



COVIDSurg-Cancer H&N Follow Up Study Data Completion Guide

The following pages will guide you through data entry for the data fields for COVIDSurg-Cancer H&N Follow Up Study. 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.

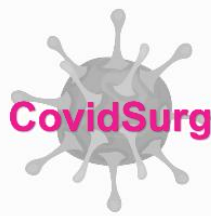
12 months follow up CRF: COVIDSurg-Cancer H&N Follow Up Study

REDCap field	Notes						
<p>CovidSurg-Cancer 30 day follow-up period Recap:</p> <table border="0"> <tr> <td>Head and Neck Cancer location</td> <td>Oral</td> </tr> <tr> <td>Operation during CovidSurg Cancer study period</td> <td>Yes</td> </tr> <tr> <td>Date original operation</td> <td>2020 Week 12 March 16, 2020 March 22, 2020</td> </tr> </table>	Head and Neck Cancer location	Oral	Operation during CovidSurg Cancer study period	Yes	Date original operation	2020 Week 12 March 16, 2020 March 22, 2020	<p>At the top of the 12 month Follow Up CRF, you will see a recap of the information entered for this patient previously for the COVIDSurg-Cancer project.</p>
Head and Neck Cancer location	Oral						
Operation during CovidSurg Cancer study period	Yes						
Date original operation	2020 Week 12 March 16, 2020 March 22, 2020						
<p>Did the patient go on to have an operation related to their tumour during the follow-up period (ie outside original 30 day COVIDSurg window (after June 2020)) <input type="radio"/> Yes <input type="radio"/> No</p> <p><small>* must provide value</small></p> <p>Actual Date of Primary Surgery <input type="text"/></p> <p><small>* must provide value</small></p>	<p>in patients for whom no operation data was entered previously during COVIDSurg-Cancer confirm if the patient had an operation related to their cancer <u>after</u> the 30 day follow period of COVIDSurg-Cancer study.</p> <p>If yes, select from the dropdown list, the week of operation.</p>						
<p>Was the human papillomavirus (HPV) status of the tumour recorded <input type="radio"/> Yes <input type="radio"/> No</p> <p><small>* must provide value</small></p> <p>p16 immunohistochemistry (IHC) <input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Not tested</p> <p><small>* must provide value</small></p> <p>High Risk HPV In situ hybridisation (HR HPV ISH) or HPV PCR <input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Not tested</p> <p><small>* must provide value</small></p>	<p>Only Oropharyngeal patients.</p> <p>Confirm if the HPV status of the tumour is known. If it is provide the test results for p16 immunohistochemistry (IHC) and HR/HPV/ISH or HPV PCR, or indicate if the tests were not carried out.</p>						



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REDCap field	Notes
<p>Readmission within 90 days of date of surgery <input type="radio"/> Yes <input type="radio"/> No <small>* must provide value</small></p>	<p>Was the patient readmitted to hospital within 90 days of date of Surgery.</p>
<p>Reoperation within 90 days of surgery <input checked="" type="radio"/> Yes <input type="radio"/> No <small>* must provide value</small></p> <p>Reoperation for cancer resection <input type="radio"/> Yes <input type="radio"/> No <small>* must provide value</small></p> <p>Reoperation for additional reconstruction procedure <input type="radio"/> Yes <input type="radio"/> No <small>* must provide value</small></p> <p>Reoperation for healing problem <input type="radio"/> Yes <input type="radio"/> No <small>* must provide value</small></p>	<p>Confirm if the patient required reoperation within 90 days of original surgery.</p> <p>If so, also confirm the indication for reoperation (cancer/reconstruction/healing problem).</p> <p>Please confirm answers for all options.</p>
<p>Oral Cavity cancer</p> <p>If neck surgery was compromised/omitted What would standard of care neck management (pre-COVID) have been <input type="radio"/> Sentinel Lymph Node Biopsy <input type="radio"/> Neck Dissection</p> <p>H&N Skin cancer</p> <p>As neck surgery was compromised/omitted What would standard of care neck management (pre-COVID-19) have been <input type="radio"/> Sentinel node biopsy <input type="radio"/> Neck Dissection <input type="radio"/> Parotidectomy <input type="radio"/> Neck Dissection AND Parotidectomy <small>* must provide value</small></p>	<p>Only for patients who had a Change in management of the neck recorded previously (eg. omission of neck dissection or altered extent of neck dissection).</p> <p>Confirm the procedure which <u>would have been undertaken</u> pre COVID (i.e. normal standard of care).</p>
<p>Did the patient have a Total Laryngectomy <input checked="" type="radio"/> Yes <input type="radio"/> No <small>* must provide value</small></p> <p>Did the type of Laryngectomy performed differ from standard of care (Pre COVID) <input checked="" type="radio"/> Yes <input type="radio"/> No <small>* must provide value</small></p> <p>How did this differ? (eg SoC would be partial laryngectomy but total undertaken) <input type="radio"/> Partial Laryngectomy <input type="radio"/> Other <small>* must provide value</small></p>	<p>Laryngeal Cancer patient only.</p> <p>Confirm if the patient had a total Laryngectomy, and:</p> <ul style="list-style-type: none"> • Did it differ from the pre-COVID standard of care • How did this differ.



