



AZIENDA OSPEDALIERA UNIVERSITARIA

DELIBERAZIONE DELLA DIRETTRICE GENERALE

OGGETTO:

L'Estensore:

Proposta N. Del

Allegati:

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

Il Direttore
Amministrativo

La Direttrice
Generale

Dott.ssa Maria Grazia Furnari

Parere

Il Direttore
Sanitario

La Direttrice Generale dell'AOUP "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



AZIENDA OSPEDALIERA UNIVERSITARIA

LA DIRETTRICE GENERALE

- 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 5 e 6";
- VISTA** la delibera n. 1161 del 29/11/2019 di sottoscrizione della Convenzione economica tra l'AOUP e per essa l'UOC di Gastroenterologia e la Società Pharmaceutical Research Associates Italy Srl, per effettuare la Sperimentazione Clinica dal titolo: "Studio di fase 3, multinazionale, in doppio cieco, randomizzato, controllato con placebo di MGL-3196 (Resmetirom) in pazienti con steatoepatite non alcolica (Non-Alcoholic Steatohepatitis, NASH) e fibrosi per risolvere la NASH e ridurre la progressione verso la cirrosi/o lo scompenso epatico" Protocollo: MGL-3196-11 - Codice Eudract: 2018-004012-22- Sperimentatore: Prof. Salvatore



AZIENDA OSPEDALIERA UNIVERSITARIA

Petta;

DATO ATTO che in data 03/02/2025 il Promotore ha ricevuto il Provvedimento AIFA che autorizza l'emendamento Sm-2-37812 per adeguare il budget al Protocollo di Studio e per informare del trasferimento aziendale di tutti i diritti, titoli e interessi e benefici della Convenzione da PRA ad ICON Italia;

VISTO l' Emendamento 1 sottoscritto e allegato alla Convenzione tra l'AOUP e la Società Icon Holdings Clinical Research International Limited per effettuare la Sperimentazione Clinica Protocollo: MGL-3196-11;

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

DELIBERA

Di prendere atto dell' Emendamento 1 sottoscritto, allegato 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: "Studio di fase 3, multinazionale, in doppio cieco, randomizzato, controllato con placebo di MGL-3196 (Resmetirom) in pazienti con steatoepatite non alcolica (Non-Alcoholic Steatohepatitis, NASH) e fibrosi per risolvere la NASH e ridurre la progressione verso la cirrosi e/o lo scompenso epatico" Protocollo: MGL-3196-11 - Codice Eudract: 2018-004012-22- Sperimentatore: Prof. Salvatore Petta;

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'AOUP approvato con Delibera n. 1152 dell' 08/11/2024

<u>AMENDMENT #1 TO THE AGREEMENT</u>	<u>EMENDAMENTO n. 1 ALLA CONVENZIONE</u>
This AMENDMENT #1 TO THE AGREEMENT ("<u>Amendment #1</u>" to the Agreement), dated as of the last signature (the "<u>Effective Date</u>"), is by and between: L'Azienda Ospedaliera-Universitaria Policlinico "Paolo Giaccone" (hereinafter abbreviated as "Hospital") located in Palermo, Via del Vespro, 129 with Tax ID Code and VAT no 05841790826, hereby represented by its Legal Representative, Dr. Maria Grazia Furnari, who possesses the appropriate powers to sign this document and ICON Holdings Clinical Research International Limited – Italian Branch (Secondary Office), with operating offices at Via Benigno Crespi, Maciachini Business Park, no. 19, 20159 Milan, Italy, tax code and VAT no. 12827880969, through its Proxy Francesco Falcicchio acting in her capacity as Senior Manager , (hereinafter the "CRO") acting as an independent contractor for Madrigal Pharmaceuticals, Inc. located at Four Tower Bridge, 200 Barr Harbor Drive, Suite 200, West Conshohocken, PA 19428 USA ("Sponsor") Hereinafter for brevity individually/collectively referred to as the Party/the Parties.	IL PRESENTE EMENDAMENTO n. 1 ALLA CONVENZIONE ("<u>Emendamento n. 1</u>" alla "Convenzione"), in vigore dalla data dell'ultima firma (la "<u>Data di decorrenza</u>"), da e tra l'Azienda Ospedaliera-Universitaria Policlinico "Paolo Giaccone" (di seguito per brevità "Azienda") con sede a Palermo, Via del Vespro, 129 C.F./P.I. 05841790826, nella persona del Legale Rappresentante, Dott.ssa Maria Grazia Furnari, munita di idonei poteri di firma del presente atto e 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 P.IVA 12827880969, nella persona del Procuratore Francesco Falcicchio in qualità di Senior Manager , (di seguito per brevità "CRO") la quale agisce come contraente indipendente per Madrigal Pharmaceuticals, Inc. con sede a Four Tower Bridge, 200 Barr Harbor Drive, Suite 200, West Conshohocken, PA 19428 USA ("Promotore") di seguito per brevità denominati/e singolarmente/collettivamente la Parte / le Parti

