Immune Tolerance Network TrialShare Clinical Trials Research Portal

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.

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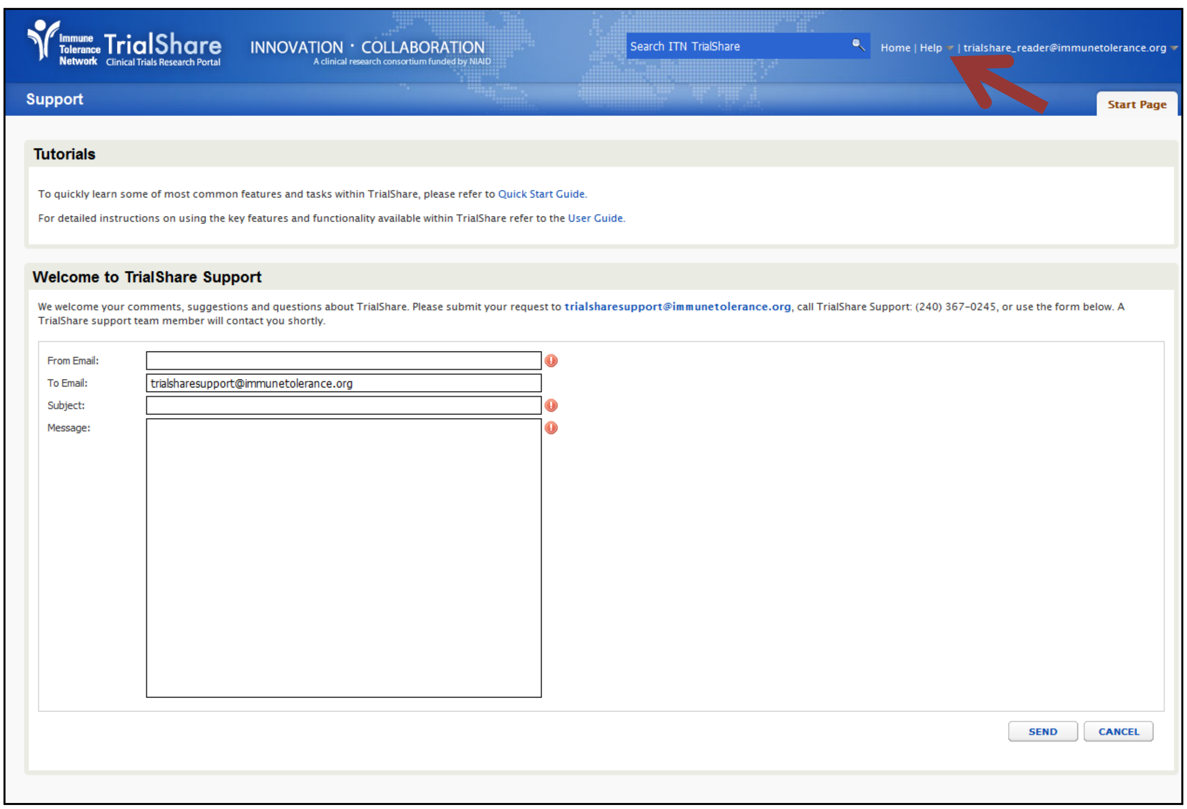
About this guide

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.



Intended Audience

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

Contents

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

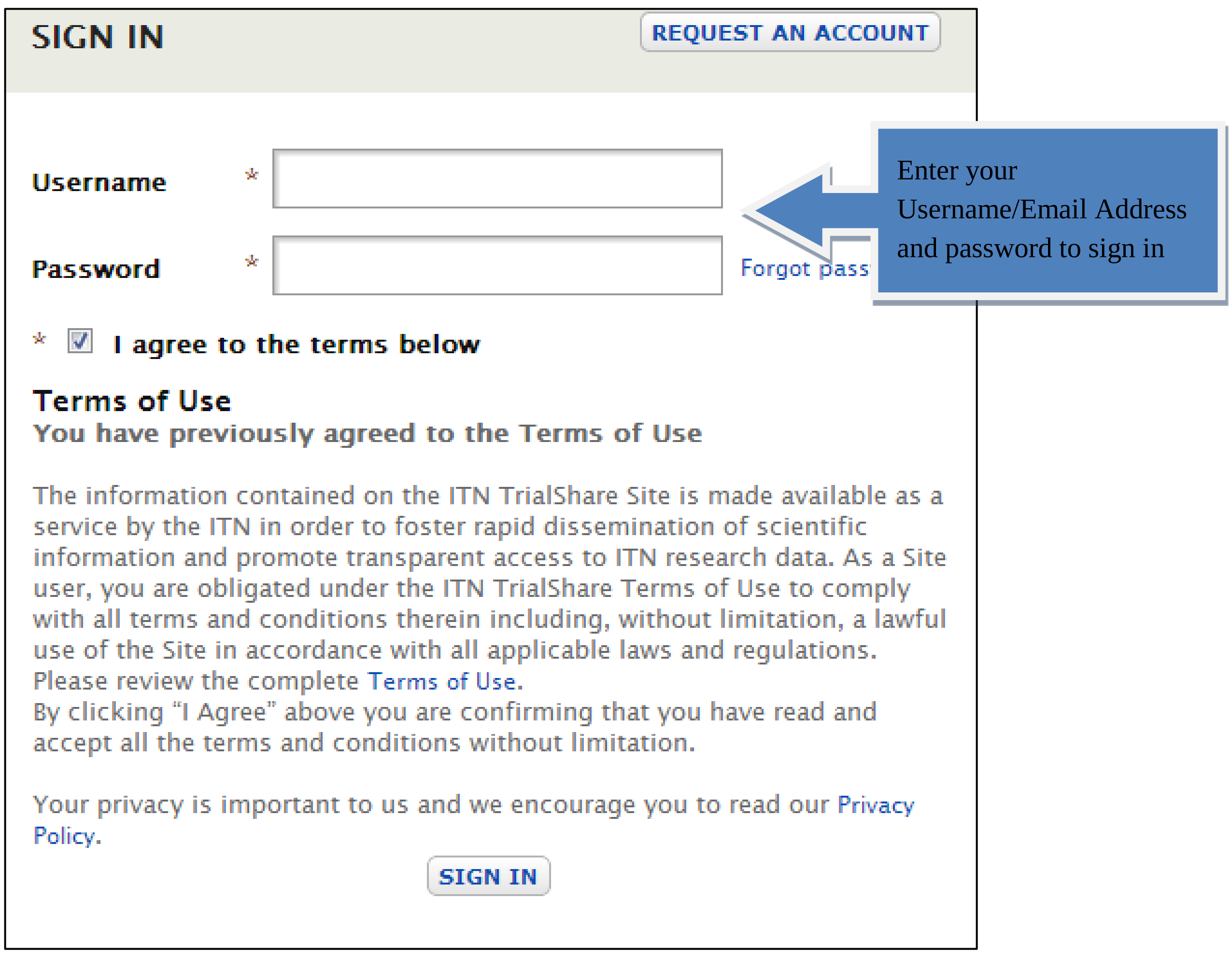
Open the TrialShare Welcome page by copying the following URL in your browser window:

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.



Terms of Use

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

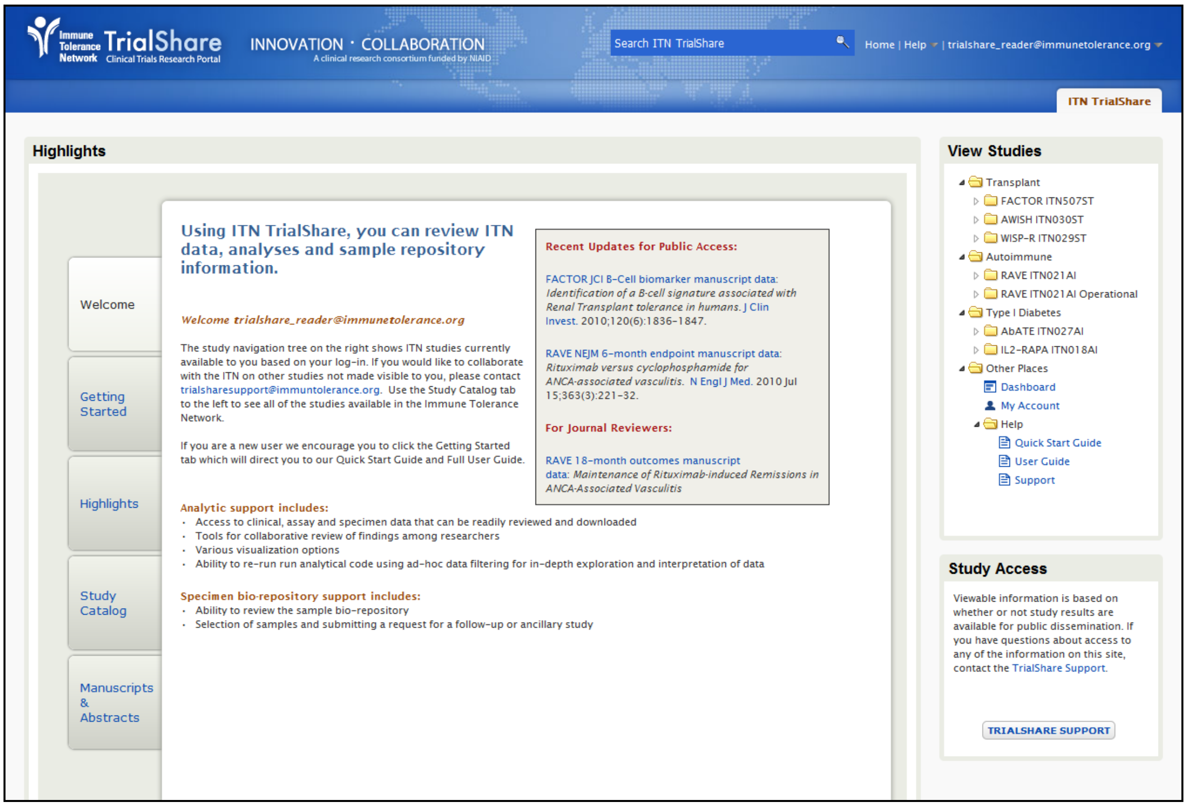
CHAPTER 3 TRIALSHARE HOME

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

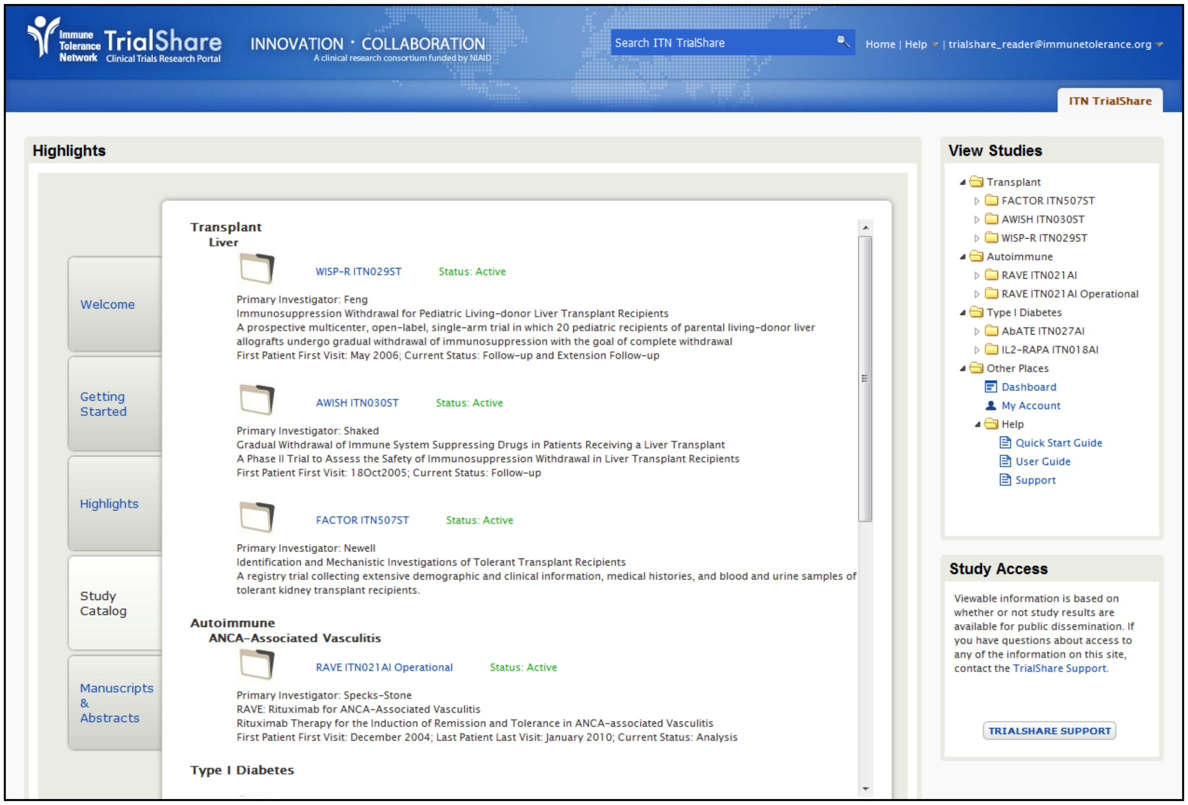
Click on the "**Getting Started**" tab to find helpful links to the Video Tutorials, Quick Start Guide, and User Guide.

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.

