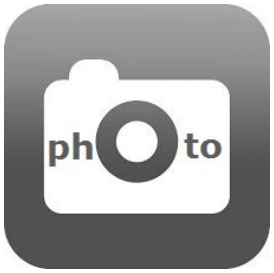


CASE REPORT FORMS (CRFs)

POTENTIALLY ELIGIBLE PATIENTS ONLY

INELIGIBLE AND DECLINED FORM

Outline data on patients who are ineligible or who decline participation

Date of attempted recruitment D D / M M / Y Y Y Y

Year of birth Y Y Y Y **Gender** **Male** ☐ **Female** ☐

Reasons for non-inclusion (tick main reason only):

Patient missed ☐

Ineligible (Please specify below**)** ☐

Visual evidence of low risk NMIBC (solitary tumour < 3cm) ☐

Visual evidence of MIBC on preliminary cystoscopy, i.e non-papillary or sessile mass (attached directly by its base without a stalk) ☐

Imaging evidence of MIBC – CT/USS (this includes the presence of hydronephrosis, which may be present despite clear imaging of MIBC in the bladder) ☐

Upper tract (kidney or ureteric) tumours on imaging ☐

Any other malignancy in the past 2 years (except: non-melanomatous skin cancer cured by excision, adequately treated carcinoma in situ of the cervix, DCIS/LCIS of the breast or prostate cancer in patients who have life expectancy of >5 years upon trial entry) ☐

Evidence of metastases ☐

Porphyria or known hypersensitivity to porphyrins ☐

Known pregnancy (based on history and without formal testing, in keeping with day-to-day NHS practice of PDD use) ☐

Unable to give informed consent ☐

Unable to complete study questionnaires ☐

Patient not interested in the study ☐

Patient does not want PDD treatment ☐

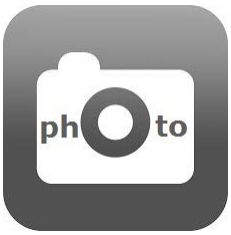
Patient opted for PDD treatment ☐

Other ☐

If other, please specify _____

Signature of recruiter _____

Print name _____



Patient Details

Study ID

Title (Mr, Mrs etc)

First names

Surname

ADDRESS

House name

House number

Street name

Town/City

Postcode

Preferred Method of Communication:

Landline ☐ **Mobile** ☐ **Email** ☐

Telephone number (including code)

Mobile tel. no.

Email address

NHS number

Hospital number

CHI number (Scotland only)

GENERAL PRACTITIONER

Initials

Surname

Practice Name

Street no. and name

Town/City

Postcode

Telephone number (including code)

HOSPITAL CONSULTANT

Initials

Surname

Demographic Details

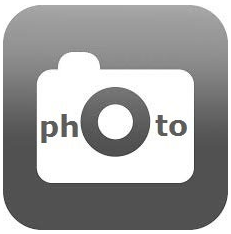
Smoking Status:

Current ☐ Previous ☐ Never ☐

If current or previous Start year

Number of Cigarettes per day?

If previous Stop year



Patient Eligibility Screening

Inclusion Criteria

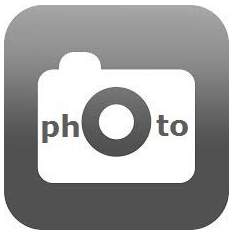
	Yes	No*
1. Is the subject age 16 or over years?	☐	☐
2. First suspected diagnosis of bladder cancer	☐	☐
3. Visual/ultrasound/CT diagnosis of intermediate/high risk NMIBC: defined by:		
a) White light visual appearance of intermediate or high risk disease tumour ≥3cm, OR two or more tumours, OR flat velvety erythematous changes alerting a clinical suspicion of CIS AND/OR	☐	☐
b) Suspicion of papillary bladder tumour ≥ 3cm based on ultrasound or computerised tomography (CT) scanning (without hydronephrosis)	☐	☐
4. Willing to comply with life style guidelines (protocol section 6.4)	☐	☐
5. Written informed consent for participation has been given	☐	☐

