# JANSSEN RESEARCH FOUNDATION
# TITUSVILLE, NEW JERSEY

## NORTH AMERICAN EXCELLENCE AWARD: IMAGING, MERIT

### EXECUTIVE SUMMARY

In 1995 Janssen Research Foundation (JRF*See* Janssen Research Foundation), a division of Janssen, which is a wholly owned subsidiary of Johnson & Johnson, embarked on a reengineering and technology implementation program to reduce drug development time by 50 percent. A shorter drug development time would help JRF meet its strategic goals of speeding to market beneficial compounds for people in need and achieving strong business performance.

One of the key areas JRF targeted was the clinical trial execution process¾ the highly complex and regulated process in which new drugs are tested on human subjects. It took JRF an average of 22 weeks to "close" a trial. Closing involves final data collection, verification, and data entry. JRF believed automated workflow and electronic imaging technologies would enable them to reach the goal of closing a trial in just four weeks.

At that time, few pharmaceutical companies had implemented imaging and workflow in managing case report forms (CRFs), the primary documentation associated with clinical trials, and none were known to have attempted it on a large, global scale. JRF teamed with USI in the implementation of Documetrix® CRF, a packaged business application built with USI's Documetrix WorkManager and document processing software. The system was installed in Belgium and the United States.

The Team used a pilot methodology to implement not only the workflow but also the newly reengineered trials process. Technical and process training was a key success factor. There were four clinical trial teams initiated during the implementation, one team started every three months and managed between one and four clinical trials. Eighty users were on-line within nine months time. The system was in full production by September 1995.

In September of 1996, the first clinical trial employing the new process and system closed in four weeks, meeting JRF's objective and beating the industry's *best average time* by almost 400 percent! Since then, three other trials have closed with the same or better results.

### *Application Description*

JRF's CRF Workflow System is a document imaging and workflow system used to process clinical trials in support of new drug applications to the Food and Drug Administration (FDA).

The primary objective of the CRF Workflow System is to increase the efficiency of processing clinical documents in order to decrease the time to market for new drugs. JRF's system supports regulated pharmaceutical processes for document control, document retrieval, document tracking, data entry, document archival and other activities associated with managing clinical trials.

The CRF Workflow System (version 3.0 is in production today) was initially implemented in May 1995. Originally installed as a pilot with 10-15 users, the system has grown to 80 production users. The system is used primarily within the Clinical Research, Biostatistics and Data Management areas and extends across other organizations such as the Medical and Regulatory departments. While the majority of users are those who process and monitor clinical trials, such as trial center managers, data entry operators, and trial center supervisors, other users, such as medical writers and regulatory personnel, use the system for ad-hoc document retrieval.

Since the system users have a varied range of computer skills, JRF required all CRF Workflow users to attend a Microsoft Windows training course in addition to a series of classes that reviewed the new business process and provided extensive training on the CRF Workflow System.

The following innovative software features made a tremendous impact at JRF in terms of decreased costs, increased efficiency, and the ability to meet business process reengineering objectives.

- Barcode and optical character recognition (OCR) indexing. Currently, JRF employs both OCR and barcode recognition for automatic indexing. The indexing module was designed to accommodate indexing differences between the Belgian and US offices. Approximately 80 percent of the documents are processed using either OCR or barcode functions. The remaining documents are ancillary and lab reports that could not be standardized by JRF. With up to 2,400 documents received per day, the automated indexing functions tremendously accelerate the availability of documents to the clinical group.
- Automated backfile scanning. The barcode indexing features also allowed JRF to scan and index approximately 300,000 backfile images. These images are now available to medical writers to include in new drug applications for submission to the FDA.
- Legacy tracking systems integration. In order to maintain data integrity across several legacy systems, USI integrated the JRF developed CIM database with the CRF Workflow System study setup functions. This preserved enterprise data integrity and supported the use of a common database for shared information.
- Data query resolution process. One of JRF's goals was to reduce the data query cycle time. Data queries are created and sent to the doctor for resolution when erroneous or illegible clinical data is submitted. Before closing a clinical trial, all data queries must

be resolved. In the old process, data queries were initiated after the last patient visit of the trial. JRF projected that compression in data query resolution time would be key to reducing in the overall clinical trial closure time by 50 percent. In response, USI designed and implemented a data query module with functions to accelerate the query resolution process. It includes:

- Fax in and out capabilities to expedite the sending and receipt of Data Queries and CRFs;
- Generation of data queries with barcodes for automated indexing upon return;
- Reports to monitor the data query status; and
- Features to maintain data query metrics.

