Advancing Premarket Safety Analytics

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Disclaimer

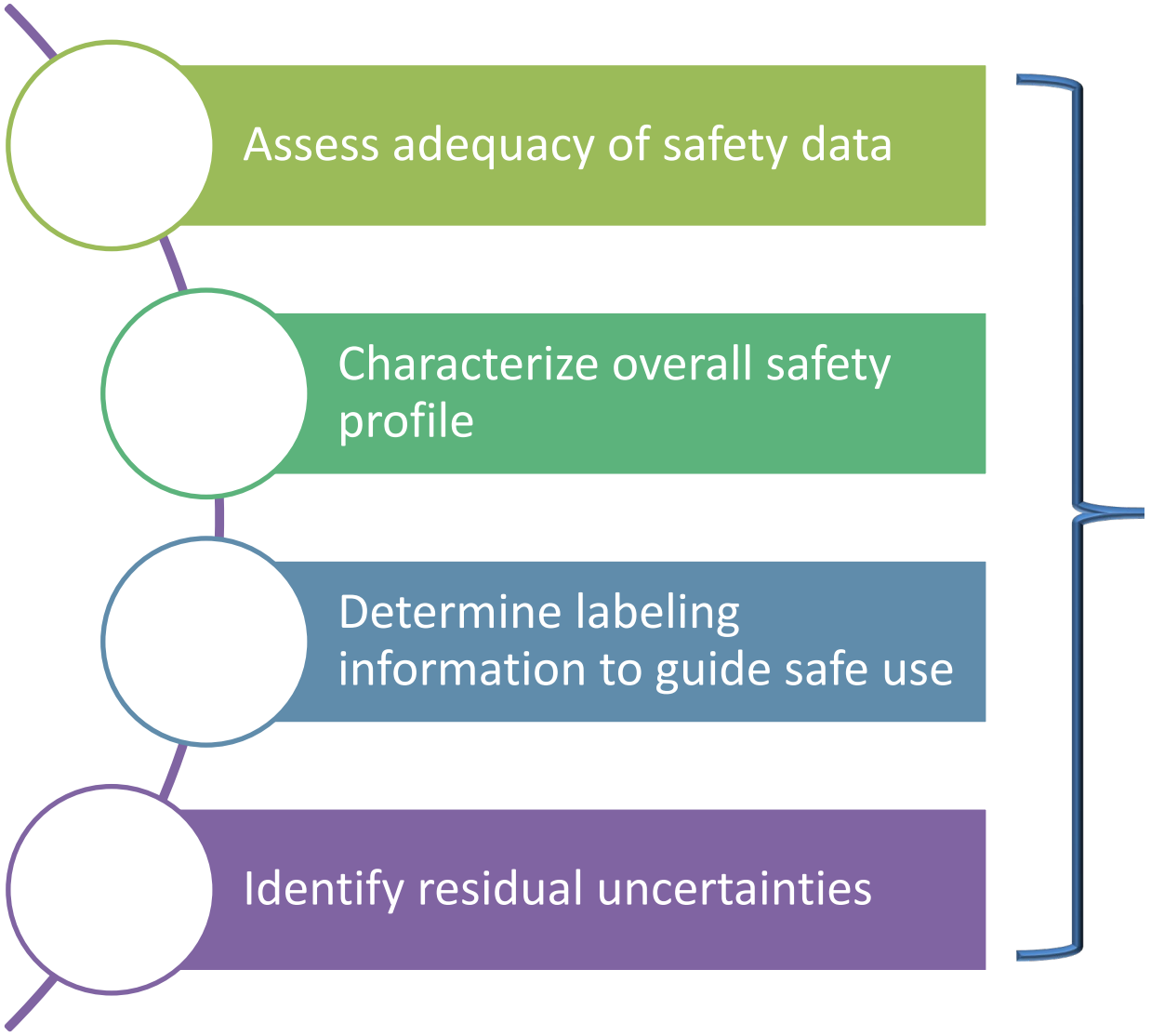
- The views and opinions expressed in this presentation are those of the presenter and do not represent official policy or position of the FDA.

- I have no relevant financial or non-financial relationships to disclose.

Agenda

- Background
- FDA Medical Queries (FMQs)
- Standard Safety Tables and Figures (STFs)

Goals of FDA Clinical Safety Assessment



Premarket Safety Analytics

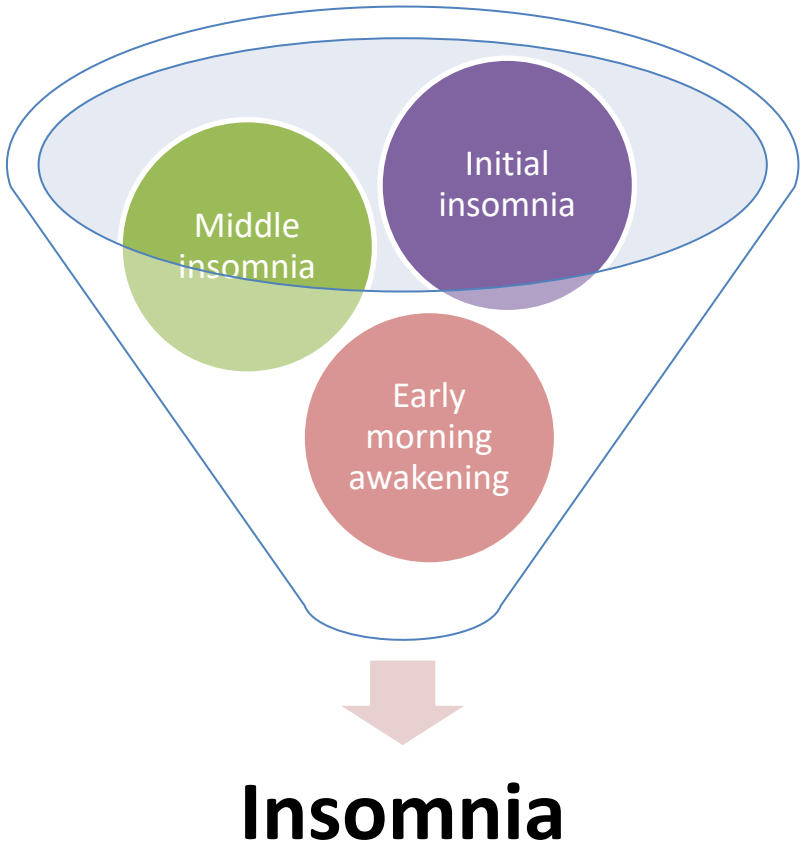
- FMQs
- STFs

FDA Medical Queries (FMQs)

What are FMQs?

