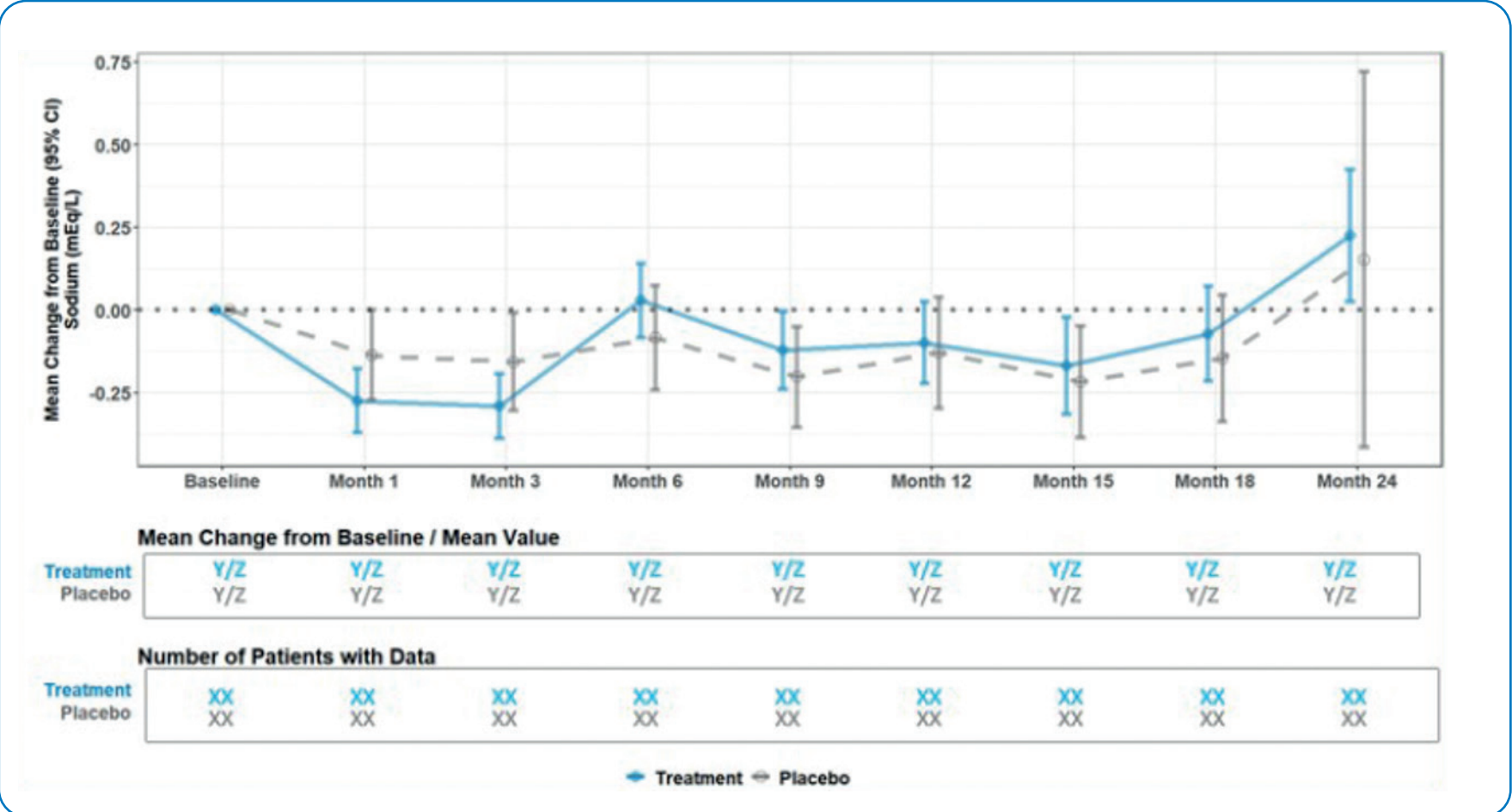


PP19: Evaluating the Impact of FDA Standard Safety Table and Figure Guidelines

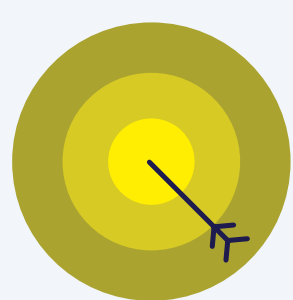
Discover the outcomes of the 2023 PHUSE US Connect Knowledge Bazaar session led by Beaconcure Technologies, about the impact of the new FDA Safety Table and Figure guidelines on current standard practices in clinical study reporting and analysis.

