

Official Title: A Phase 3 Multicenter, Single-Arm, Open-Label Study
Evaluating the Safety, Tolerability and Efficacy of StrataGraft® Construct in
Pediatric Subjects with Deep Partial Thickness (DPT) Thermal Burns

NCT Number: NCT05517902

Document, Version and Date: Statistical Analysis Plan, Version 1.0, 03 July 2024



9201 Corporate Boulevard

Suite 350

Rockville, MD 20850

Tel.: (301)294-6226

Fax: (301)294-4561

Email: [REDACTED]

Memo

To: Trial Master File – 01 DIA eTMF_Gen Section - 11 Statistics - 11.01 Statistics Oversight - 11.01.01 Statistical Analysis Plan

From: [REDACTED]

CC: [REDACTED]
[REDACTED]

Date: 03Jul2024

Re: MNK15011001 – Statistical Analysis Plan

As of January 2024, the decision was made to close enrollment to the MNK15011001 study. Due to only 1 subject enrolled in the study, there will be no formal analyses performed on the study data. As such, this memo serves as the Statistical Analysis Plan (SAP).

Listings will be produced for all data collected from the eCRF and external laboratory transfers for subject [REDACTED]. No other outputs are planned.

A table of contents of the planned output is in the following table. The file name will be provided as the [text].pdf with corresponding program file [text].txt. Study Data Tabulation Model (SDTM) datasets will be provided as .sas7bdat and .xpt files with corresponding specifications as an Excel file. Per the sponsor, there will be no ADaM datasets, define.xml files, reviewer's guides, nor SDTM annotated eCRF required. All datasets, planned output, and corresponding SAS programs will be provided to the sponsor via Mallinckrodt Secure File Transfer Protocol (SFTP) and will not be filed in the eTMF.

Planned Output:


Number	Title	CRFs / Data Source	File Name (.pdf) and Program Name (.txt)
Listing 16.2.1	Screening Status	Screen Status	I-16-2-1-screen
Listing 16.2.2	Protocol Deviations	Protocol Deviations, Protocol Deviation Clinical Trial Management System (CTMS) Transfer	I-16-2-2-dv

Number	Title	CRFs / Data Source	File Name (.pdf) and Program Name (.txt)
Listing 16.2.3.1	Subject Disposition	Informed Consent, Enrollment, Protocol Reconsent, End of Study	I-16-2-3-1-ds
Listing 16.2.3.2	Date of Visit	Date of Visit, Continuing to Visit	I-16-2-3-2-visit
Listing 16.2.3.3	Log Summary	Log Summary	I-16-2-3-3-log
Listing 16.2.4.1	Demographics	Demographics, Child Bearing Potential	I-16-2-4-1-dm
Listing 16.2.4.2	Medical History	Medical History	I-16-2-4-2-mh
Listing 16.2.4.3.1	Prior and Concomitant Medications	Concomitant Medications	I-16-2-4-3-1-cm
Listing 16.2.4.3.2	Concomitant Procedures	Concomitant Procedures	I-16-2-4-3-2-cp
Listing 16.2.4.3.3	Non-Drug Therapies	Non-Drug Therapies	I-16-2-4-3-3-non-drug
Listing 16.2.4.4	Acute Burn History	Acute Burn History	I-16-2-4-4-bh
Listing 16.2.4.5	Burn Wounds at Screening and Re-Assessment	Burn Wounds at Screening, Re-Assessment of Burn Wounds	I-16-2-4-5-bw
Listing 16.2.4.6	Study Treatment Site Identification	Study Treatment Site Identification	I-16-2-4-6-trt-id
Listing 16.2.4.7	Photography of Study Treatment Sites	Photography of Study Treatment Sites	I-16-2-4-7-photo
Listing 16.2.5.1	Treatments for Other Non-Study Site Burn Areas	Treatments for Other Non-Study Site Burn Areas	I-16-2-5-1-trt-other
Listing 16.2.5.2	Study Treatment Placement	Study Treatment Placement	I-16-2-5-2-trt-place
Listing 16.2.5.3	StrataGraft Disposition	StrataGraft Disposition	I-16-2-5-3-strata-disp
Listing 16.2.5.4	StrataGraft Thaw Time and Supply	StrataGraft Thaw Time and Supply	I-16-2-5-4-strata-thaw
Listing 16.2.5.5	Solutions Used	Solutions Used	I-16-2-5-5-solution
Listing 16.2.5.6	Additional Autografting of Treatment Sites	Additional Autografting of Treatment Sites	I-16-2-5-6-add-auto
Listing 16.2.6.1	Infection Assessment of	Infection Assessment of Study Treatment Sites	I-16-2-6-1-inf