<u>WITNESSETH:</u> WHEREAS, under the terms of a certain Agreement for the implementation of Clinical Trial dated 29 November 2019 (the “Agreement”) between and among the Parties, CRO retained the Hospital to perform the research study entitled “<i>A Phase 3, Multinational, Double-Blind, Randomized, Placebo-Controlled Study of MGL-3196 (resmetirom) in Patients With Non-Alcoholic Steatohepatitis (NASH) and Fibrosis to Resolve NASH and Reduce Progression to Cirrhosis and/or Hepatic Decompensation</i>”, Protocol No. MGL-3196-11(the “Trial”), as may be amended from time to time (the “Protocol”) WHEREAS, the Parties hereto have entered into certain additional agreements with respect to modification of the Agreement, and which they desire to memorialise in this Amendment #1 to the Agreement; 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: 1. Update to Budget. To account for changes to the budget by adding the OLE Cirrhotic Cohort, OLE OLAT Cirrhotic Cohort and OLE Noncirrhotic Cohort, the Parties agree that the Exhibit B Budget attached to the Agreement is hereby deleted and replaced in its entirety by the revised Exhibit B Budget attached hereto.	<u>SI CONVIENE E SI STIPULA QUANTO SEGUE :</u> PREMESSO CHE, secondo i termini di una Convenzione per la conduzione della Sperimentazione Clinica datata 29 novembre 2019 (la “Convenzione”) tra le parti, la CRO ha incaricato l’Azienda di eseguire lo studio clinico dal titolo “<i>Studio di fase 3, multinazionale, in doppio cieco, randomizzato, controllato con placebo di MGL-3196 (Resmetirom) in pazienti con steatoepatite non alcolica (Non-Alcoholic Steatohepatitis, NASH) e fibrosi per risolvere la NASH e ridurre la progressione verso la cirrosi e/o lo scompenso epatico</i>” protocollo n. MGL-3196-11 (la “Sperimentazione”), così come modificata di volta in volta (il “Protocollo”) PREMESSO CHE le Parti hanno stipulato alcuni accordi aggiuntivi relativi alla modifica della Convenzione e che essi desiderano definire in questo Emendamento n. 1 alla Convenzione; IN CONSEGUENZA DI CIÒ, in considerazione delle premesse e dei reciproci seguenti impegni, accordi e condizioni qui stabiliti, le Parti si impegnano a quanto segue: 1. Aggiornamento del budget. Per tener conto delle modifiche apportate sul budget, aggiungendo la Coorte Cirrotica OLE OLAT e la Coorte Non Cirrotica OLE, le Parti convengono che l’Allegato B Budget allegato alla Convenzione sia cancellato e sostituito nella sua interezza dal Budget rivisto allegato al presente documento come Allegato B – Budget.
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2. Transfer from PRA to ICON. Effective 30 June 2023, as part of the business transfer, all rights, titles, interests, and benefits relating to the Agreement between the site and Pharmaceutical Research Associates Italy S.r.l. ("PRA"), which is currently in effect, will be assigned and transferred from PRA to ICON Holdings Clinical Research International Limited – Italian Branch ("ICON Italy") with registered office at Via Benigno Crespi, Parco Maciachini n. 19, 20159, Milan, Italy, with Tax Code/VAT: 12827880969. This is primarily an administrative change of legal entity and the Agreement shall continue on existing terms in all other respects. Effective as of 30 June 2023, all references to PRA should now read as ICON Italy. 3. For clarity purposes: CRO's invoicing address under Exhibit A Payment Terms "Invoicing", section 7 "Invoicing" of the Agreement shall be replaced by the following: "ICON Holdings Clinical Research International Limited – Italian Branch (Sede Secondaria) Via Benigno Crespi, Maciachini Business Park, no. 19 20159 Milano, Italia Codice Fiscale-P.IVA: 12827880969 Codice destinatario: X2PH38J ATTN.: Accounts Payable ICON E-mail investigatorinvoices@iconplc.com 4. Ratification of Balance of Agreement. In all other respects, the terms of the Agreement are hereby	2. Trasferimento da PRA a ICON. A partire dal 30 giugno 2023, nell'ambito del trasferimento aziendale, tutti i diritti, titoli, interessi e benefici relativi alla Convenzione tra il Centro e Pharmaceutical Research Associates Italy S.r.l. ("PRA"), attualmente in vigore, saranno assegnati e trasferiti da PRA a ICON Italia con sede legale in Via Benigno Crespi, Parco Maciachini n. 19, 20159, Milano, Italia, con C.F./P.IVA: 12827880969. Si tratta principalmente di un cambiamento amministrativo di persona giuridica e per tutti gli altri aspetti la Convenzione continuerà alle condizioni esistenti. A partire dal 30 giugno 2023 tutti i riferimenti a PRA dovranno ora intendersi riferiti a ICON Italia. 3. Per motivi di chiarezza: l'indirizzo di fatturazione della CRO dell'allegato A Termini di pagamento, sezione 7 "Fatturazione" della Convenzione è sostituito dal seguente: "ICON Holdings Clinical Research International Limited" – Italian Branch (Sede Secondaria) Via Benigno Crespi, Maciachini Business Park, n. 19 20159 Milano, Italia Codice Fiscale-P.IVA: 12827880969 Codice destinatario: X2PH38J ATTN.: Accounts Payable ICON E-mail investigatorinvoices@iconplc.com 4. Ratifica delle parti restanti della convenzione. Per tutti gli altri aspetti, i termini della presente Convenzione si
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ratified and affirmed by each of the parties hereto. 5. Headings. The headings in this Amendment #1 to the Agreement are for convenience of reference only and shall not affect its interpretation.	intendono qui ratificati e confermati da ognuna delle parti. 5. Intestazioni. Le intestazioni di questo Emendamento n. 1 alla Convenzione si devono intendere soltanto di riferimento alla stessa e non avranno alcuna influenza sulla sua interpretazione.	
<i>SIGNATURES APPEAR ON FOLLOWING PAGE.</i>	<i>LE FIRME SEGUONO NELLA PAGINA SUCCESSIVA</i>	

