525/22

AMENDMENT No. 1
(hereinafter, **„Amendment"**)

To the Clinical Trial Agreement
(hereinafter, **„Agreement"**)
Dated 17.12.2020

BETWEEN:

Bayer AG
Registered office: Kaiser-Wilhelm-Allee 1, 51373 Leverkusen, Germany and having offices at Muellerstrasse 178, 13353 Berlin, Germany
VAT No.: DE123659859
Registered with the Commercial Register kept by Commercial Register B, Cologne, Amtsgericht (Local Court)
Represented by: Parexel International (IRL) Limited, One Kilmainham Square, Inchicore Road, Kilmainham, Dublin 8, Ireland
(hereinafter referred to as the "**Sponsor**")

AND

Fakultná nemocnica Trenčín
with its registered seat at: Legionárska 28,
911 71 Trenčín
Slovak Republic
Deed of Foundation of the MoH of the Slovak Republic No. 1970/1991-A/VIII-1 dated 14.6.1991
Represented by: Ing. Tomás Janík, MBA, Chief Executive Director (hereinafter referred to as the "**Center**")

AND

MUDr. Marek Káčerik, Ph.D.
date of birth:
Address:

Slovak Republic
Workplace: Fakultná nemocnica Trenčín, Ophthalmology Clinic, Legionárska 28, 911 71 Trenčín, Slovak Republic
(hereinafter **"Principal Investigator")**

Regarding:

Protocol number: **20968**

Protocol title:
Randomized, Double-Masked, Active-Controlled, Phase 3 Study of the Efficacy and Safety of High Dose Aflibercept in Patients With Neovascular Age-Related Macular Degeneration
(hereinafter "**Study**")

DODATOK č. 1
(ďalej len **„Dodatok"**)

k Zmluve o klinickom skúšaní
(ďalej len **„Zmluva"**)
zo dňa 17.12.2020

MEDZI:

Bayer AG
so sídlom: Kaiser-Wilhelm-Allee 1, 51373 Leverkusen, Nemecko a s pracoviskom Muellerstrasse 178, 13353 Berlin, Nemecko
DIČ: DE123659859
zapísaná v obchodnom registri vedenom Amtsgericht (Local Court), Cologne, Commercial Register B

konajúca: Parexel International (IRL) Limited, One Kilmainham Square, Inchicore Road, Kilmainham, Dublin 8, Irsko
(ďalej len "**Zadávateľ**")

A

Fakultná nemocnica Trenčín
so sídlom: Legionárska 28
911 71 Trenčín
Slovenská republika
Zriaďovacou listinou MZ SR č. 1970/1991-A/VIII-1 zo dňa 14.6.1991
konajúca: Ing. Tomás Janík, MBA, riaditeľ (ďalej len **"Centrum"**)

A

MUDr. Marek Káčerik, Ph.D.
dátum narodenia:
Adresa:

Slovenská republika
pracovisko: Fakultná nemocnica Trenčín, Očná klinika, Legionárska 28, 911 71 Trenčín, Slovenská republika

(ďalej len "**Hlavný skúšajúci**")

V súvislosti s:

Číslo protokolu: **20968**

Názov protokolu:
Randomizované, dvojito maskované, aktívne kontrolované klinické skúšanie III. fázy hodnotiace účinnosť a bezpečnosť vysokej dávky afliberceptu u pacientov s neovaskulárnou vekom podmienenou degeneráciou makuly
(ďalej len „**Štúdia**")

(the Center and the Principal Investigator hereinafter collectively referred to as the "**Contracting Partners**", the Sponsor with the Center and the Principal Investigator hereinafter collectively referred to as the "**Contracting Parties**")

(Centrum a Hlavný skúšajúci spolu ďalej len "**Zmluvní partneri**", Zadávateľ s Centrom a Hlavným skúšajúcim spolu ďalej len „**Zmluvné strany**")

WHEREAS, the Parties have entered into the Clinical Trial Agreement on 17. 12. 2020; and

KEĎŽE Zmluvné strany uzavreli Zmluvu o klinickom skúšaní dňa 17. 12. 2020, a

WHEREAS, the Contracting Parties are willing to amend the above referred Agreement to re-distribute the budget between the Study Personnel and add members to the same Study Personnel;

KEĎŽE Zmluvné strany sú ochotné zmeniť vyššie spomínanú Zmluvu tak, aby prerozdelili rozpočet medzi študijný personál a pridali členov do tohto študijného personálu;

Now, therefore the above-referred Agreement shall be amended as follows and shall be effective as of the 30.04.2022.

Vzhľadom na to sa vyššie uvedená Zmluva mení nasledovne a nadobúda účinnosť 30. 4. 2022.

1. The tables „Detailed Budget – Per Patient Fees" , „Detailed Budget – Conditional Fees" and „Screening Failure" in Appendices 1.3, 1.5, 1.6 and 1.7 will be deleted and replaced by the tables listed below in the Exhibit A of this Amendment.

1. Tabulky „Podrobný rozpočet – Poplatky za pacienta", "Podrobný rozpočet – podmienečné poplatky" a "Zlyhanie skríningu" v prílohách 1.3, 1.5, 1.6 a 1.7 budú vymazané a nahradené tabulkami uvedenými v Prílohe A tohto Dodatku.

2. New appendices Appendix 1.8 and Appendix 1.9 which are attached to this Amendment in Exhibit B are herby part of the Agreement.

2. Nové prílohy Príloha 1.8 a Príloha 1.9, ktoré sú pripojené k tomuto Dodatku v Prílohe B, sú súčasťou Zmluvy.

3. All other terms and conditions of the Agreement remain unchanged and in full force and effect. This Amendment shall hereafter be incorporated into and deemed part of the Agreement and any future reference to the Agreement shall include the terms and conditions of this Amendment.

3. Všetky ostatné podmienky Zmluvy zostanú nezmenené a v plnej platnosti a účinnosti. Tento Dodatok bude odteraz začlenený do Zmluvy a bude sa považovať za súčasť Zmluvy a akýkoľvek budúci odkaz na Zmluvu bude zahŕňať aj podmienky tohto Dodatku.

4. To the extent any provision of the Agreement conflicts with any provision of the Amendment, this Amendment will control. Capitalized terms used but not otherwise defined in this Amendment shall have the meanings ascribed to them in the Agreement.

4. Ak je niektoré ustanovenie Zmluvy v rozpore s niektorým ustanovením tohto Dodatku, platí tento Dodatok. Pojmy uvedené s veľkým začiatočným písmenom, ktoré sa v Dodatku používajú, ale nie sú inak definované, majú význam, ktorý je im priradený v Zmluve.

5. This Agreement will be executed in three (3) counterparts, with one (1) counterpart for the Principal Investigator, one (1) for the Center and one (1) for Sponsor. Each counterpart shall be deemed to be an original, and all of such counterparts shall together constitute one and the same document.

5. Zmluva je vyhotovená v troch (3) rovnopisoch, jeden rovnopis (1) je určený pre Hlavného skúšajúceho, jeden rovnopis (1) pre Centrum a jeden rovnopis (1) pre Zadávateľa. Každý rovnopis sa považuje za originál a všetky rovnopisy spolu predstavujú jeden a ten istý dokument.

Zadávateľ prostredníctvom svojho oprávneného zástupcu Parexel International (IRL) Limited / Sponsor by its authorized representative Parexel International (IRL) Limited

Miesto / Place _____

Dátum / Date _____

_____
Meno a priezvisko / First and last name:
Funkcia / Position:

Centrum / Center
Fakultná nemocnica Trenčín

Miesto / Place _____

Dátum / Date _____

_____

Hlavný skúšajúci / Principal Investigator

Miesto / Place _____

Dátum / Date _____

_____
MUDr. Marek Káčerík, Ph.D.

Potvrdené a odsúhlasené:
Ja, spoluskúšajúci, MUDr. Zuzana Šustykevičová, adresa:
republika, podpisom tohto dokumentu beriem na vedomie a súhlasím s plnením svojich povinností v rozsahu stanovenom Protokolom a pokynmi k Štúdii.

MUDr. Zuzana Šustykevičová

_____ _____
(Signature / Podpis) Date / Dátum

MUDr. Zuzana Šustykevičová

Acknowledged and agreed:
I, Sub-Investigator, MUDr. Zuzana Šustykevičová, address
acknowledge and agree by signing of this document to perform my obligations to the extent stipulated by the Protocol and Study Instructions.

Potvrdené a odsúhlasené:
Ja, spoluskúšajúci, MUDr. Karolina Kafková adresa:

Acknowledged and agreed:
I, Sub-Investigator, MUDr. Karolina Kafková, address

republika, podpisom tohto dokumentu beriem na vedomie a súhlasím s plnením svojich povinností v rozsahu stanovenom Protokolom a pokynmi k Štúdii.

acknowledge and agree by signing of this document to perform my obligations to the extent stipulated by the Protocol and Study Instructions.

MUDr. Karolina Kafková

(Signature / Podpis) Date / Datum

MUDr. Karolina Kafková

Potvrdené a odsúhlasené:
Ja, spoluskúšajúci, MUDr. Martina Hanicová, adresa:

republika, podpisom tohto dokumentu beriem na vedomie a súhlasím s plnením svojich povinností v rozsahu stanovenom Protokolom a pokynmi k Štúdii.

Acknowledged and agreed:
I, Sub-Investigator, MUDr. Martina Hanicová, address

Republic, acknowledge and agree by signing of this document to perform my obligations to the extent stipulated by the Protocol and Study Instructions.

MUDr. Martina Hanicová

(Signature / Podpis) Date / Datum

MUDr. Martina Hanicová

Potvrdené a odsúhlasené:
Ja, spoluskúšajúci, MUDr Ján Mihala, adresa:

podpisom tohto dokumentu beriem na vedomie a súhlasím s plnením svojich povinností v rozsahu stanovenom Protokolom a pokynmi k Štúdii.

