JMP Clinical Installation and Operation Qualification (IQ/OQ)

These instructions describe the process for qualifying the installation and operation of JMP Clinical 7 on your Windows desktop machine. They include 4 major sections:

- Step 1: Installation Qualification
- Step 2: Operation Qualification
- Step 3: NIST Testing
- Step 4: Run a Simple Analysis

Note: When you open JMP Clinical for the first time, a JMP script that generates the dialogs for all of the JMP Clinical processes is run by default. This step automatically generates new files. Because this discrepancy will be found and reported by the SAS Install Qualification Tool 9.4 utility, **you must run** the installation qualification before you open JMP Clinical for the first time.

These instructions assume you have completed the installation of JMP Clinical as described in step 2c of the **Installation Instructions for JMP Clinical**.

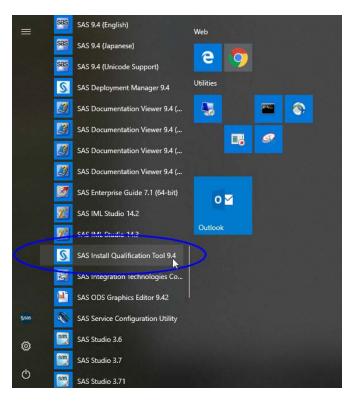
Step 1: Installation Qualification

The SAS Install Qualification Tool 9.4 utility enables you to qualify the integrity of any SAS software installation. This program, which is installed along with the other SAS programs in your order, examines and compares them with the programs that were supposed to be installed. Any deviations are reported.

In the example shown here, JMP Clinical was installed on a newly staged work station.

* Select Start > SAS > SAS Install Qualification Tool 9.4 to start the utility, as shown below:





The program opens and begins scanning and validating the installed files, as shown below:



Note: This process might take some time. Please be patient.

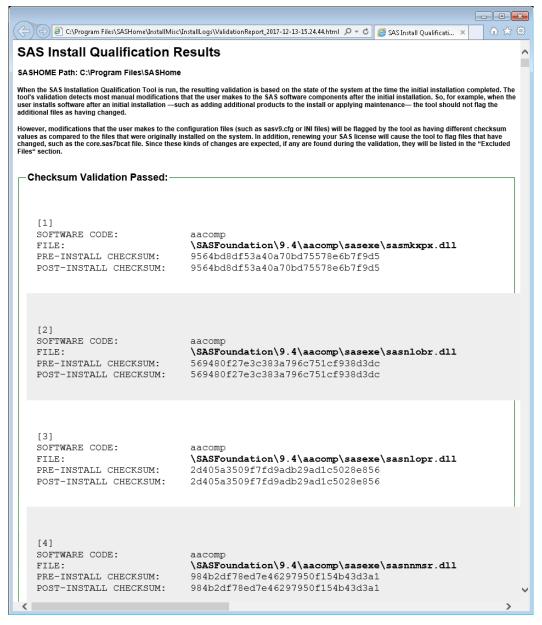
An HTML file containing the results is generated when the scan is complete. The name and path and a link to the file are displayed in a summary window, as shown below:



Note: The name of the output file contains both the date and the time at which the validation scan was run. This file is always placed in the C:\Program Files\SASHome\InstallMisc\InstallLogs directory.

In this example, there were zero (0) validation errors.

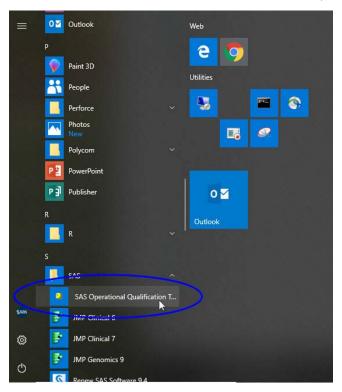
Tither click on the link or navigate to the output file to view the results, partially shown below:



Proceed to <u>Step 2: Operation Qualification</u>.

Step 2: Operation Qualification

*Belect Start > SAS > SAS Operational Qualification Tool to start the utility, as shown below:



A DOS window appears. A prompt directs you to specify the directory in which to place the output file.

The Enter the name and path to the directory in which to place the file.

Note: You should note the name and location so that you can document them at a later date.

