



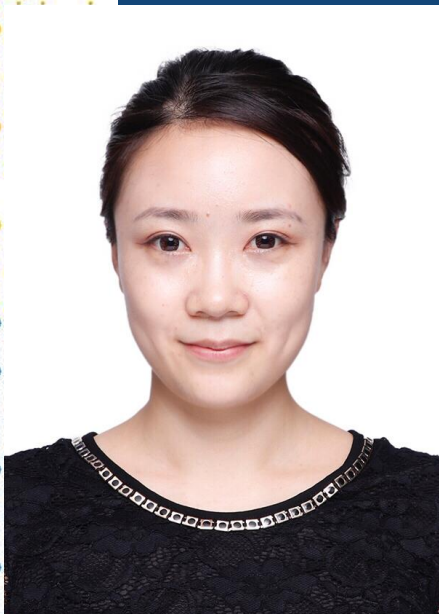
A Novel Approach for the Algorithmic FMQ Analysis Dataset (ADALGFMQ)

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Meet the Speaker

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Jiaonan Li is Senior Scientist at MSD China's Statistical Programming Group with approximately 8 years of experience in the pharmaceutical industry. She has a variety of work experience with Late-stage oncology study, Early-stage oncology study, ISS study and regulatory submission. Jiaonan holds an MS degree in Biostatistics from the University of Southern California and a BS degree in Biology Science from Jinan University.



Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
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Agenda

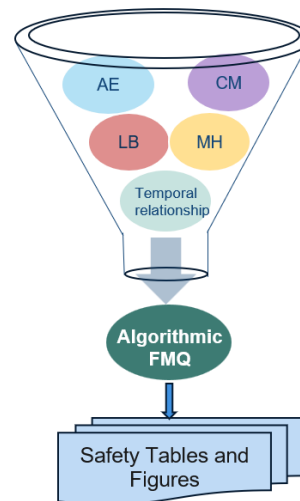
1. Introduction
2. Proposal for the Algorithmic FMQ Analysis Dataset
3. Summary

Introduction



Introduction

- U.S. Food and Drug Administration (FDA) released a draft guidance on standard safety tables and figures (ST&F) in August 2022, which includes 19 of them related to FDA Medical Queries (FMQs).
- The FMQs are standardized groupings of related Medical Dictionary for Regulatory Activities (MedDRA) preferred terms (PTs).
- Algorithmic FMQs (ALGFMQs) are an important step forward in signal detection, as these include data from:
 - Adverse Event
 - Laboratory
 - Concomitant Medications
 - Medical History
 - Temporal relationships





Introduction

- Four algorithmic FMQs* have been developed:
 - Rhabdomyolysis and other muscle injury
 - Hypoglycemia
 - Hyperglycemia
 - Hypersensitivity

*Algorithmic FMQs are still in development and will be updated as more experience is gained by using them in NDA/BLA safety evaluations.

Introduction

- Mockup of Rhabdomyolysis and Other Muscle Injury
 - 4 Algorithmic FMQ Criteria
 - Count participants per criterion and calculate risk difference

Table 39. Patients With Rhabdomyolysis and Other Muscle Injury Algorithmic FDA Medical Query, Safety Population, Pooled Analysis (or Trial X)

Algorithmic FMQ Criterion	Drug Name Dose X	Drug Name Dose Y	Control	Risk Difference
	N = XXX N (%)	N = XXX N (%)	N = XXX N (%)	(%) (95% CI) ^{1,4}
Patients with ≥1 Algorithmic Criterion	n(%)	n(%)	n(%)	X (Y, Z)
Any Rhabdomyolysis FMQ Narrow	n(%)	n(%)	n(%)	X (Y, Z)
Urine myoglobin > ULN	n(%)	n(%)	n(%)	X (Y, Z)
CPK >5 x ULN ²	n(%)	n(%)	n(%)	X (Y, Z)
Myalgia + Weakness + Chromaturia ³	n(%)	n(%)	n(%)	X (Y, Z)

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

¹ Difference is shown between [treatment arms].

² NO CPK-MB/CPK >0.05 within 3 days NOR CPK > ULN at baseline.

³ [PT Myalgia + PT Muscular Weakness + (PT Myoglobin Urine Present OR PT Chromaturia)] within 7 days.

⁴ Table display is ordered by the risk difference.

Abbreviations: CI, confidence interval; CPK, creatine phosphokinase; FMQ, FDA Medical Query; N, number of patients in group; n, number of patients meeting criteria; PT, preferred term, ULN, upper limit of normal

Introduction

• Mockup of Hypoglycemia

➤ Subgroup analysis

- ✓ No History of Diabetes
- ✓ History of Diabetes

➤ 4 Algorithmic FMQ Criteria

Table 40. Patients With Hypoglycemia Algorithmic FDA Medical Query, Safety Population, Pooled Analysis (or Trial X)

