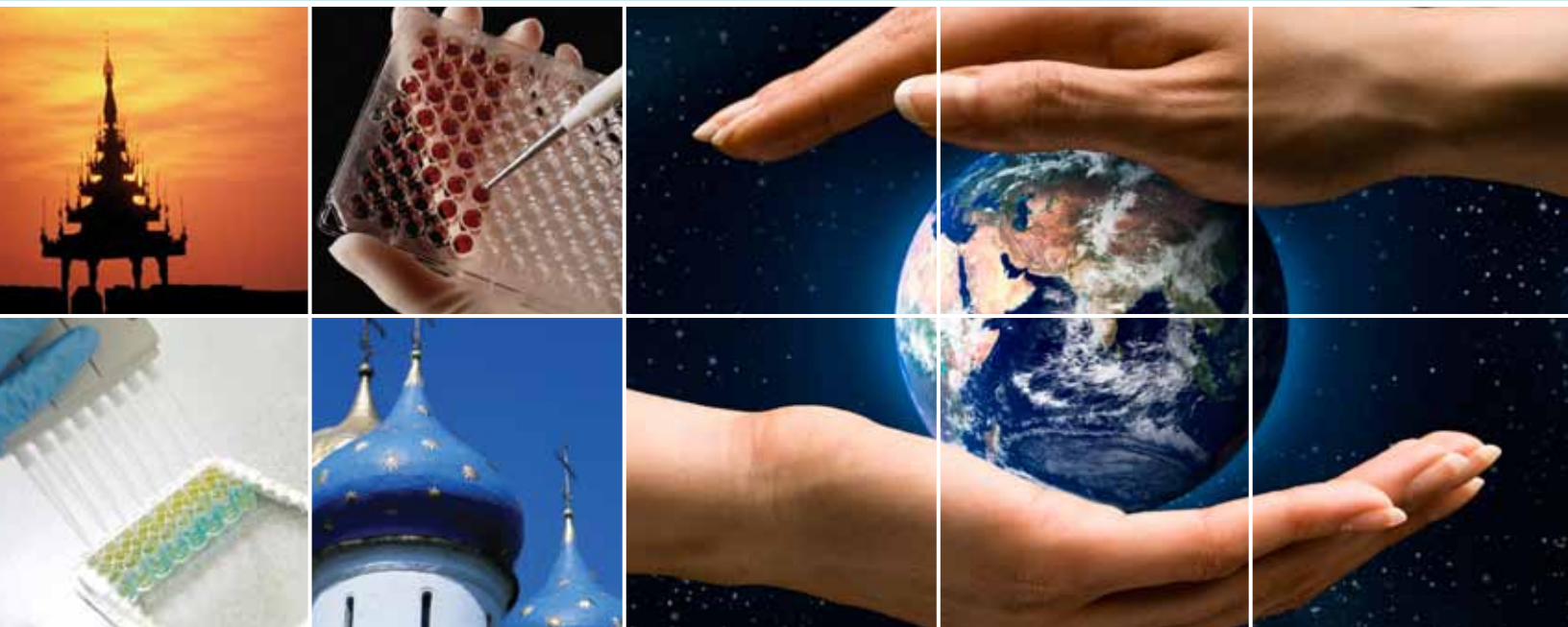




A Symbol of Excellence

Central Laboratories



# The Value of **ONE**

At ICON Central Laboratories we have one mission – providing stellar custom global laboratory service to the pharmaceutical and biotechnology industry.

This one single commitment to what we do is important to our clients – as is how we achieve quality results for them everyday by keeping **ONE** in mind.

## ONE Global Point of Contact Backed by Many Regional Resources

From our extensive experience managing global clinical trials we know that streamlined communication and timely follow-up are critical elements to success.

When you select ICON Central Laboratories to support the laboratory component of your global study you will work directly with one Global Project Manager. Your Global Project Manager will work with a team of regionally based staff to coordinate every facet of your study from custom setup and logistics planning to daily query resolution, and final data lock. In short, your Global Project Manager will make your life easier by offering one central point of contact for you and/or your CRO.

You can rely upon your Project Manager to:

- Work closely with you and your project team to plan and document all laboratory requirements and custom reporting services for your study, using our comprehensive study setup document known as a Client Laboratory Worksheet;
- Manage all setup activities to ensure that the study database, laboratory supplies and investigator site training meet project expectations and timelines;
- Present laboratory requirements and procedures at your investigator meeting;
- Participate in project team meetings and conference calls;
- Keep you and your team apprised of any issues that may arise, along with plans for resolution and monitoring;
- Supply study metrics to monitor key performance indicators and overall study progress;
- Work closely with our Site Support staff to ensure concurrent monitoring and resolution of data queries;
- Conduct all study closeout activities for timely data lock and final data submission.

And while we ensure that every aspect of your study is coordinated and communicated centrally through your ICON Central Laboratories Project Manager, we don't forget the importance of regional support. Every global study also has regionally based Project Managers who work daily to track study status and respond quickly to regionally based CRAs and sites. These activities are coordinated and reported through your Global Project Manager.