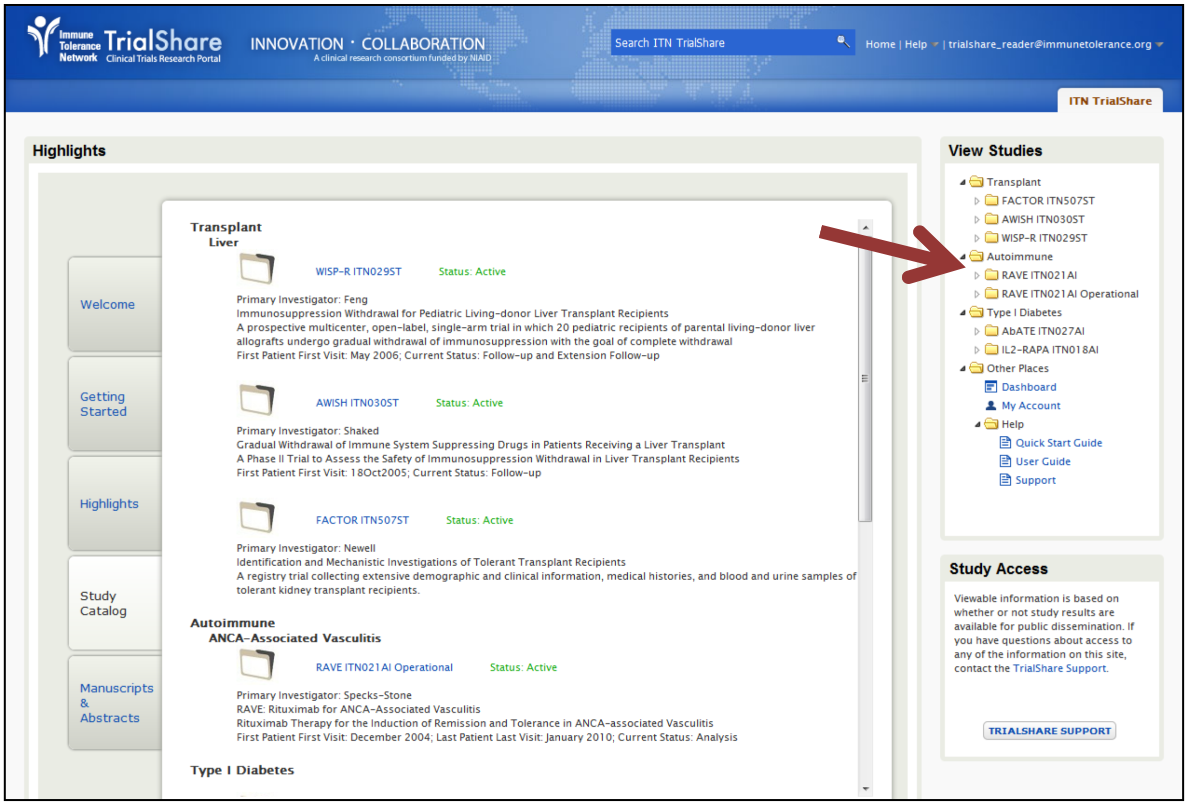
1. Click on "**ABSTRACT>**" to view and print a research abstract. The research abstract paper displays.
2. Click on "**Paper**" to view the paper.

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.



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.

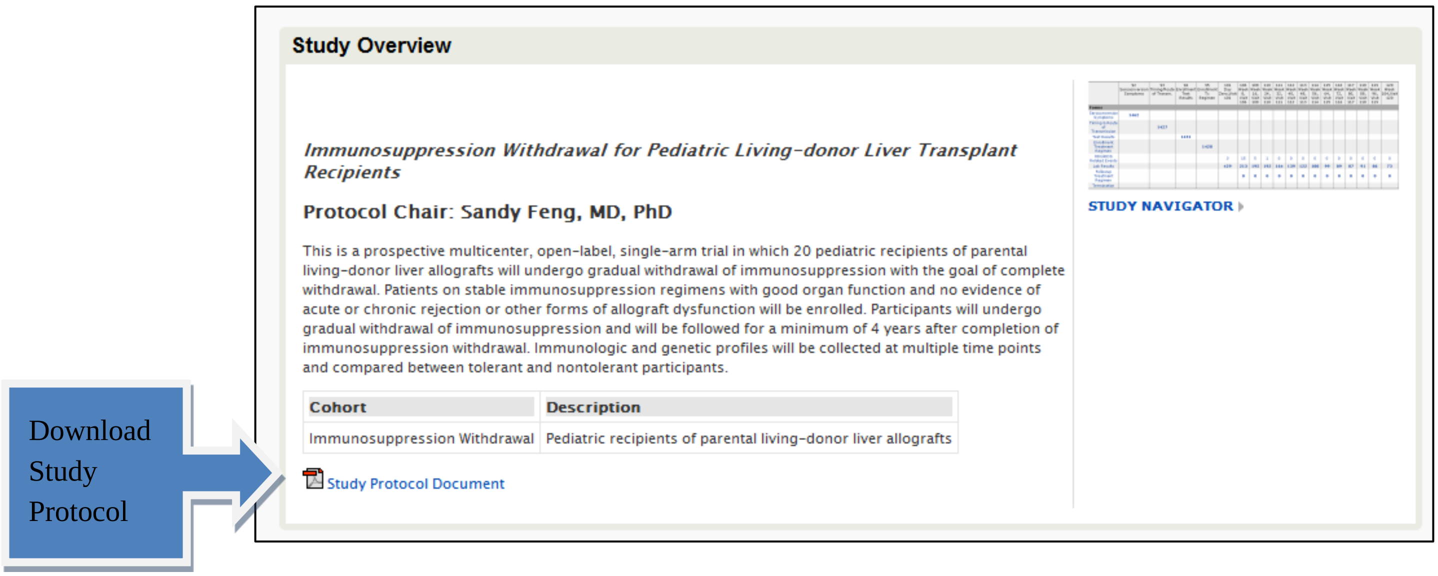
Follow the steps below to download study protocols, manage manuscripts, and navigate to Study Navigator from the Overview page.

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.

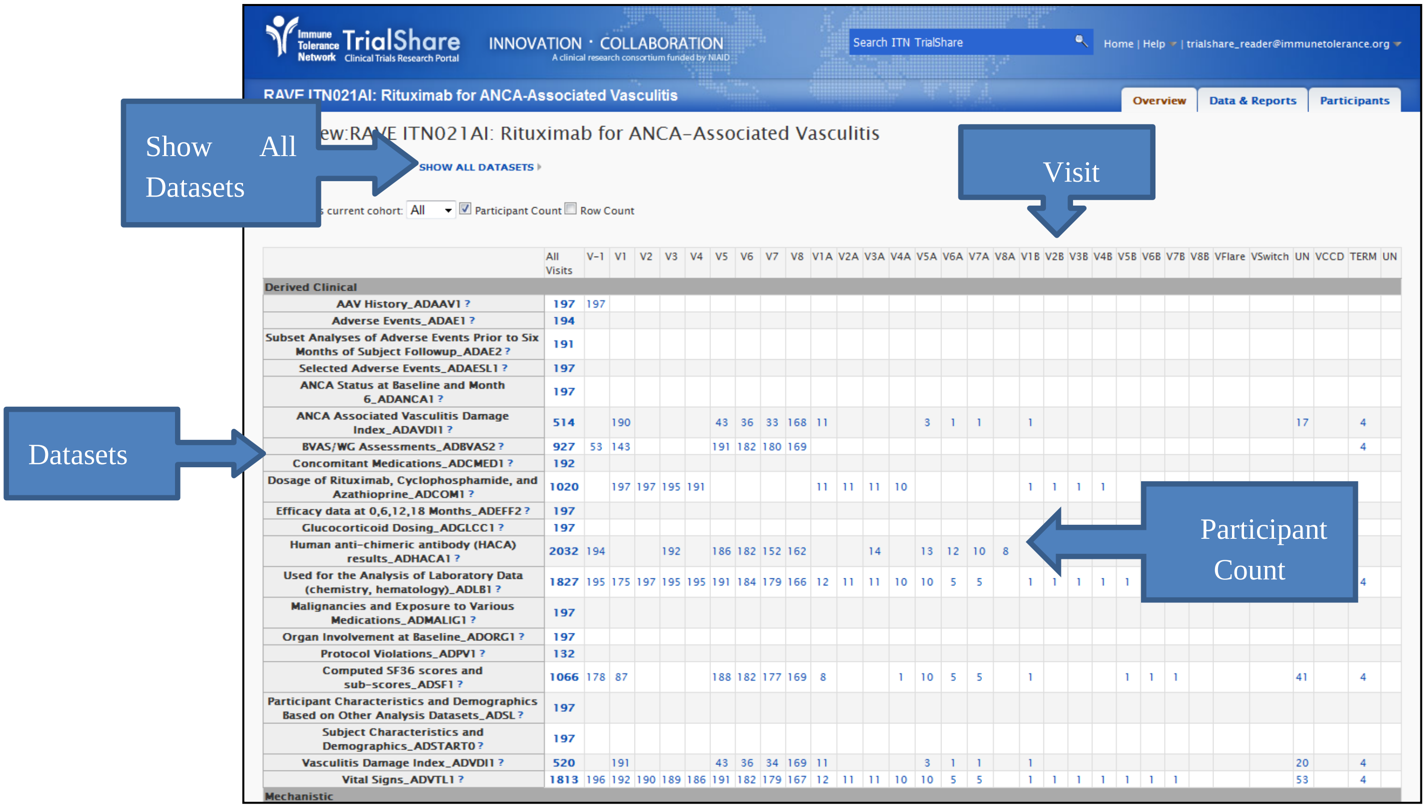


Study Navigator

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.



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.

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.**”

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.

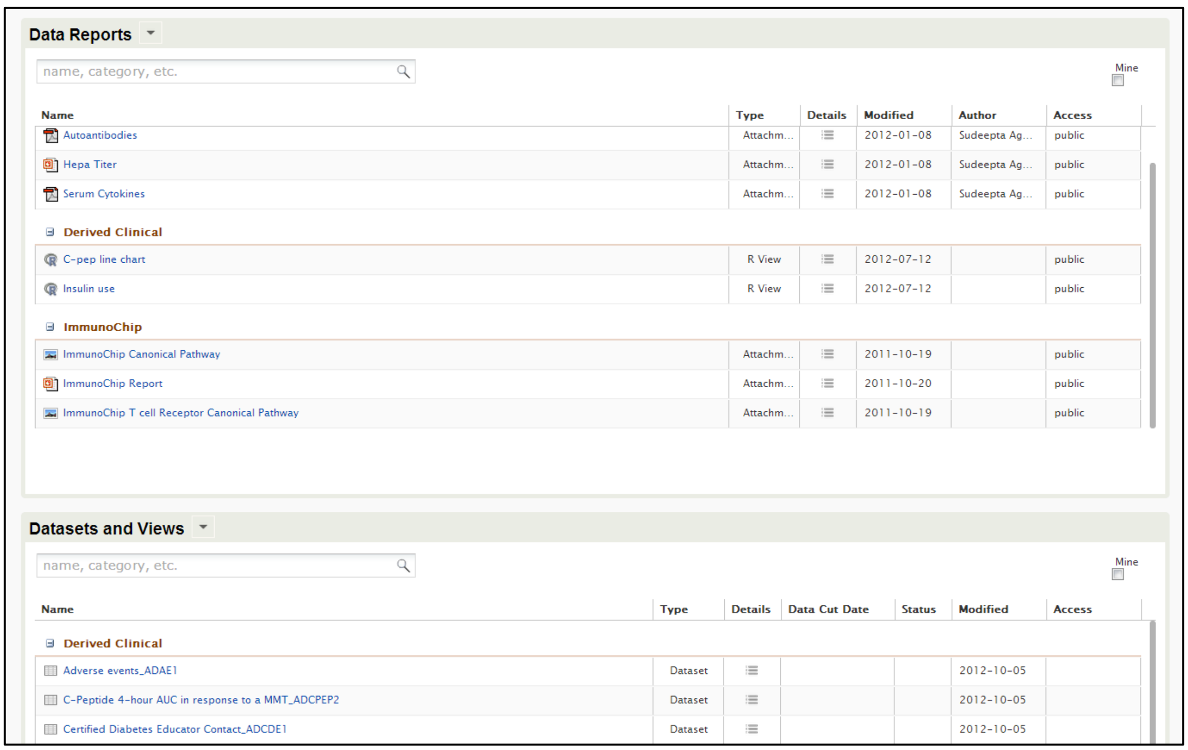
   OR

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.



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

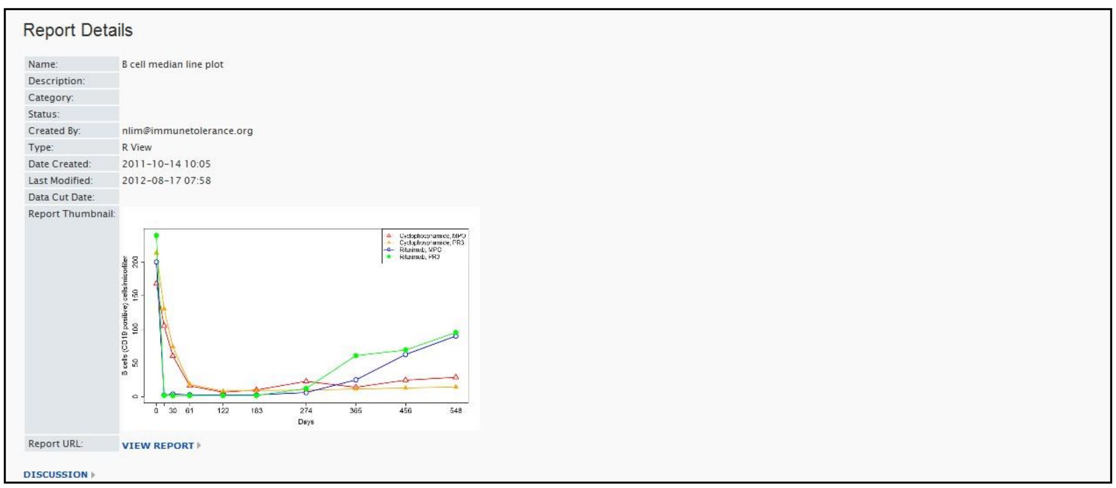
The Data Reports section is available on the “**Data & Reports**” tab.

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.”



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?"

