

Attachment 3
Summary of Changes to Data Collection Methods and Data Elements

Enhanced STD Surveillance Network (SSuN)
Revision Request

OMB# 0920-1072

March 2020

Summary of Proposed Changes in the Approved ICR for the Enhanced STD Surveillance Network (SSuN) OMB # 0920-1072

Summary of Proposed Changes

We are requesting revision to the information collection request (ICR) for the STD Surveillance Network (eSSuN), OMB #0920-1072. The revisions requested for this ICR include non-substantive response coding modifications to currently collected data elements across multiple project components as well as substantive revisions to data elements and methods with removal of 115 data elements associated with a retired activity, addition of 94 new data elements to capture HIV registry matching of STD clinic patients, gonorrhea patient symptoms, patient nativity, STD-related HIV prevention activities, monitor opioid use, antimicrobial treatment, more fully characterize patient-reported and clinician-observed signs and symptoms of STDs, and to assess patient healthcare seeking behaviors through a brief, self-administered survey in STD clinics. These revisions are responsive to NCHHSTP leadership intention to enhance existing data collection activities to support the 'End the HIV Epidemic' initiatives and to better monitor symptoms and treatments associated with STDs.

Change in burden by adding HIV registry matching and patient survey activities is partially offset by discontinuing follow-up investigations among syphilis cases reporting ocular, otic or neurologic symptoms. This activity is being discontinued because the data previously collected have been sufficient to answer the emergent surveillance questions; therefore all 115 data elements associated with this activity are being removed. Several other data elements from patient interviews and from STD clinical records are also being removed as no longer needed; see **Table 1** for listing of data elements proposed for removal. Revisions to the valid response codes for existing sentinel surveillance (Strategy A) and enhanced surveillance (Strategy B) data elements are described in Tables 2A and 3A and have no additional burden associated with them. Proposed new data elements for both strategies are summarized in Tables 2B and 3B (below).

Additionally, diagnosed and reported cases of adult syphilis are proposed for addition to case-based surveillance datasets to monitor HIV co-infection, treatment and repeat episodes of disease among persons diagnosed and reported with syphilis. Data elements associated with this activity are already collected as part of routine case reporting and are structured identically to the approved data elements currently collected for gonorrhea cases; this activity results in additional records transmitted to CDC in existing datasets rather than collection of any new data at the state/city health department level.

Burden table (**Attachment 3A**) is updated to reflect discontinuation of ocular, otic and neuro syphilis activity, addition of new HIV registry matching activities, addition of reported syphilis case data to enhanced surveillance component (using existing, generalized data elements), and to reflect a change in collaborating health departments (**Attachment 6**).

Sentinel Surveillance Data Elements and Methods in STD Clinical Facilities (SSuN Strategy A)

This component of SSuN collects existing data for patients presenting for care in STD-specialty clinical facilities. Additional data elements are proposed to characterize the offer, acceptance and use of HIV pre-and post-exposure prophylaxis as well as to better characterize patient reported and clinician-observed signs and symptoms of STDs. Additionally, participating clinics will submit patient data to the collaborating health departments for matching to the jurisdiction's HIV surveillance registry. Response options for existing laboratory data elements are revised to include the capture of HIV-related test results. These changes in laboratory data element response coding for data collected from STD clinics will accommodate collection of HIV-related tests and testing algorithms, provide additional information on the availability and use of STD-related, high-impact HIV prevention activities and provide additional information on patient-reported signs and

symptoms of STDs. The addition of a brief, anonymous, self-administered patient survey (Attachment 8) will allow for aggregate assessment of patient demographics and behaviors not otherwise available in routine medical records.

Update to the STD Surveillance Network Principal Investigator’s Contact Information in Attachment 6.

We have updated information from funded entities reflecting changes in staff and contact information for collaborating key personnel and added newly funded jurisdiction for the upcoming 5-year cooperative agreement. These changes are reflected in **Attachment 6**.

Table1. Data Elements Being Retired (Removed)

Data Element Name	Description	Response Coding
NS1_SITE	<i>Which participating site submitted this patient’s data</i>	<i>2-character code</i>
NS1_PATIENTID	<i>Unique patient identifier assigned by SSuN site</i>	<i>Alphanumeric format</i>
NS1_VISDATE	<i>Date of syphilis screening interview</i>	<i>MM/DD/YYYY</i>
NS1_DX_MM	<i>Month of syphilis diagnosis date</i>	<i>MM</i>
NS1_DX_DD	<i>Day of syphilis diagnosis date</i>	<i>DD</i>
NS1_DX_YYYY	<i>Year of syphilis diagnosis date</i>	<i>YYYY</i>
NS1_PATIENTCONSENT	<i>Did the patient agree to be screened for neuro/ocular symptoms?</i>	<i>1 = Yes, 2 = No, 9 = Unknown</i>
NS1_PARTNERSERVICES	<i>Was this patient prioritized for a partner services interview based on health department protocol?</i>	<i>1 = Yes, 2 = No, 9 = Unknown</i>
NS1_GENDER	<i>What is your current gender identity?</i>	<i>1 = Male, 2 = Female, 3 = Transgender F to M, 4 = Transgender M to F, 5 = Transgender unspecified, 6 = Other, 9 = Unknown</i>
NS1_SEX	<i>What sex were you assigned at birth?</i>	<i>1 = Male, 2 = Female, 9 = Unknown</i>
NS1_AGE	<i>How old are you?</i>	<i># (age in years), 999 = Unknown</i>

NS1_HISP	Are you of Hispanic ethnicity?	1= Yes, 2 = No, 9 = Unknown
NS1_AIAN	Are you American Indian or an Alaskan Native?	1= Yes, 2 = No
NS1_ASIAN	Are you Asian?	1= Yes, 2 = No
NS1_PIH	Are you Pacific Islander or Hawaiian?	1= Yes, 2 = No
NS1_BLACK	Are you Black?	1= Yes, 2 = No
NS1_WHITE	Are you White?	1= Yes, 2 = No
NS1_OTHERRACE	Do you identify as an Other race not included in the list above?	1= Yes, 2 = No
NS1_OTHERRACE_TEXT	If NS1_OTHERRACE = 1 include text description.	Text
NS1_RACEUNKN_REFUSED	Is patient race unknown or did patient refuse to report their race?	1= Yes, 2 = No
NS1_SEXUALITY	Do you consider yourself gay/homosexual, straight/heterosexual, or bisexual?	1 = Gay/Homosexual, 2 = Straight/Heterosexual, 3 = Bisexual, 4 = Other, 9 = Unknown
NS1_MALESP	Have you ever had sex with a male?	1 = Yes, 2 = No, 9 = Unknown
NS1_MALESPTIMEPERIOD	How recently have you had sex with a male? In the past (select most recent time period):	1 = 3 months, 2 = 6 months, 3 = 9 months, 4 = 12 months, 5=> 12 months, 9 = Unknown
NS1_MENSEX	How many male partners have you had sex with in the past 3 months?	#, 999 = Unknown
NS1_FEMALESP	Have you ever had sex with a female?	1 = Yes, 2 = No, 9 = Unknown
NS1_FEMALESPTIMEPERIOD	How recently have you had sex with a female? In the past (select most recent time period):	1 = 3 months, 2 = 6 months, 3 = 9 months, 4 = 12 months, 5=> 12 months, 9 = Unknown
NS1_FEMSEX	How many female partners have you had sex with in the past 3 months?	#, 999 = Unknown
NS1_NEUROOCULARDX	Has a doctor or	1 = Yes, 2 = No, 9 = Unknown

	<i>other medical person recently told you that you had neurosyphilis, or syphilis affecting your brain, eyes, or ears?</i>	
NS1_DXLOC	<i>If yes (NS1_NEUROOCULARDX = 1), where was this diagnosis made?</i>	<i>1 = STD Clinic, 2 = HIV Care Facility, 3 = Eye clinic, 4 = Emergency room, 5 = Primary Care Clinic, 6 = Other (please describe), 9 = Unknown</i>
NS1_DXLOCOTHER_TEXT	<i>If NS1_DXLOC = 6 include text description</i>	<i>Text</i>
NS1_HEARINGCHANGE	<i>Have you experienced a change in hearing in the past 60 days?</i>	<i>1 = Yes, 2 = No</i>
NS1_HEARINGLOSS	<i>Have you experienced hearing loss in the past 60 days?</i>	<i>1 = Yes, 2 = No</i>
NS1_TINNITUS	<i>Have you experienced ringing or buzzing in your ears (tinnitus) in the past 60 days?</i>	<i>1 = Yes, 2 = No</i>
NS1_HEADACHES	<i>Have you experienced headaches in the past 60 days?</i>	<i>1 = Yes, 2 = No</i>
NS1_ALTMENSTAT	<i>Have you experienced an altered mental status in the past 60 days?</i>	<i>1 = Yes, 2 = No</i>
NS1_STROKE	<i>Have you experienced stroke-like symptoms in the past 60 days?</i>	<i>1 = Yes, 2 = No</i>
NS1_OTHERNEUROSYP	<i>Have you experienced other neurological symptoms in the past 60 days?</i>	<i>1 = Yes, 2 = No</i>
NS1_OTHERNEUROSYP_	<i>If</i>	<i>Text</i>

TEXT	NS1_OTHERNEUR OSYMP = 1 then include text description	
NS1_EYEPAIN	Have you experienced eye pain in the past 60 days?	1 = Yes, 2 = No
NS1_BLURRYVISION	Have you experienced blurry vision in the past 60 days?	1 = Yes, 2 = No
NS1_REDEYE	Have you experienced red eye in the past 60 days?	1 = Yes, 2 = No
NS1_VISIONCHANGES	Have you experienced vision changes in the past 60 days?	1 = Yes, 2 = No
NS1_FLASHLIGHTS	Have you experienced any flashing lights in the past 60 days?	1 = Yes, 2 = No
NS1_FLOATERS	Have you experienced any floaters in the past 60 days?	1 = Yes, 2 = No
NS1_VISIONLOSS	Have you experienced vision loss in the past 60 days?	1 = Yes, 2 = No
NS1_OTHEROCULARSYMP	Have you experienced any other ocular symptoms in the past 60 days?	1 = Yes, 2 = No
NS1_OTHEROCULARSYMP _TEXT	If NS1_OTHEROCULA RSYMP = 1 include text description	Text
NS1_LUMBPUNC	As part of your care for syphilis, did you receive a spinal tap or lumbar puncture?	1 = Yes, 2 = No, 9 = Unknown
NS1_LUMBPUNC_MM	If you received a spinal tap or lumbar puncture (NS1_LUMBPUNC = 1), what was the month of the date?	MM
NS1_LUMBPUNC_DD	If you received a spinal tap or	DD

	<i>lumbar puncture (NS1_LUMBPUNC = 1), what was the day of the date?</i>	
NS1_LUMBPUNC_YYYY	<i>If you received a spinal tap or lumbar puncture (NS1_LUMBPUNC = 1), what was the year of the date?</i>	YYYY
NS1_SYPHSTAGE	<i>What stage of syphilis was this patient diagnosed with?</i>	1 = Primary, 2 = Secondary, 3 = Early Latent, 4=Late latent, 9 = Unknown
NS1_SYPHRPRTITER	<i>What was the patient's highest RPR titer recorded?</i>	1 = 1:1, 2 = 1:2, 3 = 1:4, 4 = 1:8, 5 = 1:16, 6 = 1:32, 7 = 1:64, 8 = 1:128, 9 = 1:256, 10 = 1:512, 11 = 1:1024, 12 = > 1:1024, 99 = Unknown
NS1_SYPHTPPA	<i>What was the patient's serologic TPPA result?</i>	1 = Reactive, 2 = Nonreactive, 3 = Not done, 4 = Unsatisfactory
NS1_SYPHEIA	<i>What was the patient's serologic EIA result?</i>	1 = Reactive, 2 = Non-reactive, 3 = Not done
NS1_SYPHFTA_ABS	<i>Serologic FTA-ABS result</i>	1 = Reactive, 2 = Non-reactive, 3 = Not done
NS1_BENZPENC_A	<i>Was the patient prescribed Benzathine penicillin G, 2.4 million units IM single dose?</i>	1 = Yes, 2 = No
NS1_BENZPENC_B	<i>Was the patient prescribed Benzathine penicillin G, 2,4 million units in 3 doses at 1 week intervals (max total 7.2 million units)</i>	1 = Yes, 2 = No
NS1_BENZPENC_C	<i>Was the patient prescribed Benzathine penicillin G, 50000 units/kg IM, single dose (max total 2.4 million units)</i>	1 = Yes, 2 = No

NS1_BENZPENC_D	Was the patient prescribed Benzathine penicillin G, 50000 units/kg IM, 3 doses, 1 week intervals (max total 7.2 million units)	1 = Yes, 2 = No
NS1_AQCRYSTPENG_A	Was the patient prescribed Aqueous crystalline penicillin G IV, 18-24 million units/day, administered as 3-4 million units IV every 4 hrs, for 10-14 days?	1 = Yes, 2 = No
NS1_AQCRYSTPENG_B	Was the patient prescribed Aqueous crystalline penicillin G IV, 18-24 million units/day, administered as continuous infusion, for 10-14 days?	1 = Yes, 2 = No
NS1_DOXYCYC_A	Was the patient prescribed Doxycycline, 100 mg 2x/day for 14 days?	1 = Yes, 2 = No
NS1_DOXYCYC_B	Was the patient prescribed Doxycycline, 100 mg 2x/day for 28 days?	1 = Yes, 2 = No
NS1_TETRACYC_A	Was the patient prescribed Tetracycline, 500 mg orally 4x/day for 14 days?	1 = Yes, 2 = No
NS1_TETRACYC_B	Was the patient prescribed Tetracycline, 500 mg orally 4x/day for 28 days?	1 = Yes, 2 = No
NS1_PROCPENPROB	Was the patient prescribed Procaine penicillin G 2.4 million units	1 = Yes, 2 = No

	<i>IM 1x daily, PLUS probenecid (500 mg, 4 times a day, both for 10-14 days?</i>	
NS1_PROCPEN	<i>Was the patient prescribed Procaine penicillin G 2.4 million units IM 1x daily for 10-14 days without probenecid?</i>	1 = Yes, 2 = No
NS1_CEFTRIAX_A	<i>Was the patient prescribed Ceftriaxone 250 mg IM in a single dose?</i>	1 = Yes, 2 = No
NS1_CEFTRIAX_B	<i>Was the patient prescribed Ceftriaxone 1 g IM in a single dose?</i>	1 = Yes, 2 = No
NS1_OTHERTX	<i>Was the patient prescribed any other treatment?</i>	1 = Yes, 2 = No
NS1_SYPHTX_TEXT	<i>If NS1_OTHERTX = 1 ("Yes") include text description</i>	Text
NS1_HIVTESTEVER	<i>Was this patient ever tested for HIV prior to this event?</i>	1 = Yes, 2 = No, 9 = Unknown
NS1_HIVTESTEVER_MM	<i>What was the month of the date of the most recent HIV test prior to this event?</i>	MM
NS1_HIVTESTEVER_DD	<i>What was the day of the date of the most recent HIV test prior to this event?</i>	DD
NS1_HIVTESTEVER_YYYY	<i>What was the year of the date of the most recent HIV test prior to this event?</i>	YYYY
NS1_PREVHIVRES	<i>What was the result of this prior HIV test?</i>	1 = Reactive, 2 = Nonreactive, 3 = Indeterminate, 9 = Unknown

NS1_HIVSTAT	What is final HIV test result at this event?	1 = Previous HIV positive, not retested, 2 = Tested and verified HIV positive at this event, 3 = Tested and verified HIV negative at this event, 4 = Indeterminate, 5= Not tested at this event, 9 = Unknown
NS1_HIVART	If patient is HIV positive, are they currently taking antiretrovirals?	1 = Yes, 2 = No, 9 = Unknown
NS1_HIVVLTEST_MM	When was the patient's most recent HIV viral load test?	MM
NS1_HIVVLTEST_DD	When was the patient's most recent HIV viral load test?	DD
NS1_HIVVLTEST_YYYY	When was the patient's most recent HIV viral load test?	YYYY
NS1_HIVVLRESULT	What was the result of the most recent HIV viral load test?	1 = undetectable, 2 = <500 copies/ml, 3 = 500-10,000 copies/ml, 4 = > 10,000 copies/ml, 9 = Unknown
NS2_SITE	Which participating site submitted this patient's data	FL = Florida, MC = Multnomah County, NY = New York City, PH = Philadelphia, WA = Washington State
NS2_PATIENTID	Unique patient identifier assigned by SSuN site	Alphanumeric format
NS2_VISDATE	Date of syphilis screening interview	MM/DD/YYYY
NS2_DX_MM	Month of date of syphilis diagnosis	MM
NS2_DX_DD	Day of date of syphilis diagnosis	DD
NS2_DX_YYYY	Year of date of syphilis diagnosis	YYYY
NS2_CONTACT	Were you able to contact the patient	1=Yes, 2=No

	<i>for a 3-month follow-up?</i>	
NS2_TXCOMPLETE	<i>Did you complete your prescribed syphilis treatment?</i>	1 = Yes, 2 = No, 9 = Unknown
NS2_CHANGEHEARINGRESOLV	<i>Has your change in hearing resolved?</i>	1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened
NS2_HEARINGLOSSRESOLV	<i>Has your hearing loss resolved?</i>	1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened
NS2_TINNITUSRESOLV	<i>Has the buzzing or ringing in your ears (tinnitus) resolved?</i>	1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened
NS2_HEADACHESRESOLV	<i>Have your headaches resolved?</i>	1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened
NS2_ALTMENTALRESOLV	<i>Has your altered mental status resolved?</i>	1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened

NS2_EYEPAINRESOLV	<i>Has your eye pain resolved?</i>	<i>1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened</i>
NS2_REDEYERESOLV	<i>Has your red eye resolved?</i>	<i>1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened</i>
NS2_BLURRYVISIONRESOLV	<i>Has your blurry vision resolved?</i>	<i>1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened</i>
NS2_VISIONCHANGESRESOLV	<i>Have your vision changes resolved?</i>	<i>1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened</i>
NS2_VISIONLOSSRESOLV	<i>Has your vision loss resolved?</i>	<i>1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened</i>

NS2_FLOATERSRESOLV	Have your floaters resolved?	1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened
NS2_FLASHLIGHTSRESOLV	Have the flashing lights resolved?	1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened
NS2_OTHERRESOLV_1	Were there any other symptoms not listed that have since resolved?	1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened
NS2_OTHERRESOLV_1_TEXT	If NS2_OTHERRESOLV_1 / 1 include text description	Text
NS2_OTHERRESOLV_2	Were there any other symptoms not listed that have since resolved?	1 = Never experienced this symptom, 2 = Yes, 100 % resolved 3 = Yes, mostly resolved, 4 = Yes, but only resolved somewhat, 5 = No, symptom has persisted or worsened
NS2_OTHERRESOLV_2_TEXT	If NS2_OTHERRESOLV_2 / 1 include text description	Text
NS2_SYMPADD	Did you develop any additional symptoms after treatment?	1 = Yes, 2 = No, 9 = Unknown
NS2_SYMPADDHEARINGCHANGE	Did you experience a change in hearing following	1 = Yes, 2 = No

	<i>treatment?</i>	
NS2_SYMPADDHEARINGLOSS	<i>Did you experience a loss in hearing following treatment?</i>	1 = Yes, 2 = No
NS2_SYMPADDHEADACHES	<i>Did you experience headaches following treatment?</i>	1 = Yes, 2 = No
NS2_SYMPADDSTROKE	<i>Did you experience any stroke-like symptoms following treatment?</i>	1 = Yes, 2 = No
NS2_SYMPADDALMENTAL	<i>Did you experience an altered mental status following treatment?</i>	1 = Yes, 2 = No
NS2_SYMPADDTINNITUS	<i>Did you experience a ringing or buzzing in ears (tinnitus) following treatment?</i>	1 = Yes, 2 = No
NS2_SYMPADDDEYEPAIN	<i>Did you experience any eye pain following treatment?</i>	1 = Yes, 2 = No
NS2_SYMPADDREDEYE	<i>Did you experience any red eye following treatment?</i>	1 = Yes, 2 = No
NS2_SYMPADDBLURRYVISION	<i>Did you experience any blurry vision following treatment?</i>	1 = Yes, 2 = No
NS2_SYMPADDVISIONCHANGES	<i>Did you experience any vision changes following treatment?</i>	1 = Yes, 2 = No
NS2_SYMPADDFLOATERS	<i>Did you experience any floaters following treatment?</i>	1 = Yes, 2 = No
NS2_SYMPADDVISIONLOSS	<i>Did you experience any vision loss following treatment?</i>	1 = Yes, 2 = No
NS2_SYMPADDFLASHINGLIGHTS	<i>Did you experience any flashing lights following treatment?</i>	1 = Yes, 2 = No
NS2_SYMPADDOTHER	<i>Did you experience any other symptoms</i>	1 = Yes, 2 = No

	<i>following treatment?</i>	
NS2_SYMPADDOHER_TEXT	<i>If NS2_SYMPADDOHER = 1 ("Yes") include text description</i>	Text
NS3_SITE	<i>Which participating site submitted this patient's data</i>	FL = Florida, MC = Multnomah County, NY = New York City, PH = Philadelphia, WA = Washington State
NS3_PATIENTID	<i>Unique patient identifier assigned by SSuN site</i>	Alphanumeric format
NS3_VISDATE	<i>Date of syphilis screening interview</i>	MM/DD/YYYY
NS3_DX_MM	<i>Month of date of syphilis diagnosis</i>	MM
NS3_DX_DD	<i>Day of date of syphilis diagnosis</i>	DD
NS3_DX_YYYY	<i>Year of date of syphilis diagnosis</i>	YYYY
NS3_ROUTINE	<i>Do you routinely screen your patients with syphilis for symptoms of ocular, otic, or neurosyphilis?</i>	1 = Yes, 2 = No, 9 = Unknown
NS3_ROUTINEFORM	<i>If patients with syphilis are routinely screened for ocular, otic, or neurosyphilis do you have a form that you use for screening?</i>	1 = Yes, 2 = No, 9 = Unknown
NS3_NEURODX	<i>Did this patient receive a clinical diagnosis of neurosyphilis?</i>	1 = Yes, 2 = No, 9 = Unknown
NS3_OCULARDX	<i>Did this patient receive a clinical diagnosis of ocular syphilis?</i>	1 = Yes, 2 = No, 9 = Unknown
NS3_HEARINGCHANGE	<i>Did the patient present with a change in hearing?</i>	1 = Yes, 2 = No
NS3_HEARINGLOSS	<i>Did the patient present with hearing loss?</i>	1 = Yes, 2 = No

NS3_HEADACHES	<i>Did the patient present with headaches?</i>	1 = Yes, 2 = No
NS3_STROKE	<i>Did the patient present with stroke-like symptoms?</i>	1 = Yes, 2 = No
NS3_ALTMENTENSTAT	<i>Did the patient present with an altered mental status?</i>	1 = Yes, 2 = No
NS3_TINNITUS	<i>Did the patient present with buzzing or ringing in ears (tinnitus)?</i>	1 = Yes, 2 = No
NS3_OTHERNEUROSYMP	<i>Did the patient present with other symptoms consistent with neurosyphilis?</i>	1 = Yes, 2 = No
NS3_OTHERNEUROSYMP_TEXT	<i>If NS3_OTHERNEUROSYMP = 1 ("Yes") include text description</i>	Text
NS3_EYEPAIN	<i>Did the patient present with eye pain?</i>	1 = Yes, 2 = No
NS3_REDEYE	<i>Did the patient present with red eye?</i>	1 = Yes, 2 = No
NS3_VISIONLOSS	<i>Did the patient present with vision loss?</i>	1 = Yes, 2 = No
NS3_VISIONCHANGES	<i>Did the patient present with vision changes?</i>	1 = Yes, 2 = No
NS3_FLASHINGLIGHTS	<i>Did the patient present with symptoms of flashing lights?</i>	1 = Yes, 2 = No
NS3_BLURRYVISION	<i>Did the patient present with blurry vision?</i>	1 = Yes, 2 = No
NS3_FLOATERS	<i>Did the patient present with symptoms of floaters?</i>	1 = Yes, 2 = No
NS3_OTHEROCULARSYMP	<i>Did the patient present with any other symptoms consistent with ocular syphilis?</i>	1 = Yes, 2 = No
NS3_OTHEROCULARSYMP	<i>If</i>	Text

_TEXT	NS3_OTHEROCULARSYMP = 1 ("Yes") include text description	
NS3_OPHTHALEXAM	Did the patient have an ophthalmologic exam?	1 = Yes, 2 = No, 9 = Unknown
NS3_OPHTHALEXAMUVEITIS	Was uveitis one of the ophthalmologic exam findings?	1 = Yes, 2 = No
NS3_OPHTHALEXAMSCLERITIS	Was Scleritis/keratitis one of the ophthalmologic exam findings?	1 = Yes, 2 = No
NS3_OPHTHALEXAMRETINITIS	Was Retinitis/Chorioretinitis one of the ophthalmologic exam findings?	1 = Yes, 2 = No
NS3_OPHTHALEXAMNEURITIS	Was Optic Neuritis one of the ophthalmologic exam findings?	1 = Yes, 2 = No
NS3_OPHTHALEXAMRETDETACH	Was Retinal Detachment one of the ophthalmologic exam findings?	1 = Yes, 2 = No
NS3_OTHEROPHTHALEXAM	Were there any other ophthalmologic exam findings?	1 = Yes, 2 = No
NS3_OTHEROPHTHALEXAM_TEXT	If NS3_OTHEROPHTHALEXAM = 1 ("Yes") include text description	Text
NS3_LUMBPUNC	Was a spinal tap or lumbar puncture performed?	4 = Yes, 2 = No, 9 = Unknown
NS3_LUMBPUNC_MM	If a spinal tap or lumbar puncture was done, during which month was this performed?	MM
NS3_LUMBPUNC_DD	If a spinal tap or lumbar puncture was done, on which day was this performed?	DD

NS3_LUMBPUNC_YYYY	<i>If a spinal tap or lumbar puncture was done, during which year was this performed?</i>	YYYY
NS3_LUMBPUNCROUTINE	<i>Was the lumbar puncture performed because it is a routine procedure at this facility?</i>	1 = Yes, 2 = No
NS3_LUMBPUNCSYMPTO MS	<i>Was the lumbar puncture performed based on patient symptoms?</i>	1 = Yes, 2 = No
NS3_LUMBPUNCHIVSTAT	<i>Was the lumbar puncture performed based on the patient's HIV status?</i>	1 = Yes, 2 = No
NS3_LUMBPUNCUNKNO WN	<i>Was the lumbar puncture performed for an unknown reason?</i>	1 = Yes, 2 = No
NS3_OTHERLUMBPUNC	<i>Was there another reason the lumbar puncture was performed?</i>	1 = Yes, 2 = No
NS3_OTHERLUMBPUNC_T EXT	<i>If NS3_OTHERLUMBPUNC = 1 ("Yes") include text description</i>	Text
NS3_CSFVDRL	CSF VDRL result	1 = Reactive, 2 = Non-reactive, 3 = Not done
NS3_CSFFTA_ABS	CSF FTA-ABS result	1 = Reactive, 2 = Non-reactive, 3 = Not done
NS3_CSFWBC	WBC total	# (WBC/mm ³)
NS3_CSFOTPROTEIN	CSF total protein	# (mg/100 ml)
NS3_CSFGLUCOSE	CSF glucose	# (mg/100 ml)
NS3_BENZPENG_A	<i>Was the patient prescribed Benzathine penicillin G, 2.4 million units IM single dose?</i>	1 = Yes, 2 = No
NS3_BENZPENG_B	<i>Was the patient prescribed Benzathine penicillin G, 2,4 million units in 3 doses at 1 week</i>	2 = Yes, 2 = No

	<i>intervals (max total 7.2 million units)</i>	
NS3_BENZPENG_C	<i>Was the patient prescribed Benzathine penicillin G, 50000 units/kg IM, single dose (max total 2.4 million units)</i>	<i>3 = Yes, 2 = No</i>
NS3_BENZPENG_D	<i>Was the patient prescribed Benzathine penicillin G, 50000 units/kg IM, 3 doses, 1 week intervals (max total 7.2 million units)</i>	<i>4 = Yes, 2 = No</i>
NS3_AQCRYPENG_A	<i>Was the patient prescribed Aqueous crystalline penicillin G IV, 18-24 million units/day, administered as 3-4 million units IV every 4 hrs, for 10-14 days?</i>	<i>1 = Yes, 2 = No</i>
NS3_AQCRYPENG_B	<i>Was the patient prescribed Aqueous crystalline penicillin G IV, 18-24 million units/day, administered as continuous infusion, for 10-14 days?</i>	<i>1 = Yes, 2 = No</i>
NS3_DOXYCYC_A	<i>Was the patient prescribed Doxycycline, 100 mg 2x/day for 14 days?</i>	<i>1 = Yes, 2 = No</i>
NS3_DOXYCYC_B	<i>Was the patient prescribed Doxycycline, 100 mg 2x/day for 28 days?</i>	<i>1 = Yes, 2 = No</i>
NS3_TETRACYC_A	<i>Was the patient prescribed Tetracycline, 500 mg orally 4x/day</i>	<i>2 = Yes, 2 = No</i>

	<i>for 14 days?</i>	
NS3_TETRACYC_B	<i>Was the patient prescribed Tetracycline, 500 mg orally 4x/day for 28 days?</i>	3 = Yes, 2 = No
NS3_PROCPENPROB	<i>Was the patient prescribed Procaine penicillin G 2.4 million units IM 1x daily, PLUS probenecid (500 mg, 4 times a day, both for 10-14 days?</i>	1 = Yes, 2 = No
NS3_PROCPEN	<i>Was the patient prescribed Procaine penicillin G 2.4 million units IM 1x daily for 10-14 days without probenecid?</i>	1 = Yes, 2 = No
NS3_CEFTRIAX_A	<i>Was the patient prescribed Ceftriaxone 250 mg IM in a single dose?</i>	1 = Yes, 2 = No
NS3_CEFTRIAX_B	<i>Was the patient prescribed Ceftriaxone 1 g IM in a single dose?</i>	1 = Yes, 2 = No
NS3_OTHERTX	<i>Was the patient prescribed any other treatment?</i>	1 = Yes, 2 = No
NS3_SYPHTX_TEXT	<i>If NS3_OTHERTX = 1 ("Yes") include text description</i>	Text
P3_PTX_GEOMRSP	<i>(72) Thinking back to the last person you had sex with, about how far away does that person live from you. If you don't know for sure, it's OK to make your best guess.</i>	0=Partner lives with me 1=less than 5 minutes 2=5 to 15 minutes 3=15 to 30 minutes 4=30 minutes to 1 hour 5=> 1 hour 6=They live in another state 7=They live in another country 8=Don't know / Not sure 9=Refused
F1_Sympt	<i>Does the patient have STI symptoms?</i>	1= Yes 2= No 9= Not captured

F1_prep_offer	Was the patient offered PrEP at the STD clinic?	1= Yes 2= No 9= Not captured
F1_pep_offer	Was the patient offered PEP at the STD clinic?	1= Yes 2= No 9= Not captured
F1_EPT	Is the patient eligible for expedited partner therapy?	1= Yes 2= No 3= Not indicated 9= Not captured
F1_Partner_txACCPT	Did the patient accept expedited partner therapy?	1= Yes 2= No 9= Not captured

Table2A. Proposed Response Coding changes to existing Data Elements, Strategy A, Sentinel Surveillance in STD Clinical Facilities

Data Element/Variable Name	Description	Valid Values
F1_SiteID	Unique site code	BA=Baltimore (Cycle II, Cycle III, Cycle IV) CB=Columbus (Cycle IV) CA=California (Cycle II, Cycle III, Cycle IV) FL=Florida (Cycle III & Cycle IV) IN=Indiana (Cycle IV) MC=Multnomah County (Cycle III & Cycle IV) NY=New York City (Cycle II, Cycle III, Cycle IV) PH=Philadelphia (Cycle II, Cycle III, Cycle IV) SF=San Francisco (Cycle II, Cycle III, Cycle IV) WA= Washington (Cycle II, Cycle III, Cycle IV) UT=UTAH (Cycle IV) LA=Louisiana (Cycle II) VA=Virginia (Cycle II) AL=Alabama (Cycle II) CO=Colorado (Cycle II) CH=Chicago (Cycle II) MA=Massachusetts (Cycle III) MN=Minnesota (Cycle III)
F3_Test_Type	Type of laboratory test performed	1= Culture 2= Nucleic acid amplification test (NAAT) 3= Non-amplified nucleic acid test/DNA probe 4= Gram stain 10= HIV Nucleic acid test (NAT) 11= rapid HIV-1 or HIV-1/2 antibody (Ab) test 12= HIV-1 Immunoassay (IA) 13= HIV-1/2 IA 14= HIV-1/2 Ag/Ab IA 15= HIV-1 WB

		<p> 16= HIV-1 IFA 17= HIV-1/HIV-2 differentiation IA 18= pooled RNA 19=HIV Viral Load (ultra quantitative) 20=HIV Viral Load (quantitative) 21=CD4+ assay 22=HIV-1 IA (EIA or Other) 23=HIV-1/2 IA (EIA or Other) 24=HIV-2 IA (EIA or Other) 25=HIV-1/2 Ag/Ab 26=HIV-1/2 Type-Differentiating Immunoassay 27=HIV-1 Western Blot 28=HIV-2 Western Blot 29=HIV-1 IFA 30=HIV-1 Culture 31=HIV-2 Culture 32=HIV-1 p24 Antigen 33=HIV-1 RNA/DNA NAAT (Qualitative) 34=HIV-2 RNA/DNA NAAT (Qualitative) 35=HIV-1 RNA/DNA NAAT (Quantitative viral load) 36=HIV-2 RNA/DNA NAAT (Quantitative viral load) 37=CD4 T-lymphocytes 38=CD4 Percent 39=HIV-1 Genotype (PR Nucleotide Sequence) 40=HIV-1 Genotype (RT Nucleotide Sequence) 41=HIV-1 Genotype (PR/RT Nucleotide Sequence) 42=HIV-1 Genotype (IN Nucleotide Sequence) 43=HIV-1 Genotype (PR/RT/IN Nucleotide Sequence) 44=STARHS (BED) 45=STARHS (Vironostika-LS) 46=STARHS (BIO-RAD AVIDITY) 47=STARHS (Other) 48=STARHS (Unknown) 49=Rapid (Retired) 50=HIV-1/2 Ag/Ab-Distinguishing Immunoassay 51=HIV-1 Genotype (EN Nucleotide Sequence) 52=HIV-1 Genotype (FI Nucleotide Sequence) 53=HIV-1/2 Ag/Ab and Type-Differentiating Immunoassay 54=HIV-1/2 Ag/Ab and Type-Differentiating IA - HIV-1 p24 Antigen Analyte 55=HIV-1/2 Ag/Ab and Type-Differentiating IA - HIV-1 Antibody Analyte 56=HIV-1/2 Ag/Ab and Type-Differentiating </p>
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		IA - HIV-2 Antibody Analyte 57=HIV-1/2 Type-Differentiating Immunoassay (Supplemental) 58=HIV-1/2 Type-Differentiating IA (Suppl) - HIV-1 Antibody Analyte 59=HIV-1/2 Type-Differentiating IA (Suppl) - HIV-2 Antibody Analyte 60=HIV-1 Genotype (Unspecified) 61=WB/IFA-Legacy 62=RIPA-Legacy 63=Latex Ag-Legacy 64=Peptide-Legacy 65=Rapid-Legacy 66=Iga-Legacy 67=IVAP-Legacy 68=Other HIV Antibody-Other-Legacy 69=Other HIV Antibody-Unspecified-Legacy 70=Viral Load-Other-Legacy 71=Viral Load-Unspecified-Legacy 72=HIV Detection/Antigen/Viral Load-Other-Legacy 73=HIV Detection/Antigen/Viral Load-Unspecified-Legacy 74= Pregnancy 88= Other 99=Not captured
F3_Conducted	What condition was the patient tested for?	1 = Syphilis 2 = Gonorrhea 3 = Chlamydia 4 = Chancroid 5 = Trichomoniasis 6 = HIV/AIDS 7 = Bacterial vaginosis 8 = Herpes 9 = Mycoplasma genitalium 20 = Pregnancy
F4_Medication	What medication was prescribed to the patient (brand name)?	10= Amoxicillin (Amoxil, Polymox, Trimox, Wymox) 11= Ampicillin (Omnipen, Polycillin, Polycillin-N, Principen, Totacillin) 20= Azithromycin (Zithromax) 21= Erythromycin base 22= Clindamycin (Cleocin) 23= Gentamicin (Garamycin, G-Mycin, Jenamicin) 30= Cefixime (Suprax) 31= Ceftizoxime (Cefizox) 32= Cefotaxime (Claforan) 33= Cefoxitin (Mefoxin) 34= Cefpodoxime (Vantin) 35= Ceftibuten (Cedax) 36= Cefdinir (omnicef) 37= Ceftriaxone (Rocephin) 38= Cefuroxime (Ceftin, Kefurox, Zinacef, Zinnat)

		<p>40= Ciprofloxacin (Cipro, Cipro XR, Ciprobay, Ciproxin)</p> <p>41= Levofloxacin (Cravit, Levaquin)</p> <p>42= Moxifloxacin (Avelox, Vigamox)</p> <p>43= Ofloxacin (Floxin, Oxaldin, Tarivid)</p> <p>44= Gemifloxacin (Factive)</p> <p>50= Doxycycline (Doryx, Vibramycin)</p> <p>60= Metronidazole (Flagyl, Helidac, Metizol, Metric 21, Neo-Metric, Noritate, Novonidazol)</p> <p>61= Tinidazole (Tindamax)</p> <p>70= Truvada (Tenofovir/emtricitabine)</p> <p>88= Other</p>
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Table2B. Proposed New Variables, Strategy A, Sentinel Surveillance in STD Clinical Facilities

Variable name	Description	Valid Values
F1_SEXOR3TG	Has the patient had sex with a transgender man or woman?	1= Yes 2= No 9= Not captured
F1_HregMatch	Was HIV registry match done for this patient?	1=Yes 2=No
F1_HregMatchStat	Did this patient match a registry entry in eHARS?	1=Matching Record Found 2=No Matching Record 3=Match Not Performed
F1_HregID	Unique record number from HIV registry (such as stateno from eHARS).	Alphanumeric character value (\$15)
F1_EXPMOD	Exposure mode from HIV registry.	1=Male who had sex with another male (MSM) 2=Injected illicit or non-prescription drugs (IDU) 3=Had sex with someone with either 1 or 2 (above) 4=Had Sex with Someone of the Opposite Sex but May Not whether HIV Infection was Diagnosed in that Person, or Any of the Risk factors of Sex in Items 3 or 5 5=Had Sex with Someone of the Opposite Sex in whom HIV Diagnosed after Having Any Risk Factor for HIV Infection in Items 6 (Receipt of Clot Coagulation Disorder), 7 (Receipt of Blood Transfusion), or 8 (Receipt of Transplan Insemination) 6=Received Clotting Factor Injection for Hemophilia or Anco

		Disorder 7=Received Transfusion of Blood or Blood Components (e. 8=Received a Transplant of Tissue or Organ or Artificial Ins 9=Worked in a Health-Care or Clinical Laboratory Setting w Exposure to Human Blood or Other Body Fluids 10=Had Other Exposure to Human Blood or Body Fluids 11=No Risk Reported
F1_Pelvic_exam	Was a pelvic exam performed?	1= Yes 2= No 9= Not captured
F1_prep_offer	Was the patient offered PrEP at the STD clinic?	1= Yes 2= No 3= No, but a referral to outside clinic was given
F1_PEP_offer	Was the patient offered PEP at the STD clinic?	1= Yes 2= No 3= No, but a referral to outside clinic was given
F1_prep_referral	Was the patient referred for PrEP at the STD clinic?	1= Yes 2= No
F1_condom	Does the patient report receptive anal sex without a condom with a male in the last 3 months?	1= Yes 2= No 3= Unsure/ doesn't know 9= Not captured
F1_HIVTest	Has the patient ever been tested for HIV? (excluding HIV testing on today's visit)?	1= Yes 2= No 3= Patient does not know/ not sure 9= Not captured
F1_SXAbdomen	Did the patient report abdominal pain?	1= Yes 2= No 9= Not captured
F3_QuantRes	Quantitative result from laboratory test	A-Z, 0-9,-,_, blank
F3_QuantUnits	Units for quantitative results	1=Copies/mL 2=Log Copies/mL 3=Cells/Cubic mm 4=CD4% 5=Titer Ratio 6=Cycles/Time (rtPCR) 9=Unk
F4_TxDate	Date treatment prescribed/dispensed	MMDDYYYY
F5_PrEP_Rx	Does the facility prescribe PrEP?	1= Yes 2= No, facility does not prescribe PrEP
F5_PrEP	Does the facility have written policies governing referral or management of PrEP?	1= Yes 2= No

F5_PEP_Rx	Does the facility prescribe PEP?	1= Yes 2= No, facility does not prescribe PEP
F5_PrEP_Manage	Does the facility actively manage patients on PrEP?	1= Yes 2= No, facility does not refer to or manage PrEP
FS1_FirstVis	Is this your first time to this clinic?	1=Yes 2=No
FS1_Welcome	Do you feel that this clinic provides a welcoming and respectful environment?	1=Yes 2=No 3=Not Sure
FS1_Reas1	Health problem or symptoms	1=Yes 2=No
FS1_Reas2	No health problems or symptoms, but came to get STD screening/check-up	1=Yes 2=No
FS1_Reas3	Told to get checked by partner	1=Yes 2=No
FS1_Reas4	Referred by health department/disease intervention specialist (DIS)	1=Yes 2=No
FS1_Reas5	Follow-up visit	1=Yes 2=No
FS1_Reas6	Came to get STD test results	1=Yes 2=No
FS1_Reas7	Came to get HIV test	1=Yes 2=No
FS1_Reas8	Came to get medication that I can take every day to prevent getting HIV infection before I am exposed to the virus (PrEP)	1=Yes 2=No
FS1_Reas9	Came to get medication that I can take right away because I think I was exposed to HIV in the past few days (PEP)	1=Yes 2=No
FS1_Reas10	Came to get contraception	1=Yes 2=No
FS1_Reas11	Some other reason	1=Yes 2=No
FS1_Reas12_TXT	Specify _____	
FS1_ReasThisClin	What is the main reason you chose this clinic for care (choose only one)?	1=Could walk in or get same day appointment 2=Cost 3=Privacy concern 4=Expert care 5=Embarrassed to go to usual doctor 6=Some other reason
FS1_ReasThisClin_TXT	Please specify other reason _____	

FS1_WhereElse	Where would you have gone today if this STD clinic did not exist (choose only one)?	1=I would have waited to see how I felt and then decided what to do 2=Community health center 3=Public clinic/ health department clinic 4=Family planning clinic 5=Private doctor's office 6=Urgent care clinic/walk in clinic 7=Hospital emergency room (ER) 8=Hospital outpatient department 9=School-based clinic 10=Some other place
FS1_WhereElse_TXT	Please specify other place _____	
FS1_UsualPlace	Is there a place that you USUALLY go to when you are sick or need advice about your health?	1=Yes 2=No
FS1_MostOftenGo	If YES, what kind of place do you go to most often (choose only one)?	2=Public clinic/health department clinic 3=Family planning clinic 4=Private doctor's office 5=Urgent care clinic/walk in clinic 6=Hospital emergency room (ER) 7=Hospital outpatient department 8=School-based clinic 9=Some other place
FS1_MostOftenGo_TXT	Please specify _____	
FS1_PrevCare	Is there a place you USUALLY go to when you need routine care or preventive care such as a physical exam or check-up?	1=Yes 2=No
FS1_PrevCareGo	If YES, what kind of place do you go to most often (choose only one)	1=Community health center 2=Public clinic/health department clinic 3=Family planning clinic 4=Private doctor's office 5=Urgent care clinic/walk in clinic 6=Hospital emergency room (ER) 7=Hospital outpatient department 8=School-based clinic 9=Some other place
FS1_PrevCareGo_TXT	Please specify _____	
FS1_Insurance	Do you have health insurance (choose only one)?	1=Yes, parents' insurance plan 2=Yes, government (Medicaid,

		<p>Medicare, etc.)</p> <p>3=Yes, private insurance (through employer)</p> <p>4=Yes, private insurance (purchased by yourself/healthcare.gov exchange)</p> <p>5=No coverage of any type <input type="checkbox"/> GO TO QUESTION # 13</p> <p>6=Don't know <input type="checkbox"/> GO TO QUESTION # 13</p>
FS1_UseIns	If YES, would you be willing to use your health insurance for today's visit?	<p>1=Yes</p> <p>2=No</p>
FS1_NOTUseIns1	I do not want my insurance company to know	<p>1=Yes</p> <p>2=No</p>
FS1_NOTUseIns2	Insurance company might send records home	<p>1=Yes</p> <p>2=No</p>
FS1_NOTUseIns3	I do not want my parents/spouse/significant other to know	<p>1=Yes</p> <p>2=No</p>
FS1_NOTUseIns4	Usual doctor might send records home	<p>1=Yes</p> <p>2=No</p>
FS1_NOTUseIns5	I cannot afford to pay the co-pay or deductible	<p>1=Yes</p> <p>2=No</p>
FS1_NOTUseIns6	My insurance will not cover this visit	<p>1=Yes</p> <p>2=No</p>
FS1_NOTUseIns7	Some other reason	<p>1=Yes</p> <p>2=No</p>
FS1_NOTUseIns_TXT	Please specify	
FS1_BirthSex	What sex were you assigned at birth on your original birth certificate?	<p>1=Male</p> <p>2=Female</p> <p>3=Refused</p> <p>4=Don't know</p>
FS1_GendID	How do you currently describe yourself?	<p>1=Male</p> <p>2=Female</p> <p>3=Trans, Male to Female</p> <p>4=Trans, Female to Male</p> <p>5=Gender Queer/Non-Binary</p> <p>6=Other</p>
FS1_Age	How old are you? Age in years_____	
FS1_HispEth	Do you consider yourself Hispanic/Latino/a?	<p>1=Yes, Hispanic</p> <p>2=No, Not Hispanic</p> <p>8=Unknown/Can't guess</p> <p>9=Refused</p>

FS1_RaceWhite	White	1=Yes 2=No
FS1_RaceBlack	Black	1=Yes 2=No
FS1_RaceAIAN	AI/AN	1=Yes 2=No
FS1_RaceAsian	ASIAN	1=Yes 2=No
FS1_RaceNHOPI	NH/OPI	1=Yes 2=No
FS1_RaceOther	Other race	1=Yes 2=No
FS1_RaceUnk	Unknown/Can't guess	1=Yes 2=No
FS1_RaceRef	Refused Race	1=Yes 2=No
FS1_SexOrient	Which of the following best represents how you think of yourself?	1=Heterosexual/Straight 2=Gay/Lesbian/Homosexual 3=Bisexual 4=Other 5=I don't know 9=Refused
FS1_Employ1	Full-time employment	1=Yes 2=No
FS1_Employ2	Part-time employment	1=Yes 2=No
FS1_Employ3	Unemployed	1=Yes 2=No
FS1_Employ4	Disabled	1=Yes 2=No
FS1_Employ5	Student	1=Yes 2=No
FS1_Employ6	Other	1=Yes 2=No
FS1_Educate	What is your highest level of school you have completed or the highest degree you have received	1=Middle school 2=Some high school 3=High school diploma 4=GED or equivalent 5=Some college 6=College degree or higher
LGV1_SecimenID	Specimen ID - locally assigned, unique specimen tracking ID for LGV prevalence activity	

Table 3A. Proposed Response Coding changes to existing Data Elements, Strategy B, Case-based Enhanced Surveillance

Data Element/Variable Name	Description	Valid Values
P1_SiteID	SSuN Site ID	BA=Baltimore (Cycle II, Cycle III, Cycle IV) CB=Columbus (Cycle IV) CA=California (Cycle II, Cycle III, Cycle IV) FL=Florida (Cycle III & Cycle IV) IN=Indiana (Cycle IV) MC=Multnomah County (Cycle III & Cycle IV) NY=New York City (Cycle II, Cycle III, Cycle IV) PH=Philadelphia (Cycle II, Cycle III, Cycle IV) SF=San Francisco (Cycle II, Cycle III, Cycle IV) WA= Washington (Cycle II, Cycle III, Cycle IV) UT=UTAH (Cycle IV) LA=Louisiana (Cycle II) VA=Virginia (Cycle II) AL=Alabama (Cycle II) CO=Colorado (Cycle II) CH=Chicago (Cycle II) MA=Massachusetts (Cycle III) MN=Minnesota (Cycle III)
P3_PTX_sex	What gender or sex do you consider yourself to be?	1= CIS Male 2=CIS Female 3=Male-to-Female TG 4=Female-to-Male TG 5=TG Unspecified 6=Queer, Gender Non-binary 8=Refused
P1_L1_TestType	As test technology advances, it is important to obtain the type of test performed	1= Culture 2= Nucleic acid amplification test (NAAT) 3= Non-amplified nucleic acid test/DNA probe 4= Gram stain 10= HIV Nucleic acid test (NAT) 11= rapid HIV-1 or HIV-1/2 antibody (Ab) test 12= HIV-1 Immunoassay (IA) 13= HIV-1/2 IA 14= HIV-1/2 Ag/Ab IA 15= HIV-1 WB 16= HIV-1 IFA 17= HIV-1/HIV-2 differentiation IA 18= pooled RNA 19=HIV Viral Load (ultra quantitative) 20=HIV Viral Load (quantitative)

