CovidSurg
Data Completion Guide

INTRODUCTION

- The following pages will guide you through data entry for CovidSurg. Please complete **all** fields that appear on each REDCap record. In order to provide high quality data to inform the global surgical community, it is essential that all data is as complete as possible.

- Please note, we are using the same REDCap project for both CovidSurg and CovidSurg-Cancer studies for which patients may be eligible for either or both. Therefore, if a patient is included in both studies (CovidSurg and CovidSurg-Cancer) you may see slightly different cancer-specific fields.

- To help you ensure that your data is complete, we will intermittently send 'data completion request' emails. A spreadsheet will be attached to the email you receive. In this spreadsheet:
  - Each case entered from your centre is on a separate row.
  - The first column indicates the REDCap ID number that can be used to identify the patient on the REDCap database.
  - Each column in the spreadsheet relates to a different critical data item. The guide below indicates how the headings on the columns the spreadsheet match to data fields on the online REDcap database.
  - If 'missing' is written in a cell, this denotes this specific data item is missing for that patient.
- Please examine each case/row and note the missing fields per case.
- To enter any missing data on to the online REDCap database:
  - Log into REDCap
  - Selected the CovidSurg project
  - Navigate to 'Add/ Edit Records' in the left hand side menu under 'Data Collection'.
  - Under the 'select record' dropdown list, select the record ID you need to edit

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BASELINE INFORMATION FORM

Spreadsheet Field Label	REDCap Field and Notes
Month	Month operated This is the patient was operated. If your centre does not have approval to submit information on the month of operation, please select "not stated".
Age	Patient age
Sex	Patient sex
ASA	ASA at time of surgery Full definitions are available from: https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system
BMI	Body mass index (BMI) • Please select the appropriate BMI category • This may be calculated with the formula: BMI (kg/m^2) = mass (kg) / (height(m))^2 An online BMI calculation is also available from: https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm
Comorbidity	Co-morbidity • Tick **all** boxes that apply • If the co-morbidity you would like to enter is not listed, tick 'other (including other lung disease)' and a free text box will appear to enter the relevant details. • An option for HIV infection is now available • If the patient has no co-morbidities, please confirm by selecting the option 'This patient has no comorbidities' on the data field immediately below the list of comorbidities. This field will only show if no comorbidities have been ticked.

TB	Bacillus Calmette-Guérin (BCG) / tuberculosis status (tick all that apply)
	Bacillus Calmette-Guérin (BCG) / tuberculosis status (tick all that apply) ☐ BCG vaccine - last vaccinated less than 15 years ago ☐ BCG vaccine - last vaccinated 15 or more years ago ☐ Tuberculosis - diagnosed less than 15 years ago ☐ Tuberculosis - diagnosed 15 or more years ago ☐ Close contact with an individual known to have tuberculosis under 15 years ago ☐ Close contact with an individual known to have tuberculosis 15 or more years ago ☐ No previous BCG vaccination or TB exposure ☐ BCG vaccination and TB exposure history unknown
	More than one option can be selected. Tick **all** boxes that apply If the BCG vaccination and TB exposure history is unknown please select the last box 'BCG vaccination and TB exposure history unknown'
Urgency	Urgency of surgery Full definitions are available from: https://www.ncepod.org.uk/classification.html *For patients in CovidSurg-Cancer this will appear on the 'management' form.*
Baseline_Sx	Symptoms on hospital admission
	Symptoms on hospital admission (tick all that apply) ☐ Abdominal pain ☐ Breathlessness (dyspnoea) ☐ Cough ☐ Diarrhoea ☐ Fatigue ☐ Fever (>38 celsius) ☐ Haemoptysis ☐ Myalgia ☐ Nausea/vomiting ☐ Sputum ☐ Other
	Please confirm that this patient had no symptoms at the time of admission * must provide value ○ This patient had no symptoms at the time of admission reset
	• **This is only collected for emergency patients.** • Tick all symptoms that may apply. • If the symptom you would like to enter is not listed, tick 'other' and a free text box will appear to enter the relevant details. • If the patient had no symptoms at the time of admission, please confirm by selecting the option 'This patient had no symptoms at the time of admission' on the data field immediately below the list of symptoms. This field will only show if no symptoms have been ticked.
	Please mark which tests were performed to investigate SARS-CoV-2 status, their timing, and the result

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	CT thorax scan (negative for SARS-CoV-2)	CT thorax scan (positive for SARS-CoV-2)	Swab (negative for SARS-CoV-2)	Swab (positive for SARS-CoV-2)
4-7 days before surgery	☐	☐	☐	☐
1-3 days before surgery	☐	☐	☐	☐
Day of surgery - preoperative	☐	☐	☐	☐
After surgery, during index admission	☐	☐	☐	☐
After discharge from index admission, within 30 days of surgery	☐	☐	☐	☐

Select each test used to investigate SARS-CoV-2 status and its result from the columns, then choose the time frame in which it was performed from the rows.

