



Enhancing Safety Signal Detection: Strategies for Creating FDA Medical Query Analysis Dataset

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Meet the Speaker

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- *The author(s) have no real or apparent conflicts of interest to report.*



Agenda

1. Introduction and Background
2. Methods for Creating FMQ Analysis Dataset
3. Summary and Recommendation

Introduction and Background



Introduction and Background

FDA Medical Query (FMQ):

- Standardized groupings of related preferred terms (PTs)
- One PT can appear in one or more than one FMQ (up to a maximum of 8);
One FMQ can include multiple PTs
- Categorized as either narrow or broad
- To facilitate safety signal detection

Introduction and Background

FMQ related analysis:

Over 30% (19 of 60) of the mockups in “Standard Safety Tables and Figures” are related to FMQs.

- Mostly arranged by SOC and FMQ
- Some display PT terms within FMQ



STANDARD SAFETY TABLES AND FIGURES: *INTEGRATED GUIDE*

Center for Drug Evaluation and Research (CDER)
Biomedical Informatics and Regulatory Review Science
(BIRRS) Team

Introduction and Background

Mockup for FMQ related analysis (from ST&F IG):

Table 14. Patients With Adverse Events¹ by System Organ Class and FDA Medical Query, Safety Population, Pooled Analyses²

System Organ Class ⁴ FMQ	Narrow FMQs				Broad FMQs			
	Drug Name N = XXX n (%)	Active Control N = XXX n (%)	Placebo N = XXX n (%)	Risk Difference (%) (95% CI) ³	Drug Name N = XXX n (%)	Active Control N = XXX n (%)	Placebo N = XXX n (%)	Risk Difference (%) (95% CI) ³
SOC1								
FMQ1	n (%)	n (%)	n (%)	X (Y, Z)	n (%)	n (%)	n (%)	X (Y, Z)
FMQ2	n (%)	n (%)	n (%)	X (Y, Z)	n (%)	n (%)	n (%)	X (Y, Z)
FMQ3	n (%)	n (%)	n (%)	X (Y, Z)	n (%)	n (%)	n (%)	X (Y, Z)
SOC2								
FMQ1	n (%)	n (%)	n (%)	X (Y, Z)	n (%)	n (%)	n (%)	X (Y, Z)
FMQ2	n (%)	n (%)	n (%)	X (Y, Z)	n (%)	n (%)	n (%)	X (Y, Z)
FMQ3	n (%)	n (%)	n (%)	X (Y, Z)	n (%)	n (%)	n (%)	X (Y, Z)
SOC3								
FMQ1	n (%)	n (%)	n (%)	X (Y, Z)	n (%)	n (%)	n (%)	X (Y, Z)
FMQ2	n (%)	n (%)	n (%)	X (Y, Z)	n (%)	n (%)	n (%)	X (Y, Z)
FMQ3	n (%)	n (%)	n (%)	X (Y, Z)	n (%)	n (%)	n (%)	X (Y, Z)

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

¹ Treatment-emergent adverse event 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 Each FMQ is aligned to a single SOC based on clinical judgment. However, please be aware that some FMQs may contain PTs from more than one SOC.

Abbreviations: CI, confidence interval; FMQ, FDA Medical Query; MedDRA, Medical Dictionary for Regulatory Activities; N, number of patients in treatment arm; n, number of patients with at least one event; SOC, System Organ Class

[FDA-2022-N-1961-0046 attachment 1.pdf](#)

Introduction and Background

Mockup for FMQ related analysis (from ST&F IG):

Table 37. Patients With Adverse Events by System Organ Class, FDA Medical Query (Narrow)¹ and Preferred Term, Safety Population, Pooled Analysis (or Trial X)²

System Organ Class⁴	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)^{3,5}
FMQ (Narrow) Preferred Term					
SOC1					
FMQ1	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
PT1	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
PT2	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
SOC2					
FMQ2	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
PT1	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
PT2	n (%)	n (%)	n (%)	n (%)	X (Y, Z)

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

¹ Treatment-emergent adverse event 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 Each FMQ is aligned to a single SOC based on clinical judgment. However, please be aware that some FMQs may contain PTs from more than one SOC.

