

Dynamically harvesting study dates to construct & QC the SV SDTM domain

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Overview

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- 2 Methodology
- 3 Why QC SV?
- 4 QC and Data Checks
- 5 Application to SE
- 6 Conclusion

Subject Visits (SV) Domain



The Subject Visits domain consolidates information about the timing of subject visits that is otherwise spread over domains that include the visit variables (VISITNUM and possibly VISIT and/or VISITDY).

- CDISC SDTM Implementation Guide (Version 3.2)

SV Domain: Early planning

- + What subject visits are expected?
 - + Study protocol, study design, schedule of events (SOE)

- + Identify key study dates
 - + Informed consent
 - + Randomization
 - + Treatment start/end
 - + End of study participation
 - + Death
 - + etc...

- + Location of relevant date variables
 - + Case report form (CRF)
 - + Database design specifications

SV Domain: Choosing dates

- + Should include dates for all scheduled visits and unscheduled visits
- + Should not include dates collected outside of study participation
 - + e.g., Birth date and medical history dates
- + May include dates not associated with a clinical encounter, if considered relevant
 - + Depends on specific sponsor requirements and study designs

SV Domain: Sample specification

“For each of the specified data sources, append distinct values of STUDYID, USUBJID, VISITNUM, VISIT, and assessment/collection dates. Create and sort by a common date variable. For planned/scheduled visits, choose the earliest date associated with a particular visit as SVSTDTC. Likewise, choose the latest date associated with a particular visit as SVENDTC. (For specific datasets and variables, see table)

Note: Do not consider dates from AE, CM, DM, PR, MH, and SE”

Staged Dataset	Date
BE	ATSDTC
CE	CDPDTC
DA	DADPDTC
DA	DARDDTC
DD	DTHDTC
DS	DSDTC
DS	DSIVDTC
DS	DSLDDTC
DS	EODTC
DS	SFDTC
DV	OCCURRED (convert to ISO date)
EC	EXADDTC
EC	EXENDTC
EC	EXLSDTC
EC	EXMDTC
EC	EXSTDTC
EG	EGDTC
EX	EXADDTC
EX	EXENDTC
EX	EXLSDTC
EX	EXMDTC
EX	EXSTDTC
LB	PREGDTC
LB	UNLBDTC
CLAB	LBDTC (convert to ISO date. Assign FOLDERNAME as VISIT, and then derive VISITNUM as specified in the Implementation Notes tab (part 5))
PC	PKDTC
PC	SAMPDTC
PE	PEDTC
QS	ECODTC
QS	QLQDTC
RS	RSP1DTC
SS	SURENDTC
SS	SURLKDTC
SS	SURSTDTC
SS	SURVDTC
TU	LSDTC
TU	LSDTNDTC
TU	NWASDTC
VS	VSDTC

SV Domain: Some code (manual method)

```
proc sort data=stagedr.BE out=ATSDTC nodupkey; by STUDYID USUBJID VISITNUM VISIT ATSDTC; run;
proc sort data=stagedr.CE out=CDPDTC nodupkey; by STUDYID USUBJID VISITNUM VISIT CDPDTC; run;
proc sort data=stagedr.DA out=DADPDTC nodupkey; by STUDYID USUBJID VISITNUM VISIT DADPDTC; run;
proc sort data=stagedr.DA out=DARDDTC nodupkey; by STUDYID USUBJID VISITNUM VISIT DARDDTC; run;
proc sort data=stagedr.DD out=DTHDTC nodupkey; by STUDYID USUBJID VISITNUM VISIT DTHDTC; run;
...
proc sort data=stagedr.TU out=LSDTC nodupkey; by STUDYID USUBJID VISITNUM VISIT LSDTC; run;
proc sort data=stagedr.TU out=LSDTNDTC nodupkey; by STUDYID USUBJID VISITNUM VISIT LSDTNDTC; run;
proc sort data=stagedr.TU out=NWASDTC nodupkey; by STUDYID USUBJID VISITNUM VISIT NWASDTC; run;
proc sort data=stagedr.VS out=VSDTC nodupkey; by STUDYID USUBJID VISITNUM VISIT VSDTC; run;

data alldates;
  set ATSDTC
      CDPDTC
      DADPDTC
      DARDDTC
      DTHDTC
      ...
      LSDTC
      LSDTNDTC
      NWASDTC
      VSDTC;

run;
```

And so forth...

