Prospective Clinical Validation of the Envisia Genomic Classifier

The Envisia Genomic Classifier is a molecular test used to identify UIP or non-UIP from transbronchial biopsies. And what they did is they used a second cohort of patients from the brave study to further validate the genomic classifier's performance in the original study. And they did whole transcriptome RNA sequencing in 96 transbronchial biopsy samples, and used that previously-validated algorithm of machine learning to classify each subject as whether they were UIP pattern or non-UIP pattern. And then referenced back to the histopathology specimens.

And that really was identified as what they call the Truth Label. And that helped them identify and verify UIP versus non-UIP. And what they found was a positive, predictive value of around 92% for this genomic classifier. And where we really see that it may be helpful is in those patients with difficult HRCTs that may be aren't classic for UIP or probable-UIP by the guidelines.

And that may be that indeterminate group, or those patients with early interstitial lung disease with mostly reticular markings or findings. And that, coupled with a good history and physical with physiologic data, high resolution CT, and a multidisciplinary discussion, may help us in our confidence in diagnosing. And, hopefully, perhaps save patients from needing to go on to a surgical lung biopsy.

So we're beginning to see this evolve at some medical centers, and be used. And I believe that it has been Medicare-approved, at this point, for use. But just beginning to roll out into different facilities. So again, I think it's going to be most useful in those people with early disease, or maybe indeterminate CTS, that mostly have articulation. And that, in combination with a good history physical exam physiology and multidisciplinary discussion, may help us to gain confidence in the diagnosis of UIP IPF in that subpopulation of patients especially.