HEAD & NECK 5000 DATA CAPTURE FORM

COMPLETION GUIDELINES

Please read the guidance below but if you have any questions regarding the Data Capture Form please do not hesitate to contact the Head & Neck 5000 team on 0117 342 2519 or 0117 342 4516.

- Please ensure all data boxes are completed accurately
- Please write dates in day/month/year format
- Write in black or dark blue ballpoint pen
- Please do not leave any questions unanswered. Please enter NK for 'not known' or NA for 'not available' on any data that you cannot obtain.
- To make CORRECTIONS cross out the error with a SINGLE LINE and record the correction next to the original entry, then DATE and INITIAL the change.
- Please do not use correcting fluid.
- If a question asks for a choice, indicate the correct box with a tick or a cross
- Please ensure that the patients study ID number is written on the top of the page

Please return all data capture forms to the Head & Neck 5000 team at:

Head & Neck 5000 team
Room T106A
Chapter House
Bristol Dental Hospital
Bristol BS1 2LY

Pre-paid envelopes are provided for their return. We ask that the forms are returned no less than one month after the patients consent and no less than one month after the follow up due dates. If you are having difficulty in meeting these deadlines please contact the Head & Neck 5000 team.

BASELINE DATA CAPTURE FORM

A1: DATE OF CONSENT

Please enter the date the patient the patient signed the study consent form.

A2: DATE OF BIRTH.

Please enter the patients date of birth

A3: DATE OF REFERRAL.

This is the date the patient was referred to the Head & Neck team with suspected cancer. If the patient was already under the care of the head & neck team with a benign condition then please enter the date that cancer was first suspected.

A4: DIAGNOSIS DATE

This is the date of first definitive pathology report that states that the patient has cancer. If you have consented the patient on a clinical diagnosis of cancer please write the date the clinical diagnosis was made in the comments section on the data capture form.

A5: PRIMARY DIAGNOSIS (ICD CODE)

The ICD code is a coding system applied to a tumour site by the World Health Organisation International Classification of Diseases. To find the ICD code (version 10 of the coding) you can go to the WHO ICD website at http://apps.who.int/classifications/icd10/browse/2010/en Use the search box to type in where the tumour is (eg: base of tongue, parotid) and the relevant codes will be displayed. You may find that your MDT co-ordinator records the ICD code, so an alternative way to find the code is to access your local MDT database.

Please record the detailed ICD code where possible. For example if you search for nasopharynx you will find the general code for nasopharynx is C11. However if you know that the primary tumour site is the posterior wall of the nasopharynx then the code would be C11.1, a tumour in the anterior wall of the nasopharynx is C11.3.

Some common codes are listed here but this list is not exhaustive so please use the website if the code you require is not listed.

Oral Cavity	**Nasopharynx**
C00.3 Lip, inner aspect, mucosa of upper	C11.0 Nasopharynx, roof
C00.4 Lip, inner aspect, mucosa of lower	C11.1 Nasopharynx, posterior wall
C06.0 Cheek mucosa	C11.2 Nasopharynx, lateral wall, fossa of Rosenmuller
C06.1 Mouth, vestibule (buccal sulcus and labial)	C11.3 Nasopharynx, inferior, upper surface soft palate
C06.2 Retromolar trigone	C11.8 Nasopharynx, overlapping lesion
C03.0 Gum, upper (alveolar ridge, mucosa, gingiva)	C11.9 Nasopharynx unspecified
C03.1 Gum, lower (alveolar ridge, mucosa, gingiva)	**Hypopharynx**
C04.0 Mouth, anterior floor	C12.x or C12.9 Pyriform sinus
C04.1 Mouth, lateral floor	C13.0 Postcricoid region
C04.8 Mouth, floor, overlapping lesion	C13.1 Aryepiglottic fold, hypopharyngeal aspect
C05.0 Palate, hard	C13.2 Hypopharynx, posterior wall
C02.0 Tongue, dorsal surface, anterior 2/3	C13.8 Hypopharynx, overlapping lesion
C02.1 Tongue, lateral border, tip of tongue	C13.9 Hypopharynx unspecified
C02.2 Tongue, ventral, inferior surface	**Larynx**
C02.8 Tongue, overlapping lesion of anterior two-third	Supraglottis – subsite OPTIONAL BAHNO
C02.3 Anterior two-thirds of tongue, part unspecified	

C02.4 Lingual tonsil **Oropharynx** C09.0 Tonsillar fossa C09.1 Tonsillar pillar, glossotonsillar sulcus C09.9 Tonsil, not otherwise specified C10.2 Lateral wall oropharynx C01 Base of tongue C10.3 Posterior wall oropharynx C05.1 Palate, soft, inferior surface C05.2 Uvula C05.8 Overlapping lesion palate C10.8 Overlapping lesion of oropharynx C10.9 Oropharynx unspecified **Thyroid** C73 Thyroid	SUPPLEMENTARY CODES C32.1 Supraglottis C10.1 Anterior surface epiglottis C32.1A Suprahyoid epiglottis (tip, laryngeal surface) C32.1B Aryepiglottic fold, laryngeal aspect C32.3A Arytenoid C32.0 Glottis C32.0B Anterior commissure C32.0C Posterior commissure C32.9 Larynx, not otherwise specified C32.0A Vocal cords, true Subglottis C32.2 Subglottis C32.3 Laryngeal cartilage C32.3B Cricoid cartilage C32.3C Thyroid cartilage

If you are unsure of which code to apply please ask for help from your Principal Investigator or contact the Head & Neck 5000 study team in Bristol.

A6: HISTOLOGY (SNOMED CODE)

The SNOMED code can be found on the patients pathology report. It begins with the letter M and is usually at the bottom of the report. The SNOMED 'M' code tells us the tumour histology. For example: M8070/3 is a Squamous carcinoma (Not Otherwise Specified) or M8071/3 is a Keratinising squamous carcinoma

Some common codes are listed here:

<u>Squamous carcinoma and variants</u>
M8075/3 Adenoid squamous carcinoma
M8560/3 Adenosquamous carcinoma
M8071/3 Keratinising squamous carcinoma
M8072/3 Non-keratinising squamous carcinoma
M8074/3 Spindle cell squamous carcinoma
M8070/3 Squamous carcinoma (Not Otherwise Specified)
M8051/3 Verrucous carcinoma

<u>Salivary malignancies</u>
M8550/3 Acinic cell carcinoma
M8140/3 Adenocarcinoma
M8200/3 Adenoid cystic carcinoma
M8147/3 Basal cell adenocarcinoma
M8941/3 Carcinoma in pleomorphic adenoma (malignant mixed tumour)
M8562/3 Epithelial-myoepithelial carcinoma
M8480/3 Mucinous adenocarcinoma
M8430/3 Mucoepidermoid carcinoma
M8525/3 Polymorphous low grade adenocarcinoma (terminal duct adenocarcinoma)
M8500/3 Salivary duct carcinoma
M8041/3 Small cell carcinoma
M8070/3 Squamous carcinoma (Not Otherwise Specified)

M8020/3 Undifferentiated carcinoma

If you are unsure of how to find or allocate a SNOMED code please ask for help from your Principal Investigator, or contact the Head & Neck 5000 study team in Bristol.

A7: MDT TREATMENT DECISION DATE

Please record the date of the final pre- treatment MDT decision.

