

# Meeting To Discuss The Formation of A Scottish Clinical Trials Group.

Friday 16<sup>th</sup> May 2003

Room G8124, Education Suite, Royal Infirmary of Edinburgh

## MINUTES

Present: Dr Brian Cuthbertson, Dr Sandy Binning, Dr Tim Walsh, Ms Fiona McArdle

Apologies: Dr Stephen Cole

### 1. Welcome & Introduction

As a starting point, it was agreed that a clinical trials group for critical care should retain an ethos of collective ownership. Group activity should be representative of the general membership and should reflect UK research priorities.

It was felt that initially it would be beneficial to restrict membership to Scottish centres. A strong national group identity is expected to foster greater cohesion among members. At a later date, once the group is established, it may be desirable to collaborate with centres in Northern Ireland and England. It was agreed that the ICS should be notified of the formation of the Scottish clinical trials group for critical care.

Action: TW

### 2. Aims of Clinical Trials Group:

A number of aims were suggested for the group:

- To produce high quality research in critical care.
- To design & execute high quality RCTs.
- To support research on different levels.
- To contribute to the development & design of clinical trials.
- To be inclusive.
- To promote the dissemination of research findings.
- To identify areas of research need in collaboration with the EBM Group & the SICS Audit Group.
- To establish links with agencies such as HSRU, SCIEH

A formal proposal for the development of the group will be written and presented to the SICS council later this month.

Action: TW/BC

### 3. Composition of Clinical Trials Group

There was agreement that the CTG should be composed of an executive committee, comprising research active members with proven track records and a broader group, comprising general members who demonstrate intent to participate in meetings.

#### Executive Committee

The role of the executive committee will be to support the aims of the CTG. Responsibilities of the executive group will include: overseeing the constitution of the CTG, managing a clinical trials office, sourcing & managing research funds, contributing to the evolution & design of clinical trials, managing the patient base in relation to concurrent trials, prioritising studies etc

#### Composition of The Executive Committee

It was agreed that the executive committee should be composed of a Chairperson, a study group coordinator and three other SICS members. It was felt that a small group would retain cohesion and work effectively. Non-critical care members could be co-opted on to the committee as and when specific expertise and collaboration is required. It may be desirable to have permanently co-opted members from certain agencies eg HSRU.

The Chairperson should be nominated by the CTG through the SICS Council. It was agreed that the tenure of Chairmanship should be of sufficient length to allow realistic progress towards CTG aims & objectives. Tenure should be a minimum of three

years, with no stated limit. Application for committee membership will be made through the Chairperson and will be subject to ratification by the SICS council. Disputes in relation to such applications should be referred to the SICS president.

There was some discussion around who should sit on the executive committee. It was acknowledged that in order to drive forward key studies, it would be useful to have representation from the bigger centres. However, it was agreed that there should be no geographical or other constraints to membership. All agreed that it would be useful to have a representative of the smaller hospitals.

#### Composition of Broad Clinical Trials Group

The broad CTG should have an open membership of interested clinicians and allied health professionals. There will be no membership fee.

#### 4. Infrastructure:

It was noted that there is informal agreement for a critical care trials office to operate from the NRIE. Such an office can provide a central point of contact for studies as well as forming a base for the provision of research governance arrangements. In the long term, it was envisaged that the creation of a trial coordinator post would be desirable. In the interim, Fiona McArdle (Research Coordinator ICU, RIE) will provide some informal support in this capacity.

Some concern was expressed that future appointments to the Chair could result in geographical distancing of the Chairperson from the clinical trials office. It was agreed that there could be some flexibility in the location of the trials office, though this may impact upon other personnel (trial coordinator/administrator). It was also agreed that a trials office would not have to be affiliated to one university in particular and that there would need to be some facility for investigators to run studies through their parent universities. Though the current arrangement at the NRIE is very informal, future arrangements may need to be secured formally when funding is successfully obtained.

#### 5. Funding

Financially, the long-term aim of the group is to become a major grant holder. In order to achieve this, it is in the group's interests to develop collaborative links with the MRC. This can be done independently of requests for MRC funding. A provisional approach will be made to the MRC to this effect.

Action:BC

In the short term, the group will need foundation funding and various avenues of support were discussed in relation to this. It was agreed that the group would seek assistance from industry but that this would be strictly under "no strings" conditions. A list of potential sponsors will be drawn up and a generic letter drafted which can be circulated to managing directors in industry.

Action: everyone

It was also suggested that the group embark on some public fundraising by targeting previously untapped sources such as rotary club, round table organisations. "Soft money" of this nature will be best managed through a charitable account that affords tax benefits and is subject to independent audit. Advice will be sought on the best way to proceed with financial management arrangements.

Action: TW

The group will approach the SICS for start up funding and will advise the SICS treasurer (Dr Mike Fried) of the intention to set up an account with charitable status. A budget/business plan will be prepared to present to the SICS. This will include details of office equipment and a request for part-time salary support costs to accommodate a trial coordinator/administrator post.

Action: TW

It was suggested that requests for funding should be worded in the context of a need for "ongoing support" to build on achievements to date. To this end, it would be helpful to construct a group portfolio of completed research projects/publications. It was agreed that the group would review their collective research activity at a future meeting.

Action: everyone

It was noted that among the meeting participants, there exists a wealth of data that could be used to strengthen future funding applications eg IHD & SOFA data from ATICS, QOL data from Aberdeen. It was agreed that funding should be sought for statistical support to conduct further analysis on such data. A small project grant from the CSO would be an appropriate level of support for this.

Action: SB

Management of institutional overheads related to research studies was discussed. Where possible, such overheads should be processed via Trusts. All agreed that it would be beneficial to approach their respective R&D offices to discuss means of coordinating this process.

Action: everyone

## 6. Dissemination

The executive committee will meet twice yearly and there will also be meetings of the entire CTG twice yearly, one in January (tagged on to annual SICS research meeting) and one in June. The meeting in January will provide an opportunity for the presentation of research proposals/findings and the summer meeting will provide a forum for the assessment of potential projects. The MRC checklist for research proposals will be modified to provide a local framework for the appraisal of potential projects.

Action: BC

Abstracts from the annual SICS research meeting are published in the Scottish Medical Journal. The possibility of having such abstracts published in Anaesthesia will be explored.

Action: SB

This year, the executive committee will intend to meet in August, prior to the first meeting of the broad CTG on 10th September. It is anticipated that the September meeting will take place at Stirling Royal Infirmary.

Action: TW/FM

The executive committee will report annually to the SICS AGM .

It was agreed that the SICS Nutrition Group should be made aware of the formation of a CTG. The Nutrition Group may or may not want to conduct studies in association with the CTG, this can be determined in due course.

Action: TW

The group will liaise with the SICS audit group regarding the extraction and use of data from WardWatcher for research purposes. It is anticipated that the CTG will allow such requests to be made in a focussed manner. The possibility of sourcing funding to support data extraction should also be explored. The group will write to Dr Simon Mackenzie to establish contact with SICSAG.

Action: TW

It was agreed that the CTG should develop an independent website with links to the SICS website. Chris Cairns has some experience in this matter and should be consulted for advice. Development costs should be included in the budget prepared for the SICS Council.

Action: TW

The CTG will circulate a newsletter to its membership every 6 months. It is intended that the first issue of the newsletter will be distributed in June. This will provide a medium through which the group can conduct a scoping exercise for research questions. A group name and logo will be required for the website and newsletter. Dr John Kinsella will be asked to provide a mailing list of SICS members.

Action: FM