BioBladder cohorts

Patient study ID
(this is the unique patient ID in BioBladder) _____

Cohort	Pat cohort number	Inf. consent date
First cohort	_____	_____
Second cohort	_____	_____
Third cohort	_____	_____
Fourth cohort	_____	_____
Fifth cohort	_____	_____

Baseline

This patient has cohort number: [baseline_diagnosti_arm_1][kohortnr1]

Centre
- ◯ Karolinska
- ◯ Jönköping
- ◯ Uppsala
- ◯ Gävle
- ◯ Umeå
- ◯ Västerås
- ◯ Östersund

Sex
- ◯ Male
- ◯ Female

Birth date

_____

Co-morbidities at baseline
- ☐ No
- ☐ HT
- ☐ Asthma
- ☐ Renal failure
- ☐ Hyperlipidemia
- ☐ Heart failure
- ☐ Stroke
- ☐ Rheuma
- ☐ Arthritis
- ☐ COPD
- ☐ TIA
- ☐ IBD
- ☐ Psychiatric disease
- ☐ DM1
- ☐ DM2
- ☐ Coronary disease
- ☐ Arrhytmica
- ☐ Hypotyreoidism
- ☐ Atrial fibrillation
- ☐ Deep vein thrombosis
- ☐ Pulmonary embolism
- ☐ Arthrosis
- ☐ Other

-If Other, please specify

_____

Smoking status
- ◯ Non-smoker
- ◯ Smoker
- ◯ Former smoker
- ◯ Not known

Diagnostic Data

This patient has cohort number: [baseline_diagnosti_arm_1][kohortnr1]

Date of first diagnosis(including Ta, Tis, CIS)

_____

PAD number, first diagnosis

_____

Clinical stage at diagnosis

T _____ N _____ M _____ G _____

CIS component at diagnosis

- ◯ No
- ◯ Yes
- ◯ Not known

Date of invasive disease (incl T1)

_____

PAD number (invasive disease)

_____

Primary tumor location

- ◯ Bladder
- ◯ Urethra
- ◯ Ureter
- ◯ Renal pelvis
- ◯ Urachus

Tumour histology

- ◯ Pure adenocarcinoma
- ◯ Pure small cell
- ◯ Pure SCC
- ◯ Pure UC
- ◯ Variant subtype of UC (WHO)
- ◯ Not known

- If Variant subtype of UC, please specify

- ◯ Infiltrating urothelial carcinoma with squamous differentiation
- ◯ Infiltrating urothelial carcinoma with glandular differentiation
- ◯ Poorly differentiated carcinoma
- ◯ Giant cell
- ◯ Sarcomatoid
- ◯ Lymphoepithelioma-like
- ◯ Micropapillary
- ◯ Nested, including large nested
- ◯ Microcystic
- ◯ Plasmacytoid/signet ring/diffuse
- ◯ Lipid-rich
- ◯ Clear cell
- ◯ Small cell neuroendocrine carcinoma
- ◯ Other
- ◯ Not known

- If Other, please specify

_____

PD-L1 tested at any time?	◯ No ◯ Yes ◯ Not known
- If Yes, PD-L1 result	◯ Negative ◯ Positive

PD-L1 Clone Tested Result Date PAD no.
22C3 _____ _____ _____ _____
SP142 _____ _____ _____ _____
SP263 _____ _____ _____ _____
28-8 _____ _____ _____ _____
If other clone tested, name
_____ _____ _____ _____ _____

FGFR alterations tested at any time?	◯ No ◯ Yes ◯ Not known

FGFR test Tested Result Date Type of alteration Type of test PAD no.
Blood _____ _____ _____ _____ _____ _____
Tissue _____ _____ _____ _____ _____ _____

Locally advanced or metastatic disease at initial diagnosis (T4b or N+ or M+)	◯ No ◯ Yes ◯ Not known

Curative Treatment

This patient has cohort number: [baseline_diagnosti_arm_1][kohortnr1]

Type of curative intent treatment
- ☐ None
- ☐ Bladder instillation
- ☐ Cystectomy
- ☐ Nephroureterectomy
- ☐ Curative intent radiotherapy
- ☐ Long term control intent radiotherapy
- ☐ N/K

