



WOUND CARE
COLLABORATIVE
COMMUNITY

MEMBER MEETING

APRIL 26, 2022

4:00 PM ET



Welcome and Agenda

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



Tools Work Group Update

- Continuing process of populating Tables for wound measurement/assessment, PROs, QOL and wound pain.
- Received clinical validation data & other relevant references from several Industry partners (Biovisual, Arantz, Smith & Nephew, Moleculight, Kent, eKare and Tissue Analytics).
- From the PRO side, we have clinical validation information from Wound-Q and Wound-QOL.
- Immediate goal - encourage more Industry involvement to ach a more complete list of current Tools.

Tools Work Group - Member Expansion

- **3C CHORD COUSIN Collaboration (working on measures in dermatology)**
 - Dr. Amit Garg, MD, FAAD – Chair
 - Dr. L R Thorlacius – lead of Symptoms workgroup in HISTORIC (HS), developing measure for drainage.
 - Dr. Ortega Loayza - lead of UPGRADE (PG) COS group- measure several aspects of the PG wound.
- **Smith & Nephew**
 - Mark Olmstead, Senior Director, Market Access & Reimbursement
 - Dr. Jaideep Banerjee, PhD, MSL-BC, Global Clinical & Medical Affairs | Research & Development
- **eKARE**
 - Dr. Kyle L. Wu, MD, MBA - Chief Medical Officer
- **Moleculight**
 - Dr. Monique Rennie, PhD, VP, Medical Affairs (Evidence & Reimbursement)
- **Dr. Adam L Isaac, DPM**



Gaps Work Group Update

- Survey, draft ready for Gaps committee
- The WG agreed that GAPS should be divided into:
 - (1) short term 1-2 years
 - (2) intermediate 2-4 years
 - (3) long term >4 years
 - This strategy involves a focus on the resources and time required to address the GAPS that are being considered
- Selected one GAP - Pre-Clinical Models
- Plan to select at least one short-term goal for a quick win
- Clinical trial design standards

Real World Evidence Work Group Update

Project 4

Description:

- Analysis of the “natural history” of patients with wounds, turning the focus from the wound to patient risk factors

Goals:

- Encourage the development of RCT protocols that go beyond studies of the “ideal patient” to those that better reflect the typical patient with wounds
- Establish new metrics of success that reflect the limited impact a single intervention can have on the trajectory of wound healing in real-world patients.



RWE Project 4 Approach

- Start with H/CTPs (skin substitutes) and DFU and VLU indications
 - Broaden to other wound technologies and/or indications at later date
- Focus initially on FDA PMA and Commercial Payer submissions
 - CMS coverage policies for H/CTPs are not brand specific, nor require clinical studies for inclusion in the coverage policies of the MACs that have policies
- Three Workstreams
 1. FDA PMA submissions
 2. Commercial Payer submissions
 3. Compare 1) and 2) to the demographics and characteristics of Real World Chronic Wounds and Patients



Formation of Project 4 Teams

- Looking for volunteers to assist with Project 4
- Clinical research expertise
- Payer experience – clinician and manufacturer members
- Need to be willing to assist with the research and analysis needed for the project deliverables
- Be willing to meet periodically as a team

RWE Project 8

- Define what high-quality RWE evidence and registries look like.
- Develop standardized methodologies for conducting real world studies so as to make them acceptable to FDA and payers as a basis for labeling and coverage decision making
- Next meeting will have Dr. Thomas Scarnecchia (Co-founder, Digital Aurora) as a speaker

Upcoming Webinar



WEBINAR

Real-World Evidence for Medical Devices:
An Interim Report on Lessons from the NESTcc Test-Cases

WEDNESDAY, APRIL 27 | 1:00 TO 2:00 P.M. ET



FDA Request for Member Comments

- FDA conducting 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



Webinar Opportunity with Sepsis Alliance

- Sepsis Alliance – forming a Sepsis Collaborative Community
 - Reached out to WCCC for guidance on recruitment/structure (suggested by FDA)
 - *Sepsis.org* – site serving > 2.5 M patients, family members, caregivers and medical professionals per year
- Several complimentary education initiatives/outlets that include:
 - Sepsis Alliance Clinical Community - network of sepsis coordinators & HC providers
 - Sepsis Alliance Institute - trained > 40K professionals
 - Forthcoming, Sepsis Alliance Collaborative Community (like WCCC)
- CE education for nurses is delivered through the Sepsis Alliance Institute
 - Typical attendance is 200+ participants
 - Complimentary to all participants with no charge/fees to WCCC



Webinar Opportunity with Sepsis Alliance

- Member Opportunity – to work with Sepsis Alliance on webinar
 - Member(s) experts/KOL's to develop talk & volunteer as speaker/educator
 - 1-hour live webinar (45 min. lecture / 10-15 Q & A)
 - Wounds & Sepsis

- Some of the Sepsis Alliance ideas for a presentation included:
 - How common are wounds
 - Types of wounds
 - Appropriate care and assessment of wounds
 - Amount of time to heal certain wounds
 - Best practice treatment options that help avoid infections and sepsis
 - Common co-morbidities, vulnerability, and complexity of patients with wounds
 - Percentage of wounds that become infected and go on to develop sepsis



Other Business

- New online membership application, member directory, and "member-only" web features available
- New meeting time – start one-hour later:
 - 5:00 pm ET/4:00 pm CT/3:00 pm MT/ 2:00 pm PT
- Upcoming industry events
 - FDA Wound Workshop - April 28-29
 - Alliance Wound Care Evidence Summit - May 19-20
 - Advanced Wound Care Innovation Meeting - July 12-13
 - Serena Leadership in Wound Care - September 16-17
 - Inova Healthcare Meeting - September 30-October 1



NEXT MEETING

Tuesday, June 21, 2022

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



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