

AMENDMENT N° 3
(hereinafter Amendment)

to the
Clinical Trial Agreement (hereinafter the "Agreement")
dated 25.02.2021 and Amendment No 1 dated 30.3.2022 and
Amendment No 2 dated 22th May 2023

This Amendment is made by and 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 Nitra

with its registered seat at: Špitálska 6,
950 01 Nitra

Slovak Republic

ID No.: 17336007

Tax ID No.: 2021205197

VAT No.: SK2021205197

Represented by Mgr. Michal Fajin, MBA, LL.M, MPH,
Director

(hereinafter referred to as the "**Center**")

and

MUDr. Gabriela Pavlovičová

Address: Malá Kamenná 10
949 01 Nitra

Slovak Republic

Workplace: Fakultná nemocnica Nitra, Clinic of
Ophthalmology, Špitálska 6, 950 01 Nitra, Slovak
Republic

(hereinafter "**Principal Investigator**")

Protocol No: 20968 (hereinafter Protocol)

"Randomized, Double-Masked, Active-Controlled, Phase 3 Study
of the Efficacy and Safety of High Dose Aflibercept in Patients

DODATOK ě. 3
(ďalej ako dodatok)

k
zmluve o klinickom skúšaní (ďalej len „zmluva“)
zo dňa 25.02.2021 a dodatku č. 1 zo dňa 30.3.2022 a dodatku č.
2 zo dňa 22.5.2023

Tento dodatok sa uzatvára 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 Nitra

so sídlom: Špitálska 6
950 01 Nitra

Slovenská republika

IČO: 17336007

DIČ: 2021205197

IČ DPH: SK2021205197

Zastúpená Mgr. Michal Fajin, MBA, LL.M, MPH.,
riaditeľom

(ďalej len "**Centrum**")

a

MUDr. Gabriela Pavlovičová

Adresa: Malá Kamenná 10
949 01 Nitra

Slovenská republika

pracovisko: Fakultná nemocnica Nitra, Očná klinika,
Špitálska 6, 950 01 Nitra, Slovenská republika

a týka sa

protokolu č.: 20968 (ďalej protokol)

„Randomizované, dvojito maskované, aktívne kontrolované
klinické skúšanie 3. fázy hodnotiace účinnosť a bezpečnosť

<p>With Neovascular Age-Related Macular Degeneration” (hereinafter Study) Aflibercept (hereinafter Study Drug)</p> <p>WHEREAS, SPONSOR is the sponsor of the multi-center/multi-centre Study to clinically evaluate the Study Drug;</p> <p>WHEREAS, SPONSOR has contracted with PAREXEL Parexel International (IRL) Limited to act as SPONSOR’s representative in managing the Study for SPONSOR, in accordance with the Protocol;</p> <p>WHEREAS, the parties have entered into the above-referred Agreement;</p> <p>WHEREAS the parties agreed to update in its entirety Exhibit A in Protocol Amendment Extension Period Year 3 part payments to Principle Investigator (Payment Schedule and Budget) – Detailed Budget of the Agreement due to the termination of the employment relationship of the nurse as of 29/5/2023 and part of which remuneration is added to the Principal Investigator’s remuneration. The table of payments for the study nurse in the extension period based on protocol amendment (3rd year) will be removed.</p> <p>WHEREAS, the parties are jointly willing to amend the above-referred Agreement;</p> <p>Now, therefore the above-referred Agreement shall be amended and the following Amendment No. 3 to the Clinical Trial Agreement shall enter into force on the date of signing by both Parties and shall become effective on 29.5.2023.</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 hereto have set their hands in triplicate with the intention that this is a binding agreement to amend as provided herein.</p>	<p>vysokiej dávky afliberceptu u pacientov s neovaskulárnou vekom podmienenou degeneráciou makuly“ (ďalej len „skúšanie“) Aflibercept (ďalej len „skúšaný produkt“)</p> <p>KEĎŽE ZADÁVATEĽ je zadávateľom multicentrického skúšania skúšaného produktu;</p> <p>KEĎŽE, ZADÁVATEĽ uzavrel zmluvu so spoločnosťou PAREXEL Parexel International (IRL) Limited, aby konala ako zástupca ZADÁVATEĽA pri riadení skúšania pre ZADÁVATEĽA v súlade s protokolom;</p> <p>KEĎŽE zmluvné strany uzavreli vyššie uvedenú zmluvu;</p> <p>KEĎŽE sa zmluvné strany dohodli na vypustení a úprave prílohy A v časti predĺženia obdobia platnosti zmien protokolu 3 časť platieb hlavnému skúšajúcemu (Harmonogram platieb a rozpočet) zmluvy z dôvodu ukončenia pracovného pomeru zdravotnej sestričky ku dňu 29.5.2023 a ktorej časť odmeny sa pripočíta k odmene hlavnej skúšajúcej. Tabuľka platieb pre štúdijnú sestru v časti predĺženia obdobia platnosti zmien protokolu (3.rok) bude odstránená;</p> <p>KEĎŽE zmluvné strany majú spoločnú vôľu zmeniť a doplniť uvedenú zmluvu; sa teraz preto uvedená zmluva mení a dopĺňa a nasledujúce zmenené a doplnené znenie . Dodatok č. 3 k Zmluve o klinickom skúšaní nadobudne platnosť dňom podpísania oboma zmluvnými stranami a účinnosť dňom 29.5.2023</p> <p>Všetky ostatné podmienky vyššie uvedenej zmluvy zostanú nezmenené a v plnej platnosti a účinnosti.</p> <p>NA DŮKAZ TOHO strany tejto zmluvy podpísali tri kópie tejto zmluvy so zámerom, že ide o záväznú zmluvu, ktorá bude upravená spôsobom stanoveným v tomto dokumente.</p>
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**Zadávateľ prostredníctvom svojho oprávneného zástupcu Parexel International (IRL) Limited / Sponsor
by its authorized representative Parexel International (IRL) Limited**

Miesto / Place Praha

Dátum / Date 24/1/2024

MICHAELA TICHÁ M.D.
Assc. Director Clinical Op

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

**Centrum / Center
Fakultná nemocnica Nitra**

Miesto / Place NITRA

Dátum / Date 30. 01. 2024

Mgr. Michal Pajus

ditel / Director

Hlavný skúšajúci / Principal Investigator

Miesto / Place NITRA

Dátum / Date 29/1/24

MUDr. Gabriela Pavlovic

Acknowledged and agreed:

I, Sub-Investigator, MUDr. Mariana Ďuríková, address Benkova 377/8, 949 11 Nitra, Slovak Republic, acknowledge and agree by signing of this document to perform my obligations to the extent stipulated by the Protocol and Study Instructions.

MUDr. Mariana Ďuríková



MUD

Potvrdené a odsúhlasené:

Ja, spoluskúšajúci, MUDr. Mariana Ďuríková, adresa: Benkova 377/8, 949 11 Nitra, Slovenská republika, podpisom tohto dokumentu beriem na vedomie a súhlasím s plnením svojich povinností v rozsahu stanovenom Protokolom a pokynmi k Štúdiu.

29.1.2024

Date / Datum

Exhibit A –Payment Schedule and Budget /Príloha A – Harmonogram platieb a rozpočet
Table 1 Schedule of Activities – Year 1 and Year 2 / Tabuľka č. 1 Harmonogram činností – 1. a 2. rok
Payee: Center / Prijemca platby: Centrum

Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Informed Consent (ICF)	1	✓	11,40	11,40												
Re-Consent	1	✓	9,30	9,30												
Inclusion/Exclusion Eligibility	2	✓	8,70	8,70	8,70											
Medical History	1	✓	13,20	13,20												
Demographics	1	✓	5,40	5,40												
Concomitant medications	27	✓	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60
NEI-VFQ25	5	✓	1,80	1,80								1,80				
BCVA (ETDRS) and refraction-Bilateral	13	✓	3,60	1,80	1,80	1,80	1,80		1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80
IOP-bilateral	39	✓	4,50	6,75	6,75	6,75	6,75		6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75
Slit lamp examination-bilateral	26	✓	8,70	8,70	8,70	8,70	8,70		8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70
Indirect ophthalmoscopy	14	✓	9,60	9,60	4,80	4,80	4,80		9,60	4,80	4,80	4,80	4,80	4,80	4,80	4,80
FA-unilateral	14	✓	37,80	75,60					75,60			75,60			75,60	
FP-bilateral	7	✓	13,80	13,80					13,80			13,80			13,80	
SD-OCT-bilaterally	26	✓	18,60	18,60	18,60	18,60	18,60		18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60
Interpretation and Report for SD-OCT-	26	✓	6,30	6,30	6,30	6,30	6,30		6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30
Physical examination	2	✓	13,80	13,80												
Vital signs	27	✓	9,90	9,90	9,90	9,90	9,90		9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90
ECG	3	✓	16,20	16,20												
Adverse events	27	✓	4,20	4,20	4,20	4,20	4,20		4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✓	6,30	6,30												
Collection of specimen; urine for Urinalysis/UPCR	25	✓	2,10	2,10	2,10	2,10			2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10
PK samples (Sparse)	6	✓	5,40	5,40	5,40			5,40	5,40				5,40			
Preparation of sample for shipping	27	✓	3,30	3,30	3,30	3,30		3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30
Study Drug (active or sham)-IVT injection	23	✓	76,80	76,80	76,80	76,80				76,80	76,80	76,80	76,80	76,80	76,80	76,80
Procedures Sub Total (€)				€ 246,45	€ 162,75	€ 152,25	€ 146,85	€ 26,40	€ 169,65	€ 146,85	€ 146,85	€ 238,05	€ 152,25	€ 146,85	€ 236,25	€ 146,85
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	✓	15,00	30,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00
Study nurse	28	✓	9,90	19,80	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90
PI time	28	✓	20,70	41,40	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70
Pharmacy, Complex-Dispense drug	23	✓	10,50	10,50	10,50	10,50				10,50	10,50	10,50	10,50	10,50	10,50	10,50
Physician: Ophthalmology - DRM Assessment	20	✓	20,10							20,10	20,10	20,10	20,10	20,10	20,10	20,10
Non Procedures Sub Total (€)				€ 91,20	€ 56,10	€ 56,10	€ 56,10	€ 45,60	€ 45,60	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20
Overhead (all costs) 16%				€ 54,00	€ 35,00	€ 33,30	€ 32,50	€ 11,50	€ 34,40	€ 35,70	€ 35,70	€ 50,30	€ 36,60	€ 35,70	€ 50,00	€ 35,70
Total Cost Per Visit with Overhead(€)				€ 391,65	€ 253,85	€ 241,65	€ 235,45	€ 83,50	€ 249,65	€ 258,75	€ 258,75	€ 364,55	€ 265,05	€ 258,75	€ 362,45	€ 258,75
Total Cost Per Patient (€)				€ 7 372,50												

Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27E05
Informed Consent (ICF)	1	▼	11,40														
Re-Consent	1	▼	9,30														
Inclusion/Exclusion Eligibility	2	▼	8,70														
Medical History	1	▼	13,20														
Demographics	1	▼	5,40														
Concomitant medications	27	▼	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60
NEI-VFQ25	5	▼	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80
BCVA (ETDRS) and refraction-bilateral	13	▼	3,60	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80
IOP-bilateral	39	▼	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75
Sit temp examination-bilateral	26	▼	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70
Indirect ophthalmoscopy	14	▼	9,60	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80
FA-unilateral	14	▼	37,80	75,60													75,60
FA-bilateral	7	▼	13,80	13,80													13,80
SD-OCT-bilaterally	26	▼	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60
SD-OCT-interpretation and Report for SD-OCT-	26	▼	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30
Physical examination	2	▼	13,80														13,80
Vital signs	27	▼	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90
ECG	3	▼	16,20	16,20													16,20
Adverse events	27	▼	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug-Antibody Serum Sample	3	▼	6,30														6,30
Collection of specimen; urine for Urinalysis/UPCR	25	▼	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10
PK samples (Spares)	6	▼	5,40	5,40													5,40
Preparation of sample for shipping	27	▼	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30
Study Drug (active or sham)-IVT Injection	23	▼	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80
Procedures Sub Total (€)			€ 146,85	€ 265,95	€ 146,85	€ 146,85	€ 146,85	€ 238,05	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 197,55
Non Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27E05
Study Coordinator, Simple-Randomization, Data entry	28	▼	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00
Study nurse	28	▼	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90
PI time	28	▼	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70
Pharmacy, Complex-Dispense drug	23	▼	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50
Physician: Ophthalmology - DRM Assessment	20	▼	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10
Non Procedures Sub Total (€)			€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 45,60
Overhead (all costs) 16%			€ 35,70	€ 54,70	€ 35,70	€ 35,70	€ 50,30	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 38,90
Total Cost Per Visit with Overhead(€)			€ 258,75	€ 396,85	€ 258,75	€ 258,75	€ 364,55	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 282,05

