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. 216 del 28/02/2025 di sottoscrizione della Convenzione economica tra l'AOUP e per essa l'UOC di Gastroenterologia e la Società Parexel International (IRL) che autorizza l'avvio della Sperimentazione clinica su medicinali dal titolo: "Studio di fase III, in doppio cieco, randomizzato controllato verso placebo, volto a valutare gli outcome clinici correlati al 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". Protocollo: 1404-0064 - EU CT 2024-513741-36-00 Sperimentatore: Prof. Salvatore Petta;

DATO ATTO che in data 22/08/2025 il Promotore ha ricevuto il Provvedimento EMA che autorizza l'SM-1 al Protocollo di Studio che modifica la sottosezione 4 rimborso spese di viaggio dell'allegato A – Budget;

VISTO l'Emendamento 1 sottoscritto e allegato come parte sostanziale e integrante, alla Convenzione tra l'AOUP e la Società Parexel International IRL, per effettuare la Sperimentazione Clinica su medicinali Protocollo:1404-0064;

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

DELIBERA

Di prendere atto dell' Emendamento 1, sottoscritto e allegato come parte sostanziale e integrante alla convenzione tra l'AOUP Paolo Giaccone e per essa l'UOC di Gastroenterologia e la Società Parexel International IRL, per la conduzione della Sperimentazione su medicinali dal titolo: "Studio di fase III, in doppio cieco, randomizzato controllato verso placebo, volto a valutare gli outcome clinici correlati al 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". Protocollo: 1404-0064 - EU CT 2024-513741-36-00 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. 362 dell' 04/04/2025.

AMENDMENT Nº1
(hereinafter "Amendment")
is effective as of the date of IRB/EC/RA approval of the Protocol Amendment (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 once weekly injected survodutide in participants with compensated nonalcoholic steatohepatitis/metabolic dysfunction associated

EMENDAMENTO NUMERO 1
(qui di seguito "Emendamento")
decorrerà a partire dalla data dell'approvazione dell'Emendamento al Protocollo da parte del CE / IRB / AR (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 Direttore Generale, munito 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**")
A Phase III double-blind, randomised, placebo-controlled trial to evaluate liver-related clinical outcomes and safety of once weekly injected survodutide in participants with compensated nonalcoholic steatohepatitis/metabolic

steatohepatitis (NASH/MASH) cirrhosis" (hereinafter "**Study**") Survodutide (BI 456906) (hereinafter "**Study Drug**")	*dysfunction associated steatohepatitis (NASH/MASH) cirrhosis*"(di seguito "**Studio**") Survodutide (BI 456906) (di seguito "**Medicinale Sperimentale**")
WHEREAS, SPONSOR is the sponsor of the multi-center/multi-centre Study to clinically evaluate the Study Drug;	PREMESSO che, il Promotore è lo sponsor dello Studio multicentrico per la valutazione clinica del Medicinale Sperimentale;
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;	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
WHEREAS, the Parties have entered into the above-referred AGREEMENT FOR THE CONDUCT OF A CLINICAL TRIAL ON MEDICINAL PRODUCTS (hereinafter "**Agreement**");	PREMESSO CHE le Parti hanno stipulato il suddetto CONTRATTO PER LA CONDUZIONE DELLA SPERIMENTAZIONE CLINICA SU MEDICINALI (di seguito "**Contratto**");
WHEREAS, due to Protocol amendment 3.0 dated 13 March 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.	PREMESSO CHE, a seguito dell'emendamento al Protocollo n. 3.0 del 13 Marzo 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.
WHEREAS, the Parties agreed to amend Subject Travel Reimbursement section.	PREMESSO CHE, le Parti hanno concordato di modificare la sezione relativa al Rimborso Spese di Viaggio.
WHEREAS, the Parties are jointly willing to amend the above-referred Agreement;	PREMESSO CHE, le Parti sono congiuntamente disposte a modificare il Contratto di cui sopra;
Now, therefore the above-referred Agreement shall be amended and the following amended wordings shall be effective as of the date of IRB/EC/RA approval of the above mentioned Protocol Amendment.	Pertanto, il Contratto sopra menzionato sarà modificato e le seguenti formulazioni modificate saranno efficaci a partire dalla data dell'approvazione del suddetto Emendamento al Protocollo da parte del CE / IRB / AR.
1. Due to new Protocol amendment the ANNEX A – BUDGET is being delated in its entirety and replaced with the revised ANNEX A – BUDGET attached herein.	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.
2. **Subject Travel Reimbursement** sub-section of the section 4. 'Conditional fees and Invoiceable	2. La sottosezione "**Rimborso spese di viaggio**" della sezione 4. "Costi condizionali e fatturabili" dell'ALLEGATO A - BUDGET viene eliminata e

fees' of the ANNEX A – BUDGET is being deleted and replaced with the following **Subject Reimbursement** sub-section: Subject Reimbursement: Reasonable patient's travel expenses during the Study will be reimbursed. Subject reimbursement will be managed and paid directly through CRO/SPONSOR third-party vendor and will not be considered part of the Study Subject payments made to Institution. 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.	sostituita con la seguente sottosezione "**Rimborso spese di viaggio**": Rimborso del Soggetto: Saranno rimborsate le spese di viaggio ragionevoli sostenute dal paziente durante lo Studio. Il rimborso del Soggetto sarà gestito e pagato direttamente tramite il fornitore terzo di CRO/ Promotore e non sarà considerato parte dei pagamenti effettuati dal Soggetto dello Studio all'Ente. 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.
In the event of a conflict between the terms of this Amendment and the Agreement, the terms of this Amendment shall take precedence. 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.	In caso di conflitto tra i termini del presente Emendamento e quelli del Contratto, prevarranno i termini del presente Emendamento. 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**

