



External Quick
Reference Guide

Change Log

Date	Change Description
11 Dec 2023	<ul style="list-style-type: none">• Updated guide formatting and images
05 Oct 2022	<ul style="list-style-type: none">• Added Instructions on 'How to Withdraw an Application'
08 Jul 2022	<ul style="list-style-type: none">• Added instructions on 'How to Report an Issue'
17 Mar 2022	<ul style="list-style-type: none">• Updated support contact details(Refer How to Create an Account)
05 Jan 2022	<ul style="list-style-type: none">• Revised Technical Support Contact Information(Refer How to Create an Account)
13 Dec 2021	<ul style="list-style-type: none">• Revised to include the current screenshots, links, and references.



External Quick Reference Guide

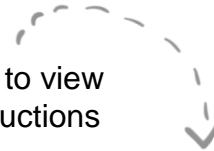
This External Quick Reference Guide is a high-level overview of the SPIRIT system and its functionalities.

To use this document; [click the tiles on table of content slide to navigate to the topic page and description.](#)

Step-by-step instructions on how to submit a Study Application can be found in the **External Submission Guide**. Login to the SPIRIT portal [here](#) and access via the homepage.

Table of Contents

Click on the task to view
the detailed instructions



How to Create a
SPIRIT Account

How to Submit a
Study Application

SPIRIT System
Overview

How to Withdraw a
Study Application

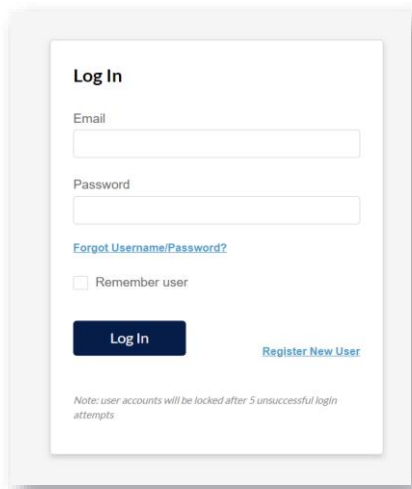
Report an Issue

How to Create an Account

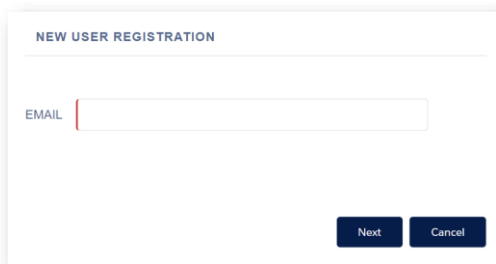
Please follow the notes below to create a SPIRIT account. For more detailed instructions, please review the External Submission Guide.

1 To create your SPIRIT account, navigate to the SPIRIT web portal by selecting:
www.abbviemedicalresearch.com/

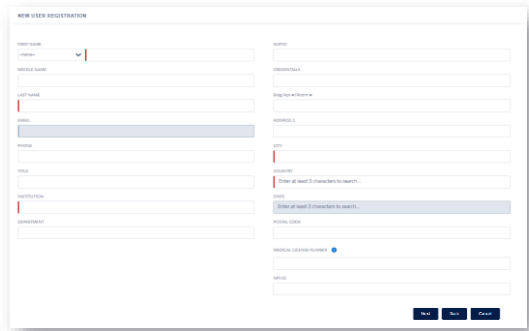
2 When the SPIRIT homepage opens, select **Register New User**



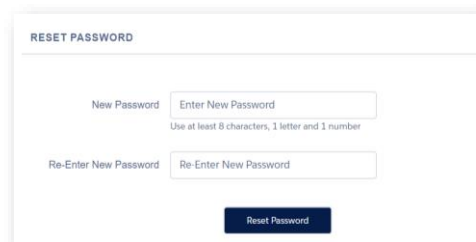
3 Enter your **email** to setup an account and select **Next**.



4 Once the **New User Registration** page opens, complete all required fields and select **Next**. *Please note: all fields marked in red are required to create an account*



5 You will receive an email with your SPIRIT username and link to reset your password. Select the link once you receive it. Fill out the Password fields and select **Reset Password**. Upon successful reset, you will be redirected to the SPIRIT homepage.



