

|                          |  |                   |   |
|--------------------------|--|-------------------|---|
| Protocol No:             | P20200828V3  |                   |   |
| Site                     | <input type="checkbox"/> <input type="checkbox"/>                          | Subject ID:       | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>                          |
| Randomisation No:        | <input type="checkbox"/> <input type="checkbox"/>                          | Subject Initials: | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| Investigator Identifier: | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                   |   |

### Case Report Form

**Sufentanil target controlled infusion (TCI) vs remifentanil TCI  
for monitored anaesthesia care for patients with severe tracheal  
stenosis undergoing fiberoptic bronchoscopy**

By  
**Shanghai Pulmonary Hospital**

V20200828-03

**Inclusion Criteria**

| Subjects who meet the following criteria may be included in the study. Did the subject meet the following criteria requirements for inclusion? (✓ Yes or No) |                           | Yes<br>1 | No*<br>2 |
|--|---------------------------|----------|----------|
| 01   | Cotton-Myer grades II-III |          |          |
| 02   | Aged 18–65 years          |          |          |
| 03   | ASA I-III                 |          |          |

\* If No, document on Subject Eligibility Page.

**Exclusion Criteria**

| The following will exclude potential subjects from the study. Does the subject have any of the following? ( √ Yes or No) |  | Yes*<br>1 | No<br>2 |
|--|--|-----------|---------|
| 01   | BMI>30 or < 18.5   |           |         |
| 02   | Baseline oxygen desaturation (resting SpO <sub>2</sub> <90%) |           |         |
| 03   | Pregnancy  |           |         |
| 04   | History of allergy to related drugs                          |           |         |
| 05   | Severe coagulation dysfunction                               |           |         |
| 06   | Severe hepatic and renal dysfunction                         |           |         |
| 07   | Gastroesophageal reflux disease                              |           |         |
| 08   | History of abnormal recovery from anaesthesia                |           |         |
| 09   | No informed consent  |           |         |
|  |  |           |         |

\*If Yes, document on Subject Eligibility Page

**Information Session**

| Date of Information Session        | Did the subject attend the Information Session?                                  | Comments |
|------------------------------------|--|----------|
| ____ / ____ / ____<br>DD / MM / YY | 1 <input type="checkbox"/> Yes<br>2 <input type="checkbox"/> No (explain, if No) |          |

**Subject Eligibility**

| Date the Subject Signed the Informed Consent Form:   |                         | ____ / ____ / ____<br>DD / MM / YY |                                |                                 |
|--|-------------------------|------------------------------------|--------------------------------|---------------------------------|
| Did the subject meet all of the inclusion/exclusion criteria?  |                         | 1 <input type="checkbox"/> Yes     |                                |                                 |
|  |                         | 2 <input type="checkbox"/> No      |                                |                                 |
| If the subject did not meet all of the Inclusion/Exclusion criteria, provide criterion number and explanation below. |                         |                                    |                                |                                 |
| Category   | Inclusion/Exclusion No. | Explanation                        | Exemption Granted?             | If Yes, Date Granted DD/MM/YYYY |
| 1 <input type="checkbox"/> Inclusion   |                         |                                    | 1 <input type="checkbox"/> Yes | ____ / ____ / ____              |
| 2 <input type="checkbox"/> Exclusion   |                         |                                    | 2 <input type="checkbox"/> No  |                                 |
| 1 <input type="checkbox"/> Inclusion   |                         |                                    | 1 <input type="checkbox"/> Yes | ____ / ____ / ____              |
| 2 <input type="checkbox"/> Exclusion   |                         |                                    | 2 <input type="checkbox"/> No  |                                 |
| 1 <input type="checkbox"/> Inclusion   |                         |                                    | 1 <input type="checkbox"/> Yes | ____ / ____ / ____              |
| 2 <input type="checkbox"/> Exclusion   |                         |                                    | 2 <input type="checkbox"/> No  |                                 |

