STATISTICAL ANALYSIS PLAN

VERSION 01.00, 08 NOVEMBER 2023

A Phase 1b/2 Open-Label Study of the Efficacy and Safety of Etigilimab (MPH313) Administered in Combination with Nivolumab to Subjects with Locally Advanced or Metastatic Solid Tumors (ACTIVATE)

MPH313-1-02

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For: Mereo BioPharma 5. Inc. (Mereo BioPharma)

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1. STATISTICAL ANALYSIS PLAN APPROVAL FORM

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3. LIST OF ABBREVIATIONS

Abbreviation	Definition
ADA	Anti-drug antibody
AE	Adverse event
AESI	Adverse Event of Special Interest
ALP	Alkaline phosphatase
ALT	Alanine transaminase
APTT	Activated partial thromboplastin time
AST	Aspartate transaminase
β-HCG	Beta human chorionic gonadotropin
BLQ	Below level of quantification
BMI	Body mass index
BOR	Best overall response
BP	Blood pressure
CC	Cervical cancer
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CPI	Immune Checkpoint Inhibitors
CPS	Combined positive score
CR	Complete Response
CRF	Case Report Form
CRP	C-reactive protein
CSR	Clinical Study Report
CTCAE	Common Terminology Criteria for Adverse Events
CV	Coefficient of Variation
DBP	Diastolic blood pressure
DCR	Disease control rate
DoR	Duration of response
DoSD	Duration of stable disease
DRM	Data review meeting
EC	Endometrial cancer
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
FSH	Follicle stimulating hormone
GC	Gastric cancer and gastro-esophageal junction carcinoma
GCV	Geometric Coefficient of Variation
GCT	Germ cell tumors
GM	Geometric Mean
GSD	Geometric Standard Deviation
HbsAg	Hepatitis B surface antigen
HCAb	Hepatitis C antibodies
HDL	High-density lipoprotein
HIV	Human immunodeficiency virus

Abbreviation	Definition
ADA	Anti-drug antibody
HNSCC	Head and neck squamous cell carcinoma
HR	Heart Rate
ICF	Informed Consent Form
iCPD	iRECIST Confirmed Progressive Disease
iCR	iRECIST Complete Response
IDMC	Independent Data Monitoring Committee
IFN	Interferon
IHC	Immunohistochemistry
IL	Interleukin
INR	International Normalized Ratio
IMP	Investigational Medicinal Product
iORR	Immune objective response rate
iPR	iRECIST Partial Response
IRAE	Immune-Related Adverse Event
iSD	iRECIST stable disease
ITT	Intention to Treat
iUPD	iRECIST unconfirmed Progressive Disease
LLOQ	Lower Limit of Quantification
LPS	Liposarcoma
MedDRA	Medical Dictionary for Regulatory Activities
mRNA	Messenger RNA
MSS	Microsatellite stable
NE	Not Evaluable
NL	Non-target lesions
OC	Ovarian cancer
ORR	Objective Response Rate
OS	Overall survival
PD	Pharmacodynamics
PD	Progressive Disease
PD	Protocol Deviation
PD-1	Programmed death-1
PD-L1	Programmed death ligand-1
PFS	Progression Free Survival
PI	Principal Investigator
PK	Pharmacokinetic
PR	Partial Response
PT	Prothrombin time
PT	Preferred Term
Q1	Lower Quartile
QTc	QT interval corrected
QTcB	QT interval corrected using Bazett's formula
QTcF	QT interval corrected using Fridericia's formula
Q3	Upper Quartile

Abbreviation	Definition
ADA	Anti-drug antibody
RE	Response evaluable
RR	Respiratory rate
RBC	Red blood cell
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SBP	Systolic blood pressure
SD	Stable Disease
SD	Standard Deviation
SE	Standard Error
SOC	System Organ Class
SR	Sarcoma
TB	Tuberculosis
TEAE	Treatment emergent adverse event
TIGIT	
TL	Target lesions
TMB	Tumor mutation burden
TFL	Tables, Figures and Listings
TPS	Tumour proportional score
ULN	upper limit of normal
UM	Uveal melanoma
UPS	Undifferentiated pleomorphic sarcoma
WBC	White blood cell
WHO	World Health Organisation

4. INTRODUCTION

This statistical analysis plan (SAP) explains in detail the statistical analyses that will be performed for the Mereo Biopharma MPH313-1-02 study. The analysis is outlined within the study protocol V4.0, dated 29 June 2022 and this SAP contains a more technical and detailed description of those analyses outlined in the protocol. In particular, information is provided on the definitions of the study populations, and it also details the list of Tables, Figures and Listings (TFL) that will be produced by S-cubed Biometrics for use and inclusion with the Clinical Study Report (CSR). This SAP provides a detailed description of the analyses that will be undertaken and has been written and finalised before locking the database for the final analysis.

A Data Review Meeting (DRM) will be conducted when the study is complete and data is cleaned, prior to final database lock.

Any deviations from the protocol specified analyses will be listed in Section 11 and any deviations from the analyses stated within this SAP, will be described within the CSR.

5. STUDY OBJECTIVES

5.1. Primary Objectives

To make a preliminary assessment of the antitumor activity of etigilimab in combination with nivolumab in subjects with pre-specified recurrent solid tumors. Each cohort will be evaluated independently.

5.2 Secondary Objectives

- Evaluate the safety and tolerability of etigilimab administered in combination with nivolumab.
- To evaluate preliminary anti-tumor activity of etigilimab in combination with nivolumab in subjects with pre-specified recurrent solid tumors. Each cohort will be evaluated independently.
- To characterize the PK of etigilimab in a subset of subjects who have advanced, relapsed, or refractory solid tumors in combination with nivolumab.
- To characterize the immunogenicity of etigilimab in a subset of subjects who have advanced, relapsed, or refractory solid tumors in combination with nivolumab.

5.3 Exploratory Objectives

- To assess exploratory pharmacodynamic biomarkers following etigilimab treatment in combination with nivolumab.
- To assess potential predictive biomarkers for correlation with response to etigilimab treatment and exploratory biomarkers with treatment response.
- To evaluate preliminary anti-tumor activity of etigilimab in combination with nivolumab according to iRECIST. Each cohort will be evaluated independently.

The secondary endpoints related to pharmacokinetic and immunogenicity will not be evaluated within the outputs specified in this analysis plan. Neither will the exploratory objectives related to biomarkers.

6. STUDY DESIGN

6.1. Summary of Study Design

This is an open-label, multicenter, Phase 1b/2 basket study designed to evaluate the efficacy, safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of etigilimab in combination with nivolumab in subjects with recurrent, locally advanced and/or metastatic solid tumors who are not candidates for available, curative standard of care therapies. In cohorts enrolling tumor types for whom anti-PD-1 antibody therapy is approved treatment for recurrent, locally advanced or metastatic disease, subjects may be enrolled prior to treatment with anti-PD-1 antibody therapy.

Subjects will be assigned to receive etigilimab ([redacted] mg every 2 weeks for subjects ≥50 kg, [redacted] mg/kg dose every 2 weeks for subjects <50 kg) in combination with nivolumab (240 mg every 2 weeks) and will continue until protocol-defined discontinuation criteria are met (refer to Section 7 of the protocol). Additional doses and schedules may also be evaluated. This study will evaluate both subjects who have not previously been treated with immune checkpoint inhibitors (CPI) as well as those who have received prior CPI therapy and will include tumor types chosen for higher prevalence of TIGIT, and in select cohorts, subjects with high PD-L1 expressing tumors as measured by immunohistochemistry (IHC). Tumor types selected for this study include recurrent, locally advanced and/or metastatic endometrial carcinoma (EC), cervical cancer (CC), gastric cancer and gastro-esophageal junction carcinoma (GC), squamous cell carcinoma of the head and neck (HNSCC), ovarian cancer (OC), rare cancers (metastatic testicular germ cell tumor, uveal melanoma and sarcoma) and any subject with concomitant tumor mutation burden high (TMB-high) and microsatellite stable (MSS) tumors. As TIGIT has been implicated in PD-L1 resistance, subjects who have received or progressed following a CPI (post-CPI subjects) will also be enrolled in select tumors including EC, HNSCC and TMB-high/MSS tumors. Parallel cohorts of up to 20 subjects per cohort will be evaluated.

Cohorts will be enrolled at the discretion of the sponsor. Selected cohorts will be open for the first 20 subjects enrolled without increasing the total number of subjects proposed for the trial. During the conduct of this open-label study an Independent Data Monitoring Committee (IDMC) will be established and will review study data on an ongoing basis. The IDMC will consist of at least 3 members with expertise in their field of practice as well as in the conduct of clinical studies. The committee members will be free of significant conflicts of interest. The IDMC will hold regularly scheduled data review meetings at pre-specified intervals as defined in the IDMC charter. The IDMC will also be available on an ad hoc basis e.g., to provide guidance related to any emerging safety signals or if requested by the sponsor.

The IDMC will have periodic safety reviews of the study that will start after the first 20 subjects are enrolled. A safety review of the study will be conducted by the IDMC approximately every 3 months. The IDMC and sponsor may decide to meet less frequently, based upon rate of accrual and the amount of new data generated (refer to the IDMC charter).

Futility monitoring will be evaluated in each cohort of the study using a Simon's two-stage design as described in Section 9.1 of the protocol. For each cohort, the second stage may be opened for enrollment only after discussion with the IDMC and the sponsor. The sponsor may have an independent assessment of responses to verify investigator-reported responses. The responses based on independent assessments, if available, will be used for sensitivity analysis with sponsor and will make recommendations regarding study conduct, including whether to continue, modify, or stop the study.

An analysis will be conducted when the first 30 TIGIT IHC biopsy results have been complete. This is to confirm the expected TIGIT positive rate based on data on file and reported in the literature. The efficacy of the combination will be evaluated by cohort and efficacy of the combination will be evaluated based on TIGIT IHC positive subjects.

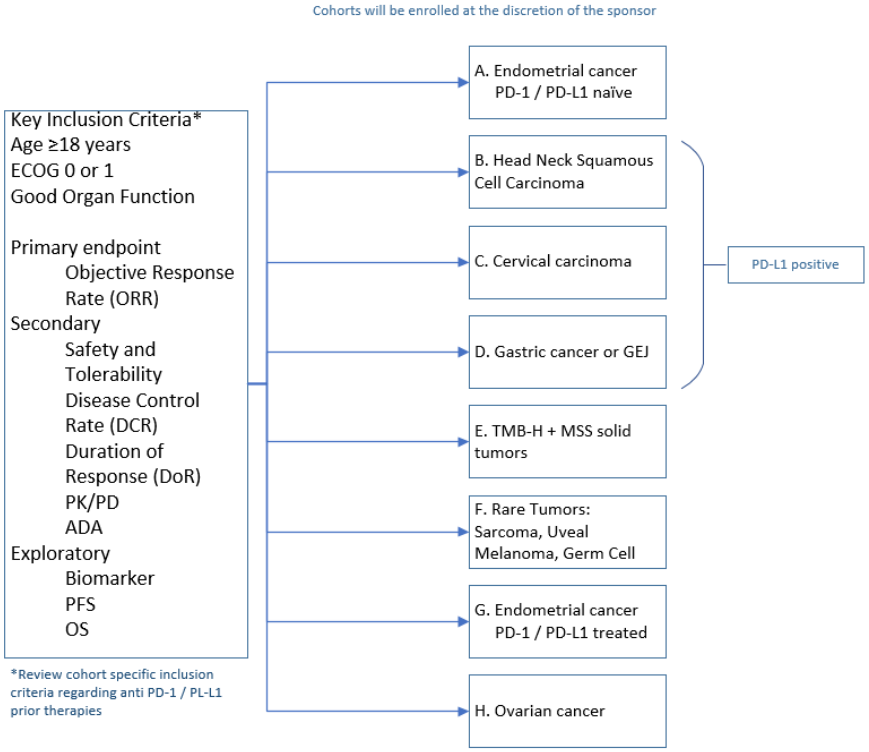

Figure 1: Study Schema

Abbreviations: ECOG = Eastern Cooperative Oncology Group; GEJ = gastroesophageal junction adenocarcinoma; Tumor mutation burden – high (TMB-H) + microsatellite stable (MSS); OS = overall survival; PD = pharmacodynamic; PD-1 = programmed death-1; PD-L1 = programmed death ligand-1; PFS = progression-free survival; PK = pharmacokinetic; ADA=anti-drug antibody

6.2. Time and Events Schedule

Table 1: Schedule of Events

Cycle Day	Screening	Cycle 1			Cycle 2		Cycle 3		Cycle 4		Cycle 5		Cycle 6[w]		Treatment Termination[x]	Follow up
		D1	D3	D8	D1	D8	D1	D8	D1	D8	D1	D8	D1	D8		
Study Day	**-28 to 1**	**1**	**3**	**8**	**15**	**22**	**29**	**36**	**43**	**50**	**57**	**64**	**71**	**78**		
Informed consent[a]	X															
Review of eligibility criteria	X															
Medical, surgical, and cancer histories, and demographic data[b]	X															
Tumor assessment[c]	X										X				X	
Concomitant medications[d]		X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Vital signs[e]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Complete physical examination[f]	X															
Symptom-directed physical examination		X		X	X	X	X		X		X		X		X	
Height	X															
Weight[g]	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
ECOG performance status	X	X		X	X	X	X		X		X		X		X	
12-Lead ECG[h]	X	X							X						X	

Cycle Day	**Screening**	**Cycle 1**			**Cycle 2**		**Cycle 3**		**Cycle 4**		**Cycle 5**		**Cycle 6[w]**		**Treatment Termination[x]**	**Follow up**
		D1	**D3**	**D8**	**D1**	**D8**	**D1**	**D8**	**D1**	**D8**	**D1**	**D8**	**D1**	**D8**		
Study Day	**-28 to -1**	**1**	**3**	**8**	**15**	**22**	**29**	**36**	**43**	**50**	**57**	**64**	**71**	**78**		
Hematology[i]	X	X		X	X	X	X	X	X	X	X	X	X	X	X	
Serum or plasma chemistry[j]	X	X		X	X	X	X	X	X	X	X	X	X	X	X	
Etigilimab infusion[k]		X			X		X		X		X		X			
Nivolumab infusion[l]			X		X		X		X		X		X			
Adverse event evaluation[m]		----------→														
TSH, free T3, free T4[n]	X										X				X	
Coagulation (INR/PT/aPTT)	X														X	
Urinalysis[o]	X					X						X			X	
Serum pregnancy test[p]	X														X	
Tumor marker assessment[q] (if applicable)	X						X				X					
Pharmacokinetics[r]	See **Error! Reference source not found.** below for PK Schedule for Ph Ib Subjects															
Anti-drug antibody[r]	See Table 2 below for ADA Schedule for Ph Ib Subjects															
Blood for PD biomarkers[s]	X	X		X		X		X						X	X	
Blood for pharmacogenomics[t]		X														
Blood for cell free DNA[u]	X	X						X						X	X	

