



2023 ANNUAL REPORT

**WOUND CARE
COLLABORATIVE
COMMUNITY**

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About the WCCC

The WCCC, a FDA 'collaborative community', is a volunteer member organization representing the broad wound care community dedicated to addressing the public health issues of complex and chronic wounds.

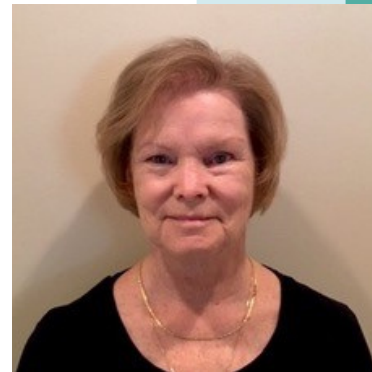
Officers



VICKIE R. DRIVER
DPM, MS, FACFAS
Chair

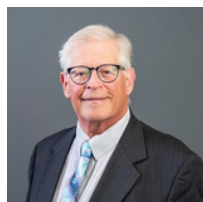


LISA GOULD
MD, PhD, FACS
Vice-Chair



PEGGY DOTSON
RN, BS
Treasurer/Secretary

Board of Directors



DAVID B. ALPER
DPM



DANA DAVIS



PATRICIA GHIKAS
PT, M.ED, DPT



SHARON GABRIELSON
RN, MBA



BRETT KOPELAN
MA



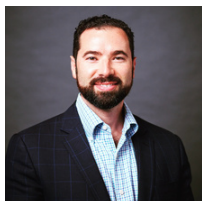
WILLIAM W. LI
MD



PATRICK MCNEES
PHD



ALISHA OROPALLO
MD



WILLIAM PADULA
PHD



RANDY SCHWARTZ
BA



THOMAS SERENA
MD



ROBERT SNYDER
DPM, MBA

Mission and Vision

Working in the pre-competitive space, the WCCC initiatives aim to improve patient access to cutting-edge medical technology (drugs, biologics, devices) while reducing cost and time to market. The goal is to accelerate the development of science-based patient-centered solutions and address public policy challenges related to assuring patients receive early access to innovative treatment options.



WORK GROUPS

The WCCC is organized into Work Groups, each with key initiatives that address identified issues, gaps and potential solutions in the wound care community that aim to improve patient access to cutting-edge medical technology while reducing cost and time to market. Current Work Groups include the following:

Gaps Work Group

Chair: Howard Walthall, JD

Co-Chair: Randy Schwartz, BA

Officer Representative: Vickie Driver, DPM, MS, FACFAS

Goal: Identification of gaps in current wound healing research and practice, including regulatory, clinical trials, clinical practice, and pre-clinical evaluation/ testing.

Related Workstreams

Clinical Trial Standards and Reporting | Led by Marissa Carter, PhD

Pre-Clinical Trial Standards and Reporting | Led by Marjana Tomic-Canic, PhD

Dressing Standards | Led by Sarah Griffiths, PhD

Real World Evidence Work Group

Chair: Joseph Rolley, MS

Co-Chairs: Caroline Fife, MD and John Lantis, MD

Officer Representative: Lisa Gould, MD, PhD

Goal: Leverage existing RWE to deepen our understanding of the complexities of patients with chronic wounds and determine which interventions achieve best outcomes for each type of patient and wound.

Related Workstreams

Standard of Care for Clinical Research and Clinical Practice | Led by Maribel Henao, DPM, MSPT, BSMAS

Natural History Project | Led by Caroline Fife, MD

Tools Work Group

Chair: Alisha Oropallo, MD

Co-Chair: Tod Brindle, PhD

Officer Representative: Peggy Dotson, RN, BS

Goal: Evaluate current tools and methods for measuring meaningful clinical endpoints in wound research, clinical practice, and in FDA trials for new drug, biologic and device approvals. Develop minimum requirements/ features for tools to be accepted as valid for clinical evaluation, assessment, and research.



OUR IMPACT IN 2023

Work Group Achievements

Gaps Work Group:

- **Pre-clinical Testing**
 - Completed research of wound models with input from Wound Healing Society and FDA
 - Developed comprehensive checklist to consolidate and standardize reporting of preclinical studies for use by researchers, journals and grant reviewers.
 - Manuscript in preparation to be submitted by Q2, 2024. Recommendations to be shared with the FDA and wound care community.
- **Clinical Trial Design**
 - Reviewed elements in current wound care clinical trial designs with the intent to develop a reporting structure for the wound care field similar to other fields of medicine and to develop standards for clinical trials in wound care.
- **Dressing Standards**
 - Formulated team to define dressing classifications, and required features for clinical effect and outcome.