- Standardized groupings of related MedDRA[1] PTs developed by FDA review staff

- Each FMQ represents a medical concept



[1] MedDRA = Medical Dictionary for Regulatory Activities

Goals of FMQs

Standardized approach to grouped AE analysis

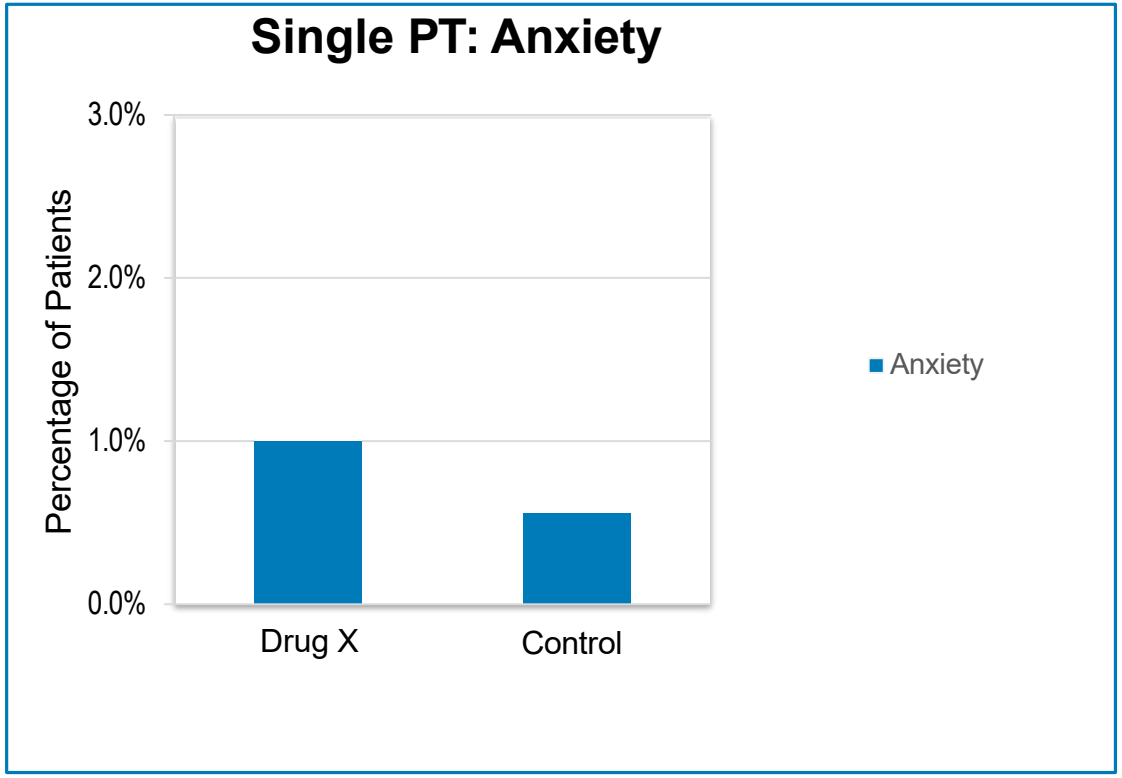
Improve safety signal detection in clinical trial datasets

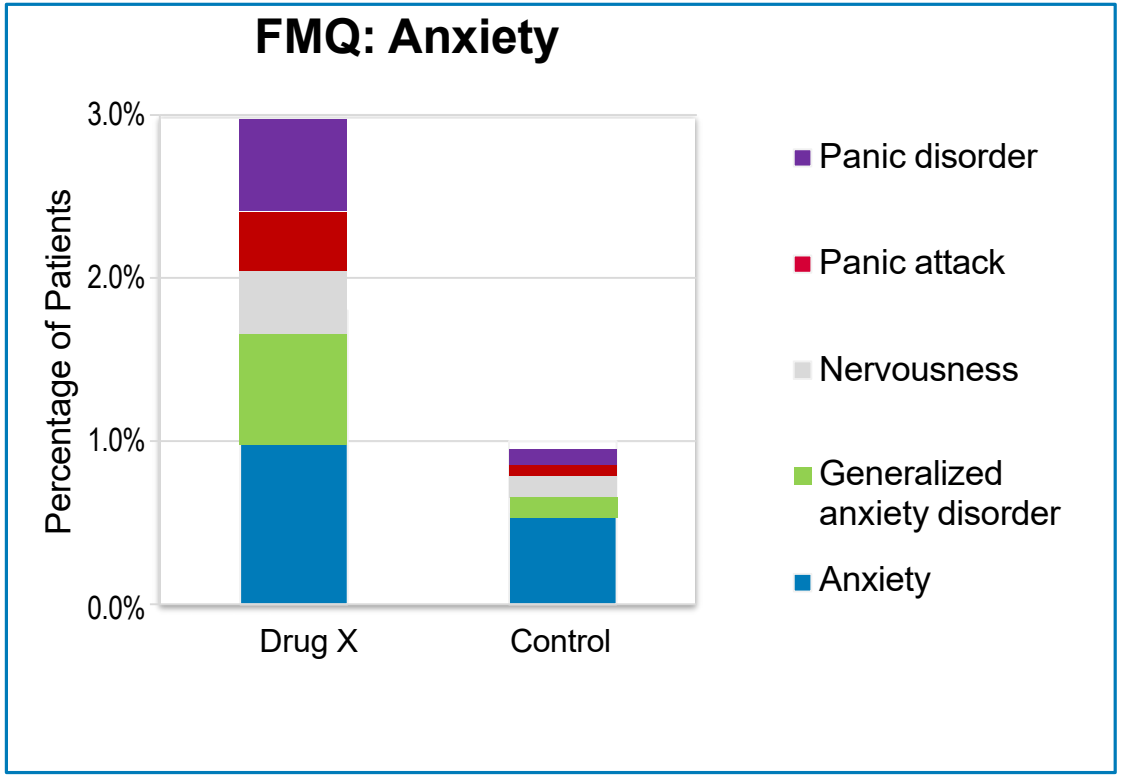
Why FDA Medical Queries?

- Different verbatim terms for similar clinical events
  - Different MedDRA PTs can be used to code for the same medical concept
- Adverse Events (AEs) may manifest in related, but different ways.

Single PT Analysis vs. FMQ

"Anxiety" safety signal may only become apparent when all variations of anxiety are included.





