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Clinical Researcher—November 2019 (Volume 33, Issue 9)

PEER REVIEWED

Cystic Fibrosis Clinical Research Coordinator Mentoring Program: A Review

Zoe Davies, NP, MS, CCRC; Colleen Dunn, MS, RRT, CCRC; Elizabeth Hartigan, MPH, RN, CRM; Kathleen Hilliard, CCRC; Patricia Burks, RN, MA, CCRC

Cystic fibrosis (CF) is an inherited, autosomal recessive, multisystem disease that affects approximately 30,000 individuals in the United States{1} and is caused by mutations in the gene that produces the CF transmembrane conductance regulator (CFTR) protein. CFTR is chiefly responsible for the transport of ions and fluid across epithelial cell membranes, such as those found in the lung, pancreas, liver, gastrointestinal tract, and skin. The abnormalities in the lung lead to airway obstruction, inflammation, and infection, which cause progressive airway damage and account for most of the morbidity and mortality seen in CF.{2}

Huge advances have been made in recent years in the knowledge about the defective gene that causes CF, its defective protein product, and the downstream clinical consequences for people with CF. This, in turn, has led to the development of multiple therapies which have improved the mean life expectancy for a person with CF to approximately 44 years of age.{1} These advances are the result of successful clinical research efforts supported, in part, by the Cystic Fibrosis Foundation (CFF).{3}

In collaboration with industry and academic partners, the CFF has developed a robust drug development pipeline to meet the overall mission of improving the lives of patients with CF. Key limiting factors to moving multiple therapies forward simultaneously have included both recruitment of subjects (since CF is considered an "orphan disease" that affects less than 200,000 people nationwide) and the availability of trained clinical research staff.{3} Recognizing this need, the CFF founded the CF Therapeutics Development Network (TDN) in 1998.{3}

The CF TDN was initially comprised of eight clinical research centers, but over the years it has expanded to its present total of 92 centers.{4} The development and expansion of the CF TDN has helped to ensure broad geographic distribution of CF clinical research centers across the United States, thereby increasing access for many additional eligible CF patients. As these new centers have been added to the network, a key goal has been to ensure that each one has dedicated, well-trained CF researchers—particularly clinical research coordinators (CRCs)—available to conduct the research.

Additionally, CRC turnover and retention are important issues facing most research programs, regardless of clinical indication. According to a 2017 survey conducted by SCORR Marketing,{5} 41% of research professionals are considering switching jobs and don't see much opportunity for career advancement within their organizations. Prior to 2008, CRC turnover in the CF TDN was *believed* to be due to the length and complexity of many of the CF research protocols, which often require specialized training; the long, often tedious working hours; the lack of career advancement; and less than optimal pay. To a new CRC, these issues can be overwhelming.

Recognizing the crucial role of the CRC, the CFF decided to pilot a CF CRC mentoring program modeled after a similar program developed for CF dieticians. The main goals of this program were to provide resources, training, and networking opportunities to those new to the CF research world, with the hope of increased retention of those same CRCs over time.

Program Description{6}

In 2008, this program consisted of four keys roles (see Figure 1):

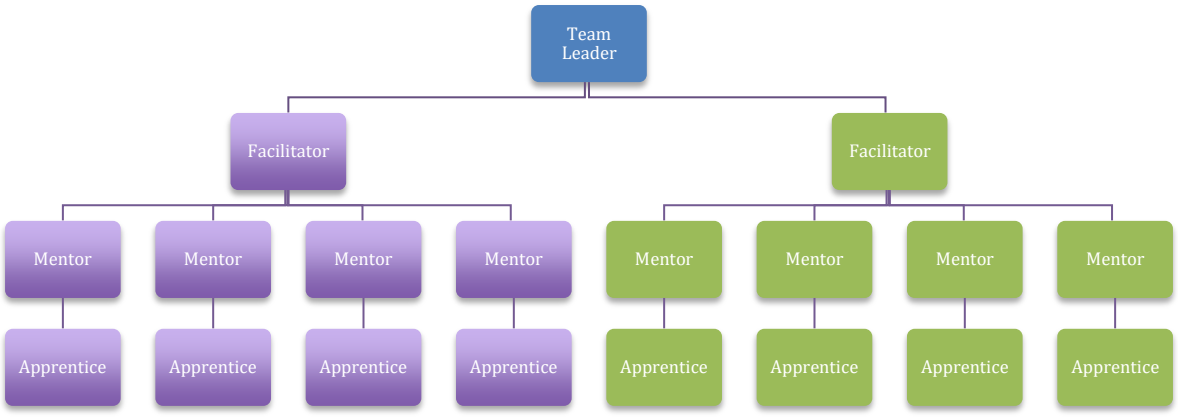
Team Leader—This person provided oversight for the entire mentoring program. The team leader coordinated all activities related to the program and served as a conduit between the CFF and the TDN. This person also helped to develop the materials needed for the program and facilitated conference calls, site visits, and e-mail contacts.

CF CRC Facilitator—The facilitators served as the organizational conduit between the mentors and the apprentices. They helped to develop and oversee the mentoring curriculum and made sure that the mentors and apprentices were "a good fit" for each other. Interactions included face-to-face meetings, site visits, phone, and e-mail contacts.

