

Example Data Transfer Agreement

**Version: 1.0  
 Date: YYYY-MM-DD**

**Project name: PROJECTNAME**

**Remote host:** **REMOTEHOSTNAME**

**Sponsor: SPONSORNAME**

**Document History**

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| --- | --- | --- | --- |
| Version | Author | Date | Change |
| 1 | PMNAME | YYYY-MM-DD | Initial version |

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1. Scope

This Data Transfer Agreement (DTA) describes the content, format, and management of the data transfer from **REMOTEHOST** hereafter named remote host, to Viedoc in support for the below-listed project:

* **Sponsor: SPONSORNAME**
* **Protocol name: PROTOCOLNAME**
* **Company X project code: PTCODE**
* **Type of data: TYPEOFDATA**

The following should be noted:

Company X will begin development of the data transfer process upon receipt of the fully signed DTA.

The remote host is responsible for:

* submitting a test data transfer once the DTA has been finalized.
* the correctness of the data in the test transfer and all subsequent transfers.
* complying with what has been agreed in the DTA.

Company X is responsible for:

* Setting up and verifying the data mapping in Viedoc
* Reviewing the file structure and format of the test file.
* Verifying that the test file is received, and that data can be imported to Viedoc

The results of the test data transfer will be approved by Company X. Should the test data transfer fail, the remote host should solve any discrepancies and re-send the test file until it is accepted by Company X. Company X will confirm in an email to the remote host when the test transfer is accepted.

Modifications to the data transfer will be addressed by an amendment to the DTA. The development of the amended data transfer will follow the same processes described within this document unless otherwise agreed. Company X receives a request to modify the data transfer, then associated costs and timeline adjustments may apply.

1. General Information

|  |  |
| --- | --- |
|  |  |
| **Company X Representative** | Name, Title  Email: email@ companyx.com,  Phone number: +X XXX |
| **Remote host contact** | Name, Title  Email: email@company.com  Phone number: +X XXX  Please copy the following recipients on emails:  name@company.com |
| **Viedoc settings** | Allow data import to create subjects  Allow data import to initiate visits |

1. Transfer Details

|  |  |
| --- | --- |
|  |  |
| **File format** | ASCII, delimiter: “;” text qualifier: “” \*  Headers must be included.  \* Note that the delimiter should not be used anywhere in the file except as a delimiter. Should it be part of a text string, it must be surrounded with the text qualifier. |
| **Transfer frequency** | Once only  Daily  Weekly on:  Upon request  Other, specify: |
| **Mode of transfer** | Email (password protected)  Viedoc Import Application run by remote host  SFTP (automatic upload into Viedoc)\*  API  \* User credentials to be provided separately |
| **Test file mode of transfer** | Email  Same as production |
| **Recipient(s) of the Live transfer** | Not applicable (e.g. file(s) sent directly to Viedoc) |
| **Transfer type** | Cumulative  Incremental |

1. Transfer File Structure
   1. General

|  |  |
| --- | --- |
|  |  |
| **Data file name** | **STUDYNAME YYYY-MM-DD.csv** |
| **Data format** | ”Tall and skinny” (every row contains **only one** data observation along with its meta-data)  ”Short and fat” (every row contains **all** variables for a single time point for a single subject) |
| **Date format** | YYYY-MM-DD (mandatory)  All dates must be in the YYYY-MM-DD format (ISO 8601). |
| **Encoding** | UTF-8  Windows-1252  Other: |
| **Clarifying note(s) if applicable  *(If the data/parts of it should be blinded, please state here who should have read access to the data if any.)*** | |

* 1. File structure

|  |  |  |
| --- | --- | --- |
| **VARIABLE** | **DESCRIPTION** | **DATA TYPE** |
| **SITE** | Site Number | Free text (mandatory) |
| **SCREENNO** | Subject screening number | Free text (mandatory) |
| **VISITID** | Visit ID | Free text. According to Visit mapping table, see 4.2.1 |
| **VISITDAT** | Visit Date | Free text; [YYYY-MM-DD] (mandatory) |
| **SAMPDAT** | Sample Date | Free text; [YYYY-MM-DD] (mandatory) |
| **SAMPTIM** | Sample Time | Free text; [HH:MM] |
| **PARAMETER** | Test Code | Free text. According to Data mapping table, see 4.2.2 |
| **RESULT** | Reported Value | Free text |
| **UNIT** | Reported Unit | Free text |
| **LNL** | Reported Normal Low | Free text |
| **UNL** | Reported Normal High | Free text |
| **OOR** | Out of range | Will be sent as “1” for Yes or “0” for No. |
| **SI\_RES** | SI Value | Free text |
| **SI\_UNIT** | SI Unit | Free text |
| **SI\_LOW** | SI Normal Low | Free text |
| **SI\_HIGH** | SI Normal High | Free text |
| **LABBARCODE** | Accession/requisition No. | Free text (e.g 1309999999, always 10 digits) |
| **COVAL** | Comments | Free text |

Example:  
SITE,SCREENNO,VISITID,VISITDAT,SAMPDAT,SAMPTIM,PARAMETER,RESULT,UNIT,LNL,UNL,OOR,SI\_RES, SI\_UNIT,SI\_LOW,SI\_HIGH,LABBARCODE, COVAL  
001,001-001,SCR,2017-02-10,2017-02-10,20:45,ALT,30,U/L,0,55,0,500,nkat/L,0,917,X246051241, Sample contaminated  
001,001-001,SCR,2017-02-10,2017-02-10,20:45,ALP,120,U/L,40,150,0,2000,nkat/L,667,2500,X246061241

