HEAD & NECK 5000 FOLLOW-UP STUDY
DATA CAPTURE FORM COMPLETION GUIDELINES VERSION 1.0

These guidelines cover each question on the Data Capture Form (DCF). If you are at all unsure of what information to record or how to record the data from the medical notes please contact the Head & Neck 5000 office. You can ring us on 0117 3429536 or 0117 3429531 or you can e-mail katrina.hurley@uhbristol.nhs.uk or christine.wood@uhbristol.nhs.uk.

However large or small you feel your question is we are always happy to help. We will amend and update these guidelines with frequently asked questions from site staff.

SYNCHRONOUS PRIMARY TUMOURS AT BASELINE

For patients with more than one head & neck primary tumour recorded on the Baseline or Month 4 DCF please check with the H&N5000 office to see if you need to complete a separate DCF for each tumour. Whether or not a separate DCF is required will depend on whether there are many differences in the follow up and treatment(s) for the tumours.

1. THE DATE UP TO WHICH DATA HAS BEEN COLLECTED

- Please record the **date to which the data has been collected** rather than the date that you complete the form. For example if you complete the form on the 1st December 2016, but the last entry in the patient notes that you have used for data collection is 01 Feb 2016, please enter 01/02/16 in Question 1.
- Participants must have consented to H&N5000 at least three years ago in order to be eligible for the Follow-up Study. We need to receive at least three years of follow up data.
- Please collect data to the most recent entry relevant to head and neck cancer in the patient notes. If the patient is due a clinic visit in a few months time please wait and collect data after that appointment.
- For participants who have died please collect data to the date of death, or as near to this as possible. If the patient has died in the community, or at another hospital, please try to collect as much information for the DCF as you can.
- For participants whose head and neck cancer follow-up has been transferred to another hospital please try to collect as much data as you can from the other hospital. We may be able to put you in touch with staff at other hospitals that can assist you.
- For participants whose head and neck follow up has been transferred to GP care and no longer have any hospital outpatients with the head and neck team (either surgery or oncology) please collect data to the last possible date from the hospital records.

1a. IF THE DATE RECORDED IN QUESTION 1 IS MORE THAN 8 MONTHS AGO OR LESS THAN THREE YEARS AFTER CONSENT PLEASE LET US KNOW WHY:

- If the date in Question 1 is less than three years after consent and no explanation has been given in Question 1a then a query will be generated to find out why. If, for example, a patient has moved abroad, been discharged to GP follow up, or has not attended their scheduled hospital appointments and you cannot collect data to three years or later please record this here.

- If the patients care has been transferred to another hospital please try and see if you can find out any information at all on the patients follow up care; staff at the other hospital may be able to help you.

- If the participant has been discharged to GP care for their follow up please record this in question 7f and collect data on all questions up to the point of discharge from the hospital clinicians.

- If the last entry in the notes is over 8 months ago but the patient has a head and neck clinic appointment due soon please hang on the DCF and complete it after the next outpatient appointment.

2. IS THE PATIENT ALIVE?

- Please check the hospital records to find this data. If the participant has died please record the date of death in question 2a.

2a. DATE OF DEATH

- Please check the hospital records to find the date of death.

- If a patient has passed away please complete as many fields on the Data Capture Form as you can from the patient notes. Complete the form up to the date of death, or as near to that as you can. There may be some questions where you know that the data is correct to the date of death but for other questions you may be unsure. In this case record the date of death in question 1 but record in the comments section those questions that are valid to an earlier date. For example: if you are unsure whether the patient had a feeding tube at the date of death but the notes state that they had a PEG tube 6 months earlier please record this in the comments section.

3: CANCER PLAN INTENT (CANCER PATHWAY INTENT)

Please tick the option that reflects the current plan of treatment. If the pathway has remained the same since month 12 please record the current pathway in question 3 and tick box 3a. If the pathway has changed since month 12 please record the previous pathways and dates in question 3b. Where the pathway has not altered question 3b should be left blank.

Information on the intent of the cancer plan may not always be written clearly in the medical notes. If you are unsure of the intent, or the date that the decision was made, please try asking a member of the patient's clinical team or contact the Head & Neck 5000 team for advice.

