## **GRANT AGREEMENT**

The **parties** to this agreement are:

Novo Nordisk Denmark A/S Att.: Markus Peter Hochmuth Ørestads Boulevard 108, 6. 2300 København S Diabetesforeningen Stationsparken 24 st.tv. 2600 Glostrup

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

Company registration no. **CVR No. 35231528** 

("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 Diabetes Impact Study is detailed in Attachment A. The Recipient shall use the grant only for the healthcare-related purpose of Diabetes awareness 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 145.000 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.

## 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:**

On behalf of Recipient: On behalf of Novo Nordisk:

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Name: Tanja Thybo Name: Markus Peter Hochmuth

Title: Head of Research Title: Market Access Director

## **Attachment A to Grant Agreement**

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

# Ansøgning om støtte til nyt "Diabetes Impact Study"

Diabetesforeningen har indgået et samarbejde med MedEngine om at kortlægge udviklingen og fremskrive prognosen for forekomsten og den sociale ulighed i diabetes og følgesygdomme hertil, samt de samlede samfundsøkonomiske omkostninger i Danmark.

Til analysen anvendes data fra det Nationale Diabetesregister, der omfatter flere indikatorer for diabetespatienter og bygger på kombinationen af data fra allerede eksisterende registre, herunder Landspatientregisteret (LPR), Sygesikringsregisteret, Lægemiddelstyrelsens Lægemiddelstatistik-register og CPR-registeret. Desuden indhentes supplerende socioøkonomiske indikatorer fra Danmarks Statistiks registrer, herunder indkomstregistret og DREAM.

Den epidemiologiske kortlægning belyser prævalens, incidens, morbiditet og mortalitet samt den socioøkonomiske ulighed og udviklingen heri. Omkostningerne ved diabetes dækker de direkte omkostninger til sundhedsbehandling, medicin og pleje samt de indirekte omkostninger i form af produktivitetstab og øgede udgifter til overførselsindkomster. Analysen af omkostningerne foretages for forskellige komplikationsgrupper, defineret med udgangspunkt i kombinationer af følgesygdomme.

Arbejdet starter 1. april 2021 og munder ud i en rapport samt manuskriptet til en videnskabelig publikation 1. februar 2022.

Undersøgelsen er en selvstændig del af projektet SPOTTED (se bilag 1 og 2), der undersøger om der er belæg for at søge Sundhedsstyrelsen om oprettelsen af et nyt nationalt screeningsprogram for type 2-diabetes.

Arbejdet med MedEngine koster 435.000 DKK + moms. Hertil kommer interne ressourcer på 0,5 FTE, som dækkes af Diabetesforeningen. Se bilag 3.

Diabetesforeningen har mundtligt tilsagn fra to medicinalvirksomheder om støtte op til i alt DKK 290.000. Vi søger derfor Novo Nordisk Denmark A/S om et sponsorat til hjælp til finansiering af projektet ifølge nedenstående model:

#### Detailed program/research project plan, timelines and budget

Novo Nordisk Denmark A/S	145.000 DKK
Medicinalfirma 1	145.000 DKK
Medicinalfirma 2	145.000 DKK
I alt	435.000 DKK
Diabetesforeningen	0.5 FTE

# Beløbet tillægges moms.

# **Baggrund**

Mere end hver tredje person har mindst en følgesygdom til diabetes på det tidspunkt de diagnosticeres med type 2-diabetes (T2D). Følgesygdomme nedsætter livskvaliteten for personer med diabetes, øger deres dødelighed og er forbundet med omfattende samfundsøkonomiske meromkostninger.

## Formål

- Påvise omkostningseffektiviteten ved målrettet screening af personer, der ikke har fået målt deres HbA1c indenfor de seneste 2 år.
- Ansøge Sundhedsstyrelsen om oprettelsen af et nyt nationalt screeningsprogram primo 2023.

## Fakta Type 2-diabetes i DK 2021

252.000 har T2D
76.000 menes at have T2D uden at vide det
360.000 menes at have præ-

diabetes

2022 2023 2021 IMPACT STUDIE -Ansøgning til Sundheds-PILOT SCREENING STUDIE • Hvad koster T2D det styrelsen om danske samfund? **COST-EFFECTIVENESS** Hvad koster screening nyt nationalt ■ De T2D relaterede for T2D? Kan vi spare penge, hvis screeningssamfundsøkonomiske ■ Sammenligning af T2D opdages tidligere? omkostninger i dag. program for screeningsmodeller ■ Komplikationer der type 2-■ Etablering af en årlig ■ Udgifter til opsporing af kan forebygges. diabetes opdatering af tallene. én person med T2D. ■ Den samlede samfunds økonomiske gevinst. ■ Barrierer for deltagelse i screening.

## Appendix 2: Workplan including budget for ApHER and tentative timeline

Yellow background: First payment Green background: Second(final) payment

Activity	Role: Danish Diabetes Association	Role: ApHER	ApHER budget (DKK)	Time usage (mths)	Time Line - Date completed*
Production of specification of work and relevant supporting material	Commenting	Primary responsible	15.000	1	01APR2021
Establishment of analysis facility at Statistics Denmark with access for selected ApHER Staff	Primary responsible	None	0		01APR2021
Specification and acquisition of data Tables and variables available at Statistics Denmark External data to be imported: The Danish Health and Medicines Authority DADD	Primary responsible	Consulting concerning Source registers Tables Variables	15.000	1 + waiting time	01JUL2021
Initial data management  Check of source data received  Preparation and validation of source data	Primary responsible	Consulting	15.000	1	01AUG2021
Creation of the diabetes population Resource tables' Identification of individuals with diabetes Diabetes trajectories enriched with demographical and clinical data	Contributing	Primary responsible	75.000	2	01OCT2021
Establishment of analysis module     Establishment of analysis facility at the Danish Diabetes Association     Creating algorithms for exporting apprepated epidemiological data     Establishment of automated epidemiological analysis module in spreadsheet(s)     Establishment of automated reporting module	Contributing	Primary responsible	75.000	2	01JAN2022*
Diabetes Impact 2019: Acquisition of socio-economic data Establisment of reference group Epidemiological analyses Health economic analyses	Primary responsible Primary responsible Contributing Contributing	Consulting Consulting Primary responsible Primary responsible	175.000	5°	01JAN2022°
Powerpoint presentation     Manuscript: First publication	Commenting Contributing	Primary responsible Primary responsible	65.000	1	01FEB2022

<sup>\*</sup> Tentative only because of uncertain waiting time for access to data
b DADD: The Danish Adult Diabetes Database (DADD), managed by the Danish Clinical Quality Program – National Clinical Registries (Regionernes Kliniske Kvalitetsudviklingsprogram, RKKP)

e Assumes work with 'Establishment of analysis module' in parallel with the health economic analyses

#### **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. Please send invoice within 15 days.

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: Markus Peter Hochmuth MRPH

#### **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**

CJZY@novonordisk.com 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