



DELIBERAZIONE DEL DIRETTORE GENERALE

N. 391 del 07/07/2026

Oggetto: APPROVAZIONE EMENDAMENTO N. 4 AL CONTRATTO PER LA SPERIMENTAZIONE CLINICA FARMACOLOGICA DAL TITOLO "TALAPRO 2 (C3441021)", AUTORIZZATO CON DELIBERAZIONE N. 595 DEL 13/11/2019 - SPERIMENTATORE RESPONSABILE: PROF.SSA CONSUELO BUTTIGLIERO, PRATICA COMITATO ETICO N. 18/2019/U.

Copia informatica , tratta, ai sensi e per gli effetti di cui all'art. 3/bis, comma 4/bis ed all'art. 23 del D.Lgs 82/2005, dal documento informatico sottoscritto con firma digitale, predisposto e conservato presso l'Amministrazione in conformità al D.Lgs. 82/2005 (C.A.D.) identificato con HASH, indicato/i in calce, dell'atto in oggetto e dei suoi allegati.

RIFERIMENTI INFORMATICI:

- DEL_2509316.pdf.p7m

90E845355C445ACC8FEB44F78E1289DE0547D2AE88A9E60EEAE8F684D9F7A704AF24136B207394560D869A
ADA1E5D907BA27A3ABF3AE8B3BE1C38D5166919B69

- Emendamento n. 4 TALAPRO 2.pdf

0F587F8200E8BDDF29E8CB678FB67C98019FB817B34E171215BD2D15A76873E014B4629BFDE94D78EA42C
3E27260C39BD87E9AC8B57C6AF438019AD4221A178C

Sistema Sanitario Regionale del Piemonte



OGGETTO: APPROVAZIONE EMENDAMENTO N. 4 AL CONTRATTO PER LA SPERIMENTAZIONE CLINICA FARMACOLOGICA DAL TITOLO "TALAPRO 2 (C3441021)", AUTORIZZATO CON DELIBERAZIONE N. 595 DEL 13/11/2019 - SPERIMENTATORE RESPONSABILE: PROF.SSA CONSUELO BUTTIGLIERO, PRATICA COMITATO ETICO N. 18/2019/U.

Struttura proponente: Affari Generali e Legali

Il Responsabile del Procedimento ex artt. 5 – 6 L. 7.8.90 n. 241 Dott. TORRE MICHELE	Il Dirigente Responsabile della struttura proponente Dott.ssa DI CUIA ANNA LISA
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Registrazione contabile

Anno	Gestore/Progetto/Commessa	Conto	Importo
Struttura titolare della spesa Dott.			

PARERE DEI DIRETTORI AMMINISTRATIVO E SANITARIO (ex D.Lgs n. 502/92 e s.m.i.)

Il Direttore Amministrativo Dott. ROBERTO D'ANGELO (Sottoscritto digitalmente ai sensi dell'art. 21 D.Lgs n. 82/2005 e s.m.i.)	Il Direttore Sanitario Dr. SALVATORE DI GIOIA (Sottoscritto digitalmente ai sensi dell'art. 21 D.Lgs n. 82/2005 e s.m.i.)
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IL DIRETTORE GENERALE
Dr. Davide Minniti

