

**PharmaSUG 2023 - Paper DS-114**  
**CDISC SDTM IG v3.4: Subject Visits**  
Ajay Gupta, Daiichi Sankyo

## ABSTRACT

The Study Data Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) Version 3.4 has been prepared by the Submissions Data Standards (SDS) team of the Clinical Data Interchange Standards Consortium (CDISC). Like its predecessors, v3.4 is intended to guide the organization, structure, and format of standard clinical trial tabulation datasets submitted to a regulatory authority. Version 3.4 supersedes all prior versions of the SDTMIG. In this paper, I will do a quick walk-through on the updates within the SDTM IG v3.4 from his predecessor. Later, I will go over the updated SUBJECT VISITS (SV) with examples e.g., new proposed mapping to include missed visits, how to use additional variables in SV.

## INTRODUCTION

Version 3.4 of the Study Data Tabulation Model Implementation Guide (SDTMIG): Human Clinical Trials is intended to guide the organization, structure, and format of standard clinical trial tabulation datasets may be used for various purposes, including publication, warehousing, meta-analyses, and regulatory submission. It should be used in close concert with SDTM v2.0. SDTMIG v3.4 provides specific domain models, assumptions, business rules, and examples for preparing standard tabulation datasets that are based on the SDTM. SDTMIG v3.4 supersedes all prior versions of the SDTMIG.

The SDTMIG should be used in close concert with Version 2.0 of the CDISC Study Data Tabulation Model (SDTM, available at <https://www.cdisc.org/standards/foundational/sdtm>), which describes the general conceptual model for representing clinical study data that is submitted to regulatory authorities and should be read prior to reading the SDTMIG. SDTMIG Version 3.4 provides specific domain models, assumptions, business rules, and examples for preparing standard tabulation datasets that are based on the SDTM.

In this paper, I will do a quick walk-through on the updates within the SDTM IG v3.4 from his predecessor. Later, I will go over the updated SUBJECT VISITS (SV) with examples e.g., new proposed mapping to include missed visits, how to use additional variables in SV.

## NOTEWORTHY UPDATES: SDTMIG V3.4 VS SDTMIG V3.3

Some noteworthy updates are given below, refer to SDTMIG v3.4 for full details.

- The Subject Visits (SV) domain includes additional variables and contains information for each subject's actual and planned visits. More information to follow on later part of the presentation
- The Morphology (MO) domain has been decommissioned
- Biospecimen Events (BE), Biospecimen Findings (BS), and Related Specimens (RELSPEC) have been copied from SDTMIG-PGx v1.0, which has been deprecated with the publication of SDTMIG v3.4
- Addition of two new domains: Genomics Findings (GF) and Cell Phenotype Findings (CP)
  1. GF is a findings domain that contains data related to genomic material of interest. The GF domain supersedes the domain Pharmacogenomics/Genetics Findings (PF) from SDTMIG-Pharmacogenomics/Genetics (PGx) v1.0
  2. CP is also a findings domain that contains data related cell phenotype, lineage, and function based on expression of specific markers in single cell or particle suspensions
- Expanded the scope of the DA domain to include study products in addition to study drugs.

- Updated the LB domain specification to include the following ten new variables: Test Condition, Binding Agent, Test Operational Objective, Result Scale, Result Type, Collected Summary Result Type, Lower Limit of Detection, Method Sensitivity, Point in Time Flag, and Planned Duration.
- Updated Controlled Terminology for applicable variables across all domains, if available.
- Added more permissible variables on AE, CE, DA, EG, IS, LB, PP, QS, RS, SC, VS, EC, DM, SE. Look at the metadata SDTMIG\_v3.4.xlsx from CDISC website for more details.

### Change in dataset and variables labels:

See below screenshot for the label change in dataset and variables.

