# MoMMs study: Instructions for GPs at CONTROL PRACTICES for 2<sup>nd</sup> 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-:-

- <u>The list of diagnoses</u> decide whether any new diagnoses may be related to discontinuing a medication or changing the dose and if so, tick the relevant box
- <u>Non-elective hospital admissions</u> 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 nonelective 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"** 

## 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** "2<sup>nd</sup> 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).

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Please provide all symptoms compromising	g 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 who	rether you think that this symptom is related to medication discontinued.	
Symptom	(Probably) Caused by the discontinuation of a drug or a change of dose	
Constipation	E Yes	
Nausea/Vomiting	E 165	
Diambea	E Yes	
M Dyspepsia/Abdominal discomfort	1 Tes	
if Cough	8 765	
Dyspnea	E Yes	
Dizzinese/Vertigo	E vis	
Fatigue/Lack of energy/Drowsiness	E Yes	
Steeping problems	1 Yes	
Cognitive impairment (incl. confusion, in problems, delirium)	mamory 🗄 Tas	
E Pain	E Yes	
Leg swelling	1 m	
Nycturia	E NS	
E Rash/Itching	E NS	
Xerostomia	E Yes	
Bleeding	745	
Involuntary weight loss	E Yes	
Sweating	C Yes	
C OTHER	745	
Please confirm		

<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 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.

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**<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.

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### **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 Appendix2. 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 (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

• 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/userdesktop/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"

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• 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).

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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) <u>To add a new medication</u> 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 <u>for PRN meds</u>, click "not applicable" for total dose; <u>for others</u> click "enter" to obtain a field to enter the total dose.
  - o Dose
  - o Route
  - $\circ \quad \text{start and end dates} \quad$ 
    - 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".

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·lease provide all permanent diagno	ses, current temporary diagnoses	and previous diagnoses possibly signifi	cant for the treatment.	
Exact diagnosis start dates are not i	seeded at baseline. Changing the	default date set by the system is not n	ecessary.	
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Hypercholesterolemia (E78)				iii yes
History of myocardial infarction				
(121)				
Chronic heart failure (150)				
Chronic ischemic heart disease I	125)			
Atrial fibrillation ([48)				
Stroke or TIA (I64)				
Asthma (J45)				
COPD (344)				
Depression (F32)				
Insomnia (F51)				
Gastroesophageal reflux (K21)				
Benign prostatic hyperplasia (N4)	0)			
Osteoporosis without fracture (	181) 17.9.1992 *	*		🗆 yes
Arthrosis (M19)				
Back pain (M54)				
Gout (M10)				· · · · · · · · · · · · · · · · · · ·
Hypothyroidism (E0.5)				
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### 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)

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	MEASUREMENTS AND PROCEDURES				
	Please provide anthropometric measurements, blood	pressure, frailty scale, smoking stat	us and creatinine. Please carry out if not available in	your records.	
	All other lab results are only to be provided if they are Measurements	e available on your records. Otherwi	se please leave blank as we want to avoid additional	laboratory analyses.	
	(c) Duodecim I	Medical Publications, 2015, Avain Technolog	Procedures ins Ltd, 2015		

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".