# EXHIBIT A BUDGET

This Budget is **Exhibit A** to the Clinical Study Agreement (“Agreement”) for the Study and parties listed below and the terms of this Budget are governed thereby.

**As**sessment of the W**A**TCHMANTM Device in **P**atients Unsui**t**able f**o**r **O**ral Anticoagulation

# ASAP-TOO

**Sponsor: Boston Scientific International SA Institution: Na Homolce Hospital**

**Investigator: xxxxxxxxxxxxxx**

The Institution and the Investigator shall be responsible for allocating the budget and staffing commitment for the Protocol. Subject to the limits below, uncovered medical costs and expenses incurred by the Institution, Investigator, and other personnel working under this Study for the Institution or Investigator shall be paid from the funds provided by Sponsor per this budget.

# Payee Information

Invoices shall be addressed to**:**

Boston Scientific International SA Parc Val Saint-Quentin,

Bâtiment H,

2 Rue René Caudron,

78960 Voisins le Bretonneux, France VAT FR07420668402

And:

For all invoiceable fees, invoices shall be sent to Sponsor at: xxxxxxxx

The Sponsor will make payments in accordance with this Agreement either itself or through an agent of Sponsor.

All payments associated with the Study shall be made in local currency to the following fund:

|  |  |
| --- | --- |
| Payee Name (Institution)\*  (title, first name, last name if payee) | Na Homolce Hospital |
| Payee Address | Roentgenova 37/2, 150 30, Motol, Prague 5 |
| Bank name and address\* | Czech National Bank, Na Prikope 28, 115 03, Prague 1 |
| Account Number (International) | 17734051/0710 (for Czech crown account) |
| BIC\* | CNBACZPP |
| IBAN\* | CZ57 0710 0000 0000 1773 4051 (for Czech crown account) |
| Preferred mention to be shown | Not yet available |

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|  |  |
| --- | --- |
| Contact person for payments\* | Name:xxxxxxxx  Email\*/phone/fax: xxxxx |

\*mandatory details

1. **Payment Terms:** As payment in full for all of the services satisfactorily provided under this Agreement, Sponsor shall make the following payments to Payee listed in Section 2.

# Study Start-up Fee (one-time payment): xxxxxxxx

Payment will be made upon receipt of invoice when all required paperwork for Study start-up has been returned to Sponsor. The Study Start-up Fee is meant to cover the costs of initiating a Study, such as supplies, IRB/EC submission preparation, administrative costs, Investigator review of Protocol, obtaining Medicare or other equivalent health reimbursement coverage, and other miscellaneous start-up costs.

# Sponsor - Initiated Protocol Amendment xxxxxxx

Sponsor will issue payment for Sponsor-Initiated amendments upon receipt of an invoice.

# Regulatory Audit xxxxxx

In the event of any audit by the FDA or other regulatory body which is (a) specific to this Study and not part of a general audit of Institution or Principal Investigator and (b) not due to any alleged or actual misconduct of Institution or Principal Investigator or a failure to follow the Protocol, Boston Scientific shall pay Institution the amount above. This amount is inclusive of overhead, all time and expense incurred by Institution in attending the audit, and in no event shall the amount invoiced exceed the above amount. Payment will be made upon receipt of invoice.

# Long-Term Document Storage xxxxxx

Payment will be made upon receipt of invoice and when all required paperwork for study close-out has been returned to Sponsor as determined by the Sponsor.

# Serious Adverse Events (per protocol only) 3 xxxxxx

Payment for Serious Adverse Event(s) will be made upon completion of the corresponding data into the electronic data capture system and confirmation that the data is query-free.

# Brain MRI Scan2 w/contrast xxxxxx

**Brain MRI Scan**2 **w/o contrast xxxxxxx**

**Brain CT Scan**2 **w/contrast xxxxxxxx**

**Brain CT Scan**2 **w/o contrast xxxx**

Brain MRI or CT is protocol-required for Subjects who have a prior history of ischemic stroke, hemorrhagic stroke, or TIA or have a stroke or TIA while participating in the study. Payment will be made upon receipt of invoice containing Subject ID and date of imaging. (Occurring at Enrollment visit if patient doesn’t have a SOC MRI/CT within the 60 days prior to randomization, or following stroke or TIA event if it wasn’t conducted as SOC.)