If the directory does not exist, it will be created. In this example, we specify a new Operation_Qualification_Results directory on the C drive.

Type C:\Operation_Qualification_Results at the prompt, as shown below:

```
SAS Operational Qualification Tool

Please specify a directory where the output files should go [.1: C:\\Operation_A Qualification_Results_
```

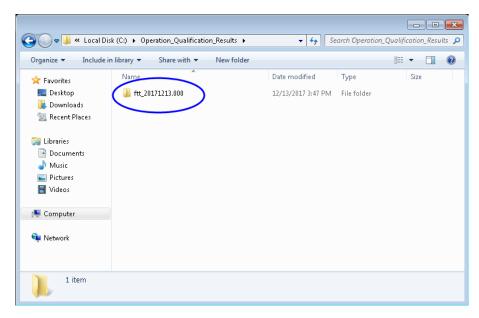
Click **Enter** to start the test.

Each step is listed in the DOS window as the test proceeds, as shown below:

```
Please specify a directory where the output files should go [.]: C:\\Operation_A Qualification_Results Running test base:tstbase:tstsql...
Running test base:tstbase:tstrpt...
Running test base:tstbase:tsttah...
Running test base:tstbase:tstrank...
Running test base:tstbase:tststan...
Running test base:tstbase:tststan...
Running test base:tstbase:tstsun...
Running test base:tstbase:tststun...
Running test base:tstbase:tstchpt...
Running test base:tstbase:tstchpt...
Running test base:tstbase:tstchpt...
Running test base:tstbase:tstchpt...
```

The DOS window closes when the test is complete.

* Navigate into the directory containing your results. In this example, the directory is C:\Operation_Qualification_Results.



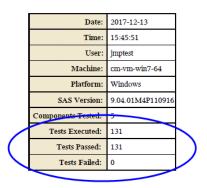
All of the results are placed in a folder within this directory. The name of the folder lists the date on which the test was performed.

*Open the folder containing your results.

Test results are summarized in the sasoq.pdf file.

Open the sasoq.pdf file.

SAS Operational Qualification - Windows



In this example, 131 tests were performed and passed. There were no failures.

Proceed to Step 3: NIST Testing.

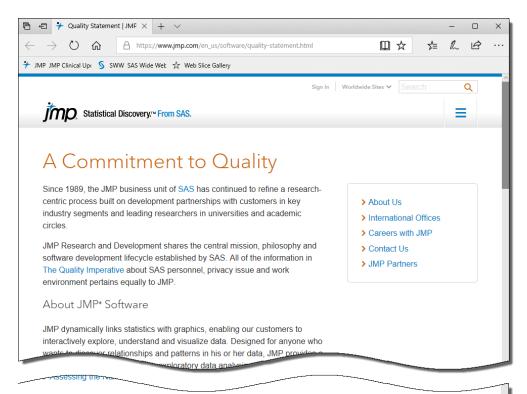
Step 3: NIST Testing

To assist customer operational qualification (OQ) efforts, JMP provides a set of tests based on the StRD in an extensible framework. These tests are available for download.

Download the NIST Testing Framework

Open your web browser and navigate to the JMP A Commitment to Quality web page (http://www.jmp.com/software/qualitystatement.shtml).

Note: The example shown here is for JMP Clinical 7, which includes JMP 14.1. Your installation might be different. Be sure to select the NIST Testing Framework that matches the version of JMP that is included in your JMP Clinical Installation. Open JMP Clinical and click **About JMP Clinical** on the **Settings** tab to find the version of JMP that you have.



Operational Qualification and Installation Qualification

To assist customer validation or operational qualification (OQ) efforts, JMP provides a set of tests based on the StRD in an extensible framework, available for download.

