



WOUND CARE  
COLLABORATIVE  
COMMUNITY

MEMBER  
MEETING

June 21, 2022  
5:00 PM ET



# Welcome and Agenda

- I. Welcome
- II. Real World Evidence Work Group Update
- III. Tools Work Group Update
- IV. Gaps Work Group Update
- V. FDA Request for Member Comments
- VI. Other Business
- VII. Q&A/Discussion
- VIII. Adjourn



## **RWE Group Goal:** Establish a clear role for RWE in regulatory and coverage decisions for novel chronic wound technologies to encourage innovation and patient access

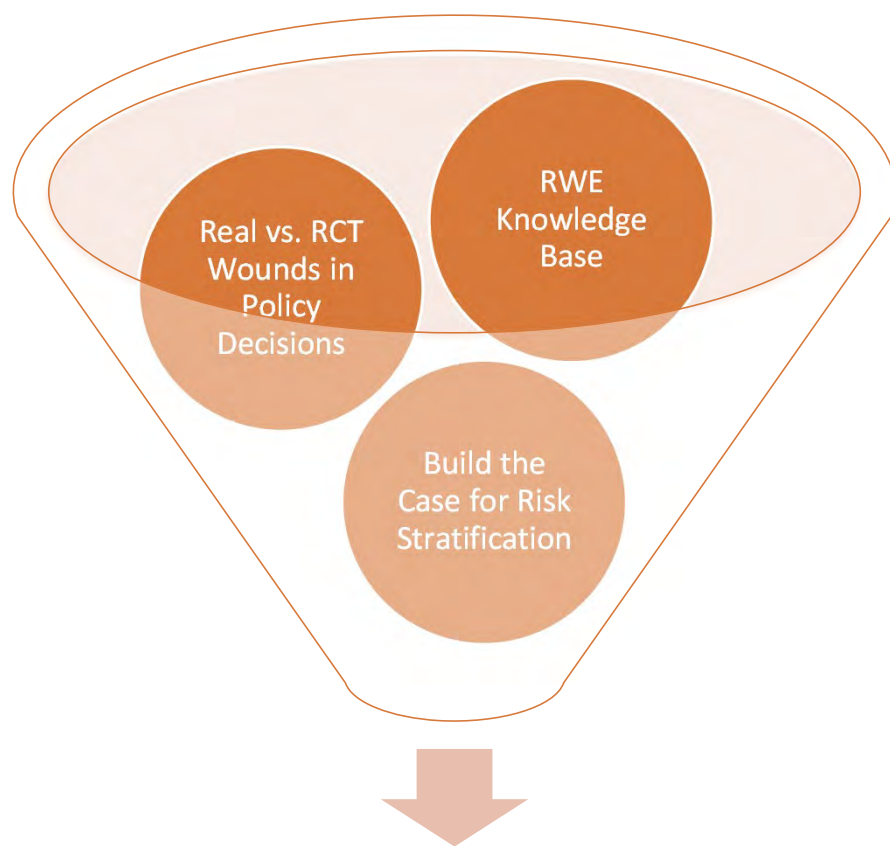
Q3/4  
2022

Q4  
2022

Q4  
2023

1. Establish an RWE Knowledge Base to ensure common understanding of RWE terminology/sources and risk severity scoring
2. Identify the gap between the inclusion and exclusion criteria of RCTs conducted for medical policy decisions and the characteristics of real-world patients with chronic wounds; build the case for using risk stratification in RCTs
3. Describe the “natural”, real-world history of patients with chronic wounds to reset expectations of ‘safety and effectiveness’ and ‘reasonable and necessary’ criteria for chronic wounds.

