



MonTe

Monitoring Temperature of Clinical Study Drugs

User Guide

[View and Download Reports](#)

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Introduction

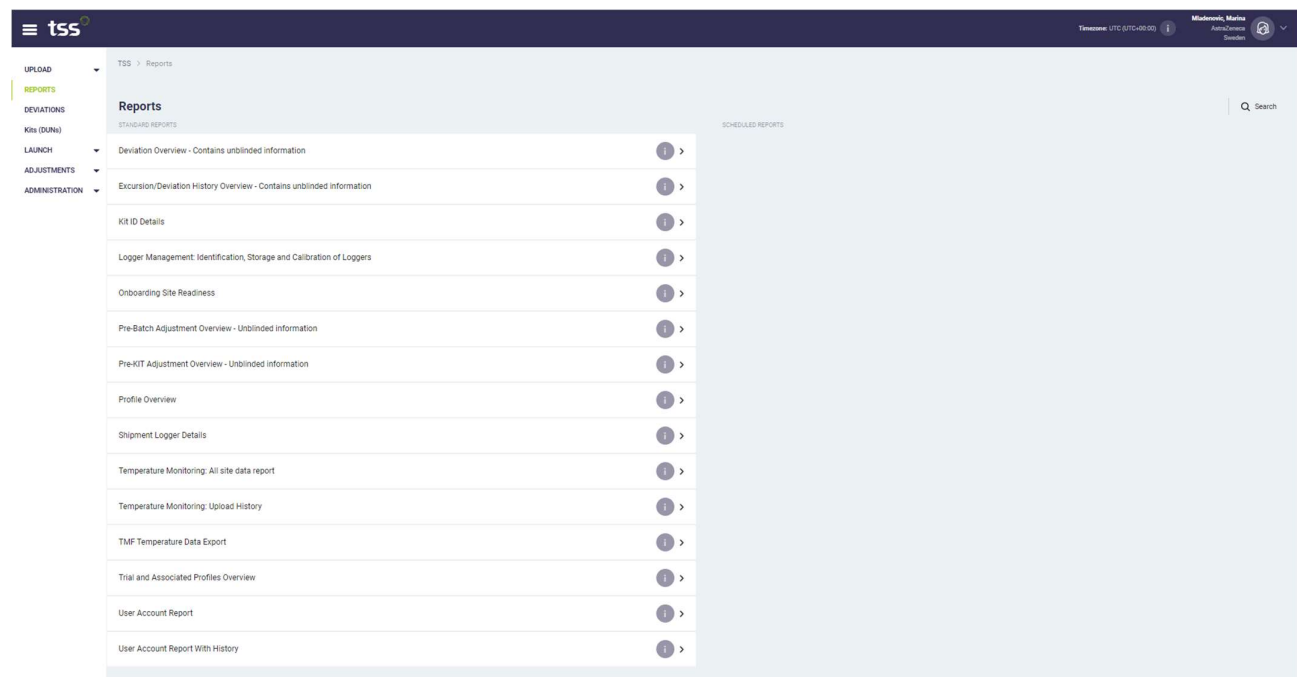
This user guide describes the standard reports available in the MonTe, their purpose and how to work with them.

The user guide will be relevant for site users, monitors and internal AstraZeneca personnel working with investigational product.

1. Reports

The system automatically generates several reports based on the data related to your specific trials and sites. These can be filtered, scheduled and downloaded to fit your needs.

Reports are accessed and managed under the **Reports** menu item in the left-hand side menu on the home page. Clicking **Reports** will take you to the Reports overview page.



- Standard reports in the system are listed on the left-hand side of the page. You open a report by clicking the report name. Reports listed are depending on what user role you have in the system.
- Click the information-icon to see a short description of what the report contains (see table below for full overview).
- Your personal scheduled reports are listed in the right-hand side of the page (see section 2.3.2 for description of how to schedule reports). Click the i icon to see report criteria.
- You can use the search field to search for specific reports.

The standard reports have different purposes and filters you can apply to narrow your data set.

