

MediCase version 6.0

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1. Summary

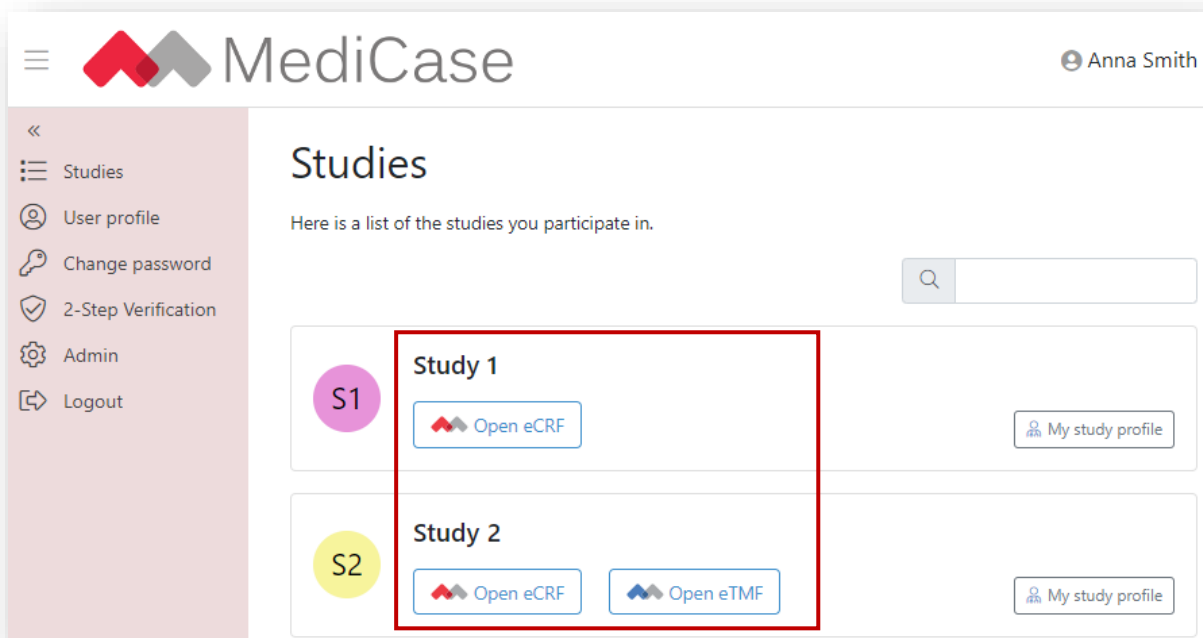
MediCase 6.0 introduces our brand-new product, the MediCase eTMF. An eTMF (electronic Trial Master File) is an online storage for documents collected in a clinical trial, along role-based processes for uploading, indexing, and managing the documents and their metadata. At the end of the study, you can export all documents as a document archive for final storage.

Apart from the eTMF this version also includes some minor updates in the eCRF.

2. General

2.1. Updated study list

The study list, displaying all MediCase studies you participate in now shows a link to the eCRF and/or the eTMF, depending on what products are available for the study.



*In the study list, click on “Open eCRF” to open the study’s eCRF.
If the study has an eTMF, click “Open eTMF” to access it.*

3. eCRF

3.1. Monitoring tool – clarified options for skipping monitoring

When a study uses monitoring plans, the monitor can easily skip monitoring for forms not included in the monitoring plan. This button has been renamed to “*Skip forms not in monitoring plan*” to clarify that only forms not included in the monitoring plan will be skipped.

Monitoring

Displaying subjects that has forms sent to monitoring.

	Subject	Site #	Site	Group	Subject status	Monitoring scheme	To be monitored	Not in monitoring plan
<input type="checkbox"/>	<input type="text"/>	(All)	(All)	(All)	(All)	(All)		
<input type="checkbox"/>	007 - MS	1	S1	X	Study	Plan A	2 forms	1 form
<input type="checkbox"/>	X-001 (001) - AS	1	S1	X	Study	Full monitoring	1 form	(None)
<input type="checkbox"/>	X-048 (066) - BG	1	S1	X	Study	Plan A	3 forms	2 forms
<input type="checkbox"/>	Y-013 (015) - TL (DEMO)	1	S1	Y	Completed	Plan B	1 form	(None)

Showing 1 to 4 of 4 rows

4 rows, 0 selected

Skip monitoring for selected subjects
Skip forms not in monitoring plan

Click “Skip forms not in monitoring plan” to skip entered forms not included in the monitoring plan.

