IMPAACT 2001
SCHEDULE OF EVALUATIONS

VERSION 1.0, 10 NOVEMBER 2015

WITH LOA 1-2, CM 1-3

STUDY VISITS AND PROCEDURES

- Appendix I-A: Maternal Schedule of Evaluations
- Appendix I-B: Infant Schedule of Evaluations
- Section 6.1 – 6.6: Detailed information on study visits and procedures
- Section 6.7: Clinical evaluations and procedures
  - Physical examinations
  - TB assessment
  - Obstetrical exam
- Section 6.8: Laboratory evaluations and procedures
  - CBC (white blood count, hemoglobin, and platelets)
  - Coagulation profile (Prothrombin time only)
  - Liver function tests (albumin, AST, ALT, and total bilirubin)

Maternal SoE

Postpartum Visit added in LoA #1

	SCR	Entry/Intensive	Weekly (7 days apart) (*weeks 1-11*)	Postpartum Visit (*within 3 days of delivery; if study drug regimen completed prior to delivery only*)	Monthly (Every 4 weeks ±2 weeks) (*until 24 weeks after delivery*)	Study Exit/ Early Discontinuation
Administrative and Regulatory						
Obtain written informed consent	X					
Assign participant identification numbers (PIDs) to mother and infant	X					
Obtain screening number from SES	X					
Complete eligibility checklist and enter into SES		X				
Assign separate study identification numbers to mother and infant		X				
Assess eligibility	X	X				
Provide meal prior to administering study drug		X	X			
Behavioral and Counseling						
Provide HIV pre-/post-test counseling if applicable	X					
Assess alcohol and drug use	X					
Signs and symptoms of active TB Counseling		X	X	X	X	X
Assess infant feeding methods (postpartum only)			X	X	X	
Clinical						
Obtain/update medical and medications history	X	X	X	X	X	X
Perform physical examination	X	X	X	X	X	X
Perform obstetrical exam/assess fetal movement and heart sounds (until delivery)	X	X	X		X	
Perform ultrasound	X					
Provide available findings/test results		X	X	X	X	X
Assess TB symptoms, risk, and exposure	X	X	X	X	X	X
Gene Xpert, shielded chest x-ray, or sputum microscopy (if needed)	X					
Record/update AEs		X	X	X	X	X
TST (if needed and not available per medical record)	X					
Study Product						
Prescribe and administer DOT of study drug regimen		X	X			

Maternal SoE

	SCR (*up to 2 weeks prior to entry*)	Entry/Intensive PK Sampling (*Days 0-3*)	Weekly (7 ± 2 days apart) (*weeks 1-11*)	Postpartum Visit (*within 3 days of delivery; if study drug regimen completed prior to delivery only*)	Monthly (Every 4 weeks ±2 weeks) (*until 24 weeks after delivery*)	Study Exit/ Early Discontinuation
Administrative and Regulatory						
Obtain written informed consent	X					
Assign participant identification numbers (PIDs) to mother and infant	X					
Obtain screening number from SES	X					
Complete eligibility checklist and enter into SES		X				
Assign separate study identification numbers to mother and infant		X				
Assess eligibility	X	X				
Provide meal prior to administering study drug		X	X			
Behavioral and Counseling						
Provide HIV pre-/post-test counseling if applicable	X					
Assess alcohol and drug use	X					
Signs and symptoms of active TB Counseling		X	X	X	X	X
Assess infant feeding methods (postpartum only)			X	X	X	
Clinical						
Obtain/update medical and medications history	X	X	X	X	X	X
Perform physical examination	X	X	X	X	X	X
Assess TB symptoms, risk, and exposure	X	X	X	X	X	X
Gene Xpert, shielded chest x-ray, or sputum microscopy (if needed)	X					
Record/update AEs		X	X	X	X	X
TST (if needed and not available per medical record)	X					
Study Product						
Prescribe and administer DOT of study drug regimen		X	X			

