

Norgine and Health Care Professionals Norgine Principles

Norgine is committed to working in a professional manner with and utilising the services of health care professionals or health care organizations comprised of healthcare professionals and appropriate administrative staff (collectively "HCPs") in various capacities as consultants and advisors, or to support specific activities and projects, whether in groups or individually, to provide services in order to promote patient health care and medical services and education in accordance with applicable codes of practices e.g. IPFMA, EFPIA, ECOMED or applicable laws (and in the case of conflict with the more onerous of those applying).

Norgine takes seriously its responsibility to comply with its ethical and legal obligations. This document establishes the governing principles of Norgine arrangements with HCPs and implements procedures to ensure compliance with applicable national regulations world-wide and applicable industry codes of conduct. The working relationship shall be founded upon the following Norgine central principles ("**Norgine Principles**"), which serve as a link between country laws, regulations and industry guidelines. The Norgine Principles have been adopted by all Norgine entities within the Norgine group and apply wherever the geographic location of the HCP and to all relationships with HCPs excluding only research services, where separate arrangements apply. The Norgine Principles are:

- Norgine will only use the services of or cooperate with HCPs where there is a genuine need for these services and the people employed are suitable and / or there is a mutual interest and benefit deriving from the cooperation for both parties;
- Prior to the commencement of any services or cooperation, the parties shall conclude a written agreement specifying the nature of the services or cooperation and the basis and the amount of any payment or transfer of value (as defined in applicable laws, whether in cash or in kind and including without limitation direct or indirect transfers of anything of value, such as compensation, reimbursement for expenses, meals, travel, medical journal reprints, medicinal products or supplies, or medical writing and publications assistance);
- Prior to the engagement of or starting of the cooperation with HCPs, Norgine will conduct appropriate and proportionate due diligence and associated risk assessments for all HCPs involved with the services, in accordance with Norgine policies and applicable laws. Particular attention shall be paid to HCPs who are also public officials, and Norgine will not offer or make any payments or transfers of value to any official or other person that is intended or could be seen, to influence any decision to obtain or retain business, to gain an improper advantage, or to induce such official or other person to perform a function in violation of any statute, rule, or regulation.
- Any payments or transfers of value to HCPs in respect of the services or the cooperation must be made pursuant to written agreements.
- Compensation paid to HCPs for performance of the services or the cooperation will be determined according to a centrally managed, pre-set rate structure that is fair, reasonable and reflects the current market value of the agreed services;

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- Norgine shall comply with applicable laws, regulations and applicable codes of conduct (including data protection requirements) in relation to its interactions with HCPs;
- Norgine shall ensure that the highest professional and ethical standards shall be adhered to in respect of any services provided or activities conducted by HCPs;
- Norgine shall monitor compliance with the Norgine Principles and applicable laws by way of regular reviews, and accountability with respect to the scope of the services performed or the activities conducted and the payments received;
- Norgine shall seek consent from HCPs in advance for any storage, use and/or public disclosure of his or her personal details (including, without limitation, his or her name and the amount and/or value of any payment or transfer of value provided by Norgine).
- Subject to such consent being given and remaining valid, Norgine shall disclose publicly (including disclosure on Norgine websites and/or third party or authorities' websites or in other appropriate media) the nature of its working relationships with HCPs to the extent required by applicable laws and codes of practice. This may include relevant specific information about payments, donations, grants or benefits in kind made by Norgine in connection with these relationships, including the names of individual HCPs. Such information may be transferred to relevant industry bodies, other Norgine affiliates and/or to third parties providing services to Norgine (each of whom may be established in or outside the jurisdiction in which the services are provided).
- If an HCP does not consent to public disclosure of his or her personal details, Norgine may refuse to enter into any proposed agreements for the provision of services, or may opt to disclose the value of any payments or transfers of value made in question on an anonymous basis (in aggregate form or otherwise).
- Norgine shall use the services of or cooperate with HCPs only where it is able to do so in accordance with the applicable laws and codes.
- Norgine shall ensure that any hiring of any HCPs to perform services or any cooperation with any HCPs does not amount to an inducement to prescribe, supply, administer, recommend, buy or sell any medicine of Norgine.
- Norgine shall maintain accurate records relating to services provided by HCPs and payments and transfers of value made to HCPs and shall retain such documentation for so long as may be required by applicable laws or codes of practice.

Application of the Norgine Principles

Norgine enters into agreements with HCPs and provides funding and other support to HCPs on the condition that the HCPs will also adopt and comply with the Norgine Principles, all applicable laws, regulations and applicable codes of conduct and confirms that he/she/they has/ve obtained all necessary approvals or authorisations from any employer or institution with which he/she/they is/are affiliated. Norgine will inform the HCPs that he/she/they is/are obliged to declare that he/she/they is/are a consultant to Norgine whenever he/she/they write(s) or speak(s) in public about a matter that is the subject of the agreement with Norgine or any other issue relating to



Norgine. Similarly, HCPs who provide consultancy services to Norgine and are still practising their profession are obliged to declare their consultancy with Norgine whenever they write or speak publicly about a matter that is the subject of the consultancy or any other issue relating to Norgine.

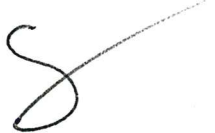
Norgine reserves the right to immediately terminate the services of or withdraw from the cooperation with the HCP upon written notice delivered to the HCP where Norgine believes that the HCP is not abiding by the Norgine Principles or the terms of any separate agreement between the parties. Templates of agreements covering Norgine's use of or cooperation with HCPs are attached as Schedules I and II and Schedule III covers interactions with MEGS (Medical & Educational Goods and Services). Whilst each of Norgine's agreements with HCPs may be tailored to meet the specific requirements of the services or the cooperation contemplated and the complexity and duration of the project, all agreements will include the essential elements contained in the relevant template.