Exclusion Criteria

	Yes*	No
1. Visual evidence of low risk NMIBC (solitary tumour < 3cm)	☐	☐
2. Visual evidence of MIBC on preliminary cystoscopy, i.e non-papillary or sessile mass (attached directly by its base without a stalk)	☐	☐
3. Imaging evidence of MIBC – CT/USS (this includes the presence of hydronephrosis, which may be present despite clear imaging of MIBC in the bladder)	☐	☐
4. Upper tract (kidney or ureteric) tumours on imaging	☐	☐
5. Any other malignancy in the past 2 years (except: non-melanomatous skin cancer cured by excision, adequately treated carcinoma in situ of the cervix, DCIS/LCIS of the breast or prostate cancer in patients who have life expectancy of >5 years upon trial entry)	☐	☐
6. Evidence of metastases	☐	☐
7. Porphyria or known hypersensitivity to porphyrins	☐	☐
8. Known pregnancy (based on history and without formal testing, in keeping with day-to-day NHS practice of PDD use)	☐	☐

9. Any other conditions that in the Principal Investigator's opinion would contraindicate protocol treatment.	☐	☐
10. Unable or unwilling to complete follow up schedule (Including Questionnaires)	☐	☐
11. Unable to provide informed consent	☐	☐

Signature of recruiter	
Print name	



Randomisation
(& consent check)

Gender M F **Date of birth** D D / M M / Y Y Y Y

INFORMED CONSENT

Please note: written informed consent must be given before any study specific procedures take place for the purpose of participation in the study.

Has the subject freely given written informed consent? ☐ **Yes** ☐ **No**

Has the subject given written informed consent to PHOTO -T? ☐ **Yes** ☐ **No**

Study Number Allocated ☐☐☐☐☐

Please ensure that the study number is also copied to the Baseline Questionnaire and Post Treatment form

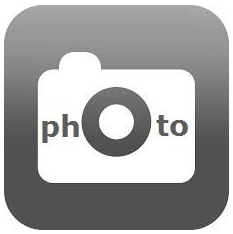
Has Participant completed Baseline Questionnaire? ☐ **Yes** ☐ **No**

If NO, please ensure this is completed prior to patient being informed of their randomised allocation.

Treatment allocated to:

White Light ☐ Blue Light ☐

Scheduled date of surgery ☐☐ / ☐☐ / ☐☐☐☐



Initial Resection Form

Study Number | | | | | |

A1 **Date of Admission** D D / M M / Y Y Y Y

A1a **Did TURBT take place as planned?** Yes ☐ No ☐

If YES go to **B1** If NO go to **A1b**

A1b **Date of abandoned TURBT** D D / M M / Y Y Y Y

please give reason TURBT was abandoned:

B1 **Date of Operation** D D / M M / Y Y Y Y

B1a **Time of entry into anaesthetic room** H H : M M

B2b **Time of leaving operating room** H H : M M

C1 **Did patient receive installation of Hexvix if allocated to Blue light?** Yes ☐ No ☐ N/A ☐

If NO, please give reason Hexvix not given :

D1 **Did patient receive allocated intervention?** Yes ☐ No ☐

If NO, please give reason:

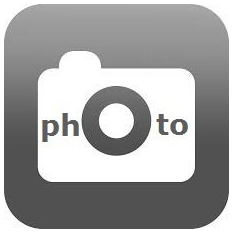
E1 **During surgery were there any Intra operative complications?** Yes ☐ No ☐

If Yes, please give details:

Extra-peritoneal perforation ☐ **Peritoneal perforation** ☐

Other* ☐

*Please give details if Other Intra operative complications:



Initial Resection Pathology Report Form

Pathological data of the initial tumour resection

Participant Study Number | | | | | |

Pathology Identifier Number | | | | | | |

Date of Completion D D / M M / Y Y Y Y

Histological Type

Predominantly TCC ☐ **Non TCC** ☐

No tumour* ☐

* No further details required if 'No tumour' Histological finding

Detrusor muscle identified in specimen **Yes** ☐ **No** ☐

Tumour Grade (WHO 1973/2003)

G1 ☐

G2 ☐ * specify High ☐ Low ☐

G3 ☐

Pathological State (please tick all that apply)

