

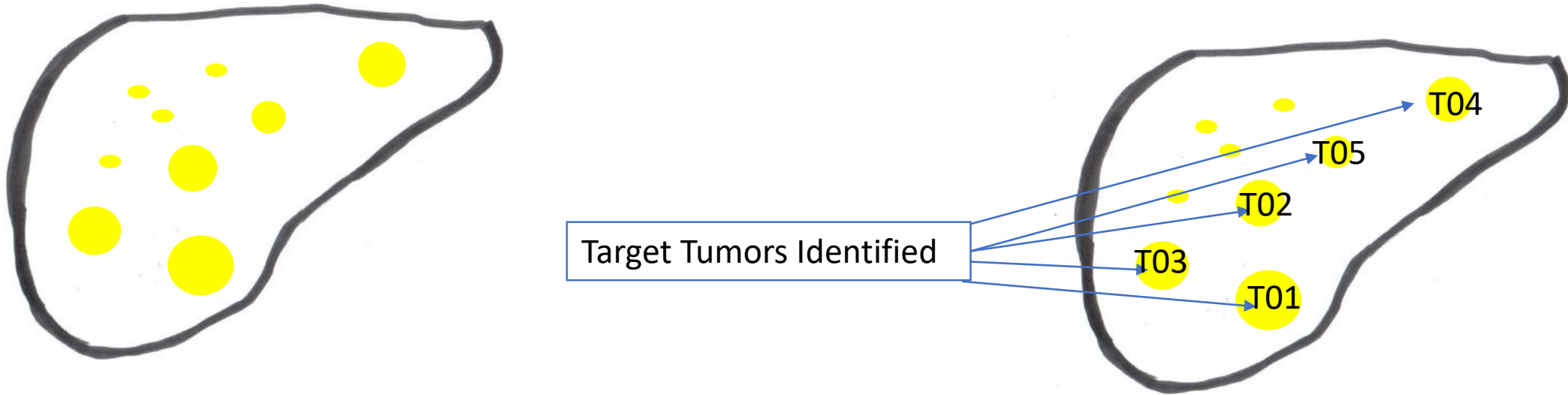
Oncology Domains

Tumor Identification (TU)

Tumor Results (TR)

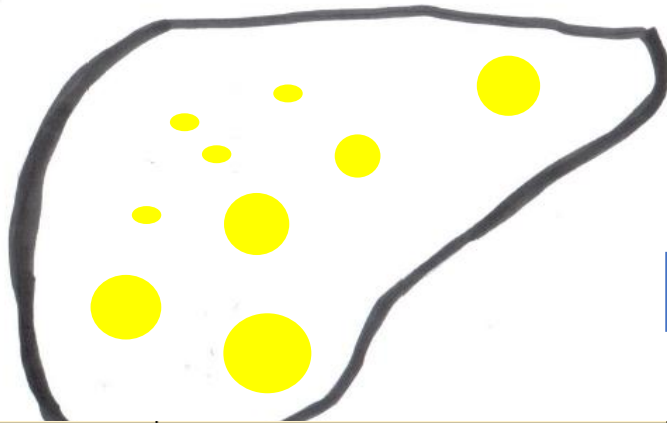
Disease Response (RS)

