

Sample MTN-003 Flow Sheet: Height and Weight

HEIGHT

Height should be measured at Screening Part 2, Semi-Annually, and at the Product Use End Visit. Compare each follow-up measurement to the Screening Part 2 measurement. Any participant with a confirmed (with repeat measurement) decrease in height of 3.8 cm or more should undergo radiography to rule out vertebral fracture (see protocol Section 9.5.13).

Date:										
Visit Code:	2.0 (SP2)									
Height (cm)										
Height (cm)										
Diff from SP 2	NA									

WEIGHT

Participant weight should be measured at Screening Part 1, Screening Part 2, Quarterly, and at the Product Use End Visit. Weight also should be measured when clinically indicated and when blood is drawn for creatinine testing. For purposes of monitoring the severity of unintentional weight loss, compare each follow-up measurement to the Screening Part 2 measurement and calculate the difference (if any) as a percentage of the Screening Part 2 measurement. See page 4 of the DAIDS Tox Table for complete guidance on severity grading.

Date:										
Visit Code:	1.0 (SP1)	2.0 (SP2)								
Weight (kg)										
Diff from SP 2	NA	NA								
% Diff from SP 2	NA	NA								

Date:										
Visit Code:										
Weight (kg)										
Diff from SP 2										
% Diff from SP 2										

Example of percent difference calculation: If a participant weighs 50.0 kg at SP2, and then is found to weigh 45.0 kg at Month 3, the percent difference is $[(50-45) \div 50] = [5 \div 50] = .10 = 10\%$

Sample MTN-003 Flow Sheet: Vital Signs

Vital signs should be measured at Screening Part 2, Month 1, Quarterly, at the Product Use End Visit, and additionally when clinically indicated. For purposes of monitoring the severity of fever, see page 3 of the DAIDS Tox Table. For purposes of monitoring the severity of hyper- and hypotension, see page 6 of the DAIDS Tox Table. Repeat blood pressure measurement should be performed at the same visit to confirm hypertension.

Date:													
Visit Code:													
	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade	
Oral temp													
Blood pressure													
Repeat BP													
Pulse		NA		NA		NA		NA		NA		NA	
Respirations		NA		NA		NA		NA		NA		NA	

Date:													
Visit Code:													
	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade	
Oral temp													
Blood pressure													
Repeat BP													
Pulse		NA		NA		NA		NA		NA		NA	
Respirations		NA		NA		NA		NA		NA		NA	

Sample MTN-003 Flow Sheet: Hematology

Complete blood count with differential and platelets should be performed at Screening Part 1, Semi-Annually, at the Product Use end Visit, and additionally when clinically indicated.
See pages 16-17 of the DAIDS Tox Table for complete guidance on severity grading.

Collection Date:												
Visit Code:												
	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade
Hemoglobin – abs												
Hgb – diff from SP1												
Hematocrit		NA		NA		NA		NA		NA		NA
MCV		NA		NA		NA		NA		NA		NA
Platelets												
White blood cells												
Neutrophils – abs												
Lymphocytes – abs												

Collection Date:												
Visit Code:												
	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade
Hemoglobin – abs												
Hgb – diff from SP1												
Hematocrit		NA		NA		NA		NA		NA		NA
MCV		NA		NA		NA		NA		NA		NA
Platelets												
White blood cells												
Neutrophils – abs												
Lymphocytes – abs												

NOTE: In addition to monitoring the above-listed parameters over time, the IoR or designee should review and provide appropriate clinical management of ALL abnormal differential results.

Sample MTN-003 Flow Sheet: Liver Function

ALT and AST levels should be tested at Screening Part 1, Month 1, Quarterly, at the Product Use End Visit, additionally when clinically indicated, and per protocol Sections 7.6.2 and 9.5.2. Severity grading is based on the site laboratory upper limit of normal (ULN). See page 17 of the DAIDS Tox Table for complete guidance on severity grading.

Site ULN for ALT:

Site ULN for AST:

Collection Date:												
Visit Code:												
	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade
ALT												
AST												

Collection Date:												
Visit Code:												
	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade
ALT												
AST												

Collection Date:												
Visit Code:												
	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade
ALT												
AST												

Sample MTN-003 Flow Sheet: Phosphate

Phosphate levels should be tested at Screening Part 1, Month 1, Quarterly, at the Product Use End Visit, additionally when clinically indicated and per protocol Section 9.5.6. Severity grading is based on the site laboratory lower limit of (LLN). See page 19 of the DAIDS Tox Table for complete guidance on severity grading.

Site LLN for Phosphate:

Collection Date:												
Visit Code:												
	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade
Phosphate												

Collection Date:												
Visit Code:												
	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade
Phosphate												

Collection Date:												
Visit Code:												
	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade
Phosphate												

Sample MTN-003 Flow Sheet: Creatinine

Creatinine levels should be tested at Screening Part 1, Month 1, Quarterly, at the Product Use End Visit, additionally when clinically indicated, and per protocol Sections 9.5.3 and 9.5.4. Severity grading is based on the site laboratory upper limit of normal (ULN). See page 18 of the DAIDS Tox Table for complete guidance on severity grading. Relative increases from baseline and creatinine clearance rates should be calculated each time creatinine is tested.

Site ULN for Creatinine:

Ppt's Baseline Creatinine:

Collection Date:												
Visit Code:												
	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade
Creatinine												
Creat – rel incr from SP1		NA		NA		NA		NA		NA		NA
Creat clearance		NA		NA		NA		NA		NA		NA

Collection Date:												
Visit Code:												
	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade	Result	Grade
Creatinine												
Creat – rel incr from SP1		NA		NA		NA		NA		NA		NA
Creat clearance		NA		NA		NA		NA		NA		NA

[[Question for Site Input: Would you prefer to combine this worksheet with the height/weight worksheet, given that weight is needed to calculate creatinine clearance?]]