**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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**From:** Wells, Chris   
**Sent:** Friday, November 24, 2023 6:48 AM

Hi Steven

Thank you so much for the work you have completed. The new stacked bar charts look good and retain all the information we require. Just a couple of comments and if possible, request for some new plots. Could you review and advise how much work this would be and if this is too time consuming, i can work with Mike and Mireille to identify if we can remove any.

General point: for the plots that are stacked bar charts and where there are a number of different plots within the main plot (like plot 6) would it be possible to put the x axis at the top of the first plot as well as below the last plot? Just that it will enable the reviewer to follow the axis up and down easier.  Think this would apply to plots 6

Plot 3 - looks great.

A graph of a number of different colored squares

Description automatically generated with medium confidence

Plot 3: Other **category breakdown**

Total Count = 08

|  |  |
| --- | --- |
| Response Number | Other Functional Area |
| 1 | Clinical Trial Supplies, Contracts, and Imaging / Diagnostics |
| 2 |  |
| 3 |  |
| 4 |  |
| 5 |  |
| 6 | Central Monitoring, Imaging / Diagnostics, Risk Manager or RBQM lead, and SaaS programmers |
| 7 | Central Monitoring |
| 8 | Central Monitoring |
| 9 |  |
| 10 |  |
| 11 |  |
| 12 |  |
| 13 |  |
| 14 |  |
| 15 | Medical Monitoring, Medical Writing, and Project Management |

Plot 4 - this one equates to question 4 and is Which functional area Leads the trial level risk based approach to Quality.  - Could we have the same plot as you have created in plot 3.  this is very similar to plot 3 but plot 3 is asking which functional area is involved and plot 4 asks which function LEADS , so very slightly different

A graph of a diagram

Description automatically generated with medium confidence

Plot 4: Other **category breakdown**

Total Count = 08

|  |  |
| --- | --- |
| Response Number | Other Functional Area |
| 1 | Risk Manager |
| 2 |  |
| 3 |  |
| 4 |  |
| 5 | RBQM working group |
| 6 | Risk Manager |
| 7 | Central Monitoring |
| 8 | Central Monitoring |
| 9 |  |
| 10 | Oversight Team |
| 11 |  |
| 12 |  |
| 13 | Clinical Quality Management |
| 14 |  |
| 15 | Project Management |

Plot 5 - Question 5 - Trial types where company does not apply Risk Based Approaches to Quality   - could we have a plot like plot 3 by trial type (trial type on y-axis)

A graph with black and blue squares

Description automatically generated

Plot 5: Comments **category breakdown**

Total Count = 09

|  |  |
| --- | --- |
| Response Number | Comments |
| 1 |  |
| 2 | Studies with less sites or small sample size. |
| 3 |  |
| 4 |  |
| 5 | We try and offer something on Phase 1, Phase II, Phase III, and complex designs but its  not always possible. |
| 6 | Risk management to all studies but cetralized monitoring not for small sample size  studies or single site studies or with short duration studies - process under  implementation |
| 7 | RBQM concept driven by early/late clinical operations. |
| 8 | All studies are in scope. |
| 9 |  |
| 10 | All areas look at risk. |
| 11 |  |
| 12 | It’s been difficult to establish meaningful QTLS. |
| 13 | Observational and epidemiology study. |
| 14 |  |
| 15 | All studies considered to take risk-based approach as risk assessments and mitigation  planning are done for all. |

Plot 6 option 1 - Looks great but could we have the x axis at the top as well as the bottom.

Not great….

A chart of music notes

Description automatically generated with medium confidence

Plot 6 option 2 - Looks great but could we have the x axis at the top as well as the bottom.

Better option.

A chart of different colored lines

Description automatically generated with medium confidence

Plot 7  - Could we have one for Question 7 like plot 3 but with the attributes on the y axis

A graph with a number and a number

Description automatically generated with medium confidence

Plot 8 Option 1- Could we have one for question 8 like plot 6b and the attributes on the y axis and responses on the x-axis.

Not great….

A group of rows of colorful dots

Description automatically generated with medium confidence

Plot 8 Option 2 - Could we have one for question 8 like plot 6b and the attributes on the y axis and responses on the x-axis.

Better option.

A group of rows of graphs

Description automatically generated

Plot 10 - could we have a plot on question 10 - like plot 6 with attributes on y axis and response on x axis (top & bottom of the plot)

A screenshot of a graph

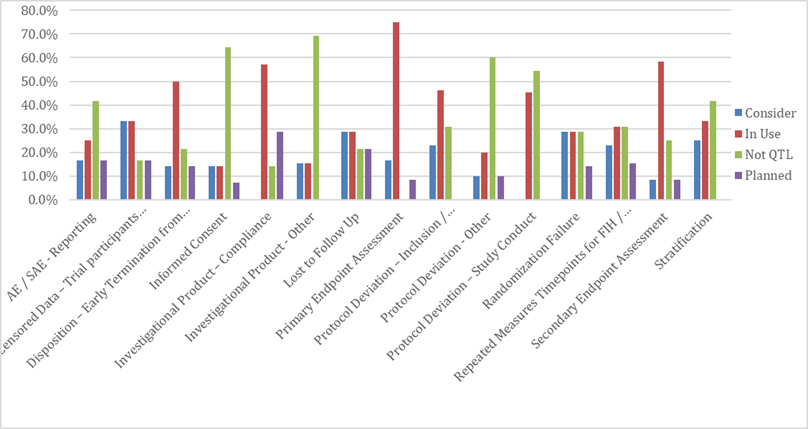
Description automatically generated

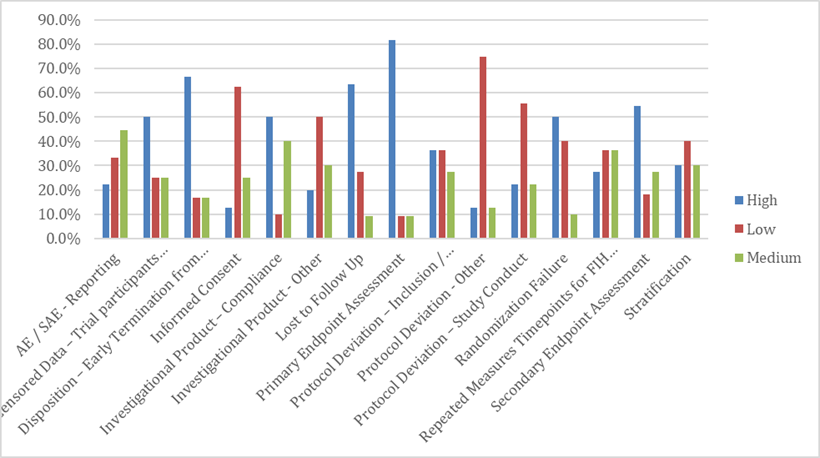
Plot 18 - Question 18 - could we have a plot like plot 6b.02

Plot 19 - Question 19 - could we have a plot like plot 6b

Plot 23 - question 20.3, could we have a plot like plot 3

Plot 25 - question 25  - Could we have new plots for these or should we stay with those we have?





Again, thank you so much

kind regards