## Julie A Neild, BS, MTSC, PMP, CCPM Professional

Profile	30 years of medical writing, scientific editing, and project management experience.
	• Medical writing / editing and clinical trial project management expertise in developing foundation proposals / budgets, grant applications, protocols, marketing applications, clinical study reports, and scientific publications / abstracts / posters.
	• Optimizing / improving clinical research site capabilities (trial-specific execution and site operations) by applying Lean six sigma principles.
	Therapeutic area experience in Alzheimer's disease, dermatology (psoriasis), rheumatology (spondyloarthritis), and musculoskeletal (osteoporosis).
Skills and Accomplishments	<ul> <li>Medical Writing   Scientific Communications</li> <li>Writing, designing, and editing scientific abstracts and posters for scientific conferences; grant applications and client-facing proposals (including budgets); and consumer-facing materials such as case studies and surveys.</li> <li>Editing informed consent documents to ensure readability.</li> <li>Interpreting and summarizing clinical data for submissions to global regulatory authorities in support of marketing applications.</li> <li>Tools and Techniques:</li> <li>Advanced Microsoft Office (Word, Excel, PowerPoint).</li> <li>Project Management   Clinical Operations</li> <li>Using strong organizational, communication, and leadership skills to enable cross-functional teams to deliver multiple projects on time and on budget.</li> <li>Managing not-for-profit transportation program to remove barriers to participating in clinical trials.</li> <li>Enabling informed decision-making by using analytics and metrics.</li> <li>Tools and Techniques:</li> <li>Timeline software (Microsoft Project, Smartsheet).</li> <li>Critical chain project management.</li> <li>Six Sigma   Process Improvement   Data Visualization</li> <li>Applying Six Sigma quality methodologies to solve problems in transactional environments and manufacturing operations.</li> <li>Identifying and documenting best practices and sharing with site network to improve overall efficiency and effectiveness.</li> </ul>
	<ul> <li>Tools and Techniques:</li> <li>Business process improvement, process mapping, and facilitation.</li> <li>Cause and effect analysis; failure modes and effects analysis (FMEA); after-action reviews.</li> <li>Visualizing data (eg, Pareto, histogram, and scatterplot) and descriptive statistics.</li> </ul>

Experience	<ul> <li>Aug 2021 to Present Freelance Medical Writer / Editor</li> <li>Substantial editing quality assurance reports (including major restructuring, clarifying key concepts, identifying missing information or areas that need more depth, and checking accuracy).</li> <li>Writing, designing, and editing research reports (including literature reviews).</li> <li>Writing and editing responses to requests for proposals (RFPs).</li> <li>Creating interactive data visualizations to enable decision making.</li> <li>Familiarity with AMA Manual of Style.</li> </ul>
	2018 to Aug 2021 Pintail Solutions Fishers, IN
	Global Alzheimer's Platform Foundation <sup>®</sup> (GAP) Clinical Operations Manager (2018 to 2021)
	Translated complex medical and scientific data for scientific and non-scientific audiences.
