

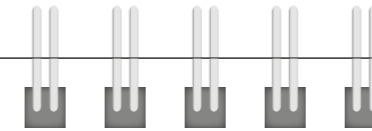
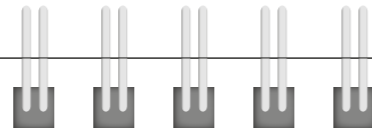
HPV

HUMAN
PAPILLOMA
VIRUS

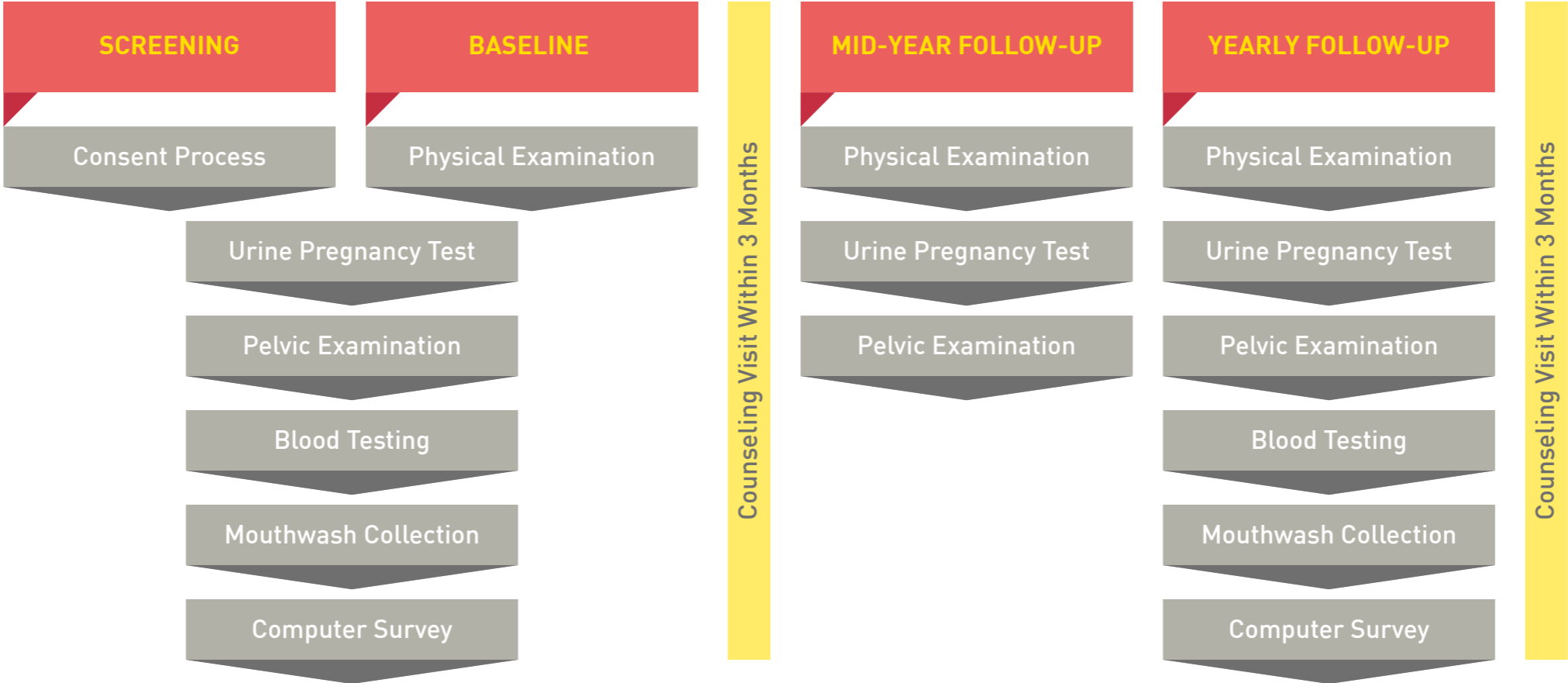
STUDY PROCEDURES

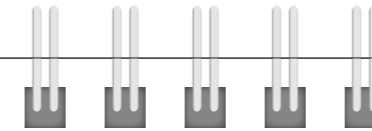
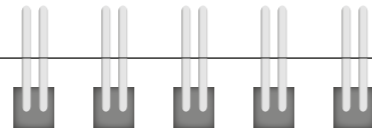
HPV in Adolescents Study

