

# ViiV ISS Portal

# ViiV ISS Portal

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## Training Guide

*January 2017*

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**This button will return you to this index page from any location.**



# Training Goals

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1. Introduce the ViiV ISS Portal and general use of its functions.
2. Explain the process for using the ViiV ISS portal for a study proposal from Concept through Study Execution and Publications.
3. Understand the system to successfully submit and share information with ViiV during ISS process.



# Overview of the ViiV ISS Portal

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- The portal is a publicly accessible web site which will allow investigators to understand the ViiV ISS program, create study proposals and interact with ViiV during the study proposal and execution process.
- Several of the portal functions require a user to log in to the system. Login credentials will be provided to approved investigators.



# Features of the ViiV ISS Portal

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- Available to all approved investigators at [iss.viivhealthcare.com](https://iss.viivhealthcare.com)
- The ViiV ISS Portal is designed as a tool for the investigator to:
  - Create and submit a study proposal to ViiV
  - Complete electronic forms which are provided by the system to collect required proposal information.
  - Share files with ViiV related to study proposal, execution, and publication.
  - Report and update on study progress
  - Be notified via email at key points in the progression of the ISS proposal submission, review, and execution processes.



# High Level Process

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- Investigator is granted access to the system
- Investigator submits a short form summarizing the Concept for the study proposal for review and acceptance.
- Following acceptance of the concept a full study proposal is submitted along with supporting documentation for review and approval.
- Following approval the system will support collaboration for collecting final protocol information, performing the safety review, and developing the contract.
- Following execution of the contract the system will support study tracking and status updates during execution including drug supply and payments.
- The system will support interactions with the publications review team for interim study presentations, final manuscript, and any publications following fulfillment of contractual obligations.



# System Use Guidance

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- The following series of slides will walk through the primary sections of the application and outline the use of the system.
- There is information in the User Guidance section of the system with general Q&A aids to assist the investigator.



# Accessing the System

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- The ViiV ISS System can be accessed by external investigators at the following URL.
  - [iss.viivhealthcare.com](https://iss.viivhealthcare.com)
- Each investigator will be asked to provide some basic information and agree to have an account created before ViiV Healthcare will create the investigator account.
- Once the investigator has received notification that the account has been created then can follow the process described on the following slides to go through the initial login and set a password, and then to complete their profile information.



# First Login (1 of 6)



Google Accounts | Inbox (7) - viivp3vision@ | ViiV Healthcare External |

qa-test2-portal.corp.idea-point.com/Default.aspx

Apps | GSK Home | Google | CognizantEmail | OneCognizant | GRC Central | CognizantPeoplesoft | ViiV Heltahcare Extern | QA ViiV ISS External F | QA IP | ViiV DM Site

**ViiV Healthcare**

Already have an account?

My Submissions | Create a Submission | Create / Edit Profile | User Guidance

## ViiV Healthcare Investigator-Sponsored Studies Programme

ViiV Healthcare is an independent, global specialist HIV company established in 2009 with commitment to deliver innovative new options for the care and treatment of people living with HIV/AIDS. As part of the commitment, we recognize the valuable role that our support of investigator-sponsored studies (ISS) plays in fulfilling this mission. An investigator-sponsored study is a research effort where the sponsor of the work is the investigator, healthcare institution, or some form of medical network external to ViiV and is seeking our support to conduct the work. This support can be in the form of product, funding, or a combination of both.

We only support ISS that have a legitimate scientific purpose. The decision to support a study proposal is based on the importance of the research objectives to medical science or patient

All Safety Reporting must be conducted as per your study agreement. If you need to report a suspected side effect for a ViiV Healthcare medicine that is not part of your study, please click the following.

### Report a side effect

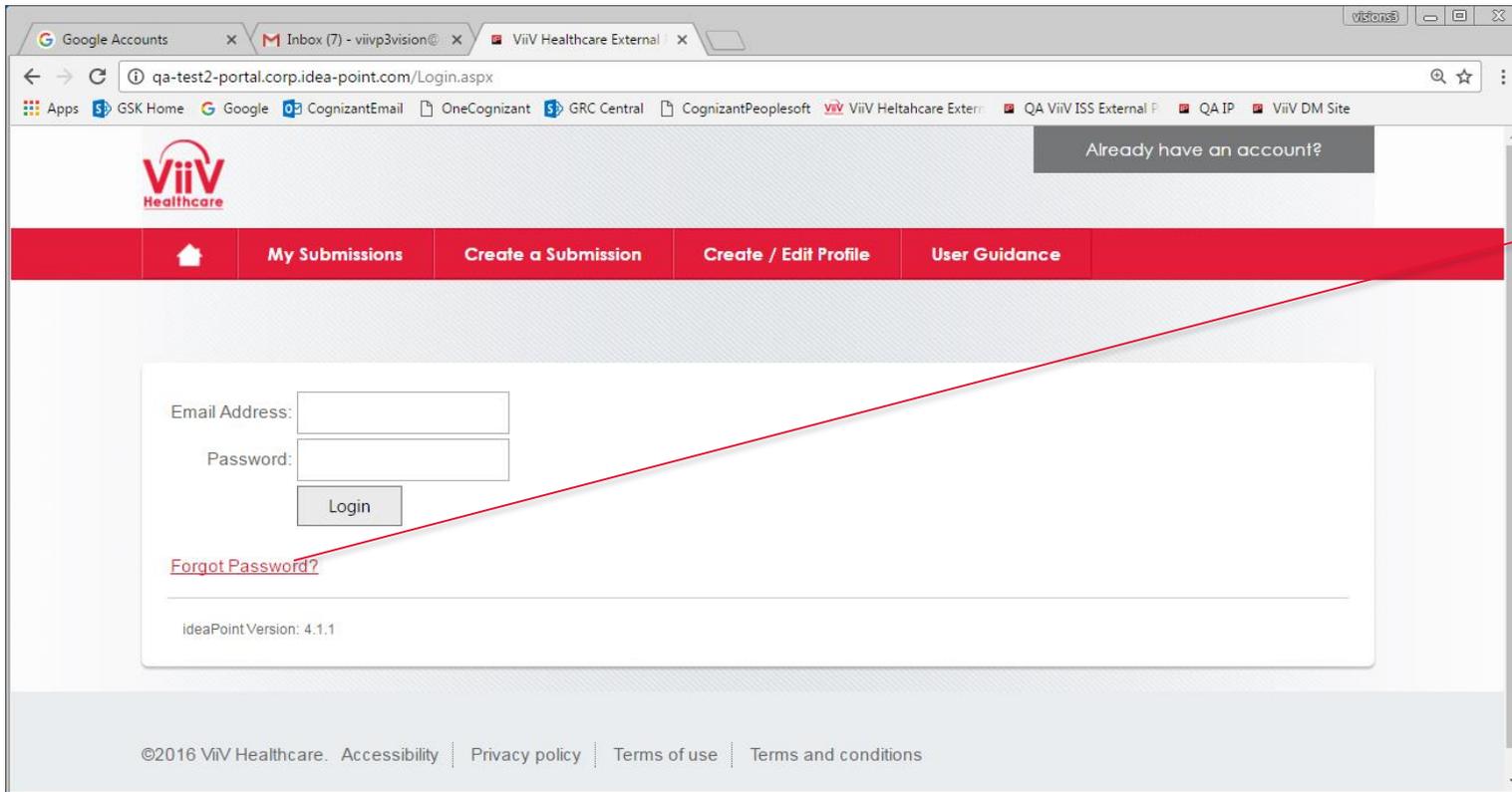
To report a suspected side effect , please use the online reporting form below. This facility is provided under our service

Click here (on the gray box) if you have received notification your account was created

Access the system at [iss.viivhealthcare.com](https://iss.viivhealthcare.com)



# First Login (2 of 6)



Google Accounts | Inbox (7) - viivp3vision@ | ViiV Healthcare External |

qa-test2-portal.corp.idea-point.com/Login.aspx

Apps | GSK Home | Google | CognizantEmail | OneCognizant | GRC Central | CognizantPeoplesoft | **ViiV Healthcare External** | QA ViiV ISS External P | QA IP | ViiV DM Site

**ViiV Healthcare** | Already have an account?

Home | My Submissions | Create a Submission | Create / Edit Profile | User Guidance

Email Address:

Password:

Login

[Forgot Password?](#)

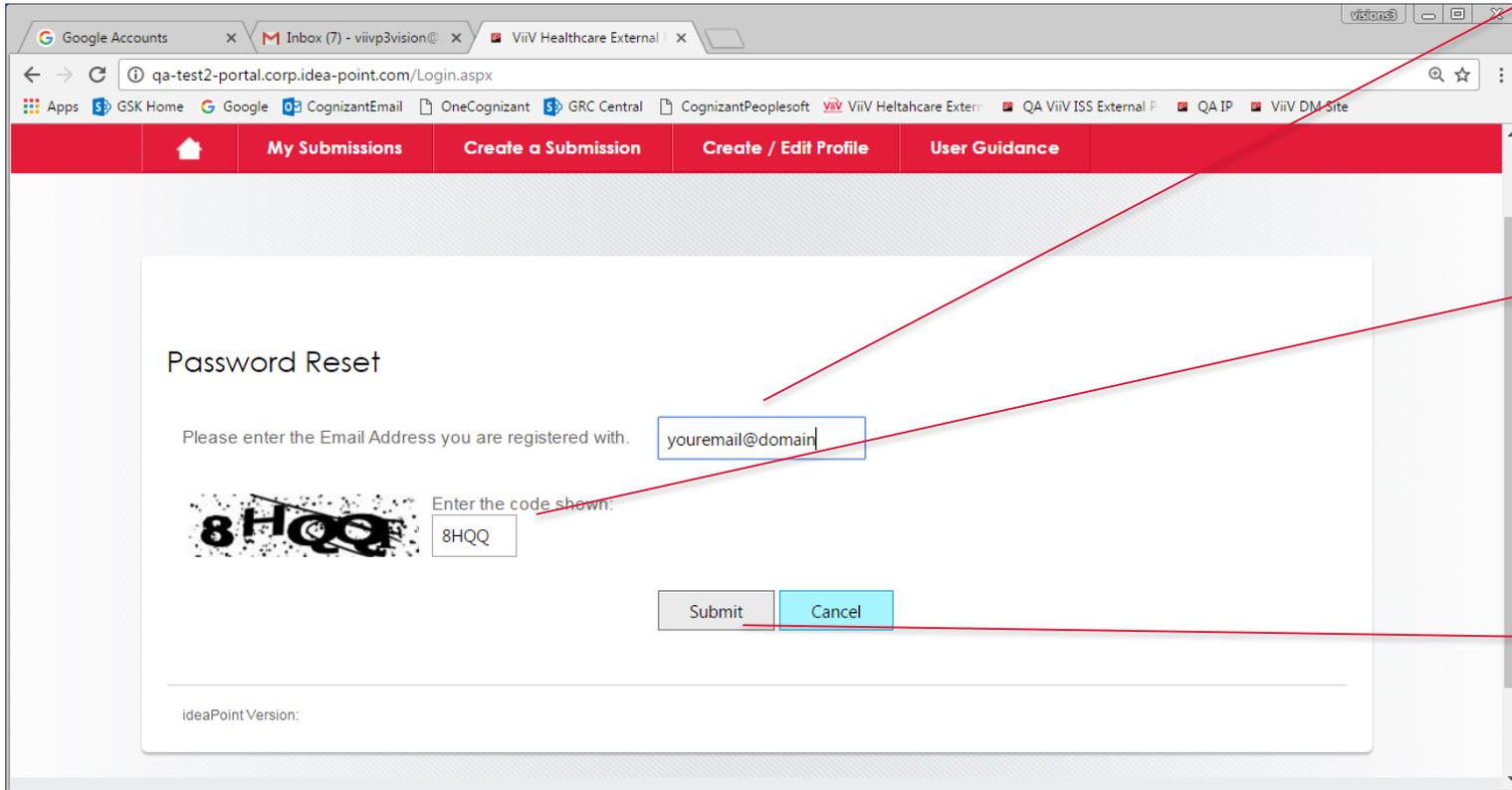
ideaPoint Version: 4.1.1

©2016 ViiV Healthcare. Accessibility | Privacy policy | Terms of use | Terms and conditions

Click on the “Forgot Password” link (in Red) to set your initial password.



# First Login (3 of 6)



Enter your email address for the account.

Enter the characters from the captcha code in this box

Click the Submit box



# First Login (4 of 6)

Password Recovery Code Inbox x  

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 **no-reply@idea-point.com** 10:52 AM (1 minute ago) ☆  

 to me ▾

Dear Viivp3,

To continue the process of resetting your password, you will need this validation code.  
Code:Pg3gzDr4

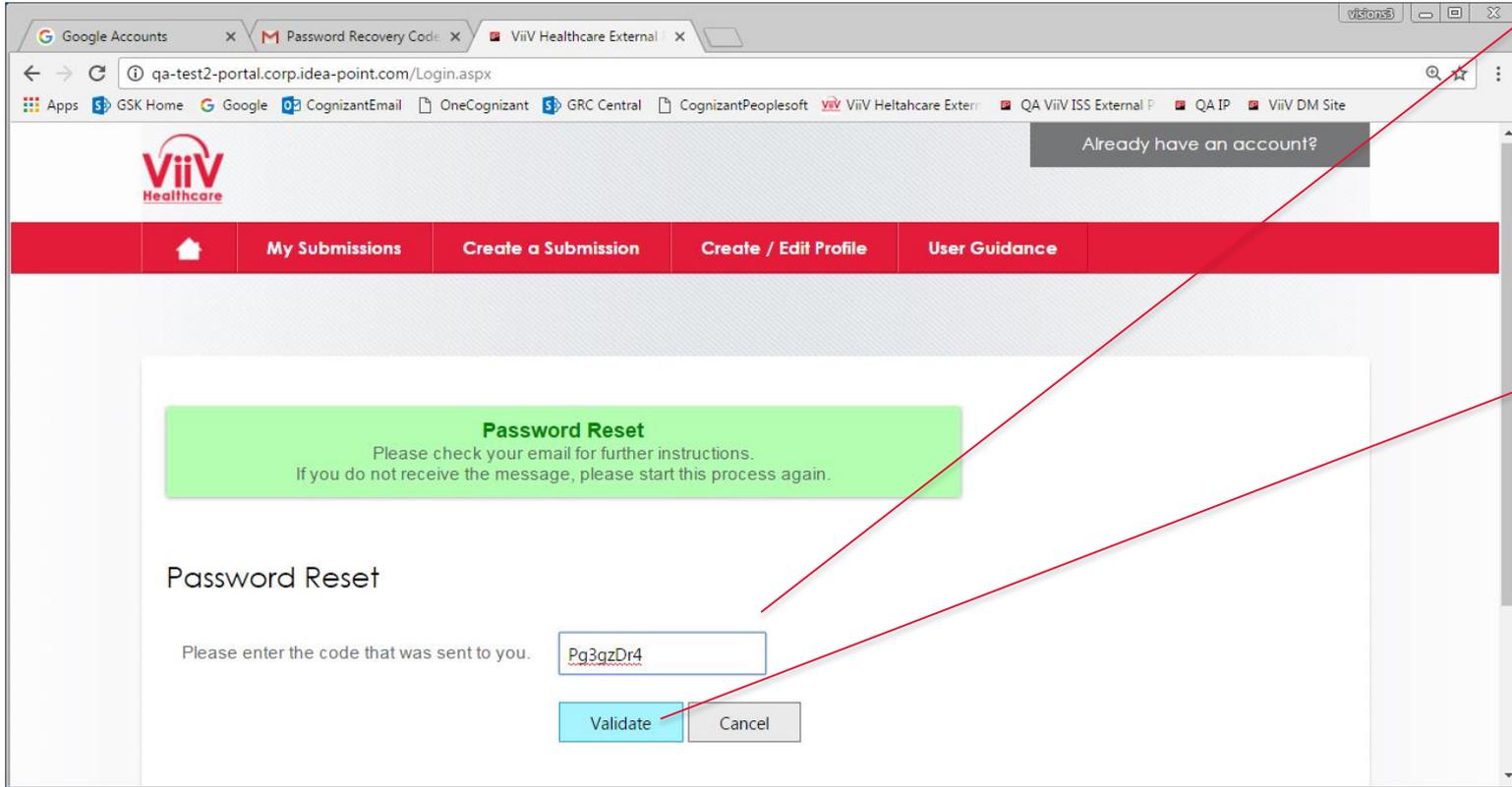
This operation has been initiated from [192.168.200.11/Mozilla/5.0](http://192.168.200.11/Mozilla/5.0) (Windows NT 6.1; WOW64) AppleWebKit/537.36 (KHTML, like Gecko) Chrome/53.0.2785.116 Safari/537.36 (<http://qa-test2-portal.corp.idea-point.com/Login.aspx>). If you did not perform this action, please take the necessary precautions to keep your account secure.

