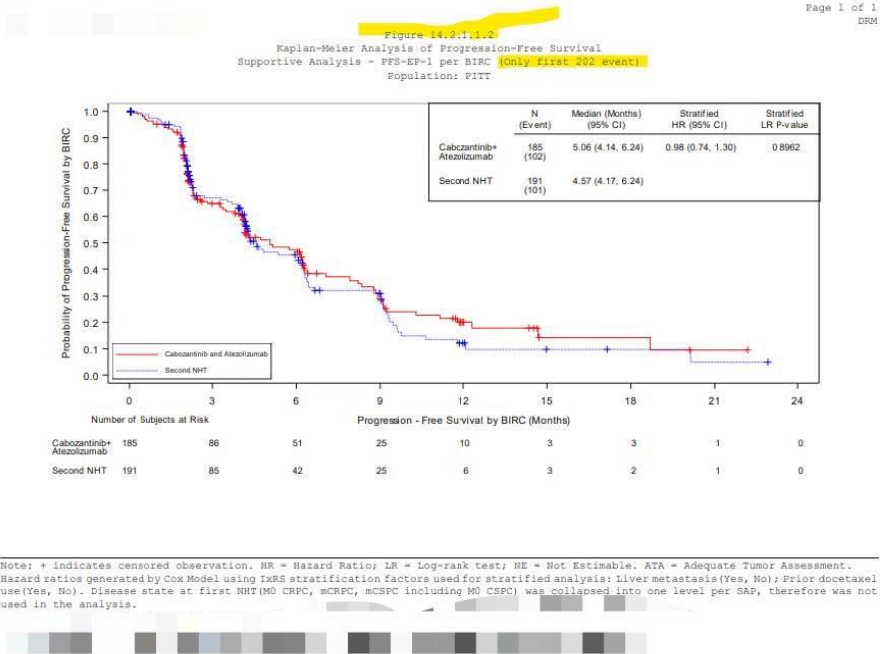


Table 14.2.2.1
Kaplan-Meier Analysis of Overall Survival
Primary Analysis
Population: mITT

	Cabozantinib and Atezolizumab (N=239)	Second Arm (N=244)
Number (%) of subjects		
Censored	167 (70%)	172 (70%)
ALIVE	161 (67%)	167 (68%)
DEATH AFTER DATA CUTOFF DATE	6 (2.5%)	5 (2.0%)
Event	72 (30%)	72 (30%)
DEATH	72 (30%)	72 (30%)
K-M estimate (months)		
n	239	244
25th percentile	8.61	9.00
Median (95% CI)	16.43 (14.29, 19.06)	16.66 (11.56, NE)
75th percentile	NE	NE
Min, Max	0.03+, 27.60+	0.03+, 27.66+
K-M landmark estimates and 95% CI of percent of subjects event-free at:		
3 months	93.5% (89.2%, 96.1%)	92.6% (88.1%, 95.4%)
6 months	83.9% (77.8%, 88.4%)	83.2% (77.0%, 87.9%)
12 months	63.1% (54.4%, 70.6%)	57.7% (48.9%, 65.6%)
18 months	45.4% (34.4%, 55.8%)	50.0% (40.3%, 58.9%)
24 months	27.1% (11.3%, 45.6%)	45.5% (34.9%, 55.5%)

Note: + indicates censored observation. NE = Not Estimable.
[1] Statistical significance is achieved if p-value <= 0.00013.
[2] Hazard ratios were calculated from Cox proportional hazards model.
Stratification factors used for stratified analysis: Liver metastasis(Yes, No); Prior docetaxel use(Yes, No). Disease state at first NHT(M0
CRPC, mCRPC including M0 CRPC) was collapsed into one level per SAP, therefore was not used in the analysis.
SAS Parameters ADSL, ADTTE

Subtitle should be “Dec12 2022 Cut off date”.
Paramc1 from PFSEP1A change to PFSEP1C according to changed on cut of date.

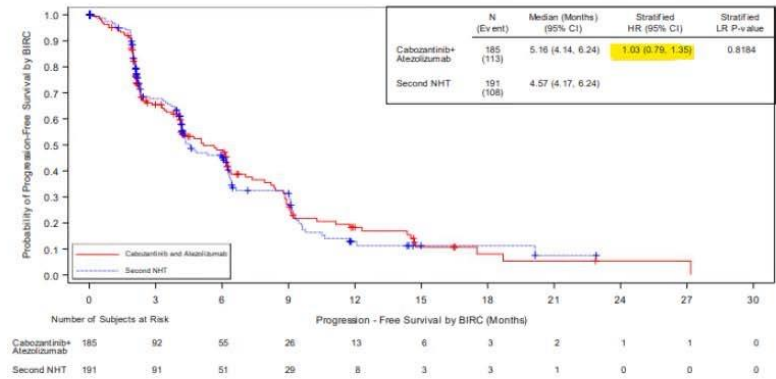


Overall analysis

Table 14-2-1-1-1
Kaplan-Meier Analysis of Progression-Free Survival
Primary Analysis - PFS-EP-1 per BIRC
Population: PITT

	Cabozantinib and Atezolizumab (N=185)	Second NHT (N=191)
Stratified (per IxRS) Log-rank test p-value [1]	0.8184	
Unstratified Log-rank test p-value	0.9544	
Stratified (per IxRS) Hazard Ratio (99.8% CI) [2]	1.03 (0.68, 1.57)	
Unstratified Hazard Ratio (99.8% CI) [2]	0.99 (0.65, 1.51)	
Stratified (per IxRS) Hazard Ratio (95% CI) [2]	1.03 (0.79, 1.35)	
Unstratified Hazard Ratio (95% CI) [2]	0.99 (0.76, 1.29)	

Figure 14-2-1-1-1
Kaplan-Meier Analysis of Progression-Free Survival
Primary Analysis - PFS-EP-1 per BIRC
Population: PITT



Note: * indicates censored observation. HR = Hazard Ratio; LR = Log-rank test; NE = Not Estimable. ATA = Adequate Tumor Assessment. * indicates p-value <= 0.05.
Hazard ratios generated by Cox Model using IxRS stratification factors used for stratified analysis: Liver metastasis(Yes, No); Prior docetaxel use(Yes, No); Disease state at first NHT(M0 CRPC or mCRPC including M0 CRPC, mCRPC). M0 CRPC and mCRPC(including M0 CRPC) were combined per pre-planned stratification factors collapsing algorithm.
Source Data: ADaM Datasets ADGL, ADTTE
f-km.sas SAS v9.4 Executed:27JUN2023 21:14 DATA CUT:28FEB2023 DATA EXTRACTION DATE: 14APR2023

Table 14-2-1-1-1 KM-pfs-ep1

For stratified trt cabo+atez HR 95% CI, figure range should be (0.68,1.57).

Table 14-2-1-1-2

SAS Writing sample

```

1
2 **** 20230612 Mike;
3 proc sort data=anadata.adsl out=adsl0;
4   by usubjid;
5   where mittfl="Y";
6 run;
7
8 data adsl0;
9   set adsl0;
10   trtn=trt01pdn;
11   trtc=trt01pd;
12 run;
13
14 ***** ODSDATA (method 1);
15 *** End of treatment (reason);
16 proc sort data=odsdata.etcdb out=etcdb0 ;
17   by studyid usubjid ;
18   *where ETDCST ne " ";
19 run;
20
21 *** Radiographic follow-up;
22 proc sort data=odsdata.ercdb out=ercdb0 ;
23   by studyid usubjid ;
24   *where ETDCST ne " ";
25 run;
26
27 *** Survival Follow-up;
28 proc sort data=odsdata.escdb out=escdb0 ;
29   by studyid usubjid ;
30   *where ETDCST ne " ";
31 run;
32
33 data etcdb0;
34   merge etcdb0(in=ina) adsl0(in=inb keep=usubjid trtn trtc trt01pdn trt01pd);
35   by usubjid;
36   if ina and inb;
37 run;
38
39 data ercdb0;
40   merge ercdb0(in=ina) adsl0(in=inb keep=usubjid trtn trtc trt01pdn trt01pd);
41   by usubjid;
42   if ina and inb;
43 run;
44
45 data escdb0;
46   merge escdb0(in=ina) adsl0(in=inb keep=usubjid trtn trtc trt01pdn trt01pd);
47   by usubjid;
48   if ina and inb;
49 run;
50
51 proc freq data=etcdb0 noprint;
52   tables trtn*trtc*PAGEID*etdcst/list missing out=_et_f;;
53 run;
54
55 proc freq data=ercdb0 noprint;
56   tables trtn*trtc*esradsr/list missing out=_er_f;;
57 run;
58
59 proc freq data=escdb0 noprint;
60   tables trtn*trtc*esdcfu/list missing out=_es_f;;
61 run;
62 *****;
63
64 ***** (method 2);
65 proc sort data=sdtmdata.ds out=ds0 ;
66   by usubjid;
67 run;
68
69 data ds0;

```

```

70     merge ds0(in=ina) adsl0(keep=usubjid trtn trtc trt01pdn trt01pd);
71     by usubjid;
72     if ina;
73 run;
74
75 proc freq data=ds0 noprint;
76     tables trtn*trtc*dscat*dsscat*dsterm/list missing out=_ds_f;
77 run;
78
79 data _ds_f1;
80     set _ds_f;
81     if dsscat="END OF STUDY TREATMENT, ATEZOLIZUMAB";
82 run;
83
84 proc freq data=adsl0;
85     tables mittfl*trtn*trtc/list missing;
86     tables mittfl*ittfl*trtn*trtc/list missing;
87 run;
88
89 data _findat;
90     set findat;
91     keep usubjid mittfl ittfl ;
92 run;
93
94 proc freq data=findat;
95     tables ittfl/list missing;
96 run;
97
98
99 ***** Part II Subjects treated;
100 /*ADSL:TRTCSDT and ADSL:TRTASDT non-missing*/
101 /*(ADSL:TRTBSDT and ADSL:TRTPSDT non-missing) or ADSL:TRTESDT non-missing*/
102 ;
103
104 data adsl0;
105     set adsl0;
106     if saffl="Y" then do;
107         if trtcsdt>. and trtasdt>. then flag21=1;
108         if (trtbsdt>. and trtpsdt>. ) or trtedt>. then flag22=1;
109     end;
110 run;
111
112 proc freq data=adsl0;
113     tables trtn*trtc*flag21/list missing;
114     tables trtn*trtc*flag22/list missing;
115     tables trtn*trtc*flag21*flag22/list missing;
116 run;
117
118
119 ***** Part III: subject on study treatment at data cutoff
120 **Ensure MSAFFL='Y' for this section:
121 ADSL: EOTDCDT >= ADSL:CUTDT or ADSL: EOTDCDT missing
122 For trt01ad= Cabozantinib+Atezolizumab: ADSL: EOCODCDT >= ADSL:CUTDT or ADSL: EOCODCDT
missing
123 For trt01ad= Cabozantinib+Atezolizumab: ADSL: EOAODT >= ADSL:CUTDT or ADSL: EOAODT
missing
124 For trt01ad= Second NHT and TRTNHT=Abi+Pred:( (ADSL: EOBODCDT >= ADSL:CUTDT or ADSL:
EOBODCDT missing) and (EOPODCDT >= ADSL:CUTDT or ADSL: EOPODCDT missing) )
125 For trt01ad= Second NHT and TRTNHT=Enza: EOEODCDT >= ADSL:CUTDT or ADSL: EOEODCDT
missing;
126
127
128
129 **** Part IV: subjects discontinued any study treatment ;
130 /*ADSL:DCTREASC or ADSL:DCTREASA or ADSL:DCTREASB or ADSL:DCTREASP or ADSL:DCTREASE or
ADSL:EOCDCT or ADSL:EOADCDT or ADSL:EOBDCDT or ADSL:EOPDCDT or ADSL:EOEDCDT */
131 /*ADSL:DCTREASC or ADSL:EOCDCT non-missing */
132 /*ADSL:DCTREASA or ADSL:EOADCDT non-missing*/
133 /*(ADSL:DCTREASC and ADSL:DCTREASA) or (ADSL:EOCDCT and ADSL:EOADCDT) non-missing*/

```

```

134
135
136 *** steven solutions ;
137 %let suffix=mitt;
138 data adsl1;
139 set anadata.adsl;
140 /*if &suffix.fl eq "Y" and trt01a=trt01ad and trt01ad ne ' ' ; */
141 /*if trt01adN = . then delete; */
142
143 if &suffix.fl eq "Y" and trt01p=trt01pd and trt01pd ne ' ' ;
144 if trt01pdN = . then delete;
145     trtn=trt01pdn;
146     trtc=trt01pd;
147     if mittfl="Y";
148 run;
149
150 ***1: ITT Population ;
151 proc freq data=adsl1;
152     tables trtn*trtc/list missing;
153 run;
154
155 proc freq data=adsl1;
156     tables trtn*trtc*ittfl/list missing;
157 run;
158
159 *** 2: subjects treated with ;
160 data adsl2;
161     set adsl1;
162     if saffl="Y" then do;
163         if trtcsdt>. and trtasdt>. then flag21=1;
164         if (trtbsdt>. and trtpsdt>. ) or trtedt>. then flag22=1;
165     end;
166 run;
167 proc freq data=adsl2;
168     tables trtn*trtc*flag21/list missing;
169     tables trtn*trtc*flag22/list missing;
170 run;
171
172 *** 3 subjects on study treatment at cut-off ;
173 data adsl3;
174     set adsl2;
175     if (EOCdcDT >= CUTDT or EOCdcDT eq .) then flag31=1;
176     if (EOAODT >= CUTDT or EOAODT eq .) then flag32=1;
177     if (EOBODCDT >= CUTDT or EOBODCDT eq .) then flag33_1=1;
178     if (EOPDCDT >= CUTDT or EOPDCDT eq .) then flag33_2=1;
179     if (EOEODCDT >= CUTDT or EOEODCDT eq .a) then flag33_3=1;
180     if (flag33_1=1 and flag33_2=1) or flag33_3=1 then flag33=1;
181 run;
182
183 proc freq data=adsl3;
184     tables trtn*trtc*flag31/list missing;
185     tables trtn*trtc*flag32/list missing;
186     tables trtn*trtc*flag33/list missing;
187 run;
188
189
190 *** 4 subjects discontinued any study treatment;
191 data adsl4;
192     set adsl2;
193     if (^missing(DCTREASC) or ^missing(EOCDCDT)) then flag41=1;
194     if (^missing(DCTREASA) or ^missing(EOADCDT)) then flag42=1;
195     if flag41=1 and flag42=1 then flag43=1;
196     if (^missing(DCTREASB) or ^missing(EOBDCDT)) then flag44_1=1;
197     if (^missing(DCTREASP) or ^missing(EOPDCDT)) then flag44_2=1;
198     if (^missing(DCTREASE) or ^missing(EOEDCDT)) then flag44_3=1;
199     if (flag44_1=1 and flag44_2=1) or flag44_3=1 then flag44=1;
200     if flag41=1 or flag42=1 or flag43=1 or flag44=1 then flag40=1;
201     *if (^missing(DCTREASC) and ^missing(DCTREASA)) or (^missing(EOCDCDT) or
    ^missing(EOADCDT)) then flag43=3;

```

```

202         *if ( (^missing(EOBDCDT) and ^missing(EOPDCDT) or ^missing(EOEDCDT)) or
203             ( ^missing(DCTREASB) and ^missing(DCTREASP) or ^missing(DCTREASE)) then
                flag44=4;
204 run;
205
206 proc freq data=adsl4;
207     tables trtn*trtc*flag40/list missing;
208     tables trtn*trtc*flag41/list missing;
209     tables trtn*trtc*flag42/list missing;
210     tables trtn*trtc*flag43/list missing;
211     tables trtn*trtc*flag44/list missing;
212 run;
213
214
215 ***6 primary reason for discontinuation from study treatment ;
216 /*DCTREASA Reason for Discont of Atez*/
217 /*DCTREASC Reason for Discont of Cabo*/
218 /*DCTREASB Reason for Discont of Abi*/
219 /*DCTREASP Reason for Discont of Pred*/
220 /*DCTREASE Reason for Discont of Enza*/
221 /*DS.DSDECOD where DS.DSSCAT='END OF STUDY TREATMENT, ATEZOLIZUMAB'*/
222 /*DS.DSDECOD where DS.DSSCAT='END OF STUDY TREATMENT, CABOZANTINIB'*/
223 /*DS.DSDECOD where DS.DSSCAT='END OF STUDY TREATMENT, ABIRATERONE'*/
224 /*DS.DSDECOD where DS.DSSCAT='END OF STUDY TREATMENT, PREDNISONE'*/
225 /*DS.DSDECOD where DS.DSSCAT='END OF STUDY TREATMENT, ENZALUTAMIDE'*/
226
227 proc freq data=adsl4;
228     tables DCTREASA/list missing;
229 run;
230
231 data adsl6;
232     length DOCTREAS $200.;
233     set adsl4;
234     if DCTREASA>' ' then do;
235         DOCTREAS=strip(DCTREASA);
236         _trtn=0;
237         output;
238     end;
239     if DCTREASC>' ' then do;
240         DOCTREAS=strip(DCTREASC);
241         _trtn=0;
242         output;
243     end;
244     if DCTREASB>' ' then do;
245         DOCTREAS=DCTREASB;
246         _trtn=1;
247         output;
248     end;
249     if DCTREASP>' ' then do;
250         DOCTREAS=DCTREASP;
251         _trtn=1;
252         output;
253     end;
254     if DCTREASE>' ' then do;
255         DOCTREAS=DCTREASE;
256         _trtn=1;
257         output;
258     end;
259
260 run;
261
262 proc sort data=adsl6 nodupkey;
263     by _trtn trtn trtc usubjid DOCTREAS;
264 run;
265
266 proc freq data=adsl6;
267     tables _trtn*trtn*DOCTREAS/list missing;
268 run;
269

```


/******

H

H PROGRAM: v_a_adsl.sas

H

H USAGE: QC adsl for 312 CSR

H

H REQUIRES anadata:

H REQUIRES odsdata:

H REQUIRES sdtmdata: AE CD CM DD DM DS EX IE PR QS SU
SUPPDM SUPPDS SV VS

H REQUIRES macros: dtimpute merge_supp probdes psort getQS labels

H

H PRODUCES anadata: adsl (in QC folder)

H

H REVISION HISTORY:

H 20220320 SC 315

H 20230515 SC pittfl population changed from 324 to 400

H NOTES:

H

H \$Id:\$

*****/

* libname sdtmdata "S:\stat\xl184\184315\dev\sdtmdata\cro\20230221";

* libname anadata "S:\stat\xl184\184315\dev\anadata\cro\20220725";

