

sanofi | *REGENERON*[®]

GLOBAL INNOVATION GRANT

PATHWAYS

IN TYPE 2 INFLAMMATION

Application Guide

Introduction – What projects are eligible for funding?

Welcome to PATHWAYS Global Innovation Grant

The PATHWAYS Global Innovation Grant program is a funding initiative by Sanofi and Regeneron, developed to **support novel research in type 2 inflammation and associated diseases**.

PATHWAYS funding is unique in many ways including:

- **Choose when to apply:** Calls for proposals are open two times a year: May and September, giving researchers the flexibility to submit their proposal at their preferred time directly through this website.
- **Fast-track review:** The review process utilizes an external scientific expert panel with industry benchmarks that have proven to accelerate research in the most efficient manner.
- **Up to 500,000 USD per project:** Researchers can apply for a grant up to 500,000 US dollars for each research project.

This document provides a guide to the application process, please follow these steps to complete an application online at <http://www.globalt2grant.com/>



Scan to Visit
the Pathways Site

Introduction – What projects are eligible for funding?



Eligible

PATHWAYS Global Innovation Grants are designed to support projects that:

- Are original and carry true scientific or clinical interest
- Benefit patients and contribute to the understanding of type 2 inflammation and associated diseases

Your research project should advance knowledge in the field of type 2 inflammation and associated diseases, including, but not limited to, atopic dermatitis, bullous pemphigoid, chronic spontaneous urticaria, prurigo nodularis, eosinophilic esophagitis, asthma, chronic obstructive pulmonary disease, chronic rhinosinusitis with nasal polyps or other type 2 immune-mediated diseases that are relevant in clinical practice. We will prioritize research projects with clear potential to significantly advance scientific understanding of type 2 immune-mediated diseases and improve outcomes in patient care or reduce individual disease burden.

Not eligible

- Studies for which extensive data is already published
- Comparative drug trials, randomized clinical trials, or placebo-controlled trials
- Studies for which the risk/benefit of any interventional treatment is considered uncertain, based on the scientific rationale, mechanism of action, and potential safety concerns
- Research projects that are already included in Investigator- Sponsored Studies by Sanofi and Regeneron; ongoing research may be listed on www.clinicaltrials.gov, however applications in the ISS or grant system will not be available to applicants

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Clickable!

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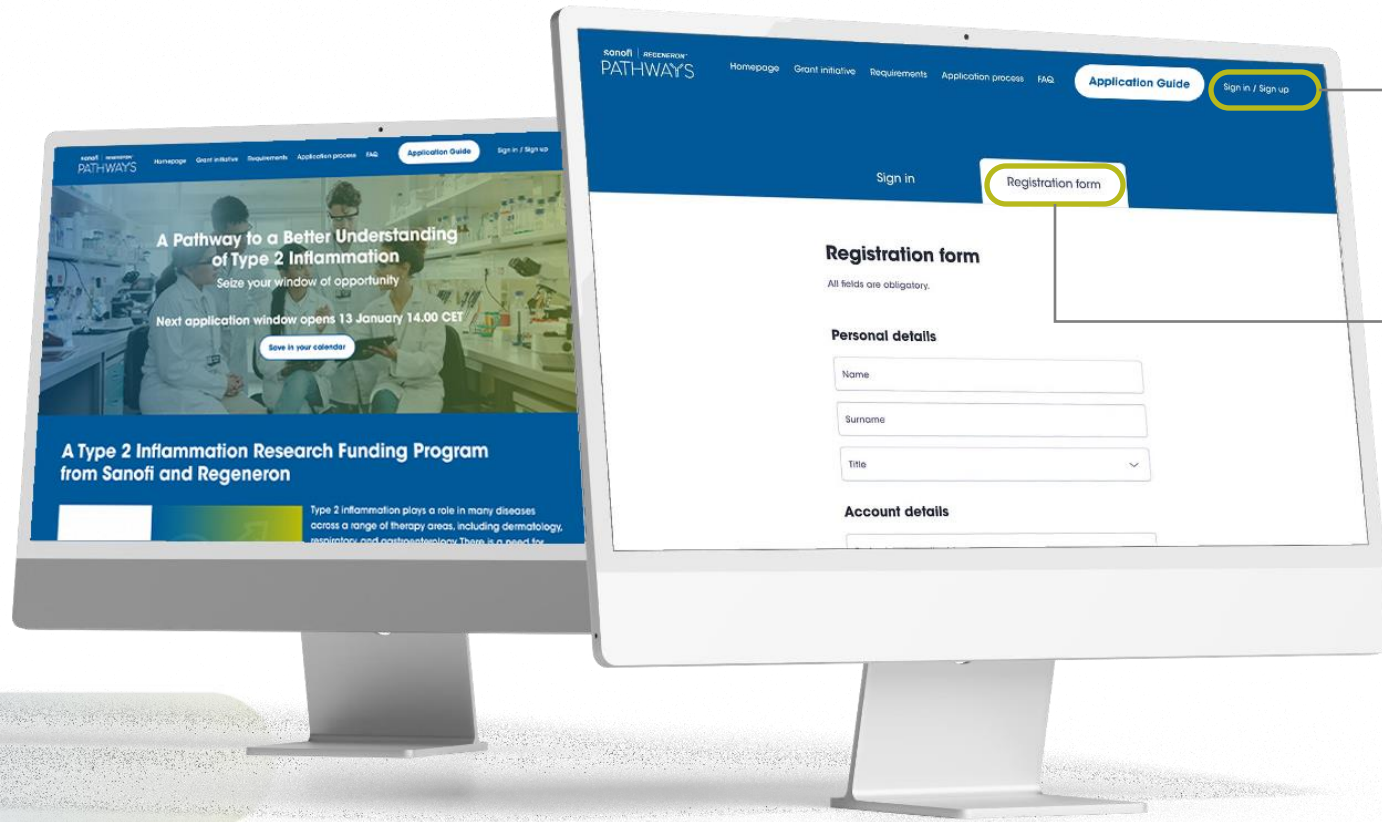
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Registering for PATHWAYS



