

## RESEARCH COLLABORATION AGREEMENT

**THIS COLLABORATION AGREEMENT** is effective as of **2019 04-09** (the “Effective Date”) between **Novartis Healthcare A/S**, Edvard Thomsens Vej 14, 3.2300 Copenhagen, Denmark

1. (“Novartis”), and Amager-Hvidovre hospital, Kardiologisk ambulatorium M41, placeret Rigshospitalet-Glostrup, Valdemar Hansens Vej 13, 2600 Glostrup. Novartis and Amager-Hvidovre hospital, Kardiologisk ambulatorium M41, placeret Rigshospitalet-Glostrup may be referred to individually as a “Party” and collectively as the “Parties” in this Agreement.

### BACKGROUND:

**WHEREAS**, Novartis is a global healthcare company that provides solutions to address the evolving needs of patients worldwide, with a mission to discover new ways to improve and extend people’s lives and a vision is to be a trusted leader in changing the practice of medicine.

**WHEREAS**, Amager-Hvidovre hospital, Kardiologisk ambulatorium M41, placeret Rigshospitalet-Glostrup develop specialized health service, where the patients experience coherence and high professional quality.

**WHEREAS**, The Parties Novartis have identified opportunities with the potential to enable an increase of the quality of the healthcare system in relation to treatment of heart failure patients, and therefore wish to collaborate with respect to certain activities described in, and in accordance with the provisions of, this Agreement.

### AGREEMENT:

**NOW, THEREFORE**, for good and valuable consideration, the Parties agree as follows:

#### 1. PURPOSE AND SCOPE

- 1.1. The Parties have agreed to collaborate in the project described in Appendix 1 (hereinafter the “Project”). The objective of the Project is to enable a possibility to increase the quality of treatment for patients that have symptomatic heartfailure.
- 1.2. Except as otherwise specifically provided in this Agreement and its appendices, each Party will be responsible for its own costs and expenses incurred in connection with the performance of its obligations in the Project, including with respect to all labor and material costs incurred by that Party.
- 1.3. Except as otherwise agreed in writing, each Party will have performed the work in the Project through its employees and personnel.
- 1.4. Neither Party shall subcontract any of its obligations under this Agreement without the prior written consent of the other Party.
- 1.5. Each Party warrants and represents that it shall perform its obligations under this Agreement (i) with high ethical and moral business and personal integrity standards, (ii) in compliance with all industry standards and applicable laws, rules and regulations, including those related to anti-corruption, and (iii) in compliance with the Novartis Global Anti-Bribery Policy attached hereto as Appendix 3.

- 1.6. Amager-Hvidovre hospital, Kardiologisk ambulatorium M41, placeret Rigshospitalet-Glostrup, Valdemar Hansens Vej 13, 2600 Glostrup shall comply with – and shall cause the nurses, clinics and others that are involved in the performance of the Project to comply with - the applicable statutory provisions regarding data protection. The parties undertake to enter into a separate agreement on personal data processing should this be required under the applicable data privacy legislation.
- 1.7. The Parties hereby clarify that it is Amager-Hvidovre hospital, Kardiologisk ambulatorium M41, placeret Rigshospitalet-Glostrup, Valdemar Hansens Vej 13, 2600 Glostrup responsibility to obtain and maintain, and ensure that clinics and health care professionals involved in the Project obtain or maintain, all authorizations, third party approvals or permissions required to perform the work in the Project, as applicable.