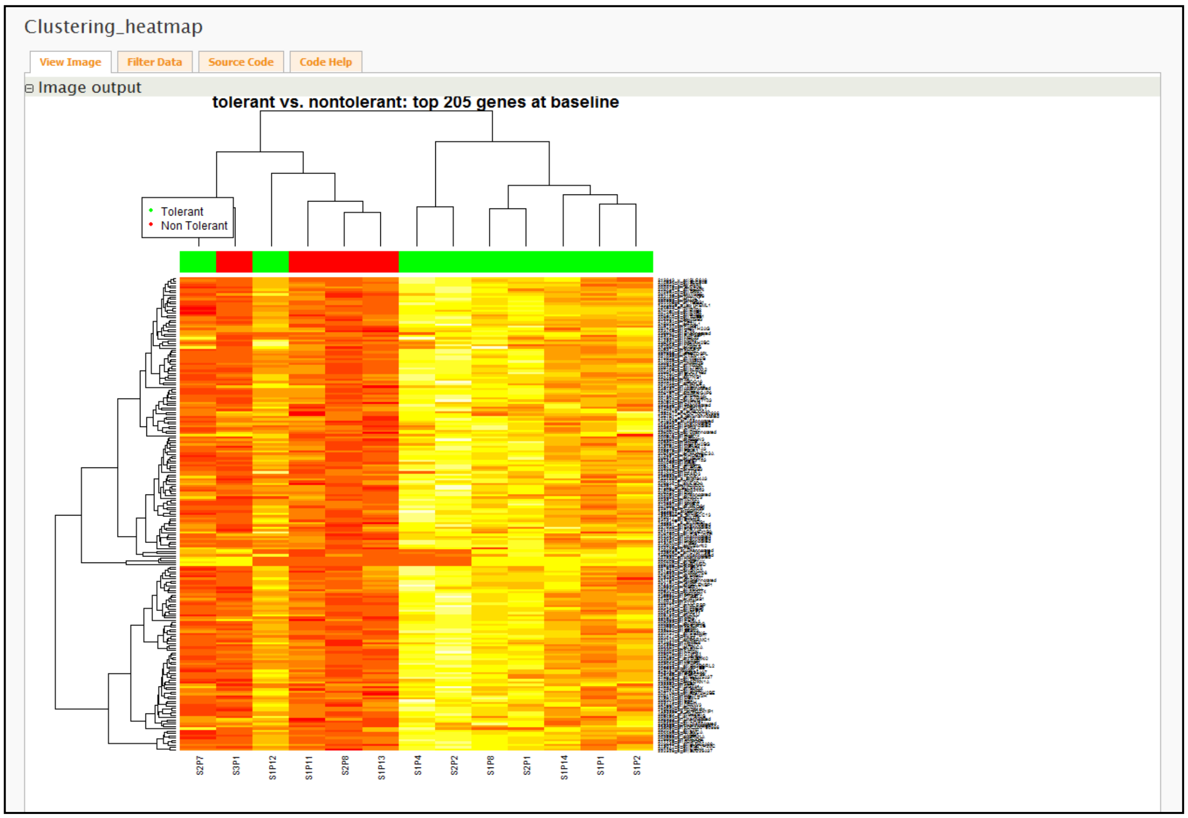
4. Click "Save" to go back to the "Data & Reports" tab. Once saved, the report gets added to the list of reports under Data Reports.

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

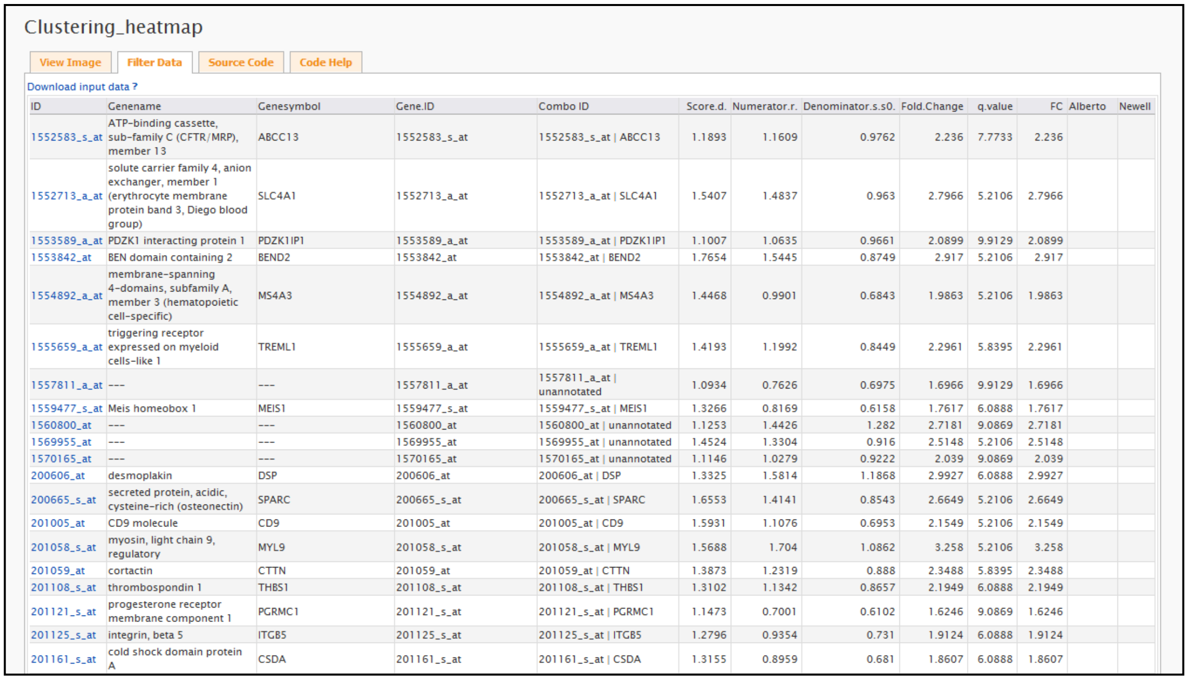
R Charts

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

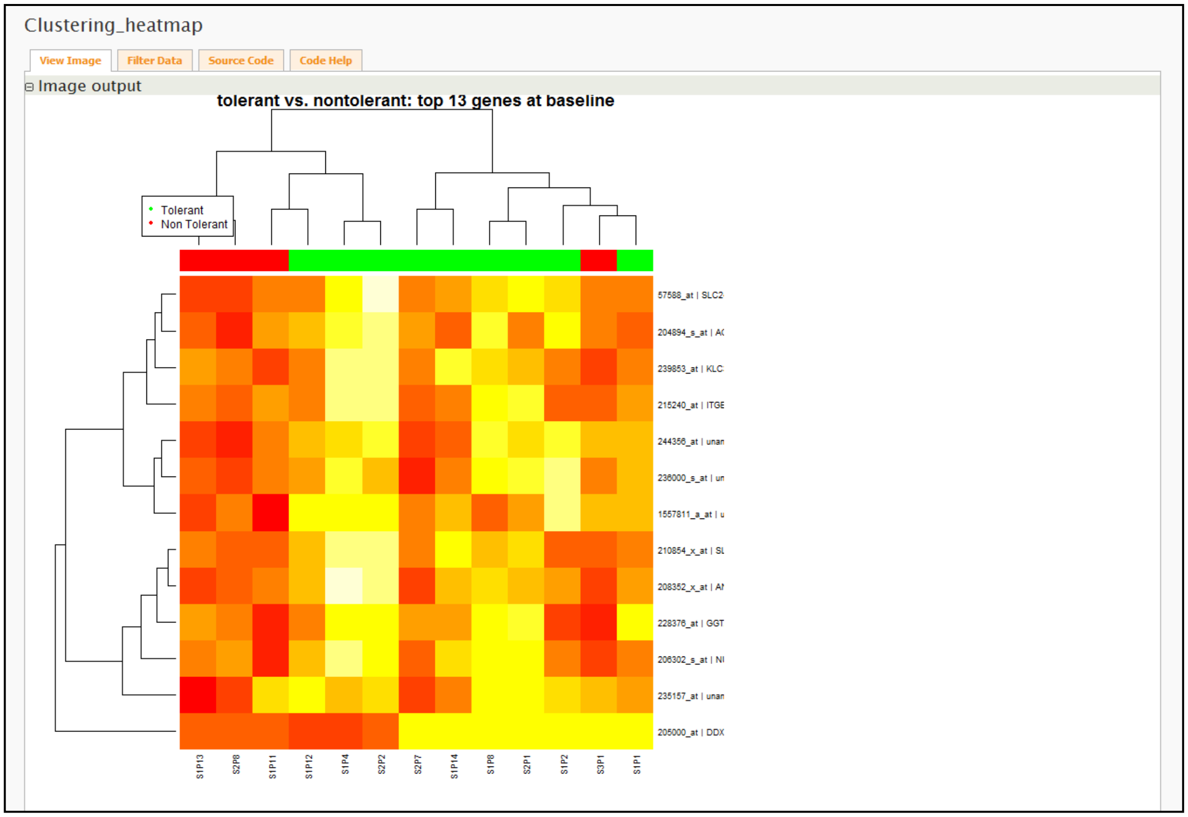
Download input data ?

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		

4. 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".

5. 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.

6. 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.

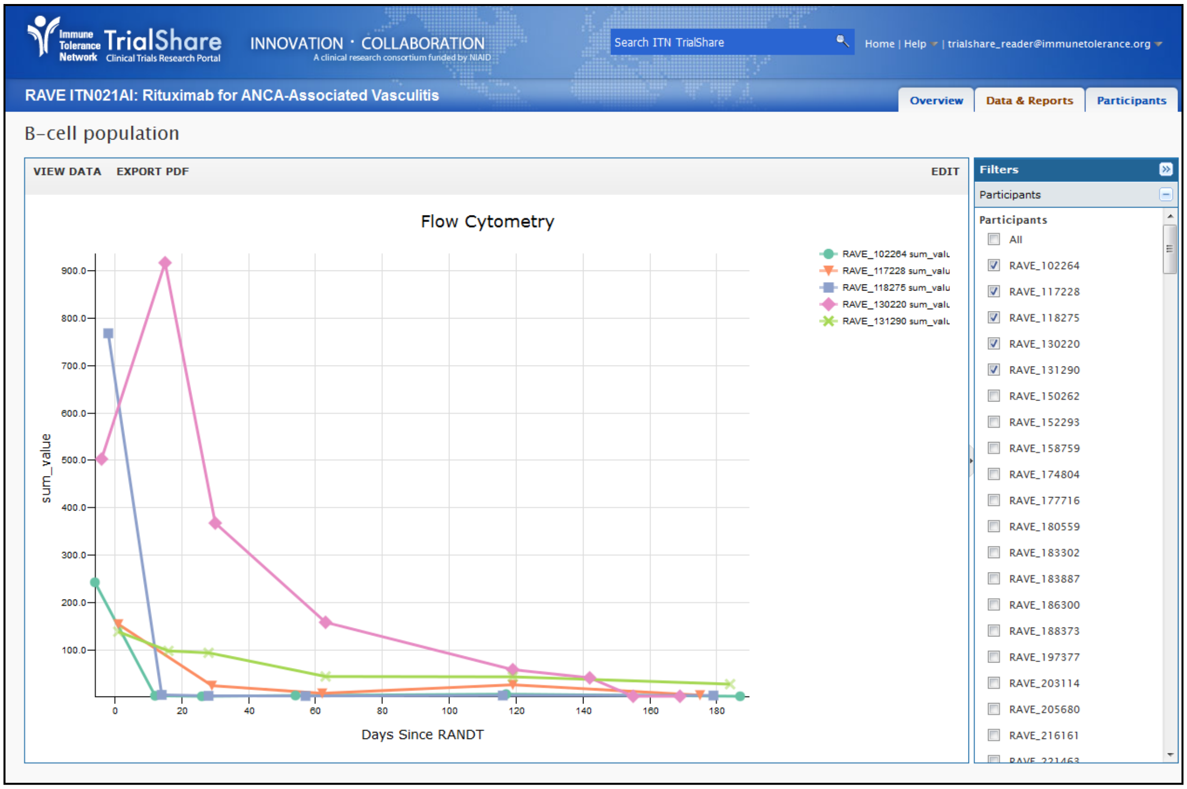
9. You can initiate a discussion using your email account or start a discussion on the same page by clicking on the "Discussion" button displayed on all tabs.

Time Chart

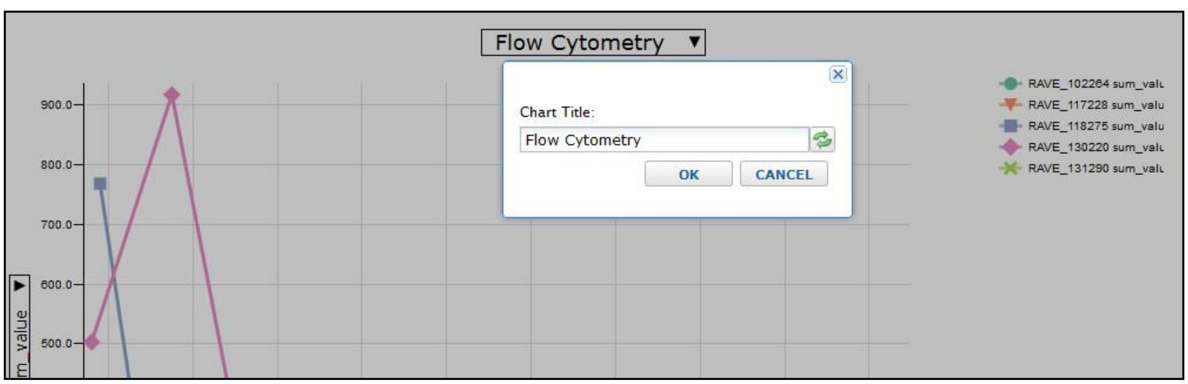
A time chart allows you to view data for a selected measure over time. Analyze the data by customizing existing time charts and saving as a new chart in the Data Reports section. Customize an existing Time Chart by following the steps below:

Customize an Existing Time Chart

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

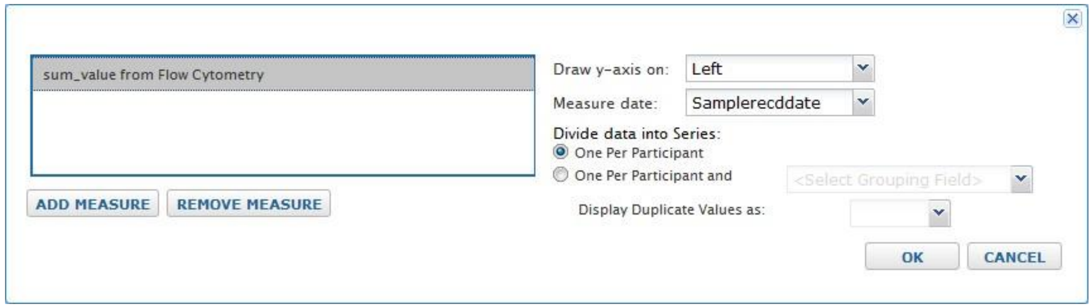


2. You can use the "Edit" button to make changes to the default chart view.
3. You can update the chart title by clicking on the title dropdown as shown below.



