

AMENDMENT N° 2  
(hereinafter “**Amendment**”)

is effective as of the date of last signature (hereinafter  
“**Effective date**”)

to the  
AGREEMENT FOR THE CONDUCT OF A CLINICAL  
TRIAL ON MEDICINAL PRODUCTS  
dated 24 February 2025

This Amendment is made by and between

(1) Azienda Ospedaliera Universitaria  
Policlinico “P. Giaccone” di Palermo  
(hereinafter referred to as the “**Institution**”),  
with registered office at Via del Vespro 129,  
Palermo - Italy Tax Code and VAT No.  
05841790826, represented by its Legal  
Representative, Dr Maria Grazia Furnari, in  
the capacity as General Director, who is  
granted the appropriate powers to sign this  
document

and

(2) Parexel International (IRL) Limited, with  
registered office at 70 Sir John Rogerson's  
Quay, Dublin 2, Ireland, VAT no. IE-  
3249971HH, represented by its authorized  
Representative, Nicola Sotira, (hereinafter  
referred to as “**CRO**”), acting on behalf of  
Boehringer Ingelheim International GmbH  
(hereinafter referred to as the “**Sponsor**”),  
pursuant to an appropriate  
delegation/mandate/power of attorney  
conferred on 20 December 2024

hereinafter individually/collectively the “**Party/Parties**”.

regarding

Protocol No: 1404-0064 (hereinafter “**Protocol**”)  
A Phase III double-blind, randomised, placebo-controlled  
trial to evaluate liver-related clinical outcomes and safety of

EMENDAMENTO NUMERO 2  
(qui di seguito “**Emendamento**”)

decorrerà a partire dalla data dell’ultima firma  
(di seguito “**Data di decorrenza**”)

al  
CONTRATTO PER LA CONDUZIONE DELLA  
SPERIMENTAZIONE CLINICA SU MEDICINALI datato  
24 febbraio 2025

Il presente Emendamento è stipulato da e tra

(1) Azienda Ospedaliera Universitaria  
Policlinico “P. Giaccone” di Palermo (di  
seguito “**Ente**”), con sede legale in Via del  
Vespro 129, Palermo - Italia C.F. e P.IVA n.  
05841790826, in persona del Legale  
Rappresentante, Dott.ssa Maria Grazia Furnari,  
in qualità di Direttrice Generale, munita di  
idonei poteri di firma

e

(2) Parexel International (IRL) Limited, con sede  
legale in 70 Sir John Rogerson's Quay, Dublino 2,  
Irlanda, C.F. e P.IVA n. IE-3249971HH, in persona  
del suo Rappresentante autorizzato, Nicola Sotira,  
(di seguito “**CRO**”), che agisce per conto di  
Boehringer Ingelheim International GmbH (di  
seguito “**Promotore**”), in forza di idonea  
delega/mandato/procura conferita in data 20  
dicembre 2024

Indicati singolarmente/ collettivamente con “**Parte/Parti**”.

In relazione a

Protocollo: 1404-0064 (di seguito “**Protocollo**”)  
“*Studio di fase III, in doppio cieco, randomizzato controllato  
verso placebo, volto a valutare gli outcome clinici correlati al*

once weekly injected survodutide in participants with compensated nonalcoholic steatohepatitis/metabolic dysfunction associated steatohepatitis (NASH/MASH) cirrhosis (hereinafter “**Study**”) Survodutide (BI 456906) (hereinafter “**Study Drug**“)

WHEREAS, SPONSOR is the sponsor of the multi-center/multi-centre Study to clinically evaluate the Study Drug;

WHEREAS, SPONSOR has contracted with Parexel International (IRL) or an Affiliate (hereinafter “**CRO**”) (under a separate written agreement) to act as SPONSOR’s contractor and designee in managing the Study for SPONSOR, in accordance with the Protocol; and

WHEREAS, the Parties have entered into the above-referred Agreement FOR THE CONDUCT OF A CLINICAL TRIAL ON MEDICINAL PRODUCTS 24 February 2025 (hereinafter “**Agreement**”);

WHEREAS, due to Protocol amendment #5.0 dated 02 September 2025 (hereinafter “**Protocol amendment**”) the Parties agree to amend the agreement to include revised budget in accordance with the changes in the said Protocol amendment.

WHEREAS, the Parties are jointly willing to amend the above-referred Agreement;

Now, therefore the above-referred Agreement shall be amended and the following amended wordings shall be effective as of IRB/EC/RA approval of the above mentioned Protocol Amendment: 6 February 2026

1. Due to new Protocol amendment the Annex A – Payments terms and Budget is being deleted in its entirety and replaced with the revised Annex A - Payments terms and Budget attached herein.

In the event of a conflict between the terms of this Amendment and the Agreement, the terms of this Amendment shall take precedence.

*fegato e la sicurezza di iniezioni settimanali di survodutide a partecipanti con steatoepatite non alcolica/steatoepatite associata a disfunzione metabolica (NASH/MASH) con cirrosi compensata” (di seguito “**Studio**”) Survodutide (BI 456906) (di seguito “**Medicinale Sperimentale**”)*

PREMESSO che, il Promotore è lo sponsor dello Studio multicentrico per la valutazione clinica del Medicinale Sperimentale;

PREMESSO CHE, il Promotore ha stipulato un contratto con Parexel International (IRL) o un affiliato (di seguito “**CRO**”) (in base a un separato accordo scritto) per agire in qualità di contraente e delegato del Promotore nella gestione dello Studio per conto del Promotore, in conformità con il Protocollo; e

PREMESSO CHE le Parti hanno stipulato il suddetto CONTRATTO PER LA CONDUZIONE DELLA SPERIMENTAZIONE CLINICA SU MEDICINALI in data 24 febbraio 2025 (di seguito “**Contratto**”);

PREMESSO CHE, a seguito dell'emendamento al Protocollo n. 5.0 del 2 settembre 2025 (di seguito "**Emendamento al Protocollo**"), le Parti convengono di modificare il Contratto per includere il budget rivisto in conformità alle modifiche apportate al suddetto Emendamento al Protocollo.

PREMESSO CHE, le Parti sono congiuntamente disposte a modificare il Contratto di cui sopra;

Pertanto, il Contratto sopra menzionato sarà modificato e le seguenti formulazioni modificate saranno efficaci a partire dalla data dell’approvazione dell’Emendamento al Protocollo da parte del CE / IRB / AR: 6 febbraio 2026

1. A seguito dell’Emendamento al Protocollo, l'ALLEGATO A - BUDGET viene eliminato nella sua interezza e sostituito con l'ALLEGATO A - BUDGET rivisto qui allegato.

In caso di conflitto tra i termini del presente Emendamento e quelli del Contratto, prevarranno i termini del presente Emendamento.

All other terms and conditions of the above-referred Agreement remain unchanged and in full force and effect.

**IN WITNESS WHEREOF**, the Parties have executed this Amendment. In the event that the Parties execute this Amendment by exchange of electronically signed copies or facsimile signed copies, upon being signed by all Parties, the Parties agree that this Amendment will become effective and legally binding and that facsimile copies and/or electronic signatures will constitute proof of a binding agreement with the expectation that original copies may later be exchanged in good faith.

Tutti gli altri termini e condizioni del Contratto sopra menzionato rimangono invariati e pienamente validi ed efficaci.

**IN FEDE DI QUANTO SOPRA ESPOSTO**, Le Parti hanno sottoscritto il presente Emendamento. Nel caso in cui le Parti sottoscrivano il presente Emendamento mediante scambio di copie firmate elettronicamente o di copie firmate via facsimile, una volta sottoscritte da tutte le Parti, le Parti convengono che il presente Emendamento diventerà efficace e giuridicamente vincolante e che le copie facsimile e/o le firme elettroniche costituiranno prova di un accordo vincolante, con l'aspettativa che le copie originali possano essere successivamente scambiate in buona fede.

**(1) On behalf of the Sponsor Boehringer Ingelheim International GmbH Parexel International (IRL) Limited on behalf of Boehringer Ingelheim International GmbH: / Per il Promotore: Parexel International (IRL) Limited per conto di Boehringer Ingelheim International GmbH**

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(Signature of Authorized Official)

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(Typed or Printed Name)

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Date

**(2) Institution Name: Nome dell'Ente: Ospedaliera Universitaria Policlinico "P. Giaccone" di Palermo General Director / Direttrice Generale**

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Dr / Dott.ssa Maria Grazia Furnari

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(Typed or Printed Name)

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Date

**For acknowledgement of the provisions that concern him/her: the Principal Investigator / Per presa visione delle disposizioni che lo riguardano: lo Sperimentatore Principale:**

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(Signature of Investigator)

Prof. Salvatore Petta

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(Typed or Printed Name)

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Date

<b>Annex A –Payment Terms and Budget</b>	<b>Allegato A – Termini di pagamento e Budget</b>
<b>1. <u>PAYEE DETAILS</u></b>	<b>1. Dettagli del Beneficiario</b>

<b>Payee / Beneficiario</b>	<b>Payee Details / Dettagli del Beneficiario</b>
<b>Protocol Number / Numero di Protocollo</b>	1404-0064
<b>Site Number / Numero del Centro</b>	ITA3
<b>Payee Name (hereinafter “Payee”) / Nome del Beneficiario (di seguito “Beneficiario”)</b>	Azienda Ospedaliera Universitaria Policlinico “P. Giaccone”
<b>Payee Address / Indirizzo del Beneficiario</b>	Via del Vespro 129
<b>Address Line 2 / Riga Indirizzo 2</b>	NA
<b>Address Line 3 / Riga Indirizzo 3</b>	NA
<b>Province/State/Country / Provincia/Stato/Paese</b>	Palermo
<b>City / Città</b>	Palermo
<b>Postal Code / Codice Postale</b>	90127
<b>Country / Paese</b>	Italy / Italia
<b>Payee Contact / Recapiti del Beneficiario</b>	Dott.ssa Rosaria Mosca
<b>Payee Contact Phone Number / Numero di telefono del Beneficiario</b>	0039 0916555535
<b>Remittance E-mail Address / Indirizzo e-mail per le ricevute</b>	Rosaria.mosca@policlinico.pa.it
<b>General Finance contact e-mail address / Indirizzo e-mail del referente della Direzione Generale Finanza</b>	Convenzioni.sperimentazioni@policlinico.pa.it
<b>NPI</b>	NA
<b>Applicable Tax ID/VAT or GST Registration/TIN/SSN / Numero di identificazione del contribuente [TIN]/Numero di previdenza sociale [SSN])</b>	05841790826
<b>Bank Account Holder Name / Nome dell’intestatario del conto corrente bancario</b>	Azienda Ospedaliera Universitaria Policlinico “P. Giaccone”
<b>Bank Account Number / Numero conto Corrente</b>	218030