## **2. COMPENSATION**

- 2.1. Novartis has agreed to financially support the Project as set out in Appendix 2 (hereinafter the “Financial Support”). The Financial Support may only be used for agreed Project activities set out in this Agreement and its appendices. If, upon completion of the Project, amounts paid out as Financial Support remain unused, such surplus shall be paid back to Novartis.
- 2.2. Amager-Hvidovre hospital, Kardiologisk ambulatorium M41, placeret Rigshospitalet-Glostrup, Valdemar Hansens Vej 13, 2600 Glostrup confirms that (i) the Financial Support may only be used for agreed Project activities set out in this Agreement and its appendices, (ii) the Financial Support represents fair market value for the work to be performed in the Project, (iii) it is not receiving any financial compensation from Novartis in exchange for any explicit or implicit agreement to cause any health care professionals or clinics to recommend, purchase, prescribe, or provide favorable status for any of Novartis’ products and (iv) the Financial Support does not constitute any reward for past or future business.
- 2.3. Novartis shall send a Purchase Order to Amager-Hvidovre hospital, Kardiologisk ambulatorium M41, placeret Rigshospitalet-Glostrup, Valdemar Hansens Vej 13, 2600 Glostrup [anne-lise.joergensen@regionh.dk](mailto:anne-lise.joergensen@regionh.dk) which shall contain the necessary details for invoicing. Payment will be made by Novartis within sixty (60) days from the date of receipt of a corresponding invoice, to the bank account specified by Consultant in accordance with 2.1
- 2.4. Amager-Hvidovre hospital, Kardiologisk ambulatorium M41, placeret Rigshospitalet-Glostrup, Valdemar Hansens Vej 13, 2600 Glostrup shall keep accounts over receipts and payments in the Project in line with applicable laws and regulations. Such accounts shall be sufficiently detailed to verify if the Financial Support has been used by Amager-Hvidovre hospital, Kardiologisk ambulatorium M41 in accordance with the provisions of this Agreement.

## **3. PROJECT MANAGEMENT**

- 3.1. Each Party shall appoint a project manager to assume overall responsibility for its respective roles and obligations under this Agreement. Each Party’s project managers will be responsible for (among other things):
  - 3.1.1. coordinating a Party’s performance of work in the Project;

- 3.1.2. participating (whether personally or through a representative) in progress meetings and other meetings, at intervals and locations as may be agreed between the Parties from time to time, to address collaborative activities in the Project and seek to resolve issues arising therefrom; and
    - 3.1.3. Day-to-day liaison between the Parties.
- 3.2. A Party may replace its project manager at any time upon prior written notice to the other Party.
- 3.3. At least once during every calendar months occurring during the term of this Agreement (or at such other intervals agreed between the Parties) and at such locations as may be agreed between the Parties from time to time, the Parties will participate in a meeting or call to discuss and review the progress and status of work performed and to be performed in the Project, and to address actions to be taken in relation to such work with a view to complete its responsibilities that are associated with such work.
- 3.4. Upon completion of the Project, the Parties shall jointly evaluate the Project and their collaboration in the Project.

#### 4. **TERM; TERMINATION; EFFECT OF TERMINATION; SURVIVAL**

- 4.1. **Term.** This Agreement shall come into effect on the Effective Date and, unless terminated earlier in accordance with the provisions of the Agreement continue in effect until completion of the Project.
- 4.2. **Termination without Cause.** Either Party may terminate without cause this Agreement upon thirty (30) days' prior written notice to the other Party.
- 4.3. **Termination for Cause.** A Party may terminate for cause this Agreement upon written notice to the other Party if:
  - (a) the other Party breaches any provision of this Agreement and, if that breach is capable of being cured, does not cure such breach within thirty (30) days following its receipt of written notice thereof from the non-breaching Party, or
  - (b) the other Party ceases business operations, becomes insolvent, or becomes subject to any bankruptcy or other similar legal process or proceeding.

#### 5. **MISCELLANEOUS**

- 5.1. **Assignment.** A Party may not assign or transfer this Agreement (or any of the Party's rights or interests under this Agreement) or delegate or transfer any of the Party's obligations under this Agreement without the other Party's prior written consent.
- 5.2. **Severability.** If any provision in this Agreement is held to be invalid or unenforceable in whole or in part (the "**Invalid Provision**"), the remaining portions of such provision (if any) and the other provisions in this Agreement will remain in effect and the Invalid Provision will remain in effect to the maximum extent allowed by law.

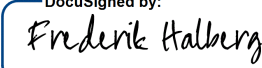
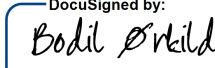


- 5.3. **Non-Waiver.** No waiver of the terms and conditions of this Agreement, or the failure of either Party strictly to enforce any such term or condition on one or more occasions, will be construed as a waiver of the same or of any other term or condition of this Agreement on any other occasion. A waiver of any right or remedy under this Agreement will be binding on a Party only if it is expressly stated in a written document signed by an authorized representative of such Party.
- 5.4. **Notices.** Any notices must be in writing and will be deemed received when delivered personally, when delivered by electronic means with proof of delivery or two business days from the date mailed, if sent by registered or certified mail. Notices will be addressed and sent as follows unless updated by a party by notice in writing

For Novartis: Inge Damsgaard, Medical Science Liaison, 51 59 05 33  
inge.damsgaard@novartis.com

