ViiV ISS Portal

CONFIDENTIAL – FOR INTERNAL USE AND PLANNING PURPOSES ONLY

ViiV ISS Portal

Training Guide

January 2017

CONFIDENTIAL – FOR INTERNAL USE ONLY

ViiV ISS Portal Training Guide Index

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

Training Goals

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

- 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

- Available to all approved investigators at 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

- 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.

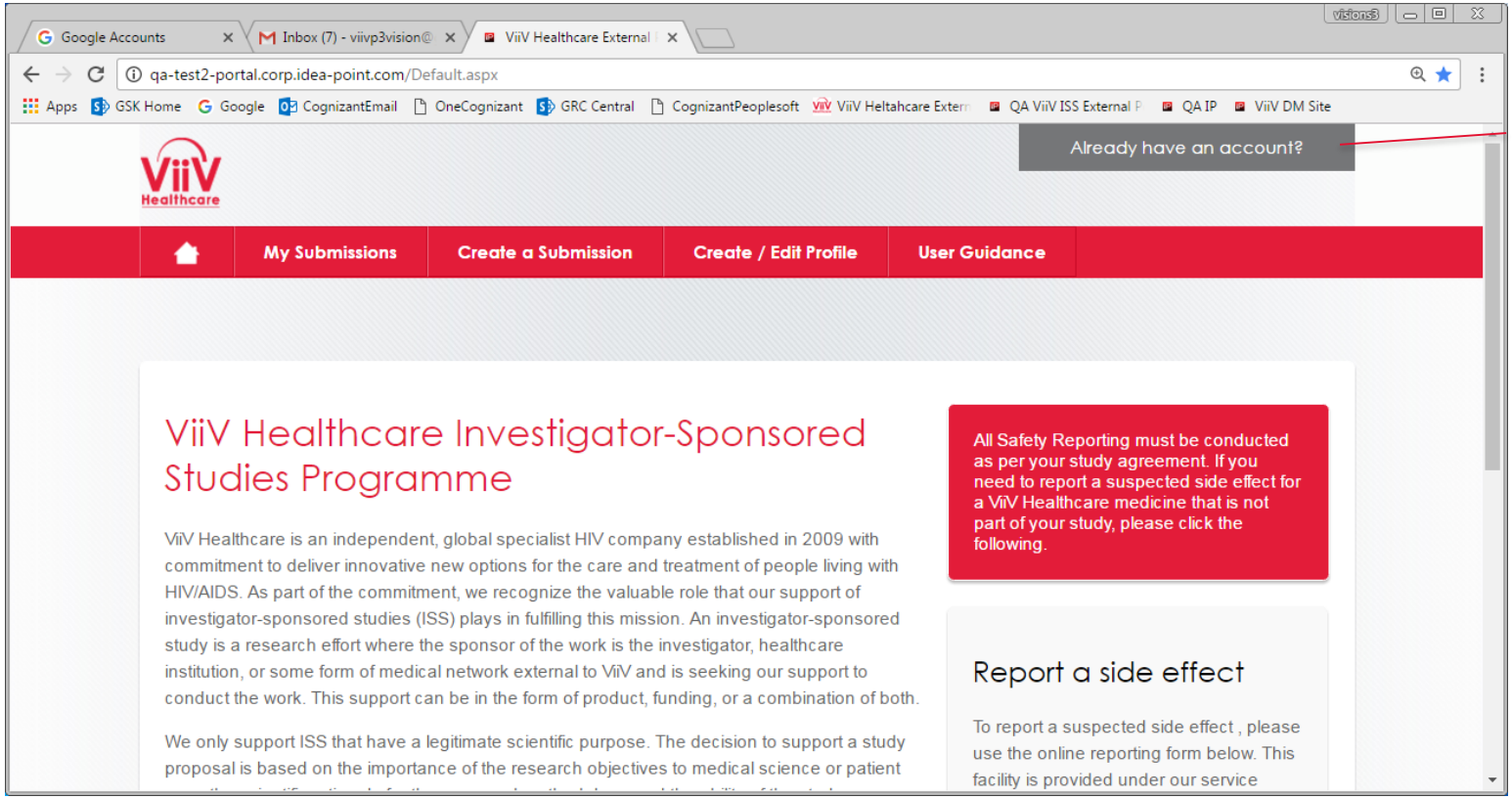
System Use Guidance

- 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

- The ViiV ISS System can be accessed by external investigators at the following URL.
  - 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.

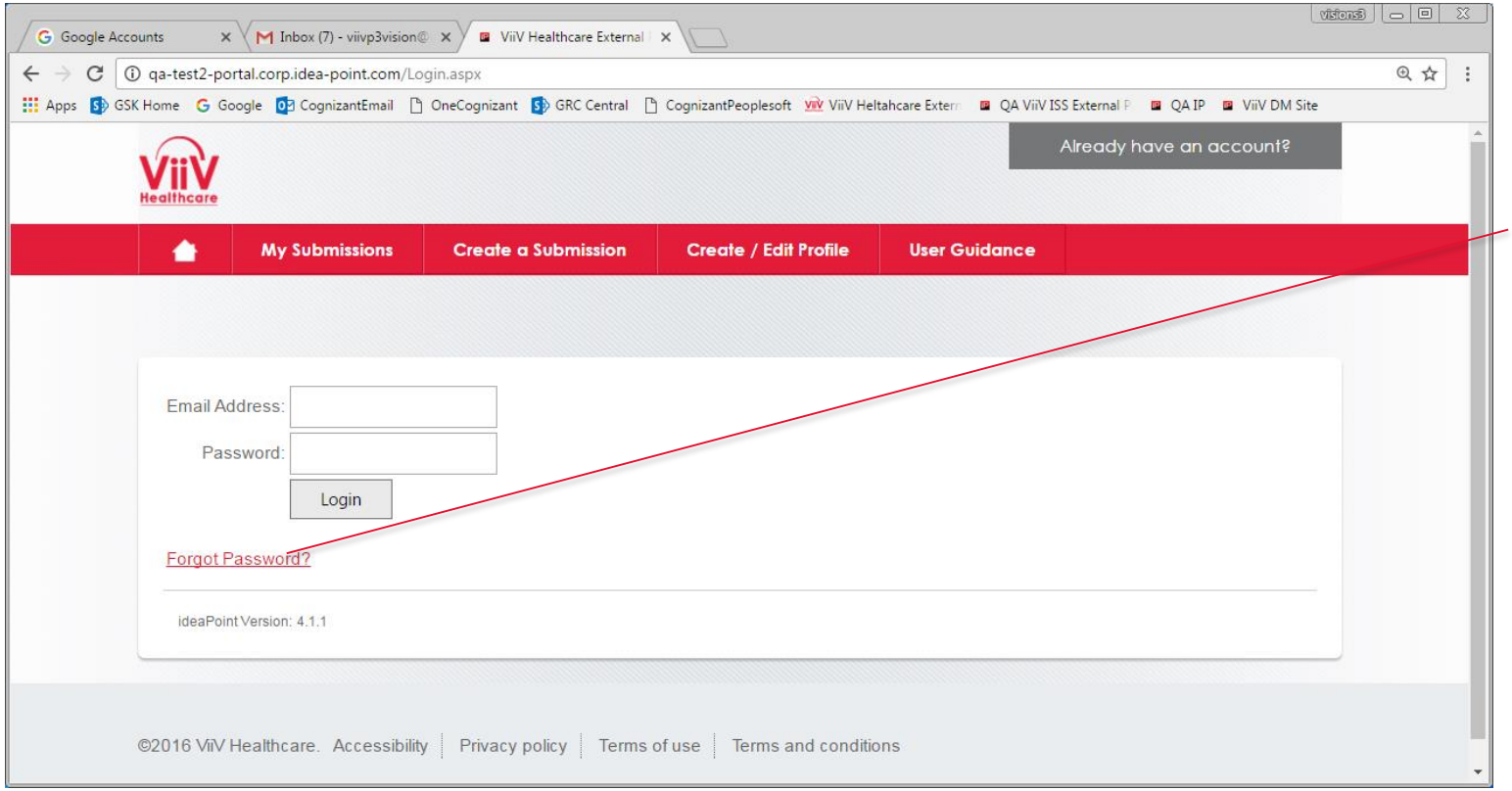
First Login (1 of 6)



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

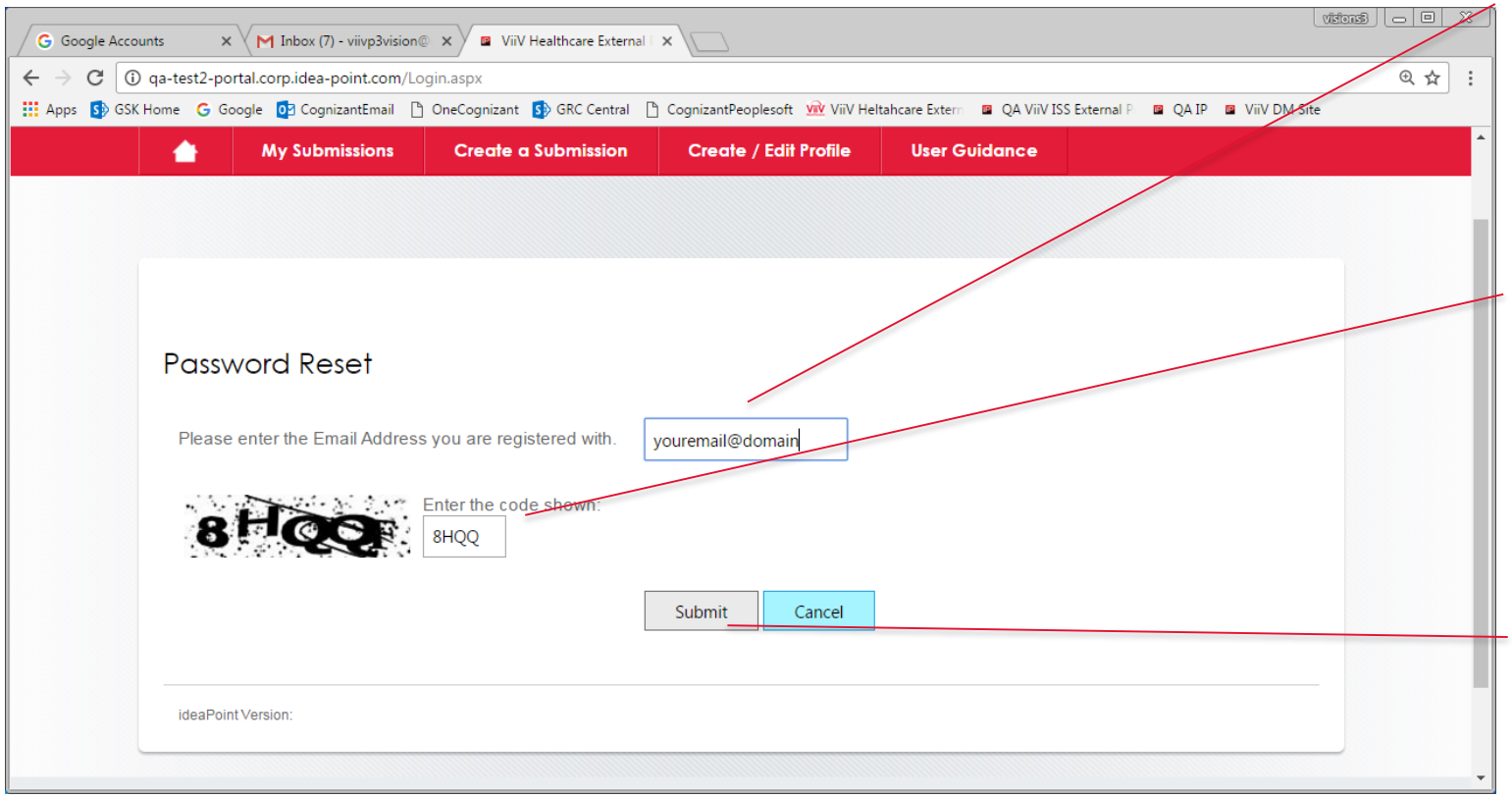
Access the system at iss.viivhealthcare.com

First Login (2 of 6)



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

First Login (3 of 6)

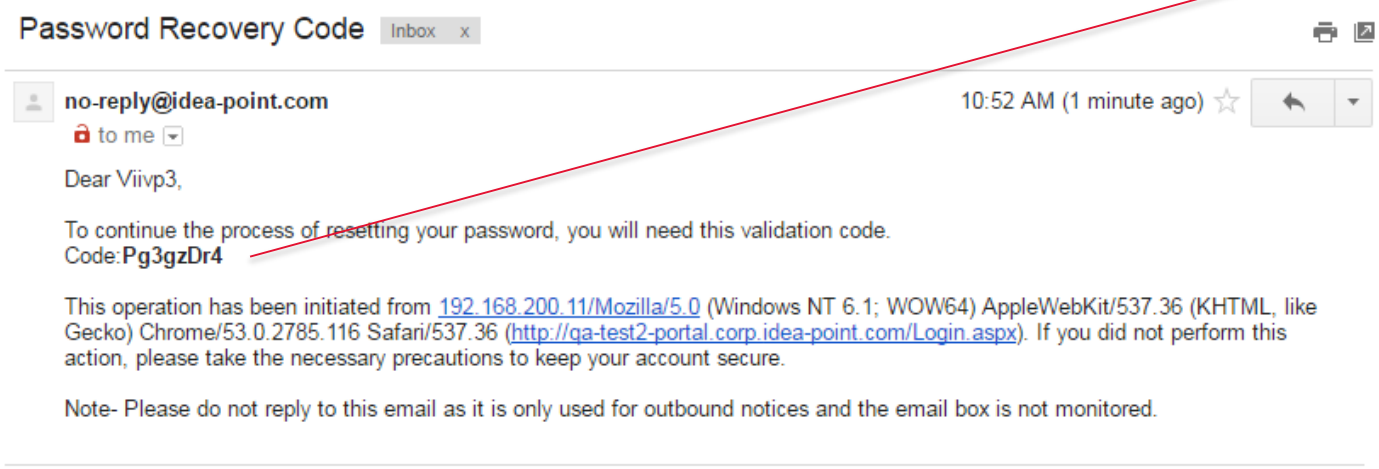


Enter your email address for the account.

