

Standard Operating Procedure / Quality Procedure		QPC39	
QPC39 CISCO-19 STUDY PROCEDURE			
Version 2 / October 2020			
Prepared by	Louise Inglis	Signature	Date
Approved by	Professor Macfarlane	Signature	Date

1. SOP Category

ECG Clinical Trials Group.

2. Staff Category

Relevant ECG Clinical Trials Group staff.

3. Scope

The procedure covers actions and processes undertaken by ECG-CTG staff in the management of ECGs in the CISCO-19 Study.

4. Purpose

The purpose of this SOP is to fully describe the management of ECGs for the CISCO-19 Study.

5. Procedures

5.1 Responsibility

The ECG Clinical Trials Manager is responsible for the contents of this procedure and for ensuring that it is followed.

5.2 Actions and Methods

The Electrocardiology (ECG) Core Laboratory will manage, review and Minnesota Code 12 lead/25 mm/s ECGs for all subjects enrolled into the CISCO-19 Study. The study sites are responsible for uploading an XML ECG file to the Robertson Centre for Biostatistics CISCO-19 web-portal on a regular basis. ECG core lab staff will download ECGs from the study web portal. Each study ECG will have the prefix 'CV' added to the front of the ID number, prior to the XML file being added to the ECStore Database. Instructions on how to download, amend and insert CISCO-19 ECGs are available in Appendix A. Instructions for downloading CISCO-19 PDF ECGs are available in Appendix B.

5.3 ECG ID Requirements

The study sites are differentiated by the study site ID (first 3 digits) followed by subject ID numbers (last 3 digits).

Examples:

191001 - Glasgow Queen Elizabeth University Hospital (QEUH)

192001 - Glasgow Royal Infirmary (GRI)

193001 - Paisley Royal Alexandra Hospital

The demographic input requirements for the ECG machines are: Site ID/Subject ID number (6 digits), subject date of birth, sex and race. Age will be automatically created once the date of birth has been entered into the ECG machine. Date of birth format is e.g., 21 07 1990. In accordance with GCP, it is the individual study nurse's responsibility at each site to ensure correct demographic data entry.

Note: The clinical responsibility for ECG review remains with the study Clinician(s) at each site.
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5.3.1 ECG ID Prefix

In order to differentiate the CISCO-19 downloaded ECGs on the ECStore ECG Management System, when they are downloaded from the CISCO-19 web-portal to the Cardiolex ECStore Server, the prefix CV is added to each ECG.

Examples: **CV**191001 (QEUH), **CV**192001 (GRI), **CV**193001 (RAH)

Once the prefix **CV** has been added to each ECG, ECGs will be copied to the EC Store Database as per Appendix A,

5.4 Mindray R3 BeneHeart ECG Machine and Set-up

All study sites have been provided with a copy of the CISCO-19 Study Site ECG Management Manual. A separate 2-page abbreviated document with instructions on how to record an ECG has been provided to sites. Pdf copies of these documents are available at [J:] – MVLPublic (J:) > HW > ECG > ECG > CISCO-19 STUDY DOCUMENTATION.

Technical support is being supplied to study sites via a designated Electrocardiology Group mobile telephone.

The contact tel. number for ECG machine technical issues is: **07738 753847**

5.5 Transmission of ECGs

Good quality 12 lead ECGs should be recorded at study sites using ONLY the R3 BeneHeart ECG machine. ECGs should be saved in XML format onto the USB flashdrive provided and uploaded to the CISCO-19 secure web-portal. Regular transmission is requested from each site to ensure prompt management of ECG recordings and compliance with GCP.

5.6 Receipt of CISCO-19 XML ECGs

Using the instructions in Appendix A, the appropriate ECG core lab staff will check on a regular basis to determine if study ECGs require to be downloaded from the study web-portal facility. If so, ECGs will be downloaded.

5.6.1 CISCO-19 PDF ECGs

Where an ECG has been saved in pdf format in error and uploaded to the CISCO-19 web-portal, the instructions in Appendix B describe how to download and manage the PDF ECGs. The PDF ECGs are located at [J:] – MVLPublic (J:) HW > ECG > CTG > CISCO19-PDFs

5.7 ECG Timelines

Timeline when study ECGs should be recorded:

Enrolment (Visit 1) Hospitalised, COVID-19	28 < Visit 2 < 38 days post discharge (Visit 2) Outpatient	1 year (Visit 3)
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ECGs should be uploaded by site staff to the identified timeline in the ECG web page of the secure CISCO-19 web-portal.

5.8 ECG Quality Control

The ECG core laboratory team will provide feedback to the study sites re the receipt of ECGs, quality of ECGs and quality of demographic ECG data entry via the Robertson Centre for Biostatistics CISCO-19 secure web-portal.

5.9 Paper Copy ECG Management

When the XML ECG files have been downloaded and the prefix CV has been added, the ECGs will be copied into the EC Store ECG Database. An automated paper copy ECG and Minnesota code sheet will be printed in the ECG core laboratory.

5.9.1 Individual Folders

The paper ECG and Minnesota code sheet for new participants will be placed in a plastic folder. The folder will be labelled with the study name, subject ID number e.g. CV191001 and the recording date of the ECG noted on the label on the front of the folder. This will be stored in room 3.43. If the participant has an additional ECG recorded, the previously created individual folder for the participant will be retrieved from room 3.43 and the new ECG and Minnesota code sheet will be inserted into the folder. The ECG recording date of the new ECG will also be written on the label on the front of the folder.

The paper ECGs/Minnesota code sheets will be kept in batches according to date of receipt at the ECG core laboratory, with a printed tracking list (QPC01 and QPC04). The batches of ECG folders and tracking list will be passed to the Director for review. When the batch of ECGs is returned from the Director, ECGs that require to be edited should be tracked on the tracking list and set aside for editing (QPC03). The remaining batches of paper copy ECGs will be retained in a secure location in a locked cabinet until ECGs out for editing or data query management have been completed and returned to the batch.

5.9.2 Paper Copy PDF ECGs

If a PDF copy of an ECG is available, it should be printed in the ECG core lab and set aside until it is married up with any previous or new automated ECG for the study participant. The printed PDF and printed automated ECG(s) will be passed to the Director for review.

