

Overview of trials running in the Benelux

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Multinational phase III, randomized, double-blind, placebo-controlled efficacy and safety study of oral MDV3100 in patients with progressive castration-resistant prostate cancer previously treated with docetaxel-based chemotherapy

after docetaxel - castration - phase III - resistant prostate cancer - small molecule androgen receptor antagonist

In clinical practice, treatment of advanced prostate cancer is limited by the development of resistance to anti-androgen therapies. Most patients receive 2 or more hormonal manipulations before offered docetaxel. Once patients progress on docetaxel, no approved second-line therapy is available. Because many of these resistant tumours continue to over-express androgen receptors, second generation anti-androgens that are more potent and pure antagonists, like MDV3100, may be effective in these patients. The primary objective of this study is to determine the benefit of MDV3100 (160 g/d orally) compared to placebo as assessed by overall survival.

For more information please contact:

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Phase I study of the combination of lapatinib and temozolomide for the treatment of progressive brain disease in HER2-positive breast cancer

brain metastasis - breast cancer - HER2-positive - lapatinib - phase I - temozolomide

This is a **phase I trial** that is being conducted at the

Jules Bordet Institute to determine the maximum tolerated dose (MTD) for lapatinib combined with temozolomide and to evaluate the dose limiting toxicities (DLT) for this combination in HER2-positive breast cancer progressing after standard local therapy.

Lapatinib is an orally active, reversible dual inhibitor of HER1 and HER2 that has shown activity in HER2-positive breast cancer. Due to its small molecular structure, lapatinib has the potential advantage to better penetrate the blood brain barrier and may therefore offer a significant benefit in patients with CNS involvement. Temozolomide is an oral alkylating agent that has shown preliminary activity in brain metastases from breast cancer. Both oral agents offer ease of administration and possess an acceptable safety profile.

Eligibility criteria include women with proven HER2-positive metastatic breast cancer with recurrent/progressive measurable brain lesions, after standard local therapy. Previous treatment with trastuzumab and/or lapatinib is allowed. Patients must have normal cardiac and hepatic functions, ECOG status 0-2 and a life expectancy of more than 3 months.

For more information please contact:

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A phase I trial of sunitinib, a tyrosine kinase inhibitor combined with ionizing irradiation in rectal cancer: protocol KIRC 08-01

phase I - radiotherapy - rectal cancer - sunitinib - tyrosine kinase inhibitor

The standard treatment for locally advanced rectal cancer combines radiotherapy with surgery and chemotherapy. It has been demonstrated that neo-adjuvant radiotherapy provides superior results

compared to the postoperative setting. Sunitinib is a tyrosine kinase inhibitor (TKI) with anti-angiogenic properties. In murine models, the combination of sunitinib and fractionated radiotherapy inhibits tumour regrowth. This **phase I trial** is therefore designed to combine conventional radiotherapy with concomitant sunitinib in a preoperative approach for locally advanced rectal cancer.

Eligibility criteria include a cT3 or N+ (confined to mesorectum) rectal adenocarcinoma considered amenable to a R0 low anterior resection.

Three different doses of sunitinib (25, 37.5, and 50 mg) will be tested. The primary objective is to establish a recommended dose of sunitinib in these conditions. Secondary endpoints include overall survival, progression-free survival, downstaging and R0 resection rate, gene expression and proteomics. These results will pave the way for the design of a phase II trial that can potentially combine radio-therapy, chemotherapy, and sunitinib in the neo-adjuvant setting.

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A dosimetric study comparing breast radiotherapy planned in prone versus supine position and via conformal 3D versus IMRT techniques: protocol B-POS

breast - dosimetry - gating - IMRT - prone - radiotherapy - supine

Breast cancer is the most frequently diagnosed cancer in women. Radiotherapy is an essential component of the curative treatment algorithm. The current standard of care is radiotherapy, in the supine position, to the whole breast by 3D conformal planning. However, several questions remain regarding dose delivery and technique optimization. Can patient positioning improve dose homogeneity? Can the prone position reduce error associated with patient breathing or decrease the dose to healthy organs and tissues? This study is designed to compare prone versus (conventional) supine treatment and the impact of respiratory motion in each position. The benefits of IMRT versus conventional 3D conformal

planning (in each position) will be compared with regard to dose delivery to the breast, dose to healthy organs and tissues and cost-efficiency regarding departmental resources. The results of this study will serve for the standardization of breast radiotherapy techniques within the Liège University Hospital.

