

## Clinical Study Protocol – Example

Section 3.1: Laboratory Assessments AST (Aspartate Aminotransferase, also called SGOT) is a liver enzyme. Definition: AST measures the concentration of aspartate aminotransferase in serum. Units: U/L (Units per Liter).

ALT (Alanine Aminotransferase, also called SGPT) is another liver enzyme. Definition: ALT measures the concentration of alanine aminotransferase in serum. Units: U/L.

BILI (Bilirubin, also called TBIL). Definition: BILI measures the concentration of bilirubin in serum. Units: U/L.

Section 4.2: Vital Signs Systolic Blood Pressure (SYSBP) is defined as the maximum arterial pressure during contraction of the left ventricle. Units: mmHg.

Diastolic Blood Pressure (DIABP) is defined as the minimum arterial pressure during relaxation of the heart. Units: mmHg.

### Section 5.1: Visit Schedule

| Visit     | Day       | Window | Assessments                    |
|-----------|-----------|--------|--------------------------------|
| Screening | -28 to -1 | ±2     | Informed Consent, Labs, Vitals |
| Visit 1   | 0         | ±1     | Dosing, Labs, Vitals           |
| Visit 2   | 7         | ±2     | Labs, Vitals                   |
| Visit 3   | 14        | ±2     | Labs, Vitals, ECG              |

### Section 6.2: Dose Escalation

| Cohort | Dose Level (mg) | Number of Subjects | Escalation Criteria                   |
|--------|-----------------|--------------------|---------------------------------------|
| 1      | 10              | 6                  | If $\leq 1/6$ subjects experience DLT |
| 2      | 20              | 6                  | If $\leq 1/6$ subjects experience DLT |
| 3      | 40              | 6                  | If $\leq 1/6$ subjects experience DLT |