

		Financial Requirements 2024	Clinical Trial Center
AAHRPP-DSQ-070	Version 11.0		Date d'application : 24/10/2024

Dear Sponsors / CRO,

The main budget only includes the procedures performed by the Principal Investigator and the Study Coordinator.

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.

All the fees are inclusive of the institutional overhead.

The fees are not exhaustive and 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. NEGOTIATION OF GENERAL BUDGET

Our budget is established as follows:

- Principal Investigator working time x hourly rate (200€/hour)
- Study Coordinator working time x hourly rate (100€/hour)
- If not standard of care: Use of the facility if applicable
 - Outpatient clinic : a cost per consultation in function of the specialization of the Principal Investigator
 - One-day clinic: 350€ for the monotherapy or 400€ for the combitherapy
 - Pediatric one-day clinic: 375€ for the monotherapy or 500€ for the combitherapy
 - Hospitalization: 1.048€ (Official INAMI price for the Cliniques Universitaires Saint-Luc)
- If not standard of care: technical acts which will be mentioned in a separate budget.

Institutional additional costs (PI budget) – not negotiable		
Start-up fee : ❖ Interventional trials ❖ Observational, retrospective or phase 4 studies	5.000€ 2.000€	This fee is independent of the patient recruitment. It covers the time spent by the investigator and by the study coordinator before the study starts and the access badges to the patients' files. The payment must be made upon signature of the agreement.
Maintenance fee : ❖ Interventional trials	1.500€ /year	

Institutional additional costs (PI budget) – not negotiable		
❖ Observational, retrospective or phase 4 studies	750€/year	
Close out fee	1000€ 500€	Interventional - Payable at the end of the study Observational, retrospective or phase 4 studies - Payable at the end of the study
Archiving fee (if not organized by the sponsor)	300€/box	For 25 years (size : 340mm x 390mm x 360mm)
Audit fees : For the PI For the study coordinator	200€/h 100€/h	In case of CRO or sponsor driven audit
Amendment fee	500€	Per amendment
Protocol amendment with new treatment arm or cohort	2500€	Per amendment
Patient travel fees	/	What is foreseen? In respect of the GDPR, in case of the use of a third-party vendor, the patient must have the choice with a system of payment through the Institution.
Screen failures	/	Best option : Same fee than the screening visit
Transfer of archival tissue from another hospital to Saint-Luc	200€	
SAE or Adverse Event of Special Interest	250€/event	Only DM & PI time. All other expenses will be invoiced at actual costs.
Unscheduled visit	600€	per event - includes consultation and DM/SC time
Phase 1 trial specific fees (in addition of the institutional additional costs)		
Protocol start-up fee	3.000€	Payable upon signature of the contract
Premature closure fee	5.000€	Compensation for premature closure due to sponsor's decision without possibility of inclusion

Explanation of the difference between the Start-up fee and the Maintenance fee

- ✓ The PI start-up fee covers :
 - feasibility questionnaire
 - pre study visit - qualification
 - protocol and IB evaluation
 - EC submission process
 - contract-budget evaluation
 - contacts with different hospital services involved in study
 - initiation visit
 - patient roadmaps preparation according to flow chart
 - investigator meeting
 - trainings required by sponsor
 - preparation of documents required by sponsor : CV and other qualifications, lab normal values, lab certificates
 - lab samples preparation-shipment procedures training – IATA certification
 - administration : lab kits request, dry ice
 - control of calibration and maintenance of study equipment such as : centrifuges, fridges, freezers, ECG, tensiometer

- ✓ The Annual Maintenance fee : This fee covers all the administrative tasks which are study-related and not patient-related.
 - Administrative charge for EC submission
 - Pharmacovigilance
 - Activation vendors
 - Technical issue (related to e-tablet/electronic system)
 - Lab kits re-ordering
 - Re-training (not included in Start-up fee)
 - Conference call (Investigator)

Medical Director's signature for institutional and specific costs

2. NEGOTIATION OF ADDITIONAL SERVICES

Negotiation is carried out with the contact person of each service: CoFi contact should be informed of the status.