Question 3b. Where there has been a change in the intent of the treatment since month 12 please record the date of the MDT or clinic where the decision was made to alter the treatment intent. This date will not necessarily be the same as the date of treatment. For example; if the decision was made on 04/04/15 that a patient's pathway was to become palliative, but the patient did not start palliative radiotherapy until 06/07/15 you would record the date of the palliative pathway as 04/04/15.

The pathways are defined as follows:

Pathway	Definition
Curative	The patient is considered to be cancer free or eligible for treatment that intends, however slight the chance of success, to cure.
Palliative	Treatments such as chemotherapy, radiotherapy or surgery are given but it is known that the cancer cannot be cured.
Supportive	Treatments to reduce symptoms are given but the cancer cannot be cured. Often called 'Best Supportive Care'. These treatments are less aggressive than 'Palliative'.
No Specific Anti-Cancer	This is where a patient has refused all input from the clinical team, not just refusal of a specific treatment. Please contact us before using this category as the circumstances may indicate a different pathway.

4. DOES THE PATIENT HAVE ANY RESIDUAL HEAD & NECK TUMOUR?

Residual tumour is the head and neck tumour recorded on the Baseline DCF that is still present following the initial curative treatment(s). The clinic letters should mention whether the patient was, or is, tumour free or if they have still have tumour remaining. If you are unsure whether a patient has residual tumour please try contacting the clinical team at your site or contact the Head & Neck 5000 office for advice.

5. HAS THE HEAD & NECK TUMOUR RECURRED SINCE MONTH 12?

Recurrence is return of the cancer listed on the Baseline DCF after the original treatment(s) and following a period of at least six months of being tumour free. When you read through the clinic letters please check to see if residual or recurrent tumour are mentioned. If the notes do not make it clear as to whether the patient has recurrent or residual disease please try contacting the patient's clinical team or discussing the clinic letters with the Head and Neck 5000 office.

5a. IF 'YES' PLEASE GIVE THE STAGING OF THE RECURRENCE:

Recurrence is not always staged; if there is no staging in the patient notes please record as detailed a description as possible of the recurrence in 5c. The clinic letters may not give a stage but they will mention where the recurrence is. Please do not allocate the staging yourself if the TNM staging is not recorded in the medical notes.

5b. WHEN WAS THE RECURRENCE CONFIRMED?

Please record the date of the clinic or the MDT meeting where the recurrence was confirmed. If the recurrence was not discussed at the MDT meeting please use the date of the clinic where confirmation of the recurrence is mentioned. Please provide as accurate a date as possible. If you can only find the month and year please record 'UK' or 'NK' to show that the day is not known.

5c. PLEASE GIVE THE LOCATION OF THE RECURRENCE:

Please record as much detail as possible on where the recurrent tumour is. For example: right tongue base, multiple bilateral neck nodes, bone metastases.

It is important to tell us whether only one lymph node is involved or if several are, and which side the nodes are on. It is also important to tell us whether there is recurrence at the primary tumour site and if distant metastases are present.

If the patient has had more than one primary head and neck cancer and the head and neck team are unsure which tumour has recurred please record this giving as much detail as you can. You may wish to anonymize and send a clinic letter or contact the Head & Neck 5000 team if you are unsure what to record.

If there has been more than one episode of recurrence please use the additional DCF pages supplied in your site file, or ask the H&N5000 office for additional DCF pages to be sent to you, so that you have enough space to record the details of each recurrence.

6. SINCE MONTH 12 HAS THERE BEEN A NEW HEAD & NECK PRIMARY CANCER?

New head and neck primary tumours are head and neck cancers that are not connected to the tumour listed on the Baseline DCF. We want to know about any new head and neck primary tumours found after the 12 month DCF was completed.

Location of new primary: please record as detailed a description of the confirmed primary site as possible eg: 'left floor of mouth' or 'right base of tongue extending to midline'. Where the tumour is recorded in the notes as 'mandible' or 'maxilla' please try to find out whether this is a tumour of bone or soft tissue (eg. the mandibular alveolus or mandible bone). If investigations are ongoing please submit the DCF later on when the full diagnosis is known.

Date diagnosis confirmed by MDT: please record the date of the MDT meeting where the new primary was confirmed.

Staging of new primary: New primary cancers are all given a TNM stage.

