Workshop on CRF mapping : General Observations Class

Anagha Bhatkhande
Varsha Mahajan

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01   **Mapping information in Events class**

02   **Mapping information in Interventions class**

03   **Mapping information in Findings class**

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Mapping data in Events Class

ADVERSE EVENT[6]

Domain: AE

N° AE *Please use a separate line for each adverse event* AE.AESPID

Symptoms or diagnosis (if available) Free text AE.AETERM

Date of start (DD.MMM.YYYY) *DD.MMM.YYYY (Eg 01 JAN 2013)* AE.AESTDTC

Date of end (DD.MMM.YYYY) *DD.MMM.YYYY (Eg 01 JAN 2013)* AE.AEENDTC

Ongoing? Checkbox AE.AEENRTPT   AE.AEENTPT =Date of last contact

Severity AESEV Codelist (Mild/Moderate/Severe)   AE.AESEV

Relation to study product AEREL Codelist (Unrelated/Unlikely/Probable/Related) AE.AEREL

Outcome OUT Codelist (Fatal/Not resolved/Resolved/Resolved with sequels/Resolving/Unknown) AE.AEOUT

Action taken with study product ACN Codelist AE.AEACN

(NA/Unknown/Dose not Changed/Dose Reduced/Dose Increased/Suspension of study product/Definitive withdrawal of study product)

Action taken in response to the AE ACTION_AE Codelist (

No action taken/   AE.AEACNOTH

Related to CM , *please specify identifier* Free text /   SUPPAE.ACNRELCM

Other, *specify* Free text) SUPPAE.ACNOSP

Seriousness NY_NUM Codelist (Yes/No) *If yes, please complete the SAE form* AE.AESER

Caused study discontinuation NY Codelist (Yes/No) *If yes, please complete the "Completion/discontinuation" form* SUPPAE.AEDISC

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SERIOUS ADVERSE EVENT[6]

SAE number *(XXX)*
AE number linked *(XXX)*

Subject Data
- ➤ Date of birth (DD.MMM.YYYY)
- ➤ Sex SEX Codelist (Female/Male)
- ➤ Current Weight *9.3 kg* SUPPAE.SWEIGHT
- ➤ Date of First Study Product Administration (DD.MMM.YYYY)
- ➤ Date and Time of Last Administration Before SAE Onset (DD.MMM.YYYY HH:MM) SUPPAE.ENAEDTC

Serious Adverse Event Information
- ➤ Diagnosis (where possible) or Signs and Symptoms Free text
- ➤ Date of SAE Onset (DD.MMM.YYYY)
- ➤ Date of Investigator's Awareness of SAE (DD.MMM.YYYY) SUPPAE.INVSDTC
- ➤ Date of SAE Resolution (DD.MMM.YYYY)
- ➤ SAE ongoing?
- ➤ Severity of the SAE AESEV Codelist (Mild, Moderate, Severe)
- ➤ Outcome -OUT Codelist (Fatal/Not resolved/Resolved/Resolved with sequels/Resolving/Unknown)
- ➤ Causal Relationship (Investigator's Opinion) AEREL Codelist (Unrelated, Unlikely, Probable, Related)
- ➤ Previous Adverse Event reaction to Similar Treatment NY2_SPEC Codelist (Yes/No/NA/UNK) SUPPAE.PRVAE
  - → *If yes*, give details Free text SUPPAE.PRVAEOTH
- ➤ Action taken in response to the AE ACTION_AE Codelist (No action taken/Related to CM, *please specify identifier*/Other, *please specify*)

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Seriousness
Please check all Seriousness Criteria that apply.

- ➢ Subject Died *Checkbox* AE.AESDTH
  - → Death Date (DD.MMM.YYYY)
- ➢ Life threatening *Checkbox* AE.AESLIFE
- ➢ Hospitalization Needed *Checkbox* AE.AESHOSP
  - → Days in hospital (XXX) days SUPPAE.HOSDAYS
- ➢ Prolongation of existing hospitalization *Checkbox* AE.AEPHOSP
  - → Days of prolongation (XXX) days SUPPAE.PHOSDAYS
- ➢ Persistent or significant disability *Checkbox* AE.AESDISAB
- ➢ Congenital anomaly / birth defect *Checkbox* AE.AESCONG
- ➢ Other medically relevant event *Checkbox* AE.AESMIE
  - → Specify Free text SUPPAE.AESMIESP

Mapping data in Interventions Class

Medication for SAE treatment [1]