Inconsistent Standards

Related PTs are not Grouped

Potential missed safety signals

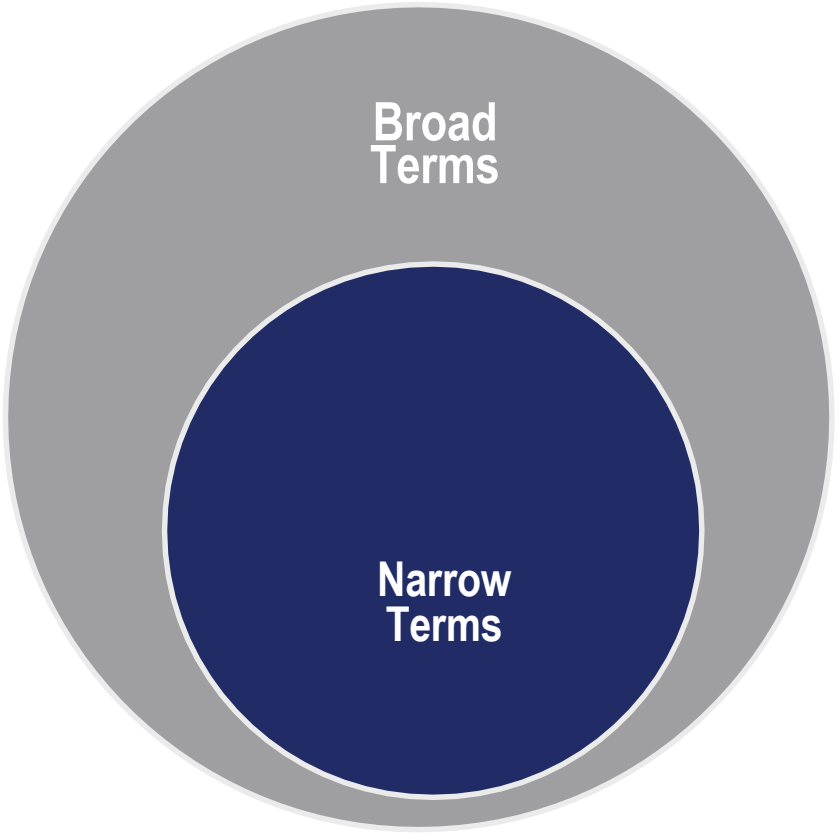
FMQ: Narrow vs. Broad Queries

Narrow FMQ terms

- Specific for the medical concept
- > ~90% probability that the medical concept occurred

Broad FMQ terms

- “Cast a wider net” than narrow query terms for signal detection
- Less specific
- Provide reasonable assurance (more than ~30% probability) that the medical concept occurred



FMQ Ground Rules: Narrow Queries

PTs that are near-synonyms of the FMQ concept	• "*Abdominal discomfort*" in FMQ Abdominal Pain
PTs that are subgroups of the FMQ concept	• *"Anaemia neonatal"* in FMQ Anemia
PTs that specify an etiology for the FMQ concept	• *"Uremic Pruritus"* in FMQ Pruritus
PTs that ensure the occurrence of the FMQ concept	• *"Aortic Rupture"* in FMQ Hemorrhage

FMQ Ground Rules: Broad Queries

PTs that may result in the FMQ concept	• *"Osteopenia"* in FMQ Osteoporosis
PTs that provide laboratory, radiologic, or other diagnostic test results reasonably suggestive of an FMQ, including PTs with ambiguous results such as "abnormal"	• *"Blood glucose abnormal"* in FMQ Hyperglycemia
PTs reasonably suggestive of the FMQ concept, but not required by the FMQ concept	• *"Bronchospasm"* in FMQ Hypersensitivity
PTs that indicate a "carrier" status for FMQ concepts that specify an infectious disease	• *"Bacterial disease carrier"* in FMQ Bacterial Infection

FMQ Ground Rules: PT's Excluded from FMQ

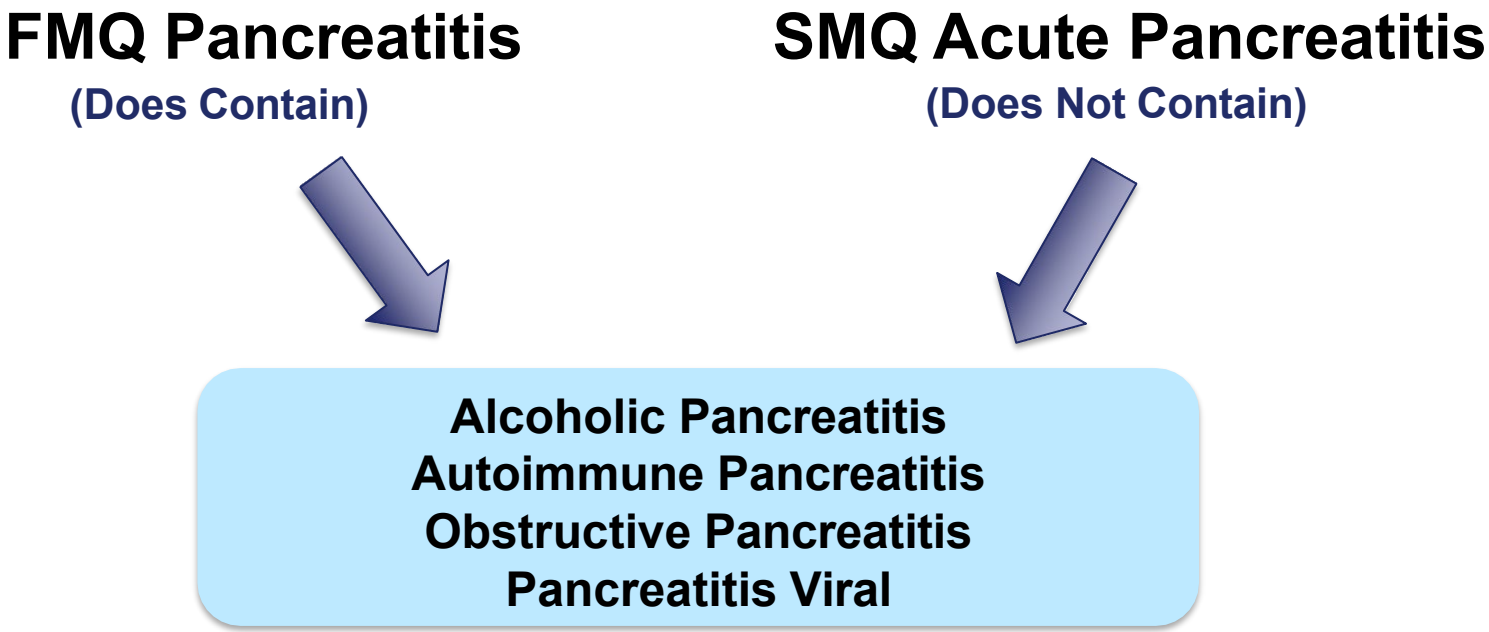
PTs that are too vague are excluded from FMQs

- Neither a required component nor reasonably specific for the FMQ concept
  - "*Nausea*" would **not** be included in FMQ Migraine

- Names of laboratory, radiologic, or other diagnostic tests without a result
  - "*Clostridium test*"
  - PTs that provide test names without a result, but would only be performed in the presence of disease, should be included if they otherwise qualify (example: "*Antipsychotic drug level*" in FMQ Psychosis).

