Annotating the Biospecimen Lifecycle: A Case Study

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Agenda

- Introduction: "Requirements for Biospecimen Lifecycle Data"

- What we learned during our site visits

- IT Strategy for addressing gaps
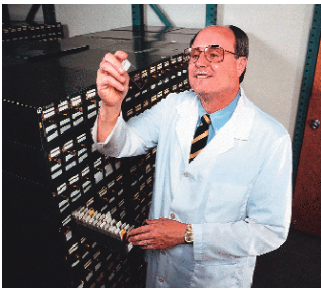
- Activities to close IT gaps / status

The Project

-Post-operative ischemia
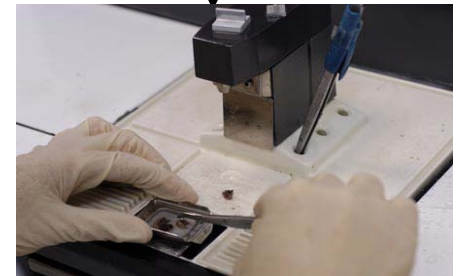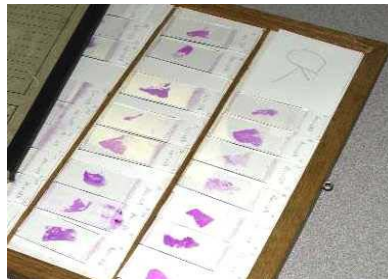-Room temperature
-Type of preservative
-Rate of freezing/fixing

Tissue processing
-Multiple formulaic variables
- Multiple time settings for each

Recorded/annotated
-Anesthesia
-Intra-operative ischemia
-Many other variables

H&E
IHC
FISH
RNA isolation
Storage

My Role

- Join the BRN team as Consultant for Site Visits last year

- Provide IT lens for team to review Sites

- Site Visits: Review people, process, and technology capabilities, limitations, and risks
  - Review Total Quality Management Program
    - Standard Operating Procedures
    - Specimen annotation & labeling
    - Use of dedicated processing equipment
  - Follow a tissue sample from consent, collection in the operating room, processing, storage and shipment
  - Discuss IT: Data Tracking & Sharing

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The Challenge: CHP

A Former Project

Multiple sites (4) operating in unison

Same protocols, training, workflows, systems, equipment, management.

BRN Project

Multiple sites (2) operating in different, but controlled ways

Same protocols, but <u>different</u> training, workflows, systems, equipment, management

Specimen Lifecycle Data Critical for:

Enforcing consistency across sites

Tracking differences across sites

The Challenge: CHP

A Former Project

Biobank operations from ground up

Implemented workflow control systems (integrated workflow)

BRN Project

Leveraging existing infrastructure

Dependant on existing systems at sites

Specimen Lifecycle Data Captured…

In real time through worfklow controls embedded in systems under sponsor's control
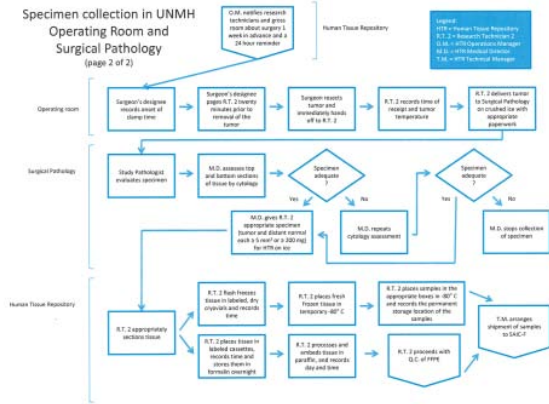
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What we learned during Site Vistis

Dr. Kay Washington (PI)

Dr. Therese Bocklage (PI)