Stamp duty is paid electronically by ICON HOLDINGS CLINICAL RESEARCH INTERNATIONAL LIMITED, with registered offices at Via Benigno Crespi 19, 20159 Milan, Italy, Italian affiliate of the CRO, pursuant to art. 15 of the Presidential Decree 642 of 1972 (Authorization of the Revenue Agency of Milan registered on 14-June-2023 in the OFFICIAL REGISTER with number 203622).	Imposta di bollo assolta in modo virtuale 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).
IN WITNESS WHEREOF , the Parties hereto, each by a duly authorised representative, have executed this Amendment #1 to the Agreement as of the date of the last signature.	IN FEDE DI CIÒ le Parti, ciascuna nella persona del/la proprio/a rappresentante debitamente autorizzato/a, hanno sottoscritto questo Emendamento n. 1 alla Convenzione a partire dalla data dell'ultima firma.

For the CRO/Per la CRO:*The Proxy/Il Procuratore*

Dr./Dott. Francesco Falcicchio

Date/Data:

Signature/Firma: _____

For the Hospital/Per l'Azienda:

Dr./Dott.ssa Maria Grazia Furnari

The Legal Representative/Il Legale Rappresentante

Date/Data:

Signature/Firma: _____

The Investigator/Lo Sperimentatore

Dott. Salvatore Petta

Date/Data:

Signature/Firma: _____

EXHIBIT B – BUDGET / ALLEGATO B - BUDGET

DB Year 1

Trial Information

Sponsor: Madrigal Pharmaceuticals
Project: MGL03196-MG3196
Protocol Number: MGL-3196-11
Location: Italy
Overhead Percent: 0%
Currency: EUR Euro
Protocol Version: Addendum V 1.0: 05 Aug 2024
Arm: Double Blind Year 1 (First 1100 Patients)
Institution: Azienda Ospedaliero-Universitaria Policlinico "Paolo Giaccone"
Principal Investigator: Salvatore Petta

Name	Selected Cost	Screening	Double Blind Treatment Period														Early Termination	Follow-up	
			Baseline	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52		28 Days	3 Months (Only Required following Early Termination)
Obtain Informed Consent	27.00	27.00																	
Determination/Confirmation of Eligibility	24.00	24.00	24.00																
Randomization	31.00		31.00																
Health-related QOL assessment (CLDQ, SF-1DQOL, WPAI-NASH)	16.00		16.00						16.00							16.00		16.00	
Complete Physical Examination including: Vital Signs/Anthropometrics, Demographic Information, Review of Complete or Symptom-Directed Physical Examination including Vital Signs/Anthropometrics and MELD Score	65.00	65.00																	
12- Lead ECG, Single or Triplicate	43.00		43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00
MRI-PDFF	38.00	38.00	38.00	38.00	38.00			38.00		38.00		38.00					38.00	38.00	
MRE	1,004.00	Invoice					Invoice					Invoice					Invoice	Invoice	
Corrected T1 (cT1)	396.00	Invoice					Invoice										Invoice	Invoice	
Fibroscan	379.00	Invoice					Invoice										Invoice	Invoice	
Liver Biopsy including Sample Handling, Anesthesia, Recovery Room Bed (Day only)	412.00	Invoice															Invoice	Invoice	
Dual Energy X-Ray Absorptiometry	1,486.00	Invoice															Invoice	Invoice	
Accountability of Blinded Study Drug	197.00	197.00															197.00	197.00	
Nutrition and Lifestyle Counseling	9.00		9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	
Specimen Collection (Blood/Urine) for Central Lab Analysis	18.00		18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	
Specimen Handling (Blood/Urine/Biopsy Slides) including Preparation and Shipment to Central Lab	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00
Review Concomitant Medications	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00
Adverse Events Assessment	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00
Per Patient Activity Totals:	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00
Per Patient Activity Totals:	432.00		260.00	189.00	189.00	151.00	151.00	189.00	167.00	189.00	151.00	189.00	151.00	151.00	151.00	402.00	402.00	124.00	124.00

Name	Selected Cost	Screening	Baseline	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52	Early Termination	28 Days	3 Months (Only Required following Early Termination)
Pharmacy Dispensing	27.00		27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00			
Physician Fee	77.00		77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00		77.00	77.00
Study Coordinator Fee	70.00		70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00		70.00	70.00
Data Entry	47.00		47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00		47.00	47.00
Per Patient Other Direct Cost Totals:	194.00		221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	194.00	194.00	194.00

	Screening	Baseline	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	Week 52	ESTIMATED TOTAL COST PER PATIENT (through Week 52)	Early Termination	28 Days	3 Months (Only Required following Early Termination)
Visit Subtotal	626.00	481.00	410.00	410.00	372.00	372.00	410.00	388.00	410.00	372.00	410.00	372.00	372.00	372.00	623.00	596.00	318.00	318.00	
Overhead at 0%	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	0.00	0.00	0.00	
TOTAL Selected Cost Per Visit	626.00	481.00	410.00	410.00	372.00	372.00	410.00	388.00	410.00	372.00	410.00	372.00	372.00	372.00	623.00	6,400.00	596.00	318.00	318.00