CF CRC Mentor—Served as a resource for new CF RC apprentices. The interactions included a face-to-face meeting, a site visit from the apprentice to the mentor's site, phone, and e-mail contacts for at least three months after the site visit.

CF CRC Apprentice—Individuals who were new to CF research and who intended to continue in CF research after program completion.

Figure 1: Key Roles of the CF CRC Mentoring Program



Today, the organizational structure remains much the same with one exception: The two facilitators absorbed the team leader position/responsibilities in 2013.

History

The rollout of the program was initially announced at a national CF CRC retreat as well as advertised on the CF CRC TDN website. Individuals for the first group of mentors were handpicked by the CF mentoring program executive committee (the team leader, facilitators, and a representative from the CFF and TDN), and those interested in being an apprentice were required to fill out an online application. The team leader and facilitators matched the available mentors to apprentices depending on various criteria; for example, patient population (adult, pediatric, or both), the specific type of experience needed, and geographical location.

The facilitators then contacted the mentor/apprentice pairs to notify them of the match as well as help to "facilitate" the overall mentoring experience. Each mentor contacted his or her apprentice to determine the specific learning needs, help develop goals and objectives, and set up a date for the site visit. Once the site visit was over, the mentor and apprentice as well as the apprentices' principal investigators (PIs) were required to complete an evaluation of the process. The mentor was also required to maintain contact for three months following the visit to provide additional support as needed.

After the apparent success of the first group of CRC apprentices in 2008, it became a regularly scheduled program offered to new CRCs within the TDN network once or twice per year. As each cohort of mentors and apprentices completed the program, any issues that had occurred during that particular match period and the post-visit evaluations were reviewed and discussed by the program leadership. This provided important feedback, which was used to update and improve the overall program; for example:

- A web-based application process using Survey Monkey is now the method that both apprentices and mentors use to apply to the mentoring program, as well as for completion of the post-visit evaluations.
- Application questions were streamlined and/or rewritten to better identify "best" candidates.

- Post-visit evaluation questions were modified in order to better understand the individual's experience.
- PI awareness and engagement is crucial for the success of the program; now they are involved from the beginning of the application process through program completion.
- To fine-tune presentation and lecturing skills, apprentices are required to present their goals and objectives, as well as a mid-and post-visit summary, to the group.
- Program documents, power point presentations reviewed and updated on a yearly basis.
- Added specialty mentoring tracts (i.e., program management, regulatory, and laboratory).

In Retrospect

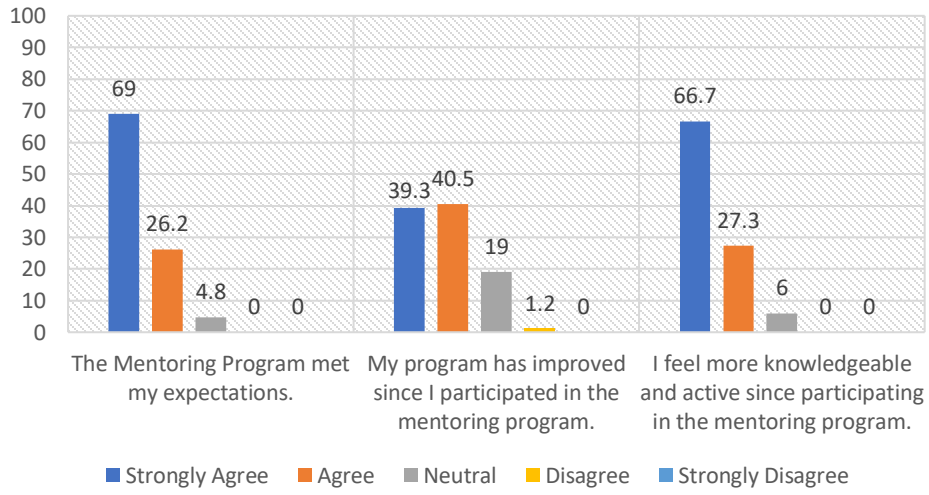
After 10 years of program implementation, a retrospective review was completed to ascertain if the program was indeed providing the necessary support, resources, and training to participants. All of the post-visit evaluations obtained from the apprentices, mentors, and PIs from 2008 until 2018 were sorted and reviewed. As edited for clarity and listed below, the questions required either open-ended, best answer, or yes/no responses (see Figures 2, 3, and 4 for highlights from the responses).

<u>Apprentice</u>

1) The CF CRC mentoring program met my expectations.
2) The CF research program has improved at my center since I participated in the mentoring program.
3) I feel I am more knowledgeable and active in CF research since I participated in the mentoring program.
4) Please briefly describe the site visit, explain what the focus of the visit was, and provide examples of what you took away from the visit.
5) Do you feel that you were adequately prepared for the visit?
6) After the site visit, please list any processes/changes you would like to incorporate at your center to improve site performance.

7) After consultation with your mentor regarding clinical trial and site management processes at your site, describe the focus of your interactions with your mentor or your learning plan.
8) Name a tool from the CF ClinicalResearchNet Toolkit (see * below) that you were able to implement at your center.
9) What do you consider the most positive change you have made in your research program as a result of the CRC mentoring program? (see ** below)

Figure 2: Apprentice Responses from Review (%)



*The toolkit contains numerous "tools" specifically for the CF CRC. The most commonly implemented tool(s) included the templates and checklists for facilitating study startup and the site budget tool to help create appropriate study budgets.

