WCCC
WOUND CARE
COLLABORATIVE
COMMUNITY

Member Meeting

July 25, 2023
5:00 PM ET

Welcome and Agenda

I. Welcome

II. Guest Speaker Introduction

III. Business and Professional Development Committee Presentation by Sharon Gabrielson, RN, MBA

IV. Q&A/Discussion

V. Work Group Updates

VI. Other Business

VII. Adjourn

Upcoming Member Meeting Schedule
5pm ET/4pm CT/3pm PT
October 24, 2023

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Business and Partnership Development Committee

Member Meeting

Sharon Gabrielson

July 25, 2023

WCCC Mission

The Overall Mission of the WCCC is to:

- Help assure patients and health care professionals have access to safe, effective, and high-quality medical devices and drugs to treat complex wounds
- Work in the pre-competitive space to identify methods, tools, approaches, and appropriate clinical evidence that will enhance understanding and improve evaluation of product safety, quality, and effectiveness
- Accelerate access to the best standards of care

WCCC Objectives

- Meet the critical healthcare needs of our patients and improve the standard of care we must work together on improving and understanding evidence; we can no longer work from independent silos
- We know we can achieve better outcomes in protecting and promoting public health when key stakeholder groups work together to achieve shared outcomes and solve shared problems

WCCC Progress Years 1-2 (Startup)

Built Operational Infrastructure

- 3 Work Groups
  - Gaps
  - Tools
  - Real World Evidence
- Relationship between FDA WCCC
- Building awareness of WCCC with/among stakeholders

WCCC Go Forward Approach 2023 – Scale and Sustain

- Board Discussion March 2023
  - WCCC growth/execution of workgroup deliverables will require additional human and financial capital
  - Development of external partnerships/relationships is critical
  - Clarity of value proposition and ROI (return on investment) is essential
  - Coordinated approach at the organizational level is necessary – Business Development and Partnership Committee

Committee Charge

The purpose of the Business Development Committee (the "Committee") of the Board of Directors (the "Board") of Wound Care Collaborative Community (WCCC) is to:

- Review and oversee the development and implementation of WCCC business opportunities
- Monitor the performance and strategy for WCCC's portfolio of business activities that are extensions of the core activities of the WCCC
- Review and endorse new business initiatives that require debt financing or meet the criteria outlined by the Board
- Provide guidance to the board on execution of the brand vision and positioning for WCCC

Committee Members

- David Alper
- Phalan Bolden
- Windy Cole
- Cyaandi Dove
- Vicki Driver (co-chair)
- Sharon Gabrielson (co-chair)
- William Li
- Patrick McNees
- Alisha Oropallo
- Thomas Serena

Next Steps

- Kickoff BDP Committee on 7/18/23
- Deliverables
  - Short Term (by Sept 1, 2023)
    - Develop Elevator Pitch
    - Develop Formal Partnership Framework (individual, private and public organizations, government)
  - Long Term
    - Business Development Plan (recommend to board and obtain endorsement by year end 2023)

Closing/Call to Action

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Our Ask

- Become actively involved as a stakeholder
  - Support in the form of human, financial, subject matter expertise
  - Introductions to connections/network
  - Other

- Champion WCCC

Thank you!

