Standard Oper	Standard Operating Procedure / Quality Procedure <b>QPC39</b>								
QPC39 CISCO	QPC39 CISCO-19 STUDY PROCEDURE								
Version 2 / C	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)

19**2**001 - 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.

<u>Note</u>: The clinical responsibility for ECG review remains with the study Clinician(s) at each site. SOP/QPC39 Version 2 / October 2020 Page 1 of 18

# 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: CV191001 (QEUH), CV192001 (GRI), CV193001 (RAH)

Once the prefix  $\mathbf{CV}$  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 webportal, 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	28 < Visit 2 < 38	1 year
(Visit 1)	days post	(Visit 3)
Hospitalised,	discharge	
COVID-19	(Visit 2)	
	Outpatient	

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 pended 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).

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GUSecure	Connect
<b>\$</b> (i)	cisco
Insert ECStore IP Address Windows Security ×	
Enter your credentials These credentials will be used to connect to 194.80.45.82.	
Admin	CStore Login box
Remember me	
More choices OK Cancel	
Remote Desktop Connection	<
The identity of the remote computer cannot be verified. Do you want to connect anyway? The remote computer could not be authenticated due to problems with its security certificate. It may be unsafe to proceed. Certificate name Image in the certificate from the remote computer: WIN-2012-ECS	
Certificate errors The following errors were encountered while validating the remote computer's certificate: The certificate is not from a trusted certifying authority.	Select Yes
Do you want to connect despite these certificate errors? Don't ask me again for connections to this computer View certificate Yes No	1

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Use the **FireFox** icon on the ECStore desktop to connect to the RCB CISCO-19 webportal.

Enter the web link noted below in the Firefox address bar (OR enter <u>https://www.rcbweb.com/CISCO19\_de2</u>)

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).

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Electrocardiology Group

		RCB Web Portal	
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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

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		Home > ECG Review Summary table of ECGs uploa Select ECGs to view All Uploaded ECGs All New ECGs (not downloade All Downloaded ECGs	or search by Participant No:			

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 :

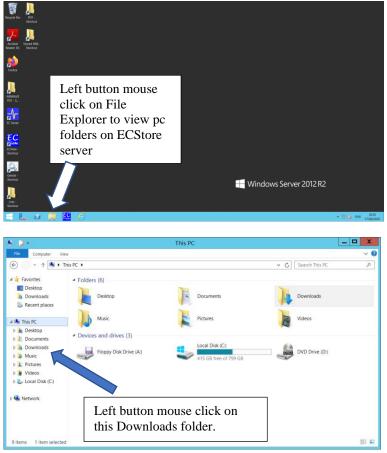
All New ECGs (not downloaded) (or one of the other options, in case you want to download ECGs which have already been previously downloaded).

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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

SOP/QPC39 Version 2 / October 2020

Page 8 of 18

		Downloads				
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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.

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📙 Backups	17/06/2020 18:23	File folder			
🐌 Cardiolex	19/12/2014 13:05	File folder			
🐌 Cardiolex_bak	26/10/2015 16:28	File folder			
I Downloaded-ECGs	03/06/2020 11:55	File folder			
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When you have pasted in the Zip file, it will be seen as below.

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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.

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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.** 

SOP/QPC39 Version 2 / October 2020

Page 10 of 18

**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

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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.

SOP/QPC39 Version 2 / October 2020

Page 11 of 18

# 2. Add modified ECGs to ECStore Database

Use single left button **mouse** click to <u>highlight</u> and <u>select</u> modified ECG files.