(Signature of Authorized Official) / (Firma)
Nicola Sotira

(Typed or Printed Name) / (Nome) Date / Data

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

(Signature of Authorized Official) / (Firma)
Dr / Dott.ssa Maria Grazia Furnari

(Typed or Printed Name) / (Nome) Date / Data

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

(Signature of Authorized Official) / (Firma)
Prof. Salvatore Petta

(Typed or Printed Name) / (Nome) Date / Data

Exhibit A –Payment Terms and Budget	Allegato A – Termini di pagamento e Budget

1. Payee Details / Dettagli del Beneficiario

Payee / Beneficiario	Payee Details / Dettagli del Beneficiario
Protocol Number / Numero di Protocollo	1404-0064
Site Number / Numero del Centro	ITA3
Payee Name (hereinafter "Payee") / Nome del Beneficiario (di seguito "Beneficiario")	Azienda Ospedaliera Universitaria Policlinico "P. Giaccone"
Payee Address / Indirizzo del Beneficiario	Via del Vespro 129
Address Line 2 / Riga Indirizzo 2	NA
Address Line 3 / Riga Indirizzo 3	NA
Province/State/Country / Provincia/Stato/Paese	Palermo
City / Città	Palermo
Postal Code / Codice Postale	90127
Country / Paese	Italy / Italia
Payee Contact / Recapiti del Beneficiario	Dott.ssa Rosaria Mosca
Payee Contact Phone Number / Numero di telefono del Beneficiario	0039 0916555535
Remittance E-mail Address / Indirizzo e-mail per le ricevute	Rosaria.mosca@policlinico.pa.it
General Finance contact e-mail address / Indirizzo e-mail del referente della Direzione Generale Finanza	Convenzioni.sperimentazioni@policlinico.pa.it
NPI	NA
Applicable Tax ID/VAT or GST Registration/TIN/SSN / Numero di identificazione del contribuente [TIN]/Numero di previdenza sociale [SSN])	05841790826
Bank Account Holder Name / Nome dell'intestatario del conto corrente bancario	Azienda Ospedaliera Universitaria Policlinico "P. Giaccone"
Bank Account Number / Numero conto Corrente bancario	218030
IBAN (18-digit International Bank Account Number)	IT86P0100504600000000218030
Bank Name / Nome dell'istituto di credito	Banca Nazionale del Lavoro S.p.A. Via Roma n. 297
Bank Routing Number / Numero di routing della banca	NA
Bank Branch Number / Codice filiale dell'istituto di credito	NA
Bank Identification Code/SWIFT Code / Codice di identificazione bancaria / Codice SWIFT	BNLIITRR
Payment Terms / Termini di pagamento	45 (forty-five) days / 45 (quarantacinque) giorni
Payment Frequency / Frequenza di pagamento	Quarterly - Trimestrale
Payment Currency / Valuta	EUR

To ensure proper payment please ensure that all fields above are completed. 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, InvestigatorPaymentHelpDesk@parexel.com. 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.	**Al fine di consentire il corretto pagamento, assicurarsi di aver compilato tutti i campi sopra riportati.** 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 InvestigatorPaymentHelpDesk@PAREXEL.com 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.
2. <u>Enrolment</u> This study is designed to evaluate Subjects in accordance with the Protocol. The Investigator on behalf of the Institution will use best efforts to enroll 2 Subjects. When enrolment is complete for the study, the Institution will be notified in writing and will discontinue enrolling Subjects.	**2. <u>Arruolamento</u>** Il presente Studio è finalizzato a valutare i pazienti in conformità al Protocollo. Lo Sperimentatore, per conto dell'Ente, farà quanto in suo potere per arruolare 2 pazienti. Una volta completato l'arruolamento per lo Studio, l'Ente sarà informato per iscritto e provvederà a interrompere l'arruolamento dei pazienti.
3. <u>Per Subject Fees:</u> 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.	**3. <u>Costi per paziente:</u>** 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.
4. <u>Conditional Fees and Invoiceable Fees:</u>	**4. <u>Costi condizionali e fatturabili:</u>** Il pagamento di altri costi o spese condizionali non inclusi nei Costi per paziente (come definito nella

