Sayana Press Extension Codebook

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FSN

ACCEPTABILITY (ACCEPT-1)
Sayana® Press Extension

FHI 360 study # 926400 STUDY	Participant # SSID ☐☐☐☐
Site # CN ☐☐☐	Contact date CONDTE ☐☐/☐☐/☐☐☐☐ (day/MON/year)

1	Visit ACVISIT SP_VIS	☐☐	00=Enrollment →**skip to #4** 04=Month 4 08=Month 8 12=Month 12 99=Early Discontinuation

<u>Vaginal Bleeding</u>: Questions 2-9 → Read each answer choice aloud to participant. At enrollment, questions 4-8 refer to her bleeding over the past 3 months; at follow-up, questions 4-8 refer to her bleeding since her last injection.

2	Have you had bleeding since your last injection?	☐1 yes ACBLEED SP_YN ☐0 no → **skip to #9**
3	Has your bleeding been "regular" or "irregular" since your last injection?	☐1 regular ACBLREG SP_REG ☐2 irregular
4	How would you describe your bleeding?	☐1 bleeding only ACBLDESC SP_BLD ☐2 spotting only → **skip to #6** ☐3 bleeding and spotting
5	Usual amount of flow	☐1 light ACFLOW SP_FLW ☐2 moderate ☐3 heavy
6	How do you feel about your bleeding frequency? ***(Check all that apply).*** SP_CHK	☐1 too infrequent ACFINFRQ ☐1 about right ACFRIGHT ☐1 too irregular ACFIRREG ☐1 too often ACFOFTEN
7	How do you feel about how long your bleeding/spotting lasts?	☐1 too short ACFLNGTH SP_LNG ☐2 about right ☐3 too long
8	How do you feel about how much you bleed?	☐1 too little ACFQUANT SP_QUN ☐2 about right ☐3 too much
9	***Only for women who responded "no bleeding" to #2 above*** Do you like not bleeding?	☐1 yes, specify why: ACNOBLD ACNOBLYT _____ ☐2 neutral SP_NEU ☐0 no, specify why: ACNOBLNT _____

<u>Product Use Acceptability</u>: Questions 10-16 are only completed at month 12 or visit of early discontinuation. Read each answer choice aloud to participant, <u>except</u> where noted.

10	Are you satisfied with Sayana Press?	☐1 very satisfied ACSATSFY SP_SAT ☐2 satisfied ☐3 neutral ☐4 dissatisfied ☐5 very dissatisfied

Version 2.0 last revised 26 Jan 2018 Completed by: _____ (initials)

Go to page 2

FSN2 SSID2

FHI 360 study # 926400	Participant # ☐☐☐☐
Site # CN2 ☐☐☐	Contact date CONDTE2 ☐☐/☐☐/☐☐☐☐ (day/MON/year)

11 What do you NOT like about Sayana Press? ***(Do NOT read response options aloud. Check all that apply.)***

INJECTION RELATED
- ☐ ACNSITE site of injection
- ☐ ACNPAIN pain at injection site
- ☐ ACNNDLE length of needle

DISCOMFORT
- ☐ ACNBACK backache
- ☐ ACNHEAD headache
- ☐ ACNABBLT abdominal bloating
- ☐ ACNABPN abdominal pain
- ☐ ACNBRST breast swelling, tenderness and/or pain
- ☐ ACNVGDIS vaginal discharge
- ☐ ACNVGDRY vaginal dryness

BLEEDING RELATED
- ☐ ACNAMEN amenorrhea
- ☐ ACNIRBLD irregular bleeding
- ☐ ACNSPOT spotting
- ☐ ACNHVBLD heavy bleeding
- ☐ ACNLFBLD less frequent bleeding

OTHER
- ☐ ACNFATG fatigue
- ☐ ACNMOOD mood changes
- ☐ ACNWTGN weight gain
- ☐ ACNACNE acne
- ☐ ACNLBDO decreased libido
- ☐ ACNLEFF length of effectiveness

SP_CHK

- ☐ ACNINO other **injection** effects, describe: ACNINOT _____
- ☐ ACNDSO other **discomfort** effects, describe: ACNDSOT _____
- ☐ ACNBLO other **bleeding** effects, describe: ACNBLOT _____
- ☐ ACNEFO other **effects**, describe: ACNEFOT _____
- ☐ ACNNOTH nothing (if this item is checked then none of the other responses should be checked)

12 What do you like about Sayana Press? ***(Do NOT read response options aloud. Check all that apply.)***

INJECTION RELATED
- ☐ ACLSITE site of injection
- ☐ ACLNDLE length of needle
- ☐ ACLPAIN injection not painful or less painful than prior DMPA IM injection(s)

BLEEDING RELATED
- ☐ ACLAMEN amenorrhea
- ☐ ACLLTBLD lighter bleeding
- ☐ ACLLFBLD less frequent bleeding

OTHER
- ☐ ACLLEFF length of effectiveness
- ☐ ACLDSCRT discreet
- ☐ ACLWTGN weight gain
- ☐ ACLSDEFF few side effects