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	3 items   1 item selected	591 KB				100 100	

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** 

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File Home Share	View Manage					$\sim$
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Favorites	Name	Date modified	Туре	Size		
Desktop	AH-Phase1-PDFs-Pre2011	10/12/2019 14:24	File folder			
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laces Recent places	AppsResults	15/05/2020 11:11	File folder			
	📕 Backups	17/06/2020 18:23	File folder			
💐 This PC	👢 Cardiolex	19/12/2014 13:05	File folder			
属 Desktop	👢 Cardiolex_bak	26/10/2015 16:28	File folder			
Documents	lownloaded-ECGs	03/06/2020 11:55	File folder			
📙 Downloads	👢 ECG Studies	21/12/2016 14:29	File folder			
🐌 Music	👢 ECS folder	26/09/2016 15:48	File folder			
E Pictures	👢 Export	02/03/2020 11:35	File folder			
廔 Videos	📕 For Mats	08/06/2016 14:34	File folder			
🤩 Local Disk (C:)	👢 For SL	31/05/2019 10:46	File folder			
	👢 FTP Contents	16/06/2020 09:44	File folder			
💺 Network	👢 HP Universal Print Driver	12/07/2017 11:24	File folder			
	👢 inetpub	23/07/2014 13:11	File folder			
	👢 Lists	16/06/2020 16:08	File folder			
	👢 Modified XML Folder	02/03/2020 11:15	File folder			
	🐌 PerfLogs	22/08/2013 16:52	File folder			
29 items						800

# 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

**<u>Right click</u>** 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

**<u>Right click</u>** 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 <u>https://www.rcbweb.com/CISCO19\_de2</u>

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

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

CISCO-19	Х	+		_ 0 X
$\leftrightarrow$ $\rightarrow$ C $\triangle$		0 Ahttps://www.rcbweb.com/CISCO19_de2/login.aspx?ReturnUrl=%2fCISCO19_de2%2f	••• 🛛 🏠 🔍 Search	∥\ 🖸 🔮 Ξ

# Study: CISCO-19

Login			
Username:			
kMcLaren			
jwatts			
linglis			
jWatts			
slatif			
	Login to	LIVE	
Forgotten Password			

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 **<u>File type</u> Click** on the <u>left-hand box</u> each PDF ECG file you wish to download. Example shows downloaded PDF ECGs.

	+													_ 0	3
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CO-19 ECG Review	Account &													jwatts -	
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		Sumn	nary tab	ole of ECC	Gs upload	led through the study p	ortal								
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			A	Gs (not do	wnloaded)	)	Search								
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				2Enrolmen	1		02S03002_T1_VT01V01_20200612_19305					16/06/2020			
			-	2Enrolmen	1		57S03002_T1_VT01V01_20200612_19311					16/06/2020			
			100300	3Enrolmen	¢	193003_120620200933	24S03003_T1_VT01V01_20200612_19323	176.xm	il Yes	Louise	Inglis	16/06/2020			

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

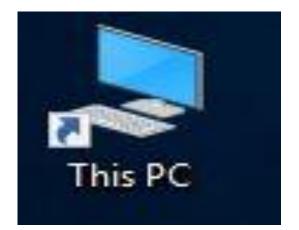
The selected ECGs will be downloaded to your PC in the **Downloads** folder as a ZIP file

# e.g. Cisco19\_Z00009.zip

Name	Date modified	Туре	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.



Electrocardiology Group

Exam	ple	of	folders	and	drives	available

∨ Folders (7)		
3D Objects	Desktop	Documents
Downloads	Music	Pictures
Videos		
<ul> <li>Devices and drives (3)</li> </ul>		
Windows (C:)	DVD RW Drive (D:)	Local Disk (E:)
828 GB free of 931 GB	DVD	306 GB free of 465 GB
Vetwork locations (4)		
HomeDrive as (H:)	[J:] - MVLPublic (J:)	[K:] - 2ndTier Home (K:)
1.84 GB free of 3.00 GB	80.3 GB free of 127 GB	2.00 GB free of 7.00 GB
[P:] - CSCEMVLS on STUPublic (P:)		
99.0 GB free of 99.0 GB		

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	Туре	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.

> This PC > [J:] - MVLPublic (J:) > HW > ECG > CTG > CISCO19-PDFs

Name	Date modified	Туре	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.SOP/QPC39Version 2 / October 2020Page 16 of 18

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 []:] – MVLPublic (]:) > HW > ECG > CTG >  ${\bf CISCO19}\text{-}{\bf PDFs}$ 

**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:

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

<u>CHECK</u> 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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