

## **Data Transfer Agreement (DTA)**

Between Beren Therapeutics, P.B.C. and Grifols Laboratory Solutions

Sponsor: Beren Therapeutics, P.B.C.

Protocol: TAU-001

Version: v1.0 08-Sep-2021

## SIGNATURE APPROVAL

The signatures below indicate approval of the Data Transfer Agreement between Grifols and Beren Therapeutics with specifications described herein.

Joel Gutierrez

Clinical Data Manager

Beren Therapeutics, P.B.C.



Electronically  
signed by: Joel  
Gutierrez  
Reason: Author  
Date: Sep 10,  
2021 09:51 PDT

10-Sep-2021

Signature

Date

Suman Bhattacharya

SVP, Head of Biometrics, Data

Management, Digital Health,

And Informatics

Beren Therapeutics, P.B.C.



Electronically  
signed by: Suman  
Bhattacharya  
Reason:  
Approver  
Date: Sep 10,  
2021 09:05 PDT

10-Sep-2021

Signature

Date

Marianne Stef

Technical Supervisor

Grifols Laboratory Solutions



Electronically  
signed by:  
Marianne Stef  
Reason:  
Approver  
Date: Sep 10,  
2021 08:15 CDT

10-Sep-2021

Signature

Date

**REVISION HISTORY**

Version	Revision Date	Description of Change
v1.0	08-Sep-2021	Initial Draft

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## 1 BEREN THERAPEUTICS CONTACT INFORMATION

Company Name: Beren Therapeutics, P.B.C.	Contact Name: Joel Gutierrez
Address: 9200 W Sunset Blvd., Ste 1010 West Hollywood, CA 90069-3502	Telephone Number: 909-235-6833
Fax Number: N/A	e-mail Address: jgutierrez@berentx.com

## 2 GRIFOLS CONTACT INFORMATION

Company Name: Grifols Laboratory Solutions, Inc.	Contact Name: Marianne Stef
Address: 201 Carlson Circle	Telephone Number: 512-749-1649
Fax Number: 512-749-1677	e-mail Address: Marianne.stef@grifols.com

## 3 OBJECTIVE

The objective of the data transmission is to transmit electronic ApoE data from Grifols (external vendor) to Beren Therapeutics for the TAU-001 study, where Beren Therapeutics is designated as the electronic data recipient.

Beren is responsible for handling the electronic data received and converting the format of the data from the original format type to SAS datasets. A validated SAS program will be developed by a SAS programmer and reviewed by a second party SAS programmer to ensure that the received electronic data is accurately uploaded to the study file on the Beren network. However, the integrity of the actual data itself is the sole responsibility of the external vendor. This document describes the specifications that will govern all transfers for the ApoE data.

## 4 REQUIREMENTS

FILE TRANSFER REQUIREMENTS		
1	Data Sender	Grifols Laboratory Solutions
2	Data Recipient	Beren Therapeutics
3	Anticipated Date of First Data Transfer	Q4 2021
4	File Transfer Frequency	<input checked="" type="checkbox"/> Per Batch <input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> End of Study
5	Method of Transfer	Primary method: Upload to Secure Box location Backup method: Password protected Zip File sent via Email
6	Transfer Type	Cumulative
7	Compression (e.g. Zip)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
8	sFTP Encryption	Yes <input type="checkbox"/> No <input type="checkbox"/> Description of encryption: N/A
9	File Format	<div> <input type="checkbox"/> ASCII  <input type="checkbox"/> XML  <input type="checkbox"/> Binary  <input type="checkbox"/> Text           </div> <div> <input type="checkbox"/> SAS Transfer Format  <input type="checkbox"/> Reference Ranges  <input checked="" type="checkbox"/> Other –Please specify:              .CSV           </div>
10	Delimiter to be Used for Text Files	<div> <input type="checkbox"/> Vertical Bar  <input type="checkbox"/> Arrobas (@)  <input checked="" type="checkbox"/> Comma*  <input type="checkbox"/> Tab  <input type="checkbox"/> Space*  <input type="checkbox"/> Semi-colon*           </div> <div> <input type="checkbox"/> NA  <input type="checkbox"/> Other –Please specify:    <i>* Please note that some results, test names, or cancellations, can have this delimiter in them.</i> </div>

## 5 DATA TYPES

The data types that will be sent to Beren include ApoE data in a data-listing format as described herein.

## 6 ACCESS CONTROL

Data will be managed under strict data access controls.

The following Beren team members will be granted access to the transferred data:

- Suman Bhattacharya
- Joel Gutierrez
- Hannes Holste
- Peter DUEWELL
- Silke Raffegerst

## 7 DATA FORMAT AND FILE NAMING CONVENTIONS

### 7.1 APOE DATA LISTING

The data listing will be transferred in example: .csv

Files will be named as follows: TAU-001\_APOE\_YYYY-MM-DD.csv

The data listing will contain the following variables:

Variable Label	Example
Subject ID	XXX-XXX
Collection Date	YYYY-Mon-DD
Collection Time	24HH:MM
External ID	GDS-YY-XXXXX
SNP at position 388 T > C (rs429358)	C (50)
SNP at position 526 C > T (rs7412)	C (50)
Results	E3/E3

### 7.2 POSSIBLE RESULTS FOR SNPs

SNP at position 388 T > C (rs429358)
SNP at position 526 C > T (rs7412)

C (XX) : Homozygous C Call; XX represents the quality value of the call

T (XX) : Homozygous T Call; XX represents the quality value of the call

Y (XX) : Heterozygous CT call; XX represents the quality value of the call

## 8 CODE LISTS

### 8.1 RESULTS

	SNP at position 388 T > C (rs429358)	SNP at position 526 C > T (rs7412)
E2/E2	TT	TT
E2/E3	TT	CT (Y)
E3/E3	TT	CC
E3/E4	CT (Y)	CC
E2/E4	CT (Y)	CT (Y)

E4/E4	CC	CC
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## 8.2 PARAMETER

Parameter Name	Parameter Description
APOE	Sanger Sequencing Assay