$_pT_x$ ☐ $_pT_a$ ☐ $_pT_1$ ☐ $_pT_2$ ☐ T_{is} /CIS ☐

Lymphovascular invasion **YES** ☐ **NO** ☐

Re-resection indicated **YES** ☐ **NO** ☐

Operation details source data form

Hospital number _____ Initials ☐☐ Date of birth ☐☐ Day ☐☐ Month ☐☐☐☐ Year

PHOTO: *Record details at initial resection, second resection if required and any subsequent treatment for recurrence*

Visual assessment: tumour details *(tick as applicable)*

Number of tumours

None ☐ 1 ☐ 2-7 ☐ ≥8 ☐

Suspected carcinoma in situ

Yes ☐ No ☐

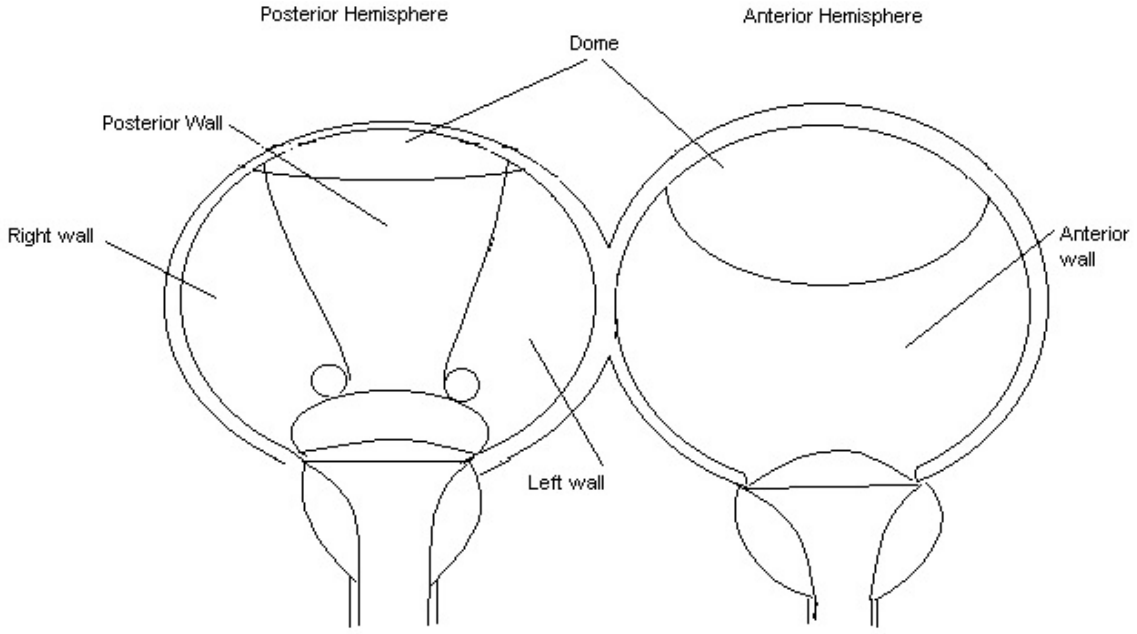
Tumour diameter (largest tumour)

< 3cm ☐ ≥ 3cm ☐

Incomplete resection

Y ☐ N ☐

Please note location of any tumours visible on cystoscopy



Surgeon details-to be collected at time of initial resection only

Grade of operating surgeon

Registrar ☐ Consultant ☐ Non Consultant Career Grade ☐

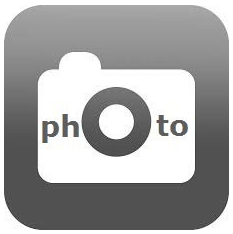
Experience of Photodynamic Diagnosis (PDD) procedures

<10 ☐ 10-19 ☐ 20-40 ☐ >40 ☐

Once completed, this form should be stored in the patient's medical notes and used as source data for completion of trial Case Report Forms (CRFs) as applicable

Signature _____ ☐☐ Day ☐☐ Month ☐☐☐☐ Year

Print name _____



Post-Operative Details

Study Number | | | | | |

Intravesical Treatment

Mitomycin-C (MMC) Administration:

Has MMC been administered to the patient after TUR-T? Yes ☐ No ☐

If NO, please give reason

Deep resection ☐ **Perforation** ☐ **Infection** ☐

Uncontrollable bleeding ☐ **Patient Choice** ☐ **Irritation** ☐

Physicians choice* ☐ **Other*** ☐

*** please give details,**

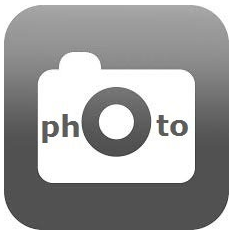
If MMC has been administered choose the timing:

< 6 hours after TURT ☐ **6-24 hours after TURT** ☐ **>24 hours after TURT** ☐

Has the patient filled in the post treatment Quality of Life Questionnaire <u>after intervention</u> **Yes** ☐ **No** ☐

If No, please ensure these are completed before patient is discharged.

