CLARIO.

Instructions for Use

MyDataUploader™

- Online Help

| Respiratory | Cardiac Safety | ePRO |

Centralized Services in Clinical Trials
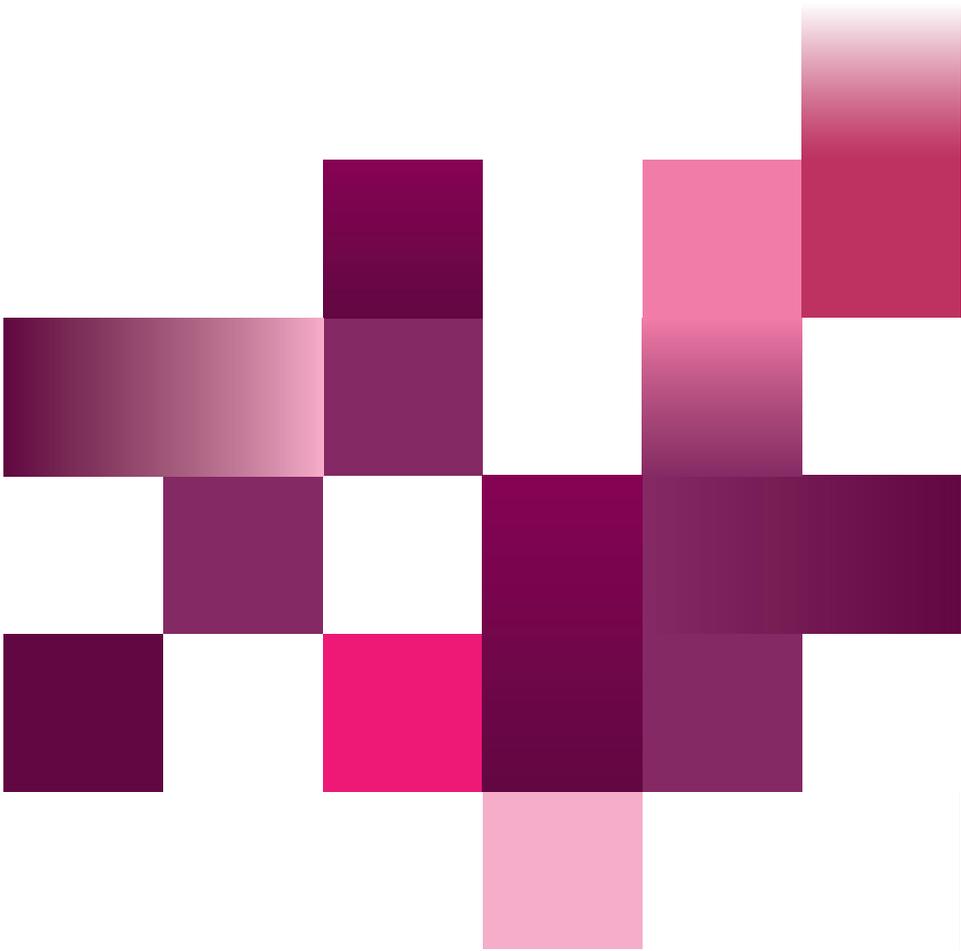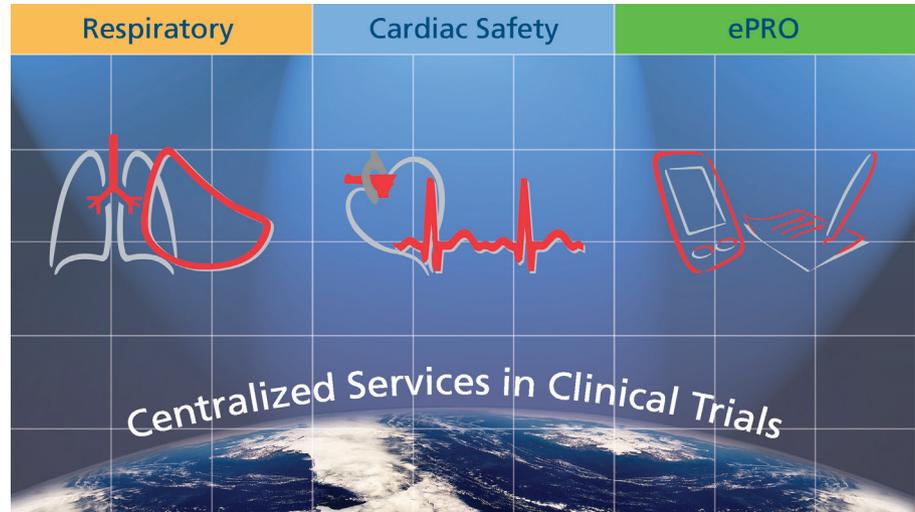
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Notes on Safety in Instructions for Use

