**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

Contents

[Q1 2](#_Toc150343424)

[Q2 3](#_Toc150343425)

[Q3 4](#_Toc150343426)

[T1 (Q3b) 5](#_Toc150343427)

[Q4 6](#_Toc150343428)

[Q5 7](#_Toc150343429)

[T2 (Q5b) 8](#_Toc150343430)

[Q6 9](#_Toc150343431)

[T3 (Q7) 10](#_Toc150343432)

[Q8 11](#_Toc150343433)

[T4 (Q9) 12](#_Toc150343434)

# Q1

A graph of a company type

Description automatically generated

Figure : placeholder

# Q2

A graph of a company size and number of trial

Description automatically generated

Figure placeholder

# Q3

A graph of a bar of data

Description automatically generated with medium confidence

Figure 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 placeholder

# Q5

A graph of a company

Description automatically generated with medium confidence

Figure 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 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 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% |