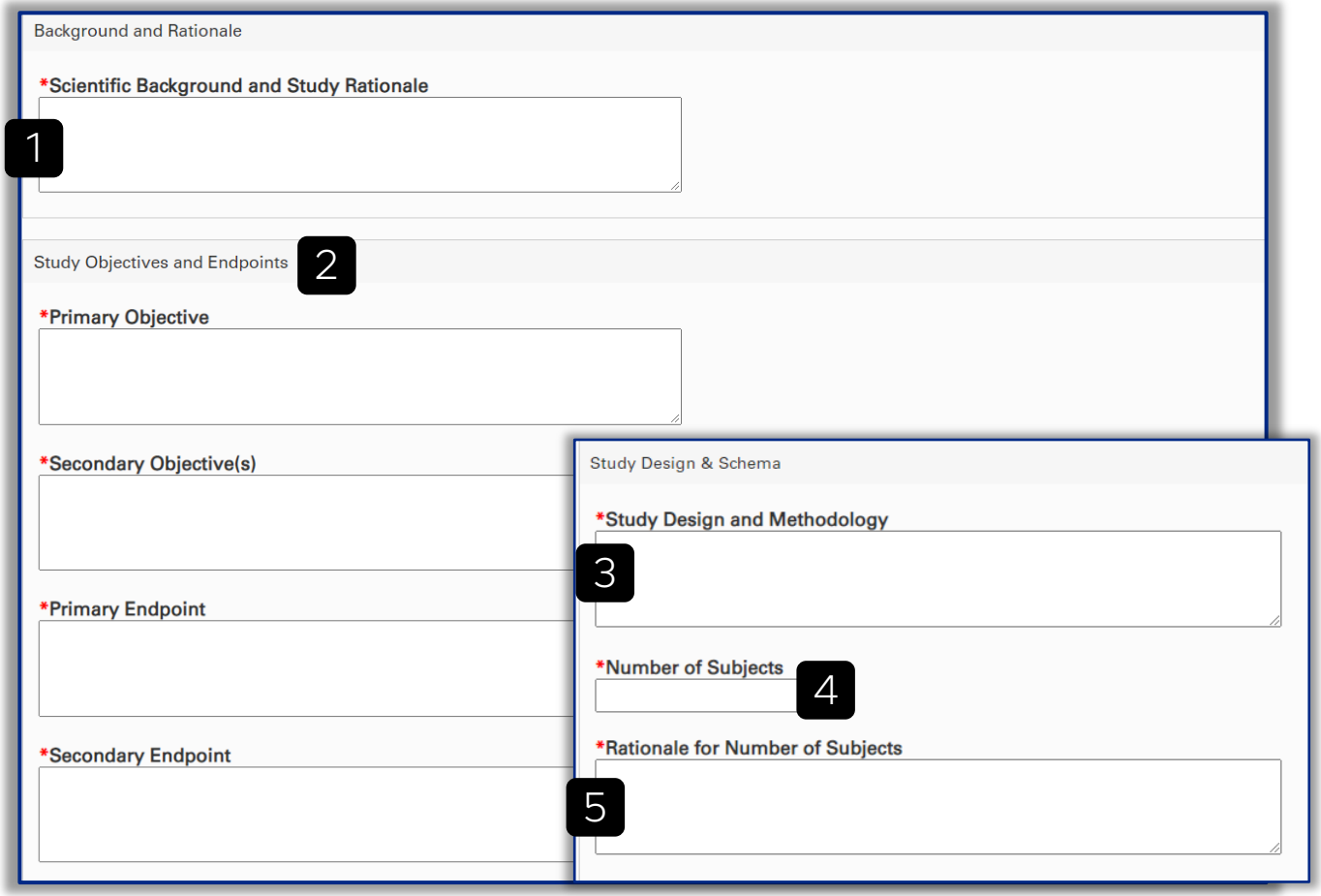
1. Click the **+** to enter the Contact Information for the Study Sponsor, Investigator(s), and Study Coordinator. Click **Submit** to save the information for each study contact.
2. Select the Therapeutic Area(s) of Interest.
3. Select the Study Type.
4. Select the Study Setting(s).
5. Enter the Number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

*These fields are required for submission



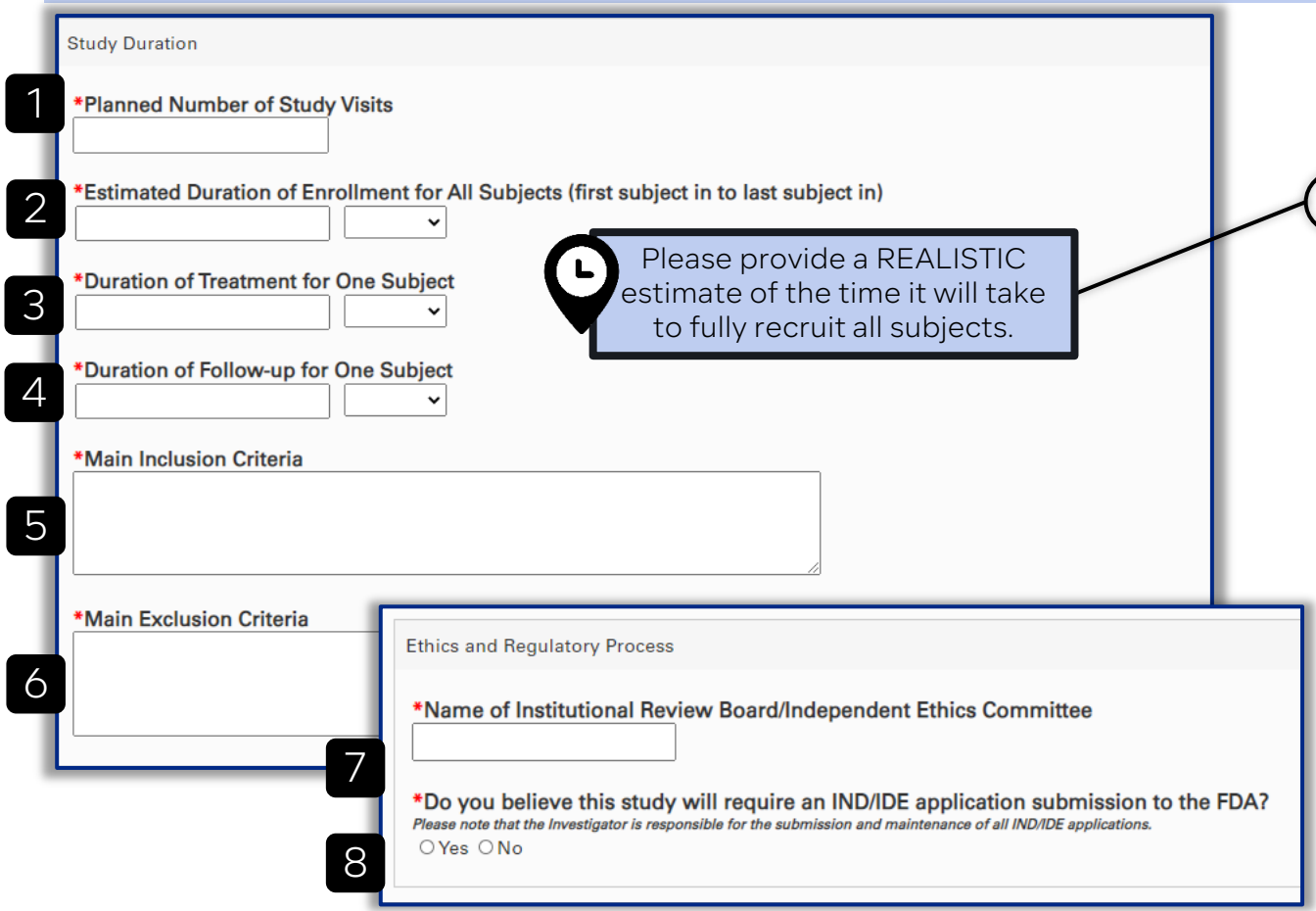
Please click *Save* to save your progress often.
The system does ***not*** automatically save your form. You may come back at a later date to complete your form, if needed.

Concept Proposal Form



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

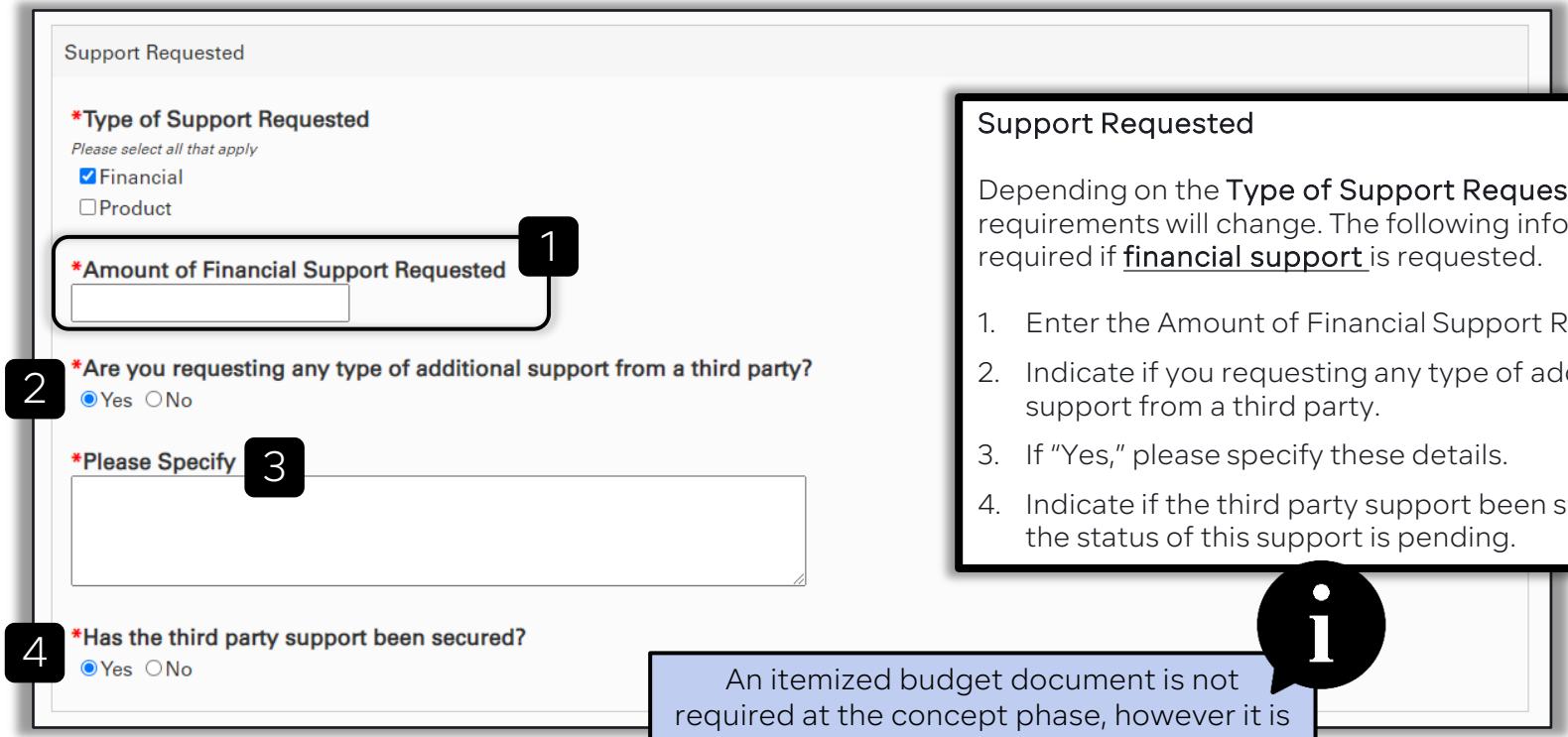


1. Enter the Planned Number of Study Visits
2. Enter the Estimated Duration of Enrollment for All Subjects (first subject in to last subject in).
3. Enter the Duration of Treatment for One Subject.
4. Enter the Duration of Follow-up for One Subject
5. Enter the Main Inclusion Criteria
6. Enter the Main 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



