



AZIENDA OSPEDALIERA UNIVERSITARIA

DELIBERAZIONE DELLA DIRETTRICE GENERALE

OGGETTO: Presa d'atto dell'Emendamento 3 alla convenzione tra l'Azienda Ospedaliera Universitaria Policlinico e per essa l'UOC di Gastroenterologia e la Società ICON Holdings Clinacal Research International Limited per effettuare la Sperimentazione clinica su medicinali Prot. 337HNAS20011 Sperimentatore Prof. Salvatore Petta.

L'Estensore: GAETANA SALETTA

Direzione Generale

Proposta N. 683 Del 12/03/2025 Responsabile

Ufficio Atti Deliberativi

Allegati: Emendamento 1 contratto di sperimentazione

GRAZIA SCALICI

Firmato da Grazia Scalici
Data 17-03-2025

Responsabile Unico del Procedimento

Numero imputazione spesa Imputazioni di spesa

Data imputazione spesa

Si autorizza l'imputazione della spesa sul conto e l'esercizio indicati entro il limite del budget annuale assegnato al centro di costo richiedente.

Nulla osta, in quanto conforme alle norme di contabilità.

Il Direttore Area Economica Finanziaria

Parere Favorevole

Il Direttore
Amministrativo

La Direttrice
Generale

Dott.ssa Maria Grazia Furnari

Firmato da Sergio Consagra
Data 17-03-2025

Firmato da Maria Grazia Furnari
Data 21-03-2025

Parere Favorevole

Il Direttore
Sanitario

Firmato da Alberto Firenze
Data 21-03-2025

La Direttrice Generale dell'A.OUP "Paolo Giaccone" di Palermo, Dott.ssa Maria Grazia Furnari, nominata con D.P. n.324 serv.1°/S.G. del 21 giugno 2024 e assistita dal segretario verbalizzante adotta la seguente delibera sulla base della proposta di seguito riportata.

Il Segretario verbalizzante

Firmato da Grazia Scalici
Data 21-03-2025



AZIENDA OSPEDALIERA UNIVERSITARIA

LA DIRETTRICE GENERALE

Dott.ssa Maria Grazia Furnari

- PRESO ATTO** che presso l'AIFA è stato istituito il Centro di Coordinamento nazionale dei Comitati Etici Territoriali e ricostituito con il Decreto del Ministro della Salute del 27/05/2021, garante dell'omogeneità delle procedure e del rispetto dei termini temporali;
- PRESO ATTO** dell'entrata in vigore in data 31/01/2022 del nuovo Regolamento (EU) n. 536/2014 del Parlamento Europeo sulla sperimentazione clinica di medicinali per uso umano;
- VISTI** il Decreto 26 gennaio 2023 recante: "individuazione di quaranta comitati etici territoriali (di seguito indicato con DM 40 CET);
- il Decreto del 27 gennaio 2023, del Ministero della Salute recante misure relative all'individuazione e competenze dei Comitati Etici Territoriali;
- il Decreto 30.01.2023 recante: "definizione dei criteri per la composizione e il funzionamento dei comitati etici territoriali";
- PRESO ATTO** che, con delibera n. 916 del 30/06/2023 e ss.mm.ii., è stato istituito il CET (Comitato Etico Territoriale) e la Segreteria Tecnico Scientifica, in applicazione al Decreto Regionale n. 541/2023;
- che con delibera n. 1072 del 03.08.2023 è stato recepito il D.A. dell'Assessorato Salute RS n. 746 del 25.07.2023, successivamente integrato dalla nota n. 57116 "corretta applicazione art. 2 commi 5e 6";
- VISTA** la delibera n. 47 del 26/01/2023 di sottoscrizione della Convenzione economica tra l'AOUP e per essa l'UOC di Gastroenterologia e la Società Pharmaceutical Research Associates Italy S.r.l. per effettuare la Sperimentazione Clinica dal titolo: "Studio multicentrico di fase 3, randomizzato, in doppio cieco, controllato con placebo, volto a valutare l'efficacia e la sicurezza a lungo termine di lanifibranor in pazienti adulti con steatoepatite non alcolica e non cirrotic (NASH) e fibrosi epatica di



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stadio 2 (F2) di stadio 3 (F3).” Codice Prot. 337HNAS20011 Codice Eudract
2020-004986-38 - Sperimentatore: Prof. Salvatore Petta;

VISTE

La delibera n. 1157 del 31/08/2023 di Emendamento 1 alla Convenzione che modifica e integra l’Allegato A, l’Aggiornamento del titolo del Protocollo e il trasferimento da PRA a ICON ;

La delibera n. 934 del 05/09/2024 di Emendamento 2 che modifica e integra l’Allegato A – Budget per l’aggiunta di alcuni esami locali per monitorare la safety del paziente;

