elios vision

Cooperation Agreement for the performance of a non-interventional study

Deleted: DRAFT¶

Deleted: ↵

Deleted: ↵

between

Elios Vision GmbH

Industriestraße 17
82110 Germering
Germany

(hereinafter: "**Principal**")

and

[.....]

[.....]

(hereinafter: "**HCP**")

(Principal and HCP also referred to as a "**Party**" and together as the "**Parties**")

Formatted: English (US)

elios vision

Preamble

The Principal is a medical technology company which markets photoablative lasers for excimer laser trabeculostomy, a micro-invasive glaucoma surgery (the "Devices").

The Principal is interested in gaining clinical data under the conditions of a clinical use of the Devices which will be shared with the manufacturer of the Devices for the purpose of post-market clinical follow-up. The data may also be used for the purpose of generating marketing claims in compliance with the intended use of the Devices and in accordance with applicable laws and regulations.

The HCP is familiar in treating patients with excimer laser trabeculostomy, using the Device within the scope of its intended purpose.

The HCP is willing to support the Principal in gaining anonymized clinical data by participating in a non-interventional study (NIS) in suitable cases, which means that following the HCP´s free and own decision a patient shall be treated with the Device within its intended purpose.

The HCP is willing to document anonymized clinical data and is willing to transfer the clinical data gained from such patients to the Principal in compliance with the documentation requirements of the NIS of the Device as outlined in this Agreement.

1. Subject Matter of the NIS

1.1 The NIS shall be performed according to the observational plan (see data collector form). It intends to observe patients treated for glaucoma with a CE-marked Device within its intended purpose.

1.2 The aim of the NIS is to gain clinical data regarding the longitudinal follow up of patient´s outcomes after receiving treatment with excimer laser trabeculostomy within the scope of the usual medical practice and clinical use of the Devices.

1.3 The Parties agree that a maximum number of 100 treatments/patients shall be documented by the HCP.

Commented [JG1]: Trabeculostomy

Deleted: the

Deleted: tom

Commented [JG2]: Trabeculostomy

Deleted: (INSERT NUMBER)

elios vision

2. Principles of cooperation

2.1 The Parties acknowledge and hereby confirm that they are aware of the legal classification of the NIS as a non-interventional study (NIS). With regard thereto, the Parties mutually agree and ensure, that the diagnosis, the therapy and the monitoring of the patients involved in the NIS **shall exclusively follow the medical considerations of the HCP** and shall be documented likewise. The Parties are aware, agree and shall ensure **that the HCP must decide freely and under his own responsibility how to treat the patients**.

2.2 Any decision of the HCP shall be free from any kind of influence. Hence, the treatment, the documentation and especially the consideration whether a patient shall join the NIS require a free and therefore independent decision from the HCP to use the Device for treatment of the patient. The Principal hereby warrants not to attempt to influence any decision regarding the inclusion of patients.

2.3 It is a requirement to be fulfilled for the inclusion of a patient in the NIS that, according to the free decision of the HCP, the patient shall be treated with the Device within its intended purpose.

3. Duties of the HCP

3.1 The HCP agrees to include patients into the NIS, that, according to the HCP´s free decision, shall be treated with the Device and in line with the CE-marking and its intended use and intended patient population,

3.2 The HCP agrees to document the treatment of such patients in the documentation template as defined in the data collector form with due care, according to the current state of scientific knowledge and medical quality standards and in compliance with the applicable statutory and other obligations and requirements. Such documentation shall take place in promptly.

3.3 For scientific reasons the Parties aim to have 50 treatment outcomes involved in the NIS. **For the avoidance of doubt this benchmark has to be interpreted and understood under the major principle of non-intervention.** This means that the Parties and especially the HCP

Deleted: , provided that the patients fulfil the requirements…

Deleted: Attachment 1

Deleted:

Deleted: the

Deleted: due time

Deleted: a number of [INSERT NUMBER]

Deleted: of patients to be

understand and warrant, that this benchmark in no event shall influence the therapeutic decision of the HCP.

3.4 The HCP agree to submit the documentation with the anonymized data collected to the Principal at the latest by **December 2024**. The HCP will only document anonymized clinical data according to the Data Collector form.