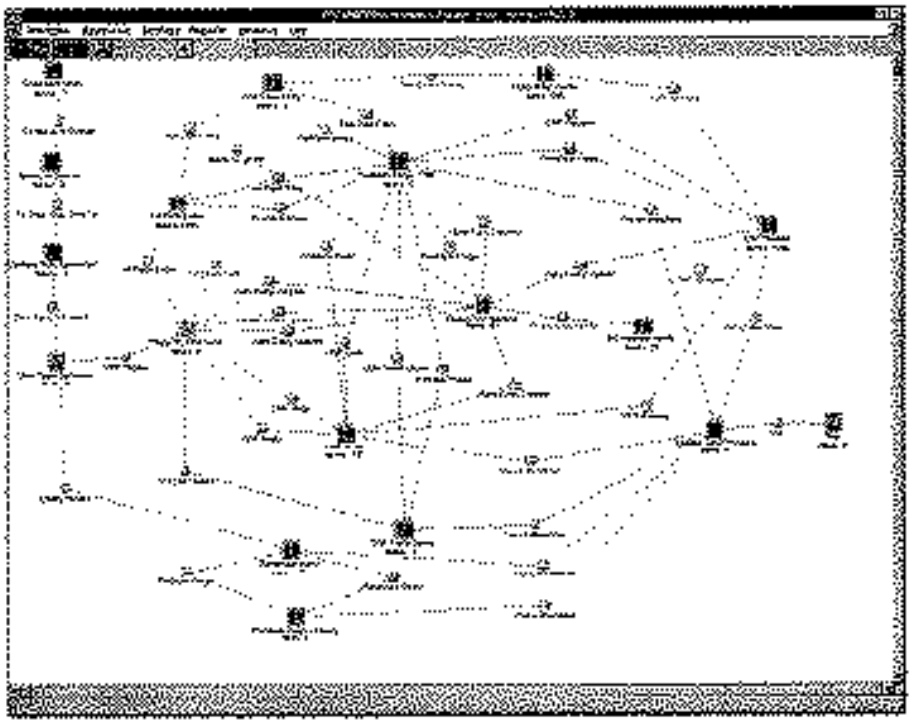
- Images used for CANDAs. JRF uses the scanned images in computer-assisted new drug applications (CANDAs). This eliminates the huge volume of paper associated with new drug applications¾an incredible feat! Using the ad-hoc retrieval module, medical writers are able to quickly locate study documents, and export these documents into the various reports and papers for submission to the FDA.
- Data Warehousing. The system captures and houses substantial data that is used to measure performance related to the clinical trial. Areas monitored include:
  - investigator performance;
  - data entry operator productivity;
  - work quality; and
  - throughput measurements.

During the design phase, JRF was very specific regarding metrics to be captured by the system. Performance evaluation against the reengineering goals relied heavily upon the ability to capture and store certain data. Data warehousing is now used more extensively than originally anticipated.

Reporting Features. The system provides the capability to generate standard reports as well as create custom reports. All of the metric reports were generated by JRF using the custom report capabilities. Users can download report data in Microsoft Excel for additional manipulation and reporting. Appendix A includes an example of a report.

Belgium and US Workflow Processing. One of the goals of the reengineering effort was to standardize the workflow process between clinical groups in the Belgian and US offices. While the workflow process was being finalized, JRF needed a flexible workflow tool that would accommodate differences in workflows between the various groups. Documetrix Workflow Builder met these requirements. It allows unique clinical study workflows to be designed and changed dynamically for each clinical trial if necessary. During the pilot phase, it also allowed JRF to experiment and gather information on different workflow approaches. The standard workflow JRF uses today is illustrated below.

