

**AMERICAN
MEDICAL WRITERS
ASSOCIATION** **AMA** **WA** **Indiana
Chapter**



2017 CONFERENCE

**April 21-22, 2017
Downtown Indianapolis**

**Register by March 14
and save \$25!**

2017 INDIANA CHAPTER AMWA CONFERENCE APRIL 21-22, 2017

Conference Locations:

FRIDAY, APRIL 21: Tavern on South • 423 West South Street
Indianapolis, IN 46225 • (317) 602-3115 • www.tavernonsouth.com

SATURDAY, APRIL 22: The Columbia Club • 121 Monument Circle
Indianapolis, IN 46204 • (317) 767-1361 • www.columbia-club.org

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ABOUT THE CONFERENCE

Join us for the 2017 American Medical Writers Association (AMWA) Indiana Chapter Conference!

This year's conference will once again be held in **downtown Indianapolis**.

Events kick off on the evening of **Friday, April 21**, at the **Tavern on South on W. South Street** with an informal networking dinner with fellow chapter members.

The conference begins on **Saturday, April 22**, with a full day of activities at the historic **Columbia Club on Monument Circle**.

Throughout the conference, attendees will be able to choose from a range of events, including:

- Five noncredit open sessions presented by experts in their fields
- Multiple informal networking opportunities and
- An opportunity to participate in our chapter's first annual membership meeting

We look forward to seeing you there!

CONFERENCE SCHEDULE AT A GLANCE

FRIDAY, APRIL 21, 2017

Afternoon	MWC™ Exam	The Columbia Club
5:30 – 8:30 p.m.	Networking Dinner	Tavern on South

For more information regarding the MWC™ Exam, please visit www.amwa.org/mwc

Please note: Dinner attendees will purchase their meals from the Tavern on South menu and pay the wait staff at the time of service. For more information about the Tavern on South, including parking and menu information, visit www.tavernonsouth.com. Driving directions are also provided on p. 9 of this brochure.

SATURDAY, APRIL 22, 2017

(ALL EVENTS AT THE COLUMBIA CLUB)

8:00 – 8:55 a.m.	Light Breakfast and Networking Opportunity	4 th Floor
8:55 – 9:05 a.m.	Welcome	4 th Floor
9:05 – 10:20 a.m.	State of Healthcare and Life Sciences in Indiana and Opportunities for Medical Communicators Moderator: <i>Esther Asplund, PhD</i>	4 th Floor
	Panel Discussion: <i>Brian Stemme, BS</i> <i>Michael Church, MA</i> <i>Karen Heraty, ELS</i> <i>Lisa Lenahan, BS</i>	
10:20 – 11:20 a.m.	Clinical Evaluation Reports for the Medical Device Industry: What You Need to Know <i>William S. Pietrzak, PhD</i>	4 th Floor
11:20 – 11:30 a.m.	Break	
11:30 – 12:30 p.m.	Clinical Pharmacology and Biopharmaceutics, Key Concepts and Contributions to Marketing Applications <i>Lisa N. Toth, BS</i>	4 th Floor
12:30 – 1:30 p.m.	Lunch and Networking Opportunity	2 nd Floor
1:30 – 1:45 p.m.	Break/Relocation to 4 th floor	
1:45 – 2:45 p.m.	Word Tips and Tricks You Can Use Now <i>Teresa Keller, PhD</i>	4 th Floor
2:45 – 2:55 p.m.	Break	
2:55 – 3:55 p.m.	The Patient-Audience Ushers in a New Paradigm for Medical Communications <i>Leigh Anne Naas, BA</i>	
3:55 – 4:25 p.m.	Membership Meeting	4 th Floor

EVENTS FOR SATURDAY, APRIL 22

All Saturday events will be held at **The Columbia Club** at **121 Monument Circle**.

