# **Conversations in Pulmonology: 2020**

Progressive Fibrosing-Interstitial Lung Diseases (PF-ILDs): Improving Diagnosis, Treatment, and Longevity



**Final Outcomes Report** 

Genentech Grant ID: G-80955

October 27, 2020





#### **Conversations in Pulmonology: 2020**

This curriculum focused on identifying patients with PF-ILD and integrating available data into their treatment

#### **Participation**



803 Total Attendees



2 Virtual Sessions



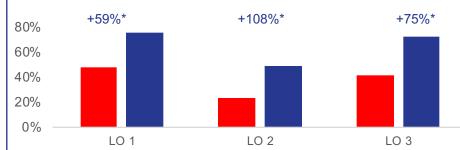
330 certificates issued to date

This education has the potential to impact 1,523,676
Patients on an annual basis.

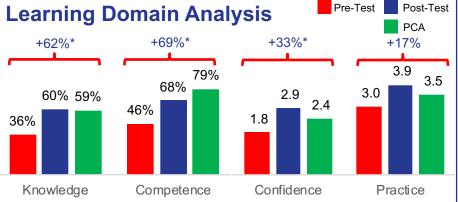
28,498 – 30,104 Patients Weekly

2020 Session	Date	Attendees
Conversations in Pulmonology	6/20/20	476
Rebroadcast	6/27/20	327
Total		803

#### **Learning Gains Across Objectives**



- LO 1, 59%\* Improvement: Incorporate a diagnostic approach to identify
  patients with PF-ILD, which incorporates current guidelines and evolving
  modalities
- LO 2, 108%\* Improvement: Recognize and understand emerging data from recent clinical trials, which concerns the management of patients with PF-ILD
- LO 3, 75%\* Improvement: Integrate available data into appropriate initial and long-term treatment strategies for patients with PF-ILD

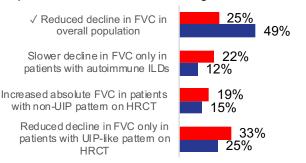


- In each of the four curriculum learning domains, substantial and significant gains were achieved from Pre- to Post-Test
- The strongest improvements were measured in Knowledge, where gains were driven by an item on characteristics of usual interstitial pneumonia on high-resolution CT
- Despite these improvements, low Post-Test averages were seen in Knowledge; low Confidence ratings may reflect possible awareness of outstanding gaps in proficiency
- In practice strategy, where learners reported how often they order high-resolution CT for patients suspected of having PF-ILD, average ratings increased to a moderate Post-Test value

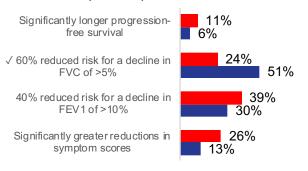
# Persistent Learning Gaps/Needs Outcomes of clinical trials of nintedanib and pirfenidone

Despite improvements in score on two Knowledge items discussing outcomes of clinical trials of agents used to manage patients with ILDs, low Post-Test scores were measured.

In the INBUILD study, which enrolled patients with progressive fibrosing interstitial lung disease (ILD) other than idiopathic pulmonary fibrosis (IPF), nintedanib was superior to placebo in which of the following outcomes?



In a phase II study of patients with unclassifiable ILD, pirfenidone was associated with which of the following outcomes compared to placebo?



Genentech Grant ID: G-80955





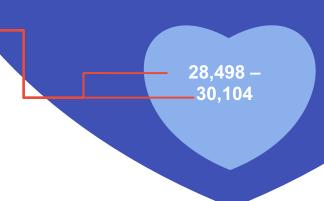
# **Curriculum Patient Impact**

In the Post-Test, learners (N = 248) were asked to report how many patients they see per week in any clinical setting by selecting a range. The resulting distribution of learner responses was then extrapolated to reflect the total number of learners who have attended the sessions.

The findings reveal that this education has the potential to impact

**1,523,676** patients on an annual basis.

28,498 – 30,104 patients on a weekly basis







#### **Course Director**

Kevin R. Flaherty, MD

Associate Professor Pulmonary and Critical Care Medicine University of Michigan Health System Ann Arbor, MI

