Statistical Analysis Plan (SAP)

Please complete all relevant sections. Instructions are in red and should be deleted when completing the SAP. The purpose of this template is to provide a general layout, but sections can be reformatted as you wish.

The creation of this template for the Duke BERD Methods Core was made possible by Grant Number UL1TR002553 from the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH), and NIH Roadmap for Medical Research.

Title	Relative Effectiveness of Social Media, Dating Apps, and Information Search Sites in Promoting HIV Self-testing: An Observational Cohort Study
CRU/Department/Division/Center	Department of Population and Public Health Sciences, University of Southern California; Division of Infectious Diseases, David Geffen School of Medicine, University of California Los Angeles; Geisel School of Medicine, Dartmouth College; Department of Emergency Medicine, School of Medicine, University of California, Irvine; Department of Informatics, Bren School of Information and Computer Sciences, University of California, Irvine; The Emmes Company LLC; Education, Training and Research Associates; National Institute on Aging
IRB Number	18-001580
Investigators:	
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Analysis Biostatistician(s)	Haiyi Xie, PhD
Biostatistics Supervisor	Not explicitly specified
Lead Biostatistician	Not explicitly specified

Subject Matter Expert	Not explicitly specified
Original Creation Date	2020-01-06
Version Date	2026-01-14
Project Folder Location	Not explicitly specified
Project Goal(s)	To support the preparation of a peer-reviewed manuscript evaluating the relative effectiveness of social media platforms, dating applications, and information search sites in promoting HIV self-testing among young Black and Latinx MSM.
Submission Deadline(s)	2020-09-25
Effort Estimate (optional)	

Investigator Agreement

☐ All statistical analyses included in an abstract or manuscript should reflect the work of the biostatistician(s) listed on this SAP. No changes or additional analyses should be made to the results or findings without discussing with the project biostatistician(s).

☐ All biostatisticians on this SAP should be given sufficient time to review the full presentation, abstract, manuscript, or grant and be included as co-authors on any abstract or manuscript resulting from the analyses.

☐ If substantial additional analysis is necessary or the aims of the project change, a new SAP will need to be developed.

☐ Publications resulting from this SAP are supported in part by the Duke CTSA and must cite grant number UL1TR002553 and be submitted to PubMed Central.

☐I have reviewed the SAP and understand that any changes must be documented.

Acknowledged by: Click or tap here to enter text.
Date: Click or tap to enter a date.

Activity Log

Date: 2026-01-14
Activity: SAP consolidation and documentation
Description:
Integrated all extracted and reconstructed components into a complete SAP document, ensuring internal consistency, alignment with the published manuscript, and appropriate use of terminology for an educational context.
Outcome: Finalized the reconstructed SAP for academic training purposes.

Activity: Modification of statistical analysis methods
Description:

	Decided to conduct pairwise comparison for all 6 sites from the 2 waves with multiple testing adjustments using the Hochberg method rather than to combine or pool sites across the same platform for statistical evaluation of the platform difference. **Activity:** Exclude Wave 3 from all the analyses **Description:** Due to COVID-19 pandemic, no participants were enrolled, and no test kits were ordered during Wave 3, which made the statistical model inestimable. The data from Wave 3 will be excluded from analyses.	
Acronyms	MSM	men who have sex with men
	PrEP	pre-exposure prophylaxis
	HIV	human immunodeficiency virus
	CDC	Centers for Disease Control and Prevention
	AIDS	acquired immunodeficiency syndrome

1 Study Overview

Background/Introduction: HIV incidence remains disproportionately high among young Black and Latinx men who have sex with men (MSM) in the United States, and regular HIV testing is a cornerstone of HIV prevention strategies. Despite its importance, uptake of facility-based HIV testing remains suboptimal in this population due to barriers such as stigma, concerns about confidentiality, medical mistrust, and limited access to testing services. Home-based HIV self-testing provides a private and convenient alternative and has demonstrated potential to reach individuals who have never previously tested. In parallel, internet-based platforms—including social media sites, dating applications, and information search engines—are increasingly used for health promotion and participant recruitment; however, their relative effectiveness in promoting HIV self-testing among high-risk populations has not been well characterized.

