Alignment of Competencies to Address Inefficiencies in Medicines Development and Clinical Research: Need for Inter-Professional Education

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CURRENT OPINION

Alignment of Competencies to Address Inefficiencies in Medicines Development and Clinical Research: Need for Inter-Professional Education

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Abstract The challenges faced by the biopharmaceutical industry in its key role to overcome the bottlenecks in innovative medicines development are related to addressing the technical knowledge gaps, the limitations to clinical trial testing, and the lack of clarity in the global pathways and processes to efficient outcomes. It is postulated that the lack of an adequately sized and appropriately trained multi-professional workforce, both in the industry and in the clinical research field, to enable fulfillment of the demanding aims for medicines development is a significant part of the problem. The current global status of pharmaceutical medicine's efforts to conduct education and training is seen as patchy, inadequate, and without recognition, direction or leadership. It is therefore proposed that the movement towards competency-based education (CBE) should be harnessed, and core competency job and role profiles and competency curricula should be developed. CBE presents a means of addressing the educational and training needs within medicines development, harmonizing the workforce and the requirement for increased inter-professional teamwork. An educational environment in which aspiring and established biomedical professionals could readily learn about the competencies they need to pursue a particular career path is envisioned. Utilizing competencies provides the building blocks to align and harmonize the desired learning outcomes for effective performance amongst a multi-professional workforce. The effective implementation of training programs as described here has the potential to transform drug development procedures into an efficient and integrated process; medical product life-cycle management would result in the availability of better and safer medicines more rapidly, for the benefit of patients and society.

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Key Points

As the medicines development enterprise enters a new complex era, the need for a comprehensively educated and trained workforce is an important priority.

Competencies for professionals in pharmaceutical medicine/medicines development and clinical research have been defined and validated by stakeholders of the different disciplines to inform academic curricula, human resource development, and training efforts.

Using competency-based education to ensure that more people working in medicines development can apply their knowledge in their core discipline and beyond to the full process from molecule identification to bedside will close existing gaps and prepare the experts for future scientific developments.

1 Introduction

For some time, the biopharmaceutical industry has been the key link between basic biomedical discovery and the emergence of novel medicines that prolong or improve life. However, the industry is facing a number of ongoing and newly emerging challenges, including lowered productivity, higher development costs, increased regulatory requirements, growing payer pressures, and patent expiration. Pharmaceutical companies are attempting to deal with these challenges by shifting to alternatives such as mergers and acquisition of companies, outsourcing, and fixed cost and personnel reductions. There is an increased focus on growing new revenue streams, by marketing products relating to personalized medicine and rare diseases [1].

In September 2012, the President's Council of Advisors on Science and Technology (PCAST) released the *Report to the President on Propelling Innovation in Drug Discovery, Development, and Evaluation*. The report identifies three principal roadblocks to more efficient drug discovery and development: (1) knowledge gaps in the science, technology, and methodologies that underlie these processes; (2) current limitations and inefficiencies in the clinical trial process; and (3) lack of clarity in development pathways for innovative medicines [2].

There is evidence to suggest that much of the inefficiency may be due to inadequate numbers of appropriately educated and trained professionals in the workforce to address the changing demands and needs of the pharmaceutical business and the clinical research enterprise that supports it [3–6].

2 Need for Education and Training of the Workforce Involved in Medicines Development and Clinical Research

In reality, there are two workforces in support of the medicines development process: (1) those involved in the discovery and early development of molecules and compounds, and who participate in the process of developing them into new medicines [primarily based in the pharmaceutical industry and contract research organizations (CROs)]; and (2) those that conduct the clinical trials that are required for the regulatory approval of new medicines (the investigators and staff who conduct clinical trials at clinical sites).

As medicines development has become a global process, an increasing number of professionals from many different countries have joined both the pharmaceutical industry and the clinical research workforce. This has provided new opportunities to work with interdisciplinary teams and increased job mobility. It has also increased the need for a larger number of professionals who understand the integrated process of medicines development at a variety of levels, since they usually work in functional silos (clinical research, medical affairs, safety, health economics, regulatory, etc.). The workforce involved in the many phases of the medicines development process includes an array of professionals with various academic degrees and backgrounds (Fig. 1).