SP_CHK

- ☐ ACLINO other **injection** effects, describe: ACLINOT _____
- ☐ ACLBLO other **bleeding** effects, describe: ACLBLOT _____
- ☐ ACLEFO other **effects**, describe: ACLEFOT _____
- ☐ ACLNOTH nothing (if this item is checked then none of the other responses should be checked)

13 Would you like to use Sayana Press as a 4-month method in the future if it is proven effective? ACUSE

SP_YN
- 1 yes
- 0 no → why? ACUSENT _____

14 Would you prefer to use Sayana Press….. ACFREQ

SP_FRQ
- 1 Every 3-months
- 2 Every 4-months
- 3 Don't have preference

15 Would you recommend Sayana Press to a friend or family member? ACRECOM

SP_YN ☐ yes ☐ no

16 If the family planning provider showed you how to give yourself Sayana Press, would you be willing to give yourself the injection? ACSELF

SP_YN ☐ yes ☐ no

ADVERSE EVENT (AE)

Sayana® Press Extension

FSN

STUDY

FHI 360 study # 926400	Participant # SSID ☐☐☐☐
Site # CN ☐☐☐	Contact date CONDTE ☐☐/☐☐☐/☐☐☐☐ (day/MON/year)

Adverse Event

1	Diagnosis	AETERM _____
2	Onset date AESTDTE	☐☐/☐☐☐/☐☐☐☐ (day/MON/year) ☐ AESTDEST SP_CHK check here if estimated
3	Relatedness to Sayana Press AEREL	☐1 related SP_REL ☐2 possibly related ☐3 not related
4	Serious AESER SP_YN	☐1 yes → **complete SAE & notify FHI 360 within 24 hrs** ☐0 no → **skip to #6**
5	Type of SAE AESECRI SP_SCR	☐1 results in death ☐2 is immediately life-threatening ☐3 requires inpatient hospitalization or prolongation of existing hospitalization ☐4 results in persistent or significant disability/incapacity ☐5 is a congenital anomaly/birth defect ☐6 jeopardizes participant or requires intervention to prevent any of the events listed above
5a	SAE onset date	☐☐/☐☐☐/☐☐☐☐ (day/MON/year) AESSTDTE
5b	SAE outcome date	☐☐/☐☐☐/☐☐☐☐ (day/MON/year) AESENDTE
6	Highest severity AESEV SP_SEV	☐1 mild ☐2 moderate ☐3 severe ☐4 possibly life threatening→ **complete SAE & notify FHI 360 within 24 hours** ☐5 death → **complete SAE & notify FHI 360 within 24 hours**
7	Treated with medication AEMED SP_YN	☐1 yes → **complete CONMED if prohibited drug, if not skip to #9** ☐0 no → **skip to #9**
8	FSN of CONMED(s)	AECMFSN1 ☐☐☐☐☐☐ AECMFSN2 ☐☐☐☐☐☐ AECMFSN3 ☐☐☐☐☐☐
9	Outcome AEOUT SP_OUT	☐1 resolved without sequelae ☐2 resolved with sequelae, specify: AESEQT _____ ☐3 condition became chronic ☐4 AE present at time of study discontinuation → **skip to #12** ☐5 participant died as a result of AE ☐6 unknown → **skip to #12**
10	Outcome date AEENDTE	☐☐/☐☐☐/☐☐☐☐ (day/MON/year) ☐ AEENDEST SP_CHK check here if estimated
11	Duration of AE if <24 hours	☐☐ Hours ☐☐ Min → **leave blank and skip to #12 if ≥24 hours** AEDURHH AEDURMM
12	Action taken with Sayana Press product AEACT SP_ACT	☐1 continued (no change) ☐0 discontinued → **complete FINAL**

FSN

BODY COMPOSITION (BODY)
Sayana® Press Extension

STUDY FHI 360 study # 926400	SSID Participant # ☐☐☐☐
Site # 003 CN	CONDATE Contact date ☐☐/☐☐/☐☐☐☐ (day/MON/year)

Only for use in the sub-study titled, "Body composition and bone mineral density in Brazilian users of Sayana® Press during the first year of use."

Pregnancy testing must ALWAYS be done before DXA scan.

1	Visit number	BOVISNUM SP_BOV	☐☐ 00=Enrollment (baseline) 08=Month 8 12=Month 12 99=Early Discontinuation/LTFU → **Skip to initials**
2	Urine pregnancy test result ***Document on this form at Month 8 only***	BOPRESLT SP_PR	☐ negative ☐ positive → **collect blood for MPA and complete PREG** ☐ indeterminate ☐ not done
3	Weight	BOWEIGHT	☐☐☐.☐ kg
4	Height	BOHEIGHT	☐☐☐.☐ cm
5	Central-peripheral fat ratio	BOFTCPR	☐.☐☐
6	Percentage of total fat mass	BOFTPCT	☐☐.☐ %
7	Total body mass	BOTLMSS	☐☐☐.☐ kg
8	Fat mass	BOFTMSS	☐☐.☐☐☐ kg
9	Lean mass	BOLNMSS	☐☐.☐☐☐ kg
10	Fat Mass Index by DXA	BOFMIDXA	☐☐.☐ kg / height^2 (m^2)
11	Bone mineral density of lumbar spine (L1-L4)	BOLSBMD	☐.☐☐☐ (g/cm^2)
12	Lumbar spine (L1-L4) T-score	BOLSTS	☐.☐
13	Bone mineral density of femoral neck (total)	BOFNBMD	☐.☐☐☐ (g/cm^2)
14	Femoral neck (FN) T-score	BOFNTS	☐.☐