3.2. Medical coding page – new filter options

The medical coding page is accessible for Medical Coders for coding but also by e.g. Data Managers to view the progress of the coding. On this page we have now added a “*Coding not completed*” filter option in the “*Status*” column that lists all terms not yet fully coded in the study, including not coded terms but also terms that need to be recoded or has a pending query.

We have also added options “*All to act on by coder*” and “*All to act on by non-coder*” which lists all not fully coded terms with action required by coder users and non-coder users, respectively.

Medical coding for "ICD-10"

Select codes by clicking the link in the "Code" column. Click "Confirm coding" at the bottom of the page to confirm all selected codes. By changing the "Status" filter you can also see previously coded items.

Subject	Visit	Coding context	Section	Term	Code	Status	Actions
	(All)	(All)				(Coding not completed)	
X-003 (3) - X	Visit 1	Medical history	Health impact	Headache	(None)	? Pending query	
X-004 (5) - X	Visit 1	Medical history	Health impact	Mild nausea	C0205	⚠ To be recoded	
X-004 (5) - X	Visit 1	Medical history	Health impact	Sore throat	(None)	Not coded	

New filter options are added in the "Status" column on the medical coding page.

3.3. Clearing values in multiple option fields

When entering multiple option fields in forms, such as radio buttons or list boxes, we have added a "Clear value" option in the menu. Clearing the value will clear any entered option in the field even if the field is mandatory, which may be needed if the value was entered by mistake.

Current smoker? ?

Yes

No

Any other current nicotine use?

Yes

No

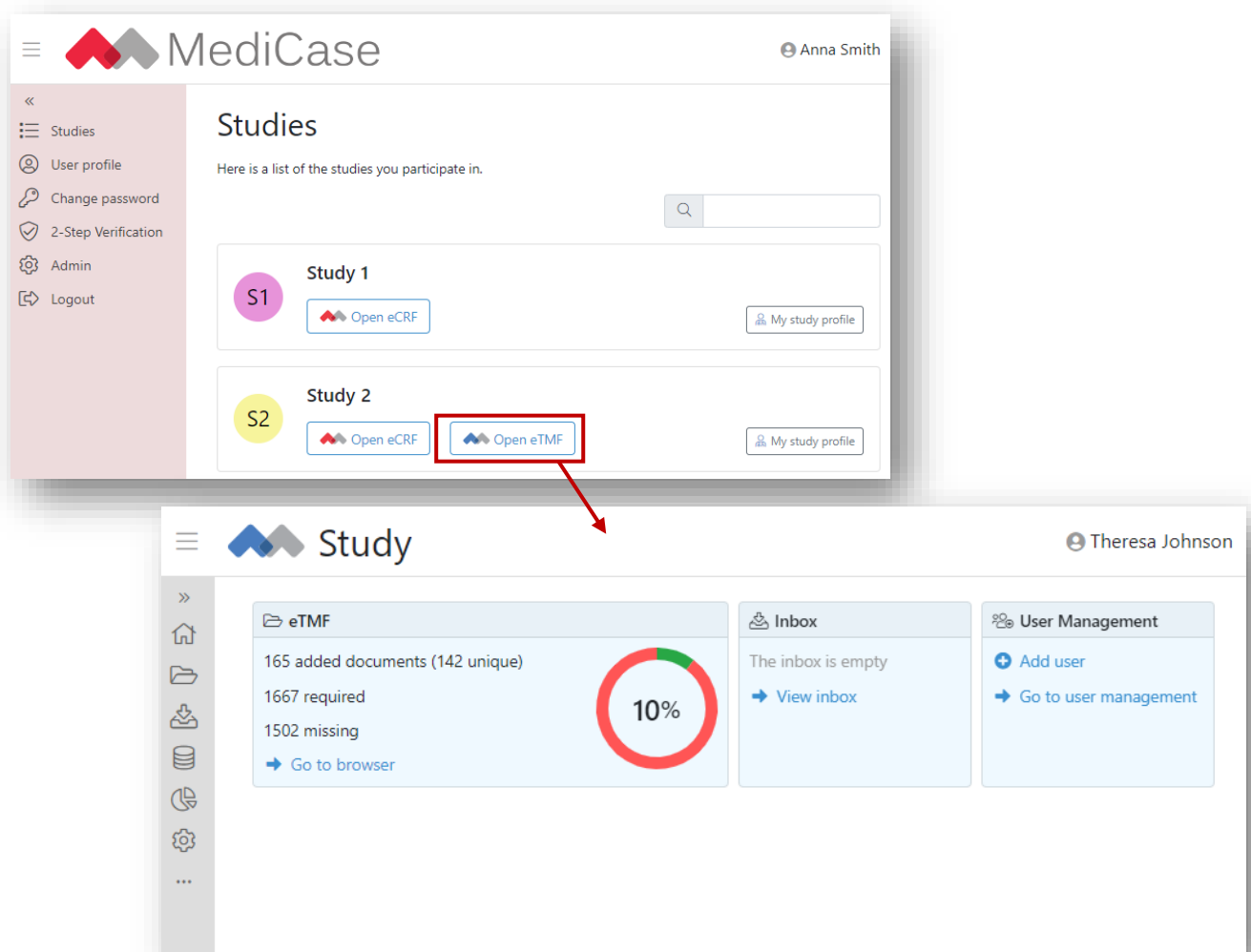
- ✖ Omit value
- 🗑 Clear value
- 💬 Add a comment
- ? Add a query
- 📄 Audit trail

