# **GRANT AGREEMENT**

The **parties** to this agreement are:

Novo Nordisk Denmark A/S Att.: Christian Klyver Tikkanen Ørestads Boulevard 108, 6. 2300 København S

Kompagnistræde 22, 2. sal, baghuset 1208 København K

Company registration no. **CVR No. 38180045** 

Company registration no. **CVR No.11802990** 

**Danmarks Bløderforening** 

("Novo Nordisk")

("Recipient")

# 1. Purpose and nature of the grant



### 1.1 Recipient's request and healthcare purpose

The Recipient's request for financial support from Novo Nordisk for its activity Undersøgelse af livskvalitet blandt danske blødere 2021-22 is detailed in Attachment A. The Recipient shall use the grant only for the healthcare-related purpose of investigate development of HRQoL and patient satisfaction amongst Danish patients with haemophilia as described in Attachment A. The Recipient's purpose must not involve promotion of any pharmaceutical product.

# 1.2 Novo Nordisk's support

Novo Nordisk has decided the Recipient's request is worthy of support as part of Novo Nordisk's commitment to healthcare research.

Novo Nordisk agrees to grant to the Recipient the amount of DKK 45.657 to support the request.

Novo Nordisk will not make any non-financial transfers of value.

# 2. Start and end dates of this agreement



This agreement shall become effective as of date of last signatory and shall remain effective until sixty (60) days after the parties have fulfilled their obligations under it.

# 3. Recipient's duties



# 3.1 Inform Novo Nordisk of changes affecting the request

The Recipient shall inform Novo Nordisk promptly of changes affecting the nature, purpose, budget, participants or timing of the requested support. Novo Nordisk may increase, decrease, withdraw or demand full or partial repayment of the grant as a result of the changes. If Novo Nordisk demands full or partial repayment, the Recipient shall comply with the demand within 14 days.

# 3.2 Account for the activity within 1 month after completion

Within 1 month after completing the activity supported by the grant, the Recipient shall provide to Novo Nordisk a report or letter evidencing that the grant was used for its intended purpose. The Recipient may provide this documentation in the form of a letter or invoice with attachments, or other similarly substantiated written form acceptable to Novo Nordisk.

## 3.3 Refund any unspent amounts

The Recipient shall refund to Novo Nordisk any amounts not spent for the requested purposes, as shown by the accounting and documentation.

# 3.4 Be responsible for proper conduct of the grant activity

The Recipient shall ensure that all activities covered by the Novo Nordisk grant are in compliance with Novo Nordisk's standards and applicable industry codes, including but not limited to:

- that the activity venue is reasonable and suitable for business meetings and only modest hospitality is offered;
- that travels are of reasonable standard within reasonable time before and after the grant activity;
- that the Novo Nordisk grant is not used for any tours, concerts, entertainment or other leisure or social activities;
- that advertising or trade names of medicinal products are not included in the educational content and materials used for the grant activity;
- that all speakers, facilitators, and chairpersons are experts in the professional fields relevant for the purpose of the grant; and
- that appropriate criteria for participation in the grant activity are applied.

### 3.5 Publicise Novo Nordisk as grant provider

The Recipient shall mention Novo Nordisk's name as a grant provider in publicity, advertising, announcements, articles, media releases or similar communications in relation to the supported activity.

### 3.6 Use Novo Nordisk branding only if approved

The Recipient may not use Novo Nordisk's logo, trademarks or other corporate identity marks or materials unless Novo Nordisk approves the use in advance in writing. Any use must comply with Novo Nordisk's Brand Manual (https://brandportal.novonordisk.com/).

### 4. General conditions



### 4.1 No conflict of interest

Recipient states it is not aware of any conflict of interest related to its acceptance of the grant. Recipient shall inform Novo Nordisk promptly if it discovers such a conflict of interest.

### 4.2 Compliance with law and ethics

When carrying out the activity supported by the grant, Recipient shall perform the activity in a proper, fair and balanced way and comply with all applicable laws, regulations, codes of practice, guidelines and industry standards, among others those related to bribery, corruption and unethical business practices. Recipient shall not give or receive bribes to obtain undue or improper advantage.