FSN

FHI 360 study # 926400 STUDY	Participant # ☐☐☐☐ SSID
Site # CN ☐☐☐	Contact date CONDTE ☐☐/☐☐/☐☐☐☐ (day/MON/year)

Demographics

1	Date of birth	BABIRDTE	☐☐/☐☐/☐☐☐☐ (day/MON/year)
2	Marital status	BAMAR / SP_MAR	☐ 1 married/cohabitating ☐ 2 regular non-cohabitating partner ☐ 3 no regular partner → **she is ineligible, finish form & complete FINAL**
3	Full years of education	BAEDUC	☐☐
4	Race	BARACE / SP_RCE	☐ 1 white ☐ 2 asian ☐ 3 black ☐ 4 biracial/pardo ☐ 5 other, specify: BAROTHT _____

Substance use history

5	Frequency of alcohol use	SP_NOR	BADRINK	☐ 0 never	☐ 1 occasionally	☐ 2 regularly
6	Smoking history	SP_NFC	BASMOKE	☐ 0 never	☐ 1 former	☐ 2 current

Reproductive and sexual history

7	Average duration of menstrual bleeding (based on last 3 cycles when not using hormonal contraception, pregnant or lactating)	BAMENDUR ☐☐ days
8	Number of prior pregnancies	BAPREG ☐☐ → **if 0, go to #11**
9	Number of ectopic pregnancies	BAECTOP ☐☐
10	Date last pregnancy ended	BALPDTE ☐☐/☐☐☐/☐☐☐☐ (day/MON/year)
11	How many times does the participant have vaginal sex per month with a male partner on average? *(average over the past 3 months)*	BASEX ☐☐ → **if 0, she is ineligible, finish form and complete FINAL**
12	About how often does the participant use a condom for STI and/or HIV prevention during vaginal sex?	BACONDM SP_ASN ☐ 1 always → **she is ineligible, finish form and complete FINAL** ☐ 2 sometimes ☐ 3 never

13 Contraceptive history – check all that apply and enter date last used as **day/MON/year. Eligibilty is based on <u>past use prior to the enrollment date.</u>**

SP_CHK

- ☐ BADMPA DMPA or NET-EN BADMPDTE ☐☐/☐☐/☐☐☐☐ → **to be eligible, she must not have used in past 12 months prior to the day of enrollment**
- ☐ BACONINJ combined injectable BAINJDTE ☐☐/☐☐/☐☐☐☐ → **to be eligible she must not have used in past 6 months prior to the day of enrollment**
- ☐ BALNG LNG-IUS BALNGDTE ☐☐/☐☐/☐☐☐☐
- ☐ BANUVA NuvaRing BANUVDTE ☐☐/☐☐/☐☐☐☐
- ☐ BAPATCH patch BAPATDTE ☐☐/☐☐/☐☐☐☐
- ☐ BAPILLS pills BAPILDTE ☐☐/☐☐/☐☐☐☐
- ☐ BAIMPLNT implant BAIMPDTE ☐☐/☐☐/☐☐☐☐

  → **to be eligible she must not have used in past 7 days prior to the day of enrollment**
- ☐ BACNDM condom BACNDDTE ☐☐/☐☐/☐☐☐☐
- ☐ BAOTHER other, specify: BAOTHERT _____ BAOTHDTE ☐☐/☐☐/☐☐☐☐
- ☐ BANONE none

CONCOMITANT MEDICATION (CONMED)
Sayana® Press Extension

FSN

FHI 360 study # STUDY 926400	Participant # SSID ☐☐☐☐
Site # CN ☐☐☐	Contact date CONDTE ☐☐/☐☐/☐☐☐☐ (day/MON/year)

Concomitant Medication

1	Generic name of medication	CMTRT _____
2	Dose frequency	CMFREQ _____
3	Dose units	CMDOSE _____
4	Administration route	CMROUTE ☐☐ SP_RTE 01=Intravenous 02=Intramuscular 03=Oral 04=Rectal 05=Vaginal 06=Nasal 07=Inhalation 08=Ocular 09=Transdermal 10=Topical 11=Subcutaneous 12=Other
5	Indication	CMINDIC _____
6	Start date CMSTDTE	☐☐/☐☐☐/☐☐☐☐ (day/MON/year)
7	End date CMENDTE	☐☐/☐☐☐/☐☐☐☐ (day/MON/year) or ☐ CMONGO ongoing SP_CHK

Version 1.0 last revised 8-Jun-17 Completed by: _____ (initials)

ELIGIBILITY (ELIG)
Sayana® Press Extension

FSN

FHI 360 study # 926400 STUDY	Participant # SSID ☐☐☐☐
Site # CN ☐☐☐	Contact date CONDTE ☐☐/☐☐☐/☐☐☐☐ (day/MON/year)