To further aggravate the situation, for the past 10–20 years pharmaceutical and medical device companies have selectively outsourced capabilities to specialized service (contract) organizations focused on early molecule development and discovery as well as to external providers specialized in the clinical trial or the regulatory process such as CROs, site management organizations, or similar organizations. This has contributed to a large extent to an additional potential loss or fragmentation of the internal expertise.

The need for interfaces between the discovery, development, regulation, market introduction, and life-cycle management of medicines was acknowledged in Europe, and thus postgraduate programs in pharmaceutical medicine (an equivalent term to medicines development) have been in place for some time. The Innovative Medicines Initiative (IMI), Europe's largest public–private initiative aiming to speed up the development of better and safer medicines for patients, identified education and training (E&T) as one of the key means to overcome the

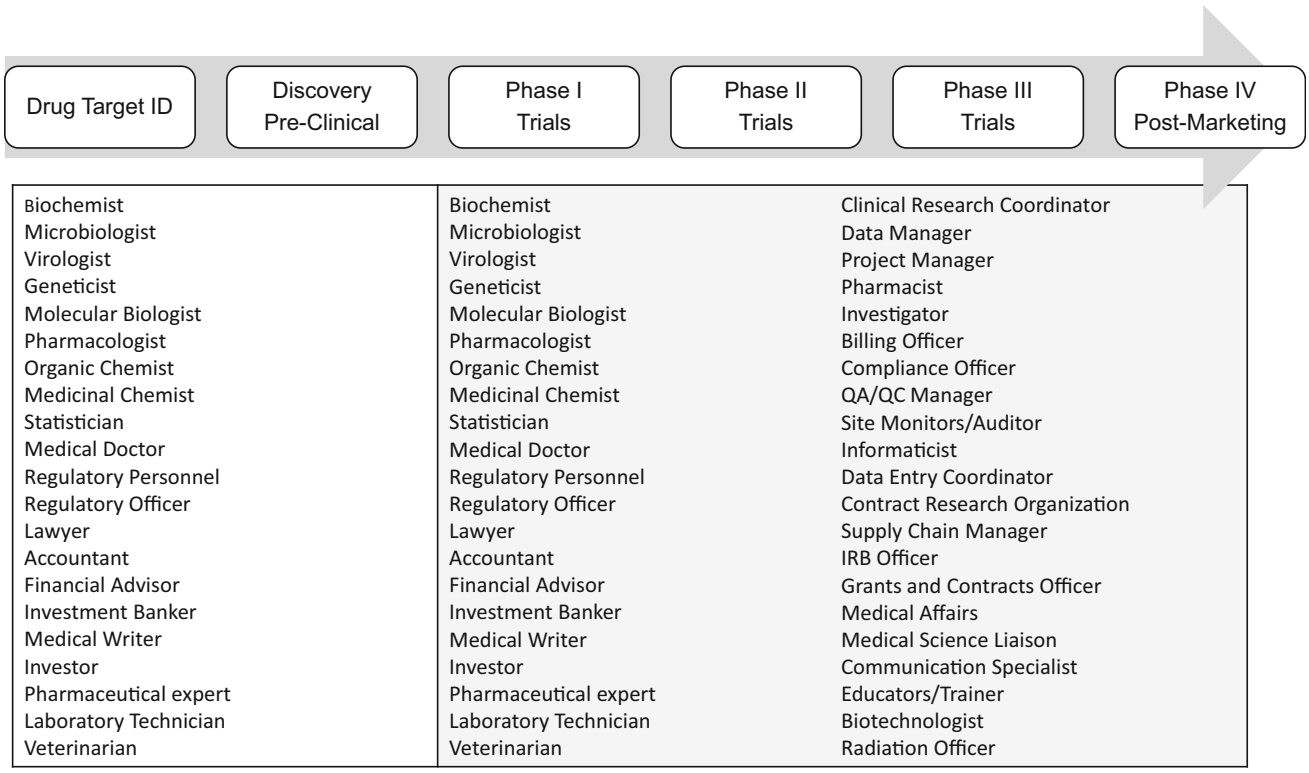

Fig. 1 Professionals involved in medicines development. *IRB* Institutional Review Board, *QA* quality assurance, *QC* quality check

