



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

Dott.ssa Maria Grazia Furnari

- PRESO ATTO** che presso l'AIFA è stato istituito il Centro di Coordinamento nazionale dei Comitati Etici Territoriali e ricostituito con il Decreto del Ministro della Salute del 27/05/2021, garante dell'omogeneità delle procedure e del rispetto dei termini temporali;
- PRESO ATTO** dell'entrata in vigore in data 31/01/2022 del nuovo Regolamento (EU) n. 536/2014 del Parlamento Europeo sulla sperimentazione clinica di medicinali per uso umano;
- VISTI**
- il Decreto 26 gennaio 2023 recante: "individuazione di quaranta comitati etici territoriali (di seguito indicato con DM 40 CET);
- il Decreto del 27 gennaio 2023, del Ministero della Salute recante misure relative all'individuazione e competenze dei Comitati Etici Territoriali;
- il Decreto 30.01.2023 recante: "definizione dei criteri per la composizione e il funzionamento dei comitati etici territoriali";
- PRESO ATTO** che, con delibera n. 916 del 30/06/2023 e ss.mm.ii., è stato istituito il CET (Comitato Etico Territoriale) e la Segreteria Tecnico Scientifica, in applicazione al Decreto Regionale n. 541/2023;
- che con delibera n. 1017 del 19/07/2023 è stato istituito il CEL Palermo 1 (Comitato Etico Locale Palermo 1);
- 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. 456 del 07/05/2025 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:



AZIENDA OSPEDALIERA UNIVERSITARIA

“Studio di fase III, randomizzato, in doppio cieco, controllato verso placebo, multicentrico, volto a valutare la sicurezza a lungo termine di iniezioni settimanali di survodutide a partecipanti con steatoepatite non alcolica non cirrotica/steatoepatite associata a disfunzione metabolica (NASH/MASH) e fibrosi epatica in stadio (F2) – (F3)”. Protocollo: 1404-0044 - EU CT 2024-513739-25-00
Sperimentatore: Prof. Salvatore Petta;

- VISTA** la delibera n. 1035 del 24/10/2025 di sottoscrizione dell’Emendamento 1 di modifica della sottosezione 4 , rimborso spese viaggi dell’Allegato A- Budget;
- DATO ATTO** che in data 30/01/2026 il Promotore ha ricevuto il Provvedimento EMA che autorizza l'emendamento relativo alla modifica del Budget per aggiornamento al Protocollo ;
- VISTO** l’ Emendamento 2, allegato alla Convenzione sottoscritta tra l’AOUP e la Società Parexel International (IRL) Limited, per effettuare la Sperimentazione Clinica Protocollo: 1404-0044;

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

DELIBERA

Di prendere atto dell’ Emendamento 2 sottoscritto, allegato come parte sostanziale e integrante alla convenzione tra l’Azienda Ospedaliera Universitaria Policlinico e per essa l’UOC di Gastroenterologia e la Società Parexel International (IRL) Limited, per effettuare la Sperimentazione Clinica dal titolo: “Studio di fase III, randomizzato, in doppio cieco, controllato verso placebo, multicentrico, volto a valutare la sicurezza a lungo termine di iniezioni settimanali di survodutide a partecipanti con steatoepatite non alcolica non cirrotica/steatoepatite associata a disfunzione metabolica (NASH/MASH) e fibrosi epatica in stadio (F2) – (F3)”. Protocollo: 1404-0044 - EU CT 2024-513739-25-00 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. 1088 dell’ 07/11/2025.

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

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

to the
**AGREEMENT FOR THE CONDUCT OF A
CLINICAL TRIAL ON MEDICINAL
PRODUCTS** dated 29 April 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: 1404-0044 (hereinafter “**Protocol**”)
“A randomised, double-blind, placebo-controlled,
multicentre, Phase III trial evaluating long-term
efficacy and safety of survodutide weekly injections in
adult participants with noncirrhotic non-alcoholic

EMENDAMENTO NUMERO 2
(qui di seguito “**Emendamento**”)
decorrerà a partire dalla data dell’ultima firma

(di seguito “**Data di decorrenza**”)

al
**CONTRATTO PER LA CONDUZIONE DELLA
SPERIMENTAZIONE CLINICA SU
MEDICINALI** datato 29 aprile 2025,

Il presente Emendamento è stipulato da e tra

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

E

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

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

In relazione a

Protocollo: 1404-0044 (di seguito “**Protocollo**”)
“*Studio di fase III, randomizzato, in doppio cieco,
controllato verso placebo, multicentrico, volto a
valutare l’efficacia e la sicurezza a lungo termine di
iniezioni settimanali di survodutide a partecipanti*

steatohepatitis/metabolic dysfunction-associated steatohepatitis (NASH/MASH) and (F2) - (F3) stage of liver fibrosis”
(hereinafter “**Study**”)
Survodutide (BI 456906) (hereinafter “**Study Drug**“)

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

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

WHEREAS, the Parties have entered into the above-referred Clinical Site Agreement dated 29 April 2025 (hereinafter “**Agreement**”);

WHEREAS, due to Protocol amendment # 5.0 dated 25 July 2025 (hereinafter “**Protocol amendment**”) the Parties agree to amend the agreement to include revised budget in accordance with the changes in the said Protocol amendment.

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

Now, therefore the above-referred Agreement shall be amended and the following amended wordings shall be effective as of IRB/EC/RA approval of the above mentioned Protocol Amendment (30 January 2026).

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

adulti con steatoepatite non alcolica non cirrotica/steatoepatite associata a disfunzione metabolica (NASH/MASH) e fibrosi epatica in stadio (F2) - (F3)”
(di seguito “**Studio**”)
Survodutide (BI 456906) (di seguito “**Medicinale Sperimentale**”)

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

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

PREMESSO CHE le Parti hanno stipulato il suddetto **CONTRATTO PER LA CONDUZIONE DELLA SPERIMENTAZIONE CLINICA SU MEDICINALI** in data 29 aprile 2025 (di seguito “**Contratto**”);

PREMESSO CHE, a seguito dell'emendamento al Protocollo n. 5.0 del 25 luglio 2025 (di seguito “**Emendamento al Protocollo**”), le Parti convengono di modificare il Contratto per includere il budget rivisto in conformità alle modifiche apportate al suddetto Emendamento al Protocollo.

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

Pertanto, il Contratto sopra menzionato sarà modificato e le seguenti formulazioni modificate saranno efficaci a partire dalla data dell’approvazione dell’Emendamento al Protocollo da parte del CE / IRB / AR (30 gennaio 2026).

1. A seguito dell’Emendamento al Protocollo, l’ALLEGATO A – Termini di pagamento e Budget viene eliminato nella sua interezza e sostituito con

<p>Annex A - Payments terms and Budget attached herein.</p> <p>In the event of a conflict between the terms of this Amendment and the Agreement, the terms of this Amendment shall take precedence.</p> <p>All other terms and conditions of the above-referred Agreement remain unchanged and in full force and effect.</p> <p>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.</p>	<p>l'ALLEGATO A - Termini di pagamento e Budget rivisto qui allegato.</p> <p>In caso di conflitto tra i termini del presente Emendamento e quelli del Contratto, prevarranno i termini del presente Emendamento.</p> <p>Tutti gli altri termini e condizioni del Contratto sopra menzionato rimangono invariati e pienamente validi ed efficaci.</p> <p>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.</p>
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

(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
Dott / Dr Nicola Sotira

(Typed or Printed Name) / Nome

Date / Data

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

(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: the Principal Investigator / Per
presa visione delle disposizioni che lo
riguardano: lo Sperimentatore Principale:**

(Signature of Investigator) / Firma

Prof Salvatore Petta

(Typed or Printed Name) / Nome

Date / Data

1. Payee Details / Dettagli del Beneficiario

Payee / Beneficiario	Payee Details / Dettagli del Beneficiario
Protocol Number / Numero di Protocollo	1404-0044
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

<p>To ensure proper payment please ensure that all fields above are completed.</p> <p>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.</p>	<p>Al fine di consentire il corretto pagamento, assicurarsi di aver compilato tutti i campi sopra riportati.</p> <p>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.</p>
<p><u>2. Enrolment</u></p>	<p><u>2. Arruolamento</u></p>
<p>This study is designed to evaluate Subjects in accordance with the Protocol. The Investigator on behalf of the Institution will use best efforts to enrol Subjects. When enrolment is complete for the study, the Institution will be notified in writing and will discontinue enrolling Subjects.</p>	<p>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 pazienti. Una volta completato l'arruolamento per lo Studio, l'Ente sarà informato per iscritto e provvederà a interrompere l'arruolamento dei pazienti.</p>
<p><u>3. Per Subject Fees:</u></p>	<p><u>3. Costi per paziente:</u></p>
<p>The amount to be paid to the Payee per completed subject is outlined in the attached Detailed Budget. Invoices should be submitted by Payee to CRO on a quarterly basis and all payments will be made electronically within forty-five (45) days of receipt, review and approval of an invoice and will be based on completed visits entered in the subject EDC (electronic data capture system) according to agreed-upon criteria.</p>	<p>L'importo da corrispondere al Beneficiario per ogni soggetto valutabile completato è specificato nel Budget dettagliato allegato. Il Beneficiario dovrà presentare le fatture alla CRO su base trimestrale e tutti i pagamenti saranno effettuati elettronicamente entro quarantacinque (45) giorni dal ricevimento, revisione e approvazione di una fattura e si baseranno sulle visite completate inserite nell'EDC del soggetto (sistema elettronico di acquisizione dati) secondo criteri concordati.</p>

<p>4. Conditional Fees and Invoiceable Fees:</p>	<p>4. Costi condizionali e fatturabili:</p>
<p>Payment for other conditional fees or expenses that are not included in the Per Subject Fees (as defined in Section 9) will be made according to the below rates as outlined in the below attached Detailed Budget:</p>	<p>Il pagamento di altri costi o spese condizionali non inclusi nei Costi per paziente (come definito nella Sezione 3) sarà effettuato secondo le tariffe sotto indicate, come specificato nel Budget dettagliato allegato:</p>
<p>PRE-SCREENING PAYMENT: Payee will receive a payment up to the maximum amount of € 994.93 per subject who completes all pre-screening activities upon CRO's receipt of an undisputed, detailed, itemized invoice, provided that the number of pre-screened subjects paid hereunder will be capped at a ratio of 8:1 (meaning the Payee will be paid a maximum of eight (8) pre-screened subjects per one (1) enrolled Subject). Payments for pre-screened subjects over (8:1 ratio) may require review and further approval by SPONSOR or CRO in writing. Pre-screening payment is not applicable for subjects who proceed directly to Screening without this preliminary pre-screening process.</p>	<p>PAGAMENTO PRE-SCREENING: Il beneficiario riceverà un pagamento fino all'importo massimo di € 994.93 per soggetto che completa tutte le attività di pre-screening al ricevimento da parte della CRO di una fattura dettagliata, non contestata e dettagliata, a condizione che il numero di soggetti pre-screening pagati ai sensi del presente documento sia limitato a un rapporto di 8:1 (il che significa che al beneficiario verrà pagato un massimo di otto (8) soggetti pre-screening per un (1) soggetto iscritto). I pagamenti per soggetti pre-screening superiori a (rapporto 8:1) potrebbero richiedere la revisione e un'ulteriore approvazione scritta da parte dello Sponsor o della CRO. Il pagamento pre-screening non è applicabile ai soggetti che procedono direttamente allo Screening senza questa procedura preliminare di pre-screening.</p>
<p>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.</p>	<p>SCREENING FAILURE: I fallimenti dello screening saranno rimborsati in base alle procedure effettivamente eseguite, in base ai costi delle singole voci indicati nel Budget dettagliato allegato di seguito, previa immissione di informazioni complete nell'EDC e ricezione da parte della CRO di una fattura dettagliata, incontestata e dettagliata. Tutti i fallimenti dello screening saranno rimborsati al 100% delle procedure effettivamente sostenute e dei costi fatturabili, come indicato nel Budget dettagliato allegato di seguito. L'Ente farà ogni sforzo per evitare procedure non necessarie e per stabilire se un soggetto è un fallimenti dello screening in base ai criteri di idoneità definiti dal Protocollo. Quando l'Ente raggiunge o supera un rapporto di fallimenti dello screening di 4:1 (quattro soggetti con fallimenti dello screening che hanno eseguito 4 MRI-PDFF o 4 biopsie epatiche, a seconda di quale evento si verifichi per primo, per un soggetto arruolato), la CRO, il Promotore o un delegato possono esaminare le caratteristiche del paziente e discutere con il centro l'individuazione dei pazienti appropriati. Il Promotore, il delegato del Promotore o la CRO hanno il diritto di limitare, ridurre o interrompere i futuri screening in base a questa valutazione. L'Ente è autorizzato a continuare le attività di screening durante il processo</p>