DATO ATTO

che in data 17/12/2024 il Promotore ha ricevuto il Provvedimento AIFA che autorizza l’Emendamento V. 7.0 che modifica e integra: l’Allegato A – Budget, rimodulato alla nuova versione approvata del Protocollo;

VISTO

L’Emendamento 3 sottoscritto, allegato , alla Convenzione, sottoscritta tra l’AOUP e la Società ICON Holdings Clinical Research International Limited per effettuare la Sperimentazione Clinica Protocollo: 337HNAS20011;

Per i motivi in premessa citati che qui si intendono ripetuti e trascritti

DELIBERA

Di prendere atto dell’ Emendamento 3 sottoscritto, allegato 1, come parte sostanziale e integrante alla convenzione tra l’Azienda Ospedaliera Universitaria Policlinico e per essa l’UOC di Gastroenterologia e la Società ICON Holdings Clinical Research International Limited, per effettuare la Sperimentazione Clinica dal titolo: “Uno studio di fase 3 randomizzato, in doppio cieco, controllato con placebo, multicentrico, che valuta l’efficacia e la sicurezza di lanifibranor seguito da un’estensione del trattamento attivo in pazienti adulti con steatoepatite non alcolica non cirrotica (NASH) e stadio fibrosi 2 (F2) fibrosi 3 (F3) della fibrosi epatica” Codice Prot. 337HNAS20011 Codice Eudract 2023-508248-23-00 Sperimentatore: Prof. Salvatore Petta;



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di prendere atto che i proventi derivanti dallo Sponsor per la conduzione dello Studio, verranno ripartiti in conformità all'art. 4 - Aspetti economici- finanziari – del Regolamento Aziendale disciplinante gli aspetti procedurali, amministrativi ed economici degli studi Osservazionali, delle Sperimentazioni cliniche, dei Dispositivi Medici e delle Iniziative di Ricerca afferenti all'A.O.U.P approvato con Delibera n . 1152 dell' 08/11/2024



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Institution/Clinical Trial Agreement Amendment
Azienda Ospedaliera Universitaria Policlinico "Paolo
Giaccone" PI Salvatore Petta
Protocol - 337HNAS20011

<i>Stamp duty is paid electronically by ICON HOLDINGS CLINICAL RESEARCH INTERNATIONAL LIMITED, with registered office in Via Benigno Crespi 19, 20159 Milan, Italy, Italian affiliate of the CRO, pursuant to art. 15 of the Presidential Decree (D.P.R.) 642 of 1972 (Authorization of the Revenue Agency of Milan registered on 14-June-2023 on the OFFICIAL REGISTER with number 203622).</i>	<i>Imposta di bollo assolta in modo virtuale da ICON HOLDINGS CLINICAL RESEARCH INTERNATIONAL LIMITED, con sede legale in Via Benigno Crespi 19, 20159 Milano, Italia, affiliata italiana della CRO, ex art. 15 del D.P.R. 642 del 1972 (Autorizzazione Agenzia delle Entrate di Milano protocollata in data 14-giugno-2023 sul REGISTRO UFFICIALE con il numero 203622).</i>
<u>CONTRACT AMENDMENT #3</u>	<u>EMENDAMENTO N. 3 AL CONTRATTO</u>
This CONTRACT AMENDMENT #3 ("Contract Amendment #3"), dated as of the date of the Last Signature below (the " Contract Amendment #3 Effective Date "), is by and between	Il presente EMENDAMENTO N. 3 AL CONTRATTO ("Emendamento n. 3 al Contratto") datato alla data dell'ultima firma sotto riportata (la " Data di Efficacia dell'Emendamento n. 3 al Contratto "), è stipulato da e tra
ICON Holdings Clinical Research International Limited – Italian Branch (Sede Secondaria), with a place of business at Via Benigno Crespi, Maciachini Business Park, no. 19, 20159 Milano, Italy, tax code and VAT no. 12827880969, through its Proxy Dr. Francesco Falcicchio as Senior Manager, (hereinafter the " CRO "), acting in its own name and in the interests of Inventiva S.A. , located at 50 rue de Dijon, 21121 Daix, France (hereinafter the "Sponsor"), by virtue of the authority of attorney granted on 19 July 2023	ICON Holdings Clinical Research International Limited – Filiale Italiana (Sede Secondaria), con sede operativa in Via Benigno Crespi, Maciachini Business Park, n. 19, 20159 Milano, Italia, C.F. e Partita IVA 12827880969, in persona del Procuratore, Dott. Francesco Falcicchio in qualità di Senior Manager, (d'ora innanzi denominato " CRO "), che agisce in nome proprio e nell'interesse di Inventiva S.A. , avente sede legale al 50 rue de Dijon, 21121 Daix, France (d'ora innanzi denominata "Promotore"), in forza di idonea delega conferita in data 19 luglio 2023
and	e



