



The JRC-ENCR Quality Check Software (QCS) for the validation of cancer registry data: user compendium

JRC-ENCR QCS 2.3.16

JRC CSV Data layout converter

Changes introduced in the current document:

Manuela Flego, Stefano Adriani

Other contributors

Francesco Giusti, Carmen Martos, Antonino Brunetto,
Tadeusz Dyba, Raquel N. Carvalho, Giorgia Randi, Joanna
Bartnicka, Manola Bettio, Enrico Ben

JRC Cancer Information Group

Manuela Flego, Joanna Bartnicka., Cristina Bosetti, Giorgia
Randi, Tadek Dyba, David Pettersson Raquel N. Carvalho,
Manola Bettio

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Introduction

The European Network of Cancer Registries (ENCR) and the European Commission's Joint Research Centre (JRC) have launched in 2022 a data call for updating cancer burden indicators available in the European Cancer Information System (ECIS) (<https://ecis.jrc.ec.europa.eu/>), following an updated [ECIS data call protocol](#).

In order to enable cancer registries to perform data quality checks and to test the adherence of their data to the protocol required format, the JRC starting from 2015 has been developing the [JRC-ENCR Data Quality Check Software](#) (QCS). Complementary to the QCS, the CSV Data Layout Converter has been released in 2021, as an additional tool to facilitate the preparation of the incidence file.

This version of the QCS is updated to the requirements of the latest ECIS data call protocol and the [ECIS Technical report](#) "Data quality checks for validation of the ECIS database". This new version benefits from the experience gathered in validation of submitted data from European registries, and from registries' feedback.

The development of the QCS is an evolving process, with regular updates that ensure alignment with European and International recommendations and classifications.

The present document provides technical guidance to the software and helps to understand and interpret its output.

The main changes and improvements included in this version compared to previous one, are detailed in ***Annex 1 – Changes and improvements from the previous versions***. A list of known bugs and issues to be addressed in a later release is available in ***Annex 2 – Known issues and future improvements***.

1 Software overview

The JRC-ENCR Quality Check Software (QCS) is an open-access software developed to facilitate standardisation and validation of population-based cancer registries (PBCRs) data.

The QCS has been designed as a stand-alone desktop application that can run locally by cancer registries, without the need for an internet connection.

Most of the checks performed by this version are based on latest version of the ECIS Technical report, which includes recommendations for checking internal consistency of the cancer incidence data and provides a comprehensive and standardised list of data quality checks to be adopted by European PBCRs.

The software checks four different data files (incidence, mortality, population and life tables) required by the ECIS protocol. The QCS output consists of four files (in PDF, TXT and CSV format) containing the detailed list of warnings and errors detected in the validation run for each record of the input data file.

Population, life tables and mortality files have a simple structure, which require univariate checks validation (checks on single variables). Incidence files are more complex, and in addition to univariate validation the QCS performs checks between variables of the same record (multivariate checks) and between variables of different records (duplicates and multiple primary tumours checks).

2 System requirements and installation

The QCS has been initially developed for Windows operating systems that support Java (Windows 10 and above).

QCS can also run on MacOS and Linux operating systems (see sections 2.5 and 2.6). Sections 2.1-2.4 below refer to Windows operating systems.

2.1 In case Java software is not installed on your computer

Java software is needed to run the QCS. In case Java is not installed on your computer, please install Java JDK version 17 or later, otherwise go to **section 2.3**.

2.2 Further information and troubleshooting related to Java

If you need help in installing Java on your machine, kindly ask to your System Administrator or local IT support to install it for you.

Remember to choose the correct version for your operating system (ex: Windows 32 bit or Windows 64 bit).

2.3 How to install the QCS

Download the latest version of the QCS software from the [JRC-ENCR website](#) and extract the files on your computer in a dedicated folder. Please follow the instructions below according to your PCs operating system.

2.4 Running on Windows

1. Open the folder containing the QCS
2. Double click on the "JRC-ENCR-QCS-2GB.bat" file (suggested option). If the QCS does not start or does not work properly, double click on the "JRC-ENCR-QCS-4GB.bat" file.

2.5 Running on macOS

1. Double click the Terminal icon (or label, depending by your view settings) to open a Terminal window
2. Enter the Terminal window and move into the folder created at **step 1**. For example, if the target QCS file was named "JRC-ENCR-QCS-version zip" (where *version* is the current software version, e.g. *version* = 2.4), then you should type the command below:

```
cd Desktop/JRC-ENCR-QCS-version
```

3. Execute the file having the extension ".sh". For example if the file is named "start-jrc-encr-qcs.sh", then type the command:

```
source jrc-encr-qcs.sh
```

2.6 Running the QCS on Linux operating systems

1. Move into the directory containing the QCS
2. Execute the QCS by running the ".sh" file:

```
source start-jrc-encr-qcs.sh
```

2.7 Verify the correct installation

Navigate to the folder where you extracted the software and before running it (as explained in section 5.1), check if it is correctly installed.

The expected directory structure is shown below:

Name	Type	Size
 config	File folder	
 docs	File folder	
 lib	File folder	
 logs	File folder	
 output	File folder	
 temp	File folder	
 JRC-ENCR-QCS.bat	Windows Batch File	4 KB
 jrc-encr-qcs.sh	SH File	1 KB
 JRC-ENCR-QCS-2GB.b...	Windows Batch File	4 KB
 JRC-ENCR-QCS-4GB.b...	Windows Batch File	4 KB
 jrc-qcs-2.x.jar	JAR File	1.489 KB
 Licence.txt	TXT File	14 KB
 Notice.txt	TXT File	89 KB
 qcs.db	Data Base File	416 KB
 RUN-BULK.bat	Windows Batch File	3 KB
 RUN-ENCR-BULK.bat	Windows Batch File	5 KB
 RUN-QCS.bat	Windows Batch File	4 KB
 test-suite-template.sh	SH File	14 KB

The folder *JRC-ENCR-QCS-V2.x* (where 2.x is the current version) includes the following files and folders:

- The License.txt file containing the usage license
- The executable files *JRC-ENCR-QCS.bat*, *JRC-ENCR-QCS-2GB.bat* and *JRC-ENCR-QCS-4GB.bat* for all JRC external users;
- The executable file *RUN-QCS.bat* for JCR internal users only;
- The executable files *RUN-BULK.bat* (for JCR internal users only) and *RUN-ENCR-BULK.bat*;
- Files *jrc-encr-qcs.sh* and *test-suite-template.sh*;

- The application's file *jrc-qcs-2.x.jar*;
- The QCS database *qcs.db*;
- Installation folders: *config*, *docs*, *lib* (installed with the QCS);
- Runtime folders: *logs*, *output*, *temp* (created at first usage);

The file *JRC-ENCR-QCS.bat* will run the QCS with 1GB of RAM memory allocated by Java, whereas *JRC-ENCR-QCS-2GB.bat* and *JRC-ENCR-QCS-4GB.bat* will use 2GB and 4GB of RAM memory respectively.

The file *RUN-ENCR-BULK.bat* will run the QCS as a background service (see detailed instructions in the manual included in the doc folder);

The file *jrc-encr-qcs.sh* is the standard ".sh" script for running the application on the macOS and Linux systems (see sections 2.5 and 2.6 above).

config: this folder contains configuration files, such as those for multivariate intra records checks, and general application settings (with the possibility to disable some functionalities) etc.

docs: this folder contains relevant documentation files in PDF format, i.e. the QCS user compendium (this document) and the manual "Run QCS as background service.pdf". The file *change_log.txt* includes the list of the most recent QCS versions and updates. The subfolder "examples" includes some sample scripts for advanced users (see *Annex 4 – Running the JRC-ENCR QCS in background*).

lib: this folder includes the jar library files used by the software at run time.

logs: this folder stores the log file of all the QCS activities.

output: this folder is created after the QCS is run for the first time. It includes four different subfolders with the output reports produced by the QCS for *Incidence*, *Mortality*, *Population* and *LifeTable* files respectively.

temp: this folder is created after the QCS is run for the first time. It contains all the raw files (working files) used to generate the final output reports.

3 How to prepare an input file for the QCS

In this section an example of input files accepted by the software is given. Input files should be formatted as follows:

- as text files (.csv or .txt) **with semicolon (;) separators only**;
- with first line as header.

3.1 Incidence File

The input incidence file must follow the format of the ECIS data call protocol. It can be either created following the instructions below (section 3.1.2) or using the [JRC CSV Data Structure Converter](#) (section 3.1.3).

3.1.1 The ECIS data call protocol

Please refer to the ECIS data call protocol, section 3.1.7 and Table 1 in which name, description and format of requested variables, with corresponding missing/unknown values and coding schema are summarized.

3.1.2 Incidence file creation

As a first step, the file header needs to be created with 39 variables, as per ECIS data call protocol. The incidence file has a fixed structure as for names, variables' order and semicolon (;) as column separators. As a consequence, the header line should be the following:

PAT; MoB; YoB; Age; Sex; Geo_Code; Geo_Label; TUM; MoI; YoI; BoD; Topo; Morpho; Beh; Grade; Autopsy; Vit_stat; MoF; YoF; Surv_time; ICD; CoD; TNM_ed; cT; cN; cM; pT; pN; pM; ToS; Stage; Surgery; Rt; Cht ; Tt; It; Ht; Ot; SCT

Please note: do NOT put a semicolon at the end of the line. The line ends in "SCT" and not in "SCT;".

After the creation of the header line, you can populate your incidence file with records (rows), each corresponding to an individual incidence case. When you finish, please save the file in csv or txt format. This will be your incidence file, ready to be run by the QCS.

The paragraph 3.1.3 below explains how to use the CSV Data Structure Converter tool if you need assistance in preparing or checking the incidence file format before running the QCS.

3.1.3 JRC CSV Data Structure Converter

The JRC CSV Data layout converter tool assists users (with Windows operating systems) in the correct preparation of incidence files and, starting from version 1.3, also mortality and population files and life tables to be run by the QCS.

To use the tool, please select a data file (incidence/mortality/population/life table) to import and convert it into the proper format. The file can be in any text format (CSV, TXT) with supported columns separators as follows:

- **TAB** (tabulation)
- | (pipe)
- , (comma)
- ; (semicolon)

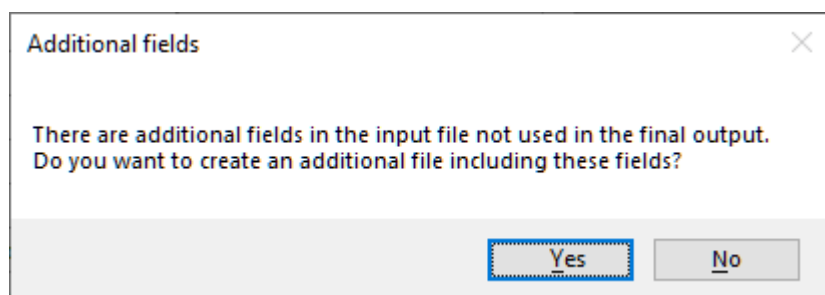
If the input file is formatted correctly, the converter tool maps the variables as defined in the ECIS protocol (Required protocol fields) with the corresponding variables of the input data file (Available fields). To facilitate the data import, the converter tool tries to automatically map fields with the same name: mapped variables are displayed in GREEN, while unmapped variables are marked in RED.