For technical support, please use the following contact information.
AbbVie Global service Desk Phone: 1-800-252-4415 (toll-free within the US)

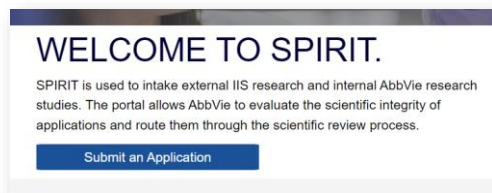
How to Submit a Study Application

Use this quick reference guide to navigate how to submit an AbbVie IIS application. For more detailed instruction, please view the External Submission Guide.

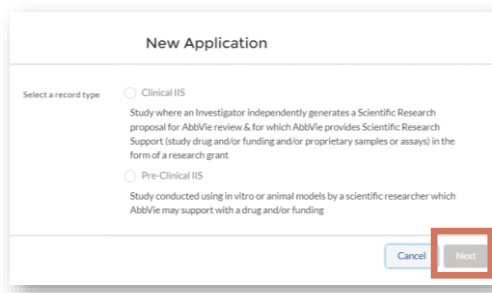
- 1 To create your IIS submission, navigate to the SPIRIT web portal:

www.abbviemedicalresearch.com/

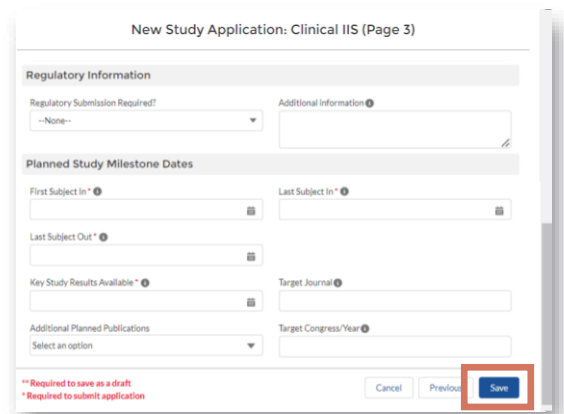
- 2 Once on the SPIRIT web portal, select **Submit a Proposal**.



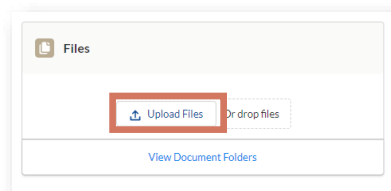
- 3 Select the appropriate **Record Type**. Then, select **Next**.



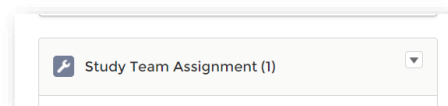
- 4 Once the **New Study Proposal** application opens, complete all mandatory fields. Use your discretion to fill out the non-mandatory fields as they apply to your application through pages 1-3. Select **Save**.



- 5 Next, upload **Study Budget** and **CV** documents to the appropriate folders.



- 6 **Add study team** and the **Principal Investigator (PI)** who will be affiliated with the study. If they are not already in the system, you will need to add them to **Personnel**.



- 7 After all required files are uploaded and personnel are added, navigate back to the Study Application and select **Submit** in the top right corner.

Homepage

The screenshot shows the SPIRIT application portal homepage. At the top left is the 'abbvie | spirit' logo. To the right is a search bar and the user name 'John Smith'. Below the logo is a navigation bar with 'Home', 'My Applications', 'Personnel', and 'Report an Issue'. The main header features a large image of a scientist in a lab coat and gloves, with the text 'Investigator Initiated Studies (IIS) Application Portal'. Below this is a 'WELCOME TO SPIRIT.' section with a brief description of the portal's purpose and a 'Submit an Application' button. The main content area is a grid of nine tiles, each with an icon and a title: 'Learn about the IIS process', 'IIS Strategic Priorities', 'Quick Reference Guide', 'External Submission Guide', 'Sponsor-Investigator Study Budget / Budget Amendment Template - Clinical', 'Frequently asked questions', 'Protocol Guideline', and 'Sponsor-Investigator Study Budget / Budget Amendment Template - Pre Clinical'. Several callout boxes are overlaid on the page, providing detailed explanations for the 'Personnel', 'My Applications', 'External Submission Guide', 'Protocol Guideline', and 'Budget request templates' features.

Personnel allows users to view and edit study team members.

My Applications includes an overview of your applications currently in process.

External Submission Guide provides detailed instructions on how to complete your role.

