

Not Done		①
Visit date		②
Age		③
Form source	VISIT	④

V13 of Impassion030_Draft_V01: Master
Form: Visit Date
Generated On: 09 Mar 2018 17:23:17

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	NOTDN	1				NOTDN
②	VISD	dd- MMM- YYYY				VISD
③	AGE	4				AGE
④	FRMSRC	\$10		VISIT		FRMSRC

V13 of Impassion030_Draft_V01: Master
Form: IxRS
Generated On: 09 Mar 2018 17:23:17

Randomization date

①

V13 of Impassion030_Draft_V01: Master
Form: IxRS
Generated On: 09 Mar 2018 17:23:17

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① RAND	dd MMM YYYY				RAND

**V13 of Impassion030_Draft_V01: Master
Form: Actual Randomization Assignment
Generated On: 09 Mar 2018 17:23:17**

Actual study arm

Arm A (Atezolizumab + ☐ ①
chemotherapy)
Arm B (Chemotherapy ☐
alone)

Form source

ACTRAGM ②

**V13 of Impassion030_Draft_V01: Master
Form: Actual Randomization Assignment
Generated On: 09 Mar 2018 17:23:17**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① TXARM	\$48		ARM A (ATEZOLIZUMAB + CHEMOTHERAPY) = Arm A (Atezolizumab + chemotherapy) ARM B (CHEMOTHERAPY ALONE) = Arm B (Chemotherapy alone)		TXARM
② FRMSRC	\$10		ACTRAGM		FRMSRC

V13 of Impassion030_Draft_V01: Master
Form: Subject Identification
Generated On: 09 Mar 2018 17:23:17

Subject number

①

Subject Identification

②

V13 of Impassion030_Draft_V01: Master
Form: Subject Identification
Generated On: 09 Mar 2018 17:23:17

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PTNUM	10				PTNUM
②	PTID	\$10				PTID

V13 of Impassion030_Draft_V01: Master
Form: Protocol Informed Consent
Generated On: 09 Mar 2018 17:23:17

Date subject or legal guardian signed protocol informed consent _____

①

Protocol version

- 2 ☐ ②
2 VHP ☐
3 ☐
4 ☐
5 ☐
6 ☐
7 ☐
8 ☐
9 ☐
10 ☐

Form source

PIC ③

**V13 of Impassion030_Draft_V01: Master
Form: Protocol Informed Consent
Generated On: 09 Mar 2018 17:23:17**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	ICD	dd MMM YYYY				ICD
②	PRTVSN	\$5		2 = 2 2 VHP = 2 VHP 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10		PRTVSN
③	FRMSRC	\$10		PIC		FRMSRC

V13 of Impassion030_Draft_V01: Master
Form: RBR Research Sample Informed Consent
Generated On: 09 Mar 2018 17:23:17

Did the subject consent to sample collection?

Yes ☐ ①
No ☐

Date subject or legal guardian signed RBR research
sample informed consent _____

②

Consent type

RBR ③

Form source

RSIC1 ④

V13 of Impassion030_Draft_V01: Master
Form: RBR Research Sample Informed Consent
Generated On: 09 Mar 2018 17:23:17

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	CONSNT1	\$3		YES = Yes NO = No		CONSNT1
②	SC1D	dd MMM YYYY				SC1D
③	CONTYP	\$30		RBR		CONTYP
④	FRMSRC	\$10		RSIC1		FRMSRC

V13 of Impassion030_Draft_V01: Master
Form: RBR Research Sample Withdrawal of Informed Consent
Generated On: 09 Mar 2018 17:23:17

Date consent withdrawn _____ ①

Consent type _____ RBR ②

Form source _____ RSIC2 ③

V13 of Impassion030_Draft_V01: Master
Form: RBR Research Sample Withdrawal of Informed Consent
Generated On: 09 Mar 2018 17:23:17

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	SCW1D	dd- MMM- YYYY				SCW1D
②	CONTYP	\$30		RBR		CONTYP
③	FRMSRC	\$10		RSIC2		FRMSRC

V13 of Impassion030_Draft_V01: Master
Form: Demographics
Generated On: 09 Mar 2018 17:23:17

Date of Birth _____ ①

Age _____ Fixed Unit: Years ②

Age unit _____ YEAR ③

Sex _____ Male ☐ ④
Female ☐

Ethnicity _____ Hispanic or Latino ☐ ⑤
Not Hispanic or Latino ☐
Not Reported ☐
Unknown ☐

Race (select all that apply):

American Indian or Alaska Native _____ ⑦

Asian _____ ⑧

If race is Asian, specify origin _____ Chinese ☐ ⑨
Taiwanese ☐
Asian Indian ☐
Korean ☐
Malaysian ☐
Vietnamese ☐
Other Asian ☐

Black or African American		10
Native Hawaiian or Other Pacific Islander		11
White		12
Unknown		13
Form source	DEM	14

V13 of Impassion030_Draft_V01: Master
Form: Demographics
Generated On: 09 Mar 2018 17:23:17

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	BRTHD	dd- MMM- YYYY				BRTHD
②	AGEIC	4				AGEIC
③	AGEU	\$6		YEAR		AGEU
④	SEX	\$6		MALE = Male FEMALE = Female		SEX
⑤	ETHNIC	\$22		HISPANIC OR LATINO = Hispanic or Latino NOT HISPANIC OR LATINO = Not Hispanic or Latino NOT REPORTED = Not Reported UNKNOWN = Unknown		ETHNIC
⑦	INDALK	1				INDALK
⑧	ASIAN	1				ASIAN