For Amager-Hvidovre hospital, Kardiologisk ambulatorium M41, placeret Rigshospitalet-Glostrup, Valdemar Hansens Vej 13, 2600 Glostrup Bodil Ørkild: [bodil.oerkild@regionh.dk](mailto:bodil.oerkild@regionh.dk)

- 5.5. **Transparency.** The Parties will be entitled to publicly disclose in the appropriate forum or media (including LIF's samarbejdsdatabas) the terms of this Agreement, the Project and any financial compensation for transparency purposes, in accordance with applicable laws, regulations and industry codes, which is accepted by the Parties without any condition nor reserve.
- 5.6. **Applicable Law; Venue; Consent to Jurisdiction.** Each of the Parties hereby agrees that this Agreement shall be solely and exclusively governed, construed and enforced in accordance with the laws of the Denmark, determined without reference to any conflict of laws principles that would otherwise result in the application of the laws of a different jurisdiction. Each of the Parties further agrees to bring or otherwise commence any suit, action, or proceeding arising from or relating to this Agreement exclusively before the Maritime and Commercial Court in Copenhagen or if this court is not competent, before competens court of laws in Denmark
- 5.7. **Independent Contractors.** The relationship between the Parties is that of independent contractors. The Parties are not joint venturers, partners, principal and agent, master and servant, or employer and employee for the purpose of this Agreement, and the Parties acknowledge and agree that they have no relationship under this Agreement other than as independent contracting parties.
- 5.8. **Entire Agreement.** This Agreement, and the documents referred to in this Agreement, constitute the entire agreement and understanding between the Parties with respect to its subject matter and supersedes all previous communications, representations, or agreements, whether written or oral, with respect to its subject matter. Any waiver, modification, or amendment of any of the provisions of this Agreement will be effective only if it is made in writing and signed by the duly authorized representatives of both Parties.
- 5.9. **Counterparts.** This Agreement may be executed in two or more identical counterparts, each of which will be deemed to be an original and all of which taken together will be deemed to constitute the Agreement when a duly authorized representative of each Party has signed a counterpart.

**IN WITNESS WHEREOF**, this Agreement has been executed by the Parties through their duly authorized representatives, to be effective as of the Effective Date.

<p><b>Novartis Healthcare Denmark AS</b></p>	<p><b>Amager-Hvidovre hospital, Kardiologisk ambulatorium M41, placeret Rigshospitalet-Glostrup, Valdemar Hansens Vej 13, 2600 Glostrup</b></p>
<p>DocuSigned by:                    By: <u>CC574A6D3E84454</u></p> <p>Printed Name: Frederik Hallberg</p> <p>Title: Franchise Head Cardio Metabolic                  09-apr-2019   5:02:21 AM EDT</p> <p>Date: _____</p>	<p>DocuSigned by:                    By: <u>6268A39EAE6046D...</u></p> <p>Printed Name: Bodil Ørkild</p> <p>Title: Chief physician                  09-Apr-2019   12:14:09 PM EDT</p> <p>Date: _____</p>
<p>DocuSigned by:                    By: <u>233C64C61CF4454</u></p> <p>Printed Name: Inge Damsgaard</p> <p>Title: Medical Science Liaison C&amp;M                  09-Apr-2019   4:32:00 AM EDT</p> <p>Date: _____</p>	<p>DocuSigned by:                    By: <u>73D2292FDCA843A...</u></p> <p>Printed Name: Jawdat Abdulla</p> <p>Title: Overlæge, ph. d.                  09-Apr-2019   3:05:35 PM EDT</p> <p>Date: _____</p>

## Appendix 1 – Project description

### Baggrund

#### Formål med samarbejdsprojektet

At sikre at patienter med diagnosen kronisk hjertesvigt og som er afsluttet til opfølgning hos praktiserende læger bliver tilbudt re-evaluering af deres tilstand. Målgruppen er patienter, som i løbet af de sidste 5 år har været igennem et behandlingsforløb på hjertesvigtsklinikken (HIK) og som på nuværende tidspunkt ikke får optimal medicinsk behandling. Patienterne vil blive kontaktet telefonisk og tilbudt et opfølgende besøg i HIK.

Ved dette besøg vil man sikre, at patienterne bliver undersøgt og på baggrund heraf får tilbudt opdateret og rekommanderet behandling i henhold til Dansk Cardiologisk Selskabs (DCS) vejledning. Hermed menes både en optimering af den medicinske behandling, men også behov for eventuel device vil blive evalueret.

