

MoMMs study: Instructions for GPs at CONTROL PRACTICES for 2nd follow-up study visits
(16 month follow-ups)

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 Appendix 2 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**”

2. At the review appointment

If you haven't already, you will need to open the patient's eCRF (see 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 data 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:

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).

The screenshot shows a web browser displaying the PRIMA-eDS eCRF form. The section is titled "SYMPTOMS WITHIN ONE MONTH". Below the title, there are instructions: "Please provide all symptoms comprising the patient's quality of life within the time frame of the previous month by ticking the appropriate box. If you report a symptom, please judge whether you think that this symptom is related to medication discontinued." The form contains a table with two columns: "Symptoms" and "(Probably) Caused by the discontinuation of a drug or a change of dose". Each symptom has two checkboxes: "Yes" and "Probably caused by...". A blue arrow points to the "Probably caused by..." column. At the bottom of the form, there is a section titled "Please confirm" with a checkbox "I have checked and recorded all symptoms within the last month." A red arrow points to this checkbox.

Non-Elective Hospital admissions – 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 in Appendix 2..

Falls since the last MoMMs study visit – 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.

The screenshot shows the PRIMA-eDS eCRF form. The 'FALLS' section is highlighted, and a red arrow points to the 'Number of falls with moderate/severe injury' dropdown menu, which is currently set to 'None'. Below this, the 'MEASUREMENTS AND PROCEDURES' section is visible, including a table for 'Measurements' with columns for Value, Unit, and Date.

Measurements	Value	Unit	Date
Height	175	cm	19.2.2015
Weight	70	kg	19.2.2015
BP	145 / 85	mmHg	19.2.2015
Smoking status	ex-smoker		
Creatinine	71	µmol/l	18.12.2015

Frailty scale – please consider the existing rating of the patient’s frailty and revise if necessary, by selecting one of the options given.

The screenshot shows the PRIMA-eDS eCRF form. The 'Frailty scale' section is highlighted, and a red arrow points to the 'Frailty scale' dropdown menu, which is currently set to '1'. Below this, the 'Frailty scale' section is visible, including a table for 'Frailty scale' with columns for Value, Unit, and Date.

Frailty scale	Value	Unit	Date
Frailty scale	1		18.12.2015

Medication review

Using your clinical judgement, decide on any changes to the patient’s medications you wish to make and issue a prescription if necessary.

3. Post-review tasks

- Enter any medication changes into the eCRF screen which should still be open for this patient, following the instructions in Appendix 2. Because you clicked a follow-up visit rather than the “update patient data”, the eCRF will recognise that these medication changes were made as part of a review.
- Update diagnoses if necessary (instructions in appendix 2)
- 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 the visit and save**” at the end of the form.

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).

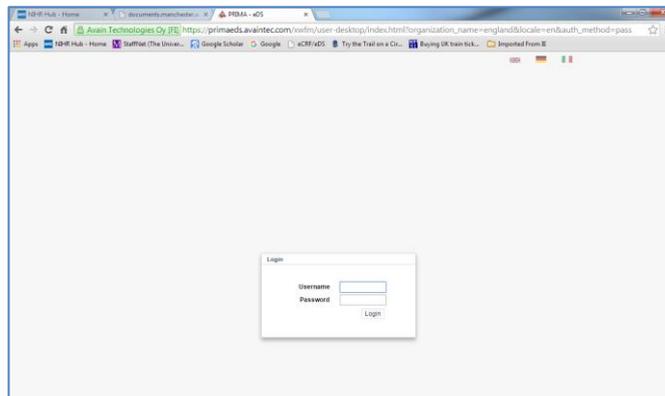
Thank you!

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

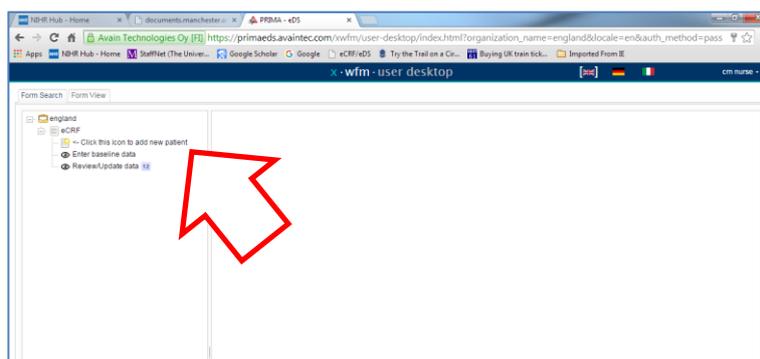
To login and open a patient’s eCRF, please open the link below in whichever browser worked best at baseline (Google chrome is fastest, but not always available on NHS computers.)

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).