5.10 Managing ECG Data Queries

If an anomaly is identified on an ECG, e.g. wrong ID number, the ECG Clinical Trials Manager (or deputy) will enter a data query request on the Data Query Database. An email will be sent to the relevant site requesting confirmation of the correct information required to resolve the query. The data query number will be recorded on the appropriate tracking list. The data query ID will be logged in the Communications Book and initialed and dated. The pending data query ECG will be set aside until it is resolved. All study centres are encouraged to answer a data query within 2 working days.

Once the study site has responded and has provided the correct information, the ECG core laboratory staff may edit the automated ECG on the EC Store system, as required, and produce a corrected confirmed ECG. Details of any change(s) made re the data query will be recorded on the original paper ECG. Another member of the team who has not made the edit/change will check the confirmed ECG against the original copy, prior to the confirmed copy being returned to the relevant batch of ECGs. The original paper ECG showing 'before' and 'after' changes will be retained and filed under recording date in a named cabinet. The relevant tracking list and the Communications Book should be updated accordingly.

5.11 Pdf Creation

Once all the ECGs in a batch have been reviewed / edited / data query resolved and any subsequent changes checked, the batch of ECGs should be checked prior to being passed for pdf creation. The person who has carried out the final check pre pdf creation should initial and date the tracking list. All 'unconfirmed' ECGs should be 'confirmed' to facilitate creation of the final pdf copy of the ECG. The ECG Clinical Trials Manager (or deputy) will inform the IT Systems Manager when the previous month's ECGs have all been reviewed, edited and pdf creation completed, as required.

5.12 Monthly Digital ECG Data

The IT Systems Manager is responsible for collating, checking and sending the digital ECG Results Files for the CISCO-19 Study to the designated recipient at the Robertson Centre for Biostatistics (RCB), University of Glasgow, via the University File Transfer Service (QPC02) or other method as advised by the RCB. The IT Systems Manager carries out visual and digital checks on all the ECGs and if anomalies are identified, these are rectified. Re-editing of an ECG may be required. A sample Results File should be sent to the RCB early in the study to ensure the format is acceptable. If necessary, changes will be made according to advice received. Thereafter, there may be a need to send data for an interim analysis or for a review of progress but ultimately, a complete set of results should be sent to the RCB as soon as possible after the completion of the study. The batch transfer will contain subject ID and demographics, Minnesota codes and other measures in a measurement matrix, e.g. ECG wave amplitude and duration for each ECG measurement. The Results File should be encrypted before being sent. A receipt is sent to the IT Systems Manager by the File Transfer Service when the data is picked up by the RCB.

5.13 Storage of Data

All electronic and paper documentation relating to the CISCO-19 Study will be appropriately retained and filed by the Electrocardiology Group. Back-ups of electronic ECG data will be carried out on a daily, Monday to Friday, basis if necessary and copies stored on the University secure server and locally at the ECG core laboratory (QPC16)

At end of study, edited paper ECGs will be filed and archived off-site in a secure location for the regulatory 25-year period under the EU Clinical Trials Regulation. [EU law may not apply after Brexit on 31/12/20]. Non-edited paper ECGs will be retained for the duration of the study and thereafter the non-edited paper ECGs will be shredded. The CISCO-19 study electronic ECG data will be retained indefinitely by the Robertson Centre for Biostatistics and the Electrocardiology core laboratory. The CISCO-19 study electronic and paper documentation will be made available for internal/external audit, as required, throughout the duration of the study.

APPENDIX A

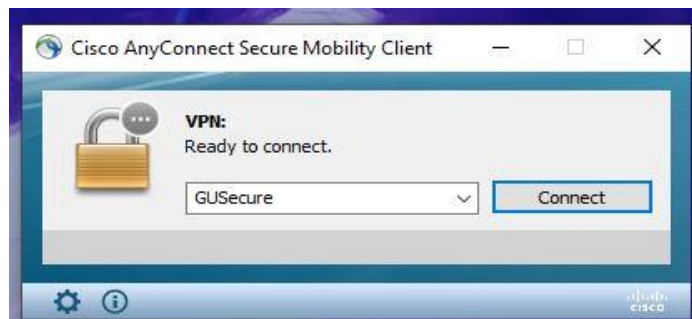
Instructions for downloading CISCO-19 ECGs

The instructions below are for downloading ECGs from the RCB web-portal for the CISCO-19 Study and then adding the study ECGs to the ECG Core Lab's ECStore ECG Management System.

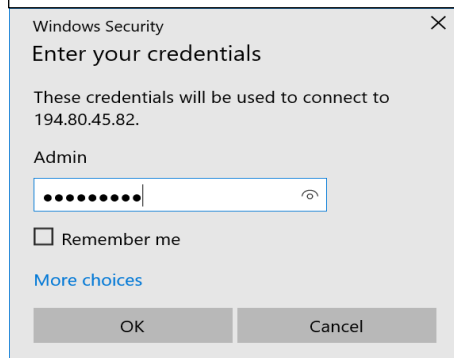
1. To download ECGs from the RCB CISCO-19 web-portal

It is recommended to perform this step while you are logged on to the **ECStore Server** (i.e. you are connected to the ECStore server via a Remote Desktop Protocol (RDP) connection).

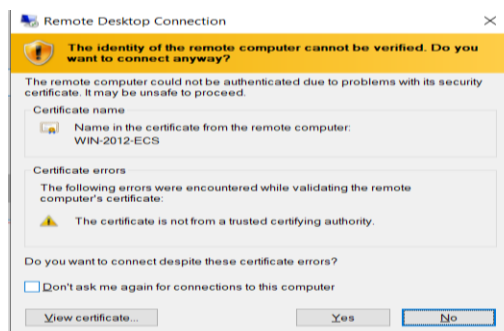
Connect via Cisco
Anywhere Connect



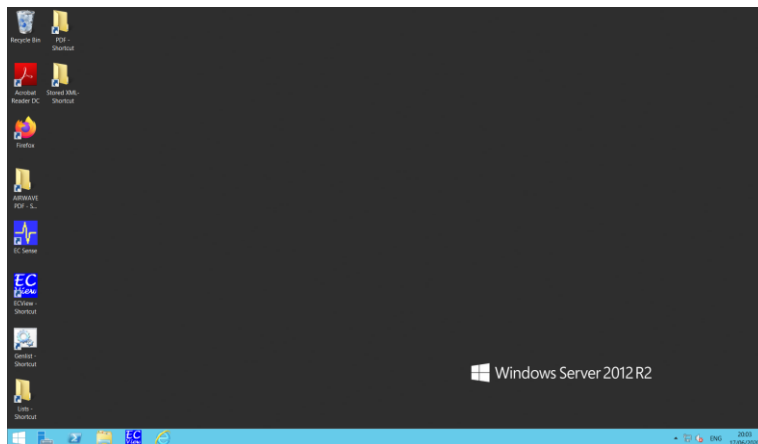
Insert ECStore IP Address



ECStore Login box



Select Yes



Use the **Firefox** icon on the ECStore desktop to connect to the RCB CISCO-19 web-portal.

