The Impact of the New FDA Safety Table & Figure Guidelines

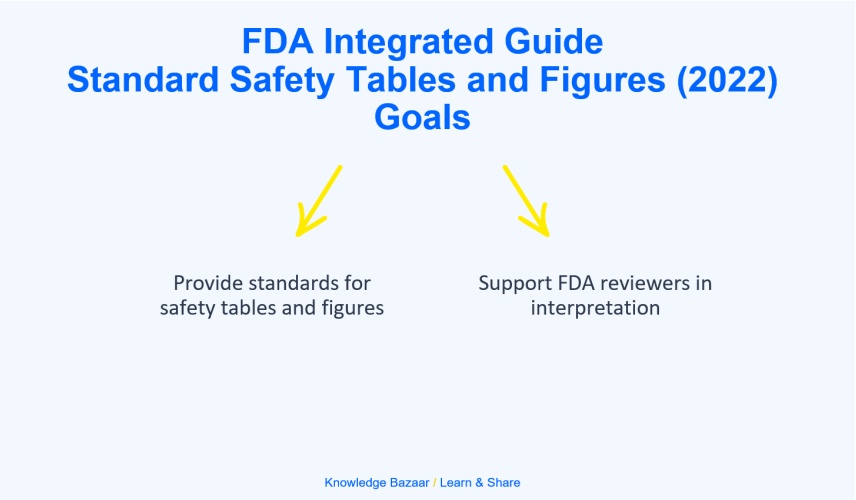
Discussions during the Knowledge Bazaar at PHUSE US Connect 2023

Discussion highlights:

👉 **Impact -** the new guidelines will greatly impact company standards and require extra assurance to comply with the guidelines.

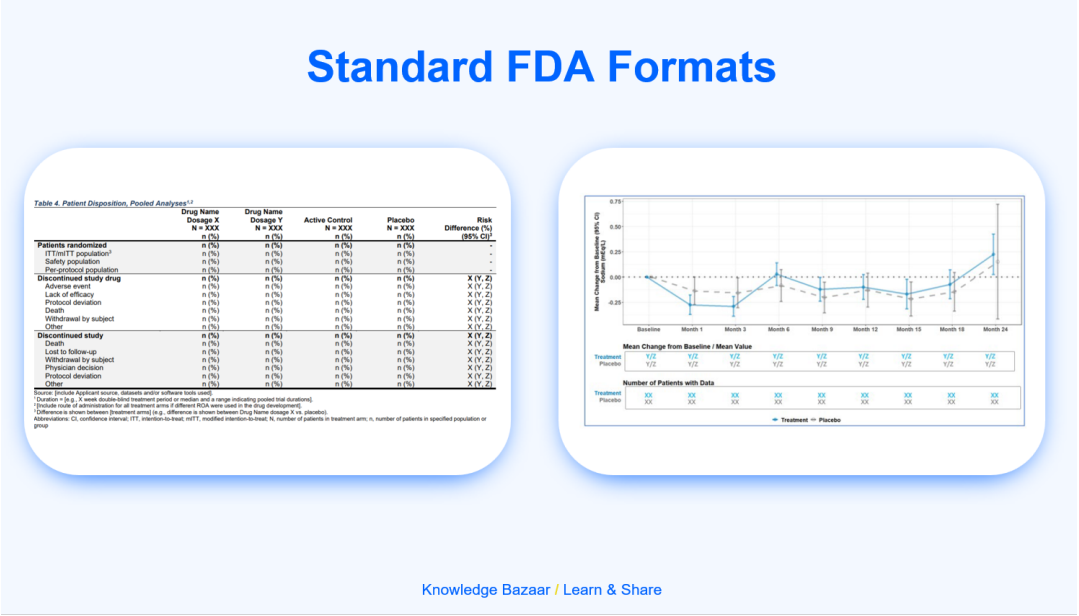
👉 **Advantages -** complying with the guidelines will have many advantages, including easier interpretation for FDA reviewers and fewer additional requests for information from the FDA.

👉 **FMQ -** we also discussed the impact of FMQs on our current work, and some of the challenges involved, such as finding a consistent approach to algorithmic FMQs.