Enter the characters from the captcha code in this box

Click the Submit box

First Login (4 of 6)



Password Recovery Code Inbox x

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

to me

Dear Viivp3,

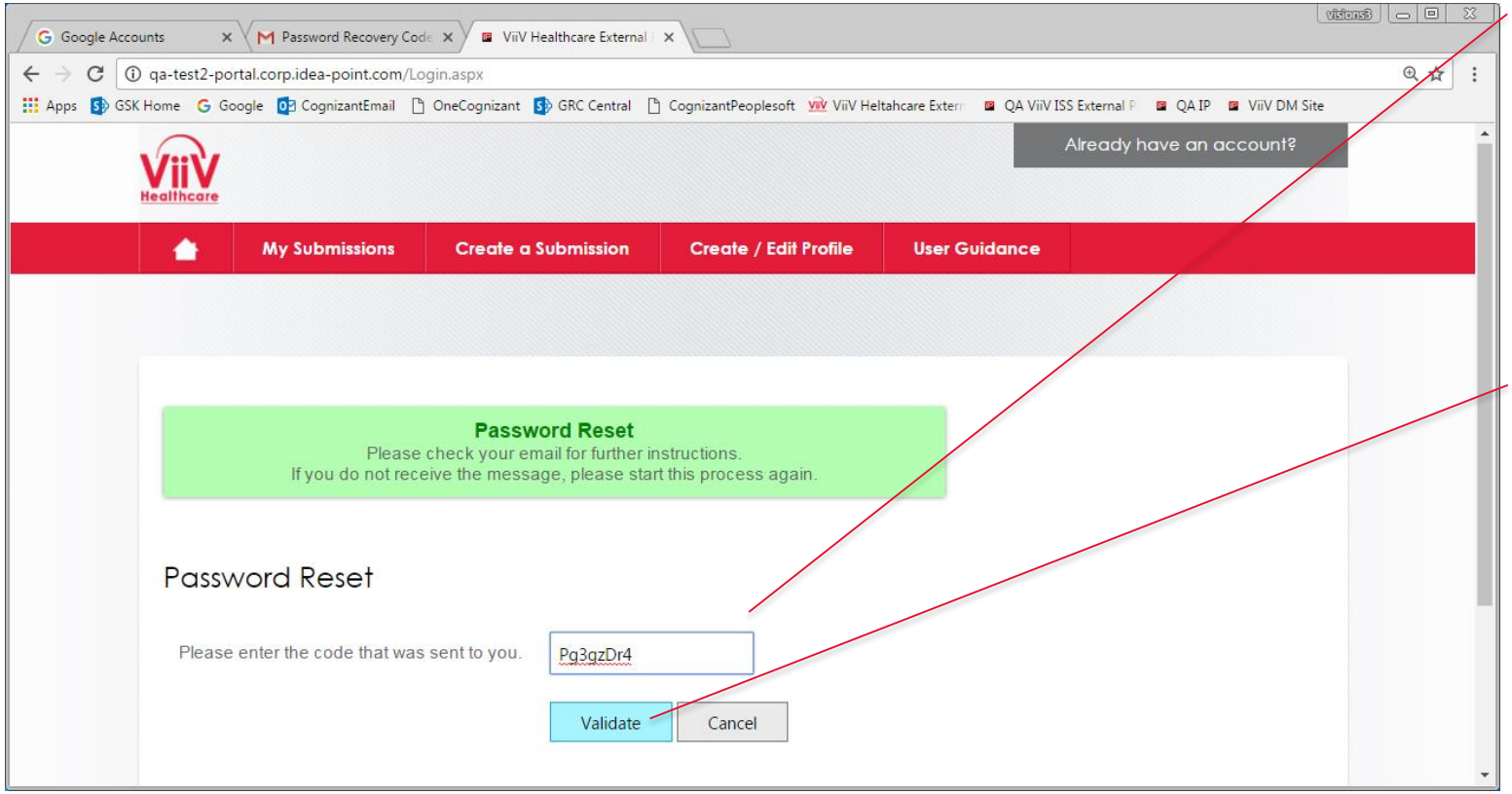
To continue the process of resetting your password, you will need this validation code.
Code:**Pg3gzDr4**

This operation has been initiated from 192.168.200.11/Mozilla/5.0 (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.

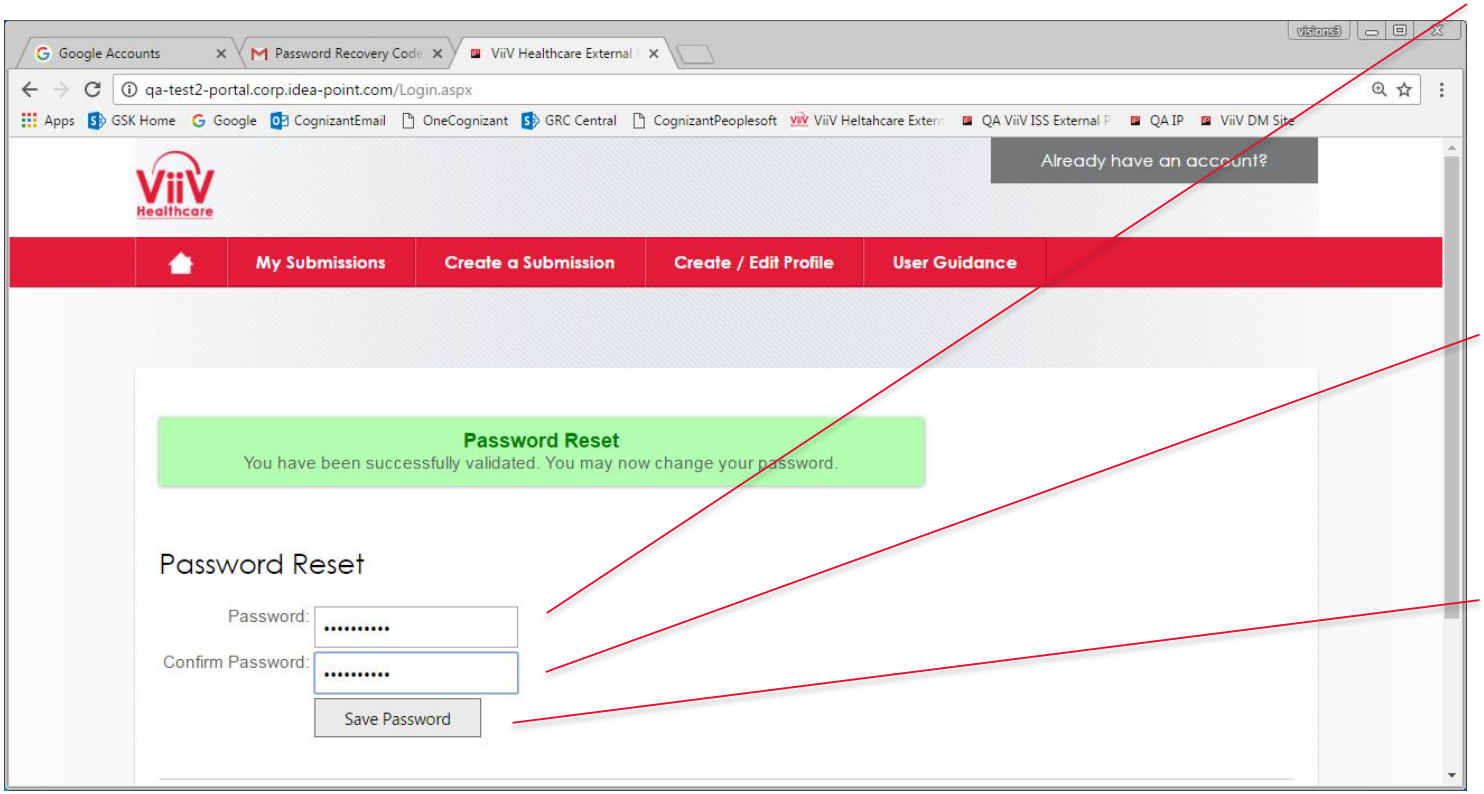
First Login (5 of 6)



Enter the code from the email in the text box

Click the validate button to finish the verification process.

First Login (6 of 6)



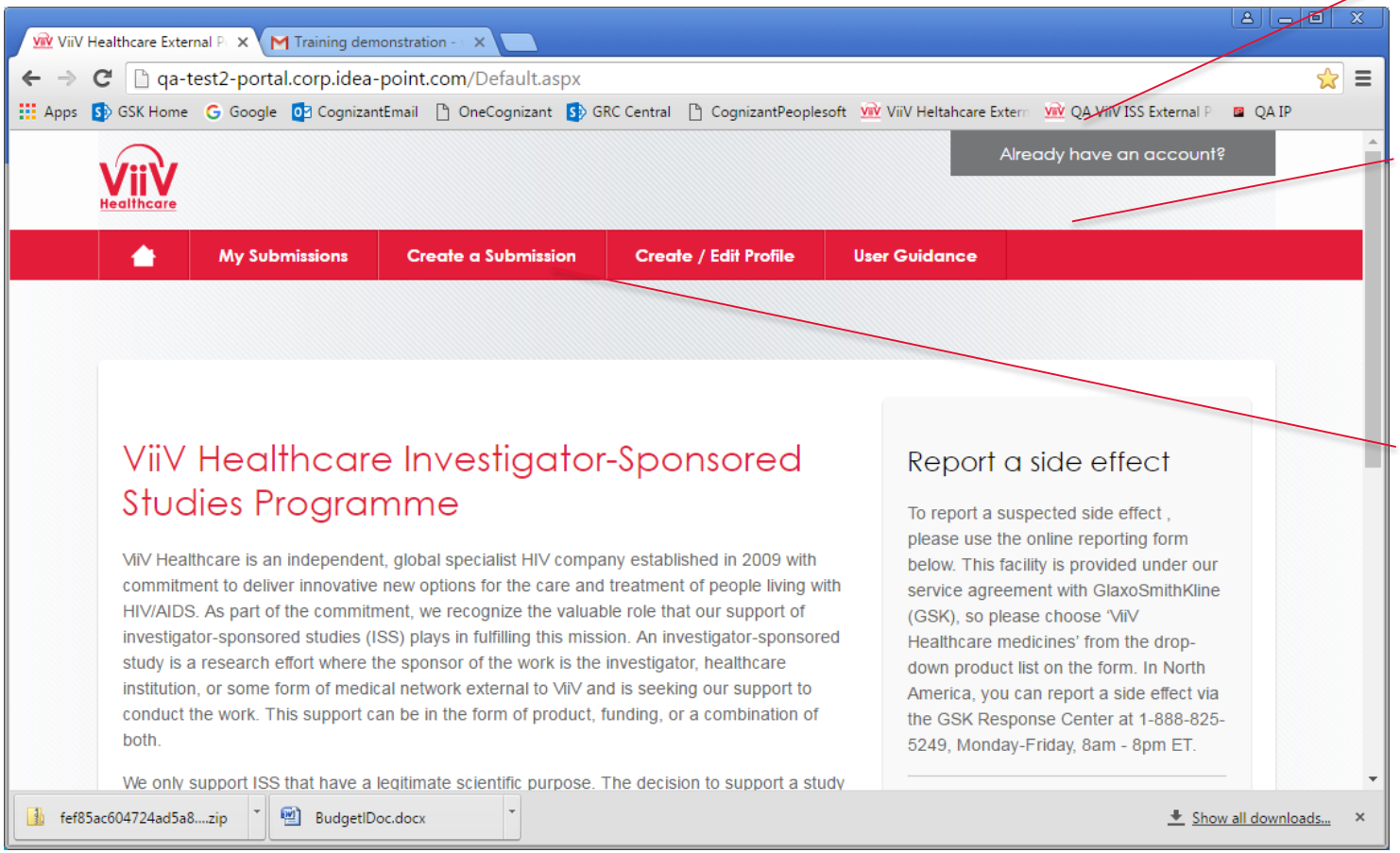
Enter the NEW password you want to select in the Password field