<b>bancario</b>	
<b>IBAN (18-digit International Bank Account Number)</b>	IT86P0100504600000000218030
<b>Bank Name / Nome dell'istituto di credito</b>	Banca Nazionale del Lavoro S.p.A. Via Roma n. 297
<b>Bank Routing Number / Numero di routing della banca</b>	NA
<b>Bank Branch Number / Codice filiale dell'istituto di credito</b>	NA
<b>Bank Identification Code/SWIFT Code / Codice di identificazione bancaria / Codice SWIFT</b>	BNLIITRR
<b>Payment Terms / Termini di pagamento</b>	45 (forty-five) days / 45 (quarantacinque) giorni
<b>Payment Frequency / Frequenza di pagamento</b>	Quarterly - Trimestrale
<b>Payment Currency / Valuta</b>	EUR
<b>To ensure proper payment please ensure that all fields above are completed.</b>	<b>Al fine di consentire il corretto pagamento, assicurarsi di aver compilato tutti i campi sopra riportati.</b>
In the event that Payee details are modified during the course of the study, the parties agree that no amendments to this Agreement shall be required, provided that Payee provides written notification to CRO with revised payee details to the following e-mail address, <a href="mailto:InvestigatorPaymentHelpDesk@parexel.com">InvestigatorPaymentHelpDesk@parexel.com</a> . CRO's Investigator Payment Office will attempt to independently verify banking information changes to ensure they are valid. If Payee does not respond to these verification attempts, CRO's Investigator Payment Office will modify the banking information as per the email but accepts no liability for incorrect payee details provided by the Payee, its representative or any other third party. Any payments that are fraudulently misdirected will not be re-paid.	In caso di variazione dei dati del Beneficiario nel corso dello Studio, le parti convengono di non emendare il presente Contratto, a condizione che l'Ente comunichi per iscritto alla CRO i dati aggiornati del beneficiario al seguente indirizzo e-mail <a href="mailto:InvestigatorPaymentHelpDesk@PAREXEL.com">InvestigatorPaymentHelpDesk@PAREXEL.com</a> . L'Investigator Payment Office della CRO tenterà di verificare in modo indipendente le modifiche alle informazioni bancarie per garantire che siano valide. Se il Beneficiario non risponde a questi tentativi di verifica, l'Investigator Payment Office della CRO modificherà le informazioni bancarie come indicato nell'e-mail ma non si assume alcuna responsabilità per i dati errati del beneficiario forniti dal Beneficiario, dal suo rappresentante o da qualsiasi altra terza parte. Eventuali pagamenti fraudolentemente indirizzati in modo errato non verranno rimborsati.
<b>2. <u>ENROLMENT</u></b>	<b>2. <u>Arruolamento</u></b>
This Study is designed to evaluate Subjects in accordance with the Protocol. The Investigator on	Il presente Studio è finalizzato a valutare i pazienti in conformità al Protocollo. Lo Sperimentatore, per conto

<p>behalf of the Institution will use best efforts to enrol Subjects. When enrolment is complete for the Study, the Institution will be notified in writing and will discontinue enrolling Subjects.</p>	<p>dell'Ente, farà quanto in suo potere per arruolare pazienti. Una volta completato l'arruolamento per lo Studio, l'Ente sarà informato per iscritto e provvederà a interrompere l'arruolamento dei pazienti.</p>
<p><b><u>3. PER SUBJECT FEES:</u></b></p>	<p><b><u>3. Costi per paziente:</u></b></p>
<p>The amount to be paid to the Payee per completed subject is outlined in the attached Detailed Budget. Invoices should be submitted by Payee to CRO on a quarterly basis and all payments will be made electronically within forty-five (45) days of receipt, review and approval of an invoice and will be based on completed visits entered in the subject EDC (electronic data capture system) according to agreed-upon criteria.</p>	<p>L'importo da corrispondere al Beneficiario per ogni soggetto valutabile completato è specificato nel Budget dettagliato allegato. Il Beneficiario dovrà presentare le fatture alla CRO su base trimestrale e tutti i pagamenti saranno effettuati elettronicamente entro quarantacinque (45) giorni dal ricevimento, revisione e approvazione di una fattura e si baseranno sulle visite completate inserite nell'EDC del soggetto (sistema elettronico di acquisizione dati) secondo criteri concordati.</p>
<p><b><u>4. CONDITIONAL FEES AND INVOICEABLE FEES:</u></b></p>	<p><b><u>4. Costi condizionali e fatturabili:</u></b></p>
<p>Payment for other conditional fees or expenses that are not included in the Per Subject Fees (as defined in Section 3) will be made according to the below rates as outlined in the below attached Detailed Budget:</p>	<p>Il pagamento di altri costi o spese condizionali non inclusi nei Costi per paziente (come definito nella Sezione 3) sarà effettuato secondo le tariffe sotto indicate, come specificato nel Budget dettagliato allegato:</p>
<p><b><i>SCREENING FAILURE:</i></b> Screening Failures will be reimbursed according to actual procedures performed, based on the individual item costs outlined on the below-attached Detailed Budget, upon entry of complete information into EDC and CRO's receipt of an undisputed, detailed, itemized invoice. All Screen Failures, will be reimbursed for 100% of actual incurred procedures and invoiceable costs as outlined on the below attached Detailed Budget. Institution will make every effort to avoid unnecessary procedures and to establish if a Subject is a screen failure based on the eligibility criteria defined by the Protocol. When the Institution reaches or exceeds a screen failure ratio of 4:1 (four screen failure Subject that have performed either 4 MRI-PDFF or 4 liver biopsy, whichever occurs first, per one enrolled Subject), the CRO,</p>	<p><b><i>SCREENING FAILURE:</i></b> I fallimenti dello screening saranno rimborsati in base alle procedure effettivamente eseguite, in base ai costi delle singole voci indicati nel Budget dettagliato allegato di seguito, previa immissione di informazioni complete nell'EDC e ricezione da parte della CRO di una fattura dettagliata, incontestata e dettagliata. Tutti i fallimenti dello screening saranno rimborsati al 100% delle procedure effettivamente sostenute e dei costi fatturabili, come indicato nel Budget dettagliato allegato di seguito. L'Ente farà ogni sforzo per evitare procedure non necessarie e per stabilire se un soggetto è un fallimenti dello screening in base ai criteri di idoneità definiti dal Protocollo. Quando l'Ente raggiunge o supera un rapporto di fallimenti dello screening di 4:1 (quattro soggetti con fallimenti dello</p>

<p>Sponsor or delegate may review the patient characteristics and discuss the targeting of appropriate patients with the site. The SPONSOR, Sponsor delegate or CRO has the right to limit, reduce or halt future screening based on this evaluation. The Institution is allowed to continue screening activities during the evaluation process until otherwise notified by the SPONSOR or CRO. A screening failure is considered a Subject who signs the informed consent form and completes screening but fails under inclusion/exclusion criteria and will not be enrolled.</p>	<p>screening che hanno eseguito 4 MRI-PDFF o 4 biopsie epatiche, a seconda di quale evento si verifichi per primo, per un soggetto arruolato), la CRO, il Promotore o un delegato possono esaminare le caratteristiche del paziente e discutere con il centro l'individuazione dei pazienti appropriati. Il Promotore, il delegato del Promotore o la CRO hanno il diritto di limitare, ridurre o interrompere i futuri screening in base a questa valutazione. L'Ente è autorizzato a continuare le attività di screening durante il processo di valutazione fino a diversa comunicazione da parte del Promotore o della CRO. Si considera fallimento dello screening quando il Soggetto firma il modulo di consenso informato e completa lo screening, ma non soddisfa i criteri di inclusione/esclusione e non verrà arruolato.</p>
<p><b>RE-SCREENING:</b> Screen failures may be re-screened once upon SPONSOR's or CRO's previous approval, in accordance with the Protocol. Re-screening will be reimbursed according to actual procedures performed, based on the individual item costs outlined in the below attached Detailed Budget. Payment will be made electronically within forty-five (45) days of receipt, review and approval of the invoice and will be validated on completed info verified and entered in the electronic case report form or supporting documentation, as applicable.</p>	<p><b>RE-SCREENING:</b> I fallimenti dello screening possono essere ricontrattati solo previa approvazione del Promotore o della CRO, in conformità con il Protocollo. Il Re-Screening sarà rimborsato secondo le procedure effettivamente eseguite, basandosi sui costi dei singoli elementi indicati nel Budget Dettagliato allegato qui sotto. Il pagamento sarà effettuato elettronicamente entro quarantacinque (45) giorni dal ricevimento, revisione e approvazione della fattura e sarà convalidato sulle informazioni completate verificate e inserite nell'electronic case report form o nella documentazione di supporto, se applicabile.</p>
<p><b>SUBJECT REIMBURSEMENT:</b> Reasonable patient's expenses during the Study will be reimbursed.</p> <p>Subject reimbursement will be managed and paid directly through CRO/SPONSOR third-party vendor (hereinafter "<b>Vendor</b>") and will not be considered part of the Study Subject payments made to payee.</p> <p>The reimbursement will be managed as follows: any travel organized independently by the patient and any costs, such as meals, parking, and mileage, will be reimbursed by Institution directly to the patient. Namely, the Vendor pays to Institution, and Institution reimburses the patient. Institution will be required to complete a form (which contains no patient information, except for the patient ID, number, and date of visits) and will be responsible for retaining the corresponding receipts.</p>	<p><b>RIMBORSO DEL SOGGETTO:</b> Saranno rimborsate le spese di viaggio ragionevoli sostenute dal paziente durante lo Studio.</p> <p>Il rimborso del Soggetto sarà gestito e pagato direttamente tramite il fornitore terzo di CRO/Promotore (di seguito "<b>Fornitore</b>") e non sarà considerato parte dei pagamenti effettuati dal Soggetto dello Studio al'Ente.</p> <p>Il rimborso avverrà come segue: qualsiasi viaggio organizzato dal paziente in autonomia e qualsiasi costo come pasti, parcheggio e chilometraggio verrà rimborsato dall'Ente direttamente al paziente, ovvero: il Fornitore paga l'Ente, l'Ente rimborsa il paziente. L'Ente sarà tenuto alla compilazione di un form (che non contiene informazioni sul paziente, ad eccezione del codice identificativo del paziente, del numero e della data delle visite), e sarà responsabile della conservazione delle ricevute corrispondenti.</p>

It is hereby noted that the Vendor will not be required to manage patient travel arrangements and that the Vendor will therefore not in any way come into possession of the patients' identifying data.

The patient reimbursement needs to be reflected in the informed consent form. In the event that there is a conflict between the informed consent form and this Agreement, the informed consent form shall govern and control in all matters relating to Subject reimbursement. In case reimbursement is managed by Institution, any request for reimbursement of Subject travel that exceeds the per visit amount set out in the Detailed Budget requires the prior written approval of the CRO and/or Sponsor on case by case basis.

Si precisa che al Fornitore non verrà richiesto di gestire l'organizzazione dei viaggi dei pazienti e che lo stesso non entrerà quindi in alcun modo in possesso dei dati identificativi dei pazienti.

Il rimborso del paziente deve essere indicato nel modulo di consenso informato. In caso di conflitto tra il modulo di consenso informato e il presente Contratto, il modulo di consenso informato prevarrà e prevarrà per tutte le questioni relative al rimborso del Soggetto. Nel caso in cui il rimborso sia gestito dall'Ente, qualsiasi richiesta di rimborso per le spese di viaggio del Soggetto che superi l'importo per visita indicato nel Budget Dettagliato richiede la previa approvazione scritta della CRO e/o del Promotore, caso per caso.