A9: ETHNICITY

The patents ethnicity can usually be obtained from the patents notes. Please use the following ethnicity codes:

A1 - White –British
B1 - White -Irish
C1 - Any other White background
D1 - Mixed -White and Black Caribbean
E1 - Mixed -White and Black African
F1 - Mixed -White and Asian
G1 - Any other Mixed background
H1 - Asian -Indian or British Indian
J1 - Asian -Pakistani or British Pakistani
L1 - Any other Asian background
M1 - Black -Caribbean or British Caribbean
N1 - Black -African or British African
P1 - Any other Black background
R1 - Chinese
S1 - Any other Ethnic group
Z1 - Not stated/given
Z2 - Patient Refused

B1: CANCER PLAN INTENT

Please tick the option that reflects the plan of treatment. 'Supportive' refers to 'best supportive care' that is aimed at relieving symptoms (eg: hospice care) but is not as intensive a treatment as ' palliative anti-cancer' where there is no intended cure but a more aggressive regime of care. For example if a patients tumour cannot be cured but they are to undergo radiotherapy this would be 'palliative anti-cancer'. If a patient refuses treatment please tick 'No specific anti cancer'.

B2: PLANNED CANCER TREATMENT TYPE

Please tick as many as many options as necessary.

Chemotherapy refers to induction or maintainance chemotherapy

If you have ticked boxes E (hormone therapy), H (biological therapy) or I (Other) please state the planned treatment.

If the patients diagnostic procedure was also their treatment eg. tonsillectomy, please include their diagnostic surgery in this section and tell us the operation name in the comments field

B3: TREATMENT TYPE SEQUENCE

Please record the planned sequence of treatments.

For example if the plan is for the patent to have surgery followed by radiotherapy you would put 'A' in box 1 and 'C' in box 2.

B3. TREATMENT TYPE SEQUENCE	1.	2.	3.	4..	5.
	A	C			

Where a patient is having more than one treatment at the same time, please put all the codes from that day in one box. For example: for a patient having surgery to the primary tumour site (A) with a neck dissection (B) and reconstruction with free flap (L) you would put ABL in the first box.

B3. TREATMENT TYPE SEQUENCE	1.	2.	3.	4.	5.
	ABL				

B4: CO-MORBIDITY INDEX

For the co-morbidity index please use the scoring system below. Please note that:

- Overall Comorbidity Score is defined according to the highest ranked single ailment, except in the case **where two or more Grade 2 ailments occur in different organ systems. In this situation, the overall comorbidity score should be designated Grade 3.**
- **Do not include the current newly diagnosed head & neck cancer when scoring the section on malignancy**. In that section only score any previously diagnosed cancer or any other newly diagnosed cancer (eg prostate, lung).
- 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%. You only need to calculate this if the patient has end stage renal disease.

Example 1:

A patient with an MI over 6 months ago and IDDM without complications would score grade 3 (overall score 'severe').

Example 2:

A patient with a CABG over 6 months ago, a stroke with no residual effects, and stomach ulcers treated with medication would score a 1 (overall score 'mild')

Where unsure how to complete the comorbidity score please complete with the patients Head & Neck clinician, the study PI, or contact the H&N5000 team in Bristol.

Adult Comorbidity Evaluation-27

Identify the important medical comorbidities and grade severity using the index.

The Comorbidity Score is defined according to the highest ranked single ailment, except in the case where two or more Grade 2 ailments occur in different organ systems. In this situation, the overall comorbidity score should be designated Grade 3.