Open Session Descriptions

STATE OF HEALTHCARE AND LIFE SCIENCES IN INDIANA AND OPPORTUNITIES FOR MEDICAL COMMUNICATORS

BRIAN STEMME, BS

PROJECT DIRECTOR, BIOCROSSROADS

KAREN HERATY, ELS

ADVISOR, GLOBAL SCIENTIFIC COMMUNICATIONS, ELI LILLY AND COMPANY

MICHAEL CHURCH, MA

SENIOR DIRECTOR, MEDICAL WRITING, INVENTIV HEALTH

LISA LENAHAN, BA

TECHNICAL WRITER, ROCHE

The panel discussion will commence with an overview of Indiana's health and life sciences industry, its impact on the economy, and demand for medical communicators. Subsequently, speakers representing a pharmaceutical company, a contract research organization, and a diagnostics company will discuss the variety of medical communication opportunities within the life sciences industry, the desired skill set for novice and experienced communicators, and their perspectives on writing as an employee of a sponsoring organization vs contract research organization.

CLINICAL EVALUATION REPORTS FOR THE MEDICAL DEVICE INDUSTRY: WHAT YOU NEED TO KNOW

WILLIAM S. PIETRZAK, PHD

FOUNDER, MUSCULOSKELETAL PUBLICATION AND ANALYSIS, INC.

Medical devices must have the CE Mark to be able to be sold in the European Union. Once obtained, the CE Mark must be periodically renewed for devices to remain compliant. One of the most critical CE Mark requirements is the Clinical Evaluation Report (CER) that examines the clinical evidence supporting the performance and safety of the device. As such, a CER is one of the most important medical writing opportunities in the Medical Device Industry and writers skilled in its preparation are highly sought. This Open Session will explain the key requirements of the Medical Device Directive (MDD) and MedDev 2.7.1 (rev. 4) and discuss, section by section, how to prepare a compelling CER.

IMPORTANT DATES

MARCH 14, 2017

Last day for discounted conference price

APRIL 15, 2017

Last day to register for conference (note: onsite registration is not available)

APRIL 21-22, 2017

2017 Indiana AMWA Chapter Conference

EVENTS FOR SATURDAY, APRIL 22

Open Session Descriptions

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS, KEY CONCEPTS AND CONTRIBUTIONS TO MARKETING APPLICATIONS

LISA N. TOTH, BS

CLINICAL PHARMACOLOGY CONSULTANT FOR SCIENTIFIC COMMUNICATIONS, ELI LILLY AND COMPANY

Sponsors of drug or biologic products intended to be submitted to regional regulatory authorities (e.g., Food and Drug Administration, European Medicines Agency) must submit marketing applications in accordance with Common Technical Document (CTD) specification, which is an internationally agreed format for the preparation of marketing applications or authorisations. The International Council for Harmonisation (ICH) M4(R4) describes the organization of the CTD, which include Modules 1 - 5. There are two high-level clinical sections in Module 2 of the CTD: the Clinical Overview (2.5), a relatively short document that provides a critical assessment of the clinical data and the Clinical Summary (2.7), a longer document that focuses on data summarization and integration. In this Open Session, an overview of the Clinical Summary will be provided followed by an in-depth discussion of the Clinical Summary Sections 2.7.1 (Biopharmaceutics) and 2.7.2 (Clinical Pharmacology).

WORD TIPS AND TRICKS YOU CAN USE NOW

TERESA KELLER, PHD

ASSOCIATE PROFESSOR OF BUSINESS OPERATIONS, APPLICATIONS, AND TECHNOLOGY (BOAT), IVY TECH COMMUNITY COLLEGE

Work is crazy — we all know that. The good news — there are shortcuts and "tricks" that Microsoft built into their product to help you be more productive and efficient. This is your invitation to learn about styles, auto text, macros, table of contents, building blocks, restricted editing, and many other Word functions. Let's make work a little less crazy by increasing your efficiency with Word!