Dataset Name	Variable Name	Attribute (updated)	Attribute (previous)
DV	DVENDY	Study Day of End of <b>Deviation Event</b> Events	Study Day of End of <b>Observation</b> Events <b>Observation Class</b>
DA		Findings About <b>Product</b> Accountability	Findings About <b>Events or Interventions</b> <b>Drug</b> Accountability
FT	FTMETHOD	Method of Test <b>or Examination</b>	Method of Test
		Findings General Observations	Findings <b>Observation Class</b> General Observation <b>Class</b>
		Interventions Relationship	Interventions <b>Observation Class</b> Relationship <b>Datasets</b>
SM	DOMAIN	Domain <b>Abbreviation</b>	Domain
SV	SVENDTC	End Date/Time of <b>Observation</b>	End Date/Time of <b>Visit</b>
SV	SVENDY	Study Day of End of <b>Observation</b>	Study Day of End of <b>Visit</b>
SV	SVSTDTTC	Start Date/Time of <b>Observation</b>	Start Date/Time of <b>Visit</b>
SV	SVSTDY	Study Day of Start of <b>Observation</b>	Study Day of Start of <b>Visit</b>
		Special-Purpose Study Reference	Special-Purpose <b>Datasets</b> <b>Datasets for Study References</b>
TM	DOMAIN	Domain <b>Abbreviation</b>	Domain
TS	TSVALNF	Parameter <b>Value</b> Null Flavor	Parameter <b>Null</b> Flavor
TS		Trial Summary	Trial Summary <b>Information</b>
		Trial Design	Trial Design <b>Model</b>

### Display 1. Label change in SDTMIG v3.4

### Variables Core value update:

See screenshot for variables where core values were updated.

Dataset Name	Variable Name	Attribute (updated)	Attribute (previous)
DS	DSDY	<b>Perm</b>	<b>Exp</b>
DS	DSSTDY	<b>Exp</b>	<b>Perm</b>
FA	FADTC	<b>Exp</b>	<b>Perm</b>
MI	MIBLFL	<b>Perm</b>	<b>Exp</b>
MI	MILOBXFL	<b>Exp</b>	<b>Perm</b>
QS	QSLOBXFL	<b>Exp</b>	<b>Perm</b>
TV	VISIT	<b>Req</b>	<b>Perm</b>

### Display 2. Core values update in SDTMIG v3.4

### Variables Role Update:

See screenshot for variables with role update

Dataset Name	Variable Name	Attribute (updated)	Attribute (previous)
EG	EGBEATNO	<b>Identifier</b>	<b>Variable Qualifier</b>
IS	ISCAT	<b>Grouping Qualifier</b>	<b>Synonym Qualifier</b>
AG	AGDOSFRQ	<b>Record Qualifier</b>	<b>Variable Qualifier</b>
CM	CMDOSFRQ	<b>Record Qualifier</b>	<b>Variable Qualifier</b>
CM	CMDOSRGM	<b>Record Qualifier</b>	<b>Variable Qualifier</b>
EC	ECDOSFRQ	<b>Record Qualifier</b>	<b>Variable Qualifier</b>
EC	ECDOSRGM	<b>Record Qualifier</b>	<b>Variable Qualifier</b>
EX	EXDOSFRQ	<b>Record Qualifier</b>	<b>Variable Qualifier</b>
EX	EXDOSRGM	<b>Record Qualifier</b>	<b>Variable Qualifier</b>
PR	PRDOSFRQ	<b>Record Qualifier</b>	<b>Variable Qualifier</b>
PR	PRDOSRGM	<b>Record Qualifier</b>	<b>Variable Qualifier</b>
SV	SVUPDES	<b>Record Qualifier</b>	<b>Synonym Qualifier</b>
TM	TMDEF	<b>Variable Qualifier</b>	<b>Rule</b>

### Display 3. Role update in SDTMIG v3.4

## Change in Structure Text:

See below screenshot for change in structured text.

Dataset Nar	Variable Name	Attribute (updated)	Attribute (previous)
DA		One record per <b>product</b> accountability	One record per <b>drug</b> accountability finding per subject
SC		One record per characteristic per <b>visit</b>	One record per characteristic per <b>subject</b> .
SS		One record per <b>status</b> per visit per	One record per <b>finding</b> per visit per subject
SUPQUAL		One record per <b>supplemental qualifier</b>	One record per <b>IDVAR, IDVARVAL, and QNAM value</b> per subject
SV		One record per <b>actual or planned visit</b>	One record per <b>subject per actual visit</b>
TI		One record per I/E criterion	One record per I/E criterion

### Display 4. Structure text update in SDTMIG v3.4

For more information on change in CDISC Notes etc. Download Diff\_SD TMIG\_v3.4\_SD TMIG\_v3.3.xlsx from CDISC website (available for CDISC member only).

