Summer A. Adams, MPH
Adams Medical Writing and Consulting Services, LLC

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Summary of Medical Writing Experience

Clinical Regulatory Writing

- Experienced in authoring:

- Phase I-III Clinical Trial Protocols and amendments
- Biobanking and Discarded Tissue Protocols
- Clinical Study Reports
- Investigator Brochures
- Monitoring Plans
- Laboratory Manuals, Pharmacy Manuals, Nutrition Journals, Patient Reported Outcome Diaries
- Informed Consent Forms (General ICF development as well as ICFs specific to Pediatric Assent, Emergency Treatment, Tissue Biobanking and Genetic Therapy, among others)
- FDA Correspondence including Investigator Initiated IND applications, Safety Reports, Emergency Treatment Use Requests, and Annual IND reports
- Patient Narratives
  - Contributes to Statistical Analysis Plans
  - Chairs meetings and facilitates communications with cross-functional groups in order to review and finalize documents and reports

Publications Writing

- Journal Articles (writing and scientific editing)

QC Reviewer

- Clinical Study Protocols and Reports
- Investigator Brochures
- Manuscripts

Education

- Patient Education Tools and Newsletters
- Study site and hospital staff Education Tools, Slide decks, and Competency Trainings
- Nationwide Clinical Research Coordinator Continuing Education Tools, Mentorship Tools, and Leadership Trainings
- CME training for medical professionals

- College-level coursework development (lectures, homework, journal article critique keys) in Medical Epidemiology and Biostatistics

General

- Grant Applications
- Surveillance Reports
- Medical News writing
- Telephone-based Interview Scripts

Therapeutic Areas of Expertise

Respiratory Disease Cardiovascular Disease
Infectious Disease
Musculoskeletal Disease
Transplant
Endocrine Disease

Relevant Professional Experience

10/2012-present **Independent Freelance Medical Writer**
Clinical Regulatory and Publications Writing

Specializing in study design and protocol development; contribution to statistical analysis plans and appropriate interpretation of statistical results; manuscript writing; clinical study report writing; scientific review and quality control check of manuscripts and clinical regulatory documents.

10/2011-8/2013 **Novartis Institute for Biomedical Research, Translational Medicine**
Cambridge, MA

Clinical Trial Leader- Translational Research Initiatives (External Consultant)

- Led a multidisciplinary team of clinical and pre-clinical individuals in the development of a major biobanking initiative in a rare disease study population.
- Authored a clinical protocol for a biobanking study and liased with other line functions to troubleshoot, strategize, and execute solutions related to writing protocols and managing diverse trial teams for non-IMP (investigational medicinal product) studies.
- Conceived of and generated a study typology tree for non-IMP studies, including both methodology trials and biobanking projects.
- Participated in ongoing general discussions, meetings, and working groups relating to the clinical support of non-IMP trials.

1/2009- 5/2011 **Novartis Institute for Biomedical Research, Translational Medicine**
Cambridge, MA

TM Clinical Trial Leader II (6/2009- 5/2011) TM Clinical Trial Leader I (1/2009- 6/2009)

- Responsible for the planning and implementation of operational aspects of Translational Medicine studies according to timelines, budget, operational and quality standards (ICH/GCP/Novartis SOPs/applicable regulations).
- Accountable for the writing of clinical trial protocols and related documents in collaboration with the Clinical Trial Team. Led the clinical trial protocol development process and contributed to both the operational and scientific input given for the development of trial- related documents and processes which reside in other line functions.
- Wrote additional trial related documents including but not limited to monitoring plans, laboratory and pharmacy manuals, subject diaries, staff and subject education materials, and general clinical trial correspondence.
- Led and matrix-managed the global multidisciplinary Clinical Trial Team (CTT) to ensure trial deliverables were met according to timelines, budget, quality standards and operational procedures. Chaired CTT meetings, reported study progress and issues to CTT and Clinical Sciences Management, lead trial level interactions with internal line functions and external research organizations (e.g. those providing monitoring and site management services).
- Liaised with international key opinion leaders to design and develop clinical trial plan.
- Identified study sites and managed study set-up, including responsibility for organizing and chairing the Initiation meeting.
- Served as point of contact for managing/answering questions relating to trial procedures and subject eligibility.
- Set up and maintained Trial Master File (TMF) for assigned studies.
- Updated all trial information databases in order to manage accuracy of information.
- Responsible for implementation of best practices and standards for trial management within Novartis Translational Medicine, including sharing lessons learned.