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AZIENDA UNIVERSITARIA "PAOLO GIACCONE" DI PALERMO ["Paolo Giaccone" University Hospital Polyclinic of Palermo] (hereinafter referred to as "Institution"), with registered office in PALERMO, Via del Vespro 129 Tax Code and VAT No. 05841790826, represented by its Legal Representative, Dr. Maria Grazia Furnari, who possesses the appropriate powers to sign this document	OSPEDALIERA POLICLINICO DI PALERMO (d'ora innanzi denominata "Ente"), con sede legale in PALERMO Via del Vespro 129, Codice Fiscale e Partita IVA 05841790826, nella persona della Legale Rappresentante, Dott.ssa Maria Grazia Furnari, munita di idonei poteri di firma del presente atto
hereinafter individually/collectively "the Party/the Parties"	di seguito, individualmente/collettivamente, "la Parte/le Parti".
<u>WITNESSETH:</u>	<u>SI ATTESTA:</u>
WHEREAS under the terms of a certain Clinical Trial Agreement, dated January 26 th 2023, as amended on 30 August 2023 and 5 th September 2024 (collectively, the "Agreement") between and among the parties, CRO retained the Institution, under the responsibility of Prof. Salvatore Petta (the "Principal Investigator") to perform the research study entitled " <i>A randomized, double-blind, placebo-controlled, multicentre, Phase 3 study evaluating efficacy and safety of lanifibranor followed by an active treatment extension in adult patients with non-cirrhotic non-alcoholic steatohepatitis (NASH) and fibrosis</i> "	PREMESSO CHE, in base ai termini di un certo Contratto di Sperimentazione Clinica, datato 26 gennaio 2023, emendato il 30 agosto 2023 e il 5 settembre 2024 (collettivamente, il "Contratto") tra le Parti, la CRO ha incaricato l'Ente, sotto la responsabilità del Prof. Salvatore Petta (lo "Sperimentatore Principale") di eseguire lo studio di ricerca intitolato " <i>Uno studio di fase 3 randomizzato, in doppio cieco, controllato con placebo, multicentrico, che valuta l'efficacia e la sicurezza di lanifibranor seguito da un'estensione del trattamento attivo in pazienti adulti con steatoepatite non alcolica non</i> "



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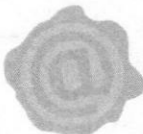
Institution/Clinical Trial Agreement Amendment
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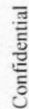
2 (F2)/fibrosis 3 (F3) stage of liver fibrosis" (the "Study"), bearing protocol number 337HNAS20011 as amended (the "Protocol") sponsored by the Inventiva S.A. (the "Sponsor"), as more particularly described in the Agreement;	<i>cirrotica (NASH) e stadio fibrosi 2 (F2)/fibrosi 3 (F3) della fibrosi epatica" (la "Sperimentazione"), recante il numero di protocollo 337HNAS20011 e successive modifiche, (il "Protocollo"), sponsorizzato da Inventiva S.A. (il "Promotore"), come descritto più dettagliatamente nel Contratto;</i>
WHEREAS, the CRO has been engaged by Sponsor to arrange, monitor, oversee and perform, or have performed, the Study pursuant to the Protocol by the Institution, and	PREMESSO CHE la CRO è stata incaricata dal Promotore di organizzare, monitorare, supervisionare ed eseguire, o far eseguire dall'Ente lo Studio ai sensi del Protocollo, e
WHEREAS, the parties hereto have entered into certain additional agreements with respect to modification of the Agreement, and which they desire to memorialize in this Contract Amendment #3;	PREMESSO CHE le Parti hanno stipulato alcuni accordi aggiuntivi relativi alla modifica del Contratto, che desiderano definire nel presente Emendamento n. 3 al Contratto;
NOW, THEREFORE, in consideration of the premises and of the following mutual promises, covenants and conditions hereinafter set forth, the parties hereto agree as follows:	ORA, PERTANTO, in considerazione delle premesse e delle seguenti promesse, patti e condizioni reciproche di seguito esposte, le Parti convengono quanto segue:
1. Update to Budget. To account for changes to the services and costs under the Contract Amendment #3 due to Protocol Amendment V. 7.0 dated 27 June 2024, the parties agree that the Budget attached to the Agreement as Annex A – Budget is hereby deleted and replaced in its entirety by the revised Budget attached hereto as Annex A –Budget.	1. Aggiornamento del budget. Per tener conto delle modifiche apportate ai servizi e ai costi previsti dall'Emendamento n. 3 al Contratto a seguito dell'Emendamento al Protocollo V. 7.0 datato 27 giugno 2024, le Parti convengono che il Budget allegato al Contratto come Allegato A – Budget, viene eliminato e sostituito nella sua interezza dal Budget rivisto allegato al presente documento come Allegato A – Budget.
2. Ratification of Balance of Agreement. In all other respects, the terms of the Agreement are hereby ratified and affirmed by each of the parties hereto.	2. Ratifica del saldo del contratto. Per tutti gli altri aspetti, i termini del Contratto sono ratificati e affermati da ciascuna delle parti.