*Figure 1: Workflow Map from the Janssen Research Foundation CRF Workflow System*



- Mark-sense: JRF plans to mark-sense clinical data in order to eliminate manual data entry. Employing the use of a third party product, USI designed a fully integrated mark-sense module and implemented it in a pilot phase. A recognition server was developed to process the data and incorporate the process into the workflow. The system includes functions to:
    - Set up mark-sense pages (create “form specifications”);
    - Recognize data;
    - Load data into the clinical trial database; and
    - Route pages to verification tasks.

Significant effort was involved to integrate the recognized data into JRF’s existing clinical database system. This area is targeted for expansion in 1997 and shows promise for further reducing the clinical trial process time as well as improving the quality of clinical data.

Integration with Clinical Trial Database: The clinical documents still must be entered into the clinical trial database so statistics and validation procedures can be run against the clinical data. The data entry operators can use the clinical trial database in conjunction with the CRF Workflow System. Split screen display enables data entry operators to enter the data

from the image, and provides features such as:

- Electronic annotations;
- The ability to maintain a central notes repository;
- The ability to view data queries while on line; and
- The option of sending documents to exception queues for exception processing.

KEY MOTIVATIONS

JRF initiated a project called the Time Compression Initiative to evaluate its global business practice and reduce drug development time by 50 percent. This initiative would help JRF better meet their crucial strategic goal of benefiting people in need of new compounds by bringing them to market more quickly. By gaining valuable market share from being first to the market and recouping the high cost of research and development, JRF could continue to meet their customer's needs.

JRF international management identified several core processes suitable for business process reengineering ¾ clinical development planning, clinical trials, and new drug applications. Clinical trials were selected as a very high return reengineering opportunity. Three areas were considered crucial to the timely completion of quality clinical trials:

- Selecting doctors to participate in the trial;
- Recruiting patients to participate in the trial; and
- Gathering and managing the clinical trial data.

The quality of the data, the timeframe in which the data is collected and processed, and the method of data capture are all key to the successful and timely closure of the clinical database. Prior to the system it took an average of six months to finalize a database after the last patient's visit to the participating doctor. JRF felt it was imperative to close the database within 4 weeks in order to achieve the goal of reducing drug development time by 50 percent.

Workflow was evaluated and shown to support intensive transaction-oriented processes such as clinical trials. JRF management expected workflow to provide information regarding efficiency of the new process and greater employee productivity. In addition, by moving documents and data electronically, information distribution time would be dramatically reduced. Workflow could be tailored to JRF's specific processes and easily changed as business needs evolved.

JRF chose to implement an imaging and workflow solution in the "mission critical" clinical trials area to manage CRFs. The system would prove to meet their ultimate goal¾ reduced time to market.

CURRENT SYSTEM CONFIGURATION (NORTH AMERICA)

The JRF CRF Workflow System is configured with 3 scan stations, 80 retrieval stations, and multiple servers providing file, optical, database, print, recognition, and other capabilities. Some key parameters of the system are shown in the table below.

| Parameter | Value |
|---|---|
| Required availability | 18 hours per day |
| Average scanning volume | 2,400 pages a day or 56,000 pages per month |
| Required system availability | 99.95 percent |
| Current active trials in workflow | 128 trials |
| Projected 1997 active trials | 136 trials |
| Average range of pages per clinical trials | 40,000 to 80,000 pages |
| Average range of pages per CRF Book | 150 to 300 pages |
| Based documents per clinical trial | 1,500 documents |
| Turnaround from document receipt to in index | Within 5 business hours |
| System users in the US | 60 users |

*Figure 2: Select System Parameters for JRF's CRF Workflow System*

HARDWARE DESCRIPTION

The CRF Workflow System architecture makes use of JRF's existing client/server environment utilizing both client and server PCs running TCP/IP - NLM and Novell 3.12 IPX network protocols. JRF's existing network is used to meet the scanning, indexing and retrieval demands of the CRF Workflow System images. In addition, workflow users and other ad hoc query users access the images stored within the CRF Workflow System. For sizing purposes, USI estimated that the average image object, once scanned and compressed, was approximately 45MB. The primary CRF Workflow System components are summarized below.