History, physical, and TB assessment at all visits

Maternal SoE

	SCR (*up to 2 weeks prior to entry*)	Entry/Intensive PK Sampling (*Days 0-3*)	Weekly (7 ± 2 days apart) (*weeks 1-11*)	Postpartum Visit (*within 3 days of delivery; if study drug regimen completed prior to delivery only*)	Monthly (Every 4 weeks ±2 weeks) (*until 24 weeks after delivery*)	Study Exit/ Early Discontinuation
Administrative and Regulatory						
Obtain written informed consent	X					
Assign participant identification numbers (PIDs) to mother and infant	X					
Obtain screening number from SES	X					
Complete eligibility checklist and enter into SES		X				
Assign separate study identification numbers to mother and infant		X				
Assess eligibility	X	X				
Provide meal prior to administering study drug		X	X			
Behavioral and Counseling						
Provide HIV pre-/post-test counseling if applicable	X					
Assess alcohol and drug use	X					
Signs and symptoms of active TB Counseling		X	X	X	X	X
Assess infant feeding methods (postpartum only)			X	X	X	
Clinical						
Obtain/update medical and medications history	X	X	X	X	X	X
Perform physical examination	X	X	X	X	X	X
Perform obstetrical exam/assess fetal movement and heart sounds (until delivery)	X	X	X		X	
Perform ultrasound	X					
Provide available findings/test results		X	X	X	X	X
Assess TB symptoms, risk, and exposure	X	X	X	X	X	X
Gene Xpert, shielded chest x-ray, or sputum microscopy (if needed)	X					
Prescribe and administer DOT of study drug regimen		X	X			

Prescribe and administer DOT at Entry and each weekly visit

Maternal SoE

	SCR (*up to 2 weeks prior to entry*)	Entry/Intensive PK Sampling (*Days 0-3*)	Weekly (7 ± 2 days apart) (*weeks 1-11*)	Postpartum Visit (*within 3 days of delivery; if study drug regimen completed prior to delivery only*)	Monthly (Every 4 weeks ±2 weeks) (*until 24 weeks after delivery*)	Study Exit/ Early Discontinuation
Laboratory						
IGRA (3-4mL) (if needed and not available per medical record)	3-4mL					
Complete blood count (CBC)	3mL		3mL (every 4 weeks)	3mL (if clinically indicated)	3mL	
Liver Function tests	3mL		3mL (every 4		3mL	
Coagulation profile	5mL		5mL (at one visit at ≥34 weeks gestational age only)	5mL (if clinically indicated)	5mL (if clinically indicated)	
HBsAG, HBsAb, HCV Ab		6mL				
Intensive PK sample collection		22mL				
Sparse PK sample collection			8mL (last dose)			
Plasma sample collection (breast milk PK eligible only)			2-4mL (first and second week postpartum)			
Breast milk PK sample collection (if eligible)			X (first and second week postpartum and last dose)			
TOTAL BLOOD	17-21mL	28-31mL	11-23mL	8mL	6-11mL	

Coagulation profile collected on all women at Screening

Maternal SoE

	SCR (*up to 2 weeks prior to entry*)	Entry/Intensive PK Sampling (*Days 0-3*)	Weekly (7 ± 2 days apart) (*weeks 1-11*)	Postpartum Visit (*within 3 days of delivery; if study drug regimen completed prior to delivery only*)	Monthly (Every 4 weeks ±2 weeks) (*until 24 weeks after delivery*)	Study Exit/ Early Discontinuation
Laboratory						
IGRA (3-4mL) (if needed and not available per medical record)	3-4mL					
Complete blood count (CBC)	3mL		3mL (every 4 weeks)	3mL (if clinically indicated)	3mL	
Liver Function tests	3mL		3mL (every 4		3mL	
Coagulation profile	5mL		5mL (at one visit at ≥34 weeks gestational age only)	5mL (if clinically indicated)	5mL (if clinically indicated)	
HBsAG, HBsAb, HCV Ab		6mL				
Intensive PK sample collection		22mL				
Sparse PK sample collection			8mL (last dose)			
Plasma sample collection (breast milk PK eligible only)			2-4mL (first and second week postpartum)			
Breast milk PK sample collection (if eligible)			X (first and second week postpartum and last dose)			
TOTAL BLOOD	17-21mL	28-31mL	11-23mL	8mL	6-11mL	