Population	Drug Name Dosage X N = XXX n (%)	Placebo N = XXX n (%)	Risk Difference (%) (95% CI) ¹
Algorithmic FMQ Criterion			
Safety Population			
Patients with ≥ 1 Algorithmic Criterion	n(%)	n(%)	
Any Hypoglycemia FMQ Narrow Term	n(%)	n(%)	X (Y, Z)
Plasma Glucose < 54 mg/dL	n(%)	n(%)	X (Y, Z)
Hypoglycemia Term ² + Plasma Glucose < 70 mg/dL ³	n(%)	n(%)	X (Y, Z)
≥ 2 Hypoglycemia Terms ² + ≥ 2 Episodes of Plasma Glucose < 70 mg/dL	n(%)	n(%)	X (Y, Z)
No History of Diabetes			
Patients with ≥ 1 Algorithmic Criterion	n(%)	n(%)	X (Y, Z)
Any Hypoglycemia FMQ Narrow Term	n(%)	n(%)	X (Y, Z)
Plasma Glucose < 54 mg/dL	n(%)	n(%)	X (Y, Z)
Hypoglycemia Term ² + Plasma Glucose < 70 mg/dL ³	n(%)	n(%)	X (Y, Z)
≥ 2 Hypoglycemia Terms ² + ≥ 2 Episodes of Plasma Glucose < 70 mg/dL	n(%)	n(%)	X (Y, Z)
History of Diabetes			
Patients with ≥ 1 Algorithmic Criterion	n(%)	n(%)	X (Y, Z)
Any Hypoglycemia FMQ Narrow Term	n(%)	n(%)	X (Y, Z)
Plasma Glucose < 54 mg/dL	n(%)	n(%)	X (Y, Z)
Hypoglycemia Term ² + Plasma Glucose < 70 mg/dL ³	n(%)	n(%)	X (Y, Z)
≥ 2 Hypoglycemia Terms ² + ≥ 2 Episodes of Plasma Glucose < 70 mg/dL	n(%)	n(%)	X (Y, Z)

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

¹ Difference is shown between [treatment arms].

² Includes any Hypoglycemia FMQ Broad term that is not a Hypoglycemia FMQ Narrow term or any of the following supplemental terms: accident, anxiety, asthenia, balance disorder, cold sweat, coma, confusional state, coordination abnormal, dysarthria, fall, fatigue, headache, hunger, hyperhidrosis, irritability, loss of consciousness, palpitations, road traffic accident, seizure, tremor, vision blurred, and visual impairment.

³ Hypoglycemia Term and Plasma Glucose level must occur within 7 days of each other.

Abbreviations: CI, confidence interval; FMQ, FDA Medical Query; N, number of patients in group; n, number of patients meeting criteria; PT, preferred term

Introduction

• Mockup of Hyperglycemia

➤ Subgroup analysis

- ✓ No History of Diabetes
- ✓ History of Diabetes

➤ 7 Algorithmic FMQ Criteria

Table 41. Patients With Hyperglycemia Algorithmic FDA Medical Query, Safety Population, Pooled Analysis (or Trial X)

Population	Drug Name Dosage X N = XXX n (%)	Placebo N = XXX n (%)	Risk Difference (%) (95% CI) ¹
Algorithmic FMQ Criterion			
Safety Population	n(%)	n(%)	
Patients with ≥ 1 Algorithmic Criterion	n(%)	n(%)	X (Y, Z)
Any Hyperglycemia FMQ Narrow term	n(%)	n(%)	X (Y, Z)
Fasting Plasma Glucose ≥ 126 mg/dL	n(%)	n(%)	X (Y, Z)
≥ 2 Plasma Glucoses > 180 mg/dL	n(%)	n(%)	X (Y, Z)
Any New Diabetes Concomitant Medication	n(%)	n(%)	X (Y, Z)
Post Baseline HbA1c ≥ 6.5%	n(%)	n(%)	X (Y, Z)
HbA1c Increase ≥ 0.3% with Post Baseline HbA1c ≥ 5.7%	n(%)	n(%)	X (Y, Z)
Change from Baseline Fasting Plasma Glucose ≥ 20 mg/dL with Post Baseline Fasting Plasma Glucose > 100 mg/dL	n(%)	n(%)	X (Y, Z)
No History of Diabetes			
Patients with ≥ 1 Algorithmic Criterion	n(%)	n(%)	X (Y, Z)
Any Hyperglycemia FMQ Narrow term	n(%)	n(%)	X (Y, Z)
Fasting plasma glucose ≥ 126 mg/dL	n(%)	n(%)	X (Y, Z)
≥ 2 Plasma Glucoses > 180 mg/dL	n(%)	n(%)	X (Y, Z)
Any New Diabetes Concomitant Medication	n(%)	n(%)	X (Y, Z)
Post Baseline HbA1c ≥ 6.5%	n(%)	n(%)	X (Y, Z)
HbA1c Increase ≥ 0.3% with Post Baseline HbA1c ≥ 5.7%	n(%)	n(%)	X (Y, Z)
Change from Baseline Fasting Plasma Glucose ≥ 20 mg/dL with Post Baseline Fasting Plasma Glucose > 100 mg/dL	n(%)	n(%)	X (Y, Z)
History of Diabetes			
Patients with ≥ 1 Algorithmic Criterion	n(%)	n(%)	X (Y, Z)
Any Hyperglycemia FMQ Narrow term	n(%)	n(%)	X (Y, Z)
Fasting plasma glucose ≥ 126 mg/dL	n(%)	n(%)	X (Y, Z)
≥ 2 Plasma Glucoses > 180 mg/dL	n(%)	n(%)	X (Y, Z)
Any New Diabetes Concomitant Medication	n(%)	n(%)	X (Y, Z)
Post Baseline HbA1c ≥ 6.5%	n(%)	n(%)	X (Y, Z)
HbA1c Increase ≥ 0.3% with Post Baseline HbA1c ≥ 5.7%	n(%)	n(%)	X (Y, Z)
Change from Baseline Fasting Plasma Glucose ≥ 20 mg/dL with Post Baseline Fasting Plasma Glucose > 100 mg/dL	n(%)	n(%)	X (Y, Z)

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

¹ Difference is shown between [treatment arms].

² Table display is ordered by the risk difference.

