AMENDMENT N. 4 TO CLINICAL STUDY AGREEMENT	**EMENDAMENTO N.4 AL CONTRATTO PER STUDIO CLINICO**
Between	**tra**
Azienda Ospedaliero-Universitaria San Luigi Gonzaga di Orbassano	**Azienda Ospedaliero-Universitaria San Luigi Gonzaga di Orbassano**
and	**e**
Università di Torino, Dipartimento di Oncologia	**Università di Torino, Dipartimento di Oncologia**
and	**e**
Pfizer Inc.	**Pfizer Inc.**
Pfizer Protocol n. C3441021	**Protocollo Pfizer n. C3441021**
This Amendment n. 4 is made	Il presente Emendamento n.4 viene perfezionato
BETWEEN THE PARTIES:	TRA LE PARTI:
Azienda Ospedaliero-Universitaria San Luigi Gonzaga di Orbassano, with headquarters at Orbassano, Regione Gonzole, 10 - 10043 Orbassano - Turin, Italy Tax ID Code No. 95501020010, VAT no. 02698540016, represented by the General Director, Dr. Davide Minniti, with the powers to enter into this Agreement**;**	**Azienda Ospedaliero-Universitaria San Luigi Gonzaga di Orbassano,** con sede legale in Orbassano, Regione Gonzole, 10 – 10043 Orbassano – Torino, Italia, Codice Fiscale n. 95501020010, Partita IVA n. 02698540016, all'uopo rappresentata dal Direttore Generale, Dott. Davide Minniti, munito di idonei poteri di firma del presente contratto;

AND	E
Università di Torino, Dipartimento di Oncologia, Tax ID Code No. 80088230018, VAT no. 02099550010, with headquarters in Turin Via Verdi 8 and amministrative office in Orbassano Regione Gonzole 10, Italy, represented by: a) Prof. Cristian Fiori - Director of the Department, identified according to the art. 66 - paragraph 2 of the "Regulation of Administration, Finance and Accounting", issued with Rector's Decree n. 3106 of 09/26/2017, b) Dr. Antonella Trombetta - Director of the Medical Center, as far as his authority permits and for the purposes of the articles 29 paragraph 1 and 66 paragraph 1 of the Regulation of Administration, Finance and Accounting issued with the Rector's Decree n. 3106 of 09.26.2017 which provides for the negotiation capacity and the stipulation of the agreement, both domiciled, for the purposes of this deed, at the headquarters of the Oncology Department; (Hospital and University jointly defined "**Institution**").	**Università di Torino, Dipartimento di Oncologia**, C.F. 80088230018, P.IVA. 02099550010, con sede legale a Torino in Via Verdi 8 e sede amministrativa a Orbassano in Regione Gonzole 10, Italia, rappresentato da: a) Prof. Cristian Fiori – Direttore del Dipartimento, individuato ai sensi dell'art. 66 – comma 2 del "Regolamento di Amministrazione, Finanza e Contabilità", emanato con Decreto Rettorale n. 3106 del 26/09/2017, b) Dott.ssa Antonella Trombetta – Il Dirigente del Polo di Medicina, per quanto di competenza e per quanto previsto dagli artt. 29 comma 1 e 66 comma 1 del Regolamento di Amministrazione, Finanza e Contabilità emanato con Decreto Rettorale n. 3106 del 26/09/2017 che dispone in ordine alla capacità negoziale e alla stipulazione del contratto, entrambi domiciliati, ai fini del presente atto, presso la sede del Dipartimento di Oncologia; (Università e Azienda denominate insieme **"Istituto"**).
AND	E
Pfizer Inc., Delaware Corporation headquartered in 66 Hudson Boulevard East, New York, NY 10001, USA, (hereinafter called "**Pfizer**").	**Pfizer Inc.**, Delaware Corporation, con sede legale 66 Hudson Boulevard East, New York, NY 10001, USA, (di seguito denominata "**Pfizer**").

This Amendment n. 4 ("**Amendment**") relates to the Clinical Study Agreement between the parties with an effective date as of 22 November 2019 ("**Agreement**"), as most recently previously amended on 3 July, 2025 ("**Amendment 3**").	Il presente Emendamento n. 4 ("**Emendamento**") si riferisce al Contratto per studio clinico tra le parti con data di decorrenza 22 novembre 2019 ("**Contratto**"), così come modificato più recentemente in data 3 luglio 2025, ("**Emendamento n. 3**").
The Entity has approved Amendment No. 4 to the Agreement by resolution No. ___ dated _____	L'Ente ha approvato l'Emendamento n. 4 alla Convenzione con deliberazione n. _____de _____
The Board of the Department of Oncology of the University of Turin authorized the execution of this Amendment on _____.	Il Consiglio del Dipartimento di Oncologia dell'Università di Torino ha autorizzato la stipula del presente emendamento in data _____.
This Amendment is effective as of the last signature date ("**Effective Date**")	Il presente Emendamento è efficace a partire dalla data dell'ultima firma ("**Data di decorrenza")**
WHEREAS	**PREMESSO CHE**
A. The Parties entered into the Agreement to provide for the conduct of a clinical trial entitled: "A PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF TALAZOPARIB WITH ENZALUTAMIDE IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER" ("**Study**") to be conducted by Principal Investigator at Institution under the Pfizer protocol identified above ("**Protocol**").	A. Le Parti hanno stipulato il Contratto per provvedere alla conduzione di una sperimentazione clinica dal titolo: "STUDIO CONTROLLATO CON PLACEBO DI FASE 3, RANDOMIZZATO, IN DOPPIO CIECO, SU TALAZOPARIB CON ENZALUTAMIDE NEL TUMORE PROSTATICO METASTATICO, RESISTENTE ALLA CASTRAZIONE" ("**Studio"**) che viene condotta dallo Sperimentatore principale presso l'Istituto ai sensi del protocollo Pfizer sopra identificato ("**Protocollo**").