*Database Server*

The database server stores all document management information associated with a scanned image (e.g., index, workflow in-process, workflow history). The CRF Workflow System utilizes a Hewlett Packard HP/9000 Model K200 Server. The HP/9000 is running HP-Unix version 10 with Oracle version 7.1.3 as the relational database management system (RDBMS). The server is configured with 512MB RAM and 12 2.1GB drives supporting 25.2GB of mirrored storage.

*File/Optical Server*

The file/optical server runs the file and optical services for the CRF Workflow System. It is a Compaq Proliant Model 4500 with 327MB of memory and 12GB of disk storage. The optical subsystem is comprised of two separate optical jukeboxes connected to the file/optical Server. The first jukebox is a Sony Model WDA-330 with one disk controller and twelve 12" platters. The total internal storage capacity of the Sony jukebox is approximately 76GB. The second jukebox is a HP Model 300st with six drives and 128 2.6GB 5.25" optical platters. The total internal storage capacity of the HP jukebox is approximately 332GB.

The Optical Subsystem provides storage for all active pages using Kofax's AscentStorage (formerly LaserData's Optical Services for NetWare) optical storage management software. An "active" page, for the purposes of the CRF Workflow System, is one that is either in-process (i.e., is being edited or entered) or one that requires immediate access.

*Scan Stations*

There are a total of three scan stations in the CRF Workflow System. Each of the scan station PC is a Compaq Pentium with 16MB of RAM. They run Microsoft Windows and Documetrix scan station software to control the scanning process. All three scan stations are configured with the Cornerstone 2176 Color Displays.

Two scan stations PCs are configured with Fujitsu M3097 scanners. This scanner model is rated at 35 pages-per-minute at 300 dots per inch. It has both flatbed and automatic simplex document feeding capability. The third scan station is configured with a Fujitsu M3099 duplex scanner with a 500-page automatic document feeder (ADF). The Fujitsu M3099 has a rated speed of 55 pages (100 images) per minute.

JRF documents are scanned at a resolution of 300 dpi. Images are compressed using CCITT Group IV compression, resulting in approximately 45 KB of data per image. The scan stations enable JRF users to scan incoming CRFs, approved data queries and other documents as they are received. As batches of images are scanned, they are saved to the file server magnetic storage. Images can be moved to optical storage after they are indexed.

*Index/View Stations*

Any image-enabled workstation can be used as a CRF Workflow System indexing station. The user who conducts, or monitors, the indexing need only be authorized by the system administrator to conduct the indexing function. JRF has a total of 80 client index/view stations, in their current configuration. Approximately half have Cornerstone monitors.

The user/index stations are connected to the TCP/IP—Novell IPX network, providing access to images located throughout the system. In addition to viewing images, the viewing

workstation will have the ability to run DOS, Windows 3.1, and Windows 95 compatible software.

*Workflow/Recognition Server*

The workflow/recognition server is a Compaq Pentium processor with 16MB of RAM and 1GB of disk space. This server runs two (separate processes in the JRF CRF Workflow System-–workflow services and document recognition services. Workflow services for the CRF Workflow System include processing Documetrix WorkManager workflow transactions and distributing updates to the workflow processes and to Documetrix clients. The recognition services include conducting all forms-recognition and mark-sense processing, such as data extraction and verification. Integration with the clinical database is accomplished utilizing the workflow/recognition Server. This server also supports ad-hoc reporting capabilities provided through the Crystal Report Writer software and a Q+E interface to the Oracle database.

*Workflow Device Server*

The device server is a Compaq Pentium PC with 16MB of RAM. It is dedicated to processing all of the automated Documetrix WorkManager workflow "devices." A workflow "device" is an automated process that completes activities, such as subject updates and annotation removal functions.

