The VIOLET Study

PATIENT DETAILS

A1

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

PATIENT DETAILS (ELIGIBLE & CONSENTED PATIENTS ONLY)

Patient's title *(tick one):* *Dr* ☐ *Miss* ☐ *Ms* ☐ *Mrs* ☐ *Mr* ☐

Patient's name: _____

Please complete the patient address below or apply addressograph.

Patient address: _____ NHS Number: ☐☐☐☐☐☐☐☐☐☐

_____ Patient's Sex: *Male* ☐ *Female* ☐

_____

_____

Patient post code: _____

PATIENT CONTACT DETAILS (ELIGIBLE & CONSENTED PATIENTS ONLY)

Patient's home phone number: _____ Patient's mobile phone number: _____

Can answer machine messages be left ? *Yes* ☐ *No* ☐

Patient's email address: _____

Can the patient be contacted by:

Post		*Phone*		*Text*		*Email*	
Yes ☐	*No* ☐	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐	*Yes* ☐	*No* ☐

Patients preferred method of completing follow-up questionnaires *(please tick)*:

Post ☐ *Online* ☐

Would the patient like to receive a summary of trial results? *Yes* ☐ *No* ☐

GP CONTACT DETAILS (ELIGIBLE & CONSENTED PATIENTS ONLY)

GP name _____ GP Address _____

GP Practice _____ _____

_____

GP Postcode: _____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

BASELINE CLINICAL DETAILS

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

BASELINE CLINICAL MEASURES

Height ☐☐☐ *cm* | Weight ☐☐☐.☐ *kg* | ECOG status *(0-5)* ☐

Haemoglobin ☐☐.☐ *g/dl* | Platelets ☐☐☐☐ *x10⁹/l* | White cell count ☐☐.☐ *x10⁹/l*

Neutrophils ☐☐.☐ *x10⁹/l* | Lymphocytes ☐☐.☐ *x10⁹/l* | CRP ☐☐☐☐ *Mg/L*

Creatinine ☐☐☐☐ *µmol/l* | Urea ☐☐.☐ *mmol/l*

SPIROMETRY

Was spirometry performed? *Yes* ☐ *No* ☐ If **YES**, provide date: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

If **YES,** provide values below:

FEV1: ☐.☐☐ L FVC: ☐.☐☐ L DLCO: ☐☐.☐☐ Mmol/min/kPa ***or*** ☐☐.☐ %

If **NO**, record the main reason: ☐ *1: Patient refused. 2: Patient unwell, 3: Patient upset, 4: Admin Failure, 5: Other*

If **OTHER**, specify: _____

SMOKING STATUS

Has the patient **ever** smoked? *Yes* ☐ *No* ☐

If **YES**, specify the average number of cigarettes smoked **per day** ☐☐

Provide the age that the patient started smoking: ☐☐☐

Provide the age that the patient ceased smoking, (if still smoking provide current age) ☐☐☐

MEDICAL HISTORY

Family history of lung cancer	*Yes* ☐	*No* ☐	CVA / TIAs	*Yes* ☐	*No* ☐
Respiratory comorbidity[+]	*Yes* ☐	*No* ☐	Cardiovascular comorbidity[°]	*Yes* ☐	*No* ☐
Neurological dysfunction[¥]	*Yes* ☐	*No* ☐	Chronic pain syndrome[*]	*Yes* ☐	*No* ☐
Diabetes mellitus	*Yes* ☐	*No* ☐	Deep Vein Thrombosis (DVT)	*Yes* ☐	*No* ☐
Alcoholism [#]	*Yes* ☐	*No* ☐	Previously treated malignancy *(other than squamous skin cancer)*	*Yes* ☐	*No* ☐
Any previous lung surgery	*Yes* ☐	*No* ☐	If **YES**, give date of diagnosis: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)		

If **YES,** specify date: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

Type of surgery: _____

Specify, malignancy: _____

[+]*Respiratory comorbidity: Any history of treated chronic obstructive pulmonary disease, asthma, interstitial lung disease or bronchiectasis*
[°]*CV comorbidity: Any history of treated angina, myocardial infarction, heart failure, heart valve disease, hypertension, pulmonary embolism, peripheral vascular disease.*
[¥]*Neurological dysfunction: Any history of persistent disease of the central or peripheral nervous system diagnosed by a medical practitioner.*
[*]*Chronic pain syndrome: As defined by chronic pain experienced >6 months after the onset of the initial acute injury or illness.*
[#]*Alcoholism: As defined by the daily consumption of >10 units for men & >5 units for women.*

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

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BASELINE CLINICAL DETAILS

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

PRE-OPERATIVE IMAGING

What pre-operative imaging has been performed?

	YES	NO		
CT	☐	☐	If **YES**, date performed:	__ __ /__ __ /__ __ __ __ (d d m m y y y y)
PET-CT	☐	☐	If **YES**, date performed:	__ __ /__ __ /__ __ __ __ (d d m m y y y y)

CURRENT MALIGNANCY—LOCATION

Please specify the location of the **primary tumour** within the lung:

	YES	NO		YES	NO		YES	NO
Left Upper Lobe	☐	☐	Right Upper Lobe	☐	☐	Other	☐	☐
Left Lower Lobe	☐	☐	Right Middle Lobe	☐	☐	If **OTHER**, please specify: _____		
			Right Lower Lobe	☐	☐			

DETAILS OF THE PLANNED RESECTION

Please identify the lobe(s) of the lung that will be resected during the procedure:

	YES	NO		YES	NO		YES	NO
Left Upper Lobe	☐	☐	Right Upper Lobe	☐	☐	Other	☐	☐
Left Lower Lobe	☐	☐	Right Middle Lobe	☐	☐	If **OTHER**, please specify: _____		
			Right Lower Lobe	☐	☐			

BIOLOGICAL SUB-STUDY—BASELINE BLOODS (only complete if patient has consented to sub-study)

Baseline blood sample taken: *Yes* ☐ *No* ☐

If **YES**, date and time taken: __ __ /__ __ /__ __ __ __ (d d m m y y y y) ☐☐:☐☐ (24 hr clock)

If **NO**, provide reason: _____

Please stick a barcode label from blood kit box in this box

FedEx Tracking Number: ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Has the blood sample box been collected by the courier?: *Yes* ☐ If **YES**, date collected: __ __ /__ __ /__ __ __ __ (d d m m y y y y)

No ☐ If **NO**, provide reason: _____

_____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

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BASELINE CLINICAL DETAILS

B3

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

CURRENT MALIGNANCY—HISTOLOGY

Has a biopsy of their lung cancer been **attempted**? Yes ☐ No ☐

If **YES,** give date of biopsy: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

If **YES,** specify biopsy modality:

	Yes	No		Yes	No		Yes	No
Image guided	☐	☐	Bronchoscopy / EBUS	☐	☐	Thoracotomy / VATS	☐	☐

If a biopsy has been **attempted**, specify the outcome:

	Yes	No		Yes	No		Yes	No
NSCLC	☐	☐	SCLC	☐	☐	Carcinoid	☐	☐
Biopsy inconclusive (was **not** diagnostic)	☐	☐	Benign	☐	☐			
Biopsy failed (cells not obtained)	☐	☐	Other	☐	☐	If **OTHER**, specify: _____		

If **NSCLC,** specify type *(tick all that apply)*:

	Yes	No		Yes	No		Yes	No
Squamous cell carcinoma	☐	☐	Adenocarcinoma	☐	☐	Large cell carcinoma	☐	☐
Other	☐	☐	If **OTHER**, please specify: _____					

PRE-OPERATIVE TREATMENT

Has the patient undergone any pre-operative treatment for their lung cancer? Yes ☐ No ☐

If **YES,** has the patient undergone:

Radiotherapy Yes ☐ No ☐ If **YES,** specify date started: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) Total dose (Gy): ☐☐

Chemotherapy Yes ☐ No ☐ If **YES,** specify date started: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) No. of cycles completed: ☐☐

If **YES,** specify drugs used:

	Yes	No		Yes	No		Yes	No
Cisplatin	☐	☐	Vinorelbine	☐	☐	Docetaxel	☐	☐
Carboplatin	☐	☐	Paclitaxel	☐	☐	Irinotecan	☐	☐
Gemcitabine	☐	☐	Etoposide	☐	☐	Other	☐	☐
If **OTHER**, specify: _____			Other	☐	☐	If **OTHER**, specify: _____		

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

B4

BASELINE MEDICATIONS

VIOLET Trial ID: [ ][ ][ ]-[ ][ ][ ][ ]

Patient Name: ______________________________

MEDICATIONS

Is the patient taking any medications at baseline? *Yes* [ ] *No* [ ] If **YES**, please specify below

Name of drug (Generic names only)	**Dose**	**Units** (please circle)	If OTHER, please specify	**Frequency** (please circle)	If OTHER, please specify
		mg / g / mL / other	________	OD / BD / TD QD / PRN / OTH	________
		mg / g / mL / other	________	OD / BD / TD QD / PRN / OTH	________
		mg / g / mL / other	________	OD / BD / TD QD / PRN / OTH	________
		mg / g / mL / other	________	OD / BD / TD QD / PRN / OTH	________
		mg / g / mL / other	________	OD / BD / TD QD / PRN / OTH	________
		mg / g / mL / other	________	OD / BD / TD QD / PRN / OTH	________
		mg / g / mL / other	________	OD / BD / TD QD / PRN / OTH	________
		mg / g / mL / other	________	OD / BD / TD QD / PRN / OTH	________
		mg / g / mL / other	________	OD / BD / TD QD / PRN / OTH	________
		mg / g / mL / other	________	OD / BD / TD QD / PRN / OTH	________
		mg / g / mL / other	________	OD / BD / TD QD / PRN / OTH	________
		mg / g / mL / other	________	OD / BD / TD QD / PRN / OTH	________
		mg / g / mL / other	________	OD / BD / TD QD / PRN / OTH	________
		mg / g / mL / other	________	OD / BD / TD QD / PRN / OTH	________

