BINF 8211/6211
Design and Implementation of Bioinformatics Databases
Lecture #24

Dr. D. Andrew Carr
Dept. Bioinformatics and Genomics UNCC
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Presentation Dates

April 19th

- 8, Danny Freese

- April 21th
  - 12, Kebba Mbye
  - 1, Carrie Barlow
  - 6, Matthew Deitz
  - 5, Molly Crowder
- April 26th
  - 14, Seyed Nader Nazami
  - 3, Shelvasha Burkes
  - 4, John Cashere
  - 9, Samantha Kaiser
  - 13, Sasan Najar
- April 28th
  - 16, Aarthi Sriram
  - 18, Lei Xu
  - 10, Amoolya Maddali
  - 17, Aneeta Uppal
- May 3rd
  - 11, Shelby Matlock
  - 15, Tyler Robbins
  - 7, Heena Desai
  - 2, Brandon Burciaga

LIMS Introduction

- Laboratory information management system
  - Tracking database
    - Data
    - Workflow
  - Similar to business keeps inventory
  - Need flexible architecture.
  - Data exchange with multiple environments.
- Also include
  - Electronic Laboratory Notebook
  - Data mining
  - Data analysis
- Challenge?
  - Why are LIMS so hard to create?

What is a LIMS?

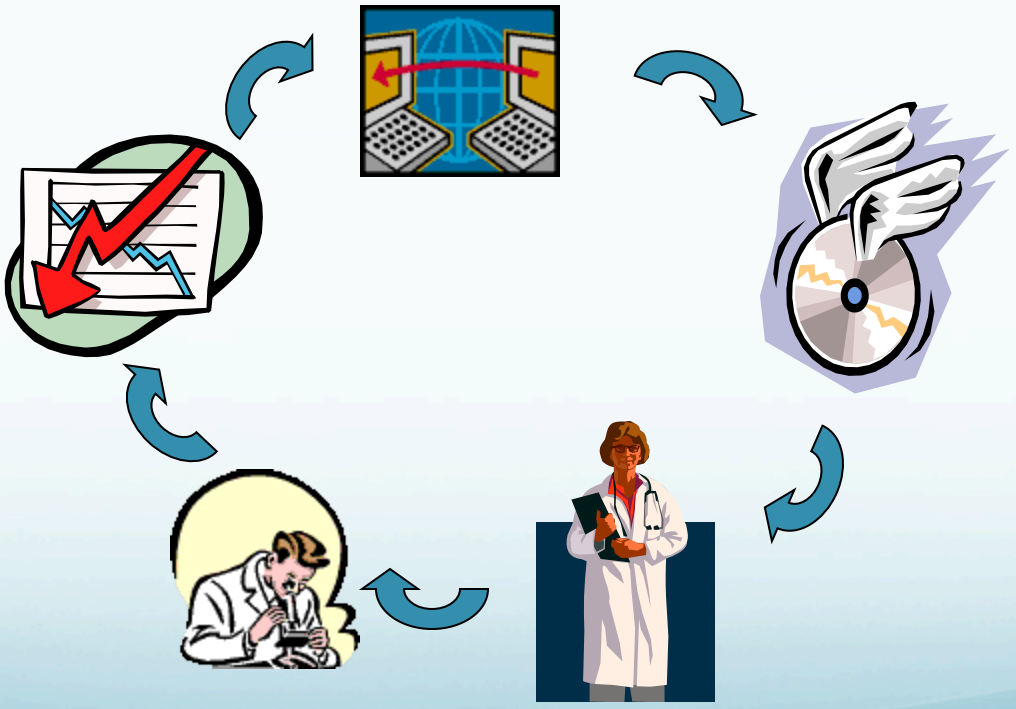
- Laboratory Information Management System
  - Computerized information tracking
    - Manages lab data from sample log-in to reporting
    - Interfaces with analytical instruments
    - Sorts and organizes data into various report formats
    - Stores data for future reference and use

    - LIS
    - Laboratory Information System
      - Biomedical

Rationale for LIMS

hardware, software, people, procedures

and data



www.GlobalHealthLaboratories.org

Roles of LIMS Systems

- To manage
  - Data
    - Sample → aliqout
    - Chain of Custody
  - Work flow
  - Changing business needs/processes
    - Inventory
  - Existing systems and improving where required
  - Resources
  - QA/QC

Why have a LIMS?

- Improve data management in lab to increase lab potential
- Enable centralization of information
- Support and enhance business processes of the lab
- Take advantage of new lab information technology
- Provide easy access to data
- Chain of custody
- Standardization of method

Functions of LIMS

- Track specimens from receipt, processing, testing, reporting to storage
  - Sample processing
  - Scheduling
  - Error monitoring
  - Report generation
- Personnel Tracking
- Equipment Tracking
- QC and Chain of Custody
- Business operations
  - Quotes and Billing

LIMS acquisition decisions

- Type of lab
  - Reference/research/public health
  - Clinical
  - Quality Control
  - Hybrid
- Volume of samples
- Types and number of tests
- Size of staff/users
- Existing system
  - Determine which areas will be affected
- Requirements and expectations
  - Avoid ‘culture shock’

Advantages of LIMS Use

- Fewer transcription errors & faster processing with direct instrument uploads
- Real time control of data quality with built in QC criteria
- Direct report generation meeting specific client requirements
- Direct electronic reporting to clients or direct client access to data

Disadvantages/Concerns/Challenges

- Customization of LIMS/interfaces required for specific lab/client needs
- Flexibility – Adaptation of system to future needs
  - Protocols and methods change
- Adequate validation to ensure data quality
- Data integrity and confidentiality, especially when clients have direct access to data
- Limited interface between lab & field computer systems

LIMS Benefits

- It improves the efficiency hence productivity.
- Improve data quality (all instrument are integrated).
- Saves time because the information centralized
  - Improve level of data access
  - Automation
    - reports (TAT, Work Load)
    - Warning
    - Ordering
    - Quoting

LIMS Types

- Frameworks
  - Schema and API
  - No standard tools
- Consolidated Single product
  - Thick and Thin Client
  - Web based

Regulatory Requirements

- ISO 9000
  - Management must define, implement, communicate and maintain quality objectives and assign personnel at all levels of the organization to be responsible for verifying the company's quality system
  - Primarily effect manufacturing laboratories
- ISO 25
  - Establishes labs technical competence
- GALP (Good Automated Laboratory Practices)
  - Union of federal regulations, policies, and guidance documents establishing a uniform set of procedures to ensure the reliability and credibility of laboratory data (EPA)
- 21 CFR 11 (1997)
  - Electronic signatures, Electronic records