PATH

Pomalidomide for the Treatment of Bleeding in HHT

Website User Guide

https://path-hht.org

Jun 2, 2019

Version 1.0

Contents

Please email pathsupport@rti.org if at any time you have questions or require assistance.

I. Introduction

Hereditary Hemorrhagic Telangiectasia (HHT) is a genetic disorder that affects 1 in 5,000 people worldwide. Malformed blood vessels cause excessive bleeding from the nose (epistaxis) and gastrointestinal (GI) tract, requiring medical treatment and impairing quality of life. There are no effective medical therapies for HHT.
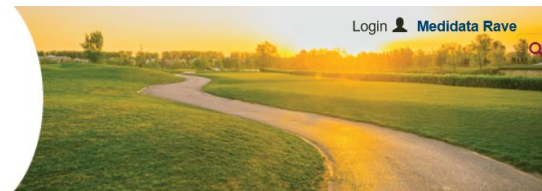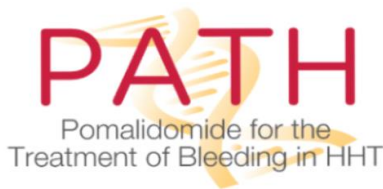
The PATH study is exploring the use of an oral medication called pomalidomide for the treatment of nosebleeds in HHT at 10 research centers across the United States. Adults suffering from HHT with moderate to severe nosebleeds (epistaxis) who require iron infusions or blood transfusions are eligible. During the 6-month study, patients might receive either pomalidomide or a matching placebo (sugar pill) in addition to their usual care.

RTI International, in the role of the Data Coordinating Center for PATH, has developed a website designed for PATH information sharing with the general public, as well as for information dissemination services for investigators and staff to facilitate data sharing. This document provides an overview of the PATH website as well as operation instructions for members of the study teams.

II. Website Overview

The PATH website is divided into public and restricted sections.

The public section with unrestricted public access and is intended for general information sharing for HHT patients, researchers, clinicians, and advocates to help drive understanding of HHT and improve the lives of members of the HHT community.

The restricted section access is limited to individuals with valid usernames and passwords and is intended only for document and information sharing within the PATH project research teams.

The PATH website must not contain any study subject information or related PHI/PII.
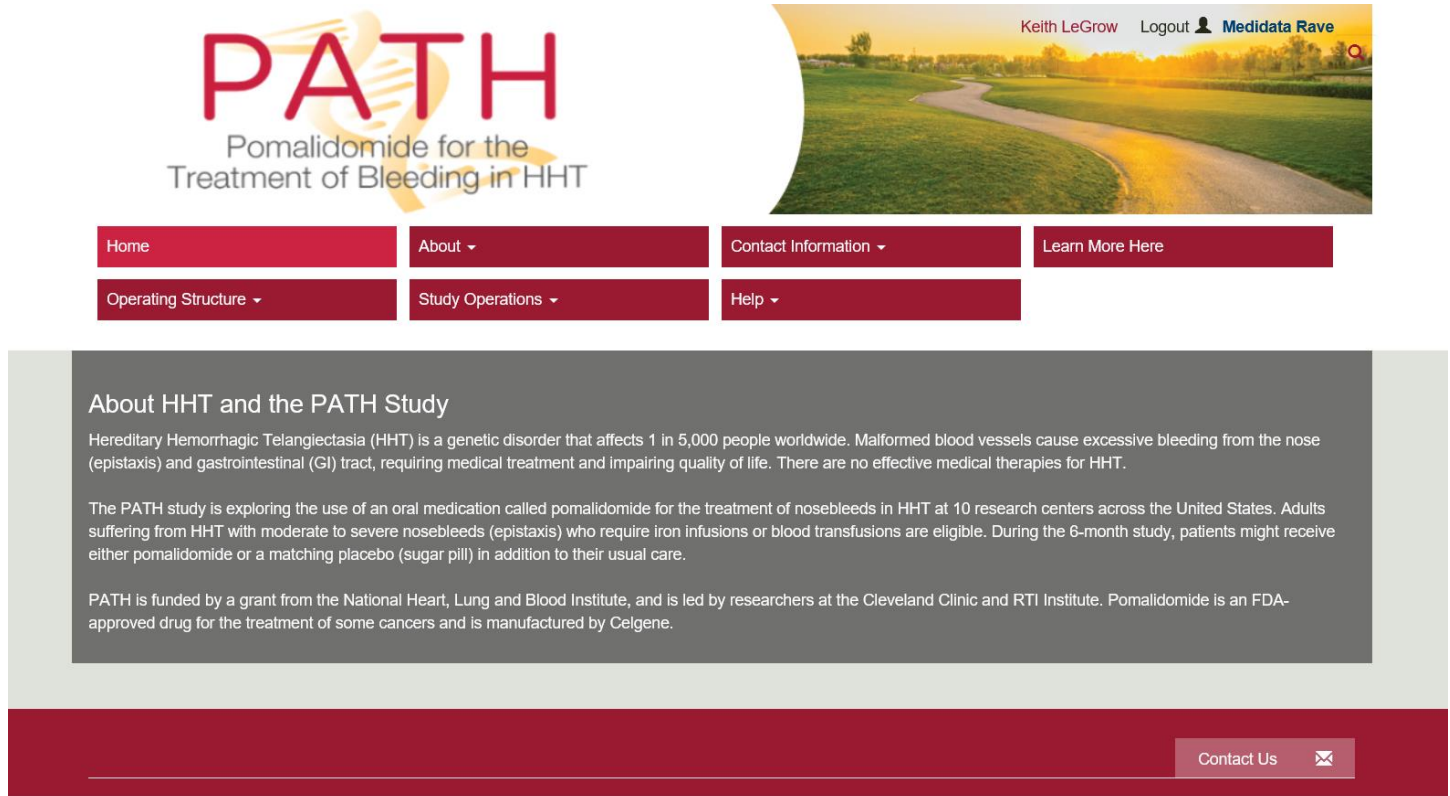
III. Account Activation

