

## TEEN-BESTrial – Instructions Research Manager

### Step 1 – Log in to Research Manager

You have received a link from the Application Manager of Research Manager to go to the login page of Research Manager.

→ Go to [www.onderzoekenanalyse.nl/MMC](http://www.onderzoekenanalyse.nl/MMC)

You have also received login information from the Application Manager. Log in with your personal *Username* and *Password*.

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Forgot password? → Request a new password via the login page

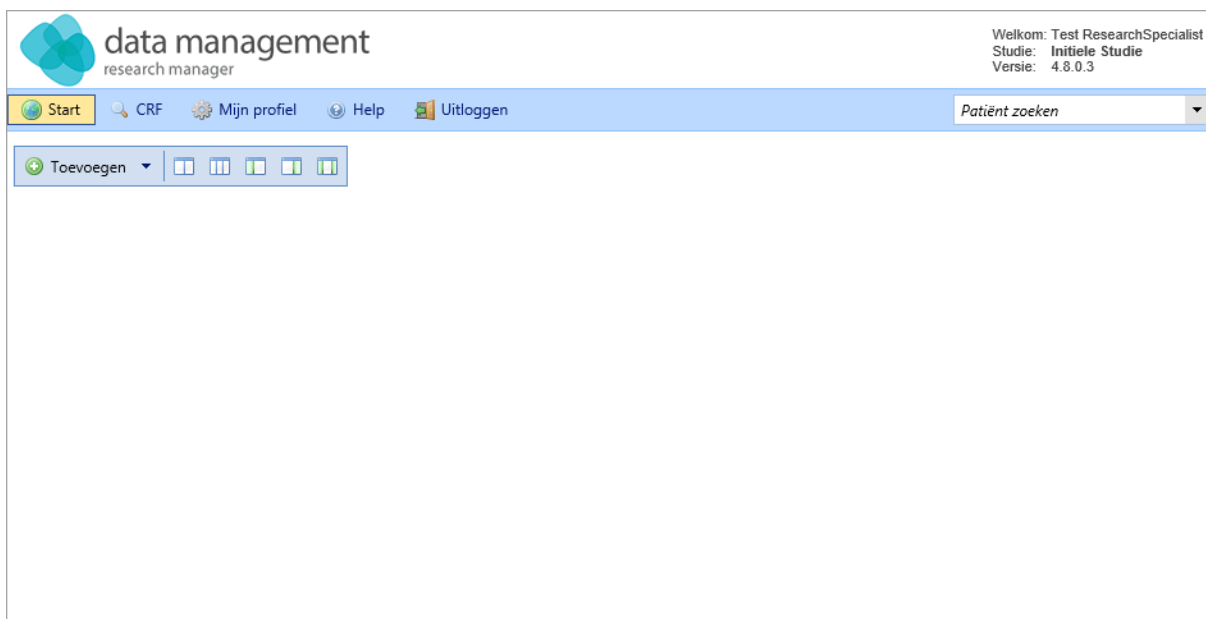
Forgot login name? → Request your login name from the coordinating researcher  
[danielle.bonouvrie@mmc.nl](mailto:danielle.bonouvrie@mmc.nl)  
+3140 888 7372

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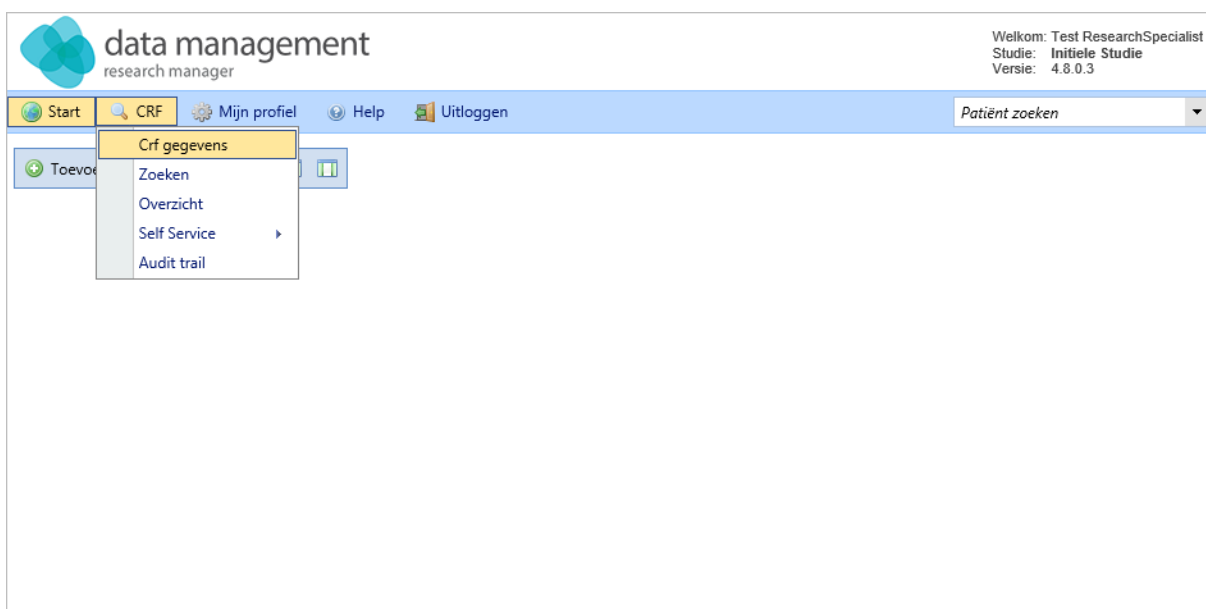


### Step 2 – Register the patient (Informed consent must be signed)

If you are logged in you will be taken to the homepage. At the top right of the screen you will see your user name and the study in which you are currently logged in (click on My Profile to select another study).