Pre-clinical Testing Gap: Objectives and Strategy

Prepared by

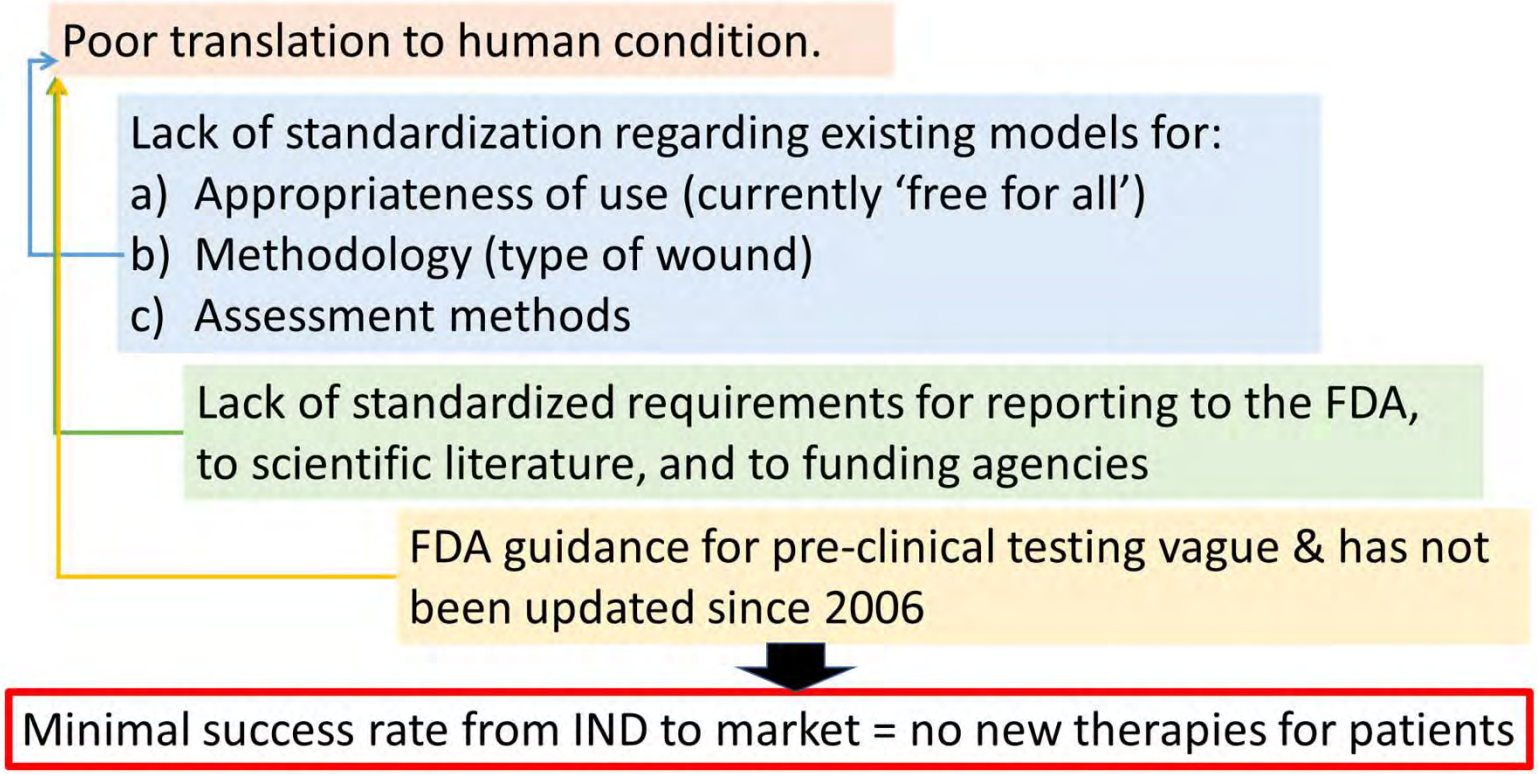
Marjana Tomic-Canic PhD on a behalf

of Pre-clinical Testing Gap Working Group:

Lisa Gould, Sharon Gabrielson, Allison Ramey, Sarah Griffiths, Noah Seitel, Mora Melican, Howard Walthall and MT-C

Standardizing Pre-clinical Testing
Important Gap and Feasible

Lack of appropriate guidelines for pre-clinical testing recognized as a significant challenge at the first WCCC SC meeting



What is the Objective of the Pre-clinical GAP Working Group?

Long-term goal is to develop a guiding document that will standardize animal/human in vivo/ex vivo/in vitro wound models for preclinical studies that are relevant to human wound healing.

Practical Guidance document would contain Guiding Principles and Good Practices for Use of Pre-clinical Models in Wound Healing Research which would be utilized for:

a) the pre-clinical testing in support for the IND for the FDA,

b) data reporting in scientific literature and

c) research grant applications (as guidance for both applicants when they consider research strategy and design and for the grant reviewers – appropriateness of use of model).

Phase 1

Goal: To consolidate and standardize reporting for pre-clinical studies. To create a checklist document (like CONSORT) but for pre-clinical studies

Currently, there are no standards to guide reporting of pre-clinical experimental information. Consistency in reporting allows transparency, critical evaluation, comparative and meta-analysis studies and avoids repetition and redundancy.

The Wound Reporting in Animal and Human Preclinical Studies (WRAHPS) Guidelines

Strategy

- Draft checklists (includes rodent, pig, rabbit and human ex vivo models) DONE
- Provide brief summaries of models DONE
- Outline justifications/rationale of specific reporting requirements IN PROGRESS
- Send for the review, edits and comments to WCCC, and other organizations who have vested interest (WHS, FDA, NIH etc) Estimated during August/September 2023
- Finalize the document for publication in multiple wound journals simultaneously (WRR, JWC, Wounds, etc) Estimated in fall of 2023