Note- Please do not reply to this email as it is only used for outbound notices and the email box is not monitored.

Check your email account inbox. You will receive an email at the email account indicated with a code you will need to supply.



# First Login (5 of 6)



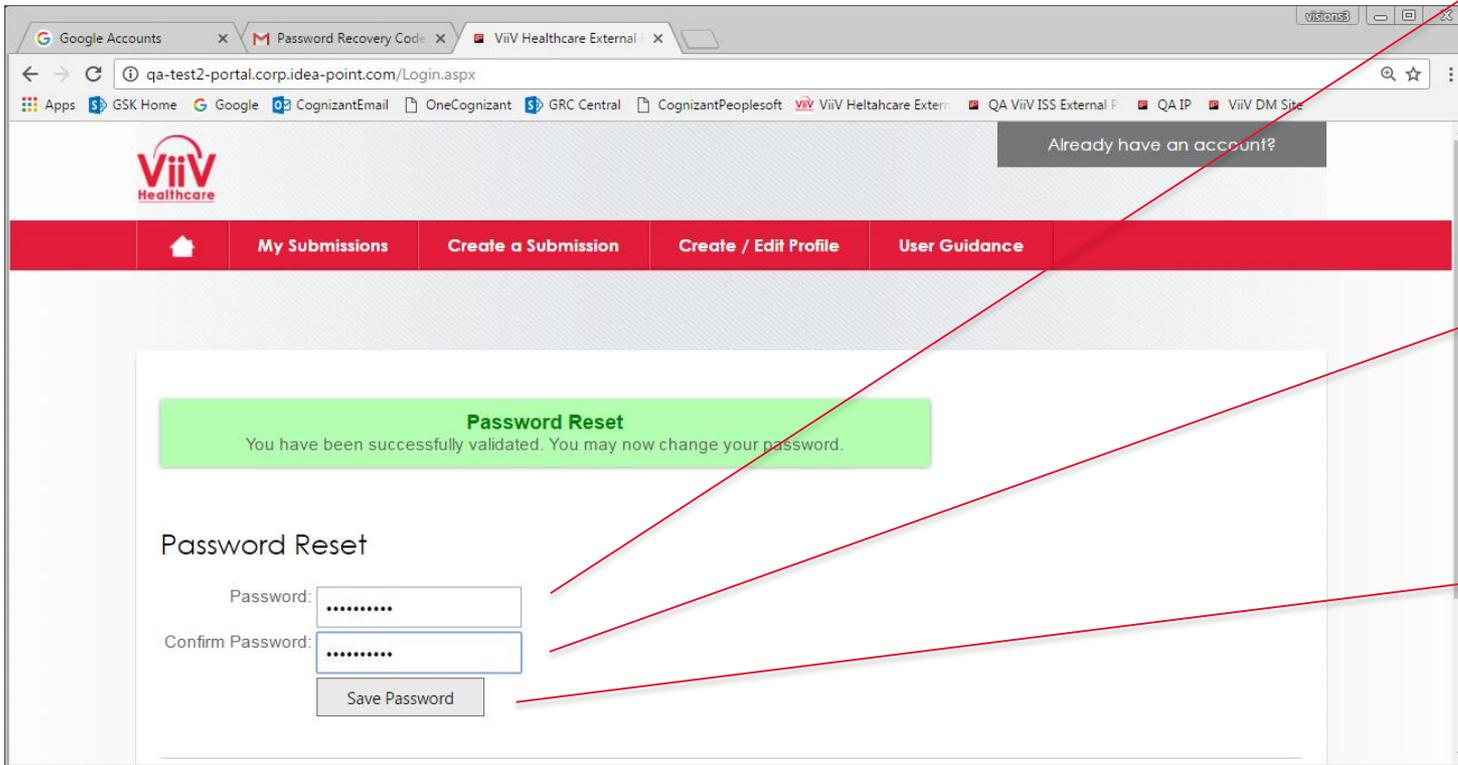
The screenshot shows a web browser window with the URL `qa-test2-portal.corp.idea-point.com/Login.aspx`. The page features the ViiV Healthcare logo and a navigation menu with items: Home, My Submissions, Create a Submission, Create / Edit Profile, and User Guidance. A green banner reads "Password Reset" with instructions: "Please check your email for further instructions. If you do not receive the message, please start this process again." Below this, a text input field contains the code "Pg3qzDr4". At the bottom, there are two buttons: "Validate" (highlighted in light blue) and "Cancel".

Enter the code from the email in the text box

Click the validate button to finish the verification process.



# First Login (6 of 6)



Enter the NEW password you want to select in the Password field

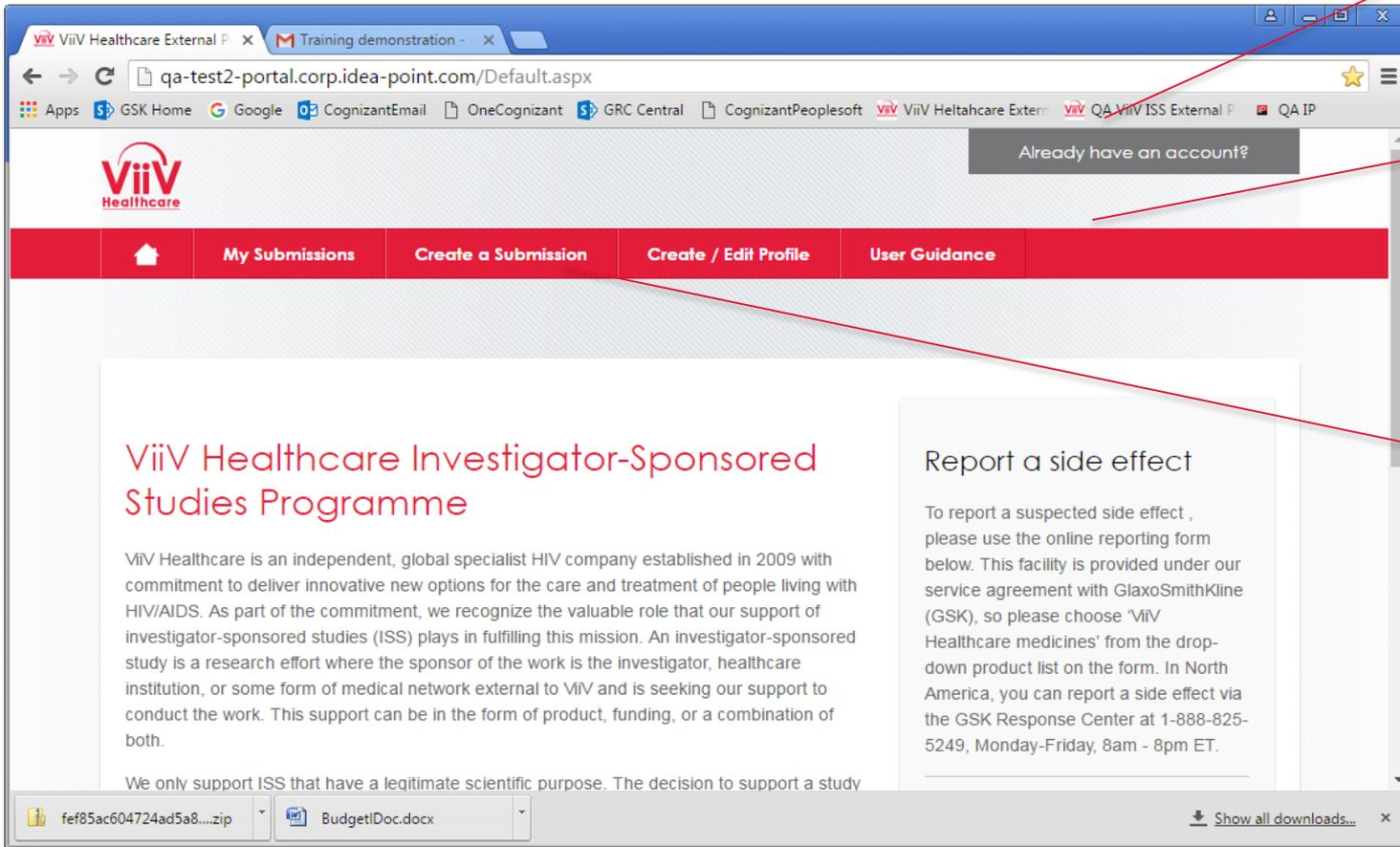
Enter the same password to confirm

Select the Save Password button to complete the process

Once the password has been set you will be returned to the normal Login screen and you can log into the application. (See [Login to the System](#))



# Accessing the System



Click here to login.

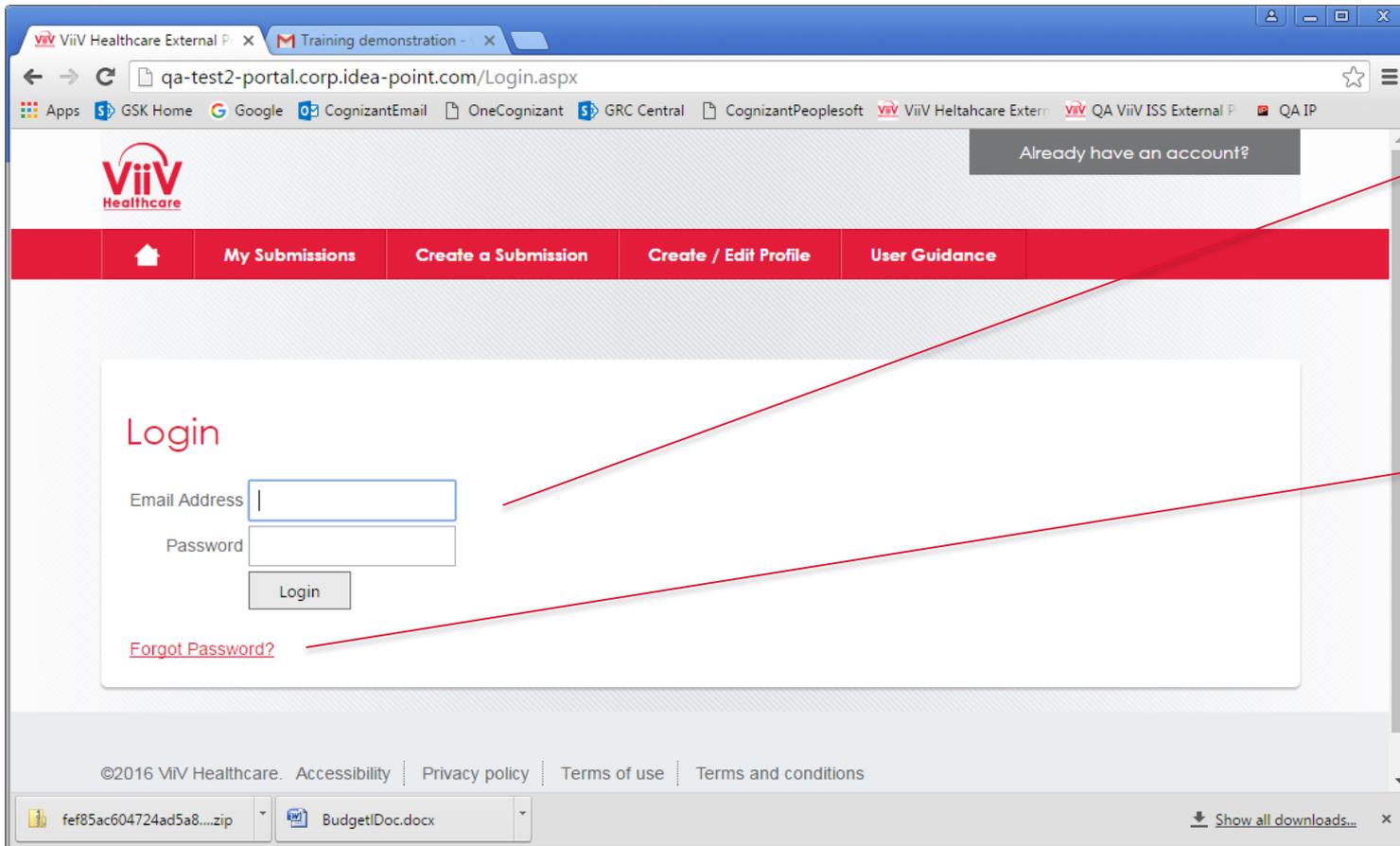
Menu bar will appear on each page

Clicking a menu option that requires login will take you to the login page if you are not logged in

Access the system at [iss.viivhealthcare.com](https://iss.viivhealthcare.com)



# Login to the System



The screenshot shows a web browser window with the URL `qa-test2-portal.corp.idea-point.com/Login.aspx`. The page features the ViiV Healthcare logo and a navigation menu with options: Home, My Submissions, Create a Submission, Create / Edit Profile, and User Guidance. A dark grey button labeled "Already have an account?" is positioned above the main content area. The central "Login" form includes an "Email Address" input field, a "Password" input field, a "Login" button, and a red link for "Forgot Password?". The footer contains copyright information for 2016 ViiV Healthcare and links to Accessibility, Privacy policy, Terms of use, and Terms and conditions. The browser's download bar at the bottom shows files like "fef85ac604724ad5a8...zip" and "Budget1Doc.docx".

