



**European Stroke Organisation Trials Alliance
Strategy and Implementation Plan
2018-2021**

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1. Context:

Promotion of stroke research in Europe is a key aim of the European Stroke Organisation (ESO)¹. Randomised clinical trials are accepted as the 'gold standard' to generate high quality evidence relating to new treatments for acute stroke, stroke prevention and recovery, and to prevent consequences of stroke such as disability, cognitive impairment and dementia. However, conducting investigator-led clinical trials is becoming increasingly complex, due to the frequent need for large trial sizes and a complex regulatory and funding environment^{2,3}.

In some countries, one response has been to establish stroke research networks, which have improved recruitment and data quality of stroke clinical trials⁴. Within Europe, despite a strong track record of collaborative research for individual projects, no structured alliance of stroke research networks across Europe exists. A natural progression is for closer international collaboration of existing stroke research networks in Europe⁵.

Other countries have developed informal collaborations to conduct stroke research but have not yet established a structured stroke research network with funding for organising collaboration. Such countries may benefit from the support of ESO to set up structured stroke research networks to support trial development at the national level as a step towards integrating with other networks.

The ESO Trials Network Committee has actively worked to support ESO members who wish to conduct clinical trials for several years. Following consultation by the Committee with ESO members and the ESO Executive Committee, it has been agreed to establish an alliance of stroke research networks in ESO member countries (ESO Trials Alliance [ESOTA])⁶. Steps to implement ESOTA began in late 2017. This document outlines the strategic goals and implementation plan for ESOTA until end 2021.

2. Mission:

The overall purpose of ESOTA is to promote research funding, collaboration, education, communication and advocacy in stroke research across Europe, thus supporting the conduct of randomised clinical trials leading to improved therapies for patients to prevent and treat acute stroke and the longer term consequences of stroke.

3. Guiding Principles:

Following consultation with ESO members the following principles have been agreed:

- 3.1. **Wide consultation** – ESOTA will have a ‘bottom up’ rather than ‘top down’ approach, where members will be involved and consulted
- 3.2. **Keep independence and identity** – In ESOTA, each participating institution or national network will be free to choose its participation in studies and activities
- 3.3 **Realistic goals** – ESOTA will avoid over-ambitious goals. It will develop in a gradual way, identifying and meeting realistic goals as it develops.

4. Governance:

Strategic goal: To establish a transparent effective ESOTA governance structure

Steps to achieve:

The ESO Trials Network Committee will simultaneously function as the ESOTA Steering Group. In addition, nominated Lead Investigators from member networks will join the Steering Group. The Chair of the Committee will function as the Chair of the ESOTA Steering Group. New positions of Vice-Chair and Secretary will be created, to assist the Chair in the expanded work programme of the ESOTA. All rules and procedures relating to ESO committees continue to apply, including reporting responsibility to the ESO President, Executive Committee, and Board. Financial governance will be via existing ESO structures overseen by the ESO Executive committee.

5. ESOTA membership and growth:

Strategic goal: To grow the membership of ESOTA in a sustainable manner.

Steps to achieve:

5.1 Membership Working Group

A Working Group will work on expansion of the membership. This is a subgroup of the ESOTA Steering Group.

5.2 Criteria for membership:

Membership criteria have been agreed by the Steering Group as follows:

- 5.2.1 Members of ESOTA will be national or regional networks whose main purpose is clinical research in stroke/cerebrovascular disease. The focus will be on clinical trials although other categories of research (eg. epidemiology or imaging research) are not excluded.
- 5.2.2 Members should be stroke research networks that are organised and stable. Organised means that there is at least one identified leader who is supported by a representative group/committee. Stable means that the network needs to have conducted more than one trial. Networks which have formed for the conduct of a single trial are encouraged to develop and conduct further trials before considering applying to join.
- 5.2.3 Participating networks are strongly encouraged to be linked to, or representative of, a national or regional stroke society and/or funded by a governmental or non-governmental organisation

5.3 Current members:

The following stroke research networks are current ESOTA members:

- NIHR Stroke Clinical Research Network (England)
- Stroke Clinical Trials Network Ireland
- CONTRAST Network, Netherlands
- Spanish Neurological Society Stroke Research Network
- Swiss Stroke Society Research Network
- Scottish Stroke Research Network

5.4 ESOTA Growth:

Via existing contacts and approaches from interested groups, the ESOTA Steering Group and Working Group will seek to identify and work with the leadership of existing stroke research networks in Europe which are candidates for inclusion in ESOTA. The goal will be for 1-2 new member networks joining each year until 2021 (8-11 member networks by end-2021).

5.5 Supporting development of new research networks:

The Membership Working Group will support groups of stroke investigators in European countries who wish to develop a new stroke research network. Approaches to achieve this include: developing a New Stroke Research Network Toolkit (a suite of supporting materials available on the ESOTA web-site), providing educational sessions at national stroke conferences, and by providing informal advice to national stroke investigators upon request.

6. Meetings:

Strategic goal: To develop effective communication between members of ESOTA Steering Group and Investigators.

Steps to achieve:

6.1 Steering Group meetings:

The ESOTA Steering Group will meet 4 or 5 times per year, in-person or by video/teleconference. Additional meetings may be scheduled as required. Materials will be forwarded at least 1 week ahead of each scheduled meeting.

