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Description of document:	National Cancer Institute (NCI) of the National Institutes of Health (NIH) Records regarding contract to prepare NCI Tobacco Control Monograph, 2019-2020
Requested date:	28-September-2020
Release date:	03-November-2020
Posted date:	30-November-2020
Source of document:	FOIA Request National Cancer Institute Building 31, Room 10A48 31 Center Drive Bethesda, MD 20892 Fax: 240-541-4519 Email: ncifoa@mail.nih.gov

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DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Cancer Institute
Freedom of Information / Privacy Act Office
Bldg. 31, Room 10A48
9000 Rockville Pike, MSC 2580
Bethesda, Maryland 20892-2580
Ph: (240) 781-3340 Fax: (240) 541-4519

November 13, 2020

Re: NCI 20-165; FOIA Case No. 55176

This is a final response to your September 28, 2020, Freedom of Information Act (FOIA) request which you submitted to the National FOIA Portal and was received in the National Cancer Institute (NCI) FOIA Office on the same date. You requested the following:

The Statement of Work from the contract, the eight most recent status reports, the delivery schedule, and each deliverable document from NIH contract parent award, HHSN261201700004I, Delivery Order 75N91019F00129, awarded on July 9, 2019, to The Bizzell Group LLC, Bowie, Maryland, modified on November 8, 2019. The responsible NCI office account is 075-2019/2019-0849-000. This award was for development, production and dissemination of a tobacco control monograph. The solicitation number was N02PC7500134.

On October 1, 2020, you limited the portion of your request related to deliverable documents to the following: "each substantive document regarding tobacco, and/or each report on progress of the contract performance only." On November 13, 2020, you agreed to accept a copy of the responsive records with the following information redacted: employee names, three cost summary statements, and a phrase related to the "Contributors" who drafted portions of the monograph chapters.

The NCI Office of Acquisitions (OA) conducted a search and located 17 pages of records responsive to your request. Attached as three PDF files are 17 pages responsive to your request. This includes the Statement of Work for task order HHSN261201700004I / 75N91019F00129 (7 pages), a list of deliverables for the task order (1 page), and 2 progress reports (9 pages).

If you are not satisfied with the processing and handling of this request you may contact the NCI FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NCI FOIA Public Liaison
M.K. Holohan
Building 31, Room 10A48
31 Center Drive
Bethesda, MD 20892-2580
240-781-3410 (phone)
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November 13, 2020

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In certain circumstances provisions of the FOIA and Department of Health and Human Services FOIA Regulations allow us to recover part of the cost of responding to your request. Because the cost is below the \$25 minimum, there is no charge for processing your request.

Sincerely,

Milliard, Suzanne
(NIH/NCI) [E]

Digitally signed by Milliard,
Suzanne (NIH/NCI) [E]
Date: 2020.11.13 11:06:32
-05'00'

Suzy Milliard, CIPP/G
Freedom of Information Coordinator
NCI/OGCR/FOIA

Attachments:

Statement of Work for task order HHSN261201700004I / 75N91019F00129 (7 pages)

List of deliverables for the task order (1 page)

Two Progress reports (9 pages)

Statement of Work: Development, Production, and Dissemination of NCI Tobacco Control Monograph

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work.

Background: Tobacco use, and in particular cigarette smoking, remains the leading cause of premature, preventable death in the United States, and is also responsible for an estimated one-third of all cancer deaths. Between 1964 and 2014, an estimated 20 million premature deaths in the U.S. were attributed to cigarette smoking. Although tobacco use has declined substantially over time, in 2017, an estimated 14% of Americans were current cigarette smokers. However, rates of use vary among different sub-populations, and tobacco use is now recognized as an important cause of health disparities. Additionally, new challenges to the field continually arise. At present, these include the diverse and changing tobacco product landscape, the ongoing revolution in communications technologies, and changes in tobacco control policies and other policies at the local, state, and federal levels.

Because of the critical importance of preventing and reducing tobacco use, and the large knowledge gaps that remain, the National Cancer Institute (NCI), Tobacco Control Research Branch (TCRB) conducts and supports a broad and robust program of tobacco control research, focusing on the diversity of tobacco products, changing patterns of product use, etiology and prevention of tobacco use by youth and young adults, individual- and population-based tobacco cessation, health communication strategies, effective tobacco control policies, and international tobacco control prevention, among others. NCI also strives to disseminate research findings to the broad scientific community, health care professionals, scientists, public health officials, policy-makers, and the general public, including cancer patients, tobacco users and their families, and other stakeholders in the U.S. and other countries.

The NCI Tobacco Control Monograph Series, established in 1991, has served as an important mechanism for dissemination of cutting-edge research findings to many audiences. As of 2019, 22 volumes have been published on a wide range of topics, often emphasizing topics of high public health significance.

Statement of Work:

Objective: The overall objective of this Task Order shall be to provide services to support the development, production, and dissemination of an NCI Tobacco Control Monograph. The specific set of services to be provided by the Contractor involve a range of activities and include administrative support, literature research and technical writing and intellectual contribution to the production of the Monograph volume. The topic of this monograph will be Addressing Tobacco Use in the Context of Oncology Care.

The Contractor shall perform the following tasks, divided across two task options. The Base task requirement consists of the development of the Monograph content and review. The Option 1 task requirement consists of the tasks involved in clearance, printing and dissemination of the Monograph as a volume.

Base Task Order Requirement:

Phase 1: Draft Monograph Development

Provide general management activities associated with supporting the development of the Monograph, including maintaining the files and materials. The Contractor shall:

- a) Meet with staff of TCRB and the Office of Acquisitions for an initial “kick-off” meeting to discuss and review the task order requirements.
- b) Develop a method for tracking the Monograph progress and the draft versions; and create and maintain shared drive folders (and an alternate file-sharing platform that may be necessary for external participants) for administrative items, in-person meeting documents, chapter versions, references, and other relevant items.
- c) Recruit 2-4 external scientists for a Monograph Scientific Editorial Committee; provide to Scientific Editorial Committee members information concerning expectations of the assigned role, time-frame, and work commitment required; subject to NCI input and approval.
- d) Prepare and execute contractual agreements (approved by NCI) with each member of the Scientific Editorial Committee.
- e) Prepare and send a proposed timeline (approved by NCI) for Monograph production to the Scientific Editorial Committee.
- f) Schedule and convene an in-person meeting of Scientific Editorial Committee, NCI staff, and Contractor staff to discuss the following:
 - i. chapter topics/proposed content and identify potential Chapter Leads;
 - ii. NCI expectations for volume format and structure;
 - iii. roles and responsibilities, timeline and processes for in-person meetings, for each step involved in completion of the volume;
 - iv. dissemination strategies and other strategies to maximize Monograph impact; and,
 - v. plans for involvement of NCI staff and assistance available from Contractor to assist Scientific Editorial Committee and Chapter Leads in researching, writing and editing.
- g) Prepare and execute contractual agreements (approved by NCI) with up to 8 Chapter Leads.
- h) Prepare and send a “welcome packet” of timeline, style guide, other materials to Chapter Leads to orient them to NCI expectations concerning the format of the Monograph chapters.
- i) Schedule and convene a virtual meeting of NCI staff, the Scientific Editorial Committee, Chapter Leads and Contractor staff to discuss the anticipated process of Monograph development including the following:
 - i. NCI expectations for volume format and structure;
 - ii. roles and responsibilities, timeline and processes for in-person meetings, completion of the volume;