Abbreviations: CI, confidence interval; FMQ, FDA Medical Query; N, number of patients in treatment arm; n, number of patients with adverse event

Introduction

- Mockup of Hypersensitivity
 - 4 Algorithmic FMQ Criteria

Table 42. Patients With Algorithmic Hypersensitivity FDA Medical Query, Safety Population, Trial X

Algorithmic FMQ Criterion	Drug Name Dose X N = XX	Drug Name Dose Y N = XX	Active Control N = XX	Risk Difference (95% CI) ^{1,3}
	n(%)	n(%)	n(%)	
Patients with ≥1 Algorithmic Criterion²	n(%)	n(%)	n(%)	X (Y, Z)
Any hypersensitivity FMQ narrow term	n(%)	n(%)	n(%)	X (Y, Z)
Respiratory + Skin Reaction	n(%)	n(%)	n(%)	X (Y, Z)
Respiratory + Systemic Reaction	n(%)	n(%)	n(%)	X (Y, Z)
Skin + Systemic Reaction	n(%)	n(%)	n(%)	X (Y, Z)

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

¹ Difference is shown between [treatment arms].

² Combinations of events must occur within 7 days of each other to qualify

³ Table display is ordered by the risk difference.

Abbreviations: CI, confidence interval; FMQ, FDA Medical Query; N, number of patients in treatment arm; n, number of patients with adverse event

Proposal for the ALGFMQ Analysis Dataset



Proposal for the ALGFMQ Analysis Dataset

Proposal 1: Specification

BDS | Key variables:

- PARAM: ALGFMQ criterion
- PARCAT1: ALGFMQ
- PARAMCD: assigned value
- AVALC: Set to 'Yes'

Variable Name	Variable Label	Type	Derivation
All core variables should be carried over from ADL			
DIABETFL	History of Diabetes	Char	ADSL.DIABETFL This variable is needed in FMQ (Hypersensitivity) related analysis table.
ASTDT	Analysis Start Date	integer	See Value-level Metadata
ASTDY	Analysis Start Relative Day	integer	ASTDT-TRTSDT + 1
PARAM	Parameter	Char	See Value-level Metadata
PARAMCD	Parameter Code	Char	See Value-level Metadata
PARAMN	Parameter (N)	integer	Derived at study level, depending on the sorting order required
PARCAT1	Parameter Category 1	Char	See Value-level Metadata
PARCAT1N	Parameter Category 1 (N)	integer	1=Rhabdomyolysis 2=Hypoglycemia 3=Hyperglycemia 4=Hypersensitivity
AVALC	Analysis Value (C)	Char	Set to 'Yes'
HYPSCAT	Hypersensitivity Category	Char	Determine if Hypersensitivity belong to category A, B, C, or D per FDA FMQ master file.
SRCVALUE	Source Value	Char	The source value that used in derived ATERM
SRCVAR	Source Variable	Char	The name of source variable used to derive ATERM
SRCDOM	Source Data	Char	The name of source dataset that used to derive ATERM. If multiple source datasets are used, set NULL.
SRCSEQ	Source Sequence Number	integer	The sequence number --SEQ or ASEQ of the row (in the domain or dataset identified by SRCDOM) that relates to the analysis variable (ATERM).
ASPID	Analysis Identifier	Char	See Value-level Metadata
ARELID	Analysis Relationship Identifier	Char	See Value-level Metadata

Proposal for the ALGFMQ Analysis Dataset

Proposal 1: Value-level Metadata

PARCAT1	PARCAT1N	PARAMCD	PARAM	PARAMN	ASTDT	ASPID	ARELID	Derivation
Hypoglycemia	2	HYP0	Any Hypoglycemia FMQ Narrow Term	21	ADAEFMQ.ASTDT	Set to missing	Set to missing	If ADAEFMQ.FMQNAM="Hypoglycemia" and ADAEFMQ.FMQCLASS="Narrow", then set PARAMCD = HYP0 , PARAMN = 21, PARAM="Any Hypoglycemia FMQ narrow term". Create a record
Hypoglycemia	2	PGLU	Plasma Glucose < 54 mg/dL	22	ADLB.ADT	Set to missing	Set to missing	From ADLB dataset. When ADLB.LCSPEC='PLASMA' and ADLB.PARAMCD='GLUC' and ADLB.AVALU='mg/dL' and ADLB.AVAL < 54, then set PARAMCD = PGLU , PARAMN = 22, PARAM="Plasma Glucose < 54 mg/dL". Create a record
Hypoglycemia	2	HYPOT	Hypoglycemia Term	231	ADAEFMQ.ASTDT/ ADAE.ASTDT	For each participant, assign a sequential number (seq) starting from 1 to n (n is number of records of PARAMN=231). ASPID is created by concatenating PARAMN and seq by dash ("-").	Set to missing	If ((ADAEFMQ.FMQNAM="Hypoglycemia" and ADAEFMQ.FMQCLASS="Broad") or ADAE.AEDECOD in Accident, Anxiety, Asthenia, Cold sweat, Coma, Confusional state, Fall, Fatigue, Hunger, Hyperhidrosis, Irritability, Loss of consciousness, Palpitations, Road traffic accident, Seizure, Tremor, Dysarthria, Balance disorder, Coordination abnormal, Headache, Vision blurred, and Visual impairment), then set PARAMCD = HYPOT , PARAMN=231, PARAM = "Hypoglycemia Term"
Hypoglycemia	2	PGLUS	Plasma Glucose < 70 mg/dL	232	ADLB.ADT	For each participant, assign a sequential number (seq) starting from 1 to n (n is number of records of PARAMN=232). ASPID is created by concatenating PARAMN and seq by dash ("-").	Set to missing	If ADLB.PARAMCD='GLUC' and ADLB.LBSPEC='PLASMA' and ADLB.AVALU='mg/dL' and ADLB.AVAL <70, then set PARAMCD = PGLUS , PARAMN=232, PARAM="Plasma Glucose < 70 mg/dL"
Hypoglycemia	2	HYP0PGLU	Hypoglycemia Term + Plasma Glucose < 70 mg/dL	23	Minimum of ASTDT that linked to the event used to derive	Set to missing	ARELID is created by concatenating the corresponding ASPID from PARAMN=231 and 232, separated by comma (",");	If a participant has both one record from PARAMN=231 and one record from PARAMN=232 with ADLB.ADT (from PARAMN=231), then set PARAMCD = HYP0PGLU , PARAMN = 23, PARAM="Hypoglycemia Term + Plasma Glucose < 70 mg/dL". Create a record
Hypoglycemia	2	HYP0EGLU	>= 2 Hypoglycemia Terms + >= 2 Episodes of Plasma Glucose < 70 mg/dL	24	Minimum of ASTDT that linked to the event used to derive	Set to missing	ARELID is created by concatenating the corresponding ASPID from PARAMN=231 and 233, separated by comma (",");	If a participant has more than 1 record from PARAMN=231 and more than 1 record from PARAMN=232, then set PARAMCD = HYP0EGLU , PARAMN = 24, PARAM=" >= 2 Hypoglycemia Terms + >= 2 Episodes of Plasma Glucose < 70 mg/dL". Create a record