Cycle Day	**Screening**	**Cycle 1**			**Cycle 2**		**Cycle 3**		**Cycle 4**		**Cycle 5**		**Cycle 6[w]**		**Treatment Termination[x]**	**Follow up**
		D1	**D3**	**D8**	**D1**	**D8**	**D1**	**D8**	**D1**	**D8**	**D1**	**D8**	**D1**	**D8**		
Study Day	**-28 to -1**	**1**	**3**	**8**	**15**	**22**	**29**	**36**	**43**	**50**	**57**	**64**	**71**	**78**		
Tumor biopsy[v]	X										X					
Archival FFPE tumor tissue[v]	X															
Survival and anti-cancer therapy follow up																X
Contrast Enhanced Head CT or MRI scan	X															

Abbreviations: ALT = alanine aminotransferase; aPTT = activated partial thromboplastin time; AST = aspartate aminotransferase; BUN = blood urea nitrogen; CBC = complete blood count; CT = computed tomography; ECG = electrocardiogram; ECOG = Eastern Cooperative Oncology Group; FFPE = formalin-fixed, paraffin-embedded; INR = international normalized ratio; IV = intravenous; MRI = magnetic resonance imaging; mRNA = messenger RNA; MSS = microsatellite stable; PBMC = peripheral blood mononuclear cells; PT = prothrombin time; RBC = red blood cell; RECIST v1.1 = Response Evaluation Criteria in Solid Tumors; TIGIT = T-cell immunoreceptor with Ig and ITIM domains; TMB-H = tumor mutational burden-high; TSH = thyroid-stimulating hormone; WBC = white blood cell

Notes to Schedule of Assessments

a. Written informed consent is required before performing any study-specific tests or procedures and may be obtained at any time prior to such tests or procedures. Results of standard-of-care tests or examinations performed prior to obtaining informed consent and within 28 days prior to Cycle 1 Day 1 may be used for screening assessments rather than repeating such tests. Results for the following laboratory tests must be obtained within 14 days prior to Cycle 1 Day 1: hematology, serum or plasma chemistry and coagulation panel.

b. Medical and surgical histories are required. Cancer history includes stage, date of diagnosis, and prior anti-cancer therapy. Demographic information includes sex, age, and self-reported race/ethnicity.

c. Screening and subsequent tumor assessments must include CT scans (with IV contrast unless contraindicated and oral contrast as appropriate per institutional standards) of the chest, abdomen, and pelvis. If a CT scan for tumor assessment is performed in a positron emission tomography (PET)/CT scanner, the CT acquisition must be consistent with the standards for a full-contrast CT scan. Brain imaging (either MRI or contrast-enhanced CT) is required at screening for all subjects. Further investigations such as bone scans and CT scans of the neck should also be performed if there is any clinical suspicion of disease at any site that may not be demonstrated by the minimum schedule of assessments listed above. At the investigator's discretion, other methods of assessment of measurable disease as per RECIST v1.1 may be used.

   The same radiographic procedures used to assess disease sites at screening should be used throughout the study (eg, the same contrast protocol for CT scans). Response will be assessed by the investigator on the basis of physical examinations and the imaging modalities detailed above, using RECIST v1.1 criteria. Assessments should be performed by the same evaluator if possible to ensure internal consistency across visits.

   Tumor assessments will be performed every 8 weeks (±1) from Cycle 1 Day 1 or as clinically indicated through to week 48 and then at least every 12 (±1) weeks. Response assessment data (i.e., progressive disease or no progression of disease) will continue to be collected (based on standard-of-care radiographs) for subjects who have not progressed at the time of the termination visit. until the subject starts alternative anti-cancer treatment or develops progressive disease, whichever occurs first. Response assessment and assessment of tumor markers will be obtained at treatment termination, unless a prior radiographic assessment has been performed within the last 14

days or at a prior response assessment that documented progressive disease. At the investigator's discretion, scans may be performed at any time if progressive disease is suspected.

d. Concomitant medications include any prescription medications or over-the-counter medications. At subsequent visits, changes to current medications, or medications used since the last documentation of medications will be recorded.
e. Vital signs include heart rate, respiratory rate, blood pressure and temperature. For the first etigilimab infusion, measure vital signs within 60 minutes before infusion, every 15 (±5 minutes) during the infusion and 30 (±10 minutes) and 90 (±15) minutes after the end of the infusion. For subsequent etigilimab infusions, measure vital signs within 60 minutes before infusion, during infusion if clinically indicated and 30 (±10) minutes after the end of the etigilimab infusion. Vital signs during and after nivolumab infusion are per institutional guidelines.
f. A complete physical examination will be done at baseline. At all other study visits a symptom-directed physical examination must be performed focusing on the subject's signs and symptoms. A more complete physical examination should be conducted when clinically indicated.
g. The etigilimab dose should be based on the Cycle 1 Day 1 weight throughout the study, unless the weight changes by >10%.
h. A 12-lead ECG will be obtained during screening, 30 (+30 minutes) after infusion of etigilimab on Cycle 1 Day 1, and 30 (+30 minutes) after infusion of etigilimab on Cycle 4 Day 1 and at treatment termination. Subjects should be resting and in a supine or semi-recumbent position for at least 10 minutes prior to each ECG collection.
i. Hematology can be performed within a -2-day window of the visit and consists of CBC, including RBC count, hemoglobin, hematocrit, WBC count with automated differential (neutrophils, lymphocytes, eosinophils, monocytes, basophils,), and platelet count. A manual differential can be done if clinically indicated. During screening, hematology results must be obtained within 14 days prior to Cycle 1, Day 1. If screening laboratory results available within 72 hours C1D1 laboratory tests do not need to be repeated.
j. Serum or plasma chemistry can be performed within a -2 day window of the visit and includes BUN, creatinine, sodium, potassium, magnesium, chloride, bicarbonate, calcium, phosphorus, glucose, total bilirubin, direct bilirubin, ALT, AST, alkaline phosphatase, lactate dehydrogenase, total protein, and albumin. During screening, serum or plasma chemistry results must be obtained within 14 days prior to Cycle 1, Day 1. If screening laboratory results available within 72 hours C1D1 laboratory tests do not need to be repeated.
k. etigilimab must be dosed as described in the Protocol. Dosing of Etigilimab should be within ± 2 days of the Study Day listed in the schedule of assessments. If etigilimab cannot be administered in this 2-day window, then that dose is considered missed. If treatment with etigilimab is delayed for >4 weeks, etigilimab will be permanently discontinued.
l. Nivolumab must be dosed as described in the Protocol within ± 2 days of the Study Day listed in the schedule of assessments. If the etigilimab dose is delayed ± 2 days then the nivolumab dose would be delayed and administered on the same day as the etigilimab (except for C1D1 where etigilimab is administered without nivolumab).
m. After initiation of study drug, report all adverse events until 90 days after the treatment termination visit.
n. Thyroid function tests (TSH, free T3, and free T4) must be performed every 8 weeks or as clinically indicated and at treatment termination.
o. Urinalysis (specific gravity, pH, glucose, protein, ketones, and blood) will be obtained during screening, at Study Days 22, 64, and at the time of treatment termination. Microanalysis is required if protein or blood is detected.
p. Serum pregnancy test (for women of childbearing potential, including women who have had a tubal ligation) must be performed and documented as negative within 7 days prior to Cycle 1, Day 1 and at treatment termination.
q. Perform tests for pertinent tumor markers (e.g., CEA for subjects with colorectal cancer or others) every 4 weeks or as needed starting at Cycle1 Day1.
r. PK and ADA samples will be drawn according to Table 2listed below.
s. A pre-dose sample of 33 mL will be drawn during screening and on Study Days, 1, 8, 22, and 36 and every 6 weeks after day 36 for subjects continuing on study drug to evaluate changes in plasma proteins (8 mL) by immunochemistry, TIGIT and immune-related gene expression by mRNA (5 mL) and changes in peripheral blood

mononuclear cell (PBMC, 20 mL) populations and activation. A sample will also be collected at the time of treatment termination, unless one has been obtained during the prior 14 days. Instructions for the collection, handling, storage, and shipment are provided in the Laboratory Manual.

t. A 6 mL of blood will be collected for pharmacogenetic testing if the subject has consented to have this optional sample collected.

u. For TMB-H/MSS cohort, a 20 mL blood collection will occur during screening using the Guardant provided IUO kit. If collected in screening for TMB-H/MSS cohort, Study Day 1 collection does not need to occur. For all other cohorts, a 10 mL of plasma for cell-free tumor DNA assessment will be collected pre-dose on Study Days 1, 36, 78, and at treatment termination. As outlined in Section 3.1 of the protocol TMB-H/MSS (Cohort E) subjects with the following solid tumors will enroll into respective tumor specific cohorts after discussion with the sponsor: Cohorts A, C, F and H. For these subjects, a 20 mL blood collection will still be required using the Guardent Health provided IUO kit.

v. Archival FFPE is required for enrolment and must have been collected preferably within 6 months but no longer than 1 year from screening. If **archival tumor tissue is not available** either fresh core or punch needle biopsy at study entry (3 fresh cores/punches preferred whenever possible) is required. Fine needle aspirate samples are not acceptable. Instructions for the collection, handling, storage, and shipment of these samples are provided in the Laboratory Manual.

. Pre-treatment Biopsy: Baseline fresh tumor tissue samples consisting of 3 core needle biopsies of deep tumor tissue or lymph nodes or excisional, incisional, punch, or forceps biopsies of cutaneous, subcutaneous, or mucosal lesions will be obtained for all subjects. Subjects undergoing core needle biopsy should have accessible lesion(s) that permit a total of at least two biopsies (pretreatment and on-treatment) without unacceptable risk of major procedural complication (one pretreatment and at least one on-treatment biopsy will be performed; minimum diameter, 18 gauge). If possible, at least 3 cores should be collected from each lesion.

Optional On-treatment Biopsy may be considered only in patients who provided fresh baseline biopsy. This subsequent fresh biopsy may be performed approximately 8 weeks (within ± 5 days of Day 57) following the first administration of etigilimab.

An additional optional biopsy may be collected per investigator discretion, preferably at the time of radiographic progression or response. Requirements and procedures for pre-treatment and on-treatment biopsy collection are identical.

For pre and on-treatment, 1-2 cores will be fixed and shipped to central lab in ethanol and an additional 1 core will be fresh frozen as specified in the Laboratory Manual.

w. At Cycle 7 and beyond. safety laboratory testing is completed every two weeks at each treatment visit only.

x. The termination visit should be done as soon as possible, but no later than 30 days, after one of the discontinuation criteria for the study are met (See Protocol). The termination visit may occur later after discussion with the Sponsor Medical Monitor for specific circumstances, such as prolonged hospitalization. The visit at which a tumor assessment shows progressive disease may be used as the treatment termination visit provided that all required assessments were performed as outlined in the Schedule of Assessments. Tumor assessments do not have to be repeated if they were performed within 14 days of the termination visit or at a prior response evaluation that documented progressive disease. ECG does not have to be repeated if they were performed within 14 days of the termination visit.

Table 2: Phase 1b Subjects: PK and ADA Sample Collection Schedule

Cycle		Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9	Cycle 10	Cycle 11	Treatment Termination	4 Week Post Termination
Visit Day		Day 1	Day 15	Day 29	Day 43	Day 57	Day 71	Day 85	Day 99	Day 113	Day 127	Day 141		
MPH313 Infusion		X	X	X	X	X	X	X	X	X	X	X		
PK	On Day												X	X
	Pre-Infusion	X	X	X	X	X	X	X	X	X	X	X		
	15 Minutes Post Infusion	X			X			X						
ADA	Pre-Infusion	X		X		X		X		X		X	X	X

Abbreviations: ADA = anti-drug antibody; AE = adverse event; PK = pharmacokinetics

PK will be drawn pre-infusion every cycle of etigilimab until treatment termination. ADA will be drawn pre-infusion every other cycle of etigilimab through the first 6 months of treatment. After 6 months, ADA will be collected pre-infusion every 3 months and then once every 6 months after the first year until treatment termination. Should any immune-related AE continue beyond the 4-week post treatment termination visit, a blood sample for PK and ADA may be requested by the Medical Monitor.

6.3. Interim Analysis

There is no formal interim analysis planned for this study, although interim futility monitoring was to be carried out using a Simon Two-Stage design for each individual cohort, when up to 10 subjects had sufficient data (either discontinued study drug treatment or have at least one post-baseline imaging assessment) for Objective Response Rate (ORR) and Duration of Response (DoR) evaluation by RECIST v1.1. This evaluation occurred for both of the cervical and uveal cohorts (cohorts C and F) and approval was given to proceed, the evaluation was not required for the other cohorts before the study was terminated.

7. STUDY ENDPOINTS

7.1. Primary Endpoint

- Objective response rate (ORR)

7.2. Secondary Endpoints

- Count and % of subjects who experience at least 1 adverse event (AE) and abnormal safety laboratory parameters
- Adverse events of special interest [(AESIs) infusion reactions, immune-related adverse events)]
- Relationship of PK and safety
- Disease control rate (DCR; is the proportion of subjects whose Best Overall Response is CR, PR, or SD)
- Duration of response (DoR)
- Duration of stable disease
- PK levels of etigilimab in combination with nivolumab
- Anti-drug antibodies (ADA) to etigilimab; Impact of developed etigilimab ADAs on PK levels of etigilimab

Note PK and ADA endpoints will not be evaluated as part of the analyses specified within this SAP.

7.3. Exploratory Endpoints

- ORR (proportion of iCR plus iPR subjects)
- DoR (iRECIST)
- Progression-free survival (PFS) using RECIST v1.1 and iRECIST
- Overall Survival (OS)

Additional exploratory endpoints were included in the protocol which will not be evaluated within this statistical analysis plan:

- Pharmacodynamic biomarkers will be assessed to determine their correlation with response to etigilimab treatment as follows:
    - Changes in peripheral blood mononuclear cell populations and activation
    - TIGIT and immune-related gene expression by messenger RNA (mRNA) detection (eg, CD226, TIGIT, T-cell genes)
    - Plasma proteins (eg, interleukin 17 [IL17], interleukin 2 [IL2], interferon gamma [IFNγ]
- To correlate levels of TIGIT, PVR, TMB, PDL1, and other immune markers with antitumor activity endpoints
- BAP1 (BRCA1 associated protein-1) tumor mutations with etigilimab treatment response

8. SAMPLE SIZE

This is a Phase 1b/2 open-label basket study of etigilimab (MPH313) ([redacted] mg dose for subjects ≥50 kg, [redacted] mg/kg dose for subjects <50 kg) IV administered Q2W with nivolumab 240 mg Q2W to evaluate preliminary anti-tumor activity, safety and tolerability, PK parameters, immunogenicity, and biomarkers in up to 9 cohorts of subjects with endometrial carcinoma, HNSCC, cervical cancer, ovarian cancer, gastric cancer and gastroesophageal junction adenocarcinoma, TMB-H/MSS cancer, sarcoma, germ cell tumors, and uveal melanoma. Each cohort will be evaluated using a Simon Two-Stage design appropriate to the clinically meaningful response rate for the indication as depicted in Figure 2 below. Interim futility monitoring for each individual cohort using the clinically meaningful response rate criteria per cohort will be carried out in accordance with the optimal Simon Two-Stage design when up to 10 subjects have sufficient data (either discontinued study drug treatment or having at least one post-baseline imaging assessment) for ORR and DoR evaluation by RECIST v1.1. For each cohort, the second stage may be opened for enrollment only after discussion with the IDMC and the sponsor. The sponsor may have an independent assessment of responses to verify investigator-reported responses. The responses based on independent assessments, if available, will be used for sensitivity analysis with sponsor and will make recommendations regarding study conduct, including whether to continue, modify, or stop the study.