# Trans-Esophageal Echocardiogram2 related to Adverse Events (Device Group Only and Cross- Over subject) xxxxx

TEE is protocol-required for Device Subjects that experience a stroke/TIA, Systemic Embolism, Device Thrombus Event during the course of the study. Payment per invoice & once data is complete and free from queries. Include Subject Id and date of TEE.

# Provide Trans-Esophageal Echo (TEE) Imaging to Core Lab2 (Device Group Only and Cross-Over subject) xxxxx

TEE imaging to core lab for images that are obtained due to stroke/TIA, Systemic Embolism and Device Thombus. Payment per invoice & once data is complete and free from queries. Include Subject Id and date of TEE

# Chart Review (One-Time payment at the end of enrollment) xxxxx

Payment will be made upon Sponsor's receipt of screening log and invoice. Sponsor will pay for 3 chart reviews per 1 subject enrolled.

# Subject Stipend to cover research-related travel expenses 4 xxxx

Sponsor shall receive an invoice from the Institution which contains actual expenses incurred by the subject for non-standard of care visits related to the **ASAP\_TOO** protocol. Invoice shall contain Subject ID, visit date, type of transportation and site number and accompany a receipt. The Sponsor completes the reimbursement to the account as stated in the budget and site is responsible for reimbursing Subjects. A maximum reimbursement per visit per patient is xxxxxxx.

Trial subjects will be informed in the Patient Informed Consent that they are entitled to claim travel expenses. The rates are as follows:

Patients using their own car**……………………………………………..………………….xxxxxxx**

Patients using Na Homolce ambulance **xxxxxx**

# Protocol Approved Cross Over Subjects xxxx

Payment will be issued for Protocol approved cross over subjects upon completion of necessary CRFs for procedures performed in the amounts listed in the payment schedule below.

# Payment Schedule

Sponsor shall make the following payments for each Study Subject to the fund specified in Section 2 of this Exhibit A according to the following schedule:

|  |  |  |
| --- | --- | --- |
| **Visit** |  | **Reimbursement (CZK)** |
| **Screening** | Informed Consent | xxxxx |
| **TOTAL** | **xxxxx** |

|  |  |  |
| --- | --- | --- |
| **Baseline** | Visit including Medical History, demographics, physical assessment, medication assessment & CRF completion | xxx |
| Transthoracic Echocardiogram (TTE) 2 | xxx |
| Trans-Esophageal Echocardiogram (TEE) 2 | xxx |
| Provide Trans-Esophageal Echo - TEE Imaging to Core Lab | xxx |
| Neurologist Exam - Initial Visit2 | xxx |
| NIH Stroke Scale2 | xxx |
| Modified Rankin Scale2 | xxx |
| Quality of Life Assessment2 | xxx |
| **TOTAL** | **xxx** |
| **Implant** | Visit including CRF completion, including medication assessment, adverse event and device deficiency monitoring and device information, procedure and discharge assessments | xxx |
| Provide Trans-Esophageal Echo - TEE Imaging to Core Lab | xxx |
| **TOTAL** | **xxx** |
| **3-Month Follow-up** | Visit including physical assessment & CRF completion, includes medication assessment, adverse event and device deficiency monitoring. | xxx |
| Provide Trans-Esophageal Echocardiogram (TEE) imaging to Core Lab(Device subjects only) | xxx |
| Trans-Esophageal Echocardiogram (TEE)  (Device subjects only) 2 | xxx |
| NIH Stroke Scale2 | xxx |
| Modified Rankin Scale2 | xxx |
| Quality of Life Assessment2 | xxx |
| **TOTAL** | **xxx** |
| **6, 18, 30, 42, 54 Month**  **Telephone Visit** | Visit including CRF completion, including medication assessment, adverse event and device deficiency monitoring. | xxx |
| Modified Rankin Scale2 | xxx |
| **TOTAL** | **xxx** |
| **12 Month Follow-up Office Visit** | Visit including physical assessment & CRF completion, includes medication  assessment, adverse event and device deficiency monitoring | xxx |
| Provide Trans-Esophageal  Echocardiogram (TEE) imaging to Core Lab (Device subjects only) | xxx |
| Trans-Esophageal Echocardiogram (TEE) (Device subjects only) | xxx |