	You may select more than one option. Please select **all** apply.
Diagnosedhow	How was SARS-CoV-2 infection confirmed (tick all that apply) **How was SARS-CoV-2 infection confirmed (tick all that apply)** * must provide value ☐ Positive SARS-CoV-2 swab - result received before surgery ☐ Positive SARS-CoV-2 swab - result received after surgery ☐ CT scan of the chest confirming SARS-CoV-2 - result received before surgery ☐ CT scan of the chest confirming SARS-CoV-2 - result received after surgery ☐ Clinical diagnosis or chest x-ray - suspected before time of surgery ☐ Clinical diagnosis or chest x-ray - suspected after time of surgery • Please confirm how SARS-Cov-2 infection was confirmed. You may select more than one option. Please select **all** that apply
Last Available Data From Before Surgery (E.G. Recorded In Anaesthetic Room Pre-Anaesthetic Induction)	
Resp	Respiratory Rate (breaths per minute)
HR	Heart rate (beats per minute)
SBP DBP_2	Systolic Blood Pressure (mmHg) Diastolic blood pressure (mmHg) **Systolic blood pressure (mmHg)** * must provide value **Diastolic blood pressure (mmHg)** * must provide value • Please ensure that these are entered the correct way round (i.e. the systolic blood pressure should be greater than the diastolic blood pressure)

CONTINUE TO NEXT PAGE FOR THE PREOPERATIVE INVESTIGATIONS FORM

PREOPERATIVE INVESTIGATIONS FORM

Spreadsheet Field Label	REDCap Field and Notes
Haemo	Haemoglobin (g/L) • Please ensure to enter the recorded haemoglobin in g/L. • The normal range will be approximately 110-170 g/L. • If your lab reports haemoglobin in g/dL (normal range 11-17 please multiply this value by 10 to get the value in g/L
WBC	White cell count (10^9/L)
CRP	C-reactive protein (mg/L)
Chest imaging before surgery	
CXR	Preoperative chest x-ray
Chest_CT	Preoperative computed tomography (CT) scan of the chest **Preoperative computed tomography (CT) scan of the chest** *(please tick all that apply)* * must provide value ☐ Not performed ☐ Yes - normal ☐ Yes - consolidation ☐ Yes - ground glass opacity ☐ Yes - pulmonary infiltration ☐ Yes - other abnormality • More than one option can be selected. Please tick all that apply. • If a CT scan was not performed tick 'not performed' only.

CONTINUE TO NEXT PAGE FOR THE MANAGEMENT FORM

Spreadsheet Field Label	REDCap Field and Notes
Preopdelay	Time from admission to operation (preoperative delay) • **This field will only appear for emergency patients.** • This is the time for hospital admission to start of surgery in theatre.
Anaesthesia	Anaesthesia type • Please tick all that apply if more than one type of anaesthesia was used

Indication2	Surgical indication
	
	Surgical indication
	* must provide value
	    ○ Benign disease
	    ○ Malignant disease (cancer)
	    ○ Obstetrics
	    ○ Trauma
	    reset
	
	Surgical diagnosis/ indication
	This field is **OPTIONAL** in case you wish to give additional details
	Expand
	
	• **This field will not appear for patients who are also included in CovidSurg-Cancer.**
	• Please select the most appropriate option for surgical indication.
	• If you want to add further details or clarificiation of the surgical diagnosis, enter this information in the 'surgical diagnosis/ indication' free text field

Surgical_procedure	Surgical procedure completed **Main surgical procedure completed - please select closest matching procedure** *If no appropriate procedures are listed, please enter free text below* *Procedures are listed by organ/ system operated.* *Please note that this list is searchavle by keyword.* **Surgical procedure completed** This field is **OPTIONAL** in case you wish to give additional details Expand • Please choose the closest matching surgical procedure from the drop down menu. • If more than one procedure was performed, enter the primary procedure only • Please used the 'surgical procedure completed' field to add further details or clarification of the procedure ***For patients who are also included in CovidSurg-Cancer, this field will apprear a little differently.***

Please mark what environment the patient was cared for

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(One selection allowed per column)	**Designated COVID treatment area (only COVID patients treated there)**	**Designated non-COVID treatment area (only non-COVID patients treated there)**	**No designation for this area (either COVID or non-COVID patients can be treated there)**
Operating theatre ⓗ 💬 * must provide value	○	○	○
			reset
Intensive care unit (leave blank if not applicable) ⓗ 💬	○	○	○
			reset
Postoperative ward ⓗ 💬 * must provide value	○	○	○
			reset

- Choose the most appropriate column for the treatment area then select it's location (operating theatre, ICU or ward) from the rows.