- ➤ N° CM (XXX)   CM.CMSPID
- ➤ Treatment name *Free text*   CM.CMTRT
- ➤ Indication *Free text*   CM.CMINDC
- ➤ Route of Admin. ROUTE   CM.CMROUTE
  Codelist(Oral/Subcutaneous/Intramuscular/Intravenous/Rectal/Topical/Nasal/Respiratory(inhalation)/Transdermal/Other *specify*, Freetext)   SUPPCM.ADMROUTE
- ➤ Dose of medication taken per administration *Free text*   CM.CMDOSE
- ➤ Dose Unit UNIT Codelist (mg/ug/mL/g/IU/tab/cap/puff/other *specify* Free text)   CM.CMDOSEU   SUPPCM.CMUSPC
- ➤ Date of start (DD.MMM.YYYY)   CM.CMSTDTC.
- ➤ Date of end (DD.MMM.YYYY) CM.CMENDTC
- ➤ Ongoing Checkbox   CM.CMENRTPT   CM.CMENTPT=LAST CONTACT DATE

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Mapping data in Findings Class

HEALTH CARE RESOURCE QUESTIONNAIRE

FA.FATESTCD=OCCUR
FA.FAOBJ=Healthcare resource questionnaire completion
FACAT=Healthcare resource Questionnaire
FA.FAORRES= Y/N

Has the Health care resource questionnaire been completed? NY Codelist (Yes/No)

If yes, Date of completion (DD.MON.YYYY) FA.FATESTCD=DATE , for above FAOBJ

1. From the last visit scheduled for this clinical study, have you made any additional visit to a physician (general practitioner, pediatrician, …) unscheduled by this clinical study
NY Codelist (Yes/No)
   ➢ If yes, how many (XX) FA.FATESTCD=OCCUR   FAOBJ=Unscheduled Visit   FACAT=Healthcare…….
   ➢ If yes, did the physician prescribe any medication NY Codelist (Yes/No)
FA.FATESTCD= OCCUR   FAOBJ=Prescribed Medication   If yes, please complete Concomitant Medication form FACAT=Healthcare…….
   ➢ If yes, did the physician prescribe any respiratory physiotherapy NY Codelist (Yes/No)
        FA.FATESTCD=OCCUR FAOBJ=Prescribed respiratory physiotherapy   FACAT=Healthcare…….

2. From the last visit scheduled for this clinical study, have you bought or given any medication outside a prescription to manage an illness for your children (self-medication)
NY Codelist (Yes/No)   FA.FATESTCD=OCCUR   FA.FAOBJ=Self medication FACT=Healthcare
        If yes, please complete Concomitant Medication form

3. From the last visit scheduled for this clinical study, have you or another adult taken any day to your workday to manage an illness for your children (under or not a seek leave)
NY Codelist (Yes/No)
   ➢ If yes, how many days (XX)   FA.TESTCD=OCCUR   FA.FAOBJ=Absence at work   FAORRES
                                    FA.FATESTCD=Total number   FAOBJ=Absence at work   FAORRES

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Disposition

COMPLETION/DISCONTINUATION FORM FOR INTERVENTION PERIOD

Domain: DS

Period EPOCH[3] EPOCH *Codelist (TREATMENT/OBSERVATION/ FOLLOW-UP)* DS.EPOCH

Date of study completion / last contact DSSTDAT *(DD.MMM.YYYY)* DS.DSSTDTC, DSCAT=DISPOSITION EVENT

What is the subject status for the period? DSDECOD STATUS *Codelist (COMPLETED /DROP-OUT/ SCREEN FAILURE)*

DS.DSDECOD

If drop-out, please specify the reason

Reason for DROP-OUT DSTERM[5] REASON_SPEC DS.DSTERM

- ☐ Because of AE or SAE *Please complete AE/SAE forms*
- ☐ The subject withdrew without explanation
- ☐ The subject withdrew with the explanation below: *Free text*
- ☐ The subject was lost during follow up. *Please specify actions taken*: *Free text*
- ☐ Other reason: *Free text*

Will the subject continue in the next period? DSCONT[5] NY *Codelist (Yes/No)*
CTMS item - Equal to yes, if treatment period CTMS[3] NY *Codelist (Yes/No)* NO SUPPDS, DSCONT

Internal use for CTMS - Date of completion CTMS_COMP[7] *(DD.MMM.YYYY)*
Internal use for CTMS - Date of drop-out CTMS_DO[7] *(DD.MMM.YYYY)*
Internal use for CTMS - Date of screen-failure CTMS_SF[7] *(DD.MMM.YYYY)*

DS_FIN_MOD

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Thank You