Reporting of Clinical Trials

Marissa J. Carter, PhD, MA, MAPWCA

Chair, Clinical Trial Committee, GAPS Work Group

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www.woundcarecc.org

Background

- Wound care journals do not insist on authors using guidelines for the reporting of clinical trials despite their existence for decades
- Frequently, important pieces of clinical studies are missing
- There are also issues in the lack of general reporting for patient- and wound-related variables
- This makes understanding of clinical studies and related health economic studies problematic
- In addition to guidelines, we need for our wound care community a "minimum core dataset"

When Guidelines Are Not Mandatory

- When journals don't insist on mandatory guidelines, crucial pieces of studies are likely to be missing:
  - Patient flowcharts
  - Detailed standard of care
  - Statistical power calculations or analytical techniques
  - Key populations
  - Demographics.
- This is because the level of effective peer review has to be much higher (most peer reviews are biased even if reviewers are experienced)
- As a result, many studies get downgraded during the systematic review process
- This is a disservice to authors, sponsors, and the community
- (Crucially flawed studies should **NOT** be published.)

Group 1: Patient Demographics Drugs that Affect Wound Healing

- Age
- Gender or sex? Sex at birth?
- Race-Ethnicity
- Education level
- Income level
- Support system
- Treatment geographic area (rural vs urban)
- Others
- Drugs.

Group 2: Patient Comorbidities

- Decide which ones to report
  - Big 5 (e.g., diabetes, CKD, afib, COPD, CHF)?
  - Report comorbidities based on affecting wound-healing, interfering with treatment, other scheme or rationale?
  - Severity or grade?
  - Duration? (Diabetes is a great example.)
  - Provide counts and percentages?
- Should we state that the primary or other endpoints be adjusted for these comorbidities?

Group 3: Wound Demographics

- Area (at randomization or first treatment? Report mean/SD; median/IQR? Range?
- Wound age (at randomization or first treatment? Report mean/SD; median/IQR? Range?)
- Wound type (categorization?)
- Severity or grade (which schemes?)
- Wound ischemia: methods/ units? Metrics?
- Neuropathy (DFUs?); extent? How defined?
- Wound exudation (type, extent)
- Others?

Clinical Reporting Project (I)

Phase 1

- Three groups of 2 persons each minimum
- What are we looking for? Primarily observation studies (cross-sectional/longitudinal); cause & effect; associations; odds ratios or relative risks
- Literature search; how to develop a literature search strategy
- Use PubMed; Google Scholar; Embase
- Develop list of papers
- Develop extraction tables in Excel.

Clinical Reporting Project (II)

Phase 2

- Analyze data
- Develop evidence base for variables that can influence wound healing
- Develop CONSORT-like checklist of reporting variables (format; explanations)
- Share results within our group; after discussion and summary we can share with other WCCC groups and FDA to get their comments/input
- Take all results and draft a manuscript for publication; prepare a slide deck for our one-day pre-SAWC spring meeting
- Disseminate results via social media and other avenues.

Questions?

Marissa J. Carter, PhD, MA, MAPWCA
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http://www.strategic-solutions-inc.com

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Gaps: Dressing Standards

Goals:

Create and promote a consistent approach in measuring the clinical effectiveness of dressings through standardized in-vitro or bench test methods to secure informed purchasing decisions are determined based on clinically relevant measured performance.

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Objectives:

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

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Current and Planned Publications from External Group

4 additional publications planned for the rest of 2023

Nr	Headline	Resp	Status	2023											
				Q1 2023			Q2 2023 (Today)			Q3 2023			Q4 2023		
				Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1.1	How Should Clinical Wound Care and Management Translate to Effective Engineering Standard Testing Requirements from Foam Dressings? Mapping the Existing Gaps and Needs	Amit	Published Feb. 2022												
1.8	The biological and physiological impact of the performance of wound dressings	Breda	Published Aug. 2022												
1.5	Fluid/structure characteristics and interactions	Amit + MHC	Slight delay, Submission June 2023						Submitted		Published				
1.6	Mechanical and contact characteristics of foam materials within wound dressings: Theoretical and practical considerations in treatment	Amit	Published Dec. 2022												
1.4	Biocompatibility, biological & physiological impact of dressing materials and structures	Breda	Delayed, Submission Aug 2023								Submitted		Published		
2.1	Clinical performance characteristics for bordered foam dressings in the treatment of complex wounds: An international wound dressing technology expert panel review	Nick S	Published May 2022		Submitted			Published							
2.2	Using Patient reported experience to inform the use of foam dressings for chronic wound care	Kevin W	Submitted		Submitted				Published						
2.3	Health Economics perspective/Cost Effectiveness	John P/Bill P	Paper to be planned/Not approved yet by the Stee. Com							Submitted		Published			
2a	Clinical research on the use of bordered foam dressings in the treatment of complex wounds: A systematic review of reported outcomes and applied measurement instruments	Dimitri B	Published May 2022												
2b	Study protocol for the development of a core outcome set (COS) for clinical effectiveness trials of bordered foam dressings in the treatment of complex wounds	Dimitri B	Published Sept. 2022												
2c	The development of a core outcome set for clinical effectiveness studies of bordered foam dressings in the treatment of complex wounds	Dimitri B	Published April 2022			Submitted	Published								

