

Monitoring Reports

Streamlining the Design, Completion, and Approval of Site Visit Reports with a Modern CTMS

Site Monitoring is at the forefront of our industry’s ongoing efforts to improve both the efficiency and scalability of trials today. Modern tools like Datatrak’s CTMS provide powerful functionality wrapped in simple and easy to understand interfaces that enable users to truly shape their CTMS to their own specific needs and business workflows. This fact sheet aims to demonstrate how this platform can both support your current Monitoring efforts, and effortlessly grow and adapt to the ways they may change in time.

Build a Library of Configurable Monitoring Report Templates

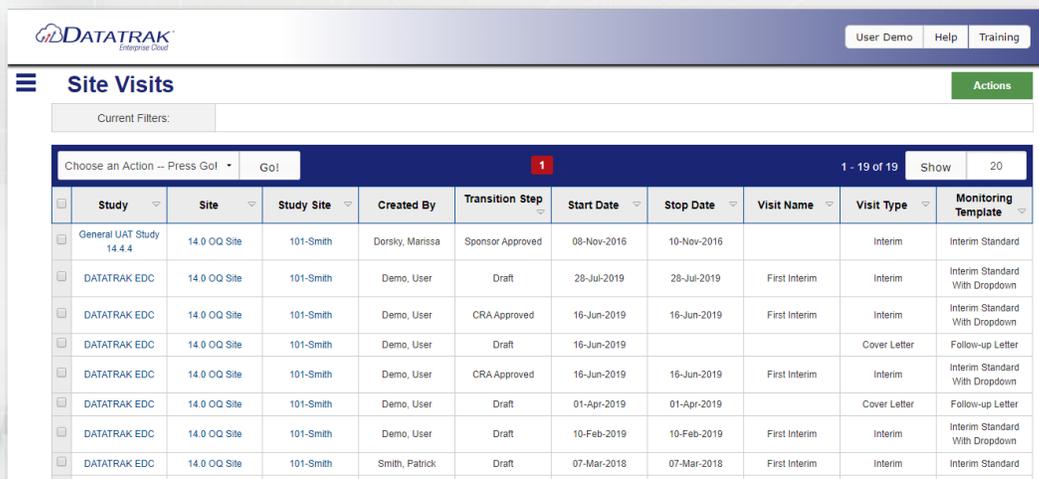
The flexible tools provided for the design of monitoring report templates allow users to easily create reports containing a wide range of fields and answer options in aesthetically pleasing arrangements. The interface is simple, requiring no coding skills, and utilizes drag and drop functionality to arrange questions and sections within reports. Once templates are created, they are version controlled, meaning they can be easily copied, modified, and reused across studies without having to ever start from scratch.

Design Report Approval Workflows

The CTMS can support as many different trip report approval workflows as needed, both simple and complex. Workflows in the CTMS are role based, and can be paired with tools like eSignature, and the ability to lock reports, ensuring that only the proper people are handling the visit report at any given time. Approval workflows can be selected on a study by study basis, so if any of your trials require specific changes to these procedures, there’s no problem at all.

Site Monitoring Planning Tools

Within each study, users are able to capture the details of their monitoring visit strategy and associated plans. In addition to attaching controlled documents, site communication letters, recording travel allowances, preferred air/hotel providers, and reimbursement procedures, the elements of the monitoring visit schedule can be built. These visit planning tools are tied directly into user calendars enabling CRA’s to see when visits are occurring and expected to occur. With study team members on the road or working remotely, having a central cloud-based environment to access information and essential documentation provides both convenience and consistency.



The screenshot shows the 'Site Visits' page in the Datatrak CTMS. It includes a search bar, a table of visit records, and navigation options. The table has columns for Study, Site, Study Site, Created By, Transition Step, Start Date, Stop Date, Visit Name, Visit Type, and Monitoring Template.

Study	Site	Study Site	Created By	Transition Step	Start Date	Stop Date	Visit Name	Visit Type	Monitoring Template
General UAT Study 14.4.4	14.0 OQ Site	101-Smith	Dorsky, Marissa	Sponsor Approved	08-Nov-2016	10-Nov-2016		Interim	Interim Standard
DATATRAK EDC	14.0 OQ Site	101-Smith	Demo, User	Draft	28-Jul-2019	28-Jul-2019	First Interim	Interim	Interim Standard With Dropdown
DATATRAK EDC	14.0 OQ Site	101-Smith	Demo, User	CRA Approved	16-Jun-2019	16-Jun-2019	First Interim	Interim	Interim Standard With Dropdown
DATATRAK EDC	14.0 OQ Site	101-Smith	Demo, User	Draft	16-Jun-2019			Cover Letter	Follow-up Letter
DATATRAK EDC	14.0 OQ Site	101-Smith	Demo, User	CRA Approved	16-Jun-2019	16-Jun-2019	First Interim	Interim	Interim Standard With Dropdown
DATATRAK EDC	14.0 OQ Site	101-Smith	Demo, User	Draft	01-Apr-2019	01-Apr-2019		Cover Letter	Follow-up Letter
DATATRAK EDC	14.0 OQ Site	101-Smith	Demo, User	Draft	10-Feb-2019	10-Feb-2019	First Interim	Interim	Interim Standard With Dropdown
DATATRAK EDC	14.0 OQ Site	101-Smith	Smith, Patrick	Draft	07-Mar-2018	07-Mar-2018	First Interim	Interim	Interim Standard