FMQs and MedDRA SMQs

FMQs attempt to capture all instances of an AE, even if PT indicates a “non-drug-related" cause:



Algorithmic FMQs

- **Narrow** – contains PTs highly specific to the FMQ concept; indicates that the FMQ occurred.

- **Broad** – casts a wider net to capture additional cases of the FMQ concept.

- **Algorithmic** – uses multiple datasets to leverage more of the available information:
  - Adverse event datasets
  - Laboratory datasets
  - Concomitant meds datasets
  - Medical history datasets
  - Temporal relationships

Example Mock Algorithm:

1. PT + PT
2. Lab value >ULN
3. PT + Con Med within 3 days
4. PT + Medical History

Algorithmic FMQ Example: Drug-Induced Muscle Injury

Patients qualify for the algorithm if they meet any of the following criteria:

1. Any Rhabdomyolysis FMQ Narrow term
2. Urine myoglobin >ULN
3. CPK >5 x ULN **AND NO:**
   - CPK >ULN at baseline OR
   - CPK-MB/CPK >0.05 with start date within 3 days
4. [PT Myalgia + PT Muscular Weakness + (PT Myoglobin Urine Present OR PT Chromaturia)] with start date within 7 days of each other

ULN= Upper limit of normal, CPK = creatine phosphokinase

FMQ Version 2.1

1. Arthritis
2. Abdominal Pain
3. Abnormal Uterine Bleeding
4. Acute Coronary Syndrome
5. Acute Kidney Injury
6. Alopecia
7. Amenorrhea
8. Anemia
9. Anaphylactic Reaction
10. Angioedema
11. Anxiety
12. Arrhythmia
13. Arthralgia
14. Back Pain
15. Bacterial Infection
16. Bacterial Vaginosis
17. Bronchospasm
18. Cachexia
19. Cardiac Conduction Disturbance
20. Cholecystitis
21. Confusional State
22. Constipation
23. Cough
24. Decreased Appetite
25. Decreased Menstrual Bleeding
26. Depression
27. Diabetic Ketoacidosis
28. Diarrhea
29. Dizziness
30. Dry Mouth
31. Dysgeusia
32. Dyspepsia
33. Dyspnoea
34. Erectile Dysfunction
35. Erythema
36. Excessive Menstrual Bleeding
37. Fall
38. Fatigue
39. Fracture
40. Fungal Infection
41. Glaucoma
42. Gout
43. Gynaecomastia
44. Hemorrhage
45. Headache
46. Heart Failure
47. Hepatic Failure
48. Hepatic Injury
49. Hyperglycemia
50. Hyperprolactinaemia
51. Hypersensitivity
52. Hypoglycemia
53. Hypotension
54. Insomnia
55. Irritability
56. Invest Agent Abuse Potential
57. Leukopenia
58. Lipid Disorder
59. Local Administration Reactions
60. Malignancy
61. Mania
62. Myalgia
63. Myocardial Infarction
64. Myocardial Ischemia
65. Nasopharyngitis
66. Nausea
67. Opportunistic Infection
68. Osteoporosis
69. Palpitations
70. Pancreatitis
71. Paraesthesia
72. Parasomnia
73. Peripheral Oedema
74. Pneumonia
75. Pneumonitis
76. Pruritus
77. Psychosis
78. Purulent Material
79. Pyrexia
80. Rash
81. Renal & Urinary Tract Infection
82. Respiratory Depression
83. Respiratory Failure
84. Rhabdomyolysis
85. Seizure
86. Self-Harm
87. Sexual Dysfunction
88. Somnolence
89. Stroke-TIA
90. Syncope
91. Systemic Hypertension
92. Tachycardia
93. Tendinopathy
94. Thrombocytopenia
95. Thrombosis
96. Thrombosis (Arterial)
97. Thrombosis (Venous)
98. Tremor
99. Urinary Retention
100. Urticaria
101. Vertigo
102. Viral Infection
103. Volume Depletion
104. Vomiting

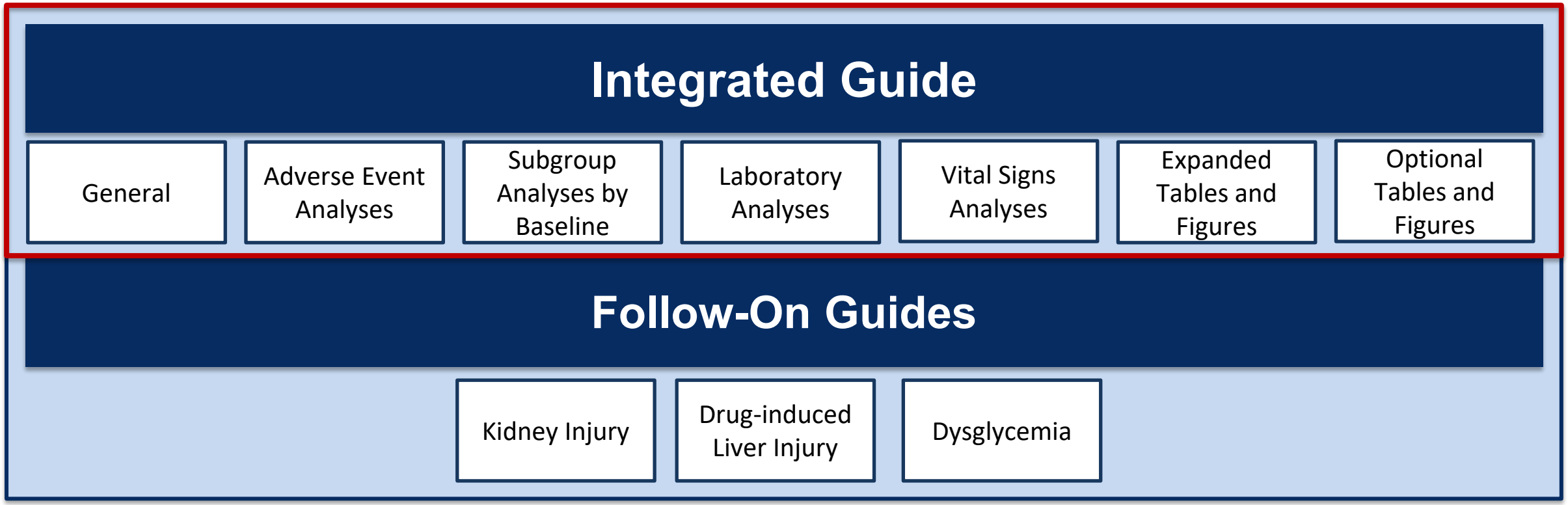
https://www.regulations.gov/docket/FDA-2022-N-1961/document