Acknowledged and agreed:
I, Sub-Investigator, MUDr Ján Mihala, address

acknowledge and agree by signing of this document to perform my obligations to the extent stipulated by the Protocol and Study Instructions.

MUDr Ján Mihala

(Signature / Podpis) Date / Datum

MUDr Ján Mihala

Acknowledged and agreed:
I, Sub-Investigator, MUDr. Kristína Dorčiaková, Birth registration number

, acknowledge and agree by signing of this document to perform my obligations to the extent stipulated by the Protocol and Study Instructions.

Potvrdené a odsúhlasené:
Ja, spoluskúšajúci, MUDr. Kristína Dorčiaková, r.č.

podpisom tohto dokumentu beriem na vedomie a súhlasím s plnením svojich povinností v rozsahu stanovenom Protokolom a pokynmi k Štúdii..

MUDr. Kristína Dorčiaková

MUDr. Kristína Dorčiaková Date / Datum

Acknowledged and agreed:

I, PhDr. Martina Tulpíková, Birth registration number , acknowledge and agree by signing of this document to perform my obligations to the extent stipulated by the Protocol and Study Instructions.

PhDr. Martina Tulpíková

(Signature / Podpis)

Date / Dátum

PhDr. Martina Tulpíková

Potvrdené a odsúhlasené:

Ja, PhDr. Martina Tulpíková, r.č. adresa: , podpisom tohto dokumentu beriem na vedomie a súhlasím s plnením svojich povinností v rozsahu stanovenom Protokolom a pokynmi k Štúdii.

Exhibit A	Príloha A

1.3. Payee Sub Investigator / 1.3 Príjemca platby: Spoluskúšajuci - MUDr. Zuzana Šustykevičová

Detailed Budget – Per Patient Fees/ Podrobný rozpočet – Poplatky za pacienta

Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Informed Consent (ICF)	1	✔														
Re-Consent	1	✔														
Inclusion/Exclusion Eligibility	2	✔														
Medical History	1	✔														
Demographics	1	✔														
Concomitant medications	27	✔														
NEI-VFQ25	5	✔														
BCVA (ETDRS) and refraction-Bilateral	13	✔														
IOP-bilateral	39	✔														
Slit lamp examination-bilateral	26	✔														
Indirect ophthalmoscopy	14	✔														
FA-unilateral	14	✔														
FP-bilateral	7	✔														
SD-OCT-bilaterally	26	✔														
Interpretation and Report for SD-OCT-	26	✔														
Physical examination	2	✔														
Vital signs	27	✔														
ECG	3	✔														
Adverse events	27	✔														
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✔														
Collection of specimen; urine for Urinalysis/UPCR	25	✔														
PK samples (Sparse)	6	✔														
Preparation of sample for shipping	27	✔														
Study Drug (active or sham)-IVT injection	23	✔														
Procedures Sub Total (€)																

Non Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Study Coordinator, Simple-Randomization, Data entry	28	✔														
Study nurse	28	✔														
PI time	28	✔														
Pharmacy, Complex-Dispense drug	23	✔														
Physician: Ophthalmology - DRM Assessment	20	✔														
Non Procedures Sub Total (€)																

Overhead (all costs) 16%

Total Cost Per Visit with Overhead(€)

Total Cost Per Patient (€)

Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Informed Consent (ICF)	1	✔															
Re-Consent	1	✔															
Inclusion/Exclusion Eligibility	2	✔															
Medical History	1	✔															
Demographics	1	✔															
Concomitant medications	27	✔															
NEI-VFQ25	5	✔															
BCVA (ETDRS) and refraction-Bilateral	13	✔															
IOP-bilateral	39	✔															
Slit lamp examination-bilateral	26	✔															
Indirect ophthalmoscopy	14	✔															
FA-unilateral	14	✔															
FP-bilateral	7	✔															
SD-OCT-bilaterally	26	✔															
Interpretation and Report for SD-OCT-	26	✔															
Physical examination	2	✔															
Vital signs	27	✔															
ECG	3	✔															
Adverse events	27	✔															
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✔															
Collection of specimen; urine for Urinalysis/UPCR	25	✔															
PK samples (Sparse)	6	✔															
Preparation of sample for shipping	27	✔															
Study Drug (active or sham)-IVT injection	23	✔															
Procedures Sub Total (€)																	

Non Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Study Coordinator, Simple-Randomization, Data entry	28	✔															
Study nurse	28	✔															
PI time	28	✔															
Pharmacy, Complex-Dispense drug	23	✔															
Physician: Ophthalmology - DRM Assessment	20	✔															
Non Procedures Sub Total (€)																	
Overhead (all costs) 16%																	
Total Cost Per Visit with Overhead(€)																	

1.3 Payee: Sub Investigator /1.3 Príjemca platby: Spoluskúšajuci - MUDr. Zuzana Šustykevičová

Detailed Budget – Conditional Fees / 1.3 Podrobný rozpočet – podmienečné poplatky

Conditional Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Physician: Ophthalmology - Rescue Treatment	20	✔														
Genomic substudy ICF	1	✔														
Blood draw for Genomic DNA sample	1	✔														
Preparation of sample for shipping	25	✔														
FBR ICF	1	✔														
ICGA-bilateral	3	✔														
OCTA-bilaterally	7	✔														
Interpretation and Report for OCTA	7	✔														
Collection of specimen; urine for Urine pregnancy	25	✔														
Serum pregnancy (Local lab)	0,5	✔														
Hematology (Local lab)	3	✔														
Blood Chemistry (Local lab)	3	✔														
Urine pregnancy test (Local lab)	12,5	✔														
Urinalysis (Local lab)	3	✔														
UPCR (Local lab)	3	✔														

Conditional Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Physician: Ophthalmology - Rescue Treatment	20	✔															
Genomic substudy ICF	1	✔															
Blood draw for Genomic DNA sample	1	✔															
Preparation of sample for shipping	25	✔															
FBR ICF	1	✔															
ICGA-bilateral	3	✔															
OCTA-bilaterally	7	✔															
Interpretation and Report for OCTA	7	✔															
Collection of specimen; urine for Urine pregnancy	25	✔															
Serum pregnancy (Local lab)	0,5	✔															
Hematology (Local lab)	3	✔															
Blood Chemistry (Local lab)	3	✔															
Urine pregnancy test (Local lab)	12,5	✔															
Urinalysis (Local lab)	3	✔															
UPCR (Local lab)	3	✔															

1.3 Payee: Sub Investigator /1.3 Príjemca platby: Spoluskúšajuci - MUDr. Zuzana Šustykevičová

Screening Failure / Zlyhanie skríningu

Procedure	Amount
Informed Consent (ICF)	
Re-Consent	
Inclusion/Exclusion Eligibility	
Medical History	
Demographics	
Concomitant medications	
BCVA (ETDRS) and refraction-Bilateral	
IOP-bilateral	
Slit lamp examination-bilateral	
Indirect ophthalmoscopy	
FA-unilateral	
FP-bilateral	
SD-OCT-bilaterally	
Interpretation and Report for SD-OCT-	
Physical examination	
Vital signs	
ECG	
Adverse events	
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	
Preparation of sample for shipping	
Procedures Sub Total (€)	

Non Procedure	SV
Study Coordinator, Simple-Randomization, Data entry	
Study nurse	
PI time	
Non Procedures Sub Total (€)	
Overhead (all costs)	
Total Cost Per Visit with Overhead(€)	

1.5 Payee: Sub Investigator / 1.5 Príjemca platby: Spoluskúšajuci: MUDr. Karolina Kafková

Detailed Budget – Per Patient Fees/ Podrobný rozpočet – Poplatky za pacienta

Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Informed Consent (ICF)	1	✔														
Re-Consent	1	✔														
Inclusion/Exclusion Eligibility	2	✔														
Medical History	1	✔														
Demographics	1	✔														
Concomitant medications	27	✔														
NEI-VFQ25	5	✔														
BCVA (ETDRS) and refraction-Bilateral	13	✔														
IOP-bilateral	39	✔														
Slit lamp examination-bilateral	26	✔														
Indirect ophthalmoscopy	14	✔														
FA-unilateral	14	✔														
FP-bilateral	7	✔														
SD-OCT-bilaterally	26	✔														
Interpretation and Report for SD-OCT-	26	✔														
Physical examination	2	✔														
Vital signs	27	✔														
ECG	3	✔														
Adverse events	27	✔														
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✔														
Collection of specimen; urine for Urinalysis/UPCR	25	✔														
PK samples (Sparse)	6	✔														
Preparation of sample for shipping	27	✔														
Study Drug (active or sham)-IVT injection	23	✔														
Procedures Sub Total (€)																

Non Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Study Coordinator, Simple-Randomization, Data entry	28	✔														
Study nurse	28	✔														
PI time	28	✔														
Pharmacy, Complex-Dispense drug	23	✔														
Physician: Ophthalmology - DRM Assessment	20	✔														
Non Procedures Sub Total (€)																
Overhead (all costs)	16%															
Total Cost Per Visit with Overhead(€)																
Total Cost Per Patient (€)																

Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Informed Consent (ICF)	1	✔															
Re-Consent	1	✔															
Inclusion/Exclusion Eligibility	2	✔															
Medical History	1	✔															
Demographics	1	✔															
Concomitant medications	27	✔															
NEI-VFQ25	5	✔															
BCVA (ETDRS) and refraction-Bilateral	13	✔															
IOP-bilateral	39	✔															
Slit lamp examination-bilateral	26	✔															
Indirect ophthalmoscopy	14	✔															
FA-unilateral	14	✔															
FP-bilateral	7	✔															
SD-OCT-bilaterally	26	✔															
Interpretation and Report for SD-OCT-	26	✔															
Physical examination	2	✔															
Vital signs	27	✔															
ECG	3	✔															
Adverse events	27	✔															
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✔															
Collection of specimen; urine for Urinalysis/UPCR	25	✔															
PK samples (Sparse)	6	✔															
Preparation of sample for shipping	27	✔															
Study Drug (active or sham)-IVT injection	23	✔															
Procedures Sub Total (€)																	

