Westat SUPPORTING SPECIMEN ANNOTATION AND QUALITY **ASSESSMENTS THROUGH INFORMATION TECHNOLOGY TOOLS** <u>A. Varanasi¹, L. Mechanic¹, D. Carrick¹, C. Lawrence¹, K. Wilson², M. Kliesch², M. Harmon², C. Ray², J. Wernimont², B. O'Brien¹</u> ¹Health Studies Area, ²Computer Systems and Applications, Westat, Rockville, Maryland 20850

Abstract

Accurately and consistently annotating collected biospecimens throughout their lifecycle from collection through exhaustion is integral to biospecimen research. consideration of pre-analytic variables, such as method of collection or time to processing, in combination with analytic outcomes can provide useful information on specimen integrity and validity of analytic results. To this end, we propose the use of several information technology tools to support and facilitate specimen annotation. We describe the use of a biospecimen tracking system that enables users to record information about individual or groups of specimens at any time in the specimen lifecycle. For example, temperature events can be added to a group of samples stored in a particular freezer when the temperature was considered out of range. In addition, tools that support data exploration allow multiple investigators to review the same data in real-time to facilitate analytic decisions. Examples are presented from several epidemiological studies that illustrate the tracking and annotation of biospecimens using information technology tools that enable specimen tracking system and data exploration. We suggest options for investigators who are interested in documenting pre-analytic variables, processing anomalies, and analytical issues in a consistent and comprehensive manner so that they are able to support their continued research efforts with confidence in the integrity of their biospecimens.

Specimen Lifecycle Phases

•To ensure specimen quality and integrity, specimens must be tracked and annotated at each phase in their lifecycle from pre-collection through exhaustion.

•Appropriate and detailed annotation that includes information about pre-analytics variables will inform both analysis and future collections.



* These phases can occur at multiple times during the specimen lifecycle.

Information Technology Tools Facilitate Tracking and **Specimen Annotation**

Biological and Environmental Sample Tracking (BEST) System

- Web-based, real-time tool designed to track and annotate biospecimens
- Tracks items from point of origin through exhaustion
- Capable of integrating with other systems Implemented for several studies including:
 - National Children's Study (NCS)
 - Retrovirus Epidemiology Donor Surveillance (REDS) Study
 - Prostate, Lung, Colorectal, & Ovarian (PLCO) Cancer Screening Trial (Etiologic Early Markers Study (EEMS))
 - Agricultural Health Study
 - Ovarian SEER Pathology Slide Review

Westat Data Explorer (WesDaX)

- Web-based query and data exploration tool
- Facilitates specimen annotation and review
- Implemented for several studies including:
 - Cohort Consortium Pancreatic Scan (PanScan)
 - Vitamin D Pooling Project (VDPP)
 - Cohort Consortium Pooling Study of BMI and Morality
- Prostate, Lung, Colorectal, & Ovarian (PLCO) Lymphoma Sub-Group

Use of Collection Kits and Barcode Labels Facilitates Tracking and Reduces Error

•Pre-made collection kits streamline collection and record keeping •Pre-labeling collection kits and primary collection containers with unique barcode identifiers reduces error and supports discrepancy resolution throughout the specimen lifecycle phases

Suggested approach:

- Individually label each kit with a 2D barcode and eye readable text containing the following information:
 - Kit ID
 - Kit Type
 - Kit Version Number
 - Kit Lot Number
 - Kit Expiration Date



Kit Number: BA1234567 (it Type: Blood Kit - T1 Mother LOT3456-23
 Version:
 V1A

 Exp Date:
 12/31/2008

• Label each primary collection container within a specific kit with a unique number based on the Kit ID and Item Type



• Collected specimens will be linked to the study participant using the Kit ID at the time of collection.

Capturing and Recording Collection and Receipt Related Information in BEST

Home Visits Sp Visits> Browse Pro	ecimens Shipments	n Process Stor	age Units Brows	e Kits Completed
Scan or enter item (s	specimen), containe	r, or a visit idei	ntifier to process	5
Process Actions		<u>G</u> o		_
Save New Clear	Delete Re <u>f</u> resh	📎 🖂 昌 🛛 Da	efault Container:	AUTO SELECT S
Hide A02	2365TJ-3 Vie	w-> Biospecime	en Items 💌 📃	Add Event
Study:	NCS Collection Phase	Q	PSU	D: UNC-DC (PSU-101)
Assignment ID:	A02365TJ-3		Event Statu	IS: PROCESSING 🔽 🗧
Subject ID:	AB1234-6		Scheduled Fo	or: 01/14/2009 🛄 09:00
Subject Type:	MOTHER			
Visit Type:	T1-MOTHER	e,		
Collection Date:	01/27/2009	(e.g. 13:15)	Centrifuged	At: SPSC
Comment:		< >	Cold Transport	Temp:

Aggregate Information: Collection and receipt data for the visit/study participant, such as date/time and transport conditions, are captured through the visit parameters screen in BEST. For example, if transport conditions are evaluated using threshold temperature monitors, then the information can be recorded in BEST upon receipt of specimens.