4. Click on the "**Measures**" tab.
   a. Click on "ADD MEASURE" or "REMOVE MEASURE" button to add/remove a measure.

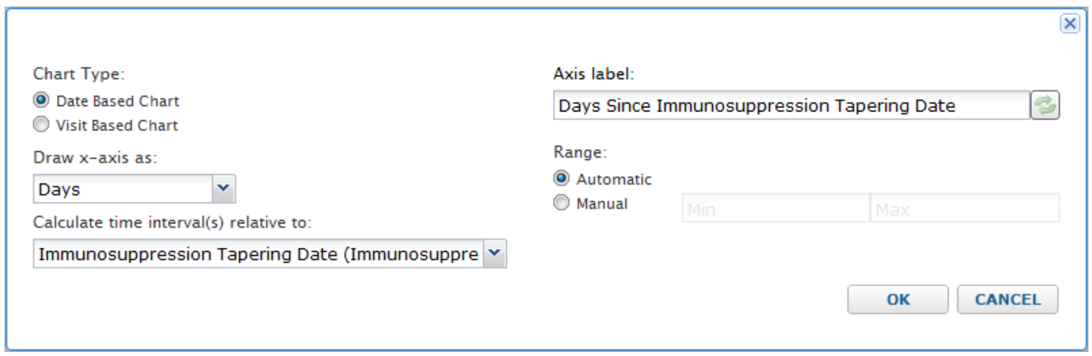
Note Contact TrialShare Support if you do not see the measure of interest.



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:

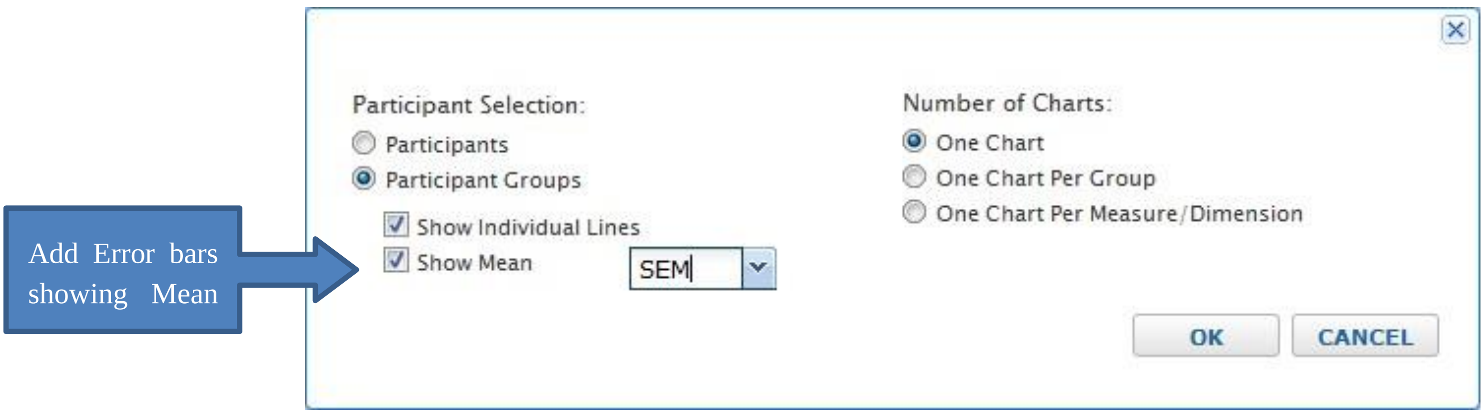
i. Click on "Participants" tab to the right of the displayed chart.

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.

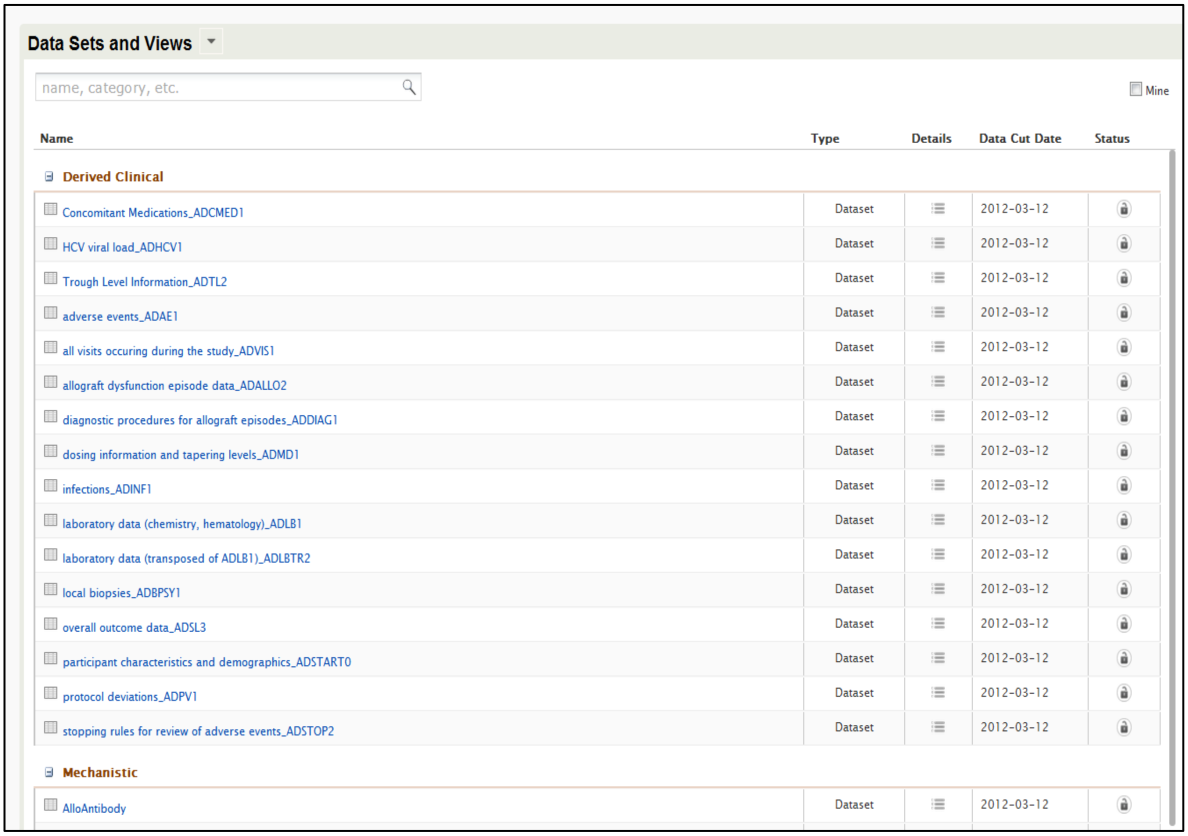
8. To download or print the chart click on the "EXPORT PDF" dropdown above the time chart.

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.



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.

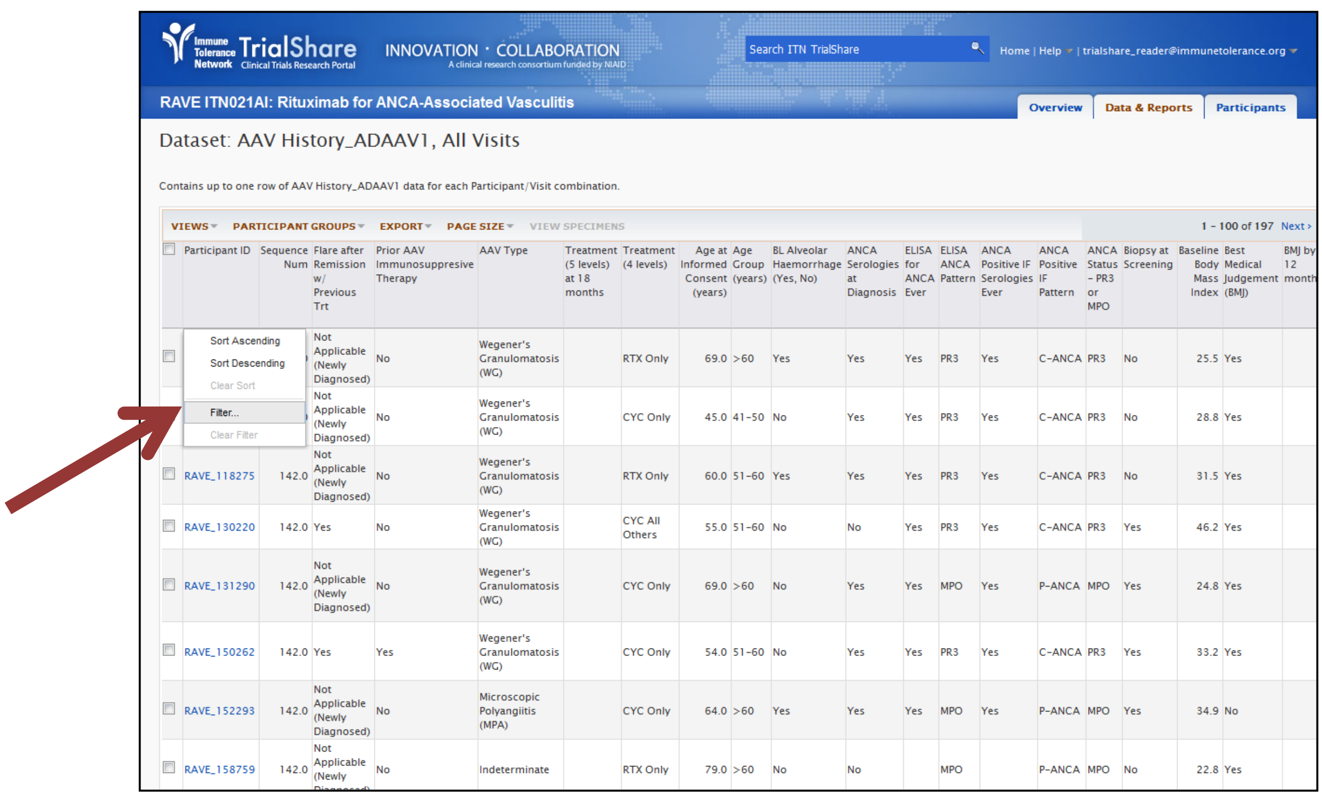
Note In case of more than one page of dataset results, you can navigate from one page to another by clicking on the “Next >,” “Last >>,” “<< First,” or “<Prev” links as displayed above/below the data grid.

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.

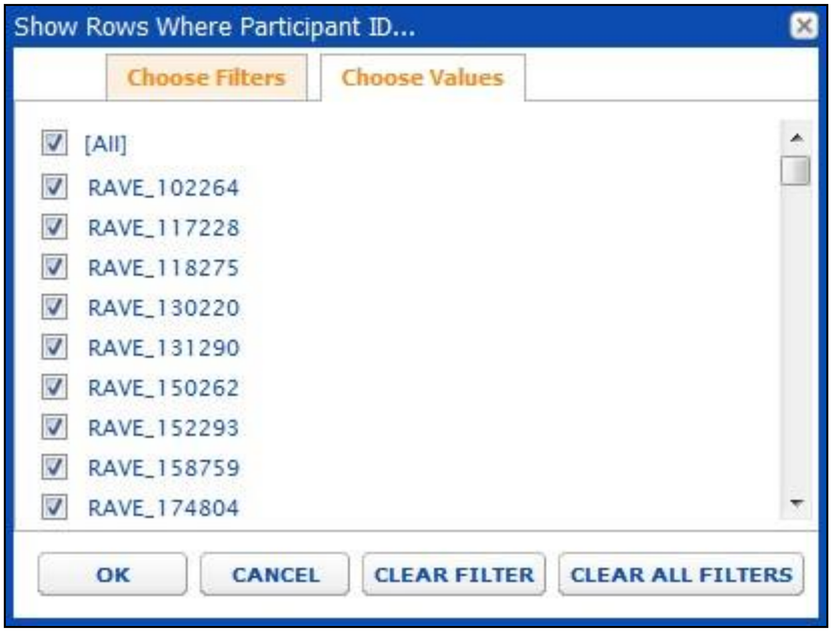
Note You can also save a dataset grid view using filter and sorts by following instructions in [Filter/Sort Data Using Custom View Designer](#).