Automatically Populate Monitoring Reports

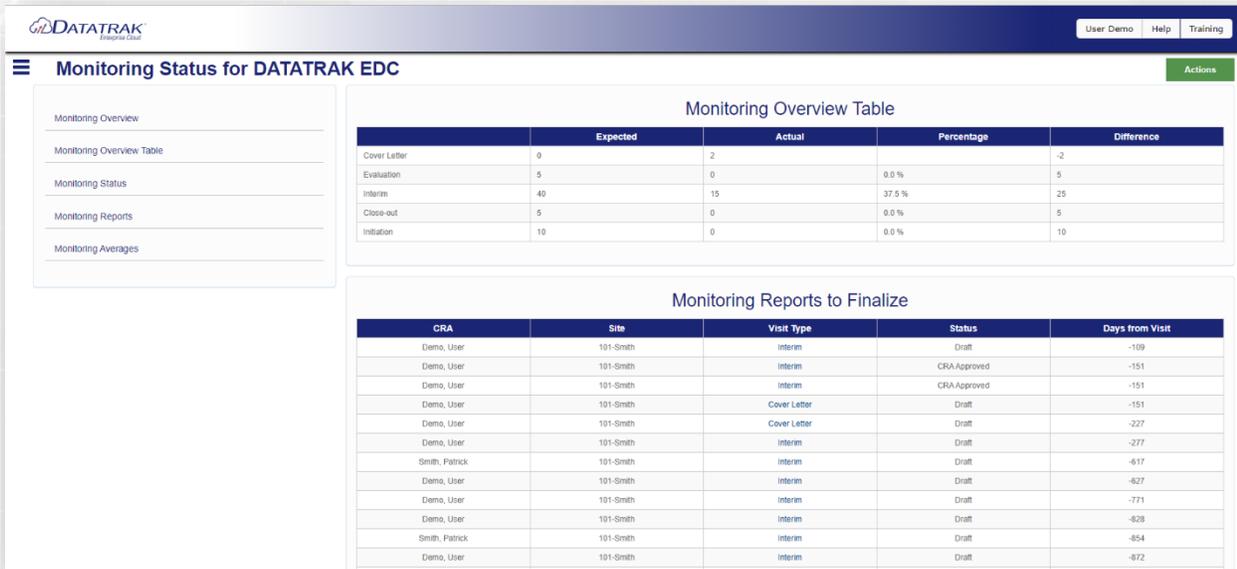
Datatrak’s CTMS can pull important information like Deviations, New and Closed Action Items, Site Information and more directly into your trip reports. This saves time as well as reducing the chance of missed data or errors. Additionally, when paired with the Datatrak EDC, we can leverage the full power of a truly unified eClinical platform to pull your monitor’s data cleaning activities, queries created and reopened, etc. from the EDC into your trip reports as well.

Offline Report Completion

In areas without a strong internet connection you can still complete your visit reports. You can download your report template ahead of your visit, complete offline, or on your flight, then simply upload to your report placeholder in the CTMS. After upload, the auto-population tool can fill out any remaining fields with existing CTMS information once a solid WIFI connection is available to you again.

End-to-End Monitoring Process

With tools like our Site Visits Manager and the user’s calendar, each step of the monitoring process can be observed and managed directly from your dashboards. Bolstered by a suite of reports giving insight into this process, and an ad-hoc reporting tool that can reach across studies, the CTMS all monitoring information more visible to the people that need it.



Monitoring Status for DATATRAK EDC

Monitoring Overview Table

	Expected	Actual	Percentage	Difference
Cover Letter	0	2		-2
Evaluation	5	0	0.0 %	5
Interim	40	15	37.5 %	25
Close-out	5	0	0.0 %	5
Initiation	10	0	0.0 %	10

Monitoring Reports to Finalize

CRA	Site	Visit Type	Status	Days from Visit
Demo, User	101-Smith	Interim	Draft	-109
Demo, User	101-Smith	Interim	CRA Approved	-151
Demo, User	101-Smith	Interim	CRA Approved	-151
Demo, User	101-Smith	Cover Letter	Draft	-151
Demo, User	101-Smith	Cover Letter	Draft	-227
Demo, User	101-Smith	Interim	Draft	-277
Smith, Patrick	101-Smith	Interim	Draft	-617
Demo, User	101-Smith	Interim	Draft	-627
Demo, User	101-Smith	Interim	Draft	-771
Demo, User	101-Smith	Interim	Draft	-828
Smith, Patrick	101-Smith	Interim	Draft	-854
Demo, User	101-Smith	Interim	Draft	-872

Unified technologies like Datatrak Enterprise Cloud aim to provide you with the greatest possible level of functionality in a single, streamlined product. If you’re interested in discussing with us how we can simplify your lives, please reach out to us to schedule a demo today.