

DM=Demographics

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Subject Identification

Study Site Identifier	SITEID	
Subject Number	[NOT SUBMITTED]	
Subject Identifier for the Study	SUBJID	
Date of Birth	BRTHDTC	
Age at Informed Consent	AGE	
Age Units at Informed Consent	AGEU	YEARS <input checked="" type="radio"/>
Sex	SEX	Male <input type="radio"/> Female <input type="radio"/>

DS=Disposition

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Project Name: Brigatinib-2002

DSCAT=DISPOSITION EVENT

Form: Screening Disposition

Did the subject enroll into the study? **[NOT SUBMITTED]** Yes ☐No ☐Did the subject experience any serious pretreatment events? **[NOT SUBMITTED]** Yes ☐*Note: ALL pretreatment events, whether determined to be serious or not, should be recorded on the appropriate eCRF.* No ☐

Date of Screen Failure

DSSTDTC

Reason for Screen Failure

DSTERMADVERSE EVENT ☐PROTOCOL DEVIATION ☐LOST TO FOLLOW-UP ☐WITHDRAWAL BY SUBJECT ☐STUDY TERMINATED BY ☐SPONSOR ☐PREGNANCY ☐DID NOT MEET ENTRANCE ☐CRITERIA ☐OTHER ☐

DS=Disposition

DM=Demographics

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DSCAT=PROTOCOL MILESTONE

Project Name: Brigatinib-2002

DSTERM=INFORMED CONSENT OBTAINED

Form: Demography

DSDECOD=INFORMED CONSENT OBTAINED

Date of Informed Consent

DSSTDTC

RFICDTC

Protocol Version

PROTVRSN in SUPPDM

AMENDMENT 1 ☐
AMENDMENT 2 ☐
AMENDMENT 3 ☐
AMENDMENT 4 ☐
AMENDMENT 5 ☐
AMENDMENT 6 ☐
AMENDMENT 7 ☐
AMENDMENT 8 ☐
AMENDMENT 9 ☐
AMENDMENT 10 ☐

Country

COUNTRY

AUSTRALIA ☐
AUSTRIA ☐
CANADA ☐
CHINA ☐
DENMARK ☐
FRANCE ☐
GERMANY ☐
HONG KONG ☐
ITALY ☐
KOREA, REPUBLIC OF; ☐
SOUTH KOREA ☐
NETHERLANDS ☐
SINGAPORE ☐
SPAIN ☐
SWEDEN ☐
TAIWAN ☐
UNITED STATES ☐

Ethnicity

ETHNIC

HISPANIC OR LATINO ☐
NOT HISPANIC OR LATINO ☐
NOT REPORTED ☐
UNKNOWN ☐

Race

RACE

Select All That Apply

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Project Name: Brigatinib-2002

Form: Demography

American Indian or Alaska Native	RACEAIAN in SUPPDM	AMERICAN INDIAN OR ALASKA NATIVE	<input type="checkbox"/>
Asian	RACEASN in SUPPDM	ASIAN	<input type="checkbox"/>
Asian Sub-Category	RACESASN in SUPPDM	ASIAN INDIAN	<input type="checkbox"/>
		CHINESE	<input type="checkbox"/>
		JAPANESE	<input type="checkbox"/>
		KOREAN	<input type="checkbox"/>
		NOT REPORTED	<input type="checkbox"/>
Black or African American	RACEBAA in SUPPDM	BLACK OR AFRICAN AMERICAN	<input type="checkbox"/>
Native Hawaiian/Other Pacific Islander	RACENHPI in SUPPDM	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	<input type="checkbox"/>
White	RACEWHT in SUPPDM	WHITE	<input type="checkbox"/>
White Sub-Category	RACESWHT in SUPPDM	ARAB	<input type="checkbox"/>
		EUROPEAN	<input type="checkbox"/>
		MIDDLE EASTERN	<input type="checkbox"/>
		NORTH AFRICAN	<input type="checkbox"/>
		NOT REPORTED	<input type="checkbox"/>
Not Reported	RACE	NOT REPORTED	<input type="checkbox"/>
Study Phase	STDYPHAS in SUPPDM	PHASE I	<input type="checkbox"/>
		PHASE II	<input checked="" type="checkbox"/>
		PHASE IIA	<input type="checkbox"/>
		PHASE IIB	<input type="checkbox"/>
		PHASE III	<input type="checkbox"/>
		PHASE IIIA	<input type="checkbox"/>
		PHASE IIIB	<input type="checkbox"/>
		PHASE IV	<input type="checkbox"/>
Date of Birth (derived from the Subject ID form)	[NOT SUBMITTED]		
Age at Informed Consent (derived from Subject ID form)	[NOT SUBMITTED]		
Age Unit at Informed Consent (derived from Subject ID form)	[NOT SUBMITTED]	YEARS	<input type="checkbox"/>

IE=Inclusion-Exclusion Criteria Not Met

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Project Name: Brigatinib-2002

Form: Inclusion/Exclusion Criteria

Did the subject meet all of the admission criteria? **[NOT SUBMITTED]** Yes ☐
No ☐

Admission Criteria Not Met (Select all that apply) **IETEST**

Exclusion Criteria 01	<input type="checkbox"/>
Exclusion Criteria 02	<input type="checkbox"/>
Exclusion Criteria 03	<input type="checkbox"/>
Exclusion Criteria 04	<input type="checkbox"/>
Exclusion Criteria 05	<input type="checkbox"/>
Exclusion Criteria 06	<input type="checkbox"/>
Exclusion Criteria 07	<input type="checkbox"/>
Exclusion Criteria 08	<input type="checkbox"/>
Exclusion Criteria 09	<input type="checkbox"/>
Exclusion Criteria 10	<input type="checkbox"/>
Exclusion Criteria 11	<input type="checkbox"/>
Exclusion Criteria 12	<input type="checkbox"/>
Exclusion Criteria 13	<input type="checkbox"/>
Exclusion Criteria 14	<input type="checkbox"/>
Exclusion Criteria 15	<input type="checkbox"/>
Exclusion Criteria 16	<input type="checkbox"/>
Exclusion Criteria 17	<input type="checkbox"/>
Exclusion Criteria 18	<input type="checkbox"/>
Exclusion Criteria 19	<input type="checkbox"/>
Exclusion Criteria 20	<input type="checkbox"/>
Exclusion Criteria 21	<input type="checkbox"/>
Inclusion Criteria 01	<input type="checkbox"/>
Inclusion Criteria 02	<input type="checkbox"/>
Inclusion Criteria 03	<input type="checkbox"/>
Inclusion Criteria 04	<input type="checkbox"/>
Inclusion Criteria 05	<input type="checkbox"/>
Inclusion Criteria 06	<input type="checkbox"/>
Inclusion Criteria 07	<input type="checkbox"/>
Inclusion Criteria 08	<input type="checkbox"/>
Inclusion Criteria 09	<input type="checkbox"/>
Inclusion Criteria 10	<input type="checkbox"/>
Inclusion Criteria 11	<input type="checkbox"/>

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Project Name: Brigatinib-2002

Form: Inclusion/Exclusion Criteria

Inclusion Criteria 12 ☐

SV=Subject Visits

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Date of Visit

Date of Visit

SVSTDTC

SV=Subject Visits

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Date of Visit Adhoc

Date of Visit		SVSTDTC
Type of Visit	[NOT SUBMITTED]	SCHEDULED <input type="checkbox"/>
		UNSCHEDULED <input type="checkbox"/>
Scheduled Visit		SCREENING <input type="checkbox"/>
		CYCLE 1 DAY 1 <input type="checkbox"/>
		CYCLE 1 DAY 8 <input type="checkbox"/>
		CYCLE 1 DAY 15 <input type="checkbox"/>
		CYCLE 2 DAY 1 <input type="checkbox"/>
		CYCLE 2 DAY 28 <input type="checkbox"/>
		CYCLE 3 DAY 1 <input type="checkbox"/>
		CYCLE 4 DAY 1 <input type="checkbox"/>
		CYCLE 4 DAY 28 <input type="checkbox"/>
		CYCLE 5 DAY 1 <input type="checkbox"/>
		CYCLE 6 DAY 1 <input type="checkbox"/>
		CYCLE 6 DAY 28 <input type="checkbox"/>
		CYCLE 7 DAY 1 <input type="checkbox"/>
		CYCLE 8 DAY 1 <input type="checkbox"/>
		CYCLE 8 DAY 28 <input type="checkbox"/>
		CYCLE 9 DAY 1 <input type="checkbox"/>
		CYCLE 10 DAY 1 <input type="checkbox"/>
		CYCLE 10 DAY 28 <input type="checkbox"/>
		CYCLE 11 DAY 1 <input type="checkbox"/>
		CYCLE 12 DAY 1 <input type="checkbox"/>
		CYCLE 12 DAY 28 <input type="checkbox"/>
		CYCLE 13 DAY 1 <input type="checkbox"/>
		CYCLE 14 DAY 1 <input type="checkbox"/>
		CYCLE 14 DAY 28 <input type="checkbox"/>
		CYCLE 15 DAY 1 <input type="checkbox"/>
		CYCLE 16 DAY 1 <input type="checkbox"/>
		CYCLE 17 DAY 1 <input type="checkbox"/>
		CYCLE 17 DAY 28 <input type="checkbox"/>
		CYCLE 18 DAY 1 <input type="checkbox"/>
		CYCLE 19 DAY 1 <input type="checkbox"/>
		CYCLE 20 DAY 1 <input type="checkbox"/>

VISIT

CYCLE 20 DAY 28	<input type="checkbox"/>
CYCLE 21 DAY 1	<input type="checkbox"/>
CYCLE 22 DAY 1	<input type="checkbox"/>
CYCLE 23 DAY 1	<input type="checkbox"/>
CYCLE 23 DAY 28	<input type="checkbox"/>
CYCLE 24 DAY 1	<input type="checkbox"/>
CYCLE 25 DAY 1	<input type="checkbox"/>
CYCLE 26 DAY 1	<input type="checkbox"/>
CYCLE 26 DAY 28	<input type="checkbox"/>
CYCLE 27 DAY 1	<input type="checkbox"/>
CYCLE 28 DAY 1	<input type="checkbox"/>
CYCLE 29 DAY 1	<input type="checkbox"/>
CYCLE 29 DAY 28	<input type="checkbox"/>
CYCLE 30 DAY 1	<input type="checkbox"/>
CYCLE 31 DAY 1	<input type="checkbox"/>
CYCLE 32 DAY 1	<input type="checkbox"/>
CYCLE 32 DAY 28	<input type="checkbox"/>
CYCLE 33 DAY 1	<input type="checkbox"/>
CYCLE 34 DAY 1	<input type="checkbox"/>
CYCLE 35 DAY 1	<input type="checkbox"/>
CYCLE 35 DAY 28	<input type="checkbox"/>
CYCLE 36 DAY 1	<input type="checkbox"/>
CYCLE 1 DAY 1	<input type="checkbox"/>
ESCALATION	<input type="checkbox"/>
CYCLE 1 DAY 15	<input type="checkbox"/>
ESCALATION	<input type="checkbox"/>
CYCLE 2 ESCALATION	<input type="checkbox"/>
CYCLE 3 ESCALATION	<input type="checkbox"/>
CYCLE 4 ESCALATION	<input type="checkbox"/>
CYCLE 5 ESCALATION	<input type="checkbox"/>
CYCLE 6 ESCALATION	<input type="checkbox"/>
CYCLE 7 ESCALATION	<input type="checkbox"/>
CYCLE 8 ESCALATION	<input type="checkbox"/>
CYCLE 9 ESCALATION	<input type="checkbox"/>
CYCLE 10 ESCALATION	<input type="checkbox"/>

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Project Name: Brigatinib-2002

Form: Date of Visit Adhoc

	CYCLE 11 ESCALATION	<input type="checkbox"/>
	CYCLE 12 ESCALATION	<input type="checkbox"/>
	CYCLE 13 ESCALATION	<input type="checkbox"/>
	CYCLE 14 ESCALATION	<input type="checkbox"/>
	CYCLE 15 ESCALATION	<input type="checkbox"/>
	CYCLE 16 ESCALATION	<input type="checkbox"/>
	CYCLE 17 ESCALATION	<input type="checkbox"/>
	CYCLE 18 ESCALATION	<input type="checkbox"/>
	CYCLE 19 ESCALATION	<input type="checkbox"/>
	CYCLE 20 ESCALATION	<input type="checkbox"/>
	CYCLE 21 ESCALATION	<input type="checkbox"/>
	CYCLE 22 ESCALATION	<input type="checkbox"/>
	CYCLE 23 ESCALATION	<input type="checkbox"/>
	CYCLE 24 ESCALATION	<input type="checkbox"/>
	CYCLE 25 ESCALATION	<input type="checkbox"/>
	CYCLE 26 ESCALATION	<input type="checkbox"/>
	CYCLE 27 ESCALATION	<input type="checkbox"/>
	CYCLE 28 ESCALATION	<input type="checkbox"/>
	CYCLE 29 ESCALATION	<input type="checkbox"/>
	CYCLE 30 ESCALATION	<input type="checkbox"/>
	CYCLE 31 ESCALATION	<input type="checkbox"/>
	CYCLE 32 ESCALATION	<input type="checkbox"/>
	CYCLE 33 ESCALATION	<input type="checkbox"/>
	CYCLE 34 ESCALATION	<input type="checkbox"/>
	CYCLE 35 ESCALATION	<input type="checkbox"/>
	CYCLE 36 ESCALATION	<input type="checkbox"/>
	END OF TREATMENT	<input type="checkbox"/>
	30 DAYS AFTER LAST DOSE	<input type="checkbox"/>
	OVERALL SURVIVAL	<input type="checkbox"/>
	FOLLOW-UP	<input type="checkbox"/>

Select the forms for which additional assessments were done for the specified visit:

Vital Signs	[NOT SUBMITTED]	
Chemistry	[NOT SUBMITTED]	
Insulin	[NOT SUBMITTED]	

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Project Name: Brigatinib-2002

Form: Date of Visit Adhoc

Testosterone	[NOT SUBMITTED]	
Hematology	[NOT SUBMITTED]	
ECOG Performance Status	[NOT SUBMITTED]	
Electrocardiogram	[NOT SUBMITTED]	
Blood Collection for PK	[NOT SUBMITTED]	
Pregnancy Test	[NOT SUBMITTED]	
Tumor Evaluation	[NOT SUBMITTED]	
New Lesion	[NOT SUBMITTED]	
EQ-5D-5L Scale	[NOT SUBMITTED]	
EORTC QLQ_C30	[NOT SUBMITTED]	
EORTC QLQ-LC-13	[NOT SUBMITTED]	

SV=Subject Visits

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Project Name: Brigatinib-2002

Form: Date of Visit - OSFUP

Date of Visit

SVSTDTC

Has the patient received a Subsequent Anticancer Therapy (systemic, such as chemotherapy, immunotherapy, biological therapy, corticosteroids etc..) related to the cancer under study?