Coagulation profile collected at one weekly visit ≥34 weeks gestational age

Maternal SoE

	SCR (*up to 2 weeks prior to entry*)	Entry/Intensive PK Sampling (*Days 0-3*)	Weekly (7 ± 2 days apart) (*weeks 1-11*)	Postpartum Visit (*within 3 days of delivery; if study drug regimen completed prior to delivery only*)	Monthly (Every 4 weeks ±2 weeks) (*until 24 weeks after delivery*)	Study Exit/ Early Discontinuation
Laboratory						
IGRA (3-4mL) (if needed and not available per medical record)	3-4mL					
Complete blood count (CBC)	3mL		3mL (every 4 weeks)	3mL (if clinically indicated)	3mL	
Liver Function tests	3mL		3mL (every 4 weeks)		3mL	
	5mL		at ≥34 weeks gestational age only)	5mL (if clinically indicated)	5mL (if clinically indicated)	
HBsAG, HBsAb, HCV Ab		6mL				
Intensive PK sample collection		22mL				
Sparse PK sample collection			8mL (last dose)			
Plasma sample collection (breast milk PK eligible only)			2-4mL (first and second week postpartum)			
Breast milk PK sample collection (if eligible)			X (first and second week postpartum and last dose)			
TOTAL BLOOD	17-21mL	28-31mL	11-23mL	8mL	6-11mL	

Intensive PK at Entry (initiated on the day of enrollment)

Maternal SoE

	SCR (*up to 2 weeks prior to entry*)	Entry/Intensive PK Sampling (*Days 0-3*)	Weekly (7 ± 2 days apart) (*weeks 1-11*)	Postpartum Visit (*within 3 days of delivery; if study drug regimen completed prior to delivery only*)	Monthly (Every 4 weeks ±2 weeks) (*until 24 weeks after delivery*)	Study Exit/ Early Discontinuation
Laboratory						
IGRA (3-4mL) (if needed and not available per medical record)	3-4mL					
Complete blood count (CBC)	3mL		3mL (every 4 weeks)	3mL (if clinically indicated)	3mL	
Liver Function tests	3mL		3mL (every 4 weeks)		3mL	
HIV-1 test (confirmatory tests as needed)	6mL					
[illegible]	5mL		[illegible] gestational age only)	clinically indicated)	clinically indicated)	
HBsAG, HBsAb, HCV Ab		6mL				
Intensive PK sample collection		22mL				
Sparse PK sample collection			8mL (last dose)			
Plasma sample collection (breast milk PK eligible only)			2-4mL (first and second week postpartum)			
Breast milk PK sample collection (if eligible)			X (first and second week postpartum and last dose)			
TOTAL BLOOD	17-21mL	28-31mL	11-23mL	8mL	6-11mL	

Sparse PK collected at last weekly visit (week 11)

Maternal SoE

	SCR (*up to 2 weeks prior to entry*)	Entry/Intensive PK Sampling (*Days 0-3*)	Weekly (7 ± 2 days apart) (*weeks 1-11*)	Postpartum Visit (*within 3 days of delivery; if study drug regimen completed prior to delivery only*)	Monthly (Every 4 weeks ±2 weeks) (*until 24 weeks after delivery*)	Study Exit/ Early Discontinuation
Laboratory						
IGRA (3-4mL) (if needed and not available per medical record)	3-4mL					
Complete blood count (CBC)	3mL		3mL (every 4 weeks)	3mL (if clinically indicated)	3mL	
Liver Function tests	3mL		3mL (every 4 weeks)		3mL	
			gestational age only)	indicated)	indicated)	
HBsAG, HBsAb, HCV Ab		6mL				
Intensive PK sample collection		22mL				
Sparse PK sample collection			8mL (last dose)			
Plasma sample collection (breast milk PK eligible only)			2-4mL (first and second week postpartum)			
Breast milk PK sample collection (if eligible)			X (first and second week postpartum and last dose)			
TOTAL BLOOD	17-21mL	28-31mL	11-23mL	8mL	6-11mL	

Safety labs should be done at Screening, every 4 weeks during *weekly visits*, and at each monthly visit

