An example of a CPD submission by a Senior Lecturer and Head of a Clinical Trials Unit

Commentary

The attached submission was made by a CSci registrant who was selected for audit as part of the CSci revalidation process in 2012. The submission consists of:

a. A 12 month summary (October 2011 to September 2012 inclusive) of the CPD programme taken from the RSS online CPD system.

b. A completed *Chartered Scientist CPD Revalidation Form.* This form contains the relevant context and reflection information necessary to assess the CPD activity against the Science Council's standards.

As this registrant had used the RSS online CPD system, both the *reviewed Activities* and *Benefits Gained* reports were submitted. In combination they provide information on the categories of activities undertaken, the number of learning hours undertaken and the reflective practice comments describing the benefits of each activity.

The panel of assessors concluded that this submission fully met the Science Council CPD standards, including the requirements of the RSS CPD Policy.

The submission has been (partially) anonymised for the purpose of providing this exemplar of good CPD practice.

REVIEWED ACTIVITIES REPORT

Activity Type	Title	Start Date	End Date	Learning Hours
Formal / Educational	[redacted] Annual Meeting	08/12/2011 00:00	13/12/2011 00:00	12
Formal / Educational	[redacted]	07/10/2011 00:00	07/10/2011 00:00	1.5
Professional activity	Collaboration on retrospective analysis	01/02/2012 00:00	30/09/2012 00:00	3.5
Professional activity	Development of [redacted] trial	01/10/2011 00:00	09/08/2012 00:00	3
Work based learning	Discussions with colleagues on risk index and transplant	01/08/2012 00:00	30/09/2012 00:00	12
Professional activity	[redacted] meeting	30/01/2012 00:00	01/02/2012 00:00	1.5
Professional activity	[redacted] meeting on monitoring	13/06/2012 00:00	13/06/2012 00:00	1
Formal / Educational	GCP training	20/10/2011 13:00	20/10/2011 17:00	2.5
Professional activity	Invited talk at the Polish [redacted] Group	16/03/2012 00:00	16/03/2012 00:00	0.5
Professional activity	Journal Review and Editorship	01/10/2011 00:00	30/09/2012 00:00	8
Professional activity	Leading [redacted] CTU	01/10/2011 00:30	30/09/2012 00:00	5
Formal / Educational	Medical Statistics Surgery Day	23/09/2012 00:00	23/09/2012 00:00	1
Formal / Educational	Medical Statistics Surgery Day	23/01/2012 00:00	23/01/2012 00:00	1
Professional activity	Membership of NIHR [redacted] board	01/01/2012 00:00	30/09/2012 00:00	3
Professional activity	Membership of CTC	01/10/2011 00:00	30/09/2012 00:00	1
Professional activity	Membership of Trial Steering Committees	01/10/2011 00:00	30/09/2012 00:00	1.5
Professional activity	NCRI [redacted] Working Party	01/10/2011 00:00	30/09/2012 00:00	4
Professional activity	NCRI [redacted] Study Group	01/10/2011 00:00	30/09/2012 00:00	2.5
Professional activity	Preparation of abstracts for [redacted]	23/07/2012 00:00	14/08/2012 00:00	4
Self-directed learning	Reading Papers	01/10/2011 00:00	30/09/2012 00:00	12

Work based learning	Representation on School Committees	01/10/2011 00:00	30/09/2012 00:00	4
Other	School Governor	01/10/2011 00:00	30/09/2012 00:00	1
Work based learning	Supervision of Intercalated Student	01/10/2011 00:00	30/06/2012 00:00	2
Formal / Educational	Writing papers	01/10/2011 00:00	30/09/2012 00:00	4
Formal / Educational	Writing papers on trial interventions [redacted]	01/11/2011 00:00	30/06/2012 00:00	3
TOTAL				94.5

BENEFITS GAINED REPORT				
Title	**Learning Hours**	**Activity Description**	**Benefit to Practice**	**Benefit to Users**
[redacted] Annual Meeting	12	Attended annual [redacted] meeting. Was author on 5 abstracts at this conference, plus attended other sessions and satellite symposia, networking, discussions about trial design and state of the art in [redacted]	Aware of latest opinion from the major conference in the world	Better informed - discussions and networking improves quality of work and widens access to clinical trials
[redacted]	1.5	Attendance at [redacted] - also wrote one talk at last moment as one speaker had pulled out.	Chance to meet world leaders in the field, discuss matters with them and learn about new phase I/II trial ideas in [redacted]	Developments in Phase I/II trials are important as the area has stagnated in [redacted] for too long and old fashioned designs are not always fit for purpose.