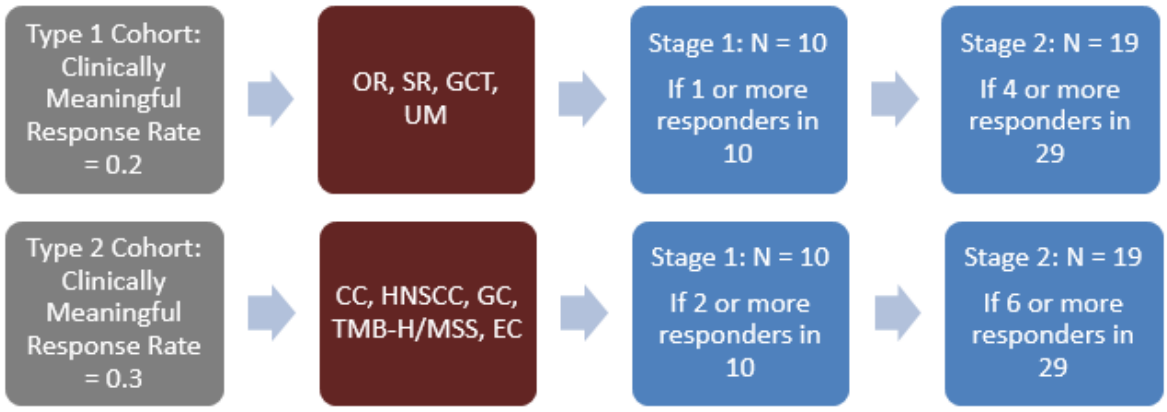

Figure 2: Simon Two-stage Study Design

Abbreviations: CC = cervical cancer; EC = endometrial cancer; GC = gastric cancer and gastroesophageal junction adenocarcinoma; GCT = germ cell tumors; HNSCC = head and neck squamous cell carcinoma; OC = ovarian cancer; SR = sarcoma; TMB-H = tumor mutational burden-high; UM = uveal melanoma

Type 1 Cohort

The null hypothesis that the true response rate is 0.05 will be tested against a one-sided alternative that the true response rate is at least 0.2. In the first stage, 10 subjects will be enrolled and enrollment in this cohort will be halted until the response data are mature. If there are fewer than 1 responder in these 10 subjects, further enrollment in the cohort may be stopped after review of efficacy and safety data, and discussion by Sponsor with the IDMC. Otherwise, once 1 or more responders in stage 1 are observed, 19 additional subjects may be enrolled for a total of 29. The null hypothesis will be rejected and the treatment will be declared effective and worthy of further testing if 4 or more responders are observed in 29 subjects. This design yields a type I error rate of 0.0468 and power of 80.11% when the true response rate is 0.2.

Type 2 Cohort

The null hypothesis that the true response rate is 0.1 will be tested against a one-sided alternative that the true response rate is at least 0.3. In the first stage, 10 subjects will be enrolled and enrollment in this cohort will be halted until the response data are mature. If there are fewer than 2 responders in these 10 subjects, enrollment in the cohort may be stopped after review of efficacy and safety data, and discussion by Sponsor with the IDMC. Otherwise, once 2 or more responders in stage 1 are observed, 19 additional subjects may be enrolled for a total of 29. The null hypothesis will be rejected and the treatment will be declared effective and worthy of further testing if 6 or more responders are observed in 29 subjects. This design yields a type I error rate of 0.0471 and power of 80.51% when the true response rate is 0.3.

9. STUDY ANALYSIS SETS

The populations defined below will be reviewed against the study database at a DRM at the time of the Final Analysis. The database at this time will be nearly final (i.e., the meeting may result in further data queries/changes post meeting), so inclusion/exclusion of subjects from study populations defined at this meeting will be further checked (post meeting) against a final locked database and will then be finalised prior to reporting.

The following analysis sets are defined:

Population	Description
Safety Analysis Set	All subjects who received any amount of study drug. All safety analyses will be performed using the Safety analysis set.
Intention to Treat (ITT) Analysis Set	All subjects who signed an informed consent form and were enrolled into the study.
Response-Evaluable (RE) Analysis Set	The Response-Evaluable analysis set is a modified ITT analysis set defined as all subjects with measurable disease at baseline who received study drug and had at least one post-baseline response assessment or discontinued treatment due to disease progression (including death due to disease progression) within 16 weeks (+ a 2-week window) of the first dose of study drug. All efficacy analyses will be performed using the Response-Evaluable analysis set

10. PLANNED STATISTICAL METHODS

10.1. Statistical Considerations

10.1.1. General Definitions

In all applicable summary/analysis presentations of safety endpoints, Baseline is defined as the last non-missing assessment value for a subject, for that particular parameter, that is prior to dosing with study drug on Day 1 (including unscheduled assessments), unless over-ruled after review of data at the DRM or otherwise stated in the appropriate endpoint sections below. Study drug includes both etigilimab and nivolumab.

For efficacy endpoints, the baseline definition is as per the appropriate endpoint sections below. For the derivation of most efficacy endpoints, the first post-baseline assessment to be used should be the first assessment that was taken after the first dose of study drug.

Within summary presentations/analyses by visit it is envisaged that only scheduled protocol visit values will be used for post-baseline time points. In the clinical database a number of data points have been labelled as unscheduled/additional recordings of data. These data points will generally be included within subject listings only. However, at the DRM the occurrence of such unscheduled data will be reviewed for each subject to decide if (and how) any such data point(s) should be included within summary presentations/analyses. Any such decisions will be documented in the DRM minutes.

Efficacy endpoints will be determined using all available data, including unscheduled visits.

10.1.2. Data Presentation

The full list of TFLs to be produced for the final study analysis are shown in Section 13, and the specific format and content of each data Table/Listing presentation is shown in Section 14.

Summary Tables and Figures will be presented by cohort. Within all Tables and Figures values for the cohorts will be labelled as follows:

- A: EC CPI-Naïve
- B: Head and Neck
- C: Cervical
- D: Gastric
    - (Note: No participants were recruited into this cohort and so it will not be included in displays)
- E: TMB-H/MSS
- F: Rare Tumours
- G: EC Post-CPI
- H: Ovarian

A Total column may be included in the disposition, and selected safety outputs which will include all cohorts. If there are no subjects in any one cohort the column will be dropped from all tables, with a footnote included as appropriate in the disposition table.

For selected efficacy outputs the Rare tumours cohort may be split out further into sub-cohorts as:

- F: Uveal
- F: Sarcoma
    - Dedifferentiated LPS
    - UPS
- F: GCT
- F: Other

The scheduled protocol visits will be labelled in (applicable) report presentations as follows:

- Screening
- CX-DY (where X is the Cycle number and Y is the Day number within the cycle).
- Treatment Termination
- Follow-up

Note that the Baseline label will be used in some summaries, where Baseline will consist of data collected at the screening visits, on Day 1 pre-dosing or unscheduled assessments prior to dosing (if they are the last non-missing assessment). The actual Baseline definition will be provided in the section relevant for each endpoint.

Unscheduled visit data will be labelled as "Unscheduled" together with a date in data Listings. Unscheduled data will generally not be used in the summary tables unless otherwise stated or agreed at the DRM.

Where duplicate information is collected in both the database and in the vendor data transfer(s) (e.g., sampling date and time) this information will be reconciled by data management and then the information from the database will be included in subject Listings.

All variables will be listed to the same number of decimal places as reported. Descriptive statistics for all endpoints that are continuous data will have the following summary statistics presented in the following order: n, (arithmetic) mean (rounded to one more decimal place than recorded), geometric mean (for pre-specified endpoints only; rounded to one more decimal place than recorded), standard deviation (rounded to two more decimal places than recorded), geometric standard deviation (for pre-specified endpoints only; rounded to two more decimal places than recorded), standard error (for pre-specified endpoints only; rounded to two more decimal places than recorded), median (rounded to one more decimal place than recorded), lower and upper quartiles (rounded to one more decimal place than recorded), minimum (as recorded), and maximum (as recorded).

Note: for endpoint(s) that require a geometric mean to be produced, and those endpoint(s) can have raw values of 0 (zero), the geometric mean calculation will add an appropriate constant value to all raw values prior to logging and will subtract that constant value from the final calculated anti-logged mean. The constant value used will be documented in the footnote of the tables. An example of such a calculation is shown below:

Geometric Mean = anti-log {mean (logged (base 10) endpoint values + 1)} - 1

Categorical variables will be summarised using proportions (counts and percentages). The specific approach to calculating percentages (relevant denominator) is detailed within each (relevant) Table template (Section 14).

Unless otherwise stated in the appropriate endpoint section(s) below, laboratory/efficacy parameter values that are below the level of quantification (BLQ), or less than the lower limit of quantification (<LLOQ) will be set to zero in computations for summary presentations and analysis but will be noted as below the limit of quantification in subject Listings.

10.1.3. Statistical Testing and Estimation

No formal statistical hypothesis testing will be performed.

10.1.4. Handling of Dropouts or Missing Data

In general, missing data will not be imputed and all summary statistics will be reported based upon observed data. For a limited number of summary presentations, missing data rules may be introduced. In particular, methods of handling incomplete dates for adverse events (Section 10.11.1) and incomplete dates for concomitant medications (Section 10.5.2) are presented. For any other data which has partial dates, which are required for use in time related calculations, these dates will be completed using a suitably conservative approach. Dates will be shown in subject Listings as they have been recorded.

10.1.5. Multiple Comparison/Multiplicity

Not applicable as no formal statistical analysis will be performed.

10.1.6. Examination of Subgroups

No examination of subgroups will be performed. However all endpoints will be summarised by cohort and, in some instances, by sub-cohorts, or groups of cohorts.

10.1.7. Model Checking

Not applicable as no formal statistical analysis will be performed.

10.1.8. Software

Data will be reported using SAS (version 9.4 or later).

10.1.9. Data Conversion (CDISC)

S-cubed Biometrics will be provided with the raw data in SDTM format (SDTM version 1.7 and SDTM Implementation Guide version 3.2). S-cubed Biometrics will produce ADaM datasets (following ADaM version 2.1 and ADaM Implementation Guide version 1.1).

10.2. Subject Disposition

The number of subjects screened, failed screening, enrolled, received at least one dose of etigilimab, received at least one dose of nivolumab, completed all dosing cycles within the treatment period, completed the treatment termination visit and completed the follow up visit will be tabulated by cohort, as well as the number who withdrew from the study and/or discontinued treatment early. The number of subjects in each analysis set will also be summarised.

The data on failed inclusion and exclusion criteria, subject disposition, informed consent and analysis set membership will also be listed.

10.3. Protocol Deviations

Subject data will be reviewed for major protocol deviations by a qualified clinical reviewer on an ongoing basis throughout the study. A final review of important protocol deviations will form part of the discussions at the DRM prior to analysis. All important protocol deviations will be listed.

10.4. Demographic and Other Baseline Characteristics

The Safety Analysis Set will be used in all presentations of demographic and baseline data. No statistical testing will be used to compare cohorts for different baseline characteristics.

10.4.1. Demographics

Demographic variables (sex, age, race, ethnicity and child bearing potential), will be summarised by cohort, sub-cohort for sarcoma subjects, and across all subjects. All demographic characteristics will be listed.

10.4.2. Baseline Disease Characteristics

Cancer diagnosis and details of cancer on entry into the study will be listed. The time since initial diagnosis until screening will be summarised by cohort. The table will also summarise the tumor staging and primary location at diagnosis, along with whether the TMB was high, whether the tumor was MSS, whether the tumor was locally advanced or metastatic, and the category of PD-L1 tumor proportional score (TPS) and the category of PD-L1 combined positive score (CPS).

10.4.3. Medical and Surgical History

All medical history, including cancer and surgical history, will be coded using MedDRA, Version 26.0 (March 2023). Medical and surgical histories will be listed.

10.4.4. Pregnancy

The results of the serum pregnancy test at screening and any others carried out throughout the study will be listed for all females. The results of the follicle stimulating hormone test will also be listed for the females who meet the post-menopausal criteria.

10.5. Medications

10.5.1. Prior Cancer Treatments

Details of all prior cancer treatments, including biologic, immunotherapy, chemotherapy, radiotherapy and surgery, will be listed. The number of previous lines of therapy will be summarised by cohort as the number and percentage who have had 0, 1, 2, 3 and 4 or more previous lines of therapy. The number, and percentage, of those who have previously had the different types of treatment will also be included.

10.5.2. Other Prior and Concomitant Medications

All medication terms will be coded using the World Health Organisation (WHO) Drug Dictionary Enhanced (WHO Drug Global B3 March 2023).

Medications will be assigned as being prior to or concomitant with treatment, based on the start and stop dates of the medication and the date of first dose of study drug. If the medication stop date is before the date of first dose of study drug, the medication will be assigned as being prior to study drug. In all other situations, the medication will be assigned as being concomitant with study drug.

All concomitant medications will be summarised by ATC class (Level 2) and preferred base name (WHO Code 01001). All medications will be listed.

10.6. Investigational Product Exposure

The number of doses of each study drug received, the total dose of each study drug received and the number of days of exposure to study drug will be tabulated by cohort.

The number of days of exposure to each study drug will be calculated as the date of the last dose of the study drug (etigilimab or nivolumab) – the date of the first dose of the study drug + 1.

The details of IMP exposure will also be listed.

10.7. Tumor Assessment

All details of tumor assessments will be listed.

10.8. Efficacy Analysis

10.8.1. Primary Endpoint

10.8.1.1. Objective Response Rate

Up to 5 target lesions are identified and measured at baseline, along with any non-target lesions. At each tumour assessment response is then recorded based on the target lesions according to the RECIST v1.1 criteria. Target lesions and non-target lesions are assigned a 'response' (as per Table 3 and Table 4). These are then combined to give an evaluation of overall response as per Table 5.

Table 3: Evaluation of Target Lesions

Complete Response (CR):	Disappearance of all target lesions. Any pathological lymph node (whether target or nontarget) must have reduction in short axis to <10 mm
Partial Response (PR):	At least a 30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters
Progressive Disease (PD):	At least a 20% increase in the sum of the diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. The appearance of one or more new lesions is also considered progression.

Table 4: Evaluation of Non-Target Lesions

Complete Response (CR):	Disappearance of all non-target lesions and normalization of tumor marker level. All lymph nodes must be non-pathological in size (ie, <10 mm short axis).
Non-CR/Non-PD	Persistence of one or more non-target lesion(s) and/or maintenance of tumor marker level above the normal limits
Progressive Disease (PD):	Unequivocal progression of the existing non-target lesions. The appearance of one or more new lesions is also considered progressive disease.

Although a clear progression of "non target" lesions only is exceptional, in such circumstances, the opinion of the investigator should prevail.

Table 5: Evaluation of Overall Response

Target lesions	Non-Target lesions	New Lesions	Overall response
CR	CR	No	CR
CR	Non-CR/Non-PD	No	PR
CR	Not evaluated	No	PR
PR	Non-PD or not all evaluated	No	PR
SD	Non-PD or not all evaluated	No	SD
Not all evaluated	Non-PD	No	NE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD
Any	Any	Yes	PD

For either CR or PR to be 'confirmed' the same overall response needs to be achieved at the subsequent visit, which should be at least 4 weeks later. The best overall response (BOR) is then the best response achieved in order of CR, PR, SD, PD, NE, where a subject cannot be defined as having BOR of CR, PR or SD if they have previously experienced PD.

