LD-21B

DRAFT CONFIDENTIAL

Universal Leucodepletion Programme Implementation Board Meeting
Thursday, 12 November 1998
As a Video Conference

Present:

Tim Wallington (Chairman) (TW)
Peter Garwood (PG)
Angela Robinson (AR)
Lorna Williamson (LW)
Alan Slopecki (AS)
Nick Tandy (NT)
Richard Bedford (RB)

17. **Apologies for Absence:** Steve Morgan (SM), Terry Male (TM)

18. **Meeting Quorate / Declaration of Interests**

The meeting was declared quorate by the Chairman. Declaration of interests of those present is as previously minuted.

19. **Minutes of Last Meeting**

These were agreed as an accurate record. They could now be distributed to colleagues as Board Members felt to be fit.

Review of Action Points:

3(4.2) **MB VIP progress**

Mike Kavanagh at the MCA has verbally given his assurances that although MB is not a licensed pharmaceutical product, it is considered appropriate for use in the VIP process in the UK. This recommendation will be put in writing in due course. As yet TW has received no reply from Richard Walker at BPL re their interest in producing a MB VIP product. **(ACTION: TW)**.

4(4.4) **Origin of filters**

AS tabled a schedule of factory visits to be finished by March 99. Each team would consist a Quality Manager and one other. Where plants have not be visited before the Quality Manager would be AS. This schedule was agreed.

12. **Production Management Information**

NT referred to document he had e:mailed previously. The figures for L&SE were indicating a higher level of leucodepletion, as a result of incorrect EIS data. NT would assess with Stuart Halson and report back once correct information received. **(ACTION: NT)**. The process by which data has to be collected and the measurement of FFP products needs to be agreed **(ACTION: NT/PG)**.

Process Stream Coding

Discussion centred around the tracking of various components. It was agreed that for leucodepleted red cells there was no merit in the user knowing whether they had been produced from filtered whole blood or from buffy coat depleted red cells - therefore no new spec/bar code needed. However it would be essential for NBS to know 'in-house'. For FFP, which would be leucodepleted and NAT tested, there was a danger of creating 4 codes none of use to the user if it was thought there was merit in knowing which process stream the FFP came from. As this would not impact on the clinical use of the FFP it was agreed that new product codes should not be made available. It was proposed to verify that full process audit trial could still be maintained for all clinical plasma which had been leucodepleted (long term) using only pack code information, **(ACTION: PG)** It should be sufficient to alter the Red Book specification, once universal leucodepletion is implemented. This, however, is a matter for the Components SAC. **(ACTION: LW)**

13. **Sickle trait donations**

LW said that there was slow progress being made studying impact on filtration with all three Zones having difficulty in locating and calling in donors. In the L&SE Zone 100 donors had been contacted and it was hoped testing would start soon. In Bristol Derwood Pamphilon has similarly recruited sickle donors to a trial. NT was aware of some historical data being available in Birmingham. AR said that Bradford may have identified donors - she would check this out **(ACTION: AR)**. Out of the three failures in filtering so far (1 North, 2 L&SE Zone) only one in L&SE Zone was linked to sickle trait. AR stated that the Commission for Racial Equality may need to be informed if we are not able to collect blood from these donors. LW asked if it was currently possible through PULSE to identify HbS positive donations such that they could have WBC counting if needed **(ACTION: LW)**

14.1 **Ops Manager for R&D/QA Group**

Alison Kruse has accepted this position and attended the last meeting.

14.1 **Signing off filters etc**

The R&D Group have signed off phase 0 trials of the NPBI red cell and MacoPharma whole blood filters.

14.1 **Process Control and NIBSC**

Taken under R&D Report.

20. **MB VIP: Option appraisal and progress**

Michelle Ashford could not be present at the meeting. She had sent a report which needed to be read in depth by most members of the PIB. Once the contents of the report were digested there should be further discussion at the December meeting of the PIB. The process of appraising options needed to be developed in more detail with timescales. In the process of discussion, two things were clarified. One that it remains firmly on the NBS Agenda to produce a VIP product. Two that it is a project running separately from the LD Project, but under the umbrella of it so as to be sure that activity in implementing VIP did not interfere with the process of implementing leucodepletion. The LD PIB agreed at this stage with RB's recommendation that the Operations Group take on board the issue of Options Appraisal for VIP and progress it, including calculating an approximate timescale and bring their conclusions back to the LD PIB in due course. **(ACTION: RB/PG)**.