**Demographics**

|  |   |   |   |
|--|---|---|---|
| Date<br>DD/MM/YYYY   | Date of Birth<br>DD/MM/YYYY   | Gender  | Ethnicity   |
| <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/><br><input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/><br><input type="checkbox"/> | 1 <input type="checkbox"/> Male   | 1 <input type="checkbox"/> Han  |
|  |   | 2 <input type="checkbox"/> Female   | 2 <input type="checkbox"/> Non-han  |
| <b>Body Measurements</b>   |   |   |   |
| Were Body Measurements Collected?  |   | Date<br>DD/MM/YYYY  |   |
| 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No   |   | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>    |   |
| Parameter  | Unit  | Result  |   |
| Height   | cm  | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>  |   |
| Weight   | Kg  | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>  |   |
| <b>Vital Signs</b>   |   |   |   |
| Were Body Measurements Collected?  |   | Date  |   |
| 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No   |   | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>    |   |
| Parameter  | Unit  | Result  |   |
| Systolic Blood Pressure  | mmHg  | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>  |   |
| Diastolic Blood Pressure   | mmHg  | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>  |   |
| Heart Rate   | beats/minute  | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>  |   |
| Respiratory Rate   | breaths/minute  | <input type="checkbox"/> <input type="checkbox"/>   |   |
| Body Temperature   | ° C   | <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/>  |   |
| <b>12-Lead Electrocardiogram Report</b>  |   |   |   |
| Was ECG performed?   |   | Date<br>DD/MM/YYYY  | Actual Time<br>24-hour clock  |
| 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No   |   | <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/><br><input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> : <input type="checkbox"/> <input type="checkbox"/> |
| ECG Interpretation:  | 1 <input type="checkbox"/> Normal   | 2 <input type="checkbox"/> Abnormal,<br>NCS   | 3 <input type="checkbox"/> Abnormal   |
| Comments Regarding CS Findings:  |   |   |   |
|  |   |   |   |

**Medical History**

| Does the subject have any relevant medical history?          |  | Date<br>DD/MM/YYYY   |                                    |
|--|--|--|------------------------------------|
| 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No |  | ____/____/____   |                                    |
| Diagnosis/Procedure  | Date of Onset<br>DD/MM/YYYY  | Date of Resolution<br>DD/MM/YYYY   |                                    |
| 1  | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | 9 <input type="checkbox"/> ONGOING |
| 2  | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | 9 <input type="checkbox"/> ONGOING |
| 3  | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | 9 <input type="checkbox"/> ONGOING |
| 4  | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | 9 <input type="checkbox"/> ONGOING |
| 5  | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | 9 <input type="checkbox"/> ONGOING |
| 6  | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | 9 <input type="checkbox"/> ONGOING |
| 7  | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | 9 <input type="checkbox"/> ONGOING |
| 8  | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | 9 <input type="checkbox"/> ONGOING |
| 9  | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> _/_/____<br><input type="checkbox"/> | 9 <input type="checkbox"/> ONGOING |

**Laboratory Analysis**

| Parameter                   | Unit  | Result |
|-----------------------------|-------|--------|
| SPO <sub>2</sub>            |       | □□□    |
| Arterial blood gas analysis |       |        |
| PH                          |       | □.□□   |
| PaCO <sub>2</sub>           | mmHg  | □□□    |
| PaO <sub>2</sub>            | mmHg  | □□□    |
| HCO <sub>3</sub>            | mEq/L | □□     |

**Intervention Phase**

|  |  |  |  |  |
|--|--|--|--|--|
| Date<br>DD/MM/YYYY   | ____ / ____ / ____   |  |  |  |
| Group  | 1 <input type="checkbox"/> Group R   |  | 2 <input type="checkbox"/> Group S   |  |
| Whether or not hypoxemia occurs                                    |  |  |  |  |
| 1 <input type="checkbox"/> subclinical hypoxemia (SPO2 of 90-95%), | 2 <input type="checkbox"/> moderate hypoxemia (SPO2 of 75-89%, $\leq 60$ s |  | 3 <input type="checkbox"/> severe hypoxemia (SpO2 < 90% for >60 s or SpO2 < 75% at any time) |  |
| Management of hypoxemia  |  |  |  |  |
| 1 <input type="checkbox"/> patient stimulation                     | 2 <input type="checkbox"/> increasing the volume of supplementary oxygen   | 3 <input type="checkbox"/> jaw-thrust maneuver | 4 <input type="checkbox"/> mask ventilation  | 5 <input type="checkbox"/> mechanical ventilation. |
| Puchner five-point fiber-optic intubation comfort scale            |  |  |  |  |
| 1 <input type="checkbox"/> No reaction                             | 2 <input type="checkbox"/> Slight grimacing                                | 3 <input type="checkbox"/> Heavy grimacing     | 4 <input type="checkbox"/> Verbal objection  | 5 <input type="checkbox"/> Defensive movement      |