Date of discharge D D / M M / Y Y Y Y



Second Resection Form

Study Number | | | | | |

Reason for second resection

Histological findings ☐ Macroscopic incomplete first resection ☐

Date of Admission D D / M M / Y Y Y Y

Date of Operation D D / M M / Y Y Y Y

Time of entry into anaesthetic room H H : M M

Time of leaving operating room H H : M M

Was TUR-T performed under same conditions as first TUR-T? Yes ☐ No ☐

Was there a tumour detected? Yes* ☐ *Please input operation details source data form No ☐

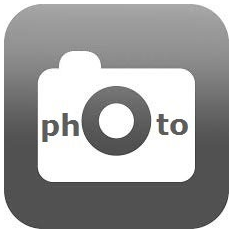
During surgery were there any Intra operative complications? Yes ☐ No ☐

If Yes, please give details:

Extra-peritoneal perforation ☐ **Peritoneal perforation** ☐

Other* ☐

*Please give details:



Second Resection Pathology Report Form

Study Number | | | | | |

Pathology Identifier Number | | | | | | |

Date of Completion D D / M M / Y Y Y Y

Histological Type

Predominantly TCC ☐ **Non TCC** ☐

No tumour* ☐

* No further details required if 'No tumour' Histological finding

Detrusor muscle identified in specimen **Yes** ☐ **No** ☐

Tumour Grade (WHO 1973/2003)

G1 ☐

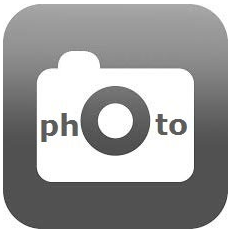
G2 ☐ * specify High ☐ Low ☐

G3 ☐

Pathological State (please tick all that apply)

$_pT_x$ ☐ $_pT_a$ ☐ $_pT_1$ ☐ $_pT_2$ ☐ T_{is} /CIS ☐

Lymphovascular invasion **YES** ☐ **NO** ☐



3 month Cystoscopy Form
(Follow Up 1)

Study Number | | | | | | |

Did participant attend for cystoscopy? Yes ☐ No* ☐

*If No please give details

Date of Cystoscopy D D M M Y Y Y Y

Method of Cystoscopic Assessment

White Light ☐ **Blue Light** ☐

Narrow Band Imaging ☐ **Other*** ☐

*Please give details

Was a tumour detected and confirmed by pathology report? Yes ☐ No ☐

If Yes, how was it managed?

Same day fulguration* ☐ Appointment for TUR-T at OR* ☐

*** Please complete the Recurrence Resection form & Recurrence Resection pathology form AND input the Operation Details Source Data form.**

Please score any adverse events experienced by participant within 30 days post operatively after initial (or second if required) TURBT using the Clavien Dindo reporting system as appropriate [nX Clavien Grade (see guide)]

Clavien Grade	Clavien I	Clavien II	Clavien IIIa	Clavien IIIb	Clavien IVa	Clavien IVb	Clavien V
nX Clavien Grade							

ADVERSE EVENTS

Did the participant encounter any adverse events after initial (or second if required) TURBT up until this visit that may be related with the procedure? Yes ☐ No ☐

If **NO,** stop here, no further details required.