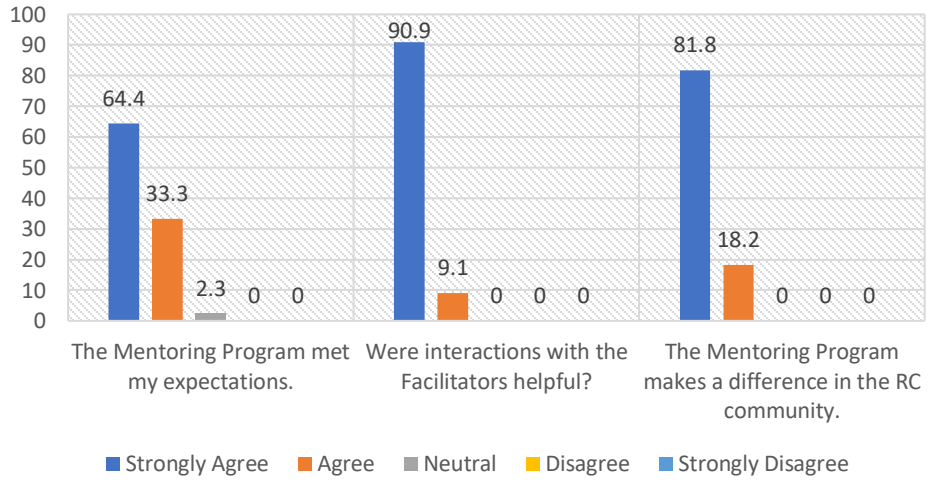
**Participating in the program helped apprentices better identify areas for improvement at their own sites, improved their overall communication skills, and facilitated networking with their colleagues.

Mentor

1) The CF CRC mentoring program met my expectations.
2) Were interactions with the facilitators helpful?

3) Please briefly describe the site visit and what the focus of the visit was**.**
4) Do you feel that you were adequately prepared for the visit?
5) After the site visit, list three things that you think would improve performance at the apprentice's site.
6) After consultation with the apprentice regarding clinical trial and site management processes at their site, describe the focus of your interactions or your learning plan.
7) Name a tool from the CF ClinicalResearchNet Toolkit that your apprentice was able to implement at his/her center.
8) I think the CRC mentoring program makes a difference in the CRC community at large.

Figure 3: Mentor Responses from Review (%)

