# SUPPORTING SPECIMEN ANNOTATION AND QUALITY ASSESSMENTS THROUGH INFORMATION TECHNOLOGY TOOLS

A. Varanasi[1], L. Mechanic[1], D. Carrick[1], C. Lawrence[1], K. Wilson[2], M. Kliesch[2], M. Harmon[2], C. Ray[2], J. Wernimont[2], B. O'Brien[1]

[1]Health Studies Area, [2]Computer Systems and Applications, Westat, Rockville, Maryland 20850
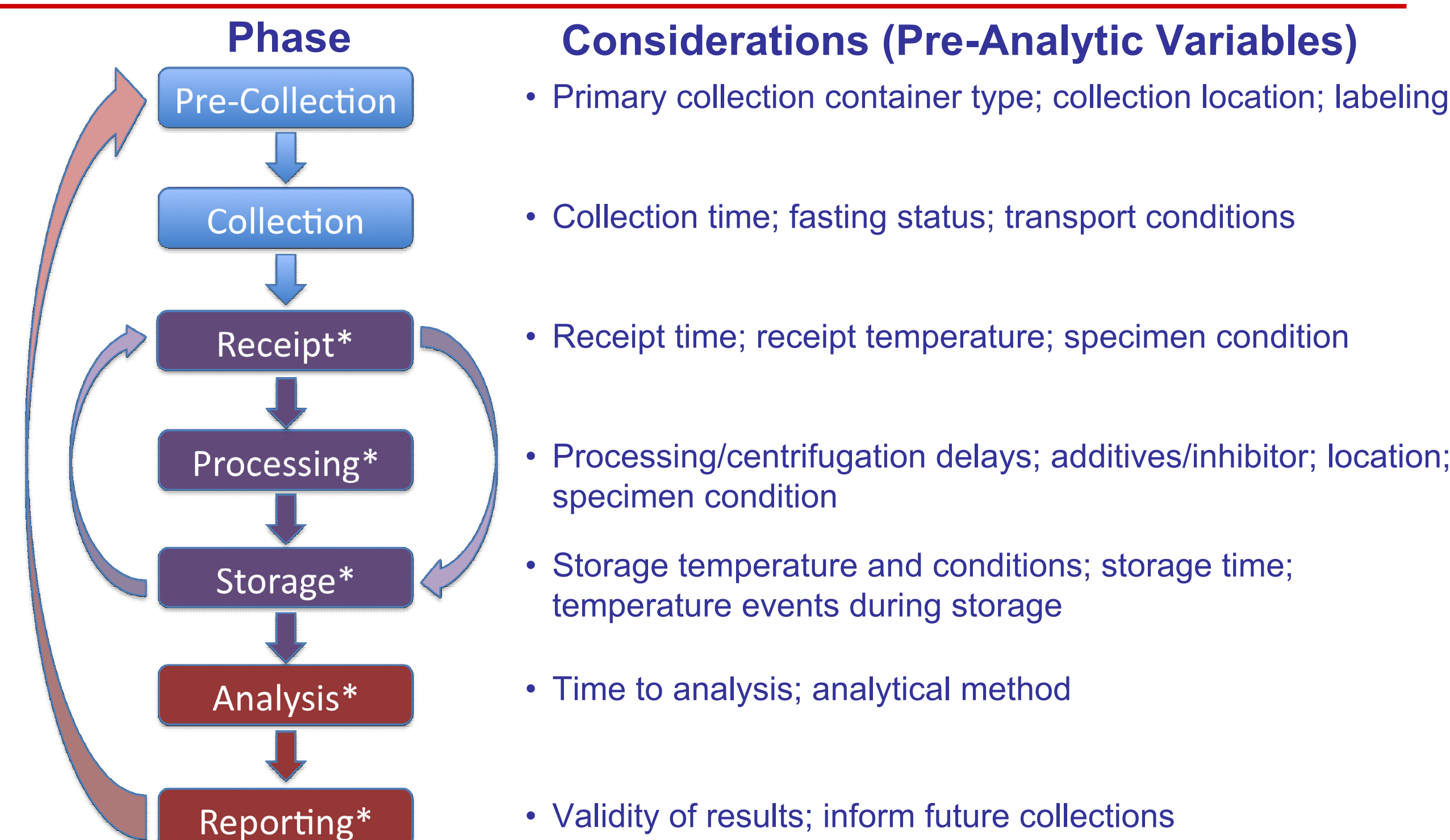
## Abstract

