# COBLAnCE - A COhort to study BLAdder CancEr

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## General

### Identification

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| Detailed name | A COhort to study BLAdder CancEr |
| Sign or acronym | COBLAnCE |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | CNIL n°912260 525/10/2012°, CPP Ile-de-France VII : CO-12-001 (01/02/2012) |

### General Aspects

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| Medical area | Cancer research |
| Health determinants | Addictions<br>Genetic<br>Geography<br>Healthcare system and access to health care services<br>Lifestyle and behavior<br>Medicine<br>Nutrition<br>Occupation<br>Social and psychosocial factors |
| Keywords | Bladder cancer, urology, cancer research, cohort |

### Scientific investigator(s) (Contact)


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| Organization | Inserm |
| **Collaborations** | |
| **Funding** | |
| Funding status | Public |
| Details | ANR "Investissements d'avenir -Grand emprunt" |
| **Governance of the database** | |
| Sponsor(s) or organisation(s) responsible | INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE - INSERM |
| Organisation status | Public |
| **Additional contact** | |
| **Main features** | |
| **Type of database** | |
| Type of database | Study databases |
| Study databases (details) | Cohort study |
| Database recruitment is carried out by an intermediary | A selection of health institutions and services |
| Database recruitment is carried out as part of an interventional study | No |
| Additional information regarding sample selection. | Cases at the participating hospitals will be identified as soon as possible after diagnosis. Early identification will be achieved through active searches, involving periodic visits to the hospital departments in which cases are diagnosed or treated. Inclusion period will last 2 years. The local coordinator will maintain a record of the cases identified and will indicate the reasons for which patients were not interviewed or material not collected (e.g., refusal, treatment). |
| **Database objective** | |
| Main objective | 1) To test the association between constitutional DNA polymorphism, environmental parameters, molecular subtype and clinical data. The inclusion of features of both the tumour and the host will |

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| | facilitate the discovery of tumourigenesis mechanisms, drugable targets and diagnostic and prognostic biomarkers.<br>2) To provide insight into the tumour progression knowledge and to help to identify biomarkers by the sequential sampling of recurrent tumors, plasma or urine from individual patients during follow_up.<br>3) To validate and extend our prior results regarding the molecular subtyping of bladder cancer on a large series of tumors collected prospectively.<br>4) To facilitate the transfer of study results into clinical practice thanks to the size and bladder cancer representativeness of the cohort.<br>5) To describe treatment patterns and to assess the direct and indirect costs of bladder cancer. The cost variability will be analyzed to identify the determinants of cost. This evaluation will pave the way for cost-benefit analyses of new biomarkers developed by the consortium.<br>6) To structure, at the national level, an interdisciplinary bladder cancer network including epidempiologists, bioinformaticians, health economists, molecular biologists, occupational physicians, pathologists and urologists, for coordinated and synergistic research actions and to make a significant contribution to a European multinational cohort and support international studies in genomics, in particular. |
| Inclusion criteria | Inclusion as soon as possible after diagnosis of bladder cancer in the 17 participating hospitals |
| **Population type** | |
| Age | Adulthood (19 to 24 years)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)<br>Elderly (65 to 79 years)<br>Great age (80 years and more) |
| Population covered | Sick population |
| Gender | Male<br>Woman |
| Geography area | National |
| Detail of the geography area | Metropolitan France |
| **Data collection** | |
| **Dates** | |

