FOR IMMEDIATE RELEASE

Interoperability for Advanced Quantitative Drug Development - a new reality!

Leiden, The Netherlands, 22nd of August 2016 – *The Modelling & Simulation community is poised to benefit from the first fully integrated open-source modelling environment, proudly released by the Drug Disease Model Resources (DDMoRe) consortium today. You can now experience true interoperability and share your own models online in a quality-assured Model Repository.*

Nobody believed it would be possible when the DDMoRe consortium came together in 2011 facing the exciting task of establishing a shared environment that would enable industry, academia and regulatory authorities to get full value from Modelling & Simulation (M&S) activities. Yet, now interoperability is real, as was demonstrated at PAGE 2016 in Lisbon and during an ISOP webinar in August. *"We have achieved a great deal in 5.5 years by delivering a working set of tools, standards and processes that enable us to share information and knowledge more effectively than ever before"* said Lutz Harnisch, DDMoRe Coordinator.

Was it easy? "*No, it has been an intense and immense team effort. What kept us going was the strong belief that our consortium had a unique opportunity to serve the community with standardization and interoperable workflows" said* Wendy Aartsen, DDMoRe Scientific Officer. Jonathan Chard, DDMoRe Technical Architect added: "*The solution had to be flexible enough to run on a local desktop computer as well as a corporate IT environment. With hindsight it looks simple, but every element in the integrated environment comes from finding common ground and compromises*"

Today, the Interoperability Framework can be downloaded from www.ddmore.eu/official-release-interoperability-framework with example use-case models, scripts and associated output. Mike Smith of the framework team said: *"The Interoperability Framework integrating the Model Description Language (MDL) and Pharmacometric Markup Language (PharmML) – the standards at the heart of DDMoRe – has been shown to deliver on the promise of writing the model once and using it for pharmacometrics tasks in a variety of target software tools."*

"*The Model Repository* (repository.ddmore.eu) *leverages the same exchange standards, records the model development history and offers an insightful search based on a novel way of capturing key information about the model, supporting knowledge sharing very effectively*" said Celine Sarr, DDMoRe Scientific Director. The Model Repository content (80 models so far) is quality assured by experts from the DDMoRe Model Review Group, who provide on-demand impartial review and assess the model's technical validity and reproducibility. *"A model that has passed the review receives the DDMoRe model certification and can be confidently reused by anyone involved in Model Informed Drug Discovery & Development (MID3)"* said Siv Jönsson, review procedure co-developer.

The DDMoRe project team now passes the baton to the DDMoRe Foundation, to drive adoption by the wider M&S community and collect feedback to guide further development. Peter Milligan, core member of the foundation and a leader in industry's adoption of MID3 highlighted DDMoRe's value, said that *"MID3 is set to transform the way we develop new medicines; DDMoRe's robust integrated modelling environment has a vital part to play in the success of that transformation"*.

About DDMoRe

The focus of the DDMoRe consortium www.ddmore.eu has been to deliver a set of integrated tools, exchange standards and training to improve the quality, efficiency and cost effectiveness of model-informed decision-making for pharmaceutical R&D. The DDMoRe consortium is a five-year project of the Innovative Medicines Initiative (IMI, www.imi.europa.eu) with 26 stakeholders from the pharmaceutical industry, small and medium-sized enterprises and academic research organizations.

About the DDMoRe Foundation

The DDMoRe Foundation has been formed by members of the DDMoRe project to create a thriving user community managed by a team of dedicated professionals, ensuring continued and growing success of DDMoRe's Integrated Environment. The not-for-profit Foundation will be responsible for maintenance, communications and training, and all future development of the platform.

About the Interoperability Framework

The DDMoRe Interoperability Framework is comprised of an integrated development environment with an editor and R console (MDL-IDE) that enables modellers to run end-to-end analyses involving several M&S software tools with a single R script. Models are translated and forwarded to software tools including Monolix, NONMEM, and WinBUGS for estimation, Xpose and PsN for model diagnostics, Simcyp and Simulx for simulation, and PFIM and PopED for optimal design. Within the MDL-IDE user interface, models are specified using the Model Description Language (MDL) and stored and processed using the Pharmacometric Markup Language (PharmML) standard. The Interoperability Framework is available for download as a stand-alone module, but it can also be integrated within high-performance IT environments, which has been demonstrated through a series of pilots among DDMoRe industry partners. Detailed documentation and explanatory videos are available from the DDMoRe website.

About the Model Repository

The DDMoRe Model Repository is an open, publicly-available, free-to-use online resource to support the development and exchange of models. It provides much of the functionality of open code hosting platforms like GitHub, but it also has dedicated features targeting the modelling community. The DDMoRe Repository can also be easily installed in a wide variety of IT environments, making it a great choice for organisations wishing to leverage the full functionality of the platform for their everyday modelling activities.

For more information

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