<p><b>UNSCHEDULED VISIT:</b> Unscheduled visits performed as part of the Study that are outside of the normal standard of patient care and visit schedule will be reimbursed according to actual procedures performed, based on the individual item costs outlined on the below-attached Detailed Budget, upon entry of complete information into EDC and CRO's receipt of an undisputed, detailed, itemized invoice.</p>	<p><b>VISITA NON PROGRAMMATA:</b> le visite non programmate eseguite come parte dello Studio che sono al di fuori del normale standard di cura del paziente e del programma delle visite saranno rimborsate in base alle effettive procedure eseguite, in base ai costi delle singole voci delineati nel Budget dettagliato allegato di seguito, a seguito dell'inserimento di informazioni complete in EDC e al ricevimento da parte della CRO di una fattura indiscussa e dettagliata.</p>
<p><b>MEDICAL CHART REVIEW FEE:</b> The Institution will receive a payment of a medical chart review fee as outlined on the below attached Detailed Budget (which includes overhead) per chart, upon receipt of an undisputed invoice from Institution. Institution will perform up to 10 chart reviews per randomized patient. CRO reserves the right to cross-check which chart reviews have been performed using a pre-screening log, and the documented inclusion/exclusion criteria.</p>	<p><b>COMPENSO PER LA REVISIONE DELLA CARTELLA MEDICA:</b> L'Ente riceverà il pagamento di una tariffa per la revisione della cartella medica come indicato nel Budget dettagliato allegato di seguito (che include le spese generali) per cartella, al ricevimento di una fattura non contestata dall'Ente fino a un massimo di 10 revisioni della cartella per un (1) paziente randomizzato. La CRO si riserva il diritto di verificare quali revisioni delle cartelle siano state eseguite utilizzando un registro di pre-screening e i criteri di inclusione/esclusione documentati.</p>
<p>Payee will issue one consolidated invoice at quarter end for all services performed and expenses incurred under this section during that quarter. Payment will be made electronically within forty-five (45) days of receipt, review and approval of the invoice and will be validated on completed info verified and entered in the electronic case report form or supporting documentation, as applicable.</p>	<p>Il Beneficiario emetterà una fattura consolidata alla fine del trimestre per tutti i servizi eseguiti e le spese sostenute ai sensi della presente sezione durante quel trimestre. Il pagamento verrà effettuato elettronicamente entro quarantacinque (45) giorni dal ricevimento, revisione e approvazione della fattura e sarà convalidato sulle informazioni completate, verificate e inserite nel modulo elettronico o nella documentazione di supporto, a seconda dei casi.</p>
<p><b>5. <u>SITE FEES:</u></b></p>	<p><b>5. <u>TARIFFE DEL CENTRO:</u></b></p>
<p><b>START-UP FEE:</b> A one-time non-refundable start-up fee in the amount outlined in the below attached Detailed Budget will be paid to Payee for start-up related activities (e.g. preparation of regulatory documents, preparation, administration and submission of Protocol and related documents to the IRB/EC, etc.). Payment will be made upon execution of the Agreement, IRB/EC approval, and Institution activation visit, all qualifiers must be completed to receive payment. This payment is considered full and</p>	<p><b>COMPENSO DI AVVIO:</b> Un compenso di avvio Studio una tantum non rimborsabile per l'importo indicato nel Budget dettagliato allegato di seguito sarà pagato al Beneficiario per le attività relative all'avvio (ad esempio preparazione di documenti normativi, preparazione, amministrazione e presentazione di Protocollo e documenti correlati all'IRB/CE, ecc.). Il pagamento verrà effettuato al momento dell'esecuzione del Contratto, dell'approvazione dell'IRB/CE e della visita di attivazione dell'Ente; tutte</p>

<p>final compensation for all activities associated with Study initiation. Payment to Payee will be made upon receipt of the corresponding invoice.</p>	<p>le qualificazioni dovranno essere completate per ricevere il pagamento. Questo pagamento è considerato un compenso completo e definitivo per tutte le attività associate all'inizio dello Studio. Il pagamento al Beneficiario verrà effettuato al ricevimento della fattura corrispondente.</p>
<p>All invoices for Services performed and expenses incurred under this Section will be paid within forty-five (45) days of receipt, review and approval of an invoice and will be based on completed info verified.</p>	<p>Tutte le fatture per i Servizi eseguiti e le spese sostenute ai sensi della presente Sezione saranno pagate entro quarantacinque (45) giorni dal ricevimento, revisione e approvazione di una fattura e saranno basate sulle informazioni completate e verificate.</p>
<p><b>6. <u>PRO-RATA PAYMENTS:</u></b></p>	<p><b><u>6. Pagamenti su base proporzionale:</u></b></p>
<p>Payment for Subjects who do not complete the Study may be made to Payee on a pro-rated basis. Payment will include only those Subjects who were enrolled before the premature termination of the Study or the date that notice is received of such premature termination, whichever is later.</p>	<p>Il pagamento per i soggetti che non completano lo Studio potrà essere effettuato al Beneficiario su base proporzionale. Il pagamento comprenderà soltanto i Soggetti arruolati prima dell'interruzione anticipata dello Studio o della data di ricevimento della notifica avente per oggetto tale interruzione anticipata, a seconda di quale situazione si verifichi per ultima.</p>
<p>Should SPONSOR terminate the Study prior to completion, pro-rated expenses and fees shall be paid as set forth in Section 3 for each Subject visit performed before the premature termination of the Study or the date notice is received of such premature termination, whichever is later.</p>	<p>Laddove il Promotore termini lo studio prima del suo completamento, le spese e i costi su base proporzionale saranno liquidati nei termini previsti dalla Sezione 3 per ogni visita del soggetto eseguita prima dell'interruzione anticipata dello studio o della data di ricezione dell'avviso di tale interruzione anticipata, a seconda di quale situazione si verifichi per ultima.</p>
<p>If other non-cancelable costs are incurred by Institution in accordance with the Agreement, written justification must be provided to SPONSOR for review and approval, and payment of such costs is subject to SPONSOR's approval</p>	<p>Laddove vengano sostenuti altri costi non cancellabili dall'Ente, in conformità al Contratto, sarà necessario fornire una giustificazione scritta al Promotore, per l'esame e l'approvazione, e il pagamento di detti costi sarà soggetto all'approvazione del Promotore.</p>
<p>In any instance where the Payee has been received unearned funds, such funds shall be returned to CRO within forty-five (45) days of notification.</p>	<p>In tutti i casi, qualora il Beneficiario dovesse ricevere finanziamenti non giustificati, tali fondi dovranno essere restituiti alla CRO entro quarantacinque (45) giorni dal relativo avviso.</p>

<p><b>7. <u>PROTOCOL VIOLATORS</u></b></p>	<p><b>7. <u>Soggetti che violano il Protocollo</u></b></p>
<p>Payments for Study Subjects who are deemed to have been in violation of the Protocol may be paid up to the point that the violation occurred at the discretion of SPONSOR.</p>	<p>I pagamenti per i Soggetti in Studio che si ritenga abbiano violato il Protocollo possono essere esigibili fino al punto in cui si sia verificata la violazione, a discrezione del Promotore.</p>
<p><b><u>8. Invoices</u></b></p>	<p><b><u>8. Fatture</u></b></p>
<p>Correct Valid Invoices should be addressed/issued to:</p> <p>Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany VAT #DE 811138149</p> <p>Payment agent: PAREXEL International (IRL) Limited</p> <p>Preferred method of invoice submission is through CRO's self-service Site Pay Portal (hereinafter "Portal"). Payee will receive instructions on how to access and register to the Portal once Detailed Budget is set up in the Portal.</p> <p>In case Payee is not able to submit invoice through the Portal, correct valid invoices should be e-mailed to <a href="mailto:sitepaymentinvoicing@parexel.com">sitepaymentinvoicing@parexel.com</a> PAREXEL Study no.: 284657</p> <p>with the following details:</p> <ul style="list-style-type: none"> <li>• Protocol number or CRO project number shall be indicated in the subject line of the email.</li> <li>• Protocol number /CRO project number, Investigator name, site name and invoice number shall be indicated in the body of the email.</li> </ul> <p>Paper invoices can be sent to: Sponsor Boehringer Ingelheim International GmbH,</p>	<p>Le fatture valide corrette devono essere intestate a:</p> <p>Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germania P.IVA #DE 811138149</p> <p>Agente di pagamento: PAREXEL International (IRL) Limited</p> <p>Il metodo preferito per l'invio delle fatture è tramite il Portale di Pagamento Self-Service per i centri della CRO (di seguito "Portale"). Il beneficiario riceverà istruzioni su come accedere e registrarsi al "Portale" una volta che il Budget Dettagliato sarà configurato nel Portale. Nel caso in cui il beneficiario non sia in grado di presentare la fattura tramite il "Portale", le fatture corrette e valide dovranno essere inviate via e-mail a: <a href="mailto:sitepaymentinvoicing@parexel.com">sitepaymentinvoicing@parexel.com</a> Studio PAREXEL n.: 284657</p> <p>con i seguenti dettagli:</p> <ul style="list-style-type: none"> <li>. il numero di protocollo o il numero di progetto CRO devono essere indicati nell'oggetto dell'e-mail</li> <li>. il numero di protocollo / numero di progetto CRO / nome dello Sperimentatore / nome del centro e numero di fattura devono essere indicati nel corpo dell'e-mail</li> </ul> <p>Le fatture cartacee possono essere intestate a: Sponsor Boehringer Ingelheim International GmbH,</p>

c/o PAREXEL International (IRL) Limited One Park Place Block C 1ST floor Upper Hatch Street Dublin 2 D02 E762 Ireland  Parexel Study no.: 284657	c/o PAREXEL International (IRL) Limited One Park Place Block C 1ST floor Upper Hatch Street Dublin 2 D02 E762 Irlanda  Studio PAREXEL n.: 284657
All invoices must contain the following information:	Tutte le fatture dovranno contenere le seguenti informazioni:
(a) Protocol Number: 1404-0064	(a) Numero di Protocollo 1404-0064
(b) Invoice Number	(b) Numero di fattura
(c) Invoice Date	(c) Data della fattura
(d) Place, Date & Description of Services Provided	(d) Luogo, data e descrizione dei servizi forniti
(e) CRO Project Number: 284657	(e) Numero del progetto della CRO 284657
(f) Total amount payable	(f) Importo totale dovuto
(g) Exchange rate used (where applicable)	(g) Tasso di cambio utilizzato (ove pertinente)
(h) Investigator Name	(h) Nome dello Sperimentatore
(i) Site Number:	(i) Numero del centro
(j) Investigator National Provider Identification (NPI) Number	(j) Codice identificativo del fornitore nazionale (NPI) dello Sperimentatore
(k) Payee Name and Address (per this Agreement)	(k) Nome e indirizzo del Beneficiario (indicati nel presente Contratto)
(l) Date of Supply	(l) Data della fornitura
Invoices and associated documentation should be de-identified of Subject personal information (e.g. name, date of birth, initials, etc.) prior to being submitted to CRO.	Le fatture e la documentazione associata devono essere private delle informazioni personali dei pazienti (per es. nome, data di nascita, iniziali, ecc.) prima di essere trasmesse alla CRO.
<b>9. <u>FINAL PAYMENT</u></b>	<b>9. <u>Pagamento finale</u></b>
Notwithstanding the foregoing, the final payment shall	Fermo restando quanto precede, il pagamento finale

