



# NACE *Conversations* in Pulmonology 2019

## Final Live Outcomes Report



## Interstitial Lung Disease: Recognizing and Managing Progressive Fibrosis

Boehringer Ingelheim Pharmaceuticals, Inc. • 2018823440

October 2, 2019





# Interstitial Lung Disease: Recognizing and Managing Progressive Fibrosis



468 Participants



1 Activity



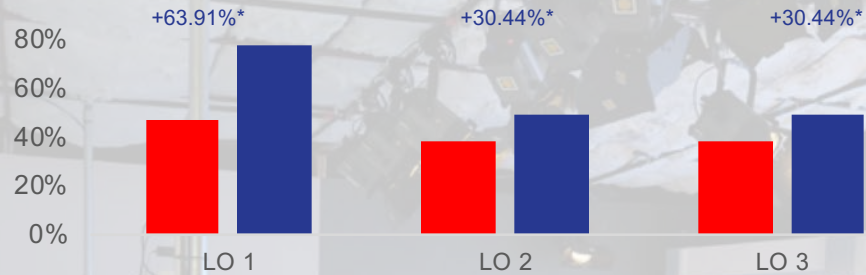
468 certificates issued to date

This education has the potential to impact 1,007,510 patients on an annual basis.

17,438-21,313 Patients Weekly

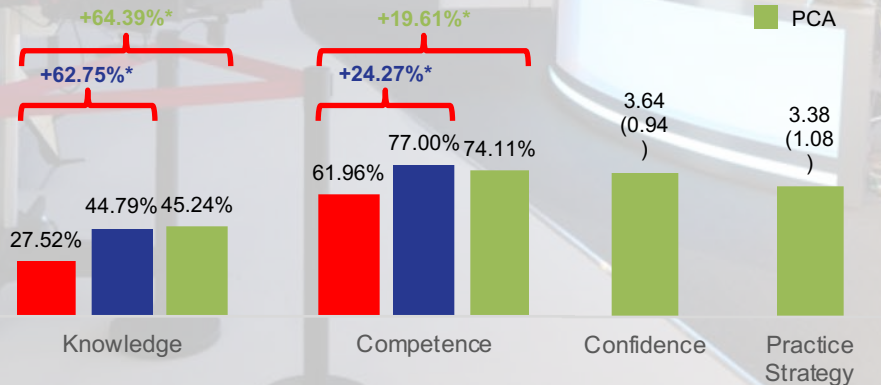
2019 Conversations Activity	Date	Participants
Conversations In Pulmonology 2019 Episode 3	4/27/19	468
<b>Total</b>		<b>468</b>

## Learning Gains Across Objectives



- ❖ **LO 1:** Incorporate a diagnostic approach to IPF and other progressive fibrosing - interstitial lung diseases that incorporates current guidelines and evolving modalities
- ❖ **LO 2:** Recognize the emerging data, from recent clinical trials, on longer term outcomes for patients with ILD treated with nintedanib/pirfenidone
- ❖ **LO 3:** Integrate available data into appropriate initial and long - term treatment strategies for patients with IPF and PF - ILD

## Learning Domain Analysis

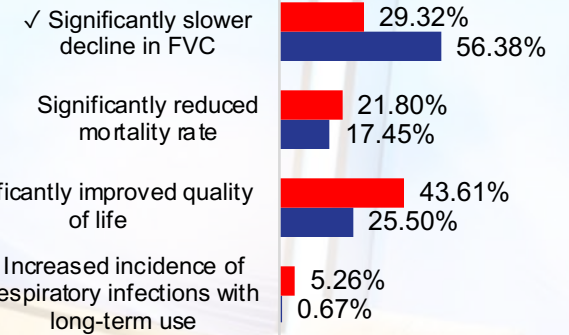


- ❖ A statistically significant net gain was measured from Pre-Test to the Post Curriculum Assessment (PCA) in both Knowledge (64%) and Competence (20%)
- ❖ In both Knowledge and Competence, improvements in Knowledge and Competence were well retained, with no meaningful change from Post-Test to PCA for either domain
- ❖ Confidence and practice strategy ratings, collected only at PCA, were moderate

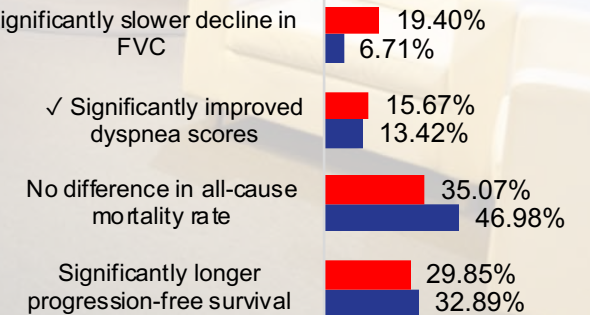
## Persistent Learning Gaps/Needs

**Results of clinical trials on emerging therapies for ILD**  
On two curriculum Knowledge items, learners struggled at Post-Test to correctly identify the results of recent clinical trials examining patient outcomes of emerging ILD therapies.

The INPULSIS study reported which of the following outcomes with nintedanib compared to placebo over 52 weeks?



The ASCEND study reported ALL of the following outcomes with pirfenidone compared to placebo over 52 weeks, EXCEPT:



**Speaker**

David J. Lederer, MD, MS  
Associate Professor of Medicine & Epidemiology  
Co-Director, NYP PFF Care Center Network ILD program  
Division of Pulmonary, Allergy, and Critical Care Medicine  
Columbia University Medical Center  
New York, NY

**Interstitial Lung Disease: Recognizing and Managing Progressive Fibrosis**

**COURSE SUMMARY**

Cost: Free  
Start Date: 06/01/2019  
Expiration Date: 05/31/2020  
Target Audience: Pulmonologists, Primary Care Physicians, Nurse Practitioners, Physician Assistants  
Format: Webcast  
Estimated Time To Complete CME Activity: 1 hour  
Credits: 1.0 AMA PRA Category 1 Credit™, 1.0 AANP Contact hour which includes 0.50 pharmacology hours  
Hardware/Software Requirements: Any web browser

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# Curriculum Patient Impact

In the evaluation, learners (N = 121) were asked to report how many patients they see in any clinical setting per week by selecting a range. The resulting distribution of learner responses was then extrapolated to reflect the total number of learners (468) who have attended the onsite and online meetings.

