Research Informatics

Lab Samples and Tracking

Patrick Murphy
Director, Research Informatics
Family Health International
DMID/ICSSC

Family Health International

International Clinical Sciences Support Center

Laboratory Samples

- Lab sample results may be the most important outcome in many of your studies.
- The Data Manager needs to have detailed plans for tracking the collection, transfer, and results of lab samples.
- These plans should be finalized in advance. The best way to make this happen is to include it in the DM plan, which should be approved before your study starts.

LIMS

- Laboratory Information Management System
- Software that is used in the laboratory for the management of samples, laboratory users, instruments, standards and other laboratory functions.
- There are many on the market, including many from small businesses or groups that have created their own and are now selling their system.

Basics of Tracking

- The most common method is to track with bar codes and bar code readers.
- Bar codes can be 2-dimensional or 3-dimensional.
- Scanners can also print out labels.

Basics of Tracking

* 2 dimensional
* 3 dimensional
* Waterproof
* Low temperature resistant

Advanced models can:
* Accept user input
* Print labels

Bar Code Data

- **Bar codes contain information, but what information?**
- **Typical data to track:**
  - Participant number/Site number
  - Date/time of collection
  - Sample type
  - Sample tracking number

Step One: Flow Chart

- **Use a flow chart to identify which steps of your lab sample lifecycle need to be tracked**
  - Point of collection
  - Transfer to lab
  - Receipt at lab
  - Results received back from lab
  - Results included in database

Step two- Assign Responsibilities

- **Site Staff**
  - Enroll participants weekly by end of day Friday
  - Enter actual ship date for kits shipped that week
  - Check whether GC/CT swab included
- **Lab Staff**
  - Document receipt of specimens by end of day Friday
  - Can enter comments
  - Can check if participant agreed to have samples stored for future use
- **Site Staff**
  - Document kits that are no longer expected
  - Change status of participant when discontinue study or complete study

Step three – What do you do with the data?

- Bar code tracking data must be stored and reported upon to be useful
- Centralized databases on web servers
- Databases on PCs that are synchronized periodically
- Query sites regarding missing samples

Research Informatics

Overdue Report Print

Overdue Report / BRAVO_9932

Center: 1001 Reference Date: 06-20-2008

Participant ID	Period	Mailed Date	Overdue Date	Test Kit	
				BVS	GC
11032	4	05-02-2008	05-16-2008	OD	OD
11034	2	01-01-2008	01-15-2008	OD	OD
11099	2	02-04-2008	02-18-2008	OD	OD
11099	4	03-04-2008	03-18-2008	OD	OD
11111	2	01-31-2008	02-14-2008	OD	NE

Rec=Received OD=Overdue NE=Not Expected

Example System (1)

- Blood sample taken from participant and placed in tube
- Enter participant number, sample type into scanner/printer
- Scanner automatically adds tracking number and date/time to the database record and to the label
- Print the label and affix to sample
- Print duplicate label and place on paper tracking sheet/CRF (optional)
- Scan tube as it leaves your facility

Example System (2)

- **Blood sample received at lab, scanned into database**
- **Blood sample analyzed and results stored on:**
  - Paper CRF with results (affix copy of label)
  - Electronic database that can be merged with clinical database
- **Paper CRF results entered into clinical database**

OR

- **Electronic database converted to format you can compare to the clinical database**

Example System (3)

- **Compare tracking information in database to results**
  - Either the initial tracking database or a lab tracking CRF
  - Are there any samples missing?
- **Generate queries if there are sample mismatches**

Research Informatics

How to Create System

- **Most systems will be highly customized**
- **Dependent on your constraints**
  - Web database
  - PC database
  - Type of scanners
  - Environment (humidity)
- **Validation plan**

