An example of a CPD submission by an experienced statistician working for a pharmaceutical company

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	Bayesian Software Training	01/12/2011 16:00	01/12/2011 18:00	2.0
Formal / Educational	CDISC AdAM Training	21/11/2011 09:00	21/11/2011 16:00	4.0
Professional activity	CHMP Scientific Advice Meeting	26/03/2012 14:00	26/03/2012 15:00	8.0
Self-directed learning	eLearning of Company Procedures	28/05/2012 10:00	28/05/2012 10:00	2.0
Self-directed learning	eLearning of Company Procedures	06/06/2012 10:00	06/06/2012 12:00	2.0
Self-directed learning	eLearning of Company Procedures	27/06/2012 14:00	27/06/2012 16:00	2.0
Self-directed learning	eLearning of Company Procedures	23/07/2012 10:00	23/07/2012 12:00	2.0
Self-directed learning	eLearning of Company Procedures	06/08/2012 15:00	06/08/2012 17:00	2.0
Professional activity	FDA Advice Meeting	26/01/2012 14:00	26/01/2012 15:00	8.0
Formal / Educational	Good Clinical Practice - ICH E6 Training	09/11/2011 08:00	09/11/2011 09:30	1.5
Professional activity	Health Canada Meeting	01/03/2012 14:00	01/03/2012 15:00	8.0
Formal / Educational	Introduction to PK/PD analysis	05/12/2011 16:00	05/12/2011 18:00	2.0
Formal / Educational	PKDM - Exposure Response Analysis	23/07/2012 15:00	23/07/2012 17:00	2.0
Professional activity	Planning for a phase 3 study	14/03/2012 10:00	14/03/2012 13:00	2.0
Professional activity	Presentation About Study Designs for Biomarker Subsets	01/05/2012 09:00	14/05/2012 09:00	2.0
Formal / Educational	PSI Biomarker Special Interest Group Meeting	11/11/2011 10:00	11/11/2011 16:00	4.0
Professional activity	Review and Comment on CHMP Points to Consider Document	13/06/2012 15:00	13/06/2012 17:00	2.0
Professional activity	Statistical Training	07/03/2012 15:00	07/03/2012 16:00	8.0
Totals				**63.5**
				Total Records: 18

BENEFITS
GAINED REPORT

Title	Learning Hours	Activity Description	Benefit to Practice	Benefit to Users
Bayesian Software Training	2.0	Review of the software available to perform MCMC and Bayesian analysis	Clearer understanding of which software to use and how to use it.	Clearer understanding of which software to use and how to use it.
CDISC AdAM Training	4.0	One day training about the AdAM data model used by FDA	Clearer understanding of the benefits of tracability from raw data to summary in a report table.	Clearer understanding of the benefits of traceability from raw data to summary in a report table.
CHMP Scientific Advice Meeting	8.0	Meeting with CHMP for scientific advice for a phase 3 study	Revision of guidance, understanding of issues relating to phase 3 study	Confidence in my knowledge and experience
eLearning of Company Procedures	2.0	Reading revised company procedures	Keep compliance with company processes up to date	Confidence that I am in compliance with company procedures
eLearning of Company Procedures	2.0	Reading revised company procedures	Keep compliance with company processes up to date	Confidence that I am in compliance with company processes up to date
eLearning of Company Procedures	2.0	Reading revised company procedures	Keep compliance with company processes up to date	Confidence that I am in compliance with company processes up to date
eLearning of Company Procedures	2.0	Reading revised company procedures	Keep compliance with company processes up to date	Confidence that I am in compliance with company processes up to date
eLearning of Company Procedures	2.0	Reading revised company procedures	Keep compliance with company processes up to date	Confidence I am in compliance with company processes up to date
FDA Advice Meeting	8.0	Discuss phase 3 study with FDA	Revision of guidance, understanding of issues relating to phase 3 study	Confidence in my knowledge and experience.
Good Clinical Practice - ICH E6 Training	1.5	Good Clinical Practice - ICH E6 Training	Demonstrate knowledge of and compliance with GCP	Compliance with key guidance.
Health Canada Meeting	8.0	Discussed phase 3 study with Canadian Regulatory Authority	Revision of guidance, understanding of issues relating to phase 3 study	Confidence in my knowledge and experience
Introduction to PK/PD analysis	2.0	Introduction to PK/PD analysis	Better understanding of the analysis undertaken by PK scientists. How they do it and what does it mean.	Better understanding of the analysis undertaken by PK scientists. How they do it and what does it mean.

