

Template for request of review for model certification

Question/Document required	Response/Documentation provided
Requested for all models irrespective of task	
Name of model, including version, to review for model certification	<i>[name of model and version as stated in model repository, link to model [http://repository.ddmore.eu/model/DDMODEL####]</i>
Name of model submitter	<i>[model submitter name]</i>
Confirm that model is coded in executable MDL/PharmML	I confirm that the uploaded model is coded in executable MDL/PharmML: <i>[choose: yes/no]</i>
Confirm that the MDL/PharmML model code represents the original model without modifications or simplifications that may alter its properties as published in the full-length peer-reviewed article	I confirm that the uploaded MDL/PharmML model code is not modified compared with the model published in the full-length peer-reviewed article: <i>[publication information as given in model repository]</i>
<p>Validation plan</p> <p>Validation approach</p> <p>The model is <i>[an estimation/a simulation]</i> model.</p> <p>Validation is achieved by</p> <p>Choose/add other:</p> <ul style="list-style-type: none"> - executing the uploaded executable MDL/PharmML code with the real original data in the DDMoRe framework - executing the uploaded executable MDL/PharmML code with the simulated data in the DDMoRe framework - executing the uploaded original target code with the simulated data - providing a table comparing i) parameter estimates and uncertainty from the original target model code and the real original data with ii) parameter estimates and uncertainty from the uploaded executable MDL/PharmML code and the real original data - Figure xrep, which is a reproduction of Figure x from the related publication by a simulation using the uploaded executable MDL/PharmML and <i>[simulation tool used]</i>. Figure x is provided as reference <i>[name of file]</i>. Add any necessary details - Figure yrep, which is a reproduction of Figure y from the related publication by a simulation using the uploaded executable MDL/PharmML and <i>[simulation tool used]</i>. Figure y is provided as reference <i>[name of file]</i>. Add any necessary details - etc <p>Validation material <i>[detail all files needed to go through this validation plan for example as follows]</i></p>	

<ul style="list-style-type: none"> • MDL/PharmML code from the repository [name] • Script used for model execution [name] • Model code/script used for simulation [name] • Reference figure x [name] • Reference figure y [name] • Script X used for generating Figure xrep [name] • Script B used for generating Figure xrep [name] <p>etc</p> <p>Validation steps</p> <ul style="list-style-type: none"> • Download to the working directory the PharmML model and other files provided • Open R and set the working directory to the directory where the PharmML file is located • Run the script name • Run the script name <p>etc</p> <ul style="list-style-type: none"> • Compare the output files from the execution of the executable MDL/PharmML code with the real original data to the same information in the related publication and to the original output files. • Compare the produced Figure xrep to the reference Figure X (name) <p>etc</p> <p>Remark: any additional information for reviewer</p>	
Other documents (optional)	The following additional documents aiming to support the conclusion of the adherence of the proposed model implementation to the published one have been uploaded/provided: [names of files]
Conclusion of model validation	The execution of the validation plan supports that the uploaded model code is executable in the DDMoRe framework, and that the model is described and coded in agreement with the related publication. In particular the following are evidence for this conclusion: <ul style="list-style-type: none"> 1. xxx 2. yyyy <p>etc</p>
Additional request for models intended for estimation - Data	
<i>Optional:</i> Provide real original	The file [name] is the real original data.

data	I confirm that this file is uploaded/provided.
<p><i>If the real original data are not provided:</i></p> <p>Description of simulated data</p>	<p>The simulated data named [name] have the following features and was generated as follows (i.e. is it a dummy dependent variable or is it simulated from the model, how were covariates included, etc. A complete script is not needed): [describe data items etc here]</p>
<p>Additional request for models intended for estimation – Output files</p> <p><i>If the real original data are not provided</i></p>	
<p>Model output file(s) including parameter estimates and uncertainty from the uploaded executable MDL/PharmML and the real original data.</p>	<p>The file(s) [name(s)] is/are the model output file(s) from the uploaded executable MDL/PharmML and the real original data.</p> <p>I confirm that this/these file is/are uploaded/provided.</p>
<p>When simulated data contain a dummy dependent variable: Original target model output file(s) using the simulated data and obtained from the execution of a model evaluation or model re-estimation.</p>	<p>The file(s) [name(s)] is/are the original target model output file(s) using the simulated data.</p> <p>I confirm that this/these file(s) is/are uploaded/provided.</p>
<p>Optional for submitter to provide for models intended for estimation</p> <p><i>If the real original data are not provided</i></p>	
<p><i>Optional:</i> Original target model code</p>	<p>The file [name] is the original target model code.</p> <p>I confirm that this file is uploaded/provided.</p>
<p><i>Optional:</i> Original target model output file(s) including parameter estimates and uncertainty from real original data. The output file must include the objective function value obtained with the final parameter estimates.</p>	<p>The file(s) [name(s)] is/are the original target model output file(s).</p> <p>I confirm that this/these file(s) is/are uploaded/provided.</p>