Statistical Analysis Plan
Version: MM/DD/YYYY

Project Title: *Title from Analysis Proposal form*

Proposal-ID: *Proposal-ID from myRADx-UPhome table*

Writing Team Lead: *First name, Last name*
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EPM # (DCRI Use Only): 8126
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Project Folder (DCRI Use Only): /dcri/ct/radx_up/manu/*RADx-UP Proposal-ID*

Background
This is an overview of the project generally copied from the project proposal form.

Data Source(s)
List all internal and external data sources used in the study, and whether any linking across will be done.
- *Core Analytic Dataset - Sociodemographic, RADx-UP CDCC*
- *Data source 2, internal*
- *Linking: data is de-identified and patient pseudo-identifier used to link across domain tables.*

Specific Aims
This is a bulleted list that concisely describes the main objectives of the study.
- *Specific aim 1*
- *Specific aim 2*
- *Include additional aims as needed*

Study Population
Describe the derivation of the study population including internal and/or external data sources used, inclusion and exclusion criteria and final sample size, if known.

Exposure Group(s)
The following exposure groups are subgroups of the study population in which metrics will be reported. This list assumes sample sizes at the given level of granularity are large enough to support the analysis. Provide sample sizes if known.
- *Exposure group 1*
- *Exposure group 2*
- *…*
- *Exposure group k*

Outcome(s)
- Primary Outcome
  - *Name and description*
- Secondary Outcome(s)
  - *Name and description of secondary outcome 1*
  - *…*
  - *Name and description of secondary outcome k*

Handling of Missing Data
If no imputation is planned for the current analysis, then please include the following sentence here: *"No imputation will be performed; Missing data will be excluded from all denominators."* If imputation is

planned, then please describe the approach taken and for what context the imputation will be applied (e.g., for adjustment covariates in multivariable statistical models only).

Quality Assurance Procedure
Each table shell and figure legend specifies what steps will be performed to ensure quality results. Based on the complexity of project specific analyses or generating analysis data sets, double programming or code review by another programmer/statistician may be implemented.

Analysis Objectives & Tasks

1. **Objective:** *A statement of the main objective under consideration.*

   Analysis: *A detailed summary of the statistical methods implemented to address the objective. This will include, but not be limited to, a description of how continuous and categorical data will be displayed; statistical tests used to compare groups; how statistical modeling assumptions (e.g., linearity, proportional hazards) will be assessed and accounted for, if violated.*
   See Appendix 1 for proposed:
   - Table 1: *Table Title*
   - List out additional tables/figures as needed. Bookmarks and hyperlinks will be used to link each table to its shell in Appendix 1.

   Potential Conclusions: *Statements that help the investigator(s) understand the results of the objective.*

2. **Objective:**

   Analysis:
   See Appendix 1 for proposed:

   Potential Conclusions:

3. **Objective:**

   Analysis:
   See Appendix 1 for proposed:

   Potential Conclusions:

4. **Objective:**

   Analysis:
   See Appendix 1 for proposed:

   Potential Conclusions:

~ Add additional objectives as needed ~

APPENDIX 1

Proposed Tables, Listings and Figures

Table 1
Baseline Characteristics of the Study Population by *Topic Condition*

Characteristic	Overall (N=n,nnn)	Exposure Group 1 (N=n,nnn)	Exposure Group 2 (N=n,nnn)	…	Exposure Group *K* (N=n,nnn)	P-value
Sociodemographics						
Age (yrs.)						x.xxx
N	n,nnn	n,nnn	n,nnn	…	n,nnn	
Median (Q1, Q3)	xx (xx, xx)	xx (xx, xx)	xx (xx, xx)	…	xx (xx, xx)	
Sex at Birth						x.xxx
Female	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	
Male	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	
Intersex	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	
None of These Describe Me	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	
Race						x.xxx
American Indian or Alaska Native	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	
Black or African American	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	
Asian	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	
Native Hawaiian or Pacific Islander	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	
White	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	
Other Race	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	
Multiple Races	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	
<Additional Sociodemographics>	…	…	…	…	…	…
Medical History						
Hypertension	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	x.xxx
Diabetes	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	x.xxx
Cardiovascular Disease	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	x.xxx
Asthma	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	x.xxx
Immunocompromised Condition	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	x.xxx
<Additional characteristics>	…	…	…	…	…	…
Alcohol and Tobacco Use						
Ever Consumed Alcohol						x.xxx
Yes	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	
No	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)	

Frequency of Alcohol Use					x.xxx
Never	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)
Monthly or Less	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)
2-4 Times a Month	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)
2-3 Times a Week	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)
4 or More Times a Week	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)
Don't Know	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)
Current Smoking Status					x.xxx
Not at All	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)
Some Days	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)
Everyday	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)
Don't Know	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	x,xxx/n,nnn (xx.x%)	…	x,xxx/n,nnn (xx.x%)
<Additional characteristics>	…	…	…	…	…
<Additional Sections>					
…	…	…	…	…	…	…
…	…	…	…	…	…	…

Note: This table will be generated as an RTF file using the %CAT and %CONT macros. The directory and program name will be included as a footnote at the bottom of this table. Please also include footnotes as needed to describe, for example, variable abbreviations, units and/or definitions.

Additional tables will follow a structure similar to the above and will be tailored specifically to each analysis objective.

Figures will be created by following the DCRI/CPM Recommended Style Guidelines for Graphics Standards. Mock figures will be included in manuscript-specific statistical analysis plans as needed.

APPENDIX 2

Variable Definitions and Derivations

For documentation and quality control purposes, this Appendix will include the definitions and derivations of manuscript-specific variables that are not included in any of the RADx-UP Core Analytic Datasets.

SAMPLE

APPENDIX 3

References

This section will contain a listing of references used to cite relevant clinical information and/or statistical methods.

History of Changes to this Document	
Date	**Description of Change(s)**
MM/DD/YYYY	Initial version