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3. Headings. The headings in this Contract Amendment #3 are for convenience of reference only and shall not affect its interpretation.	3. Titoli. I titoli del presente Emendamento n. 3 al Contratto sono solo per comodità di riferimento e non influiscono sulla sua interpretazione.
4. Counterparts. This Contract Amendment #3 will be signed digitally pursuant to current regulations. The taxes and fees inherent in and consequent to the conclusion of this contract, including the stamp tax on the computer original referred to in Article 2 of the table in Annex A - Tariff Part I of Presidential Decree No. 642/1972 and the registration tax shall be paid, in accordance with applicable regulations.	4. Controparti. Il presente Emendamento n. 3 al Contratto sarà firmato digitalmente ai sensi della normativa vigente. Le imposte e tasse inerenti e conseguenti alla stipula del presente Contratto, ivi comprese l'imposta di bollo sull'originale informatico di cui all'art. 2 della tabella nell'Allegato A – Tariffa Parte I del DPR n. 642/1972 e l'imposta di registro devono essere versate nel rispetto della normativa applicabile.
IN WITNESS WHEREOF, the parties hereto, each by a duly authorized representative, have executed this Contract Amendment #3 as of the last signature date below.	IN FEDE DI CIO', le Parti, ciascuna per mezzo di un rappresentante debitamente autorizzato, hanno sottoscritto il presente Emendamento n. 3 al Contratto alla data dell'ultima firma sotto riportata.
For the CRO / Per la CRO The Proxy / Il Procuratore Dr / Dott. Francesco Falcicchio  Digitally signed by FALCICCHIO FRANCESCO C=IT Signature / Firma _____, ____/____/____	
For the Institution / Per l'Ente The Legal Representative / Il Legale Rappresentante Dr / Dott.ssa Maria Grazia Furnari  Maria Grazia Furnari 04.03.2025 10:38:39 GMT+02:00 Signature / Firma _____	



Institution/Clinical Trial Agreement Amendment
Azienda Ospedaliera Universitaria Policlinico "Paolo Giaccone" PI Salvatore Peta
Protocol - 337HNAS20011

Allegato A - Budget

Project Name: *Immunoprecipitation of HIV-1 RNA*
Project ID: *IP2023-045*
Principal Investigator: *Dr. A. B. Smith*
Co-Investigator: *Dr. C. D. Jones*
Version: *1.0*
Date: *15 June 2024*

PI Number: Pelta, Salvatore
 Site Name: AZIENDA OSPEDALIERA UNIVERSITARIA
 POLICLINICO "PAOLO GIACONE"
 PALERMO
 Overhead Percent: 0.00%
 Total Cost per Patient: Main 13,653.70