Payment for other conditional fees or expenses that are not included in the Per Subject Fees (as defined in Section **0**) will be made according to the below rates as outlined in the below attached Detailed Budget: ***SCREENING FAILURE:*** 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 site 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, 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 site 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. **RE-SCREENING:** 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.	Sezione 3) sarà effettuato secondo le tariffe sotto indicate, come specificato nel Budget dettagliato allegato: ***MANCATO SUPERAMENTO DELLO SCREENING:*** i mancati superamenti dello Screening saranno rimborsati in base alle procedure effettivamente eseguite, in base ai costi delle singole voci delineate nel Budget dettagliato allegato di seguito, all'immissione di informazioni complete in EDC e alla ricezione da parte della CRO di una fattura dettagliata, indiscussa e completa. Tutti i mancati superamenti dello Screening saranno rimborsati per il 100% delle procedure effettivamente sostenute e dei costi fatturabili come delineato nel Budget dettagliato allegato di seguito. L'Ente farà ogni sforzo per evitare procedure non necessarie e per stabilire se un Soggetto è un fallimento dello Screening in base ai criteri di ammissibilità definiti dal Protocollo. Quando l'Ente raggiunge o supera un rapporto di Screening Failure di 4:1 (quattro mancati superamenti dello Screening che hanno eseguito 4 MRI-PDFF o 4 biopsie epatiche, a seconda di quale si verifica per primo, per un Soggetto arruolato), la CRO, il Promotore o il delegato del Promotore possono esaminare le caratteristiche del paziente e discutere l'individuazione dei pazienti appropriati con l'Ente. Il Promotore, il delegato del Promotore o la CRO hanno il diritto di limitare, ridurre o interrompere lo screening futuro in base a questa valutazione. L'Ente è autorizzato a continuare le attività di screening durante il processo di valutazione fino a diversa notifica da parte del Promotore o della CRO. Un fallimento dello screening è considerato un Soggetto che firma il modulo di consenso informato e completa lo screening ma fallisce in base ai criteri di inclusione/esclusione e non verrà arruolato. **RE-SCREENING**: I fallimenti dello screening possono essere ricontrollati 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.

SUBJECT REIMBURSEMENT: Reasonable patient's expenses during the Study will be reimbursed. Subject reimbursement will be managed and paid directly through CRO/SPONSOR third-party vendor and will not be considered part of the Study Subject payments made to payee. 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. ***UNSCHEDULED VISIT***: 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. ***MEDICAL CHART REVIEW FEE:*** 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 review up to a maximum of 10 chart reviews per one (1) randomized patient, upon receipt of an undisputed invoice from Institution.. CRO reserves the right to cross-check which chart reviews have been performed using a pre-screening log, and the documented inclusion/exclusion criteria. 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	***RIMBORSO DEL SOGGETTO***: Saranno rimborsate le spese di viaggio ragionevoli sostenute dal paziente durante lo Studio. Il rimborso del Soggetto sarà gestito e pagato direttamente tramite il fornitore terzo di CRO/Promotore e non sarà considerato parte dei pagamenti effettuati dal Soggetto dello Studio al'Ente. 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. ***VISITA NON PROGRAMMATA:*** 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. ***COMPENSO PER LA REVISIONE DELLA CARTELLA MEDICA:*** 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. 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

electronic case report form or supporting documentation, as applicable.	sarà convalidato sulle informazioni completate, verificate e inserite nel modulo elettronico o nella documentazione di supporto, a seconda dei casi.
5. <u>Site Fees:</u>	**5. <u>TARIFFE DEL CENTRO:</u>**
START-UP FEE: 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 final compensation for all activities associated with Study initiation. Payment to Payee will be made upon receipt of the corresponding invoice. 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.	***COMPENSO DI AVVIO***: 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 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. 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.
6. <u>Pro-Rata Payments:</u>	**6. <u>Pagamenti su base proporzionale:</u>**
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. 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. If other non-cancelable costs are incurred by Institution in accordance with the Agreement, written	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. 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. Laddove vengano sostenuti altri costi non cancellabili dall'Ente, in conformità al Contratto, sarà necessario