Real World Evidence Work Group:

- **RWE Database Landscape Review Project**
 - Completed an assessment of over 40 real-world wound databases to determine their suitability and usability for the Natural History Project and other real-world wound care research applications. A manuscript is in preparation for publication in early 2024.
- **Natural History Project**
 - Identified a registry for analysis of real-world data that describe the treatment, outcomes and prevalence of comorbid conditions of DFU and VLU patients and identify the difference between real world patients and subjects enrolled in most prospective wound care clinical trials.
- **Standard of Care (SOC) for Clinical Research and Clinical Practice**
 - Initiated systematic review of 32 WC standard of care guidelines published by professional societies, regulatory bodies, payers, and other organizations to identify consistencies and gaps with the goal of building SOC consensus documents for use in clinical research.
- **Fit-For-Purpose Project**
 - Initiated work in assessing how wound researchers and sponsors can best meet FDA Real-World Evidence guidelines for expanded labeling decisions and ensuring real-world data meets FDA's criteria of fit-for-purpose, sufficient quality, relevance and reliability.

Tools Work Group:

- Identified current FDA cleared/ approved tools to measure percent area reduction and/or percent volume reduction.
- Researched capabilities, features, regulatory status, image quality and security, and capability to share data.
- Evaluated key features to determine minimum requirements to be accepted as a valid, reliable tool to support use in clinical evaluations, research and FDA trials for approval, and develop recommendations.

