WITH STANDARDS – UNLOCK THE POWER OF DATA

cdisc

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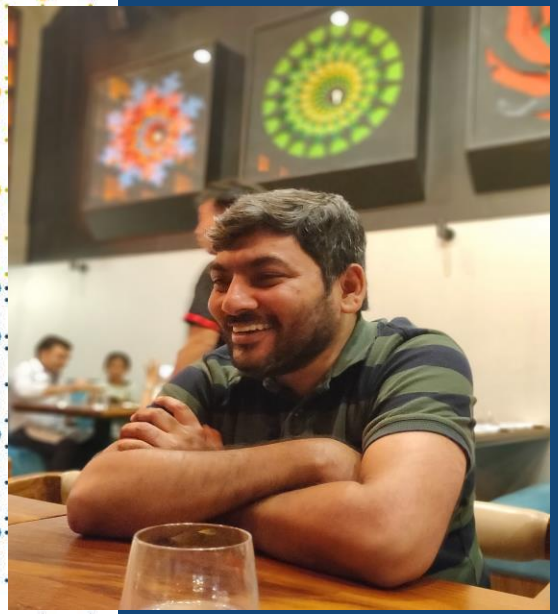
JAPAN
INTERCHANGE
13-14 JUNE | VIRTUAL EVENT

Experience with Interim User Guide for COVID Studies & Guidance for Ongoing Studies

Presented by Arvind Sri Krishna Mani, Principal Consultant

Zifo



Meet the Speaker

Arvind Sri Krishna Mani

Title: Principal Consultant

Organization: Zifo

Arvind comes with 13-years of experience in the industry and has been with Zifo RnD Solutions right from its inception. Arvind has played a significant role in setting up multiple teams within the clinical services within Zifo and has experience managing projects from across the globe. He loves the exposure and the variety in the projects by working with CROs, Technology providers and Pharma companies. He now acts as the Head of Digital Solutions and the Point of Contact for all Study Build and CDISC projects from Japan.

A serious football fan (Arsenal), who is always in the look out for good movies. Eagerly waiting to watch ドライブ・マイ・カー (Drive my Car)..

Disclaimer and Disclosures

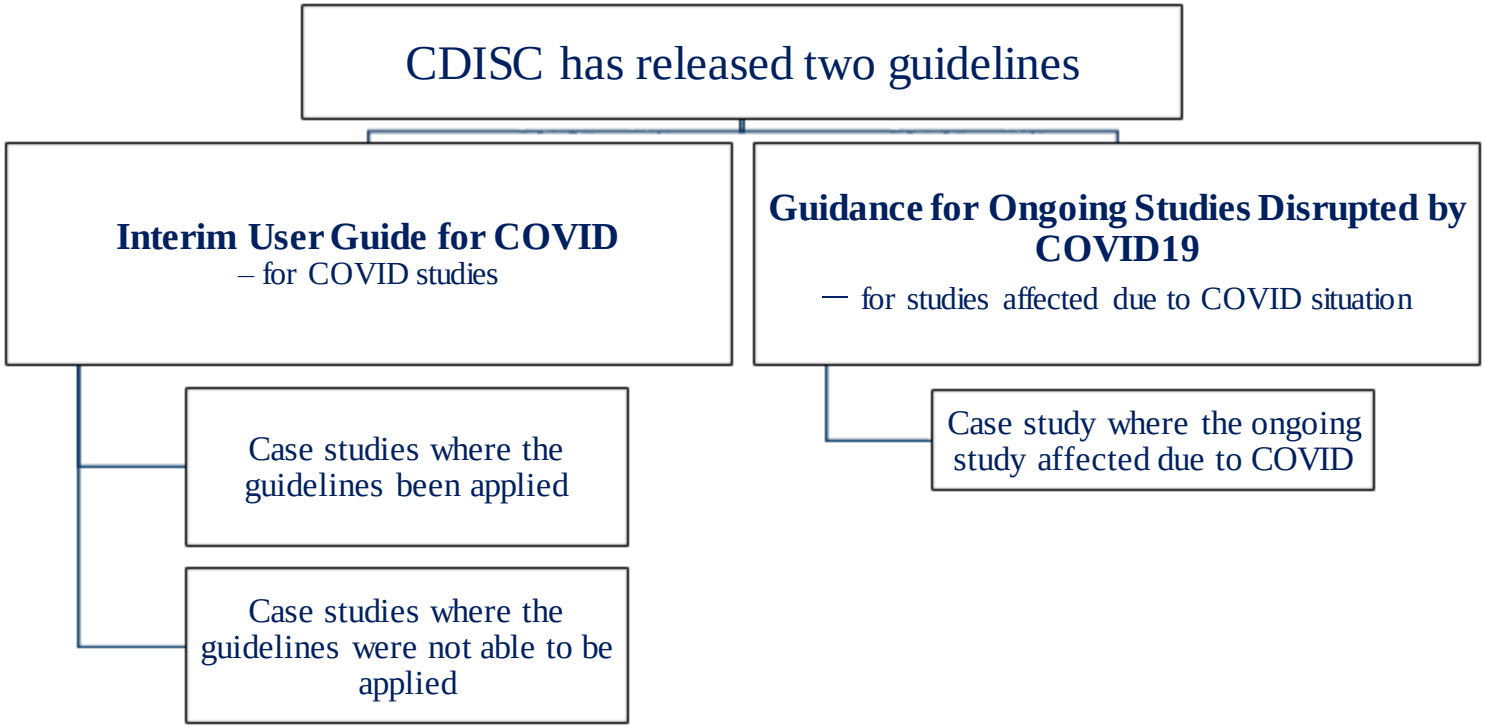
- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

Agenda

1. General Introduction
2. Risk Factors
3. Onset of Disease
4. Signs and Symptoms
5. Laboratory Results
6. Diagnostics and Virology
7. Questionnaires, Ratings and Scales

General Introduction

The Guidelines Released!!



Overview of COVID Interim User Guide

	Condition/Variable	SDTM DOMAIN
Risk Factors	Pre-existing Medical Conditions	MH
	Personal Protective Equipment-PPE	ER
	Travel	ER
	Contacts	ER
	Substance Use	SU
	Exposure to Animals	ER

	Condition/Variable	SDTM DOMAIN
Onset of Disease	MHEVDTYP	MH
Signs and Symptoms		FACE, FAMH, FAAE
Laboratory Test Results		LB
Diagnostics and Virology	Virus Identification, Antibody Testing, SARS COV-2 Viral Load	MB
Vital Sins and urine output	VSCOLSRT , VSO2SRC, VSN2SCAL	VS
Concomitant Medications	CMEVLINT	CM
Respiratory Findings	Imaging – RECLSIG, Pulmonary Functional Tests	RE
Hospitalization	HOINDC, HODISOUT	HO
Procedures		PR
Questionnaires, Rating and Scales		RS

Risk Factors

Risk Factors

The Environmental Risk Factors (ER) Domain

- An Events Domain
- Represents data collected to assess potential exposures to, or risk factors associated with, diseases by way of environmental contact or through participation in activities associated with risk.

er.xpt

Row	STUDYID	DOMAIN	USUBJID	ERLNKID	ERSEQ	ERTERM	ERCAT	ERPRESP	EROCCUR	ERSTDTC	EREVLINT
1	COVID-3	ER	100	1	1	Close contact with a confirmed or probable case of COVID-19, while that case was symptomatic	COVID-19 RISK FACTOR	Y	Y	2020-02-25	-P14D
2	COVID-3	ER	100		2	Presence in a healthcare facility where COVID-19 infections have been managed	COVID-19 RISK FACTOR	Y	N		-P14D
3	COVID-3	ER	100		3	Presence in a laboratory handling suspected or confirmed COVID-19 samples	COVID-19 RISK FACTOR	Y	N		-P14D

apmh.xpt

Row	STUDYID	DOMAIN	APID	MHSEQ	RSUBJID	SREL	MHLNKID	MHTERM	MHDECOD	MHSTDTC
1	COVID	APMH	200	1	100	MOTHER, BIOLOGICAL	1	COVID-19	Coronavirus infection	2020-04-01

The potential of AP domains when it comes to COVID ?

