



## **EVI.CT.SE and Steps for Membership**

### **1. EVI.CT.SE - What it is?**

**European Vision Institute. Clinical Trials. Sites of Excellence (EVI.CT.SE)** is a network of European Ophthalmological Clinical Research Sites, dedicated to perform clinical research in ophthalmology with the highest standards of quality, following the European and International Directives for clinical trial research.

The **EVI.CT.SE** is a Committee of the European Vision Institute, European Economic Interest Grouping (EVI<sub>eeig</sub>) legally constituted in accordance with the Council Regulation (EEC) n.º 2137/85 as a not-for-profit science-driven organisation in Brussels to function as an interface between vision researchers and the European Union central organization.

#### **Organization & Structure**

EVI.CT.SE has a Steering Committee and a Coordinating Centre. The Coordinating Centre is located in the Coimbra Branch Office of EVI<sub>eeig</sub>, in Portugal.

The Steering Committee is supported by Expert Committees that have a fundamental role in the scientific organization of EVI.CT.SE and cover the main areas of research: Retina (Age-Related Macular Degeneration and Retinal Dystrophies and Diabetic Retinopathy); Glaucoma; Cornea, Cataract and Refractive Surgery; Ocular Surface and Inflammation; and Reading Centers.

EVI.CT.SE has an Industry Advisory Board which includes the main Pharmaceutical Companies involved in Ophthalmology Research that have accepted a major role in supporting the development of EVI.CT.SE.

## **Aims and Objectives**

The main aims and objectives of EVI.CT.SE are:

- To guarantee a high level of quality and excellence in the work performed by the members according to ICH GCP Guidelines
- To serve as a resource for Industry in performing clinical trials in Ophthalmology
- To promote multicenter clinical research trials within the European Union
- To coordinate training activities for its members

## **Advantages of being a member of EVI.CT.SE**

- Receive for free the EVI.CT.SE Required SOP Templates for Clinical Trial Sites
- Obtain the status of a EVI.CT.SE Certified Centre by implementing organizational SOPs and Quality Control (ICH GCP Guidelines compliant)
- Obtain regularly Industry contracts and in this way have a constant flow of income to keep well trained personnel
- Support for Investigator Driven Clinical Trials
- Support for EU Clinical Research applications
- Access to training and certification of personnel
- Participation in subspeciality Scientific Sections: Retina (ARMD, Diabetic Retinopathy); Glaucoma; Cornea, cataract and refractive surgery and Ocular surface and inflammation
- Networking with USA and National Networks
- Promotion of your Site as a Certified Clinical Trial Centre

## **2.Requirements to become a member:**

### **2.1.Basic Requirements:**

- Dedicated clinical trial area facility with differentiated waiting zone.
- Adequate human resources: dedicated personnel including ophthalmologists, trained trial coordinators and administrative personnel.
- Scientific record in peer reviewed international journals
- Well-established experience in randomised international and multicentric clinical trials.
- Commitment to continuing investment in the development of the Clinical Trial Site, contributing to the Excellence of EVI.CT.SE.

## **2.2.Additional Requirement:**

- Have written Standard Operating Procedures (SOP) in place.

## **3. EVI.CT.SE - How to become a member**

### **3.1.Be a member of European Vision Institute – EVIeeig**

To apply for the membership in EVIeeig please download the Membership Application at <http://www.europeanvisioninstitute.org/members.html> and proceed accordingly.

### **3.2. EVI.CT.SE Membership Application**

**3.2.1.**State in writing your intention to become a member by sending an e-mail to [cvm@aibili.pt](mailto:cvm@aibili.pt) or by post to the following address: EVI.CT.SE, AIBILI, Azinhaga de Santa Comba - Celas, 3000-548 Coimbra, PORTUGAL.

**3.2.2.**The EVI.CT.SE Coordinating Centre (**EVI.CT.SE CC**) will send a Confidentiality Agreement and a Questionnaire to be filled out.

**3.2.3.**The Clinical Trial Site (CTSite) will have to return the Confidentiality Agreement and the Questionnaire completely filled out and signed. Any other relevant information on the CTSite should be sent as an annex in order to have an adequate knowledge of the CTSite. Enclosed with these documents the CTSite must pay an application fee of 500€.

**3.2.4.**EVI.CT.SE CC will analyse the Questionnaire and any information in annex and will inform in writing the CTSite one of two alternatives:

**- CTSite is accepted as a Member of EVI.CT.SE**

EVI.CT.SE CC sends to the CTSite, for free, the “EVI.CT.SE Required SOP Templates for Clinical Trial Sites” that need to be adapted and in order to do this, it should be clear to the CTSite that they will need someone to dedicate a percentage time to the Quality System.

If the CTSite already has SOPs in place than it must revise and harmonise these SOPs in place with EVI.CT.SE SOPs, in a 6 months period from the day it receives the EVI.CT.SE SOP Templates. Afterwards, the CTSite sends the

revised SOPs to the EVI.CT.SE CC, to confirm the compliance with “EVI.CT.SE Required SOP Templates for Clinical Trial Sites”.

The CTSite can then schedule the Evaluation Visit with the independent Contract Research Organization (CRO) contracted by EVI. CT.SE.

If the CTSite does not have any SOPs in place, then it must adopt the EVI.CT.SE Required SOPs Templates. A 6 months period is given for this adoption. Afterwards, the CTSite sends the adopted SOPs to the EVI.CT.SE CC, to confirm the compliance with “EVI.CT.SE Required SOP Templates for Clinical Trial Sites”.

