CJUG ADaM Team

ADaM & Analysis Specific to Oncology

CDISC Japan User Group (CJUG) ADaM Team

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Biometrics Dept.
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Agenda

- Introduction of CJUG ADaM Team Deliverables
- Explanation of Oncology ADaM
- Explanation of Analysis Results Metadata
- Difference between TAUG BrCa and PrCa

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Introduction of CJUG ADaM Team Deliverables

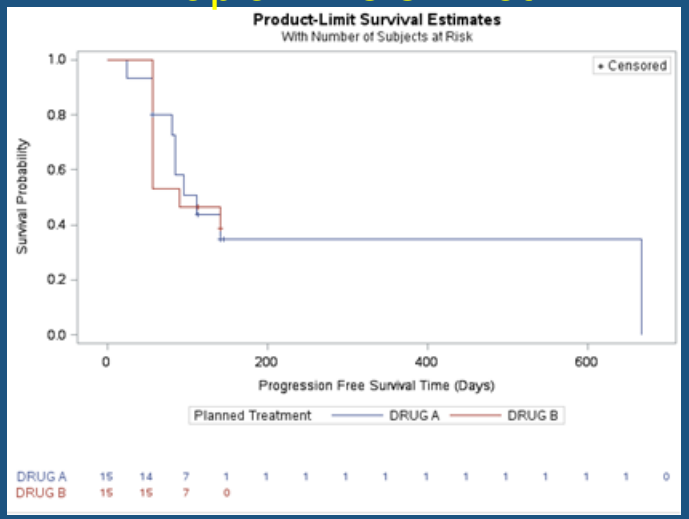
- This presentation based on 2015 CJUG ADaM / "ADaM & Analysis Specific to Oncology" sub-team deliverables.
  - Why oncology (solid tumor) region?
    - Established evaluate response to treatment (RECIST)
    - Limited TLFs for efficacy analysis
    - Released Therapeutic Area User Guide for Breast Cancer (TAUG BrCa)
    - Fulfilling ADaM samples (e.g. ADTTE)

Introduction of CJUG ADaM Team Deliverables

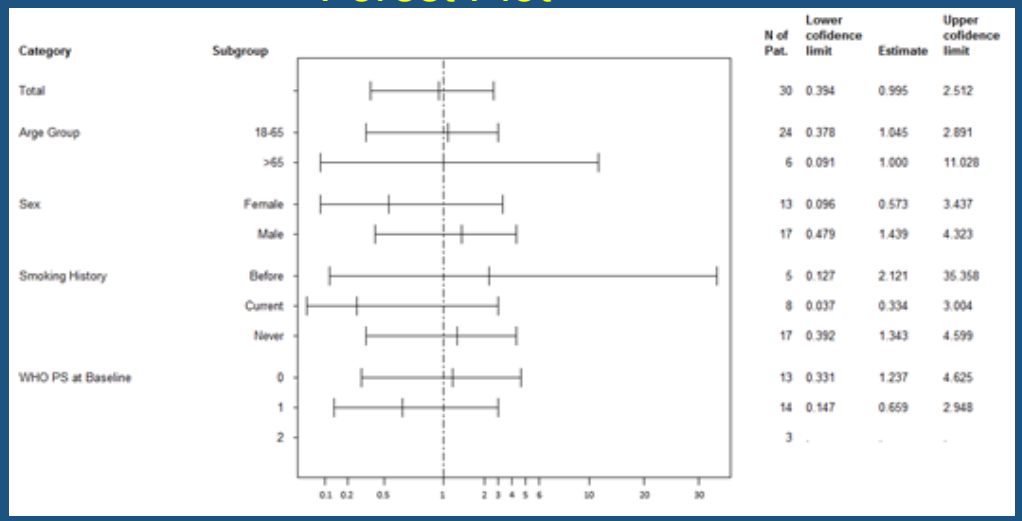
- TFLs mock
  - Generally create for efficacy analysis in oncology region
    - Survival time analysis (Kaplan-Meier method, life table, cox/logistic regression)
    - Waterfall plot
    - Response rate of treatment
    - Forest plot
    - Spider plot