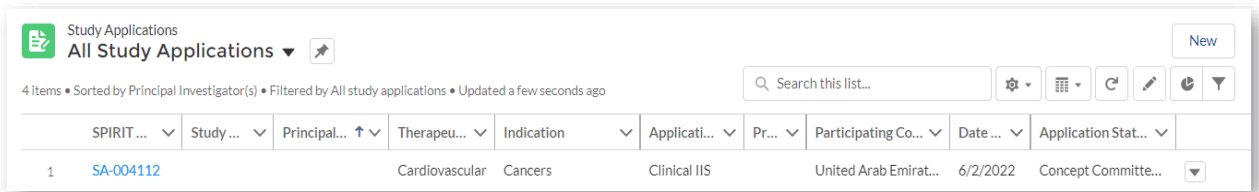
Protocol Guideline shares the AbbVie recommended template.

Detailed instructions on how to submit an application can be found in the **External Submission Guide**.

Budget request templates are categorized by Pre-Clinical and Clinical Study Application types.

My Application

To submit another Study Application, either select **New** in the top right corner of this page or navigate back to **Home** and click the **New Application** button.



The screenshot shows a web interface for 'Study Applications'. At the top left, there is a green document icon and the text 'Study Applications' followed by 'All Study Applications' with a dropdown arrow and a star icon. On the top right, there is a 'New' button. Below this, a status bar indicates '4 Items • Sorted by Principal Investigator(s) • Filtered by All study applications • Updated a few seconds ago'. A search bar contains the text 'Search this list...'. To the right of the search bar are icons for settings, view toggle, copy, edit, refresh, and filter. Below these is a table with columns: SPIRIT..., Study..., Principal... (with an up arrow), Therapeu..., Indication, Applicati..., Pr..., Participating Co..., Date..., and Application Stat... The first row of the table contains the following data: 1, SA-004112, Cardiovascular, Cancers, Clinical IIS, United Arab Emirat..., 6/2/2022, and Concept Committe... with a dropdown arrow.

	SPIRIT...	Study...	Principal... ↑	Therapeu...	Indication	Applicati...	Pr...	Participating Co...	Date ...	Application Stat...
1	SA-004112			Cardiovascular	Cancers	Clinical IIS		United Arab Emirat...	6/2/2022	Concept Committe...

View the details of a **Study Applications** by selecting the application number.

Personnel

Select **New** to add personnel to your Study Application.

Personnel
Recently Viewed

2 Items • Updated a few seconds ago

	Name	Email	Main Phone	City
1	John Smith	john.smith@company.com		Chicago
2	Jane Anderson	jane.anderson@company.com		Chicago

Use the filter button to categorize data on both the **Personnel** and **Study Application** lists.

Select the dropdown menu to choose additional **List Views**.

Personnel
Recently Viewed Personnel

0 Items

LIST VIEWS

- All Active Personnel
- All Inactive Personnel
- Clinical Personnel with eMail and phone
- CIIP Duplicate
- CIIP New Record
- CIIP Pending and Active Mix
- CIIP Pending Checked
- Recently Viewed (Pinned list)
- ✓ Recently Viewed Personnel

No items to display.

My Profile

Select **Edit** to make changes to your personal profile.

abbvie | spirit

Home My Applications Personnel Report an Issue

John Smith
Customer

Name: John Smith
Title: Manager
Company Name: _____
Phone: _____
Mobile: _____
Email: john.smith@company.com
Address: _____
About Me: _____

Post Poll

Share an update... Share

Edit User

* Name	Manager
First Name	
Middle Name	
* Last Name	
Suffix	
Title	Company Name
Email	Phone
Address	Mobile
Street	
City	State/Province
Zip/Postal Code	Country
About Me	

Cancel Save

Study Application

The screenshot displays the AbbVie Spirit Study Application interface. At the top, the navigation bar includes 'Home', 'My Applications', and 'Personnel'. The main header shows the application ID 'SA-003284' and 'Edit' and 'Submit' buttons. Below this, a progress bar with chevrons indicates the current stage: 'Draft' (highlighted), followed by 'Concept Submission', 'Concept Committee...', 'Concept Review Me...', 'Protocol Submission', 'Protocol Committee...', 'Protocol Review Me...', 'Study Endorsed', and 'Closed'. A callout box points to these chevrons, stating: 'The chevrons show where the Study Application is in the review process.'

The 'Application Status Description: Draft' section contains instructions: 'Concept application has not been submitted. To submit to...' followed by a list of tasks: 'Complete all required fields', 'Upload the CV of the sponsor-investigator', and 'Upload the study budget, if requesting funding. We recommend using AbbVie's Sponsor-Investigator Study Budget template. You can download it by navigating back to...'. A callout box explains: 'Find application status details and next steps highlighted here.'