- Vista la D.G.R. n. 27-8058/2023/XI del 29/12/2023 con la quale il sottoscritto è stato nominato Direttore Generale di quest'Azienda;
- Visti gli atti relativi alla materia in trattazione:
 - La deliberazione n. 397 del 01/08/2024 con la quale questa Azienda ha approvato il nuovo regolamento per la conduzione di sperimentazioni e studi clinici;
 - la deliberazione n. 595 del 13/11/2019 con la quale è stato autorizzato lo studio clinico dal titolo: "Protocollo C3441021 - Studio controllato con placebo di fase 3, randomizzato, in doppio cieco, talazoparib con enzalutamide nel tumore prostatico metastatico, resistente alla castrazione", effettuato presso la SCDU Oncologia Medica, Sperimentatore Responsabile dott.ssa Consuelo Buttigliero, dirigente medico in servizio presso detta struttura, pratica Comitato Etico n. 18/2019/U, nonché approvata la relativa convenzione;
 - la deliberazione n. 668 del 28/12/2020 con la quale questa Azienda ha approvato l'emendamento n. 1 relativo allo studio clinico in oggetto;
 - la deliberazione n. 463 del 27/09/2024 con la quale questa Azienda ha approvato l'emendamento n. 2 relativo allo studio clinico in oggetto;
 - la deliberazione n. 284 del 10/06/2025 con la quale questa Azienda ha approvato l'emendamento n. 3 relativo allo studio clinico in oggetto
 - l'emendamento sostanziale al protocollo n 8 col quale il promotore ha richiesto col suddetto emendamento al CET Città della Salute e della Scienza di Torino l'approvazione della versione n. 9 del protocollo di studio;
 - La nota prot n. 006587 del 22/05/2024 con la quale AIFA ha espresso il parere favorevole all'emendamento sostanziale al protocollo
 - Il CET Città della Salute e della Scienza di Torino, nella seduta del 24/07/2024, ha approvato l'emendamento sostanziale al protocollo;
 - la e.mail del 21/07/2025 con la quale il promotore dello studio ha trasmesso la proposta dell'emendamento n. 4 relativo alla sperimentazione clinica farmacologica in oggetto;
 - il parere favorevole espresso, nella seduta del 05/11/2025, dall'Università degli Studi di Torino - Dipartimento di Oncologia, all'emendamento in oggetto;
 - la corrispondenza intercorsa fra questa Azienda, l'Università degli Studi di Torino-Dipartimento di Oncologia e la società Pfizer per la finalizzazione dell'Emendamento n. 4 al contratto;
 - la e-mail del 11/06/2026 con la quale l'Azienda, d'intesa con l'Università degli Studi di Torino-Dipartimento di Oncologia ha trasmesso la versione finale e concordata dell'Emendamento n. 4 relativo alla sperimentazione clinica farmacologica in oggetto;
 - la e-mail del 16/06/2026 con la quale la società Pfizer ha espresso il parere favorevole al testo dell'emendamento trasmesso con e-mail del 11/06/2026;

- Preso atto che col suddetto emendamento viene approvato sia il cambio di sede legale del promotore che l'inclusione di un nuovo braccio OLTP con annesso il relativo budget;
- Rilevato che il presente provvedimento viene proposto dal Dirigente Responsabile della Struttura proponente, che lo sottoscrive;
- Considerato che la formulazione della proposta di un atto deliberativo impegna la responsabilità del soggetto proponente circa la regolarità amministrativa e la legittimità del contenuto della stessa;
- Acquisiti i pareri espressi dal Direttore Amministrativo e dal Direttore Sanitario, ai sensi dell'art. 3, comma 1-quinquies del D.Lgs 30.12.1992 e s.m.i;
- Per quanto sopra considerato e ritenuto;

DELIBERA

1. di approvare, in allegato al presente atto quale parte integrante e sostanziale l'emendamento n. 4 al contratto relativo alla sperimentazione clinica dal titolo: "Protocollo C3441021 - Studio controllato con placebo di fase 3, randomizzato, in doppio cieco, talazoparib con enzalutamide nel tumore prostatico metastatico, resistente alla castrazione," effettuato presso la SCDU Oncologia Medica, Sperimentatore Responsabile Prof.ssa Consuelo Buttiglieri, pratica Comitato Etico n. 18/2019/U, autorizzato con deliberazione n. 595 del 13/11/2019 e modificato con deliberazioni n. 668 del 28/12/2020, n. 463 del 27/09/2024 e n. 284 del 10/06/2025;
2. di trasmettere copia del presente provvedimento al Direttore della SCDU Oncologia Medica Prof.ssa Silvia Novello, allo sperimentatore responsabile Prof.ssa Consuelo Buttiglieri e alle SS.CC. Gestione Economico Finanziaria e Direzione Medica di Presidio per quanto di rispettiva competenza;
3. di dare atto che le informazioni relative al presente provvedimento, così come disciplinate dalla normativa vigente, verranno pubblicate sul sito internet aziendale, nell'ambito dei dati della sezione "Amministrazione Trasparente" e sulla base dell'accordo intervenuto col promotore al fine di rispettare le "informazioni riservate" dello studio clinico in oggetto;
4. di confermare la nomina dello sperimentatore responsabile quale soggetto designato al trattamento dei dati personali per lo studio clinico in oggetto;
5. di trasmettere il presente provvedimento al Collegio Sindacale per quanto di competenza;
6. di pubblicare il presente atto, per quindici giorni consecutivi, sul sito informatico dell'Azienda Ospedaliero Universitaria San Luigi Gonzaga;