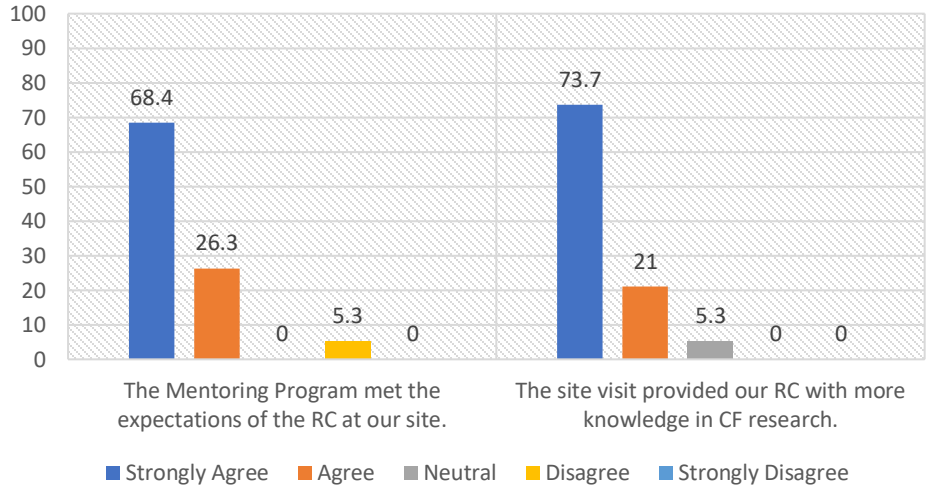


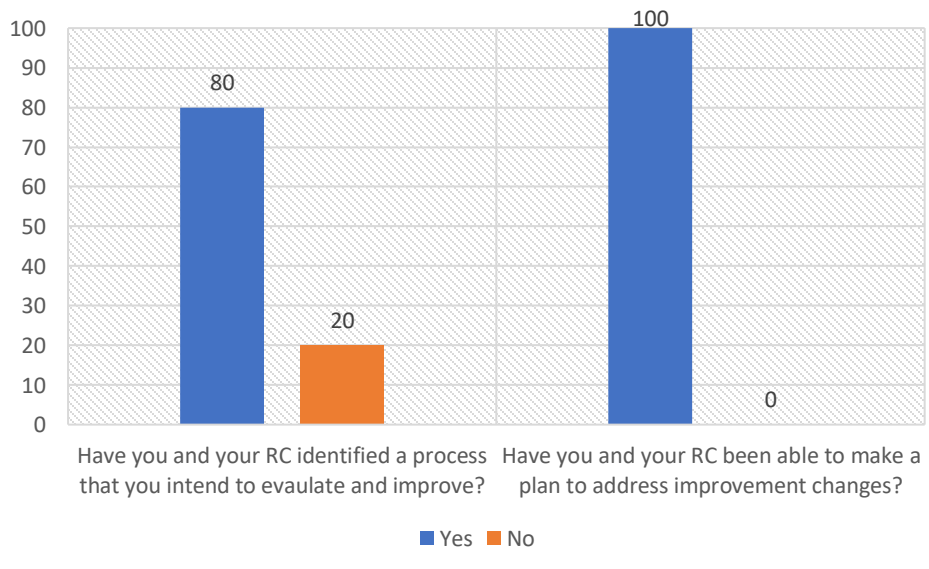
PI

1) The CF CRC mentoring program met the expectations of the CRC at our site.
2) The site visit provided our CRC with more knowledge in CF research.
3) Have you and your CRC identified a process that you intend to evaluate and improve?
4) Have you and your CRC been able to make a plan to address improvement changes?
5) List the new tools your site CRC has been able to implement at your center.
6) List changes noted in your research program since the CRC at your site participated in the mentoring program.

7) Was there an impact on the partnering between the PI, clinic nurse/coordinator, and CRC at your site after your CRC participated in the mentoring program?
8) Fostering leadership skills was an inherent part of the mentoring program. Have you witnessed an enhancement in this since your CRC participated in the program?
9) What project(s) is your CRC planning to work on over the next year?

Figure 4: PI Responses from Review (%)





Apprentice Comments

"Thank you so much for the opportunity to participate in the [mentoring program]. As a coordinator new to research entirely and the only CF research person at my site, this program has showed me how supportive and helpful the CFF/TDN community is and their commitment to fostering growth as coordinators."

"I am so thankful for being given this opportunity by the TDN. I will forever be grateful for the people I met in this program and for everything I've learned that I will take with me throughout my career."

"I had a wonderful experience and am grateful for the opportunity. My mentor is very knowledgeable and admirable. I'm certain this program contributed to improved performance of research for me, individually, and for our center."

Mentor Comments

"I love this program and the opportunity to network with new coordinators. They give me energy and new ideas. Thank you for the opportunity."

"What a wonderful program. We were able to connect at NACFC and sit in sessions together. We have continued our mentor relationship, talking briefly at least [monthly], sharing concerns [and] milestones, and having opportunity for learning from each other."

PI Comments

"I felt the program to be extremely valuable. I hope the [mentoring] will continue in the future."

"Nancy, our new [coordinator], has taken huge initiative to move our CF research program forward. We couldn't do it without her."

"My [coordinator's] mentor spent the day with her then disappeared to who knows where. Thus [she] never received any of the helpful handouts, spreadsheet formats, etc. that the mentor had promised her. Disappointing."

Status Update

By the end of 2018, 102 apprentices had completed the program: 53 (52%) of those individuals are still working as CF CRCs and 49 (48%) have since left the position. Eight (7.8%) of those apprentices eventually became mentors. There were 50 mentors, 35 (70%) of which are still in CF research and 15 (30%) of which have since left the position.

Conclusion

The data show that the vast majority of participants feel that the mentoring program is indeed a worthwhile endeavor providing new CF CRCs with tools, ideas, and support for increasing their CF knowledge base and helping make their jobs more manageable. CRC turnover continues to be an issue, but once a CRC becomes a mentor, he or she seems more likely to remain in CF research.

In September 2016, in order to track turnover rates and determine the common reasons for leaving, the TDN decided to initiate CRC exit interviews. At the time of article submission, there were 71 completed interviews. CRCs indicated issues with coworkers and supervisors, pay, and lack of career advancement as influencing their decisions to leave the job. Interestingly enough, the length and complexity of protocols and the long, often tedious working hours were not significant issues. Mentors left their positions mainly due to retirement or career change/advancement within their institutions.

Obviously, continuing to obtain post–apprentice visit surveys as well as completing CRC exit interviews will be important to help with mentoring program development, which in turn will hopefully help improve overall job satisfaction and retention amongst CF CRCs.

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PEER REVIEWED

Evaluating the Role of the Regulatory Writer

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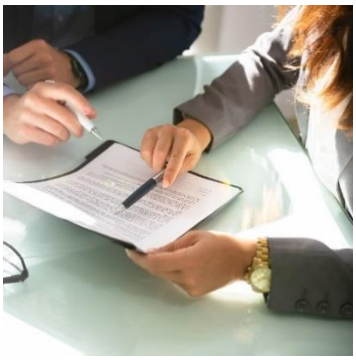


Drug development is a billion-dollar industry featuring a variety of roles necessary to pursue the goal of product approval.{1} A crucial component within this process is well-developed, well-documented, and well-communicated study research practices. Medical writers act as key communicators for study sponsors and governmental agencies, such as the U.S. Food and Drug Administration (FDA) and European Medicines Agency, to evaluate coherence, ethics, and efficacy of research practices and results for drugs and medical devices/diagnostics.{1–3}

Medical writers either within pharmaceutical companies or via contract research organizations (CROs) can be further divided by specific writing role and key composition types, such as *promotional* and/or *advertising, non-promotional education/training (*e.g., *medical affairs), publication, labeling,* and *regulatory writing,* as described in the following:

- Advertising and promotion utilize a unique set of regulations for postapproval communications to market the respective product to patients and/or healthcare providers; 21 CFR 202-203 in the FDA's *Code of Federal Regulations* and many guidance documents direct writers in this arena.
- Non-promotional education or training materials are often geared to professional audiences, such as key opinion leaders or medical affairs professionals, respectively.
- Publication writing summarizes clinical research procedures, analysis, and results into journal manuscript formats or conference materials, such as presentations, abstracts, and posters.