be made upon the completion of the following activities:	sarà liquidato al completamento delle seguenti attività:
(a) all required Subject visits have been completed	(a) tutte le visite del soggetto previste siano state completate
(b) SPONSOR has received all Subject data in a form suitable for analysis	(b) ricezione da parte del Promotore di tutti i dati del Soggetto in formato idoneo per l'analisi
(c) all data clarification queries have been resolved to SPONSOR's satisfaction	(c) risoluzione di tutte le richieste di chiarimento dei dati, in maniera soddisfacente per il Promotore
(d) SPONSOR has verified that all required regulatory documentation is complete	(d) verifica da parte del Promotore della completezza di tutta la documentazione normativa richiesta
(e) Institution has returned all required equipment, drugs and other material	(e) restituzione da parte dell'Ente di tutti gli Strumenti, farmaci e altri materiali richiesti
(f) the Study close-out visit has been completed	(f) la visita di fine Studio sia stata completata
Payee shall have thirty (30) days from the receipt of the final payment under this Agreement to identify discrepancies and resolve any payment disputes with CRO.	Il Beneficiario avrà trenta (30) giorni di tempo dalla ricezione del pagamento finale ai sensi del presente Contratto, per identificare eventuali discrepanze e risolvere qualsiasi disputa di pagamento con la CRO.
All invoices for Study payments, as outlined herein, must be submitted to the CRO within sixty (60) days of the Institution's Study close-out visit. Invoices received after this time will not be reimbursed.	Tutte le fatture per i pagamenti dello Studio, le spese aggiuntive, come indicato nel presente, devono essere presentate alla CRO entro sessanta (60) giorni dalla visita di fine studio dell'Ente. Le fatture ricevute dopo questo termine non saranno rimborsate.
<b>10. <u>TAX</u></b>	<b>10. <u>IMPOSTE</u></b>
All fees and expenses in this Annex A are exclusive of VAT or any applicable tax. All payments are subject to withholding tax as applicable.	Tutte le commissioni e spese nel presente Allegato A sono da intendersi al netto di IVA o di qualsiasi imposta applicabile. Tutti i pagamenti sono soggetti alle ritenute alla fonte ove pertinente.

## Detailed Budget – Budget dettagliato

### Budget Information

Standard Condition Overall  
 al  
 Total Cost per Patient: 37,419.28 10,506.12 47,925.40

Location: Italy  
 Site Type: All Site Types  
 Overhead Percent: 16.00%  
 Currency: EUR - Euro

### Procedures

Code	Name	OH?	Total	Selected	SV1	V2_RAND_D1	V3_D15_R	V4_D29_C	V5_D43_R	V6_D57_C	V7_D85_C	V8_D113_C	V9_D141_C	V10_D169_C	V11_D211_R	V12_D253_C	V13_D295_R	V14_D337_C	V15_D379_R	V16_D421_C
			Quantity	Cost																
*INCO	Informed consent	Y	1.00	55.00	55.00															
*INEX	Review in-/exclusion criteria	Y	2.00	30.00	30.00	30.00														
*DEMO	Demographics	Y	1.00	25.00	25.00															
*3322	Medical history	Y	1.00	50.00	50.00															
99213	Complete Physical examination including one set of Vital signs (SBP, DBP, pulse), and weight	Y	1.00	85.00	85.00															
99212	Brief Physical examination including one set of Vital signs (SBP, DBP, pulse), height and weight	Y	16.00	75.00		75.00				75.00				75.00		75.00		75.00		75.00
*BMI*	Body Mass Index (BMI)	Y	1.00	18.00	18.00															
*MEAC	Waist and hip circumference	Y	20.00	11.00		11.00		11.00		11.00	11.00	11.00	11.00	11.00		11.00		11.00		11.00
99211	Vital signs (SBP, DBP, pulse) including weight	Y	4.00	26.00				26.00		26.00		26.00	26.00							
93000	12-lead ECG w/ Interpret. & Report	Y	14.00	56.00	168.00	56.00		56.00		56.00				56.00		56.00				56.00
*RCM*	Concomitant therapy	Y	33.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00
*GADS	Evaluation of portal hypertension treatment, Evaluation of lipid-lowering treatment, Evaluation of anti-hypertension treatment, Evaluation of anti-hyperglycaemic treatment (10 mins assessment)	Y	32.00	16.00		32.00					32.00			32.00		32.00		32.00		32.00
*ADVE	All AEs/AESIs	Y	33.00	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
*ISRS	Check for injection site reaction	Y	19.00	6.00		6.00		6.00		6.00	6.00	6.00	6.00	6.00		6.00		6.00		6.00
NC011	Complex Venipuncture - Safety laboratory tests, HBV, HCV, HIV, Pregnancy testing- serum(if applicable), Liver tests (ALT, AST, GGT, ALP, TBL, ALB), HbA1c, FPG, FPL, fasting C-peptide, Lipids tests: total cholesterol, HDL, LDL, VLDL, triglycerides, and free fatty acids, eGFRcr and eGFRcys, ELF samples, Other biomarkers samples, glucagon analysis , ADA, NAb samples, Alpha-fetoprotein	Y	21.00	32.00	32.00	32.00		32.00		32.00	32.00	32.00	32.00	32.00		32.00		32.00		32.00

**Procedures**

Code	Name	V17_D463_R	V18_D505_C	V19_D533_C	V20_W82_R	V21_W88_C	V22_W94_R	V23_W100_C	V24_W106_R	V25_W112_C	V26_W118_R	V27_W124_C	V28_W130_R	V29_W136_C	V30_W142_R	V31_W148_C	EOT	FU/EOS	Total	ETD
*INCO	Informed consent																		55.00	
*INEX	Review in-/exclusion criteria																		60.00	
*DEMO	Demographics																		25.00	
*3322	Medical history																		50.00	
99213	Complete Physical examination including one set of Vital signs (SBP, DBP, pulse), and weight																		85.00	
99212	Brief Physical examination including one set of Vital signs (SBP, DBP, pulse), height and weight		75.00	75.00		75.00		75.00		75.00		75.00		75.00		75.00	75.00	75.00	1,200.00	75.00
*BMI*	Body Mass Index (BMI)																		18.00	
*MEAC	Waist and hip circumference		11.00	11.00		11.00		11.00		11.00		11.00		11.00		11.00	11.00	11.00	220.00	11.00
99211	Vital signs (SBP, DBP, pulse) including weight																		104.00	
93000	12-lead ECG w/ Interpret. & Report					56.00				56.00				56.00			56.00	56.00	784.00	56.00
*RCM*	Concomitant therapy	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	660.00	20.00
*GADS	Evaluation of portal hypertension treatment, Evaluation of lipid-lowering treatment, Evaluation of anti-hypertension treatment, Evaluation of anti-hyperglycaemic treatment (10 mins assessment)		32.00	32.00		32.00		32.00		32.00		32.00		32.00		32.00	32.00	32.00	512.00	32.00
*ADVE	All AEs/AESIs	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	561.00	17.00
*ISRS	Check for injection site reaction		6.00	6.00		6.00		6.00		6.00		6.00		6.00		6.00	6.00		114.00	6.00
NC011	Complex Venipuncture - Safety laboratory tests, HBV, HCV, HIV, Pregnancy testing- serum(if applicable), Liver tests (ALT, AST, GGT, ALP, TBL, ALB), HbA1c, FPG, FPI, fasting C-peptide, Lipids tests: total cholesterol, HDL, LDL, VLDL, triglycerides, and free fatty acids, eGFRcr and eGFRcys, ELF samples, Other biomarkers samples, glucagon analysis, ADA, NAb samples, Alpha-fetoprotein		32.00	32.00		32.00		32.00		32.00		32.00		32.00		32.00	32.00	32.00	672.00	32.00

**Procedures**

Code	Name	OH?	Total Quantity	Selected Cost	SV1	V2_RAND_D1	V3_D15_R	V4_D29_C	V5_D43_R	V6_D57_C	V7_D85_C	V8_D113_C	V9_D141_C	V10_D169_C	V11_D211_R	V12_D253_C	V13_D295_R	V14_D337_C	V15_D379_R	V16_D421_C	V17_D463_R	
NC017	Urine Collection - Urine analysis, UACR	Y	15.00	10.00		10.00				10.00				10.00		10.00		10.00		10.00		
99000	Handling and shipment - Central lab	Y	21.00	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	
91200	FibroScan® (VCTE, CAP)	Y	8.00	422.00	422.00									422.00						422.00		
*FBRS	ELF Score	Y	8.00	40.00	40.00	40.00								40.00						40.00		
80299	PK	Y	13.00	42.00		42.00		42.00			42.00			42.00		42.00				42.00	42.00	
*FAST	FAST Score	Y	8.00	35.00	35.00									35.00						35.00		
*GADS	AGILE Score	Y	8.00	16.00	16.00									16.00						16.00		
91110	UGE	Y	4.00	1,892.00	1,892.00															1,892.00		
76700	Abdominal ultrasound	Y	8.00	384.00	384.00									384.00						384.00		
76830-26	Abdominal ultrasound - Interpretation & Report Only	Y	8.00	101.00	101.00									101.00						101.00		
*CPC*	CPT	Y	21.00	15.00	15.00	15.00		15.00		15.00	15.00	15.00	15.00	15.00		15.00				15.00	15.00	
*MELD	MELD scores	Y	21.00	34.00	34.00	34.00		34.00		34.00	34.00	34.00	34.00	34.00		34.00				34.00	34.00	
*GADS	Assessment of ascites and HE	Y	21.00	16.00	16.00	16.00		16.00		16.00	16.00	16.00	16.00	16.00		16.00				16.00	16.00	
*GADS	-Liver Disease Progression (5min assessment)	Y	20.00	16.00	16.00	16.00		16.00		16.00	16.00	16.00	16.00	16.00		16.00				16.00	16.00	
*DPSD	Hand out IFU – pre-filled syringe and Hand out of SMBG device (trial participants with T2DM), and trial participant materials	Y	2.00	28.00	28.00	28.00																
*RPMD	eDiary review (IMP administration, injection site reactions, and compliance check), ePRO - NASH-CHECK Questionnaire, CLDQ NAFLD-NASH, PHQ-9, C-SSRS	Y	33.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00
98960	Training in/observe pre-filled syringe administration	Y	1.00	82.00		82.00																
98966	Vital status_Phone call	Y	1.00	25.00																		
99401	Diet and physical activity counselling	Y	29.00	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	
NC008	Remote visit	Y	12.00	23.00			23.00		23.00						23.00		23.00			23.00	23.00	
Per Patient Activity Totals:					3,539.00	688.00	91.00	417.00	91.00	319.00	508.00	319.00	319.00	1,506.00	161.00	508.00	161.00	3,342.00	161.00	508.00	161.00	

