

STUDY PARAMETERS

List out required labs, as specific labs may not be included in standard lab panels

Example:

Required biological samples

The following clinical laboratory tests will be performed:

Serum Chemistry:

Calcium, Chloride, Magnesium, Potassium, Sodium, Bicarbonate, Aspartate aminotransaminase, Alanine aminotransaminase, Alkaline Phosphatase, Total Bilirubin *If total bilirubin is $\geq 2 \times$ ULN at any time, obtain direct bilirubin at the same time points*, Gamma glutamyl transferase (GGT), Lactate dehydrogenase, Uric acid, Creatinine, Blood urea nitrogen (BUN), Glucose, Albumin, Total protein, Triglycerides, Cholesterol, Troponin

*Note for serum chemistries: Tests for AST, ALT, ALP and total bilirubin must be conducted concurrently and assessed concurrently.

Hematology:

White blood cell (WBC) count with differential, Red blood cell count, Hemacrit, Hemoglobin, Platelet count, Mean corpuscular volume (MCV), Mean corpuscular hemoglobin concentration (MCHC)

Urinalysis:

Color, Appearance, Specific Gravity, pH, Protein, Glucose, Ketones, Blood, Bilirubin, Microscopy including WBC/High power field (HPF), RBC/HPF if clinically indicated

Screening Evaluation

Screening studies and evaluations will be used to determine the eligibility of each subject for study inclusion. All evaluations must be completed \leq # days prior to administration of protocol therapy. Please consider adding separate timelines for specific study assessments (e.g scans, labs, etc).

Cycle 1, Day 1

List Cycle 1 and each visit of Cycle 1 separately from subsequent cycles if they differ. The example below is shown with differences in cycles.

Suggested text is provided below:

[Cycle 1, Day 1] evaluations do not need to be repeated if screening evaluations were conducted within # week(s) prior to administration of protocol therapy.

- EKG must be completed in triplicate prior to dosing
- [Agent X] must be administered 1 hour prior to [Agent Y]

Subsequent cycles may be grouped together, if applicable. Be sure to list each visit of the cycle separately if different testing is to be done:

Cycles 2-4, Day 1

- Single EKG required prior to dosing
- [Agent X] must be administered 1 hour prior to [Agent Y]

The following 3 visits must be listed separately: ↓

End of Treatment Visit

End of Treatment visit should occur within [# days] of the last treatment dose. Adverse events will be assessed.

30 Day Follow-Up

A phone call will be made by a member of the study team to assess any possible adverse events.

Long Term Follow-Up, if applicable

Calendar

Example: Treatment cycles are # days long.

Screening studies will studies are to be conducted within # day(s) prior to administration of protocol therapy. Exception: Scans and x-rays must be done \leq # weeks prior to administration of protocol therapy.

Be sure to include windows for labs, visits, imaging, etc in order to avoid having to repeat tests, etc; e.g., labs \pm 3 days. Short (24 hour) windows are rarely required.

Study Days	Pre-Study	Cycle 1 Day 1	Cycle 2 + Ongoing Cycles, Day 1	End of Treatment (refer to section 11.2.3 for details)	30 Day Follow-Up
REQUIRED ASSESSMENTS					
Informed Consent	X				
Demographics	X				
Medical History	X				
Height	X				
Weight	X	X	X	X	
Vitals (blood pressure, pulse, respiratory rate, and temperature)	X	X	X	X	
Physical Examination	X	X	X	X	
Concomitant Med Assessment (Rx, OTC, herbal supplements)	X	X	X	X	
ECOG PS	X	X	X	X	
Baseline Symptoms	X	X			
Adverse Event Assessment			X	X	X
Example: Pill Diary		X	X	X	
Example: EKG		X	X		
Example: MUGA or ECHO					
CBC / diff / platelets	X	X	X	X	
Serum Chemistry (described in section 11.0)	X	X	X	X	
T4, TSH			X	X	
CPT 84100			X	X	
Magnesium			X	X	
LDH			X	X	
β -HCG, women of childbearing potential	X	X			
DISEASE ASSESSMENT					
Tumor Measurements	X	Tumor measurements are repeated every # weeks weeks. Documentation (radiologic) must be provided for subject removed from study for progressive disease.			
Radiologic Evaluation	X	Radiologic measurements should be performed very # weeks weeks.			
Bone Marrow Biopsy					
TREATMENT					
Agent X		X	X		
Agent Y		X	X		
CORRELATIVE STUDIES (refer to section X for details)					
Example: Pharmacokinetic Sampling		X	X		
Example: IGF-1 in PBMC		X	X		