Maternal SoE

	SCR (*up to 2 weeks prior to entry*)	Entry/Intensive PK Sampling (*Days 0-3*)	Weekly (7 ± 2 days apart) (*weeks 1-11*)	Postpartum Visit (*within 3 days of delivery; if study drug regimen completed prior to delivery only*)	Monthly (Every 4 weeks ±2 weeks) (*until 24 weeks after delivery*)	Study Exit/ Early Discontinuation
Laboratory						
IGRA (3-4mL) (if needed and not available per medical record)	3-4mL					
Complete blood count (CBC)	3mL		3mL (every 4 weeks)	3mL (if clinically indicated)	3mL	
Liver Function tests	3mL		3mL (every 4 weeks)		3mL	
HIV-1 test (confirmatory tests as needed)	6mL					
CD4 count (HIV-1-infected only)		3mL				
Coagulation profile	5mL		5mL (at one visit at ≥34 weeks gestational age	5mL (if clinically	5mL (if clinically	
Plasma sample collection (breast milk PK eligible only)			2-4mL (first and second week postpartum)			
Breast milk PK sample collection (if eligible)			X (first and second week postpartum and last dose)			
TOTAL BLOOD	17-21mL	28-31mL	11-23mL	8mL	6-11mL	

Women who are taking the study drug regimen postpartum will have breast milk PK and plasma samples collected (refer to Section 6.3)

Infant SoE

	Newborn Visit (*within 3 days of life*)	Monthly (Every 4 weeks ± 2 weeks) (*until 24 weeks after delivery*)	Study Exit/Early Discontinuation
Clinical			
Assess eligibility for single PK sampling	X		
Physical exam	X	X	X
Record/update medical and medications history	X	X	X
Assess TB symptoms, risk and exposure		X	X
Laboratory			
Single PK sample collection (if eligible)	2mL		
Coagulation profile (if eligible)	2mL	2 mL (if clinically indicated)	
Complete blood count (if clinically indicated)		1mL	
Liver Function Test (if clinically indicated)		2mL	
Cord blood (optional if eligible, during mother's delivery)	X		
TOTAL BLOOD	2-4mL	1-5mL	

History and physical at all visits

Infant SoE

	Newborn Visit (*within 3 days of life*)	Monthly (Every 4 weeks ± 2 weeks) (*until 24 weeks after delivery*)	Study Exit/Early Discontinuation
Clinical			
Assess eligibility for single PK sampling	X		
Physical exam	X	X	X
Record/update medical and medications history	X	X	X
Record/update AEs	X	X	X
Single PK sample collection (if eligible)	2mL		
Coagulation profile (if eligible)	2mL	2 mL (if clinically indicated)	
Complete blood count (if clinically indicated)		1mL	
Liver Function Test (if clinically indicated)		2mL	
Cord blood (optional if eligible, during mother's delivery)	X		
TOTAL BLOOD	2-4mL	1-5mL	

Infants are eligible for PK collection at Newborn visit if mother took the study drug regimen *within 72 hours of drawing the infant's blood*

Infant SoE

	Newborn Visit (*within 3 days of life*)	Monthly (Every 4 weeks ± 2 weeks) (*until 24 weeks after delivery*)	Study Exit/Early Discontinuation
Clinical			
Assess eligibility for single PK sampling	X		
Physical exam	X	X	X
Record/update medical and medications history	X	X	X
Record/update AEs	X	X	X
Provide available test results to mother	X	X	X
Coagulation profile (if eligible)	2mL	2 mL (if clinically indicated)	
Complete blood count (if clinically indicated)		1mL	
Liver Function Test (if clinically indicated)		2mL	
Cord blood (optional if eligible, during mother's delivery)	X		
TOTAL BLOOD	2-4mL	1-5mL	

Coagulation profile should be collected at Newborn visit if mother is taking the study drug regimen

Infant SoE

	Newborn Visit (*within 3 days of life*)	Monthly (Every 4 weeks ± 2 weeks) (*until 24 weeks after delivery*)	Study Exit/Early Discontinuation
Clinical			
Assess eligibility for single PK sampling	X		
Physical exam	X	X	X
Record/update medical and medications history	X	X	X
Record/update AEs	X	X	X
Provide available test results to mother	X	X	X
Assess TB symptoms, risk and exposure		X	X
Laboratory			
Single PK sample collection (if eligible)	2mL		
Cord blood (optional if eligible, during mother's delivery)	X		
TOTAL BLOOD	2-4mL	1-5mL	

