

Taiho Oncology Research Portal User Guide

June 2022

Create Account

- Navigate to the Taiho Research Portal
<https://researchportal.taihooncology.com/>
- Click “Create Account”.
- Fill out the required fields for account creation.
- Complete the captcha code and click “Create Account” at the bottom of your screen.

HOME CREATE A SUBMISSION MY SUBMISSIONS **CREATE ACCOUNT**

Caring for cancer differently.....
It's all in the delivery
Taiho Oncology, Inc. is focused on bringing novel technology to cornerstone chemotherapies for a wide range of tumor types-including colorectal cancer and a variety of solid tumors.
The mission of Taiho Oncology Inc and Taiho Oncology Europe, collectively referred to as Taiho Oncology, is to improve the lives of patients with cancer, their families and their caregivers. The company specializes in the development of orally administered anti-cancer agents for a range of tumor types in Taiho Oncology's growing pipeline of antimetabolic and selectively targeted anti-cancer agents led by a world-class clinical development organization. Providing funding and/or product(s) in support of Investigator-Initiated Trials, is one manifestation of Taiho Oncology's commitment to our mission of advancing research that increases the understanding of scientific and clinical aspects of disease and therapeutics, improving medical care, promoting better healthcare delivery, and providing benefits to patients.

Please fill out the necessary information below to create an account for this Portal.

First Name* Last Name*
Email Address* e.g. +99 999 999999
Country*
Extended Profile
* Degree
* Address Line 1
Address Line 2
* City
* State/Province/Region
* Zip/Postal Code

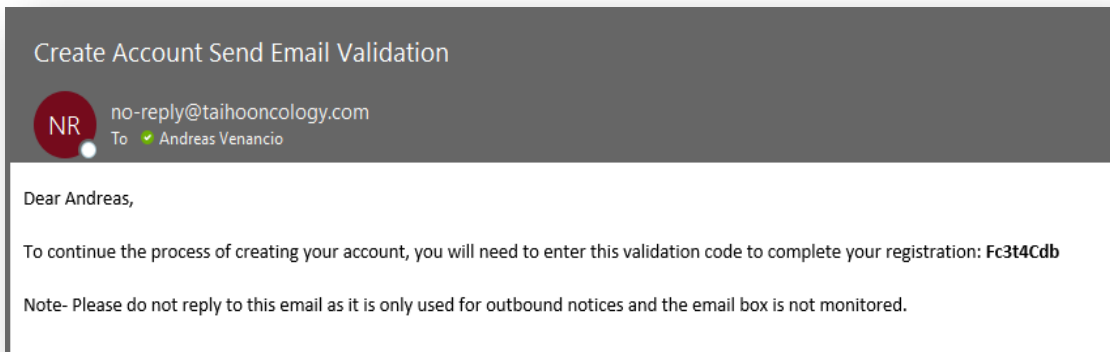
Your password must include at least 8 characters. The characters must include at least 1 of each of the following: number, symbol, UPPER case and lower case

.....
Re-type Password

1 7 x 0 6 Enter the code shown:

Create Account (Part 2)

- You can validate your account one of two ways; SMS text message, or through email.
- Select the preferred option and click “Send Validation Code”.
- When the validation code is received via SMS or email, enter the code and click “Validate Account” button.



Validate your Account

To help us verify your identity, a validation code will be sent to you.

Phone Number (Code will be sent via SMS. Message & data rates may apply.)

Email Address (Code will be sent via email. If you don't see the email in your inbox, please check your spam folder.)
avenancio@anaqua.com

Enter code here

Create a Submission

- To submit a proposal, click on “Create A Submission”.
- Title your submission, read the attestation statement, select “Agree”, and click “Create New”.
- Continue to fill out Request form and click submit. Required fields are marked with a red asterisk. Files required for submission are displayed at the top of the form and in the “Files” tab. (See slide 12 for file upload instructions)

The screenshot displays the Taiho Oncology website interface. At the top, the logo and tagline "TAIHO ONCOLOGY Making the human connection" are visible. A red arrow points to the "CREATE A SUBMISSION" button in the navigation bar. Below the navigation bar, there is a promotional banner with the text "Caring for cancer differently..... It's all in the delivery" and a photo of two women in lab coats. The main content area shows a "DRE DEMO SUBMISSION" card with details: External Status: NOT SUBMITTED, Submitted Date: 1268, Submission ID: 1268, Group: DEFAULT, and Last Modified On Portal. Below this, there are tabs for "Submission Form", "Files", "Emails", and "Data Lists", with an "Invite" button on the right. The "FORM" section contains a "Fill out the form below then Click Save or Submit to save your progress." instruction, "Save" and "Submit" buttons, and a yellow box listing required documents: Study Proposal, Budget, and Principal Sponsor-Investigator Curriculum Vitae. A red asterisk indicates that all questions marked with an asterisk are required. The form includes a "Type of Submission" field and a radio button question: "What type of request are you submitting?" with options for "Investigator Initiated Trials" and "Collaborative Research".