One selection is permitted per column

CONTINUE TO NEXT PAGE FOR THE COVID-19 TREATMENT FORM

COVID-19 TREATMENT FORM

Spreadsheet Field Label	REDCap Field and Notes
NSAIDs	Did the patient receive non-steroidal anti-inflammatory drugs (NSAIDs) - any agent, any dose • Please select the most appropriate option for any NSAID at any dose given
Treatments	At any point during the index hospital admission did the patient receive **At any point during the index hospital admission did the patient receive** * must provide value ☐ None of the treatments listed below ☐ Antibiotics ☐ Antivirals Ⓗ ☐ Quinine or derivative 💬 ☐ Corticosteroids ☐ Intravenous immunoglobulins ☐ Interferon ☐ IL-6 blocker • Please tick all COVID-19 treatments listed. Tick as many as apply. • Options should be ticked regardless of the specific durg/dose administered. • Options should be ticked if the patient received them at any point in the 30 days following surgery. • *If none of the treatments listed were given, tick 'None of the treatments listed below'.*
Dialysis	Renal dialysis - at any point during the index hospital admission
Respsupport	Preoperative respiratory support
Respsupport2	Postoperative respiratory support **Preoperative respiratory support** (please tick all that apply) * must provide value ☐ None ☐ Low-flow supplemental oxygen Ⓗ ☐ High-flow supplemental oxygen 💬 ☐ Non-invasive ventilation ☐ Invasive mechanical ventilation ☐ Extracorporeal membrane oxygenation (ECMO) • Please select the type of respiratory support given after the patient left the theatre recovery. • ==Please take particular care to note patients who received non-invasive ventilation, invasive mechanical ventilation, or extracorporeal membrane oxygenation, as these are the key secondary outcomes.== • ==If ventilation was received, a separate field will appear underneath, titled "Duration of preoperative invasive mechanical ventilation or ECMO".== Please indicate how long the patient received ventilation or ECMO

CONTINUE TO NEXT PAGE FOR THE SURGICAL OUTCOMES FORM

SURGICAL OUTCOMES FORM

Spreadsheet Field Label	REDCap Field and Notes
Mort7	Outcome at 30 days after surgery **Outcome at 30 days after surgery** * must provide value ○ Died - on-table ○ Died - on days 0-7 after surgery ○ Died - on days 8-30 after surgery ○ Alive - remains admitted in hospital ○ Alive - transferred to another hospital ○ Alive - discharged to a rehabilitation centre ○ Alive - discharged home **Please ensure this field is completed as accurately as possible as this is the primary endpoint of the study.**
Reop	Re-operation or re-intervention This includes any re-operation or re-intervention, including interventional radiology, endoscopy, or surgery.
ICU	Postoperative intensive care admission We are interested in timing of intensive care admission relative to the index procedure. If a patient returned to the ward after the index procedure, but subsequently was reoperated and went to intensive care from theatre at the end of the reoperation, this should be recorded as "unplanned from ward".
Day_Complications	Complications (if any) **Complications (if any)** ☐ Acute kidney injury ☐ Acute respiratory distress syndrome (ARDS) ☐ Anastomosis leak ☐ Bleeding requiring transfusion ☐ Cardiac arrest requiring CPR ☐ Coma >24 hours ☐ Deep vein thrombosis ☐ Graft/ prosthesis/ flap failure ☐ Myocardial infarction ☐ Pneumonia ☐ Pulmonary embolism ☐ Sepsis ☐ Septic shock ☐ Stroke/ cerebrovascular accident ☐ Surgical site infection - superficial or deep ☐ Surgical site infection - organ space ☐ Urinary tract infection ☐ Wound dehiscence ☐ Other complication **Please confirm that this patient did not have nay postoperative complications** * must provide value ○ This patient did not have any postoperative complications reset • Please tick all complications that occurred within 30 days of surgery whether directly related to the original operation or not. • Please take particular care to note **pneumonia** and **ARDS** as these are the key secondary outcomes. • If a complication occurred that is not listed, select 'other complication' and a free text field will appear to enter the relevant details • If the patient did not experience any complications, please confirm by selecting the option 'This patient has no comorbidities' on the data field immediately below the list of possible complications. This field will only show if no complication have been ticked.
Hosp_Stay	Total length of postoperative stay • Please enter the total length of postoperative stay up to the 30th postoperative day., counting the day of surgery as day 0 • If the patient was re-admitted within this 30 day period, please only include the length of stay during the index/ first admission

Datalock2	Data lock- please update this field once the patient has reached 30-days post surgery **Data lock - please update this field once the patient has reached 30-days post surgery** * must provide value ○ This patient is eligible for inclusion and has reached 30-days post-surgery ○ This patient is eligible for inclusion but has NOT yet reached 30-days post-surgery ○ This patient is NOT eligible for inclusion and should be deleted • Please pay particular attention to this field as it is crucial to ensuring appropriate case inclusion • If a suspected or clinically diagnosed COVID patient's investigations come back as negative at any time during the 30 day period, they are no longer eligible for inclusion in CovidSurg. Please select the last option in this case