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To register for PATHWAYS

- Click '**Sign-in/Sign-up**' at the top right of the homepage
- On the next screen, click '**Registration form**'
- Complete the registration form

Please note, all fields in the registration form must be completed and registrants must read and agree to the privacy policy.

Please note, accounts are deleted after 60 months of inactivity.

Registering for PATHWAYS

All fields in the registration form must be completed

- Name, Surname and Title
- Professional email: linked to the registrant's research institution. This will become their username
- Password must contain:
 - At least 8 characters
 - 1 digit
 - 1 lowercase letter
 - 1 uppercase letter
 - 1 non-alphanumeric character
- Name and country of research institution

The screenshot shows the 'Registration form' page on the PATHWAYS website. The form is titled 'Registration form' and includes a note that 'All fields are obligatory.' The form is divided into several sections: 'Personal details' with fields for Name, Surname, and Title; 'Account details' with fields for Professional email address, Confirm email, Password, and Confirm password; 'Research Institution details' with fields for Name of institution and Country/Region; and 'Other' with a dropdown menu for 'Where did you find out about the PATHWAYS Grants Initiative?'. At the bottom, there is a 'Rules and Policies' section with a checkbox for agreement and a 'Register' button. The footer contains links for Contact Us, Legal Notice, Privacy Policy, and Cookie Policy, along with the copyright notice: ©2024 Sanofi and Regeneron Pharmaceuticals Inc. All rights reserved.