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



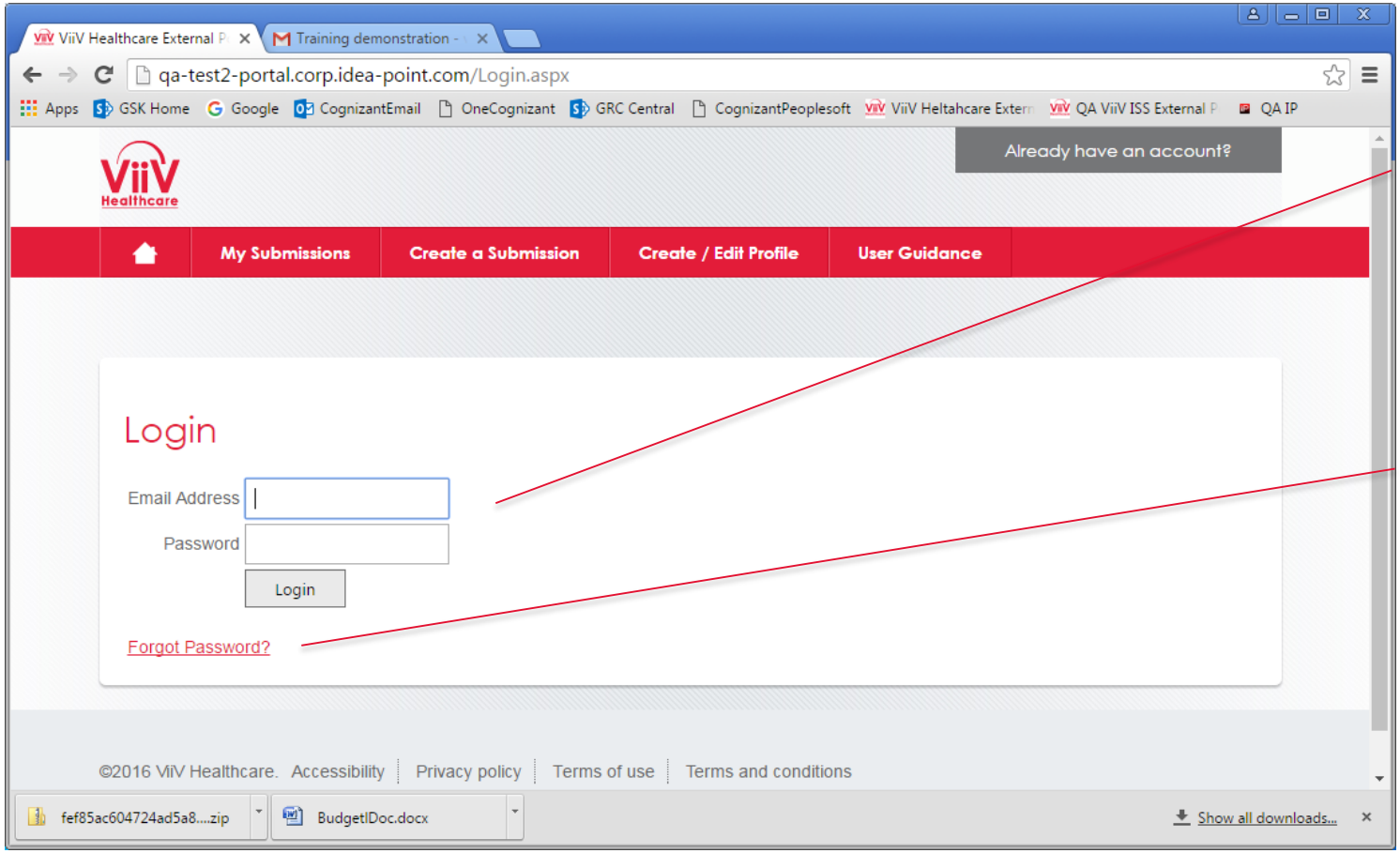
Click here to login.

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

Login to the System

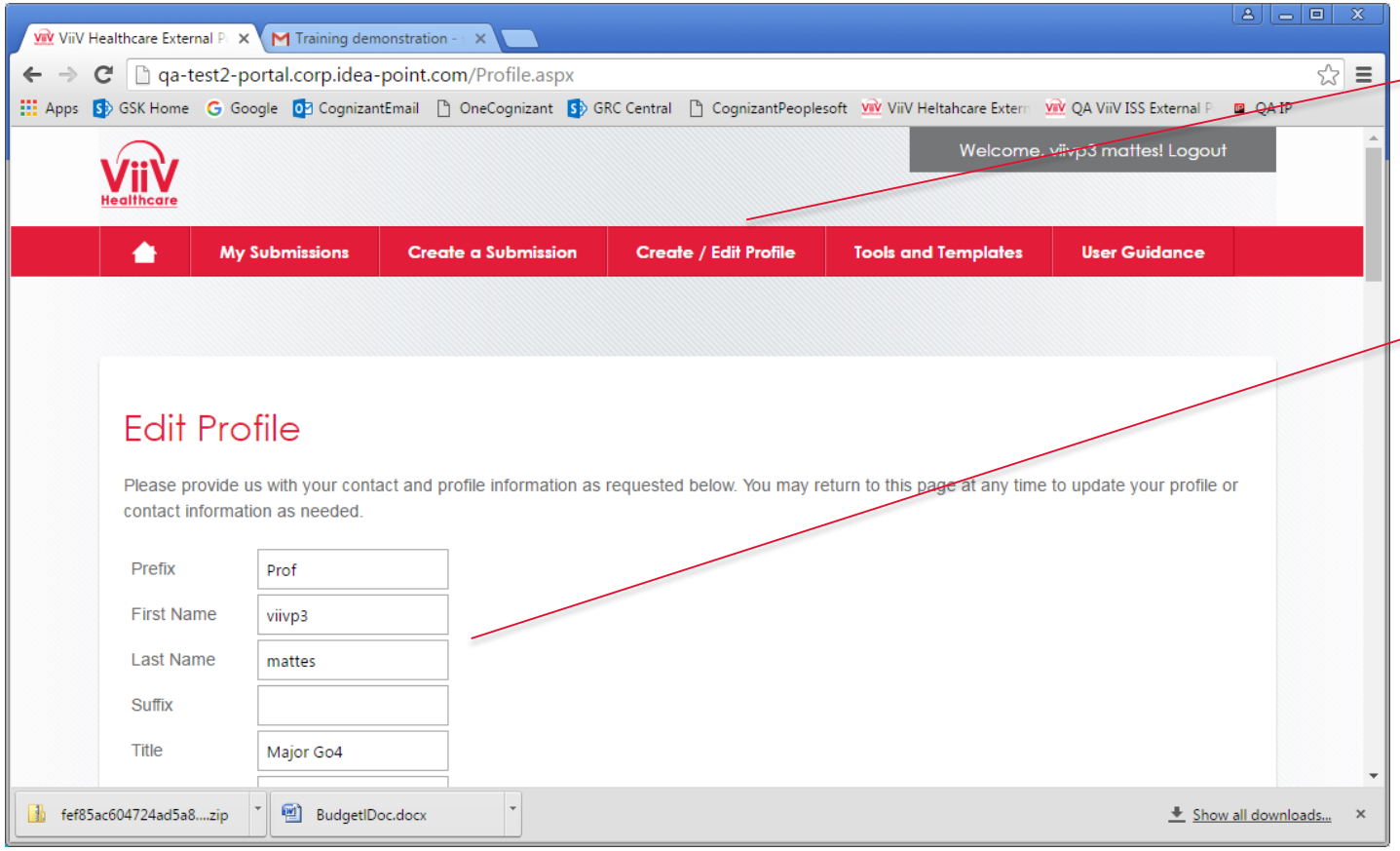


Enter email address and password to Login

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)



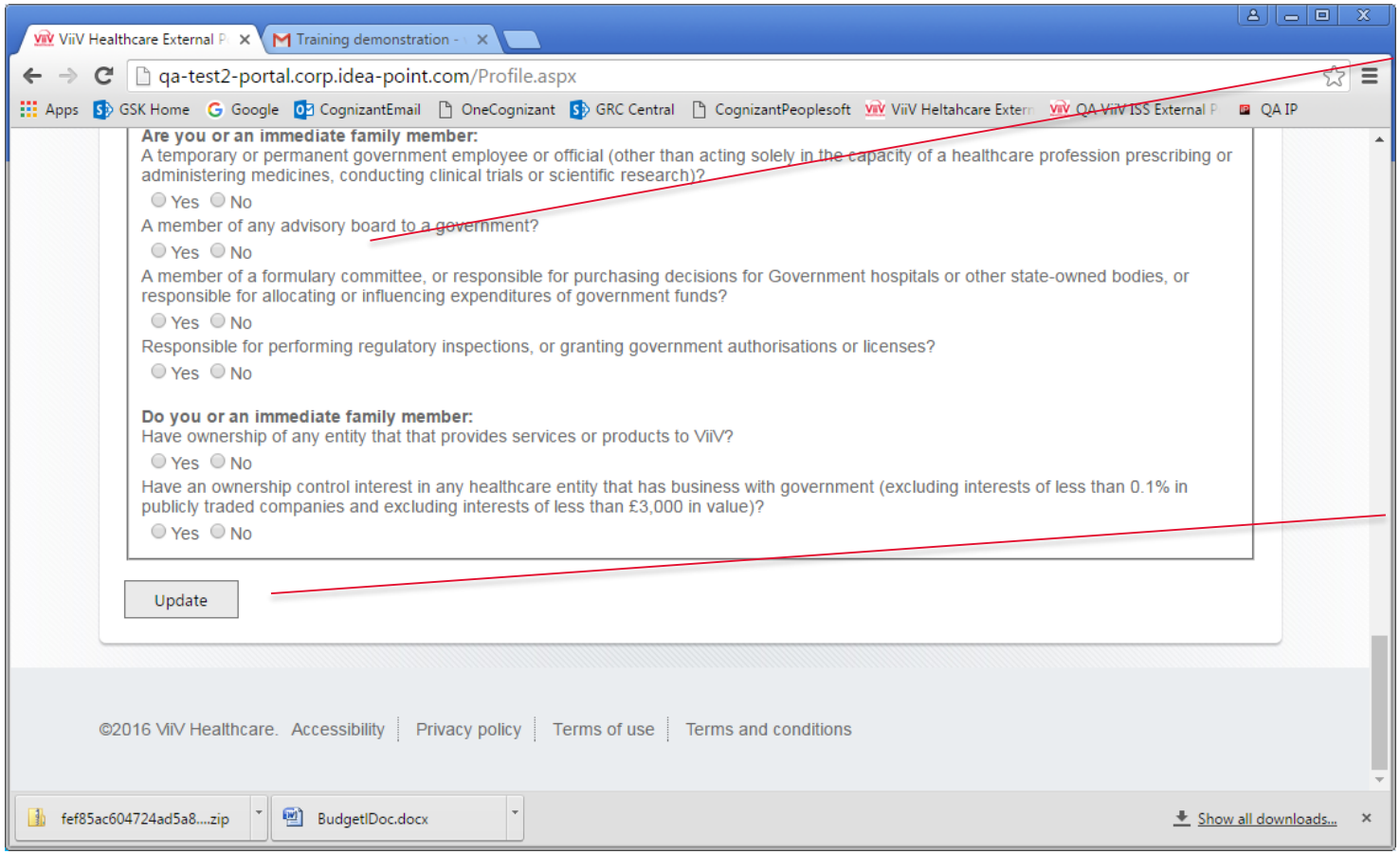
Select Create/Edit Profile

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)



Answer all the questions on the form

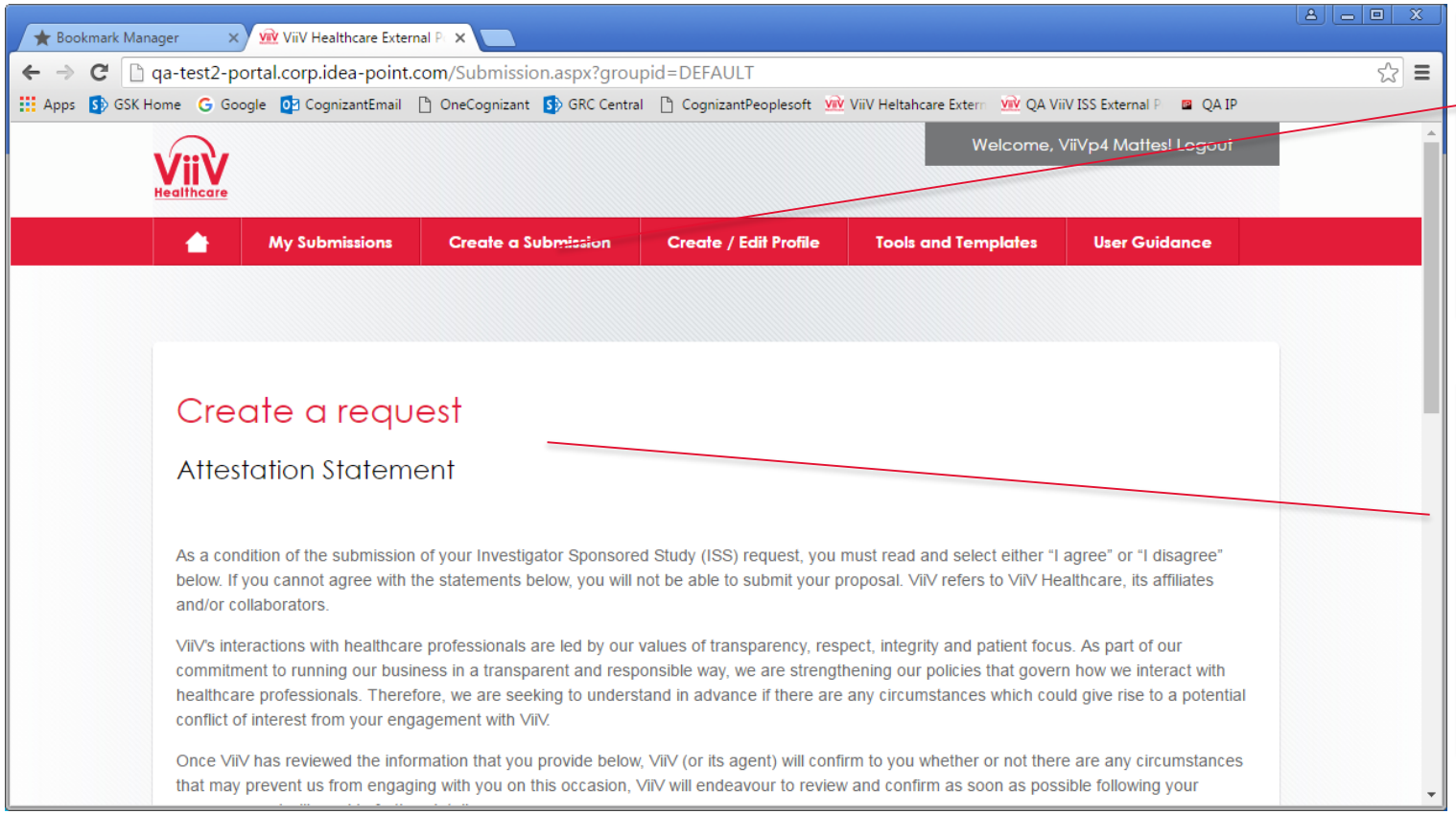
Click "Update" to save your changes.