There must be a better way!

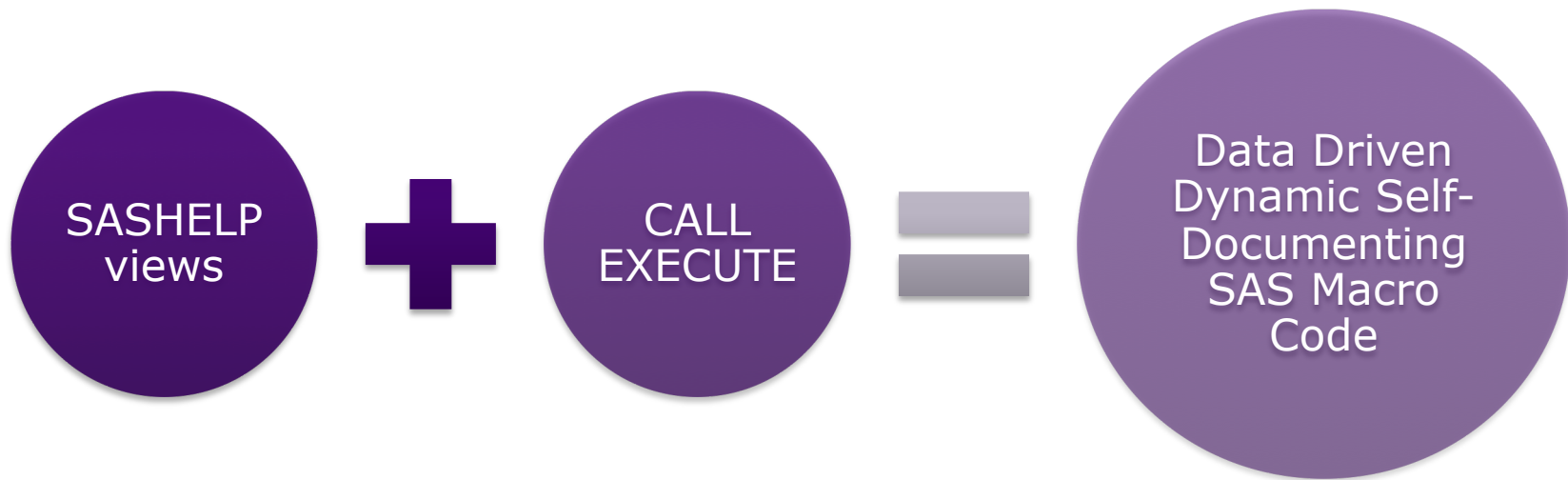
"Here is Edward Bear,
coming downstairs now,
bump, bump, bump,
on the back of his head,
behind Christopher Robin.
It is, as far as ...

It is, as far as he knows,
the only way of coming downstairs,
but sometimes he feels that there
really is another way,
if only he could stop bumping for a
moment and think of it!"

