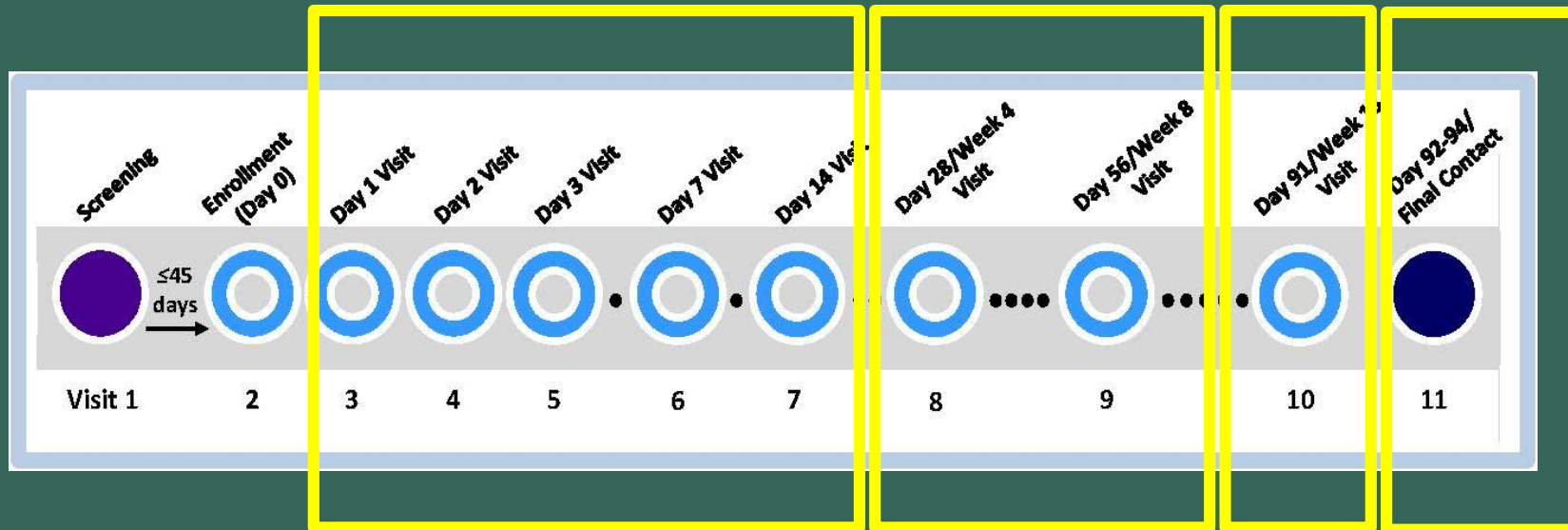


# FOLLOW-UP VISIT CONSIDERATIONS

MTN-036/ IPM 047 STUDY-SPECIFIC TRAINING



# TYPES OF FOLLOW-UP VISITS

## Scheduled Visits:

- Split visits permitted except for Visit 3/ Day 1 and Visit 4/ Day 2.
- Must occur on same day:
  - HIV counseling with HIV testing;
  - CASI with Ring Adherence CRFs
  - All PK/DP and DVP specimen collection; and with Ring Adherence CRFs and Ring Insertion and Removal CRF

