




# Local Laboratory Data Management

A solution for clinical trials needing local testing

Local laboratories are commonly on site or close to the investigator site, and are often utilized in a clinical trial when data is needed immediately for treatment or randomization. Geographical location, stability issues and other factors often necessitate local laboratories. The number of local laboratories varies by study: it is estimated that a late phase study might utilize >500 local laboratories.

Managing local laboratories can require extensive Clinical Trial Management and sponsor oversight. There are several things to take into consideration: laboratory reports vary greatly across the globe; remote laboratories and investigator sites may not have IT support; and, point of care testing can involve remote testing or satellite laboratory testing at or near a patient. Therefore, it is essential to manage all the local laboratory data.

When your trial requires local or point-of-care laboratory testing, managing the resulting data can be a significant challenge and burden to you and your sites. Some of the challenges faced include the following:

Challenge	Situation	Impact
 <b>Vendor management</b>	<ul style="list-style-type: none"> <li>Each investigator site may use a different laboratory (and possibly more than one)</li> <li>Large global studies may use several hundred local laboratories</li> <li>Reference ranges and units are gathered separately from results</li> </ul>	<ul style="list-style-type: none"> <li>Requires additional staff to oversee 100s of laboratories in addition to sites</li> <li>Translation of local laboratory results and reference ranges is difficult</li> <li>Testing methodologies are inconsistent globally</li> </ul>
 <b>Site personnel and CRA time</b>	<ul style="list-style-type: none"> <li>Investigator site personnel must enter laboratory results into the database or CRF</li> <li>CRAs required to follow up on ranges and unit updates</li> </ul>	<ul style="list-style-type: none"> <li>Increased burden on sites and CRAs</li> </ul>
 <b>Data consistency</b>	<ul style="list-style-type: none"> <li>Investigator site personnel may not have laboratory/scientific knowledge; not trained to catch errors</li> </ul>	<ul style="list-style-type: none"> <li>Results inaccurate</li> <li>Additional queries, delays in data lock</li> </ul>

Q<sup>2</sup> Solutions offers a local laboratory data management solution that takes the challenges and inconsistencies out of managing local laboratory results in a clinical trial, allowing you to focus on clinical outcomes while the Q<sup>2</sup> Solutions team puts their experience to work for you.

sponsors. This allows the investigator sites to concentrate on patient care.

Using the Q<sup>2</sup> Solutions Investigator Portal, sites complete requisitions and simply upload a copy of their laboratories' reports via the website. For sites without access to the internet, we can accommodate email, fax and hard copy reports. Toll-free fax lines are available wherever possible and local low-toll lines everywhere else.



**No data entry required:  
Simply forward the reports**

Our systems help streamline data capture, reduce errors and minimize variability, in order to simplify trial management for



### Right people, right results: Smart data entry by trained laboratory professionals

The Q<sup>2</sup> Solutions smart data entry process provides at least two sets of trained eyes to review every data value. The Local Laboratory Data Team consists of data management professionals trained in the unique challenges of local laboratory data. These experienced data-entry staff input local laboratory results with direct supervision by medical technologists and laboratory experts. Queries are handled through the portal, enabling greater efficiency for investigator sites and project managers.



### Edit checks

Our years of experience have led us to develop extensive edit checks for local laboratory data. Laboratory results go through a series of systematic edit checks, detecting all types of errors, from inconsistent units to incorrectly reported ranges to simple transposition. These checks are performed by our trained laboratory experts throughout the life of your trial.

- Customized, sponsor-specific edit checks can also be established at set-up.
- Additional edit checks are performed during the data extraction and processing of the data transmission.

## Contact us

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### Language translation

We have language translation capabilities for laboratory results in dozens of languages, including Mandarin, Polish, French, Spanish and Korean. Our global footprint and experience makes it easy to add languages to our repertoire to meet your trial's needs.



### Dedicated team support

You will be assigned a Project Services lead who will work closely with the Local Laboratory Data Team to oversee your study and assist you from database set-up to database lock. At the start of each trial, customized Data Handling Guidelines specific to the needs of your trial are developed for each study. These guidelines define exactly how Q<sup>2</sup> Solutions will handle special situations that sometimes arise with local laboratory data, assuring that the data is treated consistently and to your team's specific expectations.



### Quality data delivered: Ready access to all your results

With Q<sup>2</sup> Solutions, you receive clean quality laboratory data, without needing to convert or merge reference ranges. Local laboratory results are available for inclusion in data transfer files as soon as they are confirmed (within 24 hours). Through our web-based data viewer, you can see the results, ranges and units, as well as the performing local laboratory information. When you also use Q<sup>2</sup> Solutions as your central laboratory, you will see your local laboratory data right alongside central laboratory data.



### Data transmissions

The Q<sup>2</sup> Solutions Laboratory Data Management team works with your data manager to send the final data in whatever format is needed, from a variety of industry-standard formats to a fully customized solution. The file delivery schedule is also flexible. When your central laboratory and local laboratory data are already combined, reconciliation may be significantly reduced.

***For more information on how we can help improve your local laboratory management, contact us today.***