The draft ST&F guideline was released in 2022 for comments. This guidance contains standardised methods for visualisation of clinical trial safety data into tables and figures and descriptions of how FDA medical queries (FMQs) should be reported.

The PHUSE Safety and Analytics working group provided comments as well. Going through these comments, most of them were on the FDA Medical Queries. However, there were also comments on the risk differences (can we use other measures, not appropriate at all places) and format requirements.



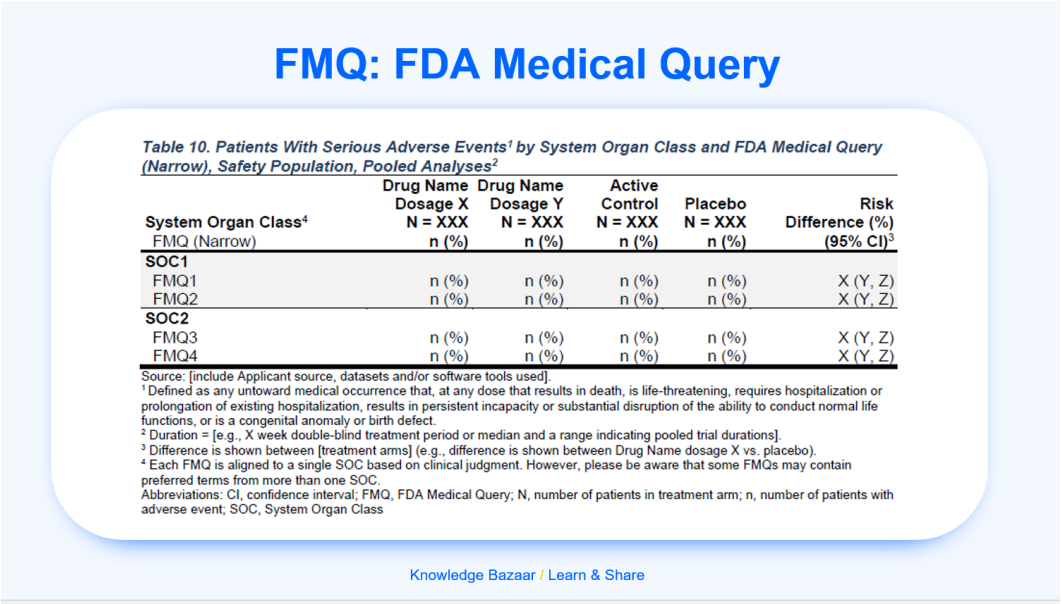
During the knowledge bazaar we discussed the impact of **the new guideline on standard formats for tables and figures** and came up with the following:

Impact

- Tremendous impact on company standards (SAP & Mock shells).
- As an industry, we need to implement extra assurance to comply with guidelines
- It will have a significant impact on programming both for table format as well as for FMQ implementation!
- Current practices and processes in our companies need to be changed to be able to comply with the guidelines, such as standard programs and macros.

Advantages

- Easier interpretation for FDA reviewers.
- It will help in-company compliance to standards: The variation between Therapeutic areas and departments can be reduced as we all have to comply with the same standard.
- Less additional requests for information from FDA.



Lastly, we discussed **the impact of FMQs on our current work**:

The comments already submitted by many parties to the FDA are for a large part towards versioning and alignment with other Medical queries and other regulatory agencies. We discussed that CDISC is updating its medical query guidance to include FMQ as well. This new update is expected by the end of 2023.

The group discussed the following challenges regarding FMQs:

FMQ Challenges

- Awareness of FMQs within the company.
- Many to Many mapping: the same MedDra preferred term (PT) may be included in more than one FMQ.
- Additional resources are needed to do this extra analysis
    - It will take time to adopt and the FMQs are subject to change
- We need to find a consistent approach to algorithmic FMQs. Algorithmic FMQs include MedDRA PTs but also out-of-range safety lab parameters. This is a new challenging approach for our programmers.

We thank all the participants for their contribution.

Please contact us if you have any additional questions, or comments or like to learn more about our product.

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