*Dear Sponsors / CRO,*

*Separate exhibits to the main contract must be drawn up with different technical departments involved in a study. The fees in this document constitute a basis for work. Each exhibit must still be validated by the responsible of the department.*

*The prices’ list is not exhaustive and the fees will be adapted according to the specificities of your study. The protocol and the imaging manual procedure will be sent to the departments.*

*Any other department not mentioned in this document may be involved in clinical research. Their specific fees will be provided on a case-by-case basis.*

1. General budget

Our budget is established as follows:

- Principal Investigator working time x hourly rate (150€/hour)

- Study Coordinator working time x hourly rate (70€/hour)

- If not standard of care: Use of the facility if applicable

* Outpatient clinic : a cost per consultation in function of the specialisation of the Principal Investigator
* One-day clinic: 325€ for the monotherapy or 375€ for the combitherapy
* Hospitalization: 834€ (Official INAMI price for the Cliniques Universitaires Saint-Luc)

- If not standard of care: technical acts which will be mentioned in a separate budget.

1. Budget of technical departments
	1. **Pharmacy**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| \* = mandatory fields | Frequency | Transfer study | Non- transfer study | Non- transfer study with preparation | Device |
| (€ HTVA) | (€ HTVA) | (€ HTVA) | (€ HTVA) |
| FIXED COSTS\* |
| Administrative cost incl SIV and COV | per study :1 | 500 € | 700 € | 1000 € | 550 € |
| Administrative cost (study not started, signed agreement, without SIV) | if applicable | 250 € | 400 € | 400 € | 300 € |
| Archiving 20 years | per study :1 | 100 €200€ > 2 binders | 100 €200€ > 2 binders | 100 €200€ > 2 binders | 100 €200€ > 2 binders |
| Audit | / h of pharmacist | 120 € | 120 € | 120 € | 120 € |
| ANNUAL FEES\* |
| Maintenance (work/follow-up of the Pharmacist in the cause of the Study: CRA, monitoring visits, etc…) | from first reception / month | 30 € | 35 € | 45 € | 35 € |
| Storage fee room temperature (volume <=2x40x60x30cm) | / month | - | 30 € | 30 € | - |
| Storage fee (fridge or freezer) (volume <=2x40x60x30cm) | / month | - | 35 € | 35 € | - |
| Additional fee if volume > 2x (40x60x30) | / month | - | 10 € | 10 € | - |
| Additional fee if volume > 2x (40x60x30) and fridge | / month | - | 20 € | 20 € | - |
| VARIABLE COSTS\* |
| Reception fee : IMP at room temperature | / shipment | 50 € | 50 € | 50 € | 100 € (first reception) /50€ |
| Reception fee : fridge T° or congelation | / shipment | 60 € | 60 € | 60 € |  |
| Return of recycling boxes (per study)  | per study :1 | 150 € | 150 € | 150 € | 150 € |
| Global Dispensation | / dispensation | 20 € | - | - | 20 € |
| IMP Nominative Dispensation | /dispensation and log | - | 30 € | incl in preparation fee | - |
| Special handling (special procedure for dispensation, blinding, repackaging…) | /dispensation | 10 € | 10 € | 10 € | 10 € |
| Standard arm per os: Nominative Dispensation | /dispensation and log | - | 10 € | 10 € | 10 € |
| Co-medication Nominative dispensation | /dispensation and log | - | 10 € | 10 € | 10 € |
| FEES IF PREPARATION AT THE PHARMACY |
| IMP preparation (incl diluent, sterile preparation in the clean room, necessary equipments for the operating staff and accountability log) | / preparation | - | - | 90 € | - |
| Preparation of ATMP | - | - | - | 200 € | - |
| Standard arm preparation (INAMI) (incl diluent and acccountability) | / preparation | - | - | 10 € | - |
| Special material (filters, needleless system, administration material, ...) | / preparation | - | - | delivered or invoiced | - |
| FEE IF APPLICABLE |
| Randomization | per study :1 | 60 € | 60 € | 60 € | 60 € |
| Accountability, return in IWRS /eCRF | Per patient | 50 € | 50 € | 50 € | 50 €  |
| Order: IMP /co-medication/material ordered by pharmacy (not delivered by sponsor)*NB: please provide the list of co-medications requested (please note that the oncology team is asking for the the anti-emetic reimbursement)* | per unit | price (ambulatory) + 10% (max 5 €/unit) |
| Emla (in case of paediatric studies) | 5,52 € per unit | - | - | - | - |
| Urine pregnancy test (if not provided by the sponsor) | 10 € per unit | - | - | - | - |
| Non automatic resupply: Order: IMP/co-medication/material ordered by pharmacy and delivered by sponsor (request) | per study :1 | 150 € | 150 € | 150 € | 150 € |
| Re-labelling | / 30min | 50 € | 50 € | 50 € | 75 € |
| Duty call (return of the Pharmacist outside of the working hours: Monday to Friday 8H-17H) | / duty call | 300 € | 300 € | 300 € | 300 € |
| Storage of used/expired or returned medication and material (if more than 6 month at the pharmacy before return to sponsor or destruction) | per case | 100 € | 100 € | 100 € | NA |
| Destruction fee \* | per year | 300 € | 300 € | 300 € | 300 € |
| Return to sponsor (exl cost for transport): used and unused IMP/non-IMP (per study) \* | per study :1 | 150 € | 150 € | 150 € | 150 € |
| Remote Monitoring | / 30 minutes | 125 € | 125 € | 125 € | 125 € |