	<ul> <li>audiences.</li> <li>Co-authored and edited materials such as scientific abstracts and posters, protocols and informed consent documents, grant applications, proposals, book chapters, case studies, and other consumer-facing materials designed to build GAP's network of clinical trial sites and raise awareness of GAP initiatives.</li> <li>Developed and managed timelines for abstracts, posters, grant applications, and book chapters.</li> <li>Ensured alignment to authorship guidelines using appropriate styles (including <i>AMA Manual of Style</i>).</li> <li>Completed final copy editing of publications including main text, tables, figures, and references.</li> <li>Responded to editorial comments and revised as needed.</li> <li>Applied lean six sigma / continuous improvement methodologies to improve the efficiency and effectiveness of Alzheimer's disease clinical research sites in GAP's network.</li> <li>Developed and applied a structured approach to select 'change-ready' sites to participate in the GAP Site Optimization Program.</li> <li>Conducted multiday on-site process evaluations (identify barriers and offer quick wins).</li> <li>Developed tools and other resources to improve performance.</li> <li>Authored reports summarizing site capabilities, barriers, and recommended solutions.</li> <li>Collaborated with sites and sponsors to develop action plans with measurable outcomes.</li> <li>Managed the GAP   Lyft Transportation Program to enable sites to provide transportation to clinical trial appointments.</li> <li>Developed budgets for proposed services.</li> <li>Authored and distributed FAQs to ensure optimal usage.</li> </ul>
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Experience	1990 to 2017 E	i Lilly and Company	Indianapolis, IN
(continued)	<ul> <li>month assignment in Shang</li> <li>Managed protocol developm assessment and addenda of</li> <li>Applied strong organization to perform their best.</li> <li>Led the development and n contingency planning to ide</li> </ul>	ment capabilities in Shang ghai with Lilly China Drug I nent activities including op levelopment. al, communication, and lea naintenance of risk assess ntify triggers; communicate	erational feasibility adership skills to enable teams
	Project Manager / Global Medical	Quality Assurance (2008 to	2012)
	Applied critical chain project global quality-system redest owned subsidiary.		ethodologies and tools to a of quality system by wholly
	Analyzed trends in deviation actions (CAPAs).	ns to inform development o	of corrective and preventive
	Facilitated development and	d deployment of critical cha	ain work rules.
	Defined and implemented a articulated key metrics, aud		
	Project Manager / Development C	Quality Assurance (2004 to 2	2008)
	<ul> <li>Provided project managem Assurance (eg, change ma implementation).</li> </ul>		rojects in Development Quality ocesses, SharePoint
	Optimized the use of Six Si	gma in Development Quali	ty Assurance.
	Designed and monitored qui making.	ality system metrics to ena	able informed decision
	Managed business operation agreements, and internal / example a second sec		ousiness plans, legal
	Senior Project Management Asso	ciate (2001 to 2004)	
		lopment to plan, monitor, a	otimization teams in all phases and control projects including alans.
	Drove implementation of hig influence.	gh-quality project plans thro	ough technical expertise and
	Facilitated planning session	is across teams.	
	Senior Discovery Project Associa	te (1999 to 2001)	
	Managed cardiovascular pr milestone tracking, and gov		planning, issue assessment, ation.
	Collaborated with senior sc maps; determined data-bas		o create and maintain process
	Managed the legal agreement	ent process.	
	Managed departmental exp	ense, capital, and externa	l research budgets.

Experience (continued)	Team Leader Medical Writing (1998 to 1999)	
	Recruited, interviewed, hired, and super assistants.	rvised medical writers and editorial
	Mentored and trained employees on devidence documents and scientific publications.	velopment of regulatory submission
	Medical Science Writer and Senior Medical Sci	ience Writer (1990 to 1997)
	<ul> <li>Interpreted and summarized global regulatory submission documents (IND, BLA, NDA, and CTD), clinical study reports (CSR), clinical investigator's brochures (CIE scientific posters, and scientific manuscripts.</li> <li>Planned and designed slide presentations for FDA advisory committee reviews.</li> </ul>	
	Co-authored high-quality manuscripts for scientific posters for consumer audience	
Education	1988 to 1990 Miami University	y Oxford, OH
	MS, Technical Communication (MTSC).	
	Graduate-level internship at National Ca	ancer Institute.
	1984 to 1988 Wheaton Colleg	e Wheaton, IL
	BS, Biology.	
	Minor in writing.	
Professional	Certifications	
Certifications / Affiliations	Project Management Professional (PMF	P) certification, March 2005.
Amilations	Six Sigma Greenbelt (Six Sigma Qualte (requalification with George Group, June	
	Critical Chain Project Management (CC 2013.	CPM) Professional certification, February
	Affiliations / Membership	
	Project Management Institute, member	2002 to 2020.
	Continuing Education	
	Writing Effective Grant Proposals (University 2011.	ersity of Indianapolis online course),

Volunteer Work	Courier Volunteer, Rutland Regional Medical Center, Rutland, VT
	Transporting and discharging patients.