Introduction of CJUG ADaM Team Deliverables

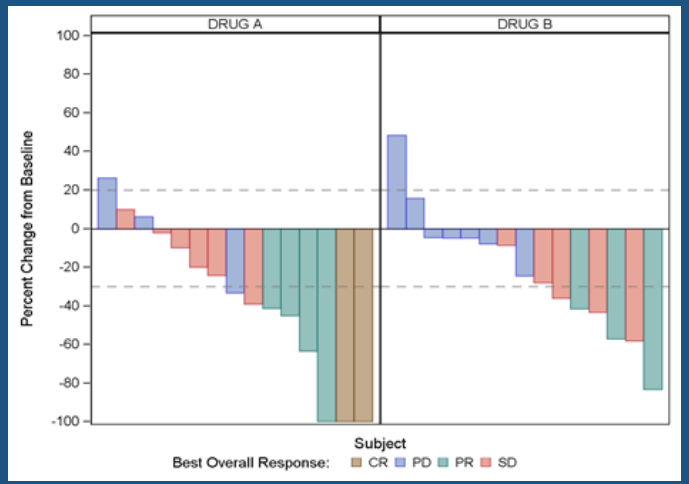
Kaplan-Meier Plot



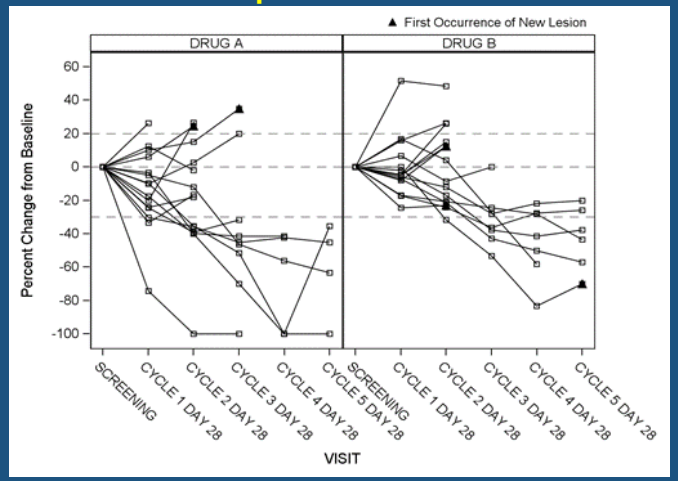
Forest Plot



Waterfall Plot



Spider Plot



Introduction of CJUG ADaM Team Deliverables

Survival Time Analysis

	DRUG A N=xxx	DRUG B N=xxx
Subjects with Events	xxx (xxx.x %)	xxx (xxx.x %)
Subjects Censored	xxx (xxx.x %)	xxx (xxx.x %)
Time to Event (days)		
Median (95% CI)	xxx.x [xxx.x , xxx.x]	xxx.x [xxx.x , xxx.x]
25% and 75%-ile	xxx.x , xxx.x	xxx.x , xxx.x
Range	xxx - xxx	xxx - xxx
P-value		x.xxxxx
Hazard Ratio		x.xx
95% CI		[x.xx , x.xx]
P-value		x.xxxxx
1 year Duration		
Subjects Remaining at Risk	xxx	xxx
Event Free Rate	x.xx	x.xx
95% CI for Rate	[x.xx , x.xx]	[x.xx , x.xx]

Kaplan-Meier Method

cox regression

Effect/Covariate	DRUG A No. of Patients	DRUG B No. of Patients	Hazard Ratio	95%CI	p-Value
Covariate 1					
xxxxxx	xxx	xxx	x.xx	[x.xx; x.xx]	0.xxxx
xxxxxx	xxx	xxx	x.xx	[x.xx; x.xx]	0.xxxx
Covariate 2					
xxxxxx	xxx	xxx	x.xx	[x.xx; x.xx]	0.xxxx
xxxxxx	xxx	xxx	x.xx	[x.xx; x.xx]	0.xxxx
Covariate 3					
xxxxxx	xxx	xxx	x.xx	[x.xx; x.xx]	0.xxxx
xxxxxx	xxx	xxx	x.xx	[x.xx; x.xx]	0.xxxx

cox regression

Effect/Covariate	DRUG A No. of Patients	DRUG B No. of Patients	Odds Ratio	95%CI	p-Value
Covariate 1					
xxxxxx	xxx	xxx	x.xx	[x.xx; x.xx]	0.xxxx
xxxxxx	xxx	xxx	x.xx	[x.xx; x.xx]	0.xxxx
Covariate 2					
xxxxxx	xxx	xxx	x.xx	[x.xx; x.xx]	0.xxxx
xxxxxx	xxx	xxx	x.xx	[x.xx; x.xx]	0.xxxx
Covariate 3					
xxxxxx	xxx	xxx	x.xx	[x.xx; x.xx]	0.xxxx
xxxxxx	xxx	xxx	x.xx	[x.xx; x.xx]	0.xxxx

logistic regression

Treatment Group	Time Point	Subjects at Risk	Number of Events	Number of Censored Cases	KM-Estimates for Event Free Rate
DRUG A	Day 1	xxx	xxx	xxx	1.000 [x.xxx, x.xxx]
	1 Year	xxx	xxx	xxx	0.xxx [x.xxx, x.xxx]
	2 Years	xxx	xxx	xxx	0.xxx [x.xxx, x.xxx]
DRUG B	Day 1	xxx	xxx	xxx	1.000 [x.xxx, x.xxx]
	1 Year	xxx	xxx	xxx	0.xxx [x.xxx, x.xxx]
	2 Years	xxx	xxx	xxx	0.xxx [x.xxx, x.xxx]

life table

Introduction of CJUG ADaM Team Deliverables

Response Rete of Treatment

	DRUG A N=xxx	DRUG B N=xxx
Responder (CR + PR)	xx (xxx.x%)	xx (xxx.x%)
95% CI	[xx.x , xx.x]	[xx.x , xx.x]
Difference in Response Rate		xx.x
95% CI		[xx.x , xx.x]
P-value		x.xxxxx
Odds Ratio		x.x
95% CI		[x.xx , x.xx]
Best Response		
Complete Respnse (CR)	xx (xxx.x%)	xx (xxx.x%)
Partial Response (PR)	xx (xxx.x%)	xx (xxx.x%)
Stable Disease (SD)	xx (xxx.x%)	xx (xxx.x%)
Progressive Disease (PD)	xx (xxx.x%)	xx (xxx.x%)
Unknown	xx (xxx.x%)	xx (xxx.x%)

CJUG ADaM Team

Introduction of CJUG ADaM Team Deliverables

- SDTM datasets
  - Domains (DM, DS, SS, DD, CM, TU, TR, RS)
  - Created only required to efficacy analysis defined in TFL mock
- ADaM metadata (define.xml)
  - ADSL, ADTR*, ADRS*, ADEVENT#, ADTTE, ADRESP#

defined in TAUG-BrCa

* proposed by CJUG ADaM sub-team

Analysis Datasets for Study CJUG-ADaM-THEME3 (ADaM-IG 1.0)