|                          |  |  |
|--------------------------|--|--|
| T0                       | 10 minutes after entering the operation room |  |
| Parameter                | Unit   | Result   |
| Systolic Blood Pressure  | mmHg   | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| Diastolic Blood Pressure | mmHg   | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| Heart Rate               | beats/minute                                 | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| Respiratory Rate         | breaths/minute                               | <input type="checkbox"/> <input type="checkbox"/>                          |
| Spo2                     |  | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |

|                          |                                    |  |                            |
|--------------------------|------------------------------------|--|----------------------------|
| T1                       | Cp and Ce has achieved equilibrium |  |                            |
| Parameter                | Unit                               | Result   |                            |
| Systolic Blood Pressure  | mmHg                               | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Diastolic Blood Pressure | mmHg                               | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Heart Rate               | beats/minute                       | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Respiratory Rate         | breaths/minute                     | <input type="checkbox"/> <input type="checkbox"/>                          |                            |
| Spo2                     |                                    | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Ramsay Sedation Scale    | 1 <input type="checkbox"/>         | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/>         | 5 <input type="checkbox"/>   | 6 <input type="checkbox"/> |
|                          | 7 <input type="checkbox"/>         | 8 <input type="checkbox"/>   |                            |
| Cough                    | 1 <input type="checkbox"/>         | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/> |



|       |                            |   |                            |
|-------|----------------------------|---|----------------------------|
|       | 4 <input type="checkbox"/> | 5 <input type="checkbox"/>                        | 6 <input type="checkbox"/> |
| EtCO2 | mmHg                       | <input type="checkbox"/> <input type="checkbox"/> |                            |

| T2                       | When bronchoscope is inserted |  |                            |
|--------------------------|-------------------------------|--|----------------------------|
| Parameter                | Unit                          | Result   |                            |
| Systolic Blood Pressure  | mmHg                          | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Diastolic Blood Pressure | mmHg                          | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Heart Rate               | beats/minute                  | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Respiratory Rate         | breaths/minute                | <input type="checkbox"/> <input type="checkbox"/>                          |                            |
| Spo2                     |                               | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Ramsay Sedation Scale    | 1 <input type="checkbox"/>    | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/>    | 5 <input type="checkbox"/>   | 6 <input type="checkbox"/> |
|                          | 7 <input type="checkbox"/>    | 8 <input type="checkbox"/>   |                            |
| Cough                    | 1 <input type="checkbox"/>    | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/>    | 5 <input type="checkbox"/>   | 6 <input type="checkbox"/> |
| EtCO2                    | mmHg                          | <input type="checkbox"/> <input type="checkbox"/>                          |                            |

| T3                       | 1 minute after bronchoscope is inserted |  |                            |
|--------------------------|---|--|----------------------------|
| Parameter                | Unit                                    | Result   |                            |
| Systolic Blood Pressure  | mmHg                                    | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Diastolic Blood Pressure | mmHg                                    | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Heart Rate               | beats/minute                            | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Respiratory Rate         | breaths/minute                          | <input type="checkbox"/> <input type="checkbox"/>                          |                            |
| Spo2                     |   | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Ramsay Sedation Scale    | 1 <input type="checkbox"/>              | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/>              | 5 <input type="checkbox"/>   | 6 <input type="checkbox"/> |
|                          | 7 <input type="checkbox"/>              | 8 <input type="checkbox"/>   |                            |
| Cough                    | 1 <input type="checkbox"/>              | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/>              | 5 <input type="checkbox"/>   | 6 <input type="checkbox"/> |
| EtCO2                    | mmHg                                    | <input type="checkbox"/> <input type="checkbox"/>                          |                            |

