

# Envisia Genomic Classifier Demonstrates Consistent Performance Across Gender, Age Group, and Smoking Status

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## BACKGROUND

- Idiopathic pulmonary fibrosis (IPF) is an idiopathic interstitial pneumonia that has a radiologic and/or pathologic pattern of usual interstitial pneumonia (UIP).
- UIP is a fibrotic lung injury pattern associated with poor prognosis and few effective treatments.
- The Envisia Genomic Classifier (EGC) is a clinically validated molecular test for a UIP pattern in transbronchial biopsies (TBBx) that was developed as a "rule in" test with high specificity in patients with Interstitial Lung Disease (ILD).
- UIP by EGC in combination with clinical factors and HRCT findings in the context of a multidisciplinary discussion has shown clinical utility in determining an accurate and confident IPF diagnosis.
- The clinical features most commonly seen in patients with IPF include:
  - Age > 65 years
  - Males
  - Ever smokers
- ILD IPF diagnoses are especially challenging for:
  - Patients aged ≤ 65 years
  - Females
  - Never smokers

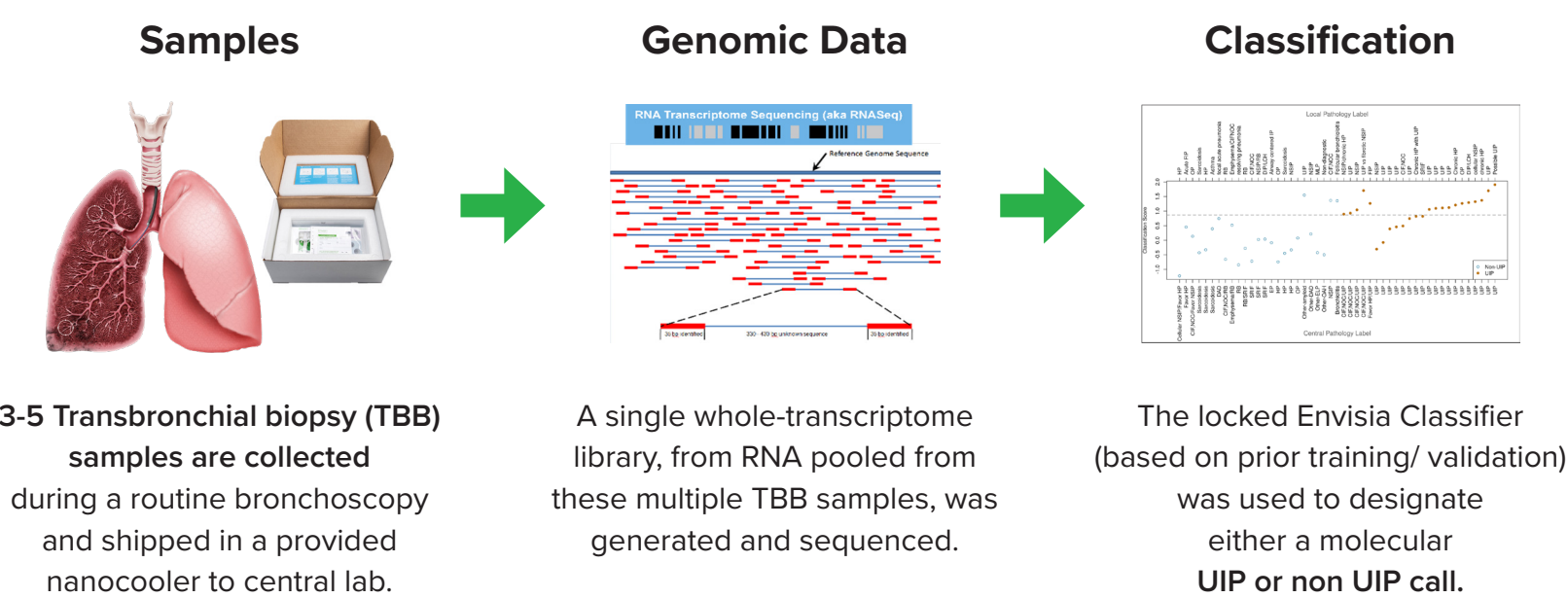
## OBJECTIVE

- We assessed the performance of the Envisia Genomic classifier for the detection of UIP in patients with ILD stratified by gender, age and smoking status.