*Auto-Index/OCR Server*

A dedicated server is configured to handle the auto indexing of CRF documents and manages all barcode and OCR functions related to indexing. The auto-index/OCR server consists of a Compaq Pentium processor with 16MB of RAM. The auto-index server manages and performs the indexing and validation of all CRF documents and distributes documents to the workflow server. The auto-index/OCR server is configured with OCR and services barcode processing.

*Image Move Server*

Given the number of images which require movement from magnetic to optical, a dedicated image move server is configured for the JRF CRF Workflow System. The image move server at JRF is a Compaq Pentium processor, and serves two main functions: it moves files to optical media, and it maintains a list of current volumes and their settings.

*Print Servers*

There are four print servers configured for the CRF Workflow System LAN. Each of the print servers is a Compaq Pentium PC with 16MB total RAM . The print servers support a variety of network printers.

The print server solution enables JRF users to print images as well as other print jobs from Windows applications at near rated speeds. In addition, the dedicated print server off-loads the CPU required for generating image print jobs to the print server, releasing resources of the client workstations for other tasks.

The print servers support the printing of images from any Windows-based application. Users can print images from the CRF Workflow System and print from applications such as Microsoft Word, WordPerfect for Windows or Microsoft Excel on the same printer.

*Fax Server*

A fax server is configured to handle inbound and outbound faxing needs for the CRF Workflow System. The fax server is a Compaq Pentium PC with a 40MB of disk space. The fax capability enables JRF users to fax CCITT Group IV compressed images as well as other document types from Windows applications across the network.

The CRF Workflow System supports fax out services for remote and local users. Users can fax out any document within the system through the fax capability. Users can specify any fax phone number.

The CRF Workflow System supports the capability of generating a fax cover sheet, and setting-up, tracking and charging accounts for connection times and fax-out services.

*System Impact*

As a direct result of imaging and workflow, JRF beat the benchmark for outstanding performance in their industry by 400 percent. They cut the time to close a clinical trial from an average of 22 weeks down to four weeks, and they are well on their way to achieving a 50 percent average reduction in drug development time. JRF's system is the foundation for rapid introductions of new compounds that can improve health and the quality of life.

The CRF Workflow System has had an immediate impact on quality, productivity, and cycle time. Improvements in these areas have brought JRF closer to achieving their ultimate strategic goals of improving customer's lives, creating competitive advantage, and recovering the high costs of research and development.

*Cycle Time*

JRF achieved a remarkable improvement in the time it takes to close a clinical trial. The figure below illustrates how imaging and workflow have impacted JRF's process and underscores how JRF has "raised the bar" in terms of industry best performance.

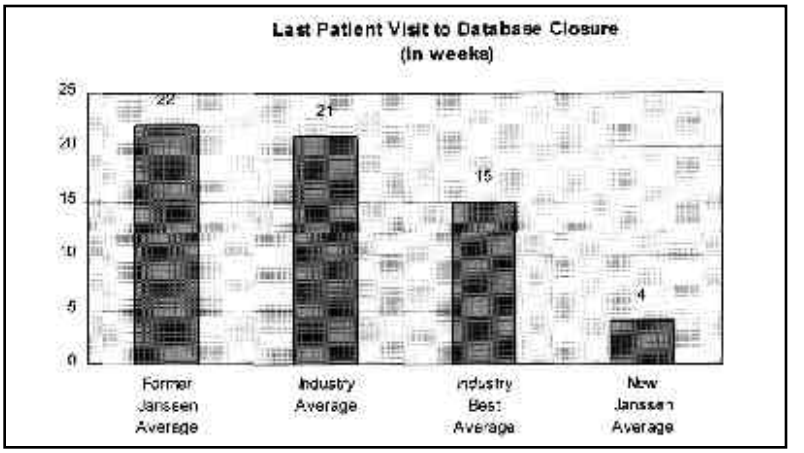



*Figure 3: JRF Raises the Bar for Industry Performance*

A core component of the shortened cycle is faster turnaround on document discrepancies (data queries). In the old paper-based process, data from the CRF typically would be logged months after a patient visited the doctor. It would take several more weeks for researchers to send out queries if data was missing or there was a question about the documentation. Currently all data capture, data checking, and queries back to the clinical site are completed within 72 hours of receiving patient information. The queries to the site are electronically sent and received via a fax server with a barcode to enable automatic indexing and routing back into the workflow.

