

Using Inclusion/Exclusion Criteria to Retrieve BioSpecimens

eSphere: Integrating Clinical, Research, Regulatory, Administrative, BioSpecimen, Case Coordination

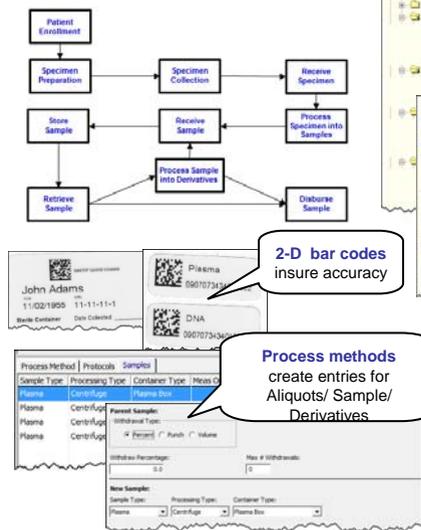


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Increase Quality and Quantity of Specimens/Samples

- Follow best practices



System generated unique ID / bar code

Specimen collection Scan bar code to verify subject/specimen

Receive Specimen in Lab Scan bar code to verify subject/specimen

Produce Wish Lists

- Filter Data / Use Rules Engine

- ✓ History
- ✓ Physical exam
- ✓ Questionnaires
- ✓ Events
- ✓ Lab results / assays
- ✓ Diagnosis
- ✓ Problem lists

- Inclusion / Exclusion criteria

Investigator defined criteria

Wizards guide creation of wish list

Annotate Specimen

- Merge subject data and specimen data

- ✓ History
- ✓ Physical exam
- ✓ Questionnaires
- ✓ Events
- ✓ Lab results / assays
- ✓ Diagnosis
- ✓ Problem lists

User defined normal values identify problems

Leading Edge Technology

- Interfaces

- ✓ HL7 interfaces
 - Demographics
 - Allergies
 - Clinical Data
- ✓ CRIS interfaces
- ✓ Lab results
- ✓ Biomedical device data

- System Platform

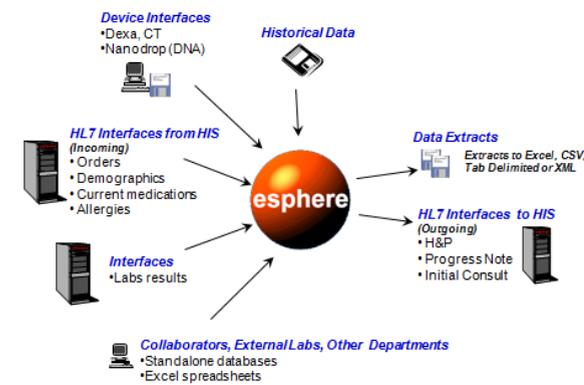
- ✓ Oracle database
- ✓ Citrix server / Windows or Mac
- ✓ Web-enabled

- Architecture

- ✓ Object oriented technology
- ✓ Three tier design
- ✓ Data warehouse

- Migrate manual / inefficient processes to best practices

- ✓ From manual / spreadsheet logs to computerized inventory
- ✓ From manual written labels to bar codes
- ✓ From manual searches that take days/weeks to searches based on rules that takes minutes
- ✓ From browsing freezers to browsing in computer
- ✓ From single user system to multi-user system
- ✓ From error prone process to fail safe verifiable process - computerized audits
- ✓ From poorly documented specimens to standardized annotation



Clinical Research Data Management