WITH STANDARDS – UNLOCK THE POWER OF DATA

cdisc

2022
CHINA
INTERCHANGE
29-30 JULY | VIRTUAL EVENT

Clinical trial data visualization application based on CDISC standard

Presented by Elma Hu, Senior R&D Analyst, R&D, Tigermed Co.,Ltd

Meet the Speaker

Elma Hu

Title: Senior R&D Analyst

Organization: Tigermed Co.,Ltd

Elma Hu is a RD Analyst from Tigermed Biometrics Group, with 3 years' industry experience. She is well skilled in multiple programming techniques, including SAS, R and Python, and has rich experience in developing CDISC related applications and data visualization platforms.

Agenda

1. Background
2. Introduction of Tigermed clinical trial data visualization platform
3. Conclusion

Background

Background

	CMTRT	CMTRT_ATC	CMTRT_ATC2	CMTRT_ATC3	CMTRT_ATC4	CMTRT_PRODUCT	CMTRT_PRODUCTSYNONYM
1	MEGLUMINE DIATRIZOATE	VARIOUS	CONTRAST MEDIA	X-RAY CONTRAST MEDIA, IODINATED	WATERSOLUBLE, NEPHROTROPIC, HIGH OSMOLAR X-RAY CONTRAST MEDIA	MEGLUMINE AMIDOTRIZOATE	MEGLUMINE DIATRIZOATE
2	HYDROXYUREA PIECE						
3	POTASSIUM CHLORIDE INJECTION						
4	VALSARTAN DISPERSIBLE TABLETS	CARDIOVASCULAR SYSTEM	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	VALSARTAN	
5	LEVAMLODIPINE BESYLATE TABLETS	CARDIOVASCULAR SYSTEM	CALCIUM CHANNEL BLOCKERS	SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS	DIHYDROPYRIDINE DERIVATIVES	LEVAMLODIPINE BESILATE	LEVAMLODIPINE BESYLATE
6	SULPERAZON	ANTIINFECTIVES FOR SYSTEMIC USE	ANTIBACTERIALS FOR SYSTEMIC USE	OTHER BETA-LACTAM ANTIBACTERIALS	THIRD-GENERATION CEPHALOSPORINS	CEFOPERAZONE SODIUM;SULBACTAM SODIUM	SULPERAZON
7	VORICONAZOLE TABLETS						
8	MUCOSOLVAN						
9	SULPERAZON	ANTIINFECTIVES FOR SYSTEMIC USE	ANTIBACTERIALS FOR SYSTEMIC USE	OTHER BETA-LACTAM ANTIBACTERIALS	THIRD-GENERATION CEPHALOSPORINS	CEFOPERAZONE SODIUM;SULBACTAM SODIUM	SULPERAZON

Visit	Nominal T	Concentration	Units	LLOQ (ng/	ULOQ	Comments
Day -3	0h	BQL<(50.0)	ng/mL	50	50000	
Day -3	2h	3540	ng/mL	50	50000	
Day -3	4h	5900	ng/mL	50	50000	
Day -3	10h	3070	ng/mL	50	50000	
Day -3	24h	2020	ng/mL	50	50000	
Day -3	48h	1430	ng/mL	50	50000	

Background

1 How to deal with data?

- CDISC standard

2 How to choose tool?

- R is a statistical language
- Free Software and multiple documentations
- Build interactive web apps easily

3 How to use?

- Interactive visualizations
- Multiple type of selections

4 How to show data?

- Different Modules

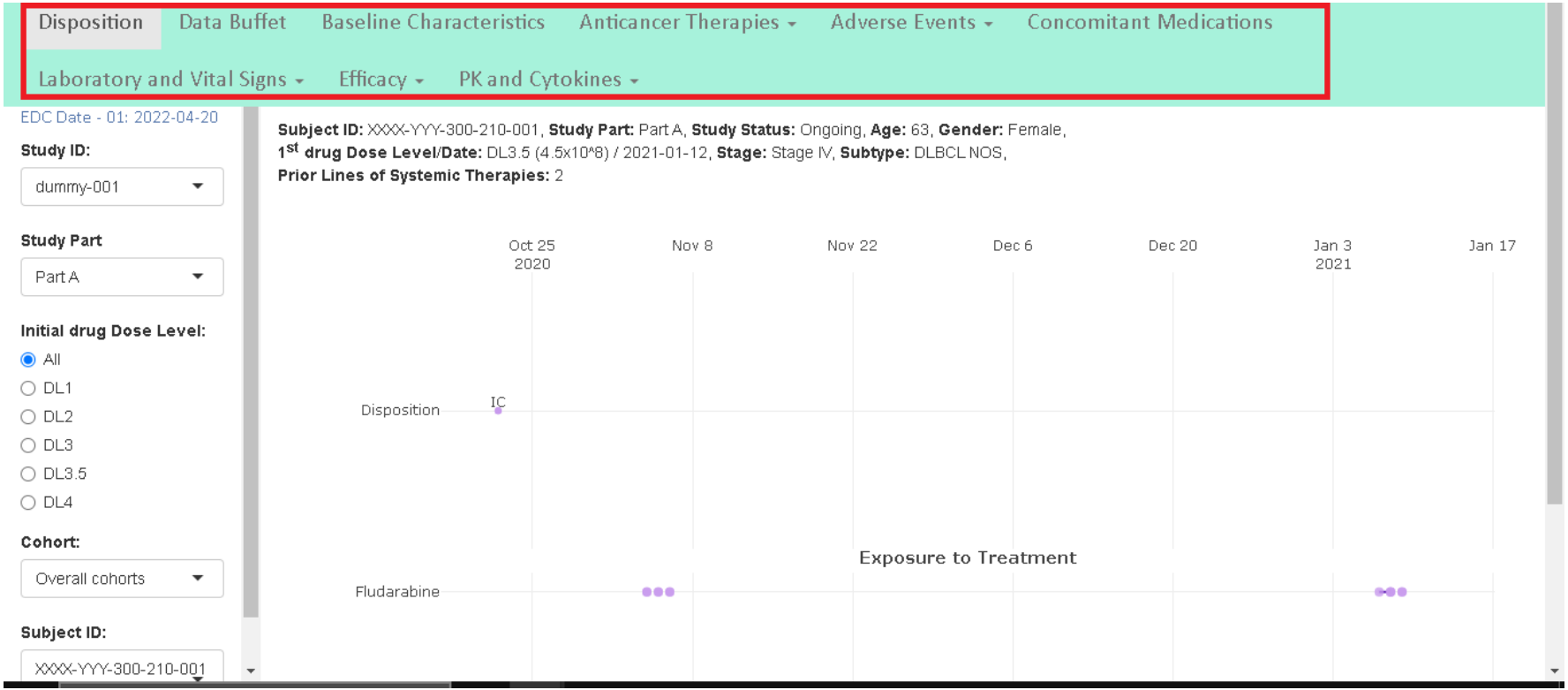
Introduction of platform

Introduction of platform

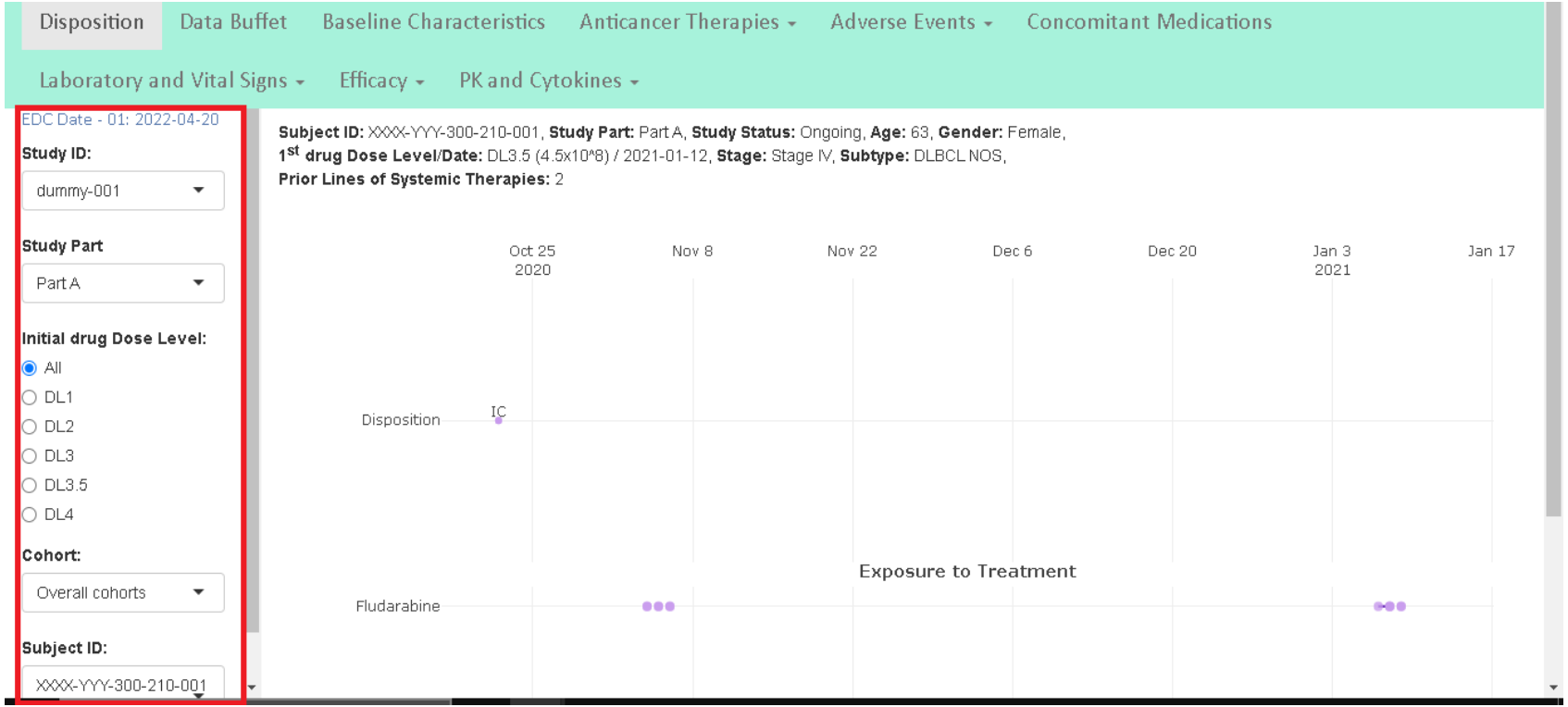
Ord	Module*	Plots
1	Patient Profile/Data Buffet	**Scatter/Table/Line**
2	Baseline Characteristics	**Pie/Box**
3	Anticancer Therapies	**Bar**
4	Adverse Events	**Line/Scatter/Bar**
5	Concomitant Medications	**Line**
6	Laboratory and Vital Signs	**Line/Bar**
7	Efficacy	**Swimmer/Waterfall**
8	PK	**Line**