## METHODS

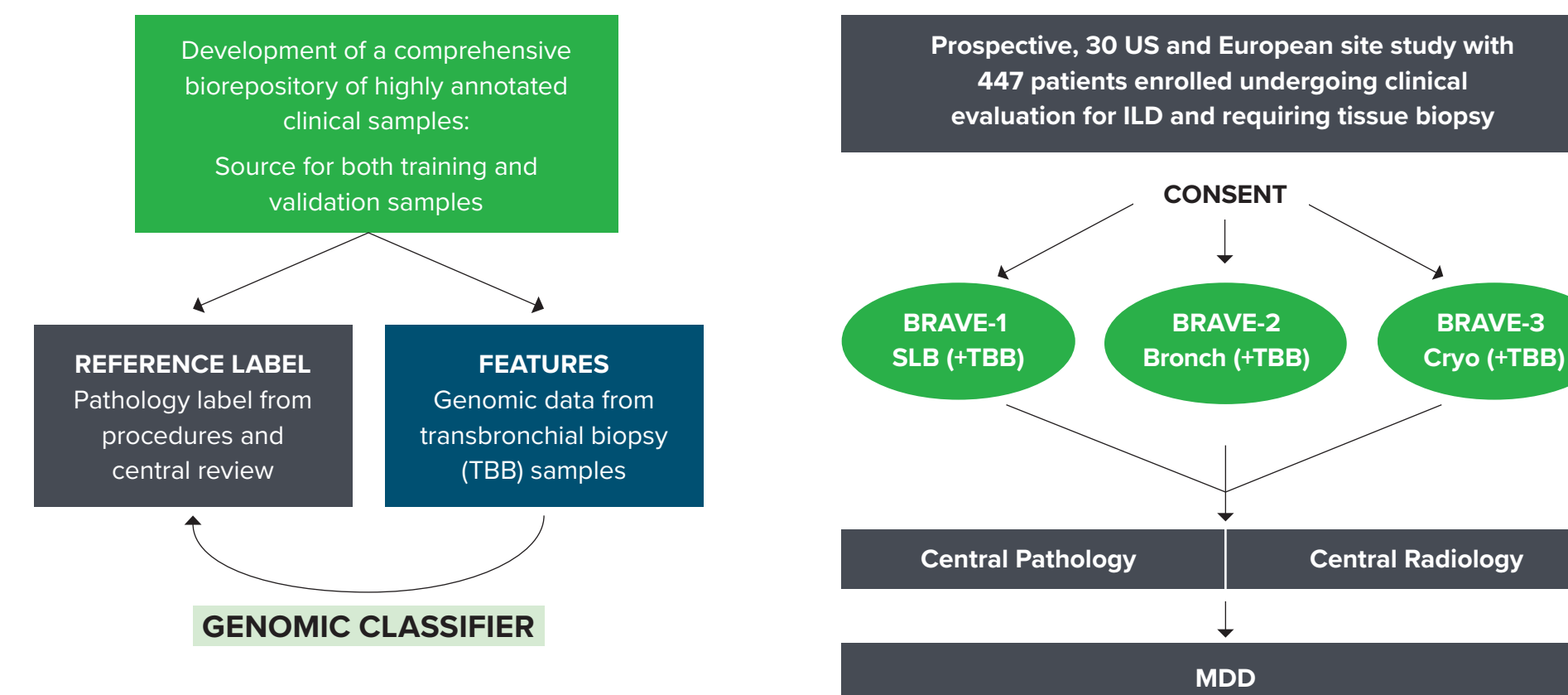
- One hundred forty-four patients from two prior independent clinical validation cohorts were included in this pooled, retrospective analysis
- These patients were initially enrolled in the BRAVE (Bronchial Sample Collection for a Novel Genomic Test) clinical sample collection study:
  - Underwent clinical evaluation for suspected fibrotic lung disease
  - Underwent standard-of-care (SOC) lung biopsies for histopathology and TBB sample for EGC validation
- Specificity and sensitivity of the EGC were compared in patients:**
  - ≤ 65 years old vs. > 65 years old
  - Female vs. male
  - Never smokers vs. ever smokers