21. **Project Initiation Document**

This document was compared to the Feasibility Report. The key differences were as follows:

1. Option 3 on page 6 - integral systems and financial information. There was a reduction in revenue costs from £80 to £65 million. **(ACTION: SM to verify)**

2. The bullet points on page 7 - this listed things excluded from the LD Project, particularly the MB VIP Project. It was felt that if this is excluded there may be a need for a separate VIP PID. This will be discussed by the Operations Directors **(ACTION: OPS DIRECTORS)**.

3. Page 4 -'a detailed option' under project objectives should be removed.

4. Page 5 - the second bullet point should read enumeration not "full enumeration".

5. Page 8, 2.3.2 - a nationally agreed protocol should be available in December. PG/NT to cross-reference the User Spec with this document and add a review date **(ACTION: PG/NT)**.

6. PG felt it should be made clear when the end date is for the PIB. This will be added to 'Business case'(section 2.1) **(ACTION: NT)**.

7. Page 11, the timetable should include the addition of a close off point. (To be added to 'Timetable'(section 5)

8. Page 11, the wording should be modified to read "assess current suppliers relevant to current products" not interview.

The Project Initiation Document should be signed off by the next meeting with copies being sent to the Executive for information. Any further comments are requested to NT by 1st Dec. **(ACTION: ALL)**.

22. **Risk Assessment**

To date 3 PIB members have responded. The weightings did differ and are now limited to 13 key issues and how we are managing these key risks. In future the Risk Assessment will be assessed on a 2 monthly basis. The main issues arising are:

1. *Temperature change* - this needed to be better understood and more closely defined.
2. *Modification to existing facilities* - the M&SW and N Zone were still planning building work required.
3. *Project staff* - all the staff involved on this project have other responsibilities but particularly the Operation Managers.
4. *Donor 2000* - this is a very large project. Although the LD Project is top NBS priority at the moment, it may be in danger of competition for resources from Donor 2000 project.
5. *Plans and estimates* - the fiscal implications are still felt to be a risk. There is still ambiguity as regards the need for facilities on cold processing. Report presented is filed with Minutes.
6. *Mandatory start date* - the PIB remains comfortable with this being less than 12 months away.
7. *Ramping up by suppliers* - felt to be a risk if undersized plants try to produce above reasonable capacity, quality may suffer as a result.

23. **Reports / Reviews**

23.1 **R&D/QA**

The pro forma for prospective and ongoing data capture on filter performance will be reviewed and Alison Kruse will finalise this with the other production managers for data to be collected in November.

AS to action through the Quality Group the need for line stripping at sessions. **(ACTION: AS)**.

The Day 0 evaluation on the Baxter whole blood filter at room temperature provided results which were marginal. Baxter are querying our procedures. The R&D Group recommend for the moment that phase 1 evaluation should not proceed.

The Pall WBF1 has been signed off by the R&D Group for Phase 0 provided PALL can provide details of modifications to produce WBF-2.

The Cutter pack audit is to be carried out in Los Angeles soon. The Phase 1 evaluation had been signed off. This should mean Phase 2 evaluation can happen earlier than planned but not at the expense of the NPBI evaluation. **(ACTION: AS)**.

The Pall plasma filter will be looked at in December.

Haemonetics MCS+ has been signed off by the Apheresis technical group. All Zones are having regular failures - 100% counting is still occurring. AR advised that Moji Gesinde should review the data as soon as possible. **(ACTION: TM)**. AR felt that more attention should be paid to the apheresis technology that is / will be used for LD platelets through Moji Gesinde's group. **(TW to action through TM)**

The IMAGN was being evaluated in all 3 zones. The kind of evaluation we should be doing was discussed including the approval of instrument suitability, linearity, correlation. RB wanted to know if it were possible to interchange between Flow and IMAGN if they correlated in the same Centre. By 2 December a report will be given to the R&D Group as to the suitability of IMAGN.