The "Clear value" option clear entered options also in required fields.

4. eTMF

The MediCase eTMF (electronic Trial Master File) is an online storage for documents collected in a clinical trial, along role-based processes for uploading, indexing and managing the documents and their metadata. The eTMF is based on the CDISC Trial Master File Reference Model for categorizing documents in a study, but the configuration can be customized to suit the needs for your study. You can read more about the CDISC model here: <https://www.cdisc.org/standards/trial-master-file-reference-model>

The eTMF is a separate product from the eCRF, but if both products are active for a study, users may access them both using their MediCase login credentials.



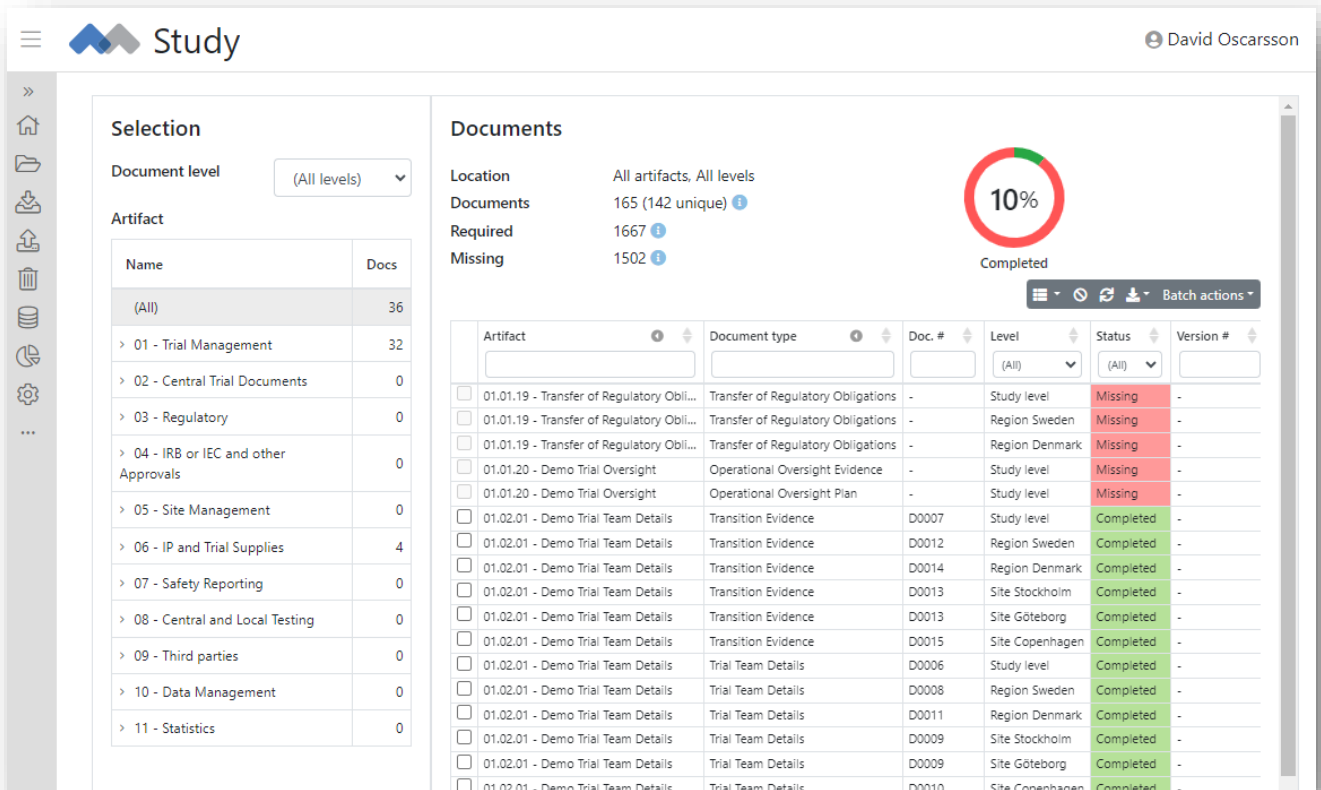
The image shows two overlapping screenshots of the MediCase web application. The top screenshot displays the 'Studies' dashboard for user Anna Smith. It lists two studies: 'Study 1' (S1) and 'Study 2' (S2). For 'Study 2', the 'Open eTMF' button is highlighted with a red box, and a red arrow points from it to the bottom screenshot. The bottom screenshot shows the 'Study' dashboard for user Theresa Johnson. The 'eTMF' section displays document statistics: 165 added documents (142 unique), 1667 required, and 1502 missing. A circular progress indicator shows 10% completion. Other sections include 'Inbox' (empty) and 'User Management'.