#### **Activity Planning Committee**

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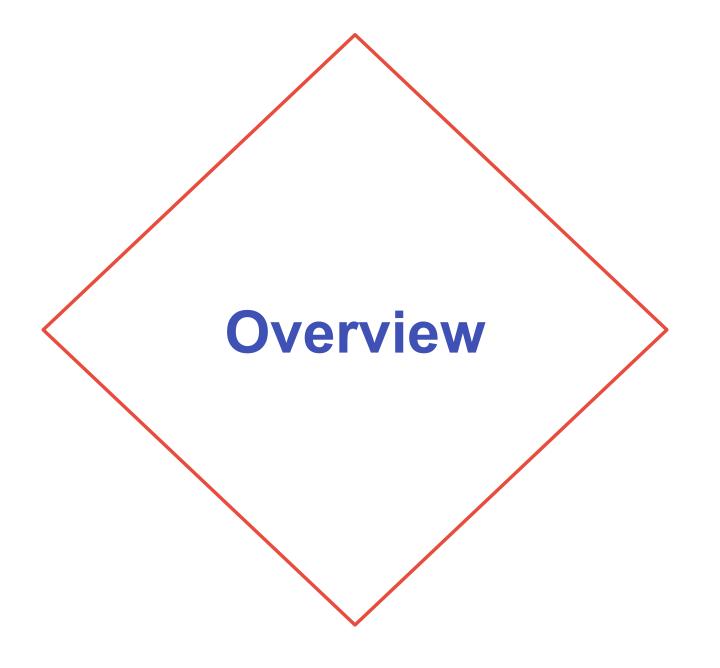
## **Commercial Support**

The Conversation in Pulmonology: 2020 CME activity was supported through educational grants or donations from the following companies:

- Actelion Pharmaceuticals US, Inc.
- Boehringer Ingelheim Pharmaceuticals, Inc.
- Genentech, a member of the Roche Group
- Mallinckrodt LLC











# **Learning Objectives**

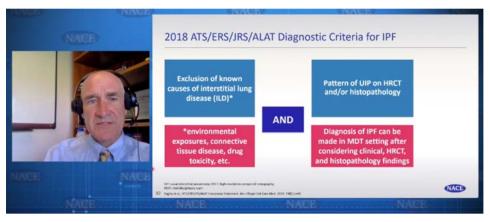
- Incorporate a diagnostic approach to identify patients with PF-ILD, which incorporates current guidelines and evolving modalities
- Recognize and understand emerging data from recent clinical trials, which concerns the management of patients with PF-ILD
- Integrate available data into appropriate initial and long-term treatment strategies for patients with PF-ILD





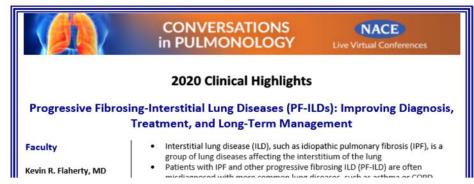
#### **Curriculum Overview**

1 Accredited Live Virtual Symposia, with 1 Virtual Rebroadcast: June 2020



#### **Clinical Highlights eMonograph**

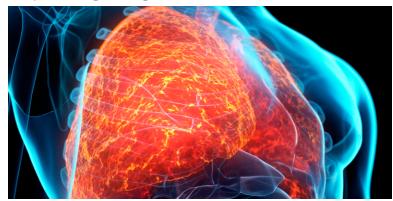
eMonograph, containing key teaching points from the CME activity, was distributed 1 week after the meeting to all attendees.



#### **Enduring CME Symposium Webcast**

Available at: <a href="https://www.naceonline.com/courses/progressive-fibrosing-interstitial-lung-diseases-pf-ilds-improving-diagnosis-treatment-and-long-term-management">https://www.naceonline.com/courses/progressive-fibrosing-interstitial-lung-diseases-pf-ilds-improving-diagnosis-treatment-and-long-term-management</a>

Progressive Fibrosing-Interstitial Lung Diseases (PF-ILDs): Improving Diagnosis, Treatment, and Long-Term Management



**▼**RealCME

#### **COURSE SUMMARY**

Cost: Free

Start Date: 07/20/2020

Expiration Date: 07/19/2021

Target Audience: Pulmonologists, Nurse Practitioners (NPs), Physician Assistants (PAs), and other clinicians engaged in the care of patients with pulmonary conditions

Format: Webcast

Estimated Time To Complete CME Activity:

1.0 hour

Credit(s):

1.0 AMA PRA Category 1 Credit<sup>TM</sup>

1.0 AANP Contact Hour which includes 0.75

pharmacology hours

Hardware/Software Requirements: Any web

browser

#### Speaker



Kevin R. Flaherty, MD Associate Professor Pulmonary and Critical Care Medicine University of Michigan Health System Ann Arbor, MI