[NOT SUBMITTED]

Yes ☐

No ☐

Unknown ☐

If Yes, please complete the subsequent therapy form located in the Subsequent Anticancer Therapy folder in the main tree.

RP=Reproductive System Findings

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Project Name: Brigatinib-2002

Form: Reproductive System Findings

Date of Reproductive System Finding

RPDTC

Female Reproductive System Status

RPTTEST

Childbearing Potential ☐

Postmenopausal ☐

Surgically Sterile ☐

Other Female Reproductive
System State ☐

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Project Name: Brigatinib-2002

Form: Any Medical History?

Has the subject had any significant conditions or diseases relevant to the condition/disease under study that stopped at or prior to Informed Consent or are ongoing at Informed Consent? **[NOT SUBMITTED]** Yes ☐
No ☐

If answered "Yes", an additional form will be added to the task list on the left. Record all Medical History information on the new form.

MH=Medical History

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Medical History

MHCAT=GENERAL MEDICAL HISTORY

Please Record:

- (1.) All significant lifetime medical history and
- (2.) All medical and surgical events from the last 5 years.
- (3.) Do NOT record diagnosis or any treatments and procedures related to the disease under study.
- (4.) Record abnormalities reported during the Screening physical examination which meet the definitions of a medical history event.

Condition	MHTERM	
Start Date	MHSTDTC	
End Date relative to signing Informed Consent	MHENRTPT	BEFORE <input type="checkbox"/>
		ONGOING <input type="checkbox"/>

PF=Pharmacogenomics Findings

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Project Name: Brigatinib-2002

Form: ALK Molecular Status

Was ALK rearrangement detected? Yes ☐
No ☐
Unknown ☐
If Yes, please specify results. **PFTESTCD=FDETECT** **PFORRES**

Date Sample Taken **PFDTC**
Fusion Partner **PFORRES when above is "Yes"** EML4 ☐
TFG ☐
KIF5B ☐
NPM ☐
Fusion partner unknown ☐
Other fusion partner ☐

If Other fusion partner, please specify **PFORRES**

Assays

FISH: Abbott-Vysis ALK Break Apart Assay
IHC: Ventana ALK (D5F3) CDx Assay
Sequencing: Foundation Medicine-FoundationOne CDx
FISH (Non-Vysis) **PFMETHOD, when more than one selected,**
IHC (Non-Ventana) **PFMETHOD=MULTIPLE and individual responses**
RT-PCR **are PFMETHOD1, PFMETHOD2, etc. in SUPPPF**
Sequencing, Non Foundation Medicine
Other

If Other, please specify the details
In case the patient did not have documented ALK rearrangement by FDA approved test, is tumor tissue sample available for the central confirmation by Vysis-FISH assay? **SAMPLE in SUPPPF** Yes ☐
No ☐
Not required ☐

Was an ALK mutation detected other than an ALK Fusion? Yes ☐
No ☐
Unknown ☐
PFTESTCD=MDETECT **PFORRES**

ALK mutation **PFORRES when above is "Yes"** T1151Tins ☐
T1151Tins ☐
L1152R ☐
C1156Y ☐
I1171T ☐
I1171N ☐
I1171S ☐

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Project Name: Brigatinib-2002

Form: ALK Molecular Status

	F1174C	<input type="checkbox"/>
	F1174L	<input type="checkbox"/>
	V1180L	<input type="checkbox"/>
	L1196M	<input type="checkbox"/>
	L1198F	<input type="checkbox"/>
	G1202R	<input type="checkbox"/>
	G1202del	<input type="checkbox"/>
	D1203N	<input type="checkbox"/>
	S1206Y	<input type="checkbox"/>
	E1210K	<input type="checkbox"/>
	G1269A	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If Other ALK Mutation, please specify	PFORRES
---------------------------------------	----------------

MI=Microscopic Findings

FA=Findings About Events or Interventions

MH=Medical History

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Project Name: Brigatinib-2002

Form: Disease Characteristics

MICAT=DISEASE CHARACTERISTICS

FACAT=DISEASE CHARACTERISTICS

MHCAT=DISEASE CHARACTERISTICS

At Initial Diagnosis

FASCAT=INITIAL DIAGNOSIS

Date of Initial Diagnosis

MIDTC

FADTC

MHSTDTC

Disease Type

FAOBJ

MHTERM

Non-Small Cell Lung Cancer

Stage at Initial Diagnosis

**FAORRES when
FATESTCD=STAGE**

IA ☐

IB ☐

IIA ☐

IIB ☐

IIIA ☐

IIIB ☐

IV ☐

Unknown or not staged ☐

Stage Classified by

**FAMETHOD when
FATESTCD=STAGE**

Clinical ☐

Pathological ☐

Unknown/Not Staged ☐

If Pathological, please specify

FAMETHP in SUPPFA

Histology ☐

Cytology ☐

Unknown ☐

At Study Entry

FASCAT=AT STUDY ENTRY

Stage at Study Entry

**FAORRES when
FATESTCD=STAGE**

IIIA ☐

IIIB ☐

IV ☐

Date of Advanced Stage Diagnosis

FADTC

Check here if Date of Advanced Stage is Not Applicable

[NOT SUBMITTED]

Histopathological Classification of NSCLC

Adenocarcinoma ☐

MIORRES when MITESTCD=HISTTYP

Adenosquamous carcinoma ☐

Large cell ☐

Squamous ☐

Unknown ☐

Other ☐

If Other, please specify the details

MIORRES when MITESTCD=HISTTYP

Lung Involvement at Screening

FAOBJ=LUNG INVOLVEMENT

FALOC=LUNG

FALAT

**FAORRES when
FATESTCD=OCCUR. Set
to Y when Left Lung,
Right Lung or Both
Lungs. Set to N when
Lungs not involved.**

Left Lung ☐

Right Lung ☐

Both Lungs ☐

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		Lungs not involved	<input type="checkbox"/>
Was pleural effusion seen at Screening?	FAOBJ=PLEURAL EFFUSION	Yes	<input type="checkbox"/>
	FALOC=LUNG FAORRES when FATESTCD=OCCUR	No	<input type="checkbox"/>
If Yes, please specify	FALAT when FAOBJ=PLEURAL EFFUSION	Single side	<input type="checkbox"/>
		Bilateral	<input type="checkbox"/>
Sites of Cancer Involvement- Select All that Apply		Adrenal	<input type="checkbox"/>
	FAORRES when FATESTCD=SITEMETS	Biliary System	<input type="checkbox"/>
		Bladder	<input type="checkbox"/>
		Bone	<input type="checkbox"/>
		Brain	<input type="checkbox"/>
		Breast	<input type="checkbox"/>
		Colon	<input type="checkbox"/>
		Effusion/Ascites	<input type="checkbox"/>
		Esophagus	<input type="checkbox"/>
		Head and Neck	<input type="checkbox"/>
		Heart	<input type="checkbox"/>
		Kidney	<input type="checkbox"/>
		Liver	<input type="checkbox"/>
		Lung	<input type="checkbox"/>
		Lymph Nodes	<input type="checkbox"/>
		Ovary	<input type="checkbox"/>
		Pancreas	<input type="checkbox"/>
		Pericardium	<input type="checkbox"/>
		Peritoneum	<input type="checkbox"/>
		Pleura	<input type="checkbox"/>
		Prostate	<input type="checkbox"/>
		Rectum	<input type="checkbox"/>
		Skin	<input type="checkbox"/>
		Small Bowel	<input type="checkbox"/>
		Soft Tissue	<input type="checkbox"/>
		Spinal Cord	<input type="checkbox"/>
		Spleen	<input type="checkbox"/>
		Stomach	<input type="checkbox"/>
		Testis	<input type="checkbox"/>

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Form: Disease Characteristics

	Thyroid <input type="checkbox"/>
	Uterus <input type="checkbox"/>
	Other <input type="checkbox"/>
Sites of Cancer Involvement (Other, specify)	FAORRES when FATESTCD=SITEMETS

SU=Substance Use

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Project Name: Brigatinib-2002

Form: Substance Use

Type	SUTRT	ALCOHOL <input checked="" type="radio"/>
		TOBACCO <input type="radio"/>
		CIGARETTE <input type="radio"/>
		CIGAR <input type="radio"/>
		PIPE <input type="radio"/>
Status as of Informed Consent	SUNCF in SUPPSU	NEVER <input type="radio"/>
	If NEVER then SUOCCUR=N	CURRENT <input type="radio"/>
	If CURRENT or FORMER then SUOCCUR=Y	FORMER <input type="radio"/>
Amount	SUDOSE	
Amount Unit	SUDOSU	PACK <input type="radio"/>
		CIGAR <input type="radio"/>
		PIPE <input type="radio"/>
		UNIT <input checked="" type="radio"/>
Amount Frequency	SUDOSFRQ	QD <input type="radio"/>
		EVERY WEEK <input type="radio"/>
Date Stopped	SUENDTC	
Duration	SUDUR	
Duration Unit	SUDUR	YEARS <input checked="" type="radio"/>
Type		ALCOHOL <input type="radio"/>
		TOBACCO <input checked="" type="radio"/>
		CIGARETTE <input type="radio"/>
		CIGAR <input type="radio"/>
		PIPE <input type="radio"/>
Status as of Informed Consent		NEVER <input type="radio"/>
		CURRENT <input type="radio"/>
		FORMER <input type="radio"/>
Amount		
Amount Unit		PACK <input checked="" type="radio"/>
		CIGAR <input type="radio"/>
		PIPE <input type="radio"/>
		UNIT <input type="radio"/>
Amount Frequency		QD <input type="radio"/>

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Form: Substance Use

	EVERY WEEK	<input type="checkbox"/>
Date Stopped		
Duration		
Duration Unit	YEARS	<input checked="" type="checkbox"/>

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Form: Cancer-Related Interventions

Has the subject received prior cancer therapy?	[NOT SUBMITTED]	Yes <input type="checkbox"/>
		No <input type="checkbox"/>
Has the subject received prior radiation therapy related to cancer?	[NOT SUBMITTED]	Yes <input type="checkbox"/>
		No <input type="checkbox"/>
Has the subject had any prior surgical procedures in the past 5 years?	[NOT SUBMITTED]	Yes <input type="checkbox"/>
		No <input type="checkbox"/>

CM=Concomitant/Prior Medications

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Project Name: Brigatinib-2002

Form: Prior Therapy

CMCAT=PRIOR SYSTEMIC THERAPY

Drug Name

CMTRT

5-FU	<input type="checkbox"/>
Alectinib	<input type="checkbox"/>
Axitinib	<input type="checkbox"/>
Bevacizumab	<input type="checkbox"/>
Bleomycin	<input type="checkbox"/>
Brigatinib	<input type="checkbox"/>
Carboplatin	<input type="checkbox"/>
Ceritinib	<input type="checkbox"/>
Cetuximab	<input type="checkbox"/>
CISplatin	<input type="checkbox"/>
Crizotinib	<input type="checkbox"/>
Docetaxel	<input type="checkbox"/>
Doxorubicin	<input type="checkbox"/>
Erlotinib	<input type="checkbox"/>
Everolimus	<input type="checkbox"/>
Etoposide	<input type="checkbox"/>
Experimental Therapy	<input type="checkbox"/>
Hormonal therapy (including aromatase inhibitors)	<input type="checkbox"/>
Interferon alpha	<input type="checkbox"/>
Liposomal Doxorubicin	<input type="checkbox"/>
Methotrexate	<input type="checkbox"/>
Mitotane	<input type="checkbox"/>
Nivolumab	<input type="checkbox"/>
Paclitaxel	<input type="checkbox"/>
Pazopanib	<input type="checkbox"/>
Pemetrexed	<input type="checkbox"/>
Perifosine	<input type="checkbox"/>
Standard therapy other	<input type="checkbox"/>
Sorafenib	<input type="checkbox"/>
Sunitinib	<input type="checkbox"/>
Trastuzumab	<input type="checkbox"/>
Torisel	<input type="checkbox"/>
Temsirolimus	<input type="checkbox"/>
Vincristine	<input type="checkbox"/>

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Form: Prior Therapy

	Zoledronic acid (Aclasta Recast <input type="checkbox"/> Zometa) <input type="checkbox"/> Other <input type="checkbox"/>
Drug, Other specify _____	CMTRT
Line of Therapy (Metastatic or Locally advanced)	THLINE in SUPPCM First <input type="checkbox"/> Second <input type="checkbox"/> Third <input type="checkbox"/> Fourth <input type="checkbox"/> Fifth <input type="checkbox"/>
Type of Therapy	THTYPE in SUPPCM Maintenance <input type="checkbox"/> Neo-adjuvant <input type="checkbox"/> Adjuvant <input type="checkbox"/> Metastatic (and Locally Advanced) <input type="checkbox"/>
Start Date _____	CMSTDTC
End Date _____	CMENDTC
Prior Med/Therapy Best Response	Complete Response (CR) <input type="checkbox"/> CMTRTBOR in SUPPCM Partial Response (PR) <input type="checkbox"/> Stable Disease (SD) <input type="checkbox"/> Progressive Disease (PD) <input type="checkbox"/> Unable to Assess (UA) <input type="checkbox"/> Unknown <input type="checkbox"/>
Date of Disease Progression _____	CMPDDTC in SUPPCM
Reason for Discontinuation	Completed Prescribed Therapy <input type="checkbox"/> RSDISC in SUPPCM Progressive Disease <input type="checkbox"/> No Response <input type="checkbox"/> Adverse Event <input type="checkbox"/> Patient Choice <input type="checkbox"/> Other <input type="checkbox"/>
Other Reason _____	RSDISC in SUPPCM

PR=Procedures

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Prior Radiation

PRCAT=PRIOR RADIOTHERAPY**PRTRT=RADIATION**

Anatomical Site	PRLOC	
Start Date	PRSTDTC	
End Date	PRENDTC	
Total Dose Unknown	[NOT SUBMITTED]	Unknown <input type="checkbox"/>
Total Dose Value	PRDOSE	
Total Dose Value Unit	PRDOSU	centigrays (cGy) <input type="checkbox"/> grays (Gy) <input type="checkbox"/> rads (RADS) <input type="checkbox"/>
Best Response	TRTBOR in SUPPPR	Complete Response (CR) <input type="checkbox"/> Partial Response (PR) <input type="checkbox"/> Stable Disease (SD) <input type="checkbox"/> Progressive Disease (PD) <input type="checkbox"/> Unable to Assess (UA) <input type="checkbox"/> Unknown <input type="checkbox"/> Symptom Relief <input type="checkbox"/>

PR=Procedures

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Prior Surgery

PRCAT=PRIOR SURGERY/PROCEDURE

Instructions: Record major surgeries that occurred in the past 5 years.