The Parties now wish to amend the Agreement as per the terms and conditions of this Amendment n. 4, as follows.	Le Parti desiderano ora emendare il Contratto secondo le condizioni e modalità del presente Emendamento n.4, come di seguito indicato:
1. Effective as from February 21, 2023, Pfizer Inc.'s business address has been changed and all references to the previous address at 235 East 42nd Street, New York, NY 10017 within the agreement shall now be revised to the following address: Pfizer Inc. 66 Hudson Boulevard East New York, NY 10001, USA.	1. Con effetto dal 21 febbraio 2023, l'indirizzo della sede legale di Pfizer Inc. è stato modificato e tutti i riferimenti al precedente indirizzo di 235 East 42nd Street, New York, NY 10017 all'interno del contratto devono essere modificati nel seguente indirizzo: Pfizer Inc. 66 Hudson Boulevard East New York, NY 10001, USA.
2. The PA09 was approved by the CET COMITATO ETICO TERRITORIALE INTERAZIENDALE A.O.U. CITTÀ DELLA SALUTE E DELLA SCIENZA DI TORINO on 01 August 2024 and by AIFA with note prot. no. 65587 dated 22 May 2024.	2. Il PA09 è stato approvato dal CET COMITATO ETICO TERRITORIALE INTERAZIENDALE A.O.U. CITTÀ DELLA SALUTE E DELLA SCIENZA DI TORINO il 01 agosto 2024 e da AIFA con nota prot n. 65587 del 22 maggio 2024.
3. Due to the approval of PA9 on October 30, 2023, it is necessary to add the OLTP Arm to the previous budget of the study, which for convenience is full attached to this Amendment #4 under the letter "A".	3. A seguito dell'approvazione del PA9 del 30 ottobre 2023, si rende necessario aggiungere il Braccio OLTP al precedente budget dello studio, che per maggiore chiarezza si allega integralmente al presente Emendamento n.4 sotto la lettera "A".
4. This Amendment No. 4 shall enter into force, for all intents and purposes, on the date of its execution by the last of the contracting parties. Where the Parties have carried out activities already approved or notified to the Ethics Committee and governed by this Amendment No. 4, such activities, if performed in the interim, shall be considered as regulated by the provisions set out in this Amendment No. 4.	4. Il presente Emendamento n.4 entra in vigore, ad ogni e qualsiasi effetto, alla data della sua sottoscrizione da parte dell'ultimo dei soggetti contraenti. Ove Parti abbiano dato esecuzione ad attività già approvate o notificate al Comitato Etico e disciplinate dal presente Emendamento n. 4, tali attività, se eseguite medio tempore, dovranno considerarsi regolamentate dalle previsioni contenute nel presente Emendamento n. 4

All other terms of the Agreement remain in effect.	Tutti gli altri termini del Contratto restano in vigore.
The taxes and fees inherent and consequent to the stipulation of this Assignment, including the stamp duty on the electronic original referred to in the art. 2 of Table Annex A – tariff part I of Presidential Decree no. 642/1972 and the registration tax must be paid, in compliance with the applicable legislation. Stamp duty is paid electronically by Pfizer Inc., with registered office at 66 Hudson Boulevard East, New York, NY, 10001, USA, pursuant to art. 15 of the Presidential Decree (D.P.R.) 642 of 1972 (Authorization of the Revenue Agency of Rome with number 12/2025)	Le imposte e tasse inerenti e conseguenti alla stipula della presente Cessione, ivi comprese l'imposta di bollo sull'originale informatico di cui all'art. 2 della Tabella Allegato A – tariffa parte I del DPR n. 642/1972 e l'imposta di registro devono essere versate, nel rispetto della normativa applicabile. Bollo assolto virtualmente da Pfizer Inc., con sede in 66 Hudson Boulevard East, New York, NY, 10001, USA, ai sensi dell'art. 15 del DPR 642 del 1972 (Autorizzazione dell'Agenzia delle Entrate di Roma numero 12/2025).
ACCEPTED AND AGREED TO BY:	ACCETTATO E CONCORDATO DA E TRA:
Signature page following	*Segue Pagina delle firme*

Azienda Ospedaliero-Universitaria San Luigi Gonzaga di Orbassano,
Name/Nome: Dr Davide Minniti
Title/Qualifica: General Director/Direttore Generale
Signature/Firma: _____

Università degli Studi di Torino, Dipartimento di Oncologia
Name/Nome: Prof. Cristian Fiori
Title/Qualifica: Department Director / Il Direttore del Dipartimento
Signature/Firma: _____

Name/Nome: Dr Antonella Trombetta
Title/Qualifica: Administrative Director of the Medicine Hub / Dirigente di Polo Medicina
Signature/Firma: _____

Per il Promotore/Sponsor
Rappresentante Legale o suo delegato / The Legal Representative or deputy
Dott./Dr. _____
Firma/Signature _____

LIST OF ATTACHMENTS
"A"
Budget tables AMENDMENT 4:
(PA6 just for convenience + PA9 OLTP new)

ELENCO DEGLI ALLEGATI
"A"
Tabelle Budget EMENDAMENTO 4:
(PA6 solo per chiarezza + PA9 OLTP nuovo)

COMPOUND :	**TALAZOPARIB**	**AMENDMENT :**	**PA09**	**INVESTIGATOR:**	Consuelo Buttigliero
STUDY NUMBER :	**C3441021**	**ARM/COHORT :**	**Part 2**	**INSTITUTION:**	AOU San Luigi Gonzaga-
TITLE :	**A PHASE 3, RANDOMIZED, DOUBLE BLIND, PLACEBO CONTROLLED STUDY OF TALAZOPARIB WITH ENZALUTAMIDE IN METASTATIC CASTRATION RESISTANT PROSTATE CANCER**			**CCID:**	1066
COUNTRY/Currency :	Italy - EUR				
OVERHEAD	11.00%				