When automatic mapping is not possible, the user can:

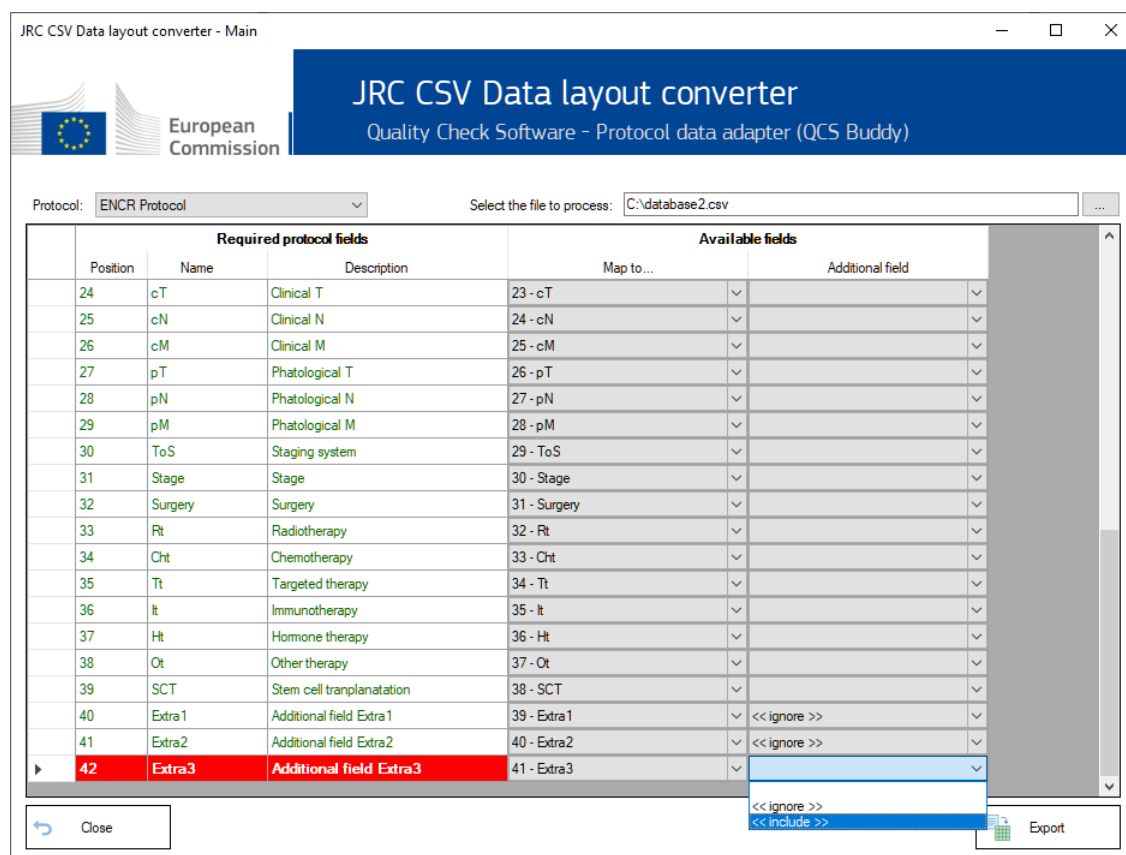
- either map manually the variables;
- or leave the field blank (for example, if no mapping is possible, data are not available, etc.).

Only when all the fields as defined in the protocol are mapped (or blank), it is possible to Export the content of the original file in the format required by the ECIS protocol.

For variables in the data file not relevant to the ECIS protocol (e.g. extra variables), the tool enables exporting an additional file including one or more of these variables, in addition to those required by the ECIS protocol.



In the example below for an incidence file, variables "Extra1", "Extra2" and "Extra3" are not relevant for incidence to the ECIS protocol. Among these, "Extra3" (marked as to be included) will be kept in the export file.



3.2 Mortality file

Similarly to incidence files, the creation of the file header is the first step. For mortality files, the number of required variables is 7.

Depending on the reporting of deaths by single years of age (Age unit) or by age range (Age range), the line header for the mortality file is the following:

`Calendar_year;Sex;Age_unit;Geo_code;Geo_label;Cause_of_death;Number_of_deaths`
`Calendar_year;Sex;Age_range;Geo_code;Geo_label;Cause_of_death;Number_of_deaths`

Please note: make sure that the 7 variables are in the correct order, and separated by semicolons (;). The header line is mandatory. Do NOT put a semicolon at the end of header.

After having created the header, you can populate your mortality file. Once done, please save it in csv or txt format. You are now ready to run the mortality file by the QCS.

The paragraph 3.1.3 above explains how to use the CSV Data Structure Converter tool if you need assistance in preparing or checking the mortality file format before running the QCS.

3.3 Population file

Please create first the header of the file. For population files, the number of required variables is 6.

Depending on the reporting of deaths by single years of age (Age unit) or by age range (Age range), the line header for the population file is the following:

`Calendar_year;Sex;Age_unit;Geo_code;Geo_label;Number_of_residents.`
`Calendar_year;Sex;Age_range;Geo_code;Geo_label;Number_of_residents`

Please note: Please make sure that the 6 variables are in the correct order and separated by semicolons (;). The header line is mandatory. Do NOT put a semicolon at the end of the header.

After having created the header, you can populate your population file. Once done, please save it in csv or txt format. You are now ready to run the population file by the QCS.

The paragraph 3.1.3 above explains how to use the CSV Data Structure Converter tool if you need assistance in preparing or checking the population file format before running the QCS.

3.4 Life Table file

Please create first the header of the file. For life table files, the number of required variables is 6.

The line header for the life table file is the following:

`Calendar_year;Sex;Annual_age;Geo_code; Geo_label;All_causes_death_probability`

Please note: Please make sure that the 6 variables are in the correct order and separated by semicolons. The header line is mandatory. Do NOT put a semicolon (;) at the end of each line.

After having created the header, you can populate your life table file. Once done, please save it in csv or txt format. You are now ready to run the population file by the QCS.

The paragraph 3.1.3 above explains how to use the CSV Data Structure Converter tool if you need assistance in preparing or checking the life table file format before running the QCS.

4 How does the software work?

The analysis process of an input *incidence* file is described below. Similar processes are performed for the other input data files: *mortality*, *population* and *life table* files.

The incidence file should include 39 variables, semicolon-separated (;), and in the correct format as described in sections 3.1.1 and 3.1.2 above.

The software checks that variable names are correct, and every single record is compliant with the valid format and value for each variable, according to the ECIS protocol as for:

- the number of variables;
- the presence of non-missing and non-blank values in the fields affecting incidence calculation (if year of incidence (variable *YoI*) is missing, the software rises the error E-MISS etc.);
- the field content against a list of valid values, when applicable. **Example:** for patient's sex (variable "Sex") only four numeric values are allowed: 1=male, 2=female, 3=other or 9=unknown. Other values will produce an error (e.g. sex=4 will produce E-OUTR, value out of range; sex=X or 11 will produce E-FORM, format error, etc.);
- the field length, which must be within the allowed range. **Example:** the maximum length for Patient identification code (variable *PAT*) is 50 characters; the maximum length for Morphology (variable *Morpho*) is 4 digits (*Morpho*=82633 will produce E-FORM, format error, etc.);
- the validity of dates, including checking that some dates are not set in the future. **Example:** YoI=2040 will produce E-OUTR, value out of range, being the current year the maximum allowed value;
- records failing the edits described in the ECIS Technical Report.

All warning and error messages produced by the QCS in each validation run are saved in four specific output files (as an example, the names below are relative to the *incidence* file):

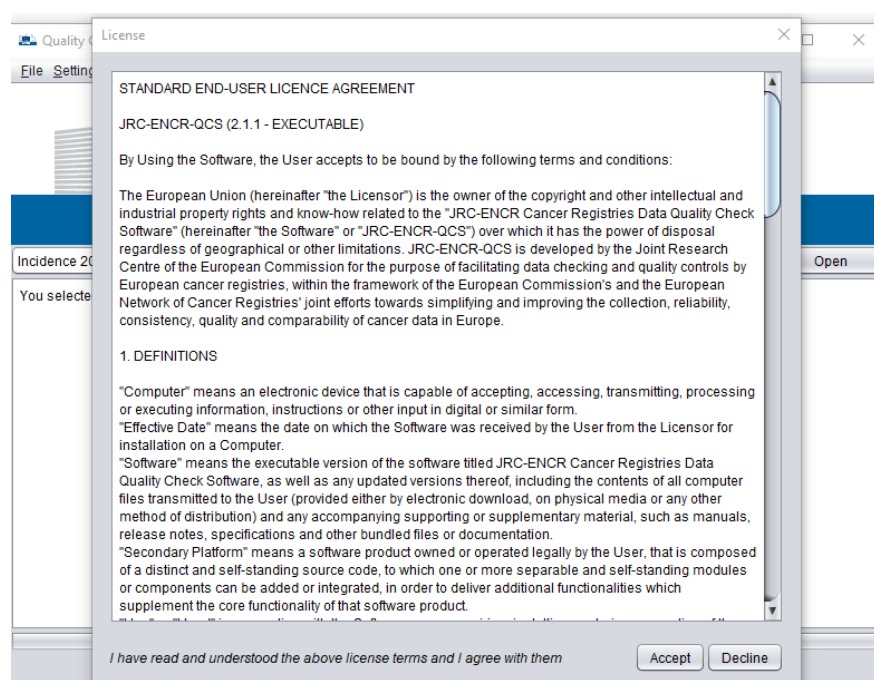
- 1) *QCS-Incidence-Output.pdf* – contains a summary of the execution process (date and time, name of the processed file, number of rows, total number of errors and warnings) and the detailed list of all errors and warnings detected for each record of the input data file. Please note that if the QCS output file "QCS-Incidence-Output.txt" is too large, the corresponding pdf file will not be produced; in this case, if in the output folder there is already an old PDF file produced in a previous run, it will be temporarily renamed "*_old", until a new PDF is produced that overwrites it.
- 2) *QCS-Incidence-Output.txt* – has the same content of the PDF file, but in text format;
- 3) *QCS-Incidence-Output.csv* – contains all errors and warnings in a format easily readable by automated procedures. This file can be used to load the results of the validation process in a database, or to perform detailed statistics and analyses. It can be imported by most software packages to allow for advanced data manipulation, such as linkage with the original file using the unique combination of patient/tumour ID. Warnings for multiple primary tumours are also included in this file. This format can be particularly useful if the input file generates a large number of errors.
- 4) *QCS-Incidence-Output-Summary.txt* – contains a summary of the execution process (date and time, name of the processed file, number of rows, total number of errors and warnings) and the summary of errors/warnings by error code, and, for univariate checks, the summary by error code and variable type.

5 Using the software

5.1 Running the software

- Please navigate to the folder in which you installed the software;
- Double click on the *JRC-ENCR-QCS.bat* file to launch the software (in case of any issue, try to run the QCS with 2GB or 4GB of RAM memory by launching the file *JRC-ENCR-QCS-2GB.bat* or *JRC-ENCR-QCS-4GB.bat*); please note that the software runs only if you double click on the .bat file;

The first time the application is launched, a warning window opens for acceptance of the software license. If the license is not accepted, the application will close. Launch the application again and accept the license to run the software.



- To quit the QCS, just close the window or select "Exit" in the File menu on the top left corner

5.2 Checking the files

From the drop-down menu select the type of file you want to check (Incidence, Population etc.), as shown below.

