

A Software Solution Integrating Disparate Components of a Healthcare System's Biobank for Translational Research

K. Rice, BS¹; C. Gillies, MS¹; G. Wilson, PhD^{1,2}; J. Akervall, MD, PhD^{1,3}

¹Beaumont BioBank, ²Radiation Oncology, ³Department of General Surgery
William Beaumont Hospital, Royal Oak, Michigan, USA



Background

Translational biomedical research is the application of a discovery to the practice of medicine; a transfer of research from “bench to bedside”. The vision for translational research is personalized medicine (Figure 1). Personalized medicine focuses on giving treatments to patients based on detailed knowledge of their individual genotype and disease characteristics. At the heart of personalized medicine are biomarkers generated from genomic and proteomic studies. A biomarker is a gene, a set of genes, or gene products such as proteins.

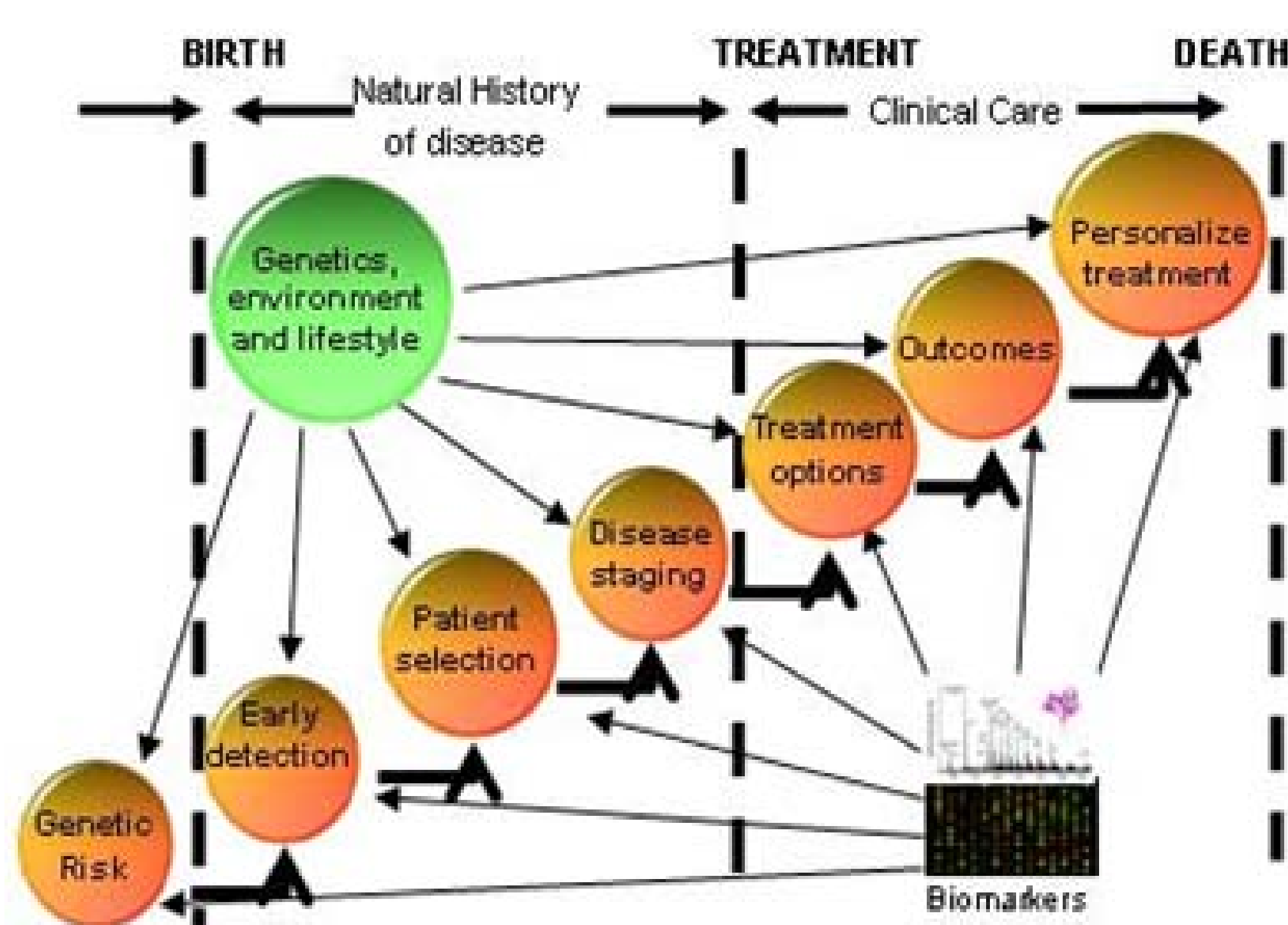


Figure 1. Translational Research Vision

The process of translational research involves a diverse group of researchers and data sources including nurses, scientists, clinicians and biostatisticians. This diversity leads to a slow, ad hoc process where progress depends on completion of tasks by individuals in a sequence of events that leads to dispersion and lack of control over information. A strong collaborative research information technology platform that securely integrates biospecimen, clinical, laboratory analysis and molecular data is needed to accelerate translational research (Figure 2). This poses several problems as each aspect of the translational research process utilizes different platforms which do not normally communicate with each other and which have their own individual issues and considerations.

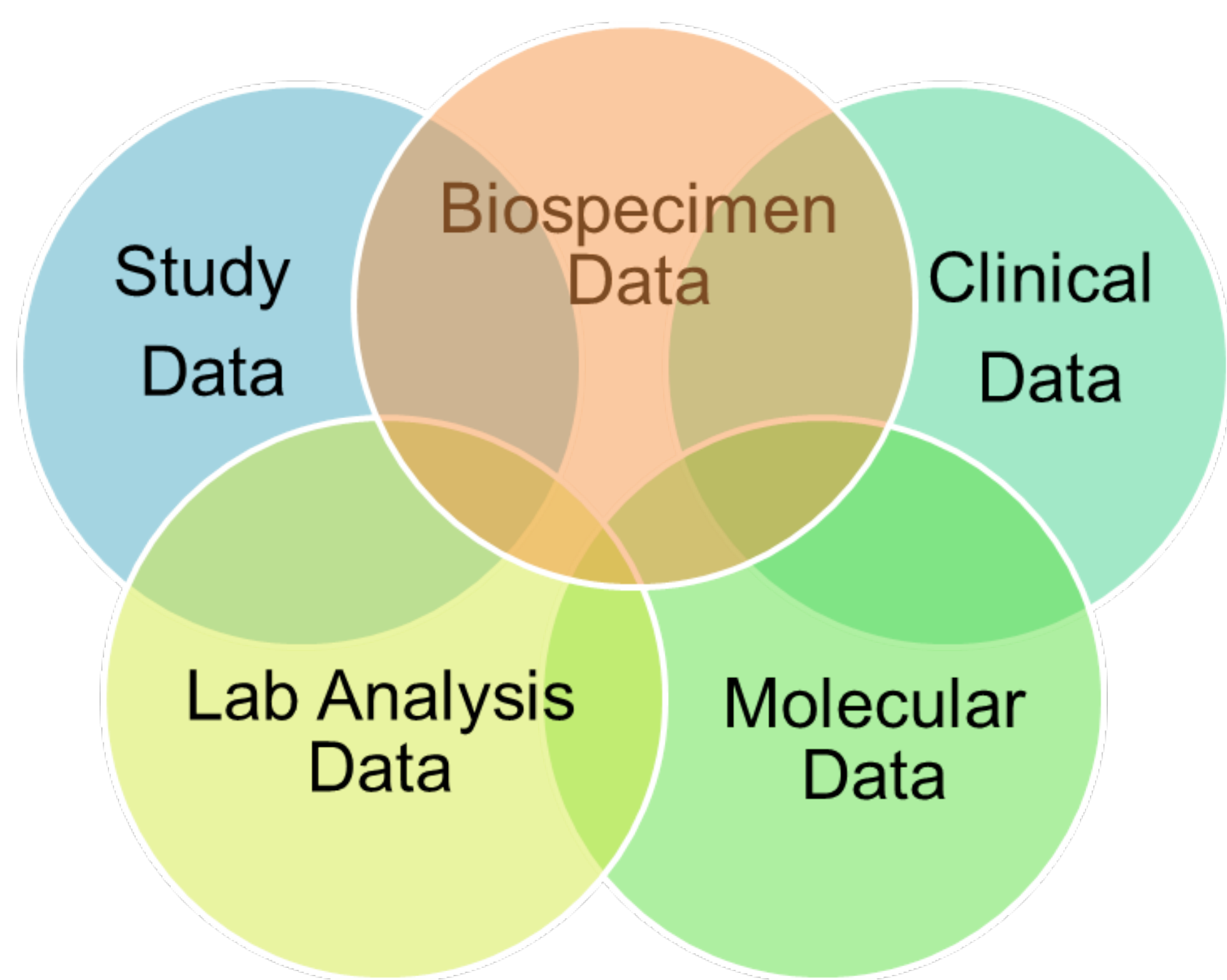


Figure 2. Integration of biospecimen, clinical, laboratory analysis, molecular and study administrative data

Solution

Utilizing the latest cutting edge technology (Microsoft Silverlight, Entity Framework, Apache Lucene) we have developed a web-based software application that integrates clinical and laboratory data: BIMS (Biobank Integration Management System) is a secure, user friendly, web-based application that allows for one-stop analysis and administration of translational research data (Figure 3).

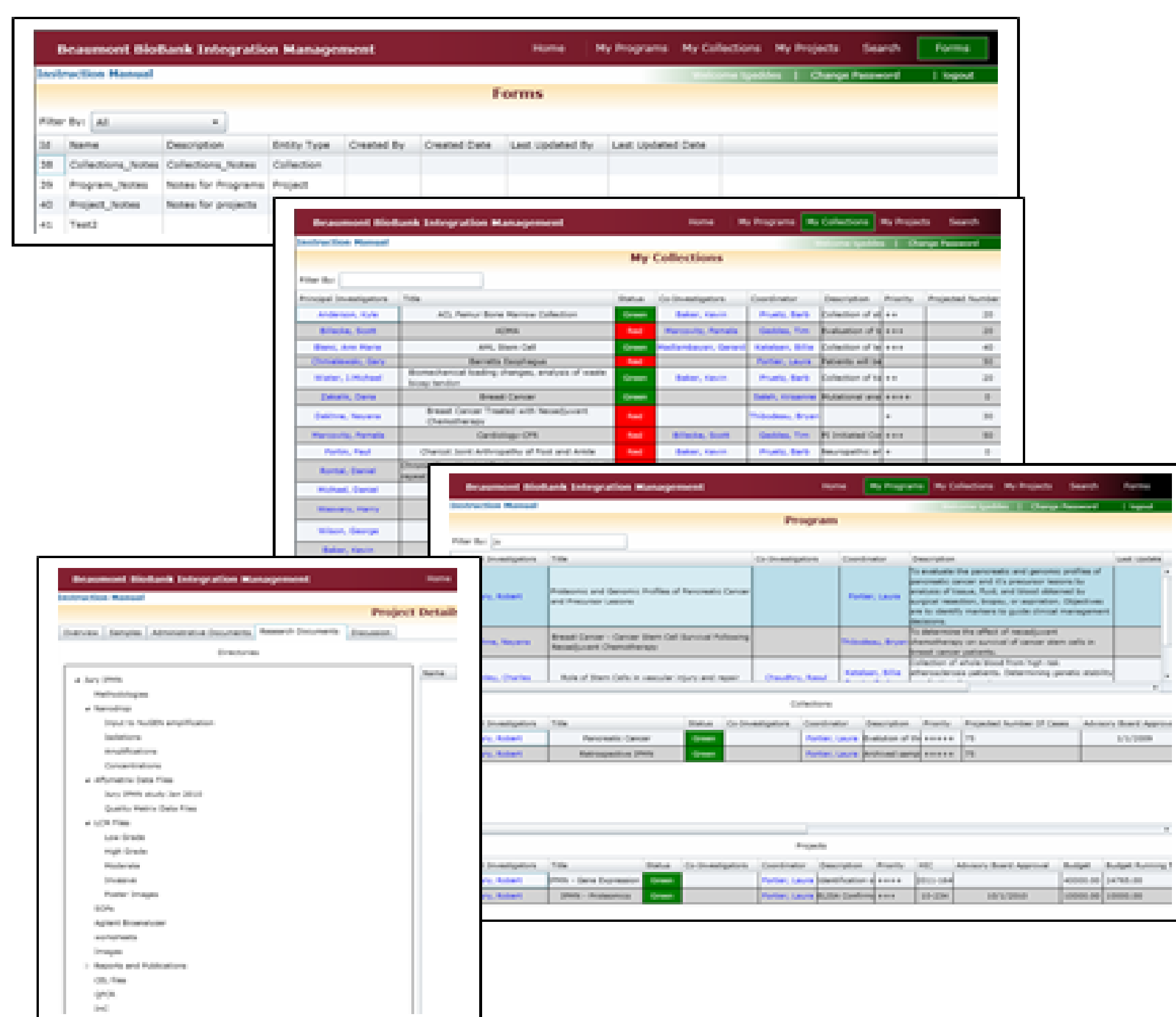


Figure 3. Sample screen shots of BIMS

Architecture

BIMS Web Application acts as the integration and administration hub for the research platform. Collaboration tools such as discussion board, notes and forms are available for researchers for each study. The BIMS system handles the role-based authorization and functionality for the diverse group of users of the system.

Study Database is the repository that stores study information, users, and all the laboratory analysis data such as Affymetrix gene expression files, SELDI-MS, microscopy, immunohistochemistry, and lab notebook entries.

Biospecimen Repository is the system that manages all the donor samples and barcodes for the Biobank. For our reference version we are using a commercial tool called BIGR from Healthcare IT; however, other biospecimen repositories could be used (such as caTissue).

Clinical Electronic Data Capture System stores all the clinical parameters for the patients involved with the studies. Specifically, our implementation uses an in house developed tool called Crossbreak.