## SV UPDATE HISTORY: MISSED VISITS DURING COVID19

See below text from Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic standard released in APR2020. As mentioned, existing SV model was not able to accommodate information about missed visits or remote visits.

### 6 Missed Visits

The COVID-19 pandemic may cause missed **visits**, and in some cases may result in remote **visits** rather than in-person **visits**. Although the Protocol Deviations (DV) domain could be used to represent missed **visits**, the following example uses a custom events domain to document all **visits**. This approach accommodates amending protocols to alter **visit** schedules and/or allow remote **visits**, and permits information about **visits** before and after any protocol amendments to be represented in a single domain.

**Known Issue:** The Subject **Visits** (SV) domain is a standard domain that includes data about **visits**. However, the SV domain includes only **visits** that occurred and there is no way within the SDTM model to add variables to the SV domain as either standard variables or supplemental qualifiers. The custom **Visit** Events (VE) domain shown in the following example is an interim solution. In the future, it is possible that the solution for recording data about **visits** that did and did not occur may mean using a modified SV domain or using a new domain (e.g., the VE domain).

### Display 5. Missed Visits Rationale

To counter this issue, Missed Visits (VE) was proposed by CDISC Team.

Row	STUDYID	DOMAIN	USUBJID	VESEQ	VERTERM	VEDECOD	VEPRESP	VEOCCUR	VISITNUM	VISIT	VISTDY	VEDTC	VESTDTC	VEDY	VESTDY	VEREASOC	VEEPCGHI	VECNTMOD
1	CVD-3	VE	301	1	ONSITE VISIT	PLANNED VISIT	Y	Y	1	BASELINE	1	2020-03-04	2020-03-04	1	1			
2	CVD-3	VE	301	2	ONSITE VISIT	PLANNED VISIT	Y	Y	2	WEEK 1	8	2020-03-11	2020-03-11	8	8			
3	CVD-3	VE	301	3	REPEAT VISIT FOR ABNORMAL LAB	UNSCHEDULED VISIT			2.5			2020-03-13	2020-03-13	10	10			
4	CVD-3	VE	301	4	ONSITE VISIT	PLANNED VISIT	Y	Y	3	WEEK 2	15	2020-03-19	2020-03-19	16	16			
5	CVD-3	VE	301	5	ONSITE VISIT	PLANNED VISIT	Y	N	4	WEEK 3	22	2020-03-25		22				Subject lacked transportation
6	CVD-3	VE	301	6	ONSITE VISIT	PLANNED VISIT	Y	N	5	WEEK 4	29	2020-04-01		29				Subject refused due to fear of epidemic
7	CVD-3	VE	301	7	ONSITE VISIT	PLANNED VISIT	Y	N	6	WEEK 5	26	2020-04-08		36				Hospital restricted access to clinic
8	CVD-3	VE	301	8	VIRTUAL VISIT	PLANNED VISIT	Y	Y	7	WEEK 6	43	2020-04-15	2020-04-15	43	43		Y	REMOTE AUDIO
9	CVD-3	VE	301	9	VIRTUAL VISIT	PLANNED VISIT	Y	Y	8	WEEK 7	50	2020-04-22	2020-04-22	50	50		Y	REMOTE AUDIO VIDEO
10	CVD-3	VE	301	10	HOSPITAL RESTRICTED ACCESS TO RADIOLOGY DUE TO COVID-19	INCOMPLETE PLANNED VISIT	Y	Y	9	WEEK 8	57	2020-04-30	2020-04-30	59	59		Y	

### Display 6. Missed Visit (VE)

See below text from study data technical conformance guide JUL2020 released by FDA. Later, it was decided to add that information in SV as per study data technical conformance guide released by FDA after APR2020.