- iii. input from NCI staff and available help from Contractor over the course of Chapter development; and,
 - iv. establish plans for upcoming calls to be held between the Scientific Editorial Committee members and their corresponding Chapter Leads to plan development of the chapter outline.
- j) Support Chapter Leads in chapter development by, including but not limited to:
 - i. Providing ongoing coordination of calls/web conferences as needed between the Scientific Editorial Committee and Chapter Leads;
 - ii. Conducting literature searches based on criteria provided by Chapter Leads, including location of references, determination of their relevance to a chapter, synthesizing the main ideas presented in publications, making recommendations concerning further literature-based searches; compiling organized lists of relevant literature sources, and placing selected publication references within formatted tables;
 - iii. Providing editing or graphics development assistance; and,
 - iv. Reviewing chapter drafts that are written by Chapter Leads, and making suggestions concerning clarity of expression, organization, coherence of ideas presented, chapter conclusions, writing style, and adherence with style standards provided by NCI.
- k) Submit chapter drafts that are received from Chapter Leads to the Scientific Editorial Committee.
- l) Schedule an in-person meeting for Scientific Editorial Committee, Chapter Leads and NCI staff for in-depth review of chapters.
- m) Provide administrative and technical support to Chapter Leads in developing PowerPoint slides summarizing Chapter contents, for presentation at the in-person Chapter Review Meeting. Take notes and summarize the comments and recommendations made at the in-person meeting. Work with Chapter Leads to make appropriate revisions, as requested.
- n) Provide first honorarium payment to the Chapter Leads, upon review and acceptance by Scientific Editorial Committee and NCI of the revised chapter

Phase 2: Review and Editing

For the support of Monograph production after Phase 1, the Contractor shall manage tracking processes, maintain version control, provide editing and graphic design support, and critically evaluate chapters for clarity and readability, as follows:

- a) Convene an in-person meeting (Chapter Review Meeting) of Scientific Editorial Committee and Chapter Leads, NCI staff, and Contractor staff to discuss the following:
 - i. in-depth review and comments provided on first drafts of individual chapters, including draft chapter conclusions.
 - ii. potential overall volume conclusions, by Scientific Editorial Committee and Chapter Leads.
 - iii. reactions and recommendations of attendees (NCI staff, SEC, Chapter Leads) to the PowerPoint presentations made for each chapter and summarize these.

- iv. solicitation of names of proposed peer-reviewers for individual chapters (aim for 3 per chapter).
- b) Assist Chapter Leads with chapter revisions, based on reactions and recommendations obtained from the in-person Chapter Review Meeting, by summarizing the comments and recommendations, keeping track of which have been addressed through revision, and providing editing suggestions for rewritten chapter versions.
- c) Provide final honorarium payment to the Chapter Leads and first honorarium payment to the Scientific Editorial Committee when the chapters are ready for peer-review, upon review and acceptance by Scientific Editorial Committee and NCI.
- d) Manage the peer-review process, including but not limited to:
 - i. identify in collaboration with NCI and invite 3 peer-reviewers to review each chapter;
 - ii. send chapter drafts to the peer-reviewers with a template and instructions;
 - iii. provide reviewers with a template and instructions, and send the chapters for simultaneous review by the Scientific Editorial Committee and NCI;
 - iv. create a master sheet of comments received from peer-review, including comments from the Scientific Editorial Committee and the NCI;
 - v. incorporate responses to master sheet comments from peer-reviewers, the Scientific Editorial Committee, and NCI into the respective chapters under NCI guidance. Work with the Scientific Editorial Committee and NCI to ensure that comments are comprehensively addressed and non-duplicative; and,
 - vi. provide second honorarium payment to the Scientific Editorial Committee, upon review and acceptance from NCI.
- e) Work with NCI staff and the Scientific Editorial Committee to produce a first draft of the Executive Summary and overall volume conclusions.

Option 1 Task Requirement:

Option 1 task involves the treatment of the Monograph as a volume: its clearance, printing and dissemination, as described below:

Phase 3: Monograph Volume Review, Clearance and Printing

- 1) The Contractor shall manage volume review, as follows:
 - a) Identify and recruit 5 volume reviewers, with input from and acceptance by the Scientific Editorial Committee and the NCI.
 - b) Provide to volume reviewers instructions and a template for volume review comments and a deadline for comments to be received.
 - c) Develop and maintain a comment sheet for compilation of volume review comments from volume reviewers and NCI staff.