- Common related records (relrec.xpt) domains for Associated persons and other standard domains

- The relec.xpt dilemma ?!

apex.xpt

Row	STUDYID	DOMAIN	APID	EXSEQ	RSUBJID	SREL	EXTRT	EXDOSE	EXDOSTXT	EXDOSU	EXDOSFRM	EXDOSFRQ	EXROUTE	EXSTDTC
1	Y6AOF7	APEX	AP_01	1	ABC_123	FAMILY MEMBER	DRUG X		SPLASH		LOTION	ONCE	TOPICAL	2005-05-05

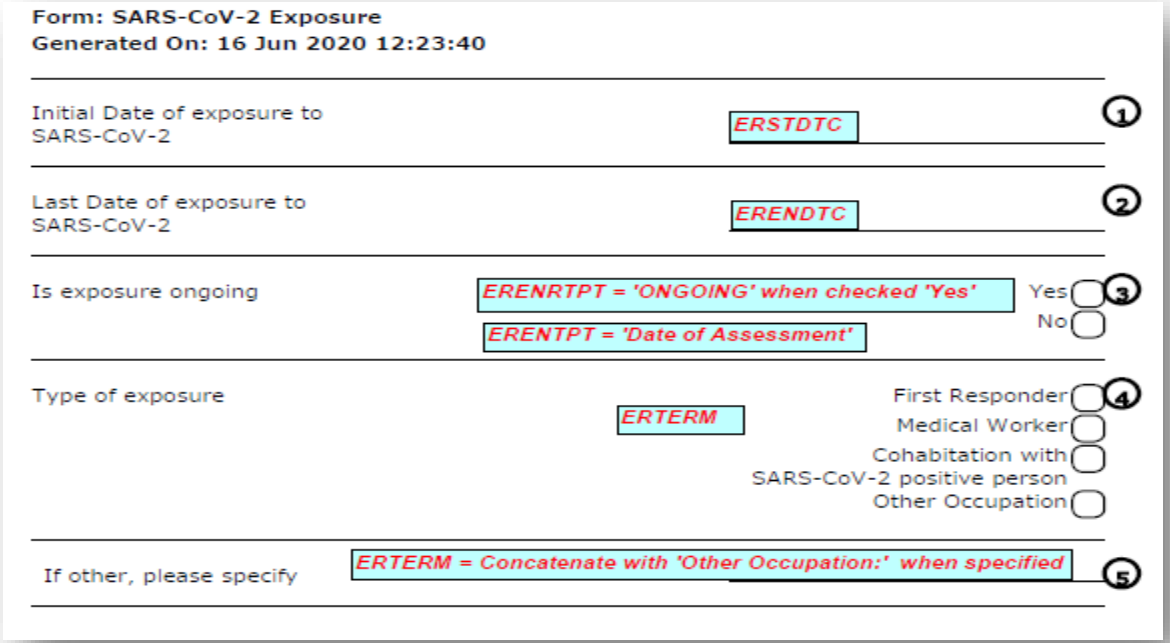
apae.xpt

Row	STUDYID	DOMAIN	APID	AESEQ	RSUBJID	SREL	AETERM	AEDECOD	AESEV	AESER	AEREL	AEOUT	AESTDTC	AEENDTC
1	Y6AOF7	APAE	AP_01	1	ABC_123	FAMILY MEMBER	Rash	Rash	MODERATE	N	RELATED	RECOVERED / RESOLVED	2005-05-05	2005-05-08

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	APID	RSUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	Y6AOF7	APEX		AP_01	ABC_123	EXTRT	DRUG X		1
2	Y6AOF7	APAE		AP_01	ABC_123	AETERM	Rash		1

Risk Factors – Case Study (ER Domain)



Form: SARS-CoV-2 Exposure
Generated On: 16 Jun 2020 12:23:40

Initial Date of exposure to SARS-CoV-2 — *ERSTDTC* — (1)

Last Date of exposure to SARS-CoV-2 — *ERENDTC* — (2)

Is exposure ongoing — *ERENRTPT = 'ONGOING' when checked 'Yes'* — *ERENTPT = 'Date of Assessment'* — Yes ☐ No ☐ (3)

Type of exposure — *ERTERM* — First Responder ☐ Medical Worker ☐ Cohabitation with SARS-CoV-2 positive person ☐ Other Occupation ☐ (4)

If other, please specify — *ERTERM = Concatenate with 'Other Occupation:' when specified* — (5)

Risk Factors – Case Study (ER Domain)

ERSEQ	ERTERM	VISITNUM	VISIT	EPOCH	ERSTDTC	ERENDTC	ERSTDY	ERENDY
1	Cohabitation with SARS-CoV-2 positive person	1	SCREENING		2020-06-14		-5	.
1	Cohabitation with SARS-CoV-2 positive person	1	SCREENING		2020-06-12		-12	.
1	Medical Worker	1	SCREENING		2020-08-13	2020-08-13	-4	-4
1	Other Occupation:Subject works in a laboratory where she is in contact with patie	1	SCREENING		2020-05-04		-80	.
1	Cohabitation with SARS-CoV-2 positive person	1	SCREENING		2020-07-13		-16	.
1	Other Occupation:Subject works in a Lab taking test to subjects positives to Cov	1	SCREENING		2020-08-23		-2	.

Onset of Disease

Onset of Disease

3 Onset of Disease

Example 1

In this example, the date of onset of symptoms and date of diagnosis were collected for the study. The date of diagnosis was based on a positive test, and the CRF collected an identifier for the laboratory test with the positive result.