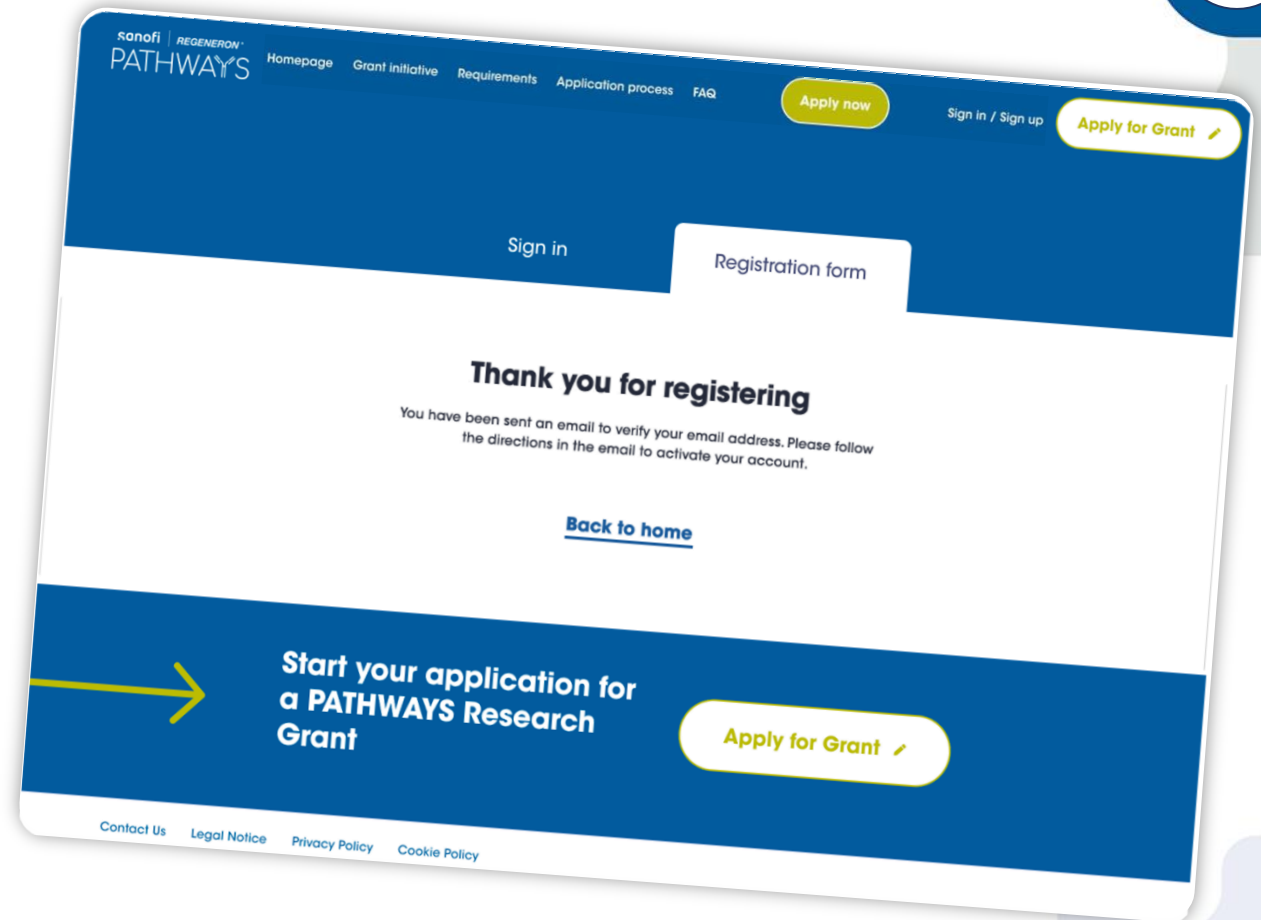
Registering for PATHWAYS

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Registration Review Process

- After submitting the registration form, registrants will receive an email with instructions to verify their email address
 - If an email is not received, please check spam and/or junk folders
- Click the link within the email to verify the email address
- After verification, registrants will receive a second email to confirm their account activation

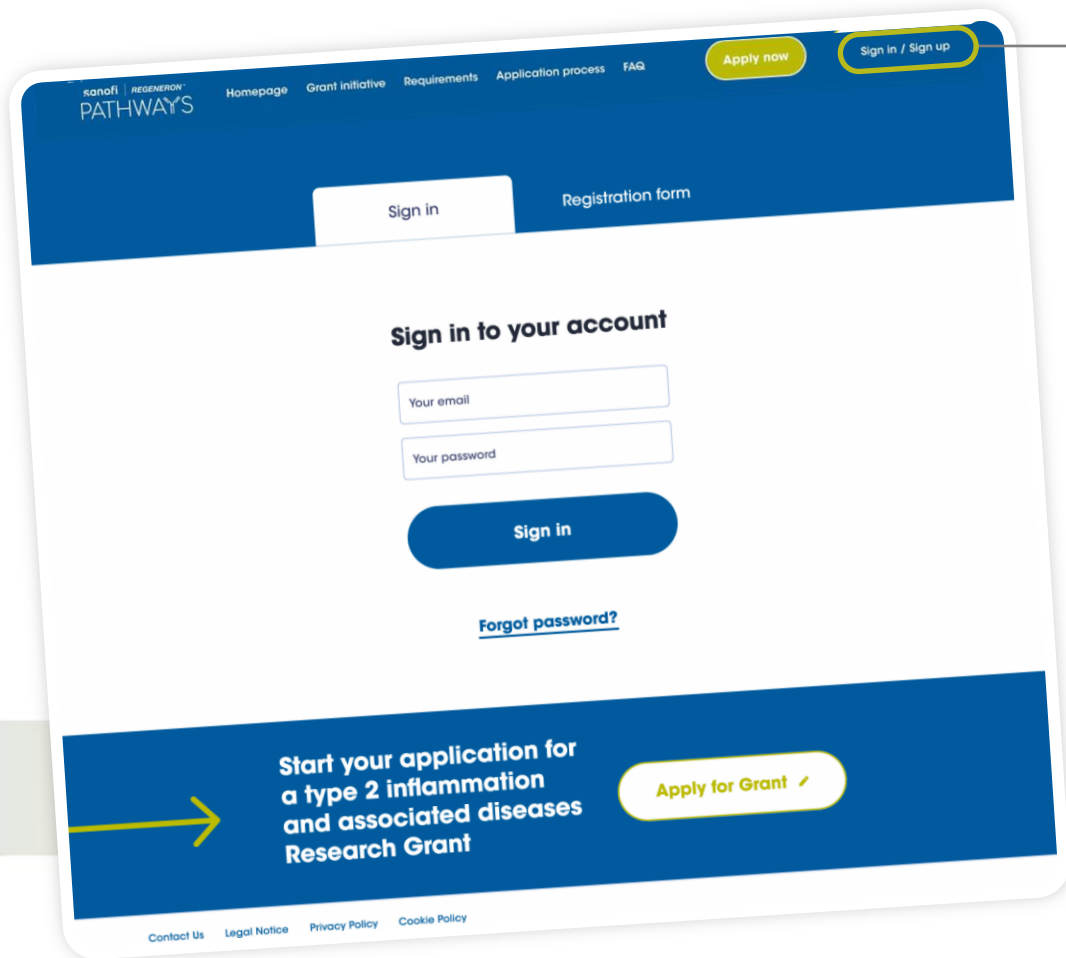
For additional support, please reach out via email to info@globalt2grant.com



