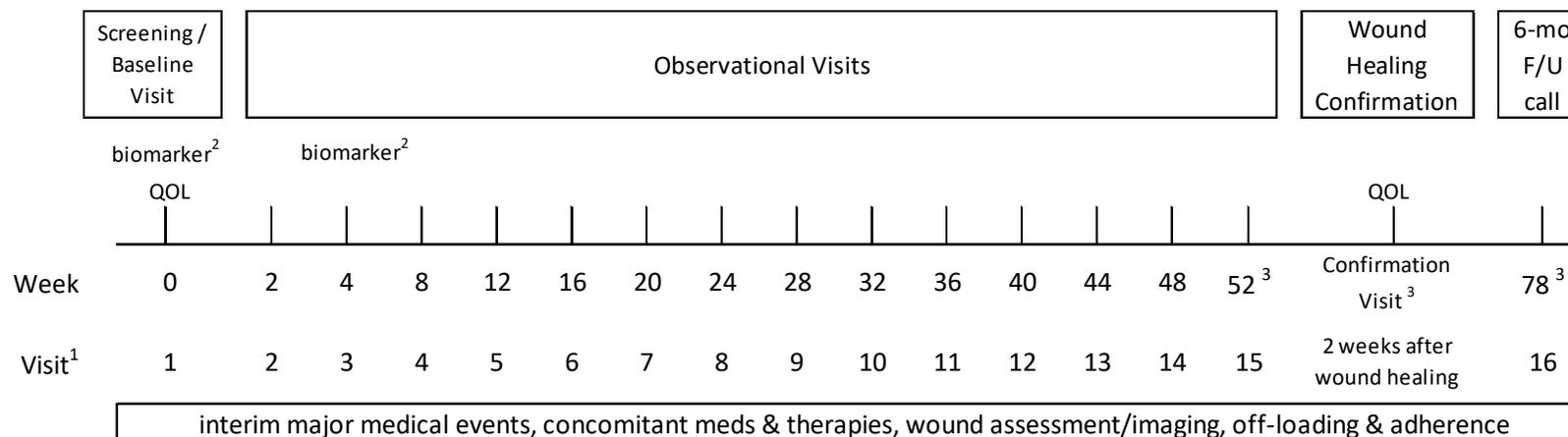


1.2 SCHEMA



¹ Most study visits are in-person clinic visits, except as otherwise indicated in the protocol.

² Biomarkers include blood, wound fluid, wound dressings, wound debridement (as clinically indicated), and urine (optional, but encouraged)

³ For participants whose DFUs have healed prior to week 52, a phone call or video visit should occur at week 52 and 78 to assess recurrence and wound status. For participants whose DFUs have healed at week 52, a phone call or video visit should occur at week 78 to assess recurrence. For participants whose DFUs have not healed by 52 weeks, a 6-month phone call or video visit should occur to assess healing and wound status.

1.3 SCHEDULE OF ACTIVITIES (SOA)

Study Phase	Screening / Baseline	Observational Visits														Wound Healing Confirmation	6-mo Follow-up Call [b] [c]
		2	3	4	5	6	7	8	9	10	11	12	13	14	15 [b] [j]		
Visit	1															Confirmation Visit [a] [b]	16
Week	0	2	4	8	12	16	20	24	28	32	36	40	44	48	52	2 wks after wound healing	78
Study Day	-10 to 0	14	28	56	84	112	140	168	196	224	252	280	208	336	364	14 d after wound healing	546
Visit Window, days	N/A	±7	±7	±7	±7	±7	±7	±7	±7	±7	±7	±7	±7	±7	±7	-3 and +7	±7
Informed Consent	X																
Inclusion/Exclusion Criteria	X																
Demographics and Social Factors [d]	X																
Medical/Surgical/Wound History [e]	X																
Lab Values [f]	X														X		
QOL Assessment (SF-12, DFS-SF) (MNSI both the symptoms questionnaire and the physical examination) [g]	X														X [g]	X [g]	
PROMIS Sleep Disturbance	X														X [g]	X [g]	
Interim Major Medical Events (including adverse events)		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant Medications & Therapies [h]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Focused Physical Exam [i]	X																