	<p>di valutazione fino a diversa comunicazione da parte del Promotore o della CRO. Si considera fallimento dello screening quando il Soggetto firma il modulo di consenso informato e completa lo screening, ma non soddisfa i criteri di inclusione/esclusione e non verrà arruolato.</p>
<p>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.</p>	<p>RE-SCREENING: I fallimenti dello screening possono essere ricontrattati solo previa approvazione del Promotore o della CRO, in conformità con il Protocollo. Il Re-Screening sarà rimborsato secondo le procedure effettivamente eseguite, basandosi sui costi dei singoli elementi indicati nel Budget Dettagliato allegato qui sotto. Il pagamento sarà effettuato elettronicamente entro quarantacinque (45) giorni dal ricevimento, revisione e approvazione della fattura e sarà convalidato sulle informazioni completate verificate e inserite nell’electronic case report form o nella documentazione di supporto, se applicabile.</p>
<p>SUBJECT REIMBURSEMENT: Reasonable patient’s expenses during the Study will be reimbursed.</p> <p>Subject reimbursement will be managed and paid directly through CRO/SPONSOR third-party vendor (hereinafter “Vendor”) and will not be considered part of the Study Subject payments made to payee.</p> <p>The reimbursement will be managed as follows: any travel organized independently by the patient and any costs, such as meals, parking, and mileage, will be reimbursed by Institution directly to the patient. Namely, the Vendor pays to Institution, and Institution reimburses the patient. Institution will be required to complete a form (which contains no patient information, except for the patient ID, number, and date of visits) and will be responsible for retaining the corresponding receipts.</p> <p>It is hereby noted that the Vendor will not be required to manage patient travel arrangements and that the Vendor will therefore not in any way come into possession of the patients' identifying data.</p> <p>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</p>	<p>RIMBORSO DEL SOGGETTO: Saranno rimborsate le spese di viaggio ragionevoli sostenute dal paziente durante lo Studio.</p> <p>Il rimborso del Soggetto sarà gestito e pagato direttamente tramite il fornitore terzo di CRO/Promotore (qui di seguito “Fornitore”) e non sarà considerato parte dei pagamenti effettuati dal Soggetto dello Studio all’Ente.</p> <p>Il rimborso avverrà come segue: qualsiasi viaggio organizzato dal paziente in autonomia e qualsiasi costo come pasti, parcheggio e chilometraggio verrà rimborsato dall’Ente direttamente al paziente, ovvero: il Fornitore paga l’Ente, l’Ente rimborsa il paziente. L’Ente sarà tenuto alla compilazione di un form (che non contiene informazioni sul paziente, ad eccezione del codice identificativo del paziente, del numero e della data delle visite), e sarà responsabile della conservazione delle ricevute corrispondenti.</p> <p>Si precisa che al Fornitore non verrà richiesto di gestire l'organizzazione dei viaggi dei pazienti e che lo stesso non entrerà quindi in alcun modo in possesso dei dati identificativi dei pazienti.</p> <p>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</p>

<p>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.</p>	<p>dall'Ente, qualsiasi richiesta di rimborso per le spese di viaggio del Soggetto che superi l'importo per visita indicato nel Budget Dettagliato richiede la previa approvazione scritta della CRO e/o del Promotore, caso per caso.</p>
<p>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.</p>	<p>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.</p>
<p>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.</p>	<p>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.</p>
<p>Payee will issue one consolidated invoice at quarter end for all services performed and expenses incurred under this section during that quarter. Payment will be made electronically within forty-five (45) days of receipt, review and approval of the invoice and will be validated on completed info verified and entered in the electronic case report form or supporting documentation, as applicable.</p>	<p>Il Beneficiario emetterà una fattura consolidata alla fine del trimestre per tutti i servizi eseguiti e le spese sostenute ai sensi della presente sezione durante quel trimestre. Il pagamento verrà effettuato elettronicamente entro quarantacinque (45) giorni dal ricevimento, revisione e approvazione della fattura e sarà convalidato sulle informazioni complete, verificate e inserite nel modulo elettronico o nella documentazione di supporto, a seconda dei casi.</p>
<p><u>5. Site Fees:</u></p>	<p><u>5. TARIFFE DEL CENTRO:</u></p>
<p>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</p>	<p>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</p>

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.	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.
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.	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.
<u>6. Pro-Rata Payments:</u>	<u>6. 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.	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.
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.	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.
If other non-cancelable costs are incurred by Institution in accordance with the Agreement, written justification must be provided to SPONSOR for review and approval, and payment of such costs is subject to SPONSOR's approval	Laddove vengano sostenuti altri costi non cancellabili dall'Ente, in conformità al Contratto, sarà necessario fornire una giustificazione scritta al Promotore, per l'esame e l'approvazione, e il pagamento di detti costi sarà soggetto all'approvazione del Promotore.
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.	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.
<u>7. Protocol Violators</u>	<u>7. Soggetti che violano il Protocollo</u>
Payments for Study Subjects who are deemed to have been in violation of the Protocol may be paid up to the	I pagamenti per i Soggetti in Studio che si ritenga abbiano violato il Protocollo possono essere esigibili

point that the violation occurred at the discretion of SPONSOR.	fino al punto in cui si sia verificata la violazione, a discrezione del Promotore.
<u>8. Invoices</u>	<u>8. Fatture</u>
<p>Correct Valid Invoices should be addressed/issued to:</p> <p>Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany VAT #DE 811138149</p> <p>Payment agent: PAREXEL International (IRL) Limited</p> <p>Preferred method of invoice submission is through CRO's self-service Site Pay Portal (hereinafter "Portal"). Payee will receive instructions on how to access and register to the Portal once Detailed Budget is set up in the Portal.</p> <p>In case Payee is not able to submit invoice through the Portal, correct valid invoices should be e-mailed to sitepaymentinvoicing@parexel.com PAREXEL Study no.: 284641</p> <p>with the following details:</p> <ul style="list-style-type: none"> • Protocol number or CRO project number shall be indicated in the subject line of the email. • Protocol number /CRO project number, Investigator name, site name and invoice number shall be indicated in the body of the email. <p>Paper invoices can be sent to: 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</p> <p>Parexel Study no.: 284641</p>	<p>Le fatture valide corrette devono essere intestate a:</p> <p>Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germania P.IVA #DE 811138149</p> <p>Agente di pagamento: PAREXEL International (IRL) Limited</p> <p>Il metodo preferito per l'invio delle fatture è tramite il Portale di Pagamento Self-Service per i centri della CRO (di seguito "Portale"). Il beneficiario riceverà istruzioni su come accedere e registrarsi al "Portale" una volta che il Budget Dettagliato sarà configurato nel Portale. Nel caso in cui il beneficiario non sia in grado di presentare la fattura tramite il "Portale", le fatture corrette e valide dovranno essere inviate via e-mail a: sitepaymentinvoicing@parexel.com Studio PAREXEL n.: 284641</p> <p>con i seguenti dettagli:</p> <ul style="list-style-type: none"> • 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 <p>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</p> <p>Studio PAREXEL n.: 284641</p>
All invoices must contain the following information:	Tutte le fatture dovranno contenere le seguenti informazioni:

<ul style="list-style-type: none"> (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 	<ul style="list-style-type: none"> (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
<p>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.</p>	<p>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</p>
<p><u>9. Final Payment</u></p>	<p><u>9. Pagamento finale</u></p>
<p>Notwithstanding the foregoing, the final payment shall be made upon the completion of the following activities:</p> <ul style="list-style-type: none"> (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 	<p>Fermo restando quanto precede, il pagamento finale sarà liquidato al completamento delle seguenti attività:</p> <ul style="list-style-type: none"> (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
<p>Payee shall have thirty (30) days from the receipt of the final payment under this Agreement to identify discrepancies and resolve any payment disputes with CRO.</p>	<p>Il Beneficiario avrà trenta (30) giorni di tempo dalla ricezione del pagamento finale ai sensi del presente Contratto, per identificare eventuali discrepanze e risolvere qualsiasi disputa di pagamento con la CRO.</p>
<p>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.</p>	<p>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</p>

	visita di fine studio dell'Ente. Le fatture ricevute dopo questo termine non saranno rimborsate.
<u>10. TAX</u>	<u>10. IMPOSTE</u>
All fees and expenses in this Annex A are exclusive of VAT or any applicable tax. All payments are subject to withholding tax as applicable.	Tutte le commissioni e spese nel presente Allegato A sono da intendersi al netto di IVA o di qualsiasi imposta applicabile. Tutti i pagamenti sono soggetti alle ritenute alla fonte ove pertinente.

Detailed Budget – Budget Dettagliato

Budget Information

	Standard	Condition	Overall
	d	al	
Total Cost per Patient:	36,016.84	68,383.16	104,400.00

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

Procedures

Code	Name	OH?	Total	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	
			Quantity															
*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													
*AUDI	AUDIT Interview	Y	1.00	35.00	35.00													
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 (at visit 2) and weight	Y	14.00	75.00		75.00					75.00			75.00		75.00		
BMI	Body Mass Index (BMI)	Y	1.00	18.00	18.00													
*MEAC	Waist and hip	Y	33.00	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	18.00	26.00				26.00		26.00		26.00	26.00					
93000	12-lead ECG w/ Interpret. & Report	Y	21.00	56.00	168.00	56.00		56.00			56.00			56.00		56.00		
RCM	Concomitant therapy	Y	56.00	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 lipid-lowering treatment, Evaluation of anti-hypertension treatment, Evaluation of anti-hyperglycaemic treatment- 10mins evaluation	Y	56.00	16.00		32.00					32.00			32.00		32.00		
*ADVE	All AEs/AESIs	Y	56.00	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	31.00	6.00		6.00		6.00		6.00	6.00	6.00	6.00	6.00	6.00	6.00	6.00	6.00

Procedures

Code	Name	V14_D337_C	V15_D365_C	V16_D379_C	V17_W60_R	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	
*INCO	Informed consent																			
*INEX	Review in-/exclusion criteria																			
*DEMO	Demographics																			
*3322	Medical history																			
*AUDI	AUDIT Interview																			
99213	Complete Physical examination including one set of Vital signs (SBP, DBP, pulse), and weight																			
99212	Brief Physical examination including one set of Vital signs (SBP, DBP, pulse), height (at visit 2) and weight	75.00	75.00	75.00		75.00								75.00						
BMI	Body Mass Index (BMI)																			
*MEAC	Waist and hip	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							26.00		26.00		26.00				26.00				26.00
93000	12-lead ECG w/ Interpret. & Report			56.00		56.00				56.00				56.00						56.00
RCM	Concomitant therapy	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00
*GADS	Evaluation of lipid-lowering treatment, Evaluation of anti-hypertension treatment, Evaluation of anti-hyperglycaemic treatment- 10mins evaluation	32.00	32.00	32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00
*ADVE	All AEs/AESIs	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00
*ISRS	Check for injection site reaction	6.00	6.00	6.00		6.00		6.00		6.00		6.00		6.00		6.00		6.00		6.00