2003-2009 **Children's Hospital Boston (CHB), Pulmonary Division and Cystic Fibrosis Center**
Boston, MA

Program Administrator (Manager), Clinical Research (2006-2009) Clinical Research Specialist (2004-2006)
Clinical Research Coordinator (2003-2004)

Fiscal Management

- Developed internal site budgets and monitored research funds.
- Negotiated with sponsors and collaborated with corporate sponsored research officers to process confidentiality agreements, clinical trial agreements and subcontracts.

Human Resource Management

- Recruited, hired, oriented, trained, and evaluated clinical research staff.
- Supervised personnel (including research coordinators, assistants, and interns), and supported growth potential for junior staff.
- Served in a leadership role as both an informational and operational resource for all members of the Pulmonary Division participating in clinical research.

Regulatory Management

- Oversaw and upheld all clinical research practices to be in accordance with ICH GCP, complying with the obligations and requirements of clinical Investigators and all other requirements listed in 21 CFR part 312, as well as Program SOPs, CHB institutional policies and Cystic Fibrosis Foundation Infection Control Guidelines.Wrote protocol applications and Informed Consent Forms (ICFs) and was ultimately responsible for all divisional General Clinical Research Center (GCRC) and Institutional Review Board (IRB) regulatory correspondence.
- Submitted SAE reports and Emergency Treatment requests.
- Performed appropriate medical and regulatory monitoring and documentation of adverse events (AEs) and protocol deviations, respectively.

Research Management

- Initiated, accomplished, and closed out study procedures for over 35 corporate sponsored and investigator-initiated Phase I, II, III, and emergency treatment use clinical research protocols.
- Developed, in conjunction with Physician staff, investigator-initiated therapeutics trials, including writing original clinical study protocols and FDA IND submissions, SAE reports and general safety updates, Emergency Treatment Use request narratives, and annual updates.
- Wrote, in conjunction with Physician staff, complex annual grant applications and co-authored two articles for submission for publication.
- Screened, recruited, obtained consent from patients, and conducted or supervised all clinical study visits (both ambulatory and inpatient) for divisional clinical research studies relating to pulmonary disorders including cystic fibrosis, asthma, and lung transplantation.
- Performed data collection, created and maintained source documentation, completed paper and electronic CRFs, and managed local electronic data capture (EDC) systems.
- Planned and ran clinical research team meetings for research and medical staff.

- Collaborated with industry, foundation, pharmacy, internal and central labs, CROs, infection control professionals, and the medical and patient communities to organize, execute, and oversee the general conduct of clinical research protocol activities for the Pulmonary Division.

Other Leadership Activities

- Implemented regular patient education regarding local research opportunities as well as more specific research methodology and science. Developed general research and protocol specific education tools for both staff and patients.
- Liased with physicians, nursing staff, administrative staff, ethics board representatives, and infection control professionals to develop and implement infection control guidelines specific to cystic fibrosis patients participating in clinical research at CHB and subsequently conducted regular continuing education for inpatient and ancillary staff regarding these guidelines. Attended regular educational meetings, multidisciplinary rounds, symposiums and conferences to enrich personal clinical and medical terminology knowledge base.
- Independently represented site at national Investigator Meetings and network conferences.

2001-2003 Massachusetts State Laboratory Institute (SLI) Jamaica Plain, MA

Data Manager for Bureau of Epidemiology and Communicable Disease (2002-2003)

Laboratory Technician for Arboviral Surveillance Program (2001- 2002)

Epidemiology

- Compiled and cleaned cumulative Massachusetts West Nile Virus mosquito, avian, and human case data and denominator data for 2000- 2002.
- Authored a comprehensive report containing recommendations for improved validity in future data collection and management procedures.
- Proposed regression analysis plans for existing data, performed exploratory data analyses, and wrote arboviral data reports.
- Presented surveillance report and results to representatives of the State Laboratory Institute, the University of Massachusetts, and Tufts University School of Medicine (August 2003).

Microbiology Laboratory

- Maintained zoonotic diseases databases, ensured accuracy and completeness of data and generated regular testing reports for the Arboviral Surveillance Program.
- Managed comprehensive vector surveillance database and imported local agency data for statewide reporting purposes.