Multiple copies of this CRF can be completed if required

Name of person completing form* (capitals): ______________________________

Signature of person completing form: ____________________ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) ______________________________

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

The VIOLET Study

SOCIO-DEMOGRAPHIC & LOGISTICAL INFORMATION B5

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

ETHNICITY

White or Caucasian	☐	Black / Black British	☐
Mixed / multiple ethnic groups	☐	Asian / Asian British	☐
Other ethnic group	☐	If **OTHER**, please specify: _____	

BASELINE QUESTIONNAIRES

	QLQ-C30	QLQ-LC13	EQ-5D
Questionnaire completed in clinic?	*Yes* ☐ *No* ☐	*Yes* ☐ *No* ☐	*Yes* ☐ *No* ☐
If **YES,** identify the help given by research nurse *(code)*:	☐	☐	☐
	1= Patient completed unaided, 2=Completed by nurse on patients behalf, 3=Other		
	If **OTHER**, please specify: _____ ☐	If **OTHER**, please specify: _____ ☐	If **OTHER**, please specify: _____ ☐
If questionnaires were **NOT** completed in clinic provide reason (code):	*1= Taken home to complete, 2= Other*		
	If **OTHER**, please specify: _____	If **OTHER**, please specify: _____	If **OTHER**, please specify: _____

BASELINE PAIN SCORE

TO BE COMPLETED BY STAFF ON BEHALF OF THE PATIENT BEFORE SURGERY

Was the patients pain score recorded at baseline? *Yes* ☐ *No* ☐ If **NO,** provide reason: ☐

1: Patient refused, 2: Patient unwell, 3: Patient upset, 4: Inconvenient, 5: Administrative failure, 6: Other

If **YES,** provide complete the following:

Date of assessment: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) Time: ☐☐:☐☐ *(24 hr clock)*

Please ask the patient to choose a number that reflects their current pain, where 0 = no pain and 10 = worst pain possible *(please circle)*:

0 1 2 3 4 5 6 7 8 9 10

NO PAIN ***WORST PAIN POSSIBLE***

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

RANDOMISATION DETAILS

B6

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

PROCEDURE DETAILS

Planned procedure date __ __ / __ __ / __ __ __ __ (*d d m m y y y y*)

Surgeon initials *(forename, surname)* ☐☐☐

Procedure type:

Frozen section biopsy with the option to proceed to lobectomy / bilobectomy ☐ Lobectomy / bilobectomy ☐

RANDOMISATION DETAILS

Has the patient completed their baseline health questionnaire booklet? ☐ Yes ☐ No

If **NO,** please ensure that the patient completes these **prior** to their operation

RANDOMISATION OUTCOME

Date of randomisation __ __ / __ __ / __ __ __ __ (*d d m m y y y y*)

Randomisation number ☐☐☐☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

OPERATION DETAILS

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

ADMISSION DETAILS

Date patient admitted (pre-procedure): __ __ /__ __ /__ __ __ __ (d d m m y y y y)

Where was the patient admitted from:

Home ☐ Ward / referring hospital ☐ Nursing home ☐

Residential home ☐ Other ☐ If **OTHER**, specify: _____

BASIC OPERATION DETAILS

Operation date: __ __ /__ __ /__ __ __ __ (d d m m y y y y) Consultant initials: ☐☐☐

First operator classification: Consultant surgeon ☐ Trainee surgeon ☐

Operation start time *(knife to skin):* ☐☐:☐☐ *(24 hr clock)* Finish time: ☐☐:☐☐ *(24 hr clock)*

Was a prophylactic mini-tracheostomy tube used? *Yes* ☐ *No* ☐

OPERATIVE STRATEGY

	Yes	*No*	
Was a frozen section biopsy **PLANNED?**	☐	☐	**Diagnostic refers to a result where a specific aetiology (benign or malignant) has been identified.*
If **YES,** was a frozen section biopsy **ATTEMPTED?**	☐	☐	If **NO,** provide reason: _____
If **YES,** was the frozen section **DIAGNOSTIC*?**	☐	☐	If **NO,** provide reason: _____
If **YES**, was malignancy confirmed?	☐	☐	

INTRA-OPERATIVE ANALGESIA

Analgesia type	Given Yes	Given No	Specify drug	Concen-tration (%)	Total Dose Given	Units (mg / g / ml)
Single-shot Paravertebral block	☐	☐			☐☐☐☐	
Epidural	☐	☐			☐☐☐☐	
Paravertebral catheter	☐	☐			☐☐☐☐	
Intercostal block	☐	☐			☐☐☐☐	
Other, specify	☐	☐			☐☐☐☐	
Other, specify	☐	☐			☐☐☐☐	
Other, specify	☐	☐			☐☐☐☐	

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

OPERATION DETAILS

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

DETAILS OF THE RESECTION

Provide details of the type / extent of surgery:

	Yes	No	
Open & Close (benign disease on frozen section)	☐	☐	If **YES,** skip remaining 'C' forms
If YES, specify biopsy type:			Needle only ☐ Wedge only ☐
Open & Close (inoperable /extensive malignancy)	☐	☐	If **YES,** skip remaining 'C' forms
Resection of airway without the removal of lung parenchyma	☐	☐	
Pneumonectomy*	☐	☐	
Lobectomy / Bilobectomy	☐	☐	If yes, specify lobe (s): ☐ & ☐
Segmentectomy*	☐	☐	If yes, specify lobe (s): ☐ & ☐
Wedge resection*	☐	☐	If yes, specify lobe (s): ☐ & ☐

1= Right upper lobe
2= Right middle lobe
3= Right lower lobe
4= Left upper lobe
5= Left lower lobe

*If a **PNEUMONECTOMY, SEGMENTECTOMY OR WEDGE RESECTION** was performed, please state reason:

_____

ALLOCATION ADHERENCE

	Yes	No
Was the patients surgery performed in accordance with their random allocation?	☐	☐

Did any of the following difficulties / complications occur?

	Yes	No		Yes	No
Technical problems					
Equipment malfunction	☐	☐	Failure to progress	☐	☐
Poor visualisation	☐	☐			
Anatomical problems					
Diffuse pleural adhesion	☐	☐	Chest wall invasion	☐	☐
Requirement for sleeve resection	☐	☐	Calcified peri-arterial nodes	☐	☐
Absent or thick fissure	☐	☐			
Oncological conditions					
Discovery of N2 tumours	☐	☐	Invasion of the parietal pleura	☐	☐
Margin extension	☐	☐	Invasion of the artery	☐	☐

	Yes	No	N/A
If VATS surgery was allocated to the patient, was conversion to open surgery necessitated?	☐	☐	☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

OPERATION DETAILS

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

LYMPH NODE MANAGEMENT

Please identify the **locations** from which lymph nodes sampled were sampled:

LEFT			***ZONE***			***RIGHT***		
#1	*Yes* ☐	*No* ☐	**Supraclavicular Zone**			*Yes* ☐	*No* ☐	
			Upper Mediastinal Zone					
#2L	*Yes* ☐	*No* ☐	Upper Paratracheal			#2R	*Yes* ☐	*No* ☐
#3aL	*Yes* ☐	*No* ☐	Pre-vascular			#3aR	*Yes* ☐	*No* ☐
			Retrotracheal #3p	*Yes* ☐	*No* ☐			
#4L	*Yes* ☐	*No* ☐	Lower paratracheal			#4R	*Yes* ☐	*No* ☐
			Aorta-Pulmonary Zone					
			Sub-aortic #5	*Yes* ☐	*No* ☐			
			Para-aortic #6	*Yes* ☐	*No* ☐			
			Subcarinal Zone					
			Subcarinal #7	*Yes* ☐	*No* ☐			
			Lower Mediastinal Zone					
#8L	*Yes* ☐	*No* ☐	Paraoesophageal			#8R	*Yes* ☐	*No* ☐
#9L	*Yes* ☐	*No* ☐	Pulmonary ligament nodes			#9R	*Yes* ☐	*No* ☐
			Hilar / Interlobar Zone					
#10L	*Yes* ☐	*No* ☐	Hilar			#10R	*Yes* ☐	*No* ☐
#11L	*Yes* ☐	*No* ☐	Interlobar			#11R	*Yes* ☐	*No* ☐
			Peripheral Zone					
#12L	*Yes* ☐	*No* ☐	Lobar			#12R	*Yes* ☐	*No* ☐
#13L	*Yes* ☐	*No* ☐	Segmental			#13R	*Yes* ☐	*No* ☐
#14L	*Yes* ☐	*No* ☐	Subsegmental			#14R	*Yes* ☐	*No* ☐

INTRA-OPERATIVE COMPLICATIONS (COMPLETE FOR ALL PATIENTS—VATS & OPEN SURGERY)

	Yes	*No*	*CTCAE GRADE v4*
Bronchus injury	☐	☐	☐
Bleeding from vascular injury	☐	☐	☐

For CTCAE grade descriptions see v4:
Bronchus injury: page 96
Bleeding from vascular injury: page 94

If **YES**, specify bleed site: _____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

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OPERATION DETAILS

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

OPERATION DETAILS

Please provide details of the thoracotomy performed:

	Yes	No	N/A
Anterior thoracotomy	☐	☐	☐
Postero-lateral thoracotomy	☐	☐	☐
Was a muscle sparing approach used?	☐	☐	☐

N/A if VATS was performed

If **YES,** specify:

Serratus muscle 'spared' *Yes* ☐ *No* ☐ Latissimus muscle 'spared' *Yes* ☐ *No* ☐

INCISIONS / PORT / STAPLE DETAILS

Specify the number of ports / incisions used: ☐ If >4 ports were used, give reason: _____

Was rib-*spreading* performed? *Yes* ☐ *No* ☐ Was rib-*resection* performed? *Yes* ☐ *No* ☐

Specify the number of staples used during the procedure *(if none enter 0)*:

Bronchus ☐☐ Lung ☐☐ Blood vessels ☐☐

Specify the brand of staples used *(tick one)*:

J & J / Ethicon ☐ Medtronic/Covidien ☐ Other ☐

If **OTHER**, specify: _____

DRAIN LOCATIONS

Specify the number of drains inserted: ☐

Were **all** drains located at the port / incision *Yes* ☐ *No* ☐

BLINDING

Did the patient remain blinded pre-operatively? *Yes* ☐ *No* ☐

If **NO,** provide reason for unblinding? _____

Have adhesive dressings been applied to cover *ALL REAL **AND** POTENTIAL* thoracotomy incision (s) / port locations? *Yes* ☐ *No* ☐

If **NO,** provide reason why the dressings were not applied: _____

PROCEDURAL OUTCOME

Did the patient die in theatre? *Yes* ☐ *No* ☐ If **YES,** complete an SAE form.