Invoiceable Procedures and Other Direct Costs

Study Total: 16,190.00

Name	Selected Cost	Overhead at 0%	Total	Considerations
*Screen Failure <u>WITH</u> Biopsy Performed at Screening	2,112.00	0.00	2,112.00	For subjects who have a biopsy performed, site will be paid the full amount of Screening visit plus the cost of biopsy at the rates set forth in the budget. Additionally, site will be paid at a 5:1 ratio (5 screen failures paid for every 1 subject enrolled). As long as the ratio is maintained, there is no cap set for the number of screen failures to be paid to site. In order to be reimbursed in this scenario, site is required to submit a detailed invoice to Sponsor/CRO (including the Protocol number on the invoice).
*Screen Failure <u>WITHOUT</u> Biopsy Performed at Screening	626.00	0.00	626.00	For subjects who <u>DO NOT</u> have a biopsy performed, site will be paid the full amount of Screening visit at the rate set forth in the budget. Additionally, site will be paid at a 10:1 ratio (10 screen failures paid for every 1 subject enrolled). As long as the ratio is maintained, there is no cap set for the number of screen failures to be paid to site. In order to be reimbursed in this scenario, site is required to submit a detailed invoice to Sponsor/CRO (including the Protocol number on the invoice).
Unscheduled Visit	318.00	0.00	318.00	Unscheduled Visit to include: Symptom-Directed Physical Exam, Safety Labs, AE Assessment, Review of Con Meds, Physician, Study Coordinator, and Data Entry effort. Unscheduled Visits will be reimbursed on receipt of a detailed invoice (including the Protocol number on the invoice) by Sponsor/CRO.
MRI-PDFF	1,004.00	0.00	1,004.00	Invoiceable as outlined in the Protocol.
MRE	396.00	0.00	396.00	
Corrected T1 (cT1)	379.00	0.00	379.00	
Optional Fibroscan	412.00	0.00	412.00	Invoiceable as performed at Screening, Week 52, Month 24, Month 36, Month 48, Month 54 and Early Termination.
Liver Biopsy	1,486.00	0.00	1,486.00	Invoiceable at Screening for patients without a historical Liver Biopsy, and at Early Termination for subjects who do not withdraw within 6 months of starting study treatment.
Patient Travel Reimbursement (per visit)	50.00	N/A	50.00	Invoiceable once per visit requiring travel to/from site. Not to exceed AUD 1,750.00 per patient.
Patient Biopsy Stipend (per visit)	150.00	N/A	150.00	Invoiceable per patient per visit at which a Biopsy is performed.
Additional Blood Draw (including Handling, Preparation and	49.00	0.00	49.00	Invoiceable for repeat Laboratory samples, if clinically indicated (per Protocol section 7.6.1).
Informed Consent for Open-Label Active Treatment Study	27.00	0.00	27.00	Invoiceable for participating subjects, as required.
HCC monitoring using ultrasound	231.00	0.00	231.00	Invoiceable for OLE Cirrhotic and Olaf Cirrhotic Cohort, depending on whether HCC monitoring available using ultrasound. If Ultrasound is unavailable, then monitor with serum AFP

*Re-screenings to be handled the same as screened/screen failed subjects. Per Protocol, subjects can be re-screened only once.

Administrative Invoiceable Costs

Name	Selected Cost	Considerations
Site Start-up Costs	1,495.00	Payable upon site activation and receipt of site-submitted invoice.
Pharmacy set-up fee	500.00	Payable upon site activation and receipt of site-submitted invoice.
Archiving/Document Storage	400.00	Payable upon site close-out and receipt of site-submitted invoice.
Prescreening Fee (PER CHART)	10.00	Site will be paid for Prescreen Failures at a 5:1 ratio (5 prescreen chart reviews paid for every 1 subject screened) on a per-chart reviewed basis upon receipt of detailed invoice by Sponsor/CRO.