If **YES**, please complete the **details below:**

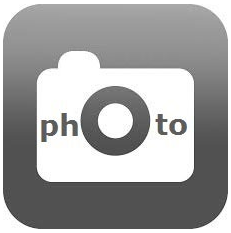
Did the Adverse Event meet the criteria for SAE reporting? Yes* ☐ No ☐

***If YES, please complete a SAE form**

Please record the number of AEs that were Grade 3* and above *According to the CTCAE v4 ☐☐

Please report the Adverse Events by crossing the box that applies in the list below (more than 1 category may be crossed)**:**

Bladder Discomfort/pain	☐	**Haematuria**	☐
Postoperative dysuria	☐	**Bleeding resulting in clot retention**	☐
Urinary retention	☐	**Bladder perforation**	☐
Urinary tract infection	☐	**Skin Rash**	☐
Nausea	☐	**Diarrhoea**	☐
Vomiting	☐	**Constipation**	☐
Urinary frequency	☐	**Fever**	☐
Increase in white blood cell count	☐	**Increased level of bilirubin**	☐
Insomnia	☐	**Headache**	☐
Anaemia	☐	**Gout**	☐
DVT	☐	**Prolonged Catheterisation**	☐
Urethral Stricture	☐		



6 month Cystoscopy Form
(Follow Up 2)

Study Number | | | | | | |

Date of Cystoscopy D D / M M / Y Y Y Y

Method of Cystoscopic Assessment

White Light ☐ **Blue Light** ☐

Narrow Band Imaging ☐ **Other*** ☐

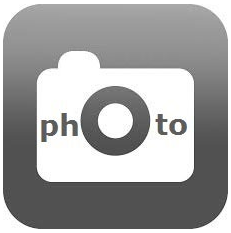
*Please give details

Was a tumour detected and confirmed by pathology report? Yes* ☐ No ☐

If Yes, how was it managed?

Same day fulguration* ☐ Appointment for TUR-T at OR* ☐

* please complete the Recurrence Resection form, input the Operation Details source data form and ensure the Recurrence Resection pathology form is completed.



9 month Cystoscopy Form
(Follow Up 3)

Study Number | | | | | | |

Date of Cystoscopy D D / M M / Y Y Y Y

Method of Cystoscopic Assessment

White Light ☐ **Blue Light** ☐

Narrow Band Imaging ☐ **Other*** ☐

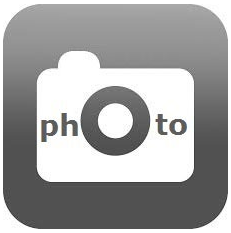
*Please give details

Was a tumour detected and confirmed by pathology report? Yes* ☐ No ☐

If Yes, how was it managed?

Same day fulguration* ☐ Appointment for TUR-T at OR* ☐

* please complete the Recurrence Resection form, input the Operation Details source data form and ensure the Recurrence Resection pathology form is completed.



12 month Cystoscopy Form
(Follow Up 4)

Study Number | | | | | | |

Date of Cystoscopy D D / M M / Y Y Y Y

Method of Cystoscopic Assessment

White Light ☐ **Blue Light** ☐

Narrow Band Imaging ☐ **Other*** ☐

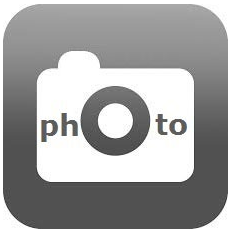
*Please give details

Was a tumour detected and confirmed by pathology report? Yes* ☐ No ☐

If Yes, how was it managed?

Same day fulguration* ☐ Appointment for TUR-T at OR* ☐

* please complete the Recurrence Resection form, input the Operation Details source data form and ensure the Recurrence Resection pathology form is completed.



18 month Cystoscopy Form
(Follow Up 5)

Study Number | | | | | | |

Date of Cystoscopy D D / M M / Y Y Y Y

Method of Cystoscopic Assessment

White Light ☐ **Blue Light** ☐

Narrow Band Imaging ☐ **Other*** ☐

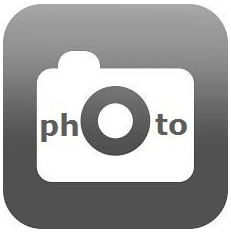
*Please give details

Was a tumour detected and confirmed by pathology report? Yes* ☐ No ☐

If Yes, how was it managed?

Same day fulguration* ☐ Appointment for TUR-T at OR* ☐

* please complete the Recurrence Resection form, input the Operation Details source data form and ensure the Recurrence Resection pathology form is completed.