%macro attrib_adsl;

attrib STUDYID	length=\$8.	format=\$8.	label="Study Identifier";
attrib USUBJID	length=\$16.	format=\$16.	label="Unique Subject Identifier";
attrib SUBJID	length=\$8.	format=\$8.	label="Subject Identifier for the Study";
attrib SITEID	length=\$4.	format=\$4.	label="Study Site Identifier";
attrib COUNTRY	length=\$3.	format=\$3.	label="Country";
attrib CNTRYGR1	length=\$40.	format=\$40.	label="Pooled Country Group 1";
attrib STRATAR	length=\$200.	format=\$200.	label="Strata Used for Randomization";
attrib STRATARN	length = \$200.		label="Strata Used for Randomization (N)";
attrib REGIONI	length=\$10.	format=\$10.	label="Geographic Region, IxRS";
attrib REGNIGR1	length=\$10.	format=\$10.	label="Pooled Geog Region, IxRS Group 1";
attrib REGION1	length=\$40.	format=\$40.	label="Geographic Region 1";
attrib SCRNFLL	length=\$1.	format=\$1.	label="Reason Arm and/or Actual Arm is Null";
attrib ETIOIXRS	length=\$200.	format=\$200.	label="Disease Etiology, IxRS";
attrib DSIXRS	length=\$200.	format=\$200.	label="Pres of Extrahep Dis or Macro Inv, IxRS";
attrib STRATAV	length=\$200.	format=\$200.	label="Strata from Verification Source ";
attrib STRATAVN	format=best20.		label="Strata from Verification Source (N)";
attrib REGIONC	length=\$10.	format=\$10.	label="Geographic Region, CRF";
attrib ETIOCRF	length=\$200.	format=\$200.	label="Disease Etiology, CRF";
attrib DSCRFL	length=\$200.	format=\$200.	label="Pres of Extrahep Dis or Macro Inv, CRF";
attrib PROTVS	length=\$20.	format=\$20.	label="Protocol Version Subject Enrolled";
attrib AGE	format=best20.		label="Age";
attrib AGEU	length=\$10.	format=\$10.	label="Age Units";
attrib AGEGR1	length=\$10.	format=\$10.	label="Pooled Age Group 1";
attrib AGEGR2	length=\$10.	format=\$10.	label="Pooled Age Group 2";
attrib AGEGR3	length=\$10.	format=\$10.	label="Pooled Age Group 3";
attrib SEX	length=\$1.	format=\$1.	label="Sex";
attrib RACE	length=\$200.	format=\$200.	label="Race";
attrib RACEOTH	length=\$200.	format=\$200.	label="Race Other Specify ";
attrib RACEMULT	length=\$200.	format=\$200.	label="Race Multiple";
attrib RACEGR1	length=\$40.	format=\$40.	label="Pooled Race Group 1";
attrib ETHNIC	length=\$22.	format=\$22.	label="Ethnicity";
attrib SAFFL	length=\$1.	format=\$1.	label="Safety Population Flag";
attrib ITTFL	length=\$1.	format=\$1.	label="Intent-To-Treat Population Flag";
attrib PITTFLL	length=\$1.	format=\$1.	label="Primary PFS Population Flag";
attrib ELIGIBFL	length=\$1.	format=\$1.	label="Met All Eligibility Criteria Flag";

attrib ARM	length=\$200.	format=\$200.	label="Description of Planned Arm";
attrib ACTARM	length=\$200.	format=\$200.	label="Description of Actual Arm";
attrib TRTSEQP	length=\$200.	format=\$200.	label="Planned Sequence of Treatments";
attrib TRT01P	length=\$25.	format=\$25.	label="Planned Treatment for Period 01";
attrib TRT01PN	format=best20.		label="Planned Treatment for Period 01 (N)";
attrib TRT01A	length=\$25.	format=\$25.	label="Actual Treatment for Period 01 ";
attrib TRT01AN	format=best20.		label="Actual Treatment for Period 01 (N)";
attrib TRT02P	length=\$25.	format=\$25.	label="Planned Treatment for Period 02";
attrib TRT02PN	format=best20.		label="Planned Treatment for Period 02 (N)";
attrib TRT02A	length=\$25.	format=\$25.	label="Actual Treatment for Period 02 ";
attrib TRT02AN	format=best20.		label="Actual Treatment for Period 02 (N)";
attrib XVRDT	format=date9.		label="Crossover Date/Time";
attrib PGICYN	length=\$2.	format=\$2.	label="Consent to Pharmacogenetic Blood Sample?";
attrib RFICDT	format=date9.		label="Date of Informed Consent";
attrib RFIC2DT	format=date9.		label="Date of Informed Consent 2";
attrib RANDDT	format=date9.		label="Date of Randomization";
attrib TRTSDT	format=date9.		label="Date of First Exposure to Treatment";
attrib TRTSDTM	format=datetime19.		label="Datetime of First Exposure to Treatment";
attrib TRTASDT	format=date9.		label="Date of First Exposure to Atezo, Core";
attrib TRTCSDT	format=date9.		label="Date of First Exposure to Cabo, Core";
attrib TRTSSDT	format=date9.		label="Date of First Exposure to Sora, Core";
attrib TRTAXSDT	format=date9.		label="Date of First Exposure to Atezo, XVR";
attrib TRTCXSDT	format=date9.		label="Date of First Exposure to Cabo, XVR";
attrib RFXENDTC	length=\$19.	format=\$19.	label="Date/Time of Last Study Treatment";
attrib TRTEDT	format=date9.		label="Date of Last Exposure to Treatment";
attrib TRTEDTF	length=\$1.	format=\$1.	label="Date of Last Exposure Imput. Flag";
attrib TR01SDT	format=date9.		label="Date of First Exposure in Period 01";
attrib TR01STM	format=time5.		label="Time of First Exposure in Period 01";
attrib TR01SDTM	format=datetime19.		label="Datetime of First Exposure in Period 01";
attrib TR01EDT	format=date9.		label="Date of Last Exposure in Period 01";
attrib TR01ETM	format=time5.		label="Time of Last Exposure in Period 01";
attrib TR01EDTM	format=datetime19.		label="Datetime of Last Exposure in Period 01";
attrib TR02SDT	format=date9.		label="Date of First Exposure in Period 02";
attrib TR02STM	format=time5.		label="Time of First Exposure in Period 02";
attrib TR02SDTM	format=datetime19.		label="Datetime of First Exposure in Period 02";
attrib TR02EDT	format=date9.		label="Date of Last Exposure in Period 02";
attrib TR02ETM	format=time5.		label="Time of Last Exposure in Period 02";
attrib TR02EDTM	format=datetime19.		label="Datetime of Last Exposure in Period 02";
attrib TRTAEDT	format=date9.		label="Date of Last Exposure to Atezo, Core";
attrib TRTAEDTF	length=\$1.	format=\$1.	label="Date Last Exp Atez Core Imput. Flag";
attrib TRTCEDT	format=date9.		label="Date of Last Exposure to Cabo, Core";
attrib TRTCEDTF	length=\$1.	format=\$1.	label="Date Last Exp Cabo Core Imput. Flag";
attrib TRTSED	format=date9.		label="Date of Last Exposure to Sora, Core";
* attrib TRTSEDTF	length=\$1.	format=\$1.	label="Date Last Exp Sora Core Imput. Flag";
attrib TRTAXEDT	format=date9.		label="Date of Last Exposure to Atezo, XVR";
attrib TRTCXEDT	format=date9.		label="Date of Last Exposure to Cabo, XVR";
attrib LTRTOGDT	format=date9.		label="Date of Last Dose Ongoing";
attrib EOADCDDT	format=date9.		label="Date of Decision to Discont. Atez";
attrib EOCDCDT	format=date9.		label="Date of Decision to Discont. Cabo";
attrib EOSDCDDT	format=date9.		label="Date of Decision to Discont. Sora";
attrib EOXADCDDT	format=date9.		label="Date of Dec to Discont. XVR Atez";
attrib EOXCDCDDT	format=date9.		label="Date of Dec to Discont. XVR Cabo";
attrib EOTDCDDT	format=date9.		label="Date of Decision to Discont. Core Tx";
attrib EOTXDCDDT	format=date9.		label="Date of Dec to Discont. XVR Tx";
attrib EOTDCDDT	format=date9.		label="Date of Last Dose Decision Ongoing, Core";
attrib EOXCDCDDT	format=date9.		label="Date of Last Dose Decision Ongoing, XVR";
attrib EOADCDDT	format=date9.		label="Date of Last Dose Dec Ongo (Atez, Core)";
attrib EOACDDT	format=date9.		label="Date of Last Dose Ongo (Atez, Core)";
attrib EOCDCCDDT	format=date9.		label="Date of Last Dose Dec Ongo (Cabo, Core)";
attrib EOSDCDDT	format=date9.		label="Date of Last Dose Dec Ongo (Sora, Core)";
attrib WDCFD	format=date9.		label="Date of Withdrawal of Full Consent";
attrib DSEVTADT	format=date9.		label="Date of Disposition Event (Atez, Core)";
attrib DSEVTCDDT	format=date9.		label="Date of Disposition Event (Cabo, Core)";
attrib DSEVTSDDT	format=date9.		label="Date of Disposition Event (Sora, Core)";
attrib DSEVXADT	format=date9.		label="Date of Disposition Event (Atez, XVR)";

attrib DSEVXCDT	format=date9.	label="Date of Disposition Event (Cabo, XVR)";
attrib LSTALVDT	format=date9.	label="Date Last Known Alive";
attrib LSALVDTF	length=\$1. format=\$1.	label="Date Last Known Alive Imp. Flag";
attrib DTHDT	format=date9.	label="Date of Death";
attrib DTHDTF	length=\$1. format=\$1.	label="Date of Death Imputation Flag";
attrib DTHDTC	length=\$19. format=\$19.	label="Date/Time of Death";
attrib DTHUNFDT	format=date9.	label="Date of Death Unfiltered";
attrib DTHUNDTF	length=\$1. format=\$1.	label="Date of Death Unf Imp Flag";
attrib DTHDY	format=best20.	label="Relative Day of Death";
attrib DTHSL0DY	format=best20.	label="Day of Death Rel to Last Non-Zero Dose";
attrib DTHPER	length=\$50. format=\$50.	label="Death Period (30 Days)";
attrib DTHAESFL	length=\$1. format=\$1.	label="Death After Ext Safety Obs Per Flag";
attrib DTHAEAFI	length=\$1. format=\$1.	label="Death After Ext Atezo Saf Obs Per Flag";
attrib DTHAECFL	length=\$1. format=\$1.	label="Death After Ext Combo Saf Obs Per Flag";
attrib EOSOBSDT	format=date9.	label="Date of Start of SOP (Standard, Core)";
attrib EOSSXSDT	format=date9.	label="Date of Start of SOP (Standard, XVR)";
attrib EOECASDT	format=date9.	label="Date of Start of SOP (Ext, Core, Atezo)";
attrib EOECSDT	format=date9.	label="Date of Start of SOP (Ext, Core, Combo)";
attrib EOECMSDT	format=date9.	label="Date of Start of SOP (Ext, Core, Mono)";
attrib EOEXASDT	format=date9.	label="Date of Start of SOP (Ext, XVR, Atezo)";
attrib EOEXCSDT	format=date9.	label="Date of Start of SOP (Ext, XVR, Combo)";
attrib EOSOBDT	format=date9.	label="Date of End of SOP (Standard, Core)";
attrib EOSSXEDT	format=date9.	label="Date of End of SOP (Standard, XVR)";
attrib EOECAEDT	format=date9.	label="Date of End of SOP (Ext, Core, Atezo)";
attrib EOECEDT	format=date9.	label="Date of End of SOP (Ext, Core, Combo)";
attrib EOECMEDT	format=date9.	label="Date of End of SOP (Ext, Core, Mono)";
attrib EOEXAEDT	format=date9.	label="Date of End of SOP (Ext, XVR, Atezo)";
attrib EOEXCEDT	format=date9.	label="Date of End of SOP (Ext, XVR, Combo)";
attrib CUTDT	format=date9.	label="Date of Data Cutoff Date";
attrib SYSACTDT	format=date9.	label="First Systemic Non-Rad Therapy Date";
attrib SYSACTWK	format=best20.	label="Time to First Systemic Non-Rad (Week)";
attrib FSBACTDT	format=date9.	label="First Subsequent Anticancer Therapy Date";
attrib TRCRDURD	format=best20.	label="Total Treatment Duration, Core (Days)";
attrib TRCRDURW	format=best20.	label="Total Treatment Duration, Core (Weeks)";
attrib TRCRDURM	format=best20.	label="Total Treatment Duration, Core (Months)";
attrib TRTXDURD	format=best20.	label="Total Treatment Duration, XVR (Days)";
attrib TRTXDURW	format=best20.	label="Total Treatment Duration, XVR (Weeks)";
attrib TRTXDURM	format=best20.	label="Total Treatment Duration, XVR (Months)";
attrib TRTDURD	format=best20.	label="Total Treatment Duration (Days)";
attrib TRTDURW	format=best20.	label="Total Treatment Duration (Weeks)";
attrib TRTDURM	format=best20.	label="Total Treatment Duration (Months)";
attrib TRTADURD	format=best20.	label="Total Atezolizumab Duration (Days)";
attrib TRTCDURD	format=best20.	label="Total Cabozantinib Duration (Days)";
attrib TRTCDURM	format=best20.	label="Total Cabozantinib Duration (Months)";
attrib TRTSDURD	format=best20.	label="Total Sorafenib Duration (Days)";
attrib TRTSDURM	format=best20.	label="Total Sorafenib Duration (Months)";
attrib TROCDURD	format=best20.	label="Total Ongoing Cabo Duration (Days)";
attrib TROCDURM	format=best20.	label="Total Ongoing Cabo Duration (Months)";
attrib TROSDURD	format=best20.	label="Total Ongoing Sora Duration (Days)";
attrib TROSDURM	format=best20.	label="Total Ongoing Sora Duration (Months)";
attrib DCTREASA	length=\$200. format=\$200.	label="Reason for Discont of Atez, Core";
attrib DCTREASC	length=\$200. format=\$200.	label="Reason for Discont of Cabo, Core";
attrib DCTREASS	length=\$200. format=\$200.	label="Reason for Discont of Sora, Core";
attrib DCTRESXA	length=\$200. format=\$200.	label="Reason for Discont of Atez, XVR";
attrib DCTRESXC	length=\$200. format=\$200.	label="Reason for Discont of Cabo, XVR";
attrib DTHCAUS	length=\$200. format=\$200.	label="Cause of Death";
attrib DTHCGRI	length=\$200. format=\$200.	label="Cause of Death Group 1 (Preferred Term)";
attrib DTHASOSI	length=\$75. format=\$75.	label="Death Associated With Study Indication";
attrib GR5RELFL	length=\$1. format=\$1.	label="GR5 AE Related to Study Treatment Flag";
attrib EOSRDTC	length=\$19. format=\$19.	label="Non-imputed End of Survival FUP Date";
attrib EOSDT	format=date9.	label="End of Survival FUP Date";
attrib EOSDTF	length=\$1. format=\$1.	label="End of Study Date Imputation Flag";
attrib DCSREAS	length=\$200. format=\$200.	label="Reason for Discont. From Survival FUP";
attrib EORDT	format=date9.	label="Date of End of Radiographic FUP";
attrib DCRREAS	length=\$200. format=\$200.	label="Reason for Discont. From Radio FUP";

SAS Writing sample

```

attrib LSTVISDT      format=date9.      label="Last Visit Date";
attrib WTBL          format=best20.      label="Baseline Weight (kg)";
attrib WTBLGR1       length=$15.        format=$15.      label="Pooled Baseline Weight (kg) Group 1";
attrib HTBL          format=best20.      label="Baseline Height (cm)";
attrib BMIBL         format=best20.      label="Baseline BMI (kg/m2)";
attrib ECOGBL        format=best20.      label="Baseline ECOG per eCRF";
attrib SMOKSTAT       length=$10.        format=$10.      label="Smoking Status";
attrib ALCHSTAT       length=$10.        format=$10.      label="Alcohol Status";
attrib DIAGDT        format=date9.      label="Cancer Diagnosis Date";
attrib DIAGDTF        length=$1.         format=$1.         label="Cancer Diagnosis Date Imputation Flag";
attrib DIAGDURD       format=best20.      label="Duration of Diagnosis to Rand (Days)";
attrib DIAGDURY       format=best20.      label="Duration of Diagnosis to Rand (Years)";
attrib NRADSDT        format=date9.      label="Last Non-Rad Tx Start Date";
attrib NRADSDTF       length=$1.         format=$1.         label="Last Non-Rad Tx Start Imp Flag";
attrib NRADEDT        format=date9.      label="Last Non-Rad Therapy End Date";
attrib NRADEDF        length=$1.         format=$1.         label="Last Non-Rad Tx End Imp Flag";
attrib NRADDURM       format=best20.      label="Dur of Last Non-Rad Tx to Rand (Months)";
attrib PNRDTXFL       length=$1.         format=$1.         label="Prior Local Non-Rad Therapy Flag ";
attrib NPNRADTX       format=best20.      label="Number of Prior Local Non-Rad Thx";
attrib NPNRDGR1       length=$10.        format=$10.      label="Num of Prior Local Non-Rad Tx Group 1";
attrib PRADTXFL       length=$1.         format=$1.         label="Prior Radiation Therapy Flag";
attrib NPRADTX        format=best20.      label="Number of Prior Radiation Therapies";
attrib NPRADGR1       length=$10.        format=$10.      label="Num of Prior Radiation Therapy Group 1";
attrib PSAFFL         length=$1.         format=$1.         label="Primary Safety Population Flag";
attrib DTHPER2        length=$50.        format=$50.      label="Death Period (100 Days)";
attrib SYSACTD        format=BEST20.     label="Time to First Systemic Non-Rad (Days)";
attrib TRTADURM       format=BEST20.     label="Total Atezolizumab Duration (Months)";
attrib FNHTGR1        length=$20.        format=$10.      label="First NHT Collapsed Group";
attrib DOCGR1         length=$10.        format=$10.      label="Prior Docetaxel Collapsed Group";
attrib DSGR1          length=$10.        format=$10.      label="Pres of Liver meta Collapsed Group";
%mend attrib_adsl;

```

```

%let var_list = %str(STUDYID, USUBJID, SUBJID, SITEID, COUNTRY, CNTRYGR1, STRATAR, STRATARN, REGIONI, REGNIGR1,
ETIOIXRS, DSIXRS,
STRATAV, STRATAVN, REGIONC, ETIOCRF, DSCRF, PROTVS, AGE, AGEU, AGEGR1, AGEGR2, AGEGR3, SEX, RACE, RACEOTH,
RACEMULT, RACEGR1,
ETHNIC, SAFFL, ITTFL, PITTF, ELIGIBFL, ARM, ACTARM, TRTSEQP, TRT01P, TRT01PN, TRT01A, TRT01AN, TRT02P, TRT02PN,
TRT02A, TRT02AN,
XVRDT, PGICYN, RFICDT, RFIC2DT, RANDDT, TRTSDT, TRTSDTM, TRTASDT, TRTCSDT, TRTSSDT, TRTAXSDT, TRTCXSDT,
RFXENDTC,
TRTEDT, TRTEDTF, TR01SDT, TR01STM,TR01SDTM, TR01EDT, TR01ETM, TR01EDTM, TR02SDT, TR02STM, TR02SDTM, TR02EDT,
TR02ETM, TR02EDTM,
TRTAEDT, TRTAEDTF, TRTCEDT, TRTCEDTF, TRTSED, TRTSEDTF, TRTAXEDT, TRTCXEDT, LTRTOGDT, EOADCDT, EOCDT,
EOSDCDT,
EOXADCDT, EOXCDCDT, EOTDCDT, EOTXDCDT, EOTDCODT, EOXCDCDT, EOAODCDT, EOAODT, EOCODCDT, EOSODCDT,
WDCFD, DSEVTADT, DSEVTCDT, DSEVTS, DSEVXADT, DSEVXCDT, LSTALVDT, LSALVD, PROTVS,
DTHDT, DTHDTF, DTHDTC, DTHUNFDT, DTHUNDTF, DTHDY, DTHSLD, DTHPER, DTHAESFL, DTHAEAF, DTHAECL,
CMSTYN,
EOSOBSDT, EOSSXSDT, EOECASDT, EOCCSDT, EOECMSDT, EOEXASDT, EOEXCSDT, EOSOBDT, EOSSXEDT, EOECAEDT,
EOECEDT, EOECMEDT, EOEXAEDT, EOEXCEDT,
CUTDT, SYSACTDT, SYSACTWK, FSBACTDT, TRCRDURD, TRCRDURW, TRCRDURM, TRTXDURD, TRTXDURW, TRTXDURM,
TRTDURD, TRTDURW, TRTDURM,
TRTADURD, TRTCDURD, TRTCDURM, TRTSDURD, TRTSDURM, TROCDURD, TROCDURM, TROSDURD, TROSDURM,
DCTREASA, DCTREASC, DCTREASS, DCTRESXA, DCTRESXC,
DTHCAUS, DTHCGR1, DTHASOSI, GR5RELFL, EOSRDTC, EOSDT, EOSDTF, DCSREAS, EORDT, DCRREAS, LSTVISDT, WTBL,
WTBLGR1, HTBL, BMIBL, ECOGBL,
SMOKSTAT, ALCHSTAT, DIAGDT, DIAGDTF, DIAGDURD, DIAGDURY, NRADSDT, NRADSDTF, NRADED, NRADEDF,
NRADDURM, PNRDTXFL, NPNRADTX, NPNRDGR1, PRADTXFL, NPRADTX, NPRADGR1,
PSAFFL, DTHPER2, SYSACTD, TRTADURM, DURNRADM, DNRADGR1 FNHTGR1 DOCGR1 DSGR1 opittfl msaffl mittfl LTFUDT
CUTRNKDT RANDCDTM
CUTRDDTM DURNRADM DNRADGR1 dcsfl derfl

```

);