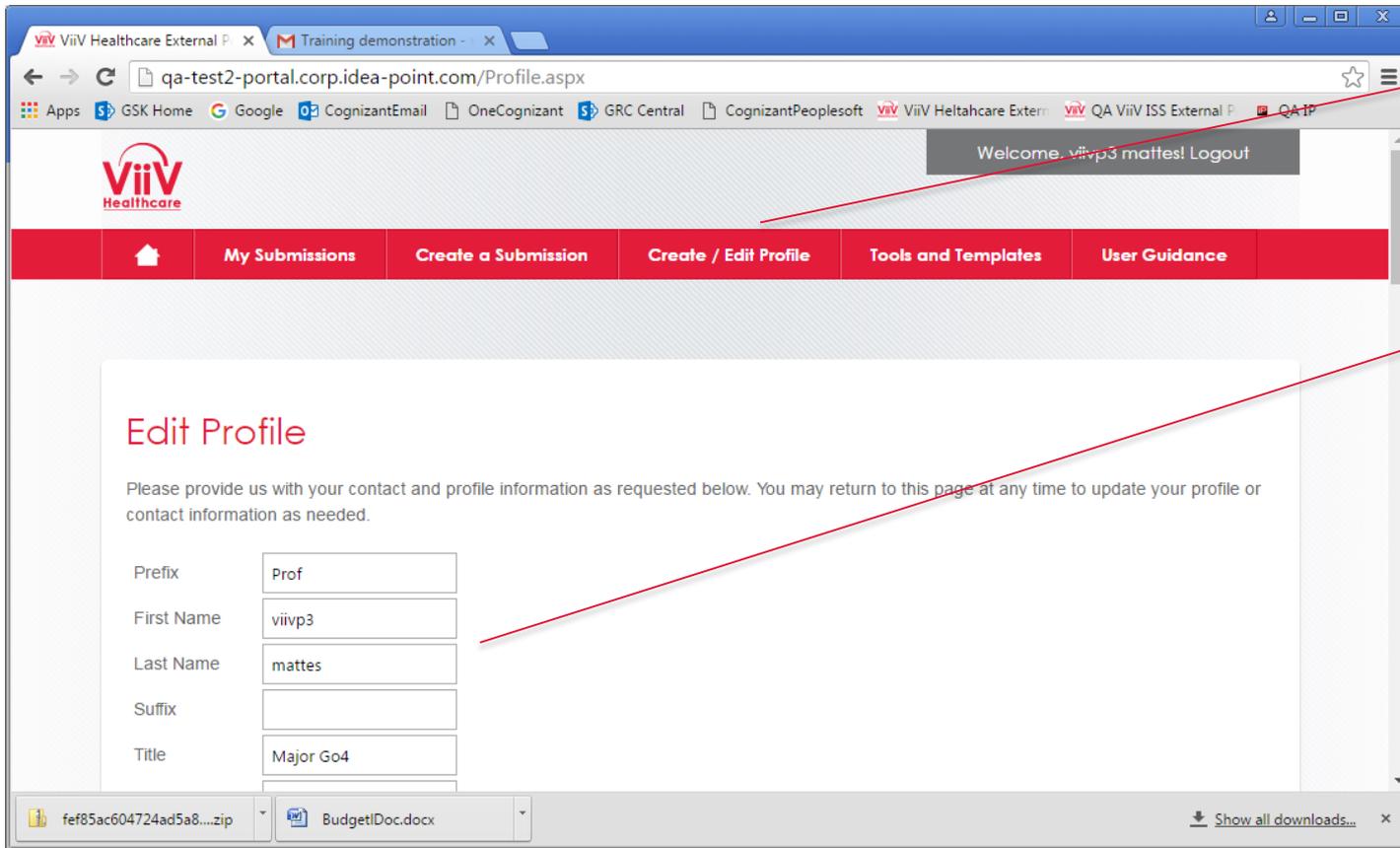
Enter email address and password to Login

If you have not been issued a password yet, or forget your password select "Forgot Password"

If you select forgot password it will take you to a screen to provide your email and limited information. You will receive a code in your email to enter which will allow you to set/reset your password. (See [Initial Login](#))



# Complete/Edit Profile (1 of 2)



qa-test2-portal.corp.idea-point.com/Profile.aspx

Welcome, viivp3 mattes! Logout

**Create / Edit Profile**

## Edit Profile

Please provide us with your contact and profile information as requested below. You may return to this page at any time to update your profile or contact information as needed.

|            |           |
|------------|-----------|
| Prefix     | Prof      |
| First Name | viivp3    |
| Last Name  | mattes    |
| Suffix     |           |
| Title      | Major Go4 |

Select  
Create/Edit  
Profile

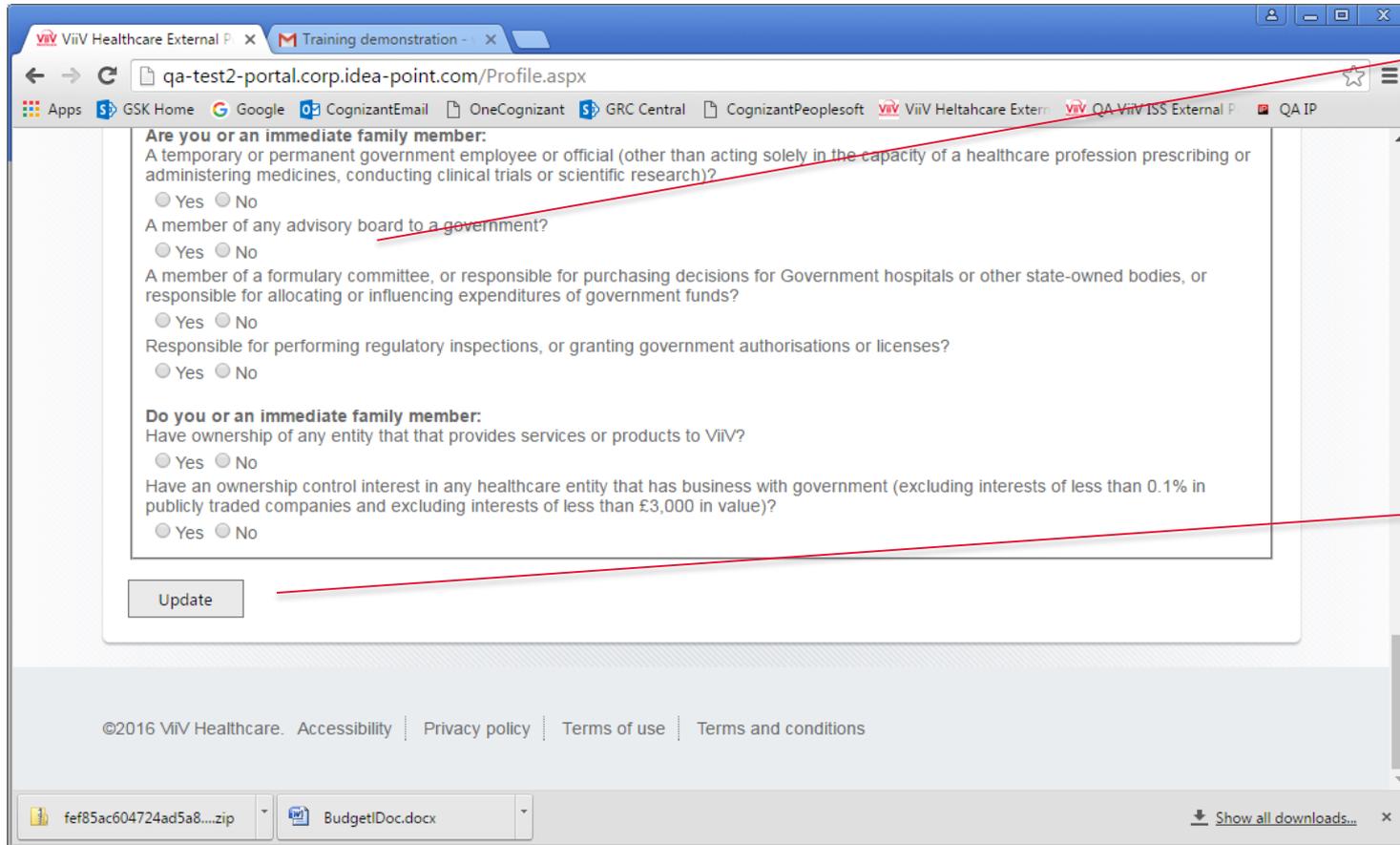
Complete or  
update  
existing  
profile  
information.

**Note:** You  
cannot change  
your email  
address.

ViiV will create a minimal user profile. However, you will be expected to update the profile and complete the extended information at or before the time your full proposal is submitted. You will also be asked to update your profile at various times to maintain compliance with ViiV standards.



# Complete/Edit Profile (2 of 2)



Are you or an immediate family member:  
A temporary or permanent government employee or official (other than acting solely in the capacity of a healthcare profession prescribing or administering medicines, conducting clinical trials or scientific research)?  
 Yes  No

A member of any advisory board to a government?  
 Yes  No

A member of a formulary committee, or responsible for purchasing decisions for Government hospitals or other state-owned bodies, or responsible for allocating or influencing expenditures of government funds?  
 Yes  No

Responsible for performing regulatory inspections, or granting government authorisations or licenses?  
 Yes  No

**Do you or an immediate family member:**  
Have ownership of any entity that that provides services or products to ViiV?  
 Yes  No

Have an ownership control interest in any healthcare entity that has business with government (excluding interests of less than 0.1% in publicly traded companies and excluding interests of less than £3,000 in value)?  
 Yes  No

Answer all the questions on the form

Click "Update" to save your changes.

The profile includes information related to conflict of interest and similar things related to ViiV standards and due diligence. Updates will be requested when needed based on ViiV policies.



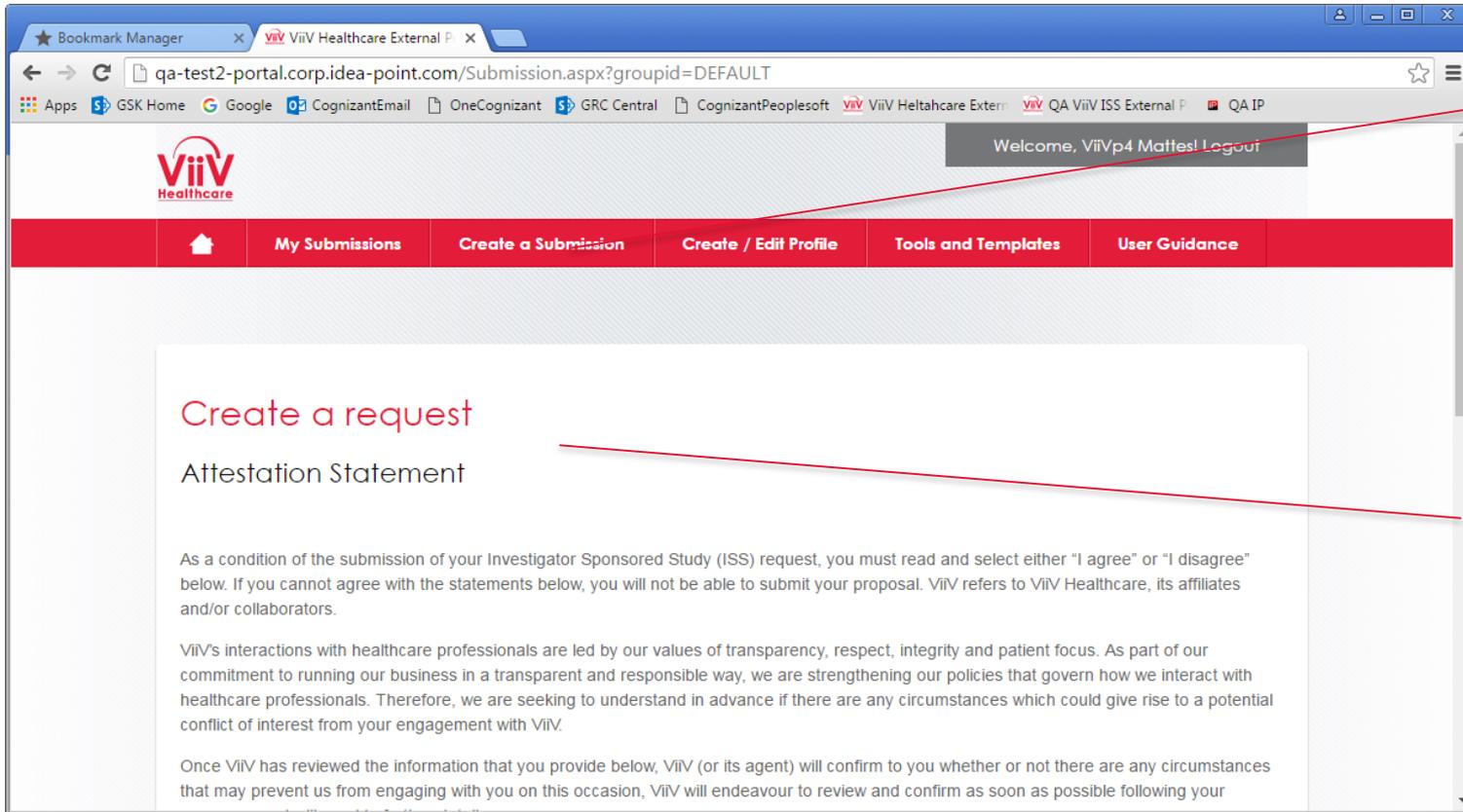
# Creating a Concept Submission

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- The first step in the process of submitting a Study Proposal to ViiV Healthcare is to create the Concept Proposal which is the initial Submission including a high level overview of the proposed study.
- This process is started by selecting the “Create a Submission” button on the main application menu bar.
- The key steps in this part of the process are:
  - Discuss Concept with ViiV Contact
  - Create a Submission
  - Complete Attestation Statement
  - Complete Concept Form



# Create a Submission (1 of 4)



Bookmark Manager x ViiV Healthcare External P x

qa-test2-portal.corp.idea-point.com/Submission.aspx?groupid=DEFAULT

Apps GSK Home Google CognizantEmail OneCognizant GRC Central CognizantPeoplesoft ViiV Healthcare Extern ViiV QA ViiV ISS External P QA IP

Welcome, ViiVp4 Mattes! Logout

My Submissions **Create a Submission** Create / Edit Profile Tools and Templates User Guidance

## Create a request

### Attestation Statement

As a condition of the submission of your Investigator Sponsored Study (ISS) request, you must read and select either "I agree" or "I disagree" below. If you cannot agree with the statements below, you will not be able to submit your proposal. ViiV refers to ViiV Healthcare, its affiliates and/or collaborators.

ViiV's interactions with healthcare professionals are led by our values of transparency, respect, integrity and patient focus. As part of our commitment to running our business in a transparent and responsible way, we are strengthening our policies that govern how we interact with healthcare professionals. Therefore, we are seeking to understand in advance if there are any circumstances which could give rise to a potential conflict of interest from your engagement with ViiV.

