



Innovative Data Support

A Focus on Local Laboratory Results

At ICON Central Laboratories our mission is to establish collaborative, long-term relationships with our clients by developing innovative solutions to meet their unique needs. This commitment includes providing comprehensive data support for clients when their studies require the use of local laboratories.

When pharmaceutical and biotechnology companies conduct clinical trials in oncology, infectious disease or other therapeutic areas involving more acutely ill study subjects, 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.



A More Efficient Process

iRIS provides full service management of local laboratory data with:

- A central result repository and point of coordination
- A system using ICON Central Laboratories' core competencies to help sponsors:
 - Compile and concurrently clean local laboratory result data
 - Better monitor the clinical status of study subjects
 - Receive local lab reports from sites around the world
 - Obtain timely, secure access to local lab data in useable formats
 - Expedite data analysis for regulatory submission

Figures 1 and 2 provide a comparison between a Typical Data Process Flow and one using the iRIS Detailed Process Flow. This comparison illustrates how the process is simplified through the implementation of iRIS.

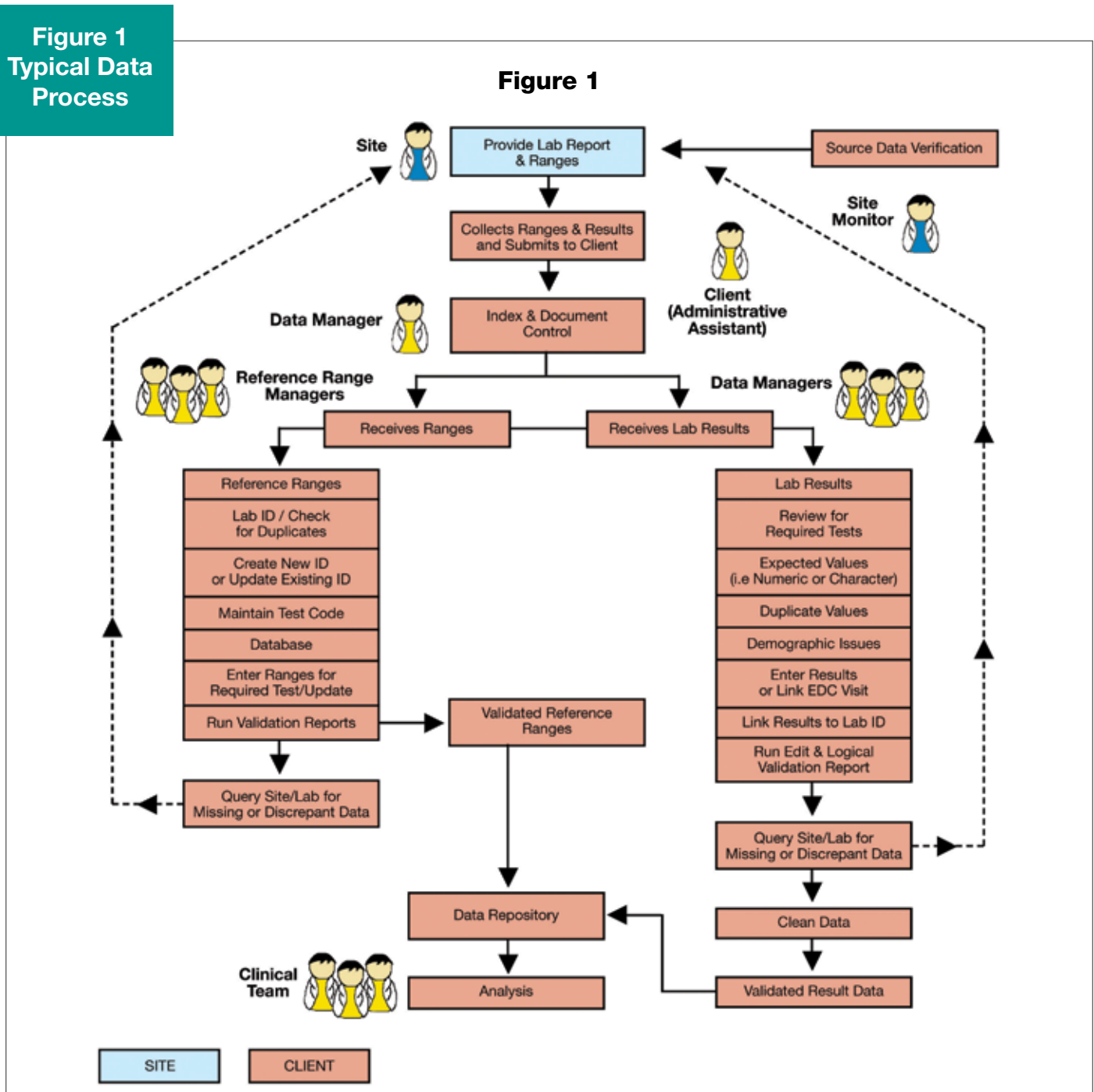
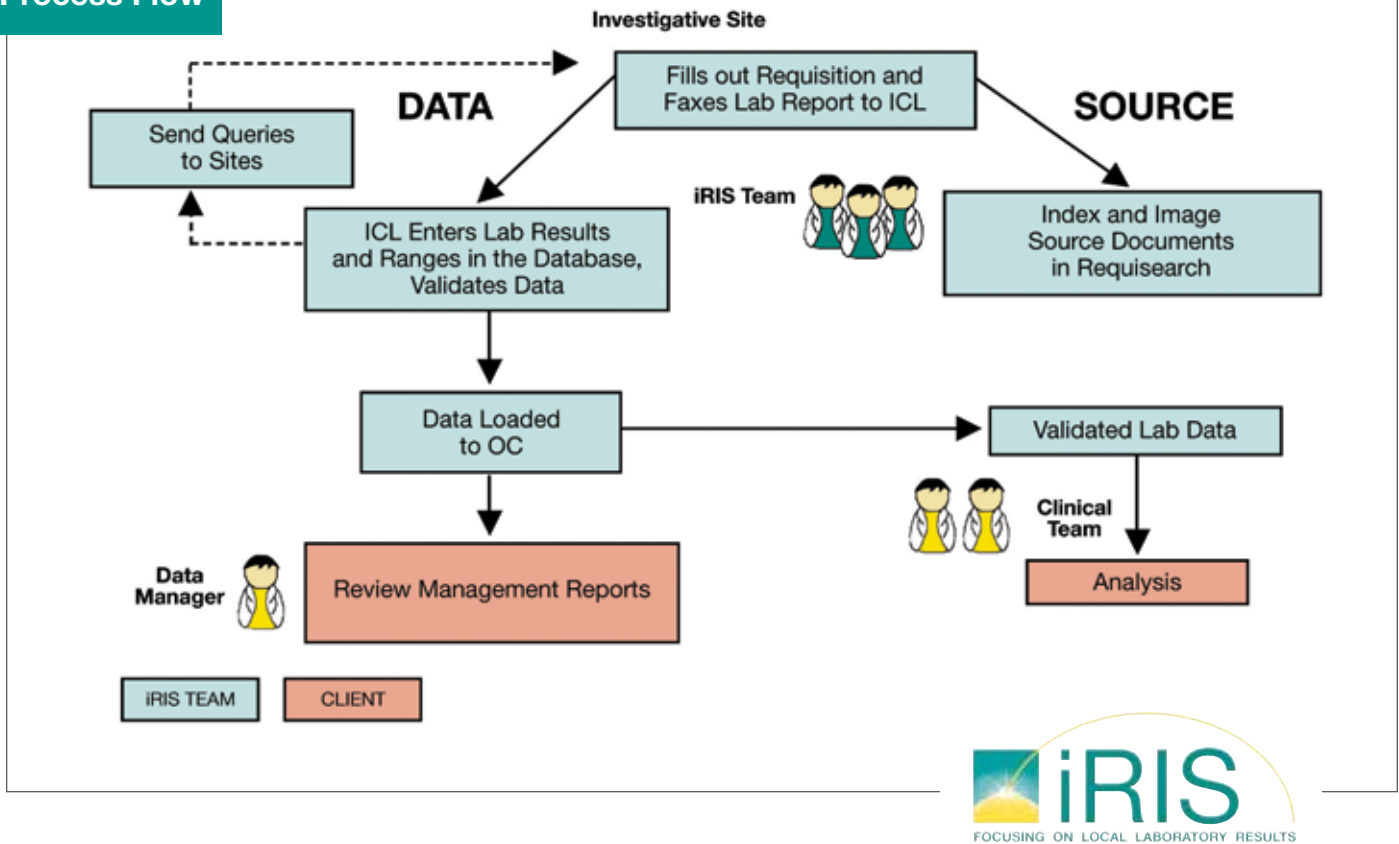