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List of standard reports

Report name	Description	Available filters
Deviation overview – may contain unblinded information	Lists all registered Deviations	Trial ID, Site, Deviation registered From, Deviation registered To, Sending Depot
Excursion/Deviation History overview – may contain unblinded information	Lists all registered excursions/deviations on Trial /Site level and the kits affected	Start Date, End Date, Trial ID, Site, Sending Depot
Logger Management: Identification, Storage and Calibration of Loggers	An overview of storage loggers associated to the trial/site	Trial ID; Site; PI; Logger status; Associated from; Associated to
Kit ID Details	An overview of Kits and their detailed information.	Trial ID, Site, Shipment
Pre-Batch Adjustment Overview – unblinded information	Lists adjusted batches	Start date; End date; Adjustment status
Pre-Kit Adjustment Overview – unblinded information	Lists adjusted kits per trial	Trial ID
Profile Overview	Lists profiles per status	Profile name; Based on blinding; Status
Shipment Logger Details	List all shipment loggers with their associated products	Trial ID, Site, Shipment, Start Date, End Date
Temperature Monitoring: All site data report	Displays complete temperature data on trial/site level. Possible to narrow search by defining period, choose logger or view on kit level	Trial ID; Site; Logger type; Plot period start date; Plot period end date
Temperature Monitoring: Upload History	An overview of loggers registered to a trial/site, number of uploads per logger and upload information	Trial ID; Site; PI
TMF Temperature Data Export	A GCP compliant overview of all temperature/gap related events on trial/site level to be exported to the TMF	Trial ID; Country; Site
Trial and Associated Profiles Overview	Lists profiles based on trial association	Approved from; Approved to; Trial ID; Status
User Account Report	Lists users' access to trial/sites and their roles	Trial ID; Site; Username; User status
Onboarding Site Readiness	Report that lists Trial/Sites and their readiness status. Report is used only when onboarding an ongoing study to MonTe	Trial ID, Site, Activation Date
User Account Report with History	Lists users' access to trial/sites and their roles in combination with status changes over time	Trial; Site; Username; User status; User role

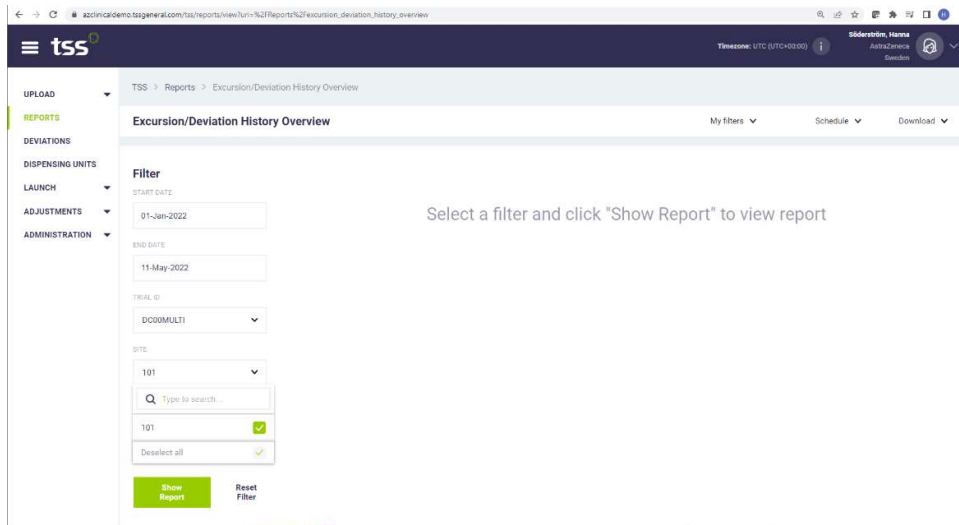
2.1 Generating a report

When you open a new report, it will be empty until you have applied filters and/or selected **Show Report**. Select your filters by choosing a value in the drop-down menu. You can also search for a specific filter value.