Once ViiV has reviewed the information that you provide below, ViiV (or its agent) will confirm to you whether or not there are any circumstances that may prevent us from engaging with you on this occasion, ViiV will endeavour to review and confirm as soon as possible following your

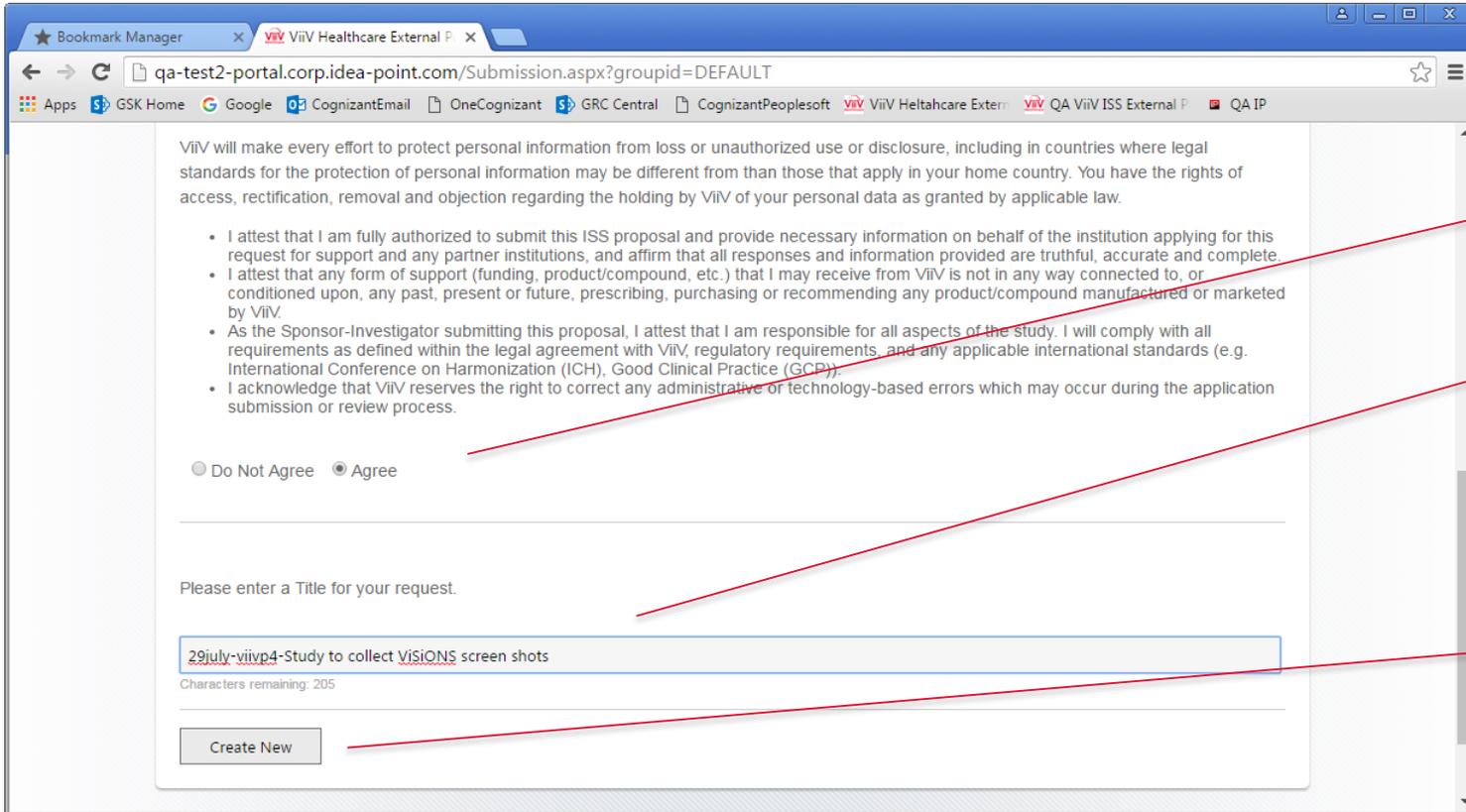
Select Create a Submission to start the proposal process.

You will be presented with a form that includes an attestation statement

The system will not allow you to create the initial proposal summary, a concept proposal, before you agree with the Attestation Statement.



# Create a Submission (2 of 4)



Bookmark Manager x ViiV ViiV Healthcare External P x

qa-test2-portal.corp.idea-point.com/Submission.aspx?groupid=DEFAULT

Apps GSK Home Google CognizantEmail OneCognizant GRC Central CognizantPeoplesoft ViiV ViiV Heltahcare Extern ViiV QA ViiV ISS External P QA IP

ViiV will make every effort to protect personal information from loss or unauthorized use or disclosure, including in countries where legal standards for the protection of personal information may be different from than those that apply in your home country. You have the rights of access, rectification, removal and objection regarding the holding by ViiV of your personal data as granted by applicable law.

- I attest that I am fully authorized to submit this ISS proposal and provide necessary information on behalf of the institution applying for this request for support and any partner institutions, and affirm that all responses and information provided are truthful, accurate and complete.
- I attest that any form of support (funding, product/compound, etc.) that I may receive from ViiV is not in any way connected to, or conditioned upon, any past, present or future, prescribing, purchasing or recommending any product/compound manufactured or marketed by ViiV.
- As the Sponsor-Investigator submitting this proposal, I attest that I am responsible for all aspects of the study. I will comply with all requirements as defined within the legal agreement with ViiV, regulatory requirements, and any applicable international standards (e.g. International Conference on Harmonization (ICH), Good Clinical Practice (GCP)).
- I acknowledge that ViiV reserves the right to correct any administrative or technology-based errors which may occur during the application submission or review process.

Do Not Agree  Agree

Please enter a Title for your request.

29 July - viivp4 - Study to collect VISIONS screen shots

Characters remaining: 205

Create New

Select the “Agree” or “Do Not Agree” option

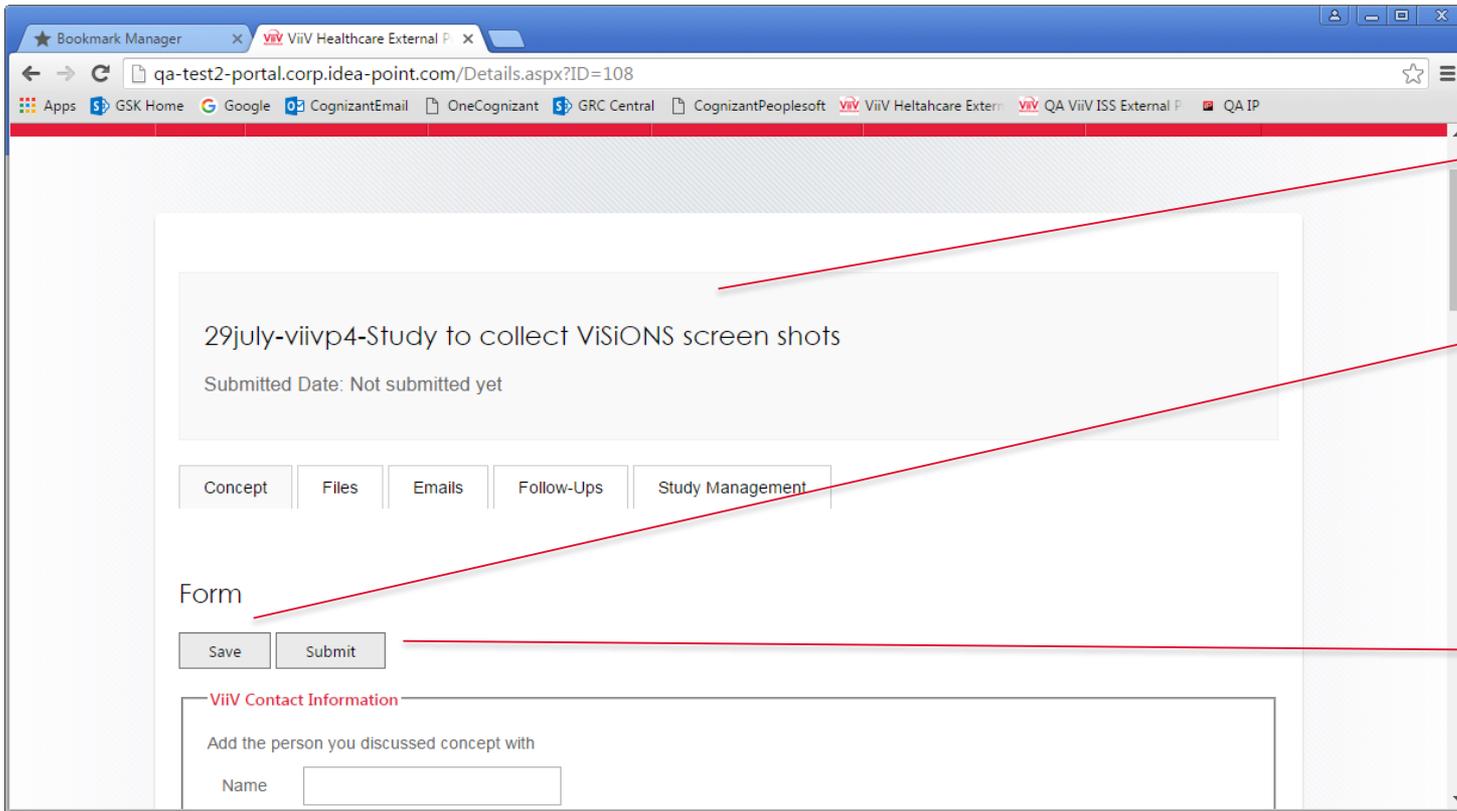
Provide a title for the proposal.

Click “Create New” once you have provided the information

The title provided here will be used by the system as the title during the lifetime of the study.



# Create a Submission (3 of 4)



29july-viivp4-Study to collect ViSiONS screen shots

Submitted Date: Not submitted yet

Concept Files Emails Follow-Ups Study Management

Form

Save Submit

**ViiV Contact Information**

Add the person you discussed concept with

Name

The concept form will be displayed

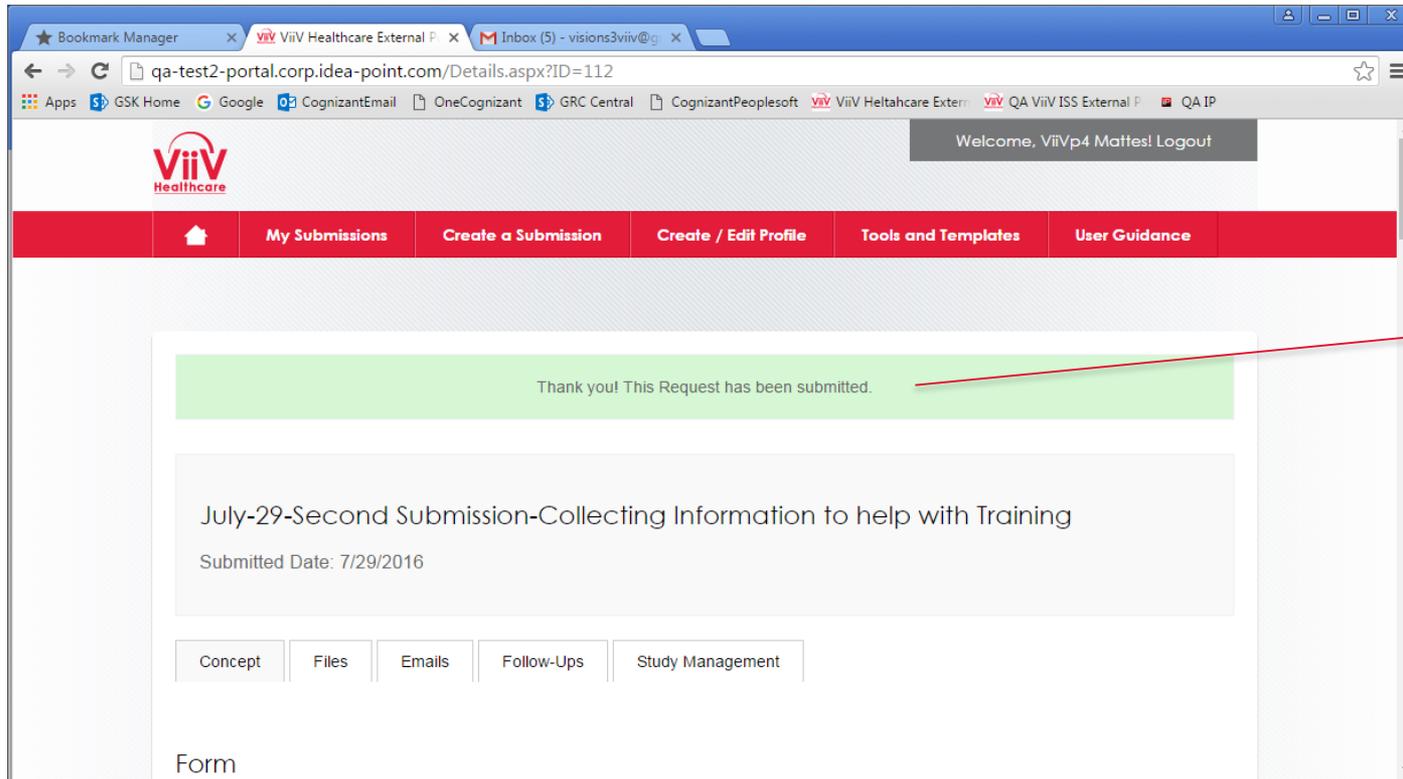
Save will keep your updates but not submit and send to ViiV.

Submit will save your updates, sent them to ViiV,

The electronic concept form will be displayed. All questions should be answered before selecting Submit to send the information to ViiV



# Create a Submission (4 of 4)



A confirmation is displayed when the form is submitted.

The system will display a confirmation when a form is saved or submitted to confirm the action taken. ViiV will be notified when the submission occurs.