Instillation

- Instillation, type of treatment
  - ◯ BCG
  - ◯ Mytomicin
  - ◯ Docetaxel/gemzar
  - ◯ Other
  - ◯ Not known

- If BCG, recurrence during or after BCG
  - ◯ Refractory
  - ◯ Recurrence after maintenance with BCG
  - ◯ Non-responsive to BCG
  - ◯ N/K

- If Other, specify _____

- Number of infusions (free text) _____

- Start date _____ Stop date _____

- Main reason for stopping
  - ◯ Planned stop
  - ◯ Progressive disease
  - ◯ Toxicity
  - ◯ Patient choice
  - ◯ Other
  - ◯ Not known

- If Other, please specify _____

- If Toxicity, type of toxicity and CTC grade _____

- If Other, please specify _____

Progressive disease after instillation?
- ◯ No
- ◯ Yes
- ◯ N/K

- If Progressive disease, date of progression _____

- If Yes, confirmed by pathology	◯ No ◯ Yes ◯ N/K
- If Yes, biopsy date	_____
If Yes, PAD number	_____
- Rechallenge BCG	◯ No ◯ Yes ◯ N/K
- Other lines infusion	◯ No ◯ Yes ◯ N/K
- If Yes, type	◯ Mitomycin ◯ Gemzar/docetaxel ◯ Other ◯ Not known
- If Other, specify	_____

Cystectomy or nephroureterectomy

Date of surgery	_____
PAD number	_____
pT	◯ T0 ◯ Tis ◯ Ta ◯ T1a ◯ T1b ◯ T2 ◯ T3 ◯ T4a ◯ T4b ◯ N/K
pN	◯ N0 ◯ N1 ◯ N2 ◯ N3 ◯ Nx ◯ N/K
Tumour histology	◯ Pure adenocarcinoma ◯ Pure small cell ◯ Pure SCC ◯ Pure UC ◯ Variant subtype of UC (WHO) ◯ Not known

- If Variant subtype of UC, please specify	◯ Infiltrating urothelial carcinoma with squamous differentiation ◯ Infiltrating urothelial carcinoma with glandular differentiation ◯ Poorly differentiated carcinoma ◯ Giant cell ◯ Sarcomatoid ◯ Lymphoepithelioma-like ◯ Micropapillary ◯ Nested, including large nested ◯ Microcystic ◯ Plasmacytoid/signet ring/diffuse ◯ Lipid-rich ◯ Clear cell ◯ Small cell neuroendocrine carcinoma ◯ Other ◯ Not known
- If Other, please specify	_____
Progressive disease after cystectomy/nephroureterectomy	◯ No ◯ Yes ◯ N/K
- If Progressive disease, first date of imaging confirming progress	_____
- Date when clinician decides on clinical progress (in case of no confirming imaging)	_____
Progression confirmed by pathology	◯ No ◯ Yes ◯ N/K
- If Yes, biopsy date	_____
- If Yes, PAD number	_____
- If Progressive disease, any new metastatic organs?	◯ No ◯ Yes ◯ N/K

- If new metastatic organ(s), please specify

- ☐ T4B
- ☐ Regional lymph node (N+)
- ☐ Distant metastasis lymph node (M1a)
- ☐ Lung
- ☐ Liver
- ☐ Bone
- ☐ Adrenal gland
- ☐ Brain
- ☐ Pleura
- ☐ Peritoneal carcinomatosis
- ☐ Soft tissue
- ☐ Skin/subcutaneous tissue
- ☐ Pancreas
- ☐ Intramuscular
- ☐ Pericardium
- ☐ Other location
- ☐ Not known

- If Other location, please specify

_____

If Radiotherapy

- Total dose planned (Gy) (free text)

_____

- Total dose given (Gy)

_____

- Number of fractions given

_____

- Start date _____ Stop date _____

- Main reason for stopping radiotherapy

- ◯ Planned
- ◯ Progression
- ◯ Toxicity
- ◯ Patient choice
- ◯ Other
- ◯ Not known

- If Toxicity, specify tox and CTC grade

_____

- If Other, specify

_____

- Progressive disease after radiotherapy?