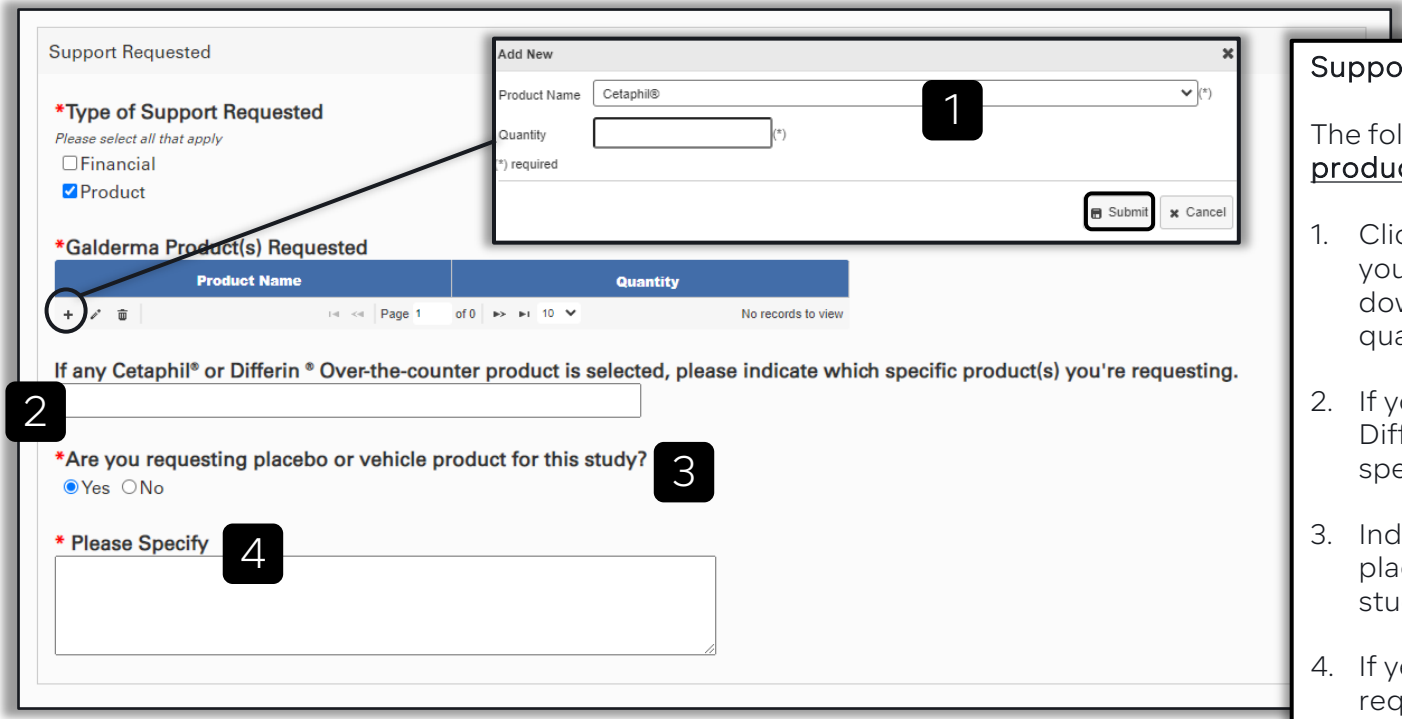
Support Requested

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.

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

Concept Proposal Form



Support Requested

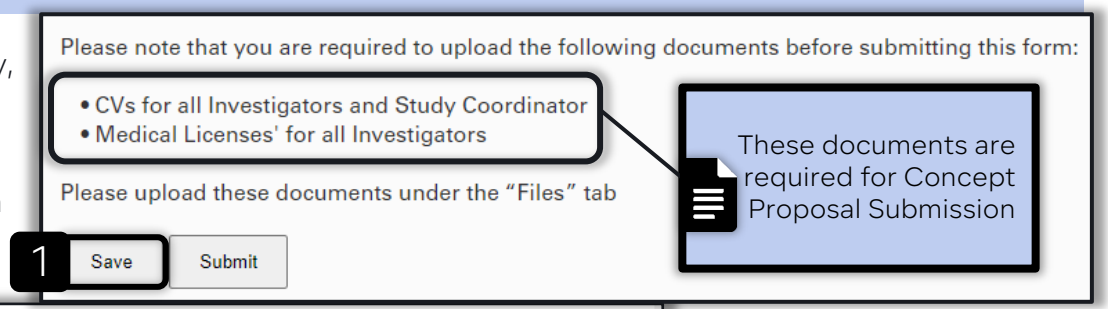
The following information is required if <u>product support</u> is requested.

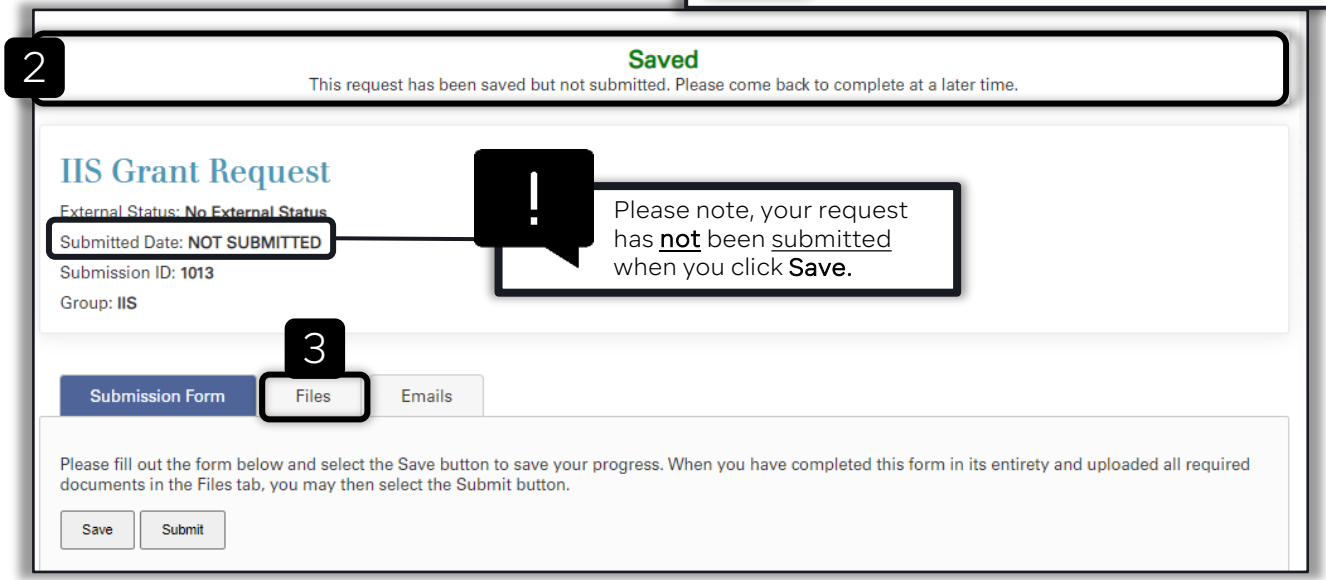
1. Click the **+** and select the product you are requesting from the drop-down list provided. Enter the quantity and click **Submit.**
2. If you are requesting Cetaphil® or Differin® OTC, please enter the specific product name here.
3. Indicate if you requesting any placebo or vehicle product for this 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 <u>not</u> been submitted when you click **Save.**





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.

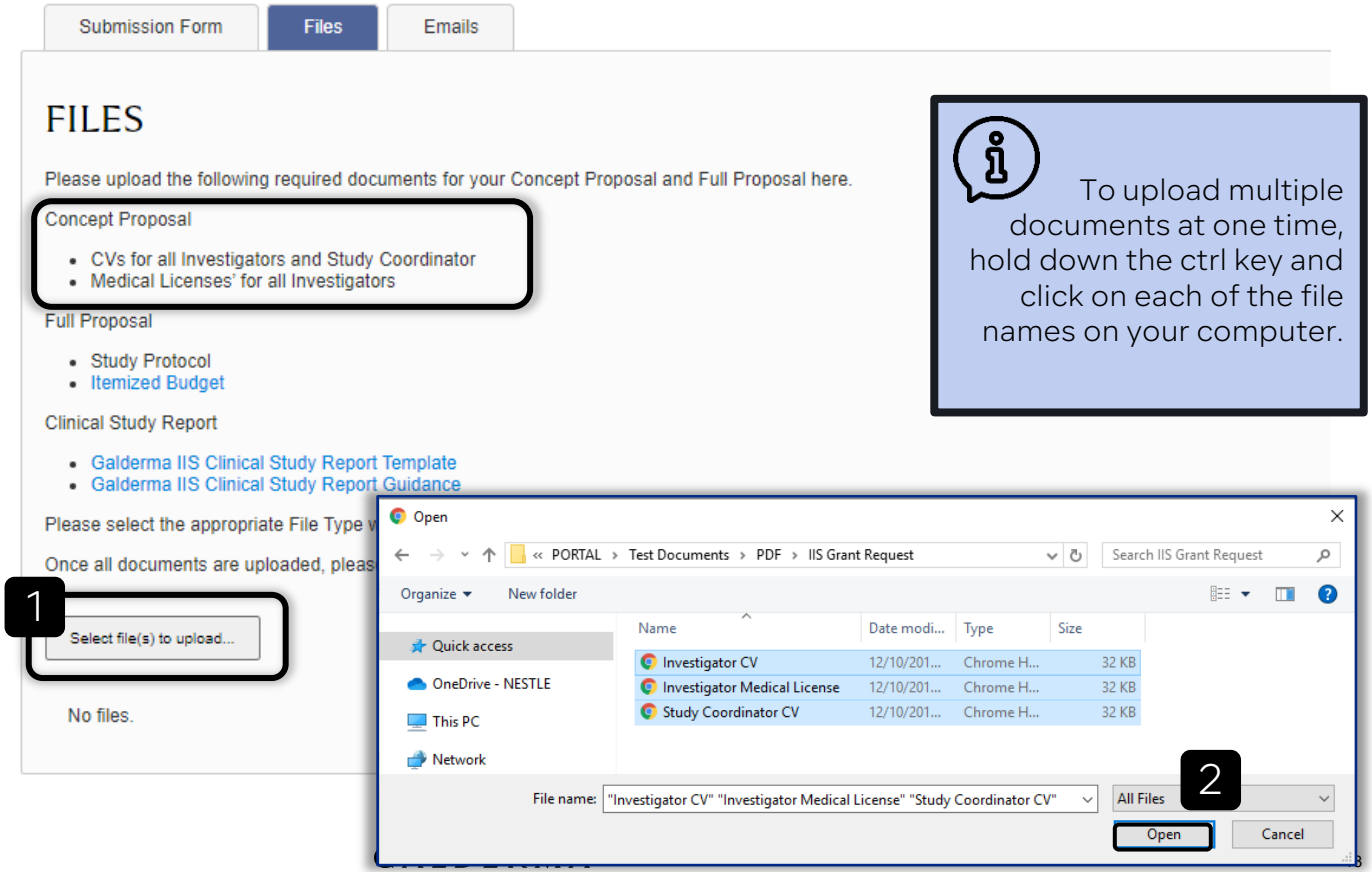
3. Click on the *Files* tab to upload these required documents.