**Procedures**

Code	Name	V18_D505_C	V19_D533_C	V20_W82_R	V21_W88_C	V22_W94_R	V23_W100_C	V24_W106_R	V25_W112_C	V26_W118_R	V27_W124_C	V28_W130_R	V29_W136_C	V30_W142_R	V31_W148_C	EOT	FU/EOS	Total	ETD
NC017	Urine Collection - Urine analysis, UACR		10.00		10.00		10.00		10.00		10.00		10.00		10.00	10.00	10.00	150.00	10.00
99000	Handling and shipment - Central lab	25.00	25.00		25.00		25.00		25.00		25.00		25.00		25.00	25.00	25.00	525.00	25.00
91200	FibroScan® (VCTE, CAP)		422.00				422.00				422.00				422.00	422.00		3,376.00	422.00
*FBRS	ELF Score		40.00		40.00								40.00			40.00		320.00	40.00
80299	PK		42.00		42.00				42.00				42.00			42.00	42.00	546.00	42.00
*FAST	FAST Score		35.00				35.00				35.00				35.00	35.00		280.00	35.00
*GADS	AGILE Score		16.00				16.00				16.00				16.00	16.00		128.00	16.00
91110	UGE						1,892.00									1,892.00		7,568.00	1,892.00
76700	Abdominal ultrasound		384.00		384.00				384.00				384.00			384.00		3,072.00	384.00
76830-26	Abdominal ultrasound - Interpretation & Report Only		101.00		101.00				101.00				101.00			101.00		808.00	101.00
*CPC*	CPT	15.00	15.00		15.00		15.00		15.00		15.00		15.00		15.00	15.00	15.00	315.00	15.00
*MELD	MELD scores	34.00	34.00		34.00		34.00		34.00		34.00		34.00		34.00	34.00	34.00	714.00	34.00
*GADS	Assessment of ascites and HE	16.00	16.00		16.00		16.00		16.00		16.00		16.00		16.00	16.00	16.00	336.00	16.00
*GADS	-Liver Disease Progression (5min assessment)	16.00	16.00		16.00		16.00		16.00		16.00		16.00		16.00	16.00	16.00	320.00	16.00
*DPSD	Hand out IFU – pre-filled syringe and Hand out of SMBG device (trial participants with T2DM), and trial participant materials																	56.00	
*RPMD	eDiary review (IMP administration, injection site reactions, and compliance check), ePRO - NASH-CHECK Questionnaire, CLDQ NAFLD NASH, PHQ-9, C-SSRS	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	1,023.00	31.00
98960	Training in/observe pre-filled syringe administration																	82.00	
98966	Vital status_Phone call																25.00	25.00	
99401	Diet and physical activity counselling	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		2,030.00	70.00
NC008	Remote visit			23.00		23.00		23.00		23.00		23.00		23.00				276.00	
Per Patient Activity Totals:		400.00	1,450.00	161.00	1,033.00	161.00	2,775.00	161.00	993.00	161.00	883.00	161.00	1,033.00	161.00	883.00	3,398.00	457.00	27,070.00	3,398.00

**Non Procedures**

Code	Name	OH?	Total	Selected	SV1	V2_RAND_D1	V3_D15_R	V4_D29_C	V5_D43_R	V6_D57_C	V7_D85_C	V8_D113_C	V9_D141_C	V10_D169_C	V11_D211_R	V12_D253_C	V13_D295_R	V14_D337_C	V15_D379_R	V16_D421_C	V17_D463_R	
			Quantity	Cost																		
*STCO	Study Coordinator; Per Visit - data entry	Y	28.00	69.00	138.00	69.00	34.50	69.00	34.50	69.00	69.00	69.00	69.00	69.00	34.50	69.00	34.50	69.00	34.50	69.00	34.50	69.00
V1110	Physician Salary	Y	28.00	41.00	82.00	41.00	20.50	41.00	20.50	41.00	41.00	41.00	41.00	41.00	20.50	41.00	20.50	41.00	20.50	41.00	20.50	41.00
*NURS	Nurse; Per Visit	Y	22.00	68.00	136.00	68.00		68.00		68.00	68.00	68.00	68.00	68.00		68.00		68.00		68.00		68.00
VPHRM	Dispensing, Simple; Per Visit - Hand out IFU – pre-filled syringe, dispense IMP	Y	18.00	34.00		34.00		34.00		34.00	34.00	34.00	34.00	34.00		34.00		34.00		34.00		34.00
Per Patient Other Direct Cost Totals:						356.00	212.00	55.00	212.00	55.00	212.00	212.00	212.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00

**Conditional**

Code	Name	OH?	Total	Selected	SV1	V2_RAND_D1	V3_D15_R	V4_D29_C	V5_D43_R	V6_D57_C	V7_D85_C	V8_D113_C	V9_D141_C	V10_D169_C	V11_D211_R	V12_D253_C	V13_D295_R	V14_D337_C	V15_D379_R	V16_D421_C	V17_D463_R	
			Quantity	Cost																		
47000	Liver biopsy	Y	1.00	800.00	800.00																	
99152	Moderate Sedation Init 15 Min 5+yrs	Y	1.00	205.00	205.00																	
NC065	Biopsy Sample Handling Simple	Y	1.00	21.00	21.00																	
91110	UGE ('For participants without 'high-risk' GOVs or previous endoscopic treatment for esophageal varices at baseline')	Y	1.00	1,892.00																		
*GNCO	Informed Consent: DNA, Genetics	Y	1.00	35.00	35.00																	
*IWQL	Assessment of obesity staging (For participants with BMI ≥30 kg/m2 (≥25 kg/m2 for Asian ethnicity)	Y	2.00	22.00		22.00																
*SAEA	All SAEs - per occurrence	Y		19.00																		
36415	Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics, - Reticulocytes (only for patients with Gilbert Syndrome), Pancreatic amylase (at screening, and CK-MB,Troponin as reflex test if amylase is elevated at all other visits, including DILI evaluation visit)	Y	4.00	29.00	29.00	29.00								29.00								
NC017	Urine Collection - Urine pregnancy test (if	Y	6.00	10.00	10.00			10.00		10.00		10.00	10.00									
80299	Additional PK sample collection	Y		42.00																		



**Conditional**

Code	Name	OH?	Total	Selected	SV1	V2_RAND_D1	V3_D15_R	V4_D29_C	V5_D43_R	V6_D57_C	V7_D85_C	V8_D113_C	V9_D141_C	V10_D169_C	V11_D211_R	V12_D253_C	V13_D295_R	V14_D337_C	V15_D379_R	V16_D421_C	V17_D463_R
			Quantity	Cost																	
99000	Preparation of sample for shipping - central lab	Y	4.00	25.00	25.00	25.00								25.00							
92012	Eye examination	Y	5.00	70.00	70.00									70.00							
*NASH	NASH-CHECK Questionnaire (only in case of paper questionnaires)	Y	10.00	18.00		18.00				18.00				18.00					18.00		18.00
*CLDQ	CLDQ NAFLD-NASH (only in case of paper questionnaires)	Y	10.00	23.00		23.00				23.00				23.00					23.00		23.00
*PHQ9	PHQ-9 (only in case of paper questionnaires)	Y	24.00	18.00	18.00	36.00					18.00			18.00		18.00			18.00		18.00
*CSSR	C-SSRS (only in case of paper questionnaires)	Y	34.00	52.00	52.00	104.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00
88363	Liver biopsy - archival	Y	1.00	84.00	84.00																
*RPM	Hyper-/hypoglycaemic episode review (eDiary - participants with T2DM)	Y	30.00	31.00			31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00
74150	CT scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated alpha-fetoprotein)	Y		919.00																	
74150-26	CT scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated alpha-fetoprotein)	Y		253.00																	
74160	CT scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated alpha-fetoprotein)	Y		1,144.00																	
74150-26	CT scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated alpha-fetoprotein)	Y		253.00																	
74181	MRI Scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated alpha-fetoprotein)	Y		1,787.00																	
74181-26	MRI Scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated alpha-fetoprotein)	Y		419.00																	
N74182	MRI Scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated alpha-fetoprotein)	Y		1,622.00																	
74181-26	MRI Scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated alpha-fetoprotein)	Y		419.00																	
NC008	Remote visit (for EOS Visit via remote visits (if allowed per local regulations))	Y	1.00	23.00																	
74181	MRI-PDFF	Y	1.00	1,787.00	1,787.00																
Per Patient Conditional Totals:					3,136.00	257.00	83.00	93.00	83.00	93.00	142.00	93.00	93.00	266.00	83.00	101.00	83.00	142.00	83.00	142.00	83.00

**Conditional**

Code	Name	V18_D505_C	V19_D533_C	V20_W82_R	V21_W88_C	V22_W94_R	V23_W100_C	V24_W106_R	V25_W112_C	V26_W118_R	V27_W124_C	V28_W130_R	V29_W136_C	V30_W142_R	V31_W148_C	EOT	FU/EOS	Total	ETD
99000	Preparation of sample for shipping - central lab															25.00		100.00	25.00
92012	Eye examination				70.00								70.00			70.00		350.00	70.00
*NASH	NASH-CHECK Questionnaire (only in case of paper questionnaires)		18.00		18.00				18.00				18.00			18.00		180.00	18.00
*CLDQ	CLDQ NAFLD-NASH (only in case of paper questionnaires)		23.00		23.00				23.00				23.00			23.00		230.00	23.00
*PHQ9	PHQ-9 (only in case of paper questionnaires)	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	432.00	18.00
*CSSR	C-SSRS (only in case of paper questionnaires)	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	1,768.00	52.00
88363	Liver biopsy - archival																	84.00	
*RPM	Hyper-/hypoglycaemic episode review (eDiary – participants with T2DM)	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	930.00	31.00
74150	CT scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated a-fetoprotein)																		
74150-26	CT scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated a-fetoprotein)																		
74160	CT scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated a-fetoprotein)																		
74150-26	CT scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated a-fetoprotein)																		
74181	MRI Scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated a-fetoprotein)																		
74181-26	MRI Scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated a-fetoprotein)																		
N74182	MRI Scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated a-fetoprotein)																		
74181-26	MRI Scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated a-fetoprotein)																		
NC008	Remote visit (for EOS Visit via remote visits (if allowed per local regulations))																23.00	23.00	
74181	MRI-PDFF																	1,787.00	
Per Patient Conditional Totals:		111.00	142.00	101.00	212.00	101.00	101.00	101.00	142.00	101.00	101.00	101.00	212.00	101.00	1,993.00	288.00	93.00	9,057.00	288.00

**Patient Cost For Standard Items**

	Screening	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment
	SV1	V2_RAND_D1	V3_D15_R	V4_D29_C	V5_D43_R	V6_D57_C	V7_D85_C	V8_D113_C	V9_D141_C	V10_D169_C	V11_D211_R	V12_D253_C	V13_D295_R	V14_D337_C	V15_D379_R	V16_D421_C	V17_D463_R	V18_D505_C
<b>Costs Not Charged with Overhead</b>																		
<b>Costs Charged with Overhead</b>	3,895.00	900.00	146.00	629.00	146.00	531.00	720.00	531.00	531.00	1,718.00	216.00	720.00	216.00	3,554.00	216.00	720.00	216.00	612.00
<b>Overhead at 16%</b>	623.20	144.00	23.36	100.64	23.36	84.96	115.20	84.96	84.96	274.88	34.56	115.20	34.56	568.64	34.56	115.20	34.56	97.92
<b>Selected Cost Per Visit</b>	4,518.20	1,044.00	169.36	729.64	169.36	615.96	835.20	615.96	615.96	1,992.88	250.56	835.20	250.56	4,122.64	250.56	835.20	250.56	709.92