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Non-Procedure Name	Selected Cost	Screening	Baseline	W4	Liver Monitoring Tests (Wk 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76, 80, 84, 88, 92, 96, 100, 104, 108, 112, 116, 120, 124, 128, 132, 136, 140, 144, 148, 152, 156, 160, 164, 168, 172, 176, 180, 184, 188, 192, 196, 200, 204, 208, 212, 216, 220, 224, 228, 232, 236, 240, 244, 248, 252, 256, 260, 264, 268, 272, 276, 280, 284, 288, 292, 296, 300, 304, 308, 312, 316, 320, 324, 328, 332, 336, 340, 344, 348, 352, 356, 360, 364, 368, 372, 376, 380, 384, 388, 392, 396, 400, 404, 408, 412, 416, 420, 424, 428, 432, 436, 440, 444, 448, 452, 456, 460, 464, 468, 472, 476, 480, 484, 488, 492, 496, 500, 504, 508, 512, 516, 520, 524, 528, 532, 536, 540, 544, 548, 552, 556, 560, 564, 568, 572, 576, 580, 584, 588, 592, 596, 600, 604, 608, 612, 616, 620, 624, 628, 632, 636, 640, 644, 648, 652, 656, 660, 664, 668, 672, 676, 680, 684, 688, 692, 696, 700, 704, 708, 712, 716, 720, 724, 728, 732, 736, 740, 744, 748, 752, 756, 760, 764, 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3464, 3468, 3472, 3476, 3480, 3484, 3488, 3492, 3496, 3500, 3504, 3508, 3512, 3516, 3520, 3524, 3528, 3532, 3536, 3540, 3544, 3548, 3552, 3556, 3560, 3564, 3568, 3572, 3576, 3580, 3584, 3588, 3592, 3596, 3600, 3604, 3608, 3612, 3616, 3620, 3624, 3628, 3632, 3636, 3640, 3644, 3648, 3652, 3656, 3660, 3664, 3668, 3672, 3676, 3680, 3684, 3688, 3692, 3696, 3700, 3704, 3708, 3712, 3716, 3720, 3724, 3728, 3732, 3736, 3740, 3744, 3748, 3752, 3756, 3760, 3764, 3768, 3772, 3776, 3780, 3784, 3788, 3792, 3796, 3800, 3804, 3808, 3812, 3816, 3820, 3824, 3828, 3832, 3836, 3840, 3844, 3848, 3852, 3856, 3860, 3864, 3868, 3872, 3876, 3880, 3884, 3888, 3892, 3896, 3900, 3904, 3908, 3912, 3916, 3920, 3924, 3928, 3932, 3936, 3940, 3944, 3948, 3952, 3956, 3960, 3964, 3968, 3972, 3976, 3980, 3984, 3988, 3992, 3996, 4000, 4004, 4008, 4012, 4016, 4020, 4024, 4028, 4032, 4036, 4040, 4044, 4048, 4052, 4056, 4060, 4064, 4068, 4072, 4076, 4080, 4084, 4088, 4092, 4096, 4100, 4104, 4108, 4112, 4116, 4120, 4124, 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Institution/Clinical Trial Agreement Amendment
Azienda Ospedaliera Universitaria Policlinico "Paolo
Giaccone" PI Salvatore Petta
Protocol - 337HNAS20011