TREATASIA

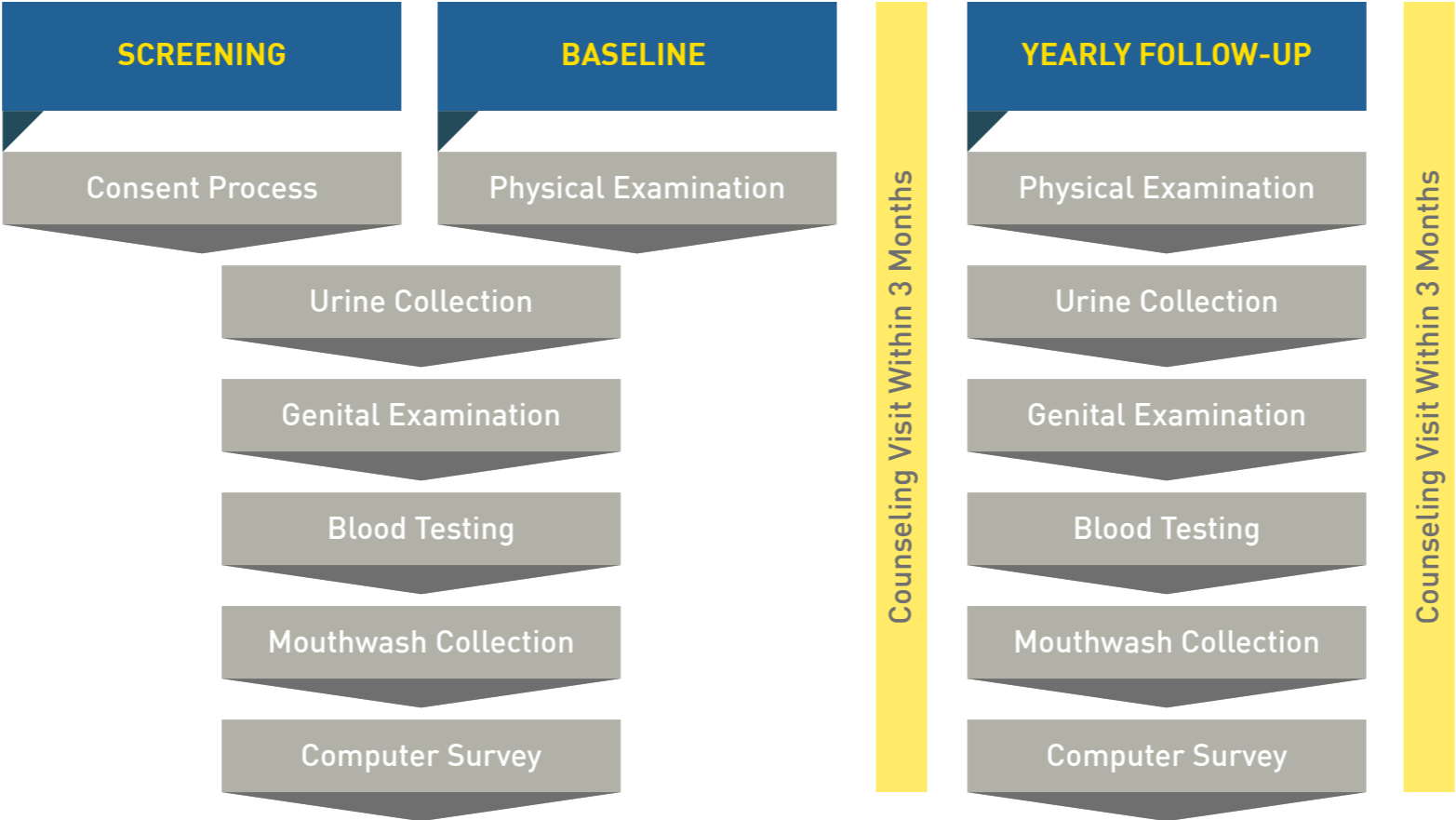


FEMALE - STUDY APPOINTMENTS





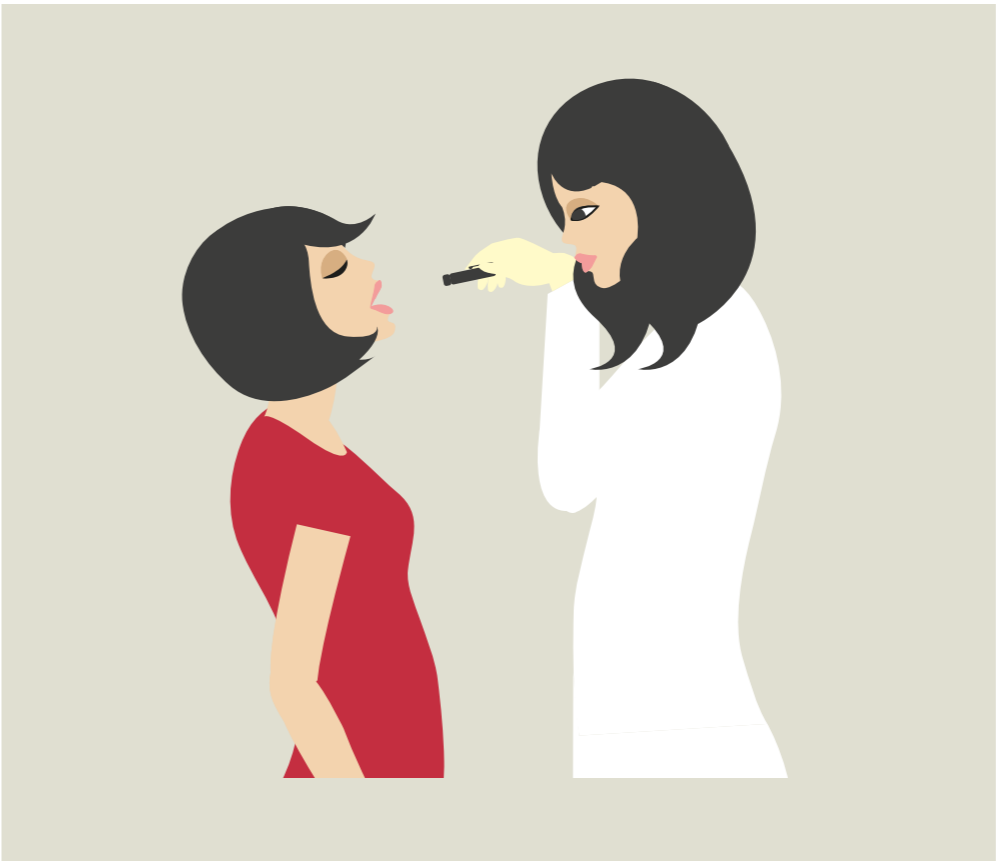
MALE - STUDY APPOINTMENTS



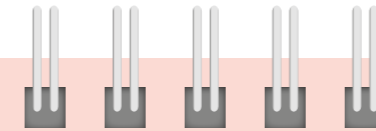
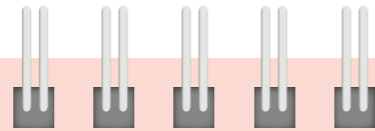
A
PHYSICAL EXAMINATION