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SORCE trial: a phase III randomized double-blind study comparing sorafenib with placebo in patients with resected primary renal cell carcinoma at high or intermediate risk of relapse

accrual ongoing - phase III - renal cell carcinoma - sorafenib

This **multicentre phase III trial** aims to assess the efficacy and tolerability of sorafenib in patients with resected renal cell carcinoma (RCC). Patients will be randomized to 3 treatment arms: 3 years placebo, 1 year sorafenib + 2 years placebo, or 3 years sorafenib. The main endpoints of the study are disease-free survival, RCC-specific survival, overall survival, and toxicity.

For more information please contact:

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EORTC 22043-30041 trial: postoperative external radiotherapy combined with concomitant and adjuvant hormonal treatment versus postoperative external radiotherapy alone in pathological stage pT3a-b R0-1 N0M0, Gleason score 5-10 prostate carcinoma

accrual start: May-June 2009 - hormonotherapy - phase III - prostate cancer - radiotherapy

This **multicentre phase III trial** aims to investigate the potential benefit of a combined adjuvant treatment (short-term androgen suppression and postoperative radiotherapy) for improving the biochemical progression-free survival of patients who have undergone radical prostatectomy for cT1-2-3a N0M0 prostate cancer with baseline prostate-specific antigen (PSA) level $\leq 5 \times$ upper limit of normal range, and who present postoperatively with pathologic stage pT2 R1 / pT3-b R0-1 N0M0, Gleason score 5-10, and an undetectable postoperative PSA level.

Patients will be randomized between postoperative irradiation alone or postoperative irradiation and short-term adjuvant androgen deprivation.

The main endpoints of the study are biochemical and clinical progression-free survival, distant metastasis-free survival, overall survival, and toxicity.

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Two trials with intra-arterial chemotherapy for unresectable isolated liver metastases from colorectal cancer

cetuximab - colorectal cancer - liver metastases - oxaliplatin - phase II

CHOICE study

The CHOICE study is a multicentre phase II study (promoter: Institute Gustave-Roussy (IGR), Villejuif, France) including 45 colorectal cancer patients with isolated liver metastases in whom the primary tumour has been removed (first-line treatment). Patients with K-RAS mutant tumours are excluded from this study. Patients will be treated as follows:

- intravenous chemotherapy: leukovorin (LV) + 5-fluorouracil (FU)2 + weekly cetuximab (provided by Merck);
- Intra-arterial chemotherapy: oxaliplatin (q 2 weeks).

OPTILIV study

The OPTILIV study is a multicentre phase II study (promoter: 'Association pour la Recherche sur le

temps Biologique et la Chronotherapie (ARTBC) internationale-Hopital P. Brousse', Villejuif, France) in which 60 colorectal cancer patients with isolated liver metastases are recruited in whom the primary tumour was removed (x^{th} treatment line).

Patients with K-RAS mutant tumours are excluded from this study. Patients will be treated as follows:

- IV: bi-weekly cetuximab (provided by Merck)
- IA: 5FU + irinotecan + oxaliplatin (q 2 weeks);
chronomodulated schedule optional.

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A phase I trial on LBH589 (panobinostat), a histone deacetylase inhibitor in combination with external radiotherapy for the treatment of prostate cancer, oesophageal cancer and head and neck cancer: protocol CLBH589CBE01

deacytase inhibitor - histones - phase I trial - radiotherapy

Radiotherapy is a keystone in the treatment of prostate cancer (PC), oesophageal cancer (EC) and head and neck cancer (HNC). In PC, LBH589 degrades androgen receptors, a key regulator for cancer cell survival and proliferation. In squamous cell cancer, LBH589 is synergistic with radiation in preclinical models. Generally, there is a strong rationale to use pan-histone deacytelase inhibitor (HDACi) in HNC and gastrointestinal cancer. A **phase I trial** designed to assess the feasibility of combined administration of different oral LBH589 dosages in combination with ionizing irradiation in a selection of patients with PC, HNC and EC is currently starting at CHU-Liège. This will allow the optimal dose-establishment for further studies.