7. di dichiarare il presente provvedimento immediatamente eseguibile al fine di permettere la sottoscrizione dell' emendamento n. 4 nel più breve tempo possibile.

IL DIRETTORE GENERALE
Dr. DAVIDE MINNITI

(Sottoscritto digitalmente ai sensi
dell'art. 21 D.Lgs n. 82/2005 e s.m.i.)

Allegati:

- 1) Emendamento n. 4 (TALAPRO 2 -C3441021)

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;

Amendment n. 4 Ariba AWS: CW2434575 Institution: AOU San Luigi Gonzaga Site Number 1066 Protocol Number: C3441021 PI: Dr- Consuelo Buttiglierio Page 1 of 20	Emendamento n.4 N. Ariba WS: CW2434575 Istituto: AOU San Luigi Gonzaga Numero del Centro: 1066 Numero di Protocollo: C3441021 PI: Dott.ssa Consuelo Buttiglierio Pagina 1 di 20
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AND	E
Università di Torino, Dipartimento di Oncologia, Tax ID Code No. 80088230018, VAT no. 02099550010, with headquarters in Turin Via Verdi 8 and administrative 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 Rettoriale 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 Rettoriale 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").
Amendment n. 4 Ariba AWS: CW2434575 Institution: AOU San Luigi Gonzaga Site Number 1066 Protocol Number: C3441021 PI: Dr- Consuelo Buttigliero Page 2 of 20	Emendamento n.4 N. Ariba WS: CW2434575 Istituto: AOU San Luigi Gonzaga Numero del Centro: 1066 Numero di Protocollo: C3441021 PI: Dott.ssa Consuelo Buttigliero Pagina 2 di 20

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 ”)
<u>WHEREAS</u>	<u>PREMESSO CHE</u>
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 ”).
Amendment n. 4 Ariba AWS: CW2434575 Institution: AOU San Luigi Gonzaga Site Number 1066 Protocol Number: C3441021 PI: Dr- Consuelo Buttiglierio Page 3 of 20	Emendamento n.4 N. Ariba WS: CW2434575 Istituto: AOU San Luigi Gonzaga Numero del Centro: 1066 Numero di Protocollo: C3441021 PI: Dott.ssa Consuelo Buttiglierio Pagina 3 di 20

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

Amendment n. 4 Ariba AWS: CW2434575 Institution: AOU San Luigi Gonzaga Site Number 1066 Protocol Number: C3441021 PI: Dr- Consuelo Buttiglierio Page 4 of 20	Emendamento n.4 N. Ariba WS: CW2434575 Istituto: AOU San Luigi Gonzaga Numero del Centro: 1066 Numero di Protocollo: C3441021 PI: Dott.ssa Consuelo Buttiglierio Pagina 4 di 20
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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:
<i>Signature page following</i>	<i>Segue Pagina delle firme</i>

Amendment n. 4 Ariba AWS: CW2434575 Institution: AOU San Luigi Gonzaga Site Number 1066 Protocol Number: C3441021 PI: Dr- Consuelo Buttiglierio Page 5 of 20	Emendamento n.4 N. Ariba WS: CW2434575 Istituto: AOU San Luigi Gonzaga Numero del Centro: 1066 Numero di Protocollo: C3441021 PI: Dott.ssa Consuelo Buttiglierio Pagina 5 di 20
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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 _____