Screening/ Baseline	6 Months	1 Year	1.5 Years	2 Years	2.5 Years	3 Years
>>	>>	>>	>>	>>	>>	>>

Screening/ Baseline	1 Year	2 Years	3 Years
>>	>>	>>	>>



TREATASIA

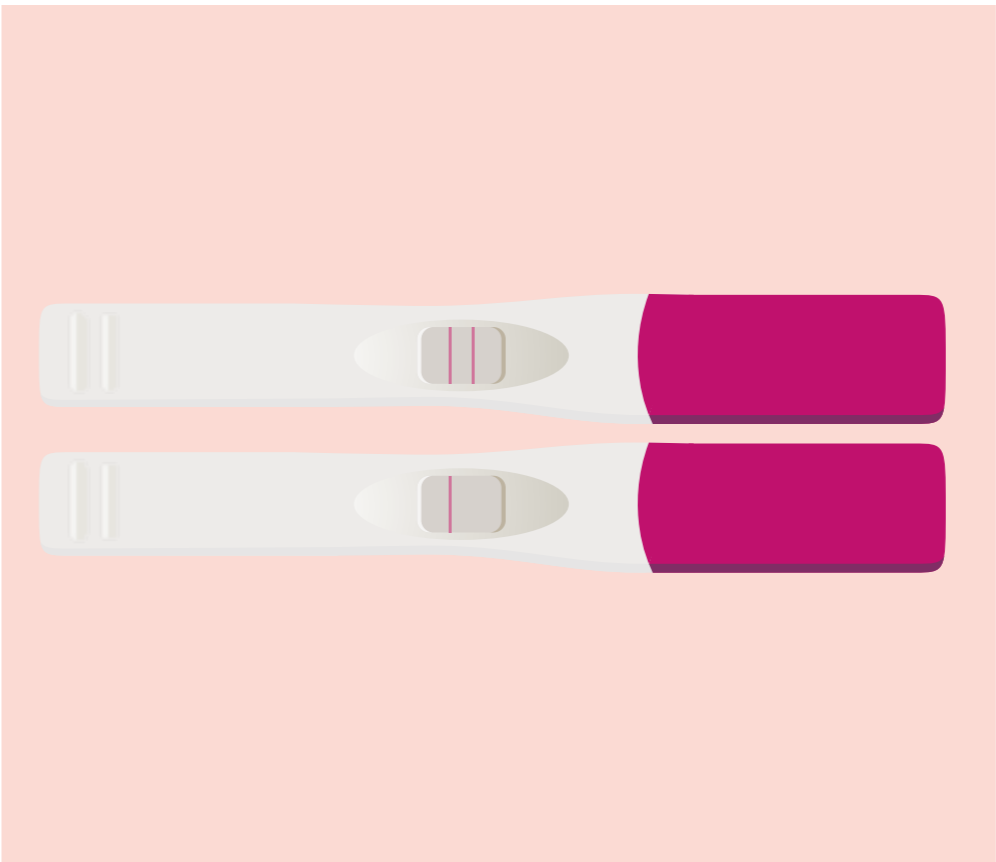
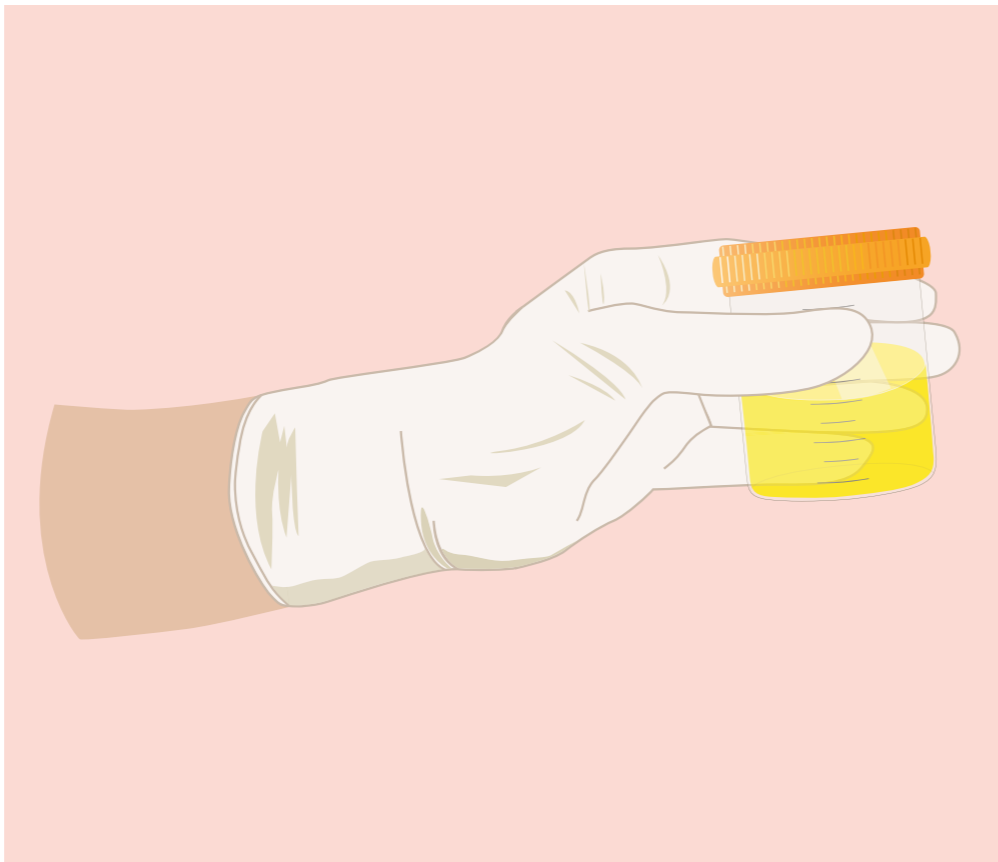


