

IMMUNE TOLERANCE NETWORK (ITN) - TRIALSHARE User Guide

A system enabling data sharing and scientific collaboration.

View interactive plots, perform custom analyses, assign group classifications
and design follow-up experiments by viewing the specimen bio-repository.

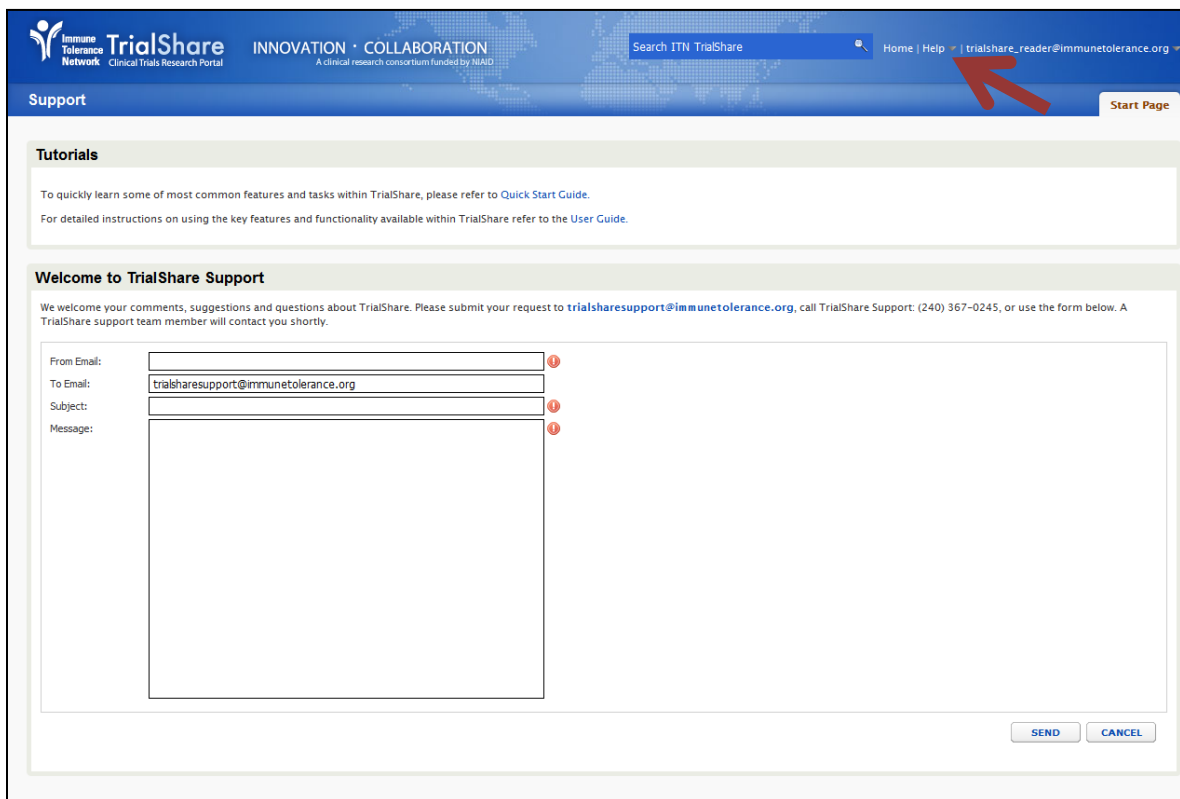
About this guide

The purpose of this guide is to give users a comprehensive and meaningful overview of the ITN TrialShare key features. This document should be used as a guideline to aid users in viewing clinical data of closed and active studies, reports, and datasets.

SUGGESTIONS AND SUPPORT

For any support needs, technical and feature requests, and data inconsistencies send an email to trialsharesupport@immunetolerance.org

Alternatively, click on “**Help > Support**” in the application header to send an email to TrialShare Support.



The screenshot shows the TrialShare application interface. At the top, there is a blue header with the Immune Tolerance Network logo, the text "TrialShare Clinical Trials Research Portal", and "INNOVATION · COLLABORATION A clinical research consortium funded by NIAID". A search bar contains "Search ITN TrialShare". On the right, there are navigation links: "Home | Help | trialshare_reader@immunetolerance.org". A red arrow points to the "Help" link. Below the header, there is a "Support" section with a "Start Page" button. The "Tutorials" section contains links to "Quick Start Guide" and "User Guide". The "Welcome to TrialShare Support" section includes contact information and a form for submitting support requests. The form has fields for "From Email:", "To Email:" (pre-filled with "trialsharesupport@immunetolerance.org"), "Subject:", and "Message:". There are "SEND" and "CANCEL" buttons at the bottom right of the form.

INTENDED AUDIENCE

The intended audience for this User Guide is the scientific community, internal staff, and the general audience.

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CHAPTER 1 INTRODUCTION

This Chapter provides the following introduction to TrialShare:

- Overview
- Access
- Key Features

OVERVIEW

ITN TrialShare is a clinical trials research system that provides clinical datasets for research and analysis as well as a platform for the scientific community to share data in a secure manner.

The system helps scientists organize, analyze, and share large quantities of biomedical research data. It also provides secure, web-based query, reporting, and collaboration services over a wide variety of data sources.

ACCESS

Access to TrialShare studies and features is based on roles. You might be able to view all or some studies depending on your access and permissions.

Certain features described in the sections below might not be available to users based on permissions.

KEY FEATURES

Some of the key features available in TrialShare are:

- Study Overview
- Data & Reports
- Specimen Inventory
- Participant Views

CHAPTER 2 GETTING STARTED

This Chapter provides information on getting started with TrialShare and logging into the application.

LOGGING IN

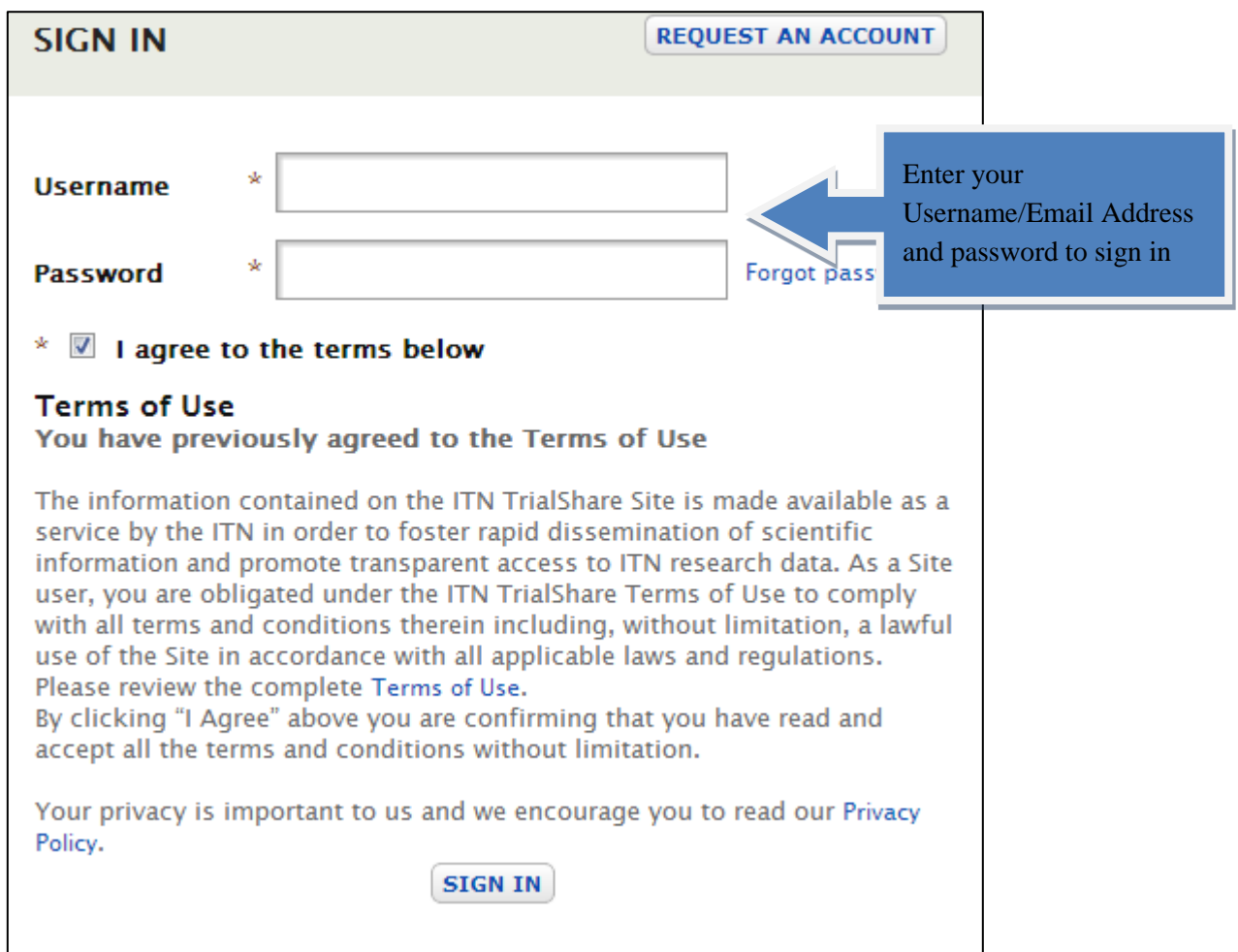
Open the TrialShare Welcome page by copying the following URL in your browser window:

itntrialshare.org

Below is the Login information that you will need to access the application:

- **User name:** ITN User Name/Email address
- **Password:** ITN Active Directory/Email Password

Enter your user name/email address and password in the appropriate fields in the Sign In box.



The screenshot shows the 'SIGN IN' form on the TrialShare website. At the top right of the form is a button labeled 'REQUEST AN ACCOUNT'. Below this are two input fields: 'Username' and 'Password', both marked with an asterisk. To the right of the 'Password' field is a link that says 'Forgot pass'. Below the input fields is a checkbox with a checkmark and the text 'I agree to the terms below'. Underneath is the section 'Terms of Use' with the heading 'You have previously agreed to the Terms of Use'. The text in this section explains that the information on the site is made available by ITN to foster rapid dissemination of scientific information and that users are obligated to comply with all terms and conditions. It also mentions that clicking 'I Agree' confirms acceptance of these terms. At the bottom of the form is a 'SIGN IN' button. A blue callout box on the right side of the form, with a white arrow pointing to the Username field, contains the text: 'Enter your Username/Email Address and password to sign in'.

Terms of Use

Accept the mandatory Terms of Use and click the “**SIGN IN**” button to access the application.

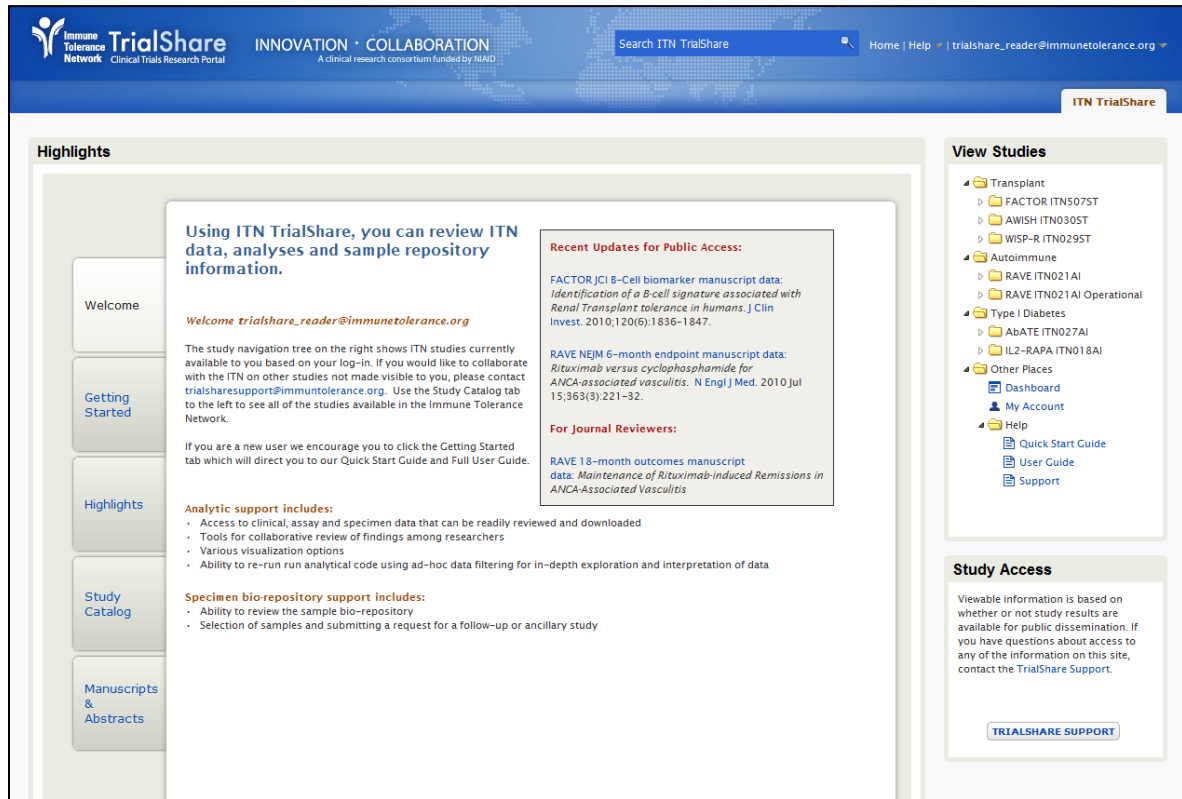
CHAPTER 3 TRIALSHARE HOME

This Chapter provides information on the following features available on TrialShare Home page:

- Welcome
- Getting Started
- Highlights
- Study Catalog
- Manuscripts and Abstracts
- View Studies

GENERAL OVERVIEW

Upon logging in, the TrialShare Home page displays general highlights across studies and links to different parts of a study.



