INTRODUCTION

The integrity of biological samples collected for clinical trials is vitally important both pre- and post-trial. The reasons for systematic biostorage are varied: Samples may need to be re-tested for regulatory compliance, data or drug-safety issues, or as part of a future genomic or biomarker research initiative. In an era when significant scientific advances can be realized in post-analysis, methods for ensuring high-quality, properly preserved patient samples have become even more critical.

Although research has shown that standardizing the sample management process creates cost efficiencies, shortens timelines and improves sample integrity, many organizations remain reticent to adopt such procedures. It remains an industry norm to have multiple therapeutic programs with samples distributed across multiple laboratories without a centralized tracking system. This behavior often leads to delays in finding and shipping necessary materials, increases the risk of diminished sample integrity and results in (avoidable) additional cost.

Due to the high cost of collecting a sample in the clinical setting (as a percentage of total trial cost), the loss of a single sample represents a significant financial loss if its integrity is compromised. (This is in addition to negatively affecting the statistical reliability of the clinical trial.) Additionally, quantifying the potential value of the lost data to some future scientific research is indeterminable. Clearly, the appropriate strategy is to invest in safeguarding the integrity of each clinical sample from the outset.

In order to ensure that samples are maintained under correct conditions (from collection through post-trial storage), LabConnect has developed a comprehensive system to digitally track and monitor each individual sample in real time, 24/7/365. The SampleGISTICS™ sample tracking system simplifies monitoring the process and keeping the plan on track. Once implemented, the system begins tracking samples as soon as they have been collected at the investigator site and assigns them a unique accessioning number that will be used throughout the life of the sample.

Niche capabilities, such as sample tracking systems, focus on monitoring the viability of individual sample assets and consolidate sample data within a single, centralized database that is accessible to the R&D customer. LabConnect is unique in the research industry because we offer the unique combination of a network of global central laboratories for sample testing, logistics management services AND advanced biorepository facilities for long-term post-trial maintenance. Once the Sample ID# is in the SampleGISTICS™ system, any sample can be easily tracked within our network (anywhere in the world) on a multitude of computer and “smart” devices.
COLLECTION AND LOGISTICS
The operating environment in a highly regulated industry, like that of biopharmaceuticals, requires documented compliance. Extreme care must be taken to provide monitored shipping kits and to follow pre-defined logistics processes that ensure that clinical samples are transported safely and efficiently within a narrow temperature range. Prior to first patient, first visit (FPFV), the investigator site list should be evaluated to determine if specific locations should be subject to a logistics dry-run shipment, enabling an opportunity to develop alternative logistics solutions and avoid potential problems.

SampleGISTICS™ is continually updated with real-time data at every stage in a sample’s life cycle, from collection to analyses to immediate retrieval and shipment. The information is documented and securely available via LabConnect’s Web-enabled client portal.

SAMPLE STORAGE AND RETRIEVAL
Safeguarding your valuable assets by using an advanced sample storage facility is only one aspect of what is required for effective biostorage. Quick and efficient sample retrieval is also often required (as requested by a regulatory agency or by a researcher for additional post-trial analysis).

Modern biorepository facilities ensure samples are documented and maintained in full compliance at all times through the utilization of validated storage units, continuous temperature and humidity monitoring, automated alerts and complete redundant backup. If a sample is requested, the aliquot-specific tracking system within SampleGISTICS™ provides a clear audit trail to identify the precise location of the requested sample for immediate retrieval and shipment.

GOOD STORAGE PRACTICE
The biopharmaceutical industry has begun to recognize a number of Good Storage Practice (GSP) standards (not yet formalized by the FDA). Chief among them are standardization and compliance with a defined set of protocols that serve to ensure consistent handling and storage of all samples, and an information management system (such as SampleGISTICS™) that provides validated audit trails. Other areas addressed by these GSP principles include operational standards for cold chain logistics and business continuity.4

STANDARD BIOREPOSITORY CAPABILITIES
Samples should be secured in a modern biorepository facility and subjected to continuous monitoring to ensure sample integrity and regulatory compliance. Detailed standard operating procedures (SOPs), a full contingency plan and a comprehensive sample tracking system should ensure research samples are accessible. SOPs should incorporate these basic parameters:

- Specimens should be logged into the relevant databases
- All refrigerators and freezers must be temperature controlled/monitored
- Backup systems must be available at all locations (including backup generators and backup refrigerators and freezers)
- Electronic manifests should be created for all outbound shipments

CONCLUSION
Preserving the integrity of scientific assets has become increasingly important as these valuable materials may also support biomarker discovery projects, personalized medicine efforts and the development of other, yet-to-be-determined, genomic-based treatments.

Comprehensive planning for both the short- and long-term storage of samples collected during clinical trials will benefit both current and future R&D efforts. Implementation of a documented biostorage plan with a compliant facility includes developing the proper protocols to enable tracking and monitoring of samples at each stage of its life cycle and to ensure clinical compliance and maximum sample lifespan. The SampleGISTICS™ sample management system provides an easy-to-use Web-based interface and a full complement of advanced capabilities to support these requirements including:

- Real-time tracking from the point of collection
- Virtual accessioning
- Virtual sample management
- Increased control of shipping logistics and costs
- Multiple-user Web access
- Customizable reports
- Chain-of-custody tracking
- Sample data integration


LABS WITHOUT BORDERS, SERVICE WITHOUT LIMITS
LabConnect provides global central laboratory services, including routine and esoteric laboratory testing, kit building, sample management, biorepository and scientific support services for biopharmaceutical, medical device and contract research organizations. A true partner, LabConnect supplies focused, client-inspired, clinical development services from sample collection through storage and beyond.