Novo Nordisk contract parties may securely and confidentially report suspected misconduct through the Novo Nordisk compliance hotline,

<u>www.novonordisk.com/compliancehotline</u> Recipient shall inform its personnel about this compliance hotline where relevant.

Novo Nordisk will not be responsible for any deviation or departure from relevant laws, standards, regulations and guidelines ("Deviations") and Recipient will indemnify, defend and hold Novo Nordisk harmless against any claim or suit brought against Novo Nordisk due to such Deviations that are not due to any act or omission by Novo Nordisk.

The Recipient acknowledges and accepts that Novo Nordisk must report the grant to ENLI (Etisk Nævn for Lægemiddelindustrien) in accordance with ENLI's advertising code for advertising, etc. directed towards healthcare professionals (Kodeks vedrørende reklame m.v. for lægemidler rettet mod sundhedspersoner).

# 4.3 Parties act independently

Recipient shall organise and conduct the supported activity independently from Novo Nordisk. Recipient shall incur all expenses and other financial commitments and take all other actions related to the supported activity in its own name and for its own account. By making the grant, Novo Nordisk does not assume any right or responsibility to influence the activity's content or conduct, or otherwise act on behalf of Recipient.

#### 4.4 Grant is not an incentive

Novo Nordisk states and Recipient acknowledges that the grant is not an incentive or reward for the past, present or future willingness of Recipient, its employees or participants in Recipient's activities to prescribe, administer, recommend, purchase, pay for, reimburse, authorise, approve or supply, or to support in any other way, Novo Nordisk's products or services.

### 4.6 Parties may terminate upon breach

Either party may terminate this agreement with immediate effect upon a material breach by the other party.

### 4.7. Dispute resolution and applicable law

The parties shall use reasonable efforts to settle all matters in dispute amicably. Where settlement is not possible, disputes will be subject to the jurisdiction of the courts in the Recipient's location. The laws of that jurisdiction will apply to all disputed matters, to the exclusion of any rule that would refer the subject matter to another forum.

### 4.8. Parties' internal approvals

Each party states that the grant and this agreement have been approved by an authorised person according to the organisation's standard procedures.

### 5. Attachments



The following attachments are part of this agreement:

Attachment A: Recipient's request for support (application form, letter or email), with detailed program plan, timeline and budget

Attachment B: Invoice instructions for Recipient

Attachment C: Grants to HCOs and Patient Organisations: required public disclosures and handling of employee data

### **SIGNED BY:**

Date: 01 september 2021 Date: 26 August 2021

On behalf of Recipient:

DocuSigned by:

Laren Binger Holm

46A0A742616D4F7...

4E1C3DF19CEF424...

Name: Karen Binger Holm Title: Sekretariatsleder

Name: Christian Klyver Tikkanen Title: Sr Market Access Manager/RMA

Date: 26 August 2021

On behalf of Novo Nordisk:

On behalf of Novo Nordisk:

DocuSigned by:

Markus Hochmuth

DocuSigned by:

Name: Makus Hochmuth

**Title: Director, MAPA Biopharm & Diabetes** 

### **Attachment A to Grant Agreement**

# Recipient's request for support (application form, letter or email)

Kære Mikkel

På vegne af Danmarks Bløderforening sender jeg her ansøgning om støtte til den kommende undersøgelse af QoL blandt danske blødere.

Vedhæftet er en kort projektbeskrivelse, budget og tidsplan.

 $Rapport\ fra\ den\ seneste\ QoL\ undersøgelse\ fra\ 2012\ kan\ ses\ på\ Bløderforeningens\ hjemmeside: \underline{https://www.bloderforeningen.dk/om-foreningen/projekter/livskvalitet/livskvalite$ 

Ring eller skriv endelig, hvis der er spørgsmål til ansøgningen.

Jeg glæder mig til at høre fra dig.

God sommer!