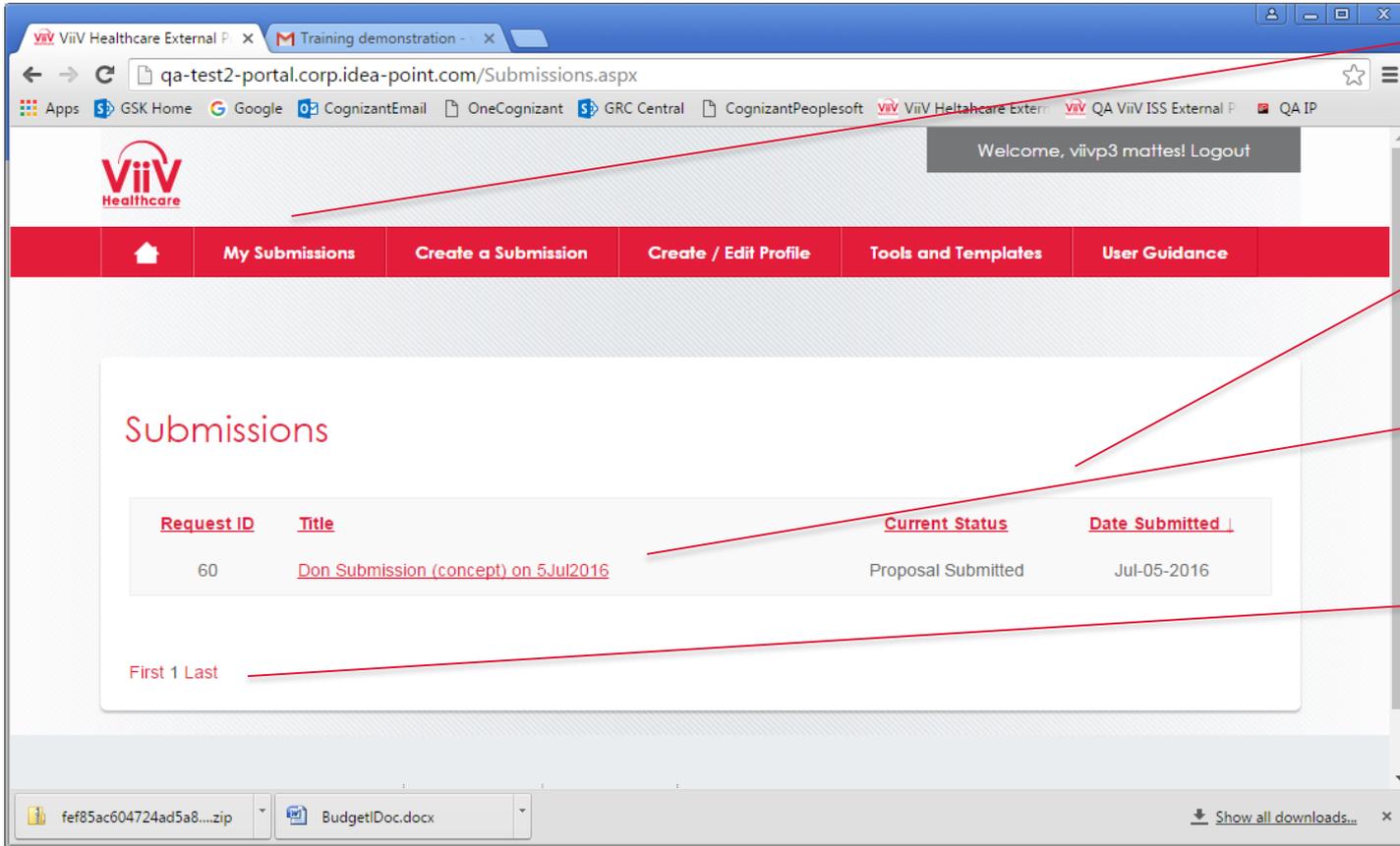
# Submitting a Proposal

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- Once a Concept has been accepted the investigator will be notified and the full proposal submission can be entered in the system.
- The following high level steps are involved in submitting a proposal.
  - Complete the Proposal Form
  - Complete Budget Tool (if requesting funding)
  - Submit Budget Tool into “Files” (if applicable)
  - Submit Protocol into “Files” (if protocol available)
  - Submit Investigator CV into “Files”
  - Submit Investigator Medical License into “Files” (if applicable)
  - Review, Confirm and Update information in Investigator Profile (for longer studies, the Investigator Profile must be Reviewed every 2 years) Should this be upload?



# My Submissions



Submissions

| Request ID | Title  | Current Status     | Date Submitted |
|------------|--|--------------------|----------------|
| 60         | <a href="#">Don Submission (concept) on 5Jul2016</a> | Proposal Submitted | Jul-05-2016    |

First 1 Last

Select "My Submissions"

Current status displayed

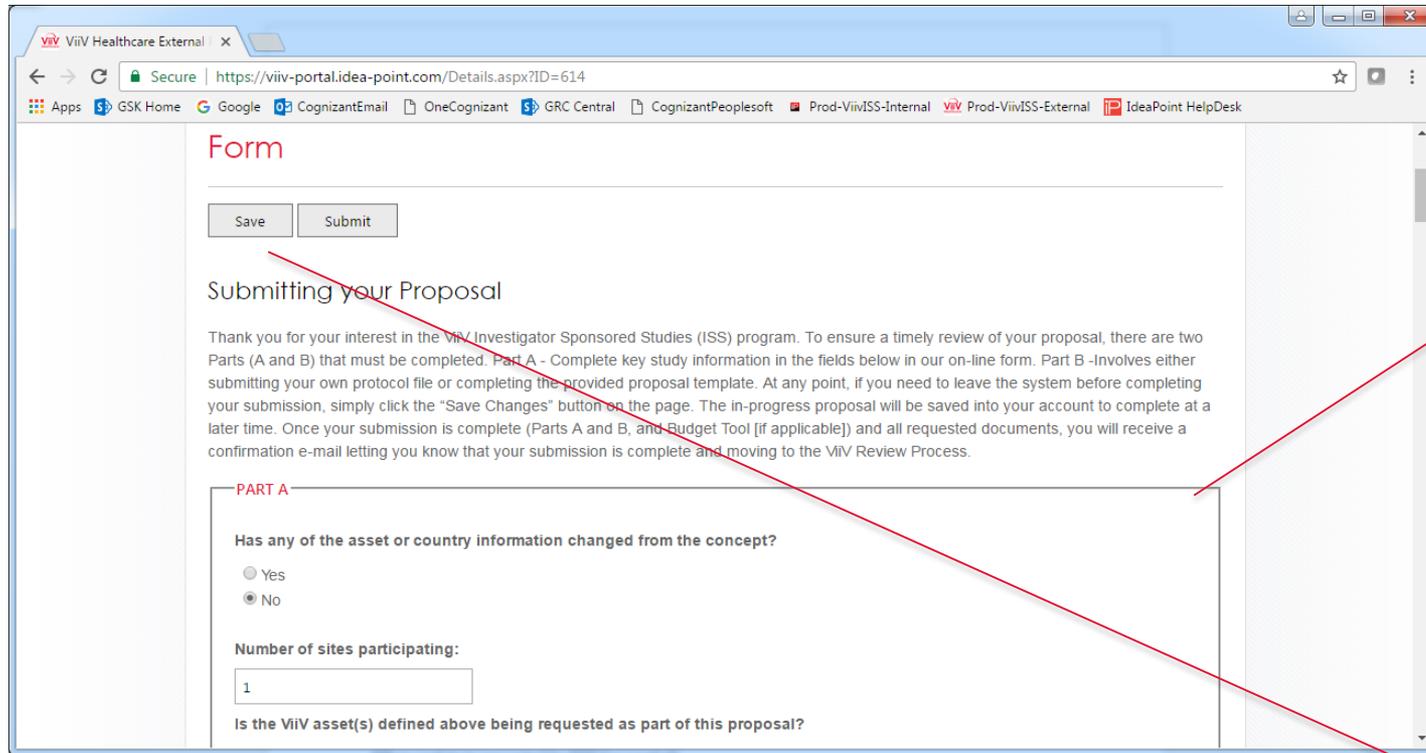
Click on the Title to open that submission

Navigation if there are multiple pages

Selecting the My Submissions option will display all of your submissions. (Clicking on this option when you are NOT logged in will start the login process then display the list of submissions after login is complete.) Clicking on a submission will select that submission and allow review and update of the information as appropriate.



# Completing the Proposal Form (1 of 2)



The screenshot shows a web browser window with the URL <https://viiv-portal.idea-point.com/Details.aspx?ID=614>. The page title is "Form". At the top, there are "Save" and "Submit" buttons. Below them is the heading "Submitting your Proposal" followed by a paragraph of instructions. The main content area is titled "PART A" and contains the following questions and input fields:

- Has any of the asset or country information changed from the concept?  
 Yes  
 No
- Number of sites participating:
- Is the ViiV asset(s) defined above being requested as part of this proposal?

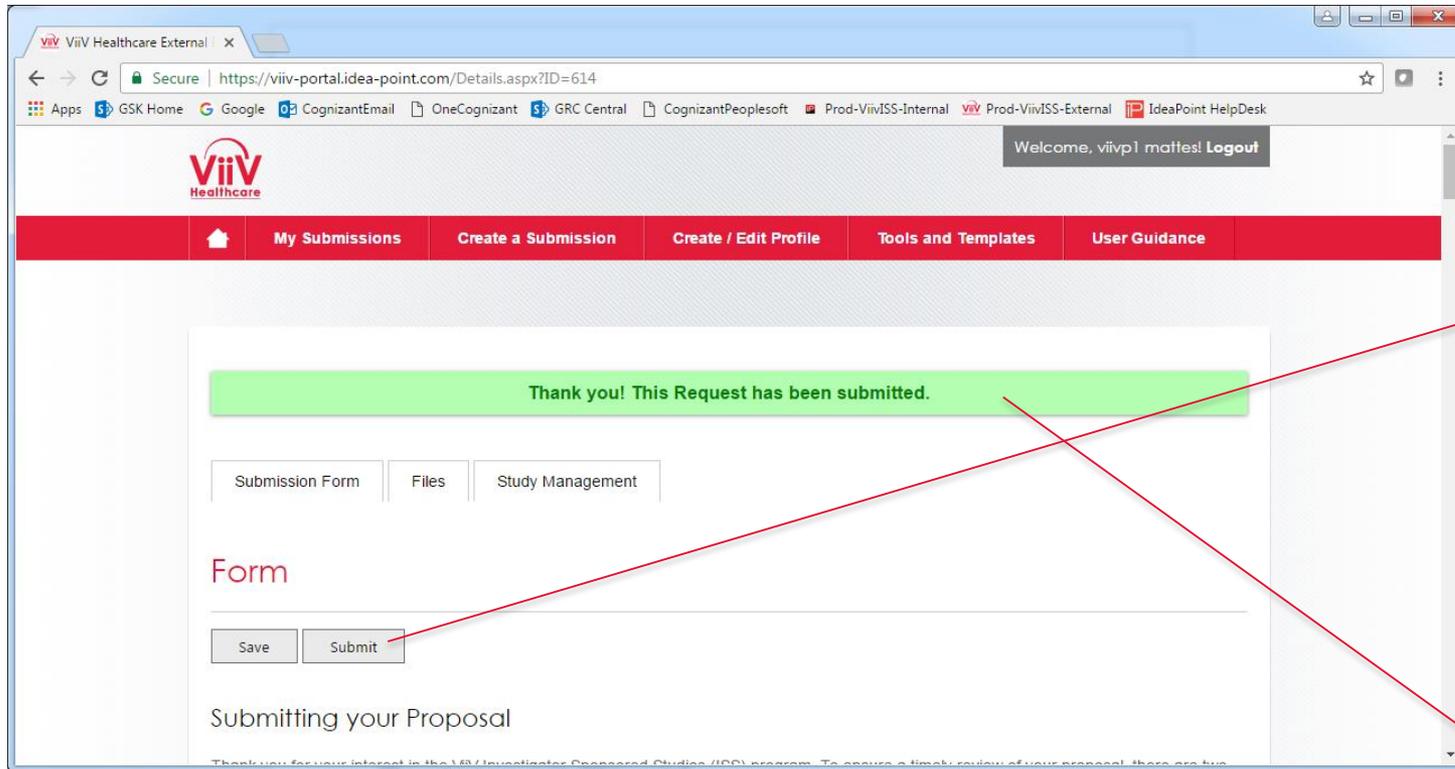
A form to provide the complete proposal information is displayed.

The Save button allows the information to be saved and editing can be continued in another session.

The Proposal Form is displayed and will allow for input until the proposal has been submitted. The form is a few pages and the user may select the save button to save information provided and continue working at a later time.



# Completing the Proposal Form (2 of 2)



The screenshot shows a web browser window with the ViiV Healthcare External portal. The address bar shows the URL: <https://viiiv-portal.idea-point.com/Details.aspx?ID=614>. The page features a navigation menu with options: My Submissions, Create a Submission, Create / Edit Profile, Tools and Templates, and User Guidance. A green confirmation banner at the top of the form area reads: "Thank you! This Request has been submitted." Below this, there are tabs for "Submission Form", "Files", and "Study Management". The "Form" section is visible, containing a "Save" button and a "Submit" button. A red line points from the "Submit" button to the confirmation message.

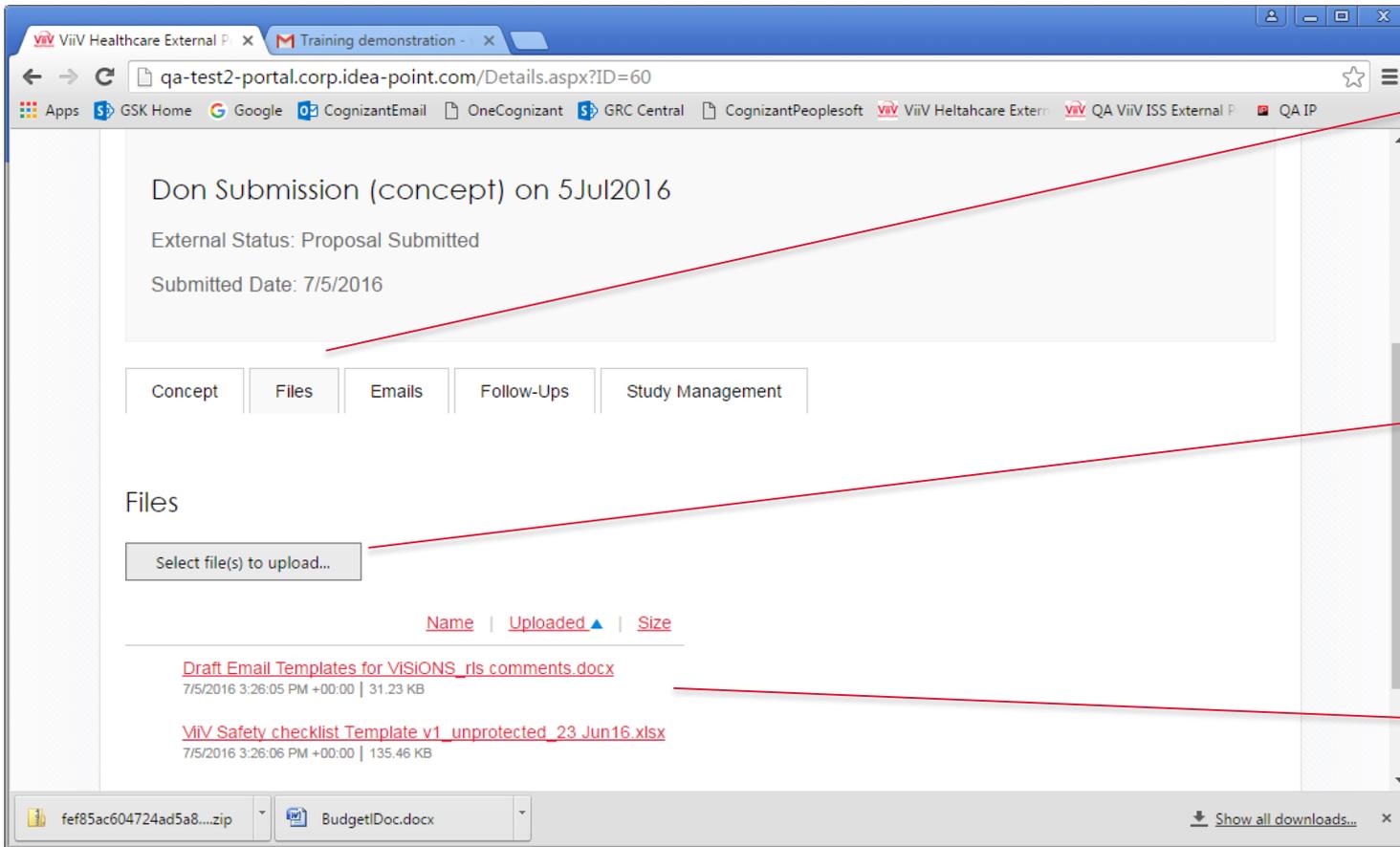
Select the Submit button to validate the entries and submit the proposal.