#### **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		
Percentage change	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		
P value (p)	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 $p \le .05$ .	Significance of differences between Pre-Test, Post-Test, and PCA scores and among cohorts		
Effect size (d)	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=.28 is a medium effect, and d > .8 is a large effect.	Differences between Pre-Test and Post-Test score averages		
Power	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		
Percentage non-overlap	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**

2020 Session	Date	Attendees
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# Level 1 Participation **Demographics Patient Reach**

# **Participation**



803\*
Total Attendees



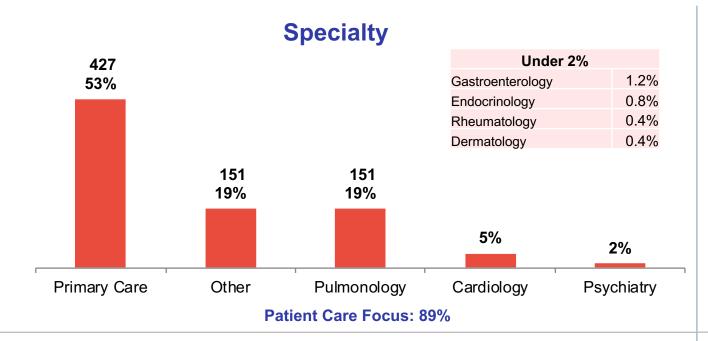
**2 Virtual Sessions** 

183 Follow-up Participants 23% Rate of follow-up engagement

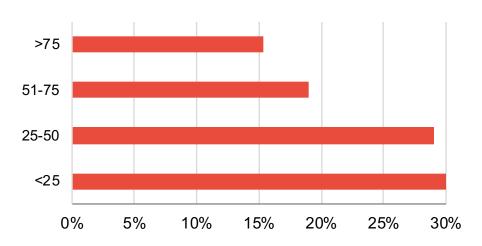




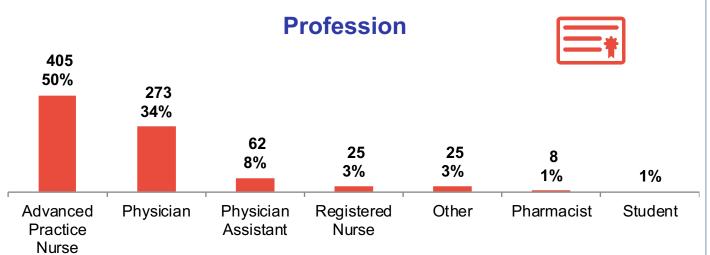
#### **Level 1: Demographics and Patient Reach**

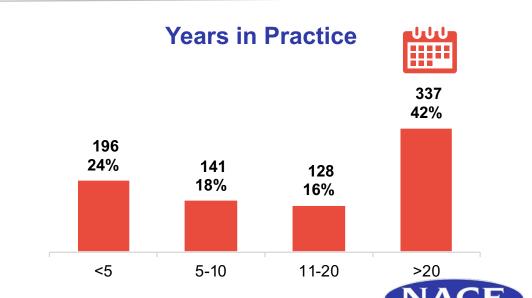


#### Patients seen each week, in any clinical setting:



Average number of patients seen each week per clinician: 41







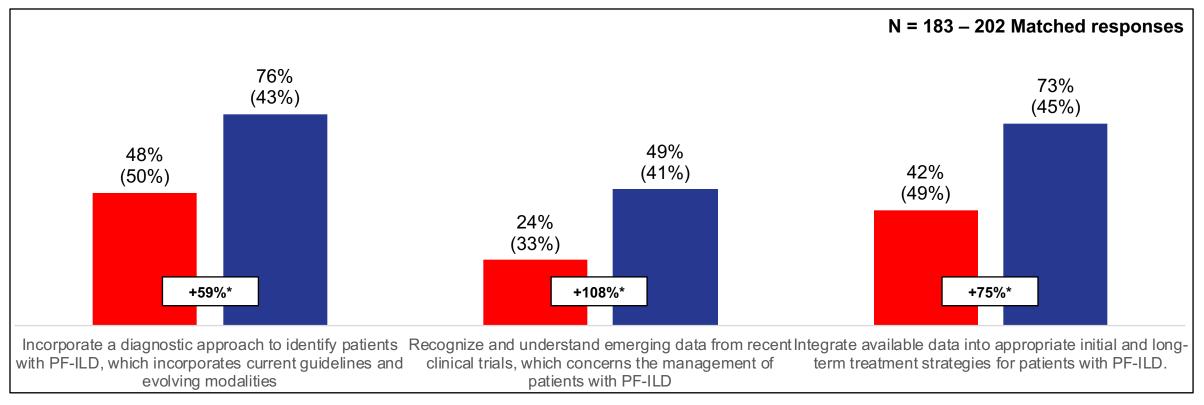






# **Learning Objective Analysis**





- Across all three curriculum Learning Objectives, substantial and significant improvements were measured from low Pre-Test scores (of 59% to 108%)
- Despite these gains, low scores at Post-Test (49%) were measured on recognizing and understanding emerging data from recent clinical trials
- Higher Post-Test scores (73% and 76%) were seen on the Objectives on a guideline-based diagnostic approach and on integrating data into initial and long-term treatment strategies