**Mention*:*** 901E study number *(will be provided at each study)*

The exhibit must be signed by Mrs D. Wouters, Head of Pharmacy department.
In case of absence, the exhibit can be signed by Mrs Stéphanie Quennery.

* 1. **Radiology**

|  |  |  |
| --- | --- | --- |
|  | Frequency | COSTS |
| (€ HTVA) |
| RADIOLOGY START-UP FEES AND ADDITIONAL COSTS FOR COMMERCIAL STUDIES |
| Start-up fees (study without OR with central reader). After contract signature, the Radiology Department will draw up an invoice for start-up fees to the attention of the Sponsor. | - | 350 € or 600 € |
| Additional cost if Phantom/Test to send for qualification | - | 400 € |
| Additional cost if Phantom/Test to resend during study for parameters modification OR modification of central reader during the study OR implementation of a central reader during the study WITH parameters modification | - | 400 € |
| Additional cost if Phantom/Test to resend during study for verification of parameters and calibration OR modification of central reader during the study OR implementation of a central reader during the study WITHOUT parameters modification | - | 200 € |
| Additional cost if sponsor ask to upload image of other CT/MRI/X ray exam (example: pre-study exam, routine exam, not performed for the study …)  | per upload  | 50 € |
| Additional cost if set up by the referent radiologist before start of study  | Radiologist fee per hour | 150 € |
| RADIOLOGY FEES FOR EXAMINATIONS FOR COMMERCIAL ONCOLOGIC STUDIES |
| CT brain/neck/chest/abdomen/pelvis/bone/other site with IV contrast NON SOC | - | 599 € |
| CT brain/neck/chest/abdomen/pelvis/bone/other site without IV contrast NON SOC | - | 499 € |
| CT brain/neck/chest/abdomen/pelvis/bone/other site with or without IV contrast SOC | - | 158 € |
| MRI brain/neck/abdomen/pelvis/bone/soft tissue/bone narrow/whole body/other | - | 599 € |
| Fee for tumor measurement done by radiologist  | per exam | 150 € |
| Chest X ray | - | 58,43 € |
| Localized bone Xray if visible lesion at bonescan (scintigraphy in Nuclear Department) | - | 70,78 € |
| Fee included examination, institutional overhead and radiology data management. Valid with our standard acquisition parameters. |
| RADIOLOGY FEES FOR TUMOR BIOPSY PERFORMED IN RADIOLOGY DPT FOR COMMERCIAL ONCOLOGIC STUDIES |
| Liver/deep node biopsy (with US) | - | 747,83 € |
| Liver/deep node biopsy (with CT scan) | - | 776,24 € |
| Breast biopsy (Microbiopsy with US) | - | 494,33 € |
| Breast biopsy (Macrobiopsy with stereotaxy) | - | 906,07 € |
| Breast biopsy (punch) | - | 436,48 € |
| Pulmonary biopsy (with CT scan) | - | 717,99 € |
| Bone biopsy (with CT scan) | - | 863,70 € |
| Soft tissue biopsy (with CT scan) | - | 688,25 € |
| Node/Cutaneous biopsy with US (if not possible in dermatology department) | - | 526,66 € |
| Fee included examination (US or CT scan + biopsy), institutional overhead, material (needle …), medication, radiology data management and interventional radiologist fees. |

These fees are given for information and are not final.

For each new study, a budget will be established by the radiology coordinators according to the protocol and vendor requests. This budget will be submitted for approval before being finalized.

The exhibit must be signed by Mrs Muriel De Cooman or Mrs Valérie Rosseels.

* 1. **Laboratory**

|  |  |  |
| --- | --- | --- |
|  | Frequency | COSTS |
| (€ HTVA) |
|  |
| Start-up fee | once | 500 € |

**Laboratory fees**: please contact Mrs Wasmine Soumaya 🡪 soumaya.wasmine@uclouvain.be

**Mention**: Invoice number – 865E

The exhibit must be signed by Prof. Pierre Wallemacq, Head of Laboratory Department.
In case of absence, the exhibit can be signed by Prof. Vincent Haufroid.