SAS Writing sample

```
%let subject= ;
%let block = ;

*PN -----*;
*PN Sorted by variables for the final permanent dataset *;
*PN -----*;
%let sortby = %str(studyid usubjid) ;
%let dsname = adsl;

*PN -----*;
*PN local macro      *;
*PN -----*;
%macro psort(ds=, where=, key=, dup=, out=);
  %if &out ^= %then %do;
    proc sort data=&ds &dup out=&out;
  %end;
  %else %do;
    proc sort data=&ds &dup out=&ds;
  %end;
  by &sortby &key;
  %if &where ^= %then %do;
    where &where.;
  %end;
run;
%mend psort;
%macro VarExist(ds, var);
  %local rc dsid varexist;
  %global varexist_&var.;
  %let dsid = %sysfunc(open(&ds));

  %if %sysfunc(varnum(&dsid, &var)) > 0 %then %do;
    %let varexist_&var. = 1;

  %end;
  %else %do;
    %let varexist_&var. = 0;
    %put WARNING: Variable &var does not exist in &ds;
  %end;

  %let rc = %sysfunc(close(&dsid));

%mend VarExist;
options mlogic mprint;

*PN -----*;
*PN Read in sdtm dm data *;
*PN -----*;

%merge_supp(domain=dm, libname=sdtmdata);
%psort(ds=dm);

*PN-----PN*;
*PN Derive: TRTSEQP TRT01P TRT01A TRT02P TRT02A TRTSDT TRTSDTM PN*;
*PN-----PN*;

data dm1;
  attrib
    CNTRYGR1    length=$40    label='Pooled Country Group 1'
    REGIONC    length=$10    label='Geographic Region, CRF'
    PROTVS     length=$20    label='Protocol Version Subject Enrolled'
    AGEGR1     length=$10    label='Pooled Age Group 1'
    AGEGR2     length=$10    label='Pooled Age Group 2'
    AGEGR3     length=$10    label='Pooled Age Group 3'
```

```

TRTSEQP length=$200 label='Planned Sequence of Treatments'
TRT01P length=$25 label='Planned Treatment for Period 01'
TRT01PN length=8 label='Planned Treatment for Period 01 (N)'
TRT01A length=$25 label='Actual Treatment for Period 01'
TRT01AN length=8 label='Actual Treatment for Period 01 (N)'
TRTSDT length=8 label='Date of First Exposure to Treatment' format=date9.
TRTSDTM length=8 label='Datetime of First Exposure to Treatment' format=datetime19.
RACEOTH length=$200 label='Race Other Specify'
RACEMULT length=$200 label='Race Multiple'
RACEGR1 length=$40 label='Pooled Race Group 1'
PGICYN length=$122 label='Consent to Pharmacogenetic Blood Sample?'
TR01SDT length=8 label='Date of First Exposure in Period 01' format=date9.
TR01STM length=8 label='Time of First Exposure in Period 01' format=time5.
TR01SDTM length=8 label='Datetime of First Exposure in Period 01' format=datetime19.
CUTDT length=8 label='Date of Data Cutoff Date' format=date9.
SAFFL length=$1 label='Safety Population Flag'
protvs length=$20 label='Protocol Version Subject Enrolled';
;

*format trtsdt xvrtd TR01SDT CUTDT date9. TR01SDTM TRTSDTM datetime19. TR01STM time5.;
*length trt01p trt02p trt01a trt02a cntrygr1 region1 agegr1 agegr2 agegr3 racemult $200;

set dm;
randdtc = RFSTDTC;

trtseqp = arm;

if armcd = 'CABO+ATEZO' then trt01p ='Cabozantinib+Atezolizumab';
else if armcd = 'ABI+PRED\ENZA' then trt01p ='Second NHT';

if actarmcd = 'CABO+ATEZO' then trt01a ='Cabozantinib+Atezolizumab';
else if actarmcd = 'ABI+PRED\ENZA' then trt01a ='Second NHT';

if trt01p='Cabozantinib+Atezolizumab' then trt01pn = 0;
else if trt01p='Second NHT' then trt01pn = 1;

if trt01a='Cabozantinib+Atezolizumab' then trt01an = 0;
else if trt01a='Second NHT' then trt01an = 1;

if length(rfxstdtc) ge 10 then trtsdt = input(substr(rfxstdtc,1,10),yymmdd10.);
if length(rfxstdtc) ge 16 then trtsdtm = input(rfxstdtc,e8601dt19.);

tr01sdt = trtsdt;
tr01sdm = trtsdtm;
if not missing(trtsdtm) then tr01stm = timepart(trtsdtm);

if not missing(country) then do;
if country in ('USA','CAN') then cntrygr1 = 'NORTH AMERICA (CANADA/USA)';
else if country in ('HKG' 'PHL' 'THA' 'KOR' 'TWN' 'SGP' 'CHN' 'JPN') then cntrygr1 = 'ASIA';
else if country in ('BEL' 'ROU' 'FRA' 'IRL' 'ITA' 'NLD' 'POL'
'ESP' 'TUR' 'GBR' 'DEU' 'AUS' 'NZL' 'AUT' 'CHE' 'CZE' 'HUN' 'GRC' 'UKR' 'PRT') then cntrygr1 =
'EUROPE/AUSTRALIA/NEW ZEALAND';
else cntrygr1 = 'OTHER';

if country in ('USA','CAN') then region1 = 'NORTH AMERICA';
else if COUNTRY in ('BEL','ROU','FRA','IRL','ITA','NLD','POL','ESP','TUR','GBR','DEU','AUT','CHE','CZE','HUN','GRC',
'UKR','RUS','PRT','GEO','ISR') then region1 = 'EUROPE';
else if COUNTRY in ('HKG','PHL','THA','KOR','TWN','SGP','CHN','JPN','AUS','NZL') then region1 = 'ASIA PACIFIC';
else if COUNTRY in ('ARG','BRA','CHL','MEX') then region1 = 'LATIN AMERICA';
Else if country ne '' then region1='OTHER';
end;

if race7 = 'OTHER' then racemult= catx(' ', of race1-race7);
/*if randpv1 = 'ORIGINAL' then protvs = '0';
else if index(randpv1,'AMEND') then protvs = scan(randpv1,2);*/

```

```

* protvs = strip(randpv1);

if . < age < 65 then agegr1 = '<65';
else if age >= 65 then agegr1 = '>=65';

if . < age < 75 then agegr2 = '<75';
else if age >= 75 then agegr2 = '>=75';

if . < age < 65 then agegr3 = '<65';
else if 65 <= age < 75 then agegr3 = '65 to <75';
else if 75 <= age < 85 then agegr3 = '75 to <85';
else if age >=85 then agegr3 = '>=85';

*pgicyn = _pgicyn;
cutdt = input("&cutdt.",yymmdd10.);

if length(rfxendtc) ge 10 then exendtn = input(substr(rfxendtc,1,10),yymmdd10.);
if exendtc ne . and exendtn > cutdt then rfxendtc = "&cutdt.";
* if rfxendtc > &cutdt. then rfxendtc = "&cutdt.";

if not missing(trtsdt) then safl = 'Y';
else safl = 'N';

STRATAR = STRATC;
STRATARN = STRAT;
STRATAV = STRATC;
    if stratar ne '' then DSIXRS=substr(scan(scan(STRATAR,1,''),2,'='),1,1);
    if stratar ne '' then DOCIXRS=substr(scan(scan(STRATAR,2,''),2,'='),1,1);
if stratar ne '' then FNHTIXRS=substr(scan(scan(STRATAR,3,''),2,'='),1,6);
    if STRATAV ="Liver metastasis disease=Yes,Prior docetaxel for mCSPC=Yes,Cancer type for first NHT given=mCRPC" then
STRATAVn=1;
if STRATAV ="Liver metastasis disease=Yes,Prior docetaxel for mCSPC=Yes,Cancer type for first NHT given=m0CRPC" then STRATAVn =2;
if STRATAV ="Liver metastasis disease=Yes,Prior docetaxel for mCSPC=Yes,Cancer type for first NHT given=mCSPC" then STRATAVn =3;
if STRATAV ="Liver metastasis disease=Yes,Prior docetaxel for mCSPC=No,Cancer type for first NHT given=mCRPC" then STRATAVn =4;
if STRATAV ="Liver metastasis disease=Yes,Prior docetaxel for mCSPC=No,Cancer type for first NHT given=m0CRPC" then STRATAVn =5;
if STRATAV ="Liver metastasis disease=Yes,Prior docetaxel for mCSPC=No,Cancer type for first NHT given=mCSPC" then STRATAVn =6;
if STRATAV ="Liver metastasis disease=No,Prior docetaxel for mCSPC=Yes,Cancer type for first NHT given=mCRPC" then STRATAVn =7;
if STRATAV ="Liver metastasis disease=No,Prior docetaxel for mCSPC=Yes,Cancer type for first NHT given=m0CRPC" then STRATAVn =8;
if STRATAV ="Liver metastasis disease=No,Prior docetaxel for mCSPC=Yes,Cancer type for first NHT given=mCSPC" then STRATAVn =9;
if STRATAV ="Liver metastasis disease=No,Prior docetaxel for mCSPC=No,Cancer type for first NHT given=mCRPC" then STRATAVn =10;
if STRATAV ="Liver metastasis disease=No,Prior docetaxel for mCSPC=No,Cancer type for first NHT given=m0CRPC" then STRATAVn =11;
if STRATAV ="Liver metastasis disease=No,Prior docetaxel for mCSPC=No,Cancer type for first NHT given=mCSPC" then STRATAVn =12;

If ARMNRS='SCREEN FAILURE' then SCRNFFL = "Y";
Else SCRNFFL = "";

protvs = strip(dspv1)||' '||strip(dspv);

    if COUNTRY='UKR' then ukrsufl = 'Y';
if COUNTRY ^='UKR' then ukrsufl = 'N';

keep arm actarm studyid usubjid subjid siteid trtsdt country randdtc age: ageu sex strataV STRATAVn race: ethnic arm actarm trtsdt trtseqp trt:
tr01: trt01: trt02:
    trtsdt: pgicyn xvrtdt rfxstdtc rfxendtc cutdt dthfl dthdtc safl regionc protvs dspv: ukrsufl
    cntygr1 STRATAR STRATARN REGIONI REGNIGR1 ETIOIXRS DSIXRS randcdtc ARMNRS region1 SCRNFFL DSIXRS DOCIXRS
FNHTIXRS exendtn cutdt;
run;

data dm1;
set dm1;
if exendtn > cutdt then do;
    rfxendtc = "&cutdt.";
end;
run;

```

SAS Writing sample

```
proc sort data=dm1 out=__dm nodupkey;
  by studyid usubjid;
run;
*PN -----*;
*PN Read in sdtm cd data *;
*PN -----*;
%merge_supp(domain=cd, libname=sdtmdata);
%psort(ds=cd);

data cdethbv cdethcv cdall(keep=studyid usubjid);
  set cd;
  if cdtstcd = 'CDETHBV' then output cdethbv;
  else if cdtstcd = 'CDETHCV' then output cdethcv;
  else output cdall;
run;

proc sort data=cdall nodupkey;
  by studyid usubjid;
run;

data etiocrf;
  merge cdall(in=cdall)
    cdethbv(in=hbv keep=studyid usubjid cdorres rename=(cdorres=cdethbv))
    cdethcv(in=hcv keep=studyid usubjid cdorres rename=(cdorres=cdethcv))
  ;
  by studyid usubjid;
  attrib
    ETIOCRF          length=$200    label='Disease Etiology, CRF'
  ;
  if cdethbv = 'Y' then etiocrf = 'HBV [with or without HCV]';
  else if cdethcv = 'Y' and cdethbv eq 'N' then etiocrf = 'HCV [without HBV]';
  else etiocrf = 'Other';
  *if cdall and ^(hbv or hcv) then etiocrf="";
  keep studyid usubjid etiocrf;
run;

data CDEXMVI CDEXEHS;
  set sdtmdata.cd;
  if cdtstcd = 'CDEXMVI' then output CDEXMVI;
  else if cdtstcd = 'CDEXEHS' then output CDEXEHS;
run;

proc sort data=CDEXMVI;
  by studyid usubjid;
run;

proc sort data=CDEXEHS;
  by studyid usubjid;
run;

proc sort data = sdtmdata.tu out=tu (keep = studyid usubjid) nodupkey;
  where VISIT= "SCREENING" and TULOC="LIVER" and TUSTRESC ^= "NEW";
  by studyid usubjid;
run;

/**

data dscrfr;
  merge CDEXMVI(keep=studyid usubjid cdstresc rename=(cdstresc=CDEXMVI))
    CDEXEHS(keep=studyid usubjid cdstresc rename=(cdstresc=CDEXEHS))
  ;
  by studyid usubjid;
```



```

attrib
  DSCRFB          length=$200    label='Pres of Extrahep Dis or Macro Inv, CRF'
;
if CDEXMVI = 'Y' or CDEXEHS = 'Y' then DSCRFB = 'Yes';
else if CDEXMVI = 'N' and CDEXEHS = 'N' then DSCRFB = 'No';
else DSCRFB = "";

keep studyid usubjid DSCRFB;
run;
*** /

%merge_supp(domain=pr, libname=sdtmdata);
****PSURSDT****;

data _PSURSDT;
  length PRSTDTC_ PSURSDTF $10;
  set pr;
  where prCAT='SURGERY AND OTHER PROCEDURES HISTORY' and PRLOC='PROSTATE GLAND' and PRSTDTC ne ''; * and
    PRSTDTC = APSETT="METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC)";

    if length(PRSTDTC)=4 then do; PRSTDTC_ = strip(PRSTDTC) || '-01-01'; PSURSDTF='M'; end;
    else if length(PRSTDTC)=7 then do; PRSTDTC_ = strip(PRSTDTC) || '-01'; PSURSDTF='D'; end;
    else if length(PRSTDTC)>=10 then PRSTDTC_ = strip(substr(PRSTDTC,1,10));

  if length (PRSTDTC_) = 10 then PSURSDT = input (PRSTDTC_, is8601da.);
  format PSURSDT date9.;
run;

proc sort data = _PSURSDT;
  by usubjid PRSTDTC_;
run;

proc freq data = _PSURSDT;
  table PRSTDTC*PRSTDTC_ *PSURSDT*PSURSDTF/list missing nocum nopct;
run;

data __PSURSDT (keep = usubjid PSURSDT PSURSDTF);
  set _PSURSDT;
  by usubjid PRSTDTC_;
  if last.usubjid;
run;

****RHTXSdT****;

data _RHTXSdT;
  length PRENDTC_ RHTXSdTF $10;
  set pr;
  where prCAT="HISTORY OF RADIATION THERAPY" and PRENDTC ne ''; * and
    PRENDTC = APSETT="METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC)";

    if length(PRENDTC)=4 then do; PRENDTC_ = strip(PRENDTC) || '-01-01'; RHTXSdTF='M'; end;
    else if length(PRENDTC)=7 then do; PRENDTC_ = strip(PRENDTC) || '-01'; RHTXSdTF='D'; end;
    else if length(PRENDTC)>=10 then PRENDTC_ = strip(substr(PRENDTC,1,10));

  if length (PRENDTC_) = 10 then RHTXSdT = input (PRENDTC_, is8601da.);
  format RHTXSdT date9.;
run;

proc sort data = _RHTXSdT;
  by usubjid PRENDTC_;
run;

proc freq data = _RHTXSdT;

```

```

table PRENDTC*PRENDTC_ *RHTXSDT*RHTXSDF/list missing nocum nopct;
run;

```

```

data __RHTXSDT (keep = usubjid RHTXSDT RHTXSDF);
  set _RHTXSDT;
  by usubjid PRENDTC_;
  if last.usubjid;
run;

```

```

%merge_supp(domain=cm, libname=sdtmdata);

```

```

*****PNRTMCFL***;
data _PNRTMC;
  set cm;
  where CMCAT="HISTORY OF NON-RADIATION ANTI-CANCER THERAPY" and APSETT eq 'MCRPC' and cmtrt ne '';
  PNRTMCFL = 'Y';
run;

```

```

proc sort data = _PNRTMC out = __PNRTMC (keep = usubjid PNRTMCFL) nodupkey;
  by usubjid;
run;

```

```

*****NPNRTXMC NPRADGR1***;

```

```

data _NPNR;
  set cm;
  where CMCAT='HISTORY OF NON-RADIATION ANTI-CANCER THERAPY' and APSETT eq 'MCRPC' and cmtrt ne '';
run;

```

```

proc sort data = _NPNR out = _NPNRn nodupkey;
  by usubjid cmtrt cmstdtc;
run;

```

```

proc freq data = _NPNRn noprint;
  table usubjid/out= onpnrn;
run;

```

```

data __NPNRn;
  length NPNRMGR1 $20;
  set oNPNRn;
  by usubjid;
  NPNRTXMC = count;
  NPNRMGR1 = put (count,1.);
  if count >= 3 then NPNRMGR1 = '>=3';
run;

```

```

****RDPRSDT***;

```

```

data _RDPRSDT;
  length APRRDTC_ RDPRSDTF $10;
  set cm;
  where CMCAT="HISTORY OF NON-RADIATION ANTI-CANCER THERAPY" and cmdecod in ("ENZALUTAMIDE" "ABIRATERONE"
"APALUTAMIDE" "DAROLUTAMIDE") and APRRDTC ne ''; * and
  APRRDTC = APSETT="METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC)";

  if length(APRRDTC)=4 then do; APRRDTC_ =strip(APRRDTC) || '-01-01'; RDPRSDTF='M'; end;
  else if length(APRRDTC)=7 then do; APRRDTC_ =strip(APRRDTC) || '-01'; RDPRSDTF='D'; end;
  else if length(APRRDTC)>=10 then APRRDTC_ =strip(substr(APRRDTC,1,10));

```

```

if length (APRRDTC_) = 10 then RDPRSDT = input (APRRDTC_, is8601da.);
format RDPRSDT date9.;
run;

proc sort data = _RDPRSDT;
  by usubjid APRRDTC_;
run;

proc freq data = _RDPRSDT;
  table APRRDTC*APRRDTC_*RDPRSDT*RDPRSDTF/list missing nocum nopct;
run;

data __RDPRSDT (keep = usubjid RDPRSDT RDPRSDTF);
  set _RDPRSDT;
  by usubjid APRRDTC_;
  if last.usubjid;
run;

**** psadsdt ***;
data _psadsdt;
  length APRBDTC_ PSADSDTF $10;
  set cm;
  where CMCAT="HISTORY OF NON-RADIATION ANTI-CANCER THERAPY" and cmdecod in ("ENZALUTAMIDE" "ABIRATERONE"
"APALUTAMIDE" "DAROLUTAMIDE") and APRBDTC ne ''; * and
  APRBDTC = APSETT="METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC)";

  if length(APRBDTC)=4 then do; APRBDTC_=strip(APRBDTC) || '-01-01'; PSADSDTF='M'; end;
  else if length(APRBDTC)=7 then do; APRBDTC_=strip(APRBDTC) || '-01'; PSADSDTF='D'; end;
  else if length(APRBDTC)>=10 then APRBDTC_=strip(substr(APRBDTC,1,10));

  if length (APRBDTC_) = 10 then psadsdt = input (APRBDTC_, is8601da.);
  format psadsdt date9.;
run;

proc sort data = _psadsdt;
  by usubjid APRBDTC_;
run;

proc freq data = _psadsdt;
  table APRBDTC*APRBDTC_*psadsdt/list missing nocum nopct;
run;

data __psadsdt (keep = usubjid psadsdt PSADSDTF);
  set _psadsdt;
  by usubjid APRBDTC_;
  if last.usubjid;
run;

data _cm;
  set cm;
  where CMCAT="HISTORY OF NON-RADIATION ANTI-CANCER THERAPY" and CMTRT="DOCETAXEL" and
APSETT="METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC)";
run;

data _nht ;
  attrib fnhtcrf length=$20 label='First NHT given for, CRF';
  set cm;
  if CMCAT="HISTORY OF NON-RADIATION ANTI-CANCER THERAPY" and CMtrt in ("ENZALUTAMIDE", "ABIRATERONE",
"APALUTAMIDE", "DAROLUTAMIDE")

```

```

and upcase(APSETT)="MCRPC" then fhhtcrf="mCRPC";

if CMCAT="HISTORY OF NON-RADIATION ANTI-CANCER THERAPY" and CMtrt in ("ENZALUTAMIDE", "ABIRATERONE",
"APALUTAMIDE", "DAROLUTAMIDE")
and upcase(APSETT)="M0 CRPC" then fhhtcrf="m0CRPC";

if CMCAT="HISTORY OF NON-RADIATION ANTI-CANCER THERAPY" and CMtrt in ("ENZALUTAMIDE", "ABIRATERONE",
"APALUTAMIDE", "DAROLUTAMIDE")
and upcase(APSETT)="METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC)" then fhhtcrf="mCSPC";
if fhhtcrf ne '';
keep usubjid studyid CMSTDTC CMCAT CMtrt APSETT fhhtcrf;
run;

proc sort data = _nht;
by studyid usubjid CMSTDTC;
run;

data _nht;
set _nht;
by studyid usubjid CMSTDTC;
if first.usubjid;
run;

proc sort data = _cm out= __cm (keep=studyid usubjid);
by studyid usubjid;
run;

proc sort data=__dm out=regionc(keep=studyid usubjid regionc randdte);
by studyid usubjid;
run;

data __crf;
attrib DSCRF length=$20 label='Pres of Liver metastasis, CRF'
DOCCRF length=$20 label='Prior Docetaxel for mCSPC, CRF';
merge __dm (in=a) etiocrf tu (in=c) __cm (in=d) _nht;
by studyid usubjid;
if c then DSCRF = 'Yes';
if d then DOCCRF = 'Yes';
if ^ d then DOCCRF = '';
run;

data _trtnht;
length trtnht $20;
set sdtmdata.ex;
if EXTRT in ("ABIRATERONE", "PREDNISONE" ) then trtnht= 'Abi+Pred';
if EXTRT in ("ENZALUTAMIDE" ) then trtnht= 'Enza';
if trtnht ne '';
run;

proc sort data = _trtnht out= __trtnht (keep = studyid usubjid trtnht) ; * nodupkey;
by usubjid trtnht;
run;

data __trtnht;
set __trtnht;
by usubjid trtnht;
if first.usubjid;
run;

```

```

*PN -----*;
*PN Read in SDTMDATA.DS      *;
*PN Derive: RFICDT, RANDDT, RFIC2DT *;
*PN -----*;

data __rficdt(keep=studyid usubjid rficdt) __randdt(keep=studyid usubjid randdt ittf);
set sdtmdata.ds;
attrib
    RFICDT      length=8    label='Date of Informed Consent'  format=date9.
    RANDDT      length=8    label='Date of Randomization'    format=date9.
    RFIC2DT      length=8    label='Date of Informed Consent 2' format=date9.
    ITTFL        length=$1   label='Intent-To-Treat Population Flag'
;

if dsdecod = 'INFORMED CONSENT OBTAINED' then do;
    if length(dsstdtc) ge 10 then rficdt = input(substr(dsstdtc,1,10),yymmdd10.);
    output __rficdt;
end;
else if dsdecod = 'RANDOMIZED' then do;
    if length(dsstdtc) ge 10 then randdt = input(substr(dsstdtc,1,10),yymmdd10.);
    if not missing(randdt) then ittf = 'Y';
    else ittf = 'N';
    output __randdt;
end;
run;

```

```

*PN -----*;
*PN Read in SDTMDATA.IE      *;
*PN Derive: ELIGIBFL        *;
*PN -----*;

proc sort data = sdtmdata.ie out=ie;
    by studyid usubjid;
run;

```

```

data __eligibfl;
set ie;
by studyid usubjid;
attrib
    ELIGIBFL      length=$1   label='Met All Eligibility Criteria Flag'
;
if first.usubjid;
eligibfl = 'N';
keep studyid usubjid eligibfl;
run;

```

```

proc sort data=sdtmdata.ds out=rficdt(keep=studyid usubjid dsstdtc);
    by studyid usubjid;
    where dsdecod = 'INFORMED CONSENT OBTAINED';
run;

```

```

*PN -----*;
*PN Read in SDTMDATA.DS      *;
*PN Derive: Disposition Dates      *;
*PN EOACDT EOCDCT EOSDCDT EOXACDT EOXCDCDT *;
*PN -----*;

```

```

*PN -----*;
*PN Read in sdtm ds data *;
*PN -----*;
%merge_suppl(domain=ds, libname=sdtmdata);