THE PATIENT-AUDIENCE USHERS IN A NEW PARADIGM FOR MEDICAL COMMUNICATIONS

LEIGH ANNE NAAS, BA

COMMUNITY MANAGER, ELI LILLY AND COMPANY

Traditionally, medical writers have written primarily for physicians and government regulators. Although patient-focused materials such as informed consent documents and patient education materials have long been a staple of the medical writer's realm, those communications take a top-down approach, treating patients as less-informed participants in health care who need to be educated about the topics at hand. But the rise of the ePatient—people who are well informed about their medical care and who want to be treated as equal partners with their doctors—is changing the nature and tone of medical communications. These days, sharing study information only with regulators and publishing only in physician-focused journals is insufficient to reach the audiences who have a vested interest in our work. This presentation will explore the importance of the patient audience and present some ways that this paradigm shift is opening up new possibilities for the role of medical writers.

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Speaker Biographical Sketches

BRIAN STEMME, BS

Brian, project director for BioCrossroads, has a strong background in life sciences market development and research, and is responsible for identifying and developing opportunities for growth within Indiana's life sciences sector. He authors reports and performs market research on the industry and supports the City of Indianapolis' and State's economic development by providing market information to attract and grow life sciences companies.

Brian led the formation of the Central Indiana Corporate Partnership's AgriNovus Indiana, a nonprofit established in 2013 to leverage Indiana's strengths in agricultural innovation, working with industry CEOs, Indiana's Lieutenant Governor and Purdue University to launch the new entity, publish a first-of-its-kind report and support early-stage ag-tech companies. In addition, he serves as an advisor to Indiana Seed Fund II. He currently serves on the board of Algaeon and Allinaire Therapeutics.

Prior to joining BioCrossroads, Brian was employed by Eli Lilly and Company in Corporate Affairs, where he ran the company's political action committee. He also worked as a Senior Analyst in the company's biotechnology unit and was a member of the team that established Lilly Systems Biology, Ltd. in Singapore. Previously, Brian was a manager in Arthur Andersen's Assurance practice, providing audit and tax consulting to companies in the energy, telecommunications, and healthcare industries.

KAREN HERATY, ELS

Karen is an Advisor in Global Scientific Communications at Eli Lilly and Company. She has worked in scientific communications at Lilly for over 20 years in a variety of roles, including writer, submission lead, recruiter, and outsourcing leader. She has led several process improvement and business initiatives that have resulted in improved efficiencies and resourcing within Lilly. She is currently responsible for technology and innovation efforts for scientific communications.

MICHAEL CHURCH, MA

Michael Church has been with inVentiv Health Clinical for 13 years and working in the area of scientific communications for 16 years. Having started his career as a medical editor, Michael was a founding member of inVentiv's strategic resourcing group and has overseen a group that began with 5 associates in 2005 and has grown to its current state of 110 medical writers, editors, technical writers, and regulatory publishers. Michael is also an active member of the Drug Information Association (DIA) and a program planner for the DIA medical affairs and scientific communications forum.

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Speaker Biographical Sketches

LISA LENAHAN, BA

Lisa has been a technical writer for Roche Diagnostics for 20 years. Prior to her position as a technical writer, she worked as a medical technologist and field support engineer. The Roche diagnostics division has an extensive portfolio of instrumentation and reagents. As a team member of the Regulatory Compliance/Technical Publications department, Lisa is responsible for writing customer communications to Roche's internal and external customers about regulatory and quality issues for Roche's diagnostic instrumentation and reagents.

WILLIAM S. PIETRZAK, PHD

Bill obtained his PhD in Bioengineering from the University of Illinois at Chicago and has worked in the medical device industry for 40 years. The bulk of his experience has been in orthopedics where he has been involved in research, product development, marketing, and medical writing. Bill retired from industry in 2015 and founded Musculoskeletal Publication and Analysis, Inc., serving as a contract medical writer with focus on Clinical Evaluation Reports.

LISA N. TOTH, BS

Lisa N. Toth, BS is a clinical pharmacology and scientific communications consultant for Eli Lilly and Company. Lisa has approximately 30 years of experience in the pharmaceutical industry as both a biochemist and scientific regulatory writer. She is a technical advisor for clinical pharmacology scientific communications management and regulatory submissions. Lisa has expertise working on multidisciplinary teams across multiple geographies and phases of drug development. She also develops training materials and serves as a mentor, coach, and technical advisor for new medical writers.