Concept Proposal Files

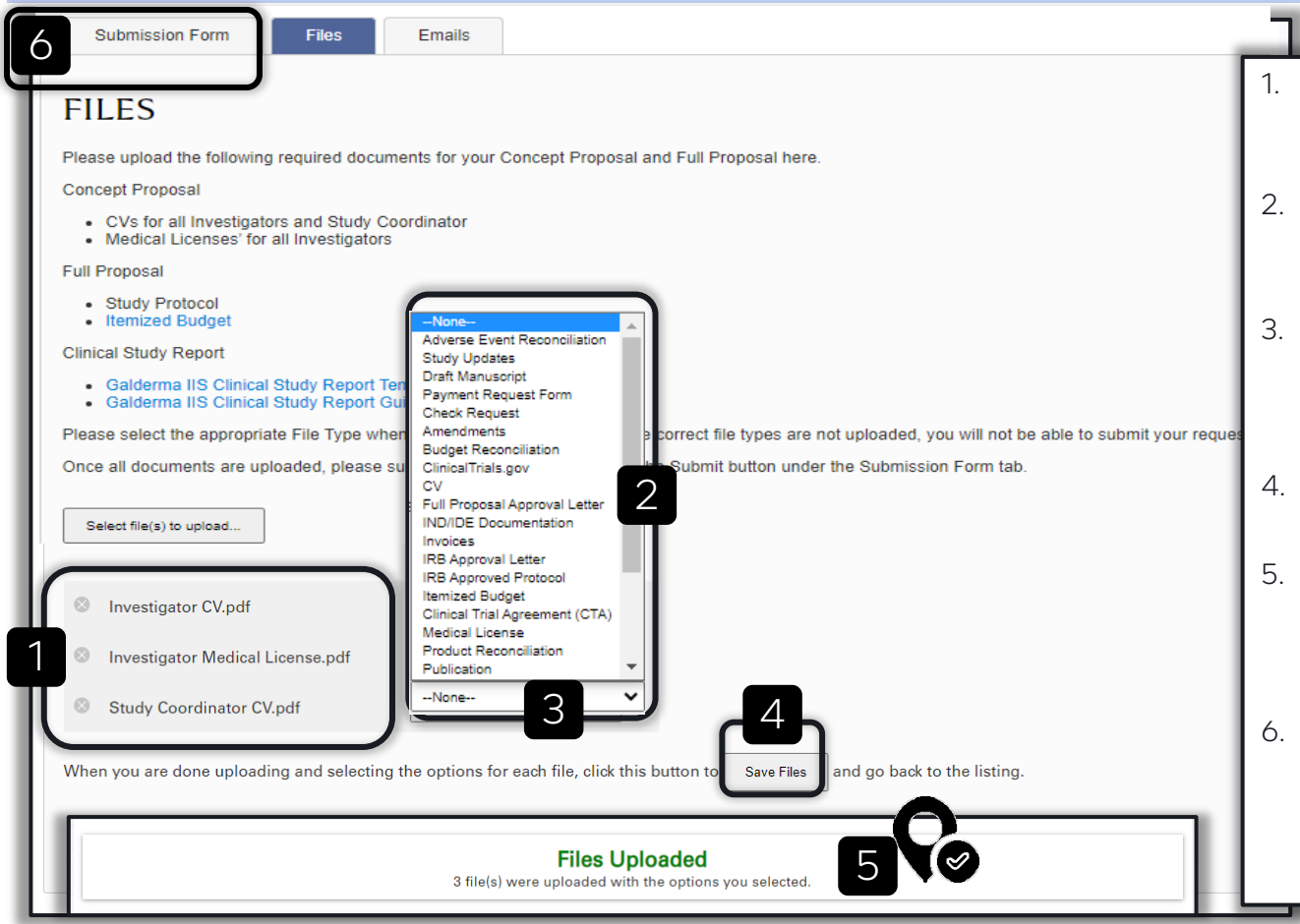
Files

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.

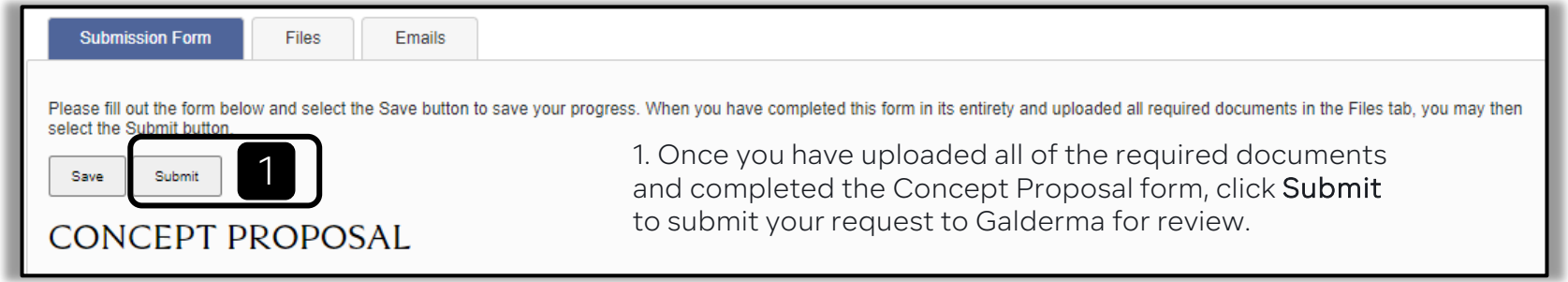


Concept Proposal Files

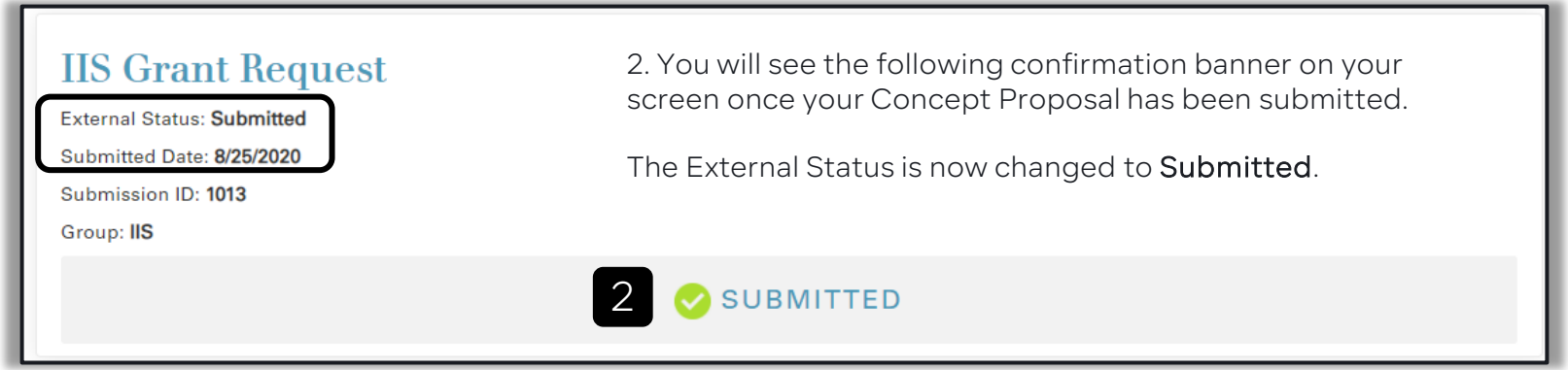


1. Your documents will now appear in this section and will require a File Type selection.
2. Click on the **v** to select the corresponding File Type from the drop-down list provided.
3. The list will refresh after each File Type selection is made so please make sure that each document has a File Type 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 has 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



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.