EQA: It was recommended that an external agency be involved in order to help validate the SPC. John Reily at NEQAS in Sheffield would be contacted. LW is also visiting NIBSC for exploratory discussions **(ACTION: LW)**.

SPC: Discussion took place as to who was the final decision body re the SPC. It was felt it should be signed off by the CD's group. **(ACTION: TW)**.

A general position statement regarding issues of principle for LD would be drafted by LW and would be sent out after the joint meeting on 17 December. **(ACTION: LW)**.

Concern was raised at the total anonymisation of LD test results. It would be necessary for the QC data to be linked to samples and processing in such a way to allow sensible investigation and adjustment. The principal that specific components would not be recalled in response to QC results remains agreed. More thought is required before the precise meaning in this context of "anonymisation" is defined. **(ACTION: LW)**.

COBE had approached LW re running the NWAQA. It was decided not to accept this offer. **(ACTION: AS)** .

SPC training - should be discussed at the next meeting. **(ACTION: LW)**.

The issue of filtering of pre-deposit autologous units was again raised. The PIB agree that LD for these units is not desirable although the risks of loosing the blood pack or of transfusing it into the wrong patient would need to be discussed at the next CD's meeting. **(ACTION: TW)**.

It was felt necessary to advertise the monies available for special projects under the umbrella of LD. This must be a transparent process and TW will mention this in his newsletter. **(ACTION: TW)**.

23.2 **Blood Pack User Group**

There was no report from the Blood Pack User Group as the next meeting was not due till December.

23.3 **Finance**

PG to raise with SM re buying stocks of filters and the accounting implications.

23.4 **Zonal Implementation Board, Northern Zone**

Report presented and filed with Minutes. LW to clarify what filter is being trialled in Manchester. **(ACTION: LW)**.

23.5 **Zonal Implementation Board, London & SE Zone**

Report presented and filed with the Minutes.

23.6 **Zonal Implementation Board, Midlands & SW Zone**

Report presented and filed with Minutes.

23.7 **Project Administrator**

Report presented and filed with Minutes.

24. **Publicity / Communication**

TW has circulated a draft of the next newsletter which attempted to explain the process control approach to the QA of LD. It was felt this was more of a policy statement on SPC that should be issued widely after further consideration by the CDs and SAC Components and TTI, but should be commented on by MB, CD and DS asap. TW to draft another newsletter

informing hospitals of progress, provisional milestones, finance and building work / staff recruitment etc.

25. **Manufacturers - apheresis**

The PIB feels it requires more information from suppliers of apheresis equipment. Baxter, Haemonetics and COBE should be invited to give presentations to the January meeting along with Moji Gesinde's group. **(ACTION: TW)**

26. **Meeting with MSF**

Richard Boggis has set a meeting for 26 November to explore the ways in which the MSF can help the NBS. TW, RB, RBog and Breffni McCormack will be attending. Issues to be covered included - the outline time plans, key milestones, the impact on present staffing and additional staff. PG believes MSF will table a framework at this meeting which they think all Centres should operate by, eg starting times etc. PG emphasised that local management teams should approve staffing requirements and this should be made clear at this meeting.

27. **AOB**

27.1 PG raised the question of sending deputies to the LD meeting. It was decided deputies could attend where necessary.

27.2 RB raised the interdependencies between the LD and NAT Projects. Between now and Feb 99 the NAT Project will be engaged in critical actions to bring it live from 1 Apr 99. Already Birmingham teams have been hit with changes in the TBQ, SOP's and LD bags all on the same day. He stressed the LD PIB should be aware and mindful of these type of changes.

27.3 Neil Beckman is to be invited to the December PIB to discuss experience with process control providing the Birmingham trial is complete. **(ACTION: TW)**

27.4 AS had been asked by Northern Ireland for reports of our evaluations. This was agreed and will be completed through the BPUG and Sci/Qual Group **(ACTION: AS)**

27.5 TW asked that when filters fail are we always looking into the possible reasons and then feeding them back. This will become an Agenda item for the next R&D Group meeting. A protocol to investigate this situation is probably desirable. **(ACTION: LW)**

At this point (16.30hrs) the meeting closed. The next meeting will be held at 10.30am on 10 December at the Queen Elizabeth Postgraduate Medical Centre, Birmingham.