Competency profiles in the biomedical sciences- sharing information and best practice

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A competency profile is a description of the knowledge, skills, values and attitudes necessary for a profession or a particular job role. Competency profiles are useful tools for a variety of stakeholder groups. For an individual, a competency profile enables them to evaluate and collect evidence of their current competencies and plan career development. For employers, they facilitate recruitment and employee development. For course providers, they can be used to match training to trainees' requirements and assess training outcomes. And for professional bodies, they define competency requirements for a specific profession.

In order to maximise the utility of existing competency profiles, identify best practice and encourage the development of new profiles, we have gathered examples relevant to the biomedical sciences and share them via the LifeTrain website (http://www.lifetrain.eu/competencies/competency-profiles/). A longer term aim is to create a searchable database of competency descriptions that can be used in the creation of customised competency profiles.

The competency profiles identified range from simple lists of knowledge, curricula topics, detailed competencies written for specific job roles, to fully formed competency frameworks with methods for assessment and documentation. We highlight examples and discuss good practices for creating new profiles.

GENERATING NEW COMPETENCY PROFILES

A review of the examples of competency profiles highlighted some common processes for generating new competency profiles:

- Set up a working group or task force
- Collate relevant information on skills, knowledge, behaviours and related content in the field (e.g. from education and training curricula, publications by academic groups or professional associations, from surveys sent to experts)
- Draft competency profile reviewed by external consultants (e.g. using Delphi method)
- Agreed version shared with the community
- Review and update at appropriate intervals

EXAMPLES OF COMPETENCY PROFILES

Domain: discovery of medicines and early development	Domain: clinical development and clinical trials
Evaluates and analyses a disease area within the industry clinical development environment and identifies unmet therapeutic needs	Evaluates the conduct and management of clinical trials within the context of the Clinical Development Plan and working as part of a Team
Evaluates the clinical and non-clinical pharmacology and toxicology evidence for a new candidate for clinical development	Designs and executes confirmatory studies and evaluates the resulting data as applied to the Clinical Development Plan and the TPP
Evaluates and applies the regulatory and ethical aspects underpinning clinical development	Evaluates and interprets the principles for the development of a clinical trial protocol applying principles of GCP in clinical pharmacology
Creates a Clinical Development Plan for a new candidate including a Target Product Profile (TPP)	Summarize the principles of Case Report Form design and clinical data management, including CDISC, EDC, and MedDRA
Designs and executes exploratory studies and evaluates the resulting data as applied to the Clinical Development Plan	Organizes the activities and processes related to the selection and management of sites for individual or multi-center clinical trials
Contrast the advances made in the clinical pharmacology of a new medicine in a stepwise manner with the overall Clinical Development Plan and the TPP	Supports and provides the clinical input into the design and review of a Statistical Analysis Plan
Defends the statistical principles for the design, conduct and assessment of exploratory studies	Appraises and reviews relevant literature and other sources and writes manuscripts for publication
Justifies the various end-points used in the clinical development program	
Appraises suspected adverse reactions during Exploratory development	Interprets and explains the outcomes of clinical studies

IFAPP/PharmaTrain 2012.

Extract from 'Core competencies for pharmaceutical physicians and drug development scientists'.
Silva H. et al., Frontiers in Pharmacology, 26 August 2013, doi: 10.3389/fphar.2013.00105'

	Bioinformatics User	Bioinformatics Scientist	Bioinformatics Engineer
(a) An ability to apply knowledge of computing, biology, statistics, and mathematics appropriate to the discipline.		X	X
(b) An ability to analyze a problem and identify and define the computing requirements appropriate to its solution.		X	X
(c) An ability to design, implement, and evaluate a computer-based system, process, component, or program to meet desired needs in scientific environments.			X
(d) An ability to use current techniques, skills, and tools necessary for computational biology practice.	X	X	X
(e) An ability to apply mathematical foundations, algorithmic principles, and computer science theory in the modeling and design of computer-based systems in a way that demonstrates comprehension of the tradeoffs involved in design choices.			X
(f) An ability to apply design and development principles in the construction of software systems of varying complexity.			X
(g) An ability to function effectively on teams to accomplish a common goal.	X	X	X
(h) An understanding of professional, ethical, legal, security, and social issues and responsibilities.	X	X	X
(i) An ability to communicate effectively with a range of audiences.	X	X	X
(j) An ability to analyze the local and global impact of bioinformatics and genomics on individuals, organizations, and society.	X	X	X
(k) Recognition of the need for and an ability to engage in continuing professional development.	X	X	X
(l) Detailed understanding of the scientific discovery process and of the role of bioinformatics in it.	X	X	X
(m) An ability to apply statistical research methods in the contexts of molecular biology, genomics, medical, and population genetics research.	X	X	X
(n) Knowledge of general biology, in-depth knowledge of at least one area of biology, and understanding of biological data generation technologies.	X	X	X

It is not the intention of the authors to imply that the skill set of one category is entirely subsumed by the skill set of another category. The focus of this document is on bioinformatics; thus, the authors did not attempt to define the full set of competencies that are required in the medical, legal, and scientific contexts.
doi:10.1371/journal.pcbi.1003496.t002

Extract from 'Bioinformatics Curriculum Guidelines: Toward a Definition of Core Competencies'
Welch L. et al. (2014) PLoS Comput Biol 10(3): e1003496.
doi:10.1371/journal.pcbi.1003496'

There is not a 'one size fits all' format for competency profiles. However, on reviewing existing examples, some good common practices can be derived.