The 'Files' section features an 'Upload Files' button and a 'Drop files' area, with a 'View Document Folders' link below. A callout box states: 'Navigate to the Files section to upload required files.'

The 'Concept Criteria' section is expanded to show 'General Information' and 'Study Overview'. The 'General Information' section includes fields for 'Study Title' (TEST - IIS), 'Principal Investigator(s)' (John Smith), 'Submitter', 'SPiRiT Number' (SA-003284), and 'Study Acronym'. The 'Study Overview' section includes 'Therapeutic Area' (Hepatology), 'Study Category' (Non-Product-Focused), 'Phase' (Ph 1), 'Type of Study' (Non-Interventional), 'Abbvie Product(s) Studied' (ABT-KALCOM), 'Indication' (Cancer - Gastric (Stomach)), and 'Participating Country(s)' (United States of America). A callout box notes: 'All details completed in the Study Application can be found in the Concept Criteria section.'

The 'Study Team Assignment' section shows a dropdown menu with '(0)' members. A callout box instructs: 'Assign study team members by clicking the drop-down arrow for Study Team Assignment.'

The 'Study Application History' section shows a list with one entry: 'Date: 8/5/2020 9:46 AM', 'Field: Created', 'User:', 'Origin:', and 'New...'. A 'View All' link is at the bottom right. A callout box says: 'Follow the Study Application progress by viewing the Study Application History.'

Submit an Application

Clicking the **'Submit an Application'** button initiates the application process— starting with choosing the record type.

New Application

Select a record type

Clinical IIS
Study where an Investigator independently generates a Scientific Research proposal for AbbVie review & for which AbbVie provides Scientific Research Support (study drug and/or funding and/or proprietary samples or assays) in the form of a research grant

Pre-Clinical IIS
Study conducted using in vitro or animal models by a scientific researcher which AbbVie may support with a drug and/or funding

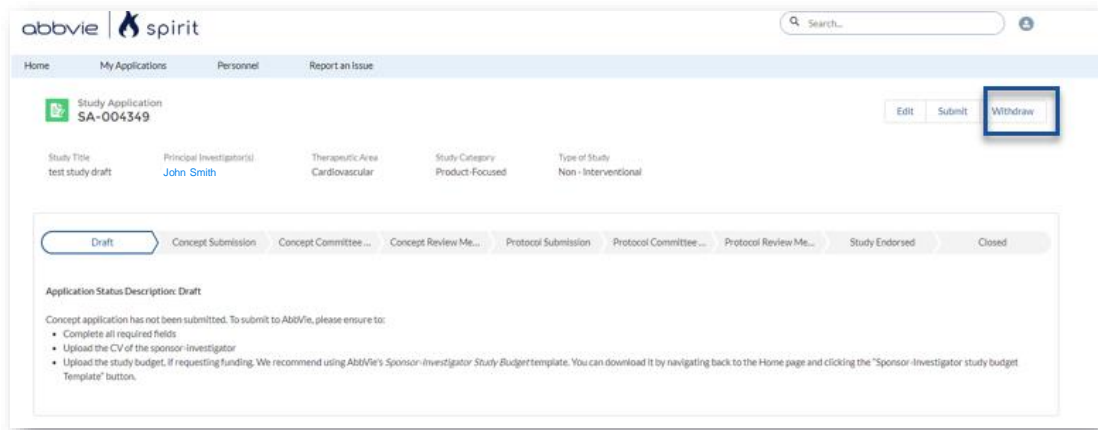
[Cancel](#) [Next](#)

For detailed instruction on how to submit a **New Study Proposal**, view the **External Submission Guide** on the **Home Page**.

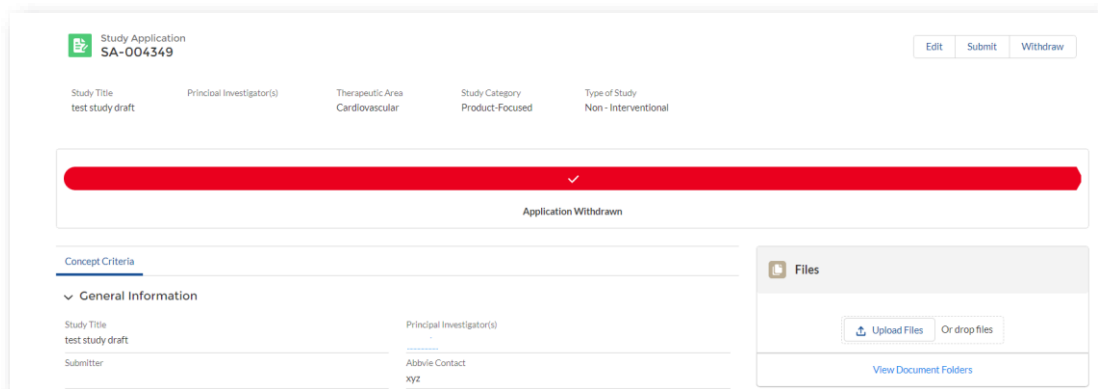
How to Withdraw an Application

For more detailed instructions, please review the **External Submission Guide**.