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

POST OPERATIVE DETAILS

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

IN HOSPITAL COMPLICATIONS

*The following events are all 'expected' and therefore **do not** require an SAE form to be completed. Please report events according to the CTCAE criteria (v4) and provide the details of the worst grade experienced during the patients in-hospital stay*

PULMONARY COMPLICATIONS

	YES	NO		CTCAE GRADE v5	SAE YES	SAE NO
Acute respiratory failure	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __	☐	☐	☐
Pulmonary collapse (requiring intervention -CPAP)	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __	☐	☐	☐
Empyema°	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __	☐	☐	☐
Surgical emphysema (requiring intervention)	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __	☐	☐	☐
Bronchopleural fistula	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __	☐	☐	☐
Post-drain pneumothorax requiring intervention*	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __	☐	☐	☐
Chylothorax	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __	☐	☐	☐
ARDS¥	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __	☐	☐	☐
Acute lung injury (ALI)#	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __	☐	☐	☐
Pulmonary embolus	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __	☐	☐	☐
Insertion of a mini-tracheostomy tube	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __	☐	☐	☐
Bronchoscopy	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐	☐

If **YES**, please specify reason:

	YES	NO		YES	NO	
Pulmonary collapse	☐	☐	Other	☐	☐	If **OTHER,** please specify: _____

Pleural effusion	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __	☐	☐	☐
Prolonged air leak	☐	☐	If yes, give date of drain removal: __ __ /__ __ /__ __ __ __	☐	☐	☐

°Defined as the requirement for antibiotics or drainage
**Other post drain pneumothorax requiring intervention*
¥ ARDS: Acute onset of respiratory failure, defined by bilaterial infiltrates on chest radiography, hypoxia defined by a Pa02 / Fi02 ratio ≤200mmHg (26.66kPa) and no evidence of left atrial hypertension or a pulmonary capillary pressure <18mmHg (2.4kPa) to rule out cardiogenic oedema
#Acute Lung Injury (ALI), defined as above but a 200 <Pa02 / Fi02 ≤300mmHg (40kPa)

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

IN-HOSPITAL COMPLICATIONS

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

*The following events are all 'expected' and therefore **do not** require an SAE form to be completed.*
Please report events according to the CTCAE (v4) criteria and provide the details of the worst grade experienced during the patients in-hospital stay

CARDIAC COMPLICATIONS

	YES	NO		CTCAE GRADE v5	SAE YES	SAE NO
Myocardial infarction	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐	☐
Arrhythmia (requirement treatment)	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐	☐

RENAL COMPLICATIONS

	YES	NO		CTCAE GRADE v5	SAE YES	SAE NO
Acute Kidney Injury	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐	☐
Haemofiltration	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐	☐

Acute Kidney Injury is defined by a rise in serum creatinine >50% preoperative value to any rise above the reference range in previously normal values

GASTRO-INTESTINAL COMPLICATIONS

	YES	NO		CTCAE GRADE v5	SAE YES	SAE NO
Peptic ulcer/ GI bleed / perforation	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐	☐
Pancreatitis	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐	☐
Other gastrointestinal complication	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐	☐

If **OTHER** gastrointestinal complication, please specify: _____

INFECTIVE COMPLICATIONS

	YES	NO		CTCAE GRADE v5	SAE YES	SAE NO
Infection*	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐	☐

If **YES**, specify the site / extent of infection:

	YES	NO		YES	NO
Pneumonia / Chest infection*	☐	☐	Wound infection*	☐	☐
Other infection*	☐	☐	If **OTHER,** please specify: _____		

**Defined as the requirement for antibiotic treatment for suspected infection*

NEUROLOGICAL COMPLICATIONS

	YES	NO		CTCAE GRADE v5	SAE YES	SAE NO
Transient ischaemic attack (TIA)	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐	☐
Stroke	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐	☐
Acute psychosis	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐	☐

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

IN-HOSPITAL COMPLICATIONS

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

*The following events are all 'expected' and therefore **do not** require an SAE form to be completed.*
Please report events according to the CTCAE criteria and provide the details of the worst grade experienced during the patients in-hospital stay

OTHER COMPLICATIONS

	YES	NO		CTCAE GRADE v5	SAE YES	SAE NO
Wound dehiscence requiring treatment	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐	☐
If **YES**, specify treatment:						
Suture / Staple	☐	☐	Vacuum assisted closure (VAC) YES ☐ NO ☐			
Other	☐	☐	If **OTHER,** please specify: _____			
Laryngeal nerve damage	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __	☐	☐	☐
Deep vein thrombosis	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __	☐	☐	☐
Haematoma	☐	☐	If yes, give __ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐	☐

REOPERATION

	YES	NO		CTCAE GRADE v5	SAE YES	SAE NO
Re-operation	☐	☐	If yes, give date: __ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐	☐

If **YES**, please identify the reason for the *reoperation*:

Bleeding	☐	☐	Prolonged air leak	☐	☐
Other	☐	☐	If **OTHER,** please specify: _____		

UNEXPECTED COMPLICATIONS

*Any other events <u>not</u> listed on CRFs D1-D3 are 'unexpected' and therefore **<u>DO</u>** require an SAE form to be completed, if they meet the SAE criteria**

Did the patient experience any OTHER events **<u>NOT</u>** listed on CRFs D1-D3 that meet the SAE criteria*? *Yes* ☐ *No* ☐

If YES, complete an SAE form (CRF S1-S2) for each event

**SAE criteria: i) Increased length of hospital admission, ii) life threatening, iii) persistent or significant disability, iv) caused death, v) Other serious (important medical event)*

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

* *Names must appear on the site signature & delegation log*

The VIOLET Study

DISCHARGE SUITABILITY

Patient Name: _____

VIOLET Trial ID: ☐☐☐-☐☐☐☐

D4

DISCHARGE SUITABILITY (TO BE COMPLETED DAILY DURING THE PATIENTS POST-OP STAY)

To be completed daily during the patients post-op recovery, starting the day **after** surgery (day of surgery +1):

Day	Date	Satisfactory mobility?	Pain under control with oral analgesia?	Satisfactory Hb & electrolytes¥?	Satisfactory chest X-ray?	**Free** from complications requiring treatment?	If **YES** (TO ALL) but the patient has not been discharged, provide reason:
		YES NO	YES NO	YES NO	YES NO N/D*	YES NO	
1.	_ _ / _ _ /_ _ _ _	☐ ☐	☐ ☐	☐ ☐	☐ ☐ ☐	☐ ☐	
2.	_ _ / _ _ /_ _ _ _	☐ ☐	☐ ☐	☐ ☐	☐ ☐ ☐	☐ ☐	
3.	_ _ / _ _ /_ _ _ _	☐ ☐	☐ ☐	☐ ☐	☐ ☐ ☐	☐ ☐	
4.	_ _ / _ _ /_ _ _ _	☐ ☐	☐ ☐	☐ ☐	☐ ☐ ☐	☐ ☐	
5.	_ _ / _ _ /_ _ _ _	☐ ☐	☐ ☐	☐ ☐	☐ ☐ ☐	☐ ☐	
6.	_ _ / _ _ /_ _ _ _	☐ ☐	☐ ☐	☐ ☐	☐ ☐ ☐	☐ ☐	
7.	_ _ / _ _ /_ _ _ _	☐ ☐	☐ ☐	☐ ☐	☐ ☐ ☐	☐ ☐	
8.	_ _ / _ _ /_ _ _ _	☐ ☐	☐ ☐	☐ ☐	☐ ☐ ☐	☐ ☐	
9.	_ _ / _ _ /_ _ _ _	☐ ☐	☐ ☐	☐ ☐	☐ ☐ ☐	☐ ☐	
10.	_ _ / _ _ /_ _ _ _ (d d m m y y y y)	☐ ☐	☐ ☐	☐ ☐	☐ ☐ ☐	☐ ☐	

¥Hb & electrolytes are considered satisfactory if no interventions are required.

****Chest X-ray not done / not repeated)***

BANG BLINDING INDEX (BBI)

2 days post-op *(Day of surgery + 2 days)*

Did the patient complete the BBI? ***YES*** ☐ ***NO*** ☐

If **NO**, provide reason code ☐ If **OTHER**, please specify: _____

Day of discharge

Did the patient complete the BBI? ***YES*** ☐ ***NO*** ☐

If **NO**, provide reason code ☐ If **OTHER**, please specify: _____

1: Patient refused, 2: Patient unwell, 3: Patient upset, 4: Inconvenient, 5: Administrative failure, 6: Other

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __ / __ __ / __ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ / __ __ / __ __ __ __

** Names must appear on the site signature & delegation log*

IN HOSPITAL PAIN SCORES

D5

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

PAIN SCORE: DAY 1

TO BE COMPLETED BY STAFF ON BEHALF OF THE PATIENT ON DAY 1 POST-OP:

NB: Day of surgery = Day 0

Was the patients pain score recorded at 1 day post-op? *Yes* ☐ *No* ☐ If **NO,** provide reason: ☐

1: Patient refused, 2: Patient unwell, 3: Patient upset, 4: Inconvenient, 5: Administrative failure, 6: Patient discharged, 7:Other

If **YES,** provide complete the following:

Date of assessment: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) Time: ☐☐:☐☐ (*24 hr clock*)

Please ask the patient to choose a number that reflects their current pain, where 0 = no pain and 10 = worst pain possible *(please circle)*:

0 1 2 3 4 5 6 7 8 9 10

NO PAIN ***WORST PAIN POSSIBLE***

PAIN SCORE: DAY 2

TO BE COMPLETED BY STAFF ON BEHALF OF THE PATIENT ON DAY 2 POST-OP:

NB: Day of surgery = Day 0

Was the patients pain score recorded at 2 day post-op? *Yes* ☐ *No* ☐ If **NO,** provide reason: ☐

1: Patient refused, 2: Patient unwell, 3: Patient upset, 4: Inconvenient, 5: Administrative failure, 6: Patient discharged, 7:Other

If **YES,** provide complete the following:

Date of assessment: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) Time: ☐☐:☐☐ (*24 hr clock*)

Please ask the patient to choose a number that reflects their current pain, where 0 = no pain and 10 = worst pain possible *(please circle)*:

0 1 2 3 4 5 6 7 8 9 10

NO PAIN ***WORST PAIN POSSIBLE***

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

IN HOSPITAL SUMMARY

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

CLAVIEN-DINDO CLASSIFICATION

Please give an **overall assessment** of patient recovery based on Clavien-Dindo classification criteria:

None	☐	*Normal recovery (no complications)*
Grade I	☐	*Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions.*
Grade II	☐	*Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.*
Grade III a	☐	*Requiring surgical, endoscopic or radiological intervention. Intervention not under general anaesthesia*
Grade III b	☐	*Requiring surgical, endoscopic or radiological intervention. Intervention under general anaesthesia*
Grade IV a	☐	*Life-threatening complication (including CNS complications) requiring IC/ICU-management . Single organ dysfunction (including dialysis)*
Grade IV b	☐	*Life-threatening complication (including CNS complications) requiring IC/ICU-management . Multi organ dysfunction.*
Grade V	☐	*Death of a patient.*

WARD MOVEMENTS

Please provide any ward movements or changes in level of care, after return from theatre until the patient is discharged.

	Transfer date & time (e.g. date & time of change in level of care/ward, discharge etc.) If the exact time is unknown, complete to the nearest hour	**New level of care/ward/discharge** (use code)
1	__ __ /__ __ /__ __ __ __ (d d m m y y y y) ___ ___ : ___ ___ (24 hr clock)	Code ☐
2	__ __ /__ __ /__ __ __ __ (d d m m y y y y) ___ ___ : ___ ___ (24 hr clock)	Code ☐
3	__ __ /__ __ /__ __ __ __ (d d m m y y y y) ___ ___ : ___ ___ (24 hr clock)	Code ☐
4	__ __ /__ __ /__ __ __ __ (d d m m y y y y) ___ ___ : ___ ___ (24 hr clock)	Code ☐
5	__ __ /__ __ /__ __ __ __ (d d m m y y y y) ___ ___ : ___ ___ (24 hr clock)	Code ☐

New level of care/ward codes: *1= Level 0 / 1 (eg. General ward), 2= Level 2, usually 2:1 nursing ratio (eg. HDU) 3= Level 3, usually 1:1 nursing ratio (eg. ICU), 4= Hospital discharge home, 5=Hospital discharge to another hospital, 6=Other hospital discharge (e.g. nursing home) 7= Patient died*

DISCHARGE DETAILS

Were all drains removed prior to discharge? ***YES*** ☐ ***NO*** ☐ If **YES,** specify date last drain removed: __ __ /__ __ /__ __ __ __ (d d m m y y y y)

Discharge destination

^If patient died, complete SAE form

Home ☐ *Nursing home* ☐ *Residential home* ☐ *Patient died^* ☐ *Other hospital** ☐

*Other ward within hospital** ☐ *Other** ☐

*Name of ward/hospital/other: _____

Date of discharge/death: __ __ /__ __ /__ __ __ __ (d d m m y y y y)

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

POST-OP TO DISCHARGE ANALGESIA

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

IN-HOSPITAL (POST-OPERATIVE) ANALGESIA

Please identify the analgesia that the patient has received throughout the **duration of their post-operative stay** (i.e from the return of patient from theatre and until discharge)

Analgesia type / name	Given YES	Given NO	Specify drug (generic name)	Route of Administration (circle)	Total Dose	Units (circle)	Units If OTHER, specify:	Treatment duration (days)
Paravertebral block	☐	☐				mg / g/ ml / OTHER		
Epidural	☐	☐				mg / g/ ml / OTHER		
Paravertebral catheter	☐	☐				mg / g/ ml / OTHER		
Intercostal block	☐	☐				mg / g/ ml / OTHER		
Patient controlled analgesia (PCA)	☐	☐				mg / g/ ml / OTHER		
Tramadol	☐	☐				mg / g/ ml / OTHER		
Dihydrocodeine	☐	☐				mg / g/ ml / OTHER		
Paracetamol	☐	☐		IV / ORAL		mg / g/ ml / OTHER		
Cocodamol	☐	☐				mg / g/ ml / OTHER		
Oxynorm	☐	☐				mg / g/ ml / OTHER		
Oxycontin	☐	☐				mg / g/ ml / OTHER		
Ibuprofen	☐	☐				mg / g/ ml / OTHER		
Diclofenac	☐	☐				mg / g/ ml / OTHER		
Oromorph	☐	☐				mg / g/ ml / OTHER		
Gabapentin	☐	☐				mg / g/ ml / OTHER		
Pregabalin	☐	☐				mg / g/ ml / OTHER		
Lidocaine patches	☐	☐				mg / g/ ml / OTHER		
Other, specify	☐	☐		IV / ORAL / SUB-CUT / OTHER		mg / g/ ml / OTHER		
Other, specify	☐	☐		IV / ORAL / SUB-CUT / OTHER		mg / g/ ml / OTHER		
Other, specify	☐	☐		IV / ORAL / SUB-CUT / OTHER		mg / g/ ml / OTHER		

Multiple copies of this CRF can be completed if required

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

D8

ANALGESIA PRESCRIBED AT DISCHARGE

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

ANALGESIA PRESCRIBED AT DISCHARGE

Has the patient been discharged with any *analgesia* ? *Yes* ☐ *No* ☐ If **YES**, please specify below

Medication at discharge: Name	Medication at discharge: If OTHER, specify	Given? Yes	Given? No	Dose	Units (circle)	If OTHER, specify:	Frequency (circle)	Frequency: If **PRN** or **OTHER**, specify frequency:
Tramadol		☐	☐		mg / g/ ml / OTHER		OD / BD / TD/ QD / PRN / OTH	
Dihydrocodeine		☐	☐		mg / g/ ml / OTHER		OD / BD / TD/ QD / PRN / OTH	
Paracetamol		☐	☐		mg / g/ ml / OTHER		OD / BD / TD/ QD / PRN / OTH	
Cocodamol		☐	☐		mg / g/ ml / OTHER		OD / BD / TD/ QD / PRN / OTH	
Oxynorm		☐	☐		mg / g/ ml / OTHER		OD / BD / TD/ QD / PRN / OTH	
Oxycontin		☐	☐		mg / g/ ml / OTHER		OD / BD / TD/ QD / PRN / OTH	
Ibuprofen		☐	☐		mg / g/ ml / OTHER		OD / BD / TD/ QD / PRN / OTH	
Diclofenac		☐	☐		mg / g/ ml / OTHER		OD / BD / TD/ QD / PRN / OTH	
Oromorph		☐	☐		mg / g/ ml / OTHER		OD / BD / TD/ QD / PRN / OTH	
Gabapentin		☐	☐		mg / g/ ml / OTHER		OD / BD / TD/ QD / PRN / OTH	
Pregabalin		☐	☐		mg / g/ ml / OTHER		OD / BD / TD/ QD / PRN / OTH	
Lidocaine patches		☐	☐		mg / g/ ml / OTHER		OD / BD / TD/ QD / PRN / OTH	
Other		☐	☐		mg / g/ ml / OTHER		OD / BD / TD/ QD / PRN / OTH	
Other		☐	☐		mg / g/ ml / OTHER		OD / BD / TD/ QD / PRN / OTH	
Other		☐	☐		mg / g/ ml / OTHER		OD / BD / TD/ QD / PRN / OTH	
Other		☐	☐		mg / g/ ml / OTHER		OD / BD / TD/ QD / PRN / OTH	

Multiple copies of this CRF can be completed if required

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

PATHOLOGY / HISTOLOGY

D9

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

SAMPLE DETAILS

Has a sample of **primary tumour** been taken for analyses? *Yes* ☐ *No* ☐

*If **NO,** please complete following question only.*
*If **YES,** please complete the entire form.*

If **NO,** please specify the reason why:

Tumour not excised (e.g. Open / close) ☐ Other ☐ If **OTHER**, please specify*:* _____

If **YES,** has the primary tumour been Formalin Fixed & Paraffin Embedded (FFPE)? *Yes* ☐ *No* ☐

TUMOUR STAGE & TYPE

Please classify the pTNM stage of the **primary tumour** by post-surgical / pathological findings: T (a/b/c) ☐☐ N ☐ M (a/b/c) ☐☐

No cancer / benign disease ☐

Specify the size of the primary tumour size *(longest dimension)*: ☐☐.☐ cm

Please identify the tumour type of the **primary tumour**:

NSCLC *Yes* ☐ *No* ☐ SCLC *Yes* ☐ *No* ☐ Carcinoid *Yes* ☐ *No* ☐

Other ☐ ☐ If **OTHER**, please specify*:* _____

If **NSCLC,** specify type *(tick all that apply)*:

Squamous cell carcinoma *Yes* ☐ *No* ☐ Adenocarcinoma *Yes* ☐ *No* ☐ Large cell carcinoma *Yes* ☐ *No* ☐

Other ☐ ☐ If **OTHER**, please specify*:* _____

RESECTION COMPLETENESS

Please provide details of the resection completeness below *(tick one)*:

R0 (No residual tumour) ☐ R1 (microscopic residual tumour) ☐

R1 (Other than microscopic residual tumour) ☐ R2 (Macroscopic residual tumour) ☐

Completeness of resection unknown ☐

If **R1,** please specify the location of the residual margin *(tick one)*:

Bronchial margin ☐ Lung tissue margin ☐

Vascular margin ☐ Other Peripheral (e.g. chest wall, mediastinum or diaphragm) ☐

No data ☐

If **R2 (macroscopic residual tumour),** please specify the location of the macroscopic residual: _____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

PATHOLOGY / HISTOLOGY

D10

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

LYMPH NODE INVOLVEMENT

Please provide details of the lymph nodes sampled *(tick all that apply)*:

+ve = positive lymph node, -ve = negative lymph node, ND = Not done (not sampled)

Left						***ZONE***						***Right***					
#1	+ve	☐	-ve	☐	ND ☐	**Supraclavicular Zone**			+ve	☐		-ve	☐		ND	☐	
						Upper Mediastinal Zone											
#2L	+ve	☐	-ve	☐	ND ☐	*Upper Paratracheal*			#2R	+ve	☐	-ve	☐		ND	☐	
#3aL	+ve	☐	-ve	☐	ND ☐	*Prevascular*			#3aR	+ve	☐	-ve	☐		ND	☐	
						Retrotracheal		#3p	+ve	☐	-ve	☐	ND	☐			
#4L	+ve	☐	-ve	☐	ND ☐	*Lower paratracheal*			#4R	+ve	☐	-ve	☐		ND	☐	
						Aorta-Pulmonary Zone											
						Sub-aortic #5			+ve	☐	-ve	☐	ND	☐			
						Para-aortic #6			+ve	☐	-ve	☐	ND	☐			
						Subcarinal Zone											
						Subcarinal #7			+ve	☐	-ve	☐	ND	☐			
						Lower Mediastinal Zone											
#8L	+ve	☐	-ve	☐	ND ☐	*Paraoesophageal*			#8R	+ve	☐	-ve	☐		ND	☐	
#9L	+ve	☐	-ve	☐	ND ☐	*Pulmonary ligament nodes*			#9R	+ve	☐	-ve	☐		ND	☐	
						Hilar / Interlobar Zone											
#10L	+ve	☐	-ve	☐	ND ☐	*Hilar*			#10R	+ve	☐	-ve	☐		ND	☐	
#11L	+ve	☐	-ve	☐	ND ☐	*Interlobar*			#11R	+ve	☐	-ve	☐		ND	☐	
						Peripheral Zone											
#12L	+ve	☐	-ve	☐	ND ☐	*Lobar*			#12R	+ve	☐	-ve	☐		ND	☐	
#13L	+ve	☐	-ve	☐	ND ☐	*Segmental*			#13R	+ve	☐	-ve	☐		ND	☐	
#14L	+ve	☐	-ve	☐	ND ☐	*Subsegmental*			#14R	+ve	☐	-ve	☐		ND	☐	

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

The VIOLET Study

VISIT DETAILS [VISIT NAME]

E1

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

VISIT / CALL DETAILS

For information, the date of the patient's previous visit/discharge from hospital was dd/mm/yyyy

Attended visit in person? *Yes* ☐ *No* ☐ If **NO**, provide reason[1]: ☐

1: Planned telephone follow-up (3 & 6 month only), 2: Other telephone consultation, 3: Patient died (complete SAE form), 4: Patient withdrawn, 5: Medical reason, 6: Unable to contact, 7: Other

If **OTHER**, please specify: _____

If patient attended visit or was followed up by telephone, provide date of visit/call: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

DISCHARGE DESTINATION—5 WEEK VISIT ONLY

After discharge from insert name of hospital where lobectomy was performed on dd/mm/yyyy, the patient was transferred to insert name of ward/ hospital/ other (D5).

How long did the patient stay at this hospital? ☐☐ days

RESOURCE USE SUMMARY

Has the patient had any of the following since their last VIOLET follow-up / discharge:

	Yes	*No*	If **YES**, how many times?	
Hospital admissions?°	☐	☐	☐☐	*Provide further details on E5*
Other hospital visits?¥	☐	☐	☐☐	*Provide further details on E6*
Care in the community?#	☐	☐	☐☐	*Provide further details on E7*

°Hospital admissions are defined as overnight stays in hospital. Include both planned and unplanned admissions
*¥Other hospital visits include any other visits to hospital that **do not** result in admission (overnight stays). Include both planned and unplanned hospital visits*
#Care in community includes all consultations (telephone and face-to-face) with medical practitioners such as GPs, nurses, and staff at NHS walk-in centres. Include both planned and unplanned care.

DO NOT INCLUDE VISITS PREVIOUS DOCUMENTED ON THE 'RESOURCE USE REPORT'

BIOLOGICAL SUB-STUDY—5 WEEK & 12 MONTH VISIT ONLY (only complete If patient has consented to sub-study)

Blood sample taken: *Yes* ☐ *No* ☐ Please indicate timepoint: *5wk* ☐ *12mth* ☐

If **YES**, date and time taken: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) ☐☐:☐☐ (*24 hr clock*)

If **NO**, provide reason: _____

Please stick a barcode label from blood kit box in this box

FedEx Tracking Number: ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Has the blood sample box been collected by the courier?: *Yes* ☐ If **YES**, date collected: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

No ☐ If **NO**, provide reason: _____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

The VIOLET Study

RESOURCE USE REPORT [VISIT NAME]

VIOLET Trial ID: | | | | - | | | | |

Patient Name: _____

PREVIOUSLY REPORTED HOSPITAL ADMISSIONS (OVERNIGHT STAYS)

Listed below are all hospital admissions (overnight stays) that have been reported in the study to date

Database will produce a list as follows:

Name of hospital	Date of admission	Length of admission	Reason for admission	Associated AE's (codes)

PREVIOUSLY REPORTED HOSPITAL VISITS

Listed below are all hospital visits that have been reported in the study to date

Database will produce a list as follows:

Name of hospital	Date of visit	Type of visit	Reason for visit

PREVIOUSLY REPORTED HEALTHCARE IN THE COMMUNITY

Listed below are the community healthcare services that the patient has reported using in the study to date

Database will produce a list as follows:

Type of service used	Date of visit	Reason for visit

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

PREVIOUSLY REPORTED / ONGOING ANALGESIA [VISIT NAME]

E2

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: ______________________________

PREVIOUSLY REPORTED / ONGOING ANALGESIA

Medication at last visit: Name	Dose	Units	Frequency	Still taking medication?	If NO, date stopped	If still taking medication, still taking same dose?	If NO, date changed	Dose	Units (circle)	Frequency (circle)	If PRN or OTHER, specify:
				Yes ☐ No ☐	d d / m m / y y y y	Yes ☐ No ☐	d d / m m / y y y y		mg / g / ml / other, specify:	OD / BD / TD QD / PRN / OTH	
				Yes ☐ No ☐	d d / m m / y y y y	Yes ☐ No ☐	d d / m m / y y y y		mg / g / ml / other, specify:	OD / BD / TD QD / PRN / OTH	
				Yes ☐ No ☐	d d / m m / y y y y	Yes ☐ No ☐	d d / m m / y y y y		mg / g / ml / other, specify:	OD / BD / TD QD / PRN / OTH	
				Yes ☐ No ☐	d d / m m / y y y y	Yes ☐ No ☐	d d / m m / y y y y		mg / g / ml / other, specify:	OD / BD / TD QD / PRN / OTH	
				Yes ☐ No ☐	d d / m m / y y y y	Yes ☐ No ☐	d d / m m / y y y y		mg / g / ml / other, specify:	OD / BD / TD QD / PRN / OTH	
				Yes ☐ No ☐	d d / m m / y y y y	Yes ☐ No ☐	d d / m m / y y y y		mg / g / ml / other, specify:	OD / BD / TD QD / PRN / OTH	
				Yes ☐ No ☐	d d / m m / y y y y	Yes ☐ No ☐	d d / m m / y y y y		mg / g / ml / other, specify:	OD / BD / TD QD / PRN / OTH	
				Yes ☐ No ☐	d d / m m / y y y y	Yes ☐ No ☐	d d / m m / y y y y		mg / g / ml / other, specify:	OD / BD / TD QD / PRN / OTH	
				Yes ☐ No ☐	d d / m m / y y y y	Yes ☐ No ☐	d d / m m / y y y y		mg / g / ml / other, specify:	OD / BD / TD QD / PRN / OTH	
				Yes ☐ No ☐	d d / m m / y y y y	Yes ☐ No ☐	d d / m m / y y y y		mg / g / ml / other, specify:	OD / BD / TD QD / PRN / OTH	

Name of person completing form* (capitals): ______________________________

Signature of person completing form: ____________________ Date completed *(dd/mm/yyyy)*: __ __/__ __/__ __ __ __

Name of person entering data* (capitals) ______________________________

Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

NEW ANALGESIA [VISIT NAME]

E3

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: ______________________________

NEW ANALGESIA

Has the patient started any new analgesia? Yes ☐ No ☐ **If YES**, please specify below

Name of drug (Generic name)	**Date started**	**Dose** Dose (e.g. 500)	Units (circle)	If OTHER, specify:	**Frequency** (circle)	If **PRN** or **OTHER**, specify:	**Still taking medica-tion?**	**If NO, date stopped**
	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)		mg / g / ml / OTHER		OD / BD / TD QD / PRN / OTH		Yes ☐ No ☐	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)
	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)		mg / g / ml / OTHER		OD / BD / TD QD / PRN / OTH		Yes ☐ No ☐	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)
	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)		mg / g / ml / OTHER		OD / BD / TD QD / PRN / OTH		Yes ☐ No ☐	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)
	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)		mg / g / ml / OTHER		OD / BD / TD QD / PRN / OTH		Yes ☐ No ☐	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)
	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)		mg / g / ml / OTHER		OD / BD / TD QD / PRN / OTH		Yes ☐ No ☐	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)
	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)		mg / g / ml / OTHER		OD / BD / TD QD / PRN / OTH		Yes ☐ No ☐	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)
	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)		mg / g / ml / OTHER		OD / BD / TD QD / PRN / OTH		Yes ☐ No ☐	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)
	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)		mg / g / ml / OTHER		OD / BD / TD QD / PRN / OTH		Yes ☐ No ☐	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)
	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)		mg / g / ml / OTHER		OD / BD / TD QD / PRN / OTH		Yes ☐ No ☐	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)
	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)		mg / g / ml / OTHER		OD / BD / TD QD / PRN / OTH		Yes ☐ No ☐	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)
	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)		mg / g / ml / OTHER		OD / BD / TD QD / PRN / OTH		Yes ☐ No ☐	_ _ / _ _ / _ _ _ _ (d d / m m / y y y y)

Multiple copies of this CRF can be completed if required

Name of person completing form* (capitals): ______________________________

Signature of person completing form: ______________________ Date completed *(dd/mm/yyyy)*: __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) ______________________________

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

ADJUVANT THERAPY [VISIT NAME]

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

PREVIOUSLY REPORTED ADJUVANT THERAPY

Listed below are details of the adjuvant (post-operative) treatments that have been reported throughout the patients involvement in the study to date.

