FDA Wound Healing Workshop Agenda
Thursday April 28th – Friday April 29th, 2022
Virtual Workshop Via Zoom

All times displayed below are EST

REQUEST FOR PUBLIC COMMENTS: https://www.federalregister.gov/documents/2021/12/20/2021-27459/wound-healing-scientific-workshop-public-workshop-request-for-comments

The overall objectives for the workshop are to:

- Communicate, seek external input, and facilitate discussions on the current barriers to product (drug/device/biologic/combination) development for non-healing chronic wounds. Codify root causes of barriers and align on highest priority barriers.
- Identify barriers that FDA could impact vs. ones that other stakeholders could impact.
- Potentially establish a working group (to work with already established Wound Care Collaborative Community) to support continued collaboration across involved stakeholders.

DAY 1: Thursday 4/28/22

MORNING SESSION 1: Pathways to Product (drug/device/biologic/combination) Development; FDA speakers

OBJECTIVES:

- State the purpose of the 2-day workshop, what groups are represented, and the conference goals/objectives.
- Outline the landscape of product development for non-healing chronic wounds, highlighting current challenges and momentum provided by the OND Wound Healing Science Strategies program.
- Identify each FDA Center's role in product development.
- Describe current standards for development as influenced by the *Guidance for Industry: Chronic Cutaneous Ulcer and Burn Wounds — Developing Products for Treatment, June 2006*.
- Outline and identify current products on the market for chronic non-healing wounds.

09:00 – 09:05 am: FDA Opening Remarks (Kendall Marcus, MD)

09:05 – 09:15 am: OND Science Strategies overview; FDA identified barriers to product development (Dev Verma, MD)

09:15 – 09:25 am: CDER Regulation of Wound Healing Products (Gary Chiang, MD, MPH)
09:25 – 09:35 am: CDRH Regulation of Wound Dressing Devices (Allan Guan, PhD)

09:35 – 09:45 am: Regulatory Considerations: Clinical Development of CBER Products for Wound Healing (Rosa Sherafat-Kazemzadeh, MD)

09:45 – 09:55 am: FDA Guidance: Chronic Cutaneous Ulcer and Burn Wounds – Developing Products for Treatment (Jennifer Bai, MD)

09:55 – 10:05 am: Break

MORNING SESSION 2: Diagnosis and Natural History of Non-Healing Chronic Wounds
OBJECTIVES:

- Identify the factors that disrupt normal wound healing and lead to chronic wounds.
- Describe the most common non-healing chronic wounds (DFU, arterial/venous wounds, pressure wounds, "nameless" wounds), currently available treatments, and identify current standards of care for each.
- Identify gaps in current treatment of chronic non-healing wounds.

10:05 – 10:10 am: FDA Intro comments (Dev Verma, MD)

10:10 – 10:20 am: Wound Healing Stages: How Acute and Chronic Wounds Differ (Kenneth Fan, MD)
10:20 – 10:30 am: The Diabetic Foot Ulcer (Paul Kim, DPM, MS)

10:30 – 10:40 am: Arterial and Venous Ulcers (Lisa Gould, MD, PhD, FACS)

10:40 – 10:50 am: Pressure Injuries (Aimee Garcia, MD, CWS, FACCWS, MAPWCA)
10:50 – 11:00 am: The Nameless Wounds (Caroline Fife, MD)

11:00 – 11: 05 am: Break

11:05 – 11:45 am: Panel discussion (FDA moderator Dr. Dev Verma, Dr. Kenneth Fan, Dr. Paul Kim, Dr. Lisa Gould, Dr. Aimee Garcia, Dr. Caroline Fife, Dr. Sharon Gerecht [non-clinical/research perspective], Dr.

Marjana Tomic-Canic [non-clinical/research perspective])

11:45 am – 12:30 pm: Lunch break

AFTERNOON SESSION 1: 12:30 – 2:30 PM Patient Voice Session (led by Director of Patient Focused Drug Development Program, Robyn Bent, RN, MS)

OBJECTIVES:

- Hear perspectives from patients, caregivers, and other patient representatives to reflect upon their comprehension of their wound (why it exists) and how it affects their QOL; understand what changes in signs or symptoms are clinically meaningful to them; and learn about their experiences with clinical trials of wound healing products and the current approaches to treating chronic, nonhealing wounds.

2:30 – 2:40: Break

AFTERNOON SESSION 2: Intro to clinical trial issues
OBJECTIVES:

- Identify strategic, operational, and tactical challenges to implementation of successful clinical trials for non-healing chronic wounds (which will be expanded upon in Day 2).

2:40 – 2:45: FDA Intro comments (Joy Mejia, MD)

2:45 – 3:05 pm: Overview of clinical trial issues for chronic wounds (Robert Kirsner, MD, PhD)

3:05 – 3:15 pm: Industry perspective to new product development for chronic wounds (Robert Bearden, PhD; Smith+Nephew representative)

3:15 – 3:30 pm: Q+A end of day (Kendall Marcus, MD)

DAY 2: Friday 4/29/22

MORNING SESSION 1: Mechanism of therapeutic action and pathophysiology of wound healing (speakers will focus on both the pathophysiology and gaps in product development)

OBJECTIVES:

- Describe current areas of research in wound healing.
- Explore how current research in wound healing may be applied for innovative product development.