The findings reveal that this education has the potential to impact

**1,007,510**  
patients on an annual basis.

17,438–21,313 patients on a weekly basis

17,438–  
21,313

## Course Director

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### **Fernando Martinez, MD, MS**

Professor of Medicine  
Weill Cornell Medical College  
New York-Presbyterian Hospital/Weill  
Cornell Medical Center,  
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## Activity Planning Committee

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Sheila Lucas, CWEP

Deborah Paschal, CRNP

## Faculty

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### **David J. Lederer, MD, MS**

Associate Professor of Medicine &  
Epidemiology  
Co-Director, NYP PFF Care Center Network  
ILD program  
Division of Pulmonary, Allergy, and Critical  
Care Medicine  
Columbia University Medical Center  
New York, NY



# NACE *Conversations* in Pulmonology 2019

## **Commercial Support**

The NACE 2<sup>nd</sup> Annual Conversations in Pulmonology of 2019 CME activity was supported through educational grants or donations from the following companies:

- ❖ Boehringer Ingelheim Pharmaceuticals, Inc.
- ❖ Shire
- ❖ Sanofi Genzyme and Regeneron Pharmaceuticals
- ❖ Mallinckrodt Pharmaceuticals, LLC

# Overview

## Learning Objectives

- ❖ Incorporate a diagnostic approach to IPF and other progressive fibrosing-interstitial lung diseases that incorporates current guidelines and evolving modalities
- ❖ Recognize the emerging data, from recent clinical trials, on longer term outcomes for patients with ILD treated with nintedanib/pirfenidone
- ❖ Integrate available data into appropriate initial and long-term treatment strategies for patients with IPF and PF-ILD



## Three Live Virtual CME Symposia



## Enduring CME Symposium Webcast

<https://www.naceonline.com/courses/interstitial-lung-disease-recognizing-and-managing-progressive-fibrosis>

### Speaker

**Interstitial Lung Disease:  
Recognizing and Managing  
Progressive Fibrosis**



**COURSE SUMMARY**

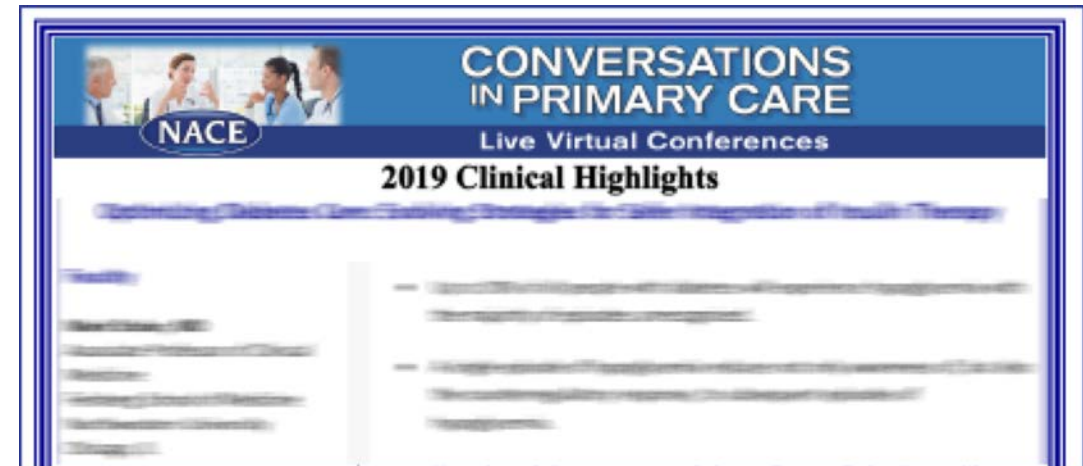
Cost: Free  
 Start Date: 06/01/2019  
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 Target Audience: Pulmonologists, Primary Care Physicians, Nurse Practitioners, Physician Assistants  
 Format: Webcast  
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 Credits: 1.0 AMA PRA Category 1 Credit™, 1.0 AANP Contact hour which includes 0.50 pharmacology hours  
 Hardware/Software Requirements: Any web browser



David J. Lederer, MD, MS  
 Associate Professor of Medicine & Epidemiology  
 Co-Director, NYP PFF Care Center Network ILD program  
 Division of Pulmonary, Allergy, and Critical Care Medicine  
 Columbia University Medical Center  
 New York, NY

## Clinical Highlights eMonograph

eMonograph, containing key teaching points from the CME activity, was distributed 1 week after the meeting to all attendees.





# Outcomes Methodology

Learning outcomes were measured using matched Pre-Test and Post-Test scores for Knowledge, Performance, Confidence, and practice strategy and across all of the curriculum's Learning Objectives.

Outcomes Metric	Definition	Application
<b>Percentage change</b>	This is how the score changes resulting from the education are measured. The change is analyzed as a relative percentage difference by taking into account the magnitude of the Pre-Test average.	Differences between Pre-Test, Post-Test, and PCA score averages
<b>P value (p)</b>	This is the measure of the statistical significance of a difference in scores. It is calculated using dependent or independent samples t-tests to assess the difference between scores, taking into account sample size and score dispersion. Differences are considered significant for when $p \leq .05$ .	Significance of differences between Pre-Test, Post-Test, and PCA scores and among cohorts
<b>Effect size (d)</b>	This is a measure of the strength/magnitude of the change in scores (irrespective of sample size). It is calculated using Cohen's d formula, with the most common ranges of d from 0-1: $d < .2$ is a small effect, $d = .2-.8$ is a medium effect, and $d > .8$ is a large effect.	Differences between Pre-Test and Post-Test score averages
<b>Power</b>	This is the probability (from 0 to 1) that the "null hypothesis" (no change) will be appropriately rejected. It is the probability of detecting a difference (not seeing a false negative) when there is an effect that is dependent on the significance (p), effect size (d), and sample size (N).	Differences between Pre-Test and Post-Test score averages
<b>Percentage non-overlap</b>	This is the percentage of data points at the end of an intervention that surpass the highest scores prior to the intervention. In this report, it will reflect the percentage of learners at Post-Test who exceed the highest Pre-Test scores.	Differences between Pre-Test and Post-Test score averages