This study was conducted as a longitudinal observational cohort study to compare the effectiveness of different types of internet-based platforms (social media, dating apps, and information search sites) in promoting the ordering of free home HIV self-test kits among young Black and Latinx MSM at increased risk of HIV infection. Test kit ordering rates were used as a proxy for promotional effectiveness, with recruitment conducted in multiple waves in which platforms from each category operated concurrently. Secondary analyses examined whether individual-level characteristics—including substance use, readiness to test for HIV, HIV-related stigma, attitudes toward HIV testing and treatment, and medical mistrust—were associated with test kit ordering.

1.1 Study Aims

The primary aim of this study is to evaluate and compare the effectiveness of different types of internet-based platforms, including social media platforms, dating applications, and information search sites in promoting HIV self-testing among young Black and Latinx men who have sex with men (MSM) at increased risk of HIV infection. Effectiveness is assessed using HIV self-test kit ordering rates as a proxy for successful promotion.

Secondary aims include these following six objectives
1. Compare the PrEP uptake across social media sites versus informational sites versus dating apps.
2. Determine how substance use modifies HIV testing and PrEP uptake.
3. Determine how the participant's psychological stage of change or readiness for HIV testing varies by recruitment method and how the stage impacts the main outcome.

4. Determine the most efficient web-based platform for advertisements related to promotion of HIV home self-test kits (primary outcome) and PrEP uptake (secondary outcome) using conversion from web-based metrics of the chosen platforms.
5. Determine how the impact of participant perceptions about HIV testing and PrEP, stigma, and mistrust of medical providers affects HIV home self-testing (primary outcome).
6. Determine how participants' rates of sexual delay discounting relate to risk behavior and HIV testing.

1.2 Study Hypotheses

The study will evaluate the relative effectiveness of using social media sites (i.e., Facebook, Instagram, Twitter), informational sites (i.e., Google, Bing, Yahoo), and dating apps (i.e., Grindr/alternative, Hornet, Jack'd) to promote self-testing of HIV infection among MSM who are at increased risk of HIV exposure and/or infection.

In statistical terms, we form a null hypothesis that
H0: The order rates of HIV self-testing rates are the same across waves and platforms.

2 Study Population

2.1 Inclusion Criteria

Participants meeting **all** of the following criteria were eligible for inclusion in the study:

- Identified as men who have sex with men (MSM)
- Aged 18–30 years at the time of enrolment
- Self-identified as Black/African American or Latinx, including multiracial or multiethnic individuals of these groups
- Reported condomless anal sex in the past 90 days **or** reported having more than one male sexual partner in the past 90 days
- Resided in one of the targeted geographic areas with high HIV incidence (District of Columbia and selected U.S. states)
- Provided electronic informed consent and completed the baseline assessment

2.2 Exclusion Criteria

Participants meeting **any** of the following criteria were excluded from the study:

- Known HIV-positive status at screening
- HIV testing within 90 days prior to enrolment
- Current use of pre-exposure prophylaxis (PrEP) or PrEP use within the 6 months prior to enrolment
- Enrollment during periods when not all platform types were active concurrently, for purposes of the primary analysis
- Invalid participants, including duplicate entries, fake accounts, or participants identified as being outside the United States

2.3 Data Acquisition

Fill in all relevant information:

Study design	Longitudinal observational cohort study
Data source/how the data were collected	Participants were recruited through online advertisements placed on social media platforms, dating applications, and information search sites. Upon enrollment, participants completed a web-based baseline survey and received an electronic code to order a free home HIV self-test kit. Follow-up surveys were conducted at 14 and 60 days post-enrollment. Test kit ordering data were

	tracked through automated reports from the test kit provider.
Contact information for team member responsible for data collection/acquisition	Not specified in the manuscript
Date or version (if downloaded, provide date)	2026-01-14
Data transfer method and date	Not specified in the manuscript
Where dataset is stored	On NIDA Data Share platform

Notes: Data acquisition relied entirely on remote, internet-based recruitment and self-reported survey data, supplemented by automated tracking of HIV self-test kit orders. No in-person data collection was conducted.

Description:
This Statistical Analysis Plan is based on a retrospective reconstruction of the study population and data acquisition procedures as described in the published manuscript, which is intended solely for academic and methodological training purposes.

3 Outcomes, Exposures, and Additional Variables of Interest

3.1 Primary Outcome(s)

You should only have 1-2 primary outcomes and the rest should be secondary.