Database will produce a list as follows:

Treatment type	Start date	No. of treatments completed	Chemotherapy agents	Treatment ongoing?	If **NO,** end date:

ONGOING & NEW ADJUVANT THERAPY

Please provide details of any treatments which are new (have started since the last follow-up visit / discharge) and / or update the details of any treatments which were previously reported as 'Ongoing'. A list of treatments previously reported is provided above.

	Chemotherapy	**Radiotherapy**
Treatment started?	*YES* ☐ *NO* ☐	*YES* ☐ *NO* ☐
Start date:	__ __ /__ __ /__ __ __ __ (*d d m m y y y y*)	__ __ /__ __ /__ __ __ __ (*d d m m y y y y*)
Treatment ongoing?	*YES* ☐ *NO* ☐	*YES* ☐ *NO* ☐
If **NO**, provide date of final cycle / treatment:	__ __ /__ __ /__ __ __ __ (*d d m m y y y y*)	__ __ /__ __ /__ __ __ __ (*d d m m y y y y*)
Total number of cycles / treatments so far:	☐☐	☐☐

Chemotherapy agent (1): _____

Chemotherapy agent (2): _____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

The VIOLET Study

RESOURCE USE IN FOLLOW-UP PERIOD [VISIT NAME]

E5

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

ADMISSION NO: ☐☐

Please specify the route of admission:

Via A & E ☐ Via Other ☐ If **OTHER,** specify _____

Please specify the hospital to which the patient was admitted: _____

Please specify the date of admission: __ __ /__ __ /__ __ __ __ (d d m m y y y y)

Please specify the length of admission (days) ☐☐ Please specify the number of days spent in ICU (enter 0 if none) ☐☐

Please specify how the patient arrived at hospital:

Ambulance ☐ Hospital Transport ☐ Other ☐

Briefly describe the reason for the admission: _____

FOR RESEARCH NURSE USE ONLY:

*If the patient **IS** having adjuvant therapy, please report any SAEs that the patient has experienced since their last follow-up from the list of **EXPECTED POST-OP EVENTS SECTION AND EXPECTED CHEMO / RADIO EVENTS***
*If the patient **IS NOT** having adjuvant therapy, please report any SAEs that the patient has experienced since their last follow-up from the list of **EXPECTED POST-OP EVENTS ONLY***

Event code	Specify (if required)	Onset / start date	CTCAE grade (v4)	Relatedness*
☐☐	_____	__ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐
☐☐	_____	__ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐
☐☐	_____	__ __ /__ __ /__ __ __ __ (d d m m y y y y)	☐	☐

**Relatedness to the intervention (surgery) should be determined by the Principal Investigator and graded as: 1) Not related, 2) Unlikely to be related, 3) Possibly related, 4) Probably related, 5) Definitely related*

EXPECTED POST-OP EVENTS

***1)** Atelectasis / pulmonary collapse, **2**) Bronchopleural fistula, **3**) Empyema, **4**) Prolonged air leak or other post-drain pneumothorax, **5**) Pleural effusion, **6**) ARDS, **7**) Acute Lung Injury, **8**) Chylothorax, **9)** Bleeding, **10**) Haematoma**, 11)** Sepsis, **12)** Infection [chest]/ pneumonia, **13**) Infection [wound], **14**) Infection [other, specify], **15**) Transient ischaemic attack, **16**) Stroke, **17**) Haemofiltration, **18**) Wound dehiscence [requiring staple / suture], **19**) Wound dehiscence [requiring vacuum assisted closure], **20**) Would dehiscence [requiring other treatment, specify], **21**) Bronchoscopy [for pulmonary collapse], **22**) Bronchoscopy [for other reason, specify], **23)** Recurrence / progression, **24**) New cancer [primary or secondary], **25)** DVT, **26)** Venous thromboembolism (VTE), **27)** Pulmonary embolism, **28)** Reoperation [specify reason]*

EXPECTED CHEMO / RADIO EVENTS

***51**) Anaemia, **52**) Thrombocytopenia, **53**) Neutropenia / Febrile neutropenia, **54**) Myelosuppression, **55**) Nausea, **56**) Vomiting, **57**) Diarrhoea, **58**) Constipation, **59**) Peripheral sensory neuropathy, **60**) Peripheral motor neuropathy, **61**) Headaches, **62**) Insomnia **63**) Anaphylaxis / hypersensitivity reaction, **64**) Athralgia, **65**) Myalgia, **66**) Leukopenia, **67**) Elevated ALT / AST, **68**) Elevated alkaline phosphatase*

Has the patient experienced any OTHER events **NOT** listed above that met the criteria for an SAE[#]? *Yes* ☐ *No* ☐

If YES, complete an SAE form, (CRF S1-S2) for each event

[#] ***Defined as an event that resulted in: i) hospital admission or increased length of hospital admission, ii) life threatening, iii) persistent or significant disability, iv) caused death, v) Other serious (important medical event)***

A copy of this CRF should be completed for each admission.

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

The VIOLET Study

RESOURCE USE IN FOLLOW-UP PERIOD [VISIT NAME]

E6

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

NEW HOSPITAL VISIT NO: ☐☐

Please specify the type of visit *(tick one):*

Outpatients appointment ☐ A & E visit ☐ Other ☐ If **OTHER,** specify _____

Please specify the hospital that the patient attended: _____

Please specify how the patient arrived at hospital *(tick one):*

Ambulance ☐ Hospital Transport ☐ Other ☐

Specify the date of visit: __ __ /__ __ /__ __ __ __ (*d d / m m / y y y y*)

Specify the reason for visit:

	Yes	*No*	
Drain removal / check	☐	☐	
Chemo or radiotherapy	☐	☐	
Diagnostic imaging (scans)	☐	☐	If **YES,** specify scan type: CT scan ☐ Other ☐
Other reason	☐	☐	If **YES** specify: _____

If a CT scan has been performed please complete form I1

NEW HOSPITAL VISIT NO: ☐☐

Please specify the type of visit *(tick one):*

Outpatients appointment ☐ A & E visit ☐ Other ☐ If **OTHER,** specify _____

Please specify the hospital that the patient attended: _____

Please specify how the patient arrived at hospital *(tick one):*

Ambulance ☐ Hospital Transport ☐ Other ☐

Specify the date of visit: __ __ /__ __ /__ __ __ __ (*d d / m m / y y y y*)

Specify the reason for visit:

	Yes	*No*	
Drain removal / check	☐	☐	
Chemo or radiotherapy	☐	☐	
Diagnostic imaging (scans)	☐	☐	If **YES,** specify scan type: CT scan ☐ Other ☐
Other reason	☐	☐	If **YES** specify: _____

If a CT scan has been performed please complete form I1

Multiple copies of this form can be completed as required

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

RESOURCE USE IN FOLLOW-UP PERIOD [VISIT NAME]

E7

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

HEALTHCARE IN THE COMMUNITY VISIT NO: ☐☐

Please specify the service provider: *(tick one):*

GP ☐ Out-of-hours GP ☐ Nurse ☐

Other ☐ If **OTHER,** specify _____

Location of service use *(tick one):*

GP Surgery ☐ NHS walk-in centre ☐ Home ☐

By telephone ☐ Other ☐ If **OTHER,** specify _____

Date of service use: __ __ /__ __ /__ __ __ __
d d m m y y y y

Main reason for service use *(tick all that apply):*

Pain management ☐ Wound management ☐ Other ☐

If **OTHER,** specify _____

HEALTHCARE IN THE COMMUNITY VISIT NO: ☐☐

Please specify the service provider: *(tick one):*

GP ☐ Out-of-hours GP ☐ Nurse ☐

Other ☐ If **OTHER,** specify _____

Location of service use *(tick one):*

GP Surgery ☐ NHS walk-in centre ☐ Home ☐

By telephone ☐ Other ☐ If **OTHER,** specify _____

Date of service use: __ __ /__ __ /__ __ __ __
d d m m y y y y

Main reason for service use *(tick all that apply):*

Pain management ☐ Wound management ☐ Other ☐

If **OTHER,** specify _____

Multiple copies of this CRF can be completed if required

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

The VIOLET Study

IMAGING: 12 MONTH CT SCAN

F1

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

DETAILS OF IMAGING PERFORMED

Has the 12 month CT scan been performed? *Yes* ☐ *No* ☐

If **YES,** please complete PART A
If **NO,** please complete PART B.