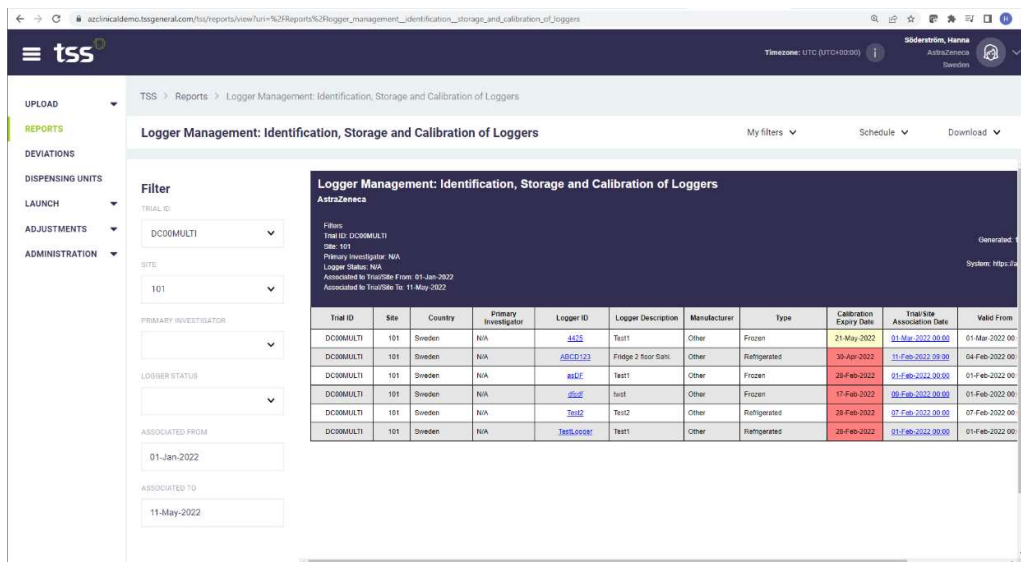
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Filters are not mandatory, and you can define all, some of them or none of them. Note that it is possible to use relative dates when generating a report in the system but is not mandatory. Details on how to use it is listed in section 2.3.3.



When you have defined your data filters, click **Show report**. If you click **Show reports** without any filters, the system will generate a report including all your available data which (depending on the data set) may take some time to load.



- The filter fields are visible on the left-hand side and can be changed at any time. Click **Show report** to update the report with new filters. Applied filters are shown at the top of the report. Please note that End Date – filter is not inclusive. If user needs to see data launched today, tomorrow’s date needs to be set as the “stop/end date”. For example: Include data for 29-Sep-2023 – End date is set to 30-Sep-2023.
- Any highlighted hyperlinks displayed within the report are sub-reports. Open them by clicking the link. To navigate back to original report, click the back button on your browser.

- The system highlights data to be aware of – in this case a past expiry date.
- You can at any time reset your filters by clicking **Reset filters** and create a new report.

The temperature monitoring report includes a graph of the temperature uploads. You can easily see temperatures at any given point of the period by hovering the mouse over a point on the graph.

2.2 Downloading a report

Reports can be downloaded as PDF files or in Excel.

The screenshot displays the TSS web application interface. The main content area is titled "Logger Management: Identification, Storage and Calibration of Loggers". On the left, there is a "Filter" section with dropdown menus for "TRIAL ID" (AZ demo), "SITE" (6 selected), "PRIMARY INVESTIGATOR", "LOGGER STATUS", "ASSOCIATED FROM" (01-Jan-2022), and "ASSOCIATED TO" (11-May-2022). The main data area shows a table with the following columns: Trial ID, Site, Country, Primary Investigator, Logger ID, Logger Description, Manufacturer, Type, Calibration Expiry Date, Trial/Site Association Date, and Valid From. The table contains 8 rows of data. A "Download" button in the top right corner has a dropdown menu open, showing options for "PDF" and "XLSX".

Trial ID	Site	Country	Primary Investigator	Logger ID	Logger Description	Manufacturer	Type	Calibration Expiry Date	Trial/Site Association Date	Valid From
AZ demo	461	Sweden	NIA	4425	Test1	Other	Frozen	21-May-2022	01-Mar-2022 00:00	01-Mar-2022 00:00
AZ demo	461	Sweden	NIA	asDE	Test1	Other	Frozen	28-Feb-2022	01-Feb-2022 00:00	01-Feb-2022 00:00
AZ demo	461	Sweden	NIA	Test2	Test2	Other	Refrigerated	28-Feb-2022	07-Feb-2022 00:00	07-Feb-2022 00:00
AZ demo	461	Sweden	NIA	Test1.opac	Test1	Other	Refrigerated	28-Feb-2022	02-Feb-2022 00:00	01-Feb-2022 00:00
AZ demo	462	Sweden	NIA	4425	Test1	Other	Frozen	21-May-2022	01-Mar-2022 00:00	01-Mar-2022 00:00
AZ demo	462	Sweden	NIA	asDE	Test1	Other	Frozen	28-Feb-2022	01-Feb-2022 00:00	01-Feb-2022 00:00
AZ demo	462	Sweden	NIA	Test2	Test2	Other	Refrigerated	28-Feb-2022	08-Feb-2022 00:00	07-Feb-2022 00:00

To download a report, click **Download** in the top right-hand side corner. From the drop-down menu choose between a PDF file or an Excel file. The report will open in a new window.