- d) Conduct a consistency review across chapters, to determine overlap, continuity of ideas, nomenclature, terminology, standard data sources, and definitions.
 - e) Schedule and convene an in-person meeting of the Scientific Editorial Committee and NCI staff, and Contractor staff to discuss the following:
 - i. incorporate comments from volume review into individual chapters; and,
 - ii. work with the Scientific Editorial Committee and NCI to ensure comments from volume review are comprehensively addressed.
- 2) The Contractor shall manage NCI, NIH, and Department of Health and Human Services (HHS) publication clearance review processes, as follows:
- a) Provide a template for comments and a deadline for comments to be received for HHS and agency-level clearances.
 - b) Consolidate comments from HHS and agency-level clearances into a master comment sheet.
 - c) Work with the Scientific Editorial Committee and NCI to ensure that HHS and agency-level comments are comprehensively addressed and non-duplicative.
 - d) Review and provide final editing of the final draft of the Monograph and Executive Summary as requested by the Scientific Editorial Committee or NCI staff.
 - e) Copy-edit the final draft of the Monograph and Executive Summary.
 - f) Verify references and prepare copyright permission requests.
 - j) Prepare draft for layout, including:
 - i. Verify listings in the acknowledgment section;
 - iii. Number all references;
 - iv. Prepare figures and graphics;
 - v. Create table layout;
 - vi. Provide publication-ready drafts to NCI for proofreading.
 - k) Proofread the complete Monograph and Executive Summary.
 - l) Coordinate printing requests with NCI for printing of the Executive Summary.
 - m) Prepare files for printing, including color-proofs.
 - n) Prepare Section 508-compliant files of the Monograph and Executive Summary for posting on the TCRB website.
 - o) Provide final honorarium payment to Scientific Editorial Committee, upon review and acceptance of the NCI.

Phase 4: Dissemination

The Contractor shall:

Design and implement a strategy for dissemination of the Monograph, including but not limited to:

- a) Create a PDF fact sheet explaining the key conclusions of the Monograph;
- b) Create a PowerPoint slide presentation about the Monograph, including key charts and tables from the Monograph to help illustrate key points;
- c) Create an infographic and other graphic cards for use in social media to promote the Monograph at conferences and to listservs;
- d) Draft an email release and blog article for potential use for NCI's *Cancer Currents* blog to promote the release of the Monograph;
- e) Draft a content outline for a short (i.e., less than 1 min, 30 second) promotion video to explain key Monograph conclusions;
- f) Work with members of the Scientific Editorial Committee to identify intermediaries to help disseminate the Monograph to relevant membership organizations;
- g) Work with the NIH Library to index NCI Tobacco Control Monograph in PubMed for citation purposes; and
- h) Maintain tracking of Monograph dissemination trends on web analytics, social media metrics, and journal searches in collaboration with NCI.

SECTION 3: SECTION 508

Section 508 of the Rehabilitation Act, as amended by the Workforce Investment Act of 1998 (P.L. 105-220) requires that when Federal agencies develop, procure, maintain, or use information and communication technology (ICT), it shall be accessible to people with disabilities. Federal employees and members of the public who have disabilities must have access to, and use of, information and data that is comparable to people without disabilities.

Products, platforms and services delivered as part of this work statement that are ICT, or contain ICT, must conform to the Revised 508 Standards, which are located at 36 C.F.R. § 1194.1 & Apps. A, C & D, and available at <https://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-ict-refresh/final-rule/text-of-the-standards-and-guidelines>

Items in this Statement of Work that contain ICT:

- Electronic documents and reports
- Multi-media

Applicable Requirements:

- All WCAG A & AA Success Criteria

- [E205.1 General](#) -
Electronic content shall comply with E205.
- [E205.2 Public Facing](#) -
Electronic content that is public facing shall conform to the accessibility requirements specified in E205.4.
- [602 Support Documentation](#) –
- [603 Support Services](#) -
- [302 Functional Performance Criteria](#) -
 - [301.1 Scope](#) - The requirements of Chapter 3 shall apply to ICT where required by 508 Chapter 2 (Scoping Requirements), 255 Chapter 2 (Scoping Requirements), and where otherwise referenced in any other chapter of the Revised 508 Standards or Revised 255 Guidelines.
 - [302.1 Without Vision](#) - Where a visual mode of operation is provided, ICT shall provide at least one mode of operation that does not require user vision.
 - [302.2 With Limited Vision](#) - Where a visual mode of operation is provided, ICT shall provide at least one mode of operation that enables users to make use of limited vision.
 - [302.3 Without Perception of Color](#) - Where a visual mode of operation is provided, ICT shall provide at least one visual mode of operation that does not require user perception of color.
 - [302.4 Without Hearing](#) - Where an audible mode of operation is provided, ICT shall provide at least one mode of operation that does not require user hearing.
 - [302.5 With Limited Hearing](#) - Where an audible mode of operation is provided, ICT shall provide at least one mode of operation that enables users to make use of limited hearing.
 - [302.6 Without Speech](#) - Where speech is used for input, control, or operation, ICT shall provide at least one mode of operation that does not require user speech.
 - [302.7 With Limited Manipulation](#) - Where a manual mode of operation is provided, ICT shall provide at least one mode of operation that does not require fine motor control or simultaneous manual operations.
 - [302.8 With Limited Reach and Strength](#) - Where a manual mode of operation is provided, ICT shall provide at least one mode of operation that is operable with limited reach and limited strength.
 - [302.9 With Limited Language, Cognitive, and Learning Abilities](#) - ICT shall provide features making its use by individuals with limited cognitive, language, and learning abilities simpler and easier.

Item	Description	Delivery Schedule
1	Semi-Annual Progress Report	Fifteenth (15 th) calendar day following the end of the reporting period.
2	Annual Progress Report	Fifteenth (15 th) calendar day following the end of the reporting period.
3	Draft Final Progress Report	Fifteen (15) calendar days before the expiration date of the Task Order.
4	Final Progress Report	On the expiration date of the Task Order.
5	Materials for meetings and conferences	As required, and by the NIH Efficient Spending Policy , for each applicable meeting.
6	Monograph documents including contractual agreements and payments, individual volume drafts, clearance review draft, layout of monograph, electronic print files, electronic ancillary files for website, PubMed Index number	As described in the Statement of Work.
7	Roster of Employees Requiring Suitability Investigations (See ARTICLE H.4. Information Security)	Within fourteen (14) calendar days of the effective date of the Task Order, and within fifteen calendar (15) days of a change to the roster.
8	Information Security Training Report	Included in the first Semi-Annual Progress Report, and any revisions to this listing as a result of staffing changes shall be submitted with next required progress report (Semi-Annual or Annual).
9	Contractor - Employee Non-Disclosure Agreement(s)	Submission from each employee, including Subcontractors, prior to performing any work under each task order, or within fifteen calendar (15) days of a personnel change.
10	Section 508 Report	Submit HHS checklists for Word and PDF products two (2) months before the anniversary of the Task Order.



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WE ACCELERATE IT.**

Tobacco Control Research Scientific and Technical Services Support Contract

Contract No. HHSN261201700004I

NCI Control No. N02PC-2017-00004

Task Order No. 75N91019F00129

Task order performance period: July 15, 2019 – July 14, 2022

Semi-Annual Progress Report

(July 15, 2019 – January 31, 2020)

Submitted to:

Kristen Mangold, Contracting Officer's Representative

Linda Park, Contracting Officer

Overview

The Bizzell Group (Bizzell) supports the development, production, and dissemination of a National Cancer Institute (NCI) Tobacco Control Monograph (monograph) under the direction of the Tobacco Control Research Branch (TCRB). Summarized below are the milestones accomplished during the period of performance from July 15, 2019 through January 31, 2020.

Phase I: Draft Monograph Development

Upon award, Bizzell set-up a meeting with TCRB and the Office of Acquisitions to review the contract requirements. Overall, monograph production is on or ahead of the schedule agreed to by Bizzell and NCI.