```

```

%psort(ds=ds);

proc sort data = ds out= lfds;
  by usubjid dsstdtc ;
  where DSTERM='LOST TO FOLLOW-UP' and DSSCAT in ('END OF SURVIVAL FOLLOW-UP','END OF RADIOGRAPHIC FOLLOW-UP');
run;

data __lfds (keep =usubjid LTFUDT);
  set lfds;
  by usubjid dsstdtc ;
  if first.usubjid;
  if length (dsstdtc) = 10 then LTFUDT = input (dsstdtc, is8601da.);
run;

data __eoadcdt(keep=studyid usubjid eoadcdt ) __eocdcdt(keep=studyid usubjid eocdcdt ) __eoedcdt(keep=studyid usubjid eoedcdt )
  __eobdcdt(keep=studyid usubjid eobdcdt ) __eopdcdt(keep=studyid usubjid eopdcdt )
  __eosdt (keep = studyid usubjid eosrdtc eosdt eosdtf )
  ;
  set ds(keep = studyid usubjid dsscat dsstdtc );

  attrib
    EOADCdT   length=8    label='Date of Decision to Discont. Atez'   format=date9.
    EOCDCDT   length=8    label='Date of Decision to Discont. Cabo'   format=date9.
    EOEDCDT   length=8    label='Date of Decision to Discont. Enza'   format=date9.
    EOBDCDT   length=8    label='Date of Dec to Discont. Abir'        format=date9.
    EOPDCDT   length=8    label='Date of Dec to Discont. Pred'        format=date9.
    EOSDT     length=8    label='End of Survival FUP Date'             format=date9.
    EOSDTF    length=$1   label='End of Study Date Imputation Flag'
  ;

  if length(dsstdtc) ge 10 then dsstdtn = input(substr(dsstdtc,1,10),ymmdd10.);
  if length(dsstdtc)=7 then do;
    /* if length(dsstdtc)=10 then */ * dsstdtn = input(substr(strip(dsstdtc)||'-1'),1,10),ymmdd10.);
    dsstdtn = input(strip(dsstdtc)||'-1'),ymmdd10.);
    * if length(dsstdtc)=7 then *;
    eosdtf = 'D';
  end;
  if dsscat = 'END OF STUDY TREATMENT, ATEZOLIZUMAB' then do;
    eoadcdt = dsstdtn;
    output __eoadcdt;
  end;
  if dsscat = 'END OF STUDY TREATMENT, CABOZANTINIB' then do;
    eocdcdt = dsstdtn;
    output __eocdcdt;
  end;
  if dsscat = 'END OF STUDY TREATMENT, ENZALUTAMIDE' then do;
    eoedcdt = dsstdtn;
    output __eoedcdt;
  end;
  if dsscat = 'END OF STUDY TREATMENT, ABIRATERONE' then do;
    eobdcdt = dsstdtn;
    output __eobdcdt;
  end;
  if dsscat = 'END OF STUDY TREATMENT, PREDNISONE' then do;
    eopdcdt = dsstdtn;
    output __eopdcdt;
  end;
  if dsscat = 'END OF SURVIVAL FOLLOW-UP' then do;
    eosdt = dsstdtn;
    eosrdtc=dsstdtc;
    if eosdt>input("&cutdt.",ymmdd10.) then eosrdtc="&cutdt.";
    if length(dsstdtc)=7 then eosdtf = 'D';
  end;

```

```

* end;
  output __eosdt;
end;
run;

*PN -----*;
*PN Read in __eoadcdt __eocdcdt __eoscdt  *;
*PN Derive: Disposition Dates          *;
*PN EOTDCDT                          *;
*PN -----*;

data __eotdcdt;
  merge __eoadcdt __eocdcdt __eocdcdt __eopdcdt __eobdcdt __dm(keep=studyid usubjid trt01an);
  by studyid usubjid;

  attrib
    EOTDCDT    length=8    label='Date of Decision to Discont. Core Tx'    format=date9.
  ;

  if nmiss(eoadcdt, eocdcdt, eocdcdt, eobdcdt, eopdcdt) lt 5 then eotdcdt = max(eoadcdt, eocdcdt, eopdcdt, eobdcdt, eocdcdt);
  if trt01an = 0 and nmiss(eoadcdt,eocdcdt) gt 0 then eotdcdt = .;
  /**
  if trt01an = 0 and nomiss(eoadcdt,eocdcdt) gt 0 then eotdcdt = .;
  else if trt01an = 1 and eocdcdt ne . then eotdcdt = eocdcdt;
  else if trt01an = 1 and nmiss( eopdcdt, eobdcdt) gt 0 then eotdcdt = .;
  ***/
  keep studyid usubjid trt01an eotdcdt eoadcdt eocdcdt eopdcdt eobdcdt eocdcdt;
run;

*PN -----*;
*PN Read in sdtmdata.ds          *;
*PN Derive: Date of Withdrawal of Full Consent *;
*PN WDCFDT DSEVTADT DSEVTCDT DSEVTSdT DSEVXADT DSEVXCdT *;
*PN -----*;

data __wdcfdt(keep=studyid usubjid wdcfdt)
  __dsevtadt(keep=studyid usubjid dsevtadt) __dsevtcdt(keep=studyid usubjid dsevtcdt)
  __dsevtbdt(keep=studyid usubjid dsevtbdt) __dsevtptdt(keep=studyid usubjid dsevtptdt)
  __dsevtedt(keep=studyid usubjid dsevtedt)
  ;
  set ds(keep = studyid usubjid dsterm dsscat dsstdtc etevdtn);

  attrib
    WDCFDT    length=8    label='Date of Withdrawal of Full Consent'    format=date9.
    DSEVTADT  length=8    label='Date of Disposition Event (Atez)' format=date9.
    DSEVTCdT  length=8    label='Date of Disposition Event (Cabo)' format=date9.
    DSEVTBDT  length=8    label='Date of Disposition Event (Arbi)' format=date9.
    DSEVXPdT  length=8    label='Date of Disposition Event (Pred)' format=date9.
    DSEVXEdT  length=8    label='Date of Disposition Event (Enza)' format=date9.
  ;

  if length(dsstdtc) ge 10 then dsstdtn = input(substr(dsstdtc,1,10),yymmdd10.);
  if length(etevdtn) ge 10 then etevdtn = input(substr(etevdtn,1,10),yymmdd10.);

  if index(strip(upcase(dsterm)), 'WITHDREW FULL CONSENT') and dsscat='RE-CONSENT OR CONSENT WITHDRAWAL' then do;
    wdcfdt = dsstdtn;
    output __wdcfdt;
  end;
  if dsscat='END OF STUDY TREATMENT, ATEZOLIZUMAB' and dsterm in ('CLINICAL DETERIORATION' 'PROTOCOL DEVIATION')
  then do;
    dsevtadt = etevdtn;
    output __dsevtadt;
  end;

```

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```
end;
if dsscat='END OF STUDY TREATMENT, CABOZANTINIB' and dsterm in ('CLINICAL DETERIORATION' 'PROTOCOL DEVIATION')
then do;
    dsevtcdt = etevdtn;
    output __dsevtcdt;
end;
if dsscat='END OF STUDY TREATMENT, ABIRATERONE' and dsterm in ('CLINICAL DETERIORATION' 'PROTOCOL DEVIATION')
then do;
    dsevtbdt = etevdtn;
    output __dsevtbdt;
end;
if dsscat='END OF STUDY TREATMENT, PREDNISONE' and dsterm in ('CLINICAL DETERIORATION' 'PROTOCOL DEVIATION')
then do;
    dsevtprd = etevdtn;
    output __dsevtprd;
end;
if dsscat='END OF STUDY TREATMENT, ENZALUTAMIDE' and dsterm in ('CLINICAL DETERIORATION' 'PROTOCOL DEVIATION')
then do;
    dsevtedt = etevdtn;
    output __dsevtedt;
end;
run;
```

```
proc sort data=__wdcfdt ;
    by studyid usubjid wdcfdt;
run;
```

```
data __wdcfdt;
    set __wdcfdt;
    by studyid usubjid wdcfdt;
    if first.usubjid;
run;
```

```
*PN -----*;
*PN Read in SDTMDATA.EX          *;
*PN Derive: First Exposure variables *;
*PN TRTASDT TRTCSDT TRTSSDT TRTAXSDT TRTCXSDT *;
*PN -----*;
```

```
data ex_a ex_c ex_e ex_b ex_p;
    merge sdtmdata.ex __dm(keep=studyid usubjid);
    by studyid usubjid;
    if length(exstdtc) ge 10 then exstdtn = input(substr(exstdtc,1,10),yymmdd10.);
```

```
    if extrt='ATEZOLIZUMAB' & exdose > 0 then output ex_a;
    if extrt='CABOZANTINIB' & exdose > 0 then output ex_c;
    if extrt='ENZALUTAMIDE' & exdose > 0 then output ex_e;
    if extrt='PREDNISONE' & exdose > 0 then output ex_p;
    if extrt='ABIRATERONE' & exdose > 0 then output ex_b;
    keep studyid usubjid exstdtn exdose;
run;
```

```
proc sort data=ex_a;
    by studyid usubjid exstdtn;
    where not missing(exstdtn) ;
run;
```

```
proc sort data=ex_c;
    by studyid usubjid exstdtn;
    where not missing(exstdtn);
run;
```

```
proc sort data=ex_e;
    by studyid usubjid exstdtn;
```



```

    where not missing(exstdtn) ;
run;

proc sort data=ex_p;
    by studyid usubjid exstdtn;
    where not missing(exstdtn) ;
run;

proc sort data=ex_b;
    by studyid usubjid exstdtn;
    where not missing(exstdtn) ;
run;

data __trtasdt;
    set ex_a;
    by studyid usubjid exstdtn;
    if first.usubjid;
    attrib TRTASDT    length=8    label='Date of First Exposure to Atezo, Core' format=date9.;
    trtasdt = exstdtn;
    drop exstdtn;
run;

data __trtesdt;
    set ex_c;
    by studyid usubjid exstdtn;
    if first.usubjid;
    attrib TRTESDT    length=8    label='Date of First Exposure to Cabo, Core' format=date9.;
    trtesdt = exstdtn;
    drop exstdtn;
run;

data __trtesdt;
    set ex_e;
    by studyid usubjid exstdtn;
    if first.usubjid;
    attrib TRTESDT    length=8    label='Date of First Exposure to Enzo' format=date9.;
    trtesdt = exstdtn;
    drop exstdtn;
run;

data __trtpsdt;
    set ex_p;
    by studyid usubjid exstdtn;
    if first.usubjid;
    attrib TRPSDT     length=8    label='Date of First Exposure to Pred' format=date9.;
    trtpsdt = exstdtn;
    drop exstdtn;
run;

data __trtbsdt;
    set ex_b;
    by studyid usubjid exstdtn;
    if first.usubjid;
    attrib TRTBSDT    length=8    label='Date of First Exposure to Arbi' format=date9.;
    trtbsdt = exstdtn;
    drop exstdtn;
run;

*PN -----*;
*PN Read in SDTMDATA.EX          *;
*PN Derive: Last Exposure variables *;
*PN -----*;

```

```

/**DTC2DT Macro**/
%macro dtc2dt(dtcvar , prefix=a, );

    if length(trim(&dtcvar))=10 and index(&dtcvar,'--')=0 then
        &prefix.dt = input(&dtcvar, yymmdd10.);
    else if length(&dtcvar)=16 and index(&dtcvar,'--')=0 and index(&dtcvar,'-:')=0 then
        do;
            &prefix.dtm = input(trim(&dtcvar)||":00", e8601dt19.);
            &prefix.dt = datepart(&prefix.dtm);
            &prefix.tm = timepart(&prefix.dtm);
            * optionally add formats: ;
            format &prefix.dtm datetime19. &prefix.dt date9. &prefix.tm time5.;
        end;
%mend dtc2dt;

data ex ;
    set sdtmdata.ex ;
    by studyid usubjid;

    if length(exendtc)=4 then exendtc="; /*Conditional Statement-Remove after data issues are fixed*/
if length(exstdtc)>=10 then do;
exstdtcx=strip(substr(exstdtc,1,10));
exstdc=substr(exstdtcx,9,2);
exstmm=substr(exstdtcx,6,2);
exstyy=substr(exstdtcx,1,4);
end;
if length(exstdtc)<10 then do ;
exstdc=substr(exstdtc,9,2);
exstmm=substr(exstdtc,6,2);
exstyy=substr(exstdtc,1,4);
end;

if length(exendtc)>=10 then do;
exendtcx=strip(substr(exendtc,1,10));
exendc=substr(exendtcx,9,2);
exenmm=substr(exendtcx,6,2);
exeny=substr(exendtcx,1,4);
end;
if length(exendtc)<10 then do ;
exendc=substr(exendtc,9,2);
exenmm=substr(exendtc,6,2);
exeny=substr(exendtc,1,4);
end;

if exendtc^=" then do;
if exendc=" then do;
exendtcx=strip(exeny)||"-||strip(put(input(exenmm, best.),z2.));
if input(exenmm,best.)=2 then do;
if intck("day", mdy(2,1,input(exeny,best.)),mdy(3,1,input(exeny,best.)))=28
then exendtc_imp=catx('-',exeny,"02","28");
else exendtc_imp=catx('-',exeny,"02","29");
end;
else if input(exenmm,best.) in (4,6,9,11) then
exendtc_imp=catx('-',exeny,put(input(exenmm, best.),z2.),"30");
else exendtc_imp=catx('-',exeny,put(input(exenmm, best.),z2.),"31");
end;
else do;
exendtcx=catx('-',exeny,put(input(exenmm, best.),z2.),put(input(exendc, best.),z2.));
exendtc_imp=exendtcx;
end;
end;
if exstdtc^=" then do;

```

```

if exstdc=" then do;
exstdtc=strip(exstyy)||"-"||strip(put(input(exstmm, best.),z2.));
if input(exstmm,best.)=2 then do;
if intck("day", mdy(2,1,input(exstyy,best.)),mdy(3,1,input(exstyy,best.)))=28
then exstdtc_imp=catx('-',exstyy,"02","28");
else exstdtc_imp=catx('-',exstyy,"02","29");
end;
else if input(exstmm,best.) in (4,6,9,11) then
exstdtc_imp=catx('-',exstyy,put(input(exstmm, best.),z2.),"30");
else exstdtc_imp=catx('-',exstyy,put(input(exstmm, best.),z2.),"31");
end;
else do;
exstdtcx=catx('-',exstyy,put(input(exstmm, best.),z2.),put(input(exstdc, best.),z2.));
exstdtc_imp=exstdtcx;
end;
end;
if length(exstdtc) ge 10 then exstdtn = input(substr(exstdtc,1,10),yymmdd10.);
%x_dtimpute(indtc=exendtc, outdt=exendtn, outdtf=EXENDTF, impalign=e);
if length(exendtc) ge 10 then exendtn = input(substr(exendtc,1,10),yymmdd10.);
%dtc2dt(exstdtc , prefix=exst );
%dtc2dt(exendtc , prefix=exen );

if nmiss(exstdtn, exendtn) lt 2 then lastdtn = max(exstdtn, exendtn);
if nmiss(exstdtm, exendtm) lt 2 then lastdtm = max(exstdtm, exendtm);
if nmiss(exsttm, exentm) lt 2 then lasttm = max(exsttm, exentm);
format lastdtn /* trtetm */ datetime19. lasttm trtetm time5. lastdtn date9.;

run;

proc print data =ex;
title 'ex 184315-1116-3061';
where usubjid = '184315-1116-3061';
run;

proc sort data=ex;
by studyid usubjid;
run;

data exl_a exl_c exl_e exl_p exl_b;
merge ex __dm(keep=studyid usubjid);
by studyid usubjid;

keep studyid usubjid exstdtn exendtn EXENDTF lastdtn lastdtm lasttm exstdtc;
if extrt='ATEZOLIZUMAB' and (exdose gt .) and (exdose ^= 0) then output exl_a;
if extrt='CABOZANTINIB' and (exdose gt .) and (exdose ^= 0) then output exl_c;
if extrt='ENZALUTAMIDE' and (exdose gt .) and (exdose ^= 0) then output exl_e;
if extrt='PREDNISONONE' and (exdose gt .) and (exdose ^= 0) then output exl_p;
if extrt='ABIRATERONE' and (exdose gt .) and (exdose ^= 0) then output exl_b;
run;

proc sort data=exl_a;
by studyid usubjid lastdtn;
run;
data __trtaedt;
set exl_a;
by studyid usubjid lastdtn;
if last.usubjid;
attrib TRTAEDT length=8 label='Date of Last Exposure to Atezo, Core' format=date9.;
trtaedt = lastdtn;
trtaedtx = lastdtn;
TRTAEDTF=strip(EXENDTF);
* drop lastdtn EXENDTF;
run;

```

```
proc print data = exl_a;
  title '184315-1636-3650';
  where usubjid = '184315-1636-3650';
run;
```

```
data __trtaedt;
merge __dm(keep=studyid usubjid trt01p cutdt rfxstdtc) __trtaedt __eoadcdt ;
by studyid usubjid ;
```

```
if ^missing(rfxstdtc) then do;
if missing(exendtn) & ^missing(eoadcdt) then do;
  TRTAEDT = min((eoadcdt-1),cutdt);
  TRTAEDTF='Y';
end;
end;
```

```
if missing(eoadcdt) then do;
  TRTAEDT=.;
  TRTAEDTF="";
end;
```

```
run;
```

```
proc sort data=exl_p;
  by studyid usubjid lastdtn;
run;
```

```
data __trtpedt;
  set exl_p;
  by studyid usubjid lastdtn;
  if last.usubjid;
  attrib TRTpEDT length=8 label='Date of Last Exposure to Pred, Core' format=date9.;
  trtpedt = lastdtn;
  trtpedtx = lastdtn;
  TRTpEDTF=strip(EXENDTF);
  * drop lastdtn EXENDTF;
run;
```

```
data __trtpedt;
merge __dm(keep=studyid usubjid trt01p cutdt rfxstdtc) __trtpedt __eopdcddt ;
by studyid usubjid ;
```

```
if ^missing(rfxstdtc) then do;
if missing(exendtn) & ^missing(eopdcddt) then do;
  TRTpEDT = min((eopdcddt-1),cutdt);
  TRTpEDTF='Y';
end;
end;
```

```
if 4 <= length(exendtc) < 10 and eopdcddt ne . then trtpedt = min((eopdcddt-1),cutdt);;
```

```
if missing(eopdcddt) then do;
  TRTpEDT=.;
  TRTpEDTF="";
end;
```

```
run;
```

```
proc sort data=exl_c;
```

```

    by studyid usubjid lastdtn;
run;
data __trtcedt;
    set exl_c;
    by studyid usubjid lastdtn;
    if last.usubjid;
    attrib TRTCEDT length=8 label='Date of Last Exposure to Cabo, Core' format=date9.;
    trtcedt = lastdtn;
    TRTCEDTF=strip(EXENDTF);
    * if usubjid='184315-4702-3525' then trtcedt = '05jun2022'd; ***ERROR this code need to be removed ***;
    * drop lastdtn EXENDTF lastdtm lasttm;
run;

proc print data=exl_c;
    title 'exl_c';
    where usubjid = '184315-4702-3525';
run;

proc print data=__trtcedt;
    title '__trtcedt';
    where usubjid = '184315-4702-3525';
run;

data __trtcedt;
merge __dm(keep=studyid usubjid trt01p cutdt rfxstdtc dthdte) __trtcedt __eocdedt;
by studyid usubjid;
if ^missing(rfxstdtc) then do;
if ^missing(exendtn) and exendtn < cutdt then trtcedt = exendtn;
if missing(exendtn) & ^missing(eocdedt) then do;
trtcedt = min((eocdedt-1),cutdt);
* TRTCEDTF='Y';
end;
if ^missing(exendtn) & ^missing(eocdedt) and exendtn > eocdedt then do;
trtcedt = min((eocdedt-1),cutdt);
* TRTCEDTF='Y';
end;
end;
if 4 <= length(exendtc) < 10 and eocdedt ne . then trtcedt = min((eocdedt-1),cutdt);
dthdtn = input(substr(dthdte,1,10),yymmdd10.);
* if 4 <= length(exendtc) < 10 and trtcedt > dthdtn then trtcedt =dthdtn -1;
if missing(eocdedt) then do;
    TRTCEDT = .;
    TRTCEDTF = "";
end;
run;

proc sort data=exl_e;
    by studyid usubjid lastdtn;
run;
data __trteedt;
    set exl_e;
    by studyid usubjid lastdtn;
    if last.usubjid;
    attrib TRTeEDT length=8 label='Date of Last Exposure to Enza, Core' format=date9.;
    trteedt = lastdtn;

    TRTeEDTF=strip(EXENDTF);
    drop lastdtn EXENDTF lastdtm lasttm;
run;

data __trteedt;
merge __dm(keep=studyid usubjid trt01p rfxstdtc cutdt) __trteedt __eocdedt;
by studyid usubjid;

```

```

if ^missing(rfxstdtc) then do;
if missing(exendtn) & ^missing(eoedcdt) then do;
trteedt = min((eoedcdt-1),cutdt);
TRTSEDTF='Y';
end;
end;

if 4 <= length(exendtc) < 10 and eoedcdt ne . then trteedt = min((eoedcdt-1),cutdt);

if missing(eoedcdt) then do;
    TRTeEDT=.;
    TRTeEDTF="";
end;
run;