24 month Cystoscopy Form
(Follow Up 6)

Study Number | | | | | | |

Date of Cystoscopy D D / M M / Y Y Y Y

Method of Cystoscopic Assessment

White Light ☐ **Blue Light** ☐

Narrow Band Imaging ☐ **Other*** ☐

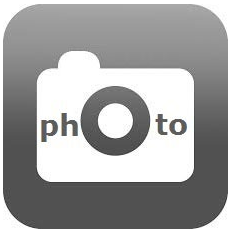
*Please give details

Was a tumour detected and confirmed by pathology report? Yes* ☐ No ☐

If Yes, how was it managed?

Same day fulguration* ☐ Appointment for TUR-T at OR* ☐

* please complete the Recurrence Resection form, input the Operation Details source data form and ensure the Recurrence Resection pathology form is completed.



36 month Cystoscopy Form (Follow up 7)

Study Number | | | | | | |

Date of Cystoscopy D D / M M / Y Y Y Y

Method of Cystoscopic Assessment

White Light ☐ **Blue Light** ☐

Narrow Band Imaging ☐ **Other*** ☐

*Please give details

Was a tumour detected and confirmed by pathology report? Yes ☐ No ☐

If Yes, how was it managed?

Same day fulguration* ☐ Appointment for TUR-T at OR* ☐

*** Please complete the Recurrence Resection form & Recurrence Resection pathology form AND input the Operation Details Source Data form.**

Intravesical Treatment

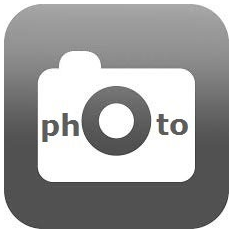
Which intravesical treatment has the participant received:

BCG Induction ☐ **BCG Induction and maintenance** ☐

MMC weekly (6 weeks) ☐ **None** ☐

Other* ☐

***If other please give details, including duration of BCG maintenance** | | **months**



Recurrence Resection Pathology Report Form

Study Number | | | | | |

Pathology Identifier Number | | | | | | |

Date of Completion D D / M M / Y Y Y Y

Histological Type **Predominantly TCC** ☐ **Non TCC** ☐

No tumour* ☐

* No further details required if 'No tumour' Histological finding

Detrusor muscle identified in specimen **Yes** ☐ **No** ☐

Tumour Grade (WHO 1973/2003)

G1 ☐

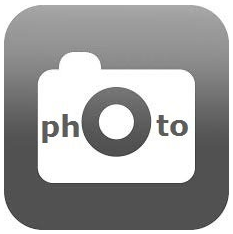
G2 ☐ * specify High ☐ Low ☐

G3 ☐

Pathological State (please tick all that apply)

$_pT_x$ ☐ $_pT_a$ ☐ $_pT_1$ ☐ $_pT_2$ ☐ T_{is} /CIS ☐

Lymphovascular invasion **YES** ☐ **NO** ☐



Recurrence Resection Form

Study Number | | | | | |

Date of Admission D D / M M / Y Y Y Y

Date of Operation D D / M M / Y Y Y Y

Time of entry into anaesthetic room H H : M M

Time of leaving operating room H H : M M

Was there a tumour detected? Yes* ☐ *Please input operation details source data form No ☐

Intravesical Treatment

Which adjuvant intravesical treatment (ie after the initial single dose post-operative MMC installation) did the participant receive prior to recurrence:

BCG Induction ☐ **BCG Induction and maintenance** ☐

MMC weekly (6 weeks) ☐ **None** ☐

Other* ☐

***If other please give details, including duration of BCG maintenance** ☐☐ **months**

Annual follow up form

(to be completed annually from date of any recurrence of NMIBC or from date of randomisation if no recurrence by 36 months post treatment)

Study number | | | | | | |

Q1. Is the patient still alive? Yes ☐ No ☐ If no, complete SAE form

Q2. Date patient last seen D D M M Y Y

Q3a. Has the patient had bladder cancer recurrence? Yes ☐ No ☐

If no disease is present patient should continue to be followed up annually using annual follow up form

Q3b. If yes, please provide details:

Recurrence of NMIBC Yes ☐ No ☐ If yes, please complete a recurrence resection pathology form

Progression to MIBC Yes ☐ No ☐ If yes, please complete a progressive disease form

Metastasis Yes ☐ No ☐ If yes, please complete a progressive disease form

Q4. Has the patient had to undergo a cystectomy? Yes ☐ No ☐

If Yes, please enter date of cystectomy D D M M Y Y

CHANGE OF STATUS

Study number | | | | | | |

Date of change D D / M M / Y Y Y Y

Q1. Is this a post-randomisation exclusion? **Yes** ☐ **No** ☐ *(go to Q2)*
(i.e. the participant was not eligible for the study)

If Yes, please state reason for the post-randomisation exclusion in the box below

Q2. Is this change of status as a result of: **Loss to follow-up** ☐

If necessary, please add further details for the change of status in the box below

Q3. Who has requested the change of status?