TERESA KELLER, PHD

Teresa Keller is an Associate Professor of Business Operations, Applications, and Technology (BOAT) at Ivy Tech Community College. She is professionally certified in Word 2013 and has 30 years of experience teaching word processing to beginning and intermediate level users. Teresa's passion is teaching individuals how to use Word functions in the most efficient way possible to save time and make more money.

EVENTS FOR SATURDAY, APRIL 22

All Saturday events will be held at **The Columbia Club** at **121 Monument Circle**.

Speaker Biographical Sketch

LEIGH ANNE NAAS, BA

Leigh Anne Naas has over 20 years of experience in the pharmaceutical industry, through various communications roles both at CROs and at Lilly. The first half of her career, she focused on medical regulatory writing and is proud to have had a hand in bringing oncolytic agents to global markets for the treatment of breast cancer, ovarian cancer, and pancreatic cancer. She is skilled at leading groups through times of transformational change. Most recently, Leigh Anne became the persona behind the blog posts and Twitter handle for LillyTrials, using those social media venues to connect and build relationships with patients, caregivers, and their advocates in discussion of topics related to clinical research.

Registration Information

Conference registration includes attendance at Friday evening's networking event (food/beverage extra, see page 3) and Saturday's meals, snacks, and Open Sessions.

[Register online](#)

CONFERENCE FEES

General Conference Registration

(This is a required fee for all attendees that covers Saturday's meals, snacks, and open sessions. Other fees can be processed at www.amwa.org for membership dues and MWC™ examination.)

Early Bird Price (<i>by March 14, 2017</i>)	(<i>member / nonmember / student member</i>)
Entire conference	\$130 / \$155 / \$105
Standard Price (<i>March 15 – April 15, 2017</i>)	(<i>member / nonmember / student member</i>)
Entire conference	\$155 / \$180 / \$130

CANCELLATION/REFUND POLICY

If you need to cancel your conference registration, you must send a written note to cancel registration and request a refund via e-mail to elainelipscomb@sbcglobal.net by **April 15, 2017**. Refunds will be issued through your method of payment, less a nonrefundable \$25 registration cancellation fee. Conference registration is nonrefundable after April 15, 2017. No refunds or credits will be given for failure to attend, late arrival, unattended events, or early departure.

LOCATION, TRAVEL, AND HOTEL DETAILS

Conference Sites

Events for this year's conference will be held at two sites in downtown Indianapolis:

- The **Tavern on South** will host Friday's causal networking dinner.
- **The Columbia Club** will host all Saturday activities. The Club also offers hotel accommodations for out-of-town attendees.

RESTAURANT INFORMATION

The Tavern on South, located next to Holiday Inn Express, offers casual [dining](#). Free on-site parking is available. Additional parking is also available at Circle City Garage located between the restaurant and Comfort Suites Hotel. Our party will dine in the second level meeting room, accessible only by stairs. Please advise if [assistance](#) is needed.

Tavern on South

423 W. South St.
(317) 602-3115

DRIVING DIRECTIONS

From I-65 Southbound (Chicago)

From I-65 South, take exit 114 toward West St. Stay straight to merge on Dr. Martin Luther King Jr. St. Dr. Martin Luther King Jr. St. becomes N. West St. Turn left on W. South St., and the Tavern will be on the right.

From I-65 Northbound (Louisville)

From I-65 North, merge onto I-70 West via exit 110B on the left toward St. Louis. Take the West St. exit, exit 79A. Keep right to take the ramp toward IUPUI Convention Center/IU Health Univ Hosp/Riley Hosp For Children. Merge onto S. Missouri St. Turn left onto W. South St., and the Tavern will be on the left.

I-70 Eastbound (Terre Haute)

From I-70 East, take the N. West St/I-70 E exit, exit 79A, toward Columbus OH/I-65/White River State Park/IN Govt Center/Conv Center. Turn left onto S. Missouri St. Then turn left onto W. South St., and the Tavern will be on the left.

