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Managing Medical Image Data in a Pharmaceutical company



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Title: Managing Medical Image Data

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Overview

- **Introduction**
- **Business processes relative to image management in clinical phases I-III**
- **Goals relative to image data analysis**
- **Current challenges in managing image data**
- **A pharmaceutical image management system**
- **Conclusions**

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Background

- **An image management (IM) system may support the loading, aggregating, viewing, storing and reporting of processed (formatted) digital image data sets, related annotations, measurements and meta data for all image modalities utilized by a company including MR, PET, CT and ultrasound (IVUS).**
- **The business process can be described by the following major components:**
 - **Clinical Image Acquisition/Storage**
 - **Clinical Image Viewing**
 - **Clinical Image Analysis**
 - **Clinical Image Data Export to Electronic Data Management (EDM)**
 - **Exception and Error handling.**

Objectives

The primary aim of an IM project may determine the best and most cost effective approach for implementing a clinical image database infrastructure which will allow ownership and control of the digital image data by a given company rather than outside service providers.

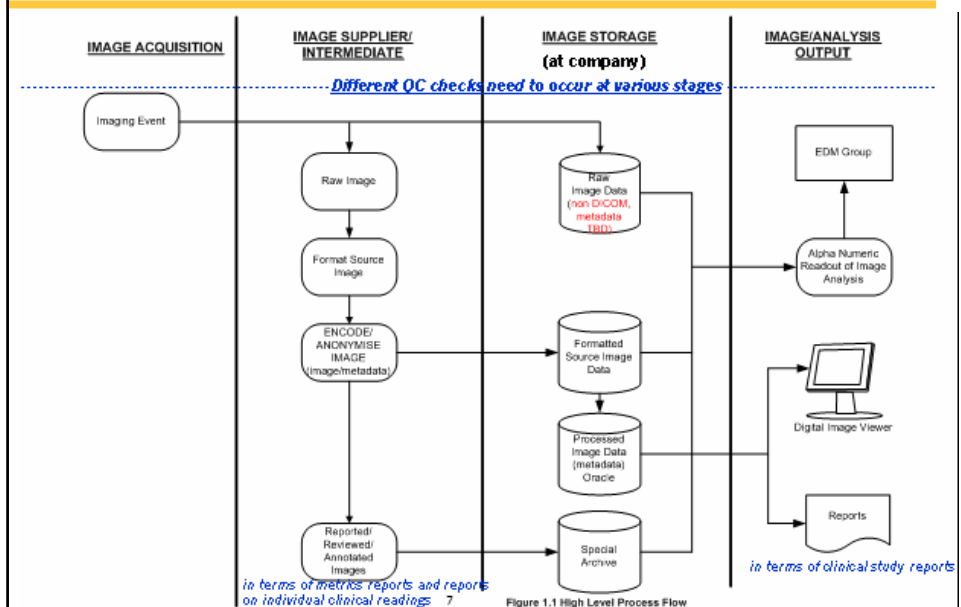
The goals of such project may include:

- Implement a clinical digital image repository which supports the various existing medical image formats and which is open for expansion to new image modalities
- Increase operational efficiency by reducing time-spent tracking, collating and preparing clinical image data
- Allow improved decision making by providing timely access to clinical image data internally at a given company
- Enable secondary analysis of clinical images at a given company which will lead to improved clinical trial and product outcomes
- Implement a solution that is compliant with regulatory requirements and which conforms to international data standards.

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High - Level Business Process Diagram



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Goals of image data analysis

- **Disease detection: Patients to be diagnosed for inclusion into study**
- **Disease modification in response to drug treatment: Non-invasive surrogate markers to be utilized for drug monitoring of safety and efficacy parameters**
- **Correlation of image datasets with clinical data and clinical endpoints across indication areas**
- **Retrospective data mining across studies to identify pattern**
- **Simulation & Modeling: Retrospective usage of image data sets for outcome prediction.**

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Challenges in managing image data

