Health Research Board
Stroke Clinical Trials Network Ireland

Strategy 2016-2021

SCTNI Team

Network Team

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SCTNI Board

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Contents

1. Background

Stroke is the second leading cause of death in the world, the leading cause of new disability, and a major cause of cognitive decline and increased health costs. Stroke Research Networks have been established in the UK, North America, and Australia, leading to improvements in the understanding of the aetiology and treatment of transient ischemic attack (TIA) and stroke, and of rehabilitation and recovery following stroke.

Established in 2016, the HRB–Stroke Clinical Trials Network, Ireland (HRB–SCTNI) is a research network partnership that brings together Irish clinical scientists, rehabilitation and health services researchers, healthcare teams, and patients, linking them with global experts in the field of stroke research.

Agreed following the 2018 mid-award review, this document outlines the strategic overview guiding SCTNI for the period 2016-2021. A strategic review and update will be undertaken at the end of this period. During its development, the document has been subject to wide consultation with relevant stakeholders in Ireland.

2. Mission

The mission of the SCTNI is to promote collaboration amongst stroke researchers, to facilitate engagement in stroke clinical trials research in Ireland, and to encourage closer collaboration with stroke research networks in Europe and around the world. This approach will provide Irish patients with access to new treatments and interventions, with the potential to improve emergency stroke treatment, prevent stroke recurrence and post-stroke cardiac events, and improve recovery after stroke.

3. Governance

Strategic Goal: To develop a clear governance and operational structure for meeting SCTNI objectives.

Approach to implement:

3.1 Network Board
The Network Board provides a high-level oversight function for SCTNI strategic direction and operations. The Network Board includes SCTNI co-investigators, Irish clinician scientists

involved in cerebrovascular disease research, the Medical Director of the Irish Heart Foundation, the Clinical Lead of the National Stroke Programme, and a patient representative. Its composition will rotate at regular intervals. The Chair of the Network Board will be independent of the SCTNI Lead Investigator and Co-Director positions. The Board will meet approximately twice per year. A three-person International Advisory Panel will provide input on overall network direction and progress at intervals of 12-18 months.

Figure 1: SCTNI Governance Structure
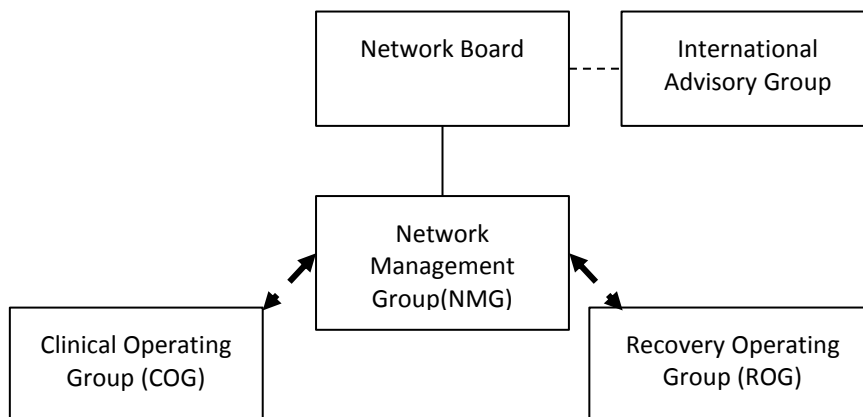
3.2 Leadership

To enable effective leadership across the wide range of activities undertaken by SCTNI, the network has developed a shared leadership model since 2018. Prof Peter Kelly is the Lead Investigator on the funding applications for SCTNI. Prof David Williams (Co-Director) is a Collaborating Investigator on all funding applicationsThe Network has also appointed a Training and Education Lead (Prof Anne Hickey). Profs Kelly and Williams work closely together in the development and implementation of the network strategy and implementation of its goals. While both provide leadership for all strands of network activity, Prof Kelly has additional focus on the CONVINCE trial, and international network relationships, including with European Stroke Organisation and other international collaborators. Prof Williams provides particular focus on other network trials and member engagement through the Clinician's Operating Group and Recovery Operating Group, and will represent the network jointly with Prof Kelly to align its activities to the needs of stroke patients and the health service.

3.3 Operating Groups

The Network Board is supported by the *Network Management Group (NMG)*, a smaller group comprised of the SCTNI Co-Directors, the SCTNI Training and Education Lead, the

SCTNI Project Manager, and other Network Project Team members as appropriate. The Network Management Group is responsible for managing the day-to-day activities of the SCTNI. The SCTNI Project Office is based within the UCD Neurovascular Research Unit at the Clinical Research Centre at the Mater University Hospital, Dublin. The NMG meets on a monthly basis, in-person or by videoconference.