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
ADEVENT	Data for the Time to Event Analyses	BASIC DATA STRUCTURE	One record per subject per evaluation	Analysis	STUDYID, USUBJID, PARAM, PARAMCD	adevent.xpt	Intermediate dataset for ADTTE.
ADRESP	Disease Response Analysis Dataset	BASIC DATA STRUCTURE	One record per subject per analysis parameter per Parameter Qualifier	Analysis	STUDYID, USUBJID, PARAM, PARAMCD	adresp.xpt	This dataset is created by RS (best overall response by Parameter Qualifier and RSTESTCD = 'OVRLRESP').
ADRS	Intermediate data for ADEVENT	ADAM OTHER	One record per subject per evaluation	Analysis	STUDYID, USUBJID, PARAM, PARAMCD	adrs.xpt	Intermediate dataset for response (RS.RSTESTCD =
ADSL	Subject Level Analysis	SUBJECT LEVEL ANALYSIS DATASET	One record per subject	Analysis	STUDYID, USUBJID	adsl.xpt	
ADTR	Tumor Results Analysis Dataset	BASIC DATA STRUCTURE	one or more records per subject, per evaluator, per analysis parameter, per analysis timepoint	Analysis	STUDYID, USUBJID, PARQUAL, PARAMN, AVISITN	adtr.xpt	
ADTTE	Time-to-Event Analysis Dataset	BASIC DATA STRUCTURE	One record per subject per analysis parameter	Analysis	STUDYID, USUBJID, PARAM, PARAMCD	adtte.xpt	

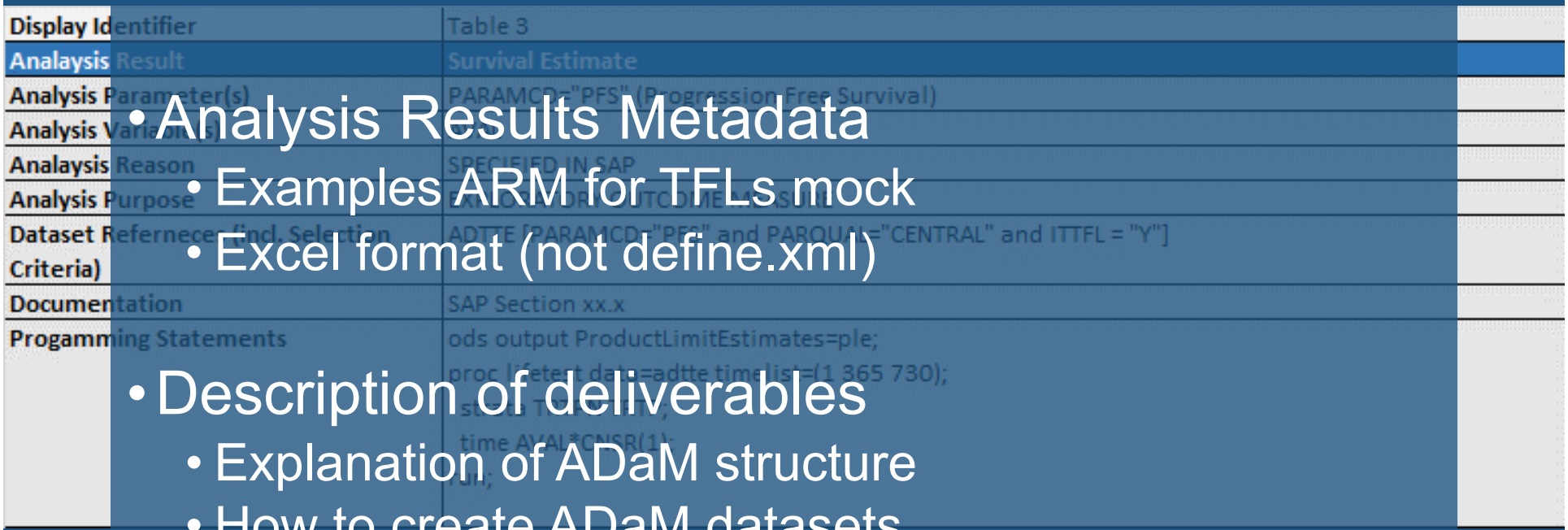
Go to the top of the define.xml

Data for the Time to Event Analyses (ADEVENT) Variable-level Metadata

Variable	Label	Type	Length / Significant Digits	Controlled Terms or Format	Source/Derivation/Comment
STUDYID	Study Identifier	text	200		Predecessor: ADSL.STUDYID
USUBJID	Unique Subject Identifier	text	200		Predecessor: ADSL.USUBJID
SUBJID	Subject Identifier for the Study	text	200		Predecessor: ADSL.SUBJID
TRTP	Planned Treatment	text	6	["DRUG A", "DRUG B"] <Planned Treatment Group>	Predecessor: ADSL.TRT01P
TRTPN	Planned Treatment (N)	integer	1	["1" = "DRUG A", "2" = "DRUG B"] <Planned Treatment Group (N)>	Predecessor: ADSL.TRT01PN
TRTA	Actual Treatment	text	6	["DRUG A", "DRUG B"] <Actual Treatment Group>	Predecessor: ADSL.TRT01P
TRTAN	Actual Treatment (N)	integer	1	["1" = "DRUG A", "2" = "DRUG B"] <Actual Treatment Group (N)>	Predecessor: ADSL.TRT01PN

Introduction of CJUG ADaM Team Deliverables

- ADaM datasets
  - ADSL, ADTR, ADRS, ADEVENT, ADTTE, ADRESP
- Analysis Results Metadata
  - Examples ARM for TFLs mock
  - Excel format (not define.xml)
- Description of deliverables
  - Explanation of ADaM structure
  - How to create ADaM datasets
  - Explanation of TFLs mock and ARM