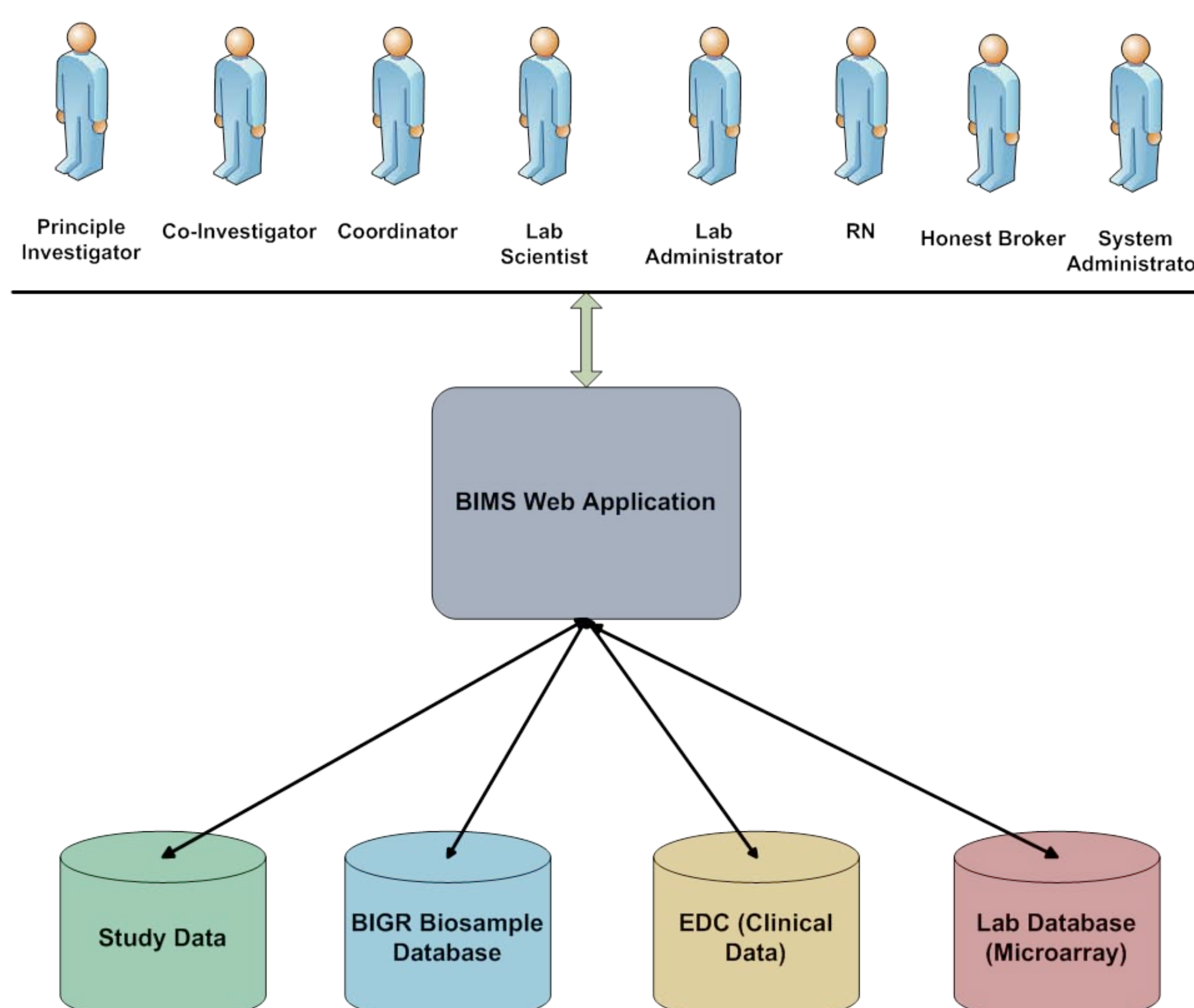


Figure 3. High Level BIMS System Interaction

Technology

Silverlight is a cross-browser, cross-platform plug-in for delivering media and rich interactive applications (RIAs) for the Web. This shows consistent look and feel when running BIMS from multiple browsers (Mozilla Firefox, Apple's Safari and Windows IE) and running on multiple operating systems (Macintosh or Windows).

Entity Framework is an object-relational mapping (ORM) framework for the .NET Framework that addresses the impedance mismatch between object-oriented programming and data storage. This essentially turns data sources into programmable ‘objects’ enhancing and streamlining the software development process.

Lucene.NET is a full-text information retrieval (IR) library written in the .NET programming language. Lucene allows developers to implement advanced searching capabilities, from multiple data sources (Figure 4). This technology allows researchers using BIMS to granularly search Beaumont Biobank's tissue database for specific samples.