Cogent comorbid ailment	Grade 3 Severe Decompensation	Grade 2 Moderate Decompensation	Grade 1 Mild Decompensation
Cardiovascular system			
Myocardial Infarct	□ MI ≤ 6 months	□ MI > 6 months ago	□ MI by ECG only, age undetermined
Angina / Coronary Artery Disease	□ Unstable angina	□ Chronic exertional angina □ Recent (≤ 6 months) Coronary Artery Bypass Graft (CABG) or Percutaneous Transluminal Coronary Angioplasty(PTCA) □ Recent (≤ 6 months) coronary stent	□ ECG or stress test evidence or catheterization evidence of coronary disease without symptoms □ Angina pectoris not requiring hospitalization □ CABG or PTCA (>6 mos.) □ Coronary stent (>6 mos.)
Congestive Heart Failure (CHF)	□ Hospitalized for CHF within past 6 months □ Ejection fraction < 20%	□ Hospitalized for CHF >6 months prior □ CHF with dyspnea which limits activities	□ CHF with dyspnea which has responded to treatment □ Exertional dyspnea □ Paroxysmal Nocturnal Dyspnea (PND)
Arrhythmias	□ Ventricular arrhythmia ≤ 6 months	□ Ventricular arrhythmia > 6 months □ Chronic atrial fibrillation or flutter □ Pacemaker	□ Sick Sinus Syndrome □ Supraventricular tachycardia
Hypertension	□ DBP>130 mm Hg □ Severe malignant papilledema or other eye changes □ Encephalopathy	□ DBP 115-129 mm Hg □ DBP 90-114 mm Hg while taking antihypertensive medications □ Secondary cardiovascular symptoms: vertigo, epistaxis, headaches	□ DBP 90-114 mm Hg while not taking antihypertensive medications □ DBP <90 mm Hg while taking antihypertensive medications □ Hypertension, not otherwise specified
Venous Disease	□ Recent PE (≤ 6 mos.) □ Use of venous filter for PE's	□ DVT controlled with Coumadin or heparin □ Old PE > 6 months	□ Old DVT no longer treated with Coumadin or Heparin
Peripheral Arterial Disease	□ Bypass or amputation for gangrene or arterial insufficiency < 6 months ago □ Untreated thoracic or abdominal aneurysm (>6 cm)	□ Bypass or amputation for gangrene or arterial insufficiency > 6 months ago □ Chronic insufficiency	□ Intermittent claudication □ Untreated thoracic or abdominal aneurysm (< 6 cm) □ s/p abdominal or thoracic aortic aneurysm repair
Respiratory System			
	□ Marked pulmonary insufficiency □ Restrictive Lung Disease or COPD with dyspnea at rest despite treatment □ Chronic supplemental O2 □ CO2 retention (pCO2 > 50 torr) □ Baseline pO2 < 50 torr □ FEV1 (< 50%)	□ Restrictive Lung Disease or COPD (chronic bronchitis, emphysema, or asthma) with dyspnea which limits activities □ FEV1 (51%-65%)	□ Restrictive Lung Disease or COPD (chronic bronchitis, emphysema, or asthma) with dyspnea which has responded to treatment □ FEV1 (66%-80%)
Gastrointestinal System			
Hepatic	□ Portal hypertension and/or esophageal bleeding ≤ 6 mos. (Encephalopathy, Ascites, Jaundice with Total Bilirubin > 2)	□ Chronic hepatitis, cirrhosis, portal hypertension with moderate symptoms "compensated hepatic failure"	□ Chronic hepatitis or cirrhosis without portal hypertension □ Acute hepatitis without cirrhosis □ Chronic liver disease manifested on biopsy or persistently elevated bilirubin (>3 mg/dl)
Stomach / Intestine	□ Recent ulcers(≤ 6 months ago) requiring blood transfusion	□ Ulcers requiring surgery or transfusion > 6 months ago	□ Diagnosis of ulcers treated with meds □ Chronic malabsorption syndrome □ Inflammatory bowel disease (IBD) on meds or h/o with complications and/or surgery
Pancreas	□ Acute or chronic pancreatitis with major complications (phlegmon, abscess, or pseudocyst)	□ Uncomplicated acute pancreatitis □ Chronic pancreatitis with minor complications (malabsorption, impaired glucose tolerance, or GI bleeding)	□ Chronic pancreatitis w/o complications

