**Submission of code and test data for publication**

This file includes documentation relevant to code and test data submitted in association with the manuscript entitled “A Standardized Metric to Enhance Clinical Trial Design and Outcome Interpretation in Type 1 Diabetes” (2023), authored by Alyssa Ylescupidez, Henry T Bahnson, Colin O’Rourke, Sandra Lord, Cate Speake, Carla J Greenbaum at the Center for Interventional Immunology, Benaroya Research Institute at Virginia Mason; Seattle, WA, USA.

Software required to run enclosed codes are JMP Pro 16 (SAS Institute Inc., Cary, NC, USA) and SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA). Run time dependent on size of dataset; using test data run time of all code <1 minute.

**Table 1. Contents of code and test data submission folder.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Type** | **File name** | **File type** | **Description** |
| Code | SAS script for QR calculations | .sas | SAS script for computing QR and relevant analyses. |
| Code | JMP JSL script for GLM | .jsl | JSL script for fitting generalized linear models. |
| Data | test\_qr\_input | .sas7bdat | Example of input data needed to run SAS script. |
| Data | test\_qr\_output | .sas7bdat | Example of output data after running SAS code to compute predicted C-peptide and QR values. |
| Data | test\_qr\_output | .jmp | Converted test\_qr\_output.sas7bdat file to JMP format for JSL script to be run. The .jmp file also has JSL script saved to table: RUN GLM. |

**Table 2. Metadata for test\_qr\_input.sas7bdat, input data required to run SAS script.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable Name** | **Variable Label** | **Variable Type\*** | **Variable Length** | **Variable Number** |
| study | Study | 2 | 5 | 1 |
| Participant\_id | Participant\_ID | 2 | 5 | 2 |
| active\_or\_placebo | Active Treatment or Placebo Group | 2 | 7 | 3 |
| Age\_at\_screening | Baseline Age (years) | 1 | 8 | 4 |
| baseline\_mean\_cpep\_auc\_nmoll | Baseline C-peptide AUC Mean (nmol/L) | 1 | 8 | 5 |
| year1\_mean\_cpep\_auc\_nmoll | 1 Year C-peptide AUC Mean (nmol/L) | 1 | 8 | 6 |
| mo3\_mean\_cpep\_auc\_nmoll | 3 Month C-peptide AUC Mean (nmol/L) | 1 | 8 | 7 |
| mo6\_mean\_cpep\_auc\_nmoll | 6 Month C-peptide AUC Mean (nmol/L) | 1 | 8 | 8 |
| mo9\_mean\_cpep\_auc\_nmoll | 9 Month C-peptide AUC Mean (nmol/L) | 1 | 8 | 9 |
| mo18\_mean\_cpep\_auc\_nmoll | 18 Month C-peptide AUC Mean (nmol/L) | 1 | 8 | 10 |
| mo24\_mean\_cpep\_auc\_nmoll | 24 Month C-peptide AUC Mean (nmol/L) | 1 | 8 | 11 |
| mo30\_mean\_cpep\_auc\_nmoll | 30 Month C-peptide AUC Mean (nmol/L) | 1 | 8 | 12 |
| mo36\_mean\_cpep\_auc\_nmoll | 36 Month C-peptide AUC Mean (nmol/L) | 1 | 8 | 13 |

\*Variable Type 1 = numeric, 2 = character.