Target (and non-target) Tumors in SDTM Tumor Identification (TU) Domain

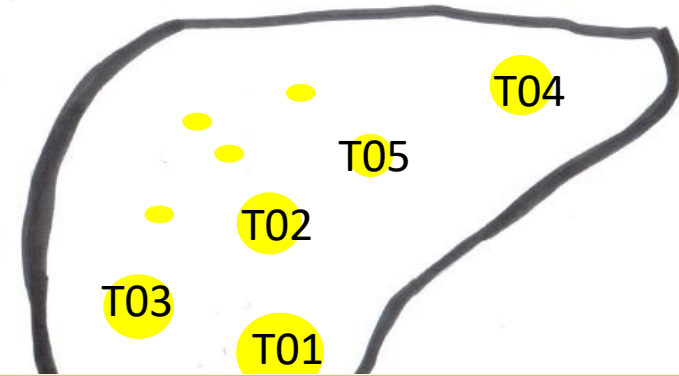


STUDYID	DOMAIN	USUBJID	TUSEQ	TULNKID	TUTESTCD	TUTEST	TUORRES	TUSTRESC	TULOC	TUMETHOD	VISITNUM	VISIT
STUDY1	TU	ABC123	1	T01	TUMIDENT	Tumor Identification	TARGET	TARGET	LIVER	PET SCAN	1	SCREEN
STUDY1	TU	ABC123	2	T02	TUMIDENT	Tumor Identification	TARGET	TARGET	LIVER	PET SCAN	1	SCREEN
STUDY1	TU	ABC123	3	T03	TUMIDENT	Tumor Identification	TARGET	TARGET	LIVER	PET SCAN	1	SCREEN
STUDY1	TU	ABC123	4	T04	TUMIDENT	Tumor Identification	TARGET	TARGET	LIVER	PET SCAN	1	SCREEN
STUDY1	TU	ABC123	5	T05	TUMIDENT	Tumor Identification	TARGET	TARGET	LIVER	PET SCAN	1	SCREEN

Tumor Measurements and Other Assessments in Tumor Results (TR)

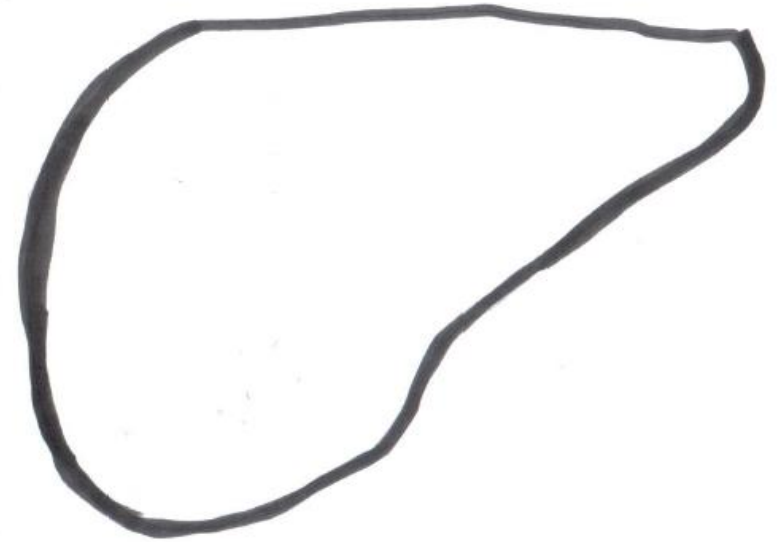
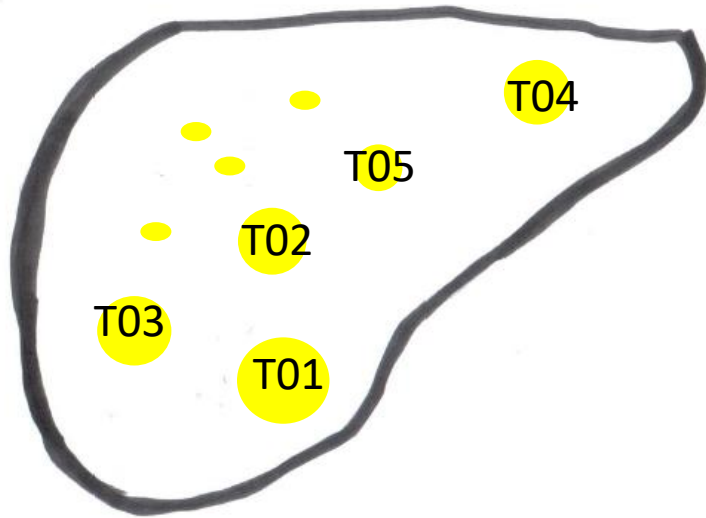