⁵ Table display is ordered by the risk difference.

Abbreviations: CI, confidence interval; FMQ, FDA Medical Query; MedDRA, Medical Dictionary for Regulatory Activities.; N, number of patients in treatment arm; n, number of patients with at least one event; PT, preferred term; SOC, System Organ Class

[FDA-2022-N-1961-0046 attachment 1.pdf](#)

Methods for Creating FMQ Analysis Dataset



Methods for Creating FMQ Analysis Dataset

FDA FMQ master file (Consolidated_List tab):

Launched 104 FMQs, 11712 FMQ-PT Combinations

	A	B	C	D
1	FMQ	PT	FMQ-PT	Final Classification
2	Abdominal Pain	Abdominal discomfort	Abdominal Pain-Abdominal discomfort	Narrow
3	Abdominal Pain	Abdominal migraine	Abdominal Pain-Abdominal migraine	Narrow
4	Abdominal Pain	Abdominal pain	Abdominal Pain-Abdominal pain	Narrow
5	Abdominal Pain	Abdominal pain aggravated	Abdominal Pain-Abdominal pain aggravated	Narrow
6	Abdominal Pain	Abdominal pain lower	Abdominal Pain-Abdominal pain lower	Narrow
7	Abdominal Pain	Abdominal pain NOS	Abdominal Pain-Abdominal pain NOS	Narrow
8	Abdominal Pain	Abdominal pain upper	Abdominal Pain-Abdominal pain upper	Narrow
9	Abdominal Pain	Abdominal rebound tenderness	Abdominal Pain-Abdominal rebound tenderness	Narrow
10	Abdominal Pain	Abdominal rigidity	Abdominal Pain-Abdominal rigidity	Narrow
11	Abdominal Pain	Abdominal tenderness	Abdominal Pain-Abdominal tenderness	Narrow
12	Abdominal Pain	Acute abdomen	Abdominal Pain-Acute abdomen	Narrow
13	Abdominal Pain	Enteric neuropathy	Abdominal Pain-Enteric neuropathy	Narrow
14	Abdominal Pain	Epigastric discomfort	Abdominal Pain-Epigastric discomfort	Narrow
15	Abdominal Pain	Gastrointestinal discomfort	Abdominal Pain-Gastrointestinal discomfort	Narrow
16	Abdominal Pain	Gastrointestinal pain	Abdominal Pain-Gastrointestinal pain	Narrow
17	Abdominal Pain	Gastrointestinal pain NOS	Abdominal Pain-Gastrointestinal pain NOS	Narrow
18	Abdominal Pain	Gastrointestinal upset	Abdominal Pain-Gastrointestinal upset	Narrow
19	Abdominal Pain	Intestinal spasm	Abdominal Pain-Intestinal spasm	Narrow
20	Abdominal Pain	Perihepatic discomfort	Abdominal Pain-Perihepatic discomfort	Narrow

Table of Contents | FMQ References | Instructions | **Consolidated_List** | Abdominal Pain | Abnormal Uterine Bleeding | Acute Coronary ...

FDA-2022-N-1961-0001_attachment_1.xlsm

Methods for Creating FMQ Analysis Dataset

Transposed FMQ (TFMQ): Transpose FMQ data into one record for each PT. Each PT can be associated with up to 8 FMQs and their respective Classifications.