Accurately and consistently annotating collected biospecimens throughout their lifecycle from collection through exhaustion is integral to biospecimen research. The 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.

| Phase | Considerations (Pre-Analytic Variables) |
|---|---|
| Pre-Collection | • Primary collection container type; collection location; labeling |
| Collection | • Collection time; fasting status; transport conditions |
| Receipt* | • Receipt time; receipt temperature; specimen condition |
| Processing* | • Processing/centrifugation delays; additives/inhibitor; location; specimen condition |
| Storage* | • Storage temperature and conditions; storage time; temperature events during storage |
| Analysis* | • Time to analysis; analytical method |
| Reporting* | • Validity of results; inform 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
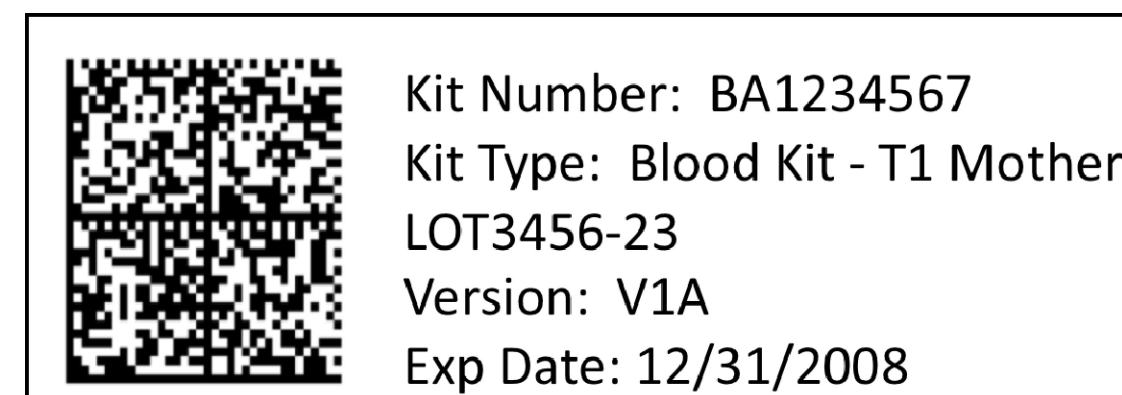  • Ovarian SEER Pathology Slide Review

**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
Kit 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

Red Top 10
BA2345671-RD10

• 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
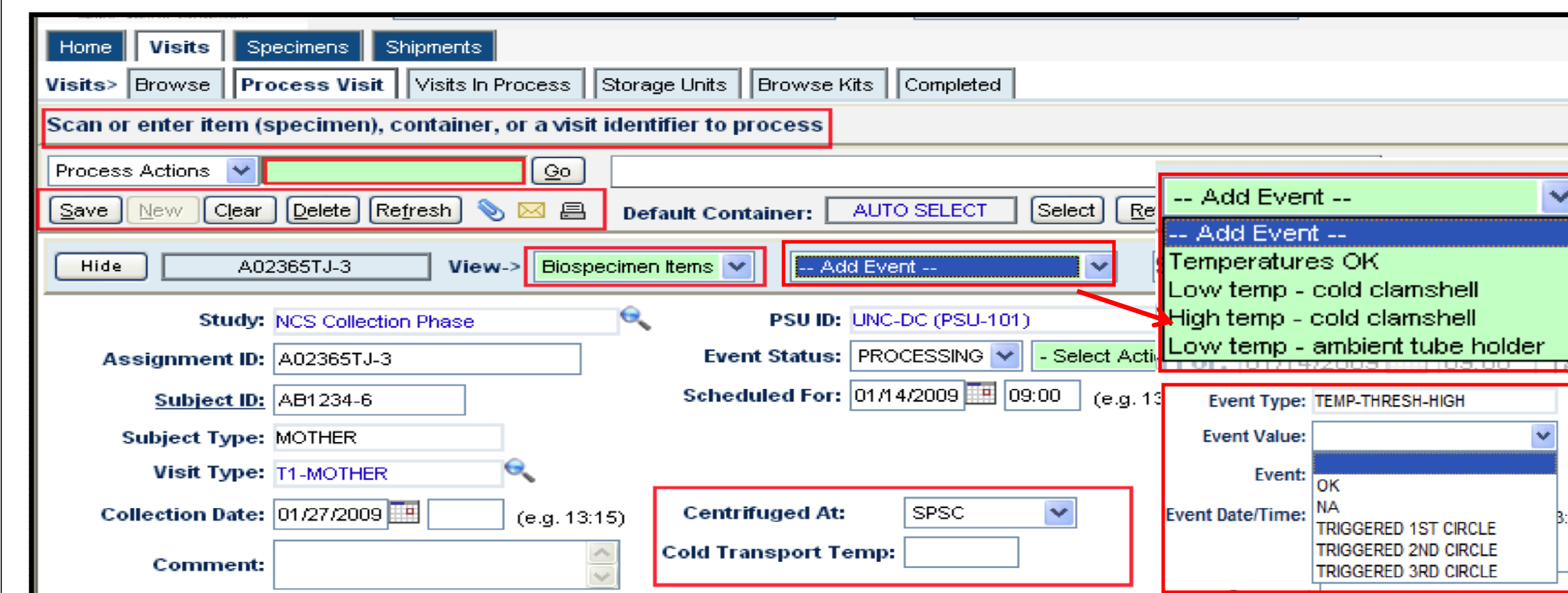


