

NHS Research Scotland

Central Management Team

Guidance on Scottish Speciality Categorisation

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1. Purpose

This guidance document describes the process of categorising Scottish Speciality in both commercial and non-commercial studies within SReDA.

2. Background

Scottish Speciality was introduced as a method of associating studies active in Scotland with the relevant supporting NRS network. This information is recorded on SReDA.

Previously, for non-commercial studies, allocation of recruitment activity for each Network or Speciality Group was based on the managing speciality within CPMS.

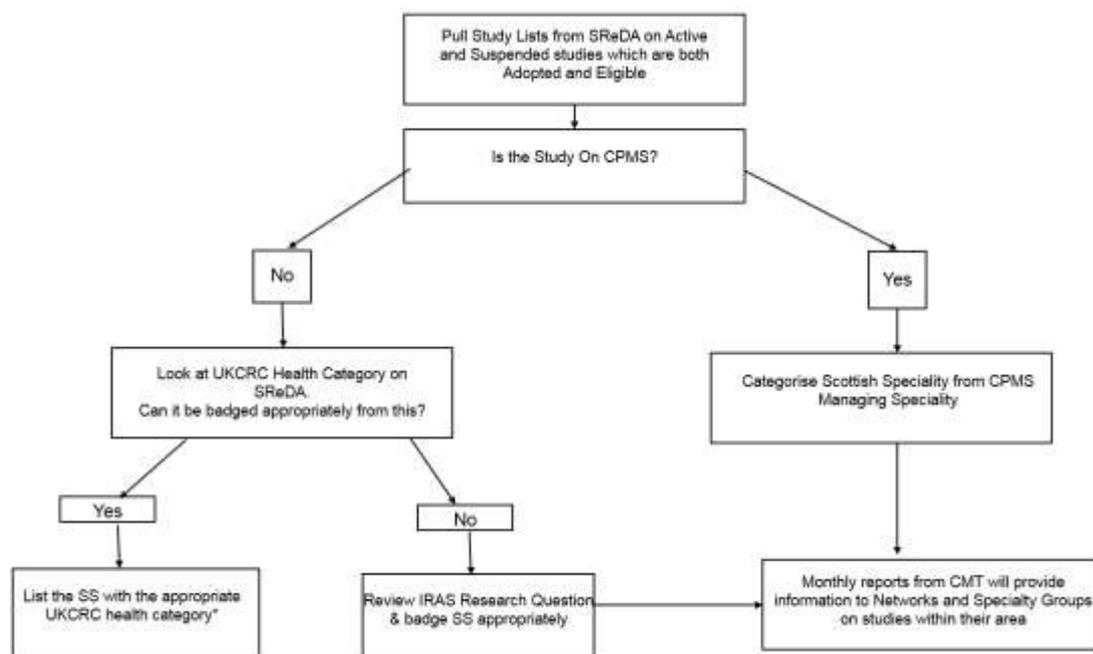
This guidance sets out how Scottish Speciality is assigned within SReDA for both commercial and non-commercial studies.

The use of Scottish Speciality in SReDA to record study association instead of relying on the CPMS managing speciality, for non-commercial studies, has many benefits:

- CPMS records owned by England may have a different CPMS managing speciality supporting the study than Scotland. Scotland cannot amend CPMS records owned by England/Wales or NI. Network and Speciality Group study association in SReDA can be amended easily regardless of where the study is led from.
- CPMS does not reflect all information on studies. SReDA can be used to report on studies which take place within NHS Scotland, but do not involve patient consent, or are otherwise ineligible for addition to CPMS (TB, Database studies, NEF).
- Studies which have yet to recruit are more easily reportable from SReDA than CPMS.
- Scottish speciality assignment in SReDA allows complete reporting of both non-commercial and commercial activity to provide an accurate reflection of the activity within the NRS Network.

3. Categorisation of Non Commercial Studies

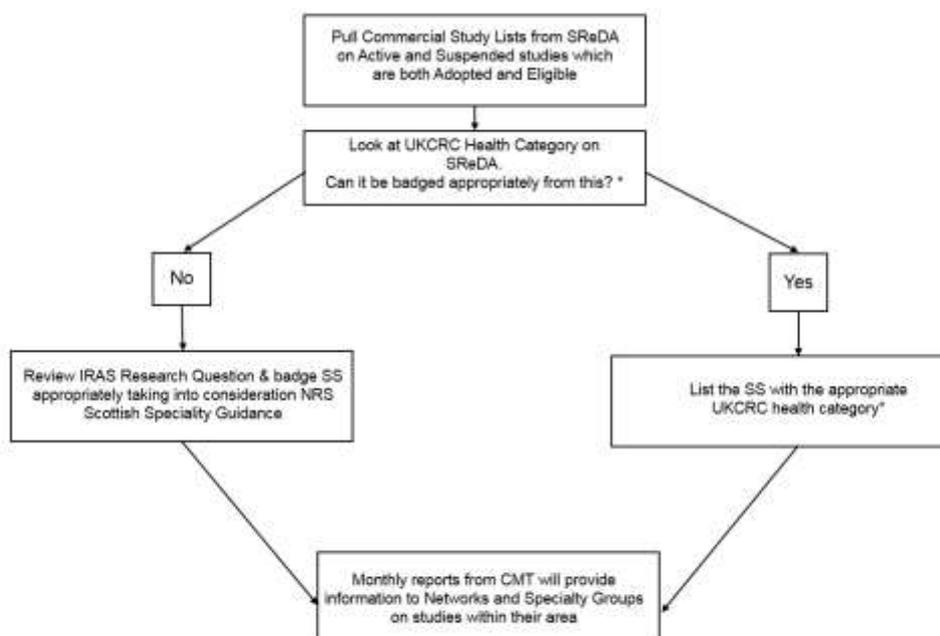
Principals of categorisation of Scottish Speciality for non-commercial studies on SReDA are performed by CMT as outlined below.