# **Learning Objective Analysis**

#### Cohort comparison by profession

Learning Objective		Advanced Practice Nurses			Physicians			
		Pre-Test	Post-Test	Change	N	Pre-Test	Post-Test	Change
Incorporate a diagnostic approach to identify patients with PF-ILD, which incorporates current guidelines and evolving modalities	79	48% (50%)	73% (44%)	+53%*	75	51% (50%)	81% (39%)	+61%*
Recognize and understand emerging data from recent clinical trials, which concerns the management of patients with PF-ILD	90	23% (36%)	51% (42%)	+117%*	81	22% (30%)	51% (40%)	+135%*
Integrate available data into appropriate initial and long-term treatment strategies for patients with PF-ILD	78	37% (48%)	72% (45%)	+93%*	75	55% (50%)	84% (37%)	+54%*

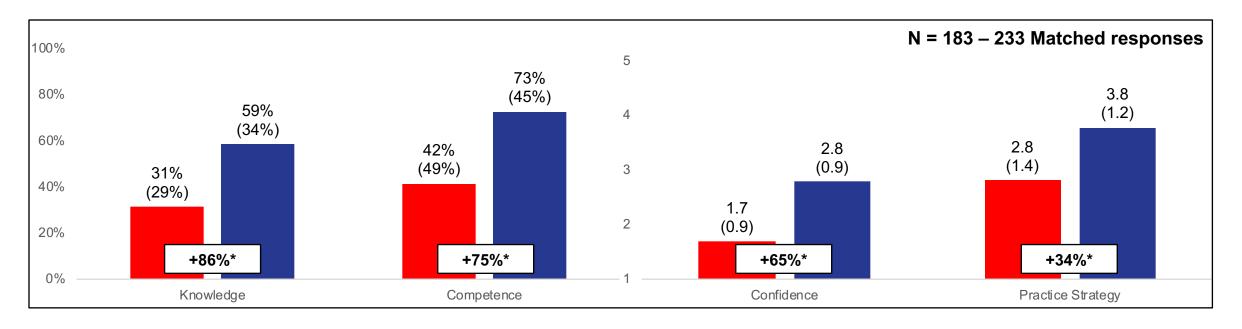
- For both advanced practice nurses and physicians, significant gains were measured from Pre- to Post-Test on each of the three curriculum Learning Objectives
- On incorporating a diagnostic approach including current guidelines and evolving modalities, and integrating available data into treatment strategies, physicians had higher Pre- and Post-Test scores compared to advanced practice nurses
- For both advanced practice nurses and physicians, lowest scores were seen on recognition and understanding of emerging clinical trial data on the management of patients with PF-ILD





# **Learning Domain Analysis**





- In each of the four curriculum learning domains, substantial and significant gains were achieved from Pre- to Post-Test
- The strongest improvements (+86%) were measured in Knowledge, where gains were driven by an item on characteristics of usual interstitial pneumonia on high-resolution CT
- Despite these improvements, low Post-Test averages were seen in Knowledge; low Confidence ratings may reflect possible awareness of outstanding gaps in proficiency
- In practice strategy, where learners reported how often they order high-resolution CT for patients suspected of having PF-ILD, average ratings increased to a moderate Post-Test value (3.8)



# **Learning Domain Analysis**

#### Cohort comparison by profession

Learning Domain	Advanced practice nurses			Physicians				
	N	Pre-Test	Post-Test	% Change	N	Pre-Test	Post-Test	% Change
Knowledge	93	31% (29%)	58% (35%)	+86%*	84	31% (29%)	62% (32%)	+101%*
Competence	78	37% (48%)	72% (45%)	+93%*	75	55% (50%)	84% (37%)	+54%*
Confidence	83	1.5 (0.8)	2.6 (0.8)	+70%*	78	1.9 (1.0)	3.0 (0.9)	+61%*
Practice	107	2.6 (1.4)	3.6 (1.2)	+40%*	90	3.3 (1.4)	4.2 (1.0)	+25%*

