

Clinical registry collecting real-world evidence on wound care treatments (SIDDX)

Submission date 06/06/2024	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/06/2024	Overall study status Ongoing	<input checked="" type="checkbox"/> Protocol
Last Edited 11/11/2025	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study will collect data on various wound treatments and their related wound-healing processes in real-life settings.

Who can participate?

All adults requiring wound care

What does the study involve?

Continuation of wound treatment as dictated by the treating physician

What are the possible benefits and risks of participating?

It is hoped that these results will help future participants benefit from an improved wound treatment regime and healing times. Possible risks are allergic or autoimmune response to the biological/synthetic grafts used, since we are strictly observing treatments, the treating providers will be strongly requested to observe for such an incident and report AE/SAE. All products observed are mandated to have FDA clearance, as such risk to the patient is minimal.

Where is the study run from?

Siddhey LLC (United States of America)

When is the study starting and how long is it expected to run for?

April 2024 to March 2029

Who is funding the study?

Siddhey LLC (United States of America)

Who is the main contact?

Mr Chinmay Chauhan (MBA, RN-BSN, BSBE), ChinmayC@siddhey.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Mr Chinmay Chauhan

Contact details

215 E Warm Springs Rd, STE 108

Las Vegas

United States of America

89119

+1 2245581092

chinmayc@siddhey.com

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

NCT06328010

Protocol serial number

Pro00070536

Study information

Scientific Title

An observational clinical registry to collect safety and efficacy data on wound care treatments from a variety of treatment settings

Acronym

SIDDX

Study objectives

The study's primary objection is to collate an observational clinical registry to collect treatment outcomes after biological and synthetic amnion grafts. It is hypothesised that wound treatment will reduce healing time by >40%

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 27/09/2023, Advarra IRB (6100 Merriweather Dr., Suite 600, Columbia, MD 21044, United States of America; +1 877-992-4724; adviser@advarra.com), ref: SIDDXAC02

The study will not challenge the treatment practice of physicians treating wound (+), and will only collect data on treatment which has been agreed upon by the physician and patients.

Study design

Multicenter observational study

Primary study design

Observational

Study type(s)

Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied

Improving heal rate in wound care

Interventions

This is a multicenter observational study enrolling deidentified patients that will collect data on the healing rate of wounds and wound care between the standard of care and many advanced therapeutic interventions.

Physicians, APRNs, and PAs treating patients for any type of "wound" care resulting from conditions such as diabetes, vascular insufficiency, dermatological conditions, or from trauma, surgical/post-surgical events, chemotherapy, burns, and degloving will be observed. The two treatment methods observed will be standard of care (SOC) and treatment with biological or synthetic grafts (advanced treatment modality). The timeframe of 12 weeks (1/week 10 treatment = 10 weeks and 2 weeks post closure/end of 10 weeks follow up) at maximum will be observed. This data will be analyzed to determine the rate of healing via the use of advanced treatment modalities. Since the observational study will not dictate therapy, and very few IC/EC this will be as close to real-world evidence data that can be gathered.

Intervention Type

Biological/Vaccine

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Cellular, Acellular, and Matrix like Products (CAMPs) amniotic tissue products

Primary outcome(s)

The rate of wound healing measured using data documented during every treatment visit (once per week), first is 20% healed, next is 50% compared to week 1, and lastly 100%

Key secondary outcome(s)

The rate of wound healing measured using data collected every week for a maximum of 10 weeks to achieve wound closure (100%), based on the assumption of one treatment (encounter) per week

Completion date

31/03/2030

Eligibility

Key inclusion criteria

1. Aged ≥ 18 years of age
2. Ulcer or a chronic wound, including an ulcer (diabetic foot ulcer, venous stasis ulcer, etc.), injury (trauma, post-surgical, Mohs surgery treatment), burns injury, and acute/chronic wounds
3. Subject agrees to the use of his health data, including photos of his wound in analysis and publications
4. The subject/subject's legally authorised representative (LAR) must be able to read and understand English and/or Spanish

Participant type(s)

Patient, Population

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

99 years

Sex

All

Total final enrolment

0

Key exclusion criteria

The subject/subject's legally authorised representative (LAR) is unable to read and understand English or Spanish.

Date of first enrolment

01/04/2024

Date of final enrolment

30/06/2029

Locations**Countries of recruitment**

United States of America

Study participating centre

Pulse Cardiovascular Institute

Scottsdale, AZ

Scottsdale

United States of America
85251

Study participating centre

Metro Foot & Ankle

Tempe

Tempe, AZ

United States of America

85282

Study participating centre

Pima Foot and Ankle Surgery LLC

Tucson, AZ

Tucson

United States of America

85718

Study participating centre

Signature Health Medical Group

Riverside, CA

Riverside

United States of America

92503

Study participating centre

The Schottenstein Center

Hallandale, FL

Hallandale

United States of America

33009

Study participating centre

The Schottenstein Center

Miami, FL

Miami

United States of America

33137

Study participating centre

PerfectFeetCare Podiatry Centers

Hialeah, FL

Hialeah

United States of America

33012

Study participating centre**PerfectFeetCare Podiatry Centers**

Miami, FL

Miami

United States of America

33175

Study participating centre**Rubin Foot & Ankle**

Naperville, IL

Naperville

United States of America

60563

Study participating centre**The Rache Clinic**

Las Vegas, NV

Las Vegas

United States of America

89147

Sponsor information

Organisation

Siddhey LLC

Funder(s)

Funder type

Industry

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Chinmay Chauhan (MBA, RN-BSN, BSBE), ChinmayC@siddhey.com. IPD and analytics will be stored in a secured web server located at <https://www.siddhey.com> and will only be made available to contracted manufacturers and any healthcare governing bodies.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Informed Consent Form	10/07/2024	16/07/2024	No	No
Participant information sheet		08/01/2008	18/06/2024	No	Yes
Protocol file		27/09/2023	18/06/2024	No	No