Agenda

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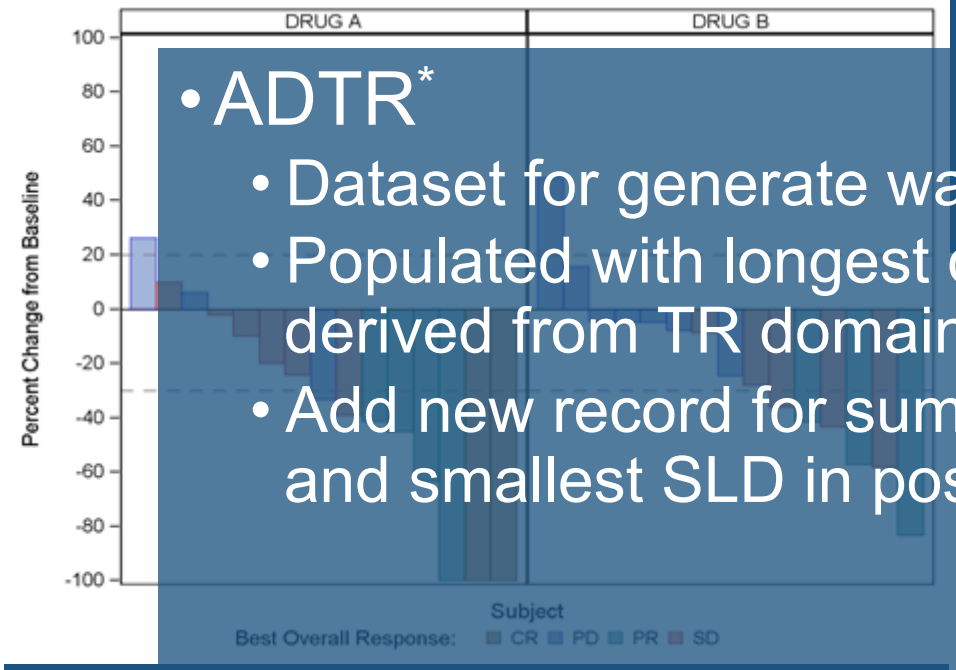
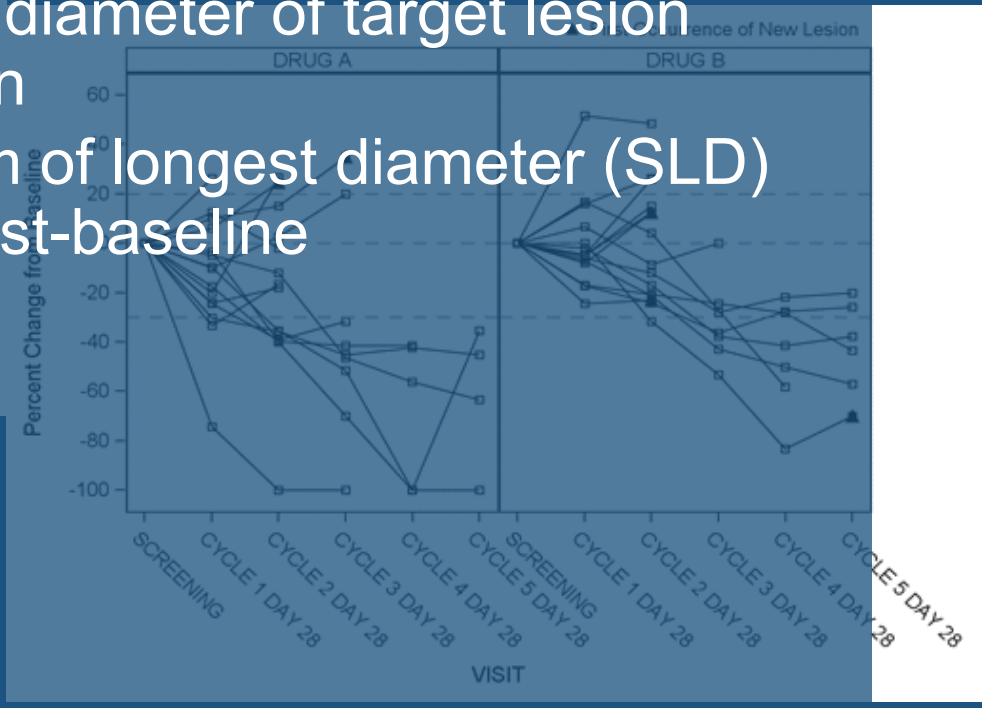
- Difference between TAUG BrCa and PrCa

Explanation of Oncology ADaM



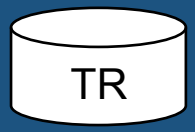
- ADTR*
  - Dataset for generate waterfall plot, spider plot
  - Populated with longest diameter of target lesion derived from TR domain
  - Add new record for sum of longest diameter (SLD) and smallest SLD in post-baseline



defined in TAUG-BrCa
* proposed by CJUG ADaM sub-team

Explanation of Oncology ADaM

- ADTR* (cont.)



where TRGRPID = 'TARGET'

