

4.2 Benefits of Proposed DBMS Architecture

Given the essential features of the UCHSC-Fudan University Health Effects Data System, it is evident that Oracle provides the best alternative. Its globalization architecture, security features, scalability and development tools can be extended to address present and future system requirements. Economic feasibility, which is a limiting factor with Oracle products in the commercial world, is not an issue in light of Oracle's Research Alliance Program. Specialized features, such as Oracle's Internet File System, can be developed to allow users to share large image files without having to implement a separate software layer. The initial configuration of a customized Oracle DBMS is time consuming and sometimes complex, however, once implemented, the system's reliability, functionality, and flexibility should instill user confidence. Once developed, the system will require limited maintenance; data entry, control, and analysis processes should be optimized; and users will have time to concentrate on other aspects of the research project. Finally, the database and interface design could be adapted to meet the needs of future research projects.

4.3 Assessment of Commercial Clinical Data Management Solutions and the Trial/DB Data Management System

Before opting to develop a customized data management system, research was conducted to identify packaged solutions for use as the research data system. The review of DBMS architectures provided in the previous section was an integral first step to both identifying the appropriate DBMS and limiting the scope of packaged product alternatives. It is important to note that a DBMS would have to be purchased or licensed separately as it is typically not included in the cost of a packaged solution alternative. During early evaluations, it became apparent that commercial clinical data management systems were aimed at supporting clinical drug trials and were primarily employed in the pharmaceutical and biotechnology industries. Much of the functionality of the systems reviewed focused on accommodating and analyzing data associated with such areas as pharmacokinetics and toxicogenomics. The systems were not viewed as appropriate alternatives and the product costs were prohibitive. One non-commercial solution was discovered, however, which looked to provide an adequate alternative.

Trial/DB was developed by a group within the Medical Informatics department at Yale University in response to the Yale Cancer Center's need for a Clinical Trials database. Over a two week period, this system was reviewed in depth and a dialogue established with the leading developer. In early assessments, Trial/DB appeared to offer much of the functionality needed for meeting the demands of the UCHSC-Fudan University Health Effects Data System project. It also offered some advanced features for the dynamic creation of study forms, export of datasets, and data randomization. Upon further review, some limitations of the system and development issues came under consideration, which could possibly develop into severe development limitations. While the data system accommodates a majority of clinical data needing to be stored by the UCHSC-Fudan University Health Effects Data System, it would need to be extended to store employment history, exposure data, and user data modifications. This was first seen as a relatively simple adjustment, however, subsequent discussions with the lead developer made it apparent that the application and database may need to undergo serious restructuring. He