Invoiceable Name	Selected Cost	Overhead at 0%	Total Cost	Considerations
Local: COVID-19 test (infectious agent detection by DNA/RNA)	31.00	0.00	31.00	Upon receipt of detailed invoice; test may be performed at any time per Investigator's discretion
Informed Consent: Dexa scan sub-study	28.00	0.00	28.00	Upon receipt of detailed invoice for patients participating in the Dexa scan sub-study
Dexa Scan for optional sub-study	242.00	0.00	242.00	Upon receipt of detailed invoice, only for participants who consent to the Dexa scan sub-study, at Baseline and Weeks 4, 72 and 120
Informed Consent: Genetic testing	55.00	0.00	55.00	Upon receipt of detailed invoice as applicable
Informed Consent for female partners of male patients	28.00	0.00	28.00	Upon receipt of detailed invoice as applicable
ECG (singular or triplicate)	75.00	0.00	75.00	Upon receipt of detailed invoice if repeat assessment is required per protocol. Triplicate ECGs at arrival (fasting), breakfast in the investigational site with study treatment intake, triplicate ECGs 3 to 5 hours after breakfast.
Blood draw for Central Lab**	30.00	0.00	30.00	Upon receipt of detailed invoice if repeat assessment is required at the investigators discretion if medically necessary and in consultation with the Medical Monitor
Central: Venipuncture for PK, Biomarkers and/or Gene sampling	30.00	0.00	30.00	
Central: Urinalysis, includes Urinary ethyl glucuronide, Urine Pregnancy	6.00	0.00	6.00	
Sample Handling and Shipping to Central lab	30.00	0.00	30.00	Upon receipt of invoice if repeat serum and/or urine samples for central lab is required
Central: Venipuncture for PK, Optional	30.00	0.00	30.00	Upon receipt of detailed invoice, for patients who have consented to the optional PK sub-study, at Week 4, 12, 24, 36 OR 48, per the timepoint indicated in the visit grid for the applicable visit
Local: Chemistry Panel, includes ALT, AST, GGT, ALP, total and direct Bilirubin, Sodium Chloride, Potassium, Bicarbonate, Creatinine, Albumin	20.00	0.00	20.00	Upon receipt of detailed invoice at Investigator's discretion and/or in cases where initiation of IMP or safety follow-up is time-sensitive and the central laboratory results will not be available in time
Local: Liver Function Panel, includes ALT, AST GGT, ALP, total and direct Bilirubin	31.00	0.00	31.00	
Local: Renal Function Panel, includes Albumin, Chloride, Creatinine, Glucose, Potassium, Sodium chloride, Urea	36.00	0.00	36.00	
Local: Lipid Profile, includes Triglycerides, total cholesterol, HDL cholesterol, LDL cholesterol	40.00	0.00	40.00	
Local: Other lipid metabolism tests, includes Apo A1, Apo B, total Apo C3, Apo C3 in LDL, Apo C3 in VLDL, Apo C3 in HDL	135.00	0.00	135.00	
Local: Fructosamine	65.00	0.00	65.00	
Local: Adiponectin	68.00	0.00	68.00	
Local: Leptin	77.00	0.00	77.00	
Local: Albumin	7.00	0.00	7.00	
Local: ALP	4.00	0.00	4.00	
Local: ALT	4.00	0.00	4.00	
Local: AST	4.00	0.00	4.00	
Local: Bicarbonate	17.00	0.00	17.00	
Local: Bilirubin, Direct	17.00	0.00	17.00	
Local: Bilirubin, Total	5.00	0.00	5.00	
Local: Chloride	4.00	0.00	4.00	
Local: Cholesterol, High Density	17.00	0.00	17.00	
Local: Density Cholesterol, High	30.00	0.00	30.00	
Local: Cholesterol, Total	15.00	0.00	15.00	
Local: Coagulation, APTT	13.00	0.00	13.00	
Local: Coagulation, INR	7.00	0.00	7.00	
Local: Complete blood count	20.00	0.00	20.00	
Local: CPK	27.00	0.00	27.00	
Local: Creatinine	4.00	0.00	4.00	
Local: eGFR	10.00	0.00	10.00	
Local: FPG (glycemic metabolism)	4.00	0.00	4.00	
Local: GST	4.00	0.00	4.00	
Local: HbA1c (glycemic metabolism)	18.00	0.00	18.00	
Local: HBV (HBsAg)	24.00	0.00	24.00	
Local: HCV (HCV antibodies)	44.00	0.00	44.00	
Local: HCV RNA	545.00	0.00	545.00	
Local: HIV-1 and HIV-2, single assay	21.00	0.00	21.00	
Local: HOMA-IR (other glycemic metabolism)	23.00	0.00	23.00	
Local: Insulin (other glycemic metabolism)	23.00	0.00	23.00	
Local: Potassium	1.00	0.00	1.00	
Local: Sodium chloride	10.00	0.00	10.00	
Local: Triglycerides	9.00	0.00	9.00	
Local: Urea	4.00	0.00	4.00	
Local: Cardiac test, NT-ProBNP	35.00	0.00	35.00	
Local: Pregnancy, Serum, WOCBP	13.00	0.00	13.00	
Local: Pregnancy, Urine, WOCBP	8.00	0.00	8.00	
Local: TSH	20.00	0.00	20.00	
Local: Free T4	15.00	0.00	15.00	
Local: Free T3	15.00	0.00	15.00	
Local: TPO	76.00	0.00	76.00	
Local: TRAb	105.00	0.00	105.00	
Local: ANA	62.00	0.00	62.00	
Local: AMA	94.00	0.00	94.00	
Local: ASMA	70.37	0.00	70.37	
Local: LKM1	94.00	0.00	94.00	
Local: LC1	76.00	0.00	76.00	