	• Delivering lab specimens, supplies, and paperwork throughout the hospital.
	Writing and Research, The Vegetarian Resource Group (VRG), Baltimore, MD
	Writing blog posts on science-related topics.
	Reviewing applications for the VRG College Scholarship Program.
	• Researching and writing restaurant entries for the Vegetarian Journal's Guide to Vegetarian and Vegan Restaurants in the U.S. and Canada.
	Grant Writing, Zion Nature Center, Zionsville, IN
	Wrote community grant applications to Boone Country Solid Waste Management District to secure funds for Zion Nature Center programs.
	Designed composting brochure for community awareness.
	Strategic Planning Workshop, Habitat for Humanity of Hendricks County, IN
	Facilitated strategic mission and vision workshop for Habitat for Humanity of Hendricks Country, IN.

Publications   Authored / Coauthored	Bork J, Cordell C, Dwyer J, et al. The Global Alzheimer's Platform Foundation®: Delivering New Medicines Faster by Accelerating Clinical Trials. In: Cummings J, Kinney J, Fillit H, eds. Alzheimer's Disease Drug Development: Research and Development Ecosystem. Cambridge: Cambridge University Press; 2022:207- 215. doi:10.1017/9781108975759.018
	Boss SM, Huster WJ, Neild JA, Glant MD, Eisenhut CC, Draper MD. Effects of raloxifene on the endometrium of postmenopausal women. <i>Am J Obstet Gynecol</i> 1997;177:1458-1464. <u>doi:10.1016/S0002-9378(97)70091-7</u> *
	Draper MW, Flowers DE, Huster WJ, Neild JA, Harper KD, Arnaud C. A controlled trial of raloxifene (LY139481) HCI: Impact on bone turnover and serum lipid profile in healthy postmenopausal women. <i>J Bone Min Res</i> 1996;11:835-842. doi:10.1002/jbmr.5650110615*
	Draper MW, Flowers DE, Huster WJ, Neild JA. Effects of raloxifene (LY139481 HCI) on biochemical markers of bone and lipid metabolism. <i>1993 Proceedings of the Fourth International Symposium on Osteoporosis</i> 1993:199-121.
	Draper MW, Flowers DE, Neild JA, Huster WJ, Zerbe R. Antiestrogenic properties of raloxifene. <i>Pharmacology</i> 1995;50:209-217. <u>doi:10.1159/000139284</u> *
	Dwyer J, Bork J, Goldfeder G, Zisko L, Trotter J, Syson J, Neild J, Ritchie C, Draper K. Global Alzheimer's Platform Foundation <sup>®</sup> (GAP) Development of a Transatlantic Alzheimer's Disease Clinical Trial Network. Abstract accepted at: Alzheimer's Association International Conference (AAIC); July 26, 2021; Denver, CO.
	Henderson J, Neild JA. Improving Alzheimer's Disease Clinical Trials Through Participant Transportation Services. <i>Outsourcing in Clinical Trials.</i> Submitted 2019.*
	Huster WJ, Allerheiligen SR, Knalder MP, Boss SM, Neild JN, Draper MW. Correlations of plasma concentrations of total raloxifene HCl with clinical response. Poster presented at American Society for Bone and Mineral Research (ASBMR); September 9, 1995; Baltimore, MD.
	Neild JA. Angioplasty in Coronary Disease. In: Kalisch JR, Williams H <i>: Courtroom Medicine – Chest Heart and Lungs</i> . New York: Matthew Bender & Co, Inc, 1991.
	Neild JA. Pfizer-BioNTech COVID-19 Vaccine Ingredients. The Vegetarian Resource Group blog. February 1, 2021. Accessed May 28, 2021. https://www.vrg.org/blog/2021/02/01/pfizer-biontech-covid-19-vaccine-ingredients/
	Neild JA. Streamlining the Selection and Qualification of Biomarker Laboratories. Diligent Qualification Platform website. October 2021. Accessed October 19, 2022. <u>https://www.diligentpharma.com/free-research-report-on-biomarker-lab-services-for-clinical-trials/</u>
	Neild JA. The Pancreas. In: Kalisch JR, Williams H <i>: Courtroom Medicine</i> – <i>Abdominal Injuries</i> . New York: Matthew Bender & Co, Inc, 1991.*
	*Publication available on https://julieaneild.journoportfolio.com/.