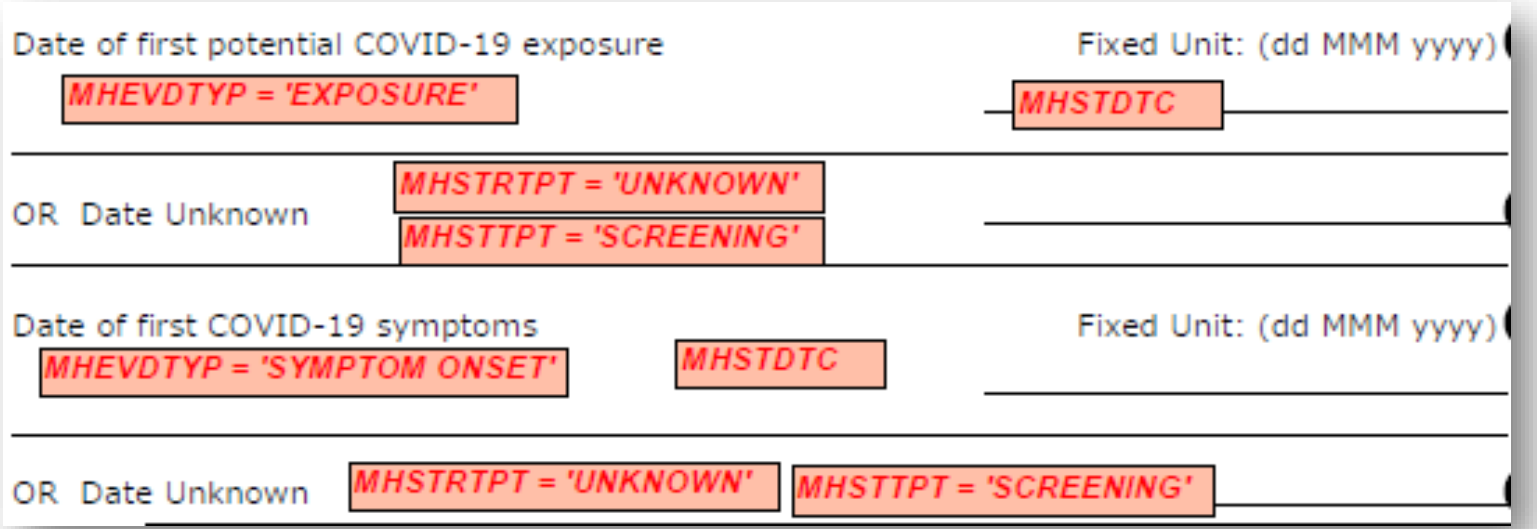
Row 1: Shows the date of onset of symptoms.

Row 2: Shows the date of diagnosis. MHLNKID has been populated so that it can be related to the lab record which confirmed diagnosis. Neither the lab dataset nor the related records (RELREC) dataset are included in this example.

mh.xpt

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHLNKID	MHTERM	MHEVDTYP	MHDTC	MHSTDTC	MHENDTC	MHDY	MHSTDY	MHENDY
1	COVID-6	MH	103	1		COVID-19	SYMPTOM ONSET	2020-04-05	2020-03-31		1	-5	
2	COVID-6	MH	103	2	1	COVID-19	DIAGNOSIS	2020-04-05	2020-04-04		1	-1	

Case Study (MH Domain)



Case Study (MH Domain)

MHSEQ	MHSPID	MHTERM	MHLLT	MHLLTCD	MHDECOD	MHPTCD	MHHLT	MHHLTCD	MHHLGT	MHHLGTCD	MHEVDTYP	MHCAT	MHPRESP	MHOCCUR	MHSOC	MHSOCCD
1		COVID-19		.		.		.		.	EXPOSURE	PRIMARY D	Y	Y		.
2		COVID-19		.		.		.		.	SYMPTOM O	PRIMARY D	Y	Y		.
3	001	COPD	COPD	10010952	Chronic o	10009033	Bronchosp	10006484	Bronchial	10006436		GENERAL M			Respirato	10038738
4	002	CAD	Coronary	10011078	Coronary	10011078	Coronary	10011083	Coronary	10011082		GENERAL M			Cardiac d	10007541
5	003	DM Type I	Type II d	10045242	Type 2 di	10067585	Diabetes	10012602	Glucose m	10018424		GENERAL M			Metabolis	10027433
6	004	Hypertens	Hypertens	10020772	Hypertens	10020772	Vascular	10020774	Vascular	10057166		GENERAL M			Vascular	10047065
1		COVID-19		.		.		.		.	EXPOSURE	PRIMARY D	Y	Y		.
2		COVID-19		.		.		.		.	SYMPTOM O	PRIMARY D	Y	Y		.
3	001	Emphysema	Emphysema	10014561	Emphysema	10014561	Parenchym	10033979	Lower res	10024967		GENERAL M			Respirato	10038738
1		COVID-19		.		.		.		.	EXPOSURE	PRIMARY D	Y	Y		.
2		COVID-19		.		.		.		.	SYMPTOM O	PRIMARY D	Y	Y		.

Signs and Symptoms

Signs and Symptoms

Questions about pre-specified symptoms collected at beginning may vary, as illustrated in the following table

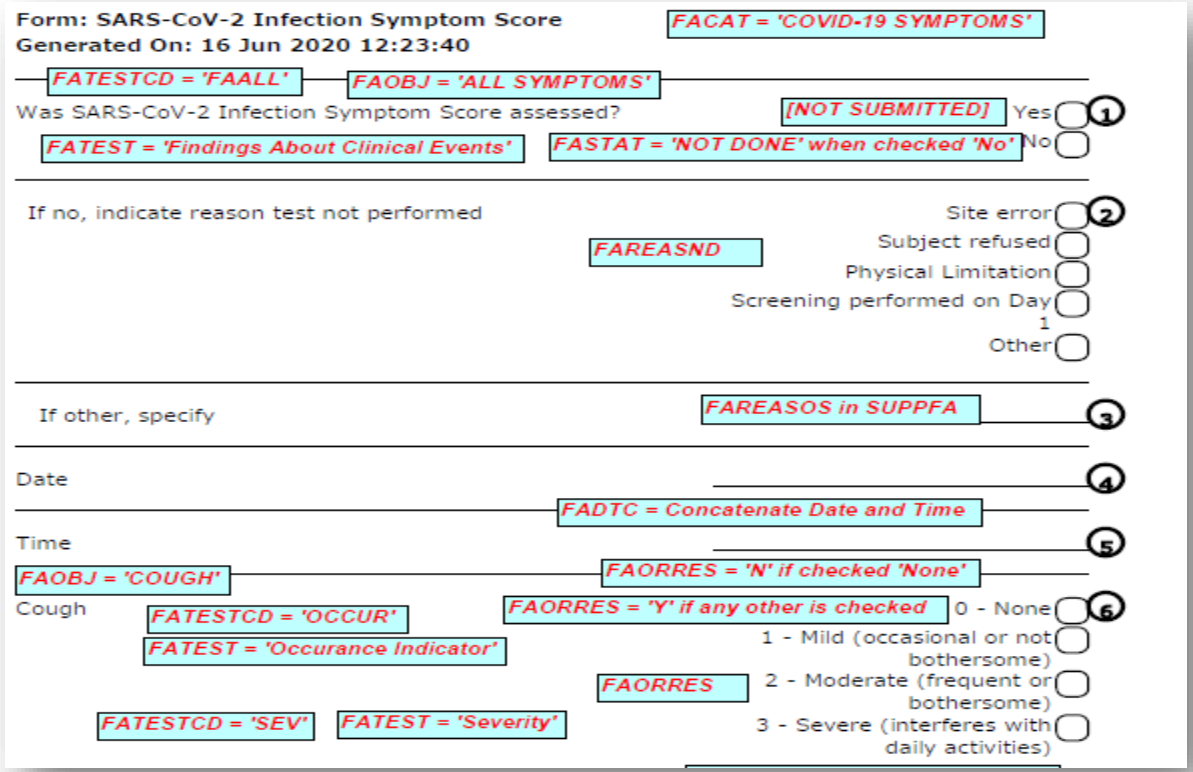
Question	SDTM Domain	Timing Variable
Has the symptom occurred since the onset of acute illness?	MH	MHDTC is date of assessment, EVINTX="SINCE ONSET OF ACUTE ILLNESS".
Was the symptom present at diagnosis?	FAMH	FADTC is date of diagnosis
Is the symptom present now?	FAMH	FADTC is date of assessment

Signs and Symptoms

Data collected about symptoms during the study may include approaches such as illustrated in the following table.

