

Supplement 1. Variables Collected

DATA VARIABLE	TEMPORALITY			SOURCE			
	HISTORICAL	ENROLLMENT	PROSPECTIVE	HCP (ECRF)	EMR	PATIENT	CLAIMS (opt)
I. Registration Information							
Participant's unique ID and PIN		X		X		X	
II. Clinical Trial/Registry Study Participation							
Participant's involvement in any clinical trials (past, present, or future)	X	X	X			X	
Date of enrollment in the DFU registry		X		X	X	X	
III. Patient History/Demographics							
Age, gender, race, ethnicity		X		X	X	X	X
Education level		X		X		X	
Employment status (full-time, part-time, or retired)							
Type of employment (does it involve being on their feet)	X	X	X	X		X	
Self-income level - Optional		X	X			X	
Household/family income level	X	X	X			X	
Are you the breadwinner?	X	X	X			X	
Time taken off work due to DFU (over what period of time to be specified at each "temporality")							
Absenteeism questionnaire	X	X	X			X	
Time taken off work due to other illness (over what period of time to be specified at each "temporality")	X	X	X			X	
Languages spoken	X	X		X		X	
Presence of a caregiver (full-time, part-time, or independent)							
What is the relationship to the caregiver? (Spouse, child, professional, etc.)	X	X	X	X		X	
Marital status	X	X	X		X	X	
Housing stability		X				X	
Do you live with any loved ones? Whom?	X	X	X	X		X	
Do you leave the house other than for doctors' appointments?	X	X	X	X		X	

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Do you take vacations?	X	X	X	X		X	
Location of clinic where they are being enrolled into STEADY (state; urban, suburban or rural; academic vs. community clinic; remote/at-home)		X	X	X	X	X	X
Time it takes to get to clinic	X	X	X	X		X	X
Means of transportation to clinic (bus, subway, car, uber, walking, biking, N/A-at home care, etc.)		X	X	X		X	
Location of podiatrist (state; urban, suburban or rural; academic vs. community clinic)		X	X	X		X	X
Time it takes to get to podiatrist	X	X	X	X		X	X
Means of transportation to podiatrist (bus, subway, car, uber, walking, biking, etc.)		X	X	X		X	
Frequency of visiting podiatrist (including date of last visit)		X	X	X	X	X	
Location of primary care provider (state; urban, suburban or rural; academic vs. community clinic)	X	X	X	X	X	X	X
Time it takes to get to PCP	X	X	X	X	X	X	X
Means of transportation to PCP (bus, subway, car, uber, walking, biking, etc.)	X	X	X	X		X	
Frequency of visiting PCP (including date of last visit)	X	X	X	X	X	X	X
Location of endocrinologist (state; urban, suburban or rural; academic vs. community clinic)	X	X	X	X	X	X	X
Time it takes to get to endocrinologist	X	X	X	X	X	X	
Means of transportation to endocrinologist (bus, subway, car, uber, walking, biking, etc.)	X	X	X	X		X	
Frequency of visiting endocrinologist (including date of last visit)	X	X	X	X	X	X	X
Payer information (Medicare, Medicaid, commercial, international, supplemental, dual coverage, etc.)	X	X	X	X	X	X	X

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IV. Disease History-DFU (if more than one DFU, this is completed for each ulcer)							
Date of diagnosis	X	X		X	X	X	X
Cause of ulcer	X	X		X	X	X	
DFU new or recurring	X	X		X	X	X	X
Location on foot or ankle (Ankle: medial-lateral, dorsal-posterior; Foot: heel, medial-lateral, dorsal-plantar, Mid foot: medial-lateral, dorsal-plantar; Forefoot: : medial-lateral, dorsal-plantar; Toes: medial-lateral, dorsal-plantar, end of toe)	X	X		X	X	X	X
V. Medical History							
Comprehensive summary of the medical history including comorbid conditions, medications, allergies, lab results, imaging, diagnostics (arterial, venous, MRI, CT, XRAY), surgical reports, and other ulcers (side)	X	X	X	X	X	X	X
Type of diabetes (type 1, type 2, etc.)	X	X	X	X	X	X	X
Year of diabetes diagnosis	X	X	X	X	X	X	X
A1C level	X	X	X	X	X	X	
Blood Glucose level	X	X	X	X	X	X	
Family history of DFU	X	X	X	X	X	X	X
History of previous DFU, number and dates	X	X	X	X	X	X	X
History of DFU-related infections, surgeries, amputations, and antibiotic use	X	X	X	X	X	X	X
History of other ulcers-related infections, surgeries, amputations, and antibiotic use	X	X	X	X	X	X	X
Presence of Charcot foot or other foot deformities	X	X	X	X	X	X	X
Body weight and BMI	X	X	X	X	X	X	
Smoking status	X	X	X	X	X	X	
Alcohol consumption	X	X	X	X	X	X	
Weight-bearing status (cane, walker, wheelchair, automated wheelchair)	X	X	X	X	X	X	
History of vascular procedures	X		X	X	X	X	