- When comparing the scores of advanced practice nurses and physicians by learning domain, both groups achieved significant gains from Pre- to Post-Test, across all four domains
- Physicians had stronger improvements in Knowledge from Pre- to Post-Test compared to advanced practice nurses,
   while advanced practice nurses had stronger gains across the other domains
- Pre- and Post-Test scores were higher or similar for physicians compared to advanced practice nurses, across all four learning domains



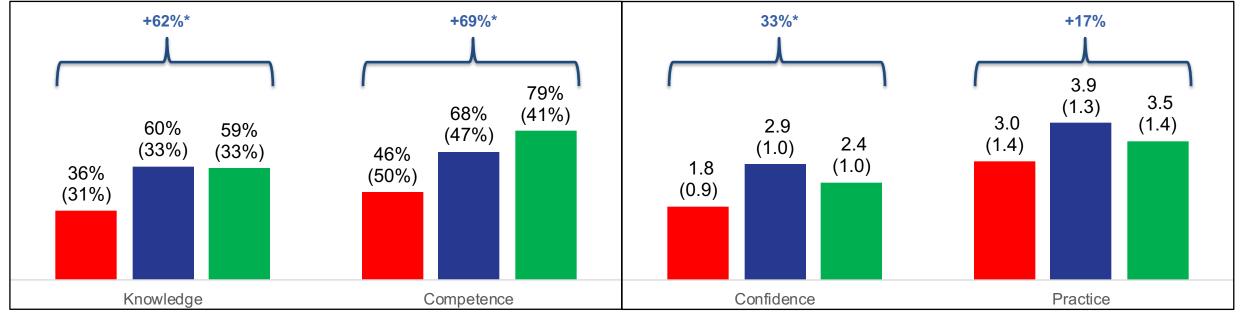


#### Pre-Test Post-T

#### Post-Test PCA

#### By Learning Domain





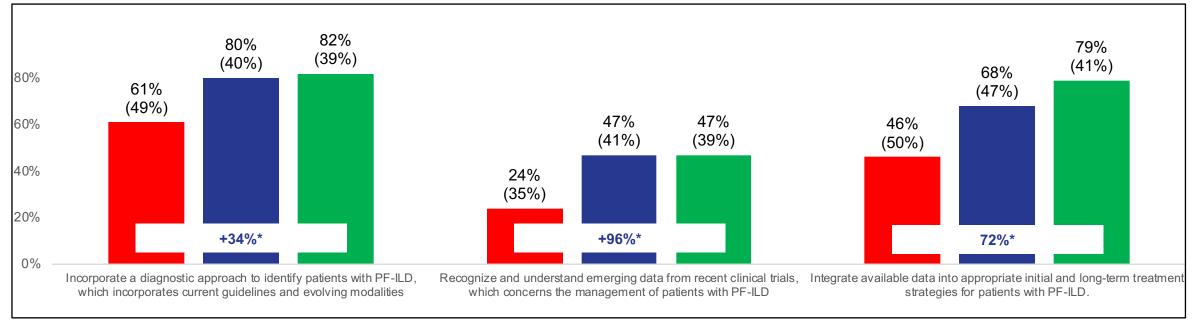
- Four to six weeks following their engagement in one of the curriculum sessions, learners were prompted to complete a brief Post Curriculum Assessment (PCA), which repeated items from each of the four curriculum learning domains
- In each domain, net gains were achieved from Pre-Test to PCA measurements; these were significant in all domains except practice strategy
- In Knowledge, Confidence, and practice strategy, some score slippage was seen from Post-Test to PCA measurements
  - In Competence, strong ongoing improvements were seen from Post-Test to PCA