	PT	FMQ1	SCOPE1	FMQ2	SCOPE2	FMQ3	SCOPE3
1	1p36 deletion syndrome	Seizure	Broad				
2	3-hydroxyacetyl-coenzyme A dehydrogenase deficiency	Rhabdomyolysis	Broad				
3	ACTH-producing pituitary tumour	Malignancy	Broad				
4	AIDS cholangiopathy	Cholecystitis	Broad	Viral Infection	Narrow		
5	AIDS dysmorphic syndrome	Viral Infection	Narrow				
6	AIDS phobia	Anxiety	Narrow				
7	AIDS related complex	Viral Infection	Narrow				
8	AIDS related complication	Viral Infection	Narrow				
9	AIDS retinopathy	Viral Infection	Narrow				
10	ATLAS score for Clostridium difficile infection	Bacterial Infection	Narrow				
11	Aase syndrome	Anemia	Broad				
12	Abasia	Fall	Broad				
13	Abdominal abscess	Bacterial Infection	Narrow	Purulent Material	Narrow		

Methods for Creating FMQ Analysis Dataset

Method 1:

Directly add FMQNAM and FMQCLASS to the existing ADAE.

Multiple records are created per AE if a PT can be assigned to multiple FMQs.

FMQ-related Variables in ADAE

Variable	Label	Description
FMQNAM	FDA Medical Query Name	Merge the current ADAE with the TFMQ dataset by PT. FMQNAM is derived from the FMQs (TFMQ.FMQx, x=1 to 8) in TFMQ dataset. If a record (PT) can be mapped to x FMQs, then x records will be created.
FMQCLASS	FDA Medical Query Class	"BROAD" or "NARROW"

Methods for Creating FMQ Analysis Dataset

Method 1:

	USUBJID	AESPID	AEDECOD	AEBODSYS	FMQNAM	FMQCLASS	ASEQ	ASTDT
1	_000100001	1	Back pain	Musculoskeletal and connective tissue disorders	Back Pain	Narrow	1	31MAY2018
2	_000100001	2	Arthropod sting	Injury, poisoning and procedural complications			2	12JUN2018
3	_000300002	1	Abdominal discomfort	Gastrointestinal disorders	Abdominal Pain	Narrow	1	11JUL2018
4	_000300002	1	Abdominal discomfort	Gastrointestinal disorders	Dyspepsia	Broad	2	11JUL2018
5	_000300002	2	Diarrhoea	Gastrointestinal disorders	Diarrhea	Narrow	3	11JUL2018
6	_000300002	3	Musculoskeletal pain	Musculoskeletal and connective tissue disorders	Myalgia	Broad	4	16AUG2018
7	_000300002	4	Hypersensitivity	Immune system disorders	Anaphylactic Reaction	Broad	5	21JUL2018
8	_000300002	4	Hypersensitivity	Immune system disorders	Hypersensitivity	Narrow	6	21JUL2018
9	_000300002	4	Hypersensitivity	Immune system disorders	Urticaria	Broad	7	21JUL2018
10	_000300002	5	Tooth abscess	Infections and infestations	Bacterial Infection	Narrow	8	13SEP2018
11	_000300002	5	Tooth abscess	Infections and infestations	Purulent Material	Narrow	9	13SEP2018
12	_000300002	6	Weight increased	Investigations			10	07NOV2018
13	_000300003	1	Ear pain	Ear and labyrinth disorders			1	11AUG2018
14	_000300003	2	Blood potassium increased	Investigations			2	11AUG2018
15	_000300006	1	Ligament sprain	Injury, poisoning and procedural complications			1	19JUN2018
16	_000300006	2	Sinus operation	Surgical and medical procedures			2	12SEP2018
17	_000300006	3	Nasal congestion	Respiratory, thoracic and mediastinal disorders			3	12SEP2018
18	_000300006	4	Headache	Nervous system disorders	Headache	Narrow	4	14OCT2018
19	_000300006	5	Anxiety	Psychiatric disorders	Anxiety	Narrow	5	14OCT2018
20	_000300006	6	Localised infection	Infections and infestations			6	24NOV2018
21	_000300006	7	Nasopharyngitis	Infections and infestations	Nasopharyngitis	Narrow	7	26NOV2018

Methods for Creating FMQ Analysis Dataset

Method 1:

Directly add FMQNAM and FMQCLASS to the existing ADAE.