Signing-in to PATHWAYS



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To sign-in to the PATHWAYS portal, click **'Sign-in/Sign-up'** at the top right of the homepage

- The username is the email address used to register the account
- The password is the one created during the registration process

If necessary, a new password can be requested using the 'Forgot password' link.

Starting or Accessing an Application



To start a grant application
Click on **Apply now** at the top right of the homepage



To access an application that has already been started
Sign-in to the portal and select
• **My profile** at the top of the homepage,
• then select **My application** from the drop-down menu

Application Overview

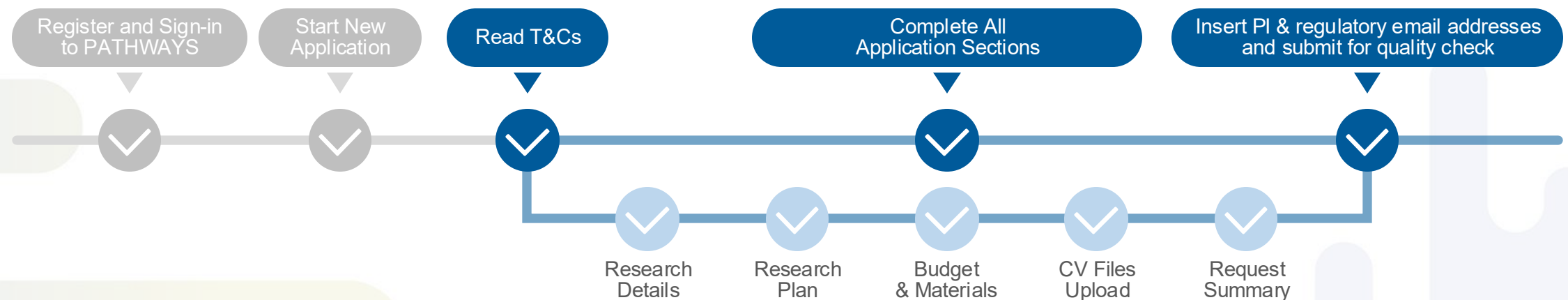


The PATHWAYS Global Innovation Grant Application has 5 sections:

- 1 Terms and Conditions
- 2 Research Details
- 3 Research Plan
- 4 Budget and Materials
- 5 CV Files Upload
- 6 Summary of Application

Please read this guide carefully to ensure all necessary information is included and all requirements are met

- All sections must be completed; incomplete applications will not be accepted
- All application information is automatically saved
- The application can be completed over multiple sessions and may be edited any time prior to submission



Application: Terms & Conditions

Section 1

Legal Terms and Conditions

Please read the Terms and Conditions carefully, they are not negotiable

- The Terms and Conditions and applicable country-specific annex information must be reviewed by the PI and their research institution's legal representative before starting an application. These are *not negotiable* and will form the basis of the contract for any approved application
- To download or print a copy of the Terms and Conditions, click on the button below the contract window
- Please note: Some applications may require an additional, country-specific annex