ALREADY HAVE AN ACCOUNT?

HOME CREATE A SUBMISSION MY SUBMISSIONS CREATE ACCOUNT

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Welcome, Dre Venancio LOGOUT

HOME CREATE A SUBMISSION EDIT PROFILE MY SUBMISSIONS

DRE DEMO SUBMISSION
External Status: **NOT SUBMITTED**
Submitted Date: **1268**
Submission ID: **1268**
Group: **DEFAULT**
Last Modified On Portal:

Submission Form Files Emails Data Lists Invite

FORM
Fill out the form below then Click Save or Submit to save your progress.
Save Submit

Please attach the following required documents with the application. Click on the "Files" tab to attach your:
• Study Proposal
• Budget
• Principal Sponsor-Investigator Curriculum Vitae
Incomplete forms will not be processed and will be returned to the submitter.

All questions marked with * are required

Type of Submission

* What type of request are you submitting?
 Investigator Initiated Trials
 Collaborative Research

ool, private foundation,
research interest.

TAIHO ONCOLOGY

Portal Teams

- Submitters can invite other users to view, edit, and submit the proposal.
- Click the “Invite” button, enter the desired invitee’s email address, title, and role, then click the “Add” button.
- **Note:** other users can only be invited to the portal team if the submission is “In Process/Editable”. Once you submit a proposal, you can no longer invite team members.

TAIHO ONCOLOGY
Making the human connect

Welcome, Yelena Submitter! LOGOUT

HOME

FIRST SUBMISSION

External Status:
Submitted Date: **NOT SUBMITTED**
Submission ID: 1210
Group: **DEFAULT**
Last Modified On Portal:

Submission Form Files

FORM

Fill out the form below then Click Save

Save Submit

Please attach the following requirements

- Study Proposal
- Budget
- Principal Sponsor-Investigator

Incomplete forms will not be processed

All questions marked with * are required

Type of Submission

Portal Team

Invite People:

Enter an Email Address * Please select a title Please select a role * **Add**

Who has access

Name	Title	Role
Submitter, Yelena yaltman@taihooncology.com		Is Creator

Items per page: 10 1 - 1 of 1 < >

Invites

Invites

Close

My Submissions

- Displays all pending and active requests. You can switch between the “Submitted” and “In Process/Editable” tab.
- Clicking the title of your submission will bring you to the details.
- Within a submission you can continue to upload files, view emails from the system, and edit/add data into your Data Lists
 - Milestones
 - Enrollment Dates
 - Study Outcomes

TAIHO ONCOLOGY
Making the human connection

Welcome, Dre Venancio! LOGOUT

HOME CREATE A SUBMISSION EDIT PROFILE MY SUBMISSIONS

MY SUBMISSIONS

Here is a collection of all your Submissions.

Submitted In Process / Editable

Title	Current Status	Date Submitted ↓
Dre Demo Submission	Submitted	12/15/2021
Dre Portal Teams Submission Test 2	Submitted	10/21/2021
Dre Portal Teams Test	Protocol Approved	10/21/2021
Phase II clinical study on efficacy of idp-123 on high risk patients	Under Review	8/19/2021
Dre Test Submission 8/19	Under Review	8/19/2021

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Milestones

- The Milestones section is used to track and manage milestones during the lifecycle of the study. The Taiho IIT coordinator will set up the milestones in the portal after the contract is executed.
- Click on *Milestones*.
- To edit, click on a row, then click on the pencil icon in the bottom left corner. Update required fields and click on Save. Note: you will only be able to update certain fields.
- *Editable Until* is the end date that the defined row will be editable to the portal user.

Submission Form Files Emails **Data Lists** Invite

DATA LISTS

- **Milestones**
- Enrollment Dates
- Study Outcomes

Milestone Type	Description	Baseline Date	Planned Date	Actual Date	Rationale for Planned Date Change	Approved Amount	Editable Until
Clinical - Signature of Contract		1/7/2022	1/7/2022			5,000.00	
Clinical - FPI		6/3/2022	6/3/2022			0.00	1/1/9999
Clinical - 50% Enrollment		1/2/2023	1/2/2023			0.00	1/1/9999
Clinical - 100% Enrollment		6/1/2023	6/1/2023			0.00	1/1/9999
Clinical - Final Report		8/1/2023	8/1/2023			0.00	1/1/9999


✎ |< << >> >| View 1 - 5 of 5

Enrollment Dates



- The Enrollment Dates section allows you to track anticipated and actual enrollment dates for your studies. Portal users can update this section from the portal without any intervention from the study coordinator.
- Click on *Enrollment Dates*.
- To add a row, click on the + icon in the bottom left corner. Update required fields and click on Save.
- To edit, click on a row, then click on the pencil icon in the bottom left corner.
- *Editable Until* is the end date that the defined row will be editable to the portal user.