- A.A. Milne



Methodology



Methodology – Step 1

Extract variable level info for relevant dates

Obs	libname	memname	name	type	length	label
1	STAGEDR	BE	ATSDTC	char	20	Date of Tumor Tissue Sample Sent (ISO)
2	STAGEDR	CE	CDPDTTC	char	20	Date of Clinical Disease Progression (ISO)
3	STAGEDR	DA	DADPDTTC	char	20	Date Dispensed (ISO)
4	STAGEDR	DA	DARDTTC	char	20	Date Returned (ISO)
...	...	...	...	...	...	...
40	STAGEDR	TU	LSDTTC	char	20	Target Lesion Scan Date (ISO)
41	STAGEDR	TU	LSDTNDTTC	char	20	Non Target Lesion Scan Date (ISO)
42	STAGEDR	TU	NWASDTTC	char	20	New Lesion Scan Date (ISO)
43	STAGEDR	VS	VSDTTC	char	20	Date of Measurement (ISO)

```
data alldates;
  set sashelp.vcolumn
    (keep=libname memname memtype name label type format

/* choose a libname from which to gather dates */
where=(libname='STAGEDR' and memtype='DATA'

/* remove irrelevant datasets */
and memname^in('FORMATS' 'MH' 'SE' 'PR')

/* remove irrelevant dates with labels and/or names */
and (upcase(label)^?('BIRTH') and name^='BRTHDTC')

/* subset for dates */
/* note, may subset for dates by name, label, even format! */
and upcase(reverse(substr(strip(reverse(name)),1,3)))='DTC' ));
```



Note: Using VCOLUMN with a WHERE clause allows for flexible, customizable selection of study dates.

Obs	libname	memname	name	type	length	label
1	STAGEDR	BE	ATSDTC	char	20	Date of Tumor Tissue Sample Sent (ISO)
2	STAGEDR	CE	CDPDTC	char	20	Date of Clinical Disease Progression (ISO)
3	STAGEDR	DA	DADPDTC	char	20	Date Dispensed (ISO)
4	STAGEDR	DA	DARDDTC	char	20	Date Returned (ISO)
...	...	...	...	...	...	...
40	STAGEDR	TU	LSDTC	char	20	Target Lesion Scan Date (ISO)
41	STAGEDR	TU	LSDTNDTC	char	20	Non Target Lesion Scan Date (ISO)
42	STAGEDR	TU	NWASDTC	char	20	New Lesion Scan Date (ISO)
43	STAGEDR	VS	VSDTC	char	20	Date of Measurement (ISO)

Generate a series of proc sorts to harvest dates

```
call execute("proc sort nodupkey data=
|| strip(libname) || "." || strip(memname)
|| "(keep=usubjid visit visitnum datapagename " || strip(name)
|| "(rename=( " || strip(name) || "=rawdttc))"
|| " where=( " || strip(name) || "^=' '))
out=SV_" || strip(memname) || "_" || strip(name);
by usubjid visitnum visit datapagename " || strip(name)
|| "; run;");
```

```
run;
```



Note: Datapagename is included for traceability and may be used for SVUPDES for unplanned visits.

And... Using the naming convention "SV_*[dataset name]*_*[date variable name]*", the code is self-documenting.

```
NOTE: There were 63 observations read from the data set
      WHERE ('libname="STAGE01" and (mtype="DATA" and ("
      "SU" and UCABLE="libname" not contains "BIRTH" and
      "REUSE="SU" and "REUSE="SU" and "REUSE="SU" and "
NOTE: The data set WORK._$ATSTC03 has 15 observations and 7
      variables
NOTE: DATA statement used (Total process time):
      real time          0.00 seconds
      cpu time           0.07 seconds

NOTE: CALL EXECUTE generated line
      visit libname datasegname ATSTC03 where(ATSTC03="1")
      by _all_ ;
      by _all_ visit libname datasegname ATSTC03; run;
NOTE: There were 131 observations read from the data set
      STAGE01
NOTE: SAS sort used.
NOTE: The data set WORK._$ATSTC03 has key values were deleted.
NOTE: The data set WORK._$ATSTC03 has 131 observations and 6
      variables
NOTE: PROCEDURE SORT used (Total process time):
      real time          0.00 seconds
      cpu time           0.00 seconds

2      proc sort nodupkey datasegname.CE[haspctidvisit]
      visit libname datasegname ATSTC03 where(COPTC="
      SU_COPTC[rename=(COPTC=>custid datasegname)wpg]; by
      _all_ visit libname datasegname ATSTC03; run;
NOTE: There were 126 observations read from the data set
      WORK._$ATSTC03
NOTE: WHERE COPTC not = ' '
NOTE: SAS sort used.
NOTE: 0 observations with duplicate key values were deleted.
NOTE: The data set WORK._$ATSTC03 has 126 observations and 6
      variables
NOTE: PROCEDURE SORT used (Total process time):
```