**Table 3. Metadata for test\_qr\_output.sas7bdat, output dataset from running SAS script.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable Name** | **Variable Label** | **Variable** | **Variable** | **Variable** |
| **Type\*** | **Length** | **Number** |
| study | Study | 2 | 5 | 1 |
| Participant\_id | Participant\_ID | 2 | 5 | 2 |
| active\_or\_placebo | Active Treatment or Placebo Group | 2 | 7 | 3 |
| Age\_at\_screening | Baseline Age (years) | 1 | 8 | 4 |
| baseline\_mean\_cpep\_auc\_nmoll | Baseline C-peptide AUC Mean (nmol/L) | 1 | 8 | 5 |
| year1\_mean\_cpep\_auc\_nmoll | 1 Year C-peptide AUC Mean (nmol/L) | 1 | 8 | 6 |
| mo3\_mean\_cpep\_auc\_nmoll | 3 Month C-peptide AUC Mean (nmol/L) | 1 | 8 | 7 |
| mo6\_mean\_cpep\_auc\_nmoll | 6 Month C-peptide AUC Mean (nmol/L) | 1 | 8 | 8 |
| mo9\_mean\_cpep\_auc\_nmoll | 9 Month C-peptide AUC Mean (nmol/L) | 1 | 8 | 9 |
| mo18\_mean\_cpep\_auc\_nmoll | 18 Month C-peptide AUC Mean (nmol/L) | 1 | 8 | 10 |
| mo24\_mean\_cpep\_auc\_nmoll | 24 Month C-peptide AUC Mean (nmol/L) | 1 | 8 | 11 |
| mo30\_mean\_cpep\_auc\_nmoll | 30 Month C-peptide AUC Mean (nmol/L) | 1 | 8 | 12 |
| mo36\_mean\_cpep\_auc\_nmoll | 36 Month C-peptide AUC Mean (nmol/L) | 1 | 8 | 13 |
| expectedy1\_meanAUC\_nmoll | Expected 1 Year C-peptide AUC Mean (nmol/L) ln(x+1) | 1 | 8 | 14 |
| expectedmo3\_meanAUC\_nmoll | Expected 3 Month C-peptide AUC Mean (nmol/L) ln(x+1) | 1 | 8 | 15 |
| expectedmo6\_meanAUC\_nmoll | Expected 6 Month C-peptide AUC Mean (nmol/L) ln(x+1) | 1 | 8 | 16 |
| expectedmo9\_meanAUC\_nmoll | Expected 9 Month C-peptide AUC Mean (nmol/L) ln(x+1) | 1 | 8 | 17 |
| expectedmo18\_meanAUC\_nmoll | Expected 18 Month C-peptide AUC Mean (nmol/L) ln(x+1) | 1 | 8 | 18 |
| expectedmo24\_meanAUC\_nmoll | Expected 24 Month C-peptide AUC Mean (nmol/L) ln(x+1) | 1 | 8 | 19 |
| expectedmo30\_meanAUC\_nmoll | Expected 30 Month C-peptide AUC Mean (nmol/L) ln(x+1) | 1 | 8 | 20 |
| expectedmo36\_meanAUC\_nmoll | Expected 36 Month C-peptide AUC Mean (nmol/L) ln(x+1) | 1 | 8 | 21 |
| baseline\_mean\_cpep\_auc\_ln\_nmoll | Baseline C-peptide AUC Mean (nmol/L) ln(x+1) | 1 | 8 | 22 |
| mo3\_mean\_cpep\_auc\_ln\_nmoll | 3 Month C-peptide AUC Mean (nmol/L) ln(x+1) | 1 | 8 | 23 |
| mo6\_mean\_cpep\_auc\_ln\_nmoll | 6 Month C-peptide AUC Mean (nmol/L) ln(x+1) | 1 | 8 | 24 |
| mo9\_mean\_cpep\_auc\_ln\_nmoll | 9 Month C-peptide AUC Mean (nmol/L) ln(x+1) | 1 | 8 | 25 |
| year1\_mean\_cpep\_auc\_ln\_nmoll | 1 Year C-peptide AUC Mean (nmol/L) ln(x+1) | 1 | 8 | 26 |
| mo18\_mean\_cpep\_auc\_ln\_nmoll | 18 Month C-peptide AUC Mean (nmol/L) ln(x+1) | 1 | 8 | 27 |
| mo24\_mean\_cpep\_auc\_ln\_nmoll | 24 Month C-peptide AUC Mean (nmol/L) ln(x+1) | 1 | 8 | 28 |
| mo30\_mean\_cpep\_auc\_ln\_nmoll | 30 Month C-peptide AUC Mean (nmol/L) ln(x+1) | 1 | 8 | 29 |
| mo36\_mean\_cpep\_auc\_ln\_nmoll | 36 Month C-peptide AUC Mean (nmol/L) ln(x+1) | 1 | 8 | 30 |
| QR\_meanAUC\_nmoll | QR | 1 | 8 | 31 |
| QR3m\_meanAUC\_nmoll | 3 Month QR | 1 | 8 | 32 |
| QR6m\_meanAUC\_nmoll | 6 Month QR | 1 | 8 | 33 |
| QR9m\_meanAUC\_nmoll | 9 Month QR | 1 | 8 | 34 |
| QR18m\_meanAUC\_nmoll | 18 Month QR | 1 | 8 | 35 |
| QR24m\_meanAUC\_nmoll | 24 Month QR | 1 | 8 | 36 |
| QR30m\_meanAUC\_nmoll | 30 Month QR | 1 | 8 | 37 |
| QR36m\_meanAUC\_nmoll | 36 Month QR | 1 | 8 | 38 |
| Resp\_Nonresp\_QR\_meanAUC | QR Responder or Non-Responder | 2 | 21 | 39 |
| Resp\_Nonresp\_QR\_meanAUC\_01 | Responder (QR >=0) | 1 | 8 | 40 |
| Weight |  | 1 | 8 | 41 |

\*Variable Type 1 = numeric, 2 = character.