GETTING STARTED

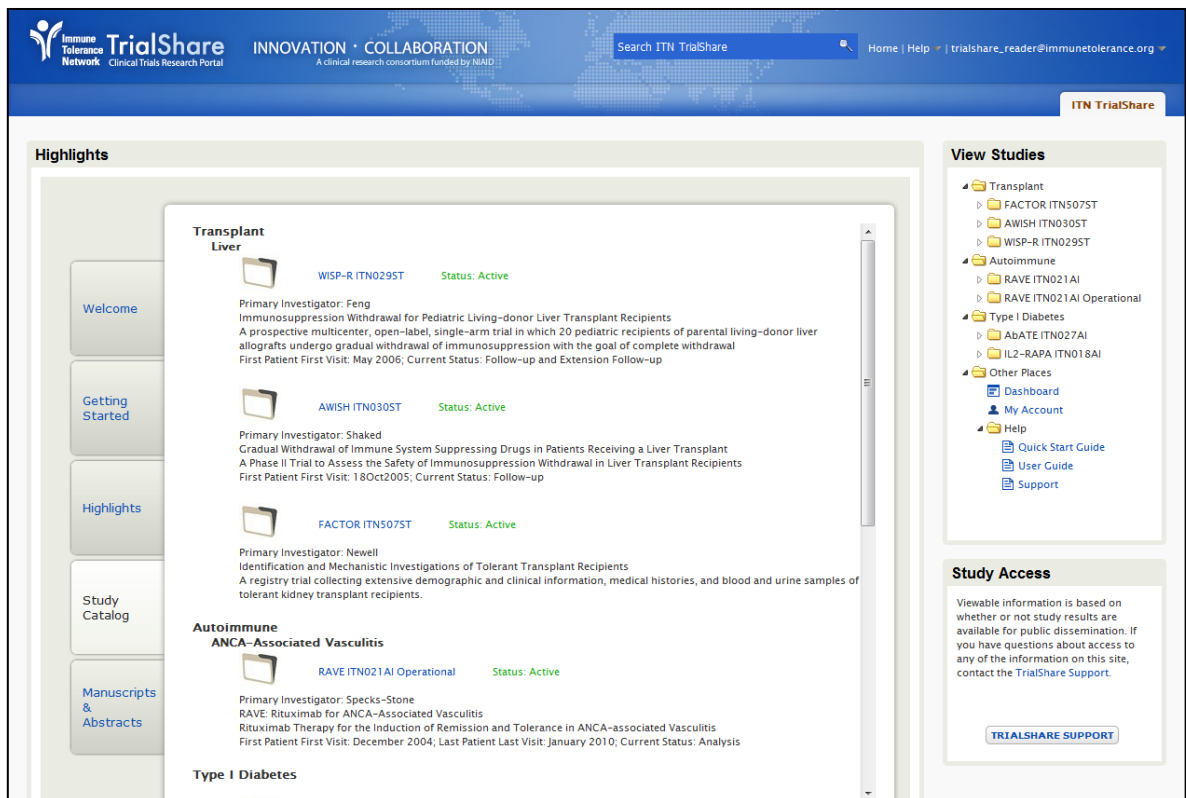
Click on the “**Getting Started**” tab to find helpful links to the Video Tutorials, Quick Start Guide, and User Guide.

HIGHLIGHTS

You can view highlights from studies as an image on the Home page. Click on the left and right arrows at the bottom of the “**Highlights**” section to view the highlights across studies.

STUDY CATALOG

Click on the “**Study Catalog**” tab to find helpful information relating to the study groupings based on therapeutic area and categories.



MANUSCRIPTS AND ABSTRACTS

Click on the “[Manuscripts and Abstracts](#)” tab to view the most recent manuscripts and abstracts from various studies available in TrialShare.

1. Click on “[ABSTRACT>](#)” to view and print a research abstract. The research abstract paper displays.
2. Click on “[Paper](#)” to view the paper.

VIEW STUDIES

Drill down into study-specific data and access various reports and datasets for a study by expanding the Study Navigator Tree under View Studies on TrialShare Home page.

1. Click on the folder containing the study under “**View Studies,**” in the right navigation pane, to expand the study tree as shown in the Figure below.

Note You might have limited access or no access to one or all of the studies depending on your permissions.

The screenshot shows the TrialShare website interface. At the top, there is a navigation bar with the TrialShare logo, the text 'INNOVATION · COLLABORATION', a search bar, and a user profile link. Below the navigation bar, the main content area is divided into several sections. On the left, there is a sidebar with navigation links: 'Welcome', 'Getting Started', 'Highlights', 'Study Catalog', and 'Manuscripts & Abstracts'. The main content area features a 'Highlights' section with a list of studies. The first study is 'Transplant Liver' with the identifier 'WISP-R ITN0295T' and 'Status: Active'. Below it are 'AWISH ITN0305T' and 'FACTOR ITN5075T', both with 'Status: Active'. The next study is 'Autoimmune ANCA-Associated Vasculitis' with the identifier 'RAVE ITN021AI Operational' and 'Status: Active'. The final study is 'Type I Diabetes'. On the right side, there is a 'View Studies' sidebar with a tree view of study categories: 'Transplant' (containing FACTOR ITN5075T, AWISH ITN0305T, WISP-R ITN0295T), 'Autoimmune' (containing RAVE ITN021AI, RAVE ITN021AI Operational), 'Type I Diabetes' (containing AbATE ITN027AI, IL2-RAPA ITN018AI), and 'Other Places'. Below this sidebar are links for 'Dashboard', 'My Account', and 'Help' (including 'Quick Start Guide', 'User Guide', and 'Support'). At the bottom right, there is a 'Study Access' section with a disclaimer and a 'TRIALSHARE SUPPORT' button. A red arrow points from the 'View Studies' sidebar towards the main content area.

2. Click on one of the following links under the study to view, analyze, customize reports, and share study data:

- **Overview:** Download Study Protocol document, View Abstract, and add manuscripts. Refer to [Chapter 4 Study Overview](#).
- **Data & Reports:** View, Customize Reports, and study datasets. Refer to [Chapter 5 Data & Reports](#).
- **Participants:** Access Participant Views (Pathology Images, Demographics, Graphs) for specific Participant IDs. Refer to [Chapter 6 Participants](#).
- **Specimens:** View and Print Specimen Report for a Specimen Type and Visit based on filters available on the page. Refer to [Chapter 7 Specimens](#).

CHAPTER 4 STUDY OVERVIEW

This Chapter provides information on the following sections available on the Overview tab of a study:

- Study Overview
- Manuscripts and Abstracts
- Messages List

OVERVIEW TAB

The Overview tab provides general background information for the study selected on the TrialShare Home page.

1. You can view this page by clicking on the “**Overview**” link below the study name on the TrialShare Home page.

OR

2. Clicking on the “**Overview**” tab from any other page in the specific study you are in.

Note

Some or all of the sections listed below might be available depending on the study selected. Additional sections might also display for a study depending on study customization.

TrialShare
Clinical Trials Research Portal

INNOVATION · COLLABORATION
A clinical research consortium funded by NIAID

[Home](#) | [Help](#) | trialshare_reader@immunetolerance.org

RAVE ITN021AI: Rituximab for ANCA-Associated Vasculitis

[Overview](#) | [Data & Reports](#) | [Participants](#)

Study Overview

RAVE: Rituximab for ANCA-Associated Vasculitis

Protocol Chairs: John H. Stone, MD, MPH and Ulrich Specks, MD

Current conventional therapies for ANCA-associated vasculitis (AAV) are associated with high incidences of treatment failure, disease relapse, substantial toxicity, and patient morbidity and mortality. Rituximab is a monoclonal antibody used to treat non-Hodgkin's lymphoma. This study will evaluate the efficacy of rituximab with glucocorticoids in inducing disease remission in adults with severe forms of AAV (WG and MPA).

The study consists of two phases: a 6-month remission induction phase, followed by a 12-month remission maintenance phase. All participants will receive at least 1 g of pulse IV methylprednisolone or a dose-equivalent of another glucocorticoid preparation. Depending on the participant's condition, he or she may receive up to 3 days of IV methylprednisolone for a total of 3 g of methylprednisolone (or a dose-equivalent). During the remission induction phase, all participants will receive oral prednisone daily (1 mg/kg/day, not to exceed 80 mg/day). Prednisone tapering will be completed by the Month 6 study visit.

Next, participants will be randomly assigned to one of two arms. Arm 1 participants will receive rituximab (375 mg/m²) infusions once weekly for 4 weeks and cyclophosphamide (CYC) placebo daily for 3 to 6 months. Arm 2 participants will receive rituximab placebo infusions once weekly for 4 weeks and CYC daily for 3 to 6 months. During the remission maintenance phase, participants in Arm 1 will discontinue CYC placebo and start oral azathioprine (AZA) placebo daily until Month 18. Participants in Arm 2 will discontinue CYC and start AZA daily until Month 18. Participants who fail treatment before Month 6 will be crossed over to the other treatment arm unless there are specific contraindications. Participants in either group who reach clinical remission before the remission induction phase may switch from CYC/placebo to AZA/placebo if directed by their physicians.

All participants will be followed for at least 18 months. Initially, study visits are weekly, progressing to monthly and then quarterly visits as the study proceeds. Blood collection will occur at each study visit.

Cohort	Description
RTX	Rituximab plus cyclophosphamide placebo (Rituximab group)
CYC	Cyclophosphamide plus rituximab placebo (Control group)

[Study Protocol Document](#)

View Studies

- Transplant
 - FACTOR ITN5075T
 - AWISH ITN0305T
 - WISP-R ITN0295T
- Autoimmune
 - RAVE ITN021AI
 - RAVE ITN021AI Operational
- Type I Diabetes
 - ABATE ITN027AI
 - IL2-RAPA ITN018AI
- Other Places
 - [Dashboard](#)
 - [My Account](#)
- Help
 - [Quick Start Guide](#)
 - [User Guide](#)
 - [Support](#)

Manuscripts and Abstracts

Circulating markers of vascular injury and angiogenesis in Antineutrophil Cytoplasmic Antibody-Associated Vasculitis.

Arthritis Rheum 63: 3988–3997, 2011

Monach PA, Tomasson C, Specks U, Stone JH, Krischer J, Ding L, Fervenza FC, Fessler BJ, Hoffman GS, Ikle D, Kallenberg CGM, Langford CA, Mueller M, Seo P, St. Clair EW, Spiera R, Tchao N, Ytterberg SR, Merkel PA, Cuthbertson D, Gu Y-Z, Snyder RD

[PAPER >](#)

Design of the Rituximab in ANCA-associated Vasculitis (RAVE) Trial.

The Open Arthritis Journal: 4, 1–18, 2011

Specks U, Merkel PA, Hoffman GS, Langford CA, Spiera R, Seo P, Kallenberg CGM, St. Clair EW, Ding L, Webber L, Mokhtariani M, Tchao NK, Sayre PH, Seyfert-Margolis V, Ikle D, Brunetta P, Mueller M, Zhang D, Sejsimundo L, Stone JH.

[PAPER >](#)

Immunoglobulin Concentrations and Infection Risk Among Patients with ANCA-Associated Vasculitis Treated with Rituximab or Cyclophosphamide.

American College of Rheumatology, Chicago, IL, November 4–9, 2011.

Specks U, Merkel PA, Seo P, Spiera R, Langford CA, Hoffman GS, Kallenberg CGM, St. Clair EW, Brunetta P, Tchao N, Fessler BJ, Webber L, Ding L, Sejsimundo LP, Mieras K, Phippard DJ, Asare A, Lim N, Ikle D, Jepson B, Lail A, Tole S, Shen S, Mueller M.

[ABSTRACT >](#)

Messages List

Showing: all messages

Title	Created By	Created	Most Recent Post By	Most Recent Post
No data to show.				

B cell median line plot

Days after Randomization	Cyclophosphamide, RTX-ANCA (Red)	Cyclophosphamide, RTX-ANCA (Blue)	Rituximab, RTX-ANCA (Green)
0	~200	~200	~200
15	~150	~150	~100
30	~100	~100	~50
60	~50	~50	~20
120	~20	~20	~10
180	~10	~10	~5

Follow the steps below to download study protocols, manage manuscripts, and navigate to Study Navigator from the Overview page.

STUDY OVERVIEW

The “**Study Overview**” section displays on the “**Overview**” tab. You can download a study protocol or see all datasets available for the study in a grid view by study visit using the features available from this section.

Download Study Protocol Document

1. In the “Study Overview” section, click on the “**Study Protocol Document**” link as shown in the figure below to download and print the study protocol as a PDF file.

Study Overview

Immunosuppression Withdrawal for Pediatric Living-donor Liver Transplant Recipients

Protocol Chair: Sandy Feng, MD, PhD

This is a prospective multicenter, open-label, single-arm trial in which 20 pediatric recipients of parental living-donor liver allografts will undergo gradual withdrawal of immunosuppression with the goal of complete withdrawal. Patients on stable immunosuppression regimens with good organ function and no evidence of acute or chronic rejection or other forms of allograft dysfunction will be enrolled. Participants will undergo gradual withdrawal of immunosuppression and will be followed for a minimum of 4 years after completion of immunosuppression withdrawal. Immunologic and genetic profiles will be collected at multiple time points and compared between tolerant and nontolerant participants.

Cohort	Description
Immunosuppression Withdrawal	Pediatric recipients of parental living-donor liver allografts

[Study Protocol Document](#)

STUDY NAVIGATOR >

Study Navigator

The Study Navigator link is available on the Overview page and provides a launching point to access other perspectives on Study datasets.

1. Click on “**STUDY NAVIGATOR>**” link to see all datasets available for the study in a grid view by study visit.
2. A grid displays showing datasets in the study and the count of unique participants per visit. Each dataset is listed as a row in Study Navigator and each time point or visit displays as a column. The default grid displays a few selected datasets and you can click on “**SHOW ALL DATASETS>**” to view all datasets for that study.

Note Only datasets you have sufficient permissions to view will be visible.