- 1 In the event a Study Application draft needs to be withdrawn, click the 'Withdraw' button on the top right corner of Study Application detail screen.

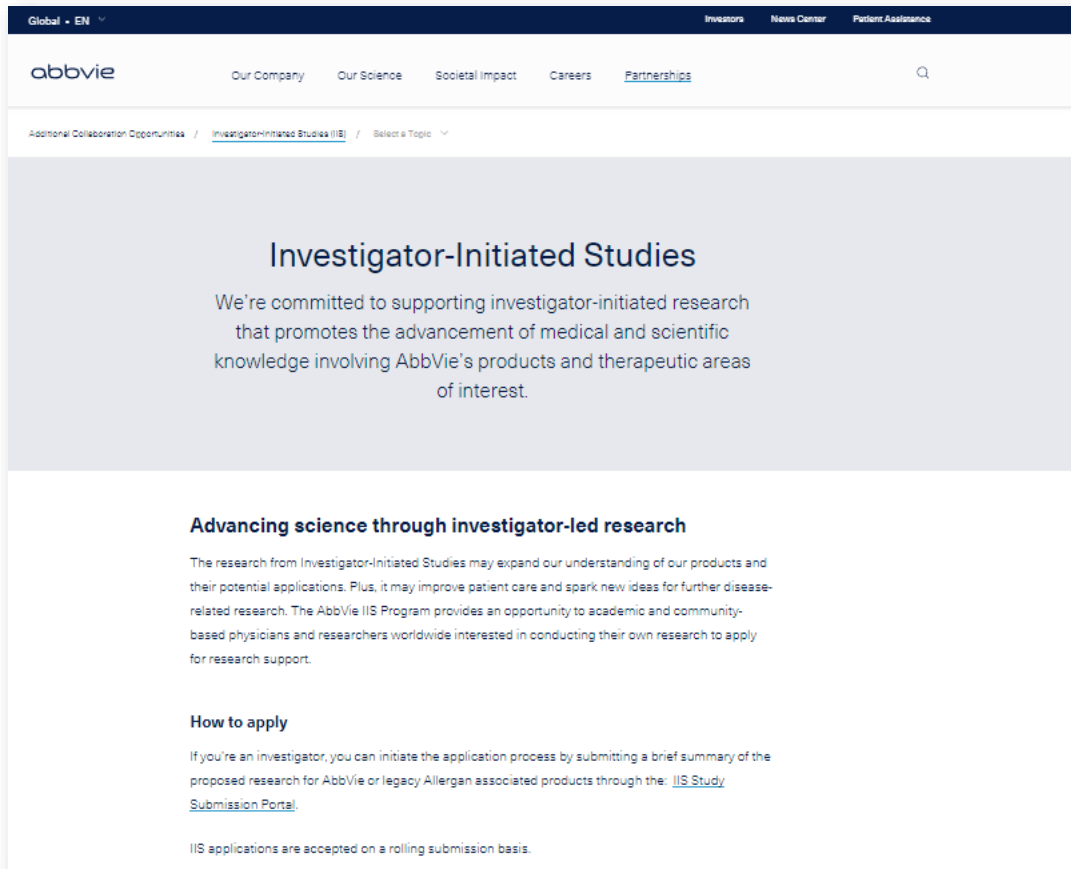


- 2 The status of the Study Application will update to 'Application Withdrawn'. No further action can be performed on this Study Application.



Learn About the IIS Process

Selecting '**Learn about the IIS process**' opens the AbbVie Investigator-Initiated Studies webpage where information about the key details and process of IIS studies is available.