bottlenecks in medicines development [7, 8]. As a result, harmonized postgraduate programs in medicines development/pharmaceutical medicine were put in place under the coordination of PharmaTrain (http://www.pharmatrain.eu), one of the IMI's educational programs sponsored by the EU. A Europe-wide network of university course providers and global 'affiliate' course providers has been established, with a common syllabus, curriculum, and defined learning outcomes. One of the PharmaTrain premises is that "better trained postgraduate professionals working in medicines development and regulation produce better medicines" (PharmaTrain Vision, 2014).

In the USA, pharmaceutical medicine is not a widely recognized discipline. The only academic program that focuses on medicines development and regulatory affairs is offered by the University of California in San Francisco [9]. A few other universities offer specialized programs in regulatory affairs and regulatory sciences, whereas approximately 30 postgraduate programs related to clinical trials management are offered [10]. This suggests that there may be a need for additional postgraduate educational opportunities in medicines development and clinical research.

Many of the academic institutions that conduct clinical trials are focused on the federally supported, basic research initiatives of the National Institutes of Health (NIH) and the National Cancer Institute (NCI) and are only minimally involved in the industry-sponsored medicines development process. The medical school curriculum at the undergraduate and postgraduate level has only minimal content related to clinical research. The federally supported Clinical and Translational Science Awards (CTSA) programs [11] produce only small numbers of graduates and are focused on continuing the NIH or NCI research model. Thus, training of the workforce through continuing professional development (CPD) sponsored by professional associations such as the Association of Clinical Research Professionals (ACRP), Model Agreements & Guidelines International (MAGI), DIA, Society of Clinical Research Associates (SoCRA), etc., or commercial education providers has grown significantly in the past few years.

The Institute of Medicine in the USA has proposed the following classification for the clinical trial workforce, so as to define the broad mission of the clinical trial enterprise [12]:

(a) *Community practitioners:* who participate in confirmatory or comparative effectiveness studies, or at least help to enroll patients as participants. In addition to physicians, this group would include nurses, pharmacists, social workers, and other health professionals.

(b) *Implementers*: individuals who devote specified portions of their professional services as principal investigators or collaborating co-investigators, with primary responsibility for implementing clinical trials at the designated research site. In addition to physician–scientists, the group would include nurse–investigators, clinical pharmacologists, research-oriented social workers, and other members of the clinical research team (clinical research coordinators, project managers, clinical research associates, etc.).

(c) *Designers and methodologists*: scientific experts who develop tools and innovative approaches for conducting trials and analyzing results. In addition to academic clinical investigators, this group would include biostatisticians, epidemiologists, informatics specialists, and health service researchers, as well as pharmaceutical physicians and drug development scientists.

The estimated size of the workforce is unknown. It has been estimated that at least 40,000 research centres and 365,000 investigators conduct phase II–IV industry-sponsored trials around the world (ViS Research Institute internal data). The estimated size of the workforce in medicines development has not been properly defined.

Appropriate E&T for all members of the clinical research team has been regarded as being of utmost importance to ensure the validity and quality of the data collected in a clinical trial. The primary training content has been focused on human subjects protection and good clinical practice (GCP) using the US FDA regulations and International Conference on Harmonization (ICH) *Guideline for Good Clinical Practice* [13]. The FDA require that investigators and staff participating in clinical trials be qualified by training and experience to investigate drugs, biologics, and medical devices. For this reason, before a clinical trial begins, trial sponsors generally require investigators to complete GCP training, applicable to any trial, as well as specific training on the plan and techniques for a particular trial. As a result, investigators who participate in clinical trials with more than one sponsor are often required to complete the same GCP training multiple times so that sponsors can document compliance with regulations. GCP has been traditionally regarded as a 'gold' standard [14].