USUBJID	AVISIT	VISIT	PARAMCD	PARAM	AVAL
TEAM3-001-08	SCREENING	SCREENING	DIAM01	Diameter of Target 01 (mm)	26
TEAM3-001-08	SCREENING	SCREENING	DIAM02	Diameter of Target 02 (mm)	15
TEAM3-001-08	CYCLE 1 DAY 28	CYCLE 1 DAY 28	DIAM01	Diameter of Target 01 (mm)	22
TEAM3-001-08	CYCLE 1 DAY 28	CYCLE 1 DAY 28	DIAM02	Diameter of Target 02 (mm)	9

derive SLD

USUBJID	AVISIT	VISIT	PARAMCD	PARAM	AVAL
TEAM3-001-08	SCREENING	SCREENING	SUMDIAM	Sum of Diameter (mm)	41
TEAM3-001-08	CYCLE 1 DAY 28	CYCLE 1 DAY 28	SUMDIAM	Sum of Diameter (mm)	31
TEAM3-001-08	CYCLE 2 DAY 28	CYCLE 2 DAY 28	SUMDIAM	Sum of Diameter (mm)	25
TEAM3-001-08	CYCLE 3 DAY 28	CYCLE 3 DAY 28	SUMDIAM	Sum of Diameter (mm)	28

smallest SLD

USUBJID	AVISIT	VISIT	PARAMCD	PARAM	AVAL	DTYPE
TEAM3-001-08	OVERALL	CYCLE 2 DAY 28	SUMDIAM	Sum of Diameter (mm)	25	MINIMUM

USUBJID	AVISIT	VISIT	PARAMCD	PARAM	AVAL	DTYPE
TEAM3-001-08	SCREENING	SCREENING	DIAM01	Diameter of Target 01 (mm)	26	
TEAM3-001-08	SCREENING	SCREENING	DIAM02	Diameter of Target 02 (mm)	15	
TEAM3-001-08	CYCLE 1 DAY 28	CYCLE 1 DAY 28	DIAM01	Diameter of Target 01 (mm)	22	
TEAM3-001-08	CYCLE 1 DAY 28	CYCLE 1 DAY 28	DIAM02	Diameter of Target 02 (mm)	9	
TEAM3-001-08	SCREENING	SCREENING	SUMDIAM	Sum of Diameter (mm)	41	
TEAM3-001-08	CYCLE 1 DAY 28	CYCLE 1 DAY 28	SUMDIAM	Sum of Diameter (mm)	31	
TEAM3-001-08	CYCLE 2 DAY 28	CYCLE 2 DAY 28	SUMDIAM	Sum of Diameter (mm)	25	
TEAM3-001-08	CYCLE 3 DAY 28	CYCLE 3 DAY 28	SUMDIAM	Sum of Diameter (mm)	28	
TEAM3-001-08	OVERALL	CYCLE 2 DAY 28	SUMDIAM	Sum of Diameter (mm)	25	MINIMUM

Explanation of Oncology ADaM

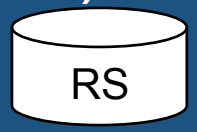
- ADRESP#
  - Dataset for generate response rate treatment
  - Populated with best overall response derived from RS domain

	DRUG A N=xxx	DRUG B N=xxx
Response Rate (CR+PR)	xx.x	xx.x
95% CI	[xx.x , xx.x]	[xx.x , xx.x]
Difference in Response Rate		xx.x
95% CI		[xx.x , xx.x]
P-value		x.xxxxx
Odds Ratio		x.x
95% CI		[x.xx , x.xx]
Best Response		
Complete Respnse (CR)	xx (xxx.x%)	xx (xxx.x%)
Partial Response (PR)	xx (xxx.x%)	xx (xxx.x%)
Stable Disease (SD)	xx (xxx.x%)	xx (xxx.x%)
Progressive Disease (PD)	xx (xxx.x%)	xx (xxx.x%)
Unknown	xx (xxx.x%)	xx (xxx.x%)

defined in TAUG-BrCa
* proposed by CJUG ADaM sub-team

Explanation of Oncology ADaM

- ADRESP# (cont.)



where RSTESTCD = 'OVRLRESP'

USUBJID	VISIT	RSTESTCD	RSSTRESC	RSEVAL
TEAM 3-001-08	CYCLE 1 DAY 28	OVRLRESP	SD	INVESTIGATOR
TEAM 3-001-08	CYCLE 2 DAY 28	OVRLRESP	PR	INVESTIGATOR
TEAM 3-001-08	CYCLE 3 DAY 28	OVRLRESP	SD	INVESTIGATOR
TEAM 3-001-08	CYCLE 1 DAY 28	OVRLRESP	SD	INDEPENDENT ASSESSOR
TEAM 3-001-08	CYCLE 2 DAY 28	OVRLRESP	PR	INDEPENDENT ASSESSOR
TEAM 3-001-08	CYCLE 3 DAY 28	OVRLRESP	SD	INDEPENDENT ASSESSOR

proposed variable in TAUG BrCa

USUBJID	PARAMCD	PARQUAL	AVALC
TEAM 3-001-08	BOR	INVESTIGATOR	SD
TEAM 3-001-08	BOR	CENTRAL	SD

Conformation
Best Overall Response
based on RECIST

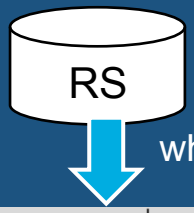
Explanation of Oncology ADaM

- ADRS*
  - Intermediate dataset of ADEVENT
  - Required when analyze duration of response (DoR)
    - Derive confirmation date of CR or PR (date of CRin or PRin)

defined in TAUG-BrCa
* proposed by CJUG ADaM sub-team

Explanation of Oncology ADaM

- ADRS* (cont.)



where RSTESTCD = 'OVRLRESP'