Procedures

Code	Name	OH?	Total	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	
			Quantity																
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, eGFRcys, ELF samples, Other biomarkers samples, glucagon, ADA, NAb samples, Alpha-fetoprotein, Blood sample for Pharmacogenomics	Y	33.00	32.00	32.00	32.00		32.00		32.00	32.00	32.00	32.00	32.00		32.00			32.00
NC017	Urine Collection - Urine analysis, UACR	Y	28.00	10.00		10.00					10.00			10.00		10.00			10.00
99000	Handling and shipment - Central lab	Y	33.00	25.00	25.00	25.00		25.00		25.00	25.00	25.00	25.00	25.00		25.00			25.00
91200	Fibroscan: (VCTE - LSM) and CAP)	Y	14.00	422.00	422.00									422.00					
*FBRS	ELF Score	Y	11.00	40.00		40.00					40.00			40.00					
80299	PK	Y	18.00	42.00		42.00		42.00			42.00			42.00		42.00			
*FAST	Fast Score	Y	14.00	35.00	35.00									35.00					
*MELD	MELD scores	Y	33.00	34.00	34.00	34.00		34.00		34.00	34.00	34.00	34.00	34.00		34.00			34.00
*GADS	Assess ascites, hepatic encephalopathy	Y	33.00	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 evaluation	Y	15.00	16.00		16.00								16.00					16.00
*RPMD	eDiary review (IMP administration, injection site reactions, and compliance check), ePRO - NASH-CHECK Questionnaire, CLDQ NAFLD NASH, PHQ-9, C-SSRS, SF36	Y	56.00	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													
*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													
98966	Vital status_Phone call	Y	1.00	25.00															
99401	Diet and physical activity counselling	Y	30.00	70.00		70.00		70.00		70.00	70.00	70.00	70.00	70.00		70.00			70.00
NC008	Remote visit	Y	23.00	23.00			23.00		23.00						23.00			23.00	

Per Patient Activity Totals: 1,137.00 673.00 91.00 386.00 91.00 288.00 517.00 288.00 288.00 990.00 91.00 477.00 91.00 395.00

Procedures

Code	Name	V15_D365_C	V16_D379_C	V17_W60_R	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	V32_W150_C	V33_W156_R	V34_W162_C	
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, eGFRcys, ELF samples, Other biomarkers samples, glucagon, ADA, NAb samples, Alpha-fetoprotein, Blood sample for Pharmacogenomics	32.00	32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00	
NC017	Urine Collection - Urine analysis, UACR	10.00	10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00	
99000	Handling and shipment - Central lab	25.00	25.00		25.00		25.00		25.00		25.00		25.00		25.00		25.00		25.00		25.00	
91200	Fibroscan: (VCTE - LSM) and CAP)	422.00			422.00				422.00				422.00				422.00				422.00	
*FBRS	ELF Score	40.00			40.00				40.00				40.00								40.00	
80299	PK	42.00			42.00				42.00				42.00				42.00				42.00	
*FAST	Fast Score	35.00			35.00				35.00				35.00				35.00				35.00	
*MELD	MELD scores	34.00	34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00	
*GADS	Assess ascites, hepatic encephalopathy	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 evaluation				16.00				16.00				16.00				16.00				16.00	
*RPMD	eDiary review (IMP administration, injection site reactions, and compliance check), ePRO - NASH-CHECK Questionnaire, CLDQ NAFLD NASH, PHQ-9, C-SSRS, SF36	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																					
*DPSD	Hand out IFU – pre-filled syringe and Hand out of SMBG device (trial participants with T2DM), and trial participant materials																					
98966	Vital status_Phone call																					
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	
NC008	Remote visit			23.00		23.00		23.00		23.00		23.00		23.00		23.00		23.00		23.00		23.00
Per Patient Activity Totals:		848.00	435.00	91.00	990.00	91.00	330.00	91.00	941.00	91.00	330.00	91.00	990.00	91.00	330.00	91.00	901.00	91.00	330.00	91.00	990.00	

Procedures

Code	Name	V35_W166_R	V36_W174_C	V37_W180_R	V38_W186_C	V39_W192_R	V40_W198_C	V41_W204_R	V42_W210_C	V43_W216_R	V44_W222_C	V45_W228_R	V46_W234_C	V47_W240_R	V48_W246_C	V49_W252_R	V50_W258_C	V51_W264_R	V52_W270_C	V53_W276_R	V54_W282_C	EOT	FU/EOS	Total	ETD
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, eGFRcys, ELF samples, Other biomarkers samples, glucagon, ADA, NAb samples, Alpha-fetoprotein, Blood sample for Pharmacogenomics		32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00	32.00	32.00	1,056.00	32.00
NC017	Urine Collection - Urine analysis, UACR		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00	10.00	10.00	280.00	10.00
99000	Handling and shipment - Central lab		25.00		25.00		25.00		25.00		25.00		25.00		25.00		25.00		25.00		25.00	25.00	25.00	825.00	25.00
91200	Fibroscan: (VCTE - LSM) and CAP)				422.00				422.00				422.00				422.00				422.00	422.00		5,908.00	422.00
*FBRS	ELF Score								40.00								40.00				40.00	40.00		440.00	40.00
80299	PK				42.00				42.00				42.00				42.00				42.00	42.00	42.00	756.00	42.00
*FAST	Fast Score				35.00				35.00				35.00				35.00				35.00	35.00	35.00	490.00	35.00
*MELD	MELD scores		34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00	34.00	34.00	1,122.00	34.00
*GADS	Assess ascites, hepatic encephalopathy		16.00		16.00		16.00		16.00		16.00		16.00		16.00		16.00		16.00		16.00	16.00	16.00	528.00	16.00
*GADS	Liver Disease Progression - 5min evaluation				16.00				16.00				16.00				16.00				16.00	16.00	16.00	240.00	16.00
*RPMD	eDiary review (IMP administration, injection site reactions, and compliance check), ePRO - NASH-CHECK Questionnaire, CLDQ NAFLD NASH, PHQ-9, C-SSRS, SF36	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	31.00	1,736.00	31.00
98960	Training in/observe pre-filled syringe administration																							82.00	
*DPSD	Hand out IFU – pre-filled syringe and Hand out of SMBG device (trial participants with T2DM), and trial participant materials																							56.00	
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		2,100.00	70.00
NC008	Remote visit	23.00		23.00		23.00		23.00		23.00		23.00		23.00		23.00		23.00		23.00				529.00	
Per Patient Activity Totals:		91.00	330.00	91.00	901.00	91.00	330.00	91.00	990.00	91.00	330.00	91.00	901.00	91.00	330.00	91.00	990.00	91.00	330.00	91.00	901.00	990.00	442.00	22,712.00	990.00

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_D365_C	V16_D379_C
V1110	Physician Salary - HOMA-IR, HOMA-β	Y	45.50	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	41.00	41.00
*STCO	Study Coordinator; Per Visit - data entry	Y	45.50	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	69.00	69.00
*NURS	Nurse; Per Visit	Y	34.00	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	Y	30.00	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	212.00	212.00

Conditional

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_D365_C	V16_D379_C
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															
74181	MRI-PDFF	Y	1.00	1,787.00	1,787.00															
*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														
NC017	Urine Collection - Urine pregnancy if applicable)	Y	33.00	10.00	10.00	10.00		10.00		10.00	10.00	10.00	10.00	10.00		10.00		10.00	10.00	10.00
36415	Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics, - Reticulocytes (only for patients with Gilbert Syndrome), Pancreatic amylase (at screening, and CK-MB,Troponin as reflex test if amylase is elevated at all other visits, including DILI evaluation visit)	Y	4.00	29.00	29.00	29.00								29.00						
99000	Preparation of sample for shipping - central lab	Y	4.00	25.00	25.00	25.00								25.00						
88363	Liver biopsy - archival	Y	1.00	84.00	84.00															
47000	Liver biopsy(a triggered biopsy if clinically indicated)	Y	2.00	800.00															800.00	
NC065	Biopsy Sample Handling Simple	Y	3.00	21.00	21.00															21.00
99152	Moderate Sedation Init 15 Min 5+yrs	Y	2.00	205.00																205.00
CPC	CTP	Y	33.00	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

Non Procedures

Code	Name	V17_W60_R	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	V32_W150_C	V33_W156_R	V34_W162_C	V35_W168_R	V36_W174_C	V37_W180_R	V38_W186_C
V1110	Physician Salary - HOMA-IR, HOMA-β	20.50	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	20.50	41.00	20.50	41.00	20.50	41.00	20.50	41.00
*STCO	Study Coordinator; Per Visit - data entry	34.50	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	34.50	69.00	34.50	69.00	34.50	69.00	34.50	69.00
*NURS	Nurse; Per Visit		68.00		68.00		68.00		68.00		68.00		68.00		68.00		68.00		68.00		68.00		68.00
VPHRM	Dispensing, Simple; Per Visit - Hand out IFU – pre-filled syringe, dispense		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:		55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00

Conditional

Code	Name	V17_W60_R	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	V32_W150_C	V33_W156_R	V34_W162_C	V35_W168_R	V36_W174_C	V37_W180_R	V38_W186_C
47000	Liver biopsy																						
99152	Moderate Sedation Init 15 Min 5+yrs																						
74181	MRI-PDF																						
*GNCO	Informed Consent: DNA, Genetics																						
*IWQL	Assessment of obesity staging - (For participants with BMI ≥30 kg/m2 (≥25 kg/m2 for Asian ethnicity)																						
NC017	Urine Collection - Urine pregnancy if applicable)		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00
36415	Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics, - Reticulocytes (only for patients with Gilbert Syndrome), Pancreatic amylase (at screening, and CK-MB,Troponin as reflex test if amylase is elevated at all other visits, including DILI evaluation visit)																						
99000	Preparation of sample for shipping - central lab																						
88363	Liver biopsy - archival																						
47000	Liver biopsy(a triggered biopsy if clinically indicated)																						
NC065	Biopsy Sample Handling Simple																						
99152	Moderate Sedation Init 15 Min 5+yrs																						
CPC	CTP		15.00		15.00		15.00		15.00		15.00		15.00		15.00		15.00		15.00		15.00		15.00