			Yes	No	Unknown
Questions 1-7 must be answered YES for study eligibility				SP_YNU	
1	18 to 35 years old	ELAGE	☐	☐	☐
2	Regular menstrual cycles (25-35 days in length when not using HC, pregnant or lactating)	ELREGMEN	☐	☐	☐
3	Has an average of 1 or more unprotected acts of vaginal intercourse per month	ELUNPROT	☐	☐	☐
4	Willing to provide informed consent	ELINFCON	☐	☐	☐
5	Willing to follow all study requirements	ELFOLLW	☐	☐	☐
6	Willing to rely on Sayana® Press injected every 4 months as only contraception for 12 months	ELONLY	☐	☐	☐
7	Has only one sexual partner and expects to have that same sexual partner for the next 12 months	ELPTNR	☐	☐	☐
Questions 8-22 must be answered NO for study eligibility.					
8	Pregnant or desires pregnancy in next 18 months	ELDEPREG	☐	☐	☐
9	Previous diagnosis of infertility or prior tubal ligation or hysterectomy	ELINFERT	☐	☐	☐
10	Primary partner has received a vasectomy or is otherwise sterile	ELVASECT	☐	☐	☐
11	Any medical contraindication to DMPA per WHO medical eligibility criteria	ELMCDMPA	☐	☐	☐
12	Known or suspected allergic reaction to DMPA	ELALDMPA	☐	☐	☐
13	Known HIV infection and/or partner known HIV infection	ELHIV	☐	☐	☐
14	Diagnosis or treatment for a STI in past month (excluding recurrent herpes or condyloma) for potential participant and/or her partner	ELSTI	☐	☐	☐
15	Received an injection of DMPA or NET-EN in past 12 months	ELUSDMPA	☐	☐	☐
16	Received an injection of a combined injectable contraceptive in past 6 months	ELCONINJ	☐	☐	☐
17	Used LNG-releasing IUS, NuvaRing, contraceptive patch, OCs or contraceptive implant in past 7 days	ELUCNTRA	■	■	■
18	Previous (within 1 month prior to enrollment), current or planned (in next 12 months) use of an investigational drug, prohibited drug per protocol or other drug which in the opinion of the investigator could complicate study findings	ELUIDRUG	☐	☐	☐
19	Pregnant within the last month	ELPREG	☐	☐	☐
20	Currently lactating	ELLACT	☐	☐	☐
21	Plans to move to another location in the next 12 months	ELMOVE	☐	☐	☐
22	Social or medical condition which in the opinion of the Investigator would make study participation unsafe, or interfere with adherence to protocol requirements	ELCOND	☐	☐	☐
Final eligibility assessment				SP_YN	
23	Based on information above, is the participant eligible	ELELIG	☐ yes	☐ no	

Version 2.0 last revised 04-Oct-18 Completed by: _____ (initials)
DM annotation 05-Oct-2018

FSN

ENROLLMENT (ENROL)
Sayana® Press Extension

STUDY	SSID
FHI 360 study # 926400	Participant # ☐☐☐☐
Site # CN ☐☐☐	CONDATE Contact date ☐☐/☐☐/☐☐☐☐ (day/MON/year)

Confirm woman is eligible per ELIG CRF prior to proceeding.

NOTE: Q7 and Q8 are for Site 3 (Brazil) ONLY. Site 1 (DR) and Site 2 (Chile), select n/a.

1	First day of last menses ENLMPDTE	☐☐/☐☐☐/☐☐☐☐ (day/MON/year) → ***If more than 5 days before today's date, do not randomize.***
2	Weight ENWEIGHT	☐☐☐ kg ☐ not done ENWGHND SP_CHK
3	Height ENHEIGHT	☐☐☐ cm ☐ not done ENHGHND SP_CHK
4	Blood pressure	ENBPSYS ☐☐☐/ EMBPDIA ☐☐☐ mm Hg **Ineligible if systolic ≥160 or diastolic ≥100 → skip to initials and complete FINAL**
4a	Pregnancy test result	☐ 0 negative ENPRESLT SP_NP ☐ 1 positive → **ineligible, skip to initials and complete FINAL**
5	Pre-existing conditions	☐ 1 yes → **specify** ENCOND SP_YN ☐ 0 no 5a) ENCONDT1 _____ 5b) ENCONDT2 _____ 5c) ENCONDT3 _____ 5d) ENCONDT4 _____ 5e) ENCONDT5 _____ 5f) ENCONDT6 _____
6	Randomization number	RANDID ☐☐☐☐ ***Select from main or PK randomization groups as appropriate***
7	Consented for BC-BMD sub-study **(Brazil participants only.)**	ENBODY SP_YNA ☐ 1 yes → **complete BODY** ☐ 0 no ☐ 9 n/a
8	Consented for vaginal immunity sub-study **(Brazil participants only.)**	ENVI SP_YNA ☐ yes → **complete VI** ☐ no ☐ n/a

FSN

FHI 360 study # 926400 STUDY	Participant # SSID ☐☐☐☐
Site # CN ☐☐☐	Contact date CONDTE ☐☐/☐☐☐/☐☐☐☐ (day/MON/year)