Infants are eligible for the cord blood collection if mother took the study drug regimen *within 72 hours prior to delivery*

Infant SoE

	Newborn Visit (*within 3 days of life*)	Monthly (Every 4 weeks ± 2 weeks) (*until 24 weeks after delivery*)	Study Exit/Early Discontinuation
Clinical			
Assess eligibility for single PK sampling	X		
Physical exam	X	X	X
Record/update medical and medications history	X	X	X
Record/update AEs	X	X	X
Provide available test results to mother	X	X	X
Assess TB symptoms, risk and exposure		X	X
Laboratory			
Safety labs collected at *each* monthly visit			
Complete blood count (if clinically indicated)		1mL	
Liver Function Test (if clinically indicated)		2mL	
Cord blood (optional if eligible, during mother's delivery)	X		
TOTAL BLOOD	2-4mL	1-5mL	

MOP Guidance

MATERNAL VISITS				INFANT VISITS		
Maternal Visits per SoE	Gestational Age/Weeks Postpartum	Maternal Target Date	Maternal Visit Window	Infant Visits per SoE	Infant Target Date	Infant Visit Window
Entry	34 weeks	1 DEC 2016				
Week 1	35 weeks	8 DEC 2016	6 DEC – 10 DEC			
Week 2	36 weeks	15 DEC 2016	13 DEC – 17 DEC			
Week 3	37 weeks	22 DEC 2016	20 DEC – 24 DEC			
Week 4	38 weeks	29 DEC 2016	27 DEC – 31 DEC			
Week 5	39 weeks	5 JAN 2017	3 JAN – 7 JAN			
Assume Delivery at 40 weeks on 12 January 2017						
Week 6	40 weeks	12 JAN 2017	10 JAN – 14 JAN	Newborn visit	12 JAN 2017	10 JAN – 14 JAN
Week 7	1 Week PP	19 JAN 2017	17 JAN – 21 JAN			
Week 8	2 Week PP	26 JAN 2017	24 JAN – 28 JAN	Week 4	9 FEB 2017	26 JAN – 23 FEB
Week 9	3 Week PP	2 FEB 2017	31 JAN – 4 FEB			
Week 10	4 Week PP	9 FEB 2017	7 FEB – 11 FEB			
Week 11	5 Week PP	16 FEB 2017	14 FEB – 18 FEB			
Maternal Weekly Visits End – Monthly Visits Begin						
Week 15	9 weeks PP	16 MAR 2017	2 MAR – 30 MAR	Week 8	9 MAR 2017	23 FEB – 23 MAR
Week 19	13 weeks PP	13 APR 2017	30 MAR – 27 APR	Week 12	6 APR 2017	23 MAR – 20 APR
Week 23	17 weeks PP	11 MAY 2017	27 APR – 25 MAY	Week 16	4 MAY 2017	20 APR – 18 MAY
Week 27	21 weeks PP	8 JUN 2017	25 MAY – 22 JUN	Week 20	1 JUN 2017	18 MAY – 15 JUN
Week 31	25 weeks PP	6 JUL 2017	22 JUN – 20 JUL	Week 24	29 JUN 2017	15 JUN – 13 JUL

IMPAACT 2001
SCHEDULE OF EVALUATIONS

What are your questions about the SoE?

PK-RELATED PROCEDURES: ENTRY AND WEEKLY VISITS

VERSION 1.0, 10 NOVEMBER 2015

WITH LOA 1-2, CM 1-3

ENTRY / INTENSIVE PK VISIT

Planning and preparation in anticipation of the visit

- Inform/remind woman of what to expect
- Remind participant to refrain from eating 2 hours *prior* to pharmacokinetic (PK) sampling dose
- Determine if the participant will stay at the site on the first day of the Entry visit or return the following day for continuation of intensive PK collection

ENTRY / INTENSIVE PK VISIT

Prior to Expected Enrollment Date

- Ensure availability and easy access to required supplies
  - Specimen collection materials
  - Meal
  - Source documents and case report forms (CRFs)
  - Paper-based eligibility checklist
  - What else?