But is GCP training enough? GCP training typically includes online slide presentations and a post-test that can be accomplished with minimal effort, and lacks applicability to complex clinical, safety, and bioethical issues beyond GCPs. Furthermore, several deficiencies have been highlighted and possible solutions proposed [15].

The Declaration of Helsinki has recently been modified to state that clinical research must be conducted by individuals with appropriate ethics and scientific education, training, and qualifications [16]. The FDA recently published a recommendation related to risk-based monitoring and required E&T [17]. It is becoming obvious that the scope of E&T should expand beyond GCP. However, there is no harmonized standard for investigator or clinical trial staff qualifications.

Although the majority of clinical studies are conducted in the USA and Western Europe, there is also a growing realization that in other emerging global centers of medicines development, such as Latin America, Eastern Europe and Asia, there is an insufficient supply of highly trained researchers to lead, conduct, and analyze clinical trials. Particular attention should be paid to Asian countries, which are increasingly involved in multi-regional clinical trials, particularly Japan, South Korea, India, China, Singapore, and Taiwan. Several proposals to overcome this shortfall have been made [5, 18], and local initiatives have emerged.

An educational needs assessment (NA) was recently conducted among clinical investigators (and associated staff) from hospitals and academic institutions and biomedical professionals serving in the pharmaceutical/biotech industry [19] in two Latin American countries. Both groups prioritized the need for additional E&T in basic knowledge areas as well as 'soft' skills (e.g., influencing, leadership, communication) as highly relevant to their daily activities. The results showed a similar profile to previous experience among pharmaceutical physicians in the USA and UK [20, 21]. The recommendation was that the above subjects should be incorporated into the basic curricula for postgraduate education and CPD. Gaps in initial and ongoing training for clinical research coordinators were also reported in a survey conducted among 22 CTSA academic centers in the USA [22].

Thus, it is becoming increasingly apparent that the requirement for redundant, yet 'minimal' GCP training must be reassessed and that changes must occur in the concept and content of formal postgraduate education in the USA, Europe, Asia, and Latin America. The movement from a knowledge-based to an outcomes-based educational concept might contribute to meeting this need.

3 Competencies and Outcomes-Based Education

Since there is a perceived mismatch between the profiles and abilities of the graduates from academic programs in healthcare professions, and the changing needs of the various health systems around the world, outcomes-based education or competency-based education (CBE) has been proposed as a suitable solution for transformative learning [23, 24]. CBE is an emerging discourse in health professions' education and has been adopted by numerous

academic institutions and professional associations around the world, at the undergraduate, postgraduate, and CPD levels [25, 26]. CBE is organized around competencies, or predefined abilities, as outcomes of the curriculum. Transformative learning involves three fundamental shifts: (1) from memorizing facts to searching for, analyzing, and synthesizing new information for decision making; (2) from collecting individual professional credentials to achieving core competencies that support effective teamwork in health systems; and (3) from the non-critical adoption of educational models to the creative adaptation of global resources to address local priorities.

'Competency' is defined as "an observable ability of any professional, integrating multiple components such as knowledge, skills, values and attitudes". Since competencies are observable, they can be measured and assessed to ensure their acquisition. Competencies can be assembled like building blocks to facilitate progressive development [27, 28].

There is a confusion that must be addressed. In the English language the term 'competency' can be used interchangeably with the term 'competence'. However, in the medical education and assessment literature, the term 'competency' should be restricted to the skill itself, while 'competence' is the "array of abilities across multiple domains or aspects of professional performance in a certain context" [29]. Competence is a point on the spectrum of improving performance; it is multidimensional and dynamic and changes with time, experience, and setting. We define a 'core' competency as that which is shared across professional boundaries by similar professional groups and is needed to perform a specific task that is used as foundation for inter-professional education (IPE). A 'competent professional' is one possessing the required abilities in all domains at a defined stage of education or practice. Competence and performance are different, although closely interrelated. Performance can be affected by a number of factors, regardless of competence [28, 29].