Participant ☐ **Clinician** ☐ **Other** ☐ *Please specify*

Q4. What does the change of status relate to? *(tick as many boxes as required)*

Having treatment/taking medication ☐

Attending follow-up appointments ☐

Completing further questionnaires ☐

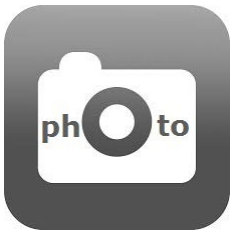
Donation of tissue samples to Biobank ☐

Donation of further blood samples to Biobank ☐

Donation of further urine samples to Biobank ☐

Future research on stored samples ☐
(Only complete if the participant requests that they do not want any collected sample used for research)

Relevant outcome data being collected via hospital and GP records ☐
(only complete if participant explicitly requests this)



Serious Adverse Event/ Death Report Form

To be completed for any Serious Adverse Event (SAE) that is:

- **Related (resulted from administration of any of the research procedures) and**
- **Expected (listed below and in section 11.2 of the protocol)**
- **Unexpected (unexpected events are not listed in section 11.2 of the protocol as a possible expected serious occurrence)**

ALL deaths must be recorded using this Report Form

Study No ☐☐☐☐☐☐

Report date D D / M M / Y Y Y Y

Initials ☐☐

Date of birth D D / M M / Y Y Y Y

Date of event D D / M M / Y Y Y Y

Is this an adverse event update? **Yes** ☐ **No** ☐

Q1. Is this event related to the Trans-urethral resection of bladder tumour (TURB-T) surgery / procedure undertaken as part of PHOTO?

Definition of related: A serious adverse event (SAE) or an adverse event (AE) is 'related' if it occurs as a result of a procedure required by the protocol, whether or not this procedure is the specific intervention under investigation and whether or not it would have been administered outside the study as normal care.

An example of an **unrelated** adverse event would be if the participant broke his leg as this is not related to the PHOTO surgery.

Yes, related ☐ **If Yes,** complete this form

No, not related ☐ **If No,** please do not complete this form unless reporting a death

On what basis was the related/or not related decision made?

Q2. Was the event expected? *(see list below)* **Yes** ☐ **No** ☐ **If no go to Q3**

Expected events: Acute kidney injury, Additional intervention to gain access to bladder for cystoscopy, Bladder discomfort/pain, Haematuria, Postoperative dysuria, Bleeding resulting in clot retention, Urinary retention, Bladder perforation, Urinary tract infection, Skin rash, Nausea, Diarrhoea, Vomiting, Constipation, Urinary frequency, Fever, Increase in white blood cell count, Increased level of bilirubin, Insomnia, Headache, Anaemia, Gout, DVT, Prolonged catheterisation, Lower urinary tract symptoms (LUTS), Sepsis, Ureteric Obstruction/hydronephrosis

Q3. Type of event? *(cross all appropriate to adverse event – if any boxes are crossed the adverse event is "**serious**")*

Prolongation of existing hospitalisation	☐
Requires re-hospitalisation after medical discharge*	☐
Persistent or significant disability or incapacity	☐
Life threatening	☐
Patient died**	☐
Considered medically significant by the investigator	☐

*** In the event of re- hospitalisation please complete:**

Date of admission D D / M M / Y Y Y Y

Date of discharge D D / M M / Y Y Y Y

**** In the event of a death please complete:**

Was the primary cause of death related to participant's bladder cancer **Yes** ☐ **No** ☐

Q3.1 Brief details of adverse event/death

Q3.2. Details of any intervention required

Q3.3. Place where adverse event/death took place/detected

Q3.4 Name and position of person (PI or delegated medical person) confirming assessment of this event.

To be completed by CI only

If SAE is unexpected and related, a CI assessment is required.