/**
proc sort data=exl_p;
    by studyid usubjid lastdtn;
run;
data __trtpedt;
    set exl_p;
    by studyid usubjid lastdtn;
    if last.usubjid;
    attrib TRTPEDT length=8 label='Date of Last Exposure to Pred, XVR' format=date9.;
    trtpedt = lastdtn;
    drop lastdtn;
run;
**/

proc sort data=exl_b;
    by studyid usubjid lastdtn;
run;
data __trtbedt;
    set exl_b;
    by studyid usubjid lastdtn;
    if last.usubjid;
    attrib TRTbEDT length=8 label='Date of Last Exposure to Arbi, XVR' format=date9.;
    trtbedt = lastdtn;
    * drop lastdtn lastdtn lasttm;
run;

data __trtbedt;
merge __dm(keep=studyid usubjid trt01p rfxstdtc cutdt) __trtbedt __eobdcdt ;
by studyid usubjid ;

if ^missing(rfxstdtc) then do;
if missing(exendtn) & ^missing(eobdcdt) then do;
trtbedt = min((eobdcdt-1),cutdt);
TRTbEDTF='Y';
end;
end;

if 4 <= length(exendtc) < 10 and eobdcdt ne . then trtbedt = min((eobdcdt-1),cutdt);

if missing(eobdcdt) then do;
    TRTbEDT=.;
    TRTbEDTF="";
end;
run;

*PN -----*;
*PN Derive TRTEDT: Max of TRTEEDT,TRTAEDT,TRTCEDT*;
*PN -----*;

```

```
proc sort data = exl_a out=exla nodupkey;
  by studyid usubjid;
run;
```

```
proc sort data = exl_p out=exlp nodupkey;
  by studyid usubjid;
run;
```

```
proc sort data = exl_e out=exle nodupkey;
  by studyid usubjid;
run;
```

```
data bpe;
  merge exla (in=a keep=studyid usubjid ) exlp (in=p keep=studyid usubjid ) exle (in=e keep=studyid usubjid );
  by studyid usubjid;
  if a then exla = 1;
  if p then exlp = 1;
  if e then exle = 1;
run;
```

```
/**
```

```
data __dm;
  length trtnht $20;
  merge __dm (in=a) bpe;
  by studyid usubjid;
  if exla = 1 or exlp = 1 then TRTNHT = 'Abi+Pred';
  if exle = 1 then TRTNHT = 'Enza';
run;
**/
```

```
data __TRTEDT; * (keep=studyid usubjid trtedt TRTEDTF lastdtm lasttm);
  attrib
    TRTEDT length=8 label='Date of Last Exposure to Treatment' format=date9.;
  merge __dm(keep=studyid usubjid trt01p ) __trtcedt __trtaedt __trteedt __trtbedt __trtpedt __trteedt __coadcdt __eocdcdt __eobdcdt
    __eopdcdt __eoedcdt __trtnht;
  by studyid usubjid ;
  if nmiss(TRTeEDT,TRTAEDT,TRTCEDT,trtpedt,trtbedt) lt 5 then trtedt=max(of TRTeEDT,TRTAEDT,TRTCEDT,trtpedt,trtbedt);

  if trt01p ="Cabozantinib+Atezolizumab" then do;
    if nmiss(eoadcdt,eocdcdt) >=1 then do;
      trtedt=.;
      * lastdtm=.;
      * lasttm=.;
    end;
  end;

  if trt01p ="Second NHT" and TRTNHT="Abi+Pred" then do;
    if nmiss(EOBDCDT, EOPDCDT) = 2 then do;
      trtedt=.;
      * lastdtm=.;
      * lasttm=.;
    end;
  end;

  if trt01p ="Second NHT" and TRTNHT="Enza" then do;
    if nmiss( EOEDCDT) >=1 then do;
      trtedt=.;
      lastdtm=.;
      lasttm=.;
    end;
  end;
end;
```

```

if nmiss(lastdtm,trtedt)=0 & datepart(lastdtm)^=trtedt then do;
lastdtm=.;
lasttm=.;
end;

if trtedt ne . then trtetm = lasttm;
if trtedt ne . and lasttm ne . then trtedtm = lastdtm;
* else if trtedt ne . and lasttm eq . then TRTEDTM = trtedt;
TRTEDTM = trtedt;
if ^missing(TRTAEDTF) then TRTEDTF=TRTAEDTF;
else if ^missing(TRTCEDTF) then TRTEDTF=TRTCEDTF;
else if ^missing(TRTeEDTF) then TRTEDTF=TRTeEDTF;
else if ^missing(TRTbEDTF) then TRTEDTF=TRTbEDTF;
format trtedtm date9.;
run;

*PN -----*;
*PN Read in SDTMDATA.EX          *;
*PN Derive: Last Exposure variables *;
*PN TR01EDT TR01ETM TR01EDTM      *;
*PN -----*;

data tr01e_core ;
merge sdtmdata.ex __dm(keep=studyid usubjid ) __TRTEDT (drop = exendtc);
by studyid usubjid;
if length(exendtc) ge 10 then exendtn = input(substr(exendtc,1,10),yymmdd10.);
if length(exstdtc) ge 10 then exstdtn = input(substr(exstdtc,1,10),yymmdd10.);

if length(rfxendtc) gt 10 then rfxentm = input(substr(rfxendtc,12),time5.);
if length(exstdtc) gt 10 then exsttm = input(substr(exstdtc,12),time5.);

run;

proc sort data=tr01e_core;
by studyid usubjid exendtn;
where exdose > 0;
run;

data tr01e_core;
set tr01e_core;
by studyid usubjid;
attrib
    TR01EDT    length=8    label='Date of Last Exposure in Period 01'    format=date9.
    TR01ETM    length=8    label='Time of Last Exposure in Period 01'    format=time5.
    TR01EDTM   length=8    label='Datetime of Last Exposure in Period 01' format=datetime19.
;

if missing(xvrtdt) then do;
tr01edt = trtedt;
tr01etm = lasttm;
tr01edtm= lastdtm;
*if nmiss(tr01edt,tr01etm)=0 and length(rfxendtc) ge 16 then tr01edtm = input(rfxendtc,e8601dt19.);
end;

if last.usubjid;

keep studyid usubjid tr01edt tr01etm tr01edtm;

run;

*PN -----*;
*PN Read in sdtm cm data *;
*PN -----*;
%merge_suppl(domain=cm, libname=sdtmdata);

```



```

%psort(ds=cm);

*PN -----*;
*PN Read in cm *;
*PN Derive: First Local Non-Rad Therapy Date *;
*PN LOCACTDT *;
*PN -----*;
*PN SM:20201102 Added Imputation to CMSTDTC *;

proc freq data =sdtmdata.suppcm;
    table qnam*qlabel/list missing;
run;

proc contents data =cm;
    title 'cmxxx';
run;

data cm1;
    merge cm __dm __randdt __TRTEDT;
    by studyid usubjid;

    if length(cmstdtc) ge 10 then cmstdtn = input(substr(cmstdtc,1,10),yymmdd10.);
        * if cmstdtn ge randdt;

    * keep studyid usubjid trtsdt randdt cmstdtc cmstdtn cmcat cmstyn cmtype cmdecod cmtrt trtedt ;

run;

proc sort data=cm1 out=locactdt;
    by studyid usubjid cmstdtn;
    where cmcat = 'CONCOMITANT AND SUBSEQUENT NON-RADIATION ANTI-CANCER THERAPY' and CMdecOD not in
('LEUPRORELIN', 'GOSERELIN', 'DEGARELIX', 'TRPTORELIN')
    and (not missing(cmtrt) and not missing(cmstdtc));
run;

data __locactdt(keep=studyid usubjid LOCACTDTC LOCACTDT LOCACTWK) ;
    merge locactdt __randdt __eotdcdt;
    by studyid usubjid;

    if first.usubjid ;

    LOCACTDTC=cmstdtc;

    if length(cmstdtc)<10 then do;
        dd=substr(cmstdtc,9,2);
        mm=substr(cmstdtc,6,2);
        yy=substr(cmstdtc,1,4);
        end;
    trtedtc=put(trtedt, yymmdd10.);
    trtedyy=substr(trtedtc,1,4);
    trtedmm=substr(trtedtc,6,2);

    if length(yy)=4 and length(mm)<2 then do;
        if input(yy,best.) > input(trtedyy,best.) then LOCACTDTC=strip(yy||'-01-01');
        if input(yy,best.) = input(trtedyy,best.) then LOCACTDT=trtedt+1;
    end;

    else if length(yy)=4 and length(mm)=2 and length(dd)<2 then do;
        LOCACTDTC=strip(substr(cmstdtc, 1, 7)) || '-01';
        if input(LOCACTDTC,yymmdd10.)<=input(trtedtc,yymmdd10.) or (input(yy,best.) = input(trtedyy,best.) and input(mm,best.) >
input(trtedmm,best.) ) then LOCACTDT=trtedt+1;

```

```

end;

if ^missing(LOCACTDTC) & ^missing(cmstdtn) then LOCACTDT=cmstdtn;
else if ^missing(LOCACTDTC) & missing(cmstdtn) then LOCACTDT=LOCACTDT;
if ^missing(LOCACTDTC) & missing(LOCACTDT) then LOCACTDT=input(LOCACTDTC,yymmdd10.);

format LOCACTDT date9.;
if nmiss(LOCACTDT,RANDDT)=0 then do;
    locactwk = (locactdt - randdt + 1) / 7;
end;

run;

/*
data anaxl.__locactdt;
    set __locactdt;
run;
*/
* Derive: First Systemic Non-Rad Therapy Date *;

proc sort data=cm1 out=sysactdt;
    by studyid usubjid cmstdtc;
    where cmcat = "CONCOMITANT AND SUBSEQUENT SYSTEMIC ANTI-CANCER THERAPY" and cmstyn = 'Y' and cmdecod
^ in ('LEUPRORELIN', 'GOSERELIN', 'DEGARELIX', 'TRPTORELIN'
)
    and (not missing(CMTRT) or not missing(CMSTDTC));
run;

data __sysactdt(keep=studyid usubjid sysactdtc sysactdt SYSACTD SYSACTWK) ;
    merge sysactdt __randdt __eotdcdt;
    by studyid usubjid;

    if first.usubjid ;
    sysactdt=cmstdtn;
    sysactdtc=cmstdtc;

    if length(cmstdtc)<10 then do;
        dd=substr(cmstdtc,9,2);
        mm=substr(cmstdtc,6,2);
        yy=substr(cmstdtc,1,4);
    end;
    *** suppressed before ***;
    trtedtc=put(trtedt, yymmdd10.);
    trtedyy=substr(trtedtc,1,4);
    trtedmm=substr(trtedtc,6,2);

    if length(yy)=4 and length(mm)<2 then do;
        if input(yy,best.) > input(trtedyy,best.) then sysactdtc=strip(yy||'-01-01');
        if input(yy,best.) = input(trtedyy,best.) then sysactdt=trtedt+1;
    end;

    else if length(yy)=4 and length(mm)=2 and length(dd)<2 then do;
        sysactdtc=strip(substr(cmstdtc, 1, 7)) || '-01';
        if input(sysactdtc,yymmdd10.)<=input(trtedtc,yymmdd10.) or (input(yy,best.) = input(trtedyy,best.) and input(mm,best.) >
input(trtedmm,best.) ) then sysactdt=trtedt+1;
    end;

    *** suppressed before ***;

    eotdcdtc=put(EOTDCDT, yymmdd10.);
    EOTDCyy=substr(eotdcdtc,1,4);
    EOTDCmm=substr(eotdcdtc,6,2);

    if length(yy)=4 and length(mm)<2 then do;

```

```

        if input(yy,best.) > input(EOTDCyy,best.) then sysactdtc=strip(yy||'-01-01');
        if input(yy,best.) = input(EOTDCyy,best.) then sysactdt=EOTDCDT+1;
    end;

    else if length(yy)=4 and length(mm)=2 and length(dd)<2 then do;
        sysactdtc=strip(substr(cmstdtc, 1, 7)) || '-01';
        if input(sysactdtc,yymmdd10.)<=input(eotdcrtc,yymmdd10.) or (input(yy,best.) <= input(EOTDCyy,best.) and input(mm,best.) <
input(EOTDCmm,best.) ) then sysactdt=EOTDCDT+1;

    end;

    if ^missing(sysactdtc) & ^missing(cmstdtn) then sysactdt=cmstdtn;
    else if ^missing(sysactdtc) & missing(cmstdtn) then sysactdt=sysactdtc;
    if ^missing(sysactdtc) & missing(SYSACTDT) then sysactdt=input(sysactdtc,yymmdd10.);
        * if usubjid='184315-5308-3020' then sysactdt = .; *** Need to put cmstyn in the suppecm data in order to use cmstyn = N records
***;

format sysactdt date9.;
if nmiss(SYSACTDT,RANDDT)=0 then do;
    SYSACTD = SYSACTDT-RANDDT+1;
    SYSACTWK =(SYSACTDT-RANDDT+1)/7;
end;
if sysactdt >= randdt;
if CMTRT = '' and CMSTDTC = '' then delete;
run;

proc print data = cm1;
    title 'xxx cm1';
    where usubjid in ('184315-8606-3568');
run;

proc print data = sysactdt;
    title 'xxx';
    where usubjid in ('184315-8606-3568');
run;

*PN -----*;
*PN Read in ds          *;
*PN Derive: Reason for Discon      *;
*PN          *;
*PN -----*;

data __dctreasa(keep=studyid usubjid DCTREASA) __dctreasc(keep=studyid usubjid DCTREASC)
    __dctreasp(keep=studyid usubjid DCTREASp) __dctrease (keep=studyid usubjid DCTREASe)
    __dctreasb (keep=studyid usubjid DCTREASb) __dcsreas (keep=studyid usubjid DCSREAS )
    __dcrreas (keep =studyid usubjid dcrreas )
    ;
set ds(keep = studyid usubjid dsscat dsdecod);

attrib
    DCTREASA length=$200    label='Reason for Discont of Atez'
    DCTREASC length=$200    label='Reason for Discont of Cabo'
    DCTREASp length=$200    label='Reason for Discont of Pred'
    DCTREASe length=$200    label='Reason for Discont of Enza'
    DCTREASb length=$200    label='Reason for Discont of Rbi'
    DCSREAS length=$200     label='Reason for Discont. From Survival FUP'
    ;

if dsscat = 'END OF STUDY TREATMENT, ATEZOLIZUMAB' then do;
    DCTREASA = dsdecod;
    output __dctreasa;
end;
if dsscat = 'END OF STUDY TREATMENT, CABOZANTINIB' then do;

```

```

    DCTREASC = dsdecod;
    output __dctreasc;
end;
if dsscat = 'END OF STUDY TREATMENT, ABIRATERONE' then do;
    DCTREASB = dsdecod;
    output __dctreascb;
end;
if dsscat = 'END OF STUDY TREATMENT, PREDNISONE' then do;
    DCTREASP = dsdecod;
    output __dctreasp;
end;
if dsscat = 'END OF STUDY TREATMENT, ENZALUTAMIDE' then do;
    DCTREASE = dsdecod;
    output __dctrease;
end;
if index(dsscat , 'END OF SURVIVAL FOLLOW-UP') gt 0 then do;
    DCSREAS = dsdecod;
    /**
        if dsdecod ne ' ' then DCSFL = 'Y';
        if dsdecod eq ' ' then DCSFL = 'N';
    **/
    output __dcsreas;
end;
if index(dsscat , 'END OF RADIOGRAPHIC FOLLOW-UP') gt 0 then do;
    DCrREAS = dsdecod;
    /* if dsdecod ne ' ' then DCrFL = 'Y';
        if dsdecod eq ' ' then DCrFL = 'N'; */
    output __dcrreas;
end;
run;

proc print data = __dcsreas;
    title 'dcsreas';
    where usubjid = '184315-7109-3072';
run;

proc print data = __dcrreas;
    title 'dcrreas';
    where usubjid = '184315-7109-3072';
run;

*PN -----*;
*PN Read in sdtm dd data *;
*PN -----*;
%merge _supp(domain=dd, libname=sdtmdata);
%psort(ds=dd);

*PN -----*;
*PN Read in dd          *;
*PN Derive: Reason for Death      *;
*PN          *;
*PN -----*;

data __dthdate(keep=studyid usubjid dthdate) __DTHASOSI(keep=studyid usubjid DTHASOSI)
;
set dd(keep = studyid usubjid ddtested ddorres dddtc );
by studyid usubjid;
attrib

    DTHASOSI length=$200    label='Death Associated With Study Indication'
;

```

```

if ddtested = 'PRCDTH' then do;
    dthdate = dddtc;
    output __dthdate;
end;
if ddtested = 'DTHRELPR' then do;
    dthasosi = ddorres;
    output __DTHASOSI;
end;

run;

proc sort data=__DTHASOSI nodupkey;
    by studyid usubjid;
run;

proc sort data=__dthdate nodupkey;
    by studyid usubjid;
run;

*PN -----*;
*PN Read in sdtm ae data *;
*PN -----*;
%merge_supp(domain=ae, libname=sdtmdata);
%psort(ds=ae);

proc sort data=ae out=aedth(keep=studyid usubjid aeterm aedecod aerela aerelb aerelc aerele aeterm aedecod aerelp aestdtc ) nodupkey;
    by studyid usubjid;
    where aetoxgr="5";
run;

proc sort data=ae out=aedthdt (keep=studyid usubjid aetoxgr aestdtc aeterm aedecod aerela aerelb aerelc aerele aerelp ) nodupkey;
    by usubjid;
    where aetoxgr="5";
run;

data __aedthdt (keep =usubjid aedthdt aestdtc );
    set aedthdt;
    by usubjid;
    if length(aestdtc) ge 10 then aedthdt = input(substr(aestdtc,1,10),yymmdd10.);
run;

proc print data = aedthdt;
    title '3632';
    where usubjid ='184315-1563-3632';
run;

proc print data = __aedthdt;
    title '3632';
    where usubjid ='184315-1563-3632';
run;

data __dthcaus /* (keep=studyid usubjid DTHCAUS ) */
    __DTHCGR1 /* (keep=studyid usubjid DTHCGR1 ) */
    __GR5RELFL /* (keep=studyid usubjid GR5RELFL ) */ ;
merge aedth(in=ae) __dthdate(in=dth) __dm (in = c keep = studyid usubjid dthdtc where =(dthdtc ne '')) ;
by studyid usubjid;
if ae or c;
attrib
    DTHCAUS length=$200 label='Cause of Death' ;

if aeterm ne '' then dthcaus = aeterm;
if aeterm = '' then dthcaus='MISSING';
output __dthcaus;

```

```

if ae decod ne '' then DTHCGR1 = ae decod;
if ae decod = '' then DTHCGR1='UNCODED/MISSING';
output __DTHCGR1;

if ae and (aerela='RELATED' or aerelc='RELATED' or aerele='RELATED' or aerelp='RELATED' or aerelb='RELATED') then GR5RELFL
='Y';
if ae and ((aerela='NOT RELATED' and aerelc='NOT RELATED') or aerele='NOT RELATED' or (aerelp='NOT RELATED' and aerelb =
'NOT RELATED')) then GR5RELFL = 'N';
if dthdte ne '' and ^ ae then GR5RELFL = 'N';
output __GR5RELFL;
run;

proc sort data=__dthcaus nodupkey;
by studyid usubjid;
run;

proc sort data=__DTHCGR1 nodupkey;
by studyid usubjid;
run;

proc sort data=__GR5RELFL nodupkey;
by studyid usubjid GR5RELFL ;
run;

proc freq data=__dthcaus;
* where dthcaus in ('MISSING','');
table dthcaus*aeterm/list missing;;
title 'dthcaus';
run;

proc freq data=__dthcgr1;
* where dthcgr1 in ('UNCODED/MISSING','');
table dthcgr1*ae decod/list missing;;
title 'dthcgr1';
run;

proc freq data=__gr5relfl;
* where gr5relfl in ('N','');
table usubjid*gr5relfl*aeterm*ae decod*aerela*aerelb*aerele*aerelp/list missing;;
title 'gr5relfl';
run;

proc freq data = __GR5RELFL;
table gr5relfl;
run;

proc print data =dm;
where usubjid ='184315-3004-3140';
run;

*PN -----*;
*PN Read in sdtm sv data *;
*PN -----*;
data sv;
set sdtmdata.sv;

if length(svstdtc) ge 10 then svstdtn = input(substr(svstdtc,1,10),yymmdd10.);
if length(svendtc) ge 10 then svendtn = input(substr(svendtc,1,10),yymmdd10.);
keep studyid usubjid svstdtn svendtn trtsdt;run;

```

```

proc sort data=sv out=sv1;
  by studyid usubjid svendtn;
run;

data __lstvisdt;
  set sv1(in=sv);
  by studyid usubjid svendtn;
  attrib LSTVISDT length=8 label='Last Visit Date' format=date9.;
  lstvisdt=svendtn;
  if last.usubjid;
  keep studyid usubjid lstvisdt;
run;

proc sort data=sv out=_lstvisdt;
  by studyid usubjid ;
run;

proc sort data=__dm;
  by usubjid ;
run;

data __lstvisdt;
  merge __dm(in=dm keep=usubjid) __lstvisdt(in=sv);
  by usubjid;
  if dm & sv;
run;

*PN-----PN*;
*PN--Macro to remove duplicate observation --*PN*;
*PN-----PN*;

%macro dup(dsn=,var=);
proc sort data=&dsn nodupkey dupout=&dsn.dup out=&dsn.nodup;
by usubjid &var;
run;
%mend;

*PN -----*;
*PN Merge supplemental qualifiers back onto parent domain ds *;
*PN -----*;
%merge_supp(domain=vs, libname=sdtmdata) ;
%merge_supp(domain=qs, libname=sdtmdata) ;

*PN-----PN*;
*PN-----BASELINE-----PN*;
*PN-----PN*;
*PN-----PN*;
*PN--Macro to subset dataset with condition----PN*;
*PN-----PN*;

%macro condn(dsn=,var=,condn1=,condn2=);
%local;
data &var;
set &dsn;
if &condn1 then &var=&condn2;
else delete;
run;
%mend;
**Macro to find Bweight,bheight,becogc**;
%macro m_base(dsn=,testcd=,result=);
data &testcd._base_m;
set &dsn;

```