* According project to create or update module and plots

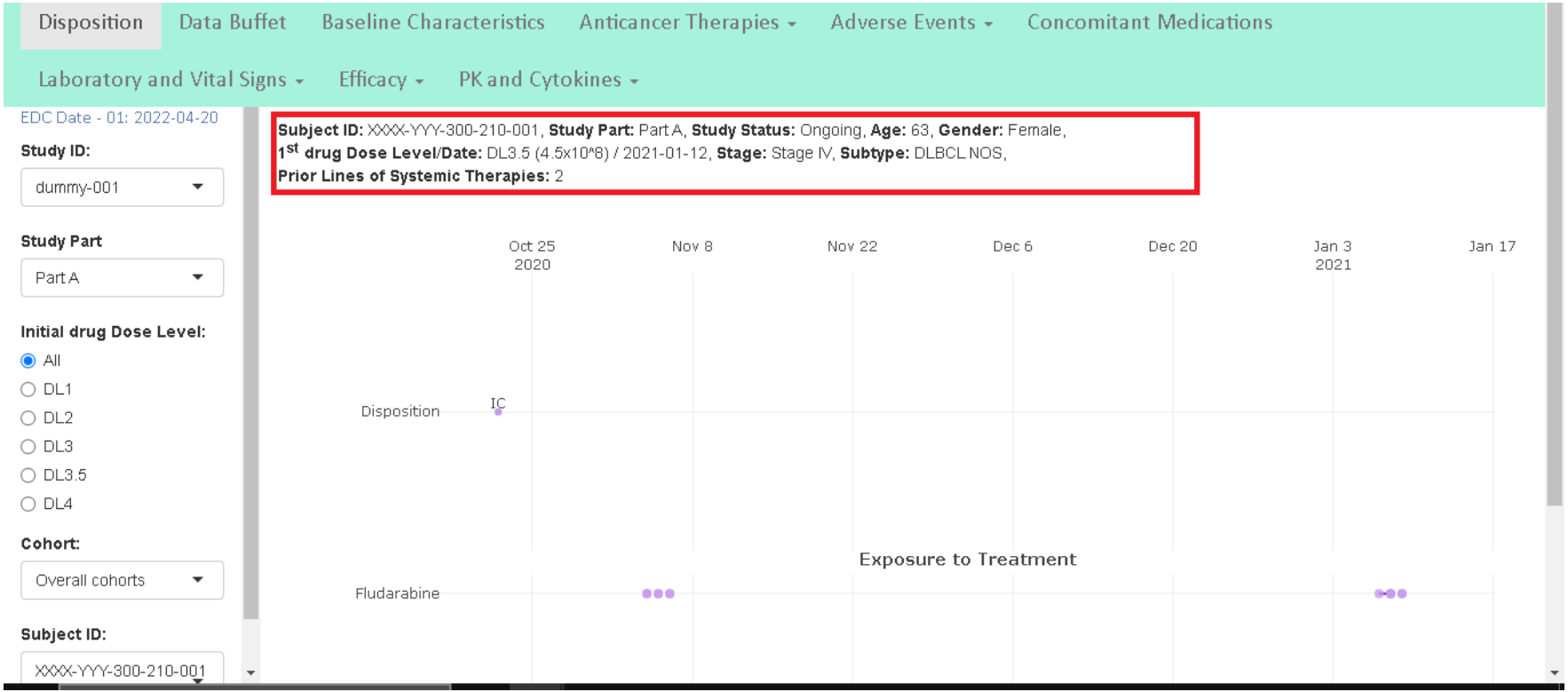
Introduction of platform——Patient Profile



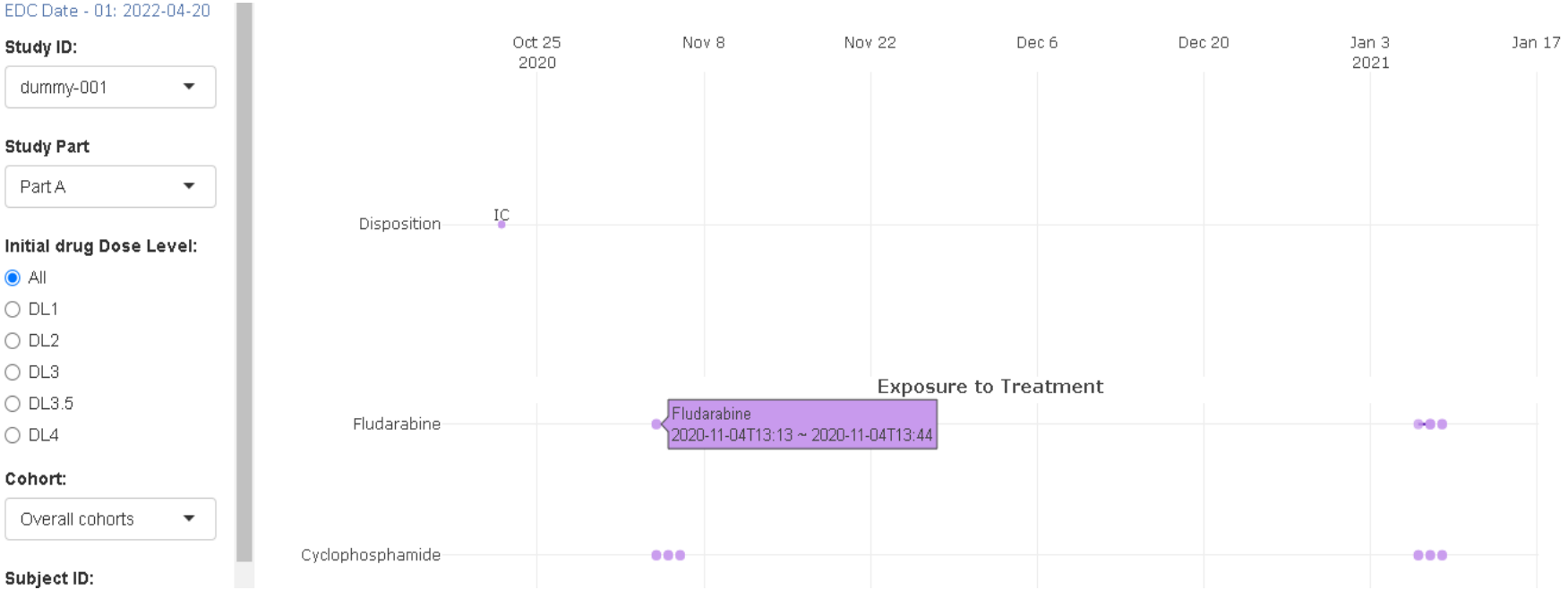
Introduction of platform——Patient Profile



Introduction of platform——Patient Profile



Introduction of platform——Patient Profile



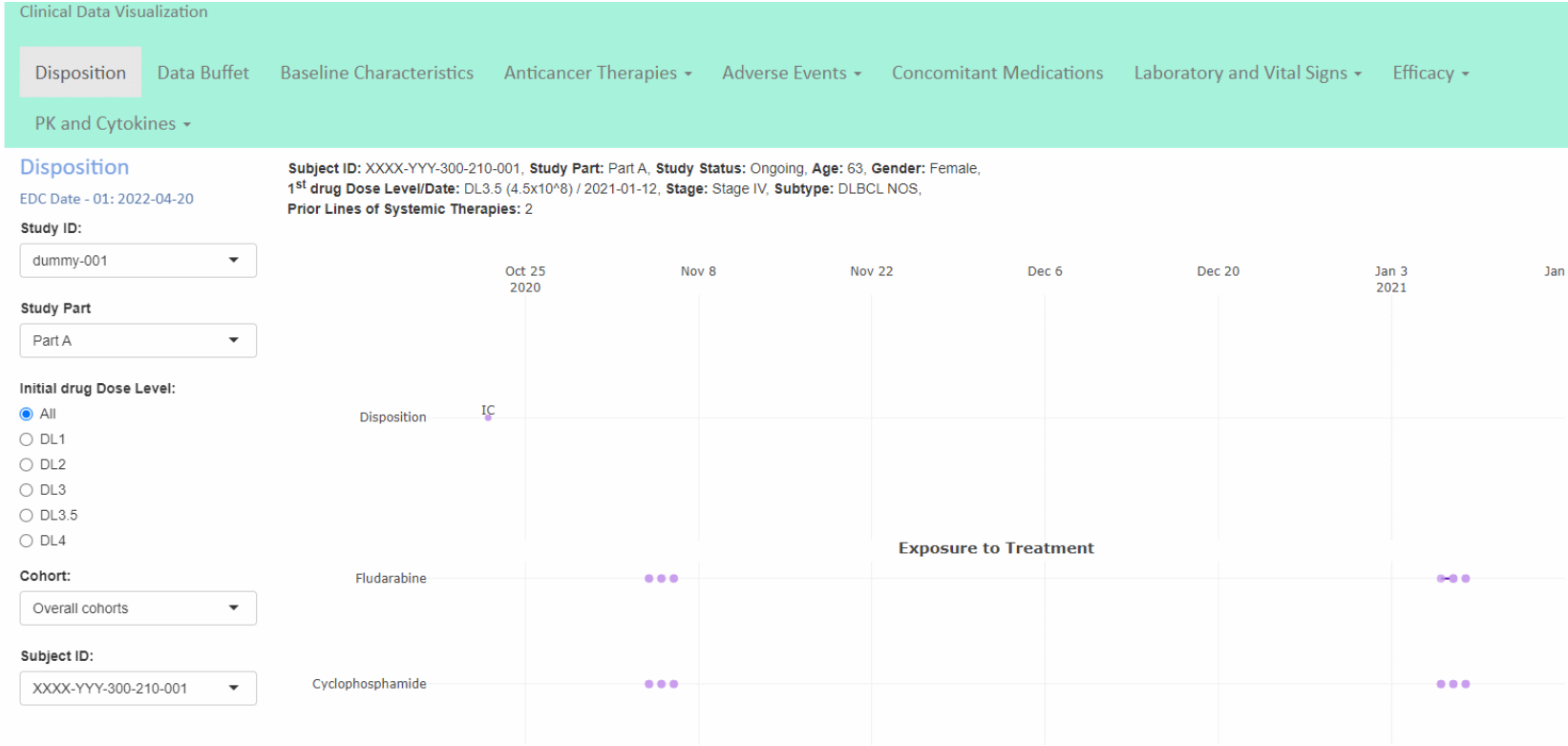
Introduction of platform——Patient Profile