Proposal for the ALGFMQ Analysis Dataset

Proposal 1: Sample Dataset

USUBJID	ASTDT	PARAM	PARAMCD	PARAMN	PARCAT1	PARCAT1N	AVALC	HYPSCAT	SRCVALUE	SRCVAR	SRCDOM	SRCSEQ	ASPID	ARELID
3002	5/2/2023	Any Hypoglycemia FMQ Narrow Term	HYPO	21	Hypoglycemia		2 YES		Hypoglycemia	FMQNAM	ADAEFMQ	39		
3002	5/21/2023	Any Hypoglycemia FMQ Narrow Term	HYPO	21	Hypoglycemia		2 YES		Hypoglycemia	FMQNAM	ADAEFMQ	48		
3002	5/3/2023	Plasma Glucose < 54 mg/dL	PGLU	22	Hypoglycemia		2 YES		32	AVAL	ADLB	100		
3002	5/2/2023	Hypoglycemia Term	HYPOT	231	Hypoglycemia		2 YES		Hypoglycemia	FMQNAM	ADAEFMQ	40	231-1	
3002	5/5/2023	Hypoglycemia Term	HYPOT	231	Hypoglycemia		2 YES		Fatigue	AEDECOD	ADAE	930	231-2	
3002	5/3/2023	Plasma Glucose < 70 mg/dL	PGLUS	232	Hypoglycemia		2 YES		32	AVAL	ADLB	100	232-1	
3002	5/2/2023	Hypoglycemia Term + Plasma Glucose < 70 mg/dL	HYPOPLU	23	Hypoglycemia		2 YES							231-1,232-1
3002		>=2 Hypoglycemia Terms + >=2 Episodes of Plasma Glucose < 70 mg/dL	HYPOEGLU	24	Hypoglycemia		2 YES	This record will not be populated in dataset since no criteria met						

Intermediate records to enhance traceability

Proposal for the ALGFMQ Analysis Dataset

Proposal 1: Specification

BDS I Key variables:

Measurement	Variable Label	Unit	Derivation
PARAM	ALGFMQ Location		The location of the ALGFMQ location.
PARCAT1	ALGFMQ		The ALGFMQ category.
PARAMCD	assigned values		The ALGFMQ category code.
AVALC	Set to YES		The ALGFMQ category code.

cdisc

Proposal for the ALGFMQ Analysis Dataset

Proposal 1:

Each ALGFMQ criterion is set as a PARAM. PARAM is the target analysis variable.



PROS

- Clear value-level metadata
- Traceability



CONS

- Not analysis ready

Proposal for the ALGFMQ Analysis Dataset

Proposal 2: Specification

BDS II Key variables:

- PARAM: ALGFMQ
- PARAMCD: assigned value
- AVALC: ALGFMQ criterion
- AVAL: assigned numeric value

Variable Name	Variable Label	Type	Derivation
All core variables should be carried over from ADSL			
DIABETFL	History of Diabetes	Char	ADSL.DIABETFL This variable is needed in FMQ (Hypersensitivity) related analysis table.
ASTDT	Analysis Start Date	integer	See Value-level Metadata
ASTDY	Analysis Start Relative Day	integer	ASTDT-TRTSDT + 1
PARAM	Parameter	Char	See Value-level Metadata
PARAMCD	Parameter Code	Char	See Value-level Metadata
PARAMN	Parameter (N)	integer	See Value-level Metadata
AVALC	Analysis Value (C)	Char	See Value-level Metadata
AVAL	Analysis Value (C)	Char	See Value-level Metadata
HYPSCAT	Hypersensitivity Category	Char	Determine if Hypersensitivity belong to category A, B, C, or D per FDA FMQ master file.
SRCVALUE	Source Value	Char	The source value that used in derived ATERM
SRCVAR	Source Variable	Char	The name of source variable used to derive ATERM
SRCDOM	Source Data	Char	The name of source dataset that used to derive ATERM. If multiple source datasets are used, set NULL.
SRCSEQ	Source Sequence Number	integer	The sequence number --SEQ or ASEQ of the row (in the domain or dataset identified by SRCDOM) that relates to the analysis variable (ATERM).
ASPID	Analysis Identifier	Char	See Value-level Metadata
ARELID	Analysis Relationship Identifier	Char	See Value-level Metadata