Question	SDTM Domain	Timing Variable
Record symptoms related to COVID-19 (not pre-specified)	CE (or AE)	CESTDTC, CEENDTC
Did the symptom occur during the study?	CE (or AE or FAAE)	EVINTX = "DURING THE STUDY"
Did the symptom occur within the past day?	FACE (or FAAE)	FADTC is date of assessment, EVLINT = "-P1D"
Has the symptom occurred since the last visit?	FACE (or FAAE)	FADTC is date of assessment, EVINTX = "SINCE LAST VISIT"

Case Study – FACE Domain



Case Study – FACE Domain

FASEQ	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES
1	FAALL	Findings About Clinical Events	ALL SYMPTOMS	COVID-19 SYMPTOMS	
2	OCCUR	Occurrence Indicator	COUGH	COVID-19 SYMPTOMS	N
3	OCCUR	Occurrence Indicator	COUGH	COVID-19 SYMPTOMS	N
4	OCCUR	Occurrence Indicator	COUGH	COVID-19 SYMPTOMS	N
5	OCCUR	Occurrence Indicator	COUGH	COVID-19 SYMPTOMS	N
6	OCCUR	Occurrence Indicator	COUGH	COVID-19 SYMPTOMS	N
7	OCCUR	Occurrence Indicator	COUGH	COVID-19 SYMPTOMS	N
8	OCCUR	Occurrence Indicator	DIFFICULTY BREATHING	COVID-19 SYMPTOMS	N
9	OCCUR	Occurrence Indicator	DIFFICULTY BREATHING	COVID-19 SYMPTOMS	N
10	OCCUR	Occurrence Indicator	DIFFICULTY BREATHING	COVID-19 SYMPTOMS	N
11	OCCUR	Occurrence Indicator	DIFFICULTY BREATHING	COVID-19 SYMPTOMS	N
12	OCCUR	Occurrence Indicator	DIFFICULTY BREATHING	COVID-19 SYMPTOMS	N
13	OCCUR	Occurrence Indicator	DIFFICULTY BREATHING	COVID-19 SYMPTOMS	N
14	OCCUR	Occurrence Indicator	FEVER	COVID-19 SYMPTOMS	N
15	OCCUR	Occurrence Indicator	FEVER	COVID-19 SYMPTOMS	N
16	OCCUR	Occurrence Indicator	FEVER	COVID-19 SYMPTOMS	N
17	OCCUR	Occurrence Indicator	FEVER	COVID-19 SYMPTOMS	N
18	OCCUR	Occurrence Indicator	FEVER	COVID-19 SYMPTOMS	N
19	OCCUR	Occurrence Indicator	FEVER	COVID-19 SYMPTOMS	N
20	OCCUR	Occurrence Indicator	MUSCLE ACHES OR FATIGUE	COVID-19 SYMPTOMS	N

Laboratory Results

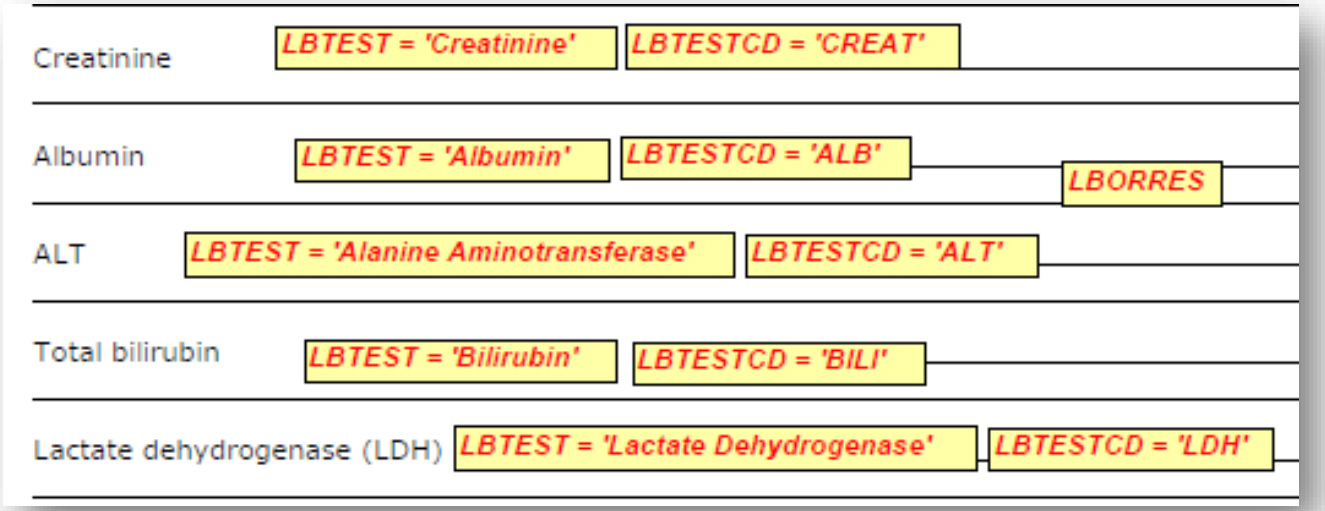
Laboratory Results Results

- Some common Lab tests taken for COVID-19

The following table shows common lab test names and test codes.

LB Test Name - LBTEST	LB Test Code - LBTESTCD
Activated partial thromboplastin time	APTT
Alanine aminotransferase	AST
Aspartate aminotransferase	ALT
Bilirubin	BILI
C reactive protein	CRP
Creatinine	CREAT
Glucose	GLUC
Hemoglobin	HGB
Hematocrit	HCT
Lactic acid	LACTICAC
Leukocytes	WBC
Lymphocytes	LYM
Neutrophils	NEUT
Platelets	PLAT
Potassium	K
Procalcitonin	PCT
Prothrombin time	PT
Prothrombin international normalized ratio	INR
Sodium	SODIUM
Urea Nitrogen	UREAN

Case Study – LB Domain



Case Study – LB Domain

LBSEQ	LBREFID	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBORNRLO	LBORNRHI	LBSTRESC	LBSTRESN	LBSTRESU
1		ALB	Albumin	CHEMISTRY	3.8	g/dL	3.5	5	38	38	g/L
2		ALB	Albumin	CHEMISTRY	3.1	g/dL	3.5	5	31	31	g/L
3		ALB	Albumin	CHEMISTRY						.	
4		ALT	Alanine Aminotransfer	CHEMISTRY	39	IU/L	5	50	39	39	U/L
5		ALT	Alanine Aminotransfer	CHEMISTRY	33	IU/L	5	50	33	33	U/L
6		ALT	Alanine Aminotransfer	CHEMISTRY						.	
7		BILI	Bilirubin	CHEMISTRY	0.9	mg/dL	0.1	1.2	15.3936	15.3936	umol/L
8		BILI	Bilirubin	CHEMISTRY	0.8	mg/dL	0.1	1.2	13.6832	13.6832	umol/L
9		BILI	Bilirubin	CHEMISTRY						.	
10		CREAT	Creatinine	CHEMISTRY	0.68	mg/dL	0.5	1.5	60.112	60.112	umol/L
11		CREAT	Creatinine	CHEMISTRY	1.08	mg/dL	0.5	1.5	95.472	95.472	umol/L
12		CREAT	Creatinine	CHEMISTRY	0.70	mg/dL	0.5	1.5	61.88	61.88	umol/L
13		LDH	Lactate Dehydrogenase	CHEMISTRY						.	
14		LDH	Lactate Dehydrogenase	CHEMISTRY						.	
15		LDH	Lactate Dehydrogenase	CHEMISTRY						.	