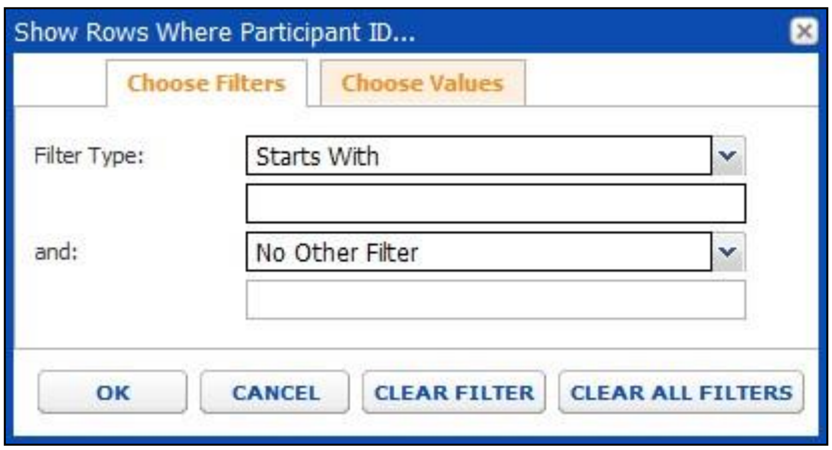
Filter Data by Column

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



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

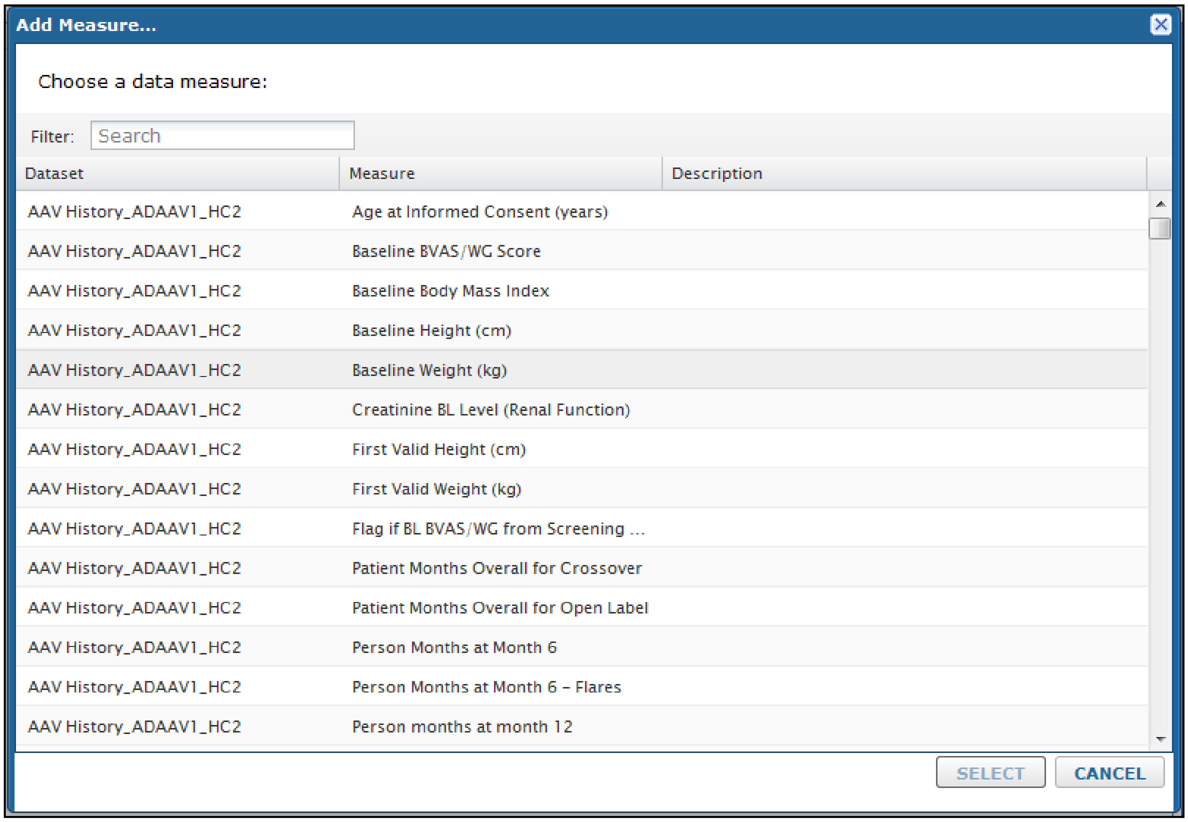
You can create a new Time Chart for a dataset by following the two paths below:

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.

2. The Time Chart Wizard "**Overview**" tab displays.
3. Click on "Choose a Measure" to get started. The "Choose a Measure…" window displays.



4. Choose a data measure and click "SELECT."
5. The "**Measures**" tab displays.
6. 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.

1. Select "Manage Views" from the "**VIEWS**" dropdown.
2. 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

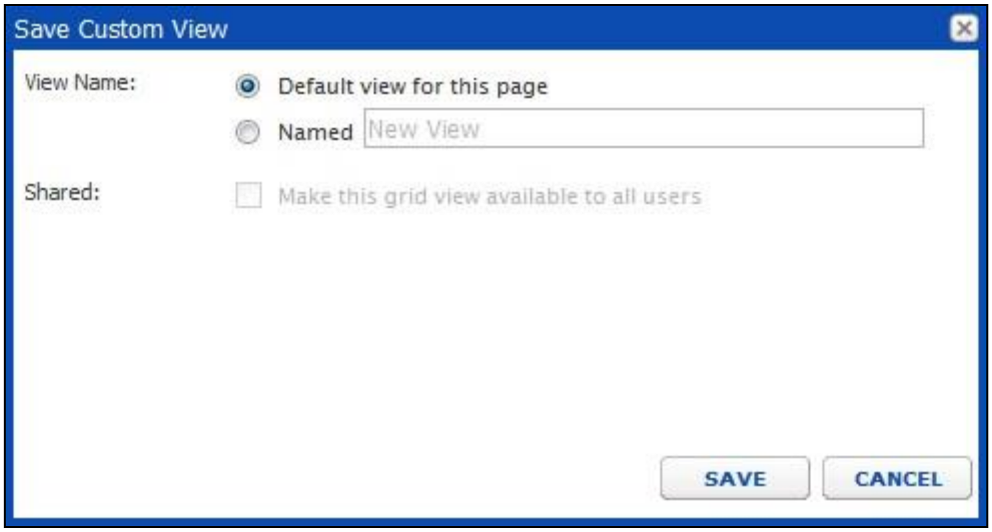
1. You can filter data from the Custom View Designer by clicking on the **Filter** tab on the left.
2. Select a field from the available fields displayed in the left column of the box to add it under Selected Filters. Once added, you can select a filter criterion from the dropdown for the added field.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

Save Customized Data Views

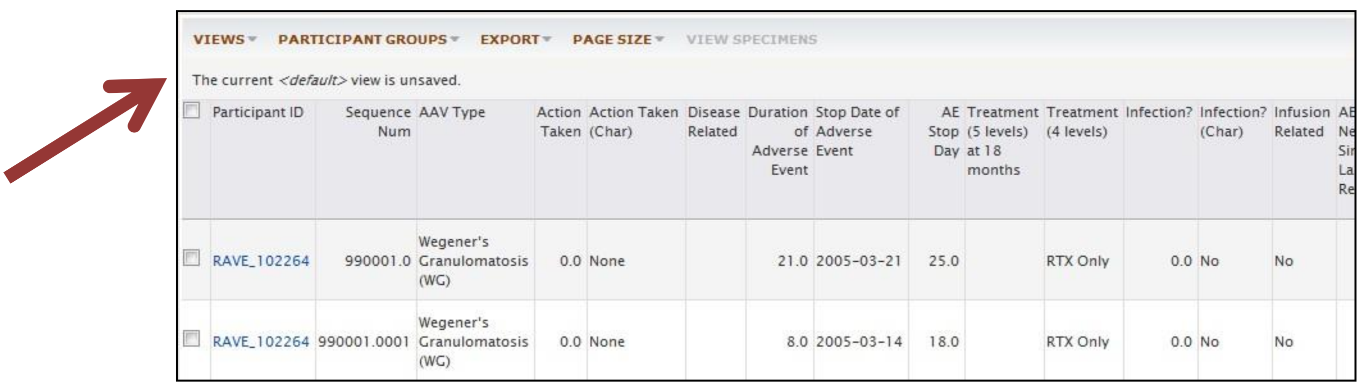
1. Click "**SAVE**" button to save the changes to the dataset as a default view or as a new customized view as shown in Figure below.



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.



Participant ID	Sequence Num	AAV Type	Action Taken	Action Taken (Char)	Disease Related	Duration of Adverse Event	Stop Date of Adverse Event	AE Stop Day	Treatment (5 levels) at 18 months	Treatment (4 levels)	Infection?	Infection? (Char)	Infusion Related
RAVE_102264	990001.0	Wegener's Granulomatosis (WG)	0.0	None		21.0	2005-03-21	25.0		RTX Only	0.0	No	No
RAVE_102264	990001.0001	Wegener's Granulomatosis (WG)	0.0	None		8.0	2005-03-14	18.0		RTX Only	0.0	No	No

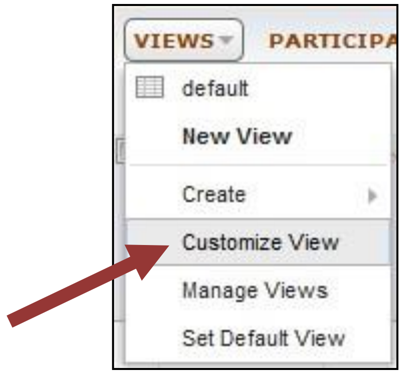
Place your cursor on the right of the message to highlight and select the Revert, Edit, and Save buttons as needed.

Delete a Custom View

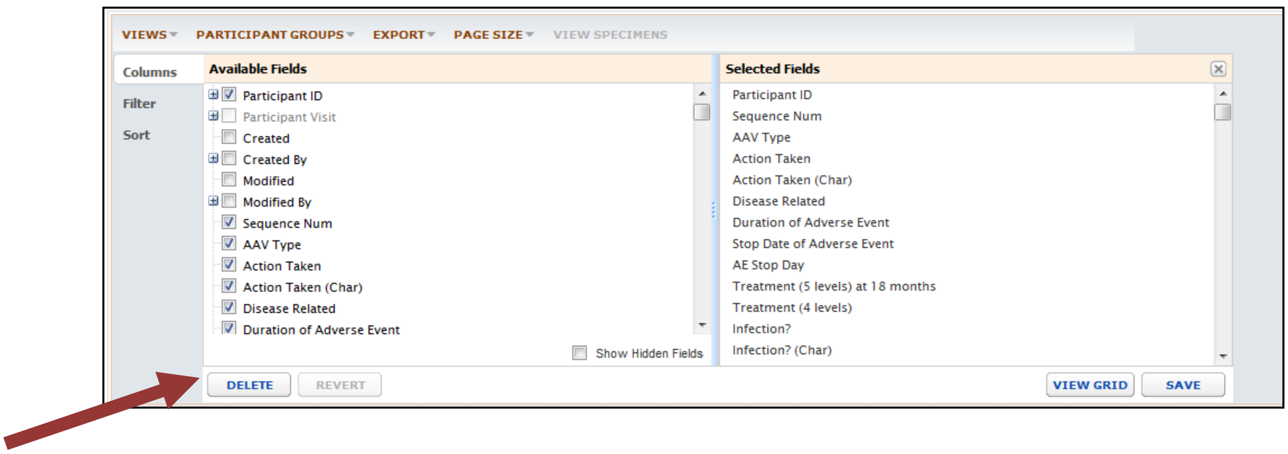
You can delete a custom view by following the steps below.

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 1was 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 redisplays 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.

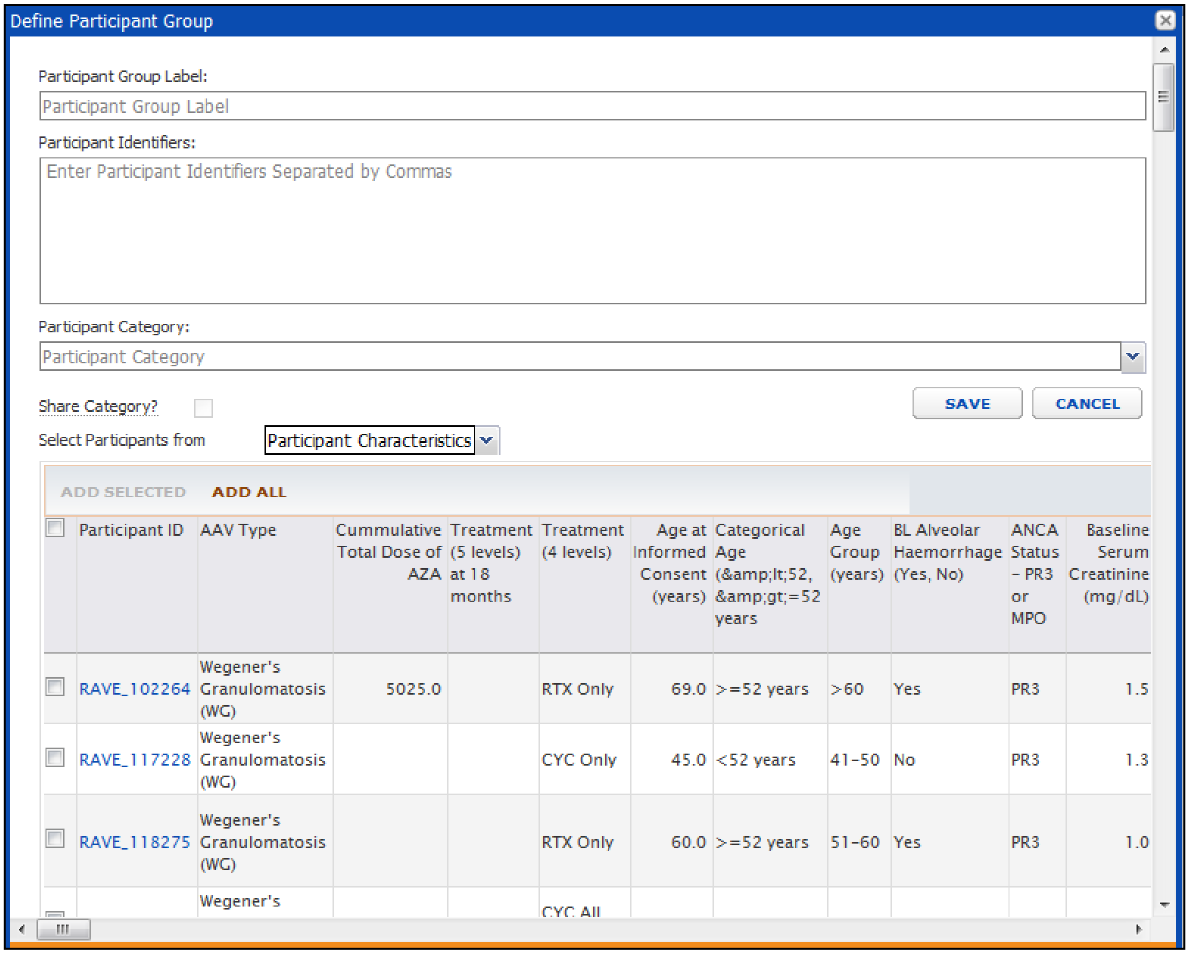
Create your own Participant Groups by selecting Create Participant Group from the "**PARTICIPANT GROUPS**" dropdown above the dataset grid OR Define and Manage Participant Groups by following instructions under Manage Participant Groups.

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.



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.

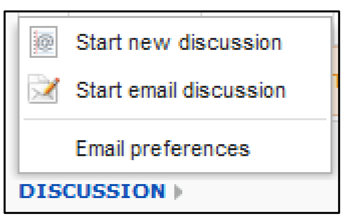
Export/Download Data

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.