Venlig hilsen Karen

Karen Binger Holm Sekretariatsleder

Danmarks Bløderforening Kompagnistræde 22, 2. sal baghuset 1208 København K Tlf. 33 14 55 05 Mobil 60 24 62 77 www.bloderforeningen.dk kbh@bloderforeningen.dk

# Detailed program/research project plan, timelines and budget

### Baggrunden for projektet

Formålet er at undersøge de forhold, der spiller ind på bløderes livskvalitet anno 2021 og at følge udviklingen i blødernes livskvalitet siden 1988. I 2012 gennemførte Danmarks Bløderforening for tredje gang en livskvalitetsundersøgelse af blødere i Danmark. Som i 1989 og 2001 var undersøgelsen målrettet blødere i alle aldre med moderat til svær hæmofili A og B samt von Willebrands sygdom type 3. Datagrundlaget fra de tre undersøgelser giver en unik mulighed for at vurdere blødernes helbred og livsforhold gennem en trediveårig periode og en enestående mulighed for at kunne sammenligne udviklingen i erhvervstilknytning, sociale forhold og fysisk funktionsevne blandt blødere over en så lang periode. Det planlægges nu at følge op med et yderligere initiativ til formidling af opdaterede data, da behandlingsmetoderne er forbedret siden 2012.

I forhold til den almene befolkning havde blødergruppen i 2001 generelt et lavere selvvurderet helbred, fortsat en generelt lavere erhvervsfrekvens og en større andel var på førtidspension. Så hvordan tegner livet sig for blødergruppen i dag? Det er et væsentligt spørgsmål at undersøge, da vi i dag har en generation af børn og unge, der har haft adgang til forebyggende behandling livet igennem samt en hel generation af ældre blødere. Hvordan klarer bløderne sig for eksempel, når de kommer op i årene efter et langt liv med blødersygdom?

Blødersygdommene hæmofili A og B samt von Willebrands sygdom er sjældne, medfødte og kroniske sygdomme. Omkring 450 danskere lider af hæmofili, mens knapt 400 har von Willebrands sygdom. Blødersygdomme skyldes en nedsat mængde af en af de komponenter, der hjælper blodet til at størkne. Hyppigst forekommer blødninger inde i kroppen i muskler eller led, hvilket på sigt kan medføre ledskader. Der er forskel på, hvor stor indvirkning sygdommen har på hverdagslivet afhængig af sygdommens sværhedsgrad, tilstedeværelsen af andre kroniske sygdomme og personens alder. I dag kan de fleste blødere behandles med faktormedicin, hvilket betyder, at personer med adgang til forebyggende og tilstrækkelig behandling kan leve et forholdsvis normalt liv med blødersygdom. Livsforholdene for de forskellige grupper af blødere er således meget forskelligartede, hvorfor det fortsat er værdifuldt at følge udviklingen i blødernes livskvalitet. Det betyder også, at alder/generation implicit bliver en signifikant

Danmarks Bløderforening

faktor i forhold til hvilke behandlingsmuligheder, den enkelte har og har haft adgang til livet igennem, og hvilke følgevirkninger af blødersygdommen, der opleves i dag.

Den væsentligste udvikling i blødernes livskvalitet siden 1988 var en generel, positiv effekt af de forbedrede behandlingsmuligheder. Langt færre børn havde oplevet at være hospitalsindlagt i længere perioder, og der var ikke længere behov for hjemmeundervisning eller fritagelse fra skolefag. Et andet træk var, at sygefraværet for alle aldersgrupper var faldet, og at stort set alle tog faktorpræparat ved blødninger. Yngre blødere oplevede i mindre grad bevægeindskrænkninger i forhold til tidligere, og en mindre andel af de 16-34-årige oplevede ledproblemer.

Det væsentligste formål med en ny undersøgelse er således fortsat at følge udviklingen i blødernes livskvalitet fra 1988 og frem til i dag.



### **Budget og finansiering**

Budget	Note	DKK
Databearbejdning, analyse og	588 timer á 450 kr., Københavns	264.600 kr.
formidling	Universitet	
Opsætning og datatræk i	200 timer á 275 kr., Københavns	55.000 kr.
SurveyXact	Universitet	
Udsendelse via centrene	Sekretærbistand til udsendelse	20.000 kr.
	via e-boks á 10.000 kr., AUH og	
	Rigshospitalet	
Artikelgebyr		30.000 kr.
Projektledelse	Danmarks Bløderforening	50.000 kr.
I alt		419.600 kr.