ENTRY / INTENSIVE PK VISIT

Morning of Enrollment Date

- Review and confirm informed consent for study participation
- Assess TB symptoms, risk and exposure
- Assess fetal movement and heart sounds
- Update history and perform targeted physical exam:
  - Temperature, pulse, blood pressure, and respirations
  - Height and weight
  - Any other clinically appropriate evaluations
- Record baseline AEs
- Confirm final eligibility determination and enter checklist data into SES to enroll mother-infant pair

ENTRY / INTENSIVE PK VISIT

Following Enrollment

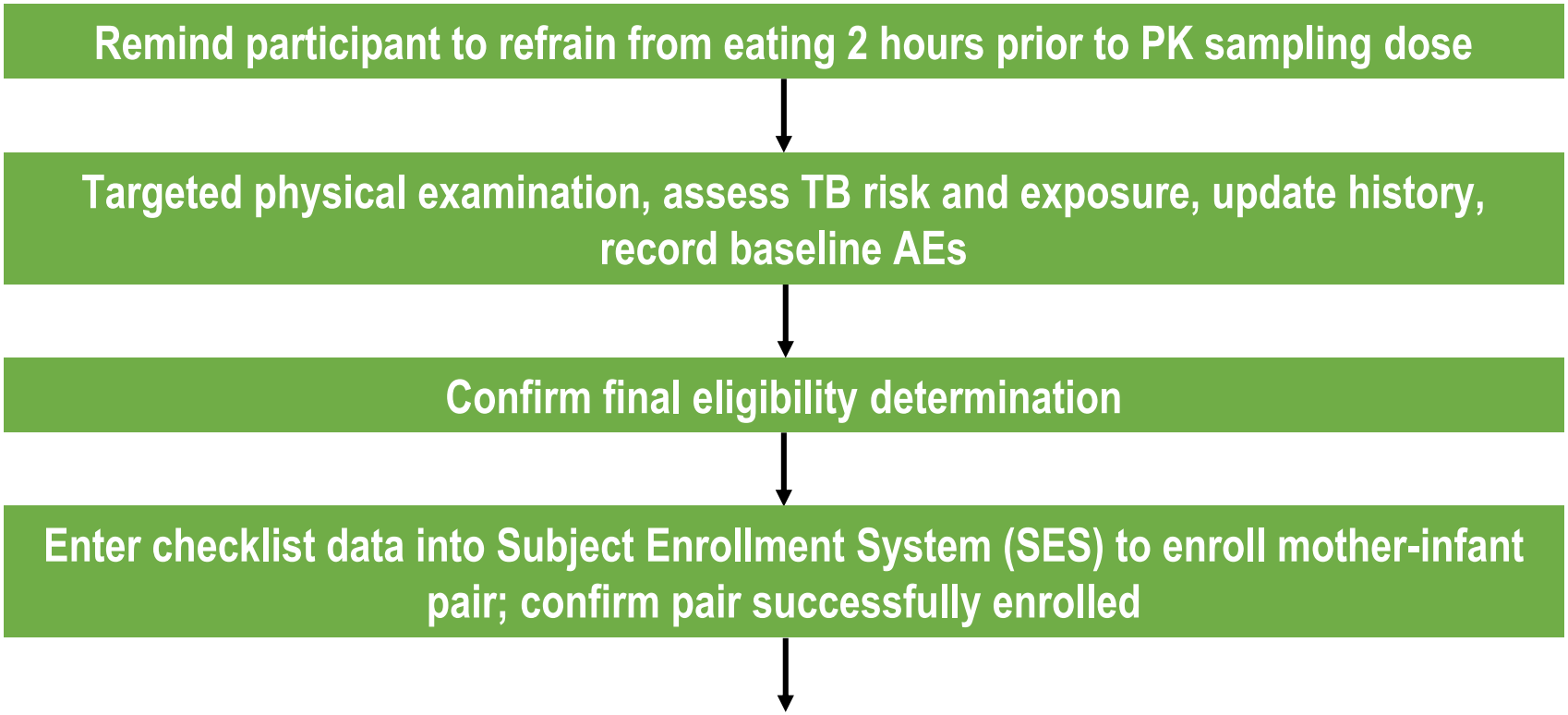
- Prescribe and dispense study drug regimen (RPT, INH, and pyridoxine)
- Provide meal to be eaten within 30 minutes of study drug administration
- Initiate Intensive PK and collect samples at the following time points: prior to first dose (t0), 0.5h, 1h, 2h, 4h, 5h, 8h, 12h, 24h, 48h, and 72h after the observed dose
  - Intensive PK must be initiated on the same day as the first dose of the study drug regimen
  - Participants should withhold further intake of food or drink (except water) until 3-4 hours after the dose.