# Participation

2019 Conversations Activity	Date	Participants
Conversations In Pulmonology 2019	4/27/19	468
<b>Total</b>		<b>468</b>

# Participation



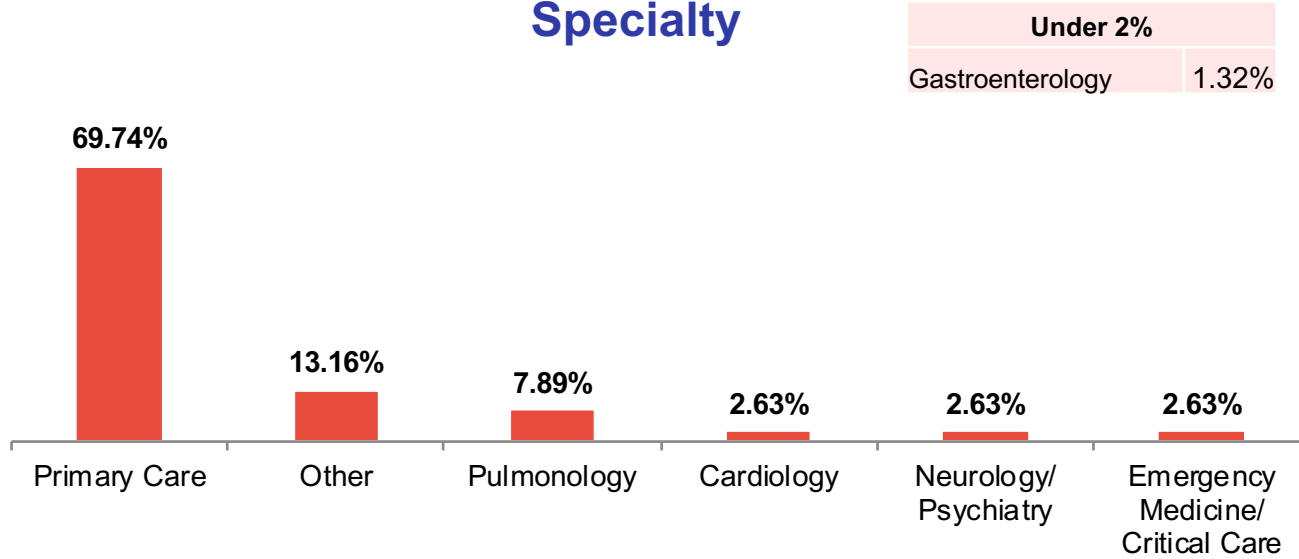
**468**  
Total Attendees



**1 Activity**

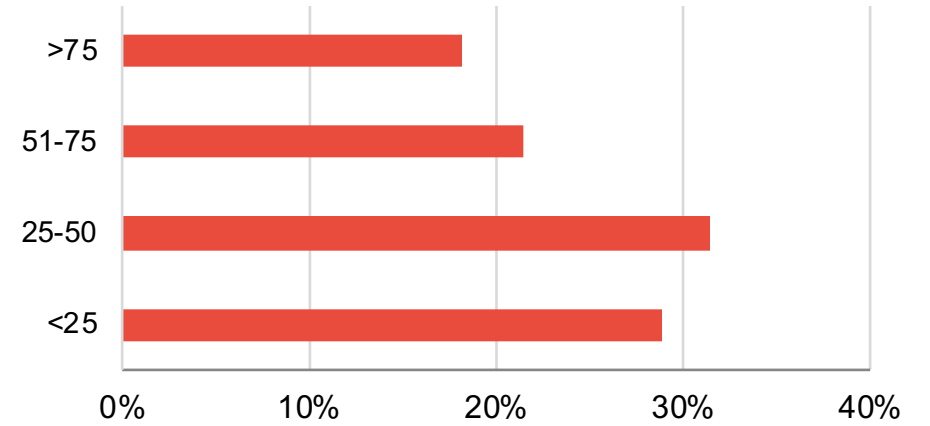
# Level 1: Demographics and Patient Reach