Following icons shown in the Instructions for Use:

!			Important and useful information. Information does not warn of dangerous or harmful situations.
!			Hints for use.

Intended Use

The MyDataUploader™ is a web application that offers a possibility to upload clinical data from a transfer medium to the backend system of Clario in a secure way using any available internet connection.

The MyDataUploader™ will be used for clinical trials when centralized processing of Clario authorized devices data is not possible.

Introduction

Ideally, data from your Clario device is transferred to the study database at Clario via modem. But in some instances a modem connection is not possible. For such cases Clario designed a web based tool: **MyDataUploader™**.

The MyDataUploader™ offers an easy, fast and secure way to upload data from your Clario device to the study database of Clario. For this you will additionally need a site-owned computer with internet connection.

A data storage medium (e.g. SD card or USB stick) labeled "Transfer" is used to transport the data between your Clario device and your site-owned computer with internet connection.

Depending on the Clario device in use at your site, two data transfer modes exist:

- **data transfer with Confirmation Code or**
- **data transfer without Confirmation Code**

MyDataUploader™ automatically selects the respective mode for your Clario device in use once the data file has been chosen for upload.

Where applicable MyDataUploader™ creates and displays a Confirmation Code once the data file has been uploaded to the Clario server. This Confirmation Code is to be entered into your Clario device. Please refer to the Instructions for Use manual for your Clario device for further details on how to enter a Confirmation Code.

The following graphs show the workflow of the two modes: **with** Confirmation Code or **without** Confirmation Code.

Workflow, Data Transfer **with** Confirmation Code:

Clario Device	Clario MyDataUploader™ website

1 USB / SD card

Clario Device (laptop)

2

2a) Insert Transfer Medium
2b) Choose Data File

3

3a) <opt.> Enter E-Mail address
3b) Upload Data File

4

4a) Retrieve Confirmation Code
4b) <opt.>E-Mail Conf. Code
4c) <opt.> Print Conf. Code

5 Confirmation Code
32475932

Enter Confirmation Code

Workflow, Data Transfer **without** Confirmation Code:

Clario Device	Clario MyDataUploader™ website

1 USB / SD card

Clario Device (laptop)

2

2a) Insert Transfer Medium
2b) Choose Data File

3

3a) <opt.> Enter E-Mail address
3b) Upload Data File

4 Confirmation "Upload Successful"

4a) E-Mail ERT staff
→ notification of file reception
4b) <opt.> E-Mail Customer
→ confirmation of successful upload

MyDataUploader™ Functions

Preparing for Data Upload

1. Transfer the data from your Clario device to a data storage medium labeled "Transfer" as described in the Instructions for Use manual for your Clario device.

2. Insert the data storage medium labeled "Transfer" containing the data file from your Clario device into your site-owned computer with internet connection.

> **!** If you are using SD cards to transfer the data, please use the SD card reader and the USB extension cable of the SD Transfer Kit, if your computer is not equipped with a SD card reader.