Collaboration on retrospective analysis	**3.5**	**I am a consulting statistician on a project to consider the outcomes in patients with [redacted] who have a particular [redacted] genetic mutation and have failed therapy. This is based around an academic collaboration involving the German [redacted] Study Group; and also the drug company [redacted] who are looking to contextualise results from one of their clinical trials and also plan a new Phase III study. The work has involved numerous meetings, and also the development of datasets to facilitate matched, stratified and propensity score analyses of data. Discussions on the optimal methodology for the comparisons have also taken place.**	**My work has benefited from the discussions regarding appropriate methodologies to compare non-randomised groups, and the pitfalls and benefits of each method.**	**The service provided here to [redacted] will benefit them in that analyses performed will be more robust, and the forthcoming Phase III trial will be designed appropriately based upon existing data, with robustness built in using sensitivity analyses.**
Development of [redacted] trial	**3**	**Development of a new protocol in [redacted] in older patients for a full grant application - funding decision expected [redacted] 2012**	**The [redacted] trial will replace the closed [redacted] trial - this is the first trial to randomise treatment based upon [redacted] monitoring post course 1 of treatment. Has required the development and checking of methods to ensure that this randomisation is as informative as possible, including reviewing existing data and producing new analyses.**	**[redacted] is an important trial - this has enabled the trial to proceed to full application**

Discussions with colleagues on risk index and transplant	**12**	**I have been involved in extensive discussions with colleagues on the correct methodology for assessing the additional prognostic and predictive impact of genetic abnormalities over and above clinical features in [redacted]. As well as identifying the "best" prognostic score (as well as defining best, since some additional data will require additional tests), the issue of what is clinically useful, particularly in identifying those patients likely to benefit from a stem cell transplant is one which current methodology is not well-equipped to answer. This work will form the basis of guidelines for the next generation of national trials in [redacted]**	**Extensive benefit from detailed discussions on this matter. Have learned a lot from colleagues, not least on the question of clinical relevance of the information.**	**The ultimate benefit will be better identifying those patients who are transplanted, improving outcomes and reducing morbidity.**
[redacted] meeting	**1.5**	**Attending European [redacted]Net meeting - member of Work Package [redacted]**	**Networking with European colleagues, who are the group leaders in [redacted] across the EU and beyond. Leading a meta-analysis of [redacted] mutation in [redacted], also represent the NCRI [redacted] trials at this meeting.**	**Cross-boundary harmonisation of objectives - studies are not competing with each other.**
[redacted] meeting on monitoring	**1**	**Invited lecture on monitoring strategies in [redacted] from the UK perspective - Amsterdam - as part of [redacted] workpackage meeting**	**Helps put UK practice into a European context, disseminate our approaches and learn from other groups (particularly Germany) on methods for monitoring and directing therapy based upon**	**Ensures that the [redacted] Monitoring randomisation is relevant and at the forefront of research -allows for any tweaks necessary based upon the findings of others**

			sequential monitoring of targets.	
GCP training	**2.5**	**Mandatory GCP training to work on clinical trials**	**Mandatory training**	**Mandatory training on good clinical practice - ensures trials are run to high standards.**
Invited talk at the Polish [redacted] Group	**0.5**	**I was invited to talk on novel trial designs in [redacted] at the meeting of the [redacted] in 2012. I have also repeated this talk for a meeting of Nordic doctors in [redacted] 2012**	**The invitation to talk to Polish and Nordic clinicians enables one to network, and also to promote novel trial designs, and the [redacted] trial, run out of [redacted]. The preparation of new materials also allowed me the opportunity ot survey the field as it currently stands.**	**Discussions with the [redacted] and Nordic doctors provided educational opportunities for both sides.**
Journal Review and Editorship	**8**	**Am an expert statistical reviewer for [redacted]- typically involves reviewing 10 articles per month. Also academic editor for [redacted], handling 2-3 papers per month. Requires me to be knowledgeable in statistics, develop knowledge of different subject areas.**	**Reviewing is an excellent way of developing one's own practice, by having wide access to other people's methodologies, as well as critiquing them to improve their work.**	**Better quality work is published.**