- > JMP 14: NIST Testing Framework (requires registration, 527 KB) > JMP 13: NIST Testing Framework (requires registration, 646 KB)
- > JMP 12: NIST Testing Framework (requires registration, 652 KB)
- > JMP 11: NIST Testing Framework (requires registration, 480 KB) > JMP 10: NIST Testing Framework (requires registration, 624 KB)
- > JMP 9: NIST Testing Framework (requires registration, 976 KB)
- > JMP 8: NIST Testing Framework (requires registration, 728 KB)

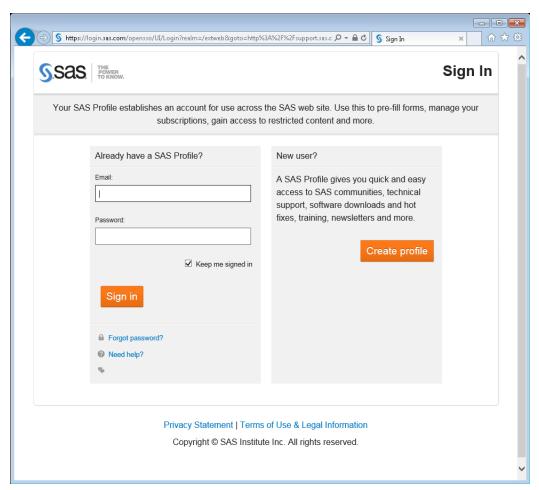
JMP also provides a tool for verifying that JMP software has been installed and maintained to the manufacturer's specifications. This tool verifies the integrity of each installed file and provides a report detailing the results.

- > JMP 14: JMP Installation Validation tool Available for Windows only (requires
- > JMP 13: JMP Installation Validation tool Available for Windows only (requires
- > JMP 12: JMP Installation Validation tool Available for Windows only (requires
- > JMP 11: JMP Installation Validation tool Available for Windows only (requires
- > JMP 10: JMP Installation Validation tool Available for Windows only (requires

Note: JMP provides a tool for verifying the installation of JMP (circled in red, above). Because JMP Clinical contains components not found in standard JMP, this test is not valid for use with JMP Clinical. **Do not use this tool because it will notify you of warnings, errors, and inconsistencies.** The SAS Install Qualification Tool 9.4 utility already run in <u>Step 1: Installation Qualification</u> is more than sufficient.

Click on the link to the JMP 14: NIST Testing Framework (circled in blue, above).

You must have a registered SAS profile to download software from this site. If you do not have a SAS Profile, you must create one before proceeding further. Follow the online instructions for registering a SAS Profile.



The Enter the email address and password associated with your SAS Profile and click **Login**. You will be taken to the JMP 14 Validation web page

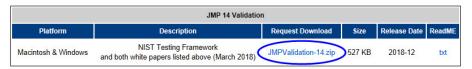
Downloads

JMP 14 Validation

JMP provides information and tools to support customer testing and validation. The following items are available for download:

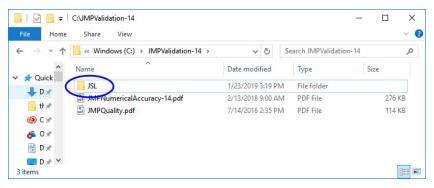
- Assessing the Numerical Accuracy of JMP a white paper describing the NIST testing framework, and numerical validation for JMP software (March 2018)
- 2. The JMP Development Process: A Process for Quality a white paper describing the JMP development and testing environment
- An extendable testing framework and set of tests based on the NIST (National Institute of Standards and Technology) standard for software validation (March 2018)
- 4. JMP Installer Validation a script used to validate the set of installer files versus a benchmark file

To begin the download process, select the item in the table below which best meets your needs.

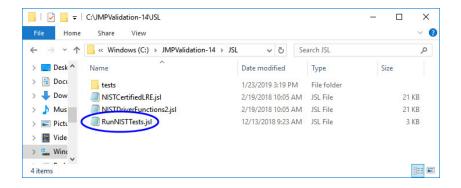


For questions you may have about this download, please contact our Product Support Group

- **Click **JMPValidation-14.zip** for the Windows NIST testing framework (circled above).
- Read the License Agreement and click **I Accept** (not shown).
- Follow the directions listed in the successive windows to download the Windows NIST testing framework to the default C:\JMPValidation-14 directory.
- * Navigate into the C:\JMPValidation-14 directory.



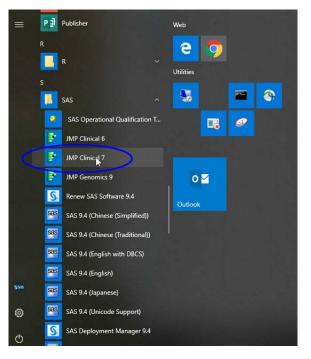
This directory contains two white papers and the JSL folder. Open the JSL folder.



