

# Use of OpenSpecimen for the NCI's NCTN 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

Whole Blood	13,077
Plasma	4,353
Fixed Tissue Slide	2,873
Serum	1,975
Fixed Tissue Block	1,815
Buffy Coat	1,329
Whole Bone Marrow	1,316
Urine	659
Feces	372
Fixed Tissue	253
Lavage	229
<b>Grand Total</b>	<b>28,415</b>

# 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

- **CLINICAL 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

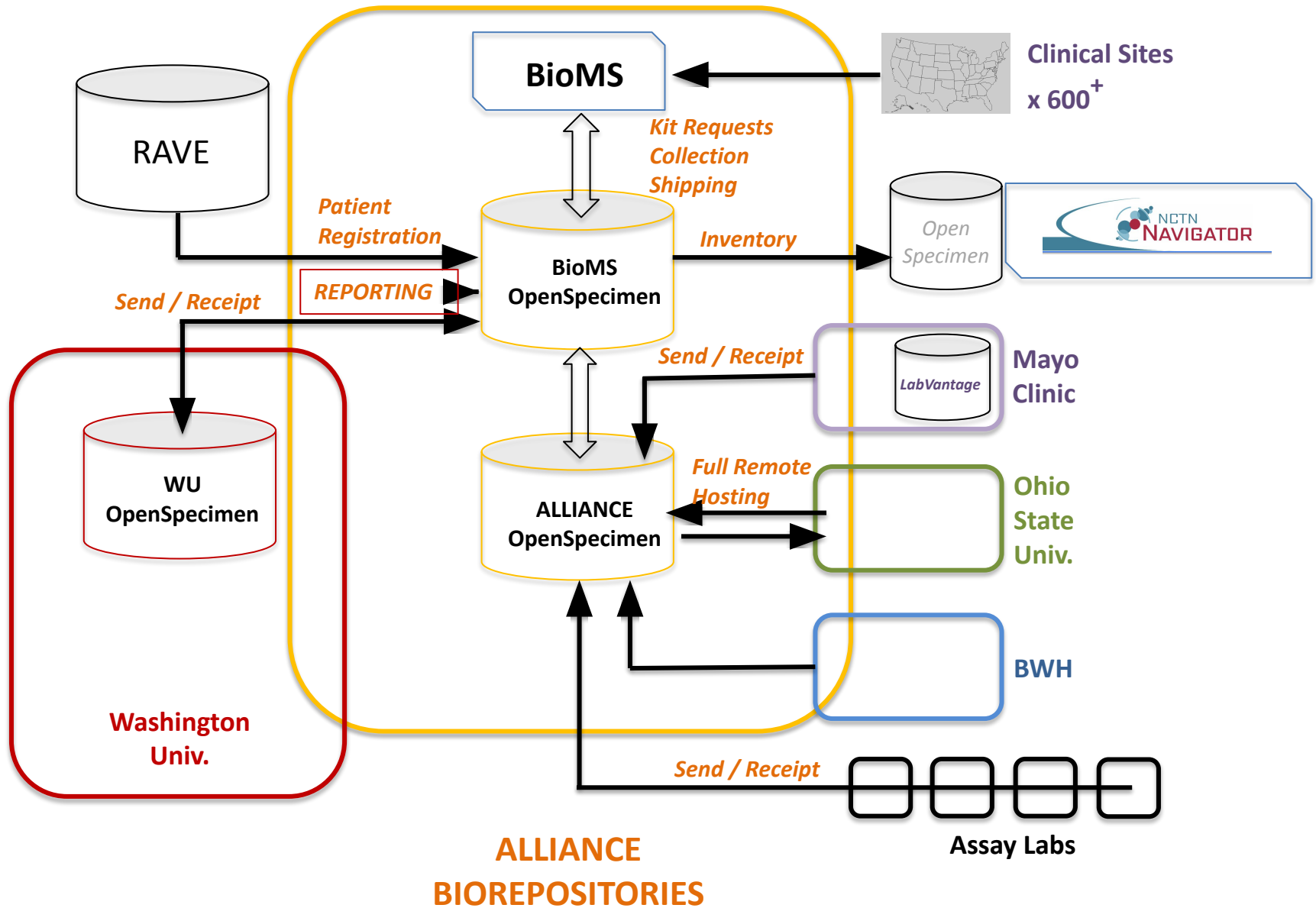
- **TRIALS**

- 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

# System Architecture



# BioMS- Participant Look Up

ALLIANCE BIOSPECIMEN MANAGEMENT SYSTEM

Logged into BMS as admin@bms.com

Logout Help

**TASKS**

- Build study
- Log specimens
- Manage shipments

**SEARCH**

- Patients
- Specimens
- Shipments

Search for a patient(s)  
Use the specimen units drop-down list below to select patient ID, name, gender, genotype or study ID. Next, type the search criteria. To search by patient ID for example, type the entire patient ID for quickest response, or type 496\* or 4967\* to find all patient IDs that start with those numbers. Finally, hit search.

**PATIENT SEARCH**

Registration ID  Search

**SEARCH RESULTS: 2 PATIENT(S) FOUND**

Patient initials	Registration ID	Study
D,V	100	10603, 8461, 9665
S	200	10603

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

Search by patient, specimen, or shipment

Patient enrolled on main trial and companion studies

# BioMS- Collection Event

Build study

Log specimens

Manage shipments

SEARCH



Patients

Specimens

Shipments

**SPECIMEN CHECKLIST FOR PATIENT 100 (D,V) FOR STUDY 10603**

Pre-Registration Remission Induction Therapy Remission Consolidation Therapy Continuation Therapy Remission Relapse

Collected	Study	Specimen expected	Quantity	Collection date	Status	Actions
<input checked="" type="checkbox"/>	10603	3ml Whole Blood (Green Top)	3.0 ml	06/21/2012 06:20	Collected	  
+ <input type="checkbox"/> Placebo : Cycle 1-Day 8						
+ <input type="checkbox"/> Midostaurin : Cycle 1-Day 21						
+ <input type="checkbox"/> Placebo : Cycle 1-Day 21						
+ <input type="checkbox"/> Midostaurin : Cycle 2-Day 24						
+ <input type="checkbox"/> Placebo : Cycle 2-Day 24						

Save Add to shipments