## Specialty



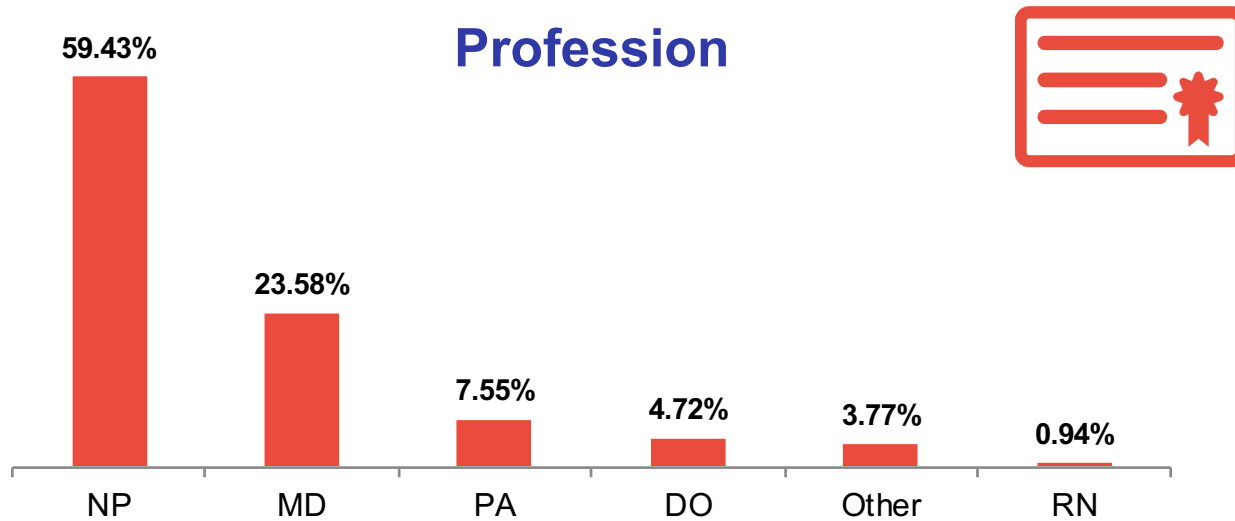
Patient Care Focus: 92%

## Patients seen each week, in any clinical setting:

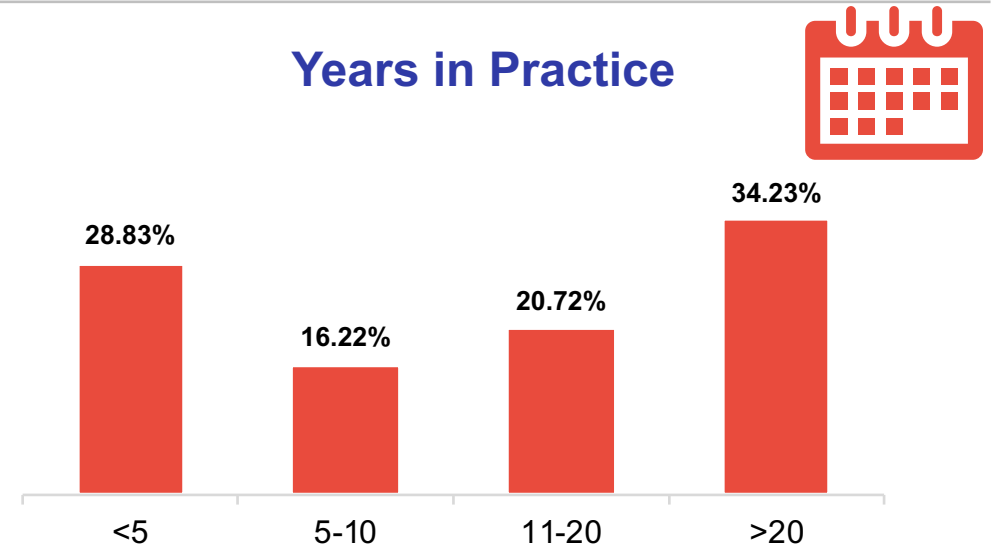


Average number of patients seen each week per clinician: 45

## Profession



## Years in Practice

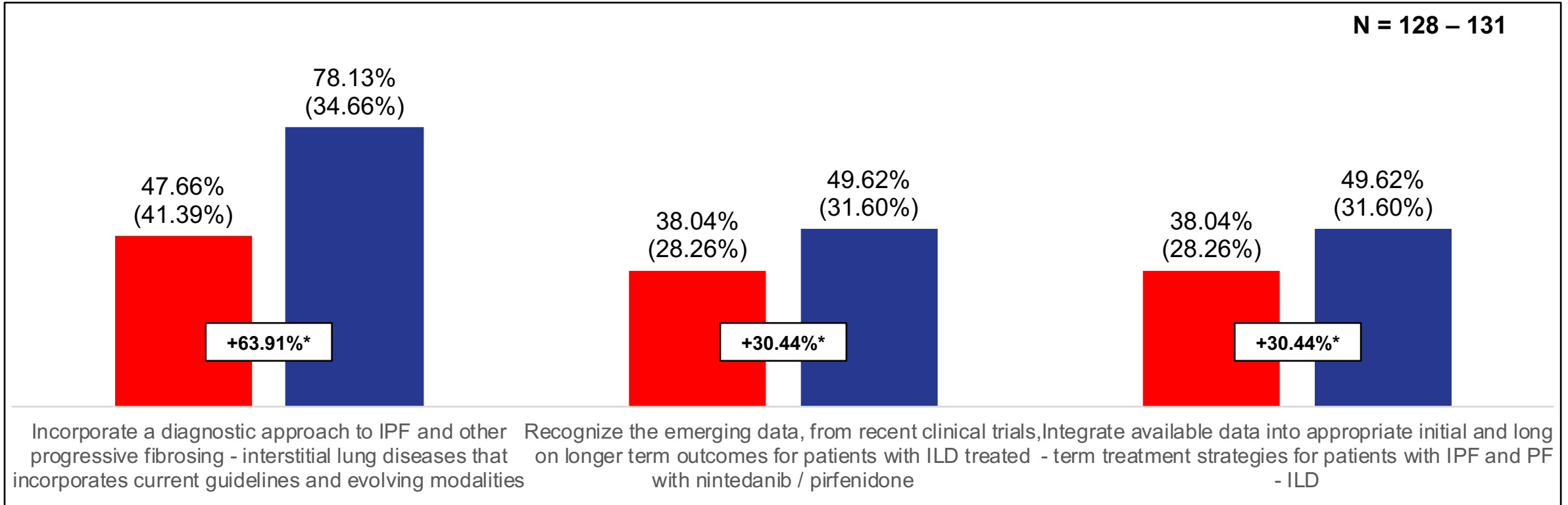




**Level 2-5:  
Outcomes Metrics**

# Learning Objectives Analysis

Pre-Test  
Post-Test



- ❖ Substantial and significant improvements in score were measured across all three curriculum Learning Objectives, from Pre- to Post-Test
- ❖ Pre- and Post-Test scores on the two Learning Objectives related to recent clinical trial data and its role in treatment strategies were driven down by two Knowledge items asking about specific trials
- ❖ High Post-Test scores on incorporating a diagnostic approach to IPF were driven by a Knowledge item on symptoms which should trigger a workup for ILD, and a Competence item addressing appropriate evaluation for a patient suspected of having ILD.

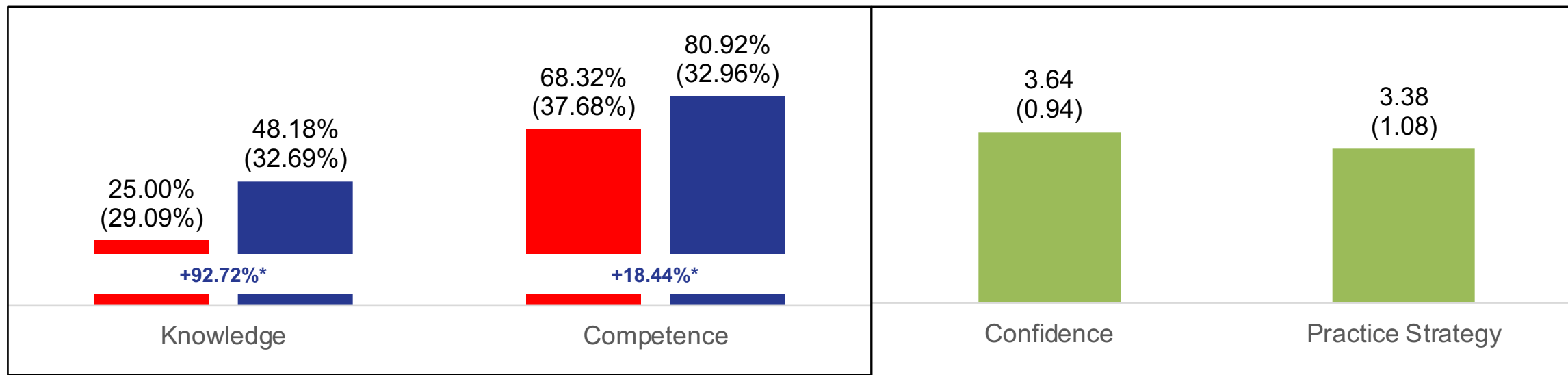
Note: data are matched.

\* indicates significance,  $p < 0.05$ .

# Learning Domain Analysis

Pre-Test Post-Test PCA

(N = 116–131)



- ❖ Substantial and significant improvements were measured from Pre- to Post-Test in both Knowledge and Competence
- ❖ Low Pre-Test scores in Knowledge were due to uniformly low Pre-Test scores across all three Knowledge items; Post-Test Knowledge scores remained low on two items related to clinical trial data
- ❖ Scores on both Competence items were similar at Post-Test (80% and 82%), on diagnostic and treatment steps for patients with dyspnea, dry cough, and other complications
- ❖ Confidence and practice strategy ratings, collected only at follow-up, were moderate. A moderate confidence score (3.64) was measured in learners' reported confidence in understanding which medications are indicated for IPF and the implications of long term use. Learners also reported a propensity to order HRCT for patients with symptoms and findings consistent with ILD (3.38).

Note: data for Knowledge and Competence is matched; learners with a score for the given domain on both the Pre-Test and Post-Test are included

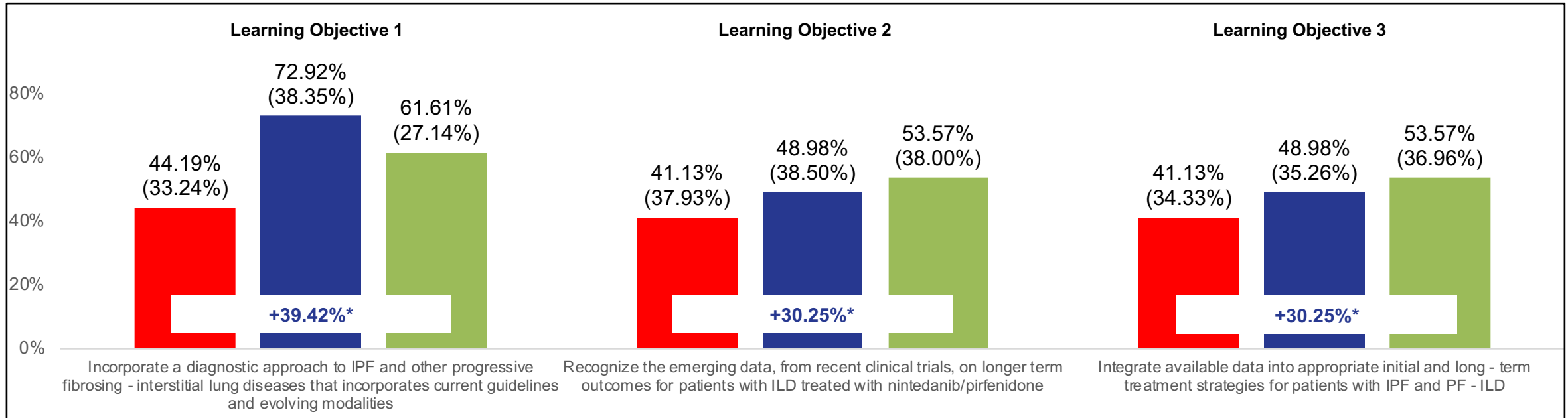
\*significant at the  $p \leq 0.05$  level, matched data