Final Status

1	Discontinuation date FIDSCDTE	☐☐/☐☐☐/☐☐☐☐ (day/MON/year)
2	Final status FISTATUS	☐ 1 not enrolled → **skip to #6** ☐ 2 early discontinuation SP_FST ☐ 3 lost to follow-up → **skip to #6** ☐ 4 completed follow-up → **skip to #4**
3	Primary reason for early discontinuation FIREASON	☐ 1 became pregnant during study SP_FRS ☐ 2 more than 28 days late for scheduled injection ☐ 3 personal decision, specify reason: FIREAPDT _____ ☐ 4 investigator decision, specify reason: FIREAIDT _____ ☐ 5 study ended early
4	Will participant continue using contraception immediately after the study? FIUSE	☐ 1 yes SP_YNU ☐ 0 no → **skip to #6** ☐ 9 undecided → **skip to #6**
5	What contraceptive method will the participant use? FICONTRA	☐ 1 OC SP_FIC ☐ 2 implant ☐ 3 patch ☐ 4 DMPA-IM ☐ 5 IUD ☐ 6 ring ☐ 7 condoms ☐ 8 sterilization ☐ 9 other, specify: FICONTOT _____

Investigator's Statement

6	I have reviewed all data contained on the case report forms for this participant and have verified that the contents are consistent with observations and source records. They accurately reflect the condition of the subject before, during, and at the completion of the study. Signature FISIGN SP_SGN _____ ☐☐/☐☐/☐☐☐☐ (day/MON/year)

FSN

FOLLOW UP (FU)
Sayana® Press Extension

FHI 360 study # 926400 STUDY	Participant # SSID ☐☐☐☐
Site # CN ☐☐☐	Contact date CONDTE ☐☐/☐☐☐/☐☐☐☐ (day/MON/year)

1	Type of visit FUVISTYP SP_VTP	☐1 scheduled	☐9 unscheduled → FUVISR Specify if reason is ISR ☐1 yes → **skip to #4** SP_YES
2	Scheduled visit number FUVISNUM SP_VNM	☐☐ 02=Month 2→ **skip to #4** 03=Month 3→ **skip to #4** 04=Month 4 08=Month 8 12=Month 12 → **skip to #5**	
3	Is participant more than 28 days late for her scheduled month 4 or 8? FULATE	☐1 yes → **skip to #5 and discontinue today** SP_YN	☐0 no
4	Does participant have any suspicions, signs, symptoms or evidence of pregnancy? FUPREG	☐ yes SP_YN	☐ no
5	Urine pregnancy test result FUPRESLT ***Required at:*** • ***Months 4 and 12*** • ***Month 8 if more than 7 days late*** • ***If suspicions, signs, symptoms or evidence of pregnancy***	☐0 negative SP_RES ☐1 positive → **collect blood for MPA and complete PREG** ☐2 indeterminate ☐9 not done	
6	Has the participant experienced an SAE or an AE leading to Sayana Press withdrawal? FUAE	SP_YN ☐ yes → **complete AE**	☐ no
7	Has participant used any other contraceptive or any new prohibited medications since her last injection? FUMEDS	SP_YN ☐ yes → **complete CONMED**	☐ no
8	Weight FUWEIGHT	☐☐☐ kg	☐1 not done FUWGHND SP_CHK
9	Blood pressure FUBPSYS FUBPDIA	☐☐☐/☐☐☐ mmHg	☐ not done FUBPND SP_CHK
10	Participant status FUSTATUS	☐1 continue SP_FUS	☐0 discontinue/final visit → **finish form & complete FINAL**

Questions 11-14 are interviewer administered at months 4, 8, 12 or at early discontinuation

11	How many times did you have vaginal sex per month on average since your last injection? FUAVGSEX	☐☐☐ → **if 0 skip to initials**	
12	Have you had vaginal sex in the last 4 weeks? FU4WKSEX	☐ yes SP_YN	☐ no
13	Have you used a condom during vaginal sex since your last injection? FUCONDM	☐ yes SP_YN	☐ no → **skip to initials**
14	When did you use condoms during vaginal sex since your last injection? FUWHEN	☐1 only in the last 4 weeks SP_WHN ☐2 not in the last 4 weeks, but before ☐3 in the last 4 weeks and before	

INJECTION (INJECT)
Sayana® Press Extension

FSN

FHI 360 study # STUDY 926400	SSID Participant # ☐☐☐☐
Site # CN ☐☐☐	CONDTE Contact date ☐☐/☐☐☐/☐☐☐☐ (day/MON/year)

Blood specimen must be collected <u>before</u> giving injection.
<u>At enrollment</u>, obtain blood specimen from all women.
<u>During follow-up</u>, obtain blood specimen from women in PK cohort only.