**Patient Cost For Conditional Items**

	Screening	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment
	SV1	V2_RAND_D1	V3_D15_R	V4_D29_C	V5_D43_R	V6_D57_C	V7_D85_C	V8_D113_C	V9_D141_C	V10_D169_C	V11_D211_R	V12_D253_C	V13_D295_R	V14_D337_C	V15_D379_R	V16_D421_C	V17_D463_R	V18_D505_C
<b>Costs Not Charged with Overhead</b>																		
<b>Costs Charged with Overhead</b>	3,136.00	257.00	83.00	93.00	83.00	93.00	142.00	93.00	93.00	266.00	83.00	101.00	83.00	142.00	83.00	142.00	83.00	111.00
<b>Overhead at 16%</b>	501.76	41.12	13.28	14.88	13.28	14.88	22.72	14.88	14.88	42.56	13.28	16.16	13.28	22.72	13.28	22.72	13.28	17.76
<b>Selected Cost Per Visit</b>	3,637.76	298.12	96.28	107.88	96.28	107.88	164.72	107.88	107.88	308.56	96.28	117.16	96.28	164.72	96.28	164.72	96.28	128.76

**Overall Patient Cost**

	Screening	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment
	SV1	V2_RAND_D1	V3_D15_R	V4_D29_C	V5_D43_R	V6_D57_C	V7_D85_C	V8_D113_C	V9_D141_C	V10_D169_C	V11_D211_R	V12_D253_C	V13_D295_R	V14_D337_C	V15_D379_R	V16_D421_C	V17_D463_R	V18_D505_C
<b>Costs Not Charged with Overhead</b>																		
<b>Costs Charged with Overhead</b>	7,031.00	1,157.00	229.00	722.00	229.00	624.00	862.00	624.00	624.00	1,984.00	299.00	821.00	299.00	3,696.00	299.00	862.00	299.00	723.00
<b>Overhead at 16%</b>	1,124.96	185.12	36.64	115.52	36.64	99.84	137.92	99.84	99.84	317.44	47.84	131.36	47.84	591.36	47.84	137.92	47.84	115.68
<b>Selected Cost Per Visit</b>	8,155.96	1,342.12	265.64	837.52	265.64	723.84	999.92	723.84	723.84	2,301.44	346.84	952.36	346.84	4,287.36	346.84	999.92	346.84	838.68

**Patient Cost For Standard Items**

	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Follow Up	Total
	V19_D533_C	V20_W82_R	V21_W88_C	V22_W94_R	V23_W100_C	V24_W106_R	V25_W112_C	V26_W118_R	V27_W124_C	V28_W130_R	V29_W136_C	V30_W142_R	V31_W148_C	EOT	FU/EOS		
<b>Costs Not Charged with Overhead</b>																	
<b>Costs Charged with Overhead</b>	1,662.00	216.00	1,245.00	216.00	2,987.00	216.00	1,205.00	216.00	1,095.00	216.00	1,245.00	216.00	1,095.00	3,576.00	635.00	32,258.00	
<b>Overhead at 16%</b>	265.92	34.56	199.20	34.56	477.92	34.56	192.80	34.56	175.20	34.56	199.20	34.56	175.20	572.16	101.60	5,161.28	
<b>Selected Cost Per Visit</b>	1,927.92	250.56	1,444.20	250.56	3,464.92	250.56	1,397.80	250.56	1,270.20	250.56	1,444.20	250.56	1,270.20	4,148.16	736.60	37,419.28	

Discontinuation
ETD
3,576.00
572.16
4,148.16

**Patient Cost For Conditional Items**

	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Follow Up	Total
	V19_D533_C	V20_W82_R	V21_W88_C	V22_W94_R	V23_W100_C	V24_W106_R	V25_W112_C	V26_W118_R	V27_W124_C	V28_W130_R	V29_W136_C	V30_W142_R	V31_W148_C	EOT	FU/EOS	
<b>Costs Not Charged with Overhead</b>																
<b>Costs Charged with Overhead</b>	142.00	101.00	212.00	101.00	101.00	101.00	142.00	101.00	101.00	101.00	212.00	101.00	1,993.00	288.00	93.00	9,057.00
<b>Overhead at 16%</b>	22.72	16.16	33.92	16.16	16.16	16.16	22.72	16.16	16.16	16.16	33.92	16.16	318.88	46.08	14.88	1,449.12
<b>Selected Cost Per Visit</b>	164.72	117.16	245.92	117.16	117.16	117.16	164.72	117.16	117.16	117.16	245.92	117.16	2,311.88	334.08	107.88	10,506.12

Discontinuation
ETD
288.00
46.08
334.08

**Overall Patient Cost**

	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Follow Up	Total
	V19_D533_C	V20_W82_R	V21_W88_C	V22_W94_R	V23_W100_C	V24_W106_R	V25_W112_C	V26_W118_R	V27_W124_C	V28_W130_R	V29_W136_C	V30_W142_R	V31_W148_C	EOT	FU/EOS	
<b>Costs Not Charged with Overhead</b>																
<b>Costs Charged with Overhead</b>	1,804.00	317.00	1,457.00	317.00	3,088.00	317.00	1,347.00	317.00	1,196.00	317.00	1,457.00	317.00	3,088.00	3,864.00	728.00	41,315.00
<b>Overhead at 16%</b>	288.64	50.72	233.12	50.72	494.08	50.72	215.52	50.72	191.36	50.72	233.12	50.72	494.08	618.24	116.48	6,610.40
<b>Selected Cost Per Visit</b>	2,092.64	367.72	1,690.12	367.72	3,582.08	367.72	1,562.52	367.72	1,387.36	367.72	1,690.12	367.72	3,582.08	4,482.24	844.48	47,925.40

Discontinuation
ETD
3,864.00
618.24
4,482.24

**Site Level Other Direct Costs**

Code	Name	OH?	Total Quantity	SITE Cost	
#1124	Study Fee: Set-Up; Fixed	N	1.00	2,000.00	
*CHARC	Chart Review Fee; Per Chart	N	1.00	25.00	
	Pharmacy Set Up fee	N	1	500	
	Pharmacy SIV Amount	N	1	150 (210) €	
	Amount for each drug supply	N	1	50	per each supply
	Randomization	N	1	28	each patient
	IWRS assignment and delivery of drugs to the enrolled subject	N	1	31	each dispensing
	supply of drugs to the enrolled subject	N	1	34	each dispensing
	Monitoring visit	N	1	100	each monitoring visit
	Remote Monitoring visit	N	1	130	each monitoring visit
	drug disposal on site	N	1	55	
	Pharmacy close out visit	N	1	150 (210) €	
	preparation of the drug to be returned	N	1	50	each prepared package and for each thermostatic container
	Assignment, preparation and deliver of infusion drugs	N	1	100	Every bag, syringe produced
	preparation and delivery of infusion drugs	N	1	95	Every bag, syringe produced
	Drug dispensing to patients via courier	N	1	60	Each packaging
	Labeling	N	1	3	Each dispensing

The figures in brackets refer to the cost of activities carried out remotely  
 Only the activities actually carried out reported by the pharmacist and with a separate invoice will be invoiced

**Sotto-Studio (applicabile solo se l'Ente viene selezionato per partecipare al sottostudio e applicabile solo ai pazienti che partecipano al sottostudio) – Sub-Study (only applicable if Institution should be selected to participate in the sub-study, and only applicable to patients partaking in the sub-study)**

**Budget Information**

Standard Condition Overall  
 Total Cost per Patient: 37,463.36 40,693.96 78,157.32

Location: Italy  
 Site Type: All Site Types  
 Overhead Percent: 16.00%  
 Currency: EUR - Euro

**Procedures**

Code	Name	OH?	Total Quantity	Selected Cost	SV1	V2_RAND_D1	V3_D15_R	V4_D29_C	V5_D43_R	V6_D57_C	V7_D85_C	V8_D113_C	V9_D141_C	V10_D169_C	V11_D211_R	V12_D253_C	V13_D295_R	V14_D337_C	V15_D379_R
*INCO	Informed consent	Y	1.00	55.00	55.00														
*INEX	Review in-/exclusion criteria	Y	2.00	30.00	30.00	30.00													
*DEMO	Demographics	Y	1.00	25.00	25.00														
*3322	Medical history	Y	1.00	50.00	50.00														
99213	Complete Physical examination including one set of Vital signs (SBP, DBP, pulse), and weight	Y	1.00	85.00	85.00														
99212	Brief Physical examination including one set of Vital signs (SBP, DBP, pulse), height and weight	Y	16.00	75.00		75.00					75.00			75.00		75.00			75.00
*BMI*	Body Mass Index (BMI)	Y	1.00	18.00	18.00														
*MEAC	Waist and hip	Y	20.00	11.00		11.00		11.00		11.00	11.00	11.00	11.00	11.00		11.00			11.00
99211	Vital signs (SBP, DBP, pulse) including weight	Y	4.00	26.00				26.00		26.00		26.00	26.00						
93000	12-lead ECG w/ Interpret. & Report	Y	14.00	56.00	168.00	56.00		56.00						56.00		56.00			
*RCM*	Concomitant therapy	Y	33.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00
*GADS	Evaluation of portal hypertension treatment, Evaluation of lipid-lowering treatment, Evaluation of anti-hypertension treatment, Evaluation of anti-hyperglycaemic treatment (10 mins assessment)	Y	32.00	16.00		32.00					32.00			32.00		32.00			32.00
*ADVE	All AEs/AESIs	Y	33.00	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
*ISRS	Check for injection site reaction	Y	19.00	6.00		6.00		6.00		6.00	6.00	6.00	6.00	6.00		6.00			6.00
NC011	Complex Venipuncture - Safety laboratory tests, HBV, HCV, HIV, Pregnancy testing- serum(if applicable), Liver tests (ALT, AST, GGT, ALP, TBL, ALB), HbA1c, FPG, FPI, fasting C-peptide, Lipids tests: total cholesterol, HDL, LDL, VLDL, triglycerides, and free fatty acids, eGFRcr and eGFRcys, ELF samples, Other biomarkers samples, glucagon analysis , ADA, NAb samples, Alpha-fetoprotein	Y	21.00	32.00	32.00	32.00		32.00		32.00	32.00	32.00	32.00	32.00		32.00			32.00

**Procedures**

Code	Name	V16_D421_C	V17_D463_R	V18_D505_C	V19_D533_C	V20_W82_R	V21_W88_C	V22_W94_R	V23_W100_C	V24_W106_R	V25_W112_C	V26_W118_R	V27_W124_C	V28_W130_R	V29_W136_C	V30_W142_R	V31_W148_C	EOT	FU/EOS	Total	ETD
*INCO	Informed consent																			55.00	
*INEX	Review in-/exclusion criteria																			60.00	
*DEMO	Demographics																			25.00	
*3322	Medical history																			50.00	
99213	Complete Physical examination including one set of Vital signs (SBP, DBP, pulse), and weight																			85.00	
99212	Brief Physical examination including one set of Vital signs (SBP, DBP, pulse), height and weight	75.00		75.00	75.00		75.00		75.00		75.00		75.00		75.00		75.00	75.00	75.00	1,200.00	75.00
*BMI*	Body Mass Index (BMI)																			18.00	
*MEAC	Waist and hip circumference	11.00		11.00	11.00		11.00		11.00		11.00		11.00		11.00		11.00	11.00	11.00	220.00	11.00
99211	Vital signs (SBP, DBP, pulse) including weight																			104.00	
93000	12-lead ECG w/ Interpret. & Report	56.00					56.00				56.00				56.00			56.00	56.00	784.00	56.00
*RCM*	Concomitant therapy	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	660.00	20.00
*GADS	Evaluation of portal hypertension treatment, Evaluation of lipid-lowering treatment, Evaluation of anti-hypertension treatment, Evaluation of anti-hyperglycaemic treatment (10 mins assessment)	32.00		32.00	32.00		32.00		32.00		32.00		32.00		32.00		32.00	32.00	32.00	512.00	32.00
*ADVE	All AEs/AESIs	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	561.00	17.00
*ISRS	Check for injection site reaction	6.00		6.00	6.00		6.00		6.00		6.00		6.00		6.00		6.00	6.00		114.00	6.00
NC011	Complex Venipuncture - Safety laboratory tests, HBV, HCV, HIV, Pregnancy testing- serum(if applicable), Liver tests (ALT, AST, GGT, ALP, TBL, ALB), HbA1c, FPG, FPI, fasting C-peptide, Lipids tests: total cholesterol, HDL, LDL, VLDL, triglycerides, and free fatty acids, eGFRcr and eGFRcys, ELF samples, Other biomarkers samples, glucagon analysis , ADA, NAb samples, Alpha-fetoprotein	32.00		32.00	32.00		32.00		32.00		32.00		32.00		32.00		32.00	32.00	32.00	672.00	32.00