- The T stage describes the size of the primary tumour and whether it has spread to nearby tissue.
- The N stage describes whether the cancer has spread to the nearby (regional) lymph nodes.
- The M stage describes whether the cancer has spread further in the body.

The TNM staging will be recorded in the clinic letters and in the MDT records. If the letters only mention the T and N stages please let us know if there is any mention of the cancer spreading beyond the lymph nodes.

If you cannot find the TNM staging recorded in the clinical letters please record this on the DCF and give as detailed a description as possible of the primary tumour site, any nodal involvement, and any tumour spread to more distant sites.

Anonymised pathology reports for new primary H&N tumours: Please send us a copy of the pathology report from diagnosis and, if applicable, from surgery for the new primary. If you are having difficulty obtaining these reports please let us know. We may ask you to send in the DCF before you obtain the pathology reports.

7. TREATMENTS RECEIVED SINCE MONTH 12.

Please record the treatments given for Head & Neck cancer since month 12. In each section record 'Yes' or 'No' to the treatment type, and where you have answered 'Yes' please complete the questions asked for that treatment. Please try to record as much detail as possible. Please do not leave any boxes blank. Where you cannot find the information in the patient notes please tell us this. Please do not record investigations, only treatments for head and neck cancer.

If there have been several operations, radiotherapy treatments etc and you need more space to record them please use the additional DCF pages from your site file or ask the H&N5000 team to send you more pages.

7a. SURGERY

Name of operation (include primary tumour site, neck dissection and name of flap reconstruction as applicable)

The name of the operation should be mentioned in the clinic letters or can be found on the operation notes. It is important to include any neck dissection and to record the name of any flap reconstruction. For example: 'maxillectomy, bilateral neck dissection and right forearm free flap'. Please record operations not investigations; if you are unsure what to record here please contact the H&N5000 office for advice.

Date: This should be documented on the operation note, the discharge summary and / or the clinic letters. If you can only find a partial date please record 'not known' (use 'NK' or 'UK') where necessary.

Laser surgery: Whether or not the surgery was laser should be written in the operation title. If you are unsure of the type of surgery please leave this field blank and write 'not known' alongside it.

Treatment intent: Where the treatment intent is palliative this may be written in the notes as part of the description of the operation. Sometimes it is the nature of the operation itself that tells us whether it is palliative or curative. The clinic letters before and after the surgery will also indicate the intent of the operation. If the treatment intent is not clearly recorded please try contacting the clinical team or your PI for help as the intent should be clear to the clinicians on reading the notes. You can also contact the H&N5000 office for advice.

Reason for treatment: This should be evident from the clinic letters before (and after) surgery. If the reason for the operation is not clearly recorded please try contacting the clinical team or your PI as the reason should be clear to the clinicians on reading the patient notes. You can also contact the H&N5000 office for advice.

Pathology staging: This is the staging recorded by the pathologist on examination of the tissue removed at surgery. Pathology staging is written with a small letter 'p' before the TNM stage. pT3 pN2a, for example, means that the pathologist has examined tissue from both the primary tumour and neck nodes. If mixed staging is recorded only the stage with a small 'p' before it is pathology staging. For example pT2 N1 M0 means that the pathologist has only examined the primary tumour. Pathology staging is recorded on the pathology report but may sometimes be found in the clinic letters.

If you cannot find the pathology staging in the pathology report or the clinic letters please leave this section blank with a note to say that you cannot find the pathology staging. Send us a copy of the pathology report and our pathologist will allocate the staging. Please do not allocate the staging yourself.

Histology: Please record the description of the tumour type from the notes (eg: squamous cell carcinoma, acinic cell carcinoma). Please do not use abbreviations. The type of cancer should be written in the clinic letters as well as on the pathology report. If you cannot find the histology in the pathology report or the clinic letters leave this

section blank with a note to say that you cannot find the histology. Send us a copy of the pathology report and our pathologist will allocate this.

Pathology report: Please send us a copy of the pathology report from the operation. If the operation took place at another site and you are having trouble obtaining the pathology report please let us know. You may find a brief summary of the pathology report in the MDT notes but it is the full pathology report that we need if possible.