# Early RWE Project Deliverables Support “Natural History” Project



**“Natural” History of Chronic Wounds**

## Potential “Natural History” Goals:

- Set realistic expectations for outcomes in real world data (e.g., real-world healing rates of Wagner 3 DFUs, % of patients hospitalized while in service and whose outcome is death or amputation)
- Define “effectiveness” in terms of % improvement in healing rate or PAR for CTPs?
- Define “necessary” treatment with CTPs in terms of identifying the wounds that are not likely to heal without advanced therapeutics?
- Test secondary endpoints if data are available

# Parking Lot: Long Term Projects to be Defined Following the Natural History of Wounds Project

- Create an acceptable platform for FDA and payers to use real-world evidence, potentially creating a checklist tool to guide researchers.
  - Leverage the new FDA guidance document and create a Strobe-like standards document specific to wound care, building on the 2017 Fife & Eckert Registry article and the USWR White paper
- Build the case for reducing or eliminating the DFU-VLU-PI distinctions between chronic wounds
- Expand Wound Healing Index to create a risk stratification tool based on ICD-10 codes for use in setting inclusion/exclusion criteria for RCT protocols that more closely align to real-world patients, and for potentially assisting in everyday clinical decision making



**We'll Revisit These Later!**

# Tools Work Group Update

- Project plan goal
  - To identify evidence that clinically validated methodology exists to accurately and reproducibly support a Clinical Trial Primary Endpoint that combines improved wound healing with improved quality of life
  
- Project plan focus
  - To gather and evaluate validation information regarding wound measurement and evaluation methods and devices
  - To gather and evaluate validation information regarding Patient Centric, Patient Reported Outcome (PRO) tools as they relate to the chronic wound care patient
  - To identify existing technology with existing, validated capabilities

# Gaps Work Group Update

- New sub-work groups formed:
  - Pre-Clinical Models
  - Dressing Standards
  - Clinical Trial Design
  - Members may sign up online to participate in a sub-work group
  
- Project plan strategy
  - Create and promote a consistent approach in measuring the effectiveness of dressings through standardized in-vitro or bench test methods to secure informed purchasing decisions can be determined based on measured performance.

# Gaps Work Group Update

- Project plan milestones

- Identify which dressings we want to include. (Can't include them all – probably top 2 or 3 by usage)
- Identify what measurements are being utilized today
- Review marketing literature
- Determine commonality
- Determine various test methods and align on tests that are indicative of clinical outcomes

- Project plan best practices

- Identify standards previously utilized
- Look for agencies who have tried this before





# FDA Request for Member Comments

- FDA conducted a Wound Healing Scientific Workshop, April 28-29
- FDA has requested comments from individuals concerning:
  - Topics discussed during the Workshop
  - Specific questions listed in the Federal Register (FR) notification announcing the meeting & requesting comments (see WCCC ALERT)
- Comments due by **June 28**
- Next steps: WCCC ALERT
  - Electronic submission or Written/Paper submission
  - Confidentiality options
  - All submissions must include the **Docket No. FDA-2021-N-1212** for “Wound Healing Scientific Workshop”



# Some of the FDA Topics in Workshop

- Available Tx & current SOC for the most common non-healing chronic wounds (DFU, AU/VU, PI/PU, “nameless” wounds).
- Gaps in current Tx [what new products would be helpful/are needed to heal specific non-healing chronic wounds.
- Strategic, operational, and tactical challenges to implementation of successful clinical trials for non-healing chronic wounds.
- Industry perspective on product development for chronic wounds.
- Role of the wound microbiome in wound healing.
- Barriers to innovative product development.
- Roadblocks to implementation of successful clinical trials for non-healing chronic wounds.
- How to design clinical trials based on RWD and risk stratification.

# FDA Request for Member Comments

- WCCC ALERT provides the main topics of Workshop and the questions in the Federal Register announcing meeting & requested comments.
- ACTION: Asking WCCC members to review the WCCC Alert instructions & provide comments
  - Can address any or all of the workshop topics or questions in the FR Notice for the workshop that apply to your practice or situation
  - Individual responses will be most meaningful / valuable for the FDA
- FDA wants to hear from clinicians, researchers, payors, developers, manufacturers, patients/ caregivers



# Other Business

## ■ Upcoming industry events

- Advanced Wound Care Innovation Meeting - July 12-13
- Serena Leadership in Wound Care - September 16-17
- Inova Healthcare Meeting - September 30-October 1
- SAWC Fall – October 14-16
- American College of Surgeons Clinical Congress – October 16-20

## ■ Pending projects

- Webinar with Sepsis Alliance
- FDA CPIM/ICWH work group project

## ■ Online member portal and directory





## NEXT MEETING

Tuesday, August 16, 2022

5:00 pm ET/4:00 pm CT/3:00 pm MT/ 2:00 pm PT



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