Application Portfolios

Process	Vanderbilt	UNM
Patient Enrollment / Consent	Custom Application (Integration EMR/Star Panel)	eVelos
Blood Specimen Collection/Processing	Custom Tissue Bank Application	Teleforms and/or TissueMetrix
Surgical Procedure		
Receipt in Pathology		
Tissue Specimen Collection		
Tissue Specimen FFPE Processing		
Pathology QC		
SOPs, Equipment, etc.	**Paper Records**	**Paper Records**
Storage Logistics	Custom Tissue Bank Application	TissueMetrix
Extended Clinical Data	**Proposed RedCap**	**Proposed Customer MS Access Clinical Data**
Shipping Logistics	Custom Tissue Bank Application	TissueMetrix
New CHP Data Collection	**Proposed Modifying Customer Application for new data entry**	**Proposed combination of Teleforms – > TissueMetrix -> MS Access**
Delivery of Data to OBBR	**Proposed RedCap and new Reporting Capabilities**	**Proposed MS Access**

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Identified Gaps

- Neither site had an integrated workflow management system to auto collect collection, handling, and processing data.

- Both sites did not have an existing system for handing comprehensive sets of discrete clinical data elements

- Both sites did not have an existing system for transferring comprehensive data sets in a coordinated way.

- We had not developed requirements for both clinical and sample collection, handling, and processing data (CHP)

Approach to Address Gaps

- Find a technical solution for the sites:

    - Agree on a strategy for how we expect the sites to **use systems** for capturing data (e.g. comprehensive integrated workflow management or "hands off" data reporting)

    - Agree on a strategy for **implementing a solution** (e.g. site development or OBBR development)

    - Pursue the solution.

- Develop clinical and CHP data and terminology requirements

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Methodologies

Pros:
-**Real time data**
-**Enforce unified workflow**

Cons:
-**Very expensive**
-**Site interruption**
-**Loss of site "differences"**
-**Loss of site infrastructure**

Integrated System/Workflow

"Hands-Off"

Usage Strategy

Methodologies

Pros: -Real time data -Enforce unified workflow	**Pros:** **-Use existing assets** **-Less costly** **-Maintain site differences**
Cons: -Very expensive -Site interruption -Loss of site "differences" -Loss of site infrastructure	**Cons:** **-Less transparent** **-Data quality risk**
Integrated System/Workflow	"Hands-Off"

Usage Strategy

Methodologies

Implementation Strategy

OBBR Provided

Site Built

Pros:	Cons:
-Sites are ready to do	-Redundant/Costly
	-Maintenance Risks
	-Dual sources for OBBR
	-No transparency

Methodologies

	Pros:	Cons:
OBBR Provided	**Pros:** **-Reduce redundancy** **-Low maintenance risk** **-Unified data transfer** **-Data workflow controls**	**Cons:** **-New contracts needed** **-New role for OBBR**
Site Built	Pros: -Sites are ready to do	Cons: -Redundant/Costly -Maintenance Risks -Dual sources for OBBR -No transparency

Implementation Strategy

Methodologies

	Integrated System/Workflow	"Hands-Off"
OBBR Provided	Complex, very expensive, disruptive, loss of site value and infrastructure, loss of site differences	✔
Site Built	Complex, very expensive, redundant, maintenance risks	costly, redundant, and maintenance risks.