Publications   Writing, Designing, and Editing Support	Dwyer J, Beauregard D, Kerwin D, Gorman E, Bork J, Smith K, Hollingshead S, Mohs R. Bio-Hermes: A Biomarker Study Initiated by The Global Alzheimer's Platform Foundation <sup>®</sup> To Compare Select Digital and Blood-Based Biomarkers with Clinical Diagnosis and Amyloid- $\beta$ PET Images. Poster presented at: Clinical Trials on Alzheimer's Disease (CTAD) conference; November 4, 2020; Digital conference. Abstract at: doi:10.14283/jpad.2020.58*
	Goldstein JD, Wilson MG. Adverse event frequencies generate hypothesis of efficacy and safety. <i>Clin Pharmacol Ther</i> 1993;54:245-251. doi:10.1038/clpt.1993.144
	Goldstein DJ. Beneficial health effects of modest weight loss. <i>Int J Obes</i> 1992;16:397-415. <u>https://www.ncbi.nlm.nih.gov/pubmed/1322866</u>
	Mohs R, Bork J, Goldfeder G. Innovations in Clinical Trials: Improving Study Start Up (SSU). Poster presented at: Alzheimer's Association International Conference (AAIC); July 25, 2018; Chicago, IL.
	Mohs R, Bork J, Smith K, Dwyer J, Bartolic E, Jenkins C. Removing Barriers to Alzheimer's Disease Clinical Trial Execution: GAP Rater Certification Program. Poster presented at: Alzheimer's Association International Conference (AAIC); July 15, 2019; Los Angeles, CA. Abstract at: <u>doi:10.1016/j.jalz.2019.06.3926</u> *
	Mohs R, Goldfeder G, Bork J, Dwyer J, Beauregard D. The Capacity of Alzheimer's Disease Clinical Trial Sites Unlikely to Meet the Demands of Pending Therapeutic Trials. Poster presented at: Alzheimer's Association International Conference (AAIC); July 25, 2018; Chicago, IL.
	Mohs R, Smith K, Bork J, Bartolic E, Jenkins C, Ward R, Rentz D. GAP Rater Certification Program Streamlines the Rater Certification Process. Poster presented at: Alzheimer's Association International Conference (AAIC); July 27, 2020; Digital conference. Abstract at: <u>doi:10.1002/alz.044936</u>
	Rodgers T, Zisko L, Dwyer J, Jeter J, Cordell. Enhancing the Enrollment of Underrepresented Minority Populations in Clinical Trials Through the Global Alzheimer's Platform Foundation's <sup>®</sup> (GAP's) Diversity and Inclusion Program. Abstract submitted to: Clinical Trials on Alzheimer's Disease (CTAD) conference; November 9, 2021; Boston, MA.
	Trotter J, Zisko L, Smith J, Reynolds A, Thurman L, Hollingshead S. Global Alzheimer's Platform Foundation <sup>®</sup> (GAP) Characterizes Successful Free Memory Screening Programs. Poster presented at: Alzheimer's Association International Conference (AAIC); July 27, 2020; Digital conference. Abstract at: doi:10.1002/alz.046237*
	Zisko L, Cordell C, Smith J, Trotter J, Thurman L, Sipchen J. Reinventing Alzheimer's Disease Prescreening: The Global Alzheimer's Platform Foundation <sup>®</sup> (GAP) Remote Recruitment and Prescreening Program. Poster presented at: Clinical Trials on Alzheimer's Disease (CTAD) conference; November 4, 2020; Digital conference. Abstract at: <u>doi:10.14283/jpad.2020.58</u> *
	*Publication available on https://julieaneild.journoportfolio.com/.