Outcome	**Description**	**Variables and Source**	**Specifications**
HIV self-test kit ordering rate	Number of HIV home self-test kits ordered as a measure of platform effectiveness	OraQuick® Test Kit Orders; electronic ordering system records	Count outcome. Defined as the number of HIV self-test kits ordered per day by promotional platform. If multiple kits are ordered by the same participant, only the first order is included. Can be expressed per unit time (e.g., per day, per 30 days) using time as an offset.

3.2 Secondary Outcome(s)

Outcome	**Description**	**Variables and Source**	**Specifications**
HIV self-test kit use	Whether the participant used the study-provided HIV self-test kit by follow-up	Self-report at 14-day or 60-day follow-up survey	Binary (Yes/No). If reported at either follow-up, participant is classified as having used the kit.
HIV self-test result	HIV test result from study-provided home test kit	Self-report and uploaded image of test result	Categorical (Positive / Negative / Invalid / Indeterminate). Image

			used for validation when available.
PrEP uptake	Whether participant sought PrEP services or initiated PrEP	Follow-up survey (14-day and/or 60-day)	Binary (Yes/No). Includes either visiting a PrEP provider or starting PrEP.
Linkage to HIV care	Linkage to HIV treatment after positive self-test	Follow-up survey	Binary (Yes/No). Defined as visiting an HIV care provider within 30 days after self-testing.
Cost per test kit ordered	Advertising and intervention cost efficiency	Website metrics and internal cost tracking	Continuous. Defined as total cost (advertisement + test kits) divided by number of kits ordered per platform type.
Advertisement engagement	Engagement with online advertisements	Website metrics (platform-specific)	Proportion. Includes click-through rates and the proportion of people from each type of website.
Kit ordering rate per visitor	Conversion rate from website visit to kit order	Website metrics and Qualtrics visitor data	Rate outcome. Defined as number of kits ordered per unique visitors to the study informational page, using number of visitors as the offset.

3.3 Additional Variables of Interest

This is optional but generally this would be all your covariates of interest. If there are any variables that need special calculations etc. include them here or in a data dictionary that is an appendix to this SAP which you can reference here.

Variable	**Description**	**Variables and Source**	**Specifications**
Recruitment platform type	Type of web-based platform through which participant was recruited	Website metrics / recruitment records	Categorical: Social media / Dating apps / Informational sites
Substance use risk	Baseline substance use severity	Tobacco, Alcohol, Prescription medications, and other Substance use (TAPS) Tool	Categorical. High-risk vs not high-risk substance use profile, derived per TAPS scoring guidelines.
Stage of change for HIV testing	Participant readiness for HIV testing	Transtheoretical Model (Stage of Change)	Categorical. Includes stages such as Precontemplation, Contemplation, Determination, Action.

HIV testing attitudes	Attitudes toward HIV testing	Attitudes Toward HIV Testing questionnaire	Scale score. Higher values indicate more favorable attitudes.
HIV-related stigma	HIV-related stigma level	Stigma Index	Continuous scale score.
Medical mistrust	Level of mistrust toward medical institutions	Group-Based Medical Mistrust Scale (GBMMS)	Continuous scale score.
Sexual delay discounting	Tendency to discount delayed sexual outcomes	Sexual Delay Discounting Task	Continuous or categorical, per task scoring method.
Demographics	Age, race/ethnicity, geographic location	Baseline survey	Age (continuous), race/ethnicity (categorical), state/region (categorical).

4 Statistical Analysis Plan

This Statistical Analysis Plan (SAP) describes the analytical procedures to address the study aims outlined in Section 1.1. Analyses are conducted to evaluate the effectiveness of internet-based recruitment platforms in promoting HIV self-testing and to explore associations between participant characteristics and HIV self-test kit ordering. All analyses are descriptive and comparative in nature. Formal confirmatory hypothesis testing is limited, and results are interpreted in an exploratory framework. Statistical analyses were conducted using SAS version 9.4 or R 4.4.3 and above.

4.1 Demographic and Clinical Characteristics ("Table 1")

Objective reference: Descriptive characterization of the study population to support interpretation of Aim 1 and Aim 2.

Analysis population: The full analysis set (FAS), defined as all eligible participants enrolled during recruitment waves in which all platform types were active concurrently.

