Emerging Challenges in Primary Care: 2018

# Managing Lipids and Cardiovascular Risk: Using the Data to Optimize Care

## Final Live Activities Outcomes Report

Amgen Grant ID: IME-145797

January 14, 2019

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# Executive Summary

- This curriculum discussed the management of hyperlipidemia, with a focus on PCSK9 inhibitors.
- Substantial improvements were measured in learners' awareness of the barriers to initiating PCSK9 inhibitor therapies and in strategies to overcome them, as well as clinical trials investigating treatment with PCSK9 inhibitors.

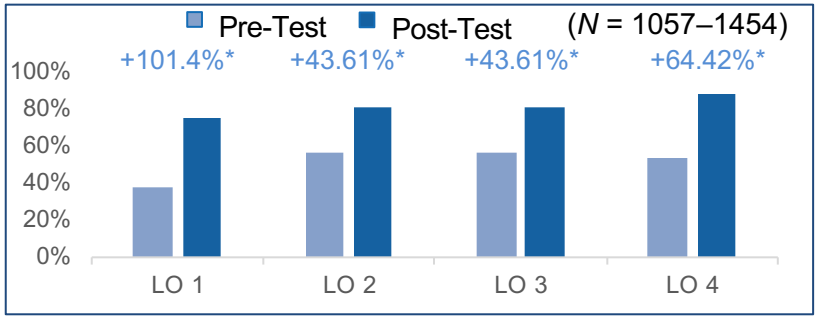
**3,019*** Total Attendees

**9 Cities**

**1,757*** On Site

**1,262*** Simulcast / Virtual Symposium

## Pre to Post-Test Results By Learning Objective




- **LO1: 101% Improvement**: Describe the findings from recent trials of PCSK9i hypercholesterolemia treatments on cardiovascular outcomes.
- **LO2: 44% Improvement**: Discuss current guidelines and recommendations for the management of hyperlipidemia in high risk patients.
- **LO3: 44% Improvement**: Incorporate current data into secondary prevention treatment strategies for patients with the highest cardiovascular risk.
- **LO4: 64% Improvement**: Recognize barriers to access for PCSK9 monoclonal antibody therapy and discuss strategies to overcome them.

## Impact

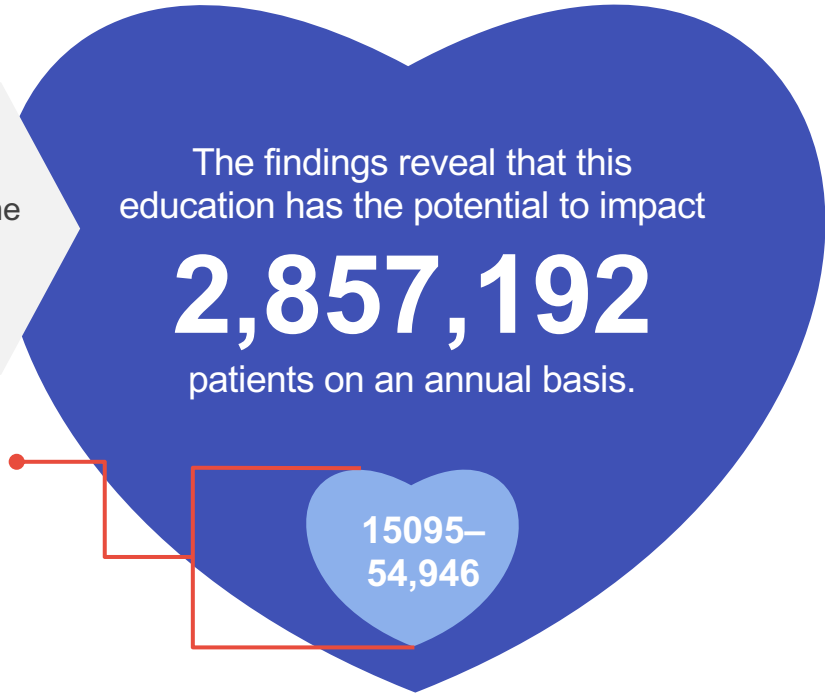
- 3,019 attendees were reached via both online and live formats, with significant gains observed across cohorts and modalities from Pre-test to Post-test.
- Learners demonstrated substantial increases in their measured knowledge of trials of two new PCSK9 inhibitors and strategies for securing their approval in practice.
- Despite substantial improvements across the intervention, learners remain challenged in their knowledge of recent trials on PCSK9 inhibitors and treatment selection for patients with high cardiovascular risk.



*These numbers represent the total number of attendees, irrespective of assessment participation

# Curriculum Patient Impact

In the evaluation, learners (N = 3,019) were asked to report how many patients with hyperlipidemia 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 who have attended the onsite and online meetings.