| T4                      | 5 minutes after bronchoscope is inserted |  |
|-------------------------|--|--|
| Parameter               | Unit                                     | Result   |
| Systolic Blood Pressure | mmHg                                     | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |

|                          |                            |  |                            |
|--------------------------|----------------------------|--|----------------------------|
| Diastolic Blood Pressure | mmHg                       | <input type="text"/> <input type="text"/> <input type="text"/> |                            |
| Heart Rate               | beats/minute               | <input type="text"/> <input type="text"/> <input type="text"/> |                            |
| Respiratory Rate         | breaths/minute             | <input type="text"/> <input type="text"/>                      |                            |
| Spo2                     |                            | <input type="text"/> <input type="text"/> <input type="text"/> |                            |
| Ramsay Sedation Scale    | 1 <input type="checkbox"/> | 2 <input type="checkbox"/>                                     | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/> | 5 <input type="checkbox"/>                                     | 6 <input type="checkbox"/> |
|                          | 7 <input type="checkbox"/> | 8 <input type="checkbox"/>                                     |                            |
| Cough                    | 1 <input type="checkbox"/> | 2 <input type="checkbox"/>                                     | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/> | 5 <input type="checkbox"/>                                     | 6 <input type="checkbox"/> |
| EtCO2                    | mmHg                       | <input type="text"/> <input type="text"/>                      |                            |

|                          |   |  |                            |
|--------------------------|---|--|----------------------------|
| T5                       | 10 minutes after bronchoscope is inserted |  |                            |
| Parameter                | Unit                                      | Result   |                            |
| Systolic Blood Pressure  | mmHg                                      | <input type="text"/> <input type="text"/> <input type="text"/> |                            |
| Diastolic Blood Pressure | mmHg                                      | <input type="text"/> <input type="text"/> <input type="text"/> |                            |
| Heart Rate               | beats/minute                              | <input type="text"/> <input type="text"/> <input type="text"/> |                            |
| Respiratory Rate         | breaths/minute                            | <input type="text"/> <input type="text"/>                      |                            |
| Spo2                     |   | <input type="text"/> <input type="text"/> <input type="text"/> |                            |
| Ramsay Sedation Scale    | 1 <input type="checkbox"/>                | 2 <input type="checkbox"/>                                     | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/>                | 5 <input type="checkbox"/>                                     | 6 <input type="checkbox"/> |
|                          | 7 <input type="checkbox"/>                | 8 <input type="checkbox"/>                                     |                            |
| Cough                    | 1 <input type="checkbox"/>                | 2 <input type="checkbox"/>                                     | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/>                | 5 <input type="checkbox"/>                                     | 6 <input type="checkbox"/> |
| EtCO2                    | mmHg                                      | <input type="text"/> <input type="text"/>                      |                            |

|                          |   |  |                            |
|--------------------------|---|--|----------------------------|
| T6                       | 15 minutes after bronchoscope is inserted |  |                            |
| Parameter                | Unit                                      | Result   |                            |
| Systolic Blood Pressure  | mmHg                                      | <input type="text"/> <input type="text"/> <input type="text"/> |                            |
| Diastolic Blood Pressure | mmHg                                      | <input type="text"/> <input type="text"/> <input type="text"/> |                            |
| Heart Rate               | beats/minute                              | <input type="text"/> <input type="text"/> <input type="text"/> |                            |
| Respiratory Rate         | breaths/minute                            | <input type="text"/> <input type="text"/>                      |                            |
| Spo2                     |   | <input type="text"/> <input type="text"/> <input type="text"/> |                            |
| Ramsay Sedation Scale    | 1 <input type="checkbox"/>                | 2 <input type="checkbox"/>                                     | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/>                | 5 <input type="checkbox"/>                                     | 6 <input type="checkbox"/> |
|                          | 7 <input type="checkbox"/>                | 8 <input type="checkbox"/>                                     |                            |
| Cough                    | 1 <input type="checkbox"/>                | 2 <input type="checkbox"/>                                     | 3 <input type="checkbox"/> |

