



8993/400

**AMENDMENT No. 1 TO INVESTIGATOR SPONSORED STUDY AGREEMENT
HUMAN SUBJECT RESEARCH**

This Amendment (the "Amendment") to the INVESTIGATOR SPONSORED STUDY AGREEMENT ("Agreement"), is made effective as of the date of execution hereunder (the "Effective Date"), is by and between Universitätsspital Basel, Spitalstrasse 21/Petersgraben 4, 4031 Basel, Switzerland ("Institution") and, BOSTON SCIENTIFIC INTERNATIONAL S.A. a French corporation, whose registered address is Parc d'Affaires Le Val Saint-Quentin, 2 rue René Caudron, 78960 Voisins-le-Bretonneux, France, registered with the Commercial Registry of Versailles under number B 420 668 402, and with intra-community VAT number FR 07 420668402 ("Company"). Institution and Company hereinafter may be referred to collectively as the "parties".

RECITALS

Institution is conducting a human subject study entitled *[ISRURO_0085] SteamOne - Prospective Registry Database for Rezum water vapor therapy of the prostate* (the "Study").

WHEREAS BSC and Institution have concluded the Agreement dated *December 22nd, 2021*, where BSC has agreed to fund the Study sponsored by the Institution.

WHEREAS, pursuant to the Agreement, Institution is the Sponsor of the Study and as such is solely responsible for developing, implementing and managing the Study.

WHEREAS, following institution's request for the data protection elements of the contract, BSC has determined that the best way to specify how BSCI safeguards the protection of patient data following to the study's data sharing, as for the fields, the method of anonymization, transmission and storage -BSCI proposes to add the following specifications:

- I- Institution agrees to provide Boston Scientific with outcome data on patients comprising the following fields only:*
- 1. Patient age range within 5-year bands e.g. 40-45, 46-50, 51-55, 56-60, 61-65, 66-70, 71-75, 76-80, 81-85, >86*
 - 2. Prostate volume*
 - 3. Rezum delivery parameters, as documented in the study database.*
 - 4. Relevant comorbidity, as documented in the study database*
 - 5. IPSS*
 - 6. Qmax*

7. Procedure-related adverse events, as documented in the study database

In such a manner as it is possible to follow a patient from baseline to post-treatment values, but that it is not possible for Boston Scientific to identify the patient provided that additional information are stored separately by the Institution (pseudonymised data) towards Boston Scientific.

This non-identifiable data will be transmitted to Boston Scientific securely in a password protected Excel file for secure storage on United States based servers.

Any data reports or de-identified data will get uploaded into the ISR database, Ideapoint. Once the study is completed and closed-out we will archive the study with the data.

Data will be provided on cohorts of patients reaching 6 months, one year, two years, three years, four years and five years of follow up as follows.

On an annual basis, starting from the recruitment of the first patient, all data available at the following time-points.

set 1: All available 6 month follow up results

set 2: All available one year follow up results

set 3: All available two year follow up results

set 4: all available three year follow up results

set 5: all available four year follow up results

set 6: all available 5 year follow up results

All sets should include all parameters on included patients, including baseline, as agreed above.

Company shall have the right to use Study Data as defined above for regulatory submissions and internal research purposes without being entitled to modify any of the Study Data subject to confidentiality and data protection laws.

Boston Scientific guarantees that its data protection in the USA is comparable to its data protection processes in Europe.

NOW, THEREFORE, the Parties hereto agree as follows:

- II- Institution will not use or disclose data subjects' PHD in violation of any Laws. Institutions shall comply with the General Data Protection Regulation 2016/679/EU (if and as far as applicable) and related applicable laws in all respects.
- III- The only Data that may be shared with BSI in the context of this Agreement are Study Data that have been duly pseudonymized (e.g. through aggregation) and which cannot be re-identified in any way ("Pseudonymized Data towards Boston Scientific").
- IV- Institution agrees to provide Boston Scientific with outcome data on patients comprising the following fields:
 - 8. Patient age range within 5-year bands e.g. 40-45, 46-50, 51-55, 56-60, 61-65, 66-70, 71-75, 76-80, 81-85, >86

9. Prostate volume
10. Rezum delivery parameters, as documented in the study database.
11. Relevant comorbidity, as documented in the study database
12. IPSS
13. Qmax
14. Procedure-related adverse events, as documented in the study database

In such a manner as it is possible to follow a patient from baseline to post-treatment values, but that it is not possible for Boston Scientific to identify the patient provided that additional information are stored separately by the Institution (pseudonymized data) towards Boston Scientific.

This non-identifiable data will be transmitted to Boston Scientific securely in a password protected Excel file for secure storage on United States based servers.

Any data reports or de-identified data will get uploaded into the ISR database, Ideapoint. Once the study is completed and closed-out we will archive the study with the data.

Data will be provided on cohorts of patients reaching 6 months, one year, two years, three years, four years and five years of follow up as follows.

On an annual basis, starting from the recruitment of the first patient, all data available at the following time-points.

set 1: All available 6 month follow up results

set 2: All available one year follow up results

set 3: All available two year follow up results

set 4: all available three year follow up results

set 5: all available four year follow up results

set 6: all available 5 year follow up results

All sets should include all parameters on included patients, including baseline, as agreed above.

Company shall have the right to use Study Data as defined above for regulatory submissions and internal research purposes without being entitled to modify any of the Study Data subject to confidentiality and data protection laws.

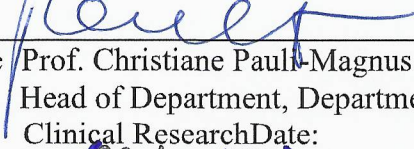
Boston Scientific guarantees that its data protection in the USA is comparable to its data protection processes in Europe.

- V- Institution declares and it is made an express condition of this Agreement, will comply with the following applicable laws, rules and regulations in conducting the Study, the Declaration of Helsinki and Good Clinical Practice for conducting clinical studies (ICH GCP Guidelines), to the General Data Protection Regulation (EU) 2016/679 (if and as far as applicable) or any applicable European and national [Law of Switzerland] health information privacy and data security laws.
- VI- Indemnification. Gross negligence or willful misconduct of Company or any Company Persons in the performance of, or its failure to perform, Company's obligations under this Agreement. Provided, however, Company shall have no obligation to indemnify, defend and hold harmless the Institution Indemnitees to the extent that any Claim is the result of gross negligence or willful misconduct on the part of the Institution's Indemnitees.

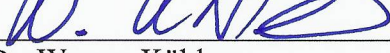
- VII- throughout the contract already signed, the word 'anonymized' can be considered as 'pseudonymized'
- VIII- Any and all other sections and Exhibits of the Agreement remain unchanged and in full force.


IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed on their behalf by their duly authorized representatives to be effective on the year and date first above written.

University Hospital Basel

By: 
Name Prof. Christiane Pauli-Magnus
Title Head of Department, Department of
Clinical Research

Date: 03. Aug 2022

By: 
Name Dr. Werner Kübler
Title Director of the Hospital
Date: _____

By: 
Name Prof. H. Seifert
Title Head of Department of Urology
Date: 20.07.2022

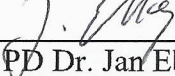
BOSTON SCIENTIFIC International SA

By: 
Name
Title sandrine Bazile

Date: 08/29/2022

READ AND ACKNOWLEDGED

PRINCIPAL INVESTIGATOR

By: 
Name: PD Dr. Jan Ebbing
Title : Principal Investigator
Date: 20.07.2022