Implementation Strategy

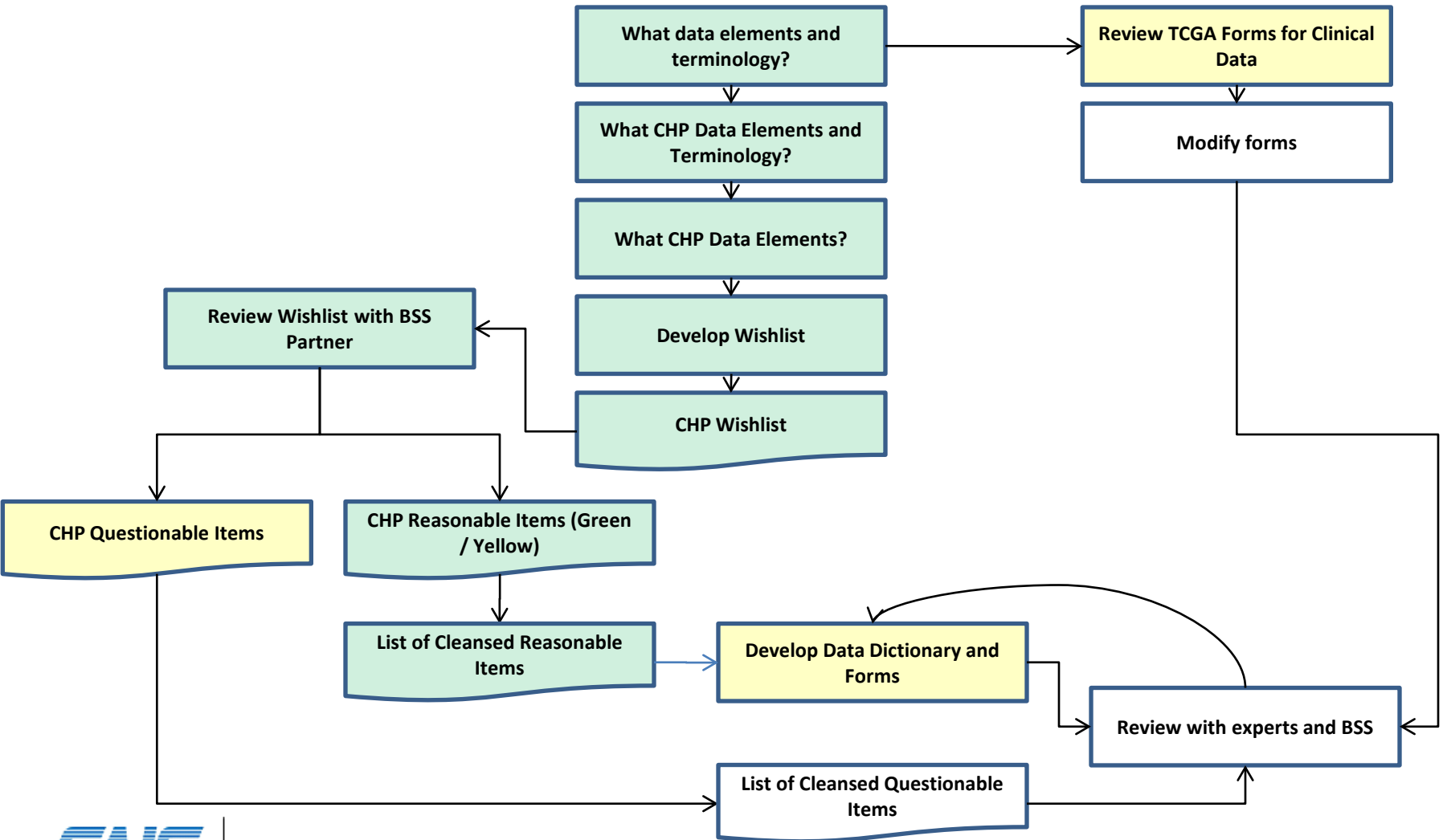*Usage Strategy*

Select an Application

- Open Source
- TCGA proven
- Support services available
- Large user/development community
- Strength in data capture
- Web – deployable

Team formed, trained, and has begun configuration of test environment.

Develop Data Requirements

```
What data elements and          →          Review TCGA Forms for Clinical
terminology?                                Data
        ↓                                          ↓
What CHP Data Elements and                  Modify forms
Terminology?
        ↓
What CHP Data Elements?
        ↓
Review Wishlist with BSS    ←    Develop Wishlist
Partner
        ↓                              ↓
                                 CHP Wishlist
```

```
CHP Questionable Items     CHP Reasonable Items (Green / Yellow)
                                   ↓
                           List of Cleansed Reasonable    →    Develop Data Dictionary and
                           Items                                Forms
                                                                        ↓
                           List of Cleansed Questionable    →    Review with experts and BSS
                           Items
```

Develop Data Requirements

**Observation
SOPs
EMR
Logs
Notes
Etc.**

- Dates / Times
- Operators
- Temperatures
- Measurements
- Volumes
- Conditions
- SOPs
- Equipment and Conditions
- Events
- Observations

OpenClinica®
Open Source for Clinical Research

Process	Elements
Patient Enrollment / Consent	10
Blood Specimen Collection/Processing	42
Surgical Procedure	34
Receipt in Pathology	7
Tissue Specimen Collection	29
Tissue Specimen FFPE Processing	26
Pathology QC	32
SOPs, Equipment, etc.	141
TOTAL	321 Data Elements

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Questions?

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