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

Payee: Center / Prijemca platby: Centrum

Pharmacy Fees / Poplatky pre lekára	Qty	OH	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
			€ 22,55	€ 14,55	€ 13,85	€ 13,45	€ 4,90	€ 14,25	€ 14,75	€ 14,75	€ 20,75	€ 15,15	€ 14,75	€ 20,65	€ 14,75
Overhead (all costs) 16%			€ 3,60	€ 2,30	€ 2,20	€ 2,20	€ 0,80	€ 2,30	€ 2,40	€ 2,40	€ 3,30	€ 2,40	€ 2,40	€ 3,30	€ 2,40
Total Cost Per Visit with Overhead(€)			€ 26,15	€ 16,85	€ 16,05	€ 15,65	€ 5,70	€ 16,55	€ 17,15	€ 17,15	€ 24,05	€ 17,55	€ 17,15	€ 23,95	€ 17,15
Total Cost Per Patient (€)			€ 488,70												

Pharmacy Fees / Poplatky pre lekára	Qty	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27E0S
		€ 14,75	€ 22,65	€ 14,75	€ 14,75	€ 20,75	€ 14,75	€ 14,75	€ 14,75	€ 14,75	€ 14,75	€ 14,75	€ 14,75	€ 14,75	€ 16,05
Overhead (all costs) 16%		€ 2,40	€ 3,60	€ 2,40	€ 2,40	€ 3,30	€ 2,40	€ 2,40	€ 2,40	€ 2,40	€ 2,40	€ 2,40	€ 2,40	€ 2,40	€ 2,60
Total Cost Per Visit with Overhead(€)		€ 17,15	€ 26,25	€ 17,15	€ 17,15	€ 24,05	€ 17,15	€ 17,15	€ 17,15	€ 17,15	€ 17,15	€ 17,15	€ 17,15	€ 17,15	€ 18,65

Detailed Budget – Conditional Fees / Podrobný rozpočet – podmienené poplatky
Payee: Center / Prijemca platby: Centrum

Conditional Procedure / Podmienené vyšetrenie	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Physician: Ophthalmology - Rescue Treatment / Lekár: Oftalmológia - záchranná liečba	20	✓	22,30							22,30	22,30	22,30	22,30	22,30	22,30	22,30
Genomic substudy ICF/ Informovaný súhlas voľiteľného genomického vedľajšieho skúšania	1	✓	5,30	5,30												
Blood draw for Genomic DNA sample / odber vzoriek genomické DNA	1	✓	4,00		4,00											
Preparation of sample for shipping / Príprava vzorky na odoslanie	25	✓	3,70		3,70	3,70	3,70		3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70
FBR ICF / Informovaný súhlas pre budúci biomedicínsky výskum	1	✓	10,30	10,30												
ICGA-bilateral / indokyanínová angiografia	3	✓	61,70	61,70												
OCTA-bilaterally / optická koherentná tomografia-angiografia - bilaterálne	7	✓	20,00	20,00					20,00			20,00			20,00	
Interpretation and Report for OCTA /optická koherentná tomografia-angiografia: Interpretácia a report	7	✓	9,00	9,00					9,00			9,00			9,00	
Collection of specimen; urine for Urine pregnancy / vzorky moču pre tehotenský test z moču	25	✓	2,30		2,30	2,30	2,30		2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30

Conditional Procedure / Podmienené vyšetrenie	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27EOS
Physician: Ophthalmology - Rescue Treatment / Lekár: Oftalmológia - záchranná liečba	20	✓	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	
Genomic substudy ICF/ Informovaný súhlas voľiteľného genomického vedľajšieho skúšania	1	✓	5,30														
Blood draw for Genomic DNA sample / odber vzoriek genomické DNA	1	✓	4,00														
Preparation of sample for shipping / Príprava vzorky na odoslanie	25	✓	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70
FBR ICF / Informovaný súhlas pre budúci biomedicínsky výskum	1	✓	10,30														
ICGA-bilateral / indokyanínová angiografia	3	✓	61,70		61,70												61,70
OCTA-bilaterally / optická koherentná tomografia-angiografia - bilaterálne	7	✓	20,00		20,00			20,00									20,00
Interpretation and Report for OCTA /optická koherentná tomografia-angiografia: Interpretácia a report	7	✓	9,00		9,00			9,00									9,00
Collection of specimen; urine for Urine pregnancy / vzorky moču pre tehotenský test z moču	25	✓	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30

LOCAL LABORATORY: Detailed Budget – Conditional Fees / LABORATÓRIUM CENTRA: Podrobný rozpočet – podmienené poplatky
Payee: Center / Prijemca platby: Centrum

LOCAL LABORATORY																
Conditional Procedure / Podmienené vyšetrenie	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Serum pregnancy (Local lab) / tehotenský test v sére (lokálne laboratórium)	0,5	✓	27,00	13,50												
Hematology (Local lab) / Hematológia (lokálne laboratórium)	3	✓	13,00	13,00												
Blood Chemistry (Local lab) / Biochemické vyšetrenia (lokálne laboratórium)	3	✓	32,00	32,00												
Urine pregnancy test (Local lab) / Tehotenský test z moču (lokálne laboratórium)	12,5	✓	12,00		6,00	6,00	6,00		6,00	6,00	6,00	6,00	6,00	6,00	6,00	6,00
Urinalysis (Local lab) / analýza moču (lokálne laboratórium)	3	✓	9,00	9,00												
UPCR (Local lab) / pomer bielkoviny v moči: kreatinín (lokálne laboratórium)	3	✓	14,00	14,00												

LOCAL LABORATORY																	
Conditional Procedure / Podmienené vyšetrenie	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27E0S
Serum pregnancy (Local lab) / tehotenský test v sére (lokálne laboratórium)	0,5	✓	27,00														
Hematology (Local lab) / Hematológia (lokálne laboratórium)	3	✓	13,00														13,00
Blood Chemistry (Local lab) / Biochemické vyšetrenia (lokálne laboratórium)	3	✓	32,00														32,00
Urine pregnancy test (Local lab) / Tehotenský test z moču (lokálne laboratórium)	12,5	✓	12,00	6,00	6,00	6,00	6,00	6,00	6,00	6,00	6,00	6,00	6,00	6,00	6,00	6,00	6,00
Urinalysis (Local lab) / analýza moču (lokálne laboratórium)	3	✓	9,00														9,00
UPCR (Local lab) / pomer bielkoviny v moči: kreatinín (lokálne laboratórium)	3	✓	14,00														14,00

Screening Failure / Zlyhanie skriningu
Payee: Center / Prijemca platby: Centrum

Procedure / Vyšetrenie	Amount / Suma
Informed Consent (ICF) / Informovaný súhlas (ICF)	11,40
Re-Consent / Opakovaný Informovaný súhlas)	9,30
Inclusion/Exclusion Eligibility / Vhodnosť – zaradenie/vylúčenie	8,70
Medical History / Zdravotná anamnéza	13,20
Demographics / Demografia	5,40
Concomitant medications / Sprievodná liečba	3,60
NEI-VFQ25 / Dotazník zrakových funkcií-25	
BCVA (ETDRS) and refraction-Bilateral / najlepšia korigovaná zraková ostrosť (ETDRS) a refrakcia - bilaterálne	1,80
IOP-bilateral / vnútroočný tlak - bilaterálne	6,75
Slit lamp examination-bilateral / Vyšetrenie štrbinovou lampou - bilaterálne	8,70
Indirect ophthalmoscopy / Nepriama oftalmoskopia	9,60
FA-unilateral / fluoresceínová angiografia	75,60
FP-bilateral / fotografie očného pozadia - bilaterálne	13,80
SD-OCT-bilaterally / optická koherentná tomografia využívajúca spektrálnu doménu - bilaterálne	18,60
Interpretation and Report for SD-OCT / interpretácia a report: Optická koherentná tomografia využívajúca spektrálnu doménu	6,30
Physical examination / Fyzikálne vyšetrenie	13,80
Vital signs / Vitálne funkcie	9,90
ECG / EKG	16,20
Adverse events / Nežiaduce udalosti	4,20
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample / vzorky odobraté pre tehotenský test v sére, hematológiu, biochemické vyšetrenia, vzorka séra protilátky proti leku	6,30
Preparation of sample for shipping / Príprava vzorky na odoslanie	3,30
Procedures Sub Total (€)	€ 246,45
Non Procedure	SV
Study Coordinator, Simple-Randomization, Data entry / Koordinátor štúdie, randomizácia, zadávanie údajov	30,00
Study nurse / študijná sestra	19,80
PI time / čas hlavného skúšajúceho	41,40
Non Procedures Sub Total (€)	€ 91,20
Overhead (all costs) / Réžia	€ 54,00
Total with Overhead(€) / Suma vrátanie réžie (EUR)	€ 391,65

Detailed Budget – Site Fees / Podrobný rozpočet – poplatky pre pracovisko
Payee: Center / Prijemca platby: Centrum

Site Costs / Poplatky pre pracovisko	Qty	Budget	SV
Study Start-Up Fee/Site Set-Up Fee	1	235,50	235,50
Document Storage, Archiving Total Cost / Archivačný poplatok	1	907,00	907,00
Total Site Costs (€) / Suma celkom EUR			€ 1 142,50

Table 2 Schedule of Activities – Extension Period Year 3 / Tabuľka č. 2 Harmonogram činností – predĺžené obdobie – 3. rok
Payee: Center / Príjemca platby: Centrum

Slovak Republic Sub-Study: Year 3															
Procedure	Qty	OH	Budget	W96-E01	W100-E02	W104-E03	W108-E04	W110	W112-E04.1	W114	W116-E04.2	W118	W120	W122	W124-E5.1
Re-Consent	1	✓	12.40	12.40											
Inclusion/Exclusion eligibility for study extension	1	✓	14.00	14.00											
Concomitant medications	16	✓	4.80	4.80	4.80	4.80	4.80		4.80		4.80		4.80		4.80
NEI-VFQ25	1	✓	2.40	2.40											
BCVA (ETDRS) and refraction-Bilateral	8	✓	4.80	2.40	2.40	2.40	2.40		2.40		2.40		2.40		2.40
IOP-bilateral	24	✓	6.00	9.00	9.00	9.00	9.00		9.00		9.00		9.00		9.00
Slit lamp examination-bilateral	16	✓	11.60	11.60	11.60	11.60	11.60		11.60		11.60		11.60		11.60
Indirect ophthalmoscopy	8	✓	12.80	6.40	6.40	6.40	6.40		6.40		6.40		6.40		6.40
FA-unilateral	4	✓	50.40												
FP-bilateral	2	✓	18.40												
SD-OCT-bilaterally	16	✓	24.80	24.80	24.80	24.80	24.80		24.80		24.80		24.80		24.80
Interpretation and Report for SD-OCT-	16	✓	8.40	8.40	8.40	8.40	8.40		8.40		8.40		8.40		8.40
Physical examination	1	✓	18.40	18.40											
Vital signs	16	✓	13.20	13.20	13.20	13.20	13.20		13.20		13.20		13.20		13.20
Adverse events	16	✓	5.60	5.60	5.60	5.60	5.60		5.60		5.60		5.60		5.60
Collection of specimen; urine for Urinalysis/UPCR	16	✓	2.80	2.80	2.80	2.80	2.80		2.80		2.80		2.80		2.80
Study Drug (active or sham)-IVT injection	15	✓	102.40	102.40	102.40	102.40	102.40		102.40		102.40		102.40		102.40
Procedures Sub Total (€)				€ 238.60	€ 191.40	€ 191.40	€ 191.40	€ 0.00	€ 191.40	€ 0.00	€ 191.40	€ 0.00	€ 191.40	€ 0.00	€ 191.40
Non Procedure	Qty	OH	Budget	W96-E01	W100-E02	W104-E03	W108-E04	W110	W112-E04.1	W114	W116-E04.2	W118	W120	W122	W124-E5.1
Study Coordinator, Simple-Randomization, Data entry	16	✓	20.00	20.00	20.00	20.00	20.00		20.00		20.00		20.00		20.00
Study nurse	16	✓	13.20	13.20	13.20	13.20	13.20		13.20		13.20		13.20		13.20
PI time	16	✓	27.60	27.60	27.60	27.60	27.60		27.60		27.60		27.60		27.60
Pharmacy, Complex-Dispense drug	15	✓	14.00	14.00	14.00	14.00	14.00		14.00		14.00		14.00		14.00
Physician: Ophthalmology - DRM Assessment	14	✓	26.80		26.80	26.80	26.80		26.80		26.80		26.80		26.80
Non Procedures Sub Total (€)				€ 74.80	€ 101.60	€ 101.60	€ 101.60	€ 0.00	€ 101.60	€ 0.00	€ 101.60	€ 0.00	€ 101.60	€ 0.00	€ 101.60