# 4-Week Retention Analysis: Learning Objectives

Pre-Test Post-Test PCA

(N = 115)



- ❖ In addition to collecting follow-up Confidence and Practice data for the curriculum, the Post Curriculum Assessment (PCA) repeated questions from the Knowledge and Competence domains
- ❖ Significant improvements in score between Pre-Test and PCA observations were measured for all curriculum Learning Objectives
- ❖ Learners continued to improve from Post-Test to PCA on the Learning Objectives related to recognizing emerging data on longer term outcomes of ILD patients treated with nintedanib/pirfenidone and integrating available data into appropriate initial and long-term treatment strategies for IPF and PF-ILD patients
- ❖ On the Learning Objective related to incorporating a diagnostic approach to IPF and other progressive fibrosing ILD, a decrease in score from Post-Test to PCA was measured

Note: data is matched; learners with a score for the given domain on both the Pre-Test and PCA are included

\*significant at the  $p \leq 0.05$  level

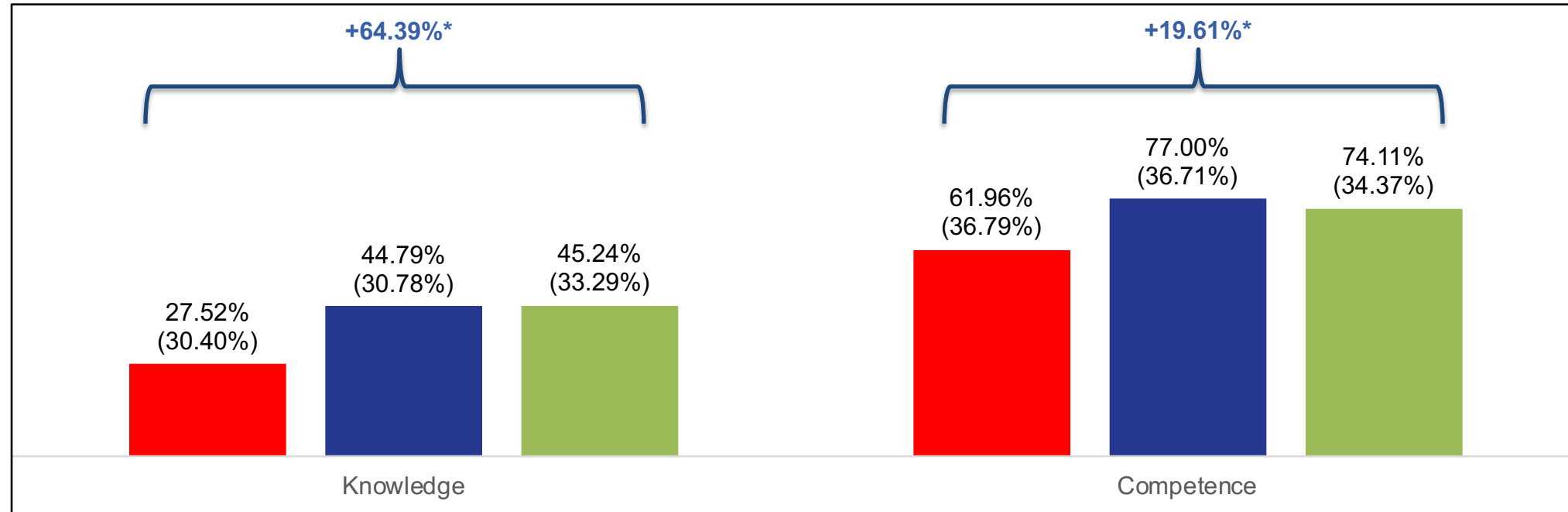




# 4-Week Retention Analysis: Learning Domains

Pre-Test Post-Test PCA

(N = 56)



At follow-up:

- ❖ A statistically significant net gain was measured from Pre-Test to the Post Curriculum Assessment (PCA) in both Knowledge (64%) and Competence (20%)
- ❖ In both Knowledge and Competence, improvements in Knowledge and Competence were well retained, with no meaningful change from Post-Test to PCA for either domain

Note: data is matched; learners with a score for the given domain on both the Pre-Test and PCA are included

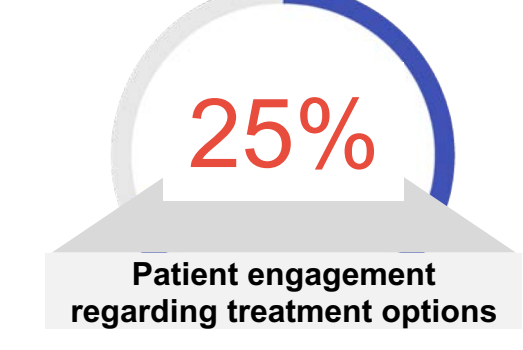
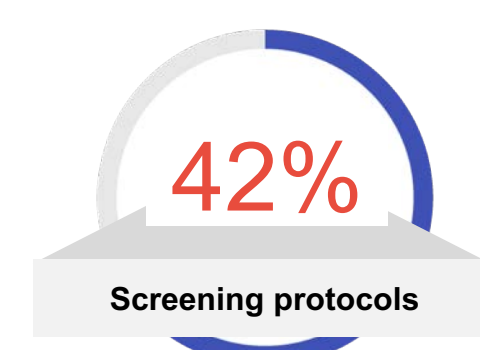
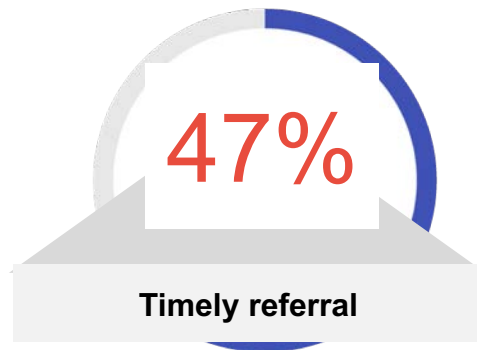
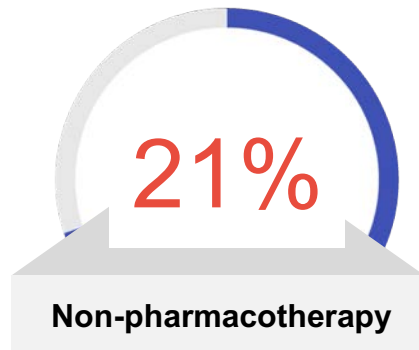
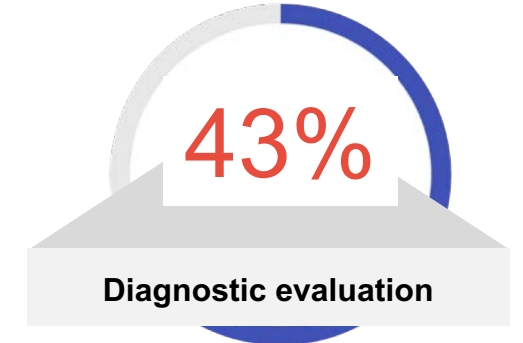
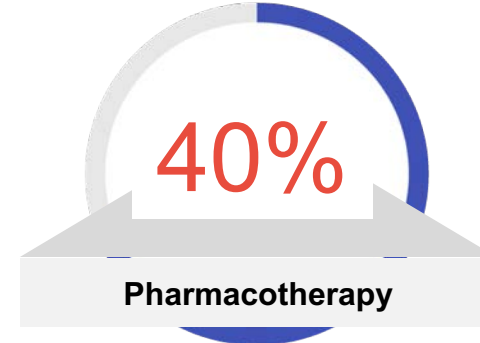
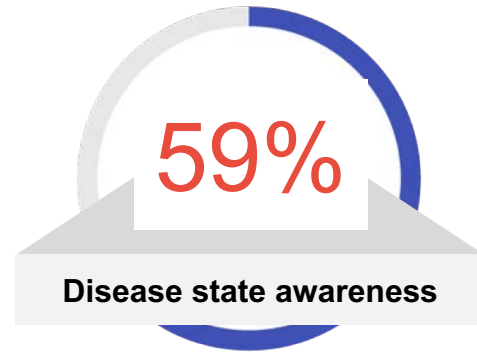
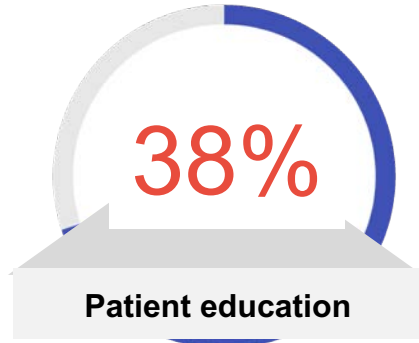
\*significant at the  $p \leq 0.05$  level