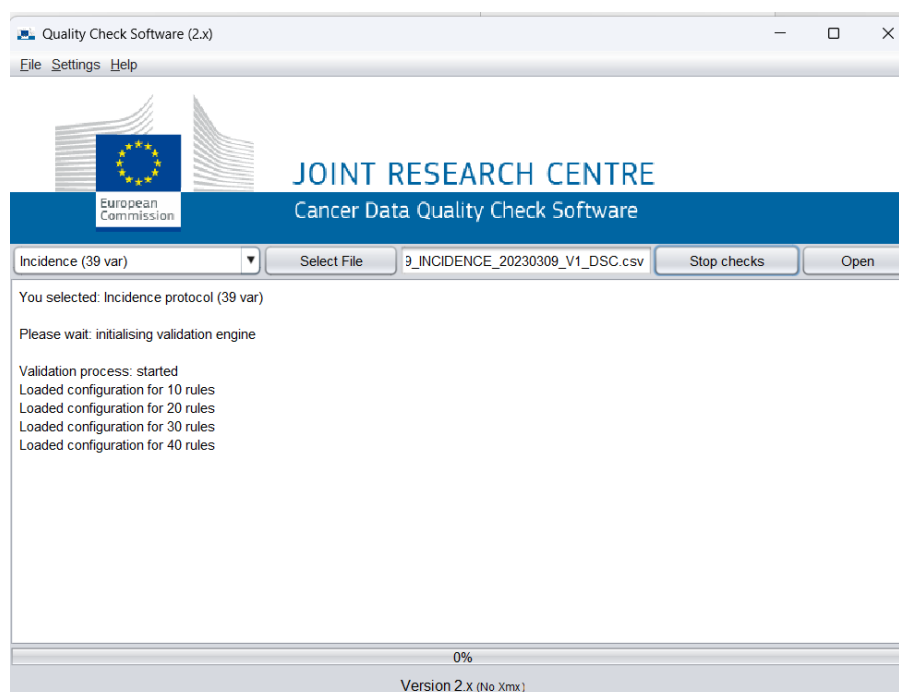


For checking the incidence file according to the ECIS data call protocol:

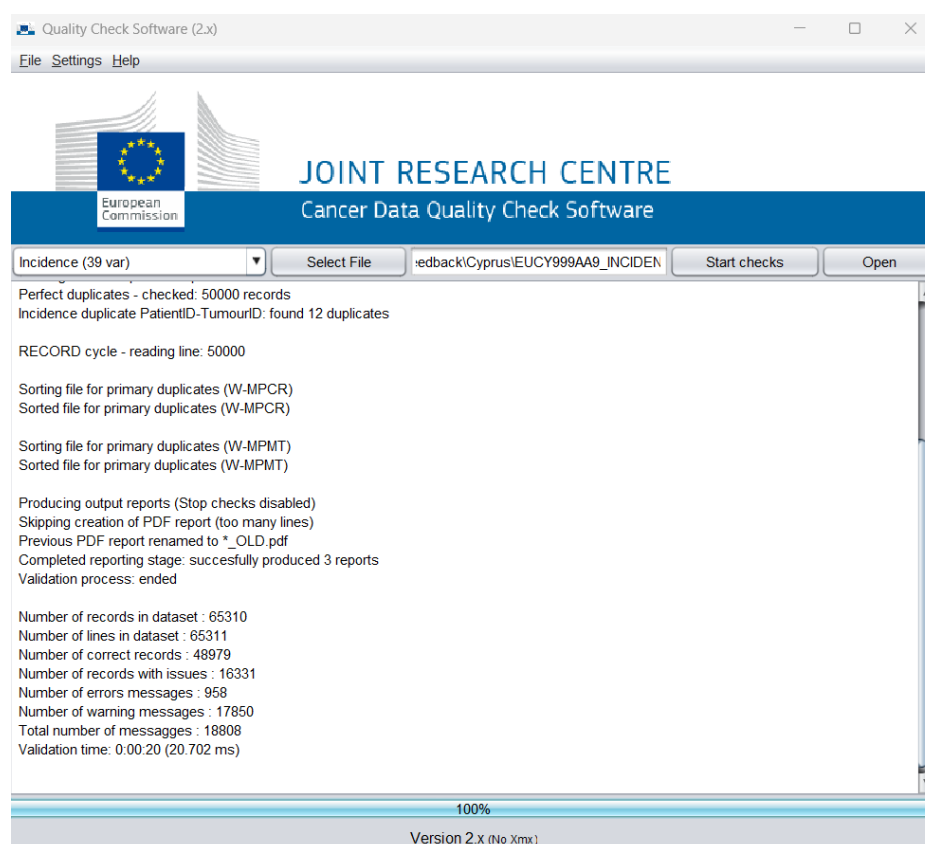
- Select the "Incidence (39 var)" option from the drop-down menu;
- Press the "Select File" button;
- A file browsing window will appear;
- Navigate to the folder where the file is located, select it (only files with extension csv or txt are accepted) and choose "Open" in the browsing window. The full path of the selected file will be displayed in the text box next to the "Select file" button;
- Press the "Start Checks" button to start the validation process.

Please note that in each validation run the output files **will be overwritten**. To keep different QCS output files, please save them in different folders or with different names.

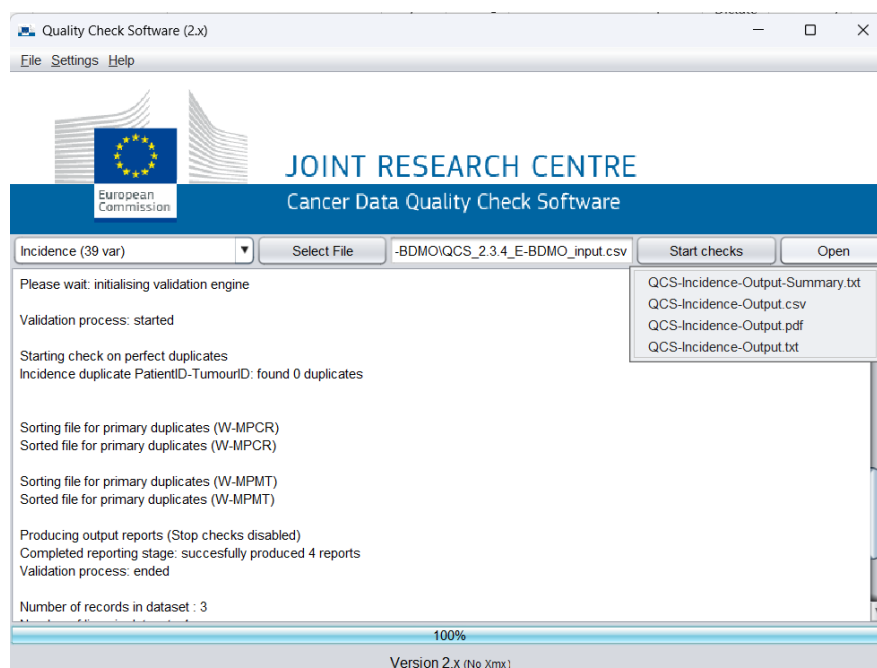
While the validation process is running, the number of checked records keeps updating in the output window. During the validation cycles the Start button becomes the Stop button so you can stop the validation process at any time before the output reports are generated.



Once the validation process is completed, the output window displays a short summary report which includes the total number of checked records and the number of errors and warning messages.



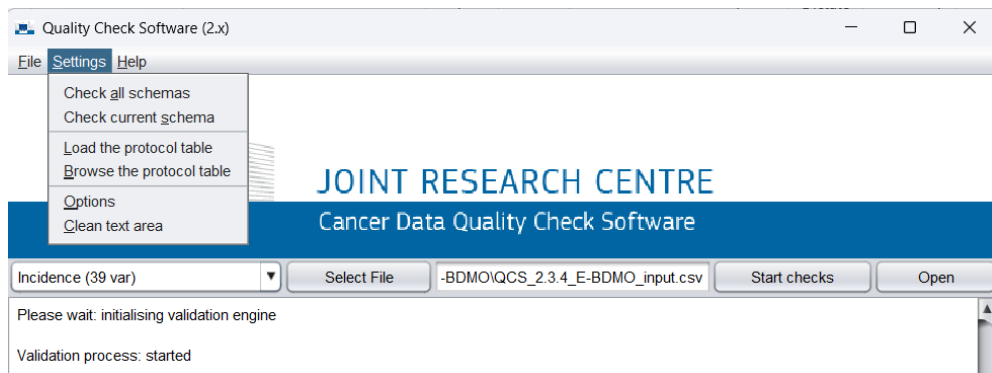
You can directly access the output files (CSV, PDF, TXT) by selecting the "Open" tab on the top right corner of the QCS window (see screenshot below). Click on a specific file to open it. These files are saved in the "output/incidence" folder created at the end of the validation process.



The procedure for checking *mortality*, *population* and *life table* files is the same as described above for *incidence* files.

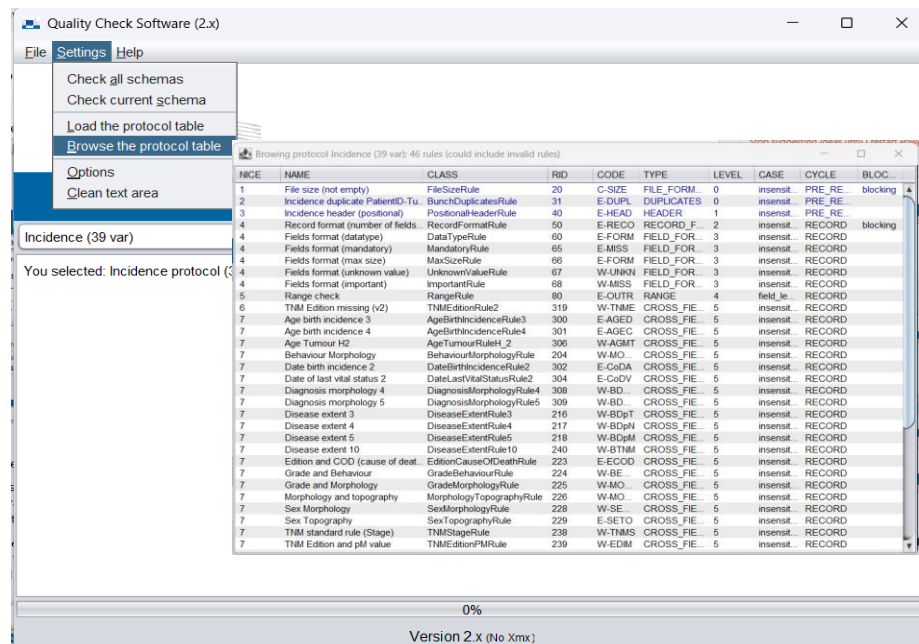
5.2.1 Settings and options

The “Settings” menu enables to select additional QCS functionalities.

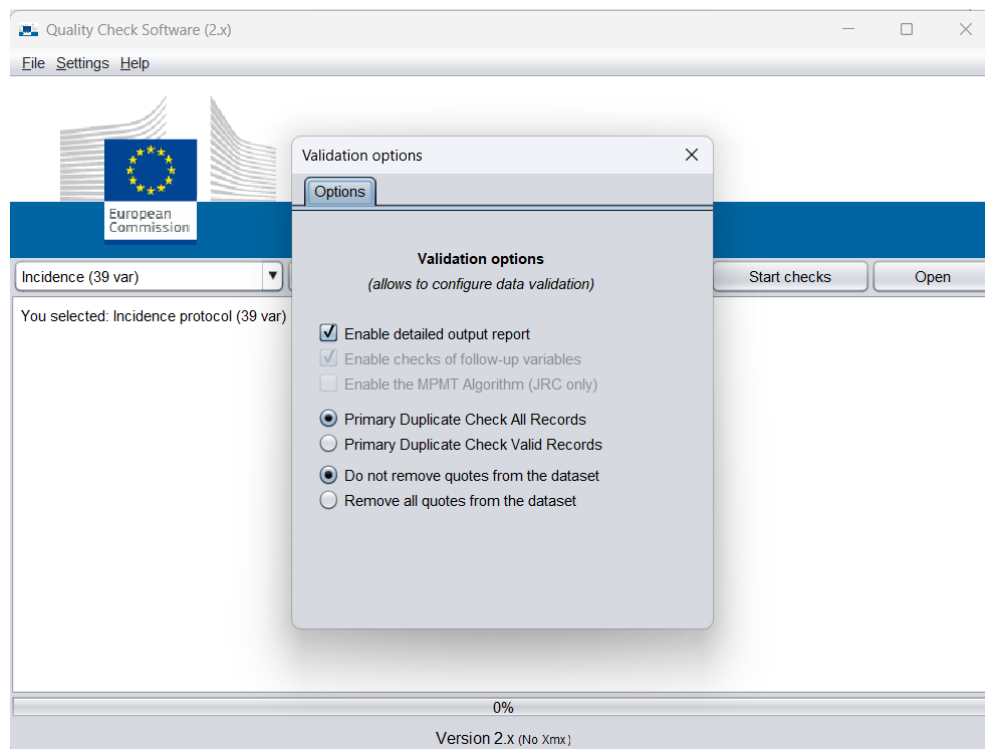


The following settings are available:

- *Check all schemas/Check current schema.* This functionality checks the existence of configuration files, the integrity of single files, the integrity of configuration files and returns the integrity status of either all schemas or the current schema;
- *Load the protocol table/Browse the protocol table.* This functionality allows to load or browse the protocol table, listing all the rules applied according to the selected protocol (see screenshot below);



- **Options.** When selected, all validation options are shown. The options active for general users (outside the JRC) are listed below:
 - *Enable detailed output report* – This option allows the creation of either detailed or aggregated pdf and txt output reports. Detailed reports are created by default.