Post-Test

PCA



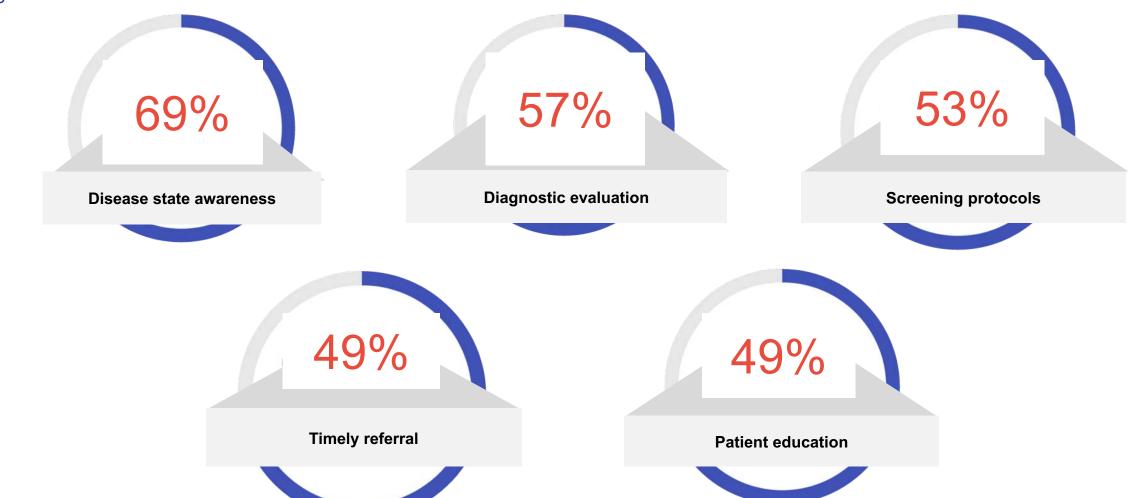
- When examining results by Learning Objective, net gains were achieved from Pre-Test to PCA measurements on each
  of the three Objectives
- Ongoing improvements in score were achieved on incorporating a diagnostic approach to identify patients with PF-ILD which incorporates current guidelines and emerging modalities, and on integrating available data into appropriate treatment strategies
  - On the other Objective, discussing emerging data from recent clinical trials, Post-Test proficiency was well retained,
     with no meaningful change between Post-Test and PCA score



(4-week Post Assessment)

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

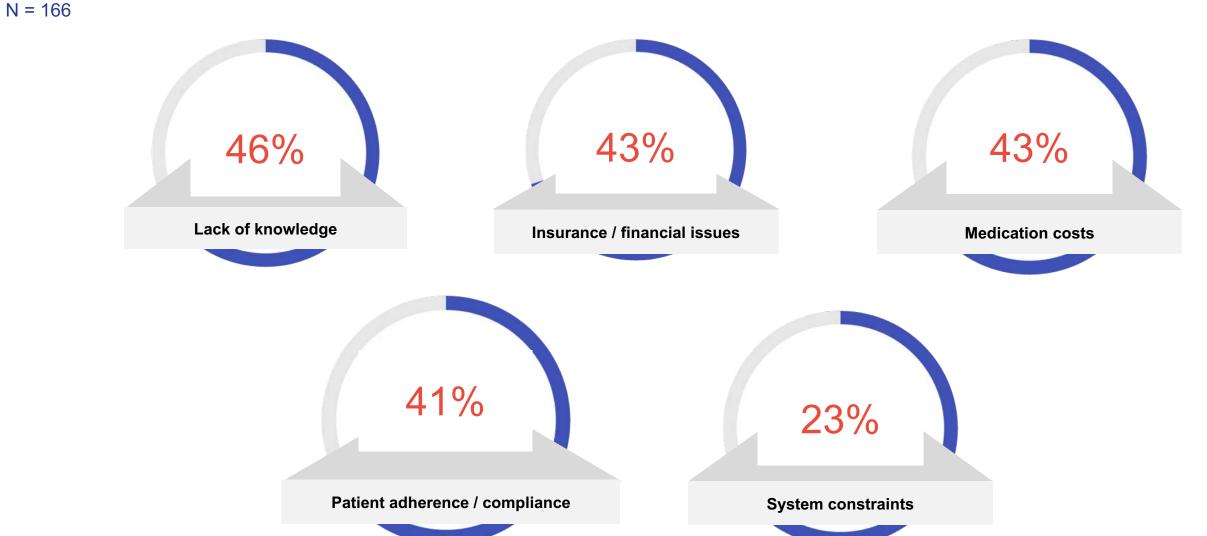
N = 166







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







# Identified Learning Gap: Outcomes of clinical trials of nintedanib and pirfenidone

Despite improvements in score on two Knowledge items discussing outcomes of clinical trials of agents used to manage patients with ILDs, low Post-Test scores were measured.

In the INBUILD study, which enrolled patients with progressive fibrosing interstitial lung disease (ILD) other than idiopathic pulmonary fibrosis (IPF), nintedanib was superior to placebo in which of the following outcomes?

#### Results:

At Post-Test, 49% of learners correctly answered: "Reduced decline in FVC in overall population"

In a phase II study of patients with unclassifiable ILD, pirfenidone was associated with which of the following outcomes compared to placebo?