- ◯ No
- ◯ Yes
- ◯ N/K

- If Progressive disease, first date of imaging confirming progress

_____

- Date when clinician decides on clinical progress (in case of no confirming imaging)

_____

- If Progressive disease, confirmed by pathology
  - ◯ No
  - ◯ Yes
  - ◯ N/K

- If Yes, biopsy date
  - _____

- If Yes, PAD number
  - _____

- If Progressive disease, any new metastatic organs?
  - ◯ No
  - ◯ Yes
  - ◯ N/K

- If new metastatic organ(s), please specify
  - ☐ T4B
  - ☐ Regional lymph node (N+)
  - ☐ Distant metastasis lymph node (M1a)
  - ☐ Lung
  - ☐ Liver
  - ☐ Bone
  - ☐ Adrenal gland
  - ☐ Brain
  - ☐ Pleura
  - ☐ Peritoneal carcinomatosis
  - ☐ Soft tissue
  - ☐ Skin/subcutaneous tissue
  - ☐ Pancreas
  - ☐ Intramuscular
  - ☐ Pericardium
  - ☐ Other location
  - ☐ Not known

- If Other location, please specify
  - _____

Radiotherapy within a clinical trial
- ◯ No
- ◯ Yes
- ◯ Not known

- If Yes, specify trial name and EU-CT or NCT number
  - _____

Concomitant chemotherapy

Concomitant chemotherapy
- ◯ No
- ◯ Yes
- ◯ N/K

- If Yes, type of treatment
  - ◯ FUMI
  - ◯ Gemzar
  - ◯ Other
  - ◯ Not known

- If Other, specify
  - _____

- Performance status at start
  - ◯ 0
  - ◯ 1
  - ◯ 2
  - ◯ 3
  - ◯ 4
  - ◯ N/K

- Start date _____ Stop date (day 1 last cycle) _____

- Number of cycles given
  _____

- Main reason for stopping chemotherapy
  - ◯ Planned
  - ◯ Progression
  - ◯ Toxicity
  - ◯ Patient choice
  - ◯ Other
  - ◯ Not known

- If Toxicity, specify tox and CTC grade
  _____

- If Other, specify
  _____

Concomitant chemotherapy within a clinical trial
- ◯ No
- ◯ Yes
- ◯ N/K

- If Yes, specify trial name and EU-CT or NCT number
  _____

Pre-operative and adjuvant systemic therapy

Pre-operative systemic therapy
- ◯ No
- ◯ Yes
- ◯ N/K

- If Yes, neoadjuvant or induction
  - ◯ Neoadjuvant
  - ◯ Induction
  - ◯ Not known

- If Yes, type of treatment
  - ◯ Cisplatin-Gemzar
  - ◯ MVAC
  - ◯ Other
  - ◯ Not known

- If Other, specify
  _____

- Performance status at start of therapy
  - ◯ 0
  - ◯ 1
  - ◯ 2
  - ◯ 3
  - ◯ 4
  - ◯ N/K

- Start date _____ Stop date (day 1 last cycle) _____	
- Number of cycles given	_____
- Main reason for stopping	◯ Planned ◯ Progression ◯ Toxicity ◯ Patient choice ◯ Other ◯ Not known
- If Toxicity, specify tox and CTC grade	_____
- If Other, specify	_____
Progressive disease after preoperative systemic treatment?	◯ No ◯ Yes ◯ N/K
- If Progression, first date of imaging confirming progress	_____
- Date when clinician decides on clinical progress (in case of no confirming imaging)	_____
- Progression confirmed by pathology?	◯ No ◯ Yes ◯ N/K
- If Yes, biopsy date	_____
- If Yes, PAD number	_____
- If Progressive disease, any new metastatic organs?	◯ No ◯ Yes ◯ N/K