Variables summarized

- Demographics: age (years), race/ethnicity, geographic region
- Behavioral characteristics: recent sexual behavior, substance use risk
- Psychosocial measures: readiness to test for HIV, HIV-related stigma, medical mistrust
- Recruitment characteristics: platform type, recruitment wave

Statistical methods

- Continuous variables will be summarized using mean, standard deviation, median, and interquartile range.
- Categorical variables will be summarized using frequencies and percentages.
- Characteristics may be summarized overall and stratified by recruitment platform type.

No formal statistical testing will be performed for between-platform comparisons in Table 1.

4.2 Analyses Plan for Aim 1

Aim 1: To compare the effectiveness of internet-based platforms in promoting HIV self-test kit ordering.

Outcome: Primary outcome: HIV self-test kit ordering rate.

Exposure: Recruitment platform (individual platform within recruitment wave).

Analysis approach: HIV self-test kit ordering rates will be analyzed using Poisson regression models with the number of test kits ordered as the outcome. Time (e.g., days of active advertising) will be

included as an offset to estimate rates. Separate models will be fit within each recruitment wave, given that platforms varied across waves and direct pooling across waves was not appropriate due to heterogeneity.

Comparisons: Within each wave, pairwise comparisons between platforms will be conducted using model-based contrasts with a significance level of 0.05. p-values for multiple pairwise platform comparisons within a wave will be adjusted using the Hochberg step-up procedure to control the family-wise error rate.

Sensitivity analyses: Exclusion of recruitment periods with incomplete platform activity; Alternative exposure definitions; Assessment of overdispersion and, if necessary, use of quasi-Poisson models.

4.3 Analyses Plan for Aim 2

Aim 2: To assess associations between participant-level characteristics and HIV self-test kit ordering.

Outcome: Binary indicator of whether a participant ordered an HIV self-test kit.

Analysis approach: Results for Aim 2 analyses are exploratory and intended to identify factors potentially associated with engagement in HIV self-testing. Analysis will be conducted using univariate tests and descriptive statistics such as counts, percentages, and 95% confidence intervals.

4.4 Missing Data

Missing data for survey-based variables will not be imputed. Analyses will be conducted using available data, and the extent of missingness will be summarized descriptively. Sensitivity analyses may be conducted to assess the impact of missing data on key results.

4.5 Analysis Model

	Information Sites	**Social Media Sites**	**Dating Apps**
Wave 1	Google	Facebook	Grindr/alternative
Wave 2	Bing	Instagram	Jack'd
Wave 3	Yahoo	Twitter	Hornet

We assume that, for a given time period i, the numbers of kits ordered from sites i_1, i_2, i_3 will be given by three independent Poisson processes with rates λ_{i1}, λ_{i2}, λ_{i3}. According to the manuscript, time period i lasts until about 133 kits have been ordered, which will take time t_i.

The primary analysis model will thus be a Poisson regression model using time as an offset, which is

$$log(o_{ij}) = log(t_i) + \alpha + \beta_i + \gamma_j + \beta\gamma_{ij}$$

where

- o_{ij} is the number of kits ordered by the site in row i, column j
- t_i is the time that the Wave platforms were recruiting
- β_i is the main row (wave) effect
- γ_j is the main column (promotional site series) effect
- $\beta\gamma_{ij}$ is the row-column interaction term Under this model, the rate for any site ij is given by

$$rate_{ij} = exp(\alpha + \beta_i + \gamma_j + \beta\gamma_{ij})$$

4.6 Sample Size

Based on the protocol and the published manuscript, the sample size for the Social Media PrEP study was determined primarily by feasibility considerations and the requirements of estimating platform-specific HIV self-test kit ordering rates, rather than by a traditional hypothesis-driven power calculation. The protocol specified enrollment of approximately 400 men who have sex with men (MSM), or until roughly 400 HIV self-test kits were ordered. This target was considered adequate to generate stable estimates of ordering rates across the three promotional platform types (social media, dating apps, and information search sites) and to support planned secondary and exploratory analyses examining PrEP uptake and key moderating factors such as substance use and stage of change.