Note: Google Chrome users must turn off pop-up blocker to see reports.

The PDF report will show the report as it is in the system.

The Excel report will contain two data sheets; One with the filters applied to generate the report, and one with the actual data.

Trial ID	Site	Country	Primary Investigator	Logger ID	Logger Description	Manufacture	Type	Calibration Expiry Date	Trial/Site Association Date	Valid From	Inactivation Date	Status
AZ demo	461	Sweden	N/A	4425	Test1	Other	Frozen	21-May-2022	01-Mar-2022 00:00	01-Mar-2022 00:00	N/A	Active
AZ demo	461	Sweden	N/A	asDF	Test1	Other	Frozen	28-Feb-2022	01-Feb-2022 00:00	01-Feb-2022 00:00	01-Mar-2022	Inactive
AZ demo	461	Sweden	N/A	Test2	Test2	Other	Refrigerated	28-Feb-2022	07-Feb-2022 00:00	07-Feb-2022 00:00	N/A	Active
AZ demo	461	Sweden	N/A	TestLogger	Test1	Other	Refrigerated	28-Feb-2022	02-Feb-2022 00:00	01-Feb-2022 00:00	N/A	Active
AZ demo	462	Sweden	N/A	4425	Test1	Other	Frozen	21-May-2022	01-Mar-2022 00:00	01-Mar-2022 00:00	N/A	Active
AZ demo	462	Sweden	N/A	asDF	Test1	Other	Frozen	28-Feb-2022	01-Feb-2022 00:00	01-Feb-2022 00:00	01-Mar-2022	Inactive
AZ demo	462	Sweden	N/A	Test2	Test2	Other	Refrigerated	28-Feb-2022	08-Feb-2022 00:00	07-Feb-2022 00:00	N/A	Active

2.3 Managing reports

There are two ways of managing your reports to make it easier for you to generate similar reports or have the system generate them automatically for you.

2.3.1 Save a filter

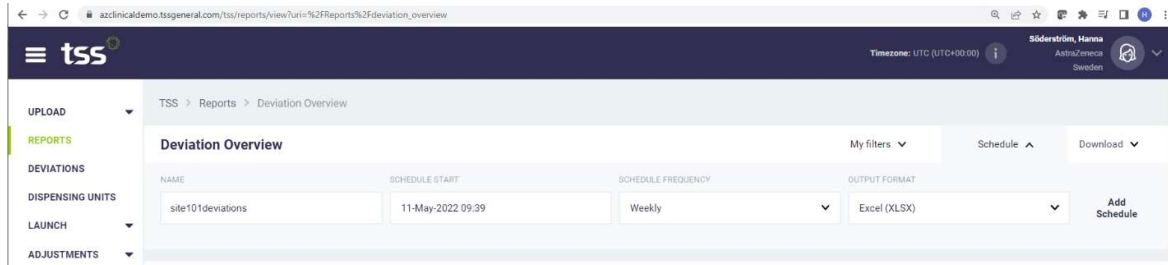
- When you have selected your filter values, click **My filters** in the top menu bar of the Reports page.
- Name your filter and click **Save pre-set filter**.
- The system indicates when the filter has been added to your list of personal pre-set filters. Personal filters are found under **My filters**. Pre-set filters can only be saved and applied within the same standard report they are created in, as available filters vary from report to report.
- You can delete your pre-set filter by clicking the “x” next to the name.

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2.3.2 Schedule a report

If you use the same report on a regular basis, it is possible to have the system automatically generate an up-to-date report at a specific frequency and send it to your email.