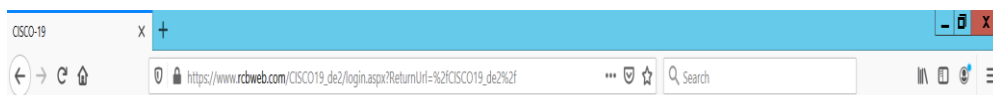
Enter the web link noted below in the Firefox address bar (OR enter https://www.rcbweb.com/CISCO19_de2)

Left button mouse click on FireFox address bar and the following login should appear in a drop down menu

https://www.rcbweb.com/CISCO19_de2/login.aspx?ReturnUrl=%2fCISCO19_de2%2f

Left button mouse click on this will take you straight to RCB CISCO-19 web portal.

Login to the CISCO-19 web-portal using your login ID and password (this should previously have been provided).



Study: CISCO-19

Login

Username:

klMcLaren

jwatts

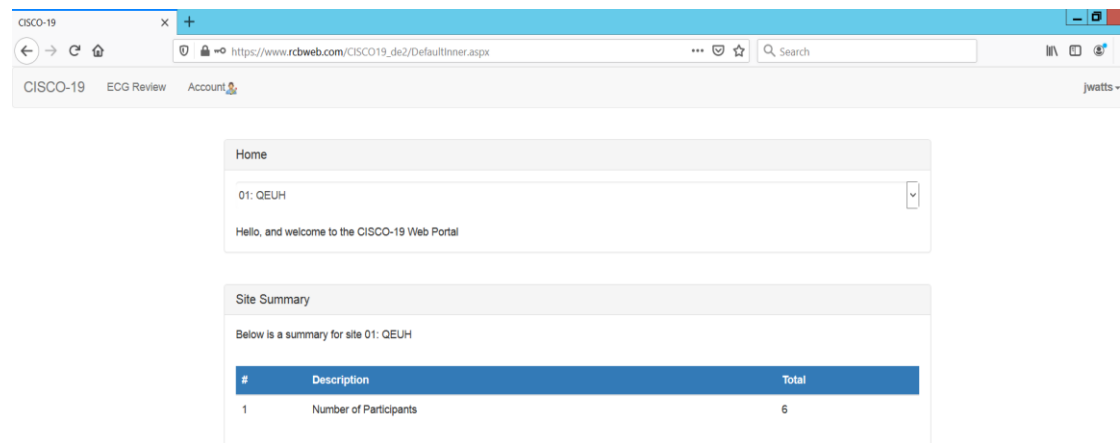
linglis

jWatts

slatiff

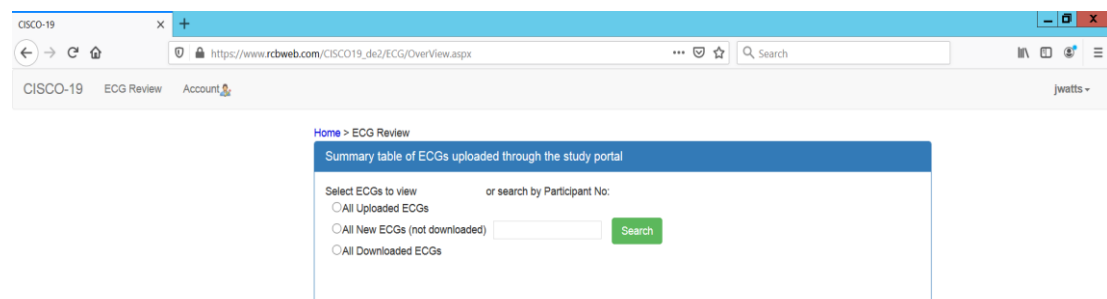
Login to LIVE

[Forgotten Password](#)



Web page will open up showing designated Home section and Site Summary sections.

Select **ECG Review** tab on top left-hand side to see the status of the ECGs



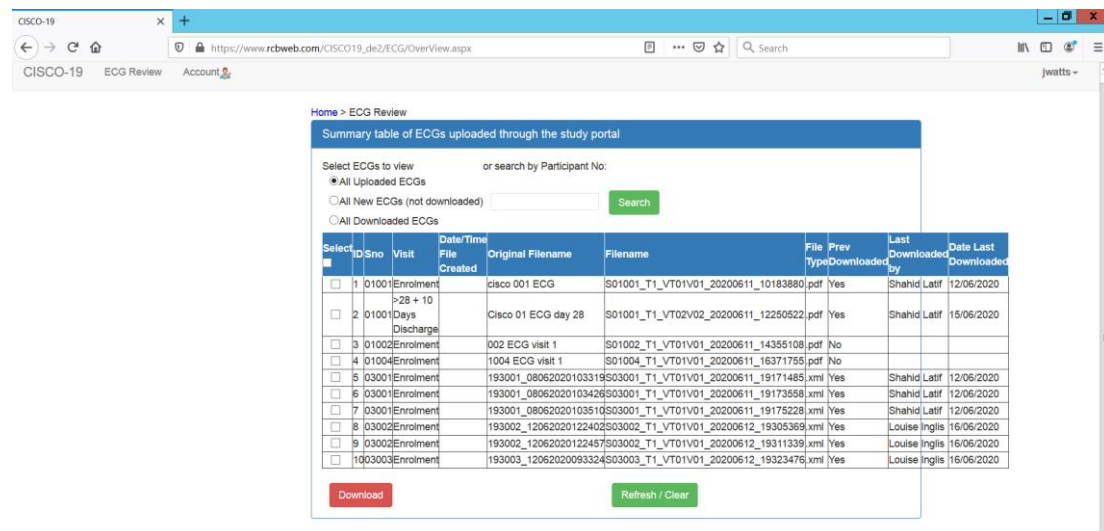
Screen will show 3 options for selection.