V13 of Impassion030_Draft_V01: Master
Form: Demographics
Generated On: 09 Mar 2018 17:23:17

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9	RACESP	\$30		CHINESE = Chinese TAIWANES E = Taiwanese ASIAN INDIAN = Asian Indian KOREAN = Korean MALAYSIAN = Malaysian VIETNAMES E = Vietnamese OTHER ASIAN = Other Asian		RACESP
10	BLACK	1				BLACK
11	ISLAND	1				ISLAND
12	WHITE	1				WHITE
13	RACEUNK	1				RACEUNK
14	FRMSRC	\$10		DEM		FRMSRC

V13 of Impassion030_Draft_V01: Master
Form: Tobacco Use History
Generated On: 09 Mar 2018 17:23:17

Has the subject ever used tobacco?

Never ☐ ①
Current ☐
Former ☐

If former, how long since subject stopped using tobacco?

Fixed Unit: years ②

End reference timepoint

SCREENING ③

Form source

TOHX ④

V13 of Impassion030_Draft_V01: Master
Form: Tobacco Use History
Generated On: 09 Mar 2018 17:23:17

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	TOBHX	\$8		NEVER = Never CURRENT = Current FORMER = Former		TOBHX
②	YRSTP	5.2				YRSTP
③	ERFPNT	\$50		SCREENING		ERFPNT
④	FRMSRC	\$10		TOHX		FRMSRC

**V13 of Impassion030_Draft_V01: Master
Form: Female Fertility Status
Generated On: 09 Mar 2018 17:23:17**

Female fertility status

Childbearing Potential ☐ ①

Surgically Sterile ☐

Post-menopausal ☐

Date of last menses

②

Date of last menses unknown

③

Complete section below if subject is of childbearing potential

④

Combined hormonal contraception

⑤

Progesterone-only hormonal contraception

⑥

Intrauterine device (IUD)

⑦

Intrauterine hormone-releasing system (IUS)

⑧

Bilateral tubal occlusion

⑨

Vasectomised partner

⑩

Sexual abstinence

⑪

Other

⑫

Other, please specify

⑬

V13 of Impassion030_Draft_V01: Master
Form: Female Fertility Status
Generated On: 09 Mar 2018 17:23:17

Surgery or Procedure that impacts fertility status

14

Did the subject have any relevant surgeries or procedures that impact fertility status?

Yes ☐ 15

No ☐

Surgery or procedure description

Total Hysterectomy ☐ 16

Partial Hysterectomy ☐

Ovariectomy/Oophorectomy ☐

Salpingectomy ☐

Salpingo-Oophorectomy ☐

Tubal Ligation ☐

Other ☐

If Other, please specify

17

Laterality of procedure

Right ☐ 18

Left ☐

Bilateral ☐

Not Applicable ☐

Surgery or procedure date

19

Surgery or procedure date unknown

20

Form source

FFTST 21

**V13 of Impassion030_Draft_V01: Master
Form: Female Fertility Status
Generated On: 09 Mar 2018 17:23:17**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	FFTST	\$60		CHILDBEARING POTENTIAL = Childbearing g Potential SURGICALLY STERILE = Surgically Sterile POST-MEN OPAUSAL = Post-menopausal		FFTST
②	MNLD	dd- MMM- YYYY				MNLD
③	MNLDTU	1				MNLDTU
④	BLUE1	\$200				BLUE1
⑤	CMHMCP	1				CMHMCP
⑥	PGHMCP	1				PGHMCP
⑦	IUD	1				IUD
⑧	IUHMRLS	1				IUHMRLS
⑨	BLTBOCC	1				BLTBOCC


V13 of Impassion030_Draft_V01: Master
Form: Female Fertility Status
Generated On: 09 Mar 2018 17:23:17

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
10	VASTPR	1				VASTPR
11	SXASTN	1				SXASTN
12	OTH	1				OTH
13	OTHSPEC	\$200				OTHSPEC
14	BLUE2	\$200				BLUE2
15	SRPREC	\$3		YES = Yes NO = No		SRPREC
16	SRRRAW1	\$40		TOTAL HYSTERECTOMY = Total Hysterectomy PARTIAL HYSTERECTOMY = Partial Hysterectomy OVARIECTOMY/OOPHORECTOMY = Ovariectomy/Oophorectomy		SRRRAW1

V13 of Impassion030_Draft_V01: Master
Form: Female Fertility Status
Generated On: 09 Mar 2018 17:23:17

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			SALPINGEC TOMY = Salpingecto my SALPINGO- OOPHOREC TOMY = Salpingo-Oo phorectomy TUBAL LIGATION = Tubal Ligation OTHER = Other		
17 SRRAW1OT HSPEC	\$200				SRRAW1OT HSPEC
18 SRPLAT	\$20		RIGHT = Right LEFT = Left BILATERAL = Bilateral NOT APPLICABL E = Not Applicable		SRPLAT
19 SRPD	dd- MMM- YYYY				SRPD
20 SRPDTU	1				SRPDTU

V13 of Impassion030_Draft_V01: Master
Form: Female Fertility Status
Generated On: 09 Mar 2018 17:23:17

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 FRMSRC	\$10		FFTST		FRMSRC