Data Abstraction Form
for population PK/PD publications

MODEL EVALUATION

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## ARTICLE IDENTIFICATION

<table>
<thead>
<tr>
<th><strong>DATE OF PUBLICATION (YEAR)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TITLE</strong></td>
</tr>
<tr>
<td><strong>FIRST AUTHOR</strong></td>
</tr>
</tbody>
</table>


## I. BASIC INTERNAL

### Goodness of fit

#### For the PK, PD study or the PKPD study

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were graphs plotted for basic evaluation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Which graphs are shown in the paper?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(OBS: Observations, PRED: Population Prediction, IPRED: Individual Prediction, WRES: Weighted residuals of population, IWRES: Weighted residuals of individual, COV: Covariates, RES: Difference between PRED and OBS, $\eta$: interindividual random effects, $\theta$: individual parameters, “X”: can be time or dose, Distribution: boxplot, histogram, or QQ plot)

- [ ] OBS vs X with PRED
- [ ] PRED vs “X”  
- [ ] PRED vs OBS  
- [ ] RES vs PRED
- [ ] WRES vs “X”  
- [ ] WRES vs PRED
- [ ] $|WRES|$ vs PRED
- [ ] Distribution of RES or WRES  
- [ ] Distribution of $\theta$
- [ ] Others: .................................................................
Uncertainty on parameters

For the PK study

☐ SE or CV or CI on fixed effects
☐ SE or CV or CI on variance of random effects

SE or CV or CI are obtained by:
☐ Fisher information matrix
☐ Profile likelihood
☐ Bootstrap

Which type of bootstrap has been performed?
☐ On individuals (wild bootstrap)
☐ Other, define: ........................................

Number of bootstrap samples: ............

☐ SD of posterior distribution of the parameters (Bayesian methods)
☐ Graphs of posterior distribution of the parameters (Bayesian methods)
☐ Correlation between estimates were reported
☐ Others: ........................................

For the PD study (or PKPD study)

☐ SE or CV or CI on fixed effects
☐ SE or CV or CI on variance of random effects

SE or CV or CI are obtained by:
☐ Fisher information matrix
☐ Profile likelihood
☐ Bootstrap

Which type of bootstrap has been performed?
☐ On individuals (wild bootstrap)
☐ Other, define: ........................................

Number of bootstrap samples: ............

☐ SD of posterior distribution of the parameters (Bayesian methods)
☐ Graphs of posterior distribution of the parameters (Bayesian methods)
☐ Correlation between estimates were reported
☐ Others: ........................................
# Evaluation of covariate model

## For the PK study

**Were graphs plotted for evaluation of covariates model?**  
☐ Yes  ☐ No

**Which graphs are shown in the paper?**  
☐ None

(WRES: Weighted residuals of population, IWRES: Weighted residuals of individual, COV: Covariates, RES: Difference between PRED and OBS, $\eta_i$: interindividual random effects, $\theta_i$: individual parameters)

- ☐ WRES vs COV  ☐ $\eta_i$ vs COV
- ☐ RES vs COV  ☐ $\theta_i$ vs COV
- ☐ Other, define: ...........................................

☐ Randomisation test  
   Number of simulations: ......................

☐ Others, define: .............................................

## For the PD study (or PKPD study)

**Were graphs plotted for evaluation of covariates model?**  
☐ Yes  ☐ No

**Which graphs are shown in the paper?**  
☐ None

(WRES: Weighted residuals of population, IWRES: Weighted residuals of individual, COV: Covariates, RES: Difference between PRED and OBS, $\eta_i$: interindividual random effects, $\theta_i$: individual parameters)

- ☐ WRES vs COV  ☐ $\eta_i$ vs COV
- ☐ RES vs COV  ☐ $\theta_i$ vs COV
- ☐ Other, define: ...........................................

☐ Randomisation test  
   Number of simulations: ......................