SDTM/ADaM	Variable
DM	STUDYID / USUBJID / RFICDTC / SITEID / AGE / SEX / ACTARM
DS	USUBJID / DSTERM / DSSTDTC
EX	USUBJID / EXTRT / EXDOSE / EXSTDTC / EXENDTC
MH	USUBJID / MHTERM / MHSTDTC / MHENDTC
FA	USUBJID / FATESTCD / FAORRES

Introduction of platform——Patient Profile

1. Overview each subject
    i. Show disposition, drug, medical history for each subject
    ii. Use same x-axis, view whole study treatment for each subject
    iii. Show more information in hover text

Introduction of platform——Patient Profile



Introduction of platform——Data Buffet

Data Buffet

EDC Date - 01: 2022-03-04

Study ID: dummy-001

Site ID: All

Study Part: All

Cohort: NHL cohorts

Initial drug Dose Level: All

Search:

Dose Level	Subject	Age	Sex	N1 vs N2 Subset	Non-Hodgkin Lymphoma Subtype	Baseline Lugano Stage of NHL	Prior Lines Immuno/Chemo
DL1(3x10^7)	302-001	52	F	N2	DLBCL NOS	Stage III	2
DL1(3x10^7)	306-001	50	M	N2	Richter's transformation of CLL	Stage IV	>=3
DL1(3x10^7)	301-001	61	M	N1	Transformed FL	Stage IV	2
DL2(1x10^8)	302-003	74	F	N1	DLBCL NOS	Stage III	>=3

Introduction of platform——Data Buffet

SDTM/ADaM	Variable
DM	STUDYID / USUBJID / RFICDTC/ SITEID / AGE / SEX / ACTARM
DS	USUBJID / DSTERM / DSSTDTC
EX	USUBJID / EXTRT / EXDOSE / EXSTDTC / EXENDTC
PR	USUBJID / PRTRT / PRSTDTC

Introduction of platform——Data Buffet

1. Overview whole study
    i. View the whole information in each site/dose level
    ii. List useful information for each subject, not only limited to DS/EX/MH
    iii. Used as a summary

Introduction of platform——Data Buffet

Data Buffet

EDC Date - 01: 2022-03-04

Study ID: dummy-001

Site ID: All

Study Part: All

Cohort: A

Initial drug Dose Level: All

Search:

Dose Level	Subject	Age	Sex	N1 vs N2 Subset	Non-Hodgkin Lymphoma Subtype	Baseline Lugano Stage of NHL	Prior Lines of Immuno/Chemotherapy	Prior Stem Cell Transplan
DL1(3x10^7)	302-001	52	F	N2	DLBCL NOS	Stage III	2	No
DL1(3x10^7)	306-001	50	M	N2	Richter's transformation of CLL	Stage IV	>=3	No
DL1(3x10^7)	301-001	61	M	N1	Transformed FL	Stage IV	2	No
DL2(1x10^8)	302-003	74	F	N1	DLBCL NOS	Stage III	>=3	No
DL2(1x10^8)	300-002	58	M	N1	DLBCL NOS	Stage IV	2	No
DL2(1x10^8)	306-003	64	M	N2	High grade B-cell lymphoma with MYC and BCL2	Stage IV	>=3	No

Introduction of platform——Baseline Characteristics

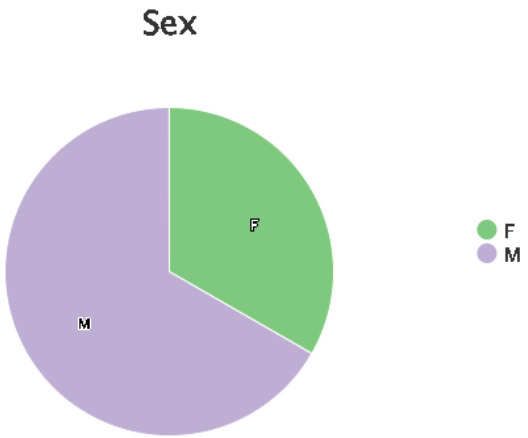
Study ID:
dummy-001

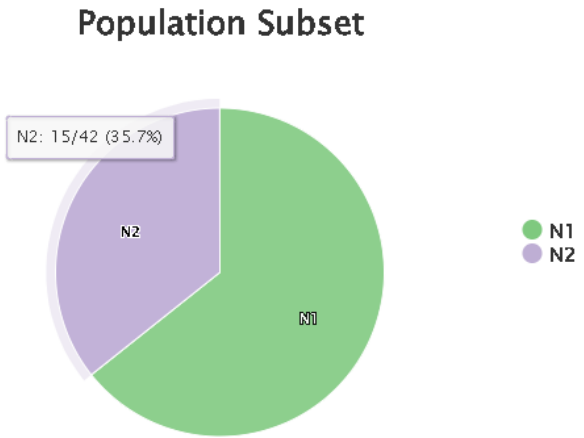
Study Part
Part A

Cohort:
NHL cohorts

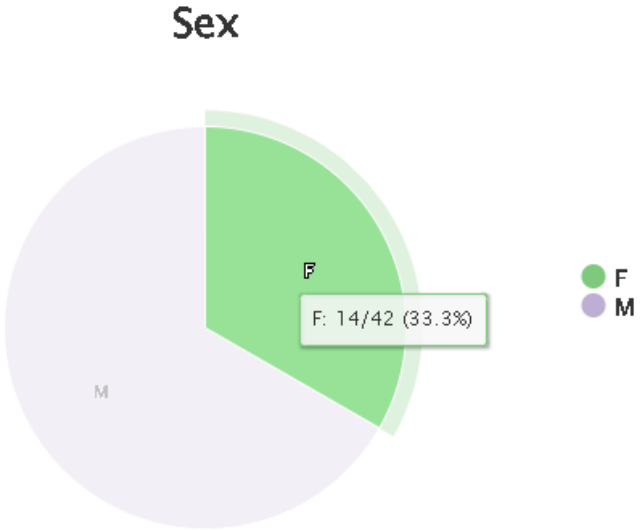
Dose Level:
- (●) All
- ( ) DL1(3x10^7)
- ( ) DL2(1x10^8)
- ( ) DL3(3x10^8)
- ( ) DL3.5(4.5x10^8)
- ( ) DL4(6x10^8)

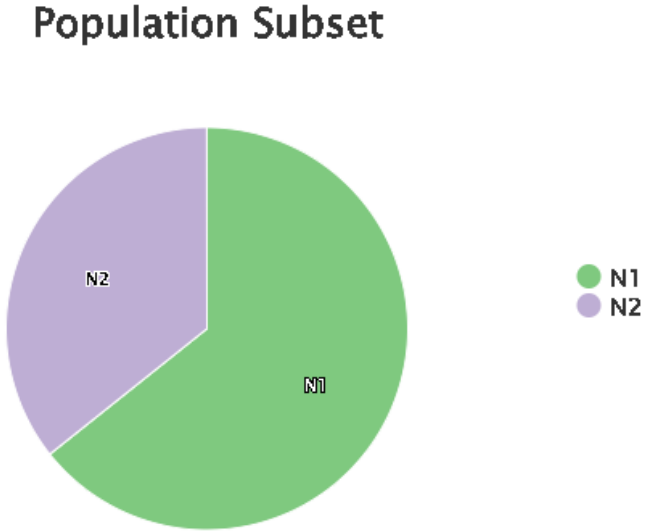
Variable Type:
Categorical



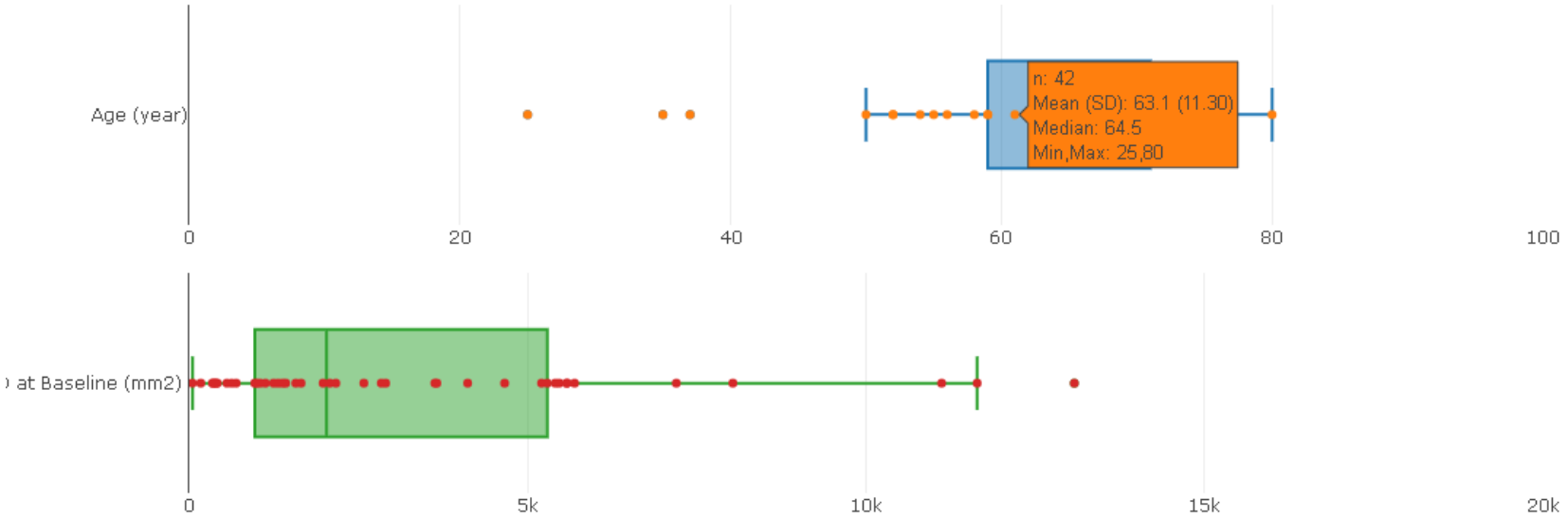


Introduction of platform——Baseline Characteristics





Introduction of platform——Baseline Characteristics



Introduction of platform——Baseline Characteristics

SDTM/ADaM	Variable
DM	STUDYID / USUBJID / AGE / SEX / ACTARM
EX	USUBJID / EXTRT / EXDOSE
RS	USUBJID / RSTEST / RSORRES

Introduction of platform——Baseline Characteristics

1. Overview each variable distribution at baseline
   i. Split to Categorical and Continuous, and use different type plots
   ii. View different variable's distribution
   iii. Combine all variable's plots
   iv. For Continuous variable, we can show statistics in hover text
2. Identifies data anomalies
   i. Show all values in box plot, find discrete value quickly