Department	Contact	Responsible signature
Laboratory (local analysis)	alexia.verroken@saintluc.uclouvain.be soumaya.wasmine@saintluc.uclouvain.be	Prof. A. Verroken, Head of Clinical Laboratory
Pathology (for archived or fresh human material)	biobanque@saintluc.uclouvain.be selda.aydin@saintluc.uclouvain.be	Prof S. Aydin – Head of Biobank
Radiology	muriel.decooman@saintluc.uclouvain.be (commercial studies in oncology except hematology) valerie.rosseels@saintluc.uclouvain.be (other commercial studies)	Mrs M. De Cooman or Mrs V. Rosseels – Clinical research coordinator of radiology department
Nuclear Medicine	francois.jamar@saintluc.uclouvain.be	Prof F. Jamar
Pharmacy	pharmaetudes@saintluc.uclouvain.be	Mrs S. Quennery – Head of Pharmacy
Cardiology	david.vancraeynest@saintluc.uclouvain.be thomas.paulus@saintluc.uclouvain.be (echocardiography) anne-catherine.pouleur@saintluc.uclouvain.be	Prof D. Vancraeynest – Head of Cardiology Department
Rheumatology	dominique.dienst@saintluc.uclouvain.be marie.mzoughui@saintluc.uclouvain.be	Prof P. Durez – Head of service

3. BUDGET OF TECHNICAL DEPARTMENTS

3.1. 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	550 €	800 €	1100 €	600 €
Administrative cost (study not started, signed agreement, without SIV)	if applicable	250 €	400 €	400 €	300 €
Archiving 25 years	per study :1	120 €	120 € 220 € > 2 binders	120 € 220€ > 2 binders	120 € 220€ > 2 binders
Audit	/ h of pharmacist	130 €	130 €	130 €	130 €
ANNUAL FEES*					
Maintenance (work/follow-up of the Pharmacist in the cause of the Study: CRA, monitoring visits, etc...)	from first reception / month until COV pharmacy	35 €	40 €	50 €	40 €
Storage fee room temperature (volume <=2x40x60x30cm)	/ month	-	35 €	40 €	-
Storage fee (fridge or freezer) (volume <=2x40x60x30cm)	/ month	-	40 €	40 €	-
Storage freezer (volume <= 2x 40x60x30)	/ month	-	50 €	50 €	-
Additional fee if volume > 2x (40x60x30)	/ month	-	10 €	10 €	-
VARIABLE COSTS*					
Reception fee : IMP at room temperature	/ shipment	55 €	55 €	55 €	100 € (first reception) /55€
Reception fee : fridge T° or congelation	/ shipment	65 €	65 €	65 €	

* = mandatory fields	Frequency	Transfer study	Non-transfer study	Non-transfer study with preparation	Device
		(€ HTVA)	(€ HTVA)	(€ HTVA)	(€ HTVA)
Reception fee for CAR-T	/shipment	100 €	100 €	100 €	-
Return of recycling boxes (per study)	per study :1	150 €	150 €	150 €	150 €
Global Dispensation	/dispensation	25 €	-	-	25 €
IMP Nominative Dispensation	/dispensation and log	-	35 €	35 € (medication without preparation)	-
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	-	-	120 €	-
Preparation of ATMP / radiopharmacy	-	-	-	220 €	-
Standard arm preparation (INAMI) (incl diluent and accountability)	/ 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 €
Destruction in IWRS /eCRF	Per destruction	20 €	20 €	20 €	20 €
Order: IMP /co-medication/material ordered by pharmacy (not delivered by sponsor) <i>NB: please</i>	per unit	price (ambulatory) + 10% (max 5 €/unit)			

* = mandatory fields	Frequency	Transfer study	Non-transfer study	Non-transfer study with preparation	Device
		(€ HTVA)	(€ HTVA)	(€ HTVA)	(€ HTVA)
<i>provide the list of co-medications requested (please note that the oncology team is asking for the the anti-emetic reimbursement)</i>					
Emla (in case of pediatric 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	/ relabeling	80 €	80 €	80 €	80 €
Duty call (return of the Pharmacist outside of the working hours: Monday to Friday 8H-17H)	/ duty call	330 €	330 €	330 €	330 €
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	110 €	110 €	110 €	NA
Destruction fee *	per year	330 €	330 €	330 €	330 €
Return to sponsor (exl cost for transport): used and unused IMP/non-IMP (per study) *	per study :1	150 €	150 €	150 €	150 €
Remote Monitoring (Excl COV)	/ 30 minutes	140 €	140 €	140 €	140 €