#### **Results:**

• At Post-Test, 51% of learners correctly answered: "60% reduced risk for a decline in FVC of >5%"





## **Overall Educational Impact**

- Substantial, significant improvements were seen across all four curriculum learning domains, from Pre- to Post-Test (Knowledge, Competence, Confidence, and practice strategy)
  - These gains were stronger for advanced practice nurses compared to physicians across all domains except Knowledge
  - Improvements were seen across all individual Knowledge and Competence items, with improvements ranging from 59% to 112%
- Significant improvements ranging from 59% to 108% were measured across all Learning Objectives, with Post-Test scores ranging from 49% to 76%
  - Low Post-Test scores (49%) were measured in recognizing and understanding emerging data from recent clinical trials
- Low Pre- and Post-Test Confidence ratings reflect possible learner awareness of gaps in proficiency
- On a follow-up assessment, strong gains were measured across all Learning Objectives from Pre-Test, with ongoing improvements from Post-Test seen in incorporating a diagnostic approach to identify patients with PF-ILD and integrating available data into treatment strategies
- The analysis of Knowledge and Competence items identified an opportunity for further education in outcomes of clinical trials of nintedanib and pirfenidone
  - Despite improvements on a two Knowledge items discussing the results of clinical trials of these two
    agents, low Post-Test scores identify this as an area of opportunity for further education





# **Appendix**

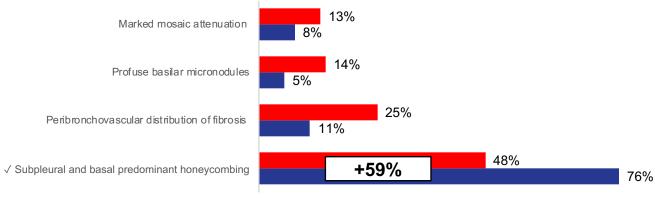
Slides 25 – 28: Pre-Test to Post-Test matched item responses

Slides 29 – 32: Pre-Test, Post-Test, and PCA matched item responses\*

# **Knowledge Items**

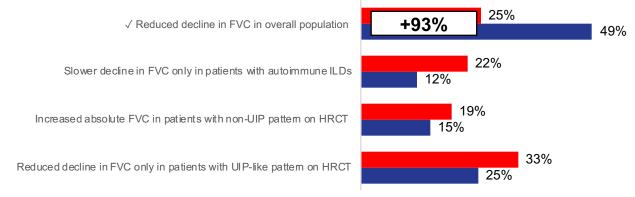
A pattern of usual interstitial pneumonia (UIP) on high-resolution CT (HRCT) is characterized by which of the following?





In the INBUILD study, which enrolled patients with progressive fibrosing interstitial lung disease (ILD) other than idiopathic pulmonary fibrosis (IPF), nintedanib was superior to placebo in which of the following outcomes?

N = 178 Matched responses



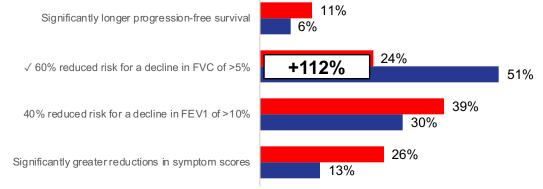




# **Knowledge Items**

In a phase II study of patients with unclassifiable ILD, pirfenidone was associated with which of the following outcomes compared to placebo?









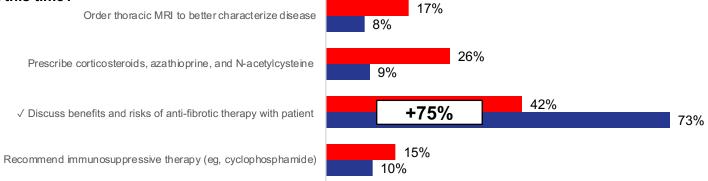
# **Competence Items**

Pre-Test
Post-Test

66 y/o man who presented with chronic dry cough and dyspnea on exertion. Symptoms worsened over last year. Initial workup identified DLco 45%, FVC 50%, inconsistent HRCT and histological pattern for UIP; other findings were unremarkable. Working diagnosis:

Unclassifiable ILD. Follow-up 9 months later: DLco 40%, FVC 45%, worsened symptoms, now out of breath when walking uphill. Which of

the following might be appropriate at this time?