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

- 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)

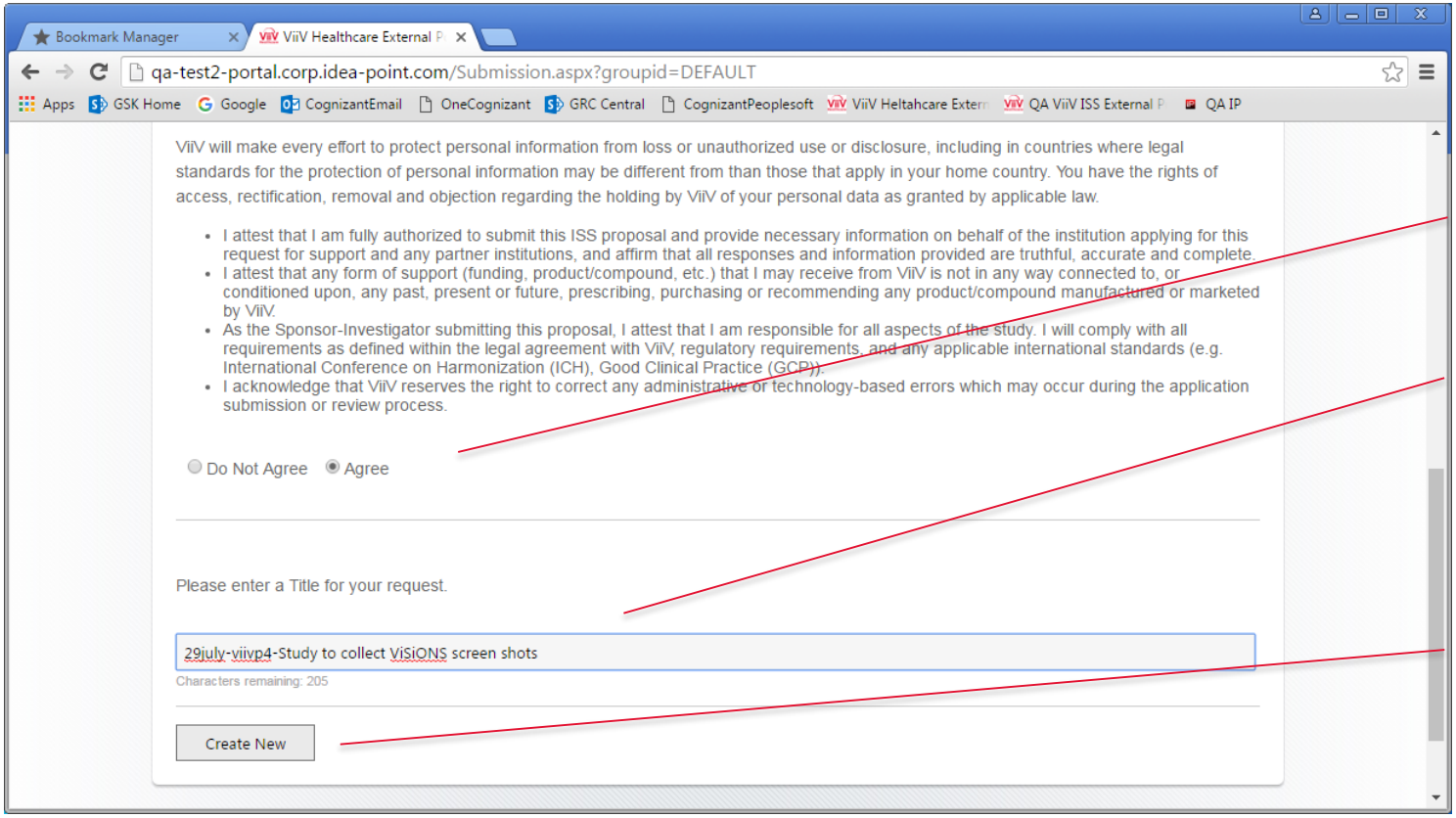


Select Create a Submission to start the proposal process.

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)



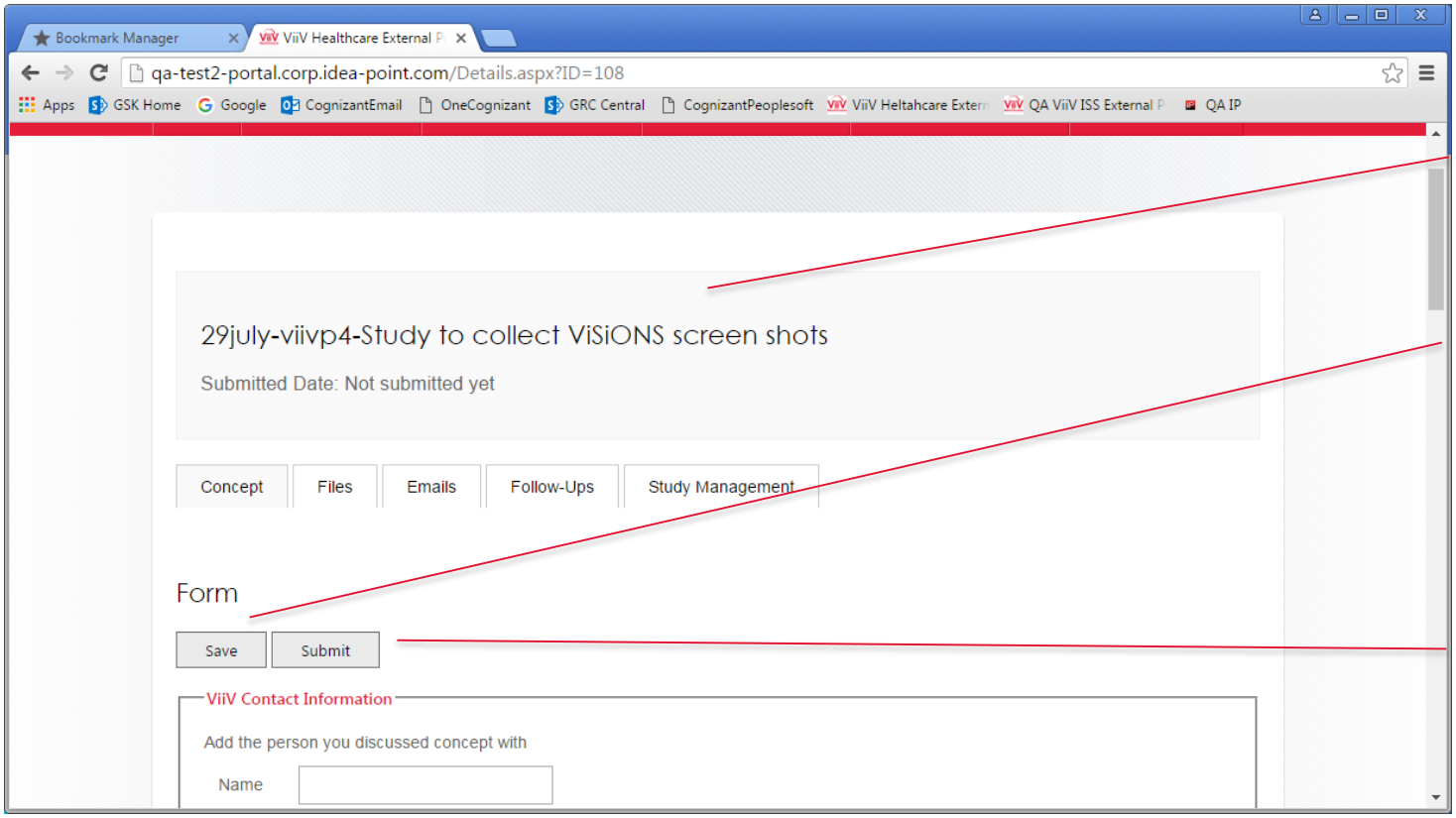
Select the "Agree" or "Do Not Agree" option

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)



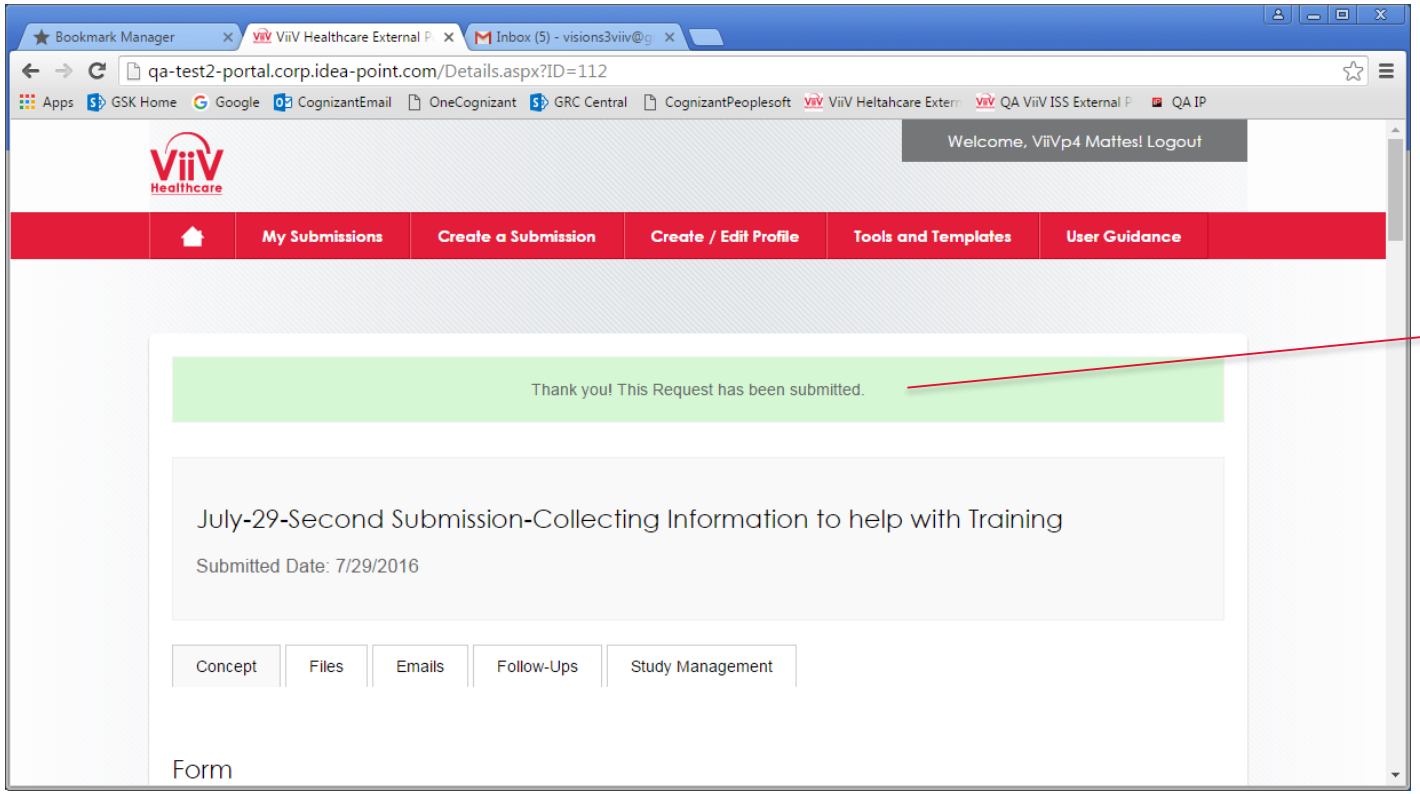
The concept form will be displayed

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)