**Procedures**

Code	Name	OH?	Total	Selected	SV1	V2_RAND_D1	V3_D15_R	V4_D29_C	V5_D43_R	V6_D57_C	V7_D85_C	V8_D113_C	V9_D141_C	V10_D169_C	V11_D211_R	V12_D253_C	V13_D295_R	V14_D337_C	
			Quantity	Cost															
NC017	Urine Collection - Urine analysis, UACR	Y	15.00	10.00		10.00					10.00			10.00		10.00		10.00	
99000	Handling and shipment - Central lab	Y	21.00	25.00	25.00	25.00		25.00		25.00	25.00	25.00	25.00	25.00		25.00		25.00	
91200	FibroScan® (VCTE, CAP)	Y	8.00	422.00	422.00									422.00				422.00	
*FBRS	ELF Score	Y	8.00	40.00	40.00	40.00								40.00				40.00	
80299	PK	Y	13.00	42.00		42.00		42.00			42.00			42.00		42.00		42.00	
*FAST	FAST Score	Y	8.00	35.00	35.00									35.00				35.00	
*GADS	AGILE Score	Y	8.00	16.00	16.00									16.00				16.00	
91110	UGE	Y	4.00	1,892.00	1,892.00													1,892.00	
76700	Abdominal ultrasound	Y	8.00	384.00	384.00									384.00				384.00	
76830-26	Abdominal ultrasound - Interpretation & Report	Y	8.00	101.00	101.00									101.00				101.00	
*CPC*	CPT	Y	21.00	15.00	15.00	15.00		15.00		15.00	15.00	15.00	15.00	15.00				15.00	
*MELD	MELD scores	Y	21.00	34.00	34.00	34.00		34.00		34.00	34.00	34.00	34.00	34.00				34.00	
*GADS	Assessment of ascites and HE	Y	21.00	16.00	16.00	16.00		16.00		16.00	16.00	16.00	16.00	16.00				16.00	
*GADS	-Liver Disease Progression (5min assessment)	Y	20.00	16.00		16.00		16.00		16.00	16.00	16.00	16.00	16.00				16.00	
*DPSD	Hand out IFU – pre-filled syringe and Hand out of SMBG device (trial participants with T2DM), and trial participant materials	Y	2.00	28.00	28.00	28.00													
*RPMd	eDiary review (IMP administration, injection site reactions, and compliance check), ePRO - NASH-CHECK Questionnaire, CLDQ NAFLD NASH, PHQ-9, C-SSRS	Y	33.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	
98960	Training in/observe pre-filled syringe administration	Y	1.00	82.00		82.00													
98966	Vital status_Phone call	Y	1.00	25.00															
99401	Diet and physical activity counselling	Y	29.00	70.00		70.00		70.00		70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	70.00	
NC008	Remote visit	Y	12.00	23.00			23.00		23.00						23.00			23.00	
*RNCO	Re-consent Process, per patient - for MRI substudy	Y	1.00	38.00	38.00														
Per Patient Activity Totals:						3,577.00	688.00	91.00	417.00	91.00	319.00	508.00	319.00	319.00	1,506.00	161.00	508.00	161.00	3,342.00

**Procedures**

Code	Name	V15_D379_R	V16_D421_C	V17_D463_R	V18_D505_C	V19_D533_C	V20_W82_R	V21_W88_C	V22_W94_R	V23_W100_C	V24_W106_R	V25_W112_C	V26_W118_R	V27_W124_C	V28_W130_R	V29_W136_C	V30_W142_R	V31_W148_C	EOT	FU/EOS	Total	ETD
NC017	Urine Collection - Urine analysis, UACR		10.00			10.00		10.00		10.00		10.00		10.00		10.00		10.00	10.00	10.00	150.00	10.00
99000	Handling and shipment - Central lab		25.00		25.00	25.00		25.00		25.00		25.00		25.00		25.00		25.00	25.00	25.00	525.00	25.00
91200	FibroScan® (VCTE, CAP)					422.00				422.00				422.00				422.00	422.00		3,376.00	422.00
*FBRS	ELF Score					40.00		40.00								40.00			40.00		320.00	40.00
80299	PK		42.00			42.00		42.00				42.00				42.00			42.00	42.00	546.00	42.00
*FAST	FAST Score					35.00				35.00				35.00				35.00	35.00		280.00	35.00
*GADS	AGILE Score					16.00				16.00				16.00				16.00	16.00		128.00	16.00
91110	UGE									1,892.00									1,892.00		7,568.00	1,892.00
76700	Abdominal ultrasound					384.00		384.00				384.00				384.00			384.00		3,072.00	384.00
76830-26	Abdominal ultrasound - Interpretation & Report					101.00		101.00				101.00				101.00			101.00		808.00	101.00
*CPC*	CPT		15.00		15.00	15.00		15.00		15.00		15.00		15.00		15.00		15.00	15.00	15.00	315.00	15.00
*MELD	MELD scores		34.00		34.00	34.00		34.00		34.00		34.00		34.00		34.00		34.00	34.00	34.00	714.00	34.00
*GADS	Assessment of ascites and HE		16.00		16.00	16.00		16.00		16.00		16.00		16.00		16.00		16.00	16.00	16.00	336.00	16.00
*GADS	Liver Disease Progression (5min assessment)		16.00		16.00	16.00		16.00		16.00		16.00		16.00		16.00		16.00	16.00	16.00	320.00	16.00
*DPSD	Hand out IFU – pre-filled syringe and Hand out of SMBG device (trial participants with T2DM), and trial participant materials																				56.00	
*RPMD	eDiary review (IMP administration, injection site reactions, and compliance check), ePRO - NASH-CHECK Questionnaire, CLDQ NAFLD NASH, PHQ-9, C-SSRS	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	1,023.00	31.00
98960	Training in/observe pre-filled syringe administration																				82.00	
98966	Vital status_Phone call																			25.00	25.00	
99401	Diet and physical activity counselling	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		2,030.00	70.00
NC008	Remote visit	23.00		23.00			23.00		23.00		23.00		23.00		23.00		23.00				276.00	
*RNC0	Re-consent Process, per patient - for MRI substudy																				38.00	
Per Patient Activity Totals:		161.00	508.00	161.00	400.00	1,450.00	161.00	1,033.00	161.00	2,775.00	161.00	993.00	161.00	883.00	161.00	1,033.00	161.00	883.00	3,398.00	457.00	27,108.00	3,398.00

**Non Procedures**

Code	Name	OH?	Total	Selected	SV1	V2_RAND_D1	V3_D15_R	V4_D29_C	V5_D43_R	V6_D57_C	V7_D85_C	V8_D113_C	V9_D141_C	V10_D169_C	V11_D211_R	V12_D253_C	V13_D295_R	V14_D337_C	V15_D379_R
			Quantity	Cost															
*STCO	Study Coordinator; Per Visit - data entry	Y	28.00	69.00	138.00	69.00	34.50	69.00	34.50	69.00	69.00	69.00	69.00	69.00	34.50	69.00	34.50	69.00	34.50
V1110	Physician Salary	Y	28.00	41.00	82.00	41.00	20.50	41.00	20.50	41.00	41.00	41.00	41.00	41.00	20.50	41.00	20.50	41.00	20.50
*NURS	Nurse; Per Visit	Y	22.00	68.00	136.00	68.00		68.00		68.00	68.00	68.00	68.00	68.00		68.00		68.00	
VPHRM	Dispensing, Simple; Per Visit - Hand out IFU – pre-filled syringe, dispense IMP	Y	18.00	34.00		34.00		34.00		34.00	34.00	34.00	34.00	34.00		34.00		34.00	
Per Patient Other Direct Cost Totals:					356.00	212.00	55.00	212.00	55.00	212.00	212.00	212.00	212.00	212.00	55.00	212.00	55.00	212.00	55.00

**Conditional**

Code	Name	OH?	Total	Selected	SV1	V2_RAND_D1	V3_D15_R	V4_D29_C	V5_D43_R	V6_D57_C	V7_D85_C	V8_D113_C	V9_D141_C	V10_D169_C	V11_D211_R	V12_D253_C	V13_D295_R	V14_D337_C	V15_D379_R
			Quantity	Cost															
47000	Liver biopsy	Y	1.00	800.00	800.00														
99152	Moderate Sedation Init 15 Min 5+yrs	Y	1.00	205.00	205.00														
NC065	Biopsy Sample Handling Simple	Y	1.00	21.00	21.00														
74181	MRI-PDFF and T1-weighted imaging	Y	6.00	1,787.00	1,787.00	1,787.00								1,787.00				1,787.00	
N76391	MRE (subset of trial participants)	Y	6.00	1,374.00	1,374.00	1,374.00								1,374.00				1,374.00	
76498	MRI for body composition	Y	5.00	1,769.00		1,769.00								1,769.00				1,769.00	
91110	UGE ('For participants without 'high-risk' GOVs or previous endoscopic treatment for esophageal varices at baseline')	Y	1.00	1,892.00															
*GNCO	Informed Consent: DNA, Genetics	Y	1.00	35.00	35.00														
*IWQL	Assessment of obesity staging (For participants with BMI ≥30 kg/m2 (≥25 kg/m2 for Asian ethnicity)	Y	2.00	22.00		22.00													
*SAEA	All SAEs - per occurrence	Y		19.00															
36415	Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics, - Reticulocytes (only for patients with Gilbert Syndrome), Pancreatic amylase (at screening, and CK-MB,Troponin as reflex test if amylase is elevated at all other visits, including DILI evaluation visit)	Y	4.00	29.00	29.00	29.00								29.00					

**Non Procedures**

Code	Name	V16_D421_C	V17_D463_R	V18_D505_C	V19_D533_C	V20_W82_R	V21_W88_C	V22_W94_R	V23_W100_C	V24_W106_R	V25_W112_C	V26_W118_R	V27_W124_C	V28_W130_R	V29_W136_C	V30_W142_R	V31_W148_C	EOT	FU/EOS	Total
*STCO	Study Coordinator; Per Visit - data entry	69.00	34.50	69.00	69.00	34.50	69.00	34.50	69.00	34.50	69.00	34.50	69.00	34.50	69.00	34.50	69.00	69.00	69.00	1,932.00
V1110	Physician Salary	41.00	20.50	41.00	41.00	20.50	41.00	20.50	41.00	20.50	41.00	20.50	41.00	20.50	41.00	20.50	41.00	41.00	41.00	1,148.00
*NURS	Nurse; Per Visit	68.00		68.00	68.00		68.00		68.00		68.00		68.00		68.00		68.00	68.00	68.00	1,496.00
VPHRM	Dispensing, Simple; Per Visit - Hand out IFU - pre-filled syringe, dispense IMP	34.00		34.00	34.00		34.00		34.00		34.00		34.00		34.00		34.00			612.00
Per Patient Other Direct Cost Totals:		212.00	55.00	212.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	178.00	178.00	5,188.00