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

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

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 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

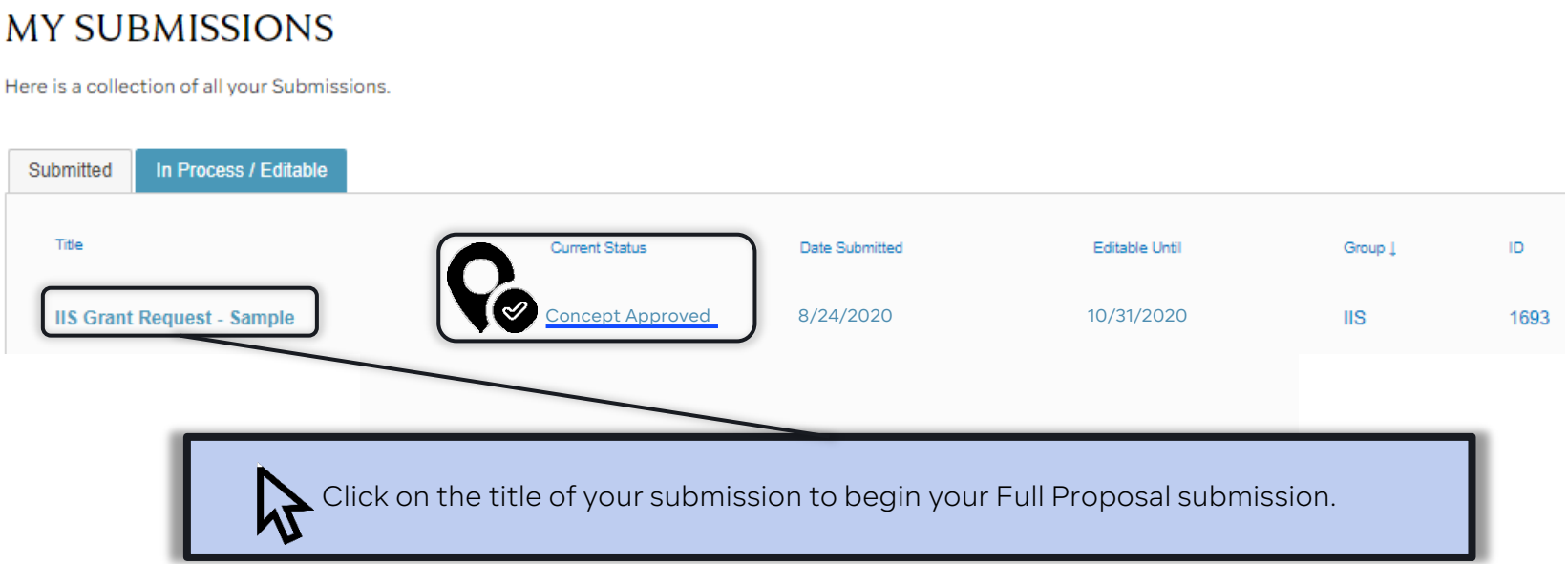
If your Concept Proposal is of interest to Galderma, you will receive a follow-up request for a **Full Proposal** submission.

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

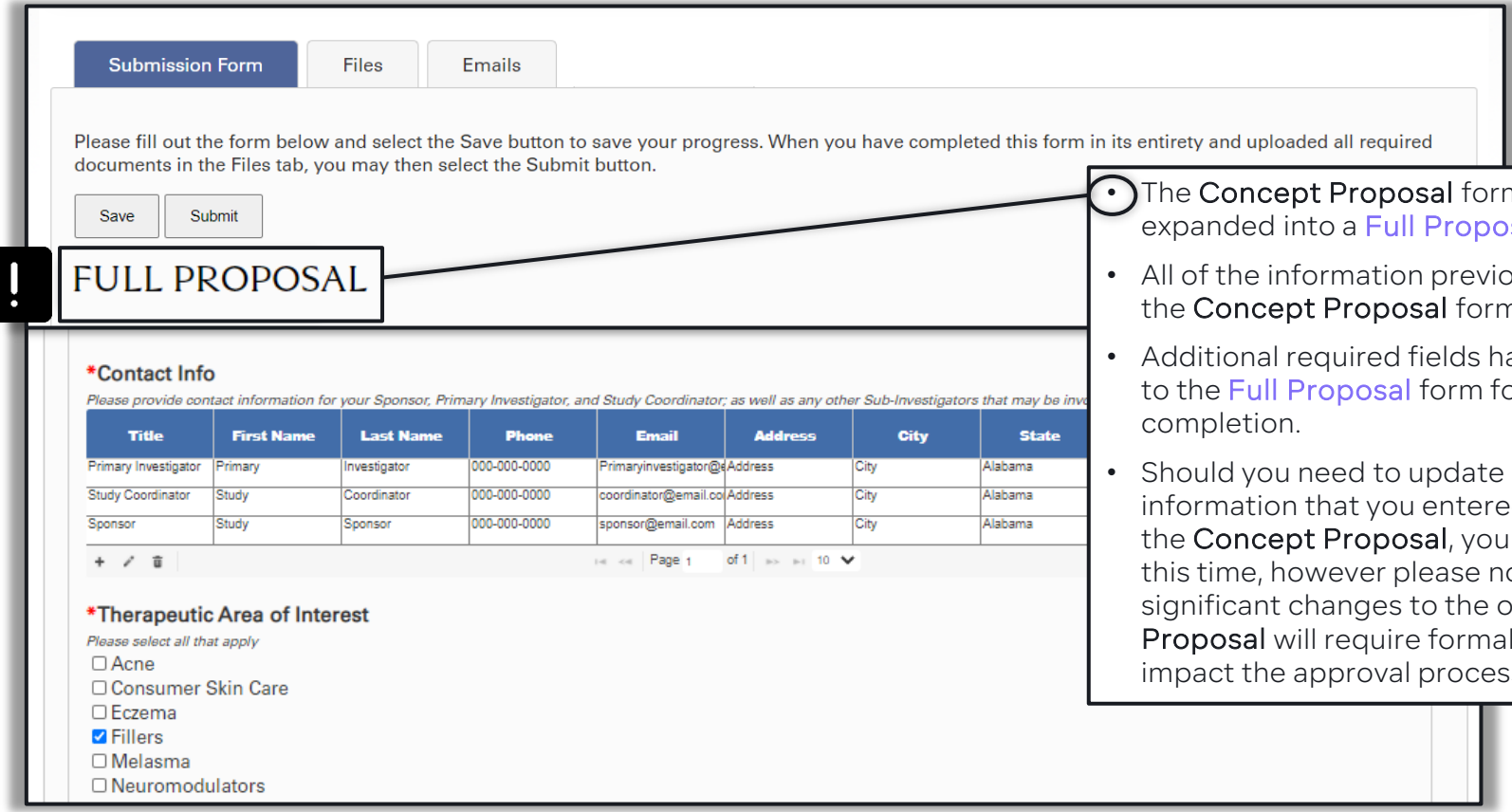
My Submissions

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.

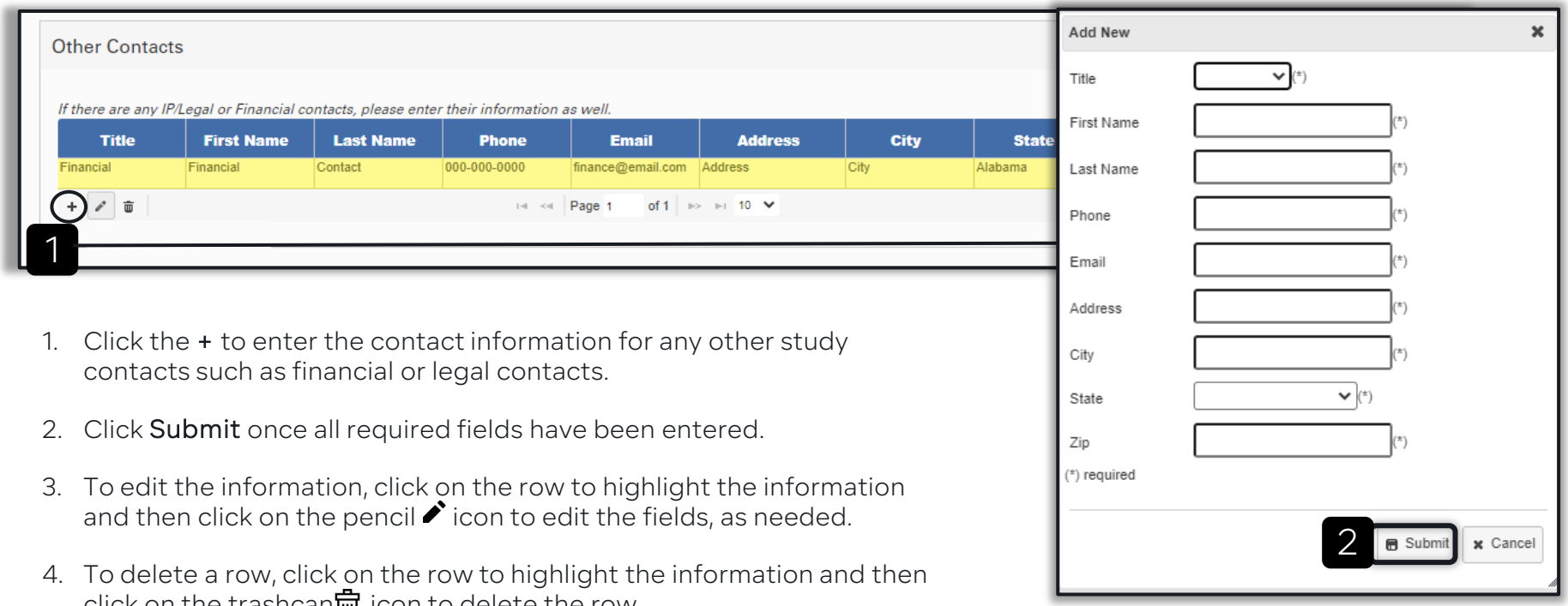


Full Proposal Form



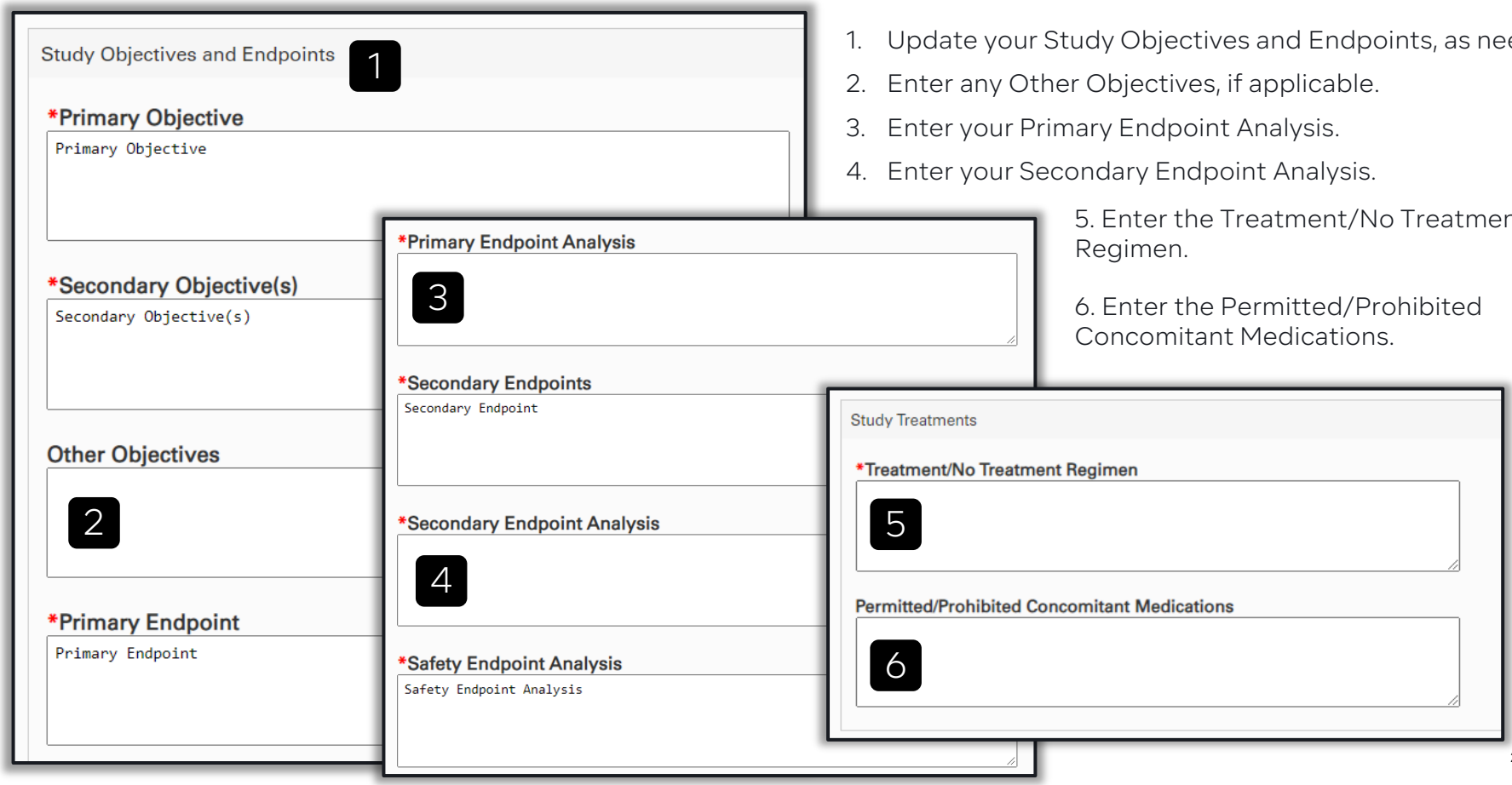
- The **Concept Proposal** form has now expanded into a Full Proposal form.
- All of the information previously entered on the **Concept Proposal** form is shown here.
- Additional required fields have been added to the Full Proposal form for your completion.
- Should you need to update any of the information 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