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

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

3.2. 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 <u>OR</u> implementation of a central reader during the study <u>WITH</u> 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 <u>OR</u> implementation of a central reader during the study <u>WITHOUT</u> 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	-	610 €
CT brain/neck/chest/abdomen/pelvis/bone/other site without IV contrast NON SOC	-	510 €
CT brain/neck/chest/abdomen/pelvis/bone/other site with or without IV contrast SOC (Fee per examination considered as « standard of care » : covers the Data management and radiologist's workload)	-	160 €
MRI brain/neck/abdomen/pelvis/bone/soft tissue/bone narrow/whole body/other	-	610 €
Fee for tumor measurement done by radiologist	per exam	150 €
Chest X ray	-	87,93 €
Localized bone X-ray if visible lesion at Bonescan (scintigraphy in Nuclear Department)	-	166,71 €
Fee included examination, institutional overhead and radiology data management. Valid with our standard acquisition parameters.		

	Frequency	COSTS
		(€ HTVA)
RADIOLOGY FEES FOR TUMOR BIOPSY PERFORMED IN RADIOLOGY DPT FOR COMMERCIAL ONCOLOGIC STUDIES		
Liver/deep node biopsy (with US)	-	907,88 €
Liver/deep node biopsy (with CT scan)	-	961,32 €
Renal biopsy (with US)		888,77 €
Renal biopsy (with CT scan)		942,20 €
Breast biopsy (Microbiopsy with US)	-	509,32 €
Breast biopsy (Macrobiopsy with stereotaxy)	-	962,62 €
Breast biopsy (punch)	-	445,83 €
Pulmonary biopsy (with CT scan)	-	792,73 €
Bone biopsy (with CT scan)	-	909,77 €
Soft tissue biopsy (with CT scan)	-	710,30 €
Node/Cutaneous biopsy with US (if not possible in dermatology department)	-	547,14 €
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.

3.3. Laboratory

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

Laboratory fees: please contact Mrs Wasmine Soumaya → soumaya.wasmine@saintluc.uclouvain.be

Mention: Invoice number – 865E

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

3.4. Nuclear Medicine

	Frequency	COSTS
		(€ HTVA)
Start-up fee (Excluding technical procedures; e.g.phantom)	-	250 €
MUGA	-	486 €
Bone scan	-	486 €
PET-SCAN	-	1.782 €
CD/upload	-	65 €
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.

3.5. Pathology

	Unit	COSTS per unit
		(€ HTVA)
Start-up fee	/study	500
Exit from the archives (FFPE & frozen blocks)	/ case	20 €
Case selection and evaluation	/ case	50 €
Histological analysis (with the report including the evaluation of the tumour cells)	/analysis	300€
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	450 € (including the pathologist case revision)
In Situ Hybridization (FISH): ALK	/ slide	250 € (including the pathologist case revision)
In Situ Hybridization (FISH): ROS1	/ slide	250 € (including the pathologist case revision)
In Situ Hybridization (ISH): EBER	/ slide	300 € (including the pathologist case revision)
In Situ Hybridization (ISH): HPV high & low risk	/ slide	300 € (including the pathologist case revision)

	Unit	COSTS per unit
		(€ HTVA)
PCR: HPV	/ test	300 € (including the pathologist case revision)
HE staining	/ slide	10 €
Special staining	/ slide	25 €
Pathology report	/ hour	300 €
Estimation of % tumor cells	/ 15 minutes	50 €
Immunohistochemistry (IHC) INAMI accredited	/ slide	250 € (including the pathologist case revision)
Immunohistochemistry (IHC) standard	/ slide	80 €
Immunohistochemistry (IHC) p16	/ slide	110 €
Renal biopsy:		
- 1 HE staining	/ slide	10 €
- 3 special stains	/ staining	25 € (total 75 €)
- 1 immunofluorescence markers	/ slide	40 €
- Pathology report	/ hour	300 €
Transmission electron microscopy (T.E.M.)	/ sample	900 €
Preparation of Material for NGS analysis:		
- Biopsy		Total cost: 260 €
▪ 1 HE	/ slide	10 €
▪ 10 unstained slides	/ 10 slides	200 €
▪ Revision of the slide	/ slide	50 €
- Macroscopic specimen		Total cost: 160 €
▪ 1 HE	/ slide	10 €
▪ 5 unstained slides	/ 5 slides	100 €
▪ Revision of the slide	/ slide	50 €

Mention: Invoice number – 868E

This exhibit will be signed by Prof Selda Aydin, head of the biobank.