Figure 2
iRIS
Detailed
Process Flow

Figure 2



iRIS From a Client's Perspective

ICL has been selected by some of the world's largest pharmaceutical and biotechnology companies to support their local laboratory data integration needs.

Having used iRIS services for four years to manage test results from local laboratories in over 40 countries, one study sponsor summarized their experience with this special service stating that ICL made a real difference in managing their global clinical trials.

Why They Chose iRIS

- Eliminated the manual entry of lab data in their system
- Limited the number of lab reference ranges collected by site monitors (or CRA's) and processed by the sponsor
- Eliminated source data verification
- Reduced the number of queries sent to sites
- Significantly reduced use of in-house personnel for data cleaning data due to improved data quality

How We Benefited from iRIS

- Access to indexed database of source documents
- Weekly e-mail notification of visit information to sites
- Weekly metrics provided to track study progress
- Language translation support for test results
- Flexible data transfer schedule
- Archival services for lab reports

Benefits of Collaboration with ICL

- Joint project planning and development
- Improved documentation to support study processes:
 - Client Laboratory Worksheet (CLW)
 - Laboratory Requisition
 - Laboratory Manual for Sites
- Comprehensive training of sites and monitors
- A better overall working relationship with the central laboratory

iRIS Benefits Beyond Data Management

In addition to improving data management efficiency, iRIS streamlines the work of the sponsor's clinical development team and the investigator sites.

Benefits for Outsourcing

- Allows ease of contracting with one agreement for both central and local service.
- Extremely cost effective.

Benefits for Sites

- CRF completion is simplified with transcription errors eliminated.
- In many studies, there is no need to split samples.

Benefits for Safety and Medical Monitoring

- Test results more readily available to safety group.
- Ability to readily view subject's clinical trends.

Benefits for CRAs and Project Manager

- Missing or discrepant information handled by iRIS.
- Accreditation documentation maintained by iRIS.
- Less documentation to review during a site visit.

Benefits for Data Review

- Standardized method of entering and reporting data to client specifications.

- Standardized results for the same test, that may be reported differently throughout the world.
- Guidelines are updated by client as required.
- Accessible to both the client and the site on a secure website.

The iRIS Advantage: An Overview of iRIS Services

iRIS is truly a full service offering, providing comprehensive support for managing local laboratory data, including:

- 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

For more information regarding local laboratory management or other central laboratory services, visit www.iconplc.com, or email us at labinfo@iconplc.com.



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