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.

Full Proposal Form

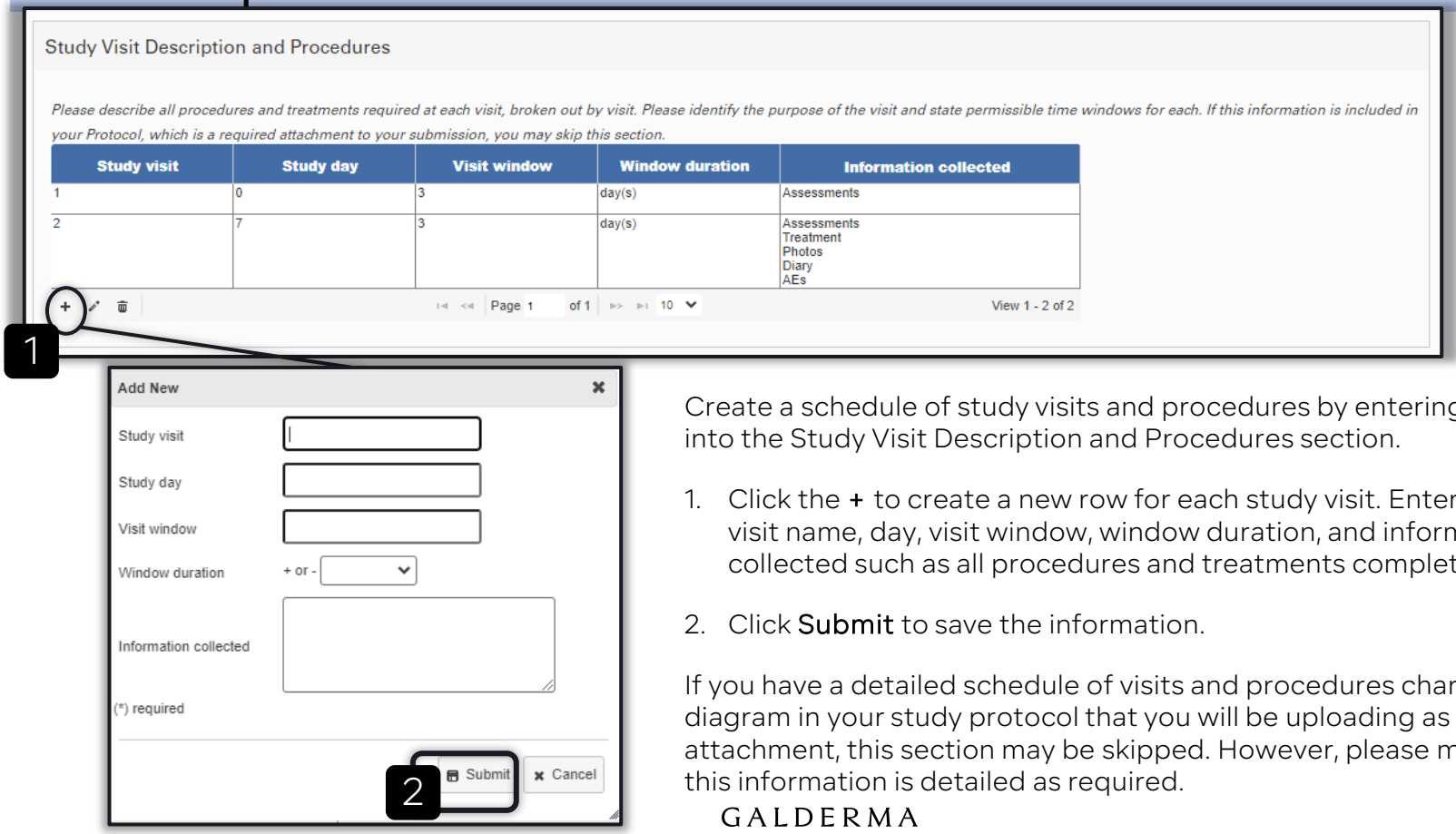


1. Update your Study Objectives and Endpoints, as needed.
2. Enter any Other Objectives, if applicable.
3. Enter your Primary Endpoint Analysis.
4. Enter your Secondary Endpoint Analysis.

5. Enter the Treatment/No Treatment Regimen.

6. Enter the Permitted/Prohibited Concomitant Medications.

Full Proposal Form



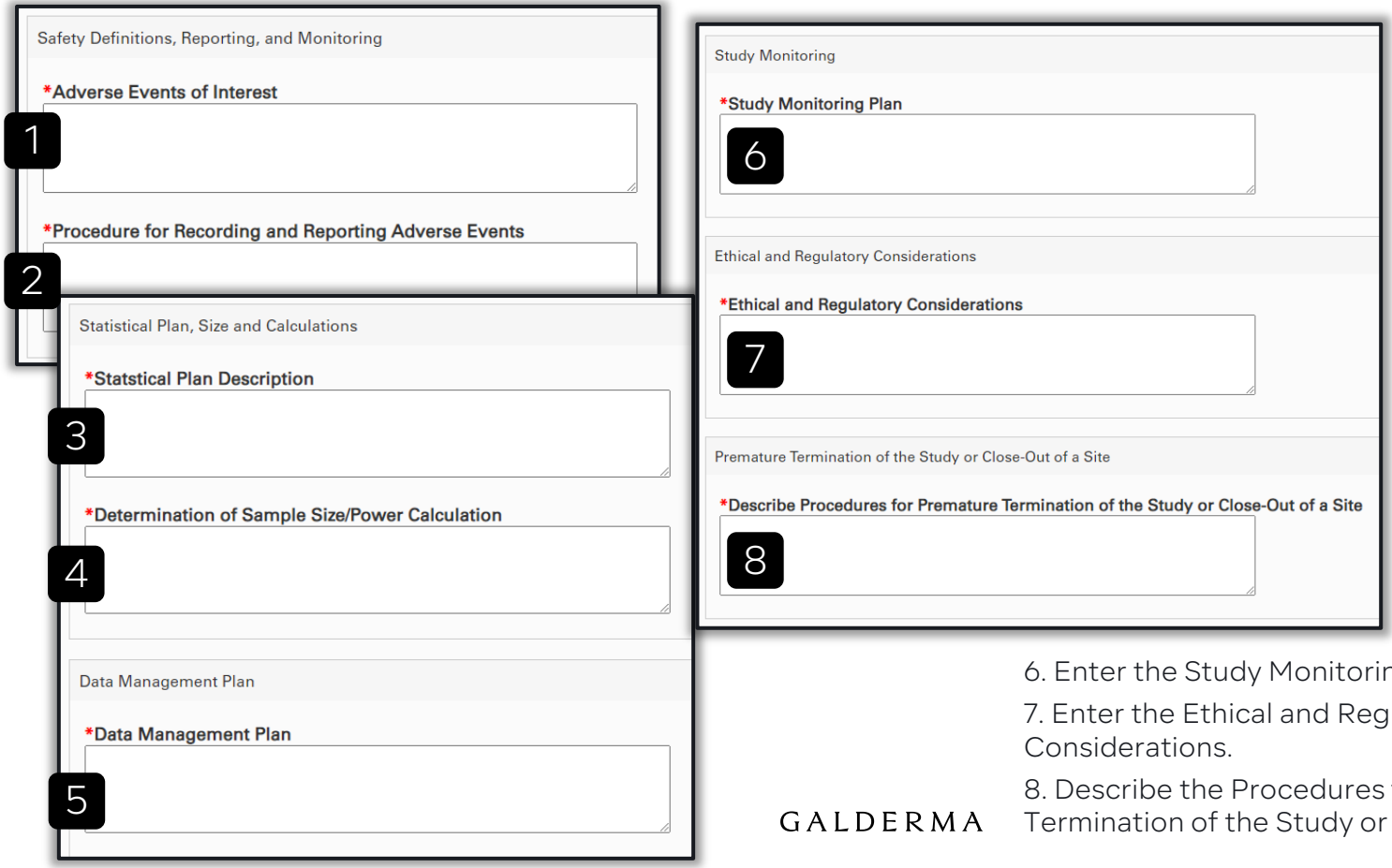
Create a schedule of study visits and procedures by entering information into the Study Visit Description and Procedures section.

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.

Full Proposal Form



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.