Note: Before you can run this test, you must open JMP Clinical. The RunNISTTests.jsl NIST testing framework utility (contained in the JSL directory) is a jsl script and must be run in JMP.

Open JMP Clinical

* Click Start > SAS > JMP Clinical 7 to open JMP Clinical.



When JMP Clinical opens for the first time, several windows open. One of these windows indicates that a JMP script is generating all of the process dialogs. When the Dialog Generator has finished, this window will close, leaving the JMP Clinical main window open.

JMP Clinical must contain at least one study in order for the NIST testing utility to run successfully. If you have a study loaded, proceed to *Run the NIST Testing Framework*. If no studies are loaded you must

run the Add Study report before proceeding further. Refer to the Add Study documentation¹ in the JMP Clinical User Guide for instructions on adding the Nicardipine study.

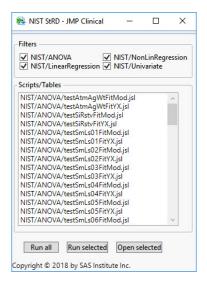
Run the NIST Testing Framework

- Go back to the C:\JMPValidation-14\JSL directory.
- Click and drag the **RunNISTTests.jsl** file into a JMP window to open the script in JMP.

```
RunNISTTests - JMP Clinical
                                                                                                       П
File Edit Tables DOE Analyze Graph Tools View Window Help
🔛 🚰 🚰 🖟 🔏 🔉 🖺 🖺 🖺 🖟 📗 (no tables) 🔻 🝵
     NIST Test Runner
     Will execute selected tests/.../testXXX.jsl files.
     Test scripts make calls to
         ut assert(Expr(TEST), EXPECTED VALUE)
     Will open and check selected tests/.../testXXX.jmp files.
 ut copyright date = "2018";
if(!(JMPVersion()=="14.0.0" | JMPVersion()=="14.1.0" | JMPVersion()=="14.2.0"),
     _NIST_dlg = dialog(title("Alert"),
         vlist(
             textbox("This version of the NIST test suite is intended for JMP 14.1, JMP 14.1, or JMP 14.2 or
              textbox("Click the OK button if you want to continue."),
                  button("OK"),button("Cancel")
     if(arg(_NIST_dlg[3])==-1,throw())
 ut notImplemented = expr(Dialog("Feature Not Implemented Yet", Button("OK")));
 ut home = Get Default Directory();
 nist home = ut home:
 ut test exclude = {}; _genrpt=1; _NIST Driver = 1; include(ut home || "NISTDriverFunctions2.JSL");
 {ut all files, ut test scripts, ut group scripts, ut_all} = ut FileStartup(files in directory("tests", re
 // JSL unit test GUT code
 uttime_bxsel=0; utst_bxsel="N"; strtebx=repeat(" ",60);
 NewWindow("NIST StRD",
     lineupbox(ncol(1),
         pbx = PanelBox("Filters"),
          PanelBox("Scripts/Tables
             selectedUTs = ListBox({}, width(if(hostis(Mac), 320, 255)), nlines(15)),
     borderBox( left(8), right(8),
         lineupbox(ncol(3), spacing(10),
             ButtonBox("Run all",
```

He Click Edit > Run Script to open the NIST Strd - JMP window.

^{1.} For JMP Clinical 7 (used for this example), these instructions can be found at http://www.jmp.com/support/downloads/JMPC70_documentation/PR_L_ST_0001.html.

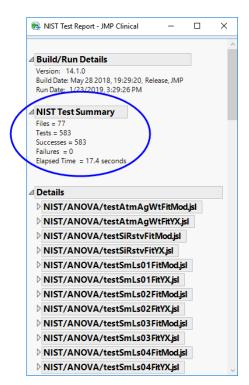


Click Run all to run the tests.

A series of windows will open and close as JMP runs through all of the tests. A summary window appears when all of the tests have run.



Here Click **OK** to view the JMP Journal containing the test results (shown below).



