

RESEARCH COLLABORATION AGREEMENT

THIS COLLABORATION AGREEMENT is effective as of June 28th. **2018** the “Effective Date”) between **Novartis Healthcare A/S**, Edvard Thomsens Vej 14, 3.2300 Copenhagen, Denmark (“Novartis”), and Regionshospitalet Viborg, Hjertemedicinsk Afdeling, Heibergs Allé 4, Postboks 130, DK-8800 Viborg, Danmark, SE nr. 29 76 29 88, og Aarhus University, Department of Clinical Medicine, Palle Juul-Jensens Boulevard 99, DK-8200 Aarhus N, Danmark, VAT 31119103 (jointly “Regionshospitalet Viborg”)

. Novartis and Regionshospitalet Viborg 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, Regionshospitalet Viborg develop specialized health service, where the patients experience coherence and high professional quality.

WHEREAS, Novartis and Regionshospitalet Viborg 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 work together 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 number of symptomatic heartfailure patients referred for re-evaluation on Regionshospitalet Viborg
- 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. Regionhospitalet Viborg shall comply with – and shall if applicable 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 Regionshospitalet Viborg 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. Regionshospitalet Viborg 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 Regionshospitalet Viborg at Jens.Refsgaard@viborg.rm.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. Regionshospitalet Viborg 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 Sahlgrenska 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. **USE AND OWNERSHIP OF DATA, RESULTS AND INTELLECTUAL PROPERTY**

- 4.1. Each Party shall own the Foreground Knowledge created solely by that Party as a result of their participation in the Project. Inventorship and or authorship of intellectual property shall be governed by national intellectual property law applicable for the respective Party and each Institution represents that it has or will obtain assignments of any and all rights in and to Inventions and any and all intellectual property rights thereof from its respective employees.
- 4.2. Foreground Knowledge created during the Project shall be owned by Regionshospitalet Viborg including any deliverable described in Appendix 1.

5. **PUBLICATION**

- 5.1. Novartis recognises the right of Regionshospitalet Viborg to publish any results of scientific interest generated by Regionshospitalet Viborg during conduct of the Project.

6. **TERM; TERMINATION; EFFECT OF TERMINATION; SURVIVAL**

- 6.1. **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.
- 6.2. **Termination without Cause.** Either Party may terminate without cause this Agreement upon thirty (30) days' prior written notice to the other Party.
- 6.3. **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.

7. MISCELLANEOUS

- 7.1. **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.
- 7.2. **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.
- 7.3. **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.
- 7.4. **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

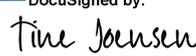
For Novartis: Inge Damsgaard, Medical Science Liaison, 51 59 05 33
inge.damsgaard@novartis.com

For Regionshospitalet Viborg: OKPL-Ledelsen@Viborg.RM.

- 7.5. **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.
- 7.6. **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 competent court of laws in Denmark
- 7.7. **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.

- 7.8. **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.
- 7.9. **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.

Novartis Healthcare Denmark AS	Regionshospitalet Viborg
<p>DocuSigned by:  By: <u>CC574A6D3E84454...</u></p> <p>Printed Name: Frederik Halberg</p> <p>Title: Franchise Head Cardio & Metabolic</p> <p>Date: <u>30-aug-2018 3:17:34 AM EDT</u></p>	<p>DocuSigned by:  By: <u>1CA9254B281C48C...</u></p> <p>Printed Name: Alle De the Bjerrum (for Jens Refsgaard)</p> <p>Title: (Head of Department) over sygeplejerske</p> <p>Date: <u>11-sep-2018 3:13:41 AM EDT</u></p>
<p>DocuSigned by:  By: <u>D750D4F95AB343D...</u></p> <p>Printed Name: Kirsten Bjørklund</p> <p>Title: Sales Manager Cardio & Metabolic</p> <p>Date: <u>30-aug-2018 3:23:58 AM EDT</u></p>	<p>DocuSigned by:  By: <u>E4DFB4894BBC4C8...</u></p> <p>Printed Name: Tine Joensen</p> <p>Title: Head of Research Unit</p> <p>Date: <u>29-aug-2018 5:02:38 AM EDT</u></p> <p>DocuSigned by:  By: <u>758ED6888A8347B...</u></p> <p>Printed Name: Jørgen Frøkiær</p> <p>Title: Head of Department, IKM, Aarhus University</p> <p>Date: <u>31-aug-2018 1:56:57 AM EDT</u></p>

Appendix 1 – Project description

Baggrund

Formål med samarbejdsprojektet

At øge identifikationen af kroniske symptomatiske hjertesvigtpatienter fra primær sektor som har forværring af symptomer og sikre at de bliver genhenvist til Viborg med henblik på optimering af den guidelinebaserede behandling

Baggrund for projektet

Kan man ved at øge fokus på patientgruppen og tilbyde undervisning af læger og sygeplejersker fra GP sektoren øge opsporingen af symptomatiske hjertesvigtpatienter?

