Integration of a commercial biospecimen management software system and an Anatomic Pathology Laboratory Information System as components in the informatics workflow of a comprehensive biobank

UW Medicine PATHOLOGY

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Background

At the 2014 ISBER meeting we described the development of an informatics system to manage study registration, patient identification, consent management, and top-level barcoded biospecimens for prospective collection (NW BioTrust Informatics System; http://goo.gl/InbGWh). We also search our Anatomic Pathology Laboratory Informatics System (AP-LIS; PowerPath, Sunquest, Tucson, AZ) to utilize retrospective materials for research projects, also creating top-level biospecimens.

We further required a system to:

- Manage visit-level data (pathology report data, neoadjuvant therapy, etc.)
- Manage *biospecimen-level* data (coded diagnoses, %neoplasia, etc.)
- Create derivative biospecimens (tissue aliquots, histologic sections, etc.)
- Manage biospecimen locations (chain of custody, freezers, etc.)

For these functions, we desired a commercial biospecimen management software system that could include the AP-LIS, intake top-level biospecimens, and manage visit- and biospecimen-level data. An ad hoc committee, including representatives from bioinformatics, pathology informatics, and the biobank director, selected the Labmatrix (BioFortis, Columbia, MD) software system.

Custom Data Field Development

We extended the core Labmatrix subject and biomaterial fields using custom forms available to all studies in the system. For Subjects, we also added multi-record MRN and Visit forms. Custom biomaterial attributes include processing information and biomaterial characteristics:

Sample Type	Processing Type	Container Type	Stain	Temp	Procedure	Disease State
Fresh	Fixed-Formalin	Cryovial	H&E	25	Surgical Resection	Malignant
Fresh in Media	Fixed-Butalin	Cryomold	ER	4	Core-Needle Biopsy	Malignant-Metastatic
Flash Frozen LN ₂	Fixed-EM	Cassette	PR	-20	Punch Biopsy	Non-Involved
Slow Frozen	Media-Saline	Centrifuge Tube-15mL	HER2	-80	Other Biopsy	Non-Involved Adjacent
Fixed	Media-RPMI	Centrifuge Tube-50mL	Ki67	-196	Pap Smear	Normal
FFPE	Media-DMEM	Paraffin Block	EGFR		ERCP Brushing	Diseased
FFPE-Core	Media-DMSO/RPMI	Glass Slide	PSA		Veinupuncture	Borderline
FFPE-Section	Unstained	Foil	p16		Buccal Swab	Benign
OCT Mounted	Stained	Vacutainer-Gold	p53		Indwelling Catheter	Undetermined
OCT Mounted-Sect.	Other	Vacutainer-Purple	p63		Lumbar Puncture	
Touchprep	Undetermined	Vacutainer-Red	CD45		Other	
Other	NA	Vacutainer-Green	CD68		Undetermined	
Undetermined		Collection Group	NA			
		Other				

These customized fields were designed to be hierarchical so that aliquotting out biomaterial derivatives with Labmatrix can quickly be performed for the most common biomaterial types:

- **Collection Group:** Fresh \rightarrow NA \rightarrow Collection Group \rightarrow NA \rightarrow 25
- **FFPE Block:** FFPE \rightarrow Fixed-Formalin \rightarrow Cassette \rightarrow NA \rightarrow 25
- **H&E Slide:** FFPE-Section \rightarrow Stained \rightarrow Glass Slide \rightarrow H&E \rightarrow 25
- **Unstained Slide:** FFPE-Section \rightarrow Unstained \rightarrow Glass Slide \rightarrow NA \rightarrow 25
- **Snap Frozen Tissue:** Flash Frozen $LN_2 \rightarrow NA \rightarrow Cryovial \rightarrow NA \rightarrow -196$
- **OCT Block:** OCT Mounted \rightarrow NA \rightarrow Cryomold \rightarrow NA \rightarrow -196

Other custom biomaterial fields included ICD-O-3/Snomed coding for assigning diagnostic information to all samples.



Labmatrix Biobanking System

CLabmatrix Data Entry 🛩	Search 🛩	Storage Workflow	s Processes	Reports		
Specimen Orders	+ Create	0 Draft	0 Submitted	Approved) Distributed	0 Rejected
Distributions For NWBT	0 Awaiting Approval	0 Approved	Ready for Distribution	Shipped		0 Rejected
CLIA Transfer Requests	+-	0 Draft	0 Submitted		Pufiled	0 Rejected
CLIA Processing Requests	+-	0 Draft	0 Submitted	Sent to Pathologist	Pethologist	Fulfiled
Transfer Requests	+ Create	Draft	Submitted	Approved	→ 0 Fulfiled	0 Rejected
Fulfiliments For NWBT	O Awaiting Approval	0 Approved	Samples pulled	Shipped		0 Rejected

Labmatrix workflow home screen

We created customized versions of the default Labmatrix workflows to fine tune the queries which drive them and capture metrics unique to our workflows. In this section we demonstrate the Labmatrix archival workflow specifically.

Reporting

Labmatrix Qiagram allows for highly customizable querying and reporting. This query report displays biomaterials by study which have been distributed to researchers (and prior to invoicing).



Biobanking Workflow

Anatomic Pathology LIS (Retrospective)

NW BioTrust Informatics System (Prospective)



The case list is refined by excluding cases based on consent (universal front desk "No"), verifying the final diagnosis text in the pathology report, and ensuring there is sufficient material to sample (e.g. biopsy versus resections).

e desired set of cases is 📑	and a second
, the associated clinical	
on and "biomaterial tree"	10.00 m
ontains the list of all clinical	144
nens created for a case) is	4
via a custom SQL query. This	-
alidation of specimens that we	
ing in Labmatrix and prevents	
~	

Exported data is copied into a custom template form and uploaded to abmatrix using the bulk upload feature.



