

**Project: RO30009**

**Protocol: WA21092**

**Customer: Roche**

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Document index:

Document version:

Template version:

Version history

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Date** | **Author** | **Description, changes/updates** |
| 1 | 01-SEP-2014 | Sneha Kamath | Initial Draft |
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Review history

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| --- | --- | --- | --- |
| **Version** | **Date** | **Author** | **Review comments** |
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# Purpose

The purpose of this document is to provide instructions on how to export data in the TrialManager (in test and production environments) and run the post-processor in order to create data transfer files. This document may also provide additional details such as the description of postprocessor log information, specification of system design.

The intended audience of this document consists of personnel at CRF Health, and possible third parties involved in this particular project.

# References, definitions and acronyms

* QMS-0-0 Quality Manual
* QMS-5-2-3 TrialMax Tailoring Process

# Overview

Data collected using CRF Health Electronic Patient Diaries, once submitted to the server by study patients or site personnel is stored in the CRF Health database.

In order to create data transfer files the collected data have to be exported from the study database using TrialManager export functionality. Data export files have to be copied to the relevant data post-processor folder and the postprocessor has to be run in order to convert the input data format to the output data format. Data transfer files are created at the end of data conversion process and then transferred to the client using one of approved transfer methods. More details on each step of data transfer process can be found below.

# Data transfer instructions

## How to get the post-processor package

In order to create data transfer files the latest version of validated post-processor package should be retrieved from the CVS repository:

**prod/proj/ro30009/postprocessor/release/RO30009-EDSSpostprocessor-v1-tst2.zip**

**Relevant structure of the installation package:**

|  |  |
| --- | --- |
| **Config(Folder)** | Holds the configuration files for this study. |
| **input** | Copy data export files into this folder |
| **output** | data transfer files created after processing RO30009PostProc-process.bat (txt format) |
| **RO30009PostProc-process.bat** | Run this to create the transfer files in the output folder |

## How to create data export files

1. Login to TrialManager, select “Management” tab and select “Exports”
2. Select button “Add export” and enter the following export information:

|  |  |
| --- | --- |
| **Name** | the name of data export |
| **Adapter** | *CSV Adapter (\*.csv)* |
| **Options** | *include audit trail* |
| **Delimiter** | *‘t’ (tab)* |
| **Text encoding** | *Default* |
| **Use Tailoring** | *No* |

1. Select button “Create export” in order to create data export files required for data processing
2. Download and unzip data export (e.g. dataexport-csv-XXXXX-YYYYMMDDTHHMMSS.zip)
3. Upload data export files to CVS

## How to create data transfer files

1. Copy extracted data export files into the “input” folder;
2. Run the post-processor by double-clicking on the batch file “**ro30009PostProc-process.bat** "
3. Data transfer files will be created in the post-processor "output" folder
4. Upload the ZIP folder into CVS and commit.

## How to review postprocessor log

In order to review additional information logged by the post-processor please open the file “Logging.txt” in the main post-processor folder.

## How to transfer data

Data transfer files must be sent using only those transfer methods (via sFTP or secure connection to web portal etc.) which are approved by the client. The instructions how to send data transfer files are listed below: