# Clinical Trials Data KIT - Document 19

# Evaluation of Rapid HIV Self-testing Among MSM (eSTAMP)

## Clinical Trial: https://clinicaltrials.gov/study/NCT02067039

"briefSummary": "This study seeks to determine the public health impact of providing rapid HIV test kits to men who have sex with men (MSM) so they may test themselves at their convenience. The study will determine if men who receive the rapid HIV test kits report HIV testing at least three times per year. This study will be conducted in four consecutive parts. The first three parts are formative in nature to guide the development and implementation of Part 4 of the study. The research study will use two different types of rapid HIV tests. The OraQuick\u00ae In-Home HIV Test for oral fluid (FDA approved for home use) and Sure Check\u00ae HIV 1/2 Assay, currently FDA-approved for professional use and distributed in the U.S. as Clearview\u00ae Complete HIV-1/2 Rapid Test. An Investigational Device Exemption will be obtained from the FDA to allow the contractor to supply the Sure Check\u00ae HIV 1/2 Assay to study participants since it is not approved for home use.",  
 "detailedDescription": "The eSTAMP project will evaluate the use and impact of providing rapid HIV tests for use to men who have sex with men (MSM) recruited via the internet. Data obtained through this study will include who will use the tests, how they were used, the utility of the tests in identifying HIV infections and promoting engagement in HIV care. This will inform policies to guide the optimal use of rapid HIV tests.\n\nThis research project will be conducted in four sequential parts to evaluate the acceptability, use and effectiveness of rapid HIV test kits among MSM in cities with high HIV prevalence. Each part will be independent and they will provide information to implement the next part of the study. At the end of each part, the data will be evaluated. The findings will guide the implementation of subsequent parts of the study.\n\nPart 1 will evaluate the materials, packaging and instructions for conducting self-testing activities. MSM will be recruited from prior research studies or over the internet to participate in focus groups and in-depth interviews by Emory University or Northwestern University. These activities will take place in Atlanta, GA and Chicago, IL. Completed.\n\nPart 2 will evaluate the user proficiency of participants performing the rapid HIV test on themselves while under observation using the instructional and materials developed in the previous part of the study. MSM who had participated in prior research studies and consented to future contact for involvement in additional studies were recruited by Emory University. Participants will conduct activities at Emory University in Atlanta, GA. Completed.\n\nPart 3 will evaluate the performance of the rapid HIV tests by the proposed study population in real world settings. Participants will be recruited via the internet and directed to a research study site for further study activities. Participants will be shipped study materials (one OraQuick In-home HIV test, one SureCheck HIV 1/2 Assay and one dried blood spot (DBS) collection kit). Participants will report their rapid HIV test results online and return the DBS card for laboratory HIV testing. Completed.\n\nPart 4 will evaluate the use and effectiveness of providing free rapid HIV tests as a public health strategy for increasing testing among MSM. We will recruit 3200 participants who report being HIV negative or unaware of their HIV status for the main trial. These participants will be randomly assigned to either the intervention or comparison condition after completing a baseline survey. An additional 150 MSM who report being HIV-positive will be recruited to evaluate the distribution of rapid HIV tests to their network partners.\n\nComparison arm: After completing the baseline survey, comparison arm participants will receive a welcome greeting and HIV prevention information. The online information will cover the importance of testing, links to AIDSVu and other resources to locate HIV testing services and prevention information in their area. Comparison arm participants will receive follow-up surveys at 3, 6, 9 and 12 months. After completing the 12 month assessment, participants will be sent a performance kit consisting of 1 oral fluid HIV test kit (OraQuick) and 1 finger-stick blood HIV test kit (Sure Check) and a DBS specimen collection kit that will be returned for HIV testing at the CDC laboratory.\n\nIntervention arm: After completing the baseline survey, a welcome kit with 4 rapid HIV tests (2 oral fluid test kits \\[OraQuick\\] and 2 finger-stick blood test kits \\[Sure Check\\] will be sent to participants in the intervention arm to use and/or give away. Intervention arm participants will receive follow-up surveys at 3, 6, 9 and 12 months and have the option to order additional test kits at 3, 6 and 9 months to replenish kits that have been used or distributed. After completing the 12 month assessment, participants will be sent a performance kit consisting of 1 oral fluid HIV test kit (OraQuick) and 1 finger-stick blood HIV test kit (Sure Check) and a DBS specimen collection kit that will be returned for HIV testing at the CDC laboratory.\n\nThe men who report being HIV-positive who will be assigned to a one-arm descriptive cohort. Participants in this group will take a baseline survey and will receive rapid HIV test kits (OraQuick) to distribute to persons in their social and sexual networks (secondary users). Men in the HIV-positive group will complete a short follow-up survey at 3 months. Secondary users who use the tests will have access to study materials and referral information."  
 "Men who have sex with men (MSM)",  
 "eligibilityCriteria": "Inclusion Criteria:\n\n\* The inclusion criteria for the Part 4 randomized controlled trial are:\n\n 1. male sex at birth\n 2. currently identify their sex as male\n 3. able to provide informed consent\n 4. at least 18 years of age\n 5. report being HIV-negative or unaware of HIV status\n 6. resident of United States and Puerto Rico.\n 7. able to read instructions and complete study survey instruments in English\n 8. reported anal sex with at least one man in the past 12 months\n 9. have a valid email address, a cell phone capable of sending and receiving text messages, and a physical shipping address to receive kits\n 10. never diagnosed with a bleeding disorder\n 11. not part of an HIV vaccine trial\n 12. not taking antiretroviral medication for HIV.\n\nExclusion Criteria:\n\n\* The exclusion criteria for the Part 4 randomized controlled trial are:\n\n 1. not male sex at birth\n 2. do not currently identify their sex as male\n 3. not able to provide informed consent\n 4. under 18 years of age\n 5. report being HIV-positive\n 6. not a resident of United States or Puerto Rico.\n 7. not able to read instructions and complete study survey instruments in English\n 8. do not report anal sex with at least one man in the past 12 months\n 9. do not have a valid email address, a cell phone capable of sending and receiving text messages, or a physical shipping address to receive kits\n 10. ever diagnosed with a bleeding disorder\n 11. part of an HIV vaccine trial\n 12. taking antiretroviral medication for HIV.",  
 "healthyVolunteers": true,  
 "sex": "MALE",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a KIT gene mutation be eligible for the clinical trial?

Answer:  
Based on the provided clinical trial information, the eligibility criteria for participation do not mention a KIT gene mutation. The inclusion and exclusion criteria focus primarily on factors related to HIV status, demographic characteristics (such as sex at birth, current sex identification, and age), residence, language capabilities, and the ability to complete study requirements (like having a valid email address, cell phone, and physical shipping address).  
  
Since a KIT gene mutation is not listed among the inclusion or exclusion criteria, the presence of such a mutation does not appear to impact eligibility for this clinical trial. However, final eligibility would depend on a more detailed review by the trial investigators, considering all the specific criteria laid out for the study.