
WCCC

WOUND CARE
COLLABORATIVE
COMMUNITY

Driving Innovation
in **Wound Care Summit**



Driving Innovation in Wound Care Summit Proceedings

*Presented by The Wound Care Collaborative
Community (WCCC) at SAWC Spring 2025
(Non-Accredited)*

Event Date: Friday, May 2, 2025

*Event Location: Gaylord Texan Resort &
Convention Center, Grapevine, TX*

Executive Summary



Morning Agenda

Session	Speakers
OPENING REMARKS: COMING TOGETHER AS A COMMUNITY	Vickie R. Driver, DPM, MS Kurt Matheson Subramanian Gunasekaran, PhD
KEYNOTE ADDRESS and Q&A	Michelle Tarver, MD, PhD
OVERVIEW AND UPDATE OF CURRENT WCCC PROJECTS	
NATURAL HISTORY PROJECT (RWE)	Lucian Vlad, MD Caroline Fife, MD
DIAGNOSTICS: TOOLS FOR WOUND HEALING	Alisha Oropallo, MD Holly Korzendorfter, PT, PhD, CWS, FACCWS
IMPROVING CLINICAL TRIAL DESIGN AND REPORTING	Marissa J. Carter, PhD, MA Marjana Tomic-Canic, PhD
Q&A: DISCUSSION OF WCCC PROJECTS	Alisha Oropallo, MD Oscar M. Alvarez, PhD Yu-Chieh Chiu, PhD Cyaandi Dove, DPM William J. Ennis, DO, MBA, MMM William Tettelbach, MD, FACP, FIDSA, FUHM, MAPWCA, CWSP Dev Verma, MD FDA CDER Emma Wright, PhD, BSc
ADVANCED WOUND CARE AND DRESSING STANDARDS	Sarah Griffiths Langbord, PhD
DEFINING STANDARD OF CARE: INTRO AND UPDATE	Maribel Henao, DPM, MSPT, BCMAS

Afternoon Agenda

**RECOMMENDATIONS FOR CHRONIC WOUNDS:
FDA GUIDANCE UPDATE ON CLINICAL TRIAL DESIGN**

Windy Cole, DPM, CWSP, FFPM, RCPS (Glasg)
Mitch Sanders, PhD

**NEW INITIATIVES: ICD-10 DFU AND 10-YEAR DFU
WOUND REGISTRY**

Vickie R. Driver, DPM, MS
Donna Cartright, MPA,RHIA, CCS, RAC, FAHIMA

Q&A: DISCUSSION OF WCCC PROJECTS

Windy Cole, DPM, CWSP, FFPM,
RCPS (Glasg)
Yu-Chieh Chiu, PhD
William J. Ennis, DO, MBA, MMM
John Lantis, MD

William Tettelbach, MD, FACP, FIDSA,
FUHM, MAPWCA, CWSP
Emma Wright, PhD, BSc
Dev Verma, MD
Dheerendra Kommala, MD
Teresa Jones, MD

**PANEL 1: AI, SHOULD WE PLAN, AND WHAT
DO WE KNOW**

Alisha Orapallo, MD
Patrick Cheng, MS, MBA
Yu-Chieh Chiu, PhD

Karen M. Cross, MD, PhD, FRCSC
Beate Hanson, MD, PhD, MPH
Christopher Harte, COO

**PANEL 2: DECENTRALIZED CLINICAL TRIALS
AND REMOTE PATIENT MONITORING**

Rob Snyder, DPM, MSc, MBA,
CWSP, FFPM RCPS (Glasg)
Karen M. Cross, MD, PhD, FRCSC

Dev Verma, MD
Emma Wright, PhD, BSc

**PANEL 3: ENGAGEMENT WITH FDA, CMS, AND
WCCC FOR START-UP COMPANIES**

Vickie R. Driver, DPM, MS
Joseph Rolley, BS, MSIA
Marissa J. Carter, PhD, MA
Yu-Chieh Chiu, PhD
Dev Verma, MD

David M. Sommers, MD, JD, LLM
Howard Walthall, BSE, JD
Kathleen Fritsch, PhD
Shabnam Vaezzadeh, MD, MPA, BCMAS