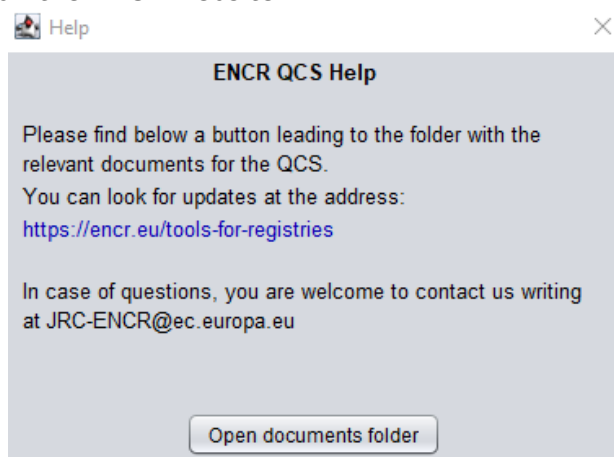
- *Primary Duplicate Check All Records/Valid Records* - These options allow to have different conditions for checking multiple primary tumours:

With the option *Primary Duplicate Check All Records* this check is performed on all records except those with errors E-MISS (Value missing), E-FORM (Format error) and E-OUTR (Value out of range) on the morphology variable (Morpho).

The option *Primary Duplicate Check Valid Records* is more selective because multiple primary tumours checks are performed only on records without the following errors/warnings: E-SETO (Topography + Sex not valid), E-AGED (DoI - DoB different from Age), E-AGEC (Age is invalid + impossible to calculate age from DoI - DoB), E-CoDA (DoB + DoI not coherent), W-AGMT (Unlikely Age + tumour type), W-MOTO (Morphology + Topography not valid) and errors as E-MISS, E-FORM and E-OUTR involving the variables topography (Topo) and morphology (Morpho) (see Annex 3 for the definition of error and warning codes)
- *Remove all quotes from the dataset.* This option allows to remove double quotes characters (") accidentally introduced into the dataset, that could cause problems with the QCS. The default configuration is *Do not remove quotes from the dataset*.
- **Clear text area.** This functionality menu deletes all text from the dialog box.

5.2.2 Help menu

This functionality includes a link to the folder with information on the QCS, a contact e-mail and the link to the QCS page on the ENCR website.



In the "Help" menu you can also find the "About" item, with copyright statement, the License, the Accessibility statement and the list of *jar* Libraries.



5.3 Output files

Each validation run generates four output files in PDF, TXT and CSV format. The output files are located in the related subfolders for *incidence*, *population*, *mortality* or *life table*, inside the "output" folder. For example, output files for incidence are located in the subfolder "**\JRC- ENCR-QCS-V2.x\output\incidence**". Please note that if the QCS output file "QCS-Incidence-Output.txt" is too large, the corresponding pdf file will not be produced; in this case, if in the output folder there is already an old PDF file produced in a previous run, it will be temporarily renamed "*_old", until a new PDF is produced that overwrites it.

5.3.1 Details of pdf/txt output file

The file "QCS-Incidence-Output-Summary.txt" contains a summary of the execution process (date and time, name of the processed file, number of rows, total number of errors and warnings) and the list of errors/warnings by error code, and the summary by error code and variable type for the univariate checks

The other pdf/txt files include also the detailed list of all errors and warnings detected for each record of the input data file.

The following screenshots refer to the different sections of the *QCS-Incidence-Output.txt* (or *pdf*) file.

Detail of upper section

```
*****
QUALITY CHECK SOFTWARE REPORT - INCIDENCE
*****
```

```
*****
PROCESSING PARAMETERS
*****
```

```
File process start : 2023-10-30 11:0:47.748
File process end   : 2023-10-30 11:0:54.749
```

```
Validated by      : QCS Version 2.1 (run 1698660055579)
```

```
File Processed:
U:\1b-Cancer Information\QCS\jrc-qcs-2.1\Test.csv (CC89315B5D)
```

```
Validation options:
```

```
Validation protocol ID      : 11
Name of validation protocol : Incidence 2020 (39 var)
Print detailed TXT report   : true
Use reference data          : true
Strip all quotes from dataset : false
Print cross-record matching info : true
```

```
ENCR Incidence options:
```

```
Acceptance MP criterion      : 2
Age-Tumour rule (W-AGMT)     : hybrid 2023 (obj 558)
Apply MPMT merging algorithm : false
```

```
*****
PROCESSING STATISTICS
*****
```

```
Number of records read      : 25573
Total number of errors       : 246
Total number of warnings     : 7273
Total number of records with issues : 6552
Total number of rejected records : 0
Preliminary rules           : nothing critical
```

```
*****
KEY TO ERROR AND WARNING CODES
*****
```

```
E-AGEC: Age is invalid + impossible to calculate age from DoI - DoB
E-AGED: DoI - DoB different from Age
E-AUVS: Autopsy+Vital status+Surv time+Date of Incidence/Date of Followup not valid (Tab. 12)
E-BDVS: BoD+Vital status+Surv time+Date of Incidence/Date of Followup not valid (Tab. 11)
E-CoDA: DoB + DoI not coherent (p.16)
E-CoDV: Date of last known vital status not valid
```

Processing parameters:

- *File process start, File process end;*
- *Validated by:* The QCS version used to produce the report;
- *File processed.* The name and the path of the file checked by the software.

Processing statistics:

- *Number of records read, Total numbers of errors, Total number of warnings;*
- *Total number of records with issues:* each record can have more errors and/or warnings;
- *Total number of records rejected:* records are rejected whenever the header is correct but some of the variables are not present, not are even blank or have a missing value.

Key to error and warning codes:

- Errors and warnings are referenced by codes, described by short labels and accompanied by the reference to the relevant table or page from the ECIS Technical Report "Data quality checks for validation of the ECIS database". See also Annex 3 – List of error and warning codes.

Detail of second part (summary of errors and warnings)

***** SUMMARY OF ERRORS BY CODE *****	
E-AUVS	Total 2
E-OUTR	Total 180
cN	10
pT	1
pN	107
Stage	62
E-SETO	Total 1
***** SUMMARY OF WARNINGS BY CODE *****	
W-AGMT	Total 75
W-BDMO	Total 594
W-BDMS	Total 49
W-BDpM	Total 618
W-BDpN	Total 615
W-BDpT	Total 426
W-BEGR	Total 109
W-BTNM	Total 3945
W-EDIM	Total 3413
W-MOGR	Total 3095

Summary of detected errors and/or warnings by code and by variable type (only for univariate checks, e.g. E-OUTR, E-MISS, W-UNKN etc.): see Annex3 – List of error and warning codes.

Detail of Multiple Primary Tumours checks: W-MPCR and W-MPMT sections

The QCS 2.x performs MPMTs quality checks for computing incidence according to the 2004 International Rules for Multiple Primary Cancers, also referenced in the ECIS Technical Report (Chapter 4).

In addition to checks on multiple primary tumours with behavior 3 (malignant), the QCS 2.x performs also checks on tumours with behavior <3 using new and more precise filtering criteria. For example, multiple primary tumours with topography codes C50 (breast) or C65-C68 (urothelial tumours) and behaviour 2 (in situ), or CNS tumours with codes C70-C72, C751-C753 and behaviour 0 (benign) or 1 (uncertain) and specific morphologies, are also checked.

These filtering criteria are detailed in the configuration file located in the QCS 2.x subfolder "...\\jrc-qcs-2.x\\config\\rules\\encr2014\\PrimaryMultipleFilter.csv".

```
*****
MULTIPLE PRIMARY MALIGNANT TUMOUR CHECK (W-MPCR)
*****

-----
PAT 234281                               Tum 572373
Duplicated record:                       Tum 572375
-----
BoD Topo Morpho      Beh Sex DoI        DoB
-----
2   C619 8000        3   1  12/2008    9/1924
-----

PAT 234281                               Tum 572375
Duplicated record:                       Tum 572375
-----
BoD Topo Morpho      Beh Sex DoI        DoB
-----
2   C343 8000        3   1  1/2012    9/1924
-----

*****
MULTIPLE PRIMARY MALIGNANT TUMOUR CHECK (W-MPMT)
*****

-----
PAT 135639                               Tum 165025
Duplicated record:                       Tum 426753
-----
BoD Topo Morpho      Beh Sex DoI        DoB
-----
7   C509 8503        2   2  4/2007    8/1936
-----

PAT 135639                               Tum 426753
Duplicated record:                       Tum 165025
-----
BoD Topo Morpho      Beh Sex DoI        DoB
-----
7   C509 8480        3   2  9/2008    8/1936
-----
```

For each W-MPMT/W-MPCR warning the following variables are reported: PAT, Tum, BoD (basis of diagnosis), Topo (topography), Morpho (morphology), Beh (behaviour), Sex, DoI (date of incidence), DoB (date of birth).

The output sections for multiple primaries, list all multiple tumours detected by the QCS 2.x in the same patient. Two types of warnings are reported, **W-MPCR** or **W-MPMT**, according to some conditions defined for specific subgroups of topography/morphology codes.

- The warning **W-MPMT** applies, under certain conditions, only to subgroups of multiple solid tumours of the same patient with specific topography codes:
 - tumours diagnosed in paired organs (e.g. C50, C62, C69 etc.);
 - tumours which occur in some 4th character subcategory of colon (C18.0-C18.7) and skin (C44.0-C44.7);

- tumours with different first 3 digits in the site code, belonging to groups of topography codes considered as a single site according to Table 17 of the ECIS Technical report (e.g. C01, C02; C00, C03-C06; C65-C68 etc.).

All equivalent tumours (same topography and morphology groups) with **W-MPMT** warnings in the same patient should be counted only once for incidence analysis, according to the 2004 International Rules for Multiple Primary Cancers, and the ENCR recommendations as referenced in the ECIS Technical report. See some examples at point 6) of Chapter 6.

- The warning **W-MPCR** applies to all tumours not belonging to the subgroups defined above, e.g. solid tumours with topography codes such as C61 (prostate), C73 (thyroid) etc. and all hematological malignancies regardless of topography code.

Equivalent tumours with **W-MPCR** warnings in the same patient should be further checked by the cancer registry to decide if only one tumour should be considered for incidence analysis. See some examples at point 6) of Chapter 6.

Detail on section with errors and warnings

***** ERRORS AND WARNINGS *****										
PAT 208387					Tum 248485					
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code	
7	C710	9441	3	1	1/2008	2/1937	Surgery pT	9 x	W-SUpT W-SUpT	
PAT 521016					Tum 655821					
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code	
7	C492	8920	3	2	11/2012	4/2008	Surgery pT	9 x	W-SUpT W-SUpT	
PAT 1388134					Tum 1514686					
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code	
7	C221	8000	3	2	11/2018	2/1949	Topo	C221	W-TNMM	
							Morpho	8000	W-TNMM	
							TNM_ed	8	W-TNMM	
							Stage	3B	W-TNMM	
							pT	x	W-TNMM	
							pN	x	W-TNMM	
							pM	0	W-TNMM	
							cT	2	W-TNMM	
							cN	1	W-TNMM	
							cM	0	W-TNMM	
							Surgery	9	W-SUpT	
							pT	x	W-SUpT	

Errors and warnings: key variables are reported for each error and warning, namely: *PAT*, *Tum*, *Topo* (topography), *Morpho* (morphology), *Beh* (behaviour), *Sex*, *DoI* (date of incidence), *DoB* (date of birth), *Var_Name* and *Var_Value* (list of relevant variables which caused the warning/error with the corresponding name and value), *Error_Code* (code according to list in Annex 3 – List of error and warning codes).

5.3.2 Details of csv output files

The csv output file contains all errors and warnings in a format easily readable by automated procedures, which can be used to perform detailed statistics and analyses.