Proposal for the ALGFMQ Analysis Dataset

Proposal 2: Value-level Metadata

PARAM	PARAMN	PARAMCD	AVALC	AVAL	ASTDT	ASPID	ARELID
Hypoglycemia	2	HYPOG	<p>If ADAEFMQ.FMQNAM="Hypoglycemia" and ADAEFMQ.FMQCLASS="Narrow", then Any Hypoglycemia FMQ Narrow Term; From ADLB dataset. When ADLB.LCSPEC="PLASMA" and ADLB.PARAMCD="GLUC" and ADLB.AVALU="mg/dL" and ADLB.AVAL < 54, then 'Plasma Glucose < 54 mg/dL'. Create a record;</p> <p>If ((ADAEFMQ.FMQNAM="Hypoglycemia" and ADAEFMQ.FMQCLASS="Broad") or ADAE.AEDECOD in Accident, Anxiety, Asthenia, Cold sweat, Coma, Confusional state, Fall, Fatigue, Hunger, Hyperhidrosis, Irritability, Loss of consciousness, Palpitations, Road traffic accident, Seizure, Tremor, Dysarthria, Balance disorder, Coordination abnormal, Headache, Vision blurred, and Visual impairment), then 'Hypoglycemia Term';</p> <p>If ADLB.PARAMCD="GLUC" and ADLB.LBSPEC="PLASMA" and ADLB.AVALU="mg/dL" and ADLB.AVAL <70, then "Plasma Glucose < 70 mg/dL";</p> <p>If a participant has both one record from PARAMN=231 and one record from PARAMN=232 with ADLB.ADT (from PARAMN=232) within 1 week of the AE (from PARAMN=231), then 'Hypoglycemia Term + Plasma Glucose < 70 mg/dL'. Create a record;</p> <p>If a participant has more than 1 record from PARAMN=231 and more than 1 record from PARAMN=232, then '>= 2 Hypoglycemia Terms + >= 2 Episodes of Plasma Glucose < 70 mg/dL'. Create a record.</p>	<p>If ADAEFMQ.FMQNAM="Hypoglycemia" and ADAEFMQ.FMQCLASS="Narrow", then 21; From ADLB dataset. When ADLB.LCSPEC="PLASMA" and ADLB.PARAMCD="GLUC" and ADLB.AVALU="mg/dL" and ADLB.AVAL < 54, then 22;</p> <p>If ((ADAEFMQ.FMQNAM="Hypoglycemia" and ADAEFMQ.FMQCLASS="Broad") or ADAE.AEDECOD in Accident, Anxiety, Asthenia, Cold sweat, Coma, Confusional state, Fall, Fatigue, Hunger, Hyperhidrosis, Irritability, Loss of consciousness, Palpitations, Road traffic accident, Seizure, Tremor, Dysarthria, Balance disorder, Coordination abnormal, Headache, Vision blurred, and Visual impairment), then 23;</p> <p>If ADLB.PARAMCD="GLUC" and ADLB.LBSPEC="PLASMA" and ADLB.AVALU="mg/dL" and ADLB.AVAL <70, then 232;</p> <p>If a participant has both one record from PARAMN=231 and one record from PARAMN=232 with ADLB.ADT (from PARAMN=232) within 1 week of the AE (from PARAMN=231), then 23;</p> <p>If a participant has more than 1 record from PARAMN=231 and more than 1 record from PARAMN=232, then 24.</p>	<p>If ADAEFMQ.FMQNAM="Hypoglycemia" and ADAEFMQ.FMQCLASS="Narrow", then ADAEFMQ.ASTDT;</p> <p>From ADLB dataset. When ADLB.LCSPEC="PLASMA" and ADLB.PARAMCD="GLUC" and ADLB.AVALU="mg/dL" and ADLB.AVAL < 54, then ADLB.ADT;</p> <p>If ((ADAEFMQ.FMQNAM="Hypoglycemia" and ADAEFMQ.FMQCLASS="Broad") or ADAE.AEDECOD in Accident, Anxiety, Asthenia, Cold sweat, Coma, Confusional state, Fall, Fatigue, Hunger, Hyperhidrosis, Irritability, Loss of consciousness, Palpitations, Road traffic accident, Seizure, Tremor, Dysarthria, Balance disorder, Coordination abnormal, Headache, Vision blurred, and Visual impairment), then ADAEFMQ.ASTDT/ADAE.ASTDT;</p> <p>If ADLB.PARAMCD="GLUC" and ADLB.LBSPEC="PLASMA" and ADLB.AVALU="mg/dL" and ADLB.AVAL <70, then ADLB.ADT;</p> <p>If a participant has both one record from PARAMN=231 and one record from PARAMN=232 with ADLB.ADT (from PARAMN=232) within 1 week of the AE (from PARAMN=231), then minimum of ASTDT that linked to the event used to derive;</p> <p>If a participant has both one record from PARAMN=231 and one record from PARAMN=232 with ADLB.ADT (from PARAMN=232) within 1 week of the AE (from PARAMN=231), then minimum of ASTDT that</p>	<p>If ADAEFMQ.FMQNAM="Hypoglycemia" and ADAEFMQ.FMQCLASS="Narrow", then set to missing; From ADLB dataset. When ADLB.LCSPEC="PLASMA" and ADLB.PARAMCD="GLUC" and ADLB.AVALU="mg/dL" and ADLB.AVAL < 54, then set to missing;</p> <p>If ((ADAEFMQ.FMQNAM="Hypoglycemia" and ADAEFMQ.FMQCLASS="Broad") or ADAE.AEDECOD in Accident, Anxiety, Asthenia, Cold sweat, Coma, Confusional state, Fall, Fatigue, Hunger, Hyperhidrosis, Irritability, Loss of consciousness, Palpitations, Road traffic accident, Seizure, Tremor, Dysarthria, Balance disorder, Coordination abnormal, Headache, Vision blurred, and Visual impairment), then for each participant, assign a sequential number (seq) starting from 1 to n (n is number of records of PARAMN=231). ASPID is created by concatenating PARAMN and seq by dash ("-");</p> <p>If ADLB.PARAMCD="GLUC" and ADLB.LBSPEC="PLASMA" and ADLB.AVALU="mg/dL" and ADLB.AVAL <70, then for each participant, assign a sequential number (seq) starting from 1 to n (n is number of records of PARAMN=232). ASPID is created by concatenating PARAMN and seq by dash ("-");</p> <p>If a participant has both one record from PARAMN=231 and one record from PARAMN=232 with ADLB.ADT (from PARAMN=232) within 1 week of the AE (from PARAMN=231), then set to missing;</p> <p>If a participant has both one record from PARAMN=231 and one record from PARAMN=232 with ADLB.ADT (from PARAMN=232) within 1 week of the AE (from PARAMN=231), then set to missing.</p>	<p>If ADAEFMQ.FMQNAM="Hypoglycemia" and ADAEFMQ.FMQCLASS="Narrow", then set to missing; From ADLB dataset. When ADLB.LCSPEC="PLASMA" and ADLB.PARAMCD="GLUC" and ADLB.AVALU="mg/dL" and ADLB.AVAL < 54, then set to missing;</p> <p>If ((ADAEFMQ.FMQNAM="Hypoglycemia" and ADAEFMQ.FMQCLASS="Broad") or ADAE.AEDECOD in Accident, Anxiety, Asthenia, Cold sweat, Coma, Confusional state, Fall, Fatigue, Hunger, Hyperhidrosis, Irritability, Loss of consciousness, Palpitations, Road traffic accident, Seizure, Tremor, Dysarthria, Balance disorder, Coordination abnormal, Headache, Vision blurred, and Visual impairment), then set to missing;</p> <p>If ADLB.PARAMCD="GLUC" and ADLB.LBSPEC="PLASMA" and ADLB.AVALU="mg/dL" and ADLB.AVAL <70, then set to missing;</p> <p>If a participant has both one record from PARAMN=231 and one record from PARAMN=232 with ADLB.ADT (from PARAMN=232) within 1 week of the AE (from PARAMN=231), then ARELID is created by concatenating the corresponding ASPID from PARAMN=231 and 232, separated by comma (",");</p> <p>If a participant has both one record from PARAMN=231 and one record from PARAMN=232 with ADLB.ADT (from PARAMN=232) within 1 week of the AE (from PARAMN=231), then ARELID is created by concatenating the corresponding ASPID from PARAMN=231 and 233, separated by comma (",").</p>