The screenshot shows the 'Grant Application' page for Sanofi | Regeneron PATHWAYS. The page title is 'Grant Application' and the sub-section is 'Terms and Conditions'. A warning message states: 'Please read the legal terms and conditions of participation carefully. These are not negotiable. By ticking the box below, the applicant acknowledges these terms and conditions and confirms that a legal representative from their research institution has reviewed and understands these will be the basis of the contract. To apply, the Principal Investigator and legal representative will be required to electronically sign these terms and conditions. Where applicable, a country-specific annex will also be provided. Note: Blank fields are not to be completed at this time. They will be populated if the grant application is successful.' Below this is a progress bar with steps: 1. Legal terms and conditions (highlighted), 2. Research Details, 3. Research Plan, 4. Budget and Expenses, 5. CVs and resumes, 6. Letters of support, 7. Additional information. The main content is an 'INVESTIGATOR SPONSORED STUDY AGREEMENT' document. It includes sections for 'DEFINITIONS' and checkboxes for acknowledgment and representation. A 'Download PDF file' link is visible. At the bottom, there is a 'Research Details' button.





Grant Application

Please note that you are filling out/editing the form while the application window is closed. You will only be able to submit this application when the submission window opens. We accept new applications in May and September, from the 13th to the 30th of each month.

1. Legal terms and Conditions 2. Research Details 3. Research Plan 4. Budget and Materials 5. CV files upload 6. Summary of application 7. Submitted application

Download PDF file

Research Project

Title of Research Project

Therapeutic Area of Research Project

Please select area of research

Please select disease area of research

Principal Investigator Personal Details

Name

Surname

Professional email address

Phone number

Sanofi MSL Contact's Email Address

Enter your Sanofi MSL contact's email address. The email must end with @sanofi.com.

Enter email

I do not have a Sanofi MSL contact

Section 2

Research Details

- Enter the full name of the research project
- Select the appropriate therapeutic area and disease area from the drop-down menu
- Enter the contact information for the PI
 - All phone numbers must include the country code
- Enter the contact information for the Requestor if different from the PI
- If known, enter your Sanofi MSL contact's email address
 - If you do not know anyone, please select “None.”

Application: Research Details



The screenshot shows a web form with two main sections. The first section, titled "Research Institution Details", contains five input fields: "Name of institution", "Institution street", "Institution city", "Institution postcode", and "Institution Country/Region" (a dropdown menu). The second section, titled "Research Project Summary", includes a character count "(Maximum of 2,000 characters with spaces)", a list of labels for the summary (Background/rationale, Hypothesis, Overall objectives, Methods, Expected results, Impact), and a "Characters: 88" indicator. At the bottom, there are two buttons: "Previous Terms and Conditions" and "Next Research Plan".

- Enter the name and address of the research institution
- Provide a summary of the research project. Recommended details include background/rationale, hypothesis, overall objectives, methods, expected results and impact
 - **Please note: Scientific review is blinded**
For the research project summary area, please ensure identifying information (such as the applicant's name, lab group, research institution) is not included
 - Avoid 1st person: statements like “our research showed” should be changed to “research showed”
 - Previous research: reference like an external reference e.g., “Author et al, journal - year of publication”

Application: Research Plan – Overview

Section 3

Research Plan

- **Scientific review is blinded.**
Please remove any identifying information from all content in this section, including attachments
- Publications should be cited in text (first author, journal, year)
- Upload an alphabetized bibliography according to the surname of the first author (all authors to be included) in the dedicated field
- Upload supporting files like images, figures, and diagrams in the dedicated area below each field
 - Acceptable formats: jpg, png, and pdf
 - Maximum file size: 10MB
 - **All files, including the file names, must be anonymized**

The image displays two overlapping screenshots of a grant application form. The top screenshot shows the 'Grant Application' overview page with a progress bar and a 'Research Plan' section. The 'Research Plan' section includes a 'Research Background and Rationale' field (10,000 characters), a 'Preliminary Experiments and Hypothesis' field (5,000 characters), and a 'Detailed Research Plan' field (10,000 characters). The bottom screenshot shows the 'Backup Strategies and Contingencies' section, which includes a 'Research Milestones' table with columns for name, start date, and end date, and a 'Risks' section with a table for name, impact, and risk level. Both screenshots show 'Previous' and 'Next' buttons at the bottom.

