Introduction to the RSS, membership and role. The concerns raised by members about the REC process.

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Co-sponsored RSS/HRA workshop to consider the provision of statistical advice to RECs

27th November 2014

The Royal Statistical Society

Founded in 1834 as the Statistical Society of London and became the Royal Statistical Society by Royal Charter in 1887.

Merged with the Institute of Statisticians in 1993 – a learned society and professional body.

Today: RSS has >6200 members, of whom >1200 are Chartered Statisticians (CStats), >200 are Chartered Scientists (CSci), >450 are Graduate Statisticians (GradStats).

RSS Strategic Plan : 2014-18

STATISTICS AND THE PUBLIC INTEREST. For statistics to be used effectively in the public interest, so that policy formulation and decision-making are informed by evidence, for the good of society.

EDUCATION AND STATISTICAL LITERACY. For society to be more statistically literate, so that people's understanding of data, risk, and probability can inform their daily decision-making, leading to better outcomes.

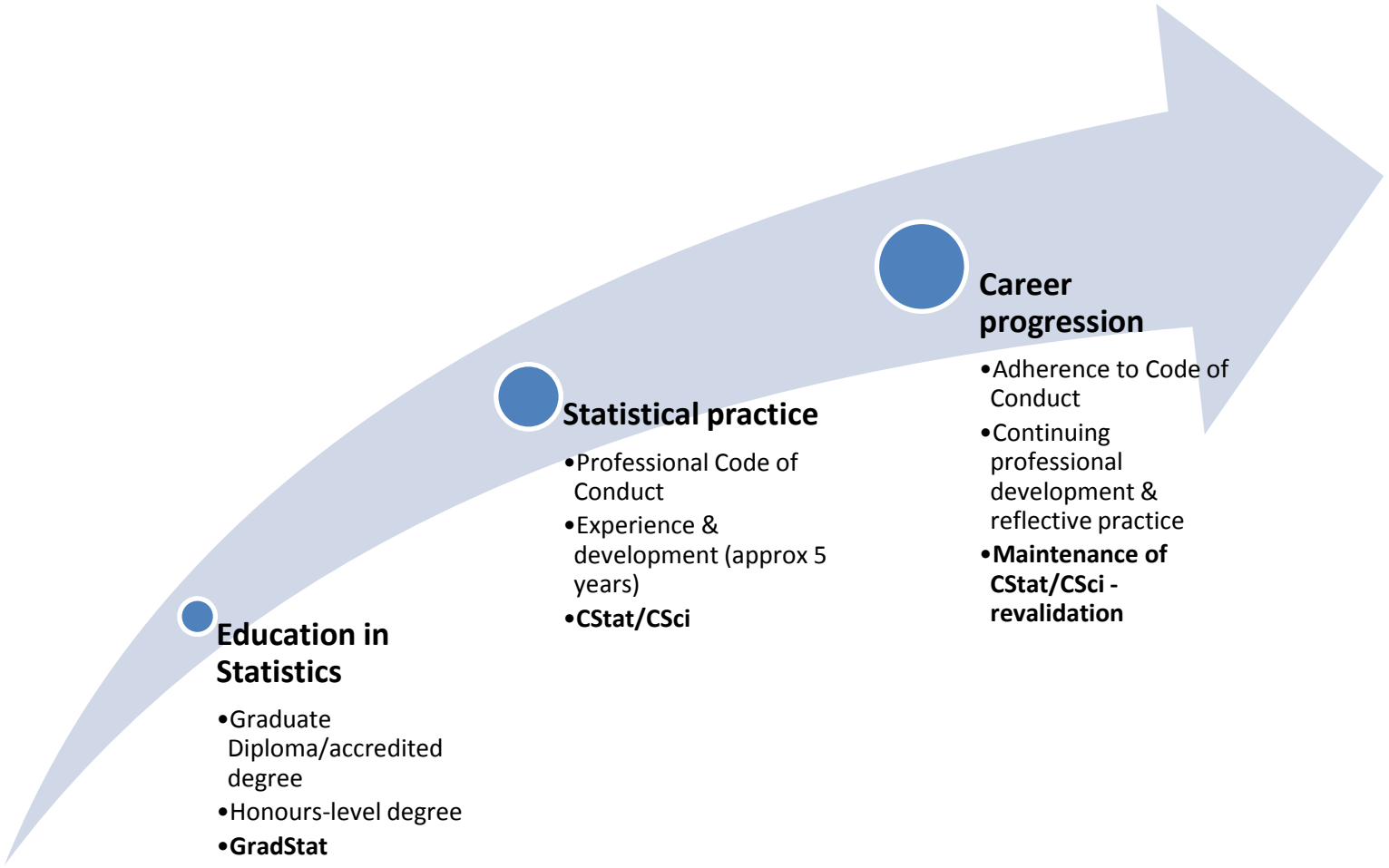
DEVELOPING THE PROFESSION. For a strong body of professional statisticians to maintain and develop the skills they need so that they can critically apply methodology, interpret results and communicate findings.

