



DDMoRe Standalone Execution Environment (SEE) Version 1.2.0 Software Release Note

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| Project: | DDMoRe WP2 |
| Job No: | 2107 |
| Software Version: | Demonstrator 1.2.0 (Beta release for Interoperability Framework and MDL IDE) |
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| Reason for issue: | Release of DDMoRe Demonstrator 1.2.0 to Consortium members and the General Public |
| Prepared by: | Richard Kaye |
| Approved by: (Project Management or Company Director) | Jonathan Chard (11-Dec-2015) |

Document Approval

Completion of the following signature blocks signifies the approver has read, understands, and agrees with the content of this document.

| Name | Job Title or Role | Signature | Date (dd-mmm-yyyy) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-----------|-----------------------|
| The Author is signing to indicate that there is the appropriate technical accuracy and completeness | | | |
| Authored by: Richard Kaye | Technical Lead | Authored | 10-Dec-2015 |
| Reviewed by: Jonathan Chard | Technical Architect | Reviewed | 11-Dec-2015 |
| <<The Technical Lead is signing to indicate that the coverage and completeness of the technical detail is appropriate and that the document has been prepared in accordance with applicable quality processes >> | | | |
| Approved by: Richard Kaye | Technical Lead | Approved | 11-Dec-2015 |
| <<The Project Manager is signing to confirm that this document has been prepared in accordance with an approved document management process, that content is consistent with the deliverable definition found in the governing Plan, that relevant input from authors has been included and that an appropriate review / editing process has been conducted.>> | | | |
| Approved by: Jonathan Chard | Product Director | Approved | 11-Dec-2015 |

Document Revision History

| Version | Author | Date | Description |
|---------|--------------|-------------|-----------------------------------------------------------------------------------------------|
| 1.0 | Richard Kaye | 10-Dec-2015 | First version for release of Demonstrator 1.2.0. QAT-3861 covers review and approval history. |

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1 Reference documents

| Document Reference | Document Description |
|--------------------|--------------------------------------------|
| Installation Guide | SEEInstallationGuide_Demonstrator1.2.0.pdf |
| Test Summaries | See Section: 5 Test Summary |

2 Introduction and overview of the release

This is a Public Beta Release of the MDL IDE and Interoperability Framework. The purpose of the release is to allow access to DDMoRe Consortium members and the General Public to assess the deployment, features and usability of the system.

As this is a beta release, functionality is limited and testing is by no means exhaustive.

This software must not be used in production under any circumstances.

2.1 Scope

This release is applicable to all DDMoRe Consortium members and members of the General Public wishing to assess the deployment, features and usability of the Demonstrator Release 1.2.0.

3 Contents of the release

This release contains the following main software artefacts from different providers. Note that the presence of components in ***bold italics*** will depend on the specific plugins installed:

| Directory | Description | Provider |
|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| \ConfigureRConsole.R | R script for configuring the R Console environment | Mango Solutions |
| \converter-toolbox-distribution | Converter Toolbox distribution including the following converter modules: <ul style="list-style-type: none"> MDL-to-PharmML <i>PharmML->MLXTRAN</i> <i>PharmML->NM-TRAN</i> | Mango Solutions Leiden University Lixoft SAS |
| \docs | Accompanying documentation | Mango Solutions Uppsala University Lixoft SAS |
| \fis | Framework Integration Service (FIS) | Mango Solutions |
| \gfortran | <i>FORTRAN 95 compiler</i> | GNU |
| \InstallNonmem.bat | A script for installing the (separately available) NONMEM binaries into the SEE | Mango Solutions |
| \MDL_IDE | Directory containing MDL IDE products | Leiden University |
| \MDL_IDE\mdl_ide.exe | MDL IDE executable | Leiden University Mango Solutions Pfizer Inc. |
| \MDL_IDE\jre | Java Runtime Environment 32-bit or 64-bit | Oracle |
| \mif-exec | Mango Interoperability Framework with the following Windows-based connectors: <ul style="list-style-type: none"> <i>Local Monolix execution</i> <i>Local NONMEM execution</i> <i>Local PsN (VPC/SEE/bootstrap) execution</i> Local command-line execution | Mango Solutions Uppsala University Lixoft SAS |
| \MlxLibrary1.1.0 | <i>MlxLibrary installation 32-bit or 64-bit</i> | Lixoft SAS |
| \Monolix432s | <i>Monolix installation</i> | Lixoft SAS |
| \nm_7.3.0_g | <i>NONMEM installation</i> | ICON |
| \perl | <i>Perl and PsN installation</i> | The Perl Foundation Uppsala University |
| \R | R Statistical Analysis Environment with preinstalled R <i>DDMoRe R package and corresponding</i> | R (Mango Solutions) |

| Directory | Description | Provider |
|----------------------------------------------------|----------------------------------------------------------------------------------|-----------------------------------------------------|
| | dependencies and a selection of other utility packages | (Pfizer Inc) |
| README.txt | Text file providing further details and information about the release | Mango Solutions |
| SEE_VERSION | Text file providing the version identifier of the release | Mango Solutions |
| \setup-XXX.bat \setup-XXX.pl | Scripts for configuring the environment for running modelling tools | Mango Solutions Uppsala University Lixoft SAS |
| \startup.bat | A script for starting up the FIS, CTS and MIF-EXEC background services | Mango Solutions |
| \XXX-see-env-setup.bat \XXX-see-env-plugin.info | Scripts for describing and starting up modelling tools and accompanying services | Mango Solutions Uppsala University Lixoft SAS |

The release also contains the following:

- Documentation
 - See [Installation Guide]
- Installation Qualification
 - See [Installation Guide]
- Release Note
 - This document

4 System requirements for the release

The SEE has been formally validated by Mango Solutions on the following platform:

- Windows 7 (32-bit or 64-bit) with SP1 or above

Additionally, during ad-hoc testing, DDMoRe Consortium members outside of Mango Solutions experienced no adverse effects on the following platforms:

- Windows XP (32-bit or 64-bit)
- Windows 8 (32-bit or 64-bit)
- Windows 10 (32-bit or 64-bit)
- Any non-Windows operating system running a correctly configured Virtual Machine (e.g. VirtualBox) with one of the above Windows versions installed

5 Test Summary

The following test scripts were executed:

1. On Windows 7 64-bit:
 - a. DDM-001- Download and Install SEE Package
 - b. DDM-003-NONMEM Execution
 - c. DDM-004-PsN Bootstrap Execution
 - d. DDM-005-PsN VPC Execution
 - e. DDM-006-PsN Estimation
 - f. DDM-007-PsN SSE
 - g. DDM-008-Simulx Execution
 - h. DDM-009-Monolix Execution
2. On Windows 7 32-bit:
 - a. DDM-001- Download and Install SEE Package
 - b. DDM-003-NONMEM Execution

The results of this testing can be found in the Mango internal document management system in the 'DDMoRe Demonstrator 1.2.0' Test Reports folder.

Tests are by no means exhaustive and there are known issues (see Section 6) however all test criteria passed successfully.

6 Known issues with this release

A high-level list of supported/unsupported features and known issues and can be found on the [DDMoRe Consortium](#) web-site at:

<http://www.ddmore.eu/sites/ddmore/files/instructions/pdf/List%20of%20supported%20and%20unsupported%20features.pdf>

7 Receiving support for this release

To receive support with the installation and/or use of this software release, please post questions or comments to the relevant DDMoRe Forum:

1. Installation issues/questions/comments: <http://www.ddmore.eu/forum/beta-release-installation>
2. Usage issues/questions/comments: <http://www.ddmore.eu/forum/beta-release-usage>