* 1. **Nuclear Medicine**

|  |  |  |
| --- | --- | --- |
|  | Frequency | COSTS |
| (€ HTVA) |
|  |
| Start-up fee (Excluding technical procedures; e.g.phantom) | - | 250 € |
| MUGA | - | 450 € |
| Bone scan | - | 450 € |
| PET-SCAN | - | 1.650 € |
| CD | - | 60 € |
| Can be adapted in function of the specificities or additional requirements of each protocol. |

**Mention**: Invoice number – 531E

The exhibit must be signed by Prof. François Jamar, clinical research responsible for Nuclear Medicine.
In case of absence, the exhibit can be signed by Prof. Renaud Lhommel, Head of the Department.

* 1. **Pathology**

|  |  |  |
| --- | --- | --- |
|  | **Unit** | **COSTS per unit** |
| (€ HTVA) |
|  |
| Start-up fee  | /study | 250 € |
| Exit from the archives (FFPE & frozen blocks) | / case | 10 € |
| Case selection and evaluation | / case | 25 € |
| Preparation of unstained slides on positively charged slides (white SuperFrost Plus slides) | / slide | 20 € |
| Preparation of unstained slides on standard slides (colored SuperFrost slides) | / slide | 20 € |
| Sections preparation: |  |  |
| * in RNase free tubes (FFPE blocks)
 | / block | 50 € |
| * in RNase free tubes (Frozen blocks)
 | / block | 60 € |
| * on slides (FFPE blocks)
 | / slide | 30 € |
| * on slides (Frozen blocks)
 | / slide | 40 € |
| Preparation of FFPE blocks | / block | 200 € |
| Preparation of frozen OCT embedded blocks | / block | 200 € |
| In Situ Hybridization (ISH) : HER2 | / slide | 400 € (including the pathologist case revision) |
| In Situ Hybridization (FISH): ALK | / slide | 200 €(including the pathologist case revision) |
| In Situ Hybridization (FISH): ROS1 | / slide | 200 €(including the pathologist case revision) |
| In Situ Hybridization (ISH): EBER | / slide | 250 €(including the pathologist case revision) |
| In Situ Hybridization (ISH): HPV high & low risk | / slide | 250 €(including the pathologist case revision) |
| PCR: HPV | / test | 250 €(including the pathologist case revision) |
| HE staining | / slide | 5 € |
| Special staining | / slide | 20 € |
| Pathology report | / hour | 300 € |
| Estimation of % tumor cells | / 15 minutes | 50 € |
| Immunohistochemistry (IHC) INAMI accredited | / slide | 200 €(including the pathologist case revision) |
| Immunohistochemistry (IHC) standard  | / slide | 75 € |
| Immunohistochemistry (IHC) p16  | / slide | 90 € |
| Renal biopsy: |  |  |
| * 1 HE staining
 | / slide | 5 € |
| * 3 special stains
 | / staining | 20 €(total 60 €) |
| * 1 immunofluorescence markers
 | / slide | 30 €  |
| * Pathology report
 | / hour | 300 € |
| Transmission electron microscopy (T.E.M.) | / sample | 900 € |
| Preparation of Material for NGS analysis: |  |  |
| * Biopsy
 |  | Total cost: 210 € |
| * 1 HE
 | / slide | 5 € |
| * 10 unstained slides
 | / 10 slides | 200 € |
| * Revision of the slide
 | / slide | 5 € |
| * Macroscopic specimen
 |  | Total cost: 110 € |
| * 1 HE
 | / slide | 5 € |
| * 5 unstained slides
 | / 5 slides | 100 € |
| * Revision of the slide
 | / slide | 5 € |

**Mention**: Invoice number – 868E

Costs to be negotiated with the Sponsor, first. Upon agreement, notify CoFi.

CoFi, not the Sponsor, will send the approved exhibit to Prof. Etienne Marbaix (Head of CUSL Biobank) for final approval and signature.