The CTSite may adopt the SOPs on its own or if needed may contact directly an external entity to perform this task or contact EVI.CT.SE CC in order to discuss possible alternatives.

The CTSite can then schedule the Evaluation Visit with the CRO.

- CTSite is not accepted as a Member of EVI.CT.SE

If the CTSite is considered not to fulfil the Basic Requirements to become a member of EVI.CT.SE network, it will be informed in writing by EVI.CT.SE CC with an explanation.

#### **4. Certification Process: Audit “On Site Evaluation Visit”**

**4.1.**The Clinical Trial Site (CTSite) will be contacted by the Contract Research Organization (CRO) under contract with the EVI.CT.SE CC, in order to schedule the On Site Evaluation Visit.

**4.2.**After a date has been agreed upon between the CTSite and the CRO for the “On Site Evaluation Visit”, the CRO will inform EVI.CT.SE CC of the scheduled date.

**4.3.**In order for the “On Site Evaluation Visit” takes place, the CTSite will have to pay:

**4.3.1.**Audit - Evaluation Visit - 3.000€ (to be paid directly to the EVI.CT.SE CC)

**4.3.2.**Travel and stay expenses for the auditors (will vary according to the location of the CTSite – may ask previously for an estimate), to be paid directly to the CRO that will be performing the Audit.

**4.4.**After the payment of the Evaluation Visit fee is confirmed, EVI.CT.SE CC informs the authorized CRO in order to be performed the Evaluation Visit.

**4.5.**After the Evaluation Visit takes place, the CTSite will receive a Follow-Up Letter summarising all tasks performed and a detailed list of action points and propositions to the responsible physician at the CTSite. The CTSite has 1 month to reply by written to the Follow-Up Letter and establish a timeline to perform the necessary action points.

After receiving the reply from the CTSite, the EVI.CT.SE CC can issue a:

**4.5.1.**Conditional Certification as a CTSite of Excellence, for the agreed timeline, in order to give time for the CTSite to implement all the agreed action points and if the period required is more than 6 months.

After the agreed timeline expires:

- a) the CTSite has implemented all action points. Informs the EVI.CT.SE CC, who will confirm the implementation of the action points and proceed with the certification process (see 4.6.)
- b) the CTSite did not implemented all the action points, the EVI.CT.SE CC officially closes the process and informs that the CTSite will have to re-apply.

**4.5.2.**Full Certification as a CTSite of Excellence, for 2 years, because the CTSite has implemented all the action points and has SOPs implemented that comply with “EVI.CT.SE Required SOP Templates for Clinical Trial Sites”.

**4.6.**Upon fulfilling the requirements to be certified the CTSite receives a document entitled “Statement: Rights and Obligations as a Certified Member of EVI.CT.SE” to be signed by the CTSite. This statement summarises the rights and obligations of a certified member of EVI.CT.SE. This statement must be returned signed together with the Entry Fee (1.000€). After the signed statement is available at EVI.CT.SE and the payment confirmed, a Certificate will be issued by EVI.CT.SE CC certifying the CTSite as Clinical Trial Site of Excellence.

**4.7.** Three months after the Full Certification, the EVI.CT.SE CC asks for a proof of implementation of the adopted SOPs, in order to confirm that the CTSite uses the approved SOPs in its daily routine.

## **5. Re-Certification Process: Questionnaire of Re-Certification**

**5.1.** 6 months before the Certificate expires, the CTSite receives a letter with a questionnaire which is completed and returned to EVI.CT.SE CC with the propose of renewing the Full Certification as a Clinical Trial Site of Excellence.

**5.2.** After the analysis of the fulfilled questionnaire by the EVI.CT.SE CC, the CTSite receives a Follow-Up Letter with a detailed list of action points and propositions to the responsible physician at the CTSite. The CTSite must reply in 1 month by writing to the Follow-Up Letter and establish a timeline to perform the necessary action points.

After receiving the reply from the CTSite, the EVI.CT.SE CC issues a:

**5.2.1.** Conditional Certification as a CTSite of Excellence, for the agreed timeline, in order to implement all the agreed action points.

After the timeline expires:

- a) the CTSite has to have all action points implemented. Informs the EVI.CT.SE CC, who proceeds with the certification process.
- b) the CTSite did not implemented all the action points, the EVI.CT.SE contacts the CTSite in order to establish a new timeline to implement the missing Action Points.

**5.2.2.** Full Certification as a CTSite of Excellence, for 2 years, because the CTSite has implemented all the action points and has SOPs implemented that comply with “EVI.CT.SE Required SOP Templates for Clinical Trial Sites”.

**5.3.** EVI.CT.SE sends to the CTSite a document entitled “Statement: Rights and Obligations as a Certified Member of EVI.CT.SE” to be signed by the CTSite. This statement summarises the rights and obligations of a certified member of EVI.CT.SE. After the signed statement is available at EVI.CT.SE CC a Certificate

will be issued by EVI.CT.SE certifying the CTSite as Clinical Trial Site of Excellence for another period of 2 years.

## **6. EVI.CT.SE - Summary of Financial Obligations**

### **5.1.To become a certified member**

To be a member of the EVI.CT.SE Network, the CTSite will have the following expenses:

- Application fee: 500€
- Evaluation Visit: 3.000€
- Travel and stay expenses for the CRO (will vary according to the location of the CTSite) – these expenses will have to be negotiated between the Site and the CRO.
- Entry fee: 1.000€

### **5.2.Annual Membership**

- Annual Membership fee: 1.500€.