For more information please contact:

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Assessing the efficacy of the combination of gemcitabine and cetuximab (ECHO) in advanced cholangiocarcinoma

BGDO - cetuximab - cholangiocarcinoma - gemcitabine - phase II

The Belgian Group of Digestive Oncology (BGDO) is launching a **phase II trial** assessing the efficacy of the combination of gemcitabine and cetuximab in advanced cholangiocarcinoma: the **ECHO trial**. These rare tumours represent an orphan disease, with no standard treatment and only phase II trials in the literature. If efficacy is shown after the first 13 patients, this study will hopefully include 45 patients. The aim of the study is to assess progression-free survival at 6 months, hoping to improve it from 20% (as estimated from the trials using gemcitabine) to 40% with the combined regimen. As biliary tract tumours express K-RAS in 50% of the cases, translational research will also be performed to see if mutated K-RAS can be predictive of response.

For more information please contact:

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FIELT study: first-line inhibitor of EGFR in lung cancer treatment

EGFR mutation - EGFR-1 tyrosine kinase inhibition - NSCLC - phase II

The **FIELT study** is a **multicentre prospective phase II study** evaluating small molecule EGFR-1 tyrosine kinase inhibition as first-line treatment in patients with advanced non-small cell lung cancer (NSCLC) harbouring a mutant EGFR gene. Patients with adenocarcinoma of the lung with a little (<15 pack years) or non-smoking history are genotyped for mutations in the EGFR gene in the central laboratory of the Free University of Brussels. This is performed on the normal formalin-fixed lung cancer biopsies used for diagnosis. The results are returned within maximally 2 weeks. The patients with an EGFR gene mutation are then eligible for first-line

treatment with erlotinib. The primary endpoint of this trial is progression-free survival. FISH analysis and additional genotyping is also performed to identify potential eligibility for other targeted therapies in patients that do not have an EGFR gene mutation in their tumour. This study continues to recruit patients.

For more information please contact:

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Single-arm trial of BIBW2992 in demographically and genotypically selected non-small cell lung cancer patients

BIBW2992 - EGFR inhibitor - HER2-neu inhibitor - NSCLC - phase II

The primary objective of this **phase II trial** is to explore the efficacy of **BIBW2992**, a dual inhibitor of EGFR and HER2-neu, in patients with advanced non-small cell lung cancer (NSCLC) stage IIIB or IV whose tumours:

1. harbour activating **mutations** within exon 18 to exon 21 of the **EGFR receptor** and who have become **resistant to treatment with gefitinib or erlotinib**;
2. are **EGFR FISH-positive** and who have become resistant to treatment with **gefitinib or erlotinib**;
3. harbour **activating mutations in the HER2-neu receptor**.

The HER2 mutation screens are routinely performed in patients who were screened in the Laboratory of Molecular Oncology, Oncology Centre, University Hospital Brussels, and who were EGFR mutation negative.

The laboratory can also perform **HER2 mutation screens in phenotypically selected lung adenocarcinomas in never or past smokers** who have failed prior chemotherapy and were not previously considered for the FIELT study.

These mutation screens are performed on paraffin-embedded, formalin-fixed tissues.

For more information please contact:

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Activity of sunitinib in oesophageal cancer, melanoma and sarcoma (SEMS)

melanoma - oesophageal cancer - phase II - sarcoma - sunitinib

The melanoma and sarcoma cancer cohorts have been completed. Accrual continues in oesophageal cancer.

Therapeutic options in patients with advanced oesophageal cancer, melanoma and sarcoma are limited after failure of standard first-line chemotherapy. In the present, **multicentre 2-stage phase II trial** the activity of the single agent sunitinib malate (Sutent®) administered orally at 50 mg/day, 4 weeks on followed by 2 weeks off, will be examined.