Non Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Study Coordinator, Simple-Randomization, Data entry	28	✔															
Study nurse	28	✔															
PI time	28	✔															
Pharmacy, Complex-Dispense drug	23	✔															
Physician: Ophthalmology - DRM Assessment	20	✔															
Non Procedures Sub Total (€)																	
Overhead (all costs)	16%																
Total Cost Per Visit with Overhead(€)																	

1.5 Payee: Sub Investigator / 1.5 Príjemca platby: Spoluskúšajuci: MUDr. Karolina Kafková

Detailed Budget – Conditional Fees / Podrobný rozpočet – podmienečné poplatky

Conditional Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Physician: Ophthalmology - Rescue Treatment	20	✔														
Genomic substudy ICF	1	✔														
Blood draw for Genomic DNA sample	1	✔														
Preparation of sample for shipping	25	✔														
FBR ICF	1	✔														
ICGA-bilateral	3	✔														
OCTA-bilaterally	7	✔														
Interpretation and Report for OCTA	7	✔														
Collection of specimen; urine for Urine pregnancy	25	✔														
Serum pregnancy (Local lab)	0,5	✔														
Hematology (Local lab)	3	✔														
Blood Chemistry (Local lab)	3	✔														
Urine pregnancy test (Local lab)	12,5	✔														
Urinalysis (Local lab)	3	✔														
UPCR (Local lab)	3	✔														

Conditional Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Physician: Ophthalmology - Rescue Treatment	20	✔															
Genomic substudy ICF	1	✔															
Blood draw for Genomic DNA sample	1	✔															
Preparation of sample for shipping	25	✔															
FBR ICF	1	✔															
ICGA-bilateral	3	✔															
OCTA-bilaterally	7	✔															
Interpretation and Report for OCTA	7	✔															
Collection of specimen; urine for Urine pregnancy	25	✔															
Serum pregnancy (Local lab)	0,5	✔															
Hematology (Local lab)	3	✔															
Blood Chemistry (Local lab)	3	✔															
Urine pregnancy test (Local lab)	12,5	✔															
Urinalysis (Local lab)	3	✔															
UPCR (Local lab)	3	✔			0,33												

1.5 Payee: Sub Investigator / 1.5 Príjemca platby: Spoluskúšajuci: MUDr. Karolina Kafková

Screening Failure / Zlyhanie skríningu

Procedure	Amount
Informed Consent (ICF)	
Re-Consent	
Inclusion/Exclusion Eligibility	
Medical History	
Demographics	
Concomitant medications	
BCVA (ETDRS) and refraction-Bilateral	
IOP-bilateral	
Slit lamp examination-bilateral	
Indirect ophthalmoscopy	
FA-unilateral	
FP-bilateral	
SD-OCT-bilaterally	
Interpretation and Report for SD-OCT-	
Physical examination	
Vital signs	
ECG	
Adverse events	
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	
Preparation of sample for shipping	
Procedures Sub Total (€)	

Non Procedure	SV
Study Coordinator, Simple-Randomization, Data entry	
Study nurse	
PI time	
Non Procedures Sub Total (€)	
Overhead (all costs)	
Total Cost Per Visit with Overhead(€)	

1.6 Payee: Sub Investigator / 1.6 Príjemca platby: Spoluskúšajuci: MUDr. Martina Hanicová

Detailed Budget – Per Patient Fees/ Podrobný rozpočet – Poplatky za pacienta

Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Informed Consent (ICF)	1	✔														
Re-Consent	1	✔														
Inclusion/Exclusion Eligibility	2	✔														
Medical History	1	✔														
Demographics	1	✔														
Concomitant medications	27	✔														
NEI-VFQ25	5	✔														
BCVA (ETDRS) and refraction-Bilateral	13	✔														
IOP-bilateral	39	✔														
Slit lamp examination-bilateral	26	✔														
Indirect ophthalmoscopy	14	✔														
FA-unilateral	14	✔														
FP-bilateral	7	✔														
SD-OCT-bilaterally	26	✔														
Interpretation and Report for SD-OCT-	26	✔														
Physical examination	2	✔														
Vital signs	27	✔														
ECG	3	✔														
Adverse events	27	✔														
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✔														
Collection of specimen; urine for Urinalysis/UPCR	25	✔														
PK samples (Sparse)	6	✔														
Preparation of sample for shipping	27	✔														
Study Drug (active or sham)-IVT injection	23	✔														
Procedures Sub Total (€)																

Non Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Study Coordinator, Simple-Randomization, Data entry	28	✔														
Study nurse	28	✔														
PI time	28	✔														
Pharmacy, Complex-Dispense drug	23	✔														
Physician: Ophthalmology - DRM Assessment	20	✔														
Non Procedures Sub Total (€)																
Overhead (all costs)	16%															
Total Cost Per Visit with Overhead(€)																
Total Cost Per Patient (€)																

Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Informed Consent (ICF)	1	✔															
Re-Consent	1	✔															
Inclusion/Exclusion Eligibility	2	✔															
Medical History	1	✔															
Demographics	1	✔															
Concomitant medications	27	✔															
NEI-VFQ25	5	✔															
BCVA (ETDRS) and refraction-Bilateral	13	✔															
IOP-bilateral	39	✔															
Slit lamp examination-bilateral	26	✔															
Indirect ophthalmoscopy	14	✔															
FA-unilateral	14	✔															
FP-bilateral	7	✔															
SD-OCT-bilaterally	26	✔															
Interpretation and Report for SD-OCT-	26	✔															
Physical examination	2	✔															
Vital signs	27	✔															
ECG	3	✔															
Adverse events	27	✔															
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✔															
Collection of specimen; urine for Urinalysis/UPCR	25	✔															
PK samples (Sparse)	6	✔															
Preparation of sample for shipping	27	✔															
Study Drug (active or sham)-IVT injection	23	✔															
Procedures Sub Total (€)																	

Non Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Study Coordinator, Simple-Randomization, Data entry	28	✔															
Study nurse	28	✔															
PI time	28	✔															
Pharmacy, Complex-Dispense drug	23	✔															
Physician: Ophthalmology - DRM Assessment	20	✔															
Non Procedures Sub Total (€)																	
Overhead (all costs)	16%																
Total Cost Per Visit with Overhead(€)																	

1.6 Payee: Sub Investigator /1.6 Príjemca platby: Spoluskúšajuci\. MUDr. Martina Hanicová

Detailed Budget – Conditional Fees / Podrobný rozpočet – podmienečné poplatky

Conditional Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Physician: Ophthalmology - Rescue Treatment	20	✔														
Genomic substudy ICF	1	✔														
Blood draw for Genomic DNA sample	1	✔														
Preparation of sample for shipping	25	✔														
FBR ICF	1	✔														
ICGA-bilateral	3	✔														
OCTA-bilaterally	7	✔														
Interpretation and Report for OCTA	7	✔														
Collection of specimen; urine for Urine pregnancy	25	✔														
Serum pregnancy (Local lab)	0,5	✔														
Hematology (Local lab)	3	✔														
Blood Chemistry (Local lab)	3	✔														
Urine pregnancy test (Local lab)	12,5	✔														
Urinalysis (Local lab)	3	✔														
UPCR (Local lab)	3	✔														

Conditional Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Physician: Ophthalmology - Rescue Treatment	20	✔															
Genomic substudy ICF	1	✔															
Blood draw for Genomic DNA sample	1	✔															
Preparation of sample for shipping	25	✔															
FBR ICF	1	✔															
ICGA-bilateral	3	✔															
OCTA-bilaterally	7	✔															
Interpretation and Report for OCTA	7	✔															
Collection of specimen; urine for Urine pregnancy	25	✔															
Serum pregnancy (Local lab)	0,5	✔															
Hematology (Local lab)	3	✔															
Blood Chemistry (Local lab)	3	✔															
Urine pregnancy test (Local lab)	12,5	✔															
Urinalysis (Local lab)	3	✔															
UPCR (Local lab)	3	✔															

1.6 Payee: Sub Investigator / 1.6 Príjemca platby: Spoluskúšajuci: MUDr. Martina Hanicová

Screening Failure / Zlyhanie skríningu

Procedure	Amount
Informed Consent (ICF)	
Re-Consent	
Inclusion/Exclusion Eligibility	
Medical History	
Demographics	
Concomitant medications	
BCVA (ETDRS) and refraction-Bilateral	
IOP-bilateral	
Slit lamp examination-bilateral	
Indirect ophthalmoscopy	
FA-unilateral	
FP-bilateral	
SD-OCT-bilaterally	
Interpretation and Report for SD-OCT-	
Physical examination	
Vital signs	
ECG	
Adverse events	
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	
Preparation of sample for shipping	
Procedures Sub Total (€)	

Non Procedure	SV
Study Coordinator, Simple-Randomization, Data entry	
Study nurse	
PI time	
Non Procedures Sub Total (€)	
Overhead (all costs)	
Total Cost Per Visit with Overhead(€)	

1.7 Payee: Sub Investigator / 1.7 Príjemca platby: Spoluskúšajuci: MUDr. Ján Mihala

Detailed Budget – Per Patient Fees/ Podrobný rozpočet – Poplatky za pacienta

Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Informed Consent (ICF)	1	✔														
Re-Consent	1	✔														
Inclusion/Exclusion Eligibility	2	✔														
Medical History	1	✔														
Demographics	1	✔														
Concomitant medications	27	✔														
NEI-VFQ25	5	✔														
BCVA (ETDRS) and refraction-Bilateral	13	✔														
IOP-bilateral	39	✔														
Slit lamp examination-bilateral	26	✔														
Indirect ophthalmoscopy	14	✔														
FA-unilateral	14	✔														
FP-bilateral	7	✔														
SD-OCT-bilaterally	26	✔														
Interpretation and Report for SD-OCT-	26	✔														
Physical examination	2	✔														
Vital signs	27	✔														
ECG	3	✔														
Adverse events	27	✔														
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✔														
Collection of specimen; urine for Urinalysis/UPCR	25	✔														
PK samples (Sparse)	6	✔														
Preparation of sample for shipping	27	✔														
Study Drug (active or sham)-IVT injection	23	✔														
Procedures Sub Total (€)																

