Use of OpenSpecimen for the NCI’s NCTN Alliance Biorepositories and Biospecimen Resource

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Dir., Alliance Biorepositories and Biospecimen Resource
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Quantitative Collection Metrics (2021)

62  clinical trials supported
5,003  participants
9,020  procurement kits
681  sites
39  trials

28,415  biospecimens received
97.8%  biospecimens received ‘Adequate’
0.5%  Thawed
1.1%  Delayed shipment

17,691  biospecimens distributed
22  Source trials
21  Investigators (integrated and secondary use)
37  manuscripts and abstracts
Unique Requirements

• **BIOREPOsITORies**
  ▪ Federated system of *five* biorepositories at *four* institutions
  ▪ Each facility has its own institutional biorepository and informatics system
  ▪ Concerns about IT security and data transfer between institutions and systems

• **CINICAL SITES**
  ▪ Hundreds of sites collecting and shipping biospecimens, nationally and globally
  ▪ Complex user / institution provisioning
  ▪ Limited training, tenure, expertise, prioritization, and time for clinical staff
  ▪ Sites are rated based on submission compliance and biospecimen adequacy
Unique Requirements

• TRIALS
  ▪ 50-70 trials active at one time, each with their own unique biospecimen requirements and collection schedule
  ▪ Many trials / collections require use of specialized collection kits
  ▪ Many collections are mandatory and follow a pre-specified collection calendar; many do not.
  ▪ Regular reporting of trial biospecimen collection and QA required for many different stakeholders
  ▪ Remnant trial collections are uploaded into NCTN Biospecimen Navigator to be made available to the broader scientific community using standardized data vocabularies across NCTN groups.
The Solution

- Multiple instances of OpenSpecimen to support different stakeholder requirements
- Secure data transfer between instances via API and a common data model
- Alliance **BioMS** user interface (now 10 years old):
  - Uses OpenSpecimen data model / DB layer
  - NCI CTEP-based user authentication and provisioning
  - Receipt of registration messages from external CTMS
  - Simple and friendly user interface for recording planned biospecimen collections and shipments, with abundant tool tips
  - Kit request / ordering and tracking functionality (integration with FedEx pending)
  - Automated emails to sites about receipt quality and (overdue reminders).
- Integration across all biorepositories and assay labs
- Conduit for loading biospecimen inventory into NCTN Navigator
BioMS- Participant Look Up

Search by patient, specimen, or shipment

Search by registration ID or patient initials, based on patients at your institution

Patient enrolled on main trial and companion studies
BioMS- Collection Event

Required specimen collections, grouped by study calendar times

Further groupings based on collection time points and study arms
BioMS- Specimen Collection

Equivalent specimen requirements across companion protocols are noted.

Mark specimens as not collected or recollected.

Complete form questions associated with a specimen.

Add collected specimens to a shipment.

Indicate specimen collected, collection date, and quantity.
BioMS- Shipment Creation

- Search for collected specimens based on destination repository, patient, or trial
- Assign specimens to shipments manually or automatically based on shipping conditions and destination
- Collected specimens ready for shipment
- Create and view shipments based on shipping conditions and destination biorepository
- Mark a shipment as sent
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<tr>
<th>SAMPLE_ID</th>
<th>PATIENT_ID</th>
<th>STUDY_ID</th>
<th>TIME_PERIOD</th>
<th>SPECIMEN_EXPECTED</th>
<th>COLLECTION_DATE</th>
<th>SHIPPED_BY</th>
<th>SHIPPED_DATE</th>
<th>SHIPMENT_ID</th>
<th>CARRIER_NAME</th>
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Dear BioMS User,

NOTE: PLEASE DO NOT REPLY TO THIS EMAIL. This is an automated email from the BioMS application. Please note that in most cases, this email notification is only for your informational purpose and no actions are required.

**Shipment #** has been received at the **Alliance Biorepository at Washington University in St. Louis**. The received quality status for all specimens in the shipment are indicated below. If there are problematic specimens, then the detailed reasons are given below. Please review the specimen status in the BioMS application check-list view or contact the biorepository for further instructions if necessary. If you would like to review patient/specified details, then login to BioMS application first and then click on the specimen URL given below.

<table>
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<tr>
<th>Specimen expected</th>
<th>EDTA Buffy Coat (2x1ml)</th>
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<tr>
<td>Collection date</td>
<td>:</td>
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<tr>
<td>Study</td>
<td>: A031704-ST1</td>
</tr>
<tr>
<td>Epoch,Arm,Collection event</td>
<td>: On Therapy A031704-ST1, All, End of Study Treatment</td>
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<tr>
<td>Receive quality</td>
<td>: Acceptable</td>
</tr>
<tr>
<td>CRA action</td>
<td>: None.</td>
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</table>

<table>
<thead>
<tr>
<th>Specimen expected</th>
<th>EDTA Plasma (2x1ml)</th>
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<tr>
<td>Collection date</td>
<td>: 9</td>
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<tr>
<td>Study</td>
<td>: CALGB 150712</td>
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<tr>
<td>Epoch,Arm,Collection event</td>
<td>: Post Therapy 150712, All, 48 Month Follow-up</td>
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<tr>
<td>Receive quality</td>
<td>: Unacceptable-Thawed</td>
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<tr>
<td>CRA action</td>
<td>: Contact the appropriate protocol coordinator to determine if a replacement specimen can be recollected and submitted. Please ensure that all specimens are properly packaged with sufficient dry ice to avoid thawing.</td>
</tr>
</tbody>
</table>

If there are questions about the shipment or the specimens the repository can be contacted, contact details given below.
- **Contact Person**: Coordinator PCO
- **Contact Phone**: 614-
- **Contact Email**: path.calgb@osumc.edu

Thanks.
Conclusions

• The **Alliance Biorepositories and Biospecimen Resource** provides a prototype for a federated, multi-institutional biorepository network, united by a single informatics system (OpenSpecimen).

• We have used multiple instances of **OpenSpecimen** to satisfy unique functional and access requirements for multiple stakeholders.

• Data is transferred across systems by secure API using a common data model and vocabulary set.

• A novel UI (BioMS) has been created that is simplified and focused on the specific needs of clinical team stakeholders and provides critical functionality extended from basic OpenSpecimen functions (i.e. kit ordering, automated receipt and QA feedback).

• Continued use and end-user feedback over the past decade has resulted in refinements to functionality, usability, and system-to-system interoperability.