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| Date of first collection (YYYY or MM/YYYY) | 09/2012 |
| **Size of the database** | |
| Size of the database (number of individuals) | [1000-10 000[ individuals |
| Details of the number of individuals | 2000 patients |
| **Data** | |
| Database activity | Current data collection |
| Type of data collected | Clinical data<br>Declarative data<br>Biological data |
| Clinical data (detail) | Direct physical measures |
| Details of collected clinical data | DISEASE MANAGEMENT > Disease presentation: presence of symptoms (hematuria, pollakuria, dysuria, urgency, hydronephrosis), alteration of health status > Procedures before diagnostic resection: urinary cytology, urine culture, abdominal ultrasound, urinary tract fibroscopies, imaging (scanner, MRI) > Diagnosis through transurethral resection of the bladder: Hervix or Narrow-Band-Imaging fluorescence, number and location of resected tumors, size and aspect of the largest tumor > Treatment: for NMIBC: intravesical instillations and cystectomy; for MIBC: chemotherapy, radiotherapy, for both NMIBC and MIBC: lymphadenectomy, urethrectomy, nephro-urethrectomy, urinary diversion, blood transfusion, any hospitalization and complications > Outcomes: locoregional and distant recurrences (dates, sites, pathology, treatments, etc.) and death (date and place). PATHOLOGY > Histological type and subtype, prognostic factors, pathological review for all cases at initial diagnosis and in case of recurrence. quality of life > Generic measures (EuroQol EQ-5D-3L & EORTC QLQ-C30) > Specific measures (EORTC-BLS24 & EORTC-BLM30) |
| Declarative data (detail) | Face to face interview |
| Details of collected declarative data | EPIDEMIOLOGIE : - Sociodemographic characteristics: age, gender, place of birth, educational level, marital status, household income, working situation, history of residences and of occupations - Lifestyle: history of tobacco |

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| | consumption, dietary habits and physical activity > Medical history and medication use: weight, height, urinary tract infection, hematuria, kidney stones, skin or respiratory allergies, anti-hypercholesteremic and anti-inflammatory drugs, hormonal treatment, personal and family history of cancer. |
| Biological data (detail) | DNA, RNA, plasma, protein extracts from blood, tumors and/or urine |
| Presence of a biobank | Yes |
| Contents of biobank | Whole blood<br>Serum<br>Blood cells isolated<br>Fluids (saliva, urine, amniotic fluid, ?)<br>Tissues |
| Details of biobank content | Lymphocytes, plasma and red blood cells.Tumour tissues at first transurethral resection enbedding in paraffin. If the tumour is sufficiently large, a sample will be snap-frozen and stored at -80°. |
| Health parameters studied | Health event/mortality<br>Health care consumption and services<br>Quality of life/health perception<br>Others |
| Care consumption (detail) | Hospitalization<br>Medical/paramedical consultation<br>Medicines consumption |
| Other (detail) | LQ (Lifestyle questionnaire) : demographic details (age/sex/education/ place of residence/ social class), complete smoking history, history of drinking habits (water, coffee, tea, alcohol, etc), occupational history and physiqcal activity, and personal medical history and familial history of cancer. ---- Economic questionnaire : all medical resources related to bladder cancer and their cost for each patient. |
| **Procedures** | |
| Data collection method | Clinical data on the tumour present on inclusion will be obtained from the review of clinical charts by trained monitors. The clinical and pathologic data will include all EAU factors used to predict recurrence and progression (tumour size, multiplicity, stage, grade, associated CIS). All patients will undergo identical interviews, during which they will complete a lifestyle questionnaire (LQ) and quality of life |

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| | questionnaire (QOL). The lifestyle questionnaire is structured and will be used to collect the following information: demographic details (age/sex/education/place of residence/social class), complete smoking history, history of drinking habits (water, coffee, tea, alcohol, etc), occupational history and physical activity, and personal medical history and familial history of cancer.Health care resources use and quality of life data will be collected for each patient at baseline and every year during follow-up. Healthcare resource use will be collected both from the medical records in the participating centres and interviewing the patients by telephone. Each patient should give its consent to this data collection including access to national health insurance claims data. The economic questionnaire will be structured according the course of the disease (diagnosis, initial treatment, follow-up, recurrences, and progression including metastatic disease). All medical resources (inpatient - surgery, chemotherapy, etc?- , and, outpatient services and visits) related to bladder cancer will be collected for each patient and during the whole study period. Sick leaves will be collected on a yearly basis until the end of follow-up (e.g. 6 years after inclusion). Unit cost information will be gathered from official sources (mainly national health insurance) to cost each type of resources and compute direct and indirect costs. A special attention will be paid to innovative drugs and technologies including biomarkers research. All this information will be collected on specific structured logsheets. |
| Participant monitoring | Yes |
| Details on monitoring of participants | 6 years |
| Links to administrative sources | No |
| **Promotion and access** | |
| **Promotion** | |
| **Access** | |
| Presence of document that lists variables and coding procedures | Yes |
| Terms of data access (charter for data provision, format of data, availability delay) | Terms are currently being defined |

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| Access to aggregated data | Access on specific project only |
| Access to individual data | Access on specific project only |