Setting-up the Scientific Editorial Committee (SEC)

We worked closely with Dr. Gordon Willis and Ms. Kristen Mangold to recruit the four external scientists to serve on the SEC. Together, we drafted guidelines for the role based on previous experience with monograph development and the overall timeline. The SEC members were under contract within 3 weeks. Bizzell identified meeting space, provided travel support and logistics, and actively participated in the SEC kickoff meeting on September 25-26, 2019. During that meeting, we documented outline revisions and suggestions of contributors, discussed the timeline, and agreed on communication touchpoints. Bizzell scheduled monthly check-ins and takes notes to ensure adherence to the project timeline.

Securing Chapter Leads and Creating Contributor Role

Bizzell refined the Chapter Lead guidelines with input from NCI and the SEC and increased the honorarium considering the need for only four leads and to further incentive the group to adhere to the timeline. We also proposed extending their commitment through peer-review based on lessons learned from previous monographs. We reached out to Chapter Leads after invitations were extended by the SEC members, and agreements were fully executed with Chapter Leads within 2 weeks. Bizzell organized a virtual meeting with the SEC and Chapter Leads on November 5, 2019, to review expectations and discuss questions and revisions to the monograph outline, and we documented the changes. We hold bimonthly calls with SEC members and Chapter Leads to review progress and discuss challenges and potential overlap.

Based on input from the SEC members, Bizzell drafted guidelines for Contributors, who are experts recruited to draft select sections of each chapter [REDACTED] We revised these guidelines with input from NCI and the SEC Chair and ensured all recruited Contributors acknowledged the timeline and confidentiality of the document. We also support ad-hoc Chapter Lead and Contributor meetings, as requested.

Writing Resources

Bizzell worked closely with Ms. Mangold to identify a collaboration platform for the writing team and NCI to use to securely exchange resources. We maintain the NIH Box platform with writing resources including the style guide, which was developed by Bizzell, and a chapter template for writing teams to use. The style guide also provides guidance for writing teams, which was developed in consultation with NCI, to ensure chapters have uniform components and flow and proposed changes to make the executive summary a standalone document.

Literature Reviews

Bizzell provides writing teams with literature search support to aid in the development of chapters. As of January 31, we received fifteen requests (some questions were combined into one search string after further clarifications) and eight were completed. Upon receipt of the requests, we propose search terms and databases containing the most relevant results. We also work with writing teams to identify information that would be helpful to abstract from relevant articles. We summarize the approach and results and deliver an Excel and EndNote file containing this information and relevant article PDFs. Writing team feedback is very positive about the added value this support provides.

Monograph 2.0 Website

Bizzell proposed updates to the organization and layout of the NCI tobacco control monograph web pages to prepare for the 2022 launch and pilot changes. We collected feedback on this vision and will work with the Behavioral Research Program communications team to discuss feasibility during the next 6 months.

Challenges and Solutions

Proprietary
Information, Redacted
Per Agreement

Proprietary
Information, Redacted
Per Agreement

An administration challenge arose when [redacted] resigned from [redacted] position one month after beginning work on the task order due to an unforeseeable event. Bizzell launched rigorous recruitment efforts to identify qualified candidates with the required niche expertise. In the interim, [redacted] worked together to fill the role and ensure all milestones were met on or ahead of schedule. Given [redacted] experience producing past monographs, they were able to provide seamless coverage and maintain momentum. [redacted] joined Bizzell on December 5, 2019 and worked closely with [redacted] to get acclimated to the role.

Proprietary
Information, Redacted
Per Agreement

Proprietary
Information, Redacted
Per Agreement

Cost Summary

Proprietary Information, Redacted Per Agreement

Information Security Training

The table of individuals below completed the NIH information security and records management training on the dates noted below as a result of having access to Federal information or a Federal information system or may become privy to sensitive data/information.