The screenshot shows the AbbVie website's Investigator-Initiated Studies (IIS) page. The top navigation bar includes 'Global - EN', 'Investors', 'News Center', and 'Patient Assistance'. The main navigation menu features 'Our Company', 'Our Science', 'Societal Impact', 'Careers', and 'Partnerships'. A search icon is located on the right. Below the navigation, there are breadcrumb links: 'Additional Collaboration Opportunities / Investigator-Initiated Studies (IIS) / Select a Topic'. The main heading is 'Investigator-Initiated Studies', followed by a paragraph: 'We're committed to supporting investigator-initiated research that promotes the advancement of medical and scientific knowledge involving AbbVie's products and therapeutic areas of interest.' Below this, there is a section titled 'Advancing science through investigator-led research' with a paragraph explaining the program's goals. Another section titled 'How to apply' provides instructions on submitting research proposals through the 'IIS Study Submission Portal'. At the bottom, it states 'IIS applications are accepted on a rolling submission basis.'

IIS Strategic Priorities

Selecting 'IIS Strategic Priorities' downloads the current **AbbVie IIS Strategic Priorities** document with details on the IIS priorities.

2022 IIS Strategic Priorities	
<u>Contents</u>	
Body Contouring: Coolsculpting, CoolTone	2
Facial Aesthetics: Botox/Vistabel, Fillers (Juvederm, Vycross, Hylacross, HArmonyCa), Kybella/Belkyra	3
Plastics and Regenerative Medicine: Breast Implants, ADMs, Fat Grafting	4
CNS – Migraine: OnabotulinumtoxinA/BoNTA from AbbVie (Botox), Ubrogapant (Ubrelyvy), Atogepant (Qulipta)	5
CNS – Neurotoxin Therapeutics – Botox (OnabotulinumtoxinA): Toxin Science, Spasticity and Movement Disorder, Urology	7
CNS – Psychiatry– Vraylar (Cariprazine): Bipolar Disorder I, Schizophrenia	9
Eye Care: Durysta, XEN 45/63, Ozurdex, AGN-190584 Pilocarpine 1.25% ophthalmic solution (Vuity) ..	11
Immunology – Gastroenterology: Risankizumab & Upadacitinib	12
Immunology – Dermatology: Adalimumab (HUMIRA), Risankizumab (SKYRIZI), Upadacitinib (RINVOQ)	13
Immunology – Rheumatology: Upadacitinib (RINVOQ)	15
Oncology: Venetoclax (ABT-199).....	16
Oncology: Navitoclax (ABT-263).....	17
Oncology: Epcoritamab (NHL)	18
Oncology: Telisotuzumab vedotin (Teliso-V), Non-small cell lung cancer (NSCLC)	19
Specialty – Hepatology – Maviret/Mavyret : Hepatitis C Virus (HCV)	20
Specialty – COVID-19	21

External Submission Guide

Selecting '**External Submission Guide**' downloads the **External Submitter Training** document with step-by-step instructions on how to submit a study.



Supporting Documents

Selecting **'Supporting Documents'** downloads the **AbbVie's Sponsor-Investigator Study Budget Template**. We recommend using this template when completing your study budget.

The image shows a screenshot of a Microsoft Excel spreadsheet titled "Sponsor-Investigator Study Budget Request". The spreadsheet is organized into several sections for data entry:

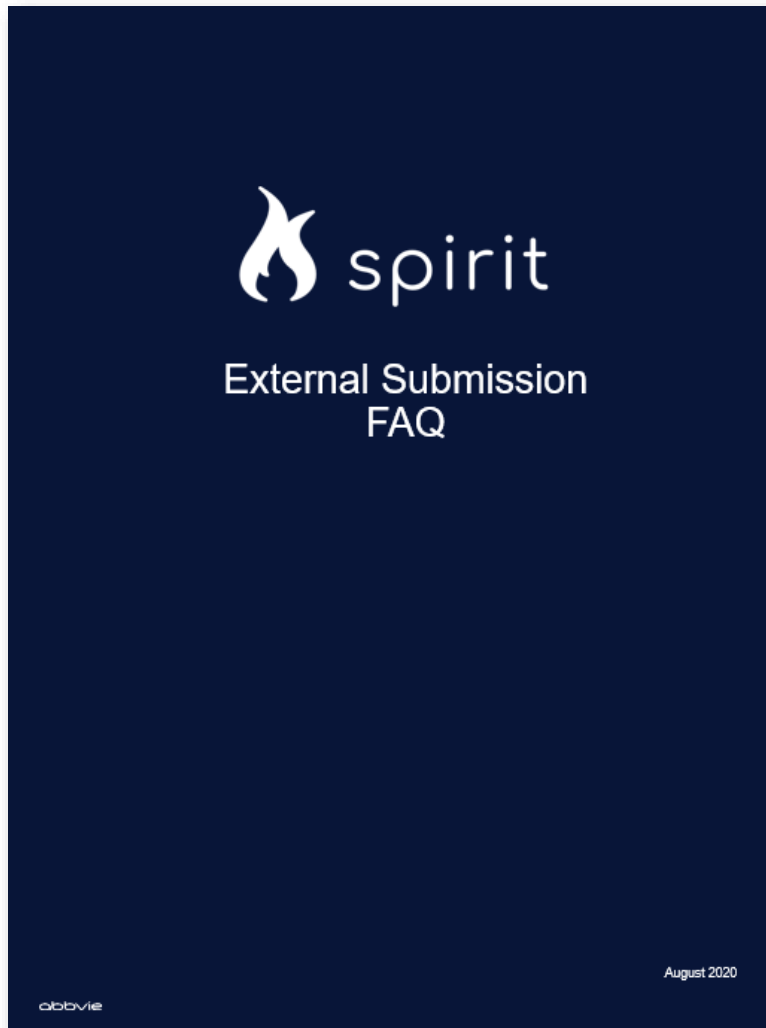
- Section I: Study Procedures** (Rows 11-23): A table with columns for Study Procedures, Description, CPT Code, Unit Cost, Number of Units, and Total (USD). It includes a Subtotal row.
- Section II: Administrative Services (if applicable)** (Rows 25-29): A table with columns for Name of Administrative Services, Unit Description, CPT Code, Unit Cost, Number of Units, and Total (USD). It includes a Subtotal row.
- Section III: Technical Services (if applicable)** (Rows 31-35): A table with columns for Name of Technical Services, Unit Description, CPT Code, Unit Cost, Number of Units, and Total (USD). It includes a Subtotal row.
- Section IV: Other Services/Data Analysis/Publication Costs (if applicable)** (Rows 36-37): A table with columns for Other Services/Data Analysis/Publication, Unit Description, CPT Code, Rate per, Number of, and Total (USD).

The spreadsheet also includes a header section (Rows 2-10) for Institution, Institution's Address, Name, Phone Number and Email Address of Contact(s) in Institution's Grants and Contracts, Sponsor-Investigator/ PI, Protocol Title, Total Number of Subjects, and Study Duration. The interface shows the Excel ribbon with tabs for "Instructions" and "Budget Proposal".

Budget request templates are categorized by Pre-Clinical and Clinical Study Application types.

Frequently Asked Questions

Selecting '**Frequently Asked Questions**' downloads the **External Submission FAQ** document.