Diagnostics and Virology

Diagnostics and Virology

- All concepts represented in MB (LB is not appropriate for these concepts)
- MBTSTDTL (Measurement, Test or Examination Detail) –
- Further description of MBTESTCD and MBTEST. Example: "VIRAL LOAD" (when MBTESTCD represents viral genetic material); "QUANTIFICATION" when MBTESTCD represents any organism being quantified.

Diagnostics and Virology

1) Virus Identification

- Includes results of testing for the presence of SARS-CoV-2.
- Example:
  - PCR test conducted to detect the presence of SARS-CoV-2

mb.xpt

Row	STUDYID	DOMAIN	USUBJID	MBSEQ	MBREFID	MBGPRID	MBTESTCD	MBTEST	MBTSTDTL	MBORRES	MBSTRESC	MBSPEC	MBLOC	MBMETHOD
1	ABC	MB	ABC-01-601	1	60101	1	SARSCOV2	Severe Acute Resp Syndrome Coronavirus 2	DETECTION	POSITIVE	POSITIVE	ENDOTRACHEAL FLUID		QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
2	ABC	MB	ABC-01-722	2	72201	1	SARSCOV2	Severe Acute Resp Syndrome Coronavirus 2	DETECTION	NEGATIVE	NEGATIVE	SWABBED MATERIAL	THROAT	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION

Diagnostics and Virology

2. Antibody Testing:

- Provides a more rapid indication of current or past infection.
- Example:
  - Testing of immunoglobulin M (IgM)/immunoglobulin G (IgG) antibodies to the SARS-CoV-2 virus
  - Example does not cover quantification of antibodies instead covers Detection.

mb.xpt

Row	STUDYID	DOMAIN	USUBJID	MBSEQ	MBREFID	MBTESTCD	MBTEST	MBTSTDTL	MBORRES	MBSTRESC	MBSPEC	MBMETHOD
1	COVID-ABC	MB	COVID-ABC-011	1	13668	SAR2IGM	SARS-CoV-2 IgM Antibody	DETECTION	POSITIVE	POSITIVE	SERUM	ELISA
2	COVID-ABC	MB	COVID-ABC-011	2	13668	SAR2IGG	SARS-CoV-2 IgG Antibody	DETECTION	NEGATIVE	NEGATIVE	SERUM	ELISA
3	COVID-ABC	MB	COVID-ABC-022	1	23433	SAR2IGGM	SARS-CoV-2 IgG/IgM Antibody	DETECTION	POSITIVE	POSITIVE	SERUM	ELISA

Diagnostics and Virology

2. SARS-COV2-Viral Load

- The testing process took place in 2 parts: determination of threshold cycle and conversion of the threshold cycle readout to a viral load readout
- Example 1:

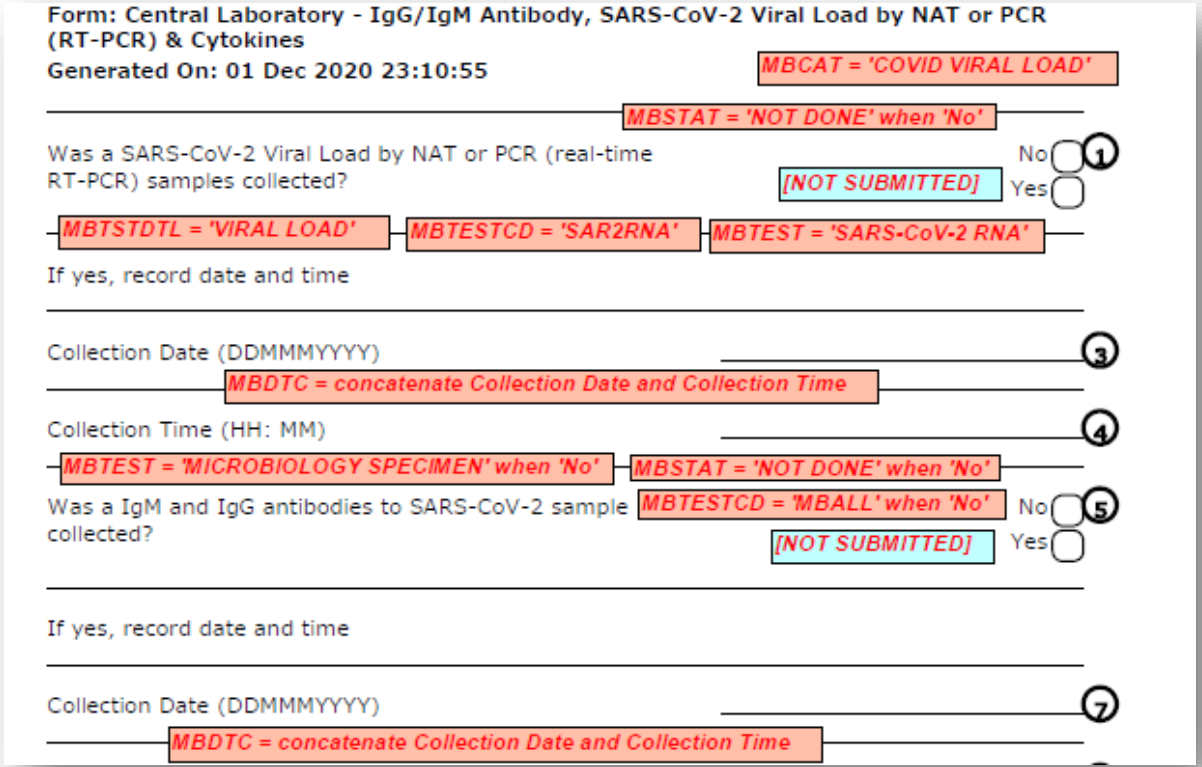
MBSEQ	MBGRPID	MBREFID	MBTESTCD	MBTEST	MBTSTDTL	MBORRES	MBORRESU	MBSTRESC	MBSTRESN	MBSTRESU	MBSPEC	MBMETHOD
1	1	001-02	SAR2RNA	SARS-CoV-2 RNA	VIRAL LOAD	3.9	log 10 copies/mL	3.9	3.9	log 10 copies/mL	SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
2	1	001-02	SAR2RNA	SARS-CoV-2 RNA	THRESHOLD CYCLE	27.43		27.43	27.43		SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION

Diagnostics and Virology

- Example 2: When SARS-CoV-2 RNA isn't detected in the subject sample, MBTSTDTL is null.

