

An example of a CPD submission by a Director of Biostatistics in a global pharmaceutical/biotechnology 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.

This registrant submitted 2 summaries of CPD activities undertaken. One summary was the output from the registrant's company Learning Management System (LMS) which primarily captures training focused on the job role and fulfilling obligations to be trained in Standard Operating Procedures (SOPs). The registrant also submitted a personally-developed spreadsheet of additional CPD activities undertaken.

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. In particular, the details of the training recorded on the company LMS output have not been included.

Student Transcript Report **Learning Management System**

All LMS Date Fields Reported as Greenwich Mean Time (GMT)

Student: [REDACTED]
Manager: [REDACTED]

Learning Activity:	
Completion Date Range:	Between Oct 1, 2011 and Sep 30, 2012

Code	Learning Activity	Completed	Expired
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The registrant submitted the output from the employer's Learning Management System for the period 1st October 2011 to 30th September 2012.

This system focuses on company organised activities related to training to ensure compliance with company SOPs and the acquisition of skills and knowledge required for the job role.

Over 50 activities were listed.

For confidentiality reasons, the activities in the LMS system are not listed here.

In addition, the registrant submitted a personally-developed spreadsheet of additional CPD activities. This spreadsheet is included on the next 3 pages.

CPD Additional Details Sheet

Date	Activity	Work	Prof	Form	Self	Oth	Hours	Value	L Hours
	Total	19	11	32	2	3	367		232.9
	1 October 2011 to 30 September 2012								
01/11/2011	Basic Clinical Trial Design (BCTD) Presenter			1			5	0.2	1
04/11/2011	█████ Critical Literature Review (CLR) Course Preparation			1			4	1	4
8-9/11/11	█████ CLR Course Presenter			1			16	0.5	8
11/11/2011	PSI Biomarker SIG Meeting			1			6	1	6
14/11/2011	RSS CSci Revalidation Audit		1				4	1	4
16/11/2011	RSS █████ Meeting		1				5	1	5
01/12/2011	Bayes Software Training Presenter			1			4	1	4
05/12/2011	Preparing for █████ Approval Training			1			2	0.5	1
10/12/2011	Key Opinion Leader (KOL)Training █████			1			8	0.2	1.6
16/12/2011	█████ (Performance Review) Discussion Preparation	1					2	1	2
20/12/2011	█████ (Performance Review) and Discussion	1					3	1	3
06/01/2012	TAG Rugby Training █████ School					1	1	1	1
13/01/2012	EFSPI Meeting		1				1	1	1
20/01/2012	TAG Rugby Training █████ School					1	1	1	1
17/01/2012	EFSPI Benefit/Risk Meeting Organisation		1				2	0.5	1
24/01/2012	RSS █████ meeting		1				3	1	3
30/01/2012	█████ Team Meeting	1					1	1	1
02/02/2012	EFSPI Benefit/Risk Meeting Organisation		1				2	0.5	1

06/02/2012	Product Adaptive Design Discussion	1					2	1	2
07/02/2012	██████ Team Meeting	1					1	1	1
Feb/Mar	BCTD Webex Course Presenter			1			5	1	5
15/02/2012	██████ KOL Forum Preparation	1					16	1	16
21-22Feb2012	██████ F2F Project Meeting	1					16	0.5	8
23/02/2012	Bayesian Software Training (Presenter)			1			4	1	4
28/02/2012	EFSPI Benefit/Risk Meeting Organisation		1				2	0.5	1
Mar-12	Cost Analysis Methodology Reading				1		16	1	16
6-8 March 2012	████████████████████	1					6	0.2	1.2
15/03/2012	██████ (KOL) ██████ Presentation			1			4	1	4
20/03/2012	██████ Training (Trainer)			1			5	1	5
22/03/2012	Network Meta-Analysis (NMA) Training (Trainer)			1			5	0.5	2.5
12/03/2012	██████ Process Meeting	1					1	0.5	0.5
27/04/2012	Meta-Analysis Discussion	1					3	1	3
28/03/2012	████████████████████ Project Meeting	1					2	0.2	0.4
30/03/2012	NMA Training (Trainer)			1			5	1	5
01/04/2012	Multivariate Analysis Reading/Software Update				1		8	1	8
12/04/2012	██████ Process Update	1					2	0.5	1
16/04/2012	NMA Technical Training (Trainer)	1					5	0.2	1
18/04/2012	Before the Headlines Training		1				3	1	3
24/04/2012	██████ Medical Training (Trainer)			1			4	0.5	2
26/04/2012	Comparative Effectiveness Training			1			4	1	4
03/05/2012	██████ Team Initiation	1					3	0.1	0.3
9-10May12	██████ Dept Conference			1			8	0.25	2
13-16May12	PSI Conference + Presentation			1			24	0.25	6

