The document contains a protocol synopsis for a clinical trial, specifically trial ISS P-002. The table outlines various aspects of the trial, including:

- **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 per 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)