3. Open an internet browser of your choice on your site-owned computer with internet connection and enter the following internet address (URL) to open the MyDataUploader™ website:

    https://mdu.ert.com

    mdu=**m**y**d**ata**u**ploader (MyDataUploader™)

4. Follow the step-by-step instructions shown on the screen of the MyDataUploader™.

Uploading a Data File

5. Browse for the data file on the inserted transfer medium by clicking on the <**Choose File**> button.

6. A window will open to search for the data file. Select the data file stored on the transfer medium and press the button to open the file.

> **!** Only one data file is on the inserted transfer medium.
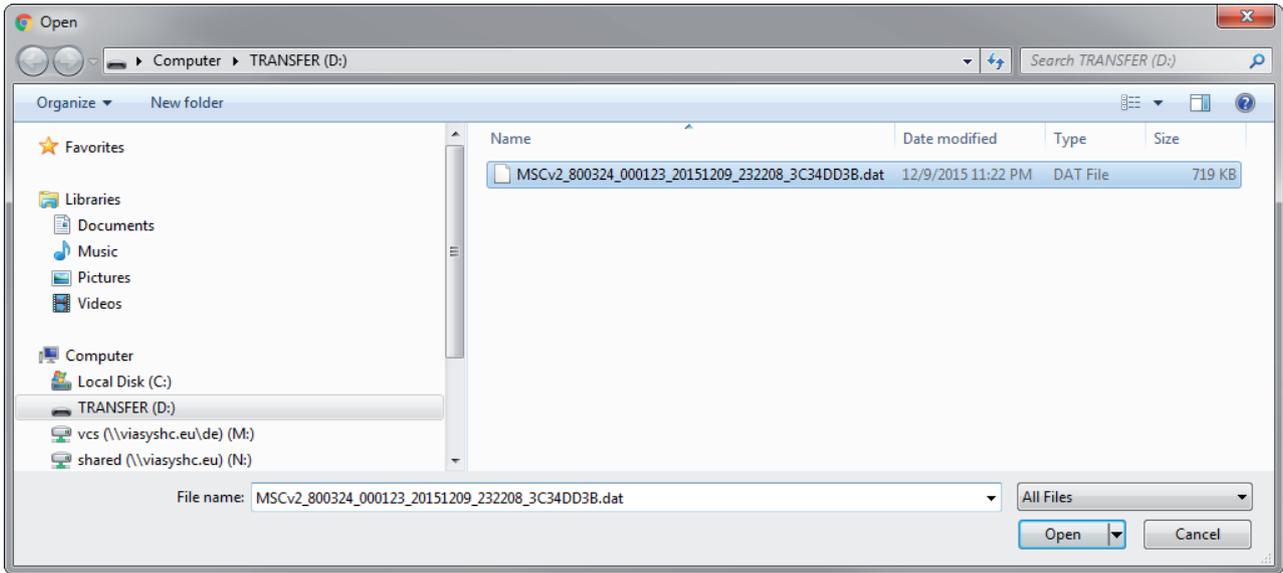
This window depends on the internet browser in use.