Type of Surgical Procedure

PTRT

Date of Surgical Procedure

PRSTDTC

LB=Laboratory Test Results

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Pregnancy Test

LBCAT=CHEMISTRY

LBSCAT=PREGNANCY

Specimen Type

LBSPEC

PLASMA

☐

Check here if sample collection was not done

LBSTAT

NOT DONE

☐

Reason Test Not Done

LBREASND

Sample Collection Date

LBDTC

Result

LBORRES when LBTESTCD=HCG

POSITIVE

☐

NEGATIVE

☐

LB=Laboratory Test Results

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Pregnancy Test - Unscheduled

LBCAT=CHEMISTRY

LBSCAT=PREGNANCY

Specimen Type

LBSPEC

PLASMA

☐

Sample Collection Date

LBDTC

Result

LBORRES when LBTESTCD=HCG

POSITIVE

☐

NEGATIVE

☐

VS=Vital Signs

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Vital Signs - Screening

Date Performed	VSDTC	
Vital Signs Test	VSTEST	Pulse Pressure <input type="checkbox"/>
		Body Mass Index <input type="checkbox"/>
		Body Surface Area <input type="checkbox"/>
		Temperature <input type="checkbox"/>
		Weight <input type="checkbox"/>
		Systolic Blood Pressure <input type="checkbox"/>
		Diastolic Blood Pressure <input type="checkbox"/>
		Height <input checked="" type="checkbox"/>
		Pulse Rate <input type="checkbox"/>
		Heart Rate <input type="checkbox"/>
		Respiratory Rate <input type="checkbox"/>
		Oxygen Saturation <input type="checkbox"/>

Result	VSORRES	
Units	VSORRESU	

Vital Signs Test	Pulse Pressure <input type="checkbox"/>
	Body Mass Index <input type="checkbox"/>
	Body Surface Area <input type="checkbox"/>
	Temperature <input type="checkbox"/>
	Weight <input checked="" type="checkbox"/>
	Systolic Blood Pressure <input type="checkbox"/>
	Diastolic Blood Pressure <input type="checkbox"/>
	Height <input type="checkbox"/>
	Pulse Rate <input type="checkbox"/>
	Heart Rate <input type="checkbox"/>
	Respiratory Rate <input type="checkbox"/>
	Oxygen Saturation <input type="checkbox"/>

Result	
Units	

Vital Signs Test	Pulse Pressure <input type="checkbox"/>
	Body Mass Index <input type="checkbox"/>
	Body Surface Area <input type="checkbox"/>
	Temperature <input checked="" type="checkbox"/>

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Vital Signs - Screening

	Weight	<input type="text"/>
	Systolic Blood Pressure	<input type="text"/>
	Diastolic Blood Pressure	<input type="text"/>
	Height	<input type="text"/>
	Pulse Rate	<input type="text"/>
	Heart Rate	<input type="text"/>
	Respiratory Rate	<input type="text"/>
	Oxygen Saturation	<input type="text"/>

Result

Units

Vital Signs Test	Pulse Pressure	<input type="text"/>
	Body Mass Index	<input type="text"/>
	Body Surface Area	<input type="text"/>
	Temperature	<input type="text"/>
	Weight	<input type="text"/>
	Systolic Blood Pressure	<input checked="" type="text"/>
	Diastolic Blood Pressure	<input type="text"/>
	Height	<input type="text"/>
	Pulse Rate	<input type="text"/>
	Heart Rate	<input type="text"/>
	Respiratory Rate	<input type="text"/>
	Oxygen Saturation	<input type="text"/>

Result

Units

Vital Signs Test	Pulse Pressure	<input type="text"/>
	Body Mass Index	<input type="text"/>
	Body Surface Area	<input type="text"/>
	Temperature	<input type="text"/>
	Weight	<input type="text"/>
	Systolic Blood Pressure	<input type="text"/>
	Diastolic Blood Pressure	<input checked="" type="text"/>
	Height	<input type="text"/>
	Pulse Rate	<input type="text"/>
	Heart Rate	<input type="text"/>

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Vital Signs - Screening

	Respiratory Rate	<input type="text"/>
	Oxygen Saturation	<input type="text"/>

Result	
--------	--

Units	
-------	--

Vital Signs Test	Pulse Pressure	<input type="text"/>
	Body Mass Index	<input type="text"/>
	Body Surface Area	<input type="text"/>
	Temperature	<input type="text"/>
	Weight	<input type="text"/>
	Systolic Blood Pressure	<input type="text"/>
	Diastolic Blood Pressure	<input type="text"/>
	Height	<input type="text"/>
	Pulse Rate	<input checked="" type="text"/>
	Heart Rate	<input type="text"/>
	Respiratory Rate	<input type="text"/>
	Oxygen Saturation	<input type="text"/>

Result	
--------	--

Units	
-------	--

Vital Signs Test	Pulse Pressure	<input type="text"/>
	Body Mass Index	<input type="text"/>
	Body Surface Area	<input type="text"/>
	Temperature	<input type="text"/>
	Weight	<input type="text"/>
	Systolic Blood Pressure	<input type="text"/>
	Diastolic Blood Pressure	<input type="text"/>
	Height	<input type="text"/>
	Pulse Rate	<input type="text"/>
	Heart Rate	<input type="text"/>
	Respiratory Rate	<input checked="" type="text"/>
	Oxygen Saturation	<input type="text"/>

Result	
--------	--

Units	
-------	--

VS=Vital Signs

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Vital Signs

Date Performed	VSDTC	
Vital Signs Test	VSTEST	Pulse Pressure <input type="checkbox"/>
		Body Mass Index <input type="checkbox"/>
		Body Surface Area <input type="checkbox"/>
		Temperature <input type="checkbox"/>
		Weight <input checked="" type="checkbox"/>
		Systolic Blood Pressure <input type="checkbox"/>
		Diastolic Blood Pressure <input type="checkbox"/>
		Height <input type="checkbox"/>
		Pulse Rate <input type="checkbox"/>
		Heart Rate <input type="checkbox"/>
		Respiratory Rate <input type="checkbox"/>
		Oxygen Saturation <input type="checkbox"/>

Result	VSORRES	
Units	VSORRESU	

Vital Signs Test	Pulse Pressure <input type="checkbox"/>
	Body Mass Index <input type="checkbox"/>
	Body Surface Area <input type="checkbox"/>
	Temperature <input checked="" type="checkbox"/>
	Weight <input type="checkbox"/>
	Systolic Blood Pressure <input type="checkbox"/>
	Diastolic Blood Pressure <input type="checkbox"/>
	Height <input type="checkbox"/>
	Pulse Rate <input type="checkbox"/>
	Heart Rate <input type="checkbox"/>
	Respiratory Rate <input type="checkbox"/>
	Oxygen Saturation <input type="checkbox"/>

Result	
Units	

Vital Signs Test	Pulse Pressure <input type="checkbox"/>
	Body Mass Index <input type="checkbox"/>
	Body Surface Area <input type="checkbox"/>
	Temperature <input type="checkbox"/>

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Vital Signs

	Weight	<input type="text"/>
	Systolic Blood Pressure	<input checked="" type="text"/>
	Diastolic Blood Pressure	<input type="text"/>
	Height	<input type="text"/>
	Pulse Rate	<input type="text"/>
	Heart Rate	<input type="text"/>
	Respiratory Rate	<input type="text"/>
	Oxygen Saturation	<input type="text"/>

Result

Units

Vital Signs Test	Pulse Pressure	<input type="text"/>
	Body Mass Index	<input type="text"/>
	Body Surface Area	<input type="text"/>
	Temperature	<input type="text"/>
	Weight	<input type="text"/>
	Systolic Blood Pressure	<input type="text"/>
	Diastolic Blood Pressure	<input checked="" type="text"/>
	Height	<input type="text"/>
	Pulse Rate	<input type="text"/>
	Heart Rate	<input type="text"/>
	Respiratory Rate	<input type="text"/>
	Oxygen Saturation	<input type="text"/>

Result

Units

Vital Signs Test	Pulse Pressure	<input type="text"/>
	Body Mass Index	<input type="text"/>
	Body Surface Area	<input type="text"/>
	Temperature	<input type="text"/>
	Weight	<input type="text"/>
	Systolic Blood Pressure	<input type="text"/>
	Diastolic Blood Pressure	<input type="text"/>
	Height	<input type="text"/>
	Pulse Rate	<input checked="" type="text"/>
	Heart Rate	<input type="text"/>

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Vital Signs

	Respiratory Rate	<input type="text"/>
	Oxygen Saturation	<input type="text"/>
Result		
Units		
Vital Signs Test	Pulse Pressure	<input type="text"/>
	Body Mass Index	<input type="text"/>
	Body Surface Area	<input type="text"/>
	Temperature	<input type="text"/>
	Weight	<input type="text"/>
	Systolic Blood Pressure	<input type="text"/>
	Diastolic Blood Pressure	<input type="text"/>
	Height	<input type="text"/>
	Pulse Rate	<input type="text"/>
	Heart Rate	<input type="text"/>
	Respiratory Rate	<input checked="" type="text"/>
	Oxygen Saturation	<input type="text"/>
Result		
Units		

QS=Questionnaires

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: ECOG Performance Status

QSCAT=ECOG

QSTESTCD=ECOG101

Was ECOG Performance Status Obtained?

Yes ☐

If No then QSSTAT=NOT DONE

No ☐

Assessment Date

QSDTC

Result

QSORRES

0=Fully active, able to carry on
all predisease performance
without restriction. ☐

1=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=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=Capable of only limited
self-care, confined to bed or chair
more than 50% of waking hours. ☐

4=Completely disabled. Cannot
carry on any self-care. Totally
confined to bed or chair. ☐

EG=ECG Test Results

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Electrocardiogram

Date of ECG	EGDTC	
Category for ECG	EGCAT	STANDARD <input checked="" type="radio"/> HOLTER <input type="radio"/>
Time of ECG (24 hr clock)	EGDTC	
ECG Ventricular Rate	EGORRES when EGTESTCD=EGVR	
ECG Ventricular Rate (Unit)	EGORRESU when EGTESTCD=EGVR	msec <input type="text"/> BEATS/MIN <input type="text"/>
PR Interval	EGORRES when EGTESTCD=PR	
PR Interval (Unit)	EGORRESU when EGTESTCD=PR	msec <input type="text"/> BEATS/MIN <input type="text"/>
QT Interval	EGORRES when EGTESTCD=QT	
QT Interval (Unit)	EGORRESU when EGTESTCD=QT	msec <input type="text"/> BEATS/MIN <input type="text"/>
QTcF Interval	EGORRES when EGTESTCD=QTcF	
QTcF Interval (Unit)	EGORRESU when EGTESTCD=QTcF	msec <input type="text"/> BEATS/MIN <input type="text"/>
Interpretation	EGSTRESC when EGTESTCD=INTP EGCLSIG in SUPPEG	WITHIN NORMAL LIMITS <input type="radio"/> ABNORMAL, NOT CLINICALLY SIGNIFICANT <input type="radio"/> ABNORMAL, CLINICALLY SIGNIFICANT <input type="radio"/> NOT EVALUABLE <input type="radio"/>
Interpretation, Specify	EGORRES when EGTESTCD=INTP	

BE=Biospecimen Events

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Fresh Tumor Tissue Biopsy Sample

BETERM=FRESH SAMPLE**BECAT=BIOMARKER**

Was Fresh Tumor Tissue Biopsy Sample Collected? **BEOCCUR** Yes ☐
No ☐

Date Sample Taken **BEDTC**

Specimen Type **BESPEC** PLASMA ☐
TUMOR TISSUE ☒
EPITHELIAL CELL ☐

Testing Method **BEMETHOD** Fine Needle Aspirates ☐
Lymph Node Biopsies ☐
Incisional Biopsies ☐
Bone Marrow Biopsies ☐
Bone Marrow Aspirates ☐
Other ☐

Site of Sample **BELOC** Adrenal Glands ☐
Bladder ☐
Bone ☐
Brain - Leptomenigeal ☐
Brain - Parenchymal ☐
Colon ☐
Breast ☐
Esophagus ☐
Kidney ☐
Liver ☐
Lymph Nodes - distant ☐
Lymph Nodes - regional ☐
Muscle/soft tissue ☐
Ovaries ☐
Pancreas ☐
Pelvis ☐
Pericardium - Solid Lesion(s) ☐
Pericardium - Ascites ☐
Peritoneum - Solid Lesion(s) ☐
Peritoneum - Ascites ☐
Pleura - Effusion ☐
Prostate ☐

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Fresh Tumor Tissue Biopsy Sample

		Rectum	<input type="checkbox"/>
		Skin	<input type="checkbox"/>
		Small Intestine	<input type="checkbox"/>
		Spinal Cord - Leptomeningeal	<input type="checkbox"/>
		Spinal Cord - Parenchymal	<input type="checkbox"/>
		Stomach	<input type="checkbox"/>
		Uterus	<input type="checkbox"/>
		Unknown	<input type="checkbox"/>
		Other	<input type="checkbox"/>
Other, Site of Sample	BELOC		
Specimen Collection	BESPCND	Fresh	<input checked="" type="radio"/>
		Banked	<input type="checkbox"/>
SMP Number	BESPID		2

BE=Biospecimen Events

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Archival (Banked) Tumor Tissue Sample

BETERM=ARCHIVAL SAMPLE**BECAT=BIOMARKER**

Was Archival (Banked) Tumor Tissue Sample Collected?

BEOCCURYes ☐No ☐

Date Sample Taken

BEDTC

Specimen Type

BESPECPLASMA ☐TUMOR TISSUE ☒EPITHELIAL CELL ☐

Testing Method

BEMETHODFine Needle Aspirates ☐Lymph Node Biopsies ☐Incisional Biopsies ☐Bone Marrow Biopsies ☐Bone Marrow Aspirates ☐Other ☐

Site of Sample

BELOCAdrenal Glands ☐Bladder ☐Bone ☐Brain - Leptomenigeal ☐Brain - Parenchymal ☐Colon ☐Breast ☐Esophagus ☐Kidney ☐Liver ☐Lymph Nodes - distant ☐Lymph Nodes - regional ☐Muscle/soft tissue ☐Ovaries ☐Pancreas ☐Pelvis ☐Pericardium - Solid Lesion(s) ☐Pericardium - Ascites ☐Peritoneum - Solid Lesion(s) ☐Peritoneum - Ascites ☐Pleura - Effusion ☐Prostate ☐

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Archival (Banked) Tumor Tissue Sample

		Rectum	<input type="checkbox"/>
		Skin	<input type="checkbox"/>
		Small Intestine	<input type="checkbox"/>
		Spinal Cord - Leptomeningeal	<input type="checkbox"/>
		Spinal Cord - Parenchymal	<input type="checkbox"/>
		Stomach	<input type="checkbox"/>
		Uterus	<input type="checkbox"/>
		Unknown	<input type="checkbox"/>
		Other	<input type="checkbox"/>
Other, Site of Sample	BELOC		
Specimen Collection	BESPCND	Fresh	<input type="checkbox"/>
		Banked	<input checked="" type="checkbox"/>
SMP Number	BESPID		1

BE=Biospecimen Events

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

BETERM=CIRCULATING TUMOR DNA SAMPLE

Form: Plasma Sample for Circulating Tumor DNA

BECAT=BIOMARKER

Was Plasma Sample for Circulating Tumor DNA Collected?