Exported data is automatically uploaded to the Labmatrix servers on an ongoing basis every 4 hours using the Labmatrix Simple Object Access Protocol (SOAP) web services API.



CLIA Transfer Request (PULL BM's from archives) Draft (User Creates) Submitted Approved Rejected Canceled Awaiting Approved (BM's ordered from slide recorn(JM) Rejected Canceled

CLIA Transfer Request

After biomaterial data are uploaded to Labmatrix, a **CLIA Transfer Request** is created to transfer biomaterials to/from the CLIA pathology archives and NW BioTrust facility. Once approvals are in place, the biomaterials are ordered and an External **Fulfillment** is automatically generated Upon receipt, an **Intake** is automatically generated and all biomaterial barcode labels (generated from source system) are scanned as an tracking/QC step. Biomaterials can be flagged as "Lost" at this point. A similar process is followed for returning biomaterials to the CLIA pathology archives.





(automatic)

CLIA Processing Request

Received biomaterials are reviewed and authorized by the pathologist. Custom forms in Labmatrix collect additional attributes.

General	Child Biomate	rials	Forms	Path ID	Hist IDs	Ch
NWBT Bioma	terial Attributes	Llie	tology OC			
Post Collection	on Details	nis	lology QC			
Tickets				% Neoplasia:		
				%	Necrosis:	

Individual biomaterials that do not meet the study criteria (e.g. insufficient %tumor) are rejected from the **CLIA Processing Request**. At this point, biomaterials can also be removed from the entire research pool (e.g. block exhausted) so that they are never even requested to begin with.

Removed From Research Pool: Removal Reason

Removal Date

Finally, biomaterials are sent through the Histology Fulfillment workflow and new biomaterial derivative specimens, ordered in the AP-LIS source system, are exported and uploaded to Labmatrix via a custom SQL query.



Specimen Order & Distribution

New biomaterial derivatives (e.g. unstained sections, H&E's) are carefully tracked and delivered to researchers through the **Specimen** Order and Distribution workflows. Specimens go through a final QC and are packaged in containers for delivery.

	1. Print Pull List	2. Prepare Shipm
💠 Add Container 🔤 R	emove Container	
Containers	Scan barcode: Progres Scan a biomaterial to place it in the highlighted slot.	0 ou
	Box 1	
	A 4 40	

A shipping manifest is generated and included in the delivery. A signed manifest is returned to NW BioTrust to verify receipt. These workflows are also linked to invoicing systems (Quick Books, Intuit, Mountain View, CA) to track billing.







Canceled appts an Patients with with Print Grid	e shaded yelow. drawn consent are shaded red
Diegnosis	Procedure
154.1 MALIGNANT NEOPL RECTUM	OSTOMY TAKEDOWN/OL
416-2 CHRONEC PULMONARY EMBOL2	SM PULMONARY THROMEEC
585.6 END STAGE RENAL DISEASE	PERITONEAL CATHETER LAPAROSCOPIC ASSIST
592.0 CALCULUS OF KIDNEY	CYSTOSCOPY, URETERO
V 10.3 PERS HK OF BREAST MALIGNAM	CY FLAP FREE DOEP BILATER (PLASTICS)
153.9 MALIGNART NEOPLASH COLON	NOS ROBOT-ASSISTED LIVER
	(DF MOLECUTE)
POST LUNG TX, 1 wk f/u, ktb	LUNG BIOPSY, (VATS)
174.9 - RIGHT BREAST CANCER	BREAST BOOPSY COMPLE
V10.3 PERS HX OF BREAST MALIGNAY	CY BREAST IMPLANT TISSU

2-Colorectal CA pat 4-Over Repository -6

Normal tissue adjacent to n

Normal tissue adjacent to prim site (same organ)

Normal tissue adjacent to primar site (same organ)

Normal tissue adjacent to meta

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	Other - Unspecified	1	Other , cancero		
	Flash Frozen	1	Other		
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Importing Data to Labmatrix from Source Systems

To import top-level biospecimens into Labmatrix from our two source systems (AP-LIS and NW BioTrust IT System), we implemented Extract, Transform, and Load (ETL) data import mappings. For importing *retrospective* biospecimens, custom PowerPath reports were designed to export biospecimen trees from each pathology case for uploading to Labmatrix. For importing *prospective* biospecimens, a Java client process that uses the Labmatrix Simple Object Access Protocol (SOAP) web services API was designed to automatically upload top-level biospecimens from the NW BioTrust IT System to Labmatrix. Each subject and biomaterial record is imported with an external identifier+source combination key to allow for record updates in Labmatrix from the source systems.

Custom forms were used to input visit-level data, link derivative specimens to their parent biomaterial, and manage biospecimen-level data including location. Tracking of transfers and final distribution to researchers was achieved by customization of the Labmatrix workflows feature and creation of queries for routine reporting.



Conclusions

- Successful integration of Labmatrix biospecimen management software allowed data feeds from two sources (NW BioTrust Informatics System and AP-LIS) as components of a larger biobanking informatics workflow. We are now live with the archival workflow with plans to go live with the
- prospective workflow in the next month. These tools allow us to precisely QC all biomaterials that enter and leave the NW BioTrust facility and track pathologist authorization and histology workflows.
- Further, these tools enable creation of highly custom reports to track important metrics.

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