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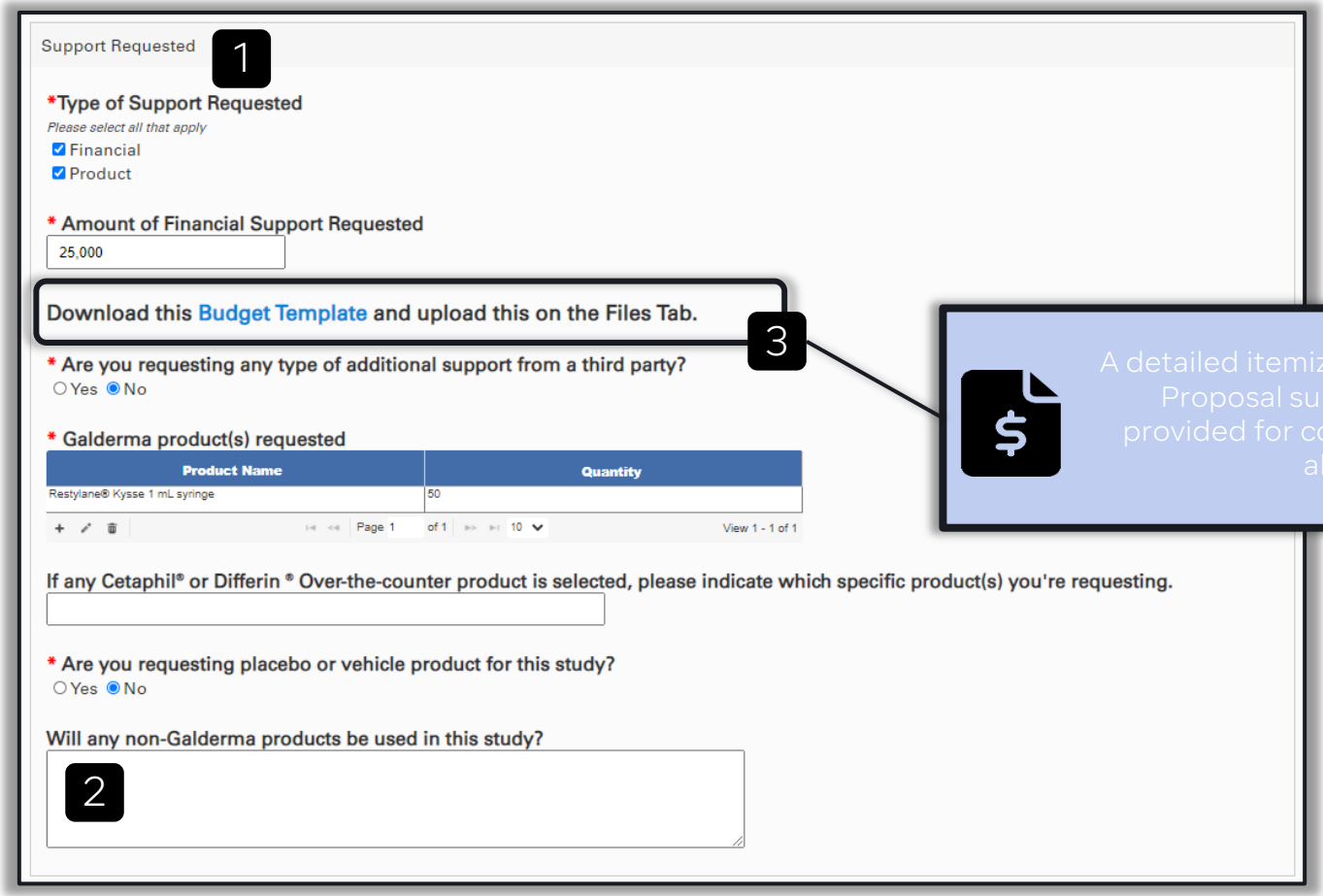
Full Proposal Form

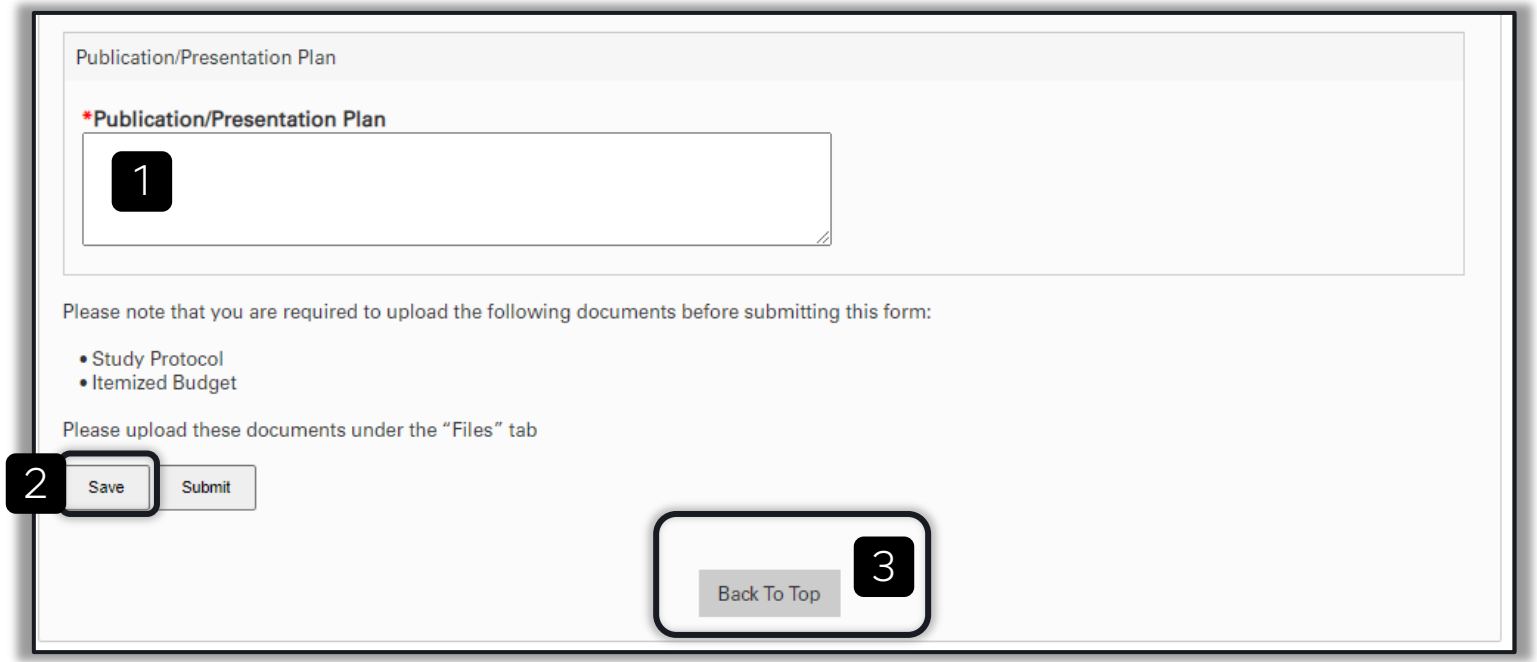


1. Update the Support Requested section, if needed.
2. Indicate if any non-Galderma product will be used in the study.

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.

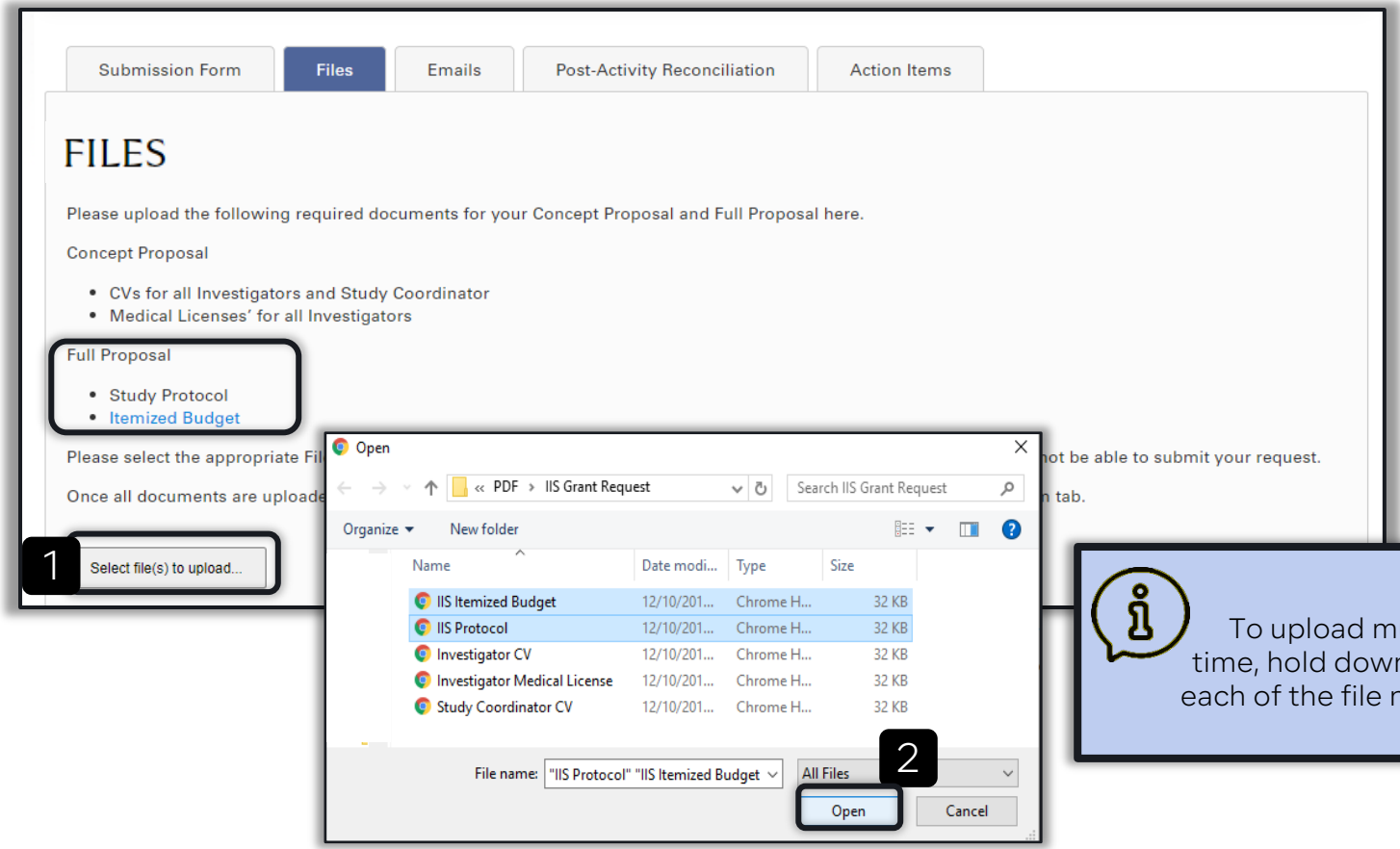
3. Should you elect to use the Galderma Template, click on the hyperlink to download the excel spreadsheet for completion.