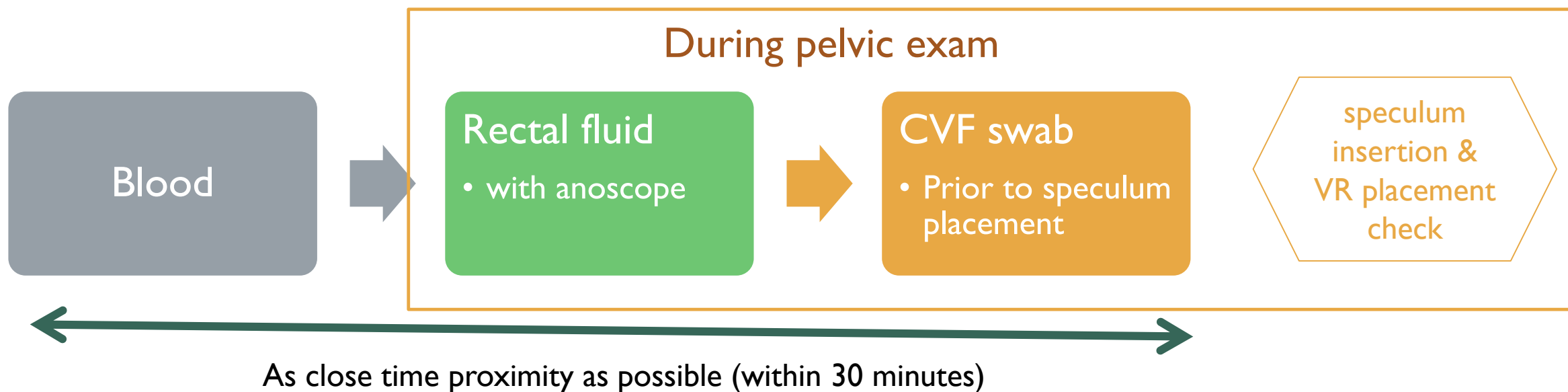
## Interim visits:

- Phone calls and clinic visits that take place between scheduled visits.
- Procedures required will depend on the reason for the visit
  - For administrative reasons,
  - For product-related reasons
  - In response to AEs and/or SAEs.
  - For additional STI counseling and testing in response to STI symptoms.
  - For any needed HIV counseling and testing in response to participant report of symptoms consistent with acute infection or presumed exposure to HIV.
  - For other reasons at participant request

## VISITS 3-7 (DAY 1, 2, 3, 7, AND 14)

<b>Administrative</b>	Co-enrollment check, update locator, provide results from last visit, schedule next visit, provide reimbursement, offer condoms
<b>Behavioral</b>	Ring Adherence CRF
<b>Counseling</b>	<i>HIV Pre-Post Test and STI Risk Reduction</i> Contraceptive Protocol Adherence
<b>Clinical</b>	Review/update medical/menstrual/meds history Assess AEs <i>Targeted Physical Exam</i> Pelvic Exam VR placement check Evaluate findings; <i>RX/refer for RTI/UTI/STI</i>
<b>Laboratory</b>	Blood – DVP levels, <i>CBC w/ platelets/diff., Syphilis, HIV</i> Pelvic – CVF for DVP levels, <i>NAAT for Trich and GC/CT, wet mount w/ pH</i> Rectal fluid (Days 3, 7, and 14 only) <i>Urine – Pregnancy/ dipstick/ Culture analysis</i>