Cogent comorbid ailment	Grade 3 Severe Decompensation	Grade 2 Moderate Decompensation	Grade 1 Mild Decompensation
Renal System			
End-stage renal disease	□ Creatinine > 3 mg% with multi-organ failure, shock, or sepsis □ Acute dialysis	□ Chronic Renal Insufficiency with creatinine >3 mg% □ Chronic dialysis	□ Chronic Renal Insufficiency with creatinine 2-3 mg%.
Endocrine System (Code the comorbid ailments with the (*) in both the Endocrine system and other organ systems if applicable)			
Diabetes Mellitus	□ Hospitalization ≤ 6 months for DKA □ Diabetes causing end-organ failure □ retinopathy □ neuropathy □ nephropathy* □ coronary disease* □ peripheral arterial disease*	□ IDDM without complications □ Poorly controlled AODM with oral agents	□ AODM controlled by oral agents only
Neurological System			
Stroke	□ Acute stroke with significant neurologic deficit	□ Old stroke with neurologic residual	□ Stroke with no residual □ Past or recent TIA
Dementia	□ Severe dementia requiring full support for activities of daily living	□ Moderate dementia (not completely self-sufficient, needs supervising)	□ Mild dementia (can take care of self)
Paralysis	□ Paraplegia or hemiplegia requiring full support for activities of daily living	□ Paraplegia or hemiplegia requiring wheelchair, able to do some self care	□ Paraplegia or hemiplegia, ambulatory and providing most of self care
Neuromuscular	□ MS, Parkinson's, Myasthenia Gravis, or other chronic neuromuscular disorder and requiring full support for activities of daily living	□ MS, Parkinson's, Myasthenia Gravis, or other chronic neuromuscular disorder, but able to do some self care	□ MS, Parkinson's, Myasthenia Gravis, or other chronic neuromuscular disorder, but ambulatory and providing most of self care
Psychiatric			
	□ Recent suicidal attempt □ Active schizophrenia	□ Depression or bipolar disorder uncontrolled □ Schizophrenia controlled w/ meds	□ Depression or bipolar disorder controlled w/ medication
Rheumatologic (Incl. Rheumatoid Arthritis, Systemic Lupus, Mixed Connective Tissue Disorder, Polymyositis, Rheumatic Polymyositis)			
	□ Connective Tissue Disorder with secondary end-organ failure (renal, cardiac, CNS)	□ Connective Tissue Disorder on steroids or immunosuppressant medications	□ Connective Tissue Disorder on NSAIDS or no treatment
Immunological System (AIDS should not be considered a comorbidity for Kaposi's Sarcoma or Non-Hodgkin's Lymphoma)			
AIDS	□ Fulminant AIDS w/KS, MAI, PCP (AIDS defining illness)	□ HIV+ with h/o defining illness. CD4+ < 200/μL	□ Asymptomatic HIV+ patient. □ HIV+ w/o h/o AIDS defining illness. CD4+ > 200/μL
Malignancy (Excluding Cutaneous Basal Cell Ca., Cutaneous SCCA, Carcinoma in-situ, and Intraepithelial Neoplasm)			
Solid Tumor including Melanoma*	□ Uncontrolled cancer □ Newly diagnosed but not yet treated** □ Metastatic solid tumor	□ Any controlled solid tumor without documented metastases, but initially diagnosed and treated within the last 5 years	□ Any controlled solid tumor without documented metastases, but initially diagnosed and treated > 5 years ago
Leukemia and Myeloma	□ Relapse □ Disease out of control	□ 1st remission or new dx <1yr □ Chronic suppressive therapy	□ H/o leukemia or myeloma with last Rx > 1 yr prior
Lymphoma	□ Relapse	□ 1st remission or new dx <1yr □ Chronic suppressive therapy	□ H/o lymphoma w/ last Rx >1 yr prior
Substance Abuse (Must be accompanied by social, behavioral, or medical complications			
Alcohol	□ Delirium tremens	□ Active alcohol abuse with social, behavioral, or medical complications	□ H/o alcohol abuse but not presently drinking
Illicit Drugs	□ Acute Withdrawal Syndrome	□ Active substance abuse with social, behavioral, or medical complications	□ H/o substance abuse but not presently using
Body Weight			
Obesity		□ Morbid (i.e., BMI ≥ 38)	

*** please do not include the current newly diagnosed head & neck cancer in this score**

OVERALL COMORBIDITY SCORE (circle one.)	**0**	**1**	**2**	**3**	**9**
	None	**Mild**	**Moderate**	**Severe**	**Unknown**

B5: TNM STAGING

This is the **T**umour **N**odes **M**etastases staging system.