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Application: Research Plan

The screenshot shows the 'Grant Application' page on the PATHWAYS portal. A progress bar at the top indicates the current step is '3. Research Plan'. Below the progress bar, there is a 'Download PDF file' link. The 'Research Plan' section is highlighted with a yellow border and contains three sub-sections, each with a text area and a file upload field:

- Research Background and Rationale**: (Maximum of 9,000 characters with spaces). You can include one or two images to help illustrate the proposal.
- Preliminary Experiments and Hypothesis**: (Maximum of 6,000 characters with spaces). You can include one or two images.
- Detailed Research Plan**: (Maximum of 18,000 characters with spaces).

• Background and rationale

- Describe the background and rationale for the research. This may include a literature review and gap analysis. Citations should appear in text (first author, journal, year)
- Up to 2 files may be uploaded for support like relevant charts or visualization of disease mechanism

• Preliminary results and hypothesis

- Describe the preliminary results of the research and how they support the hypothesis on which this project is based
- Up to 2 documents may be uploaded for support

• Detailed research plan

- Describe the research plan in as much detail as possible, including detailed methods, key endpoints, statistical analysis and study population recruitment, where applicable
- This may be divided into subsections

Application: Research Plan

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Backup Strategies and Contingencies

Research Milestones

These could include:

- Institutional review board and ethics approval
- Database lock
- First patient recruited
- Database analyses
- Last patient recruited
- Study report

1.
2.
3.

Risks

1.
2.
3.

Relevance, Originality, and International Impact

(Maximum of 1,000 characters with spaces)

References

You can use up to 100 references.
Citations in the text (first author, journal, year).
Bibliography List (alphabetical order according to the surname of the first author).
All author names should be listed.

[Previous](#)
Research Details

[Next](#)
Budget and Materials

• Backup strategies and contingencies

- Indicate the predicted milestones of the research project
- Describe associated risks that could affect achieving the milestones and how they will be managed

• Relevance, originality and international impact

- Applicants should describe why they believe the project is relevant, original research and how it makes an impact on current thinking and practice

• References

- Provide a list of references cited in the research plan, in alphabetical order according to the surname of the first author
- All author names should be listed
- Bibliography may include up to 100 references

Application: Budget and Materials

Section 4

Budget and Materials

- Insert the final requested funding amount in US dollars
- Select the appropriate research type from the drop-down menu
- Download and complete the budget template(s) with as much detail as possible
- Upload the completed budget file to the dropbox field
- Upload the **Formal Overhead Policy** of the applicant's research institution in English
- You may upload up to two additional supporting files, if needed

To help achieve a timely review please ensure

- All content and supporting documents are in **English**
- All content is in only **one currency**
- All costs are **documented with references** and weblinks (including salaries)
 - Study costs are **documented with the catalog** they will be purchased from
- All **drug supply fields are complete** where relevant

To assist with this section, a Budget and Materials checklist is available at the end of this document



Application: CV Files Upload

Section 5

CV Files Upload

In this section the applicant (PI) can upload documents detailing their professional experience. The PATHWAYS panel of external experts will utilize these documents to evaluate applications separately from the anonymized study information.

CV up to 4 pages

- Education, employment history, institutional responsibilities, and main research projects, funding etc.

Major achievements 1 page

- Theses supervision, teaching activities, panels, boards or scientific society membership(s), prizes and awards, etc.

Research experience up to 2 pages

- Previous research experience, number of publications and/or peer-reviewed publications in the last 5 years, invitations to speak, original research articles, reviews, editorials, etc.

The screenshot displays the 'Grant Application' interface for Sanofi Regeneron PATHWAYS. The top navigation bar includes 'Homepage', 'Grant initiative', 'Requirements', 'Application process', and 'FAQ', along with an 'Apply now' button and a 'My profile' link. A progress indicator shows seven steps: 1. Legal terms and Conditions, 2. Research Details, 3. Research Plan, 4. Budget and Materials, 5. CV files upload (current step), 6. Summary of application, and 7. Submitted application. Below the progress bar, there is a 'Download PDF file' link. The main content area is titled 'Upload Documents for Principal Investigator' and lists three categories: 'CV', 'Major Achievements', and 'Research Experience'. Each category includes a list of required information and a 'Drop your files here or browse your computer' upload area. The 'CV' section specifies a maximum of 4 pages and lists items like personal information, education, employment history, institutional responsibilities, and main research projects. The 'Major Achievements' section allows for a maximum of 1 page and lists teaching activities, memberships, and awards. The 'Research Experience' section has no page limit and lists peer-reviewed publications, PubMed citations, original research articles, reviews, book chapters, patents, and board memberships. At the bottom, there are 'Previous' and 'Next' buttons.