ETD
69.00
41.00
68.00
178.00

**Conditional**

Code	Name	V16_D421_C	V17_D463_R	V18_D505_C	V19_D533_C	V20_W82_R	V21_W88_C	V22_W94_R	V23_W100_C	V24_W106_R	V25_W112_C	V26_W118_R	V27_W124_C	V28_W130_R	V29_W136_C	V30_W142_R	V31_W148_C	EOT	FU/EOS	Total
47000	Liver biopsy																			800.00
99152	Moderate Sedation Init 15 Min 5+yrs																			205.00
NC065	Biopsy Sample Handling Simple																			21.00
74181	MRI-PDFF and T1-weighted imaging				1,787.00													1,787.00		10,722.00
N76391	MRE (subset of trial participants)				1,374.00													1,374.00		8,244.00
76498	MRI for body composition				1,769.00													1,769.00		8,845.00
91110	UGE ("For participants without 'high-risk' GOVs or previous endoscopic treatment for esophageal varices at baseline")																1,892.00			1,892.00
*GNCO	Informed Consent: DNA, Genetics																			35.00
*IWQL	Assessment of obesity staging (For participants with BMI ≥30 kg/m2 (≥25 kg/m2 for Asian ethnicity)																	22.00		44.00
*SAEA	All SAEs - per occurrence																			
36415	Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics, - Reticulocytes (only for patients with Gilbert Syndrome), Pancreatic amylase (at screening, and CK-MB,Troponin as reflex test if amylase is elevated at all other visits, including DILI evaluation visit)																	29.00		116.00

ETD
1,787.00
1,374.00
1,769.00
22.00
29.00

**Conditional**

Code	Name	OH?	Total	Selected	SV1	V2_RAND_D1	V3_D15_R	V4_D29_C	V5_D43_R	V6_D57_C	V7_D85_C	V8_D113_C	V9_D141_C	V10_D169_C	V11_D211_R	V12_D253_C	V13_D295_R	V14_D337_C	V15_D379_R
			Quantity	Cost															
NC017	Urine Collection - Urine pregnancy test (if	Y	6.00	10.00	10.00			10.00		10.00		10.00	10.00						
80299	Additional PK sample collection	Y		42.00															
99000	Preparation of sample for shipping - central lab	Y	4.00	25.00	25.00	25.00								25.00					
92012	Eye examination	Y	5.00	70.00	70.00									70.00					
*NASH	NASH-CHECK Questionnaire (only in case of paper questionnaires)	Y	10.00	18.00		18.00				18.00				18.00					18.00
*CLDQ	CLDQ NAFLD-NASH (only in case of paper questionnaires)	Y	10.00	23.00		23.00				23.00				23.00					23.00
*PHQ9	PHQ-9 (only in case of paper questionnaires)	Y	24.00	18.00	18.00	36.00				18.00				18.00		18.00			18.00
*CSSR	C-SSRS (only in case of paper questionnaires)	Y	34.00	52.00	52.00	104.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00
88363	Liver biopsy - archival	Y	1.00	84.00	84.00														
*RPM	Hyper-/hypoglycaemic episode review (eDiary - participants with T2DM)	Y	30.00	31.00			31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00
74150	CT scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated a-fetoprotein)	Y		919.00															
74150-26	CT scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated a-fetoprotein)	Y		253.00															
74160	CT scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated a-fetoprotein)	Y		1,144.00															
74150-26	CT scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated a-fetoprotein)	Y		253.00															
74181	MRI Scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated a-fetoprotein)	Y		1,787.00															
74181-26	MRI Scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated a-fetoprotein)	Y		419.00															
N74182	MRI Scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated a-fetoprotein)	Y		1,622.00															
74181-26	MRI Scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated a-fetoprotein)	Y		419.00															
NC008	Remote visit (for EOS Visit via remote visits (if allowed per local regulations))	Y	1.00	23.00															

Per Patient Conditional Totals:

4,510.00 5,187.00 83.00 93.00 83.00 93.00 142.00 93.00 93.00 5,196.00 83.00 101.00 83.00 5,072.00 83.00



**Patient Cost For Standard Items**

	Screenin g	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment
	SV1	V2_RAND_D1	V3_D15_R	V4_D29_C	V5_D43_R	V6_D57_C	V7_D85_C	V8_D113_C	V9_D141_C	V10_D169_C	V11_D211_R	V12_D253_C	V13_D295_R	V14_D337_C	V15_D379_R	V16_D421_C
<b>Costs Not Charged with Overhead</b>																
<b>Costs Charged with Overhead</b>	3,933.00	900.00	146.00	629.00	146.00	531.00	720.00	531.00	531.00	1,718.00	216.00	720.00	216.00	3,554.00	216.00	720.00
<b>Overhead at 16%</b>	629.28	144.00	23.36	100.64	23.36	84.96	115.20	84.96	84.96	274.88	34.56	115.20	34.56	568.64	34.56	115.20
<b>Selected Cost Per Visit</b>	4,562.28	1,044.00	169.36	729.64	169.36	615.96	835.20	615.96	615.96	1,992.88	250.56	835.20	250.56	4,122.64	250.56	835.20

**Patient Cost For Conditional Items**

	Screenin g	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment
	SV1	V2_RAND_D1	V3_D15_R	V4_D29_C	V5_D43_R	V6_D57_C	V7_D85_C	V8_D113_C	V9_D141_C	V10_D169_C	V11_D211_R	V12_D253_C	V13_D295_R	V14_D337_C	V15_D379_R	V16_D421_C
<b>Costs Not Charged with Overhead</b>																
<b>Costs Charged with Overhead</b>	4,510.00	5,187.00	83.00	93.00	83.00	93.00	142.00	93.00	93.00	5,196.00	83.00	101.00	83.00	5,072.00	83.00	142.00
<b>Overhead at 16%</b>	721.60	829.92	13.28	14.88	13.28	14.88	22.72	14.88	14.88	831.36	13.28	16.16	13.28	811.52	13.28	22.72
<b>Selected Cost Per Visit</b>	5,231.60	6,016.92	96.28	107.88	96.28	107.88	164.72	107.88	107.88	6,027.36	96.28	117.16	96.28	5,883.52	96.28	164.72

**Overall Patient Cost**

	Screenin g	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment
	SV1	V2_RAND_D1	V3_D15_R	V4_D29_C	V5_D43_R	V6_D57_C	V7_D85_C	V8_D113_C	V9_D141_C	V10_D169_C	V11_D211_R	V12_D253_C	V13_D295_R	V14_D337_C	V15_D379_R	V16_D421_C
<b>Costs Not Charged with Overhead</b>																
<b>Costs Charged with Overhead</b>	8,443.00	6,087.00	229.00	722.00	229.00	624.00	862.00	624.00	624.00	6,914.00	299.00	821.00	299.00	8,626.00	299.00	862.00
<b>Overhead at 16%</b>	1,350.88	973.92	36.64	115.52	36.64	99.84	137.92	99.84	99.84	1,106.24	47.84	131.36	47.84	1,380.16	47.84	137.92
<b>Selected Cost Per Visit</b>	9,793.88	7,060.92	265.64	837.52	265.64	723.84	999.92	723.84	723.84	8,020.24	346.84	952.36	346.84	10,006.16	346.84	999.92

**Patient Cost For Standard Items**

	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Follow Up	Total
	V17_D463_R	V18_D505_C	V19_D533_C	V20_W82_R	V21_W88_C	V22_W94_R	V23_W100_C	V24_W106_R	V25_W112_C	V26_W118_R	V27_W124_C	V28_W130_R	V29_W136_C	V30_W142_R	V31_W148_C	EOT	FU/EOS		
Costs Not Charged with Overhead																			
Costs Charged with Overhead	216.00	612.00	1,662.00	216.00	1,245.00	216.00	2,987.00	216.00	1,205.00	216.00	1,095.00	216.00	1,245.00	216.00	1,095.00	3,576.00	635.00	32,296.00	
Overhead at 16%	34.56	97.92	265.92	34.56	199.20	34.56	477.92	34.56	192.80	34.56	175.20	34.56	199.20	34.56	175.20	572.16	101.60	5,167.36	
Selected Cost Per Visit	250.56	709.92	1,927.92	250.56	1,444.20	250.56	3,464.92	250.56	1,397.80	250.56	1,270.20	250.56	1,444.20	250.56	1,270.20	4,148.16	736.60	37,463.36	

Discontinuation
ETD
3,576.00
572.16
4,148.16

**Patient Cost For Conditional Items**

	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Follow Up	Total	
	V17_D463_R	V18_D505_C	V19_D533_C	V20_W82_R	V21_W88_C	V22_W94_R	V23_W100_C	V24_W106_R	V25_W112_C	V26_W118_R	V27_W124_C	V28_W130_R	V29_W136_C	V30_W142_R	V31_W148_C	EOT	FU/EOS		
Costs Not Charged with Overhead																			
Costs Charged with Overhead	83.00	111.00	5,072.00	101.00	212.00	101.00	101.00	101.00	142.00	101.00	101.00	101.00	212.00	101.00	1,993.00	5,218.00	93.00	35,081.00	
Overhead at 16%	13.28	17.76	811.52	16.16	33.92	16.16	16.16	16.16	22.72	16.16	16.16	16.16	33.92	16.16	318.88	834.88	14.88	5,612.96	
Selected Cost Per Visit	96.28	128.76	5,883.52	117.16	245.92	117.16	117.16	117.16	164.72	117.16	117.16	117.16	245.92	117.16	2,311.88	6,052.88	107.88	40,693.96	

Discontinuation
ETD
5,218.00
834.88
6,052.88

**Overall Patient Cost**

	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Follow Up	Total	
	V17_D463_R	V18_D505_C	V19_D533_C	V20_W82_R	V21_W88_C	V22_W94_R	V23_W100_C	V24_W106_R	V25_W112_C	V26_W118_R	V27_W124_C	V28_W130_R	V29_W136_C	V30_W142_R	V31_W148_C	EOT	FU/EOS		
Costs Not Charged with Overhead																			
Costs Charged with Overhead	299.00	723.00	6,734.00	317.00	1,457.00	317.00	3,088.00	317.00	1,347.00	317.00	1,196.00	317.00	1,457.00	317.00	3,088.00	8,794.00	728.00	67,377.00	
Overhead at 16%	47.84	115.68	1,077.44	50.72	233.12	50.72	494.08	50.72	215.52	50.72	191.36	50.72	233.12	50.72	494.08	1,407.04	116.48	10,780.32	
Selected Cost Per Visit	346.84	838.68	7,811.44	367.72	1,690.12	367.72	3,582.08	367.72	1,562.52	367.72	1,387.36	367.72	1,690.12	367.72	3,582.08	10,201.04	844.48	78,157.32	

Discontinuation
ETD
8,794.00
1,407.04
10,201.04