Leading [redacted]CTU	**5**	**As Head of [redacted]CTU I am responsible for mentoring and training staff as well the strategic direction of the unit**	**Makes me a more reflective practitioner and a better strategic thinker, balancing needs and resources during a challenging year in which there was an MHRA inspection. Am a better manager as a result, have developed methods for delegation. Writing and reviewing SOPs ensure that the trials in [redacted]CTU run better**	**Enables a better and more productive unit. Ensures quality as witnessed by the award of provisional registration status.**
Medical Statistics Surgery Day	**1**	**Production of new material for surgery day, as well as participating in an extempore session**	**Provides an opportunity to test my own knowledge as well as reflect in the writing of the new work**	**Direct benefit - these are the people attending the surgery.**
Medical Statistics Surgery Day	**1**	**Production of new material for surgery day, as well as participating in an extempore session**	**Ensures I am informed, and am a better teacher through feedback sessions. Requires preparation to familiarise myself with matters arising**	**Direct benefit to members of the University to improve their research.**

Membership of NIHR [redacted] board	**3**	**The NIHR [redacted] Board meets three times yearly. It considers grant applications for studies, reviews progress of existing studies, and also has an education element with a seminar at each meeting.**	**The seminars in particular are stimulating and relevant to my work**	**I provide expert statistical input to the board to enable decisions to be made; other users of my service benefit because I am educated in the seminar series.**
Membership of CTC	**1**	**The [redacted] Clinical Trials Committee meets twice per year to review new grant applications**	**I am expert statistician to this group. The group meets twice per year and reviews grant applications; I therefore network with the other members of the group, some of whom are based internationally, and provide expert statistical advice. The other advantage of this is that one is able to see what trial designs are out there and either adopt, adapt or improve them as appropriate.**	**The committee receives expert statistical input; my other colleagues benefit from the discussions at the committee**
Membership of Trial Steering Committees	**1.5**	**I am a member of a number of TSCs and DMECs - these will tend to meet twice a year for each of them**	**In-depth discussions of trial design issues, especially novel trial design which involve adapting sample size based upon conditional power**	**Better informed about novel trial designs**

NCRI [redacted] Working Party	**4**	**The NCRI [redacted] Working Party is forum for the ongoing and developing trials in [redacted]. I am a statistical member and this work involves developing and reviewing protocols as well as looking at current progress and interpreting this for future directions. The group meet 3-4 times annually for about 4 hours each time.**	**I am better informed about the [redacted] trial portfolio as well as having my own design and methodology expertly critiqued.**	**Produces better [redacted] trials; ensures that trials are properly designed and critiqued.**
NCRI [redacted] Study Group	**2.5**	**Expert statistical member of the NCRI [redacted] Clinical Studies Group. Establish priorities across the [redacted] portfolio and review new studies for adoption/funding**	**Enables my work to be fitted into the national context; also committee skills, and learning from the UK leaders in [redacted]**	**Ensures that trials fit in with national priorities - leads to better research**
Preparation of abstracts for [redacted]	**4**	**Preparation of abstracts to be presented at [redacted] meeting; includes arriving at suitable methodology and learning to produce relevant interpretations of analyses -**	**Improves methodological knowledge; also requires preparation of abstracts**	**High quality research is performed and presented at the main meeting for this disease area.**
Reading Papers	**12**	**Reading relevant journals to identify new work in my area, either methodological or [redacted]. This will include review of each copy of [redacted], British Journal of [redacted] Clinical Trials, RSS Series C; as well as scanning the contents of Lancet, Lancet [redacted], Journal of Clinical [redacted] for relevant papers and then reading them.**	**Crucial to keep abreast of the latest practice and research - e.g. novel trial design methodology, and relating current work to other work in the area - such as reports of clinical trials which influence future studies; likewise for translational work in [redacted].**	**I am better informed about the state of the art.**
Representation on School Committees	**4**	**My involvement in the wider work of the employer has seen me become a member of the Clinical Trials Governance Group, the Clinical Trials Operation**	**I am more fully apprised of the policy of the University and am able**	**Better involvement in the work of the school**

		Group, the IT/Information Management Working Group, the Research Degrees Committee	**to influence decisions on policy for clinical trials**	
School Governor	**1**	**Vice Chair of Governors for [redacted] Primary School in [redacted]**	**Vice chair of governors and chair of subcommittees improve my leadership skills, finance skills**	**Leadership and finance skills crucial for role as Head of [redacted]CTU**
Supervision of Intercalated Student	**2**	**Supervisor for Student, working on a statistical investigation of whether there is a natural age cut-off for different treatment modalities given in [redacted] and whether the current split of trials is suitable.**	**The question of whether there should be different trials for different ages is one of the hot topics in [redacted]. The supervision work therefore gave me an insight into the issue form the UK perspective as well as improving my one-to-one coaching skills**	**See above =-this is a hot topic**
Writing papers	**4**	**Prepared an educational review article [redacted]. Have written papers for results from [redacted] trials (2 papers, two sets of interventions based upon diagnosis type); additionally have provided statistical input to papers on laboratory (translational studies) in [redacted]**	**The review article required reflective thinking on one's own role as statistician in terms of what methodologies have been proven to work and not work. The other work requires analysis of large datasets and interactions with colleagues in the**	**As a result of this work, users will benefit from being able to see the results of the clinical trials and translational studies; I am also better informed about trial design from writing the review article.**

