**Assessing the Use of Quality Tolerance Limits in the Pharmaceutical Industry**

**PHUSE RBM Working Group – Quality Tolerance Limits Industry Survey 01Feb2022**

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Q = Question; T = Table

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# Q1

A graph of a company type

Description automatically generated

Figure 1: placeholder

# Q2

A graph of a company size and number of trial

Description automatically generated

Figure 2 placeholder

# Q3

A graph of a bar of data

Description automatically generated with medium confidence

Figure 3 placeholder

# T1 (Q3b)

**(Q3: Other category breakdown)**

*Table 1: placeholder*

Total Count = 13

|  |  |  |
| --- | --- | --- |
| Others: | Count | Percentage |
| Central Monitoring | 3 | 23.1% |
| Clinical Trial Supplies | 1 | 7.7% |
| Contracts | 1 | 7.7% |
| Diagnostics | 1 | 7.7% |
| IT developers | 1 | 7.7% |
| Imaging | 1 | 7.7% |
| Medical Monitoring | 1 | 7.7% |
| Medical Writing | 1 | 7.7% |
| Project Management | 1 | 7.7% |
| Risk Manager or RBQM lead | 1 | 7.7% |
| SaaS programmers | 1 | 7.7% |

# Q4

A graph with numbers and text

Description automatically generated with medium confidence

Figure 4 placeholder

# Q5

A graph of a company

Description automatically generated with medium confidence

Figure 5 placeholder

# T2 (Q5b)

**(Q5: Comment why category breakdown)**

*Table 2: placeholder*

Total Count = 09

|  |  |
| --- | --- |
| Comment why: | Count |
| Studies with less sites or small sample size | 1 |
| We try and offer something on Phase I, PhaseII, Phase III, and complex designs, but it’s not always possible | 1 |
| Risk management to all studies but centralized monitoring not for small sample size studies or single site studies or with short duration studies - process under implementation | 1 |
| RBQM concept driven by early/late clinical operations | 1 |
| All studies are in scope | 1 |
| All areas look at risk | 1 |
| It’s been difficult to establish meaningful QTLs | 1 |
| Observational and epidemiology study | 1 |
| All studies considered to take risk-based approach as risk assessments and mitigation planning are done for all. | 1 |

**Note**: perhaps we should remove the count column.

# Q6

A screenshot of a graph

Description automatically generated

Figure 6 placeholder

# T3 (Q7)

**Q7: If you answered Yes to Other Risk Based Approaches used in Question 6, please identify those used (Check all that apply)**

*Table 3: placeholder*

Total Count = 27

|  |  |  |
| --- | --- | --- |
| Others RBM Approach | Count | Percentage |
| KRI's | 13 | 48% |
| Team Tracking risk items | 7 | 26% |
| Other | 4 | 15% |
| KPI's | 3 | 11% |

# Q8

A chart of a graph

Description automatically generated with medium confidence

Figure 7 placeholder

# T4 (Q9)

**Q9: Does your company have a process in place with regard to completing a Feedback Loop?**

*Table 4: placeholder*

Total Count = 15

|  |  |  |
| --- | --- | --- |
| Response | Count | Percentage |
| Yes | 11 | 73% |
| No | 4 | 27% |

# Q10

A chart of a company's risk-based approach

Description automatically generated

Figure 8 placeholder