USUBJID	RSSEQ	ASEQ	AVISIT	PARQUAL	PARAMCD	AVALC
TEAM3-001-01	12	1	CYCLE 1 DAY 28	CENTRAL	OVRLRESP	SD
TEAM3-001-01	14	2	CYCLE 2 DAY 28	CENTRAL	OVRLRESP	PR
TEAM3-001-01	16	3	CYCLE 3 DAY 28	CENTRAL	OVRLRESP	PR
TEAM3-001-01	18	4	CYCLE 4 DAY 28	CENTRAL	OVRLRESP	CR
TEAM3-001-01	20	5	CYCLE 5 DAY 28	CENTRAL	OVRLRESP	CR
TEAM3-001-01	2	6	CYCLE 1 DAY 28	INVESTIGATOR	OVRLRESP	SD
TEAM3-001-01	4	7	CYCLE 2 DAY 28	INVESTIGATOR	OVRLRESP	PR
TEAM3-001-01	6	8	CYCLE 3 DAY 28	INVESTIGATOR	OVRLRESP	PR
TEAM3-001-01	8	9	CYCLE 4 DAY 28	INVESTIGATOR	OVRLRESP	CR
TEAM3-001-01	10	10	CYCLE 5 DAY 28	INVESTIGATOR	OVRLRESP	CR

populated with overall response of last tumor evaluation

populated with date of last tumor evaluation

USUBJID	RSSEQ	ASEQ	AVISIT	PARQUAL	PARAMCD	AVALC	PRERESP	ADT	INDT	CRIT1	CRIT1FL
TEAM3-001-01	12	1	CYCLE 1 DAY 28	CENTRAL	OVRLRESP	SD		2016-01-06		CRin/PRin	
TEAM3-001-01	14	2	CYCLE 2 DAY 28	CENTRAL	OVRLRESP	PR	SD	2016-02-03	2016-01-06	CRin/PRin	
TEAM3-001-01	16	3	CYCLE 3 DAY 28	CENTRAL	OVRLRESP	PR	PR	2016-03-02	2016-02-03	CRin/PRin	Y
TEAM3-001-01	18	4	CYCLE 4 DAY 28	CENTRAL	OVRLRESP	CR	PR	2016-03-30	2016-03-02	CRin/PRin	Y
TEAM3-001-01	20	5	CYCLE 5 DAY 28	CENTRAL	OVRLRESP	CR	CR	2016-04-27	2016-03-30	CRin/PRin	Y
TEAM3-001-01	2	6	CYCLE 1 DAY 28	INVESTIGATOR	OVRLRESP	SD		2016-01-06		CRin/PRin	
TEAM3-001-01	4	7	CYCLE 2 DAY 28	INVESTIGATOR	OVRLRESP	PR	SD	2016-02-03	2016-01-06	CRin/PRin	
TEAM3-001-01	6	8	CYCLE 3 DAY 28	INVESTIGATOR	OVRLRESP	PR	PR	2016-03-02	2016-02-03	CRin/PRin	Y
TEAM3-001-01	8	9	CYCLE 4 DAY 28	INVESTIGATOR	OVRLRESP	CR	PR	2016-03-30	2016-03-02	CRin/PRin	Y
TEAM3-001-01	10	10	CYCLE 5 DAY 28	INVESTIGATOR	OVRLRESP	CR	CR	2016-04-27	2016-03-30	CRin/PRin	Y