PART A: THE 12 MONTH CT WAS PERFORMED

Please provide scan date: __ __ /__ __ /__ __ __ __
d d m m y y y y

Was the scan performed in accordance with the protocol *(1 year + / - 4 weeks)?*

Yes ☐ *No* ☐

If the scan was performed but was **not within** 4 weeks of the above date, please provide the main reason *(tick one)*:

Logistical issues ☐ Oversight / Error ☐

Other ☐ If **OTHER,** please specify: _____

TO BE COMPLETED BY A TRIAL SURGEON OR RADIOLOGIST

SCAN RESULTS:

Please identify the category that best describes the results of the scan *(select imaging classification below)* ☐

Imaging classification
1: No unequivocal evidence of progression –normal post lobectomy CT appearances
2: No unequivocal evidence of progression –however new CT findings warrant surveillance (e.g. indeterminate or inflammatory appearing lung nodules)
3: Disease status unknown –indeterminate CT findings require immediate work-up (e.g. new pleural effusion, new soft tissue at the surgical resection site)
4: Unequivocal radiological evidence of progression (e.g. new lymphadenopathy, distant metastasis, lymphangitis)
5: Unequivocal evidence of progression—pathologically proven

If the imaging has been classified as **4 or 5,** please complete the Recurrence form (G1)

Name of radiologist*: _____

PART B: THE 12 MONTH CT WAS NOT PERFORMED

If the 12 month CT scan was **NOT PERFORMED,** specify reason (s):

	Yes	*No*		*Yes*	*No*
Logistical issues	☐	☐	Oversight / Error	☐	☐
Recurrence confirmed ° *(scan not required)*	☐	☐	Scan recently performed so 12 month scan not appropriate/ required	☐	☐
Other	☐	☐	If **OTHER,** please specify: _____		

°If recurrence has been confirmed, please complete the Recurrence form (G1)
If a CT scan has recently been performed, please provide details on the I1 CRF

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

ADDITIONAL IMAGING

I1

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

DETAILS OF IMAGING PERFORMED

Provide date of the CT scan: __ __ /__ __ /__ __ __ __
d d m m y y y y

Identify the main reason why the additional imaging was performed *(tick one)*:

- ☐ Suspicion of recurrence prior to 12 month scan
- ☐ Assessment of a post-procedural complication
- ☐ Scan indicated by unrelated disorder / condition
- ☐ Other

If **OTHER**, please specify: _____

TO BE COMPLETED BY A TRIAL SURGEON OR RADIOLOGIST

SCAN RESULTS:

Please identify the category that best describes the results of the scan *(select imaging classification below)* ☐

Imaging classification
1: No unequivocal evidence of progression –normal post lobectomy CT appearances
2: No unequivocal evidence of progression –however new CT findings warrant surveillance (e.g. indeterminate or inflammatory appearing lung nodules)
3: Disease status unknown –indeterminate CT findings require immediate work-up (e.g. new pleural effusion, new soft tissue at the surgical resection site)
4: Unequivocal radiological evidence of progression (e.g. new lymphadenopathy, distant metastasis, lymphangitis)
5: Unequivocal evidence of progression—pathologically proven

If the imaging has been classified as **4 or 5,** please complete the Recurrence form (G1)

Name of radiologist*: _____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

The VIOLET Study

ACCESS TO MEDICAL RECORDS & FOLLOW-UP

MR$_1$

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

BASELINE QUESTIONNAIRES

Has the patient completed the baseline health questionnaire booklet? *Yes* ☐ *No* ☐

If **NO,** please ensure that the patient completes this prior to the their operation

TREATMENT DETAILS

Date of procedure / cycle / treatment: __ __ /__ __ /__ __ __ __
d d m m y y y y

What treatment did the patient undergo?

VATS Lobectomy ☐ Lobectomy via Open Surgery ☐

Other ☐ If **OTHER**, please specify*:* _____

SURVIVAL STATUS AT 1 YEAR POST-OP

Please identify the patients survival status 1 year after their operation:

Alive ☐ Lost to follow-up ☐

Dead ☐

If **DEAD,** please provide the date of death: __ __ /__ __ /__ __ __ __
d d m m y y y y

If **DEAD,** please specify the cause of death: _____

*NB: An SAE form is **NOT** required for patients participating in Access to Medical Records & FU only*

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

NOTE TO FILE

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

Please use this form to record details of important events for formal documentation in the database.
Please also use this form to document breaches of GCP.

Does this note relate to a page in the CRFs? *Yes* ☐ *No* ☐ If **YES**, give page number (e.g. C1) ☐☐☐

If E1-E7, please specify which follow-up visit to which the note to file relates):

5 weeks visit ☐ 3 month telephone call ☐ 6 month telephone call ☐

12 months visit ☐

Date and time of event (where applicable, or record NA):

__ __ /__ __ /__ __ __ __ ___ ___ : ___ ___

d d m m y y y y ***(24 hr clock)***

File note (include all relevant details of event)

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) Date data entered *(dd/mm/yyyy)*

_____ __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

RECURRENCE / PROGRESSION / NEW CANCER

G1

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

DETAILS OF THE DISEASE RECURRENCE / PROGRESSION

Please complete this form for each instance of disease recurrence / progression experienced during the follow-up period.

Please specify the type of recurrence / progression / new cancer:

	Yes	No		Yes	No
Local recurrence	☐	☐	Distant recurrence	☐	☐
Regional recurrence	☐	☐	New primary cancer	☐	☐
New secondary cancer	☐	☐			

Specify location of the recurrence / new cancer / metastases: _____

Please provide the date that recurrence was reported: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

How was the recurrence / progression diagnosed *(tick all that apply)*

	Yes	No		Yes	No
CT scan¥	☐	☐	PET-CT	☐	☐
MRI	☐	☐	X-ray	☐	☐
Patient symptomatic (clinical progression)	☐	☐	Pathologically diagnosed recurrence	☐	☐
Post-mortem results	☐	☐	Other	☐	☐

If **OTHER**, please specify: _____

¥Details of the scan which identified recurrence / progression at 12 months (+/- 4 weeks) from the date randomisation should be reported on F1. Details of any scan which identified recurrence / progression at any other time after randomisation should be reported on I1.

	Yes	No
Has the MDT ratified the diagnosis of recurrence?	☐	☐
Has treatment been initiated for the recurrence / progression?	☐	☐

If **YES,** specify start date: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

If treatment has been started, please specify treatment type:

	Yes	No		Yes	No
Further surgery	☐	☐	Radiotherapy	☐	☐
Chemotherapy	☐	☐	Palliative care	☐	☐
Other	☐	☐	If **OTHER**, specify: _____		

If **FURTHER SURGERY,** please specify the extent of the surgery:

	Yes	No		Yes	No
Biopsy	☐	☐	Wedge resection	☐	☐
Lobectomy	☐	☐	Completion pneumonectomy	☐	☐
Open & Close (inoperable / extensive malignancy)	☐	☐	Other	☐	☐
			If **OTHER**, specify: _____		

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

AUDIO RECORDINGS

AR$_1$

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

RECORDING 1

Was an audio-recording taken? *Yes* ☐ *No* ☐

*If **YES,** please complete Part A.*
*If **NO,** please complete Part B.*

PART A: AUDIO-RECORDING MADE

Provide the date the recording was taken: __ __ /__ __ /__ __ __ __
d d m m y y y y

Provide the staff ID's of those present:

VIOLET staff ID (1): ☐☐☐-☐☐☐ VIOLET staff ID (2): ☐☐☐-☐☐☐

Was the patient accompanied? *Yes* ☐ *No* ☐

If **YES,** state their relationship to the patient (e.g. partner, friend etc.): _____

When was the recording taken?

At the surgical consultation ☐ Other time point ☐ If **OTHER**, please specify: _____

PART B: AUDIO-RECORDING NOT MADE

If the patient consented but the audio-recording was not taken, please specify the reasons:

	Yes	*No*		*Yes*	*No*
Equipment malfunction	☐	☐	Patient changed their mind	☐	☐
Staff member had not consented	☐	☐	Logistical issues	☐	☐
Other	☐	☐	If **OTHER**, specify:	_____	

RECORDING 2

Was an audio-recording taken? *Yes* ☐ *No* ☐

*If **YES,** please complete Part A.*
*If **NO,** please complete Part B.*

PART A: AUDIO-RECORDING MADE

Provide the date the recording was taken: __ __ /__ __ /__ __ __ __
d d m m y y y y

Provide the staff ID's of those present:

VIOLET staff ID (1): ☐☐☐-☐☐☐ VIOLET staff ID (2): ☐☐☐-☐☐☐

Was the patient accompanied? *Yes* ☐ *No* ☐

If **YES,** state their relationship to the patient (e.g. partner, friend etc.): _____

When was the recording taken?

At the surgical consultation ☐ Other time point ☐ If **OTHER**, please specify: _____

PART B: AUDIO-RECORDING NOT MADE

If the patient consented but the audio-recording was not taken, please specify the reasons:

	Yes	*No*		*Yes*	*No*
Equipment malfunction	☐	☐	Patient changed their mind	☐	☐
Staff member had not consented	☐	☐	Logistical issues	☐	☐
Other	☐	☐	If **OTHER**, specify:	_____	

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

Study Details
Sponsor Ref: *2014LS004B*
REC Ref: 14/LO/2129

The VIOLET Study
SAE MASTER FORM

SAE ref: ___
SAE report page ___ of ___

S0

VIOLET Trial ID: | | | | - | | | | |

An SAE report should be completed for each event that fulfils the following criteria and that is not listed as expected on CRFs D1-D3 or E5.

i) increases length of hospital admission, ii) causes hospitalisation, iii) is life-threatening, iv) results in persistent of significant disability, v) results in death

For each event that meets the above criteria, please complete a line in the below table. An initial report (S1 & S2) should be completed for each event and follow-up forms should be completed every five days until the event is considered as resolved (if initially reported as ongoing) or until the patient has died.

Please ensure all SAE reports are identified with the correct SAE reference, which is derived by the table below.