```

        if &dsn.testcd="&tested" and &dsn.blfl="Y";
        _base="Y";
        _base_n=&dsn.&result;
run;

proc sort data=&tested._base_m;
by usubjid;
run;
%condn(dsn=&dsn,condn1=&dsn.testcd="&tested" and &dsn.&result ne .,var=&tested,condn2=&dsn.&result);
data &tested._no_basefl;
merge &tested._base_m(in=b drop=&dsn.blfl) &tested(in=a);
by usubjid;
if a and not b;
&dsn.testcd="&tested";
put "WAR" "NING: Baseline flag is missing for " "&tested. : " Usubjid=;
run;
data &tested._base_m2;
merge sdtmdata.dm (in=a) &tested._base_m(in=b);
by usubjid;
if a;
if _base="Y" and _base_n=. and &dsn.testcd="&tested" then put "WAR" "NING: baseline value missing for" "&tested." Usubjid=;
run;
%mend;

****WEIGHT*****;
options mprint symbolgen;
%condn(dsn=vs,condn1=vstestcd="WEIGHT" and vsblfl="Y",var=wtbl,condn2=vsstresn);
%m_base(dsn=vs,testcd=WEIGHT,result=stresn);
%dup(dsn=WEIGHT_no_basefl,var=);

data weight_sub_no_fl;
merge WEIGHT_no_baseflnodup(in=a) vs(where=(vstestcd="WEIGHT"));
by usubjid;
if a;
if visit="SCREENING" or (visit='WEEK 1 DAY 1' and epoch='BASELINE' and vsdy le 1);
wtbl=vsstresn;
run;

data wtbl0;
merge wtbl weight_sub_no_fl;
by usubjid;
run;

proc sort data=wtbl0;
by usubjid vsdy;
run;

data weightbl(keep= studyid usubjid wtbl wtblgr1);
set wtbl0;
by usubjid vsdy;
attrib
    WTBL    length=8    label='Baseline Weight (kg)'
    WTBLGR1 length=$15    label='Pooled Baseline Weight (kg) Group 1'
;
if . lt wtbl lt 60 then wtblgr1 = '<60 kg';
else if 60 le wtbl le 80 then wtblgr1 = '>=60 to <=80 kg';
else if wtbl gt 80 then wtblgr1 = '>80 kg';
if last.usubjid;
run;

****HEIGHT*****;
%condn(dsn=vs,condn1=vstestcd="HEIGHT" and vsblfl="Y",var=htbl,condn2=vsstresn);
%m_base(dsn=vs,testcd=HEIGHT,result=stresn);
%dup(dsn=HEIGHT_no_basefl,var=);

```



```

data height_sub_no_fl;
merge HEIGHT_no_baseflnodup(in=a) vs(where=(vstested="HEIGHT"));
by usubjid;
if a;
if visit="SCREENING" or (visit="WEEK 1 DAY 1" and epoch='BASELINE' and vsdy le 1);
htbl=vsstresn;
run;

```

```

data htbl0;
merge htbl height_sub_no_fl;
by usubjid;
run;

```

```

proc sort data=htbl0;
by usubjid vsdy;
run;

```

```

data heighttbl(keep= studyid usubjid htbl);
set htbl0;
by usubjid vsdy;
attrib
    htbl    length=8    label='Baseline Height (cm)' ;
if last.usubjid;
run;

```

```

data __bmibl;
label  bmibl ='Baseline BMI (kg/m2)';
merge weightbl heightbl;
by usubjid;
if wtbl ne . and htbl ne . then bmibl=wtbl/((htbl*0.01)*(htbl*0.01));
run;

```

```

*****BECOGC*****;

```

```

data becogc_;
merge __dm(in=a keep=usubjid trtsdt) qs;
by usubjid;
if a;
if qstested="ECOG101";
if length(qsdtc)>=10 then becogcdt=input(substr(qsdtc,1,10),yymmdd10.);
format becogcdt date9.;
if .<becogcdt<=trtsdt;
run;
proc sort data=becogc_;
by usubjid becogcdt;
run;

```

```

data becogcdt;
set becogc_;
by usubjid becogcdt;
if last.usubjid;
ecogbl=qsstresn;
run;

```

```

proc sort data = __dm;
by usubjid;
run;

```

```

data becogc_2;
merge __dm(in=a keep=usubjid trtsdt) qs;
by usubjid;
if a;
if trtsdt eq .;
if qstested="ECOG101";

```

SAS Writ

```
if visit="SCREENING" or (visit='WEEK 1 DAY 1' and epoch='BASELINE' and qsdyle 1);
ecogbl=qsstresn;
run;

proc sort data=becogc_2;
by usubjid qsdyle;
run;

data becogc_2;
set becogc_2;
by usubjid qsdyle;
if last.usubjid;
run;

data __becogcdt;
merge becogcdt becogc_2;
by usubjid;
run;

*PN -----*;
*PN Read in __dm *;
*PN Derive: PITTFLL *;
*PN *;
*PN -----*;

proc sort data=__dm;
by studyid usubjid randdtc;
run;

data pittfl ;
set __dm;
by studyid usubjid randdtc;
if not missing(trt01p) and not missing(randdtc) ;
keep studyid randdtc usubjid trt01p randdtc ukrsufl;
run;

proc sort data = pittfl;
by randdtc usubjid;
run;

data __pittfl (drop = ukrsufl);
attrib OPITTFLL length=$1. format=$1. label="Original Prim PFS Population Flag";
attrib PITTFLL length=$1 label='Primary PFS Population Flag';
set pittfl;
by randdtc usubjid;
if _n_ = 1 then count=0;
count + 1;
if count le 400 and ukrsufl ne 'Y' then pittfl = 'Y';
if count le 300 and ukrsufl ne 'Y' then opittfl = 'Y';
run;

proc sort data=__pittfl;
by studyid usubjid;
run;

*PN -----*;
*PN Derive: LSTALVDT *;
*PN *;
*PN -----*;

data aedth;
```

```

set sdtmdata.ae;
  where AETOXGR = '5';
  dthdte = aetdte;
  keep studyid usubjid dthdte AETOXGR;
run;

```

```

data lsalvdt_ (keep=studyid usubjid lsalvdt_ lsalvdtf);
  length lsalvdtf $1;
  set dm (keep=studyid usubjid dthdte ) aedth;
  where dthdte > ";;
*   lsalvdt_ = input(dthdte,yymmdd10.);
  if length (dthdte) = 7 then    dthdte_ = strip(dthdte)||'-01';
  else if length (dthdte) = 10 then dthdte_ = dthdte;
  if length (dthdte_) = 10 then    lsalvdt_ = input(dthdte_,yymmdd10.);
  if length (dthdte) = 7 then    lsalvdtf = 'D';;
run;

```

```

proc sort data = lsalvdt_ nodupkey ;
  by studyid usubjid lsalvdt_ ;
run;

```

```

data dsa(keep=studyid usubjid dsadt) dsb(keep=studyid usubjid dsbdt) ;
  set sdtmdata.ds;
  if dsscat = 'RE-CONSENT OR CONSENT WITHDRAWAL' and index(dsterm,'WITHDREW FULL CONSENT') = 1 then do;
    if length(dsstdte) ge 10 then dsadt = input(substr(dsstdte,1,10),yymmdd10.);
    output dsa;
  end;
  else if dsscat = 'END OF SURVIVAL FOLLOW-UP' and dsdecod ^= "DEATH" then do;
    if length(dsstdte) ge 10 then dsbdt = input(substr(dsstdte,1,10),yymmdd10.);
    output dsb;
  end;
run;

```

```

proc sort data=dsa;
  by studyid usubjid dsadt;
run;

```

```

data dsa;
set dsa;
  by studyid usubjid dsadt;
if last.usubjid;
run;

```

```

proc print data = dsa;
  where usubjid = '184315-3005-3492';
run;

```

```

proc sort data=dsb;
  by studyid usubjid dsbdt;
run;

```

```

data dsb;
set dsb;
  by studyid usubjid dsbdt;
if last.usubjid;
run;

```

```

%merge_supp(domain=ss, libname=sdtmdata);
%psort(ds=ss);

```

```

data ssc(keep=studyid usubjid ALIVEDT);

```

```

        set ss;
    if SSCAT = "SURVIVAL FOLLOW-UP" and SSORRES="ALIVE";
    alivedt=input(alivedtc,ymmdd10.);
run;

proc sort data=ssc;
    by studyid usubjid ALIVEDT;
run;

data ssc;
set ssc;
    by studyid usubjid ALIVEDT;
if last.usubjid;
run;

/**
data eot (keep=studyid usubjid eotdt);
    set sdtmdata.ds;
    if index(dsscsc,'END OF STUDY TREATMENT') = 1 then do;
        if length(dsstdtc) ge 10 then eotdt = input(substr(dsstdtc,1,10),ymmdd10.);
        output eot;
    end;
run;
**/

data eot (keep=studyid usubjid dsstdtc);
    set sdtmdata.ds;
    if index(dsscsc,'END OF STUDY TREATMENT') = 1 ;
run;

/**
proc sort data =eot;
    by studyid usubjid eotdt;
run;

data eot;
    set eot;
    by studyid usubjid eotdt;
    if last.usubjid;
run;
**/

data dsds (keep=studyid USUBJID dsstdtc dscat dsterm dsscsc);
    set sdtmdata.ds ;
    where dsscsc in ('END OF RADIOGRAPHIC FOLLOW-UP','END OF STUDY TREATMENT' ,'RE-CONSENT OR CONSENT
WITHDRAWAL');
run;

data sv (drop = svstdtc svendtc cmstdtc cmendtc aestdte aeendtc exstdtc extendtc lbdte);
    set sdtmdata.sv (keep=studyid USUBJID svstdtc)
    sdtmdata.sv (keep=studyid USUBJID svendtc)
        sdtmdata.cm (keep=studyid USUBJID cmstdtc)
    sdtmdata.cm (keep=studyid USUBJID cmendtc)
        sdtmdata.ex (keep=studyid USUBJID exstdtc)
    sdtmdata.ex (keep=studyid USUBJID extendtc)
        sdtmdata.lb (keep=studyid USUBJID lbdte)
        sdtmdata.ss (keep=studyid USUBJID ssdte)
        sdtmdata.ae (keep=studyid USUBJID aestdte)
    eot
    dsds (keep=studyid usubjid dsstdtc)
    sdtmdata.ds (keep=studyid USUBJID dsstdtc dscat dsterm dsscsc where = (dsscsc ='END OF RADIOGRAPHIC
FOLLOW-UP' or dscat in ('END OF STUDY TREATMENT')
    or (dscat ='RE-CONSENT OR CONSENT WITHDRAWAL' and DSTERM in ( 'WITHDREW CONSENT FROM STUDY
INTERVENTIONS', 'NON-INTERVENTIONAL STUDY ASSESSMENTS MAY CONTINUE') )))
    */

```

```

        sdtmdata.ae (keep=studyid USUBJID aeendtc);
    if not missing(svstdtc) then svall = substr(svstdtc,1,10);
        if not missing(svendtc) then svall = substr(svendtc,1,10);
        if not missing(cmstdtc) then svall = substr(cmstdtc,1,10);
        if not missing(cmendtc) then svall = substr(cmendtc,1,10);
        if not missing(exstdtc) then svall = substr(exstdtc,1,10);
        if not missing(exendtc) then svall = substr(exendtc,1,10);
    if not missing(aestdte) then svall = substr(aestdte,1,10);
        if not missing(aeendtc) then svall = substr(aeendtc,1,10);
        if not missing(lbdtc) then svall = substr(lbdtc,1,10);
        if not missing(ssdte) then svall = substr(ssdte,1,10);
        if not missing(dsstdtc) then svall = substr(dsstdtc,1,10);
        if not missing(aestdte) then svall = substr(aestdte,1,10);
        if not missing(aeendtc) then svall = substr(aeendtc,1,10);
    if length(svall) = 10 then svstdt = input(svall,yymmdd10.);
        format svstdt date9.;

proc sort data=sv ;
    by studyid usubjid svstdt;
    * where length (strip(svall)) = 10 ;
run;

data sv;
    set sv;
    by studyid usubjid svstdt;
    if last.usubjid;
run;

data __lstalvdt ; * (keep=studyid usubjid lstalvdt lsalvdt) ;
    merge dsa(in=a) dsb(in=b) ssc(in=c) lstalvdt_ (in=d) eot (in=e) sv (in=max) ;
        by studyid usubjid;
    cutdt = &cutdt.;
    if dsbdt ne . or ALIVEDT ne . then maxdate = max(dsbdt, ALIVEDT);
    if d and lstalvdt_ ne . then lstalvdt=lstalvdt_ ;
    else if dsadt ne . then lstalvdt=dsadt;
    else if dsadt eq . and dsbdt ne . or ALIVEDT ne . then lstalvdt=max(dsbdt, ALIVEDT);
    else if dsadt eq . and dsbdt eq . and ALIVEDT eq . and svstdt ne . then lstalvdt=svstdt;
    else if dsadt eq . and dsbdt eq . and ALIVEDT eq . and svstdt eq . then lstalvdt=cutdt;

    * else if (not a) and (not b) and ^ c and ^ max and e and eotdt ne . then lstalvdt=eotdt;
    /*
    else lstalvdt= max( dsadt,dsbdt ,ALIVEDT,eotdt);
        else if a then lstalvdt=dsadt;
        else if (not a) and b then lstalvdt=dsbdt;
        else if (not a) and (not b) and c then lstalvdt=ALIVEDT;
        else if (not a) and (not b) and (not c) then lstalvdt=eotdt;
    **/
    /* else lstalvdt= .; */
    * lsalvdtf=";
    *if lstalvdt > &cutoffdt. then lstalvdt=&cutoffdt. ;
    * lstalvdt= max( dsadt,dsbdt ,ALIVEDT,eotdt);
    format lstalvdt date9.;
run;

proc sort data = __lstalvdt;
    by usubjid lstalvdt;
run;

data __lstalvdt;
    set __lstalvdt;

```

```

        by usubjid lstalvdt;
        if last.usubjid;
run;

```

```

proc freq data=__lstalvdt;
    table usubjid* lstalvdt* lstalvdt_ * dsadt* dsbdt* ALIVEDT* svstdt* eotdt/list missing nopct nocum;
    format lstalvdt lstalvdt_ dsadt dsbdt ALIVEDT svstdt eotdt date9.;
run;

```

```

*PN -----*;
*PN read in sdtm su data          *;
*PN -----*;
data smok(keep=&sortby smokstat) ;
    set sdtmdata.su;
    length smokstat $10;
    if suotr = 'TOBACCO' then do;
        if suoccur = 'N' then smokstat = 'NEVER';
        else if suoccur = 'Y' then do;
            if suenrtpt = 'BEFORE' then smokstat = 'FORMER';
            if suenrtpt = 'ONGOING' then smokstat = 'CURRENT';
        end;
    end;
    output smok;
end;

```

```
run;
```

```
%psort(ds=smok);
```

```

proc sort data=smok out=__smok nodupkey;
    by studyid usubjid;
run;

```

```

data alch(keep=&sortby alchstat);
    set sdtmdata.su;
    length ALCHSTAT $10;

    if suotr = 'ALCOHOL' then do;
        if suoccur = 'N' then ALCHSTAT = 'NEVER';
        else if suoccur = 'Y' then do;
            if suenrtpt = 'BEFORE' then ALCHSTAT = 'FORMER';
            if suenrtpt = 'ONGOING' then ALCHSTAT = 'CURRENT';
        end;
    end;
    output alch;
end;
run;
%psort(ds=alch);

```

```

proc sort data=alch out=__alch nodupkey;
    by studyid usubjid;
run;

```

```

*PN -----*;
*PN Read in sdtm ds data *;
*PN -----*;
%merge_supp(domain=ds, libname=sdtmdata);
%psort(ds=ds);

```

```

data __dsstdtc_withdrew;
    set ds;
    by usubjid;
    if index(upcase(dsterm),'WITHDREW FULL CONSENT') and upcase(dsscatt) in("RE-CONSENT OR CONSENT WITHDRAWAL") then do;
        __dsstdtc_withdrew = input(substr(DSSTDTC,1,10),yymmdd10.);
    end;
end;

```

```

end;
if last.usubjid;
keep studyid usubjid __dsstdtc __withdrew;
run;

*PN -----*;
*PN Read in sdtm cm data *;
*PN -----*;
%merge_supp(domain=cm, libname=sdtmdata);
%psort(ds=cm, key=usubjid cmstdtc cmendtc);

proc sql undo_policy=none;
create table cm as
select a.*, b.randdt
from cm a left join __randdt b
on a.usubjid=b.usubjid
order by a.studyid, a.usubjid, a.cmstdtc,a.cmendtc;
quit;

data cm2(keep=studyid usubjid cmstdtc cmendtc NRADSDT NRADSDTF NRAEDT NRAEDTF nraddurd nraddurw nraddurm);
set cm;
by usubjid cmstdtc cmendtc;
if cmat="HISTORY OF NON-RADIATION ANTI-CANCER THERAPY" and cmdecod in ("ENZALUTAMIDE" "ABIRATERONE"
"APALUTAMIDE" "DAROLUTAMIDE") and cmstdtc>" and (not (cmtrt=" and cmstdtc=")) ; * and cmtpe ="SYSTEMIC" ;
* if last.usubjid;
format NRADSDT NRAEDT date9.;
length NRADSDTF NRAEDTF $3;

if cmstdtc = '21' then cmstdtc = '2021'; *** ERROR 2229-3633 partial yr 20 and 21 **;
if cmstdtc = '20' then cmstdtc = '2020'; *** ERROR 2229-3633 partial yr 20 and 21 **;
if length(cmstdtc)>=10 then NRADSDT=input(cmstdtc, yymmdd10.);
else do;
* to be confirmed if imputation is needed??;
dd=substr(cmstdtc,9,2);
mm=substr(cmstdtc,6,2);

if 4<=length(cmstdtc)<10 then do;
if dd=" and mm=" then do; cmstdtc=substr(cmstdtc,1,4)||'-01-01'; NRADSDTF='M'; end; ***ERROR 2229-3633 partial yr 21 and 20 **;
else if dd=" then do; cmstdtc=substr(cmstdtc,1,7)||'-01'; NRADSDTF='D'; end;
end;
NRADSDT=input(substr(cmstdtc,1,10),yymmdd10.);
end;

if length(cmendtc)>=10 then NRAEDT=input(substr(cmendtc,1,10),yymmdd10.);
else do;
* impute cmendtc;
if length(cmendtc)>=" then do;
dd=substr(cmendtc,9,2);
mm=substr(cmendtc,6,2);
yy=substr(cmendtc,1,4);
end;

if length(yy)=4 and mm=" then do;
* missing month/day or month;
cmendtc=compbl(strip(yy))||'-12-31';
NRAEDT=input(cmendtc, yymmdd10.);
NRAEDTF='M';
end;
else if dd=" then do;
* missing day;
%x_dtimpute(indtc=cmendtc, outdt=NRAEDT, outdtf=NRAEDTF, impalgn=e);
NRAEDTF='D';
end;

```

```

end;

* if NRADED>randdt then NRADED=randdt-1;
  if nmiss(randdt, NRADED)=0 then nraddurd = randdt - NRADED ;
if ^missing(nraddurd) then nraddurw = nraddurd / 7;
if ^missing(nraddurd) then nraddurm = nraddurd / 30.4375;
run;

proc print data =cm2;
  title 'cm2';
  where usubjid = '184315-3420-3774';
run;

proc freq data = cm2;
  table cmendtc* NRADED* NRADEDTF/list missing;
run;

data __NRAD;
  set cm2;
  by usubjid cmstdtc cmendtc;
  if last.usubjid;
  NRADEF=NRADEDTF;
  keep studyid usubjid NRASDT NRASDTF NRADED NRADEF NRADEDTF nraddurd nraddurw nraddurm;
run;

*PN -----*;
*PN Read in sdtm cm HISTORY OF NON-RADIATION ANTI-CANCER THERAPY data *;
*PN -----*;
data ypnr npnr;
  set cm;
  by usubjid cmstdtc cmendtc;
  if cecat='HISTORY OF NON-RADIATION ANTI-CANCER THERAPY' then do;
    PNRDTXFL='Y';
    output ypnr;
  end;
  else if cecat ^='HISTORY OF NON-RADIATION ANTI-CANCER THERAPY' then do;
    PNRDTXFL='N';
    output npnr;
  end;

run;
/**
data PRNHTGR;
  length PRNHTGR1 $20;
  set sdtmdata.cm;
  if CMCAT='HISTORY OF NON-RADIATION ANTI-CANCER THERAPY' and CMDECOD= 'ABIRATERONE' then PRNHTGR1 =
'ABIRATERONE' ;
  if CMCAT='HISTORY OF NON-RADIATION ANTI-CANCER THERAPY' and CMDECOD= 'ENZALUTAMIDE' then PRNHTGR1 =
'ENZALUTAMIDE' ;
  if CMCAT='HISTORY OF NON-RADIATION ANTI-CANCER THERAPY' and CMDECOD in ('APALUTAMIDE','DAROLUTAMIDE')
then PRNHTGR1 = 'OTHER' ;
run;
**/

proc sort data=ypnr nodupkey;
  by usubjid cmtrt cmstdtc cmendtc;
  * by usubjid regnum;
run;

data ypnr0(keep=studyid usubjid PNRDTXFL NPNRADTX);
  set ypnr;
  NPNRADTX + 1;
  by usubjid cmtrt cmstdtc cmendtc;

```



```

* by usubjid regnum;
if first.usubjid then NPNRADTX = 1;
if last.usubjid;
run;

```

```

proc sort data=npnr;
by usubjid cmtrt cmstdtc cmendtc;
* by usubjid regnum;
run;

```

