

# 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



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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/lnbGWh>). 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 <sub>2</sub>	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				

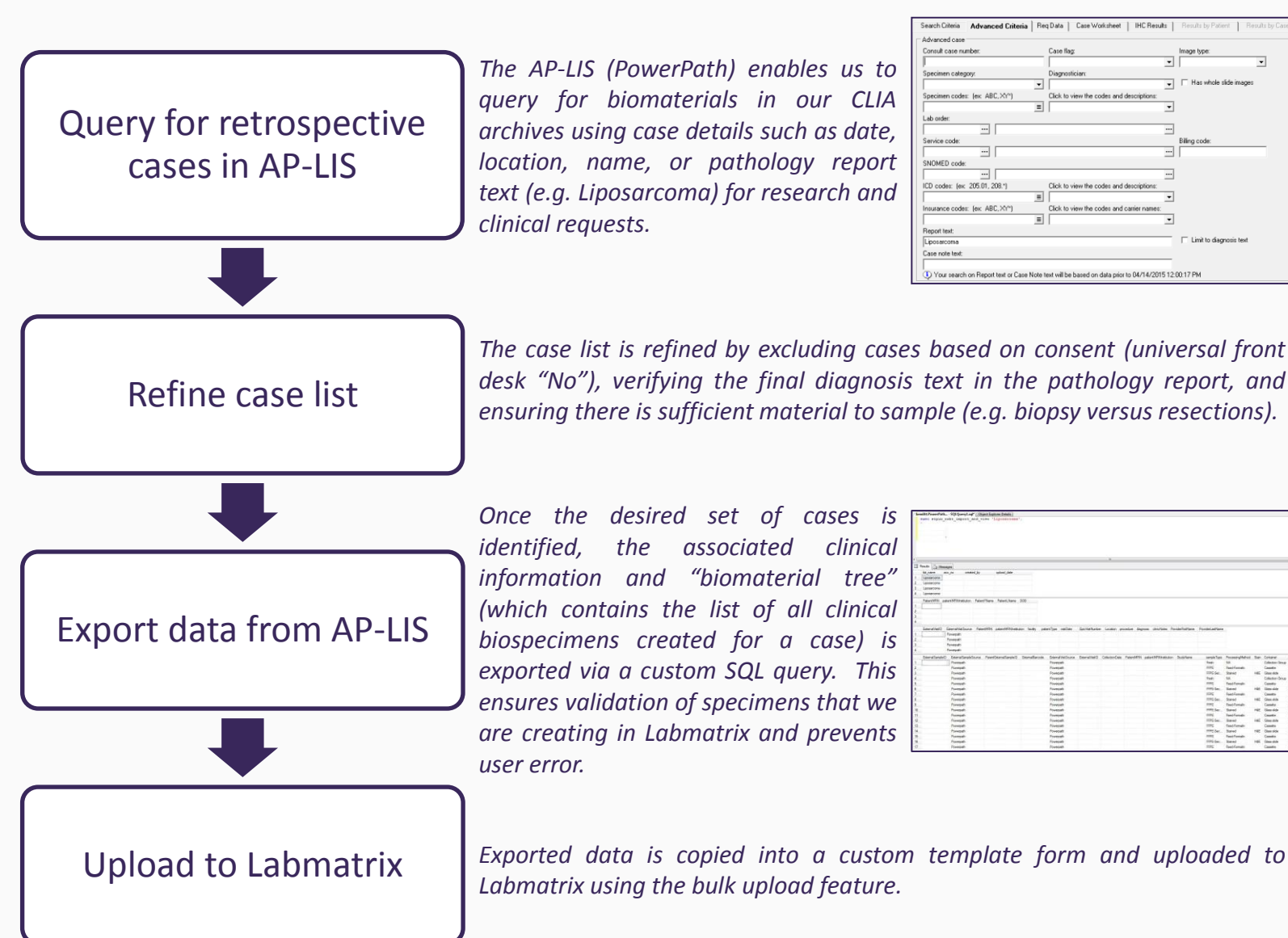
These customized fields were designed to be hierarchical so that aliquotting out biomaterial derivatives with Labmatrix can quickly be performed for the most common biomaterial types:

- Collection Group:** Fresh → NA → Collection Group → NA → 25
- FFPE Block:** FFPE → Fixed-Formalin → Cassette → NA → 25
- H&E Slide:** FFPE-Section → Stained → Glass Slide → H&E → 25
- Unstained Slide:** FFPE-Section → Unstained → Glass Slide → NA → 25
- Snap Frozen Tissue:** Flash Frozen LN<sub>2</sub> → NA → Cryovial → NA → -196
- OCT Block:** OCT Mounted → NA → Cryomold → NA → -196

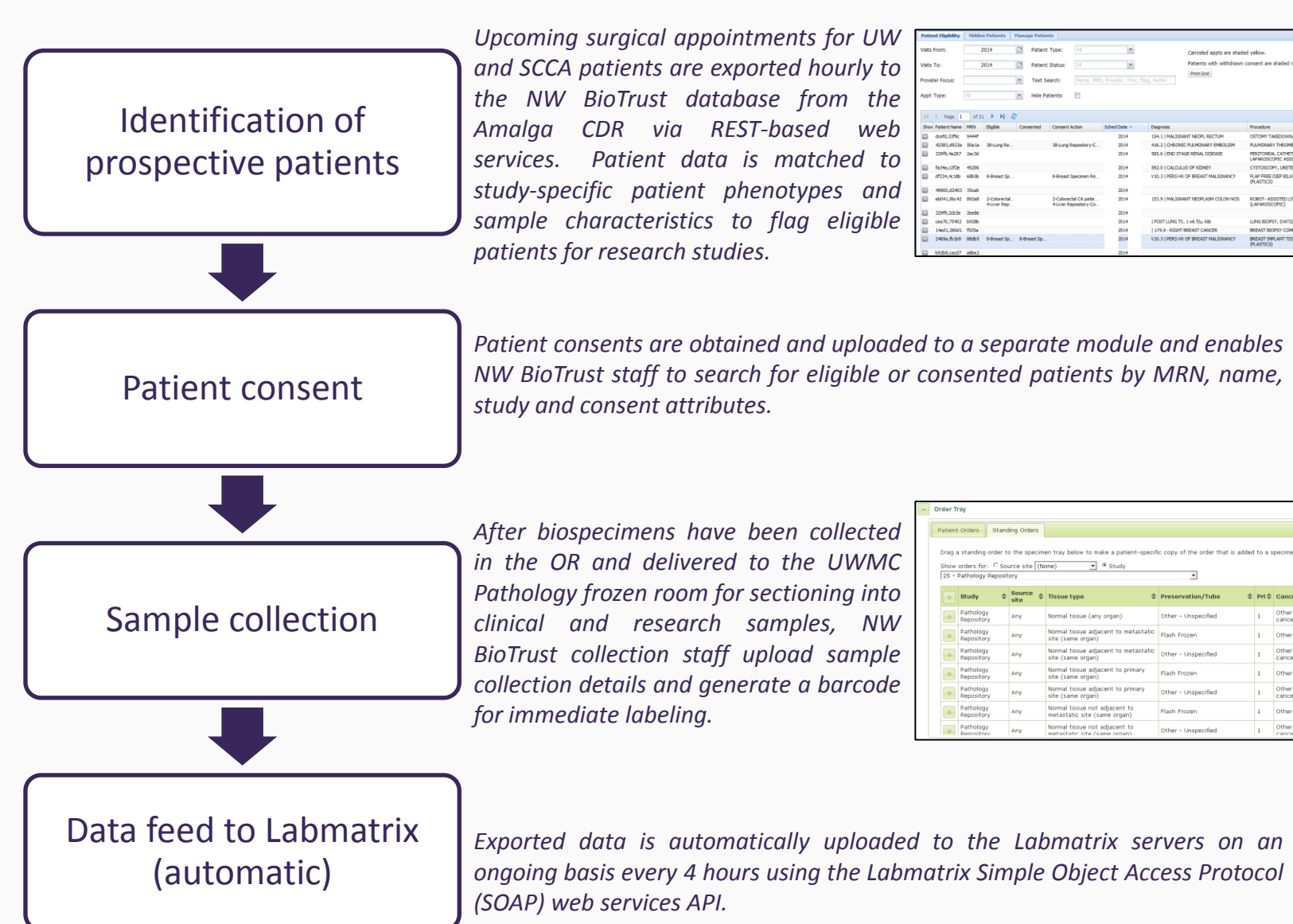
Other custom biomaterial fields included ICD-O-3/Snomed coding for assigning diagnostic information to all samples.