NOTE: There were 63 observations read from the data set SASHELP.VCOLUMN.
WHERE (libname='STAGEDR') and (memtype='DATA') and memname not in ('AE', 'CM', 'FA', 'FORMATS', 'MH', 'SE', 'SU') and UPCASE(label) not contains 'BIRTH' and (UPCASE(REVERSE(SUBSTR(STRIP(REVERSE(name)), 1, 3)))='DTC') and (name not = 'BRTHDTC');

NOTE: The data set WORK.ALLDATES has 43 observations and 7 variables.

NOTE: DATA statement used (Total process time):
real time 1.49 seconds
cpu time 0.57 seconds

NOTE: CALL EXECUTE generated line.

```
1 + proc sort nodupkey data=stagedr.BE(keep=studyid usubjid  
visit visitnum datapagename ATSDTC where=(ATSDTC^=''))  
out=SU_BE_ATSDTC(rename=(ATSDTC=svstdtc datapagename=qg)); by  
studyid usubjid visitnum visit datapagename ATSDTC; run;
```

NOTE: There were 131 observations read from the data set STAGEDR.BE.
WHERE ATSDTC not = ' ';

NOTE: SAS sort was used.

NOTE: 0 observations with duplicate key values were deleted.

NOTE: The data set WORK.SU_BE_ATSDTC has 131 observations and 6 variables.

NOTE: PROCEDURE SORT used (Total process time):
real time 0.01 seconds
cpu time 0.00 seconds

```
2 + proc sort nodupkey data=stagedr.CE(keep=studyid usubjid  
visit visitnum datapagename CDPDTC where=(CDPDTC^=''))  
out=SU_CE_CDPDTC(rename=(CDPDTC=svstdtc datapagename=qg)); by  
studyid usubjid visitnum visit datapagename CDPDTC; run;
```

NOTE: There were 126 observations read from the data set STAGEDR.CE.
WHERE CDPDTC not = ' ';

NOTE: SAS sort was used.

NOTE: 0 observations with duplicate key values were deleted.

NOTE: The data set WORK.SU_CE_CDPDTC has 126 observations and 6 variables.

NOTE: PROCEDURE SORT used (Total process time):

Methodology – Finalize SV

- + Append “sv_*[dataset name]*_*[date variable name]*” datasets
- + Derive SVSTDTC (minimum RAWDTTC) and SVENDTC (maximum RAWDTTC) for distinct values of USUBJID, VISITNUM/VISIT
- + Complete special handling for unplanned/unscheduled visits
- + *Done!?*
- + **Data checks and QC!**

Why QC SV?

- + Contains the entirety of the study's subjects, visits and associated dates
 - + Allows reviewers a good feel for the breadth of the data
- + Visit start and end dates are *derived*. Therefore, sensitive to data anomalies
- + Acting on early identification of visit date anomalies pays off
 - + Would otherwise be caught when aggregated and reviewed in ADaM or TLFs
- + *Why not?! Saved a ton of time with clever code... do more than program SV, analyze the data!*

QC Visit Anomalies

+ Merge SV with key dates

```
+ merge tsv stagedm(keep=usubjid rficdtc rfstdtc dthdtc);
```

SVSTDTC	RFICDTC	RFSTDTC	DTHDTC	EXTRACT
2018-10-01	2018-01-01	2018-01-10	2018-06-01	2018-12-31
2019-01-01	2018-12-01	2018-12-10		2018-12-31
2018-12-31	2019-01-01	2019-01-10		2018-12-31

1. QC: Dates past Death date
2. QC: Dates past Extraction date
3. QC: Dates prior to Informed Consent date

QC Date Anomalies – Out of Order

- + Lag SVSTDTC and compare with the next SVSTDTC
- + Calculate number of days difference between the two visits
 - + Study may allow variance between visits