Number	Title	CRFs / Data Source	File Name (.pdf) and Program Name (.txt)
	Study Treatment Sites		
Listing 16.2.6.2	Wound Closure Assessment	Wound Closure, Continued Wound Closure Assessment	I-16-2-6-2-wc
Listing 16.2.6.3.1	Initial Study Site Hospitalization	Initial Study Site Hospitalization	I-16-2-6-3-1-init-hosp
Listing 16.2.6.3.2	Additional Hospitalizations	Additional Hospitalizations	I-16-2-6-3-2-add-hosp
Listing 16.2.6.4	POSAS – Patient Scale	POSAS – Patient Scale	I-16-2-6-4-posas
Listing 16.2.6.5	POSAS – Observer Scar Assessment Questionnaire	POSAS – Observer Scar Assessment Questionnaire	I-16-2-6-5-posas
Listing 16.2.6.6	PSAQ – Patient Scar Assessment Questionnaire	PSAQ – Patient Scar Assessment Questionnaire	I-16-2-6-6-psaq
Listing 16.2.6.7	Evendol Pain Scale	Evendol Pain Scale	I-16-2-6-7-evandol
Listing 16.2.6.8	Pain Assessment	Pain Assessment	I-16-2-6-8-pain
Listing 16.2.7.1	Adverse Events	Adverse Events	I-16-2-7-1-ae
Listing 16.2.7.2	Serious Adverse Events	Adverse Events	I-16-2-7-2-sae
Listing 16.2.7.3	Adverse Events Leading to Discontinuation	Adverse Events	I-16-2-7-3-aedisc
Listing 16.2.8.1	Chemistry Laboratory Results	Lab Summary, Local Chemistry, Lab Vendor Transfer	I-16-2-8-1-chem
Listing 16.2.8.2	Hematology Laboratory Results	Lab Summary, Local Hematology, Lab Vendor Transfer	I-16-2-8-2-hema
Listing 16.2.8.3	Immunogenicity Laboratory Results	Lab Summary, Lab Vendor Transfer	I-16-2-8-3-immu
Listing 16.2.8.4	Archival Sample Collection	Archival Sample Collection	I-16-2-8-4-arch
Listing 16.2.8.5	Pregnancy Test	Pregnancy Test	I-16-2-8-5-preg
Listing 16.2.9	Vital Signs	Vital Signs	I-16-2-9-vs
Listing 16.2.10	Physical Examination	Physical Examination	I-16-2-10-pe

Signatures:

_____:

DocuSigned by:
 Signer Name: _____
 Signing Reason: I approve this document
 Signing Time: 03-Jul-2024 | 2:14:30 PM EDT
 AB5E0253680E41C5AC79F08422C0D1AF

03-Jul-2024

Date: _____

_____, MS
 DP Clinical, Inc.

_____:

DocuSigned by:
 Signer Name: _____
 Signing Reason: I approve this document
 Signing Time: 03-Jul-2024 | 2:58:24 PM EDT
 9CCE005915234582922510379343B57D

03-Jul-2024

Date: _____

_____, MPH
 DP Clinical, Inc.

_____:

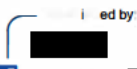


DocuSigned by:
 Signer Name: _____
 Signing Reason: I approve this document
 Signing Time: 03-Jul-2024 | 2:23:59 PM EDT
 98C58F586F5840ADBEC537D88147FC1B

03-Jul-2024


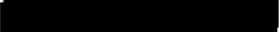
Date: _____

 DP Clinical, Inc.

Sponsor:

ed by

Signer Name: 
Signing Reason: I approve this document
Signing Time: 03-Jul-2024 | 2:32:03 PM EDT
27482BA1EECE4923B709D873EF584E2F

Date: 03-Jul-2024

, PhD
Mallinckrodt Pharmaceuticals


Approved