MoMMs study: Instructions for GPs at INTERVENTION PRACTICES

2nd follow-up study visits (16 month follow-ups)

Both components of the MoMMs software are used when conducting a medication review:-

A) **eCRF (electronic Case Report Form):** stores relevant data obtained from the patient's record
B) **CMR (Comprehensive Medication Review):** Evaluates the above and summarises the review (including recommendations tailored to the patient, plus information about drug interactions, contraindications and adverse events.

1. Pre-review tasks

Shortly before the review appointment, the data in the eCRF should have been updated from the patient's record, (usually by a nurse, HCA or PM) including medications, diagnoses and non-elective admissions. However, before you commence your medication review you should check for very recent changes to:-

- The list of diagnoses – decide whether any new diagnoses may be related to discontinuing a medication or changing the dose and if so, tick the relevant box
- Non-elective hospital admissions - decide whether any non-elective admissions may be related to discontinuing a medication or changing the dose, and if so, tick the relevant box.

Instructions on how to open the eCRF are given in Appendix 1; and information on how to update this information in Appendix 2.

There are also boxes in the eCRF to indicate whether changes in medication, new diagnoses and non-elective admissions may be related to adverse drug events. Instructions are given in Appendix2 and are highlighted. Please note that if all changes to the eCRF cannot be completed at one time, the form can be saved and returned it by scrolling down to the bottom of the form and clicking on **"Save draft and close"**

Many GPs also like to run a "preview" CMR before the actual review appointment with the patient

2. Running a "preview" CMR

If you would like to preview the CMR output before seeing the patient please log into the patient's eCRF as explained in Appendix 1 then follow the instructions in the blue box overleaf. When previewing the CMR it is best to select **"Additional Visit"** when opening the eCRF, so that the preview is not stored as the actual 16 month CMR for the patient(see the blue box below).

Note that a preview CMR does not have updated information on symptoms, falls and frailty, which require patient input, so it can only be considered as a guide.

To preview the CMR (if desired)

- **After the correct Patient Identifier has been selected, as per Appendix 1, click "Additional visit" (under "CHOOSE AN OPERATION").** *Please do not select "2nd Follow-up Visit (16 months)", or any other follow-up visit: these should only be used for the actual CMR.*
- **Scroll down to the bottom of the screen and click "Start Medication Review"**
- **Click "OK" in the dialogue box twice**

  If some of the data is missing, a dialogue box opens to request it:-

  - Enter the information and click "start review". N.B. Two boxes automatically empty themselves to ensure that their contents really have been updated:-
    - *Declaration at the bottom of Symptoms* – please ensure that it is ticked
    - If there have been *no falls, you will need to re-enter "none"* in the drop-down box for Falls in the eCRF.
- You can click "Close" on the dialogue box which showed progress.
- The CMR report opens in a new window – for explanations see the "Interpreting Review Results" sheet. The review can be printed by clicking "print review".
- To close the CMR page, click the red X symbol in the page's top RH corner, then "End Review" on the eCRF page.
- To close the eCRF, please click "End Review" (orange bar).

3. At the Medication Review Appointment

If you haven't already, you will need to get the patient's eCRF back on screen as described in Appendix 1. When opening, at the step "Please check this box to select an available action", **make sure that you select "2nd follow-up visit (16 months)".** This is important, otherwise the review will not be correctly stored in the system.

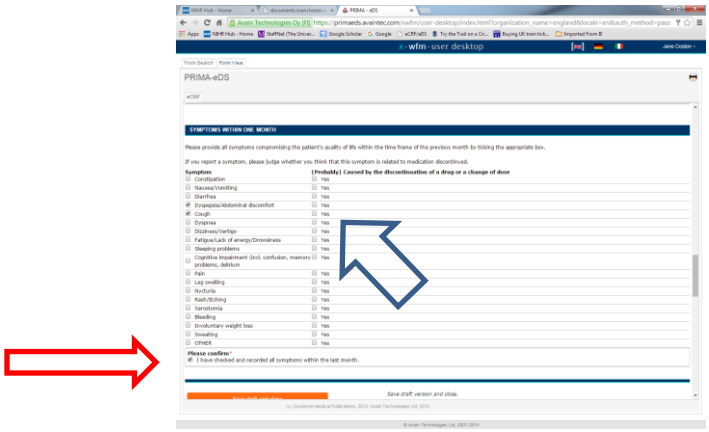
The **list of medications and diagnoses** should already be up-to-date, but we suggest confirming this. If there have been changes, please enter the information following the instructions in Appendix 2.