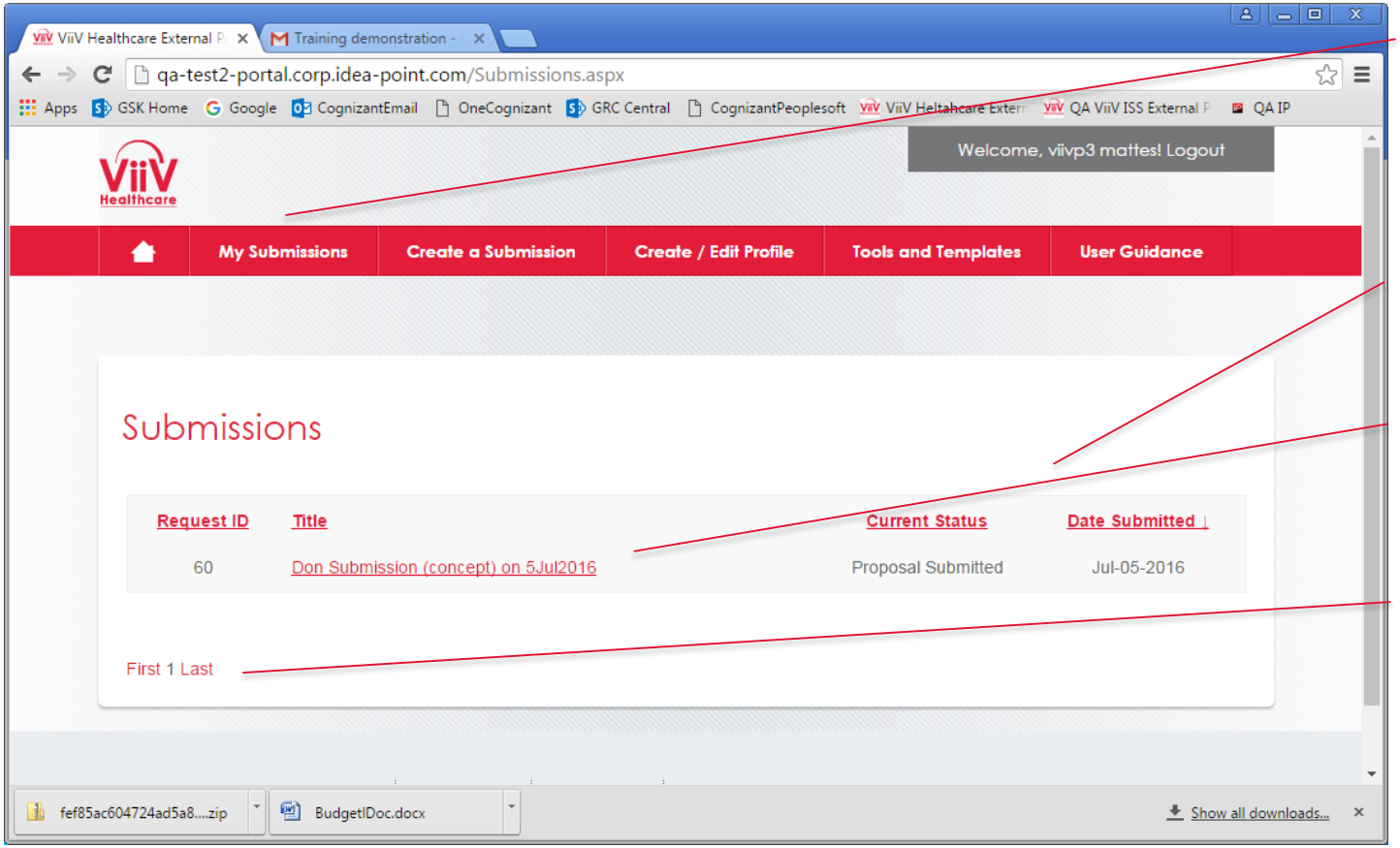
A confirmation is displayed when the form is submitted.

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

- 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



Select "My Submissions"

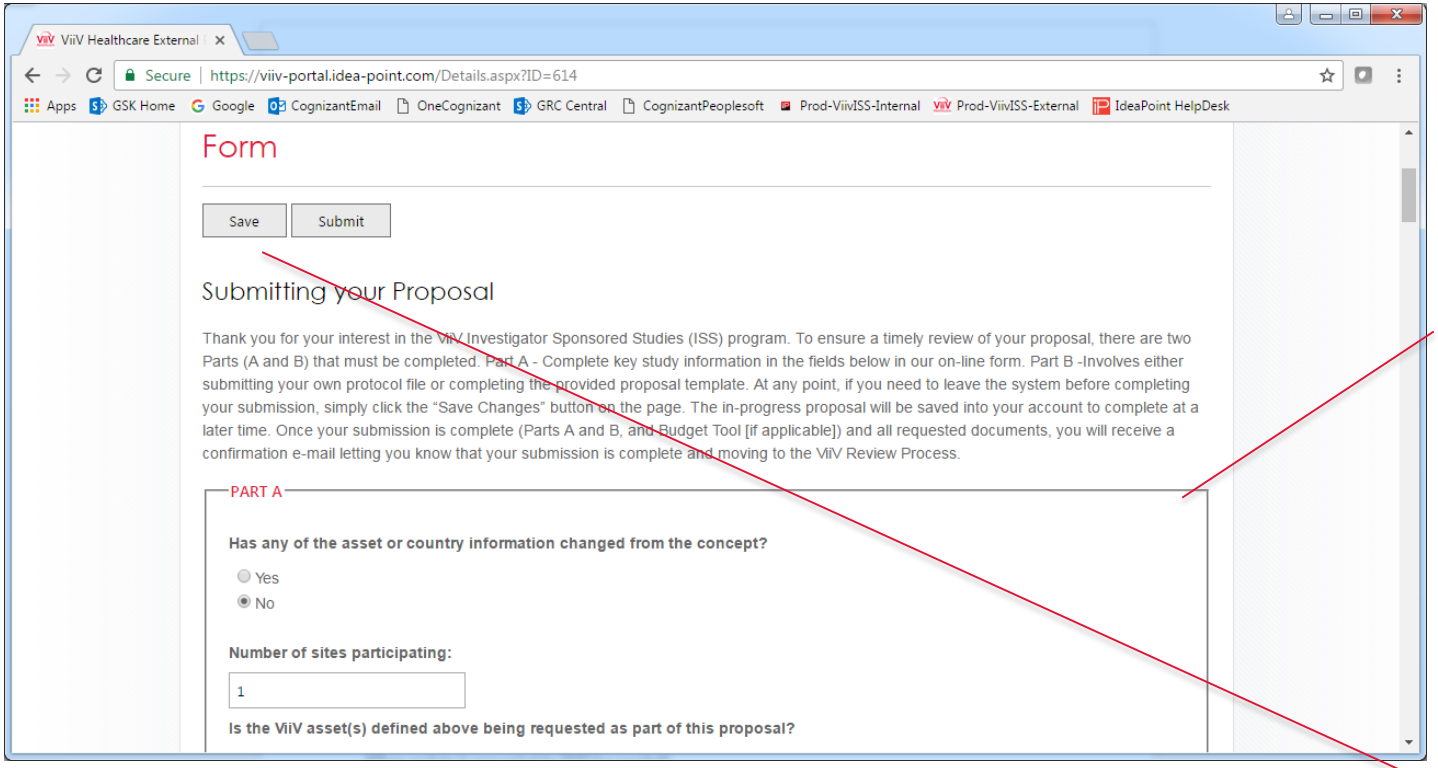
Current status displayed

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)

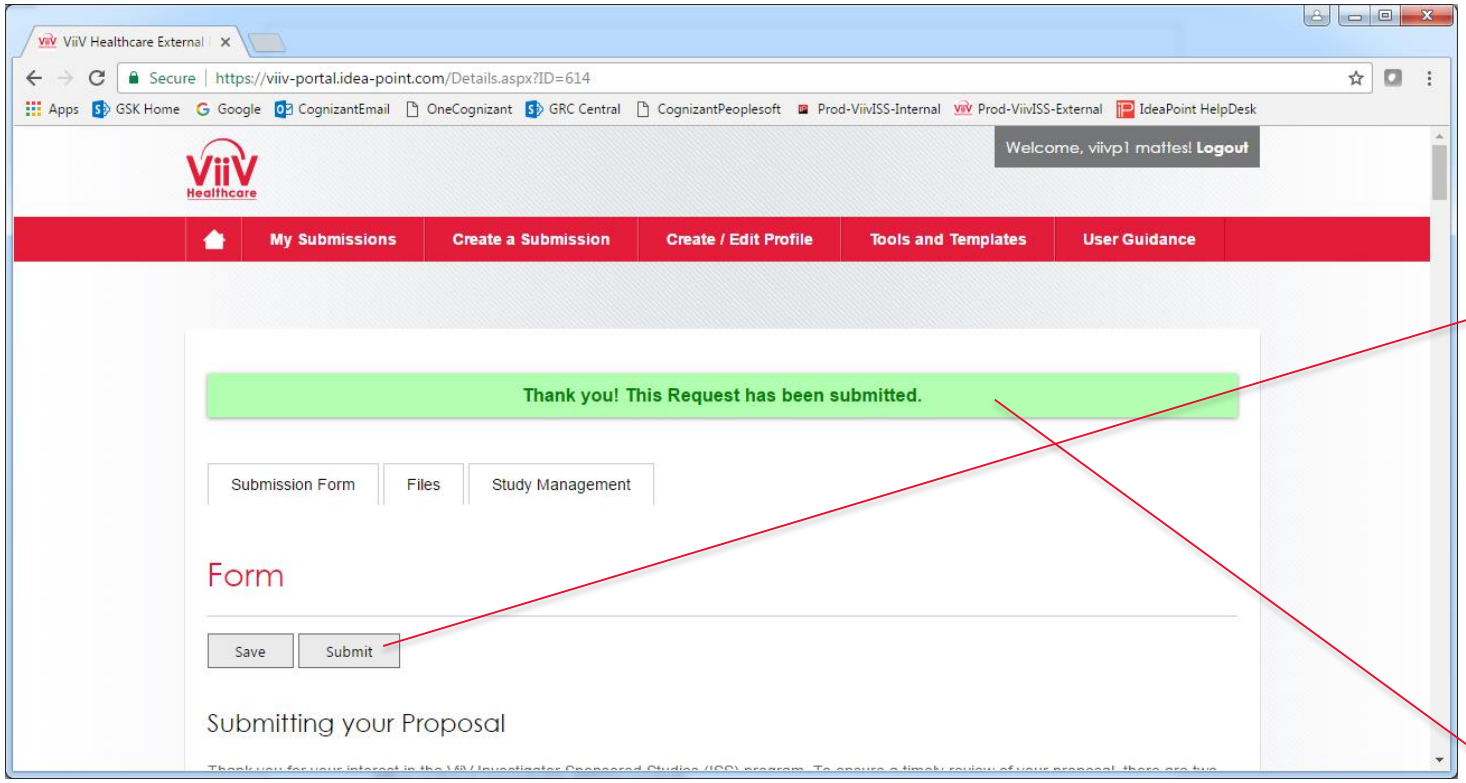


A form to provide the complete proposal information is displayed.

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)

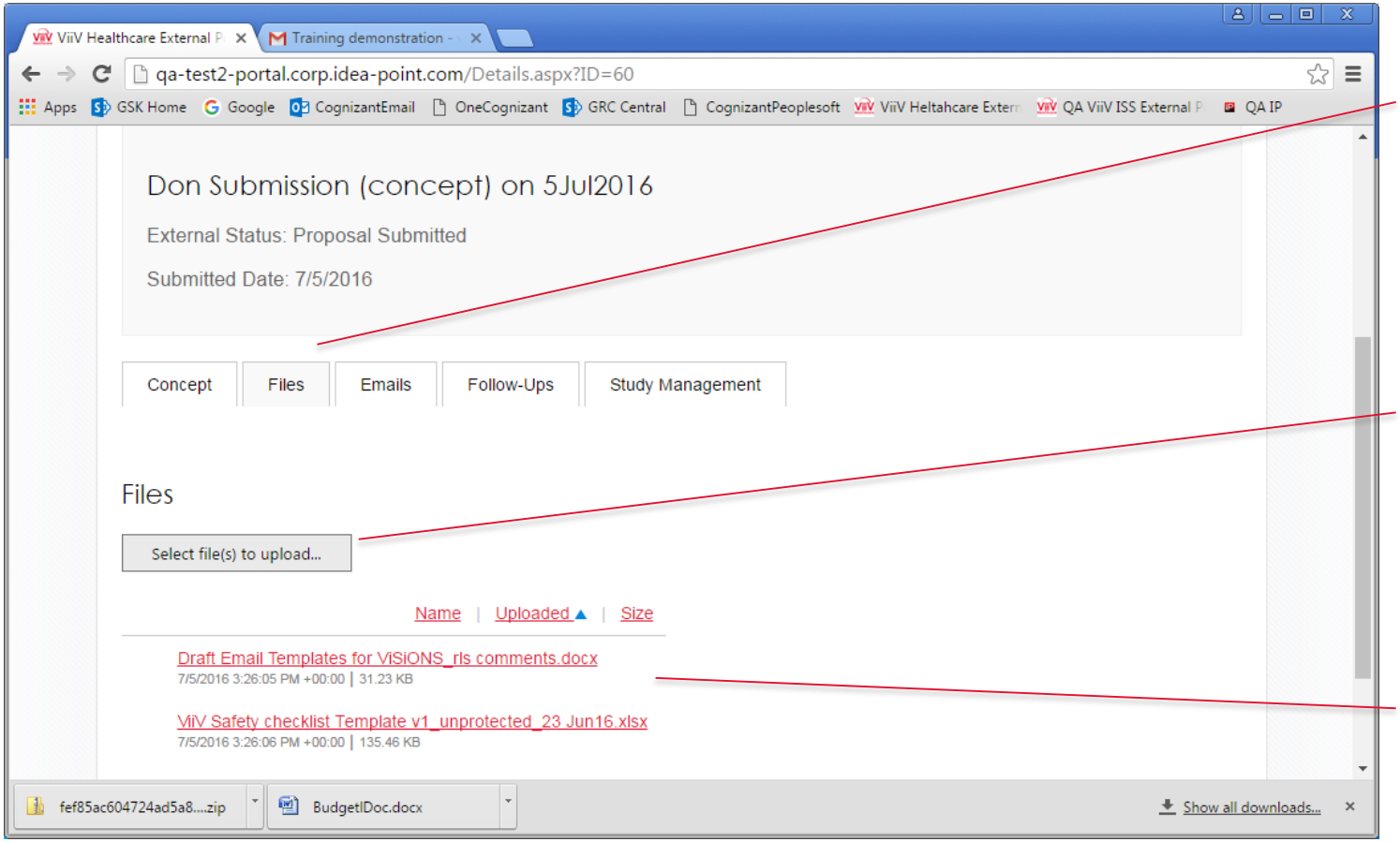


Select the Submit button to validate the entries and submit the proposal.