Next Steps

- Align external group activities with WCCC
- Gain consensus on how to proceed
- Develop a 2024 strategy and implement

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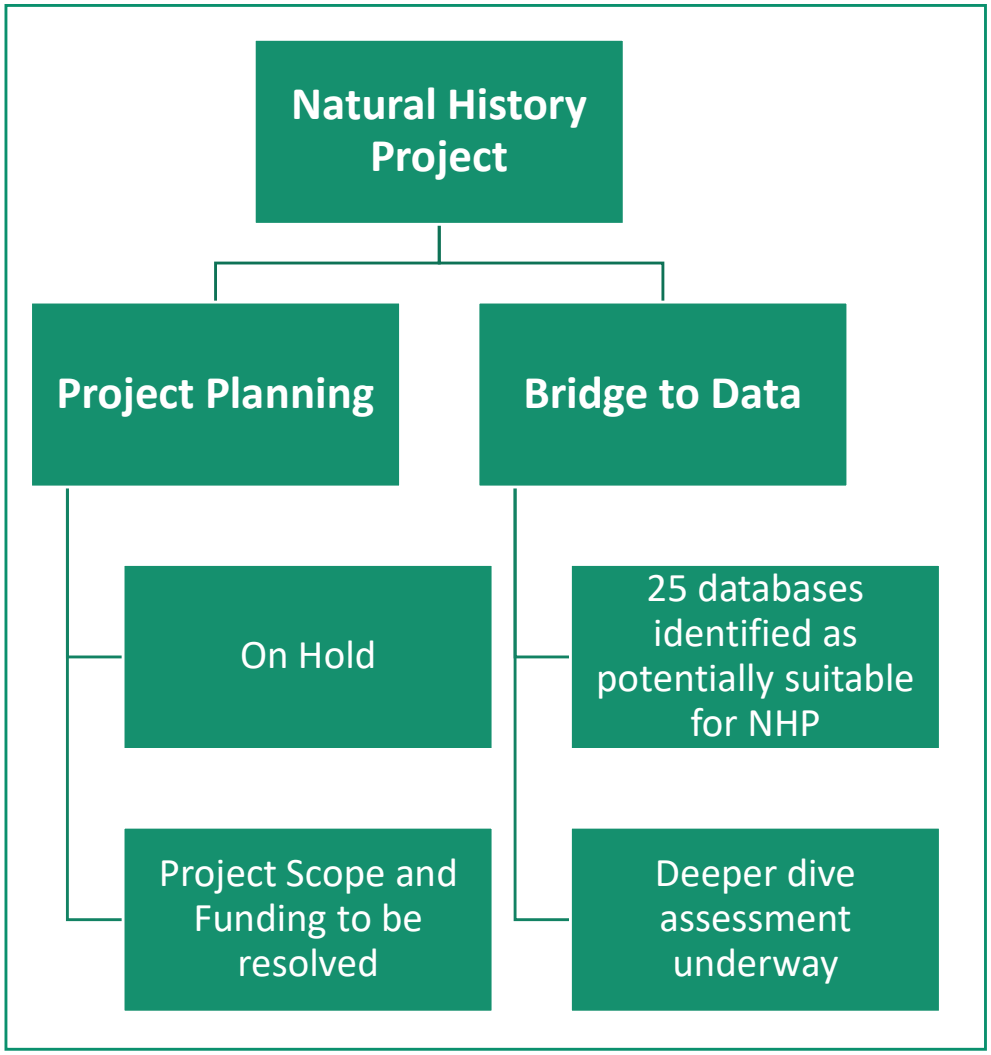
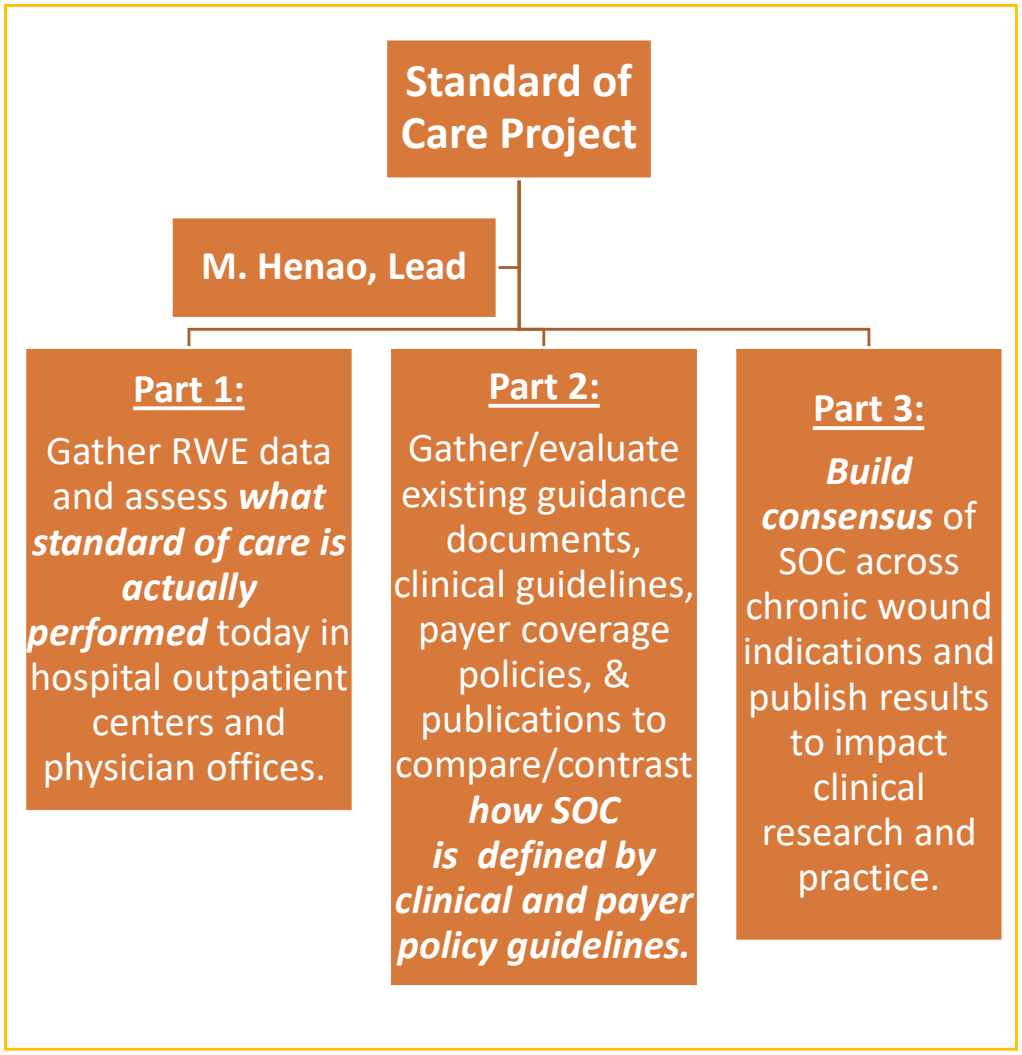
RWE Work Group Update