RAVE ITN021AI: Rituximab for ANCA-Associated Vasculitis

NEW: RAVE ITN021AI: Rituximab for ANCA-Associated Vasculitis

SHOW ALL DATASETS >

current cohort: All Participant Count Row Count

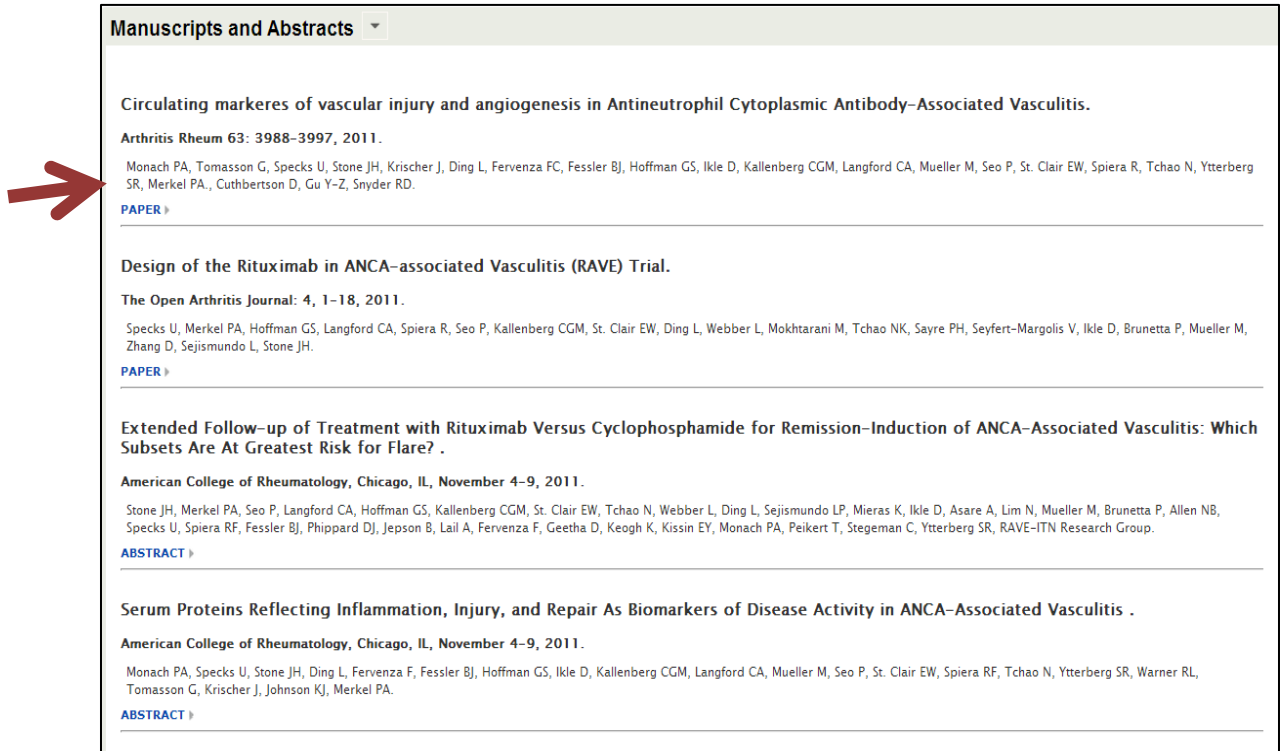
	All Visits	V-1	V1	V2	V3	V4	V5	V6	V7	V8	V1A	V2A	V3A	V4A	V5A	V6A	V7A	V8A	V18	V28	V38	V48	V58	V68	V78	V88	VFlare	VSwitch	UN	VCCD	TERM	UN
Derived Clinical																																
AAV History_ADAAV1 ?	197	197																														
Adverse Events_ADAE1 ?	194																															
Subset Analyses of Adverse Events Prior to Six Months of Subject Followup_ADAE2 ?	191																															
Selected Adverse Events_ADAESL1 ?	197																															
ANCA Status at Baseline and Month 6_ADANCA1 ?	197																															
ANCA Associated Vasculitis Damage Index_ADAVDI1 ?	514	190				43	36	33	168	11				3	1	1												17		4		
BVAS/WG Assessments_ADBVAS2 ?	927	53	143			191	182	180	169																						4	
Concomitant Medications_ADCMED1 ?	192																															
Dosage of Rituximab, Cyclophosphamide, and Azathioprine_ADCOM1 ?	1020	197	197	195	191					11	11	11	10							1	1	1	1									
Efficacy data at 0,6,12,18 Months_ADEFF2 ?	197																															
Glucocorticoid Dosing_ADGLCC1 ?	197																															
Human anti-chimeric antibody (HACA) results_ADHACA1 ?	2032	194		192		186	182	152	162			14	13	12	10	8																
Used for the Analysis of Laboratory Data (chemistry, hematology)_ADLE1 ?	1827	195	175	197	195	195	191	184	179	166	12	11	11	10	10	5	5		1	1	1	1								4		
Malignancies and Exposure to Various Medications_ADMALIG1 ?	197																															
Organ Involvement at Baseline_ADORG1 ?	197																															
Protocol Violations_ADPV1 ?	132																															
Computed SF36 scores and sub-scores_ADSF1 ?	1066	178	87			188	182	177	169	8			1	10	5	5			1					1	1	1		41		4		
Participant Characteristics and Demographics Based on Other Analysis Datasets_ADSL ?	197																															
Subject Characteristics and Demographics_ADSTART0 ?	197																															
Vasculitis Damage Index_AVDI1 ?	520	191				43	36	34	169	11				3	1	1												20		4		
Vital Signs_ADTV1 ?	1813	196	192	190	189	186	191	182	179	167	12	11	11	10	10	5	5		1	1	1	1	1	1	1	1		53		4		

3. You can click “**VIEWS>**” link to view all the associated reports and graphs for the study.
4. Alternatively, click “**SHOW ALL DATASETS>**” or “**SHOW DEFAULT DATASETS>**” to view datasets.
5. Click the participant count at the intersection of the dataset and visit which you are interested in.
6. You will be navigated to the dataset’s grid view under the “**Data & Reports**” tab. The grid displays the values in the selected dataset and visit in the study for each participant. The timepoint for all participants listed in the grid view is the same, even though the visit “Date” differs for each one. Each participant started the study on a different date, so the selected time point visits fall on different dates for each person. For detailed instructions on utilizing datasets for further analysis refer to “[Datasets and Views](#)” under “Data & Reports.”

MANUSCRIPTS AND ABSTRACTS

The “**Manuscripts and Abstracts**” section displays on the “**Overview**” tab. You can view Manuscripts and Abstracts for the study or add a new one to the list.

1. Click on “**ABSTRACT>**” in the “**Manuscripts and Abstracts**” section to view a research abstract. The research abstract will then display.
2. Click on “**Paper**” to view the paper.



Manuscripts and Abstracts ▾

Circulating markers of vascular injury and angiogenesis in Antineutrophil Cytoplasmic Antibody–Associated Vasculitis.
Arthritis Rheum 63: 3988–3997, 2011.
Monach PA, Tomasson G, Specks U, Stone JH, Krischer J, Ding L, Fervenza FC, Fessler BJ, Hoffman GS, Ikle D, Kallenberg CGM, Langford CA, Mueller M, Seo P, St. Clair EW, Spiera R, Tchao N, Ytterberg SR, Merkel PA., Cuthbertson D, Gu Y-Z, Snyder RD.
[PAPER >](#)

Design of the Rituximab in ANCA–associated Vasculitis (RAVE) Trial.
The Open Arthritis Journal: 4, 1–18, 2011.
Specks U, Merkel PA, Hoffman GS, Langford CA, Spiera R, Seo P, Kallenberg CGM, St. Clair EW, Ding L, Webber L, Mokhtarani M, Tchao NK, Sayre PH, Seyfert-Margolis V, Ikle D, Brunetta P, Mueller M, Zhang D, Sejismundo L, Stone JH.
[PAPER >](#)

Extended Follow-up of Treatment with Rituximab Versus Cyclophosphamide for Remission–Induction of ANCA–Associated Vasculitis: Which Subsets Are At Greatest Risk for Flare? .
American College of Rheumatology, Chicago, IL, November 4–9, 2011.
Stone JH, Merkel PA, Seo P, Langford CA, Hoffman GS, Kallenberg CGM, St. Clair EW, Tchao N, Webber L, Ding L, Sejismundo LP, Mieras K, Ikle D, Asare A, Lim N, Mueller M, Brunetta P, Allen NB, Specks U, Spiera RF, Fessler BJ, Phippard DJ, Jepson B, Lail A, Fervenza F, Geetha D, Keogh K, Kissin EY, Monach PA, Peikert T, Stegeman C, Ytterberg SR, RAVE-ITN Research Group.
[ABSTRACT >](#)

Serum Proteins Reflecting Inflammation, Injury, and Repair As Biomarkers of Disease Activity in ANCA–Associated Vasculitis .
American College of Rheumatology, Chicago, IL, November 4–9, 2011.
Monach PA, Specks U, Stone JH, Ding L, Fervenza F, Fessler BJ, Hoffman GS, Ikle D, Kallenberg CGM, Langford CA, Mueller M, Seo P, St. Clair EW, Spiera RF, Tchao N, Ytterberg SR, Warner RL, Tomasson G, Krischer J, Johnson KJ, Merkel PA.
[ABSTRACT >](#)

MESSAGES LIST

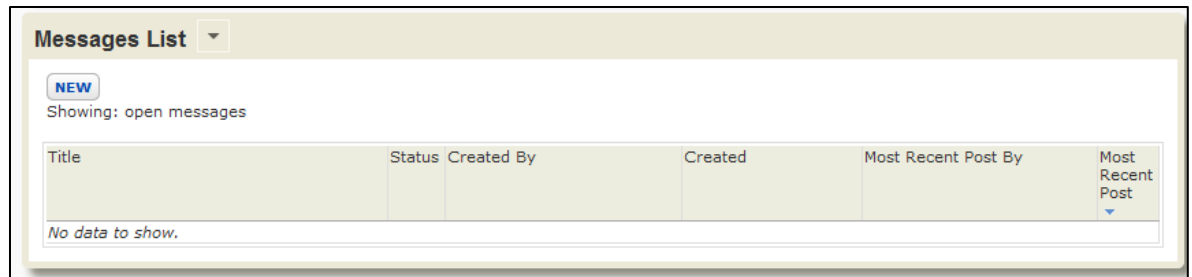
The “**Messages List**” section displays on the “**Overview**” tab.

Note Limited features might be available to users with Read only access.

View all the open messages relating to a study posted by the users.

1. You can add a new message relating to a study topic or report by clicking on the button under “**Messages List.**”

NEW



2. The “**New Message**” page will display.
 - a. Enter information including the Title, Recipient email address or addresses, and message text.
 - b. Attach a file by clicking on the “**Attach a file**” link.
 - c. Click “**SUBMIT**” to respond or “**CANCEL**” to cancel the message.
3. Click on the Title in the Messages List table to view the message text.
4. The “**Messages >**” page will display with the “**View Message**” section.
 - a. Respond to the message by clicking on the “**RESPOND**” button.
 - b. The “**Response**” box will display fields where you can enter your response to the previous page.
 - c. You can also click on “**PRINT**” to print the message or “**VIEW LIST**” to have a full page view of the message table.
 - d. To set your email preferences, click on the dropdown arrow on the right of the Messages List section.
 - e. The “**Email Preferences**” page will display. Select the preferences and click “**UPDATE.**”
 - OR
 - f. Click “**CANCEL**” to go back to the Overview page.

CHAPTER 5 DATA & REPORTS

This Chapter provides information on the following key features available on the Data & Reports tab:

- Data Reports
- Data Sets and Views

DATA & REPORTS TAB

You can analyze, compare, and review datasets and reports using key TrialShare features and functionality available from the Data & Reports tab. Navigate to this page by:

3. Clicking on “[Data & Reports](#)” link under the study name in the “View Studies” tree on the TrialShare Home page.

OR

4. Clicking on the “[Data & Reports](#)” tab from any other page in the specific study you are in.

Note To view and analyze previously created reports and graphs go to “[Data Reports.](#)”
 To view datasets go to “[Data Sets and Views.](#)” Follow instructions from [Dataset Grid View](#) onwards to sort/filter data and prepare a customized dataset or create views.

To define Participant Groups go to [Participant Groups.](#)

The screenshot shows two panels from the TrialShare interface. The top panel is titled "Data Reports" and contains a search bar with the placeholder text "name, category, etc." and a "Mine" button. Below the search bar is a table with columns: Name, Type, Details, Modified, Author, and Access. The table lists several reports, including "Autoantibodies", "Hepa Titer", "Serum Cytokines", "Derived Clinical" (with sub-items "C-pep line chart" and "Insulin use"), and "ImmunoChip" (with sub-items "ImmunoChip Canonical Pathway", "ImmunoChip Report", and "ImmunoChip T cell Receptor Canonical Pathway").

The bottom panel is titled "Datasets and Views" and also has a search bar with the placeholder text "name, category, etc." and a "Mine" button. Below the search bar is a table with columns: Name, Type, Details, Data Cut Date, Status, Modified, and Access. The table lists datasets under the "Derived Clinical" category, including "Adverse events_ADAE1", "C-Peptide 4-hour AUC in response to a MMT_ADCPEP2", and "Certified Diabetes Educator Contact_ADCDE1".

Sections like the Data Sets and Views, and Data Reports, link to the core data. These features provide the enhanced capability to filter, sort, and modify existing datasets and reports to create new reports and graphs for further analysis.


DATA REPORTS

The Data Reports section is available on the “[Data & Reports](#)” tab.

You can utilize Data Reports to analyze existing R charts and Time Charts that provide a visualization of data trends. The charts and reports displayed in the Data Reports section are specific to the study selected on the Home page.

Some of the types of study reports and charts that you can view and analyze in the Data Reports are Time Charts, R Charts, Box & Scatter Plots, and Study Attachment Reports.

Place your cursor on a chart/report name to view the thumbnail. You can also click on a chart/report name to view the images or details. Filter the Data Reports based on name, category, and other key words related to a study.

1. Enter the filter criteria in the “Filter” field to filter reports. 
2. The Data Reports section provides additional report information like Status, Author, and Type in addition to functionality like customizing available graphs.
3. Click on the “Mine” checkbox to view only the reports that you have created. Mine
4. Click on a Report type to navigate to the Detail view. The Report Details page provides the report URL and other details like the “Date Created” and “Last Modified.”

Report Details

Name: B cell median line plot

Description:

Category:

Status:

Created By: nilim@immunetolerance.org

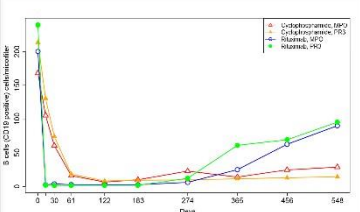
Type: R View

Date Created: 2011-10-14 10:05

Last Modified: 2012-08-17 07:58

Data Cut Date:

Report Thumbnail:



Report URL: [VIEW REPORT >](#)

[DISCUSSION >](#)

5. Click on “[DISCUSSION>](#)” to start a new discussion on the list item. Click “Start New Discussion.”
 - a. The “Start a new discussion” box displays.
 - b. Fill in the required information. The feature also allows you to attach related files for sharing.

- c. Click “**SUBMIT**” to start the discussion thread or “**CANCEL**” to cancel the discussion.
- d. Click the page name in the header to go back to the previous page.

OR

- e. Alternatively, click on “Start email discussion” to initiate a discussion via your email account.

Attachment Reports (PDF/Word/Excel/PowerPoint)

You can view, print, and save Attachment Reports available in the Data Reports section. Click on a report under Data Reports to view and download it.

Upload Reports

You can upload a report by following the steps below:

1. Click the dropdown arrow next to “Data Reports,” mouse over “Add Report,” and select “From File” or “From Link.”



2. On the Create Attachment Report page enter the report name, description and other fields as needed and click “Browse” to upload the report. To add a link report, enter the link URL in the text box.
3. You can also share the report by selecting the checkbox “Share this report with all users?”
4. Click “Save” to go back to the “Data & Reports” tab. Once saved, the report gets added to the list of reports under Data Reports.

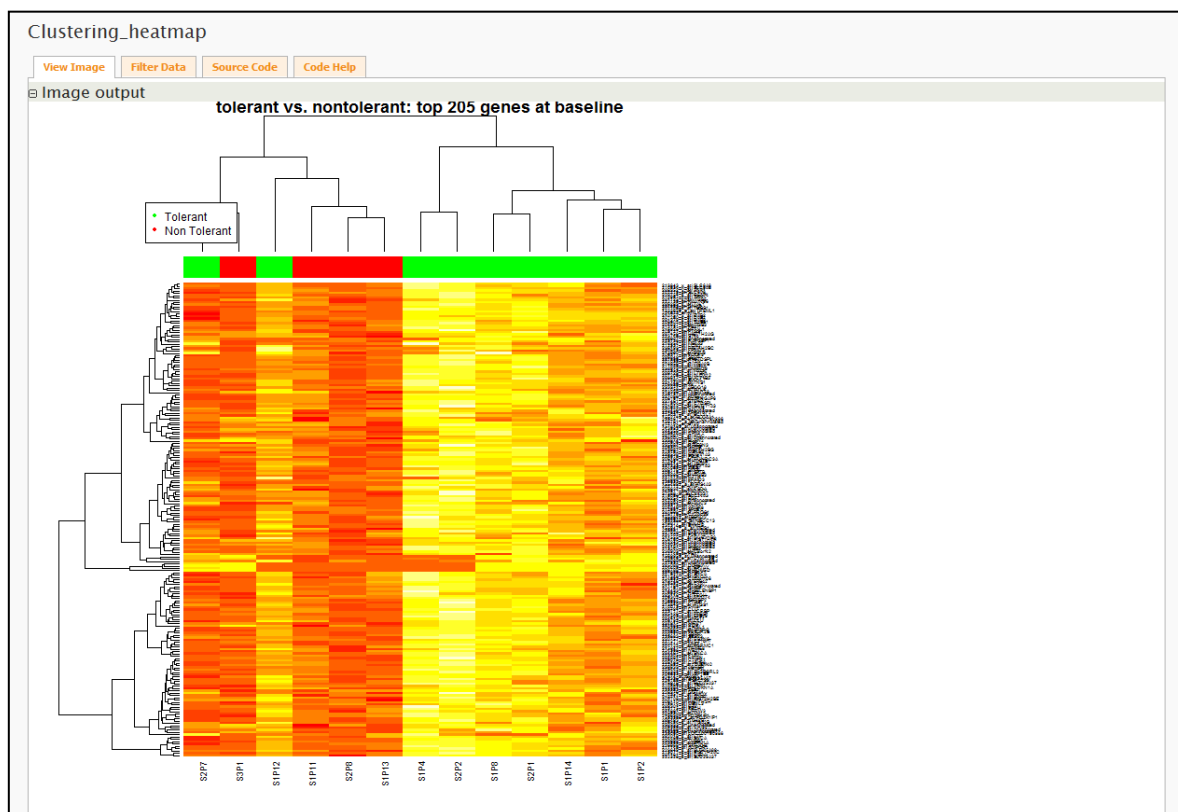
Note

The Upload Report feature is not available to users with read-only access.