* 1. **Rheumatology**

|  |  |  |
| --- | --- | --- |
|  | **Frequency** | **COSTS** |
| (€ HTVA) |
|  |
| Start-up fee  | - | 874,50 € |
| Lumbar vertebrae DXA (L1-L4 together) & proximal femur (total hip and neck)  | - | 255,35 € |
| Wrist | - | 255,35 € |
| W body Composition | - | 314,59 € |
| QUALITY CONTROL IF CENTRAL READER IF REQUESTED |
| Total Baseline IQC | - | 272,85 € |
| Total Cross Calibration | - | 272,85 € |
| Monthly IQC Data Management and Submission | - | 80,25 € |
| Training if requested | - | 160,50 € |
| IF PATIENT YOUNGER THAN 5 YEARS OR PATIENT WITH COMPLICATION |
| Under narcosis  | - | 131,89 € |
| DXA Lumbar & Hip | - | 328,32 € |
| DXA WRIST  | - | 328,32 € |
| W body  | - | 476,43 € |
| ADD COSTS FOR PAEDIATRICS STUDIES LESS THAN 18 Y |
| Growth curve for children less than 18 y Add for calculation | - | 32,10 € |

Per patient per DXA VISIT & scan INDEPENDENDTLY FROM CRF completion. Screen failure will be paid without rate as independent of the department.

DEXA will be paid for scans required by the protocol and as requested by the Principal Investigator.

In the event it is not possible to obtain adequate scans.

DEXA will be paid, provided all reasonable measures are used in obtaining the scans.

If adequate scans can’t be obtained, it will be clearly documented in the medical report”

**Mention**: Invoice number – 517E

The exhibit must be signed by Prof. Bernard Lauwerys, Head of Rheumatology department.

In case of absence, the exhibit can be signed by Prof. Durez.

* 1. **Cardiology**

|  |  |  |
| --- | --- | --- |
|  | **Frequency** | **COSTS** |
| (€ HTVA) |
|  |
| Simple ECG (A separate exhibit with the cardiology department is not necessary if simple ECG is the only cardiology exam requested by the Protocol -->To be included in the PI budget) | / ECG | 60 € |
| Cardiac echography (A separate exhibit with the cardiology department is necessary)  | / echo | 350 € |
| Simple ECG + Cardiac echography (A separate exhibit with the cardiology department is necessary) | / ECG/ echo | 60 €350 € |
| ECG with specific requirements (measures, interpretation…)(A separate exhibit with the cardiology department is necessary) | - | TBD |
| In case you provide the ECG machine, this procedure will be included in the data management fees of the main budget. |

**Mention**: Invoice number – 752E

The exhibit must be signed by Prof. Christophe Beauloye, Head of Cardiology department.

* 1. **Pneumology**

|  |  |  |
| --- | --- | --- |
|  | **Frequency** | **COSTS** |
| (€ HTVA) |
| PROF. LIISTRO G. |
| Spirometry (FEV1 + FVC, FEV1/FVC) | - | 14,60 € |
| Spirometry + bronchoconstriction (Histamine) | - | 57,74 € |
| Residual volume (and TLC measurement) | - | 58,40 € |
| Spirography + bronchodilator test | - | 29,20 € |
| Spirography + bronchodilator test (under 7 years old)  | - | 33 € |
| Diffusion capacity(= DLCO) | - | 58,40 € |
| Expired NO Measurement (Cost not reimbursed) | - | 12 € |
| Intellectual fee | / visit | 100 € |
| These tests can be combined. |

Signature by Prof. Pieters after validation of Prof. Liistro’s budget

**Mention**: Invoice number – 545E

|  |  |  |
| --- | --- | --- |
|  | **Frequency** | **COSTS** |
| (€ HTVA) |
| PROF. PIETERS T. |
| Bronchoscopy with broncho-alveolar lavage | - | 197,09 € |
| Intellectual fee | / visit | 75 € |

Signature by Prof. Pieters

**Mention**: Invoice number – 916E

The exhibit must be signed by Prof. Thierry Pieters, Head of Pneumology department.

* 1. **Ophthalmology**

|  |  |  |
| --- | --- | --- |
|  | **Frequency** | **COSTS per procedure** |
| (€ HTVA) |
|  |
| Ophthalmologist consultation (Including PI fee) | - | 105 € |
| Visual Field | - | 31,80 € |
| Funduscopy - dilated funduscopy | - | 9,08 € |
| Slit lamp | - | 9,08 € |
| Tonometry (Goldmann) - IOP | - | 9,08 € |
| Fluoroangiography with protocol | - | 275 € |
| Optical coherence tomography (OCT) (Mesure épaisseur de la rétine) | - | 90 € |
| Endothelial cells count by specular microscopy | - | 68,14 € |
| Visual acuity | - | 7,27 € |
| Eyes Ultrasound (bimontlhy) (1/2 yx) | - | 23,74 € |
| Electroretinography | - | 68,14 € |
| Counting endothelial cells of the cornea (tachymetric corner) | - | 68,14 € |
| Schirmer Test | - | 9 € |
| Color fundus photography | - | 50 € |

**Mention**: Invoice number – 818E

The exhibit must be signed by the ophthalmologist who will be in charge of the study.