VISIT	VISITNUM	SVSTDTC	LAGDTC	DIFFSV
WEEK 2	2	2018-10-02		.
WEEK 3	3	2018-10-09	2018-10-02	7
WEEK 4	4	2018-10-12	2018-10-09	3
WEEK 5	5	2018-10-23	2018-10-12	11
WEEK 6	6	2018-09-30	2018-10-23	-23

OKAY



QC Date Anomalies – Expected Visit Windows

+ Merge SV with Trial Visits (TV) Domain by VISIT(NUM)

1. QC: Visit in SV and TV?

2. QC: Within expected visit window?

+ For example, +/- 7 days of planned study day (TV.VISITDY)

SVSTDTC	SVSTDY	VISITNUM	VISIT	VISITDY	TVDIFF
2014-12-04	29	3	WEEK 3	21	8



Note: $\text{tvdiff} = \text{abs}(\text{svstdy} - \text{visitdy})$;

Application to Subject Elements (SE) Domain

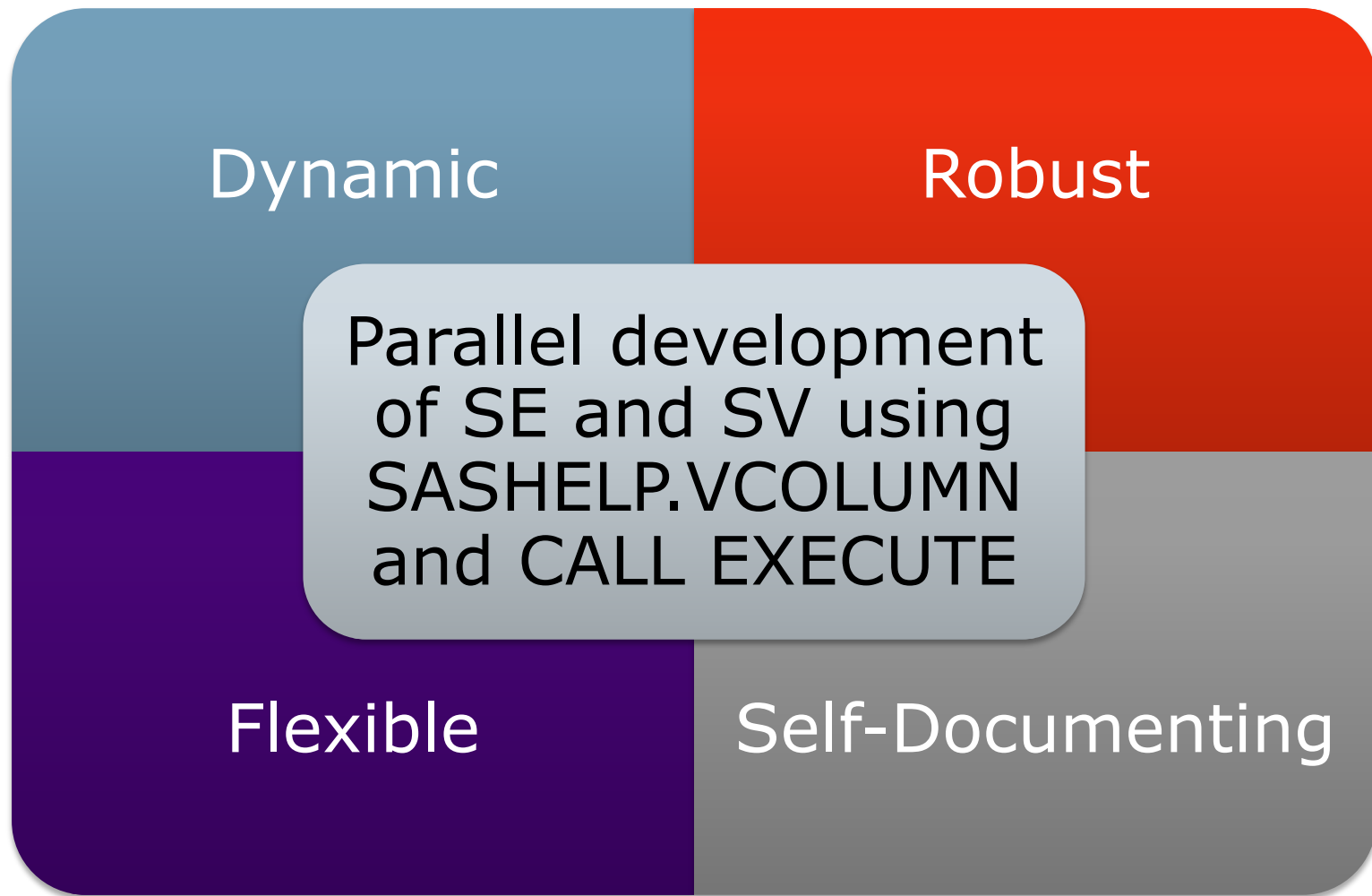
- + SE is a summary view of subject's progress through major study element
- + Key dates for QC checks in SV can be used to demarcate EPOCHs
- + Parallel development of SV and SE