```

data npnr0(keep=studyid usubjid PNRDTXFL NPNRADTX);
set npnr;
by usubjid cmtrt cmstdtc cmendtc;
* by usubjid regnum;
NPNRADTX = 0;
if last.usubjid;
run;

```

```

data npryn;
length NPNRDGR1 $8.;
set ypnr0 npnr0;
by usubjid ;
if NPNRADTX=0 then NPNRDGR1='0';
else if NPNRADTX=1 then NPNRDGR1='1';
else if NPNRADTX=2 then NPNRDGR1='2';
else if NPNRADTX>=3 then NPNRDGR1='>=3';
run;

```

```

proc sort data=npryn out=__npryn nodupkey dupout=test;
by usubjid ;
run;

```

```

*PN -----*;
*PN read in PR (PRCAT=HISTORY OF RADIATION THERAPY) and (PR.PRINDC=DISEASE UNDER STUDY) & PROCCUR in (",Y") *;
*PN -----*;

```

```

proc sort data=sdtmdata.pr out=pr1;
by studyid usubjid prtrt prstdtc prendtc ;
run;

```

```

data yprad nprad;
set pr1;
by usubjid prtrt prstdtc prendtc;
if (PRCAT='HISTORY OF RADIATION THERAPY') and (PRINDC='DISEASE UNDER STUDY') and (PROCCUR in (",Y")) then do;
PRADTXFL='Y';
output yprad;
end;
else do;
PRADTXFL='N';
output nprad;
end;

run;

```

```

proc sort data=yprad nodupkey;
by usubjid prtrt prstdtc prendtc;
run;

```

```

data yprad0(keep=studyid usubjid PRADTXFL NPRADTX);
set yprad;

```

```

NPRADTX + 1;
by usubjid prtrt prstdtc prentdc;
if first.usubjid then NPRADTX = 1;
if last.usubjid;
run;

proc sort data=nprad;
  by usubjid prtrt prstdtc prentdc;
run;

data nprad0(keep=studyid usubjid PRADTXFL NPRADTX);
  set nprad;
  by usubjid prtrt prstdtc prentdc;
  NPRADTX = 0;
  if last.usubjid;
run;

data pradyn;
  length NPRADGR1 $8.;
  set yprad0 nprad0;
  by usubjid ;
  if NPRADTX=0 then NPRADGR1='0';
  else if NPRADTX=1 then NPRADGR1='1';
  else if NPRADTX=2 then NPRADGR1='2';
  else if NPRADTX>=3 then NPRADGR1='>=3';
run;

proc sort data=pradyn out=__pradyn nodupkey dupout=test;
  by usubjid ;
run;

*PN -----*;
*PN Read in sdtm pr data *;
*PN -----*;
%merge_supp(domain=pr, libname=sdtmdata);
%psort(ds=pr);

* Derive: First Subsequent Radiation Therapy Date *;

data pr1;
  merge pr __dm __randdt __TRTEDT;
  by studyid usubjid;

  if length(prstdtc) ge 10 then prstdtn = input(substr(prstdtc,1,10),yymmdd10.);

  keep studyid usubjid trtsdt randdt prstdtn prstdtc prcat prindc prtrt rasityp csitl /* csprel */ visit TRTEDT;

run;

proc sort data=pr1 out=prsrdt;
  by studyid usubjid prstdtc;
  where prcat = 'CONCOMITANT AND SUBSEQUENT RADIATION THERAPY' and PRINDC='DISEASE UNDER STUDY' and
  RASITYP^='BONE' and VISIT^='SCREENING'
  and (not missing(prtrt) and not missing(prstdtc)) ;
run;

data __prsrdt(keep=studyid usubjid prsrdtc prsrdt ) ;
  merge prsrdt __randdt;
  by studyid usubjid;

  if first.usubjid ;

```

```

*sysactdt=cmstdtn;
prsrdtc=prstdtc;

if length(prstdtc)<10 then do;
  dd=substr(prstdtc,9,2);
  mm=substr(prstdtc,6,2);
  yy=substr(prstdtc,1,4);
  end;
trtedtc=put(trtedt, yymmdd10.);
trtedyy=substr(trtedtc,1,4);
trtedmm=substr(trtedtc,6,2);

  if length(yy)=4 and length(mm)<2 then do;
    if input(yy,best.) > input(trtedyy,best.) then prsrdtc=strip(yy||'-01-01');
    if input(yy,best.) = input(trtedyy,best.) then prsrdt=trtedt+1;
  end;

else if length(yy)=4 and length(mm)=2 and length(dd)<2 then do;
  prsrdtc=strip(substr(prstdtc, 1, 7)) || '-01';
  if input(prsrdtc,yymmdd10.)<=input(trtedtc,yymmdd10.) or (input(yy,best.) = input(trtedyy,best.) and input(mm,best.) >
input(trtedmm,best.) ) then prsrdt=trtedt+1;
end;

if ^missing(prsrdtc) & ^missing(prstdtn) then prsrdt=prstdtn;
else if ^missing(prsrdtc) & missing(prstdtn) then prsrdt=prsrdt;
if ^missing(prsrdtc) & missing(prsrdt) then prsrdt=input(prsrdtc,yymmdd10.);

format prsrdt date9.;

if prsrdt >= randdt;
run;

*Derive: First Date of Subsequent Surgery / Procedure Impacting Tumor Lesion *;

proc sort data=pr1 out=prssptldt;
  by studyid usubjid prstdtn;
  where prcat = 'CONCOMITANT/SUBSEQUENT SURGERY AND PROCS' and csitl='Y' /* and csprel='Y' */ and VISIT^='SCREENING'
/* and (not missing(prtrt) and not missing(prstdtn)) and prstdtn ge trtsdt */;
run;

data __prssptldt;
  set prssptldt;
  by studyid usubjid;

  attrib
    prssptldt   length=8   label='First Date of Subsequent Surgery or Procedure Impacting Tumor Lesion'   format=date9.
  ;
  if first.usubjid;
  prssptldt = prstdtn;
  keep studyid usubjid prssptldt;

run;

*PN -----*;
*PN Read in sdtm cd data *;
*PN -----*;
%merge_supp(domain=cd, libname=sdtmdata);
%psort(ds=cd);

data __diag; *(keep=studyid usubjid DIAGDT DIAGDTF diagdurd diagdury);
merge cd __dm __randdt __rficdt;
by studyid usubjid;

```

```

    if CDTESTCD="CDPCDTC" and cdstresc > ' '; ***ERROR suppress > ' ' just for matching purpose **;
format DIAGDT date9.;
length DIAGDTF $3;
if length(cdstresc) >= 10 then DIAGDT=input(cdstresc, yymmdd10.);
else do;
    dd=substr(cdstresc,9,2);
    mm=substr(cdstresc,6,2);
    if 4<=length(cdstresc)<10 then do;
        if dd=" and mm=" then do; cdstresc=substr(cdstresc,1,4)||'-07-01'; DIAGDTF='M'; end;
        else if dd=" then do; cdstresc=substr(cdstresc,1,7)||'-15'; DIAGDTF='D'; end;
    end;
    DIAGDT=input(substr(cdstresc,1,10),yymmdd10.);
end;
* if DIAGDT>rficdt then DIAGDT=rficdt-1;
diagdurd = randdt - diagdt;
diagdury = diagdurd / 365.25;

run;

proc print data = __diag;
    title 'diag';
    where usubjid = '184315-2229-3633'; *** ALLUCENT ERROR need to reset to inform consent date ***;
run;

*PN -----*;
*PN Read in sdtm ds data *;
*PN -----*;
%merge_supp(domain=ds, libname=sdtmdata);
%psort(ds=ds);

data __eordt(keep=studyid usubjid DCRREAS eordt eslctdt eslbsdt eslmrtd);
set ds;
format eordt eslctdt eslbsdt eslmrtd date9.;
if upcase(dsscat) in("END OF RADIOGRAPHIC FOLLOW-UP");
eslctdt =input(eslctdt,yymmdd10.);
eslbsdt =input(eslbsdt,yymmdd10.);
eslmrtd =input(eslmrtd,yymmdd10.);
DCRREAS=dsdecd;
if nmiss(eslctdt, eslbsdt, eslmrtd) lt 3 then eordt=max( of eslctdt, eslbsdt, eslmrtd );
run;

proc sort data = __eordt;
    by usubjid eordt;
run;

data __eordt;
set __eordt;
where eordt ne .;
by usubjid eordt;
if last.usubjid;
run;

proc datasets lib=work nolist;
    change __dm=__dm;
run;
quit;

proc sort data = __dm;
    by usubjid;
run;

```

```

proc sort data = __CRF;
  by usubjid;
run;

proc sort data = __EOTDCDT;
  by usubjid;
run;

proc sort data = __EOTDCDT;
  by usubjid;
run;

proc sort data = __LOCACTDT;
  by usubjid;
run;

proc sort data = __SYSACTDT;
  by usubjid;
run;

proc sort data = __TRTAEDT;
  by usubjid;
run;

proc sort data = __TRTCEDT;
  by usubjid;
run;

proc sort data = __TRTEDT;
  by usubjid;
run;

proc sort data = __TRTEEDT;
  by usubjid;
run;

proc sort data = __EORDT nodupkey;
  by usubjid;
run;

data __dsx (keep=studyid usubjid dsxdt) ;
  set sdtmdata.ds;
  if dsscat = 'RE-CONSENT OR CONSENT WITHDRAWAL' and index(dsterm,'WITHDREW FULL CONSENT FROM ALL STUDY
INTERVENTIONS AND NON-INTERVENTIONAL STUDY ASSESSMENTS.') > 0 then do;
    if length(dsstdtc) ge 10 then dsxdt = input(substr(dsstdtc,1,10),yymmdd10.);
    output __dsx;
  end;
run;

proc sort data=__dsx;
  by usubjid;
run;

/**
%merge_supp(domain=cm, libname=sdtmdata);
%merge_supp(domain=pr, libname=sdtmdata);

data npact;
  merge __trtend (keep= studyid usubjid trtedt)
        cm      (in=cm keep= studyid usubjid cmstdtc cmcat cmtype
                  where= (cmcat='CONCOMITANT AND SUBSEQUENT NON-RADIATION ANTI-CANCER THERAPY' and cmtype='SYSTEMIC'));
  by studyid usubjid;
  if cm;

```

```

run;

data sprod;
  merge __trtend (keep= studyid usubjid trtedt)
        pr      (in=pr);
  by studyid usubjid;
  if pr;
run;

%xl313imp (indsn=sprod, indate=prstdtc, refdt=trtedt, conmed_npact=y);

data raddt;
  set sprod;
  where prcat='CONCOMITANT AND SUBSEQUENT RADIATION THERAPY' and rasityp ne 'BONE' and visit ne 'SCREENING' and
  PRINDC='DISEASE UNDER STUDY';
run;
%psort (ds=raddt, out=raddt2, where=%str(prstdtc ne ' '), key= prstdtc, first_last=first);

data surgdt;
  set sprod;
  where prcat='CONCOMITANT AND SUBSEQUENT SURGERIES AND PROCEDURES' and csitl='Y' and visit ne 'SCREENING' ;
run;
%psort (ds=surgdt, out=surgdt2, where=%str(prstdtc ne ' '), key= prstdtc, first_last=first);
***/

*PN -----*;
*PN END OF ADSL DERIVATIONS, MERGE ALL DATASETS BELOW AND COMPARE *;
*PN -----*;

proc sort data = sdtmdata.pr out = prpg nodupkey;
  by usubjid PRTRT PRSTDTC;
  where PRCAT='SURGERY AND OTHER PROCEDURES HISTORY' and PRLOC='PROSTATE GLAND';
run;

proc freq data =prpg noprint;
  table usubjid/ out= prpgout ;
run;

data __prpgout;
  length NPSURGR1 $20;
  set prpgout;
  by usubjid;
  npsurg = count;
  NPSURGR1 = put (count,1.);
  if count >= 3 then NPSURGR1 = '>=3';
run;

proc sort data=__dm;
  by usubjid;
run;

proc sort data = odsdata.randomdo out = __randomdo (keep=usubjid armed);
  by usubjid;
run;

proc sort data = sdtmdata.ds out = dsfu (keep= usubjid dsstdtc);
  where DSTERM="LOST TO FOLLOW-UP" and DSSCAT in ('END OF SURVIVAL FOLLOW-UP','END OF RADIOGRAPHIC FOLLOW-
  UP');
  by usubjid;
run;

data __dsfu (keep = usubjid LTFUDT);
  attrib LTFUDT format = date9. label ="Date of Lost to Follow Up";
  set dsfu;

```

```

    by usubjid;
    if dsstdtc ne '' then LTFUDT = input (dsstdtc , is8601da.);
run;

```

```

data all;
  merge __dm(in=dm) __aedthdt __dsx __dcrreas __diag __dthcaus __dthcgr1 __sysactdt __dcsreas __gr5relfl __eosdt __dsfu __;
  ;
  by usubjid;
if dm;
  attrib
    TRT01PD length=$25      label='Dummy TRT01P'
    TRT01AD length=$25      label='Dummy TRT01A'
    EOTDCODT length=8       label='Date of Last Dose Decision Ongoing, Core' format=date9.
    EOAODCDT length=8       label='Date of Last Dose Dec Ongo (Atez, Core)' format=date9.
    EOAODT length=8         label='Date of Last Dose Ongo (Atez, Core)' format=date9.
    EOCODCDT length=8       label='Date of Last Dose Dec Ongo (Cabo, Core)' format=date9.
    EOBOCDT length=8        label='Date of Last Dose Dec Ongo (ARBI)' format=date9.
    EOEODCDT length=8       label='Date of Last Dose Dec Ongo (ENZO)' format=date9.
    EOPOCDT length=8        label='Date of Last Dose Dec Ongo (PRED)' format=date9.
    EOECASDT length=8       label='Date of Start of SOP (Ext, Core, Atezo)' format=date9.
    EOECSDT length=8       label='Date of Start of SOP (Ext, Core, Combo)' format=date9.
    EOECMSDT length=8       label='Date of Start of SOP (Ext, Core, Mono)' format=date9.
    EOSOBEDT length=8       label='Date of End of SOP (Standard, Core)' format=date9.
    EOECAEDT length=8       label='Date of End of SOP (Ext, Core, Atezo)' format=date9.
    EOECEDT length=8       label='Date of End of SOP (Ext, Core, Combo)' format=date9.
    EOECMEDT length=8       label='Date of End of SOP (Ext, Core, Mono)' format=date9.

    TRCRDURD length=8       label='Total Treatment Duration, Core (Days)'
    TRCRDURW length=8       label='Total Treatment Duration, Core (Weeks)'
    TRCRDURM length=8       label='Total Treatment Duration, Core (Months)'
    TRTXDURD length=8       label='Total Treatment Duration, XVR (Days)'
    TRTXDURW length=8       label='Total Treatment Duration, XVR (Weeks)'
    TRTXDURM length=8       label='Total Treatment Duration, XVR (Months)'
    TRTDURD length=8        label='Total Treatment Duration (Days)'
    TRTDURW length=8        label='Total Treatment Duration (Weeks)'
    TRTDURM length=8        label='Total Treatment Duration (Months)'
    TRTADURD length=8       label='Total Atezolizumab Duration (Days)'
    TRTCDURD length=8       label='Total Cabozantinib Duration (Days)'
    TRTCDURM length=8       label='Total Cabozantinib Duration (Months)'
    TRTSDURD length=8       label='Total Sorafenib Duration (Days)'
    TRTSDURM length=8       label='Total Sorafenib Duration (Months)'
    LSTALVDT length=8       label='Last Known Alive' format=date9.
    STRATAV length=$200     label='Strata from Verification Source'

    DTHDT length=8          label='Date of Death' format=date9.
    DTHDTF length=$1        label='Date of Death Imputation Flag'
    DTHUNFDT length=8       label='Date of Death Unfiltered' format=date9.
    DTHUNDTF length=$1      label='Date of Death Unf Imp Flag'
    DTHDY length=8          label='Relative Day of Death'
    DTHSL0DY length=8       label='Day of Death Rel to Last Non-Zero Dose'
    DTHPER length=$50       label='Death Period (30 Days)'
    DTHPER2 length=$50      label='Death Period (100 Days)'
    DURNRAD length=8        label='Dur Lst Non-Rad Tx (Mnths)'
    DNRADGR1 length=$15     label='Dur Lst Non-Rad Tx Group 1'
    FNHTGR1 length=$20.     format=$10. label='First NHT Collapsed Group'
    DOCGR1 length=$10.       format=$10. label='Prior Docetaxel Collapsed Group'
    DSGR1 length=$10.        format=$10. label='Pres of Liver meta Collapsed Group'
    MSAFFL length=$1.        format=$1. label='Modified Safety Population Flag'
    MITTFL length=$1.        format=$1. label='Modified ITT Population Flag'
    CUTRNKDT length=8        label='Date of 202nd Event Date' format=date9.
    RANDCDTM length=8        label='Randomization Datetime' format=DateTime19.
    CUTRDDTM length=8        label='Rand Datetime of 202nd Event Date' format=Date9.
    DURNRAD length=8        label='Dur Lst Non-Rad Tx (Mnths)' format=best20.

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```

DNRADGR1 length=$15.      format=$15.      label="Dur Lst Non-Rad Tx Group 1"
DCSFL      length=$1.      format=$1.      label="Reason for Discont. From Surv FUP Flag"
DCRFL      length=$1.      format=$1.      label="Reason for Discont. From Radio FUP Flag"
;
    if saffl = 'Y' and dcsreas ne '' then dcsfl = 'Y';
    else if saffl = 'Y' and dcsreas eq '' then dcsfl = 'N';
    if saffl = 'Y' and dcrreas ne '' then dcrfl = 'Y';
    * else dcrfl = 'N';
CUTRNKDT = "12dec2022"d;
RANDCDTM = input (RANDCDTC,is8601dt.);
    CUTRDDTM = 1975755005;
DURNRADM = (NRAEDT-NRADSdT)/30.4375;
if . < DURNRADM < 1 then DNRADGR1 = '< 1';
if 1 le DURNRADM < 3 then DNRADGR1 = '>= 1 to 3';
    if 3 le DURNRADM < 6 then DNRADGR1 = '>= 3 to 6';
    if 6 le DURNRADM then DNRADGR1 = '>= 6';
if SAFFL='Y' /** and PITTFLL='Y' **/ and UKRSUFL ^= 'Y' then MSAFFL = 'Y';
    else MSAFFL = 'N';
    if RANDDT ^= . and UKRSUFL ^= 'Y' then MITTFLL = 'Y';
    Else MITTFLL = 'N';
    if armed = 'ABI+PRED\ENZA' then do;
        trt01pd = 'Second NHT';
    trt01pdn = 1;
        trt01ad = 'Second NHT';
    trt01adn = 1;
    end;
if armed = 'CABO+ATEZO' then do;
    trt01pd = 'Cabozantinib+Atezolizumab';
    trt01pdn = 0;
        trt01ad = 'Cabozantinib+Atezolizumab';
    trt01adn = 0;
    end;

if lstalvdt > cutdt then lstalvdt=cutdt ;
if . < lstalvdt <= randdt then lstalvdt = randdt;
    if lstalvdt = . and trtsdt = . and randdt ne . then lstalvdt = randdt;
if length(dthdte) ge 10 then dthdtn = input(substr(dthdte,1,10),yymmdd10.);
dddd=substr(dthdte,9,2);
ddmm=substr(dthdte,6,2);
ddyy=substr(dthdte,1,4);
dddd=substr(dthdte,9,2);
ddmm=substr(dthdte,6,2);
ddyy=substr(dthdte,1,4);
if dthdtn ne . then do;
    %dtimpute(outvar=dthdtn ,day=dddd, month=ddmm, year=ddyy,flagvar=dthundtf,align=b);
end;

if dthdte ne . and LTRTOGDT ne . then dthsl0dy = DTHDT - LTRTOGDT + 1;
if dthfl = 'Y' then do;
    if ^missing(dthdtn) then dthunfdt = dthdtn;
    if missing(dthdtn) then do;
        if LSTALVDT ne . then dthunfdt = LSTALVDT; *** +1 ;

        if length(deathc) <7 then do;
            dthundtf='Y';
            dthdtf='Y';

            end;
            * if length(deathc) =7 then do;
            if dddd = '' and ddmm ne '' then do;

            dthundtf='D';
            dthdtf='D';

            end;

            if LSTALVDT eq . and aedthdtn ne . then dthunfdt = aedthdtn;
end;

```



```

end;

if not missing(dthunfdt) then dthdt = dthunfdt;
if dthunfdt gt cutdt then dthdt = .;
* if not missing(dthdt) then dthdtf=dthunfdt;
if nmiss(dthdt, trtsdt)=0 then dthdy = dthdt - trtsdt + 1;
* if nmiss(dthdt, trtedt)=0 then dthsl0dy = dthdt - trtedt + 1;
* if dthdt ne . and LTRTOGDT ne . then dthsl0dy = DTHDT - LTRTOGDT + 1;

format LTRTOGDT date9.;
if not missing(trtsdt) then do;
if not missing(trtedt) then LTRTOGDT=trtedt;
else if not missing(dthdt) then LTRTOGDT= min(dthdt, cutdt);
else LTRTOGDT= cutdt;
end;

if nmiss(dthdt,ltrtogdt)=0 and (((dthdt - ltrtogdt + 1)) <= 30) then dthper = 'Death <= 30 days within last dose';
if nmiss(dthdt,ltrtogdt)=0 and (((dthdt - ltrtogdt + 1)) > 30) then dthper = 'Death > 30 days after last dose';

if nmiss(dthdt,ltrtogdt)=0 and (((dthdt - ltrtogdt + 1)) <= 100) then dthper2 = 'Death <= 100 days within last dose';
if nmiss(dthdt,ltrtogdt)=0 and (((dthdt - ltrtogdt + 1)) > 100) then dthper2 = 'Death > 100 days after last dose';

if not missing(TRTBEDT) and missing(EOBDCDT) then TRTBEDT=.;
if not missing(TRTPEDT) and missing(EOPDCDT) then TRTPEDT=.;
if not missing(TRTEEDT) and missing(EOEDCDT) then TRTEEDT=.;

if not missing(eotdcodt) and safl = 'Y' then eotdcodt = eotdcodt;
else if not missing(dthdt) and safl = 'Y' then eotdcodt = min(dthdt,cutdt);
else IF DTHDT = . and safl = 'Y' then eotdcodt = cutdt;

format FSBACTDT date9.;
* if n(locactdt,sysactdt,prsrdt,prssptldt)<=4 then FSBACTDT = min(locactdt,sysactdt,prsrdt,prssptldt);
if n(locactdt,sysactdt,prsrdt,prssptldt)<=4 then FSBACTDT = min(sysactdt,prsrdt,prssptldt);
* FSBACTDT = min(of locactdt,sysactdt,prsrdt,prssptldt);

if trt01an = 0 then do;
if not missing(eoadcdt) and safl = 'Y' then eoadcdt = eoadcdt;
else if not missing(dthdt) and safl = 'Y' then eoadcdt = min(dthdt,cutdt);
else if safl = 'Y' and dthdt = . then eoadcdt = cutdt;
end;

if trt01an = 0 then do;;
if not missing(eocodedt) and safl = 'Y' then eocodedt = TRTCEDT;
else if not missing(dthdt) and safl = 'Y' then eocodedt = min(dthdt,cutdt);
else if safl = 'Y' and dthdt = . then eocodedt = cutdt;
if safl ne 'Y' then eocodedt = .;
end;

if trt01an = 1 then do;;
if not missing(eobcdt) and safl = 'Y' and TRTNHT='Abi+Pred' then eobcdt = TRTBEDT;
else if not missing(dthdt) and safl = 'Y' and TRTNHT='Abi+Pred' then eobcdt = min(dthdt,cutdt);
else if safl = 'Y' and dthdt = . and TRTNHT='Abi+Pred' then eobcdt = cutdt;
* if safl ne 'Y' then eobcdt = .;
end;

if trt01an = 1 then do;;
if not missing(eoecodt) and safl = 'Y' and TRTNHT='Enza' then eoecodt = TRTEEDT;
else if not missing(dthdt) and safl = 'Y' and TRTNHT='Enza' then eoecodt = min(dthdt,cutdt);
else if safl = 'Y' and dthdt = . and TRTNHT='Enza' then eoecodt = cutdt;
* if safl ne 'Y' then eoecodt = .;
end;

if trt01an = 1 then do;;
if not missing(eopcdt) and safl = 'Y' and TRTNHT='Abi+Pred' then eopcdt = TRTPEDT;
else if not missing(dthdt) and safl = 'Y' and TRTNHT='Abi+Pred' then eopcdt = min(dthdt,cutdt);
else if safl = 'Y' and dthdt = . and TRTNHT='Abi+Pred' then eopcdt = cutdt;
* if safl ne 'Y' then eopcdt = .;
end;

```