Response is recorded for each participant at each tumor response visit using the criteria outlined above. The response recorded in the database will be used to evaluate the objective response rate and all other endpoints related to the response based on RECIST v1.1 guidelines.

Objective Response Rate (ORR) is then defined as the proportion of subjects who achieve a best overall response of Confirmed CR or Confirmed PR. Subjects with not-evaluable response (NE) are counted as non-responders.

The number and percentage of subjects who have achieved objective response will be summarised, by cohort, including sub-cohort, along with the 95% Clopper-Pearson CI.

Additionally the number and percentage of subjects with CR and PR (confirmed and unconfirmed), SD, PD and NE will be summarised by cohort, including sub-cohort.

A swimmer plot, displaying the response for each subject over their time in the study, will be presented for all subjects as well as for gynaecological cohorts (Cohort A, E and H) and rare tumor sub-cohorts (Cohort F) with a line per subject and each response/important event highlighted on the line as appropriate.

A waterfall plot will also display the percentage reduction in overall sum of diameters over the time in study for each subject. This will again be presented for all subjects and for gynaecological cohorts

(Cohort A, E and H) and rare tumor sub-cohorts (Cohort F). Additionally a spider plot will be produced for each set of cohorts, which will display the percentage change from baseline in sum of the longest diameter over time, where the lines will be displayed by best overall response.

10.8.2. Secondary Endpoints

10.8.2.1. Disease Control Rate

Disease control rate (DCR) is defined as the proportion of subjects who have achieved CR, PR, and SD. The number and percentage of subjects who have achieved disease control will be summarised, by cohort, including sub-cohort, along with the 95% Clopper-Pearson CI.

10.8.2.2. Duration of Response

Duration of response (DoR) is defined as the time, in days, from the first of the 2 assessments required for confirmed PR or CR to the time of the PD or death due to underlying cancer.

The duration will be calculated (in days) as:

> Date of first overall response of PD or date of death due to underlying cancer (whichever is first) – Date of first of the two assessments required for confirmed CR or PR.

The duration of response will be summarised by cohort using descriptive summaries, which will not account for censoring. Additionally, Kaplan-Meier curves will be produced for each cohort along with a table summarising the median and 25^{th} and 75^{th} percentiles of the duration of response, inclusive of censoring, for each cohort, including sub-cohort.

[Kaplan-Meier plot: y-axis = cumulative proportion of participants who still have response, x-axis = day, one line for each cohort, including sub-cohort, overlayed on the same plot].

Exclusion

If a subject does not achieve confirmed CR or PR they will be excluded from this analysis.

Censoring

If a subject does not experience PD or death due to underlying cancer their duration will be censored at the date of their last disease assessment.

If a subject dies due to a cause other than underlying cancer they will be censored at the date of death.

If a subject does not have a disease assessment after their assessment confirming their response as CR or PR they will be censored at the date of their last disease assessment.

If a subject initiates another cancer treatment prior to PD/death their duration of response will be censored at the last assessment prior to initiation of the alternative cancer treatment.

If a subject experiences PD or death immediately following 2 or more visits at which their response was missing or NE their duration of response will be censored at the time of their last assessment prior to missing/NE response.

10.8.2.3. Duration of Stable Disease

Duration of stable disease (DoSD) is defined as the time, in days, from the first date of treatment until the first date at which PD is experienced or the subject dies due to underlying cancer.

The duration will be calculated (in days) as:

> Date of first overall response of PD or date of death from underlying cancer (whichever is first) – Date of first treatment.

The duration of stable disease will be summarised by cohort using descriptive summaries, which will not account for censoring. Additionally, Kaplan-Meier curves will be produced for each cohort along with a table summarising the median and 25th and 75th percentiles of the duration of stable disease, inclusive of censoring, for each cohort, including sub-cohort.

[Kaplan-Meier plot: y-axis = cumulative proportion of participants who still have stable disease, x-axis = day, one line for each cohort, including sub-cohort, overlayed on the same plot].

Censoring

If a subject does not experience PD or death due to underlying cancer their duration will be censored at the date of their last disease assessment.

If a subject dies due to a cause other than underlying cancer they will be censored at the date of death.

If a subject does not have a disease assessment after their first treatment they will be censored at the date of their first treatment.

If a subject initiates another cancer treatment prior to PD/death their duration of stable disease will be censored at the last assessment prior to initiation of the alternative cancer treatment.

If a subject experiences PD or death immediately following 2 or more visits at which their response was missing or NE their duration of stable disease will be censored at the time of their last assessment prior to missing/NE response.

10.8.3. Exploratory Endpoints

10.8.3.1. Objective Response Rate (iRECIST)

The same target and non-target lesions will be used to assess response as per the iRECIST criteria.

One key difference for iRECIST as compared to RECIST v1.1 is that PD has to be confirmed. As per iRECIST, the appearance of new lesions will result in immune unconfirmed progressive disease (iUPD), with immune confirmed progressive disease (iCPD) being assigned if additional new lesions appear or new lesions increase in size (≥5 mm for sum of new target lesions or any increase in new non-target lesions).

iCR, iPR, iSD are defined as per Table 6, with the main difference from the assignments per RECIST v1.1 being that a subject can experience iUPD prior to iCR, iPR, iSD but not iCPD, i.e. they can have progression recorded at a visit but it needs to be confirmed at the subsequent visit for the overall response to be iCPD.

Table 6: Some Examples for Assigning Timepoint Response for iRECIST

			Time Point Response	
Target lesions	**Non-Target lesions**	**New Lesions**	**No Prior iUPD**	**Prior iUPD**
iCR	iCR	No	iCR	iCR
iCR	Non-iCR/Non-iUPD	No	iPR	iPR
iPR	Non-iCR/Non-iUPD	No	iPR	iPR
iSD	Non-iCR/Non-iUPD	No	iSD	iSD
iUPD with no change OR decrease from last TP	iUPD with no change OR decrease from last TP	Yes	NA	NLs confirms iCPD if NLs were previously identified and increase in size (≥5 mm in SOM for NLT or any increase for NLNT) or number; If no change in NLs (size or number) from last TP, remains iUPD
iSD, iPR, iCR	iUPD	No	iUPD	Remains iUPD unless iCPD confirmed based in further increase in size of NT disease (need not meet RECIST v1.1 criteria for unequivocal PD)
iUPD	Non-iCR/Non-iUPD ; iCR	No	iUPD	Remains iUPD unless iCPD confirmed based on: further increase in SOM of at least 5 mm, otherwise remains iUPD
iUPD	iUPD	No	iUPD	Remains iUPD unless iCPD confirmed based on further increase in: • previously identified T lesion iUPD in SOM ≥5 mm and / or NT lesion iUPD (prior assessment – need not be unequivocal PD)
iUPD	iUPD	Yes	iUPD	Remains iUPD unless iCPD confirmed based on further increase in • previously identified T lesion iUPD SOM ≥5 mm and / or • previously identified NT lesion iUPD (need not be unequivocal) and /or size or number of new lesions previously identified
Non-iUPD/PD	Non-iUPD/PD	Yes	iUPD	Remains iUPD unless iCPD confirmed based on increase in size or number of new lesions previously identified

As with RECIST v1.1, iRECIST defines confirmed iCR and iPR response as the same overall response being achieved at the subsequent visit, which should be at least 4 weeks later. The best overall

response is then the best response achieved in order of iCR, iPR, iSD, iUPD, iCPD, NE. A subject can experience iUPD prior to any response, but not iCPD.

Immune Objective Response Rate (iORR) is then defined as the proportion of subjects who achieve a best overall response of iCR or iPR (confirmed). Subjects with not-evaluable response (NE) are counted as non-responders.

The number and percentage of subjects who have achieved objective response will be summarised, by cohort, including sub-cohort, along with the 95% Clopper-Pearson CI.

Additionally the number and percentage of subjects with iCR and iPR (confirmed and unconfirmed), iSD, iUPD, iCPD and NE will be summarised by cohort, including sub-cohort.

10.8.3.2. Duration of Response (iRECIST)

Duration of response (DoR) is defined as the time, in days, from the first of the 2 assessments required for confirmed iPR or iCR to the time of the iCPD or death due to underlying cancer.

The duration will be calculated (in days) as:

> Date of first overall response of iCPD or date of death due to underlying cancer (whichever is first) – Date of first of the two assessments required for confirmed iCR or iPR.

The duration of response will be summarised by cohort using descriptive summaries, which will not account for censoring. Additionally, Kaplan-Meier curves will be produced for each cohort along with a table summarising the median and 25^{th} and 75^{th} percentiles of the duration of response, inclusive of censoring, for each cohort, including sub-cohort.

[Kaplan-Meier plot: y-axis = cumulative proportion of participants who still have response, x-axis = day, one line for each cohort, including sub-cohort, overlayed on the same plot].

Exclusion

If a subject does not achieve confirmed iCR or iPR they will be excluded from this analysis.

Censoring

If a subject does not experience iCPD or death due to underlying cancer their duration will be censored at the date of their last disease assessment.

If a subject dies due to a cause other than underlying cancer they will be censored at the date of death.

If a subject does not have a disease assessment after their assessment confirming their response as iCR or iPR they will be censored at the date of their last disease assessment.

If a subject initiates another cancer treatment prior to iCPD/death their duration of response will be censored at the last assessment prior to initiation of the alternative cancer treatment.

If a subject experiences iCPD or death immediately following 2 or more visits at which their response was missing or NE their duration of response will be censored at the time of their last assessment prior to missing/NE response.

10.8.3.3. Progression Free Survival (RECIST)

Progression-free survival (PFS) is defined as the time, in days, from the first date of treatment until the first date at which PD is experienced or the subject dies due to any cause. Only deaths that occur within 30 days of the last tumor assessment will be included.

The duration will be calculated (in days) as:

> Date of first overall response of PD or date of death due to any cause (whichever is first) – Date of first treatment.

Progression-free survival will be summarised by cohort, and sub-cohort for cohort F, using descriptive summaries, which will not account for censoring. Additionally, Kaplan-Meier curves will be produced for each cohort, and sub-cohort for cohort F, along with a table summarising the median and 25th and 75th percentiles of the progression-free survival, inclusive of censoring, for each cohort, including sub-cohort.

[Kaplan-Meier plot: y-axis = cumulative proportion of participants who are progression free, x-axis = day, one line for each cohort, including sub-cohort, overlayed on the same plot].

Censoring

If a subject does not experience PD or death they will be censored at the date of their last disease assessment.

If a subject does not have a disease assessment after their first treatment they will be censored at the date of their first treatment.

If a subject initiates another cancer treatment prior to PD/death they will be censored at the last assessment prior to initiation of the alternative cancer treatment.

If a subject experiences PD or death immediately following 2 or more visits at which their response was missing or NE they will be censored at the time of their last assessment prior to missing/NE response.

10.8.3.4. Progression Free Survival (iRECIST)

Progression-free survival (iPFS) is defined as the time, in days, from the first date of treatment until the first date at which iCPD is experienced or the subject dies due to any cause. Only deaths that occur within 30 days of the last tumor assessment will be included.

The duration will be calculated (in days) as:

> Date of first overall response of iCPD or date of death due to any cause (whichever is first) – Date of first treatment.

Progression-free survival will be summarised by cohort, and sub-cohort for cohort F, using descriptive summaries, which will not account for censoring. Additionally, Kaplan-Meier curves will be produced for each cohort, and sub-cohort for cohort F, along with a table summarising the median and 25th and 75th percentiles of the progression-free survival, inclusive of censoring, for each cohort, including sub-cohort.

[Kaplan-Meier plot: y-axis = cumulative proportion of participants who are progression free, x-axis = day, one line for each cohort, including sub-cohort, overlayed on the same plot].

Censoring

If a subject does not experience iCPD or death they will be censored at the date of their last disease assessment.

If a subject does not have a disease assessment after their first treatment they will be censored at the date of their first treatment.

If a subject initiates another cancer treatment prior to iCPD/death they will be censored at the last assessment prior to initiation of the alternative cancer treatment.

If a subject experiences iCPD or death immediately following 2 or more visits at which their response was missing or NE they will be censored at the time of their last assessment prior to missing/NE response.

10.8.3.5. Overall Survival

Overall survival (OS) is defined as the time from the first dose of study drug to death due to any cause.

For analysis of OS, all subjects will be followed for survival for up to 2 years, until withdrawal of consent, loss to follow up, or death, whichever occurs first. At the time of analysis of OS, any subjects who remain alive will be censored at the last date they were known to be alive.

The duration will be calculated (in days) as:

Date of death due to any cause – Date of first treatment.

Overall Survival will be summarised by cohort, and sub-cohort for cohort F, using descriptive summaries, which will not account for censoring. Additionally, Kaplan-Meier curves will be produced for each cohort, and sub-cohort for cohort F, along with a table summarising the median and 25th and 75th percentiles of the overall survival, inclusive of censoring, for each cohort, including sub-cohort.

[Kaplan-Meier plot: y-axis = cumulative proportion of participants who are alive, x-axis = day, one line for each cohort, including sub-cohort, overlayed on the same plot].

Censoring

If a subject is still alive at the end of follow-up they will be censored at the date they were last known to be alive.

10.9. Pharmacokinetic Analysis

The pharmacokinetic data will not be evaluated within the outputs outlined within this SAP. Instead the summary and analysis of these outputs will be outlined within a separate analysis plan.

10.10. Immunogenicity Analysis

The anti-drug antibodies data will not be evaluated within the outputs outlined within this SAP. Instead the summary and analysis of these outputs will be outlined within a separate analysis plan.

10.11. Safety Analysis

All analyses of safety endpoints will be descriptive and will use the Safety Analysis Set. No formal statistical analysis of safety data will be performed.

10.11.1. Adverse Events

Adverse event (AE) data presentations will be produced for adverse events that occur during the study.

All adverse events will be coded using MedDRA, Version 26.0.

An adverse event is defined as treatment emergent if the onset date is on or after the date of first dose of study drug up to 100 days after the last dose of study drug and before starting any subsequent cancer treatment. Should any onset date for an adverse event be missing or only a partial date recorded (such that it cannot be determined if the event onset was prior to the date of first dose) then it will be assumed that the event is treatment emergent, unless the adverse event stop date indicates otherwise. Any adverse event with an onset date earlier than the date of first dose of study drug will be classified as a pre-treatment adverse event and will be identified in subject listings only.

A summary of treatment-emergent AEs will be presented by cohort showing the number of subjects with events (also split by severity; mild, moderate, severe), number of subjects with SAEs, number of subjects with related events and number of subjects with events leading to early withdrawal from the study.