*UKCRC Health Category badging won't identify Aging, Anaesthesia, Critical Care, Hepatology or Surgery studies. Careful review of reports provided from CMT in these disease areas will highlight any omitted studies.

4. Categorisation of Commercial Studies

Principals of categorisation of Scottish Speciality for commercial studies on SReDA are performed by CMT as outlined below.



*UKCRC Health Category badging won't identify Aging, Anaesthesia, Critical Care, Hepatology or Surgery studies. Careful review of reports provided from CMT in these disease areas will highlight any omitted studies.

5. Principles for Specialty Allocation:

Scottish Speciality is allocated differently for non-commercial (section 3) and commercial studies (section 4). Scotland does not make use of CPMS records for commercial studies, however, studies led from NIHR with Scottish participation may be initiated on CPMS through NIHR processes. Therefore CPMS cannot provide a complete overview of commercial studies ongoing in Scotland. As a result all Scottish speciality will be assigned using the UKCRC field as highlighted in section 4.

Where Scottish Speciality is based on the allocation of managing specialty in CPMS this has been based on review of the whole IRAS form, in particular considering where the majority of recruitment will take place, where interventions are taking place and the age of participants.

Where Scottish Speciality is based on the UKCRC field, information is taken from the IRAS application for the study. Where an appropriate speciality cannot be identified through this process CMT will review the IRAS research question and make an informed decision on where this resides. It is then the responsibility of each Network or Specialty Group to review the list of studies sent to them from CMT each month in order to ensure that the studies listed are appropriate for their portfolio; any concerns over misallocation should be raised with CMT.

Some specific considerations to the categorisations of Scottish speciality are listed below:

- All studies where participants are under 18 years old are allocated to Children, except for Cancer and some Mental Health studies (Where the study is recruiting both children and adults the lead Specialty will be determined by the population from which the most participants are expected to, or will be, recruited).
- If inclusion criteria requires all participants to be over 60 years of age, consider allocation to Ageing
- Leukaemia is allocated to Cancer, not Haematology
- The NRS Neuroprogressive and Dementia Network will receive studies on Dementia, Parkinson's, Alzheimer's and other neurodegenerative diseases (but not TSEs)
- Neuroprogressive and Dementia Network will also receive studies on Epilepsy, HD, MND, MS and TSEs which may be allocated as Neurological on CPMS.
- Urogenital studies are generally allocated to Renal

- Reproductive Health and Childbirth accept studies on pregnancy up until childbirth.
- Neonatal studies (including premature babies) are allocated to Children
- Chronic and acute pain is allocated to Anaesthesia, peri-operative medicine and pain management
- Studies which utilise solely General Practice to recruit patients into studies and/or PIC sites to identify recruitment should consider Scottish Speciality allocation to Primary Care.
- Studies badged as Public Health, Health Services and delivery research on CPMS are allocated to Primary Care.
- Hepatitis studies:
 - All Infective Hepatitis studies are led by Hepatology and supported by Infectious Diseases and Microbiology (includes C, B, E).
 - Non infective hepatitis should be led by Hepatology only (include alcoholic, non-alcoholic Steatohepatitis etc.)
 - Studies that require patients co-infected with HIV should be led by Infectious Diseases and Microbiology, and supported by Hepatology
 - Any studies on virology should be led by Infectious Diseases (these are rare)
- Studies in the following areas will be allocated to the following specialties:
 - Musculoskeletal: Arthritis, SLE, Lupus, Rheumatology, Autoimmunity / autoimmune disease, Sjogren's Syndrome
 - Hepatology: Pancreatitis
 - Infectious Diseases: Pathogens, Meningococcal, Sepsis, Tuberculosis, Vaccines, Infection
 - Dermatology: Skin, Scleroderma, Polymyositis, Dermatomyositis
 - Nervous Systems Disorders: MS, Encephalitis

6. Process of re-categorising existing Scottish Speciality disease areas

- Re-assigning an existing Scottish specialty categorisation should always involve contacting the owning speciality via the network or portfolio manager in the first instance. Reasons should be provided for the re-categorisation to their disease area taking into account this guidance.

- If necessary, the study CI may be asked to give their opinion or clarify detail, however the CI in England may have different views on how the study is supported in England than Scotland. The view of the CI should be considered persuasive, not definitive.
- Details of network and speciality group contacts can be located here <http://www.nhsresearchscotland.org.uk/contact/networks-and-speciality-group>
- Upon agreement the Network and Speciality Group Support Manager at CMT should be contacted to update the Scottish Speciality within SReDA and track studies which have been amended.
- Where the study is on CPMS and led from Scotland the managing speciality should also be amended in CPMS.

7. Dispute Resolution

- If there is a dispute around the assignment of a study to a Scottish Specialty, the issue should be raised in the first instance with the Network and Speciality group Manager at CMT.
- If the decision of the Network and Specialty Group Manager is not accepted by the parties involved, the issue can be escalated to the NRS CMT General Manager.
- If the parties remain unable to accept the decision of the CMT General Manager, then CMT will escalate to CSO, whose decision will be considered definitive.
- The decision provided by CMT/CSO will reflect the information in this guidance and take into account the intent and protocol of the study.
- CMT will note disputes for future reference.