Non Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Study Coordinator, Simple-Randomization, Data entry	28	✔														
Study nurse	28	✔														
PI time	28	✔														
Pharmacy, Complex-Dispense drug	23	✔														
Physician: Ophthalmology - DRM Assessment	20	✔														
Non Procedures Sub Total (€)																
Overhead (all costs)	16%															
Total Cost Per Visit with Overhead(€)																
Total Cost Per Patient (€)																

Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Informed Consent (ICF)	1	✔															
Re-Consent	1	✔															
Inclusion/Exclusion Eligibility	2	✔															
Medical History	1	✔															
Demographics	1	✔															
Concomitant medications	27	✔															
NEI-VFQ25	5	✔															
BCVA (ETDRS) and refraction-Bilateral	13	✔															
IOP-bilateral	39	✔															
Slit lamp examination-bilateral	26	✔															
Indirect ophthalmoscopy	14	✔															
FA-unilateral	14	✔															
FP-bilateral	7	✔															
SD-OCT-bilaterally	26	✔															
Interpretation and Report for SD-OCT-	26	✔															
Physical examination	2	✔															
Vital signs	27	✔															
ECG	3	✔															
Adverse events	27	✔															
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✔															
Collection of specimen; urine for Urinalysis/UPCR	25	✔															
PK samples (Sparse)	6	✔															
Preparation of sample for shipping	27	✔															
Study Drug (active or sham)-IVT injection	23	✔															
Procedures Sub Total (€)																	

Non Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Study Coordinator, Simple-Randomization, Data entry	28	✔															
Study nurse	28	✔															
PI time	28	✔															
Pharmacy, Complex-Dispense drug	23	✔															
Physician: Ophthalmology - DRM Assessment	20	✔															
Non Procedures Sub Total (€)																	
Overhead (all costs)	16%																
Total Cost Per Visit with Overhead(€)																	

1.7 Payee: Sub Investigator / 1.7 Príjemca platby: Spoluskúšajuci: MUDr. Ján Mihala

Detailed Budget – Conditional Fees / Podrobný rozpočet – podmienečné poplatky

Conditional Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Physician: Ophthalmology - Rescue Treatment	20	✔														
Genomic substudy ICF	1	✔														
Blood draw for Genomic DNA sample	1	✔														
Preparation of sample for shipping	25	✔														
FBR ICF	1	✔														
ICGA-bilateral	3	✔														
OCTA-bilaterally	7	✔														
Interpretation and Report for OCTA	7	✔														
Collection of specimen; urine for Urine pregnancy	25	✔														
Serum pregnancy (Local lab)	0,5	✔														
Hematology (Local lab)	3	✔														
Blood Chemistry (Local lab)	3	✔														
Urine pregnancy test (Local lab)	12,5	✔														
Urinalysis (Local lab)	3	✔														
UPCR (Local lab)	3	✔														

Conditional Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Physician: Ophthalmology - Rescue Treatment	20	✔															
Genomic substudy ICF	1	✔															
Blood draw for Genomic DNA sample	1	✔															
Preparation of sample for shipping	25	✔															
FBR ICF	1	✔															
ICGA-bilateral	3	✔															
OCTA-bilaterally	7	✔															
Interpretation and Report for OCTA	7	✔															
Collection of specimen; urine for Urine pregnancy	25	✔															
Serum pregnancy (Local lab)	0,5	✔															
Hematology (Local lab)	3	✔															
Blood Chemistry (Local lab)	3	✔															
Urine pregnancy test (Local lab)	12,5	✔															
Urinalysis (Local lab)	3	✔															
UPCR (Local lab)	3	✔															

1.7 Payee: Sub Investigator / 1.7 Príjemca platby: Spoluskúšajuci: MUDr. Ján Mihala

Screening Failure / Zlyhanie skríningu

Procedure	Amount
Informed Consent (ICF)	
Re-Consent	
Inclusion/Exclusion Eligibility	
Medical History	
Demographics	
Concomitant medications	
BCVA (ETDRS) and refraction-Bilateral	
IOP-bilateral	
Slit lamp examination-bilateral	
Indirect ophthalmoscopy	
FA-unilateral	
FP-bilateral	
SD-OCT-bilaterally	
Interpretation and Report for SD-OCT-	
Physical examination	
Vital signs	
ECG	
Adverse events	
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	
Preparation of sample for shipping	
Procedures Sub Total (€)	

Non Procedure	SV
Study Coordinator, Simple-Randomization, Data entry	
Study nurse	
PI time	
Non Procedures Sub Total (€)	
Overhead (all costs)	
Total Cost Per Visit with Overhead(€)	

Exhibit B	Príloha B

Appendix 1.8 – payment of Sub-Investigator grants MUDr. Kristína Dorčiaková	Príloha 1.8 - platby pre Spoluskúšajúceho MUDr. Kristína Dorčiaková.

1. Údaje príjemcu platby	1. Payee details

Protocol Number / Číslo Protokolu	20968
Site Number / Číslo centra	52001
Payee Name / Menu príjemcu platby	MUDr. Kristína Dorčiaková rod. Igazová
Payee Address / Adresa příjemcu platby	
Address Line 2 / 2. riadok adresy	
Address Line 3 / 3. riadok adresy	
Province/State/Country / Provnicia/Štát	
City / Mesto	
Postal Code / Poštové směrovacie číslo	
Country / Štát	
Payee Contact / Kontaktná osoba príjemcu platby	
Payee Contact Phone Number / Tel. číslo kontaktné osoby příjemcu platby	
Remittance E-mail Address / E-mailová adresa kontaktné osoby príjemcu platby	
General Finance contract e-mail address if different from above / Obecná Emailová adresa finančného útvaru, pokiaľ sa liší od e-mailové adresy vyššie	
NPI	
Tax ID (VAT) / Daňová identifikace (DPH)	
Bank Account Holder Name / Meno majitela bankového účtu	
Bank Account Number / Číslo účtu	
IBAN (International Bank Account Number) / IBAN	
Bank Name / Názov banky	
Bank Number / Číselný kód banky	
Bank Branch Number / Číslo bankové pobočky	
Bank Identification Code / SWIFT kód	
Bank Type / Druh banky	
MUST INCLUDE IDENTIFICATOR: Payment/transaction reference / NUTNÉ: "variabilný symbol"	Number of the respective invoice / číslo faktúry
MUST INCLUDE IDENTIFICATOR: Sender to Recipient information / NUTNÉ: zpráva pro príjemncu platby	"20968" (i.e. protocol number)

V záujme správneho vykonania platby vyplňte všetky polia vyššie.	**To ensure proper payment please ensure that all fields above are completed.**
Strany sa zaväzujú, že v prípade zmeny údajov príjemcu platby počas trvania Klinického skúšania nebudú potrebné žiadne dodatky k tejto zmluve, ak príjemca platby poskytne zadávateľovi alebo jeho poverenej osobe písomné oznámenie so svojimi upravenými údajmi na e-mailovú adresu InvestigatorPaymentHelpDesk@PAREXEL.com. Zadávateľ nepreberá žiadnu zodpovednosť za to, že	In the event that payee details are modified during the course of the Clinical Trial, the parties agree that no amendments to this Agreement shall be required, provided that Payee provides written notification to Sponsor or its designee with revised payee details to the following e-mail address InvestigatorPaymentHelpDesk@PAREXEL.com.

príjemca platby alebo jeho zástupca poskytne nesprávne údaje príjemcu platby.	Sponsor accepts no liability for incorrect payee details provided by the Payee or its representative.
2. <u>Zaradenie do štúdie</u>	**2. <u>Enrolment</u>**
Toto Klinické skúšanie bude hodnotiť pacientov v súlade s Protokolom. Skúšajúci vynaloží v mene Centra maximálne úsilie, aby boli do Klinického skúšania zaradení najmenej 3 pacienti. Centrum bude o skončení náboru do štúdie písomne informované a prestane prijímať ďalších pacientov.	This Clinical Trial is designed to evaluate patients in accordance with the Protocol. The Investigator on behalf of the Center will use best efforts to enrol at least 3 patients in the Study. When enrolment is complete for the study, the Center will be notified in writing and will dis-continue enrolling patients.
3. <u>Poplatok za pacienta</u>	**3. <u>Per Patient Fee</u>**
Suma, ktorá bude príjemcovi platby vyplatená za ukončeného účastníka, je uvedená v priloženej tabulke **Podrobný rozpočet – poplatky za pacienta**. Všetky platby budú vykonávané štvrťročne elektronicky a budú založené na overených absolvovaných návštevách uvedených v EDC účastníka (systéme evidencie elektronických údajov).	The amount to be paid to the Payee per completed subject is outlined in the attached table **Detailed Budget – Per Patient Fees**. All payments will be made on a quarterly basis electronically and will be based on completed visits verified and entered in the subject EDC (electronic data capture system).
4. <u>Podmienečné poplatky</u>	**4. <u>Conditional Fees</u>**
ZLYHANIE SKRÍNINGU: V prípade zlyhania skríningu bude platba vykonaná za skutočné postupy vykonané počas skríningovej návštevy. Jedno zlyhanie skríningu bude odmenené sumou uvedenou v priloženej tabulke **Podrobný rozpočet – podmienečné poplatky**. Za zlyhanie skríningu sa považuje prípad účastníka, ktorý podpíše formulár informovaného súhlasu a podstúpi skríning, ale nesplní kritériá zahrnutia/vylúčenia a nebude randomizovaný do udržiavacej fázy. Platba sa v prospech príjemcu platby vykoná po prijatí príslušnej faktúry.	***SCREENING FAILURE:*** Screening failures will be paid for actual procedures performed on screening visit. The single screening failure will be remunerated with an amount outlined in the attached table **Detailed Budget – Conditional Fees**. 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 randomized to the maintenance phase. Payment to Payee will be made upon receipt of the corresponding invoice.
NEPLÁNOVANÁ NÁVŠTEVA: Neplánovaná návšteva vykonaná v Klinickom skúšaní nad rámec bežného štandardu starostlivosti o pacienta a harmonogramu návštev bude uhradená podľa vykonaných postupov na základe sadzieb uvedených v priloženej tabulke **Podrobný rozpočet – podmienečné poplatky**. Platba sa začne spracúvať po prijatí faktúry (resp. žiadosti o platbu) s adekvátnou podpornou dokumentáciou podľa požiadaviek a na základe súhlasu Zadávateľa alebo ním poverenej osoby.	***UNSCHEDULED VISIT***: Unscheduled visit performed as part of the Study that are outside of the normal standard of patient care and visit schedule will be paid per procedure done, according to the rates outlined in the attached table **Detailed Budget – Conditional Fees**. Processing of payment will begin upon receipt of invoice (or Payment request) with adequate supporting documentation in accordance and approval of Sponsor or its designee.
NÁHRADA ZA INDOKYANÍNOVÚ ZELENÚ ANGIOGRAFIU (ICGA): Za postup ICGA bude za jednu návštevu vyplatená maximálna suma uvedená v priloženej tabulke **Podrobný rozpočet – podmienečné poplatky.** ICGA je dobrovoľná a možno ju vykonať, ak má pracovisko k dispozícii vhodné vybavenie. Náhrada bude vyplatená po prijatí faktúry a príslušnej podpornej dokumentácie.	***INDOCYANINE GREEN ANGIOGRAPHY (ICGA) REIMBURSEMENT:*** A maximum amount as outlined in the attached table **Detailed Budget – Conditional Fees** per visit will be paid for ICGA procedure. ICGA is optional and can performed if site has the appropriate equipment. The reimbursement will be paid against the receipt of the invoice and corresponding support documentation.
NÁHRADA ZA OPTICKÚ KOHERENTNÚ TOMOGRAFICKÚ ANGIOGRAFIU (OCT-A): Za postup OCT-A bude za jednu návštevu vyplatená maximálna suma uvedená v priloženej tabulke **Podrobný rozpočet – podmienečné poplatky.** OCT-	***OPTICAL COHERENCE TOMOGRAPHY ANGIOGRAPHY (OCT-A) REIMBURSEMENT:*** A maximum amount as outlined in the attached table **Detailed Budget – Conditional Fees** per visit will be paid for OCT-A procedure. OCT-A is optional and can