Multiple records are created per AE if a PT can be assigned to multiple FMQs.



PROS

- Simple, no additional dataset
- Analysis ready



CONS

- Additional records in ADAE.
- Traceability: The number of records in ADAE may not match those in AE.
- Potential issues with existing AE reporting tools.

Methods for Creating FMQ Analysis Dataset

Method 2:

ADAEFMQ dataset with FMQNAM and FMQCLASS.

No changes to ADAE.

FMQ-related Variables in ADAEFMQ

Variable	Label	Description
FMQNAM	FDA Medical Query Name	Merge ADAE with the TFMQ dataset by PT. FMQNAM is derived from the FMQs (TFMQ.FMQx, x=1 to 8) in TFMQ dataset. If a record (PT) can be mapped to x FMQs, then x records will be created.
FMQCLASS	FDA Medical Query Class	"BROAD" or "NARROW"
ASEQ	Analysis Sequence Number	Sort by dataset keys and increment for each record.

Methods for Creating FMQ Analysis Dataset

Method 2:

	USUBJID	AESPID	AEDECOD	AEBODSYS	FMQNAM	FMQCLASS	ASEQ	ASTDT
1	_000100001	1	Back pain	Musculoskeletal and connective tissue disorders	Back Pain	Narrow	1	31MAY2018
3	_000300002	1	Abdominal discomfort	Gastrointestinal disorders	Abdominal Pain	Narrow	1	11JUL2018
4	_000300002	1	Abdominal discomfort	Gastrointestinal disorders	Dyspepsia	Broad	2	11JUL2018
5	_000300002	2	Diarhoea	Gastrointestinal disorders	Diarhea	Narrow	3	11JUL2018
6	_000300002	3	Musculoskeletal pain	Musculoskeletal and connective tissue disorders	Myalgia	Broad	4	16AUG2018
7	_000300002	4	Hypersensitivity	Immune system disorders	Anaphylactic Reaction	Broad	5	21JUL2018
8	_000300002	4	Hypersensitivity	Immune system disorders	Hypersensitivity	Narrow	6	21JUL2018
9	_000300002	4	Hypersensitivity	Immune system disorders	Urticaria	Broad	7	21JUL2018
10	_000300002	5	Tooth abscess	Infections and infestations	Bacterial Infection	Narrow	8	13SEP2018
11	_000300002	5	Tooth abscess	Infections and infestations	Purulent Material	Narrow	9	13SEP2018
18	_000300006	4	Headache	Nervous system disorders	Headache	Narrow	4	14OCT2018
19	_000300006	5	Anxiety	Psychiatric disorders	Anxiety	Narrow	5	14OCT2018
21	_000300006	7	Nasopharyngitis	Infections and infestations	Nasopharyngitis	Narrow	7	26NOV2018
22	_000300008	1	Lower respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	Pneumonia	Broad	1	03OCT2018
23	_000300008	1	Lower respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	Pneumonitis	Broad	2	03OCT2018
24	_000300008	1	Lower respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	Viral Infection	Broad	3	03OCT2018
25	_000300008	2	Nausea	Gastrointestinal disorders	Nausea	Narrow	4	05DEC2018
26	_000300008	2	Nausea	Gastrointestinal disorders	Vomiting	Broad	5	05DEC2018
27	_000300008	3	Vomiting	Gastrointestinal disorders	Nausea	Broad	6	05DEC2018
28	_000300008	3	Vomiting	Gastrointestinal disorders	Vomiting	Narrow	7	05DEC2018

Methods for Creating FMQ Analysis Dataset

Method 2:

- Multiple records are created per AE if a PT can be assigned to multiple FMQs.
- May not include all AE records. AE records with no matching PT in the TFMQ can be removed. At a minimum, records with FMQNAM ne NULL should be included.
- Sponsor may choose to retain or drop variables from ADAE.

```
data temp;
  merge adae (in=a) tfmq (rename = (pt=aeecod));
  by aeecod;
  if a;
run;

data adae_fm;
  set temp;
  array fmq(8) fmq1-fmq8 scope(8) scope1-scope8;
  length FMQNAM $40 FMQCLASS $6;
  do i= 1 to 8;
    FMQNAM = fmq(i);
    FMQCLASS = scope(i);
    if FMQNAM ne '' then output;
  end;
run;
```



Methods for Creating FMQ Analysis Dataset

Method 2:

ADAEFMQ dataset with FMQNAM and FMQCLASS.

No changes to ADAE.

PROS

- No changes to the ADAE, ensuring compatibility with existing tools.
- Ready for analysis

CONS

- Additional dataset

Methods for Creating FMQ Analysis Dataset

Method 3:

Using the same approach as Standardized MedDRA Query (SMQ), add FMQ-related variables to the existing ADAE.

FMQ-related Variables in ADAE

Variable	Label	Description
FMQzzzNM	FDA Medical Query zzz Name	It would be left blank for terms not included in the FMQ. Consequently, this variable could be blank for all records if no terms within the study were included in the FMQ. The zzz is derived from the table of contents tab of the FMQ Excel data file, ranging from 001 to 104.
FMQzzzCS	FDA Medical Query zzz Class	"BROAD" or "NARROW"

Methods for Creating FMQ Analysis Dataset

Method 3:

	USUBJID	AESEQ	AESPID	AEDECOD	AEBODSYS	FMQ001NM	FMQ001CS	FMQ002NM	FMQ002CS
1	_000100001	32469428383911	1	Back pain	Musculoskeletal and connective tissue disorders				
2	_000100001	32469428383921	2	Arthropod sting	Injury, poisoning and procedural complications				
3	_000300002	36350728383911	1	Abdominal discomfort	Gastrointestinal disorders	Abdominal Pain	Narrow		
4	_000300002	36350728383921	2	Dianhoea	Gastrointestinal disorders				
5	_000300002	36350728383931	3	Musculoskeletal pain	Musculoskeletal and connective tissue disorders				
6	_000300002	36350728383941	4	Hypersensitivity	Immune system disorders				
7	_000300002	36350728383951	5	Tooth abscess	Infections and infestations				
8	_000300002	36350728383961	6	Weight increased	Investigations				
9	_000300003	35319228383911	1	Ear pain	Ear and labyrinth disorders				
10	_000300003	35319228383921	2	Blood potassium increased	Investigations				
11	_000300006	48725028383911	1	Ligament sprain	Injury, poisoning and procedural complications				
12	_000300006	48725028383921	2	Sinus operation	Surgical and medical procedures				
13	_000300006	48725028383931	3	Nasal congestion	Respiratory, thoracic and mediastinal disorders				
14	_000300006	48725028383941	4	Headache	Nervous system disorders				
15	_000300006	48725028383951	5	Anxiety	Psychiatric disorders				
16	_000300006	48725028383961	6	Localised infection	Infections and infestations				
17	000300006	48725028383971	7	Nasopharyngitis	Infections and infestations				

Methods for Creating FMQ Analysis Dataset

Method 3:

Using the same approach as SMQ, add FMQ-related variables to the existing ADAE.



PROS

- No changes to the original ADAE records. Just add new variables as SMQ.
- Ensuring compatibility with existing tools.



CONS

- Complexity: 208 FMQ-related variables are added
- Very challenging to map FMQ to those 208 variables
- Not ready for analysis
- Low readability
- Low traceability

Methods for Creating FMQ Analysis Dataset

Method 4:

Builds on method 1: ADAE +

ADAEFMQ: Variables transposed from FMQ-related variables in ADAE.

