

Informed Consent and Demographic Data id DM

Was Informed Consent obtained? #1

id ICYN☐ Yes ☐ No

Informed Consent date and time

id ICDATSubject ID id SUDJIDGender #2 id SEX☐ Female ☐ Male

Age

id AGE

Age unit #3

id AGEU

Choose one.. ▾

Is the subject of childbearing potential?

#4

id CHILDPOT☐ Yes ☐ NoReason #5 id MENOSTAT

- ☐ ≥1 Year post-menopausal
- ☐ Hysterectomy
- ☐ Bilateral tubal ligation

Is the subject pregnant, breast-feeding or of childbearing potential without appropriate contraceptive methods in place for 2 months before enrolment, or with positive pregnancy test on the day of vaccination? #6

id CHILDPOTY☐ Yes ☐ NoRace #7 id RACE

Choose one.. ▾

Specification other race id RACESPEthnicity #8 id ETHNIC

Choose one.. ▾

**Informed Consent and Demographic Data - Code Lists****#1 Informed Consent Obtained**

Y	Yes
N	No

**#2 Gender**

F	Female
M	Male

**#3 Age Unit**

1	Years
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**#4 Childbearing Potential**

Y	Yes
N	No

**#5 Reason**

1	≥1 Year post-menopausal
2	Hysterectomy
3	Bilateral tubal ligation

**#6 Violation of exclusion criterion #7**

Y	Yes
N	No

**#7 Race**

0	Not collected
1	Asian
2	Black or African American
3	White
OT	Other

## #8 Ethnicity

HISPANIC OR LATINO	Hispanic or Latino
NOT HISPANIC OR LATINO	Not Hispanic or Latino
NOT REPORTED	Not reported
UNKNOWN	Unknown