Internal Study ID	Patient Identifier	Year of Birth	Gender	Created on	Last modified on	Creator
PID2126	James1	1938	F	14.8.2015 at 4:31 PM	7.7.2015 at 1:38 PM	ukdemo_doctor1
PID2723	emma1	1932	F	21.4.2015 at 10:53 PM	7.7.2015 at 1:31 PM	amy.acker@nhs.net
PID2724	emma1	1932	F	17.7.2015 at 10:46 AM	7.7.2015 at 1:11 PM	ukdemo_doctor1
PID2726	JMC	1932	F	21.4.2015 at 9:53 PM	7.7.2015 at 1:11 PM	adrian.vandenberg@manchester.ac.uk
PID21187	Jenny's	1932	F	29.8.2015 at 10:10 AM	6.7.2015 at 1:31 PM	ukdemo_doctor1
PID2725	emma1	1932	F	17.7.2015 at 10:46 AM	7.7.2015 at 10:46 AM	ukdemo_doctor1
PID2756	Mrs M	1932	F	15.4.2015 at 2:03 PM	18.6.2015 at 1:17 PM	n.wade@nhs.net
PID2727	emma1	1932	F	29.8.2015 at 10:10 AM	8.2.2015 at 10:46 AM	penelope.gunn@addenbrookes.nhs.uk
PID2728	emma1	1932	F	14.4.2015 at 7:56 PM	28.5.2015 at 5:32 PM	ukdemo_nurse1
PID2589	emma1	1936	M	13.3.2015 at 10:10 AM	28.5.2015 at 12:27 PM	ukdemo_nurse1
PID2729	emma1	1936	M	17.7.2015 at 10:46 AM	27.5.2015 at 6:33 PM	ukdemo_nurse1
PID2730	emma1	1932	F	13.4.2015 at 11:25 AM	27.5.2015 at 6:31 PM	ukdemo_nurse1
PID2826	emma1	1936	F	18.5.2015 at 3:24 PM	18.5.2015 at 5:14 PM	ukdemo_doctor1
PID2731	emma1	1932	F	21.4.2015 at 10:25 PM	22.4.2015 at 4:49 PM	penelope.gunn@addenbrookes.nhs.uk
PID2732	emma1	1932	F	21.4.2015 at 9:38 PM	22.4.2015 at 4:24 PM	penelope.gunn@addenbrookes.nhs.uk

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"

PRIMA-eDS

eCRF

CHOOSE AN OPERATION

Please check this box to select an available action

Status of visits

Baseline visit:
OK

1st follow up visit:
--

2nd follow up visit:
--

Final study visit:
--

Quality of Life Questionnaire (For the research personnel only)

Discard changes and close

Close WITHOUT SAVING.

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... 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) **To discontinue a medication** - enter the End Date from the patient record. Another drop-down box appears for “Reason for Discontinuation”, with options to select.
- iii) **To change a dose** - 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”.

PRIMA-eDS
eCRF

DIAGNOSES

Please provide all permanent diagnoses, current temporary diagnoses and previous diagnoses possibly significant for the treatment. Exact diagnosis start dates are not needed at baseline. Changing the default date set by the system is not necessary.

Name	Start	Set end date	Reason for removal (if end date is set)	New diagnosis probably related to end/change of drug dose
<input checked="" type="checkbox"/> Primary hypertension (I10)	17.9.1998			<input type="checkbox"/> yes
<input checked="" type="checkbox"/> Type 2 diabetes (E11)	17.9.1994			<input type="checkbox"/> yes
<input type="checkbox"/> Hypercholesterolemia (E78)				<input type="checkbox"/> yes
<input type="checkbox"/> History of myocardial infarction (I21)				<input type="checkbox"/> yes
<input type="checkbox"/> Chronic heart failure (I50)				<input type="checkbox"/> yes
<input type="checkbox"/> Chronic ischaemic heart disease (I25)				<input type="checkbox"/> yes
<input type="checkbox"/> Atrial fibrillation (I48)				<input type="checkbox"/> yes
<input type="checkbox"/> Stroke or TIA (I64)				<input type="checkbox"/> yes
<input type="checkbox"/> Asthma (J45)				<input type="checkbox"/> yes
<input type="checkbox"/> COPD (J44)				<input type="checkbox"/> yes
<input type="checkbox"/> Depression (F32)				<input type="checkbox"/> yes
<input type="checkbox"/> Insomnia (F51)				<input type="checkbox"/> yes
<input type="checkbox"/> Gastroesophageal reflux (K21)				<input type="checkbox"/> yes
<input type="checkbox"/> Benign prostatic hyperplasia (N40)				<input type="checkbox"/> yes
<input checked="" type="checkbox"/> Osteoporosis without fracture (M81)	17.9.1992			<input type="checkbox"/> yes
<input type="checkbox"/> Arthritis (M19)				<input type="checkbox"/> yes
<input type="checkbox"/> Back pain (M54)				<input type="checkbox"/> yes
<input type="checkbox"/> Gout (M10)				<input type="checkbox"/> yes
<input type="checkbox"/> Hypothyroidism (E03)				<input type="checkbox"/> yes
<input type="checkbox"/> Rheumatoid arthritis (M06)				<input type="checkbox"/> yes

Save draft and close. Save draft version and close.

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)

PRIMA-eDS
eCRF

HOSPITALISATIONS (NON ELECTIVE)

Please provide information about all non-elective hospitalisations of this patient during the course of the study. If you wish to add a diagnosis and cannot find it on the list, please give your feedback [here](#).

Please confirm I have checked and recorded all hospitalisations since the last scheduled visit.

Reason	Admission date	Length (nights)	<input type="checkbox"/> (Probably) Caused by the discontinuation of a drug or a change of dose
Reason	2.1.2016	4	<input type="checkbox"/>

Type ICD-10 code or disease name

Save draft and close. Save draft version and close.

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”.