		<p> 21=CD4+ assay 22=HIV-1 IA (EIA or Other) 23=HIV-1/2 IA (EIA or Other) 24=HIV-2 IA (EIA or Other) 25=HIV-1/2 Ag/Ab 26=HIV-1/2 Type-Differentiating Immunoassay 27=HIV-1 Western Blot 28=HIV-2 Western Blot 29=HIV-1 IFA 30=HIV-1 Culture 31=HIV-2 Culture 32=HIV-1 p24 Antigen 33=HIV-1 RNA/DNA NAAT (Qualitative) 34=HIV-2 RNA/DNA NAAT (Qualitative) 35=HIV-1 RNA/DNA NAAT (Quantitative viral load) 36=HIV-2 RNA/DNA NAAT (Quantitative viral load) 37=CD4 T-lymphocytes 38=CD4 Percent 39=HIV-1 Genotype (PR Nucleotide Sequence) 40=HIV-1 Genotype (RT Nucleotide Sequence) 41=HIV-1 Genotype (PR/RT Nucleotide Sequence) 42=HIV-1 Genotype (IN Nucleotide Sequence) 43=HIV-1 Genotype (PR/RT/IN Nucleotide Sequence) 44=STARHS (BED) 45=STARHS (Vironostika-LS) 46=STARHS (BIO-RAD AVIDITY) 47=STARHS (Other) 48=STARHS (Unknown) 49=Rapid (Retired) 50=HIV-1/2 Ag/Ab-Distinguishing Immunoassay 51=HIV-1 Genotype (EN Nucleotide Sequence) 52=HIV-1 Genotype (FI Nucleotide Sequence) 53=HIV-1/2 Ag/Ab and Type-Differentiating Immunoassay 54=HIV-1/2 Ag/Ab and Type-Differentiating IA - HIV-1 p24 Antigen Analyte 55=HIV-1/2 Ag/Ab and Type-Differentiating IA - HIV-1 Antibody Analyte 56=HIV-1/2 Ag/Ab and Type-Differentiating IA - HIV-2 Antibody </p>
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		Analyte 57=HIV-1/2 Type-Differentiating Immunoassay (Supplemental) 58=HIV-1/2 Type-Differentiating IA (Suppl) - HIV-1 Antibody Analyte 59=HIV-1/2 Type-Differentiating IA (Suppl) - HIV-2 Antibody Analyte 60=HIV-1 Genotype (Unspecified) 61=WB/IFA-Legacy 62=RIPA-Legacy 63=Latex Ag-Legacy 64=Peptide-Legacy 65=Rapid-Legacy 66=Iga-Legacy 67=IVAP-Legacy 68=Other HIV Antibody-Other-Legacy 69=Other HIV Antibody-Unspecified-Legacy 70=Viral Load-Other-Legacy 71=Viral Load-Unspecified-Legacy 72=HIV Detection/Antigen/Viral Load-Other-Legacy 73=HIV Detection/Antigen/Viral Load-Unspecified-Legacy 74= Pregnancy 88= Other 99=Not captured
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Table 3B. Proposed New Variables, Strategy B, Case-based Enhanced Surveillance

Data Element/Variable Name	Description	Valid Values
P1_L1_QuantUnits	Units for quantitative results:	1=Copies/mL 2=Log Copies/mL 3=Cells/Cubic mm 4=CD4% 5=Titer Ratio 6=Cycles/Time (rtPCR)
P3_PTX_TGSP	During the past 12 months, have you had sex with a transgender man or transgender woman?	1=Yes 2=No 3=Don't Know /Don't Remember/ Not Sure 4=Refused
P3_PTX_EPTPARTAKE	Do you <i>think</i> at least one of your sex partners took this medication?	1=Yes, I think at least one of my partner(s) took this medicine 2=No, I do not think any of my partner(s) took these medicines 9=Refused
P3_PTXBirtCount	Birth Country	Text
P3_PTXBirtState	Birth State	Text
P3_PTXNativity	Where were you born?	1=In the US 2=Outside the US

P3_PTX_PIOrgin	(21) patient reported NHOPI origin	1=Native Hawaiian 2=Guamanian/Chamorro/Fijian/Chuukese/Carolinian 3=Samoan/Tokelauan/Tongan/Yapese 4=Niuean/Palauan/Pohnpeian 5=Kosraean/Marshallese 6=Other Pacific Island 9=Refused
P3_PTX_AsianOrigin	Asian Origin	1=Asian Indian (India) 2 =Japanese 3=Chinese/Taiwanese 4=Korean 5=Filipona/o 6=Southeast Asian (Vietnamese, Thai, Cambodian, Burmese) 7=Indonesian 8=West Asians (Middle East) 9=Other/Unk Asian 10=Refused
P3_PTX_AIAN_TXT	Tribal Affiliation	Text
P3_PTX_HISPTXT	Other Hispanic Origin	Text
P3_PTX_HISPOrgin	Do you consider yourself to be...?	1=Mexican, Mexican Am., Chicano/a, Latino/a 2=Puerto Rican 3=Cuban 4=Central American (Guatemalan, Honduran, Nicaraguan, El Salvadoran) 5=Other Hispanic Origin 6=Unknown 9=Refused
P2_PR_Duration_Number	Days duration or frequency of doses	Number of days
P2_PR_Number	Number of doses/day	0=Single dose, STAT; Numeric value for all other
P2_PR_Method	Method of administration	01=PO - oral dosing 02=IM - intramuscular 03=IV - intravenous/infusion
P2_PR_Dose_Units	Dosage units	01-Miligrams (mg) 02-Grams (g) 03-Units 04-Units/Kilogram 05-Million Units 06-Million Units/Kilogram 07-Milliliters (ml)
P2_PR_Dosage	Dosage - numeric	Number
P2_PR_OthMedTXT	Other medication if value of 88 selected for P2_PR_DrugName	Text
P2_PR_DrugName	What drug was patient treated with?	01=Penicillin G (benzathine, aqueous procaine, or aqueous crystalline)

		02=Probenacid 10= Amoxicillin (Amoxil, Polymox, Trimox, Wymox) 11= Ampicillin (Omnipen, Polycillin, Polycillin-N, Principen, Totacillin) 20= Azithromycin (Zithromax) 21= Erythromycin base 22= Clindamycin (Cleocin) 23= Gentamicin (Garamycin, G-Mycin, Jenamicin) 30= Cefixime (Suprax) 31= Ceftizoxime (Cefizox) 32= Cefotaxime (Claforan) 33= Cefoxitin (Mefoxin) 34= Cefpodoxime (Vantin) 35= Ceftibuten (Cedax) 36= Cefdinir (omnicef) 37= Ceftriaxone (Rocephin) 38= Cefuroxime (Ceftin, Kefurox, Zinacef, Zinnat) 40= Ciprofloxacin (Cipro, Cipro XR, Ciprobay, Ciproxin) 41= Levofloxacin (Cravit, Levaquin) 42= Moxifloxacin (Avelox, Vigamox) 43= Ofloxacin (Floxin, Oxaldin, Tarivid) 44= Gemifloxacin (Factive) 50= Doxycycline (Doryx, Vibramycin) 60= Metronidazole (Flagyl, Helidac, Metizol, Metric 21, Neo-Metric, Noritate, Novonidazol) 61= Tinidazole (Tindamax) 70= Truvada (Tenofovir/emtricitabine) 88= Other (provide text in P2_PR_OthMedTXT)
P1_PtxGendID	Gender Identity of the patient as indicated on initial health department report.	1=Male-to-Female Transgender 2=Female-to-Male Transgender 3=Transgender, not specified 4=CIS Gender (Male or Female, NOT transgendered) 9=Gender Identity not documented
P1_ConcurCTDx	Was this patient diagnosed with CT at the same time as their current GC diagnoses?	1=Yes, tested and found to be CT positive 2=No, tested and found to be CT negative 3=No, patient not tested for CT/No CT information available

Changes in Estimates of Annualized Burden Hours

We estimate increase in estimated annualized burden hours from the previously approved 3,479 to 6,303 for this ICR as part of this change request, as described in Exhibit 12.A (below), which provides the current burden table for this ICR with the requested revisions.

Exhibit 12.A Estimates of Annualized Burden Hours

Type of Respondents	Form Name (if applicable)	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Data managers at	Electronic Clinical	11	6	4	264

sentinel STD clinics (Table B.1.A)	Record Abstraction (ATT5)				
General Public – Adults (persons diagnosed with gonorrhea)	Patient interviews for a random sample of gonorrhea cases (ATT5, ATT8)	7,380	1	10/60	1,230
General Public – Adults (STD Clinic Patients)	STD Clinic survey (ATT5, ATT8)	3,850	1	5/60	321
Data Managers: 11 local/state health departments (ATT6)	HIV registry matching (ATT5)	11	6	20	1,320
Data Managers: 11 local/state health departments (ATT6)	Data cleaning/ validation, HIV registry matching and data transmission (ATT5)	11	12	24	3,168
Total	6,303