**PANEL 4: SUPPORTING INNOVATION:
ROUNDTABLE DISCUSSION WITH FDA AND CMS**

Howard Walthall, BSE, JD
Joseph Rolley, BS, MSIA
Vickie R. Driver, DPM, MS
David M. Sommers, MD, JD, LLM
Dev Verma, MD
Dheerendra Kommala, MD
Beate Hanson, MD, PhD, MPH

Marissa J. Carter, PhD, MA
Yu-Chieh Chiu, PhD
Windy Cole, DPM, CWSP, FFPM
RCPS (Glasg)
Julia Ju, PharmD, PhD
Weimeng Wang, PhD

Q&A AND CLOSING REMARKS

Vickie R. Driver, DPM, MS

Key Takeaways From the 2025 Driving Innovation in Wound Care Summit



Collaboration within our community allows us to achieve more together than we could individually



Integrate real-world data (RWD) into all trial designs



Adopt validated digital measurement tools across studies



Implement standardized reporting in preclinical and clinical trials



Establish and enforce a universal clinical standard of care (SOC) framework



Engage early and frequently with the Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS)



The WCCC must continue to identify and resolve gaps that are hampering innovation and denying our patients the best care

Discussions From the Summit



Real-World Evidence (RWE): Catalyst for Change in Clinical Trial Models

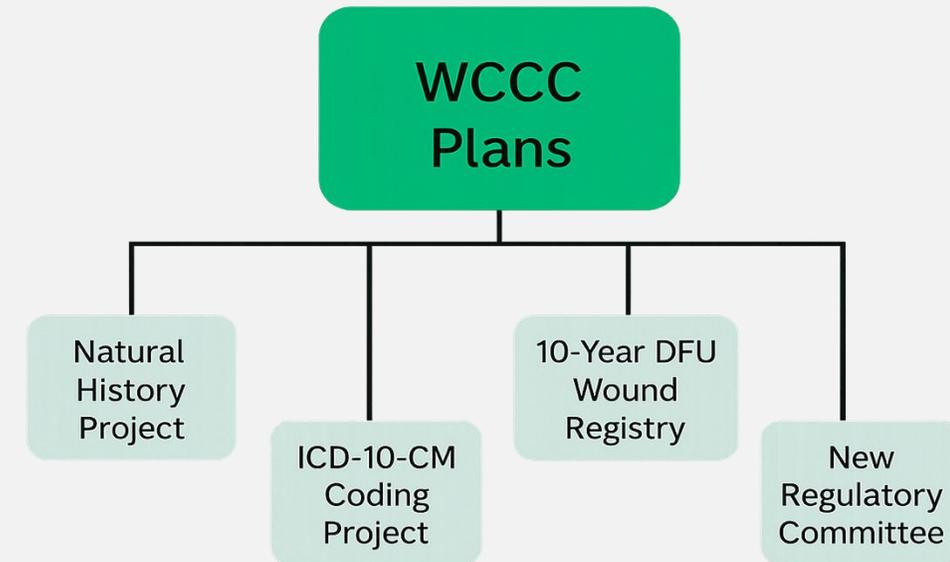
- **Registries and RWD are Essential Tools:** The consensus is that registries are the most practical and economic path to gathering evidence for wound dressings and chronic wound interventions, replacing or supplementing expensive randomized controlled trials (RCTs)
- **RWD Seen as Confirmation, Not Replacement for RCTs:** The FDA reiterated that, while RWD informs natural history and can supplement RCTs, it cannot yet fully replace randomized controlled data for initial drug approvals
- **New Dialogue Between Industry, Regulators, and Payors:** The importance of early conversations and joint design of data collection strategies that satisfy regulatory and payer needs was emphasized



Real-World Evidence: WCCC Plans

The WCCC has work groups and committees addressing these important topics through the following projects or committees:

- **Natural History Project:** Analyzing real-world wound care data to better understand patient complexity, wound burden, and outcomes, with the aim of improving clinical trial design and relevance
- **ICD-10-CM Coding Project:** To improve clinical accuracy and outcomes, a new ICD-10-CM code set for diabetic foot ulcers (DFUs) will enhance specificity, guide treatment, support data collection, and align with real-world care
- **10-Year DFU Wound Registry (Project STEADY):** The goal of this registry is to generate high-quality, long-term RWE on DFUs to inform regulatory and coverage decisions, support post-approval studies, and advance research on DFU outcomes and burden
- **New Regulatory Committee:** Developing a new regulatory committee to facilitate conversations between the FDA and CMS



Diagnostic Innovation and Standards Development

- ***Push for Diagnostic Standards:*** The FDA and clinicians called for the collaborative creation of standards for new diagnostic tools, including near-infrared imaging, fluorescence imaging, and infection diagnostics, which would enable safer and broader use in clinical trials and practice
- ***Industry Urged to Collaborate on Standards:*** Panels urged industry competitors to work together pre-competitively on imaging and diagnostic standardization, reducing investment risk and driving faster innovation adoption
- ***Flaws in Current Practices:*** Many clinics still rely on ruler measurements and smartphone images, underlining the need for standardized, validated wound-imaging tools to improve reliability and patient outcomes



(Left to Right) Peggy Dotson, Patty Ghikas, Beate Hanson, Emma Wright, Vickie Driver, David Alper, Windy Cole, Joe Rolley

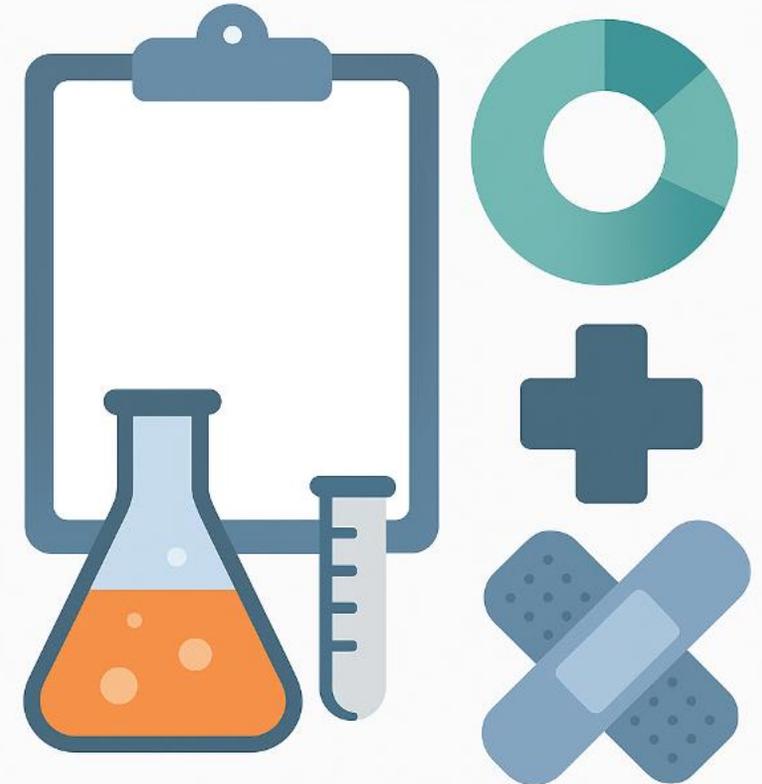
Addressing Gaps: Improving Clinical Trial Design in Wound Care

- **Lack of Standardized Reporting Undermines Trial Value:** Clinical trials in wound care often miss critical patient and wound variables, limiting reproducibility, clinical application, and payer support
- **New Evidence-Based Guidelines Developed:** Using GRADE methodology, a standardized set of patient and wound variables (eg, age, BMI, wound severity) was identified for consistent trial reporting
- **RWD Exposes Poor RCT Generalizability:** Most DFU/MLU patients are excluded from trials; the call is for more inclusive, pragmatic designs that reflect true patient populations and outcomes



