

FDA and EMA issue first-of-their-kind Letters of Support for two Kidney Biomarkers

The U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) have each independently issued first-of-their kind Biomarker Letters of Support for two essential kidney safety biomarkers identified and evaluated by the Predictive Safety Testing Consortium (PSTC)'s Nephrotoxicity Working Group.

The Letters of Support intend to encourage scientists to collect data from nonclinical and exploratory clinical studies, which may lead to qualification of these biomarkers. The respective Letters of Support are posted on the [FDA website](#) and [EMA website](#) and can also be accessed via the [PSTC section of the C-Path website](#) under the [Regulatory Successes](#) tab, along with a summary data package describing the studies that support the use of these kidney safety biomarkers.