Required specimen collections, grouped by study calendar times

Further groupings based on collection time points and study arms



# BioMS- Specimen Collection

ALLIANCE BIOSPECIMEN MANAGEMENT SYSTEM

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### Specimen Preparation and Shipping Instructions

5 ml Bone Marrow Aspirate (Green Top)

Specimen Class :Fluid  
Tissue Site : Not Specified  
Tissue Side : Not Specified  
Expected Volume : 5.0 ml  
Expected Tube Type :

#### Specimen Preparation Instructions

Draw bone marrow aspirate in a green top tube (heparinized). Label the tube with the patients CALGB patient ID number, sample collection period (prior to initiation of treatment, remission or relapse etc.), the date of collection and the source of the material (i.e. bone marrow). Samples should be packaged to prevent breakage.

#### Shipping Instructions









Samples must be shipped on the same day they are obtained. Send the samples at room temperature, any day of the week, via overnight carrier for next day (check AM) delivery to the CALGB LTB. If samples are sent on Friday, check Saturday delivery on the overnight carrier invoice. If holiday schedules prevent same day shipment, please contact the LTB at 614-292-5888 for sample shipment instructions.

collected, click on the ... men, click on the Note icon.

Add collected specimens to a shipment

Add to shipments

Therapy Continuation Therapy Remission Relapse

Quantity	Collection date	Status	Actions
0.0 ml	06/21/2012		 
0.0 gm		Nat-Collected	 
0.0 gm		Pending	 
<input checked="" type="checkbox"/>	10603	2 Bone Marrow Biopsy Sections (for Immuno)	2.0 gm 06/21/2012 06:06 14 Collected  

Mark specimens as not collected or recollected

Complete form questions associated with a specimen

Indicate specimen collected, collection date, and quantity

# BioMS- Shipment Creation

**ALLIANCE BIOSPECIMEN MANAGEMENT SYSTEM**  
Logged into BMS as admin@bms.com | Logout | Help

**TASKS**  
Build study  
Log specimens  
Manage shipments

**SEARCH**  
Patients  
Specimens  
Shipments

**Review Pending Shipments**  
Review the list of pending Shipments on the right side of the screen. To view the contents of a particular shipment, select it first by clicking on the round button, then click on the Packing Slip icon.