*Quality*

Timely access to data has enabled JRF to take quick action, such as training, if procedures or standards aren't followed during a clinical trial. The clinical trial execution process has been standardized across all therapeutic areas, both in the US and in Europe. Appendix A includes an example of one tracking report that measures the response time of each site to data queries.

Other quality improvements include the ability to:

- Monitor and continuously improve processes to help meet timeline goals;
- Graphically review the location of documents in the workflow instantaneously;

- Create new paths “on the fly” to support new business requirements;
- Track all trials for management and validation purposes;
- Ensure data security and integrity;
- Utilize workflow statistics to determine new resource needs;
- Monitor the clinical trials site and employee performance;
- Enable sharing of information;
- Ensure consistency and compliance with the new process while increasing quality; and
- Protect legal documents by storing them on secondary media.

*Productivity*

Prior to implementing the CRF Workflow System, JRF typically dedicated staff over a period of almost 6 months in order to close a clinical trial. Today, the same number of staff can perform the same job in just 4 weeks. This productivity gain can be realized both in reduced cost and in improved capacity. Janssen has grown 35-40 percent annually. The productivity gains of the system and new process have enabled Janssen to grow quickly without hiring as many new people.

*Better Customer Health*

JRF plays a vital role in the discovery and development of therapeutic compounds through innovation. Their research has led to the synthesis of more than 82,000 molecules, yielding an extraordinary number of new drugs undergoing clinical trials and more than 70 marketed products worldwide. These products have lead to substantial improvement in the quality of life for conditions such as chronic pain and schizophrenia. The CRF Workflow System and new process have made it possible for JRF to bring benefits to customers sooner.

*Market Share and Cost Recovery*

In the pharmaceutical business, a developer of a new compound strives to recover the costs of research and development during the early introduction of the drug before significant competitive pressures impact sales. On average, it takes a pharmaceutical company between 10 to 12 years to bring a new compound to market at an average cost of $300 million. These figures are benchmark guidelines from the Pharmaceutical Research and Manufacturers of America (PhRMA). By implementing the CRF Workflow System and new processes, JRF has reduced some of these costs, however, tremendous upfront investments are still necessary. Each day that JRF can market a new compound ahead of competitors brings them closer to

recovering costs and establishing significant market share to ensure profitability needed to fund continued research and development in new areas that benefit people. The CRF Workflow System and new process have already removed 18 weeks from the development cycle. For compounds that have revenue potential of $250 million and greater, this time savings translates into $90 million in cost recovery and reinvestment for each compound that is approved.

## IMPLEMENTATION PROCESS AND METHODOLOGY

### *Business Process Reengineering and Initial System Installation*

Early in JRF's reengineering and technology implementation program, JRF executives recognized that the new processes and time compression initiatives they were defining could only be implemented through the application of sophisticated and proven imaging, workflow, and document management technologies. USI's experience in implementing several custom CRF Workflow Systems for other clients was recognized as a solid starting point. However, the functionality and performance demanded by JRF's initiatives required that significant new capabilities be added to the system.

Another important objective of JRF's business process reengineering was to "harmonize" the clinical development processes used by JRF's principal research and development facilities in the United States and Belgium. Although much of the data collected and used for a new drug application in one country is used in submissions made in other countries, the regulatory and organizational differences between US and European operations can result in unnecessary duplication of effort, additional costs, and submission delays.

CRFs are central to the clinical data management process, and JRF recognized that the CRFs themselves would need to be re-designed to take maximum advantage of the new processes and systems. Working closely with USI, JRF defined standard document types and formats that could be used with little or no change for many trials. The new CRFs utilize a revamped identification scheme and pre-printed barcodes that speed data capture and dramatically reduce error rates.