Standard Safety Tables & Figures (ST & F)

Why Standard Tables & Figures?

- Standardize safety signal evaluation across divisions
- Uniform safety data presentation and visualization (e.g., color, table layout)
- Follow formatting standards used in major medical journals
- Save reviewer time

Standard Safety Tables & Figures Organization



Standard Safety Tables & Figures Integrated Guide (ST&F IG): Components

Integrated Guide

General

- Clinical Trials Summary
- Demographic and Clinical Characteristics
- Patient Disposition
- Duration of Exposure

Adverse Event Analyses

- Overview of Adverse Events
- Deaths
- Serious Adverse Events
- Adverse Events Leading to Discontinuation
- FDA Medical Queries (FMQs)

Subgroup Analyses

- Overview of certain AEs or SAEs across demographic characteristics

Laboratory Analyses

- Analyses of Central Tendency
- Analyses of Abnormalities and Outliers
- DILI Screening subsection:
  - Missing Data Analysis
  - Potential Hy's Law Screening Plot

Vital Signs Analyses

- VS distribution by Treatment Group
- Baseline vs. Max/Min by Treatment Group
- Blood Pressure Post-Baseline Data

Expanded Tables and Figures

- Expanded AE Analyses
  - SAEs
  - TEAEs
- Expanded Laboratory Analyses
  - Change Over Time
  - Outlier Criteria
  - Last Value on Treatment

Optional Tables and Figures

- Optional AE Analyses
  - Exposure-Adjusted Analyses
  - Relatedness Analyses
  - Additional FMQ Tables
- Optional Laboratory and Vital Signs Analyses
  - Median and Interquartile Range Plots

Standardization of Data Presentation: Tables

Table 6. Overview of Adverse Events[1], Safety Population, Pooled Analyses[2]

Event	Drug Name Dosage X N=XXX n (%)	Drug Name Dosage Y N=XXX n (%)	Active Control N=XXX n (%)	Placebo N=XXX n (%)	Risk Difference (%) (95% CI)[3]
SAE	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
SAEs with fatal outcome	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Life-threatening SAEs	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
SAEs requiring hospitalization	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
SAEs resulting in substantial disruption of normal life functions	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Congenital anomaly or birth defect	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Other	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
AE leading to permanent discontinuation of study drug	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
AE leading to dose modification of study drug	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
AE leading to interruption of study drug	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
AE leading to reduction of study drug	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
AE leading to dose delay of study drug	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Other	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Any AE[4]	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Severe	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Moderate	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Mild	n (%)	n (%)	n (%)	n (%)	X (Y, Z)

Source: [include Applicant source, datasets and/or software tools used

[1] Treatment-emergent AE defined as [definition]. MedDRA version X.

is shown between [treatment arms] (e.g., difference is shown between Drug Name dosage X vs. placebo).

[4] Se[2] Duration = [e.g., X-week double-blind treatment period or, median and a range indicating pooled trial durations].

[3] Difference verity as assessed by the investigator

Abbreviations: AE, adverse event; CI, confidence interval; N, number of patients in treatment arm; n, number of patients with at least one event; SAE, serious adverse event

Note the order of the treatment columns: drug arms followed by active control, and placebo

Subtext is indented

Footnotes provide important definitions and context

Bolded column headers

10 pt. Arial font for all table text (including headers)

Only horizontal borders in the table for easier side by side comparisons

Standardization of Data Presentation: Figures

To ensure standardization, all generated figures follow the below formatting principles.

Figure X. Mean Laboratory (Chemistry) Data Change from Baseline Over Time by Treatment Arm, Safety Population, Trial X

The y-axis is scaled appropriately

Colors, symbol, and line types can be used to distinguish between series in a graph.

Standardized color selection and consistency across trials.

When the x-axis is used to represent time, labeled by **protocol specified visit** schedule

When displaying data over time, total "n's" are presented per time period at the bottom of the figure

Adverse Event Analyses

- Provides analysis of AEs including:
  - Serious AEs (SAEs)
  - AEs leading to discontinuation
  - FDA Medical Queries (FMQs)
  - AEs of special interest (AESIs)

- All AE tables and figures present treatment-emergent adverse events (TEAEs) as a default

Serious Adverse Events - FMQs

Adverse Event Tables also include FDA Medical Queries (FMQs) arranged by System Organ Class (SOC). FMQs are standardized groupings of adverse event terms developed by FDA reviewers.

Tables are arranged by SOC, and within the SOC if there are multiple FMQs, FMQs are ordered by decreasing RD.

Table 10. Patients with Serious Adverse Events[1] by SOC and FDA Medical Query (Narrow), Safety Population, Pooled Analyses[2]

System Organ Class[4] FMQ (Narrow)	**Drug Name Dosage X N=XXX n (%)**	**Drug Name Dosage Y N=XXX n (%)**	**Active Control N=XXX n (%)**	**Placebo N=XXX n (%)**	**Risk Difference (%) (95% CI)**[3]
SOC1					
FMQ1	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
FMQ2	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
SOC2					
FMQ3	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
FMQ4	n (%)	n (%)	n (%)	n (%)	X (Y, Z)

Overview of Adverse Events

SAE determination includes all AEs that met individual SAE criteria

Table 6. Overview of Adverse Events[1], Safety Population, Pooled Analyses[2]

Event	Drug Name Dosage X N=XXX n (%)	Drug Name Dosage Y N=XXX n (%)	Active Control N=XXX n (%)	Placebo N=XXX n (%)	Risk Difference (%) (95% CI)[3]
SAE	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
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SAEs requiring hospitalization	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
SAEs resulting in substantial disruption of normal life functions	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Congenital anomaly or birth defect	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Other	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
AE leading to permanent discontinuation of study drug	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
AE leading to dose modification of study drug	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
AE leading to interruption of study drug	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
AE leading to reduction of study drug	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
AE leading to dose delay of study drug	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Other	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Any AE[4]	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Severe	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Moderate	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Mild	n (%)	n (%)	n (%)	n (%)	X (Y, Z)

TEAE definition and MedDRA version is also included in footnotes.