Trial activities of the SCTNI are supported by the _Clinician's Operating Group_ (COG) and the _Recovery Operating Group (ROG)_. The COG is comprised of leading stroke clinicians in the SCTNI network working together to select, plan and implement trials and related network studies. The ROG is comprised of SCTNI network members working on rehabilitation and recovery research and trials, with members working together to conduct person-centred research to improve the health and well-being of individuals with stroke and enhance the rehabilitation environment for this population. The Clinical and Recovery Operating Groups meet regularly (about 4 times/year) and report to the Network Management Group, with some membership shared with the Network Board.

3.4 Meetings

SCTNI Network Board: Biannual meetings
SCTNI Network Management Group: Monthly meetings
SCTNI Clinical Operating Group: Quarterly meetings
SCTNI Recovery Operating Group: Quarterly meetings

4. Research

Strategic Goal: To provide Irish patients with access to participate in research studies of new treatments and related studies with the potential to treat and prevent TIAs/strokes and enhance recovery after stroke

Approach to implement:

4.1 Overview
Members of the SCTNI will conduct randomised clinical trials and related studies in the fields of acute TIA/stroke, stroke prevention, and stroke recovery/rehabilitation trials. To achieve this, SCTNI will take four approaches:
1. Adoption of relevant studies and trials which were ongoing at the time the network began.
2. Conducting a definitive trial, as required by the terms of the initial award funding the network by the Health Research Board (CONVINCE, see below)

3. Supporting the development of other new Irish-led stroke trials and related studies within the Network.

4. Reviewing proposals received from international investigators for academic clinical trials and related studies, and from industry.

To achieve its research goal, the SCTNI will link with other related initiatives in Ireland (eg. Clinical Research Coordination Ireland, HRB Trials Methodology and Research Network), leading university-affiliated Irish hospitals, the six Irish universities, Hospital Groups, and Clinical Research Centres.

4.2 CONVINCE trial

The initial award funding the network provided by the Health Research Board required the network to conduct a definitive intervention trial. CONVINCE (COlchicine for preventioN of Vascular Inflammation in Non-CardioEmbolic stroke) is a large international randomised clinical trial of low-dose colchicine for secondary prevention after stroke, led by the SCTNI (Prof Kelly, Chief Investigator). CONVINCE is a Prospective, Randomised Open-label, Blinded Endpoint assessment (PROBE) Phase 3 trial comparing low-dose colchicine (0.5mg/day) plus usual care, to usual care alone, to prevent recurrent ischaemic stroke and coronary events after non-cardioembolic stroke and TIA.

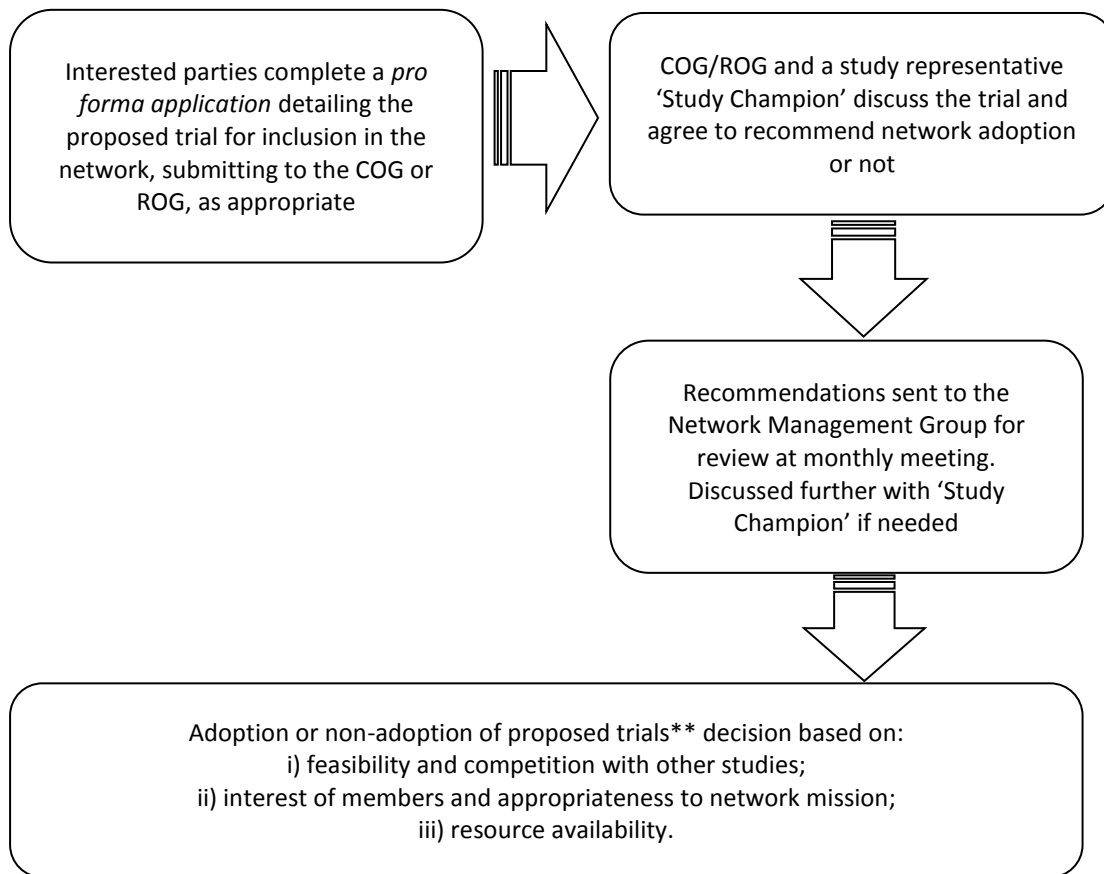### 4.3 Process for identifying and including new trials in the Network