Study	Open eCRF	Open eTMF	My study profile
Study 1 (S1)	Yes	No	Yes
Study 2 (S2)	Yes	Yes	Yes

Section	Content
eTMF	165 added documents (142 unique) 1667 required 1502 missing 10% progress Go to browser
Inbox	The inbox is empty View inbox
User Management	Add user Go to user management

If the eTMF is active for a study, invited users may access it from the MediCase dashboard.

The eTMF is a role-based system, just like the eCRF, but the user roles are separated from the eCRF, and a user may have access to the eCRF and not the eTMF, and vice versa. In the eTMF a user manager can give users access to upload, index and/or view the documents stored in the eTMF.



The screenshot shows the eTMF Browser interface. On the left, there is a 'Selection' panel with a 'Document level' dropdown set to '(All levels)'. Below it is an 'Artifact' table listing various trial management categories and their document counts. The main area is titled 'Documents' and shows a summary: 'Location: All artifacts, All levels', 'Documents: 165 (142 unique)', 'Required: 1667', and 'Missing: 1502'. A circular progress indicator shows '10%' completed. Below the summary is a table of documents with columns for Artifact, Document type, Doc. #, Level, Status, and Version #. The Status column uses color coding: red for 'Missing' and green for 'Completed'.

Artifact	Document type	Doc. #	Level	Status	Version #
01.01.19 - Transfer of Regulatory Oblig...	Transfer of Regulatory Obligations	-	Study level	Missing	-
01.01.19 - Transfer of Regulatory Oblig...	Transfer of Regulatory Obligations	-	Region Sweden	Missing	-
01.01.19 - Transfer of Regulatory Oblig...	Transfer of Regulatory Obligations	-	Region Denmark	Missing	-
01.01.20 - Demo Trial Oversight	Operational Oversight Evidence	-	Study level	Missing	-
01.01.20 - Demo Trial Oversight	Operational Oversight Plan	-	Study level	Missing	-
01.02.01 - Demo Trial Team Details	Transition Evidence	D0007	Study level	Completed	-
01.02.01 - Demo Trial Team Details	Transition Evidence	D0012	Region Sweden	Completed	-
01.02.01 - Demo Trial Team Details	Transition Evidence	D0014	Region Denmark	Completed	-
01.02.01 - Demo Trial Team Details	Transition Evidence	D0013	Site Stockholm	Completed	-
01.02.01 - Demo Trial Team Details	Transition Evidence	D0013	Site Göteborg	Completed	-
01.02.01 - Demo Trial Team Details	Transition Evidence	D0015	Site Copenhagen	Completed	-
01.02.01 - Demo Trial Team Details	Trial Team Details	D0006	Study level	Completed	-
01.02.01 - Demo Trial Team Details	Trial Team Details	D0008	Region Sweden	Completed	-
01.02.01 - Demo Trial Team Details	Trial Team Details	D0011	Region Denmark	Completed	-
01.02.01 - Demo Trial Team Details	Trial Team Details	D0009	Site Stockholm	Completed	-
01.02.01 - Demo Trial Team Details	Trial Team Details	D0009	Site Göteborg	Completed	-
01.02.01 - Demo Trial Team Details	Trial Team Details	D0010	Site Copenhagen	Completed	-

In the eTMF Browser you get an overview of all documents in the eTMF and the progress of the collection of required documents.

At the end of the study, you can export all documents as a document archive for final storage.

There are of course many more features included in the eTMF that we would be happy to show you. Please contact us at MediCase for more information about the eTMF.

5. What do you think?

At MediCase, we always strive to make our system more powerful and easier to use. Your point of view is valuable – if you have requests for improvements or other comments, please don't hesitate to tell us what you think. Contact your MediCase contact person or send an email to support@medicase.se.