A je dobrovoľná a možno ju vykonať, ak má pracovisko k dispozícii príslušné vybavenie. Náhrada bude vyplatená po prijatí faktúry a príslušnej podpornej dokumentácie.	performed if site has the relevant equipment. The reimbursement will be paid against the receipt of the invoice and corresponding support documentation.
LOKÁLNE LABORATÓRNE VYŠETRENIA: Maximálna suma za jednu návštevu uvedená v priloženej tabulke **Podrobný rozpočet – podmienečné poplatky** bude vyplatená za laboratórne vyšetrenia (tehotenský test zo séra, hematológia, biochemický rozbor krvi, tehotenský test z moču, rozbor moču, UPCR) ***len*** v prípade, ak včas nebudú k dispozícii výsledky z centrálneho laboratória na to, aby bolo možné vykonať zákrok v štúdii a/alebo vyhodnotiť odpoveď. Náhrada bude vyplatená po prijatí faktúry a príslušnej podpornej dokumentácie.	***LOCAL LABORATORY TESTS:*** A maximum as outlined in the attached table **Detailed Budget – Conditional Fees** per visit will be paid for laboratory tests (serum pregnancy, hematology, blood chemistry, urine pregnancy test, urinalysis, UPCR) ***only*** in the event that central laboratory results are not available in time for either study intervention administration and/or response evaluation. The reimbursement will be paid against the receipt of the invoice and corresponding support documentation.
Príjemcovia platby predložia faktúry (resp. žiadosti o platby) za vykonané služby a vzniknuté výdavky podľa časti 4 a všetky platby budú vykonané do štyridsiatich piatich (45) dní od prijatia platnej faktúry podľa tejto zmluvy. Všetky platby budú poukazované elektronicky na bankové účty uvedené vyššie.	Payees shall submit invoices (or Payment requests) for Services performed and expenses incurred under Section 4, all payments will be made within forty-five (45) days of receipt from the date of receipt of valid invoice in accordance with this Agreement. All payments will be made electronically to the bank accounts stated above.
5. Ostatné ustanovenia.	**5. Other provisions**
NÁHRADA LIEČBY DRUHÉHO OKA: Náhrada nákladov na liečbu druhého oka bude vyplatená, len ak na to Zadávateľ alebo ním poverená osoba vopred poskytne Hlavnému Skúšajúcemu súhlas. Náhrada bude vyplatená po prijatí faktúry a príslušnej podpornej dokumentácie.	***FELLOW EYE TREATEMENT REIMBURSEMENT:*** Reimbursement for the fellow eye treatment costs will be done only if Principal Investigator has received prior approval for such treatment from Sponsor or its designee. The reimbursement will be paid against receipt of the invoice and corresponding support documentation.
6. Pomerné platby	**6. Pro-rata Payments**
6.1 Platba za účastníkov, ktorí nedokončili Klinické skúšanie, sa môže príjemcovi platby vyplatiť pomerne. Platba bude zahŕňať iba tých účastníkov, ktorí boli zaradení pred predčasným ukončením Klinického skúšania alebo pred dátumom, keď bolo prijaté oznámenie o takomto predčasnom ukončení, podľa toho, čo nastane neskôr.	6.1 Payment for Subjects who do not complete the Study may be made to Payee on a pro rata 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.
6.2 V prípade, že Zadávateľ ukončí Klinické skúšanie pred dokončením, uhradia sa pomerné náklady a poplatky, ktoré sú stanovené podľa časti 3, za každú návštevu účastníka uskutočnenú pred predčasným ukončením Klinického skúšania alebo pred dátumom, keď bolo prijaté oznámenie o takomto predčasnom ukončení, podľa toho, čo nastane neskôr.	6.2 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.
6.3 Ak Centru vzniknú ďalšie nezrušiteľné náklady, Zadávateľovi je potrebné predložiť písomné odôvodnenie na kontrolu a schválenie, pričom zaplatenie takýchto nákladov podlieha súhlasu Zadávateľa.	6.3 If other non-cancelable costs are incurred by Center, written justification must be provided to Sponsor for review and approval, and payment of such costs is subject to Sponsor's approval.
6.4. Vždy keď príjemca platby dostane finančné prostriedky, na ktoré nemá nárok, musí ich Zadávateľovi vrátiť do štyridsiatich piatich dní od oznámenia.	6.4 In any instance where the Payee has been rec eived unearned funds, such funds shall be returned to Sponsor within forty-five days of notification.
7. Porušovatelia protokolu	**7. Protocol Violators**

Platby za účastníkov skúšania, o ktorých sa predpokladá, že porušujú protokol, sa môžu vyplatiť, len ak k porušeniu došlo na základe rozhodnutia zadávateľa.	Payments for Study Subjects who are deemed to have been in violation of the Protocol may be paid up to the point that the violation occurred at the discretion of Sponsor.
8. Faktúry	**8. Invoices**
Zadávateľ poskytne príjemcovi platby prostredníctvom svojej poverenej osoby informácie potrebné na určenie výšky odmeny pre príjemcu platby. Na základe týchto informácií vystaví príjemca platby faktúru. Originály správnych faktúr s rozpisom položiek posielajte na adresu: **Prednostná adresa** Faktúry je možné zasielať e-mailom na adresu: PIILPayablesInvoices@parexel.com Bayer AG c/o PAREXEL International (IRL) Limited One Kilmainham Square Inchicore Road, Kilmainham Dublin 8 Írsko Č. štúdie spoločnosti PAREXEL: 245919 Všetky faktúry musia obsahovať nasledujúce informácie: (a) číslo protokolu (b) číslo faktúry (c) dátum vystavenia faktúry (d) miesto, dátum a opis poskytnutých služieb (e) číslo projektu (f) celková splatná suma (g) použitý výmenný kurz (podľa potreby) (h) meno skúšajúceho (i) číslo pracoviska (j) štátne identifikačné číslo skúšajúceho (NPI) (k) názov a adresa príjemcu platby (podľa tejto zmluvy) (l) adresa uvedená vyššie (m) dátum dodania Pred odovzdaním na úhradu je z faktúr a súvisiacej dokumentácie potrebné odstrániť identifikačné osobné údaje pacientov (napr. meno, dátum narodenia, iniciály atď.).	Sponsor through its designee shall provide Payee with the information necessary to determine the amount of remuneration due to Payee. Payee shall issue their in voice based on this information. Please send original, correct and itemized invoices to the following address : **Preferred** Invoices may be e-mailed to: PIILPayablesInvoices@parexel.com Bayer AG c/o PAREXEL International (IRL) Limited One Kilmainham Square Inchicore Road, Kilmainham Dublin 8 Ireland PAREXEL Study no.: 245919 All invoices must contain the following information: (a) Protocol Number (b) Invoice Number (c) Invoice Date (d) Place, Date & Description of Services Provided (e) 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) Address listed above (m) Date of Supply Invoices and associated documentation should be de-identified of patient personal information (e.g. name, date of birth, initials, etc.) prior to being submitted for reimbursement.
9. Záverečná platba	**9. Final Payment**
Bez ohľadu na vyššie uvedené ustanovenia bude záverečná platba uhradená po dokončení nasledujúcich činností: (a) všetky požadované návštevy účastníkov boli ukončené; (b) zadávateľ dostal všetky údaje o účastníkoch vo forme vhodnej na analýzu;	Notwithstanding the foregoing, the final payment shall be paid upon the completion of the following activities: (a) all required Subject visits have been completed (b) Sponsor has received all Subject data in a form suitable for analysis