The SCTNI welcomes the inclusion of additional trials within the Network, based on feasibility and absence of competition with existing trials, member interest and appropriateness to the network mission, and resource availability. Figure 2 overleaf sets out the process for identifying and including trials with the SCTNI. The study feasibility application form is included at the end of this document as an Appendix.

4.4 Identification of new trials/related studies in the Network

New studies will be identified via 6 main routes:
1. Applications for existing trials from network members
2. New trials developed by network members
3. Regular contact with National Institutes of Health Research (NIHR) Clinical Research Network in United Kingdom
4. Regular contact with European Stroke Organisation Trials Alliance (ESOTA), via membership of ESOTA by SCTNI
5. Direct approaches by industry to the network project office
6. Approaches by industry or investigators to related research infrastructures in Ireland (eg. HRB Clinical Research Coordination Ireland)

Figure 2: Adoption process for new trials and related studies

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┌─────────────────────────────┐          ┌─────────────────────────────┐
│ Interested parties complete  │          │ COG/ROG and a study          │
│ a pro forma application      │   ═══>   │ representative 'Study         │
│ detailing the proposed trial │          │ Champion' discuss the trial   │
│ for inclusion in the network,│          │ and agree to recommend        │
│ submitting to the COG or ROG,│          │ network adoption or not       │
│ as appropriate               │          │                              │
└─────────────────────────────┘          └─────────────────────────────┘
                                                        ║
                                                        ▼
                                          ┌─────────────────────────────┐
                                          │ Recommendations sent to the   │
                                          │ Network Management Group for   │
                                          │ review at monthly meeting.     │
                                          │ Discussed further with 'Study  │
                                          │ Champion' if needed            │
                                          └─────────────────────────────┘
                                                        ║
                                                        ▼
┌───────────────────────────────────────────────────────────────────────┐
│ Adoption or non-adoption of proposed trials** decision based on:         │
│ i) feasibility and competition with other studies;                       │
│ ii) interest of members and appropriateness to network mission;          │
│ iii) resource availability.                                              │
└───────────────────────────────────────────────────────────────────────┘
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**Individual centres or groups of centres are free to participate in any project even if not formally adopted by the SCTNI, for any reason.

4.5 Criteria for adoption of additional trials/related studies:

New trials will be adopted within the Network, based on the following scientific and logistical criteria:
1. Importance of the research question
2. Scientific quality of the study protocol
3. Study feasibility within existing network capacity
4. Potential to compete with existing trials
5. Member interest
6. Availability of resources (financial, personnel, laboratory, imaging, other)

4.6 Types of research studies adopted:

The SCTNI will adopt randomised clinical trials, at Phase 2 or 3 stage. It will also adopt selected non-randomised studies which are closely related to randomised trials. Such studies are expected to provide important information likely to lead to randomised trials of

improved treatments for acute stroke, recovery, or prevention or assessing new treatments in clinical practice. Examples include preparatory studies for planned trials (systematic reviews, studies developing new interventions, pilot or feasibility studies, studies within a trial), studies of new imaging or other markers likely to improve patient selection for future trials, and phase 4 studies assessing the safety and efficacy of new treatments in practice. Laboratory studies, translational research and epidemiological studies where a clear relationship to a planned or potential trial cannot be demonstrated will not be considered.

4.7 Support for adopted studies:

Adopted studies will:
1. be conducted by at least 2 or more network partners (hospitals and/or universities)
2. receive support by the network Project Office, for advice and other support where possible
3. receive advice where needed by the network leadership team
4. be conducted in partnership with research nurses and other staff at Irish Clinical Research Centres/Clinical Research Facilities

Studies are expected to have obtained adequate funding to support their operation within the network.