A confirmation is displayed when the form is submitted.

Once all the information for the proposal has been completed select the "Submit" button at the top of the form. This will check the information for valid entries and submit the information to ViiV Healthcare.



# Submitting/Sharing Files (1 of 4)



The screenshot shows a web browser window with the URL `qa-test2-portal.corp.idea-point.com/Details.aspx?ID=60`. The page title is "Don Submission (concept) on 5Jul2016". The external status is "Proposal Submitted" and the submitted date is "7/5/2016". There are five tabs: "Concept", "Files", "Emails", "Follow-Ups", and "Study Management". The "Files" tab is active, showing a "Select file(s) to upload..." button and a table of uploaded files.

| Name  | Uploaded                   | Size      |
|---|----------------------------|-----------|
| <a href="#">Draft Email Templates for VISIONS_rts comments.docx</a>         | 7/5/2016 3:26:05 PM +00:00 | 31.23 KB  |
| <a href="#">ViiV Safety checklist Template v1_unprotected_23 Jun16.xlsx</a> | 7/5/2016 3:26:06 PM +00:00 | 135.46 KB |

At the bottom of the browser window, there are two download items: "fef85ac604724ad5a8....zip" and "BudgetDoc.docx".

Select a submission and then select the "Files" tab

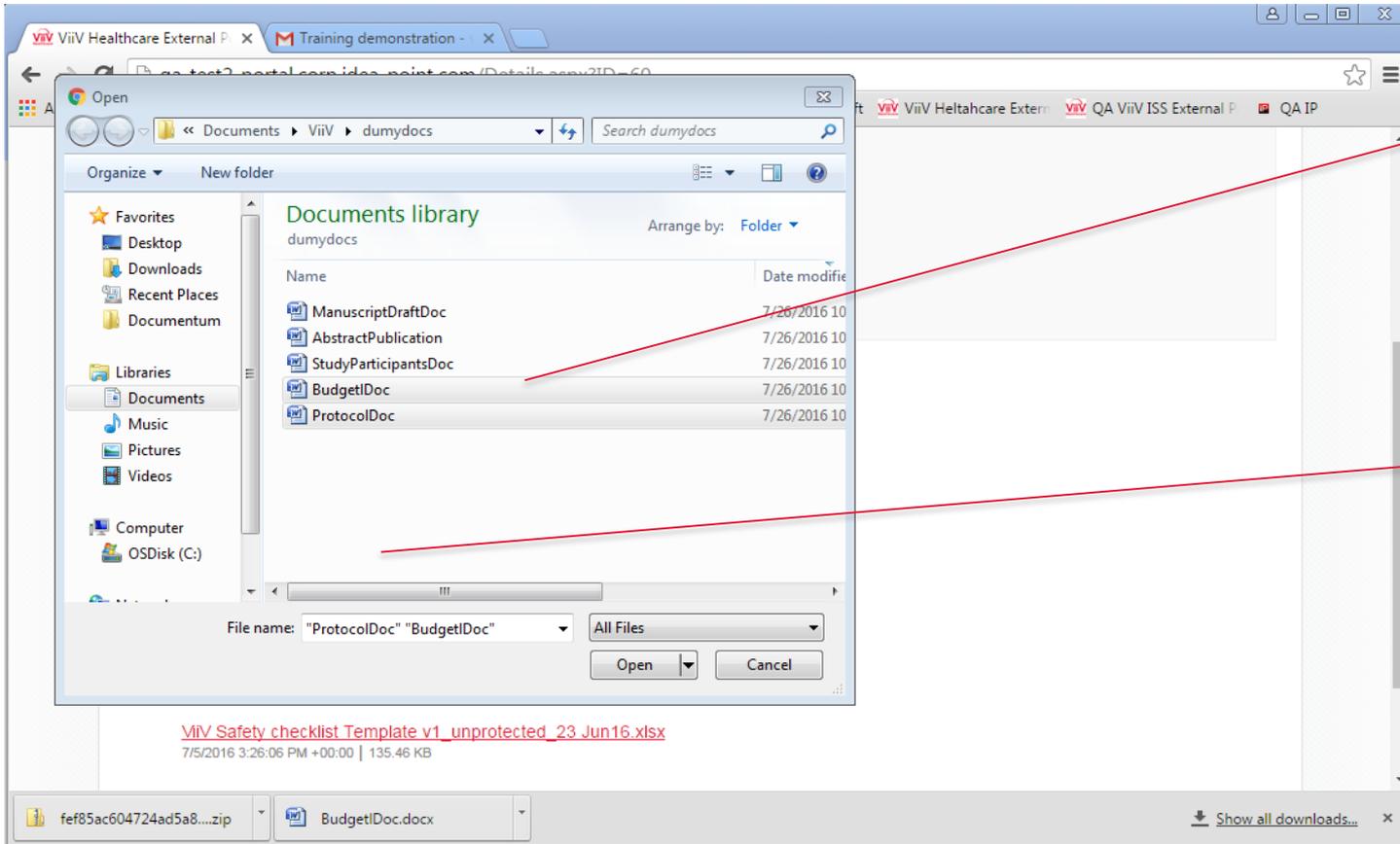
Click "Select files to upload.." to upload new files

Previously uploaded files will be displayed

Files can be uploaded to the system to allow sharing with ViiV.



# Submitting/Sharing Files (2 of 4)



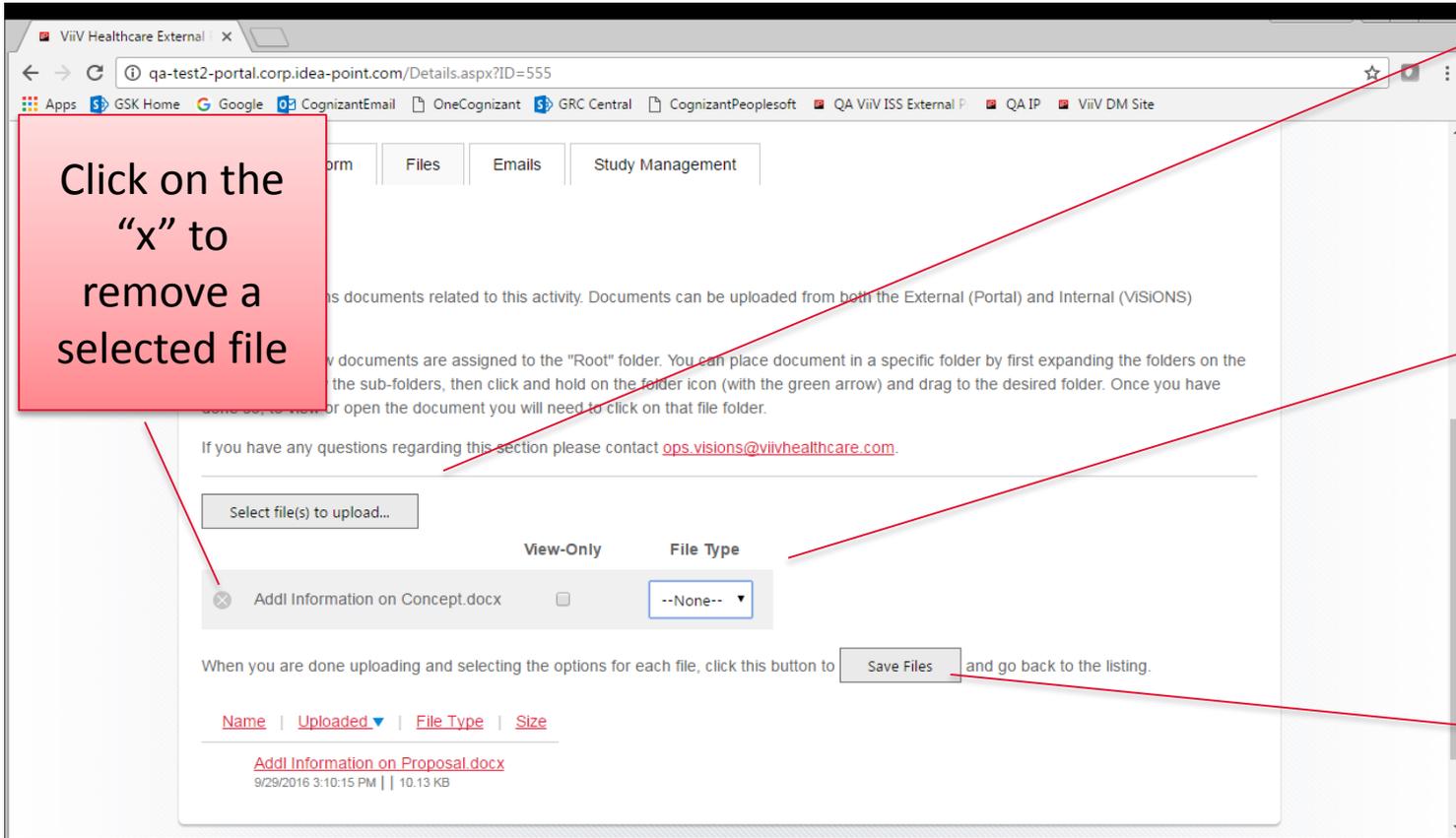
Select files you want to upload from the window

Click "Open" to save the selected files for upload

The upload can occur for any files you can access from your local machine via the files navigation window.



# Submitting/Sharing Files (3 of 4)



Click on the "x" to remove a selected file

Selected files displayed for confirmation

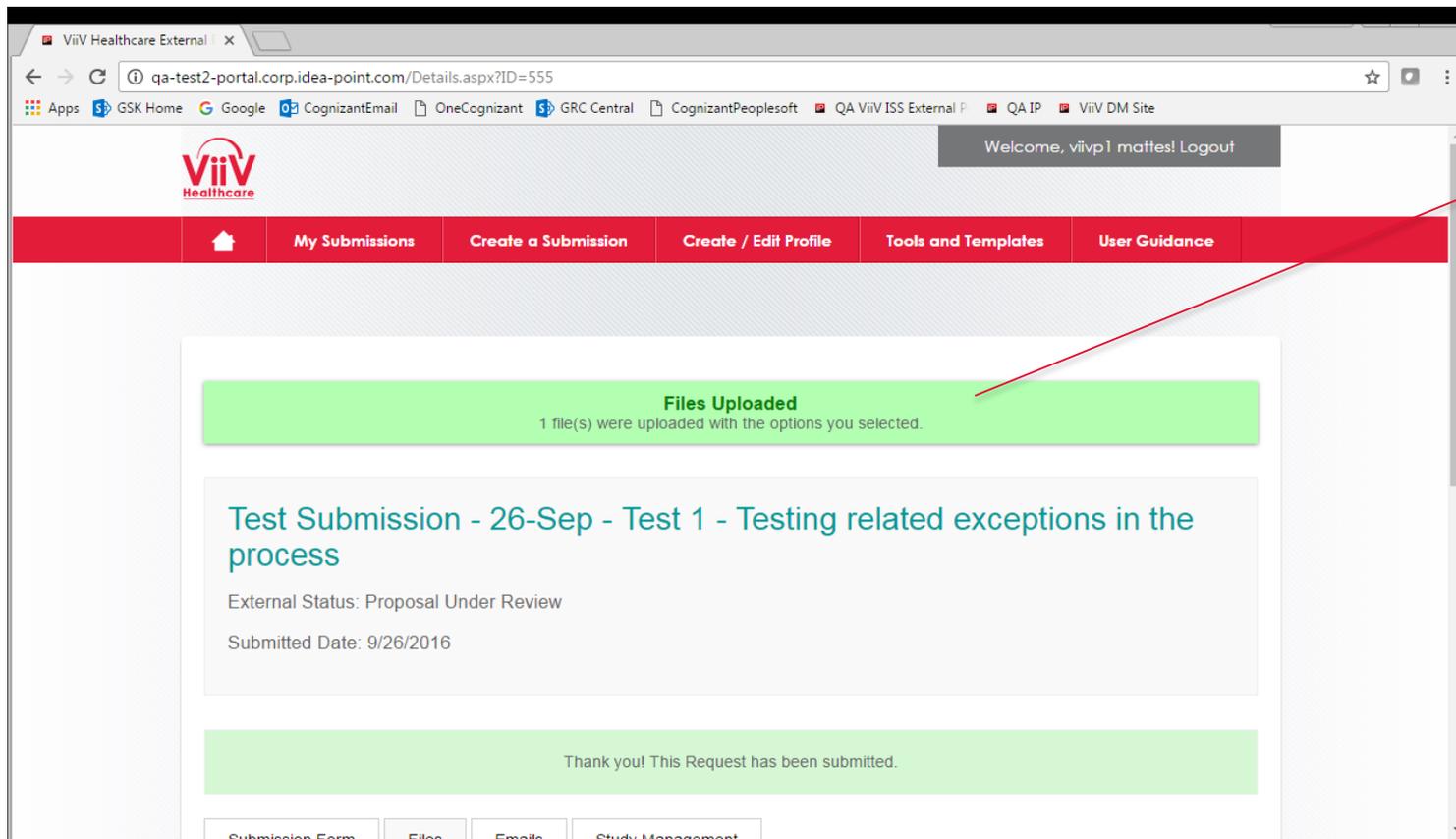
Select the appropriate file type and select View Only for Publication Submissions

Click "Save files" to complete the upload process

The selected files will be listed and can be marked for view only. Once ready click "Save Files" to complete the upload process.



# Submitting/Sharing Files (4 of 4)



The screenshot shows a web browser window with the URL `qa-test2-portal.corp.idea-point.com/Details.aspx?ID=555`. The page features a red navigation bar with the ViiV Healthcare logo and several menu items: Home, My Submissions, Create a Submission, Create / Edit Profile, Tools and Templates, and User Guidance. A grey banner at the top right says "Welcome, viivp1 mattes! Logout". The main content area displays a green confirmation banner that reads "Files Uploaded" and "1 file(s) were uploaded with the options you selected." Below this, a card shows the submission details: "Test Submission - 26-Sep - Test 1 - Testing related exceptions in the process", "External Status: Proposal Under Review", and "Submitted Date: 9/26/2016". At the bottom of the card, another green banner says "Thank you! This Request has been submitted." A red arrow points from the text box on the right to the green confirmation banner.