BEOCCUR

Yes ☐

No ☐

Date Sample Taken

BEDTC

Specimen Type

BESPEC

PLASMA ☒

TUMOR TISSUE ☐

EPITHELIAL CELL ☐

SMP Number

BESPID

4

BE=Biospecimen Events

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Buccal Epithelial Cells Sample for DNA

BETERM=DNA SAMPLE

BECAT=BIOMARKER

Was Buccal Epithelial Cells Sample for DNA Collected

BEOCCUR

Yes ☐

No ☐

Date Sample Taken

BEDTC

Specimen Type

BESPEC

PLASMA ☐

TUMOR TISSUE ☐

EPITHELIAL CELL ☒

Testing Method

BEMETHOD

Buccal Swab ☒

Site of Sample

BELOC

Oral Mucosa ☒

Specimen Condition

BESPCND

Fresh ☒

Banked ☐

SMP Number

BESPID

5

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Any Concomitant/Prior Medications?

Did the subject take any Concomitant Medications during the study?

Yes ☐

[NOT SUBMITTED]

No ☐

If answered "Yes", an additional form will be added to the task list on the left. Record all Concomitant Medication information on the new form.

CM=Concomitant/Prior Medications

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Concomitant/Prior Medications

Reported Name of Drug, Medication, or Therapy	CMTRT	
Category for Medication	CMCAT	ALTERNATE THERAPY <input type="checkbox"/>
		ANALGESIC <input type="checkbox"/>
		GENERAL CONMED <input checked="" type="checkbox"/>
		CONDITIONING REGIMEN <input type="checkbox"/>
		EXCLUDED <input type="checkbox"/>
		MOBILIZATION REGIMEN <input type="checkbox"/>
Dose per Administration	CMDOSE	CMDOSTXT
Dose Units	CMDOSU	% <input type="checkbox"/>
		APPLICATION <input type="checkbox"/>
		CAPSULE <input type="checkbox"/>
		g <input type="checkbox"/>
		gtt <input type="checkbox"/>
		IU <input type="checkbox"/>
		IU/mL <input type="checkbox"/>
		mEq <input type="checkbox"/>
		mg <input type="checkbox"/>
		mL <input type="checkbox"/>
		PUFF <input type="checkbox"/>
		TABLET <input type="checkbox"/>
		UNIT <input type="checkbox"/>
		ug <input type="checkbox"/>
		SPRAY <input type="checkbox"/>
		Tbsp <input type="checkbox"/>
		tsp <input type="checkbox"/>
		mg/m2 <input type="checkbox"/>
		mg/kg <input type="checkbox"/>
		mg/L <input type="checkbox"/>
Dosing Frequency per Interval	CMDOSFRQ	QD <input type="checkbox"/>
		ONCE <input type="checkbox"/>
		BID <input type="checkbox"/>
		PRN <input type="checkbox"/>
		Q12H <input type="checkbox"/>
		Q24H <input type="checkbox"/>

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Concomitant/Prior Medications

		Q8H	<input type="checkbox"/>
		QID	<input type="checkbox"/>
		QM	<input type="checkbox"/>
		QOD	<input type="checkbox"/>
		TID	<input type="checkbox"/>
		UNKNOWN	<input type="checkbox"/>
		2 TIMES PER WEEK	<input type="checkbox"/>
		3 TIMES PER MONTH	<input type="checkbox"/>
		3 TIMES PER WEEK	<input type="checkbox"/>
		4 TIMES PER WEEK	<input type="checkbox"/>
		CONTINUOUS	<input type="checkbox"/>
		EVERY 2 WEEKS	<input type="checkbox"/>
		EVERY 3 WEEKS	<input type="checkbox"/>
		EVERY 4 WEEKS	<input type="checkbox"/>
		EVERY WEEK	<input type="checkbox"/>
		INTERMITTENT	<input type="checkbox"/>
		Q4H	<input type="checkbox"/>
		Q6H	<input type="checkbox"/>
		QH	<input type="checkbox"/>
		BIM	<input type="checkbox"/>
Route of Administration	CMROUTE	ORAL	<input type="checkbox"/>
		INTRAVENOUS	<input type="checkbox"/>
		SUBCUTANEOUS	<input type="checkbox"/>
		TOPICAL	<input type="checkbox"/>
		TRANSDERMAL	<input type="checkbox"/>
		RESPIRATORY (INHALATION)	<input type="checkbox"/>
		INTRAMUSCULAR	<input type="checkbox"/>
		NASAL	<input type="checkbox"/>
		RECTAL	<input type="checkbox"/>
		INTRAVENOUS BOLUS	<input type="checkbox"/>
		INTRAVENOUS DRIP	<input type="checkbox"/>
		AURICULAR (OTIC)	<input type="checkbox"/>
		BUCCAL	<input type="checkbox"/>

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Concomitant/Prior Medications

	CONJUNCTIVAL	<input type="checkbox"/>
	CUTANEOUS	<input type="checkbox"/>
	ENTERAL	<input type="checkbox"/>
	EPIDURAL	<input type="checkbox"/>
	INTRA-ARTICULAR	<input type="checkbox"/>
	INTRADERMAL	<input type="checkbox"/>
	INTRAOCULAR	<input type="checkbox"/>
	INTRAPERITONEAL	<input type="checkbox"/>
	INTRASINAL	<input type="checkbox"/>
	NASOGASTRIC	<input type="checkbox"/>
	OPHTHALMIC	<input type="checkbox"/>
	OROMUCOSAL	<input type="checkbox"/>
	OROPHARYNGEAL	<input type="checkbox"/>
	PARENTERAL	<input type="checkbox"/>
	PERCUTANEOUS	<input type="checkbox"/>
	SUBLINGUAL	<input type="checkbox"/>
	VAGINAL	<input type="checkbox"/>
Start Date of Medication	CMSTDTC	
If unknown, select if Start Date was BEFORE or AFTER signing Informed Consent.	CMSTRTP	BEFORE <input type="checkbox"/> AFTER <input type="checkbox"/>
End Date of Medication	CMENDTC	
Select if End Date is ONGOING or UNKNOWN 30 days after the last dose of study drug(s).	CMENRTP	ONGOING <input type="checkbox"/> UNKNOWN <input type="checkbox"/>
Indication	CMINDC	
Related Adverse Event (Primary):	Linked to related AE record via RELREC	
Related Adverse Event (#2, if applica	Linked to related AE record via RELREC	
Related Adverse Event (#3, if applica	Linked to related AE record via RELREC	

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Any Adverse Events?

Did the subject experience any Adverse Events during the study?

Yes ☐

[NOT SUBMITTED]

No ☐

If answered "Yes", an additional form will be added to the task list on the left. Record all Adverse Event information on the new form.

AE=Adverse Events

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Adverse Events

Reported Term for the Adverse Event	AETERM	
Start Date of Adverse Event	AESTDTC	
End Date of Adverse Event	AEENDTC	
Pattern of Adverse Event	AEPATT	ONCE <input type="checkbox"/> CONTINUOUS <input type="checkbox"/> INTERMITTENT <input type="checkbox"/>
Standard Toxicity Grade	AETOXGR	Grade 1 <input type="checkbox"/> Grade 2 <input type="checkbox"/> Grade 3 <input type="checkbox"/> Grade 4 <input type="checkbox"/> Grade 5 <input type="checkbox"/>
Causality	AEREL	RELATED <input type="checkbox"/> NOT RELATED <input type="checkbox"/>
Action Taken with Study Treatment	AEACN	DOSE NOT CHANGED <input type="checkbox"/> DOSE REDUCED <input type="checkbox"/> DRUG INTERRUPTED <input type="checkbox"/> DRUG WITHDRAWN <input type="checkbox"/> NOT APPLICABLE <input type="checkbox"/> UNKNOWN <input type="checkbox"/>
Outcome of Adverse Event	AEOUT	RECOVERED/RESOLVED <input type="checkbox"/> RECOVERING/RESOLVING <input type="checkbox"/> NOT RECOVERED/NOT RESOLVED <input type="checkbox"/> RECOVERED/RESOLVED WITH SEQUELAE <input type="checkbox"/> FATAL <input type="checkbox"/> UNKNOWN <input type="checkbox"/>
Serious Event	AESER	Yes <input type="checkbox"/> No <input type="checkbox"/>
Death Related to Disease	AEDTHREL in SUPPAE	Yes <input type="checkbox"/>
Category for Adverse Event	AECAT	ADVERSE <input checked="" type="radio"/>

DD=Death Details**AE=Adverse Events**

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Serious Adverse Events

Select all seriousness criteria that apply:

Congenital Anomaly or Birth Defect	AESCONG	Yes <input type="checkbox"/>
Persistent or Significant Disability/Incapacity	AESDISAB	Yes <input type="checkbox"/>
Specify Disability/Incapacity	[NOT SUBMITTED]	
Results in Death	AESDTH	Yes <input type="checkbox"/>
General Cause of Death #1	DDORRES when DDTESTCD=GENCDTH	
General Cause of Death, #2 if applicable	DDORRES when DDTESTCD=GENCDTH	
General Cause of Death, #3 if applicable	DDORRES when DDTESTCD=GENCDTH	
Autopsy Performed	DDORRES when DDTESTCD=DDAUTOP	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Death Certificate Obtained	DDORRES when DDTESTCD=DDDTHCRT	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Requires or Prolongs Hospitalization	AESHOSP	Yes <input type="checkbox"/>
Date of Hospitalization	AEHOSPD in SUPPAE	
Date of Discharge	AEDISCDT in SUPPAE	
Is Life Threatening	AESLIFE	Yes <input type="checkbox"/>
Other Medically Important Serious Event	AESMIE	Yes <input type="checkbox"/>
Narrative	[NOT SUBMITTED]	
Log Line Number (derived from AE form)	AESPID	
Event (derived from AE form)	AETERM	
Start Date of Adverse Event (derived from AE form)	AESTDTC	
Causality (derived from AE form)	AEREL	RELATED <input type="checkbox"/> NOT RELATED <input type="checkbox"/>

LB=Laboratory Test Results

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

LBCAT=CHEMISTRY

Form: Chemistry

Lab Name:

LBNAM

Sample Collection Date

LBDTC

Lab - Age

[NOT SUBMITTED]

eGFR Result

LBORRES when LBTESTCD=EGFR

eGFR Unit

LBORRESU when LBTESTCD=EGFR

mL/min/1.73m²

Glucose

LBORRES when LBTESTCD=GLUC

Creatinine

LBORRES when LBTESTCD=CREAT

Sodium

LBORRES when LBTESTCD=SODIUM

Potassium

LBORRES when LBTESTCD=K

Chloride

LBORRES when LBTESTCD=CL

Calcium

LBORRES when LBTESTCD=CA

Magnesium

LBORRES when LBTESTCD=MG

Phosphate

LBORRES when LBTESTCD=PHOS

Albumin

LBORRES when LBTESTCD=ALB

Total Bilirubin

LBORRES when LBTESTCD=BILI

Aspartate Aminotransferase

LBORRES when LBTESTCD=AST

Alanine Aminotransferase

LBORRES when LBTESTCD=ALT

Alkaline Phosphatase

LBORRES when LBTESTCD=ALP

Lactate Dehydrogenase

LBORRES when LBTESTCD=LDH

Lipase

LBORRES when LBTESTCD=LIPASET

Amylase

LBORRES when LBTESTCD=AMYLASE

Creatine Kinase

LBORRES when LBTESTCD=CK

LB=Laboratory Test Results

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

LBCAT=CHEMISTRY

Form: Testosterone

Lab Name:

LBNAM

Sample Collection Date

LBDTC

Lab - Age

[NOT SUBMITTED]

Testosterone

LBORRES when LBTESTCD=TESTOS

LB=Laboratory Test Results

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

LBCAT=CHEMISTRY

Form: Insulin

Lab Name:

LBNAM

Sample Collection Date

LBDTC

Lab - Age

[NOT SUBMITTED]

Insulin

LBORRES when LBTESTCD=INSULIN

LB=Laboratory Test Results

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

LBCAT=CHEMISTRY

Form: Chemistry - Unscheduled

Lab Name:

LBNAM

Sample Collection Date

LBDTC

Lab - Age

[NOT SUBMITTED]

eGFR Result

LBORRES when LBTESTCD=EGFR

eGFR Unit

LBORRESU when LBTESTCD=EGFR

mL/min/1.73m²

Glucose

LBORRES when LBTESTCD=GLUC

Creatinine

LBORRES when LBTESTCD=CREAT

Sodium

LBORRES when LBTESTCD=SODIUM

Potassium

LBORRES when LBTESTCD=K

Chloride

LBORRES when LBTESTCD=CL

Calcium

LBORRES when LBTESTCD=CA

Magnesium

LBORRES when LBTESTCD=MG

Phosphate

LBORRES when LBTESTCD=PHOS

Albumin

LBORRES when LBTESTCD=ALB

Total Bilirubin

LBORRES when LBTESTCD=BILI

Aspartate Aminotransferase

LBORRES when LBTESTCD=AST

Alanine Aminotransferase

LBORRES when LBTESTCD=ALT

Alkaline Phosphatase

LBORRES when LBTESTCD=ALP

Lactate Dehydrogenase

LBORRES when LBTESTCD=LDH

Lipase

LBORRES when LBTESTCD=LIPASE

Amylase

LBORRES when LBTESTCD=AMYLASE

Creatine Kinase

LBORRES when LBTESTCD=CK

LB=Laboratory Test Results

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

LBCAT=HEMATOLOGY

Form: Hematology

Lab Name:

LBNAM

Sample Collection Date

LBDTC

Lab - Age

[NOT SUBMITTED]

Indicate the unit type for Differential results to be entered

[NOT SUBMITTED]