## Biobanking Workflow

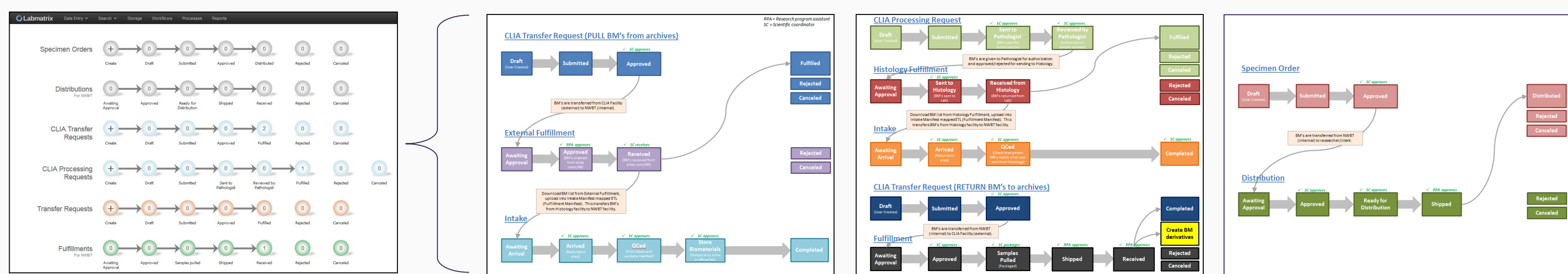
### Anatomic Pathology LIS (Retrospective)



### NW BioTrust Informatics System (Prospective)



## Labmatrix Biobanking System



### 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.

### 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.

### CLIA Processing Request

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

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.

### Specimen Order & Distribution

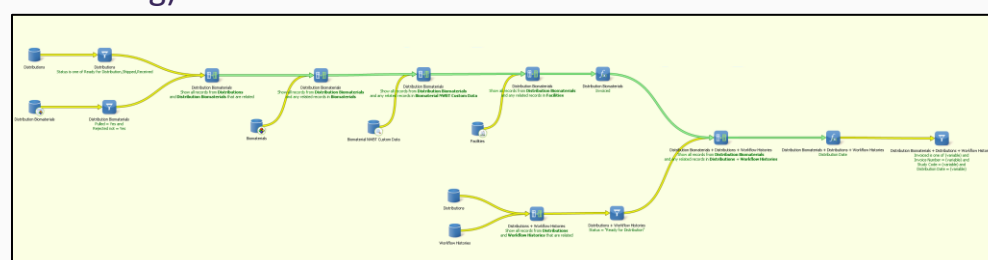
New biomaterial derivatives (e.g. unstained sections, H&E's) are carefully tracked and delivered to researchers through the **Specimen Order** and **Distribution** workflows. Specimens go through a final QC and are packaged in containers for delivery.

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.

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.