Procedure	Qty	OH	Budget	W126	W128-E5.2	W130	W132-E06	W134	W136-E06.1	W138	W140-E06.2	W142	W144	W146	W148-E07.1	W150	W152-E07.2	EOS-W156
Re-Consent	1	✓	12.40															
Inclusion/Exclusion eligibility for study extension	1	✓	14.00															
Concomitant medications	16	✓	4.80		4.80		4.80		4.80		4.80		4.80		4.80		4.80	4.80
NEI-WFQ25	1	✓	2.40															
BCVA (ETDRS) and refraction-Bilateral	8	✓	4.80		2.40		2.40		2.40		2.40		2.40		2.40		2.40	2.40
IOP-bilateral	24	✓	6.00		9.00		9.00		9.00		9.00		9.00		9.00		9.00	9.00
Slit lamp examination-bilateral	16	✓	11.60		11.60		11.60		11.60		11.60		11.60		11.60		11.60	11.60
Indirect ophthalmoscopy	8	✓	12.80		6.40		6.40		6.40		6.40		6.40		6.40		6.40	6.40
FA-unilateral	4	✓	50.40				100.80											100.80
FP-bilateral	2	✓	18.40				18.40											18.40
SD-OCT-bilaterally	16	✓	24.80		24.80		24.80		24.80		24.80		24.80		24.80		24.80	24.80
Interpretation and Report for SD-OCT-	16	✓	8.40		8.40		8.40		8.40		8.40		8.40		8.40		8.40	8.40
Physical examination	1	✓	18.40															
Vital signs	16	✓	13.20		13.20		13.20		13.20		13.20		13.20		13.20		13.20	13.20
Adverse events	16	✓	5.60		5.60		5.60		5.60		5.60		5.60		5.60		5.60	5.60
Collection of specimen; urine for Urinalysis/UPCR	16	✓	2.80		2.80		2.80		2.80		2.80		2.80		2.80		2.80	2.80
Study Drug (active or sham)-IVT Injection	15	✓	102.40		102.40		102.40		102.40		102.40		102.40		102.40		102.40	102.40
Procedures Sub Total (€)				€ 0.00	€ 191.40	€ 0.00	€ 310.60	€ 0.00	€ 191.40	€ 0.00	€ 191.40	€ 0.00	€ 191.40	€ 0.00	€ 191.40	€ 0.00	€ 191.40	€ 208.20
Non Procedure	Qty	OH	Budget	W126	W128-E5.2	W130	W132-E06	W134	W136-E06.1	W138	W140-E06.2	W142	W144	W146	W148-E07.1	W150	W152-E07.2	EOS-W156
Study Coordinator, Simple-Randomization, Data entry	16	✓	20.00		20.00		20.00		20.00		20.00		20.00		20.00		20.00	20.00
Study nurse	16	✓	13.20		13.20		13.20		13.20		13.20		13.20		13.20		13.20	13.20
PI time	16	✓	27.60		27.60		27.60		27.60		27.60		27.60		27.60		27.60	27.60
Pharmacy, Complex-Dispense drug	15	✓	14.00		14.00		14.00		14.00		14.00		14.00		14.00		14.00	14.00
Physician: Ophthalmology - DRM Assessment	14	✓	26.80		26.80		26.80		26.80		26.80		26.80		26.80		26.80	26.80
Non Procedures Sub Total (€)				€ 0.00	€ 101.60	€ 0.00	€ 101.60	€ 0.00	€ 101.60	€ 0.00	€ 101.60	€ 0.00	€ 101.60	€ 0.00	€ 101.60	€ 0.00	€ 101.60	€ 60.80

Conditional Procedure	Qty	OH	Budget	W96-E01	W100-E02	W104-E03	W108-E04	W110	W112-E04.1	W114	W116-E04.2	W118	W120	W122	W124-E5.1
BCVA (ETDRS) and refraction-Bilateral	6	✓	4.80					2.40		2.40		2.40		2.40	
IOP-bilateral	18	✓	6.00					9.00		9.00		9.00		9.00	
Slit lamp examination-bilateral	12	✓	11.60					11.60		11.60		11.60		11.60	
Indirect ophthalmoscopy	6	✓	12.80					6.40		6.40		6.40		6.40	
SD-OCT-bilaterally	12	✓	24.80					24.80		24.80		24.80		24.80	
Interpretation and Report for SD-OCT-	12	✓	8.40					8.40		8.40		8.40		8.40	
Vital signs	12	✓	13.20					13.20		13.20		13.20		13.20	
Adverse events	12	✓	5.60					5.60		5.60		5.60		5.60	
Collection of specimen; urine for Urinalysis/UPCR	12	✓	2.80					2.80		2.80		2.80		2.80	
Preparation of sample for shipping	12	✓	4.40					4.40		4.40		4.40		4.40	
Study Drug (active or sham)-IVT Injection	11	✓	102.40					102.40		102.40		102.40		102.40	
Study Coordinator, Simple-Randomization, Data entry	12	✓	20.00					20.00		20.00		20.00		20.00	
Study nurse	12	✓	13.20					13.20		13.20		13.20		13.20	
PI time	12	✓	27.60					27.60		27.60		27.60		27.60	
Pharmacy, Complex-Dispense drug	11	✓	14.00					14.00		14.00		14.00		14.00	
Physician: Ophthalmology - DRM Assessment	11	✓	26.80					26.80		26.80		26.80		26.80	
Study supplies – needles, syringes and all other required consumables	26	✓	15.60	15.60	15.60	15.60	15.60	15.60	15.60	15.60	15.60	15.60	15.60	15.60	15.60
Serious adverse events (SAE)	27	✓	17.20	17.20	17.20	17.20	17.20	17.20	17.20	17.20	17.20	17.20	17.20	17.20	17.20
Physician: Ophthalmology - Rescue Treatment	26	✓	26.80	26.80	26.80	26.80	26.80	26.80	26.80	26.80	26.80	26.80	26.80	26.80	26.80
ICGA-bilateral	1	✓	74.00												
OCTA-bilaterally	2	✓	24.00												
Interpretation and Report for OCTA	2	✓	10.80												
Hematology (Local lab)	1	✓	8.84												
Blood Chemistry (Local lab)	1	✓	21.76												
Urine pregnancy test (Local lab)	13.5	✓	8.16	4.08	4.08	4.08	4.08	4.08	4.08	4.08	4.08	4.08	4.08	4.08	4.08
Urinalysis (Local lab)	1	✓	6.12												
UPCR (Local lab)	1	✓	9.52												
Overhead (all costs) 16%				€ 50.14	€ 46.88	€ 46.88	€ 46.88	€ 0.00	€ 46.88	€ 0.00	€ 46.88	€ 0.00	€ 46.88	€ 0.00	€ 46.88
Total Cost Per Visit with Overhead(€)				€ 363.54	€ 339.88	€ 339.88	€ 339.88	€ 0.00	€ 339.88	€ 0.00	€ 339.88	€ 0.00	€ 339.88	€ 0.00	€ 339.88
Total Cost Per Patient (€)				€ 5,572.17											

Conditional Procedure	Qty	OH	Budget	W126	W128-E5.2	W130	W132-E06	W134	W136-E06.1	W138	W140-E06.2	W142	W144	W146	W148-E07.1	W150	W152-E07.2	EOS-W156
BCVA (ETDRS) and refraction-Bilateral	6	✓	4.80	2.40		2.40		2.40		2.40		2.40		2.40		2.40		2.40
IOP-bilateral	18	✓	6.00	9.00		9.00		9.00		9.00		9.00		9.00		9.00		9.00
Slit lamp examination-bilateral	12	✓	11.60	11.60		11.60		11.60		11.60		11.60		11.60		11.60		11.60
Indirect ophthalmoscopy	6	✓	12.80	6.40		6.40		6.40		6.40		6.40		6.40		6.40		6.40
SD-OCT-bilaterally	12	✓	24.80	24.80		24.80		24.80		24.80		24.80		24.80		24.80		24.80
Interpretation and Report for SD-OCT-	12	✓	8.40	8.40		8.40		8.40		8.40		8.40		8.40		8.40		8.40
Vital signs	12	✓	13.20	13.20		13.20		13.20		13.20		13.20		13.20		13.20		13.20
Adverse events	12	✓	5.60	5.60		5.60		5.60		5.60		5.60		5.60		5.60		5.60
Collection of specimen; urine for Urinalysis/UPCR	12	✓	2.80	2.80		2.80		2.80		2.80		2.80		2.80		2.80		2.80
Preparation of sample for shipping	12	✓	4.40	4.40		4.40		4.40		4.40		4.40		4.40		4.40		4.40
Study Drug (active or sham)-IVT Injection	11	✓	102.40	102.40		102.40		102.40		102.40		102.40		102.40		102.40		102.40
Study Coordinator, Simple-Randomization, Data entry	12	✓	20.00	20.00		20.00		20.00		20.00		20.00		20.00		20.00		20.00
Study nurse	12	✓	13.20	13.20		13.20		13.20		13.20		13.20		13.20		13.20		13.20
PI time	12	✓	27.60	27.60		27.60		27.60		27.60		27.60		27.60		27.60		27.60
Pharmacy, Complex-Dispense drug	11	✓	14.00	14.00		14.00		14.00		14.00		14.00		14.00		14.00		14.00
Physician: Ophthalmology - DRM Assessment	11	✓	26.80	26.80		26.80		26.80		26.80		26.80		26.80		26.80		26.80
Study supplies - needles, syringes and all other required consumables	26	✓	15.60	15.60	15.60	15.60	15.60	15.60	15.60	15.60	15.60	15.60	15.60	15.60	15.60	15.60	15.60	15.60
Serious adverse events (SAE)	27	✓	17.20	17.20	17.20	17.20	17.20	17.20	17.20	17.20	17.20	17.20	17.20	17.20	17.20	17.20	17.20	17.20
Physician: Ophthalmology - Rescue Treatment	26	✓	26.80	26.80	26.80	26.80	26.80	26.80	26.80	26.80	26.80	26.80	26.80	26.80	26.80	26.80	26.80	26.80
ICGA-bilateral	1	✓	74.00															74.00
OCTA-bilaterally	2	✓	24.00			24.00												24.00
Interpretation and Report for OCTA	2	✓	10.80			10.80												10.80
Hematology (Local lab)	1	✓	8.84															8.84
Blood Chemistry (Local lab)	1	✓	21.76															21.76
Urine pregnancy test (Local lab)	13.5	✓	8.16	4.08	4.08	4.08	4.08	4.08	4.08	4.08	4.08	4.08	4.08	4.08	4.08	4.08	4.08	4.08
Urinalysis (Local lab)	1	✓	6.12															6.12
UPCR (Local lab)	1	✓	9.52															9.52

Overhead (all costs) 16%

€ 0.00 € 46.88 € 0.00 € 65.95 € 0.00 € 46.88 € 0.00 € 46.88 € 0.00 € 46.88 € 0.00 € 46.88 € 0.00 € 46.88 € 0.00 € 46.88 € 43.04

Total Cost Per Visit with Overhead(€)

€ 0.00 € 339.88 € 0.00 € 478.15 € 0.00 € 339.88 € 0.00 € 339.88 € 0.00 € 339.88 € 0.00 € 339.88 € 0.00 € 339.88 € 0.00 € 339.88 € 312.04

**Table 2 Schedule of Activities – Extension Period Year 3 / Tabuľka č. 2 Harmonogram činností – predĺžené obdobie – 3. rok
Detailed Budget - PHARMACY– Per Patient Fees/ Podrobný rozpočet – Lekáreň - Poplatky za pacienta**