Proprietary Information, Redacted Per Agreement

Proprietary
Information, Redacted
Per Agreement

Proprietary Information,Redacted Per Agreement



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**Tobacco Control Research Scientific and Technical Services
Support Contract**

Contract No. HHSN261201700004I

NCI Control No. N02PC-2017-00004

Task Order No. 75N91019F00129

Task order performance period: July 15, 2019 – July 14, 2022

**Annual Progress Report
July 15, 2019 – July 31, 2020**

**Submitted to:
Kristen Mangold, Contracting Officer's Representative
Linda Park, Contracting Officer**

Overview

The Bizzell Group (Bizzell) supports the development, production, and dissemination of a National Cancer Institute (NCI) Tobacco Control Monograph (monograph) under the direction of the Tobacco Control Research Branch (TCRB). This report summarizes the milestones accomplished during the period of performance from July 15, 2019 through July 31, 2020.

Phase 1: Draft Monograph Development

Phase 1 of development was completed on-time between July 15, 2019 and June 14, 2020. First drafts were submitted by writing teams on or close to the June 1, 2020 deadline. Summarized below are the areas where Bizzell support enhanced the process to support the on-time delivery of the chapter first drafts.

Securing Writing Teams

We worked closely with Dr. Gordon Willis and Ms. Kristen Mangold to recruit the four external scientists to serve on the SEC. The SEC members were under contract within 3 weeks. Bizzell increased the honorarium considering the need for only four leads and to further incentive the group to adhere to the timeline and extended the commitment of Chapter Leads through peer-review based on lessons learned from previous monographs. Agreements were fully executed with Chapter Leads within 2 weeks. We worked with NCI and the SEC Chair to create a Contributor role and ensured all recruited Contributors acknowledged the timeline, expectations, and confidentiality of the document.

Setting Expectations and Maintaining Momentum

Bizzell developed guidelines for the SEC, Chapter Lead, and Contributor roles, in collaboration with NCI, based on previous experience with monograph development and lessons learned. The guidelines and timeline were presented multiple times at the start of the process to set expectations. The outline, developed by the SEC with input from Chapter Leads and Contributors, also helped achieve buy-in from all stakeholders and develop expectations. The style guide, which was developed by Bizzell in consultation with NCI, provided guidance to writing teams to ensure chapters have uniform components and flow and proposed changes to make the executive summary a standalone document. We held monthly SEC meetings and bimonthly SEC and Chapter Lead meetings to facilitate discussions on progress, questions that arose during Phase 1, and challenges encountered. We also developed a chapter check-points document to help assess whether chapter first drafts were on track.

Literature Reviews, Graphic Design, and Ad Hoc Support

Throughout Phase 1, chapter writing teams made use of the Bizzell team and its available resources. In total, 22 literature reviews were completed in Phase 1. Notably, the request form that Bizzell developed made making requests simpler and more streamlined. The request form also provided a mechanism for documenting the requests received. While we only received one request for table or figure support in Phase 1, and one ad hoc request (portfolio analysis), we anticipate more requests in Phase 2. Similarly, a template for literature review results ensured consistency across reviews and a cover page “snapshot” of what information might be gleaned from a deeper look at the relevant review articles and included the methodology undertaken for replication.

Prior to the start of any literature review, its scope, search string(s), and database(s) were confirmed via email between the requestor and contractor support staff. The average time from request to delivery was approximately 24 days, with delivery occurring, on average, 16 days after search string approval. Writing team feedback has been very positive about the added value this support provides.

File Sharing and Version Control

Thus far, the NIH Box has been a useful tool in supporting file sharing and version control. Links were set up for Chapter Leads to seamlessly share their first drafts. Detailed instructions were developed for the monograph folders on Box and shared with writing teams. The Bizzell team has been archiving different drafts and locking drafts to preserve edits and changes made for record-keeping purposes. We plan to continue these best practices through future chapter iterations in Phase 2. Having the Bizzell Monograph Manager serve as the “key holder” for the latest monograph drafts moving forward could be beneficial in ensuring version control.

Monograph 2.0 Website

Bizzell proposed updates to the organization and layout of the NCI tobacco control monograph web pages to prepare for the 2022 launch and pilot changes. We worked with BRP Communications, Ms. Kristen Mangold, and ICF Next to refine proposed enhancements to the webpages. We provided feedback on wireframes, suggested users to participate in usability testing, and reviewed the usability testing results.