Joe Rolley
Maribel Henao

July 25, 2023

RWE Focus on Two Workstreams





NATURAL HISTORY OF WOUNDS PROJECT

OVERVIEW

Goal

Provide a scientifically-based "roadmap" for RCTs **that better defines appropriate inclusion and exclusion criteria** to demonstrate the impact of an intervention in the real world, and to help regulators and payers **better interpret study results** for approval and coverage decisions.

Aims

- **Reduce risk for study sponsors** with increased predictability to how clinical results will be interpreted
- Produce **higher quality evidence** for regulatory decision making
- Drive **more informed payer coverage decisions** and level-set acceptable **evidence thresholds of 'significant benefit'**
- Strengthen the quality of wound care evidence **for quicker clinical adoption**

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Standard of Care Project Overview

Maribel Henao, Project Lead

- **Goal:** Build consensus of what constitutes “standard of care” across chronic wound indications for adoption in clinical practice and research
  - Define for diabetic, venous, arterial, pressure, and mixed etiology ulcers including but not limited to:
    - Specifications of standard (non advanced) interventions and technologies
    - Minimal required diagnostic tests
    - Wound progression metrics (biomarker-based?)
    - Definition of non progression
- **Impact:** Disseminate through publication or white paper

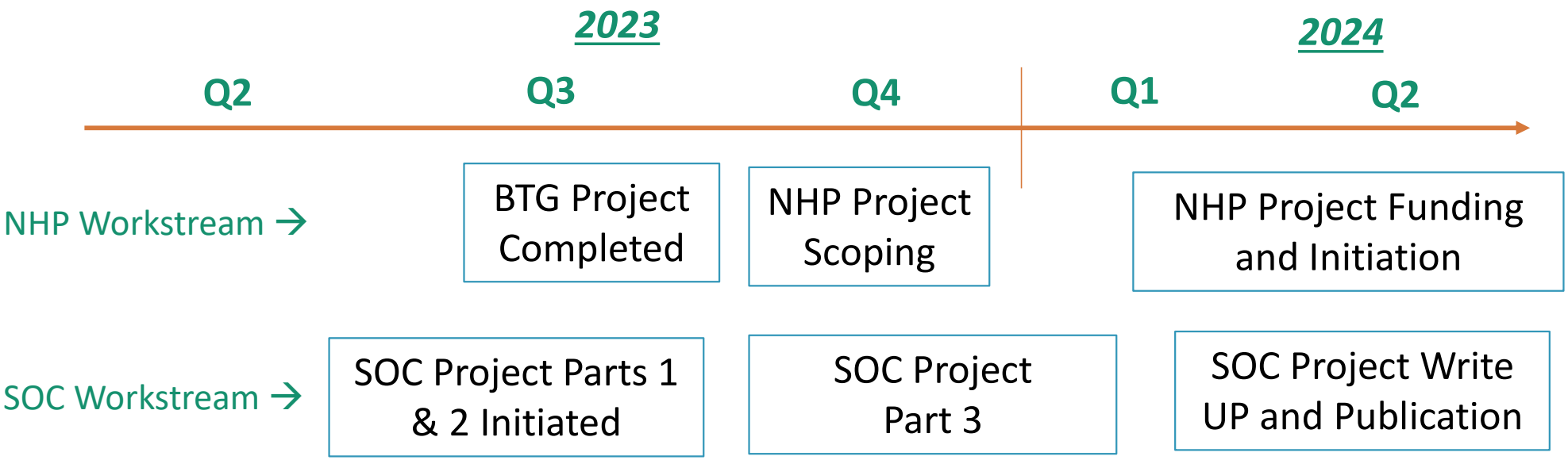
PROJECT OVERVIEW

Part 1	Gather RWE data and assess what **standard of care is actually performed today** in hospital outpatient centers and physician offices.
Part 2	Gather and evaluate existing guidance documents, clinical guidelines, Medicare and commercial payer coverage policies, publications, etc.. to compare/contrast **how SOC is defined by clinical and payer policy guidelines**.
Part 3	Build **consensus of SOC** across chronic wound indications and publish results.

Current Progress

- Initial Kick-Off Meeting held with group or individual members
- Systematic Literature Review Process Worksheet distributed to team for feedback
- Designated different documents for review to team, along with excel spreadsheets
- Next Virtual Meeting August 8th
- Review of Documents to be completed by September 5th