#### Baggrund for projektet

På trods af specialiseret og dedikeret indsats fra hjerteinsufficiensklinikker (HIK), er der fortsat en betydelig del af patienterne der bliver genindlagt eller genhenvist med suboptimal behandling eller med en behandling der ikke er up-to-date. Kvalitetsundersøgelsen vil belyse og forbedre den videre strategi for håndtering af HFrEF patienter og have stor klinisk og kvalitetsmæssig betydning for de mest kritisk syge patienter i kardiologisk regi.

#### Gennemførelse

Novartis og Amager-Hvidovre hospital, Kardiologisk ambulatorium M41, placeret Rigshospitalet-Glostrup er blevet enige om at gennemføre dette samarbejdsprojekt i henhold til de kriterier der er beskrevet i projektplanen.

#### Tidsplan

Projektet igangsættes 09-04-2019 og forventes afsluttet 31-12-2019.

#### Novartis forpligtelser

Novartis forpligter sig til at samarbejde omkring udarbejdelsen af praktiske redskaber så som

- Interviewguide
- Symptomtjekker til registrering af data
- Følge projektets fremdrift ved forudplanlagte møder

men har ingen indflydelse på projektets protokol, indsigt i patientdata, behandling eller arbejdsgang.

#### Kardiologisk Ambulatorium, M41, Glostrup Sygehus forpligter sig til

Ansvarlig overlæge Jawdat Abdulla forpligter sig til

- At sikre de fornødne godkendelser fra Datatilsynet og den lokale sygehusledelse
- At sikre at dataregistreringen foregår i overensstemmelse med patientsikkerhedslovgivningen
- At publicere resultaterne enten i form af artikler i nationale eller internationale tidsskrifter eller abstracts ved sygeplejerske/lægekongresser

## **Appendix 2 – Financiel kompensation**

### **Fase 1 Overlæge Jawdat Abdulla:**

Udvikling og udarbejdelse af projekt og indhentning og overholdelse af nødvendige tilladelser

Varetage og koordinere intern kommunikation omkring projektet

Publicering af data som beskrevet i projektplan

**Beløb: 36.000 kr**

### **Fase 2 Præscreening (ca 500 pt)**

Gennemgå NIP database og journaler

Gennemgå notater efter at pt er afsluttet fra HIK

Sygeplejersker á 500kr/ time

**Beløb: 50.000kr**

### **Fase 3 Screening (ca. 200 pt)**

Pt. kontaktes telefonisk

Gennemgå medicin, almen tilstand, evt nye diagnoser behandling

Sygeplejerske á 500kr/time

**Beløb 50.000kr**

### **Fase 4 Ambulant samtale (ca. 70 pt)**

Planlægge blodprøver, EKG, evt ekko ud fra valgbarhedskriterier

NYHA vurdering, medicingennemgang,

Dokumentation i pt-journal

Sygeplejerske á 500kr/time

**Beløb 98.000kr**

### **Fase 5 Opgørelse af data og publicering af resultater**

Publiceres i form af artikler i nationale eller internationale tidsskrifter eller abstracts ved sygeplejerske/lægekongresser

Hospitalet pålægger alle projekter et overhead på 18%, hvilket også fremgår af nedestående oversigt

Udbetaling sker via fakturering til Novartis i **2 etaper** med forbehold for at de respektive milestone beskrevet herunder er opfyldt

	I alt DKK.	Overhead 18%	Samlet beløb incl. overhead	Fakturerings tidspunkt
Fase 1-3: Planlægning og udarbejdelse af projekt, præscreening og screening	136.000kr	24.480kr	160.480kr	Når alle parter er enige om aftalens indhold og har underskrevet denne
Fase 4-5: Sygeplejerske amb. samtale: Opgørelse af data, publicering af resultat , evaluering	98.000kr	17.640 kr	115.640kr	01-11-2019
<b>TOTAL</b>	<b>234.000kr</b>	<b>42.120kr</b>	<b>276.120kr</b>	

Hvis det estimeres antal patienter i Fase 4 reduceres med 10% eller mere, forbeholder Novartis sig ret til at reducere betalingen for Fase 4-5 (98.000kr + overhead) tilsvarende

### **Appendix 3 Novartis Anti-bribery Policy**

<https://www.novartis.com/about-us/corporate-responsibility/doing-business-responsibly/ethics-compliance/anti-bribery-anti-corruption>