Tumors Measured/Assessed



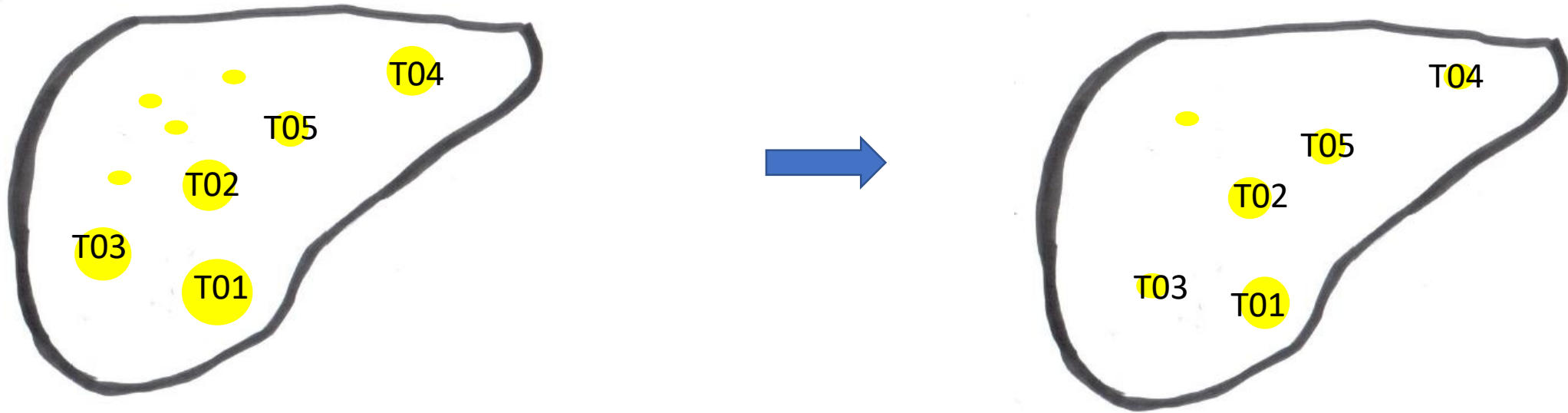
STUDYID	DOMAIN	USUBJID	TRSEQ	TRGRPID	TRLNKGRP	TRLNKID	TRTESTCD	TRTEST	TRORRES	TRORRESU	TRSTRES	RSTRES	RSTRES	RMETHO	TREVAL	VISITNUM	VISIT	TRDTC	TRDY
STUDY1	TR	ABC123	1	TARGET	A1	T01	DIAMETER	Diameter	17	mm	17	17	mm	CT SCAN	INVESTIGATOR	10	SCREEN	1/1/2010	-3
STUDY1	TR	ABC123	2	TARGET	A1	T02	DIAMETER	Diameter	16	mm	16	16	mm	CT SCAN	INVESTIGATOR	10	SCREEN	1/1/2010	-3
STUDY1	TR	ABC123	3	TARGET	A1	T03	DIAMETER	Diameter	15	mm	15	15	mm	MRI	INVESTIGATOR	10	SCREEN	1/2/2010	-2
STUDY1	TR	ABC123	4	TARGET	A1	T04	DIAMETER	Diameter	14	mm	14	14	mm	PHOTOGRAPHY	INVESTIGATOR	10	SCREEN	1/3/2010	-1
STUDY1	TR	ABC123	5	TARGET	A1		SUMDIAM	Sum of Diameter	62	mm	62	62	mm		INVESTIGATOR	10	SCREEN		
STUDY1	TR	ABC123	6	TARGET	A1		SUMNLNLD	Sum Diameters of Non Lymph Node Tumors	47	mm	47	47	mm		INVESTIGATOR	10	SCREEN		
STUDY1	TR	ABC123	7	NON-TARGET	A1	NT01	TUMSTATE	Tumor State	PRESENT		PRESENT			CT SCAN	INVESTIGATOR	10	SCREEN	1/1/2010	-3
STUDY1	TR	ABC123	8	NON-TARGET	A1	NT02	TUMSTATE	Tumor State	PRESENT		PRESENT			MRI	INVESTIGATOR	10	SCREEN	1/2/2010	-2
STUDY1	TR	ABC123	9	TARGET	A2	T01	DIAMETER	Diameter	0	mm	0	0	mm	CT SCAN	INVESTIGATOR	40	WEEK 6	2/18/2010	46
STUDY1	TR	ABC123	10	TARGET	A2	T02	DIAMETER	Diameter	TOO SMALL TO MEASURE	mm	5	5	mm	CT SCAN	INVESTIGATOR	40	WEEK 6	2/18/2010	46

Disease Response and Clin Classification (RS)



