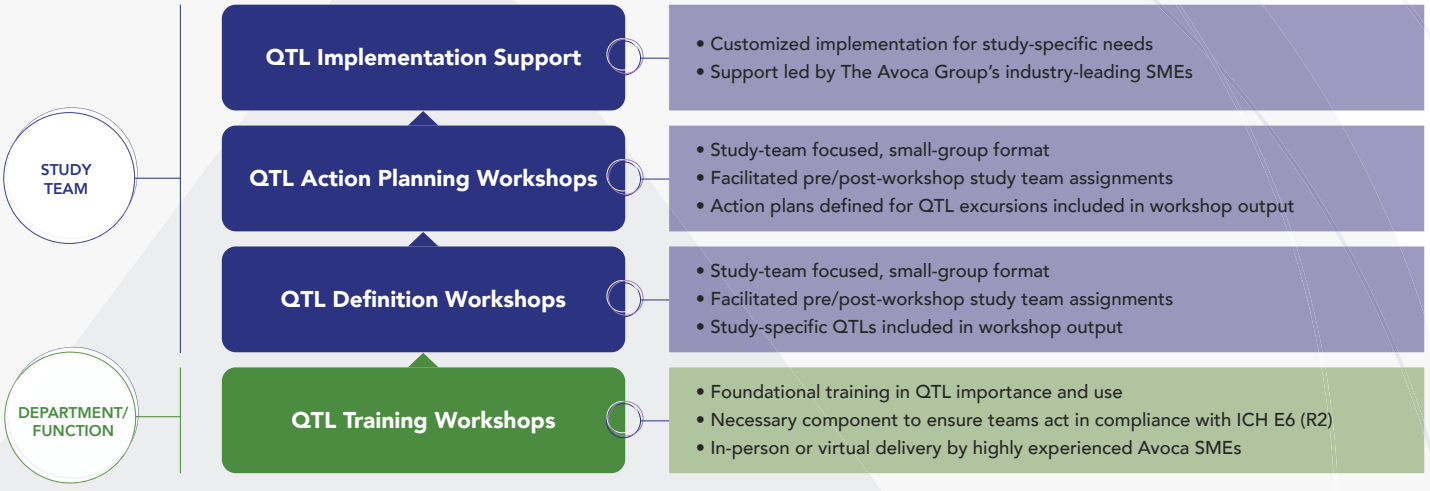
Avoca®
THE AVOCA GROUP

Quality Tolerance Limit Consulting Service

The Avoca Group's Consulting Service for Quality Tolerance Limits (QTLs) aims to help sponsors and CROs comply with ICH E6 (R2) by providing study teams with training and support for QTL implementation.

The Avoca Group Advantage

This service is based on The Avoca Group's 20+ years of experience in clinical quality improvement - helping sponsors and CROs to measure, manage, and improve quality in clinical trial execution. Our subject matter experts (SMEs) provide comprehensive support for planning and implementing QTLs for ICH E6 (R2) compliance, either as individualized study QTL support or as part of overall Quality Management System implementations.



Leverage Our Expertise

What is a QTL?

A QTL is a level, point, or value associated with a parameter that, when a deviation is detected, should trigger an evaluation to determine if there is a possible systemic issue. A QTL is a trial-level parameter, not a patient-level parameter. QTL parameters are absolutely critical to basic trial integrity, patient safety, and the study endpoints. Examples include inclusion/exclusion protocol violations, incomplete/missing endpoint data, and AEs/SAEs of special interest.

When should they be identified?

QTLs need to be defined at the planning level of the trial in coordination with risk assessment activities.[1] The plan should also include strategies for monitoring these parameters, determining the root cause, and addressing any deviations. Modifications to the QTLs during the clinical trial are acceptable as long as sufficient rationale and documentation are provided in both trial documentation and the CSR to justify the changes.

How are they identified?

It is important to define the expectations and variability that are inherent in executing the clinical trial to accurately define the limit that might indicate systemic problems. Therefore, QTLs should be based on:[1]

Medical and statistical expert knowledge of similar trials

Historical data from similar trials

Statistical methods and modeling

Known or anticipated risks of the agent under study, based on the mechanism of action or other parameters

1 TransCelerate Biopharma, Inc. Risk-based quality management: quality tolerance limits and risk reporting. 2017.

To ensure your QTLs are appropriate and compliant, email us at info@theavocagroup.com.