5. Supporting women in SCTNI:

Goal: To promote fairness and balance between men and women in the representation of SCTNI leadership, membership, and trial participation

Approach to implement: A priority will be to pro-actively support female stroke researchers in the leadership and membership of SCTNI. The ESO Women Initiative for Stroke in Europe (WISE) group have identified issues and barriers experienced by women in stroke research. These will be considered on an ongoing basis at SCTNI leadership meetings, as a first step towards identifying areas for improvement. Specific steps that will be taken include:
1. Promotion of gender balance in network leadership groups
2. Encouragement and support of female researchers in SCTNI activities
3. Invitation of female researchers to speak at SCTNI conferences and to chair conference sessions
4. Support of female researchers for career development, including participation in trial committee meetings, and mentorship for new research projects and research papers
5. Promotion and monitoring of female patient participation in SCTNI studies with remedial action if barriers to participation are identified where possible

6. Training & Education

Strategic Goal: To support the training and education needs of SCTNI members who wish to conduct stroke clinical trials and related studies

Approach to implement: The Training and Education strand of the SCTNI is focused on supporting the training and educational needs of SCTNI members to enable them to fulfil the requirements of developing, conducting, analysing and reporting SCTNI trials (Appendix 2).

Specific training and education strands include:

- Clinical trial design and methodology;
- Clinical trial delivery and management;
- Biostatistics;
- Trials of complex interventions in prevention and recovery
- Population health and health services training

This will be achieved through developing and maintaining an up-to-date database of existing and new training and education opportunities of relevance to SCTNI members, including workshops, certified and uncertified courses, seminars, and conferences. Access to the training and education database will be through a dedicated section on the SCTNI website. Training and education opportunities will also be detailed in regular communication to network members, including a regular SCTNI newsletter.

In addition to supporting access to existing training and education opportunities, the SCTNI will also appoint research fellows to conduct research connected with SCTNI activities to be submitted for PhD/MD degrees. Fellows will be appointed to SCTNI centres as suitable mentors and projects are identified.

The SCTNI will also organise an annual conference focussing on new advances in stroke treatment. Including international and national leaders in stroke research, this will be an annual opportunity to educate physicians, nurses, allied health professionals, and the wider public about new developments and current research in stroke treatment.

6. Membership

Strategic Goal: To establish and sustain SCTNI membership

Approach to implement: Existing institutions affiliated with SCTNI include 10 leading university-affiliated Irish hospitals (6 in Dublin, 1 each in Cork, Galway, Limerick, and Waterford) and 6 Irish universities (University College Dublin, Royal College of Surgeons Ireland, Trinity College Dublin, NUI Galway, University College Cork, University of Limerick). Within these, institutions individual members of the SCTNI will be those engaged in stroke research, including health professionals and university-based researchers.

In addition, health professionals within seven affiliated regional hospitals are either active participants, or have expressed interest in participating in, selected SCTNI studies (Our Ladys Hospital Drogheda, St Lukes Hospital Kilkenny, South Tipperary University Hospital Clonmel, University Hospital Sligo, Cavan General Hospital, Letterkenny University Hospital, Naas General Hospital). Because these hospitals currently lack access to research infrastructure or support, their involvement will be mainly in selected low-complexity studies, assessed on a case-by-case basis.

7. Communications & Outreach

Strategic Goal: To promote the work of the SCTNI to a range of stakeholders to meet strategic goals

Approach to implement: The SCTNI has developed a communications plan centred around four key objectives:

- To promote and achieve continued engagement of the network within the Irish research community
- To promote public investment in Irish stroke research infrastructure, via meetings and submissions to policy-makers within the Department of Health and the Health Service Executive, working closely with the Clinical Advisory Group of the National Stroke Programme, which directly communicates with health policy-makers and funders and submits annual funding plans for stroke services development.
- To promote private investment in SCTNI, via unrestricted educational and research funding, via communication with the healthcare industry in Ireland and abroad.
- To encourage input from patients and patient groups, as well as raising patient awareness and securing participation in the SCTNI's work.

The SCTNI has developed a [website](). This website is updated regularly to include details of network trials, training and educational opportunities, and member profiles (among other things). A social media presence, e.g. on Twitter, ResearchGate and/or other platforms, as deemed appropriate by the SCTNI Network Management Group, will further promote the work of the SCTNI and link to a range of stakeholders. In addition, a regular e-mail newsletter will be sent to SCTNI members summarising information on SCTNI activities, upcoming events, training and education, new resources and opportunities (e.g. publications, funding availability etc), and member profiles. Members will be asked to submit details of items for inclusion in newsletters, which will be posted on the website.