- If new metastatic organ(s), please specify	☐ T4B ☐ Regional lymph node (N+) ☐ Distant metastasis lymph node (M1a) ☐ Lung ☐ Liver ☐ Bone ☐ Adrenal gland ☐ Brain ☐ Pleura ☐ Peritoneal carcinomatosis ☐ Soft tissue ☐ Skin/subcutaneous tissue ☐ Pancreas ☐ Intramuscular ☐ Pericardium ☐ Other location ☐ Not known
- If Other location, please specify	_____
- Pre-operative therapy within clinical trial	◯ No ◯ Yes ◯ N/K
- If Yes, study name and EU-CT or NCT no.	_____
Adjuvant therapy	◯ No ◯ Yes ◯ N/K
- If Yes, type of treatment	◯ Cisplatin-Gemzar ◯ Carboplatin-Gemzar ◯ Nivolumab ◯ Pembrolizumab ◯ Other ◯ Not known
- If Other, specify	_____
- Performance status at start	◯ 0 ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ N/K
- Start date _____ Stop date (day 1 last cycle) _____	
- Number of cycles given	_____

- Main reason for stopping	◯ Planned ◯ Progression ◯ Toxicity ◯ Patient choice ◯ Other ◯ Not known
- If Toxicity, specify tox and CTC grade	_____
- If Other, specify	_____
Progressive disease after adjuvant treatment?	◯ No ◯ Yes ◯ N/K
- If Progression, first date of imaging confirming progress	_____
- Date when clinician decides on clinical progress (in case of no confirming imaging)	_____
- Progression confirmed by pathology?	◯ No ◯ Yes ◯ /N/K
- If Yes, biopsy date	_____
- If Yes, PAD number	_____
- If Progressive disease, any new metastatic organs?	◯ No ◯ Yes ◯ /N/K
- If new metastatic organ(s), please specify	☐ T4B ☐ Regional lymph node (N+) ☐ Distant metastasis lymph node (M1a) ☐ Lung ☐ Liver ☐ Bone ☐ Adrenal gland ☐ Brain ☐ Pleura ☐ Peritoneal carcinomatosis ☐ Soft tissue ☐ Skin/subcutaneous tissue ☐ Pancreas ☐ Intramuscular ☐ Pericardium ☐ Other location ☐ Not known
- If Other location, please specify	_____

- Adjuvant therapy within clinical trial	◯ No ◯ Yes ◯ N/K
- If Yes, study name and EU-CT or NCT no.	_____

Locally advanced and/or metastatic disease

This patient has cohort number(s): [baseline_diagnosti_arm_1][kohortnr1], [baseline_diagnosti_arm_2][kohortnr2], [baseline_diagnosti_arm_3][kohortnr3]

Locally advanced and/or metastatic disease (incl T4b, N1, M1)
- ◯ No
- ◯ Yes
- ◯ Not known

- If Yes, location(s)
- ☐ T4B
- ☐ Regional lymph node (N+)
- ☐ Distant metastasis lymph node (M1a)
- ☐ Lung
- ☐ Liver
- ☐ Bone
- ☐ Adrenal gland
- ☐ Brain
- ☐ Pleura
- ☐ Peritoneal carcinomatosis
- ☐ Soft tissue
- ☐ Skin/subcutaneous tissue
- ☐ Pancreas
- ☐ Intramuscular
- ☐ Pericardium
- ☐ Other location
- ☐ Not known

- If Other location, please specify
_____

- If Yes, date of first radiology with locally advanced or metastastic disease
_____

- If Yes, pathologically confirmed locally advanced or metastastic disease
- ◯ No
- ◯ Yes
- ◯ Not known

- If Yes, biopsy date
_____

- If Yes, PAD number
_____

1st Line therapy

Started first line systemic therapy
- ◯ No
- ◯ Yes
- ◯ Not known

- If No, reason
_____

- If Yes, treatment initiated as induction
- ◯ No
- ◯ Yes
- ◯ Not known

- 1st line systemic therapy type

◯ EV + pembrolizumab
◯ MVAC
◯ Cisplatin + gemcitabine
◯ Carboplatin + gemcitabine
◯ Pembrolizumab
◯ Atezolizumab
◯ Gemcitabine monotherapy
◯ Carboplatin + etoposide
◯ Cisplatin + etoposide
◯ Cisplatin + gemcitabine + nivolumab (incl switch to carboplatin+gemcitabine+nivolumab)
◯ Other
◯ Not known

- If Other, specify

_____

- Performance status at start of therapy

◯ 0
◯ 1
◯ 2
◯ 3
◯ 4
◯ N/K

- Start date _____ Stop date (Day 1 last cycle)

_____

- Number of cycles given

_____
(If combination treatment with immunotherapy is used, this refers to the number of cycles in combination. For maintenance, see below.)

