



CorEvitas Statistical Analysis Report: Report Title
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1. List of Abbreviations

This is optional. List can be obtained from the SAP associated with this query.

2. Amendments and Updates

Include this section if report is amended or updated due to additional data and/or inconsistencies before reissuing report to subscriber. Date should match report delivery date. For the initial report delivery mark the summary of changes as N/A.

Date of Delivery	Summary of Change(s)	Reason
<hr/>		

3. Executive Summary

This section is developed by the Clinical Epidemiologist and Lead Biostatistician with input and assistance from the Analyst and Clinical Research Manager. This section will be updated after review of final results. Executive summary should be no more than 2 pages, single spaced and abstract ready. (Exclude this section for Internal reports, which do not require an executive summary.)

(Optional: Can also include a table/figure of results to help frame the executive summary.)

[Guidance_reports_including_executive_summaries.docx \(sharepoint.com\)](#)

3.1 Introduction

3.2 Methods

3.3 Results

3.4 Conclusion

4. Research Report

This section will include language from the SAP associated with this query. Make sure you use past tense in this section. You may also shorten any of these sections as needed to make the report succinct. You can use guidance from this document or opt to paste this section into the SAP. The Clinical Research Manager can copy and paste this section within the SAP as needed. As a rule, for common queries, body of the report should be no more than 8 pages (descriptive studies) to 12 pages (comparative studies) (not including Tables).

4.1 Background

This information comes from the SAP associated with this query. Literature references can be retrieved from the SAP.

4.2 Objectives

This information comes from the SAP associated with this query.

4.3 Hypotheses

This information comes from the SAP associated with this query.

4.4 Methods

This information comes from the SAP associated with this query. Include details on study design.

4.4.1 Data Source

This information comes from the SAP associated with this query. Include the data cut used for analysis.

4.4.2 Study Population of Interest

This information comes from the SAP associated with this query.

4.4.3 Time Period Definitions

This information comes from the SAP associated with this query.

4.4.4 Exposure/Independent variable

This information comes from the SAP associated with this query.

4.4.5 Study Outcomes

This information comes from the SAP associated with this query.

4.4.5.1 Primary outcomes

This information comes from the SAP associated with this query.

4.4.5.2 Secondary outcomes

This information comes from the SAP associated with this query.

4.5 Covariates

This information comes from the SAP associated with this query.

4.6 Analysis Plan

This information comes from the SAP associated with this query. Include the statistical program and version from the SAP (double check that the team used the statistical program/version dictated in the SAP. May need to be updated accordingly).

4.6.1 Power analysis (for comparative studies as applicable)

This information comes from the SAP associated with this query.

5. Results

5.1 Result Summary

This will be written by the lead biostatistician based on the results from this query. Unless specifically requested otherwise, should be a stand-alone section reporting results in a succinct manner. Subsection headings from the SAP may be used to address results pertaining to each of the query objectives. All numeric values (e.g. summary statistics, confidence intervals, regression coefficients, p-values) mentioned in the text should be reported with leading zeros.

6. Discussion and Conclusions

Update title, accordingly, if you include key findings retain “Discussion” in title otherwise delete.

6.1 Key Findings (Optional)

This section is developed by the Clinical Epidemiologist and Lead Biostatistician with input and assistance from the Analyst and Clinical Research Manager. This section will put into context key findings or inferences that tie back to the study objectives, to deliver a manuscript-ready report. These could be additional findings (not listed in the Executive Summary) that we may want to mention. Delete section if not applicable.

6.2 Strengths

This information can be retrieved from the SAP associated with this query. Make sure the strengths are relevant to the query. Suggestion: You may consider combining the section on strengths and limitations and countering each limitation with a strength.

6.3 Limitations

This information can be retrieved from the SAP associated with this query. Make sure the limitations are relevant to the query. Suggestion: You may consider combining the section on strengths and limitations and countering each limitation with a strength.

6.4 Conclusion

You can use the conclusion from the executive summary as a guide and expand upon it. Do not include this section for an internal subscriber report.

7. List of Tables and Figures

8. Tables and Figures

- Use the landscape page as needed
- Font type suggestion: Calibri, Times New Roman or Arial. Adjust font size as needed to ensure tables are legible and read consistently.
- If the tables continue beyond 1 page, make sure the table headers are included on each page
- Start a new section on the next page
- Include appropriate footnotes and references as needed, including tests conducted, abbreviations used, etc.
- Footnote preference is to use a, b, c, etc. and remain consistent throughout document
- Figure 1 will typically be flow diagram of study population (unless not applicable).
- Make sure all figures include appropriate legends
- Each table or figure should be able to “stand alone”, e.g., Titles should be clear and concise; from the title and content it should be evident what is being presented even if separated from the report
- All numeric values (e.g. summary statistics, confidence intervals, regression coefficients, p-values) should be reported with leading zeros in the tables

9. Appendices

This is optional and to be used only if applicable. Include supplementary tables and/or figures.

10. References

Update references using built in bibliography in Word Document. References could be moved to section 8 (after the text portion) if preferred.