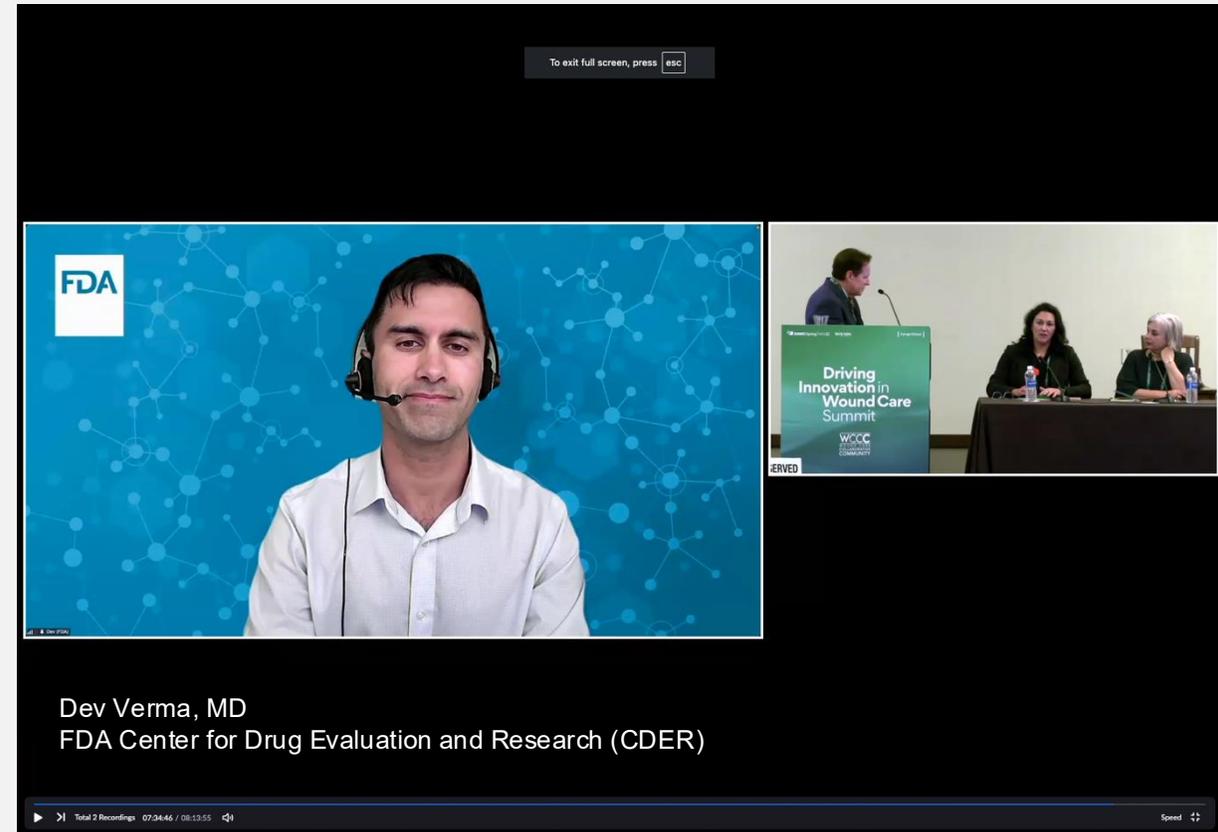
Wound Dressing Standards: Closing the Gaps

- **Lack of Standardized Testing Undermines Product Evaluation:** Current dressing assessments are inconsistent, clinically irrelevant, and make it difficult to compare products or support evidence-based decisions
- **The WCCC Is Building Clinically Relevant Benchmarks:** A new framework is being developed to align preclinical testing with real-world needs—like fluid handling, antimicrobial action, and durability—starting with sheet-based dressings
- **Innovation Demands Better Standards:** Emerging technologies (eg, smart hydrogels, microneedles) require more advanced, validated test methods to ensure they're safe, effective, and ready for clinical use



Defining Standard of Care in Wound Trials: Findings & Progress

- **Wound Care Lacks a Universal SOC:** Inconsistent definitions across trials and guidelines reduce comparability, limit generalizability, and hinder optimal patient care
- **22 Guidelines Reviewed to Identify Core SOC Elements:** Key practices include debridement, infection control, offloading, compression, and nutritional support—building a foundation for trial standardization
- **Consensus Framework in Development:** The WCCC is applying artificial intelligence (AI) tools and the Delphi method to create a flexible, evidence-based SOC framework tailored for clinical research