proposed **proposed**

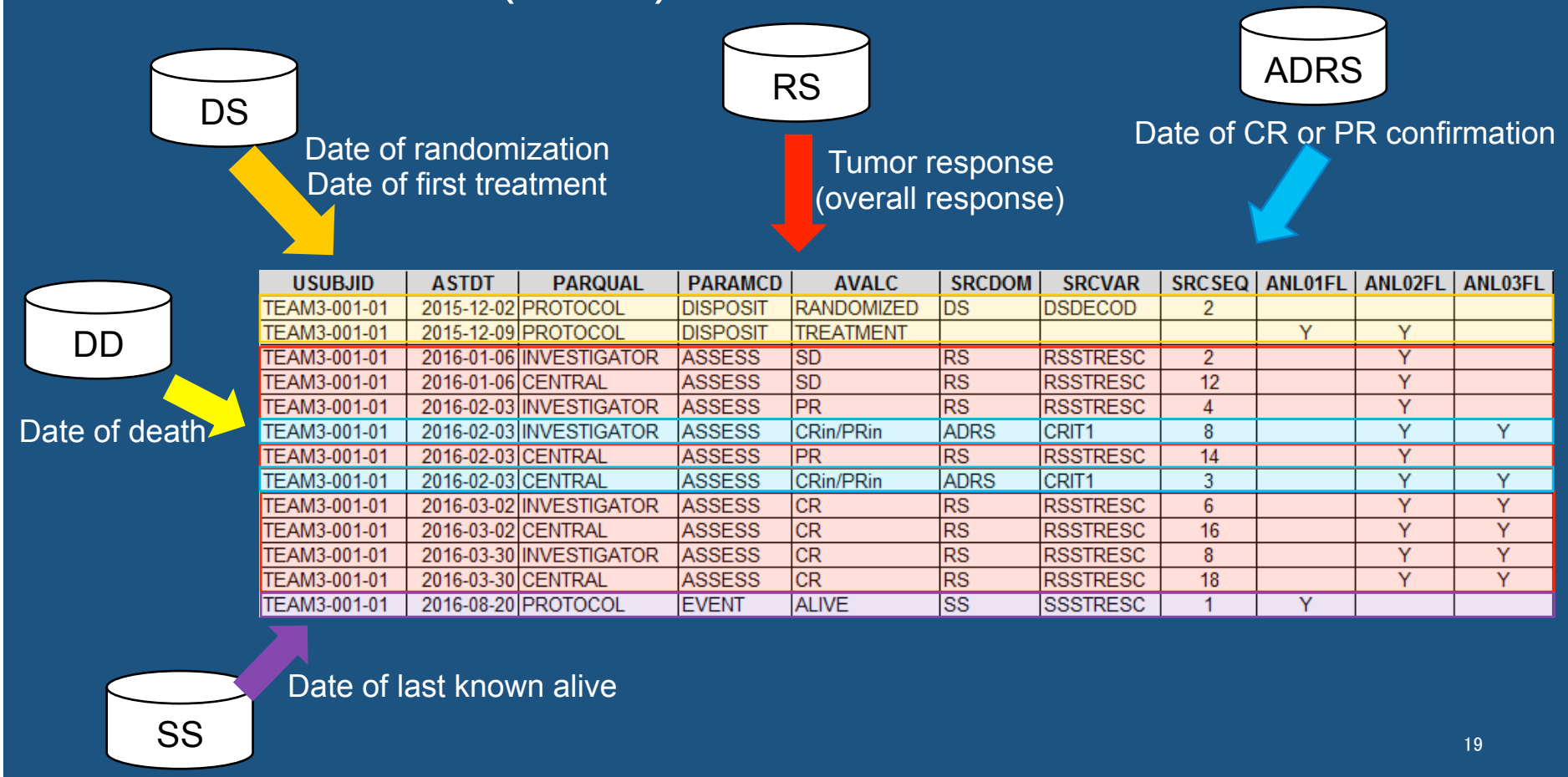
Explanation of Oncology ADaM

- ADEVENT#
  - Intermediate dataset for ADTTE
  - Populated with data information relevant to survival time analysis (OS: Overall Survival, PFS: Progression Free Survival, DoR: Duration of Response)
    - date of randomization, date of first study treatment, date of death, date of disease progression, date of last known alive, date of last tumor assessment, etc.

defined in TAUG-BrCa
* proposed by CJUG ADaM sub-team

Explanation of Oncology ADaM

- ADEVENT# (cont.)



USUBJID	ASTDT	PARQUAL	PARAMCD	AVALC	SRCDOM	SRCVAR	SRCSEQ	ANL01FL	ANL02FL	ANL03FL
TEAM3-001-01	2015-12-02	PROTOCOL	DISPOSIT	RANDOMIZED	DS	DSDECOD	2			
TEAM3-001-01	2015-12-09	PROTOCOL	DISPOSIT	TREATMENT				Y	Y	
TEAM3-001-01	2016-01-06	INVESTIGATOR	ASSESS	SD	RS	RSSTRESC	2		Y	
TEAM3-001-01	2016-01-06	CENTRAL	ASSESS	SD	RS	RSSTRESC	12		Y	
TEAM3-001-01	2016-02-03	INVESTIGATOR	ASSESS	PR	RS	RSSTRESC	4		Y	
TEAM3-001-01	2016-02-03	INVESTIGATOR	ASSESS	CRin/PRin	ADRS	CRIT1	8		Y	Y
TEAM3-001-01	2016-02-03	CENTRAL	ASSESS	PR	RS	RSSTRESC	14		Y	
TEAM3-001-01	2016-02-03	CENTRAL	ASSESS	CRin/PRin	ADRS	CRIT1	3		Y	Y
TEAM3-001-01	2016-03-02	INVESTIGATOR	ASSESS	CR	RS	RSSTRESC	6		Y	Y
TEAM3-001-01	2016-03-02	CENTRAL	ASSESS	CR	RS	RSSTRESC	16		Y	Y
TEAM3-001-01	2016-03-30	INVESTIGATOR	ASSESS	CR	RS	RSSTRESC	8		Y	Y
TEAM3-001-01	2016-03-30	CENTRAL	ASSESS	CR	RS	RSSTRESC	18		Y	Y
TEAM3-001-01	2016-08-20	PROTOCOL	EVENT	ALIVE	SS	SSSTRESC	1	Y		

Explanation of Oncology ADaM

ADEVENT

OS PFS DoR

USUBJID	ASEQ	ASTDT	PARQUAL	PARAMCD	AVALC	ANL01FL	ANL02FL	ANL03FL
TEAM3-001-02	1	2015-12-17	PROTOCOL	DISPOSIT	RANDOMIZED			
TEAM3-001-02	2	2015-12-24	PROTOCOL	DISPOSIT	TREATMENT	Y	Y	
TEAM3-001-02	3	2016-01-21	CENTRAL	ASSESS	PR		Y	
TEAM3-001-02	4	2016-01-21	CENTRAL	ASSESS	CRin/PRin		Y	Y
TEAM3-001-02	6	2016-02-18	CENTRAL	ASSESS	CR		Y	Y
TEAM3-001-02	9	2016-03-17	CENTRAL	ASSESS	CR		Y	Y
TEAM3-001-02	11	2016-03-28	PROTOCOL	EVENT	DEATH	Y	Y	

ADTTE

USUBJID	STARTDT	PARQUAL	PARAMCD	CNSR	ADT	AVAL	SRCDOM	SRCVAR	SRCSEQ
TEAM3-001-02	2015-12-24	PROTOCOL	OS	0	2016-03-28	96	ADEVENT	ASTDT	11
TEAM3-001-02	2015-12-24	CENTRAL	PFS	0	2016-03-28	96	ADEVENT	ASTDT	11
TEAM3-001-02	2016-01-21	CENTRAL	DOR	1	2016-03-17	57	ADEVENT		

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Explanation of Analysis Results Metadata

