Collaboration Agreement Patient Organisation

between

Bayer A/S
Company registration number (CVR) 16 08 98 18
Arne Jacobsens Allé 13, 6.
2300 Københaven S
Denmark
("Bayer")

and

Danmarks Bloderforeningen Kompagnistraede 22, sal baghuset 1208 København K CVR 11 80 29 90 ("Organisation")

Bayer and Organisation jointly referred to as "Parties".

Hereby the Parties agree as follows:

1. Project description

In collaboration with the highly specialized hemophilia centers at Rigshospitalet and Aarhus University Hospital since 1989, the Danish Hemophilia Association has conducted quality of life surveys among Danish haemophilia patients with moderate to severe degree of haemophilia or von Willebrand type 3.

The quality of life surveys were conducted in 1989, 2001 and 2012 and show increased quality of life among Danish haemophilia patients for more than three decades. The results have been disseminated in two articles published in resp. 2018 and 2019.

Given that several new treatments have been approved and put into use within the last few years, it is

relevant to conduct a new study and thereby gain current knowledge about the development in quality of life among Danish haemophilia patients.

RESTRICTED

Organisation is active in the field of *Haemophilia*. Bayer is active in the field of *Haemophilia*. The Parties have agreed to collaborate on a project named "Undersøgelse af livskvalitet blandt danske blødere 2021-22"

Bayer will sponsor this project ("Project").

The project is set out to be conducted in accordance with relevant laws and regulations including, but not limited to, the Ethical rules for Collaboration with Patient Groups etc. (Patientforeningskodeks) effective from 1/1-2017, until further notice.

2. Parties obligations

- 2.1. Bayer shall provide financial support to the event.
- 2.2. The Organisation shall provide following:

In the forthcoming issue of the member magazine BløderNyt, which will be published in December 2021, there will be an article about the new quality of life survey, including mention of sponsors, and an invitation to answer the questionnaire. Blødernyt is published in a circulation of 750 and is available in electronic form on the association's website.

To ensure that as many as possible in the target group answer the questionnaire, the Danish Bleeding Association will send a direct letter to members of the target group with an invitation to answer the questionnaire. The letter will indicate which companies support the implementation of the survey.

On the association's Facebook page and Instagram profile, awareness-raising postings will be posted on an ongoing basis from the broadcast until the response deadline. Here too, it will be clear which companies support the implementation of the quality of life survey. On Facebook, the association has 969 followers, and on Instagram the association has 319 followers.

Based on the results of the survey, 1-2 articles are published in international journals, from which it must be stated which companies have supported the implementation of the survey. The results - including sponsorships - will be presented at the EHC conference for European hemophilia associations in October 2022, which will be held in Copenhagen.

The results - including sponsorships - will also be disseminated to the Danish Bleeding Association's own members and followers via articles published on the association's website, electronic newsletter, social media and in Blødernyt (December 2022).

3. Finance

- 3.1.1. Bayer has committed to finance the Project with the amount of DK 74 000 (Seventhy four thousand Danish Kroner). Bayer's finance is to support the production of the podcast and video. The finance shall not be used for other costs such as; social activities, costs for ordinary business, internal activities or otherwise in conflict with applicable laws and regulations.
- 3.2. Any payments made by Bayer will be upon receipt of a proper invoice (to be issued in the name and on the letterhead of the Organisation) including reference- Purchase Order number and which meets all requirements according to applicable VAT requirements. Bayer shall pay within 45 days from receipt of the correct invoice.
- Payment will be administrated and invoiced by Bloderforeningen to Bayer on the following address.

Invoice address:
Bayer A/S
c/o Invoice reception point
D-51368 Leverkusen
Germany

Reference:

4. Transparency

- 4.1. The Parties agree that the content of this agreement can at any time be disclosed to a third party on request.
- 4.2. The parties agree that Bayer will upload the content of this Agreement on their website no later than project start and have it published until at least six months after the collaboration has ended.
- 4.3. The Parties declare that this Agreement is not in any way associated with any business or sales activities between the Parties hereto and in particular Organisation is by no means obligated to prescribe, recommend or purchase any goods from Bayer.