5 Limitations

This study has several limitations. First, the observational design and non-randomized recruitment strategy limit causal interpretation. Participants were exposed to recruitment platforms through online advertising rather than random assignment, and platform-specific user characteristics, engagement patterns, or algorithms may underlie observed differences in HIV self-test kit ordering. Although platforms were operated concurrently within recruitment waves to reduce temporal confounding, heterogeneity across waves limited statistical power for some comparisons. In addition, recruitment was conducted in selected high HIV-incidence areas and focused on a subset of popular apps and websites grouped into platform categories; therefore, findings may not be generalizable beyond the included sites and settings.

Additionally, secondary outcomes relied largely on self-reported follow-up data and were subject to missingness, recall bias, and potential misclassification. Analyses were primarily descriptive and exploratory. Consequently, results should be interpreted cautiously and viewed as hypothesis-generating rather than confirmatory.

6 Appendix

Please find the data dictionary or any other related files on the project website https://datashare.nida.nih.gov/study/nida-ctn-0083

7 References

Klausner, J. D., Young, S. D., Stafylis, C., Vavala, G., Mehta, S., Marsch, L. A., Lemley, S. M., McLeman, B., Xie, H., Moran, L. M., Jacobs, P., & Lambert-Harris, C. A. (2020). *Using social media to deliver HIV self-testing kits and link to online PrEP services (Social Media PrEP): NIDA CTN Protocol 0083* (Version 5.0). National Institute on Drug Abuse.

Stafylis, C., Vavala, G., Wang, Q., McLeman, B., Lemley, S. M., Young, S. D., Xie, H., Matthews, A. G., Oden, N., Revoredo, L., Shmueli-Blumberg, D., Hichborn, E. G., McKelle, E., Moran, L. M., Jacobs, P., Marsch, L. A., & Klausner, J. D. (2022). Relative effectiveness of social media, dating apps, and information search sites in promoting HIV self-testing: Observational cohort study. *JMIR Formative Research, 6*(9), e35648. DOI: https://doi.org/10.2196/35648

Statistical Analysis Plan Checklist

Below you will find a checklist of recommended items to include in a statistical analysis plan. Some of these are specific to clinical trials (based on this JAMA paper) and some are other are specific to observational studies (based on STROBE/RECORD guidelines), so every item will not be necessary for every project. The biostatistician should start with the SAP template above and add in necessary information from the checklist. Item numbers that are starred (*) are not explicitly included in the SAP template and should be added by the author if relevant to the project. This checklist was developed using the CONSORT 2010 Checklist.

Section/Topic	Item #	Description	Included (Yes/No/NA)
Administrative Information			
Study Information	1a	Descriptive title that matches the protocol, with SAP either as a forerunner or subtitle	Yes
	1b	Trial registration number, protocol version number, and/or IRB number.	Yes
	1c	CRU/Department/Division/Center/other collaborative unit that the study falls under	Yes
Roles and	2a	Listing of principal investigators, clinical leads, and co-authors (if known)	Yes
responsibility	2b	Name and affiliation of SAP author(s)	Yes
	2c	Names, affiliations, and roles of other SAP contributors (e.g. senior statistician)	Yes
SAP Information	3	SAP version number, with date of current version and original creation date	Yes
Project Information	4a	Project folder location	NA
	4b	Project goals (e.g. manuscript, abstract, presentation, etc.)	Yes
	4c	Project deadlines (of listed goals)	Yes
	4d	Effort estimate	No
Investigator Agreement			
Investigator Agreement	5	Confirmation that BERD Method Core's collaborative process has been reviewed, that all statistical analyses included in an abstract or manuscript should reflect the SAP, no changes should be made to the SAP without discussing with the SAP author, all biostatisticians on the SAP are co-authors on the manuscript, and that publications resulting from the SAP must cite grant number UL1TR002553 and be submitted to PubMed Central	NA
Signatures	6	Signatures of SAP author, senior statistician, and principal investigator(s)	NA
Activity Log			
SAP revisions	7a	SAP revision history with dates	NA
	7b	Justification for each SAP revision	NA
	7c*	Timing of SAP revision in relation to any interim analyses or submissions	NA

[1]Turner L, Shamseer L, Altman DG, et al. Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RCTs) published in medical journals. *Cochrane Database Syst Rev*. 2012;11:MR000030. Published 2012 Nov 14. doi:10.1002/14651858.MR000030.pub2

