

# Central Office for Research Ethics Committees (COREC)

## 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:	N/A

#### 3. Commencement and termination dates

Has the study started in the UK?	<b>Yes</b>
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?	<b>No</b> <i>If yes, complete and submit "Declaration of end of trial" form at Annex 3 to ENTR/CT1, available at: <a href="http://eudract.emea.eu.int/document.html#guidance">http://eudract.emea.eu.int/document.html#guidance</a></i>
If no, what is the expected completion date?	September 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:	64
Do you plan to increase the total number of UK sites proposed for the trial?  <i>All sites must be approved by the main REC as part of the favourable opinion.</i>	<b>Yes</b>
Has the Site Specific Information Form (SSIF)* been submitted to the LREC for each local Principal Investigator?  <i>*or Part C or Annex D of the former MREC application form if submitted prior to 1 March 2004</i>	<b>Yes</b>

#### 5. Recruitment of participants

*Number of participants recruited:	<i>Proposed in original application: 2200 Actual number recruited to date: 860 Recruited/expected 800</i>
*Number of participants completing trial:	Nil expected at this point in the trial
*Number of withdrawals due to: (a) lack of efficacy (b) adverse events (c) self-withdrawal (d) non-compliance Total number of withdrawals:	0 0 1 (withdrawal of consent) + 6 (moved or emigrated) 0 7
Have there been any serious difficulties in recruiting participants?	<b>Yes</b>
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 trial? <i>Any increase in planned recruitment should be notified to the main REC as a substantial amendment for ethical review.</i>	<b>No</b>

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

## 6. Safety reports

Have there been any Suspected Unexpected Serious Adverse Reactions (SUSARs) in this trial in the UK?	<b>No</b>
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>	<i>Not applicable</i>
On what date was the first clinical trial authorisation given for a trial of the IMP in any EU member state?  <i>This date determines the dates on which periodic safety reports should be sent to the main REC during the trial.</i>	<i>DDXs 16/08/2002 rolled over to CTA 11/03/2004.</i> <b>DDX No: MF 8000/12172</b> <b>MF 8000/12713</b> <b>CTA NO: 21304/0002/001</b>
Have all quarterly safety reports been submitted?  <i>Applies only to sponsors undertaking this trial or other trials of the IMP outside the UK.</i>	<i>Not applicable</i>
Has the Annual Safety Report been submitted?	<i>Attached</i>
When is the next ASR due?	February 2008

## 7. Amendments

Have any substantial amendments been made to the trial during the year?	<b>Yes</b>
If yes, please give the date and amendment number for each substantial amendment made.	<i>February 2006 Version 4 Released May 2006</i>

## 8. Other issues

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

Signature of Chief Investigator:	
Print name:	
Date:	