|       |                            |   |                            |
|-------|----------------------------|---|----------------------------|
|       | 4 <input type="checkbox"/> | 5 <input type="checkbox"/>                        | 6 <input type="checkbox"/> |
| EtCO2 | mmHg                       | <input type="checkbox"/> <input type="checkbox"/> |                            |

|                          |   |  |                            |
|--------------------------|---|--|----------------------------|
| T6                       | 20 minutes after bronchoscope is inserted |  |                            |
| Parameter                | Unit                                      | Result   |                            |
| Systolic Blood Pressure  | mmHg                                      | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Diastolic Blood Pressure | mmHg                                      | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Heart Rate               | beats/minute                              | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Respiratory Rate         | breaths/minute                            | <input type="checkbox"/> <input type="checkbox"/>                          |                            |
| Spo2                     |   | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Ramsay Sedation Scale    | 1 <input type="checkbox"/>                | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/>                | 5 <input type="checkbox"/>   | 6 <input type="checkbox"/> |
|                          | 7 <input type="checkbox"/>                | 8 <input type="checkbox"/>   |                            |
| Cough                    | 1 <input type="checkbox"/>                | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/>                | 5 <input type="checkbox"/>   | 6 <input type="checkbox"/> |
| EtCO2                    | mmHg                                      | <input type="checkbox"/> <input type="checkbox"/>                          |                            |

|                          |   |  |                            |
|--------------------------|---|--|----------------------------|
| T7                       | 25 minutes after bronchoscope is inserted |  |                            |
| Parameter                | Unit                                      | Result   |                            |
| Systolic Blood Pressure  | mmHg                                      | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Diastolic Blood Pressure | mmHg                                      | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Heart Rate               | beats/minute                              | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Respiratory Rate         | breaths/minute                            | <input type="checkbox"/> <input type="checkbox"/>                          |                            |
| Spo2                     |   | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Ramsay Sedation Scale    | 1 <input type="checkbox"/>                | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/>                | 5 <input type="checkbox"/>   | 6 <input type="checkbox"/> |
|                          | 7 <input type="checkbox"/>                | 8 <input type="checkbox"/>   |                            |
| Cough                    | 1 <input type="checkbox"/>                | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/>                | 5 <input type="checkbox"/>   | 6 <input type="checkbox"/> |
| EtCO2                    | mmHg                                      | <input type="checkbox"/> <input type="checkbox"/>                          |                            |

|                         |   |  |  |
|-------------------------|---|--|--|
| T8                      | 30 minutes after bronchoscope is inserted |  |  |
| Parameter               | Unit                                      | Result   |  |
| Systolic Blood Pressure | mmHg                                      | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |  |

|                          |                            |  |                            |
|--------------------------|----------------------------|--|----------------------------|
| Diastolic Blood Pressure | mmHg                       | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Heart Rate               | beats/minute               | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Respiratory Rate         | breaths/minute             | <input type="checkbox"/> <input type="checkbox"/>                          |                            |
| Spo2                     |                            | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Ramsay Sedation Scale    | 1 <input type="checkbox"/> | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/> | 5 <input type="checkbox"/>   | 6 <input type="checkbox"/> |
|                          | 7 <input type="checkbox"/> | 8 <input type="checkbox"/>   |                            |
| Cough                    | 1 <input type="checkbox"/> | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/> | 5 <input type="checkbox"/>   | 6 <input type="checkbox"/> |
| EtCO2                    | mmHg                       | <input type="checkbox"/> <input type="checkbox"/>                          |                            |