7b: RADIOTHERAPY

Type of radiotherapy: This should be documented in the discharge summary and / or the clinic letters. The most common type of radiotherapy given for head and neck cancer is external beam (EBRT). Intensity modulated radiotherapy (IMRT) is a type of EBRT that is a more precise way of giving radiotherapy. Brachytherapy is an internal radiotherapy treatment.

If you cannot find any specific details and only the generic word 'radiotherapy' is mentioned in the patients notes please record this in 7b under 'other' stating 'radiotherapy, no further details found'.

Radioiodine is a systemic treatment; please record radioiodine in section 7g.

Dose Received: This should be documented in the discharge summary and / or clinic letters. If you cannot find the dose please record this alongside the question. The radiotherapy dose is normally measured in 'Gray' (abbreviated to 'Gy') and is spread out over time in fractions, so a dosing schedule may be written as Gy in fractions over weeks. For example: 40Gy in 15 fractions over 4 weeks.

Treatment intent: Where the treatment intent is palliative this is normally written alongside the description of the radiotherapy. Sometimes the word 'radical' is used to show curative intent. If the treatment intent is not clearly recorded please try contacting the clinical team or your PI for help as the intent should be clear to the clinicians on reading the medical notes. You can also contact the H&N5000 office for advice.

Reason for treatment: This should be evident from the clinic letters before and after the radiotherapy. If the reason for the radiotherapy is not clearly recorded please try contacting the clinical team, or your PI, as the reason should be clear to the clinicians on reading the medical notes. You can also contact the H&N5000 office for advice.

Location of treatment: Please record where the treatment has been given. For example: 'metastases in the ribs' or 'primary site' (eg: 'tonsil').

Start date and End date: This should be documented in the discharge summary and / or clinic letters. If you can only find partial dates please record 'NK' or 'UK' where necessary.

If course not completed please give the reason: If a course was stopped short, for example at the patients request or due to side effects, please record this. If the dose was reduced please record the new dose and the date of the change as well as the reason.

7c. CHEMOTHERAPY, BIOLOGICAL AND IMMUNOTHERAPY

This section refers to chemotherapy treatments such as Cisplatin and monoclonal antibody treatments such as Cetuximab. The drug given should be recorded in the clinic letters. Treatment is often given in cycles where the dose is given daily or weekly for several cycles. Eg: 100 mg/m^2 IV 3 weekly for 3 cycles.

Treatment Name: Please record the drug given eg: Cisplatin, Carboplatin, Docetaxel, 5FU, Cetuximab

Treatment intent: Where the treatment intent is palliative this is normally written alongside the description of the drug. Sometimes the word 'radical' is used to show curative intent. If the treatment intent is not clearly recorded please try contacting the clinical team or your PI for help as the intent should be clear to the clinicians on reading the medical notes. You can also contact the H&N5000 office for advice.

Initial dose per cycle: Please record the dose given at the start of the treatment. (The dose can sometimes be reduced if side effects occur).

'Given' and 'Cycles': Please circle how often the dose was given and record how many cycles were given.

Duration of treatment in weeks if given daily: Please only fill this in if the treatment was given daily.

Was this treatment combined with radiotherapy? Please tick 'Yes' if a course of treatment was given alongside radiotherapy, for example radiotherapy and Cetuximab or Cisplatin and radiotherapy. This is often referred to as 'chemoradiotherapy'.

Reason for treatment: This should be evident from the clinic letters before, during and after the treatment. If the reason for the treatment is not clearly recorded please try contacting the clinical team or your PI as the reason should be clear to the clinicians on reading the medical notes. You can also contact the H&N5000 office for advice.

Start date and End date: This should be documented in the discharge summary and / or clinic letters. If you can only find partial dates please record 'NK' or 'UK' where necessary.

If course not completed please give the reason: If a course of treatment was stopped short, for example at the patients request, please record this. If the drug dose was reduced, for example due to side effects, please record the new dose and the date of the change.

7d HORMONE THERAPY

This usually given for thyroid cancers.

Drug Name & Dose: Please record the name of the drug given eg: Levothyroxine, and the dose where known. If the does is not recorded please record U/K or N/K on the Data Capture Form.

Start date and End date: This should be documented in the discharge summary and / or clinic letters. Please record 'N/K' where a date, or part of a date, is not known. If the treatment has been ongoing since prescription please tick the 'ongoing' box.