The system administrator will create your account. All study team members who require website access shall have their accounts created automatically. Your level of access will be based on your affiliation and your role within the Study. You will receive an e-mail notifying you of your account creation.

Your username and the email address used for all website-related communications will be the email address used for your professional affiliation (i.e. your "work email") unless otherwise specified.
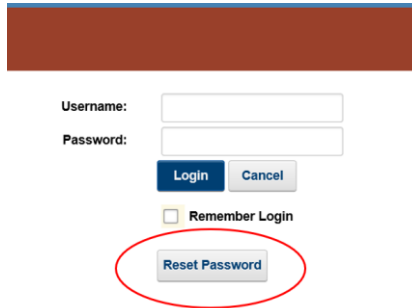
IV. Website Access

There are two ways to access the PATH website login page:

- Select "Login" in the upper right section of the public website;
- Navigate directly using the following link: https://path-hht.org/Home/Login
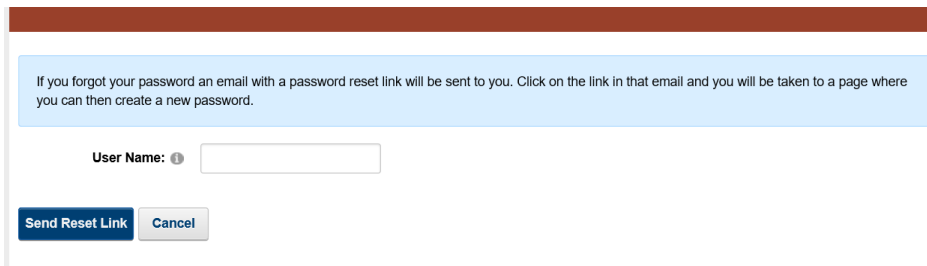
To access restricted website content, you will be required to create a personalized password. Note that a password is not created for you – you must create it yourself. To create your password:

From the Login page, pick the Reset Password button:

Enter your username; and

Click "Send Reset Link."

The system will display the following message:

You will receive an e-mail from "Account Website Administrator" (note that the email may be delivered to your Junk or Spam folder). The e-mail will contain your username and a link to a page where you can create your personalized password.

Upon clicking the link, the system will display a page which will show your username and prompt you to enter and confirm a new password.

If you have an existing password, it will not be affected by clicking the Send Reset Link button unless you click the e-mail link and proceed to enter and confirm a new password.

Note: The reset password link will expire after 24 hours and once it has been used, it cannot be reused. If the password link expires, you can request a new reset password link by returning to the Login page and clicking the "Reset Password" button again.