Modernizing Clinical Trial Guidance: WCCC's Role in FDA Update

- **Outdated FDA Guidance Requires Urgent Revision:** The current FDA guidance for chronic wound trials was last updated 20 years ago. The WCCC is addressing this by developing and submitting updated recommendations based on current science and practice
- **The WCCC Is Driving Consensus and Submission Efforts:** A multidisciplinary WCCC committee has compiled input from across the field—including SOC definitions, validated digital tools, and grading systems—and is formally submitting these to the FDA and publishing them independently
- **Patient-Centered Endpoints and Advanced Methods are Central:** Through its WEF-CEP initiative, the WCCC identified 15 meaningful endpoints and is recommending modern statistical approaches, such as Bayesian estimation, to enhance clinical trial design and real-world relevance



Bridging the AI Education Gap in Clinical Wound Care Practice

- **Identified Gap:** Recent discussions reveal a significant lack of education around AI integration in clinical practice and research
- **Stakeholder Insight:** The community is currently unprepared for AI implementation, affecting both care delivery and clinical trial readiness
- **Proposed Solution:** Organize future multi-stakeholder working sessions, that will include clinicians, educators, and technology experts, to develop structured AI training and resources
- **Goal:** Foster collaboration and build foundational knowledge to enable successful, responsible adoption of AI in wound care



Preparing Wound Care for the Future of Clinical Trials

- **Improved Access and Retention:** Hybrid and decentralized models reduce the burden of travel for participants, enable broader geographic and demographic inclusion, and support better recruitment and retention
- **FDA Supports Decentralized Elements, With Safeguards:** The FDA is open to decentralized clinical trials (DCTs), provided that safety, data integrity, and tool validation are ensured
- **Developing a Strategic Framework:** The WCCC is establishing best practices for wound care DCTs in real-world settings
- **Supporting Digital Tool Validation:** The WCCC is assessing wound care technologies to ensure regulatory alignment and DCT integration
- **Call for Education and Collaboration:** The WCCC is aligning key stakeholders and addressing the education gap by planning collaborative sessions focused on AI, digital integration, and safe, equitable decentralized trial implementation



WCCC Regulatory Committee: Enhancing Trial Collaboration

- **New Committee:** The WCCC has launched a Regulatory Committee to strengthen dialogue around clinical trial requirements. The committee will include professionals from the FDA, CMS, MACs, as well as commercial payers, clinicians, researchers, academics, and industry leaders. Overall, this initiative aims to streamline regulatory processes and foster cross-sector collaboration
- **Objectives**
 - **Facilitate Communication:** Serve as a bridge for clearer discussion of FDA and CMS clinical trial expectations
 - **Engage Stakeholders:** Ensure CMS and payer perspectives are included in regulatory planning



Holly Franzen-Korzendorfer

WCCC Strategies to Address Clinical Trial Bottlenecks

1. **Identify Barriers:** Conduct evaluations to uncover key challenges in trial design and reporting
2. **Engage Stakeholders:** Collaborate with patients, providers, regulators, and the industry to inform solutions
3. **Develop Expert Committees:** Form multidisciplinary groups to address specific issues from a broad variety of perspectives
4. **Advance Research:** Initiate targeted studies to explore and validate innovative trial approaches
5. **Publish Standards:** Release consensus-driven reporting criteria, with review by the FDA for regulatory alignment



(Left to Right) Joe Rolley; Vickie Driver

Driving Initiatives at WCCC



Real-World Evidence Work Group

- Natural History
- Standard of Care
- ICD-10-CM Coding



Gaps Work Group

- Clinical Trial Design and Reporting
- Preclinical Trial Design and Reporting
- Dressings Standards



Tools Work Group

- Artificial Intelligence
- Near-Infrared Spectroscopy (NIRS)



Committees

- Patient Initiative Committee
- Regulatory Committee
- Strategic Planning Board Committee
- FDA Recommendations Committee
- Business Development and Planning Committee

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