ABSOLUTE ☐

PERCENT ☐

BOTH ☐

NOT APPLICABLE ☐

Leukocytes	LBORRES when LBTESTCD=WBC
Hemoglobin	LBORRES when LBTESTCD=HGB
Hematocrit	LBORRES when LBTESTCD=HCT
Platelets	LBORRES when LBTESTCD=PLAT
Neutrophils	LBORRES when LBTESTCD=NEUT
Lymphocytes	LBORRES when LBTESTCD=LYM
Monocytes	LBORRES when LBTESTCD=MONO
Eosinophils	LBORRES when LBTESTCD=EOS
Basophils	LBORRES when LBTESTCD=BASO
Lymphocytes/Leukocytes (%)	LBORRES/LBORRESU when LBTESTCD=LYMLE
Monocytes/Leukocytes (%)	LBORRES/LBORRESU when LBTESTCD=MONOLE
Eosinophils/Leukocytes (%)	LBORRES/LBORRESU when LBTESTCD=EOSLE
Basophils/Leukocytes (%)	LBORRES/LBORRESU when LBTESTCD=BASOLE
Neutrophils/Leukocytes (%)	LBORRES/LBORRESU when LBTESTCD=NEUTLE

LB=Laboratory Test Results

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

LBCAT=HEMATOLOGY

Form: Hematology - Unscheduled

Lab Name:

LBNAM

Sample Collection Date

LBDTC

Lab - Age

[NOT SUBMITTED]

Indicate the unit type for Differential results to be entered

[NOT SUBMITTED]

ABSOLUTE ☐

PERCENT ☐

BOTH ☐

NOT APPLICABLE ☐

Leukocytes	LBORRES when LBTESTCD=WBC
Hemoglobin	LBORRES when LBTESTCD=HGB
Hematocrit	LBORRES when LBTESTCD=HCT
Platelets	LBORRES when LBTESTCD=PLAT
Neutrophils	LBORRES when LBTESTCD=NEUT
Lymphocytes	LBORRES when LBTESTCD=LYM
Monocytes	LBORRES when LBTESTCD=MONO
Eosinophils	LBORRES when LBTESTCD=EOS
Basophils	LBORRES when LBTESTCD=BASO
Lymphocytes/Leukocytes (%)	LBORRES/LBORRESU when LBTESTCD=LYMLE
Monocytes/Leukocytes (%)	LBORRES/LBORRESU when LBTESTCD=MONOLE
Eosinophils/Leukocytes (%)	LBORRES/LBORRESU when LBTESTCD=EOSLE
Basophils/Leukocytes (%)	LBORRES/LBORRESU when LBTESTCD=BASOLE
Neutrophils/Leukocytes (%)	LBORRES/LBORRESU when LBTESTCD=NEUTLE

EC=Exposure as Collected

PC=Pharmacokinetic Concentrations

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Plasma Collection for PK

Date of Specimen Collection	PCDTC	
Specimen Material Type	PCSPEC	PLASMA <input checked="" type="radio"/>
Brigatinib Dosing Details	ECCAT	PHARMACOKINETIC DOSE
Category	ECSCAT	DOSE PRIOR TO LAST DOSE OF INVESTIGATIONAL PRODUCT
Start Date of Treatment	ECSTDTC	
Start Time of Treatment	ECSTDTC	
Category	ECSCAT	LAST DOSE OF INVESTIGATIONAL PRODUCT
Start Date of Treatment	ECSTDTC	
Start Time of Treatment	ECSTDTC	
Category	ECSCAT	AT CLINIC VISIT
Start Date of Treatment	ECSTDTC	
Start Time of Treatment	ECSTDTC	
Check here if specimen collection was not done	PCSTAT	NOT DONE <input type="radio"/>
Reason Test Not Done	PCREASND	
Planned Time Point Name	PCTPT	Predose <input checked="" type="radio"/> 1 Hour Postdose <input type="radio"/> 4 Hours Postdose <input type="radio"/> Unscheduled <input type="radio"/>
Time of Specimen Collection (24 hr clock)	PCDTC	
Check here if specimen collection was not done		NOT DONE <input type="radio"/>
Reason Test Not Done		
Planned Time Point Name		Predose <input type="radio"/> 1 Hour Postdose <input checked="" type="radio"/> 4 Hours Postdose <input type="radio"/> Unscheduled <input type="radio"/>
Time of Specimen Collection (24 hr clock)		
Check here if specimen collection was not done		NOT DONE <input type="radio"/>
Reason Test Not Done		
Planned Time Point Name		Predose <input type="radio"/> 1 Hour Postdose <input type="radio"/> 4 Hours Postdose <input checked="" type="radio"/> Unscheduled <input type="radio"/>

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Plasma Collection for PK

Time of Specimen Collection (24 hr clock)

PC=Pharmacokinetic Concentrations

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Plasma Collection for PK - Unscheduled

Date of Specimen Collection	PCDTC	
Specimen Material Type	PCSPEC	PLASMA <input checked="" type="radio"/>
Planned Time Point Name	PCTPT	Predose <input type="radio"/> 1 Hour Postdose <input type="radio"/> 4 Hours Postdose <input type="radio"/> Unscheduled <input checked="" type="radio"/>
Time of Specimen Collection (24 hr clock)	PCDTC	

EC=Exposure as Collected

PC=Pharmacokinetic Concentrations

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Plasma Collection for PK - Predose

Date of Specimen Collection	PCDTC	
Specimen Material Type	PCSPEC	PLASMA <input checked="" type="radio"/>
Brigatinib Dosing Details	ECCAT	PHARMACOKINETIC DOSE
Category	ECSCAT	DOSE PRIOR TO LAST DOSE OF INVESTIGATIONAL PRODUCT
Start Date of Treatment	ECSTDTC	
Start Time of Treatment	ECSTDTC	
Category	ECSCAT	LAST DOSE OF INVESTIGATIONAL PRODUCT
Start Date of Treatment	ECSTDTC	
Start Time of Treatment	ECSTDTC	
Category	ECSCAT	AT CLINIC VISIT
Start Date of Treatment	ECSTDTC	
Start Time of Treatment	ECSTDTC	
Check here if specimen collection was not done	PCSTAT	NOT DONE <input type="radio"/>
Reason Test Not Done	PCREASND	
Planned Time Point Name	PCTPT	Predose <input checked="" type="radio"/> 1 Hour Postdose <input type="radio"/> 4 Hours Postdose <input type="radio"/> Unscheduled <input type="radio"/>
Time of Specimen Collection (24 hr clock)	PCDTC	

EC=Exposure as Collected

PC=Pharmacokinetic Concentrations

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

ECCAT=PHARMACOKINETIC DOSE

Form: Plasma Collection for PK - Cycle 1 Day 1

Date of Specimen Collection	PCDTC	
Specimen Material Type	PCSPEC	PLASMA <input checked="" type="radio"/>
Category	ECSCAT	AT CLINIC VISIT
Start Date of Treatment	ECSTDTC	
Start Time of Treatment	ECSTDTC	
Check here if specimen collection was not done	PCSTAT	NOT DONE <input type="radio"/>
Reason Test Not Done	PCREASND	
Planned Time Point Name	PCTPT	Predose <input type="radio"/> 1 Hour Postdose <input checked="" type="radio"/> 4 Hours Postdose <input type="radio"/> Unscheduled <input type="radio"/>
Time of Specimen Collection (24 hr clock)	PCDTC	
Check here if specimen collection was not done		NOT DONE <input type="radio"/>
Reason Test Not Done		
Planned Time Point Name		Predose <input type="radio"/> 1 Hour Postdose <input type="radio"/> 4 Hours Postdose <input checked="" type="radio"/> Unscheduled <input type="radio"/>
Time of Specimen Collection (24 hr clock)		

FA=Findings About Events or Interventions

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Tumor Measurement Events

Were Target tumors identified?

Yes ☐

FAORRES when FATESTCD=OCCUR **FAOBJ=TARGET TUMORS**

No ☐

FASTAT=NOT DONE when Not Done

Not Done ☐

Were Non-target tumors identified?

Yes ☐

FAORRES when FATESTCD=OCCUR **FAOBJ=NON-TARGET TUMORS**

No ☐

FASTAT=NOT DONE when Not Done

Not Done ☐

Has the scanned assessment been sent to the IRC vendor?

Yes ☐

FAOBJ=SENT TO IRC VENDOR **FAORRES when FATESTCD=OCCUR**

No ☐

Date scanned assessments were sent to the IRC vendor **FADTC when FAOBJ=SENT TO IRC VENDOR**

RELREC=Related Records

TR=Tumor Results

TU=Tumor Identification

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Target Lesion

TRGRPID=TARGET

Lesion Number	TRLNKID	TULNKID	TL01	<input type="checkbox"/>
Linked to related TR/TU record via RELREC			TL02	<input type="checkbox"/>
			TL03	<input type="checkbox"/>
			TL04	<input type="checkbox"/>
			TL05	<input type="checkbox"/>

Date of Assessment	TRDTC	TUDTC	
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Anatomical location	TULOC	Adrenal gland	<input type="checkbox"/>
		Arm	<input type="checkbox"/>
		Arm skin	<input type="checkbox"/>
		Axilla	<input type="checkbox"/>
		Biliary tract	<input type="checkbox"/>
		Bladder	<input type="checkbox"/>
		Bone	<input type="checkbox"/>
		Bone marrow	<input type="checkbox"/>
		Brain	<input type="checkbox"/>
		Breast	<input type="checkbox"/>
		Buttock	<input type="checkbox"/>
		Chest	<input type="checkbox"/>
		Colon	<input type="checkbox"/>
		Ear	<input type="checkbox"/>
		Esophagus	<input type="checkbox"/>
		Facial nerve	<input type="checkbox"/>
		Floor of mouth	<input type="checkbox"/>
		Forearm	<input type="checkbox"/>
		Forehead	<input type="checkbox"/>
		Gastrointestinal tract, lower	<input type="checkbox"/>
		Gastrointestinal tract, upper	<input type="checkbox"/>
		Glossopharyngeal nerve	<input type="checkbox"/>
		Head and neck	<input type="checkbox"/>
		Heart	<input type="checkbox"/>
		Hip	<input type="checkbox"/>
		Hypoglossal nerve	<input type="checkbox"/>
		Kidney	<input type="checkbox"/>
		Leg	<input type="checkbox"/>

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Target Lesion

Leg skin	<input type="checkbox"/>
Liver	<input type="checkbox"/>
Lung	<input type="checkbox"/>
Lymph node	<input type="checkbox"/>
Neck	<input type="checkbox"/>
Oculomotor nerve	<input type="checkbox"/>
Olfactory nerve	<input type="checkbox"/>
Oral cavity	<input type="checkbox"/>
Ovary	<input type="checkbox"/>
Pancreas	<input type="checkbox"/>
Pelvis	<input type="checkbox"/>
Pericardium	<input type="checkbox"/>
Peripheral blood mononuclear cell	<input type="checkbox"/>
Peritoneum	<input type="checkbox"/>
Pleura	<input type="checkbox"/>
Pleural cavity	<input type="checkbox"/>
Prostate gland	<input type="checkbox"/>
Rectum	<input type="checkbox"/>
Skin	<input type="checkbox"/>
Small intestine	<input type="checkbox"/>
Spinal accessory nerve	<input type="checkbox"/>
Spinal cord	<input type="checkbox"/>
Spleen	<input type="checkbox"/>
Stomach	<input type="checkbox"/>
Subcutis	<input type="checkbox"/>
Testis	<input type="checkbox"/>
Thigh	<input type="checkbox"/>
Thymus gland	<input type="checkbox"/>
Trigeminal nerve	<input type="checkbox"/>
Trochlear nerve	<input type="checkbox"/>
Umbilical cord	<input type="checkbox"/>
Uterus	<input type="checkbox"/>
Vagus nerve	<input type="checkbox"/>
Vestibulocochlear nerve	<input type="checkbox"/>

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Target Lesion

		Other, Specify <input type="checkbox"/>
Other, specify	TULOC	
Laterality	TULAT	Left <input type="checkbox"/>
		Right <input type="checkbox"/>
Directionality	TUDIR	Anterior <input type="checkbox"/>
		Apical <input type="checkbox"/>
		Basal <input type="checkbox"/>
		Caudal <input type="checkbox"/>
		Central <input type="checkbox"/>
		Cranial <input type="checkbox"/>
		Deep <input type="checkbox"/>
		Distal <input type="checkbox"/>
		Dorsal <input type="checkbox"/>
		Dorsolateral <input type="checkbox"/>
		Fore <input type="checkbox"/>
		Hind <input type="checkbox"/>
		Inferior <input type="checkbox"/>
		Inner <input type="checkbox"/>
		Intermediate <input type="checkbox"/>
		Lateral <input type="checkbox"/>
		Lower <input type="checkbox"/>
		Medial <input type="checkbox"/>
		Midline <input type="checkbox"/>
		Nasal <input type="checkbox"/>
		Outer <input type="checkbox"/>
		Peripheral <input type="checkbox"/>
		Posterior <input type="checkbox"/>
		Proximal <input type="checkbox"/>
		Rostral <input type="checkbox"/>
		Superficial <input type="checkbox"/>
		Superior <input type="checkbox"/>
		Surface <input type="checkbox"/>
		Temporal <input type="checkbox"/>
		Tip <input type="checkbox"/>

		Upper	<input type="checkbox"/>
		Ventral	<input type="checkbox"/>
		Ventrolateral	<input type="checkbox"/>
Method of evaluation	TUMETHOD	TRMETHOD	Scintigraphy <input type="checkbox"/>
			X-Ray <input type="checkbox"/>
			Clinical Evaluation <input type="checkbox"/>
			CT Scan <input type="checkbox"/>
			Echocardiography <input type="checkbox"/>
			Endoscopy <input type="checkbox"/>
			Mammography <input type="checkbox"/>
			MRI <input type="checkbox"/>
			PET <input type="checkbox"/>
			FDG-PET Scan <input type="checkbox"/>
			PET/CT Scan <input type="checkbox"/>
			Ultrasound <input type="checkbox"/>
			Other <input type="checkbox"/>
What was the diameter of tumor?	TRORES when TRTESTCD=DIAMETER		
What were the units for the diameter?	TRORESU	mm	<input type="checkbox"/>
		cm	<input type="checkbox"/>
Reason not measured	TRSTAT	TRREASND	Coalesce <input type="checkbox"/>
			Split <input type="checkbox"/>
			Too Small to Measure <input type="checkbox"/>
			Not Evaluated/Inevaluable (NE) <input type="checkbox"/>
If Not Evaluated/Inevaluable (NE), select	TRREASNE in SUPPTR		Cavitation <input type="checkbox"/>
			Fibrosis <input type="checkbox"/>
			Necrosis <input type="checkbox"/>
			Other <input type="checkbox"/>
			Poor Scan Quality <input type="checkbox"/>
Sum of Target Lesion Diameters	TRORES when TRTESTCD=SUMDIAM		

