

CLINICAL TRIAL OF AN INVESTIGATIONAL MEDICINAL PRODUCT (CTIMP)

ANNUAL PROGRESS REPORT TO MAIN RESEARCH ETHICS COMMITTEE

To be completed in typescript and submitted by the Chief Investigator. Please send this report only to the main REC. For questions with Yes/No options please indicate answer in bold type.

1. Details of Chief Investigator

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2. Details of study

Full title of study:	UNITED KINGDOM CHILDHOOD ACUTE LYMPHOBLASTIC LEUKAEMIA RANDOMISED TRIAL 2003
Name of main REC:	Scottish MREC
REC reference number:	MREC/02/10/52
Date of favourable ethical opinion:	25/02/2003
Sponsor:	University of Sheffield
EudraCT Number:	2007-004013-34

3. Commencement and termination dates

Has the study started in the UK?	Yes
If yes, what was the actual start date in the UK?	October 2003
If no, what are the reasons for the study not commencing in the UK?	N/A
What is the expected start date?	N/A

Has the study finished? <i>If yes, complete and submit EudraCT "Declaration of end of trial" form at Annex 3 to ENTR/CT1, available at: https://eudract.emea.europa.eu/document.html</i>	No
If no, what is the expected completion date? <i>If you expect the study to overrun the planned completion date this should be notified to the main REC for information.</i>	The trial has been extended one year to August 2010. (The low-risk randomisation closed on 19/8/2009 and the Quality of Life study closed 15/10/2009)
If you do not expect the study to be completed, give reason(s)	

4. Site information

Number of UK research sites proposed in original application:	25
Number of UK research sites recruited to date:	77
Do you plan to increase the total number of UK sites proposed for the study? <i>The addition of any new sites not listed in the original applications to the REC and the MHRA should be notified to both bodies by submitting a substantial amendment using the form at Annex 2 to ENTR/CT1, available at https://eudract.emea.europa.eu/document.html</i>	Yes

5. Recruitment of participants

* Number of participants recruited:	<i>Proposed in original application: 2200 Actual number recruited to date: 2512</i>
* Number of participants completing trial:	<i>Actual number completed to date: 0</i>
* Number of withdrawals from trial to date due to:	
(a) withdrawal of consent	6
(b) loss to follow-up	13
(c) death (where not the primary outcome)	139
Total study withdrawals:	19
*Number of treatment failures to date (prior to reaching primary outcome) due to:	
(a) adverse events	77
(b) lack of efficacy	Not reported as part of primary outcome measure
Total treatment failures:	

* In the case of international trials, please provide separate figures for UK and non-UK participants.

Have there been any serious difficulties in recruiting participants?	Yes
If yes, give details:	Accrual to high risk randomisation remains lower than anticipated, but data from elsewhere suggests the risk may be higher than estimated, and hence statistical power for given patient number will be higher.
Do you plan to increase the planned recruitment of participants into the study? <i>Any increase in planned recruitment should be notified to the main REC as a substantial amendment for ethical review.</i>	No

6. Safety reports

Have there been any Suspected Unexpected Serious Adverse Reactions (SUSARs) in this trial in the UK?	No
Have these SUSARs been notified to the Committee within 7/15 days under Article 17 of EU Directive? <i>If no, please arrange urgently and give reasons for late notification.</i>	N/A
What is the reporting date for periodic safety reports to the main REC during this trial? <i>This is the date of first authorisation of the trial in any EU member state or, if the sponsor is the Marketing Authorisation Holder, the International Birth Date for the product.</i>	16 th August
Has a 6 monthly safety report been submitted? <i>Applies only to commercial sponsors undertaking this trial or other trials of the IMP outside the UK.</i>	Not applicable
Has the Annual Safety Report been submitted?	Yes
When is the next ASR due?	August 2010

7. Amendments

Have any substantial amendments been made to the trial during the year?	Yes
If yes, please give the date and amendment number for each substantial amendment made.	Version 6, June 2008 Version 7, August 2009

8. Serious breaches of the protocol or Good Clinical Practice

Have any serious breaches of the protocol or GCP occurred in relation to this trial during the year? <i>Under the Clinical Trials Regulations, all serious breaches must be notified to the MHRA GCP inspectors within 7 days of the matter coming to the sponsor's attention.</i>	No
If yes, please give the date of each notification to the MHRA. <i>Please provide the REC with a copy of each notification for information (unless previously notified).</i>	N/A

9. Other issues

Are there any other developments in the trial that you wish to report to the Committee?	No
Are there any ethical issues on which further advice is required? <i>If yes to either, please attach separate statement with details.</i>	No

10. Declaration

Signature of Chief Investigator:	
Print name:	Professor Ajay Vora
Date of submission:	