The following screenshots refer to the *QCS-Incidence-Output.csv* file:

Detail of the left part of the csv file

Line	Patient	Tumour	BoD	Topo	Morpho	Beh	Sex	DoI	DoB
4	1388134	1514686		7 C221	8000	3	2	Nov-18	Feb-49
6	2709	2726		5 C424	9836	3	2	Aug-04	Dec-93
9	2778	2793		5 C424	9836	3	1	Apr-05	Nov-99
14	2972	2975		5 C424	9872	3	1	Sep-05	Sep-02
23	3222	3208		7 C480	9500	3	1	Jun-06	Sep-03
24	3223	3209		5 C424	9874	3	1	Jan-06	Jul-92

Detail of the right part of the csv file

Error_Cod	Error_Description	Var1_Nam	Var1_Valu	Var2_Nam	Var2_Valu	Var3_Nam	Var3_Valu
W-TNMM	Morphology not addressed by the Topograp	Topo	C221	Morpho	8000	TNM_ed	8
W-MOTO	Morphology + Topography not valid (tab.8)	Morpho	9836	Topo	C424		
W-MOTO	Morphology + Topography not valid (tab.8)	Morpho	9836	Topo	C424		
W-MOTO	Morphology + Topography not valid (tab.8)	Morpho	9872	Topo	C424		
W-TNMM	Morphology not addressed by the Topograp	Topo	C480	Morpho	9500	TNM_ed	6
W-MOTO	Morphology + Topography not valid (tab.8)	Morpho	9874	Topo	C424		

6 How to interpret the output files generated by the QCS

Two types of messages are included in the output reports: W-YYYY (warning code) and E-YYYY (error code), where the code YYYY identifies the specific type of message.

This section describes how to interpret the outcomes of the QCS for some of the variables having an impact on the incidence, survival or stage estimation. Some examples of errors on key variables for incidence, and warnings on survival variables, TNM classification variables and on multiple primary tumours are also reported.

1) Errors due to single variable format and values (ECIS technical report, Table 1)

- **E-OUTR:** out of range.

When the variables have values different from those allowed by the ECIS *Data Call Protocol*, the QCS returns the error E-OUTR.

PAT 000001		Tum 02								
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code	
1	C427	9800	3	2	9/2010	2/1924	Topo	C427	E-OUTR	

In this example the QCS gives the error E-OUTR on the variable *Topo* because topography C427 does not exist in the International Classification of Diseases for Oncology, third edition¹⁵ (ICD-O-3).

PAT 000002		Tum 01								
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code	
7	C620	9999	9	1	10/2012	4/1935	Morpho	9999	E-OUTR	
							Beh	9	E-OUTR	

In this example the QCS returns the error E-OUTR on the variables *Morpho* and *Beh* because morphology 9999 does not exist in the ICD-O-3, and behaviour 9 is not allowed according to the ECIS data call protocol.

- **E-MISS:** missing value.

PAT 000003		Tum 01								
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code	
7	C187		3	1	8/2011	3/1945	Morpho		E-MISS	

In this example the QCS returns the error E-MISS because the variable *morphology* (impacting on incidence calculations) is missing.

¹⁵ International Classification of Diseases for Oncology, Third Edition, First Revision. Geneva: World Health Organization, 2013

- **E-OUTR:** out of range value.

PAT 000002		Tum 01							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C620	9999	9	1	10/2012	4/1935	Morpho	9999	E-OUTR
							Beh	9	E-OUTR

In this example the QCS returns the error E-OUTR on the variables *Morpho* and *Beh* because morphology 9999 does not exist in the ICD-O-3, and behaviour 9 is not allowed according to the ECIS data call protocol.

- **E-AGEC:** Age is invalid or missing, and it is impossible to calculate.

PAT 5		Tum 2,96E+11							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C501	8020	3	2	10/9999	6/1954	Age		W-MISS
							YoI	9999	E-OUTR
							Age		E-AGEC
							YoB	1954	E-AGEC
							YoI	9999	E-AGEC

In this example the QCS gives the error E-AGEC because the variable *Age* (impacting on incidence calculations) is missing and cannot be calculated from DoI (9999) – DoB (1954). All the related variables *Age*, *YoB* and *YoI* are reported with the same error. Furthermore, the QCS reports an E-OUTR error for the variable *YoI* (9999 is not allowed), and a W-MISS warning for the variable *Age*.

- **E-FORM:** format error.

PAT 000005		Tum 01							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C443	80984	3	1	9/2011	2/1933	Morpho	80984	E-FORM

In this example the QCS gives the error E-FORM on variable *Morpho* (80984) because morphology should have four digits, not five, according to ICD-O-3.

2) Errors due to inconsistency of dates (ECIS technical report, §3.1.1).

- **E-CoDA:** date of birth and date of incidence are not consistent.

PAT 000006					Tum 01				
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C159	8140	3	2	12/1992	8/2016	YoB	2016	E-CoDA

In this example the QCS gives the error E-CoDA on the variable *YoB* because the year of birth (2016) is set after the year of incidence (1992).

PAT 000007					Tum 01				
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C741	9490	3	1	2/1992	3/1992	MoB	3	E-CoDA

In this example the QCS gives the error E-CoDA because the date of birth (3/1992) occurs after the date of incidence (2/1992).

- **E-CoDV:** date of the incidence and date of the last known vital status are not consistent.

PAT 000008					Tum 01				
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
2	C549	8000	3	2	8/2013	4/1933	MoI	8	E-CoDV
							YoI	2013	E-CoDV
							MoF	8	E-CoDV
							YoF	2012	E-CoDV

In this example the QCS gives the error E-CoDV because the year of incidence (*YoI* 2013) occurs later than the date of last known vital status (*YoF* 2012).

PAT 000009					Tum 01				
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
2	C160	8000	3	1	6/2009	10/1924	MoI	6	E-CoDV
							YoI	2009	E-CoDV
							MoF	4	E-CoDV
							YoF	2009	E-CoDV

In this example the QCS gives the error E-CoDV because the date of incidence (6/2009) occurs later than the date of last known vital status (4/2009).

3) Errors and warnings due to tumour and demographic variables combinations (ECIS technical report, §3.1.2).

- **E-SETO**: sex and topography combinations are not valid (table 3).

PAT 000010					Tum 01				
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
2	C569	8000	3	1	10/2013	3/1935	Sex Topo	1 C569	E-SETO E-SETO

In this example the QCS returns the error E-SETO because the combination of *topography*=C569 (ovary) and *sex*=1 (men) is not valid.

- **W-AGMT**: age and morphology/topography combinations are unlikely (table 2).

PAT 000011		Tum 01							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C424	9652	3	1	12/2003	10/2003	Age Morpho	0 9652	W-AGMT W-AGMT

In this example the QCS gives the warning W-AGMT because the morphology 9652 (Hodgkin lymphoma, mixed cellularity, NOS) is unlikely between ages 0-2 (see Table 2 of the ECIS technical report).

PAT 000012					Tum 01				
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C619	8140	3	1	3/2007	5/1996	Age Topo Morpho	10 C619 8140	W-AGMT W-AGMT W-AGMT

In this example the QCS gives the warning W-AGMT because the topography C619 (prostate) in combination with morphology 8140/3 (adenocarcinoma, NOS) is unlikely under the age of 35 (see Table 2 of the ECIS technical report).

4) Consistency between tumour variables (ECIS technical report, §3.1.3).

- **W-MOBE**: morphology and behaviour combinations are not included in the ICD-O-3 (tab. 9).

According to Rule F of the ICD-O-3 it is exceptionally possible to have a morphology and behaviour combination not listed in the ICD-O-3. Starting from version 2.0 the QCS reports as warnings such combinations, while previous versions reported as errors (E-MOBE). The list of accepted combinations of morphology and behaviour is reported in Table 9 of the ECIS technical report; these combinations are now allowed and do not produce W-MOBE warnings.

PAT 5					Tum 2				
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C501	8509	1	2	2/2021	10/1954	Morpho Beh	8509 1	W-MOBE W-MOBE

In this example the QCS gives the warning W-MOBE because the morphology 8509 cannot have behaviour 1 (borderline), only 2 (solid papillary carcinoma in situ) and 3 (invasive solid papillary carcinoma) are allowed, according to ICD-O-3.

PAT 000013					Tum 01				
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C569	8621	3	2	4/2005	6/1982	Morpho Beh	8621 3	W-MOBE W-MOBE

In this example the QCS gives error the W-MOBE because morphology 8621 (granulosa cell-theca cell tumour) with behaviour 3 (malignant tumour) is not listed in the ICD-O-3. This combination is possible, but unlikely.

PAT 000014		Tum 01							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C421	9950	1	1	12/1989	3/1921	Morpho Beh	9950 1	W-MOBE W-MOBE

In this example the QCS gives the W-MOBE warning because morphology 9950 (polycythaemia vera) has behaviour 3 (malignant tumour) in ICD-O-3. This morphology (polycythaemia vera) changed from borderline tumour (behaviour 1) in ICD-O-2¹⁶ to malignant tumour (behaviour 3) in ICD-O-3.

- **W-BDMO:** morphology too specific according to the basis of diagnosis (table 4). This rule has been updated according to Table 4 of the ECIS technical report.

PAT 311683				Tum 729324					
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
2	C710	9530	0	2	6/2013	7/1936	BoD	2	W-BDMO
							Morpho	9530	W-BDMO
							Topo	C710	W-BDMO
							Beh	0	W-BDMO

In the example above the QCS returns the warning W-BDMO because the combination of morpho/beh 9530/0 (Meningioma, NOS) with topography C71 (Brain) and basis of diagnosis 2 (clinical) is not allowed.

PAT 5		Tum 3							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
2	C710	9445	3	2	10/2023	10/1954	BoD	2	W-BDMO
							Morpho	9445	W-BDMO
							Topo	C710	W-BDMO
							Beh	3	W-BDMO
							Grade	2	W-BDMO

In this example the QCS gives the warning W-BDMO because the morphology 9445/3 (Glioblastoma, IDH-mutant of the cerebrum) is too specific for the reported basis of diagnosis (BoD 2, clinical investigation). This morphology requires BoD 8 (Cytogenetic and/or molecular testing) according to table 4 of the ECIS technical report.

¹⁶ International Classification of Diseases for Oncology, Second Edition. Geneva: World Health Organization, 1990.

- **W-BDMS**: morphology not specific enough according to the basis of diagnosis.

This rule has been updated according to Table 4 of the ECIS technical report.

PAT 10542					Tum 13064				
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
5	C421	9866	3	1	9/2004	3/1936	BoD	5	W-BDMS
							Morpho	9866	W-BDMS
							Beh	3	W-BDMS

In this example the QCS gives the warning W-BDMS because the combination of *morpho/beh* 9866/3 (Acute promyelocytic leukemia,) with basis of diagnosis 5 (cytology) is not allowed.

PAT 30407					Tum 33085				
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C421	9896	3	2	4/2004	9/1953	BoD	7	W-BDMS
							Morpho	9896	W-BDMS
							Beh	3	W-BDMS

In this example the QCS gives the warning W-BDMS because the combination of *morpho/beh* 9896/3 (Acute myeloid leukemia) with basis of diagnosis 7 (histology) is not allowed.

PAT 4					Tum 3				
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C710	9400	3	2	10/2023	10/1954	BoD	7	W-BDMS
							Morpho	9400	W-BDMS
							Beh	3	W-BDMS

In this example the QCS gives the warning W-BDMS because the morphology 9400/3 (malignant astrocytoma) is not enough specific for the reported basis of diagnosis (BoD 7, histology). This morphology requires BoD 2 (Cytogenetic and/or molecular testing) according to table 4 of the ECIS technical report.

- **W-TBGR:** topography, morphology, behaviour and grade combinations are unlikely.

This new rule follows Table 5 of the ECIS technical report, checking the grade of some tumours with behavior <3 for specific morphologies. In addition to the combinations reported in Table 5, the grade of CNS tumours with behaviours 0 and 1 is also checked according to the new ENCR Recommendations for coding tumours of the CNS (to be published).

PAT 5104					Tum 5517				
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C679	8130	2	1	2/2004	7/1953	Topo	C679	W-TBGR
							Morpho	8130	W-TBGR
							Beh	2	W-TBGR
							Grade	2	W-TBGR

In this example the QCS gives the warning W-TBGR because topography C679 (Bladder, NOS) with behavior 2 and morphology 8130 should have grade set to 1 or 3.