PROCEDURE NOTES for urine pregnancy tests:

- If the screening or baseline (week 0) pregnancy test is positive, the participant will be excluded from study participation.
- If a future test is positive, the participant will remain in the study but no procedures related to the pelvic examination will be conducted until after delivery.
- Any pregnant or post-partum participant may choose to withdraw from the study at any time.

B
URINE PREGNANCY TEST

Screening/ Baseline	6 Months	1 Year	1.5 Years	2 Years	2.5 Years	3 Years
➤	➤	➤	➤	➤	➤	➤



C URINE COLLECTION

Baseline



1 Year



2 Years

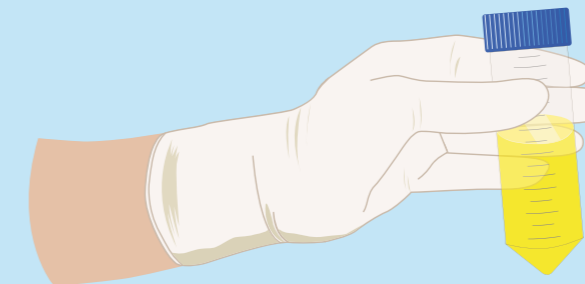


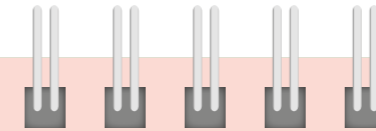
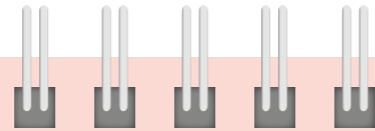
3 Years



PROCEDURE:

- Do not urinate for at least 1 hour before urine collection.
- Provide first-void urine (approximately 20 to 30 ml of initial urine stream) into the collection tube.
- Collection of a larger volume of urine may result in specimen dilution that may reduce test sensitivity.



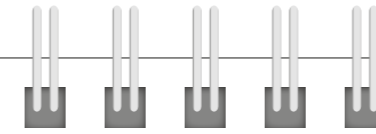
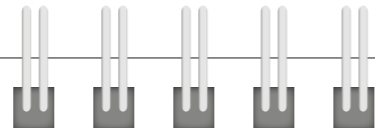


INSTRUCTIONS for pelvic examination:

- Participants should not have any type of sexual activity, including placing any products into the genitalia, for 24 hours before the study visit.
- Participants should not use vaginal suppositories for 24 hours before the study visit.
- If participants are menstruating or pregnant, please inform the study nurse to postpone their appointment, e.g., 3-7 days after menstruation, 6 weeks after delivery.

PROCEDURE NOTE for pelvic examination:

- At 6 months after the baseline visit and between yearly study visits, a vaginal sample will be collected for HPV-related testing using a cotton-like swab and without using a speculum.