Application: Request Summary

Section 6

Summary of Application

- Submission requires a review of the application summary. Please ensure that the correct emails for both the Principal Investigator and the research institution's Legal Representative are entered
- **Please note that the email addresses for the PI and Legal contacts cannot be identical**
 - Please carefully review the application summary
 - **Once submitted, no additional edits can be made** until QC and/or evaluation are complete
 - Once you confirm your application, it will go to QC and, if it passes, a request for e-signatures will be sent automatically to provided addresses via Adobe Sign
 - If the QC identifies any necessary revisions, the application is returned to the applicant in the portal for edits
 - E-signature collection is managed through Adobe Sign and does not require registration
 - Please note that editing the signatory or sending a follow-up email from this page is permitted

The screenshot displays the 'Grant Application' page on the 'sanofi REGENERON PATHWAYS' portal. The page includes a navigation bar with 'Apply now' and 'My profile' buttons. A progress indicator shows seven steps: 1. Legal forms and Conditions, 2. Research Details, 3. Research Plan, 4. Budget and Attachments, 5. CV files upload, 6. Summary of application (highlighted in green), and 7. Submitted application. Below the progress bar, the 'Summary of your application' section contains a warning message: 'You're almost done! Please carefully check the summary, as any errors or missing information could delay the approval process. Once you have reviewed your summary, please insert the correct e-signature email addresses and confirm your application by clicking the button.' The 'Research Details' section includes fields for 'Research Project' (Title of research project: Implications for Severe Uncontrolled Asthma Management: The Clinical Significance of OX40 and OX40L Expression in Type 2 High and T2-Low Asthma) and 'Therapeutic Area of Research Project' (Therapeutic area of research project: Dermatology; Disease area of research project: Atopic Dermatitis). Below this are sections for 'Principal Investigator Personal Details' and 'Requestor Personal Details', each with fields for Name, Surname, Telephone, and Professional email address. The 'Research Institution Details' section is partially visible at the bottom.

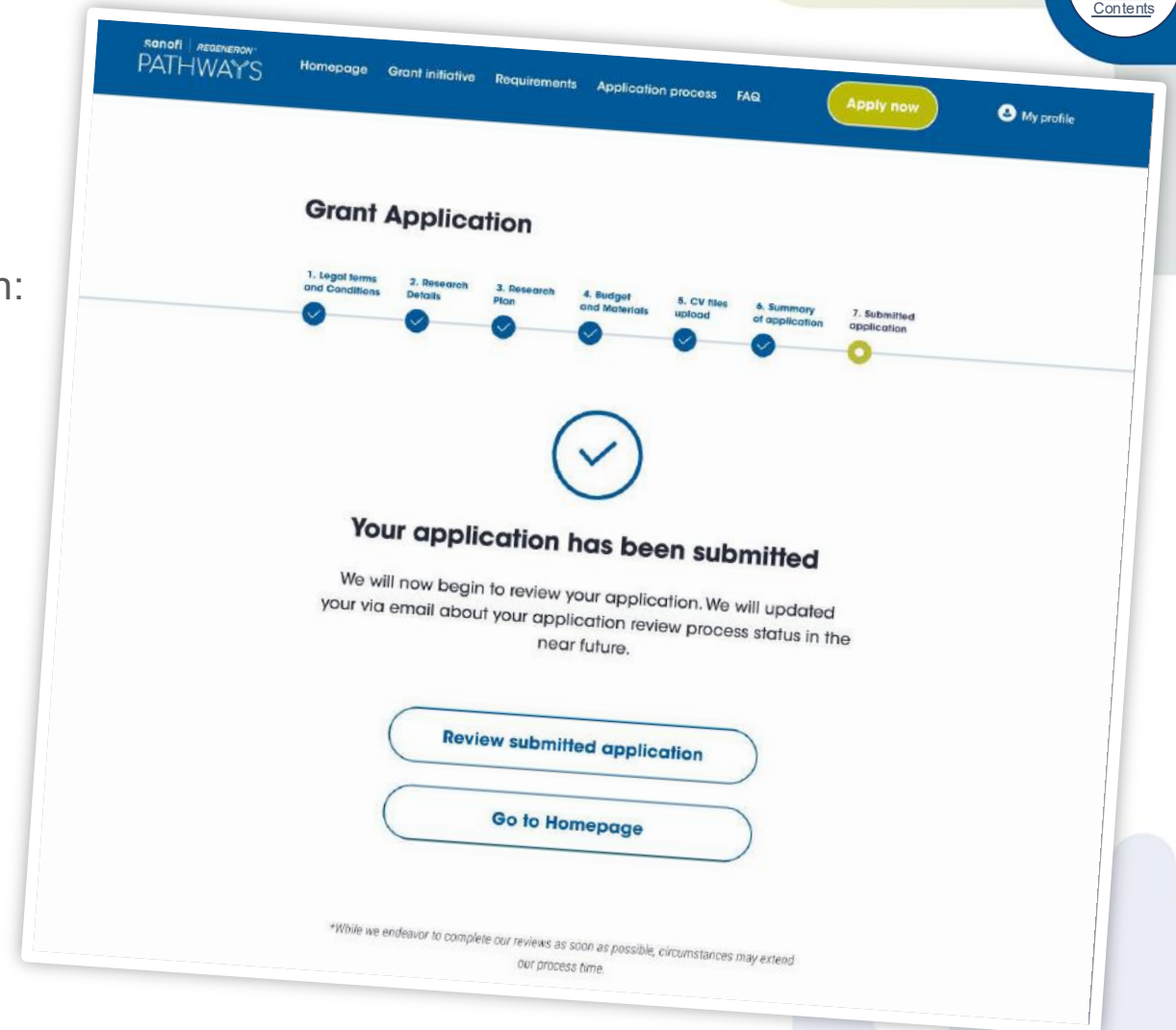
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Application Evaluation