(4-week Post Assessment)

**Please select the specific areas of *skills, or practice behaviors*, you have improved regarding the treatment of patients with ILD since this CME activity. (Select all that apply.)**

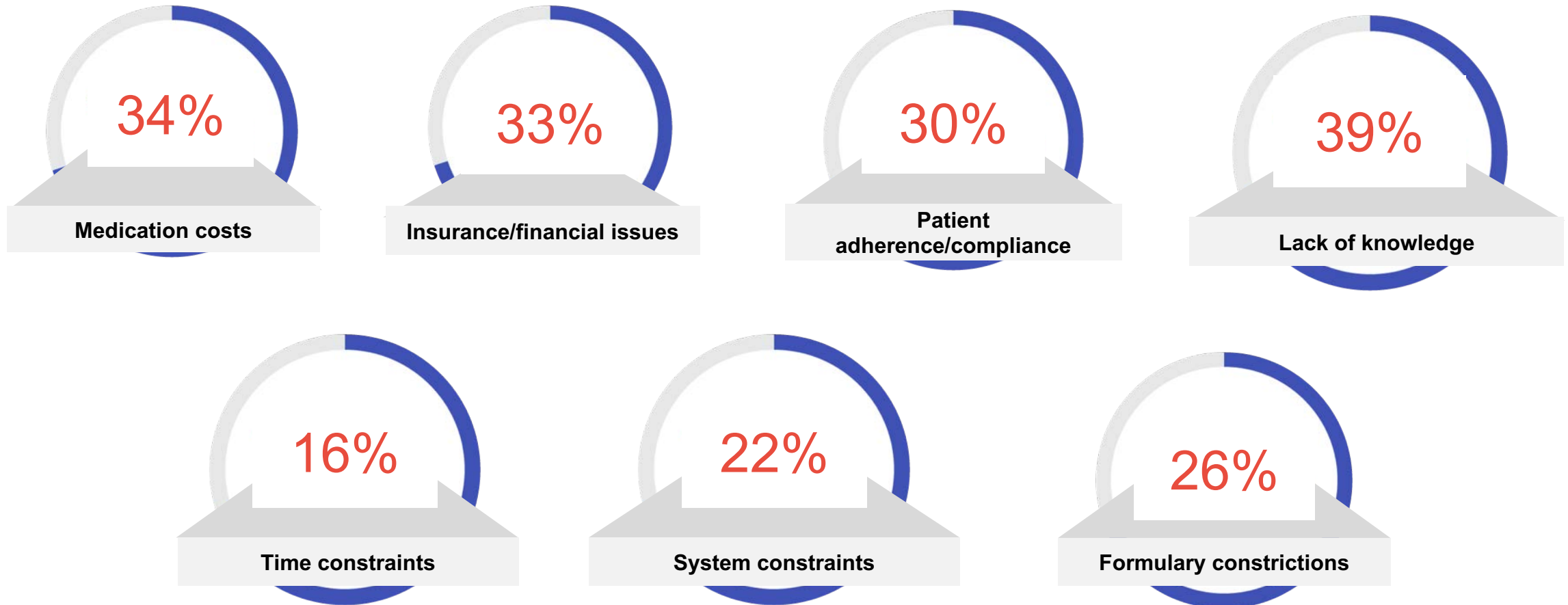
N=116



(4-week Post Assessment)

## What specific *barriers* have you encountered that may have prevented you from successfully implementing strategies for patients with ILD since this CME activity? (Select all that apply.)

N=116



# Cohort Comparison by Profession: Learning Objectives

Learning Objective	Nurse Practitioners				Physicians			
	N	Pre-Test	Post-Test	% Change	N	Pre-Test	Post-Test	% Change
Incorporate a diagnostic approach to IPF and other progressive fibrosing - interstitial lung diseases that incorporates current guidelines and evolving modalities	44	56.82% (37.83%)	82.95% (30.04%)	+45.99%*	26	55.77% (42.35%)	84.62% (30.28%)	+51.73%*
Recognize the emerging data, from recent clinical trials, on longer term outcomes for patients with ILD treated with nintedanib/pirfenidone	45	38.52% (24.80%)	51.48% (28.29%)	+33.64%*	26	48.08% (27.08%)	60.26% (25.35%)	+25.33%*
Integrate available data into appropriate initial and long - term treatment strategies for patients with IPF and PF - ILD	45	38.52% (24.80%)	51.48% (28.29%)	+33.64%*	26	48.08% (27.08%)	60.26% (25.35%)	+25.33%*

- ❖ On all three curriculum Learning Objectives, nurse practitioners and physicians both demonstrated significant improvements from Pre- to Post-Test
- ❖ Physicians had higher Post-Test scores compared to nurse practitioners, on all three Learning Objectives

## Cohort Comparison by Profession: Learning Domains

Learning Domain	Nurse Practitioners				Physicians			
	N	Pre-Test	Post-Test	% Change	N	Pre-Test	Post-Test	% Change
Knowledge	45	24.44% (25.24%)	51.85% (29.23%)	+112.15%*	26	38.46% (31.27%)	57.69% (28.21%)	+50.00%*
Competence	44	76.14% (34.52%)	86.36% (26.89%)	+13.42%	26	71.15% (34.45%)	88.46% (25.22%)	+24.33%*

- ❖ In both Knowledge and Competence, nurse practitioners and physicians both demonstrated significant improvements from Pre- to Post-Test
- ❖ No substantial differences in scores were measured between the nurse practitioner group and the physician group

# Identified Learning Gap:

## *Results of clinical trials on emerging therapies for ILD*

On two curriculum Knowledge items, learners struggled at Post-Test to correctly identify the results of recent clinical trials examining patient outcomes for emerging ILD therapies.