## VISITS 3-7: SPECIMEN COLLECTION FOR DPV LEVELS



All specimens collected with VR in place

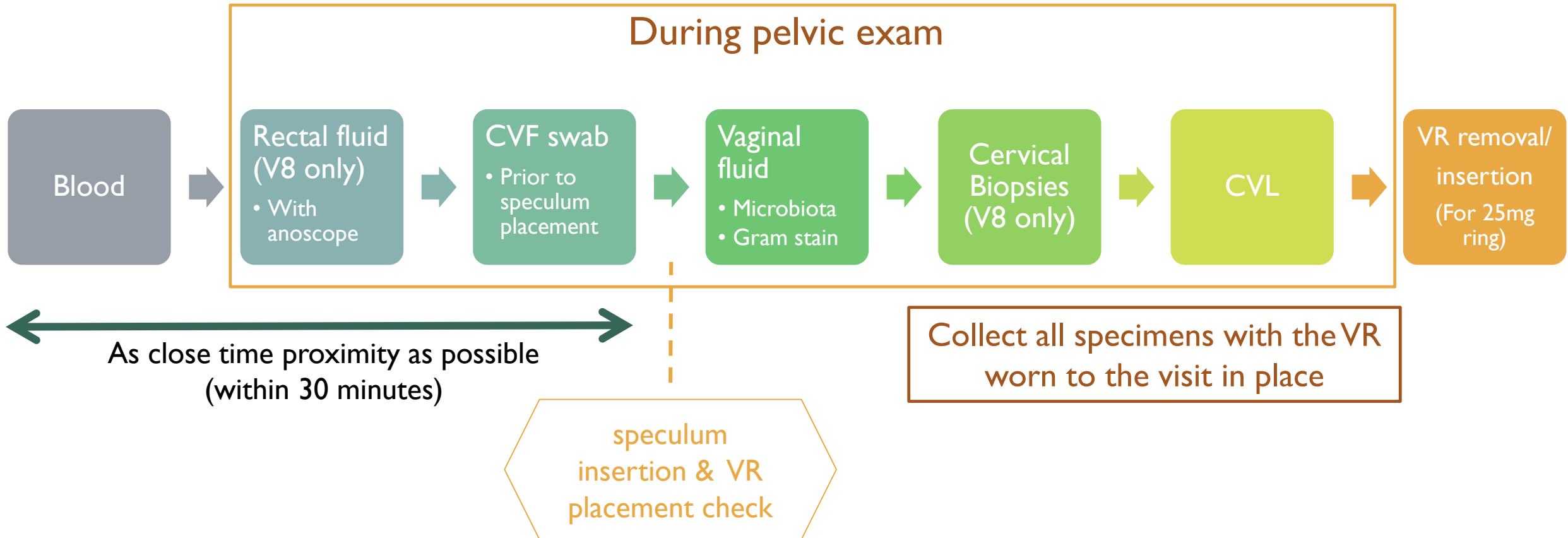
## VISITS 8 AND 9 (DAY 28 AND 56)

<b>Administrative</b>	Co-enrollment check, update locator, provide results from last visit, schedule next visit, provide reimbursement, offer condoms
<b>Behavioral</b>	Ring Adherence CRF Follow-up CASI questionnaire
<b>Counseling</b>	<i>HIV Pre-Post Test and STI Risk Reduction</i> Contraceptive Protocol Adherence

## VISITS 8 AND 9 (DAY 28 AND 56), CON'T

<b>Clinical</b>	<p>Review/update medical/menstrual/meds history</p> <p>Assess AEs</p> <p><i>Targeted Physical Exam</i></p> <p>Pelvic Exam</p> <p>VR placement check</p> <p>Evaluate findings; <i>RX/refer for RTI/UTI/STI</i></p> <p>VR re-supply (for ppts with 25mg VR)</p>
<b>Laboratory</b>	<p>Blood – DPV levels; <i>HIV-1, AST/ALT, CBC w/ platelets/Diff., Syphilis</i></p> <p>Pelvic – vaginal swabs for microbiota, CVF for DVP levels, Gram stain, cervical biopsies (Day 28 only), CVL, <i>NAAT for Trich and GC/CT, wet mount</i></p> <p>Rectal fluid (Day 28 only)</p> <p>Urine – Pregnancy, <i>dipstick/ Culture analysis</i></p>

# VISITS 8-9: SPECIMEN COLLECTION FOR DPV LEVELS AND VR PROCEDURES



## VISIT 10/ PUEV (DAY 91)/ EARLY TERMINATION

<b>Administrative</b>	Co-enrollment check, update locator, provide results from last visit, schedule next visit, provide reimbursement, offer condoms
<b>Behavioral</b>	Ring Adherence CRF Exit CASI questionnaire <i>IDI (if selected/agreed at enrollment)</i>
<b>Counseling</b>	HIV Pre-Post Test and STI Risk Reduction Contraceptive Protocol Adherence