### Envisia Genomic Classifier: Sample Collection, Processing, and Test Results



## METHODS (CONT'D.)

### The BRAVE Study Methodology

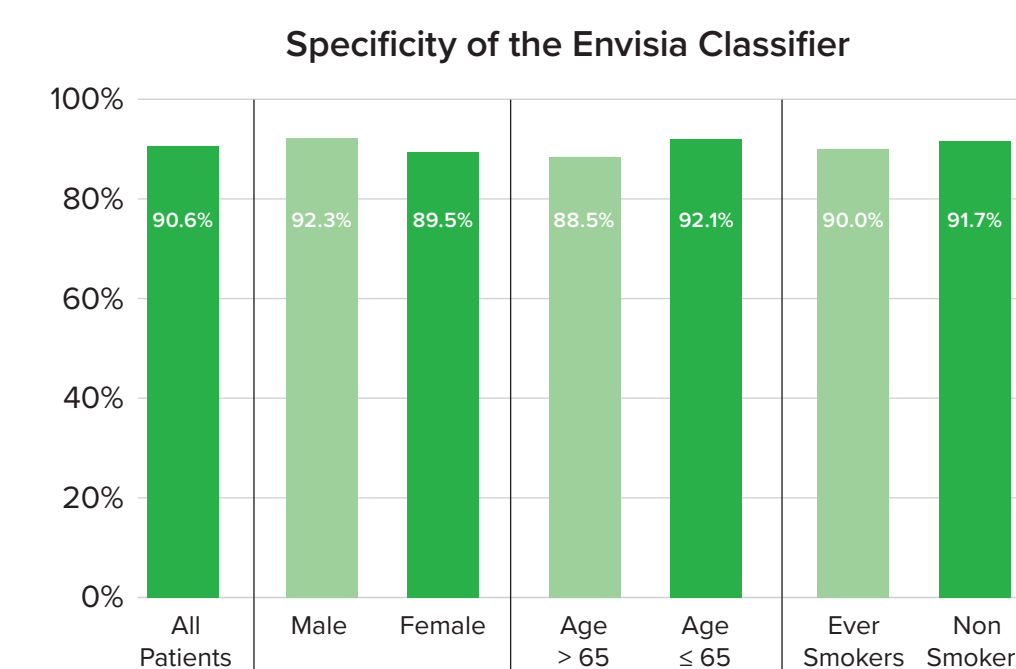


## RESULTS

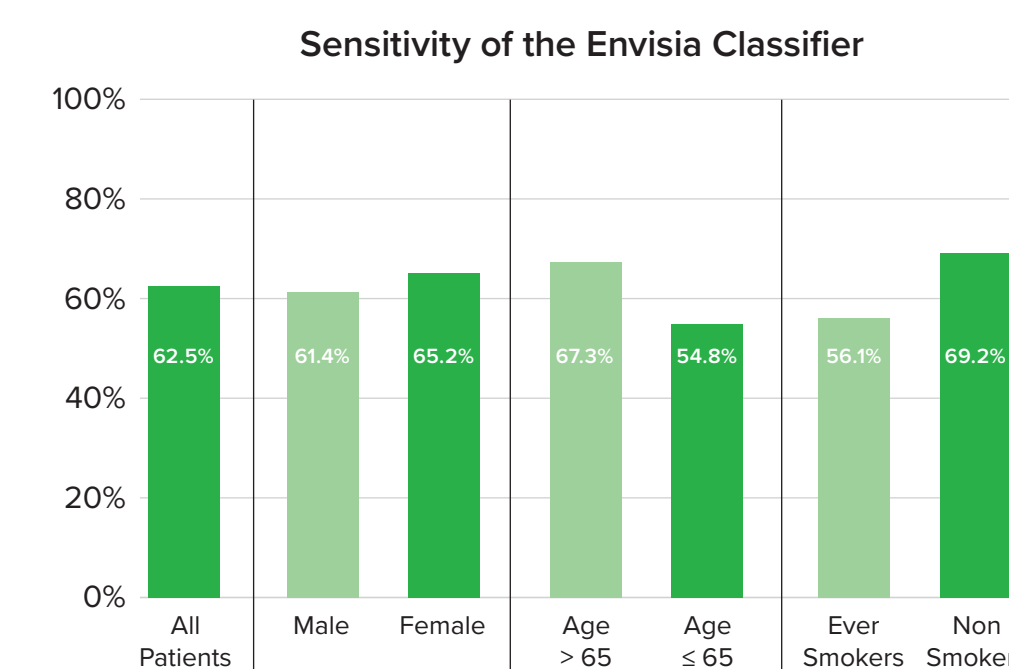
### Performance of the Envisia Genomic Classifier

- For histology-proven UIP pattern among 144 patients, the Envisia Classifier showed:
  - 90.6% Specificity [Confidence Interval (CI): 80.7, 96.5]
  - 62.5% Sensitivity [Confidence Interval (CI): 51.0, 73.1]
- No significant difference in EGC performance in patients:
  - ≤ 65 years old vs. > 65 years old
  - Female vs. male
  - Never smokers vs. ever smokers

### Envisia retains high specificity across gender, age, and smoking status



### Envisia retains sensitivity across gender, age and smoking status



## RESULTS (CONT'D.)

	Specificity	P value	Sensitivity	P value
<b>All Patients (144)</b>	90.6% [80.7, 96.5]	Not Applicable	62.5% [51.0, 73.1]	Not Applicable
<b>Males (83)</b>	92.3% [74.9, 99.1]	1.00	61.4% [47.6, 74.0]	0.75
<b>Females (61)</b>	89.5% [75.2, 97.1]		65.2% [42.7, 83.6]	
<b>Age &gt; 65 years old (75)</b>	88.5% [69.8, 97.6]	0.68	67.3% [52.5, 80.1]	0.26
<b>Age ≤ 65 Years old (69)</b>	92.1% [78.6, 98.3]		54.8% [36.0, 72.7]	
<b>Ever Smokers (81)</b>	90.0% [76.3, 97.2]	1.0	56.1% [39.7, 71.5]	0.23
<b>Never Smokers (63)</b>	91.7% [73.0, 99.0]		69.2% [52.4, 83.0]	

## CONCLUSIONS

- The Envisia Genomic Classifier (EGC) achieved 90.6% specificity and 62.5% sensitivity on 144 patients combining two prospective validation cohorts. This performance is largely retained across gender, age group and smoking status.
- This indicates robust performance of EGC in the subset of patients that are less likely to have a UIP pattern or IPF (younger, female or never smokers).
- This suggests that the EGC can provide useful diagnostic information to guide management in patients where an IPF diagnosis is less common.
- These results support the use of the Envisia Classifier as a surrogate measure of pathologic UIP in patients whose clinical characteristics and HRCT scan are inconclusive for IPF.

## References

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## Disclosures

Dr. Luca Richeldi: Veracyte, Inc. Advisory Board