Inclusion criteria:

- advanced cancer, locally or metastatic;
- presence of plasma and tissue sample;
- life expectancy of >3 months;
- measurable disease or disease evaluable with non-measurable lesions or tumour marker;
- disease progression on prior treatment and anti-cancer therapy-free period of >4 weeks before baseline examination for current study;
- Tumour-specific inclusion criteria:
 - **sarcoma and melanoma cohorts are closed (recruitment completed);**
 - **oesophageal cancer:** second line after cisplatin based chemotherapy.

The study comprises a translational component including

- baseline plasma levels of VEGF-A, sVEGFR-2, sVEGFR-3 and placenta growth factor (PlGF);
- tumour gene copy number of VEGFR-2;
- evolution during treatment of circulating endothelial and tumour cells. Perfusion imaging with dynamic contrast enhanced MRI.

For more information please contact:

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The PATSGO trial

chemotherapy - glioblastoma - phase II - progression-free survival - temozolomide

The PATSGO trial is a randomized phase II trial evaluating the benefit of a prolonged adjuvant treatment in glioblastoma patients. Some patients present at the end of the 6 months adjuvant treatment with residual tumours that are still regressing. These patients could benefit from prolonged treatment. This study will also evaluate the efficacy of rechallenging patients with temozolomide when their tumour progresses. As temozolomide is thought to be inactive at relapse most relapsing patients do not receive it. However, some responses have been reported. The major endpoints of this trial are (1) progression-free and overall survival at 6 months; (2) safety and adverse event profile of prolonged adjuvant temozolomide; (3) comparison of the health-related quality of life of the patients randomized in the 2 arms; (4) overall tumour response in patients when they are rechallenged with temozolomide.

For more information please contact:

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The SOLE trial

disease free survival - early stage breast cancer - endocrine therapy - letrozole - phase III trial

The SOLE trial is a phase III trial evaluating the role of continuous letrozole versus intermittent letrozole following 4 to 6 years of prior adjuvant endocrine therapy in postmenopausal women with hormone receptor-positive, node-positive, early stage breast cancer (SOLE / IBCSG 35-07 / BIG 1-07).

For more information please contact:

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Ongoing and expected trials in oncology at the Antwerp University Hospital (UZA)

- A prospective, randomized study comparing the 70-gene signature with the common clinical-pathological criteria in selecting patients for adjuvant chemotherapy in breast cancer with 0-3 positive nodes (MINDACT).
Setting: breast cancer, adjuvant therapy
Status: ongoing
For more information please contact Joke Dyck, e-mail: joke.dyck@uza.be
- A randomised, multi-centre, open-label, phase III study of adjuvant lapatinib, trastuzumab, their sequence, and their combination in patients with HER2/Erb2-positive primary breast cancer (ALTTO).
Setting: breast cancer, adjuvant therapy
Status: ongoing
For more information please contact Joke Dyck, e-mail: joke.dyck@uza.be
- A multicentre, multinational, randomized, double-blind, phase III study of IMC-1121B plus docetaxel versus placebo plus docetaxel in previously untreated patients with HER2-negative, unresectable, locally-recurrent or metastatic breast cancer (TRIO-012).
Setting: breast cancer, first-line treatment
Status: ongoing
For more information please contact Joke Dyck, e-mail: joke.dyck@uza.be
- A multicentre, open-label, phase II study to evaluate the safety of NKTR-102 (PEG-irinotecan) when given on a q14 day or q21 day schedule in patients with metastatic or locally advanced breast cancer whose disease has failed prior taxane-based treatment.
Setting: breast cancer, second- and third-line treatment
Status: ongoing
For more information please contact Joke Dyck, e-mail: joke.dyck@uza.be
- A randomized phase III trial of neoadjuvant chemotherapy followed by surgery versus concomitant radiotherapy and chemotherapy in FIGO Ib2, Iia, >4 cm or IIb cervical cancer (EORTC 55994).
Setting: gynecological cancer, preoperative
Status: ongoing
For more information please contact Joke Dyck, email: joke.dyck@uza.be
- A randomized, multicentre, open-label, phase III study comparing the efficacy and safety of panitumumab and cetuximab in subjects with previously treated, wild-type KRAS, metastatic colorectal cancer (Amgen 20080763).
Setting: colorectal cancer, third-line treatment
Status: ongoing
For more information please contact Peggy De Clercq, e-mail: peggy.de.clercq@uza.be
- A randomized, multicentre, phase II study to compare the efficacy of panitumumab in combination with oxaliplatin/5-fluorouracil (5-FU)/leucovorin in patients with previously untreated, KRAS wild-type, unresectable, metastatic colorectal cancer (Amgen 20070509).
Setting: colorectal cancer, first-line treatment
Status: ongoing
For more information please contact Peggy De Clercq, e-mail: peggy.de.clercq@uza.be
- Preoperative chemosensitivity testing as predictor of treatment benefit in adjuvant stage III colon cancer (PePiTA trial).
Setting: colon cancer, adjuvant setting
Status: ongoing
For more information please contact Peggy De Clercq, e-mail: peggy.de.clercq@uza.be
- Preoperative chemotherapy and postoperative chemotherapy with capecitabine and oxaliplatin versus capecitabine alone in locally advanced rectal cancer (PETACC 6).
Setting: rectal cancer, pre- and postoperative
Status: ongoing
For more information please contact Peggy De Clercq, e-mail: peggy.de.clercq@uza.be