A few **final data items** that require patient involvement will need to be added to the eCRF before the CMR can be run: -

- symptoms within the last month
- non-elective hospital admissions
- falls
- frailty scale

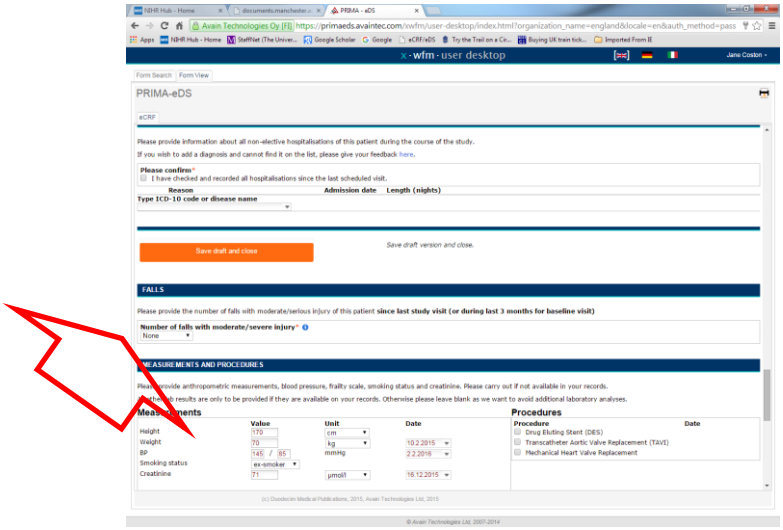
Symptoms within the past month: –

- Go through the list with the patient and tick the left-hand boxes for any symptoms present.
- If you think that the symptom was probably caused by the discontinuation of a drug or change of dose, please tick the relevant box in the right-hand column (see blue arrow).
- Tick the overall confirmation box at the bottom of the list (see red arrow).

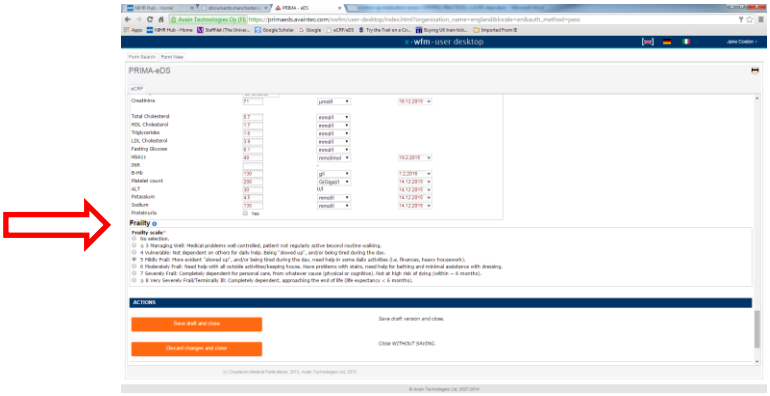


<u>Non-Elective Hospital admissions</u> –These should have already been updated from the patient record, but we suggest checking with the patient themselves if there have been any not recorded. If there have, please enter the information following the instructions on p3.

<u>Falls since the last MoMMs study visit</u> – please ask the patient about any falls they have experienced since their last study-related visit and enter the total in the drop-down box.



<u>Frailty scale</u> – please consider the existing rating of the patient's frailty and revise if necessary, by selecting one of the options given.



You are now ready to run the medication review.

4. To run the medication review

- Scroll down to the bottom of the screen and click "Start Medication Review"
- Click "OK" in the two dialogue boxes.

  If some of the data is missing, a dialogue box opens to request it:-

  - Enter the information and click "start review". N.B. Two boxes automatically empty themselves to ensure that their contents really have been updated:-

    - *Declaration at the bottom of Symptoms* – please ensure that it is ticked
    - If there have been *no falls, you will need to re-enter "none"* into drop-down box for Falls in the eCRF.

- You can click "Close" on the dialogue box which showed progress.
- The CMR report opens in a new window – for explanations see "Interpreting Review Results" sheet. The review can be printed by clicking "print review".
- *Please do not close down the eCRF window, as you will need this for the post-review tasks (instructions below).*
- Consider the actions suggested and discuss with the patient to decide together about changes to the medications.