**Aggregate Information:** Collection and receipt data for the visit/study participant, such as date/time and transport conditions, are captured through the visit parameters screen in BEST. For example, if transport conditions are evaluated using threshold temperature monitors, then the information can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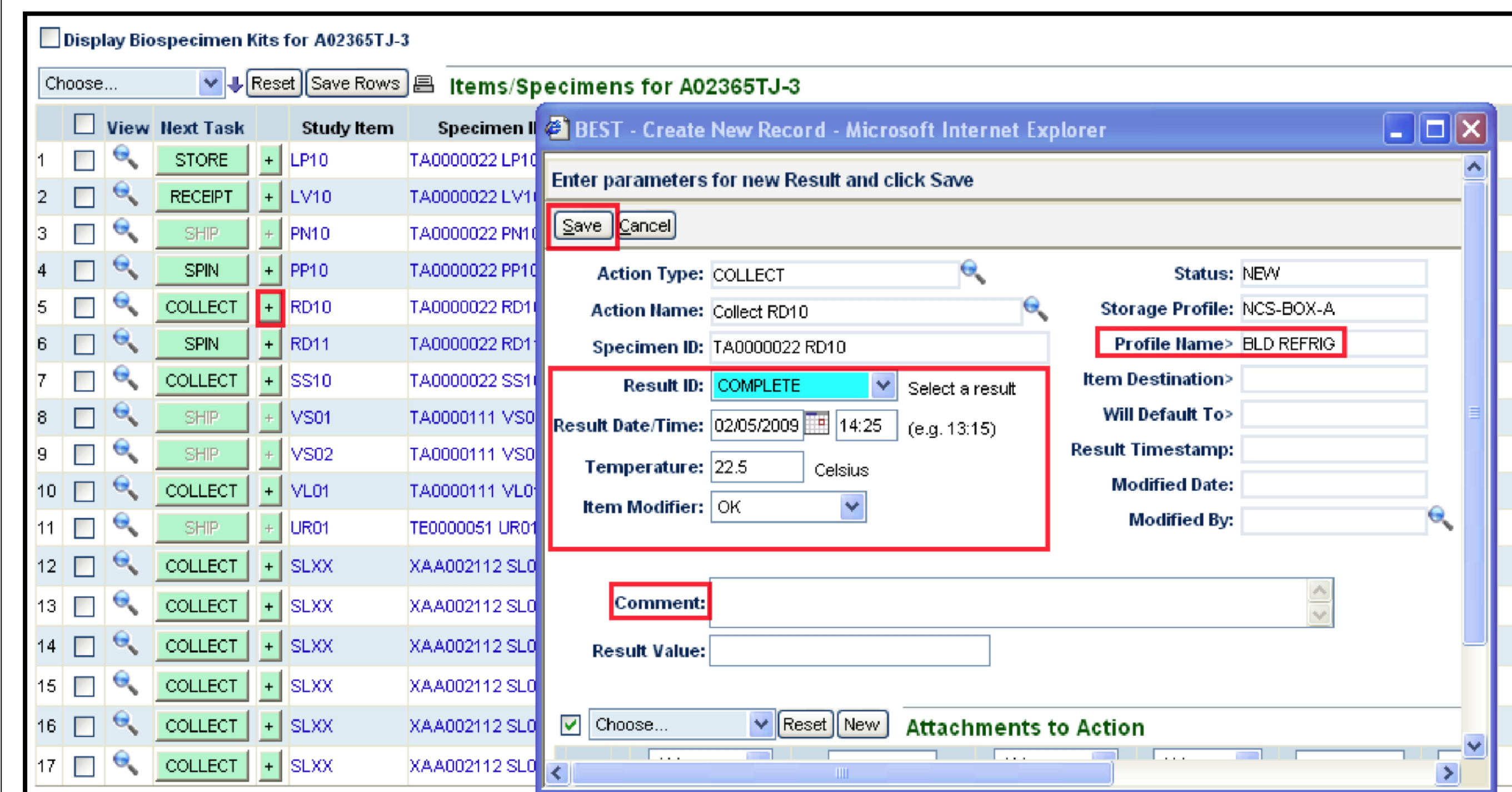


