

CSM/QTL ESIG Charter

<p>Responsibilities/ Primary Goal</p>	<ul style="list-style-type: none"> • To create a forum to collaborate and discuss strategies and methodology with other interested parties in Centralised Statistical Monitoring and Quality Tolerance Limits • To recommend best practices and share new methodologies with BIOP Section/EFSPI members and broader statistical community • To facilitate adoption of such methods by statisticians and non-statisticians to better serve future monitoring needs in clinical trials
<p>Accountability</p>	<ul style="list-style-type: none"> • EFSPI Council / PSI Board / ASA BIOP EC
<p>Chair</p>	<ul style="list-style-type: none"> • Tim Rolfe & Susan Talbot
<p>Members</p>	<p>Tim Rolfe, GSK Susan Talbot, Amgen Rakhi Kilaru, PPD Magali Traskine, GSK Chris Wells, Roche</p> <p><i>Other members tbc. Anticipated initial membership: ~10 statisticians with members from industry, regulatory bodies and academia</i></p>
<p>Team & Other Participants</p>	<ul style="list-style-type: none"> • Representatives from EFSPI, ASA and local statistics associations, EFPIA, regulatory and academia • Partner with the COVID-19 ESIG on topics relating to COVID-19 • Potential Collaboration with PHUSE newly formed Risk Based Monitoring Working Group
<p>Format</p>	<ul style="list-style-type: none"> • Monthly teleconferences
<p>Input required</p>	<ul style="list-style-type: none"> • Sharing experiences • Discussing methodology • CSM/QTL related publications, white papers, and regulatory guidance
<p>Deliverables</p>	<p>Draft deliverables:</p> <ul style="list-style-type: none"> • Review regulatory guidance and associated publications (including TransCelerate) and write article for BIOP Report/EFSPI in 2021 to bring awareness to BIOP Section/EFSPI members • Highlight new techniques and best practices through whitepaper. Draft 2022 • Recommend speaker for BIOP section webinar series and PSI conference in 2022 • Paper on methodology in 2024

CSM/QTL ESIG Charter – additional information for ASA

<p><i>Potential Impact</i></p>	<ul style="list-style-type: none"> • There is a key role for statisticians in Risk-Based Quality Management (RBQM), in particular in the areas of Centralised Statistical Monitoring (CSM) and Quality Tolerance Limits (QTL). CSM/QTL are often mentioned within the RBQM framework where key players are from operations and less so statisticians. Given our training and background, statisticians can add a lot of value and shape the future of RBQM. Leadership role for statisticians alongside the growth of RBQM. • Both the FDA and EMA have released guidance on RBM approaches to help facilitate implementation. TransCelerate has further provided best practices for detecting data anomalies (2016) and QTL Framework (2021). • As companies look to enhance RBQM, new techniques and best practices are being established. • The ESIG/SWG will create a forum where statisticians can collaborate and research/discuss strategies and methodology. The ESIG/SWG will bring awareness of this developing area to BIOP Section members/EFSPI members – a new area for career development opportunities. • Through the research and discussions, new methodologies and best practices can be recommended, along with lessons learned shared. This is an evolving field where traditional statistical methodologies fit alongside machine learning approaches. Through the information sharing from the ESIG/SWG, BIOP Section members/EFSPI members can broaden their view of application of statistical techniques and learn new approaches.
<p><i>Why ASA BIOP sponsorship?</i></p>	<ul style="list-style-type: none"> • There is an anticipated greater update and utilization of CSM/QTL in medical research as clinical trials evolve to become increasingly decentralized and utilizing new technologies. The section members come from diverse backgrounds and share a strong interest in resolving important statistical issues. Whilst this is a growing field of interest, there are relatively a small number of statisticians with a specific interest in CSM and/or QTLs. In order to maximize the success of this SIG/WG, the ASA BIOP Section would be the best co-sponsor for this working group initiative along with the EU based EFSPI/PSI to ensure a broad representation from the statistical community. We see value and agree to the BIOP annual health check.
<p><i>Other Scientific WG</i></p>	<ul style="list-style-type: none"> • There are no known statistical working groups focused on this area. PHUSE are currently forming a Risk Based Monitoring Working Group, which will be an area for collaboration. The PHUSE RBM WG has a broader focus. TransCelerate established a QTL Interpretation of Guidance and Regulation initiative and provided a publication and framework. This SWG will build on the work of the TransCelerate initiative.
<p><i>How long to reach its goals</i></p>	<ul style="list-style-type: none"> • Anticipated 3 years, though as technology advances and the role of RBM grows the goals may evolve and become longer term
<p><i>Financial support from BIOP</i></p>	<ul style="list-style-type: none"> • None
<p><i>Best avenues of communication</i></p>	<ul style="list-style-type: none"> • Articles, presentations, training • Collaborate with PSI/EFSPI/ASA/PHUSE for larger impact