- An open-label, multicentre, expanded access study of imatinib mesylate (Glivec®) in adult patients with GIST in adjuvant setting after R0-resection.
Setting: GIST, postoperative
Status: ongoing
For more information please contact Peggy De Clercq, e-mail: peggy.de.clercq@uza.be
- A phase III randomized, placebo-controlled, double-blind trial of sorafenib (BAY 43-9006) plus erlotinib versus sorafenib plus placebo as first-line systemic treatment for hepatocellular carcinoma (Search).
Setting: hepatocellular cancer, first-line treatment
Status: ongoing
For more information please contact Peggy De Clercq, e-mail: peggy.de.clercq@uza.be
- An open-label, randomized phase III study on the efficacy and tolerability of linifanib (ABT-869) versus sorafenib in subjects with advanced hepatocellular carcinoma (protoc M10-963).
Setting: hepatocellular cancer, first-line treatment
Status: ongoing
For more information please contact Véronique Derwael, e-mail: veronique.derwael@uza.be
- Intravenous versus intra-arterial fotemustine chemotherapy in patients with liver metastases from uveal melanoma: a randomized phase III study (EORTC 18021).
Setting: melanoma, second-line treatment
Status: ongoing
For more information please contact Joke Dyck, e-mail: joke.dyck@uza.be
- Study of bevacizumab, temozolomide, and radiotherapy in patients with newly diagnosed glioblastoma (AVAGLIO).
Setting: glioblastoma, first-line treatment
Status: ongoing
For more information please contact Ingrid Aelbrecht, e-mail: ingrid.aelbrecht@uza.be
- A randomized trial of single agent doxorubicin versus doxorubicin plus ifosfamide in the first-line treatment of advanced or metastatic soft tissue sarcoma (EORTC 62012).
Setting: soft tissue sarcoma, first-line treatment
Status: ongoing
For more information please contact Joke Dyck, e-mail: joke.dyck@uza.be
- A randomized phase II feasibility study of cetuximab combined with 4 cycles of docetaxel, cisplatin, and 5-FU (TPF) followed by platinum-based chemoradiation strategies (EORTC 24061).
Setting: head and neck cancer, first-line treatment
Status: on hold
For more information please contact Ingrid Aelbrecht, e-mail: ingrid.aelbrecht@uza.be
- Open-label, randomized, controlled phase I/II study of cilengitide to evaluate the safety and efficacy of the combination of different regimens of cilengitide added to cisplatin, 5-FU and cetuximab in subjects with recurrent/metastatic squamous cell cancer of the head and neck (ADVANTAGE).
Setting: head and neck cancer, first-line treatment
Status: ongoing
For more information please contact Ingrid Aelbrecht, e-mail: ingrid.aelbrecht@uza.be
- Phase II study of pemetrexed in combination with cisplatin and cetuximab in recurrent and metastatic squamous cell carcinoma of the head and neck (Eli Lilly).
Setting: head and neck cancer, recurrent and metastatic
Status: ongoing
For more information please contact Ingrid Aelbrecht, e-mail: ingrid.aelbrecht@uza.be
- Phase IIIb, randomized, open-label study of bevacizumab + temsirolimus (Torisel®) versus bevacizumab + interferon-alpha as first-line treatment in subjects with advanced renal cell carcinoma (Wyeth).
Setting: renal cell carcinoma, first-line treatment
Status: ongoing
For more information please contact Ingrid Aelbrecht, e-mail: ingrid.aelbrecht@uza.be
- A phase I/II open-label study of bosutinib (SKI-606) administered in combination with capecitabine in subjects with solid tumor (colorectal, pancreatic, cholangio, glioblastoma) and ErbB2-negative