Introduction of platform——Baseline Characteristics

Baseline Characteristics

EDC Date - 01: 2022-03-04

Study ID:

dummy-001

Study Part

Part A

Cohort:

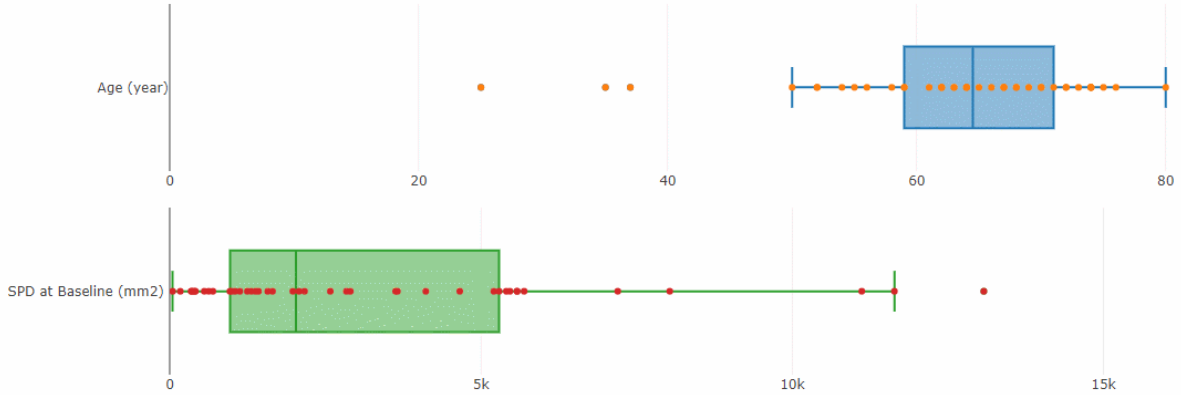
NHL cohorts

Dose Level:

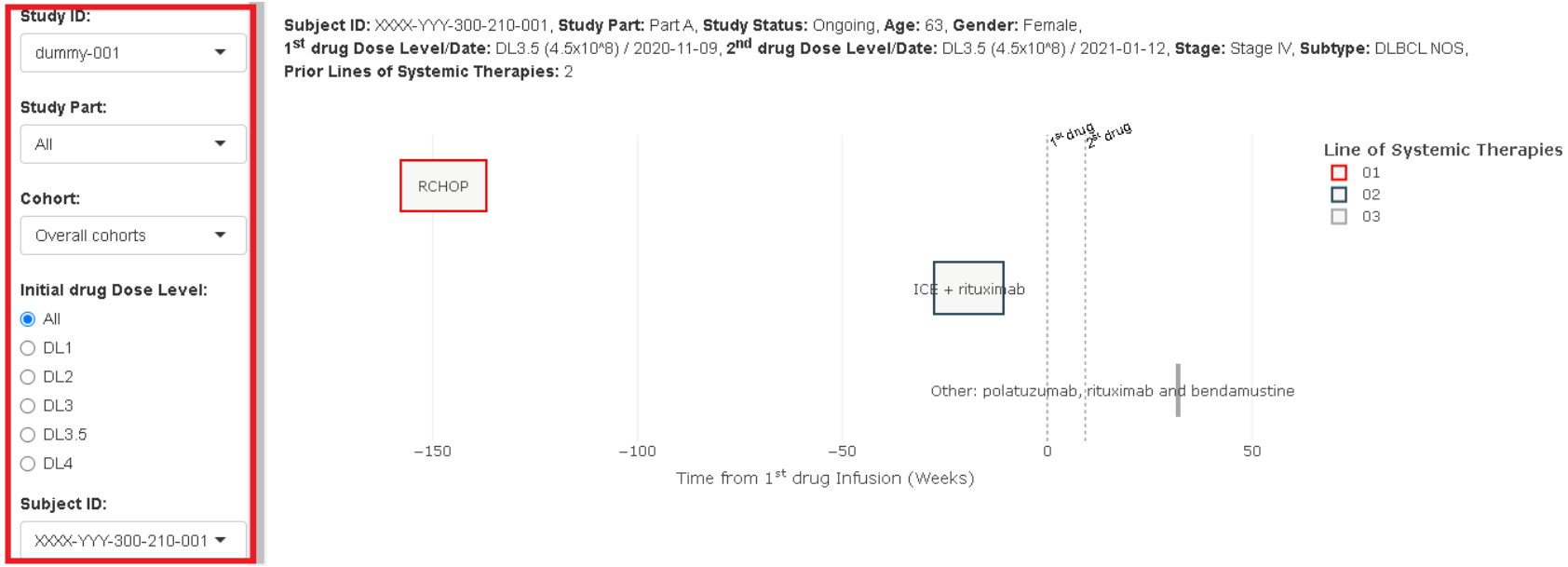
- (●) All
- ( ) DL1(3x10^7)
- ( ) DL2(1x10^8)
- ( ) DL3(3x10^8)
- ( ) DL3.5(4.5x10^8)
- ( ) DL4(6x10^8)

Variable Type:

Continuous



Introduction of platform——Anticancer Therapies



Introduction of platform——Anticancer Therapies

Study ID:
dummy-001

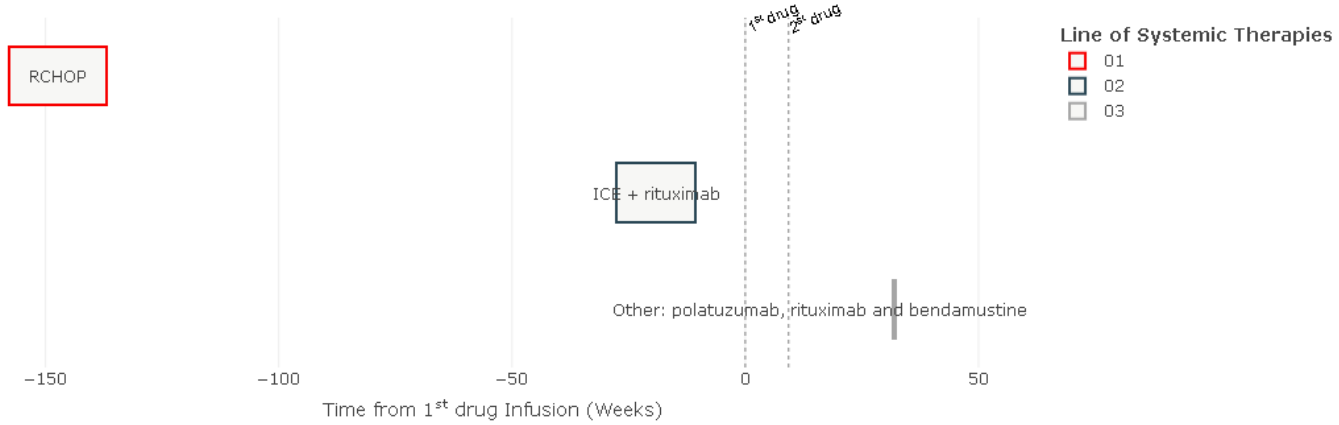
Study Part:
All

Cohort:
Overall cohorts

Initial drug Dose Level:
- (●) All
- ( ) DL1
- ( ) DL2
- ( ) DL3
- ( ) DL3.5
- ( ) DL4

Subject ID:
XXXX-YYY-300-210-001

Subject ID: XXXX-YYY-300-210-001, **Study Part:** Part A, **Study Status:** Ongoing, **Age:** 63, **Gender:** Female,
1st drug Dose Level/Date: DL3.5 (4.5x10^8) / 2020-11-09, **2nd drug Dose Level/Date:** DL3.5 (4.5x10^8) / 2021-01-12, **Stage:** Stage IV, **Subtype:** DLBCL NOS,
Prior Lines of Systemic Therapies: 2



Introduction of platform——Anticancer Therapies

Study ID:
dummy-001

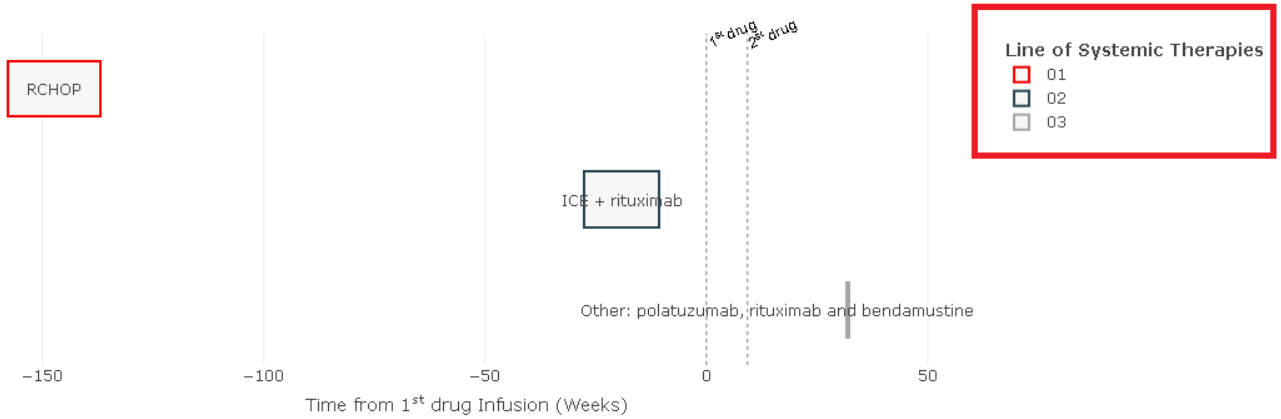
Study Part:
All

Cohort:
Overall cohorts

Initial drug Dose Level:
- (●) All
- ( ) DL1
- ( ) DL2
- ( ) DL3
- ( ) DL3.5
- ( ) DL4