ENTRY / INTENSIVE PK VISIT

Following Enrollment

- Collect blood for hepatitis testing (all women) and CD4 count (HIV-1-infected only)
- Provide any available findings or test results from screening
- Inform participant of the signs and symptoms of active TB

SEQUENCE OF INTENSIVE PK-RELATED PROCEDURES



SEQUENCE OF INTENSIVE PK-RELATED PROCEDURES

Provide meal within 30 minutes of scheduled study drug administration
Pre-dose blood draw (t0, morning of study Day 0)

↓

Dispense study drug regimen (RPT, INH, and pyridoxine)

↓

0.5 hour blood draw (withhold intake of food or drink).

↓

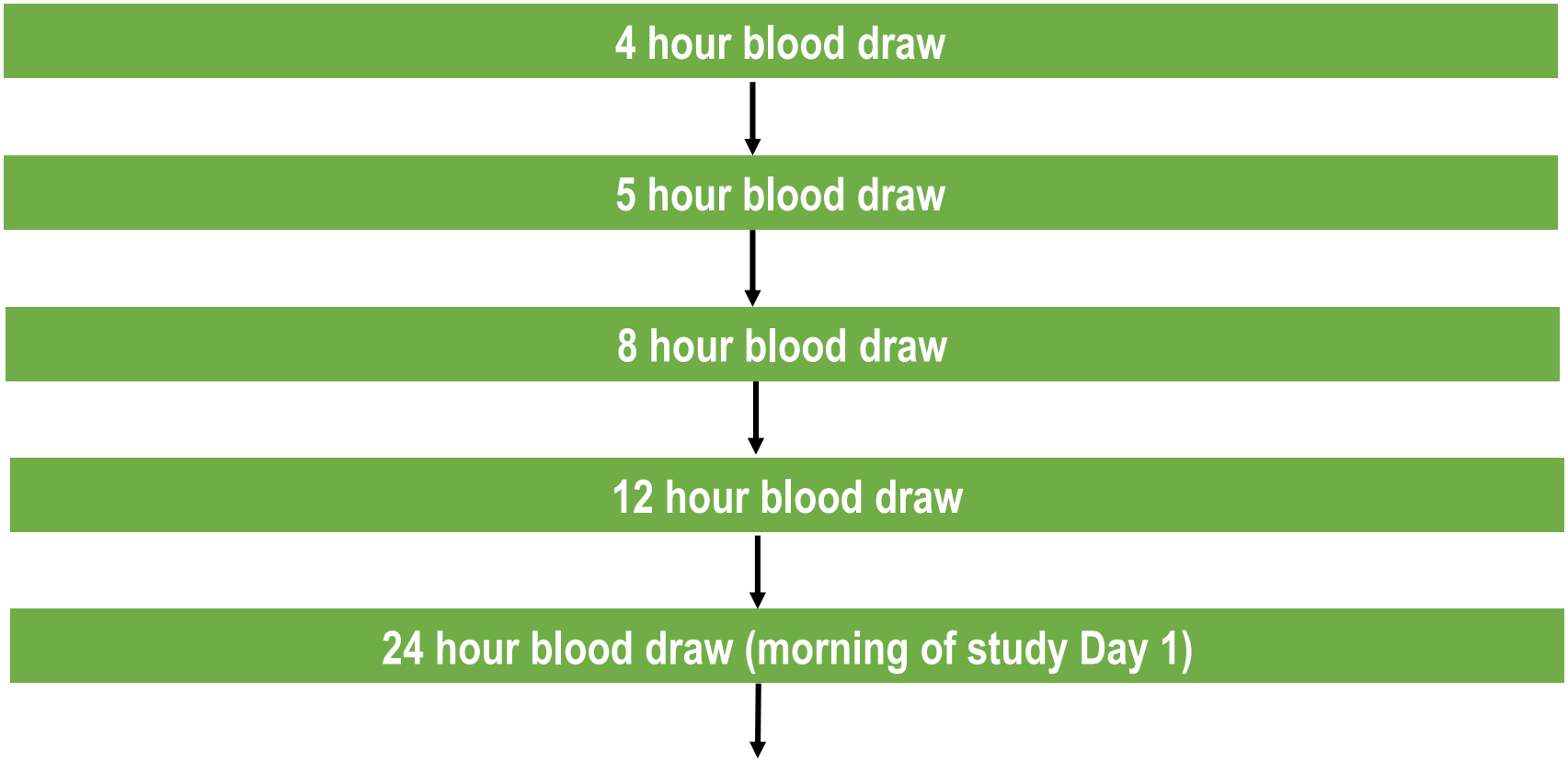
1 hour blood draw (withhold intake of food or drink)