3.5 The HCP shall comply with any other local laws, regulations and professional rules applicable to him.

4. Duties of the Principal

4.1 The Principal shall pay to the HCP the compensation agreed in Sect. 5.

4.2 The Principal shall announce a contact person with scientific expertise for the aim of the NIS. The contact data (name, email, phone, mobile) forms part of the Data Collector form.

5. Compensation

5.1 For the efforts of the performance of this NIS, the Principal shall pay an appropriate compensation to the HCP. Such compensation shall be £100/€100/CHF100 (in words: One Hundred [pounds/euros/Swiss francs]) for each complete patient documentation at 1 and 12 months post-operatively compliant to the Agreement.

5.2 The compensation is understood to compensate and cover any and all efforts taken in connection with the NIS from the HCP, especially, but not limited to, the patient education including the informed consent, the documentation and the transfer of the data to the Principal.

5.3 The compensation shall become due and shall be paid after the Principal reviewed the documentation for compliance with the requirements agreed upon between the Parties in this Agreement, such review to be initiated without delay.

Deleted: following the receipt of a proper invoice and

5.4 Payments under this Agreement shall be made exclusively non-cash with reference to the purpose ELIOS NIS to the following account of the HCP:

Deleted: [PLEASE INSERT]

Account Holder:

Bank:

elios vision

Account Number:
Banc Code Number:
IBAN
BIC

6. Rights on the results of the NIS

6.1 The Principal is entitled to any and all rights to the results and the data gained in the NIS, including the right of publication.

6.2 For the avoidance of doubt, it shall be clarified that the Principal does not own any rights regarding the patient files as such.

Deleted: e

7. Principle of separation

7.1 The Parties hereby confirm and the HCP warrants that the cooperation on the occasion of this NIS and the conclusion of this Agreement does not and shall not influence any therapeutic decision, procurement or turnover transaction, sales or pricing decision and that it shall not be referred to such transactions in the past. The Parties point out that in this respect no expectations from either Party exist.

7.2 The Parties agree and ensure each other that the cooperation at the occasion of the NIS does not cause an incentive for a preferential prescription and/or application and/or recommendation of the Devices.

8. Term

8.1 This Agreement enters into force upon signing by the Parties. It shall remain in force until the NIS has been completed as foreseen in the observational plan according to Attachment 1 and the documentation requirements of Section 3.4.

Formatted: Not Highlight

9. Written Form

Changes and amendments to this Agreement must be made in written form to be valid. This shall also apply to the cancellation of the written form requirement.

Deleted: require

10. Entire agreement

This Agreement and its Attachments contain the entire agreement between the Parties in connection with the conduct of the NIS. Oral side agreements do not exist.

11. Governing law and jurisdiction

11.1 This Agreement shall be governed by German law.

11.2 The place of jurisdiction for all disputes arising out of or in connection with this Agreement or its performance shall be Munich (Germany).

Commented [BH|P3]: Please note: Even if German law is generally applicable to this cooperation Agreement, local laws and professional rules may have to be observed in case of cooperations with HCPs in other countries. It should therefore be checked whether local laws impose additional duties on the Parties also with regard to healthcare comliance practice.

12. Partial invalidity

If any of the provisions in this Agreement is or becomes invalid or unenforceable, the Parties undertake to replace the invalid or unenforceable provision by another valid or enforceable provisions which is so close to the economic success of the invalid or unenforceable provision that it can reasonably be assumed that the Parties would have signed the Agreement also with such provision instead of the invalid or unenforceable provision. If such provision cannot be found, the invalidity or unenforceability of one or several provisions shall not affect the validity of the Agreement as a whole. This shall not apply if the invalid or unenforceable provisions are of such importance for the present Agreement that it can reasonably be assumed that the Parties would not have signed the Agreement without the invalid or unenforceable provision. The foregoing shall analogously apply in the case of a gap in the Agreement.

The following documents are attached to this Agreement as Attachments and shall form integral part hereof:

Attachment 1: Observation plan.

Elios Vision GmbH	HCP
Name:	Name:
_____	_____
Position:	Position:
_____	_____
Date:	Date:
_____	_____
Signature:	Signature:
_____	_____