

DHF 0019250

File AIDS

HAM 22/11 VOL. 44

SCREENING FOR HTLV III ANTIBODIES: NOTES OF A MEETING HELD AT
HANNIBAL HOUSE ON 13 FEBRUARY 1985

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Present:

Dr Alison Smithies)
████████████████████) MEDSEB
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████████████████████) STB3
████████████████████)

1. R & D Project at Middlesex Hospital

████████████████████ reported that Mr Rogers had given the go-ahead for a project with two objectives. These objectives were (i) to scale up the RIA and to carry out field trials with the co-operation of the NLBTC and (ii) to carry out follow-up studies on positive results. It had been agreed that the Middlesex Hospital was not an appropriate site for evaluation of commercial kits because the staff had played a significant part in the development of the RIA. It was reported that STB5 would be looking into the patent application on the RIA and the commercial interest of Wellcome Reagents.

2. Proposed Evaluation of Commercial Kits

2.1 It was known that Ortho, Travenol, Abbott and Centocor had plans to introduce ELISA kits into the UK. Other USA firms were involved as was the Institute Pasteur in France.

2.2 It was agreed that a screening evaluation was necessary in order to be able to guide would-be purchasers. The idea would be to inform the NHS through suitable media of those products which were worthy of consideration. Thereafter, the would-be purchasers could make a decision based on price and the results of appraisal with local circumstances in mind. In due course, it should be possible to publish the results of these studies.

2.3 The screening evaluation would have to be based on a panel of positive and negative sera specially chosen to cover the range of samples likely to be encountered in practice. Such a panel was being put together by Drs Richard Tedder and Philip Mortimer. Dr Mortimer (Director, PHLS Virus Reference Laboratory) had expressed a willingness to undertake an evaluation on behalf of the DHSS and he had agreed to submit a draft protocol shortly.

It was agreed that Dr Mortimer would be acceptable to the DHSS.

2.4 Dr Mortimer would require the assistance of two basic grade scientists and this would cost about £20,000 per annum inclusive of overheads. It was agreed that this staffing level was necessary in order to ensure a quick turnaround of work. It was also agreed that the best approach would be to lease from each

manufacturer a package of equipment and consumables for evaluation. Thus, there could be no question of unsatisfactory performance being due to incompatible equipment or ancillary reagents; the manufacturer would have to supply on a commercial basis and so could not argue later that what was supplied was a developmental product and therefore had to be accepted as such; and importantly the DHSS would not be beholden to the manufacturers, nor could be accused of 'blackmailing' them into the supply of free products. It was agreed that in the case of USA manufacturers only those with FDA clearance should be evaluated and that all manufacturers should be asked to supply data in support of their performance claims.

2.5 It was agreed that an ad hoc expert working group should be set up to help in the management of the evaluation scheme. [REDACTED] agreed to draft terms of reference for consideration by MEDSEB and STB - see Appendix. It was agreed that the following should be invited to take part.

Dr Mortimer
 2 Consultant Virologists - to be suggested/invited by MEDSEB
 Dr Pritchard - Expert Observer from Wales)
 Expert Observer from Scotland) to be suggested/invited
 Expert Observer from Northern Ireland) by MEDSEB
 [REDACTED] to be Chairman
 [REDACTED] to be Secretary

2.6 [REDACTED] would seek funding from Supply Division.

13 February 1985,

[REDACTED]
 STB3A