Drs. Yazici and Yazici question a specific aspect of the methodology used to develop and validate the 2022 ACR/EULAR classification criteria for ANCA-associated vasculitides. They state concerns with the fact that patients recruited into the Diagnostic and Classification Criteria in Vasculitis (DCVAS) study were included into either a set of patients used to develop the criteria or an independent set of patients used to validate the criteria. They argue that this methodology constitutes "randomization," resulting in 2 groups that are not truly independent but rather are perfectly balanced in terms of potential confounding differences. We disagree with this argument because it confuses "random sampling" with "random assignment." For the DCVAS project, we went to great efforts to recruit 6,991 study participants from 136 sites from around the world. When deriving the classification criteria, we randomly sampled patients from this diverse and representative study population for inclusion into a development set or a validation set. Not every patient with ANCA-associated vasculitis in the cohort was included in either the development or validation set. Random sampling ensures that the study results are generalizable to the population at large, and the use of completely different sets of patients ensures that the development and validation sets are indeed independent. In contrast to random sampling, random assignment occurs after participants are selected for a study, whereby all study participants are randomly assigned either to receive an intervention or to act as a control.

The alternative to our approach of random sampling within the large DCVAS study cohort would be to validate the criteria in a set of patients not recruited through the DCVAS project. While we welcome independent investigators from around the world to validate the new criteria in other study populations, it is unlikely that another data set would represent as broad a spectrum of patients as the DCVAS study cohort. Rather, it is highly likely that these types of data sets would be prone to selection bias.

We also contend that, although the performance characteristics of the new criteria were similar in the development and validation sets, it does not mean, as suggested by Yazici and Yazici, that the development and validation sets were not independent. Rather, these results emphasize that the criteria are highly valid.

Finally, Yacizi and Yazici expressed concerns that classification criteria are "generic" and "in vogue." We respectfully disagree with both of these points. Classification criteria ensure that a study population is homogeneous for inclusion to research trials. Homogeneity is important to ensure that research studies are more easily comparable. Use of classification criteria in a research study in no way precludes investigators from developing additional study-specific selection criteria, a common practice and application of such criteria. Notably, classification criteria have been used to facilitate research in rheumatology for more than 50 years.

We anticipate that the new 2022 ACR/EULAR classification criteria for ANCA-associated vasculitides will support the conduct of successful research for decades to come.