Amendment n. 4 Ariba AWS: CW2434575 Institution: AOU San Luigi Gonzaga Site Number 1066 Protocol Number: C3441021 PI: Dr- Consuelo Buttiglierio Page 6 of 20	Emendamento n.4 N. Ariba WS: CW2434575 Istituto: AOU San Luigi Gonzaga Numero del Centro: 1066 Numero di Protocollo: C3441021 PI: Dott.ssa Consuelo Buttiglierio Pagina 6 di 20
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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 :	TALAZOPARI B	AMENDMEN T :	PA09	INVESTIGATO R:	Consuelo Buttigliero
STUDY NUMBER :	C3441021	ARM/COHOR T :	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/Curren cy :	Italy - EUR				
OVERHEAD	11.00%				

Amendment n. 4 Ariba AWS: CW2434575 Institution: AOU San Luigi Gonzaga Site Number 1066 Protocol Number: C3441021 PI: Dr- Consuelo Buttiglierio Page 7 of 20	Emendamento n.4 N. Ariba WS: CW2434575 Istituto: AOU San Luigi Gonzaga Numero del Centro: 1066 Numero di Protocollo: C3441021 PI: Dott.ssa Consuelo Buttiglierio Pagina 7 di 20
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DESCRIPTION OF COST	Comments	COST (EUR)	Frequency of Procedure	Total PSC (EUR)	Total Visit Structure Total	VISIT 1		VISIT 2		VISIT 3		VISIT 4		VISIT 5		VISIT 6	
			Total Number of times a procedure occurs based on PSC Structure			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		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	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	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	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	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	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 €

Amendment n. 4 Ariba AWS: CW2434575 Institution: AOU San Luigi Gonzaga Site Number 1066 Protocol Number: C3441021 PI: Dr- Consuelo Buttigliero Page 8 of 20	Emendamento n.4 N. Ariba WS: CW2434575 Istituto: AOU San Luigi Gonzaga Numero del Centro: 1066 Numero di Protocollo: C3441021 PI: Dott.ssa Consuelo Buttigliero Pagina 8 di 20
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DESCRIPTION OF COST	Comments	COST (EUR)	Frequency of Procedure	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	
			Total Number of times a procedure occurs based on PSC Structure			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
	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
	Magnesium	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
	Phosphate	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
	LDH	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	
Testosterone	amount to be shared at 50% between Hospital and University)																																		
Central lab	Blood samples for CTC analysis, blood samples for ctDNA, blood sample for protein 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
	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
Additional Central lab	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
Symptom directed physical examination	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	1.00	20.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Blood sample for PK	amount to be shared at 50% between Hospital and University)																																		
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
	PSC Subtotal w/out Overhead																																		
Amount to be shared at 50% between Hospital and University)				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)				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 €

Amendment n. 4 Ariba AWS: CW2434575 Institution: AOU San Luigi Gonzaga Site Number 1066 Protocol Number: C3441021 PI: Dr- Consuelo Buttigliero Page 9 of 20	Emendamento n.4 N. Ariba WS: CW2434575 Istituto: AOU San Luigi Gonzaga Numero del Centro: 1066 Numero di Protocollo: C3441021 PI: Dott.ssa Consuelo Buttigliero Pagina 9 di 20
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DESCRIPTION OF COST	Comments	COST (EUR)	Frequency of Procedure	Total PSC (EUR)	Total Visit Structure Total	VISIT 22		VISIT 23		VISIT 24		VISIT 25		VISIT 26		VISIT 27		VISIT 28		VISIT 29		VISIT 30		VISIT 31	
			Total Number of times a procedure occurs based on PSC Structure			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
PRIO	EC-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)	48.00	1.0	48.00	48.00		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 protein 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
	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 €
	PSC Subtotal with Overhead			10,293.03 €			354.09 €		130.98 €		354.09 €		354.09 €		354.09 €		130.98 €		354.09 €		354.09 €		389.01 €		65.49 €

Amendment n. 4
Ariba AWS: CW2434575
Institution: AOU San Luigi Gonzaga
Site Number 1066
Protocol Number: C3441021
PI: Dr- Consuelo Buttiglieri

