

## Managing Biospecimens & Biorepositories

## Biospecimen Management

### The Problem

In the context of clinical research centers, the nature of biospecimen management is considerably more complex than the prospective banking of discarded tissues. There are several additional requirements and challenges. These challenges include accommodating access to biorepository inventories and associated clinical and analytical data by a large organization of people while protecting the donors' privacy and complying with HIPAA regulations. Additionally, the quality of each specimen as well as the quality of the clinical and analytical data linked to it, throughout the lifecycle the specimen and all of its derivatives must be assured.

### The Solution

Responding to the challenge and complexity of biospecimen data management, PercipEnz collaborated with three nationally recognized, clinical research centers in the development of a feature-rich biospecimen management system.

Leveraging PercipEnz's experience and OnCore's core functionality in the area of clinical trial management, OnCore supports all aspects of biospecimen and biorepository management from scheduling, collection and annotation, through specimen processing, storage, quality assurance and requisition to withdrawal, distribution, and depletion. It is a web-based system that includes support for key workflow, specimen-centric data storage, and access controls based on patient consent and researcher intent. It has been architected to support logically centralized but physically distributed specimen collection and banking, it is fully integrated with the OnCore clinical trials management system, and supports both prospective banking as well as correlative studies.

OnCore has been developed in accordance with the published NCI caBIG™ compatibility guidelines<sup>1</sup> and the relevant portions of the Office of Biorepositories and Biospecimen Research guidelines<sup>2</sup>.

### Specimen and Donor Data Collection

OnCore supports de-identified specimen banking with only specimen registration, full donor registration, and automatic linking to registration data for donors that are already subjects in the OnCore clinical trials management system. Upon specimen collection, the workflow-based interface enforces capture of donor consent along with donor demographics and relevant diagnoses — data which is tracked throughout the lifecycle of the specimen and its derivatives. Registering a specimen entails entering only a minimal data set including specimen type, body site, specimen quantity, and, optionally, attaching diagnostic reports and images. Extensible annotations allow collecting additional specimen information in accordance with changing research needs.

### Processing, Annotation, Request and Distribution

Accessible through a web-based interface, OnCore makes it easy to maintain control of the data while providing an appropriate level of access to information for a distributed group of people. Comprehensive search and *ad hoc* reporting features provide a flexible specimen reporting capability with a means of automatically creating a Working List of specimens to be processed. The Working List feature, in conjunction with integrated barcode printing and scanning capabilities, makes reserving, labeling, checking-in, checking-out, and shipping specimens efficient and intuitive.



### Key Capabilities

- Specialized specimen handling for prospective banking as well as correlative studies
- Collection schedules driven by subject calendars
- Patient consent, registration, and withdrawal tracking
- Working Lists to simplify routine tasks on groups of specimens
- Barcode printing and scanning for specimen tracking
- Specimen history tracking including chain of custody
- Extensible specimen annotations
- Web-based access for on-site and off-site users

With OnCore®, investigators and repository administrators have access to nearly real-time specimen status, location, and inventory information. A complete status history is maintained for every specimen and its derivatives.

Protocol management and tracking is supported for both prospective banking as well as correlative studies.

### Security, Administration and Reporting

The foundation of the security and access controls in OnCore is the Model Based Access Control technology that has been proven over the last few years at numerous clinical research centers. This has been extended to provide a detailed representation of patient consent, access requests and institutional policies concerning Protected Health Information (PHI), intellectual property, and institutional approvals for specimen requests. Thus, the system will support robust security and access control mechanisms sufficient to comply with both regulatory requirements such as HIPAA as well as institutional policies.

In addition to the *ad hoc* reporting capabilities noted previously, there are standard inventory reports with breakdowns by specimen type, storage unit, location, protocol, or other characteristics. Transaction reports can also be obtained as well as performance reports compliant with the NCI recommendations for specimen resources<sup>3</sup> (e.g., the number of specimens provided to researchers, specimen types available and requested, etc.).

For in-depth analysis, institution-specific custom reports are available via integration with the third-party report engine technology, JasperReports. These reports can be loaded into the system to be produced as needed in HTML, PDF, Excel, CSV, and RTF file formats.

### Storage Location and Inventory Management

Storing, and later locating, specimens is made simple by comprehensive storage device management features including inventory management and reporting. In addition to storage location and description, OnCore defines and tracks the operational characteristics of storage devices including capacity, structure, and status. Storage can be pre-allocated and associated with a specific study. Groups of storage locations can be moved *en masse*, e.g., moving a box from one shelf to another or moving a freezer from one room to another room in another building to keep a group of specimens co-located.

### Key Benefits

- Unified biorepository management for distributed environments.
- Comprehensive specimen and data quality management.
- Fully integrated clinical data management when used with the OnCore clinical trials management system.
- Simple yet flexible specimen searching and ad hoc reporting.
- Compatibility with appropriate guidelines, regulations, and standards including HIPAA, Common Rule, OBRR, and caBIG.

<sup>1</sup> caBIG™ Compatibility Guidelines Revision 2, July 2005.

<sup>2</sup> First-Generation Guidelines for NCI-Supported Biorepositories, Office of Biorepositories and Biospecimen Research, December 2005.

<sup>3</sup> How to Establish and Manage A Tissue Bank or Other Specimen Resource, the NCI Cancer Diagnosis Program.