If the hormone treatment started before month 12 please state this and do not record the start date.

Reason for treatment: This should be evident from the clinic letters. If the reason for the hormone therapy is not clearly recorded please try contacting the clinical team or your PI as the reason should be clear to the clinicians on reading the medical notes. You can also contact the H&N5000 office for advice.

If the treatment has been ongoing since thyroid surgery please tick the relevant box.

Treatment intent: Where the treatment intent is not clearly mentioned in the notes please try contacting the clinical team or your PI for help as the intent should be clear to the clinicians on reading the medical notes. You can also contact the H&N5000 office for advice.

7e: SPECIALIST PALLIATIVE

This section refers to input from the palliative care team for the head and neck cancer.

Start date: Please record as accurate a start date as possible but if you cannot find the exact date please write 'UK' or 'NK' or 'not known' where applicable.

Brief description of input: Please provide a brief description of the input given eg: pain control. Please record 'not known' if the medical notes do not mention the input given.

7f: OUTPATIENT FOLLOW-UP (ACTIVE MONITORING)

Please record whether the participant is still having hospital outpatient follow up with the head and neck team for their head and neck cancer. Hospital follow-up may be with maxillofacial or ENT surgeons, or under the oncologists, and may be at any hospital.

Discharge to GP care refers to the end of all head and neck cancer specialist outpatient follow-up (surgical and / or oncology), with any further care being taken over by the GP. This is more than a post treatment discharge letter.

If the participant is currently an inpatient under another clinical team but they have follow up planned or arranged with the head and neck team please tick 'ongoing follow up by head and neck clinicians'.

7g: OTHER

This section is for any treatment that does not fit in to the other categories in section seven.

Treatment name: Please record the name of the treatment(s). If the participant is taking part in a clinical trial please record the short name of the study and the treatments given. It is important to let us know if a trial is placebo controlled eg: LUXII trial placebo vs. Afatinib.

Reason for treatment: This should be evident from the clinic letters before, during and after the treatment. If the reason for the treatment is not clearly recorded please try contacting the clinical team or your PI as the reason should be clear to the clinicians on reading the patient notes. You can also contact the H&N5000 office for advice.

Treatment intent: Where the treatment intent is palliative this will sometimes be written alongside the treatment name; sometimes the word 'radical' is used to show curative intent. If the treatment intent is not clearly recorded

please try contacting the clinical team or your PI for help as the intent should be clear to the clinicians on reading the notes. You can also contact the H&N5000 office for advice.

8. CO-MORBIDITY INDEX

For the co-morbidity index please look at the patient's medical history as recorded in the medical notes and tick every relevant box in the comorbidity section.

For Head & Neck 5000 only the overall comorbidity score was required however for the Follow-up Study we are asking for the full table to be completed.

Do not include the head & neck cancer listed on the baseline DCF, or any spread or recurrence of that cancer, in the section on malignancy. In that section score only any previously diagnosed cancer or any other newly diagnosed cancer eg: prostate, lung, or other head and neck cancer(s).

For the section on end stage renal disease please note that it uses the measurement mg%. Mg% is the same as mg/dL. If your hospital measures creatinine in umol/L then take the result in umol/L and divide it by 88.4 to get mg%.

There is a space for you to record any conditions that you cannot see in the comorbidity tables. If you record information here please record the name of the condition and the date of diagnosis. For example: 'epilepsy 2004'.

Please contact us if you are unsure how to record information.

If the participant has no medical history at all please tick the box to say that they have no comorbidities, otherwise a blank comorbidity table will be prompt a data query.

9. DOES THE PATIENT HAVE A FEEDING TUBE?

Please tick 'Yes' if the patient has any type of feeding tube (eg: PEG, RIG, NG or other tube used to administer feed). We do not require the type of feeding tube to be recorded.

If the feeding tube has been inserted as the result of a condition unrelated to the head and neck cancer listed on the baseline DCF please let us know this. Where this is the case please record a brief description of the reason, eg: bowel surgery.

9a: APPROXIMATELY HOW MUCH DIETARY INTAKE IS THROUGH THE FEEDING TUBE?