Submission Form Files Emails **Data Lists** Invite

DATA LISTS

- Milestones
- **Enrollment Dates** 
- Study Outcomes

Enrollment Type	First Patient First Visit	Last Patient Last Visit	Total # of Patients Enrolled to Date	Total # of Patients Discontinued to Date	Total # of Patients Active to Date	Today's Date	Contact	Editable Until
Anticipated	4/13/2022	4/1/2023	0.00	0.00	0.00	4/13/2022	Submitter, Yelena	12/31/9999


  View 1 - 1 of 1

Study Outcomes



- The Study Outcomes section allows you to manage/track any study outcomes, including publications, abstracts, manuscripts, presentations, etc. Portal users can update this section from the portal without any intervention from the study coordinator.
- Click on *Study Outcomes*.
- To add a row, click on the + icon in the bottom left corner. Update required fields and click on Save.
- To edit, click on a row, then click on the pencil icon in the bottom left corner.
- *Editable Until* is the end date that the defined row will be editable to the portal user.

Submission Form Files Emails **Data Lists** Invite

DATA LISTS

- Milestones
- Enrollment Dates
- **Study Outcomes** 

Type	Document Status	Date Submitted to Taiho	Title	Summary	Journal	Congress	Planned Submission Date	Status	Actual Submission Date	Taiho Review Complete	Contact	Editable Until
Publication	Final	4/13/2022	Publication XYZ			ASH 2022	4/13/2022	Submitted	4/13/2022		Submitter, Yelena	12/31/9999

  View 1 - 1 of 1

Chat

- You can chat with invited users or the Taiho team on your submission.
- Click on the blue chat icon in the bottom right corner of your submission.
- Select Internal or Public, type a message, and click “Share”.
 - Internal is used to chat with invited users.
 - Public is used to chat with the Taiho team.

The screenshot displays the Taiho Oncology submission portal. At the top, the logo and tagline "TAIHO ONCOLOGY Making the human connection" are visible, along with the user name "Welcome, Yelena Submitter" and a "LOGOUT" link. A navigation bar contains "HOME", "CREATE A SUBMISSION", "EDIT PROFILE", and "MY SUBMISSIONS". The main content area shows "TESTING UAT NOTIFICATIONS" with details: External Status: Study In Progress, Submitted Date: 1/27/2022, Submission ID: 1287, Group: DEFAULT, and Last Modified On Portal: 2/23/2022 11:58:19 AM. A "SUBMITTED" status is indicated with a green checkmark.

An overlay chat window is shown in the foreground. It has a "SUBMITTED" header with a green checkmark. The chat window has tabs for "Internal" and "Public". The "Internal" tab is selected. The text input field contains "What's on your mind?". A "Share" button is visible below the input field. A character count "0 / 4000" is shown to the right of the input field. Below the input field, there are tabs for "All", "Internal", and "Public". A list of chat messages is displayed, each with a user profile picture, name, and timestamp. The messages are:

- Altman, Yelena posted publicly 31 Jan 2022 03:39 PM
- Altman, Yelena posted publicly 31 Jan 2022 03:15 PM
- Submitter, Yelena posted publicly 31 Jan 2022 02:46 PM
- Submitter, Yelena posted Internally 31 Jan 2022 01:56 PM

At the bottom of the chat window, there is a blue chat icon. A red arrow points to this icon. Below the chat window, there are buttons for "Submission Form", "Files", "Emails", and "Data Lists". The "FORM" label is visible at the bottom left of the page.

Additional Instructions



File Upload Instructions

- To upload a file for a submission, click the Files tab.
- Click the “Select file(s) to upload” button.
- Use the following naming convention to properly name all saved files – “IIT-XX-####_File Type_ DDMMYYYY”. *Kindly note that mis-naming files could result in a processing delay.*
- You may select “None” when uploading a file that may not match the pre-selected File Type.
- **Note:** When uploading and saving required QA documentation for drug release, please select the ‘IRB/EC Approval’ file type and use the following naming conventions
 - IIT-XX-####_IRB approval notification letter – protocol_ DDMMYYYY
 - IIT-XX-####_IRB approval notification letter – ICF_ DDMMYYYY
 - IIT-XX-####_IRB approved – protocol version date_ DDMMYYYY
 - IIT-XX-####_IRB approved – ICF version date_ DDMMYYYY
 - IIT-XX-####_IRB Statement of Compliance_ DDMMYYYY
 - IIT-XX-####_IRB Membership List/Roster_ DDMMYYYY