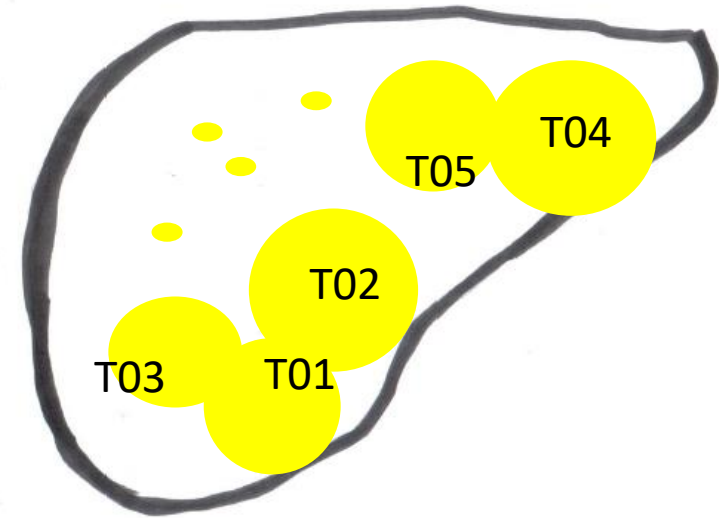
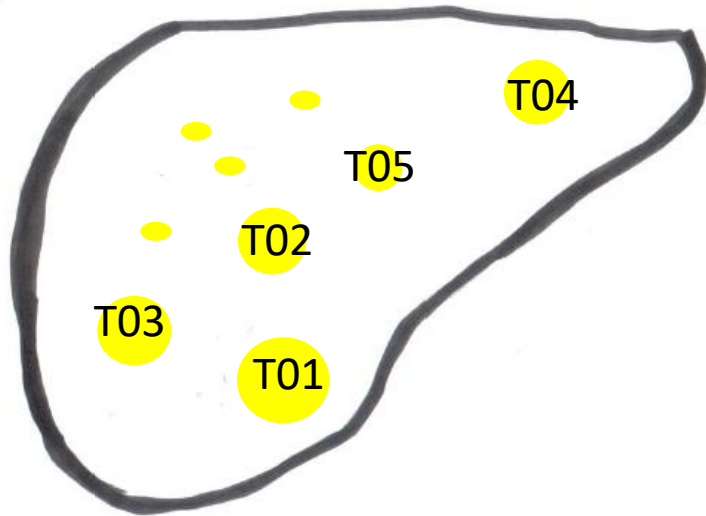
Complete Response (CR)

Disease Response and Clin Classification (RS)



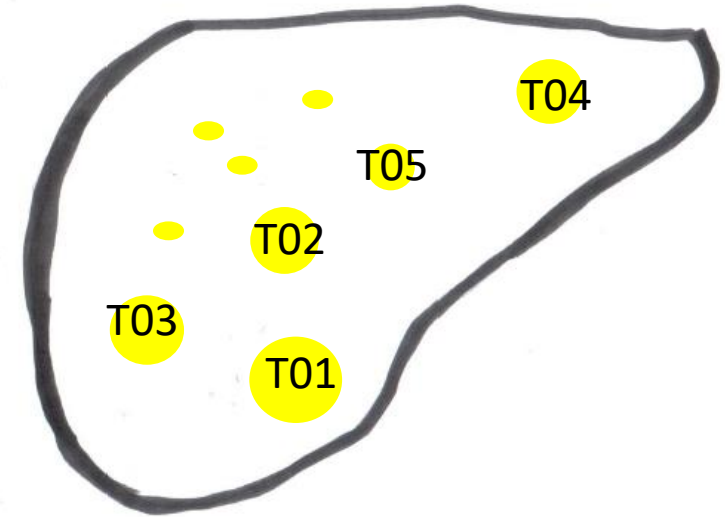
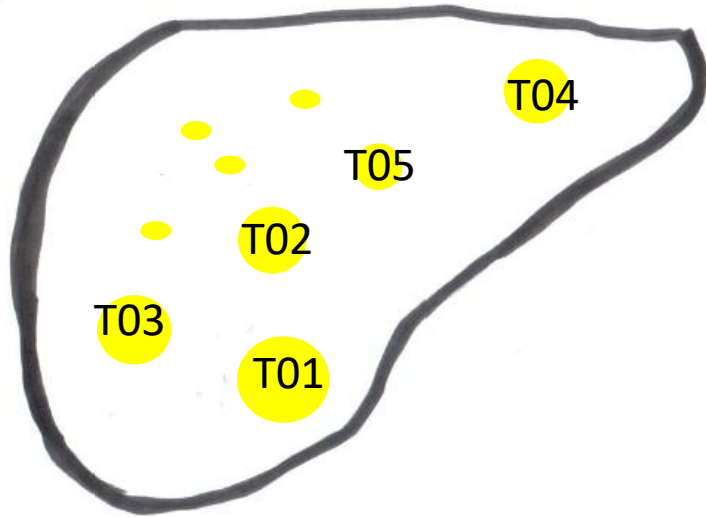
Partial Response (PR)

Disease Response and Clin Classification (RS)