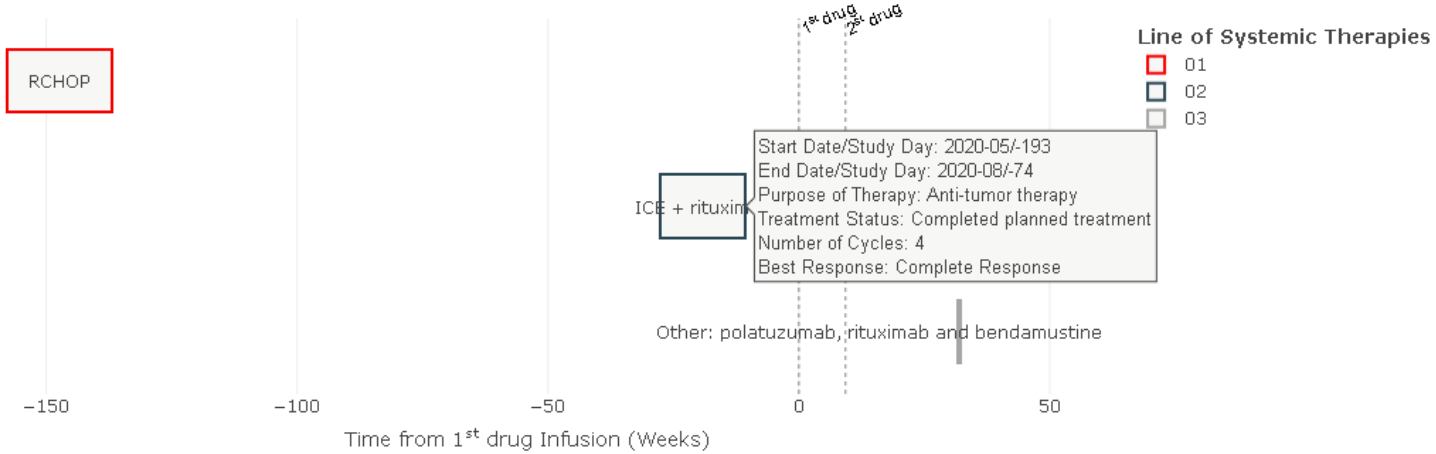
Subject ID:
XXXX-YYY-300-210-001

Subject ID: XXXX-YYY-300-210-001, **Study Part:** Part A, **Study Status:** Ongoing, **Age:** 63, **Gender:** Female,
1st drug Dose Level/Date: DL3.5 (4.5x10^8) / 2020-11-09, **2nd drug Dose Level/Date:** DL3.5 (4.5x10^8) / 2021-01-12, **Stage:** Stage IV, **Subtype:** DLBCL NOS,
Prior Lines of Systemic Therapies: 2



Introduction of platform——Anticancer Therapies

Subject ID: XXXX-YYY-300-210-001, **Study Part:** Part A, **Study Status:** Ongoing, **Age:** 63, **Gender:** Female,
1st drug Dose Level/Date: DL3.5 (4.5x10^8) / 2020-11-09, **2nd drug Dose Level/Date:** DL3.5 (4.5x10^8) / 2021-01-12, **Stage:** Stage IV, **Subtype:** DLBCL NOS,
Prior Lines of Systemic Therapies: 2



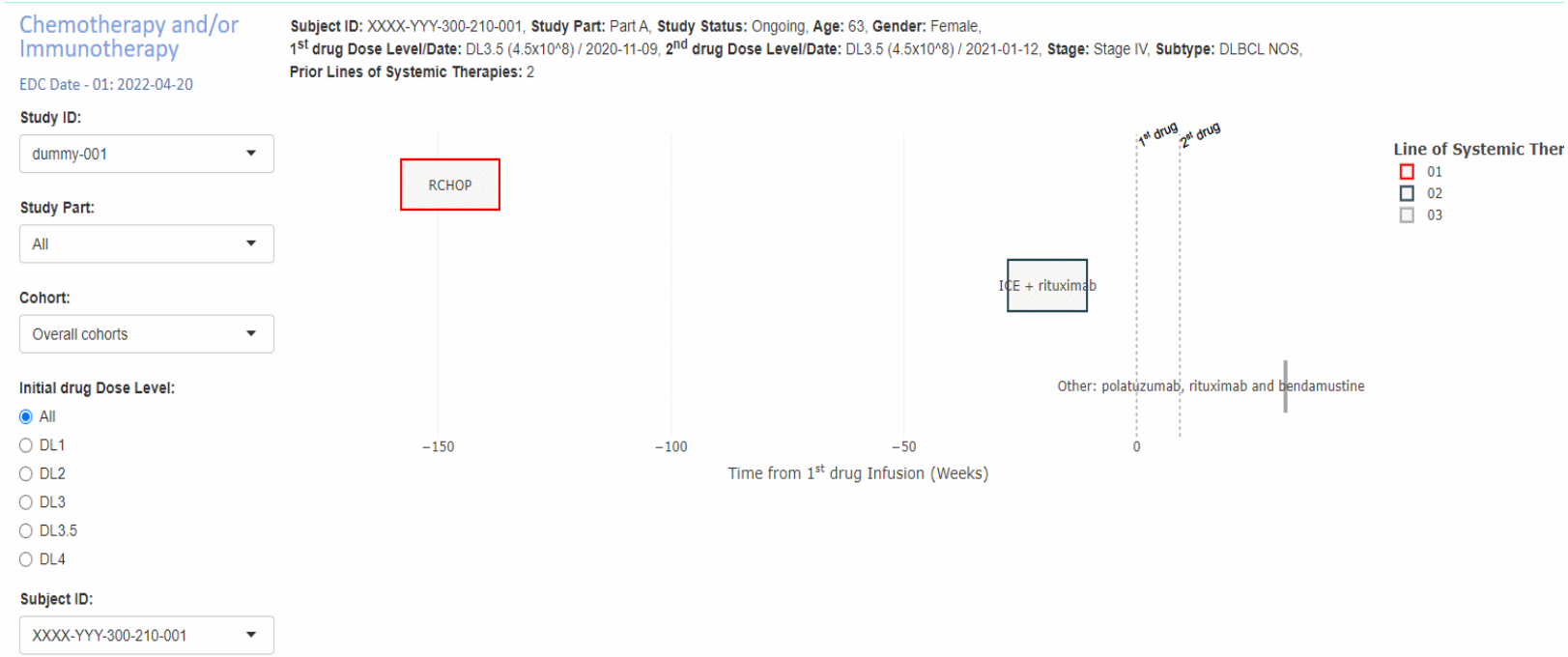
Introduction of platform——Anticancer Therapies

SDTM/ADaM	Variable
DM	STUDYID / USUBJID / RFICDTC / SITEID / AGE / SEX / ACTARM
DS	USUBJID / DSTERM / DSSTDTC / DSSCAT
EX	USUBJID / EXTRT / EXDOSE / EXSTDTC / EXENDTC
PR	USUBJID / PRGRPID / PRTRT / PRSTDTC / PRENDTC
FA	USUBJID / FATESTCD / FAORRES

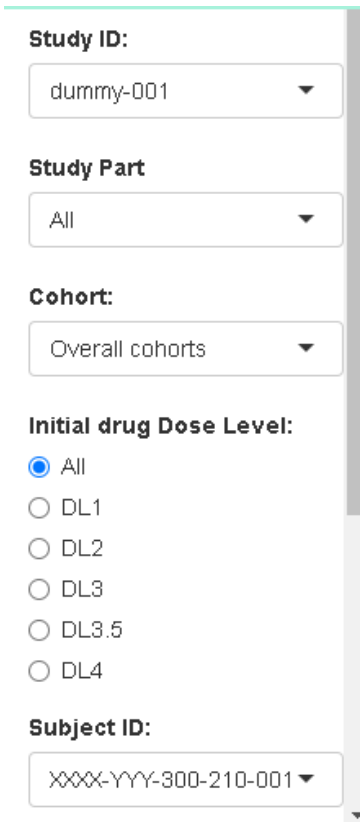
Introduction of platform——Anticancer Therapies

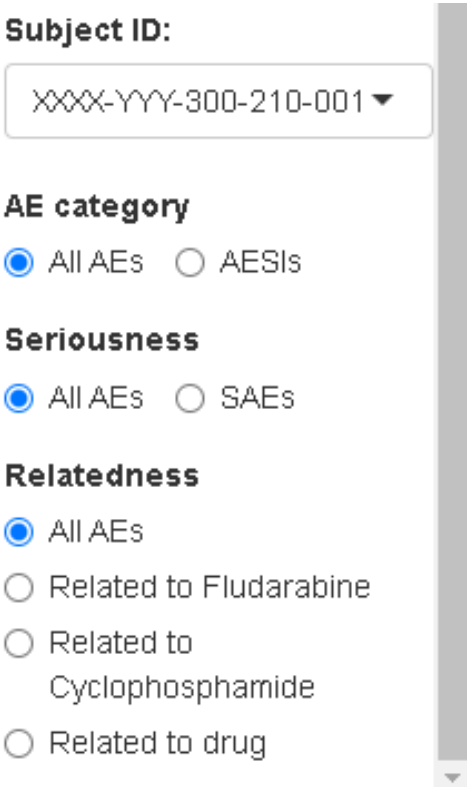
1. Overview each subject's therapies
   i. Use the width of box to represent duration
   ii. Use different color to represent different systemic therapies
   iii. View all anticancer therapies for each subject
2. Show date of 1st drug