- **T** describes the size of the original (primary) tumour and whether it has invaded nearby tissue
- **N** describes nearby (regional) lymph nodes that are involved
- **M** describes metastasis (spread of cancer from one part of the body to another)

Please record the final pre-treatment staging (which is based on clinical findings and any radiological staging). Please enter a score in each section, do not leave blank. The MDT outcomes are often the easiest place to find this information as TNM staging should be recorded at the MDT meeting.

An 'x' indicates 'cannot be assessed'. For example in the case of primary of unknown origin the T stage cannot be given so the 'T' staging would be Tx.

An '0' indicates that there is no evidence of tumour

If you are unable to find the staging in the patients notes, or the MDT records, please ask advice from the study Principal Investigator or the patients consultant.

B6: SIDE OF PRIMARY TUMOUR

Please record the location of the primary tumour. In the case of a primary of unknown origin please write 'PUO' in the space at the end of this row.

B7: SIDE OF ANY POSITIVE NECK NODES

Please record the location of any positive lymph nodes in the neck.

B8: IS THIS TUMOUR?

This question is asking if the tumour is the patients first head and neck primary tumour or whether the patient has had a previous head and neck primary tumour. Patients with recurrence are not eligible to join the study, however a patient may have had a separate, previously diagnosed, primary tumour in the head and neck. If the patient has more than one *new* tumour at the same time please record this in the comments section.

B9: HPV (HUMAN PAPILLOMA VIRUS) STATUS

The HPV test is not to be done specifically for the Head & Neck 5000 study but please record the outcome if it has been done as part of routine care. The testing is done on tissue so the result can be found on the pathology report. If HPV testing has not been done then there will be no mention of it on the pathology report. The method of testing for HPV will be either by immunohistochemistry testing for P16, in situ hybridization (ISH) or PCR (polymerase chain reaction testing). Sometimes more than one method may be used. The method used will always be reported on the pathology report. Often the HPV status is issued as a supplementary report at the bottom of the pathology report. If the MDT mention that HPV testing is to be done, please wait for the result before sending in the data capture form.

C1: TRIAL STATUS

Please record here whether the patient is eligible for any other head & neck research studies

C2: COMMENTS:
Please add here any information that you feel may help to clarify information on the data capture form

4 MONTH DATA CAPTURE FORM

A1: DATE OF 4 MONTH DATA COLLECTION

The four month data collection is due four months from consent with an allowance of two weeks either side of this date. If you get behind with data collection and are collecting the data retrospectively after this time, please do not collect data beyond the scheduled time point. For example if the patient was consented on the 02/08/13 the four month data is due on 02/12/13. The time windows for this period mean that you can collect the 4 month data between 18/11/13 – 16/12/13. If you are completing the form in January please only collect data up until the 18/11/13 – 16/12/13 timepoint.

A10: IS THE PATIENT ALIVE? & A11: DATE OF DEATH

If the patient has passed away please enter the date of death on the data capture form and complete the Head & Neck 5000 mortality form. The information for the mortality form may be available in the patients notes but you may also need to ask their clinical team.

B1: ACTUAL CANCER PLAN & B2: ACTUAL CANCER TREATMENT & B3: TREATMENT TYPE SEQUENCE

These questions refer to the actual treatment plan and the actual treatment received as this may be different to that which was initially planned at baseline.

B10: PROCEDURE / TREATMENT START DATE
This is the date of the patients first treatment procedure. For example if the patient is having surgery followed by radiotherapy please give the date of surgery. Where the patients treatment was also their diagnostic procedure please give the date of any further treatment in the comments field. For example: if the patient had a tonsillectomy before consent, and then went on to have radiotherapy, please give the tonsillectomy date here and the radiotherapy date in the comments field (details of the treatment that was also diagnosis can be recorded on the four month or on the baseline form)

B4: CO-MORBIDITY INDEX

Please record the patients co-morbidity score at the 4 month timepoint as it may have changed since baseline. Please use the comorbidity scoring system as shown under baseline.