Additionally, each of the summaries below will be presented for treatment emergent AEs:

- Adverse Events by cohort, System Organ Class (SOC) and Preferred Term (PT).
- Adverse Events by cohort, SOC, PT and severity.
- Adverse Events related to study drug by cohort, SOC and PT:
  - etigilimab
  - nivolumab
  - etigilimab and nivolumab
  - etigilimab or nivolumab
- Serious Adverse Events by cohort, SOC and PT.
- Serious Adverse Events related to study drug by cohort, SOC and PT:
  - etigilimab
  - nivolumab
  - etigilimab and nivolumab
  - etigilimab or nivolumab
- Adverse Events that led to death by cohort, SOC and PT.
- Adverse Events that led to treatment discontinuation by cohort, SOC and PT.
- Adverse Events that led to withdrawal from the study by cohort, SOC and PT.
- Adverse Events of Grade 3 or Higher by cohort, SOC and PT.
- Adverse Events of Special Interest by cohort, SOC and PT:

- Infusion Related Adverse Events
- Immune Related Adverse Events
- Infusion or Immune Related Adverse Events

Additionally an overall summary of treatment emergent adverse events that occur within 100 days of last dose of study drug regardless of whether they receive any subsequent cancer treatment between last dose of study drug and the adverse event will be presented, along with a summary of these by SOC and PT.

Listings will be provided for AEs, serious adverse events (SAEs), adverse events directly resulting in discontinuation of study drug or withdrawal from study.

Tables presented by relationship will only include the subset of adverse events that are judged as being 'Related' to study drug (etigilimab, nivolumab, either or both).

If a subject experiences more than one AE with the same preferred term, that preferred term will be counted only once. It will be assigned the greatest observed severity and the strongest relationship to viral challenge among those events for the tables in which those characteristics are summarised.

In all AE summary tables results will be displayed ordered in terms of decreasing frequency of SOC occurrence (based on total across all subjects), and within each SOC also ordered in terms of decreasing frequency of preferred term occurrence (also based on total across all subjects). In all AE summary tables a total column including data across all subjects will also be presented.

10.11.2. Laboratory Variables

The following haematology, biochemistry, coagulation, viral serology and urinalysis parameters (as shown within the protocol) will be included within subject listings (and presented in the units as shown) and summary tables where relevant:

- Haematology: Red blood cell (RBC) count (10^12/L), mean cell haemoglobin (MCH) (pg), mean cell volume (MCV) (fL), hematocrit, haemoglobin (g/L), platelet count (10^9/L), white blood cell (WBC) count (absolute) (10^9/L), neutrophils (% and absolute (10^9/L)), lymphocytes (% and absolute (10^9/L)), monocytes (% and absolute (10^9/L)), eosinophils (% and absolute (10^9/L)), basophils (% and absolute (10^9/L)).
- Biochemistry: Alanine transaminase (ALT) (IU/L), albumin (g/L), alkaline phosphatase (ALP) (IU/L), aspartate transaminase (AST) (IU/L), bicarbonate (mmol/L), total bilirubin (umol/L), blood urea nitrogen (BUN) (mmol/L), calcium (mmol/L), chloride (mmol/L), creatinine (umol/L), glucose (mmol/L), lactate dehydrogenase (LDH) (IU/L), magnesium (mmol/L), potassium (mmol/L), phosphate (mmol/L), total protein (g/L), sodium (mmol/L), carbon dioxide (mmol/L).
- Coagulation: prothrombin time (PT) (secs), activated partial thromboplastin time (APTT) (secs), International normalised ratio (INR).
- Thyroid Function Tests: Thyroid Stimulating Hormone (TSH), Free Triiodothyronine (T3), Free Thyroxine (T4).
- Other: β-HCG.
- Urinalysis: Specific gravity, pH, blood, glucose, protein, ketones.
- Urinalysis (microscopy): Urine RBC (/HPF), Urine WBC (/HPF), bacteria, casts and epithelial cells.

Laboratory data collected in different units to that shown will be converted to the above specified units (if possible) for presentation in subject Listings.

Summary statistics for absolute and changes from baseline by scheduled timepoint will be tabulated, by cohort, for haematology, biochemistry, thyroid function tests and coagulation. Baseline here will be the last non-missing measurements taken prior to the first infusion of etigilimab.

Laboratory parameters (Haematology, Biochemistry, Thyroid function tests, Coagulation, Urinalysis and Urinalysis (microscopy), where done) will be included in subject listings. Laboratory values outside the normal range will be identified in subject listings as above or below the normal range, and, where available, the CTCAE Toxicity Grade will be listed.

Unscheduled visit assessments will be included within subject listings.

10.11.3. Vital Signs

Vital signs will be measured at every visit throughout the trial. Specifically vital signs being measured prior to infusion of etigilimab, every 15 mins during the infusion and 30 and 60 mins after infusion for the first infusion with etigilimab. For subsequent infusions with etigilimab vital signs will be measured prior to infusion and 30 mins post-infusion.

Summary statistics for absolute and changes from baseline will be tabulated, by scheduled timepoint and by cohort, for vital signs parameters (systolic blood pressure (SBP) (mmHg), diastolic blood pressure (DBP) (mmHg), pulse rate (beats/min), respiratory rate (breaths/min), and temperature) and will be included within subject listings. Baseline vital signs are the last non-missing values taken prior to the first infusion with etigilimab.

10.11.4. Physical Examination

Any physical examination findings are reported as Adverse Events and will be listed there.

10.11.5. ECOG Performance Status

Eastern Cooperative Oncology Group (ECOG) Performance is rated from Grade 0 to Grade 5, as per the table below. ECOG performance status will be summarised as a shift from the status at baseline and will also be listed.

10.11.6. 12-Lead ECG

ECGs will be carried out at screening, 30 mins post-infusion on Cycle 1 Day 1, 30 mins post-infusion on Cycle 4 Day 1 and at treatment termination. Baseline will be the last non-missing results observed prior to infusion on Cycle 1 Day 1.

Summary statistics for absolute values and change from baseline by scheduled time point will be tabulated, by cohort and for all subjects, for ECG parameters (PR interval, QRS duration, QTc interval (sec) and QTcF interval (sec)).

10.11.7. Contrast Enhanced Head CT or MRI Scan

Any data collected for this test will be listed.

11. CHANGES TO THE PROTOCOL SPECIFIED ANALYSIS DETAILED IN THE STATISTICAL ANALYSIS PLAN

An additional definition of Treatment Emergent Adverse Event was added to the SAP:

Any adverse event that occurs after first dose of study treatment and within 100 days of last dose of study treatment regardless of whether they receive any subsequent cancer treatment between last dose of study drug and the adverse event.

Toxicity grades of laboratory parameters are not summarised.

12.REFERENCES

13.TABLES, FIGURES AND LISTINGS

13.1. Specific Presentation Details

Tables, Listings and Figures will be provided in pdf and WORD format. All summary Tables and Figures will have source data footnotes that refer to the relevant Listings. Dates will appear as DDMMMYYYY and times as hh:mm (24-hour clock times). All Listings will be ordered by cohort, subject number and scheduled visit. Any unscheduled visit information will also be included within the Listings, identified as unscheduled.

For the presentation of summary data, values will be aligned based on the unit column, and not left/right justified. For example:

Parameter		n	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x
	[optional]	GM (GSD)	xx.x	xx.x
		Q1, Q3	xx.x, xx.x	xx.x, xx.x
		Min, Max	xx, xx	xx, xx

All Tables, Listings and Figures will have the SAS program name, output filename and date of production in the footnote.

All Tables, Listings and Figures will include the following study header and footer:

CONFIDENTIAL Mereo Biopharma Page x of y
MPH313-1-02

Table x.x
Title
Population

Source Data: Listing 16.2.x {Source data footnote only appears for tables, where x references relevant listing number}

Program: XXXXXXXXX Output: XXXXXX Date: XXXXXXXXX

13.2. List of Tables

Table Number	Table Title
14.3.1.2	Treatment Emergent Adverse Events by System Organ Class and Preferred Term – Safety Analysis Set
14.3.1.3	Treatment Emergent Adverse Events by System Organ Class, Preferred Term and Severity – Safety Analysis Set
14.3.1.4.1	Treatment Emergent Adverse Events Related to Etigilimab by System Organ Class and Preferred Term – Safety Analysis Set
14.3.1.4.2	Treatment Emergent Adverse Events Related to Nivolumab by System Organ Class and Preferred Term – Safety Analysis Set
14.3.1.4.3	Treatment Emergent Adverse Events Related to Etigilimab and Nivolumab by System Organ Class and Preferred Term – Safety Analysis Set
14.3.1.4.4	Treatment Emergent Adverse Events Related to Etigilimab or Nivolumab by System Organ Class and Preferred Term – Safety Analysis Set
14.3.1.5	Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term – Safety Analysis Set
14.3.1.6.1	Serious Treatment Emergent Adverse Events Related to Etigilimab by System Organ Class and Preferred Term – Safety Analysis Set
14.3.1.6.2	Serious Treatment Emergent Adverse Events Related to Nivolumab by System Organ Class and Preferred Term – Safety Analysis Set
14.3.1.6.3	Serious Treatment Emergent Adverse Events Related to Etigilimab and Nivolumab by System Organ Class and Preferred Term – Safety Analysis Set
14.3.1.6.4	Serious Treatment Emergent Adverse Events Related to Etigilimab or Nivolumab by System Organ Class and Preferred Term – Safety Analysis Set
14.3.1.7.1	Treatment Emergent Adverse Events that Led to Treatment Discontinuation by System Organ Class and Preferred Term – Safety Analysis Set
14.3.1.7.2	Treatment Emergent Adverse Events that Led to Withdrawal from the Study by System Organ Class and Preferred Term – Safety Analysis Set
14.3.1.7.3	Treatment Emergent Adverse Events that Led to Death by System Organ Class and Preferred Term – Safety Analysis Set
14.3.1.8.1	Treatment Emergent Adverse Events of Special Interest (Infusion or Immune Related) by System Organ Class and Preferred Term – Safety Analysis Set
14.3.1.8.2	Treatment Emergent Adverse Events of Special Interest (Infusion Related) by System Organ Class and Preferred Term – Safety Analysis Set
14.3.1.8.3	Treatment Emergent Adverse Events of Special Interest (Immune Related) by System Organ Class and Preferred Term – Safety Analysis Set

Table Number	Table Title
14.3.1.9	Overall Summary of Treatment Emergent Adverse Events Regardless of Subsequent Cancer Treatment – Safety Analysis Set
14.3.1.10	Treatment Emergent Adverse Events Regardless of Subsequent Cancer Treatment by System Organ Class and Preferred Term – Safety Analysis Set
14.3.2.1	Haematology Parameters Summary – Safety Analysis Set
14.3.2.2	Biochemistry Parameters Summary – Safety Analysis Set
14.3.2.3	Coagulation Parameters Summary – Safety Analysis Set
14.3.2.4	Thyroid Function Parameters Summary – Safety Analysis Set
14.3.3	Vital Signs Parameters Summary – Safety Analysis Set
14.3.4	ECOG Performance Status – Shift from Baseline – Safety Analysis Set
14.3.5	Electrocardiogram Parameters Summary – Safety Analysis Set

13.3. List of Figures

13.4. List of Listings

Listing Number	Listing Title
16.2.1.1	Subject Disposition
16.2.1.2	Survival and Follow-up Status
16.2.1.3	Failed Inclusion and Exclusion Criteria
16.2.2	Important Protocol Deviations
16.2.3	Subject Populations
16.2.4.1	Demographic Characteristics
16.2.4.2	Cancer Diagnosis
16.2.4.3	Cancer on Entry Into Study
16.2.4.4.1	Medical and Surgical History
16.2.4.4.2	Prior Biologic or Immune Therapy Cancer Treatments
16.2.4.4.3	Prior Systemic Chemotherapy Cancer Treatments
16.2.4.4.4	Prior Surgical Cancer Treatments
16.2.4.4.5	Prior Radiotherapy Cancer Treatments
16.2.4.4.6	Other Prior and Concomitant Medications
16.2.5.1	Study Drug Infusion – Etigilimab
16.2.5.2.2	Study Drug Infusion – Nivolumab
16.2.6.1.1	Screening Tumor Tissue Sample Collection
16.2.6.1.2	On-Treatment Tumor Tissue Sample Collection
16.2.6.1.3	Tumor Markers
16.2.6.1.4	Screening Contrast Enhanced Head CT or MRI Scan
16.2.6.2.1	Tumor Evaluation – Target Lesions

Listing Number	Listing Title
16.2.6.2.2	Tumor Evaluation – Non-Target Lesions
16.2.6.2.3	Tumor Evaluation – New Lesions
16.2.6.3.1	Tumor Response Evaluation (RECIST v1.1)
16.2.6.3.2	Tumor Response Evaluation (iRECIST)
16.2.6.4.1	Overall Response (RECIST v1.1)
16.2.6.4.2	Overall Response (iRECIST)
16.2.7	Adverse Events
16.2.8.1	Haematology
16.2.8.2	Biochemistry
16.2.8.3	Coagulation
16.2.8.4	Urinalysis
16.2.8.5	Thyroid Function
16.2.9.1	Other Laboratory Tests: Pregnancy
16.2.9.2	Other Blood Sample Collection
16.2.10	Vital Signs
16.2.11	ECOG Performance Status
16.2.12	Electrocardiogram
16.2.13	Transfusions
16.2.14	Subsequent Cancer Treatment
16.2.15	Visit Dates

14.TABLE AND LISTING SHELLS

Table 14.1.1
Participant Disposition
All Participants

	Cohort A EC CPI-Naïv (N = XX) n (%)	Cohort B Head and Neck (N = XX) n (%)	Cohort C Cervical (N = XX) n (%)	Cohort E TMB-H/MSS (N = XX) n (%)	Cohort F Rare Tumors (N = XX) n (%)	Cohort G Post-CPI (N = XX) n (%)	Cohort H Ovarian (N = XX) n (%)	Total (N = XX) n (%)
Screened	X	X	X	X	X	X	X	X
Screen Failure	X	X	X	X	X	X	X	X
Intention-to-Treat Analysis Set [1]	X	X	X	X	X	X	X	X
Safety Analysis Set [2]	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Response-Evaluable Analysis Set [3]	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Received at Least One Dose of								
Etigilimab	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Nivolumab	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Completed all Dosing Cycles	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Completed Treatment Termination Visit	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Completed Follow-up Visit	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Discontinued Treatment	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Reason for Discontinuation								
XXXXX	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
XXXXX	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
XXXXX	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
XXXXX	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Discontinued Study	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Reason for Discontinuation								
XXXXX	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
XXXXX	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
XXXXX	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
XXXXX	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)

[1] Intention-to-Treat Analysis Set: All subjects who signed an informed consent form and were enrolled into the study.
[2] Safety Analysis Set: All subjects who received any amount of study drug.
[3] Response Evaluable Analysis Set: All subjects with measurable disease at baseline, with at least one post-baseline response assessment or discontinues treatment due to disease progression or death within 16 weeks of first dose of study drug.
Note: No subjects were recruited into Cohort D and so this cohort is not displayed.
Note: The Intention-to-Treat Analysis Set is used as the denominator for all percentages.

Source: Listing 16.2.1.1 and 16.2.3

Table 14.1.2.1
Demography
Safety Analysis Set

		Cohort A EC CPI-Naïve (N = XX)	Cohort B Head and Neck (N = XX)	Cohort C Cervical (N = XX)	Cohort E TMB-H/MSS (N = XX)	Cohort F Rare Tumors (N = XX)	Cohort G Post-CPI (N = XX)	Cohort H Ovarian (N = XX)	Total (N = XX)
Age	n	X	X	X	X	X	X	X	X
	Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Sex									
Male	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Female	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Race									
American Indian or Alaska Native	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Asian	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Black or African American	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Native Hawaiian or Other Pacific Islander	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
White	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Ethnicity									
Hispanic or Latino	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Hispanic or Latino	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Child-Bearing Potential									
Yes	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: No subjects were recruited into Cohort D and so this cohort is not displayed.
Note: Percentages are based on the safety analysis set.