Conditional

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_D365_C	V16_D379_C
91110	UGE (only for participants who progressed to cirrhosis)-at the diagnosis of cirrhosis at all scheduled visits until the end of trial	Y	20.00	1,892.00																
76700	Abdominal ultrasound (only for participants who progressed to cirrhosis)	Y	11.00	384.00																
76830-26	Abdominal ultrasound - Interpretation & Report Only (only for participants who progressed to cirrhosis)	Y	11.00	101.00																
92012	Eye examination	Y	8.00	70.00	70.00								70.00							
*NASH	NASH-CHECK Questionnaire (only in case of paper questionnaires)	Y	16.00	18.00		18.00				18.00			18.00					18.00	18.00	
*CLDQ	CLDQ NAFLD-NASH (only in case of paper questionnaires)	Y	15.00	23.00		23.00				23.00			23.00						23.00	
*SF36	SF-36 (only in case of paper questionnaires)	Y	15.00	19.00		19.00				19.00			19.00						19.00	
*PHQ9	PHQ-9 (only in case of paper questionnaires)	Y	29.00	18.00	18.00	36.00				18.00			18.00		18.00			18.00		18.00
*CSSR	C-SSRS (only in case of paper questionnaires)	Y	57.00	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
*TOHM	Hand out of SMBG device (trial participants with T2DM)	Y	2.00	37.00	37.00	37.00														
*RPMD	Hyper-/hypoglycaemic episode review (eDiary – participants with T2DM)	Y	53.00	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
85025	haematology - Haematocrit Haemoglobin Mean corpuscular volume Mean corpuscular haemoglobin Mean cellular haemoglobin concentration Red blood cell distribution width Red blood cells count / erythrocytes White blood cell count / leukocytes Platelet count / thrombocytes Differential automatic (relative and absolute count): Neutrophils, eosinophils, basophils, monocytes, lymphocytes	Y	33.00	22.00	22.00	22.00		22.00		22.00	22.00	22.00	22.00			22.00		22.00	22.00	22.00
80053	clinical chemistry - Albumin ALP ALT AST Bicarbonate TBL, fractionated Calcium Chloride Potassium Protein total Sodium Urea (blood urea nitrogen)	Y	33.00	45.00	45.00	45.00		45.00		45.00	45.00	45.00	45.00	45.00		45.00		45.00	45.00	45.00

Conditional

Code	Name	V17_W60_R	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	V32_W150_C	V33_W156_R	V34_W162_C	V35_W168_R	V36_W174_C	V37_W180_R	
91110	UGE (only for participants who progressed to cirrhosis)-at the diagnosis of cirrhosis at all scheduled visits until the end of trial		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00
76700	Abdominal ultrasound (only for participants who progressed to cirrhosis)		384.00				384.00				384.00				384.00				384.00				
76830-26	Abdominal ultrasound - Interpretation & Report Only (only for participants who progressed to cirrhosis)		101.00				101.00				101.00				101.00				101.00				
92012	Eye examination		70.00								70.00								70.00				
*NASH	NASH-CHECK Questionnaire (only in case of paper questionnaires)		18.00				18.00				18.00				18.00				18.00				
*CLDQ	CLDQ NAFLD-NASH (only in case of paper questionnaires)		23.00				23.00				23.00				23.00				23.00				
*SF36	SF-36 (only in case of paper questionnaires)		19.00				19.00				19.00				19.00				19.00				
*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
*CSSR	C-SSRS (only in case of paper questionnaires)	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00
*TOHM	Hand out of SMBG device (trial participants with T2DM)																						
*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	31.00	31.00	31.00	31.00	31.00	31.00	31.00	31.00
85025	haematology - Haematocrit Haemoglobin Mean corpuscular volume Mean corpuscular haemoglobin Mean cellular haemoglobin concentration Red blood cell distribution width Red blood cells count / erythrocytes White blood cell count / leukocytes Platelet count / thrombocytes Differential automatic (relative and absolute count): Neutrophils, eosinophils, basophils, monocytes, lymphocytes		22.00		22.00		22.00		22.00		22.00		22.00		22.00		22.00		22.00		22.00		22.00
80053	clinical chemistry - Albumin ALP ALT AST Bicarbonate TBL, fractionated Calcium Chloride Potassium Protein total Sodium Urea (blood urea nitrogen)		45.00		45.00		45.00		45.00		45.00		45.00		45.00		45.00		45.00		45.00		45.00

Conditional

Code	Name	V38_W186_C	V39_W192_R	V40_W198_C	V41_W204_R	V42_W210_C	V43_W216_R	V44_W222_C	V45_W228_R	V46_W234_C	V47_W240_R	V48_W246_C	V49_W252_R	V50_W258_C	V51_W264_R	V52_W270_C	V53_W276_R	V54_W282_C	EOT	FU/EOS	Total	ETD	
91110	UGE (only for participants who progressed to cirrhosis)-at the diagnosis of cirrhosis at all scheduled visits until the end of trial	1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00			37,840.00	1,892.00	
76700	Abdominal ultrasound (only for participants who progressed to cirrhosis)	384.00				384.00				384.00				384.00				384.00	384.00			4,224.00	384.00
76830-26	Abdominal ultrasound - Interpretation & Report Only (only for participants who progressed to cirrhosis)	101.00				101.00				101.00				101.00				101.00	101.00			1,111.00	101.00
92012	Eye examination					70.00								70.00					70.00			560.00	70.00
*NASH	NASH-CHECK Questionnaire (only in case of paper questionnaires)	18.00				18.00				18.00				18.00				18.00	18.00			288.00	18.00
*CLDQ	CLDQ NAFLD-NASH (only in case of paper questionnaires)	23.00				23.00				23.00				23.00				23.00	23.00			345.00	23.00
*SF36	SF-36 (only in case of paper questionnaires)	19.00				19.00				19.00				19.00				19.00	19.00			285.00	19.00
*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		522.00	18.00
*CSSR	C-SSRS (only in case of paper questionnaires)	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	2,964.00	52.00
*TOHM	Hand out of SMBG device (trial participants with T2DM)																					74.00	
*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	31.00	31.00	31.00	31.00			1,643.00	31.00
85025	haematology - Haematocrit Haemoglobin Mean corpuscular volume Mean corpuscular haemoglobin Mean cellular haemoglobin concentration Red blood cell distribution width Red blood cells count / erythrocytes White blood cell count / leukocytes Platelet count / thrombocytes Differential automatic (relative and absolute count): Neutrophils, eosinophils, basophils, monocytes, lymphocytes	22.00		22.00		22.00		22.00		22.00		22.00		22.00		22.00		22.00	22.00	22.00		726.00	22.00
80053	clinical chemistry - Albumin ALP ALT AST Bicarbonate TBL, fractionated Calcium Chloride Potassium Protein total Sodium Urea (blood urea nitrogen)	45.00		45.00		45.00		45.00		45.00		45.00		45.00		45.00		45.00	45.00	45.00		1,485.00	45.00

Conditional

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_D365_C	V16_D379_C	V17_W60_R
82150	Clinical chemistry - Amylase (local lab)	Y	33.00	8.00	8.00	8.00		8.00		8.00	8.00	8.00	8.00	8.00		8.00		8.00	8.00	8.00	
83690	Clinical chemistry - Lipase (local lab)	Y	33.00	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	
80299	Additional PK sample collected at the time of a potential DILI event for later analysis of drug exposure	Y		42.00																	
*SAEA	All SAEs - per occurrence	Y		19.00																	
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																	
74181	MRI Scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		1,787.00																	
74181-26	MRI Scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		419.00																	
N74182	MRI Scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		1,622.00																	
74181-26	MRI Scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated α-fetoprotein)	Y		419.00																	
NC008	Remote visit (EoS Visit via remote visits (if allowed per local regulations))	Y	1.00	23.00																	
Per Patient Conditional Totals:					3,279.00	429.00	83.00	199.00	83.00	199.00	277.00	199.00	199.00	401.00	83.00	217.00	83.00	235.00	1,285.00	217.00	83.00

Conditional

Code	Name	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	V32_W150_C	V33_W156_R	V34_W162_C	V35_W168_R	V36_W174_C	V37_W180_R	V38_W186_C
82150	Clinical chemistry - Amylase (local lab)	8.00		8.00		8.00		8.00		8.00		8.00		8.00		8.00		8.00		8.00		8.00
83690	Clinical chemistry - Lipase (local lab)	16.00		16.00		16.00		16.00		16.00		16.00		16.00		16.00		16.00		16.00		16.00
80299	Additional PK sample collected at the time of a potential DILI event for later analysis of drug exposure																					
*SAEA	All SAEs - per occurrence																					
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 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)																					
N74182	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)																					
NC008	Remote visit (EoS Visit via remote visits (if allowed per local regulations))																					
Per Patient Conditional Totals:		2,724.00	83.00	2,109.00	83.00	2,654.00	83.00	2,109.00	83.00	2,724.00	83.00	2,109.00	83.00	2,654.00	83.00	2,109.00	83.00	2,724.00	83.00	2,109.00	83.00	2,654.00

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_D365_C	V16_D379_C	V17_W60_R
Costs Not Charged with Overhead																	
Costs Charged with Overhead	1,493.00	885.00	146.00	598.00	146.00	500.00	729.00	500.00	500.00	1,202.00	146.00	689.00	146.00	607.00	1,060.00	647.00	146.00
Overhead at 16%	238.88	141.60	23.36	95.68	23.36	80.00	116.64	80.00	80.00	192.32	23.36	110.24	23.36	97.12	169.60	103.52	23.36
Selected Cost Per Visit	1,731.88	1,026.60	169.36	693.68	169.36	580.00	845.64	580.00	580.00	1,394.32	169.36	799.24	169.36	704.12	1,229.60	750.52	169.36

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_D365_C	V16_D379_C	V17_W60_R
Costs Not Charged with Overhead																	
Costs Charged with Overhead	3,279.00	429.00	83.00	199.00	83.00	199.00	277.00	199.00	199.00	401.00	83.00	217.00	83.00	235.00	1,285.00	217.00	83.00
Overhead at 16%	524.64	68.64	13.28	31.84	13.28	31.84	44.32	31.84	31.84	64.16	13.28	34.72	13.28	37.60	205.60	34.72	13.28
Selected Cost Per Visit	3,803.64	497.64	96.28	230.84	96.28	230.84	321.32	230.84	230.84	465.16	96.28	251.72	96.28	272.60	1,490.60	251.72	96.28

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_D365_C	V16_D379_C	V17_W60_R
Costs Not Charged with Overhead																	
Costs Charged with Overhead	4,772.00	1,314.00	229.00	797.00	229.00	699.00	1,006.00	699.00	699.00	1,603.00	229.00	906.00	229.00	842.00	2,345.00	864.00	229.00
Overhead at 16%	763.52	210.24	36.64	127.52	36.64	111.84	160.96	111.84	111.84	256.48	36.64	144.96	36.64	134.72	375.20	138.24	36.64
Selected Cost Per Visit	5,535.52	1,524.24	265.64	924.52	265.64	810.84	1,166.96	810.84	810.84	1,859.48	265.64	1,050.96	265.64	976.72	2,720.20	1,002.24	265.64

Patient Cost For Standard Items

	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt
	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	V32_W150_C	V33_W156_R	V34_W162_C	V35_W168_R	
Costs Not Charged with Overhead																			
Costs Charged with Overhead	1,202.00	146.00	542.00	146.00	1,153.00	146.00	542.00	146.00	1,202.00	146.00	542.00	146.00	1,113.00	146.00	542.00	146.00	1,202.00	146.00	
Overhead at 16%	192.32	23.36	86.72	23.36	184.48	23.36	86.72	23.36	192.32	23.36	86.72	23.36	178.08	23.36	86.72	23.36	192.32	23.36	
Selected Cost Per Visit	1,394.32	169.36	628.72	169.36	1,337.48	169.36	628.72	169.36	1,394.32	169.36	628.72	169.36	1,291.08	169.36	628.72	169.36	1,394.32	169.36	

Patient Cost For Conditional Items

	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt
	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	V32_W150_C	V33_W156_R	V34_W162_C	V35_W168_R	
Costs Not Charged with Overhead																			
Costs Charged with Overhead	2,724.00	83.00	2,109.00	83.00	2,654.00	83.00	2,109.00	83.00	2,724.00	83.00	2,109.00	83.00	2,654.00	83.00	2,109.00	83.00	2,724.00	83.00	
Overhead at 16%	435.84	13.28	337.44	13.28	424.64	13.28	337.44	13.28	435.84	13.28	337.44	13.28	424.64	13.28	337.44	13.28	435.84	13.28	
Selected Cost Per Visit	3,159.84	96.28	2,446.44	96.28	3,078.64	96.28	2,446.44	96.28	3,159.84	96.28	2,446.44	96.28	3,078.64	96.28	2,446.44	96.28	3,159.84	96.28	