One of USI's early CRF Workflow Systems was installed at JRF to provide a foundation and framework for evaluating and planning the implementation of the production CRF Workflow System. In parallel with this effort, JRF Belgium took the lead in using the results of JRF's reengineering work to develop production CRF Workflow System specifications.

## PRODUCTION SYSTEM IMPLEMENTATION AND INSTALLATION

As the results of the reengineering and CRF redesign efforts were available, USI began implementing the production CRF Workflow System. JRF and USI used a standard

methodology for deploying the CRF Workflow System. It focused on user involvement and feedback as the principle axiom.

The high-level implementation tasks are listed below.

- Orientation/Kickoff
- Requirements Verification
- Technical Design Specification
- System Development
- Site Preparation
- User Testing and Acceptance
- System Installation (includes: Acceptance Test, Documentation, Training)
- Post-Acceptance Training and Support

The following discusses some of the details of the implementation process and methodologies.

*Requirements Verification*

The principal objectives of the Requirements Verification task were to confirm the information contained in the system requirements and specification, to determine if any unidentified requirements or assumptions existed, and to resolve any open issues. This was a formal process during which USI studied JRF's operations, procedures, and infrastructure. Important components of this process were interviews with representative JRF staff and evaluations of the initial system.

During the requirements phase, USI personnel observed the current procedures and discussed current and new procedures with the end-user and technical staffs. The requirements verification process helped USI gain an in-depth understanding in areas such as: indexing requirements (fields, sizes, and types), document relationships, user familiarity with graphical user interface-specific screen layouts, and other system interface requirements.

Upon completion of the Requirements Verification task, USI conducted a working session to review system requirements and objectives, provide input to the system design, and identify system constraints. The objectives of this session were to:

- Review requirements;
- Identify additional requirements;
- Review system processes;
- Gain concurrence on an initial logical model; and
- Provide input into the detailed system design specification.

System processes were discussed, relevant procedural documentation was reviewed, sample documents were collected, and workload estimates were verified. This information provided USI with an in-depth understanding of the operational environment in order to accurately design and develops the system to meet JRF's needs.

The Requirements Verification task was closely aligned with the process reengineering taking place at JRF and provided it with pertinent process information. Some of the activities of these two tasks were performed in parallel.

### *Technical Design Specification*

Information collected during the Requirements Verification and process reengineering tasks was used to develop the technical design specification (TDS). The first step in the Technical Design Specification task was to gain formal acceptance and approval of the requirements and re-engineered process specifications captured during the previous tasks. Based on the original design concept developed in the logical model, USI developed a detailed technical design specification that validated the system hardware and software architecture and system configuration. This specification documented the application system inputs/outputs and system interfaces, database design (entity/relationship diagram), data dictionary, screen designs, indices, access methods, procedures, and processes, and report formats. Illustrations were provided detailing the hardware configuration, software components, and system links. The TDS also included a project completion schedule approved by the USI and JRF technical team.

### *System Development and Installation*

During the software development period, numerous prototype reviews were conducted at JRF and USI to allow end user feedback on the system while it was developed. This hands-on interaction gave end users and managers an opportunity to become familiar with the system and ensured that the functionality of the system clearly addressed JRF's requirements.

At the conclusion of system development, the application was installed at JRF's Belgium facilities and US. JRF and USI personnel executed test scripts and system loading procedures that were derived from the requirements and specification. This marked the conclusion of the "traditional" system development process and the beginning of the critical tasks of training JRF personnel in the use of JRF's new standard operating procedures (SOPs) and the new system, and the ramp-up into production utilization.

### *Training and Production Ramp-up*

JRF and USI had devoted significant effort towards redefining processes and implementing a system capable of supporting those processes, but there were some processes

that JRF wanted to evaluate and refine by using the system. Four pilot teams were formed and several projects were defined to run actual trials on the system. As the pilots progressed, participants were extensively trained in the new processes and system operation. A new pilot team started three months after the previous team so system performance and results could be carefully monitored to ensure that expected time compression improvements were realized. When necessary, SOPs were modified to maximize the benefit.