- a) All Uploaded ECGs
- b) All New ECGs (not downloaded)
- c) All downloaded ECGs

Note: there is also an option to Search by subject ID number (Participant Number)

Select option :

All New ECGs (not downloaded) (or one of the other options, in case you want to download ECGs which have already been previously downloaded).

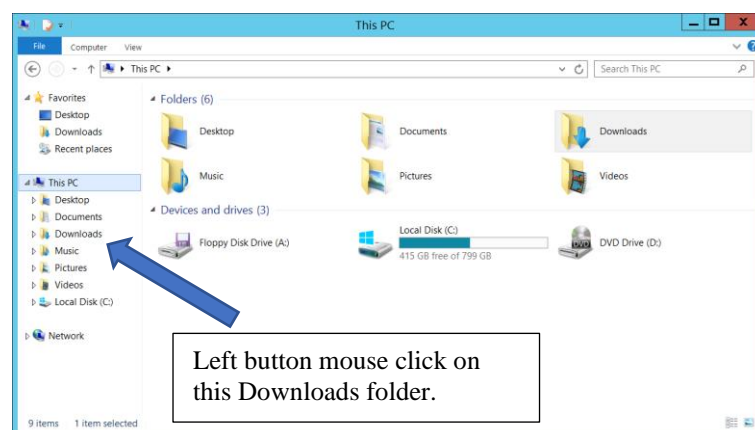
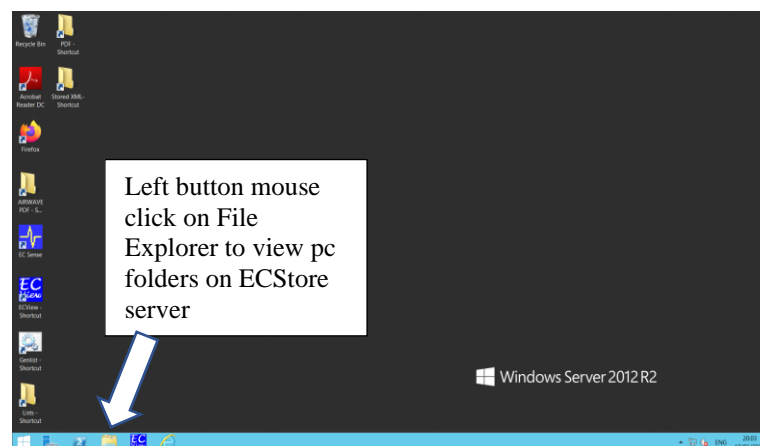


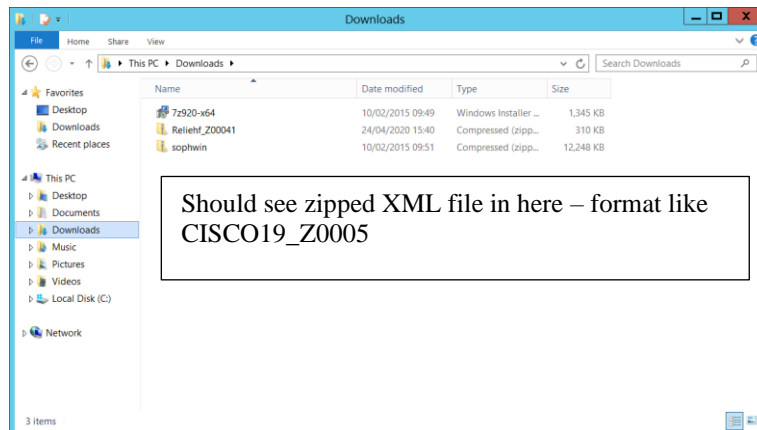
ECGs will be presented as a list. Select the ones you want to download are XML ECG files. If there are any PDF ECG files these should be managed using the instructions in Appendix B.

Click on the Download tab. A new screen will appear with the option to SAVE the download. Select **SAVE**.

The selected XML ECGs will be downloaded to the ECStore server as a ZIP file into the Windows **Downloads** folder on the ECStore server.

Left button mouse click on ECStore File Explorer





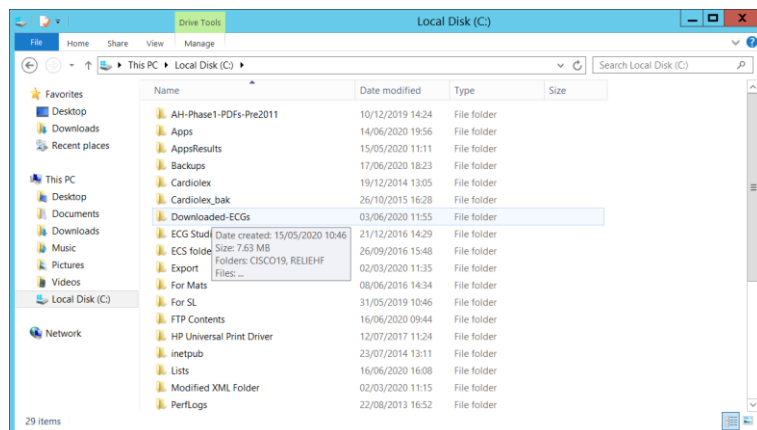
In the Windows **Downloads** folder, put mouse over the ZIP file, **right click** and then select **Cut** from the list and open the folder:

C:\Downloaded-ECGs\CISCO19 (SHORT CUT 1)

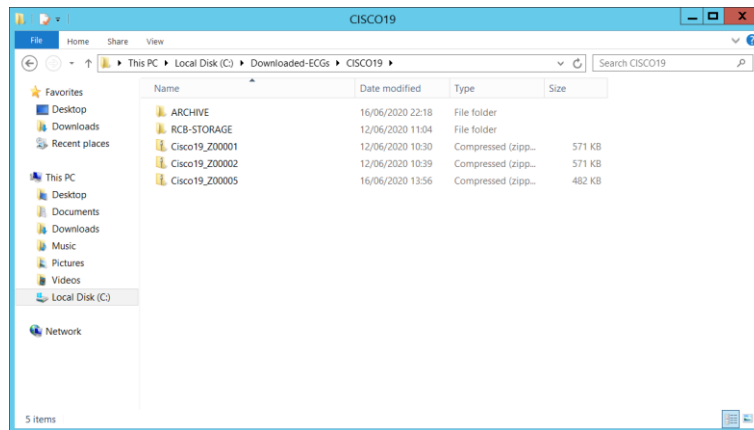
Right click, select **Paste** from the menu and the ZIP file will be pasted into the folder.