PKDM - Exposure Response Analysis	2.0	Description of the methods used to analyse exposure / response data	Increased my understanding of the methods used	Enables me to describe methods and interpret results of exposure response analyses.
Planning for a phase 3 study	2.0	Working on possible designs for a phase 3 trial with co-primary time to event endpoints.	Robust phase 3 study design options	Robust phase 3 study design options
Presentation About Study Designs for Biomarker Subsets	2.0	Researched study designs to investigate biomarker subgroups, prepared a presentation for company medical staff.	Developed understanding of relevant trial design	Developed understanding of relevant trial design
PSI Biomarker Special Interest Group Meeting	4.0	One day meeting of the Biomarkers SIG hosted by Amgen	Broader understanding of the use of biomarkers in drug development	I am now able to speak to the broader understanding of the use of biomarkers in drug development
Review and Comment on CHMP Points to Consider Document	2.0	Reviewed and commented on CHMP guidance document relating to oncology medicines	Gained understanding of CHMP view of requirements relating to oncology medicines.	Gained understanding of CHMP view of requirements relating to oncology medicines.
Statistical Training	8.0	Presented some statistical training to company medical staff	Extended knowledge of literature review process	Increased the knowledge of attendees, boosted the awareness of statistical thinking within the audience.
Totals	**63.5**			
				Total Records:18

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 completed my sixteenth year with [redacted] in March.

My current functional role is leader of 5 UK-based statisticians who are on teams responsible for one or more global oncology trials. In this position I have line management responsibility for them. I hold weekly review meetings with them where we discuss project progress, try to solve issues that have arisen, discuss relevant statistical methodology, progress towards personal goals and their career development. As a senior manager I also meet with my head of department and other managers to discuss resource issues, staff development opportunities and cross-functional issues.

I also have a project role and am the global lead statistician for 2 oncology treatments. One project is being closed out [redacted]. The second is entering phase 3 development. During the first quarter I attended three meetings with Regulatory Agencies where we sought opinions and advice about our development plans.

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** ✓ **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.

My CPD has broadly been in three areas this year.

Firstly there is training and certification that is required of all staff in my company so that we can show compliance with policies and procedures. The new pharmacovigilance legislation within the EU has led to several new procedures and I have learnt a lot about what is required and how my organisation is ensuring compliance with that legislation.

Secondly there have been several opportunities to present to statistical and medical colleagues within my organisation. Preparing these talks has taught me a lot about, for example, designs to explore biomarker subgroups and deepened my understanding of the issues around these studies.

Thirdly my global statistical lead role has meant contributing to the preparation for, attendance at, and the follow up from three meetings with Regulatory Authorities. The experience of attending the meetings has increased my confidence about dealing with Agency interaction in the future.

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.

My CPD has broadly been in three areas this year.

Firstly there is training and certification that is required of all staff in my company so that we can show compliance with policies and procedures. The new pharmacovigilance legislation within the EU has led to several new procedures and I have learnt a lot about what is required so that I can ensure we are doing the right thing on the studies I am responsible for.

Secondly there have been several opportunities to present to statistical and medical colleagues within my organisation. Preparing these talks has taught me a lot about, for example, designs to explore biomarker subgroups. This in turn has improved my ability to advise on designs for studies I am responsible for.

Thirdly my global statistical lead role has meant contributing to the preparation for, the attendance at, and the follow up from three meetings the Regulatory Authorities. I have needed to revise my knowledge of the relevant guidance so we are sure we are aware of where we are in or out of step with current regulatory thinking. I believe this has improved the advice I am able to offer study teams and colleagues who may be attending Regulatory meetings in the future.

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)**
eLearning of Company Procedures	Printout of training records from Learning Management System
Presentation About Study Designs for Biomarker Subsets	Copy of slides
Statistical training	Copy of slides
CHMP Scientific Advice Meeting	Copy of minutes

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 ✓

Print name: [redacted]

Date: 13 November 2012