(c) všetky otázky na objasnenie údajov boli vyriešené k spokojnosti zadávateľa; (d) zadávateľ overil, že všetka požadovaná regulačná dokumentácia je úplná; (e) zariadenie vrátilo všetko požadované vybavenie, lieky a iný materiál; (f) bola vykonaná záverečná návšteva v rámci štúdie. Na základe tejto zmluvy má príjemca platby šesťdesiat (60) dní od prijatia záverečnej platby, aby zistil nezrovnalosti a vyriešil všetky platobné spory so zadávateľom. Všetky faktúry na účely platieb v rámci štúdie, ako sú uvedené v tejto zmluve, musia byť zadávateľovi odovzdané do šesťdesiatich (60) dní od návštevy zariadenia kvôli ukončeniu štúdie. Faktúry prijaté po tomto termíne nebudú uhradené.	(c) all data clarification queries have been resolved to Sponsor's satisfaction (d) Sponsor has verified that all required regulatory documentation is complete (e) Center has returned all required equipment, drugs and other material (f) the Study close-out visit has been completed Payee shall have sixty (60) days from the receipt of the final payment under this Agreement to identify discrepancies and resolve any payment disputes with Sponsor. All invoices for Study payments, as outlined herein, must be submitted to the Sponsor within sixty (60) days of the Center's Study close-out visit. Invoices received after this time will not be reimbursed.
10. Daň	**10. Tax**
Všetky poplatky a výdavky v tomto rozpise sú uvedené bez DPH alebo inej príslušnej dne. Všetky platby podliehajú príslušnej zrážkovej dani.	All fees and expenses in this Schedule are exclusive of VAT or any applicable tax. All payments are subject to withholding tax as applicable.

1.8 Payee: Sub Investigator / 1.8 Príjemca platby: Spoluskúšajuci: MUDr. Kristína Dorčiaková

Detailed Budget – Per Patient Fees/ Podrobný rozpočet – Poplatky za pacienta

Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Informed Consent (ICF)	1	✔														
Re-Consent	1	✔														
Inclusion/Exclusion Eligibility	2	✔														
Medical History	1	✔														
Demographics	1	✔														
Concomitant medications	27	✔														
NEI-VFQ25	5	✔														
BCVA (ETDRS) and refraction-Bilateral	13	✔														
IOP-bilateral	39	✔														
Slit lamp examination-bilateral	26	✔														
Indirect ophthalmoscopy	14	✔														
FA-unilateral	14	✔														
FP-bilateral	7	✔														
SD-OCT-bilaterally	26	✔														
Interpretation and Report for SD-OCT-	26	✔														
Physical examination	2	✔														
Vital signs	27	✔														
ECG	3	✔														
Adverse events	27	✔														
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✔														
Collection of specimen; urine for Urinalysis/UPCR	25	✔														
PK samples (Sparse)	6	✔														
Preparation of sample for shipping	27	✔														
Study Drug (active or sham)-IVT injection	23	✔														
Procedures Sub Total (€)																

Non Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Study Coordinator, Simple-Randomization, Data entry	28	✔														
Study nurse	28	✔														
PI time	28	✔														
Pharmacy, Complex-Dispense drug	23	✔														
Physician: Ophthalmology - DRM Assessment	20	✔														
Non Procedures Sub Total (€)																
Overhead (all costs)	16%															
Total Cost Per Visit with Overhead(€)																
Total Cost Per Patient (€)																

Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Informed Consent (ICF)	1	✔															
Re-Consent	1	✔															
Inclusion/Exclusion Eligibility	2	✔															
Medical History	1	✔															
Demographics	1	✔															
Concomitant medications	27	✔															
NEI-VFQ25	5	✔															
BCVA (ETDRS) and refraction-Bilateral	13	✔															
IOP-bilateral	39	✔															
Slit lamp examination-bilateral	26	✔															
Indirect ophthalmoscopy	14	✔															
FA-unilateral	14	✔															
FP-bilateral	7	✔															
SD-OCT-bilaterally	26	✔															
Interpretation and Report for SD-OCT-	26	✔															
Physical examination	2	✔															
Vital signs	27	✔															
ECG	3	✔															
Adverse events	27	✔															
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✔															
Collection of specimen; urine for Urinalysis/UPCR	25	✔															
PK samples (Sparse)	6	✔															
Preparation of sample for shipping	27	✔															
Study Drug (active or sham)-IVT injection	23	✔															
Procedures Sub Total (€)																	

Non Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Study Coordinator, Simple-Randomization, Data entry	28	✔															
Study nurse	28	✔															
PI time	28	✔															
Pharmacy, Complex-Dispense drug	23	✔															
Physician: Ophthalmology - DRM Assessment	20	✔															
Non Procedures Sub Total (€)																	
Overhead (all costs)	16%																
Total Cost Per Visit with Overhead(€)																	

1.8 Payee: Sub Investigator /1.8 Príjemca platby: Spoluskúšajuci - MUDr. Kristína Dorčiaková

Detailed Budget – Conditional Fees / 1.3 Podrobný rozpočet – podmienečné poplatky

Conditional Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Physician: Ophthalmology - Rescue Treatment	20	✔														
Genomic substudy ICF	1	✔														
Blood draw for Genomic DNA sample	1	✔														
Preparation of sample for shipping	25	✔														
FBR ICF	1	✔														
ICGA-bilateral	3	✔														
OCTA-bilaterally	7	✔														
Interpretation and Report for OCTA	7	✔														
Collection of specimen; urine for Urine pregnancy	25	✔														
Serum pregnancy (Local lab)	0,5	✔														
Hematology (Local lab)	3	✔														
Blood Chemistry (Local lab)	3	✔														
Urine pregnancy test (Local lab)	12,5	✔														
Urinalysis (Local lab)	3	✔														
UPCR (Local lab)	3	✔														

Conditional Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Physician: Ophthalmology - Rescue Treatment	20	✔															
Genomic substudy ICF	1	✔															
Blood draw for Genomic DNA sample	1	✔															
Preparation of sample for shipping	25	✔															
FBR ICF	1	✔															
ICGA-bilateral	3	✔															
OCTA-bilaterally	7	✔															
Interpretation and Report for OCTA	7	✔															
Collection of specimen; urine for Urine pregnancy	25	✔															
Serum pregnancy (Local lab)	0,5	✔															
Hematology (Local lab)	3	✔															
Blood Chemistry (Local lab)	3	✔															
Urine pregnancy test (Local lab)	12,5	✔															
Urinalysis (Local lab)	3	✔															
UPCR (Local lab)	3	✔															

1.8 Payee: Sub Investigator / 1.8 Príjemca platby: Spoluskúšajuci: MUDr. Kristína Dorčiaková

Screening Failure / Zlyhanie skríningu

Procedure	Amount
Informed Consent (ICF)	
Re-Consent	
Inclusion/Exclusion Eligibility	
Medical History	
Demographics	
Concomitant medications	
BCVA (ETDRS) and refraction-Bilateral	
IOP-bilateral	
Slit lamp examination-bilateral	
Indirect ophthalmoscopy	
FA-unilateral	
FP-bilateral	
SD-OCT-bilaterally	
Interpretation and Report for SD-OCT-	
Physical examination	
Vital signs	
ECG	
Adverse events	
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	
Preparation of sample for shipping	
Procedures Sub Total (€)	

Non Procedure	
Study Coordinator, Simple-Randomization, Data entry	
Study nurse	
PI time	
Non Procedures Sub Total (€)	
Overhead (all costs)	
Total Cost Per Visit with Overhead(€)	

Appendix 1.9 – payment of Sub-Investigator grants PhDr. Martina Tulpíková	Príloha 1.9 - platby pre Spoluskúšajúceho PhDr. Martina Tulpíková.

1. Údaje príjemcu platby	1. Payee details

Protocol Number / Číslo Protokolu	20968
Site Number / Číslo centra	52001
Payee Name / Menu príjemcu platby	PhDr. Martina Tulpíková
Payee Address / Adresa příjemcu platby	
Address Line 2 / 2. riadok adresy	
Address Line 3 / 3. riadok adresy	
Province/State/Country / Provnicia/Štát	
City / Mesto	
Postal Code / Poštové směrovacie číslo	
Country / Štát	
Payee Contact / Kontaktná osoba príjemcu platby	
Payee Contact Phone Number / Tel. číslo kontaktné osoby příjemcu platby	
Remittance E-mail Address / E-mailová adresa kontaktné osoby príjemcu platby	
General Finance contract e-mail address if different from above / Obecná Emailová adresa finančného útvaru, pokiaľ sa liší od e-mailové adresy vyššie	
NPI	
Tax ID (VAT) / Daňová identifikace (DPH)	
Bank Account Holder Name / Meno majitela bankového účtu	
Bank Account Number / Číslo účtu	
IBAN (International Bank Account Number) / IBAN	
Bank Name / Názov banky	
Bank Number / Číselný kód banky	
Bank Branch Number / Číslo bankové pobočky	
Bank Identification Code / SWIFT kód	
Bank Type / Druh banky	
MUST INCLUDE IDENTIFICATOR: Payment/transaction reference / NUTNÉ: "variabilný symbol"	Number of the respective invoice / číslo faktúry
MUST INCLUDE IDENTIFICATOR: Sender to Recipient information / NUTNÉ: zpráva pro príjemncu platby	"20968" (i.e. protocol number)

V záujme správneho vykonania platby vyplňte všetky polia vyššie. Strany sa zaväzujú, že v prípade zmeny údajov príjemcu platby počas trvania Klinického skúšania nebudú potrebné žiadne dodatky k tejto zmluve, ak príjemca platby poskytne zadávateľovi alebo jeho poverenej osobe písomné oznámenie so svojimi upravenými údajmi na e-mailovú adresu InvestigatorPaymentHelpDesk@PAREXEL.com. Zadávateľ nepreberá žiadnu zodpovednosť za to, že príjemca platby alebo jeho zástupca poskytne nesprávne údaje príjemcu platby.	**To ensure proper payment please ensure that all fields above are completed.** In the event that payee details are modified during the course of the Clinical Trial, the parties agree that no amendments to this Agreement shall be required, provided that Payee provides written notification to Sponsor or its designee with revised payee details to the following e-mail address InvestigatorPaymentHelpDesk@PAREXEL.com. Sponsor accepts no liability for incorrect payee details provided by the Payee or its representative.
2. Zaradenie do štúdie	**2. Enrolment**