Source: [include Applicant source, datasets and/or software tools used

[1] Treatment-emergent AE defined as [definition]. MedDRA version X.

[2] Duration = [e.g., X-week double-blind treatment period or, median and a range indicating pooled trial durations].

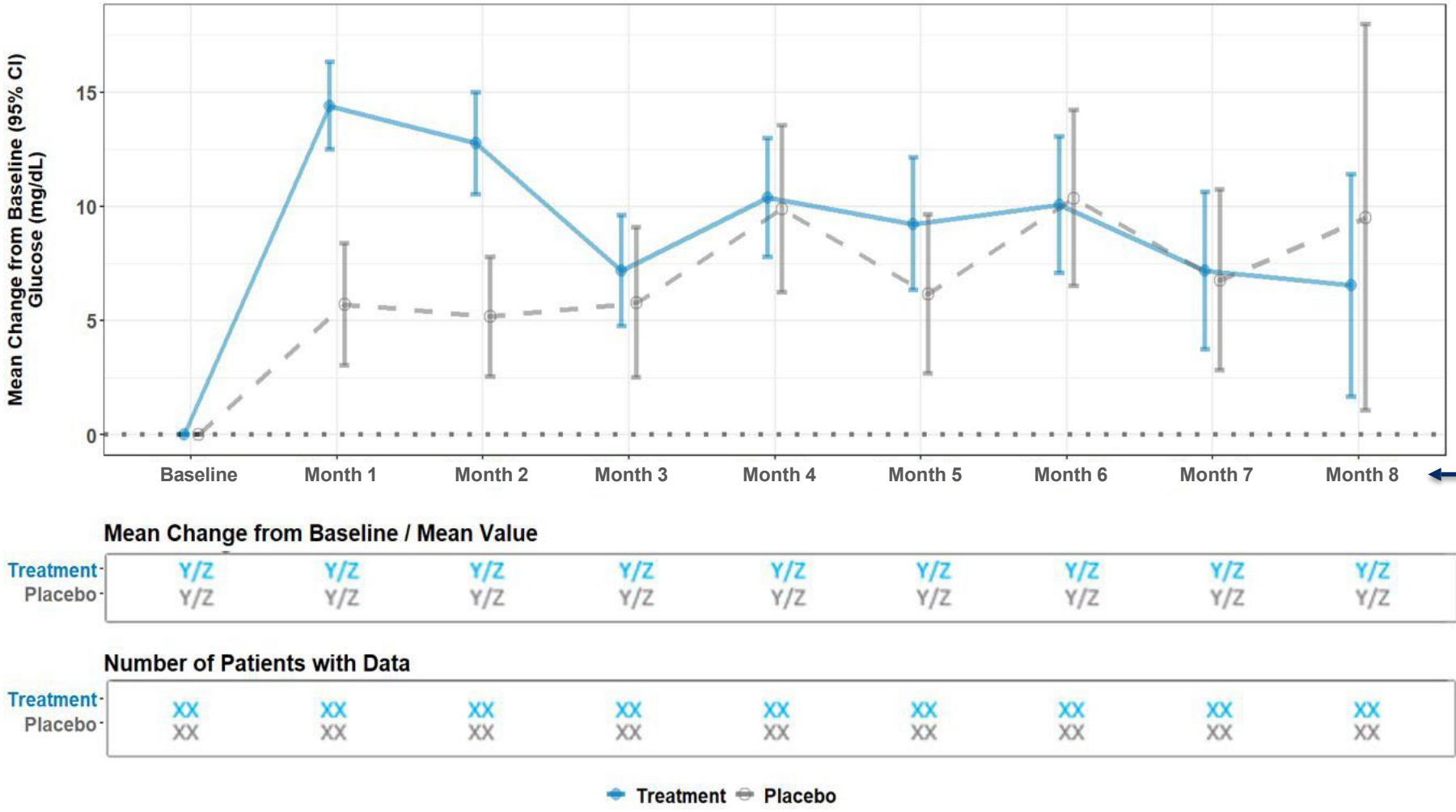
[3] Difference is shown between [treatment arms] (e.g., difference is shown between Drug Name dosage X vs. placebo). [4] Severity as assessed by the investigator

Standard Laboratory Analyses

- Provides an analysis of routine laboratory parameters including:
  - Missing data analyses
  - Measures of central tendency
  - Outlier analyses
- Additional analyses can be found in the Standard Expanded Safety Tables and Figures section (Expanded Section)
  - Specific outlier criteria and analyses
  - Last value on-treatment analyses
  - Alternate tabulations and visualizations

Laboratory Analyses Over Time

Figure X. Mean Laboratory (Chemistry) Data Change from Baseline Over Time by Treatment Arm, Safety Population, Trial X



