

SSC Subcommittee Project/Collaborative Project

- Name of the Project: **POTENCY LABELLING OF CLOTTING FACTOR CONCENTRATES**
- Person responsible (Chair / Principal Investigator): Dr. Anthony Hubbard (UK)
- Members: Dr. Mark Weinstein (USA)
 Dr. Rainer Seitz (Germany)
 Dr Johannes Dodt (Germany)
 Dr Timothy Lee (USA)
 Dr Alok Srivastava
- Aim / Mandate of the project: The mandate of the project will be to find ways to harmonize the recommendations for the methods to be used for assigning potency of clotting factor concentrates. This will also include recommendations for assay of post-infusion samples to assess recovery.
- Methodology: The project members will review the literature on the subject, discuss the issue with as many concerned scientists in the academia and industry as possible and recommend test methods for assignment of potency of clotting factor concentrates as well as methods for evaluation of clinical samples to assess recovery after infusion of these concentrates. Information will also be gathered through the circulation of questionnaires and meetings with other groups/committees considering related initiatives.
- Year of starting: Oct 2010
- Annual report of project: The project members have held two teleconferences to consider the project remit and various options on how to proceed. It was agreed that the project should focus on new products in the FVIII and FIX areas. The utility of some form of decision tree for potency labeling which could be followed by regulators and manufacturers has been discussed. Information on the current practice for post-infusion testing is being gathered through a questionnaire circulated to expert clinical laboratories.
- Year of completion (expected): 2012 – dependent on progress both within the group and also on the outcome of related initiatives by other parties.