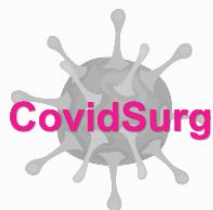
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REDCap field	Notes
<p>Patient who had 'decision for non-surgical treatment' on the original CovidSurg-Cancer study.</p> <p>Date of definitive first treatment * must provide value</p> <p>Patients who were operated on</p> <p>Was the MDT (Tumour board) decision for adjuvant radiotherapy (or chemoradiotherapy) * must provide value</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>Date of commencement of adjuvant treatment * must provide value</p>	<p>Confirm the date the patient started <u>definitive non-surgical</u> treatment.</p> <p>For patients who had an operation;</p> <p>confirm if adjuvant treatment was recommended and if so the start date of adjuvant treatment.</p>
<p>Adjuvant treatment given * must provide value</p> <p><input checked="" type="radio"/> Radiotherapy <input type="radio"/> Chemoradiotherapy</p> <p>Regarding the Radiotherapy element of Adjuvant treatment - was this altered from standard of care * must provide value</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown</p> <p>Radiotherapy dose * must provide value</p> <p><input type="radio"/> Standard <input type="radio"/> Reduced <input type="radio"/> Omitted <input type="radio"/> Unknown</p> <p>Fractionation * must provide value</p> <p><input type="radio"/> Standard <input type="radio"/> Hypofractionated <input type="radio"/> Unknown</p> <p>Radiotherapy fields * must provide value</p> <p><input type="radio"/> Standard <input type="radio"/> Reduced <input type="radio"/> Unknown</p> <p>Chemoradiotherapy patient also answer.</p> <p>Regarding the Chemotherapy element of patients chemoradiotherapy - was this altered from standard of care * must provide value</p> <p><input type="radio"/> Standard <input type="radio"/> Reduced or altered regime <input type="radio"/> Omitted <input type="radio"/> Unknown</p>	<p>For adjuvant treatment patients</p> <p>Confirm whether Radiotherapy of Chemoradiotherapy was recommended.</p> <p>For the Radiotherapy element; was this altered from standard care? If so confirm the changes (to radiotherapy dose, fractionation, fields).</p> <p>If chemoradiotherapy was recommended, please confirm if there were changes to the chemotherapy element.</p>
<p>Recurrence occurred * must provide value</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>Date of recurrence * must provide value</p> <p>Site of recurrence</p> <p>Local * must provide value</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>Regional * must provide value</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>Distant * must provide value</p> <p><input type="radio"/> Yes <input type="radio"/> No</p>	<p>Confirm if recurrence has occurred and if so</p> <ul style="list-style-type: none"> • The date of recurrence • Site of recurrence (any/all sites)



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REDCap field	Notes
<p>To be able to assess survival, please enter the last date that the patient is known to be alive (ie last patient contact) <input type="text"/></p> <p><small>* must provide value</small></p>	<p>Select the week of last recorded patient contact (in any context).</p>
<p>Has the patient died <input checked="" type="radio"/> Yes <input type="radio"/> No <small>* must provide value</small></p> <p>Date of Death <input type="text"/> <small>* must provide value</small></p> <p>Cause of Death <input type="radio"/> Death attributed to head and neck cancer <input type="radio"/> Other cause <small>* must provide value</small></p>	<p>Confirm if the patient is still alive, if the patient has died, please record the</p> <ul style="list-style-type: none"> • Week of death • Cause of death (classified as either death attributed to H&N cancer OR any other cause)
<p>Nutritional Support</p> <p>Nasogastric feeding tube in situ at 12 months <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <small>* must provide value</small></p> <p>Gastrostomy feeding tube (PEG/RIG) in situ at 12 months <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <small>* must provide value</small></p>	<p>Confirm if the patient had either of the following in situ at 12 months</p> <ul style="list-style-type: none"> • Nasogastric feeding tube • Gastrostomy feeding tube (PEG/RIG)
<p>Airway</p> <p>Tracheostomy in situ at 12 months <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <small>* must provide value</small></p> <p>Date trache decannulation <input type="text"/></p>	<p>Confirm if the patient had a tracheostomy in situ at 12 month.</p> <p>Also for patients with a recorded 'Intraoperative airway management' of tracheostomy originally recorded in the COVIDSurg study,'</p> <p>Confirm if/when it was (week of removal)</p>