DB Subsequent Patients

Trial Information												
Sponsor: Madrigal Pharmaceuticals												
Project: MGL03196-MG3196												
Protocol Number: MGL-3196-11												
Location: Italy												
Overhead Percent: 0%												
Currency: EUR Euro												
Protocol Version: Addendum V 1.0: 05 Aug 2024												
Arms: Double Blind Year 1 (Subsequent Patients)												
Institution: Azienda Ospedaliero-Universitaria Policlinico " Paolo Giaccone"												
Principal Investigator: Salvatore Petta												
Name	Selected Cost	Double Blind Treatment Period									Follow-Up	
		Screening	Baseline	Week 4	Week 8	Week 12	Week 16 (Imaging Substudy Participants)	Week 24	Week 38	Week 52	Early Termination	3 Months (Only Required following Early Termination)
Obtain Informed Consent	27.00	27.00										
Determination of Eligibility	24.00	24.00	24.00									
Randomization	31.00		31.00									
Health-related QOL assessment (CLDQ, SF-LDQOL, WPAI-NASH)	16.00		16.00					16.00		16.00	16.00	
Complete Physical Examination including: Vital Signs/Anthropometrics, Demographic Information, Review of Complete or Symptom-Directed Physical Examination including Vital Signs/Anthropometrics and MELD Score	65.00	65.00										
I2- Lead ECG, Single or Triplicate	38.00	38.00	38.00	38.00	38.00			38.00		38.00	38.00	
MRI-PDFF	1,004.00	Invoice					Invoice			Invoice	Invoice	
MRE	396.00	Invoice					Invoice			Invoice	Invoice	
Corrected T1 (cT1)	379.00	Invoice					Invoice			Invoice	Invoice	
Fibroscan	412.00	Invoice								Invoice	Invoice	
Liver Biopsy including Sample Handling, Anesthesia, Recovery Room Bed (Day only)	1,486.00	Invoice								Invoice	Invoice	
Dual Energy X-Ray Absorptiometry	197.00	197.00								197.00	197.00	
Accountability of Blinded Study Drug	9.00		9.00	9.00	9.00	9.00		9.00	9.00	9.00	9.00	
Nutrition and Lifestyle Counseling	18.00		18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	
Specimen Collection (Blood/Urine) for Central Lab Analysis	25.00	25.00	25.00	25.00	25.00	25.00		25.00	25.00	25.00	25.00	
Specimen Handling (Blood/Urine/Biopsy Slides) including Preparation and Shipment to Central Lab	24.00	24.00	24.00	24.00	24.00	24.00		24.00	24.00	24.00	24.00	
Review Concomitant Medications	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	
Adverse Events Assessment	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	
Per Patient Activity Totals:	432.00	260.00	189.00	189.00	189.00	151.00	93.00	205.00	151.00	402.00	402.00	124.00
Name	Selected Cost											
		Screening	Baseline	Week 4	Week 8	Week 12	Week 16 (Imaging Substudy Participants)	Week 24	Week 38	Week 52	Early Termination	3 Months (Only Required following Early Termination)
Pharmacy Dispensing	27.00		27.00	27.00	27.00	27.00		27.00	27.00	27.00	77.00	77.00
Physician Fee	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00
Study Coordinator Fee	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00
Data Entry	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00
Per Patient Other Direct Cost Totals:	194.00	221.00	221.00	221.00	221.00	221.00	194.00	221.00	221.00	221.00	194.00	194.00
		Screening	Baseline	Week 4	Week 8	Week 12	Week 16 (Imaging Substudy Participants)	Week 24	Week 38	Week 52	Early Termination	3 Months (Only Required following Early Termination)
Visit Subtotal	626.00	481.00	410.00	410.00	410.00	372.00	287.00	426.00	372.00	623.00	596.00	318.00
Overhead at 0%	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
TOTAL Selected Cost Per Visit	626.00	481.00	410.00	410.00	410.00	372.00	287.00	426.00	372.00	623.00	596.00	318.00
											ESTIMATED TOTAL COST PER PATIENT (through Week 52)(inc. Week 16 Substudy	
											4,007.00	

Trial Information	
Study ID	123456789
Study Title	Phase I/II Study of [Drug Name] in [Disease]
Study Design	Randomized, Double-Blind, Placebo-Controlled
Study Phase	Phase I/II
Study Location	[Country], [City]
Study Period	[Start Date] to [End Date]
Study Status	Completed
Study Sponsor	[Sponsor Name]
Study Investigator	[Investigator Name]
Study Protocol	[Protocol Number]
Study Version	[Version Number]
Study Date	[Date]
Study Contact	[Contact Information]
Study Reference	[Reference Number]
Study Identifier	[Identifier Number]
Study Description	[Description]
Study Objectives	[Objectives]
Study Population	[Population]
Study Interventions	[Interventions]
Study Outcomes	[Outcomes]
Study Results	[Results]
Study Conclusions	[Conclusions]
Study References	[References]
Study Appendices	[Appendices]
Study Documents	[Documents]
Study Data	[Data]
Study Analysis	[Analysis]
Study Reporting	[Reporting]
Study Publication	[Publication]
Study Archiving	[Archiving]
Study Access	[Access]
Study Sharing	[Sharing]
Study Collaboration	[Collaboration]
Study Partnership	[Partnership]
Study Network	[Network]
Study Community	[Community]
Study Stakeholders	[Stakeholders]
Study Partners	[Partners]
Study Sponsors	[Sponsors]
Study Investigators	[Investigators]
Study Researchers	[Researchers]
Study Clinicians	[Clinicians]
Study Patients	[Patients]
Study Public	[Public]
Study Media	[Media]
Study Government	[Government]
Study Industry	[Industry]
Study Academia	[Academia]
Study Non-Profit	[Non-Profit]
Study Foundation	[Foundation]
Study Organization	[Organization]
Study Institution	[Institution]
Study Center	[Center]
Study Site	[Site]
Study Location	[Location]
Study Address	[Address]
Study City	[City]
Study State	[State]
Study Country	[Country]
Study Continent	[Continent]
Study Region	[Region]
Study District	[District]
Study Suburb	[Suburb]
Study Township	[Township]
Study Village	[Village]
Study Hamlet	[Hamlet]
Study Settlement	[Settlement]
Study Community	[Community]
Study Population	[Population]
Study Demographics	[Demographics]
Study Statistics	[Statistics]
Study Data	[Data]
Study Analysis	[Analysis]
Study Reporting	[Reporting]
Study Publication	[Publication]
Study Archiving	[Archiving]
Study Access	[Access]
Study Sharing	[Sharing]
Study Collaboration	[Collaboration]
Study Partnership	[Partnership]
Study Network	[Network]
Study Community	[Community]
Study Stakeholders	[Stakeholders]
Study Partners	[Partners]
Study Sponsors	[Sponsors]
Study Investigators	[Investigators]
Study Researchers	[Researchers]
Study Clinicians	[Clinicians]
Study Patients	[Patients]
Study Public	[Public]
Study Media	[Media]
Study Government	[Government]
Study Industry	[Industry]
Study Academia	[Academia]
Study Non-Profit	[Non-Profit]
Study Foundation	[Foundation]
Study Organization	[Organization]
Study Institution	[Institution]
Study Center	[Center]
Study Site	[Site]
Study Location	[Location]
Study Address	[Address]
Study City	[City]
Study State	[State]
Study Country	[Country]
Study Continent	[Continent]
Study Region	[Region]
Study District	[District]
Study Suburb	[Suburb]
Study Township	[Township]
Study Village	[Village]
Study Hamlet	[Hamlet]
Study Settlement	[Settlement]
Study Community	[Community]
Study Population	[Population]
Study Demographics	[Demographics]
Study Statistics	[Statistics]
Study Data	[Data]
Study Analysis	[Analysis]
Study Reporting	[Reporting]
Study Publication	[Publication]
Study Archiving	[Archiving]
Study Access	[Access]
Study Sharing	[Sharing]
Study Collaboration	[Collaboration]
Study Partnership	[Partnership]
Study Network	[Network]
Study Community	[Community]
Study Stakeholders	[Stakeholders]
Study Partners	[Partners]
Study Sponsors	[Sponsors]
Study Investigators	[Investigators]
Study Researchers	[Researchers]
Study Clinicians	[Clinicians]
Study Patients	[Patients]
Study Public	[Public]
Study Media	[Media]
Study Government	[Government]
Study Industry	[Industry]
Study Academia	[Academia]
Study Non-Profit	[Non-Profit]
Study Foundation	[Foundation]
Study Organization	[Organization]
Study Institution	[Institution]
Study Center	[Center]
Study Site	[Site]
Study Location	[Location]
Study Address	[Address]
Study City	[City]
Study State	[State]
Study Country	[Country]
Study Continent	[Continent]
Study Region	[Region]
Study District	[District]
Study Suburb	[Suburb]
Study Township	[Township]
Study Village	[Village]
Study Hamlet	[Hamlet]
Study Settlement	[Settlement]
Study Community	[Community]
Study Population	[Population]
Study Demographics	[Demographics]
Study Statistics	[Statistics]
Study Data	[Data]
Study Analysis	[Analysis]
Study Reporting	[Reporting]
Study Publication	[Publication]
Study Archiving	[Archiving]
Study Access	[Access]
Study Sharing	[Sharing]
Study Collaboration	[Collaboration]
Study Partnership	[Partnership]
Study Network	[Network]
Study Community	[Community]
Study Stakeholders	[Stakeholders]
Study Partners	[Partners]
Study Sponsors	[Sponsors]