Payee: Center / Prijemca platby: Centrum

Slovak Republic		Sub-Study: Year 3															
Non Procedure	Qty OH	Budget	W96-E01	W100-E02	W104-E03	W108-E04	W110	W112-E04.1	W114	W116-E04.2	W118	W120	W122	W124-E5.1			
Pharmacy, Complex-Dispense drug	15 ✓	14.00	14.00	14.00	14.00	14.00		14.00		14.00		14.00		14.00			
Non Procedures Sub Total (€)			€ 14.00	€ 14.00	€ 14.00	€ 14.00	€ 0.00	€ 14.00	€ 0.00	€ 14.00	€ 0.00	€ 14.00	€ 0.00	€ 14.00			
Conditional Procedure	Qty OH	Budget	W96-E01	W100-E02	W104-E03	W108-E04	W110	W112-E04.1	W114	W116-E04.2	W118	W120	W122	W124-E5.1			
Pharmacy, Complex-Dispense drug	11 ✓	14.00					14.00		14.00		14.00		14.00				
Overhead (all costs) 16%			€ 2.24	€ 2.24	€ 2.24	€ 2.24	€ 0.00	€ 2.24	€ 0.00	€ 2.24	€ 0.00	€ 2.24	€ 0.00	€ 2.24			
Total Cost Per Visit with Overhead(€)			€ 16.24	€ 16.24	€ 16.24	€ 16.24	€ 0.00	€ 16.24	€ 0.00	€ 16.24	€ 0.00	€ 16.24	€ 0.00	€ 16.24			
Total Cost Per Patient (€)			€ 243.60														
Slovak Republic		Sub-Study: Year 3															
Non Procedure	Qty OH	Budget	W126	W128-E5.2	W130	W132-E06	W134	W136-E06.1	W138	W140-E06.2	W142	W144	W146	W148-E07.1	W150	W152-E07.2	EOS-W156
Pharmacy, Complex-Dispense drug	15 ✓	14.00		14.00		14.00		14.00		14.00		14.00		14.00		14.00	
Non Procedures Sub Total (€)			€ 0.00	€ 14.00	€ 0.00	€ 14.00	€ 0.00	€ 14.00	€ 0.00	€ 14.00	€ 0.00	€ 14.00	€ 0.00	€ 14.00	€ 0.00	€ 14.00	€ 0.00
Conditional Procedure	Qty OH	Budget	W126	W128-E5.2	W130	W132-E06	W134	W136-E06.1	W138	W140-E06.2	W142	W144	W146	W148-E07.1	W150	W152-E07.2	EOS-W156
Pharmacy, Complex-Dispense drug	11 ✓	14.00	14.00		14.00		14.00		14.00		14.00		14.00		14.00		
Overhead (all costs) 16%			€ 0.00	€ 2.24	€ 0.00	€ 2.24	€ 0.00	€ 2.24	€ 0.00	€ 2.24	€ 0.00	€ 2.24	€ 0.00	€ 2.24	€ 0.00	€ 2.24	€ 0.00
Total Cost Per Visit with Overhead(€)			€ 0.00	€ 16.24	€ 0.00	€ 16.24	€ 0.00	€ 16.24	€ 0.00	€ 16.24	€ 0.00	€ 16.24	€ 0.00	€ 16.24	€ 0.00	€ 16.24	€ 0.00

Exhibit A –Payment Schedule and Budget /Príloha A – Harmonogram platieb a rozpočet
Table I Schedule of Activities – Year 1 and Year 2 / Tabuľka č. 1 Harmonogram činností – 1. a 2. rok
Pavee: Principal Investigator / Prijemca platby: Hlavný skúšajúci

Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Informed Consent (ICF)	1	✓	11,40	11,40												
Re-Consent	1	✓	9,30	9,30												
Inclusion/Exclusion Eligibility	2	✓	8,70	8,70	8,70											
Medical History	1	✓	13,20	13,20												
Demographics	1	✓	5,40	5,40												
Concomitant medications	27	✓	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60
NEI-VFQ25	5	✓	1,80	1,80												
BCVA (ETDRS) and refraction-Bilateral	13	✓	3,60	1,80	1,80	1,80	1,80		1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80
IOP-bilateral	39	✓	4,50	6,75	6,75	6,75	6,75		6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75
Slit lamp examination-bilateral	26	✓	8,70	8,70	8,70	8,70	8,70		8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70
Indirect ophthalmoscopy	14	✓	9,60	9,60	4,80	4,80	4,80		9,60	4,80	4,80	4,80	4,80	4,80	4,80	4,80
FA-unilateral	14	✓	37,80	75,60					75,60			75,60				75,60
FP-bilateral	7	✓	13,80	13,80					13,80			13,80				13,80
SD-OCT-bilaterally	26	✓	18,60	18,60	18,60	18,60	18,60		18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60
Interpretation and Report for SD-OCT	26	✓	6,30	6,30	6,30	6,30	6,30		6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30
Physical examination	2	✓	13,80	13,80												
Vital signs	27	✓	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90
ECG	3	✓	16,20	16,20												
Adverse events	27	✓	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✓	6,30	6,30												
Collection of specimen; urine for Urinalysis/UPCR	25	✓	2,10		2,10	2,10	2,10		2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10
PK samples (Sparse)	6	✓	5,40		5,40	5,40		5,40	5,40				5,40			
Preparation of sample for shipping	27	✓	3,30	3,30	3,30	3,30	3,30	3,30					3,30	3,30	3,30	3,30
Study Drug (active or sham)-IVT injection	23	✓	76,80	76,80	76,80	76,80				76,80	76,80	76,80	76,80	76,80	76,80	76,80
Procedures Sub Total (€)				€ 246,45	€ 162,75	€ 152,25	€ 146,85	€ 26,40	€ 169,65	€ 146,85	€ 146,85	€ 238,05	€ 152,25	€ 146,85	€ 236,25	€ 146,85
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	✓	15,00	30,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00
Study nurse	28	✓	9,90	19,80	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90
PI time	28	✓	20,70	41,40	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70
Pharmacy, Complex-Dispense drug	23	✓	10,50	10,50	10,50	10,50				10,50	10,50	10,50	10,50	10,50	10,50	10,50
Physician: Ophthalmology - DRM Assessment	20	✓	20,10							20,10	20,10	20,10	20,10	20,10	20,10	20,10
Non Procedures Sub Total (€)				€ 91,20	€ 56,10	€ 56,10	€ 56,10	€ 45,60	€ 45,60	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20
Overhead (all costs) 16%				€ 54,00	€ 35,00	€ 33,30	€ 32,50	€ 11,50	€ 34,40	€ 35,70	€ 35,70	€ 50,30	€ 36,60	€ 35,70	€ 50,00	€ 35,70
Total Cost Per Visit with Overhead(€)				€ 391,65	€ 253,85	€ 241,65	€ 235,45	€ 83,50	€ 249,65	€ 258,75	€ 258,75	€ 364,55	€ 265,05	€ 258,75	€ 362,45	€ 258,75
Total Cost Per Patient (€)				€ 7 372,50												

Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27E05
Informed Consent (ICF)	1	✓	11,40														
Re-Consent	1	✓	9,30														
Inclusion/Exclusion Eligibility	2	✓	8,70														
Medical History	1	✓	13,20														
Demographics	1	✓	5,40														
Concomitant medications	27	✓	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60
NEI-VFQ25	5	✓	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80
BCVA (ETDRS) and refraction-Bilateral	13	✓	3,60	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80
IOP-bilateral	39	✓	4,50	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75
Slit lamp examination-bilateral	26	✓	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70
Indirect ophthalmoscopy	14	✓	9,60	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80
FA-unilateral	14	✓	37,80	75,60													75,60
FP-bilateral	7	✓	13,80	13,80													13,80
SD-OCT-bilaterally	26	✓	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60
Interpretation and Report for SD-OCT-	26	✓	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30
Physical examination	2	✓	13,80														13,80
Vital signs	27	✓	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90
ECG	3	✓	16,20	16,20													16,20
Adverse events	27	✓	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✓	6,30	6,30													6,30
Collection of specimen; urine for Urinalysis/UPCR	25	✓	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10
PK samples (Sparse)	6	✓	5,40														
Preparation of sample for shipping	27	✓	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30
Study Drug (active or sham)-IVT injection	23	✓	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80
Procedures Sub Total (€)			€ 146,85	€ 265,95	€ 146,85	€ 146,85	€ 146,85	€ 238,05	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 197,55
Non Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27E05
Study Coordinator, Simple-Randomization, Data entry	28	✓	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00
Study nurse	28	✓	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90
PI time	28	✓	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70
Pharmacy, Complex-Dispense drug	23	✓	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50
Physician: Ophthalmology - DRM Assessment	20	✓	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10
Non Procedures Sub Total (€)			€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 45,60
Overhead (all costs) 16%			€ 35,70	€ 54,70	€ 35,70	€ 35,70	€ 35,70	€ 50,30	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 38,90
Total Cost Per Visit with Overhead(€)			€ 258,75	€ 396,85	€ 258,75	€ 258,75	€ 258,75	€ 364,55	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 282,05

Detailed Budget – Conditional Fees / Podrobný rozpočet – podmiennečné poplatky

Payee: Principal Investigator / Prijemca platby: Hlavný skúšajúci

Conditional Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Patient Reimbursement, Expenses, Patient Travel - Per Visit	34	✓	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
Physician: Ophthalmology - Rescue Treatment	20	✓	22,30							22,30	22,30	22,30	22,30	22,30	22,30	22,30
Genomic substudy ICF	1	✓	5,30	5,30												
Blood draw for Genomic DNA sample	1	✓	4,00		4,00											
Preparation of sample for shipping	25	✓	3,70		3,70	3,70	3,70		3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70
FBR ICF	1	✓	10,30	10,30												
ICGA-bilateral	3	✓	61,70	61,70												
OCTA-bilaterally	7	✓	20,00	20,00					20,00			20,00			20,00	
Interpretation and Report for OCTA	7	✓	9,00	9,00					9,00			9,00			9,00	
Collection of specimen; urine for Urine pregnancy	25	✓	2,30		2,30	2,30	2,30		2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30

Conditional Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27E05
Patient Reimbursement, Expenses, Patient Travel - Per Visit	34	✓	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
Physician: Ophthalmology - Rescue Treatment	20	✓	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	
Genomic substudy ICF	1	✓	5,30														
Blood draw for Genomic DNA sample	1	✓	4,00														
Preparation of sample for shipping	25	✓	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70
FBR ICF	1	✓	10,30														3,70
ICGA-bilateral	3	✓	61,70		61,70												
OCTA-bilaterally	7	✓	20,00		20,00			20,00									61,70
Interpretation and Report for OCTA	7	✓	9,00		9,00			9,00									20,00
Collection of specimen; urine for Urine pregnancy	25	✓	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	9,00

Screening Failure / Zlyhanie skriningu
Payee: Principal Investigator / Prijemca platby: Hlavný skúšajúci

Procedure	Amount
Informed Consent (ICF)	11,40
Re-Consent	9,30
Inclusion/Exclusion Eligibility	8,70
Medical History	13,20
Demographics	5,40
Concomitant medications	3,60
BCVA (ETDRS) and refraction-Bilateral	1,80
IOP-bilateral	6,75
Slit lamp examination-bilateral	8,70
Indirect ophthalmoscopy	9,60
FA-unilateral	75,60
FP-bilateral	13,80
SD-OCT-bilaterally	18,60
Interpretation and Report for SD-OCT-	6,30
Physical examination	13,80
Vital signs	9,90
ECG	16,20
Adverse events	4,20
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	6,30
Preparation of sample for shipping	3,30
Procedures Sub Total (€)	€ 246,45
Non Procedure	SV
Study Coordinator, Simple-Randomization, Data entry	30,00
Study nurse	19,80
PI time	41,40
Non Procedures Sub Total (€)	€ 91,20
Overhead (all costs)	€ 54,00
Total Cost Per Visit with Overhead(€)	€ 391,65

Detailed Budget – Site Fees / Podrobný rozpočet – poplatky pre pracovisko
Payee: Principal Investigator / Prijemca platby: Hlavný skúšajúci

Site Costs	Qty	Budget	SV
Study Start-Up Fee/Site Set-Up Fee	1	235,50	235,50
Site Costs Sub Total (CPV) (€)			€ 235,50

Table 2 Schedule of Activities – Extension Period Year 3 / Tabuľka č. 2 Harmonogram činností – predĺžené obdobie – 3. rok – new PI part / nová časť pre Hlavnú skúšajúcu
Payee: Principal Investigator / Prijemca platby: Hlavný skúšajúci

