Summary of drug arrangements for sites

There are a total of 8 IMPs for the R-CODOX-M/IVAC trial.

Drug name	Brand	Supply arrangements
Pegfilgrastim	Neulasta	Supplied free of charge by Amgen
Rituximab	Mabthera	From hospital stock
Cyclophosphamide	Any brand permitted	From hospital stock
Cytarabine	Any brand permitted	From hospital stock
Methotrexate	Any brand permitted	From hospital stock
Ifosfamide	Any brand permitted	From hospital stock
Etoposide	Any brand permitted	From hospital stock
Doxorubicin	Any brand permitted	From hospital stock

This document focuses in particular on the supply arrangement for the only supplied drug for the trial: Pegfilgrastim, and will provide information on how to order the drugs, how the drugs should be stored, and destruction of unused or expired stock.

Drugs for this study will be labelled at site. Please refer to the sample label sent to sites for the minimum wording required for labelling drug on receipt from supplier and when dispensed for a patient.

Drug ordering

You will need various details in order to complete the drug order form for the pegfilgrastim (Neulasta®). These are:

- Site name
- Site delivery address
- PI name
- Patient trial number
- Pharmacy contact name, phone & fax number
- Product required; number of syringes needed.

Please ensure that you fill out the order forms correctly, as failure to do so may lead to your order being delayed.

Pegfilgrastim (Amgen Ltd)

Amgen are providing Pegfilgrastim (Neulasta) free of charge for the trial. This is a prophylactic drug used to support the white blood count.

Neulasta should be ordered directly from Amgen. This should be ordered on a strictly per-patient basis, and the patient's trial number must be provided on the order form.

The current version of the order form at the time of writing is version 3 (March 2010); a sample is shown in figure 1 below. If you do not have a copy of this version of the order form, please contact the trial team at UCL CTC (r-codox-mivac@ctc.ucl.ac.uk) and we will send you a copy. **Order forms are updated from time to time. UCL CTC will issue sites with new copies when they are available, but please contact the trial team if you are unsure whether you have the correct version.**

Please complete the form with Name of the PI, the Pharmacist's name, telephone and fax numbers and the address for delivery. The patient's trial number must be entered on the form. The number of syringes of pegfilgrastim must also be entered.

The completed form should be faxed to Amgen Customer Services on 0203 024 0073. Please allow 5 working days for delivery.

Patients have Neulasta on day 13 of the CODOX-M cycles (1 & 3) and day 7 of the M-IVAC cycles (2 & 4), and the supplier will not permit sites to order stock in advance of entering a patient into the trial.

Please order the drug promptly when a patient is registered in order to ensure that their drug arrives in time.

Please file a copy of your drug order in your pharmacy site file.

Figure 1

R-CODOX/M-IVAC Trial Order Form
Per Patient Order

Fax

To:	Customer Services, Amgen Ltd	**From:**	
Fax:	0203 0240073	**Pages:**	
Phone:	0203 0240072	**Date:**	

Please forward Neulasta® for the R-CODOX/M-IVAC trial patient listed below:

REQUESTED BY			
Clinician:		**Pharmacist:**	
Contact Tel:		**Contact Fax:**	
Hospital Address:			

PATIENT INFORMATION	
Trial Number: (must be completed)	

PRODUCT REQUIRED	
Neulasta® (pegfilgrastim) 6mg /0.6ml/ Syringe	**Supplied Free Of Charge**
No. Syringes Required:	

AMGEN CUSTOMER SERVICES DETAILS	
Fax:	0203 0240073
E-mail:	cs-uk@amgen.com

Version 3 (March 2010)

Drug must be labelled 'FOR CLINICAL TRIALS USE ONLY' on receipt at site. UCL CTC will provide sites with a document containing the minimal wording for these labels (see sample label). A further dispensing label will need to be added once a prescription is made.

Storage & destruction of supplied drugs

The supplied drug must be kept segregated from hospital stock in a designated area. Temperature logs must be kept and UCL CTC must be notified if there are any temperature excursions (email r-codox-mivac@ctc.ucl.ac.uk).

Guidelines for the supplied drug are as follows:

IMP	Storage guidelines	Destruction guidelines
Neulasta	Store in a refrigerator (2°C - 8°C), and protect from light. Do not freeze. Do not shake. Handle gently to avoid foaming.	Unused or expired units of drug to be destroyed at site according to local protocol

(Based on SmPC for Neulasta, and correct as at 26.03.2010)

Storage & destruction of drugs from hospital stock

Drugs sourced from hospital stock should be stored in accordance with the Summary of Product Characteristics (SmPCs), and any unused drug should be destroyed in accordance to local protocols.

Drug accountability logs

Sites have been issued with accountability logs for all the IMPs on the trial. Sites are encouraged to use the study-specific accountability logs. Sites are permitted to use in-house records but they must include all the information requested in the trial-specific logs.

Drug receipts and all subsequent drug movements should be recorded in the accountability logs. These must be filed in the pharmacy site file, and must be sent to UCL CTC on request.

Problems or queries

Please contact the R-CODOX-M/IVAC trial team at UCL CTC if you have any queries or there are any problems with your study drug.

Email: r-codox-mivac@ctc.ucl.ac.uk
Tel: 0207 679 9860 (Mon-Fri, 9am-5pm)