OpenVal® CHEAT SHEET

learn more at https://www.atorusresearch.com/openval/

Validated by Us, **Ready for You**

openval

Open-source languages, such as R, **accelerate your data analytics**, unlocking greater overall value for your clinical research

With open-source packages, users have access and opportunity to learn code that can be used in any company and on any project. This **dramatically reduces ramp-up time** and need for company or project specific macros

Through R, companies can leverage interactive and engaging web applications. Think interactive figures where the reviewer can change the parameter presented on a graph, or an interactive table where the reviewer can drill down on the actual data points. This allows a reviewer to explore the data on their own, eliminating time-consuming ad hoc requests



A **function** is a piece of code that takes some inputs and does something specific with them. In R the majority of programming is done using functions

A **package** is a collection of R functions, and sometimes other programming languages, in a well-defined format. An R installation comes with a set of base packages, plus there are over 20,000 user contributed packages on CRAN that can be installed

What Is OpenVal?

OpenVal is a subscription-based validated package delivery system in support of the R programming language.

A subscription includes:

- Two Major Release installations of OpenVal
- Additional packages
- An updated R version and updated package versions as applicable
- Two Minor Release installations of OpenVal
- Additional packages
- Patch Release installations as required
- Product Support of current and prior releases of OpenVal
- Initial OpenVal Installation and Subsequent Release Support

Who Uses OpenVal?



Anyone working on a task requiring a validated or GxP compliant environment is an end user of OpenVal

Both novice and expert R users can leverage and benefit from OpenVal

Why OpenVal?

OpenVal harnesses the best parts of open-source and applies the necessary control needed for a GxP environment

WE DID THE WORK, SO YOU DON'T HAVE TO



Leverage the flexibility, transparency, and deep community support of open-source with no extended build time, no cumbersome code, and no change management

Unlock the confidence and trust in our thousands of test scripts, cited references, and specialized programming hours



Use across multiple business units and departments giving users the capabilities to do all tasks they currently do in SAS® in R

OpenVal expedites R adoption by reducing the effort of cross-collaboration between IT, QA, and Operations. The framework is all code-based, resulting in programmatic execution, creating a Validation Report to store as an artifact of the validation process



How Is OpenVal Used?

OpenVal can be installed in any platform with an R environment, and Atorus' experts can help with every step of the process

To use OpenVal:

Open an R
session• All OpenVal packages and their
dependencies will already be installedUse
packages• Choose from a variety of packages
applicable to day-to-day clinical
programming tasksGenerate
output• Packages are validated on system — giving
the ability to create accurate results

General users cannot install additional packages or update existing package versions, which ensures a consistent and controlled environment

All releases of OpenVal are maintained, and concurrent installations can be managed, allowing different projects to use different versions as applicable to maintain a stable environment for the duration of a project



Did You Know? Atorus is committed to the continued advancement of open-source technologies in clinical research. We have made investments into contributing to a multitude of consortia including PHUSE, PharmaSUG, CDISC, R/Pharma, R Validation Hub, and R Consortium. Additionally, we have developed or collaborated on over 25 open-source clinical programming packages

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Discovery and Planning

Package selection is driven by Atorus' industru experts and collaboration with our customers

Current packages focus on common statistical programming activities enabling the **GxP use of R** for clinical programming

SDTM/ADaM





A snapshot date is determined for each OpenVal release to create a **frozen** point in time for the environment

Analysis is performed to determine the effects of changes in the R version and the R package versions from one OpenVal release to another

4-5 major/minor R version changes are released annually



annually

of the packages in OpenVal are updated



Risk Assessment

Packages are assessed for their level of **risk** to determine the scope of the testing

Initial considerations for risk are looking at the type of package as well as **metrics** such as # of downloads. # and tupe of references. and vionettes

ow risk criteria: Utility/interactive/ visualization package High # downloads Has references Has vignettes	 Medium risk criteria: Statistics/PK/machine learning package Low # downloads No references No vignettes 		
High risk criteria:			

• Packages not on CRAN/Bioconductor

Risk is determined based on category in which greatest number of requirements are met. Tie goes to the riskier category

Example logrx				
Utility package 🗮	Low criteria	No references	=	Medium criteria
Low # downloads	Medium criteria	Has vignettes	=	Low criteria
Risk = Medium				

A validator looks at the package and its documentation to determine the final assigned risk

Some packages may be accepted for validation without additional testing based on their high degree of reliability and **prior testing** within their software development life cycle

If the risk of a desired oackage is too high. Atorus will make **recommendations for** alternative packages



Testing

The scope of testing is determined using information from the previous phases

Requirements, test cases, and test code are written by validators to verify the package produces an **accurate and/or** acceptable result

- **Requirements** establish what needs to be tested
- **Test cases** describe how the requirements will be tested. They are written in English (i.e., "we are testing that the package does x")
- **Test code** is written to verify the test cases

Testing uses Atorus' automated framework. This saves the human time of manual execution of tests

Our tests are run across multiple operating systems

Validators select the most applicable **testing scenario** to ensure the highest quality testing

Testing Scenarios		
Verified Output Comparison	Compares the programming output o a statistical test to trusted sources	
Expectation Testing	Confirms the expected message, warning, or error is returned in a given situation	
Double Program	Reproduces the same result as the package code	
Snapshot Testing	Manually verifies package output to store as a reference; tests then ensure regenerated output matches the reference	

Installation

OpenVal is set up to ensure **stabilitu** and to ensure the environment maintains a validated state

Atorus **works with customers** to determine how OpenVal will be installed in their environment

Installation is simple and is detailed in a customer specific Installation Guide

As part of the installation process, the Validation Report is rendered on a customer's system, showing the results of testing in the customer environment

Excerpt from Validation Report:

Risk Assessment				
Package	Version	Туре	Risk	
logrx	0.2.2	Utility	Medium	

Validation Assessment

Package	N Tests	Tests Passed	Tests Failed
logrx	19	19	0

{logrx} 0.3.1 - Medium				
Spec ID	Test ID	Test Description	Test Result	
pkg_logrx.4 Logs the start and stop times for a short	pkg_logrx.4.1	Logs the start and stop times for a short running program	\checkmark	
running program when run with execute (2)	pkg_logrx.4.2	Logs the start and stop times for a long running program	\checkmark	
pkg_logrx.5 Logs the log's output file and path when run with execute (1)	pkg_logrx.5.1	Logs the log's output file and path when run with execute	\checkmark	