- Collaborated with state and local agencies to collect, receive, document, and process vector samples from across the Commonwealth.
- Coordinated weekly vector trapping routes for seasonal technicians.
- Trapped, sorted, and identified mosquitoes for Arboviral testing.
- Performed nucleic acid extractions on mosquito and avian samples.

2000-2001 Massachusetts General Hospital (MGH), Institute for Health Policy Boston, MA

Research Assistant

- Assisted Principal Investigator in designing and carrying out pilot phase of Mom and Me Smokefree (MOMS) Study for pregnant smokers, including writing protocols and writing/editing article for medical journal submission.
- Coordinated grand rounds visits to metro Boston hospitals, organized an incentive program for participating mothers, tracked cotinine specimen collection and participant follow-up. Worked with collaborating institutions to ensure referrals through participating obstetricians, obtained appropriate consent forms, and assisted with the development of methods to be employed in data collection.
- Participated in the creation, writing and implementation of sub-protocols for telephone-based intervention study and in the implementation of Motivational Interviewing (MI) training for employees of Tufts Health Plan (THP) in Watertown, MA.

Education

Tufts University, Medford, MA

B.A. Dual majors of Environmental Health and Spanish Minor of Environmental Engineering

Certificate of Community Health (Professional certificate necessitated ten additional courses plus three month field experience in healthcare environment)

Completed graduate level night courses at Tufts University School of Medicine in order to accelerate Master of Public Health program upon completion of undergraduate studies.

Tufts University School of Medicine, Boston, MA

Master of Public Health

Concentration of Study in Medical Epidemiology and Biostatistics Master's Thesis Topic: Vitamin A and Zinc Levels as Predictors of Pediatric Pneumonia in Low-Income Populations

Advanced Learning Experience Project: A Regression Analysis of Environmental Predictors of Human West Nile Virus Infection in Massachusetts

Emma Hitt's Freelance Medical Writing Course
(Intensive 6 week Online Training with interactive homework and subcontracted writing assignments)

Teaching Experience

2000-2002 Tufts University, Medford, MA

Teaching Assistantship in Fundamentals of Epidemiology

- Graded student homework and exams, attended course regularly, taught weekly review sessions, and was available for student help through regular communication.
- Designated epidemiologic studies for student critiques and wrote critique keys.
- Worked in a partnership with Instructor to write homework and exams.
- Composed and presented lectures and created slide decks in basic medical epidemiologic methods.

Professional Society Involvement

2003- present American Public Health Association (APHA), Member

2007- present Association of Clinical Research Professionals (ACRP), Member

2012- present American Medical Writers Association (AMWA), Member

Professional Certification

2012- *Ongoing* AMWA Medical Writing Essential Skills Certification
(6/8 credits complete as of November 2013)
AMWA Medical Writing Regulatory and Research Certification (2/8 credits complete as of November 2013)

2008- present ACRP Certified Clinical Research Coordinator

Committee Assignments

2003-2004 Study Initiation Committee, Cystic Fibrosis Foundation Therapeutics Development Network, Elected Member

2004-2006 Patient Advocacy and Ethics Committee, Cystic Fibrosis Foundation Therapeutics Development Network, Member

2006- 2009 Protocol Review Committee, Cystic Fibrosis Foundation Therapeutics Development Network, Elected Member
Paid position to provide detailed feedback and scientific editing to corporate sponsors regarding clinical trial protocol drafts

2008- 2009 Clinical Research Mentoring Committee, Cystic Fibrosis Foundation, Mentor

National Programs Involvement

6/2008 Cystic Fibrosis Foundation Clinical Research Coordinator Retreat, Instructor

6/2008 Invited Speaker, "Study Management Tools"
Cystic Fibrosis Foundation Clinical Research Coordinator Retreat

10/2008 Invited Speaker, "Defining the Research Coordinator Role at Your Site"
North American Cystic Fibrosis Conference

International Clinical Trial Expertise

United States Canada
Europe (United Kingdom, Germany, Sweden, Spain, Italy, Poland and Russia)

Languages

English and Professional Spanish

Therapeutic Areas of Expertise

Respiratory Disease
Cardiovascular Disease
Endocrine Disease I
nfectious Disease
Musculoskeletal Disease
Transplant