**Individual Information:** Collection and receipt data for individual specimens, such as damaged primary collection containers, are captured through the result parameters screen associated with each specimen action (collect, receipt, spin, store, ship).

## Capturing and Recording Processing and Storage Related Information in BEST
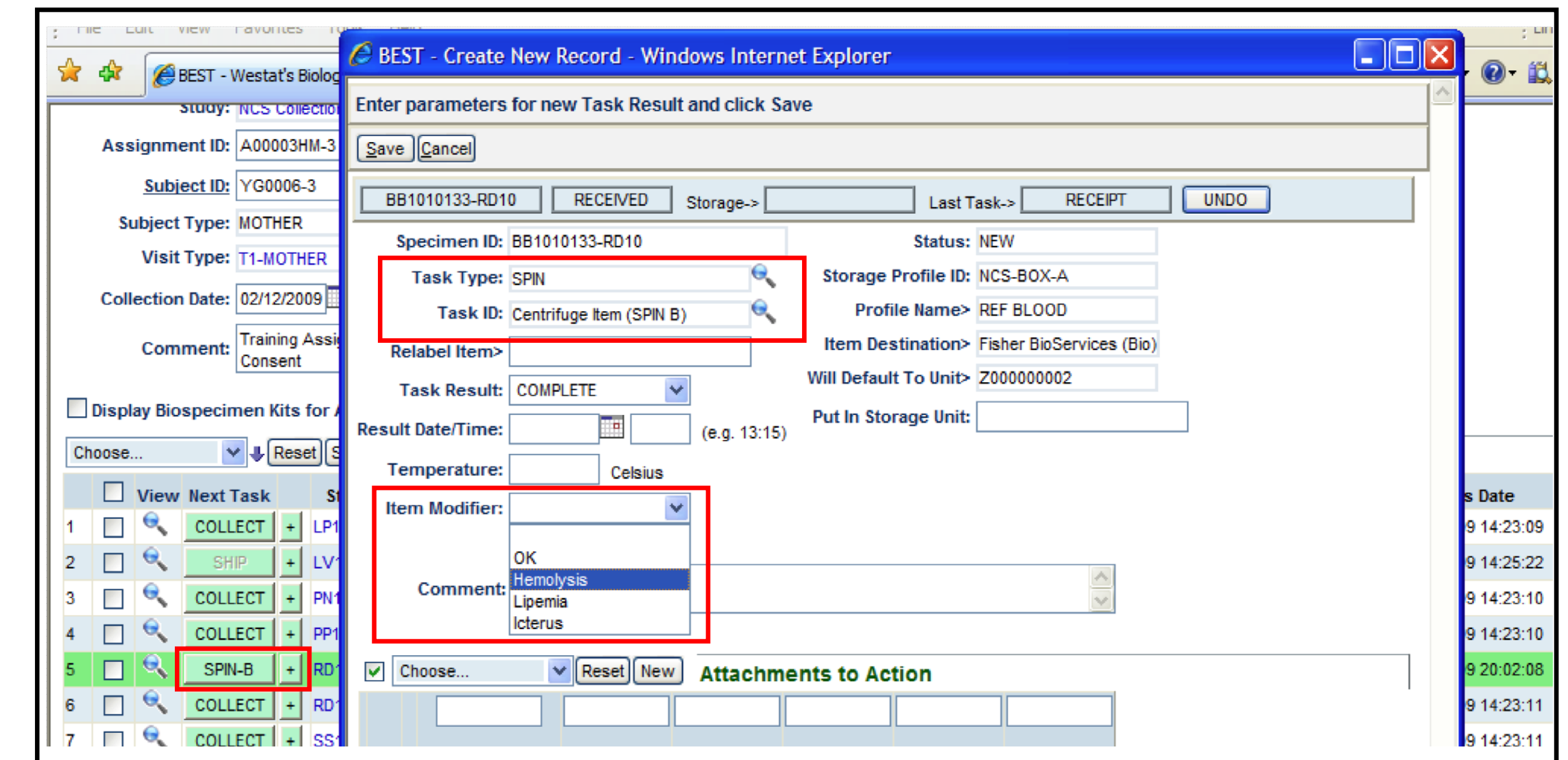


**Individual Information:** Processing data for individual specimens, such