justification must be provided to SPONSOR for review and approval, and payment of such costs is subject to SPONSOR's approval 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.	fornire una giustificazione scritta al Promotore, per l'esame e l'approvazione, e il pagamento di detti costi sarà soggetto all'approvazione del Promotore. 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.
7. Protocol Violators 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.	**7. Soggetti che violano il Protocollo** 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.
8. Invoices Correct Valid Invoices should be addressed/issued to: Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany VAT #DE 811138149 C Payment agent: PAREXEL International (IRL) Limited Preferred method of invoice submission is through CRO site self-service Site Pay Portal (hereinafter "Portal") Payee will receive instruction on how to access and register to the "Portal" once Detailed Budget is set-up in the Portal. In case Payee is not able to submit invoice through the "Portal", correct valid invoices should be emailed to: sitepaymentinvoicing@parexel.com PAREXEL Study no.: 284657 with the following details: . protocol number or CRO project number shall be indicated in the subject line of the e-mail . protocol number / CRO project number / Investigator name / site name and invoice number shall be indicated in the body of the email Paper invoices can be headed to: Sponsor Boehringer Ingelheim International GmbH, c/o PAREXEL International (IRL) Limited	**8. Fatture** Le fatture valide corrette devono essere intestate a: Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germania P.IVA #DE 811138149 Agente di pagamento: PAREXEL International (IRL) Limited 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: sitepaymentinvoicing@parexel.com Studio PAREXEL n.: 284657 con i seguenti dettagli: . il numero di protocollo o il numero di progetto CRO devono essere indicati nell'oggetto dell'e-mail . 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 Le fatture cartacee possono essere intestate a: Sponsor Boehringer Ingelheim International GmbH, 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 All invoices must contain the following information: (a) Protocol Number (b) Invoice Number (c) Invoice Date (d) Place, Date & Description of Services Provided (e) CRO Project Number (f) Total amount payable (g) Exchange rate used (where applicable) (h) Investigator Name (i) Site Number (j) Investigator National Provider Identification (NPI) Number (k) Payee Name and Address (per this Agreement) (l) Date of Supply 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*.	One Park Place Block C 1ST floor Upper Hatch Street Dublin 2 D02 E762 Ireland Studio PAREXEL n.: 284657 Tutte le fatture dovranno contenere le seguenti informazioni: (a) Numero di Protocollo (b) Numero di fattura (c) Data della fattura (d) Luogo, data e descrizione dei servizi forniti (e) Numero del progetto della CRO (f) Importo totale dovuto (g) Tasso di cambio utilizzato (ove pertinente) (h) Nome dello Sperimentatore (i) Numero del centro (j) Codice identificativo del fornitore nazionale (NPI) dello Sperimentatore (k) Nome e indirizzo del Beneficiario (indicati nel presente Contratto) (l)Data della fornitura 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.
9. <u>Final Payment</u> Notwithstanding the foregoing, the final payment shall be made upon the completion of the following activities: (a) all required Subject visits have been completed (b) SPONSOR has received all Subject data in a form suitable for analysis (c) all data clarification queries have been resolved to SPONSOR's satisfaction (d) SPONSOR has verified that all required regulatory documentation is complete (e) Institution has returned all required equipment, drugs and other material (f) the Study close-out visit has been completed Payee shall have thirty (30) days from the receipt of the final payment under this Agreement to identify	**9. <u>Pagamento finale</u>** Fermo restando quanto precede, il pagamento finale sarà liquidato al completamento delle seguenti attività: (a) tutte le visite del soggetto previste siano state completate (b) ricezione da parte del Promotore di tutti i dati del Soggetto in formato idoneo per l'analisi (c) risoluzione di tutte le richieste di chiarimento dei dati, in maniera soddisfacente per il Promotore (d) verifica da parte del Promotore della completezza di tutta la documentazione normativa richiesta (e) restituzione da parte dell'Ente di tutti gli Strumenti, farmaci e altri materiali richiesti (f) la visita di fine Studio sia stata completata Il Beneficiario avrà trenta (30) giorni di tempo dalla ricezione del pagamento finale ai sensi del presente

discrepancies and resolve any payment disputes with *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. **10. <u>TAX</u>** All fees and expenses in this Exhibit A are exclusive of VAT or any applicable tax. All payments are subject to withholding tax as applicable.	Contratto, per identificare eventuali discrepanze e risolvere qualsiasi disputa di pagamento con la CRO. 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. **10. <u>IMPOSTE</u>** 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	Conditional	Overall
Total Cost per Patient:	40,804.16	8,346.20	49,150.36

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	V16_D421_C	V17_D463_R	V18_D505_C	V19_D533_C	V20_W82_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		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		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	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		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	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		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		32.00		32.00	32.00	

Procedures

Code	Name	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	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	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	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	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	561.00	17.00
*ISRS	Check for injection site reaction	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	672.00	32.00

Budget Information

	Standard	Conditional	Overall
Total Cost per Patient:	40,804.16	8,346.20	49,150.36

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	V16_D421_C	V17_D463_R	V18_D505_C	V19_D533_C	V20_W82_R
NC017	Urine Collection - Urine analysis, UACR	Y	15.00	10.00		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	25.00	
*FBRS	ELF Score	Y	8.00	40.00	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			42.00	
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																			
91200	FibroScan® (VCTE, CAP)	Y	8.00	422.00	422.00									422.00				422.00					422.00	
*FAST	FAST Score	Y	8.00	35.00	35.00									35.00				35.00					35.00	
*GADS	AGILE Score	Y	8.00	16.00	16.00									16.00				16.00					16.00	
91110	UGE	Y	5.00	1,892.00	1,892.00													1,892.00						
76700	Abdominal ultrasound	Y	8.00	384.00	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					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		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		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		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	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	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	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			23.00
	Per Patient Activity Totals:				4,565.00	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	400.00	1,450.00	161.00

Procedures

Code	Name	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	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	525.00	25.00
*FBRS	ELF Score	40.00								40.00			40.00		320.00	40.00
80299	PK	42.00				42.00				42.00			42.00	42.00	546.00	42.00
47000	Liver biopsy														800.00	
99152	Moderate Sedation Init 15 Min 5+yrs														205.00	
NC065	Biopsy Sample Handling Simple														21.00	
91200	FibroScan® (VCTE, CAP)			422.00				422.00				422.00	422.00		3,376.00	422.00
*FAST	FAST Score			35.00				35.00				35.00	35.00		280.00	35.00
*GADS	AGILE Score			16.00				16.00				16.00	16.00		128.00	16.00
91110	UGE			1,892.00								1,892.00	1,892.00		9,460.00	1,892.00
76700	Abdominal ultrasound	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		808.00	101.00
CPC	CPT	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	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	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	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	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		2,030.00	70.00
NC008	Remote visit		23.00		23.00		23.00		23.00		23.00				276.00	
	Per Patient Activity Totals:	1,033.00	161.00	2,775.00	161.00	993.00	161.00	883.00	161.00	1,033.00	161.00	2,775.00	3,398.00	457.00	29,988.00	3,398.00