X-axis shows scheduled visits per protocol

Mean change from baseline and mean value

Figure truncated when less than 5-10% of subjects with data remain in trial

Laboratory Analyses Over Time – Expanded Section

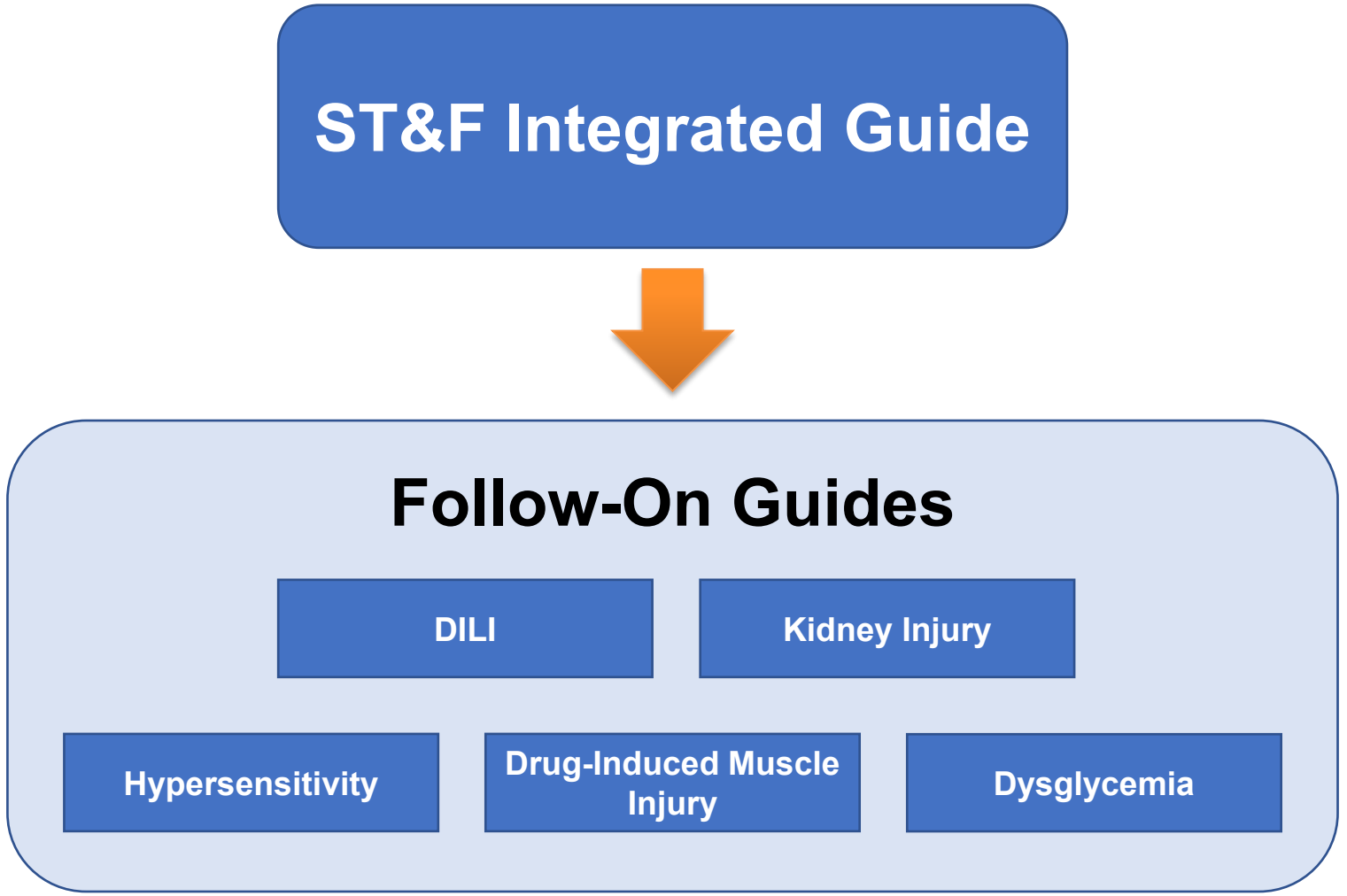
Table 45. Mean Change From Baseline for General Chemistry Data Over Time by Treatment Arm, Safety Population, Pooled Analysis (or Trial X)

Parameter	Study Visit time[1] (Study Day/Week/Month)	Treatment Arm (N = X)			Control Arm (N = X)			Difference in Mean Change (95% CI)[2]
		n (%) at Visit	Mean (95% CI)	Mean Change From Baseline (95% CI)	n (%) at Visit	Mean (95% CI)	Mean Change From Baseline (95% CI)	
Sodium (mEq/L)	Baseline	n (%)	X (Y,Z)	X (Y,Z)	n (%)	X (Y,Z)	X (Y,Z)	X (Y,Z)
	Week X	n (%)	X (Y,Z)	X (Y,Z)	n (%)	X (Y,Z)	X (Y,Z)	X (Y,Z)
	Week Y	n (%)	X (Y,Z)	X (Y,Z)	n (%)	X (Y,Z)	X (Y,Z)	X (Y,Z)
Potassium (mEq/L)	Baseline	n (%)	X (Y,Z)	X (Y,Z)	n (%)	X (Y,Z)	X (Y,Z)	X (Y,Z)
	Week X	n (%)	X (Y,Z)	X (Y,Z)	n (%)	X (Y,Z)	X (Y,Z)	X (Y,Z)
	Week Y	n (%)	X (Y,Z)	X (Y,Z)	n (%)	X (Y,Z)	X (Y,Z)	X (Y,Z)

ST&F IG vs. Follow-On Guides (FOGs)

Follow-On Guides

- Available by request
- Therapeutic area-specific tables and figures
- More in-depth analyses



Standard Safety Tables & Figures
Follow-On Guide: Components

Follow-On Guide

1.0 - Introduction
Background on ST&F

2.0 - Screening Analyses
Tables and figures from the Integrated Guide

3.0 - Follow-On Analyses
Further explore therapeutic area of interest

4.0 - Appendix
Supplemental information

Standard Tables & Figures: DILI Follow-on Guide

For each section, an explanation of what is contained and Reviewer instructions to inform clinical interpretation of the outputs are provided.