|                          |   |  |                            |
|--------------------------|---|--|----------------------------|
| T9                       | 60 minutes after bronchoscope is inserted |  |                            |
| Parameter                | Unit                                      | Result   |                            |
| Systolic Blood Pressure  | mmHg                                      | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Diastolic Blood Pressure | mmHg                                      | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Heart Rate               | beats/minute                              | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Respiratory Rate         | breaths/minute                            | <input type="checkbox"/> <input type="checkbox"/>                          |                            |
| Spo2                     |   | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |                            |
| Ramsay Sedation Scale    | 1 <input type="checkbox"/>                | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/>                | 5 <input type="checkbox"/>   | 6 <input type="checkbox"/> |
|                          | 7 <input type="checkbox"/>                | 8 <input type="checkbox"/>   |                            |
| Cough                    | 1 <input type="checkbox"/>                | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/> |
|                          | 4 <input type="checkbox"/>                | 5 <input type="checkbox"/>   | 6 <input type="checkbox"/> |
| EtCO2                    | mmHg                                      | <input type="checkbox"/> <input type="checkbox"/>                          |                            |

|  |   |  |                            |  |
|--|---|--|----------------------------|--|
| Type of fiberoptic bronchoscopy procedure          |   |  |                            |  |
| 1 <input type="checkbox"/> Diagnostic              |   | 2 <input type="checkbox"/> Therapeutic |                            |  |
| If it is Therapeutic bronchoscopy                  |   |  |                            |  |
| 1 <input type="checkbox"/> Injection of medication | 2 <input type="checkbox"/> Endotherm knife  | 3 <input type="checkbox"/> Cryotherapy |                            |  |
| 4 <input type="checkbox"/> Laser                   | 5 <input type="checkbox"/> Stent  |  |                            |  |
| Operation time                                     | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | min                                    | Endoscopist                | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| Satisfaction scores of bronchoscopist              | 1 <input type="checkbox"/>  | 2 <input type="checkbox"/>             | 3 <input type="checkbox"/> |  |
|  | 4 <input type="checkbox"/>  | 5 <input type="checkbox"/>             |                            |  |
| Satisfaction scores of anaesthesiologist           | 1 <input type="checkbox"/>  | 2 <input type="checkbox"/>             | 3 <input type="checkbox"/> |  |
|  | 4 <input type="checkbox"/>  | 5 <input type="checkbox"/>             |                            |  |

| Vasoactive drugs used   |                                |   |   |
|---|--------------------------------|---|---|
| Whether or not vasoactive drugs are used  | 1 <input type="checkbox"/> Yes | 2 <input type="checkbox"/> No   |   |
| Vasoactive drug type  | name                           | dosage  | whether it is effective or not                                  |
| 1 <input type="checkbox"/> vasoconstrictor<br>2 <input type="checkbox"/> vasodilator<br>3 <input type="checkbox"/> Inotropic agents |                                | 1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> $\mu$<br>g<br>2 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/><br>mg | 1 <input type="checkbox"/> Yes<br>2 <input type="checkbox"/> No |
| 1 <input type="checkbox"/> vasoconstrictor<br>2 <input type="checkbox"/> vasodilator<br>3 <input type="checkbox"/> Inotropic agents |                                | 1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> $\mu$<br>g<br>2 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/><br>mg | 1 <input type="checkbox"/> Yes<br>2 <input type="checkbox"/> No |
| 1 <input type="checkbox"/> vasoconstrictor<br>2 <input type="checkbox"/> vasodilator<br>3 <input type="checkbox"/> Inotropic agents |                                | 1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> $\mu$<br>g<br>2 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/><br>mg | 1 <input type="checkbox"/> Yes<br>2 <input type="checkbox"/> No |
| 1 <input type="checkbox"/> vasoconstrictor<br>2 <input type="checkbox"/> vasodilator<br>3 <input type="checkbox"/> Inotropic agents |                                | 1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> $\mu$<br>g<br>2 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/><br>mg | 1 <input type="checkbox"/> Yes<br>2 <input type="checkbox"/> No |
| 1 <input type="checkbox"/> vasoconstrictor<br>2 <input type="checkbox"/> vasodilator<br>3 <input type="checkbox"/> Inotropic agents |                                | 1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> $\mu$<br>g<br>2 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/><br>mg | 1 <input type="checkbox"/> Yes<br>2 <input type="checkbox"/> No |
| 1 <input type="checkbox"/> vasoconstrictor<br>2 <input type="checkbox"/> vasodilator<br>3 <input type="checkbox"/> Inotropic agents |                                | 1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> $\mu$<br>g<br>2 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/><br>mg | 1 <input type="checkbox"/> Yes<br>2 <input type="checkbox"/> No |
| 1 <input type="checkbox"/> vasoconstrictor<br>2 <input type="checkbox"/> vasodilator<br>3 <input type="checkbox"/> Inotropic agents |                                | 1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> $\mu$<br>g<br>2 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/><br>mg | 1 <input type="checkbox"/> Yes<br>2 <input type="checkbox"/> No |
| 1 <input type="checkbox"/> vasoconstrictor<br>2 <input type="checkbox"/> vasodilator<br>3 <input type="checkbox"/> Inotropic agents |                                | 1 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> $\mu$<br>g<br>2 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/><br>mg | 1 <input type="checkbox"/> Yes<br>2 <input type="checkbox"/> No |

