Abstract
Data collected throughout the course of a clinical research trial must be reviewed for accuracy and completeness continually. The Oracle Clinical® (OC) data management application utilized to capture clinical data facilitates data integrity through pre-programmed validations, edit and range checks, and discrepancy management modules. These functions were not enough. Coupled with the use of specially created reports in Oracle Discoverer® and Integrated Review™, both ad-hoc query and reporting tools, research staff have enhanced their ability to clean, analyze and report more accurate data captured within and among Case Report Forms (eCRFs) by individual study or across multiple studies.

Introduction and Background
Once data are entered in eCRFs, custom validation procedures programmed within the OC application flag discrepant data. The research team then uses OC’s interface to manage study specific discrepancies, but this task is inefficient in many situations. Also, some validations are not implemented because they are not cost effective to implement and, consequently, possible discrepancies may not be flagged. Periodically, data is transmitted to monitoring agencies and research staff may receive data queries or clarifications concerning questionable or missing data. Corrective actions are taken by the research staff. The management and quality teams lacked adequate quality and productivity tools to monitor discrepancies across studies. Also, they were not able to identify more complex relationships between certain data fields.

Method
Faced with these challenges, the research and programming teams developed a suite of custom quality and productivity tools to enhance their surveillance of data captured in OC. An application was created in Microsoft® Access to track and analyze the monitoring agencies’ data queries regarding incomplete, out of sequence and missing data. Charts and reports were designed to quickly surface errors, omissions, inconsistencies arising from data entry activities versus database or system type issues. A set of discrepancy monitoring reports, for the management and quality teams, were created in Oracle Discoverer to identify patterns in data quality across multiple studies. In Integrated Review, a tool better suited for study specific use, discrepancy management type reports, as well as standardized clinically focused reports, were created to complement the OC validation procedures and ad hoc query functions of Oracle Discoverer. A sample of the specialized reports developed are:

- Missing eCRFs;
- Adverse events lacking an associated reference;
- Adverse events without a resolve date;
- Inconsistent study drug administration documentation;
- Invalid or inconsistent dates associated with dates within and/or across other eCRFs.

Results
Data clarifications and discrepancies have decreased by more than 50% following the implementation of our quality and productivity reports. It is the blending of all these tools that have improved our research sites ability to clean data continually throughout the life cycle of all trials captured in OC. Other research sites may find these tools equally helpful for clinical studies captured in OC.

References