A confirmation is displayed when the form is submitted.

One 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)



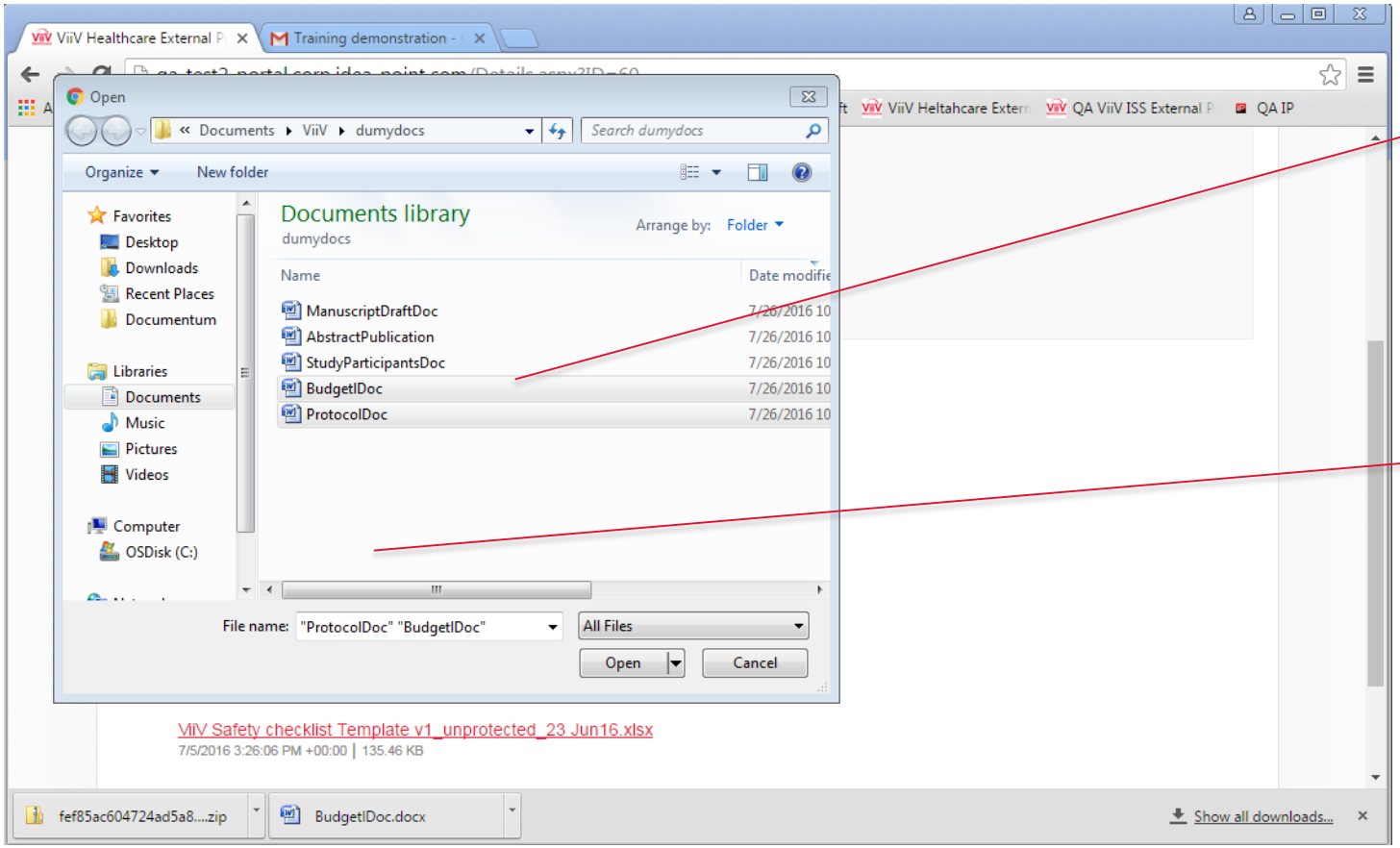
Select a submission and then select the “Files” tab

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)

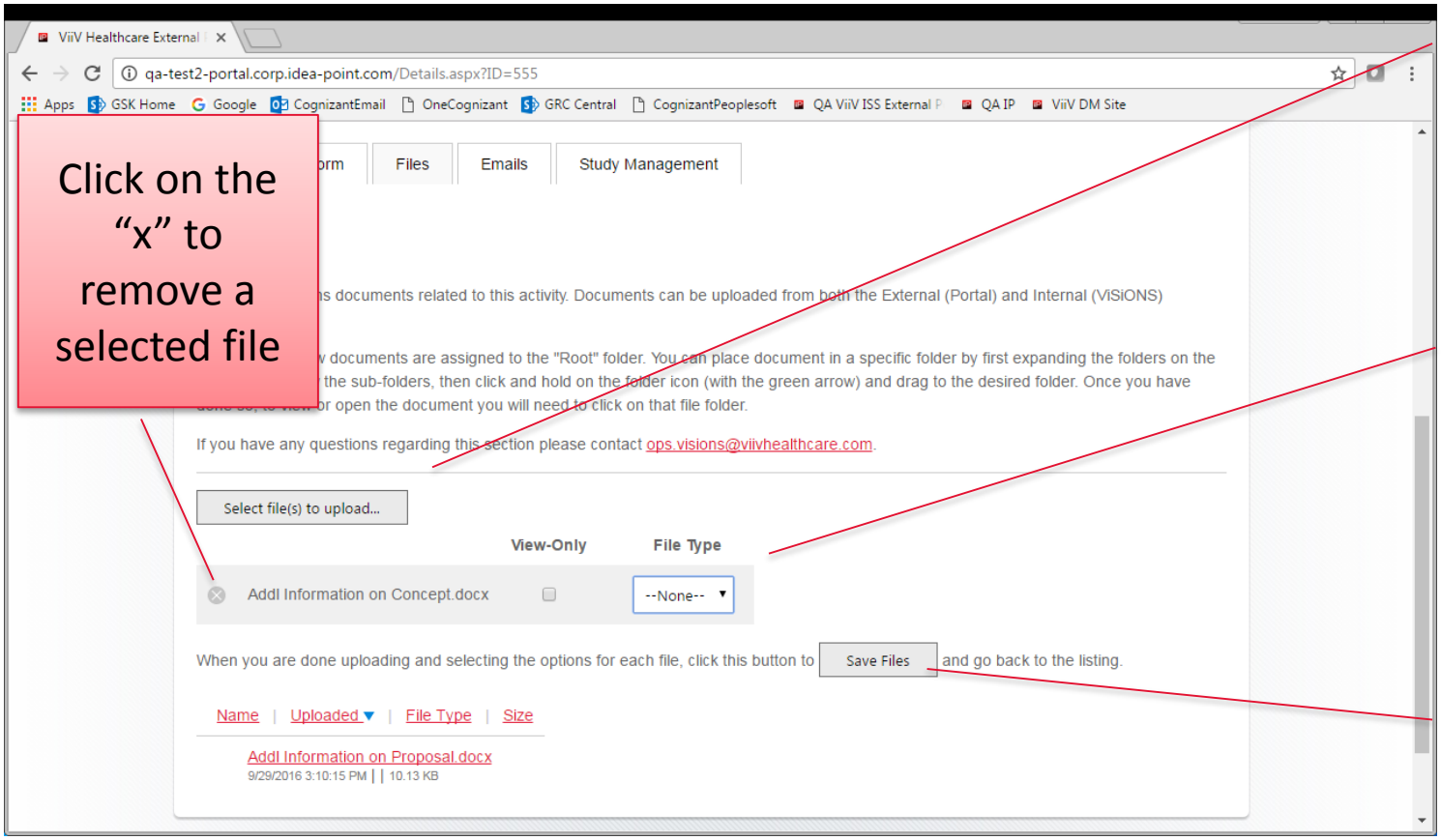


Select files you want to upload from the window

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 widow.

Submitting/Sharing Files (3 of 4)



Click on the "x" to remove a selected file

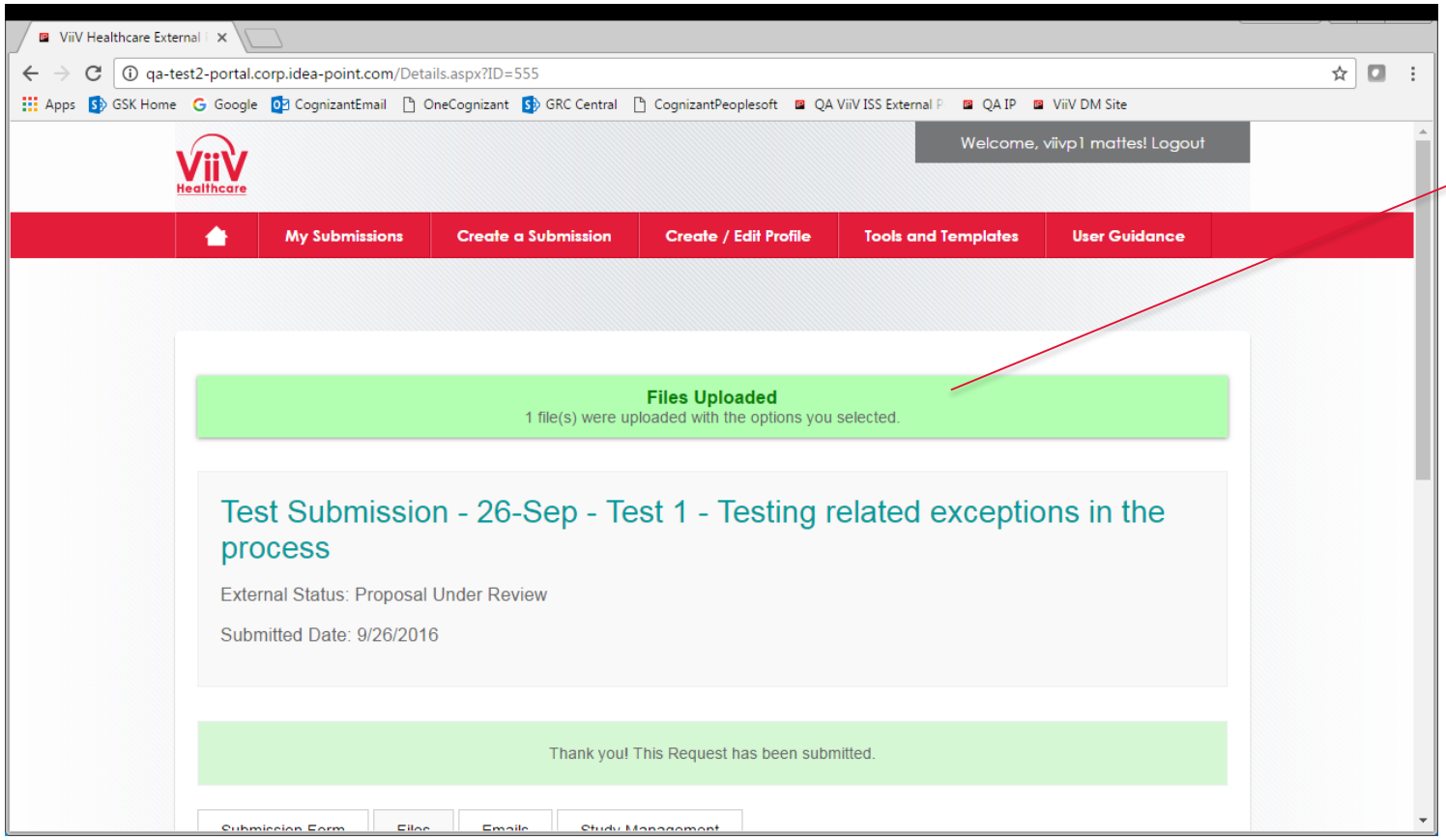
Selected files displayed for confirmation

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)