```

* if nmiss(trtaedtx,dthdt,cutdt)=0 then eoaodt = min(trtaedtx+21,dthdt,cutdt);
  if nmiss(trtaedtx,dthdt,cutdt) <= 2 and trtaedtx ne . then eoaodt = min(trtaedtx,dthdt,cutdt);

if not missing(eosdcddt) then eosodcdt = eosdcddt;
else if not missing(dthdt) then eosodcdt = min(dthdt,cutdt);
else eosodcdt = cutdt;
if safl1 ne 'Y' then eosodcdt = .;

if not missing(tr01edt) then do;
  if not missing(trtaedt) then eoecasdt = trtaedt + 30;
  if eoecasdt gt cutdt gt .z then eoecasdt = .;
  if eoecasdt gt dthdt gt .z then eoecasdt = .;
  if eoecasdt gt wdcfdt gt .z then eoecasdt = .;
end;

if not missing(tr01edt) then do;
  if trt01p ^= 'Cabozantinib+Atezolizumab' then EOECSSDT = tr01edt + 30;
  if EOECSSDT gt cutdt gt .z then EOECSSDT = .;
  if EOECSSDT gt dthdt gt .z then EOECSSDT = .;
  if EOECSSDT gt wdcfdt gt .z then EOECSSDT = .;
end;

if not missing(tr01edt) then do;
  if trt01p ^= 'Cabozantinib+Atezolizumab' then eoecmsdt = tr01edt + 30;
  if eoecmsdt gt cutdt gt .z then eoecmsdt = .;
  if eoecmsdt gt dthdt gt .z then eoecmsdt = .;
  if eoecmsdt gt wdcfdt gt .z then eoecmsdt = .;
end;

EOSOBSDT=TRTSDDT;

if trtedt ne . then eoecsdtdt = trtsddt;

if not missing(eosobddt) then eosobddt = min((trtedt+30),dsxdt,DTHUNFDT,cutdt);
if trtedt ne . then trtedtdt = trtedt + 100;
if eoecsdtdt ne . then eoecsdtdt = min(trtedtdt,dsxdt,dthunfdt,cutdt);
if not missing(eoecmsdt) then eoecmedt = min((tr01edt+100),(xvrddt-1),__dsstdtc__withdrew,dthdt,cutdt);
  if not missing(eoecasdt) then eoecaedt = min((trtaedt+100),__dsstdtc__withdrew,dthdt,cutdt);

if nmiss(eotdcodt,trtsdt)=0 then do;
  trcrdurd = eotdcodt - trtsdt + 1;
  trcrdurw = trcrdurd / 7;
  trcrdurm = trcrdurd / 30.4375;
end;
if nmiss(eotxddd, tr02sdt)=0 then do;
  trtxdurd = eotxddd - tr02sdt + 1;
  trtxdurw = trtxdurd / 7;
  trtxdurm = trtxdurd / 30.4375;
end;

  if trt01pn = 0 then do;
    TRTDURD = max(EOTDCODT,TRTAEDT)-TRTSDDT +1;
    TRTDURw = (max(EOTDCODT,TRTAEDT)-TRTSDDT +1)/7;
    TRTDURm = (max(EOTDCODT,TRTAEDT)-TRTSDDT +1)/30.4375;
  end;
if trt01pn = 1 then do;
  TRTDURD = EOTDCODT-TRTSDDT +1;
  TRTDURw = (EOTDCODT-TRTSDDT +1 )/7;
  TRTDURm = (EOTDCODT-TRTSDDT +1 )/30.4375;
end;

if nmiss(trtaedt,trtsdt)=0 then trtadurd = trtaedt - trtsdt +1;
if nmiss(trtaedt,trtsdt)=0 then trtadurm = (trtaedt - trtsdt +1)/30.4375;

```

```

if nmiss(eocdcdt,trtesdt)=0 then trtedurd = eocdcdt - trtesdt +1;
if nmiss(eocdcdt,trtesdt)=0 then trtedurm = (eocdcdt - trtesdt +1)/30.4375;
if nmiss(eobdcdt,trtbsdt)=0 then trtburd = eobdcdt - trtbsdt +1;
if nmiss(eobdcdt,trtbsdt)=0 then trtburm = (eobdcdt - trtbsdt +1)/30.4375;
    if nmiss(eopdcdt,trtpsdt)=0 then trtpdurd = eopdcdt - trtpsdt +1;
if nmiss(eopdcdt,trtpsdt)=0 then trtpdurm = (eopdcdt - trtpsdt +1)/30.4375;
    if nmiss(eoedcdt,trtesdt)=0 then trtedurd = eoedcdt - trtesdt +1;
if nmiss(eoedcdt,trtesdt)=0 then trtedurm = (eoedcdt - trtesdt +1)/30.4375;

if nmiss(eocodedt,trtesdt)=0 then trocdurd = eocodedt - trtesdt + 1;
if not missing(trocdurd) then trocdurm = (eocodedt - trtesdt + 1)/ 30.4375;
    if nmiss(eoaodedt,trtasdt)=0 then troadurd = eoaodedt - trtasdt + 1;
if not missing(troadurd) then troadurm = (eoaodedt - trtasdt + 1)/ 30.4375;
    if nmiss(eobodedt,trtbsdt)=0 then trobdurd = eobodedt - trtbsdt + 1;
if not missing(trobdurd) then trobdurm = (eobodedt - trtbsdt + 1)/ 30.4375;
    if nmiss(eoecodedt,trtesdt)=0 then troedurd = eoecodedt - trtesdt + 1;
if not missing(troedurd) then troedurm = (eoecodedt - trtesdt + 1)/ 30.4375;
    if nmiss(eopodedt,trtpsdt)=0 then tropdurd = eopodedt - trtpsdt + 1;
if not missing(tropdurd) then tropdurm = (eopodedt - trtpsdt + 1)/ 30.4375;

    if PSADSDT ne . then PSADDURM=      (RANDDT- PSADSDT )/30.4375;
if PSADSDT ne . then PSADDURW=      (RANDDT- PSADSDT )/7;

    if RHTXSDT ne . then RHTXDURM=      (RANDDT- RHTXSDT )/30.4375;
if RHTXSDT ne . then RHTXDURW=      (RANDDT- RHTXSDT )/7;

    if PSURSDT ne . then PSURDURM=      (RANDDT- PSURSDT )/30.4375;
if PSURSDT ne . then PSURDURW=      (RANDDT- PSURSDT )/7;

    if RDPRSDT ne . then RDPRDURM=      (RANDDT- RDPRSDT )/30.4375;
if RDPRSDT ne . then RDPRDURW=      (RANDDT- RDPRSDT )/7;

if missing(eligibfl) then eligibfl = 'Y';
if missing(ittfl) then ittfl = 'N';
    if missing(pittfl) then pittfl = 'N';
if missing(opittfl) then opittfl = 'N';
if SAFFL='Y' and PITTFLL='Y' then PSAFFL='Y';
else PSAFFL= 'N';
*else PSAFFL=";

if missing(PNRDTXFL) then do;
    PNRDTXFL='N';NPNRADTX=0;NPNRDGR1='0';
end;

if missing(PRADTXFL) then do;
    PRADTXFL='N';NPRADTX=0;NPRADGR1='0';
end;

if DTHDT>EOECAEDT>. then DTHAEAFLL='Y'; else DTHAEAFLL= 'N';
if DTHDT>EOECCEDT>. then DTHAECFL='Y'; else DTHAECFL= 'N';
***Still Pending ***;
if DTHDT>max (of EOECCEDT,EOECAEDT, EOECCEDT, EOECMEDT/*, EOEXAEDT, EOEXCEDT*/) >. then DTHAESFL='Y'; else
DTHAESFL= 'N';

TRTAXSDT = .;
TRTCXSDT = .;
EOXDCODT = .;
EOSSXSDT = .;
EOEXASDT = .;
EOEXCSDT = .;
EOSSXEDT = .;
EOEXAEDT = .;
EOEXCEDT = .;

```

```

if RACE = "WHITE" then racegr1 = "White";
else if RACE in ( "Black or African American","BLACK OR AFRICAN AMERICAN") then racegr1 = "Black/African American" ;
else if RACE = "ASIAN" then racegr1 = "Asian";
else racegr1 ="Other"; * "Rest of the races reported/Not Reported";

```

```

if dthdt ne . and LTRTOGDT ne . then dthsl0dy = DTHDT - LTRTOGDT + 1;

```

```

    if nradedt = . then nradedf = '';
    if TRTeEDT = . then TRTeEDTf = '';
    if TRTEDT = . then TRTEDTf = '';
    if trt01pn = 0 then trtnht = '';
    * if safl = 'Y' and DCSREAS ne '' then DCSFL = 'Y';
    * else if safl = 'Y' and DCSREAS eq '' then DCSFL = 'N';

```

```

if safl = 'Y' and DCRREAS ne '' then DCRFL = 'Y';
else if safl = 'Y' and DCRREAS eq '' then DCRFL = 'N';
if PNRTMCFL ^ = 'Y' then PNRTMCFL = 'N';
if NPNRTXMC < 1 then NPNRTXMC = 0;
if NPNRMGR1 = '' then NPNRMGR1 = '0';

```

```

    DURNRADM = (NRADEDT-NRADSDT)/30.4375;

```

```

if . lt DURNRADM lt 1 then DNRADGR1 = '< 1';
    if 1 le DURNRADM lt 3 then DNRADGR1 = '>= 1 to < 3';
        if 3 le DURNRADM lt 6 then DNRADGR1 = '>=3 to < 6';
            if DURNRADM ge 6 then DNRADGR1 = '>=6';

```

```

    if region1 = '' then region1 = 'MISSING';
    if dscr = '' and randdt ne . then dscr = 'No';
    if doccrf = '' and randdt ne . then doccrf = 'No';

```

```

    cut76dt = cutdt;
    dth76dt = dthunfdt;
    lst76adt = lstalvdt;
    dth76dtf = dthunfdtf;
    ls76adtf = lstalvdtf;

```

```

    if dth76dt > cutdt then dth76dt = .;

```

```

    If (LSTVISDT > CUTDT > . or LSTVISDT > DTHDT > .) then LSTVISDT= min(DTHDT, CUTDT);

```

```

if rfxendtc > &cutdt then rfxendtc = &cutdt.;

```

```

    if pittfl = 'Y' then do;

```

```

        FNHTGR1 = 'mCSPC/m0CRPC/mCRPC';

```

```

    DOCCR1 =DOCIXRS;

```

```

    DSGR1 =DSIXRS;

```

```

    end;

```

```

run;

```

```

proc sort data = __WDCFDT out=dup nodupkey;
    by usubjid;
run;

```

```

proc sort data =all dupout=dup nodupkey;
    by usubjid;
run;

```

```

proc print data =all ;
    title 'check dthunf';
    where usubjid = '184315-1563-3632';
run;

```

```

data adsl;

```

```

    %attrib_adsl;

```

```

    set all;

```

```

    keep STUDYID USUBJID SUBJID SITEID COUNTRY STRATAR STRATARN DSIXRS DOCIXRS FNHTIXRS STRATAV STRATAVN
    DSCRf DOCCRf FNHTCRf PROTvs REGION1

```

```

AGE AGEU AGEGR1 AGEGR2 AGEGR3 SEX RACE RACEOTH RACEMULT RACEGR1 ETHNIC SAFFL PSAFFL ITTFL PITTF
ELIGIBFL UKRSUFL ARM ACTARM SCRNFLL
TRT01P TRT01PN TRT01A TRT01AN TRT01PD TRT01PDN TRT01AD TRT01ADN TRTNHT PGICYN RFICDT RANDDT TRTSDT
TRTSDTM TRTASDT TRTCSDT TRTBSDT TRTPSDT
TRTESDT RFXENDTC TRTEDT TRTEDTF TRTETM TRTEDTM DTH76DTF LS76ADTF TRTAEDT TRTAEDTF TRTCEDT
TRTCEDTF TRTBEDT TRTBEDTF TRTPEDT TRTPEDTF TRTEEDT TRTEEDTF LTRTOGDT
EOADCDT EOCDT EOBDCDT EOPDCDT EOEDCDT EOTDCDT EOTDCODT EOAODCDT EOAODT EOCODCDT EOBODCDT
EOPODCDT EOEODCDT WDCFDT LTFUDT LSTALVDT LSALVDTF
LST76ADT LS76ADTF DTHDT DTHDTF DTHDTC DTHUNFDT DTHUNDTF DTHDY DTH76DT DTH76DTF DTHSL0DY DTHPER
DTHPER2 DTHAESFL EOSOBSDT EOECSDT EOSOBDT
EOECEDT CUTDT CUT76DT SYSACTDT SYSACTD SYSACTWK FSBACTDT TRTDURD TRTDURW TRTDURM TRTADURD
TRTADURM TRTCDURD TRTCDURM TRTBDURD TRTBDURM
TRTPDURD TRTPDURM TRTEDURD TRTEDURM TROADURD TROADURM TROCDURD TROCDURM TROBDURD
TROBDURM TROPDURD TROPDURM TROEDURD TROEDURM DCTREASA
DCTREASC DCTREASB DCTREASP DCTREASE DTHCAUS DTHCGR1 DTHASOSI GR5RELFL EOSRDTC EOSDT EOSDTF
DCSREAS DCSFL EORDT DCRREAS DCRFL LSTVISDT
WTBL WTBLGR1 HTBL BMIBL ECOGBL SMOKSTAT ALCHSTAT DIAGDT DIAGDTF DIAGDURD DIAGDURY NRADSDT
NRADSDTF NRAEDT NRAEDF NRADDURM PSADSDT PSADSDTF
PSADDURM PSADDURW RDPRSDT RDPRSDTF RDPRDURM RDPRDURW RHTXSDT RHTXSDTF DURNRADM DNRADGR1
RHTXDURM RHTXDURW PSURSDT PSURSDTF PSURDURW NPSURG NPSURGR1 PNRDTXFL NPNRADTX NPNRDGR1
PNRTMCFL NPNRTXMC NPNRMGR1 PRADTXFL NPRADTXNPRADGR1 FNHTGR1 DOCGR1 DSGR1
opittfl msaffl mitfl LTFUDT CUTRNKDT RANDCDTM CUTRDDTM DURNRADM DNRADGR1 dcsfl dcrfl;

run;

proc sort data=adsl nodupkey;
    by _all_;
run;

*PN -----*;
*PN Create permanent dataset for analysis *;
*PN -----*;

data anaxl.&dsname(
    type = ANALYSIS
    label = "Subject-Level Analysis Dataset"
    sortedby = &sortby
);
retain &sortby subjid ;

set &dsname ;

run ;

%mktitles();

proc sort data = anadata.adsl out=adsl_P;
    by usubjid;
run;

data adsl_p (drop=TRTEDTMx);
set adsl_p (rename=(TRTEDTM=TRTEDTMx));
by usubjid;
TRTEDTM = datepart(TRTEDTMx);
run;

proc compare base=adsl_p compare=anaxl.adsl (drop = TRTETM) maxprint=10000 listall;
id usubjid;
run;
%mkpages();

```

```

data anaxl.&dsname(
    type    = ANALYSIS
    label   = "Subject-Level Analysis Dataset"
    sortedby = &sortby
);
%attrib _adsl;

set &dsname ;
run ;

/****

libname export xport "../export/&anadate/&dsname..xpt";

data export.&dsname(replace=yes);
    set anaxl.&dsname ;
run;
****/

%*-----;
%* QC comparison          ;
%*-----;

data adsl;
    set anadata.adsl;
    * keep usubjid EOADCDT EOBDCDT EOEDCDT EOCDCDT EOPDCDT dthdt cutdt;
    drop M    NPSURG NPSURGR1 PNRTMCFL NPNRTXMC NPNRMGR1 ;
    *format _all_;
    /* &block if usubjid="&subject"; */
run;

data v_adsl;
    set anaxl.adsl;
    drop trtetm trtedtm CNTRYGR1 REGIONI REGNIGR1 ETIOIXRS REGIONC ETIOCRF TRTSEQP TRT02P TRT02PN TRT02A
    TRT02AN XVRDT RFIC2DT TRTSSDT
        TRTAXSDT TRTCXSDT TR01SDT TR01STM TR01SDTM TR01EDT TR01ETM TR01EDTM TR02SDT TR02STM
    TR02SDTM TR02EDT TR02ETM
        TR02EDTM TRTSEDt TRTAXEDT TRTCXEDT EOSDCDT EOXADCDT EOXCDCDT EOTXDCDT
    EOXCDCDT EOSODCDT DSEVTADT DSEVTCDT DSEVTSdT DSEVXADT
        DSEVXCDT DTHAEAFD DTHAECFL EOSSXSDT EOECASDT EOECMSDT EOEXASDT EOEXCSDT
    EOSSXEDT EOECAEDT EOECMEDT EOEXAEDT EOEXCEDT TRCRDURD
        TRCRDURW TRCRDURM TRTXDURD TRTXDURW TRTXDURM TRTSDURD TROSDURD TROSDURM
    DCTREASS DCTRESXA DCTRESXC /* NPNRMGR1 NPNRTXMC PNRTMCFL NPSURGR1 NPSURG */ ;
run;

%mktitles();
proc compare base=adsl compare=v_adsl maxprint=10000 listall ;
    id usubjid;
    * var EOADCDT EOBDCDT EOEDCDT EOCDCDT EOPDCDT dthdt cutdt;
run;
%mkpages();

/****
%mktitles();
proc contents data=anaxl.adsl;
run;
%mkpages();
****/

/****

```

```

data PRNHTGR1 ;
  length PRNHTGR1 $20;
  set sdtmdata.cm;
  if CMCAT='HISTORY OF NON-RADIATION ANTI-CANCER THERAPY' and CMDECOD= 'ABIRATERONE' then PRNHTGR1 =
'ABIRATERONE' ;
  if CMCAT='HISTORY OF NON-RADIATION ANTI-CANCER THERAPY' and CMDECOD= 'ENZALUTAMIDE' then PRNHTGR1 =
'ENZALUTAMIDE' ;
  if CMCAT='HISTORY OF NON-RADIATION ANTI-CANCER THERAPY' and CMDECOD in ('APALUTAMIDE','DAROLUTAMIDE')
then PRNHTGR1 = 'OTHER' ;
run;

```

```

libname oldadsl "\\celerra03\SAS\stat\x1184\184315\dev\anadata\cro\20221219\archive\20230222";
libname newadsl "\\celerra03\SAS\stat\x1184\184315\dev\anadata\cro\20221219";

```

```

proc compare data =oldadsl.adsl compare =newadsl.adsl listall;
  id studyid usubjid;
run;

```

```

**/

```