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1.0 Purpose

This report summarizes the testing performed to validate the Report function in the ClearView software.

2.0 Executive Summary

Version 1.1.1.2 implemented a new algorithm which is used to create the values displayed in the ClearView Report. The development of the algorithm is documented in two engineering studies, ENG-025 which documents the development of the Naïve Bayes and Logistic Regression portions of the algorithm and ENG-026 which documents the development of the EPIC Score portion of the algorithm. These two development documents were translated into software requirements which were documented in SR-203-01, Algorithm Requirements. These requirements were then used to develop the ClearView Software as documented in the Analysis Functions- Specifications (SS-203). A protocol was developed to verify and validate the values reported on the ClearView Report. This report is being written to summarize the activities performed and the results of the verification and validation activities.

The verification and validation activities demonstrate that the values displayed on the ClearView Report perform as expected. The ClearView Report functions are considered validated for use in IDE investigations.

3.0 Protocol Execution and Results

All validation activities were conducted by EPIC staff on 1/27/12 through 2/6/12. The technician completed the protocol, recording the results directly on the protocol. The original protocol is located in Attachment A.

3.1   Revision History- In order to establish a method for tracking changes to the software code during validation testing, a versioning system has been established. The last digit in the version number (for this round, the "2" in version 1.1.1.2) is replaced with an alpha character. This alpha character is then revised for any coding changes implemented during the verification and validation test cycle. As such, the version used to execute the ClearView Report values test protocol was version 1.1.1.e. The additional versions were created to respond to non-conformances raised during the verification and validation test cycle. A summary of these test versions will be collated and

presented at the final design review and approval of version 1.1.1.2. This summary will demonstrate the justification for testing of the final version of 1.1.1.2 released for use.

3.2   Protocol Printouts- The protocol required multiple versions of data to be printed and verified. The following lists all printouts and their location in this final report:

3.2.1   Full License Data Verification Printouts (i.e., ClearView Report, Calibration Data, Raw Data) are filed in Attachment B.

3.2.2   Full License Resubmit Data Verification Printouts (i.e., ClearView Reports) are filed in Attachment C.

3.2.3   Full License Modified Angles Data Verification Printouts (i.e., ClearView Reports) are filed in Attachment D.

3.2.4   Full License Modified Angles with Modified Age and Gender Data Verification Printouts (i.e., ClearView Reports) are filed in Attachment E.

3.2.5   CV License and Basic License Data Verification Printouts (i.e., ClearView Reports) are filed in Attachment F.

3.3   Deviations- Minor red-lined protocol instructions will be included in future version of this protocol. These changes did not affect the tests performed but would provide clearer instructions for future testing. However, a documented deviation to the test protocol occurred in section 10.0 of the protocol. This section instructs the user to resubmit the original NewSubmit data for resubmission after modification of the subject age and gender. When comparing the expected report values, many non-conformances were identified. The investigation determined that the Biostatistics group (who generated the expected values from the development samples using the SAS programming) used the modified angles raw data instead of the NewSubmit raw data. The protocol was modified to instruct the technician to resubmit the modified angles data and compare the expected to the output from the ClearView Report.

3.4   Non-conformances- Several non-conformances were observed and are summarized in the Table 1.

Table 1
Non-Conformances

No.	Description of Non-conformance (include reference to the protocol section)	Resolution/Action Taken
1	Section 7- NewSubmit subjects 1, 2, and 3 had NS Analysis data on the RawData that	Not an issue, per the design, not all NS values are plotted.

Table 1
Non-Conformances

No.	Description of Non-conformance (include reference to the protocol section)	Resolution/Action Taken
	did not appear in the software (see attached for descriptions). Some of the NS Values in the Raw Data did not match the values in the software (see attached for details).	Regarding the non-matching values. This was a combination of a difficulty in in reading he values combined with a lack of clear definition as to which fields were graphed. IT added a switch to display the values and the organ system to the EPIC Administrator role so that these values can be properly verified. This section of the protocol was retested using version 1.1.1.g and met all requirements. The retest documentation is located in Attachment G.
2	Section 7- The treatment ID, date analyzed, analysis results ID (on raw data), and the software versions are different between raw data comparisons. Also, the NS Point Value on the Development Raw Data file is equal to the NS on the Raw Data file column (this is also labeled "Transform").	The treatment ID, date analyzed, analysis results ID (on raw data), and the software versions are all data points that are unique to the actual data analysis run and should not match to the expected. Future protocols will be modified to exempt the verification of these data points.
3	Section 11.2- The Basic License report did not have matching numerical scores for the "middle" fingers section (i.e., middle #1-9 was listed in the protocol, but the middle #1-8 was listed on the report in the software.	Bug was corrected in version 1.1.1.f. This was an incorrect if branch in the code causing this data not to appear. This section was retested using version 1.1.1.g and met all requirements. The retest documentation is located in Attachment H.

All non-conformances were successfully resolved upon retest. All test requirements were found to function as expected.

4.0   Conclusions

The Report Functions of version 1.1.1.2 of ClearView Software Solution are considered validated for use in IDE investigations.

5.0   Attachments

Attachment A- Original Signed Protocol
Attachment B- Full License Data Verification Printouts
Attachment C- Full License Resubmit Data Verification Printouts

Attachment D- Full License Modified Angles Data Verification Printouts

Attachment E- Full License Modified Angles with Modified Age and Gender Data Verification Printouts

Attachment F- CV License and Basic License Data Verification Printouts

Attachment G- Nonconformance #1 NS Analysis Tab Retest Documentation

Attachment H- Nonconformance #2 Basic License Report Retest Documentation