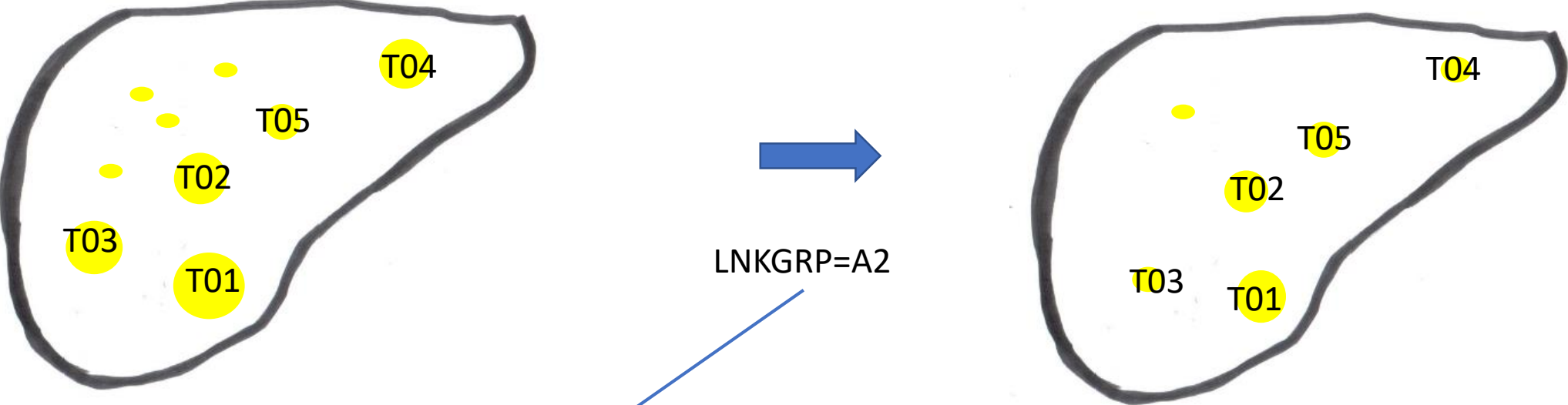
Progressive Disease (PD)

Disease Response and Clin Classification (RS)



Stable Disease (SD)

Disease Response and Clin Classification (RS)



STUDYID	DOMAIN	USUBJID	RSSEQ	RSLNKGR	RSTESTCD	RSTEST	RSCAT	RSORRES	RSSTRES	RSEVAL	VISITNUM	VISIT	RSDTC	RSDY
STUDY1	RS	ABC123	1		TRGRESP	Target Response	RECIST 1.1	PR	PR	INVESTIGATOR	40	WEEK 6	2/18/2010	46
STUDY1	RS	ABC123	2		NTRGRESP	Non-target Response	RECIST 1.1	SD	SD	INVESTIGATOR	40	WEEK 6	2/18/2010	46
STUDY1	RS	ABC123	3	A2	OVRLRESP	Overall Response	RECIST 1.1	PR	PR	INVESTIGATOR	40	WEEK 6	2/18/2010	46
STUDY1	RS	ABC123	4		TRGRESP	Target Response	RECIST 1.1	NE	NE	INVESTIGATOR	60	WEEK 12	4/2/2010	88
STUDY1	RS	ABC123	5		NTRGRESP	Non-target Response	RECIST 1.1	NE	NE	INVESTIGATOR	60	WEEK 12	4/2/2010	88
STUDY1	RS	ABC123	6		SYMPTDTR	Symptomatic Deterioration	PROTOCOL DEFINED RESPONSE CRITERIA	Pleural Effusion	PD	INVESTIGATOR	60	WEEK 12	4/2/2010	88
STUDY1	RS	ABC123	7	A3	OVRLRESP	Overall Response	PROTOCOL DEFINED RESPONSE CRITERIA	PD	PD	INVESTIGATOR	60	WEEK 12	4/2/2010	88

TU +
TR +
RS

Tumor Identification (TU) - Topic is the identification of target and non-target tumors / lesions

STUDYID	DOMAIN	USUBJID	TUSEQ	TULNKID	TUTESTCD	TUTEST	TUORRES	TUSTRESC	TULOC	TUMETHO	VISITNUM	VISIT
STUDY1	TU	ABC123	1	T01	TUMIDENT	Tumor Identification	TARGET	TARGET	LIVER	PET SCAN	1	SCREEN
STUDY1	TU	ABC123	2	T02	TUMIDENT	Tumor Identification	TARGET	TARGET	LIVER	PET SCAN	1	SCREEN
STUDY1	TU	ABC123	3	T03	TUMIDENT	Tumor Identification	TARGET	TARGET	LIVER	PET SCAN	1	SCREEN
STUDY1	TU	ABC123	4	T04	TUMIDENT	Tumor Identification	TARGET	TARGET	LIVER	PET SCAN	1	SCREEN
STUDY1	TU	ABC123	5	T05	TUMIDENT	Tumor Identification	TARGET	TARGET	LIVER	PET SCAN	1	SCREEN