☐ Others, define: .............................................
**Model sensitivity**

**For the PK study**

- [ ] Sensitivity analysis to data outliers  
  - Define method: .................................................................
- [ ] Sensitivity analysis to individual outliers  
  - Define method: .................................................................
- [ ] Sensitivity analysis with respect to some parameters  
  - Define method: .................................................................

**For the PD study (or PKPD study)**

- [ ] Sensitivity analysis to data outliers  
  - Define method: .................................................................
- [ ] Sensitivity analysis to individual outliers  
  - Define method: .................................................................
- [ ] Sensitivity analysis with respect to some parameters  
  - Define method: .................................................................
## II. ADVANCED INTERNAL

**Data splitting**

**For the PK study**

<table>
<thead>
<tr>
<th>Data (Validation dataset)</th>
<th>□ Yes □ No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection</td>
<td>□ Not reported</td>
</tr>
<tr>
<td>□ Within patient</td>
<td>□ Between patient</td>
</tr>
<tr>
<td>□ Sequential</td>
<td></td>
</tr>
<tr>
<td>□ Randomisation</td>
<td></td>
</tr>
<tr>
<td>□ Stratification on covariates</td>
<td></td>
</tr>
</tbody>
</table>

□ Covariate distribution compared between validation and building datasets

<table>
<thead>
<tr>
<th>Number of subjects (PK):</th>
<th>□ Not reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of observations (PK):</td>
<td>□ Not reported</td>
</tr>
</tbody>
</table>

**Final Data**

Was the data reanalyzed by pooling building and validation datasets? □ Yes □ No

**For the PD study (or PKPD study)**

<table>
<thead>
<tr>
<th>Data (Validation dataset)</th>
<th>□ Yes □ No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection</td>
<td>□ Not reported</td>
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<tbody>
<tr>
<td>Number of observations (PK):</td>
<td>□ Not reported</td>
</tr>
</tbody>
</table>

**Final dataset**

Was the data reanalyzed by pooling building and validation datasets? □ Yes □ No
Bootstrap

For the PK study

- Which type of bootstrap has been performed?
  - [] Not reported
  - [ ] On individuals (wild bootstrap)
  - [ ] Stratification on covariates
  - [ ] Others, define: ........................................

- Number of bootstrap samples: ............

For the PD study (or PKPD study)

- Which type of bootstrap has been performed?
  - [] Not reported
  - [ ] On individuals (wild bootstrap)
  - [ ] Stratification on covariates
  - [ ] Others, define: ........................................

- Number of bootstrap samples: ............

Cross-validation

For the PK study

- How cross-validation was performed?
  - [] Not reported
  - [ ] Stratification on covariates
  - [ ] Others, define: ........................................

- Number of groups: ............

For the PD study (or PKPD study)

- How cross-validation was performed?
  - [] Not reported
  - [ ] Stratification on covariates
  - [ ] Others, define: ........................................

- Number of groups: ............
### Monte Carlo simulation of datasets

#### For the PK study

- Number of datasets: [ ] Not reported
- Was design identical to original dataset? [ ] Yes  [ ] No
- **If no,** Number of subjects: [ ] Not reported
  - Other differences, define:
- How simulations were performed? [ ] Not reported
- With uncertainty on population parameters? [ ] Yes  [ ] No
- **If yes:**
  - SE only [ ]
  - Full covariance matrix [ ]
  - Using bootstrap techniques [ ]
- Distribution for the population parameter:
  - Multivariate normal or lognormal [ ]
  - Full posterior [ ]
  - Other, define: [ ]
- Which Software has been used?
  - NONMEM [ ]
  - SAS [ ]
  - R/S [ ]
  - TS2 [ ]
  - Not reported [ ]
- Were simulated datasets fitted? [ ] Yes  [ ] No

#### For the PD study (or PKPD study)

- Number of datasets: [ ] Not reported
- Was design identical to original dataset? [ ] Yes  [ ] No
- **If no,** Number of subjects: [ ] Not reported
  - Other differences, define:
### MODEL EVALUATION

**How simulations were performed?**
- [ ] Not reported

**With uncertainty on population parameters?**
- [ ] Yes
- [ ] No

If yes:
- [ ] SE only
- [ ] Full covariance matrix
- [ ] Using bootstrap techniques

**Distribution for the population parameter:**
- [ ] Multivariate normal or lognormal
- [ ] Full posterior
- [ ] Other, define: ..............................