### 3. CDISC Document: Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic

It is the current preference of the Agency that for all clinical studies, not limited to those impacted by COVID-19, subject visit data for scheduled (whether or not they occurred), and unscheduled visits be submitted in one single dataset structured as the current CDISC Subject Visits (SV) domain. It is also Agency preference that three non-standard variables (NSVs) for missed visits, --REASOC (Reason for Occur Value), --EPCHGI (Epi/Pandemic Related Change Indicator), and --CNTMOD (Contact Mode), outlined in the CDISC document “Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic” be included within the SV domain and not within the supplemental SUPPSV domain or in other SDTM datasets. Submitting subject visits information in one single structured dataset allows both the human and technology consumer of this information to operate efficiently and with confidence that all visit data are considered during regulatory review.

#### Display 7. FDA Guidance on Missed Visits

### SDTM IG v3.3: SUBJECT VISITS METADATA

See below screenshot for the SUBJECT VISITS METADATA from SDTMIG v3.3. Missing visits are not covered here.

<b>SV – Specification</b>						
<b>sv.xpt, Subject Visits — Special Purpose, Version 3.2. One record per subject per actual visit, Tabulation.</b>						
Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format <sup>1</sup>	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	SV	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
VISITNUM	Visit Number	Num		Topic	Clinical encounter number. (Decimal numbering may be useful for inserting unplanned visits.) Numeric version of VISIT, used for sorting.	Req
VISIT	Visit Name	Char		Synonym Qualifier	Protocol-defined description of clinical encounter. May be used in addition to VISITNUM and/or VISITDY as a text description of the clinical encounter.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the start of the visit based upon RFSTDTC in Demographics.	Perm
SVSTDTC	Start Date/Time of Visit	Char	ISO 8601	Timing	Start date/time for a Visit.	Exp
SVENDTC	End Date/Time of Visit	Char	ISO 8601	Timing	End date/time of a Visit.	Exp
SVSTDY	Study Day of Start of Visit	Num		Timing	Study day of start of visit relative to the sponsor-defined RFSTDTC.	Perm
SVENDY	Study Day of End of Visit	Num		Timing	Study day of end of visit relative to the sponsor-defined RFSTDTC.	Perm
SVUPDES	Description of Unplanned Visit	Char		Synonym Qualifier	Description of what happened to the subject during an unplanned visit.	Perm

#### Display 8. SDTMIG v3.3 SV Metadata

### SDTM IG v3.4: SUBJECT VISITS METADATA

See below updates in SUBJECT VISITS domain in SDTMIG v3.4:

- Now contains visits that did not occur as well as those that did occur
- New variables were added: SVPRESP, SVOCCUR, SVREASOC, SVCNTMOD, SVEPCHGI

- Information was added about contacts with subjects which may not have been designated as "visits" in the protocol
  - Planned and unplanned visits with a subject, whether or not they are physical visits to the investigational site, are represented in this domain
  - SVPRESP = "Y" identifies rows for planned visits
  - For planned visits, SVOCCUR indicates whether the visit occurred
  - For unplanned visits, SVPRESP and SVOCCUR are null
  - See Section 4.5.7, Presence or Absence of Prespecified Interventions and Events, for more information on the use of --PRESP and --OCCUR
  - SVOCCUR = "N" records are only to be created for planned visits that were expected to occur before the end of the subject's participation
- The variable SVCNTMOD is used to record the way in which the visit was conducted. For example, for visits to a clinic, SVCNTMOD = "IN PERSON", visits conducted remotely might have values such as "TELEPHONE", "REMOTE AUDIO VIDEO", or "IVRS". If there are multiple contact modes, refer to Section 4.2.8.3, Multiple Values for a Non-result Qualifier Variable
- In studies disrupted by an epidemic, the permissible variable SVEPCHGI (Epi/Pandemic Related Change Indicator) was included in the SV dataset. When the change to a remote visit was a change due to the pandemic set SVEPCHGI = 'Y'