There is also a growing appreciation of learner professional evolution, a realization that there is also a 'progression of competence' from novice to expert. This means that learners advance along a series of defined milestones on their way to the explicit outcome goals of training in order to perform as per the expectations of the employers and of society at large [27–29].

4 Alignment of Competencies in Medicines Development

The responsibility for defining professional competencies has been traditionally left to the respective professional groups. Thus, the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) assumed the task of producing the defined core competencies that orient the discipline and academic programs which develop the future competent professionals that advance the profession. Since PharmaTrain aims to enable postgraduate courses that are designed to meet the needs of professionals working in medicines development, a working group was formed between IFAPP and PharmaTrain that included representatives from academic institutions and IFAPP national member associations, with special interest in quality improvement through education. The objectives were to define a set of core competencies for pharmaceutical physicians and drug development scientists, which would be summarized in a statement of competence.

As a result, three areas, seven domains, and 57 core competencies were identified [30]. The PharmaTrain–IFAPP statement of competence is shown in Fig. 2. The core competencies were aligned with the learning outcomes of the basic course (Diploma) offered by PharmaTrain. Therefore, the PharmaTrain base course curriculum might provide the cognitive framework to achieve the desired statement of competence for pharmaceutical physicians and drug development scientists worldwide.

5 Alignment of Competencies in Clinical Research

As the concept of CBE and training has spread to the medicines development industry, many groups have produced lists of knowledge, skills, and attitudes, which define the core competencies for the clinical research professional [31]. In an attempt to bring these different efforts together, a broad-based and widely representative group including representatives from pharmaceutical companies, CROs, academic institutions, clinical research sites, and professional societies was hosted under the auspices of the Alliance for Clinical Research Excellence and Safety (ACRES), Multi-Regional Clinical Trials Center at Harvard University (MRCT), PharmaTrain, MAGI, and the DIA. The members of this Joint Task Force for Clinical Trial Competency (JTF) agreed to work toward aligning and harmonizing the many focused statements relating to core competency into a single, high-level set of standards that could be adopted globally and serve as a framework for defining professional competence throughout the clinical research enterprise. A total of 51 competencies distributed among eight domains were agreed upon and a Core Competency Framework (CCF) was defined (Fig. 3) [10]. The CCF can be used in many ways to improve the quality and safety of clinical trials, define certification criteria, formulate standards for academic programs and site

Fig. 2 Statement of competence in pharmaceutical medicine and medicines development

- Is able to identify unmet therapeutic needs, evaluate the evidence for a new candidate for clinical development and design a Clinical Development Plan for a Target Product Profile.
- Is able to design, execute and evaluate exploratory and confirmatory clinical trials and prepare manuscripts or reports for publication and regulatory submissions.
- Is able to interpret effectively the regulatory requirements for the clinical development of a new drug through the product life-cycle to ensure its appropriate therapeutic use and proper risk management.
- Is able to evaluate the choice, application and analysis of post-authorization surveillance methods to meet the requirements of national/international agencies for proper information and risk minimization to patients and clinical trial subjects.
- Is able to combine the principles of clinical research and business ethics for the conduct of clinical trials and commercial operations within the organization.
- Is able to appraise the pharmaceutical business activities in the healthcare environment to ensure that they remain appropriate, ethical and legal to keep the welfare of patients and subjects at the forefront of decision making in the promotion of medicines and design of clinical trials.
- Is able to interpret the principles and practices of people management and leadership, using effective communication techniques and interpersonal skills to influence key stakeholders and achieve the scientific and business objectives.

