

Quality Tolerance Limits – Threshold Setting Methodologies



Project Scope

The Project has successfully completed the first step of clarifying the definitions and labels linked to QTL monitoring. Recommendations on how to derive thresholds for QTL monitoring have been developed.

The next stage shall be to:

- Share this acquired knowledge and common understanding within the industry.
- Continue the discussion on further refining the (statistical) methodology regarding threshold derivation for QTL monitoring.

Closely follow ICH (R3) developments regarding risk-based monitoring and discuss/evaluate whether this has impacts on the guidance provided so far (QTL vs. acceptable range).

| Project Leads | Email |
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| Nathalie van Borrendam, <i>Johnson & Johnson</i> | nvanborr@its.jnj.com |
| Annett Keller, <i>Boehringer Ingelheim</i> | annett.keller@boehringer-ingelheim.com |
| Alex Pearce, <i>PHUSE Project Assistant</i> | alexandra@phuse.global |

| Objectives & Deliverables | Timelines |
|--|-----------|
| Challenges in QTL threshold setting – Experience sharing and high-level recommendations for the industry | Q3 2022 |
| Guidance document on QTL threshold-setting methodologies | Q1 2023 |

CURRENT STATUS Q4 2023

- Developing the 2nd White Paper