RELREC=Related Records

RS=Disease Response

TU=Tumor Identification

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

RSCAT=RECIST 1.1

Form: Non-Target Lesion

Lesion Number	RSLNKID	TULNKID	NTL01	<input type="checkbox"/>
			Linked to related TU/RS record via RELREC	<input type="checkbox"/>
			NTL03	<input type="checkbox"/>
			NTL04	<input type="checkbox"/>
			NTL05	<input type="checkbox"/>
			NTL06	<input type="checkbox"/>
			NTL07	<input type="checkbox"/>
			NTL08	<input type="checkbox"/>
			NTL09	<input type="checkbox"/>
			NTL10	<input type="checkbox"/>
			NTL11	<input type="checkbox"/>
			NTL12	<input type="checkbox"/>
			NTL13	<input type="checkbox"/>
			NTL14	<input type="checkbox"/>
			NTL15	<input type="checkbox"/>
			NTL16	<input type="checkbox"/>
			NTL17	<input type="checkbox"/>
			NTL18	<input type="checkbox"/>
			NTL19	<input type="checkbox"/>
			NTL20	<input type="checkbox"/>
Date of Assessment	RSDTC	TUDTC		
Anatomical location	TULOC		Adrenal gland	<input type="checkbox"/>
			Arm	<input type="checkbox"/>
			Arm skin	<input type="checkbox"/>
			Axilla	<input type="checkbox"/>
			Biliary tract	<input type="checkbox"/>
			Bladder	<input type="checkbox"/>
			Bone	<input type="checkbox"/>
			Bone marrow	<input type="checkbox"/>
			Brain	<input type="checkbox"/>
			Breast	<input type="checkbox"/>
			Buttock	<input type="checkbox"/>
			Chest	<input type="checkbox"/>
			Colon	<input type="checkbox"/>

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Non-Target Lesion

Ear	<input type="checkbox"/>
Esophagus	<input type="checkbox"/>
Facial nerve	<input type="checkbox"/>
Floor of mouth	<input type="checkbox"/>
Forearm	<input type="checkbox"/>
Forehead	<input type="checkbox"/>
Gastrointestinal tract, lower	<input type="checkbox"/>
Gastrointestinal tract, upper	<input type="checkbox"/>
Glossopharyngeal nerve	<input type="checkbox"/>
Head and neck	<input type="checkbox"/>
Heart	<input type="checkbox"/>
Hip	<input type="checkbox"/>
Hypoglossal nerve	<input type="checkbox"/>
Kidney	<input type="checkbox"/>
Leg	<input type="checkbox"/>
Leg skin	<input type="checkbox"/>
Liver	<input type="checkbox"/>
Lung	<input type="checkbox"/>
Lymph node	<input type="checkbox"/>
Neck	<input type="checkbox"/>
Oculomotor nerve	<input type="checkbox"/>
Olfactory nerve	<input type="checkbox"/>
Oral cavity	<input type="checkbox"/>
Ovary	<input type="checkbox"/>
Pancreas	<input type="checkbox"/>
Pelvis	<input type="checkbox"/>
Pericardium	<input type="checkbox"/>
Peripheral blood mononuclear cell	<input type="checkbox"/>
Peritoneum	<input type="checkbox"/>
Pleura	<input type="checkbox"/>
Pleural cavity	<input type="checkbox"/>
Prostate gland	<input type="checkbox"/>
Rectum	<input type="checkbox"/>
Skin	<input type="checkbox"/>

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Non-Target Lesion

	Small intestine	<input type="checkbox"/>
	Spinal accessory nerve	<input type="checkbox"/>
	Spinal cord	<input type="checkbox"/>
	Spleen	<input type="checkbox"/>
	Stomach	<input type="checkbox"/>
	Subcutis	<input type="checkbox"/>
	Testis	<input type="checkbox"/>
	Thigh	<input type="checkbox"/>
	Thymus gland	<input type="checkbox"/>
	Trigeminal nerve	<input type="checkbox"/>
	Trochlear nerve	<input type="checkbox"/>
	Umbilical cord	<input type="checkbox"/>
	Uterus	<input type="checkbox"/>
	Vagus nerve	<input type="checkbox"/>
	Vestibulocochlear nerve	<input type="checkbox"/>
	Other, Specify	<input type="checkbox"/>
Other, Specify	TULOC	
Laterality	TULAT	Left <input type="checkbox"/>
		Right <input type="checkbox"/>
Directionality	TUDIR	Anterior <input type="checkbox"/>
		Apical <input type="checkbox"/>
		Basal <input type="checkbox"/>
		Caudal <input type="checkbox"/>
		Central <input type="checkbox"/>
		Cranial <input type="checkbox"/>
		Deep <input type="checkbox"/>
		Distal <input type="checkbox"/>
		Dorsal <input type="checkbox"/>
		Dorsolateral <input type="checkbox"/>
		Fore <input type="checkbox"/>
		Hind <input type="checkbox"/>
		Inferior <input type="checkbox"/>
		Inner <input type="checkbox"/>
		Intermediate <input type="checkbox"/>

		Lateral	<input type="checkbox"/>
		Lower	<input type="checkbox"/>
		Medial	<input type="checkbox"/>
		Midline	<input type="checkbox"/>
		Nasal	<input type="checkbox"/>
		Outer	<input type="checkbox"/>
		Peripheral	<input type="checkbox"/>
		Posterior	<input type="checkbox"/>
		Proximal	<input type="checkbox"/>
		Rostral	<input type="checkbox"/>
		Superficial	<input type="checkbox"/>
		Superior	<input type="checkbox"/>
		Surface	<input type="checkbox"/>
		Temporal	<input type="checkbox"/>
		Tip	<input type="checkbox"/>
		Upper	<input type="checkbox"/>
		Ventral	<input type="checkbox"/>
		Ventrolateral	<input type="checkbox"/>
Method of Evaluation	TUMETHOD	Scintigraphy	<input type="checkbox"/>
		X-Ray	<input type="checkbox"/>
		Clinical Evaluation	<input type="checkbox"/>
		CT Scan	<input type="checkbox"/>
		Echocardiography	<input type="checkbox"/>
		Endoscopy	<input type="checkbox"/>
		Mammography	<input type="checkbox"/>
		MRI	<input type="checkbox"/>
		PET	<input type="checkbox"/>
		FDG-PET Scan	<input type="checkbox"/>
		PET/CT Scan	<input type="checkbox"/>
		Ultrasound	<input type="checkbox"/>
		Other	<input type="checkbox"/>
Other, specify	TUMETHOD		
Status	RSORRES when RSTESTCD=NTRGRES	Complete Response (CR)	<input type="checkbox"/>
		Non-CR/Non-PD	<input type="checkbox"/>

		Progressive Disease (PD)	<input type="checkbox"/>
<div>RSSTAT</div>	<div>RSREASND</div>	Not Evaluated/Inevaluable (NE)	<input type="checkbox"/>

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: New Tumor Measurement Events

Were New tumors identified?	[NOT SUBMITTED]	Yes <input type="checkbox"/>
		No <input type="checkbox"/>
		Not Done <input type="checkbox"/>
Has the scanned assessment been sent to the IRC vendor?	[NOT SUBMITTED]	Yes <input type="checkbox"/>
		No <input type="checkbox"/>
Date scanned assessments were sent to the IRC vendor	[NOT SUBMITTED]	

TU=Tumor Identification

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: New Lesion

Lesion Number	TULNKID	N01	<input type="checkbox"/>
		N02	<input type="checkbox"/>
		N03	<input type="checkbox"/>
		N04	<input type="checkbox"/>
		N05	<input type="checkbox"/>
		N06	<input type="checkbox"/>
		N07	<input type="checkbox"/>
		N08	<input type="checkbox"/>
		N09	<input type="checkbox"/>
		N10	<input type="checkbox"/>
		N11	<input type="checkbox"/>
		N12	<input type="checkbox"/>
		N13	<input type="checkbox"/>
		N14	<input type="checkbox"/>
		N15	<input type="checkbox"/>
		N16	<input type="checkbox"/>
		N17	<input type="checkbox"/>
		N18	<input type="checkbox"/>
		N19	<input type="checkbox"/>
		N20	<input type="checkbox"/>

Date of Assessment	TUDTC	
Anatomical location	TULOC	Adrenal gland <input type="checkbox"/>
		Arm <input type="checkbox"/>
		Arm skin <input type="checkbox"/>
		Axilla <input type="checkbox"/>
		Biliary tract <input type="checkbox"/>
		Bladder <input type="checkbox"/>
		Bone <input type="checkbox"/>
		Bone marrow <input type="checkbox"/>
		Brain <input type="checkbox"/>
		Breast <input type="checkbox"/>
		Buttock <input type="checkbox"/>
		Chest <input type="checkbox"/>
		Colon <input type="checkbox"/>

Ear	<input type="checkbox"/>
Esophagus	<input type="checkbox"/>
Facial nerve	<input type="checkbox"/>
Floor of mouth	<input type="checkbox"/>
Forearm	<input type="checkbox"/>
Forehead	<input type="checkbox"/>
Gastrointestinal tract, lower	<input type="checkbox"/>
Gastrointestinal tract, upper	<input type="checkbox"/>
Glossopharyngeal nerve	<input type="checkbox"/>
Head and neck	<input type="checkbox"/>
Heart	<input type="checkbox"/>
Hip	<input type="checkbox"/>
Hypoglossal nerve	<input type="checkbox"/>
Kidney	<input type="checkbox"/>
Leg	<input type="checkbox"/>
Leg skin	<input type="checkbox"/>
Liver	<input type="checkbox"/>
Lung	<input type="checkbox"/>
Lymph node	<input type="checkbox"/>
Neck	<input type="checkbox"/>
Oculomotor nerve	<input type="checkbox"/>
Olfactory nerve	<input type="checkbox"/>
Oral cavity	<input type="checkbox"/>
Ovary	<input type="checkbox"/>
Pancreas	<input type="checkbox"/>
Pelvis	<input type="checkbox"/>
Pericardium	<input type="checkbox"/>
Peripheral blood mononuclear cell	<input type="checkbox"/>
Peritoneum	<input type="checkbox"/>
Pleura	<input type="checkbox"/>
Pleural cavity	<input type="checkbox"/>
Prostate gland	<input type="checkbox"/>
Rectum	<input type="checkbox"/>
Skin	<input type="checkbox"/>

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Project Name: Brigatinib-2002

Form: New Lesion

	Small intestine	<input type="checkbox"/>
	Spinal accessory nerve	<input type="checkbox"/>
	Spinal cord	<input type="checkbox"/>
	Spleen	<input type="checkbox"/>
	Stomach	<input type="checkbox"/>
	Subcutis	<input type="checkbox"/>
	Testis	<input type="checkbox"/>
	Thigh	<input type="checkbox"/>
	Thymus gland	<input type="checkbox"/>
	Trigeminal nerve	<input type="checkbox"/>
	Trochlear nerve	<input type="checkbox"/>
	Umbilical cord	<input type="checkbox"/>
	Uterus	<input type="checkbox"/>
	Vagus nerve	<input type="checkbox"/>
	Vestibulocochlear nerve	<input type="checkbox"/>
	Other, Specify	<input type="checkbox"/>
Other, specify	TULOC	
Laterality	TULAT	Left <input type="checkbox"/>
		Right <input type="checkbox"/>
Directionality	TUDIR	Anterior <input type="checkbox"/>
		Apical <input type="checkbox"/>
		Basal <input type="checkbox"/>
		Caudal <input type="checkbox"/>
		Central <input type="checkbox"/>
		Cranial <input type="checkbox"/>
		Deep <input type="checkbox"/>
		Distal <input type="checkbox"/>
		Dorsal <input type="checkbox"/>
		Dorsolateral <input type="checkbox"/>
		Fore <input type="checkbox"/>
		Hind <input type="checkbox"/>
		Inferior <input type="checkbox"/>
		Inner <input type="checkbox"/>
		Intermediate <input type="checkbox"/>

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Project Name: Brigatinib-2002

Form: New Lesion

	Lateral	<input type="checkbox"/>
	Lower	<input type="checkbox"/>
	Medial	<input type="checkbox"/>
	Midline	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Outer	<input type="checkbox"/>
	Peripheral	<input type="checkbox"/>
	Posterior	<input type="checkbox"/>
	Proximal	<input type="checkbox"/>
	Rostral	<input type="checkbox"/>
	Superficial	<input type="checkbox"/>
	Superior	<input type="checkbox"/>
	Surface	<input type="checkbox"/>
	Temporal	<input type="checkbox"/>
	Tip	<input type="checkbox"/>
	Upper	<input type="checkbox"/>
	Ventral	<input type="checkbox"/>
	Ventrolateral	<input type="checkbox"/>
Method of evaluation	Scintigraphy	<input type="checkbox"/>
	X-Ray	<input type="checkbox"/>
	Clinical Evaluation	<input type="checkbox"/>
	CT Scan	<input type="checkbox"/>
	Echocardiography	<input type="checkbox"/>
	Endoscopy	<input type="checkbox"/>
	Mammography	<input type="checkbox"/>
	MRI	<input type="checkbox"/>
	PET	<input type="checkbox"/>
	FDG-PET Scan	<input type="checkbox"/>
	PET/CT Scan	<input type="checkbox"/>
	Ultrasound	<input type="checkbox"/>
	Other	<input type="checkbox"/>

RS=Disease Response

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Investigator Response Assessment

RSCAT=PHYSICIAN DECISION

Was the Investigator's assessment of overall response obtained during Yes ☐

If No then RSSTAT=NOT DONE when RSTESTCD=OVLRESP No ☐

Investigator Assessment of Overall Response Complete Remission (CR) ☐

RSORRES when RSTESTCD=OVLRESP Partial Response (PR) ☐

Stable Disease (SD) ☐

Progressive Disease (PD) ☐

Response Assessment Date **RSDTC when RSTESTCD=OVLRESP**

Reason the Investigator's assessment of overall response was not Not Evaluable (NE) ☐

obtained during **RSREASND when RSTESTCD=OVLRESP** No Assessment Performed ☐

Symptomatic Deterioration

Symptomatic Deterioration is defined as a global deterioration of health status requiring discontinuation of treatment without objective evidence of disease progression at this visit.

Did the patient experience Symptomatic Deterioration? Yes ☐

RSORRES when RSTESTCD=SYMPDTR No ☐

Date of Symptomatic Deterioration **RSDTC when RSTESTCD=SYMPDTR**

BE=Biospecimen Events

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Fresh Tumor Tissue Biopsy Sample at PD

BETERM=FRESH SAMPLE

BECAT=BIOMARKER

Was Fresh Tumor Tissue Biopsy Sample at PD Collected?