**Post Intervention Phase**

|  |  |  |                                |  |
|--|--|--|--------------------------------|--|
| Recovery time  | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | min  |                                |  |
| Whether nausea and vomiting occur                          |  |  |                                |  |
| 1 <input type="checkbox"/> Yes                             | 2 <input type="checkbox"/> No  |  |                                |  |
| Assessment of PONV   |  |  |                                |  |
| 1 <input type="checkbox"/> Mild                            | 2 <input type="checkbox"/> moderate  | 3 <input type="checkbox"/> severe  |                                |  |
| Satisfaction scores of the patient                         |  |  |                                |  |
| 1 <input type="checkbox"/>                                 | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/>   | 4 <input type="checkbox"/>     | 5 <input type="checkbox"/>                       |
| willingness of the patient to undergo repeat bronchoscopy. |  |  |                                |  |
| 1 <input type="checkbox"/> Not at all likely               | 2 <input type="checkbox"/> 1-3   | 3 <input type="checkbox"/> 4-6   | 4 <input type="checkbox"/> 7-9 | 5 <input type="checkbox"/> Extremely likely (10) |
| VAS scores of sore throat                                  |  |  |                                |  |
| 1 <input type="checkbox"/>                                 | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/>   | 4 <input type="checkbox"/>     | 5 <input type="checkbox"/>                       |
| 6 <input type="checkbox"/>                                 | 7 <input type="checkbox"/>   | 8 <input type="checkbox"/>   | 9 <input type="checkbox"/>     | 10 <input type="checkbox"/>                      |
| T10  | At PACU  |  |                                |  |
| Parameter  | Unit   | Result   |                                |  |
| Systolic Blood Pressure                                    | mmHg   | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>   |                                |  |
| Diastolic Blood Pressure                                   | mmHg   | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>   |                                |  |
| Heart Rate   | beats/minute   | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>   |                                |  |
| Respiratory Rate   | breaths/minute   | <input type="checkbox"/> <input type="checkbox"/>                            |                                |  |
| Spo2   |  | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>   |                                |  |
| Ramsay Sedation Scale                                      | 1 <input type="checkbox"/>   | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/>     |  |
|  | 4 <input type="checkbox"/>   | 5 <input type="checkbox"/>   | 6 <input type="checkbox"/>     |  |
|  | 7 <input type="checkbox"/>   | 8 <input type="checkbox"/>   |                                |  |
| Cough  | 1 <input type="checkbox"/>   | 2 <input type="checkbox"/>   | 3 <input type="checkbox"/>     | 4 <input type="checkbox"/>                       |
| Arterial blood gas analysis                                |  |  |                                |  |
| PH   |  | <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/> |                                |  |
| PaCO <sub>2</sub>  | mmHg   | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>   |                                |  |
| PaO <sub>2</sub>   | mmHg   | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>   |                                |  |
| HCO <sub>3</sub>   | mEq/L  | <input type="checkbox"/> <input type="checkbox"/>                            |                                |  |

