**Comparability of CTCAE grading and clinical significance in abnormal clinical laboratory results**

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In clinical trials, laboratory data is a key element of the safety profile for the treatment being studied. When local labs are used, there may be a large amount of variance in determining clinically significant abnormal lab values in the reporting of adverse events (AEs). Many clinical trials are moving towards the use of grading scales such as the National Cancer Institute common terminology criteria for adverse events (NCI-CTCAE) to provide standard ranges and implement suggested grading across clinical sites.

Rho, Inc. has developed a macro to incorporate the CTCAE grading criteria into laboratory analysis datasets. The CTCAE grading is complex and encompasses a wide variety of laboratory tests making this macro extremely useful.

The purpose of this poster is to explore the differences in AEs generated by CTCAE and those generated by clinical significance alone across local sites. Discussion will be presented on various reporting techniques and the distribution and comparability of abnormal clinical laboratory results across sites. This paper will also present the above macro that requires minimal user input to efficiently grade abnormal lab values based on the CTCAE.