Full Proposal Form



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

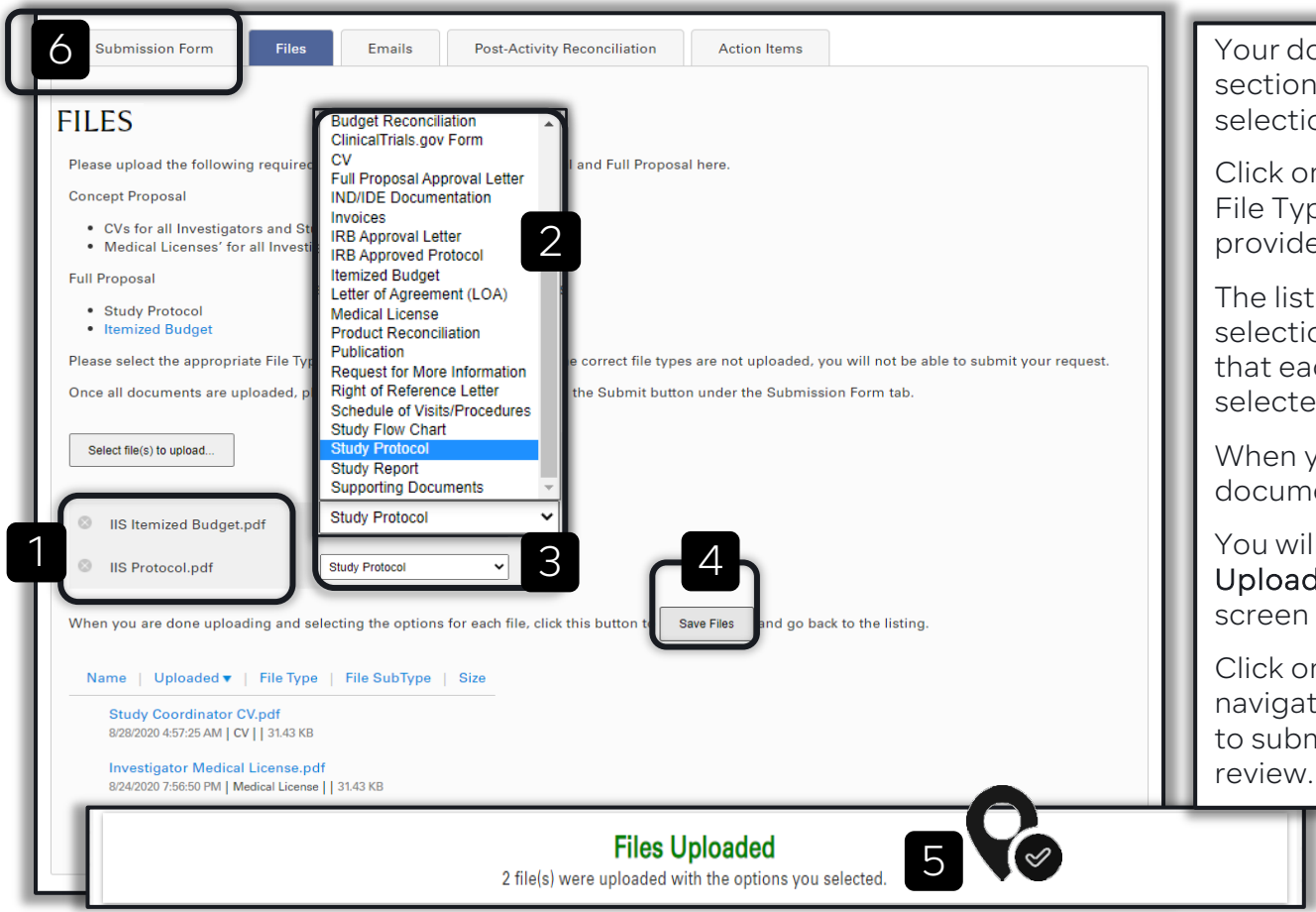


1. Upload your Study Protocol and Itemized Budget. Click **Select file(s) to upload…**

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



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

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

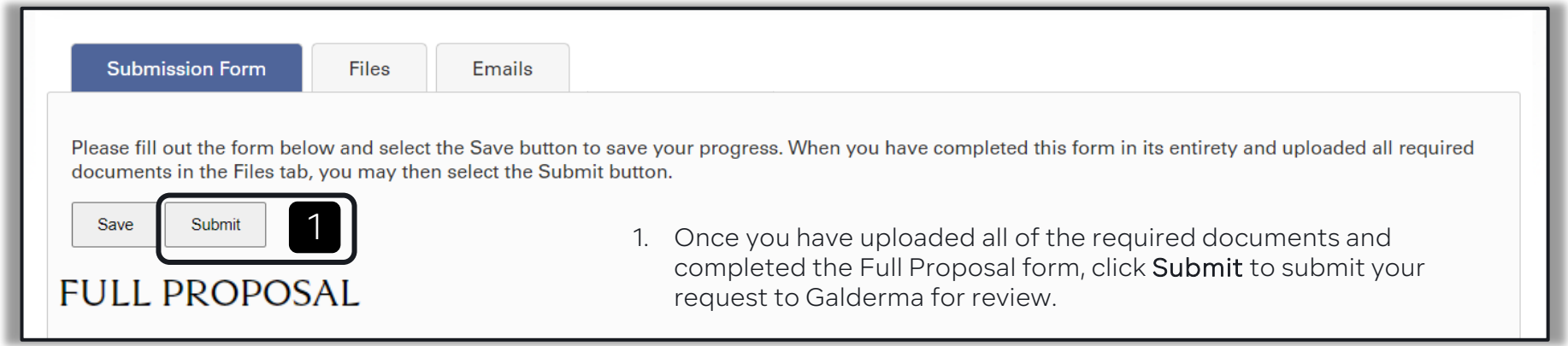
The list will refresh after each File Type selection is made so please make sure that each document has a File Type selected.

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

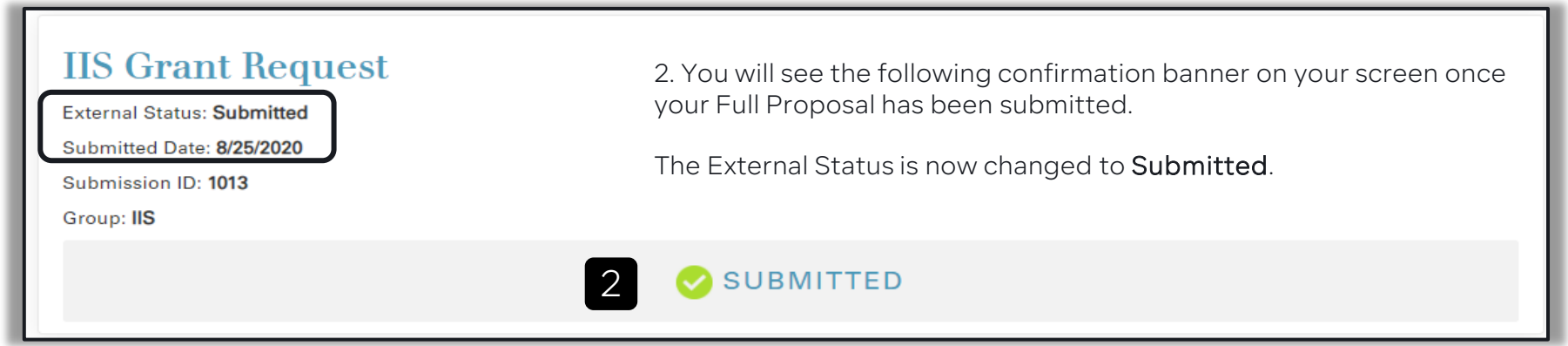
You will see the following **"Files Uploaded"** confirmation banner on your screen once your files has been saved.

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



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.



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**.

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."

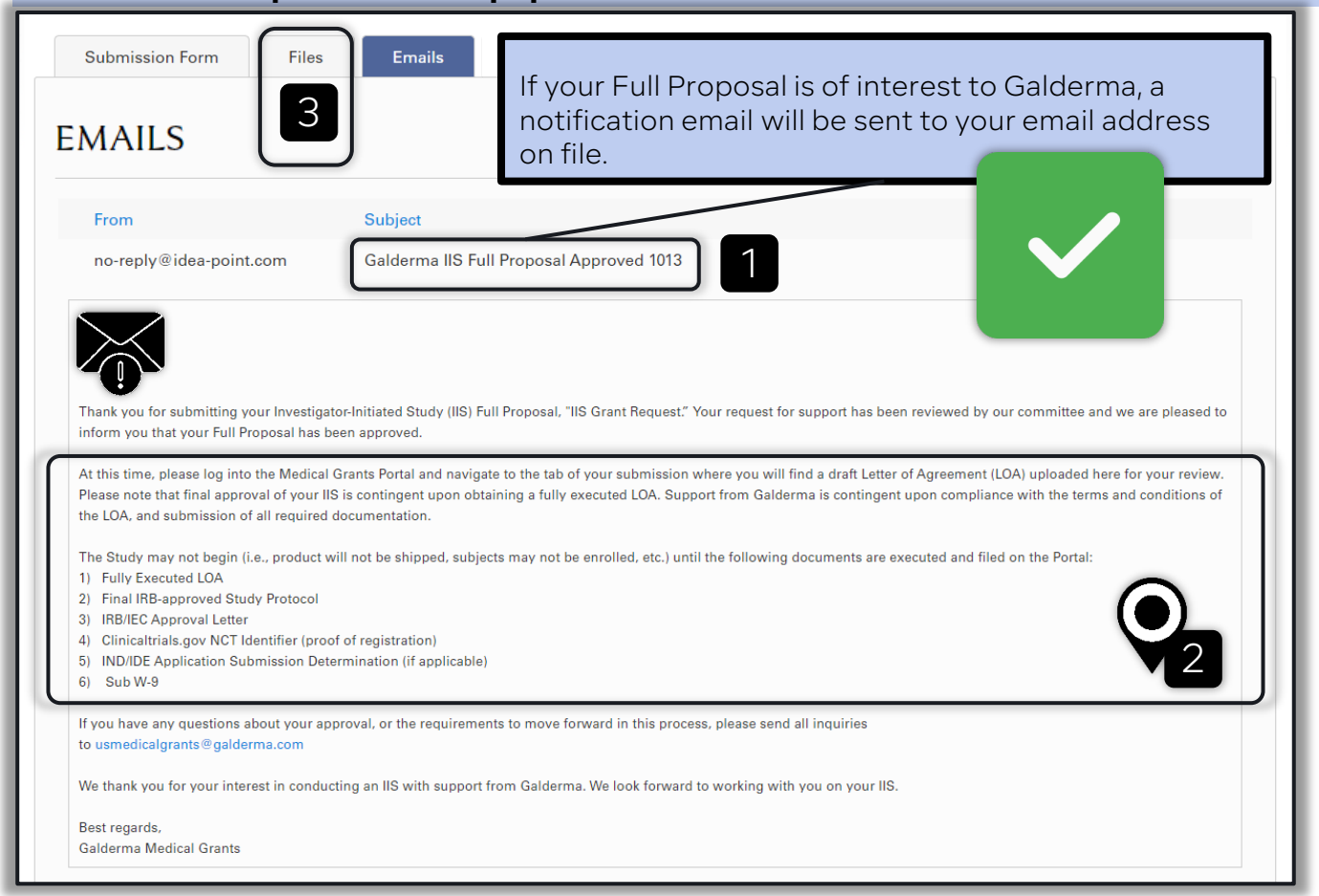
All requests for IIS research grants are vetted by an internal committee. Support is awarded based on the scientific merit of each submitted proposal, investigator qualifications, study budget, alignment with company objectives, and site feasibility. Should your Full Proposal be of interest, you will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