**SPECIMENS AND SHIPMENTS**  
WASHU Repository

**SPECIMENS FOR 100 (D,V) STUDY 10603**  
Last 30 days

ID	Specimen	Patient	Study
<input checked="" type="checkbox"/>	82	5 ml Bone Marrow Aspirate (Green Top)	100 (D,V) 10603
<input checked="" type="checkbox"/>	86	2 Bone Marrow Biopsy Sections (for immu	100 (D,V) 10603
<input checked="" type="checkbox"/>	102	3ml W (Gree	
<input type="checkbox"/>	103	5 ml E Aspirin Top)	
<input type="checkbox"/>	104	3ml W (Gree	
<input type="checkbox"/>	105	5 ml E Aspirin	
<input type="checkbox"/>	137	24ml Whole Blood (Green top)	100 (D,V) 9665
<input type="checkbox"/>	139	2 Buccal Swab	100 (D,V) 9665

**SHIPMENTS**  
Create shipment | Send shipment | Delete shipment

Shipment ID: 1012  
Ship to: WASHU Repository  
Ship method: Cold Pack  
Status: In Transit

ID	Specimen	Patient	Study
<input type="checkbox"/>	101	3ml Whole Blood (Green Top)	100 (D,V) 10603
<input type="checkbox"/>	138	5 ml Bone Marrow Aspirate (Green Top)	100 (D,V) 9665
<input type="checkbox"/>	142	20 ml Whole Blood (4 X 5ml Green Top)	100 (D,V) 8461
<input type="checkbox"/>	161	3ml Whole Blood (Green Top)	200 (J,S) 10603
<input type="checkbox"/>	164	3ml Whole Blood (Green Top)	200 (J,S) 10603

Shipment ID: 1011  
Ship to: WASHU Repository  
Ship method: Dry Ice Pack

**Annotations:**  
- Search for collected specimens based on destination repository, patient, or trial  
- Create and view shipments based on shipping conditions and destination biorepository  
- Mark a shipment as sent  
- Assign specimens to shipments manually or automatically based on shipping conditions and destination  
- Collected specimens ready for shipment

# BioMS- Shipment Manifest

Participant registration

Sync errors

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**TASKS**

Build study

Log specimens

Manage shipments

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**SEARCH**

Patients

Specimens

Shipments

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**QUESTIONS & FEEDBACK**

Contact Us

[BioMS Overview](#)

## PACKING SLIP FOR SHIPMENT 1923

Send shipment
Back



1923

<b>Shipment ID</b>	1923	<b>Status</b>	Not Shipped	
<b>Sender site *</b>	<input type="text" value="Please select"/>	<b>Receiver site</b>	PCO Repository	<b>Carrier *</b>
<b>From *</b>	<input type="text"/>	<b>To *</b>	2001 Polaris Parkway Columbus, Ohio 55905	<b>Tracking number</b>
<b>Sender contact</b>	<input type="text" value="Admin BMS"/>	<b>Receiver contact *</b>	<input type="text" value="Please select"/>	<b>Shipping date *</b>
<b>Phone *</b>	<input type="text"/>	<b>Phone *</b>	614-293-7073	<input type="text" value="14"/>

**CONTENTS**

Specimen ID	Specimen	Patient ID	Study ID	Epoch, Arm, CPE
1393	Heparin Plasma (2x1ml)	GU_30504 (G,U)	CALBG 30504	Post Therapy, All, Post Therapy (within 7 Days)