- Key examples of labeling documents include therapeutic ingredients, dosing directions, and warnings on the exterior of therapeutic packaging and inserts; the core purpose is to update and list all risks and directions for safety of therapeutic use following approval.
- Regulatory writing is the development of preclinical and clinical research procedures into documents and submission packets that review and record essential study conduct, practices, and results.{2,3} Writers within this discipline ensure clarity of study statistical analyses, protocol guidelines, toxicology reporting, and completion of study and governmental agency-specific documentation and submission packets needed for approval and ongoing research practices.{2,3}

In summary, Table 1 reviews the key types of medical writing and provides brief descriptions and examples of content.

Table 1: Key Types of Medical Writing

Medical Writing Types	Brief Description	Examples of Documents
Promotional/advertising	Composition of therapeutic and product information to patients/consumers and clinicians for commercial and instructional use	Promotional presentations, direct-to-consumer ads, sales aids (e.g., brochures), and digital/media promotion (e.g., websites, social media)
Non-promotional education/training	Composition of therapeutic and product information to educate clinicians and other medical professionals	Internal educational/ training content (e.g., advisory board slide decks) or external scientific content (e.g., exposition information, standard response letters)
Publication	Composition of study design/methods, data analyses, and clinical trial results of an intervention(s) or studied medical topic for peer review	Journal manuscripts; conference materials such as posters, abstracts, and oral presentations; and internal documents (i.e., publication planning)
Labeling	Composition of medical directions and warnings	Drug labels, package inserts/instruction pamphlets, warning

	for drug use to patients and clinicians	boxes/lists, lists of active/non-active ingredients
Regulatory	Composition of study documents for use in research conduction and summary of research results	Informed consent form, study protocol, clinical study report, risk evaluation and mitigation plans

The regulatory writer is the focus of this review, and this role can be represented by a variety of individuals from multiple backgrounds, experiences, and education.{1} However, there is a lack of published literature of the necessary proficiencies and specific tasks required of regulatory writers.

A forum held by the American Medical Writer's Association (AMWA) in 2019 reported the need for, and difficulties associated with, organizational efforts to recruit and train medical writers in the regulatory field.{4} This paper explores and characterizes the attributes and importance of the regulatory writer role in drug development as it may pertain to small-scale pharmaceutical or biotech companies. Moreover, defining the practices and requirements of a regulatory writer can encourage interest in, and inspire novice candidates to consider joining, this field.

Select Examples of Regulatory Documents for Regulatory Writers

Regulatory writing includes a variety of documents utilized in different functions in the conduct of clinical research. The following sections summarize several core research documents that are chiefly written by regulatory writers.

Informed Consent Form

Informed consent forms (ICFs) are the main documents used by study site personnel for familiarizing potential volunteer subjects with the details of a specific clinical trial. Per international and governmental agency criteria, such as FDA's 21 CFR 50, volunteers cannot proceed into the study protocol activities without first providing voluntary consent via the ICF, after having a discussion about any and all risks associated with study interventions, as well as

about the participant requirements for completing the study. ICFs should include information on any possible adverse events and on the study's purpose/practices, so regulatory writers must have insight and knowledge of the study protocol to ensure all the study parameters are summarized.

From a participant perspective, appropriate "understanding" of an ICF is imperative to adequately *inform* the participant of risks. There are different levels of understanding, including objective vs. subjective understanding (i.e., correct knowledge vs. personal impression of facts) and general understandability—all of which need to be considered in ICF creation.{5} Further, a study comparing ICFs over a period of 17 years for rheumatology studies identified a need for ICFs to be written between a third- and eighth-grade reading level.{6}

Conciseness is another important component in ICF creation, whereby higher page counts in ICFs result in participants being less likely to fully review document content.{6} Developing and abiding to structural ICF templates can assist regulatory writers so that content is full and clear.{7} Additionally, regulatory writers need to reliably incorporate multi-disciplinary feedback (e.g., from legal experts and clinicians) all while ensuring the participant will fully understand the document.

Study Protocol

Regulatory writers help to develop the protocol's explanations of guidelines and study procedures with oversight and input from the study investigators.{2,3} Protocols usually follow a generalized structure that includes sections on therapeutic background, study design, inclusion and exclusion criteria for participation, treatment formulation and administration criteria, toxicities and reporting criteria, statistical considerations for efficacy determination, and appendices to summarize section content in figure and tabular form (21 CFR 312).

Regulatory writers also assist with the memos and amendments to the study protocol to establish additional information and altered directions for therapeutic use and minimization of risks. Regulatory writers must ensure these modifications are articulated coherently and be responsible for version control across affected documents (e.g., protocol sections and study supplemental materials)—all in a timely fashion.

