

# The VIOLET Study - Screening Log

(To be completed for all patients referred for surgical resection for known / suspected lung cancer)

Patient Initials:

Patient DOB:

Patient Hospital No.:

VIOLET Trial ID:

## ELIGIBILITY CRITERIA

| Inclusion criteria  | YES                      | NO                       | Exclusion criteria   | YES                      | NO                       |
|---|--------------------------|--------------------------|--|--------------------------|--------------------------|
| Aged ≥ 16 years of age  | <input type="checkbox"/> | <input type="checkbox"/> | Planned wedge resection  | <input type="checkbox"/> | <input type="checkbox"/> |
| Able to give written informed consent   | <input type="checkbox"/> | <input type="checkbox"/> | Planned segmentectomy  | <input type="checkbox"/> | <input type="checkbox"/> |
| Disease suitable for VATS <b>AND</b> open surgery   | <input type="checkbox"/> | <input type="checkbox"/> | Planned pneumonectomy  | <input type="checkbox"/> | <input type="checkbox"/> |
| If <b>NO</b> , provide reason: _____  |                          |                          | Planned robotic surgery  | <input type="checkbox"/> | <input type="checkbox"/> |
| Lobectomy/bilobectomy or frozen section biopsy with the option to proceed to lobectomy/bilobectomy                    | <input type="checkbox"/> | <input type="checkbox"/> | Previous malignancy that influences life expectancy                                  | <input type="checkbox"/> | <input type="checkbox"/> |
| Known or suspected primary lung cancer beyond the lobar orifice for lobectomy or bronchus intermedius for bilobectomy | <input type="checkbox"/> | <input type="checkbox"/> | Any serious concomitant disorder that would compromise patient safety during surgery | <input type="checkbox"/> | <input type="checkbox"/> |
| TNM8 Stage cT1-3, N0-1 and M0*  | <input type="checkbox"/> | <input type="checkbox"/> |  |                          |                          |

\* Please note the change in staging criteria now excludes patients with known chest wall invasion

Specify TNM8 disease stage: T (a/b/c)   N  M (a/b/c)

IF ANY OF THE ☐ ARE TICKED THE PATIENT IS **NOT** ELIGIBLE FOR THE TRIAL

## APPROACH & CONSENT DETAILS (MUST BE COMPLETED FOR ALL ELIGIBLE PATIENTS)

Was the patient given / sent a Patient Information Leaflet? Yes ☐ No ☐ If **YES**, give date:           PIL version:

If **NO**, give reason: (e.g. competing study) \_\_\_\_\_

## INFORMATION STUDY

Was the patient approached? Yes ☐ No ☐ If **YES**, give date:           If **NO**, give reason: \_\_\_\_\_

Was the patient consented? Yes ☐ No ☐ If **YES**, give date:           If **NO**, give reason: \_\_\_\_\_

If the patient **was consented**, did they consent to audio-recorded interviews? Yes ☐ No ☐ If patient consents, please complete **A1 & AR1 CRFs**

## MAIN STUDY

Was the patient approached? Yes ☐ No ☐ If **YES**, give date:           If **NO**, give reason: \_\_\_\_\_

Was the patient consented? Yes ☐ No ☐ If **YES**, give date:           If **NO**, give reason: \_\_\_\_\_

If the patient **was consented**, did they consent to a sample of their tumour to be used for future research? Yes ☐ No ☐ If patient consents, please complete from **A1 CRF onwards**

## BIOLOGICAL SUB-STUDY (only available for patients consented to the main study)

Was the patient approached? Yes ☐ No ☐ If **YES**, give date:           If **NO**, give reason: \_\_\_\_\_

Was the patient consented? Yes ☐ No ☐ If **YES**, give date:           If **NO**, give reason: \_\_\_\_\_

If patient consents, please complete from **A1 CRF onwards**

## ACCESS TO MEDICAL RECORDS AND FOLLOW-UP (Only approach if patient declines main study)

Was the patient approached? Yes ☐ No ☐ If **YES**, give date:           If **NO**, give reason: \_\_\_\_\_

Was the patient consented? Yes ☐ No ☐ If **YES**, give date:           If **NO**, give reason: \_\_\_\_\_

If patient consents, please **A1 & MR1 CRFs**

## SURGICAL CONSULTATION DETAILS

Surgeon name & ID:  Consultation date:

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:

Version 3.0, 01/06/2018

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

(dd/mm/yyyy)