3.6. Rheumatology

	Frequency	COSTS
		(€ HTVA)
Start-up fee	-	950 €
Lumbar vertebrae DXA (L1-L4 together) & proximal femur (total hip and neck)	-	300 €
Wrist	-	300 €
W body Composition	-	345 €
Musculoskeletal ultrasound (MSUS)		350 €
Knee Needle Arthroscopy (KNA)		1.500 €
Ultrasound-guided synovial biopsy (USGB)		1.500 €
QUALITY CONTROL IF CENTRAL READER IF REQUESTED		
Total Baseline IQC	-	297 €
Total Cross Calibration	-	297 €
Monthly IQC Data Management and Submission	-	90 €
Training if requested	-	175 €
IF PATIENT YOUNGER THAN 5 YEARS OR PATIENT WITH COMPLICATION		
Under narcosis	-	150 €
DXA Lumbar & Hip	-	360 €
DXA WRIST	-	360 €
W body	-	518 €
ADD COSTS FOR PAEDIATRICS STUDIES LESS THAN 18 Y		
Growth curve for children less than 18 y Add for calculation	-	35 €

Per patient per DXA VISIT & scan INDEPENDENTLY 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. Patrick Durez, Head of Rheumatology department.
In case of absence, the exhibit can be signed by Prof. A. Nzeuseu.

3.7. Cardiology

A separate cardiology exhibit will not be necessary in the following two cases:

	Frequency	COSTS
		(€ HTVA)
Simple ECG (A simple ECG is the only cardiology exam requested by the Protocol. In this case, it will be included in the PI's budget)	/ ECG	60 €
In case you provide the ECG machine, this procedure will be included in the data management fees of the main budget.		

A dedicated cardiology exhibit will be required for the following elements:

	Frequency	COSTS
		(€ HTVA)
Start-up fee (in case of cardiology exhibit)	1	250 €
Cardiac echography – without any upload of images on a platform or request to burnt it on a medium	/ echo	380 €
Cardiac echography – with anonymization of the image and availability of the images to the sponsor (platform or DVD)		750€
Simple ECG + Cardiac echography	/ ECG	60 €
- without sending any images	/ echo	380 €
- with sending images	/ echo	750€
ECG with specific requirements (measures, interpretation...)	/ ECG	90 €

Please note that the start-up fee will be invoiced only if a separate exhibit is created for the cardiology department.

Mention: Invoice number – 504E

The exhibit must be signed by Prof. David Vancraeynest, Head of Cardiology department.

3.8. Pneumology

	Frequency	COSTS
		(€ HTVA)
PROF. LIISTRO G.		
Spirometry (FEV1 + FVC, FEV1/FVC)	-	18 €
Spirometry + bronchoconstriction (Histamine)	-	65 €
Residual volume (and TLC measurement)	-	69 €
Spirography + bronchodilator test	-	35 €
Spirography + bronchodilator test (under 7 years old)	-	35 €
Diffusion capacity (= DLCO)	-	69€
Expired NO Measurement (Cost not reimbursed)	-	15 €
Intellectual fee	/ visit	120 €
These tests can be combined.		

Signature by Prof. Pilette after validation of Prof. Liistro's budget

Mention: Invoice number – 545E

	Frequency	COSTS
		(€ HTVA)
PROF. PILETTE Ch.		
Bronchoscopy with broncho-alveolar lavage	-	235 €
Intellectual fee	/ visit	120 €

Signature by Prof. Pilette

Mention: Invoice number – 542E

The exhibit must be signed by Prof. Charles Pilette, Head of Pneumology department.

3.9. Ophthalmology

	Frequency	COSTS per procedure
		(€ HTVA)
Ophthalmologist consultation (Including PI fee)	-	120 €
Visual Field	-	37 €
Funduscopy - dilated funduscopy	-	11 €
Slit lamp	-	11 €
Tonometry (Goldmann) - IOP	-	11 €
Fluoroangiography with protocol	-	280 €
Optical coherence tomography (OCT) (Mesure épaisseur de la rétine)	-	90 €
Endothelial cells count by specular microscopy	-	70 €
Visual acuity	-	11 €
Eyes Ultrasound (bimonthly) (1/2 yx)	-	28 €
Electroretinography	-	80 €
Counting endothelial cells of the cornea (tachymetric corner)	-	70 €
Schirmer Test	-	11 €
Color fundus photography	-	50 €
Ocular motility		55 €

Mention: Invoice number –

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