7.   After opening the data file, MyDataUploader™ validates the selected data file.
     The progress of this process is shown on the screen.
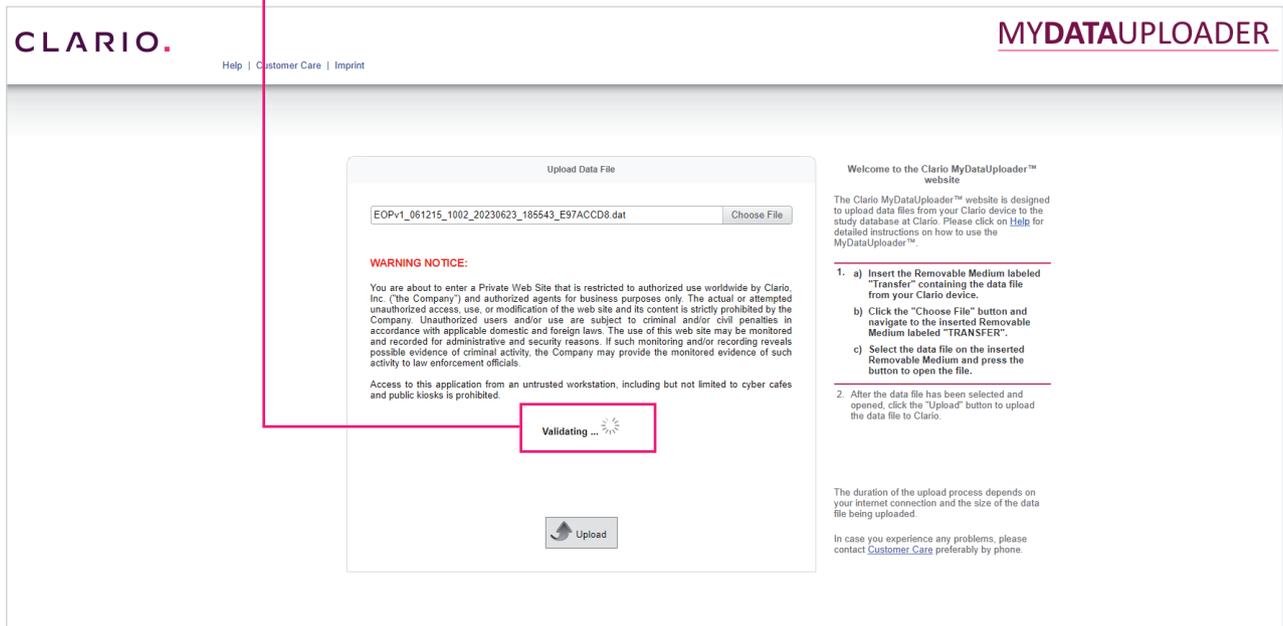
8. If the opened data file is valid, MyDataUploader™ will display this by showing the study information.
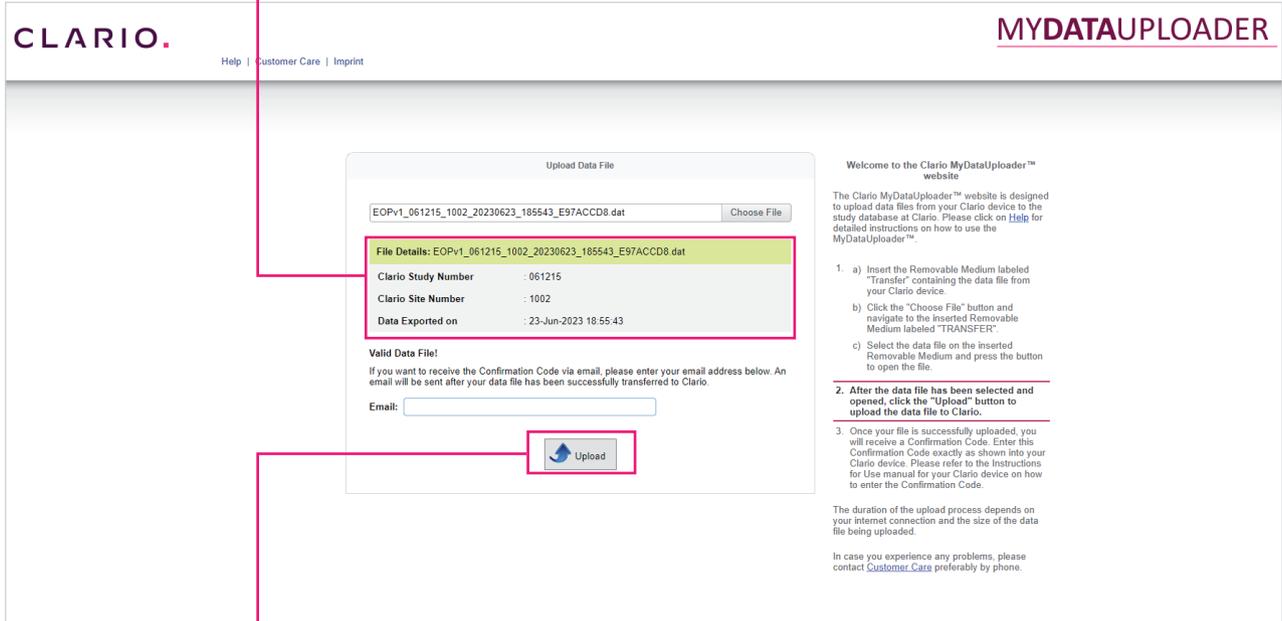
9. Now click the <**Upload**> button to start the process to upload the data file to the Clario server, which is shown on the screen.