Principal Investigator: Salvatore Petta

Early Termination	Follow-Up	
	28 Days	3 Months (Only Required following Early Termination)
16.00		
43.00	43.00	43.00
38.00		
Invoice		
Invoice		
Invoice		
Invoice		
Invoice		
197.00		
9.00		
18.00		
25.00	25.00	25.00
24.00	24.00	24.00
15.00	15.00	15.00
17.00	17.00	17.00
402.00	124.00	124.00

Early Termination	28 Days	3 Months (Only Required following Early Termination)
77.00	77.00	77.00
70.00	70.00	70.00
47.00	47.00	47.00
194.00	194.00	194.00

Early Termination	28 Days	3 Months (Only Required following Early Termination)
596.00	318.00	318.00
0.00	0.00	0.00
596.00	318.00	318.00

OLE Cirrhotic Cohort

Trial Information

Sponsor: Madrigal Pharmaceuticals
Project: MGL03196-MG3196
Protocol Number: MGL-3196-11
Location: Italy
Overhead Percent: 0%
Currency: EUR Euro
Protocol Version: Addendum V 1.0: 05 Aug 2024
Arm: OLE Cirrhotic Cohort
Institution: Azienda Ospedaliero-Universitaria Policlinico " Paolo Giaccone"
Principal Investigator: Salvatore Petta

Name	Selected Cost	OLE Cirrhotic Cohort																
		Baseline	Week 2	Week 4	Week 12	Week 24	Week 38	Week 52	Month 15	Month18	Month 21	Month 24	Month 27	Month 30	Month 33	Month 36	Month 39	Month 42
Obtain OLE Informed Consent	27.00	27.00																
Determination of Eligibility	24.00	24.00																
Health-related QOL assessment (CLDQ, SF-LDQOL, WPAI-NASH)	16.00	16.00				16.00		16.00		16.00		16.00		16.00		16.00		16.00
Complete or Symptom-Directed Physical Examination including Vital Signs/Anthropometrics and MELD Score	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00
12- Lead ECG, Single or Triplicate	38.00	38.00						38.00										
MRI-PDFF	1,004.00	Invoice						Invoice				Invoice				Invoice		
MRE	396.00	Invoice						Invoice				Invoice				Invoice		
Fibroscan	412.00	Invoice				Invoice		Invoice		Invoice		Invoice		Invoice		Invoice		Invoice
HCC monitoring using ultrasound	231.00	Invoice				Invoice		Invoice		Invoice		Invoice		Invoice		Invoice		Invoice
Disposition and Accountability of blinded study drug	9.00	9.00		9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00
Nutrition and Lifestyle Counseling	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00
Specimen Collection (Blood/Urine) for Central Lab Analysis	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00
Specimen Handling (Blood/Urine/Biopsy Slides) including Preparation and Shipment to Central Lab	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00
Review Concomitant Medications	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00
Adverse Events Assessment	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00
Per Patient Activity Totals:	256.00	142.00	151.00	151.00	151.00	167.00	151.00	205.00	151.00	167.00	151.00	167.00	151.00	167.00	151.00	167.00	151.00	167.00