- **W-MOGR:** morphology, behaviour and grade combinations are unlikely (tab.6-7).

This rule has been updated according to Tables 6 and 7 of the ECIS technical report.

PAT 000022					Tum 01				
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C569	8620	3	2	5/2012	7/1954	Grade	5	W-MOGR
							Morpho	8620	W-MOGR
							Beh	3	W-MOGR

In the example above the QCS gives the warning W-MOGR because grade 5 (T-cell) is used to denote cell lineage for haematological malignancies (leukaemia and lymphoma), while morphology 8620 (granulosa cell tumour, malignant) is not an hematological malignancy. In general, the combination between grades 5-8 and morphology out of the range 9590-9993 is impossible, and produces the warning W-MOGR, except for 9801/34.

PAT 000023					Tum 01				
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C445	9709	3	1	11/2013	4/1935	Grade	6	W-MOGR
							Morpho	9709	W-MOGR
							Beh	3	W-MOGR

In this example, the QCS gives the warning W-MOGR because morphology 9709 (Cutaneous T-cell lymphoma, NOS) should have grade 5 (T-cell) instead of 6.

1	C381	8112	3	5	10/2013	10/1924	Grade	5	M-MOGR
							Beh	3	M-MOGR
							Morpho	8112	M-MOGR
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
EVL	4								

In this example the QCS gives the warning W-MOGR because the haematological

morphology 9715/3 (Angioimmunoblastic T-cell lymphoma) should have grade 5, according to table 6 of the ECIS technical report.

PAT 3				Tum 2					
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C441	8070	2	2	2/2021	10/1954	Morpho	8070	W-MOGR
							Beh	2	W-MOGR
							Grade	1	W-MOGR

In this example the QCS gives the warning W-MOGR because the morphology 8070/2 (Squamous cell carcinoma in situ) should have grade 0 (or 9 (unknown)/blank).

- **W-BEGR:** Behaviour + grade not valid (pg. 18 and tab. 5)

PAT 4				Tum 2					
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C441	8935	0	2	2/2021	10/1954	Topo	C441	W-BEGR
							Morpho	8935	W-BEGR
							Beh	0	W-BEGR
							Grade	2	W-BEGR

In this example the QCS gives the warning W-BEGR because a benign tumour (8935/2, benign fibromatous lesion) cannot have grade 2.

- **W-MOTO:** morphology and topography combinations are unlikely (tab.8).

This rule has been updated according to Tables 8 of the ECIS technical report.

PAT 000024					Tum 01				
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C779	8070	3	1	12/2008	10/1946	Morpho Topo	8070 C779	W-MOTO W-MOTO

The QCS gives the warning W-MOTO because the combination of topography C779 (Lymph node, NOS) and morphology 8070 (squamous cell carcinoma, NOS) is not allowed; this combination is probably a metastasis and the topography should be coded as C809.

PAT 000025				Tum 01					
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C539	8120	3	2	11/2007	9/1959	Morpho Topo	8120 C539	W-MOTO W-MOTO

In the example above the QCS gives the warning W-MOTO because the combination of topography C539 (cervix uteri) and morphology 8120 (transitional cell carcinoma, NOS) is very rare.

PAT 6		Tum 2							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C443	8509	3	2	2/2021	10/1954	Morpho	8509	W-MOTO
							Topo	C443	W-MOTO

In this example the QCS gives the warning W-MOTO because the combination between the morphology 8509/3 (solid papillary carcinoma) and the topography C44 (skin) is highly unlikely. This morphology is typically coded under C50 (breast), according to table 8 of the ECIS technical report.

5) Errors and warnings due to combinations of follow-up variables and basis of diagnosis (ECIS technical report, §3.1.4)

The following rules have been implemented to check consistency between important variables related to survival. Univariate checks (E-FORM, E-OUTR, W-UNKN, W-MISS) are performed on the variables Vital status (Vit_stat), Year of last known vital status (YoF), Month of last known vital status (MoF), Autopsy and Survival time (Surv_time).

Examples of multivariate checks are provided below.

- **E- AUVS:** autopsy, vital status, survival time and date of incidence/date of follow-up combination not valid (tab. 12).

This rule checks the consistency between the variables autopsy, vital status, survival time and date of incidence/date of follow-up, according to Table 12 of the ECIS technical report.

PAT 10855					Tum 13439				
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C779	9663	3	2	1/2004	7/1929	Autopsy	1	E-AUVS
							Vit_stat	2	E-AUVS
							Surv_time	221	E-AUVS
							YoI	2004	E-AUVS
							MoI	1	E-AUVS
							YoF	2004	E-AUVS
							MoF	9	E-AUVS

In this example the QCS gives the error E-AUVS because Autopsy (incidental finding of cancer at autopsy) is 1, vital status is set to 2 (dead) but the survival time (in days) is not zero and DoI is not equal to DoF.

- **E-BDVS:** basis of diagnosis, vital status, survival time and date of incidence/date of follow-up combination not valid (tab. 11).

This rule checks consistency between the variables basis of diagnosis, vital status, survival and date of incidence/date of follow-up according to Table 11 of the ECIS technical report.

PAT	3					Tum	3		
<u>BoD</u>	<u>Topo</u>	<u>Morpho</u>	<u>Beh</u>	<u>Sex</u>	<u>DoI</u>	<u>DoB</u>	<u>Var_Name</u>	<u>Var_Value</u>	<u>Error_Code</u>
0	C039	8010	3	2	2/2021	10/1954	<u>BoD</u>	0	E-BDVS
							<u>Vit_stat</u>	1	E-BDVS
							<u>Surv_time</u>	984	E-BDVS
							<u>YoI</u>	2021	E-BDVS
							<u>MoI</u>	2	E-BDVS
							<u>YoF</u>	2023	E-BDVS
							<u>MoF</u>	10	E-BDVS

In this example the QCS gives the error E-BDVS because basis of diagnosis is 0 (DCO) but vital status is 1 (alive), survival time is not 0 and date of incidence is not equal to date of follow-up.

- **E-VSBD:** vital status, basis of diagnosis and autopsy combination not valid (tab. 10).

This rule checks consistency between the variables vital status, basis of diagnosis and autopsy, according to Table 10 of the ECIS technical report.

PAT	3					Tum	3741		
<u>BoD</u>	<u>Topo</u>	<u>Morpho</u>	<u>Beh</u>	<u>Sex</u>	<u>DoI</u>	<u>DoB</u>	<u>Var_Name</u>	<u>Var_Value</u>	<u>Error_Code</u>
0	C509	8500	3	2	12/2004	11/1948	<u>Vit_stat</u>	1	E-VSBD
							<u>BoD</u>	0	E-VSBD
							<u>Autopsy</u>	1	E-VSBD

In this example the QCS gives the error E-VSBD because vital status set to 1 (alive) is not coherent with basis of diagnosis 0 (DCO) and autopsy 1 (incidental finding of cancer at autopsy). Autopsy should not be 1 and Basis of Diagnosis should not be 0.

- **W-SUMU:** combination of missing/unknown survival time and date of follow-up (tab. 13).

This rule checks consistency between the variables survival time and date of follow-up if survival time is missing/unknown, according to Table 13 of the JRC technical report.

PAT	3					Tum	3		
<u>BoD</u>	<u>Topo</u>	<u>Morpho</u>	<u>Beh</u>	<u>Sex</u>	<u>DoI</u>	<u>DoB</u>	<u>Var_Name</u>	<u>Var_Value</u>	<u>Error_Code</u>
0	C039	8010	3	2	2/2021	10/1954	<u>Surv_time</u>	99999	W-SUMU
							<u>YoF</u>	9999	W-SUMU
							<u>MoF</u>	10	W-SUMU

In this example the QCS gives the warning W-SUMU because survival time is unknown and the year of follow-up is unknown.

- **W-SUDA:** combination of survival time, date of follow-up and date of incidence (tab. 14).

This rule checks consistency between the variables survival time, date of follow-up and date of incidence, according to Table 14 of the ECIS technical report.

PAT 3				Tum 3					
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
0	C039	8010	3	2	2/2021	10/1954	Surv_time	45	W-SUDA
							YoI	2021	W-SUDA
							MoI	6	W-SUDA
							YoF	2021	W-SUDA
							MoF	10	W-SUDA

In this example the QCS gives the warning W-SUDA because survival time is 45 days but the difference between year of follow-up and year of incidence is about 4 months (the allowed interval is 94-153 d, according to tab. 14)

- **W-SUBA:** Survival time zero with ambiguous/unlikely values of BoD/Autopsy (Tab. 15)

This rule checks consistency between the variables Survival time, BoD and Autopsy, when Survival time is zero (with any vital status), according to Table 15 of the ECIS technical report.

PAT 4					Tum 1				
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C039	8010	3	2	10/2023	10/1954	Surv_time	0	W-SUBA
							BoD	7	W-SUBA
							Autopsy	0	W-SUBA
							Vit_stat	2	W-SUBA

In this example the QCS gives the error E-SUBA because Survival time is 0, but BoD is 7 and Autopsy is 0 (no autopsy). If Survival time is 0 then BoD should be 0 (DCO) or Autopsy should be 1.

PAT 3				Tum 1					
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
x	C039	8010	3	2	10/2023	10/1954	Surv_time	0	W-SUBA
							BoD	x	W-SUBA
							Autopsy		W-SUBA
							Vit stat	1	W-SUBA

In this example the QCS gives the error E-SUBA because Survival time is 0, but BoD is invalid (x, E-FORM) and Autopsy is missing (W-MISS).

6) Consistency between stage/treatment variables and other tumour variables (ECIS technical report, §3.1.5)

- **W-BTNM:** behaviour and TNM combination not valid (pg. 31).

This rule has been updated according to the additional checks suggested in section 3.2.5 of the ECIS technical report.

PAT 000021		Tum 01							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C629	9061	3	1	2/2011	9/1991	Beh pT cT	3 is 9	W-BTNM W-BTNM W-BTNM

In this example the QCS gives the warning W-BTNM because behaviour 3 (malignant tumour) is not coherent with pathological T (*pT*) set to *is* (carcinoma in situ).

PAT 3		Tum 1							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C671	8050	2	2	10/2023	10/1954	Beh pT cT Stage	2 is 1	W-BTNM W-BTNM W-BTNM W-BTNM

In the example above the QCS gives the warning W-BTNM because behavior 2 (in situ) should have stage set to 0.

- **W-TNMM:** TNM and stage are present, but morphology is not included in the TNM.

The groups of morphology codes used in the TNM classification rules have been updated to TNM edition 6, 7 and 8, according to Table 15 of the ECIS technical report.

PAT 000026		Tum 01							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C505	9120	3	2	11/2007	3/1971	Topo Morpho TNM_ed Stage pT pN pM cT cN cM	C505 9120 6 IIB 3 0 0 9 9 9	W-TNMM W-TNMM W-TNMM W-TNMM W-TNMM W-TNMM W-TNMM W-TNMM W-TNMM W-TNMM

In the example above the QCS returns the warning W-TNMM because the tumour is a breast angiosarcoma (morphology 9120) with stage IIB. When topography is set to C50 (breast) only carcinomas should be staged.

- **W-TNMS:** TNM and stage are not consistent.

PAT 000027		Tum 01							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
7	C502	8140	3	2	8/2013	6/1965	Topo	C502	W-TNMS
							Morpho	8140	W-TNMS
							TNM_ed	7	W-TNMS
							Stage	IIIA	W-TNMS
							pT	3	W-TNMS
							pN	1	W-TNMS
							pM	1	W-TNMS
							cT	9	W-TNMS
							cN	9	W-TNMS
							cM	9	W-TNMS
							Grade	3	W-TNMS
							Age	48	W-TNMS
							Beh	3	W-TNMS

In the example above the QCS returns the warning W-TNMS because the tumour is a breast carcinoma with $pT=3$, $pN=1$, $pM=1$ and $Stage=IIIA$. This combination is not consistent, according to TNM Ed.7, $Stage$ should be IV.