**Which Software has been used?**
- [ ] NONMEM
- [ ] SAS
- [ ] R/S
- [ ] TS2
- [ ] Not reported

**Were simulated datasets fitted?**
- [ ] Yes
- [ ] No

---

### Other methods

**For the PK study**

- Denomination: ..........................
- Purpose: ..................................
- Method steps: ..........................

**For the PD study**

- Denomination: ..........................
- Purpose: ..................................
- Method steps: ..........................

---
## Metrics

### For the PK study

**Prediction of validation dataset obtained:**

- [ ] Not reported
- [ ] with the model based on the building dataset without refitting
  - [ ] without covariate
  - [ ] with covariates
- [ ] with the model based on the building dataset and refitting
  - [ ] without covariate
  - [ ] with covariates
- [ ] without a model (Non Compartmental Analysis, individual parameters)
- [ ] Other, define: .................................................................

### Metrics on observations (concentrations)

**Types of metrics**

- [ ] Not reported
- [ ] Prediction errors PE (*residuals RES*)
- [ ] Square prediction errors MSE or Root mean square prediction errors RMSE
- [ ] Absolute prediction errors APE
- [ ] Standardised prediction errors SPE (*weighted residuals WRES*)
- [ ] SPE where E(C) and SD(C) obtained with Monte carlo simulations
- [ ] Other metric : .................................................................

**Tests performed on metrics**

- [ ] Yes
- [ ] No
- [ ] Define : .................................................................

**Graphs**

- [ ] Yes
- [ ] No
- [ ] Define : .................................................................
**On individual statistic or parameter**

<table>
<thead>
<tr>
<th>Estimated parameters</th>
<th>θ_i</th>
<th>η_i</th>
<th>All_i</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other, define:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Statistic on</th>
<th>AUC_i</th>
<th>Clearance_i</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other, define:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Types of metrics**

- [ ] Prediction errors PE
- [ ] Square prediction errors MSE or Root mean square prediction errors RMSE
- [ ] Absolute prediction errors APE
- [ ] Standardised prediction errors SPE
- [ ] Other metric: .................................................................

**Tests performed on metrics**

- [ ] Yes
- [ ] No

**Graphs**

- [ ] Yes
- [ ] No

**On population statistic or parameter**

<table>
<thead>
<tr>
<th>Estimated parameters</th>
<th>θ</th>
<th>Variability</th>
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<td>Other, define:</td>
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</table>

<table>
<thead>
<tr>
<th>Statistic on</th>
<th>AUC</th>
<th>Clearance</th>
</tr>
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<tbody>
<tr>
<td>mean</td>
<td></td>
<td>quartile</td>
</tr>
<tr>
<td>Other, define:</td>
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</table>

**Types of metrics**

- [ ] Prediction errors PE
- [ ] Square prediction errors MSE or Root mean square prediction errors RMSE
- [ ] Absolute prediction errors APE
- [ ] Standardised prediction errors SPE
- [ ] Other metric: .................................................................

**Tests performed on metrics**

- [ ] Yes
- [ ] No

**Graphs**

- [ ] Yes
- [ ] No
### For the PD study (or PKPD study)

**Prediction of validation dataset obtained:**
- [ ] Not reported
- [ ] with the model based on the building dataset without refitting
  - [ ] without covariate
  - [ ] with covariates
- [ ] with the model based on the building dataset and refitting
  - [ ] without covariate
  - [ ] with covariates
- [ ] without a model (Non Compartmental Analysis, individual parameters)
- [ ] Other, define: ……………………………………………………………..