5. Post-review tasks

- Enter any medication changes into the eCRF screen which should still be open for this patient, following the instructions in section. Because you clicked a follow-up visit rather the "update patient data", the eCRF will recognise that these medication changes were made as part of a review.
- Update diagnoses if necessary
- If the patient has reported Adverse Drug Events which are also Serious Adverse Events, please complete the form "Report of a Serious Adverse Event" in the Momms Site File. More detail is given in the sheet "Recording and Reporting Adverse Drug Events and Serious Adverse Events in the Momms study".
- After making any changes, save the form by clicking on the button **"End Review"** at the end of the form in order for the software to recognise that the review has been completed.

This will complete the study visit so that the review shows as completed on the eCRF.

- To close the Review page, click the red X symbol in the page's top RH corner.

A NOTE ABOUT SERIOUS ADVERSE EVENTS (SAEs)

The following are Serious Adverse Events whatever the circumstances which must be reported to the Momms study office at University of Manchester:-

- Any death or other life-threatening event
- Any hospital admission (or prolongation of existing admission), whether elective or not
- Development of a significant disability or incapacity
- Anything else with serious consequences

Please use the form "Report of a Serious Adverse Event" in the Momms site file. Further details are on the document "Recording and Reporting Adverse Drug Events for Momms" (in Momms site file).

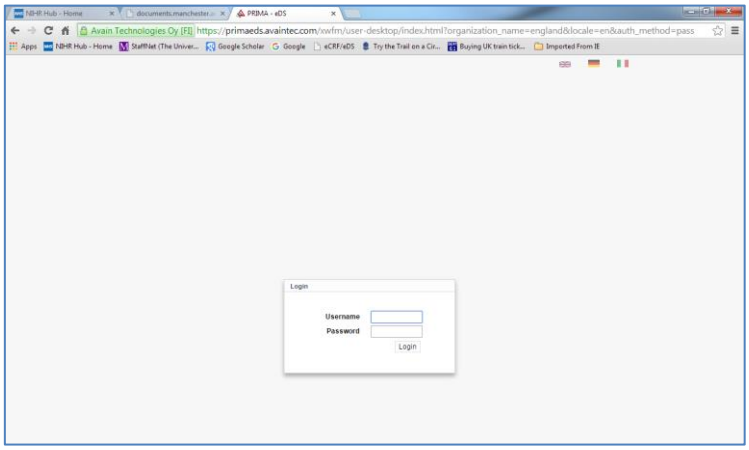
Thank you!

APPENDIX 1: Logging in and opening a patient's eCRF

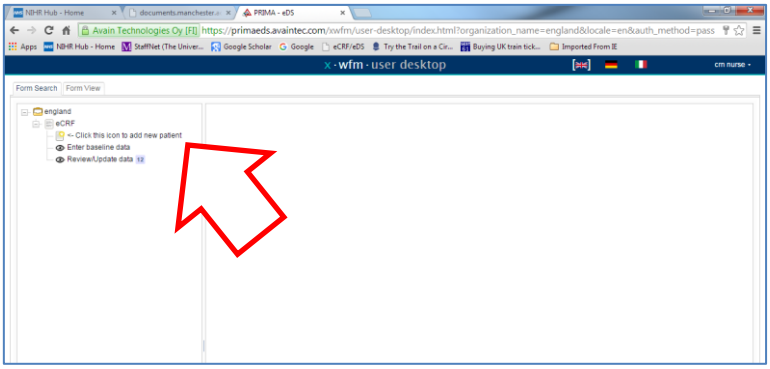
To login and open a patient's eCRF, please open the link below in whichever browser worked best at baseline (Google chrome is fastest, but not always available on NHS computers.)

https://primaeds.avaintec.com/xwfm/user-desktop/index.html?organization_name=england&locale=en&auth_method=pass