	Display Biospecimen Kits for A02365TJ-3										
Ch	Choose 🔽 Reset Save Rows 🖷 Items/Specimens for A02365TJ-3										
		View	Next Task		Study Item	Specimen I	🕘 BEST	- Create	New Reco	rd - Mic	rosoft Internet
1			STORE	+	LP10	TA0000022 LP10	Enter na	ramatare	for new R	seult and	click Save
2		٩,	RECEIPT	+	LV10	TA0000022 LV1			TOT HEW IN	suit anu	CIICK Save
3			SHIP	÷	PN10	TA0000022 PN10	Save C	ancel			
4			SPIN	+	PP10	TA0000022 PP10	Acti	ion Type:	COLLECT		0
5			COLLECT	+	RD10	TA0000022 RD1	Actie	on Name:	Collect RD1()	
6		٩	SPIN	+	RD11	TA0000022 RD1	Spe	cimen ID:	TA0000022	RD10	
7			COLLECT	+	SS10	TA0000022 SS1		Result ID:	COMPLETE	•	Select a result
8			SHIP	+	VS01	TA0000111 VS0	Result Da	ate/Time:	02/05/2009	14:25	(e.g. 13:15)
9			SHIP	+	VS02	TA0000111 VS0	Tem	perature:	22.5	Calsius	
10		Q	COLLECT	+	VL01	TA0000111 VL0	Hom	Modifier	 OK		
11			SHIP	÷	UR01	TE0000051 UR01	item	mounter.	ON		
12			COLLECT	+	SLXX	XAA002112 SL0	<u> </u>				
13		e,	COLLECT	+	SLXX	XAA002112 SL0	с	omment:			
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17		~	COLLECT	+	SLXX	AA002112 SE0	<			1111	

Individual Information: Collection and receipt data for individual specimens, such as damaged primary collection containers, are captured through the result parameters screen associated with each specimen action (collect, receipt, spin, store, ship)





Capturing and Recording Processing and Storage Related Information in BEST



File Luit View Favorites Turn can	;
🔶 🔥 🖉 BEST - Create New Record - Windows Internet Explorer	
Study: INCS Collection Enter parameters for new Task Result and click Save	
Assignment ID: A00003HM-3 Save Cancel	
Subject ID: YG0006-3	
Subject Type: MOTHER BB1010133-RD10 RECEIVED Storage-> Last Task-> RECEIPT UNDO	
Visit Type: T1-MOTHER Specimen ID: BB1010133-RD10 Status: NEW	
Collection Date: 02/12/2009	
Commont Training Assignment Training Assignmen	
Consent Relabel Item> Will Default To Unit> Z00000002	
Display Biospecimen Kits for A	
Choose V Result Date/Time: (e.g. 13:15)	
View Next Task St	s Date
1 COLLECT + LP1	9 14:23:09
2 SHP + LV	9 14:25:22
3 COLLECT + PN1 Comment: Lipemia	9 14:23:10
4 COLLECT + PP1	9 14:23:10
5 SPIN-B + RD' Choose Reset New Attachments to Action	9 20:02:08
6 COLLECT + RD	9 14:23:11
7 🗖 🔍 COLLECT + SS ¹	9 14:23:11
Storage Unit Record Details	
Find/Edit V Go	k Save
Save New Clear Delete Refresh Save Cancel	
Add Items> Scan item or box ID Go Select Add Event Validate Entity Type: Batch	
Add Event Entity: 1599	
Starses Profiles Monitored temperature too high Event Type: MONITOR-TEMP-LOW	
Storage Profile: Event Value:	
Container Type: FREEZER-NCS #Slots Filled: 0 Event: Event:	
Storage Unit ID: FRZ-101-01-LOWER Status: NEW	
Event Date/Time. Duration > 15 min and < 30	min ,
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the given location at the time of the event.

Annotating Specimens for Analysis and Reporting Through WesDaX



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Aggregate and Individual Information: WesDaX can be configured based on user defined needs to provide summary specimen related information for data exploration, analysis, and reporting. For example, information about the number and types of specimens that experienced out-of-range temperatures during transport could be obtained. In addition, phenotype data, such as gender and smoking status, can be associated with specimens. All WesDaX queries are given a time/date stamp and can be saved for future needs.