1	Injection number	INJNUM SP_INJ	☐ 1 1st ☐ 2 2nd ☐ 3 3rd
2	Time of injection	INJHH INJMM	☐☐ : ☐☐ (24-hour clock)
3	Side of injection	INSIDE SP_SDE	☐ 1 right ☐ 2 left
4	Was blood specimen collected for MPA testing?	INSPEC SP_YNN	☐ 1 yes ☐ 0 no ☐ 9 not in PK cohort
5	Were there any issues with administration of Sayana Press?	INISSUE SP_YN	☐ 1 yes, specify: INISSUET _____ _____ ☐ 0 no
6	Injection site reaction?	INISR SP_YN	☐ yes → **Complete ISR** ☐ no

Version 3.0 last revised 30-Nov-17

Completed by: _____ (initials)

INJECTION SITE (INJECTSITE)
Sayana® Press Extension

FSN

STUDY FHI 360 study # 926400	IJSSID Participant # ☐☐☐☐ - 1
CN Site # ☐☐☐	CONDTE Contact date ☐☐ / ☐☐☐ / ☐☐☐☐ (day/MON/year)

Complete this CRF each time a Sayana Press injection is given

1	RANDID Randomization number	☐☐☐☐
2	IJSITE Site of injection SP_ISS	☐ 1 abdomen ☐ 2 thigh ☐ 3 upper arm

Version 1.0 last revised 8-Jun-17

Completed by: _____ (initials)

FSN

STUDY

INJECTION SITE REACTION (ISR)

Sayana® Press Extension

FHI 360 study # 926400	Participant # ☐☐☐☐
Site # CN ☐☐☐	Contact date CONDTE ☐☐/☐☐☐/☐☐☐☐ (day/MON/year)

1	Date of injection ISINJDTE	☐☐/☐☐☐/☐☐☐☐ (day/MON/year)
2	Injection site reactions (ISR) -Participant reported complaints or observed upon clinical inspection ***(Check all that apply.)*** SP_CHK	☐ pain ISCPAIN — ☐ check if participant reported ISPAINPR ☐ itching ISCITCH — ☐ check if participant reported ISITCHPR ☐ tenderness ISITENDR — ☐ check if participant reported ISTNDRPR ☐ warmth ISIWARM — ☐ check if participant reported ISWARMPR ☐ redness, specify diameter ISIRED ISREDSZE ☐☐.☐ cm (SP_CHK) — ☐ check if participant reported ISREDPR ☐ swelling, specify diameter ISISWELL ISSWSZE ☐☐.☐ cm — ☐ check if participant reported ISSWLLPR ☐ bruising/haematoma, specify diameter ISIBRUIS ISBRUSZE ☐☐.☐ cm — ☐ check if participant reported ISBRUSPR ☐ hypopigmentation, specify diameter ISHYPOPG ISHYPOSZE ☐☐.☐ cm — ☐ check if participant reported ISHYPOPR ☐ atrophy (dent or dimple) ISIATRPH — ☐ check if participant reported ISATRPPR ☐ other, specify: _____ ISIOTHER ISIOTHT ☐ none ISCNONE
3	Injection site reaction (ISR) started ISSTART SP_ITM	☐ 0 at the time of (or during) injection ☐ 1 within 15 minutes after injection ☐ 2 between 15 min and 24 hrs after injection ☐ 3 > 1 day but < 7 days after injection ☐ 4 between 7 days and 1 month after injection ☐ 5 between 1-2 months after injection ☐ 6 between 2-3 months after injection ☐ 7 > 3 months after injection
4	ISR is Grade 1 or higher ISGRADE1	☐ 1 yes → **complete AE** (SP_YN) ☐ 0 no → **skip to #6**
5	FSN of AE ISAEFSN	☐☐☐☐☐☐ → **form is complete, skip to initials**

Complete Questions 6-8 only if the ISR is NOT an AE.

6	Outcome of ISR ISOUT SP_IOT	☐ 1 resolved without sequelae ☐ 2 resolved with sequelae, specify: _____ ISSEQT ☐ 4 ongoing at exit ☐ 3 unknown → **skip to initials**
7	Date of ISR outcome ISENDTE	☐☐/☐☐☐/☐☐☐☐ (day/MON/year) ☐ check if estimated ISENDEST (SP_CHK)
8	Duration of ISR ISDURHH ISDURMM	☐☐:☐☐ Hours Min → **leave blank and continue to initials if ≥24 hours**

Version 2.0 last revised 26-Sep-18 Completed by: _____ (initials)

MPALOG
Sayana® Press Extension

FSN

FHI 360 study # STUDY 926400	Participant # SSID PN ☐☐☐☐
Site # CN ☐☐☐	Page # MPPAGE ☐☐

Date of blood collection *day/MON/year*	Visit code	Time of blood collection *24 hr clock*	Specimen label
MPLINE SP_MPL MPBCDTE ☐☐/☐☐/☐☐☐☐	MPVISIT SP_MPV ☐☐	MPBCHH MPBCMM ☐☐:☐☐	Participant # MPLSSID Sample # MPLSNUM Date MPLDTE Sample Type MPLSTYP SP_MPS
☐☐/☐☐/☐☐☐☐	☐☐	☐☐:☐☐	
☐☐/☐☐/☐☐☐☐	☐☐	☐☐:☐☐	
☐☐/☐☐/☐☐☐☐	☐☐	☐☐:☐☐	
☐☐/☐☐/☐☐☐☐	☐☐	☐☐:☐☐	
☐☐/☐☐/☐☐☐☐	☐☐	☐☐:☐☐	

Version 1.0 last revised 8-Jun-17 Completed by: _____ (initials)

FSN

FHI 360 study # 926400 **STUDY**	**SSID** Participant # ☐☐☐☐
Site # **CN** ☐☐☐	**CONDTE** Contact date ☐☐/☐☐☐/☐☐☐☐ (day/MON/year)