USUBJID	VISITNUM	VISIT	RAWDT	TRTSDT	TRTEDT	EPOCH	SVUPDES
ANY-STUDY-999-9999	-1	Screening	2017-11-20	30MAY2018	04SEP2018	SCREENING	Central Labs
ANY-STUDY-999-9999	-1	Screening	2018-05-15	30MAY2018	04SEP2018	SCREENING	Non-Target Lesion, Target Lesion
ANY-STUDY-999-9999	-1	Screening	2018-05-17	30MAY2018	04SEP2018	SCREENING	12-Lead EKG, ECOG, IWRS, Informed Consent, Central Labs, Physical Exam 1, Vital Signs-Screening
ANY-STUDY-999-9999	-1	Screening	2018-05-29	30MAY2018	04SEP2018	SCREENING	IWRS, Randomization
ANY-STUDY-999-9999	1	Week 1	2018-05-30	30MAY2018	04SEP2018	TREATMENT	ECOG, Exposure1, Exposure2, Exposure3, IWRS, Central Labs, Physical Exam 2, Vital Signs
ANY-STUDY-999-9999	2	Week 2	2018-06-11	30MAY2018	04SEP2018	TREATMENT	ECOG, Exposure1, Exposure2, Exposure3, Central Labs, Physical Exam 2, Vital Signs
ANY-STUDY-999-9999	2	1	2018-06-19	30MAY2018	04SEP2018	TREATMENT	ECOG, Central Labs, Unscheduled Local Laboratory, Vital Signs
ANY-STUDY-999-9999	2	Week 2	2018-06-25	30MAY2018	04SEP2018	TREATMENT	IWRS
ANY-STUDY-999-9999	3	Week 3	2018-06-25	30MAY2018	04SEP2018	TREATMENT	ECOG, Exposure1, Exposure2, Exposure3, IWRS, Central Labs, Physical Exam 2, Vital Signs
ANY-STUDY-999-9999	4	Week 4	2018-07-09	30MAY2018	04SEP2018	TREATMENT	ECOG, Exposure1, Exposure2, Exposure3, Central Labs, Physical Exam 2, Vital Signs
ANY-STUDY-999-9999	4	Week 4	2018-07-10	30MAY2018	04SEP2018	TREATMENT	IWRS
ANY-STUDY-999-9999	5	Week 5	2018-07-20	30MAY2018	04SEP2018	TREATMENT	Non-Target Lesion, RECIST Response, Target Lesion
ANY-STUDY-999-9999	5	Week 5	2018-07-23	30MAY2018	04SEP2018	TREATMENT	ECOG, Exposure1, Exposure2, Exposure3, IWRS, Central Labs, Physical Exam 2, Vital Signs
ANY-STUDY-999-9999	6	Week 6	2018-08-06	30MAY2018	04SEP2018	TREATMENT	ECOG, Exposure1, Exposure2, Exposure3, Central Labs, Physical Exam 2, Vital Signs
ANY-STUDY-999-9999	6	Week 6	2018-08-07	30MAY2018	04SEP2018	TREATMENT	IWRS
ANY-STUDY-999-9999	7	Week 7	2018-09-04	30MAY2018	04SEP2018	TREATMENT	ECOG, Exposure1, Exposure2, Exposure3, IWRS, Central Labs, Physical Exam 2, Vital Signs
ANY-STUDY-999-9999	99	End of Treatment	2018-09-04	30MAY2018	04SEP2018	TREATMENT	Study Treatment Completion
ANY-STUDY-999-9999	99	End of Treatment	2018-09-14	30MAY2018	04SEP2018	FOLLOW-UP	New Lesion, Non-Target Lesion, RECIST Response, Target Lesion
ANY-STUDY-999-9999	99	End of Treatment	2018-09-17	30MAY2018	04SEP2018	FOLLOW-UP	12-Lead EKG, ECOG, Central Labs, Physical Exam 2, Vital Signs
ANY-STUDY-999-9999	101	Follow-Up Day 30	2018-10-01	30MAY2018	04SEP2018	FOLLOW-UP	ECOG, Central Labs, Physical Exam 2, Vital Signs
ANY-STUDY-999-9999	102	Follow-Up Week 8	2018-10-09	30MAY2018	04SEP2018	FOLLOW-UP	Survival
ANY-STUDY-999-9999	102	Follow-Up Week 8	2018-11-19	30MAY2018	04SEP2018	FOLLOW-UP	Survival