Non 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	V18_D505_C	V19_D533_C	V20_W82_R
*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	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	41.00	20.50	41.00	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		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	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	212.00	55.00	212.00	212.00	55.00

Conditionals

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	V18_D505_C	V19_D533_C	V20_W82_R
91110	UGE (For participants who develop 'high-risk' GOVs or experience certain hepatic events)	Y		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 occurence	Y		19.00																				
36415	Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics	Y	4.00	29.00	29.00	29.00								29.00										
NC017	Urine Collection - Urine pregnancy test (if apllicable)	Y	6.00	10.00	10.00			10.00		10.00		10.00	10.00									10.00		
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		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			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		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	52.00	52.00	52.00
88363	Liver biopsy - archival	Y	1.00	84.00	84.00																			
*RPMD	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	31.00	31.00	31.00

Non Procedures

Code	Name	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
*STCO	Study Coordinator; Per Visit - data entry	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	69.00
V1110	Physician Salary	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	41.00
*NURS	Nurse; Per Visit	68.00		68.00		68.00		68.00		68.00		68.00	68.00	68.00	1,496.00	68.00
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			612.00	
Per Patient Other Direct Cost Totals:		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	178.00

Conditionals

Code	Name	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
91110	UGE (For participants who develop 'high-risk' GOVs or experience certain hepatic events)															
*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	22.00
*SAEA	All SAEs - per occurence															
36415	Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics												29.00		116.00	29.00
NC017	Urine Collection - Urine pregnancy test (if apllicable)														60.00	
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		180.00	18.00
*CLDQ	CLDQ NAFLD-NASH (only in case of paper questionnaires)	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	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	1,768.00	52.00
88363	Liver biopsy - archival														84.00	
*RPMD	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		930.00	31.00

Conditionals

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	V18_D505_C	V19_D533_C	V20_W82_R
74150	CT scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		919.00																				
74150-26	CT scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		253.00																				
74160	CT scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		1,144.00																				
74150-26	CT scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		253.00																				
74181	MRI -PDFF	Y	1.00	1,787.00	1,787.00																			
74181	MRI Scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		1,787.00																				
74181-26	MRI Scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		419.00																				
N74182	MRI Scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		1,622.00																				
74181-26	MRI Scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		419.00																				
NC008	Remote visit (for EOS Visit via remote visits (if allowed per local regulations))	Y	1.00	23.00																				
VREIM	Patient Reimbursement, Per Visit ("a written Sponsor approval will suffice to cover higher costs, if needed, but no contract AMD will be needed")	Y	21.00	33.00	33.00	33.00		33.00		33.00	33.00	33.00	33.00	33.00		33.00		33.00		33.00		33.00	33.00	
VREIM	Patient Reimbursement, Per Visit (applicable for remote visit if done as clinic visits	Y	11.00	33.00			33.00		33.00						33.00		33.00				33.00			33.00
	Per Patient Conditional Totals:				2,143.00	290.00	116.00	126.00	116.00	126.00	175.00	126.00	126.00	299.00	116.00	134.00	116.00	175.00	83.00	175.00	116.00	144.00	175.00	134.00

Conditionals

Code	Name	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
74150	CT scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)															
74150-26	CT scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)															
74160	CT scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)															
74150-26	CT scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)															
74181	MRI -PDFF														1,787.00	
74181	MRI Scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)															
74181-26	MRI Scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)															
N74182	MRI Scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)															
74181-26	MRI Scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)															
NC008	Remote visit (for EOS Visit via remote visits (if allowed per local regulations))													23.00	23.00	
VREIM	Patient Reimbursement, Per Visit ("a written Sponsor approval will suffice to cover higher costs, if needed, but no contract AMD will be needed")	33.00		33.00		33.00		33.00		33.00		33.00	33.00	33.00	693.00	33.00
VREIM	Patient Reimbursement, Per Visit (applicable for remote visit if done as clinic visits		33.00		33.00		33.00		33.00		33.00				363.00	
	Per Patient Conditional Totals:	245.00	134.00	134.00	134.00	175.00	134.00	134.00	134.00	245.00	134.00	134.00	321.00	126.00	7,195.00	321.00

Patient Cost For Standard Items

	Screening	Treatment	Treatment	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	V19_D533_C	V20_W82_R
Costs Not Charged with Overhead																				
Costs Charged with Overhead	4,921.00	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	1,662.00	216.00
Overhead at 16%	787.36	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	265.92	34.56
Selected Cost Per Visit	5,708.36	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	1,927.92	250.56

Patient Cost For Conditional Items

	Screening	Treatment	Treatment	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	V19_D533_C	V20_W82_R
Costs Not Charged with Overhead																				
Costs Charged with Overhead	2,143.00	290.00	116.00	126.00	116.00	126.00	175.00	126.00	126.00	299.00	116.00	134.00	116.00	175.00	83.00	175.00	116.00	144.00	175.00	134.00
Overhead at 16%	342.88	46.40	18.56	20.16	18.56	20.16	28.00	20.16	20.16	47.84	18.56	21.44	18.56	28.00	13.28	28.00	18.56	23.04	28.00	21.44
Selected Cost Per Visit	2,485.88	336.40	134.56	146.16	134.56	146.16	203.00	146.16	146.16	346.84	134.56	155.44	134.56	203.00	96.28	203.00	134.56	167.04	203.00	155.44