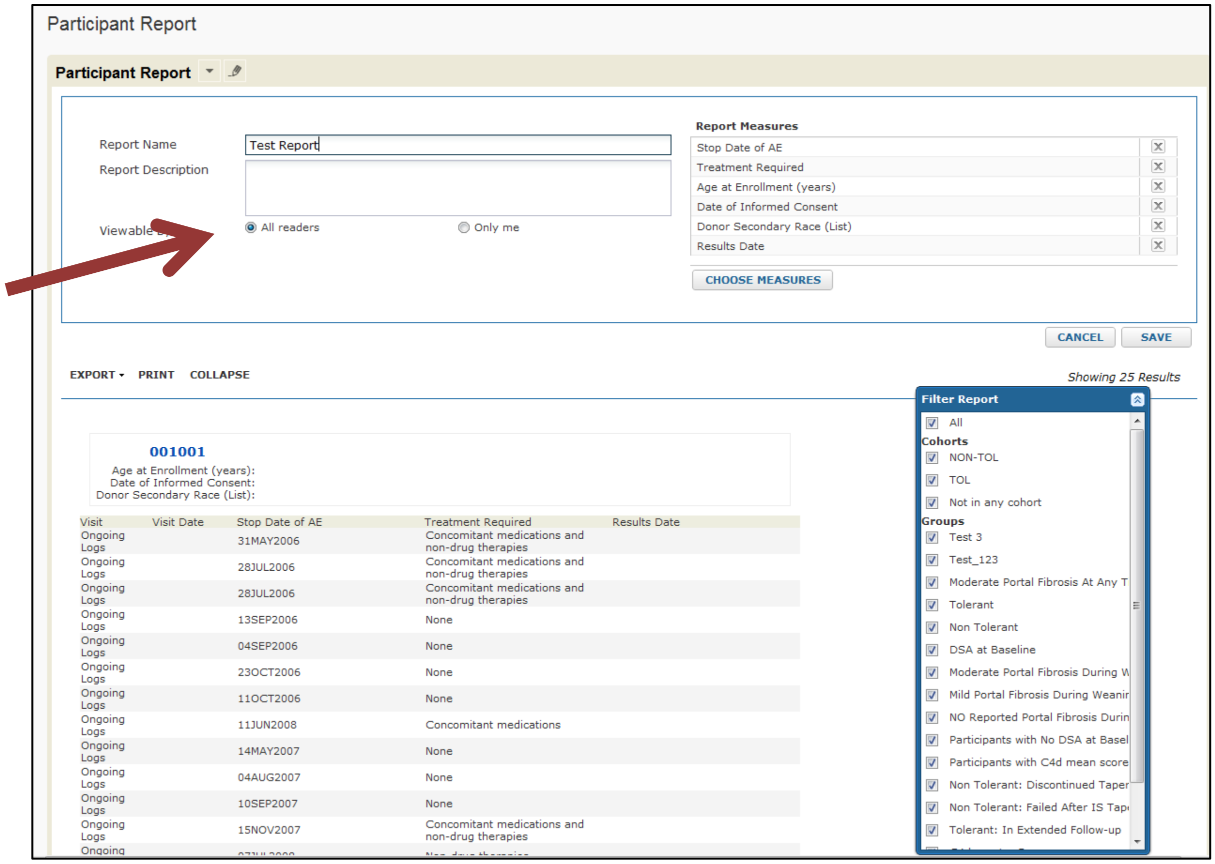
- "Start email discussion" allows you to start a private email discussion using your email client.
- "Start new discussion" opens up a form for initiating a discussion from the same page.

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.



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

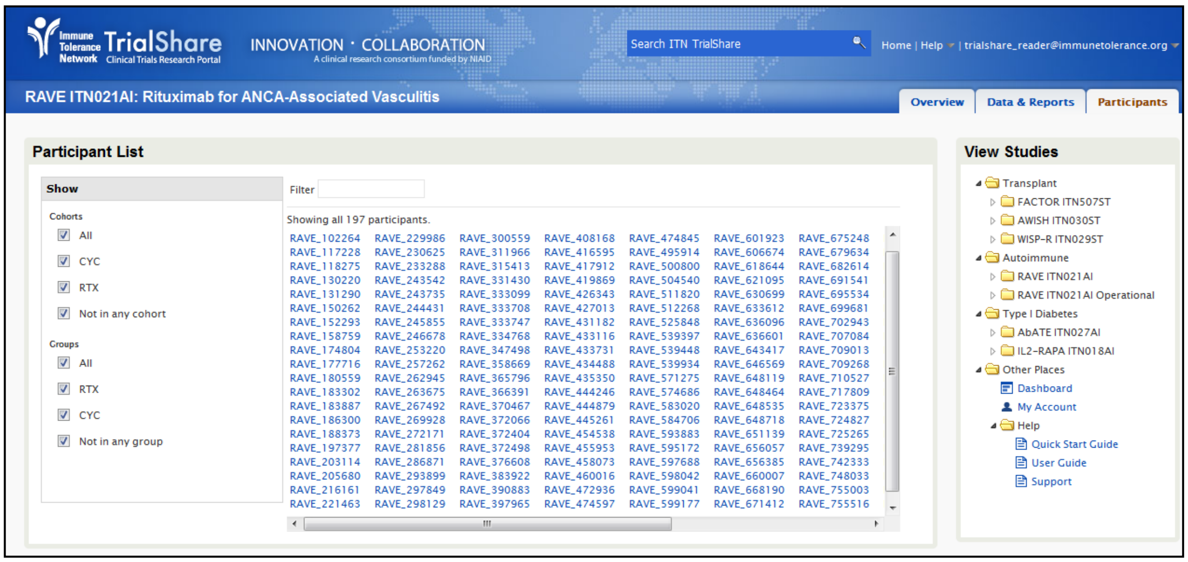
PARTICIPANTS TAB

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.

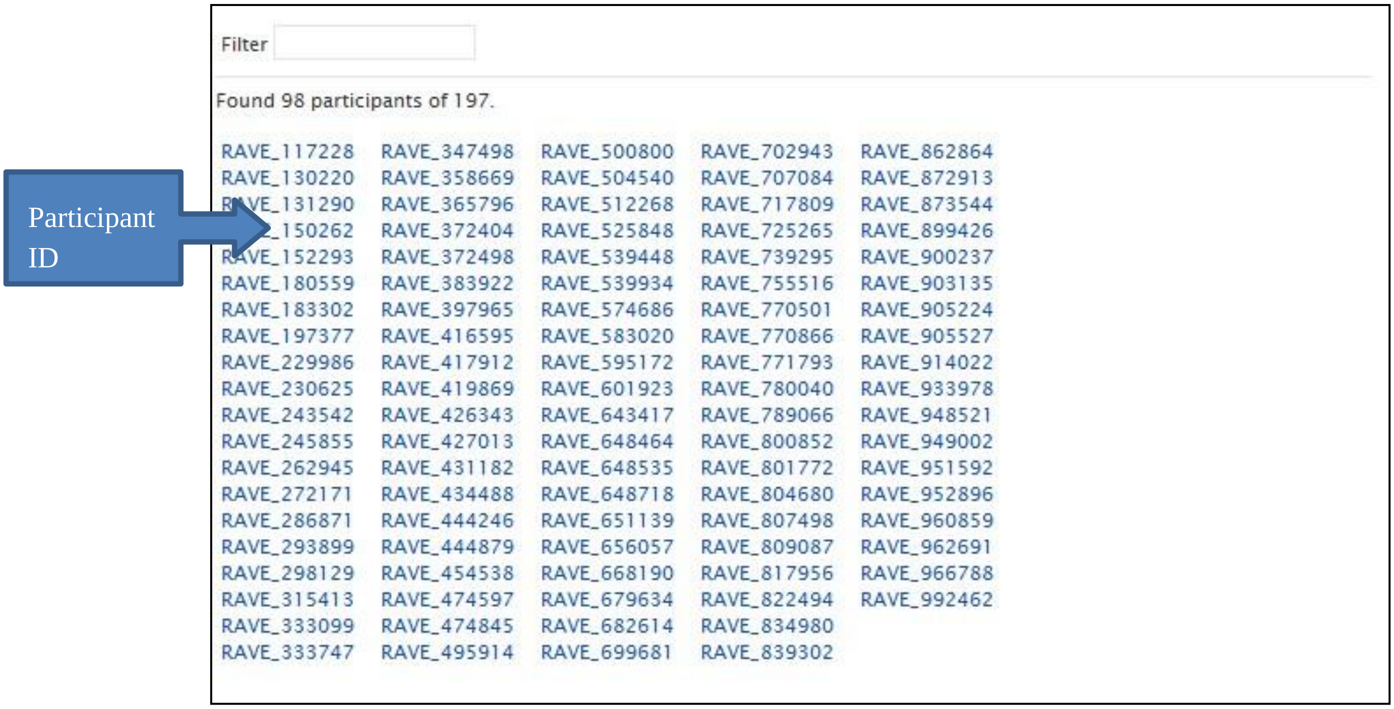


PARTICIPANT LIST

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.



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.

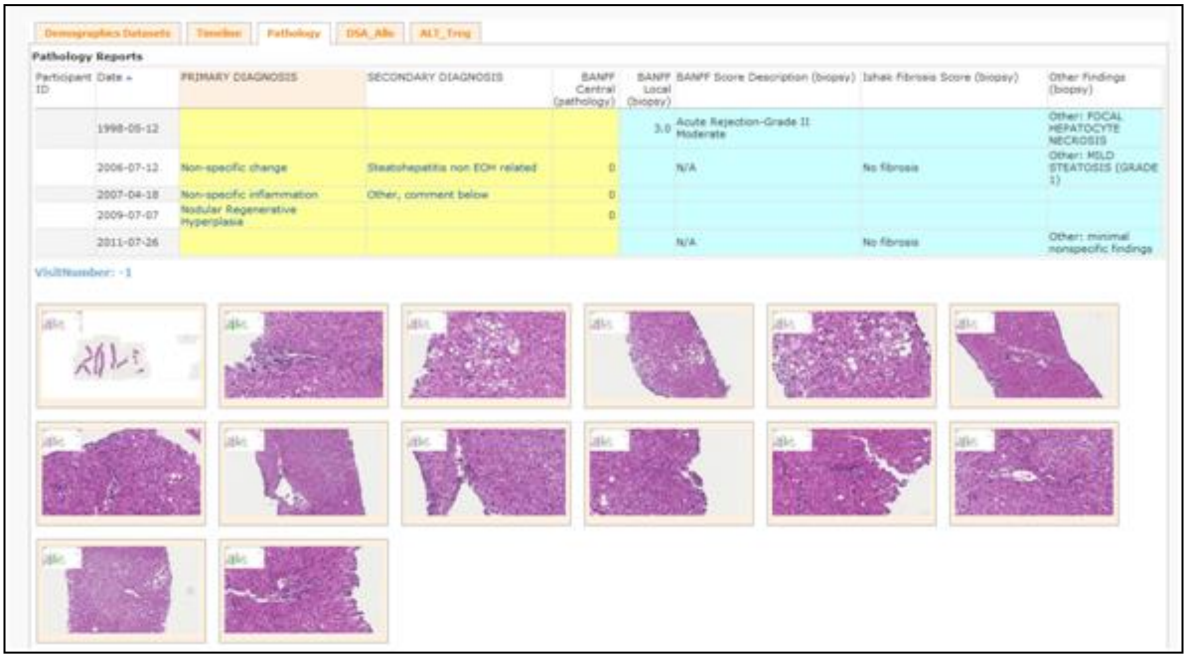
Timeline Tab

The "**Timelin**e" 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.

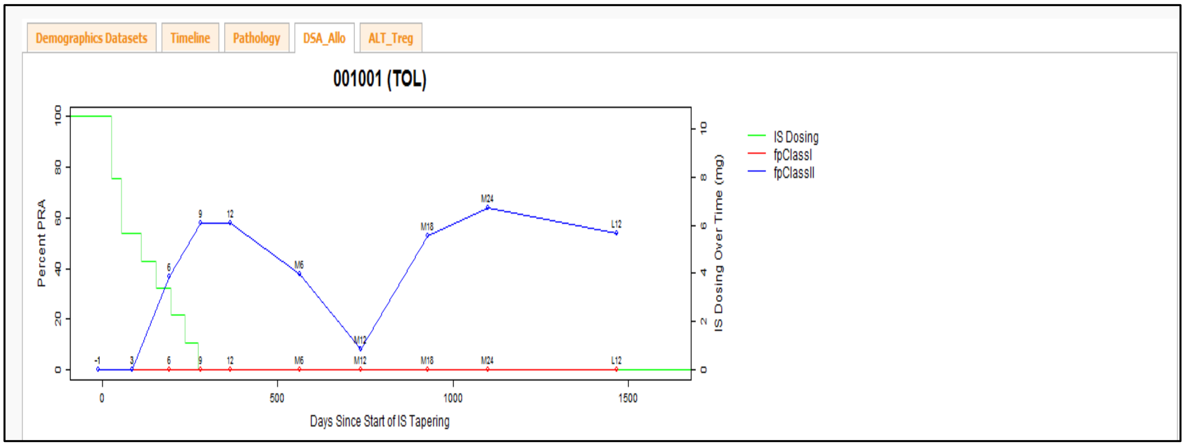


Click on an image to have an enlarged view. You can also filter and sort the reports using the filter/sort feature available for each column.

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.