Emendamento n.4
N. Ariba WS: CW2434575
Istituto: AOU San Luigi Gonzaga
Numero del Centro: 1066
Numero di Protocollo: C3441021
PI: Dott.ssa Consuelo Buttiglieri

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 available at the site lab 50% Hospital University	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 available at the site lab 50% Hospital University	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 available at the site lab 50% Hospital University	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 available at the site lab 50% Hospital 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	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 Biopsy	Applicable at either Prescreening or Screening 50%Hospital University	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 €	-	1.00	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 €

Amendment n. 4 Ariba AWS: CW2434575 Institution: AOU San Luigi Gonzaga Site Number 1066 Protocol Number: C3441021 PI: Dr- Consuelo Buttigliero Page 11 of 20	Emendamento n.4 N. Ariba WS: CW2434575 Istituto: AOU San Luigi Gonzaga Numero del Centro: 1066 Numero di Protocollo: C3441021 PI: Dott.ssa Consuelo Buttigliero Pagina 11 di 20
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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 available 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 available 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 available 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 available 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 €

Amendment n. 4 Ariba AWS: CW2434575 Institution: AOU San Luigi Gonzaga Site Number 1066 Protocol Number: C3441021 PI: Dr- Consuelo Buttigliero Page 12 of 20	Emendamento n.4 N. Ariba WS: CW2434575 Istituto: AOU San Luigi Gonzaga Numero del Centro: 1066 Numero di Protocollo: C3441021 PI: Dott.ssa Consuelo Buttigliero Pagina 12 di 20
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CONFIDENTIAL / RISERVATO

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 available 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 available 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 available 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 available 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 Biopsy	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 €		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 €		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 €		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 €		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 €		130.98 €		520.59 €		520.59 €		520.59 €		556.11 €		150.96 €	591.63 €

Amendment n. 4 Ariba AWS: CW2434575 Institution: AOU San Luigi Gonzaga Site Number 1066 Protocol Number: C3441021 PI: Dr- Consuelo Buttiglierio Page 13 of 20	Emendamento n.4 N. Ariba WS: CW2434575 Istituto: AOU San Luigi Gonzaga Numero del Centro: 1066 Numero di Protocollo: C3441021 PI: Dott.ssa Consuelo Buttiglierio Pagina 13 di 20
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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

Amendment n. 4 Ariba AWS: CW2434575 Institution: AOU San Luigi Gonzaga Site Number 1066 Protocol Number: C3441021 PI: Dr- Consuelo Buttiglierio Page 14 of 20	Emendamento n.4 N. Ariba WS: CW2434575 Istituto: AOU San Luigi Gonzaga Numero del Centro: 1066 Numero di Protocollo: C3441021 PI: Dott.ssa Consuelo Buttiglierio Pagina 14 di 20
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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

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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 Buttiglierro
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%				

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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		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	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	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	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	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	1.00	11.00		0.00
	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																																		
Study Coordinator fee (Hourly)		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		58.00	
	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	

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				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				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

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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	Please see main budget for site fees	
Local IRB/EC Fees - Initial Review		
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

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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 based on EDC completion (amount to be shared at 50% between Hospital and University)	235.32

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Struttura Affari Generali
Relazione di Pubblicazione

Delibera N. 391 del 07/07/2026

Oggetto: APPROVAZIONE EMENDAMENTO N. 4 AL CONTRATTO PER LA SPERIMENTAZIONE CLINICA FARMACOLOGICA DAL TITOLO "TALAPRO 2 (C3441021)", AUTORIZZATO CON DELIBERAZIONE N. 595 DEL 13/11/2019 - SPERIMENTATORE RESPONSABILE: PROF.SSA CONSUELO BUTTIGLIERO, PRATICA COMITATO ETICO N. 18/2019/U..

La su estesa deliberazione viene oggi pubblicata all'Albo Pretorio per quindici giorni consecutivi sul sito informatico dell'AOU San Luigi Gonzaga.

08/07/2026

Sottoscritta dal funzionario incaricato
(BERTOLO FULVIA)