



## **Use of Freezerworks in Epidemiological Studies**

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1999

As clinical researcher with the Research Triangle Institute my job has been to manage large-scale epidemiological studies related to infectious disease, primarily human viruses. Research Triangle Institute is an independent nonprofit organization performing research in many disciplines for government, industry, and other clients throughout the United States and abroad. Incorporated in 1958 by University of North Carolina, North Carolina State University and Duke University, RTI concentrates on public health, medical research, environmental protection, advanced technologies, and policy issues such as education and economic development.

A few years ago, I became aware of a serious situation in one of our collaborator's laboratory. We had valuable data recorded in logbooks and irreplaceable samples stored in unreliable freezers- two very insecure places. In an effort to find a solution, I became involved in a research project I was unaccustomed to—finding software to track these samples. Researching the market for useful yet affordable software for this task was eye opening and educational in its own right.

We have been supporting human retrovirus research in Trinidad for the National Cancer Institute (NCI) since 1985. During that time, we have accumulated nearly 35,000 patient samples. These invaluable samples represent years of vital epidemiological research. While thousands of samples are being transferred to NCI repositories on the U.S. mainland, many remain on site in Trinidad, accessible to the scientists working there. We saw a tremendous need to act quickly in order to preserve and catalog this sample collection for future research use.

The problem was two-fold however. First, the samples themselves were stored in mechanical freezers located throughout the facility. Second, the sample data were recorded in logbooks with various entries made by technicians who no longer worked in the laboratory. If a logbook was destroyed or lost, or a power failure caused a freezer to break down, valuable data and samples would be irretrievably lost.

To solve the first problem, we purchased a liquid nitrogen freezer. It was set up to house all of the samples within footsteps of the high security laboratory where the sample processing and testing were being done.

### **Cataloging the Samples**

The other pressing need, cataloging the samples into a computer database, was more difficult to solve. In addition to the basis criteria of storing data and vial locations, the software needed to contain some unique features as well. For example, since many samples would be transferred to the NCI repository in Rockville, MD, the software needed to be able to create shipping data files that would accompany the samples to the repository. Because these files would then be uploaded to the NCI mainframe computer system that tracked the specimens stored there, the files needed to be compatible with this mainframe system.

I began to search for a software firm that offered such a program. My contacts at the National Institutes of Health and the Centers for Disease Control led me to a few highly regarded inventory system for a large repository in the Washington D.C. area. We discussed our needs with these firms and requested price estimates. The best proposal came in at \$57,000.

I was stunned at the price of the software, but many colleagues informed me that software development was expensive, especially when it involved custom work. As my research continued, I began to fear there were only two available choices: either opt for custom work and pay a high price, or buy a cheaper off-the-shelf package that was limited in scope and couldn't meet our customized needs. Hoping to find an alternative, I began to make phone calls to laboratories and repositories I had been associated with in the past. Surely they were using something that didn't cost an arm and a leg, I told myself. During my phone research, I began to hear the name of a certain program, Freezerworks.

Freezerworks, a freezer inventory database program is written by Dataworks Development (Seattle, WA). The technicians using the program appeared to be quite satisfied. I contacted Dataworks and saw that just about everything I needed was included in the package. However, there was still the issue of modifying it to include exporting features in order to transmit data to the repository. I called Dataworks and was again surprised to learn that they were very willing to customize their product to meet my specific needs. After working out the details, the final price for Freezerworks, including customization represented a saving of at least \$50,000 for a program that Dataworks informed me was written in accordance to FDA guidelines for software development. The project was completed in a matter of a few months, and the program is installed and working to my complete satisfaction.

### **Modifying the Software**

Freezerworks uniquely identifies each specimen by a specimen ID/storage type/"key" date combination. This identification system allows our laboratory to differentiate between the serum and plasma (storage type) samples generated from the same specimen.

The “key” date can be renamed—in our case, we renamed it “draw date.” And selected the European day/month/year date format. Besides these three specimen identifier fields, a user can configure the specimen entry screen to include nine additional data entry fields and three additional date fields. These fields can be selected, named, and configured to meet special edit criteria at the User-Defined Fields configuration screen. The screen is password protected so that only a system administrator can access it. For our purposes, we use five of these additional user-defined fields. In addition to specimen ID, storage type and draw date, we track:

1. The subject ID (patient identifier). This serves as a link between the storage system and the patient record system.
2. A specimen viability number that indicates the percentage of viability of lymphocytes in the sample.
3. The study ID, which indicates the site where the investigation/research took place.
4. A material modifier that reports which anticoagulants were added to the sample.
5. A shipping flag—a simple “yes/no” field indicating whether or not the sample has been flagged for shipment to the NCI repository. This field can only be viewed for reference at the entry screen, since flagging for shipping is done at another screen.

To ensure data integrity, we defined various edit checks for these fields at the configuration screen. An edit is a parameter(s) placed on a field to determine and control the type of information a field can receive. there. For example, some edits only allow numbers to be entered into a field, while others only allow alpha characters to be entered. Incorrect entries are rejected. The edit feature is important because it ensures that the samples shipped to the NCI repository match the requirements of the repository software system in place there.

### **Using the System**

After samples are processed and ready for storage, the technician enters the necessary data, either from a logbook or directly into Freezerworks. After entering the specimen information described above, the laboratory technician enters the number of vials extant for each unique sample ID. The vials are then assigned to one or more freezers, all from the same screen. A running total of specimen volumes/or number of cells is tracked, as well as number of thaws. Information of any vial transferred to another facility can be tracked through the vial transaction screen. A shipped vial can have a date, destination, and length of thaw stamp entry. A special “batch update” option allows our laboratory to select a number of samples we have flagged for shipment, and then enter the identical transaction stamp for all selected samples in one process. This is a real time saver.

Our customization was limited to reconfiguring the specimen ID to match the NCI repository system. Also, a special shipping menu was created for flagging specimens to

ship to the NCI repository. Samples are flagged by selecting a batch stored in a certain place in a freezer, or by selecting from a range of specimen identifiers, study identifiers, or draw dates. Flagged specimens are then included in a shipping manifest and a computer file for easy upload.

After the shipping manifest is created, the program prompts us to indicate whether we want to delete the current freezer locations. A “yes” response allows us to free up the freezer space, while keeping the specimen data. Thus, we can keep vital information on samples that we have shipped to the repository in case we need to refer back to it for any reason. This feature is a tremendous help in tracking the history of transferred samples if we need to search for information later. We can quickly tell whether they were shipped off site, and if so, when.

## **Conclusion**

The process of searching for freezer inventory software taught me some valuable lessons. First, there is no need to re-invent the wheel. Many people don’t need a system built from scratch to address their specific needs. Moreover, a software package should not be rejected because it isn’t designed for you personally. It is a misconception that a non-customized program is a lesser choice. Second, if you need customization, it is easier and more cost effective to have the company that wrote the program customize it for you. Lastly, expensive does not necessarily equal “good.”

The bottom line is that many of the 35,000 samples now catalogued in our Freezerworks database are increasing in research value, especially as patients die from very rare diseases and as new virologic/immunologic assays are developed. Locating those samples now using logbooks would be a frightening prospect.