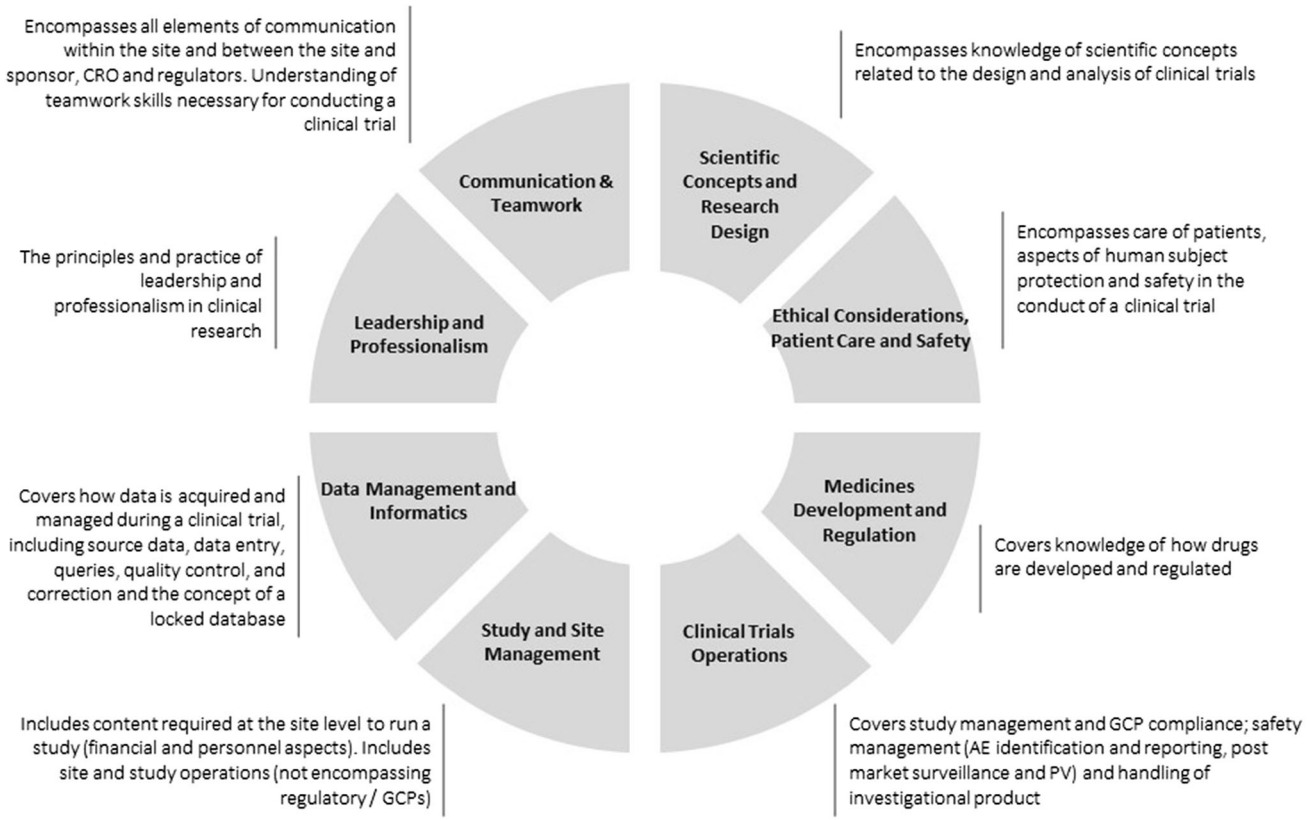

Fig. 3 Core competency domains for clinical research professionals: Joint Task Force for Clinical Research Competence. *AE* adverse event, *CRO* contract research organization, *GCP* good clinical practice, *PV* pharmacovigilance

accreditation, as well as to standardize curricula and to ensure that programs are sufficiently comprehensive.

Clinical research is one of the critical components of the medicines development process. The professional profile of individuals functioning exclusively in clinical trials is somewhat different to that of those involved in the varied domains of drug development. However, every professional involved in medicines development should include clinical research in their desired portfolio of competencies.

6 Competencies for Inter-Professional Education

It is clear that the diverse background of biomedical professionals involved in medicines development and clinical research lends itself well to the concept of IPE, which is defined as "students from two or more professions who learn about, from and with each other to enable effective collaboration and improve health outcomes" [32]. The goal of inter-professional learning is to prepare all health-related

professions for working together with the common goal of building a safe and better patient-centered and community/population-oriented healthcare system.