To locate folder C:\Downloaded-ECGs\CISCO19, left button click on File Explorer to show ECStore folders as below. Left button click on Downloaded-ECGs

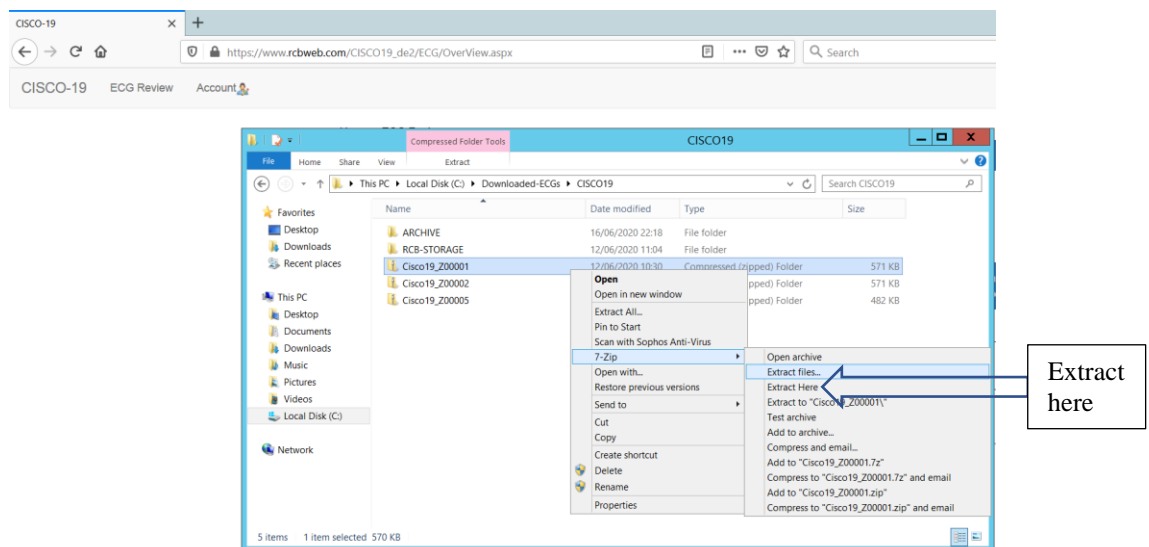
Folder to open and then Left button click on CISCO19 folder.



When you have pasted in the Zip file, it will be seen as below.



To **EXTRACT** ECG files from the ZIP file, **Right click** on the ZIP file, move down to **7-Zip** in the list and then select **Extract Here**.



The Extracted ECG files automatically go to the folder:

C:\Downloaded-ECGs\CISCO19\RCB-STORAGE\UploadArea\CISCO19\ECG (SHORT CUT 2)

Note: the extracted files should be ECG XML files in the **ECG** subfolder which are the ones we are interested in to insert into the ECStore database but there may also be other files e.g. PDFs.

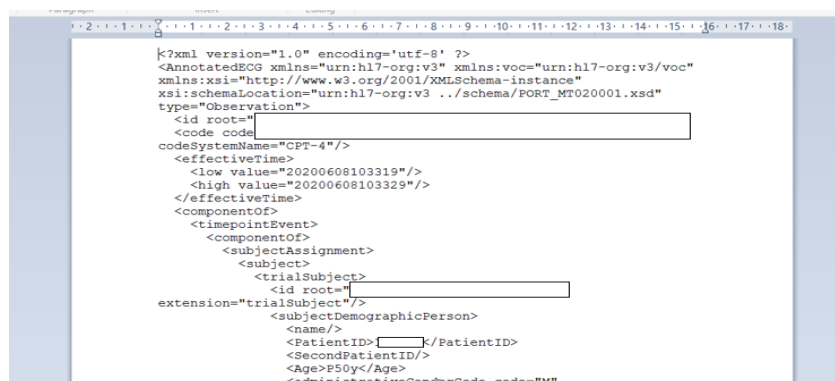
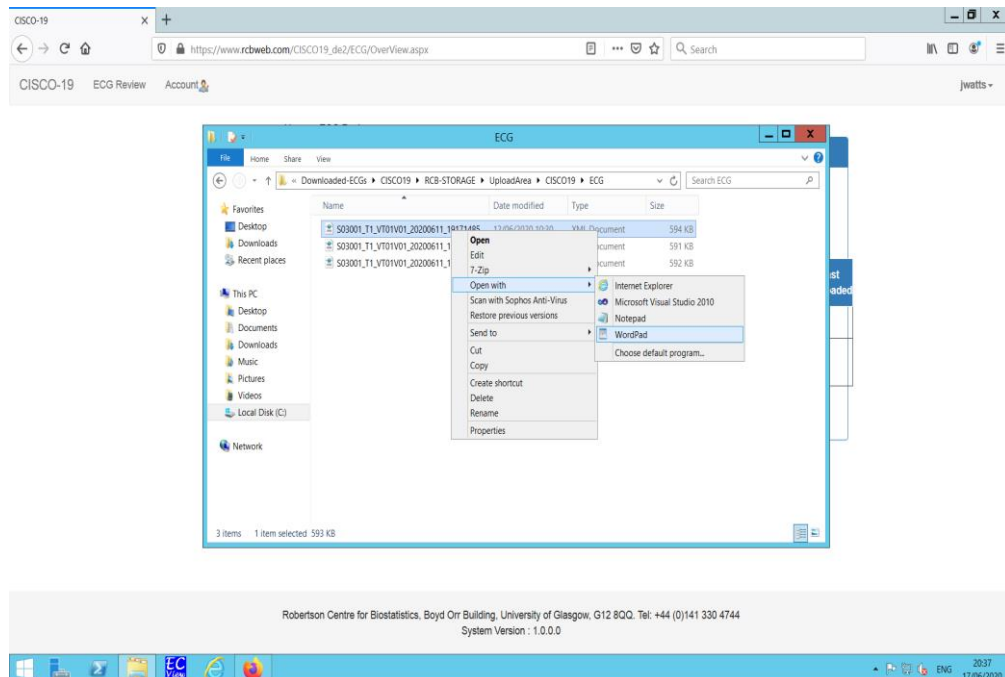
2. Modify the Patient ID with Prefix letters

The extracted files in the above **ECG** folder will be in XML format.