FMQ-related Variables in ADAEFMQ

Variable	Label	Description
FMQNAM	FDA Medical Query Name	Transpose FMQzzzNM from ADAE.
FMQCLASS	FDA Medical Query Class	Transpose FMQzzzCS from ADAE. "BROAD" or "NARROW"

Methods for Creating FMQ Analysis Dataset

Method 4:

	USUBJID	AESPID	AEDECOD	AEBODSYS	FMQNAM	FMQCLASS	ASEQ	ASTDT
1	_000100001	1	Back pain	Musculoskeletal and connective tissue disorders	Back Pain	Narrow	1	31MAY2018
3	_000300002	1	Abdominal discomfort	Gastrointestinal disorders	Abdominal Pain	Narrow	1	11JUL2018
4	_000300002	1	Abdominal discomfort	Gastrointestinal disorders	Dyspepsia	Broad	2	11JUL2018
5	_000300002	2	Diarhoea	Gastrointestinal disorders	Diarhea	Narrow	3	11JUL2018
6	_000300002	3	Musculoskeletal pain	Musculoskeletal and connective tissue disorders	Myalgia	Broad	4	16AUG2018
7	_000300002	4	Hypersensitivity	Immune system disorders	Anaphylactic Reaction	Broad	5	21JUL2018
8	_000300002	4	Hypersensitivity	Immune system disorders	Hypersensitivity	Narrow	6	21JUL2018
9	_000300002	4	Hypersensitivity	Immune system disorders	Urticaria	Broad	7	21JUL2018
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19	_000300006	5	Anxiety	Psychiatric disorders	Anxiety	Narrow	5	14OCT2018
21	_000300006	7	Nasopharyngitis	Infections and infestations	Nasopharyngitis	Narrow	7	26NOV2018
22	_000300008	1	Lower respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	Pneumonia	Broad	1	03OCT2018
23	_000300008	1	Lower respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	Pneumonitis	Broad	2	03OCT2018
24	_000300008	1	Lower respiratory tract congestion	Respiratory, thoracic and mediastinal disorders	Viral Infection	Broad	3	03OCT2018
25	_000300008	2	Nausea	Gastrointestinal disorders	Nausea	Narrow	4	05DEC2018
26	_000300008	2	Nausea	Gastrointestinal disorders	Vomiting	Broad	5	05DEC2018
27	_000300008	3	Vomiting	Gastrointestinal disorders	Nausea	Broad	6	05DEC2018
28	000300008	3	Vomiting	Gastrointestinal disorders	Vomiting	Narrow	7	05DEC2018

Methods for Creating FMQ Analysis Dataset

Method 4:

Builds on method 1: ADAE +

ADAEFMQ: Variables transposed from FMQ-related variables in ADAE.



PROS

- No changes to the original ADAE records. Just add new variables as SMQ.
- Ensuring compatibility with existing tools.
- Ready for analysis




CONS

- Complexity: 208 FMQ-related variables are added
- Very challenging to map FMQ to those 208 variables
- Low readability
- Low traceability
- Additional dataset

Summary and Recommendation



Summary and Recommendation

Method	Description
1	ADAE: Add two variables (FMQNAM and FMQCLASS), presenting all FMQ information in rows. Multiple records per AE if a PT can be mapped to multiple FMQs. May introduce problems with existing AE reporting tools.
2	ADAE (No update) + ADAEFMQ Use ADAE as source and add two variables (FMQNAM and FMQCLASS). May have multiple records per AE. May not include all AE records. Sponsor may choose to retain or drop variables from ADAE. Mapping FMQ in a separate dataset provides sponsor with flexibility and does not touch current ADAE and the related report programs.  Recommended for its balance of compatibility and analysis readiness!
3	One ADAE dataset with all FMQ information as variables: Add 208 FMQ variables (FMQzzzNM, FMQzzzCS) Data complexity, unreadiness for analysis, difficulty in dataset creation, low readability and traceability
4	ADAE (same as Method 1) + ADAEFMQ Analysis-ready, but still faces challenges as in Method 3.

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Thank You!

I'M SPEAKING!

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