Proposal for the ALGFMQ Analysis Dataset

Proposal 2: Sample Dataset

USUBJID	ASTDT	PARAM	PARAMCD	PARAMN	AVALC	AVAL	HYPSCAT	SRCVALUE	SRCVAR	SRCDOM	SRCSEQ	ASPID	ARELID	
3002	5/2/2023	Hypoglycemia	HYPOG	2	Any Hypoglycemia FMQ Narrow Term	21		Hypoglycemia	FMQNAM	ADAEFMQ	39			
3002	5/21/2023	Hypoglycemia	HYPOG	2	Any Hypoglycemia FMQ Narrow Term	21		Hypoglycemia	FMQNAM	ADAEFMQ	48			
3002	5/3/2023	Hypoglycemia	HYPOG	2	Plasma Glucose < 54 mg/dL	22		32	AVAL	ADLB	100			
3002	5/2/2023	Hypoglycemia	HYPOG	2	Hypoglycemia Term	231		Hypoglycemia	FMQNAM	ADAEFMQ	40	231-1		
3002	5/5/2023	Hypoglycemia	HYPOG	2	Hypoglycemia Term	231		Fatigue	AEDECOD	ADAE	930	231-2		
3002	5/3/2023	Hypoglycemia	HYPOG	2	Plasma Glucose < 70 mg/dL	232		32	AVAL	ADLB	100	232-1		
3002	5/2/2023	Hypoglycemia	HYPOG	2	Hypoglycemia Term + Plasma Glucose < 70 mg/dL	23							231-1,232-1	
3002		Hypoglycemia	HYPOG	2	>=2 Hypoglycemia Terms + >=2 Episodes of Plasma Glucose < 70 mg/dL	24	This record will not be populated in dataset since no criteria met							



Proposal for the ALGFMQ Analysis Dataset

Proposal 2: Specification

BDS # Key variables:

- PARAM: ALGFMQ
- PARAMCD: assigned value
- AVALC: ALGFMQ criterion
- AVAL: assigned numeric value

Variable Name	Variable Label	Type	Description
USUBJID	Subject ID Number	Text	USUBJID, Subject ID
ASTDT	Start Date	Date	Start date in YYYYMMDD format in Pacific (responsibility, system, source)
ASTDTM	Start Time	Text	Start time in HH:MM:SS format in Pacific (responsibility, system, source)
ASPID	Analysis Set Protocol Day	Integer	Day number in analysis set (responsibility, system, source)
ARELID	Analysis Set Relative Day	Integer	Day number in analysis set (responsibility, system, source)
PARAMCD	Parameter Code	Text	See Table 2.1.1 (responsibility, system, source)
PARAMN	Parameter Number	Integer	See Table 2.1.1 (responsibility, system, source)
AVALC	Analysis Value C	Text	See Table 2.1.1 (responsibility, system, source)
AVAL	Analysis Value	Text	See Table 2.1.1 (responsibility, system, source)
HYPSCAT	Hypoglycemia Category	Text	See Table 2.1.1 (responsibility, system, source)
SRCVALUE	Source Value	Text	See Table 2.1.1 (responsibility, system, source)
SRCVAR	Source Variable	Text	See Table 2.1.1 (responsibility, system, source)
SRCDOM	Source Domain	Text	See Table 2.1.1 (responsibility, system, source)
SRCSEQ	Source Sequence Number	Integer	See Table 2.1.1 (responsibility, system, source)
ASPID	Analysis Set Protocol Day	Integer	See Table 2.1.1 (responsibility, system, source)
ARELID	Analysis Set Relative Day	Integer	See Table 2.1.1 (responsibility, system, source)

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Proposal for the ALGFMQ Analysis Dataset

Proposal 2:

Each ALGFMQ criterion is set as an AVALC. AVALC is the target analysis variable.