|  |  |  |
| --- | --- | --- |
|  | Neurologist Exam - Follow-up Visit2 | xxx |
| NIH Stroke Scale2 | xxx |
| Modified Rankin Scale2 | xxx |
| Quality of Life Assessment2 | xxx |
| **TOTAL** | **xxx** |
| **24 Month Follow-up Office Visit** | Visit including physical assessment & CRF completion, includes medication  assessment, adverse event and device deficiency monitoring | xxx |
| Neurologist Exam - Follow-up Visit2 | xxx |
| NIH Stroke Scale2 | xxx |
| Modified Rankin Scale2 | xxx |
| Quality of Life Assessment2 | xxx |
| **TOTAL** | **xxx** |
| **36, 48, 60 Month Follow-up Office Visit** | Visit including physical assessment & CRF completion, includes medication assessment, adverse event and device  deficiency monitoring | xxx |
| NIH Stroke Scale2 | xxx |
| Modified Rankin Scale2 | xxx |
| Quality of Life Assessment2 | xxx |
| **TOTAL** | **xxx** |
| **Unscheduled Visits** | Visit including CRF completion, adverse event and device deficiency monitoring | xxx |
| **TOTAL** | **xxx** |
| **End of Study Form** | Visit CRF Completion | xxx |
| **TOTAL** | **xxx** |
| **ESTIMATED TOTAL for Control Group** | Without Implant, 3 & 12 Month Follow- up TEE image & TEE image to Core Lab | **xxx** |
| **ESTIMATED TOTAL for Device Group** |  | **xxx** |

1 Payment for CRF completion and other data collection *only* and does not reflect the provider’s charges for the actual medically necessary services performed (i.e., “usual” care).

2 Payment for the provider’s protocol-driven services *only* (i.e. not “usual” care), which are *not* further payable by third-party payers (Payable upon receipt of corresponding CRF with all data clarifications/queries resolved).

3 Serious Adverse Events will be paid based on Protocol requirements. An Adverse event that: Led to death

Led to serious deterioration in the health of the subject, that either resulted in:

* + a life-threatening illness or injury, or
  + a permanent impairment of a body structure or a body function, or
  + in-patient hospitalization or prolongation of existing hospitalization or
  + medical or surgical intervention to prevent life-threatening illness or
  + injury or permanent impairment to a body structure or a body function

Led to fetal distress, fetal death, or a congenital abnormality or birth defect.

**NOTE:** Planned hospitalization for a pre-existing condition, or a procedure required by the clinical investigational plan, without a serious deterioration in health, is not considered a serious adverse event.

4 Institution is responsible for issuing Patient stipend payments to Subject.

* Payments will be made quarterly after Sponsor’s (or designee’s) receipt of complete, query free electronic data modules for each Subject enrolled into the Study. Electronic data must be entered into the electronic data collection system within 5 calendar days of a Subject visit and be complete and “clean”.
* Should a Subject die or otherwise justifiably discontinue from the Study, compensation will be paid for data collection requirements and all forms completed prior to the Subject’s discontinuation, provided the forms are received without missing data.
* All payments are made in considering EU directive related VAT; Section 2, art 44 of the Council Directive 2008/8/CE of 12 February 2008, Value Added Tax is due by the beneficiary of the service (Boston Scientific International VAT FR07420668402 and VAT reverse charge mechanism is applicable.
* All invoices issued by the Site/Investigator should mention the VAT number of both parties and reference to the article 44 of the EU Council Directive 2008/8/CE.

# Reimbursement for travel expenses

Sponsor may reimburse Institution, or upon Sponsor’s and Institution’s agreement, Institution’s employee for all reasonable, preapproved travel expenses actually incurred by any Institution employee while traveling to Study meetings at the request of Sponsor and all reasonable expenses, such as meals and lodging, incurred while attending such meetings (collectively, the “Expenses”), provided that such Expenses are approved in advance and in writing and are in compliance with Sponsor’s travel policy. Air travel required for Study meetings will generally be reimbursed at coach rates, in any event applicable rules will apply (such as but not limited to AdvaMed or EucoMed guidelines). Institution, or Institution’s employee, shall submit reimbursement requests, together with proper original invoices and receipts in support thereof, to Sponsor and Sponsor will reimburse such expenses within thirty (30) days after receipt of Institution’s reimbursement request, unless Sponsor in good faith disputes any such amount. Sponsor shall not be obligated to reimburse Expenses if receipts are not received by Sponsor within ninety (90) days of the date of the Study meeting.

|  |  |
| --- | --- |
| **INSTITUTION:**  **Na Homolce Hospital**  By: Print Name: Petr Polouček, MD, MBA Print Title: Hospital Director  Date: | **SPONSOR:**  **Boston Scientific International SA**  By: Print Name: xxxxx  Print Title: Attorney in Fact  Date: |