	DRUG A N=xxx	DRUG B N=xxx
Subjects with Events	xxx (xxx.x %)	xxx (xxx.x %)
Subjects Censored	xxx (xxx.x %)	xxx (xxx.x %)
Time to Event (days)		
Median (95% CI)	xxx.x [xxx.x , xxx.x]	xxx.x [xxx.x , xxx.x]
25% and 75%-ile	xxx.x , xxx.x	xxx.x , xxx.x
Range	xxx - xxx	xxx - xxx
P-value		x.xxxxx
Hazard Ratio		x.xx
95% CI		[x.xx , x.xx]
P-value		x.xxxxx
1 year Duration		
Subjects Remaining at Risk	xxx	xxx
Event Free Rate	x.xx	x.xx
95% CI for Rate	[x.xx , x.xx]	[x.xx , x.xx]

Number of event/censor subjects

Time to event (Kaplan-Meier method estimated values)

Hazard ration

Event occurrence rate (Kaplan-Meier method estimated values)

Explanation of Analysis Results Metadata

	DRUG A N=xxx	DRUG B N=xxx
Subjects with Events	xxx (xxx.x %)	xxx (xxx.x %)
Subjects Censored	xxx (xxx.x %)	xxx (xxx.x %)
Time to Event (days)		
Median (95% CI)	xxx.x [xxx.x , xxx.x]	xxx.x [xxx.x , xxx.x]
25% and 75%-ile	xxx.x , xxx.x	xxx.x , xxx.x
Range	xxx - xxx	xxx - xxx
P-value		x.xxxxx
Hazard Ratio		x.xx
95% CI		[x.xx , x.xx]
P-value		x.xxxxx
1 year Duration		
Subjects Remaining at Risk	xxx	xxx
Event Free Rate	x.xx	x.xx
95% CI for Rate	[x.xx , x.xx]	[x.xx , x.xx]

Display Identifier	Table 2
Analaysis Result	Time to event
Analysis Parameter(s)	PARAMCD="PFS"
Analysis Variable(s)	AVAL
Analaysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE
Dataset Refernces (Incl. Selection Criteria)	ADTTE [PARAMCD="PFS" and PARQUAL="CENTRAL" and ITTFL = "Y"]
Documentation	SAP Section XX.X

Progamming Statements	ods output Quartiles=qt ProductLimitEstimates=ple HomTests=test;
	proc lifetest data=adtte;
	strata TRTPN TRTP;
	time AVAL*CNSR(1);
	run;

Analaysis Result	Hazard Ratio
Analysis Parameter(s)	PARAMCD="PFS"
Analysis Variable(s)	AVAL
Analaysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE
Dataset Refernces (Incl. Selection Criteria)	ADTTE [PARAMCD="PFS" and PARQUAL="CENTRAL" and ITTFL = "Y"]
Documentation	SAP Section XX.X

Progamming Statements	ods output ParameterEstimates=pm;
	proc phreg data=adtte;
	class TRTPN / descending;
	model AVAL*CNSR(1) = TRTPN / rl;
	run;

Analaysis Result	Event Occurrence Rate
Analysis Parameter(s)	PARAMCD="PFS"
Analysis Variable(s)	AVAL
Analaysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE
Dataset Refernces (Incl. Selection Criteria)	ADTTE [PARAMCD="PFS" and PARQUAL="CENTRAL" and ITTFL = "Y"]
Documentation	SAP Section XX.X

Progamming Statements	ods output ProductLimitEstimates=ple(where=(AVAL<=365));
	proc lifetest data=adtte atrisk outsurv=ple_ci(where=(AVAL<=365));
	strata TRTPN TRTP;
	time AVAL*CNSR(1);
	run;

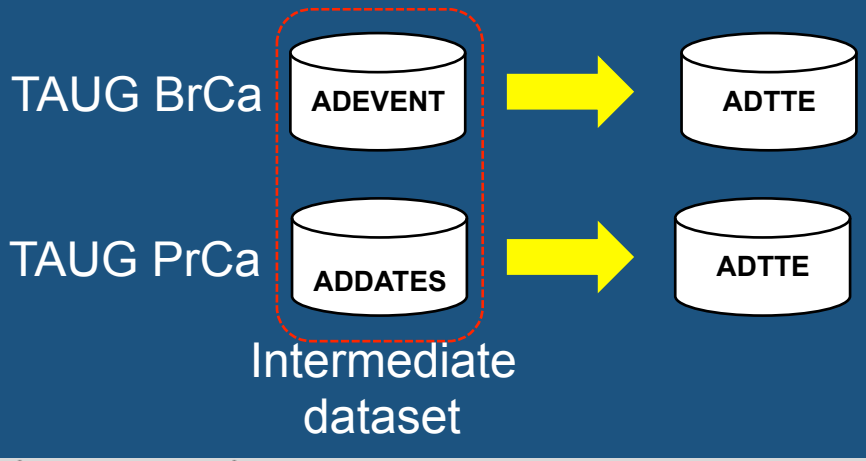
Agenda

- Introduction of CJUG ADaM Team Deliverables
- Explanation of Oncology ADaM
- Explanation of Analysis Results Metadata
- Difference between TAUG BrCa and PrCa

Difference of between TAUG BrCa and PrCa

TAUG PrCa : DRAFT status

- Process of create ADTTE



USUBJID	ADT	ADTDESC	ADTDESCCD
1	2015-12-02	Date of Randomization	RANDDT
1	2016-02-09	Change in Anti-Cancar Therapy	RXCHGDT
1	2016-03-20	Date of Last Tumor Assessment with No PD	LNOPDDT
1	2017-01-06	Date Last Known Alive	LSTALVDT
2	2016-02-03	Date of Randomization	ASSESS
2	2017-08-10	Date of Last Tumor Assessment with No PD	LNOPDDT
2	2017-08-19	Date of Analysis Cutoff	CUTOFFDT

CJUG ADaM sub-team member

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CJUG ADaM Team