Slovak Republic		Sub-Study: Year 3													
Procedure	Qty	OH	Budget	W96-E01	W100-E02	W104-E03	W108-E04	W110	W112-E04.1	W114	W116-E04.2	W118	W120	W122	W124-E5.1
Re-Consent	1	✓	11.78	11.78											
Inclusion/Exclusion eligibility for study extension	1	✓	13.30	13.30											
Concomitant medications	16	✓	4.56	4.56	4.56	4.56	4.56		4.56		4.56		4.56		4.56
NEI-VFQ25	1	✓	2.28	2.28											
BCVA (ETDRS) and refraction-Bilateral	8	✓	4.56	2.28	2.28	2.28	2.28		2.28		2.28		2.28		2.28
IOP-bilateral	24	✓	5.70	8.55	8.55	8.55	8.55		8.55		8.55		8.55		8.55
Slit lamp examination-bilateral	16	✓	11.02	11.02	11.02	11.02	11.02		11.02		11.02		11.02		11.02
Indirect ophthalmoscopy	8	✓	12.16	6.08	6.08	6.08	6.08		6.08		6.08		6.08		6.08
FA-unilateral	4	✓	47.88												
FP-bilateral	2	✓	17.48												
SD-OCT-bilaterally	16	✓	23.56	23.56	23.56	23.56	23.56		23.56		23.56		23.56		23.56
Interpretation and Report for SD-OCT-	16	✓	7.98	7.98	7.98	7.98	7.98		7.98		7.98		7.98		7.98
Physical examination	1	✓	17.48	17.48											
Vital signs	16	✓	12.54	12.54	12.54	12.54	12.54		12.54		12.54		12.54		12.54
Adverse events	16	✓	5.32	5.32	5.32	5.32	5.32		5.32		5.32		5.32		5.32
Collection of specimen; urine for Urinalysis/UPCR	16	✓	2.66	2.66	2.66	2.66	2.66		2.66		2.66		2.66		2.66
Study Drug (active or sham)-IVT injection	15	✓	97.28	97.28	97.28	97.28	97.28		97.28		97.28		97.28		97.28
Procedures Sub Total (€)				€ 226.67	€ 181.83	€ 181.83	€ 181.83	€ 0.00	€ 181.83	€ 0.00	€ 181.83	€ 0.00	€ 181.83	€ 0.00	€ 181.83
Non Procedure	Qty	OH	Budget	W96-E01	W100-E02	W104-E03	W108-E04	W110	W112-E04.1	W114	W116-E04.2	W118	W120	W122	W124-E5.1
Study Coordinator, Simple-Randomization, Data entry	16	✓	19.00	19.00	19.00	19.00	19.00		19.00		19.00		19.00		19.00
Study nurse	16	✓	12.54	12.54	12.54	12.54	12.54		12.54		12.54		12.54		12.54
PI time	16	✓	26.22	26.22	26.22	26.22	26.22		26.22		26.22		26.22		26.22
Pharmacy, Complex-Dispense drug	15	✓	13.30	13.30	13.30	13.30	13.30		13.30		13.30		13.30		13.30
Physician: Ophthalmology - DRM Assessment	14	✓	25.46		25.46	25.46	25.46		25.46		25.46		25.46		25.46
Non Procedures Sub Total (€)				€ 71.06	€ 96.52	€ 96.52	€ 96.52	€ 0.00	€ 96.52	€ 0.00	€ 96.52	€ 0.00	€ 96.52	€ 0.00	€ 96.52

Procedure	Qty	OH	Budget	W126	W128-E5.2	W130	W132-E06	W134	W136-E06.1	W138	W140-E06.2	W142	W144	W146	W148-E07.1	W150	W152-E07.2	EOS-W156	
Re-Consent	1	✓	11.78																
Inclusion/Exclusion eligibility for study extension	1	✓	13.30																
Concomitant medications	16	✓	4.56		4.56		4.56		4.56		4.56		4.56		4.56		4.56	4.56	
NEI-VFQ25	1	✓	2.28																
BCVA (ETDRS) and refraction-Bilateral	8	✓	4.56		2.28		2.28		2.28		2.28		2.28		2.28		2.28	2.28	
IOP-bilateral	24	✓	5.70		8.55		8.55		8.55		8.55		8.55		8.55		8.55	8.55	
Slit lamp examination-bilateral	16	✓	11.02		11.02		11.02		11.02		11.02		11.02		11.02		11.02	11.02	
Indirect ophthalmoscopy	8	✓	12.16		6.08		6.08		6.08		6.08		6.08		6.08		6.08	6.08	
FA-unilateral	4	✓	47.88					95.76											95.76
FP-bilateral	2	✓	17.48					17.48											17.48
SD-OCT-bilaterally	16	✓	23.56		23.56		23.56		23.56		23.56		23.56		23.56		23.56	23.56	
Interpretation and Report for SD-OCT-	16	✓	7.98		7.98		7.98		7.98		7.98		7.98		7.98		7.98	7.98	
Physical examination	1	✓	17.48																
Vital signs	16	✓	12.54		12.54		12.54		12.54		12.54		12.54		12.54		12.54	12.54	
Adverse events	16	✓	5.32		5.32		5.32		5.32		5.32		5.32		5.32		5.32	5.32	
Collection of specimen; urine for Urinalysis/UPCR	16	✓	2.66		2.66		2.66		2.66		2.66		2.66		2.66		2.66	2.66	
Study Drug (active or sham)-IVT Injection	15	✓	97.28		97.28		97.28		97.28		97.28		97.28		97.28		97.28	97.28	
Procedures Sub Total (€)				€ 0.00	€ 181.83	€ 0.00	€ 295.07	€ 0.00	€ 181.83	€ 0.00	€ 181.83	€ 0.00	€ 181.83	€ 0.00	€ 181.83	€ 0.00	€ 181.83	€ 197.79	
Non Procedure	Qty	OH	Budget	W126	W128-E5.2	W130	W132-E06	W134	W136-E06.1	W138	W140-E06.2	W142	W144	W146	W148-E07.1	W150	W152-E07.2	EOS-W156	
Study Coordinator, Simple-Randomization, Data entry	16	✓	19.00		19.00		19.00		19.00		19.00		19.00		19.00		19.00	19.00	
Study nurse	16	✓	12.54		12.54		12.54		12.54		12.54		12.54		12.54		12.54	12.54	
PI time	16	✓	26.22		26.22		26.22		26.22		26.22		26.22		26.22		26.22	26.22	
Pharmacy, Complex-Dispense drug	15	✓	13.30		13.30		13.30		13.30		13.30		13.30		13.30		13.30	13.30	
Physician: Ophthalmology - DRM Assessment	14	✓	25.46		25.46		25.46		25.46		25.46		25.46		25.46		25.46	25.46	
Non Procedures Sub Total (€)				€ 0.00	€ 96.52	€ 0.00	€ 96.52	€ 0.00	€ 96.52	€ 0.00	€ 96.52	€ 0.00	€ 96.52	€ 0.00	€ 96.52	€ 0.00	€ 96.52	€ 57.76	

Conditional Procedure	Qty	OH	Budget	W96-E01	W100-E02	W104-E03	W108-E04	W110	W112-E04.1	W114	W116-E04.2	W118	W120	W122	W124-E5.1
BCVA (ETDRS) and refraction-Bilateral	6	✓	4.56					2.28		2.28		2.28			2.28
IOP-bilateral	18	✓	5.70					8.55		8.55		8.55			8.55
Slit lamp examination-bilateral	12	✓	11.02					11.02		11.02		11.02			11.02
Indirect ophthalmoscopy	6	✓	12.16					6.08		6.08		6.08			6.08
SD-OCT-bilaterally	12	✓	23.56					23.56		23.56		23.56			23.56
Interpretation and Report for SD-OCT-	12	✓	7.98					7.98		7.98		7.98			7.98
Vital signs	12	✓	12.54					12.54		12.54		12.54			12.54
Adverse events	12	✓	5.32					5.32		5.32		5.32			5.32
Collection of specimen; urine for Urinalysis/UPCR	12	✓	2.66					2.66		2.66		2.66			2.66
Preparation of sample for shipping	12	✓	4.18					4.18		4.18		4.18			4.18
Study Drug (active or sham)-IVT Injection	11	✓	97.28					97.28		97.28		97.28			97.28
Study Coordinator, Simple-Randomization, Data entry	12	✓	19.00					19.00		19.00		19.00			19.00
Study nurse	12	✓	12.54					12.54		12.54		12.54			12.54
PI time	12	✓	26.22					26.22		26.22		26.22			26.22
Pharmacy, Complex-Dispense drug	11	✓	13.30					13.30		13.30		13.30			13.30
Physician: Ophthalmology - DRM Assessment	11	✓	25.46					25.46		25.46		25.46			25.46
Patient Reimbursement, Expenses, Patient Travel - Per Visit	12	✓	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
Caregiver Reimbursement, Expenses, Caregiver Travel- Per Visit	27	✓	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Study supplies – needles, syringes and all other required consumables	26	✓	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82
Serious adverse events (SAE)	27	✓	16.34	16.34	16.34	16.34	16.34	16.34	16.34	16.34	16.34	16.34	16.34	16.34	16.34
Physician: Ophthalmology - Rescue Treatment	26	✓	25.46	25.46	25.46	25.46	25.46	25.46	25.46	25.46	25.46	25.46	25.46	25.46	25.46
ICGA-bilateral	1	✓	70.30												
OCTA-bilaterally	2	✓	22.80												
Interpretation and Report for OCTA	2	✓	10.26												
Hematology (Local lab)	1	✓	4.94												
Blood Chemistry (Local lab)	1	✓	12.16												
Urine pregnancy test (Local lab)	13.5	✓	4.56	2.28	2.28	2.28	2.28	2.28	2.28	2.28	2.28	2.28	2.28	2.28	2.28
Urinalysis (Local lab)	1	✓	3.42												
UPCR (Local lab)	1	✓	5.32												

Overhead (all costs) 16%

€ 47.64 € 44.54 € 44.54 € 44.54 € 0.00 € 44.54 € 0.00 € 44.54 € 0.00 € 44.54 € 0.00 € 44.54 € 0.00 € 44.54

Total Cost Per Visit with Overhead(€)

€ 345.37 € 322.89 € 322.89 € 322.89 € 0.00 € 322.89 € 0.00 € 322.89 € 0.00 € 322.89 € 0.00 € 322.89 € 0.00 € 322.89

Total Cost Per Patient (€)

€ 5,293.62

Conditional Procedure	Qty	OH	Budget	W126	W128-E5.2	W130	W132-E06	W134	W136-E06.1	W138	W140-E06.2	W142	W144	W146	W148-E07.1	W150	W152-E05-W156-E07.2
BCVA (ETDRS) and refraction-bilateral	6	✓	4.56	2.28	2.28	2.28	2.28	2.28	2.28	2.28	2.28	2.28	2.28	2.28	2.28	2.28	2.28
IOP-bilateral	18	✓	5.70	8.55	8.55	8.55	8.55	8.55	8.55	8.55	8.55	8.55	8.55	8.55	8.55	8.55	8.55
Slit lamp examination-bilateral	12	✓	11.02	11.02	11.02	11.02	11.02	11.02	11.02	11.02	11.02	11.02	11.02	11.02	11.02	11.02	11.02
Indirect ophthalmoscopy	6	✓	12.16	6.08	6.08	6.08	6.08	6.08	6.08	6.08	6.08	6.08	6.08	6.08	6.08	6.08	6.08
SD-OCT-bilaterally	12	✓	23.56	23.56	23.56	23.56	23.56	23.56	23.56	23.56	23.56	23.56	23.56	23.56	23.56	23.56	23.56
Interpretation and Report for SD-OCT-	12	✓	7.98	7.98	7.98	7.98	7.98	7.98	7.98	7.98	7.98	7.98	7.98	7.98	7.98	7.98	7.98
Vital signs	12	✓	12.54	12.54	12.54	12.54	12.54	12.54	12.54	12.54	12.54	12.54	12.54	12.54	12.54	12.54	12.54
Adverse events	12	✓	5.32	5.32	5.32	5.32	5.32	5.32	5.32	5.32	5.32	5.32	5.32	5.32	5.32	5.32	5.32
Collection of specimen; urine for Urinalysis/UPCR	12	✓	4.18	2.66	2.66	2.66	2.66	2.66	2.66	2.66	2.66	2.66	2.66	2.66	2.66	2.66	2.66
Preparation of sample for shipping	12	✓	4.18	4.18	4.18	4.18	4.18	4.18	4.18	4.18	4.18	4.18	4.18	4.18	4.18	4.18	4.18
Study Drug (active or sham)-TVT injection	11	✓	97.28	97.28	97.28	97.28	97.28	97.28	97.28	97.28	97.28	97.28	97.28	97.28	97.28	97.28	97.28
Study Coordinator, Simple-Randomization, Data entry	12	✓	19.00	19.00	19.00	19.00	19.00	19.00	19.00	19.00	19.00	19.00	19.00	19.00	19.00	19.00	19.00
Study nurse	12	✓	12.54	12.54	12.54	12.54	12.54	12.54	12.54	12.54	12.54	12.54	12.54	12.54	12.54	12.54	12.54
PI time	12	✓	26.22	26.22	26.22	26.22	26.22	26.22	26.22	26.22	26.22	26.22	26.22	26.22	26.22	26.22	26.22
Pharmacy, Complex-Dispense drug	11	✓	13.30	13.30	13.30	13.30	13.30	13.30	13.30	13.30	13.30	13.30	13.30	13.30	13.30	13.30	13.30
Physician: Ophthalmology - DRM Assessment	11	✓	25.46	25.46	25.46	25.46	25.46	25.46	25.46	25.46	25.46	25.46	25.46	25.46	25.46	25.46	25.46
Physician: Ophthalmology - DRM Treatment	26	✓	16.34	16.34	16.34	16.34	16.34	16.34	16.34	16.34	16.34	16.34	16.34	16.34	16.34	16.34	16.34
Serious adverse events (SAE)	27	✓	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82
Study supplies - needles, syringes and all other requires consumables	26	✓	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82	14.82
Travel- Per Visit	27	✓	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Caregiver Reimbursement, Expenses, Caregiver Per Visit	12	✓	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
Parent: Reimbursement, Expenses, Patient Travel-	12	✓	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
ICGA-bilateral	1	✓	70.30	70.30	70.30	70.30	70.30	70.30	70.30	70.30	70.30	70.30	70.30	70.30	70.30	70.30	70.30
OCTA-bilaterally	2	✓	22.80	22.80	22.80	22.80	22.80	22.80	22.80	22.80	22.80	22.80	22.80	22.80	22.80	22.80	22.80
Interpretation and Report for OCTA	2	✓	10.26	10.26	10.26	10.26	10.26	10.26	10.26	10.26	10.26	10.26	10.26	10.26	10.26	10.26	10.26
Hematology (Local lab)	1	✓	4.94	4.94	4.94	4.94	4.94	4.94	4.94	4.94	4.94	4.94	4.94	4.94	4.94	4.94	4.94
Blood Chemistry (Local lab)	1	✓	12.16	12.16	12.16	12.16	12.16	12.16	12.16	12.16	12.16	12.16	12.16	12.16	12.16	12.16	12.16
Urine pregnancy/ test (Local lab)	13.5	✓	4.56	4.56	4.56	4.56	4.56	4.56	4.56	4.56	4.56	4.56	4.56	4.56	4.56	4.56	4.56
Urinalysis (Local lab)	1	✓	3.42	3.42	3.42	3.42	3.42	3.42	3.42	3.42	3.42	3.42	3.42	3.42	3.42	3.42	3.42
UPCR (Local lab)	1	✓	5.32	5.32	5.32	5.32	5.32	5.32	5.32	5.32	5.32	5.32	5.32	5.32	5.32	5.32	5.32