Introduction of platform——Anticancer Therapies

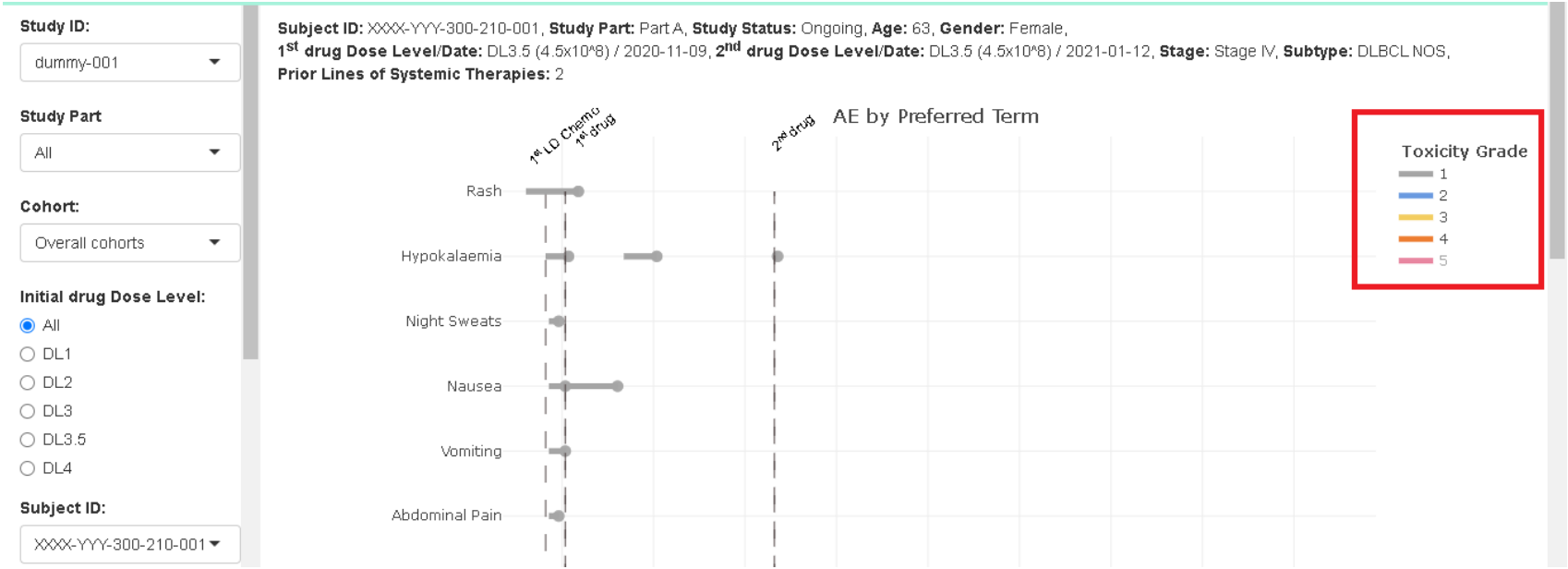


Introduction of platform——AE/CM



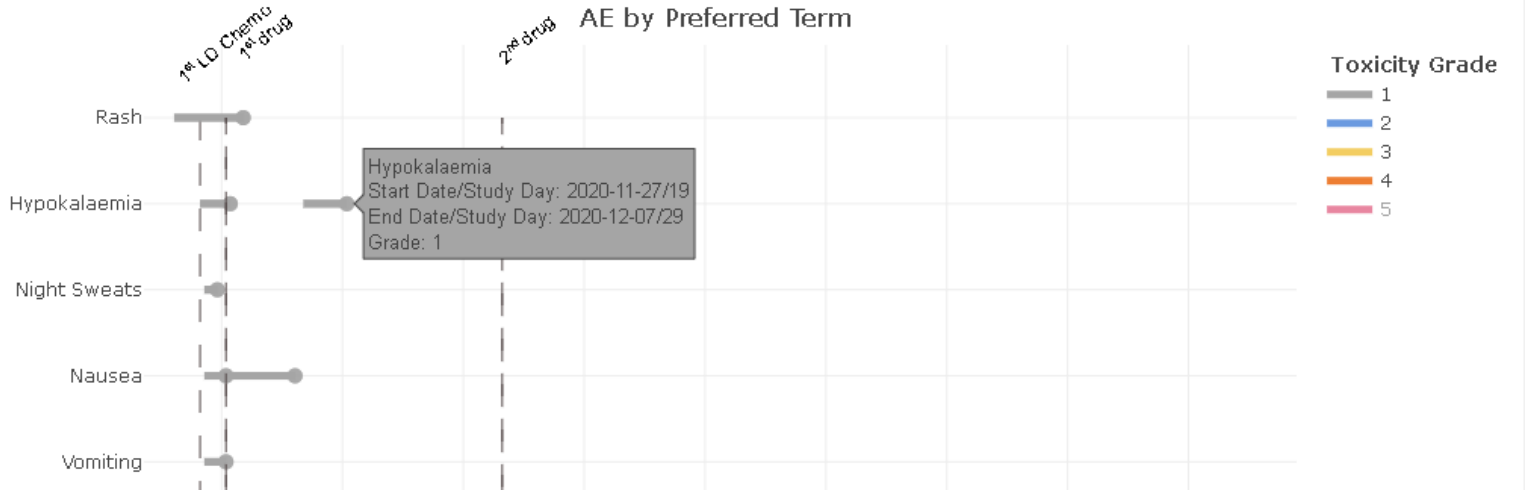


Introduction of platform——AE/CM



Introduction of platform——AE/CM

Subject ID: XXXX-YYY-300-210-001, **Study Part:** Part A, **Study Status:** Ongoing, **Age:** 63, **Gender:** Female,
1st drug Dose Level/Date: DL3.5 (4.5x10^8) / 2020-11-09, **2nd drug Dose Level/Date:** DL3.5 (4.5x10^8) / 2021-01-12, **Stage:** Stage IV, **Subtype:** DLBCL NOS,
Prior Lines of Systemic Therapies: 2



Introduction of platform——AE/CM

SDTM/ADaM	Variable
DM	STUDYID / USUBJID / RFICDTC / SITEID / AGE / SEX / ACTARM / DTHDTC
DS	USUBJID / DSTERM / DSSTDTC
EX	USUBJID / EXTRT / EXDOSE / EXSTDTC / EXENDTC
AE	USUBJID / AETOXGR / AEOUT / AEDECOD / AETERM / AEREL / AESER
CM	USUBJID / CMENDTC / CMSTDTC / CMDOSE / CMDECOD / CMINDC

Introduction of platform——AE/CM

1. Overview each subject's AE/CM
   i. View each AE/CM's duration
   ii. Show all AE/CM for each subject
   iii. Show toxicity grade for each AE and use different color to represent each toxicity grade
   iv. Use different color to represent each indication for CM
2. Show date of 1st drug
3. Special selections for AE/CM, such as SAE, AESI, relatedness, indication

Introduction of platform——AE/CM

Patient Level

EDC Date - 01: 2022-04-20

Study ID:

dummy-001

Study Part

All

Cohort:

Overall cohorts

Initial drug Dose Level:

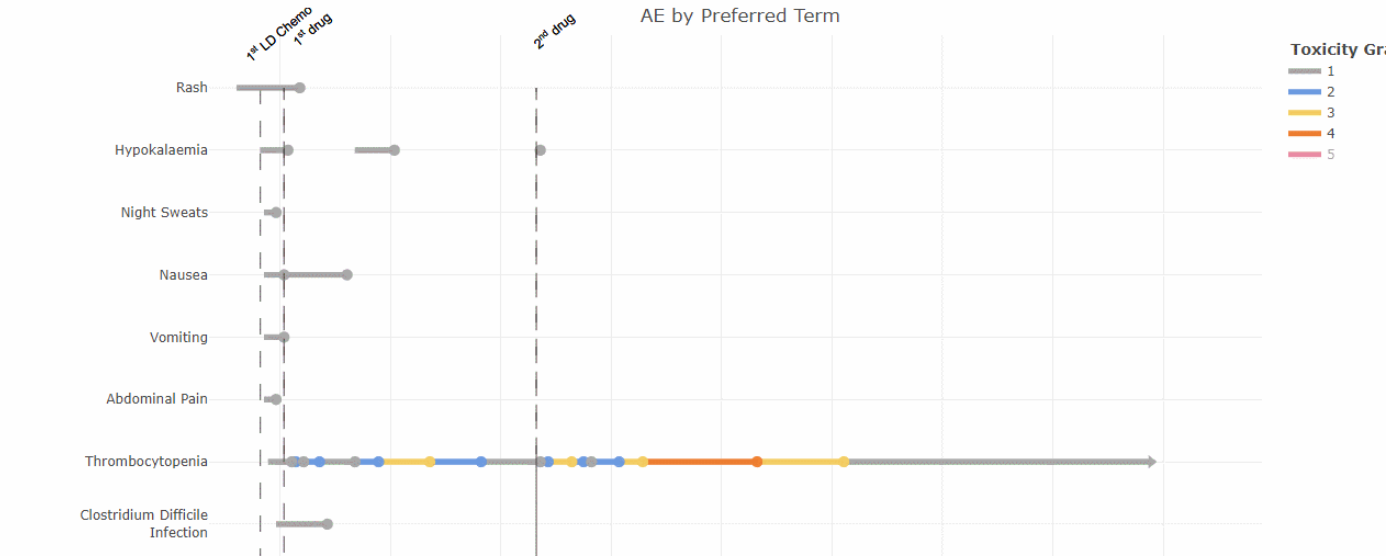
- (●) All
- ( ) DL1
- ( ) DL2
- ( ) DL3
- ( ) DL3.5
- ( ) DL4

Subject ID:

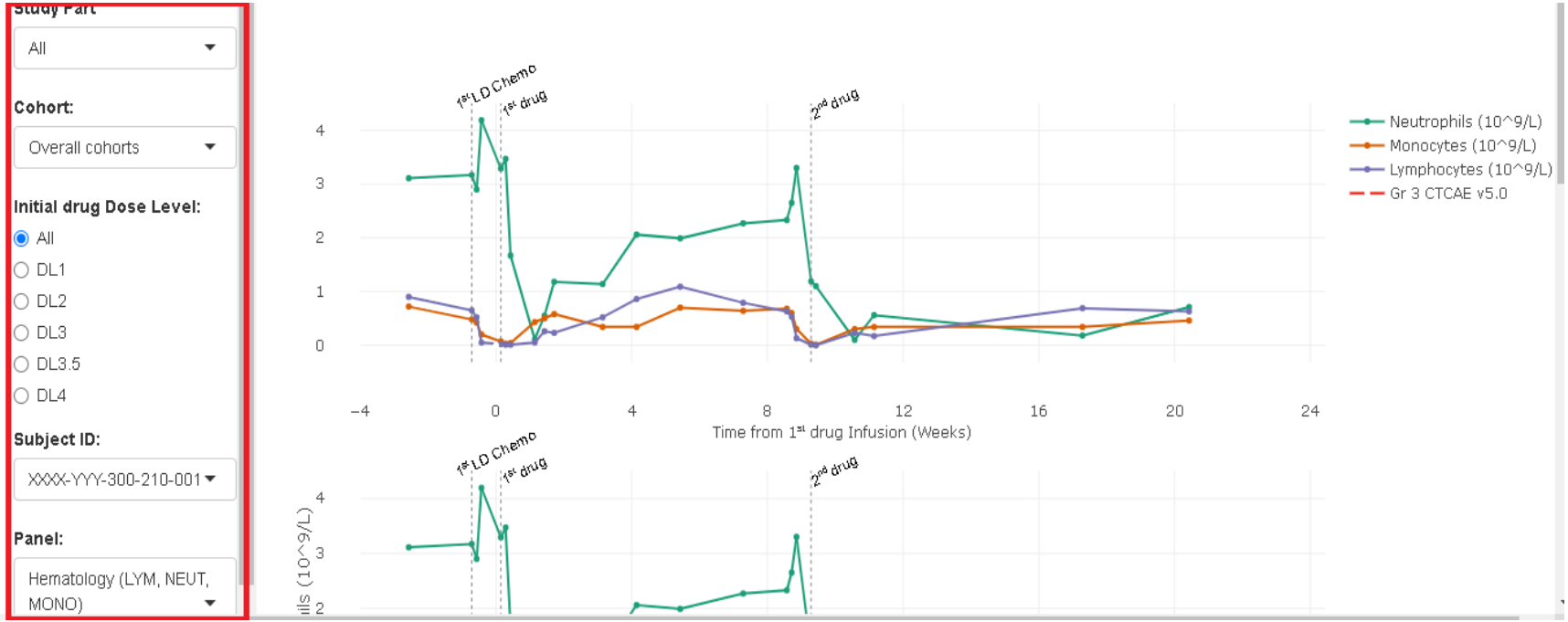
XXXX-YYY-300-210-001

AE category

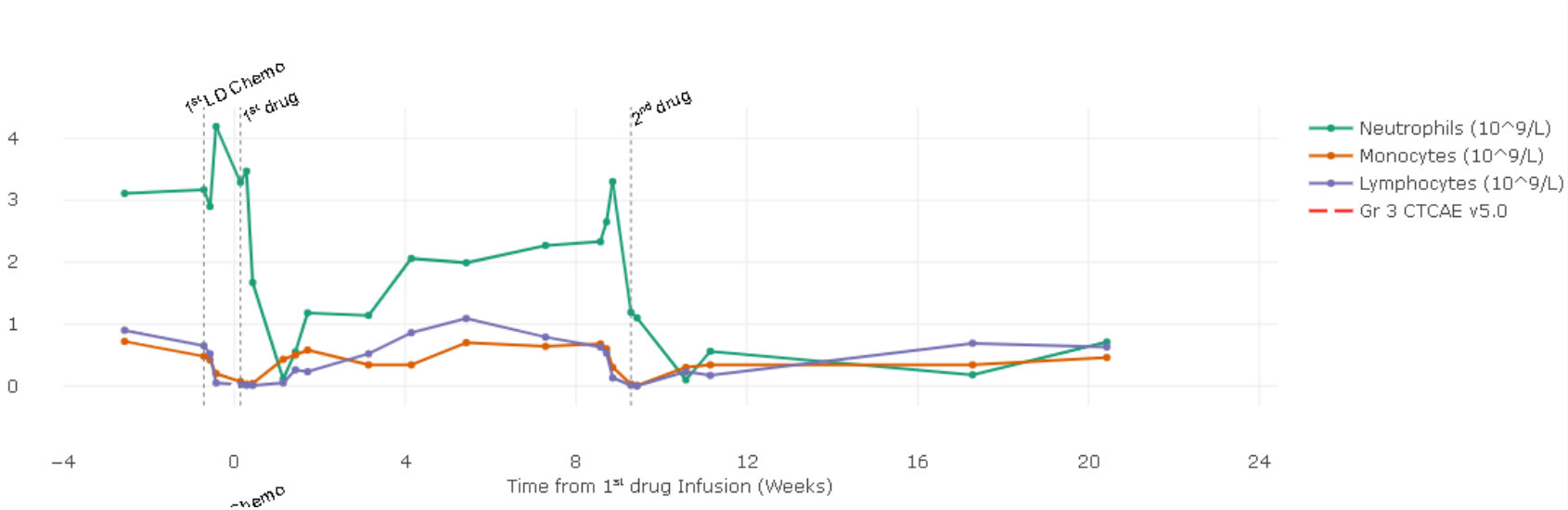
Subject ID: XXXX-YYY-300-210-001, **Study Part:** Part A, **Study Status:** Ongoing, **Age:** 63, **Gender:** Female,
1st drug Dose Level/Date: DL3.5 (4.5x10^8) / 2020-11-09, **2nd drug Dose Level/Date:** DL3.5 (4.5x10^8) / 2021-01-12, **Stage:** Stage IV, **Subtype:** DLBCL NOS,
Prior Lines of Systemic Therapies: 2



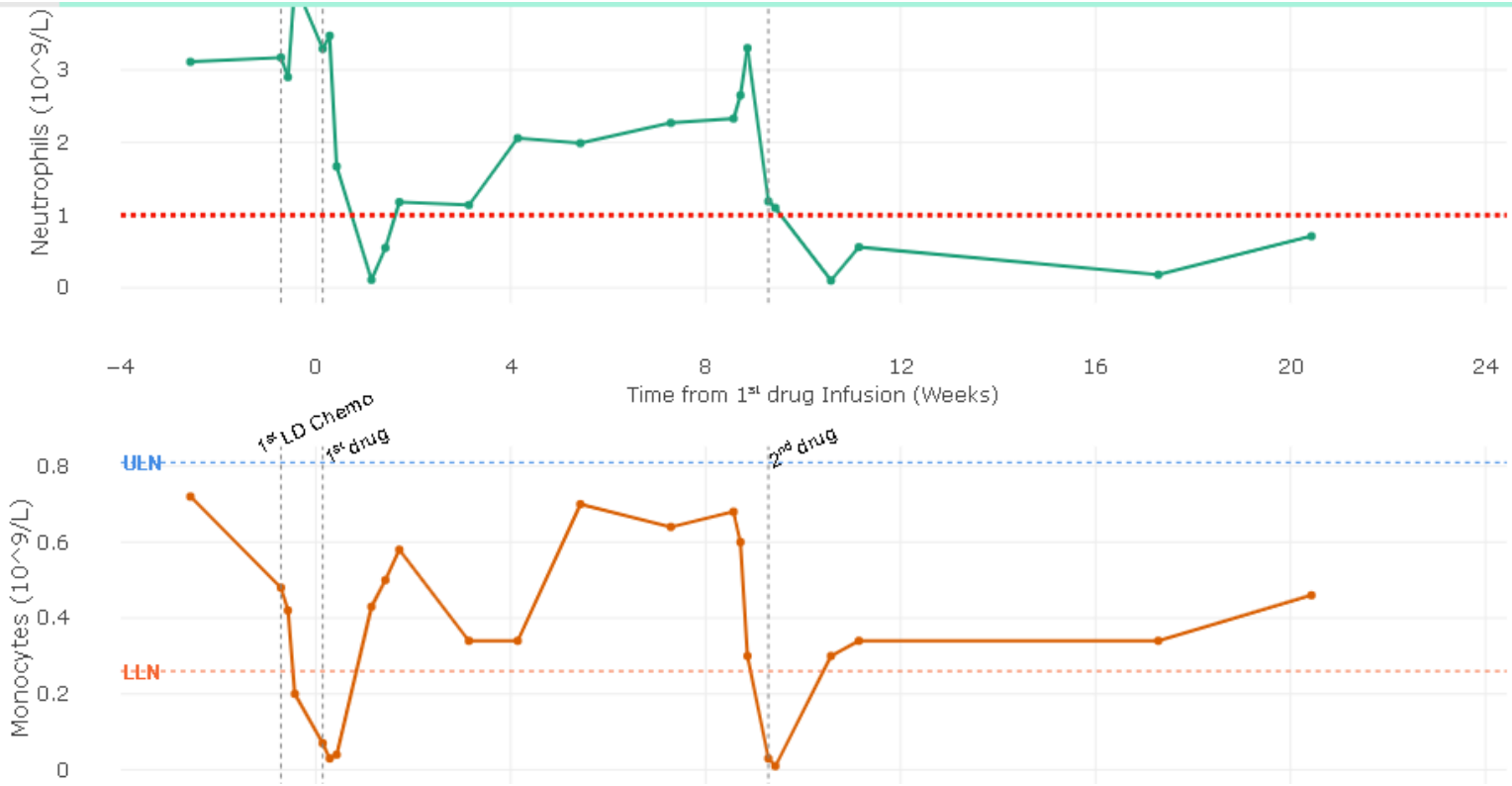
Introduction of platform——Laboratory/Vital Signs/PK



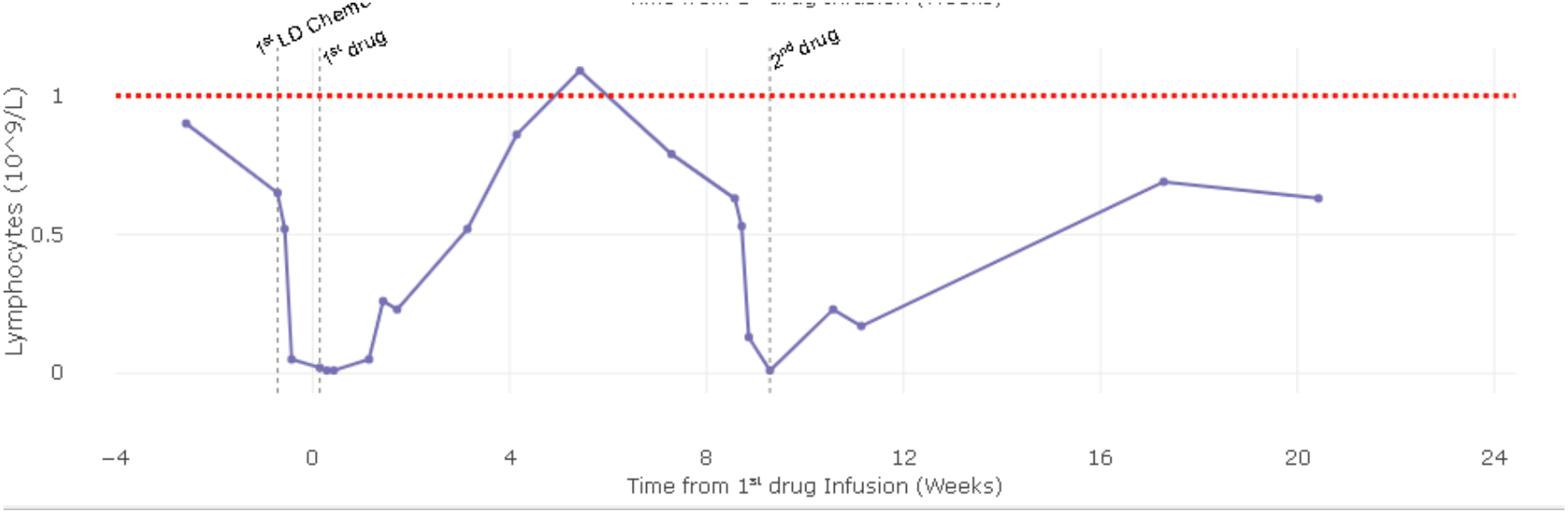
Introduction of platform——Laboratory/Vital Signs/PK