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Protocol - 337HNAS20011

Liver biopsy (fresh)	1,043.00	0.00	1,043.00	Upon receipt of detailed invoice if fresh biopsy is required at Screening and/or if a repeat biopsy is required due to increased liver stiffness compared to Baseline. Also, at EOT and/or EOS unless there is previous confirmation of progression to F4, any liver outcome event or an available biopsy within the past 6 months prior. If there is no historical biopsy available at screening, it is recommended to not perform a liver biopsy in patients with low liver stiffness (i.e. FibroScan value < 6kPa or other value if elastography performed with another tool) and AST/ULN < 0.65.
Biopsy Sample Handling/Shipping	304.00	0.00	304.00	Upon receipt of detailed invoice if Fresh Biopsy is required at Screening, EOT and/or EOS
Historical Biopsy Sample Handling/Shipping	304.00	0.00	304.00	Upon receipt of detailed invoice at Screening if historical biopsy is available (historical biopsy must have been performed within 6 months of Screening). Upon receipt of detailed invoice at additional necessary visits according to the Protocol.
Anesthesia	575.00	0.00	575.00	Upon receipt of detailed invoice if required for Fresh Biopsy
CT Guidance for Needle Placement	531.00	0.00	531.00	Upon receipt of detailed invoice if required for Fresh Biopsy
Day Bed fee	250.00	0.00	250.00	Upon receipt of invoice if required for fresh biopsy at Screening and/or EOT/EOS; And at the applicable visit requiring extensive PK draws for the PK sub-study
FibroScan (or equivalent elastography exam approved by Inventiva)	65.00	0.00	65.00	Upon receipt of detailed invoice if repeat scan is required due to progression of cirrhosis
Unscheduled / Additional Phone Visit	20.00	0.00	20.00	Upon receipt of detailed invoice
Follow-up Patient training on mobile app	37.00	0.00	37.00	Upon receipt of detailed invoice if follow-up app training is required after Baseline
Mobile Device Dispense	26.00	0.00	26.00	Upon receipt of detailed invoice at Baseline for patients requiring a device for the app
Mobile Device Collection	14.00	0.00	14.00	Upon receipt of detailed invoice as patient returns device
Pharmacy Dispense	20.00	0.00	20.00	Upon receipt of detailed invoice for study drug replacement if patient's supply is lost, damaged or destroyed
Patient Meals: breakfast, per person	8.44	n/a	8.44	Upon receipt of detailed invoice and supporting documentation, up to the amount indicated, only if breakfast is not provided by site
Patient Meals: Lunch and/or Dinner, per person	46.43	n/a	46.43	Upon receipt of detailed invoice and supporting documentation, up to the amount indicated
Patient Travel Reimbursement, includes mileage, parking, uber/taxi, tolls, etc.	19.00	n/a	19.00	
Hotel	131.00	n/a	131.00	Upon receipt of detailed invoice and supporting documentation, up to the amount indicated, if applicable, only for patients participating in the ECG sub-study and/or PK sub-study
Hospitalization, includes meals	461.00	0.00	461.00	Upon receipt of detailed invoice for patient required overnight hospital stay for the ECG sub-study
Breakfast reimbursement to site	At Cost			Upon receipt of detailed invoice with supporting documentation for bulk breakfast purchase to provide to patients participating in the ECG sub-study
Screen Failures (excluc. Biopsy)	504.75	0.00	504.75	Upon receipt of detailed invoice. Biopsy, if provided, will be invoiced based on archival or fresh, and in accordance to the cost provided in the invoiceable section.
Compensation for Time loss - biopsy	250.00			Upon receipt of detailed invoice. As needed.
Purchase of EtG Kits	At cost			EtG kits purchase to be reimbursed at real cost upon presentation of a valid invoice
Randomisation	20.00	0.00	20.00	Upon receipt of detailed invoice. As applicable per protocol.
Lunch & learn	At Cost			Upon receipt of detailed invoice. As necessary.
Pre-screening activities	1,500.00			Upon receipt of detailed invoice. As applicable, one-time fee only .



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Azienda Ospedaliera Universitaria Policlinico "Paolo
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Protocol - 337HNAS20011

Site Administrative Fee Name	Total Cost	Frequency	Considerations
Site Start-up	1,495.00	1	Upon receipt of detailed invoice
Archiving/Document storage	400.00	1	Upon receipt of detailed invoice
Pharmacy Start-up	500.00	1	Upon receipt of detailed invoice
Administrative Fees	4,035.00		Upon receipt of detailed invoice. *Enrollment 2 to 4 patients - 50% of the fee will be paid *Enrollment over 5 patients - 100% of the fee will be paid
Protocol Amendment Fee (per amendment)(assessed by site)	73.00	3	Upon receipt of detailed invoice with supporting documentation. (Starting from Pv4)

Screening Failure(s)	Upon receipt of detailed invoice at the flat rate detailed in the invoiceable section. Biopsy, if provided, will be invoiced based on archival or fresh, and in accordance to the cost provided in the invoiceable section.
Unscheduled Visit(s)	Upon receipt of detailed invoice for procedures performed according to the protocol

Maximum Number of Screening Failures	Screen Failure payments must not exceed 8 per each randomized patient. Such maximum number may be increased with the written approval of Sponsor; the written approved increase will not require an amendment to this Agreement.
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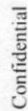
Institution/Clinical Trial Agreement Amendment

Azienda Ospedaliera Universitaria Policlinico "Paolo Giaccone" PI Salvatore Petta
Protocol - 337HINAS20011

Trial Name: Invention, 研究計畫之名稱
Project: MPP-278-A-02
Protocol Number: 33764AS/20011 (NACTW2)
Protocol Version: V 7.0, 27-June-2024
Phase: II
Title: A randomised, double-blind,
by an active treatment either
(12) Fibrosis 3 (F3) stage of
Arms ECG Study

Location:	Italy
Currency:	EUR - Euro
Total Cost Per Patient ECG Sub-	13,981.70
PI Name:	Petta, Salvatore
Site Name:	AZIENDA OSPEDALIERA
Overhead Percent:	0.00%

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Protocol - 337HNAS200011

*** Correlated alteration parameter (CAP) will be quantified by Harman's (only 4 variables).



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Azienda Ospedaliera Universitaria Policlinico "Paolo
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Protocol - 337HNAS20011