Overhead (all costs) 16%

Total Cost Per Visit with Overhead(€)

€ 0.00	€ 44.54	€ 0.00	€ 62.65	€ 0.00	€ 44.54	€ 0.00	€ 44.54	€ 0.00	€ 44.54	€ 0.00	€ 44.54	€ 0.00	€ 44.54	€ 0.00	€ 44.54	€ 0.00	€ 44.54
€ 0.00	€ 322.89	€ 0.00	€ 454.24	€ 0.00	€ 322.89	€ 0.00	€ 322.89	€ 0.00	€ 322.89	€ 0.00	€ 322.89	€ 0.00	€ 322.89	€ 0.00	€ 322.89	€ 0.00	€ 322.89
€ 296.44	€ 40.89	€ 0.00	€ 44.54	€ 0.00	€ 44.54	€ 0.00	€ 44.54	€ 0.00	€ 44.54	€ 0.00	€ 44.54	€ 0.00	€ 44.54	€ 0.00	€ 44.54	€ 0.00	€ 44.54

Exhibit A –Payment Schedule and Budget /Príloha A – Harmonogram platieb a rozpočet
Table I Schedule of Activities – Year 1 and Year 2 / Tabuľka č. 1 Harmonogram činností – 1. a 2. rok
Payee: Sub-Investigator / Prijemca platby: Spoluskúšajúci

Procedure	QTY	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Informed Consent (ICF)	1	✓	11,40	11,40												
Re-Consent	1	✓	9,30	9,30												
Inclusion/Exclusion Eligibility	2	✓	8,70	8,70	8,70											
Medical History	1	✓	13,20	13,20												
Demographics	1	✓	5,40	5,40												
Concomitant medications	27	✓	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60
NEI-VFQ25	5	✓	1,80	1,80	1,80							1,80				
BCVA (ETDRS) and refraction-Bilateral	13	✓	3,60	3,60	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80
ITOP-bilateral	39	✓	4,50	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75
SEI lamp examination-bilateral	26	✓	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70
Indirect ophthalmoscopy	14	✓	9,60	9,60	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80
FA-unilateral	14	✓	37,80	75,60								75,60				
FP-bilateral	7	✓	13,80	13,80								13,80				
SD-OCT-bilaterally	26	✓	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60
Interpretation and Report for SD-OCT-	26	✓	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30
Physical examination	2	✓	13,80	13,80												
Vital signs	27	✓	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90
ECG	3	✓	16,20	16,20												
Adverse events	27	✓	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✓	6,30	6,30												
Collection of specimen; urine for Urinalysis/UPCR	25	✓	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10
PK samples (Sparse)	6	✓	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40
Preparation of sample for shipping	27	✓	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30
Study Drug (active or sham)-IVT injection	23	✓	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80
Procedures Sub Total (€)				€ 246,45	€ 162,75	€ 152,25	€ 146,85	€ 26,40	€ 169,65	€ 146,85	€ 146,85	€ 238,05	€ 152,25	€ 146,85	€ 236,25	€ 146,85
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	✓	15,00	30,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00
Study nurse	28	✓	9,90	19,80	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90
PI time	28	✓	20,70	41,40	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70
Pharmacy, Complex-Dispense drug	23	✓	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50
Physician: Ophthalmology - DRM Assessment	20	✓	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10
Non Procedures Sub Total (€)				€ 91,20	€ 56,10	€ 56,10	€ 56,10	€ 45,60	€ 45,60	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20
Overhead (all costs) 16%				€ 54,00	€ 35,00	€ 33,30	€ 32,50	€ 11,50	€ 34,40	€ 35,70	€ 35,70	€ 50,30	€ 36,60	€ 35,70	€ 50,00	€ 35,70
Total Cost Per Visit with Overhead(€)				€ 391,65	€ 253,85	€ 241,65	€ 235,45	€ 83,50	€ 249,65	€ 258,75	€ 258,75	€ 364,55	€ 265,05	€ 258,75	€ 362,45	€ 258,75
Total Cost Per Patient (€)				€ 7 372,50												

Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27E05
Informed Consent (ICF)	1	✓	11,40														
Re-Consent	1	✓	9,30														
Inclusion/Exclusion Eligibility	2	✓	8,70														
Medical History	1	✓	13,20														
Demographics	1	✓	5,40														
Concomitant medications	27	✓	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60	3,60
NEI-VFQ25	5	✓	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80
BCVA (ETRS) and refraction-bilateral	13	✓	3,60	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80
IOP-bilateral	39	✓	4,50	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75	6,75
Slit lamp examination-bilateral	26	✓	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70	8,70
Indirect ophthalmoscopy	14	✓	9,60	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80	4,80
FA-unilateral	14	✓	37,80	75,60	13,80	13,80	13,80	13,80	75,60	13,80	13,80	13,80	13,80	13,80	13,80	13,80	13,80
SD-OCT-bilaterally	26	✓	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60
SD-OCT-bilaterally	26	✓	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60	18,60
Interpretation and Report for SD-OCT-	26	✓	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30
Physical examination	2	✓	13,80	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90
Vital signs	27	✓	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90
ECG	3	✓	16,20	16,20	16,20	16,20	16,20	16,20	16,20	16,20	16,20	16,20	16,20	16,20	16,20	16,20	16,20
Adverse events	27	✓	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20	4,20
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug-Antibody Serum	3	✓	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30	6,30
Sample	25	✓	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10
Collection of specimen; urine for Urinalysis/UPCR	25	✓	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10	2,10
PK samples (Sparse)	6	✓	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40
Preparation of sample for shipping	27	✓	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30	3,30
Study Drug (active or sham)-IVT injection	23	✓	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80	76,80
Procedures Sub Total (€)			€ 146,85	€ 265,95	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 146,85	€ 197,55
Non Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27E05
Study Coordinator, Simple-Randomization, Data entry	28	✓	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00	15,00
Study nurse	28	✓	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90	9,90
PI time	28	✓	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70	20,70
Pharmacy, Complex-Dispense drug	23	✓	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50	10,50
Physician: Ophthalmology - DRM Assessment	20	✓	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10	20,10
Non Procedures Sub Total (€)			€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 76,20	€ 45,60
Overhead (all costs) 16%			€ 35,70	€ 54,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 35,70	€ 38,90
Total Cost Per Visit with Overhead(€)			€ 258,75	€ 396,85	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 258,75	€ 282,05

Detailed Budget – Conditional Fees / Podrobný rozpočet – podmienené poplatky

Payee: Sub-Investigator / Prijemca platby: Spoluskúšajúci

Conditional Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Physician: Ophthalmology - Rescue Treatment	20	✓	22,30						22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30
Genomic substudy ICF	1	✓	5,30	5,30												
Blood draw for Genomic DNA sample	1	✓	4,00	4,00												
Preparation of sample for shipping	25	✓	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70
FBR ICF	1	✓	10,30	10,30												
ICGA-bilateral	3	✓	61,70	61,70												
OCTA-bilaterally	7	✓	20,00	20,00				20,00				20,00				20,00
Interpretation and Report for OCTA	7	✓	9,00	9,00				9,00				9,00				9,00
Collection of specimen; urine for Urine pregnancy	25	✓	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30

Conditional Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27E0S
Physician: Ophthalmology - Rescue Treatment	20	✓	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30	22,30
Genomic substudy ICF	1	✓	5,30														
Blood draw for Genomic DNA sample	1	✓	4,00														
Preparation of sample for shipping	25	✓	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70	3,70
FBR ICF	1	✓	10,30														
ICGA-bilateral	3	✓	61,70														61,70
OCTA-bilaterally	7	✓	20,00					20,00									20,00
Interpretation and Report for OCTA	7	✓	9,00					9,00									9,00
Collection of specimen; urine for Urine pregnancy	25	✓	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30

Screening Failure / Zlyhanie skríningu
Payee: Sub-Investigator / Prijemca platby: Spoluskúšajúci

Procedure	Amount
Informed Consent (ICF)	11,40
Re-Consent	9,30
Inclusion/Exclusion Eligibility	8,70
Medical History	13,20
Demographics	5,40
Concomitant medications	3,60
BCVA (ETDRS) and refraction-Bilateral	1,80
IOP-bilateral	6,75
Slit lamp examination-bilateral	8,70
Indirect ophthalmoscopy	9,60
FA-unilateral	75,60
FP-bilateral	13,80
SD-OCT-bilaterally	18,60
Interpretation and Report for SD-OCT-	6,30
Physical examination	13,80
Vital signs	9,90
ECG	16,20
Adverse events	4,20
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	6,30
Preparation of sample for shipping	3,30
Procedures Sub Total (€)	€ 246,45
Non Procedure	SV
Study Coordinator, Simple-Randomization, Data entry	30,00
Study nurse	19,80
PI time	41,40
Non Procedures Sub Total (€)	€ 91,20
Overhead (all costs)	€ 54,00
Total Cost Per Visit with Overhead(€)	€ 391,65

Detailed Budget – Site Fees / Podrobný rozpočet – poplatky pre pracovisko
Payee: Sub-Investigator / Prijemca platby: Spoluskúšajúci

Site Costs	Qty	Budget	SV
Study Start-Up Fee/Site Set-Up Fee	1	235,50	235,50
Site Costs Sub Total (CPV) (€)			€ 235,50

Table 2 Schedule of Activities – Extension Period Year 3 / Tabuľka č. 2 Harmonogram činností – predĺžené obdobie – 3. rok
 Payee: Sub-Investigator / Prijemca platby: Spoluskúšajúci