Hoffmanns og Husmans Fond har bevilget 100.000 kr. Restfinansieringen søges gennem tilskud fra medicinalfirmaer med produkter til behandling af hæmofili og von Willebrands sygdom. Der søges i alt om støtte på 319.600 kr., estimeret til 45.657 kr. pr. firma.

### Tidsplan

Udgangspunktet er at der i september 2022 vil kunne præsenteres data om danske blødere når den europæiske paraplyorganisation for blødere European Haemophilia Consortium (EHC) afholder sin årlige konference i København.

### Milestones:

- Formulere og revidere spørgeskema i august-september 2021
- Undersøgelsen gennemføres i oktober 2021
- Data renses og bearbejdes i november-december 2021
- Artikler skrives januar-april 2022 (udarbejdelse af to artikler)
- Rapport skrives i maj-juni og sendes til følgegruppe midt juni 2022
- Revideret rapport og forberedelse til konference august-september (ferie i juli) 2022

Eftersom data der præsenteres på konferencer skal være publiceret i videnskabelige artikler afsættes tid til artikler før rapportskrivning.

### **Attachment B to Grant Agreement**

### **Invoice instructions for Recipient**

Novo Nordisk requires a complete and correct invoice from the recipient before paying the grant amount.

Novo Nordisk will pay invoices only via electronic funds transfer to the Recipient's account.



### **INVOICE CONTENTS**

Any invoice that does not meet the criteria below will be returned for correction.

### Recipient's information

- Recipient's full company name and address (the company signing the Grant Agreement)
- Bank account for electronic payment: account holder name, account number (IBAN), bank name and address, routing number or code (SWIFT/BIC in EU )

### **Invoice information**

- Invoice number or reference
- Invoice date
- > Specification of the account entry type (invoice, credit note, etc.)

#### **Grant information**

- Quantity and nature of the grant activity covered by the invoice
- > Date (if known) of the grant activity covered by the invoice
- Grant amount payable and currency

### **Novo Nordisk information**

- Novo Nordisk's full company name and address (the company signing the Grant Agreement):
  - Novo Nordisk Denmark A/S, Ørestads Boulevard 108, 6., 2300 København S
- Novo Nordisk contact person's full name and initials: CTIK Christian Klyver Tikkanen

### **VAT or sales tax information** (only where applicable by law)

- VAT or other tax amount payable
- > VAT or other tax rate applied
- Novo Nordisk company VAT number: 38180045

### Send invoices or credit notes by email with attached pdf (no paper copy) to:

### **Novo Nordisk Denmark A/S**

<u>CJZY@novonordisk.com</u> with a copy to Novo Nordisk contact person

### **Attachment C to Grant Agreement**

Grants to HCOs and Patient Organisations: required public disclosures and handling of employee data

Novo Nordisk, as a member of EFPIA (the European Federation of Pharmaceutical Industries and Associations), is required to make public the details of payments or inkind transfers made to Recipient.

Novo Nordisk will publish information relating to this Grant on Novo Nordisk's website (<a href="https://www.novonordisk.dk/about/etiske-regler.html">https://www.novonordisk.dk/about/etiske-regler.html</a>). According to local regulations Novo Nordisk may in addition make this Grant Agreement publicly available.

The Recipient shall provide to Novo Nordisk upon request all information reasonably required for Novo Nordisk's compliance with legal and/or regulatory requirements for contracting, tracking and disclosing transfer of values (ToVs) to the Recipient.

Recipient will publish information on the Grant on the Recipient's webpage. The information will include the Grant amount and, if applicable, any in kind transfer, cf. the Danish Pharmaceutical Promotional Act (Reklamebekendtgørelsen) § 21. Publication must be made ensuring that support received from pharmaceutical companies is clearly separated. The information must be available on the Recipient's webpage no later than one (1) month after the Recipient received the Grant. The information must be publicly available for at least two (2) years.

Novo Nordisk hereby informs the Recipient that information about the Recipient is collected, used, stored, transferred and disclosed (collectively "Processed") by or on behalf of Novo Nordisk. Novo Nordisk processes information such as name, business address, contact details, nature of relationship with Novo Nordisk, tax number, unique identifier, and any ToVs from Novo Nordisk to the Recipient.