A confirmation banner will be displayed when the process is complete.

Once the process is complete the files loaded will be visible in the list of uploaded files.



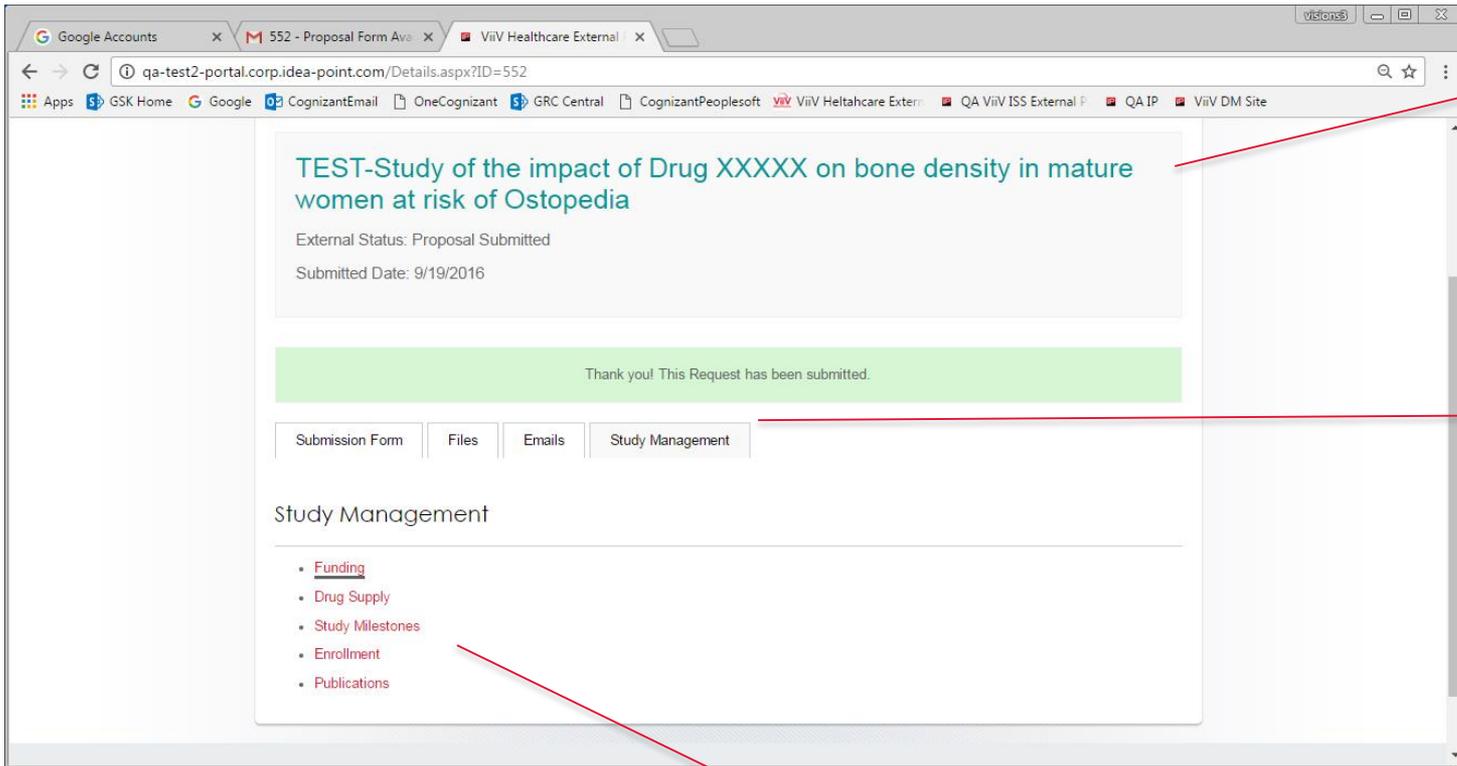
# Study Management Information

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- From the main screen of the proposal information there is a tab labeled Study Management. This tab will open a list of various types of Study information which can be viewed and updated from the portal. The various types are:
  - Funding: Information about funding payments agreed in the contract
  - Drug Supply: Allows the investigator to request a supply of drug materials and see the status of current and previous requests.
  - Study Milestone: Key milestones of the project can be reviewed and updated.
  - Enrollment: Dates and status of enrollment versus target can be provided.
  - Publications: Publications can be submitted and the status and history tracked.
- **Monthly Update Tasks**
  - Review and Update (if necessary) Funding Tab information (if applicable)
  - Review and Update (if necessary) Study Milestones Tab information
  - Review and Update Enrollment Tab information (From 1<sup>st</sup> Screening visit to Last Subject Last Visit)



# Study Management Information Page



The screenshot shows a web browser window with the URL `qa-test2-portal.corp.idea-point.com/Details.aspx?ID=552`. The page title is "TEST-Study of the impact of Drug XXXXX on bone density in mature women at risk of Osteoporosis". Below the title, it displays "External Status: Proposal Submitted" and "Submitted Date: 9/19/2016". A green banner indicates "Thank you! This Request has been submitted." Below this, there are four tabs: "Submission Form", "Files", "Emails", and "Study Management", with "Study Management" being the active tab. Under the "Study Management" tab, a list of sections is displayed: "Funding", "Drug Supply", "Study Milestones", "Enrollment", and "Publications".

Submission title and status are at the top

Study Management tab selected

The various sections are displayed. Clicking on the section name will display the data.



# Study Management Information Tables

- General Information on Working with the Study Information Management Tables
  - Each list will have zero or more rows in a table.
  - The column heading for each row will be displayed
  - In the lower left corner of the table is a pencil icon if any of the rows are editable.
  - To edit row select the row and then click the pencil icon.
  - A form will appear that will allow you to edit data for the selected row.
    - ***For all DATE fields a calendar Pop-Up will be displayed that should be used to select the date to minimize date format issues.***
  - When done editing information click the Save button at the bottom of the form to save your changes, click cancel to not make any changes.



# Study Management Information – Funding (1 of 2)



Thank you! This Request has been submitted.

Submission Form | Files | Emails | Study Management

### Study Management

- Funding**
- Drug Supply
- Study Milestones
- Enrollment
- Publications

| Payment Milestone Description | Currency Type in Contract | Amount in Contract | Target Date (Forecast) | Reason for Target Date Change | Date Milestone Complete | Supporting Documentation Received | Invoice Date (if applicable) | Amount of Invoice | Status | Editable Until |
|-------------------------------|---------------------------|--------------------|------------------------|-------------------------------|-------------------------|-----------------------------------|------------------------------|-------------------|--------|----------------|
| LSLV                          | USD                       | 40,000.00          | 2018-12-01             |                               |                         |                                   |                              | 0.00              |        | 2025-09-30     |
| Contract Execution            | USD                       | 20,000.00          | 2016-10-01             |                               |                         |                                   |                              | 0.00              |        | 2025-09-30     |
| Study Report Complete         | USD                       | 140,000.00         | 2020-09-01             |                               |                         |                                   |                              | 0.00              |        | 2025-09-30     |
| FSFV                          | USD                       | 20,000.00          | 2017-02-01             |                               |                         |                                   |                              | 0.00              |        | 2025-09-30     |

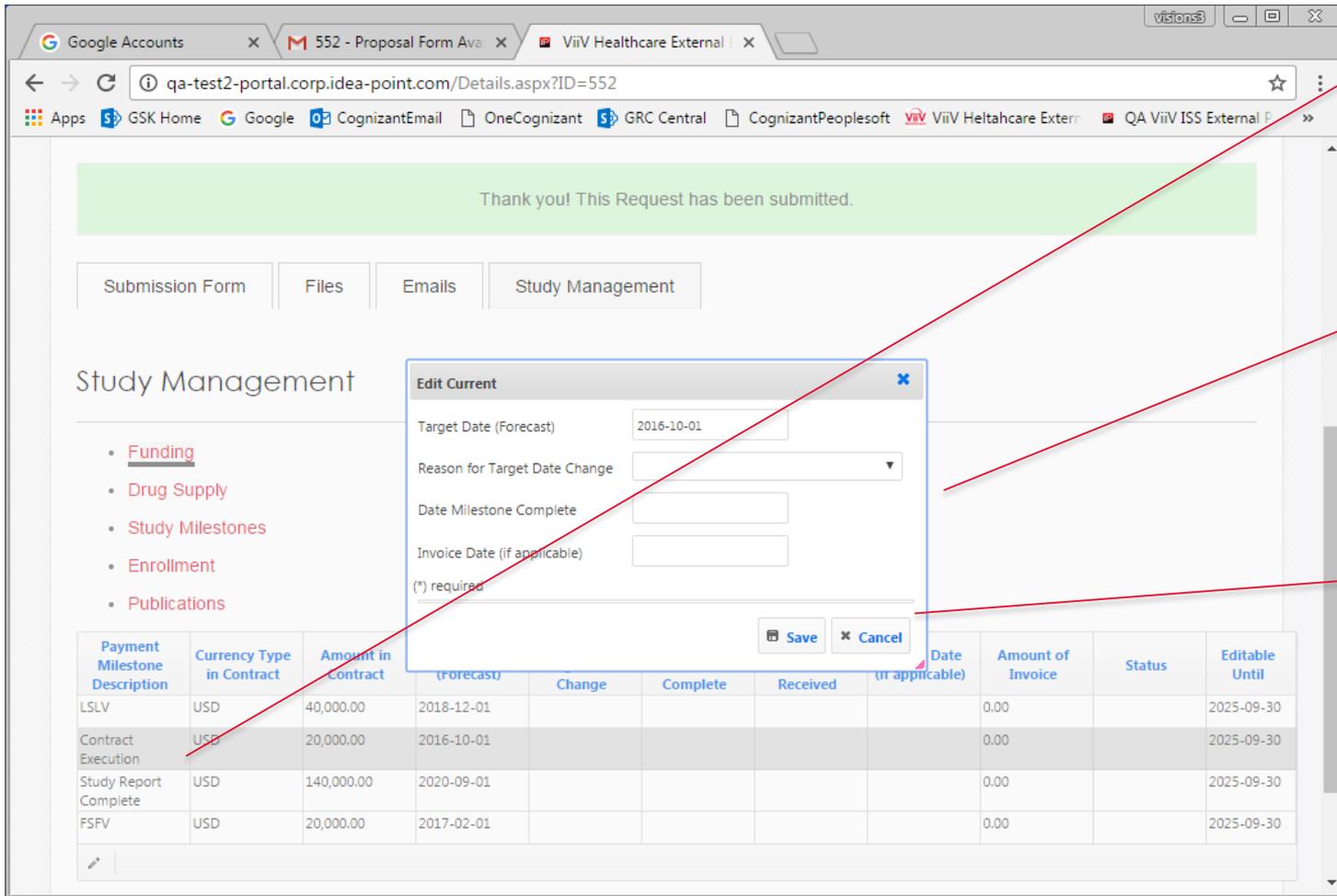
Funding Selected

Funding data table displayed

Pencil Icon for editing rows



# Study Management Information – Funding (2 of 2)



Thank you! This Request has been submitted.

Submission Form | Files | Emails | Study Management

Study Management

- Funding
- Drug Supply
- Study Milestones
- Enrollment
- Publications

| Payment Milestone Description | Currency Type in Contract | Amount in Contract | (Forecast) | Change | Complete | Received | Date (if applicable) | Amount of Invoice | Status | Editable Until |
|-------------------------------|---------------------------|--------------------|------------|--------|----------|----------|----------------------|-------------------|--------|----------------|
| LSLV                          | USD                       | 40,000.00          | 2018-12-01 |        |          |          |                      | 0.00              |        | 2025-09-30     |
| Contract Execution            | USD                       | 20,000.00          | 2016-10-01 |        |          |          |                      | 0.00              |        | 2025-09-30     |
| Study Report Complete         | USD                       | 140,000.00         | 2020-09-01 |        |          |          |                      | 0.00              |        | 2025-09-30     |
| FSFV                          | USD                       | 20,000.00          | 2017-02-01 |        |          |          |                      | 0.00              |        | 2025-09-30     |

**Edit Current**

Target Date (Forecast)

Reason for Target Date Change

Date Milestone Complete

Invoice Date (if applicable)

(\*) required

Funding Data row Selected

Funding data editing form display

Save and Cancel buttons

To edit a row. Select the row and then click on the pencil icon in the lower left corner (see previous slide). Complete the information in the pop-up form and then click Save.



# Study Management – Funding Checklist

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- The following is a checklist of Funding Updates to be made by the investigator during the study if applicable.
  - **Monthly**
    - Review and Update (if necessary) Target Dates for Milestone Payments
  - **When Milestone is Completed**
    - Update “Date Milestone Complete”
  - **When invoice is submitted (if applicable)**
    - Complete Invoice information
  - **When update is requested by ViiV (as needed)**
    - Review and Update (if necessary) Target Dates for Milestone Payments



# Study Management Information – Drug Supply

Thank you! This Request has been submitted.

Submission Form | Files | Emails | Study Management

### Study Management

- Funding
- Drug Supply
- Study Milestones
- Enrollment
- Publications

| Request Date | Product Name | Dose | Quantity Requested | Quantity Ordered | Order Date | Shipment Date | Drug Received by Site Confirmation Date | Status | Editable Until |
|--------------|--------------|------|--------------------|------------------|------------|---------------|---|--------|----------------|
|              |              | 0.00 | 0.00               | 0.00             |            |               |   |        | 2025-09-30     |
|              |              | 0.00 | 0.00               | 0.00             |            |               |   |        | 2025-09-30     |

Drug Supply Selected

Drug Supply data table displayed

Pencil Icon for editing rows

To edit a row. Select the row and then click on the pencil icon in the lower left corner. Complete the information in the pop-up form and then click Save. For a new request click on a row with NO request date, click edit, and add the appropriate request information.