To Open an XML ECG file a **text editor** must be used, e.g. WordPad.

DO NOT Double-click on ECG file.

Right-click on ECG file, select **Open With** and then **Wordpad**, to open the XML file. When the ECG file is opened, the XML lines of text will be visible



Move down the lines of text and locate the ECG ID number in the following format:

<PatientID>191001</PatientID>

Insert the letters CV before the ID number.

e.g. <PatientID>CV191001</PatientID>

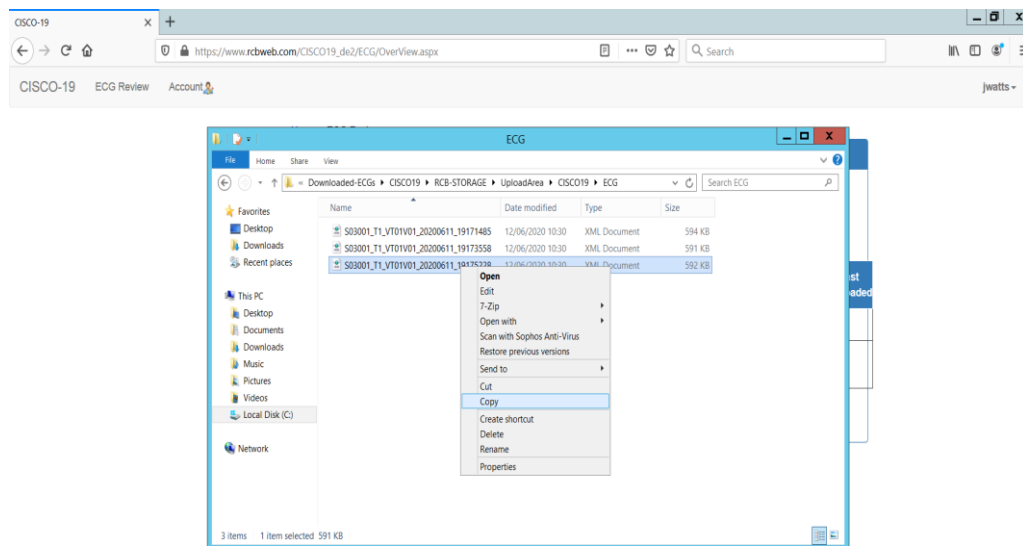
If there is a 0 between the 19 and the next digit remove the 0.

SAVE the ECG file.

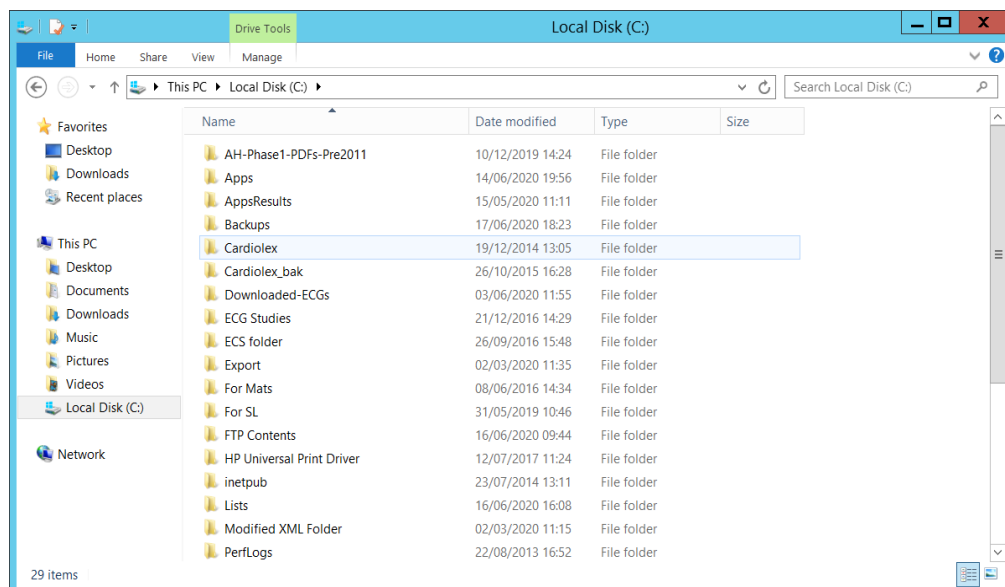
NOTE: Continue to modify all the downloaded ECGs as above, adding in CV to each ECG, **BEFORE** the downloaded ECGs are added to the ECStore database.

2. Add modified ECGs to ECStore Database

Use single left button **mouse** click to highlight and select modified ECG files.



If there are multiple ECGs, use left button mouse click to select first, hold down shift key and select last and all in between should be selected. **Right button mouse click to Copy** the list of ECG files to local disk (**C:**) and open path of folders from **Cardiolex**



C:\Cardiolex\ECStore\Data\Dir2DB_Mindray\ToECStore (SHORT CUT 3)

When you have opened the folder "ToECStore" right click mouse and select **Paste** to copy the list of ECG files into this folder. These ECGs will be picked up automatically to go into the ECStore (provided correct services are already running).

ECG files should now be in ECStore database and will be automatically printed out in the ECG core lab.

4. Archive ECGs

When ECGs have been copied into ECStore database, the original ECG files should be **cut and pasted** into the relevant **archive folder**.