Tumor Results (TR) - Topic is the measurement and other assessments for target and non-target tumors/lesions

STUDYID	DOMAIN	USUBJID	TRSEQ	TRGRPID	TRLNKGRP	TRLNKID	TRTESTCD	TRTEST	TRORRES	TRORRESU	TRSTRESC	RSTRES	RSTRESU	RMETHO	TREVAL	VISITNUM	VISIT	TRDTC	TRDY
ABC	TR	44444	1	TARGET	A1	T01	DIAMETER	Diameter	17	mm	17	17	mm	CT SCAN	INVESTIGATOR	10	SCREEN	1/1/2010	-3
ABC	TR	44444	2	TARGET	A1	T02	DIAMETER	Diameter	16	mm	16	16	mm	CT SCAN	INVESTIGATOR	10	SCREEN	1/1/2010	-3
ABC	TR	44444	3	TARGET	A1	T03	DIAMETER	Diameter	15	mm	15	15	mm	MRI	INVESTIGATOR	10	SCREEN	1/2/2010	-2
ABC	TR	44444	4	TARGET	A1	T04	DIAMETER	Diameter	14	mm	14	14	mm	PHOTOGRAPHY	INVESTIGATOR	10	SCREEN	1/3/2010	-1
ABC	TR	44444	5	TARGET	A1		SUMDIAM	Sum of Diameter	62	mm	62	62	mm		INVESTIGATOR	10	SCREEN		
ABC	TR	44444	6	TARGET	A1		SUMNLNLD	Sum Diameters of Non Lymph Node Tumors	47	mm	47	47	mm		INVESTIGATOR	10	SCREEN		
ABC	TR	44444	7	NON-TARGET	A1	NT01	TUMSTATE	Tumor State	PRESENT		PRESENT			CT SCAN	INVESTIGATOR	10	SCREEN	1/1/2010	-3
ABC	TR	44444	8	NON-TARGET	A1	NT02	TUMSTATE	Tumor State	PRESENT		PRESENT			MRI	INVESTIGATOR	10	SCREEN	1/2/2010	-2
ABC	TR	44444	9	TARGET	A2	T01	DIAMETER	Diameter	0	mm	0	0	mm	CT SCAN	INVESTIGATOR	40	WEEK 6	2/18/2010	46
ABC	TR	44444	10	TARGET	A2	T02	DIAMETER	Diameter	TOO SMALL TO MEASURE	mm	5	5	mm	CT SCAN	INVESTIGATOR	40	WEEK 6	2/18/2010	46

Disease Response and Clin Classification (RS) - Topic is disease response (e.g., RECIST)

STUDYID	DOMAIN	USUBJID	RSSEQ	RSLNKGRP	RSTESTCD	RSTEST	RSCAT	RSORRES	RSSTRESC	RSEVAL	VISITNUM	VISIT	RSDTC	RSDY
ABC	RS	44444	1		TRGRES	Target Response	RECIST 1.1	PR	PR	INVESTIGATOR	40	WEEK 6	2/18/2010	46
ABC	RS	44444	2		NTRGRES	Non-target Response	RECIST 1.1	SD	SD	INVESTIGATOR	40	WEEK 6	2/18/2010	46
ABC	RS	44444	3	A2	OVRGRES	Overall Response	RECIST 1.1	PR	PR	INVESTIGATOR	40	WEEK 6	2/18/2010	46
ABC	RS	44444	4		TRGRES	Target Response	RECIST 1.1	NE	NE	INVESTIGATOR	60	WEEK 12	4/2/2010	88
ABC	RS	44444	5		NTRGRES	Non-target Response	RECIST 1.1	NE	NE	INVESTIGATOR	60	WEEK 12	4/2/2010	88
ABC	RS	44444	6		SYMPTDTR	Symptomatic Deterioration	PROTOCOL DEFINED RESPONSE CRITERIA	Pleural Effusion	PD	INVESTIGATOR	60	WEEK 12	4/2/2010	88
ABC	RS	44444	7	A3	OVRGRES	Overall Response	PROTOCOL DEFINED RESPONSE CRITERIA	PD	PD	INVESTIGATOR	60	WEEK 12	4/2/2010	88