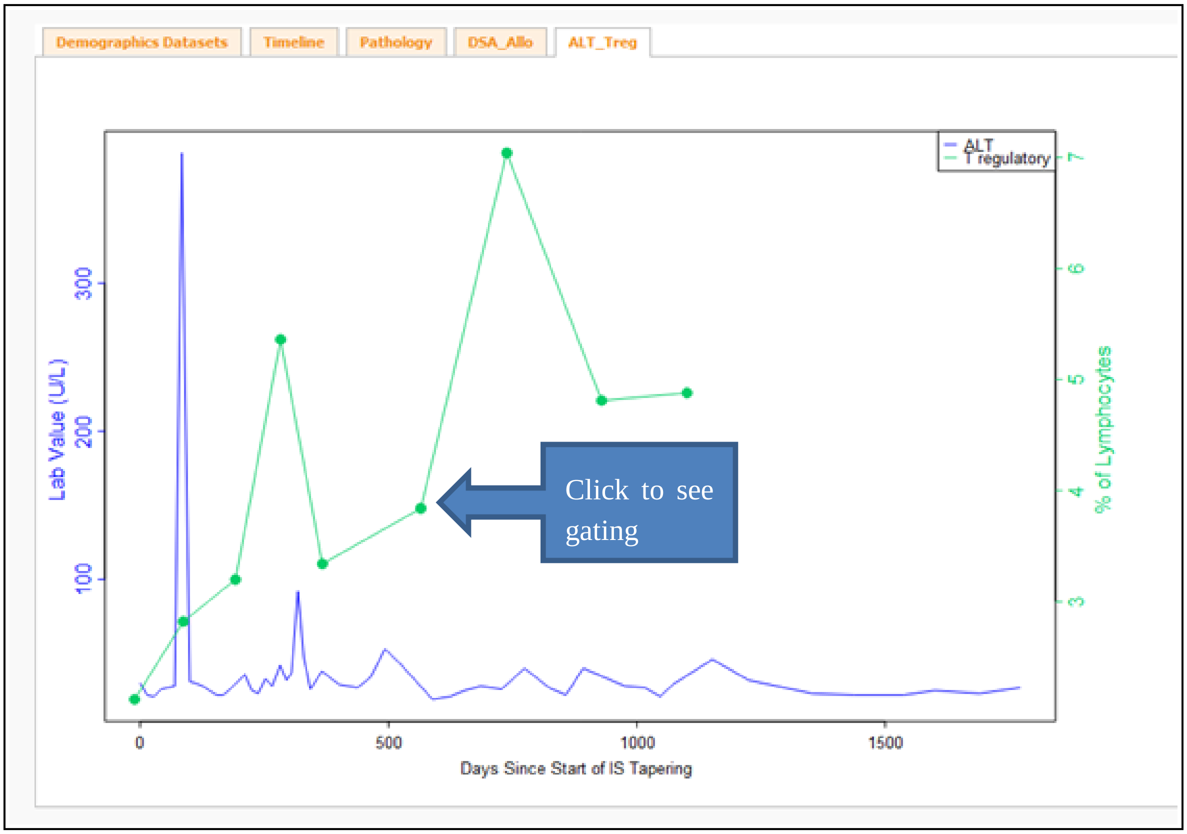
DSA_AlloTab

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



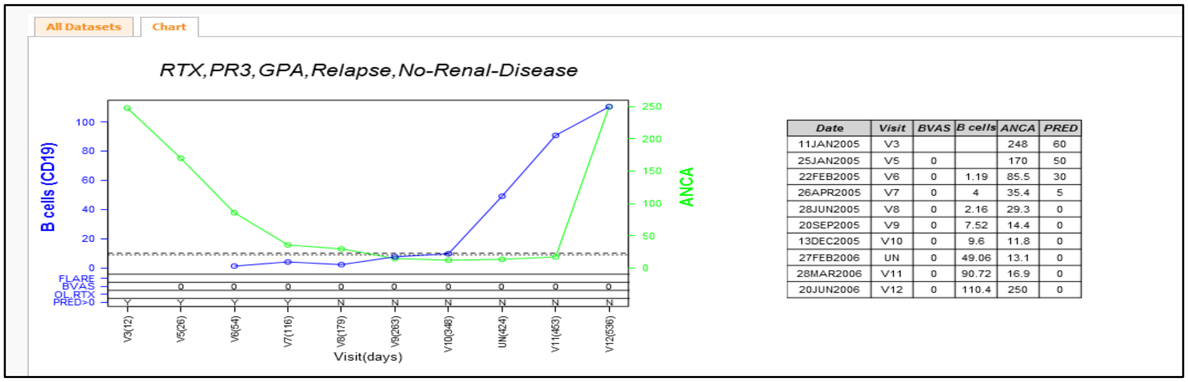
ALT_Treg Tab

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.



Date	Visit	BVAS	B cells	ANCA	PRED
11JAN2005	V3			248	60
25JAN2005	V5	0		170	50
22FEB2005	V6	0	1.19	85.5	30
26APR2005	V7	0	4	35.4	5
28JUN2005	V8	0	2.16	29.3	0
20SEP2005	V9	0	7.52	14.4	0
13DEC2005	V10	0	9.6	11.8	0
27FEB2006	UN	0	49.06	13.1	0
28MAR2006	V11	0	90.72	16.9	0
20JUN2006	V12	0	110.4	250	0

CHAPTER 7 SPECIMENS

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

- Specimen Report
- Specimens

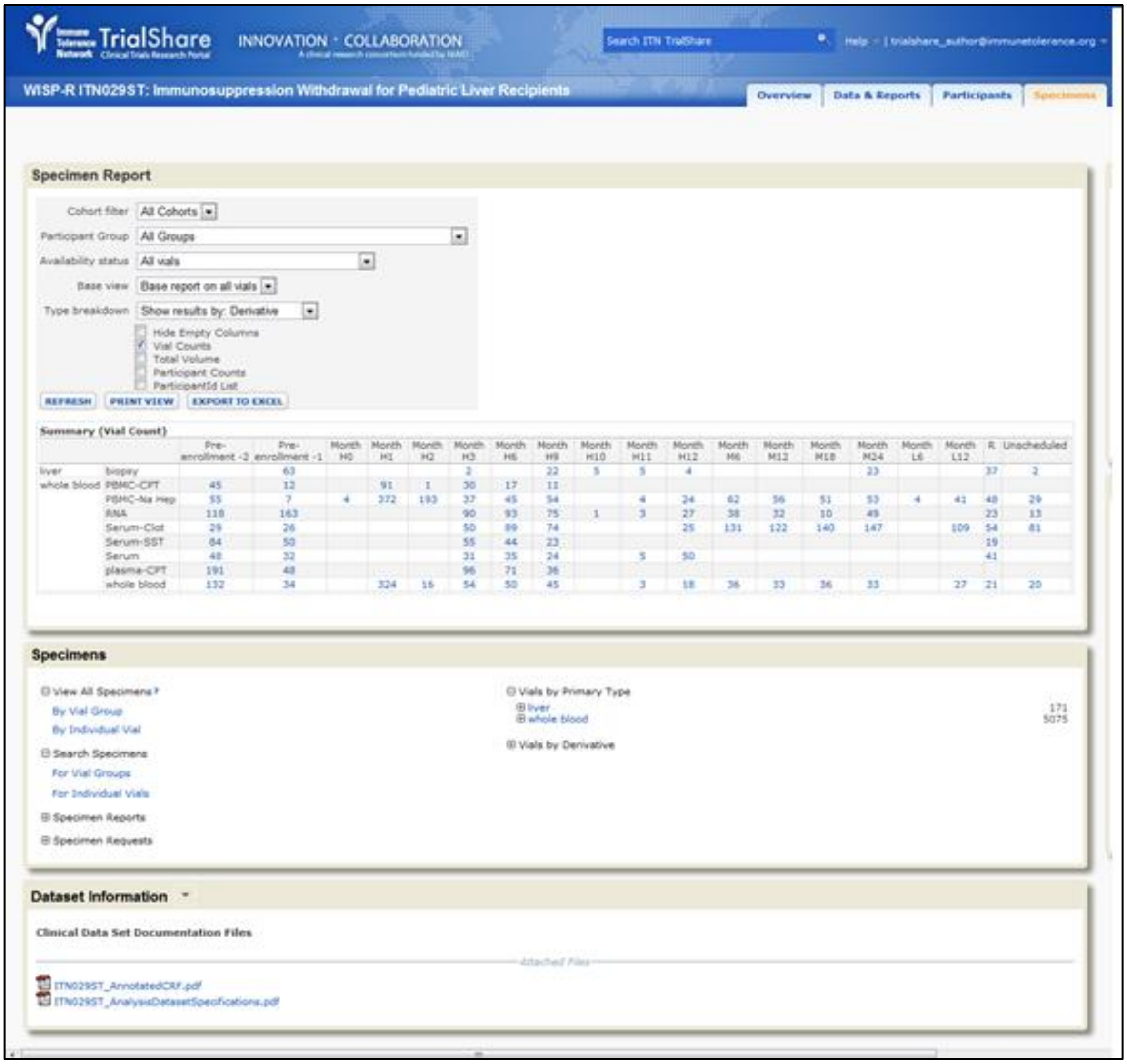
SPECIMENS TAB

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.

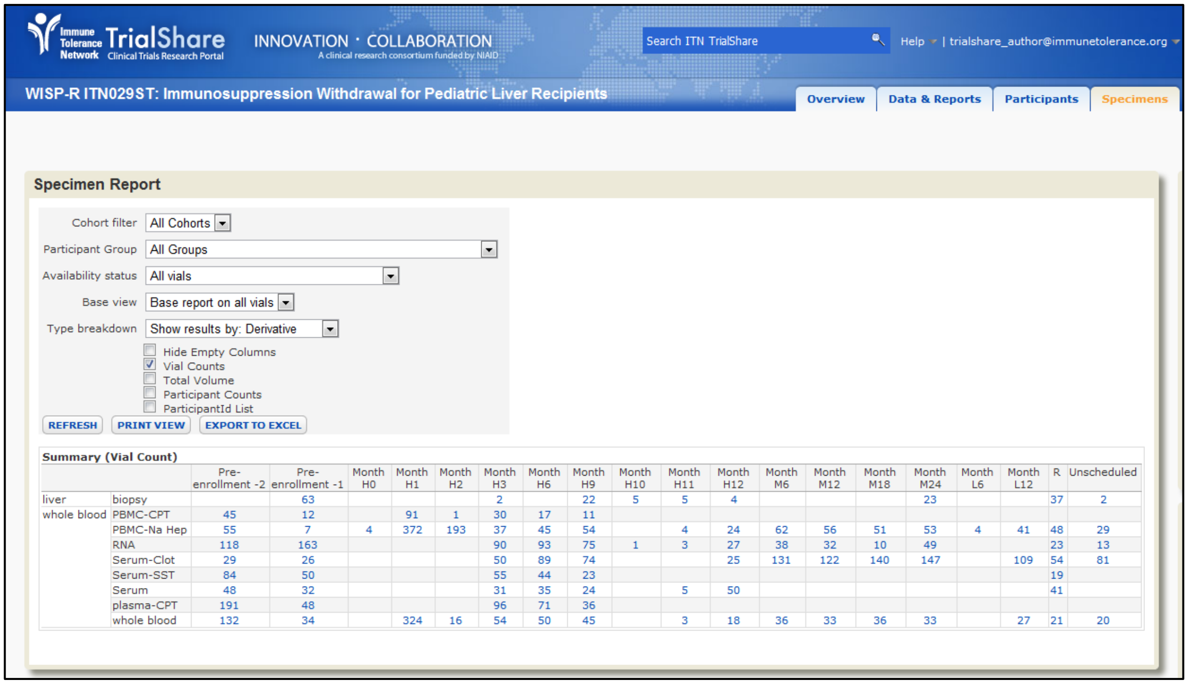
   OR

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



SPECIMEN REPORT

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.

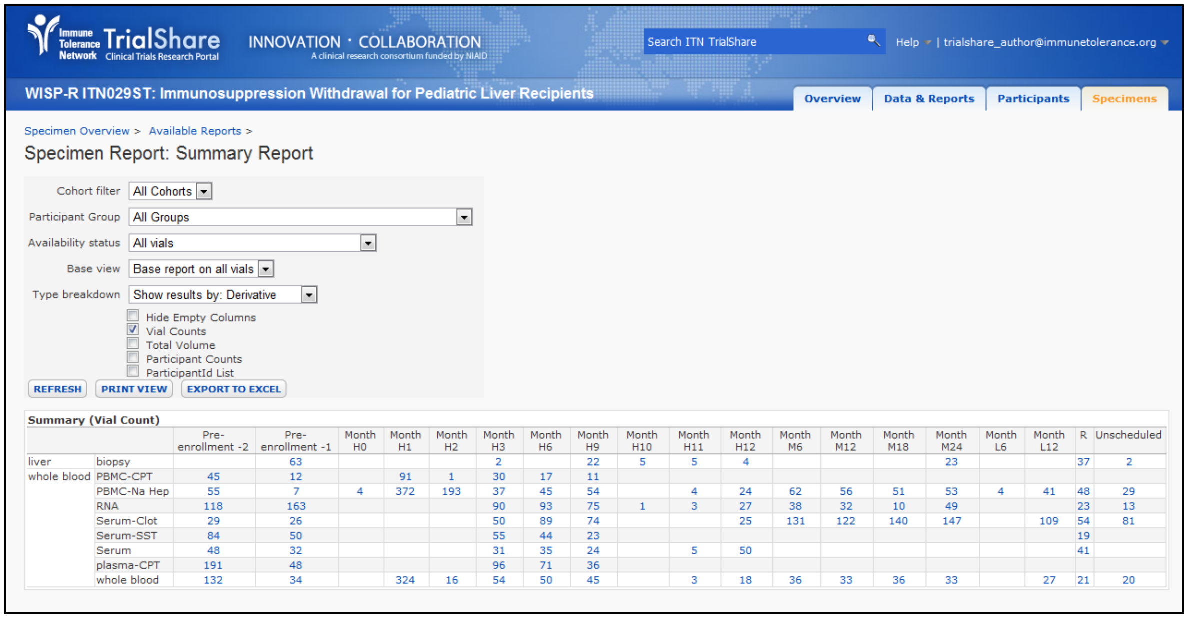


		Pre-enrollment -2	Pre-enrollment -1	Month H0	Month H1	Month H2	Month H3	Month H6	Month H9	Month H10	Month H11	Month H12	Month M6	Month M12	Month M18	Month M24	Month L6	Month L12	R	Unscheduled
liver	biopsy		63				2		22	5	5	4				23			37	2
whole blood	PBMC-CPT	45	12		91	1	30	17	11											
	PBMC-Na Hep	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.



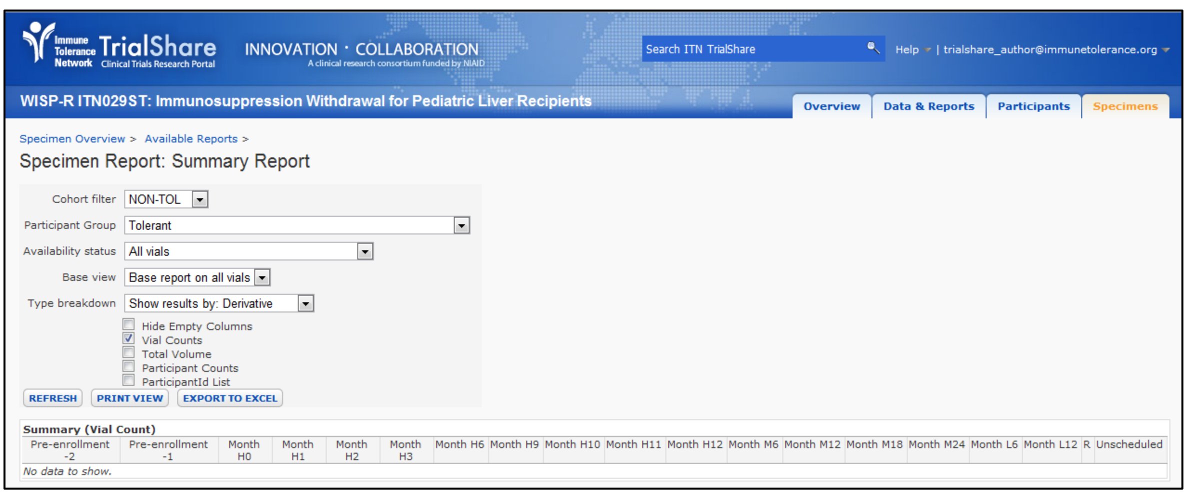
Summary (Vial Count)

		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											
	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

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.