**Knowledge: The INPULSIS study reported which of the following outcomes with nintedanib compared to placebo over 52 weeks?**

**Results:**

- At Post-Test, only 56% of learners correctly answered: “Significantly slower decline in FVC”

**Knowledge: The ASCEND study reported ALL of the following outcomes with pirfenidone compared to placebo over 52 weeks, EXCEPT:**

**Results:**

- At Post-Test, only 13% of learners correctly answered: “Significantly improved dyspnea scores”

# Overall Educational Impact

- ❖ Significant increases in score were measured in both Knowledge and Competence, from Pre- to Post-Test
  - The strongest improvements in score (+128%) were on a Knowledge item asking which symptoms and findings should trigger a workup for ILD
  - Competence gains were greater (33%) on an item asking learners which diagnostic steps might be appropriate for a patient suspected of having ILD, with similar (80% and 82%) scores measured at Post-Test on both Competence items
  - Significant increases on all curriculum Learning Objectives were measured from Pre-Test to Post-Test
    - Low scores on items related to recent clinical trials drove scores down for two of the three Learning Objectives
  - Final scores on Confidence and practice strategy questions were moderate (3.64 and 3.38). The confidence score (3.64) was measured in learners' reported confidence in understanding which medications are indicated for IPF and the implications of long term use. Learners also reported a propensity to order HRCT for patients with symptoms and findings consistent with ILD (3.38).
- ❖ The analysis of scored items in the curriculum identified a **persistent learning gap related to the results of clinical trials on emerging therapies for ILD**
  - Learners struggled on two Knowledge items to correctly identify the results of recent clinical trials (INPULSIS and ASCEND) examining patient outcomes for emerging ILD therapies

# Appendix

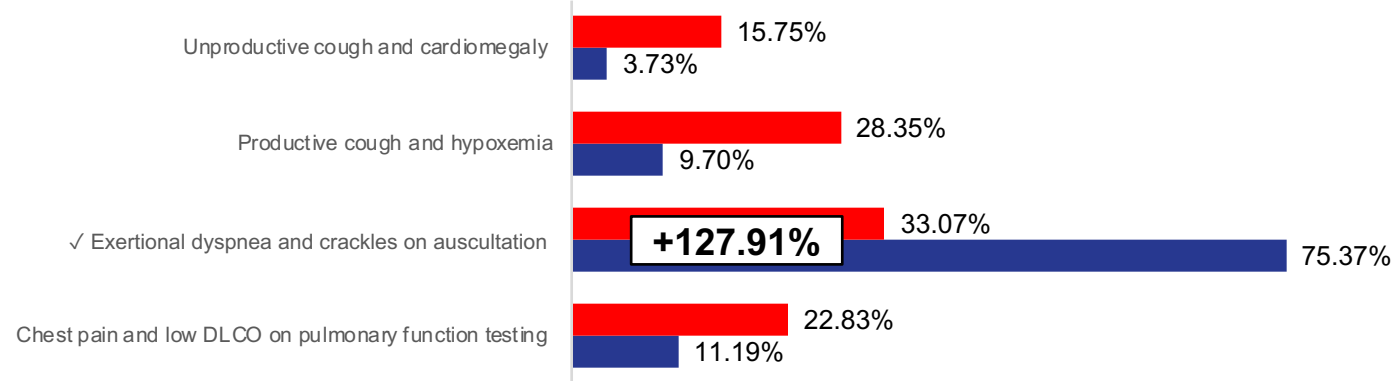


# Knowledge Items

Pre-Test  
Post-Test

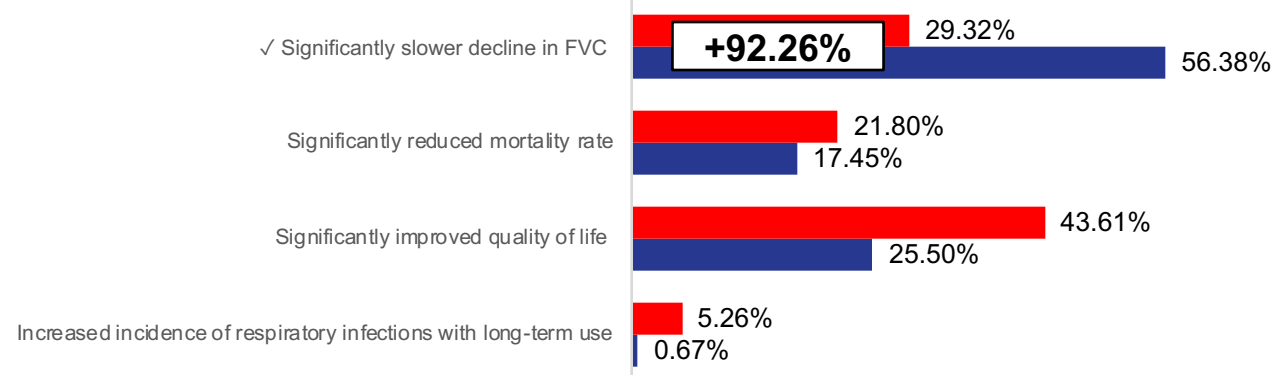
Which pair of symptoms and findings should trigger a workup for ILD?

N = 127 – 134



The INPULSIS study reported which of the following outcomes with nintedanib compared to placebo over 52 weeks?

N = 133 – 149

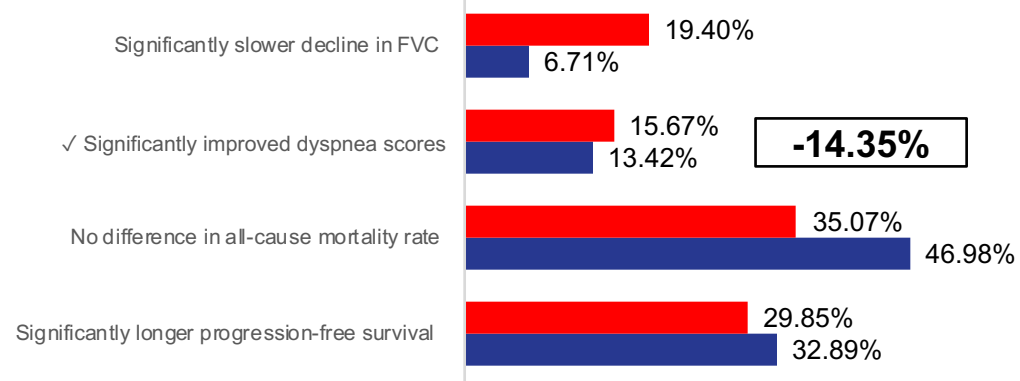


# Knowledge Items

Pre-Test  
Post-Test

The ASCEND study reported ALL of the following outcomes with pirfenidone compared to placebo over 52 weeks, EXCEPT:

N = 134 – 149

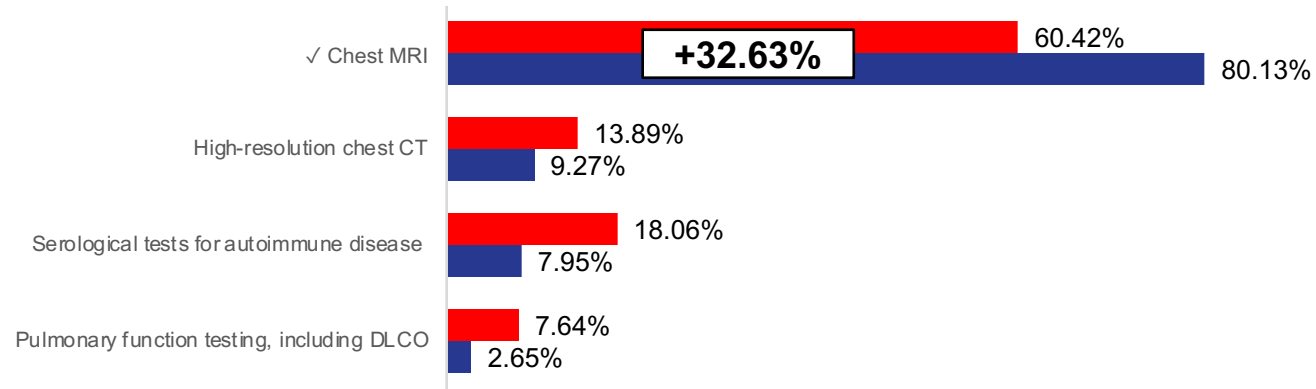


# Competence Items

Pre-Test  
Post-Test

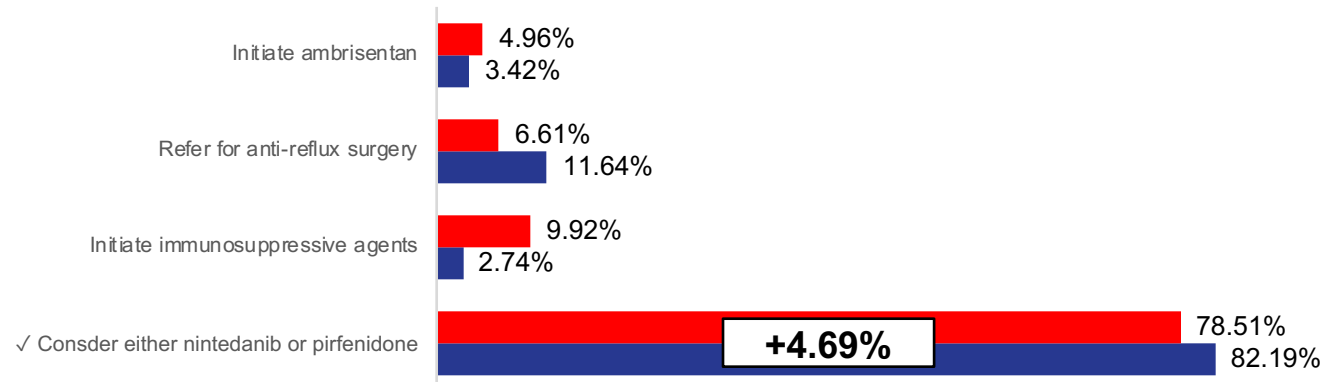
69-y/o man p/w with 10-year history of hypertension and 1-year history of progressive dry cough and exertional dyspnea; Exam: BP 134/78, HR 68 bpm, bilateral basilar crackles, cardiac exam WNL, no edema; O2Sat: 92% at rest on room air; Chest X-ray: Unremarkable; Meds: Hydrochlorothiazide 25 mg qd. Based on this presentation, ALL of the following tests should be considered, EXCEPT:

N = 144 – 151



71-y/o woman p/w 2-year history of progressive dyspnea on exertion, dry cough and GERD; Normal cardiac workup; Bilateral basilar crackles; Desaturation on exertion; Reduced DLCO on pulmonary function testing; Imaging and biopsy: Probable UIP pattern with moderate traction bronchiectasis; Autoimmune serologies WNL. What might be an appropriate next step for this patient?

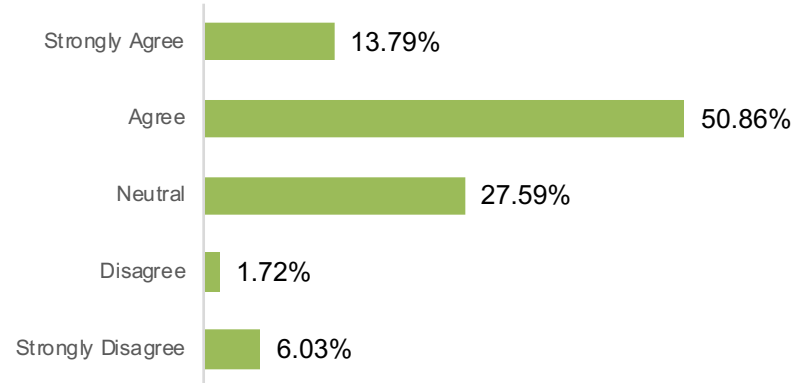
N = 121 – 146



# Confidence items (given at 4 week follow-up)

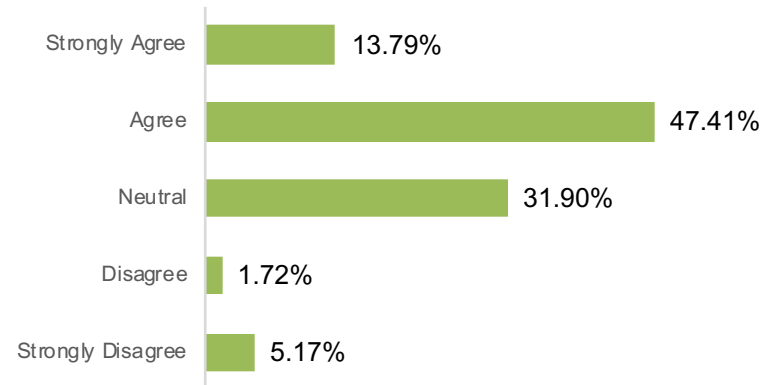
Please rate your level of agreement with the following statement: "I am much more confident in understanding which therapies are recommended for use in patients with IPF."

N = 116



Please rate your level of agreement with the following statement: "I am much more confident in my understanding of the long-term efficacy and safety of therapies specifically approved for IPF."

N = 116



# Practice Strategy Item (given at 4 week follow-up)

Please rate your level of agreement with the following statement: "I more often order HRCT for patients with symptoms and findings consistent with ILD."

N = 116