DESCRIPTION OF COST	Comments		Frequency of Procedure			VISIT 1		VISIT 2		VISIT 3		VISIT 4		VISIT 5		VISIT 6	
		COST (EUR)	Total Number of times a procedure occurs based on PSC Structure	Total PSC (EUR)	Total Visit Structure Total	f	Prescreening	f	Screening	f	Week 1	f	Week 3	f	Week 5	f	Week 7
Informed Consent/Medical History	(amount to be shared at 50% between Hospital and University)	88.00	2.0	176.00	176.00	1.00	88.00	1.00	88.00		0.00		0.00		0.00		0.00
ECOG performance status	amount to be shared at 50% between Hospital and University)	18.00	23.0	414.00	414.00		0.00	1.00	18.00	1.00	18.00		0.00	1.00	18.00		0.00
Complete physical examination	amount to be shared at 50% between Hospital and University)	82.00	1.0	82.00	82.00		0.00	1.00	82.00		0.00		0.00		0.00		0.00
PRO	EQ-5D-5L, Pain Log, Analgesic Log	18.00	23.0	414.00	414.00		0.00	1.00	18.00	1.00	18.00		0.00	1.00	18.00		0.00
Hematology	Hematocrit, hemoglobin, mean corpuscular volume, RBC, platelets, WBC	22.00	27.0	594.00	594.00		0.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00
Serum chemistry	Albumin, total protein, alkaline phosphatase, ALT, AST, total bilirubin, BUN, creatinine, glucose (non-fasting), bicarbonate, calcium, chloride, potassium, sodium amount to be shared at 50% between Hospital and University)	45.00	27.0	1215.00	1,215.00		0.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00
Magnesium	amount to be shared at 50% between Hospital and University)	9.00	27.0	243.00	243.00		0.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00
Phosphate	amount to be shared at 50% between Hospital and University)	7.00	27.0	189.00	189.00		0.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00
LDH	amount to be shared at 50% between Hospital and University)	11.00	27.0	297.00	297.00		0.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00
Testosterone	amount to be shared at 50% between Hospital and University)	46.00	1.0	46.00	46.00		0.00	1.00	46.00		0.00		0.00		0.00		0.00
Central lab	Blood samples for CTC analysis, blood samples for ctDNA, blood sample for protien biomarkers, blood sample for banked biospecimen amount to be shared at 50% between Hospital and University)	32.00	6.0	192.00	192.00		0.00	1.00	32.00	1.00	32.00		0.00		0.00		0.00
Additional Central lab	Blood sample to be stored for reflex testing for HBV and HCV, saliva sample for germline comparator amount to be shared at 50% between Hospital and University)	59.00	1.0	59.00	59.00		0.00		0.00	1.00	59.00		0.00		0.00		0.00
Symptom directed physical examination	amount to be shared at 50% between Hospital and University)	71.00	22.0	1562.00	1,562.00		0.00		0.00	1.00	71.00		0.00	1.00	71.00		0.00
Blood sample for PK	amount to be shared at 50% between Hospital and University)	20.00	8.0	160.00	160.00		0.00		0.00		0.00	2.00	40.00	2.00	40.00		0.00
Study Coordinator fee (Hourly)	Includes demographics, prior treatment for prostate cancer, adverse event review, SSID number, eligibility criteria, randomization authorization form, vital signs, weight, height, prior and concomitant medications, contraception/contraception use, symptomatic skeletal event evaluation, study treatment dispensing, study treatment accountability, new antineoplastic therapy, diagnosis of myelodysplastic syndrome or acute myeloid leukemia, survival status amount to be shared at 50% between Hospital and University)	31.00	62.0	1922.00	1,922.00	2.00	62.00	3.00	93.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00
Admin/Data Entry fee		28.00	61.0	1708.00	1,708.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00
	Amount to be shared at 50% between Hospital and University)	**PSC Subtotal w/out Overhead**		9,273.00 €			206.00 €		527.00 €		410.00 €		252.00 €		359.00 €		212.00 €
	Amount to be shared at 50% between Hospital and University)	**PSC Subtotal with Overhead**		10,293.03 €			228.66 €		584.97 €		455.10 €		279.72 €		398.49 €		235.32 €

DESCRIPTION OF COST	Comments	COST (EUR)	Frequency of Procedure Total Number of times a procedure occurs based on PSC Structure	Total PSC (EUR)	Total Visit Structure Total	VISIT 7		VISIT 8		VISIT 9		VISIT 10		VISIT 11		VISIT 12		VISIT 13		VISIT 14		VISIT 15		VISIT 16		VISIT 17		VISIT 18		VISIT 19		VISIT 20		VISIT 21	
						f	Week 9	f	Week 11	f	Week 13	f	Week 15	f	Week 17	f	Week 21	f	Week 25	f	Week 29	f	Week 33	f	Week 37	f	Week 41	f	Week 45	f	Week 49	f	Week 53	f	Week 61
Informed Consent/Medical History	(amount to be shared at 50% between Hospital and University)	88.00	2.0	176.00	176.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
ECOG performance status	amount to be shared at 50% between Hospital and University)	18.00	23.0	414.00	414.00	1.00	18.00		0.00	1.00	18.00		0.00	1.00	18.00	1.00	18.00	1.00	18.00	1.00	18.00	1.00	18.00	1.00	18.00	1.00	18.00	1.00	18.00	1.00	18.00	1.00	18.00	1.00	18.00
Complete physical examination	amount to be shared at 50% between Hospital and University)	82.00	1.0	82.00	82.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
PRO	EQ-5D-5L, Pain Log, Analgesic Log	18.00	23.0	414.00	414.00	1.00	18.00		0.00	1.00	18.00		0.00	1.00	18.00	1.00	18.00	1.00	18.00	1.00	18.00	1.00	18.00	1.00	18.00	1.00	18.00	1.00	18.00	1.00	18.00	1.00	18.00	1.00	18.00
Hematology	Hematocrit, hemoglobin, mean corpuscular volume, RBC, platelets, WBC	22.00	27.0	594.00	594.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00
Serum chemistry	Albumin, total protein, alkaline phosphatase, ALT, AST, total bilirubin, BUN, creatinine, glucose (non-fasting), bicarbonate, calcium, chloride, potassium, sodium amount to be shared at 50% between Hospital and University)	45.00	27.0	1215.00	1,215.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00
Magnesium	amount to be shared at 50% between Hospital and University)	9.00	27.0	243.00	243.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00
Phosphate	amount to be shared at 50% between Hospital and University)	7.00	27.0	189.00	189.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00
LDH	amount to be shared at 50% between Hospital and University)	11.00	27.0	297.00	297.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00
Testosterone	amount to be shared at 50% between Hospital and University)	46.00	1.0	46.00	46.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Central lab	Blood samples for CTC analysis, blood samples for ctDNA, blood sample for protien biomarkers, blood sample for banked biospecimen amount to be shared at 50% between Hospital and University)	32.00	6.0	192.00	192.00	1.00	32.00		0.00		0.00		0.00	1.00	32.00		0.00	1.00	32.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Additional Central lab	Blood sample to be stored for reflex testing for HBV and HCV, saliva sample for germline comparator amount to be shared at 50% between Hospital and University)	59.00	1.0	59.00	59.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Symptom directed physical examination	amount to be shared at 50% between Hospital and University)	71.00	22.0	1562.00	1,562.00	1.00	71.00		0.00	1.00	71.00		0.00	1.00	71.00	1.00	71.00	1.00	71.00	1.00	71.00	1.00	71.00	1.00	71.00	1.00	71.00	1.00	71.00	1.00	71.00	1.00	71.00	1.00	71.00
Blood sample for PK	amount to be shared at 50% between Hospital and University)	20.00	8.0	160.00	160.00	2.00	40.00		0.00	1.00	20.00		0.00	1.00	20.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Study Coordinator fee (Hourly)	Includes demographics, prior treatment for prostate cancer, adverse event review, SSID number, eligibility criteria, randomization authorization form, vital signs, weight, height, prior and concomitant medications, contraception/contraception use, symptomatic skeletal event evaluation, study treatment dispensing, study treatment accountability, new antineoplastic therapy, diagnosis of myelodysplastic syndrome or acute myeloid leukemia, survival status amount to be shared at 50% between Hospital and University)	31.00	62.0	1922.00	1,922.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00
Admin/Data Entry fee		28.00	61.0	1708.00	1,708.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00
	Amount to be shared at 50% between Hospital and University)	**PSC Subtotal w/out Overhead**		9,273.00 €			391.00 €		212.00 €		339.00 €		212.00 €		371.00 €		319.00 €		351.00 €		319.00 €		319.00 €		319.00 €		319.00 €		319.00 €		319.00 €		319.00 €		319.00 €
	Amount to be shared at 50% between Hospital and University)	**PSC Subtotal with Overhead**		10,293.03 €			434.01 €		235.32 €		376.29 €		235.32 €		411.81 €		354.09 €		389.61 €		354.09 €		354.09 €		354.09 €		354.09 €		354.09 €		354.09 €		354.09 €		354.09 €

DESCRIPTION OF COST	Comments		Frequency of Procedure			VISIT 22		VISIT 23		VISIT 24		VISIT 25		VISIT 26		VISIT 27		VISIT 28		VISIT 29		VISIT 30		VISIT 31	
		COST (EUR)	Total Number of times a procedure occurs based on PSC Structure	Total PSC (EUR)	Total Visit Structure Total	f	Week 69	f	Week 73	f	Week 77	f	Week 85	f	Week 93	f	Week 97	f	Week 101	f	Week 109	f	Safety Follow up	f	Long Term Follow Up
Informed Consent/Medical History	(amount to be shared at 50% between Hospital and University)	88.00	2.0	176.00	176.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
ECOG performance status	amount to be shared at 50% between Hospital and University)	18.00	23.0	414.00	414.00	1.00	18.00		0.00	1.00	18.00	1.00	18.00	1.00	18.00		0.00	1.00	18.00	1.00	18.00	1.00	18.00		0.00
Complete physical examination	amount to be shared at 50% between Hospital and University)	82.00	1.0	82.00	82.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
PRO	EQ-5D-5L, Pain Log, Analgesic Log	18.00	23.0	414.00	414.00	1.00	18.00		0.00	1.00	18.00	1.00	18.00	1.00	18.00		0.00	1.00	18.00	1.00	18.00	1.00	18.00		0.00
Hematology	Hematocrit, hemoglobin, mean corpuscular volume, RBC, platelets, WBC	22.00	27.0	594.00	594.00	1.00	22.00		0.00	1.00	22.00	1.00	22.00	1.00	22.00		0.00	1.00	22.00	1.00	22.00	1.00	22.00		0.00
Serum chemistry	Albumin, total protein, alkaline phosphatase, ALT, AST, total bilirubin, BUN, creatinine, glucose (non-fasting), bicarbonate, calcium, chloride, potassium, sodium amount to be shared at 50% between Hospital and University)	45.00	27.0	1215.00	1,215.00	1.00	45.00		0.00	1.00	45.00	1.00	45.00	1.00	45.00		0.00	1.00	45.00	1.00	45.00	1.00	45.00		0.00
Magnesium	amount to be shared at 50% between Hospital and University)	9.00	27.0	243.00	243.00	1.00	9.00		0.00	1.00	9.00	1.00	9.00	1.00	9.00		0.00	1.00	9.00	1.00	9.00	1.00	9.00		0.00
Phosphate	amount to be shared at 50% between Hospital and University)	7.00	27.0	189.00	189.00	1.00	7.00		0.00	1.00	7.00	1.00	7.00	1.00	7.00		0.00	1.00	7.00	1.00	7.00	1.00	7.00		0.00
LDH	amount to be shared at 50% between Hospital and University)	11.00	27.0	297.00	297.00	1.00	11.00		0.00	1.00	11.00	1.00	11.00	1.00	11.00		0.00	1.00	11.00	1.00	11.00	1.00	11.00		0.00
Testosterone	amount to be shared at 50% between Hospital and University)	46.00	1.0	46.00	46.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Central lab	Blood samples for CTC analysis, blood samples for ctDNA, blood sample for protien biomarkers, blood sample for banked biospecimen amount to be shared at 50% between Hospital and University)	32.00	6.0	192.00	192.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	32.00		0.00
Additional Central lab	Blood sample to be stored for reflex testing for HBV and HCV, saliva sample for germline comparator amount to be shared at 50% between Hospital and University)	59.00	1.0	59.00	59.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Symptom directed physical examination	amount to be shared at 50% between Hospital and University)	71.00	22.0	1562.00	1,562.00	1.00	71.00		0.00	1.00	71.00	1.00	71.00	1.00	71.00		0.00	1.00	71.00	1.00	71.00	1.00	71.00		0.00
Blood sample for PK	amount to be shared at 50% between Hospital and University)	20.00	8.0	160.00	160.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Study Coordinator fee (Hourly)	Includes demographics, prior treatment for prostate cancer, adverse event review, SSID number, eligibility criteria, randomization authorization form, vital signs, weight, height, prior and concomitant medications, contraception/contraception use, symptomatic skeletal event evaluation, study treatment dispensing, study treatment accountability, new antineoplastic therapy, diagnosis of myelodysplastic syndrome or acute myeloid leukemia, survival status amount to be shared at 50% between Hospital and University)	31.00	62.0	1922.00	1,922.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	1.00	31.00
Admin/Data Entry fee		28.00	61.0	1708.00	1,708.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	1.00	28.00
	Amount to be shared at 50% between Hospital and University)	**PSC Subtotal w/out Overhead**		9,273.00 €			319.00 €		118.00 €		319.00 €		319.00 €		319.00 €		118.00 €		319.00 €		319.00 €		351.00 €		59.00 €
	Amount to be shared at 50% between Hospital and University)	**PSC Subtotal with Overhead**		10,293.03 €			354.09 €		130.98 €		354.09 €		354.09 €		354.09 €		130.98 €		354.09 €		354.09 €		389.61 €		65.49 €

Additional Procedures that may not apply to all Patients		COST (EUR)	Total Number of times a procedure may occur	Total Potential PSC (EUR)		f	Prescreening	f	Screening	f	Week 1	f	Week 3	f	Week 5	f	Week 7	f	Week 9	f	Week 11	f	Week 13	f	Week 15	f	Week 17	f	Week 21	f	Week 25
Symptom directed physical examination	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	71.00	1.0	71.00	71.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
ECOG performance status	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	18.00	1.0	18.00	18.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
PRO	Applicable at follow up visits if performed at clinic (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	18.00	1.0	18.00	18.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Hematology	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	22.00	1.0	22.00	22.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Reticulocyte count	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	13.00	1.0	13.00	13.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Erythropoietin	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	64.00	1.0	64.00	64.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Serum chemistry	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	45.00	1.0	45.00	45.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Magnesium	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	9.00	1.0	9.00	9.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Phosphate	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	7.00	1.0	7.00	7.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
LDH	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	11.00	1.0	11.00	11.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Folate	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	37.00	1.0	37.00	37.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
B12	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	28.00	1.0	28.00	28.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
PSA	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	38.00	1.0	38.00	38.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Central lab	the activity performed by the SCDU radiodiagnostics)	32.00	1.0	32.00	32.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
PK Sample	the activity performed by the SCDU radiodiagnostics)	20.00	1.0	20.00	20.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Study Coordinator fee (Hourly)	Applicable at follow up visits if performed at clinic, and unscheduled visits	31.00	3.0	93.00	93.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Admin/Data Entry fee	Applicable at follow up visits if performed at clinic, and unscheduled visits	28.00	3.0	84.00	84.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
B12	Only applicable if avaliable at the site lab 50% Hospital Univeristy	28.00	27.0	756.00	756.00		0.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00
Reticulocyte count	Only applicable if avaliable at the site lab 50% Hospital Univeristy	13.00	27.0	351.00	351.00		0.00	1.00	13.00	1.00	13.00	1.00	13.00	1.00	13.00	1.00	13.00	1.00	13.00	1.00	13.00	1.00	13.00	1.00	13.00	1.00	13.00	1.00	13.00	1.00	13.00
Erythropoietin	Only applicable if avaliable at the site lab 50% Hospital Univeristy	64.00	27.0	1728.00	1,728.00		0.00	1.00	64.00	1.00	64.00	1.00	64.00	1.00	64.00	1.00	64.00	1.00	64.00	1.00	64.00	1.00	64.00	1.00	64.00	1.00	64.00	1.00	64.00	1.00	64.00
Bicarbonate	Only applicable if avaliable at the site lab 50% Hospital Univeristy	45.00	27.0	1215.00	1,215.00		0.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00
Liquid Biospy	Applicable at either Prescreening or Screening 50%Hospital Univeristy	454.00	2.0	908.00	908.00	1.00	454.00	1.00	454.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Per Subject Cost Subtotal				9,273.00 €	- €		206.00 €		527.00 €		410.00 €		252.00 €		359.00 €		212.00 €		391.00 €		212.00 €		339.00 €		212.00 €		371.00 €		319.00 €		351.00 €
Additional Cost Subtotal				5,568.00 €	5,568.00 €		454.00 €		604.00 €		150.00 €		150.00 €		150.00 €		150.00 €		150.00 €		150.00 €		150.00 €		150.00 €		150.00 €		150.00 €		150.00 €
Subtotal				14,841.00 €	5,568.00 €		660.00 €		1,131.00 €		560.00 €		402.00 €		509.00 €		362.00 €		541.00 €		362.00 €		489.00 €		362.00 €		521.00 €		469.00 €		501.00 €
Overhead				1,632.51 €	612.48 €		72.60 €		124.41 €		61.60 €		44.22 €		55.99 €		39.82 €		59.51 €		39.82 €		53.79 €		39.82 €		57.31 €		51.59 €		55.11 €
INVESTIGATOR COST PER SUBJECT with Overhead				**16,473.51 €**	**6,180.48 €**		**732.60 €**		**1,255.41 €**		**621.60 €**		**446.22 €**		**564.99 €**		**401.82 €**		**600.51 €**		**401.82 €**		**542.79 €**		**401.82 €**		**578.31 €**		**520.59 €**		**556.11 €**

Additional Procedures that may not apply to all Patients		COST (EUR)	Total Number of times a procedure may occur	Total Potential PSC (EUR)		f	Week 29	f	Week 33	f	Week 37	f	Week 41	f	Week 45	f	Week 49	f	Week 53	f	Week 61
Symptom directed physical examination	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	71.00	1.0	71.00	71.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
ECOG performance status	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	18.00	1.0	18.00	18.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
PRO	Applicable at follow up visits if performed at clinic (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	18.00	1.0	18.00	18.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Hematology	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	22.00	1.0	22.00	22.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Reticulocyte count	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	13.00	1.0	13.00	13.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Erythropoietin	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	64.00	1.0	64.00	64.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Serum chemistry	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	45.00	1.0	45.00	45.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Magnesium	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	9.00	1.0	9.00	9.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Phosphate	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	7.00	1.0	7.00	7.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
LDH	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	11.00	1.0	11.00	11.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Folate	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	37.00	1.0	37.00	37.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
B12	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	28.00	1.0	28.00	28.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
PSA	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	38.00	1.0	38.00	38.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Central lab	the activity performed by the SCDU radiodiagnostics)	32.00	1.0	32.00	32.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
PK Sample	the activity performed by the SCDU radiodiagnostics)	20.00	1.0	20.00	20.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Study Coordinator fee (Hourly)	Applicable at follow up visits if performed at clinic, and unscheduled visits	31.00	3.0	93.00	93.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Admin/Data Entry fee	Applicable at follow up visits if performed at clinic, and unscheduled visits	28.00	3.0	84.00	84.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
B12	Only applicable if avaliable at the site lab 50% Hospital Univeristy	28.00	27.0	756.00	756.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00
Reticulocyte count	Only applicable if avaliable at the site lab 50% Hospital Univeristy	13.00	27.0	351.00	351.00	1.00	13.00	1.00	13.00	1.00	13.00	1.00	13.00	1.00	13.00	1.00	13.00	1.00	13.00	1.00	13.00
Erythropoietin	Only applicable if avaliable at the site lab 50% Hospital Univeristy	64.00	27.0	1728.00	1,728.00	1.00	64.00	1.00	64.00	1.00	64.00	1.00	64.00	1.00	64.00	1.00	64.00	1.00	64.00	1.00	64.00
Bicarbonate	Only applicable if avaliable at the site lab 50% Hospital Univeristy	45.00	27.0	1215.00	1,215.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00
Liquid Biospy	Applicable at either Prescreening or Screening 50%Hospital Univeristy	454.00	2.0	908.00	908.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Per Subject Cost Subtotal				9,273.00 €	- €		319.00 €		319.00 €		319.00 €		319.00 €		319.00 €		319.00 €		319.00 €		319.00 €
Additional Cost Subtotal				5,568.00 €	5,568.00 €		150.00 €		150.00 €		150.00 €		150.00 €		150.00 €		150.00 €		150.00 €		150.00 €
Subtotal				14,841.00 €	5,568.00 €		469.00 €		469.00 €		469.00 €		469.00 €		469.00 €		469.00 €		469.00 €		469.00 €
Overhead				1,632.51 €	612.48 €		51.59 €		51.59 €		51.59 €		51.59 €		51.59 €		51.59 €		51.59 €		51.59 €
INVESTIGATOR COST PER SUBJECT with Overhead				**16,473.51 €**	**6,180.48 €**		**520.59 €**		**520.59 €**		**520.59 €**		**520.59 €**		**520.59 €**		**520.59 €**		**520.59 €**		**520.59 €**

Additional Procedures that may not apply to all Patients		COST (EUR)	Total Number of times a procedure may occur	Total Potential PSC (EUR)		f	Week 69	f	Week 73	f	Week 77	f	Week 85	f	Week 93	f	Week 97	f	Week 101	f	Week 109	f	Safety Follow up	f	Long Term Follow Up	f	Unscheduled Visit
Symptom directed physical examination	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	71.00	1.0	71.00	71.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	71.00
ECOG performance status	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	18.00	1.0	18.00	18.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	18.00
PRO	Applicable at follow up visits if performed at clinic (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	18.00	1.0	18.00	18.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	18.00		0.00
Hematology	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	22.00	1.0	22.00	22.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	22.00
Reticulocyte count	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	13.00	1.0	13.00	13.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	13.00
Erythropoietin	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	64.00	1.0	64.00	64.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	64.00
Serum chemistry	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	45.00	1.0	45.00	45.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	45.00
Magnesium	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	9.00	1.0	9.00	9.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	9.00
Phosphate	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	7.00	1.0	7.00	7.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	7.00
LDH	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	11.00	1.0	11.00	11.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	11.00
Folate	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	37.00	1.0	37.00	37.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	37.00
B12	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	28.00	1.0	28.00	28.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	28.00
PSA	Applicable at unscheduled visits (amount to be paid only to the Hospital for the activity performed by the SCDU radiodiagnostics)	38.00	1.0	38.00	38.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	38.00
Central lab	the activity performed by the SCDU radiodiagnostics)	32.00	1.0	32.00	32.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	32.00
PK Sample	the activity performed by the SCDU radiodiagnostics)	20.00	1.0	20.00	20.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	20.00
Study Coordinator fee (Hourly)	Applicable at follow up visits if performed at clinic, and unscheduled visits	31.00	3.0	93.00	93.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	31.00	2.00	62.00
Admin/Data Entry fee	Applicable at follow up visits if performed at clinic, and unscheduled visits	28.00	3.0	84.00	84.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00	1.00	28.00	2.00	56.00
B12	Only applicable if avaliable at the site lab 50% Hospital Univeristy	28.00	27.0	756.00	756.00	1.00	28.00		0.00	1.00	28.00	1.00	28.00	1.00	28.00		0.00	1.00	28.00	1.00	28.00	1.00	28.00		0.00		0.00
Reticulocyte count	Only applicable if avaliable at the site lab 50% Hospital Univeristy	13.00	27.0	351.00	351.00	1.00	13.00		0.00	1.00	13.00	1.00	13.00	1.00	13.00		0.00	1.00	13.00	1.00	13.00	1.00	13.00		0.00		0.00
Erythropoietin	Only applicable if avaliable at the site lab 50% Hospital Univeristy	64.00	27.0	1728.00	1,728.00	1.00	64.00		0.00	1.00	64.00	1.00	64.00	1.00	64.00		0.00	1.00	64.00	1.00	64.00	1.00	64.00		0.00		0.00
Bicarbonate	Only applicable if avaliable at the site lab 50% Hospital Univeristy	45.00	27.0	1215.00	1,215.00	1.00	45.00		0.00	1.00	45.00	1.00	45.00	1.00	45.00		0.00	1.00	45.00	1.00	45.00	1.00	45.00		0.00		0.00
Liquid Biospy	Applicable at either Prescreening or Screening 50%Hospital Univeristy	454.00	2.0	908.00	908.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Per Subject Cost Subtotal				9,273.00 €	- €		319.00 €		118.00 €		319.00 €		319.00 €		319.00 €		118.00 €		319.00 €		319.00 €		351.00 €		59.00 €		- €
Additional Cost Subtotal				5,568.00 €	5,568.00 €		150.00 €		- €		150.00 €		150.00 €		150.00 €		- €		150.00 €		150.00 €		150.00 €		77.00 €		533.00 €
Subtotal				14,841.00 €	5,568.00 €		469.00 €		118.00 €		469.00 €		469.00 €		469.00 €		118.00 €		469.00 €		469.00 €		501.00 €		136.00 €		533.00 €
Overhead				1,632.51 €	612.48 €		51.59 €		12.98 €		51.59 €		51.59 €		51.59 €		12.98 €		51.59 €		51.59 €		55.11 €		14.96 €		58.63 €
INVESTIGATOR COST PER SUBJECT with Overhead				**16,473.51 €**	**6,180.48 €**		**520.59 €**		**130.98 €**		**520.59 €**		**520.59 €**		**520.59 €**		**130.98 €**		**520.59 €**		**520.59 €**		**556.11 €**		**150.96 €**		**591.63 €**

Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead		
Procedure	**Comments**	**Cost (EUR)**
Local IRB/EC Fees - Initial Review		
Local IRB/EC Fees - Amendment		
Local IRB/EC Fees - Annual Review		
Screen Fails	Applicable to subjects who SF at Visit 2. Cost reflects V2 with 25% reduction, no overhead paid. Max 10 SFs per site.)(amount to be shared at 50% between Hospital and University)	395.25
12-Lead electrocardiogram	To be invoiced as clinically indicated (amount to be paid 100% to the Entity)	57.72
ECOG performance status	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	19.98
Symptom directed physical examination	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	78.81
PRO	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	19.98
Hematology	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	24.42
Reticulocyte count	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	14.43
Erythropoietin	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	71.04
Serum chemistry	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	49.95
Magnesium	To be invoiced as clinically indicated(amount to be shared at 50% between Hospital and University)	9.99
Phosphate	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	7.77
LDH	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	12.21
Folate	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	41.07
B12	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	31.08
Testosterone	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	51.06
PSA	To be invoiced as performed: at screening and then Q8W until radiographic progression and as clinically indicated.(amount to be shared at 50% between Hospital and University)	42.18
Central lab	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	35.52

Fresh tumor tissue	To be invoiced as clinically indicated(amount to be paid only to the Hospital for the activity performed by the SCDU radio diagnostics)	1,701.63
Archival tissue	To be invoiced as clinically indicated (amount to be paid only to the Hospital for the activity performed by the SCDU radio diagnostics)	55.50
CT Chest	Either CT or MRI to be performed, not both (amount to be shared at 50% between Hospital and University)	612.72
CT Abdomen	Either CT or MRI to be performed, not both (amount to be shared at 50% between Hospital and University)	684.87
CT Pelvis	Either CT or MRI to be performed, not both (amount to be shared at 50% between Hospital and University)	483.96
MRI Abdomen	Either CT or MRI to be performed, not both (amount to be shared at 50% between Hospital and University)	956.82
MRI Pelvis	Either CT or MRI to be performed, not both (amount to be shared at 50% between Hospital and University)	719.28
Bone Scan	Either CT or MRI to be performed, not both (amount to be shared at 50% between Hospital and University)	334.11
RECIST 1.1/PCWG3 Assessment	To be invoiced as performed (amount to be paid only to the Hospital for the activity performed by the SCDU radio diagnostics)	18.87
Long Term Follow Up-phone	(amount to be shared at 50% between Hospital and University)	65.49
Long Term Follow Up-clinic	(amount to be shared at 50% between Hospital and University)	150.96
Week 121, every 12 weeks thereafter	(amount to be shared at 50% between Hospital and University)	130.98
Telephone call for additional safety FU visits.	To be invoiced as performed. Includes 1 hr SC and 1 hr Data entry.	65.49
Weeks 69, 77, 93 & 101	To be paid based on EDC Data.	354.09
Subjects **WITHOUT DP** who remain on IP - **Every 8 weeks** (Weeks 85, 109 and beyond)	Applicable to subjects who remain on study without Progressive Disease; Fee includes ECOG, PRO, Hematology, Serum chemistry, Magnesium, Phosphate, LDH, Symptom-directed PE, SC Fee and Admin/DE Fee Invoice as incurred	354.09
Subjects **WITHOUT DP** who remain on IP **-** **Every 12 weeks** visit (Weeks 73, 97 and beyond; not overlapping with a regularly scheduled visit) - Staff and Admin/DE Fees	Includes staff fees for 12 Week Visits that do not overlap regularly scheduled visits. Fee includes 2 hour of SC time and 2 hr of Admin/DE time	130.98
Subjects **WITH DP** who remain on IP - **Every 8 weeks** (Weeks 85, 109 and beyond)	Fee includes ECOG, PRO, Hematology, Serum chemistry, Magnesium, Phosphate, LDH, Symptom-directed PE, SC Fee and Admin/DE Fee Invoice as incurred	354.09

Subjects **WITH DP** who remain on IP - **Every 12 weeks** visit (Weeks 73, 97 and beyond; not overlapping with a regularly scheduled visit) - Staff and Admin/DE Fees	Includes staff fees for 12 Week Visits that do not overlap regularly scheduled visits. Fee includes 2 hour of SC time and 2 hr of Admin/DE time	130.98
Unscheduled Visit - Staff Fees and Admin/DE Fees	Invoice as incurred	130.98
Budget Amendment Fee	Sponsor initiated budget amendments only Fee includes 4 hours of SC time	137.64

COMPOUND :	**TALAZOPARIB**	**AMENDMENT :**	**PA9**	**INVESTIGATOR:**	Consuelo Buttigliero
STUDY NUMBER :	**C3441021**	**ARM/COHORT :**	**OLTP Exhibit I**	**INSTITUTION:**	AOU San Luigi Gonzaga -
TITLE :	A PHASE 3, RANDOMIZED, DOUBLE BLIND, PLACEBO CONTROLLED STUDY OF TALAZOPARIB WITH ENZALUTAMIDE IN METASTATIC CASTRATION RESISTANT PROSTATE CANCER			**CCID:**	1066
COUNTRY/Currency :		Italy - EUR			
OVERHEAD		11.00%			

DESCRIPTION OF COST	Comments		Frequency of Procedure		VISIT 1		VISIT 2		VISIT 3		VISIT 4		VISIT 5		VISIT 6		VISIT 7		VISIT 8		VISIT 9		VISIT 10		VISIT 11		VISIT 12		VISIT 13		VISIT 14		VISIT 15	
		COST	Total Number of times a procedure occurs based on PSC Structure	Total PSC	f	Open Label Treatment Day 1	f	Open Label Treatment Period C1	f	Open Label Treatment Period C2	f	Open Label Treatment Period C3	f	Open Label Treatment Period C4	f	Open Label Treatment Period C5	f	Open Label Treatment Period C6	f	Open Label Treatment Period C7	f	Open Label Treatment Period C8	f	Open Label Treatment Period C9	f	Open Label Treatment Period C10	f	Open Label Treatment Period C11	f	Open Label Treatment Period C12	f	Open Label Treatment Safety Follow Up	f	Open Label Treatment LTFU
Informed Consent/Medical History		88.00	1.0	88	1.00	88.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Hematology	Hematocrit, hemoglobin, mean corpuscular volume, RBC, platelets, WBC with differential (ANC, lymphocytes, monocytes, eosinophils, basophils)	22.00	13.0	286		0.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00	1.00	22.00		0.00
Serum chemistry	Albumin, total protein, alkaline phosphatase, ALT, AST, total bilirubin, BUN, creatinine, glucose (non-fasting), bicarbonate, calcium, chloride, potassium, sodium	45.00	13.0	585		0.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00	1.00	45.00		0.00
Magnesium		9.00	13.0	117		0.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00	1.00	9.00		0.00
Phosphate		7.00	13.0	91		0.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00	1.00	7.00		0.00
LDH		11.00	13.0	143		0.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00	1.00	11.00		0.00
Study Coordinator fee (Hourly)	Includes demographics, prior treatment for prostate cancer, adverse event review, SSID number, eligibility criteria, randomization authorization form, vital signs, weight, height, prior and concomitant medications, contraception/contraception use, symptomatic skeletal event evaluation, study treatment dispensing, study treatment accountability, new antineoplastic therapy, diagnosis of myelodysplastic syndrome or acute myeloid leukemia, survival status	31.00	29.0	899	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	2.00	62.00	1.00	31.00
Admin/Data Entry fee		28.00	29.0	812	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	2.00	56.00	1.00	28.00
	Amount to be shared at 50% between Hospital and University)	**PSC Subtotal w/out Overhead**		3,021.00		206.00		212.00		212.00		212.00		212.00		212.00		212.00		212.00		212.00		212.00		212.00		212.00		212.00		212.00		59.00
	Amount to be shared at 50% between Hospital and University)	**PSC Subtotal with Overhead**		3,353.31		228.66		235.32		235.32		235.32		235.32		235.32		235.32		235.32		235.32		235.32		235.32		235.32		235.32		235.32		65.49

				Total Potential PSC	f	Open Label Treatment Day 1	f	Open Label Treatment Period C1	f	Open Label Treatment Period C2	f	Open Label Treatment Period C3	f	Open Label Treatment Period C4	f	Open Label Treatment Period C5	f	Open Label Treatment Period C6	f	Open Label Treatment Period C7	f	Open Label Treatment Period C8	f	Open Label Treatment Period C9	f	Open Label Treatment Period C10	f	Open Label Treatment Period C11	f	Open Label Treatment Period C12	f	Open Label Treatment Safety Follow Up	f	Open Label Treatment LTFU
Per Subject Cost Subtotal				3,021.00		206.00		212.00		212.00		212.00		212.00		212.00		212.00		212.00		212.00		212.00		212.00		212.00		212.00		212.00		59.00
Overhead				332.31		22.66		23.32		23.32		23.32		23.32		23.32		23.32		23.32		23.32		23.32		23.32		23.32		23.32		23.32		6.49
INVESTIGATOR COST PER SUBJECT with Overhead	Amount to be shared at 50% between Hospital and University)			**3,353.31**		**228.66**		**235.32**		**235.32**		**235.32**		**235.32**		**235.32**		**235.32**		**235.32**		**235.32**		**235.32**		**235.32**		**235.32**		**235.32**		**235.32**		**65.49**

Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead		
Procedure	**Comments**	**Cost**
Central IRB Fees		
Local IRB/EC Fees - Initial Review	**Please see main budget for site fees**	
Local IRB/EC Fees - Amendment		
Local IRB/EC Fees - Annual Review		
Pharmacy start-up fee		
Admin start-up fee		
Advertising		
Record Archiving		
Radiology start-up		
Screen Fails	Applicable to subjects who SF at Visit 1. Cost reflects V1 with 25% reduction, no overhead paid. **Max 10 SFs per site** (amount to be shared at 50% between Hospital and University).	154.50
Symptom directed physical examination	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	78.81
Hematology	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	24.42
Reticulocyte count	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	14.43
Erythropoietin	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	71.04
Serum chemistry	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	49.95
Magnesium	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	9.99
LDH	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	12.21
Folate	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	41.07
B12	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	31.08

PSA	To be invoiced as performed: at screening and then Q8W until radiographic progression and as clinically indicated.(amount to be shared at 50% between Hospital and University)	42.18
Central lab	To be invoiced as clinically indicated (amount to be shared at 50% between Hospital and University)	35.52
Long Term Follow Up-phone	**Invoice as incurred** (amount to be shared at 50% between Hospital and University)	32.75
Long Term Follow Up-clinic	**Invoice as incurred** (amount to be shared at 50% between Hospital and University)	65.49
CT Chest	Either CT or MRI to be performed, not both (amount to be shared at 50% between Hospital and University)	612.72
CT Abdomen	Either CT or MRI to be performed, not both (amount to be shared at 50% between Hospital and University)	684.87
CT Pelvis	Either CT or MRI to be performed, not both (amount to be shared at 50% between Hospital and University)	483.96
MRI Abdomen	Either CT or MRI to be performed, not both (amount to be shared at 50% between Hospital and University)	956.82
MRI Pelvis	Either CT or MRI to be performed, not both (amount to be shared at 50% between Hospital and University)	719.28
Bone Scan	**Invoice as incurred** (amount to be shared at 50% between Hospital and University)	334.11
Unscheduled Visit	Includes 1HR SC and DE fee plus OH. Invoice as incurred (amount to be shared at 50% between Hospital and University)	65.49
Additional Cycles	Invoicing not required - paid pased on EDC completion (amount to be shared at 50% between Hospital and University)	235.32