Toto Klinické skúšanie bude hodnotiť pacientov v súlade s Protokolom. Skúšajúci vynaloží v mene Centra maximálne úsilie, aby boli do Klinického skúšania zaradení najmenej 3 pacienti. Centrum bude o skončení náboru do štúdie písomne informované a prestane prijímať ďalších pacientov.	This Clinical Trial is designed to evaluate patients in accordance with the Protocol. The Investigator on behalf of the Center will use best efforts to enrol at least 3 patients in the Study. When enrolment is complete for the study, the Center will be notified in writing and will dis-continue enrolling patients.
3. <u>Poplatok za pacienta</u>	**3. <u>Per Patient Fee</u>**
Suma, ktorá bude príjemcovi platby vyplatená za ukončeného účastníka, je uvedená v priloženej tabulke **Podrobný rozpočet – poplatky za pacienta**. Všetky platby budú vykonávané štvrťročne elektronicky a budú založené na overených absolvovaných návštevách uvedených v EDC účastníka (systéme evidencie elektronických údajov).	The amount to be paid to the Payee per completed subject is outlined in the attached table **Detailed Budget – Per Patient Fees**. All payments will be made on a quarterly basis electronically and will be based on completed visits verified and entered in the subject EDC (electronic data capture system).
4. <u>Podmienečné poplatky</u>	**4. <u>Conditional Fees</u>**
ZLYHANIE SKRÍNINGU: V prípade zlyhania skríningu bude platba vykonaná za skutočné postupy vykonané počas skríningovej návštevy. Jedno zlyhanie skríningu bude odmenené sumou uvedenou v priloženej tabulke **Podrobný rozpočet – podmienečné poplatky**. Za zlyhanie skríningu sa považuje prípad účastníka, ktorý podpíše formulár informovaného súhlasu a podstúpi skríning, ale nesplní kritériá zahrnutia/vylúčenia a nebude randomizovaný do udržiavacej fázy. Platba sa v prospech príjemcu platby vykoná po prijatí príslušnej faktúry.	***SCREENING FAILURE:*** Screening failures will be paid for actual procedures performed on screening visit. The single screening failure will be remunerated with an amount outlined in the attached table **Detailed Budget – Conditional Fees**. 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 randomized to the maintenance phase. Payment to Payee will be made upon receipt of the corresponding invoice.
NEPLÁNOVANÁ NÁVŠTEVA: Neplánovaná návšteva vykonaná v Klinickom skúšaní nad rámec bežného štandardu starostlivosti o pacienta a harmonogramu návštev bude uhradená podľa vykonaných postupov na základe sadzieb uvedených v priloženej tabulke **Podrobný rozpočet – podmienečné poplatky**. Platba sa začne spracúvať po prijatí faktúry (resp. žiadosti o platbu) s adekvátnou podpornou dokumentáciou podľa požiadaviek a na základe súhlasu Zadávateľa alebo ním poverenej osoby.	***UNSCHEDULED VISIT***: Unscheduled visit performed as part of the Study that are outside of the normal standard of patient care and visit schedule will be paid per procedure done, according to the rates outlined in the attached table **Detailed Budget – Conditional Fees**. Processing of payment will begin upon receipt of invoice (or Payment request) with adequate supporting documentation in accordance and approval of Sponsor or its designee.
NÁHRADA ZA INDOKYANÍNOVÚ ZELENÚ ANGIOGRAFIU (ICGA): Za postup ICGA bude za jednu návštevu vyplatená maximálna suma uvedená v priloženej tabulke **Podrobný rozpočet – podmienečné poplatky.** ICGA je dobrovoľná a možno ju vykonať, ak má pracovisko k dispozícii vhodné vybavenie. Náhrada bude vyplatená po prijatí faktúry a príslušnej podpornej dokumentácie.	***INDOCYANINE GREEN ANGIOGRAPHY (ICGA) REIMBURSEMENT:*** A maximum amount as outlined in the attached table **Detailed Budget – Conditional Fees** per visit will be paid for ICGA procedure. ICGA is optional and can performed if site has the appropriate equipment. The reimbursement will be paid against the receipt of the invoice and corresponding support documentation.
NÁHRADA ZA OPTICKÚ KOHERENTNÚ TOMOGRAFICKÚ ANGIOGRAFIU (OCT-A): Za postup OCT-A bude za jednu návštevu vyplatená maximálna suma uvedená v priloženej tabulke **Podrobný rozpočet – podmienečné poplatky.** OCT-A je dobrovoľná a možno ju vykonať, ak má pracovisko k dispozícii príslušné vybavenie. Náhrada bude vyplatená po prijatí faktúry a príslušnej podpornej dokumentácie.	***OPTICAL COHERENCE TOMOGRAPHY ANGIOGRAPHY (OCT-A) REIMBURSEMENT:*** A maximum amount as outlined in the attached table **Detailed Budget – Conditional Fees** per visit will be paid for OCT-A procedure. OCT-A is optional and can performed if site has the relevant equipment. The reimbursement will be paid against the receipt of the invoice and corresponding support documentation.

LOKÁLNE LABORATÓRNE VYŠETRENIA: Maximálna suma za jednu návštevu uvedená v priloženej tabulke **Podrobný rozpočet – podmienečné poplatky** bude vyplatená za laboratórne vyšetrenia (tehotenský test zo séra, hematológia, biochemický rozbor krvi, tehotenský test z moču, rozbor moču, UPCR) ***len*** v prípade, ak včas nebudú k dispozícii výsledky z centrálneho laboratória na to, aby bolo možné vykonať zákrok v štúdii a/alebo vyhodnotiť odpoveď. Náhrada bude vyplatená po prijatí faktúry a príslušnej podpornej dokumentácie.	*LOCAL LABORATORY TESTS:* A maximum as outlined in the attached table **Detailed Budget – Conditional Fees** per visit will be paid for laboratory tests (serum pregnancy, hematology, blood chemistry, urine pregnancy test, urinalysis, UPCR) ***only*** in the event that central laboratory results are not available in time for either study intervention administration and/or response evaluation. The reimbursement will be paid against the receipt of the invoice and corresponding support documentation.
Príjemcovia platby predložia faktúry (resp. žiadosti o platby) za vykonané služby a vzniknuté výdavky podľa časti 4 a všetky platby budú vykonané do štyridsiatich piatich (45) dní od prijatia platnej faktúry podľa tejto zmluvy. Všetky platby budú poukazované elektronicky na bankové účty uvedené vyššie.	Payees shall submit invoices (or Payment requests) for Services performed and expenses incurred under Section 4, all payments will be made within forty-five (45) days of receipt from the date of receipt of valid invoice in accordance with this Agreement. All payments will be made electronically to the bank accounts stated above.
5. Ostatné ustanovenia.	**5. Other provisions**
NÁHRADA LIEČBY DRUHÉHO OKA: Náhrada nákladov na liečbu druhého oka bude vyplatená, len ak na to Zadávateľ alebo ním poverená osoba vopred poskytne Hlavnému Skúšajúcemu súhlas. Náhrada bude vyplatená po prijatí faktúry a príslušnej podpornej dokumentácie.	*FELLOW EYE TREATEMENT REIMBURSEMENT:* Reimbursement for the fellow eye treatment costs will be done only if Principal Investigator has received prior approval for such treatment from Sponsor or its designee. The reimbursement will be paid against receipt of the invoice and corresponding support documentation.
6. Pomerné platby	**6. Pro-rata Payments**
6.1 Platba za účastníkov, ktorí nedokončili Klinické skúšanie, sa môže príjemcovi platby vyplatiť pomerne. Platba bude zahŕňať iba tých účastníkov, ktorí boli zaradení pred predčasným ukončením Klinického skúšania alebo pred dátumom, keď bolo prijaté oznámenie o takomto predčasnom ukončení, podľa toho, čo nastane neskôr.	6.1 Payment for Subjects who do not complete the Study may be made to Payee on a pro rata 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.
6.2 V prípade, že Zadávateľ ukončí Klinické skúšanie pred dokončením, uhradia sa pomerné náklady a poplatky, ktoré sú stanovené podľa časti 3, za každú návštevu účastníka uskutočnenú pred predčasným ukončením Klinického skúšania alebo pred dátumom, keď bolo prijaté oznámenie o takomto predčasnom ukončení, podľa toho, čo nastane neskôr.	6.2 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.
6.3 Ak Centru vzniknú ďalšie nezrušiteľné náklady, Zadávateľovi je potrebné predložiť písomné odôvodnenie na kontrolu a schválenie, pričom zaplatenie takýchto nákladov podlieha súhlasu Zadávateľa.	6.3 If other non-cancelable costs are incurred by Center, written justification must be provided to Sponsor for review and approval, and payment of such costs is subject to Sponsor's approval.
6.4. Vždy keď príjemca platby dostane finančné prostriedky, na ktoré nemá nárok, musí ich Zadávateľovi vrátiť do štyridsiatich piatich dní od oznámenia.	6.4 In any instance where the Payee has been rec eived unearned funds, such funds shall be returned to Sponsor within forty-five days of notification.
7. Porušovatelia protokolu	**7. Protocol Violators**
Platby za účastníkov skúšania, o ktorých sa predpokladá, že porušujú protokol, sa môžu vyplatiť, len ak k porušeniu došlo na základe rozhodnutia zadávateľa.	Payments for Study Subjects who are deemed to have been in violation of the Protocol may be paid up to the

