Appendix 19

Title: Collaboration with Orange County Medical Device Network

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Presenting Problem: Firms are required by 21 CFR 803 to submit a Medical Device Report (MDR) when they learn of an incident of device malfunction. The MDR reporting requirement generates a large number of device malfunction reports. The preparation of large numbers of individual incident device malfunction reports by industry is resource intensive. The review and analysis of large numbers of single incident, malfunction reports by FDA is resource intensive and inefficient.

INTENT OF PROJECT: To identify 'best practices' quality statistical methods for the analysis of MDR malfunction reports. If 'best practices' quality methods are identified and broadly accepted by industry, the project will investigate the feasibility of using statistical analyses of malfunction reports as a new form of MDR summary reporting. Preparing the statistical analysis would qualify as meeting some of the quality data analysis requirements of 21 CFR 820 while providing a report the firm could use to meet the MDR reporting requirements of 21 CFR 803. The MDR Summary Report comprised of a statistical analysis of many malfunction reports might replace a stream of individual incident MDR reports.

BASELINE MEASURES: The number of statistical methods identified and accepted by participating firms. The total number of malfunction reports received for each device category. The number of inspections finding adequate quality data analysis by participating firms. The total number of MDR malfunction reports for a device category, both from individual companies and in total.

RESULTS TO DATE: MDR Network accepted the offer and work has begun to identify analysis methods that are appropriate for different generic types of devices. Members of the Network are enthusiastic and have suggested several new ideas offering benefits beyond those of the original concept. The project has revealed that progress would be well served if this project were combined with the effort to develop definitions for key regulatory phrases, e.g., "likely to cause" and "remote."

LEASONS LEARNED: Industry is very interested in expanding the ways that the MDR reporting system can alert FDA to important problems, reduce the burden of reporting known problems, and take advantage of the statistical analysis requirements of the QSR. An important proportion of firms are interested in developing trending analysis skills and in using MDR analysis to improve the safety and effectiveness of their products.

CHRONOLOGY:

04/99 The concept presented to MDR Network

07/99 Conference call discussed results of MDR Network survey of members which revealed several companies very interested in participating in the project

08/99 Conference call discussed the results of MDR Network member statistical methods survey and determined appropriate next steps.

09/99 Conference call discussed results of the Network's initial working meetings, further identified statistical issues and designed a working meeting with OSB staff

09/99 Working meeting held in Orange County identified trending strategies and other MDR issues important to Network members

12/99 Letter sent to MDR Network providing feedback on trending strategies identified during September meeting and encouraging group to continue work.

02/00 MDR Network meeting to continue work on trending strategies and how methods could be used to develop requests for summary reporting.

NEXT STEPS: Continue working with MDR Network to develop trending methods and document on how firms can use trending as a basis for requesting reporting exemptions.

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