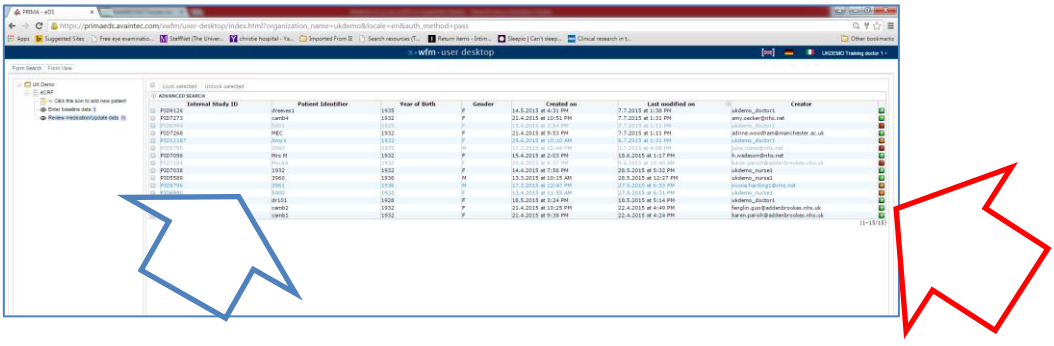
- Please enter the same username and password as at baseline.



- On the next screen (below), click "Review Medication/update data"

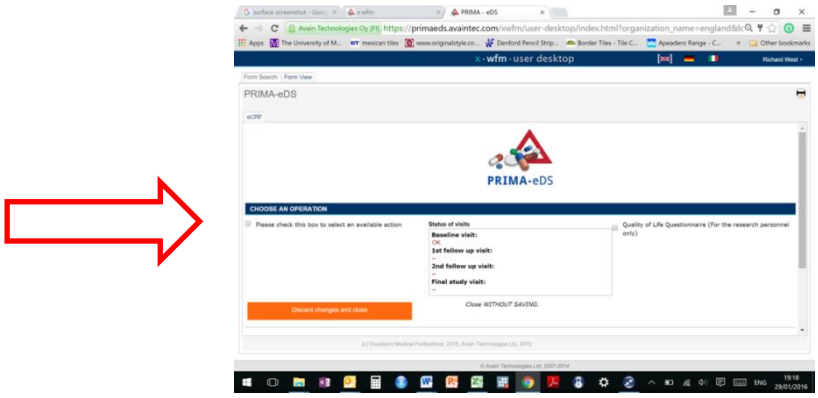


- Find the patient's number (blue arrow below) and click on the relevant patient (if necessary this can be found in the Patient Recruitment Log (in the Momms Site File).



N.B. If the 'traffic-light' for this patient at the right hand side of the screen above is not green, please 'unlock' by clicking the "light" (red arrow above) which turns green, allowing you to open the eCRF.

- Click “Please check this box to select an available action”….



… and options appear below the tick box.

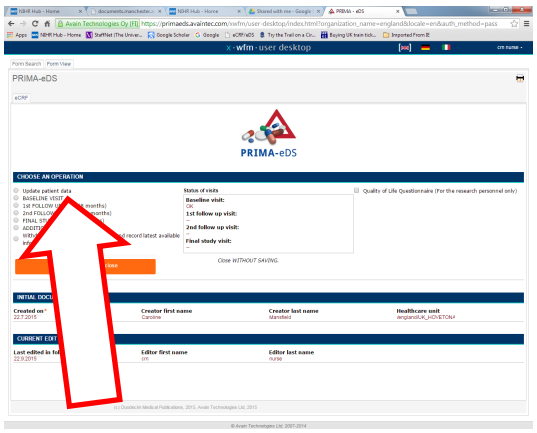
If you will be seeing the patient for their study visit straight-away after checking/updating the patient’s eCRF (ie in the same session)

- click the option “2nd follow-up visit (16 months)

OR

If you will be seeing the patient for their study visit on a different occasion.

- click the option “Update patient data”



The patient’s eCRF will appear underneath – scroll down the screen to view it.

APPENDIX 2:
Instructions for updating medications, diagnoses and hospital admissions in the eCRF

Medications

i) To add a new medication - Scroll to the bottom of the list of medications and in the field labelled “Type ATC code or generic name” type in the generic name of the drug. New fields for appear for:-

- Frequency
- Total dose - for PRN meds, click “not applicable” for total dose; for others click “enter” to obtain a field to enter the total dose.
- Dose
- Route
- start and end dates
  - *start dates of longstanding medications do not need to be precise if an exact date is not available*
  - *Current meds will not have an end date*