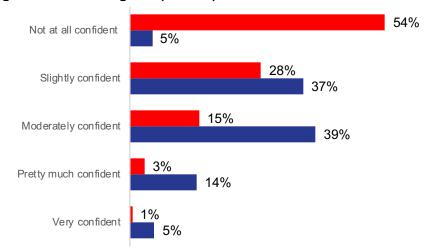
**N** = 183 Matched responses





# **Confidence and Practice Strategy Items**

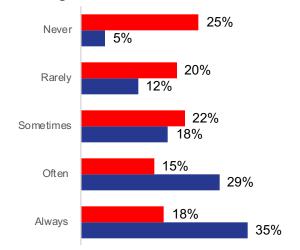
How confident are you in your ability to manage patients with progressive fibrosing ILD (PF-ILD)?



N = 191 Matched responses

**N = 233 Matched responses** 

How often do/will you order high-resolution CT for patients you suspect of having PF-ILD?







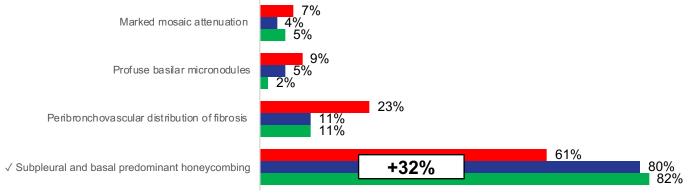
## **Knowledge Items**

Post Curriculum Assessment (PCA)

Pre-Test
Post-Test
PCA

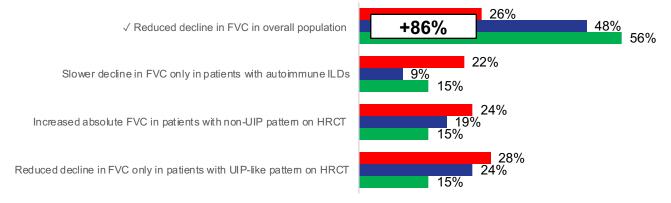
A pattern of usual interstitial pneumonia (UIP) on high-resolution CT (HRCT) is characterized by which of the following?





In the INBUILD study, which enrolled patients with progressive fibrosing interstitial lung disease (ILD) other than idiopathic pulmonary fibrosis (IPF), nintedanib was superior to placebo in which of the following outcomes?









# **Knowledge Items**

placebo?

Post Curriculum Assessment (PCA)

Pre-Test
Post-Test
PCA

N = 56 Matched responses

Significantly longer progression-free survival

9%
9%

46%
46%

46%

46%

46%

46%

45%

In a phase II study of patients with unclassifiable ILD, pirfenidone was associated with which of the following outcomes compared to

Significantly greater reductions in symptom scores





## **Competence Items**

#### Post Curriculum Assessment (PCA)

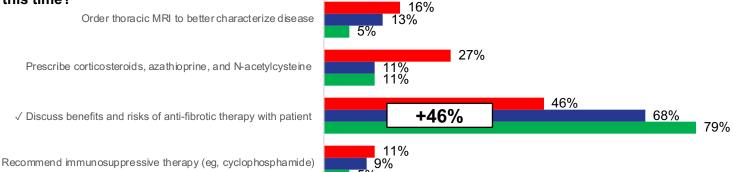
Pre-Test
Post-Test
PCA

N = 56 Matched responses

66 y/o man who presented with chronic dry cough and dyspnea on exertion. Symptoms worsened over last year. Initial workup identified DLco 45%, FVC 50%, inconsistent HRCT and histological pattern for UIP; other findings were unremarkable. Working diagnosis:

Unclassifiable ILD. Follow-up 9 months later: DLco 40%, FVC 45%, worsened symptoms, now out of breath when walking uphill. Which of

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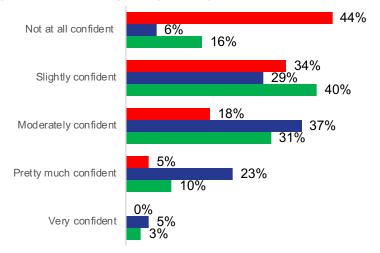




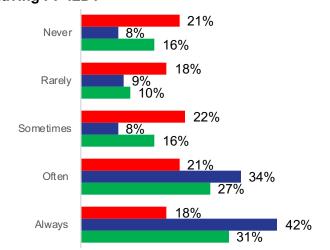
# **Confidence and Practice Strategy Items**

Post Curriculum Assessment (PCA)

How confident are you in your ability to manage patients with progressive fibrosing ILD (PF-ILD)?



How often do you order high-resolution CT for patients you suspect of having PF-ILD?



Pre-Test
Post-Test
PCA

**N = 62 Matched responses** 

**N = 77 Matched responses** 



