Statistical Analysis Validation

Author:

Version:

Date:

|  |  |
| --- | --- |
| TRIAL FULL TITLE |  |
| EUDRACT NUMBER (if applicable)  |  |
| REC No |  |
| Sponsor ref: |  |
|  |  |
|  |  |
|  |  | Date finalized |
| PROTOCOL VERSION |  |  |
| SAP VERSION |  |  |
| DATA LOCK  |  |  |
| FINAL STATISTICAL REPORT NAME |  |  |

|  |  |
| --- | --- |
| TRIAL STATISTICIAN |  |
| INDEPENDENT STATISTICIAN |  |
| TCTU SENIOR MANAGER  |  |
| TRIAL CHIEF INVESTIGATOR |  |

1. Details about statistical analysis validation process

*Provide a list of all programs involved in statistical analysis and the purpose of each program.*

Location of programs:

|  |  |  |  |
| --- | --- | --- | --- |
| Program name | Purpose | Validation level | Checked byName/date |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*Validation level:
1: Program runs free from errors and warnings as checked by the trial statistician.*

*2: Program has checked visually by an independent reviewer*

*3: Program has been verified by independent programming*

1. Details of independent verification

*Not applicable if no independent program verification. Provide Location of the independent program, comparison and resolution of discrepancies.*

1. Statistical Analysis Report

*Not applicable if no separate statistical report is created. Provide location and name of the final Statistical report.*

The undersigned confirm that the above statistical analysis validation process has been carried out to the appropriate standards

**Signatures:**

Trial Statistician (name)

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Trial Statistician (signature) Date

Independent Statistician (name)

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Independent Statistician (signature) Date