Overall Patient Cost

	Screening	Treatment	Treatment	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	V19_D533_C	V20_W82_R
Costs Not Charged with Overhead																				
Costs Charged with Overhead	7,064.00	1,190.00	262.00	755.00	262.00	657.00	895.00	657.00	657.00	2,017.00	332.00	854.00	332.00	3,729.00	299.00	895.00	332.00	756.00	1,837.00	350.00
Overhead at 16%	1,130.24	190.40	41.92	120.80	41.92	105.12	143.20	105.12	105.12	322.72	53.12	136.64	53.12	596.64	47.84	143.20	53.12	120.96	293.92	56.00
Selected Cost Per Visit	8,194.24	1,380.40	303.92	875.80	303.92	762.12	1,038.20	762.12	762.12	2,339.72	385.12	990.64	385.12	4,325.64	346.84	1,038.20	385.12	876.96	2,130.92	406.00

Patient Cost For Standard Items

	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Follow Up	Total	Discontinuation
	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		ETD
Costs Not Charged with Overhead															
Costs Charged with Overhead	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	2,987.00	3,576.00	635.00	35,176.00	3,576.00
Overhead at 16%	199.20	34.56	477.92	34.56	192.80	34.56	175.20	34.56	199.20	34.56	477.92	572.16	101.60	5,628.16	572.16
Selected Cost Per Visit	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	3,464.92	4,148.16	736.60	40,804.16	4,148.16

Patient Cost For Conditional Items

	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Follow Up	Total	Discontinuation
	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		ETD
Costs Not Charged with Overhead															
Costs Charged with Overhead	245.00	134.00	134.00	134.00	175.00	134.00	134.00	134.00	245.00	134.00	134.00	321.00	126.00	7,195.00	321.00
Overhead at 16%	39.20	21.44	21.44	21.44	28.00	21.44	21.44	21.44	39.20	21.44	21.44	51.36	20.16	1,151.20	51.36
Selected Cost Per Visit	284.20	155.44	155.44	155.44	203.00	155.44	155.44	155.44	284.20	155.44	155.44	372.36	146.16	8,346.20	372.36

Overall Patient Cost

	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Follow Up	Total	Discontinuation
	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		ETD
Costs Not Charged with Overhead															
Costs Charged with Overhead	1,490.00	350.00	3,121.00	350.00	1,380.00	350.00	1,229.00	350.00	1,490.00	350.00	3,121.00	3,897.00	761.00	42,371.00	3,897.00
Overhead at 16%	238.40	56.00	499.36	56.00	220.80	56.00	196.64	56.00	238.40	56.00	499.36	623.52	121.76	6,779.36	623.52
Selected Cost Per Visit	1,728.40	406.00	3,620.36	406.00	1,600.80	406.00	1,425.64	406.00	1,728.40	406.00	3,620.36	4,520.52	882.76	49,150.36	4,520.52

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
	Randomization	N	1	28
	IWRS assignment and delivery of drugs to the enrolled subject	N	1	31
	supply of durgs to the enrolled subject	N	1	34
	Monitoring visit	N	1	100
	Remote Monitoring visit	N	1	130
	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
	Assignment, preparation and deliver of infusion drugs	N	1	100
	preparation and delivery of infusion drugs	N	1	95
	Drug dispensing to patients via courier	N	1	60
	Labeling	N	1	3

The figures in brackets refer to the cost of activities carried out remote

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	Conditional	Overall
Total Cost per Patient:	73,109.00	6,273.28	79,382.28

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	V16_D421_C	V17_D463_R	V18_D505_C	V19_D533_C
*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		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		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	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		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	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		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		32.00		32.00	32.00

Procedures

Code	Name	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	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	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	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	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	561.00	17.00
*ISRS	Check for injection site reaction		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	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	V18_D505_C	V19_D533_C	V20_W82_R
NC017	Urine Collection - Urine analysis, UACR	Y	15.00	10.00		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	25.00	
*FBRS	ELF Score	Y	8.00	40.00	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			42.00	
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																			
91200	FibroScan® (VCTE, CAP)	Y	8.00	422.00	422.00									422.00				422.00					422.00	
*FAST	FAST Score	Y	8.00	35.00	35.00									35.00				35.00					35.00	
*GADS	AGILE Score	Y	8.00	16.00	16.00									16.00				16.00					16.00	
91110	UGE	Y	5.00	1,892.00	1,892.00													1,892.00						
76700	Abdominal ultrasound	Y	8.00	384.00	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					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		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		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		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	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	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	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			23.00
*RNCO	Re-consent Process, per patient - for MRI substudy	Y	1.00	38.00	38.00																			
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					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					1,374.00	
76498	MRI for body composition	Y	5.00	1,769.00		1,769.00								1,769.00				1,769.00					1,769.00	
		Per Patient Activity Totals:			7,764.00	5,618.00	91.00	417.00	91.00	319.00	508.00	319.00	319.00	6,436.00	161.00	508.00	161.00	8,272.00	161.00	508.00	161.00	400.00	6,380.00	161.00

