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CORRECTION

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Correction: Mixed-effects models for slope-based endpoints in clinical trials of chronic kidney disease

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In the SOFTWARE CODE AND DATA ACCESSIBILITY statement at the end of our article "Mixed-effects models for slope-based endpoints in clinical trials of chronic kidney disease," we provide access to two SAS programs used in the article through the repository Figshare. We recently became aware of two errors in our SAS code, one error in the SAS program file "SIM Supplement - SAS code for MDRD-B Example.sas" and one in the SAS program file "SIM Supplement - SAS MACRO GFR_Slope_Power.sas" both of which are located in the Figshare repository which can be accessed via the link at the end of our article.

When running the SAS program "SIM Supplement - SAS code for MDRD-B Example.sas", an error will occur whenever one uses the FIXED_KNOT= option of the SAS macro %GetKnot. The program was designed initially to run using %GetKnot without any options (as illustrated with the MDRD-B study example). This performs a grid search of knot values ranging from 3 to 12 months in 1-month increments and selects the knot that provides the best fit (lowest AIC) which turns out to be 6 months for the MDRD-B study. It also provides good starting estimates of SIGMA (the within-subject variance σ^2) and THETA (the power of mean parameter θ) in addition to a grid of starting values for these parameters within the macro %GetParam_SP. We decided later to add a macro variable option, FIXED_KNOT=, to the macro %GetKnot that allows the user to specify a fixed knot point without performing a grid search. However, whenever %GetKnot(FIXED_KNOT="value") is specified, the program will produce an error as a result of not computing the estimates of SIGMA and THETA that would otherwise be assigned to macro variables &sigma and &theta within %GetKnot. The error occurs when the macro %GetParam_SP is called within the overall program as this macro expects that the macro variables &sigma and &theta have been assigned values from %GetKnot but instead are missing. This error has been corrected so that the program will run whether one specifies %GetKnot alone (ie, performs a grid search which selects a knot that provides the best fit) or one specifies %GetKnot(FIXED_KNOT="value") which forces the knot to occur at a user-specified value. The revised program with the necessary corrections has been added to Figshare as "SIM Supplement - SAS code for MDRD-B Example Revised - 10MAR2021.sas" which one can download from https://figshare.com by doing a simple search for the keywords Vonesh or the actual SAS program file name.

When running the SAS program "SIM Supplement - SAS MACRO GFR_Slope_Power.sas" we discovered that, although the program computes the correct power estimates for comparing the acute, chronic, and delta slopes between treatment groups, it incorrectly computes power for the total slope comparisons at 2, 3, and 4 years using a fixed knot of 4 months (as was determined for the IDNT example) rather than a knot that the user actually specifies within a call to the macro. This has now been corrected and also added to Figshare as "SIM Supplement - SAS MACRO GFR_Slope_Power_Ver2.sas".

The illustrative examples (IDNT and MDRD-B studies) as well as the power calculations based on the IDNT study parameters (with the knot fixed at 4 months) are not affected by this error nor are the power estimates for comparing chronic slopes at different knots as shown in Table 9 of our article.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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