OUR IMPACT IN 2023

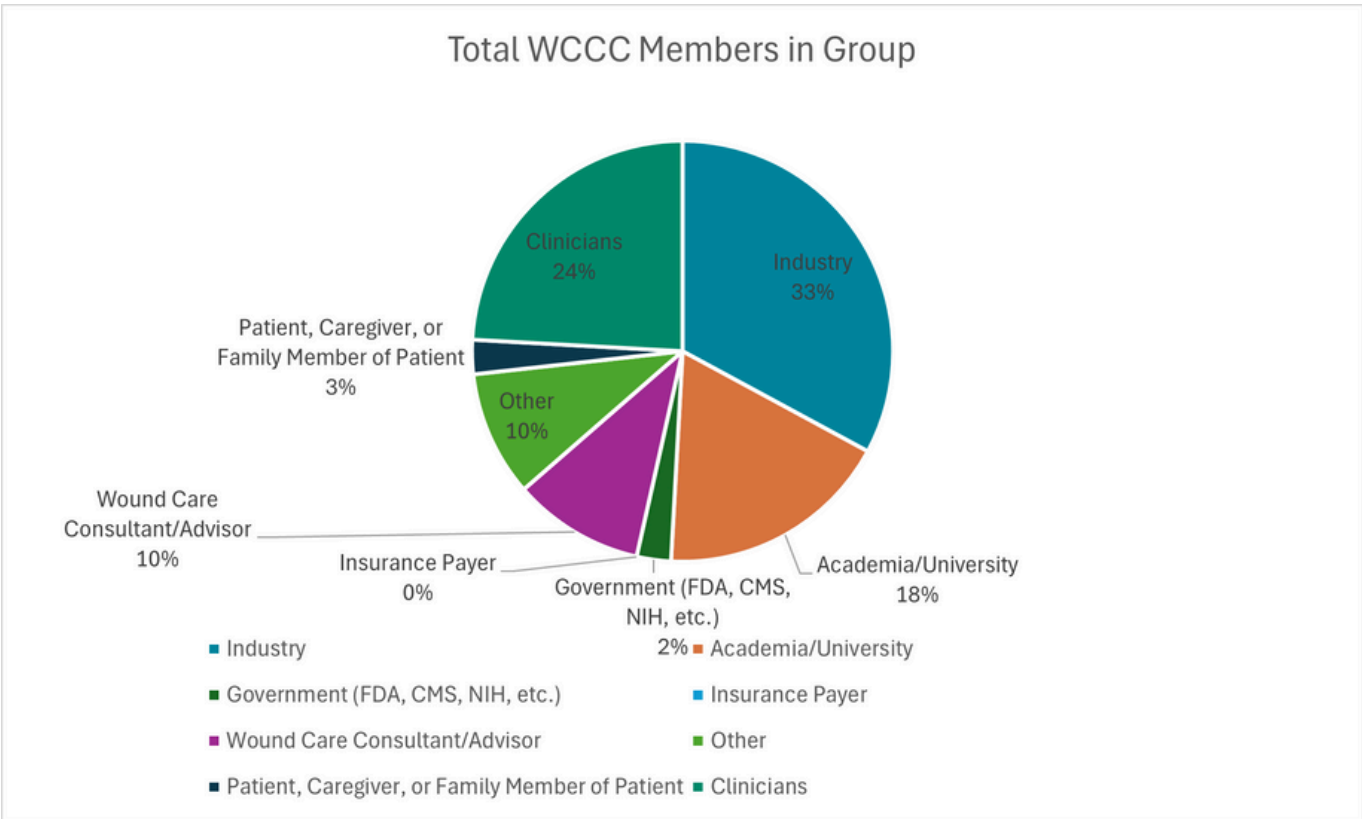
Achievements

Collaborative Partnerships

Building on our meaningful partnership with the Symposium on Advanced Wound Care (SAWC) and the Wound Healing Society (WHS), the WCCC engaged with the community at the 2023 Spring and Fall SAWC conferences. To further support our efforts in innovative research, awareness, and helping those who suffer from chronic wounds, WCCC in collaboration with HMP, has organized an all-day, working meeting 'Driving Innovation in Wound Care Summit', that will be a pre-conference at the 2024 Spring SAWC. The summit will address the major issues facing the wound care community with participation of the FDA, the CMS, payers, industry, and wound care experts.

Volunteers

The WCCC Board expanded in 2023 with the addition of Ms. Patricia Ghikas, DPT, M.Ed. The WCCC overall volunteer members grew to over 200.





Meetings

In 2023, the WCCC held over 80 meetings to further our mission and projects.



Events

In 2023, the WCCC participated in several key events, including SAWC Spring and Fall, the Innovations in Wound Care meeting, and the Advanced Wound Care Summit.

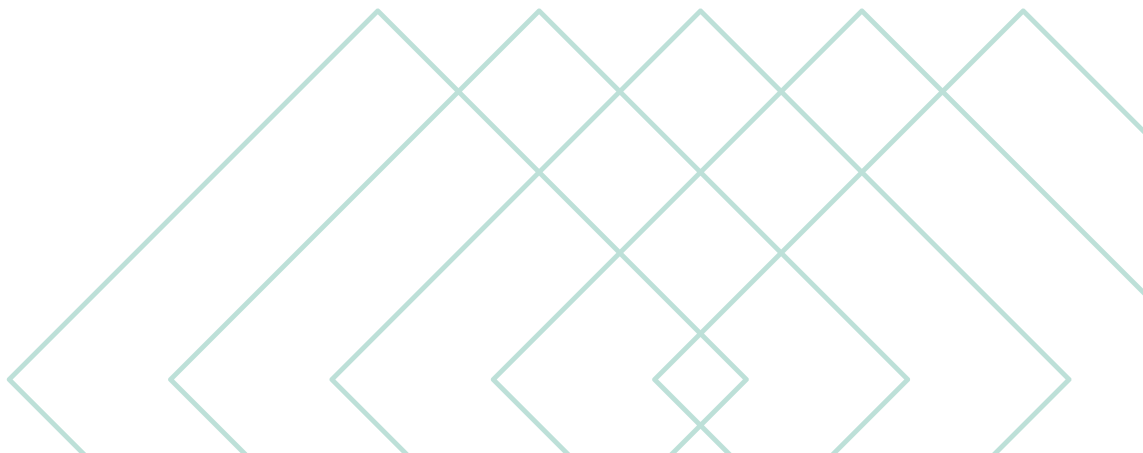
Presentations

2023 SAWC Fall: The Business of Wound Care: Opportunities and Barriers to Innovation in Wound Care.



Sponsor Support

The WCCC expanded our collaboration with major industry supporters in 2023 who provided expertise for Work Groups, and financial support for the WCCC to conduct our critical initiatives. In addition, 3M/ Solventum provided generous in-kind expert staff support to assist in the research efforts for the Clinical Trial Design and the Standard of Care projects. We are grateful for all our supporters' knowledge and support.





POISED TO IMPACT THE FUTURE OF WOUND CARE

In 2024, the WCCC will host the inaugural **Driving Innovation in Wound Care Summit** to be held in conjunction with the SAWC Spring/WHS 2024 conference in Orlando, Florida. The Summit is an all-day event taking place on May 13, 2024.

The Summit will bring together senior representatives from the WCCC, FDA, and CMS along with leading clinicians and researchers, and representatives from industry, health systems, and payers to work to evaluate the barriers to wound care innovation and learn how we can overcome those barriers together. WCCC, FDA, and CMS will share the progress on their current initiatives, focus on how to leverage what has been done so far and plan for what needs to be done next.

Due to generous financial backing, membership growth during 2023, the groundwork of many volunteer members, and our strong partnership with the FDA, we are well positioned to make a major impact on the future of wound care. Stay tuned for additional activities and publications slated for 2024.



CONTACT US

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