



Excellence in Oncology Clinical Trials

We create innovative solutions for our sponsors' oncology clinical trials. Whether it's a comprehensive centralized service approach or global coordination of data from locally performed testing, ICON Central Laboratories can help.

ICON Central Laboratories has provided central laboratory support and local laboratory result coordination for hundreds of oncology studies in over 55 different countries. Our experience includes the following oncology indications:

Bone	Gastrointestinal	Melanoma	Prostate
Brain	Head and Neck	Multiple Myeloma	Renal
Breast	Leukemia	Ovarian	Skin
Chemoprotective Agents	Lung	Pancreatic	Solid Tumors
Colorectal	Lymphoma	Peritoneal	Thyroid

An Extensive Test Menu that Includes Biomarkers and Custom Assays

ICON Central Laboratories provides standard platforms in North America, Europe and Asia to support the global needs of Oncology clinical trial sponsors.

We offer a broad range of assays to monitor key Oncology therapeutic molecules, targets and receptors, such as:

- Angiogenesis
- Chemokines
- **Circulating Tumor Cells**
- **Global Flow Cytometry**
- Immunomodulation
- Multiplex Protein Expression
- Oncology Vaccine Response Testing
- **Pathology**
- Tumor Markers



A Focus on Local Laboratory Results

When pharmaceutical and biotechnology companies conduct clinical trials in oncology, they often face special challenges. Collecting and cleaning local laboratory results is resource intensive, reactive, re-iterative and prone to rework.

ICON Central Laboratories (ICL) now offers **iRIS** (ICON Results Integration Service), an innovative system that compiles, cleans and manages local laboratory result data. Developed in response to the special challenges our clients faced when conducting global studies, utilizing local laboratories, iRIS provides an efficient solution for receiving and combining data from multiple laboratories into one central database, facilitating streamlined analysis and an expedited regulatory submission.

iRIS provides full service management of local laboratory data, with:

- Investigator site setup and management
- Established systems built to capture demographic and study specific requirements
- IT infrastructure with worldwide toll free faxing
- Entry of results from imaged source data by lab experienced staff
- Imaged file management
- Built in system checks for logical results
- Mapping of results from performing laboratory
- Laboratory results and ranges sent to Sponsor
- Management of local laboratory certifications and accreditations
- Metrics and tracking reports



Support for Locally Performed Flow Cytometry

For sponsors with studies utilizing locally performed flow cytometry services, ICON Central Laboratories can provide added support. Using validated data transmission software, developed specifically for transmission and review of raw data produced from flow cytometers, our Flow Cytometry Department can:

- Receive the locally produced flow data;
- Gate the data to the sponsor's specifications; and
- Generate a single test result database that can be used for the statistical analysis and the regulatory submission.

This approach optimizes specimen integrity while providing the gating consistency and central database so critical to quality, efficient analysis.

Quality is a Key

Rigorous quality control is an important part of ICON Central Laboratories' custom flow cytometry service. Our quality control program includes:

- Utilization of eight-color instrumentation and identical testing platforms in our U.S., Bangalore, European and Singapore laboratories to ensure standardized results;
- Use of same lot number or custom preparation of antibody reagents to maintain consistency of signals;
- Thorough training of all laboratory personnel performing the test to ensure strict compliance with the SOP;
- Use of beads, human cells and cRBCs to calibrate the instrument so that any shifts in signals can be readily identified and traced to their source;
- Two levels of laboratory review and confirmation prior to releasing test results.

For more information regarding our central laboratory services for oncology clinical trials, visit www.iconplc.com, or email us at labinfo@iconplc.com.



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