**Metrics on observations (effects)**

Types of metrics
- [ ] Not reported
- [ ] Prediction errors PE (*residuals RES*)
- [ ] Square prediction errors MSE or Root mean square prediction errors RMSE
- [ ] Absolute prediction errors APE
- [ ] Standardised prediction errors SPE (*weighted residuals WRES*)
- [ ] SPE where E(C) and SD(C) obtained with Monte carlo simulations
- [ ] Other metric : ……………………………………………………………..

Tests performed on metrics
- [ ] Yes
- [ ] No

- Define : ………………………………………………………………………..

Graphs
- [ ] Yes
- [ ] No

- Define : ………………………………………………………………………..
### On individual statistic or parameter

<table>
<thead>
<tr>
<th>Estimated parameters</th>
<th>$\theta_i$</th>
<th>$\eta_i$</th>
<th>$\text{All}_i$</th>
<th>Other, define:..............................</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statistic on</td>
<td>$\text{AUC(}\text{ef}t)_i$</td>
<td>$\text{EC50/ED50}_i$</td>
<td>Other, define:..............................</td>
<td></td>
</tr>
</tbody>
</table>

**Types of metrics**

- [ ] Prediction errors PE
- [ ] Square prediction errors MSE or Root mean square prediction errors RMSE
- [ ] Absolute prediction errors APE
- [ ] Standardised prediction errors SPE
- [ ] Other metric : .................................................................

**Tests performed on metrics**

- [ ] Yes
- [ ] No

**Graphs**

- [ ] Yes
- [ ] No

### On population statistic or parameter

<table>
<thead>
<tr>
<th>Estimated parameters</th>
<th>$\theta$</th>
<th>Variability</th>
<th>Other, define:..............................</th>
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</thead>
<tbody>
<tr>
<td>Statistic on</td>
<td>$\text{AUC(}\text{ef}t)$</td>
<td>$\text{EC50/ED50}$</td>
<td>$\text{mean}$</td>
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</tbody>
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**Types of metrics**

- [ ] Prediction errors PE
- [ ] Square prediction errors MSE or Root mean square prediction errors RMSE
- [ ] Absolute prediction errors APE
- [ ] Standardised prediction errors SPE
- [ ] Other metric : .................................................................

**Tests performed on metrics**

- [ ] Yes
- [ ] No

**Graphs**

- [ ] Yes
- [ ] No
III. EXTERNAL

<table>
<thead>
<tr>
<th>For the PK study</th>
<th>☐ Not reported</th>
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</thead>
<tbody>
<tr>
<td><strong>Validation dataset</strong> <em>(in comparison to building dataset)</em></td>
<td>☐ Not reported</td>
</tr>
<tr>
<td>same inclusion criteria</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>if no, differences in:</td>
<td>☐ Pathology ☐ Age ☐ Ethnic group</td>
</tr>
<tr>
<td>☐ Other, define:</td>
<td>..................................</td>
</tr>
<tr>
<td>similar dose regimen</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>if no, differences in:</td>
<td>☐ Dose ☐ Administration rhythm</td>
</tr>
<tr>
<td>similar sampling scheme</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>if no:</td>
<td>☐ Richer ☐ More sparse</td>
</tr>
</tbody>
</table>

Number of subjects (PK): .......... ☐ Not reported
Number of observations (PK): ......... ☐ Not reported
☐ Covariates compared between the validation and building datasets

**Final datasets**
Were the data reanalyzed by pooling building and validation datasets ?
☐ yes ☐ no

<table>
<thead>
<tr>
<th>For the PD study (or PKPD study)</th>
<th>☐ Not reported</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Validation dataset</strong> <em>(in comparison to building dataset)</em></td>
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</tr>
<tr>
<td>if no:</td>
<td>☐ Richer ☐ More sparse</td>
</tr>
</tbody>
</table>
---