Overall Patient Cost

	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt	Treatme nt
	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	V32_W150_C	V33_W156_R	V34_W162_C	V35_W168_R	
Costs Not Charged with Overhead																			
Costs Charged with Overhead	3,926.00	229.00	2,651.00	229.00	3,807.00	229.00	2,651.00	229.00	3,926.00	229.00	2,651.00	229.00	3,767.00	229.00	2,651.00	229.00	3,926.00	229.00	
Overhead at 16%	628.16	36.64	424.16	36.64	609.12	36.64	424.16	36.64	628.16	36.64	424.16	36.64	602.72	36.64	424.16	36.64	628.16	36.64	
Selected Cost Per Visit	4,554.16	265.64	3,075.16	265.64	4,416.12	265.64	3,075.16	265.64	4,554.16	265.64	3,075.16	265.64	4,369.72	265.64	3,075.16	265.64	4,554.16	265.64	

Patient Cost For Standard Items

	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Follow Up	Total
	V36_W174_C	V37_W180_R	V38_W186_C	V39_W192_R	V40_W198_C	V41_W204_R	V42_W210_C	V43_W216_R	V44_W222_C	V45_W228_R	V46_W234_C	V47_W240_R	V48_W246_C	V49_W252_R	V50_W258_C	V51_W264_R	V52_W270_C	V53_W276_R	V54_W282_C	EOT	FU/EOS	
Costs Not Charged with Overhead																						
Costs Charged with Overhead	542.00	146.00	1,113.00	146.00	542.00	146.00	1,202.00	146.00	542.00	146.00	1,113.00	146.00	542.00	146.00	1,202.00	146.00	542.00	146.00	1,113.00	1,168.00	620.00	31,049.00
Overhead at 16%	86.72	23.36	178.08	23.36	86.72	23.36	192.32	23.36	86.72	23.36	178.08	23.36	86.72	23.36	192.32	23.36	86.72	23.36	178.08	186.88	99.20	4,967.84
Selected Cost Per Visit	628.72	169.36	1,291.08	169.36	628.72	169.36	1,394.32	169.36	628.72	169.36	1,291.08	169.36	628.72	169.36	1,394.32	169.36	628.72	169.36	1,291.08	1,354.88	719.20	36,016.84

Discontinuation
ETD
1,168.00
186.88
1,354.88

Patient Cost For Conditional Items

	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Follow Up	Total	
	V36_W174_C	V37_W180_R	V38_W186_C	V39_W192_R	V40_W198_C	V41_W204_R	V42_W210_C	V43_W216_R	V44_W222_C	V45_W228_R	V46_W234_C	V47_W240_R	V48_W246_C	V49_W252_R	V50_W258_C	V51_W264_R	V52_W270_C	V53_W276_R	V54_W282_C	EOT	FU/EOS	
Costs Not Charged with Overhead																						
Costs Charged with Overhead	2,109.00	83.00	2,654.00	83.00	2,109.00	83.00	2,724.00	83.00	2,109.00	83.00	2,654.00	83.00	2,109.00	83.00	2,724.00	83.00	2,109.00	83.00	2,654.00	3,826.00	209.00	58,951.00
Overhead at 16%	337.44	13.28	424.64	13.28	337.44	13.28	435.84	13.28	337.44	13.28	424.64	13.28	337.44	13.28	435.84	13.28	337.44	13.28	424.64	612.16	33.44	9,432.16
Selected Cost Per Visit	2,446.44	96.28	3,078.64	96.28	2,446.44	96.28	3,159.84	96.28	2,446.44	96.28	3,078.64	96.28	2,446.44	96.28	3,159.84	96.28	2,446.44	96.28	3,078.64	4,438.16	242.44	68,383.16

Discontinuation
ETD
3,826.00
612.16
4,438.16

Overall Patient Cost

	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Follow Up	Total	
	V36_W174_C	V37_W180_R	V38_W186_C	V39_W192_R	V40_W198_C	V41_W204_R	V42_W210_C	V43_W216_R	V44_W222_C	V45_W228_R	V46_W234_C	V47_W240_R	V48_W246_C	V49_W252_R	V50_W258_C	V51_W264_R	V52_W270_C	V53_W276_R	V54_W282_C	EOT	FU/EOS	
Costs Not Charged with Overhead																						
Costs Charged with Overhead	2,651.00	229.00	3,767.00	229.00	2,651.00	229.00	3,926.00	229.00	2,651.00	229.00	3,767.00	229.00	2,651.00	229.00	3,926.00	229.00	2,651.00	229.00	3,767.00	4,994.00	829.00	90,000.00
Overhead at 16%	424.16	36.64	602.72	36.64	424.16	36.64	628.16	36.64	424.16	36.64	602.72	36.64	424.16	36.64	628.16	36.64	424.16	36.64	602.72	799.04	132.64	14,400.00
Selected Cost Per Visit	3,075.16	265.64	4,369.72	265.64	3,075.16	265.64	4,554.16	265.64	3,075.16	265.64	4,369.72	265.64	3,075.16	265.64	4,554.16	265.64	3,075.16	265.64	4,369.72	5,793.04	961.64	104,400.00

Discontinuation
ETD
4,994.00
799.04
5,793.04

Site Level Other Direct Costs

Code	Name	OH?	Total Quantity	SITE Cost
#1124	Study Fee: Set-Up; Fixed	N	1.00	2,000.00
*CHARC	Chart Review Fee; Per Chart	N	1.00	25.00
	Pharmacy Set Up fee	N	1	500
	Pharmacy SIV Amount	N	1	150 (210) €
	Amount for each drug supply	N	1	50 per each supply
	Randomization	N	1	28 each patient
	IWRS assignment and delivery of drugs to the enrolled subject	N	1	31 each dispensing
	supply of drugs to the enrolled subject	N	1	34 each dispensing
	Monitoring visit	N	1	100 each monitoring visit
	Remote Monitoring visit	N	1	130 each monitoring visit
	drug disposal on site	N	1	55
	Pharmacy close out visit	N	1	150 (210) €
	preparation of the drug to be returned	N	1	50 each prepared package and for each thermostatic container
	Assignment, preparation and deliver of infusion drugs	N	1	100 Every bag, syringe produced
	preparation and delivery of infusion drugs	N	1	95 Every bag, syringe produced
	Drug dispensing to patients via courier	N	1	60 Each packaging
	Labeling	N	1	3 Each dispensing
	Pre-screening	N	1.00	994.93
	Patient Reimbursement, Per Pre-Screening Visit (a written Sponsor approval will suffice to cover higher costs, if needed, but no contract AMD will be needed)	N	1.00	33.00

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

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

Budget Information

Standard Condition Overall
 Total Cost per Patient: 36,060.92 94,050.48 130,111.40

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

Procedures

Code	Name	OH?	Total	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_D365_C	V16_D379_C	V17_W60_R	
			Quantity																			
*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																	
*AUDI	AUDIT Interview	Y	1.00	35.00	35.00																	
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 (at visit 2) and weight	Y	14.00	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	Y	33.00	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	18.00	26.00				26.00		26.00		26.00	26.00									
93000	12-lead ECG w/ Interpret. & Report	Y	21.00	56.00	168.00	56.00		56.00		56.00				56.00		56.00					56.00	
RCM	Concomitant therapy	Y	56.00	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 lipid-lowering treatment, Evaluation of anti-hypertension treatment, Evaluation of anti-hyperglycaemic treatment- 10mins evaluation	Y	56.00	16.00		32.00					32.00			32.00		32.00		32.00	32.00	32.00		
*ADVE	All AEs/AESIs	Y	56.00	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	31.00	6.00		6.00		6.00		6.00	6.00	6.00	6.00	6.00		6.00		6.00	6.00	6.00		

Procedures

Code	Name	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	V32_W150_C	V33_W156_R	V34_W162_C	V35_W168_R	V36_W174_C	
*INCO	Informed consent																				
*INEX	Review in-/exclusion criteria																				
*DEMO	Demographics																				
*3322	Medical history																				
*AUDI	AUDIT Interview																				
99213	Complete Physical examination including one set of Vital signs (SBP, DBP, pulse), and weight																				
99212	Brief Physical examination including one set of Vital signs (SBP, DBP, pulse), height (at visit 2) and weight	75.00								75.00										75.00	
BMI	Body Mass Index (BMI)																				
*MEAC	Waist and hip	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			26.00		26.00		26.00		26.00		26.00		26.00		26.00		26.00		26.00	
93000	12-lead ECG w/ Interpret. & Report	56.00				56.00				56.00				56.00					56.00		
RCM	Concomitant therapy	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00
*GADS	Evaluation of lipid-lowering treatment, Evaluation of anti-hypertension treatment, Evaluation of anti-hyperglycaemic treatment- 10mins evaluation	32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00	
*ADVE	All AEs/AESIs	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00
*ISRS	Check for injection site reaction	6.00		6.00		6.00		6.00		6.00		6.00		6.00		6.00		6.00		6.00	

Procedures

Code	Name	V37_W180_R	V38_W186_C	V39_W192_R	V40_W198_C	V41_W204_R	V42_W210_C	V43_W216_R	V44_W222_C	V45_W228_R	V46_W234_C	V47-W240_R	V48_W246_C	V49_W252_R	V50_W258_C	V51_W264_R	V52_W270_C	V53_W276_R	V54_W282_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	
*AUDI	AUDIT Interview																						35.00	
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 (at visit 2) and weight						75.00								75.00						75.00	75.00	1,050.00	75.00
BMI	Body Mass Index (BMI)																						18.00	
*MEAC	Waist and hip		11.00		11.00		11.00		11.00		11.00		11.00		11.00		11.00		11.00	11.00	11.00	11.00	363.00	11.00
99211	Vital signs (SBP, DBP, pulse) including weight		26.00		26.00				26.00		26.00		26.00				26.00		26.00				468.00	
93000	12-lead ECG w/ Interpret. & Report		56.00				56.00				56.00				56.00				56.00	56.00	56.00		1,176.00	56.00
RCM	Concomitant therapy	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	1,120.00	20.00
*GADS	Evaluation of lipid-lowering treatment, Evaluation of anti-hypertension treatment, Evaluation of anti-hyperglycaemic treatment- 10mins evaluation		32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00	32.00	32.00		896.00	32.00
*ADVE	All AEs/AESIs	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	952.00	17.00
*ISRS	Check for injection site reaction		6.00		6.00		6.00		6.00		6.00		6.00		6.00		6.00		6.00	6.00			186.00	6.00

Procedures

Code	Name	OH?	Total	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_D365_C
			Quantity																
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, eGFRcys, ELF samples, Other biomarkers samples, glucagon, ADA, NAb samples, Alpha-fetoprotein, Blood sample for Pharmacogenomics	Y	33.00	32.00	32.00	32.00		32.00		32.00	32.00	32.00	32.00	32.00		32.00		32.00	32.00
NC017	Urine Collection - Urine analysis, UACR	Y	28.00	10.00		10.00					10.00			10.00		10.00		10.00	10.00
99000	Handling and shipment - Central lab	Y	33.00	25.00	25.00	25.00		25.00		25.00	25.00	25.00	25.00	25.00		25.00		25.00	25.00
91200	Fibroscan: (VCTE - LSM) and CAP)	Y	14.00	422.00	422.00									422.00					422.00
*FBRS	ELF Score	Y	11.00	40.00		40.00					40.00			40.00					40.00
80299	PK	Y	18.00	42.00		42.00		42.00			42.00			42.00		42.00			42.00
*FAST	Fast Score	Y	14.00	35.00	35.00									35.00					35.00
*MELD	MELD scores	Y	33.00	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	Assess ascites, hepatic encephalopathy	Y	33.00	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 evaluation	Y	15.00	16.00		16.00								16.00					16.00
*RPMD	eDiary review (IMP administration, injection site reactions, and compliance check), ePRO - NASH-CHECK Questionnaire, CLDQ NAFLD NASH, PHQ-9, C-SSRS, SF36	Y	56.00	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													
*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													
98966	Vital status_Phone call	Y	1.00	25.00															
99401	Diet and physical activity counselling	Y	30.00	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	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														
Per Patient Activity Totals:					1,175.00	673.00	91.00	386.00	91.00	288.00	517.00	288.00	288.00	990.00	91.00	477.00	91.00	395.00	848.00