Slovak Republic		Sub-Study: Year 3													
Procedure	Qty	OH	Budget	W96-E01	W100-E02	W104-E03	W108-E04	W110	W112-E04.1	W114	W116-E04.2	W118	W120	W122	W124-E5.1
Re-Consent	1	✓	9.30	9.30											
Inclusion/Exclusion eligibility for study extension	1	✓	10.50	10.50											
Concomitant medications	16	✓	3.60	3.60	3.60	3.60	3.60		3.60		3.60		3.60		3.60
NEI-VFQ25	1	✓	1.80	1.80											
BCVA (ETDRS) and refraction-Bilateral	8	✓	3.60	1.80	1.80	1.80	1.80		1.80		1.80		1.80		1.80
IOP-bilateral	24	✓	4.50	6.75	6.75	6.75	6.75		6.75		6.75		6.75		6.75
Slit lamp examination-bilateral	16	✓	8.70	8.70	8.70	8.70	8.70		8.70		8.70		8.70		8.70
Indirect ophthalmoscopy	8	✓	9.60	4.80	4.80	4.80	4.80		4.80		4.80		4.80		4.80
FA-unilateral	4	✓	37.80												
FP-bilateral	2	✓	13.80												
SD-OCT-bilaterally	16	✓	18.60	18.60	18.60	18.60	18.60		18.60		18.60		18.60		18.60
Interpretation and Report for SD-OCT-	16	✓	6.30	6.30	6.30	6.30	6.30		6.30		6.30		6.30		6.30
Physical examination	1	✓	13.80	13.80											
Vital signs	16	✓	9.90	9.90	9.90	9.90	9.90		9.90		9.90		9.90		9.90
Adverse events	16	✓	4.20	4.20	4.20	4.20	4.20		4.20		4.20		4.20		4.20
Collection of specimen; urine for Urinalysis/UPCR	16	✓	2.10	2.10	2.10	2.10	2.10		2.10		2.10		2.10		2.10
Study Drug (active or sham)-IVT injection	15	✓	76.80	76.80	76.80	76.80	76.80		76.80		76.80		76.80		76.80
Procedures Sub Total (€)				€ 178.95	€ 143.55	€ 143.55	€ 143.55	€ 0.00	€ 143.55	€ 0.00	€ 143.55	€ 0.00	€ 143.55	€ 0.00	€ 143.55
Non Procedure	Qty	OH	Budget	W96-E01	W100-E02	W104-E03	W108-E04	W110	W112-E04.1	W114	W116-E04.2	W118	W120	W122	W124-E5.1
Study Coordinator, Simple-Randomization, Data entry	16	✓	15.00	15.00	15.00	15.00	15.00		15.00		15.00		15.00		15.00
Study nurse	16	✓	9.90	9.90	9.90	9.90	9.90		9.90		9.90		9.90		9.90
PI time	16	✓	20.70	20.70	20.70	20.70	20.70		20.70		20.70		20.70		20.70
Pharmacy, Complex-Dispense drug	15	✓	10.50	10.50	10.50	10.50	10.50		10.50		10.50		10.50		10.50
Physician: Ophthalmology - DRM Assessment	14	✓	20.10		20.10	20.10	20.10		20.10		20.10		20.10		20.10
Non Procedures Sub Total (€)				€ 56.10	€ 76.20	€ 76.20	€ 76.20	€ 0.00	€ 76.20	€ 0.00	€ 76.20	€ 0.00	€ 76.20	€ 0.00	€ 76.20

Procedure	Qty	OH	Budget	W126	W128-E5.2	W130	W132-E06	W134	W136-E06.1	W138	W140-E06.2	W142	W144	W146	W148-E07.1	W150	W152-E07.2	EOS-W156
Re-Consent	1	✓	9.30															
Inclusion/Exclusion eligibility for study extension	1	✓	10.50															
Concomitant medications	16	✓	3.60		3.60		3.60		3.60		3.60		3.60		3.60		3.60	3.60
NEI-VFQ25	1	✓	1.80															
BCVA (ETDRS) and refraction-Bilateral	8	✓	3.60		1.80		1.80		1.80		1.80		1.80		1.80		1.80	1.80
IOP-bilateral	24	✓	4.50		6.75		6.75		6.75		6.75		6.75		6.75		6.75	6.75
Slit lamp examination-bilateral	16	✓	8.70		8.70		8.70		8.70		8.70		8.70		8.70		8.70	8.70
Indirect ophthalmoscopy	8	✓	9.60		4.80		4.80		4.80		4.80		4.80		4.80		4.80	4.80
FA-unilateral	4	✓	37.80				75.60											75.60
FP-bilateral	2	✓	13.80				13.80											13.80
SD-OCT-bilaterally	16	✓	18.60		18.60		18.60		18.60		18.60		18.60		18.60		18.60	18.60
Interpretation and Report for SD-OCT-	16	✓	6.30		6.30		6.30		6.30		6.30		6.30		6.30		6.30	6.30
Physical examination	1	✓	13.80															
Vital signs	16	✓	9.90		9.90		9.90		9.90		9.90		9.90		9.90		9.90	9.90
Adverse events	16	✓	4.20		4.20		4.20		4.20		4.20		4.20		4.20		4.20	4.20
Collection of specimen; urine for Urinalysis/UPCR	16	✓	2.10		2.10		2.10		2.10		2.10		2.10		2.10		2.10	2.10
Study Drug (active or sham)-IVT injection	15	✓	76.80		76.80		76.80		76.80		76.80		76.80		76.80		76.80	76.80
Procedures Sub Total (€)				€ 0.00	€ 143.55	€ 0.00	€ 232.95	€ 0.00	€ 143.55	€ 0.00	€ 143.55	€ 0.00	€ 143.55	€ 0.00	€ 143.55	€ 0.00	€ 143.55	€ 156.15
Non Procedure	Qty	OH	Budget	W126	W128-E5.2	W130	W132-E06	W134	W136-E06.1	W138	W140-E06.2	W142	W144	W146	W148-E07.1	W150	W152-E07.2	EOS-W156
Study Coordinator, Simple-Randomization, Data entry	16	✓	15.00		15.00		15.00		15.00		15.00		15.00		15.00		15.00	15.00
Study nurse	16	✓	9.90		9.90		9.90		9.90		9.90		9.90		9.90		9.90	9.90
PI time	16	✓	20.70		20.70		20.70		20.70		20.70		20.70		20.70		20.70	20.70
Pharmacy, Complex-Dispense drug	15	✓	10.50		10.50		10.50		10.50		10.50		10.50		10.50		10.50	10.50
Physician: Ophthalmology - DRM Assessment	14	✓	20.10		20.10		20.10		20.10		20.10		20.10		20.10		20.10	20.10
Non Procedures Sub Total (€)				€ 0.00	€ 76.20	€ 0.00	€ 76.20	€ 0.00	€ 76.20	€ 0.00	€ 76.20	€ 0.00	€ 76.20	€ 0.00	€ 76.20	€ 0.00	€ 76.20	€ 45.60

Conditional Procedure	Qty	OH	Budget	W96-E01	W100-E02	W104-E03	W108-E04	W110	W112-E04.1	W114	W116-E04.2	W118	W120	W122	W124-E5.1
BCVA (ETDRS) and refraction-Bilateral	6	✓	3.60					1.80		1.80		1.80		1.80	
IOP-bilateral	18	✓	4.50					6.75		6.75		6.75		6.75	
Slit lamp examination-bilateral	12	✓	8.70					8.70		8.70		8.70		8.70	
Indirect ophthalmoscopy	6	✓	9.60					4.80		4.80		4.80		4.80	
SD-OCT-bilaterally	12	✓	18.60					18.60		18.60		18.60		18.60	
Interpretation and Report for SD-OCT-	12	✓	6.30					6.30		6.30		6.30		6.30	
Vital signs	12	✓	9.90					9.90		9.90		9.90		9.90	
Adverse events	12	✓	4.20					4.20		4.20		4.20		4.20	
Collection of specimen; urine for Urinalysis/UPCR	12	✓	2.10					2.10		2.10		2.10		2.10	
Preparation of sample for shipping	12	✓	3.30					3.30		3.30		3.30		3.30	
Study Drug (active or sham)-IVT Injection	11	✓	76.80					76.80		76.80		76.80		76.80	
Study Coordinator, Simple-Randomization, Data entry	12	✓	15.00					15.00		15.00		15.00		15.00	
Study nurse	12	✓	9.90					9.90		9.90		9.90		9.90	
PI time	12	✓	20.70					20.70		20.70		20.70		20.70	
Pharmacy, Complex-Dispense drug	11	✓	10.50					10.50		10.50		10.50		10.50	
Physician: Ophthalmology - DRM Assessment	11	✓	20.10					20.10		20.10		20.10		20.10	
Patient Reimbursement, Expenses, Patient Travel - Per Visit	12	✓	0.00					0.00		0.00		0.00		0.00	
Caregiver Reimbursement, Expenses, Caregiver Travel- Per Visit	27	✓	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Study supplies – needles, syringes and all other required consumables	26	✓	11.70	11.70	11.70	11.70	11.70	11.70	11.70	11.70	11.70	11.70	11.70	11.70	11.70
Serious adverse events (SAE)	27	✓	12.90	12.90	12.90	12.90	12.90	12.90	12.90	12.90	12.90	12.90	12.90	12.90	12.90
Physician: Ophthalmology - Rescue Treatment	26	✓	20.10	20.10	20.10	20.10	20.10	20.10	20.10	20.10	20.10	20.10	20.10	20.10	20.10
ICGA-bilateral	1	✓	55.50												
OCTA-bilaterally	2	✓	18.00												
Interpretation and Report for OCTA	2	✓	8.10												
Hematology (Local lab)	1	✓	3.90												
Blood Chemistry (Local lab)	1	✓	9.60												
Urine pregnancy test (Local lab)	13.5	✓	3.60	1.80	1.80	1.80	1.80	1.80	1.80	1.80	1.80	1.80	1.80	1.80	1.80
Urinalysis (Local lab)	1	✓	2.70												
UPCR (Local lab)	1	✓	4.20												

Overhead (all costs) 16%

	€ 37.61	€ 35.16	€ 35.16	€ 35.16	€ 0.00	€ 35.16	€ 0.00	€ 35.16	€ 0.00	€ 35.16	€ 0.00	€ 35.16	€ 0.00	€ 35.16	€ 0.00	€ 35.16
Total Cost Per Visit with Overhead(€)	€ 272.66	€ 254.91	€ 254.91	€ 254.91	€ 0.00	€ 254.91	€ 0.00	€ 254.91	€ 0.00	€ 254.91	€ 0.00	€ 254.91	€ 0.00	€ 254.91	€ 0.00	€ 254.91
Total Cost Per Patient (€)	€ 4,179.13															

Conditional Procedure	Qty	OH	Budget	W126	W128-ES.2	W130	W132-E06	W134	W136-E06.1	W138	W140-E06.2	W142	W144	W146	W148-E07.1	W150	W152-E07.2	EOS-W156
BCVA (ETDRS) and refraction-Bilateral	6	✓	3.60	1.80		1.80		1.80		1.80		1.80		1.80		1.80		1.80
IOP-bilateral	18	✓	4.50	6.75		6.75		6.75		6.75		6.75		6.75		6.75		6.75
Slit lamp examination-bilateral	12	✓	8.70	8.70		8.70		8.70		8.70		8.70		8.70		8.70		8.70
Indirect ophthalmoscopy	6	✓	9.60	4.80		4.80		4.80		4.80		4.80		4.80		4.80		4.80
SD-OCT-bilaterally	12	✓	18.60	18.60		18.60		18.60		18.60		18.60		18.60		18.60		18.60
Interpretation and Report for SD-OCT-	12	✓	6.30	6.30		6.30		6.30		6.30		6.30		6.30		6.30		6.30
Vital signs	12	✓	9.90	9.90		9.90		9.90		9.90		9.90		9.90		9.90		9.90
Adverse events	12	✓	4.20	4.20		4.20		4.20		4.20		4.20		4.20		4.20		4.20
Collection of specimen; urine for Urinalysis/UPCR	12	✓	2.10	2.10		2.10		2.10		2.10		2.10		2.10		2.10		2.10
Preparation of sample for shipping	12	✓	3.30	3.30		3.30		3.30		3.30		3.30		3.30		3.30		3.30
Study Drug (active or sham)-IVT Injection	11	✓	76.80	76.80		76.80		76.80		76.80		76.80		76.80		76.80		76.80
Study Coordinator, Simple-Randomization, Data entry	12	✓	15.00	15.00		15.00		15.00		15.00		15.00		15.00		15.00		15.00
Study nurse	12	✓	9.90	9.90		9.90		9.90		9.90		9.90		9.90		9.90		9.90
PI time	12	✓	20.70	20.70		20.70		20.70		20.70		20.70		20.70		20.70		20.70
Pharmacy, Complex-Dispense drug	11	✓	10.50	10.50		10.50		10.50		10.50		10.50		10.50		10.50		10.50
Physician: Ophthalmology - DRM Assessment	11	✓	20.10	20.10		20.10		20.10		20.10		20.10		20.10		20.10		20.10
Patient Reimbursement, Expenses, Patient Travel - Per Visit	12	✓	0.00	0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
Caregiver Reimbursement, Expenses, Caregiver Travel- Per Visit	27	✓	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Study supplies - needles, syringes and all other required consumables	26	✓	11.70	11.70	11.70	11.70	11.70	11.70	11.70	11.70	11.70	11.70	11.70	11.70	11.70	11.70	11.70	11.70
Serious adverse events (SAE)	27	✓	12.90	12.90	12.90	12.90	12.90	12.90	12.90	12.90	12.90	12.90	12.90	12.90	12.90	12.90	12.90	12.90
Physician: Ophthalmology - Rescue Treatment	26	✓	20.10	20.10	20.10	20.10	20.10	20.10	20.10	20.10	20.10	20.10	20.10	20.10	20.10	20.10	20.10	20.10
ICGA-bilateral	1	✓	55.50															55.50
OCTA-bilaterally	2	✓	18.00			18.00												18.00
Interpretation and Report for OCTA	2	✓	8.10			8.10												8.10
Hematology (Local lab)	1	✓	3.90															3.90
Blood Chemistry (Local lab)	1	✓	9.60															9.60
Urine pregnancy test (Local lab)	13.5	✓	3.60	1.80	1.80	1.80	1.80	1.80	1.80	1.80	1.80	1.80	1.80	1.80	1.80	1.80	1.80	1.80
Urinalysis (Local lab)	1	✓	2.70															2.70
UPCR (Local lab)	1	✓	4.20															4.20
Overhead (all costs) 16%				€ 0.00	€ 35.16	€ 0.00	€ 49.46	€ 0.00	€ 35.16	€ 0.00	€ 35.16	€ 0.00	€ 35.16	€ 0.00	€ 35.16	€ 0.00	€ 35.16	€ 32.28
Total Cost Per Visit with Overhead(€)				€ 0.00	€ 254.91	€ 0.00	€ 358.61	€ 0.00	€ 254.91	€ 0.00	€ 254.91	€ 0.00	€ 254.91	€ 0.00	€ 254.91	€ 0.00	€ 254.91	€ 234.03