Study Overview			
Background and introduction	8	Synopsis of scientific background and rationale for the study	Yes
Aims and Hypotheses	9a	List of all scientific aims/objectives of the study, with specifications of primary, secondary, etc.	Yes
	9b	List of all statistical hypotheses (corresponding to the scientific aims), with specifications of primary, secondary, etc.	Yes
Variables of Interest	10a	List of all outcome/endpoint variables, with a description of their coding/units, timing, and source, corresponding to the statistical hypotheses. If any variables are defined using ICD or CPT codes, list them out.	Yes
	10b	List of all exposure variables, with a description of their coding/units, timing, and source, corresponding to the statistical hypotheses. If any variables are defined using ICD or CPT codes, list them out.	Yes
	10c	List of any additional variables of interest (e.g. covariates, potential confounders, effect modifiers, etc.) in the analysis	Yes
	10d*	Location of data dictionary (or provided as an appendix)	Yes
	10e*	Report category boundaries if continuous variables are collapsed into categories, and describe any other relevant data transformations	Yes
Causal Graph	11*	May be helpful to include a DAG or other graph/diagram that describes the way the variables of interest are presumed to relate to each other	No
Study Methods			
Study Plan and Design	12a	Description of the study design (e.g. parallel group randomized trial, case-control study, cohort study, etc.)	Yes
	12b*	Study setting, location, and relevant dates (e.g. periods of enrolment, exposure, follow-up, and collection)	NA
	12c*	Description of intervention or exposure groups, with allocation ratios, and details of any matching criteria	Yes
	12d*	Details on randomization (e.g. stratification factors) and blinding procedures	NA
	12e	List of eligibility and/or inclusion/exclusion criteria	Yes
	12f*	Description of screening/enrolment/recruitment processes	Yes
	12g*	Description of patient flow (e.g. CONSORT diagram)	NA
	12h*	Description of analysis population (e.g. intention to treat, per protocol, etc.)	Yes
	12i*	Definitions of adherence/compliance, protocol deviations, loss-to-follow-up, adverse events, etc.	NA
	12j*	Time points at which outcomes are measured	NA

	12k*	Timing of final analyses (are all outcomes analysed collectively, or will short-term outcomes be analysed separately from long-term outcomes, etc.)	Yes
Sample Size	13a*	Sample size calculation or justification (either provided in full or summarized, with link to original source)	Yes
	13b*	Description of pre-planned subgroup analyses, power for these analyses, and planned multiple comparison adjustment procedures	Yes
Interim Analyses	14a*	Description of what interim analyses will be conducted at which time points, and what methods used to adjust significance levels due to the interim analysis	NA
	14b*	Details of any guidelines (e.g. safety, futility) for stopping the study early	NA
	14c*	Details of any changes to trial design due to interim analyses (e.g. enrolling more patients)	NA
Data	15a	Description of data collection/acquisition process, with contact information for team member responsible	Yes
	15b	Description of data flow/transfer from primary data collection through to creation of final analysis dataset	NA
	15c	Data transfer method and date	NA
	15d	Folder location where datasets are stored	NA
	15e*	Description of any additional data management, quality control, or processing undertaken	NA
	15f*	If any data are extracted from a database, a description of the database and the query used for the extraction, and whether/how it was merged with any data from outside that database. If the study involved linkage of databases, consider use of a flow diagram to demonstrate the data linkage process, including the number of individuals with linked data at each stage.	NA
	15f*	Description of any other data sources incorporated in the analysis	NA
Missing Data	16a*	Description of sources and magnitudes of missing data	Yes
	16b*	Description of how missing data patterns will be presented/summarized (may be helpful to have a table shell or draft CONSORT-style diagram)	Yes
	16c*	Description of contingency plans for handling missing data in analysis	Yes
Simulations	17a*	If conducting a simulation, a description of the purpose of the simulation and its design (e.g. fully factorial, partially factorial, grid search, etc.)	NA
	17b*	Define the fixed and variable factors or parameters in the simulation, the estimands/targets of the simulation, and the performance measures to be estimated (with justifications of their relevance to the estimands/targets)	NA
	17c*	Description of the tabular and graphical presentations of simulation results and their interpretation	NA