Where needed, the Communication teams in the Irish Heart Foundation and UCD, which have close links with general news and specialist print and broadcast media, will advise on the delivery of SCTNI communications objectives.

The SCTNI annual conference also provides a forum for communication and knowledge exchange between network members and other stakeholders, including international colleagues.

8. Public & Patient Engagement (PPI)

Strategic goal: To achieve involvement and active engagement of patients and public in SCTNI activities

Approach to implement:

8.1 Existing PPI within the SCTNI
The SCTNI has sought to involve and engage with the public, patients and patient advocacy representatives since its formation. Members of the SCTNI team have been involved in radio and press coverage to bring stroke research to a wider public audience. The SCTNI has also engaged with patients and patient advocacy groups in the early planning for the SCTNI and the CONVINCE trial, and through focus group activities with patients with the Cross-border Healthcare Intervention Trials in Ireland Network (CHITIN). At the governance level, a representative from a patient advocate organisation participates in the SCTNI National Executive Committee, which provides a high-level oversight function for SCTNI strategic direction and operations. As the main patient representative organisation for stroke in Ireland, the Irish Heart Foundation is also affiliated with the Network.

8.2 Increasing PPI within the SCTNI
As the SCTNI evolves, and in recognition of the multiple ways in which patients and the public can be involved in the research lifecycle (see Figure 1), the SCTNI aims to further develop and deepen the involvement and engagement of patients and the public in SCTNI activities.

Towards this, the SCTNI leadership team organised meetings with the Irish Platform for Patient Organisations, Science, and Industry (IPPOSI) and UCD PPI Ignite in 2019. Discussions were also held at the National Executive Committee and Network Operating Group to internally review steps aimed at strengthening the PPI component in SCTNI activities.

With the aims of enhancing patient and public involvement in SCTNI activities, and of increasing awareness and understanding of the PPI voice in a range of research contexts, the SCTNI will undertake the following steps:

1. Continue the existing patient advocate representation on the Network Board

2. Identify 2-4 Patient Ambassadors who will engage with SCTNI leadership and members for key SCTNI activities. These Patient Ambassadors will ideally be patients who have had stroke and participated in or are familiar with clinical trials. They will be paid for their time and reimbursed for expenses.

3. Specifically, these Patient Ambassadors will be asked to contribute to SCTNI reviews of requests for adoption of new clinical trials and related studies, to ensure that the patient perspective is considered and represented

4. Patient Ambassadors will be consulted at an early stage in the development of new clinical trials and related studies (eg. feasibility studies) undertaken and led by SCTNI members. In addition, wider focus groups involving patients may be held.

5. Patient Ambassadors will be invited participants and speakers at SCTNI meetings

6. Where possible, SCTNI will work with IPPOSI to promote stroke patients and/or family members taking part in clinical trials to access the IPPOSI patient education programme

7. SCTNI members will be encouraged and supported to incorporate public and patient involvement as a standard in research protocols for current and future studies, including
    o Identification and promotion of PPI engagement and education opportunities via the SCTNI website, newsletters, and social media.
    o Provision of lay summaries for SCTNI-associated studies and research applications, disseminated through the SCTNI website, newsletters, and social media.

8. Strengthen connections with organisations external to the SCTNI, including
    o Engaging with the PPI Ignite teams awarded funding from the Health Research Board
    o Continuing to work closely with voluntary sector patient organisations, including the Irish Heart foundation(IHF,) Stroke Association of Northern Ireland, and Northern Ireland Chest, Heart, and Stroke.

9. Strategic collaboration with international partners:

Strategic goal: Develop sustained collaborations with international researchers

Approach to achieve:
The population of the Republic of Ireland is approximately 5 million inhabitants, extending to 6.5 million on the entire island of Ireland. This is in the same population range as Scotland, the Nordic countries (Finland, Norway, Denmark), and the state of Massachusetts in the United States. It is important that the SCTNI has a strategic approach to collaboration with international partners, given the large size often required of modern clinical trials.

The following approach will be implemented:

1. As a priority, given the geographic proximity and close professional linkages with colleagues in the United Kingdom, SCTNI members will work closely with colleagues in the National Institute for Health Research (NIHR) Clinical Research Network (England and Wales) and the Scottish Stroke Research Network (SSRN). Special emphasis will be placed on developing linkages with the Northern Ireland Clinical Research Network Stroke Group.

2. Equal priority will be given to European collaborations. SCTNI is a founding member of the European Stroke Organisation Trials Alliance (ESOTA) and Prof Kelly the founding chair of the ESOTA Steering Group. In addition to the NIHR CRN and SSRN, SCTNI will work closely with other ESOTA networks in Spain, Switzerland, and Netherlands on common projects. SCTNI (as part of the CONVINCE and other studies) also works with collaborators in 11 other European countries, with particularly strong collaborations in Germany and Belgium. A main focus will be on further developing these relationships in European Union countries, a pre-requisite for competing for EU research funding.