BE OCCUR

Yes ☐

No ☐

Date Sample Taken

BEDTC

Specimen Type

BESPEC

PLASMA ☐

TUMOR TISSUE ☒

EPITHELIAL CELL ☐

Testing Method

BEMETHOD

Needle Aspirates ☐

Lymph Node Biopsies ☐

Incisional Biopsies ☐

Bone Marrow Biopsies ☐

Bone Marrow Aspirates ☐

Other ☐

Site of Sample

BELOC

Adrenal Glands ☐

Bladder ☐

Bone ☐

Brain - Leptomenigeal ☐

Brain - Parenchymal ☐

Colon ☐

Breast ☐

Esophagus ☐

Kidney ☐

Liver ☐

Lymph Nodes - distant ☐

Lymph Nodes - regional ☐

Muscle/soft tissue ☐

Ovaries ☐

Pancreas ☐

Pelvis ☐

Pericardium - Solid Lesion(s) ☐

Pericardium - Ascites ☐

Peritoneum - Solid Lesion(s) ☐

Peritoneum - Ascites ☐

Pleura - Effusion ☐

Prostate ☐

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Fresh Tumor Tissue Biopsy Sample at PD

	Rectum	<input type="checkbox"/>
	Skin	<input type="checkbox"/>
	Small Intestine	<input type="checkbox"/>
	Spinal Cord - Leptomeningeal	<input type="checkbox"/>
	Spinal Cord - Parenchymal	<input type="checkbox"/>
	Stomach	<input type="checkbox"/>
	Uterus	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
	Other	<input type="checkbox"/>
Other, Site of Sample	BELOC	
Specimen Collection	BESPCND	Fresh <input checked="" type="radio"/>
		Banked <input type="radio"/>
SMP Number	BESPID	3

QS=Questionnaires

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: EQ-5D-5L Scale

QSCAT=EQ-5D-5L

Was an EQ-5D-5L Questionnaire Obtained?

Yes ☐

If No then QSSTAT when QSTESTCD=QSALL

No ☐

Date Questionnaire Obtained

QSDTC

Under each heading, please tick the ONE box that best describes your health today.

QSEVINTX=TODAY

Mobility

I have no problems walking ☐

QSORRES when QSTESTCD=EQ5D0201

I have slight problems walking ☐

I have moderate problems walking ☐

I have severe problems walking ☐

I am unable to walk ☐

Self-Care

I have no problems washing or dressing myself ☐

QSORRES when QSTESTCD=EQ5D0202

I have slight problems washing or dressing myself ☐

I have moderate problems washing or dressing myself ☐

I have severe problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems doing my usual activities ☐

QSORRES when QSTESTCD=EQ5D0203

I have slight problems doing my usual activities ☐

I have moderate problems doing my usual activities ☐

I have severe problems doing my usual activities ☐

I am unable to do my usual activities ☐

Pain/Discomfort

I have no pain or discomfort ☐

QSORRES when QSTESTCD=EQ5D0204

I have slight pain or discomfort ☐

I have moderate pain or discomfort ☐

I have severe pain or discomfort ☐

I have extreme pain or discomfort ☐

Anxiety/Depression

I am not anxious or depressed ☐

QSORRES when QSTESTCD=EQ5D0205

I am slightly anxious or depressed ☐

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: EQ-5D-5L Scale

I am moderately anxious or
depressed ☐

I am severely anxious or
depressed ☐

I am extremely anxious or
depressed ☐

We would like to know how good or bad your health is TODAY.

This scale is numbered from 0 to 100. 100 means the best health
you can imagine. 0 means the worst health you can imagine.

Mark an X on the scale to indicate how your health is TODAY.

Now, please write the number you marked on the scale in the box
below.

QSEVINTX=TODAY

Your health today

QSORRES when QSTESTCD=EQ5D0206

QS=Questionnaires

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: EORTC QLQ_C30

QSCAT=EORTC QLQ-C30

Was an EORTC QLQ_C30 Questionnaire Obtained?

Yes ☐

If No then QSTAT when QSTESTCD=QSALL

No ☐

Date Questionnaire Obtained

QSDTC

Q1 Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?

1:Not at all ☐

2:A little ☐

3:Quite a bit ☐

4:Very much ☐

QSORRES when QSTESTCD=QLQ30_1

Q2 Do you have any trouble taking a LONG walk?

1:Not at all ☐

2:A little ☐

3:Quite a bit ☐

4:Very much ☐

QSORRES when QSTESTCD=QLQ30_2

Q3 Do you have any trouble taking a SHORT walk outside of the house?

1:Not at all ☐

2:A little ☐

3:Quite a bit ☐

4:Very much ☐

QSORRES when QSTESTCD=QLQ30_3

Q4 Do you need to stay in bed or a chair during the day?

1:Not at all ☐

2:A little ☐

3:Quite a bit ☐

4:Very much ☐

QSORRES when QSTESTCD=QLQ30_4

Q5 Do you need help with eating, dressing, washing yourself or using the toilet?

1:Not at all ☐

2:A little ☐

3:Quite a bit ☐

4:Very much ☐

QSORRES when QSTESTCD=QLQ30_5

During the past week:

QSEVLINT=-P1W

Q6 Were you limited in doing either your work or other daily activities?

1:Not at all ☐

2:A little ☐

3:Quite a bit ☐

4:Very much ☐

QSORRES when QSTESTCD=QLQ30_6

Q7 Were you limited in pursuing your hobbies or other leisure time activities?

1:Not at all ☐

2:A little ☐

3:Quite a bit ☐

4:Very much ☐

QSORRES when QSTESTCD=QLQ30_7

Q8 Were you short of breath?

1:Not at all ☐

QSORRES when QSTESTCD=QLQ30_8

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		2: A little	<input type="radio"/>
		3: Quite a bit	<input type="radio"/>
		4: Very much	<input type="radio"/>
Q9 Have you had pain?	1: Not at all	<input type="radio"/>	
	2: A little	<input type="radio"/>	
	3: Quite a bit	<input type="radio"/>	
	4: Very much	<input type="radio"/>	
Q10 Did you need to rest?	1: Not at all	<input type="radio"/>	
	2: A little	<input type="radio"/>	
	3: Quite a bit	<input type="radio"/>	
	4: Very much	<input type="radio"/>	
Q11 Have you had trouble sleeping?	1: Not at all	<input type="radio"/>	
	2: A little	<input type="radio"/>	
	3: Quite a bit	<input type="radio"/>	
	4: Very much	<input type="radio"/>	
Q12 Have you felt weak?	1: Not at all	<input type="radio"/>	
	2: A little	<input type="radio"/>	
	3: Quite a bit	<input type="radio"/>	
	4: Very much	<input type="radio"/>	
Q13 Have you lacked appetite?	1: Not at all	<input type="radio"/>	
	2: A little	<input type="radio"/>	
	3: Quite a bit	<input type="radio"/>	
	4: Very much	<input type="radio"/>	
Q14 Have you felt nauseated?	1: Not at all	<input type="radio"/>	
	2: A little	<input type="radio"/>	
	3: Quite a bit	<input type="radio"/>	
	4: Very much	<input type="radio"/>	
Q15 Have you vomited?	1: Not at all	<input type="radio"/>	
	2: A little	<input type="radio"/>	
	3: Quite a bit	<input type="radio"/>	
	4: Very much	<input type="radio"/>	
Q16 Have you been constipated?	1: Not at all	<input type="radio"/>	
	2: A little	<input type="radio"/>	

	3: Quite a bit <input type="radio"/>
	4: Very much <input type="radio"/>
<div style="display: flex; justify-content: space-between;"> During the past week: QSEVLINT=-P1W </div>	
Q17 Have you had diarrhea?	1: Not at all <input type="radio"/>
QSORRES when QSTESTCD=QLQ30_17	2: A little <input type="radio"/>
	3: Quite a bit <input type="radio"/>
	4: Very much <input type="radio"/>
Q18 Were you tired?	1: Not at all <input type="radio"/>
QSORRES when QSTESTCD=QLQ30_18	2: A little <input type="radio"/>
	3: Quite a bit <input type="radio"/>
	4: Very much <input type="radio"/>
Q19 Did pain interfere with your daily activities?	1: Not at all <input type="radio"/>
QSORRES when QSTESTCD=QLQ30_19	2: A little <input type="radio"/>
	3: Quite a bit <input type="radio"/>
	4: Very much <input type="radio"/>
Q20 Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1: Not at all <input type="radio"/>
QSORRES when QSTESTCD=QLQ30_20	2: A little <input type="radio"/>
	3: Quite a bit <input type="radio"/>
	4: Very much <input type="radio"/>
Q21 Did you feel tense?	1: Not at all <input type="radio"/>
QSORRES when QSTESTCD=QLQ30_21	2: A little <input type="radio"/>
	3: Quite a bit <input type="radio"/>
	4: Very much <input type="radio"/>
Q22 Did you worry?	1: Not at all <input type="radio"/>
QSORRES when QSTESTCD=QLQ30_22	2: A little <input type="radio"/>
	3: Quite a bit <input type="radio"/>
	4: Very much <input type="radio"/>
Q23 Did you feel irritable?	1: Not at all <input type="radio"/>
QSORRES when QSTESTCD=QLQ30_23	2: A little <input type="radio"/>
	3: Quite a bit <input type="radio"/>
	4: Very much <input type="radio"/>
Q24 Did you feel depressed?	1: Not at all <input type="radio"/>
QSORRES when QSTESTCD=QLQ30_24	2: A little <input type="radio"/>

	3:Quite a bit	<input type="radio"/>
	4:Very much	<input type="radio"/>
<hr/>		
Q25 Have you had difficulty remembering things?	1:Not at all	<input type="radio"/>
QSORRES when QSTESTCD=QLQ30_25	2:A little	<input type="radio"/>
	3:Quite a bit	<input type="radio"/>
	4:Very much	<input type="radio"/>
<hr/>		
Q26 Has your physical condition or medical treatment interfered with your FAMILY life?	1:Not at all	<input type="radio"/>
QSORRES when QSTESTCD=QLQ30_26	2:A little	<input type="radio"/>
	3:Quite a bit	<input type="radio"/>
	4:Very much	<input type="radio"/>
<hr/>		
Q27 Has your physical condition or medical treatment interfered with your SOCIAL activities?	1:Not at all	<input type="radio"/>
QSORRES when QSTESTCD=QLQ30_27	2:A little	<input type="radio"/>
	3:Quite a bit	<input type="radio"/>
	4:Very much	<input type="radio"/>
<hr/>		
Q28 Has your physical condition or medical treatment caused you financial difficulties?	1:Not at all	<input type="radio"/>
QSORRES when QSTESTCD=QLQ30_28	2:A little	<input type="radio"/>
	3:Quite a bit	<input type="radio"/>
	4:Very much	<input type="radio"/>

For the following questions please circle the number between 1 and 7 that best applies to you

Q29 How would you rate your overall HEALTH during the past week?	1:Very poor	<input type="radio"/>
QSEVLINT=-P1W QSORRES when QSTESTCD=QLQ30_29	2	<input type="radio"/>
	3	<input type="radio"/>
	4	<input type="radio"/>
	5	<input type="radio"/>
	6	<input type="radio"/>
	7:Excellent	<input type="radio"/>
<hr/>		
Q30 How would you rate your overall QUALITY OF LIFE during the past week?	1:Very poor	<input type="radio"/>
QSEVLINT=-P1W QSORRES when QSTESTCD=QLQ30_30	2	<input type="radio"/>
	3	<input type="radio"/>
	4	<input type="radio"/>
	5	<input type="radio"/>
	6	<input type="radio"/>

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Project Name: Brigatinib-2002

Form: EORTC QLQ_C30

7:Excellent ☐

QS=Questionnaires

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: EORTC QLQ-LC-13

QSCAT=EORTC QLQ-LC13

Was an EORTC QLQ-LC-13 Questionnaire Obtained?

Yes ☐

If No then QSSTAT when QSTESTCD=QSALL

No ☐

Date Questionnaire Obtained

QSDTC

During the past week:

QSEVLINT=-P1W

31. How much did you cough?

1:Not at all ☐

QSORRES when QSTESTCD=LC13_31

2:A little ☐

3:Quite a bit ☐

4:Very much ☐

32. Did you cough up blood?

1:Not at all ☐

QSORRES when QSTESTCD=LC13_32

2:A little ☐

3:Quite a bit ☐

4:Very much ☐

33. Were you short of breath when you rested?

1:Not at all ☐

QSORRES when QSTESTCD=LC13_33

2:A little ☐

3:Quite a bit ☐

4:Very much ☐

34. Were you short of breath when you walked?

1:Not at all ☐

QSORRES when QSTESTCD=LC13_34

2:A little ☐

3:Quite a bit ☐

4:Very much ☐

35. Were you short of breath when you climbed stairs?

1:Not at all ☐

QSORRES when QSTESTCD=LC13_35

2:A little ☐

3:Quite a bit ☐

4:Very much ☐

36. Have you had a sore mouth or tongue?

1:Not at all ☐

QSORRES when QSTESTCD=LC13_36

2:A little ☐

3:Quite a bit ☐

4:Very much ☐

37. Have you had trouble swallowing?

1:Not at all ☐

QSORRES when QSTESTCD=LC13_37

2:A little ☐

3:Quite a bit ☐

4:Very much ☐

38. Have you had tingling hands or feet?

1:Not at all ☐

QSORRES when QSTESTCD=LC13_38

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		2: A little <input type="radio"/>
		3: Quite a bit <input type="radio"/>
		4: Very much <input type="radio"/>
<hr/>		
39. Have you had hair loss?	1: Not at all <input type="radio"/>	
QSORRES when QSTESTCD=LC13_39	2: A little <input type="radio"/>	
	3: Quite a bit <input type="radio"/>	
	4: Very much <input type="radio"/>	
<hr/>		
40. Have you had pain in your chest?	1: Not at all <input type="radio"/>	
QSORRES when QSTESTCD=LC13_40	2: A little <input type="radio"/>	
	3: Quite a bit <input type="radio"/>	
	4: Very much <input type="radio"/>	
<hr/>		
41. Have you had pain in your arm or shoulder?	1: Not at all <input type="radio"/>	
QSORRES when QSTESTCD=LC13_41	2: A little <input type="radio"/>	
	3: Quite a bit <input type="radio"/>	
	4: Very much <input type="radio"/>	
<hr/>		
42. Have you had pain in other parts of your body?	1: Not at all <input type="radio"/>	
QSORRES when QSTESTCD=LC13_42	2: A little <input type="radio"/>	
	3: Quite a bit <input type="radio"/>	
	4: Very much <input type="radio"/>	
<hr/>		
If yes, where	QSLOC when QSTESTCD=LC13_42	
<hr/>		
43. Did you take medication for pain?	Yes <input type="radio"/>	
QSORRES when QSTESTCD=LC13_43A	No <input type="radio"/>	
<hr/>		
If yes, how much did it help?	1: Not at all <input type="radio"/>	
QSORRES when QSTESTCD=LC13_43B	2: A little <input type="radio"/>	
	3: Quite a bit <input type="radio"/>	
	4: Very much <input type="radio"/>	

EX=Exposure

EC=Exposure as Collected

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Project Name: Brigatinib-2002