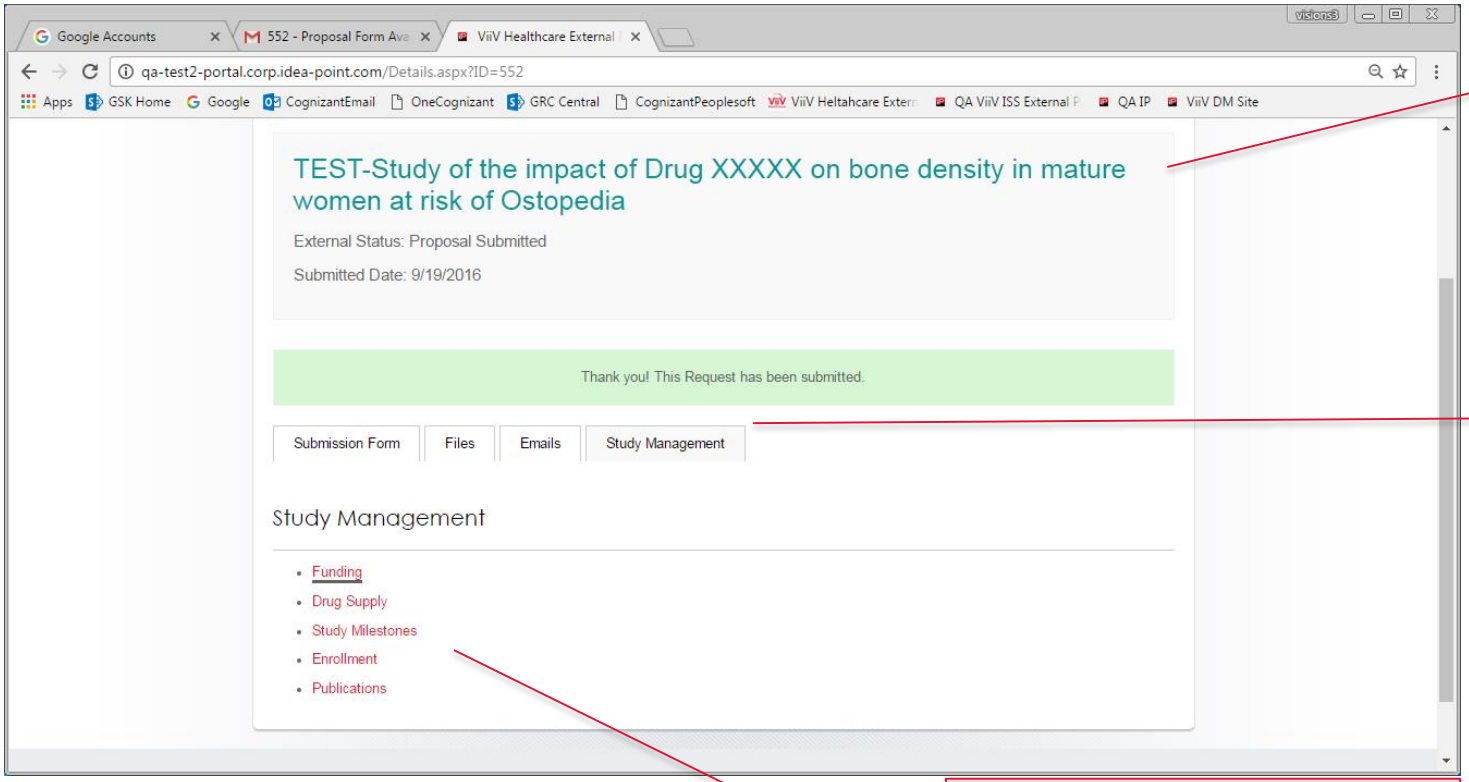
A confirmation banner will be displayed when the process is complete.

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

Study Management Information

- 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 1st Screening visit to Last Subject Last Visit)

Study Management Information Page



Submission title and status are at the top

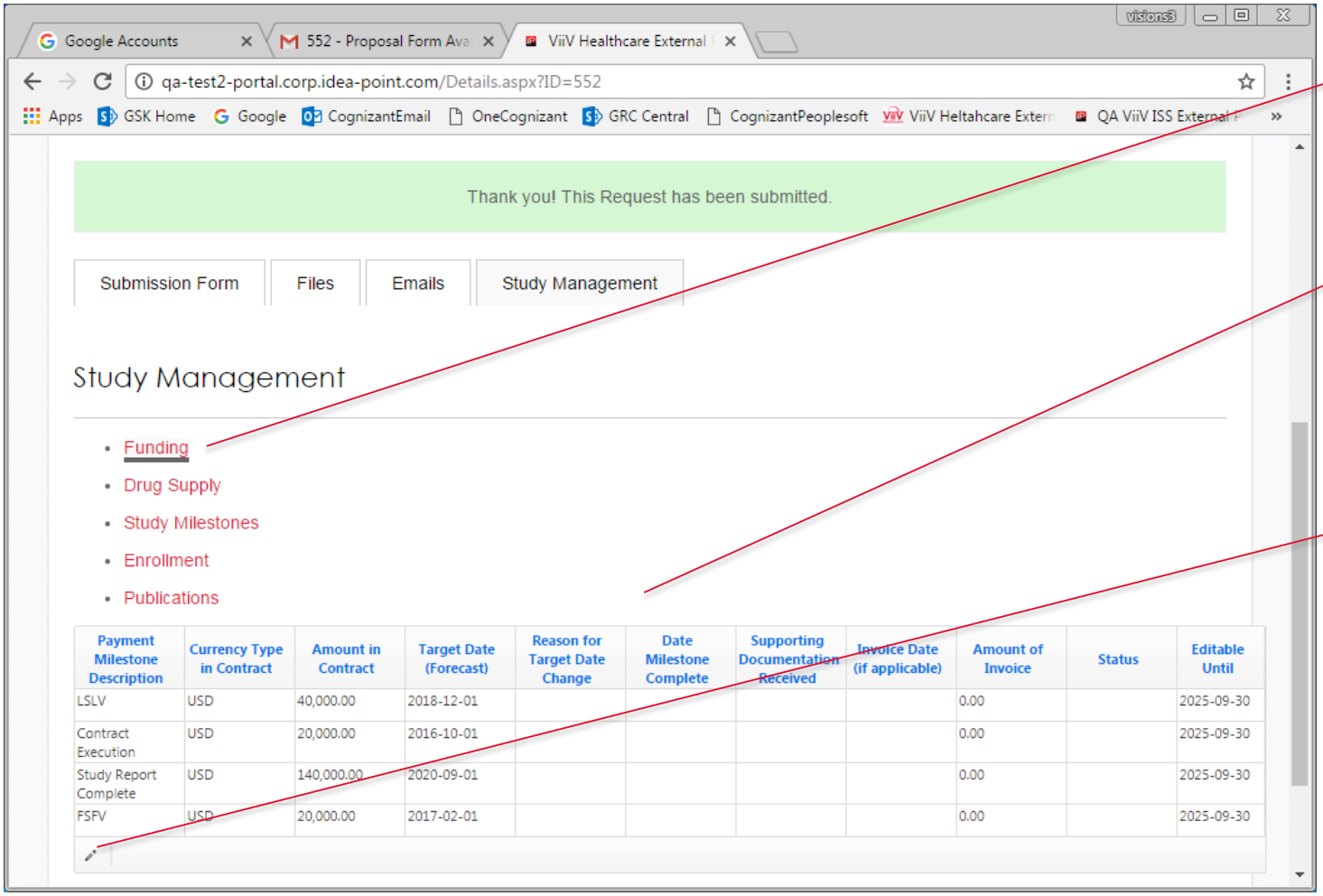
Study Management tab selected

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)

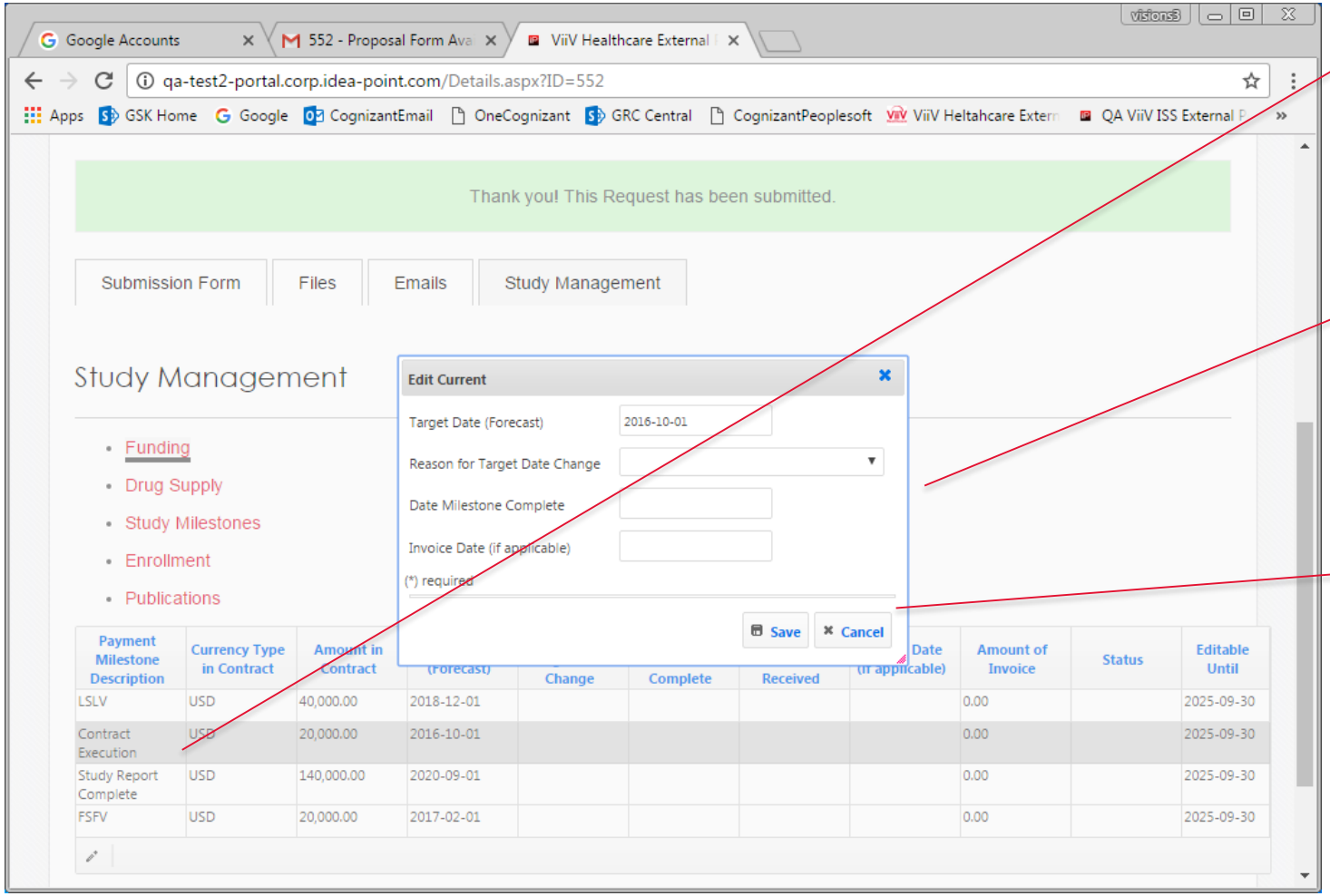


Funding Selected

Funding data table displayed

Pencil Icon for editing rows

Study Management Information – Funding (2 of 2)



Funding Data row Selected

Funding data editing form display

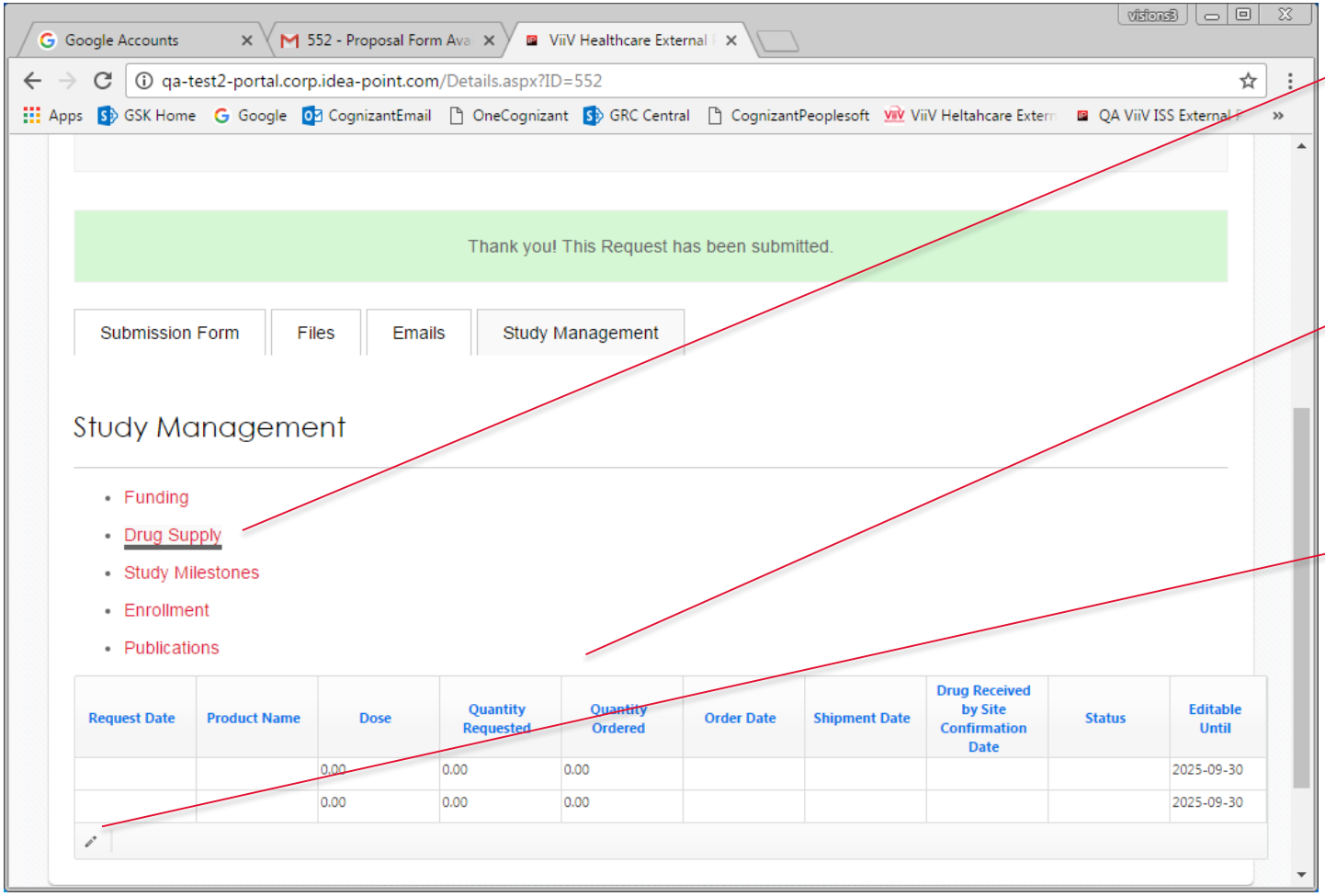
Save and Cancel buttons

To edit a row. Select the row and then clock 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