Study Phase	Screening / Baseline	Observational Visits														Wound Healing Confirmation	6-mo Follow-up Call [b] [c]
		1	2	3	4	5	6	7	8	9	10	11	12	13	14		
Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15 [b] [j]	Confirmation Visit [a] [b]	16
Week	0	2	4	8	12	16	20	24	28	32	36	40	44	48	52	2 wks after wound healing	78
Study Day	-10 to 0	14	28	56	84	112	140	168	196	224	252	280	208	336	364	14 d after wound healing	546
Visit Window, days	N/A	±7	±7	±7	±7	±7	±7	±7	±7	±7	±7	±7	±7	±7	±7	-3 and +7	±7
Wound Assessment/ Imaging	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X [j]
Wound Debridement as clinically indicated	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Biospecimen collection [k]: Blood	X		X														
Biospecimen collection [k]: Wound materials (fluid, dressings, debridement)	X		X														
Biospecimen collection [k]: Urine (optional but encouraged)	X		X														
Amputation		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Off-loading and Adherence	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
[a] Wound healing confirmation visit occurs 2 weeks after wound closure.																	
[b] For participants whose DFUs have healed prior to week 52, a phone call or video visit should occur at week 52 and 78 to assess recurrence and wound status. For participants whose DFUs have healed at week 52, a phone call or video visit should occur at week 78 to assess recurrence.																	
[c] For participants whose DFUs have not healed by 52 weeks, a 6-month phone call or video visit should occur to assess healing and wound status.																	
[d] Social factors (e.g., SDOH) will be collected via The Social Determinants Battery - Short Form (SDB-SF) administered by the coordinator or directly by the participant, and via EMR extraction of these factors																	
[e] Includes history of previous treatments of diabetic foot ulcers																	
[f] Values are to be collected from the medical record, except for HbA1c which is collected at Visit 1 (if not collected within 3 months of V1 and available in the medical record)																	

Study Phase	Screening / Baseline	Observational Visits														Wound Healing Confirmation	6-mo Follow-up Call [b] [c]
Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15 [b] [j]	Confirmation Visit [a] [b]	16
Week	0	2	4	8	12	16	20	24	28	32	36	40	44	48	52	2 wks after wound healing	78
Study Day	-10 to 0	14	28	56	84	112	140	168	196	224	252	280	208	336	364	14 d after wound healing	546
Visit Window, days	N/A	±7	±7	±7	±7	±7	±7	±7	±7	±7	±7	±7	±7	±7	±7	-3 and +7	±7
Lab Values for week 52 will be collected from participant’s chart only. Values recorded should be within the previous 3 months of V15; however, if 3-month values are not available values within the previous 6 months of V15 is acceptable.																	
[g] SF-12 = Medical Outcomes Study Short Form; DFS-SF = Diabetic Foot Ulcer Scale-short form. These and the PROMIS instrument are collected at the Confirmation Visit for those whose index DFU has healed and at Week 52 for those whose index DFU has not healed by Week 52. Additional patient questionnaires may be obtained at these or other visits.																	
[h] Standard of care medications and therapies will begin after baseline assessments are collected																	
[i] Description of focused physical exam in section 8.1.7; it includes a vascular and neurologic evaluation																	
[j] Wound assessment will be made via phone call or video visit and no imaging will be performed. For participants whose DFUs have healed prior to week 52, a phone call or video visit should occur at week 52 and 78 to assess recurrence and wound status																	
[k] Blood (for serum and plasma) and urine samples (optional, if participant agrees to provide) are obtained at Visits 1 and 3. Wound materials include wound fluid, dressings that have been in direct contact with wound and show evidence of wound slough or drainage, and wound tissue debrided in the course of the participant’s clinical care. Additional biospecimens may be obtained at these or other visits for appendix protocols.																	