Form: Dosing - Brigatinib

Name of Treatment	EXTRT	ECTRT	BRIGATINIB	<input checked="" type="radio"/>
Start Date of Treatment	EXSTDTC	ECSTDTC		
End Date of Treatment	EXENDTC	ECENDTC		
Scheduled Dose	ECDOSE when ECMOOD=SCHEDULED			
Scheduled Dose Unit	ECDOSU when ECMOOD=SCHEDULED			mg <input checked="" type="radio"/>
Scheduled Dosing Frequency per Interval	ECDOSFRQ when ECMOOD=SCHEDULED			QD <input checked="" type="radio"/>
				EVERY WEEK <input type="radio"/>
Actual Dose	EXDOSE when ECMOOD=PERFORMED	ECDOSE when ECMOOD=PERFORMED		
Actual Dose Units	EXDOSU when ECMOOD=PERFORMED	CMOOD=PERFORMED	mg	<input checked="" type="radio"/>
Actual Dosing Frequency per Interval	ECDOSFRQ when ECMOOD=PERFORMED			QD <input checked="" type="radio"/>
	EXDOSFRQ when ECMOOD=PERFORMED			EVERY WEEK <input type="radio"/>
Dose Form	EXDOSFRM	ECDOSFRM	CAPLET	<input type="radio"/>
			CAPSULE	<input type="radio"/>
			CAPSULE, COATED PELLETS	<input type="radio"/>
			CAPSULE, DELAYED RELEASE	<input type="radio"/>
			CAPSULE, EXTENDED RELEASE	<input type="radio"/>
			TABLET	<input checked="" type="radio"/>
			TABLET, COATED	<input type="radio"/>
			TABLET, DELAYED RELEASE	<input type="radio"/>
			TABLET, EXTENDED RELEASE	<input type="radio"/>
			SOLUTION	<input type="radio"/>
			SOLUTION, CONCENTRATE	<input type="radio"/>
			SUSPENSION	<input type="radio"/>
			SUSPENSION, EXTENDED RELEASE	<input type="radio"/>
			SUSPENSION/DROPS	<input type="radio"/>
Route of Administration	EXROUTE	ECROUTE	ORAL	<input checked="" type="radio"/>
Action Taken With Study Treatment	DOSE ESCALATION			<input type="radio"/>
	ECACN in SUPPEC when ECMOOD=PERFORMED			DOSE REDUCED <input type="radio"/>
	EXACN in SUPPEX when ECMOOD=PERFORMED			DRUG INTERRUPTED <input type="radio"/>
				DRUG WITHDRAWN <input type="radio"/>

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Project Name: Brigatinib-2002

Form: Dosing - Brigatinib

Reason for Dose Adjustment	ECADJ when ECMOOD=PERFORMED	ADVERSE EVENT	<input type="checkbox"/>
	EXADJ when ECMOOD=PERFORMED	DISEASE PROGRESSION	<input type="checkbox"/>
		SCHEDULED DOSE	<input type="checkbox"/>
		ESCALATION PER	
		PROTOCOL	
		OTHER	<input type="checkbox"/>

Other Specify	EXADJ when ECMOOD=PERFORMED	ECADJ when ECMOOD=PERFORMED
---------------	-----------------------------	-----------------------------

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Project Name: Brigatinib-2002

Form: Any Healthcare Encounters?

Were there any healthcare encounters since the previous visit?

[NOT SUBMITTED]

Yes ☐

No ☐

RELREC=Related Records

FA=Findings About Events or Interventions

HO=Healthcare Encounters

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Project Name: Brigatinib-2002

Form: Healthcare Encounters

Category of Encounter **HOCAT** **FAOBJ** Hospitalization ☐

Linked to related HO/FA record via RELREC Outpatient ☐

Encounter **HOTERM** Non-intensive Care Unit ☐

Intensive Care Unit ☐

Emergency Room ☐

Clinical Study Site ☐

Physician office (not study site) ☐

Laboratory or Pathology ☐

Department ☐

Radiology/Bioengineering ☐

Department ☐

Homecare ☐

Other ☐

Encounter, other specify **HOTERM**

Admission or Visit Date **HOSTDTC**

Discharge Date **HOENDTC**

Reason for Admission (select all that apply): Management of Existing Non-cancer Medical Condition ☐

HOREASMC in SUPPHO

HOREASMP in SUPPHO Emergent Medical Procedure ☐

HOREASAE in SUPPHO Adverse Event, including Toxicity ☐

HOREASSS in SUPPHO Lung Cancer Related Sign or Symptom ☐

HOREASCH in SUPPHO Chemotherapy ☐

HOREASRT in SUPPHO Radiation Therapy ☐

HOREASSP in SUPPHO Elective Surgical Procedure ☐

[NOT SUBMITTED] Other ☐

Other, specify **HOREASO in SUPPHO**

Did the patient miss any work days? Yes ☐

FAORRES where FATESTCD=SMISSWO No ☐

FAORRES where FATESTCD=SMISSWO NA; Not Applicable ☐

Number of Days Missed Work **FATESTCD=SMISSWOD** **FAORRESU=DAYS**

Did the caregiver miss any work days? Yes ☐

FAORRES where FATESTCD=CMISSWO No ☐

Caregiver is a person accompanying the patient for this encounter. NA; Not Applicable ☐

Number of Days Missed Work	<i>FAORRES where</i>	<i>FAORRESU=DAYS</i>	
	<i>FATESTCD=CMISSWOD</i>		

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Project Name: Brigatinib-2002

Form: Study Status

Is the subject continuing to the next cycle?	[NOT SUBMITTED]	Yes <input type="checkbox"/>
		No <input type="checkbox"/>
If Progressive Disease, will the subject's dose be increased to 240 mg?	[NOT SUBMITTED]	Yes <input type="checkbox"/>
		No <input type="checkbox"/>

DS=Disposition

DD=Death Details

SS=Subject Status

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Project Name: Brigatinib-2002

DSCAT=DISPOSITION EVENT

Form: Subject Survival Status

Survival Status Obtained? **SSSTAT when SSTECD=SSALL** NOT DONE ☐

Date of Contact **DDTC** **SSDC**

Method of Contact **SSMETHOD** TELEPHONE ☐

OFFICE VISIT ☐

E-MAIL ☐

MAIL ☐

SOCIAL SECURITY DEATH ☐

INDEX (SSDI) ☐

OTHER ☐

Other, specify **SSMTHDO in SUPPSS**

Survival Status **SSORRES when SSTECD=SURVSTAT** ALIVE ☐

DEAD ☐

Date of Death **DSSTDTC**

Primary Cause of Death **DSTERM** RELATED TO DISEASE ☐

DDORRES when DDTESTCD=PRCDTH UNDER STUDY OR ☐

COMPLICATIONS THEREOF

OTHER ☐

Other, specify **DSTERM** **DDORRES when DDTESTCD=PRCDTH**

Autopsy Performed? **DDORRES when DDTESTCD=DDAUTOP** Yes ☐

No ☐

Unknown ☐

CM=Concomitant/Prior Medications

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Subsequent Anticancer Therapy

CMCAT=ANTI-CANCER THERAPY

Sequence of Therapy (Metastatic or Locally advanced)

THLINE in SUPPCM

First ☐

Second ☐

Third ☐

Fourth ☐

Fifth ☐

Drug Name

CMTRT

5-FU ☐

Alectinib ☐

Axitinib ☐

Bevacizumab ☐

Bleomycin ☐

Brigatinib ☐

Carboplatin ☐

Ceritinib ☐

Cetuximab ☐

CISplatin ☐

Crizotinib ☐

Docetaxel ☐

Doxorubicin ☐

Erlotinib ☐

Everolimus ☐

Etoposide ☐

Experimental Therapy ☐

Hormonal therapy (including
aromatase inhibitors) ☐

Interferon alpha ☐

Liposomal Doxorubicin ☐

Methotrexate ☐

Mitotane ☐

Nivolumab ☐

Paclitaxel ☐

Pazopanib ☐

Pemetrexed ☐

Perifosine ☐

Standard therapy other ☐

		Sorafenib	<input type="checkbox"/>
		Sunitinib	<input type="checkbox"/>
		Trastuzumab	<input type="checkbox"/>
		Torisel	<input type="checkbox"/>
		Temsirolimus	<input type="checkbox"/>
		Vincristine	<input type="checkbox"/>
		Zoledronic acid (Aclasta Reclast Zometa)	<input type="checkbox"/>
		Other	<input type="checkbox"/>
Drug, Other specify		CMTRT	
Type of Therapy		THTYPE in SUPPCM	
		Maintenance	<input type="checkbox"/>
		Neo-adjuvant	<input type="checkbox"/>
		Adjuvant	<input type="checkbox"/>
		Metastatic (and Locally Advanced)	<input type="checkbox"/>
Start Date		CMSTDTC	
End Date		CMENDTC	
Ongoing?		CMENRTPT	
		Yes	<input type="checkbox"/>
		No	<input type="checkbox"/>
Dose		CMDOSE	
		CMDOSTXT	
Dose Unit		CMDOSU	
		%	<input type="checkbox"/>
		APPLICATION	<input type="checkbox"/>
		CAPSULE	<input type="checkbox"/>
		g	<input type="checkbox"/>
		gtt	<input type="checkbox"/>
		IU	<input type="checkbox"/>
		IU/mL	<input type="checkbox"/>
		mEq	<input type="checkbox"/>
		mg	<input type="checkbox"/>
		mL	<input type="checkbox"/>
		PUFF	<input type="checkbox"/>
		TABLET	<input type="checkbox"/>
		UNIT	<input type="checkbox"/>
		ug	<input type="checkbox"/>
		SPRAY	<input type="checkbox"/>

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Project Name: Brigatinib-2002

Form: Subsequent Anticancer Therapy

		Tbsp	<input type="checkbox"/>
		tsp	<input type="checkbox"/>
		mg/m2	<input type="checkbox"/>
		mg/kg	<input type="checkbox"/>
		mg/L	<input type="checkbox"/>
Frequency	CMDOSFRQ	QD	<input type="checkbox"/>
		ONCE	<input type="checkbox"/>
		BID	<input type="checkbox"/>
		PRN	<input type="checkbox"/>
		Q12H	<input type="checkbox"/>
		Q24H	<input type="checkbox"/>
		Q8H	<input type="checkbox"/>
		QID	<input type="checkbox"/>
		QM	<input type="checkbox"/>
		QOD	<input type="checkbox"/>
		TID	<input type="checkbox"/>
		UNKNOWN	<input type="checkbox"/>
		2 TIMES PER WEEK	<input type="checkbox"/>
		3 TIMES PER MONTH	<input type="checkbox"/>
		3 TIMES PER WEEK	<input type="checkbox"/>
		4 TIMES PER WEEK	<input type="checkbox"/>
		CONTINUOUS	<input type="checkbox"/>
		EVERY 2 WEEKS	<input type="checkbox"/>
		EVERY 3 WEEKS	<input type="checkbox"/>
		EVERY 4 WEEKS	<input type="checkbox"/>
		EVERY WEEK	<input type="checkbox"/>
		INTERMITTENT	<input type="checkbox"/>
		Q4H	<input type="checkbox"/>
		Q6H	<input type="checkbox"/>
		QH	<input type="checkbox"/>
		BIM	<input type="checkbox"/>
Best Response	CMTRTBOR in SUPPCM	Complete Response (CR)	<input type="checkbox"/>
		Partial Response (PR)	<input type="checkbox"/>
		Stable Disease (SD)	<input type="checkbox"/>

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Project Name: Brigatinib-2002

Form: Subsequent Anticancer Therapy

		Progressive Disease (PD)	<input type="checkbox"/>
		Unable to Assess (UA)	<input type="checkbox"/>
		Unknown	<input type="checkbox"/>
Date of Disease Progression	<i>CMPDDTC in SUPPCM</i>		
Reason for Discontinuation	<i>RSDISC in SUPPCM</i>	Completed Prescribed Therapy	<input type="checkbox"/>
		Progressive Disease	<input type="checkbox"/>
		No Response	<input type="checkbox"/>
		Adverse Event	<input type="checkbox"/>
		Patient Choice	<input type="checkbox"/>
		Other	<input type="checkbox"/>
Other Reason	<i>RSDISC in SUPPCM</i>		

DS=Disposition

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: End of Study Treatment

DSCAT=DISPOSITION EVENT

DSSCAT=END OF TREATMENT

Did the patient prematurely discontinue from study treatment?

Yes ☐

If No then DSTERM=COMPLETED

No ☐

Primary reason off study treatment

DSDECOD

ADVERSE EVENT ☐

PROTOCOL DEVIATION ☐

LOST TO FOLLOW-UP ☐

WITHDRAWAL BY SUBJECT ☐

INVESTIGATOR DISCRETION ☐

CLINICAL PROGRESSION ☐

WITHOUT RADIOLOGICAL ☐

PD BY RECIST ☐

PROGRESSIVE DISEASE PER ☐

RECIST ☐

OTHER ☐

Other, specify

DSTERM

DS=Disposition

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: End of Study

DSCAT=DISPOSITION EVENT

DSSCAT=END OF STUDY

Did the patient prematurely discontinue from the study?

Yes ☐

If No then DSTERM=COMPLETED

No ☐

Primary reason off study

DSDECOD

DEATH ☐

ADVERSE EVENT ☐

PROTOCOL DEVIATION ☐

LOST TO FOLLOW-UP ☐

WITHDRAWAL BY SUBJECT ☐

OTHER ☐

Other, specify

DSTERM

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Any Concomitant Procedures?

Has the subject reported any Concomitant Procedures?

[NOT SUBMITTED]

Yes ☐

No ☐

If answered "Yes", an additional form will be added to the task list on the left. Record all Concomitant Procedures information on the new form.

PR=Procedures

Brigatinib-2002 Version 2.0 26Oct2018: PDF Uniques

Project Name: Brigatinib-2002

Form: Concomitant Procedures

PRCAT=CONCOMITANT PROCEDURE

Reported Name of Procedure	PRTRT	Thoracentesis	<input type="checkbox"/>
		Paracentesis	<input type="checkbox"/>
		Pleurodesis	<input type="checkbox"/>
		IVC filter placement	<input type="checkbox"/>
		Neurosurgery to manage brain metastasis	<input type="checkbox"/>
		Stereotactic Radiation therapy for brain metastasis	<input type="checkbox"/>
		Localized radiation therapy for brain metastasis	<input type="checkbox"/>
		Localized radiation therapy for non-brain lesions	<input type="checkbox"/>
		Whole brain radiation therapy	<input type="checkbox"/>
		Other	<input type="checkbox"/>

Procedure other, specify	PRTRT	
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Date of Procedure	PRSTDTC	
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Indication		Brain metastasis	<input type="checkbox"/>
	PRINDC	Pleural effusion	<input type="checkbox"/>
		Prevention of DVT	<input type="checkbox"/>
		Other	<input type="checkbox"/>

Indication other, specify	PRINDC	
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