D

PELVIC EXAMINATION AND SAMPLE COLLECTION I

Baseline



6 Months



1 Year



1.5 Years



2 Years



2.5 Years

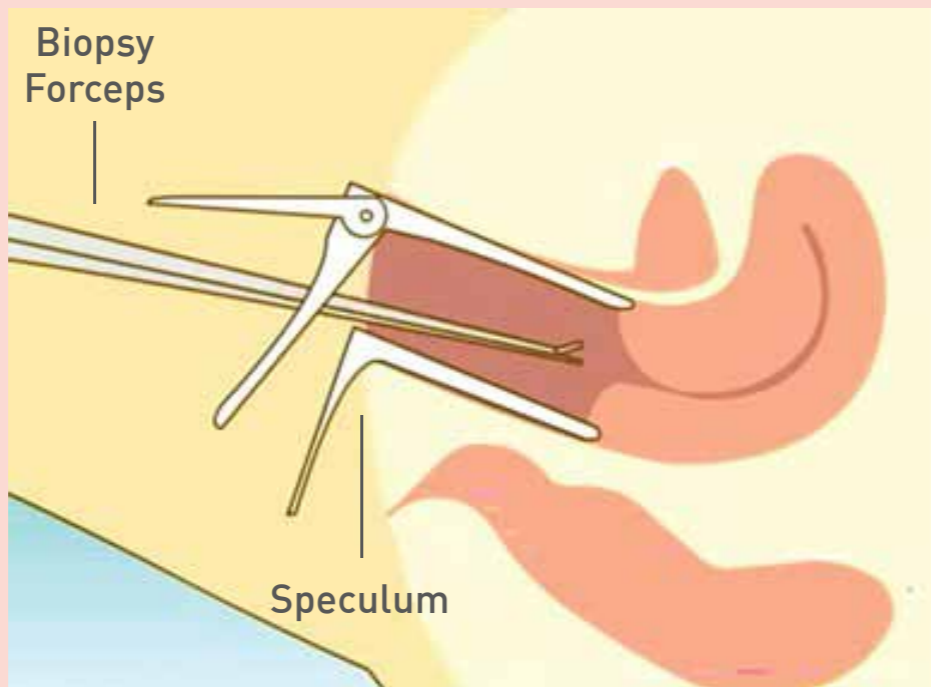


3 Years



TREATASIA





Cervical Biopsy

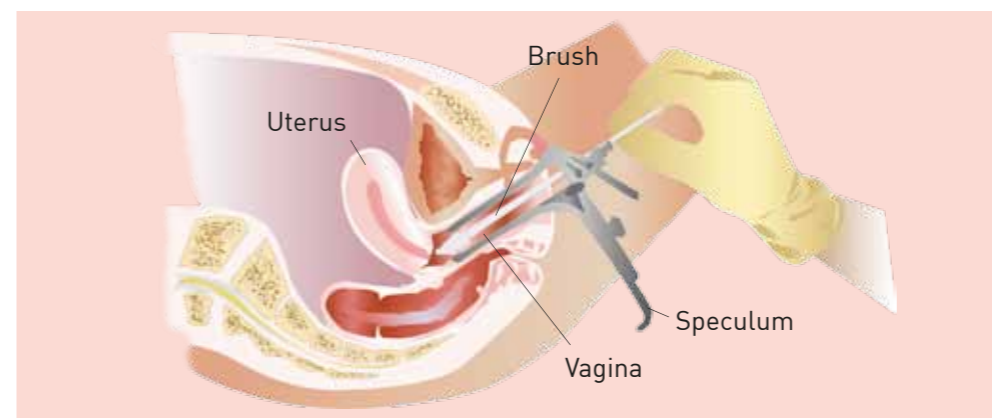
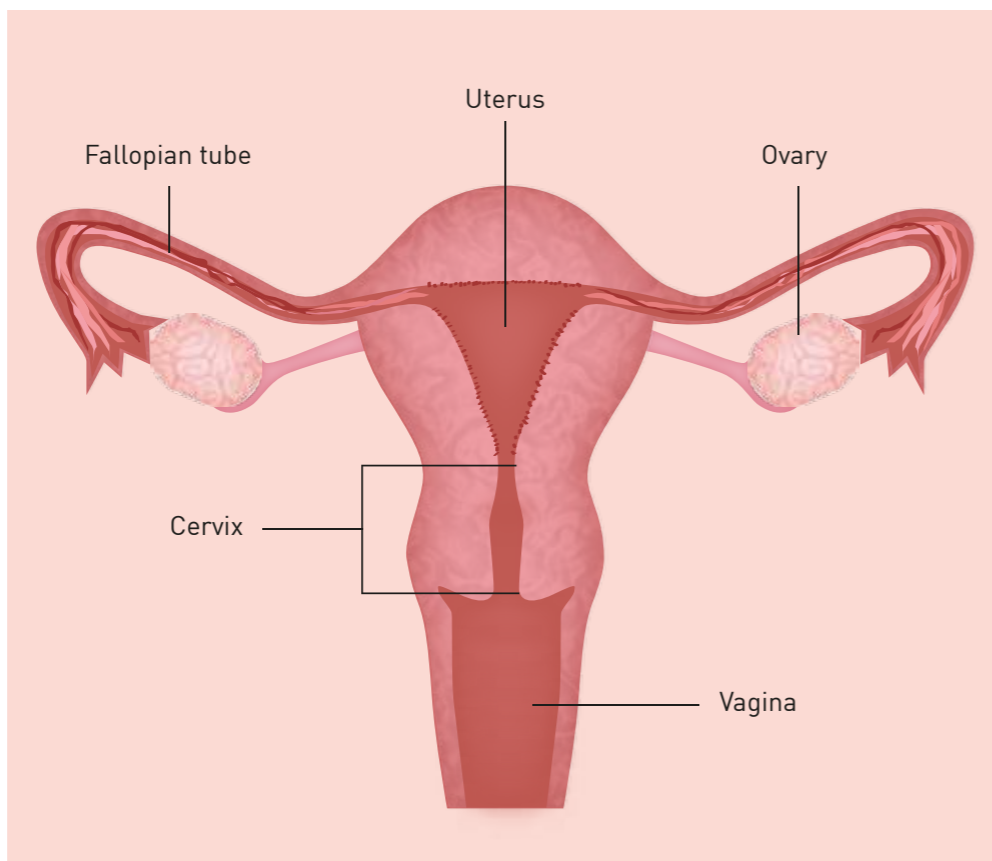
TREATASIA

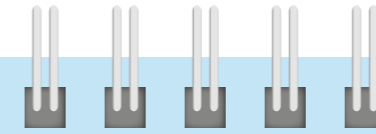
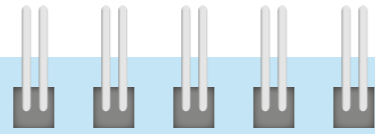
PROCEDURE NOTES for colposcopy with/without biopsy:

- Participants will be referred for colposcopy if they have mildly abnormal Pap smears (not pre-cancer) and the HPV-related laboratory tests are abnormal.
- Colposcopy is an examination using a special magnifying lens to look at the cervix. The doctor will apply diluted vinegar and Lugol's iodine solution to the cervix to identify abnormal areas. If abnormalities are seen, small samples of tissue may be taken for further laboratory testing (also known as a biopsy).
- Having pre-cancers or cancer would not affect the study participation, and participants would remain enrolled in the study.