- 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



Drug Supply Selected

Drug Supply data table displayed

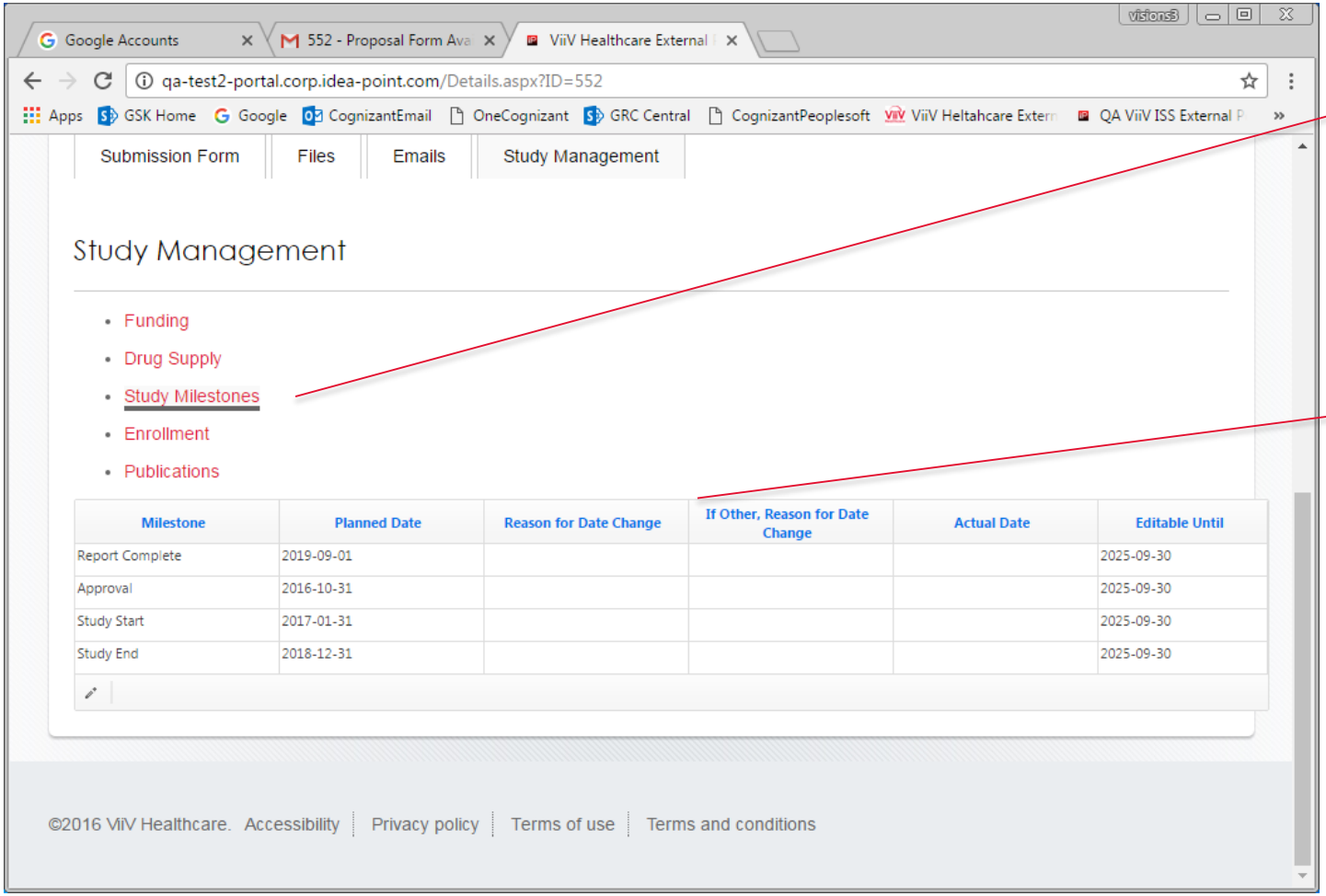
Pencil Icon for editing rows

To edit a row. Select the row and then clock 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

- 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 Milestones Selected

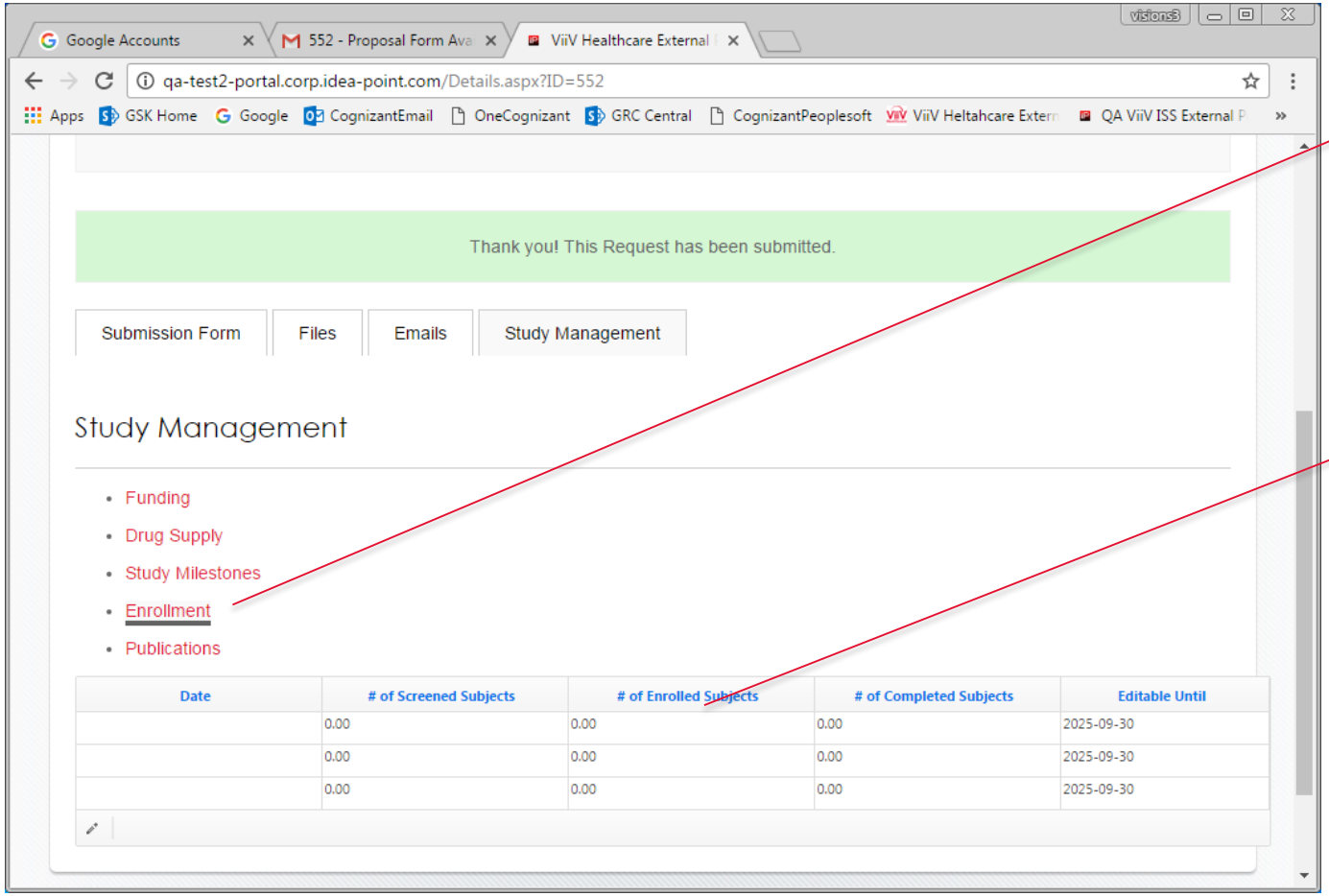
Study Milestone data table displayed

To edit a row. Select the row and then clock 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

- 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



Enrollment Selected

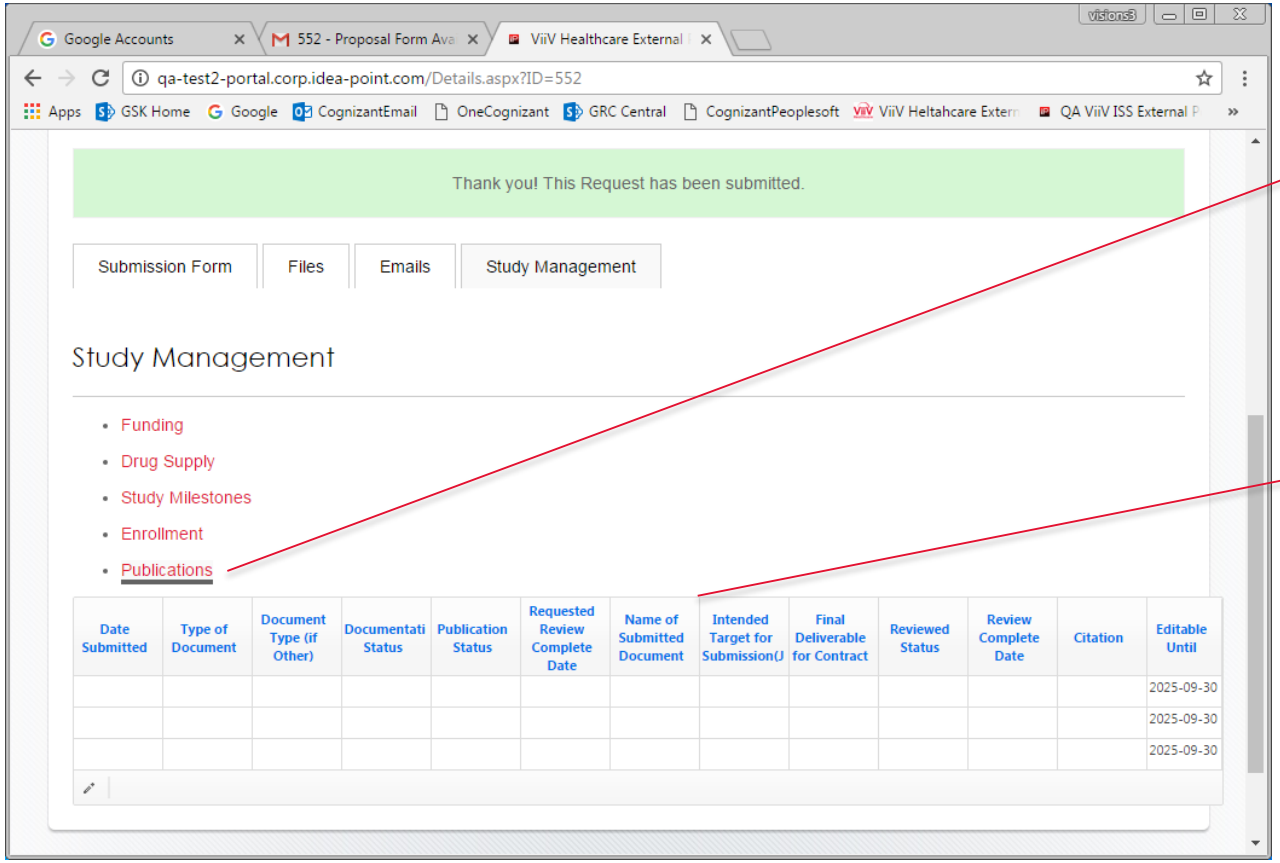
Enrollment data table displayed

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

- The following is a checklist for Enrollment Updates to be made by the investigator during a Clinical study with Human Subjects.
  - ***Monthly – From 1st 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



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