

	<b>Record Form</b> <b>RF1 TA013</b> <b>Version 1.0</b>
<b>Title:</b> TRIAL AMENDMENT LOG	
<b>Reference SOP:</b> TA013	

Trial Title: The clinical and cost-effectiveness of temporarily quadrupling the dose of inhaled steroid to prevent asthma exacerbations; a pragmatic, randomised, normal care-controlled, clinical trial

Sponsor's Protocol Number: 13027

Eudract Number: N/A  
(as applicable)

REC reference: 13/NW/0184

Trial Amendment Code MA/xx/yy or SA/xx/yy	Date	Summary of Changes	Documents changed and new version numbers (list)	Approvals: codes and dates		Date Implemented
				REC	MHRA	
MA/01/13	01May2013	Removal of 'Emergency contact number for trial related issues' on cover of diary cards	<u>Original versions:</u> Diary Final Version 1.0 Inhaled steroid Diary Final Version 1.0 Combination Inhaler <u>New versions:</u> Diary Final Version 1.1 Inhaled steroid Diary Final Version 1.1 Combination Inhaler	30-May-2013	N/A	01May2013
SA/01/13	05Aug2013	Minor wording added to the protocol to clarify that potential participants can be recruited from clinic appointments in primary care.	<u>Original version:</u> Protocol 1.0 Dated 21-Feb-2013 <u>New version:</u> Protocol 2.0 Dated 05-Aug-2013	25-Sep-2013	N/A	25-Sep-2013

Originated by: A. C. Shone  
 Authorised by: P. Cartledge

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SA/01/13	05Aug2013	Addition of the following documents: <ul style="list-style-type: none"> <li>primary care patient invitation letter,</li> <li>patient reminder letter</li> </ul>	<u>Previous version:</u> Primary Care Patient Invitation Letter Version 2.0 Dated 19-Sep-2013 <u>Original version:</u> Patient Reminder Letter Version 1.0 Dated 05-Aug-2013	25-Sep-2013	N/A	25-Sep-2013
SA/02/13	23Oct2013	<u>Table 3 – How to achieve a quadrupling dose for participants on a combination inhaler (Pg 19)</u>  Clarification of the dose strength for Symbicort,  Clarification of inhaler type  The addition of a new dose of Fostair & QVAR  Clarification of a typographic error	<u>Previous version:</u> Protocol 2.0 Dated 05-Aug-2013 <u>New version:</u> Protocol 3.0 Dated 23-Oct-2013		N/A	

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SA/02/13	23Oct2013	Addition of a Short Patient Information Sheet	<b>Original version:</b> Patient Information Sheet Version 1, Dated 23Oct2013		N/A	
MA/01/13	05Dec2013	Removal of version and date from the title of the participant information sheet	<b>Original version:</b> Short Patient Information Sheet Version 1.0, Dated 04Nov2013	05Dec2013	N/A	05Dec2013
SA_01_14	03Feb2014	Clarification of SAE reporting timeframe	<b>Previous version:</b> Protocol 3.0 Dated 23-Oct-2013 <b>New version:</b> Protocol 4.0 Dated 03-Feb-2014	21Feb2014	N/A	21Feb2014
SA_01_14	03Feb2014	Addition of the following documents: <ul style="list-style-type: none"><li>Summary Information Leaflet (Mailshot &amp; Patient Waiting areas)</li></ul>	<b>Original version:</b> Version 1, Dated 03Feb2014			

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SA_01_14	03Feb2014	Revised primary care patient invitation letter	<b>Previous version:</b> Primary Care Patient Invitation Letter Version 2.0 Dated 19-Sep-2013 <b>New version:</b> Primary Care Patient Invitation Letter Version 3.0 Dated 03-Feb-2014	21Feb2014	N/A	21Feb2014
SA_01_14	03Feb2014	Poster / Flyer wording	<b>Original version:</b> Advert Version 1.0 Dated 21-Feb-2013 <b>New version:</b> Advert version 2.0 Dated 03-Feb-2014	21Feb2014	N/A	21Feb2014
MA_01_14	26Aug2014	Addition of wording to specify patients will be seen at their own GP practice (For use in East Midlands only)	<b>Previous version:</b> Primary Care Patient Invitation Letter Version 3.0 Dated 03-Feb-2014 <b>New version:</b> Primary Care Patient Invitation Letter Version 3.1 Dated 26-Aug-2014	26Aug2014	N/A	26Aug2014
SA_02_14	23Oct2014	<b>Protocol:</b> Use of the current approved advert to be placed on public notice boards, universities, and on websites and social media. Use of DocMail in GP practices Telephone consultation at 6 & 12 months in patient has not exacerbated	<b>Previous version:</b> Protocol 4.0 Dated 23-Oct-2013 <b>New version:</b> Protocol 5.0 Dated 03-Feb-2014	04Nov2014	N/A	04Nov2014

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SA_02_14	23Oct2014	<b>Participant Information Sheet:</b> Inclusion of the option for sites to conduct a telephone consultation at 6 & 12 months if the participant has not exacerbated during this time and send out questionnaires by post	<b>Original version:</b> PIS 1.0 Dated 03-Apr-2013 <b>New version:</b> PIS 2.0 Dated 14-Oct-2014	04Nov2014	N/A	04Nov2014
SA_02_14	23Oct2014	<b>ICF:</b> Reference to updated PIS Version 2 dated 14Oct14	<b>Original version:</b> ICF 1.0 Dated 21-Feb-2013 <b>New version:</b> PIS 2.0 Dated 14-Oct-2014	04Nov2014	N/A	04Nov2014

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SA01_15	27Feb2015	<b>Short PIS</b> Inclusion of the option for sites to conduct a telephone consultation at 6 & 12 months if the participant has not exacerbated during this time and send out questionnaires by post	<b>Original version:</b> ICF 1.0 Dated 04-Nov-2013 <b>New version:</b> PIS 2.0 Dated 18-Feb-2015	02Mar2015	N/A	02Mar2015
SA01_15	27Feb2015	Addition of the following documents:  FAST Patient Follow-up Visit Letter	<b>Original version:</b> Version 1.0, Dated 18Feb2015	02Mar2015	N/A	02Mar2015

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(name)  
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MA01_15	07May2015	Change of sponsor representative name from Paul Cartledge to Angela Shone	N/A	07May2015	N/A	07May2015
MA02_15	02Nov2015	Addition of n/a option in the drop down box for Service Use Questionnaire Part 4: Question 5b: How long does the return journey usually take? & Question 5e: How long does the return journey usually take?  Changes approved by Steve Parrott (Health Economist)	<b>Original version:</b> Protocol 1.0 Dated 21-Feb-2013 <b>New version:</b> Protocol 1.1 Dated 02-Nov-2015	N/A	N/A	02-Nov-2015

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 Authorised by: P. Cartledge (name)  
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SA02_15	13Nov2015	Additional wording to the sample size justification section of the protocol, reduction of sample size from 2,300 to between 1774 and 1850, removal of paragraph and references pertaining to electronic dose counters (Smart-inhalers) and other minor typographic clarifications	<b>Previous version:</b> Protocol 5.0 Dated 03-Feb-2014 <b>New version:</b> Protocol 6.0 Dated 11-Nov-2015	08-Dec-2015	N/A	14-Dec-2015
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