09:00 – 09:05 am: FDA Intro comments (Felisa [Sally] Lewis, MD)

09:05 – 09:20 am: Dynamic Reciprocity in the Wound Microenvironment (Ira Herman, PhD)

09:20 – 09:30 am: The role of the wound microbiome in wound healing (Robert Kirsner, MD, PhD)

09:30 – 09:50 am: Mechanotransduction in wound healing, and barriers to innovative product development (Geoffrey Gurtner, MD, FACS)

09:50 – 10:30 am: Panel discussion (FDA moderator Dr. Felisa [Sally] Lewis, Dr. Ira Herman, Dr. Robert Kirsner, Dr. Geoffrey Gurtner, Dr. Sharon Gerecht [engineered bioscaffolds perspective], Dr. Teresa Jones [biomarkers perspective], Dr. Marjana Tomic-Canic [translational research perspective]), Dr. Chandan Sen [biomarkers and translational research perspective])

10:30 – 10:40 am: Break

MORNING SESSION 2: Clinical trial issues including execution feasibility (barriers to enrollment e.g: inclusion/exclusion criteria), patient registries, Real World Evidence

OBJECTIVES:

- Elaborate on roadblocks to implementation of successful clinical trials for non-healing chronic wounds.
- Explore how to design clinical trials based on real world data and risk stratification.

10:40 – 10:45 am: FDA Intro Comments (Joy Mejia, MD)

10:45 – 11:05 am: Wound Closure in Clinical Trials and Comparative Effectiveness Research (Lisa Gould, MD, PhD, FACS)

11:05 – 11:15 am: Applicability of Wound Care RCTs to General Wound Care Populations (Marissa Carter, PhD, MA, MAPWCA)

11.15 – 11:35 am: Patient registries and RWE (Caroline Fife, MD)
11:35 – 11: 40 am: Break

11:40 am – 12:20 pm: Panel discussion (FDA moderator Dr. Joy Mejia, FDA RWE representative Dr. John Concato, Dr. Marissa Carter, Dr. Caroline Fife, Dr. Jaideep Banerjee [Smith+Nephew], Dr. Matthew Cooper [3M], Dr. Thomas Serena, Mr. Nico O'Kuinghttons [Huma], Mr. Joseph Rolley [Industry consultant perspective, JTR Business Consulting LLC])

12:20 – 1:05 pm: Lunch break

AFTERNOON SESSION 1: Assessing Clinical Benefit in Non-Healing Chronic Wounds
OBJECTIVES:

- Recognize the importance of COAs that are context relevant for patients with non-healing chronic wounds.
- Identify the process of how to develop fit-for-purpose COAs.

1:05 – 1:10 pm: FDA Intro Comments (Dev Verma, MD)

1:10 – 1:20 pm: Regulatory Approach for the Development of Clinical Outcome Assessments (Julia Ju, PharmD, PhD)

1:20 – 1:35 pm: Wound Care Collaborative Community (Vickie Driver, DPM, MS, FACFAS, FAAWC)

1:35 – 1:45 pm: The WOUND-Q: A New Patient-Reported Outcome Measure for Chronic Wounds (Anne Klassen, DPhil; Andrea Pusic, MD, MHS, FRCSC, FACS)

1:45 – 2:20 pm: Panel discussion (FDA DCOA co-moderator Dr. Selena Daniels, Dr. Julia Ju, FDA statistician Dr. Kathleen Fritsch, Dr. Vickie Driver, Dr. Andrea Pusic, Dr. Anne Klassen)

2:20 – 2:28 pm: Break

AFTERNOON SESSION 2: CMS and Industry Perspective
OBJECTIVES:

- Discuss current acceptable evidence for coverage decisions related to wound care devices, drugs, and biologics.
- Identify improved processes to provide patients access to the devices and drugs necessary for non-healing chronic wounds.

2:28 – 2:30 pm: Intro Comments (Dev Verma, MD)

2:30 – 2:40 pm: Medicare Coverage and Reimbursement (James Rollins, MD)

2:40 – 2:50 pm: An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds (Marcia Nusgart, R.Ph. and Caroline Fife, MD)

2:50 – 3:20 pm: Panel discussion (FDA moderator Dr. Rochelle Fink*;* Dr. James Rollins, Ms. Marcia Nusgart, Dr. Caroline Fife, Mr. Joseph Rolley [Industry consultant perspective, JTR Business Consulting LLC], Mr. Mark Olmstead [Smith+Nephew], Ms. Amy Law [3M]), Mr. John Ferros [Organogenesis])

Lessons Learned
OBJECTIVES:

- Summarize key take-aways from 2-day conference.
- Identify next steps.

3: 20 – 3:30 pm: FDA Closing Remarks (Kendall Marcus, MD)

Abbreviations (meeting agenda)

CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CED	coverage with evidence development
CMS	Centers for Medicare and Medicaid Services
COA	clinical outcome assessment
CTP	cellular and tissue-based product
EMR	electronic medical record
LCD	local coverage determination
NCD	national coverage determination
RCT	randomized clinical trial