### Reporting

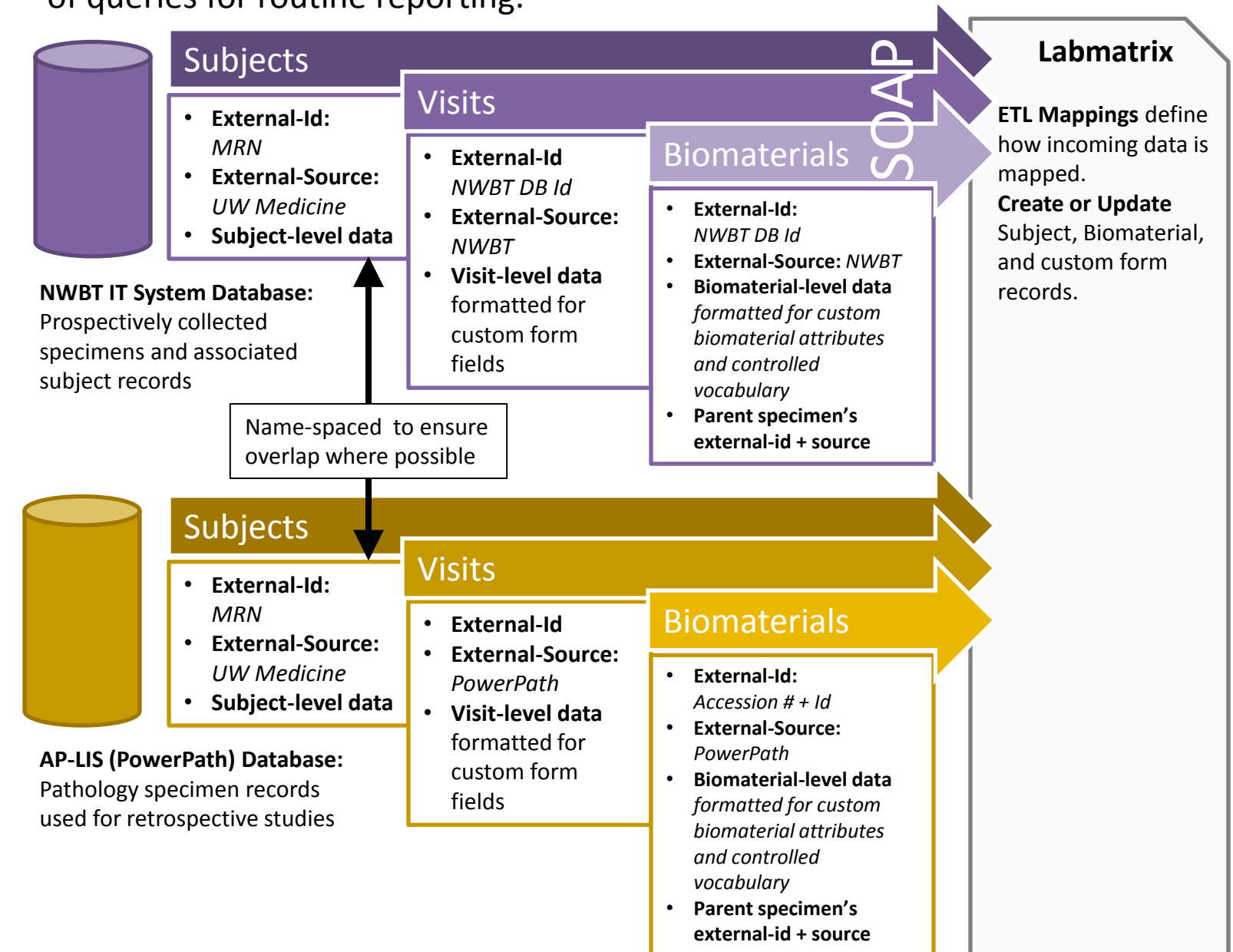
Labmatrix Qigram allows for highly customizable querying and reporting. This query report displays biomaterials by study which have been distributed to researchers (and prior to invoicing).



## 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.

## Acknowledgements

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