* + 1. Visit mapping table

|  |  |
| --- | --- |
| **VISIT** | **CODED VALUE** |
| **Screening** | E01\_SCR |
| **Visit 1** | E02\_V1 |
| **Visit 2** | E03\_V2 |
| **Visit 3** | E04\_V3 |
| **Visit 4** | E05\_V4 |
| **Visit 5** | E06\_V5 |
| **Visit 6** | E07\_V6 |
| **Visit 7** | E08\_V7 |
| **Visit 8** | E09\_V8 |
| **Visit 9** | E10\_V9 |
| **Follow-up 1** | E16\_F1 |
| **Follow-up 2** | E17\_F2 |
| **End of Study** | E21\_EOS |
| **Early Discontinuation** | E99\_ET |
| **Unscheduled** | E98\_UNS |

All other codes are discarded.

* + 1. Data mapping table

|  |  |  |
| --- | --- | --- |
| **CATEGORY** | **DATA** | **CODED VALUE** |
| **Haematology** | **Erythrocytes** | RBC |
| **Haematology** | **Hemoglobin** | HGB |
| **Haematology** | **Hematocrit** | HCT |
| **Haematology** | **Ery. Mean Corpuscular Volume** | MCV |
| **Haematology** | **Ery.Mean Corpuscular Hemoglobin** | MCH |
| **Haematology** | **Ery. Mean Corpuscular HGB Concentration** | MCHC |
| **Haematology** | **Leukocytes** | WBC |
| **Haematology** | **Neutrophils** | NEUT |
| **Haematology** | **Eosinophils** | EOS |
| **Haematology** | **Basophils** | BASO |
| **Haematology** | **Lymphocytes** | LYM |
| **Haematology** | **Monocytes** | MONO |
| **Haematology** | **Neutrophils/Leukocytes** | NEUTLE |
| **Haematology** | **Eosinophils/Leukocytes** | EOSLE |
| **Haematology** | **Basophils/Leukocytes** | BASOLE |
| **Haematology** | **Lymphocytes/Leukocytes** | LYMLE |
| **Haematology** | **Monocytes/Leukocytes** | MONOLE |
| **Haematology** | **Platelets** | PLAT |
| **Haematology** | **Prothrombin Time** | PT |
| **Haematology** | **Prothrombin Intl. Normalized Ratio** | INR |
| **Haematology** | **Activated Partial Thromboplastin Time** | APTT |
| **Haematology** | **C Reactive Protein** | CRP |
| **Clinical Chemistry** | **Bilirubin** | BILI |
| **Clinical Chemistry** | **Albumin** | ALB |
| **Clinical Chemistry** | **Alkaline Phosphatase** | ALP |
| **Clinical Chemistry** | **Alanine Aminotransferase** | ALT |
| **Clinical Chemistry** | **Aspartate Aminotransferase** | AST |
| **Clinical Chemistry** | **Creatinine** | CREAT |
| **Clinical Chemistry** | **Gamma Glutamyl Transferase** | GGT |
| **Clinical Chemistry** | **Urea Nitrogen** | UREAN |
| **Clinical Chemistry** | **Calcium** | CA |
| **Clinical Chemistry** | **Chloride** | CL |
| **Clinical Chemistry** | **Phosphate** | PHOS |
| **Clinical Chemistry** | **Potassium** | K |
| **Clinical Chemistry** | **Sodium** | SODIUM |
| **Clinical Chemistry** | **Glucose** | GLUC |
| **Clinical Chemistry** | **Protein** | PROT |
| **Clinical Chemistry** | **Thyrotropin** | TSH |
| **Clinical Chemistry** | **Triiodothyronine, Free** | T3FR |
| **Clinical Chemistry** | **Triiodothyronine** | T3 |
| **Clinical Chemistry** | **Thyroxine, Free** | T4FR |
| **Clinical Chemistry** | **Thyroxine** | T4 |
| **Urinalysis** | **pH** | PH |
| **Urinalysis** | **Specific Gravity** | SPGRAV |
| **Urinalysis** | **Erythrocytes** | URBC |
| **Urinalysis** | **Leukocytes** | UWBC |
| **Urinalysis** | **Glucose** | UGLUC |
| **Urinalysis** | **Protein** | UPROT |
| **Urinalysis** | **Bilirubin** | UBILI |
| **Urinalysis** | **Urobilinogen** | UROBIL |
| **Urinalysis** | **Ketones** | KETONES |
| **Urinalysis** | **Nitrite** | NITRITE |

All other codes are discarded.

1. Data Recall and Errors

All errors detected (e.g. by site staff, monitor, sponsor etc.) shall be reported to the remote host. The remote host should correct possible errors and resend a corrected file. The new correct data will over-write and replace the previous incorrect data imported. All changes will be audit trailed in Viedoc.

Company X will not edit any files. All change(s)/corrections must be performed by the remote host.

Data that needs to be recalled or deleted is not covered by this DTA and must be handled manually on a case-by-case basis.

1. Approval

By signing below, I confirm that I have read this Data Transfer Agreement and understand its contents. I agree that this document represents my best understanding of the data transfer user requirements and is in line with my expectations. I further represent that I am the duly authorized individual for the company I represent, with appropriate signature authority therefore.

A copy of the fully executed signature page shall be sent to all signatories upon request.

|  |  |  |
| --- | --- | --- |
| **NAME** | **SIGNATURE** | **DATE** |
| PMNAME Title Company X |  |  |
| NAME Title REMOTEHOST |  |  |
| NAME Title SPONSOR/CRO |  |  |