RWE Projects Timeline



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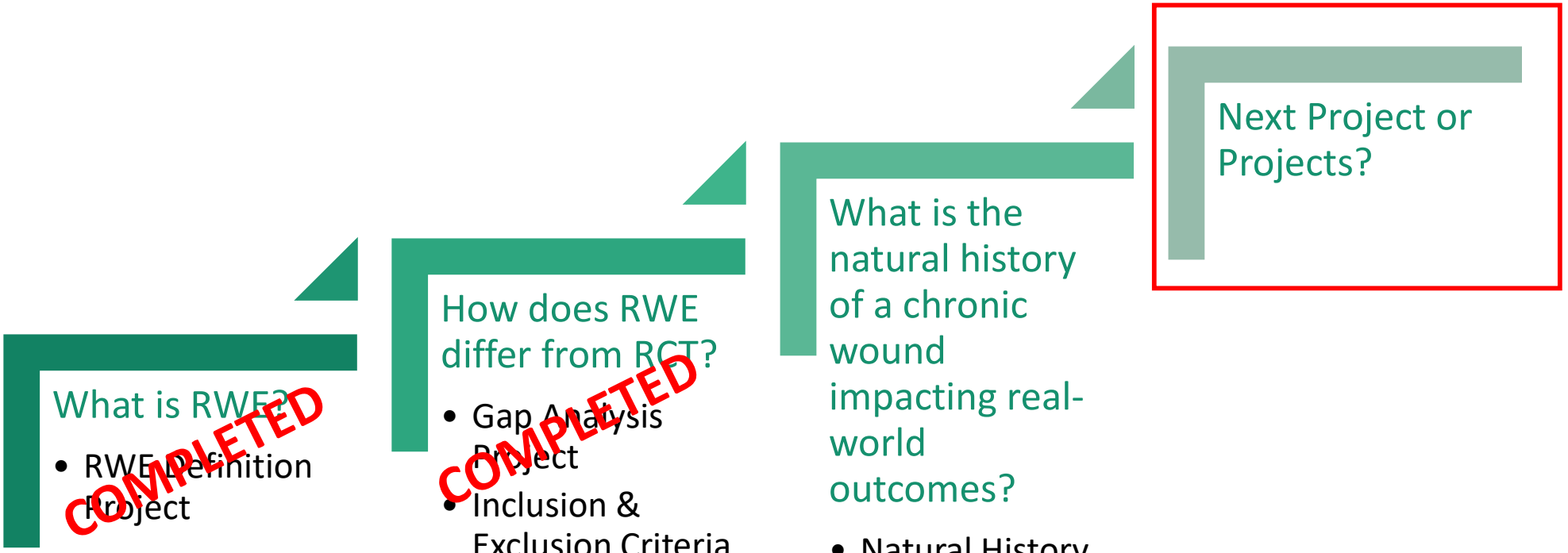
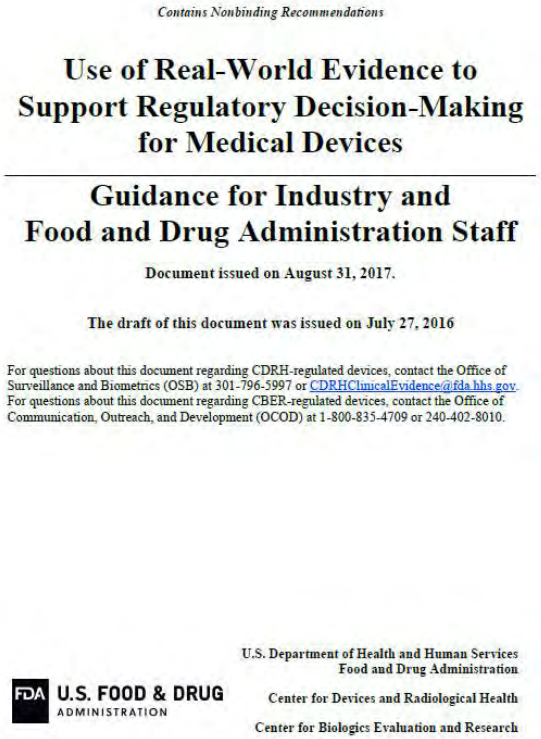
RWE Group Update to WCCC Board of Directors March 2023

WHICH PROJECTS TO CONTINUE OUR JOURNEY?



Our RWE Projects Should be Framed Around FDA RWE Guidance Documents



Contains Nonbinding Recommendations

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

Guidance for Industry and Food and Drug Administration Staff

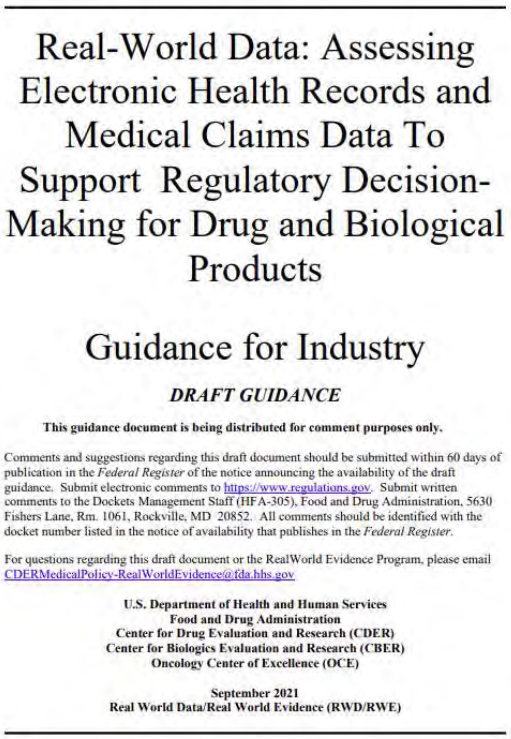
Document issued on August 31, 2017.

The draft of this document was issued on July 27, 2016

For questions about this document regarding CDRH-regulated devices, contact the Office of Surveillance and Biometrics (OSB) at 301-796-5997 or CDRHClinicalEvidence@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research



Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document or the RealWorld Evidence Program, please email CDERMedicalPolicy-RealWorldEvidence@fda.hhs.gov

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Oncology Center of Excellence (OCE)

September 2021
Real World Data/Real World Evidence (RWD/RWE)

Documents provide guidance on:

- ✓ Whether RWD are 'fit for use'
- ✓ Whether a trial or study design used to generate RWE can provide adequate scientific evidence to answer or help answer the regulatory question
- ✓ Whether a study conduct meets FDA regulatory requirements (e.g., for study monitoring and data collection)

FDA: Regulatory Context in Which RWE May be Used

Which of these regulatory decisions based on RWD are of highest priority?