Klik in de menubalk op CRF en selecteer CRF Gegevens.



### Step 3 – Add the patient to your own hospital

Open your hospital by clicking on the "plus" in front of the name of the hospital. Then click on Add Patient to create a new file. When creating a patient file, an empty CRF is automatically added.

### Step 4 – Save and open the patient

You will enter the Patient Details screen. The patient number is generated automatically. The notification field may be left blank. Enter the patient's email address and registration date and click on save & open \*.

\* Do not press save & new, because another patient will be added.

**Patiënt details**

Patiëntnummer:  Notificatie:

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Patient Self Service

E-mailadres:  E-mailadres is verplicht bij het gebruik van Self-Service

E-mailadres: (bevestiging)  Typ nogmaals het emailadres ter bevestiging.

Inschrijfdatum:  Het instellen van de inschrijfdatum zal alle uitstaande uitnodigingen bijwerken. Het leegmaken hiervan zal alle activiteiten en uitnodigingen van de Self-Service verwijderen.

Patient number	The patient number is generated automatically.
Email address	The e-mail address is mandatory as we use Patient Self Service for the questionnaires. You can also change the email address here. The e-mail address is only displayed with the first entry, after which it is no longer legible.
Registration date	The patient's registration date must be entered here. This date is used as the start date for the Patient Self Service.
Notification	Here you can enter information regarding the patient, this is readable for users with access to this patient file. You can leave this field empty.
Inclusion	This shows whether the patient meets the inclusion criteria based on the entered data.
Randomisation Option	Here it is shown in which stratification class a patient falls and if randomized, which option is randomly selected by the Research Manager. This is pre-set by the Data Manager. The Data Manager also sets whether a user can view the randomization data.
Randomisation number	The assigned randomization number is shown here.
Added on	Date this file was created and by which user.
Last updated on	Date on which this file was last updated and by which user.
Randomized on	Date this dossier was randomized and by which user.

If you have clicked on save & open, you will see a warning: the patient will be excluded.

### Step 5 – Adding research data

Click on the plus sign on the left of the patient number. You now see all chapters of the CRF. Click on the chapter to open and to see all underlying subchapters.

Now click on a sub-chapter for which you want to enter the research data. You now see the variables/questions from the subchapter. You can now enter the research data in the relevant fields.

Once you have entered the research data, you can perform various actions per subchapter to save the research data:

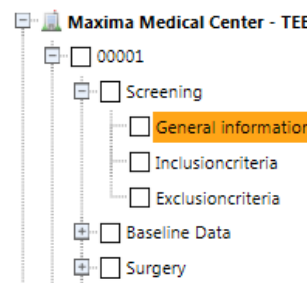
Cancel	All changes to the subchapter will be reversed.
Empty everything	This makes it possible to empty the entered research data in the subchapter in one click
Save as missing	This allows you to save the subchapter even though the research data is not complete. When saving, it is not checked for mandatory fields, the fields that have already been filled in are saved.
Save as incomplete	This saves the research data that has already been entered in the sub-chapter, you can enter the other research data at a later time. In this case, it is allowed to leave required fields empty.
Save as complete	This stores the entered research data in the sub-chapter and indicates that the research data for this sub-chapter has been completed.
Signing	This allows the Research Specialist to indicate that the entered research data has been entered correctly.
Monitor	This allows the Monitor to indicate that the data has been monitored. To be able to monitor, a subchapter must first be signed by the Research Specialist.
To block	This blocks the sub-chapter and the research data can no longer be adjusted.
Unblock	This removes the block on the sub-chapter.

Click on the relevant action. You can now select the next (sub) chapter or add a new patient.

### Step 6 – Randomisation data

To be able to randomize, the inclusion criteria must first be met and the exclusion criteria must not be met.

Open the CRF by clicking on the plus sign in front of the patient number. Then click on the plus sign for the chapter ' Screening'. The subchapters of the Screening are now visible: General information - Inclusion criteria - Exclusion criteria.



Enter these subchapters and fill out the research data (see step 4). After answering the questions, confirm with the Save as completed button. If all conditions are met, the form can be saved with the button: signatures, top right.

### Step 7 – Randomisation

If you have filled out the subchapters under Screening and then open the Patient Details (by clicking on the patient number), you will see that the warning about the patient's exclusion has disappeared.

At Inclusion the following is now stated: The patient will be included in the study. In addition, the Randomize button is activated (if the inclusion criteria are met and none of the exclusion criteria are met).

→ Press the randomize button: the patient will now be randomized\*. The result is shown directly on your screen.

\*Important! - Randomized patients cannot be removed