From I-70 Westbound (Columbus, OH)

From I-70 West, take the West St. exit, exit 79A. Keep right to take the ramp toward IUPUI Convention Center/IU Health Univ Hosp/Riley Hosp For Children. Merge onto S. Missouri St. Turn left onto W. South St., and the Tavern will be on the left.

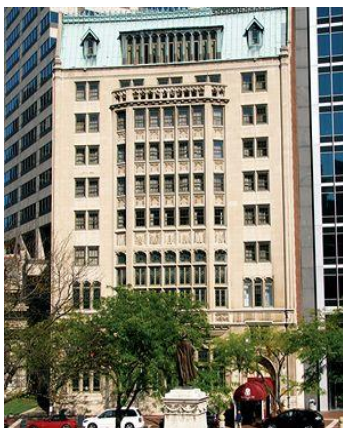
From I-69 Southbound (Fort Wayne)

From I-69 South, take the 465 South exit, exit 200. Keep right to take the ramp for I-70 West. From I-70 West, take the West St. exit, exit 79A. Keep right to take the ramp toward IUPUI Convention Center/IU Health Univ Hosp/Riley Hosp For Children. Merge onto S. Missouri St. Turn left onto W. South St., and the Tavern will be on the left.

From The Columbia Club (Downtown Indianapolis)

Drive approximately ¼ ways around traffic circle and exit the circle onto W. Market St. Turn left onto N. Capitol Ave. Continue straight onto S. Capital Ave. Then, turn right onto W. South St., and the Tavern will be on the left.

LOCATION, TRAVEL, AND HOTEL DETAILS



THE COLUMBIA CLUB

The Columbia Club is located at 121 Monument Circle in downtown Indianapolis. Several parking options are available. The lowest-priced alternative is the Club's valet, at a cost of \$15 per day. Self-service parking is available at the Chase Tower garage (adjacent to the Club), subject to availability. For other parking options, please visit <http://www.indydt.com/parking.cfm>.

Please note that The Columbia Club maintains a strict [dress code](#) policy. All persons are required to wear neat, clean business casual attire in all common areas. Please also note that cell phone use is prohibited in all dining areas and during meals.

HOTEL ACCOMMODATIONS

For your convenience, onsite accommodations are available at The Columbia Club. A block of rooms has been reserved at a rate of \$138 per night with overnight valet parking at \$25.00 per car. To receive the discounted conference rate, you must book your room by **March 20**. Another nearby lodging option is the Hilton Garden Inn, located one block from the Club. Please contact either facility directly for information and reservations.

The Columbia Club
121 Monument Circle
(317) 767-1361
www.columbia-club.org

Hilton Garden Inn
10 E. Market Street
(317) 955-9700
<http://www.hiltongardeninn.com/>

DRIVING DIRECTIONS

From I-65 Southbound (Chicago)

From I-65 South, take exit 113 toward Meridian St. Merge onto W. 11th St., then turn right onto N. Meridian St. Enter the traffic circle, and the Club will be on the right.

From I-65 Northbound (Louisville)

From I-65 North, take exit 110B and merge onto I-70 W toward St. Louis. Take exit 79B toward Meridian St., then make a slight right onto E. Madison Ave. Continue onto S. Meridian St. Enter the traffic circle, and the Club will be on the right.

From I-70 Eastbound (Terre Haute)

From I-70 East, take exit 79B to merge onto S. Illinois St. Turn right onto W. South St., then take the second left onto S. Meridian St. Enter the traffic circle, and the Club will be on the right.

From I-70 Westbound (Columbus, OH)

From I-70 West, take exit 83A to merge onto E. Ohio St. Turn left onto N. Pennsylvania St., then take the first right onto E. Market St. Enter the traffic circle, and the Club will be on the right.

From I-69 Southbound (Fort Wayne)

From I-69 South, take exit 200 to merge onto I-465 South. After about 7.5 miles, take exit 44 for I-70 West toward Indianapolis. Travel about 6 miles, then take exit 83A to merge onto E. Ohio St. Turn left onto N. Pennsylvania St., then take the first right onto E. Market St. Enter the traffic circle, and the Club will be on the right.