PROS

- Analysis ready



CONS

- Specification hard to read

Proposal for the ALGFMQ Analysis Dataset



Proposal 3: Specification

OCCDS Key variables:

- ATERM: ALGFMQ criterion
- ACAT1: ALGFMQ
- ASPID, ARELID, SRCVALUE, SRCVAR, SRCDOM, SRCSEQ: created for traceability

Variable Name	Variable Label	Type	Derivation
All core variables should be carried over from ADSL			
DIABETFL	History of Diabetes	Char	ADSL.DIABETFL This variable is needed in FMQ (Hypersensitivity) related analysis table.
ASTDT	Analysis Start Date	integer	See Value-level Metadata
ASTDY	Analysis Start Relative Day	integer	ASTDT-TRTSDT + 1
ACAT1	Analysis Category 1	Char	See Value-level Metadata
ACAT1N	Analysis Category 1 (N)	integer	1=Rhabdomyolysis 2=Hypoglycemia 3=Hyperglycemia 4=Hypersensitivity
ATERM	Analysis Term	Char	See Value-level Metadata
ATERMN	Analysis Term (N)	integer	See Value-level Metadata
HYPSCAT	Hypersensitivity Category	Char	Determine if Hypersensitivity belong to category A, B, C, or D per FDA FMQ master file.
SRCVALUE	Source Value	Char	The source value that used in derived ATERM
SRCVAR	Source Variable	Char	The name of source variable used to derive ATERM
SRCDOM	Source Data	Char	The name of source dataset that used to derive ATERM. If multiple source datasets are used, set NULL.
SRCSEQ	Source Sequence Number	integer	The sequence number --SEQ or ASEQ of the row (in the domain or dataset identified by SRCDOM) that relates to the analysis variable (ATERM).
ASPID	Analysis Identifier	Char	See Value-level Metadata
ARELID	Analysis Relationship Identifier	Char	See Value-level Metadata

Proposal for the ALGFMQ Analysis Dataset

Proposal 3: Value-level Metadata

ACAT1	ACAT1N	ATERM	ATERMN	ASTDT	ASPID	ARELID	Derivation
Hypoglycemia	2	Any Hypoglycemia FMQ Narrow Term	21	ADAEFMQ.ASTDT	Set to missing	Set to missing	If ADAEFMQ.FMQNAM="Hypoglycemia" and ADAEFMQ.FMQCLASS="Narrow", then set ATERMN = 21, ATERM="Any Hypoglycemia FMQ narrow term": Create a record
Hypoglycemia	2	Plasma Glucose < 54 mg/dL	22	ADLB.ADT	Set to missing	Set to missing	From ADLB dataset. When ADLB.LCSPEC="PLASMA" and ADLB.PARAMCD="GLUC" and ADLB.AVALU="mg/dL" and ADLB.AVAL < 54, then set ATERMN = 22, ATERM="Plasma Glucose < 54 mg/dL": Create a record
Hypoglycemia	2	Hypoglycemia Term	231	ADAEFMQ.ASTDT/ADAE.ASTDT	For each participant, assign a sequential number (seq) starting from 1 to n (n is number of records of ATERMN=231). ASPID is created by concatenating ATERMN and seq by dash ("-").	Set to missing	If ((ADAEFMQ.FMQNAM="Hypoglycemia" and ADAEFMQ.FMQCLASS="Broad") or ADAE.AEDECOD in Accident, Anxiety, Asthenia, Cold sweat, Coma, Confusional state, Fall, Fatigue, Hunger, Hyperhidrosis, Irritability, Loss of consciousness, Palpitations, Road traffic accident, Seizure, Tremor, Dysarthria, Balance disorder, Coordination abnormal, Headache, Vision blurred, and Visual impairment), then set ATERMN=231, ATERM = "Hypoglycemia Term"
Hypoglycemia	2	Plasma Glucose < 70 mg/dL	232	ADLB.ADT	For each participant, assign a sequential number (seq) starting from 1 to n (n is number of records of ATERMN=232). ASPID is created by concatenating ATERMN and seq by dash ("-").	Set to missing	If ADLB.PARAMCD="GLUC" and ADLB.LBSPEC="PLASMA" and ADLB.AVALU="mg/dL" and ADLB.AVAL < 70, then set ATERMN=232, ATERM="Plasma Glucose < 70 mg/dL"
Hypoglycemia	2	Hypoglycemia Term + Plasma Glucose < 70 mg/dL	23	Minimum of ASTDT that linked to the event used to derive	Set to missing	ARELID is created by concatenating the corresponding ASPID from ATERMN=231 and 232, separated by comma (",");	If a participant has both one record from ATERMN=231 and one record from ATERMN=232 with ADLB.ADT (from ATERMN=232) within 1 week of the AE (from ATERMN=231), then set ATERMN = 23, ATERM="Hypoglycemia Term + Plasma Glucose < 70 mg/dL": Create a record
Hypoglycemia	2	>= 2 Hypoglycemia Terms + >= 2 Episodes of Plasma Glucose < 70 mg/dL	24	Minimum of ASTDT that linked to the event used to derive	Set to missing	ARELID is created by concatenating the corresponding ASPID from ATERMN=231 and 233, separated by comma (",");	If a participant has more than 1 record from ATERMN=231 and more than 1 record from ATERMN=232, then set ATERMN = 24, ATERM=">= 2 Hypoglycemia Terms + >= 2 Episodes of Plasma Glucose < 70 mg/dL": Create a record