OLE EOS/Early Term	OLE 28-day Follow-up	OLE 3-mon Follow-up (only for ET subjects)
16.00		
43.00	43.00	43.00
38.00		
Invoice		
Invoice		
Invoice		
Invoice		
18.00		
9.00		
25.00	25.00	25.00
24.00	24.00	24.00
15.00	15.00	15.00
17.00	17.00	17.00
205.00	124.00	124.00

Name	Selected Cost	Baseline	Week 2	Week 4	Week 12	Week 24	Week 38	Week 52	Month 15	Month18	Month 21	Month 24	Month 27	Month 30	Month 33	Month 36	Month 39	Month 42
Pharmacy Dispensing	27.00	27.00		27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00
Physician Fee	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00
Study Coordinator Fee	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00
Data Entry	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00
Per Patient Other Direct Cost Totals:	221.00	194.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00

OLE EOS/Early Term	OLE 28-day Follow-up	OLE 3-mon Follow-up (only for ET subjects)
27.00	27.00	27.00
77.00	77.00	77.00
70.00	70.00	70.00
47.00	47.00	47.00
221.00	221.00	221.00

	Baseline	Week 2	Week 4	Week 12	Week 24	Week 38	Week 52	Month 15	Month18	Month 21	Month 24	Month 27	Month 30	Month 33	Month 36	Month 39	Month 42	ESTIMATED TOTAL COST PER PATIENT (from Baseline to
Visit Subtotal	477.00	336.00	372.00	372.00	388.00	372.00	426.00	372.00	388.00	372.00	388.00	372.00	388.00	372.00	388.00	372.00	388.00	
Overhead at 0%	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	0.00	0.00	
TOTAL Selected Cost Per Visit	477.00	336.00	372.00	372.00	388.00	372.00	426.00	372.00	388.00	372.00	388.00	372.00	388.00	372.00	388.00	372.00	388.00	6,543.00

* Any previously negotiated costs, and procedures from the DB portion of the study, that have been finalized, are not subject to change and part of the negotiations for the OLE portion of the study, including the Administrative Invoiceable Costs

Invoiceable Procedures and Other Direct Costs

Name	0	Overhead at 0%	Total	Considerations
Informed Consent for Open-Label Active Treatment Study	27.00	0.00	27.00	Invoiceable for participating subjects, as required.
HCC monitoring using ultrasound	231.00	0.00	231.00	Invoiceable for OLE Cirrhotic and Olat Cirrhotic Cohort, depending on whether HCC monitoring available using ultrasound. If Ultrasound is unavailable, then monitr with serum AFP

OLE OLAT Cirrhotic Cohort

Trial Information

Sponsor: Madrigal Pharmaceuticals
Project: MGL03196-MG3196
Protocol Number: MGL-3196-11
Location: Italy
Overhead Percent: 0%
Currency: EUR Euro
Protocol Version: Addendum V 1.0: 05 Aug 2024
Arm: OLE OLAT Cirrhotic Cohort
Institution: Azienda Ospedaliero-Universitaria Policlinico " Paolo Giaccone"
Principal Investigator: Salvatore Petta

		OLE OLAT Cirrhotic Cohort														
Name	Selected Cost	Baseline	Week 12	Week 24	Week 38	Week 52	Month 15	Month18	Month 21	Month 24	Month 27	Month 30	Month 33	Month 36	Month 39	Month 42
Obtain OLE Informed Consent	27.00	27.00														
Determination of Eligibility	24.00	24.00														
Health-related QOL assessment (CLDQ, SF-1DQOL, WPAI-NASH)	16.00	16.00		16.00		16.00		16.00		16.00		16.00		16.00		16.00
Complete or Symptom-Directed Physical Examination including Vital Signs/Anthropometrics and MELD Score	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00
12- Lead ECG, Single or Triplicate	38.00	38.00				38.00										
MRI-PDFF	1,004.00	Invoice				Invoice				Invoice				Invoice		
MRE	396.00	Invoice				Invoice				Invoice				Invoice		
Fibroscan	412.00	Invoice		Invoice		Invoice		Invoice		Invoice		Invoice		Invoice		Invoice
HCC monitoring using ultrasound	231.00	Invoice		Invoice		Invoice		Invoice		Invoice		Invoice		Invoice		Invoice
Disposition and Accountability of blinded study drug	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00
Nutrition and Lifestyle Counseling	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00
Specimen Collection (Blood/Urine) for Central Lab Analysis	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00
Specimen Handling (Blood/Urine/Biopsy Slides) including Preparation and Shipment to Central Lab	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00
Review Concomitant Medications	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00
Adverse Events Assessment	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00
Per Patient Activity Totals:		256.00	151.00	167.00	151.00	205.00	151.00	167.00	151.00	167.00	151.00	167.00	151.00	167.00	151.00	167.00