			drafting of the paper and responding to reviewers comments.	
Writing papers on trial interventions [redacted]	**3**	**Writing papers on interventions in closed parts of clinical trials Involves analysing data and interpreting, drafting paper, gaining comments etc.**	**Writing a paper is a collaborative process so this was part of the requirement here; also the trial design itself is novel so the analysis had to be developed here**	**Reduces the use of expensive novel treatments with added toxicity but no proven effect. Better informed about novel trial design and the limitations of it.**
TOTAL	**94.5**			

Chartered Scientist CPD Revalidation Form
[For use by Royal Statistical Society]

Name:	[redacted]
RSS Membership No:	[redacted]
Email address:	[redacted]

This form is provided for you to assess your CPD activities over the 12 month period October 2011 to September 2012 inclusive and demonstrate that you meet the CPD standards for CSci revalidation.

General guidance on the revalidation process can be found on the CSci website at http://www.charteredscientist.org/about-csci/cpd-standards

Specific guidance for the revalidation of Chartered Scientists registered through the Royal Statistical Society can be found at www.rss.org.uk/csci_revalidation .

SECTION 1: Career Status & Job Role

Provide a brief summary of your career status and job role during the 12 month period (October 2011 to September 2012). Provide sufficient detail to give an understanding of the scope of your role and the skills and knowledge required to fulfil the role. This will enable the relevance of your CPD activities to your current job role and future career progression to be understood.

It is recommended that your summary is between 100 and 250 words.

I am a Senior Lecturer in [redacted] Statistics in [redacted] University and the Head of the [redacted] Clinical Trials Unit. The main focus of my work is the national (NCRI) trials in [redacted], which are run from [redacted]. I am the statistician to these trials. This involves working with the NCRI Clinical Studies Group and Working Parties on the development of protocols, applying for funding, the running of the trials, including the provision of reports to the Trial Steering Committee and Data Monitoring Committee, and the preparation of publications. Additionally I act as statistician for the [redacted] tissue bank, analysing the many translational studies associated with the trials. I also serve upon the Trial Steering Committees and Data Monitoring Committees of several trials, and am a member of the NIHR [redacted] Evaluation Board; the NCRI [redacted] Clinical Study Group, The NCRI [redacted] Working Party, the [redacted] Research Clinical Trials Committee. I am a member of the group for Workpackage [redacted] of the European [redacted]Net, representing the NCRI trials group.

Much of my CPD activity comes from networking with colleagues, particularly internationally, and keeping abreast of the latest happenings in my field. As an established statistician, the CPD value of many of my working hours is relatively low; consequently my submission refers to those activities which have a large CPD Value and learning hours.

SECTION 2: Summary of CPD activities & the RSS CPD Policy

Have you used the RSS online CPD system to record your individual CPD activities over the 12 month period October 2011 to September 2012? **Yes** X **No** ☐
(tick one box)

If **Yes**, you can leave this section blank and go to Section 3.

If **No**, please complete this Section.

The information that is required in this Section is:

a) The nature of the system you have used to record your CPD (e.g. employer's system, self-created spreadsheet, etc).
b) Information to supplement your summary of CPD activities.

Separate to this document you will be required to provide a copy of the summary of CPD activities from the system you have used. This summary may not provide all the information necessary to confirm that you have satisfied the requirements of the RSS CPD Policy (go to www.rss.org.uk/cpd for details). In this section provide any additional information that may be required to supplement your summary. For example, it may be necessary to clarify that you have carried out activities in at least 3 of the 5 categories of activity described in the RSS CPD Policy and/or that you have undertaken at least 60 learning hours.

a) CPD system used :

b) Additional information necessary to confirm compliance with RSS CPD Policy :

If information on categorisation of activities and/or learning hours is not included in your summary of CPD activities, please additionally provide
(i) a mapping of activities in your summary to categories, and
(ii) complete the following table:

Category of activity	**Total number of learning hours for activities in category**
Work based learning	
Professional activity	
Formal/educational	
Self-directed learning	
Other	
TOTAL	

SECTION 3: Reflection on benefit to professional practice

Please provide examples of specific skills and/or knowledge that you have developed through your CPD activities and explain how these have contributed to the quality of your professional practice and service delivery.