Full Proposal Approval

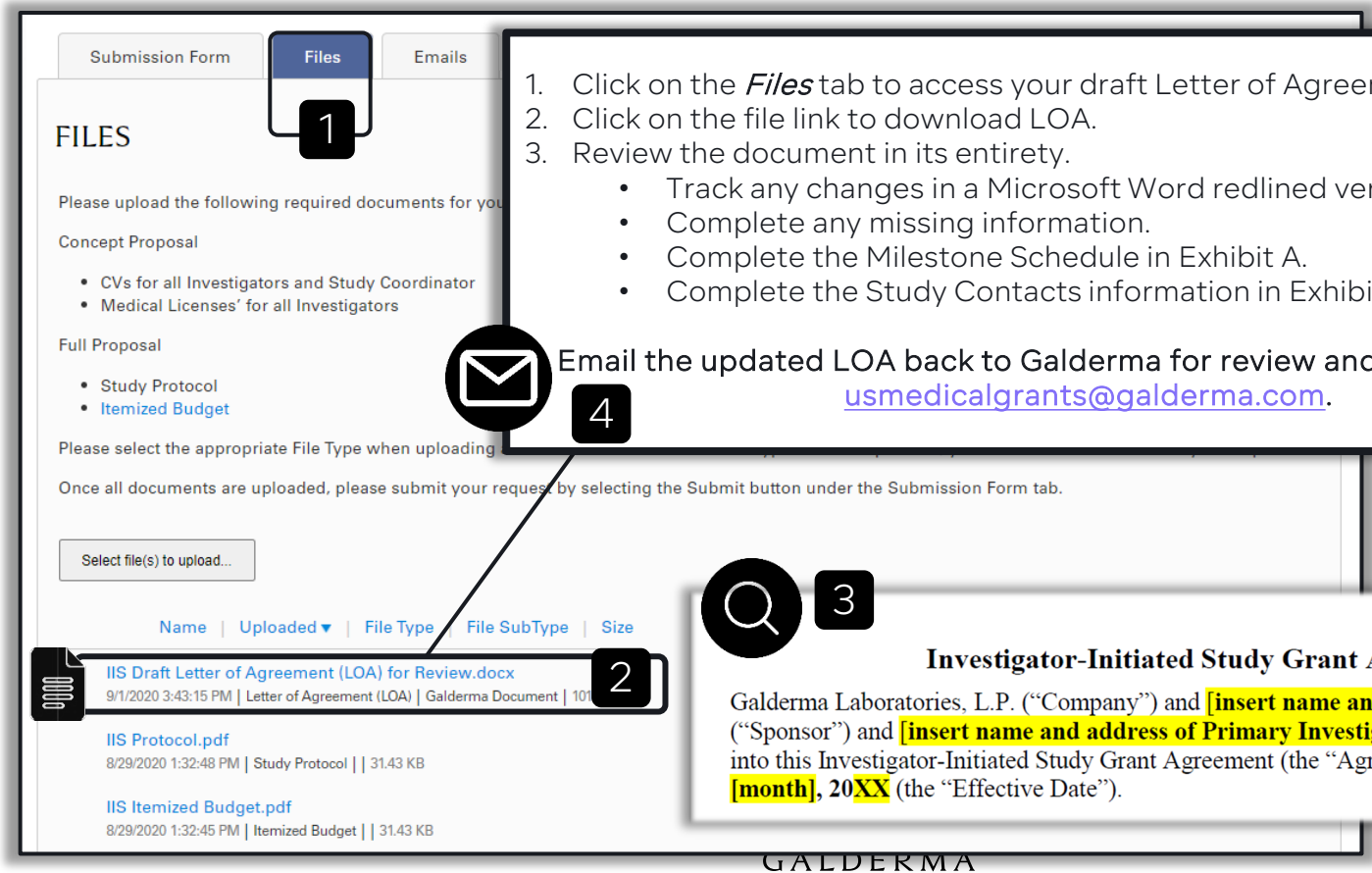


1. If the Full Proposal is approved, you will receive an approval notification to your email address on file containing instructions regarding the next steps of the process including obtaining a fully executed Letter of Agreement (LOA).

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



1. Click on the *Files* tab to access your draft Letter of Agreement (LOA).
2. Click on the file link to download LOA.
3. 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.

4 Email the updated LOA back to Galderma for review and full execution at usmedicalgrants@galderma.com.

3

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

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

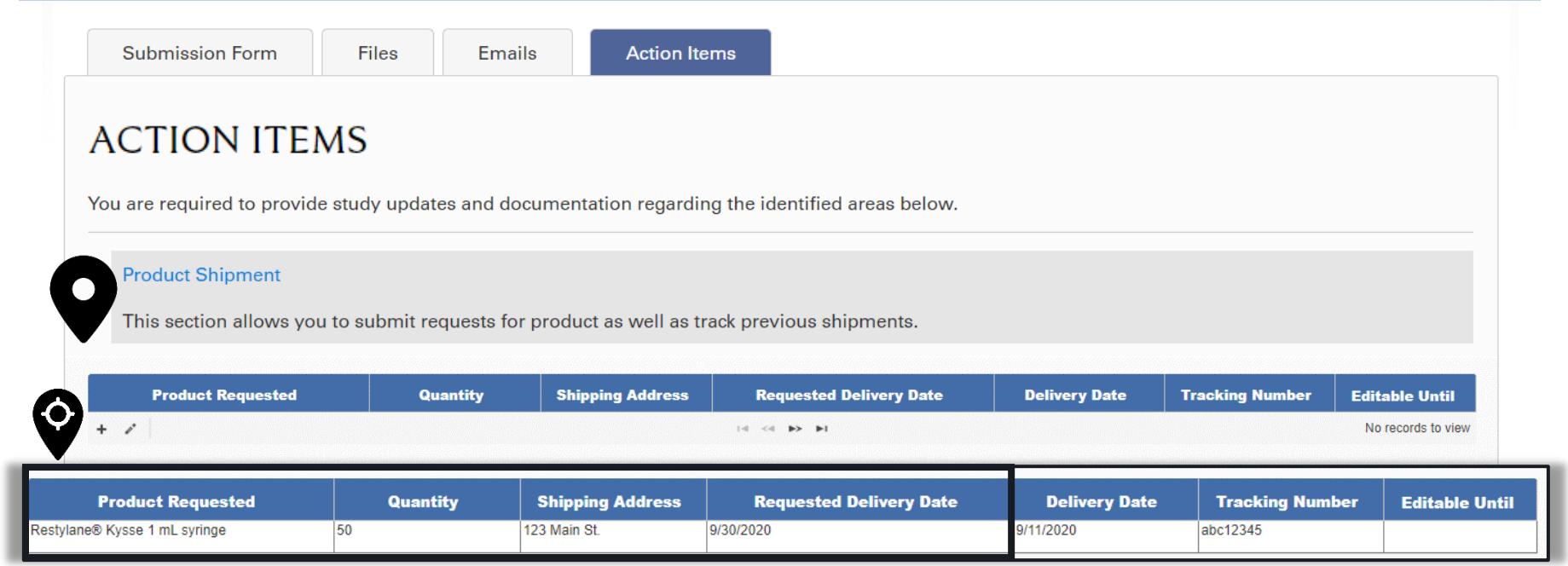
View 1 - 5 of 5

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



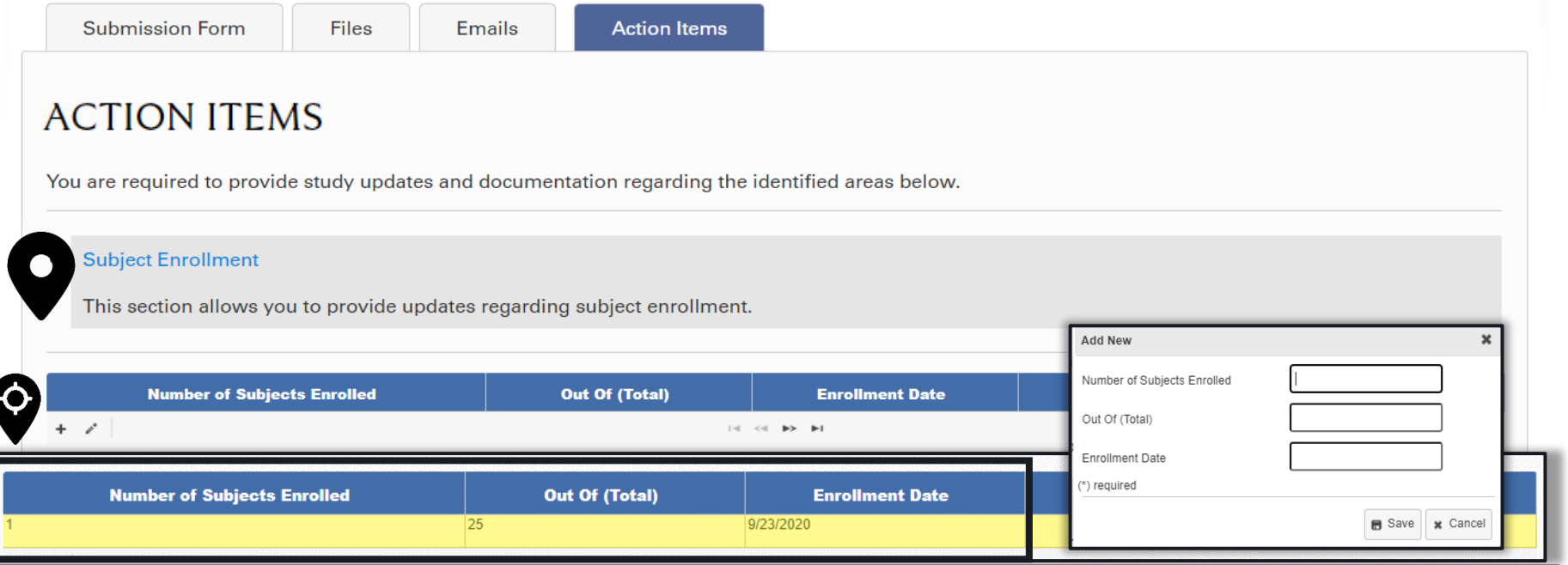
Product Requested	Quantity	Shipping Address	Requested Delivery Date	Delivery Date	Tracking Number	Editable Until
Restylane® Kysse 1 mL syringe	50	123 Main St.	9/30/2020	9/11/2020	abc12345	

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



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