TNM/stage at diagnosis and BoD

- **W-BDpT:** pT + BoD not valid (p. 32)

PAT 3		Tum 1							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
2	C719	9420	3	1	9/2020	4/1981	Beh	3	W-BDpT
							BoD	2	W-BDpT
							pT	2	W-BDpT

In the example above the QCS returns the warning W-BDpT because $pT=2$ and $BoD=2$ (clinical investigation) but it should be 7 (histology).

- **W-BDpN:** pN + BoD not valid (p. 32)

PAT 3		Tum 1							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
2	C719	9420	3	1	9/2020	4/1981	Beh	3	W-BDpN
							BoD	2	W-BDpN
							pN	1	W-BDpN

In the example above the QCS returns the warning W-BDpN because $pN=1$ and $BoD=2$ (clinical investigation) but it should be 7 (histology).

- **W-BDpM:** pM + BoD not valid (p. 32)

PAT 3		Tum 1							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
2	C719	9420	3	1	9/2020	4/1981	Beh	3	W-BDpM
							BoD	2	W-BDpM
							pM	1	W-BDpM
							cT	9	W-BDpM
							pT	is	W-BDpM

In the example above the QCS returns the warning W-BDpM because pM=1, BoD=2 (clinical investigation) but it should be 7 (histology) and pT should not be in situ (is).

TNM/stage at diagnosis

- **W-SSMI:** Stage not available and cannot be computed (p. 32)

PAT 1		Tum 1							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
2	c719	9420	3	1	9/2020	4/1981	Stage		W-SSMI
							cT	9	W-SSMI
							pT	9	W-SSMI
							cN	9	W-SSMI
							pN	9	W-SSMI
							pM	9	W-SSMI
							cM	9	W-SSMI

In the example above the QCS returns the warning W-SSMI because Stage is missing and cannot be computed from the TNM variables which are unknown.

PAT 1		Tum 1							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
2	c719	9420	3	1	9/2020	4/1981	Stage	9	W-SSMI
							cT	9	W-SSMI
							pT	1	W-SSMI
							cN	9	W-SSMI
							pN	9	W-SSMI
							pM	0	W-SSMI
							cM	9	W-SSMI

In the example above the QCS returns the warning W-SSMI because Stage is unknown and cannot be computed because pN and cN are both unknown and only pT=1 e pM=0 are available.

Stage at diagnosis/staging system (ToS)

- **W-TOST:** staging system is not defined (p. 32)

PAT 3		Tum 1							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
2	c719	9420	3	1	9/2020	4/1981	ToS		W-TOST
							Stage	3	W-TOST

In the example above the QCS returns the warning W-TOST because Stage is valid but the staging system (ToS) is not defined (missing).

Treatment variables, BoD and TNM stage

- **W-SUBD:** Surgery+BoD not valid (p. 32)

PAT	2	Tum 1							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
6	C719	9420	3	1	9/2020	4/1981	Surgery	3	W-SUBD
							BoD	2	W-SUBD

In the example above the QCS returns the warning W-SUBD because Surgery=3 (operative surgery) but BoD=2 (clinical investigation), in this case BoD should be 7.

- **W-SUpT:** Surgery+BoD+Autopsy+pT not valid (p. 32)

PAT	7	Tum 1							
BoD	Topo	Morpho	Beh	Sex	DoI	DoB	Var_Name	Var_Value	Error_Code
2	C719	9420	3	1	9/2020	4/1981	Surgery	0	W-SUpT
							pT	1	W-SUpT
							Autopsy	9	W-SUpT
							BoD	2	W-SUpT

In the example above the QCS returns the warning W-SUpT because Surgery=0 (no surgery), BoD=2 (clinical investigation), Autopsy=9 (unknown) but pT=1, in this case pT should be coded as unknown or missing.

7) W-MPMT and W-MPCR: Warnings for multiple primary tumours (ECIS technical report, Chapter 4).

The QCS produces two types of warnings, W-MPMT and W-MPCR, for multiple tumours of the same patient which are no duplicates. These warnings are based on specific combinations of topography and morphology codes, as explained in § 5.3.1 of this document.

If a patient has two or more multiple tumours, or groups of multiple tumours, flagged with **W-MPMT**, only one primary tumour in each group will be considered for incidence analysis, according to the 2004 International Rules for Multiple Primary cancer.

If a patient has two or more multiple tumours, or groups of multiple tumours, flagged with **W-MPCR**, only one primary tumour could be selected for incidence analysis, but this should be confirmed by the CR.

Below some examples:

- **W-MPCR:** Multiple primary malignant tumour 'strict', to be checked by the Cancer Registry

PAT 000028						Tum 01
BoD	Topo	Morpho	Beh	Sex	DoI	DoB
7	C717	8000	3	2	12/2016	12/1954
PAT 000028						Tum 02
BoD	Topo	Morpho	Beh	Sex	DoI	DoB
7	C717	9590	3	2	11/2016	12/1954

In the example above, the QCS gives the warning **W-MPCR** because the two records could refer to the same primary tumour, a malignant lymphoma, not otherwise specified (9590/3) of the brain (C71), to be confirmed by the CR.

PAT	000029						Tum	01
BoD	Topo	Morpho		Beh	Sex	DoI		DoB
7	C679	8130		3	2	5/2003		1/1930
PAT	000029						Tum	02
BoD	Topo	Morpho		Beh	Sex	DoI		DoB
7	C809	8000		3	2	11/2010		1/1930

In this example, the QCS gives the warning **W-MPCR** because the two records could refer to the same primary tumour, a urothelial carcinoma (8130/3) of the bladder (C679, site unspecified), to be confirmed by the CR.

- **W-MPMT**: Multiple primary malignant tumour

PAT	000030						Tum	01
BoD	Topo	Morpho		Beh	Sex	DoI		DoB
7	C501	8500		3	2	1/2001		7/1960
PAT	000030						Tum	02
BoD	Topo	Morpho		Beh	Sex	DoI		DoB
7	C508	8520		3	2	10/2002		7/1960

In the example above, the QCS gives the warning **W-MPMT** because these are two tumours diagnosed in breast (C50, tab.17) with equivalent morphology codes (8500 and 8520, Adenocarcinomas, tab. 18). According to the 2004 International Rules, only one primary tumour should be considered for incidence analysis (the first to be diagnosed in 2001, an invasive ductal carcinoma of the breast).

PAT	1141980						Tum	1230495
Duplicated record:							Tum	1567154
BoD	Topo	Morpho		Beh	Sex	DoI		DoB
7	C182	8140		3	1	12/2017		4/1960
PAT	1141980						Tum	1567154
Duplicated record:							Tum	1230495
BoD	Topo	Morpho		Beh	Sex	DoI		DoB
7	C184	8140		3	1	12/2018		4/1960

In this example, the QCS gives the warning **W-MPMT** because these are two tumours diagnosed in colon (C18, tab.17) with the same morphology code (8140, Adenocarcinoma, tab.18). According to the 2004 International Rules, only one tumour should be considered for incidence analysis (the first to be diagnosed in 2017).

Annex 1 – Major changes and improvements

Since March 2026, the source code of the QCS application has been published on [Code Europa EU](#), the European Commission's platform for open source collaboration, managed by the Open Source Programme Office (EC OSPO)."

Major updates and new features available from previous versions are listed below. Please refer to the change log file "change_log.txt" in the docs folder for more details.

Changes in CSV Data Structure Converter 1.3

Changes in QCS version 2.3.16

Validation protocols updates:

- Updated Population/Mortality/Life table validation protocols according the latest version of the [ECIS data call protocol](#) (new variable names in the file header of each protocol)

Univariate/multivariate checks updates:

- Updated configuration files for univariate checks of staging variables (E-OUTR, E-FORM)
- Updated configuration files for multivariate checks of staging variables (W-TNMM, W-TNMS)
- Updated rule W-TNMS for checking TNM values and TNM Stage according to TNM edition

Changes in previous QCS version 2.3.9

GUI:

- New "Stop checks" button available during the validation process;
- Accessibility statement added in the Help/About menu;
- Updated menu for selection of validation protocol;

Output Reports:

- Detailed list of error codes by variable type for univariate checks in the output summary report (txt);

New features:

- Added BAT file with 4GB in QCS folder;
- Implemented "stop validation" feature and new feature to check if any report is open;

Univariate/multivariate checks updated according to the latest version of the ECIS Technical report:

- New multivariate check for follow-up variables (rule SUBA) according to Table 15;
- Updated conditions for multivariate checks of follow-up variables (rules E-VSBD, E-BDVS and E-AUVS) according to tables 10, 11 and 12;

- Updated conditions for multivariate checks for follow-up variables (rules W-SUMU, W-SUDA) according to Tables 13, 14;
- New multivariate checks for staging variable (rules W-SSMI and W-TOST), p. 33;
- Updated conditions for multivariate checks of staging variables (updated rules W-BTNM, W-TNME, W-TNMM, W-TNMS, W-BDpT, W-BDpN and W-BDpM);
- Updated configuration files for multivariate rules W-BDpT, W-BDpN and W-BDpM;
- Updated logic of univariate checks E-MISS, W-MISS and W-UNKN for follow-up and stage variables;
- **NEW:** Updated configuration files for checking Stage and TNM variables (rule W-TNMS) (TNM tables with alphanumeric TNM values);
- **NEW:** Updated conditions for multivariate check of DoB and DoI (rule E-CoDA);
- **NEW:** Updated range for YoB, YoI, YoF and Surv_time;

Changes in previous QCS versions

GUI:

- Option "Enable checks of follow-up variables" has been added in the Settings/Options menu (currently active for JRC internal users only);
- A reminder to accept the user license has been added the first time the software is launched;
- Additional messages on the status of the validation process have been added;
- A short summary on the results of the validation process has been added at the end of each run;
- A new option "Remove/do not remove quotes from the dataset" has been added in the Settings/Options menu to help users in cleaning the dataset;

Output Reports:

- Details on the set of "Validation options" used in the last run have been added;
- A new TXT output file with a summary of the validation output (from version 2.1.1);

New features:

- Implemented support for running the QCS in background as a service. This allows to validate dataset with just one or few lines in real time;

Code and configuration files:

- Upgrade of Log4j to version 2.17.1 to mitigate vulnerability risk;
- Better usage of the computer's memory during validation;

Univariate/multivariate checks updated according to the latest version of the ECIS Technical report:

- Update of consistency checks between morphology and topography (rule W-MOTO) according to the updated Table 8;
- Update of consistency checks between basis of diagnosis, morphology and behaviour by topography (rule W-BDMO) according to the updated Table 4;
- Update of consistency checks between morphology and grade for haematological malignancies, according to the updated Table 6;
- Update of configuration files used to define multiple primaries malignant tumours (MPMT) groups (rules W-MPMT and W-MPCR);
- Update of checks between morphology and grade (rule W-MOGR) for haematological and solid tumours, and update of morphology and grade checks for CNS tumours according to the ENCR recommendations;
- Update of checks between basis of diagnosis, morphology and behaviour by topography (rule W-BDMS) according to the updated Table 4;
- Updated logic for multivariate checks of morphology/behaviour and grade for some combinations with behaviour 3 (rule W-BEGR) according to Table 7 and with behaviour 2 (W-TBGR) according to Table 5;
- Update of univariate checks, compliant to Table1;
- Update of consistency checks between morphology and topography (rule W-MOTO) according to the updated Table 8;
- Update of consistency checks between morphology and grade of CNS tumours with Beh=3 (rule W-MOGR), according to the new ENCR Recommendations for coding tumours of the CNS (to be published);
- Update of consistency checks between morphology and grade of CNS tumours with Beh<3 (rule W-TBGR), according to the new ENCR Recommendations for coding tumours of the CNS;
- Update of consistency checks between Surgery, Basis of Diagnosis (BoD), Autopsy and the variable pT, according to the updated rules on p.33 of the ECIS Technical report;
- Update of consistency checks between age and tumour type (rule W-AGMT) according to the updated Table 2;
- Update of consistency checks between basis of diagnosis, morphology and behaviour by topography (rules W-BDMO, W-BDMS), according to Table 4 and to the 2022 ENCR Recommendations on Basis of Diagnosis;
- Update of consistency checks between morphology and grade compliant to Table 5 and to the WHO grading system, table 27 of the ICD-O-3.1 (rule **W-TBGR**) for CNS tumours;
- Update of consistency checks between morphology and grade compliant to Table 6 and 7 of the ECIS Technical report for rule W-MOGR;
- Update of consistency checks between morphology and topography codes (rule W-MOTO) according to Table 8;
- Selected combinations of morphology/behaviour not included in any version of the ICD-O-3 are now accepted, according to Table 9;
- Update of consistency checks for follow-up variables according to Tables 10, 11, 12 (rules **E-VSBD**, **E-BDVS** and **E-AUVS** replacing the rule E-VBDA in previous versions of the QCS;