D
**PELVIC EXAMINATION
AND SAMPLE
COLLECTION II**

Baseline	6 Months	1 Year	1.5 Years	2 Years	2.5 Years	3 Years
➤	➤	➤	➤	➤	➤	➤



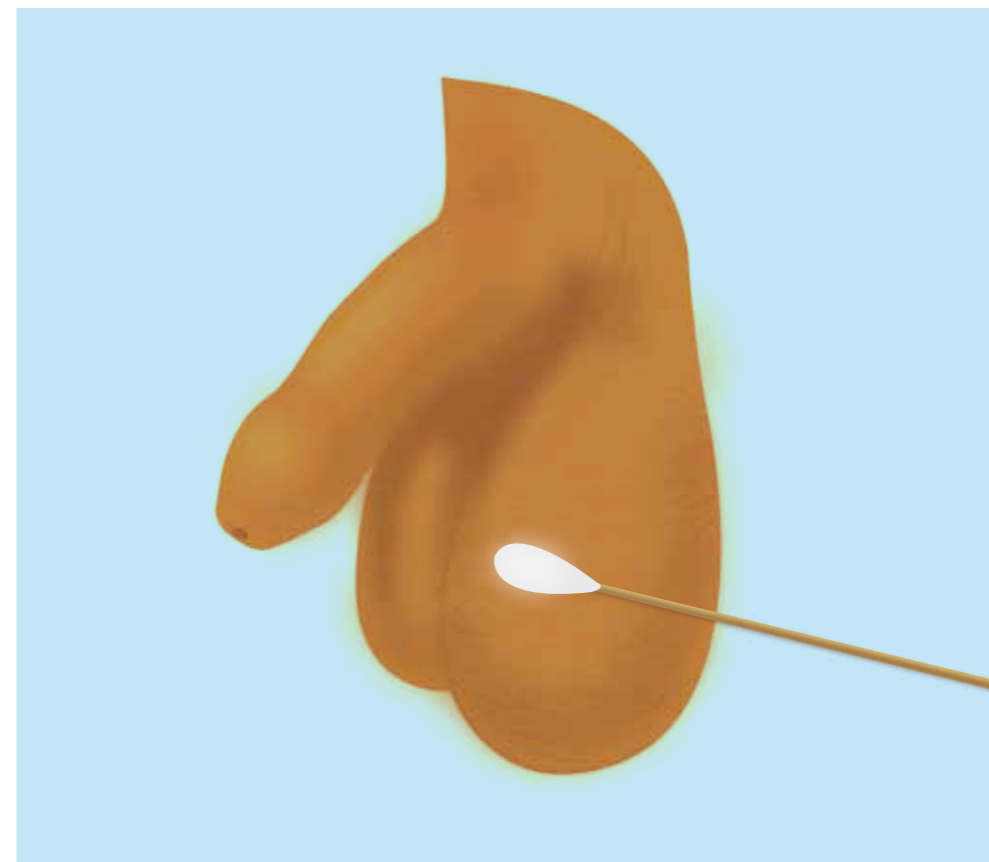
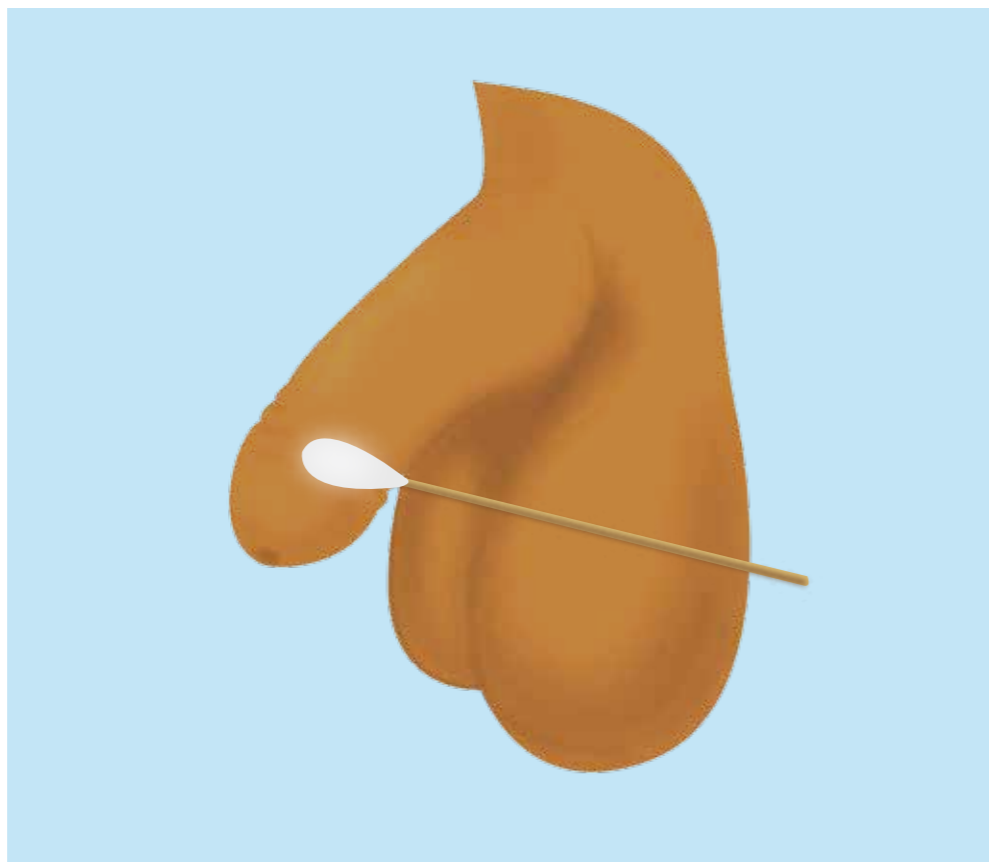


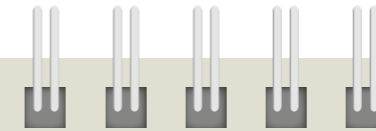
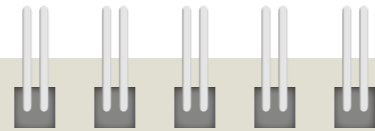
INSTRUCTION for male genital examination:

- Participants should not have any type of sexual activity for 24 hours before their study visits.