**Adverse Event information**

|  |   |   |
|--|---|---|
| Whether adverse events occurred                          |   |   |
| 1 <input type="checkbox"/> Yes                           | 2 <input type="checkbox"/> No                               |   |
| Whether serious adverse events occurred                  |   |   |
| 1 <input type="checkbox"/> Yes                           | 2 <input type="checkbox"/> No                               |   |
| Describe the AE and the connection to project procedures |   |   |
|  |   |   |
| AE onset date  | □□/□□/□□□□  | DD/MM/YYYY  |
| AE stop date   | □□/□□/□□□□  | DD/MM/YYYY  |
| Date of AE awareness                                     | □□/□□/□□□□  | DD/MM/YYYY  |
| Severity   |   |   |
| 1 <input type="checkbox"/> mild                          | 2 <input type="checkbox"/> moderate                         | 3 <input type="checkbox"/> severe                 |
| Outcome  |   |   |
| 1 <input type="checkbox"/> recovered/resolved            | 2 <input type="checkbox"/> recovered/resolved with sequelae | 3 <input type="checkbox"/> study participant died |
| 4 <input type="checkbox"/> continuing                    | 5 <input type="checkbox"/> unknown                          | 6 <input type="checkbox"/> other                  |
| SAE causality  |   |   |
| 1 <input type="checkbox"/> Not related                   | 2 <input type="checkbox"/> Unlikely                         | 3 <input type="checkbox"/> Possibly               |
| 4 <input type="checkbox"/> Probably                      | 5 <input type="checkbox"/> Definitely                       |   |
| Describe the AE and the connection to project procedures |   |   |
|  |   |   |
| AE onset date  | □□/□□/□□□□  | DD/MM/YYYY  |
| AE stop date   | □□/□□/□□□□  | DD/MM/YYYY  |
| Date of AE awareness                                     | □□/□□/□□□□  | DD/MM/YYYY  |
| Severity   |   |   |
| 1 <input type="checkbox"/> mild                          | 2 <input type="checkbox"/> moderate                         | 3 <input type="checkbox"/> severe                 |
| Outcome  |   |   |
| 1 <input type="checkbox"/> recovered/resolved            | 2 <input type="checkbox"/> recovered/resolved with sequelae | 3 <input type="checkbox"/> study participant died |

|  |  |   |
|--|--|---|
| 4 <input type="checkbox"/> continuing                    | 5 <input type="checkbox"/> unknown                                 | 6 <input type="checkbox"/> other                  |
| SAE causality  |  |   |
| 1 <input type="checkbox"/> Not related                   | 2 <input type="checkbox"/> Unlikely                                | 3 <input type="checkbox"/> Possibly               |
| 4 <input type="checkbox"/> Probably                      | 5 <input type="checkbox"/> Definitely                              |   |
| Describe the AE and the connection to project procedures |  |   |
|  |  |   |
| AE onset date  | <input type="text"/> / <input type="text"/> / <input type="text"/> | DD/MM/YYYY  |
| AE stop date   | <input type="text"/> / <input type="text"/> / <input type="text"/> | DD/MM/YYYY  |
| Date of AE awareness                                     | <input type="text"/> / <input type="text"/> / <input type="text"/> | DD/MM/YYYY  |
| Severity   |  |   |
| 1 <input type="checkbox"/> mild                          | 2 <input type="checkbox"/> moderate                                | 3 <input type="checkbox"/> severe                 |
| Outcome  |  |   |
| 1 <input type="checkbox"/> recovered/resolved            | 2 <input type="checkbox"/> recovered/resolved with sequelae        | 3 <input type="checkbox"/> study participant died |
| 4 <input type="checkbox"/> continuing                    | 5 <input type="checkbox"/> unknown                                 | 6 <input type="checkbox"/> other                  |
| SAE causality  |  |   |
| 1 <input type="checkbox"/> Not related                   | 2 <input type="checkbox"/> Unlikely                                | 3 <input type="checkbox"/> Possibly               |
| 4 <input type="checkbox"/> Probably                      | 5 <input type="checkbox"/> Definitely                              |   |