Introduction of platform——Laboratory/Vital Signs/PK



Introduction of platform——Laboratory/Vital Signs/PK



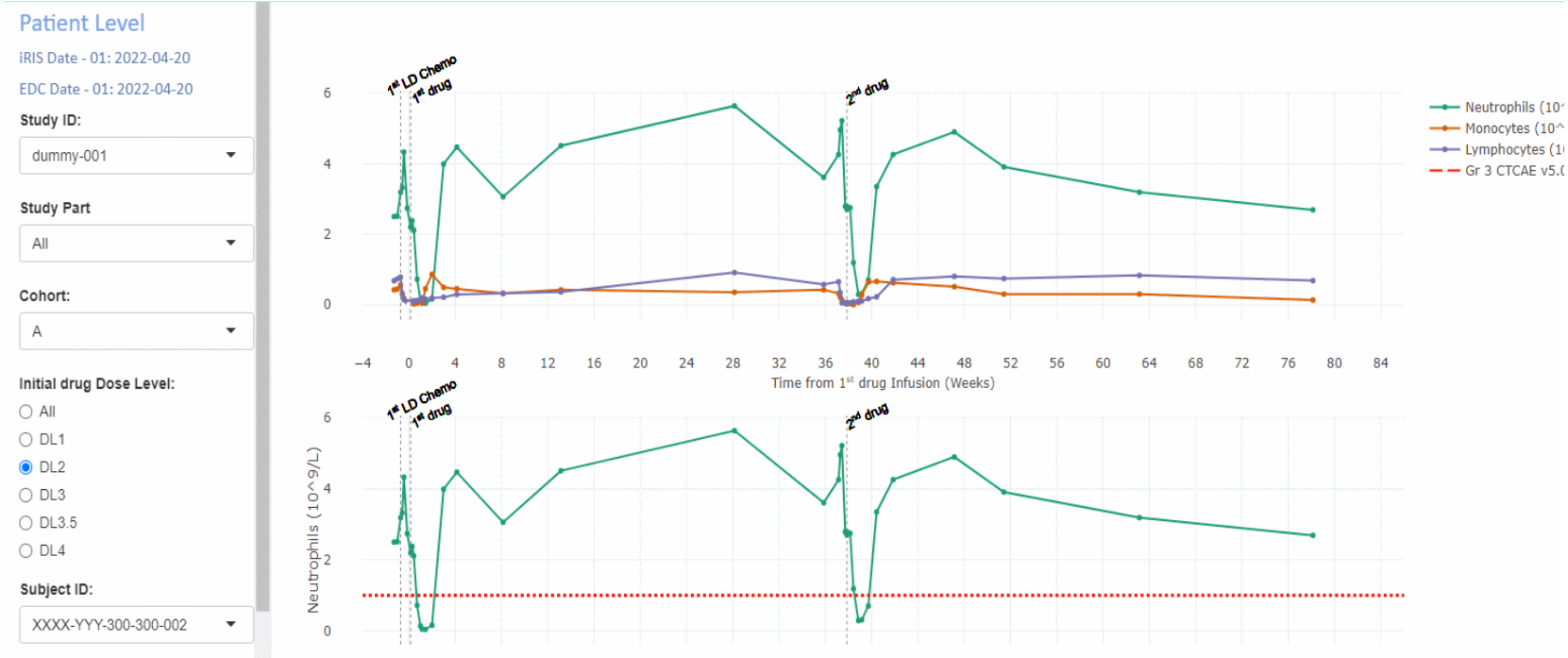
Introduction of platform——Laboratory/Vital Signs/PK

SDTM/ADaM	Variable
DM	STUDYID / USUBJID / RFICDTC / SITEID / AGE / SEX / ACTARM
EX	USUBJID / EXTRT / EXDOSE / EXSTDTC / EXENDTC
LB	USUBJID / LBSTRESN / LBSTRESC / LBSTNRHI / LBSTNRLO / LBTESTCD / LBSTRESU / LBDTC
VS	USUBJID / VSDTC / VSTEST / VSSTRESN / VSSTRESU
PC	USUBJID / PCDTC / PCSTRESN / PCTPT

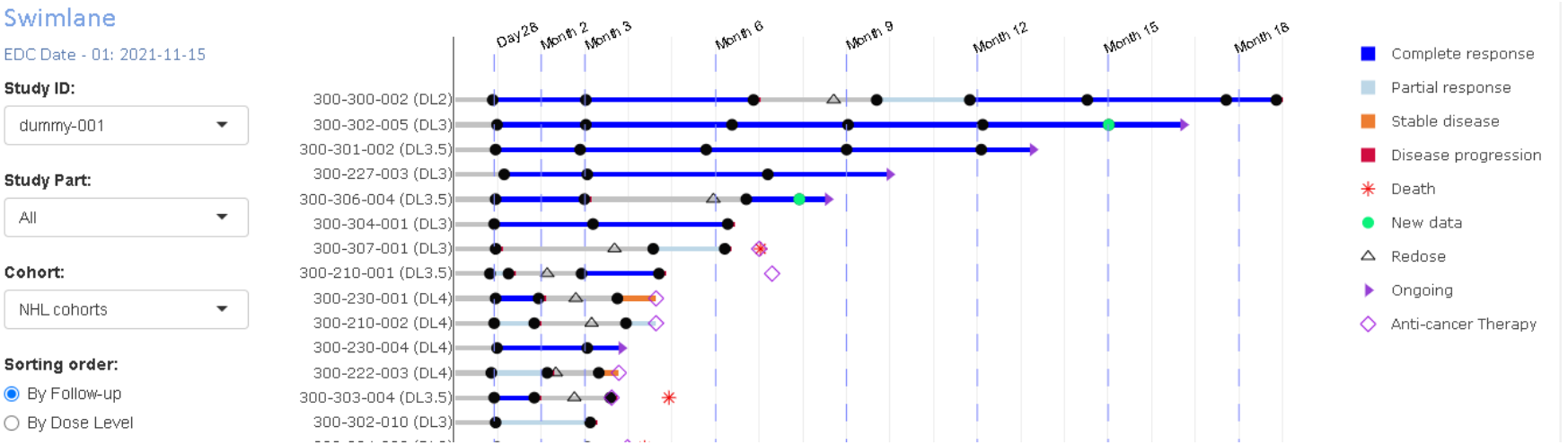
Introduction of platform——Laboratory/Vital Signs/PK

1. Overview each subject's LB/VS/PK
   i. Show ULN and LLN
   ii. Split LBTEST to some panels
   iii. View change of each test at whole study
2. Show date of 1st drug and ref standard value

Introduction of platform——Laboratory/Vital Signs/PK



Introduction of platform——Efficacy



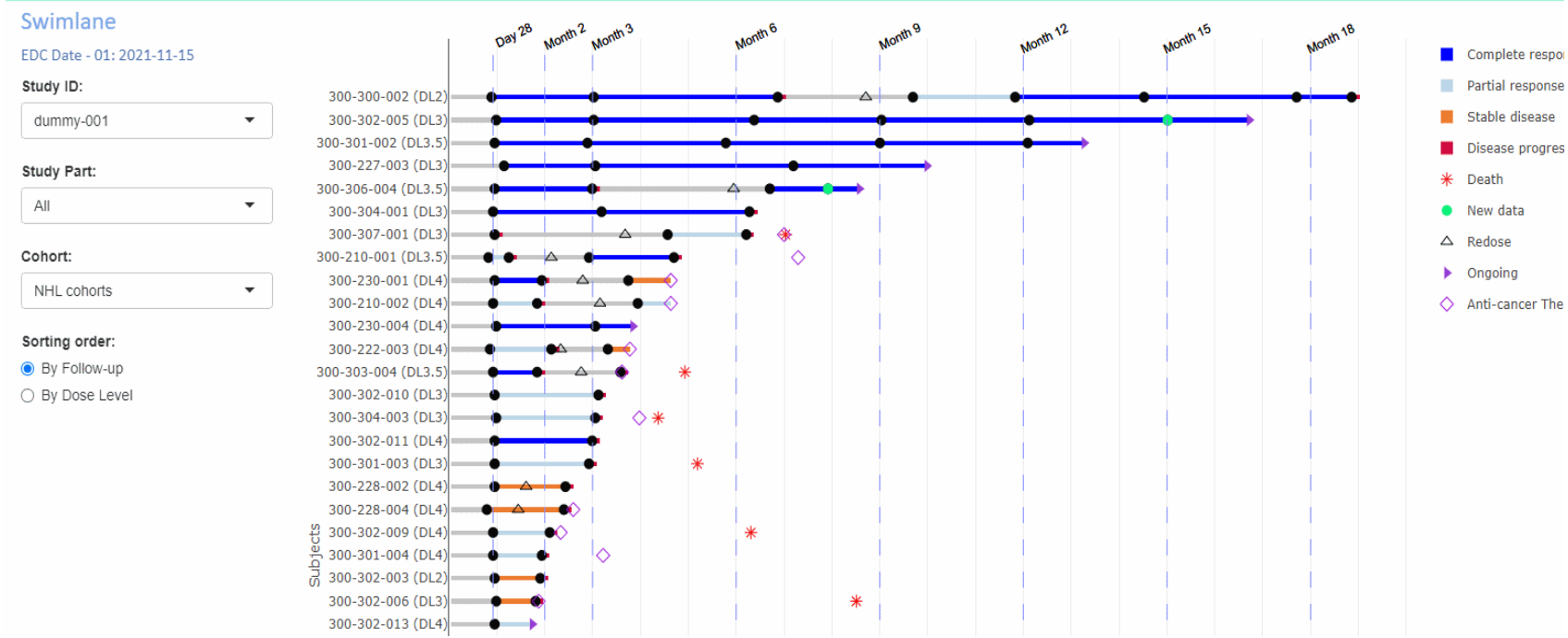
Introduction of platform——Efficacy

SDTM/ADaM	Variable
DM	STUDYID / USUBJID / RFICDTC / SITEID / AGE / SEX / ACTARM
DS	USUBJID / DSTERM / DSSTDTC
EX	USUBJID / EXTRT / EXDOSE / EXSTDTC / EXENDTC

Introduction of platform——Efficacy

1. Overview each subject's disposition
   i. View disposition of each subject at whole duration
   ii. Use different type of marker or color to represent different distribution
   iii. Overview all subject's efficacy
2. Show ref date

Introduction of platform——Efficacy



Conclusion

Conclusion

- Using CDISC datasets, it's more efficient to create high quality Data visualization application
- Multiple and different type figures, split to many modules by CDISC standards.
- User-friendly. This platform can help the medical, regulatory and commercial sectors to make fast and accurate decisions.
- Only use SDTM/ADaM right now

Thank You!