- locally advanced or metastatic breast cancer.
Setting: phase I
Status: ongoing
For more information please contact Joke Dyck, e-mail: joke.dyck@uza.be
- A randomized phase III study comparing trastuzumab plus docetaxel (HT) followed by 5-FU, epirubicin, and cyclophosphamide (FEC) to the same regimen followed by single-agent trastuzumab as adjuvant treatments for early breast cancer (SOLD).
Setting: breast cancer, adjuvant therapy
Status: expected
For more information please contact Joke Dyck, e-mail: joke.dyck@uza.be
- A multicentre, randomised, double-blind phase III trial to investigate the efficacy and safety of BIBF 1120 in combination with carboplatin and paclitaxel compared to placebo plus carboplatin and paclitaxel in patients with advanced ovarian cancer.
Setting: ovarian cancer
Status: expected
For more information please contact Joke Dyck, e-mail: joke.dyck@uza.be
- A single-arm, open-label phase II study: treatment beyond progression by adding bevacizumab to capecitabine plus oxaliplatin (XELOX) chemotherapy in patients with metastatic colorectal cancer and disease progression under first-line leucovorin, 5-FU, and irinotecan (FOLFIRI) + bevacizumab combination (AVASTAY).
Setting: colorectal cancer, second-line treatment
Status: expected
For more information please contact Peggy De Clercq, e-mail: peggy.de.clercq@uza.be
- A phase II, open-label study to assess the efficacy and safety of lenalidomide in combination with cetuximab in pretreated subjects with KRAS mutant metastatic colorectal cancer (Celgene).
Setting: colorectal cancer, third-line treatment
Status: expected
For more information please contact Peggy De Clercq, e-mail: peggy.de.clercq@uza.be
- Asymptomatic colon cancer with synchronous resectable liver metastases: a pilot phase II multicentre study.
Setting: colon cancer
Status: expected
For more information please contact Peggy De Clercq, e-mail: peggy.de.clercq@uza.be
- Evaluation of preoperative induction chemotherapy and chemoradiation using cisplatin, infusional 5-FU and panitumumab in locally advanced oesogastric adenocarcinomas: a phase IIa study.
Setting: gastric cancer, neoadjuvant treatment
Status: ongoing
For more information please contact Peggy De Clercq, e-mail: peggy.de.clercq@uza.be
- A pharmacokinetic and safety study of a new docetaxel GP-Pharm formulation (polysorbate-free) compared to standard reference docetaxel (Taxotere®) in patients with hormone-refractory prostate cancer (HRPC) or biochemical progression (rising PSA) during androgenic suppression therapy.
Setting: prostate cancer
Status: ongoing
For more information please contact Ingrid Aelbrecht, e-mail: ingrid.aelbrecht@uza.be

Institutional websites with information on recruiting trials

Medische Oncologie UZ Leuven

<http://www.uzleuven.be/nl/ig-algemeen-medische-oncologie/klinische-studies>

Medische Oncologie UZ Brussel

<http://www.uzbrussel.be/u/view/nl/2555295-Medische+oncologie.html>

Password needed for access to in/exclusion criteria can be requested at datamanagement.oncologischcentrum@uzbrussel.be