- Multivariate checks for treatment variables, basis of diagnosis and TNM stage implemented according to rules reported at p.33 of the latest version of the JRC report (new rules **W-SUBD** and **W-SUpT**);
- Update of consistency checks between behaviour and TNM/stage (rule **W-BTNM** now checking also the stage, see p.33 of the latest version of the JRC report);
- Update of consistency checks between TNM/stage and basis of diagnosis (rules **W-BDpT**, **W-BDpN** and **W-BDpM**, see p.33 of the latest version of the JRC report);
- Update of groups of morphology codes used to check consistency between TNM variables and stage according to TNM editions 6,7 and 8 (rules **W-TNMM** and **W-TNMS**);
- Update of NUTS codes for the geographical variables Geo_code according to the EUROSTAT Nuts 2021 classification (<https://ec.europa.eu/eurostat/web/nuts/background>);
- Update of MPMT checks according to the 2004 International Rules and Chapter 4 of the latest version of the ECIS Technical report:
 - Groups of morphology codes considered as a single entity updated according to Table 15, following the adoption of the new ICD-O-3.2 codes;
 - Groups of topography codes considered as a single site updated according to Table 14;
 - More precise filtering criteria for MPMTs for records with behavior less than 3, implemented in the new configuration file located in the QCS 2.1.x *config* folder: "...\\jrc-qcs-2.1.x\\config\\rules\\encr2014\\PrimaryMultipleFilter.csv".
- More precise identification and classification of MPMTs (old rule W-MPMT splitted into the new rules **W-MPMT** and **W-MPCR**);
- Update of morphology groups for checking multiple primaries according to the latest version of the ECIS Technical report;
- Update of consistency checks between TNM values and basis of diagnosis (new rule **W-BDpM**);
- Update of topography codes according to ICD-O-3 (wrong code C74.4 has been removed).

Annex 2 – Known issues and bugs, and future improvements

Issues arising from cancer registries data validation through the QCS are continuously collected, to be fixed in next versions. The following lists includes already known issues:

- The QCS could not run properly on computers with very low RAM memory (less than 4GB). If the application does not start, or if it blocks during execution, make sure that your local machine supports at least 4GB of memory and that your internal policies allow to use all the available memory (e.g. you use a corporate PC);
- To avoid memory issues, the QCS should be run clicking on the BAT file with label "2GB" or "4GB" in the file's name. This solution could be blocked by strict system policies, such as those applied by universities, corporate environments, governments etc. If you experience memory issues and can't run the BAT file with the "2GB" or "4GB" label, please ask support to your local system administrator and ask to be granted the necessary permissions for running the "2GB" or "4GB" file;
- If the TXT files located in the Output directory cannot be opened with your text editor, please set Notepad++ as the default application to open them;
- The MPMT/W-MPCR warnings could be wrongly assigned to some rare combinations of solid or haematological MPMTs: in case, please notify;
- If the input dataset has a critically wrong header (the first line), with errors or missing variables, the QCS might not correctly produce output reports;
- The QCS still checks for the previous version's warning W-SEMO, which is not relevant anymore for the ECIS data call protocol. Should your dataset trigger any W-SEMO message, please ignore related warnings;

Annex 3 – List of error and warning codes

This annex reports the list of error and warning codes included in the output files "QCS- Incidence-Output.pdf" and "QCS-Incidence-Output.txt". The table or page numbers referenced in the list are from the latest version of the [ECIS Technical report](#).

Error codes

E-AGEC: Age is invalid or missing and cannot be calculated age by subtracting date of incidence from date of birth, since one or both dates are invalid or missing.

E-AGED: The age calculated as difference in years from (Date of incidence – Date of birth) differs from the value of variable *Age* by more than one year.

E-AUVS: the combination of Autopsy 1 with vital status and/or survival (Date of incidence – Date of follow-up in days) is not valid. Vital status should be 2 and Survival should be 0 (Table 12).

E-BDVS: the combination of Basis of diagnosis 0 (DCO) with vital status and/or survival is not valid. Vital status should be 2 and survival should be 0 (Table 11).

E-CoDA: The date of birth is not consistent with the date of incidence, i.e. the latter occurs before the date of birth.

E-CoDV: The date of last known vital status is not valid (e.g. when the date of the incidence and the date of the last known vital status are not consistent).

E-DUPL: The same patient ID/tumour ID combination is repeated in two or more records.

E-ECOD: ICD¹⁷ edition and cause of death combination are not valid, e.g. cause of death 157 (pancreatic cancer) with ICD edition 10 (the correct value for pancreatic cancer is C25 for ICD-10, and 157 in ICD-7, ICD-8 and ICD-9). The check is performed for ICD editions from 7 to 10.

E-FORM: Format error, e.g. when a character value is used when a numeric one is required.

E-HEAD: Errors in the file header, e.g invalid number/order of columns, invalid header's separator etc.

E-MISS: Value missing, e.g. when variable *morphology* is unknown. This errors applies to variables whose invalid/missing/unknown values have an impact on incidence statistics.

E-OUTR: Value out of range; value is not in agreement with the ones allowed by the ECIS data call protocol (for instance, behavior equal to 6 or sex set to 4).

E-RECO: The record has the wrong number of fields.

E-SETO: Sex and topography combinations are not valid (Table 3).

E-VSBD: the combination of vital status 1 with autopsy and/or basis of diagnosis is not valid. Autopsy should be not 1 and Basis of diagnosis should be not 0 (Table 10).

¹⁷ International Classification of Diseases (<https://www.who.int/standards/classifications/other-classifications/international-classification-of-diseases-for-oncology>)

Warning codes

W-AGMT: Unlikely age and morphology/topography combinations (Table 2).

W-BDMO: Morphology too specific according to the basis of diagnosis. See pages 17-18 for valid combinations of basis of diagnosis and morphology.

W-BDMS: Morphology not specific enough according to the basis of diagnosis. See page 19 for valid combinations of basis of diagnosis and morphology.

W-BDpM: Basis of diagnosis and *pM* combination is not valid. If *pM* is 1 then basis of diagnosis should be 7 or 6 (see page 33).

W-BDpN: Basis of diagnosis and *pN* combination is not valid. If *pN* is not *NX* and is not missing then basis of diagnosis should be 7 (see page 33).

W-BDpT: Basis of diagnosis and *pT* combination is not valid. If *pT* is not *TX* and is not missing then basis of diagnosis should be 7 (see page 33).

W-BEGR: Behavior and grade combination is not valid (Table 7).

W-BTNM: Invalid behavior and TNM combination, e.g. *Behavior*=3 and *pT*=*Tis* (see page 33).

W-EDIM: TNM edition and *pM* are not consistent. The warning is returned when TNM edition is 7 or 8, and *pM* or *cM* are "X", since this value should be "0".

W-MISS: Value missing, e.g. when variable *Autopsy* is blank. This check applies to variables whose invalid/missing/unknown values is not impacting on incidence statistics.

W-MOBE: Morphology and behavior combinations not included in the ICD-O-3 (some combinations are allowed, according to Table 9).

W-MOGR: Morphology and grade combination is unlikely (Tables 6 and 7).

W-MOTO: Morphology and topography combination is unlikely (see table 8)

W-MPCR: Multiple primary tumour (see § 5.3 of this document)

W-MPMT: Multiple primary tumour (see § 5.3 of this document)

W-SEMO: Sex and morphology combination is unlikely, e.g. female with seminoma. See table 5 for the list of unlikely combinations.

W-SSMI (NEW): Stage not available and cannot be computed.

W-SUBA (NEW): Survival time zero with ambiguous/unlikely values of BoD/Autopsy (Tab. 15).

W-SUBD: Surgery+BoD not valid (p.33)

W-SUDA: combination of survival time (in days) not consistent with date of incidence and date of follow-up (Tab. 14).

W-SUMU: combination of survival time missing/unknown and date of follow-up missing/unknown is not valid (Tab. 13).

W-SUpT: Surgery+BoD+Autopsy+pT not valid (p. 33)

W-TBGR (NEW): combination of morphology/behavior and grade not valid for tumours with behavior <3 (Tab. 5).

W-TNME: TNM and stage are present, but TNM edition is not valid or missing. The warning is returned since it is not possible to make a consistency check between TNM and stage.

W-TNMM: TNM and stage are present, but the morphology is not included in the TNM, e.g. when only carcinomas can be staged in a given topography, but stage is filled in for sarcomas.

W-TNMS: TNM and stage are not consistent, e.g. pT is 1, pN is 0, pM is 0 and stage is *IV*. In case both pathological (pT , pN and pM) and clinical (cT , cN and cM) TNM are provided for a tumour, the QCS will check the consistency between the pathological TNM and stage.

W-TOST (NEW): Staging system is not defined (p. 33).

W-UNKN: missing/unknown value for variables with no impact on incidence calculations, which however could be important for quality evaluations or survival analysis (e.g. basis of diagnosis=9, or year of follow up=9999).

Annex 4 – Running the JRC-ENCR QCS in background

Overview

The QCS can be run in different modes as listed below:

- **GUI** (standard execution): opens the main window and wait for user's actions;
- **Silent** (background process): run in background and validate the file passed as argument;
- **Introspection** (console): prints information about protocols and rules.

To view all supported arguments, please run the application with the **-h** option. The actual syntax may depend by your Java installation, and should be something like:

```
java -jar jrc-qcs-2.1.jar -h
```

The main supported runtime arguments are the following (see *Command line examples* below):

- **-gui**: opens the application in GUI mode (standard execution);
- **-v**: validates target dataset using the target validation protocol;
- **-p**: prints the list of rules defining target protocol;
- **-s**: prints the list of variables addressed by target protocol;
- **-fi**: prints all the information about the target variable (aka *field*);
- **-rf**: prints the list of rules addressing the target variable (aka *field*).

Command line examples

Validation of a dataset using the ECIS data call protocol (i.e. protocol with ID = 11):

```
java -jar jrc-qcs-2.1.jar -v 11 C:/Home/incidence_1.csv
```

List of rules for the ECIS data call protocol (i.e. protocol with ID = 11):

```
java -jar jrc-qcs-2.1.jar -p 11
```

Description of the topography field in the ECIS data call protocol (field with ID = 80):

```
java -jar jrc-qcs-2.1.jar -fi 80
```

List of rules addressing the topography field in the ECIS data call protocol (field ID = 80):

```
java -jar jrc-qcs-2.1.jar -rf 80
```

Sample scripts

The *Examples* directory of the application contains two sample files showing examples of usage as a **background** process:

- **Run-qcs.bat**: example of executing the application in Windows OS;
- **run-qcs.sh**: example of executing the application in Linux OS.

Remark: the sample files listed above DO NOT provide complete management of possible execution errors, and DO NOT access (nor read, nor parse) the output reports produced at the end of the validation process. The actual management of the execution outcome MUST BE handled by the caller, with respect of his/her specific client's *execution context* (e.g. type of operative system, execution from webapp, execution as system service, etc.) and of the specific client's *needs and business* (e.g. validation of a single line, validation of big files, synchronous validation, asynchronous validation, etc.).

These sample files are provided only to show an example of executing the application as a background process and how to intercept the possible process outcomes.

Output reports

At the end of the validation process, the application should produce output reports in path:

<application base path>/output

Guidelines

Some of the reports produced in the *output* directory are intended to be accessed directly by the final user, therefore they are in a easy readable format (PDF or TXT). If the client application needs to read, parse, analyse or process the results of the validation process, usage of the following report is recommended:

- **QCS-Incidence-Output.csv:** read this file in order to acknowledge the detailed result of the validation process, line by line. This should be the core report when the application is run as a background process.