as hemolysis or centrifugation temperature, are captured through the result parameters screen associated with each specimen action (collect, receipt, spin, store, ship).
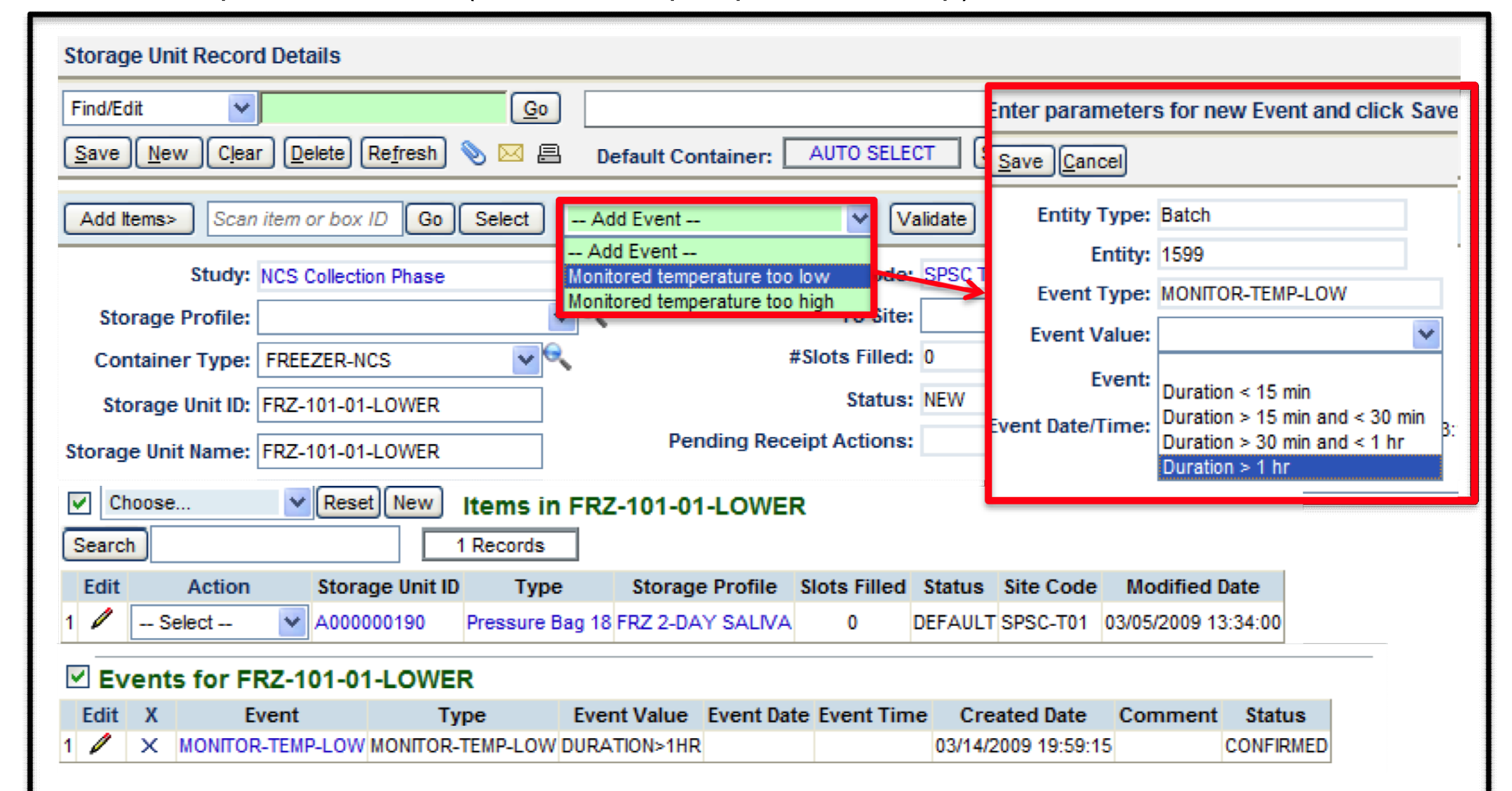


**Aggregate Information:** Storage data and related temperature events for "storage units", such as freezers and refrigerators, are documented in BEST and applied to all specimens in the given location at the time of the event.