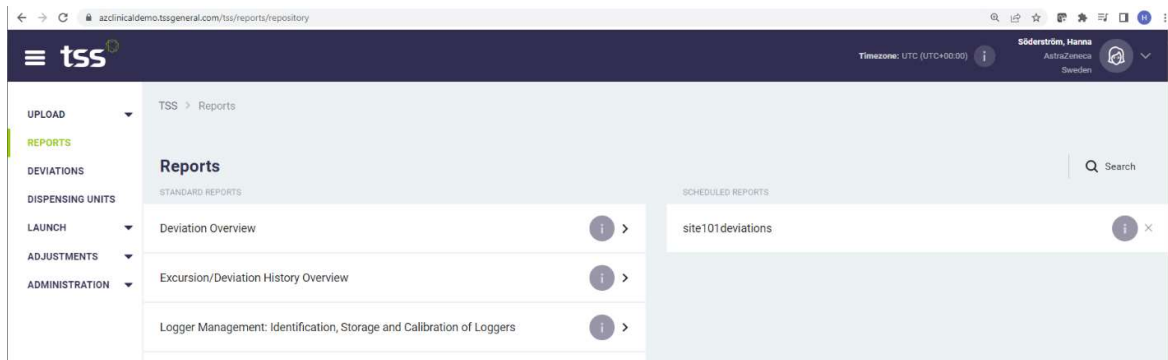


From the main page of the report you want to schedule, click **Schedule** in the top menu bar.

Fill out the data fields for the schedule:

- Name your report. *Note:* Spaces are not accepted in the naming
- Pick a start date and time (see chapter 2.3.3) for the report and a frequency. This can be once, daily, weekly or monthly (see section below how to schedule with date intervals)
- Choose the report format; choose between PDF and Excel.

When you are done, click **Add Schedule**. The system will indicate the schedule has been added and the scheduled report will now appear on your Report overview page.



A scheduled report can be deleted by clicking the “x” symbol.

2.3.3 How to schedule a report with Start and End Dates

When scheduling a report using “Date” filters it should be configured with a date interval using key words for relative dates.

The key words that are to be used for configuring the date interval is the following: “**DAY, WEEK, MONTH, QUARTER, SEMI, YEAR**”.

For example, to get the current month’s data when receiving the report “MONTH” should be used. “Start Date” filter will fetch the first date of the selected period and “End Date” filter will fetch the last date of the selected period.

Below is an example using relative dates “MONTH” and date of scheduling is 25-Jun-2020.

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Filter "Start Date" = "MONTH"

Filter "End Date" = "MONTH"

This is equivalent to the following:

Filter "Start Date" = "01-Jun-2020 00:00:00"

Filter "End Date" = "30-Jun-2020 23:59:59"

Temperature Monitoring: All Document Uploads

Filter

TRIAL ID

SITE

UPLOAD TYPE
Storage Upload

UPLOAD FROM
MONTH

UPLOAD TO
MONTH

Show Report **Reset Filter**

Temperature Monitoring: All Document Uploads
Novo Nordisk

Filters
Trial ID: N/A
Site: N/A
Upload Type: Storage Upload
Upload From: 01-Jun-2020
Upload To: 30-Jun-2020

Data in "Start Date" and "End Date" is refreshed every 15 minutes

Logger ID	Shipment Number	Trial ID	Site
OQ414	N/A	ivanongo	448
OQ414	N/A	ivanongo	448
OQ414	N/A	ivanongo	448
OQ414	N/A	ivanongo	448
OQ414	N/A	ivanongo	448

To get previous month's data "-1" is added to the key word: "MONTH-1".

Temperature Monitoring: All Document Uploads

Filter

TRIAL ID

SITE

UPLOAD TYPE
Storage Upload

UPLOAD FROM
MONTH-1

UPLOAD TO
MONTH-1

Show Report **Reset Filter**

Temperature Monitoring: All Document Uploads

Novo Nordisk

Filters
Trial ID: N/A
Site: N/A
Upload Type: Storage Upload
Upload From: 01-May-2020
Upload To: 31-May-2020

Data in "Start Date" and "End Date" is refreshed every 15 minutes

Logger ID	Shipment Number	Trial ID	Site
Narrower	N/A	1337773	215
130500065440	N/A	IQPT1-1911	101
130500065440	N/A	IQPT1-1911	101
16032408	N/A	TSSPQ2	734
16032408	N/A	Trial284Rerun1	1284
16032408	N/A	TC1OQP284	1284
16032408	N/A	1OQP284	1284
16032408	N/A	Trial284Rerun1	1284
16032408	N/A	IQP Trial Test 100050	109
16032408	N/A	TSSPQ2	734
16032408	N/A	TC1OQP284	1284
16032408	N/A	IQP Trial Test 100050	109
16032408	N/A	1OQP284	1284
oqp390-tc5	N/A	OQP390-TC5_1	1
B2TC2_OQP390	N/A	OQP390-TC2_Y	2