USUBJID	VISITNUM	VISIT	RAWDT	TRTSDT	TRTEDT	EPOCH	SVUPDES
ANY-STUDY-999-9999	-1	Screening	2017-11-20	30MAY2018	04SEP2018	SCREENING	Central Labs
ANY-STUDY-999-9999	-1	Screening	2018-05-15	30MAY2018	04SEP2018	SCREENING	Non-Target Lesion; Target Lesion
ANY-STUDY-999-9999	-1	Screening	2018-05-17	30MAY2018	04SEP2018	SCREENING	12-Lead EKG; ECOG; IWRS; Informed Consent; Central Labs; Physical Exam 1; Vital Signs-Screening
ANY-STUDY-999-9999	-1	Screening	2018-05-29	30MAY2018	04SEP2018	SCREENING	IWRS; Randomization
ANY-STUDY-999-9999	1	Week 1	2018-05-30	30MAY2018	04SEP2018	TREATMENT	ECOG; Exposure1; Exposure2; Exposure3; IWRS; Central Labs; Physical Exam 2; Vital Signs
ANY-STUDY-999-9999	2	Week 2	2018-06-11	30MAY2018	04SEP2018	TREATMENT	ECOG; Exposure1; Exposure2; Exposure3; Central Labs; Physical Exam 2; Vital Signs
ANY-STUDY-999-9999	2.1	Unscheduled Week 2.1	2018-06-19	30MAY2018	04SEP2018	TREATMENT	ECOG; Central Labs; Unscheduled Local Laboratory; Vital Signs
ANY-STUDY-999-9999	2	Week 2	2018-06-25	30MAY2018	04SEP2018	TREATMENT	IWRS
ANY-STUDY-999-9999	3	Week 3	2018-06-25	30MAY2018	04SEP2018	TREATMENT	ECOG; Exposure1; Exposure2; Exposure3; IWRS; Central Labs; Physical Exam 2; Vital Signs
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ANY-STUDY-999-9999	4	Week 4	2018-07-10	30MAY2018	04SEP2018	TREATMENT	IWRS
ANY-STUDY-999-9999	5	Week 5	2018-07-20	30MAY2018	04SEP2018	TREATMENT	Non-Target Lesion; RECIST Response; Target Lesion
ANY-STUDY-999-9999	5	Week 5	2018-07-23	30MAY2018	04SEP2018	TREATMENT	ECOG; Exposure1; Exposure2; Exposure3; IWRS; Central Labs; Physical Exam 2; Vital Signs
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Conclusion



Questions?



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