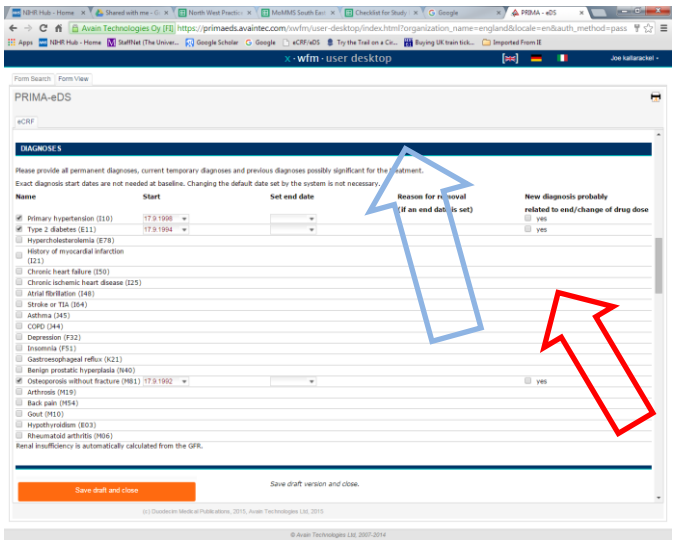
ii) <u>To discontinue a medication</u> - enter the End Date from the patient record. Another drop-down box appears for "Reason for Discontinuation", with options to select.

iii) <u>To change a dose</u> - discontinue the drug as above and re-enter as a new medication with the start date of the new dose.

If a drug has been discontinued or the dose reduced DUE TO AN ADVERSE DRUG EVENT (one of the drop-down reasons for discontinuation), please tick relevant symptoms in the section "Symptoms within one month". If the event was serious (death or anything life-threatening, admission or development of a significant disability) please complete a Serious Adverse Event Report Form.

Diagnoses

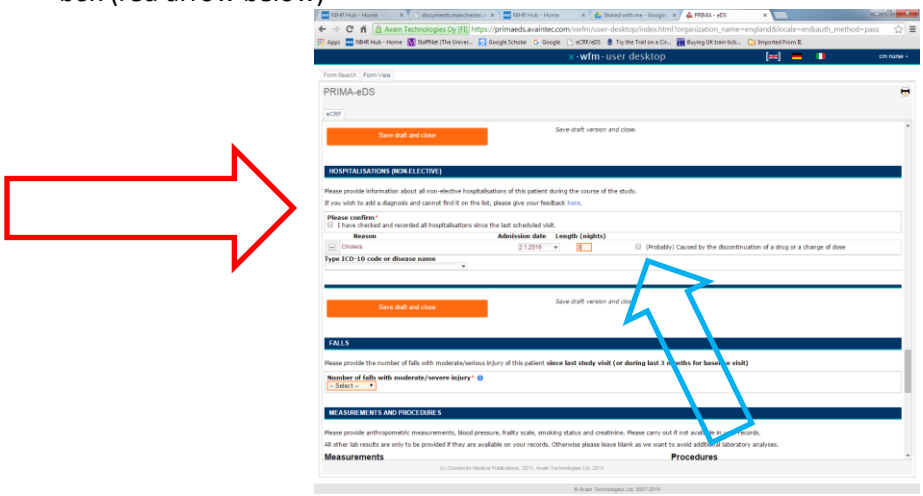
You need to consider whether any new diagnoses are related to ending a medication or change of dose, and if appropriate to tick the box labelled "yes" in the column "New diagnosis probably related to end/change of drug dose".



Non-elective hospital admissions

For any new non-elective hospital admissions, please complete by entering the reason for hospitalisation in the field "Type ICD-10 code or disease name", and complete the boxes which appear for Admission date and Length (nights).

- *For each admission* please consider whether the cause could have been the discontinuation of a drug or a change of dose and if applicable, tick the box "(Probably) Caused by the discontinuation of a drug or a change of dose" (blue arrow below)
- *Whether or not any non-elective admissions have been added*, please tick the Confirmation box (red arrow below)



PLEASE NOTE THAT ANY ADMISSION (whether non-elective or elective) REQUIRES COMPLETION OF A SERIOUS ADVERSE EVENT REPORT FORM. (More details are in the document "Recording and reporting Adverse Drug Events and Serious Adverse Events for Momms", or contact the study office at Manchester University.)

After completing all the changes, please click **"Save draft and close"**.

If you are updating information in the eCRF

- click the option "Update patient data" - at the top of the list in the screenshot below

OR

If you want to do a preview

- click the option "Additional visit" - at the bottom of the list

OR

If you are now ready to do the CMR review

- click the option "2nd follow-up visit (16 months) – 4th item in the list

If you are running the CMR straightaway, please return to section 3 of this document.