22/05/2012	NMA Training (Trainer)			1			3	0.2	0.6
29-30May	██████████ Team Meeting	1					16	0.25	4
01/06/2012	KOL Training ██████			1			8	0.2	1.6
13/06/2012	RSS ██████		1				5	1	5
14/06/2012	██████ Project Meeting	1					1	1	1
19-20June12	CLR Training (Trainer)			1			16	0.5	8
26/06/2012	RSS/PSI Pharm Award Preparation		1				2	1	2
28/06/2012	Student Discussion	1					2	1	2
03/07/2012	PSI Conference Debrief	1					1	1	1
10-11Jul2012	Understanding Statistics Training (Trainer)			1			16	1	16
17-18 Jul12	██████████ Project Meeting	1					16	0.2	3.2
19/07/2012	██████████ Methodology Training (Trainer)			1			4	1	4
26/07/2012	Survival Analysis Switchover Training			1			3	1	3
31/07/2012	ICH E9 Training (Trainer)			1			2	1	2
28/08/2012	Health Economics Training			1			2	1	2
31/08/2012	██████████ Training Preparation			1			3	1	3
31/08/2012	SAS ██████ Training			1			3	1	3
31/08/2012	RSS Conference preparation			1			1	1	1
03/09/2012	Department Charity Day Leader					1	8	0.25	2
04/09/2012	RSS Conference + Presentation			1			6	0.5	3
11/09/2012	KOL Training ██████			1			8	0.5	4
17/09/2012	KOL Training ██████████			1			8	0.5	4
19/09/2012	RSS Meeting ██████		1				5	1	5
20/09/2012	SAS ██████ Training			1			4	0.5	2
	TOTAL LEARNING HOURS	51.6	31.0	122.3	24.0	4.0			232.9

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.

During this period I have been employed as a full time statistician for [REDACTED], a global pharmaceutical/biotechnology company with the job title Director of Biostatistics in the role of Biostatistical Scientist. In this role I act as a global internal consultant on statistical methodology in the design, conduct, analysis and interpretation of clinical trials for the development of new treatments for serious diseases. This extends to the development and application of statistical methods to enhance decision-making in the clinical development process. I also act as the chairman of the protocol review committee that provides final review and approval of clinical trial documents in the non-US region, and as an internal training provider for non-statisticians and the statistical community within the company globally, and outside to trial investigators and key opinion leaders.

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 :

The [REDACTED] Learning Management System, supplemented with a self-created spreadsheet to track other non-[REDACTED] process based CPD.

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	51.6
Professional activity	31.0
Formal/educational	122.3
Self-directed learning	24.0
Other	4.0
TOTAL	232.9

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.

During this period my CPD activity has contributed to the quality of my professional practice in the following areas:

- Improving my ability to prepare communication and training plans within a large company on important final review and approval processes for trial documents.
- Improving my understanding of requirements for cost effectiveness analyses and reimbursement portfolios for recently approved products.
- Reviewing and updating my knowledge of simple and more complex methods for indirect comparisons, especially those utilizing Bayesian network meta-analysis methods.
- Improving my presentation and influencing skills at senior company committee level and externally.
- Improving my leadership skills on a company-wide [REDACTED] project and by [REDACTED] the statistics group of a public private partnership ([REDACTED]) project to validate safety biomarkers for use in clinical development of new treatments.

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 activity during this period has benefited my employer and users of my services in the following areas:

- Improving the quality, efficiency and transparency of the review and approval process for trial documents within the company's non-US region.
- Investigating, implementing, documenting and communicating company standards and processes for the planning and conduct of indirect treatment comparison analyses for reimbursement filing for newly approved products.
- Enhancing development decision making by planning, preparing and introducing a statistical process to include quantitative assessments.
- Contributing to the activities of external workgroups and professional bodies by participating in committees of professional and industrial societies.

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)
Training Course (Trainer)	Course agenda and materials
Training Course (Attendee)	Course materials
PSI Conference	Conference agenda and presentation slides
RSS Conference	Conference agenda and presentation slides
Process Training	LMS transcript (Attached)
██████████ Project	Draft Publication
██████████	<i>Web address given</i>

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:

██

Date:

13 November 2012