SPDEVID	MBSEQ	MBGRPID	MBREFID	MBTESTCD	MBTEST	MBTSTDTL	MBORRES	MBORRESU	MBSTRESC	MBSTRESN	MBSTRESU	MBSPEC	MBMETHOD
													POLYMERASE CHAIN REACTION
PCR01	8		001-06	SAR2RNA	SARS-CoV-2 RNA		TARGET NOT DETECTED		TARGET NOT DETECTED			SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
PCR02	9		001-07	SAR2RNA	SARS-CoV-2 RNA		TARGET NOT DETECTED		TARGET NOT DETECTED			SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION

Case Study – MB Domain



Case Study – MB Domain

MBSEQ	MBTESTCD	MBTEST	MBTSTDTL	MBCAT	MBORRES	MBORRESU	MBSTRESC	MBSTRESN	MBSTRESU	MBSTAT
1	SAR2RNA	SARS-CoV-	VIRAL LOAD	COVID VIRAL LOAD				.		
2	SAR2RNA	SARS-CoV-	VIRAL LOAD	COVID VIRAL LOAD				.		
3	SAR2RNA	SARS-CoV-	VIRAL LOAD	COVID VIRAL LOAD				.		NOT DONE
1	SAR2RNA	SARS-CoV-	VIRAL LOAD	COVID VIRAL LOAD				.		NOT DONE
2	SAR2RNA	SARS-CoV-	VIRAL LOAD	COVID VIRAL LOAD				.		NOT DONE
3	SAR2RNA	SARS-CoV-	VIRAL LOAD	COVID VIRAL LOAD				.		
4	SAR2RNA	SARS-CoV-	VIRAL LOAD	COVID VIRAL LOAD				.		
5	SARSCOV2	Severe Ac	DETECTION	HISTORICAL SARS-COV-2 PCR (RT-PCR) OR NAT	Positive		POSITIVE	.		
1	SAR2RNA	SARS-CoV-	VIRAL LOAD	COVID VIRAL LOAD				.		
2	SAR2RNA	SARS-CoV-	VIRAL LOAD	COVID VIRAL LOAD				.		
3	SAR2RNA	SARS-CoV-	VIRAL LOAD	COVID VIRAL LOAD				.		
4	SAR2RNA	SARS-CoV-	VIRAL LOAD	COVID VIRAL LOAD				.		

Questionnaires, Ratings and Scales

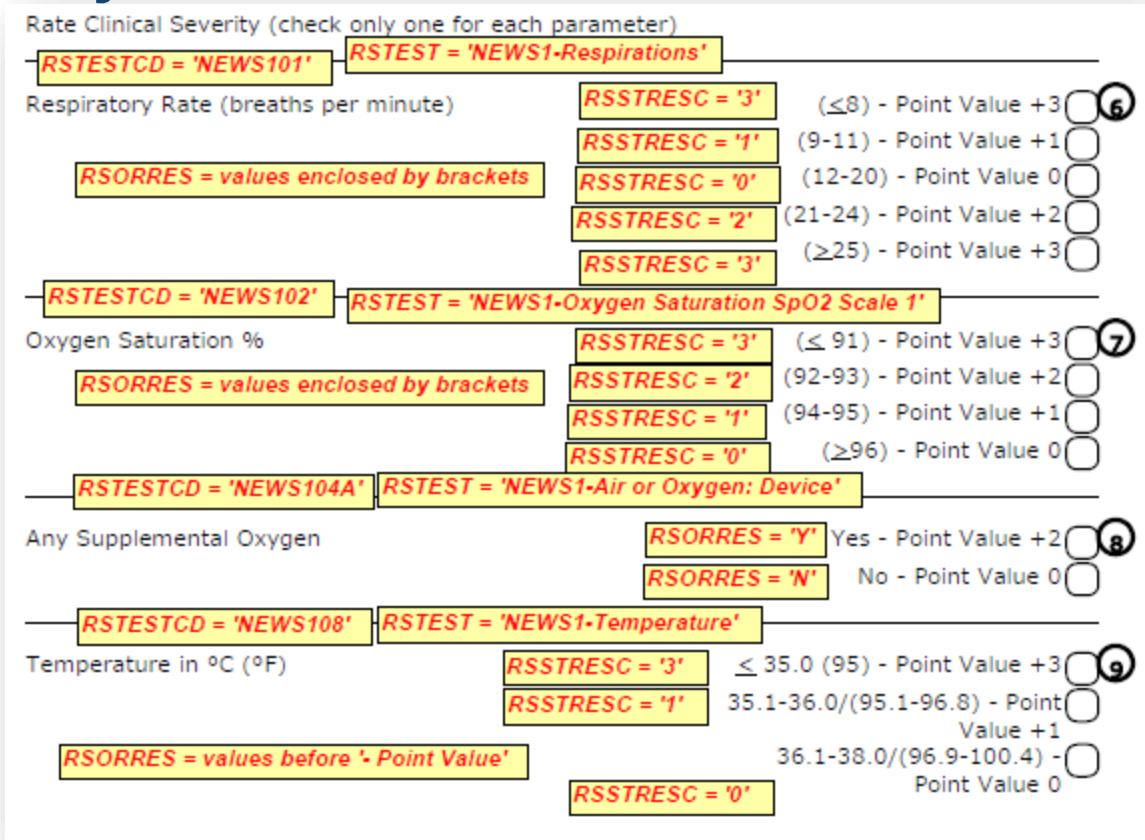
Questionnaires, Ratings and Scales

The NEWS2 consciousness score can be represented in SDTM using RSTESTCD = "NEWS107"/RSTEST = "NEWS1-Consciousness". The possible responses on the CRF include "Alert", "Confusion", "V", "P", or "U". After consulting with subject matter experts and the NEWS2 phone application, it was determined that the most meaningful data would be to represent these as "Alert", "New Confusion", "Verbal Responsive", "Pain Responsive", or "Unresponsive". The mapping strategy is included in the following tables.

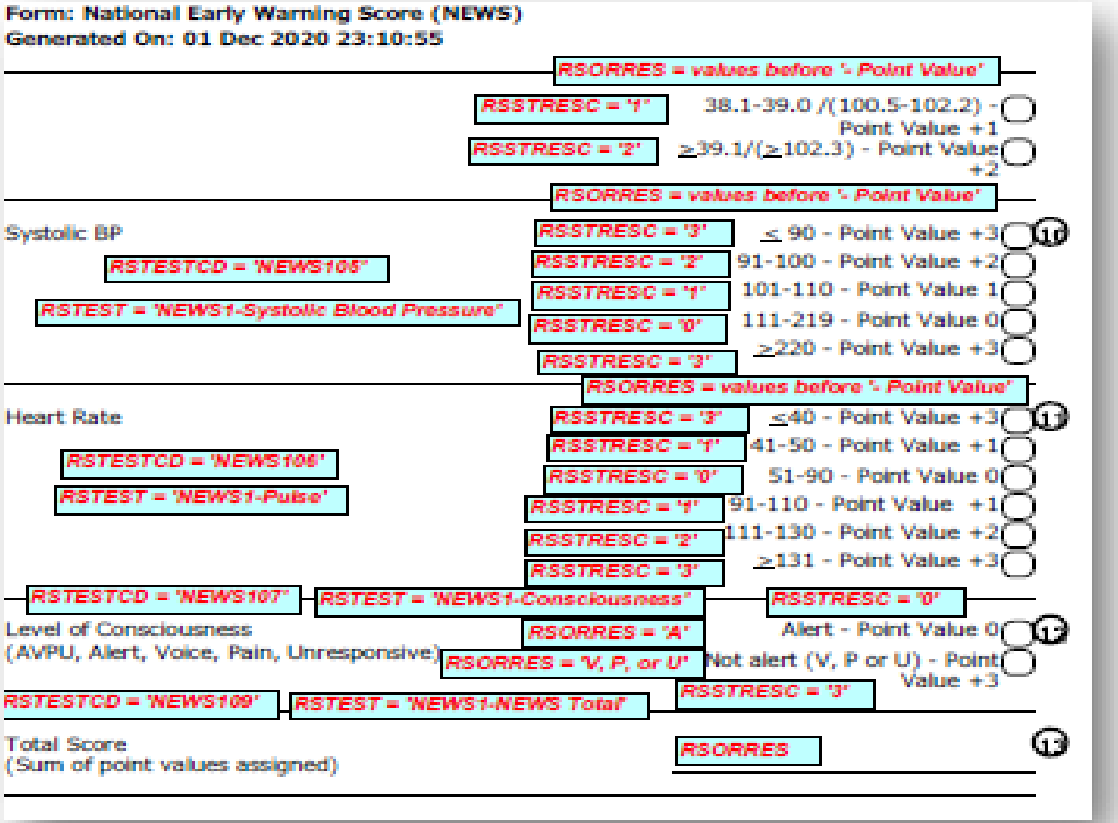
RSTESTCD	RSTEST
NEWS107	NEWS1-Consciousness