R Charts

Each Study will have one or more R charts that have been created by ITN to display study data in an interesting and informative manner. These can be anything from simple graphs to histograms to heat maps, and you can filter the data you want to display.

1. Click on an R Chart in Data Reports to open up the R chart.
2. The “**View Image**” tab displays with the image output.



3. Click on the “**Filter Data**” tab to view the raw data.

Clustering_heatmap

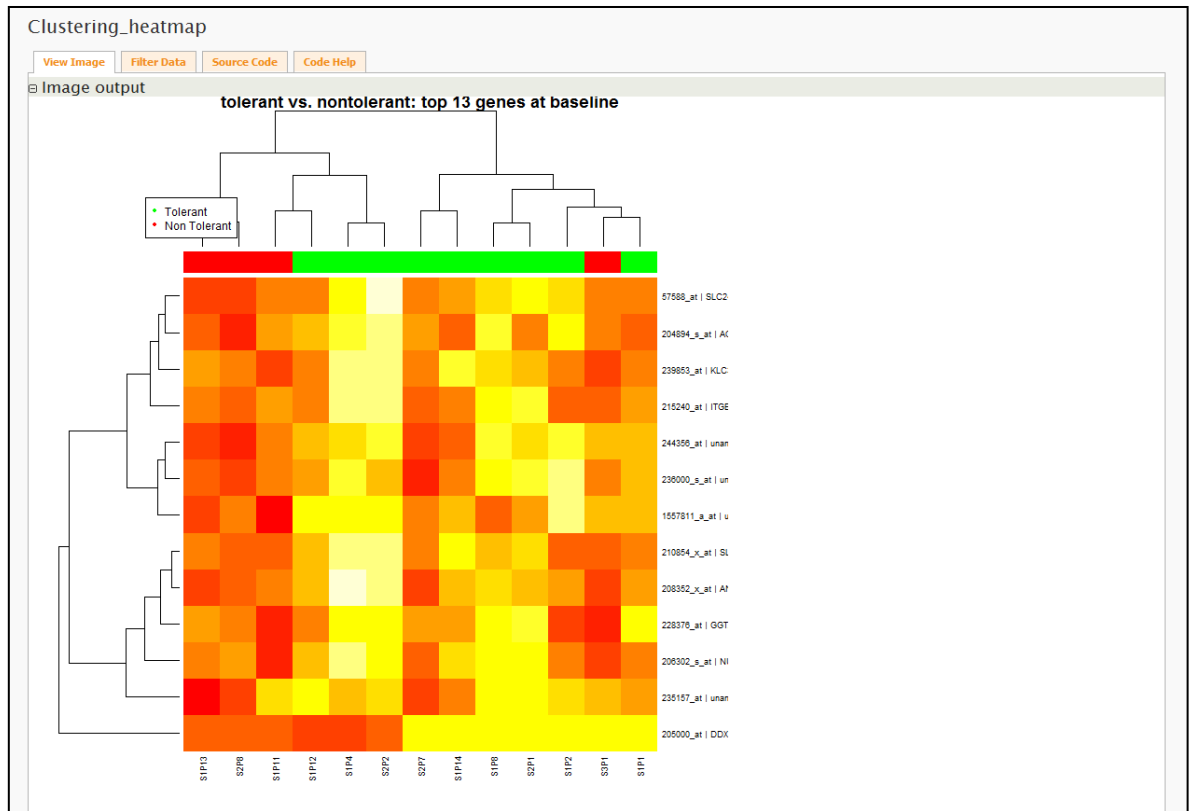
View Image | Filter Data | Source Code | Code Help

Download input data ?

ID	Genename	Genesymbol	Gene.ID	Combo ID	Score.d	Numerator.r.	Denominator.s.s0.	Fold Change	q.value	FC	Alberto	Newell
1552583_s_at	ATP-binding cassette, sub-family C (CFTR/MRP), member 13	ABCC13	1552583_s_at	1552583_s_at ABCC13	1.1893	1.1609	0.9762	2.236	7.7733	2.236		
1552713_a_at	solute carrier family 4, anion exchanger, member 1 (erythrocyte membrane protein band 3, Diego blood group)	SLC4A1	1552713_a_at	1552713_a_at SLC4A1	1.5407	1.4837	0.963	2.7966	5.2106	2.7966		
1553589_a_at	PDZK1 interacting protein 1	PDZK1IP1	1553589_a_at	1553589_a_at PDZK1IP1	1.1007	1.0635	0.9661	2.0899	9.9129	2.0899		
1553842_at	BEN domain containing 2	BEND2	1553842_at	1553842_at BEND2	1.7654	1.5445	0.8749	2.917	5.2106	2.917		
1554892_a_at	membrane-spanning 4-domains, subfamily A, member 3 (hematopoietic cell-specific)	MS4A3	1554892_a_at	1554892_a_at MS4A3	1.4468	0.9901	0.6843	1.9863	5.2106	1.9863		
1555659_a_at	triggering receptor expressed on myeloid cells-like 1	TREML1	1555659_a_at	1555659_a_at TREML1	1.4193	1.1992	0.8449	2.2961	5.8395	2.2961		
1557811_a_at	---	---	1557811_a_at	1557811_a_at unannotated	1.0934	0.7626	0.6975	1.6966	9.9129	1.6966		
1559477_s_at	Meis homeobox 1	MEIS1	1559477_s_at	1559477_s_at MEIS1	1.3266	0.8169	0.6158	1.7617	6.0888	1.7617		
1560800_at	---	---	1560800_at	1560800_at unannotated	1.1253	1.4426	1.282	2.7181	9.0869	2.7181		
1569955_at	---	---	1569955_at	1569955_at unannotated	1.4524	1.3304	0.916	2.5148	5.2106	2.5148		
1570165_at	---	---	1570165_at	1570165_at unannotated	1.1146	1.0279	0.9222	2.039	9.0869	2.039		
200606_at	desmoplakin	DSP	200606_at	200606_at DSP	1.3325	1.5814	1.1868	2.9927	6.0888	2.9927		
200665_s_at	secreted protein, acidic, cysteine-rich (osteonectin)	SPARC	200665_s_at	200665_s_at SPARC	1.6553	1.4141	0.8543	2.6649	5.2106	2.6649		
201005_at	CD9 molecule	CD9	201005_at	201005_at CD9	1.5931	1.1076	0.6953	2.1549	5.2106	2.1549		
201058_s_at	myosin, light chain 9, regulatory	MYL9	201058_s_at	201058_s_at MYL9	1.5688	1.704	1.0862	3.258	5.2106	3.258		
201059_at	cortactin	CTTN	201059_at	201059_at CTTN	1.3873	1.2319	0.888	2.3488	5.8395	2.3488		
201108_s_at	thrombospondin 1	THBS1	201108_s_at	201108_s_at THBS1	1.3102	1.1342	0.8657	2.1949	6.0888	2.1949		
201121_s_at	progesterone receptor membrane component 1	PGRMC1	201121_s_at	201121_s_at PGRMC1	1.1473	0.7001	0.6102	1.6246	9.0869	1.6246		
201125_s_at	integrin, beta 5	ITGB5	201125_s_at	201125_s_at ITGB5	1.2796	0.9354	0.731	1.9124	6.0888	1.9124		
201161_s_at	cold shock domain protein A	CSDA	201161_s_at	201161_s_at CSDA	1.3155	0.8959	0.681	1.8607	6.0888	1.8607		

- You can filter data by clicking on a column name and selecting filter for further analysis. In the example below a filter was selected for the column “Score.d”.

- Click “OK” after selecting a filter type. Once you have filtered on a column, the filter icon (▼) appears next to the title of that column in your data grid view.
- Based on the data filter the image is refreshed. Click on “View” tab to see the new image.



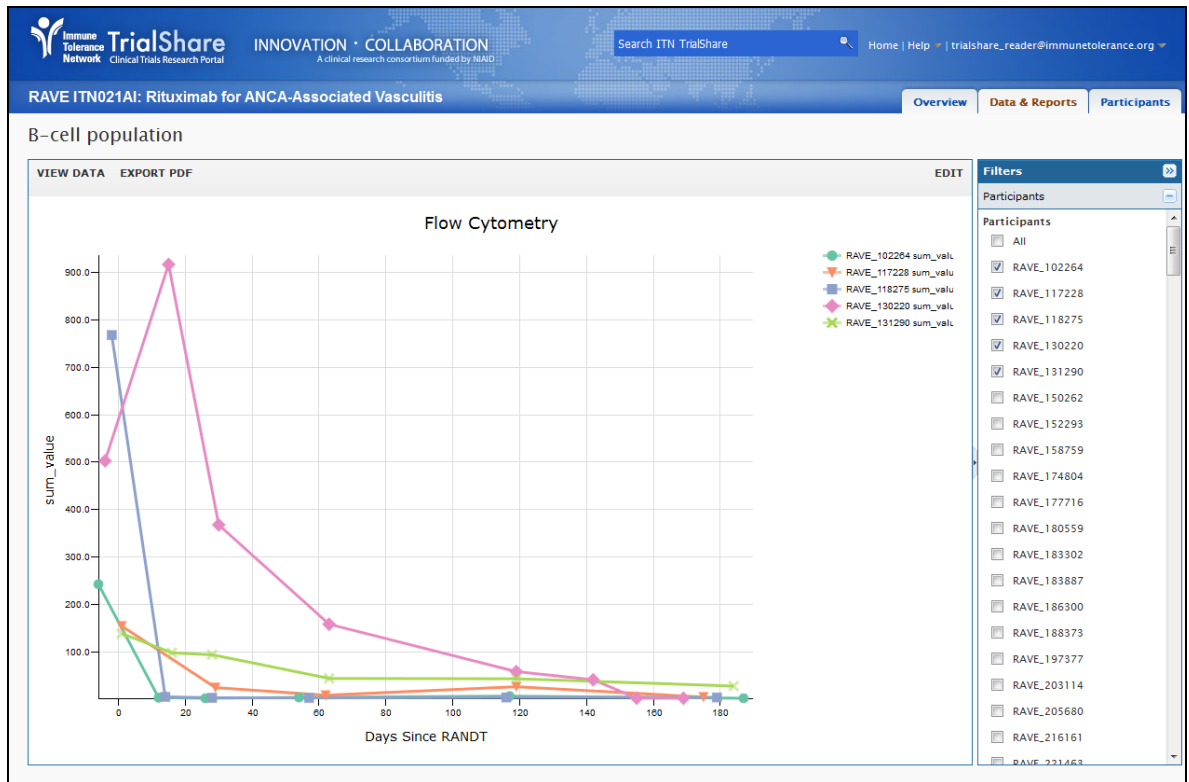
7. To clear a filter from a single column, click on the column heading and select Clear Filter.
8. Click on the “Source Code” or “Code Help” tabs to view the source code and referential content.
9. You can initiate a discussion using your email account or start a discussion on the same page by clicking on the “Discussion” button displayed on all tabs.

Time Chart

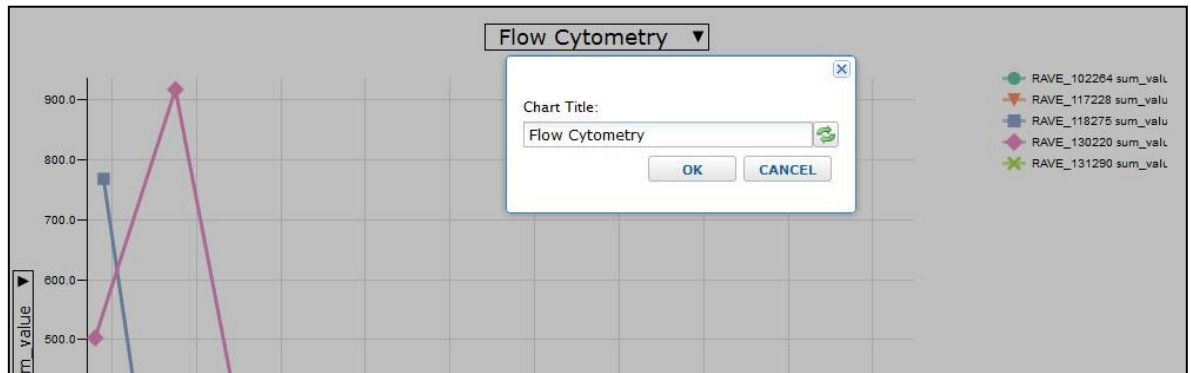
A time chart allows you to view data for a selected measure over time. Analyze the data by customizing existing time charts and saving as a new chart in the Data Reports section. Customize an existing Time Chart by following the steps below:

[Customize an Existing Time Chart](#)

1. Click on a Time Chart under Data Reports to navigate to the chart view.



2. You can use the “Edit” button to make changes to the default chart view.
3. You can update the chart title by clicking on the title dropdown as shown below.



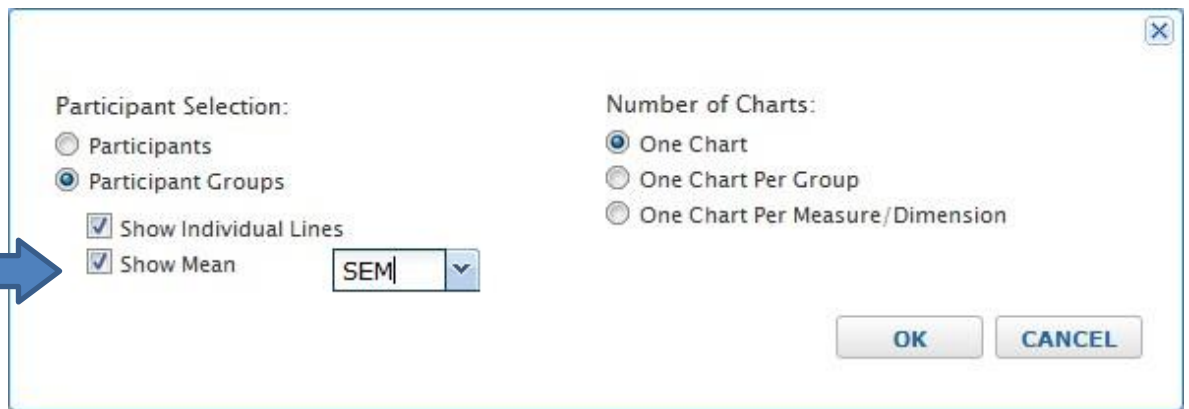
4. Click on the “Measures” tab.
 - a. Click on “ADD MEASURE” or “REMOVE MEASURE” button to add/remove a measure.

