Work Plan & Methodology –

- Literature survey
- Design & Development of study protocol, ICF, CRF
- Generation of TMF
- Ethics committee approval for the proposed phenotyping study
- Procurement of study drugs and reference standards
- Method development and validation for analysis of drug
- Related review and research article publications
- Study subject recruitment
- Drug dosing to subjects and sample collection
- Sample processing and analysis
- Data collection and reanalysis (if required)
- Statistical analysis
- Related review and research article publications
- Report and thesis submission

METHODOLOGY

Subjects & Method

Study Subjects: One hundred and eight healthy, male, human subjects from Maharashtra region with age ranging between 18-45 years will enroll in this Phenotyping study. The screening consent & study consent shall be taken respectively before drug application. Thereafter subject’s medical records will be documented and physical examination will be conducted. The subject’s health status will be endorsed by medically qualified expert study personnel.

Study Design: This study will carried out as per the ICH (Step 5), ‘Guidance for Good Clinical Practices (GCP)’ and the principles of Declaration of Helsinki (Scotland, October 2000). The
Independent Ethics Committee will review the protocol and the inform consent form for this study. A single dose, NAT enzyme Phenotyping study using healthy human subject of Maharashtra region will conduct.

**Clinical Method:** A single oral dose of Dapsone 100 mg, Pfizer Ltd tablet shall be administered to the study subjects at a pre-decided time. The dose shall be administered with 250 ml of water. No water and food of any kind will be allowed for 2 hours post dose. After 2 hours post dose, the subjects will be allowed food and water ad libium.

**Sampling Schedule:** Single blood sample of 10 ml will be collected two hours post dose:

**Blood Loss:** The total volume of blood withdrawn from each subject will not exceed 10 ml throughout the study.

**Washout Period:** There will be no washout period for this study.

**Safety Assessments:** Subjects will be monitored during the entire clinical period of the study for the evidence of any ADR they may experience or any adverse event they may get as a part of study procedure.

**Bio-analytical Procedure:** Plasma levels of Dapsone and its metabolite N-Acetyltransferase shall be examined.

**Statistical Analysis:** The drug and metabolite concentration values for each subjects will be used to calculate the D/M ratio, which further by the frequency distribution curve will be used to determine the Phenotyping distribution of the selected Maharashtra Population.