Pregnancy

1	First day of last menses **PRLMPDTE**	☐☐/☐☐☐/☐☐☐☐ (day/MON/year) **or** ☐ 1 **PRLMPUNK** participant does not know SP_CHK
2	Ultrasound done **PRULTRA**	☐ 1 yes SP_YN ☐ 0 no → **skip to #5**
3	Date of ultrasound **PRULTDTE**	☐☐/☐☐☐/☐☐☐☐ (day/MON/year)
4	Gestational age based on ultrasound **PRULTAGE**	☐☐ weeks
5	Serum hCG obtained **PRHCGOBT**	☐ yes SP_YN ☐ no → **skip to #7**
6	Serum hCG result **PRHCGRES**	☐☐☐☐☐☐ IU/mL
7	Other evidence of pregnancy **PROTHEV**	☐ yes SP_YN ☐ no → **skip to #9**
8	Evidence	**PROTHEVT** _____
9	Pregnancy confirmed **PRCONFRM**	☐ yes SP_YN ☐ no
10	Investigator's best estimate of date of fertilization (EDF) **PREDFDTE**	☐☐/☐☐☐/☐☐☐☐ (day/MON/year)
11	How was EDF calculated **PREDFCLC**	SP_EDF ☐ 1 ultrasound → **skip to #13** ☐ 2 menses → **skip to #13** ☐ 3 other
12	Specify other information	**PREDFCOT** _____
13	Pregnancy status today **PRSTATUS**	SP_ONG ☐ 1 ongoing ☐ 0 not ongoing → **skip to initials, complete PREGOUT**
14	Estimated date of delivery **PREDDTE**	☐☐/☐☐☐/☐☐☐☐ (day/MON/year)

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PREGNANCY OUTCOME (PREGOUT)

Sayana® Press Extension

FSN

FHI 360 study # STUDY 926400	Participant # SSID ☐☐☐☐
Site # CN ☐☐☐	Contact date CONDTE ☐☐/☐☐☐/☐☐☐☐ (day/MON/year)

Pregnancy Outcome

1	Actual pregnancy outcome date	POOUTDTE ☐☐/☐☐☐/☐☐☐☐ (day/MON/year) POOTDUNK ☐ unknown SP_CHK
2	Gestational age at outcome	POGAGE ☐☐ weeks POGAGUNK ☐ unknown SP_CHK
3	Pregnancy outcome SP_CHK ***Check all that apply***	☐ POLIVE Live birth(s) ☐ POSTILL Still birth(s) ☐ POECTPRG Ectopic pregnancy ☐ POMOLPRG Molar pregnancy ☐ POABRTS Abortion, spontaneous ☐ POUNKNW Unknown ☐ POABRTI Abortion, induced, specify why POABRTIT _____
4	Number of newborns/fetuses PONUM SP_PON	1 single 2 twins 3 triplets 4 other, specify PONUMOT _____ 9 unknown
5	Gender ***Check all that apply*** SP_CHK	☐ POGENFEM female ☐ POGENMAL male ☐ POGENUNK unknown
6	Complications during pregnancy that required medical attention POCOMPL SP_YN	1 yes 0 no → **skip to #8**
7	Specify complications during pregnancy that required medical attention	POCOMPLT _____ _____ _____
8	Any fetal/neonatal abnormalities noted at any time during or after pregnancy POABNOR SP_YN	☐ yes ☐ no → **skip to initials**
9	Specify any fetal/neonatal abnormalities noted at any time during or after pregnancy	POABNORT _____ _____ _____

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FSN

PROTOCOL VIOLATION (PV)
Sayana® Press Extension

FHI 360 study # STUDY 926400	Participant # SSID ☐☐☐☐
Site # CN ☐☐☐	Contact date CONDTE ☐☐/☐☐☐/☐☐☐☐ (day/MON/year)

Protocol Violation

1	Date of violation PVSTDTE	☐☐/☐☐☐/☐☐☐☐ (day/MON/year) PVSTDEST SP_CHK 1 check if estimated
2	Date of site awareness PVSADTE	☐☐/☐☐☐/☐☐☐☐ (day/MON/year)
3	Violation code PVVIOL ☐☐ SP_VIO	01 = ineligible enrollment 02 = failure to follow randomization 03 = missed protocol required procedure 04 = conduct of non-protocol/non-standard clinical procedure 05 = unreported SAE 06 = breach of confidentiality 07 = informed consent process violation 08 = wrong injection site 09 = other, specify: PVVIOLOT _____
4	Description of the violation	PVTERM1 PVTERM2 _____ _____ _____
5	Has this violation been or will it be reported to the local IRB? PVIRB SP_YN	☐ 1 yes ☐ 0 no
6	Date violation ended PVENDTE	☐☐/☐☐☐/☐☐☐☐ (day/MON/year) ☐ PVONGO ongoing SP_CHK
7	Plans and/or action taken to address violation	_____ PVAACTN1 PVAACTN2 _____ _____
8	Plans and/or action taken to prevent recurrence of violation	_____ PVPACTN1 PVPACTN2 _____ _____

Version 1.0 last revised 8-Jun-17 Completed by: _____ (initials)