Those of you who have used the RSS online CPD system to record your activities will have commented on how each individual activity has benefited your practice. The purpose of this Section is for you to reflect on how, in combination, the programme of CPD activities you have undertaken in the 12 month period have maintained or enhanced your professional skills and knowledge in order for you to fulfil the requirements of your job role or progress your career.

It is recommended that your summary is between 100 and 250 words.

One cannot work in isolation particularly on large scale international collaborations such as those of the NCRI trials in [redacted], or on the international meta-analysis of [redacted]. Consequently consultation with one's peers is vital. Additionally, it is crucial to be abreast of the latest developments both in methodological and in [redacted] research; this comes from attending meetings where breaking results are presented, and also by regular reading of the trials and [redacted] literature. The [redacted] trial run from [redacted] is novel methodologically, and the increasing need to design efficient pilot trials for novel interventions means that it is necessary to keep abreast of these developments. My practice therefore benefits enormously from being relevant, and up-to-date.

Additionally, I have a leadership role within the [redacted]CTU, which has been put under particular scrutiny because of the recent successful application for provisionally registered trials unit status, and also by the MHRA inspection of [redacted] University in late [redacted]. My work on committees has ensured that my unit is ready for the challenges, and it has also enabled me to identify (and appropriate) examples of good practice. Through my work I have become a more effective and efficient manager as well, building a working environment that allows people to flourish in a supportive, yet structured way.

SECTION 4: Reflection on benefit to users of your service

Please provide examples of how your CPD activity has benefited the users of your work (e.g. employers, clients, colleagues, students, etc).

Those of you who have used the RSS online CPD system to record your activities will have commented on how each activity has benefited users of your service. The purpose of this Section is for you to reflect on how, in combination, the programme of CPD activities you have undertaken in the 12 month period have enabled you to better deliver to users of your service (e.g. complete projects, give advice to clients, make decisions, manage your group, supervise colleagues, teach students, etc.)

It is recommended that your summary is between 100 and 250 words.

The "service users" for a medical statistician are numerous. I have summarised the benefits from a variety of perspectives:

a) the University as employer – the trials unit achieved provisional registration, and the MHRA inspection passed without critical finding. I am also contributing my expertise on an increasing number of panels.
b) Colleagues: through my CPD I am better informed and therefore able to give better and more relevant advice.
c) Learned bodies/charities: my CPD allows me to give the benefit of my knowledge and experience to enable the groups to make better funding decisions; the skills learnt at the different committees are transferable
d) Students: the courses provide specific insights into statistics for students in a way that is timely and relevant to their particular projects
e) The unit: I am a more efficient and effective manager and can provide better "soft touch" leadership with better interpersonal skills allowing talent to thrive
f) Patients: the ultimate aim of the clinical trial is to improve outcomes for patients – consequently this is probably the most important area. Through my work we have identified a new standard of care for patients with [redacted], by which a single dose of drug can improve survival by at least 5%. The CPD work associated with trial design also means that new drugs can be tested reliably more quickly and efficiently than before speeding up their introduction in practice, or indeed reducing the number of patients given unpromising treatments.

SECTION 5: Summary of supporting evidence that is available, and can be provided on request.

Only complete this Section if you are included in the Audit.
Otherwise go to Section 6.

Please provide a list of documents that you hold in your CPD portfolio and that provide evidence of the CPD activities undertaken. It is not expected that you will have documents for all activities (particularly the more 'informal' activities), but it is expected that most of the key activities will have such documentary evidence.

We would normally expect documents to be listed covering between 4 and 8 key activities.

There is no need to provide the actual documents, unless requested to do so by the panel of assessors undertaking the Audit process.

Activity title or brief description	**Evidence of activity (e.g. certificates of attendance, course material, reports, research papers)**
GCP training	Certificate
Invited talks	Letters of invitation
[redacted] meeting	Confirmation of registration, travel etc.
Papers written	Full document history for each paper, including each iteration
Journal reviews	Copies of acknowledgement of review/CPD certificates
Committee work	Minutes, invitations, agendas

Section 6: Declaration

This Section is to be completed by all CSci registrants.

I hereby agree that the information given is correct and supports my wish to revalidate as a Chartered Scientist (CSci).

Please tick the box below to indicate your agreement to the declaration.

I agree to the declaration X☐

Print name: [redacted]

Date: 8/11/2012