Procedures

Code	Name	V16_D379_C	V17_W60_R	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	V32_W150_C	V33_W156_R	V34_W162_C	V35_W168_R
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, eGFRcys, ELF samples, Other biomarkers samples, glucagon, ADA, NAb samples, Alpha-fetoprotein, Blood sample for Pharmacogenomics	32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00	
NC017	Urine Collection - Urine analysis, UACR	10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00	
99000	Handling and shipment - Central lab	25.00		25.00		25.00		25.00		25.00		25.00		25.00		25.00		25.00		25.00	
91200	Fibroscan: (VCTE - LSM) and CAP)			422.00				422.00				422.00				422.00				422.00	
*FBRS	ELF Score			40.00				40.00				40.00				40.00				40.00	
80299	PK			42.00				42.00				42.00				42.00				42.00	
*FAST	Fast Score			35.00				35.00				35.00				35.00				35.00	
*MELD	MELD scores	34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00	
*GADS	Assess ascites, hepatic encephalopathy	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 evaluation			16.00				16.00				16.00				16.00				16.00	
*RPMD	eDiary review (IMP administration, injection site reactions, and compliance check), ePRO - NASH-CHECK Questionnaire, CLDQ NAFLD NASH, PHQ-9, C-SSRS, SF36	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																				
*DPSD	Hand out IFU – pre-filled syringe and Hand out of SMBG device (trial participants with T2DM), and trial participant materials																				
98966	Vital status_Phone call																				
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	
NC008	Remote visit		23.00		23.00		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																				
Per Patient Activity Totals:		435.00	91.00	990.00	91.00	330.00	91.00	941.00	91.00	330.00	91.00	990.00	91.00	330.00	91.00	901.00	91.00	330.00	91.00	990.00	91.00

Procedures

Code	Name	V36_W174_C	V37_W180_R	V38_W186_C	V39_W192_R	V40_W198_C	V41_W204_R	V42_W210_C	V43_W216_R	V44_W222_C	V45_W228_R	V46_W234_C	V47_W240_R	V48_W246_C	V49_W252_R	V50_W258_C	V51_W264_R	V52_W270_C	V53_W276_R	V54_W282_C	EOT	FU/EOS	Total	ETD
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, eGFRcys, ELF samples, Other biomarkers samples, glucagon, ADA, NAb samples, Alpha-fetoprotein, Blood sample for Pharmacogenomics	32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00		32.00	32.00	32.00	1,056.00	32.00
NC017	Urine Collection - Urine analysis, UACR	10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00	10.00	10.00	280.00	10.00
99000	Handling and shipment - Central lab	25.00		25.00		25.00		25.00		25.00		25.00		25.00		25.00		25.00		25.00	25.00	25.00	825.00	25.00
91200	Fibroscan: (VCTE - LSM) and CAP)			422.00				422.00				422.00				422.00				422.00	422.00		5,908.00	422.00
*FBRS	ELF Score							40.00								40.00					40.00		440.00	40.00
80299	PK			42.00				42.00				42.00				42.00				42.00	42.00	42.00	756.00	42.00
*FAST	Fast Score			35.00				35.00				35.00				35.00				35.00	35.00	35.00	490.00	35.00
*MELD	MELD scores	34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00	34.00	34.00	1,122.00	34.00
*GADS	Assess ascites, hepatic encephalopathy	16.00		16.00		16.00		16.00		16.00		16.00		16.00		16.00		16.00		16.00	16.00	16.00	528.00	16.00
*GADS	Liver Disease Progression - 5min evaluation			16.00				16.00				16.00				16.00				16.00	16.00	16.00	240.00	16.00
*RPMD	eDiary review (IMP administration, injection site reactions, and compliance check), ePRO - NASH-CHECK Questionnaire, CLDQ NAFLD-NASH, PHQ-9, C-SSRS, SF36	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	1,736.00	31.00
98960	Training in/observe pre-filled syringe administration																						82.00	
*DPSD	Hand out IFU – pre-filled syringe and Hand out of SMBG device (trial participants with T2DM), and trial participant materials																						56.00	
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	2,100.00	70.00
NC008	Remote visit		23.00		23.00		23.00		23.00		23.00		23.00		23.00		23.00		23.00				529.00	
*RNCO	Re-consent Process, per patient - for MRI substudy																						38.00	
Per Patient Activity Totals:		330.00	91.00	901.00	91.00	330.00	91.00	990.00	91.00	330.00	91.00	901.00	91.00	330.00	91.00	990.00	91.00	330.00	91.00	901.00	990.00	442.00	22,750.00	990.00

Non Procedures

Code	Name	OH?	Total	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_D365_C
			Quantity																
V1110	Physician Salary - HOMA-IR, HOMA-β	Y	45.50	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	41.00
*STCO	Study Coordinator; Per Visit - data entry	Y	45.50	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	69.00
*NURS	Nurse; Per Visit	Y	34.00	68.00	136.00	68.00		68.00		68.00	68.00	68.00	68.00	68.00		68.00		68.00	68.00
VPHRM	Dispensing, Simple; Per Visit - Hand out IFU - pre-filled syringe, dispense IMP	Y	30.00	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	212.00

Conditional

Code	Name	OH?	Total	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_D365_C
			Quantity																
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														
74181	MRI-PDFF	Y	1.00	1,787.00	1,787.00														
*GNCO	Informed Consent: DNA, Genetics	Y	1.00	35.00	35.00														
74181	MRI-PDFF and T1-weighted imaging	Y	7.00	1,787.00		1,787.00								1,787.00					1,787.00
*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													
N76391	MRE (subset of trial participants)	Y	7.00	1,374.00		1,374.00								1,374.00					1,374.00
NC017	Urine Collection - Urine pregnancy if applicable)	Y	33.00	10.00	10.00	10.00		10.00		10.00	10.00	10.00	10.00	10.00		10.00		10.00	10.00
36415	Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics, - Reticulocytes (only for patients with Gilbert Syndrome), Pancreatic amylase (at screening, and CK-MB, Troponin as reflex test if amylase is elevated at all other visits, including DILI evaluation visit)	Y	4.00	29.00	29.00	29.00								29.00					
99000	Preparation of sample for shipping - central lab	Y	4.00	25.00	25.00	25.00								25.00					

Non Procedures

Code	Name	V16_D379_C	V17_W60_R	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	V32_W150_C	V33_W156_R	V34_W162_C	V35_W168_R	V36_W174_C
V1110	Physician Salary - HOMA-IR, HOMA-β	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	20.50	41.00	20.50	41.00	20.50	41.00	20.50	41.00
*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	34.50	69.00	34.50	69.00	34.50	69.00	34.50	69.00
*NURS	Nurse; Per Visit	68.00		68.00		68.00		68.00		68.00		68.00		68.00		68.00		68.00		68.00		68.00
VPHRM	Dispensing, Simple; Per Visit - Hand out IFU – pre-filled syringe, dispense IMP	34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00
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	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00

Conditional

Code	Name	V16_D379_C	V17_W60_R	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	V32_W150_C	V33_W156_R	V34_W162_C	V35_W168_R	V36_W174_C
47000	Liver biopsy																					
99152	Moderate Sedation Init 15 Min 5+yrs																					
74181	MRI-PDF																					
*GNCO	Informed Consent: DNA, Genetics																					
74181	MRI-PDF and T1-weighted imaging											1,787.00										
*IWQL	Assessment of obesity staging - (For participants with BMI ≥30 kg/m2 (≥25 kg/m2 for Asian ethnicity)																					
N76391	MRE (subset of trial participants)											1,374.00										
NC017	Urine Collection - Urine pregnancy if applicable)	10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00
36415	Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics, - Reticulocytes (only for patients with Gilbert Syndrome), Pancreatic amylase (at screening, and CK-MB, Troponin as reflex test if amylase is elevated at all other visits, including DILI evaluation visit)																					
99000	Preparation of sample for shipping - central lab																					

Non Procedures

Code	Name	V37_W180_R	V38_W186_C	V39_W192_R	V40_W198_C	V41_W204_R	V42_W210_C	V43_W216_R	V44_W222_C	V45_W228_R	V46_W234_C	V47_W240_R	V48_W246_C	V49_W252_R	V50_W258_C	V51_W264_R	V52_W270_C	V53_W276_R	V54_W282_C	EOT	FU/EOS	Total
V1110	Physician Salary - HOMA-IR, HOMA-β	20.50	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	20.50	41.00	20.50	41.00	41.00	41.00	1,865.50
*STCO	Study Coordinator; Per Visit + data entry	34.50	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	34.50	69.00	34.50	69.00	69.00	69.00	3,139.50
*NURS	Nurse; Per Visit		68.00		68.00		68.00		68.00		68.00		68.00		68.00		68.00		68.00	68.00	68.00	2,312.00
VPHRM	Dispensing, Simple; Per Visit - Hand out IFU - pre-filled syringe, dispense IMP		34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00		34.00			1,020.00
Per Patient Other Direct Cost Totals:		55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	55.00	212.00	178.00	178.00	8,337.00

ETD
41.00
69.00
68.00
178.00

Conditional

Code	Name	V37_W180_R	V38_W186_C	V39_W192_R	V40_W198_C	V41_W204_R	V42_W210_C	V43_W216_R	V44_W222_C	V45_W228_R	V46_W234_C	V47_W240_R	V48_W246_C	V49_W252_R	V50_W258_C	V51_W264_R	V52_W270_C	V53_W276_R	V54_W282_C	EOT	FU/EOS	Total
47000	Liver biopsy																					800.00
99152	Moderate Sedation Init 15 Min 5+yrs																					205.00
74181	MRI-PDF																					1,787.00
*GNCO	Informed Consent: DNA, Genetics																					35.00
74181	MRI-PDF and T1-weighted imaging		1,787.00												1,787.00					1,787.00		12,509.00
*IWQL	Assessment of obesity staging - (For participants with BMI ≥30 kg/m2 (≥25 kg/m2 for Asian ethnicity)																			22.00		44.00
N76391	MRE (subset of trial participants)		1,374.00												1,374.00					1,374.00		9,618.00
NC017	Urine Collection - Urine pregnancy if applicable)		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00		10.00	10.00	10.00	330.00
36415	Blood draw - Optional biobanking samples, FSH, ADA, NAb samples(unscheduled), HCV RNA, Blood sample for pharmacogenomics, - Reticulocytes (only for patients with Gilbert Syndrome), Pancreatic amylase (at screening, and CK-MB, Troponin as reflex test if amylase is elevated at all other visits, including DILI evaluation visit)																			29.00		116.00
99000	Preparation of sample for shipping - central lab																			25.00		100.00