SOCIAL HARM (SHARM)
Sayana® Press Extension

FSN

FHI 360 study # **STUDY** 926400		Participant # **SSID** ☐☐☐☐
Site # **CN** ☐☐☐		Contact date **CONDTE** ☐☐/☐☐/☐☐☐☐ (day/MON/year)
1	Social Harm Onset Date **SHSTDTE**	☐☐/☐☐☐/☐☐☐☐ (day/MON/year)
2	Concise description of social harm	**SHDESC1** **SHDESC2**
3	**SHIMPCT** SP_SHI What impact did the social harm have on the participant's quality of life	☐ 1 minimal disturbance ☐ 2 moderate disturbance; no significant impact ☐ 3 major disturbance with significant impact
4	Action taken, if any, by Investigator/study staff to address the social harm	**SHACTN1** **SHACTN2**
5	Current status **SHSTATUS** SP_SHS	☐ 1 unresolved → **skip to #7** ☐ 2 unable to resolve; no further action to be taken → **skip to #7** ☐ 3 resolved
6	Resolution date **SHENDTE**	☐☐/☐☐☐/☐☐☐☐ (day/MON/year)
7	Did the participant discontinue from the research study? **SHDISCON** SP_YN	☐ 1 Yes → **Continue to signature and complete FINAL** ☐ 0 No
8	**SHSIGN** SP_SGN Investigator (or Designee) Signature	☐☐/☐☐☐/☐☐☐☐ (day/MON/year)
Version 1.0 last revised 8-Jun-17		

FSN

VAGINAL IMMUNITY (VI)
Sayana® Press Extension

FHI 360 study # STUDY 926400	SSID Participant # ☐☐☐☐
Site # CN ☐☐☐	CONDATE Contact date ☐☐/☐☐☐/☐☐☐☐ (day/MON/year)

1	Visit number	VIVISNUM SP_VIV ☐☐	88=Screening (baseline), 01=Month 1, 03=Month 3, 04=Month 4, 08=Month 8, 12=Month 12, 99=Early Discontinuation/LTFU → **Skip to initials**

Genital specimens

2	Time collected	VIGSCHH ☐☐:☐☐ (24-hour clock)	VIGSCMM
3	Date received at lab	VIGSRDTE ☐☐/☐☐☐/☐☐☐☐ (day/MON/year)	
4	Time received at lab	VIGSRHH ☐☐:☐☐ (24-hour clock)	VIGSRMM

5	Specimens collected	Stored	NOT stored	Blood visible	Blood NOT visible
a	LVW 1 (Dacron dry)	SP_SN 1 VILVW1S	0	1 VILVW1B	0 SP_BN
b	LVW 2 (Dacron dry)	☐ VILVW2S	☐	☐ VILVW2B	☐
c	LVW (slide for Nugent)	☐ VILVWNUS	☐	☐ VILVWNUB	☐
d	LVW (cotton dry)	☐ VILVWCTS	☐	☐ VILVWCTB	☐
e	LVW (Copan flocked dry)	☐ VILVWCPS	☐	☐ VILVWCPB	☐
f	Vaginal vault/posterior fornix (Dacron dry)	☐ VIVVPFS	☐	☐ VIVVPFB	☐
g	Endocervical (Dacron dry)	☐ VIENDOS	☐	☐ VIENDOB	☐
h	Cytobrush 1 (media)	☐ VICYTO1S	☐	☐ VICYTO1B	☐
i	Cytobrush 2 (media)	☐ VICYTO2S	☐	☐ VICYTO2B	☐

Blood sample

6	Time collected	VIBSCHH ☐☐:☐☐ (24-hour clock)	VIBSCMM
7	Date received at lab	VIBSRDTE ☐☐/☐☐☐/☐☐☐☐ (day/MON/year)	
8	Time received at lab	VIBSRHH ☐☐:☐☐ (24-hour clock)	VIBSRMM

Behavior

9	Has the participant put anything inside her vagina in the last 7 days?	VIINSIDE ☐ 1 yes SP_YN ☐ 0 no → **skip to #11**
10	What did she insert? ***(Check all that apply.)***	SP_CHK ☐ VIOBHERB traditional herbs/medicines ☐ VIOBPAPR paper/cotton/cloth/wool ☐ VIOBTMPN tampon ☐ VIOBOTH other, specify: VIOBOTHT _____
11	Has the participant washed inside her vagina in the last 7 days?	VIWASH ☐ yes SP_YN ☐ no → **skip to #14**
12	What did she wash with? ***(Check all that apply.)***	SP_CHK ☐ VIWAWTR water only ☐ VIWASOP soap and water ☐ VIWADET detergent/antiseptic ☐ VIWAOTH other, specify: VIWAOTHT _____
13	What did she use to wash with? ***(Check all that apply.)***	SP_CHK ☐ VIUSFING fingers only ☐ VIUSCLTH cloth/sponge ☐ VIUSOTH other, specify: VIUSOTHT _____
14	Has the participant douched in the last 7 days?	VIDOUCHE ☐ yes SP_YN ☐ no
15	Has the participant used anything for drying/tightening the vagina in the last 7 days?	VIVDRY ☐ yes SP_YN ☐ no
16	Does participant have any clinical signs of vaginal/cervical infection on day specimens were collected?	VIVINF ☐ yes, specify: SP_YN VIVINFT _____ ☐ no