6.2 Investigator meetings:

It will be important for ESOTA investigators to meet on a regular basis, in person whenever possible. An investigator meeting will take place each year at ESOC. Additional ad hoc meetings may be arranged linked to other conferences (eg. Karolinska Stroke Update, ESO Stroke Science Workshop, national stroke conferences) or to work on specific projects.

7. Collaboration on clinical trials:

Strategic goal: To support collaboration among ESOTA investigators on clinical trials for stroke prevention, acute treatment, and recovery

Steps to achieve:

7.1 Existing trials:

A database of investigator-led randomized clinical trials which are ongoing in ESOTA countries will be compiled and maintained on the ESOTA web-site. This will be updated regularly. Lead investigators will be invited to discuss their trials at ESOTA investigator meetings. Researchers from ESOTA countries will be invited to participate in existing trials

7.2 New trials:

Ideas or protocols for new trials may be proposed by ESOTA investigators and circulated to investigators in other ESOTA countries to seek their collaboration. In

addition, workshops and writing groups of ESOTA investigators may be established to develop new trial proposals for funding submissions.

8. Supporting women and young investigators:

Strategic goal: To establish pro-active mechanisms to encourage participation of women and young investigators in ESOTA

Steps to achieve:

A priority will be to pro-actively support female stroke researchers and young investigators in the leadership of ESOTA⁷. Within ESO rules, we will work to ensure reasonable gender balance in the composition of the Trials Network Committee. Working with the ESO Women Initiative for Stroke in Europe (WISE) group, issues and barriers experienced by women in stroke research will be considered at ESOTA meetings, as a first step towards identifying areas for improvement. In collaboration with the ESO Young Stroke Physicians and Researchers Committee, sessions targeted towards young investigators will be supported by ESOTA. ESOTA investigators will provide teaching on clinical trials to young investigators at ESO educational meetings (eg. ESO Summer School, Masters in Stroke Medicine teaching courses).

9. Education:

Strategic goal: To provide education to ESO members who wish to conduct investigator-initiated stroke trials.

Steps to achieve:

9.1 Education programme with ESO Educational Committee:

In collaboration with the ESO Educational Committee, ESOTA will work with existing ESO initiatives (eg. ESO Summer School, ESO Winter School, training courses held at ESOC) to lead a programme of training, education, and mentorship to teach young European physicians and healthcare professionals the skills to participate in multi centre trials and be future leaders of European trials. The target audience will be young European stroke physicians and stroke physicians of any age interested in developing investigator-initiated stroke trials.

Specific actions will include:

- 2019: To collaborate with the ESOC2019 Educational Committee in the development of one teaching course focused on stroke trials design and development.
- 2020: To collaborate with the ESO Young Stroke Physicians and Researchers Committee in the development of an Early Researcher Career workshop
- 2020: To participate in the ESO Winter School with one talk focused on the key steps to develop an academic clinical trial in stroke.
- 2021: To participate in the ESO Summer Summer School with one talk focused on the key steps to develop an academic clinical trial in stroke.

9.2 Other steps:

Other steps may include development of an ESOTA educational workshop or Early Researcher Career workshop as a pre-conference meeting at the 2020 ESO-Karolinska meeting and to develop a mentorship program consisting of two-week visits to established stroke research centers. The specific program, number of grants, and criteria for the selection of candidates to be developed in collaboration with the ESO Executive Committee/Educational Committee.

10. Communications:

Strategic goal: To improve communication between stroke researchers and other stakeholders in Europe and to increase awareness and update progress of ESOTA **Steps to achieve:**

10.1 Communications Working Group:

A Working Group will work on communications activity. This is a subgroup of the ESOTA Steering Group.

10.2 Website development and updating:

ESOTA has developed a website (www.eso-trialsalliance.org). Further development of this website will involve linking or merging to the ESO Trials Committee website, increasing awareness of the ESOTA activities, highlighting ESOTA meetings (with photographs), and posting the database of existing ESOTA trials. Links to websites of national member organisations will be provided. The website will be updated regularly.

10.3 ESO blog, newsletter, and Twitter:

ESOTA Steering Group members will contribute materials regularly for posting. Examples may include clinical trial stroke news, hot topics, trial-related interesting case reports..

10.4 Journal publications:

Review articles describing symposium proceedings of the Trials Network Committee and ESOTA have already been published or will be submitted for publication to journals such as the European Stroke Journal. Links to these will be posted on the ESOTA website. Links to publications of ESOTA members may also be added.

10.5 Global Alliance of Networks in Stroke (GAINS):

ESOTA Steering Group members are members of the Executive Committee of the GAINS group. Ongoing representation of ESOTA at GAINS will ensure the participation and leadership of ESOTA and ESO in the planning of global stroke trials.

11. Advocacy:

Strategic goal: To promote measures to support the conduct of stroke trials to key European stakeholders

Steps to achieve:

11.1 Patient groups:

Working in coordination with the ESO Executive Committee, ESOTA will link with patient representative groups at European/national levels (eg. Stroke Alliance For Europe) to establish and implement shared priorities for advocacy for stroke clinical trials.

11.2 Funding agencies:

Working closely with the ESO Executive Committee, ESOTA has coordinated the ESO response to the consultation phase for the European Union Horizon 2020 funding call planned for 2019. In collaboration with patient support groups and the ESO Executive Committee, the ESOTA Steering Group will continue to engage with relevant funding agencies to promote adequate funding of investigator-led stroke trials.

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