OLE Early Termination	Follow-Up	
	28 Days	OLE ET 3 Months (Only Required following Early Termination)
16.00		
43.00	43.00	43.00
38.00		
Invoice		
Invoice		
Invoice		
Invoice		
9.00		
18.00		
25.00		
24.00		
15.00	15.00	15.00
17.00	17.00	17.00
205.00	75.00	75.00

Name	Selected Cost	Baseline	Week 12	Week 24	Week 38	Week 52	Month 15	Month18	Month 21	Month 24	Month 27	Month 30	Month 33	Month 36	Month 39	Month 42
Pharmacy Dispensing	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00
Physician Fee	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00
Study Coordinator Fee	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00
Data Entry	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00
Per Patient Other Direct Cost Totals:		221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00

OLE Early Termination	28 Days	OLE ET 3 Months (Only Required following Early Termination)
77.00	77.00	77.00
70.00	70.00	70.00
47.00	47.00	47.00
194.00	194.00	194.00

		Baseline	Week 12	Week 24	Week 38	Week 52	Month 15	Month18	Month 21	Month 24	Month 27	Month 30	Month 33	Month 36	Month 39	Month 42	ESTIMATED TOTAL COST PER PATIENT (from Baseline to 5,835.00)
Visit Subtotal	477.00	372.00	388.00	372.00	426.00	372.00	388.00	372.00	388.00	372.00	388.00	372.00	388.00	372.00	388.00	388.00	
Overhead at 0%	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	0.00	
TOTAL Selected Cost Per Visit	477.00	372.00	388.00	372.00	426.00	372.00	388.00	372.00	388.00	372.00	388.00	372.00	388.00	372.00	388.00	388.00	

OLE Early Termination	28 Days	OLE ET 3 Months (Only Required following Early Termination)
399.00	269.00	269.00
0.00	0.00	0.00
399.00	269.00	269.00

OLE Noncirrhotic Cohort

Trial Information

Sponsor: Madrigal Pharmaceuticals
Project: MGL03196-MG3196
Protocol Number: MGL-3196-11
Location: Italy
Overhead Percent: 0%
Currency: EUR Euro
Protocol Version: Addendum V 1.0: 05 Aug 2024
Arm: OLE Noncirrhotic Cohort
Institution: Azienda Ospedaliero-Universitaria Policlinico " Paolo Giaccone"
Principal Investigator: Salvatore Petta

Name	Selected Cost	OLE Noncirrhotic Cohort									
		Baseline	Week 12	Week 24	Week 38	Week 52	Month 18	Month 24	Month 30	Month 36	Month 42
Obtain OLE Informed Consent	27.00	27.00									
Determination of Eligibility	24.00	24.00									
Health-related QOL assessment (CLDQ, SF-LDQOL, WPAI-NASH)	16.00	16.00		16.00		16.00	16.00	16.00	16.00	16.00	16.00
Complete or Symptom-Directed Physical Examination including Vital Signs/Anthropometrics and MELD Score	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00	43.00
12- Lead ECG, Single or Triplicate	38.00	38.00				38.00					
MRI-PDFF	1,004.00	Invoice				Invoice	Invoice	Invoice	Invoice	Invoice	Invoice
MRE	396.00	Invoice				Invoice	Invoice	Invoice	Invoice	Invoice	Invoice
Fibroscan	412.00	Invoice		Invoice		Invoice	Invoice	Invoice	Invoice	Invoice	Invoice
Disposition and Accountability of blinded study drug	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00
Nutrition and Lifestyle Counseling	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00
Specimen Collection (Blood/Urine) for Central Lab Analysis	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00
Specimen Handling (Blood/Urine/Biopsy Slides) including Preparation and Shipment to Central Lab	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00	24.00
Review Concomitant Medications	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00
Adverse Events Assessment	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00
Per Patient Activity Totals:		256.00	151.00	167.00	151.00	205.00	167.00	167.00	167.00	167.00	167.00

Early Termination	Follow-Up	
	28 Days	3 Months (Only Required following Early Termination)
16.00		
43.00	43.00	43.00
38.00		
Invoice		
Invoice		
Invoice		
9.00		
18.00		
25.00	25.00	25.00
24.00	24.00	24.00
15.00	15.00	15.00
17.00	17.00	17.00
205.00	124.00	124.00

Name	Selected Cost	Baseline	Week 12	Week 24	Week 38	Week 52	Month 18	Month 24	Month 30	Month 36	Month 42
Pharmacy Dispensing	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00	27.00
Physician Fee	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00	77.00
Study Coordinator Fee	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00
Data Entry	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00	47.00
Per Patient Other Direct Cost Totals:		221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00	221.00

Early Termination	28 Days	3 Months (Only Required following Early Termination)
77.00	77.00	77.00
70.00	70.00	70.00
47.00	47.00	47.00
194.00	194.00	194.00

	Baseline	Week 12	Week 24	Week 38	Week 52	Month 18	Month 24	Month 30	Month 36	Month 42	ESTIMATED TOTAL COST PER PATIENT (from Baseline to
Visit Subtotal	477.00	372.00	388.00	372.00	426.00	388.00	388.00	388.00	388.00	388.00	
Overhead at 0%	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
TOTAL Selected Cost Per Visit	477.00	372.00	388.00	372.00	426.00	388.00	388.00	388.00	388.00	388.00	3,975.00

Early Termination	28 Days	3 Months (Only Required following Early Termination)
399.00	318.00	318.00
0.00	0.00	0.00
399.00	318.00	318.00



AZIENDA OSPEDALIERA UNIVERSITARIA

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