The following screen is shown.

> ❗ The duration of the upload process depends on your internet connection and the size of the data file being uploaded.

> ❗ To ensure a successful upload of the data file to the Clario server, please do not disconnect the transfer medium nor remove the transfer medium during the upload process.

10. A message will appear on the screen once the data file has been successfully uploaded and received on the Clario server. MyDataUploader™ now performs an integrity and virus check.

11. The following Screen will appear, as soon as the integrity and virus check has been successfully completed.

12. If a Confirmation Code is displayed as shown above, then either note the code or print it or have it sent to your Email address. This Confirmation Code is to be entered into the Clario device at your site. Please refer to the Instructions for Use manual for your Clario device for further details on how to enter the Confirmation Code.

> ❗ If no Confirmation Code is displayed, it is not required to enter a code into your Clario device.

13. In any case (with or without Confirmation Code), you can either print or email the data transfer information as shown on the MyDataUploader™ screen.
To print the data transfer information, please click the <**Print**> button. This will open your standard printer dialog window and you can proceed as usual.

To Email the data transfer information, enter your email address and press the <**Send Email**> button.

If you want to receive this information via email, please enter your email address and click "Send Email" button.

Email: user@clario.com   Send Email

! **The Confirmation Code is also mailed, if a Confirmation Code is displayed.**
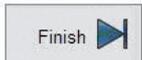
14. To finish the data transfer procedure click the <**Finish**> button.

Possible MyDataUploader™ Errors

Detected Virus

MyDataUploader™ checks the uploaded and received data file for virus infection. If a virus is detected, the MyDataUploader™ will display the following message:

> **!**
> If a virus is detected, Clario will not process the data file any further.
>
> Please contact Clario Customer Care immediately for further advice, preferably by phone.

Invalid Data File

If the data file is invalid, MyDataUploader™ will display the following message:
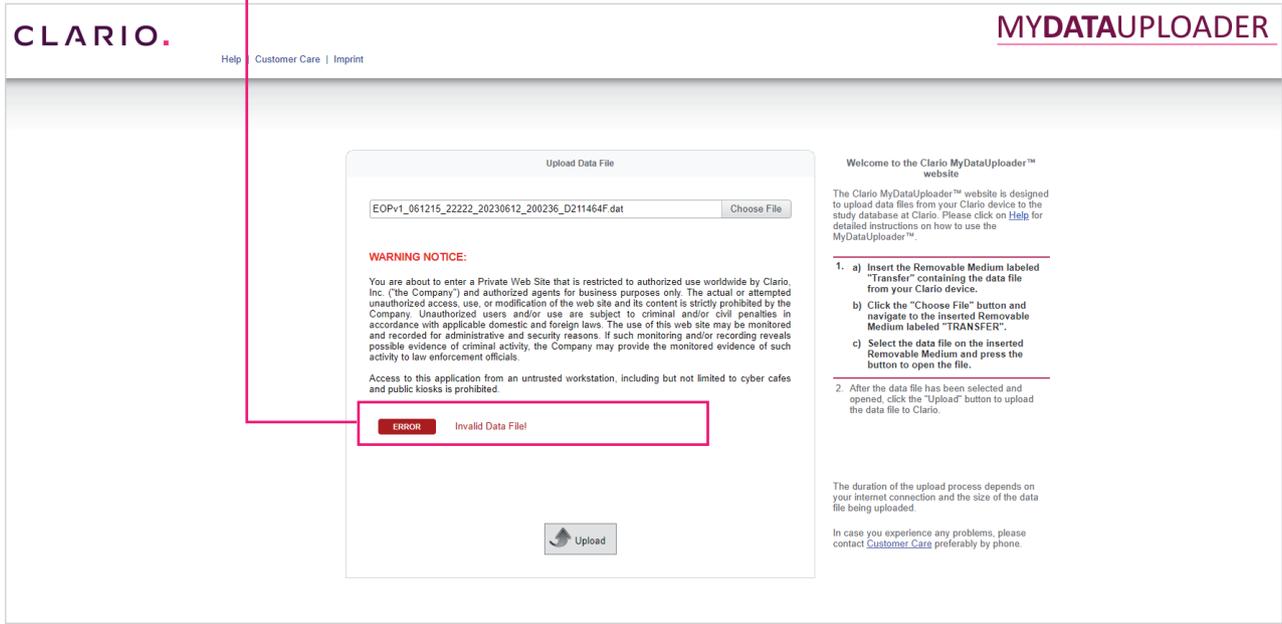
Please assure that a valid data file is uploaded.

