**Vendor Assessment Statement for R**

**Document Properties**

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**Document Change History**

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# Introduction

## What is the R Foundation?

“***The R Foundation*** is a not-for-profit organization working in the public interest. It has been founded by the members of the R Development Core Team in order to

* Provide support for the R project and other innovations in statistical computing. We believe that R has become a mature and valuable tool, and we would like to ensure its continued development and the development of future innovations in software for statistical and computational research.
* Provide a reference point for individuals, institutions or commercial enterprises that want to support or interact with the R development community.
* Hold and administer the copyright of R software and documentation.

R is an official part of the Free Software Foundation's GNU project.” (A Guidance Document for the Use of R, 2021)
**Goals** of the R Foundation are:

* the support of continued development of R,
* the exploration of new methodology,
* teaching and training for statistical computing and
* the organization of meetings and conferences with a statistical computing orientation.

The R Foundation is a registered association under Austrian law and active worldwide.

R Foundation **contact information:**

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R has a strong community and is organised by the [board](https://www.r-project.org/foundation/board.html) and elected [members](https://www.r-project.org/foundation/members.html).

The main [contributors](https://www.r-project.org/contributors.html) maintain the **R base installation (R official distribution)** which can be downloaded from the [CRAN mirrors](https://cran.r-project.org/mirrors.html).

## What is R?

“***R*** is a language and environment for statistical computing and graphics. […] R provides a wide variety of statistical (linear and nonlinear modelling, classical statistical tests, time-series analysis, classification, clustering, etc.) and graphical techniques, and is readily extensible. […] R is available as Free Software under the terms of the Free Software Foundation's GNU General Public License in source code form. It compiles and runs on a wide variety of UNIX platforms and similar systems (including FreeBSD and Linux), Windows and MacOS.” (A Guidance Document for the Use of R in Regulated Environments, 2021).

## What is the R Environment?

“**R** is an integrated suite of software facilities for data manipulation, calculation and graphical display. It includes:

* an effective data handling and storage facility,
* a suite of operators for calculations on arrays, in particular matrices,
* a large, coherent, integrated collection of intermediate tools for data analysis,
* graphical facilities for data analysis and display either on-screen or on hardcopy, and
* a well-developed, simple and effective programming language that includes conditionals, loops, user-defined recursive functions and input and output facilities.”

(A Guidance Document for the Use of R in Regulated Environments, 2021).

The R base installation can be extended by, for example:

* R users defining new functions and adding new functionality
* R add-on packages available via CRAN and other sources.

# Quality Assurance

The development, release and maintenance of the R official distribution is a collaborative process of the R Development Core Team. The core team applies software development and testing methodologies to maximize accuracy, reliability, and consistency of R’s performance. In addition, the source code is available for review by all members of the R community. This ensures continuous improvement. (see R: Software Development Life Cycle, 2021 for more details).

## Software Development Lifecycle

The official R distribution is developed following a defined Software Development Lifecycle process which describes the operational overview, the source code management, tasting and validation, release cycles as well as maintenance, the management of qualified personnel, physical and logical security and disaster recovery procedures (see R: Software Development Life Cycle).

### Regulatory Compliance and Validation

The R foundation released a document “A Guidance Document for the Use of R in Regulated Environments” describing their approach regarding compliance issues.

Only the R official distribution is in scope of this document.

When using R in a validated environment it has to be ensured that:

* the R official distribution installations are properly documented.
* any changes to the system (e.g., adding new functions or add-on packages) are properly documented.
* any new functions used that are not part of the R base installation are properly tested before use.

# Conclusion

R is a widely used programming language for statistical computing and graphics. It is an open source software project, meaning: there is no specific vendor but a community of developers and users that provide input for the continuous improvement of R. R official distribution follows defined processes for software lifecycle management and provides a clear definition of each versions content, ensuring that the packages delivered by the R official distribution are working as expected.

# References

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| **Reference Title** | **Full Title & Link to PDF (as appearing in the document)** |
| A Guidance Document for the Use of R in Regulated Environments | R: Regulatory Compliance and Validation IssuesA Guidance Document for the Use of R in Regulated Clinical Trial Environments(Link PDF R-Guidance\_for\_Use\_in\_CTE.PDF) |
| R: Software Development Life Cycle | R: Software Development Life CycleA Description of R's Development, Testing, Release and Maintenance Processes(Link PDF R-SDLC.PDF) |