B5: DEFINITIVE PRE- TREATMENT STAGING

Please record the final pre-treatment staging as this may have been updated since completion of the baseline CRF. If it has not changed please repeat the staging results from baseline or write 'as per baseline'.

B5a: PATHOLOGICAL TNM STAGING

This refers to staging from a surgical procedure if surgery has been performed as the patients treatment. Please enter the score in each section of the TNM staging, do not leave blank. The pathological stage can be found on the pathology report or on the post-operative MDT outcomes.

In TNM staging an 'x' indicates 'cannot be assessed' an '0' indicates that there is no evidence of tumour

If the patient has not had surgery please write n/a

B11: WAS THE PRESCRIBED RADIOTHERAPY TREATMENT COMPLETED? & B12: WAS THE PRESCRIBED CHEMOTHERAPY TREATMENT COMPLETED?

Please tick N/A if these questions are not applicable. If the treatment was not completed tick the reason in B11a or B12a as appropriate.

B13: DOES THE PATIENT HAVE A FEEDING TUBE?

This refers to any form of feeding tube (eg: PEG, RIG or NG tube).

B14: APPROXIMATELY HOW MUCH DIETARY INTAKE IS THROUGH THE FEEDING TUBE?

This information is often best asked in clinic when the patient is in follow up. Alternatively the dietician, specialist nurse or the patient's clinician are good sources of this information.

B16: HAS THERE BEEN TUMOUR RECURRENCE?

Please record if there has been any tumour recurrence. If the patient is not on a curative pathway and the original tumour has not been treated, the answer to this would be 'not applicable'.

B16a: IF YES, WHAT IS THE STAGING OF THE RECURRENCE?

Tumour recurrence it is not always staged. Please write not known (N/K) or if you are unable to find this data.

C1: PATIENT TRIAL STATUS

Please tick as appropriate for any trials that the patient may be in at the 4 month timepoint.

12 MONTH DATA CAPTURE FORM

This form is the very similar to the month 4 follow up form with the following exceptions:

B1: CANCER PLAN OF ANY TREATMENT SINCE MONTH 4
B2: TREATMENT TYPE RECEIVED SINCE MONTH 4
B3: TREATMENT TYPE SEQUENCE

These questions refer to any treatment received between months 4 and 12. If the pathway has changed during this period (for example at month 6 the patient was on a curative pathway but at month 12 they are on a palliative pathway) please add a note in the comments section.

If a patient is having no specific treatment, but is under outpatient follow up, please tick the intent of the pathway and 'J' for active montoring. (For example: In this instance if the patient is still on a curative pathway you would tick 'A' for question B1 and tick 'J' for question B2.). We are asking you to code this section slightly differently to how you may have been doing it before. Please do not worry about correcting previous forms, we will do this at the Bristol office.

B10: PROCEDURE/TREATMENT START DATE

These questions refer to any further treatment that has occurred since month 4.

B4: CO-MORBIDITY INDEX

Please record the patient's co-morbidities at the 12 month time point. Please use the comorbidity scoring system as shown under baseline.

B5: MOST RECENT TNM STAGING

If there has been no further staging since month 4 please write N/A (not applicable).

B11: WAS THE PRESCRIBED RADIOTHERAPY TREATMENT COMPLETED? & B12: WAS THE PRESCRIBED CHEMOTHERAPY TREATMENT COMPLETED?

Questions B11, B11a, B12, B12a refer to any treatments carried out as part of the original treatment plan. In some instances these may not have been completed by the month 4 timepoint.

B12b: WAS ANY FURTHER TREATMENT COURSE COMPLETED?

Question B12b refers to any further treatments required since month 4 that were not part of the original planned treatment.

B18: IS THE PATIENT CLINICALLY DISEASE FREE?

If this has not been recorded in the notes please ask advice from the patients Head & Neck clinician.