Procedures

Code	Name	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	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	525.00	25.00
*FBRS	ELF Score	40.00								40.00			40.00		320.00	40.00
80299	PK	42.00				42.00				42.00			42.00	42.00	546.00	42.00
47000	Liver biopsy														800.00	
99152	Moderate Sedation Init 15 Min 5+yrs														205.00	
NC065	Biopsy Sample Handling Simple														21.00	
91200	FibroScan® (VCTE, CAP)			422.00				422.00				422.00	422.00		3,376.00	422.00
*FAST	FAST Score			35.00				35.00				35.00	35.00		280.00	35.00
*GADS	AGILE Score			16.00				16.00				16.00	16.00		128.00	16.00
91110	UGE			1,892.00								1,892.00	1,892.00		9,460.00	1,892.00
76700	Abdominal ultrasound	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		808.00	101.00
CPC	CPT	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	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	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	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	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		2,030.00	70.00
NC008	Remote visit		23.00		23.00		23.00		23.00		23.00				276.00	
*RNCO	Re-consent Process, per patient - for MRI substudy														38.00	
74181	MRI-PDFF and T1-weighted imaging												1,787.00		10,722.00	1,787.00
N76391	MRE (subset of trial participants)												1,374.00		8,244.00	1,374.00
76498	MRI for body composition												1,769.00		8,845.00	1,769.00
	Per Patient Activity Totals:	1,033.00	161.00	2,775.00	161.00	993.00	161.00	883.00	161.00	1,033.00	161.00	2,775.00	8,328.00	457.00	57,837.00	8,328.00

Non 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	V18_D505_C
*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	212.00	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00

Conditionals

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	V18_D505_C
91110	UGE (For participants who develop 'high-risk' GOVs or experience certain hepatic events)	Y		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 occurence	Y		19.00																		
36415	Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics	Y	4.00	29.00	29.00	29.00								29.00								
NC017	Urine Collection - Urine pregnancy test (if apllicable)	Y	6.00	10.00	10.00			10.00		10.00		10.00	10.00									10.00
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		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		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	52.00
88363	Liver biopsy - archival	Y	1.00	84.00	84.00																	

Non Procedures

Code	Name	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
*STCO	Study Coordinator; Per Visit - data entry	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	69.00
V1110	Physician Salary	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	41.00
*NURS	Nurse; Per Visit	68.00		68.00		68.00		68.00		68.00		68.00		68.00	68.00	68.00	1,496.00	68.00
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			612.00	
Per Patient Other Direct Cost Totals:		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	178.00

Conditionals

Code	Name	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
91110	UGE (For participants who develop 'high-risk' GOVs or experience certain hepatic events)																	
*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	22.00
*SAEA	All SAEs - per occurence																	
36415	Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics														29.00		116.00	29.00
NC017	Urine Collection - Urine pregnancy test (if apllicable)																60.00	
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	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	1,768.00	52.00
88363	Liver biopsy - archival																84.00	

Conditionals

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	V18_D505_C
91110	UGE (For participants who develop 'high-risk' GOVs or experience certain hepatic events)	Y		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 occurence	Y		19.00																		
36415	Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics	Y	4.00	29.00	29.00	29.00								29.00								
NC017	Urine Collection - Urine pregnancy test (if apllicable)	Y	6.00	10.00	10.00			10.00		10.00		10.00	10.00									10.00
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		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		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	52.00
88363	Liver biopsy - archival	Y	1.00	84.00	84.00																	
*RPMD	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	31.00
74150	CT scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		919.00																		
74150-26	CT scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		253.00																		
74160	CT scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		1,144.00																		
74150-26	CT scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		253.00																		

Conditionals

Code	Name	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
91110	UGE (For participants who develop 'high-risk' GOVs or experience certain hepatic events)																	
*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	22.00
*SAEA	All SAEs - per occurence																	
36415	Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics														29.00		116.00	29.00
NC017	Urine Collection - Urine pregnancy test (if apllicable)																60.00	
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	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	1,768.00	52.00
88363	Liver biopsy - archival																84.00	
*RPMD	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		930.00	31.00
74150	CT scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)																	
74150-26	CT scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)																	
74160	CT scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)																	
74150-26	CT scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)																	

Conditionals

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
74181	MRI Scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		1,787.00																	
74181-26	MRI Scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		419.00																	
N74182	MRI Scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		1,622.00																	
74181-26	MRI Scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		419.00																	
NC008	Remote visit (for EOS Visit via remote visits (if allowed per local regulations))	Y	1.00	23.00																	
VREIM	Patient Reimbursement, Per Visit ("a written Sponsor approval will suffice to cover higher costs, if needed, but no contract AMD will be needed")	Y	21.00	33.00	33.00	33.00		33.00		33.00	33.00	33.00	33.00	33.00		33.00		33.00		33.00	
VREIM	Patient Reimbursement, Per Visit (applicable for remote visit if done as clinic visits	Y	11.00	33.00			33.00		33.00						33.00		33.00				33.00
	Per Patient Conditional Totals:				356.00	290.00	116.00	126.00	116.00	126.00	175.00	126.00	126.00	299.00	116.00	134.00	116.00	175.00	83.00	175.00	116.00