Phase 1 Cost Summary

Proprietary Information, Redacted Per Agreement

Phase 2: Review and Editing

Phase 2 began on June 15, 2020, with the start of the review meetings for each chapter. The first chapter drafts required varying amounts of revisions from the chapter writing teams and a plan was developed for second and third drafts prior to peer-review. Despite changing formats for review meetings and writing team competing responsibilities due to the COVID-19 pandemic, monograph development remains on schedule.

Research Needs Chapter Development

Bizzell reviewed the submitted chapters to identify research needs included for the monograph topics to inform the final chapter of the monograph. We developed a rough draft of the chapter that included this information. We also lightly coded the portfolio analysis results and drafted as summary of the findings to include within the chapter. We will continue to provide writing support for this chapter to NCI.

Chapter Review Meetings

Bizzell adapted the planned in-person review meeting to a series of shorter meetings, in multiple phases, focused on discussing review comments from the SEC co-leads with each Chapter Lead and SEC member. We assisted with the development of a review checklist for reviewers, review

schedule, and ensured delivery to the writing team prior to the scheduled review meeting. Bizzell scheduled, attended, and took notes during the review meetings between June 15, 2020 and June 23, 2020. Chapter 2 was the only incomplete chapter submitted by the June 1, 2020, submission deadline, and a separate review meeting was scheduled for the missing section. The missing section was submitted on July 1, 2020 and a Bizzell coordinated a review meeting on July 24, 2020. Action items and decisions made at all meetings were recorded in the meeting notes and shared with writing teams.

Second chapter drafts are due on August 1, 2020, and we will provide similar support for the second draft review process.

Literature Reviews, Graphic Design, and Ad Hoc Support

Six literature review requests were submitted in Phase 2, with five delivered by July 31, 2020. These requests were based on review meeting discussions of topics areas in need of further discussion or review within chapters. We anticipate conducting an update for 27 literature searches to include through the summer of 2020. Additionally, we anticipate monitoring the literature on emerging topics that will be covered within the monograph up until clearance.

We received a request for the development of 6 forest plots to describe findings from various studies by cancer site, which were delivered by July 31, 2020. We anticipate additional graphic design requests throughout Phase 2.

Monograph 2.0 Website

Bizzell drafted descriptions and keywords for each monograph in the series to be used for the new monograph landing page and search feature. We provided feedback on a mockup of the webpages. The new monograph website is under development by ICF Next.

Continuous Process Improvement and Anticipating Needs

Bizzell reflected on Phase 1 and began updating the Phase 1 standard operating procedures and creating an outline of lessons learned, some of which will be incorporated into Phase 2. These documents will help NCI ensure future monograph processes are based on practices that were effective and anticipate challenges or needs that may arise. Bizzell will continue to manage the timeline and make adjustments as needed and is in the process of refining the standard operating procedure for peer and volume reviews.

Phase 2 Cost Summary

Proprietary Information, Redacted Per Agreement

Challenges and Solutions

An administration challenge arose early in monograph development that resulted in a transition of the Monograph Manager position. Given Proprietary Information, Redacted Per Agreement experience producing past monographs, they were able to provide seamless coverage, maintain momentum, and train Proprietary Information, Redacted Per Agreement

It is important to note that the COVID-19 pandemic began around the mid-point of Phase 1, yielding several implications. Several key contributors, including Chapter Leads and SEC members, also work in the clinical setting and on COVID-related tasks, taking some of their focus away from the monograph. Monograph co-leads worked closely with those impacted by COVID-19 to adjust deadlines while remaining on track for overall publication. The pandemic also has negated the ability to convene in-person meetings. Bizzell worked closely with NCI and the SEC to develop a phased virtual review process for chapters to maintain momentum and offer opportunities to provide feedback on the drafts to ensure they will be ready to progress to peer-review in the late fall/early winter.

Information Security Training

There were no staffing updates; however, all staff completed the 2020 NIH information security and records management refresher training. The table of individuals below shows those who completed the NIH information security and records management training as a result of having access to Federal information or a Federal information system or may become privy to sensitive data/information.

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