A Biopharma Company is a long-time user of DSI telemetry in conjunction with the Ponemah data acquisition and analysis software for Safety Pharmacology and Toxicology studies. In addition to the assessment of electrophysiologic and hemodynamic cardiovascular parameters, they perform a qualitative ECG waveform analysis at the approximate C_{max} for test agents to monitor potential changes in cardiac rate, rhythm and waveform morphology. This Biopharma Company found that by using Data Insights they achieved a more accurate and consistent arrhythmia assessment of all data collected in less time than standard methods.

The Challenge. A repeat dose toxicology study for a potential drug candidate required a detailed analysis to identify ventricular arrhythmias over a 20 hour data acquisition period in 40 Jacketed External Telemetry (JET) instrumented monkeys at pre-study, week 3 and 5 of dosing, and week 8 of recovery, for a total of 3200 hours of data. The Biopharma Company used Ponemah in an attempt to semi-automate the identification of arrhythmias for the pre-study day. This method proved to be cumbersome, time consuming, and the resultant quantitative assessment of arrhythmias was not as comprehensive.

The Solution. The Biopharma Company deployed Data Insights to automate their arrhythmia assessment for all 3200 hours of data collected.

The Outcome. The Biopharma Company compared the results and experience using Data Insights with those of their standard practices and found the following advantages with Data Insights:
- Greater Efficiency
  - Analysis time was reduced by approximately 50% relative to the semi-automated method.
  - Analysis time was mainly driven by the amount of signal noise present in the JET data. Data Insights' tools were more efficient for managing signal noise and excluding these data as compared to standard signal noise elimination methods.
- Improved Accuracy
  - Data Insights identified ventricular arrhythmias in 16 of the 40 subjects as compared to only 8 when using the semi-automated method. Of these 8 subjects, Data Insights identified additional arrhythmias in 4 of the subjects.
  - Data Insights provided an additional and unexpected diagnostics component by further differentiating ventricular arrhythmias, such as bigemini/ trigemini.
- Improved Consistency
  - In the 20-hour pre-study day, analysis with Data Insights determined that 40% of the monkeys had ventricular arrhythmias, as compared to only 20% using Ponemah standard toolsets. The results obtained from Data insights were in close agreement with the ventricular arrhythmia rates and incidences reported in the literature.[1,2]

This case study demonstrates that DSI's Data Insights provided a more accurate, comprehensive arrhythmia assessment that was consistent with published literature and required less time than standard methods.

1 Macallum, G.E., Houston, B.J. Characterization of cardiac alterations in nonsedated cynomolgus monkeys. American Journal of Veterinary Research. 1993; 54 No.2:327-332.
2 Chui, R.W., Derakhchan, K. Vargas, H.M. Comprehensive analysis of cardiac arrhythmias in telemetered cynomolgus monkeys over a 6-month period. Journal of Pharmacological and Toxicological Methods. 2012, 66:84-91.

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