Name of the project: **CONSENSUS DEFINITIONS AND RECOMMENDATIONS FOR IMMUNE TOLERANCE INDUCTION (ITI) IN HEMOPHILIA WITH INHIBITORS**

Person responsible (Chair / Principal Investigator): Dr. Elena Santagostino (Italy)

Members:
- Dr. Donna DiMichele (USA)
- Dr. Leonard Valentino (USA)
- Dr. Charles Hay (UK)
- Dr. Carmen Escuriola Ettingshausen (Germany)
- Dr. Johannes Oldenburg (Germany)
- Dr. Evelin Mauser-Bunschoten (The Netherlands)
- Dr. Bert Verbruggen (The Netherlands)

Aim / Mandate of the project: The mandate of the project will be to propose consensus definitions of ITI outcome standardizing the methodologies for the assessment of treatment endpoints. An additional aim will be to establish harmonized strategies for ITI treatment in inhibitor patients belonging to different and well defined prognostic groups.

Methodology: The project members will review published literature and registry data on ITI treatment in patients with hemophilia and inhibitors with a special focus on the following issues:

1. ITI outcome definitions
   - clinical endpoints and definitions of response
   - laboratory endpoints and methodologies
2. Characteristics of patients receiving ITI
   - age at inhibitor development and at ITI start, inhibitor titer at ITI start, historical inhibitor peak, peak on ITI
   - other putative prognostic factors
   - ITI outcome in different patient groups
3. ITI regimens
   - type of FVIII product
   - FVIII dose, treatment duration, tailing off and/or maintenance treatment
   - ITI outcome with different regimens in specific patient groups
4. Treatment recommendations and guidelines

As soon as literature reviewing will be completed, the project group starts its deliberations. This work will be carried out through a series of teleconferences in order to discuss all the issues outlined above. The proposal for consensus definitions and recommendations on ITI should be prepared as a manuscript to be published on JTH as SSC communication.

Year of starting: March 2013

Year of completion (expected): March 2015