Clinical Study Reports{8}

Clinical study reports (CSRs) act as comprehensive summaries of the efficacy, accumulated toxicity, and other statistical outcomes of clinical data, and are one of the International Council for Harmonization (ICH) E6 Essential Documents following a clinical trial. Regulatory writers are tasked with composing these reports about the safety and efficacy raw data outputs, which can be quite extensive with a multitude of statistical variation.

Per FDA guidance and ICH E3 criteria, CSRs should specifically include participant demographics, review of each proposed outcome, and review of adverse events that have occurred. Regulatory writers require a strong understanding of guidance documents/guidelines for characterizations and completeness over the outcomes of statistical analyses and tabular and/or graphical constructs.

Risk Evaluation and Mitigation Strategies{9}

Risk evaluation and mitigation strategies (REMS) are developed as guides to educate consumers about warnings/safety issues concerning a drug and to give specific directions for therapeutic use. REMS plans have become a requirement for certain pharmaceutical products since initiated by the FDA Amendments Act of 2007 in order to impose greater safety measures on those therapeutics with seemingly higher risk-to-benefit levels. Regulatory writers document step-by-step instructions and/or safety precautions for patient use that would also be included within the New Drug Application (NDA) submission review to FDA.

Additional FDA Submissions{10,11}

Governmental agency submissions for clinical trial initiation or drug marketing require completion of specific forms and attenuation of several different study documents within the submissions. Regulatory writers often develop these large submissions, such as for Investigational New Drugs or NDAs, assembling investigator summaries, protocols, CSRs, integrated summaries of safety, and other sources of information. Amendments to any of these documents require complete updating and re-submission of the documents with a brief summary of the submitted changes.

Core Expertise of a Regulatory Writer

Inherent Proficiencies

In order to identify an individual's interest or suitability to the role of a regulatory writer, an implicit set of expertise must be demonstrated. The role requires collaboration with many members of the research team, such as the sponsor, research site investigators, statisticians, research managers, and/or coordinators. Regulatory writers in pharmaceutical companies or CROs often have direct communication among these team members by way of telephone, in-person contact, and/or e-mail to be able to obtain, verify, and deliver content for institutional review board, sponsor, and/or governmental agency review submission. Below are key proficiencies often not evident with merely a degree or certificate:

- Clear and accurate communication: Content must be written in a manner that is comprehensible to the entire research team. For example, protocols used to describe the intricacies of a clinical study should be written to allow for all researcher roles to properly understand each section. Clarity and concision are valuable characteristics, especially in composition of study documents for general audience (e.g., ICFs). Additionally, regulatory writers often interact with various disciplines, making professional and clear communication skills vital to this role.
- Agility and reliability: Timeliness is essential to ensure study conduct meets requirements for submission. In accordance with governmental specific regulatory documentation, regulatory writers must have awareness of submission details and deadlines. Regulatory writers need to respond to rapid changes in protocols and other documents that require fast updates, making adaptability and efficiency important skills. Additionally, deadlines are often immovable (e.g., following FDA approval or for NDA submission), elevating the need for project and time management skills.
- Data comprehension and dissemination: Volumes of raw data need to be dissected and accurately communicated in many types of regulatory documents. Regulatory writers are required to have a basic understanding of statistics and medical information in order to choose the most appropriate outputs that convey a true reflection of the trial (e.g., protocol, results in CSR).

- Document management: Lastly, regulatory writers are in charge of the collection, recording, and management/upkeep of various regulatory documents that are required by law per governmental agency for ethical review of drug marketing. These various documents require proper organization and time-sensitive submission per report type. Additionally, requests to update study details require all regulatory documents and components (sections, tables, figures, and supplemental materials) to be edited accordingly.

Academic and Real-World Experience

To be successful, regulatory writers harness various skills in order to provide detailed and appropriate regulatory document compositions by accessing their education, research experience, and knowledge of regulatory science.{2,3} The following summarizes key areas of expertise, with some overlap possible:

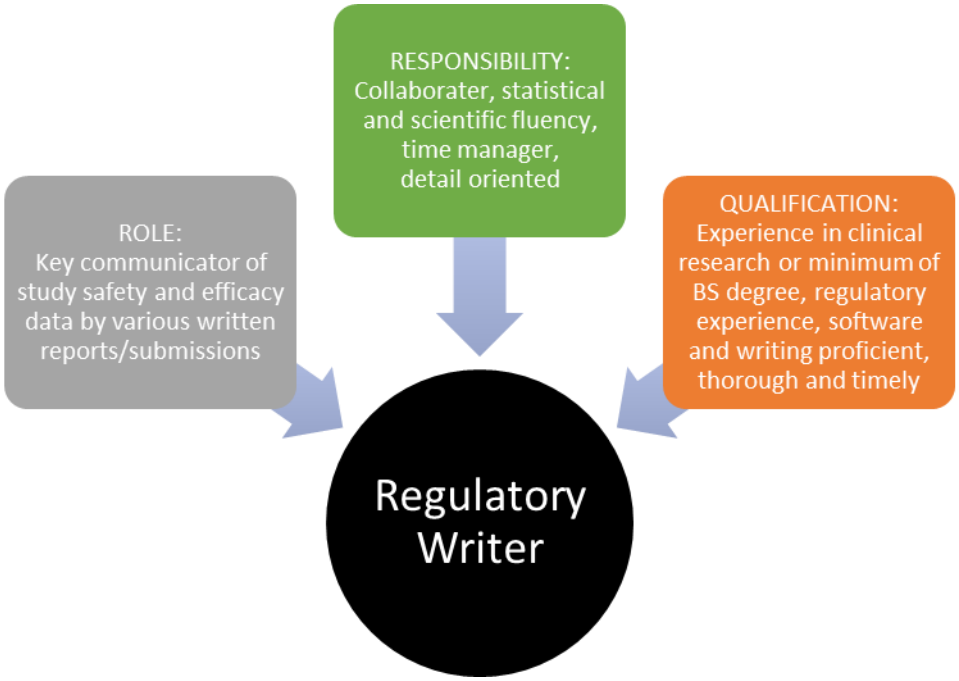
- Formal education: Regulatory writers must have a solid educational background to demonstrate adeptness for writing within the respective specialty. A master's degree and/or a connection to clinical research is desirable in order to obtain competencies of reviewing and interpreting statistical data results; moreover, the ability to simplify all research procedural communications to the variety of research roles is essential. In an assessment of regulatory job postings from 2009 to 2011, 68% of those analyzed required a scientific degree.{3} However, it should be noted that an advanced degree is not always required, and that work experience is a significant factor for success.
- Editorial and software competence: Regulatory writers should also be equipped with refined editorial skills, since they verify and edit a multitude of documentation to reduce likelihood of errors and ensure completeness. As noted earlier, superb communication skills are needed for computation and interacting with the research team regarding expectations and expert analyses of data such as within CSRs, safety reports, or amended documents.{2,3} Each company may also utilize its own software for data outputs or document containment; hence the regulatory writer should be familiar with and comfortable traversing many types of software. These skills can be learned through

literacy courses and/or onsite experience per preferences of the sponsor and/or governmental body.

- Real-world training: Direct research experience within the topics related to clinical research (e.g., oncology) is also highly valuable in order to more easily translate and utilize verbiage associated with the evaluations of therapeutic safety and efficacy results (e.g., pharmacovigilance, toxicity reports). This experience can also provide the regulatory writer with knowledge of the clinical research workflow and previous completion or orientation to respective documents. In addition to working experience within the clinical research field, continuing education courses on clinical research practices from organizations such as the Regulatory Affairs Professional Society (RAPS), Drug Information Association (DIA), and the Association of Clinical Research Professionals (ACRP) can be utilized. Networking among clinical research professionals and medical writers is another valuable experience that can help to increase awareness of, and connect a regulatory writer to, the aforementioned areas.
- Regulatory expertise: Regulatory writers require deep understanding of regulations governing research conduction, as well as of the respective governing bodies.{2,3} A thorough understanding of regulations and guidance documents is crucial for content development, along with governmental agency–specific expectations for reporting and submitting those documents. Knowledge of regulatory requirements can be demonstrated by previous work experience, education, and/or professional certifications such as Regulatory Affairs Certification (RAC) from RAPS. Experience in governmental regulatory policy, statistical methodology, biological mechanisms, therapeutic indication, and pharmacology are other desirable competencies for a regulatory writer.{2,3} Work experience in these areas allows for a more seamless transfer of data and an accurate data "storyline" in a wide variety of document types.

In summary, Figure 1 reviews key elements of a regulatory writer by role, responsibilities, and qualifications.

Figure 1: Key Elements of a Regulatory Writer



Conclusion

Regulatory writers have been identified as an important component of clinical research, and may act as the main communicator among the researcher roles and governing bodies concerning required research procedures and reports. An efficient regulatory writer demonstrates expertise in clarity and attention to detail, timeliness, and collaboration.

Pharmaceutical companies and CROs may approach the regulatory writer's responsibilities with a greater concentration on specialized regulatory writing assignments. In addition, lengthy research documents can be assigned to a group of regulatory writers rather than an individual, depending on submission timelines and individual workloads. As such, written communication is the crux of successful regulatory writers' output—within their team, to governmental bodies, to clinical study staff and investigators, and possibly to study participants/patients—with the ultimate goal of patient safety throughout a product's lifecycle.

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CLINICAL RESEARCHER—NOVEMBER 2019 (Volume 33, Issue 9)

HOME STUDY

Charting Early and Changing Career Courses

Cystic Fibrosis Clinical Research Coordinator Mentoring Program: A Review

LEARNING OBJECTIVE

After reading this article, the participant will be able to describe challenges to longevity for CRCs in cystic fibrosis research and the structure of a mentoring program designed to improve on the situation.

DISCLOSURE

Zoe Davies, NP, MS, CCRC; Colleen Dunn, MS, RRT, CCRC; Elizabeth Hartigan, MPH, RN, CRM; Kathleen Hilliard, CCRC; Patricia Burks, RN, MA, CCRC: *Nothing to disclose*

1. Recent development of multiple therapies for cystic fibrosis (CF) is credited to advancements in what areas?

A. Knowledge about how CF in newborns is related to maternal diet and exercise habits in pregnancy.
B. Knowledge about how to treat CF using drugs and devices originally developed for other conditions.
C. Knowledge about using CRISPR and radiation technologies to edit defective genes in unborn children.
D. Knowledge about the defective gene involved in CF and its subsequent consequences for CF patients.