Whenever the Recipient shares with Novo Nordisk information about its employees, the Recipient shall inform the employees that their information is being shared and provide them with all information required under Article 13 and 14 of the General Data Protection Regulation, if applicable, and under other applicable data privacy laws. The Recipient shall indemnify Novo Nordisk and any affiliate of Novo Nordisk against all claims, expenses, losses and damages or liabilities arising from the Recipient's breach of its obligations to provide this information to its employees.

### Certifikat for færdiggørelse

Kuvert-id: 24E4EB2BD95646BBA7187A24B2BE7803

Emne: Please DocuSign: Grant Agreement\_Livskvalitet blandt blødere\_Aug2021.doc

Kildekuvert:

Dokumentsider: 10 Underskrifter: 3 Certifikatsider: 2 Initialer: 0

Autonavigation: Aktiveret Kuvertstempling: Aktiveret

Tidszone: (UTC+01:00) Brussels, Copenhagen, Madrid, Paris

Status: Gennemført

Kuvertskaber: Charlotte Jensen

**Tidsstempel** 

Sendt: 26 august 2021 | 14:14

Signeret: 26 august 2021 | 15:01

Sendt: 26 august 2021 | 15:01

Vist: 26 august 2021 | 15:02 Signeret: 26 august 2021 | 15:02

Vist: 26 august 2021 | 14:56

Ørestad Boulevard 108 København S, Denmark 2300

cizy@novonordisk.com IP-adresse: 152.73.10.43

Sporing af poster

Status: Original Ihændehaver: Charlotte Jensen Sted: DocuSign

4E1C3DF19CEF424.

Vælg underskrift: Forudvalgt stil

Brug af IP-adresse: 152.73.10.47

26 august 2021 | 14:12 cizy@novonordisk.com

Hændelser for underskriver **Underskrift** 

Christian Klyver Tikkanen Christian Elguer Tikkanen CTIK@novonordisk.com

Sr. Market Access Manager/RMA

Sikkerhedsniveau: E-mail, Kontogodkendelse

(ingen)

Oplysninger om elektroniske poster og underskrifter:

Tilbydes ikke via DocuSign

Markus Hochmuth Markus Hodimuth MRPH@novonordisk.com

MAPA DIR

Sikkerhedsniveau: E-mail, Kontogodkendelse

(ingen)

Vælg underskrift: Forudvalgt stil Brug af IP-adresse: 213.237.69.98 Underskrevet vha. mobil

Oplysninger om elektroniske poster og underskrifter:

Tilbydes ikke via DocuSign

Karen Binger Holm kbh@bloderforeningen.dk

CEO

Sikkerhedsniveau: E-mail, Kontogodkendelse

(ingen)

Vælg underskrift: Forudvalgt stil Brug af IP-adresse: 188.182.250.158

karen Binger Holm

Sendt: 26 august 2021 | 15:03

Gensendt: 01 september 2021 | 14:21 Vist: 01 september 2021 | 14:24 Signeret: 01 september 2021 | 14:26

Oplysninger om elektroniske poster og underskrifter:

Tilbydes ikke via DocuSign

Hændelser for personlig underskriver	Underskrift	Tidsstempel
Hændelser for redaktørlevering	Status	Tidsstempel
Hændelser for agentlevering	Status	Tidsstempel
Hændelser for midlertidig levering	Status	Tidsstempel
Hændelser for certificeret levering	Status	Tidsstempel
Hændelser for kopi (cc:)	Status	Tidsstempel

Vidnehændelser	Underskrift	Tidsstempel
Notarhændelser	Underskrift	Tidsstempel
Hændelser for kuvertoversigt	Status	Tidsstempler
Kuvert sendt	Med hash/krypteret	26 august 2021   14:14
Leveret certificeret	Sikkerhedskontrolleret	01 september 2021   14:24
Signering fuldført	Sikkerhedskontrolleret	01 september 2021   14:26
Gennemført	Sikkerhedskontrolleret	01 september 2021   14:26
Betalingshændelser	Status	Tidsstempler