- Best response

◯ CR
◯ PR
◯ SD
◯ PD
◯ NE
◯ Not known

- Main reason for stopping

◯ Planned stop
◯ Progressive disease
◯ Toxicity
◯ Patient choice
◯ Other
◯ Not known

- If Toxicity, type of toxicity (tox and CTC grade)

_____

- If Other, please specify

_____

Progressive disease after 1st line treatment?

◯ No
◯ Yes
◯ N/K

- If Progressive disease, first date of imaging confirming progress

_____

- Date when clinician decides on clinical progress (in case of no confirming imaging)

_____

Progression confirmed by pathology

◯ No
◯ Yes
◯ N/K

- If Yes, biopsy date

_____

- If Yes, PAD number

_____

- If Progressive disease, any new metastatic organs?

◯ No
◯ Yes
◯ N/K

- If new metastatic organ(s), please specify

☐ T4B
☐ Regional lymph node (N+)
☐ Distant metastasis lymph node (M1a)
☐ Lung
☐ Liver
☐ Bone
☐ Adrenal gland
☐ Brain
☐ Pleura
☐ Peritoneal carcinomatosis
☐ Soft tissue
☐ Skin/subcutaneous tissue
☐ Pancreas
☐ Intramuscular
☐ Pericardium
☐ Other location
☐ Not known

- If Other location, please specify

_____

- Therapy within clinical trial

◯ No
◯ Yes
◯ N/K

- If Yes, trial name and EU-CT or NCT no.

_____

1 line therapy baseline laboratory

CRP

_____

B-leukocyter

_____

B-Neutrophiles

_____

B-lymfocytes

Hb

ASAT

ALAT

ALP

P-LD

Glukos

eGFR(cystC), relative

eGFR(krea), relative

P-Albumin

Calcium

Fosfat

TSH

T4

T3

Troponin T

proBNP

Kortisol

Maintenance therapy

Maintenance therapy given	◯ No ◯ Yes ◯ N/K
- If Yes, regimen	☐ Avelumab ☐ Nivolumab (within platinum + gemcitabine + nivolumab regimen) ☐ Pembrolizumab (within ev + pembrolizumab regimen) ☐ Other ☐ Not known
- If Other, please specify	_____
- Performance status at therapy start	◯ 0 ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ N/K
- Start date _____ Stop date (Day 1 last cycle) _____	
- Number of cycles given	_____
- Best response	◯ CR ◯ PR ◯ SD ◯ PD ◯ NE ◯ Not known
- Main reason for stopping	◯ Planned stop ◯ Progressive disease ◯ Toxicity ◯ Patient's choice ◯ Other ◯ Not known
- If Toxicity, type of toxicity and CTC grade	_____
- If Other reason, please specify	_____
- Progressive disease after maintenance therapy?	◯ No ◯ Yes ◯ N/K
- If Progression, first date of imaging confirming progress	_____
- Date when clinician decides on clinical progress (in case of no confirming imaging)	_____

- Progression confirmed by pathology?
  - ◯ No
  - ◯ Yes
  - ◯ N/K

- If Yes, biopsy date
  - _____

- If Yes, PAD number
  - _____

- If Progressive disease, any new metastatic organs?
  - ◯ No
  - ◯ Yes
  - ◯ N/K

- If new metastatic organ(s), please specify
  - ☐ T4B
  - ☐ Regional lymph node (N+)
  - ☐ Distant metastasis lymph node (M1a)
  - ☐ Lung
  - ☐ Liver
  - ☐ Bone
  - ☐ Adrenal gland
  - ☐ Brain
  - ☐ Pleura
  - ☐ Peritoneal carcinomatosis
  - ☐ Soft tissue
  - ☐ Skin/subcutaneous tissue
  - ☐ Pancreas
  - ☐ Intramuscular
  - ☐ Pericardium
  - ☐ Other location
  - ☐ Not known