- 4.4. The parties agree that Bayer will at the end of each calendar year submit information regarding the collaboration to LIF in accordance with the applicable ethical rules.
- 4.5. The Parties warrant that the collaboration subject to this Agreement is in no way associated with influencing the Organisations opinions on professional and political issues.
- 4.6. The Parties declare that this Agreement is not in any way associated with any business or sales activities between the Parties hereto and in particular Organisation is by no means obligated to prescribe, recommend or purchase any goods from Bayer.
- 4.7. Bayer warrants that it does not hold any position within the organisation which might cause any unethical conflicts of interest for the purpose of this Agreement.

5. Contact

5.1. Bayer has appointed Lars Lunau, <u>lars.lunau@bayer.com</u>, +45 40567950 contact person for enquires regarding this Agreement.

Organisation has appointed Karen Binger Holm, kbh@bloederforeningen.dk, mobile 60 24 62 77 as a contact person for enquiries relating to this Agreement

6. Usage of Logo- intellectual property trademark etc.

The parties should not use each other's logos without a prior written consent. When acquiring such consent, the requesting Party shall state for which specific purposes and in which way the logo and name shall be used.

7. Term

Duration of the project is 2021-2022

This contract comes into force of upon signature of both Parties and continues until end of 2022.

8. Termination

If either Party is in breach or default in the performance of its obligations under this Agreement, and such breach or default continues for thirty (30) days after written notice by the other Party, may the non-breaching or non-defaulting Party have the right to terminate the Agreement with immediate effect.

9. Adverse Event/Product Technical Complaint

Under EU legislation Bayer and its contracted partners are obliged to fulfil certain Pharmacovigilance responsibilities stated in the Good Pharmacovigilance Practice (GVP) and relevant guidelines. Therefore Organisation agrees to provide to Bayer written reports of all Adverse Events, Product Technical Complaints regarding Bayer product(s) and service(s) covered by this Agreement that come to their attention by fax (+46 8 580 224 02) or e-mail (drugsafety.scand@bayer.com) within one (1) business day from receipt of information.

All known cases of exposure during pregnancy (including paternal exposure) and breastfeeding, misuse, abuse, lack of drug effect, overdose (accidental and intentional), medication error/use error, drug dependency, suspected transmission of an infectious agent, withdrawal syndrome, drug interactions, occupational exposure, off-label use, or unexpected Product benefit with respect to the Product(s) must be reported in the same manner as an Adverse Event /Product Technical Complaint.

For the purposes of this Agreement, an "Adverse Event "shall mean any untoward medical occurrence in a patient administered the Bayer product, which does not necessarily have to have a causal relationship with this treatment. A "Product Technical Complaint "is any report (written, electronic or verbal communication) about a potential or alleged failure of the Bayer product in its quality (including the identity, durability, reliability, safety, efficacy or performance) or suspected counterfeit. The complaint may or may not represent a potential risk to the patient.

10. Miscellaneous

- 10.1. This Agreement contains the entire agreement between the Parties. Any amendments to this Agreement shall be made in writing and duly signed by the Parties. If any provision of this Agreement is or becomes invalid or unenforceable, shall this not affect the remaining provisions hereof. The Parties shall in this case replace the invalid or unenforceable provision with a provision that is as close as possible to the economic effect of the invalid or unenforceable provision.
- 10.2. This Agreement shall be construed, controlled and interpreted by the Laws of Denmark. The Parties agree to the exclusive jurisdiction of the Copenhagen District Court as first instance.

This Agreement has been executed in two (2) copies, with each party receiving one (1) copy.

(Place)	(Date)	
ORGANISATION		
Signature KAREN B Clarification of signa		Danmarks Bløderforening Kompagnistræde 22, 2. 1208 København K Tlf. 33 14 55 05 CVR-nr. 11 80 29 90
	(Date)	(Place) (Date)
(Place) BAYER A/S Cecilia Bernd	Cecilia Berndt	(Place) (Date) BAYER A/S
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