Statistical Analysis Plan

Statistical Significance	18a*	Hypothesis testing framework (e.g. superiority, equivalence, non-inferiority), or description of alternative analytic framework (e.g. evaluation of a posterior in a Bayesian analysis, etc.)	Yes
	18b*	Level of significance for primary hypotheses, including a description and rationale for any multiple comparisons adjustment or Type I error control procedures	Yes
	18c*	Description of any decision-making rules based on confidence intervals, credible intervals, prediction intervals, Bayes' factors, or other alternative inferential methods	Yes
	18d*	Description of how the results of any hypothesis tests (or alternative inferential methods) will be interpreted with respect to both the statistical hypotheses and scientific aims/objectives of the study	Yes
Descriptive Statistics	19a*	List of characteristics (e.g. demographic, clinical) to be summarized descriptively (e.g. "Table 1")	Yes
	19b*	Description of how these characteristics will be summarized descriptively (e.g. means/medians vs. N (%), tabular displays, graphical displays, etc.)	Yes
	19c*	Summarize follow-up time (e.g. average and total amount) and number of events	NA
Analysis Methods	20a	For each aim/hypothesis (see items 9a/9b), a description of what analysis method will be used and how the results from this method will be reported and interpreted	Yes
	20b*	Description of any transformations, standardizations, covariate or confounder adjustments, weighting, or stratification methods to be used and why.	Yes
	20c*	For each analytic method proposed, a description of the assumptions of that method and what processes will be used to evaluate whether or not those assumptions hold	Yes
	20d*	Details of contingency plans/alternative methods to be used if the assumptions are found not to hold	NA
	20e*	In the case of non-standard test statistics, formulas provided for the test statistic with a description of the mathematical null hypothesis, how significance is determined, and how the test statistic is interpreted	NA
	20f*	In the case of regression models, formulas provided for the full model with a description of which parameters are to be used, how they will be interpreted, how confidence intervals will be constructed, etc.	Yes
	20g*	In the case of survey, hierarchical/nested, or clustered data, a description of what methods will be used to adjust for the data structure and why (e.g. if using a GEE, describing which correlation structure and why it was chosen, etc.)	NA
	20h*	For non-continuous outcomes, clearly explain the effect used (e.g. risk difference, risk ratio, odds ratio, etc.), whether it is relative or absolute, and justify why that was chosen as the effect measure of interest	Yes
	20i*	Documentation of any non-standard methods used (e.g. using alternative degree of freedom calculation methods, using a non-canonical link function, etc.)	NA

	20j*	Description of any limitations, sources of bias, internal/external validity, and other relevant discussions concerning the interpretation and generalizability of the design or methods used	Yes
Additional Analysis Methods	21a*	Description of any pre-planned sensitivity analyses and how they will be interpreted	Yes
	21b*	Description of pre-planned subgroup analyses, power for these analyses, and planned multiple comparison adjustment procedures	Yes
	21c*	Description of any additional post-hoc calculations or analyses (e.g. evaluating interaction/modification effects, calculating mediation or local average treatment effects, evaluation of AUROC curves, etc.)	NA
	21d*	If conducting any bootstrap analyses, a description of the sampling algorithm and number of iterations used	NA
	21e*	If conducting any cross-validation procedures, a description of how the cross-validation is conducted (e.g. leave-one-out, train/validation/test, etc.)	NA
Exploratory Analyses	22a*	Description and justification for any pre-planned exploratory analyses and what methods will be used to conduct them	Yes
	22b*	Framework for conducting any unplanned exploratory analyses and how they will be integrated into the planned analysis	NA
Software	23*	List of statistical software (along with version numbers) to be used for each phase of the analysis; in the case of R or Stata, additionally list any requisite installed packages and their version numbers	Yes
Other	24*	Description of any additional planned analyses of the data (e.g. a safety analysis looking at adverse event rates for a Data Safety Monitoring Board, etc.)	NA
Tables and Figures			
Table Shells	25*	Example tables related to any of the conducted analyses; if possible including any available preliminary data	NA
Example Figures	26*	Example figures related to any of the conducted analyses; if possible including any available preliminary data.	NA
References			
References	27a	References for any non-standard statistical methods used	NA
	27b	References (and locations) for any relevant protocols, standard operating procedures, or other documents cited in the SAP	Yes
Additional Information			
Appendices	28*	If necessary, appendices may be included (e.g. a full data dictionary, a copy of a Case Report Form, etc.)	Yes
Addendums	29*	Any additional analyses conducted that were not included in the SAP should be documented in an addendum, describing the purpose of the additional analysis, when it was conducted, and by whom	NA