- If Other location, please specify
  - _____

- Therapy within clinical trial
  - ◯ No
  - ◯ Yes
  - ◯ Not known

- If Yes, trial name and EU-CT or NCT no.
  - _____

Maintenance therapy baseline laboratory

CRP
- _____

B-leukocyter
- _____

B-Neutrophiles
- _____

B-lymfocytes
- _____

Hb
- _____

ASAT

ALAT

ALP

P-LD

Glukos

eGFR(cystC), relative

eGFR(krea), relative

P-Albumin

Calcium

Fosfat

TSH

T4

T3

Troponin T

proBNP

Kortisol

Subsequent treatments

Any subsequent treatment? If Yes, please go to the Subsequent treatment screen.

- ◯ No
- ◯ Yes
- ◯ Not known

Subsequent Treatments

This patient has cohort number(s): [baseline_diagnosti_arm_1][kohortnr1], [baseline_diagnosti_arm_2][kohortnr2], [baseline_diagnosti_arm_3][kohortnr3], [baseline_diagnosti_arm_4][kohortnr4]

Line no.

- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6
- ◯ 7

Treatment given

- ◯ EV
- ◯ Gem/Pak
- ◯ Gem/Cis
- ◯ Pembro
- ◯ Saci/Govi
- ◯ Vin
- ◯ Gem
- ◯ Nivo
- ◯ Doc
- ◯ Gem/Carbo
- ◯ HD-MVAC
- ◯ Erdaf
- ◯ Pak
- ◯ Other
- ◯ Not known

If Other, specify

_____

Performance status

- ◯ 0
- ◯ 1
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ N/K

Start date _____ Stop date
(day 1 last cycle)

_____

No. Of cycles

_____

Best response

- ◯ CR
- ◯ PR
- ◯ SD
- ◯ PD
- ◯ NE
- ◯ N/K

Main reason for stopping	◯ Planned stop ◯ Progressive disease ◯ Toxicity ◯ Patient's choice ◯ Other ◯ Not known
- If Toxicity, type of toxicity (tox and CTC grade)	_____
- If Other reason, please specify	_____
Progressive disease after this treatment line?	◯ No ◯ Yes ◯ N/D
- If Progressive disease, first date of imaging confirming progress	_____
- Date when clinician decides on clinical progress (in case of no confirming imaging)	_____
- Progression confirmed by pathology?	◯ No ◯ Yes ◯ N/K
- If Yes, biopsy date	_____
- If Yes, PAD number	_____
- If progressive disease, any new metastatic organs?	◯ No ◯ Yes ◯ N/K
- If new metastatic organ(s), please specify	☐ T4B ☐ Regional lymph node (N+) ☐ Distant metastasis lymph node (M1a) ☐ Lung ☐ Liver ☐ Bone ☐ Adrenal gland ☐ Brain ☐ Pleura ☐ Peritoneal carcinomatosis ☐ Soft tissue ☐ Skin/subcutaneous tissue ☐ Pancreas ☐ Intramuscular ☐ Pericardium ☐ Other location ☐ Not known
- If Other location, please specify	_____

Therapy within clinical trial	◯ No ◯ Yes ◯ N/K
- If Yes, trial name and EU-CT or NCT no.	_____

Baseline laboratory this subsequent therapy

CRP	_____
B-leukocyter	_____
B-neutrofiles	_____
B-lymfocytes	_____
Hb	_____
ASAT	_____
ALAT	_____
ALP	_____
P-LD	_____
Glukos	_____
eGFR(cystC), relative	_____
eGFR(krea), relative	_____
P-Albumin	_____
Calcium	_____
Fosfat	_____
TSH	_____

T4	_____
T3	_____
Troponin T	_____
proBNP	_____
Kortisol	_____

Samples

Sampling date

_____

Sample ID (T0, T1 etc)

_____

Survival Status

Status at last follow up at the clinic	◯ Alive ◯ Dead ◯ Lost to follow up
-If Alive, last follow up date	_____
- If Dead, date of death	_____
- Cancer related death?	◯ No ◯ Yes ◯ Not known