

ISS P-002: Protocol synopsis

PROTOCOL ISS P-002

Investigational product	Biotechnological Vaccine
Country	Italy
Patients	50
Duration	Project duration: at least 4 years Duration for each patient: about 3 years
Dedicated Personnel	About 50 persons, with at least 45 individuals distributed between ISS and cooperating companies (CNAIDS, Core Lab, TVA, Opera, Diatheva, Injectalia), and at least 15(5/site) at the 3 Clinical Centres
Visits	At least 1,000 clinical visits
Clinical Centres	3 (MO, MB, RM)
Laboratory	Centralized (Core Lab IFO - S. Gallicano, Rome) A total of 5,500 person-hours per year are foreseen
Biological samples delivery from Clinical Centres to the Core Laboratory at Rome	Dedicated Courier to the release within 8 hours About 240 deliveries/year at RT and 55 deliveries/year at CT (- 80 °C)
Laboratory tests	Immunological, virological and safety testing (about 37,450 tests)
Production	Tat protein: Diatheva, Urbino University V2-deleted Env protein: Novartis Vaccines & Diagnostics
Packaging and release	Injectalia Biopharma (Pomezia, Rome) (About 260 vaccine vials will be used for the trial)
Vaccine delivery to Clinical Centres	Specialized Courier for shipment delivery at - 80 °C (About 250 deliveries/year)
Monitoring and Data Management Activities	Contract Research Organization Opera Srl (Genoa) (A total of 8,000 person-hours per year are foreseen)
Clinical Data	Electronic Case Report Forms (Oracle Remote Data Capture). The study will imply the storage and the management for about 5 billions of data
Insurance	HDI-Gerling
Psychological support to the patients	Psychological Evaluation Protocol coordinated by "Università Vita-Salute" (San Raffaele, Milan)