Note Contact TrialShare Support if you do not see the measure of interest.

- b. Customize the chart by selecting options from the drop-downs displayed on the right.
5. Click on the **X-Axis** label to customize the X-Axis.
 - a. Click on “Visit Based Chart” or “Date Based Chart” radio buttons to view charts based on visits or dates.

- b. For a Date Based Chart select an option from the “Draw x-axis as:” dropdown to draw x-axis as days/weeks/months/years.
 - c. Select an option from the “Calculate time interval(s) relative to:” dropdown to select a demographic.
 - d. Click on “Visit Based Chart” radio button to display Visit based chart view.
6. Click on the “**Measures**” or “**Grouping**” buttons to customize the chart and add error bars.
 - a. Select “Participants” or “Participant Groups” radio buttons to view charts based on Participant/Participant Groups type.
 - b. If the chart displayed is based on Participants:
 - i. Click on “Participants” tab to the right of the displayed chart.

- ii. On the **Participants** tab you can select which individual participants appear in the chart. The Time Chart Wizard displays charts only for the selected participants.
- c. If the chart displayed is based on “Participant Groups” type:
 - i. Under the **Groups** tab displayed to the right of the chart, manage groups by selecting/deselecting a participant group. The chart is refreshed to display the selected groups.
 - ii. Add error bars to the chart to show mean by selecting “Show Mean” checkbox and selecting a measure of variability.



- d. You can select the appropriate radio buttons on the **Grouping** popup to view one chart for all participants/groups or one chart per measure/dimension or one chart per participant/group.
- 7. You have the option of saving the chart by clicking on the “[SAVE/SAVE AS](#)” button on the “**Overview**” tab. The chart will display under the appropriate category in the Data Reports section after saving.
- 8. To download or print the chart click on the “[EXPORT PDF](#)” dropdown above the time chart.
- 9. Click on “[VIEW DATA](#)” to view raw data for the chart.

DATA SETS AND VIEWS

The “**Data Sets and Views**” section is available on the “[Data & Reports](#)” tab. This section displays a listing of datasets selected by ITN for the specific study. You can also view all datasets for that study by navigating to the [Study Navigator](#) page.

This section displays a Status column for each dataset with corresponding status icons. Unlocked conveys the possibility of future changes to the dataset. The “locked” status icon displays for

clinical datasets once the clinical database has been locked. Final indicates that a dataset has been used for a specific publication, abstract or presentation analysis/figure.

Name	Type	Details	Data Cut Date	Status
Derived Clinical				
Concomitant Medications_ADCMED1	Dataset		2012-03-12	🔒
HCV viral load_ADHCV1	Dataset		2012-03-12	🔒
Trough Level Information_ADTL2	Dataset		2012-03-12	🔒
adverse events_ADAE1	Dataset		2012-03-12	🔒
all visits occurring during the study_ADVIS1	Dataset		2012-03-12	🔒
allograft dysfunction episode data_ADALLO2	Dataset		2012-03-12	🔒
diagnostic procedures for allograft episodes_ADDIAG1	Dataset		2012-03-12	🔒
dosing information and tapering levels_ADMD1	Dataset		2012-03-12	🔒
infections_ADINF1	Dataset		2012-03-12	🔒
laboratory data (chemistry, hematology)_ADLB1	Dataset		2012-03-12	🔒
laboratory data (transposed of ADLB1)_ADLBTR2	Dataset		2012-03-12	🔒
local biopsies_ADBPSY1	Dataset		2012-03-12	🔒
overall outcome data_ADSL3	Dataset		2012-03-12	🔒
participant characteristics and demographics_ADSTART0	Dataset		2012-03-12	🔒
protocol deviations_ADPV1	Dataset		2012-03-12	🔒
stopping rules for review of adverse events_ADSTOP2	Dataset		2012-03-12	🔒
Mechanistic				
AlloAntibody	Dataset		2012-03-12	🔒

1. To navigate to a dataset’s grid view, click on a dataset name or the Details icon.
2. A page displays showing the data collected for all participants and visits in a grid view.

Note Contact TrialShare Support if you need assistance in creating a dataset by merging two datasets in a study.

DATASET GRID VIEW

The default dataset grid view displays data for all participants. The data displayed in the dataset grid view is a snapshot of the data as of the last refreshed date provided.

All datasets display with the status clearly visible above the grid. Graphs and Reports are current to the extent of the data they are based on. The reports and plots are refreshed every time the dataset gets refreshed from the database. Follow the instructions in the sections below to customize and view data using the grid view.

Note In case of more than one page of dataset results, you can navigate from one page to another by clicking on the “Next >,” “Last >>,” “<< First,” or “<Prev” links as displayed above/below the data grid.

1. Click on a participant ID to view and analyze graphs and reports for that participant.
2. The participant view is displayed. For information relating to the participant view go to [Chapter 6 Participants](#).
3. You can filter and sort data to create a subset of data by following instructions in the following two sections. This subset can be used to create graphs and charts that provide a snapshot of the dataset.

Note You can also save a dataset grid view using filter and sorts by following instructions in [Filter/Sort Data Using Custom View Designer](#).

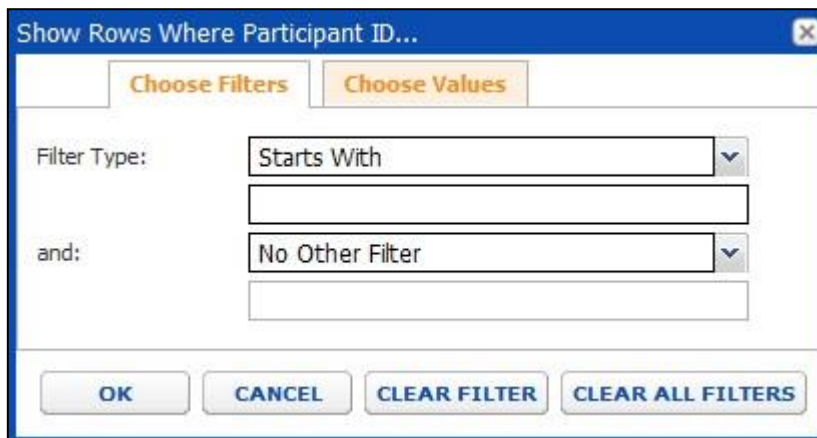
Filter Data by Column

1. To filter on a column, click on the column name and select the Filter option in the menu that appears.

The screenshot shows the TrialShare interface for the dataset 'RAVE ITN021A1: Rituximab for ANCA-Associated Vasculitis'. The dataset is titled 'Dataset: AAV History_ADAAV1, All Visits' and contains up to one row of data for each participant/visit combination. The table has 20 columns: Participant ID, Sequence Num, Flare after Remission w/ Previous Trt, Prior AAV Immunosuppressive Therapy, AAV Type, Treatment (5 levels) at 18 months, Treatment (4 levels), Age at Informed Consent (years), Age Group (years), BL Alveolar Haemorrhage (Yes, No), ANCA Serologies at Diagnosis, ELISA for ANCA Ever, ELISA ANCA Pattern, ANCA Positive IF Serologies Ever, ANCA Positive IF Pattern, ANCA Status - PR3 or MPO, Biopsy at Screening, Baseline Body Mass Index (BMI), Best Medical Judgement, and BMJ by 12 months. A dropdown menu is open for the 'Participant ID' column, showing options for 'Sort Ascending', 'Sort Descending', and 'Filter...'. A red arrow points to the 'Filter...' option.

Participant ID	Sequence Num	Flare after Remission w/ Previous Trt	Prior AAV Immunosuppressive Therapy	AAV Type	Treatment (5 levels) at 18 months	Treatment (4 levels)	Age at Informed Consent (years)	Age Group (years)	BL Alveolar Haemorrhage (Yes, No)	ANCA Serologies at Diagnosis	ELISA for ANCA Ever	ELISA ANCA Pattern	ANCA Positive IF Serologies Ever	ANCA Positive IF Pattern	ANCA Status - PR3 or MPO	Biopsy at Screening	Baseline Body Mass Index (BMI)	Best Medical Judgement	BMJ by 12 months
		Not Applicable (Newly Diagnosed)	No	Wegener's Granulomatosis (WG)	RTX Only		69.0	>60	Yes	Yes	Yes	PR3	Yes	C-ANCA	PR3	No	25.5	Yes	
		Not Applicable (Newly Diagnosed)	No	Wegener's Granulomatosis (WG)	CYC Only		45.0	41-50	No	Yes	Yes	PR3	Yes	C-ANCA	PR3	No	28.8	Yes	
RAVE_118275	142.0	Not Applicable (Newly Diagnosed)	No	Wegener's Granulomatosis (WG)	RTX Only		60.0	51-60	Yes	Yes	Yes	PR3	Yes	C-ANCA	PR3	No	31.5	Yes	
RAVE_130220	142.0	Yes	No	Wegener's Granulomatosis (WG)	CYC All Others		55.0	51-60	No	No	Yes	PR3	Yes	C-ANCA	PR3	Yes	46.2	Yes	
RAVE_131290	142.0	Not Applicable (Newly Diagnosed)	No	Wegener's Granulomatosis (WG)	CYC Only		69.0	>60	No	Yes	Yes	MPO	Yes	P-ANCA	MPO	Yes	24.8	Yes	
RAVE_150262	142.0	Yes	Yes	Wegener's Granulomatosis (WG)	CYC Only		54.0	51-60	No	Yes	Yes	PR3	Yes	C-ANCA	PR3	Yes	33.2	Yes	
RAVE_152293	142.0	Not Applicable (Newly Diagnosed)	No	Microscopic Polyangiitis (MPA)	CYC Only		64.0	>60	Yes	Yes	Yes	MPO	Yes	P-ANCA	MPO	Yes	34.9	No	
RAVE_158759	142.0	Not Applicable (Newly Diagnosed)	No	Indeterminate	RTX Only		79.0	>60	No	No		MPO		P-ANCA	MPO	No	22.8	Yes	

2. One of the following filter dialogs will appear:



Note The Choose Values option might not be available for all columns.

3. You can select checkboxes under Choose Values.

OR

Choose a filter type under the Choose Filters tab. Choose the desired filtering option from the list, and if a comparative value is required, enter it in the text field beneath the options list. You can also filter the same column on another set of criteria by choosing a filtering option from the second options list in the filter dialog.

4. Once you have filtered on a column, the filter icon (▼) appears next to the title of that column in your data grid view. Also, a description of the current filters appears below the button bar, along with a link to clear all filters.
5. To clear a filter from a single column, click on the column heading and select Clear Filter.
6. To clear all filters (and all sorts), hover above the data grid headings to click on the “[CLEAR ALL](#)” link that appears above the column headings.

Sort Data by Column

1. To **sort** data displayed in a grid view, click on the column name. If the column is sortable (and most columns you will encounter in grids are sortable), the sort/filter popup menu will appear.
2. Choose Sort **Ascending** or Sort **Descending** to sort the dataset based on the contents of the chosen column.
3. Once you have sorted your dataset using a particular column, a **triangle icon** will appear in the column header. If the column's sort is ascending, the triangle points up; if the column's sort is descending, the triangle points down.
4. To remove a sort on an individual column, click the column caption and select **Clear Sort**.

Create Views/Charts (Time Chart, Box Plots, Scatter Plots)

Graph Data or create your own views for a dataset using the Views dropdown above the data grid. You can create different types of charts including Time Charts, Box Plots, and Scatter Plots.

To create a new view, you first need to navigate to a dataset grid view, typically by clicking on the name of a dataset on the Data & Reports tab. You can create views for subsets of data by first filtering data or creating a custom grid view. Once saved, the views are added to the appropriate category under the Data Reports section.

You can also delete newly created views by following the instructions in the section [Manage Views/Delete Views](#).

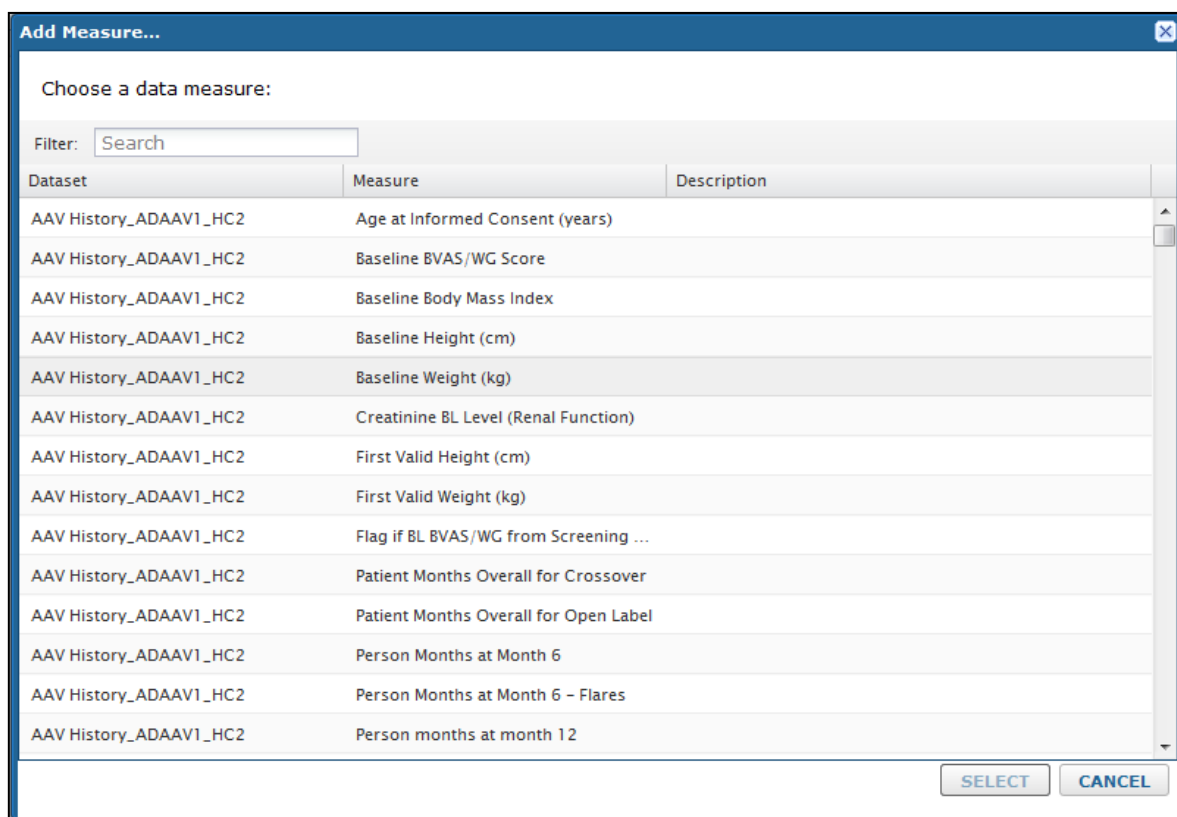
[Create Graphs using Time Chart Wizard](#)

You can create a new Time Chart for a dataset by following the two paths below:

1. Click on the “NEW TIME CHART” link on the Data & Reports tab.

OR

- Click Create > Time Chart from the “**VIEWS**” dropdown above the dataset grid.
- The Time Chart Wizard “**Overview**” tab displays.
 - Click on “[Choose a Measure](#)” to get started. The “Choose a Measure...” window displays.