Passwords must be at least seven characters long. It is a good idea to include a combination of upper- and lower-case letters, numbers, and special characters in your password. You will be required to enter your password twice. The reset page will indicate the strength (i.e., complexity) of your password and confirm that both password entries match.
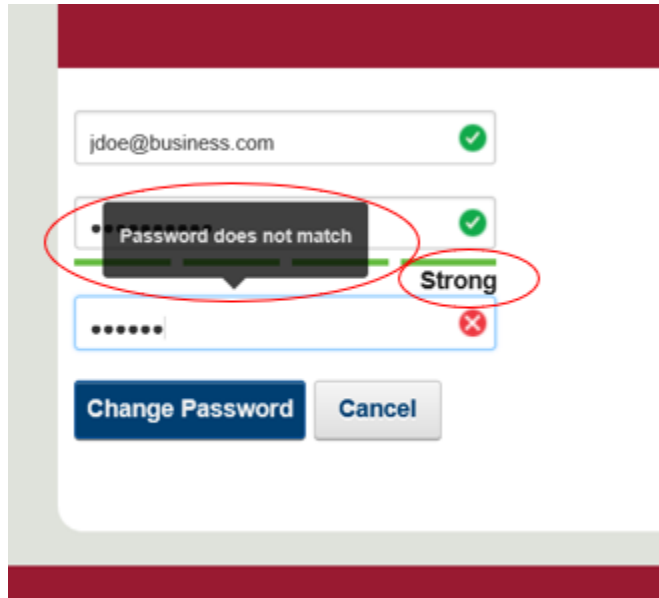
Upon successfully resetting your password, you will be authenticated into the system.

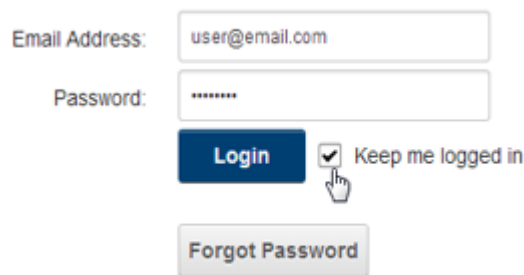Simply enter your username and password at any time to log onto the system. If you wish to stay logged into the site from a specific computer or device, select the "Keep me logged in" option. You will not be prompted again for your username and password for a period of 1 month (Note: This functionality works only if you have cookies enabled).

V. Supported Devices

The website is supported by most browsers and works best using modern browsers such as Internet Explorer 10+, Chrome, and Firefox. It is also supported by most modern mobile devices.

The website is designed to accommodate different device and screen sizes. You will notice that the website will adapt and display in a mobile-friendly manner depending on the device and browser window size.

VI.   General Functionality of the Public Site

The public home page displays general information about the PATH Study, including study aims, objectives, management and resources, as well as information about HHT. It also contains a Directory with contact information for the study Principal Investigators, as well as a Contact Us/Contact Support link, which emails pathsupport@rti.org, and a link to this user guide.

The public section of the website does not contain any study-specific documentation or data.

VII.   General Functionality of the Private Website

i.   Home Page

Authenticated users see the same public Home page with additional menus. Note that specific menu tabs and submenu options displayed to each user may vary, depending on the user's role(s).

Depending on the user role(s), authenticated users will also see up to two additional menus – Operating Structure and Study Operations.

ii.   Operating Structure menu

The Operating Structure menu contains various collaborator, committee and board-specific pages containing information about how the various study partners' roles, as well as document sharing functionality.

iii. Study Operations menu

The Study Operations menu contains pages intended for study document sharing. Each page title describes the subject matter of the document(s) stored on that page.

The Study Operations section includes Study Dashboards, which are interactive graphical displays of study data.

VIII. Document Management and Sharing

The primary function of the website is to facilitate document management and sharing within and between study teams. Documents are stored and shared in Document Modules. All Document Modules work the same way and vary only by content posted and user roles with access.

Each Document Module displays a title and a list of documents and file folders contained within.

DMCC RTI International

- Meetings
  - Documents
- Administration
  - Interviews
  - Meeting Minutes (Posted On: 12/13/2018)
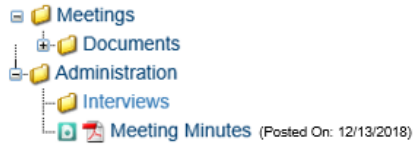
For each posted file the following controls/indicators are displayed:

- ![PDF icon] : Icon illustrating document type (MS Word, Excel, PDF, etc.);

- ![versions icon] : Select this icon to view a list of versions of this file;

- Hover over the filename to display any existing Document Notes. Note that Document Notes are optional when uploading a file;

- The date on which the document was uploaded or last edited.