↓

2 hour blood draw (withhold intake of food or drink)

↓

SEQUENCE OF INTENSIVE PK-RELATED PROCEDURES



SEQUENCE OF INTENSIVE PK-RELATED PROCEDURES

48 hour blood draw (morning of study Day 2)

↓

72 hour blood draw (morning of study Day 3)

↓

Provide any available test or laboratory results

↓

Schedule Week 1 visit and provide site contact instructions

SPARSE PK VISIT

- Sparse PK collection will be conducted on the visit of the woman's last dose of the study drug regimen or final weekly visit (ideally week 11)
- Prescribe and dispense study drug regimen (RPT, INH, and pyridoxine)
- Provide meal to be eaten within 30 minutes of study drug administration
  - Remind participant to refrain from eating 2 hours *prior* to PK sampling dose
- Sparse PK and collect samples at the following time points:
  - 1h, 4h, 24h, and 48h after the observed dose
- Participants should withhold further intake of food or drink (except water) until 3-4 hours after the dose.

BREAST MILK PK AND PLASMA COLLECTION

- Women who are taking the study drug regimen and breastfeeding postpartum are eligible to participate in the breast milk PK and plasma collection
- Prescribe and dispense study drug regimen (RPT, INH, and pyridoxine)
- Provide meal to be eaten within 30 minutes of study drug administration
  - Remind participant to refrain from eating 2 hours *prior* to PK sampling dose
  - Participants should withhold further intake of food or drink (except water) until 3-4 hours after the dose.

First Weekly Visit After Delivery	Second Weekly Visit After Delivery	Last Study Drug Dose Visit
Collect breast milk and plasma **3-4 hours** after the study drug dose	Collect breast milk and plasma **6 hours** after the study drug dose	Collect breast milk ***only*** **24 hours** after the study drug dose

CORD BLOOD PK COLLECTION

- Women who have taken the study drug regimen *within 72 hours prior to delivery* are eligible to participate in the cord blood PK collection
- There will be no cord blood collection from women who deliver at home or at a non-research facility.
- If feasible, the cord blood will be collected when delivery takes place in the clinic during the hours when a study nurse is available. However, if it is possible to collect cord blood during off clinic hours, then collect it following your institution's chain of custody procedure.
- See Laboratory Processing Chart (LPC) for shipping guidance and Manual of Procedures (MOP) for collection instructions

INFANT SINGLE PK COLLECTION

- Infants meeting the following criteria should have a single PK sample collected at the Newborn visit:
  - Infant birth weight > 1000 grams
  - Infant NOT receiving disallowed medications described in protocol Section 5.5
  - Infant does not have any severe congenital malformation or other medical condition not compatible with life or that would interfere with study participation or interpretation, as judged by the site investigator
  - The mother's most recent dose was taken *within 72 hours of drawing the infant's blood*
- Ideally, the single PK sample should be collected prior to the mother being discharged from the hospital
- See Laboratory Processing Chart (LPC) for further instructions

PK-RELATED PROCEDURES: ENTRY AND WEEKLY VISITS

What are your questions?