# BioMS- Incoming Shipment Notification

SAMPLE_ID	PATIENT_ID	STUDY#_TIMEPERIOD	SPECIMEN_EXPECTED	COLLECTION_DATE	SHIPPED_BY	SHIPPED_DATE	SHIPMENT_ID	CARRIER_NAME	TRACKING_NUMBER	STATUS
124388332	0141958	A021703_Consented to Biobanking_For Patient Consented to BioBankin	Fixed Tissue Slide	01/6/22 18:21	Well Medical Collections	01/6/22 0:00	126233682	FedEx	818587789081	In Transit
124388295	0141958	A021703_Consented to Biobanking_For Patient Consented to BioBankin	Fixed Tissue Slide	01/6/22 18:21	Well Medical Collections	01/6/22 0:00	126233682	FedEx	818587789081	In Transit
124388258	0141958	A021703_Consented to Biobanking_For Patient Consented to BioBankin	Fixed Tissue Slide	01/6/22 18:21	Well Medical Collections	01/6/22 0:00	126233682	FedEx	818587789081	In Transit
125085982	0141970	A021703_Consented to Biobanking_For Patient Consented to BioBankin	Fixed Tissue Slide	01/6/22 12:20	Well Medical Collections	01/6/22 0:00	126233682	FedEx	818587789081	In Transit
125085945	0141970	A021703_Consented to Biobanking_For Patient Consented to BioBankin	Fixed Tissue Slide	01/6/22 12:20	Well Medical Collections	01/6/22 0:00	126233682	FedEx	818587789081	In Transit
125085908	0141970	A021703_Consented to Biobanking_For Patient Consented to BioBankin	Fixed Tissue Slide	01/6/22 12:20	Well Medical Collections	01/6/22 0:00	126233682	FedEx	818587789081	In Transit
126248214	0141958	A212102_At Registration_All	Whole Blood	01/6/22 12:47	Stanford Regeneron	01/6/22 0:00	126251156	FedEx	777987848974	In Transit
126248160	0141958	A212102_At Registration_All	Whole Blood	01/6/22 12:47	Stanford Regeneron	01/6/22 0:00	126251156	FedEx	777987848974	In Transit
126248115	0141958	A212102_At Registration_All	Whole Blood	01/6/22 12:47	Stanford Regeneron	01/6/22 0:00	126251156	FedEx	777987848974	In Transit
126248065	0141958	A212102_At Registration_All	Whole Blood	01/6/22 12:47	Stanford Regeneron	01/6/22 0:00	126251156	FedEx	777987848974	In Transit
126248016	0141958	A212102_At Registration_All	Whole Blood	01/6/22 12:47	Stanford Regeneron	01/6/22 0:00	126251156	FedEx	777987848974	In Transit
126247963	0141958	A212102_At Registration_All	Whole Blood	01/6/22 12:47	Stanford Regeneron	01/6/22 0:00	126251156	FedEx	777987848974	In Transit

# BioMS- Receipt Acknowledgment

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 #                      shipped on                      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/specimen details, then login to BioMS application first and then click on the specimen URL given below.

Specimen expected                      : [EDTA Buffy Coat \(2x1ml\)](#)  
Collection date                      :  
Study                      : A031704-ST1  
Epoch,Arm,Collection event                      : On Therapy A031704-ST1,All,End of Study Treatment  
Receive quality                      : [Acceptable](#)  
CRA action                      : None.



Specimen expected                      : [3ml No Additive Serum \(3x1ml\)](#)  
Collection date                      :  
Study                      : A031704-ST1  
Epoch,Arm,Collection event                      : On Therapy A031704-ST1,All,End of Study Treatment  
Receive quality                      : [Acceptable](#)

Dear BioMS User,

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Shipment #                      shipped on                      /2022 has been received at the **Alliance Biorepository at Ohio State University**. 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/specimen details, then login to BioMS application first and then click on the specimen URL given below.

Specimen expected                      : [EDTA Plasma \(2x1ml\)](#)  
Collection date                      : 9  
Study                      : CALGB 150712  
Epoch,Arm,Collection event                      : Post Therapy 150712,All,48 Month Follow-up  
Receive quality                      : [Unacceptable-Thawed](#)  
CRA action                      : [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.](#)

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.