Rare Diseases Ascertainment and Recruitment (RaDAR)

The Association of British Neurologists, 27 Boswell Street, London WC1N 3JZ
Tel: 020 7405 4060   Fax: 020 7405 4070   Email: admin@abn.org.uk

GUIDELINES ON APPLICATIONS FOR INCLUSION OF STUDIES

1 INTRODUCTION

1.1 Applications for inclusion of a study in RaDAR will be considered by the Research Committee (RC).

1.2 RC will give fair and impartial consideration to all applicants. However, applicants (at least one) have to be members of the ABN. Applicants may be invited to a meeting of RC to discuss their project.

1.3 Applications should be submitted on the RaDAR application form enclosed with these guidelines.

1.4 A single fee of £250 for the 3-year maximum duration is requested by as a contribution towards administration costs.

2 IMPORTANT CONSIDERATIONS

2.1 A study is eligible for inclusion in the scheme if the condition of interest is a relatively rare neurological disorder (or a rare complication of a more common one), of such low incidence or prevalence as to require ascertainment of cases on a national scale in order to generate sufficient numbers for meaningful study.

2.2 There is no age limit, but obviously ascertainment of paediatric cases will be very limited.

2.3 RC will take into consideration the scientific interest and general neurological importance of the proposed study, its methodology, and suitability for ascertainment via the RaDAR scheme.

2.4 RC recognises that more than one year of surveillance may be required for a very rare condition. However inclusion will be initially be for one year, with renewal for a maximum of two more years provided at least one case has been ascertained in the first year of surveillance.

2.5 It is important not to overburden the reporting doctors. RC will therefore take into account the demands individual studies make on the time and goodwill of ABN members.

2.6 The maximum number of conditions under surveillance by RaDAR at any one time is 8. A waiting list will operate for all additional submissions.

2.7 Extension of inclusion of a study beyond 3 years will require a written case for support to be reviewed by RC and weighed alongside any studies-in-waiting.
3 ETHICAL CONSIDERATIONS

3.1 Ethical considerations are vitally important and RC will take this into account when it reviews applications.

3.2 Issues that will be looked at are:
- preservation of patient confidentiality,
- use of data,
- consequences for the patient of being referred

3.3 REC approval must have been received and documentation forwarded prior to any study being included.

3.4 Consultants should not release identifiable patient data (such as hospital notes) to the investigator without the written and informed consent of the patient or their approved consultee. RC will need to see the proposed consent form for such release.

4 STUDY DESIGN

4.1 The normal design is by obtaining relevant copies of the patient’s notes from the consultant, or by a questionnaire or information sheet sent to the consultant by the investigator. The ABN does not assume any responsibility for chasing up responders for information.

4.2 Further data can be obtained by direct patient contact, special blood tests, scans etc. Where this is required the ethical ramifications must have been fully addressed.

5 FORMAL REQUIREMENTS

Prior to acceptance, the ABN requires the following in writing:

5.1 The proposed study must have REC approval and written details must be included.

5.2 A patient consent form must be produced by each investigator and sent to each reporting doctor for completion and filing before any patient details are released to the investigator.

5.3 Every investigator must agree to submit the findings of their study to one of the ABN meetings.

5.4 The assistance of the ABN must be acknowledged in all publications and the investigator agrees on acceptance of their study to send copies of all publications that come out of studies that utilise RaDAR.

5.5 The investigator must agree to provide for the ABN an annual account of referral numbers during the course of the study, and a brief report of <500 words on completion.