The page content displayed to a user depends on that user's role(s) in the system. A user may have read-only access or read-write access to Document Module(s) on a page.
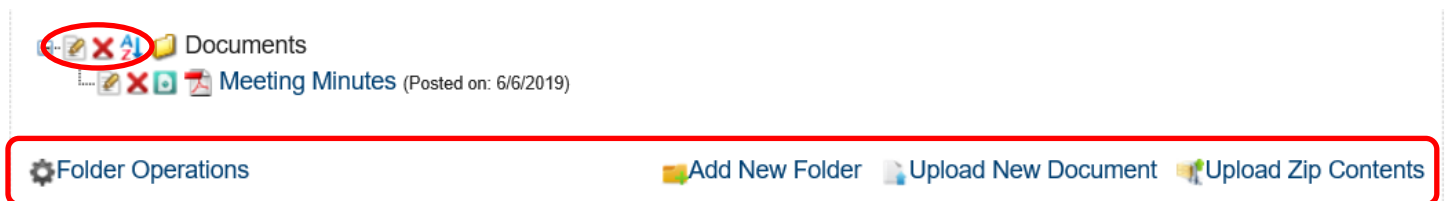
- Read-only means that a user can read any existing content and documents but cannot edit or remove existing documents or folders and cannot upload new documents or create new folders.

- Read-write means that a user can read any existing content and documents and remove existing documents or folders, upload new documents, and create new folders.

Note that a user may have no access to any Document Modules page. In this case, the page is not displayed or available to the user.

If you have an Edit Role, you will see an Edit Icon appear in the lower left corner of the screen. Click this icon to enter Edit Mode.
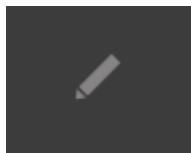
When you enter Edit mode, you will see one or more action icons to the left of the file/folder names and a series of Document Actions at the bottom of the Document Module.

![Documents with edit icons]
- Documents
  - Meeting Minutes (Posted on: 6/6/2019)

⚙ Folder Operations   Add New Folder   Upload New Document   Upload Zip Contents

: Enables renaming or moving an existing folder or file to a new parent folder.

: Deletes the existing file or folder. Note that deleting a folder also deletes all of that folder's contents.

: Changes the sorting criterion of files within the selected folder.

The **Folder Operations** action at the bottom of the module enable a user to take the following folder-level actions:

: Moves the folder up or down by one level within the current parent folder.

: Moves the folder to any other folder or to the top folder level.

: Toggles a setting to display all folders as collapsed or as expanded by default within the Document Module.

: Share as Zip – enables sharing of the contents of the folder as a zipped (compressed) folder to Facebook, Twitter or as an email attachment.

: Creates a zip file of all the folder contents (includes subfolders and documents).

Back – returns the user to the folder view without taking any action

The **Add New Folder** action creates a new folder within the Document Module. The user will be required to enter a Folder Name and specify the existing folder in which the new folder will be created (i.e., the parent folder).

The **Upload New Document** action uploads a new document to the Document Module. The user will be required to enter a Document Name, a target Folder, and browse to the local file to be uploaded. Note that the file will be named using the Document Name value entered by the user, which may differ from the uploaded filename. The user may also enter optional Document Notes. Sort Order is auto populated.

Document Name:	
Document notes:	
Select Folder:	-- Please Select -- ⌄
Sort order:	
Select file:	Browse...
	Upload Cancel

- **Upload Zip Contents** uploads the entire contents of a compressed file to a target folder. Note that the contents will be unzipped into the target folder. This does not upload the zipped file itself.

IX. Help and Support

The system has a Help page, which is accessible by all users. The Help page displays a link to this User Guide and an e-mail link to pathsupport@rti.org. You can e-mail the support team any time for help or with questions.

X. FAQs

I don't know if I have a site account. How do I find out?

- You can check your e-mail account for an e-mail from Account Website Administrator informing you of account activation or a password reset request. You can click the Reset Password button on the Login page and enter your project-related email address - if you have an existing account with that username, you will receive an e-mail from Account Website Administrator with a password reset link (note that your password will not be affected unless you click the link and proceed with resetting your password). You can also contact Pathsupport@rti.org to request whether you have an existing account.

I've forgotten my password. What should I do?

- You can click the Reset Password button on the Login page, enter your username, and click Send Reset Link. You will receive an e-mail from Account Website Administrator with a password reset link (note that your password will not be affected unless you click the link and proceed with resetting your password).

I am expecting to see a specific Document Module when I log on, but I cannot see it.

- This occurs because either you do not have permission to view the Document Module of interest or the Document Module does not exist. You can contact pathsupport@rti.org to confirm whether a Document Module exists and request access. If the Document Module does not exist, you can request to have it created.

I need to share documents with a specific group of users, but I do not see a suitable Document Module or page. What should I do?

- You can contact pathsupport@rti.org to request a suitable Document Module with appropriate permissions.