RSORRES	RSSTRESC	RSSTRESN
Alert	0	0
New Confusion	3	3
Verbal Responsive	3	3
Pain Responsive	3	3
Unresponsive	3	3

Case Study – RS Domain



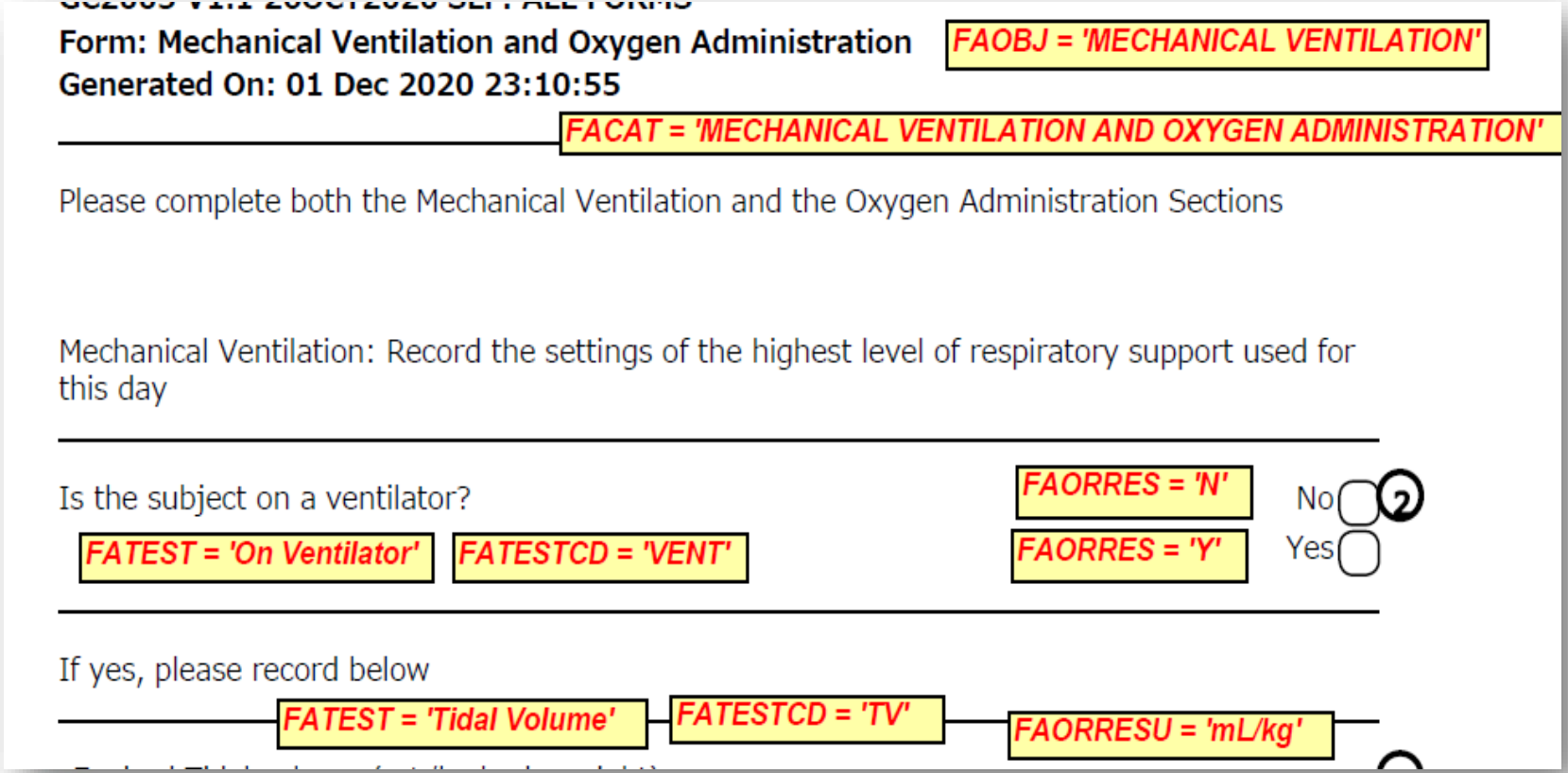
Case Study – RS Domain



Case Study – RS Domain

75	NEWS105	NEWS1-Systolic Blood Press	NEWS2	101-110	1	1				4	Day 3	TREATMENT
161	NEWS105	NEWS1-Systolic Blood Press	NEWS2	101-110	1	1				30	Day 29	TREATMENT
79	NEWS102	NEWS1-Oxygen Saturation Sp	NEWS2	94-95	1	1				20	Day 19	TREATMENT
44	NEWS102	NEWS1-Oxygen Saturation Sp	NEWS2	94-95	1	1				9	Day 8	TREATMENT
111	NEWS106	NEWS1-Pulse	NEWS2	91-110	1	1				15	Day 14	TREATMENT
148	NEWS106	NEWS1-Pulse	NEWS2	41-50	1	1				17	Day 16	TREATMENT
77	NEWS102	NEWS1-Oxygen Saturation Sp	NEWS2	94-95	1	1				18	Day 17	TREATMENT
233	NEWS108	NEWS1-Temperature	NEWS2	38.1-39.0	1	1				15	Day 14	TREATMENT
165	NEWS106	NEWS1-Pulse	NEWS2	41-50	1	1				5	Day 4	TREATMENT
146	NEWS106	NEWS1-Pulse	NEWS2	91-110	1	1				10	Day 9	TREATMENT
146	NEWS106	NEWS1-Pulse	NEWS2	41-50	1	1				15	Day 14	TREATMENT
92	NEWS105	NEWS1-Systolic Blood Press	NEWS2	101-110	1	1				13	Day 12	TREATMENT
164	NEWS106	NEWS1-Pulse	NEWS2	41-50	1	1				4	Day 3	TREATMENT

Case study: Mechanical Ventilation details - FA or PR??