4.1 XML ECGs –

Go back to C:\Downloaded-ECGs\CISCO19\RCB STORAGE
\UploadArea\CISCO19\ ECG (SHORT CUT 2)

Highlight list of **XML ECGs**

Right click and select **Cut** from the list of options. Then Right Click and **Paste** these ECGs into the following folder:

C:\Downloaded-ECGs\CISCO19\Archive (SHORT CUT 4)

Moved ECGs will remain in the Archive folder long term as a back-up copy.

4.2 Zipped Folder ECGs

Go back to **C:\Downloaded-ECGs\CISCO19 (SHORT CUT 1)**

Highlight list of **Zipped Folder ECGs**

Right click and select **Cut** from the list of options. Then Right Click and **Paste** these ECGs into the following folder:

C:\Downloaded-ECGs\CISCO19\ZIP_Archive (SHORT CUT 5)

APPENDIX B

Instructions for downloading CISCO-19 PDF ECGs

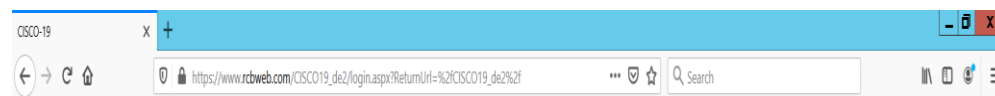
3. To download PDF ECGs from the RCB CISCO-19 web-portal

Note: If you are home-working, use Remote Desktop Connection to connect to your office PC desktop.

Open web-browser and enter https://www.rcbweb.com/CISCO19_de2

(or use CISCO shortcut if available on web-browser)

Login to the CISCO-19 web-portal using your login ID and password.



Study: CISCO-19

Select **ECG Review** tab on top left-hand side to see the status re ECGs.

Screen will show 3 options for selection.

- d) All Uploaded ECGs
- e) All New ECGs (not downloaded)
- f) All downloaded ECGs

Note: there is also an option to Search by subject ID number.

Select **option b) All New ECGs**

All New uploaded ECGs will be presented as a list of either XML or PDF ECG files.

Go down the list to see relevant **PDF** ECG(s). This is shown under column **File type**. Click on the left-hand box each PDF ECG file you wish to download. Example shows downloaded PDF ECGs.

Home > ECG Review

Summary table of ECGs uploaded through the study portal

Select ECGs to view: ☒ All Uploaded ECGs ☐ All New ECGs (not downloaded) ☐ All Downloaded ECGs

or search by Participant No:

Select	ID Sno	Visit	Date/Time File Created	Original Filename	Filename	File Type	Prev Downloaded	Last Downloaded by	Date Last Downloaded
<input type="checkbox"/>	1	0100	Enrolment	cisco 001 ECG	S01001_T1_VT01V01_20200611_10183880.pdf	pdf	Yes	Shahid Latif	12/06/2020
<input type="checkbox"/>	2	0100	Discharge	Cisco 01 ECG day 28	S01001_T1_VT02V02_20200611_12250522.pdf	pdf	Yes	Shahid Latif	15/06/2020
<input type="checkbox"/>	3	01002	Enrolment	002 ECG visit 1	S01002_T1_VT01V01_20200611_14355106.pdf	pdf	No		
<input type="checkbox"/>	4	01004	Enrolment	1004 ECG visit 1	S01004_T1_VT01V01_20200611_16371755.pdf	pdf	No		
<input type="checkbox"/>	5	03001	Enrolment	193001_08062020103319S03001_T1_VT01V01_20200611_19171485.xml		xml	Yes	Shahid Latif	12/06/2020
<input type="checkbox"/>	6	03001	Enrolment	193001_08062020103426S03001_T1_VT01V01_20200611_19173558.xml		xml	Yes	Shahid Latif	12/06/2020
<input type="checkbox"/>	7	03001	Enrolment	193001_08062020103510S03001_T1_VT01V01_20200611_19175228.xml		xml	Yes	Shahid Latif	12/06/2020
<input type="checkbox"/>	8	03002	Enrolment	193002_12062020122402S03002_T1_VT01V01_20200612_19305369.xml		xml	Yes	Louise Inglis	16/06/2020
<input type="checkbox"/>	9	03002	Enrolment	193002_12062020122457S03002_T1_VT01V01_20200612_19311339.xml		xml	Yes	Louise Inglis	16/06/2020
<input type="checkbox"/>	10	03003	Enrolment	193003_120620202093324S03003_T1_VT01V01_20200612_19323476.xml		xml	Yes	Louise Inglis	16/06/2020

When all the PDF ECGs are selected, Click on the **Download** tab.

The selected ECGs will be downloaded to your PC in the **Downloads** folder as a ZIP file
e.g. **Cisco19_Z00009.zip**

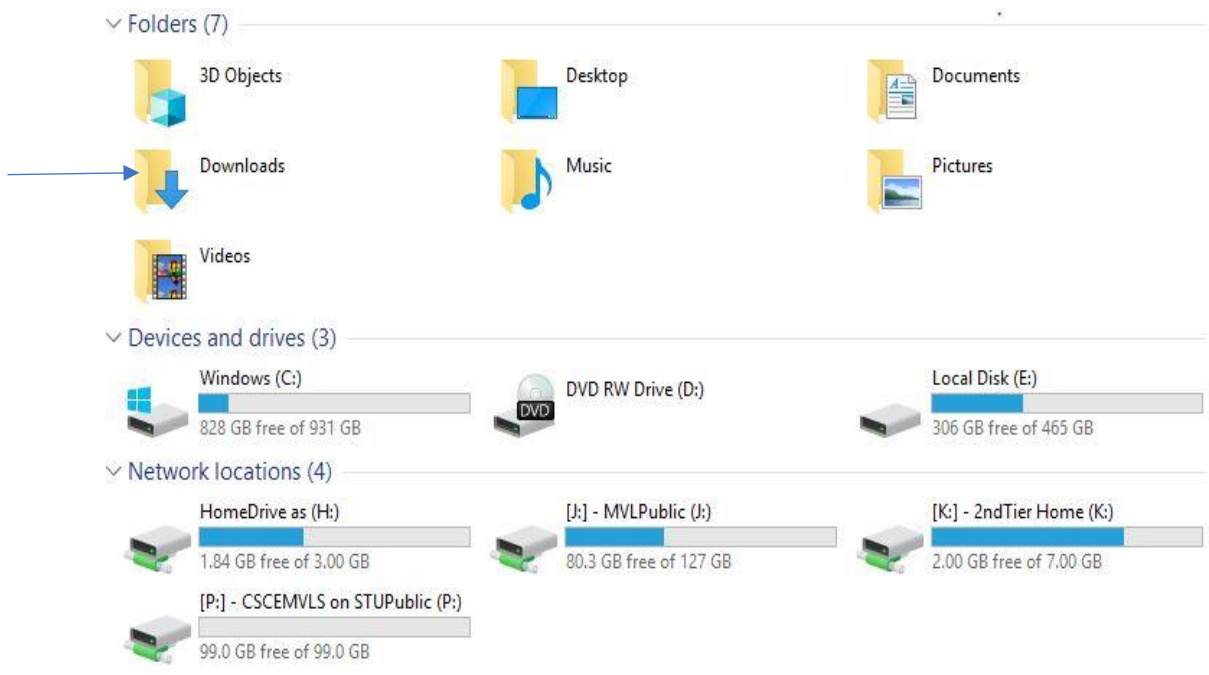
Name	Date modified	Type	Size
Cisco19_Z00009.zip	24/06/2020 08:42	Compressed (zipp...	729 KB