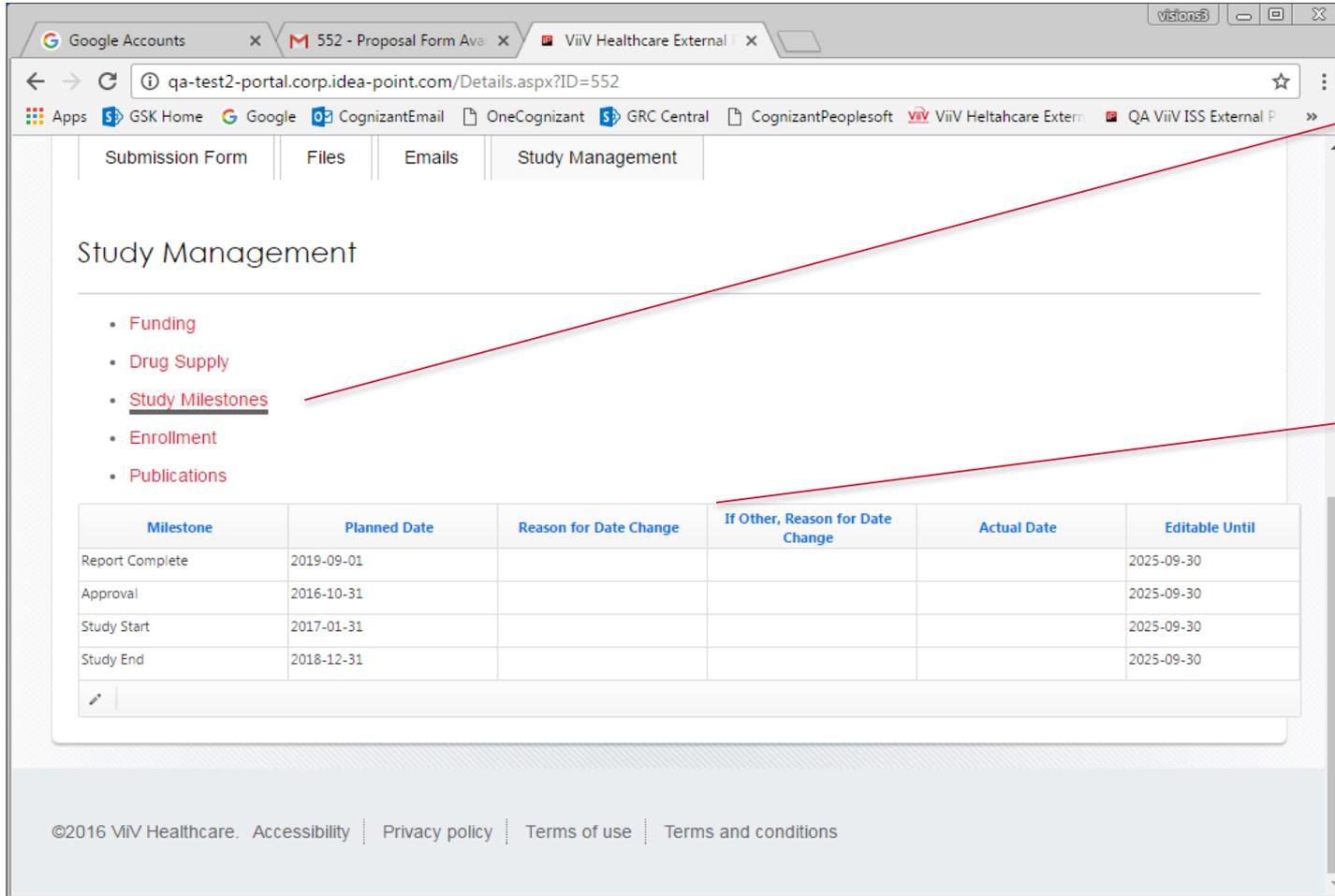
# Study Management – Drug Supply Checklist

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- The following is a checklist of Drug Supply Updates to be made by the investigator during the study if applicable.
  - ***When Requesting Drug***
    - Complete Request information
    - Confirm that “Enrollment” tab information is current and correct
  - ***When Drug is received at site***
    - Confirm receipt by completing “Drug Received by Site Confirmation”



# Study Management Information – Study Milestones



Study Management

- Funding
- Drug Supply
- Study Milestones
- Enrollment
- Publications

| Milestone       | Planned Date | Reason for Date Change | If Other, Reason for Date Change | Actual Date | Editable Until |
|-----------------|--------------|------------------------|----------------------------------|-------------|----------------|
| Report Complete | 2019-09-01   |                        |                                  |             | 2025-09-30     |
| Approval        | 2016-10-31   |                        |                                  |             | 2025-09-30     |
| Study Start     | 2017-01-31   |                        |                                  |             | 2025-09-30     |
| Study End       | 2018-12-31   |                        |                                  |             | 2025-09-30     |

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Study Milestones Selected

Study Milestone data table displayed

To edit a row. Select the row and then click on the pencil icon in the lower left corner. Update the information in the pop-up form and then click Save.



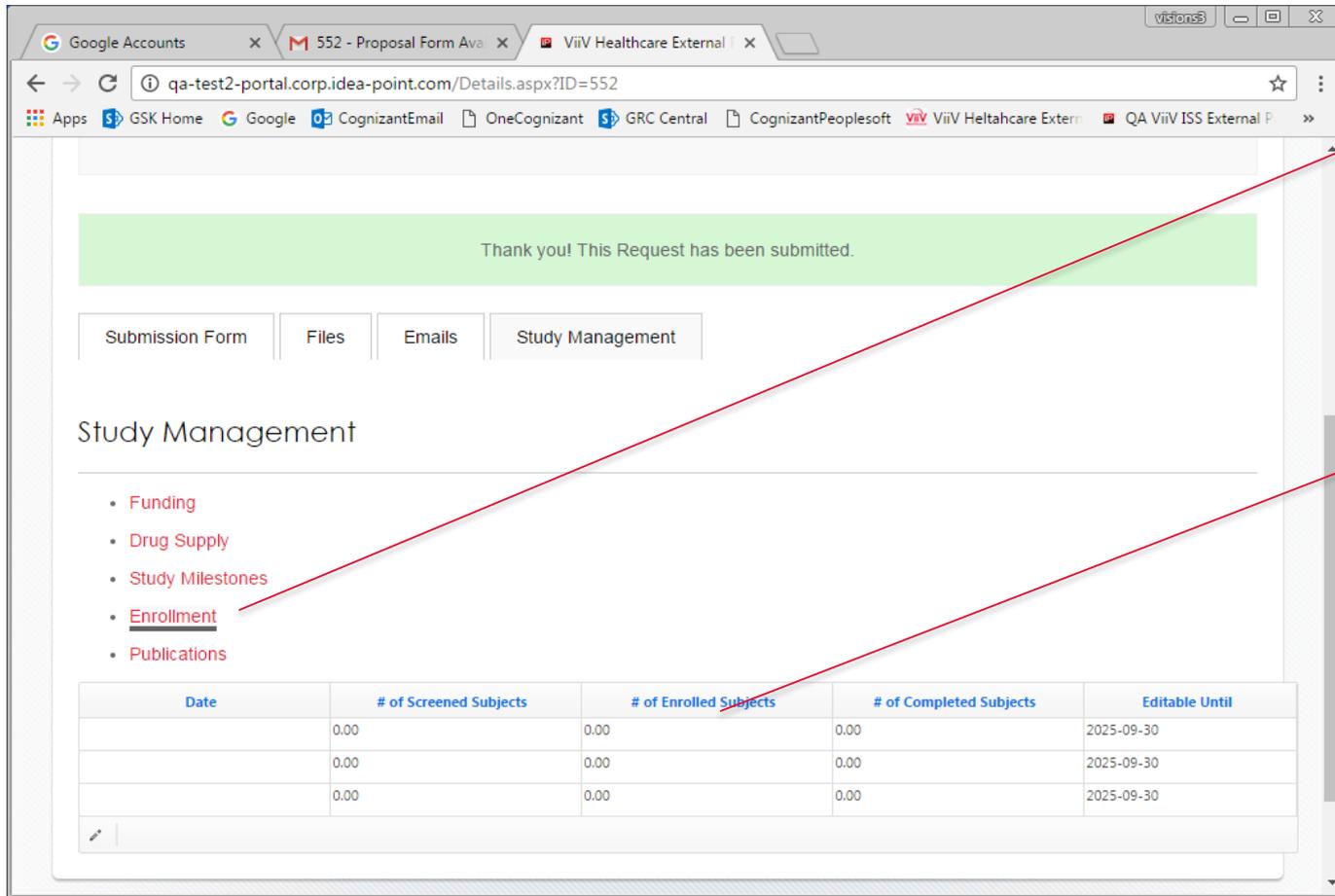
# Study Management – Study Milestones Checklist

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- The following is a checklist of Study Milestone Updates to be made by the investigator during the study.
  - **Monthly**
    - Review and Update (if necessary) Target Dates for Study Milestone
  - **When Milestone is completed**
    - Update “Date Milestone Complete”
  - **When update is requested by ViiV (as needed)**
    - Review and Update (if necessary) Target Dates for Study Milestone



# Study Management Information – Enrollment



The screenshot shows a web browser window with the URL `qa-test2-portal.corp.idea-point.com/Details.aspx?ID=552`. A green banner at the top of the page reads "Thank you! This Request has been submitted." Below this, there are navigation tabs for "Submission Form", "Files", "Emails", and "Study Management". The "Study Management" section is active, displaying a sidebar menu with options: "Funding", "Drug Supply", "Study Milestones", "Enrollment" (which is underlined and highlighted), and "Publications". Below the menu is a table with the following data:

| Date | # of Screened Subjects | # of Enrolled Subjects | # of Completed Subjects | Editable Until |
|------|------------------------|------------------------|-------------------------|----------------|
|      | 0.00                   | 0.00                   | 0.00                    | 2025-09-30     |
|      | 0.00                   | 0.00                   | 0.00                    | 2025-09-30     |
|      | 0.00                   | 0.00                   | 0.00                    | 2025-09-30     |

Enrollment Selected

Enrollment data table displayed

To provide an enrollment update select a row with no Date and then click on the pencil icon in the lower left corner. Complete the information in the pop-up form and then click Save. To correct information select the desired row, click on the pencil icon, update the information and then click Save.



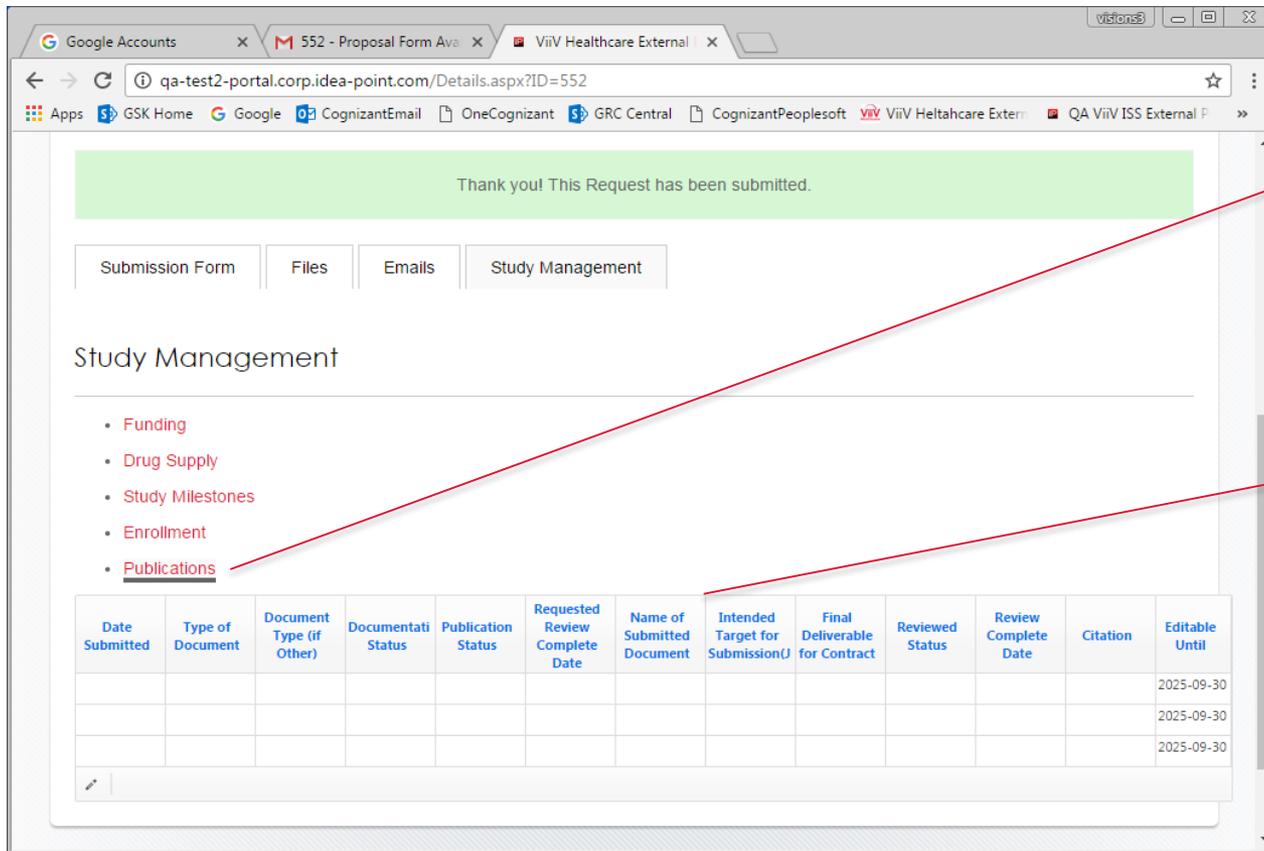
# Study Management – Enrollment Checklist

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- The following is a checklist for Enrollment Updates to be made by the investigator during a Clinical study with Human Subjects.
  - ***Monthly – From 1<sup>st</sup> Screening visit to Last Subject Last Visit***
    - Review and Update (if necessary) enrollment information
  - ***When requesting Study Drug***
    - Review and Confirm enrollment information
  - ***When update is requested by ViiV (as needed)***
    - Review and Update (if necessary) enrollment information



# Study Management Information – Publications



Thank you! This Request has been submitted.

Submission Form | Files | Emails | Study Management

### Study Management

- Funding
- Drug Supply
- Study Milestones
- Enrollment
- Publications**

| Date Submitted | Type of Document | Document Type (if Other) | Document Status | Publication Status | Requested Review Complete Date | Name of Submitted Document | Intended Target for Submission(J | Final Deliverable for Contract | Reviewed Status | Review Complete Date | Citation | Editable Until |
|----------------|------------------|--------------------------|-----------------|--------------------|--------------------------------|----------------------------|----------------------------------|--------------------------------|-----------------|----------------------|----------|----------------|
|                |                  |                          |                 |                    |                                |                            |                                  |                                |                 |                      |          | 2025-09-30     |
|                |                  |                          |                 |                    |                                |                            |                                  |                                |                 |                      |          | 2025-09-30     |
|                |                  |                          |                 |                    |                                |                            |                                  |                                |                 |                      |          | 2025-09-30     |

Publications Selected

Publications data table displayed

To indicate a new publication select a row with no “Date Submitted” and then click on the pencil icon in the lower left corner. Complete the form and click Save. To correct information select the desired row, click on the pencil icon, update the information in the pop-up and then click Save. The publication document should be submitted on the Files Tab.



# Study Management – Publications Checklist

- The following is a checklist Publication Updates to be made by the investigator during the study.
  - ***When submitting a document for ViiV Review***
    - Complete document information
  - ***When submitting the ViiV Reviewed document for Publication***
    - Update the “Publication Status” to “Submitted”
  - ***When document has been “accepted” for Publication***
    - Update the “Publication Status” to “Accepted”
  - ***When document has been “Published”***
    - Update the “Publication Status” to “Published”
    - Complete “Citation” information

