

CLL Autograft Trial – Quality of Life Study **Standard Procedure in the Local Centres.**

1) Supply of Baseline Questionnaires.

The Baseline questionnaires can either be downloaded from the website in the centre or downloaded by the central co-ordinator and posted to the centres. They can also be made available by Email or as paper copies by the data centre in Leiden on request.

Each centre should ensure that they hold at least two Baseline questionnaires in reserve, so that they are readily available to give to the patient at randomisation.

- Please ensure that***
- 1) the pages are stapled together to form a booklet***
 - 2) details of the local contact is printed on the front page so that patients know who to ask if they have any problems with the questionnaire***
 - 3) the relevant return address is printed on the last page***
 - 4) the patient's TRIAL NUMBER and the DATE is entered on the front page.***
 - 5) a prepaid addressed envelope is available to give to the patient with the questionnaire.***

When the supply falls to the last questionnaire either download another one or request a further supply from the Central Co-ordinator.

2) Issue of Questionnaires at Randomisation

1. Identify eligible patients
2. Ensure eligibility criteria are met
3. Print the appropriate randomisation form and either contact Oxford by telephone or fax the form to Oxford (or (soon) email it to Oxford)
4. On receipt of the randomly allocated treatment from Oxford, fill in the patient registration form and fax or send it to Leiden Data Centre.
5. Enter the patient's TRIAL NUMBER and the DATE on the front of a baseline Quality of Life questionnaire and give it to the patient with a reply paid envelope . The patient should be asked to complete the questionnaires and post to the central co-ordinator in the envelope provided.
6. If for any reason the clinician doesn't feel it is appropriate to enter a particular patient into the Quality of Life study, or if a patient refuses to take part, an Investigators Form should be completed for that patient and sent to the central co-ordinator. (Investigator's Form to be downloaded from the Web Site., or it can be supplied by the Central Co-ordinator on request)

3) Supply and Issue of Questionnaires at Follow-up

1. About one month before a follow up is due, a QoL follow up form with reply envelope will be received from the central co-ordinator for each patient randomized. This will have the patient's trial number recorded on the front cover. A reply paid envelope for return of the questionnaire to the central co-ordinator should be provided.

2. The questionnaire and envelope will either:-

a) be given to the patient at a clinic visit (i.e. 4 month, 8 month, 12,24,36 and 48 months)

or

b) be posted to the patient if for any reason the patient does not attend at the right time.

3. The patient will be asked to complete the questionnaire and post it to the central coordinator.

4. In the event of the patient not returning the questionnaire, the central co-ordinator will alert the centre so that either the patient can be encouraged to comply, or information regarding the reasons for non compliance can be reported on an investigator's form. (Investigator's Form to be downloaded from the Web Site., or it can be supplied by the Central Co-ordinator on request)