ETD
1,787.00
22.00
1,374.00
10.00
29.00
25.00

Conditional

Code	Name	OH?	Total	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_D365_C
			Quantity																
88363	Liver biopsy - archival	Y	1.00	84.00	84.00														
47000	Liver biopsy(a triggered biopsy if clinically indicated)	Y	2.00	800.00															800.00
NC065	Biopsy Sample Handling Simple	Y	3.00	21.00	21.00														21.00
99152	Moderate Sedation Init 15 Min 5+yrs	Y	2.00	205.00															205.00
CPC	CTP	Y	33.00	15.00	15.00	15.00		15.00		15.00	15.00	15.00	15.00	15.00		15.00		15.00	15.00
91110	UGE (only for participants who progressed to cirrhosis)-at the diagnosis of cirrhosis at all scheduled visits until the end of trial	Y	20.00	1,892.00															
76700	Abdominal ultrasound (only for participants who progressed to cirrhosis)	Y	11.00	384.00															
76830-26	Abdominal ultrasound - Interpretation & Report Only (only for participants who progressed to cirrhosis)	Y	11.00	101.00															
92012	Eye examination	Y	8.00	70.00	70.00									70.00					
*NASH	NASH-CHECK Questionnaire (only in case of paper questionnaires)	Y	16.00	18.00		18.00					18.00			18.00				18.00	18.00
*CLDQ	CLDQ NAFLD-NASH (only in case of paper questionnaires)	Y	15.00	23.00		23.00					23.00			23.00					23.00
*SF36	SF-36 (only in case of paper questionnaires)	Y	15.00	19.00		19.00					19.00			19.00					19.00
*PHQ9	PHQ-9 (only in case of paper questionnaires)	Y	29.00	18.00	18.00	36.00					18.00			18.00		18.00		18.00	
*CSSR	C-SSRS (only in case of paper questionnaires)	Y	57.00	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
*TOHM	Hand out of SMBG device (trial participants with	Y	2.00	37.00	37.00	37.00													
*RPM	Hyper-/hypoglycaemic episode review (eDiary – participants with T2DM)	Y	53.00	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
85025	haematology - Haematocrit Haemoglobin Mean corpuscular volume Mean corpuscular haemoglobin Mean cellular haemoglobin concentration Red blood cell distribution width Red blood cells count / erythrocytes White blood cell count / leukocytes Platelet count / thrombocytes Differential automatic (relative and absolute count): Neutrophils, eosinophils, basophils, monocytes, lymphocytes	Y	33.00	22.00	22.00	22.00		22.00		22.00	22.00	22.00	22.00	22.00		22.00		22.00	22.00

Conditional

Code	Name	V16_D379_C	V17_W60_R	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	V32_W150_C	V33_W156_R	V34_W162_C	V35_W168_R	
88363	Liver biopsy - archival																					
47000	Liver biopsy(a triggered biopsy if clinically indicated)																					
NC065	Biopsy Sample Handling Simple																					
99152	Moderate Sedation Init 15 Min 5+yrs																					
CPC	CTP	15.00		15.00		15.00		15.00		15.00		15.00		15.00		15.00		15.00		15.00		15.00
91110	UGE (only for participants who progressed to cirrhosis)-at the diagnosis of cirrhosis at all scheduled visits until the end of trial			1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00
76700	Abdominal ultrasound (only for participants who progressed to cirrhosis)			384.00				384.00				384.00				384.00					384.00	
76830-26	Abdominal ultrasound - Interpretation & Report Only (only for participants who progressed to cirrhosis)			101.00				101.00				101.00				101.00					101.00	
92012	Eye examination			70.00								70.00										70.00
*NASH	NASH-CHECK Questionnaire (only in case of paper questionnaires)			18.00				18.00				18.00				18.00					18.00	
*CLDQ	CLDQ NAFLD-NASH (only in case of paper questionnaires)			23.00				23.00				23.00				23.00					23.00	
*SF36	SF-36 (only in case of paper questionnaires)			19.00				19.00				19.00				19.00					19.00	
*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
*CSSR	C-SSRS (only in case of paper questionnaires)	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00
*TOHM	Hand out of SMBG device (trial participants with																					
*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	31.00	31.00	31.00	31.00	31.00	31.00	31.00
85025	haematology - Haematocrit Haemoglobin Mean corpuscular volume Mean corpuscular haemoglobin Mean cellular haemoglobin concentration Red blood cell distribution width Red blood cells count / erythrocytes White blood cell count / leukocytes Platelet count / thrombocytes Differential automatic (relative and absolute count): Neutrophils, eosinophils, basophils, monocytes, lymphocytes	22.00		22.00		22.00		22.00		22.00		22.00		22.00		22.00		22.00		22.00		22.00
80053	clinical chemistry - Albumin ALP ALT AST Bicarbonate TBL, fractionated Calcium Chloride Potassium Protein total Sodium Urea (blood urea nitrogen)	45.00		45.00		45.00		45.00		45.00		45.00		45.00		45.00		45.00		45.00		45.00

Conditional

Code	Name	V36_W174_C	V37_W180_R	V38_W186_C	V39_W192_R	V40_W198_C	V41_W204_R	V42_W210_C	V43_W216_R	V44_W222_C	V45_W228_R	V46_W234_C	V47_W240_R	V48_W246_C	V49_W252_R	V50_W258_C	V51_W264_R	V52_W270_C	V53_W276_R	V54_W282_C	EOT	FU/EOS	Total	ETD	
88363	Liver biopsy - archival																						84.00		
47000	Liver biopsy(a triggered biopsy if clinically indicated)																					800.00		1,600.00	800.00
NC065	Biopsy Sample Handling Simple																					21.00		63.00	21.00
99152	Moderate Sedation Init 15 Min 5+yrs																					205.00		410.00	205.00
CPC	CTP	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	495.00	15.00
91110	UGE (only for participants who progressed to cirrhosis)-at the diagnosis of cirrhosis at all scheduled visits until the end of trial	1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00		1,892.00	1,892.00		37,840.00	1,892.00	
76700	Abdominal ultrasound (only for participants who progressed to cirrhosis)			384.00				384.00				384.00				384.00				384.00	384.00		4,224.00	384.00	
76830-26	Abdominal ultrasound - Interpretation & Report Only (only for participants who progressed to cirrhosis)			101.00				101.00				101.00				101.00				101.00	101.00		1,111.00	101.00	
92012	Eye examination							70.00								70.00					70.00		560.00	70.00	
*NASH	NASH-CHECK Questionnaire (only in case of paper questionnaires)			18.00				18.00				18.00				18.00				18.00	18.00		288.00	18.00	
*CLDQ	CLDQ NAFLD-NASH (only in case of paper questionnaires)			23.00				23.00				23.00				23.00				23.00	23.00		345.00	23.00	
*SF36	SF-36 (only in case of paper questionnaires)			19.00				19.00				19.00				19.00				19.00	19.00		285.00	19.00	
*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	522.00	18.00	
*CSSR	C-CSSR (only in case of paper questionnaires)	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	52.00	2,964.00	52.00	
*TOHM	Hand out of SMBG device (trial participants with																						74.00		
*RPMD	Hyper-/hypoglycaemic episode review (eDiary – participants with TZDM)	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		1,643.00	31.00	
85025	haematology - Haematocrit Haemoglobin Mean corpuscular volume Mean corpuscular haemoglobin Mean cellular haemoglobin concentration Red blood cell distribution width Red blood cells count / erythrocytes White blood cell count / leukocytes Platelet count / thrombocytes Differential automatic (relative and absolute count): Neutrophils, eosinophils, basophils, monocytes, lymphocytes	22.00		22.00		22.00		22.00		22.00		22.00		22.00		22.00		22.00		22.00	22.00	22.00	726.00	22.00	
80053	clinical chemistry - Albumin ALP ALT AST Bicarbonate TBL, fractionated Calcium Chloride Potassium Protein total Sodium Urea (blood urea nitrogen)	45.00		45.00		45.00		45.00		45.00		45.00		45.00		45.00		45.00		45.00	45.00	45.00	1,485.00	45.00	

Conditional

Code	Name	OH?	Total	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_D365_C	V16_D379_C
			Quantity																	
82150	Clinical chemistry - Amylase (local lab)	Y	33.00	8.00	8.00	8.00		8.00		8.00	8.00	8.00	8.00	8.00		8.00		8.00	8.00	8.00
83690	Clinical chemistry - Lipase (local lab)	Y	33.00	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
80299	Additional PK sample collected at the time of a potential DILI event for later analysis of drug exposure	Y		42.00																
*SAEA	All SAEs - per occurrence	Y		19.00																
74150	CT scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated a-fetoprotein)	Y		919.00																
74150-26	CT scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated a-fetoprotein)	Y		253.00																
74160	CT scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated a-fetoprotein)	Y		1,144.00																
74150-26	CT scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated a-fetoprotein)	Y		253.00																
74181	MRI Scan - Abdomen w/ Contrast - (only if there is suspicion of HCC on elevated a-fetoprotein)	Y		1,787.00																
74181-26	MRI Scan - Abdomen w/ Contrast - interpretation and report (only if there is suspicion of HCC on elevated a-fetoprotein)	Y		419.00																
N74182	MRI Scan - Abdomen w/o Contrast - (only if there is suspicion of HCC on elevated a-fetoprotein)	Y		1,622.00																
74181-26	MRI Scan - Abdomen w/o Contrast - interpretation and report (only if there is suspicion of HCC on elevated a-fetoprotein)	Y		419.00																
NC008	Remote visit (EoS Visit via remote visits (if allowed per local regulations))	Y	1.00	23.00																
Per Patient Conditional Totals:					3,279.00	3,590.00	83.00	199.00	83.00	199.00	277.00	199.00	199.00	3,562.00	83.00	217.00	83.00	235.00	4,446.00	217.00

Conditional

Code	Name	V17_W60_R	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	V32_W150_C	V33_W156_R	V34_W162_C	V35_W168_R	V36_W174_C
82150	Clinical chemistry - Amylase (local lab)		8.00		8.00		8.00		8.00		8.00		8.00		8.00		8.00		8.00		8.00
83690	Clinical chemistry - Lipase (local lab)		16.00		16.00		16.00		16.00		16.00		16.00		16.00		16.00		16.00		16.00
80299	Additional PK sample collected at the time of a potential DILI event for later analysis of drug exposure																				
*SAEA	All SAEs - per occurrence																				
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 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)																				
N74182	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)																				
NC008	Remote visit (EoS Visit via remote visits (if allowed per local regulations))																				
Per Patient Conditional Totals:		83.00	2,724.00	83.00	2,109.00	83.00	2,654.00	83.00	2,109.00	83.00	5,885.00	83.00	2,109.00	83.00	2,654.00	83.00	2,109.00	83.00	2,724.00	83.00	2,109.00

Patient Cost For Standard Items

	Screenin g	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment
		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_D365_C	V16_D379_C
Costs Not Charged with Overhead																
Costs Charged with Overhead	1,531.00	885.00	146.00	598.00	146.00	500.00	729.00	500.00	500.00	1,202.00	146.00	689.00	146.00	607.00	1,060.00	647.00
Overhead at 16%	244.96	141.60	23.36	95.68	23.36	80.00	116.64	80.00	80.00	192.32	23.36	110.24	23.36	97.12	169.60	103.52
Selected Cost Per Visit	1,775.96	1,026.60	169.36	693.68	169.36	580.00	845.64	580.00	580.00	1,394.32	169.36	799.24	169.36	704.12	1,229.60	750.52
Cumulative Cost Per Patient	1,775.96	2,802.56	2,971.92	3,665.60	3,834.96	4,414.96	5,260.60	5,840.60	6,420.60	7,814.92	7,984.28	8,783.52	8,952.88	9,657.00	10,886.60	11,637.12