- Competency profiles may be specific for a role or a discipline
- The role or discipline is divided into areas/clusters/domains
- Each area/cluster/domain contains a number of relevant competencies
- Each competency has a description which encompasses the knowledge, intellectual abilities, skills, techniques, experience, behaviours or professional standards required
- For each competency there may also be
  - a description of the depth required for different levels of practice, or a scale or description of its relevance across different roles
  - guidance on or examples of how competencies could be achieved
- Competency frameworks additionally include:
  - gathering and documenting evidence
  - a process for assessment
  - guidance on career progression

Subject Area	The Core Professional Competencies for Clinical Research Investigators	Guidance - Examples of how the Investigator can demonstrate they have achieved the standard required
Protocol Compliance	Describes the rationale for complying with any given clinical study protocol in terms of protecting the rights and wellbeing of the patients and the integrity of the data	Description of the reasons for complying with clinical trial protocols in terms of protecting the rights and wellbeing of the patients and the integrity of the data
	Implements the requirements of the protocol including any amendments to ensure compliance with and protection of the rights and wellbeing of patients and integrity of data	Implementation of the protocol
	Demonstrates diligence in compliance with the protocol and the protection of the rights and wellbeing of patients and the integrity of the data	Compliance with the protocol in line with the protection of the rights and wellbeing of patients and the integrity of the data
Regulatory / Ethics	Describes the role of ethics committees/IRBs in upholding the purpose and principles of ICH GCP E6	Description of the role of ethics committees/IRBs in upholding the purpose and principles of ICH GCP E6
	Applies the appropriate procedures when making applications/submitting reports to the appropriate ethics committee/IRB	Implementation of the appropriate procedures when making applications/submitting reports to the appropriate ethics committee/IRB
	Demonstrates a collaborative attitude towards the relevant ethics committee/IRB	Demonstration of a collaborative attitude towards the relevant ethics committee/IRB
	Summarises the need for regulatory authority inspections	Description of the need for regulatory authority inspections
	Demonstrates cooperation with regulatory authority inspectors	Cooperation with regulatory authority inspectors before, during and after regulatory authority inspections. Adequate and timely response to findings including any CAPAs

Extract from 'Core competencies for clinical research investigators', IAOCR Global Clinical Research Competency Frameworks (www.iaocr.org)

2.2 Contributes to the preparation of submissions for regulatory reviews

Skills and behaviours	Knowledge and understanding	KSF
• Aware of application processes and requirements for document management. • Leads or contributes to the preparation of paperwork and submission of applications.	• REC and R&D application processes (IRAS) [19, 44, 55-57]. • Other centralised permissions [58]. • Key documentation required to support REC and R&D submissions [19, 56]. • Protocol development. • Local review and reporting of research studies [59]. • Clinical Research Agreements [60-61]. • Risk assessment and feasibility. • Local and national policy developments. • Research sponsorship and researcher roles [31-32, 48, 56]. • Professional responsibilities and potential for conflict with research role [62].	C1 C2 C3 C5 G5 HWB2

Examples:

Band 5	Band 6	Band 7	Band 8
• Articulates the importance of clear, complete and accurate submissions. • Familiar with application processes.	• Act as a knowledgeable resource for staff and researchers making applications for regulatory approvals. • Raises concerns and seeks to address incomplete, inaccurate or misleading documentation. • Contributes to supervision and meeting the educational needs of staff.	• Act as expert resource for staff and researchers preparing submissions for regulatory approval. • Prepares, or makes significant contribution to the preparation of applications for regulatory approval. • Contributes to the professional and educational development of staff and researchers.	Demonstrates leadership by: • Ensuring that all processes, policies and standard operating procedures are in place. • Contributing to quality assurance. • Leading and taking responsibility for research in position of PI or CI.

Assessment

	Evidence of achievement	Band 5	Band 6	Band 7	Band 8
Level 1 Is competent with assistance and supervision					
Level 2 Is competent with supervision.					
Level 3 Is competent and autonomous with minimal assistance and supervision.					
Level 4+ Supports, trains and supervises others.					

Extract from 'Competency framework for clinical research nurses', Royal College of Nursing (www.rcn.org.uk)

DATABASE OF COMPETENCY PROFILES ON THE LIFETRAIN WEBSITE

Specialist in medicines development	
What is it?	A set of core competencies for pharmaceutical physicians and drug development scientists. It can be summarized in a Statement of Competence; it has been benchmarked against the learning outcomes of the PharmaTrain Base Course
Who is it relevant to?	Pharmaceutical physicians and other biomedical professionals involved in drug development
How was the profile developed?	A working group with experience of teaching pharmaceutical medicine at undergraduate, postgraduate and CPD level was convened and performed a thorough review of published competencies related to pharmaceutical medicine (more…)
Who developed it?	International Federation of Pharmaceutical Physicians and Pharmaceutical Medicine in collaboration with PharmaTrain
How is it being used?	The competencies are intended to serve as a resource and guide for those interested in improving the quality and accountability of pharmaceutical medicine education and training (more…)
What is the process for keeping the profile up to date?	An iterative 3-5-year cycle of refinement and development in light of feedback from IFAPP's national member associations.
Reference(s)	Core competencies for pharmaceutical physicians and drug development scientists Silva, H. et al. Front Pharmacol. (2013) 4: 105. doi: 10.3389/fphar.2013.00105

Description of an existing competency profile

To make the information in competency profiles more accessible and be available for generating bespoke competency profiles, we are aiming to build a database of competency profiles with searchable competencies. Examples of what this could look like are given.

	Competence	Role 1	Role 2	Role 3
Domain 1	Comp. 1	Awareness	Working knowledge	…
	Comp. 2		Specialist knowledge	
Domain 2	Comp. 3	Working knowledge	Awareness	
	Comp. 4	Specialist knowledge	Working knowledge	
Domain 3	Comp. 5		Working knowledge	
	Comp. 6	Awareness		
Domain 4	Comp. 7			
	Comp. n	Awareness	Specialist knowledge	

Searchable database of competences

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