3. SCTNI is a member of the Global Alliance of International Networks for Stroke (GAINS), which includes the USA (NIH StrokeNET), Canada, Australia, Japan, and other global networks. SCTNI leaders and members have close relationships with colleagues in North America and Australia and have collaborated on shared studies, some led by Irish investigators. SCTNI will continue to collaborate with US, Canadian, and other investigators on selected trials and related studies.

10. Sustainability

Strategic goal: To support the Network structures and activities beyond the lifespan of the original HRB award.

Approach to achieve: The SCTNI is core-funded by a HRB Clinical Trials Network grant, with additional support secured from successful grant applications to the Irish Heart Foundation, and industry. An active strategy of engagement with industry stakeholders has been implemented, and further grant applications will be submitted to Irish public and international funding agencies. Contingent on feasibility, at least one application for future EU funding (usually in the range €1-10 million) will be made. Additional funds will be raised by payments from industry and academic trials. A charging model will be introduced to contribute agreed funding proportions to the Network and to participating sites. A detailed business and sustainability plan has been developed.

References:

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2. GBD 2013 Causes of Death and Mortality Collaborators. Global, regional, and national age-sex specific all-cause and cause-specific mortality and causes of death for 240 diseases, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. Lancet 2015:385:117-171

3. Stroke Alliance for Europe. The Burden of Stroke in Europe report. 2017. ISBN 978-1-5272-0858-2

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5. Norrving B, Barrick J, Davalos A, et al. Action plan for stroke in Europe 2018-2030. Eur Stroke J 2018;doi 10.1177/2396987318808719

6. Berge E, Al-Shahi Salman R, van der Worp B, Stapf C, Sandercock P, Sprigg N, McLeod M, Kelly PJ, Nederkoorn P, Ford G on behalf of the ESO Trials Committee. Increasing value and reducing waste in stroke research. Lancet Neurol 2017;16:399-408

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8. Berge E, Ford GA, Stapf C, et al. Are there opportunities for a closer collaboration on clinical stroke research in Europe? Eur Stroke J 2018;3(1);22-28

9. Kelly P, Al-Shahi Salman R, Arsovska A, Dippel D, Fischer U, Ford GA, et al on behalf of the ESO Trials Network Committee and ESOTA Steering Group. Building a European 'network of networks' for stroke clinical research - the European Stroke Organisation Trials Alliance (ESOTA). Eur Stroke J 2019 (in press)

10. https://www.eso-trialsalliance.org accessed 28th October 2018

11. https://www.globalstroketrials.org accessed 28th October 2018

Appendix 1

Study Feasibility Application Form

Study Summary to assess Feasibility for adoption in HRB Stroke Clinical Trials Network Ireland
Study Title:
Chief Investigator:
Institution:
Email:
Project Manager/CRO:
Email:
Date:

Overview for Chief Investigators:

HRB SCTNI comprises 8 hospitals linked to Clinical Research Centres/Clinical Research Facilities and 6 additional hospitals, with a coordinating Project Team. SCTNI aims to support investigator-led and industry-led clinical trials and related studies in the field of stroke acute -treatment, prevention, and recovery. To select appropriate studies which fit the capacity and resources of participating hospitals, Chief Investigators and/or CROs are requested to provide an overview of their study. This will be reviewed by the Clinical Operating Group (lead hospital clinicians) and/or Recovery Operating Group (lead therapists/allied health professionals), depending on the nature of the study. Based on feedback received at these reviews, the feasibility of conducting the study in SCTNI hospitals will be assessed. The Network team will communicate the results of the review to the study team within 4-8 weeks.

The information within this questionnaire is confidential, not for circulation beyond SCTNI, and will be used by SCTNI solely for the purpose of feasibility assessment for the conduct of the study.

STUDY DETAILS

Indication:	☐ Acute stroke ☐ Stroke prevention ☐ Stroke recovery ☐ Other – please specify
Type of study:	☐ Phase 3 randomised trial ☐ Phase 2 randomised trial ☐ Pilot study for randomised trial (pilot studies test aspects of a trial, once the trial design is near final) ☐ Feasibility study for randomised trial (feasibility studies are earlier studies to inform the design of a trial, which examine the feasibility of key design components) ☐ Observational study, providing data to inform a future randomised trial ☐ Phase 4 study (phase 4 studies collect 'real-world' data about treatment safety and implementation) ☐ Other: please specify
Number of SCTNI centres needed:	
Number of Patients (total):	
Number of Patients requested in Ireland	
Study Duration:	
Study Design:	
Primary Objectives:	
Key Inclusion Criteria	
Key Exclusion Criteria	