	point that the violation occurred at the discretion of Sponsor.
8. Faktúry	**8. Invoices**
Zadávateľ poskytne príjemcovi platby prostredníctvom svojej poverenej osoby informácie potrebné na určenie výšky odmeny pre príjemcu platby. Na základe týchto informácií vystaví príjemca platby faktúru. Originály správnych faktúr s rozpisom položiek posielajte na adresu: **Prednostná adresa** Faktúry je možné zasielať e-mailom na adresu: PIILPayablesInvoices@parexel.com Bayer AG c/o PAREXEL International (IRL) Limited One Kilmainham Square Inchicore Road, Kilmainham Dublin 8 Írsko Č. štúdie spoločnosti PAREXEL: 245919 Všetky faktúry musia obsahovať nasledujúce informácie: (a) číslo protokolu (b) číslo faktúry (c) dátum vystavenia faktúry (d) miesto, dátum a opis poskytnutých služieb (e) číslo projektu (f) celková splatná suma (g) použitý výmenný kurz (podľa potreby) (h) meno skúšajúceho (i) číslo pracoviska (j) štátne identifikačné číslo skúšajúceho (NPI) (k) názov a adresa príjemcu platby (podľa tejto zmluvy) (l) adresa uvedená vyššie (m) dátum dodania Pred odovzdaním na úhradu je z faktúr a súvisiacej dokumentácie potrebné odstrániť identifikačné osobné údaje pacientov (napr. meno, dátum narodenia, iniciály atď.).	Sponsor through its designee shall provide Payee with the information necessary to determine the amount of remuneration due to Payee. Payee shall issue their in voice based on this information. Please send original, correct and itemized invoices to the following address : **Preferred** Invoices may be e-mailed to: PIILPayablesInvoices@parexel.com Bayer AG c/o PAREXEL International (IRL) Limited One Kilmainham Square Inchicore Road, Kilmainham Dublin 8 Ireland PAREXEL Study no.: 245919 All invoices must contain the following information: (a) Protocol Number (b) Invoice Number (c) Invoice Date (d) Place, Date & Description of Services Provi ded (e) 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 Agreemen t) (l) Address listed above (m) Date of Supply Invoices and associated documentation should be de-identified of patient personal information (e.g. name, date of birth, initials, etc.) prior to being submitted for reimbursement.
9. Záverečná platba	**9. Final Payment**
Bez ohľadu na vyššie uvedené ustanovenia bude záverečná platba uhradená po dokončení nasledujúcich činností: (a) všetky požadované návštevy účastníkov boli ukončené; (b) zadávateľ dostal všetky údaje o účastníkoch vo forme vhodnej na analýzu; (c) všetky otázky na objasnenie údajov boli vyriešené k spokojnosti zadávateľa;	Notwithstanding the foregoing, the final payment shall be paid upon the completion of the following activities: (a) all required Subject visits have been complet ed (b) Sponsor has received all Subject data in a for m suitable for analysis (c) all data clarification queries have been resolv ed to Sponsor's satisfaction

(d) zadávateľ overil, že všetka požadovaná regulačná dokumentácia je úplná; (e) zariadenie vrátilo všetko požadované vybavenie, lieky a iný materiál; (f) bola vykonaná záverečná návšteva v rámci štúdie.	(d) Sponsor has verified that all required regulat ory documentation is complete (e) Center has returned all required equipment, d rugs and other material (f) the Study close-out visit has been completed
Na základe tejto zmluvy má príjemca platby šesťdesiat (60) dní od prijatia záverečnej platby, aby zistil nezrovnalosti a vyriešil všetky platobné spory so zadávateľom. Všetky faktúry na účely platieb v rámci štúdie, ako sú uvedené v tejto zmluve, musia byť zadávateľovi odovzdané do šesťdesiatich (60) dní od návštevy zariadenia kvôli ukončeniu štúdie. Faktúry prijaté po tomto termíne nebudú uhradené.	Payee shall have sixty (60) days from the receipt of the final payment under this Agreement to identify discrepancies and resolve any payment disputes with Sponsor. All invoices for Study payments, as outlined herein, must be submitted to the Sponsor within sixty (60) days of the Center's Study close-out visit. Invoices received after this time will not be reimbursed.
10. Daň	**10. Tax**
Všetky poplatky a výdavky v tomto rozpise sú uvedené bez DPH alebo inej príslušnej dne. Všetky platby podliehajú príslušnej zrážkovej dani.	All fees and expenses in this Schedule are exclusive of VAT or any applicable tax. All payments are subject to withholding tax as applicable.

1.9 Payee: Sub Investigator / 1.9 Príjemca platby: Spoluskúšajuci: PhDr. Martina Tulpíková

Detailed Budget – Per Patient Fees/ Podrobný rozpočet – Poplatky za pacienta

Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Informed Consent (ICF)	1	✔														
Re-Consent	1	✔														
Inclusion/Exclusion Eligibility	2	✔														
Medical History	1	✔														
Demographics	1	✔														
Concomitant medications	27	✔														
NEI-VFQ25	5	✔														
BCVA (ETDRS) and refraction-Bilateral	13	✔														
IOP-bilateral	39	✔														
Slit lamp examination-bilateral	26	✔														
Indirect ophthalmoscopy	14	✔														
FA-unilateral	14	✔														
FP-bilateral	7	✔														
SD-OCT-bilaterally	26	✔														
Interpretation and Report for SD-OCT-	26	✔														
Physical examination	2	✔														
Vital signs	27	✔														
ECG	3	✔														
Adverse events	27	✔														
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✔														
Collection of specimen; urine for Urinalysis/UPCR	25	✔														
PK samples (Sparse)	6	✔														
Preparation of sample for shipping	27	✔														
Study Drug (active or sham)-IVT injection	23	✔														
Procedures Sub Total (€)																

Non Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Study Coordinator, Simple-Randomization, Data entry	28	✔														
Study nurse	28	✔														
PI time	28	✔														
Pharmacy, Complex-Dispense drug	23	✔														
Physician: Ophthalmology - DRM Assessment	20	✔														
Non Procedures Sub Total (€)																
Overhead (all costs)	16%															
Total Cost Per Visit with Overhead(€)																
Total Cost Per Patient (€)																

Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Informed Consent (ICF)	1	✔															
Re-Consent	1	✔															
Inclusion/Exclusion Eligibility	2	✔															
Medical History	1	✔															
Demographics	1	✔															
Concomitant medications	27	✔															
NEI-VFQ25	5	✔															
BCVA (ETDRS) and refraction-Bilateral	13	✔															
IOP-bilateral	39	✔															
Slit lamp examination-bilateral	26	✔															
Indirect ophthalmoscopy	14	✔															
FA-unilateral	14	✔															
FP-bilateral	7	✔															
SD-OCT-bilaterally	26	✔															
Interpretation and Report for SD-OCT-	26	✔															
Physical examination	2	✔															
Vital signs	27	✔															
ECG	3	✔															
Adverse events	27	✔															
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✔															
Collection of specimen; urine for Urinalysis/UPCR	25	✔															
PK samples (Sparse)	6	✔															
Preparation of sample for shipping	27	✔															
Study Drug (active or sham)-IVT injection	23	✔															
Procedures Sub Total (€)																	

Non Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Study Coordinator, Simple-Randomization, Data entry	28	✔															
Study nurse	28	✔															
PI time	28	✔															
Pharmacy, Complex-Dispense drug	23	✔															
Physician: Ophthalmology - DRM Assessment	20	✔															
Non Procedures Sub Total (€)																	
Overhead (all costs)	16%																
Total Cost Per Visit with Overhead(€)																	

1.9 Payee: Sub Investigator /1.9 Príjemca platby: Spoluskúšajuci PhDr. Martina Tulpíková

Detailed Budget – Conditional Fees / 1.3 Podrobný rozpočet – podmienečné poplatky

Conditional Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Physician: Ophthalmology - Rescue Treatment	20	✔														
Genomic substudy ICF	1	✔														
Blood draw for Genomic DNA sample	1	✔														
Preparation of sample for shipping	25	✔														
FBR ICF	1	✔														
ICGA-bilateral	3	✔														
OCTA-bilaterally	7	✔														
Interpretation and Report for OCTA	7	✔														
Collection of specimen; urine for Urine pregnancy	25	✔														
Serum pregnancy (Local lab)	0,5	✔														
Hematology (Local lab)	3	✔														
Blood Chemistry (Local lab)	3	✔														
Urine pregnancy test (Local lab)	12,5	✔														
Urinalysis (Local lab)	3	✔														
UPCR (Local lab)	3	✔														

Conditional Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Physician: Ophthalmology - Rescue Treatment	20	✔															
Genomic substudy ICF	1	✔															
Blood draw for Genomic DNA sample	1	✔															
Preparation of sample for shipping	25	✔															
FBR ICF	1	✔															
ICGA-bilateral	3	✔															
OCTA-bilaterally	7	✔															
Interpretation and Report for OCTA	7	✔															
Collection of specimen; urine for Urine pregnancy	25	✔															
Serum pregnancy (Local lab)	0,5	✔															
Hematology (Local lab)	3	✔															
Blood Chemistry (Local lab)	3	✔															
Urine pregnancy test (Local lab)	12,5	✔															
Urinalysis (Local lab)	3	✔															
UPCR (Local lab)	3	✔															

1.9 Payee: Sub Investigator / 1.9 Príjemca platby: Spoluskúšajuci: PhDr. Martina Tulpíková

Screening Failure / Zlyhanie skríningu

Procedure	Amount
Informed Consent (ICF)	
Re-Consent	
Inclusion/Exclusion Eligibility	
Medical History	
Demographics	
Concomitant medications	
BCVA (ETDRS) and refraction-Bilateral	
IOP-bilateral	
Slit lamp examination-bilateral	
Indirect ophthalmoscopy	
FA-unilateral	
FP-bilateral	
SD-OCT-bilaterally	
Interpretation and Report for SD-OCT-	
Physical examination	
Vital signs	
ECG	
Adverse events	
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	
Preparation of sample for shipping	
Procedures Sub Total (€)	

Non Procedure
Study Coordinator, Simple-Randomization, Data entry
Study nurse
PI time
Non Procedures Sub Total (€)

Overhead (all costs)

Total Cost Per Visit with Overhead(€)