This information is not always easy to find in the medical notes, but the dieticians, specialist nurses or other members of the clinical team may be able to help you with this information. Sometimes it is easiest to find out when the patient is in a routine follow up in clinic.

If you cannot find the information please let us know this by writing 'not known' alongside this question.

10. DOES THE PATIENT HAVE A TEMPORARY TRACHEOSTOMY?

Please ensure that if the tracheostomy was inserted during a treatment after month 12 that this treatment has been recorded in question B2.

If a tracheostomy has been inserted for a condition other than head and neck cancer please record a brief description of the reason. For example: breathing difficulties following a stroke.

11. DOES THE PATIENT HAVE A PERMANENT LARYNGEAL STOMA?

If a permanent laryngeal stoma was created after month 12 please ensure that the operation is documented in section 7a.

12. AT THE TIME OF DATA COLLECTION DOES THE PATIENT HAVE RESIDUAL HEAD & NECK TUMOUR OR ARE THEY CONSIDERED TO BE FREE OF THE HEAD AND NECK CANCER?

Please ensure that each section is answered as missing data will be queried. Record 'N/K' where not known.

a. Residual tumour remaining from the initial H&N cancer diagnosis
This question refers to residual tumour remaining from the head and neck cancer that was recorded on the baseline DCF. If you have ticked 'Yes' to question '12a' please ensure that the residual tumour has also been recorded in question 4.

b. Residual tumour remaining from recurrence of the H&N cancer
This question refers to recurrence of the head and neck cancer that was recorded on the baseline DCF. If you have ticked 'Yes' to question '12b' please ensure that the recurrence of the head and neck cancer has also been recorded in question 5.

c. Residual tumour remaining from a new H&N primary cancer
If you have ticked 'Yes' to question '12c' please ensure that the new head and neck primary cancer has also been recorded in question 6.

d. Considered to be tumour free from H&N cancer
Please look through the clinic letters to see if they mention that there is no sign of head and neck cancer.

e. Is the participant under investigation for a suspicious H&N lesion?
If the patient is undergoing investigations at the time of DCF completion you may wish to wait and send the form in later, or you can record the details below question 12e. We may contact you later on to see if the investigations showed head and neck cancer.

Please note that:

- Questions 12a and 12b cannot both be ticked 'Yes'.
- If you have ticked 'Yes' to any of questions 12a, 12b or 12c then 12d cannot also be recorded as 'Yes'.

MORTALITY QUESTIONS 1-9

If this information is not available from the patient's hospital notes we would be grateful if you could contact a member of the patients clinical team, for example their Head & Neck Clinical Nurse Specialist or their Consultant, to help provide answers to these questions. If the patient died in a hospice the staff there may be able to help with some of the questions.

Q1. You may find that you need to speak to a member of the clinical team to find the answer to this question. Please ask them to review the notes and see if they can provide the answer to this as it may not always be obvious from the patient's notes.

Q2. Please record whether the death was a gradual deterioration of more than a week or more rapid deterioration of less than a week. If this is not known please record 'NK' alongside this question.

Q3. Please record the cause of death as recorded on the death certificate. If there isn't a copy of the death certificate in the medical notes but the cause of death is known, please record this in the comments section and state where you have obtained the information.

Q4. A catastrophic bleed is where the patient has a 'carotid blow out' which is a rupture of the carotid artery and its branches. This is not common but is a devastating complication of some head and neck cancers.

Q5. Please record 'Yes' if this patent died from airway obstruction.

Q6. Please record if the patient had any aggressive interventions (for example an emergency tracheostomy) in the 48 hours before their death. Please list any interventions, or ask us if you are unsure whether something qualifies as 'aggressive'.

Q7. Please record if the patient had continuous sedation for difficult respiratory symptoms at the time of their death.

Q8.Please record the place of death. This may be recorded in the medical notes or in the MDT records.

Q9. This can be a difficult question to answer as it is not always recorded. If the death was recent you may find that the palliative care team or the specialist nurses can help with the answer to this question.

COMMENTS SECTION

Please use this section to record any comments or additional information that you may wish to tell us to clarify the answers that you have given on the form.

SIGNATURE

Please ensure that the completed DCF is signed by a staff member who is listed on the site signature & delegation log in the study site file, and has been delegated this duty by the Principal Investigator.