Study Schedule:
Please insert a table outlining the study schedule here

STUDY LOGISTICS AND RESOURCE REQUIREMENTS:

1	When is recruitment to be done for this trial or study?	☐ Mon-Fri 0800-1700 ☐ Evenings, nights, and weekends ☐ Both
2	Is recruitment for this trial or study urgent (ie. To be done by on-call stroke teams)?	☐ Yes ☐ No
3	What is the time estimated for initial recruitment and baseline visit for this trial or study?	☐ less than 1 hour ☐ 1-2 hours ☐ greater than 2 hours, please specify: _____
4	Is patient consent by a stroke consultant required? (note, this is mandatory for regulated trials involving medications, and is recommended for non-regulated trials involving medications and other studies where risk may occur due to patient participation)	☐ Yes ☐ No
5	How many follow up assessments are needed?	please specify: _____
6	Can follow up assessments be conducted by a research nurse or therapist?	☐ Yes ☐ No
7	Is funding available to support research nurse or therapist time?	☐ Yes ☐ No
8	If yes, please detail funding amounts available to support nurse or therapist time	
9	Is additional imaging required for this trial or study?	☐ Yes ☐ No
10	If yes, please indicate type of additional imaging:	☐ CT ☐ CTA or CTP ☐ MRI ☐ Other, please specify: _____
11	When is the imaging needed?	☐ Mon-Fri 0800-1700 ☐ Evenings, nights, and weekends ☐ Both
12	Does the study require images to be sent to the study office?	☐ Yes ☐ No
13	Is funding available for the imaging components?	☐ Yes ☐ No ☐ Not applicable
14	If yes, please detail funding amounts available to support imaging	
15	What other support is available for imaging procedures?	
16	Are additional laboratory tests required for this trial or study?	☐ Yes ☐ No
17	If yes, please detail	_____
18	Where are laboratory tests to be done?	☐ Local lab ☐ Shipped to central lab ☐ Both
19	Is centrifuging or other test processing required at sites by study teams excluding laboratory staff?	☐ Yes ☐ No

20	If yes, what is the time estimated for laboratory test processing by study teams?	☐ less than 1 hour ☐ 1-2 hours ☐ greater than 2 hours, please specify: _____
21	Is funding available for the laboratory components?	☐ Yes ☐ No ☐ Not applicable
22	Is funding for the study or trial in place?	☐ Yes ☐ No
23	If yes, please detail funder	
24	What is the planned payment schedule?	
25	Are overhead payments included?	☐ Yes ☐ No ☐ For negotiation
26	Does this study or trial require the support of a Clinical Research Centre/Clinical Research Facility?	☐ Yes ☐ No
27	Does this study or trial require the support of a Research Pharmacy? (note that for many studies, drug storage may be done on a clinical unit)	☐ Yes ☐ No
28	Does this study or trial require the support of a therapy unit?	☐ Yes ☐ No
29	If yes, which therapy discipline is involved	☐ Physiotherapy ☐ Occupational therapy ☐ Psychology ☐ Speech and language
30	Is funding available to support therapist time or is a research therapist to be appointed?	☐ Yes ☐ No ☐ therapist appointment ☐ Not applicable
31	Is the study or trial requesting SCTNI to prepare ethics and/or regulatory submissions?	☐ Yes ☐ No
32	Does this study or trial have a PPI (Public & Patient Involvement) component?	☐ Yes ☐ No
33	If yes, please detail further	

Appendix 2: SCTNI Education and Training Plan

Aims:
The SCTNI aims to promote education and training for health professionals in stroke research, with a focus on clinical trials, via 3 approaches:

1. Mentorship of individual candidates for Masters or PhD degrees by SCTNI investigators
Eligible candidates may be from any area of health or social care relevant to stroke clinical trials. Such candidates will be supported in raising intra- or extra-mural funding for salary and project support.

2. Partnership with existing or new programmes to educate postdoctoral clinical investigators:
Examples include the Masters in Clinical Research programme at NUI Galway, SPHeRE Diploma in Population Health and Health-services Research programme, and Irish Clinical Academic Training Programme.

3. Web-based linkage of Irish health professionals who wish to train further with existing courses and training resources:
Via an Education Hub page on the SCTNI main site, trainee physician researchers, research nurses and other health professionals will be linked to access flexible choices in relevant areas of education and training, provided either as stand-alone short courses, as modular courses with potential for incorporation into Diploma or Masters-level qualifications, or as structured components of PhD degrees. Accessibility of training and education will be a core focus of the network, with online provision of content and delivery in a blended learning format, wherever possible. This will maximize availability, accessibility and flexibility of the Network's training initiatives.