1. Generating hypotheses to be tested in a prospective clinical study
2. As a historical control, a prior in a Bayesian trial, or as one source of data in a hierarchical model or a hybrid data synthesis
3. As a concurrent control group or as a mechanism for collecting data related to a clinical study to support device approval or clearance in a setting where a registry or some other systematic data collection mechanism exists
4. As evidence to identify, demonstrate, or support the clinical validity of a biomarker
5. As evidence to support approval or granting of an Humanitarian Device Exemption, Premarket Approval Application (PMA), or De Novo request
6. As support for a petition for reclassification of a medical device under section 513(e) or (f)(3) of the FD&C Act
7. As evidence for expanding the labeling of a device to include additional indications for use or to update the labeling to include new information on safety and effectiveness
8. For public health surveillance efforts. Through ongoing surveillance, signals are at times identified that suggest there may be a safety issue with a medical device. RWE may be used to refine these signals for purposes of informing appropriate corrective actions and communication
9. To conduct post-approval studies that are imposed as a condition of device approval or to potentially preclude the need for post market surveillance studies ordered under section 522 of the FD&C Act

Sub-Group Recommendations for Projects 2023+

What do real world patients look like?

- Natural History Project

What is the true standard of care today?

- Usual Best Care Project

Which patients benefit from immediate access to advanced care?

- Conservative Treatment Period Challenge Project

What specific RWD/RWE meets FDA thresholds for regulatory decisions?

- Fit for Purpose Project

Usual Best Care Project

- Replace ill-defined "standard of care" with consensus “Usual Best Care"
- Develop specifically defined Usual Best Care for diabetic, venous, arterial, pressure, and mixed etiology ulcers including:
  - Minimal required diagnostic tests
  - Specifications of standard (non advanced) interventions and technologies
  - Wound progression metrics (biomarker-based?)
  - Definition of non progression

Conservative Treatment Period Challenge Project

- Challenge the “30 day conservative treatment followed by 12 -16 weeks of advanced car” paradigm.
- Create a decision algorithm that identifies chronic wound patients that:
  - Are likely to heal with "usual best care"
  - Are likely to never heal
  - Are likely to benefit with immediate access to advanced treatments

Fit for Purpose Project

- Expand the use of RWD/RWE in regulatory decision making
- Gain agreement on:
  - The type of RWD that would be "fit for purpose" and meet the threshold of "sufficient quality, relevance and reliability"
  - The type of RWE to demonstrate safety and effectiveness for labeling expansion decisions, among others.
- Create a toolkit for study sponsors for:
  - Creating RCTs with pragmatic features that allow for generalizability of results
  - Qualifying existing real-world databases and designing new RW studies and registries that meet FDA's quality, relevance and reliability thresholds

GROUP RATINGS SO FAR

Natural History Project Update

- Overall project cost estimate of $250k requires us to segment the project into prioritized deliverables over the next 12 – 36 months
  - We may lose some efficiencies, but gain a hedge if early findings do not provide meaningful results
- Exploring potential databases and vendors
  - NetHealth
  - USWR
  - NESTcc
  - Medicare claims databases?
- Bridge-to-Data (Database profiling service)
  - Obtaining a quote within next 2 weeks to conduct database vendor search
  - Expect cost to be between $12k and $20k
  - Once we have a refined, prioritized vendor list, submission of Requests for Information will follow
- Natural History Project plan will be segmented and restructured based on available evidence and sources
  - Requests for Quotation to be issued to select data vendors including USWR and NetHealth

Our Goal

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

Tools Work Group

- 2023 Objectives:
  - Complete a review of the provided data from manufactures on their devices [evidence, testing, publications, clinical uses]
  - Establish similarities & potential quantification of testing per technology types
  - Work through the potential Pfizer/ DiME collaboration to review their evaluation of imaging devices
  - Compare data sources, develop a working list of requirements for validation of measurement devices for PAR/PVR
  - Incorporate 1 or more patient endpoints w/ PAR/PVR & tools to measure to validate for use in FDA trials
  - Prepare publication of findings as a guidance for future devices

Other Business

- 2023 WCCC Innovations Summit at SAWC Spring 2024
- Q&A
- Discussion

Upcoming Member Meeting Schedule

5pm ET/4pm CT/3pm PT

October 24, 2023

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