Proposal for the ALGFMQ Analysis Dataset

Proposal 3: Sample Dataset

USUBJID	ASTDT	ACAT1	ACAT1N	ATERM	ATERMN	HYPSCAT	SRCVALUE	SRCVAR	SRCDOM	SRCSEQ	ASPID	ARELID	
3002	5/2/2023	Hypoglycemia	2	Any Hypoglycemia FMQ Narrow Term	21		Hypoglycemia	FMQNAM	ADAEFMQ	39			
3002	5/21/2023	Hypoglycemia	2	Any Hypoglycemia FMQ Narrow Term	21		Hypoglycemia	FMQNAM	ADAEFMQ	48			
3002	5/3/2023	Hypoglycemia	2	Plasma Glucose < 54 mg/dL	22		32	AVAL	ADLB	100			
3002	5/2/2023	Hypoglycemia	2	Hypoglycemia Term	231		Hypoglycemia	FMQNAM	ADAEFMQ	40	231-1		
3002	5/5/2023	Hypoglycemia	2	Hypoglycemia Term	231		Fatigue	AEDECOD	ADAE	930	231-2		
3002	5/3/2023	Hypoglycemia	2	Plasma Glucose < 70 mg/dL	232		32	AVAL	ADLB	100	232-1		
3002	5/2/2023	Hypoglycemia	2	Hypoglycemia Term + Plasma Glucose < 70 mg/dL	23							231-1,232-1	
3002		Hypoglycemia	2	>=2 Hypoglycemia Terms + >=2 Episodes of Plasma Glucose < 70 mg/dL	24	This record will not be populated in dataset since no criteria met							



Proposal for the ALGFMQ Analysis Dataset

Proposal 3: Specification

OCDD5 Key variables:

- ATERM: ALGFMQ criterion
- ACAT1: ALGFMQ
- ASPID, ARELID, SRCVALUE, SRCVAR, SRCDOM, SRCSEQ created for traceability

Variable	Variable Label	Type	Description
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M1
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M2
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M3
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M4
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M5
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M6
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M7
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M8
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M9
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M10
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M11
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M12
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M13
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M14
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M15
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M16
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M17
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M18
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M19
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M20
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M21
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M22
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M23
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M24
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M25
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M26
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M27
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M28
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M29
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M30
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M31
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M32
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M33
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M34
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M35
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M36
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M37
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M38
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M39
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M40
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M41
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M42
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M43
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M44
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M45
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M46
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M47
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M48
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M49
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M50
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M51
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M52
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M53
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M54
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M55
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M56
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M57
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M58
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M59
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M60
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M61
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M62
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M63
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M64
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M65
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M66
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M67
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M68
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M69
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M70
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M71
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M72
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M73
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M74
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M75
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M76
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M77
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M78
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M79
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M80
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M81
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M82
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M83
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M84
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M85
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M86
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M87
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M88
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M89
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M90
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M91
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M92
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M93
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M94
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M95
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M96
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M97
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M98
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M99
OCDD5	Primary of Occurrence	Char	OCDD5_OBDD5M100

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Proposal for the ALGFMQ Analysis Dataset

Proposal 3:

Each ALGFMQ criterion is set as an ATERM. ATERM is the target analysis variable.

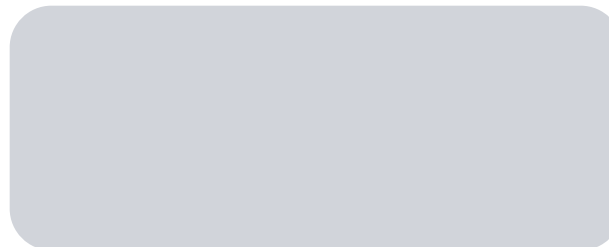


PROS

- Analysis ready
- Traceability
- Clear value-level metadata



CONS



Proposal for the ALGFMQ Analysis Dataset

Programming of Dataset

Designing characteristics:

- Use frame to read source datasets and create attribute generally.
- Create 4 independent sub-macro to update each ALGFMQ easily; Develop new sub-macro to add new ALGFMQ in future.
- Load sub-macro flexibly as needed.


```
*****  
%*-- Step 01: Create dataset from lptda.adsl and lptda.adaefmq and other datasets --*  
*****  
  
%data adsl;  
  set lptda.adsl;  
run;  
%data adaefmq;  
  set lptda.adaefmq;  
run;  
  
*****  
%*-- Step 02: Create adecode for each FMQ--*  
*****  
  
/*Rhabdomyolysis*/  
%rhabdo(output_dataset = rhab_all);  
  
/*Hypoglycemia*/  
%hypog(output_dataset = hypog_all);  
  
/*Hyperglycemia*/  
%hyper(output_dataset = hyper_all);  
  
/*Hypersensitivity*/  
%hyps(input_dataset=adaefmq, dict_dataset=lptde.hyps2024, output_dataset=hyps_all, debug=0);  
%data _adalqfmq;  
  set rhab_all /*hypog_all hyper_all*/ hyps_all;  
run;  
%proc sort data=_adalqfmq; by usubjid acatin atermn astdt srcseq; run;  
*****  
%*-- Step 03: ADALGFMQ --- Create final dataset --*  
*****  
  
%data final;  
  merge _adalqfmq(in=b) adsl(in=a);  
  by usubjid;  
  if a and b;  
run;  
  
*****  
%*-- Step 04: create attribute of ADALGFMQ dataset --*  
*****
```



Summary



Summary

Proposal	Description
1	Each ALGFMQ criterion is set as a PARAM. PARAM is the target analysis variable. Value-level metadata is clear. Traceability can be achieved. However, the dataset is not analysis-ready.
2	Each ALGFMQ criterion is set as an AVALC. AVALC is the target analysis variable. The dataset is analysis-ready. But Value-level metadata is hard to read. Compared to the others, traceability is complex.
3 	Each ALGFMQ criterion is set as an ATERM. ATERM is the target analysis variable. The dataset is analysis-ready. Value-level metadata is clear. Traceability can be achieved too.



Acknowledgements

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Thank You!



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