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VI. Wound Characterization							
WIFI class, UT grade, Wagner grade	X	X	X	X	X		
Depth		X	X	X	X		
Partial thickness		X	X	X	X		
Subcutaneous tissue exposed		X	X	X	X		
Muscle exposed		X	X	X	X		
Tendon exposed		X	X	X	X		
Bone exposed		X	X	X	X		
Measurements (length x width; depth)	X	X	X	X	X		
Tissue type in the wound (% granulation, etc.)							
necrotic/granulation/exposed/viable structures		X	X	X	X		
Drainage amount (Taken during dressing change)							
Low – Medium – High							
Characteristics	X	X	X	X	X		
Peri-wound tissue type (caloused, inflamed, macerated)		X	X	X	X		
Edema							
Characteristics: Pitting/non pitting, localized/diffused		X	X	X	X		
Infection							
Mild/Moderate/Severe; Superficial/Deep/Osteomyelitis	X	X	X	X	X	X	X
If infection present: culture info, antibiotics (PO, IV, Topical)	X	X	X	X	X	X	X
Diagnostics (lab results, imaging, diagnostics [arterial, MRI, CT, XRAY], surgical reports)	X	X	X	X	X		X
Diabetic Neuropathy SW Score		X	X	X	X		
VII. Wound Treatment							
Type of debridement							
Debridement's depth	X	X	X	X	X	X	X
Health care facility where debridement is done							

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Health care provider providing care	X	X	X	X	X	X	X
Advanced care received, such as CAMP's, PRP, GF's, NPWT, HBOT, Topical Oxygen, etc.	X	X	X	X	X	X	X
Primary dressing (SOC-moist-gel, foam, etc.) including brand name	X	X	X	X	X	X	X
Secondary dressing (gauze, 4x4, etc.)	X	X	X	X	X	X	X
Compression	X	X	X	X	X	X	X
Offloading method (TCC, boot, shoe)	X	X	X	X	X	X	X
Medications prescribed (class, type, and dosage)	X	X	X	X	X	X	X
VII. Health Care Resource Use							
Number and duration of hospitalizations of any type	X	X	X	X	X	X	X
Number and duration of hospitalizations due to diabetes	X	X	X	X	X	X	X
Number and duration of hospitalizations due to DFU	X	X	X	X	X	X	X
Number of urgent care or ER visits of any type	X	X	X	X	X	X	X
Number of urgent care or ER visits due to diabetes	X	X	X	X	X	X	X
Number of urgent care or ER visits due to DFU	X	X	X	X	X	X	X
Number of HCP office visits of any type	X	X	X	X	X	X	X
Number of HCP office visits due to diabetes	X	X	X	X	X	X	X
Number of HCP office visits due to DFU	X	X	X	X	X	X	X
VIII. Adverse Events							
Type, severity, and outcomes	X	X	X	X	X	X	X
Treatment provided for AE	X	X	X	X	X	X	X

Abbreviations: AE: adverse event; BMI: body mass index; CAMP: cyclic adenosine monophosphate; CT: computed tomography; DFU: diabetic foot ulcer; EMR: electronic medical report; ER: emergency room; FF: forefoot; GF: granulocyte factor; HBOT: hyperbaric oxygen therapy; HCP: healthcare professional; ID: Identity; IV: intravenous; MRI: magnetic resonance imaging; NPWT: negative pressure wound therapy; OR: operating room; PIN: personal identification number; PCP: primary care physician; PMD: primary myxomatous degeneration; PO: orally; PRP: platelet-rich plasma; RF: rearfoot; SOC: System Organ Class; SW: Semmes-Weinstein; TCC: total contact cast; UT: University of Texas; WIfI: wound, ischemia, foot infection.