**Serves as Early Study Termination Visit:** Complete all procedures and Study Discontinuation CRF

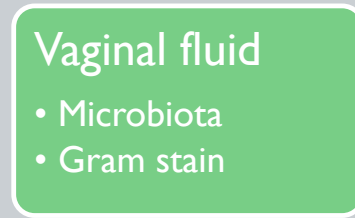
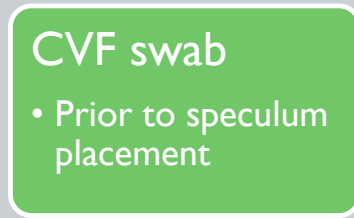
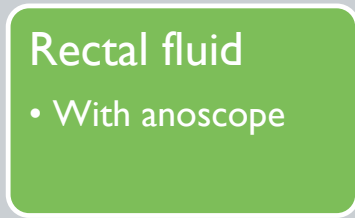
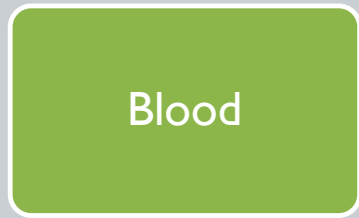


## VISIT 10/ PUEV (DAY 91) / EARLY TERMINATION, CON'T

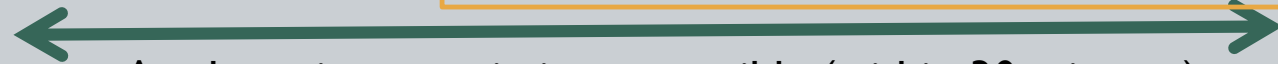
<b>Clinical</b>	Review/update medical/menstrual/meds history Assess AEs <i>Targeted Physical Exam</i> Pelvic Exam VR placement check Evaluate findings; <i>RX/refer for RTI/UTI/STI</i> VR removal
<b>Laboratory</b>	Blood – DPV levels, HIV-1, AST/ALT, CBC w/ platelets/Diff., <i>Syphilis</i> Pelvic – vaginal swab for microbiota, CVF for DVP levels, Gram stain, cervical biopsies, CVL, <i>NAAT for Trich and GC/CT, wet mount</i> Rectal fluid Urine – Pregnancy, <i>dipstick/ Culture analysis</i>

# VISIT 10/PUEV: SPECIMEN COLLECTION FOR DPV LEVELS AND VR PROCEDURES

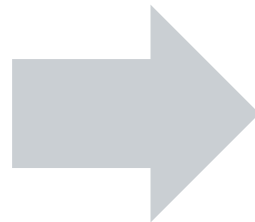
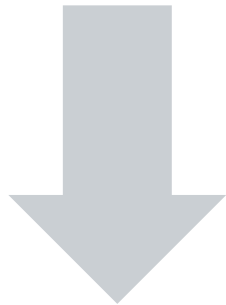
## Pre-VR Removal



## During pelvic exam



As close time proximity as possible (within 30 minutes)



## Post-VR Removal

\*Collect blood and CVF within 30 minutes

Hour 1

- Blood
- CVF

Hour 2

- Blood
- CVF

Hour 4

- Blood
- CVF
- CVL (w/ Speculum)

## VISIT 11 / FINAL CONTACT (IN-CLINIC)

<b>Administrative</b>	Update locator, provide results from last visit, schedule next visit if needed, provide reimbursement, offer condoms
<b>Behavioral</b>	None
<b>Counseling</b>	<i>HIV Pre-Post Test and STI Risk Reduction</i>
<b>Clinical</b>	Review/update medical/menstrual/meds history Assess AEs <i>Targeted Physical Exam</i> Evaluate findings; <i>RX/refer for RTI/UTI/STI</i>
<b>Laboratory</b>	Blood – DPV levels, <i>CBC w/ platelets/Diff.</i> Rectal fluid for DPV levels Pelvic – CVF for DPV levels, <i>wet mount</i> <i>Urine – Pregnancy, dipstick/ Culture analysis</i>

Schedule 24-72 hours  
after Visit 10/PUEV



QUESTIONS? COMMENTS?