Source: Listing 16.2.4.1

Programming Note: Repeat the table for the sub-cohorts in Cohort F using this shell.

Table 14.1.3.1
Baseline Disease Characteristics
Safety Analysis Set

		Cohort A EC CPI-Naïve (N = XX)	Cohort B Head and Neck (N = XX)	Cohort C Cervical (N = XX)	Cohort E TMB-H/MSS (N = XX)	Cohort F Rare Tumors (N = XX)	Cohort G Post-CPI (N = XX)	Cohort H Ovarian (N = XX)	Total (N = XX)
Time Since Initial Diagnosis	n	X	X	X	X	X	X	X	X
	Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Primary Tumor Location									
Head and Neck	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Gastric	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Cervical	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Endometrial	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Germ Cell	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Sarcoma	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Salivary Gland	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Mesothelioma	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Uveal Melanoma	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Ovarian	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Tumor Staging at Initial Diagnosis									
1A	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1B	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1C	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2A	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2B	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2C	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3A	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3B	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3C	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4A	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4B	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
4C	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Unknown/Other	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Tumor TMB High									
Yes	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Tumor MSS									
Yes	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Locally Advanced									

Yes	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Metastatic									
Yes	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
PD-L1 TPS									
< 1%	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 - 49%	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
>= 50%	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Done	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
PD-L1 CPS									
< 1%	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1 - 10%	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
> 10%	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Not Done	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Other	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: No subjects were recruited into Cohort D and so this cohort is not displayed.
Note: Percentages are based on the safety analysis set.

Source: Listing 16.2.4.2 and 16.2.4.3

Programming Note: Repeat the table for the sub-cohorts in Cohort F using this shell.

Table 14.1.4.1
Prior Cancer Treatments
Safety Analysis Set

		Cohort A EC CPI-Naïve (N = XX)	Cohort B Head and Neck (N = XX)	Cohort C Cervical (N = XX)	Cohort E TMB-H/MSS (N = XX)	Cohort F Rare Tumors (N = XX)	Cohort G Post-CPI (N = XX)	Cohort H Ovarian (N = XX)	Total (N = XX)
Number of Lines of Therapy									
0	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
1	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
2	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
3	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
>=4	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Biologic or Immunotherapy									
Yes	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Chemotherapy									
Yes	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Surgery									
Yes	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Radiotherapy									
Yes	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
No	n (%)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

Note: No subjects were recruited into Cohort D and so this cohort is not displayed.
Note: Percentages are based on the safety analysis set.

Source: Listing 16.2.4.4.2, 16.2.4.4.3, 16.2.4.4.4, 16.2.4.4.5

Table 14.1.4.2
Other Prior Medications
Safety Analysis Set

Drug Class (L2)/ WHO Drug Preferred Base Name [1]	Cohort A EC CPI-Naïve (N = XX) n (%)	Cohort B Head and Neck (N = XX) n (%)	Cohort C Cervical (N = XX) n (%)	Cohort E TMB-H/MSS (N = XX) n (%)	Cohort F Rare Tumors (N = XX) n (%)	Cohort G Post-CPI (N = XX) n (%)	Cohort H Ovarian (N = XX) n (%)	Total (N = XX) n (%)
Number of Participants with any Medication	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Drug Class 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
WHO Drug Name 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
WHO Drug Name 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Drug Class 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
WHO Drug Name 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
WHO Drug Name 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[1] WHO Drug Dictionary Global version 2023(March 2023). L2: The second level of Anatomical Therapeutic Chemical (ATC) classification.
Note: No subjects were recruited into Cohort D and so this cohort is not displayed.
Note: Percentages are based on the safety analysis set.

Source: Listing 16.2.4.4.6

Table 14.1.4.3
Concomitant Medications
Safety Analysis Set

Drug Class (L2)/ WHO Drug Preferred Base Name [1]	Cohort A EC CPI-Naïve (N = XX) n (%)	Cohort B Head and Neck (N = XX) n (%)	Cohort C Cervical (N = XX) n (%)	Cohort E TMB-H/MSS (N = XX) n (%)	Cohort F Rare Tumors (N = XX) n (%)	Cohort G Post-CPI (N = XX) n (%)	Cohort H Ovarian (N = XX) n (%)	Total (N = XX) n (%)
Number of Participants with any Medication	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Drug Class 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
WHO Drug Name 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
WHO Drug Name 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Drug Class 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
WHO Drug Name 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
WHO Drug Name 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)

[1] WHO Drug Dictionary Global version 2023(March 2023). L2: The second level of Anatomical Therapeutic Chemical (ATC) classification.
Note: No subjects were recruited into Cohort D and so this cohort is not displayed.
Note: Percentages are based on the safety analysis set.

Source: Listing 16.2.4.4.6

Table 14.1.5
Investigational Product Exposure
Safety Analysis Set

		Cohort A EC CPI-Naïve (N = XX)	Cohort B Head and Neck (N = XX)	Cohort C Cervical (N = XX)	Cohort E TMB-H/MSS (N = XX)	Cohort F Rare Tumors (N = XX)	Cohort G Post-CPI (N = XX)	Cohort H Ovarian (N = XX)	Total (N = XX)
Etigilimab									
Number of Doses Received	n	X	X	X	X	X	X	X	X
	Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Total Dose Received (mg)	n	X	X	X	X	X	X	X	X
	Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Duration of Exposure (Days)	n	X	X	X	X	X	X	X	X
	Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Nivolumab									
Number of Doses Received	n	X	X	X	X	X	X	X	X
	Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Total Dose Received (mg)	n	X	X	X	X	X	X	X	X
	Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Number of Days of Exposure	n	X	X	X	X	X	X	X	X
	Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX

Note: Number of Days Exposure = Date of Last Dose of Study drug – Date of First Dose of Study drug + 1.
Note: No subjects were recruited into Cohort D and so this cohort is not displayed.

Source: Listing 16.2.5.1 and 16.2.5.2

Table 14.2.1
Response (RECIST v1.1)
Response Evaluable Analysis Set

				Cohort F Rare Tumors (N = XX)					
					Sarcoma (N= XX)				
	Cohort A EC CPI-Naïve (N = XX) n (%)	Cohort C Cervical (N = XX) n (%)	Cohort E TMB-H/MSS (N = XX) n (%)	Uveal (N = XX) n (%)	De-Diff LPS (N = XX) n (%)	UPS (N = XX) n (%)	GCT (N = XX) n (%)	Cohort G Post-CPI (N = XX) n (%)	Cohort H Ovarian (N = XX) n (%)
Confirmed CR	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Unconfirmed CR	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Confirmed PR	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Unconfirmed PR	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
1 SD [1]	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
2 SD [1]	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
PD	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
NE	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Objective Response Rate	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Disease Control Rate	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
95% CI	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X

Response as per RECIST v1.1: CR = Complete Response, PR = Partial Response, SD = Stable Disease, PD = Progressive Disease.
De-Diff LPS = Dedifferentiated Liposarcoma, UPS = Undifferentiated pleomorphic sarcoma, GCT = Germ Cell Tumors.
[1] 1 SD includes Stable Disease following one scan. 2 SD includes Stable Disease following 2 or more scans.
Note: Objective Response Rate is calculated as the number of subjects with a confirmed complete response or partial response divided by the number of subjects in the analysis set.
Note: Disease Control Rate is calculated as the number of subjects with a confirmed complete response, partial response or stable disease divided by the number of subjects in the analysis set.
Note: No subjects were recruited into Cohort D and so this cohort is not displayed.
Note: No subjects in Cohort B are in the Response-Evaluable Analysis Set and so this cohort is not displayed here.

Source: Listing 16.2.6.4.1

This table shell will be used for
14.2.4 Response (iRECIST)

Table 14.2.2.1
Duration of Response (RECIST)
Response Evaluable Analysis Set

				Cohort F Rare Tumors (N = XX)					
					Sarcoma (N= XX)				
Duration (Days)	Cohort A EC CPI-Naïve (N = XX)	Cohort C Cervical (N = XX)	Cohort E TMB-H/MSS (N = XX)	Uveal (N = XX)	De-Diff LPS (N = XX)	UPS (N = XX)	GCT (N = XX)	Cohort G Post-CPI (N = XX)	Cohort H Ovarian (N = XX)
n	X	X	X	X	X	X	X	X	X
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
n	X	X	X	X	X	X	X	X	X
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX

De-Diff LPS = Dedifferentiated Liposarcoma, UPS = Undifferentiated pleomorphic sarcoma, GCT = Germ Cell Tumors.
Note: Duration of response is the Date of first overall response of PD or date of death due to underlying cancer (whichever is first) – Date of first of the two assessments required for confirmed CR or PR. Note: No subjects were recruited into Cohort D and so this cohort is not displayed.
Note: No subjects in Cohort B are in the Response-Evaluable Analysis Set and so this cohort is not displayed here.

Source: Listing 16.2.4.1

This table shell will be used for
14.2.3.1 Duration of Stable Disease (RECIST v1.1)
14.2.5.1 Duration of Response (iRECIST)
14.2.6.1 Duration of Stable Disease (iRECIST)

Table 14.2.2.2
Duration of Response (RECIST) - KM
Response Evaluable Analysis Set

	Cohort A EC CPI-Naïve (N = XX)			Cohort C Cervical (N = XX)			Cohort G Post-CPI (N = XX)			Cohort H Ovarian (N = XX)		
Time (days)	n	N#	Kaplan-Meier Estimate	n	N#	Kaplan-Meier Estimate	n	N#	Kaplan-Meier Estimate	n	N#	Kaplan-Meier Estimate
XX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX
XX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX
XX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX
XX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX
XX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX
XX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX
XX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX
XX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX
XX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX
XX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX
XX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX
XX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX	XXX	XXX	0.XXX
Q1 (days)			XX.X			XX.X			XX.X			XX.X
Median (days)			XX.X			XX.X			XX.X			XX.X
Q3 (days)			XX.X			XX.X			XX.X			XX.X

De-Diff LPS = Dedifferentiated Liposarcoma, UPS = Undifferentiated pleomorphic sarcoma, GCT = Germ Cell Tumors.
Note: N is the number of participants in the Response-Evaluable Analysis Set. N is the number of participants with disease progression or death due to underlying cancer by the end of the period. N# is the number of participants at risk.
Note: No subjects were recruited into Cohort D and so this cohort is not displayed.
Note: No subjects in Cohort B are in the Response-Evaluable Analysis Set and so this cohort is not displayed here.

Source: Listing 16.2.6.4.1

Programming Note: Repeat this table for Cohort E: TMB-H/MSS, Cohort F: Uveal, Cohort F: Sarcoma: De-Diff LPS, Cohort F: Sarcoma: UPS, Cohort F: GCT, Cohort F: Other.

This table shell will be used for
- 14.2.3.2 Duration of Stable Disease (RECIST v1.1) - KM
- 14.5.2 Duration of Response (iRECIST) - KM
- 14.2.6.2 Duration of Stable Disease (iRECIST) - KM
- 14.2.7 Progression-Free Survival (RECIST v1.1)
- 14.2.8 Progression Free Survival (iRECIST)
- 14.2.9 Overall Survival

Table 14.3.1.1
Overall Summary of Treatment Emergent Adverse Events
Safety Analysis Set

Overall Incidence	Cohort A EC CPI-Naïve (N = XX) n (%)	Cohort B Head and Neck (N = XX) n (%)	Cohort C Cervical (N = XX) n (%)	Cohort E TMB-H/MSS (N = XX) n (%)	Cohort F Rare Tumors (N = XX) n (%)	Cohort G Post-CPI (N = XX) n (%)	Cohort H Ovarian (N = XX) n (%)	Total (N = XX) n (%)
Number of TEAEs	XX	XX	XX	XX	XX	XX	XX	XX
Number of Subjects with at least one TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
Subjects with any TEAEs Related to:								
Etigilimab	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Nivolumab	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Etigilimab and Nivolumab	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Etigilimab or Nivolumab	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Subjects with TEAEs by Maximum NCI CTCAE Grade								
Grade 1	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Grade 2	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Grade 3	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Grade 4	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Grade 5	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
All Grades	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Grade >= 3	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Missing	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Subjects with any TEAEs Leading to:								
Etigilimab Dose Held	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Nivolumab Dose Held	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Both Dose Held	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Etigilimab Interrupted	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Nivolumab Interrupted	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Both Interrupted	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Etigilimab Discontinued	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Nivolumab Discontinued	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Both Discontinued	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Death	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
[Repeat for TEAES Related to Etigilimab, TEAEs Related to Nivolumab, TEAES Related to Etigilimab and Nivolumab, TEAES Related to Etigilimab or Nivolumab],								
Subjects with SAEs	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Subjects with SAEs Related to:								
Etigilimab	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Nivolumab	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)

Etigilimab and Nivolumab	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Etigilimab or Nivolumab	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Subjects with any SAEs leading to Death	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Subjects with any AESIs	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Subjects with any AESI Immune Related Adverse Event	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Subjects with any AESI Infusion Reaction	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)

TEAE = Treatment Emergent Adverse Event; SAE = Serious Adverse Event; AESI = Adverse Events of Special Interest;
NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events (version 5.0)
Note: A TEAE is an AE that emerges or worsens in the period from the first dose of study drug to 100 days after the last dose of study drug.
Note: A TEAE is considered related to study drug if relationship is missing.
Note: No subjects were recruited into Cohort D and so this cohort is not displayed.
Note: Percentages are based on the safety analysis set.

Source: Listing 16.2.7

The Table shell will be used for
Table 14.3.1.9 Overall Summary of Treatment Emergent Event Regardless of Subsequent Cancer Treatment by System Organ Class and Preferred Term.

Table 14.3.1.2
Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set

System Organ Class Preferred Term [1]	Cohort A EC CPI-Naïve (N = XX) n (%)	Cohort B Head and Neck (N = XX) n (%)	Cohort C Cervical (N = XX) n (%)	Cohort E TMB-H/MSS (N = XX) n (%)	Cohort F Rare Tumors (N = XX) n (%)	Cohort G Post-CPI (N = XX) n (%)	Cohort H Ovarian (N = XX) n (%)	Total (N = XX) n (%)
Number of TEAE	XX	XX	XX	XX	XX	XX	XX	XX
Number of Subjects with any TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)	XX (XX.X)
System Organ Class 1	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Preferred Term 1	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Preferred Term 2	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
System Organ Class 2	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Preferred Term 1	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Preferred Term 2	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)

[1] MedDRA Version 26.0.
TEAE = Treatment Emergent Adverse Event.
Note: A TEAE is an AE that emerges or worsens in the period from the first dose of study drug to 100 days after the last dose of study drug.
Note: Table shows distinct number of subjects with events for each system organ class/preferred term.
Note: No subjects were recruited into Cohort D and so this cohort is not displayed.
Note: Percentages are based on the safety analysis set.