STRENGTHENING THE DISCIPLINE. For statistics as a discipline to thrive, so that methodology is advanced, applied and made accessible, leading to greater understanding of an increasingly complex world.

Professional Affairs Committee

The award and repeal of qualifications	• GradStat, CStat • CSci (licensed by Science Council)
Professional education	• Professional examinations (Ordinary certificate, Higher certificate, Graduate diploma) • Accreditation of university courses
Standards of professional competence and conduct	• CPD policy • Code of Conduct • Events/services of value to professional statisticians

The professional pathway



Retaining professional status (CStat/CSci)
The basis of revalidation

Professionals are Trustworthy, Ethical, Up-to-date & Competent

Adherence to the Society's Code of Conduct

- Working in the public interest
- Obligations to employers/clients
- Obligations to the profession
- Professional competence & integrity

Compliance with the Society's CPD Policy

- Maintenance, improvement and broadening of knowledge and skill
- Maintenance of CPD records

The aim of the workshop

- Address concerns raised by RSS members regarding the quality of the statistical aspects of submissions to RECs and the process for ensuring an appropriate statistical input/review of submissions
- To review the guidance given by the HRA on the design of clinical trials and statistical aspects of submissions
- To identify ways of encouraging appropriately qualified and experienced statisticians to become members of RECs

Research Ethics Committee process - issues raised by RSS members

Recommendations following discussion of these issues

(and others)

at the workshop

- Take no action
- Modify guidance
- Modify/add questions
- Improve training/communication/ audit to ensure consistent implementation and action across RECs
- Establish post-workshop action plan to develop a response to issues

A56. How have the statistical aspects of the research been reviewed?

Info requested

- Select from 8 options describing the role of the person who carried out the review.
- Name, department, institution, contact details of individual responsible (or dept. only if advice provided in confidence).

Issues raised

- Identified statistician has no knowledge of the research project
- Identified statistician gave some input, but unaware of the submitted version of the research proposal
- Identified person not a statistician
- Academic/educational supervisor not an appropriate person to provide statistical review

Statistical review - some questions and thoughts

- As the qualifications of the statistical reviewer are not requested, how is their suitability assessed? Is it by the responses to questions A57 to A62 and/or a detailed review of the protocol?
- RSS view - CStat is a sufficient qualification, but not a necessary requirement.
- Access to statisticians – RSS Directory of Statistical Consultants.
- The guidance indicates that the REC may ask to see the CV of the statistical reviewer, contact the individual, ask for an independent statistical review or commission its own review. Is there advice on what triggers each of these actions?
- Statistician on a REC – what is the desired profile in terms of experience and expertise?
- Statisticians need training on the remit of the REC and the contribution expected of them.

ICH-E6 : Good Clinical Practice

Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and wellbeing of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

- This guidance should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities.
- The principles established in this guidance may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.

ICH-E6 : Good Clinical Practice

5.4 Trial Design

5.4.1 The sponsor should utilize qualified individuals (e.g., biostatisticians, clinical pharmacologists, and physicians) as appropriate, throughout all stages of the trial process, from designing the protocol and CRFs and planning the analyses to analyzing and preparing interim and final clinical trial/study reports.

5.5 Trial Management, Data Handling, Recordkeeping, and Independent Data Monitoring Committee

5.5.1 The sponsor should utilize appropriately qualified individuals to supervise the overall conduct of the trial, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports.

ICH-E9 : Statistical Principles for Clinical Trials

…. it is assumed that the actual responsibility for all statistical work associated with clinical trials will lie with an appropriately qualified and experienced statistician, as indicated in ICH E6.

….. the trial statistician should have a combination of education/training and experience sufficient to implement the principles articulated in this guidance.

D2. Declaration by the sponsor's representative

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

ICH-E6 : Good Clinical Practice

5.1 Quality Assurance and Quality Control

5.1.1 The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).

5.1.3 Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.

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The relationship between scientific quality and ethical standards

- The degree to which poor science (statistical or otherwise) is unethical depends on the nature of the project.
- Question 2 of the IRAS form identifies 12 categories of studies.
- Statisticians on RECs have expressed some dis-satisfaction with the way that RECs have addressed the relationship between scientific quality and ethical standards.
- Maybe better guidance (at the category of study level?) would be helpful on the extent to which 'the validity of the research' is to be assessed by RECs.

In summary …. Issues raised

- statistical review in applications being carried out by people not qualified in statistics
- statistical review in applications being attributed to statisticians who may (or may not) have given input, but who have not seen the version of the research proposal submitted
- dissatisfaction with participation on RECs e.g. due to statistical issues (thought to impact the validity of the research) not being considered as ethical issues