2. Which of the following are noted as a limiting factor in advancing multiple CF therapies at the same time?

A. Recruitment of knowledgeable investigators and availability of study drugs.
B. Recruitment of study subjects and availability of suitable research staff.
C. Recruitment of international study sites and availability of research grants.
D. Recruitment of study sponsors and availability of clinical research associates.

3. Which of the following is cited as a likely cause of CRC turnover in the CF Therapeutic Development Network before creation of the CF CRC mentoring program?

A. Protocol lengths and complexity.
B. Regulatory confusion and shortcomings.
C. Overabundance of already-approved therapies.
D. Frequent study cancellations.

4. As originally established, which role in the CF CRC mentoring program ensured that mentors and apprentices complemented one another?

A. CF CRC Mentor
B. Team Leader
C. CF CRC Facilitator
D. CF CRC Apprentice

5. What is the obligation of a mentor in the CF CRC mentoring program following a visit to a apprentice's site?

A. To test the apprentice's progress in the field every three months.
B. To maintain contact with the apprentice for three months.
C. To advocate for the apprentice's promotion within one year.
D. To conduct an unannounced inspection of the site within one year.

6. Review and discussion of the mentor/apprentice match periods and post-visit evaluations led to which of the following updates/improvements in the overall program?

A. Increases in private giving for the program to the Cystic Fibrosis Foundation.
B. Involvement of principal investigators throughout the program cycle.
C. Limitations on the number of apprentices from outside the United States.
D. Lengthening the program cycle by at least six weeks at each site.

7. Which of the following are the most commonly implemented features of the CF ClinicalResearchNet Toolkit?

A. Study startup templates/checklists and site budget tool.
B. Protocol interpreter and informed consent waiver forms.
C. Delegation of authority tool and case report form templates.
D. Regulatory deadline alerts and Form FDA 1572 guidance.

8. Through 2018, how many of the mentoring program apprentices were still working as CF CRCs?

A. A little more than one third.
B. A little less than one half.
C. A little more than one half.
D. A little less than two thirds.

9. What trend is mentioned among CRCs who become mentors in the program?

A. Less likely to become certified CRCs.
B. More likely to complete essential documents.
C. Less likely to change employers.
D. More likely to remain in CF research.

10. An examination of CRC exit interviews found which of the following trends in reasons for leaving the job?

A. Protocol complexity and working hours were not significant issues.
B. Coworker/supervisor issues and pay were not significant factors.
C. An abundance of career advancement opportunities was a significant issue.
D. Principal investigators opting out of clinical trials were a factor.

Evaluating the Role of the Regulatory Writer

LEARNING OBJECTIVE

After reading this article, the participant should be able to describe specific duties of regulatory writers in clinical research, the kinds of documents upon which they concentrate, and desirable qualifications for candidates for the role.

DISCLOSURE

Ridge Archer, MACPR; Mary Raber Johnson, PhD, RAC; Esther Chipps, PhD, RN, NEA-BC: *Nothing to disclose*

11. Regulatory writing is considered a sub-role within what larger professional category?

A. Study coordination
B. Monitoring
C. Informed consent
D. Medical writing

12. Regulatory writing covers what range of procedures?

A. Pre-visit and site initiation
B. Preclinical and clinical
C. Pre-marketing and post-approval
D. Preventive and post mortem

13. Research documents written chiefly by regulatory writers include which of the following?

A. Good clinical practice guideline, Form FDA 1572, adverse events report
B. 21 CFR Part 11, Delegation of Authority, standard operating procedure
C. Clinical study report, study protocol, informed consent form
D. FDA Warning Letter, Belmont report, Declaration of Helsinki

14. A study of informed consent forms identified which of the following needs?

A. For the forms to be written at a certain reading level.
B. For the forms to include more details on reimbursement.
C. For the forms to be approved by independent reviewers.
D. For the forms to describe penalties for study noncompliance.

15. The clinical study report is mentioned as listed in an "Essential Documents" guideline from which organization?

A. Institutional review board
B. World Health Organization
C. International Council for Harmonization
D. Office for Human Research Protections

16. Which of the following documents serve specifically as guides to educate consumers?

A. New Drug Approval applications
B. Risk evaluation and mitigation strategies
C. ClinicalTrials.gov registry listings
D. Corrective and Preventive Action plans

17. Which of the following is cited as a proficiency often not evident from one's education?

A. Financial acumen
B. Legal savvy
C. Document management
D. Benefit/risk analysis

18. What level of education is recommended but not mandatory for the regulatory writer role?

A. PhD degree
B. Associate degree
C. Bachelor's degree
D. Master's degree

19. What do the authors indicate about regulatory writers having direct experience within topics related to clinical research?

A. It is highly valuable.
B. It is mandated by FDA.
C. It is unnecessary in most cases.
D. It is too costly.

20. Which of the following is crucial for regulatory writers in terms of regulatory expertise?

A. Understanding the principal investigator's opinions about drug efficacy and toxicity reports.

B. Understanding the historic background of the development of the U.S. Food and Drug Administration.

C. Understanding governmental agency–specific expectations for reporting and submitting documents.

D. Understanding when published deadlines for submitting documents can be ignored.