- Choose a data measure and click “SELECT.”
- The “**Measures**” tab displays.
- Follow instructions from step 4 onwards in the section “[Customize an Existing Time Chart](#).”

[Manage Views/Delete Views](#)

You can manage any views you have created for a dataset using this feature.

- Select “Manage Views” from the “**VIEWS**” dropdown.
- Rename a chart created by you by selecting “RENAME” in the header row or highlight the chart view and click “**DELETE SELECTED**” in the header row.


Filter/Sort Data using Custom View Designer

To filter and sort the default dataset view and save alternative views, click the "Customize View" link from the "VIEWS" drop-down above the data grid to open up the "Custom View Designer." The Custom View Designer allows you to create subsets of data using available filters and sorts and saving them as views. You can also create graphs and charts from this subset using the new views created.


Select "Customize View" from the dropdown. The "Custom View Designer" box displays with the available field selection for data grid columns.

1. Select fields to add to the grid. They are added to the "Selected Fields" box. You can select the "Show Hidden Fields" checkbox to view all available fields.
2. To remove a field from the grid, place your cursor on the field under Selected Fields and click on the Remove Column button on the right.

Filter Data

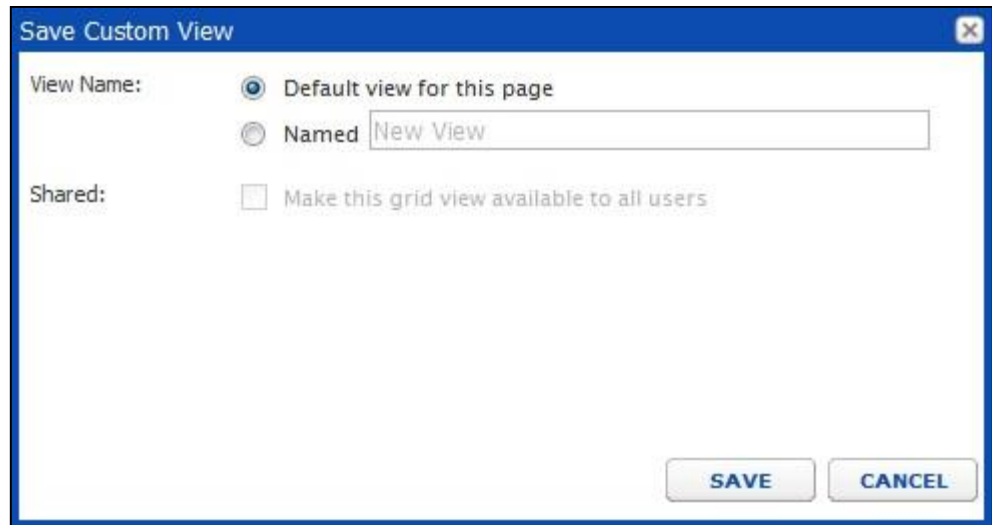
1. You can filter data from the Custom View Designer by clicking on the **Filter** tab on the left.
2. Select a field from the available fields displayed in the left column of the box to add it under Selected Filters. Once added, you can select a filter criterion from the dropdown for the added field.
3. Click ADD  **ADD** to add the filter.

Sort Data

1. Click on the **Sort** tab on the left. This feature allows you to sort and rearrange data for viewing and analysis.
2. Select fields from the Available Fields box. Once selected, they display under the **Selected Sort** box. You can select Ascending/Descending to sort data accordingly.
3. Click Add  **ADD** to add the sort.

Save Customized Data Views

1. Click "SAVE" button to save the changes to the dataset as a default view or as a new customized view as shown in Figure below.



The dialog box titled "Save Custom View" has a close button (X) in the top right corner. It contains the following fields:

- View Name:**
 - Default view for this page
 - Named
- Shared:**
 - Make this grid view available to all users

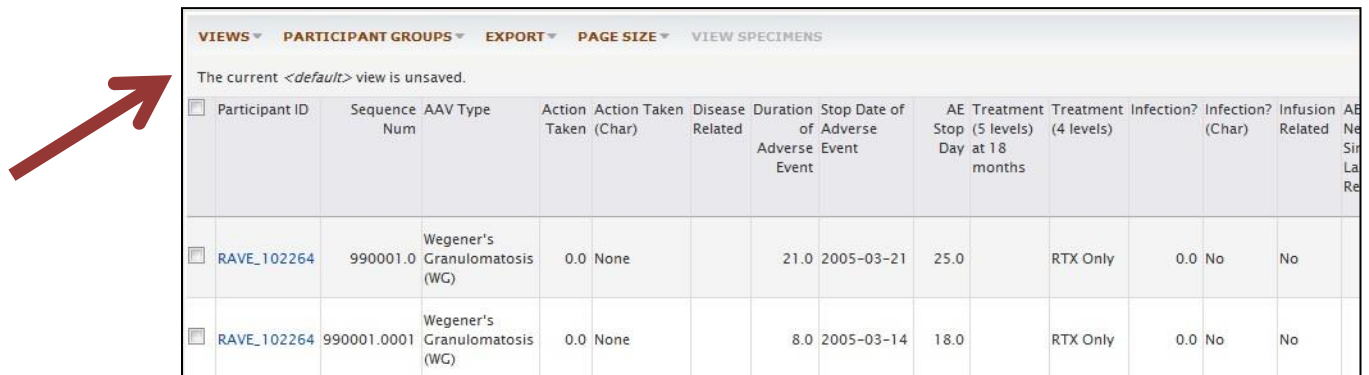
At the bottom right, there are two buttons: **SAVE** and **CANCEL**.

2. The customized data grid displays.

Note

You can also click on **“VIEW GRID”** anytime from the Custom View Designer box to view the data grid.

After adding a filter/sort, if you click on **“View Grid”** without saving the view, the following message is displayed above the grid view.



A red arrow points to a message above the data grid: "The current <default> view is unsaved." The grid has a header with tabs: VIEWS, PARTICIPANT GROUPS, EXPORT, PAGE SIZE, and VIEW SPECIMENS. The grid contains the following data:

Participant ID	Sequence Num	AAV Type	Action Taken	Action Taken (Char)	Disease Related	Duration of Adverse Event	Stop Date of Adverse Event	AE Treatment Stop (5 levels) Day at 18 months	Treatment (4 levels)	Infection? (Char)	Infection? (Char)	Infusion Related	AE Ne Sir La Re
<input type="checkbox"/> RAVE_102264	990001.0	Wegener's Cranulomatosis (WG)	0.0	None		21.0	2005-03-21	25.0	RTX Only	0.0	No	No	
<input type="checkbox"/> RAVE_102264	990001.0001	Wegener's Cranulomatosis (WG)	0.0	None		8.0	2005-03-14	18.0	RTX Only	0.0	No	No	

Place your cursor on the right of the message to highlight and select the Revert, Edit, and Save buttons as needed.

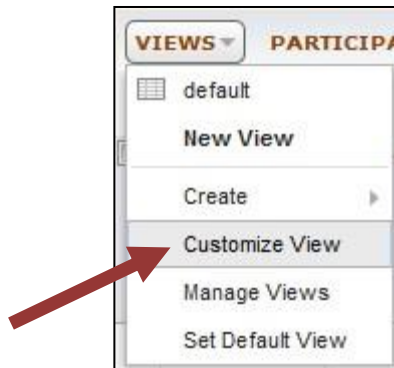
Delete a Custom View

You can delete a custom view by following the steps below.

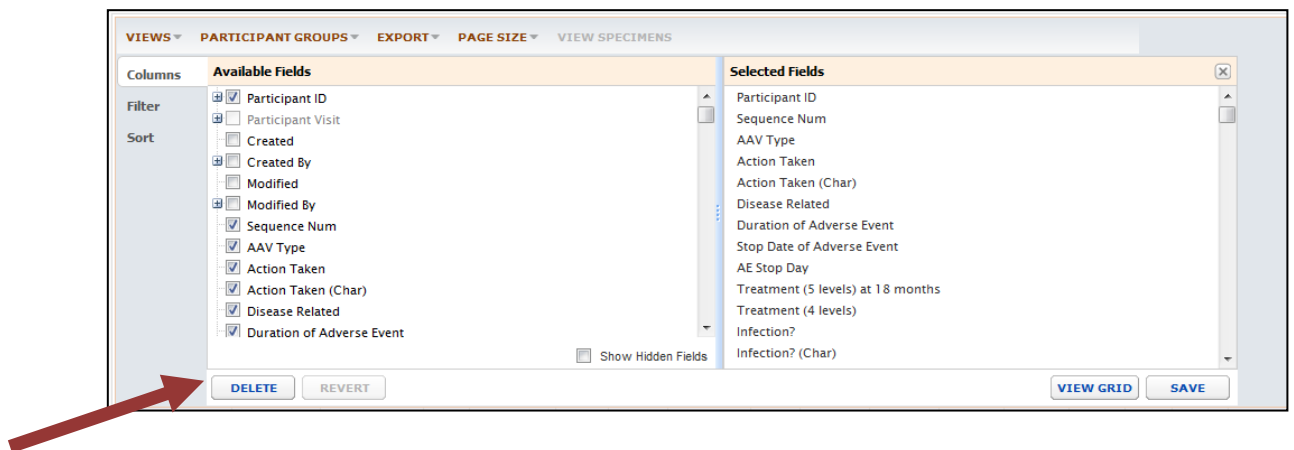
1. Open the view by selecting the view name from the **“VIEWS”** dropdown above the grid. In the example below the view name is **“New View.”**

Note

If custom view was saved as the default view and Option 1 was selected in Figure above, follow instructions under **“Set Default View”** to revert back to the default view.



2. Select “Customize View” from the “VIEWS” dropdown.
3. Click “**DELETE**” to delete the customized view.



Set Default View

1. To revert a updated default view to the original grid view:
 - a. Select “Customize View” from the “VIEWS” dropdown.
 - b. Click on “**REVERT**” button to return to the original default view.

Participant Groups 🌿

Filter Dataset

You can filter a dataset using Participant Groups and Cohorts.

1. Click on the “**PARTICIPANT GROUPS**” dropdown above the grid view and select any available criteria.

2. The data grid redisplay with the filter selected.
3. Click “Clear All” button above the data grid to clear the participant group filter.
Note: Place your cursor after the text “Filter:...” above the data grid to select the button.
4. Select a Cohort criterion to change the current cohort.

Create/Define Participant Groups

This feature provides you the ability to group subjects and create your own participant groups for further analysis. The participant groups are useful when creating or customizing Time Charts. The participant groups are also useful when filtering Specimen Reports and are available as a filter criterion on the Specimens page.

Note You can also create participant groups by following instructions under Shortcuts.

Create your own Participant Groups by selecting Create Participant Group from the “**PARTICIPANT GROUPS**” dropdown above the dataset grid OR Define and Manage Participant Groups by following instructions under [Manage Participant Groups](#).

1. You can create Participant Groups from all participants in the data grid or select participants. Name the group.

Note Participant group names must be unique within the study they are associated with.

The groups created by you will be private and not visible to other users unless you choose to share them.

2. Click “Save” to save the participant group.

Define Participant Group

Participant Group Label:

Participant Identifiers:

Participant Category:

Share Category?

Select Participants from

ADD SELECTED ADD ALL

<input type="checkbox"/>	Participant ID	AAV Type	Cumulative Total Dose of AZA at 18 months	Treatment (5 levels)	Treatment (4 levels)	Age at Informed Consent (years)	Categorical Age (<52, >=52 years)	Age Group (years)	BL Alveolar Haemorrhage (Yes, No)	ANCA Status - PR3 or MPO	Baseline Serum Creatinine (mg/dL)
<input type="checkbox"/>	RAVE_102264	Wegener's Granulomatosis (WG)	5025.0		RTX Only	69.0	>=52 years	>60	Yes	PR3	1.5
<input type="checkbox"/>	RAVE_117228	Wegener's Granulomatosis (WG)			CYC Only	45.0	<52 years	41-50	No	PR3	1.3
<input type="checkbox"/>	RAVE_118275	Wegener's Granulomatosis (WG)			RTX Only	60.0	>=52 years	51-60	Yes	PR3	1.0
		Wegener's			CYC All						

Manage Participant Groups

Follow the instructions below to manage participant groups created by you.

1. Click Manage Participant Groups from the “**PARTICIPANT GROUPS**” dropdown.
2. Define your own participant groups by clicking on “Create” button in the header. The **Define Participant Group** page displays.
3. Enter a group label. Select a Participant category from the dropdown and click checkboxes in the first column to select Participant IDs from the list. Click on “ADD SELECTED” in the header to add Participant IDs to the group. Alternatively, select “ADD ALL” to add all participants.
4. Click “Save” to save the new participant group.
5. You can edit/delete a participant group created by you. Highlight the participant group to edit/delete.

6. Click “Edit Selected” to edit the group. Make the updates and save the group.
7. Click “Delete Selected” to delete the group. Click “YES.”
8. The “Manage Participant Groups” page displays without the group.

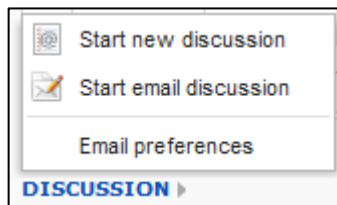
Export/Download Data

TrialShare provides a variety of methods to export data. Your choice of export format determines whether the exported dataset is a static snapshot of the dataset, or a dynamic reflection that updates as the dataset updates. The Excel and TSV formats supply static snapshots, while the Excel Web Query and all three types of scripts allow you to display versions of the dataset that update dynamically.

1. Click on the “**EXPORT**” dropdown above the grid view to download and save the data. A section displays showing the export options. Select one of the following options to download data:
 - Excel
 1. 97-2003Excel File (.xls)
 2. 2007 Excel File (.xlsx)
 3. Refreshable Web Query (.iqy)
 - Text
 - Script
2. Click the “**EXPORT**” dropdown again to collapse the export options section.

Discussion

You can start a discussion for a dataset by selection the options available from the “**DISCUSSION**>” button displayed under the grid view.



- “Start email discussion” allows you to start a private email discussion using your email client.
- “Start new discussion” opens up a form for initiating a discussion from the same page.

NEW PARTICIPANT REPORT

The New Participant Report feature is available under the Study Data Tools. You can create a new participant report by merging available data measures. The resultant report provides a report for all participants in the study for the measures selected.

1. To create a participant report click on the “NEW PARTICIPANT REPORT” under “Study Data Tools.”



2. Click on “CHOOSE MEASURES” button on the Participant Report page and select the measures to create the report. Enter a report name and description.