Interest in promoting more team-based education in the USA is not new. The initial recommendations were released by the Institute of Medicine in 1972 [33] and extended to several levels (organizational, administrative, instructive, and national), including the need to develop new faculty skills in instruction that would present role models of cooperation across the health professions. Even though the recommendations are focused on patient care, the principles of IPE also apply to clinical research and medicines development.

Regrettably, teamwork training for inter-professional collaborative practice in health professions education has lagged dramatically behind the changes in the healthcare landscape and the changing world of clinical research. Recent trends to ensure quality through a coordinated oversight process (accreditation of institutions and educational programs, professional certification, recertification, and licensure) have emerged in a few countries. However, very few are competency based. Thus, there is a critical need for defined competencies that relate to inter-professional collaborative practice across the professions.

A recent report from the Institute of Medicine [34] identified four competency domains (values/ethics; roles and responsibilities; communication; and teams/teamwork) and 38 related core competencies for inter-professional collaborative practice. However the progress in its implementation, particularly as related to clinical research and medicines development, has been extremely slow.

7 The Way Forward: Initiatives in the USA, Europe, and Latin America

There are several initiatives currently ongoing that address many of the issues related to the E&T of clinical research and medicines development professionals discussed earlier.

1. Validation of competencies and competency portfolios in clinical research and medicines development through a competency-based needs assessment
   As mentioned before, it is essential that organizations and professionals involved in clinical research and medicines development are able to objectively assess their individual or group competence against a globally recognized framework. An NA is a systematic process for determining needs or gaps between current conditions and desired conditions. Such discrepancies should be measured to identify the needs appropriately. Very little information on the use of NAs in planning systematic E&T in the above-mentioned disciplines is available. An international initiative is underway that includes Latin American countries, the USA, Canada and Australia, and is aimed at validating competencies through an online questionnaire including members of local professional organizations. The relevance of the individual competency to the job, the level of individual progression in achieving the specific competency, in addition to the educational needs is included. Competency portfolios and standardized job descriptions may result as an outcome of this initiative.
2. The specialist in medicines development concept and vocational education
   To date, there is neither a defined path nor a qualification available for any professional in medicines development at the global level. As mentioned elsewhere, PharmaTrain, supported by the EU commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA), has developed a standardized syllabus, curriculum, and multiple course programs for medicines development and is about to implement a professional qualification, the PharmaTrain Specialist in Medicines Development (SMD). The SMD is a competency-based, workplace-centred 4-year E&T program in medicines development, comprising a knowledge base covering the PharmaTrain syllabus for medicines development, delivered and assessed through modular curricula and the acquisition and demonstration of competencies for medicines development across seven domains [30]. Participants in this mentored program will become competent within a framework of assessment, appraisal, and annual review of progress and achievement. On completion, participants achieve SMD certification from the PharmaTrain Certification Board. The program is modelled after that of the UK's Faculty of Pharmaceutical Medicine. The initial experience will be piloted in Italy, as part of a collaborative effort with the Italian Association of Pharmaceutical Medicine (SSFA) and IFAPP, and with the support of key local stakeholders, including the Italian regulatory agency, the Italian Pharmaceutical Industry (Farmindustria), other national professional associations, and IMI-TRAIN, one of the latest IMI projects. A joint task force including representatives from academia and the professional associations will coordinate the implementation during the period 2015–2018.
3. Post-graduate, competency-based certification for pharmaceutical physicians in the UK
   The medical specialty of pharmaceutical medicine was listed and recognized officially in the UK in 2002, and

a post-graduate certification program of pharmaceutical medicine specialty training (PMST) was introduced for physicians working in the field of pharmaceutical medicine with the pharmaceutical industry. It is a mentored, monitored, and quality-managed program under the auspices of the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK, regulated by the General Medical Council (GMC). PMST is a CBE program over 4 years comprising a knowledge base leading to the Diploma in Pharmaceutical Medicine and an in-work competencies curriculum covering seven domains of pharmaceutical medicine, including interpersonal, management, and leadership skills. The CBE program operates within a framework of assessment, appraisal, and annual review of achievement and progression. To date, 260 pharmaceutical physicians have completed PMST and been awarded the Certificate of Completion of Training by the GMC, and on a rolling basis there are 160 physicians actively undertaking PMST across the UK.