E
GENITAL EXAMINATION

Baseline	1 Year	2 Years	3 Years
➤	➤	➤	➤





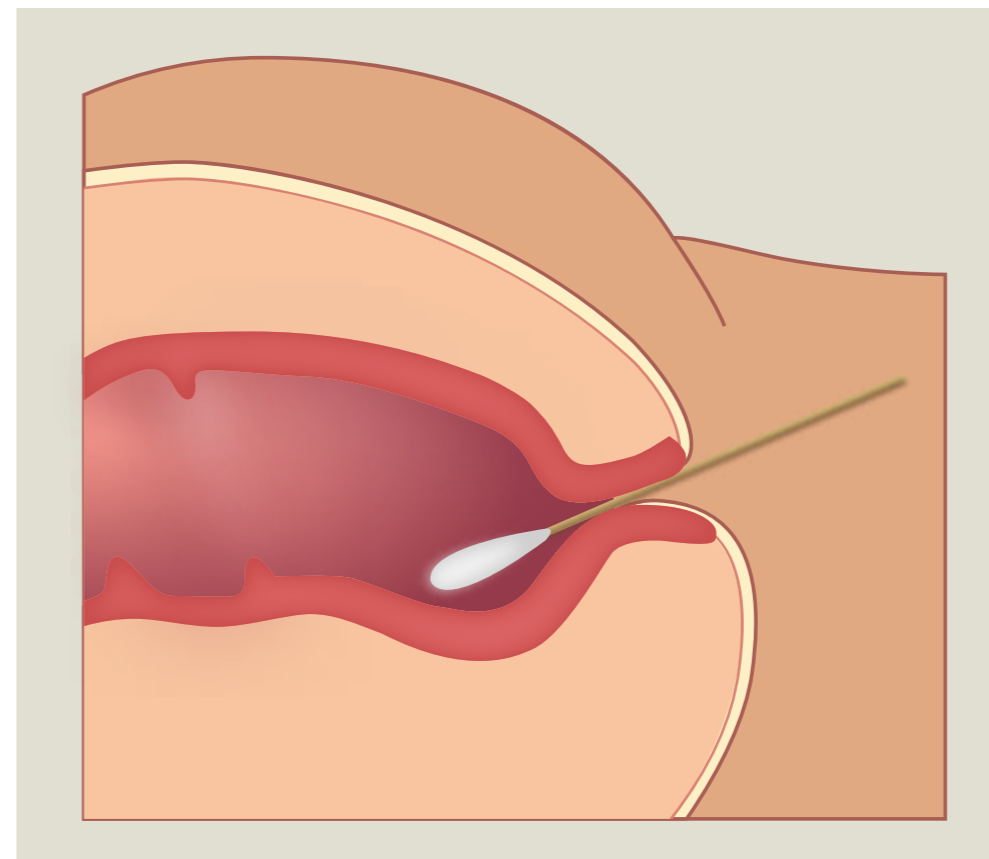
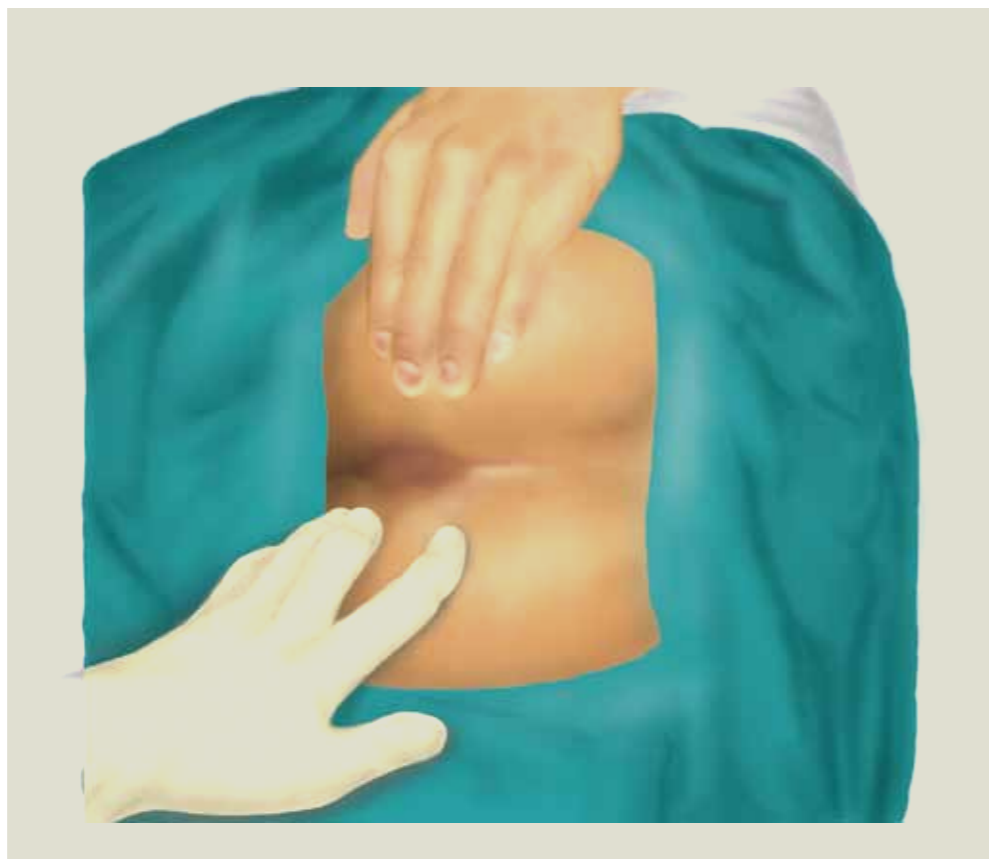
INSTRUCTIONS **for anal swab collection:**