Conditionals

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
74181	MRI Scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)																		
74181-26	MRI Scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)																		
N74182	MRI Scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)																		
74181-26	MRI Scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)																		
NC008	Remote visit (for EOS Visit via remote visits (if allowed per local regulations))																23.00	23.00	
VREIM	Patient Reimbursement, Per Visit ("a written Sponsor approval will suffice to cover higher costs, if needed, but no contract AMD will be needed")	33.00	33.00		33.00		33.00		33.00		33.00		33.00		33.00	33.00	33.00	693.00	33.00
VREIM	Patient Reimbursement, Per Visit (applicable for remote visit if done as clinic visits			33.00		33.00		33.00		33.00		33.00		33.00				363.00	
	Per Patient Conditional Totals:	144.00	175.00	134.00	245.00	134.00	134.00	134.00	175.00	134.00	134.00	134.00	245.00	134.00	134.00	321.00	126.00	5,408.00	321.00

Patient Cost For Standard Items

	Screening	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
Costs Not Charged with Overhead																	
Costs Charged with Overhead	8,120.00	5,830.00	146.00	629.00	146.00	531.00	720.00	531.00	531.00	6,648.00	216.00	720.00	216.00	8,484.00	216.00	720.00	216.00
Overhead at 16%	1,299.20	932.80	23.36	100.64	23.36	84.96	115.20	84.96	84.96	1,063.68	34.56	115.20	34.56	1,357.44	34.56	115.20	34.56
Selected Cost Per Visit	9,419.20	6,762.80	169.36	729.64	169.36	615.96	835.20	615.96	615.96	7,711.68	250.56	835.20	250.56	9,841.44	250.56	835.20	250.56

Patient Cost For Conditional Items

	Screening	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
Costs Not Charged with Overhead																	
Costs Charged with Overhead	356.00	290.00	116.00	126.00	116.00	126.00	175.00	126.00	126.00	299.00	116.00	134.00	116.00	175.00	83.00	175.00	116.00
Overhead at 16%	56.96	46.40	18.56	20.16	18.56	20.16	28.00	20.16	20.16	47.84	18.56	21.44	18.56	28.00	13.28	28.00	18.56
Selected Cost Per Visit	412.96	336.40	134.56	146.16	134.56	146.16	203.00	146.16	146.16	346.84	134.56	155.44	134.56	203.00	96.28	203.00	134.56

Overall Patient Cost

	Screening	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
Costs Not Charged with Overhead																	
Costs Charged with Overhead	8,476.00	6,120.00	262.00	755.00	262.00	657.00	895.00	657.00	657.00	6,947.00	332.00	854.00	332.00	8,659.00	299.00	895.00	332.00
Overhead at 16%	1,356.16	979.20	41.92	120.80	41.92	105.12	143.20	105.12	105.12	1,111.52	53.12	136.64	53.12	1,385.44	47.84	143.20	53.12
Selected Cost Per Visit	9,832.16	7,099.20	303.92	875.80	303.92	762.12	1,038.20	762.12	762.12	8,058.52	385.12	990.64	385.12	10,044.44	346.84	1,038.20	385.12

Patient Cost For Standard Items

	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Follow Up	Total	Discontinuation
	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		ETD
Costs Not Charged with Overhead																		
Costs Charged with Overhead	612.00	6,592.00	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	2,987.00	8,506.00	635.00	63,025.00	8,506.00
Overhead at 16%	97.92	1,054.72	34.56	199.20	34.56	477.92	34.56	192.80	34.56	175.20	34.56	199.20	34.56	477.92	1,360.96	101.60	10,084.00	1,360.96
Selected Cost Per Visit	709.92	7,646.72	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	3,464.92	9,866.96	736.60	73,109.00	9,866.96

Patient Cost For Conditional Items

	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Follow Up	Total	Discontinuation
	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		ETD
Costs Not Charged with Overhead																		
Costs Charged with Overhead	144.00	175.00	134.00	245.00	134.00	134.00	134.00	175.00	134.00	134.00	134.00	245.00	134.00	134.00	321.00	126.00	5,408.00	321.00
Overhead at 16%	23.04	28.00	21.44	39.20	21.44	21.44	21.44	28.00	21.44	21.44	21.44	39.20	21.44	21.44	51.36	20.16	865.28	51.36
Selected Cost Per Visit	167.04	203.00	155.44	284.20	155.44	155.44	155.44	203.00	155.44	155.44	155.44	284.20	155.44	155.44	372.36	146.16	6,273.28	372.36

Overall Patient Cost

	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Follow Up	Total	Discontinuation
	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		ETD
Costs Not Charged with Overhead																		
Costs Charged with Overhead	756.00	6,767.00	350.00	1,490.00	350.00	3,121.00	350.00	1,380.00	350.00	1,229.00	350.00	1,490.00	350.00	3,121.00	8,827.00	761.00	68,433.00	8,827.00
Overhead at 16%	120.96	1,082.72	56.00	238.40	56.00	499.36	56.00	220.80	56.00	196.64	56.00	238.40	56.00	499.36	1,412.32	121.76	10,949.28	1,412.32
Selected Cost Per Visit	876.96	7,849.72	406.00	1,728.40	406.00	3,620.36	406.00	1,600.80	406.00	1,425.64	406.00	1,728.40	406.00	3,620.36	10,239.32	882.76	79,382.28	10,239.32