## Annotating Specimens for Analysis and Reporting Through WesDaX
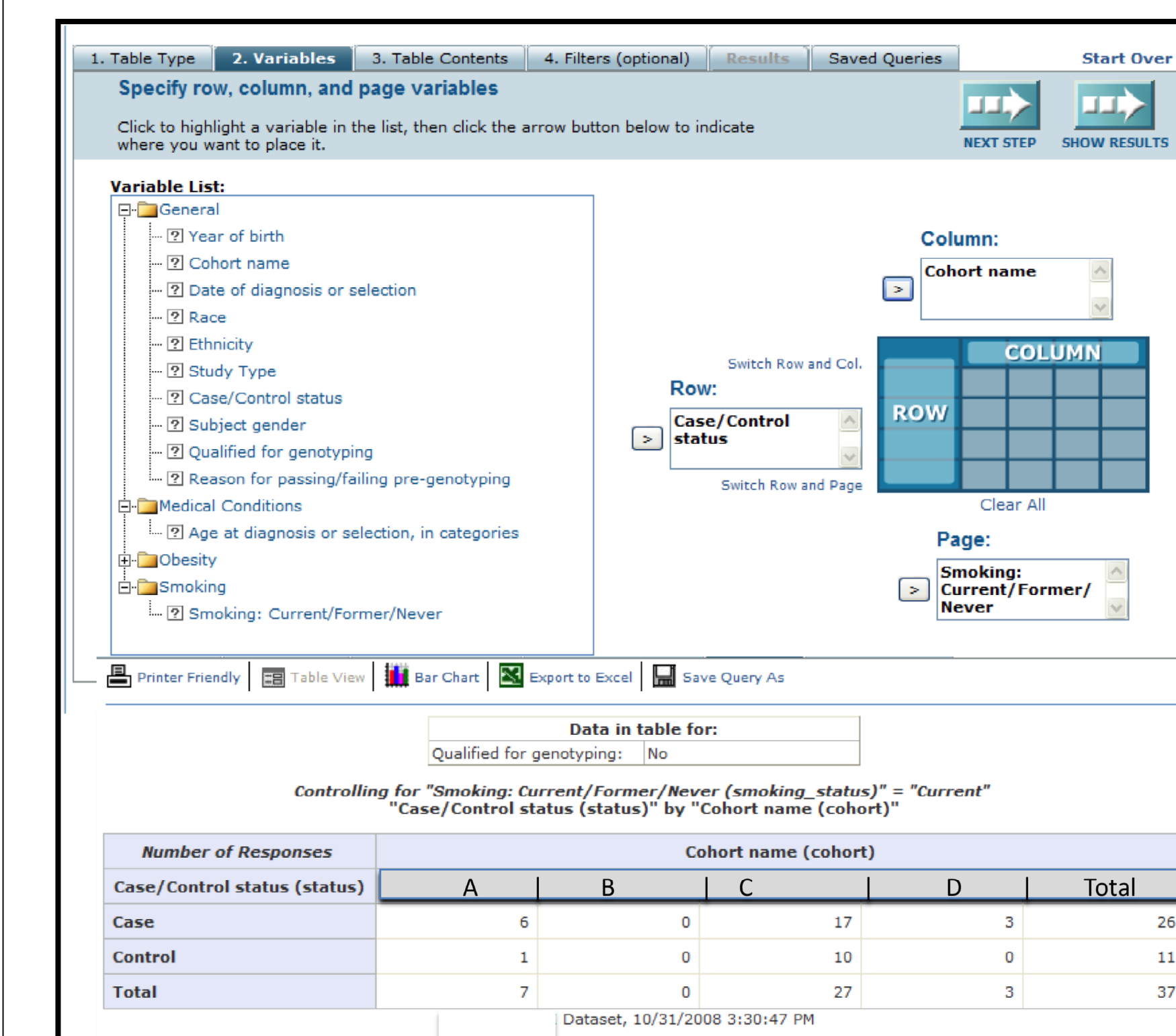


**Aggregate and Individual Information:** WesDaX can be configured based on user defined needs to provide summary specimen related information for data exploration, analysis, and reporting. For example, information about the number and types of specimens that experienced out-of-range temperatures during 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.