Integrated Guide

DILI Screening Analyses

1. Missing Data
2. DILI Case
3. Cholestatic Screening Plots
4. Comparison of Treatment with Maximal Treatment

DILI Guide

DILI Screening Analyses

DILI Follow-On Guide*

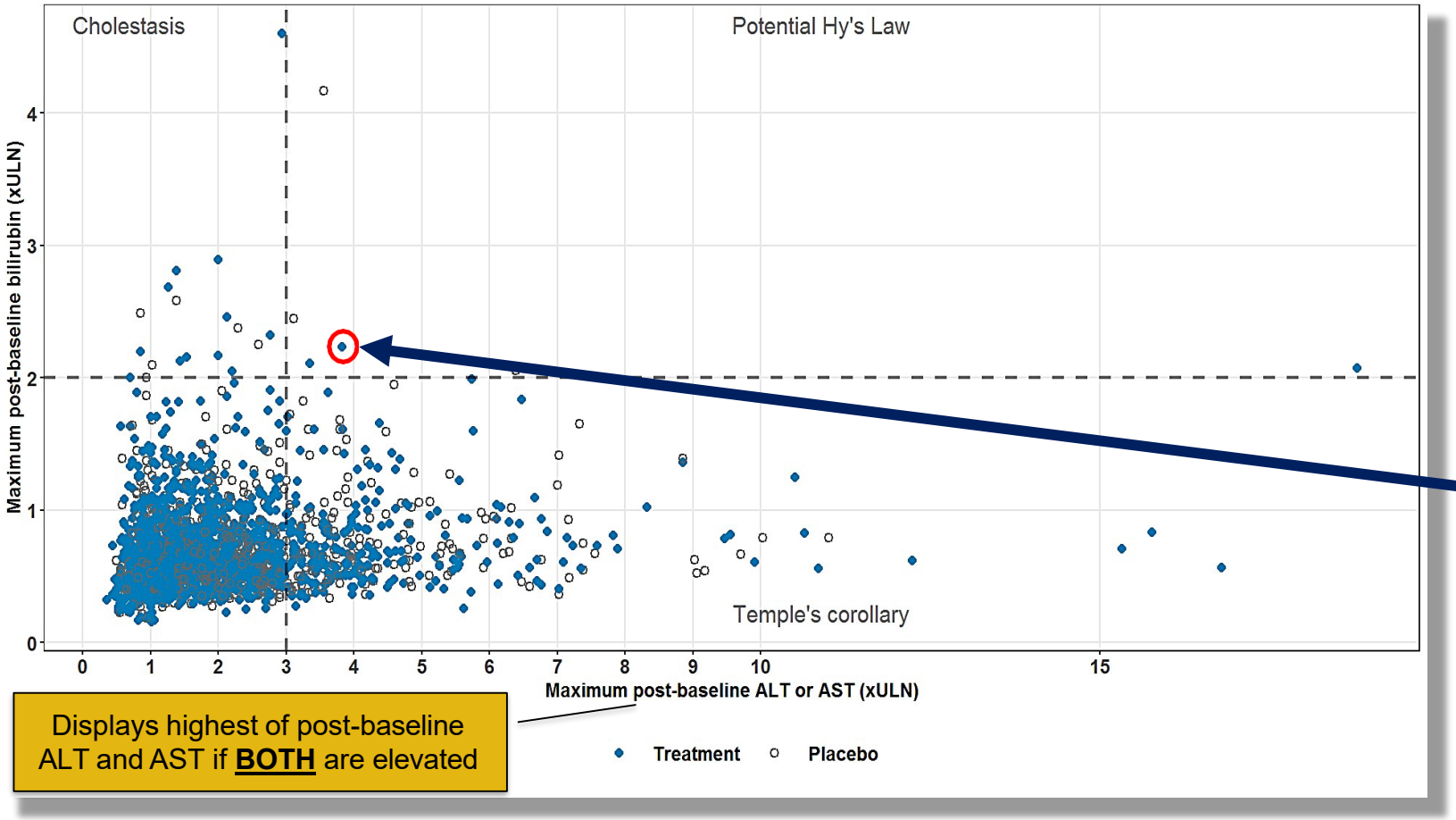
1. Analyses of hepatic AEs and early discontinuation between arms.
2. Analyses of liver biochemistry studies between arms.
3. Patient level analyses to determine true DILI from other etiologies.

*Produced upon request by reviewer

Hepatocellular DILI Case Screening Plot

Note: Default cut-offs are TB ≥ 2xULN and ALT or AST ≥ 3x ULN

Figure 12. Hepatocellular Drug-Induced Liver Injury Screening Plot, Safety Population, Pooled Analyses



Displays highest of post-baseline ALT and AST if **BOTH** are elevated

Each data point represents a patient plotted by their maximum ALT or AST versus their maximum TB values in the postbaseline period.

Red circle indicates this patient meets timing and ALP criteria:

Any postbaseline TB ≥2x ULN within 30 days after apostbaseline ALT or AST ≥3x ULN

DILI FOG Example Analysis: Liver Biochemistry Elevations Between Arms

Frequency of Hepatic Safety Laboratory Parameter Elevations at any Post-Baseline Visit, by Treatment Arm

Laboratory Abnormality	Active N=X n (%)	Comparator N=X n (%)	Risk Difference (95% CI)[1]
ALT			
≥ULN	n (%)	n (%)	X (Y, Z)
≥3x ULN	n (%)	n (%)	X (Y, Z)
≥5x ULN	n (%)	n (%)	X (Y, Z)
≥10x ULN	n (%)	n (%)	X (Y, Z)
≥20x ULN	n (%)	n (%)	X (Y, Z)
AST			
≥ULN	n (%)	n (%)	X (Y, Z)
≥3x ULN	n (%)	n (%)	X (Y, Z)
≥5x ULN	n (%)	n (%)	X (Y, Z)
≥10x ULN	n (%)	n (%)	X (Y, Z)
≥20x ULN	n (%)	n (%)	X (Y, Z)
Alkaline Phosphatase			
≥2x ULN	n (%)	n (%)	X (Y, Z)
≥3x ULN	n (%)	n (%)	X (Y, Z)
Total Bilirubin			
≥2x ULN	n (%)	n (%)	X (Y, Z)
≥5x ULN	n (%)	n (%)	X (Y, Z)
≥8x ULN	n (%)	n (%)	X (Y, Z)
Direct Bilirubin			
≥2x ULN	n (%)	n (%)	X (Y, Z)
≥5x ULN	n (%)	n (%)	X (Y, Z)
GGT			
≥2x ULN			
INR			
≥1.5x ULN	n (%)	n (%)	X (Y, Z)
≥3x ULN	n (%)	n (%)	X (Y, Z)
≥5x ULN	n (%)	n (%)	X (Y, Z)

Source: [include Applicant source and/or Software tools used].
Note: The frequency represented here are based on peak levels. Appropriate cut-off for liver biochemistries should be adjusted based on the study population (e.g., pediatric population, those with underlying liver disease etc.). For patients with chronic liver disease, cut-of should be established using multiples of baseline (e.g. 2x, 3x, 5x).
[1]Difference is shown between [treatment arms]. (E.g, Difference is shown between Drug Name Dosage X vs. Placebo)
Abbreviations: ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; CI, confidence interval; GGT, Gamma-glutamyl transferase; INR, prothrombin international normalized ratio; ULN, upper level of normal; N, number of patients in group; n, number of patients meeting criteria

DILI FOG: Example Graphical Patient Profile

Concluding Remarks

Standard Safety Tables and Figures and FMQs

- Aid FDA clinical review staff in safety signal detection
  - Provide standard approach to categorize and group adverse events
  - Provide standard approach to safety data analysis and visualization
- Foster consistency in data visualizations

Acknowledgements: Core Workgroup Members*

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