Source: Listing 16.2.7

The Table shell will be used for:
14.3.1.4.1 Treatment Emergent Adverse Events Related to Etigilimab by System Organ Class and Preferred Term
14.3.1.4.2 Treatment Emergent Adverse Events Related to Nivolumab by System Organ Class and Preferred Term
14.3.1.4.3 Treatment Emergent Adverse Events Related to Etigilimab and Nivolumab by System Organ Class and Preferred Term
14.3.1.4.4 Treatment Emergent Adverse Events Related to Etigilimab or Nivolumab by System Organ Class and Preferred Term
14.3.1.5 Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term
14.3.1.6.1 Serious Treatment Emergent Adverse Events Related to Etigilimab by System Organ Class and Preferred Term
14.3.1.6.2 Serious Treatment Emergent Adverse Events Related to Nivolumab by System Organ Class and Preferred Term
14.3.1.6.3 Serious Treatment Emergent Adverse Events Related to Etigilimab and Nivolumab by System Organ Class and Preferred Term
14.3.1.6.4 Serious Treatment Emergent Adverse Events Related to Etigilimab or Nivolumab by System Organ Class and Preferred Term
14.3.1.7.1 Treatment Emergent Adverse Events that Led to Treatment Discontinuation by System Organ Class and Preferred Term
14.3.1.7.2 Treatment Emergent Adverse Events that Led to Withdrawal from the Study by System Organ Class and Preferred Term
14.3.1.7.3 Treatment Emergent Adverse Events that Led to Death by System Organ Class and Preferred Term
14.3.1.8.1 Treatment Emergent Adverse Events of Special Interest (Infusion or Immune Related) by System Organ Class and Preferred Term
14.3.1.8.2 Treatment Emergent Adverse Events of Special Interest (Infusion Related) by System Organ Class and Preferred Term
14.3.1.8.3 Treatment Emergent Adverse Events of Special Interest (Immune Related) by System Organ Class and Preferred Term
14.3.1.10 Treatment Emergent Adverse Events Regardless of Subsequent Cancer Treatment by System Organ Class and Preferred Term

Table 14.3.1.3
Treatment Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Analysis Set

System Organ Class Preferred Term [1]	Cohort A EC CPI-Naïve (N = XX) n (%)	Cohort B Head and Neck (N = XX) n (%)	Cohort C Cervical (N = XX) n (%)	Cohort E TMB-H/MSS (N = XX) n (%)	Cohort F Rare Tumors (N = XX) n (%)	Cohort G Post-CPI (N = XX) n (%)	Cohort H Ovarian (N = XX) n (%)	Total (N = XX) n (%)
System Organ Class 1								
Mild	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Moderate	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Severe	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Preferred Term 1								
Mild	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Moderate	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Severe	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Preferred Term 2								
Mild	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Moderate	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Severe	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)

[1] MedDRA Version 26.0
TEAE = Treatment Emergent Adverse Event.
Note: A TEAE is an AE that emerges or worsens in the period from the first dose of study drug to 100 days after the last dose of study drug.
Note: Table shows distinct number of subjects with events for each system organ class/preferred term/severity.
Note: If a subject experienced a specific event more than once then the event with the worst severity is summarised.
Note: No subjects were recruited into Cohort D and so this cohort is not displayed.
Note: Percentages are based on the safety analysis set.

Source: Listing 16.2.7

Table 14.3.2.1
Haematology Parameters Summary
Safety Analysis Set

Parameter / Visit		Cohort A EC CPI-Naïve (N = XX) Absolute	Cohort A EC CPI-Naïve (N = XX) Change From Baseline	Cohort B Head and Neck (N = XX) Absolute	Cohort B Head and Neck (N = XX) Change From Baseline	Cohort C Cervical (N = XX) Absolute	Cohort C Cervical (N = XX) Change From Baseline	Cohort E TMB-H/MSS (N = XX) Absolute	Cohort E TMB-H/MSS (N = XX) Change From Baseline
RBC (10^12/L)									
Baseline	n	X		X		X		X	
	Mean (SD)	XX.X (XX.XX)		XX.X (XX.XX)		XX.X (XX.XX)		XX.X (XX.XX)	
	Median	XX.X		XX.X		XX.X		XX.X	
	Q1, Q3	XX.X, XX.X		XX.X, XX.X		XX.X, XX.X		XX.X, XX.X	
	Min, Max	XX, XX		XX, XX		XX, XX		XX, XX	
Day X	n	X	X	X	X	X	X	X	X
	Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
Day X	n	X	X	X	X	X	X	X	X
	Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX

[[Repeat for each Visit and for each parameter]

Note: No subjects were recruited into Cohort D and so this cohort is not displayed.
Note: Percentages are based on the safety analysis set.

Source: Listing 16.2.8.1

Programming Note: Repeat the table for Cohort F Rare Tumors, Cohort G Post-CPI and Cohort H Ovarian.

This table shell will be used for:
14.3.2.2 Biochemistry Parameters Summary
14.3.2.3 Coagulation Parameters Summary
14.3.2.4 Thyroid Function Parameters Summary

Table 14.3.3
Vital Signs Parameters Summary
Safety Analysis Set

		Cohort A EC CPI-Naïve (N = XX)		Cohort B Head and Neck (N = XX)		Cohort C Cervical (N = XX)		Cohort E TMB-H/MSS (N = XX)	
Parameter Visit Timepoint		Absolute	Change From Baseline	Absolute	Change From Baseline	Absolute	Change From Baseline	Absolute	Change From Baseline
Systolic Blood Pressure (mmHg)									
Baseline	n	X		X		X		X	
60 Mins									
Pre-Infusion	Mean (SD)	XX.X (XX.XX)		XX.X (XX.XX)		XX.X (XX.XX)		XX.X (XX.XX)	
	Median	XX.X		XX.X		XX.X		XX.X	
	Q1, Q3	XX.X, XX.X		XX.X, XX.X		XX.X, XX.X		XX.X, XX.X	
	Min, Max	XX, XX		XX, XX		XX, XX		XX, XX	
15 Mins									
Post-Infusion	n	X	X	X	X	X	X	X	X
	Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
30 Mins									
Post-Infusion	n	X	X	X	X	X	X	X	X
	Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
	Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX

[[Repeat for each Visit, timepoint and for each parameter]

Note: No subjects were recruited into Cohort D and so this cohort is not displayed.
Note: Percentages are based on the safety analysis set.

Source: Listing 16.2.10

Programming Note: Repeat the table for Cohort F Rare Tumors, Cohort G Post-CPI and Cohort H Ovarian.

This shell will be used for
14.3.5 Electrocardiogram Parameters Summary

Table 14.3.4
ECOG Performance Status – Shift from Baseline
Safety Analysis Set

		Cohort A EC CPI-Naïve (N = XX)						
		Baseline						
Visit Toxicity Grade		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
Day X								
Grade 0	n(%)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Grade 1	n(%)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Grade 2	n(%)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Grade 3	n(%)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Grade 4	n(%)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Grade 5	n(%)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
Total	n(%)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)	X (XX.X)
[[Repeat for each Visit and for each parameter]								

Note: No subjects were recruited into Cohort D and so this cohort is not displayed.
Note: Percentages are based on the number of subjects with results available at both the baseline and the specific visit.

Source: Listing 16.2.11

Programming Note: Repeat for each of the other cohorts.

Listing 16.2.1.1Subject Disposition

Cohort/ Subject Number	Informed Consent V: Date [1]	Was Additional Consent Given? [2] 1 / 2 / 3 / 4	Date of: Date of First Infusion Study Completion Withdrawal from Treatment Withdrawal from Study	Reason for Withdrawal: From Treatment From Study	Comments
XXXXX / XXXXX	X: DDMMMYYYY	Yes:DDMMMYYYY / No	DDMMMYYYY (XX) /	XXXXXXXXXXXXXXXXX /	XXXXXXXXXXXXXXXXX
		Yes / No	DDMMMYYYY (XX) /	XXXXXXXXXXXXXXXXX	
		Yes / No	DDMMMYYYY (XX) /		
		Yes / No	DDMMMYYYY (XX)		

[1] V = Protocol Version. Initial consent and all reconsent recorded are listed.
[2] Additional Consent: 1 = Pharmacogenomic Sample, 2 = Screening Fresh Core Biopsy Tissue Sample, 3 = On-treatment Fresh Tumor Biopsy, 4 = Treatment Beyond Progression

Listing 16.2.1.2
Survival and Follow-up Status

Cohort/ Subject Number	Date of Follow-up	Type of Contact	Status	Any New Anti-Cancer Therapy?	Disease Progression : Date	Date of Death / Timepoint	Cause of Death
XXXXX / XXXXX	DDMMMYYYY	XXXXXX	XXXXXX	Yes / No	Yes:DDMMMYYYY / No	DDMMMYYYY / XXXXXXXXX	

Listing 16.2.1.3
Failed Inclusion and Exclusion Criteria for Screen Failures

Cohort/ Subject Number	Protocol Version	Failed Exclusion Criteria [1]	Failed Inclusion Criteria [1]	Screen Failure Date	Comments
XXXXX / XXXXX	X	X X X X X X	X X X X X X	DDMMMYYYY	XXXXXXXXX

[1] The failed inclusion/exclusion numbers are listed.

Programming note: If no subjects fail the criteria the listing will state 'No Data to Report'.

Listing 16.2.2
Important Protocol Deviations

Cohort/ Subject Number	Start Date (Study Day)	Stop Date (Study Day)	Deviation Description	Deviation Category
XXXXX / XXXXX	DDMMMYYYY (XX)	DDMMMYYYY (XX)	XXXXXXXXX	Important/ Not Important

Listing 16.2.3
Subject Populations

Cohort/ Subject Number	Safety Analysis Set [1]	Intention-to-Treat Analysis Set [2]	Response Evaluable Analysis Set [3]
XXXXX / XXXXX	Yes / No	Yes / No	Yes / No

[1] Intention-to-Treat Analysis Set: All subjects who signed an informed consent form and were enrolled into the study.
[2] Safety Analysis Set: All subjects who received any amount of study drug.
[3] Response Evaluable Analysis Set: All subjects with measurable disease at baseline, with at least one post-baseline response assessment or discontinues treatment due to disease progression or death within 16 weeks of first dose of study drug.

Listing 16.2.4.1
Demographic Characteristics

Cohort/ Subject Number	Age at consent (years)	Sex	If female, of Child-Bearing Potential?	Race	Ethnicity
XXXXX / XXXXX	xx	Male / Female	Yes / No	XXXXXX	XXXXX

Listing 16.2.4.2
Cancer Diagnosis

Cohort/ Subject Number	Initial Cancer Diagnosis Date	Cancer Diagnosis/ Primary Tumor Location	Is Tumor TMB High?	Is Tumor MSS?	Histology	Stage at Initial Diagnosis	Date Metastatic Disease First Diagnosed	Date Locally Advance Disease First Diagnosed
XXXXX / XXXXX	DDMMMYYYY	XXXXXXXX	Yes / No	Yes / No	XXXXXXXXXXXXX	XX	DDMMMYYYY	DDMMMYYYY

TMB = Tumor Mutational Burden, MSS = Microsatellite Stable.

Listing 16.2.4.3
Cancer On Entry Into Study

Cohort/ Subject Number	Site of Disease at Study Entry	Lesion Type	Location	Current Stage	PD-L1 Test Assay [1] : Date	PD-L1 TPS / PD-L1 CPS	TMB Test Assay [2] : Date	No. of Mutations	MSS Status [3] : Date
XXXXX / XXXXX	XXXXXXXX	Nodal / Extra/Non -Nodal	XXXXXXX	XXXXX	X: DDMMMYYYY	XXXXXX / XXXXXX	X: DDMMMYYYY	XX	X : DDMMMYYYY

TPS = Tumor Proportional Score, CPS = Combined Positive Score.
[1] PD-L1 Assay: 1 = Dako 28-8, 2 = Dako 22C3, 3 = Ventana SP263, 4 = Ventana SP142, 5 = Dako 73-10, 6 = Not Done, 7 = Other.
[2] Tumor Mutation Burden (TMB) Assay: 1 = MSK-IMPACT, 2 = G360LDT, 3 = FoundationOne, 4 = Other.
[3] Microsatellite Status (MSS): 1 = MS-Stable (MSS), 2 = Microsatellite Instability (MSI).

Listing 16.2.4.4.1
Medical and Surgical History

Cohort/ Subject Number	MedDRA SOC / Preferred Term [1] / Medical Condition	Start Date / End Date	Line No.
XXXXX / XXXXX	XXXXXXXXX	DDMMMYYYY /	XXX
	XXXXXXXXX	DDMMMYYYY	
	XXXXXXXXX		

[1] MedDRA Version 26.0.

Listing 16.2.4.4.2
Prior Biologic or Immune Therapy Cancer Treatments

Cohort/ Subject Number	Any Prior biologic or immune therapy?	If Prior PD-1 or PD-L1 Inhibitor	
		Last Dose	Best Response [1]
XXXXX / XXXXX	Yes / No	DDMMMYYYY	XX

[1] Best Response: CR = Complete Response, PR = Partial Response, SD = Stable Disease, PD = Progressive Disease.

Listing 16.2.4.4.3
Prior Systemic Chemotherapy Cancer Treatments

Cohort/ Subject Number	Systemic Therapy Line	Type	Intent	Drug Name / Dose / Dose Unit	Start / End Date	Number of: Cycles / Days per Cycle Dosing Days per Cycle	Best Response [1]/ Date of Response	Reason Discontinued	Progress During or After Systemic Line?	Date, If Discontinued Due to PD
XXXXX / XXXXX	XXXXXXXX	XXXXXX	XXXXX	XXXXXXXX / XX / XX	DDMMMYYYY / DDMMMYYYY	XX / XX / XX	XX/ DDMMMYYYY	XXXXXXX	Yes / No	DDMMMYYYY

[1] Best Response: CR = Complete Response, PR = Partial Response, SD = Stable Disease, PD = Progressive Disease NE = Not Evaluated, I = Indeterminate, UK = Unknown.

Listing 16.2.4.4.4
Prior Surgical Cancer Treatments

Cohort/ Subject Number	Surgical Procedure	Date of Procedure
XXXXX / XXXXX	XXXXXXXX	DDMMMYYYY

Listing 16.2.4.4.5
Prior Radiotherapy Cancer Treatments

Cohort/ Subject Number	Type of Radiotherapy	Site of Treatment	Total cGY	Start / End Date
XXXXX / XXXXX	XXXXXXXX	XXXXXXXX	XX	DDMMMYYYY / DDMMMYYYY

Listing 16.2.4.4.6
Other Prior and Concomitant Medications

Cohort/ Subject Number	Drug Class (L2) / WHO Drug Preferred Base Name [1] / Medication (verbatim)	Start Date (Study Day)/ End Date (Study Day) (Ongoing)	Indication / AE Line / Med History Line	Route	P / C [2]
XXXXX / XXXXX	XXXXXXXXX XXXXXXXXX XXXXXXXXXXX	DDMMMYYYY (XX) / DDMMMYYYY (XX)	XXXXXX / Aen / MHn	XXX	P / C

[1] WHO Drug Dictionary Global version 2023 (March 2023). L2: The second level of Anatomical Therapeutic Chemical (ATC) classification.

[2] P = Prior, C = Concomitant from first dose of study drug.
Note: If the medication stop date is before the date of first dose of study drug the medication is assigned as being prior. In all other cases, the medication is assigned as being concomitant with study drug.