Participant Report

Participant Report

Report Name:

Report Description:

Viewable by: All readers Only me

Report Measures:

Stop Date of AE	<input type="checkbox"/>
Treatment Required	<input type="checkbox"/>
Age at Enrollment (years)	<input type="checkbox"/>
Date of Informed Consent	<input type="checkbox"/>
Donor Secondary Race (List)	<input type="checkbox"/>
Results Date	<input type="checkbox"/>

EXPORT PRINT COLLAPSE

Showing 25 Results

001001

Age at Enrollment (years):
Date of Informed Consent:
Donor Secondary Race (List):

Visit	Visit Date	Stop Date of AE	Treatment Required	Results Date
Ongoing Logs		31MAY2006	Concomitant medications and non-drug therapies	
Ongoing Logs		28JUL2006	Concomitant medications and non-drug therapies	
Ongoing Logs		28JUL2006	Concomitant medications and non-drug therapies	
Ongoing Logs		13SEP2006	None	
Ongoing Logs		04SEP2006	None	
Ongoing Logs		23OCT2006	None	
Ongoing Logs		11OCT2006	None	
Ongoing Logs		11JUN2008	Concomitant medications	
Ongoing Logs		14MAY2007	None	
Ongoing Logs		04AUG2007	None	
Ongoing Logs		10SEP2007	None	
Ongoing Logs		15NOV2007	Concomitant medications and non-drug therapies	
Ongoing			non-drug therapies	

Filter Report

All

Cohorts

NON-TOL

TOL

Not in any cohort

Groups

Test 3

Test_123

Moderate Portal Fibrosis At Any T

Tolerant

Non Tolerant

DSA at Baseline

Moderate Portal Fibrosis During W

Mild Portal Fibrosis During Weanir

NO Reported Portal Fibrosis Durin

Participants with No DSA at Basel

Participants with C4d mean score

Non Tolerant: Discontinued Taper

Non Tolerant: Failed After IS Taper

Tolerant: In Extended Follow-up

3. Click “Save” to save the report and view it in the “Data Reports” section.
4. You have the option to make the report public by selecting the “All Readers” radio button, or select “Only me” to save the report as private.
5. You can export the report into an excel format by clicking on the “EXPORT” dropdown.

CHAPTER 6 PARTICIPANTS

This Chapter provides information on the following key features available on the Participants tab of a study:

- Participant List
- Participant View

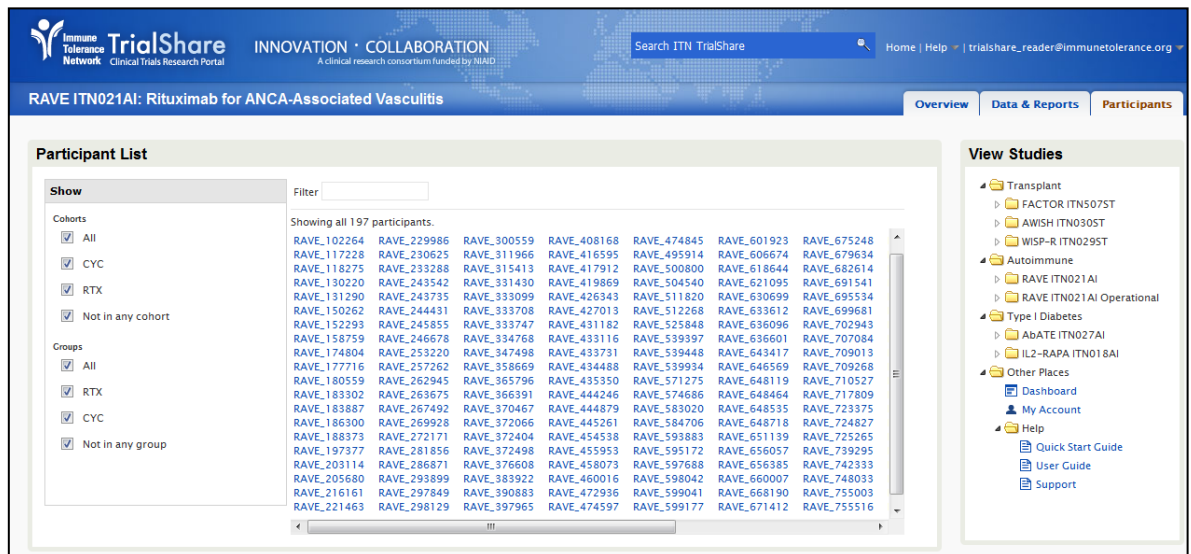
PARTICIPANTS TAB

You can search participant-specific data by clicking on a specific participant ID on the Participants tab. You can navigate to this page by:

1. Clicking on “**Participants**” link under the study name in the “View Studies” tree on the TrialShare Home page.

OR

2. Clicking on the “**Participants**” tab from any other page in the specific study you are in.



PARTICIPANT LIST

The **Participant List** section displays filtering option by participant groups and cohort. You can also filter on a Participant ID by entering key words in the Filter box. You can view Participant Group membership upon hovering over a Participant ID as shown below.

Note Select a Cohort and a Group to view a subset of participants. You can also select two groups or two cohorts to see a combined result of participants for a study.

Click on a participant ID to navigate to the Participant View for associated demographics, graphs, and pathology images.

Filter

Found 98 participants of 197.

RAVE_117228	RAVE_347498	RAVE_500800	RAVE_702943	RAVE_862864
RAVE_130220	RAVE_358669	RAVE_504540	RAVE_707084	RAVE_872913
RAVE_131290	RAVE_365796	RAVE_512268	RAVE_717809	RAVE_873544
RAVE_150262	RAVE_372404	RAVE_525848	RAVE_725265	RAVE_899426
RAVE_152293	RAVE_372498	RAVE_539448	RAVE_739295	RAVE_900237
RAVE_180559	RAVE_383922	RAVE_539934	RAVE_755516	RAVE_903135
RAVE_183302	RAVE_397965	RAVE_574686	RAVE_770501	RAVE_905224
RAVE_197377	RAVE_416595	RAVE_583020	RAVE_770866	RAVE_905527
RAVE_229986	RAVE_417912	RAVE_595172	RAVE_771793	RAVE_914022
RAVE_230625	RAVE_419869	RAVE_601923	RAVE_780040	RAVE_933978
RAVE_243542	RAVE_426343	RAVE_643417	RAVE_789066	RAVE_948521
RAVE_245855	RAVE_427013	RAVE_648464	RAVE_800852	RAVE_949002
RAVE_262945	RAVE_431182	RAVE_648535	RAVE_801772	RAVE_951592
RAVE_272171	RAVE_434488	RAVE_648718	RAVE_804680	RAVE_952896
RAVE_286871	RAVE_444246	RAVE_651139	RAVE_807498	RAVE_960859
RAVE_293899	RAVE_444879	RAVE_656057	RAVE_809087	RAVE_962691
RAVE_298129	RAVE_454538	RAVE_668190	RAVE_817956	RAVE_966788
RAVE_315413	RAVE_474597	RAVE_679634	RAVE_822494	RAVE_992462
RAVE_333099	RAVE_474845	RAVE_682614	RAVE_834980	
RAVE_333747	RAVE_495914	RAVE_699681	RAVE_839302	

Participant ID

PARTICIPANT VIEW

Based on the study type the participant view might display one or all of the following tabs.

All Datasets/Demographic Datasets Tab

The “**All Datasets/Demographic Datasets**” tab displays the demographics and all of the datasets for the selected participant depending on the study selected.

Flow Cytometry Tab

The “**Flow Cytometry**” tab displays graphs based on flow cytometry data.

Timeline Tab

The “**Timeline**” tab displays the timeline for the participant across the time span of a trial with information on the clinical events as they occurred.



Click on an event to see the timeline. The figure below shows the timeline for the event “Biliary Stricture (Resolved).”



Pathology Tab

The Pathology tab displays Pathology Reports for the selected participant for various visits.

Demographics Data Sets								Timeline		Pathology		DSA_Ab		ALT_Treg	
Pathology Reports															
Participant ID	Date	PRIMARY DIAGNOSIS	SECONDARY DIAGNOSIS	BANFF Central (pathology)	BANFF Local (biopsy)	BANFF Score Description (biopsy)	Ishak Fibrosis Score (biopsy)	Other Findings (biopsy)							
1998-06-12						3.0 Acute Rejection-Grade II Moderate		Other: FOCAL HEPATOCYTE NECROSIS							
2006-07-12		Non-specific change	Steatohepatitis non EOH related	0		N/A	No fibrosis	Other: MILD STEATOSIS (GRADE 1)							
2007-04-18		Non-specific inflammation	Other, comment below	0											
2009-07-07		Nodular Regenerative Hyperplasia		0											
2011-07-26						N/A	No fibrosis	Other: minimal nonspecific findings							

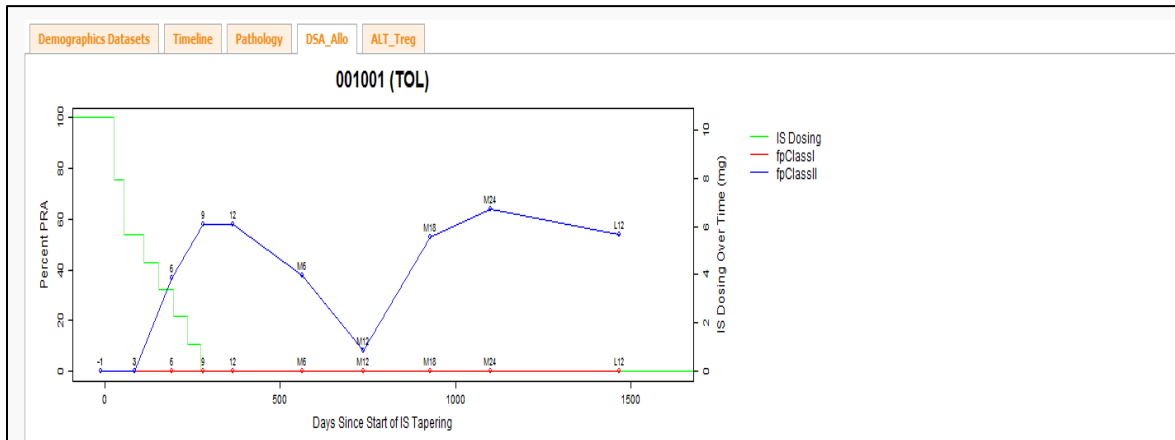
VisitNumber: - 1

Click on an image to have an enlarged view. You can also filter and sort the reports using the filter/sort feature available for each column.

You can click on a Primary or Secondary Diagnosis under “**Pathology Reports**” to view the Diagnosis codes. Click on the “**SHOW GRID**” button on the “View List Item” page to navigate to the Diagnosis Codes listing.

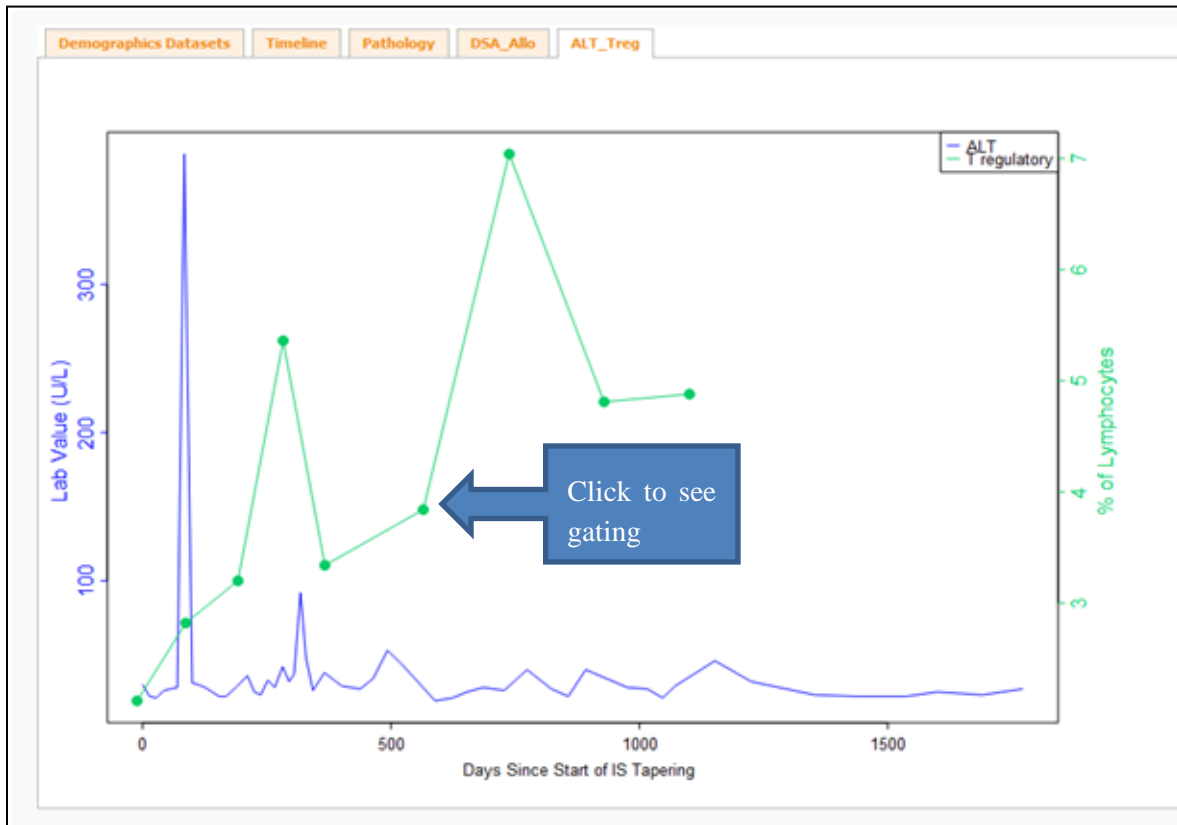
DSA_AlloTab

DSA_Allo tab displays combined graphs of DSA data plotted against alloantibodies for viewing and analysis.



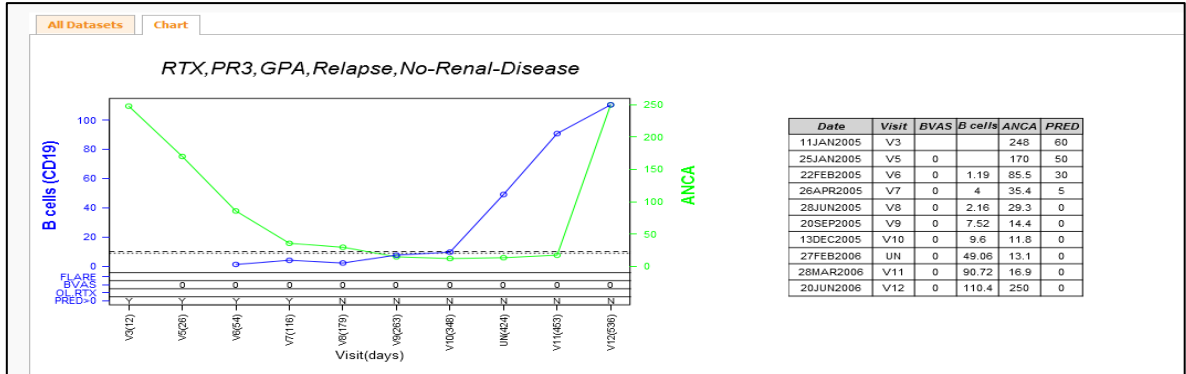
ALT_Treg Tab

The ALT_Treg tab displays combined graphs of ALT data plotted against Treg data for analysis. It displays one graph per participant depending on whether there is flow cytometry data available. You can click on the individual dots to see gating.



Chart

The chart tab displays Visit charts for the dataset selected.



CHAPTER 7 SPECIMENS

This Chapter provides information on the following key features available on the Specimens tab of a study:

- Specimen Report
- Specimens

SPECIMENS TAB

You can search specimens and view specimen reports using the Specimen page. You can navigate to this page by:

1. Clicking on “**Specimens**” link under the study name in the “View Studies” tree on the TrialShare Home page.

OR

2. Clicking on the “**Specimens**” tab from any other page in the study you are in.

Specimen Report

Cohort filter: All Cohorts
 Participant Group: All Groups
 Availability status: All vials
 Base view: Base report on all vials
 Type breakdown: Show results by: Derivative

REFRESH PREVIEW EXPORT TO EXCEL

		Pre-enrollment -2	Pre-enrollment -1	Month M0	Month M1	Month M2	Month M3	Month M5	Month M8	Month M10	Month M11	Month M12	Month M6	Month M12	Month M18	Month M24	Month L6	Month L12	R	Unscheduled	
liver	biopsy		63				3		22	5	5	4								37	2
whole blood	PBMC-CPT	45	12		91	1	30	17	11												
	PBMC-Na Hep	55	7	4	372	193	37	45	54		4	24	62	56	51	53	4	41	48	29	
	RNA	118	163				90	93	75	1	3	27	38	32	10	49				23	13
	Serum-Clot	29	26				50	89	74			25	131	122	140	147				109	54
	Serum-SST	84	50				55	44	23												19
	Serum	48	32				31	35	24		5	50									41
	plasma-CPT	191	48				96	71	36												
	whole blood	132	34		324	16	54	50	45		3	18	36	33	36	33				27	21

Specimens

View All Specimens
 By Vial Group
 By Individual Vial
 Search Specimens
 For Vial Groups
 For Individual Vials
 Specimen Reports
 Specimen Requests

Vials by Primary Type
 liver 171
 whole blood 5075
 Vials by Derivative

Dataset Information

Clinical Data Set Documentation Files

attached files

- ITN0295T_AnnotatedCRF.pdf
- ITN0295T_AnalysisDatasetSpecifications.pdf

SPECIMEN REPORT

The “**Specimen Report**” section displays on the “**Specimens**” tab. You can view and print the Specimen Summary report from this page. This type of report provides an overall summary of specimens taken by type and time point. Filter and view the available specimen reports by following instructions under [Specimen Reports](#).

		Pre-enrollment -2	Pre-enrollment -1	Month H0	Month H1	Month H2	Month H3	Month H6	Month H9	Month H10	Month H11	Month H12	Month M6	Month M12	Month M18	Month M24	Month L6	Month L12	R	Unscheduled
liver	biopsy		63				2		22	5	5	4				23			37	2
whole blood	PBMC-CPT	45	12		91	1	30	17	11											
	PBMC-Na Hep	55	7	4	372	193	37	45	54		4	24	62	56	51	53	4	41	48	29
	RNA	118	163				90	93	75	1	3	27	38	32	10	49			23	13
	Serum-Clot	29	26				50	89	74			25	131	122	140	147		109	54	81
	Serum-SST	84	50				55	44	23										19	
	Serum	48	32				31	35	24		5	50							41	
	plasma-CPT	191	48				96	71	36											
	whole blood	132	34		324	16	54	50	45		3	18	36	33	36	33		27	21	20

1. Click “**PRINT VIEW**” to print the default Summary Report. Note that after selecting "Print View," you will still need to use the File->Print option in your browser to send your print-ready report to your printer.
2. Click “**EXPORT TO EXCEL**” to export the summary count to a spreadsheet format.
3. You can customize the default report by selecting options from the available filters that include participant groups, cohort, vial availability, and specimen type.

Note Cohorts are groupings defined by the Study Protocol, while Participant Groups are defined by end users or the data management team at ITN.

4. Click “**REFRESH**” to refresh the “**Summary (Vial Count)**” grid.
5. The “**Specimen Report: Summary Report**” page displays.

WISP-R ITN029ST: Immunosuppression Withdrawal for Pediatric Liver Recipients

Specimen Report: Summary Report

Cohort filter: All Cohorts
 Participant Group: All Groups
 Availability status: All vials
 Base view: Base report on all vials
 Type breakdown: Show results by: Derivative

Summary (Vial Count)

	Pre-enrollment -2	Pre-enrollment -1	Month H0	Month H1	Month H2	Month H3	Month H6	Month H9	Month H10	Month H11	Month H12	Month M6	Month M12	Month M18	Month M24	Month L6	Month L12	R	Unscheduled
liver biopsy		63				2		22	5	5	4				23			37	2
whole blood PBMC-CPT	45	12		91	1	30	17	11											
whole blood PBMC-Na Hep	55	7	4	372	193	37	45	54		4	24	62	56	51	53	4	41	48	29
whole blood RNA	118	163				90	93	75	1	3	27	38	32	10	49			23	13
whole blood Serum-Clot	29	26				50	89	74			25	131	122	140	147		109	54	81
whole blood Serum-SST	84	50				55	44	23										19	
whole blood Serum	48	32				31	35	24		5	50							41	
whole blood plasma-CPT	191	48				96	71	36											
whole blood	132	34		324	16	54	50	45		3	18	36	33	36	33		27	21	20

6. The Cohort filter you select should fall in the same category or classification as the Participant Groups for results to show up in the grid.

For e.g. the figures below show two different results based on the filters selected.

The first figure shows a scenario when no results are displayed, because the Cohort and Participant Group are not from the same category.

WISP-R ITN029ST: Immunosuppression Withdrawal for Pediatric Liver Recipients

Specimen Report: Summary Report

Cohort filter: NON-TOL
 Participant Group: Tolerant
 Availability status: All vials
 Base view: Base report on all vials
 Type breakdown: Show results by: Derivative

Summary (Vial Count)

	Pre-enrollment -2	Pre-enrollment -1	Month H0	Month H1	Month H2	Month H3	Month H6	Month H9	Month H10	Month H11	Month H12	Month M6	Month M12	Month M18	Month M24	Month L6	Month L12	R	Unscheduled
No data to show.																			

The second figure displays the data results when the selected filters are from the same category:

		Pre-enrollment -2	Pre-enrollment -1	Month H0	Month H1	Month H2	Month H3	Month H6	Month H9	Month H10	Month H11	Month H12	Month M6	Month M12	Month M18	Month M24	Month L6	Month L12	R	Unscheduled	
liver	biopsy		22				2		2	2		2								12	
whole blood	PBMC-CPT	9					4	1	2												
	PBMC-Na Hep	36	7	4			23	23	14				4							18	15
	RNA	22	75				36	22	19											8	6
	Serum-Clot	24	26				30	31	29							13				9	37
	Serum-SST	24	8																	19	
	Serum	14	4				13													4	
	plasma-CPT	32					12														
	whole blood	35	21				18	12	9							2				6	9

- Click on a Specimen type number in the “**Summary (Vial Count)**” grid to view the specimen availability.
- The “**Vials**” page displays with the Vial report with the Vial count, available count, and the unavailability reason for a vial etc. Go to [View Specimens](#).

SPECIMENS

The Specimens section is available under the “**Specimens**” tab of a study. The Specimens section on the Study page provides the jumping-off point for accessing specimen records. The links available in the "Specimens" section provide multiple options for finding and listing particular groups of specimens.

View Specimens

You can view all available specimens for the study by clicking on “**By Vial Group**” or “**By Individual Vial**” links under the “**View All Specimens?**” section.

The following figure displays the “**Vials**” page which displays when the “**By Individual Vial**” link is selected:

Specimen Overview >
Vials

GROUP VIALS SEARCH REPORTS

VIEWS EXPORT PRINT PAGE SIZES PARTICIPANT GROUPS REQUEST OPTIONS

View default

Filter: (SequenceNumMin = 1000.0) AND (PrimaryType = whole blood) AND (DerivativeType = PBMC-Na Hep) AND (Non Tolerant = Non Tolerant)

Participant ID	Status	Group	Global Unique Id	Visit Label	Volume	Volume Units	Primary Type	Derivative Type	Additive	Draw Timestamp	Clinic	Processing Location	First Processed By Initials	Primary Volume	Primary Volume Units	Total Volume	Total Volume Units	Comments	Locked In Request
[history]	NON-TOL			Pre-enrollment -2			whole blood	PBMC-Na Hep	01.8 ml cryovial	2008-02-07 00:00	001-University of California San Francisco	Fisher Bioservices							false
[history]	NON-TOL			Pre-enrollment -2			whole blood	PBMC-Na Hep	01.8 ml cryovial	2008-02-07 00:00	001-University of California San Francisco	Fisher Bioservices							false
[history]	NON-TOL			Pre-enrollment -2			whole blood	PBMC-Na Hep	01.8 ml cryovial	2008-02-07 00:00	001-University of California San Francisco	Fisher Bioservices							false
[history]	NON-TOL			Pre-enrollment -2			whole blood	PBMC-Na Hep	01.8 ml cryovial	2008-02-07 00:00	001-University of California San Francisco	Fisher Bioservices							false
[history]	NON-TOL			Pre-enrollment -2			whole blood	PBMC-Na Hep	01.8 ml cryovial	2008-02-07 00:00	001-University of California San Francisco	Fisher Bioservices							false
[history]	NON-TOL			Pre-enrollment -2			whole blood	PBMC-Na Hep	01.8 ml cryovial	2008-02-07 00:00	001-University of California San Francisco	Fisher Bioservices							false
[history]	NON-TOL			Pre-enrollment -2			whole blood	PBMC-Na Hep	01.8 ml cryovial	2008-02-07 00:00	001-University of California San Francisco	Fisher Bioservices							false

Note The availability count on the left shows the number of vials available from the group, even when viewing by individual vial.

1. Click on “[history]” in the second column to view the Vial History. The Vial History page provides a summary of the Vial including the Collection location.
2. Click on a participant ID in the third column to navigate to the participant view. Refer to [Participant View](#) for more details.
3. Use the “Views” dropdown to create your own custom chart views. Once created, these charts can be viewed in the Data Reports section.
4. You can also create a subset of the specimen data for export by filtering the data using the filter by column option or Custom View Designer.

Note Refer to the instructions under [Dataset Grid View](#) for filtering/sorting data, customizing and managing views using the buttons above the grid on the “Vials” page.

5. You can use the “EXPORT” and “PRINT” buttons to export the Specimen Details. For more information on exporting data refer to [Export/Download Data](#).

6. Filter data using previously created Participant Groups by clicking on the “**PARTICIPANT GROUPS**” dropdown and selecting an available group. The Specimen grid is refreshed and displays with the selected filter. Clear the filter criteria by selecting “**CLEAR ALL**” button that appears above the grid.

Note Place your cursor above the grid to show the button.

7. Create and manage your own Participant Groups by selecting “**Manage Participant Groups**” from the “**PARTICIPANT GROUPS**” dropdown. Participant Groups allow you to quickly filter data in a study to groups of participants you define. Refer to [Manage Participant Groups](#) in Chapter 5 for more details.
8. Click on “REQUEST OPTIONS” dropdown to view existing requests. Go to [Specimen Requests](#) for instructions on requesting vials.

Search Specimens

To search for Specimens click on “**For Vial Groups**” or “**For Individual Vials**” links under “**Search Specimens.**”

1. Clicking on **For Vial Groups** will display the “**Grouped Vial Search**” page. This page may be used to search for vials grouped by participant, time point, and type. Click on the “**SEARCH**” button after selecting your filters to view the Grouped Vials.
2. Clicking on **For Individual Vials** will display the “**Individual Vial Search**” page. Select from the criteria to search for individual vials. For example, you can find all vials available for request using the "Available" drop-down menu.

WISP-R ITN029ST: Immunosuppression Withdrawal for Pediatric Liver Recipients > [Specimen Overview](#) >

Individual Vial Search

This page may be used to search for individual vials.
[SEARCH GROUPED VIALS](#) >

Participant Id

Global Unique Id

Primary Type

Derivative Type

Additive Type

Clinic

Available

[SHOW ALL COLUMNS](#) >

Specimen Reports

To access Specimen Reports click [View Available Reports](#) under “**Specimen Reports.**” You will see the three major types of specimen reports, each with 3-4 sub options.

The screenshot displays the 'Specimen Reports' page. At the top, there is a breadcrumb 'Specimen Overview >' and the title 'Specimen Reports'. The page is organized into three main sections:

- Collected Vials by Type and Timepoint:** This section contains three sub-options: 'Summary Report SHOW OPTIONS' with a 'VIEW' button, 'By Participant SHOW OPTIONS' with a 'VIEW' button, and 'By Cohort SHOW OPTIONS' with a 'VIEW' button.
- Requested Vials by Type and Timepoint:** This section contains four sub-options: 'Request Summary SHOW OPTIONS' with a 'VIEW' button, 'By Requesting Location SHOW OPTIONS' with a 'VIEW' button, 'Requests by Enrollment Site SHOW OPTIONS' with a 'VIEW' button, and 'Requests by Participant SHOW OPTIONS' with a 'VIEW' button.
- Collected Vials by Participant By Timepoint:** This section contains three sub-options: 'Participant Summary SHOW OPTIONS' with a 'VIEW' button, 'By Specimen Type SHOW OPTIONS' with a 'VIEW' button, and 'By Enrollment Site SHOW OPTIONS' with a 'VIEW' button.

- Customize:** To customize your report, click “[SHOW OPTIONS](#)” next to the sub option of your choice under the report type of your choice. You can then select filters to winnow your specimen data, plus metrics to display for your data. Filters can include Cohort, Availability Status, and Participant Group, depending on the report type. Metrics can include Vial Counts, Total Volume, Participant Counts, and/or Participant ID List, also depending on the report type.

- **View Results:** If you are creating a new specimen report, click “**VIEW**” next to the suboption that you wish to display after you have finished customization. If you have already clicked “**VIEW**” and you have changed your custom options, click “**REFRESH**” to update the report.
- **Export/Print Results:** After you have viewed your results as described above, you can select either “**PRINT VIEW**” or “**EXPORT TO EXCEL**” on the “**Specimen Report**” page.

Specimen Requests

1. Click on **View Current Requests** under “**Specimen Requests**” to view all specimen requests.
2. You can filter the requests by status like “Shipped,” “Submitted,” etc. on the Specimen Requests page. The example below shows specimen requests for status filter “Shipped.”

Request Id	Status	Destination	Created By	Created
5	Not Yet Submitted	002-Northwestern University	trialshare_editor@immunetolerance.org	2011-12-06 12:24

3. Alternatively, click on column headings to filter/sort requests.
4. Click on “**DETAILS**” in the first column to view the request details including the Requestor, Requesting Location, Request Date, and any Associated Specimens.

View Vials by Type

You can view Vials by Primary Type and Derivative using the links available in the Specimens section. A total count of the Vials based on type is also available for the study under “**Vials by Primary Type**” and “**Vials by Derivative.**”