- **Lack of harmonization of image acquisition in multi center trials**
- **Lack of infrastructure in processing and storing huge volumes of image datasets. Currently, only basic image data sets (e.g. scores or measurements but not the image itself) may be available or image data are stored eventually on CD-ROMs**
- **Lack of Computer Aided Diagnosing (CAD) methods analyzing image data sets**
- **Lack of content based image data retrieval**
- **Uncertainty about the endpoints to be used.**

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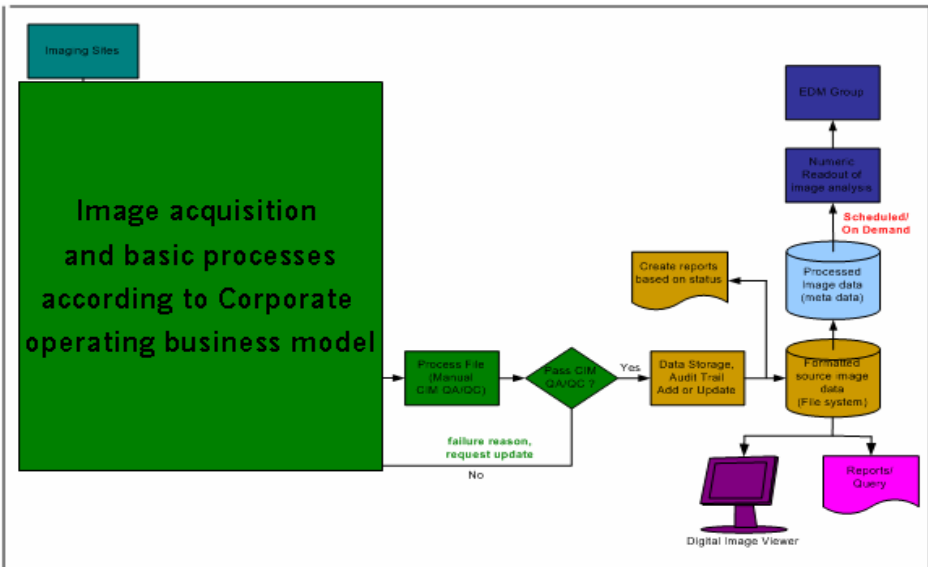
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Seven key functional domains

1. Import and process DICOM image data with annotations, meta data, and 3rd Party analytical data for i.e. MR image data sets.
2. Perform QC -
 - Automatic – edit rules with valid values
 - Manual – Image reviewer QC's digital images
 - QC exceptions reported to 3rd party – images and data
3. Populate an image repository with MR images and annotations
4. Populate Oracle DB with parsed meta data and analytical data
5. Provide an image viewing capability
6. Export ASCII data from Pharma IM to EDM clinical DB
7. Provide Query and Reporting tools that support data mining of image data sets and related meta/analytical data

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...and a potential initial system release.



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Pharma IM vs. PACS

Key Differences

- **Process workflow**
- **Databases**
- **Meta-data**
- **Sets of image workstations**
- **Actors (user groups)**
- **Network requirements**
- **Regulatory compliance in drug development (i.e., FDA's 21 CFR Part 11).**

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Pharma IM vs. PACS (cont.)

PACS may not have

- **An automatic QC functionality based on edit rules**
- **An export capability (i.e. to external partners such as FDA)**
- **Search or interactive database query capability**
- **A data mining capability on result and meta data**

Pharma IM don't need

- **Dedicated, high power PACS workstations for main users**
- **Dedicated RIS workflow**
- **Near real time data transfer and processing**
- **A high level of system redundancy.**

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Conclusions

- **Currently a single product that satisfies all of Pharma IM systems requirements does not exist in the marketplace.**
 - Suppliers offer digital imaging products in the PACS/RIS area that are designed for the clinical environment.
- **Discussions are needed with the suppliers regarding their product's adaptability to Pharma and its compatibility with Pharma corporate IT standards.**
 - Any products built around a closed proprietary architecture may preclude integration of e.g., other third party analytical tools.

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- In 2004, the Group's businesses achieved sales of USD 28.2 billion and a net income of USD 5.8 billion.
- The Group invested approximately USD 4.2 billion in R&D.
- Headquartered in Basel, Switzerland, Novartis Group companies employ about 81,400 people and operate in over 140 countries around the world.
- Further information is available at www.novartis.com .

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