### Number of subjects (PK):  
- ☐ Not reported

### Number of observations (PK):  
- ☐ Not reported

- ☐ Covariates compared between the validation and building datasets

---

### Final datasets

Were the data reanalyzed by pooling building and validation datasets?
- ☐ Yes
- ☐ No

---

### Monte Carlo simulation of datasets

**For the PK study**

- Yes ☐ No ☐

- Number of datasets: ☐ Not reported

- Was design identical to original dataset? ☐ Yes ☐ No ☐

- **If no,**

  - Number of subjects: ☐ Not reported

  - Other differences, define:  

- How simulations were performed? ☐ Not reported

- With uncertainty on population parameters? ☐ Yes ☐ No ☐

- If yes:

  - ☐ SE only
  - ☐ Full covariance matrix
  - ☐ Using bootstrap techniques

- Distribution for the population parameter:

  - ☐ Multivariate normal or lognormal
  - ☐ Full posterior
  - ☐ Other, define:  

- Which Software has been used?

  - ☐ NONMEM
  - ☐ SAS
  - ☐ R/S
  - ☐ TS2
  - ☐ Not reported

- ☐ Other, define:  

- Were simulated datasets fitted?

  - ☐ Yes
  - ☐ No
For the PD study (or PKPD study) | Yes ☐ | No ☐
--- | --- | ---
Number of datasets | .......... | ☐ Not reported
Was design identical to original dataset? | Yes ☐ | No ☐
If no, Number of subjects: | .......... | Other differences, define: ............................................................
How simulations were performed? | ☐ Not reported
With uncertainty on population parameters? | Yes ☐ | No ☐
If yes :
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☐ Full covariance matrix
☐ Using bootstrap techniques
Distribution for the population parameter:
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☐ Full posterior
☐ Other, define: ....................
Which Software has been used ?
☐ NONMEM ☐ SAS ☐ R/S ☐ TS2 ☐ Not reported
☐ Other, define: .................................................................
Were simulated datasets fitted? | Yes ☐ | No ☐

Other methods

For the PK study
Denomination: .................................................................
Purpose: .................................................................
Method steps: .................................................................

For the PD study
Denomination: .................................................................
Purpose: .................................................................
Method steps: .................................................................
Metrics

For the PK study

Prediction of validation dataset obtained: □ Not reported

□ with the model based on the building dataset without refitting
  □ without covariate □ with covariates
□ with the model based on the building dataset and refitting
  □ without covariate □ with covariates
□ without a model (Non Compartmental Analysis, individual parameters)
□ Other, define: .................................................................

Metrics on observations (concentrations)

Types of metrics □ Not reported
□ Prediction errors PE (residuals RES)
□ Square prediction errors MSE or Root mean square prediction errors RMSE
□ Absolute prediction errors APE
□ Standardised prediction errors SPE (weighted residuals WRES)
□ SPE where E(C) and SD(C) obtained with Monte carlo simulations
□ Other metric : ........................................................................

Tests performed on metrics □ Yes □ No
□ Define : ........................................................................

Graphs □ Yes □ No
□ Define : ........................................................................
### On individual statistic or parameter

Estimated parameters
- θᵢ
- ηᵢ
- Allᵢ
- Other, define:

Statistic on
- AUCᵢ
- Clearanceᵢ
- Other, define:

Types of metrics
- Prediction errors PE
- Square prediction errors MSE or Root mean square prediction errors RMSE
- Absolute prediction errors APE
- Standardised prediction errors SPE
- Other metric:

Tests performed on metrics
- Yes
- No
- Define:

Graphs
- Yes
- No
- Define:

### On population statistic or parameter

Estimated parameters
- θ
- Variability
- Other, define:

Statistic on
- AUC
- Clearance
- mean
- quartile
- Other, define:

Types of metrics
- Prediction errors PE
- Square prediction errors MSE or Root mean square prediction errors RMSE
- Absolute prediction errors APE
- Standardised prediction errors SPE
- Other metric:

Tests performed on metrics
- Yes
- No
- Define:

Graphs
- Yes
- No
- Define:
For the PD study (or PKPD study)

**Prediction of validation dataset obtained:**  
☐ Not reported  
☐ with the model based on the building dataset without refitting  
☐ without covariate  
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☐ with the model based on the building dataset and refitting  
☐ without covariate  
☐ with covariates  
☐ without a model (Non Compartmental Analysis, individual parameters)  
☐ Other, define: ...........................................................................

**Metrics on observations (effects)**

Types of metrics  
☐ Not reported  
☐ Prediction errors PE (*residuals RES*)  
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☐ Absolute prediction errors APE  
☐ Standardised prediction errors SPE (*weighted residuals WRES*)  
☐ SPE where E(C) and SD(C) obtained with Monte carlo simulations  
☐ Other metric : .................................................................

Tests performed on metrics  
☐ Yes  
☐ No  
☐ Define : ...........................................................................

Graphs  
☐ Yes  
☐ No  
☐ Define : .............................................................................
<table>
<thead>
<tr>
<th>On individual statistic or parameter</th>
<th>□ Not reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated parameters</td>
<td>□ $\theta_i$, □ $\eta_i$, □ All $i$</td>
</tr>
<tr>
<td>Statistic on</td>
<td>□ AUC(efet)$_i$, □ EC50/ED50$_i$</td>
</tr>
<tr>
<td>Types of metrics</td>
<td>□ Prediction errors PE</td>
</tr>
<tr>
<td></td>
<td>□ Square prediction errors MSE or Root mean square prediction errors RMSE</td>
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<tr>
<td></td>
<td>□ Absolute prediction errors APE</td>
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<tr>
<td></td>
<td>□ Standardised prediction errors SPE</td>
</tr>
<tr>
<td></td>
<td>□ Other metric: ……………………………</td>
</tr>
<tr>
<td>Tests performed on metrics</td>
<td>□ Yes, □ No</td>
</tr>
<tr>
<td>Define</td>
<td>□ Yes, □ No</td>
</tr>
<tr>
<td>Graphs</td>
<td>□ Yes, □ No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>On population statistic or parameter</th>
<th>□ Not reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated parameters</td>
<td>□ $\theta$, □ Variability</td>
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<tr>
<td>Statistic on</td>
<td>□ AUC(efet), □ EC50/ED50</td>
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<tr>
<td>Mean</td>
<td>□ quartile</td>
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<tr>
<td>Types of metrics</td>
<td>□ Prediction errors PE</td>
</tr>
<tr>
<td></td>
<td>□ Square prediction errors MSE or Root mean square prediction errors RMSE</td>
</tr>
<tr>
<td></td>
<td>□ Absolute prediction errors APE</td>
</tr>
<tr>
<td></td>
<td>□ Standardised prediction errors SPE</td>
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<td></td>
<td>□ Other metric: ……………………………</td>
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<tr>
<td>Tests performed on metrics</td>
<td>□ Yes, □ No</td>
</tr>
<tr>
<td>Define</td>
<td>□ Yes, □ No</td>
</tr>
<tr>
<td>Graphs</td>
<td>□ Yes, □ No</td>
</tr>
</tbody>
</table>

□ Define : ………………………………………………. |
SUBJECTIVE SYNTHESIS

Was there an attempt to evaluate the model?

☐ No  ☐ Poor  ☐ Good  ☐ Excellent

Was the choice of the metrics appropriate?

☐ No  ☐ Poor  ☐ Good  ☐ Excellent

Was the model evaluated?

☐ No  ☐ Poor  ☐ Good  ☐ Excellent