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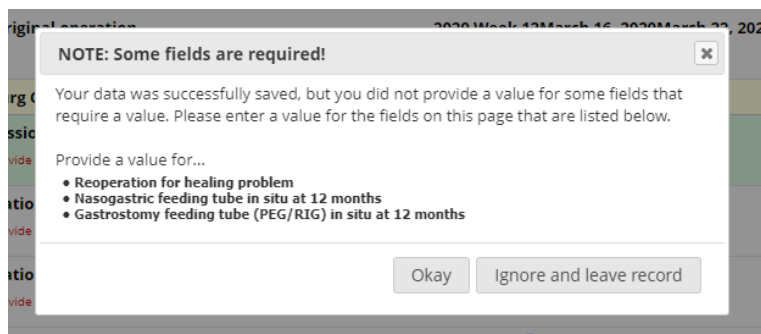
REDCap field	Notes
<p>Assessment of Swallow Function - Functional Oral Intake Score (FOIS)</p> <div style="border: 1px solid #ccc; padding: 10px;"><p><input type="radio"/> 1 No oral intake</p><p><input type="radio"/> 2 Tube dependent with minimal/inconsistent oral intake</p><p><input type="radio"/> 3 Tube supplements with consistent oral intake</p><p><input type="radio"/> 4 Total oral intake of a single consistency</p><p><input type="radio"/> 5 Total oral intake of multiple consistencies requiring special preparation</p><p><input type="radio"/> 6 Total oral intake with no special preparation, but must avoid specific foods or liquid items</p><p><input type="radio"/> 7 Total oral intake with no restrictions</p></div>	<p>From the Patients notes, please make an assessment of the patients Functional Oral Intake Score (FOIS) at the following time points:</p> <ul style="list-style-type: none">• Diagnosis• 3 months post operation• 12 months (for those patients seen on/or after 01 March 2021)

Remember to maintain and store securely the COVIDSurg-Cancer link sheet which contains the patient identifier against the REDCap ID. This will be needed again at the 2 year timepoint in June 2022. If your team changes remember to alert new team members to it's location.

FREQUENTLY ASKED QUESTIONS;

I do not have all the data needed to complete the form yet, can I still save my record?

Yes. A message will appear listing fields that are missing. If you select "Ignore and leave record" your CRF will be saved until you are ready to open the form again and input the missing data.



Missing data

- To help you ensure that your data is complete, we will intermittently send 'data completion request' emails for missing data or any other queries about the data
- Enter any missing data on to the online REDCap database:
 - Log into REDCap
 - Selected the COVIDSurg-Cancer H&N Follow Up Study 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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- Please note, we are using the same REDCap records as the original project, so **no new records** will be entered, you will need to add the follow up data for the patients already recruited into the CovidSurg-Cancer project who had head and neck cancer.
- If there is a field that you will never be able to complete please open up a note in the database to explain why the data is missing. Next to each field you will see a small speech bubble. Clicking on this will bring up the 'Data Resolution Workflow' window.

Nutritional Support	
Nasogastric feeding tube in situ at 12 months <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
	<small>reset</small>

Complete the comment box to explain why the data is missing.

Date/Time	User	Comments and Details
16/05/2021 11:53pm	perryry	<input checked="" type="radio"/> Verified data value — OR — <input type="radio"/> Open query Assign query to a user (optional): -- select user -- Notify this user of their assignment using: <input type="checkbox"/> Email <input type="checkbox"/> REDCap Messenger Comment (optional): <input type="text"/>

[Thank you for participating in CovidSurg-Cancer Head and Neck Follow Up Study](#)
[If you have any questions, you can contact us at hncovidsurgfu@contacts.bham.ac.uk](mailto:hncovidsurgfu@contacts.bham.ac.uk)