Agreed on behalf of **NORGINE DANMARK A/S**

Name: Peter Legarth

Title: GM, Norgine Denmark A/S

Signature:



Date:

15.00.14

Agreed on behalf of ~~Silkeborg Hospital~~ (Institutleder for Klinisk Medicin, AU):

Name: Kristjar Skajaa


AARHUS UNIVERSITY
DEPARTMENT OF CLINICAL MEDICINE

Signature:



Title: Kristjar Skajaa

Date: of Department

22/4-15

Palle Juul-Jensens Boulevard 82 · DK-8200 Aarhus I

Agreed on behalf of **Diagnostisk Center:**

Name: Ulrich Fredberg

Regionshospitalet Silkeborg

Title: ~~LEVENDE OVERLÆGE~~

Signature:



Ulrich Fredberg
Ledende Overlæge
Diagnostisk Center
Falkevej 1-3, 8600 Silkeborg
E-mail: ulrifred@rm.dk

Date:

9/4-2015

Agreed on behalf of **Principal Investigator:**

Name: Ole Bonderup

Title: Dr, Ph.D

Signature:



Date:

9/4-2015

Schedule II Model Agreement - Sponsorship of Health Care professional(s) for Specific Joint Activities

This Agreement is entered into December 18, 2014 between Norgine Nordics, having offices at Lyskær 1, 3. floor, 2730 Herlev, Denmark ("NORGINE") CVR-NR. 29310025 and Diagnostic Center, Silkeborg Hospital, Falkevej 1, 8600 Silkeborg, Denmark ("Silkeborg Hospital"), and sets forth the basis of collaboration between NORGINE and Silkeborg Hospital. NORGINE and Silkeborg Hospital are each referred to as a "Party" and collectively as the "Parties". The parties agree to cooperate and support the project described below (the "Project") in accordance with Norgine and health care professionals guiding principles ("Norgine Principles"), and confirms that he/she has obtained all required approvals and consents in order to enter and perform into this agreement.

Name of the Project	Research in Collagen Colitis (CC)
Names of all the partnering organisations or associations participating in the Project	N/A
Type of Project	Clinical project
Summary of Scope and Intended Objectives	To be decided by investigator solely.
Agreed role of NORGINE, Silkeborg Hospital and each partner	Norgine Nordics provides an unrestricted grant for research study activities at Section for Gastroenterology, Silkeborg Hospital.
Timeframe for the Project (start date & finish date)	December 2014 – December 2016
Amount and nature of financial support of NORGINE	DKK 40.000 equal to 5370 EUR. Financial; unrestricted grant, <i>no drug supply requested</i> . Silkeborg Hospital is entirely responsible for clinical trial related activities.
Payment Schedule	DKK 40.000 equal to 5370 EUR. Transferred to <i>See Attachment A</i>
Anticipated amount and nature of non-financial support of NORGINE, Silkeborg Hospital and any partners	N/A
Description of how NORGINE Project resources/costs will be monitored	N/A
Terms and conditions relating to NORGINE's use of Silkeborg Hospital's logo and proprietary material, if applicable, including without limitation, permitted purpose	N/A

and manner of such use and any express limitations.	
Country Code(s) of Practice that will apply	LIF
Decision making process of the Project	Approved by General Manager Peter Legarth and Medical Director John Stone
NORGINE CONTACT	Christina Hartøft, Norgine Nordics +45 25100127
Silkeborg Hospital CONTACT	Ole Bonderup, Silkeborg Hospital +45 784 17856 / +45 20212579
Management of the Project - designate responsibility for key objectives	Ole Bonderup, Silkeborg Hospital Tlf. 784 17856 / Mobil: 20212579
Review of the Project- describe process of evaluating whether objectives have been achieved	Unrestricted grant for Section of Gastroenterology for research study activities.

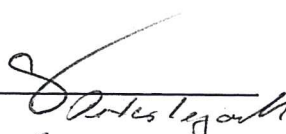
Each party declares that the material or arrangements will be certified where required or examined in accordance with the appropriate internal approval procedures. All Parties are fully aware that acknowledgment of the support described herein must be prominently displayed from the start.

NORGINE may terminate this Agreement immediately by written notice to Silkeborg Hospital in the event that Silkeborg Hospital does not comply with the terms of this Agreement, applicable laws, regulations and NORGINE Principles. This Agreement shall be governed by and construed in accordance with the laws of Denmark and the Parties hereto hereby submit to the exclusive jurisdiction of the courts of Denmark.

This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of the Agreement, and all of which when taken together shall be deemed to constitute one and the same agreement. Signatures to this Agreement transmitted by facsimile transmission, by electronic mail in "portable document format" (.pdf) form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, will have the same effect as physical delivery of the paper document bearing the original signature.

This Agreement is entered into as of the date referenced above and may only be amended in writing by duly authorised representatives of each of the Parties.

NORGINE NORDICS

By 
 Name: Peter Legarth
 Title: General Manager Nordic

Silkeborg Hospital

By 
 Name: Regionshospitalet Silkeborg
 Title: Ulrich Fredberg
Ledende Overlæge
Diagnostisk Center
Falkevej 1-3, 8600 Silkeborg
 E-mail: ulrifred@rm.dk