Table 2. Baseline Demographic and Clinical Characteristics, Safety Population, Pooled Analyses (or Trial X)

Characteristic	Drug Name N = XXX	Drug Name N = XXX	Placebo N = XXX	Active Control N = XXX	Total Population N = XXX
Sex, n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Male	n (%)	n (%)	n (%)	n (%)	n (%)
Female	n (%)	n (%)	n (%)	n (%)	n (%)
Age, years	XX (Y, Y)	XX (Y, Y)	XX (Y, Y)	XX (Y, Y)	XX (Y, Y)
Mean (SD)	XX (Y, Y)	XX (Y, Y)	XX (Y, Y)	XX (Y, Y)	XX (Y, Y)
Median (min, max)	XX (Y, Y, Z, Z)	XX (Y, Y, Z, Z)	XX (Y, Y, Z, Z)	XX (Y, Y, Z, Z)	XX (Y, Y, Z, Z)
Age groups (years), n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
≤ 17 to <18	n (%)	n (%)	n (%)	n (%)	n (%)
18 to <25	n (%)	n (%)	n (%)	n (%)	n (%)
25 to <35	n (%)	n (%)	n (%)	n (%)	n (%)
35 to <45	n (%)	n (%)	n (%)	n (%)	n (%)
45 to <55	n (%)	n (%)	n (%)	n (%)	n (%)
55 to <65	n (%)	n (%)	n (%)	n (%)	n (%)
65 to <75	n (%)	n (%)	n (%)	n (%)	n (%)
75 to <85	n (%)	n (%)	n (%)	n (%)	n (%)
85 to <95	n (%)	n (%)	n (%)	n (%)	n (%)
≥ 95	n (%)	n (%)	n (%)	n (%)	n (%)
Race, n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
American Indian or Alaska Native	n (%)	n (%)	n (%)	n (%)	n (%)
Black or African American	n (%)	n (%)	n (%)	n (%)	n (%)
Native Hawaiian or Other Pacific Islander	n (%)	n (%)	n (%)	n (%)	n (%)
White	n (%)	n (%)	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)	n (%)	n (%)
Ethnicity, n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Hispanic	n (%)	n (%)	n (%)	n (%)	n (%)
Not Hispanic or Latino	n (%)	n (%)	n (%)	n (%)	n (%)
Unknown	n (%)	n (%)	n (%)	n (%)	n (%)
Country of participation, n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
United States	n (%)	n (%)	n (%)	n (%)	n (%)
Country A	n (%)	n (%)	n (%)	n (%)	n (%)
Country B	n (%)	n (%)	n (%)	n (%)	n (%)
Country C	n (%)	n (%)	n (%)	n (%)	n (%)

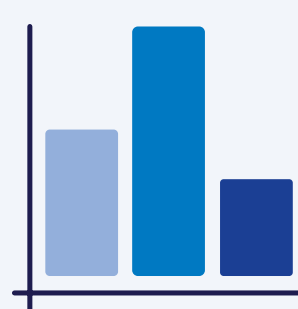


Source: STANDARD SAFETY TABLES AND FIGURES: INTEGRATED GUIDE, August 2022



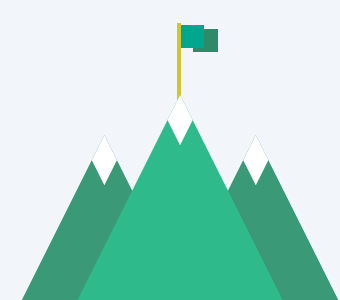
Industry Impact of Guideline Compliance

- Significant changes to internal standards for presenting clinical trial safety data, including SAP and mock shells.
- Programming changes to implement guidelines on table formats and FDA Medical Queries (FMQs), including new or modified programs and macros.
- Development of new internal procedures, SOPs, audit processes, quality assurance, and training.



Advantages of Standardization Guidelines

- Reduced errors and misinterpretations due to clear and consistent reporting, facilitating decision-making processes during data review.
- Simplified internal processes, as compliance with guidelines reduces variations between therapeutic areas and departments.
- Improved interpretability by FDA reviewers can result in fewer requests for further information and can expedite regulatory approval.



Challenges of FMQ Guidelines

- Internal awareness of FMQ significance in reporting processes requires ongoing training to integrate FMQs into data presentation and submission workflows.
- Mapping multiple MedDRA preferred terms (PTs) to one or more FMQs requires new strategies to maintain consistency in FMQ reporting.
- Additional resources are required to implement new analyses and procedures, and to regularly monitor for changes to FMQ guidelines.



Recommendations Going Forward

- Develop a consistent approach to algorithmic FMQs, which include MedDRA PTs and out-of-range safety lab parameters.
- Automate validation using an AI model and advanced algorithms to align with FMQs and standardization guidelines.
- Use automated solutions to check consistency with FDA guidelines for standardized mock shells, structures, and formats.



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