## ONE Source for Testing and ONE Standard Testing Platform

As a laboratory dedicated to clinical trials, ICON Central Laboratories' global laboratory team, led by MDs and PhD level scientists, is committed to providing virtually all testing services required by our clients in our own facilities. Over 98% of the testing services study sponsors require are performed in ICON Laboratories' facilities. In addition to our extensive menu of safety testing and biomarkers, we are a recognized industry leader in the setup, validation and performance of custom flow cytometry assays.



ICON Central Laboratories owns testing facilities throughout the world so we can offer our clients standardized testing platforms with consistent test methodologies and result reporting. Our laboratories are accredited by the College of American Pathologists and hold numerous other regional licenses and certifications. We are particularly proud to have been one of the first laboratories in the central laboratory industry to obtain ISO 17025 certification.

## ONE Global Site Support Service to Respond to Investigator Sites

ICON Central Laboratories has served thousands of investigator sites in over 70 countries. We realize that the quality results we produce for our sponsors are largely dependent upon the quality of support we provide to their sites. That's why we've structured our global Client Services Department to respond to our sites seven days per week, with the ability to track and follow up on data queries and site questions using one globally accessible site management database.



## ONE Global Database with Secure Client Access

The ultimate service we offer our clients is clean, timely laboratory and related demographic data. ICON Central Laboratories' Information Technology (IT) and Global Data Services Departments meet this important client need via our own proprietary global IT system. This system captures and manages all custom study parameters, laboratory results and demographic data in one comprehensive global database.

While offering clients one global repository for study data with multiple data formatting and delivery options, the system architecture utilizes the latest technology with respect to system security, data redundancy and disaster recovery.



ICON Central Laboratories also offers clients a secure, web-based, remote data access tool known as ICOLabs™. This proprietary software is fully supported by our Information Technology Department and provides clients an easy-to-use, yet powerful system that features:

- Comprehensive filtering criteria using drop-down menus;

- Custom views and reports that can be generated and saved by the user to meet study management, clinical safety or site monitoring needs;
- Study and subject trend reports that include both numeric and graph displays;
- A menu of standard reports, based upon client input;
- Ready on-line access to each study subject's visit-specific laboratory report;
- Easily accessible investigator contact information for streamlined follow-up with sites;
- Kit inventory reports to better track supply levels at investigator sites;
- Frozen specimen reports that track storage and shipping status at the container level;
- Ability to export and save reports in Excel formats.

## ONE Quality Standard and Process

Our goal is to provide custom laboratory and related study management services while ensuring quality, consistency and full regulatory compliance through one quality standard and set of operating procedures.

Our global Quality Assurance Department works closely with each department to document and monitor adherence to global procedures. In addition to hosting numerous sponsor visits and audits each year, our Quality Assurance Department conducts rigorous internal audits to ensure that our commitment to one quality standard and process is achieved.



## Finding That ONE Unique Solution to a Study Challenge

While standard processes are a key feature of our service, so is working with a client to identify the one best solution to a unique study challenge. Our clients tell us that our willingness to seek innovative ways to respond to unique situations is a major reason they select ICON Central Laboratories as their service provider.



Here are just two examples of how we helped our clients find that one best way to solve a special study challenge:

- A major global pharmaceutical company was challenged by the need to compile test results from hundreds of laboratories around the world. We created a global fax network to receive the local lab reports, then compiled the local lab results in a central database that could be readily accessed by medical monitors to review subject safety. This system also cut the data analysis time significantly and expedited the regulatory submission.
- A large biotechnology company had to expand the number of investigator sites to include study subjects in more geographically remote countries. The study required WBC phenotyping and measurement of a series of cell surface markers for samples that could not be frozen and had limited stability periods. Our scientists collaborated with the client to set up and validate special testing services to support this unique need.

## Knowing When ONE is Not Enough

As much as we value what “one” can bring to the central laboratory service we offer our clients, we know there are times when one just isn’t enough to ensure excellent service. That’s why we offer:

**More than one laboratory location...**with ICON-owned facilities in North America, Europe, Asia, India and China.

**Investigator Site Support in more than one language...**with an immediately accessible language line for calls to our global Site Services Department.

**More than one approach to reporting lab results...**with flexible reporting options in conventional as well as standard international units and a variety of abnormal result flagging features.

**For more information regarding our central laboratory services, please contact:**

**More than one database format...**with Global Data Management specialists available to provide sponsors with custom data formats.

**More than one way to seek client and site feedback...**by encouraging routine input through annual surveys of both our clients and their sites to learn more about what we can do to provide new and better services.

**When it’s time to select a global provider of quality, custom central laboratory service, we hope you’ll make ICON Central Laboratories the ONE.**

For more information regarding our central laboratory services, visit [www.iconplc.com](http://www.iconplc.com), or email us at [labinfo@iconplc.com](mailto:labinfo@iconplc.com).



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