SV – Specification						
sv.xpt, Subject Visits — Special Purpose. One record per actual or planned visit per subject, Tabulation.						
Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format <sup>1</sup>	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	SV	Identifier	Two-character abbreviation for the domain most relevant to the observation. The domain abbreviation is also used as a prefix for variables to ensure uniqueness when datasets are merged.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
VISITNUM	Visit Number	Num		Topic	Clinical encounter number. Numeric version of VISIT, used for sorting.	Req
VISIT	Visit Name	Char		Synonym Qualifier	Protocol-defined description of a clinical encounter.	Perm
SVPRESP	Pre-specified	Char	(NY)	Variable Qualifier	Used to indicate whether the visit was planned (i.e., visits specified in the TV domain). Value is "Y" for planned visits, null for unplanned visits.	Exp
SVOCCUR	Occurrence	Char	(NY)	Record Qualifier	Used to record whether a planned visit occurred. The value is null for unplanned visits.	Exp
SVREASOC	Reason for Occur Value	Char		Record Qualifier	The reason for the value in SVOCCUR. If SVOCCUR="N", SVREASOC is the reason the visit did not occur.	Perm
SVCNTMOD	Contact Mode	Char	(CNTMODE)	Record Qualifier	The way in which the visit was conducted. Examples: "IN PERSON", "TELEPHONE CALL", "IVRS".	Perm
SVEPCHGI	Epi/Pandemic Related Change Indicator	Char	(NY)	Record Qualifier	Indicates whether the visit was changed due to an epidemic or pandemic.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of VISIT. Should be an integer.	Perm
SVSTDTC	Start Date/Time of Observation	Char	ISO 8601 datetime or interval	Timing	Start date/time of an observation represented in ISO 8601 character format.	Exp
SVENDTC	End Date/Time of Observation	Char	ISO 8601 datetime or interval	Timing	End date/time of the observation represented in ISO 8601 character format.	Exp
SVSTDY	Study Day of Start of Observation	Num		Timing	Actual study day of start of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.	Perm
SVENDY	Study Day of End of Observation	Num		Timing	Actual study day of end of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.	Perm
SVUPDES	Description of Unplanned Visit	Char		Record Qualifier	Description of what happened to the subject during an unplanned visit. Only populated for unplanned visits.	Perm

### Display 9. SDTMIG v3.4 SV metadata

## SUBJECT VISITS EXAMPLE

Below is the example from SDTMIG v3.4.

Row	STUDYID	DOMAIN	USUBJID	VISITNUM	VISIT	SVPRESP	SVOCCUR	SVREASOC	SVCNTMOD	SVEPCHGI	VISITDY	SVSTDTC	SVENDTC	SVSTDY	SVENDY	SVUPDES
1	123456	SV	37	1	SCREEN	Y	Y		IN PERSON			2019-09-10	2019-09-16			
2	123456	SV	85	1	SCREEN	Y	Y		IN PERSON			2019-12-13	2019-12-18	-6	-1	
3	123456	SV	85	2	DAY 1	Y	Y		IN PERSON		1	2019-12-19	2019-12-19	1	1	
4	123456	SV	85	3	WEEK 1	Y	N	SUBJECT LACKED TRANSPORTATION			8					
5	123456	SV	85	4	WEEK 2	Y	Y		IN PERSON		15	2020-01-02	2020-01-02	15	15	
6	123456	SV	85	5	WEEK 4	Y	Y		IN PERSON		29	2020-01-16	2020-01-16	30	30	
7	123456	SV	85	6	WEEK 6	Y	Y		IN PERSON		43	2020-01-30	2020-01-30	43	43	
8	123456	SV	85	7	WEEK 8	Y	Y		IN PERSON		57	2020-02-13	2020-02-13	57	57	
9	123456	SV	85	8	FOLLOW-UP	Y	Y		IN PERSON			2020-02-27	2020-02-27	72	72	
10	123456	SV	101	1	SCREEN	Y	Y		IN PERSON			2020-02-13	2020-02-18	-6	-1	
11	123456	SV	101	2	DAY 1	Y	Y		IN PERSON		1	2020-02-19	2020-02-19	1	1	
12	123456	SV	101	3	WEEK 1	Y	Y		IN PERSON		8	2020-02-25	2020-02-25	7	7	
13	123456	SV	101	4	WEEK 2	Y	N	CLINIC CLOSED DUE TO BAD WEATHER			15					
14	123456	SV	101	4.1					REMOTE AUDIO VIDEO	Y		2020-03-07	2020-03-07	18	18	EVALUATION OF AE
15	123456	SV	101	8	FOLLOW-UP	Y	Y		TELEPHONE CALL	Y		2020-03-16	2020-03-16	26	26	