Exhibit A –Payment Schedule and Budget /Príloha A – Harmonogram platieb a rozpočet
Table 1 Schedule of Activities – Year 1 and Year 2 / Tabuľka č. 1 Harmonogram činností – 1. a 2. rok
Pavee: Study Nurse / Prijemca platby: Štúdičná sestra

Procedure	Qty	OH	Budget	SV	V2BL	V3D29	V4W8	V5D60-64	V6D85	V7D113	V8D141	V9D169	V10D197	V11D225	V12D253	V13D281
Informed Consent (ICF)	1	✓	3,00	3,00												
Re-Consent	1	✓	2,50	2,50												
Inclusion/Exclusion Eligibility	2	✓	2,30	2,30	2,30											
Medical History	1	✓	3,50	3,50												
Demographics	1	✓	1,40	1,40												
Concomitant medications	27	✓	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00
NEI-VFQ25	5	✓	0,50	0,50								0,50				
BCVA (ETDRS) and refraction-Bilateral	13	✓	1,00	0,50	0,50	0,50	0,50		0,50	0,50	0,50	0,50	0,50	0,50	0,50	0,50
IOP-bilateral	39	✓	1,20	1,80	1,80	1,80	1,80		1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80
Slit lamp examination-bilateral	26	✓	2,30	2,30	2,30	2,30	2,30		2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30
Indirect ophthalmoscopy	14	✓	2,60	2,60	1,30	1,30	1,30		2,60	1,30	1,30	1,30	1,30	1,30	1,30	1,30
FA-unilateral	14	✓	10,10	20,20					20,20			20,20			20,20	
FP-bilateral	7	✓	3,70	3,70					3,70			3,70			3,70	
SD-OCT-bilaterally	26	✓	5,00	5,00	5,00	5,00	5,00		5,00	5,00	5,00	5,00	5,00	5,00	5,00	5,00
Interpretation and Report for SD-OCT-	26	✓	1,70	1,70	1,70	1,70	1,70		1,70	1,70	1,70	1,70	1,70	1,70	1,70	1,70
Physical examination	2	✓	3,70	3,70												
Vital signs	27	✓	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60
ECG	3	✓	4,30	4,30												
Adverse events	27	✓	1,10	1,10	1,10	1,10	1,10	1,10	1,10	1,10	1,10	1,10	1,10	1,10	1,10	1,10
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✓	1,70	1,70												
Collection of specimen; urine for Urinalysis/UPCR	25	✓	0,60	0,60	0,60	0,60		0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60
PK samples (Sparse)	6	✓	1,40	1,40	1,40		1,40	1,40				1,40				
Preparation of sample for shipping	27	✓	0,90	0,90	0,90	0,90	0,90	0,90	0,90	0,90	0,90	0,90	0,90	0,90	0,90	0,90
Study Drug (active or sham)-IVT injection	23	✓	20,50	20,50	20,50	20,50			20,50	20,50	20,50	20,50	20,50	20,50	20,50	20,50
Procedures Sub Total (€)				€ 65,80	€ 43,50	€ 40,70	€ 39,30	€ 7,00	€ 45,40	€ 39,30	€ 39,30	€ 63,70	€ 40,70	€ 39,30	€ 63,20	€ 39,30
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	✓	4,00	8,00	4,00	4,00	4,00	4,00	4,00	4,00	4,00	4,00	4,00	4,00	4,00	4,00
Study nurse	28	✓	2,60	5,20	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60
PI time	28	✓	5,50	11,00	5,50	5,50	5,50	5,50	5,50	5,50	5,50	5,50	5,50	5,50	5,50	5,50
Pharmacy, Complex-Dispense drug	23	✓	2,80	2,80	2,80	2,80				5,40	5,40	5,40	5,40	5,40	5,40	5,40
Physician: Ophthalmology - DRM Assessment	20	✓	5,40													
Non Procedures Sub Total (€)				€ 24,20	€ 14,90	€ 14,90	€ 14,90	€ 12,10	€ 12,10	€ 20,30	€ 20,30	€ 20,30	€ 20,30	€ 20,30	€ 20,30	€ 20,30
Overhead (all costs) 16%				€ 14,40	€ 9,30	€ 8,90	€ 8,70	€ 3,10	€ 9,20	€ 9,50	€ 9,50	€ 13,40	€ 9,80	€ 9,50	€ 13,40	€ 9,50
Total Cost Per Visit with Overhead(€)				€ 104,40	€ 67,70	€ 64,50	€ 62,90	€ 22,20	€ 66,70	€ 69,10	€ 69,10	€ 97,40	€ 70,80	€ 69,10	€ 96,90	€ 69,10
Total Cost Per Patient (€)				€ 1 968,80												

Procedure Qty OH Budget V14B309 V15D337 V16D365 V17D393 V18D421 V19D449 V20D447 V21D505 V22D533 V23D561 V24D589 V25D617 V26D645 V27E05

Informed Consent (ICF)	1	✓	3,00														
Re-Consent	1	✓	2,50														
Inclusion/Exclusion Eligibility	2	✓	2,30														
Medical History	1	✓	3,50														
Demographics	1	✓	1,40														
Concomitant medications	27	✓	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,00
NEI-VFQ25	5	✓	0,50	0,50													0,50
BCVA (ETDRS) and refraction-bilateral	13	✓	1,00	0,50	0,50	0,50	0,50	0,50	0,50	0,50	0,50	0,50	0,50	0,50	0,50	0,50	0,50
IOP-bilateral	39	✓	1,20	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80	1,80
SR lamp examination-bilateral	26	✓	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30	2,30
Indirect ophthalmoscopy	14	✓	2,60	1,30	1,30	1,30	1,30	1,30	1,30	1,30	1,30	1,30	1,30	1,30	1,30	1,30	1,30
FA-unilateral	14	✓	10,10	20,20													20,20
FP-bilateral	7	✓	3,70	3,70													3,70
SD-OCT-bilaterally	26	✓	5,00	5,00	5,00	5,00	5,00	5,00	5,00	5,00	5,00	5,00	5,00	5,00	5,00	5,00	5,00
Interpretation and Report for SD-OCT-	26	✓	1,70	1,70	1,70	1,70	1,70	1,70	1,70	1,70	1,70	1,70	1,70	1,70	1,70	1,70	1,70
Physical examination	2	✓	3,70														3,70
Vital signs	27	✓	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60
ECG	3	✓	4,30	4,30													4,30
Adverse events	27	✓	1,10	1,10	1,10	1,10	1,10	1,10	1,10	1,10	1,10	1,10	1,10	1,10	1,10	1,10	1,10
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	3	✓	1,70	1,70													1,70
Collection of specimen; urine for Urinalysis/UPCR	25	✓	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60
PK samples (Sparse)	6	✓	1,40	1,40													1,40
Preparation of sample for shipping	27	✓	0,90	0,90	0,90	0,90	0,90	0,90	0,90	0,90	0,90	0,90	0,90	0,90	0,90	0,90	0,90
Study Drug (active or sham)-IVT injection	23	✓	20,50	20,50	20,50	20,50	20,50	20,50	20,50	20,50	20,50	20,50	20,50	20,50	20,50	20,50	20,50
Procedures Sub Total (€)			€ 39,30	€ 71,10	€ 39,30	€ 39,30	€ 63,70	€ 39,30	€ 39,30	€ 39,30	€ 39,30	€ 39,30	€ 39,30	€ 39,30	€ 39,30	€ 39,30	€ 52,90

Non Procedure	Qty	OH	Budget	V14D309	V15D337	V16D365	V17D393	V18D421	V19D449	V20D447	V21D505	V22D533	V23D561	V24D589	V25D617	V26D645	V27E05
Study Coordinator, Simple-Randomization, Data entry	28	✓	4,00	4,00	4,00	4,00	4,00	4,00	4,00	4,00	4,00	4,00	4,00	4,00	4,00	4,00	4,00
Study nurse	28	✓	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60	2,60
PI time	28	✓	5,50	5,50	5,50	5,50	5,50	5,50	5,50	5,50	5,50	5,50	5,50	5,50	5,50	5,50	5,50
Pharmacy, Complex-Dispense drug	23	✓	2,80	2,80	2,80	2,80	2,80	2,80	2,80	2,80	2,80	2,80	2,80	2,80	2,80	2,80	2,80
Physician: Ophthalmology - DRM Assessment	20	✓	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40	5,40
Non Procedures Sub Total (€)			€ 20,30	€ 20,30	€ 20,30	€ 20,30	€ 20,30	€ 20,30	€ 20,30	€ 20,30	€ 20,30	€ 20,30	€ 20,30	€ 20,30	€ 20,30	€ 20,30	€ 12,10

Overhead (all costs) 16%
Total Cost Per Visit with Overhead(€)
€ 69,10 € 106,00 € 69,10 € 69,10 € 97,40 € 69,10 € 69,10 € 69,10 € 69,10 € 69,10 € 69,10 € 69,10 € 69,10 € 69,10 € 69,10 € 69,10 € 69,10 € 75,40

Detailed Budget – Conditional Fees: / Podrobný rozpočet – podmienené poplatky
Screening Failure / Zlyhanie skriningu
Payee: Study Nurse / Prijemca platby: Štúdičná sestra

Procedure	SV
Informed Consent (ICF)	3,00
Re-Consent	2,50
Inclusion/Exclusion Eligibility	2,30
Medical History	3,50
Demographics	1,40
Concomitant medications	1,00
BCVA (ETDRS) and refraction-Bilateral	0,50
IOP-bilateral	1,80
Slit lamp examination-bilateral	2,30
Indirect ophthalmoscopy	2,60
FA-unilateral	20,20
FP-bilateral	3,70
SD-OCT-bilaterally	5,00
Interpretation and Report for SD-OCT-	1,70
Physical examination	3,70
Vital signs	2,60
ECG	4,30
Adverse events	1,10
Blood draw for Serum pregnancy, Hematology, Blood Chemistry, Anti-Drug- Antibody Serum Sample	1,70
Preparation of sample for shipping	0,90
Procedures Sub Total (€)	€ 65,80
Non Procedure	SV
Study Coordinator, Simple-Randomization, Data entry	8,00
Study nurse	5,20
PI time	11,00
Non Procedures Sub Total (€)	€ 24,20
Overhead (all costs)	€ 14,40
Total Cost Per Visit with Overhead(€)	€ 104,40

Detailed Budget – Site Fees / Podrobný rozpočet – poplatky pre pracovisko
Payee: Study Nurse / Prijemca platby: Štúdičná sestra

Site Costs	Qty	Budget
Study Start-Up Fee/Site Set-Up Fee	1	78,50