Implementation:

1. **Training and Education Leadership:**
2. **Needs assessment survey:**
3. **Identification of education resources and website development**
4. **Appointment of SCTNI research fellows**
5. **Establishment of partnerships with other courses**

Training and Education Leadership:
A Network Training Lead has been agreed (Prof. Anne Hickey, RCSI). She is developing training in conjunction with Network collaborators and co-applicants. The Training Plan is dynamic, taking maximum advantage of the considerable training and education expertise of the Network co-investigators and Network membership, and accessing additional training through national, UK and European training initiatives (see below). Network training and education activities will also involve accessing freely available online content, and bespoke educational seminars, workshops, conferences and courses organized by the Network.

Needs assessment:
Health professionals connected with SCTNI will be surveyed in 2017 about their perceived training needs. This information will guide development and implementation of training resources.

Identification of education resources and website development
The SCTNI website will have a dedicated Education page listing education resources available to clinical investigators. Examples of activities currently available to network members are as follows:

MSc and Diploma courses:
MSc in Clinical Research:
Led by Professor Martin O'Donnell (NUI Galway; SCTNI co-investigator), this Masters programme is run in collaboration with McMaster University Canada. Aimed at healthcare professionals, the

course's primary objective is to provide training to an advanced level in clinical research, providing a platform for more enhanced efficiencies in the translation of medical discoveries into clinical practice. Compulsory course modules are (i) Fundamentals of Health Research and Evaluation Methods; (ii) Introduction to Biostatistics I; and (iii) Ethics of Health Research. There is also a choice of additional modules including Observational & Analytical Research Methods, Systematic Reviews, Health Systems & Policy Analysis, and Translational Medicine.

SPHeRE Diploma in Population Health and Health-services Research (PHHSR):
The SPHeRE Diploma comprises six modules, with a particular focus on Irish population health, health systems and policy, and health services. It is a fully online Diploma, comprising of six modules which can be taken individually, building to a Certificate (successful completion of 3 modules), or Diploma level (requiring successful completion of all six modules). The SPHeRE modules are as follows: (i) Perspectives on PHHSR – linking context and methods; (ii) Health Systems, Policy and Management; (iii) Systematic Reviewing & Protocol Development; (iv) Practical Approaches to PHHSR – methods and study design; (v) Working with Health Information and Data – informatics and statistical analysis; (vi) Health Economics

HRB-Trials Methodology Research Network (HRB-TMRN):
Professor Declan Devane (NUI Galway and Director of HRB-TMRN) is a collaborator of SCTNI. The HRB-TMRN have an extensive range of training and education material available to network members under the Training and Education section of its website. It holds regular trials-related education and training events, from introductory to advanced levels, including summer and winter schools, study day workshops, conferences and online events, such as webinars and provision of online material.

CSTAR:
CSTAR is the Centre for Support and Training in Analysis and Research, located in University College Dublin. Led by Professor Leslie Daly (SCTNI co-investigator), CSTAR specialises in biostatistical and methodological areas of health research, both quantitative and qualitative, and provides regular courses in biostatistics, research methods and qualitative data analysis.

HRB-Clinical Research Cooperation Ireland:
HRB-CRCI run regular training courses in Good Clinical Practice (GCP) in Clinical Research Facilities in both Dublin and Cork. These courses include Introduction to GCP; GCP course training; and GCP Refresher Course Training.

A range of additional courses available both internationally and online are also available to network members, including the following:
Edinburgh Winter School:
A 3-day course designed to help clinical academics develop a research question for a stroke-related PhD or MD project.

European Stroke Organisation Summer School:
A 5-day course held annually, taking place in 2018 in Berlin (11th-15th September).

NIH Stroke Scale:
Free online training and certification; registering at National Stroke Association:
http://www.stroke.org/we-can-help/healthcare-professionals/improve-your-skills/tools-training-and-resources/training/nih

Modified Rankin Scale:
Free online training and certification (valid for 2 years); registering at National Stroke Association: https://secure.trainingcampus.net/uas/modules/trees/windex.aspx?rx=rankin-asa.trainingcampus.net

Montreal Cognitive Assessment (MoCA):
Free online training and certification; registering at MoCA website:
http://www.mocatest.org/training-certification/

<u>Appointment of SCTNI research fellows</u>

2 SCTNI research fellows have been appointed to date (Drs Sarah Coveney and John McCabe). These are conducting research connected with SCTNI activities to be submitted for PhD degrees. Further fellows will be appointed to SCTNI centres as suitable mentors and projects are identified.

<u>Establishment of partnerships with other courses</u>

SCTNI will explore partnerships with other courses to support health professionals interested in conducting post-doctoral research (eg. SPHERE, ICAT).