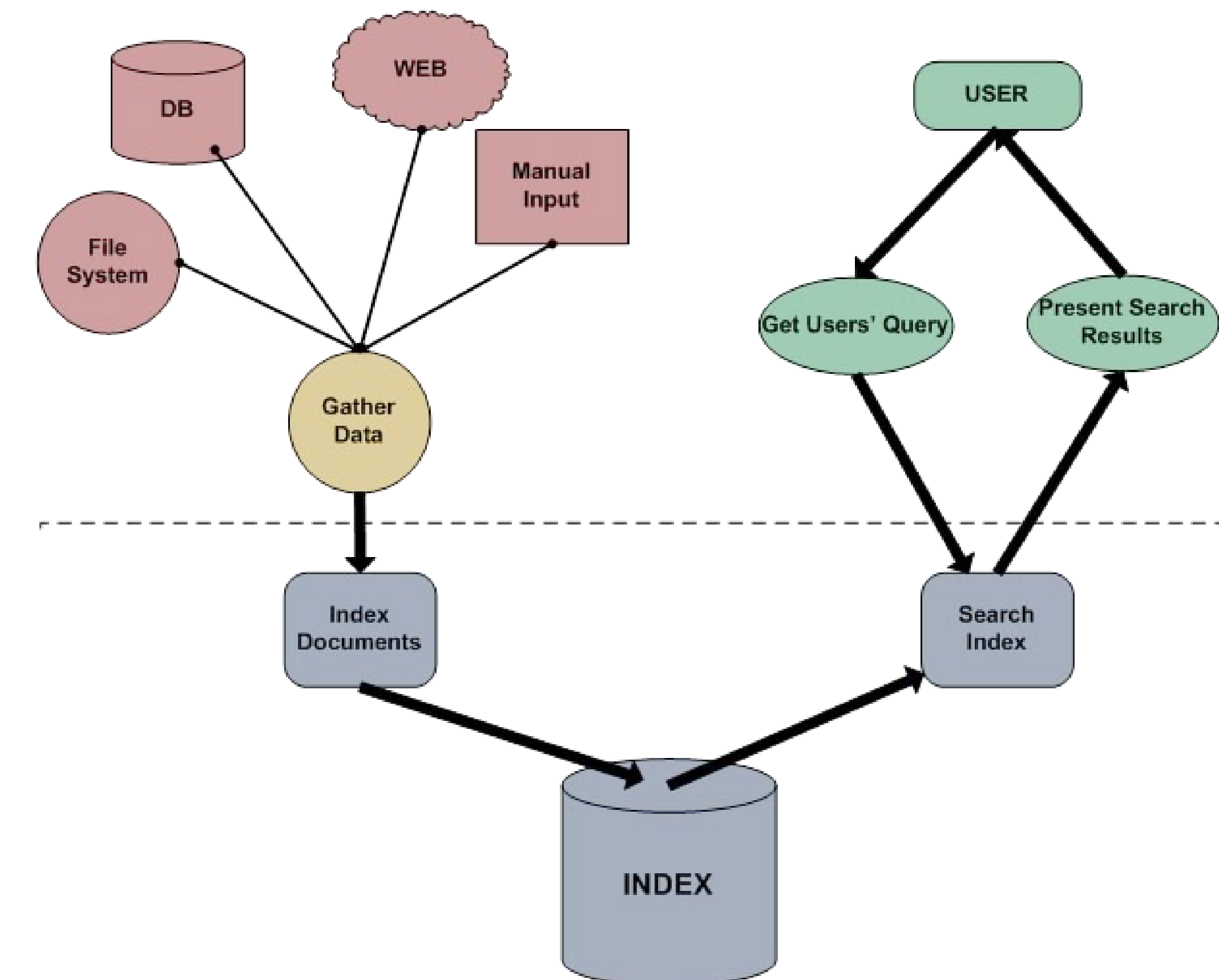


Figure 4. Lucene diagram showing the indexing process from multiple data sources (left) and subsequent user querying process (right)

Compliance

BIMS ensures HIPAA / FDA compliance by following the **AAA** Protocol:

Authentication refers to the process where a user's identity is authenticated when logging into BIMS. This is carried out by enforcing strong passwords (eight or more characters, with mandatory capital letter/digit/special character combinations), mandatory password updates every 90 days, and session limits (session inactivity for more than 20 minutes and the user is logged out).

Authorization refers to the amount of access and functionality, inside BIMS, a user has at their disposal once they are authenticated. Each respective user is assigned one or more roles based on their involvement with BIMS projects thus limiting their access to what is only pertinent to their assignment.

Accounting refers to an electronic audit trail of user activity over the course of their session in BIMS. What data points a users sees and any action taken on that data (Select/Create/Update/Delete) is stored in an audit trail table with the user's credentials and a timestamp.

Significance

BIMS allows researchers a one-stop safe and secure environment with which to search, retrieve, analyze and administer multiple data sources, as well as administer projects and facilitate real time communication. BIMS offers clinicians and researchers a streamlined process for collaborating on everything from research ideas to transcript writing, and grant applications – bringing research from bench to bedside with the ultimate goal of increased patient care.