4. Downloaded PDF ECG files

To view the downloaded pdf ECG files. On your **PC desktop**, double-click and open **This PC** icon.



Example of folders and drives available:



Open **Downloads** folder, put mouse over the new ZIP file, **right click** and then select **Cut** from the list.

Example Zip file to be opened:

Name	Date modified	Type	Size
Cisco19_Z00009.zip	24/06/2020 08:42	Compressed (zipp...	729 KB

While still in **Downloads**, on left hand side of screen move down list and

Click [J:] – MVLPUBLIC (J:)

Navigate to: **HW > ECG > CTG > CISCO19-PDFs**

Paste the copied ZIP file.



Name	Date modified	Type	Size
RCB-STORAGE	12/06/2020 11:44	File folder	
Cisco19_Z00004.zip	15/06/2020 09:12	Compressed (zipp...	205 KB
Cisco19_Z00009.zip	24/06/2020 08:42	Compressed (zipp...	729 KB

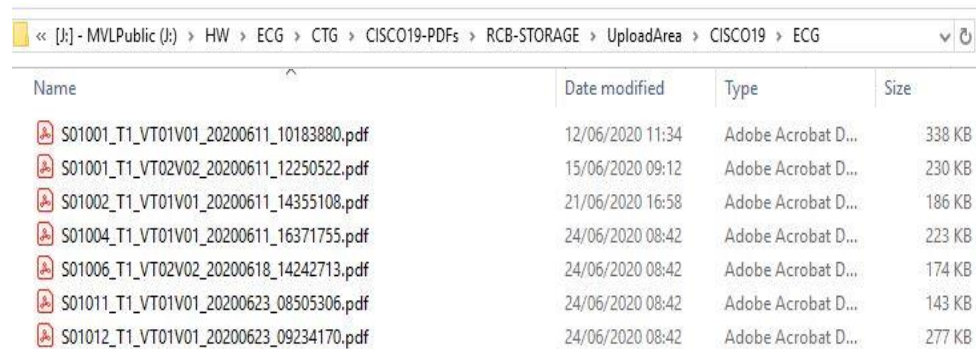
As noted above, **HW > ECG > CTG > CISCO19-PDFs** will show a sub-folder for **RCB-STORAGE** and a list of downloaded ZIP file folders.

To **EXTRACT** PDF ECG files from the recently downloaded ZIP file, **right click** on the appropriate ZIP Folder file, select **7-Zip** and then select **Extract Here**.

To view the extracted PDF ECG files at [J:] – MVLPublic (J:) > HW > ECG > CTG > **CISCO19-PDFs**

Click on the sub-folders **RCB-STORAGE** > **UploadArea** > **CISCO19** > **ECG** and individual PDF ECG files will be visible on screen.

Example of list of extracted PDF ECG files:



The screenshot shows a Windows File Explorer window with the address bar displaying the path: << [J:] - MVLPublic (J:) > HW > ECG > CTG > CISCO19-PDFs > RCB-STORAGE > UploadArea > CISCO19 > ECG. The main pane displays a list of PDF files with columns for Name, Date modified, Type, and Size.

Name	Date modified	Type	Size
S01001_T1_VT01V01_20200611_10183880.pdf	12/06/2020 11:34	Adobe Acrobat D...	338 KB
S01001_T1_VT02V02_20200611_12250522.pdf	15/06/2020 09:12	Adobe Acrobat D...	230 KB
S01002_T1_VT01V01_20200611_14355108.pdf	21/06/2020 16:58	Adobe Acrobat D...	186 KB
S01004_T1_VT01V01_20200611_16371755.pdf	24/06/2020 08:42	Adobe Acrobat D...	223 KB
S01006_T1_VT02V02_20200618_14242713.pdf	24/06/2020 08:42	Adobe Acrobat D...	174 KB
S01011_T1_VT01V01_20200623_08505306.pdf	24/06/2020 08:42	Adobe Acrobat D...	143 KB
S01012_T1_VT01V01_20200623_09234170.pdf	24/06/2020 08:42	Adobe Acrobat D...	277 KB

CHECK that each of the recently downloaded PDF files can be opened and viewed.

6. Referenced documents

CISCO-19 ECG Management for Sites
CISCO-19 ECG Management 2-pages
QPC01 Management of Incoming Digital ECGs
QPC02 Digital ECG Transfer
QPC03 ECG Editing
QPC04 ECG Tracking
Appendix A – Downloading and Inserting ECGs to ECStore Database
Appendix B – Downloading CISCO-19 PDF ECGs
Data Query Database
Communications Book

7. Related documents

Paper and electronic ECG records.

8. Document History

Version	Date	Description
Draft version 1 / June 2020	08 06 20	Draft SOP for the new CISCO-19 Study
Version 1 / July 2020	23 07 20	Release of version.
Draft version 2 / October 2020	01 10 20	Update to procedure items 5.9.1 and 5.10 re using individual participant folders/labels. Data queries are managed by email and not via the study web-portal. Data query database and Communications added to Referenced documents.
Version 2 / October 2020	14 10 20	Release of version

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