Listing 16.2.5.1
Study Drug Infusion – Etigilimab

Cohort/ Subject Number	Visit	Date (Study Day) Start/End Time	Administered? LOT Number/ Number of Vials	Subject Weight (kg)/ Intended Dose (mg)/ Actual Dose (mg)/ Total Volume (mL)	Full Dose Given? / If Not, mg Given	Infusion Site	Infusion: Interrupted?/ Restarted? Reaction?	Reason: Not Administered/ Interrupted/ Not Restarted	Time of Restart/ Final Stop
XXXXX / XXXXX	XXXXXX	DDMMMYYYY (XX) HH:MM / HH:MM	Yes/No XX / XX	XX / XX / XX / XX	Yes/No / XXX	XXXX	Yes/No Yes/No Yes/No	XXXXXXX/ XXXXXXX/ XXXXXXX	HH:MM / HH:MM

Listing 16.2.5.2
Study Drug Infusion – Nivolumab

Cohort/ Subject Number	Visit	Date (Study Day) Start/End Time	Administered? LOT Numbers	Intended Dose (mg)/ Actual Dose (mg)/ Total Volume (mL)	Full Dose Given?	Infusion Site	Infusion: Interrupted?/ Restarted? Reaction?	Reason: Not Administered/ Interrupted/ Not Restarted	Time of Restart/ Final Stop
XXXXX / XXXXX	XXXXXX	DDMMMYYYY (XX) HH:MM / HH:MM	Yes/No XX /	XX / XX / XX	Yes/No	XXXX	Yes/No Yes/No Yes/No	XXXXXXX/ XXXXXXX/ XXXXXXX	HH:MM / HH:MM

Listing 16.2.6.1.1
Screening Tumor Tissue Sample Collection

Cohort/ Subject Number	Cancer Diagnosis	Tumor TMB-H or MSS	Tissue Collected and sent to FM / Sent to CL for PDL1 Test	Date: Biopsy Sent to FM Sent to CL	Archival or Fresh Biopsy / Location	Date: Biopsy Sent to CL	Primary Diagnosis? At recurrence? Recurrence number Site
XXXXX / XXXXX	XXXXX	TMB-H / MSS	Yes/No Yes/No	DDMMMYYYY DDMMMYYYY DDMMMYYYY	Archival/Fresh / XXXXX	DDMMMYYYY DDMMMYYYY	XXXX/ Yes/No/ XX/ XXXXXX

TMB = Tumor Mutational Burden, MSS = Microsatellite Stable, FM = Foundation Medicine, CL = Central Lab.

Listing 16.2.6.1.2
On-Treatment Tumor Tissue Sample Collection

Cohort/ Subject Number	Biopsy Done / Location	Flash Frozen or Ethanol	Date: Biopsy Sent to CL	At recurrence? Site
XXXXX / XXXXX	Yes/No / XXXXX	Flash-Frozen / Ethanol	DDMMMYYYY DDMMMYYYY	Yes/No/ XXXXXX

CL = Central Lab.

Listing 16.2.6.1.3
Tumor Markers

Cohort/ Subject Number	Visit	Sample Collected?	Date (Study Day)	Parameter	Result	Comments
XXXXX / XXXXX	XXX	Yes / No	DDMMMYYYY (XX)	CEA	XXX	XXXXXXXXX
				AFP	XXX	
				PSA	XXX	
				CA 15-3	XXX	
				CA 19-9	XXX	
				CA 27-29	XXX	
				CA 125	XXX	

Listing 16.2.6.1.4
Screening Contrast Enhanced Head CT or MRI Scan

Cohort/ Subject Number	Visit	CT or MRI Performed?	Done with Contrast?	Type	Date (Study Day)	Brain Metastases Present?
XXXXX / XXXXX	XXX	Yes / No	Yes / No	Head CT / MRI Scan	DDMMMYYYY (XX)	Yes / No

Listing 16.2.6.2.1
Tumor Evaluation – Target Lesions

Cohort/ Subject Number	Visit	Method	Lesion Number	Type	Location	Date of Assessment (Study Day)	Short Axis (mm)	Longest Diameter (mm)	Sum of Longest Diameters
XXXXX / XXXXX	XXX	XXXX	1	Nodal / Extra/Non-Nodal	XXXXXX	DDMMMYYYY (XX)	XX	XX	XX
			2	Nodal / Extra/Non-Nodal	XXXXXX	DDMMMYYYY (XX)	XX	XX	
			3	Nodal / Extra/Non-Nodal	XXXXXX	DDMMMYYYY (XX)	XX	XX	
			4	Nodal / Extra/Non-Nodal	XXXXXX	DDMMMYYYY (XX)	XX	XX	
			5	Nodal					

Programming Note: Sum of Longest Diameters will be shown only on the top row for each subject.

Listing 16.2.6.2.2
Tumor Evaluation – Non-Target Lesions

Cohort/ Subject Number	Visit	Date of Assessment (Study Day)	Method	Lesion Number	Type	Location
XXXXX / XXXXX	XXX	DDMMMYYYY (XX)	XXXXX	X	Nodal / Extra/Non-Nodal	XXXX

Listing 16.2.6.2.3
Tumor Evaluation – New Lesions

Cohort/ Subject Number	Visit	New Lesions?	Lesion Number	Type	Location	Method	Date of Assessment (Study Day)	Short Axis (mm)	Longest Diameter (mm)	Sum of Longest Diameters
XXXXX / XXXXX	XXX	Yes/No	X	Nodal / Extra/Non-Nodal	XXXX	XXXX	DDMMMYYYY (XX)	XX	XX	XX

Programming Note: Sum of Longest Diameters will be shown only on the top row for each subject.

Listing 16.2.6.3.1
Tumor Response Evaluation (RECIST v1.1)

Cohort/ Subject Number	Visit	Date of Assessment (Study Day)	Target Lesion Response	Non-Target Lesion Response	Overall Tumor Response	Continue Follow-up for Tumor Response	If Yes, Reason	If Treatment Beyond Progression, Consent?
XXXXX / XXXXX	XXX	DDMMMYYYY (XX)	Nodal / Extra/Non-Nodal	XX	XX	Yes or No	XX	Yes/No

[Response: CR = Complete Response, PR = Partial Response, SD = Stable Disease, PD = Progressive Disease, NE = Not Evaluated, ND = Not Done.

Listing 16.2.6.3.2
Tumor Response Evaluation (iRECIST)

Cohort/ Subject Number	Visit	Date of Assessment (Study Day)	New Lesion Response	Overall Tumor Response[1]
XXXXX / XXXXX	XXX	DDMMMYYYY (XX)	Nodal / Extra/Non-Nodal	XX

[1] Response: iCR = iRECIST Complete Response, iPR = iRECIST Partial Response, iSD = iRECIST Stable Disease, iUPD = iRECIST Unconfirmed Progressive Disease, iCPD = iRECIST Confirmed Progressive Disease, NE = Not Evaluated, ND = Not Done.

Listing 16.2.6.4.1
Overall Response (RECIST v1.1)

Cohort/ Subject Number	Best Overall Response	Duration of Response (Days)	Duration of Stable Disease (Days)	Progression Free Survival (Days)	Overall Survival (Days)
XXXXX / XXXXX	XXX	XXX	XXX	XXX	XXX

Listing 16.2.6.4.2
Overall Response (iRECIST)

Cohort/ Subject Number	Best Overall Response	Duration of Response (Days)	Duration of Stable Disease (Days)	Progression Free Survival (Days)
XXXXX / XXXXX	XXX	XXX	XXX	XXX

Listing 16.2.7
Adverse Events

Cohort/ Subject Number	MedDRA SOC / Preferred Term [1] / Adverse event (verbatim)	Start Date (Study Day) / Stop Date (Study Day)	TE [2] / TE_S [3] / NCI CTCAE Grade [4]	SAE / Serious Criteria [5]	Infusion Reaction? / Infection or Infestation?	AESI Infusion Immune	Related to: Etig/ Nivo/ Both	Outcome [6] / Action Taken Etig [7] / Nivo [7] / Other Action [8] /	Comments
XXX / XXXXX	XXXXXXXXX/ XXXXXX/ XXXXXX	DDMMMYYYY (XX) / DDMMMYYYY (XX)	Yes or No / Yes or No / X	Yes or No / XX	Yes or No / Yes, Yes COVID or No	Yes or No/ Yes or No	Related or Not Related/ Related or Not Related/ Related or Not Related	X / X / X / X	XXXXXXXXX XXXXXXXXX

NA = Not applicable, TE = Treatment Emergent, SAE = Serious Adverse Event, AESI = Adverse Event of Special Interest, NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events (version 5.0).

[1] MedDRA Version 26.0.
[2] An AE occurring on or after the first dose of study drug and within 100 days of last dose of study drug.
[3] An AE occurring on or after the first dose of study drug, within 100 days of last dose of study drug and regardless of any other subsequent cancer treatment.
[4] Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Severe, Grade 4 = Life threatening, Grade 5 = Fatal.
[5] 1 = Death; 2 = Life-threatening; 3 = Hospitalization; 4 = Persistent or significant disability/incapacity; 5 = Congenital anomaly/birth defect; 6 = Other.
[6] Outcome: 1 = Resolved; 2 = Resolved with Minor Sequelae; 3 = Resolved with Major Sequelae; 4 = Ongoing; 5 = Fatal; 6 = Unknown.
[7] Action Taken: 1 = None; 2 = Dose held; 3 = Infusion interrupted; 4 = Drug permanently discontinued, 5 = Not applicable
[8] Other Action: 1 = None; 2 = Non-drug therapy given; 3 = Concomitant medication taken; 4 = Diagnostic procedure performed; 5 = Subject withdrawn; 6 = Subject hospitalized; 7 = Other.

Listing 16.2.8.1
Haematology

Cohort/ Subject Number	Visit	Collection Date (Study Day)	Parameter	Result	Change from Baseline	Units	Lower Limit	Upper Limit	Flag	Comments
XXXXX / XXXXX	XXX	DDMMMYYYY (xx)	Basophils (abs) XXXX XXXX XXXX	X.XX	X.XX	X10^9/L	X.XX	X.XX	L / H	XXXXXXXXXXX

Flag: L =below lower limit, H = above upper limit. # = Baseline.
Note: Values prefixed with < are treated as 0 when calculating the change from baseline.

Programming Note: The parameters should be listed in the order that they appear in the protocol.
Programming Note: # should be placed against the baseline measurement for each parameter.

The same listing template will be used for

16.2.8.2 Biochemistry
16.2.8.3 Coagulation
16.2.8.5 Thyroid Function

Listing 16.2.8.4
Urinalysis

Cohort/ Subject Number	Visit	Collection Date (Study Day)	Parameter	Result	Microscopy Done?	Microscopy Parameter	Microscopy Result	Microscopy Units	Comments
XXXXX / XXXXX	XXX	DDMMMYYYY (XX)	Protein XXXX XXXX XXXX	XXXX	Yes / No	Bacteria	XXXX	XXXX	XXXXXXXXXXX

Flag: L =below lower limit, H = above upper limit. # = Baseline.

Programming Note: The parameters should be listed in the order that they appear in the protocol.
Programming Note: # should be placed against the baseline measurement for each parameter.

Listing 16.2.9.1
Other Laboratory Tests: Pregnancy

Cohort/ Subject Number	Visit	Test Performed?	If Not Performed, Reason	Test Date (Study Day)	Result	Comments
XXXXX / XXXXX	XXX	Yes / No	XXXXXXXXXXX	DDMMMYYYY (XX)	Positive / Negative	XXXXXXXXXXXXXXXXX

Note: Only females are included in this listing.

Listing 16.2.9.2
Other Blood Sample Collection

Cohort/ Subject Number	Visit	Date of Collection (Study Day)	Sample Collected
XXXXX / XXXXX	XXX	DDMMMYYYY (XX)	mRNA Biomarkers / Plasma Biomarkers / PBMC Biomarkers / Cell Free DNA for TMB-H/MSS Screening* / Pharmacogenomic

* Sample only required for TMB-H/MSS (Cohort E) at Screening. Post-screening sample only required for Cohorts A, C, E, F and H if not already submitted at screening.

Listing 16.2.10
Vital Signs

Cohort/ Subject Number	Visit	Date	Infusion			Parameter	Result	Change from Baseline	Units
			Drug Name	Timepoint	Time				
XXXXX / XXXXX	XXXXX	DDMMMYYYY	Etigilimab / Nivolumab	Pre-Infusion / During Infusion / Post-Infusion / Other	HH:MM		XX	XX	
						Temperature			C/F
						Pulse Rate	XX	XX	Bpm
						Respiratory Rate	XX	XX	Bpm
						Systolic BP	XX	XX	mmHg
						Diastolic BP	XX	XX	mmHg
						Weight	XX	XX	kg
						Height	XX	XX	cm

= Baseline.

Programming Note: # should be placed against the baseline measurement for each parameter.

Listing 16.2.11
ECOG Performance Status

Cohort/ Subject Number	Visit	Date	Score [1]
XXXXX / XXXXX	XXXXX	DDMMMYYYY	X

= Baseline.
[1] ECOG: 0 = Normal activity. Fully active, able to carry on all pre-disease performance without restriction, 1 = Symptoms, but ambulatory. Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work), 2 = In bed less than 50% of the time. Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50% of waking hours, 3 = In bed greater than 50% of the time. Capable of only limited self-care, confined to bed or chair more than 50% of waking hours, 4 = 100% bedridden. Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair, 5 = Dead.

Programming Note: # should be placed against the baseline measurement.

Listing 16.2.12
Electrocardiogram

Cohort/ Subject Number	Visit	Timepoint	Date / Time (Study Day)	Parameter	Result [1]	Change from Baseline	Comments	If Abnormal, reported as AE?
XXXXX / XXXXX	XXX	XXX	DDMMMYYYY / HH:MM (XX)	XXX	XXX	XX	XXXXXXXXX	Yes/No

= Baseline.

Programming Note: The interpretation will be shown as an additional parameter, with the interpretation outcome shown in the result column and any description in the comments column.
Programming Note: # should be placed against the baseline measurement for each parameter.

Listing 16.2.13
Transfusions

Cohort/ Subject Number	Any Transfusions?	Date (Study Day)	Type	Number of Units	Reason for Transfusion	If AE, Specify
XXXXX / XXXXX	Yes / No	DDMMMYYYY (XX)	XXXXXX	XXX	XXXXXXX	XXXXXXXXXX

Listing 16.2.14
Subsequent Cancer Treatment

Cohort/ Subject Number	Subsequent Treatment	Start/End Date	Treatment Type/ Procedure	Treatment Site	Best Overall Response [2]
XXXXX / XXXXX	Yes: X or No	DDMMMYYYY / DDMMMYYYY	XXXXXXXXXX	XXXXXXXX	XX

[1] 1 = Chemotherapy, biologic therapy or immunotherapy, 2 = Surgery, 3 = Radiotherapy.
[2] Best Response completed for chemotherapy, biologic therapy or immunotherapy only: CR = Complete Response, PR = Partial Response, SD = Stable Disease, PD = Progressive Disease, UK = Unknown.

Listing 16.2.15
Visit Dates

Cohort/ Subject Number	Visit	Date	Source of Unscheduled Visit	Comments
XXXXX / XXXXX	XXX	DDMMMYYYY	XXXXXXXXX	XXXXXXXXXXX

Programming note: Unscheduled visits and visit information will be taken from specific database modules and the "Reason for additional collection" will be placed in the comments column in this listing.