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

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

Steven Ponce (work: [Steven.Ponce@bms.com](mailto:Steven.Ponce@bms.com); personal: [stevenponce090@gmail.com](mailto:stevenponce090@gmail.com))

A graph of a company type

Description automatically generated

Figure : placeholder

A graph of a company size and number of trial

Description automatically generated

Figure placeholder

A graph of a bar of data

Description automatically generated with medium confidence

Figure placeholder

**(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% |

A graph with numbers and text

Description automatically generated with medium confidence

Figure placeholder

A graph of a company

Description automatically generated with medium confidence

Figure placeholder

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

*Table 1: 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 |