As additional pilot projects were added, the processing volume and user experience increased and smoothly merged into a production mode.

### *Post-Production Support*

The pilot projects resulted in production operations and several production qualified users. Now, a large number of users had to be trained in both the new processes and system operation. Additionally, improvements and new requirements were identified and unique demands from individual trials arose as system usage increased. These challenges were addressed by the joint development of a comprehensive training package and the assignment of an onsite senior USI developer at both JRF's US and Belgium facilities.

The training package focused on the new processes developed under JRF's time compression initiative. Although the CRF Workflow System is a critical and integral part of the process, the business imperatives clearly drove the technology and are the focus of the training.

USI's onsite technical support in the US and Belgium provide system support, training, and maintenance functions. They work closely with colleagues at USI's headquarters to ensure that improvements to the application are coordinated and propagated to all CRF Workflow system clients. They also provide ad hoc support for reports or utilities that may be required to meet unique demands of individual trials.

## TECHNICAL AND BUSINESS INNOVATION

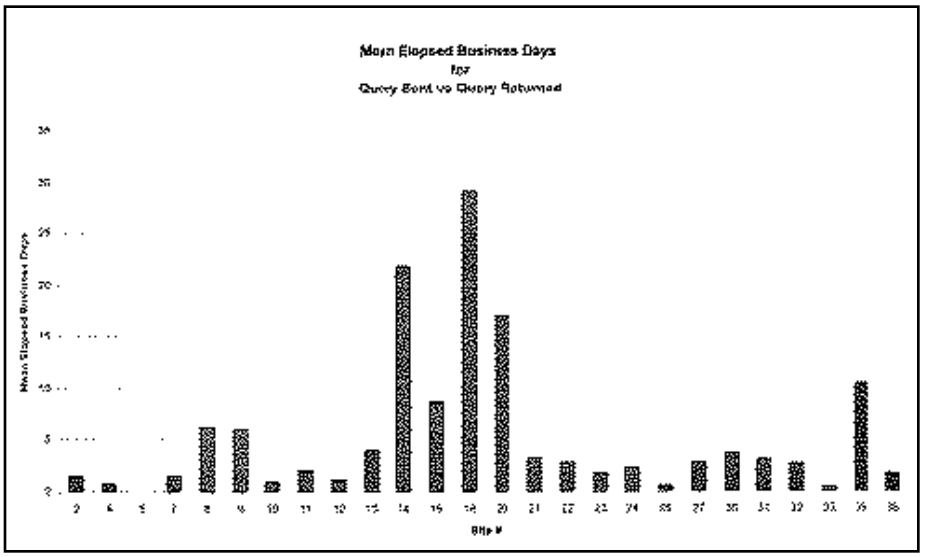
JRF's implementation of imaging and workflow pushed the boundaries of large-scale, mission-critical systems. JRF was willing to employ relatively new technologies at the heart of their business in conjunction with business process re-engineering. At that time, they had no other large pharmaceutical company upon which to model their solution. JRF was a pioneer.

JRF implemented advanced technology and re-engineered their business during the highest growth period in Janssen history. At each stage of the project, JRF considered where an innovative approach could make a dramatic difference in their business. For example, they redesigned their CRF forms, added barcodes, and employed fax for a virtually hands-off paper capture process and standardized workflows on two continents. Datawarehousing was

another innovative element of the solution. These elements combined to make JRF's initiative to reduce drug development time highly complex.

As a business, JRF identified the constraints of their old technology and processes for case report forms. They committed the company to a dramatic solution requiring new technologies and drastic changes in the way they did business. JRF moved swiftly and effectively to design and roll-out their imaging and workflow solution.

With Janssen Research Foundation and USI showing the way, virtually every pharmaceutical company in the world has a new benchmark for performance in clinical trials and a mandate to implement imaging and workflow in their clinical trials process.




Appendix A