Research Informatics

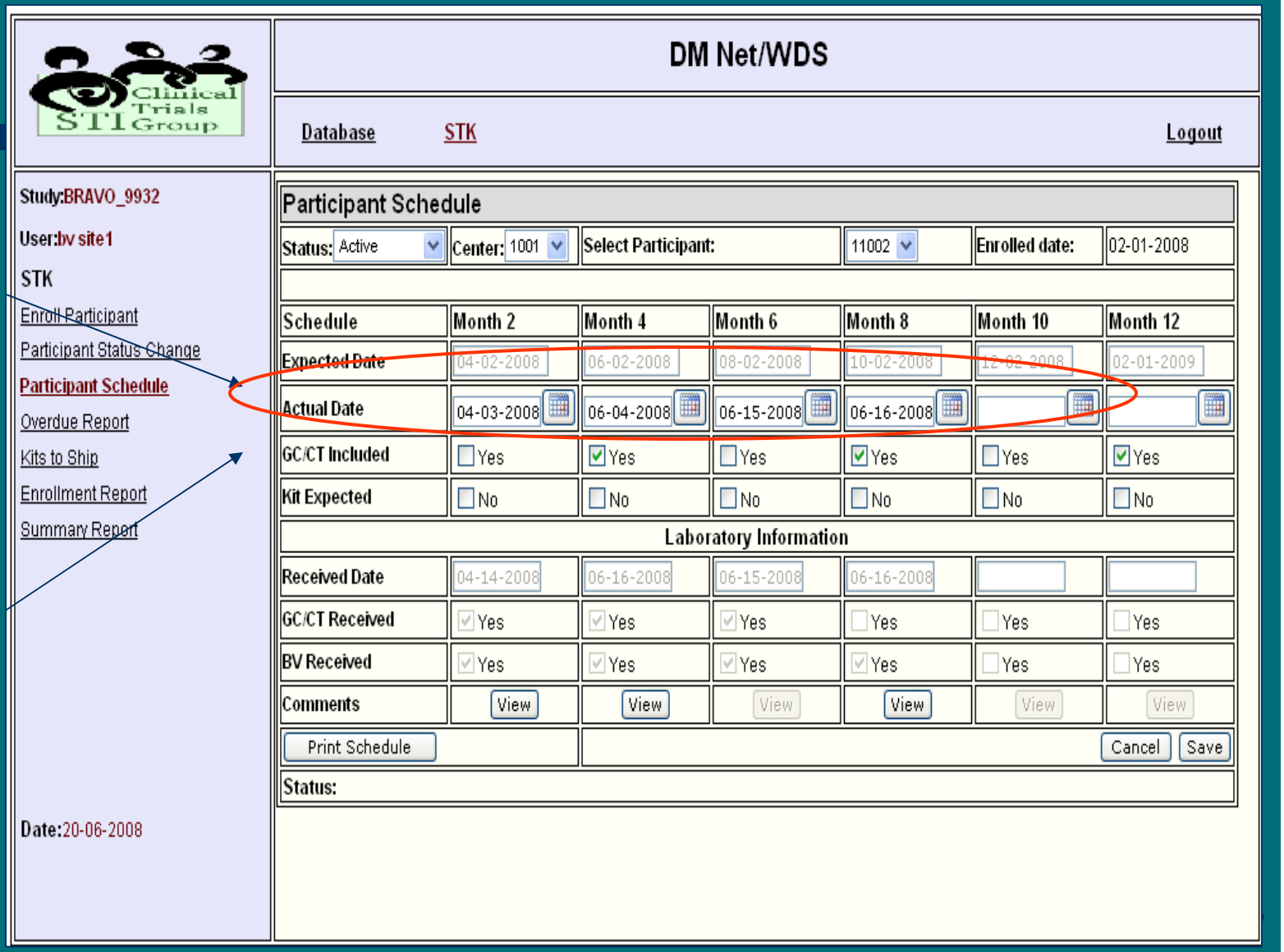
Additional Requirements

- **21 CFR Part 11 compliant**
- **Reports**
  - Samples obtained
  - Shipped to lab
  - Returned from lab
  - Results integrated into clinical database

Research Informatics

Site enters Actual Date Shipped

Site enters if GC/CT included



Family Health International

ICSSC International Clinical Sciences Support Center

Conclusions

- Systems should be in place to track collected lab samples
- Process should be set up for data transfer from lab to data center. Ensure that participant confidentiality is not compromised.
- Need personnel in charge at each step of the process
- All steps and responsibilities should be documented in the DM plan.