

How might we structure an ESO Trials Alliance?

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Disclosures

- Lead, Stroke Trials Network Ireland (funding Irish Health Research Board, IHF, industry)
- Chief Investigator CONVINCE trial
- Steering Committees, TEMPO2, TWIST
- Speakers honorarium: Daichii Sankyo 2015

Stroke Research Network Models

1. Convenience Network:

Set up and disbands after a single trial.

2. Local Identification and Outreach Network (LION):

- Regional.
- AHC acts as Coordinating Centre for regional hospitals and smaller clinics, conducting regulatory, data Mx, contracts, insurance, PV, etc
- Eg. Yale University/Connecticut

Stroke Research Network Models

3. Gateway Network:

- Key feature is agreement by network members that a representative committee will select trials for adoption by the entire network, after considering funding and competing studies.
- Varying degrees of support provided (eg. nurse and pharmacy in UK SRN)
- Trial PI and team provide funding and manage trial
- Eg. UK SRN, Australasian STN, Canadian Stroke Consortium

Stroke Research Network Models

4. Fully-managed Network:

- A 'full service model'.
- Combines 'gateway' committee to select trials with full support for trial management, monitoring, data management.
- Investigators provide scientific leadership.
- Eg. USA StrokeNet (NINDS)

Differences among Stroke Research Networks

1. **Size and scope** – regional, national, international
2. **Role in trial conduct** – simple facilitating collaboration between centres, ‘gateway’, full trial management
3. **Funding** – small amounts/ad hoc, or reliable long-term ‘hard money’

Is it possible to apply one of these models to an ESO Stroke Research collaboration?

Guiding Principles of an ESOTA

1. Must be *feasible* – avoid over-ambitious project with high risk of failure
2. Maintain *member independence* for participation in specific projects
3. Strong focus on regular consultation with members – ie. *owned by the members*, not ‘top down’

>90% support in survey for all

External Constraints on ESOTA

1. **Complexity**

- Likely complex differences in structures, regulation and practice across ESO countries (eg. trial monitoring)
- If 'fully-managed model' - large staff needed to manage multiple trials in multiple countries

2. **Funding:**

- No large sustainable core funding to support large numbers of Network staff to manage trials across Europe
- H2020 limited by 5 years – suited for specific projects, not infrastructure
- Limited core funding might be available (national agencies, ESO)

3. **Autonomy:**

- Concerns about small group selecting trials to be conducted across European network

Possible solution – Alliance model

- Unlike national networks, Alliance model better suited to international collaboration
- Aim – foster research, education, advocacy but *not to manage trials*

The InFACT Alliance

- International Forum of Acute Care Trialists (InFACT) www.infactglobal.org
- A global alliance of national/regional networks for Critical Care research
- 21 members – Europe, USA, Canada, S America, Australia, Asia
- Similar approach being adopted by GAINS

			
<p>AMC ACADEMIC MEDICAL CENTER, AMSTERDAM</p>	<p>ANZICS AUSTRALIAN AND NEW ZEALAND INTENSIVE CARE SOCIETY</p>	<p>BRICNet BRAZILIAN RESEARCH IN INTENSIVE CARE NETWORK</p>	<p>CCCCTG CHINESE CRITICAL CARE CLINICAL TRIALS GROUP</p>
			
<p>CCCTG CANADIAN CRITICAL CARE TRIALS GROUP</p>	<p>CRISMA CLINICAL RESEARCH, INVESTIGATION, AND SYSTEMS MODELING OF ACUTE ILLNESS CENTER</p>	<p>ESICM ESICM CLINICAL TRIALS GROUP</p>	<p>George Institute THE GEORGE INSTITUTE FOR GLOBAL HEALTH</p>
			
<p>GiVITI GRUPPO ITALIANO PER LA VALUTAZIONE DEGLI INTERVENTI IN TERAPIA INTENSIVA</p>	<p>GSA HELLENIC SEPSIS STUDY GROUP</p>	<p>ICNARC INTENSIVE CARE NATIONAL AUDIT AND RESEARCH CENTRE</p>	<p>ICS UK INTENSIVE CARE SOCIETY UK CLINICAL TRIALS GROUP</p>
			
<p>ICCTG IRISH CRITICAL CARE TRIALS GROUP</p>	<p>LASI LATIN AMERICAN SEPSIS INSTITUTE</p>	<p>NCRN NEUROCRITICAL CARE RESEARCH NETWORK</p>	<p>PETAL PREVENTION AND EARLY TREATMENT OF ACUTE LUNG INJURY</p>

The InFACT Alliance

Key features:

1. Emphasis on fostering collaboration. Annual meeting with balance of work and social activities.
2. Small Executive Committee and Council of members representatives
3. No large staff
4. Meetings/website funded by small grants (national, professional organisations)
5. No 'gateway' – trials not formally 'approved', but discussed at meetings – investigators can participate if interested
6. Not involved in trial management – done by investigators
7. Working Groups on specific projects – eg. H1N1 pandemic trial

InFACT mission statement

‘ supports the activities of its member groups by:

- Addressing research challenges and needs that are common to researchers around the world
- Providing an informal forum to promote collegiality and collaboration between and among its members
- Linking acute care clinical sites around the world to facilitate global collaboration in research, public health activities, and education
- Raising the profile of investigator-led acute care research with funding bodies, health care policy and decision-makers, and the general public’

ESOTA mission statement??

‘ supports the activities of its member groups by:

- Addressing **Stroke** research challenges and needs that are common to researchers around **Europe**
- Providing an informal forum to promote collegiality and collaboration between and among its members
- Linking **Stroke** clinical sites around **Europe** to facilitate **European** collaboration in research, public health activities, and education
- Raising the profile of investigator-led **Stroke** research with funding bodies, health care policy and decision-makers, and the general public’

Possible structure of an ESO Trials Alliance

- Model on successful InFACT Alliance
- Goal to support research collaboration and education but not to manage trials
- Small Executive, supported by Member's Council
- Regular meeting(s), possibly linked to ESOC and/or stand-alone
- Focus on trials but inclusive of other research areas

Initial priorities? For discussion

- Identify Executive, seed funding and support team (ESO?)
- Invite member applicants
- Working groups on Specific projects:
 1. Website/communications
 2. ESO database of trial-ready centres
 3. On-line Stroke research support tool-box (Database of funding sources, monitoring, contracts, regulatory for IITs)
 4. GAINS linkage
 5. ESOTA conference

Your comments are welcome



Core features of Stroke Research Networks

1. Organised collaboration of stroke clinical researchers across multiple centres
2. Some coordinating structure (Board, Exec Committee)
3. Focus on trials, but may include other research areas (eg. epidemiology)
4. Multiple studies run simultaneously
5. Infrastructure remains after completion of individual projects