### Display 10. SV Example from SDTMIG v3.4

More details on the rows are given below:

<p>Because the study in this example was disrupted by an epidemic, the permissible variable SVEPCHGI (Epi/Pandemic Related Change Indicator) was included in the SV dataset. As originally planned, visits were to be conducted in person, but pandemic disruption included conducting some visits remotely. When the change to a remote visit was a change due to the pandemic, SVEPCHGI = "Y".</p>	
<b>Row 1:</b>	Shows that screening data for subject 37 was collected during a period of 4 days. This subject is shown as a screen failure in ds.xpt and therefore would have a null DM.RFSTDTC, hence the study day values in SVSTDY and SVENDY, which are based on the sponsor-defined reference start date, are null.
<b>Rows 2-3:</b>	Show normal completion of the first 2 visits for subject 85.
<b>Row 4:</b>	Shows that for subject 85, the visit called "WEEK 1" did not occur; the reason it did not occur is represented in SVREASOC.
<b>Rows 5-9:</b>	Normal completion of remaining visits for subject 85.
<b>Row 10:</b>	Data for the screening visit was gathered over the course of six days. For this and subsequent visits, SVPRESP = "Y" indicates that a visit was planned and SVOCCUR = "Y" indicates that the visit occurred.
<b>Row 11:</b>	The visit called "DAY 1" started and ended as planned, on Day 1.
<b>Row 12:</b>	The visit scheduled for Day 8 occurred one day early, on Day 7.
<b>Row 13:</b>	The visit called "WEEK 2" did not occur due to clinic closure. SVOCCUR = "N" and SVREASOC contains the reason the visit did not occur.
<b>Row 14:</b>	Shows an unscheduled visit. SVUPDES provides the information that this visit dealt with evaluation of an adverse event. Since this visit was not planned, VISITDY was not populated, SVPRESP and SVOCCUR are both null. VISITNUM is populated as required, but the sponsor chose not to populate VISIT. Data collected at this encounter may be in a Findings domain such as EG, LB, or VS, in which VISITNUM is treated as an important timing variable. This visit was over remote audio video due to having an adverse event during a pandemic.
<b>Row 15:</b>	This subject had their last visit, a follow-up visit on study day 26, eight days after the unscheduled visit.

### Display 11. SV example details

## CONCLUSION

There are some notable changes in SDTM IG v3.4 in terms of metadata from his predecessor e.g., new domains added, variables and datasets labels updated, change in role for some variables, structure for some variables SV Now contains visits that did not occur as well as those that did occur. Five new variables SVPRESP, SVOCCUR, SVREASOC, SVCNTMOD, SVEPCHGI were added to cover missed visits and mod of contact information

## REFERENCES

[CDISC | Clear Data. Clear Impact.](#)

[Study Data Standards Resources | FDA](#)

## ACKNOWLEDGMENTS

Thanks to Antonio Lovatin and Giacomo Mordenti for their reviews and comments. Thanks to my family for their support.

## CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Ajay Gupta, M.S.  
Daiichi Sankyo, Inc  
211 Mt Airy Rd  
Basking Ridge, NJ 07920  
Phone: (269)-873-1145  
E-mail: [Ajgupta@dsi.com](mailto:Ajgupta@dsi.com),  
[Ajaykailasgupta@aol.com](mailto:Ajaykailasgupta@aol.com)

## DISCLAIMER

The content of this paper are the works of the authors and do not necessarily represent the opinions, recommendations, or practices of Daiichi Sankyo.

Any brand and product names are trademarks of their respective companies.