- Participants should not have any type of sexual activity or place any products into the anus for 24 hours before their study visits.
- Participants should not use rectal suppositories for 24 hours before their study visits.

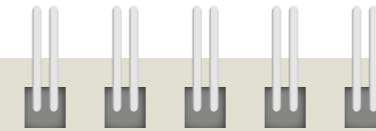
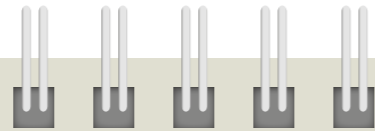
F
ANAL SWAB

Baseline	1 Year	2 Years	3 Years
➤	➤	➤	➤

Baseline	1 Year	2 Years	3 Years
➤	➤	➤	➤



TREATASIA



INSTRUCTION for blood testing:

- If participants are having a fasting blood test done, they should not eat or drink anything other than water for at least 8 hours before their study visits.

PROCEDURE NOTES for blood testing:

- Participants may not need to repeat some of the laboratory tests (complete blood count, CD4, HIV RNA viral load, and serum chemistry) that were previously tested within 12 weeks prior to the baseline (week 0) visit. However, copies of the laboratory reports are required for the study record.
- A total of 17 ml blood (3.5 teaspoons) will be collected at each visit.

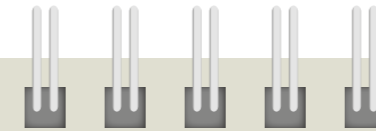
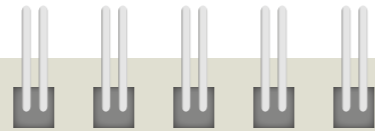
G
BLOOD TESTING

Screening/ Baseline ➤	1 Year ➤	2 Years ➤	3 Years ➤
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Screening/ Baseline ➤	1 Year ➤	2 Years ➤	3 Years ➤
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TREATASIA



INSTRUCTIONS for mouthwash collection:

- Participants should not use mouthwash on the morning of their study visits.
- Participants should not brush their teeth right before their oral sample collection process.

PROCEDURE NOTES for mouthwash collection:

- Try to instruct the participant to gargle such that the mouthwash to contact with the oropharyngeal area for sampling remains.
- Regardless of the amount of the oral rinse sample in the collection cup, do not have the participant regargle.
- If the participant cannot gargle the whole 10 ml mouthwash at once, please instruct them to gargle 2 times with 5 ml each.
- Please encourage the participant to gargle for 30 seconds before spitting out into the collection cup or for as long as they can.

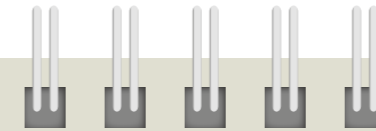
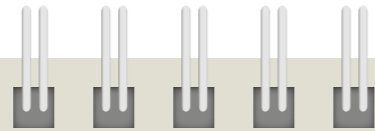
H MOUTHWASH COLLECTION

Baseline	1 Year	2 Years	3 Years
➤	➤	➤	➤
Baseline	1 Year	2 Years	3 Years
➤	➤	➤	➤

PROCEDURE:

- Rinse mouth with 10 ml of normal saline solution for 10 seconds and spit out.
- Gargle with 10 ml of SCOPE[®] mouthwash for 30 seconds and spit back into the specimen collection cup.





PROCEDURE NOTES for computer survey:

- The ACASI responses will be confidential, except in cases of suspected or confirmed immediate danger to the adolescents, when a parent/ legal guardian will be informed.
- Participants do not need to repeat the ACASI for the HPV in Adolescents Study if it was previously completed within 12 weeks prior the baseline (week 0) visit.

I
COMPUTER SURVEY

Baseline	1 Year	2 Years	3 Years
➤	➤	➤	➤

Baseline	1 Year	2 Years	3 Years
➤	➤	➤	➤





ACKNOWLEDGEMENTS

Funder:

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National Institutes of Health, USA

Participating sites:

1. HIV Netherlands-Australia-Thailand Research Collaboration (HIV-NAT)/
Thai Red Cross AIDS Research Centre (TRC-ARC), Bangkok, Thailand
2. Siriraj Hospital, Bangkok, Thailand
3. Chiangrai Prachanukroh Hospital, Chiangrai, Thailand
4. Children's Hospital 1, Ho Chi Minh City, Vietnam
5. Hung Vuong Hospital, Ho Chi Minh City, Vietnam

Central laboratory and data management center:

HIV-NAT/ Thai Red Cross AIDS Research Centre, Bangkok, Thailand

Coordinating and management center:

TREAT Asia/ amfAR – The Foundation for AIDS Research, Bangkok, Thailand