Rhône-Poulenc Rorer
Document Management System Project

1993 Call for Tender
Preliminary Visit

Strategic Approach

Major areas where electronic document management systems can provide significant operational and competitve edge to RPR

- **Case Report Form Management**
- **Regulatory Document Management**

IA CORPORATION'S UNDERSTANDING OF THE BUSINESS PROBLEM

- **Business Environment**
- **Problem Statement**
- **Expected Benefits**

CASE REPORT FORMS

- Clinical trials or studies
- Request information in a prescribed format (CRFs)
- On average, 30-40% of the CRFs require correction
- Various data capture alternatives
  - Central key-entering
  - Remote key-entering + magnetic media
- Quick dispacth to Investigators for review

Problem Statement

CASE REPORT FORMS

- **Automate the capture of CRFs and of the data they contain**
- **Capture associated source documents**
  - **Continuous blood pressure recording**
  - **Cardiac catherization**
  - **X-ray reports**
  - **Holter monitoring**
  - **laboratory slips**
  - **etc.**
- **Support Medical Research work groups by enabling immediate and transparent access and referral to:**
  - **CRF and source documents images**
  - **Clinical trial data base (i.e., all information needed to plan, conduct, analyse and report clinical studies)**

Expected Benefits

CASE REPORT FORMS

- **Reduce lag time by making CRFs rapidly available to everyone who needs them**
- **Eleminate photocopying of CRFs**
- **Scan, received CRFs and immediatly store paper**
- **Support head-up data entry**
- **Automate login**
- **Reduce manual data entry**
- **Improve data quality and timeless**
- **Improve work flow**
- **Trigger immediatly safety data review upon CRF receipt**
- **Facilitate management tracking of CRF review process**

IA CORPORATION'S UNDERSTANDING OF THE BUSINESS PROBLEM

- **Business Environment**
- **Problem Statement**
- **Project Scope**
- **Expected Benefits**

Business Environment

- **Purpose**
  - **Reporting to regulatory agencies worldwide**
  - **Approval of new drugs**
- **Accessed throughout the drug development process**
  - **Corporate compliance services**
  - **Central files**
  - **Pharmaceutical development**
  - **Regulatory affairs**

Corporate compliance services

- **Responsible for**
  - **Regulatory compliance**
  - **Drug experience reporting**
  - **Post-marketing regulatory activities**
- **Access/maintain vault of**
  - **Finalized and approved reports**
  - **Regulatory correspondence and documents**
- **Key activities**
  - **Tracking of all preclinical and clinical reports**
  - **Audit of Case Report Forms (CRFs)**
  - **Audit of regulatory documentation**

Central files

- Central repository
  - General study files,
  - Investigator files,
  - Project-specific files.
- Accessed by
  - Clinical Research Associates (CRAs)
  - Medical Monitors (MMs)
- Key activities
  - Storage of originals
  - Back-up microfiching
  - Distribution
    - Clinical research personnel
    - Internal/external regulatory reviewers

Pharmaceutical development

- **Responsible for**
  - **Development and analysis of drug products**
  - **Manufacture of clinical trial supplies**
  - **Preparation of Phar/Chem portion of regulatory submissions**
- **Require**
  - **Central files,**
  - **Manufacturing and quality assurance files,**
  - **Aanalytical methods and specifications of regulatory submissions.**
- **Key activities**
  - **Support of pharmaceutical development staff**
    - **Coding/filing the documents they produce**
    - **Providing appropriate supporting documentation**
      - Including regulatory submissions

Regulatory affairs

- **Responsible for**
  - **Regulatory planning**
  - **Assembly and prosecution of submissions**
- **Key activities**
  - **maintenance of regulatory intelligence and PCR documentation**
  - **identification of nature, composition and documentary content**
  - **assembly of regulatory submissions**
  - **submission of required documentation**
  - **maintenance of ongoing liaisons**

Problem Statement

- **Many dupplicates**
- **Dramatic volumes**
- **Non-concurrency**
- **Untimely hand-distribution**
- **Files occasionally misfiled or lost**
- **Increasingly complex tracking**

Project Scope

Speed up submissions to get products to market faster and realize product revenues as soon as possible.

- **Automate the capture/storage of**
  - **Paper/microfiche documents**
  - **Electronically created documents**
- **Provide efficient retrieval**
  - **Support worldwide concurrency**
  - **Improve searching capabilities**
  - **Enable content portion handling**
- **Eliminate**
  - **Redundant storage**
  - **Dupplicates**

Expected Benefits

Gain control over submissions, and better manage/track vital information in the NDA production process.

- **Simplified procedures**
- **Expedite the preparation of submissions**
- **Concurrent and worldwide access to latest copy**
- **Significantly reduced retrieval time with increased accuracy**
- **Shorter response time to regulatory agency requests**
- **Reduced file storage space**
- **Increased security**
- **Easily accessible backups**
- **Increase intercompany communications**
- **Reduced administrative effort**