In this example, 583 tests were run and passed. No tests failed.

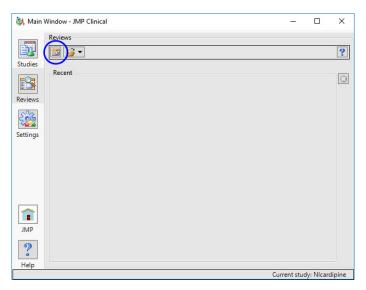
Note: You should save this journal (click **File > Save as**) for later documentation.

Step 4: Run a Simple Analysis

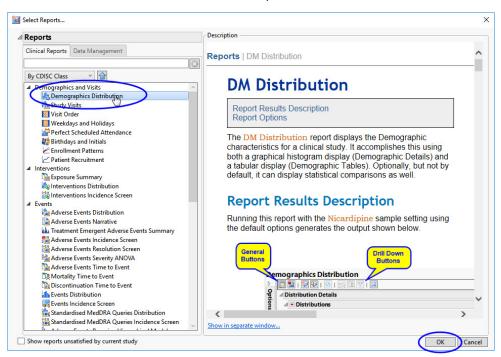
As a final check for JMP Clinical, we shall run a simple analysis.

- ^⁴ Open JMP Clinical.
- Trom the JMP Clinical main window, click the **Reviews** tab.

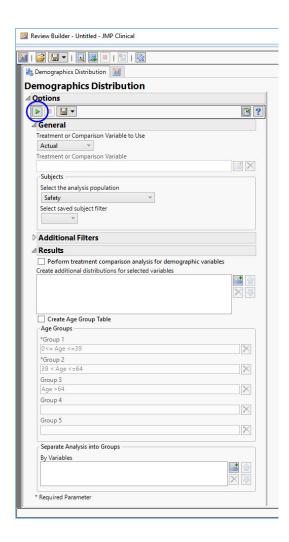
Proceed to Step 4: Run a Simple Analysis.



- Click the **Start a new Review** icon to open the Review Builder.
- The Select **DM Distribution** from the list of Clinical Reports and click **OK**.

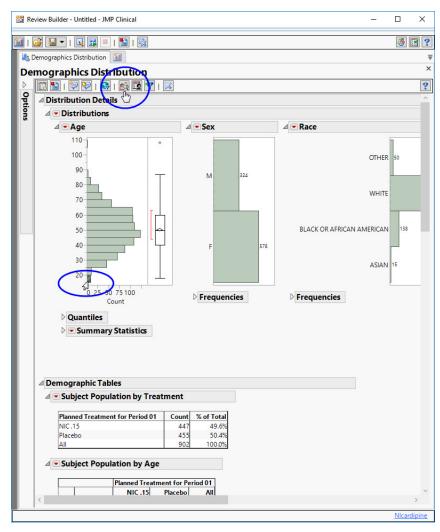


The DM Distribution dialog opens with the included Nicardipine sample data loaded.



Click Run.

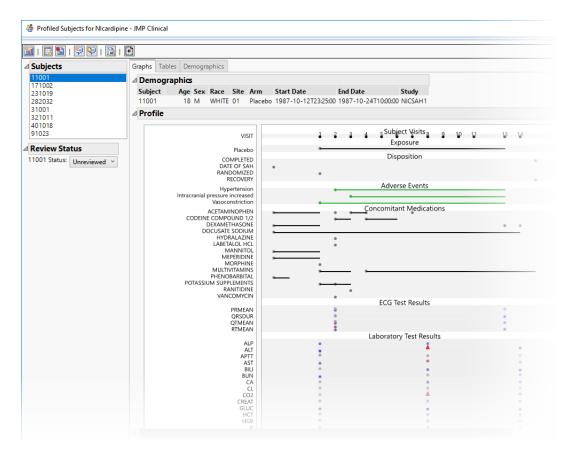
A Results window (partially shown below) opens, showing an analysis dashboard and the distribution results.



Click on the bottom bar of the Age distribution panel (corresponds to all subjects younger than 20 years of age). The bar will change color.

A Profile Subjects window appears.

[↑] Click **Profile Subjects**.



If these analyses run as shown, JMP Clinical has been successfully installed.