SAE Ref	Brief description of the event	Onset date	Date of initial report	Date of follow-up 1	Date of follow-up 2	Date of follow-up 3	Event resolved? (Tick)
1.		__/__/_____	__/__/_____	__/__/_____	__/__/_____	__/__/_____	
2.		__/__/_____	__/__/_____	__/__/_____	__/__/_____	__/__/_____	
3.		__/__/_____	__/__/_____	__/__/_____	__/__/_____	__/__/_____	
4.		__/__/_____	__/__/_____	__/__/_____	__/__/_____	__/__/_____	
5.		__/__/_____	__/__/_____	__/__/_____	__/__/_____	__/__/_____	
6.		__/__/_____	__/__/_____	__/__/_____	__/__/_____	__/__/_____	
7.		__/__/_____	__/__/_____	__/__/_____	__/__/_____	__/__/_____	
8.		__/__/_____ (d d m m y y y y)	__/__/_____ (d d m m y y y y)	__/__/_____ (d d m m y y y y)	__/__/_____ (d d m m y y y y)	__/__/_____ (d d m m y y y y)	

Use the space below to provide details of any further SAE follow-ups and be sure to annotate with the SAE reference number:

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

Study Details
Sponsor Ref: *2014LS004B*
REC Ref: 14/LO/2129

The VIOLET Study

SAE INITIAL REPORT FORM

SAE ref: ___
SAE report page ___ of ___

S1

VIOLET Trial ID: ☐☐☐-☐☐☐☐

1. PARTICIPANT DETAILS

Patient initials ☐☐ *Male* ☐ *Female* ☐ Date of Birth __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

2. SAE CLASSIFICATION

	YES	*NO*		*YES*	*NO*
Prolonged an ongoing hospitalisation	☐	☐	Required inpatient hospitalisation	☐	☐
Resulted in persistent or significant disability / incapacity	☐	☐	Is / was life-threatening	☐	☐
Resulted in death	☐	☐	If **YES,** give date of death: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)		
Other serious (important medical event)	☐	☐	If **YES,** specify: _____		

If the event **RESULTED IN DEATH,** was this due to disease progression? *Yes* ☐ *No* ☐

3. EVENT DETAILS

Full description of event *(including body site, reported signs and symptoms and diagnosis where possible):*

Specify the adverse event term and CTCAE grade:

Adverse Event term:	CTCAE grade:	Adverse Event term:	CTCAE grade:
E.g. Atrial fibrillation	4	3. _____	☐
1. _____	☐	4. _____	☐
2. _____	☐	5. _____	☐

4. DETAILS OF ONSET AND OUTCOME

Date of onset: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) Time of onset: ___ ___ : ___ ___ (*24 hr clock*)

Resolved, no sequelae ☐ *Resolved, with sequelae* ☐ *Ongoing (please complete & return the S3 CRF <5 days)* ☐ *Died* ☐

If **RESOLVED** or **RESOLVED WITH SEQUELAE,** specify end date & time: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) ___ ___ : ___ ___ (*24 hr clock*)

If **Resolved with sequelae, ongoing or **died,** please give details:*

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

Study Details
Sponsor Ref: *2014LS004B*
REC Ref: 14/LO/2129

The VIOLET Study

SAE INITIAL REPORT FORM

SAE ref: ___
SAE report page ___ of ___

S2

VIOLET Trial ID:

			-			

5. DETAILS OF RESEARCH INTERVENTION

Date of intervention: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

Patient treated according to allocation *Yes* ☐ *No* ☐

6. ACTION TAKEN AND FURTHER INFORMATION

Please describe action taken *e.g. treatment stopped, rescue therapy, any interventions performed):*

Provide any other relevant information *(e.g. medical history, test results):*

7. WITHDRAWAL

Has the patient been withdrawn? *Yes* ☐ *No* ☐ If **YES** date withdrawn __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

8. RELATEDNESS

In the opinion of the PI or delegated doctor, was the event related to the study intervention

Not related ☐ *Unlikely to be related* ☐ *Possibly related** ☐ *Probably related** ☐ *Definitely related** ☐

*If *possibly, probably or definitely related* to the study intervention, please provide a justification:

9. DETAILS OF PRINCIPAL INVESTIGATOR, OR DELEGATED DOCTOR

The completed SAE form must be signed off by the **PI or other delegated doctor** prior to faxing to the sponsor

I confirm that the contents of this form (pages S1 and S2) are accurate and complete

Name _____ Signature _____ Date __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

FOR CTEU USE ONLY

Does the event require reporting to REC? *Yes* ☐ *No* ☐ If **NO,** reason: _____

Does the Chief Investigator **disagree** with the assessment of relatedness? *Yes* ☐ *No* ☐

If **YES,** reason: _____

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

Study Details
Sponsor Ref: *2014LS004B*
REC Ref: 14/LO/2129

The VIOLET Study

SAE FOLLOW-UP REPORT FORM

SAE ref: ___
SAE report page ___ of ___

S3

VIOLET Trial ID: ☐☐☐-☐☐☐☐

1. PARTICIPANT DETAILS

Patient initials ☐☐ Sex *Male* ☐ *Female* ☐ Date of Birth __ __ /__ __ /__ __ __ __
d d m m y y y y

2. SAE DETAILS

Date of onset __ __ /__ __ /__ __ __ __
d d m m y y y y

Time of onset ___ ___ : ___ ___
(24 hr clock)

3. FURTHER DETAILS OF EVENT

Maximum intensity of event (up until time of follow-up report)

Specify the adverse event term and CTCAE grade:

Adverse Event term:	CTCAE grade:	Adverse Event term:	CTCAE grade:
E.g. Atrial fibrillation	4	3.	
1.		4.	
2.		5.	

Additional actions / further information since initial report *(e.g. medical history, test results etc)*

4. OUTCOME OF EVENT

Resolved, no sequelae ☐ *Resolved, with sequelae ** ☐ *Ongoing * (complete follow-up form within 5 days, unless otherwise agreed by sponsor)* ☐ *Died * (give cause and PM details or Death Certificate)* ☐

If **RESOLVED,** please specify end date & time: __ __ /__ __ /__ __ __ __ (*d d m m y y y y*) ___ ___ : ___ ___ (*24 hr clock*)

If **Resolved with sequelae, ongoing or **died,** please give details:*

If a long term SAE that is possibly/probably/definitely related to the intervention and a new follow-up schedule has been agreed with the Sponsor, give date of next follow-up __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

5. WITHDRAWAL

Has the patient been withdrawn from the study completely since initial report? *Yes* ☐ *No* ☐ If **YES** date withdrawn __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

6. DETAILS OF PRINCIPAL INVESTIGATOR OR DELEGATED DOCTOR

The completed SAE form must be signed off by the **PI or other delegated doctor** prior to faxing to the sponsor
I confirm that the contents of this form are accurate and complete

Name _____ Signature _____ Date __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

Study Details
Sponsor Ref: *2014LS004B*
REC Ref: 14/LO/2129

The VIOLET Study

SAE ADDITIONAL INFORMATION FORM

S4

SAE ref: ___
SAE report page ___ of ___

VIOLET Trial ID:

			-			

ADDITIONAL INFORMATION

Section No	Further Information

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

WITHDRAWAL FORM

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

WITHDRAWAL DETAILS

Date of withdrawal from study __ __ /__ __ /__ __ __ __ (*d d m m y y y y*)

Which part of the study did the patient withdraw from (*tick all that apply)*?

Information Study ☐ RCT (main study) ☐ Biological sub- study ☐ Medical Records & FU ☐

If **RCT,** when was the withdrawal:

Before randomisation ☐ After randomisation but before intervention ☐ After intervention ☐

Reason for exiting study

Patient's choice ☐ Clinician choice ☐ Admin / Logistical ☐

If **PATIENT CHOICE,** please specify reason:

Referral to another centre ☐ Patient changed their mind about study ☐

Refused to give reason ☐ Patient no longer wants surgery ☐

Other ☐ If **OTHER,** please specify: _____

If **CLINICIAN CHOICE,** please specify below:

Surgery no longer appropriate ☐ Patient no longer eligible ☐

Other ☐ If **OTHER,** please specify: _____

Name of clinician withdrawing patient: _____

If **ADMIN / LOGISTICAL REASONS,** please specify below:

Surgeon changed ☐ Other ☐

If **OTHER,** please specify: _____

Is patient willing for data and samples already collected to be used? *Yes* ☐ *No* ☐

Is patient willing for data routinely collected about them by the NHS to be used in this study? *Yes* ☐ *No* ☐

Is the patient willing to participate in follow-up? *Yes* ☐ *No* ☐

If the patient **withdraws / is withdrawn from the study**, **a photocopy** of the **completed withdrawal form** should be **stapled to the front of the copy of the Patient Consent Form in the patient's notes**.

Additional information (only complete if relevant)

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

BANG BLINDING INDEX-PATIENT

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

TO BE COMPLETED BY STAFF ON BEHALF OF THE PATIENT:

To be completed two days after surgery & on the date of discharge

(NB: Day of surgery is Day 0)

Today's date: __ __ /__ __ /__ __ __ __
d d m m y y y y

Read the following to the patient:

We would like to ask you some brief questions to find out more about your experience of your operation. There is no right or wrong answer and the information will be confidential.

1) What type of surgery do you think that you received (*tick one)?*

VATS ☐ Open Surgery ☐ Don't know ☐

2) Why do you think this?

3) If you answered "Don't know", please guess which one you think you received: *(tick one)*

VATS ☐ Open Surgery ☐ Don't know ☐

Bang H, Ni L, Davis CE. Assessment of blinding in clinical trials. *Controlled Clinical Trials* 2004; 25: 143-56.

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

BANG BLINDING INDEX-NURSE

VIOLET Trial ID: ☐☐☐-☐☐☐☐

Patient Name: _____

BANG BLINDING INDEX—NURSE

TO BE COMPLETED BY THE RESEARCH NURSE RESPONSIBLE FOR DATA COLLECTION:

- At patient discharge
- Immediately after the patients 5 week visit
- Immediately after the patients 12 month visit

Today's date: __ __ /__ __ /__ __ __ __
d d m m y y y y

You have just had a follow-up appointment with a patient participating in VIOLET. Please complete the following questions so that we can assess the efficacy of blinding the research nurse responsible for data collection. There are no right or wrong answers and the information will be confidential.

1) What type of surgery do you think that the patient received (*tick one)?*

VATS ☐ Open Surgery ☐ Don't know ☐

2) Why do you think this?

3) If you answered "Don't know", please guess which one you think the patient received: *(tick one)*

VATS ☐ Open Surgery ☐ Don't know ☐

Bang H, Ni L, Davis CE. Assessment of blinding in clinical trials. *Controlled Clinical Trials* 2004; 25: 143-56.

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*