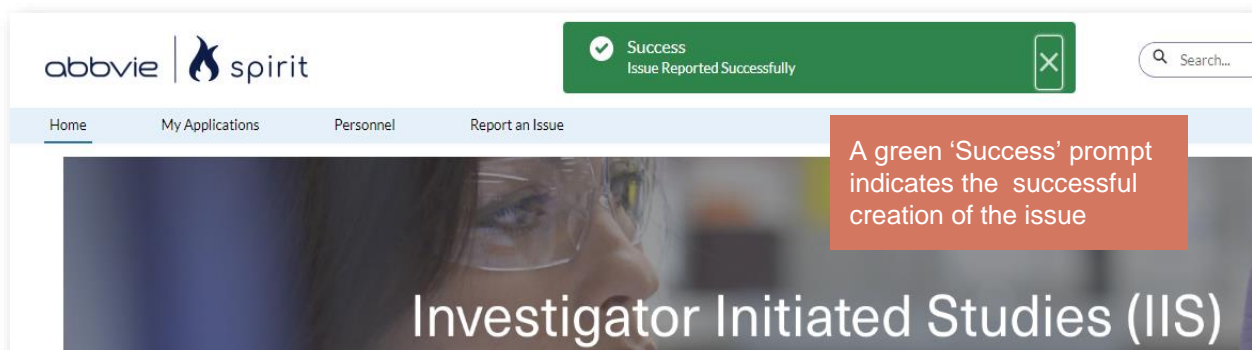
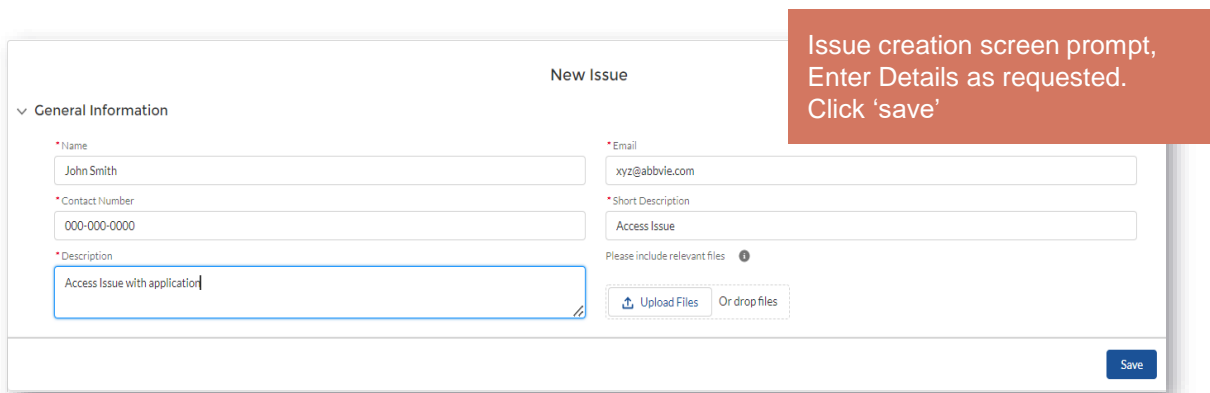
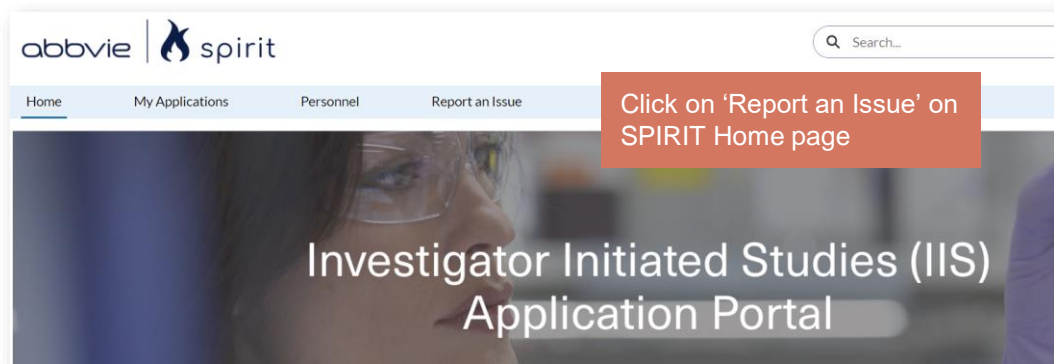


Protocol Guideline

Selecting 'Protocol Guideline' downloads the AbbVie recommended template.

Protocol Content Guidance	
Section	Please note this is a guidance document to ensure there is adequate scientific rigor for review.
1.0	General Information
1.1	Study Title & Study Phase: Protocol title, study phase,
1.1B	Protocol Version Number & Date protocol identifying version number (if any), and date . Any amendments should also bear the amendment version number(s) and date(s).
1.2	Institution Name:
1.3	Investigator Contact Information: Name and title of the investigator responsible for conducting the research, and the full address and telephone number(s) of the research site(s). Please include the name (if different from investigator) and e-mail address of a primary contact for the study.
2.0	Background information
2.1	Rationale & Background Information The rationale specifies the reasons for conducting the research. Include a well-documented statement of the need/problem that is the basis of the project, the cause of this problem and its possible solutions. Answer the questions: why the research needs to be done and what will be its relevance and impact. Include selected literature references critical to the study design, medication or treatment or intervention selection, if appropriate dosage selection, or rationale for the study with citations, as appropriate.
3.0	Core Protocol
3.1	Study Objectives and Purpose State primary objective of the study in a simple and specific manner, include secondary, tertiary and/or exploratory objective(s) as appropriate.
3.2	Study Design <p>This section is a concise overview of the study design, including the following:</p> <ul style="list-style-type: none"> Type of experimental design (prospective or retrospective, observational or interventional, cross sectional or longitudinal, randomized block, crossover, etc.); Description of study controls, if applicable (treatments or interventions other than the test product and/or placebo); Description of the type (e.g., open-label, single or double-blind, study phase); A specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the study; and, The number of the study centers (single or multi-center). <p>The number of study centers and country (single or multi-center/country) and the total number of subjects included in the study and how they will be assigned to treatment groups and countries must be indicated. When appropriate, state if and how the subjects will be stratified.</p>
3.3	Inclusion Criteria
3.4	Exclusion Criteria

How to Report an Issue



After an issue is submitted, a support Team member will reach out between 24-48 hours via email on the email address provided during issue creation.