Patient Cost For Conditional Items

	Screenin g	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment
		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_D365_C	V16_D379_C
Costs Not Charged with Overhead																
Costs Charged with Overhead	3,279.00	3,590.00	83.00	199.00	83.00	199.00	277.00	199.00	199.00	3,562.00	83.00	217.00	83.00	235.00	4,446.00	217.00
Overhead at 16%	524.64	574.40	13.28	31.84	13.28	31.84	44.32	31.84	31.84	569.92	13.28	34.72	13.28	37.60	711.36	34.72
Selected Cost Per Visit	3,803.64	4,164.40	96.28	230.84	96.28	230.84	321.32	230.84	230.84	4,131.92	96.28	251.72	96.28	272.60	5,157.36	251.72
Cumulative Cost Per Patient	3,803.64	7,968.04	8,064.32	8,295.16	8,391.44	8,622.28	8,943.60	9,174.44	9,405.28	13,537.20	13,633.48	13,885.20	13,981.48	14,254.08	19,411.44	19,663.16

Overall Patient Cost

	Screenin g	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment
		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_D365_C	V16_D379_C
Costs Not Charged with Overhead																
Costs Charged with Overhead	4,810.00	4,475.00	229.00	797.00	229.00	699.00	1,006.00	699.00	699.00	4,764.00	229.00	906.00	229.00	842.00	5,506.00	864.00
Overhead at 16%	769.60	716.00	36.64	127.52	36.64	111.84	160.96	111.84	111.84	762.24	36.64	144.96	36.64	134.72	880.96	138.24
Selected Cost Per Visit	5,579.60	5,191.00	265.64	924.52	265.64	810.84	1,166.96	810.84	810.84	5,526.24	265.64	1,050.96	265.64	976.72	6,386.96	1,002.24
Cumulative Cost Per Patient	5,579.60	10,770.60	11,036.24	11,960.76	12,226.40	13,037.24	14,204.20	15,015.04	15,825.88	21,352.12	21,617.76	22,668.72	22,934.36	23,911.08	30,298.04	31,300.28

Patient Cost For Standard Items

	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t
	V17_W60_R	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	V32_W150_C	V33_W156_R	V34_W162_C	
Costs Not Charged with Overhead																			
Costs Charged with Overhead	146.00	1,202.00	146.00	542.00	146.00	1,153.00	146.00	542.00	146.00	1,202.00	146.00	542.00	146.00	1,113.00	146.00	542.00	146.00	1,202.00	
Overhead at 16%	23.36	192.32	23.36	86.72	23.36	184.48	23.36	86.72	23.36	192.32	23.36	86.72	23.36	178.08	23.36	86.72	23.36	192.32	
Selected Cost Per Visit	169.36	1,394.32	169.36	628.72	169.36	1,337.48	169.36	628.72	169.36	1,394.32	169.36	628.72	169.36	1,291.08	169.36	628.72	169.36	1,394.32	
Cumulative Cost Per Patient	11,806.48	13,200.80	13,370.16	13,998.88	14,168.24	15,505.72	15,675.08	16,303.80	16,473.16	17,867.48	18,036.84	18,665.56	18,834.92	20,126.00	20,295.36	20,924.08	21,093.44	22,487.76	

Patient Cost For Conditional Items

	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t
	V17_W60_R	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	V32_W150_C	V33_W156_R	V34_W162_C	
Costs Not Charged with Overhead																			
Costs Charged with Overhead	83.00	2,724.00	83.00	2,109.00	83.00	2,654.00	83.00	2,109.00	83.00	5,885.00	83.00	2,109.00	83.00	2,654.00	83.00	2,109.00	83.00	2,724.00	
Overhead at 16%	13.28	435.84	13.28	337.44	13.28	424.64	13.28	337.44	13.28	941.60	13.28	337.44	13.28	424.64	13.28	337.44	13.28	435.84	
Selected Cost Per Visit	96.28	3,159.84	96.28	2,446.44	96.28	3,078.64	96.28	2,446.44	96.28	6,826.60	96.28	2,446.44	96.28	3,078.64	96.28	2,446.44	96.28	3,159.84	
Cumulative Cost Per Patient	19,759.44	22,919.28	23,015.56	25,462.00	25,558.28	28,636.92	28,733.20	31,179.64	31,275.92	38,102.52	38,198.80	40,645.24	40,741.52	43,820.16	43,916.44	46,362.88	46,459.16	49,619.00	

Overall Patient Cost

	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t	Treatmen t
	V17_W60_R	V18_W66_C	V19_W72_R	V20_W78_C	V21_W84_R	V22_W90_C	V23_W96_R	V24_W102_C	V25_W108_R	V26_W114_C	V27_W120_R	V28_W126_C	V29_W132_R	V30_W138_C	V31_W144_R	V32_W150_C	V33_W156_R	V34_W162_C	
Costs Not Charged with Overhead																			
Costs Charged with Overhead	229.00	3,926.00	229.00	2,651.00	229.00	3,807.00	229.00	2,651.00	229.00	7,087.00	229.00	2,651.00	229.00	3,767.00	229.00	2,651.00	229.00	3,926.00	
Overhead at 16%	36.64	628.16	36.64	424.16	36.64	609.12	36.64	424.16	36.64	1,133.92	36.64	424.16	36.64	602.72	36.64	424.16	36.64	628.16	
Selected Cost Per Visit	265.64	4,554.16	265.64	3,075.16	265.64	4,416.12	265.64	3,075.16	265.64	8,220.92	265.64	3,075.16	265.64	4,369.72	265.64	3,075.16	265.64	4,554.16	
Cumulative Cost Per Patient	31,565.92	36,120.08	36,385.72	39,460.88	39,726.52	44,142.64	44,408.28	47,483.44	47,749.08	55,970.00	56,235.64	59,310.80	59,576.44	63,946.16	64,211.80	67,286.96	67,552.60	72,106.76	

Patient Cost For Standard Items

	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Follow Up	Total
	V35_W168_R	V36_W174_C	V37_W180_R	V38_W186_C	V39_W192_R	V40_W198_C	V41_W204_R	V42_W210_C	V43_W216_R	V44_W222_C	V45_W228_R	V46_W234_C	V47_W240_R	V48_W246_C	V49_W252_R	V50_W258_C	V51_W264_R	V52_W270_C	V53_W276_R	V54_W282_C	EOT	FU/EOS	
Costs Not Charged with Overhead																							
Costs Charged with Overhead	146.00	542.00	146.00	1,113.00	146.00	542.00	146.00	1,202.00	146.00	542.00	146.00	1,113.00	146.00	542.00	146.00	1,202.00	146.00	542.00	146.00	1,113.00	1,168.00	620.00	31,087.00
Overhead at 16%	23.36	86.72	23.36	178.08	23.36	86.72	23.36	192.32	23.36	86.72	23.36	178.08	23.36	86.72	23.36	192.32	23.36	86.72	23.36	178.08	186.88	99.20	4,973.92
Selected Cost Per Visit	169.36	628.72	169.36	1,291.08	169.36	628.72	169.36	1,394.32	169.36	628.72	169.36	1,291.08	169.36	628.72	169.36	1,394.32	169.36	628.72	169.36	1,291.08	1,354.88	719.20	36,060.92
Cumulative Cost Per Patient	22,657.12	23,285.84	23,455.20	24,746.28	24,915.64	25,544.36	25,713.72	27,108.04	27,277.40	27,906.12	28,075.48	29,366.56	29,535.92	30,164.64	30,334.00	31,728.32	31,897.68	32,526.40	32,695.76	33,986.84	35,341.72	36,060.92	

Discontinuation
ETD
1,168.00
186.88
1,354.88
37,415.80

Patient Cost For Conditional Items

	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Follow Up	Total	
	V35_W168_R	V36_W174_C	V37_W180_R	V38_W186_C	V39_W192_R	V40_W198_C	V41_W204_R	V42_W210_C	V43_W216_R	V44_W222_C	V45_W228_R	V46_W234_C	V47_W240_R	V48_W246_C	V49_W252_R	V50_W258_C	V51_W264_R	V52_W270_C	V53_W276_R	V54_W282_C	EOT	FU/EOS	
Costs Not Charged with Overhead																							
Costs Charged with Overhead	83.00	2,109.00	83.00	5,815.00	83.00	2,109.00	83.00	2,724.00	83.00	2,109.00	83.00	2,654.00	83.00	2,109.00	83.00	5,885.00	83.00	2,109.00	83.00	2,654.00	6,987.00	209.00	81,078.00
Overhead at 16%	13.28	337.44	13.28	930.40	13.28	337.44	13.28	435.84	13.28	337.44	13.28	424.64	13.28	337.44	13.28	941.60	13.28	337.44	13.28	424.64	1,117.92	33.44	12,972.48
Selected Cost Per Visit	96.28	2,446.44	96.28	6,745.40	96.28	2,446.44	96.28	3,159.84	96.28	2,446.44	96.28	3,078.64	96.28	2,446.44	96.28	6,826.60	96.28	2,446.44	96.28	3,078.64	8,104.92	242.44	94,050.48
Cumulative Cost Per Patient	49,715.28	52,161.72	52,258.00	59,003.40	59,099.68	61,546.12	61,642.40	64,802.24	64,898.52	67,344.96	67,441.24	70,519.88	70,616.16	73,062.60	73,158.88	79,985.48	80,081.76	82,528.20	82,624.48	85,703.12	93,808.04	94,050.48	

Discontinuation
ETD
6,987.00
1,117.92
8,104.92
102,155.40

Overall Patient Cost

	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Treatment t	Follow Up	Total	
	V35_W168_R	V36_W174_C	V37_W180_R	V38_W186_C	V39_W192_R	V40_W198_C	V41_W204_R	V42_W210_C	V43_W216_R	V44_W222_C	V45_W228_R	V46_W234_C	V47_W240_R	V48_W246_C	V49_W252_R	V50_W258_C	V51_W264_R	V52_W270_C	V53_W276_R	V54_W282_C	EOT	FU/EOS	
Costs Not Charged with Overhead																							
Costs Charged with Overhead	229.00	2,651.00	229.00	6,928.00	229.00	2,651.00	229.00	3,926.00	229.00	2,651.00	229.00	3,767.00	229.00	2,651.00	229.00	7,087.00	229.00	2,651.00	229.00	3,767.00	8,155.00	829.00	112,165.00
Overhead at 16%	36.64	424.16	36.64	1,108.48	36.64	424.16	36.64	628.16	36.64	424.16	36.64	602.72	36.64	424.16	36.64	1,133.92	36.64	424.16	36.64	602.72	1,304.80	132.64	17,946.40
Selected Cost Per Visit	265.64	3,075.16	265.64	8,036.48	265.64	3,075.16	265.64	4,554.16	265.64	3,075.16	265.64	4,369.72	265.64	3,075.16	265.64	8,220.92	265.64	3,075.16	265.64	4,369.72	9,459.80	961.64	130,111.40
Cumulative Cost Per Patient	72,372.40	75,447.56	75,713.20	83,749.68	84,015.32	87,090.48	87,356.12	91,910.28	92,175.92	95,251.08	95,516.72	99,886.44	100,152.08	103,227.24	103,492.88	111,713.80	111,979.44	115,054.60	115,320.24	119,689.96	129,149.76	130,111.40	

Discontinuation
ETD
8,155.00
1,304.80
9,459.80
139,571.20



AZIENDA OSPEDALIERA UNIVERSITARIA

PUBBLICAZIONE ALBO ONLINE

Pubblicazione. .

Atto:

Atto N°:

Registrato il:

Oggetto:

**È pubblicato in forma integrale sull'Albo online del sito policlinico.pa.it
dal al**