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

**Submission date**
06/06/2024

**Recruitment status**
Recruiting

**Registration date**
18/06/2024

**Overall study status**
Ongoing

**Last Edited**
11/11/2025

**Condition category**
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

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# Additional identifiers

**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**
Tuson, AZ
Tuson
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**
Siddhey LLC

## 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 |