Trial Information

Trial Name: Inventiva_IVPF2F3F-F2F3LF
Project: IVPF2F3F-F2F3LF
Protocol Number: 337HNAS20011 (NATV3)
Protocol Version: V 7.0, 27-June-2024
Phase: III
Title: A randomised, double-blind, placebo-controlled, multicentre, Phase 3 study evaluating efficacy and safety of lanifibranor followed by an active treatment extension in adult patients with non-cirrhotic non-alcoholic steatohepatitis (NASH) and

Budget Information

Location: Italy
Currency: EUR - Euro
Total Cost per Patient Main: 13,651.70
Total Cost Per Patient ECG Sub-study: 13,981.70
PI Name: Petta, Salvatore
Site Name: AZIENDA OSPEDALIERA
Overhead Percent: 0.00%

Main study					
Visit Name	Visit Cost Subtotal	Overhead at 0%	Total Cost Per Visit	Visit Quantity	Cumulative Visit Cost
Screening	673.00	0.00	673.00	1.00	673.00
Baseline	675.00	0.00	675.00	1.00	675.00
W4	474.00	0.00	474.00	1.00	474.00
Liver Monitoring Tests (W8, 16, 20, 28, 32, 40, 44, 54, 60, 66, 78, 84, 90, 102, 108, 114)	145.25	0.00	145.25	16.00	2,324.00
W12	474.00	0.00	474.00	1.00	474.00
W24	676.00	0.00	676.00	1.00	676.00
W36	496.10	0.00	496.10	1.00	496.10
W48	698.10	0.00	698.10	1.00	698.10
Phone Visit, W60	176.25	0.00	176.25	1.00	176.25
W72	786.50	0.00	786.50	1.00	786.50
Phone visits (W84, W108)	176.25	0.00	176.25	2.00	352.50
W96	545.00	0.00	545.00	1.00	545.00
Site Visit (End of DBPC period - Maximum Week 120)	676.00	0.00	676.00	1.00	676.00
4 weeks after LV Part A	444.00	0.00	444.00	1.00	444.00
Liver Monitoring Tests (W8, 16, 20, 28, 32, 36, 40 and 44 After LV Part A)	145.25	0.00	145.25	8.00	1,162.00
12 weeks after LV Part A	444.00	0.00	444.00	1.00	444.00
24 weeks after LV Part A	601.00	0.00	601.00	1.00	601.00
Phone visit 36 weeks after LV Part A	161.25	0.00	161.25	1.00	161.25
48 weeks after LV Part A	656.00	0.00	656.00	1.00	656.00
pEoT	656.00	0.00	656.00	1.00	656.00
Follow-up (4 weeks after last dose of study drug)	501.00	0.00	501.00	1.00	501.00
Total Cost per Patient Main study:					13,651.70

ECG Sub-study					
Visit Name	Visit Cost Subtotal	Overhead at 0%	Total Cost Per Visit	Visit Quantity	Cumulative Visit Cost
Screening	673.00	0.00	673.00	1.00	673.00
Baseline	675.00	0.00	675.00	1.00	675.00
W4	639.00	0.00	639.00	1.00	639.00
Liver Monitoring Tests (W8, 16, 20, 28, 32, 40, 44, 54, 60, 66, 78, 84, 90, 102, 108, 114)	145.25	0.00	145.25	16.00	2,324.00
W12	639.00	0.00	639.00	1.00	639.00
W24	676.00	0.00	676.00	1.00	676.00
W36	496.10	0.00	496.10	1.00	496.10
W48	698.10	0.00	698.10	1.00	698.10
Phone Visit, W60	176.25	0.00	176.25	1.00	176.25
W72	786.50	0.00	786.50	1.00	786.50
Phone visits (W84, W108)	176.25	0.00	176.25	2.00	352.50
W96	545.00	0.00	545.00	1.00	545.00
Site Visit (End of DBPC period - Maximum Week 120)	676.00	0.00	676.00	1.00	676.00
4 weeks after LV Part A	444.00	0.00	444.00	1.00	444.00
Liver Monitoring Tests (W8, 16, 20, 28, 32, 36, 40 and 44 After LV Part A)	145.25	0.00	145.25	8.00	1,162.00
12 weeks after LV Part A	444.00	0.00	444.00	1.00	444.00
24 weeks after LV Part A	601.00	0.00	601.00	1.00	601.00
Phone visit 36 weeks after LV Part A	161.25	0.00	161.25	1.00	161.25
48 weeks after LV Part A	656.00	0.00	656.00	1.00	656.00
pEoT	656.00	0.00	656.00	1.00	656.00
Follow-up (4 weeks after last dose of study drug)	501.00	0.00	501.00	1.00	501.00
Total Cost Per Patient ECG Sub-study:					13,981.70