Kan man udvikle værktøjer som vil hjælpe GP'er med at identificere denne patientgruppe?

Gennemførelse

Novartis og Viborg Sygehus er blevet enige om at gennemføre dette samarbejdsprojekt i henhold til de kriterier der er beskrevet i projektplanen.

Tidsplan

Projektet igangsættes 28. August 2018 og forventes afsluttet 31-05-2019. I løbet af august/september måned vil der blive afholdt 3 uddannelsesmøder for praktiserende læger og deres klinisygeplejersker i Kjellerup, Skive og Viborg. De praktiserende læger skal herefter fokusere på patienter med diagnosen hjertesvigt i deres klinik og hvis der ved re-evaluering opdages forværring af symptomer, skal disse genhenvises til fornyet evaluering på Viborg Sygehus. Henvisningen markeres med ”Kvalitetsprojekt HF”.

Novartis forpligtelser

Novartis forpligter sig til at samarbejde omkring udarbejdelsen og gennemførelse af dette projekt

- ansvarlig for det praktiske arrangement ved de 3 planlagte undervisningsmøder
- i samarbejde med overlæge Malene Hollingdal, at udvikle værktøj der kan understøtte identifikation af den symptomatisk kroniske hjertesvigtpatienter

Kardiologisk Afdeling, Viborg Sygehus forpligter sig til

Ansvarlig overlæge Malene Hollingdal forpligter sig til

- at koordinere projektet med den lokale praksiskoordinator
- at undervise de praktiserende læge ved 3 møder af 2 ½ times varighed i samarbejde med en hjertesvigt sygeplejerske fra hjerteinsufficiensklinikken (for denne opgave indgås separat kontrakt)
- at udvikle en symptomtjeklister i samarbejde med sponsor, der kan understøtte identifikation af symptomatiske kroniske hjertesvigtpatienter i GP sektoren
- at foretage en klinisk vurdering af de patienter der henvises som ”Kvalitetsprojekt HF” i samarbejde med hjertesvigtsygeplejerske udpeget til dette projekt

- at evaluere projektet ved hjælp af spørgeskemaer og beskrive resultatet i en rapport

Appendix 2 – Financiel kompensation

Økonomi

Udvikling og udarbejdelse af projekt og tilhørende redskaber

Varetage og koordinere intern kommunikation omkring projektet

Læge og sygeplejerske undervisning af GP's 2,5 time x 3

Kontakt og koordinering med praksiskoordinator, lokalt lab etc

Læge og sygeplejerske klinisk vurdering af de genhenviste patienter: BT, p, NT-proBNP, vægt, evt ekko

Opfølgning og evaluering af projektet

196.000 kr

35.280,00 kr (18% overhead)

Ialt 231.280,00 kr

Novartis er ansvarlig for at arrangere de 3 planlagte undervisningsmøder

Udbetaling til Viborg Sygehus sker via fakturering til Novartis i **3 etaper** med forbehold for at de respektive milestone beskrevet herunder er opfyldt

	I alt DKK. (incl overhead)	Fakturerings tidspunkt
Part 1: Planlægning, uadbejdelse af projektet og tools projektledelse	109.760,00	Ved projektstart og når alle parter er enige om aftalens indhold og har underskrevet denne
Part 2: Koordinering af projektet, undervisning, vurdering af henviste patienter, registrere antal genhenviste patienter	60760,00	01-11-2018
Part 3: Opgørelse af antal genhenviste patienter, færdiggørelse af rapport, evaluering	60760,00	31-05-2019
Sum	231.280,00	

Payment details

Account Holder and address:	Region Midtjylland Skottenborg 26, 8800 Viborg
Registration Number:	7831
Account Number:	0004003001
Bank name & address:	Jyske Bank, Sct Mathias Gade 21, 8800 Viborg

IBAN:	DK4078310004003001
SWIFT:	JYBADKKK
VAT/SE-number:	29762988
Reference:	AGR-2018-731-4870

Appendix 3 Novartis Anti-bribery Policy

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