Does the CI confirm that this is a serious, unexpected and related SAE?

Yes ☐ **No** ☐

Chief Investigator signature _____

Date of CI assessment D D / M M / Y Y Y Y

Pregnancy report form

PHOTO study number | | | | | | |

Q1 Prenatal details

Q1a. Does the pregnancy relate to a female participant or the female partner of a male participant?

Female participant ☐ Female partner of a male participant ☐

Q1b. Expected delivery date D D M M Y Y

Q1c. Was contraception used as instructed? Yes ☐ No ☐

Q2. Study treatment received

Q2a. Date of PHOTO treatment D D M M Y Y

Q2b. Was trial treatment continuing at estimated time of conception? Yes ☐ No ☐

Q2c. Was trial treatment stopped as a result of this event? Yes ☐ No ☐

Q2d. Was trial treatment delayed as a result of this event? Yes ☐ No ☐

To be completed once outcome of pregnancy known

Q3. Pregnancy/birth outcome assessment

Q3a. Did the pregnancy/birth outcome meet the criteria for expedited reporting as an SAE? Yes ☐ No ☐

If yes, please complete an SAE form ☐

Q4. Any additional information

Progressive disease

NOTE: Any progression to muscle invasive bladder cancer or metastases should be reported as progressive disease

PHOTO study number | | | | | | |

Q1. Date disease progression confirmed: D D / M M / Y Y

Q2 Specify method of confirmation of progression:

*TUR/Histological evidence ☐ Ultrasound ☐ *Pathology ☐

CT scan ☐ Bone scan ☐ X-ray ☐ MRI ☐

***Pathology Identifier Number** (if known) | | | | | | |

Q3. Site(s) of progression

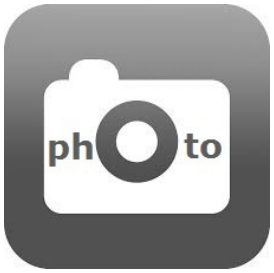
Regional: Yes ☐ No ☐ If yes, please specify: Bladder ☐ Other site in pelvis ☐

Other regional site please specify:

Distant: Yes ☐ No ☐ If yes, please specify:

Distant lymph nodes ☐ Lung ☐ Liver ☐ Bone ☐

Other distant site please specify:



SURGEON QUESTIONNAIRE CRF

PI name:

Site name:

Surgeon questionnaire

LEARNING CURVE FOR PDD ASSISTED TUR-T

Carrying out clinical trials in the field of surgery is very difficult and the presence of a learning curve may confound trial results making our speciality less appealing to funding bodies and journals. The aim of this questionnaire is for you to express ***your*** belief about the learning curve related to surgery for PDD assisted TUR-T. We are interested in ***both*** white light and blue light (PDD) TUR-Ts. This questionnaire will help with the design of future surgical trials and has been sent to you with the full approval of the PHOTO Trial group. ***To be completed by the site PI.***

GENERAL INFORMATION

1. What is your clinical position? _____

2. Do you carry out both white and blue light tumour resection?

Both/White light/Blue light TUR-T only *(please circle your choice)*

3. How many cases of TUR-Ts would you typically perform in a year?

a) White light _____ cases
b) Blue light _____ cases

4. How many cases of TUR-Ts have you performed in your career?

a) White light _____ cases
b) Blue light _____ cases

SURGICAL TRAINING

For a typical urology trainee who has completed higher surgical training in urology and has TUR-T**:**

5. How many procedures' experience do you think is required to acquire proficiency in this surgical operation?

a) White light _____ cases
b) Blue light _____ cases

What is an interquartile range?

The interquartile range varies from the number you would expect 25% of surgical trainees to require to the number that would cover 75% of surgical trainees. For example, an interquartile range of 5 to 10 procedures' experience would imply you believed that 25% of surgical trainees needed 5 or less procedures' experience and 75% of trainees would require 10 or less procedures' experience. Similarly, an interval of 35 to 150 procedures' experience would state your belief that 75% of trainees need no more than 150 procedures' experience whereas 25% of trainees required 35 or less.

6. What is your estimate of the corresponding *interquartile range*? *(see box above)*

a) White light *interquartile range* _____ to _____ cases
b) Blue light *interquartile range* _____ to _____ cases