4. The possible role of the joint task force in consolidating the competency-based education and training in clinical research

   As mentioned above, the JTF has developed a framework of domains and competencies required for high-quality, ethical, and safe clinical trials. Its aim is to move clinical research from an activity motivated by compliance to a profession motivated by competency. A next step is to link these efforts so that clinical research professionals, like other health professionals, would complete an accredited educational program, a supervised hands-on experience, and sit a personal certification examination. Pilot programs in collaboration with accredited academic organizations and professional associations are underway.

5. Competency-based accreditation of educational programs in the USA

   As academic programs have emerged in the USA and the rest of the world, it is imperative that academic leaders of these programs collectively adopt CBE as a method to standardize curriculum development. To facilitate that process, the Consortium of Academic Programs in Clinical Research (http://www.coapcr.org), in collaboration with the Commission for the Accreditation of Allied Health Education Programs (http://www.caahep.org), is developing an accrediting process for academic programs in clinical research based upon the JTF core competencies.

6. Planning for inter-professional education in academic institutions

   Graduate medical education and allied health professions are years ahead of clinical researchers in formalizing the roles and responsibilities of each member of the healthcare and drug development team. Thomas Jefferson University in Philadelphia (USA) has been a leader in this area and founded the Jefferson Center for Inter-Professional Education [35], which provides training to help students from a variety of health professions achieve the core competencies composing the four inter-professional collaborative practice domains mentioned earlier. More recently, Rutgers Biomedical and Health Sciences (RBHS) in New Jersey (USA) has brought together pharmacy, medicine, physical and occupational therapy, social work, physicians assistants, nursing, dentistry, and clinical laboratory sciences students to participate in a series of case studies, which follow the patient from the first encounter in the emergency department through to discharge and beyond [36]. Faculty act as facilitators as the team navigates the patient's care in all venues. Additionally, trained patient actors (standard patients) represent the patient and family, helping the students to appreciate the complexities of patient care as they encounter issues surrounding advanced directives, homecare, structural barriers influencing patient independence, and other real-world issues that go beyond each student's discipline. The goal is for students to graduate who are focused on a team approach to patient-centered medicine. A similar approach is currently used in the Masters Program on Clinical Trials offered by the institution. It is hoped, and expected, that these IPE experiences would help transform the clinical trial enterprise into team-based, patient-centered medicines development.

8 Conclusions

An educational environment in which aspiring and established biomedical professionals around the world could readily learn about the competencies they need to pursue, relating to a particular career path, has been envisioned [37]. Professional associations working in close collaboration with employers could define competency profiles for different roles.

Since there are several approaches to lifelong learning for a biomedical professional (formal education, informal education, non-formal education, vocational training, CPD, etc.), competencies can be used as the 'currency' to align and harmonize the desired learning outcomes for effective performance. Formal validation of the educational method is still a work in progress.

Competency-based profiles of key roles in medicines development can be effectively prepared. The same

principles outlined and discussed could be applied equally to inter-professional learning and teamwork for improved performance.

Standardized position descriptions for various functions could also be developed globally. The effective implementation of training programs as described in this paper has the potential to transform drug development procedures into an efficient and integrated process, and medical products' life-cycle management would result in the availability of better and safer medicines for the benefit of patients and society.

Since the public is both the end-user of and stakeholder in the medicines development process, another significant outcome of advanced inter-professional E&T would be a renewed assurance to the public that the clinical research enterprise is in the hands of competent people who are evaluated against a set of performance standards.

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Conflict of interest Honorio Silva, MD is Adjunct Professor, BioPharma Educational Initiative, Rutgers University Biomedical and Health Sciences, School of Health Related Professions, Newark, NJ, USA and a Board Member of PharmaTrain Federation and the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP).

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