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Review Process

- When both required e-signatures are received, the application will undergo scientific review
- Scientific review is conducted by an external panel of experts. They evaluate applications based on:
 - Strength of the research
 - Innovation and novelty
 - Relevance and impact
 - Potential for success
- The applicant will be notified of the panel's decision via email





Applicants will receive an email notifying them of the decision on their application

- If an application is unsuccessful, applicants are welcome to revise and re-apply if desired
- If an application is successful, some additional steps will be required and the PATHWAYS team will reach out to outline next steps

Thank you

for your interest in the PATHWAYS
Global Innovation Grant

For any further information, please visit the [FAQ](#) page of the PATHWAYS portal or use the [Contact Us](#) form to contact the PATHWAYS team

Appendix

Budget and Materials Checklist



To help achieve a timely review, please ensure the following actions have been taken to ensure the budget section is complete:

- 1 Complete the appropriate budget template(s) with accurate and detailed information
- 2 **Study supply:** Provide as much detail as possible including sources to validate cost per item (e.g., reference documents or weblinks)
- 3 **Purchase orders:** Provide reference documents or weblinks for each purchase order
- 4 **Salary justification:** Provide reference documents or weblinks for salary, duration, and stipend
- 5 **Animals & housing:** If applicable, provide justification documents with quotes or weblinks
- 6 **Overhead policy:** Upload the formal Overhead Policy documentation for the research institution in English

Q: Our study is a pre-clinical study. Why are there contractual requirements for a clinical study?

A. The PATHWAYS Global Innovation Grant program is intended for pre-clinical and clinical studies and utilizes a contract template that can be used for any type of study suitable for the grant program. Sanofi only expects investigators and institutions to comply with the requirements that are applicable to each individual study as set forth in the Investigator Sponsored Agreement. We recommend that the parties specify in the protocol if certain requirements are inapplicable to the study. For example, for a pre-clinical study the parties could include the following clarification in the protocol: ‘the parties agree that informed consent is not required for this study’.

Q: Why does the agreement include IRB or IND requirements that are not applicable for our study?

A. The PATHWAYS Global Innovation Grant program is designed for studies in different jurisdictions worldwide. For this reason, the Investigator Sponsored Agreement includes requirements for the United States as well as European and other countries. Sanofi only expects investigators and institutions to comply with the laws and regulations that apply to their individual study.

FAQs Cont.

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Q: What study data will Sanofi have access to under the agreement?

- A. Only de-identified study data should be provided as part of study milestone reports. If for any reason the parties anticipate the need to share personally identifiable information or protected health information in connection with their study, the parties will need to enter into a separate data protection agreement prior to sharing any such data.

Q: We would like to request changes to the study agreement. Is this possible?

- A. The intent of PATHWAYS is to expedite the support of innovative research on type 2 inflammation and associated diseases. To enable this, we have developed Terms and Conditions common to these types of study agreements. Once a proposal is approved by external expert review, after prior alignment with the Terms and Conditions, study research can be vastly accelerated versus current timelines. For this reason, Sanofi cannot accept changes to its Terms and Conditions at this time. Under the current framework, the PATHWAYS Global Innovation Grant program has already approved and successfully contracted over a dozen innovative studies with prestigious research institutions across the globe.

Q: I have additional questions, who should I contact?

- A. If you have additional questions, please contact us via email at info@globalt2grant.com