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Integration of Clinical Study and Distributed Data Management Systems: Does groupware provide a solution ?

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Introduction

An increasing number of pharmaceutical companies and CRO's are turning their attention to *groupware* technologies (a set of applications which allow a group of people to share information simultaneously; Lotus Notes™ or Microsoft Exchange™) to address their information management needs, including clinical study management. In a series of articles, we will review the key characteristics of *groupware*, the specific requirements of a clinical study management system and its possible extension to incorporate data management. We will assess the feasibility of a distributed data management system which creates the necessary environment for data entry and review to be performed at various study locations, e.g., at investigational sites and/or regional CRO offices.

Clinical Study Management System Requirements

A clinical trial team may include permanent or temporary employees of the sponsor company (or companies), central CRO, regional CRO's or regional CRO offices, central laboratories and investigational sites. These groups may be located in different parts of the country, in different countries or continents. All team members must share study related information which must be kept synchronized and consistent. Team members must be able to create, sign, approve, retrieve, distribute, respond to, and file study management related information independent of their geographic location. Groupware was specifically developed to address the information management needs of such project management systems. For reasons given below, we set out to evaluate the feasibility of incorporating the traditional data entry/management segment to the overall clinical study management system.

Figure 1 illustrates the study related information load over time as the study progresses from the planning stage starting with a few paragraphs of "Objectives", through the clinical phase which generates a large amount of study data (patient specific information) and ending with the most condensed form of the collected information: a few paragraphs of "Conclusions". Study data (patient information captured on CRFs; electronic format or hard copy) and study management information are intrinsically interrelated. This is best illustrated by the "data review and cleaning" process which involves many project management steps (creating, forwarding, tracking, and responding to data queries) but may lead to new patient/study data. From a project management point of view, we may wish to review the history/audit trail of query. Alternatively, from a data/study results point of view we may wish to track all changes made to the a variable (e.g. adverse event) or observation. Therefore, for the sake of completeness, consistency and clarity of documentation, the two types of information (study data and trial management information) should be managed under the control of one integrated system.

Groupware Technologies

In this article the key characteristics of groupware is illustrated by Lotus Notes/Domino™. Earlier versions (version 4 or before) of Lotus Notes were based on replication of databases over LAN or dedicated dial-up lines. Later versions (versions 4.1 and up) include an HTML server/interface (called Domino) which allows access/replication via the internet.

Lotus Notes offers the following key technologies:

Data/object stores

Messaging

Replication

Security.

Data/object stores

Lotus Notes can store, retrieve and organize all types of information: a Notes document may include traditional data, such as numerical, character, date, time, and simple text, as well as graphic images, videos plus complex documents such as those produced by word processors or spreadsheets. Various programming tools are available to create data entry screens and perform calculations and transformations on variables.

Messaging

Lotus Notes provides an effective messaging system which is the backbone of any project management system. Messaging is used to send, retrieve and respon to memos, forms, or documents. Messages can be sent to any team member independent of their geographic location, time of the day and method of replication or access to the central database. Messaging includes not only the basic E-mail system but complex functions such as "threaded discussion".

Replication

Lotus Notes allows all team members to share information independent of their location without having on-line connection to a central server/database. Lotus Notes manages multiple copies of the same database (referred to as replicas) on multiple computers (servers or desktops). The database manager defines the protocol for replication of the databases between computers. Typically, replication is done via direct modem connection between computers: the central server calls up the local sites (usually once or twice a day) and exchanges information with them to ensure that all replicas are identical over time.

Alternatively, Lotus Notes (version 4.1 and above) offers a secure on-line access to the database via the internet using any Web browser at the local sites.

Security

Indisputably, the most important element of any computer system is the security it offers to the information stored in it: it should guard against both accidental and intentional breach of confidentiality and any types of unauthorized access of information. The security system has to be extremely rigorous yet flexible enough to avoid creating an administrative havoc in the management of the system.

Lotus Notes incorporates four levels of security:

Bidirectional authentication: servers and desktops (called clients) must identify themselves before they exchange information.

Access control can be defined to servers, databases, documents (records), and even fields within a document. The manager(s) of the servers/databases can define these access codes to authorized users.

Field level encryption protects documents.

Digital signatures are used to ensure/verify that a given document/record was indeed sent by the sender indicated by the document.

An Implementation: SciaNotes™

The backbone of an integrated clinical study and distributed data management system, named SciaNotes™ has been developed at SciAn.

Figure 2 depicts one of many different configurations of SciaNotes™. In this configuration, investigational sites communicate with the system via the internet using Web browsers (running on any system). Site personnel would use the internet to access, deposit and retrieve trial management related information primarily. If required, site personnel could enter some or all of patient data directly into the study database parallel with maintaining the same information on hard copy (CRF) or without this duplication, as dictated by the Sponsor's SOP's.

In this configuration, regional CRO offices and the Sponsor would be provided with dedicated computers configured to access/manage a given study. These computers would have replicas of all relevant study information which would be updated daily. (As an alternative solution, study sites could also be supplied with pre-configured laptops/desktops with full replicas of the relevant databases/information; ie. the use of the internet can be avoided).

SciaNotes™ will be used in subsequent publications to evaluate the feasibility of integrating trial and distributed data management into one system. We will discuss both technical issues (design, programming, system setup and administration) as well as issues relating to the usability of the system under different system configurations in phase II-IV trials.