Case study: Mechanical Ventilation details - FA or PR??

FASEQ	FALNKID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FAORRESU	FASTRESC	FASTRESN	FASTRESU	FAST
251		VENT	On Ventilator	MECHANICAL VENTILATION	MECHANICAL VENTILATION	Y		Y	.		
252		VENT	On Ventilator	MECHANICAL VENTILATION	MECHANICAL VENTILATION	Y		Y	.		

FASEQ	FALNKID	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FAORRESU	FASTRESC	FASTRESN	FASTRESU	FASTAT
221		TV	Tidal Volume	MECHANICAL VENTILATION	MECHANICAL VENTILATION	6	mL/kg	6	6	mL/kg	
222		TV	Tidal Volume	MECHANICAL VENTILATION	MECHANICAL VENTILATION	6	mL/kg	6	6	mL/kg	

Case Study on Multiple Hospital Admissions

SDTM HO Domain

USUBJID	HOTERM	HOSTDTC	HOENDTC
1001	HOSPITAL	2021-01-03	2021-01-31
1001	HOSPITAL	2021-02-05	2021-02-09

ADaM ADHO Domain

USUBJID	PARAMCD	ASTDT	AENDT	AVAL
1001	HOSPITAL	03JAN2021	31JAN2021	28
1001	HOSPITAL	05FEB2021	09FEB2021	4

The Difference in ADTTE!

ADaM ADTTE Domain

USUBJID	PARAM	ASTDT	AENDT	AVAL	CNSR
1001	Time to Hospital Discharge	03JAN2021	09FEB2021	37	0

- Worst case scenario handling
- Based on First Hospital Admission and Last Hospital discharge

Age as stratification factor

Subject	Folder	FolderName	BALAGERANGE
Subject1	SCRN	Screening / Baseline 0	65+
Subject2	SCRN	Screening / Baseline 0	18-64
Subject3	SCRN	Screening / Baseline 0	18-64

Age Range is categorized into

- 18 – 64
- 65 and above

This is mapped to SUPPDM in SDTM

In ADAM, a standard variable named AGEGR is used for capturing Age group in ADSL

AGE	AGEU	AGEGR1	AGEGR1N
51	YEARS	<65 years	1
72	YEARS	>=65 years	2
44	YEARS	<65 years	1

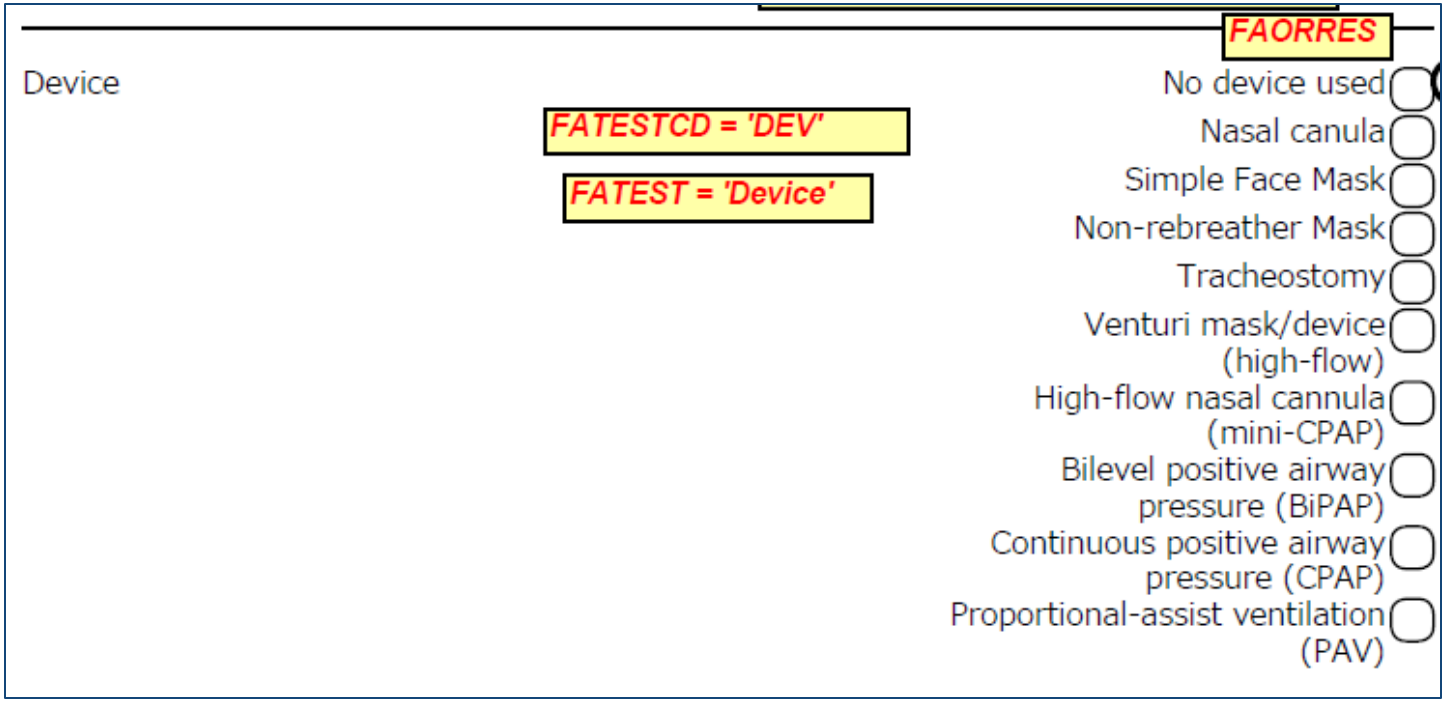
Diagnostics and Virology

Device type, manufacturer, trade name, and lot number for the RT-qPCR kit mapped to DI domain.

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	ABC	DI	PCR01	1	DEVTYPE	Device Type	RT-qPCR kit
2	ABC	DI	PCR01	2	MANUF	Manufacturer	Acme
3	ABC	DI	PCR01	3	TRADENAM	Trade Name	DetectPRO
4	ABC	DI	PCR01	4	LOTNUM	Lot Number	20160202013
5	ABC	DI	PCR02	1	DEVTYPE	Device Type	RT-qPCR kit
6	ABC	DI	PCR02	2	MANUF	Manufacturer	Acme
7	ABC	DI	PCR02	3	TRADENAM	Trade Name	DetectPRO
8	ABC	DI	PCR02	4	LOTNUM	Lot Number	20161101004

Case Study – DI Domain is not used!



According to COVID Technical conformance guidelines, any device related information must be captured in DI domain. But since we don't have much information about the devices like manufacturer, trade name, and lot number, we have captured this information in FA

Case Study – DI Domain is not used!

50		DEV	Device	OXYGEN ADMINISTRATION	MECHANICAL VENTILATION				.	
51		DEV	Device	OXYGEN ADMINISTRATION	MECHANICAL VENTILATION				.	
52		DEV	Device	OXYGEN ADMINISTRATION	MECHANICAL VENTILATION	No device		NO DEVICE	.	
53		DEV	Device	OXYGEN ADMINISTRATION	MECHANICAL VENTILATION				.	

Thank You!

ご質問・お問い合わせ等は以下にご連絡ください：

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