Follow the Instructions for Use of your Clario device on how to create and store a data transfer file onto a data storage medium labeled "Transfer" and retry uploading this data file using MyDataUploader™.

> **!** **Never change the file name of the data file and avoid choosing an invalid file.**

Should you receive this error message again, please contact Clario Customer Care for further advice, preferably by phone.

Closing MyDataUploader™ during Upload

If you try to close the internet browser during the upload process the following message will appear:
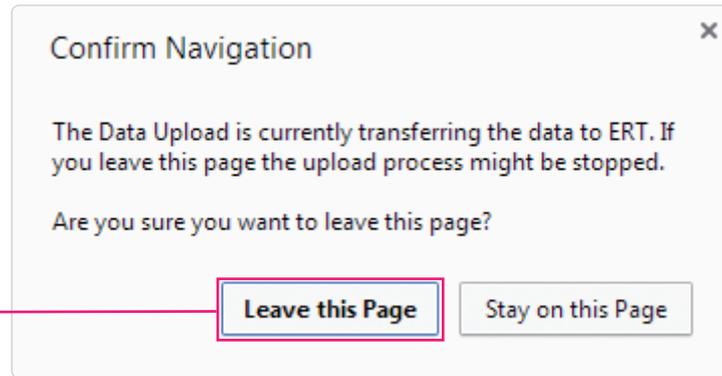
This window depends on the internet browser in use.

If you click the <**Leave this Page**> button the upload process will be stopped and the data file will not be received by Clario.

! Should it anyway be required to stop the data upload process by pressing the <**Leave this Page**> button, you can upload the data file at any time at your convenience.

Retrieving the Confirmation Code

In case of loss or misplacement of the Confirmation Code, you can retrieve the Confirmation Code at any time after you have uploaded a data file. Simply restart the upload process as described in this Online Help manual. After choosing the data file, MyDataUploader™ will display that Clario has already received this data file and will also display the Confirmation Code.

Now you can either note the Confirmation Code or print or Email the data transfer information that also includes the Confirmation Code as described previously in this manual.

FAQ's

1.	Why is the Sponsor Site ID on my Clario device different than the one presented by the MyDataUploader™?
	It is possible that the Sponsor Site ID has been changed on your Clario device and the MyDataUploader™ gets its information from the Clario study database.
2.	What happens if I upload a data file more than once?
	If a data file is uploaded more than once, MyDataUploader™ will recognize this and a message will inform you accordingly. In case that a Confirmation Code has been created and displayed initially, the same Confirmation Code will appear on the screen again.
3.	What happens if I open the MyDataUploader™ in more than one tab using Microsoft Internet Explorer (IE) Versions 6 thru 9?
	It is possible that MyDataUploader™ cannot be opened, if these Microsoft Internet Explorer versions are used. It is recommended not to open more than six ⑥ tabs at the same time.
4.	Which internet browsers are supported by MyDataUploader™?
	Safari Chrome Firefox Internet Explorer

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