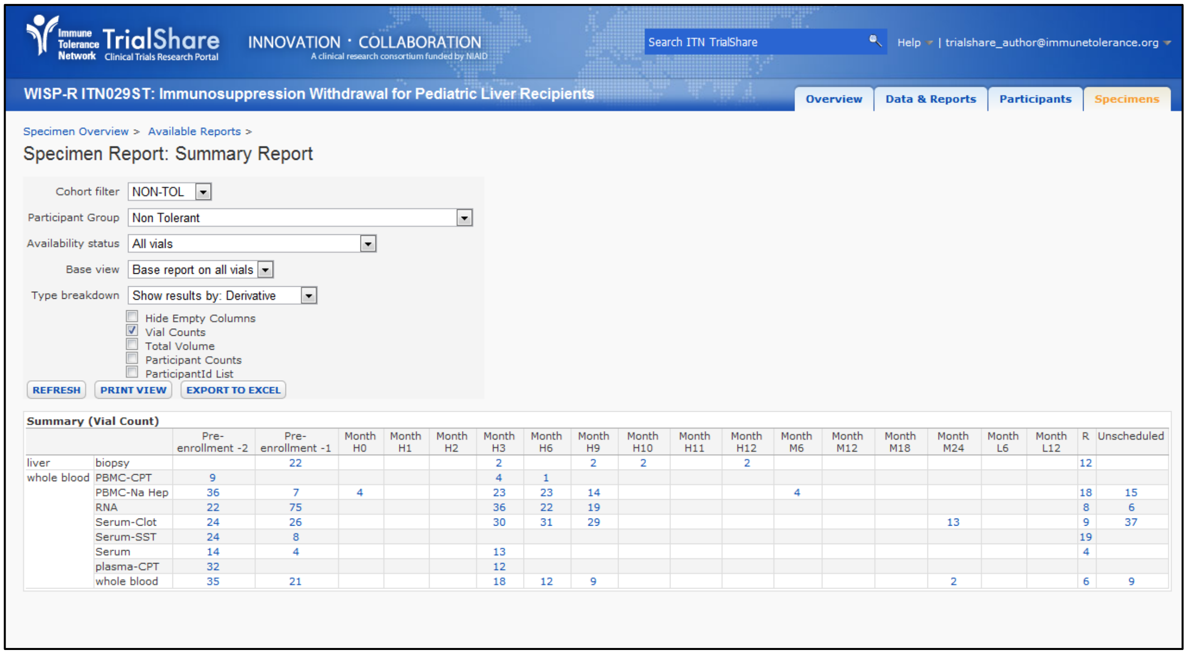
   The first figure shows a scenario when no results are displayed, because the Cohort and Participant Group are not from the same category.



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												
	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

7. Click on a Specimen type number in the "**Summary (Vial Count)**" grid to view the specimen availability.

8. 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](#view-specimens).

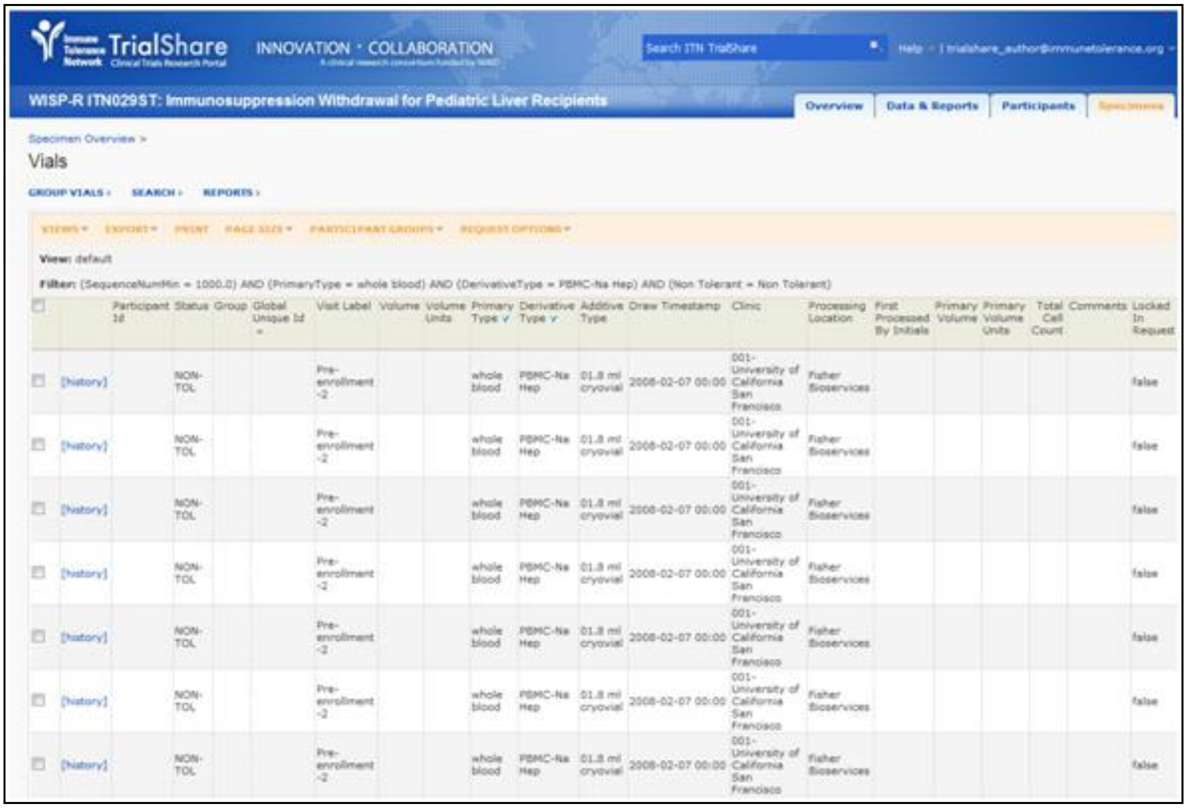
SPECIMENS

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:



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.

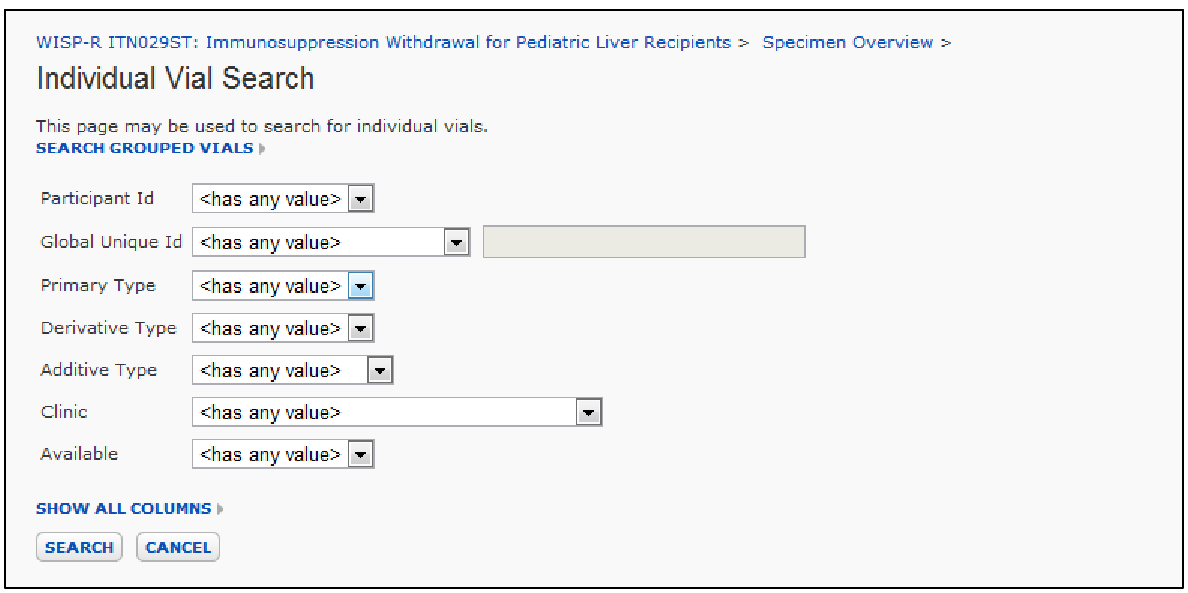
8. Click on "REQUEST OPTIONS" dropdown to view existing requests. Go to Specimen Requests for instructions on requesting vials.

Search Specimens

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

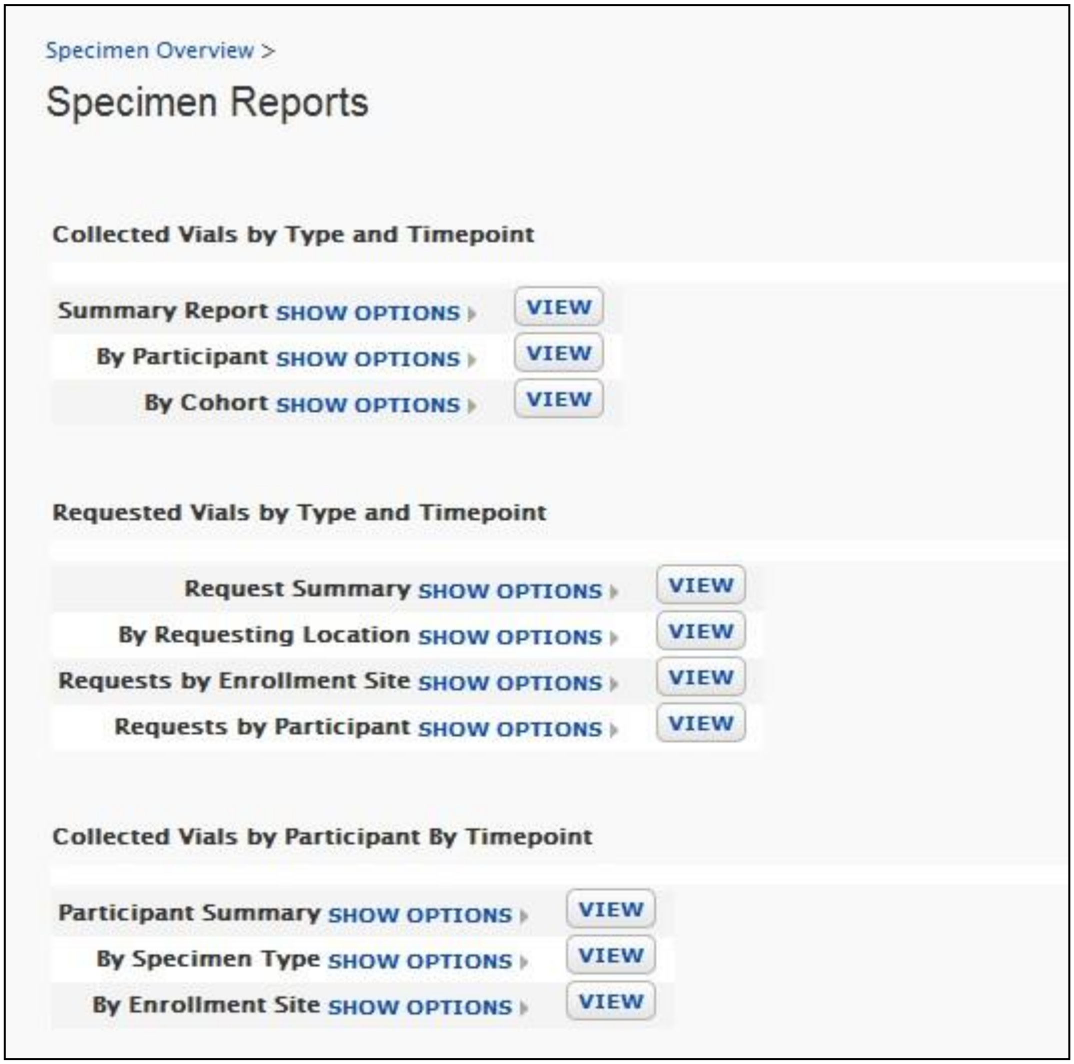
1. Clicking on **For Vial Groups** will display the "**Grouped Vial Search**" page. This page may be used to search for vials grouped by participant, time point, and type. Click on the "**SEARCH**" button after selecting your filters to view the Grouped Vials.

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.



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.

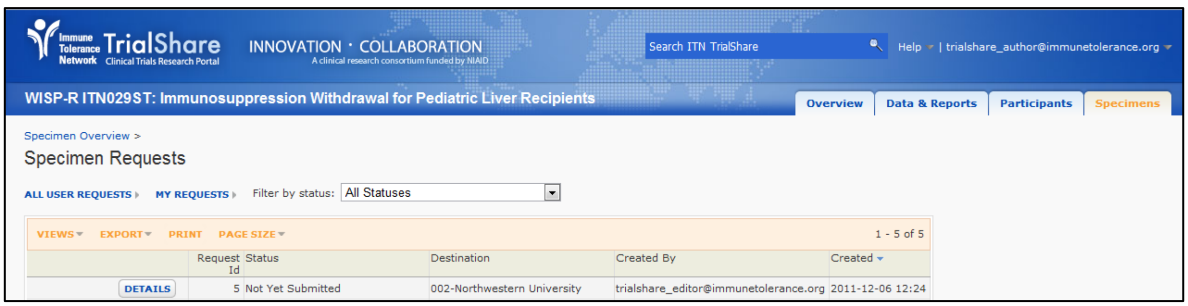


- **Customize:** To customize your report, click "**SHOW OPTIONS**" next to the sub option of your choice under the report type of your choice. You can then select filters to winnow your specimen data, plus metrics to display for your data. Filters can include Cohort, Availability Status, and Participant 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."



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.**"