**15095–54,946 patients on a weekly basis**

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Professor of Medicine/Cardiology
Co-director, UCLA Program in Preventive Cardiology
Director, UCLA Barbra Streisand Women's Heart Health Program
Los Angeles, CA

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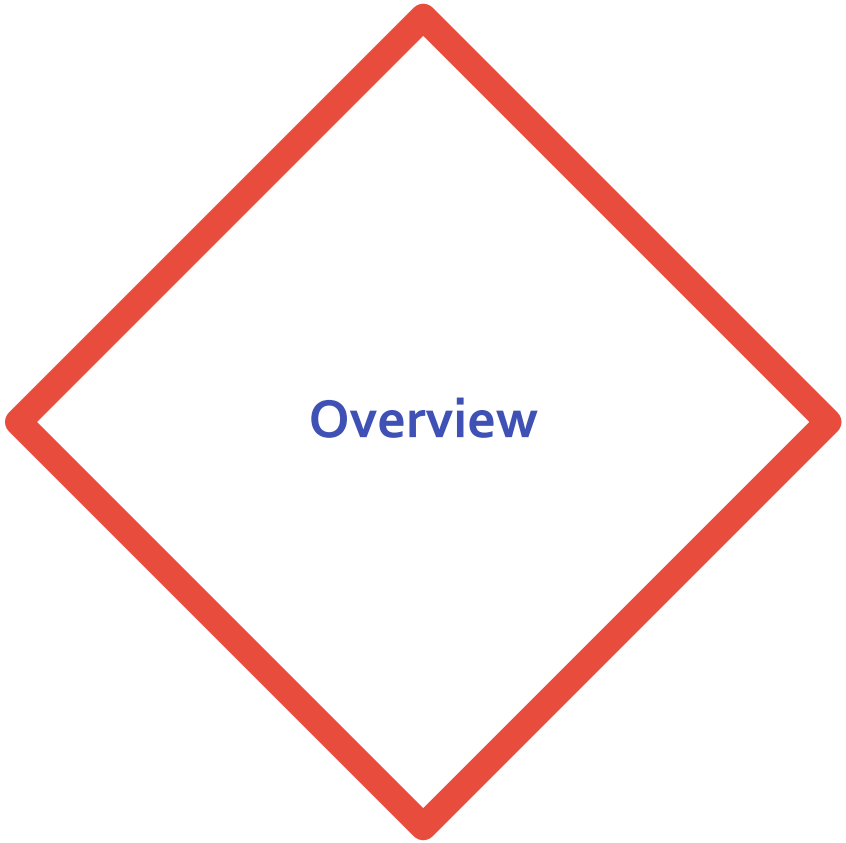
## Commercial Support

The Emerging Challenges in Primary Care: 2018 series of CME activities were supported through educational grants or donations from the following companies:

- Actelion Pharmaceuticals US, Inc.
- Amgen, Inc.
- AstraZeneca Pharmaceuticals LP
- Boehringer Ingelheim Pharmaceuticals, Inc.
- ER/LA Opioid Analgesic REMS Program Companies
- Lilly USA, LLC
- Novo Nordisk, Inc.
- Sanofi Genzyme and Regeneron Pharmaceuticals
- Sanofi US


Overview

# Learning Objectives

- Describe the findings from recent trials of PCSK9i hypercholesterolemia treatments on cardiovascular outcomes.
- Discuss current guidelines and recommendations for the management of hyperlipidemia in high risk patients.
- Incorporate current data into secondary prevention treatment strategies for patients with the highest cardiovascular risk.
- Recognize barriers to access for PCSK9 monoclonal antibody therapy and discuss strategies to overcome them.

# Emerging Challenges in Primary Care 2018
## 17th Annual Regional and Online CME Conference Series

## Curriculum Overview

**9 Accredited Live Regional Symposia**

**August 11, 2018 – October 28, 2018**

**1 Accredited Live Virtual Symposium:**

**September 22, 2018**

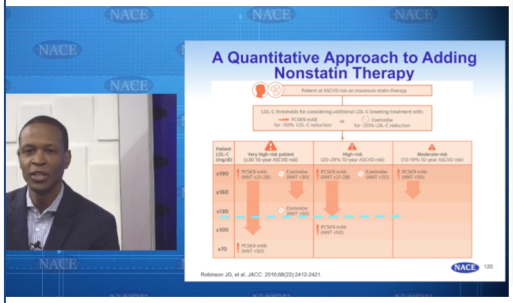

### Enduring CME Symposium Webcast

Launch Date: October 15, 2018

End Date: October 14, 2019

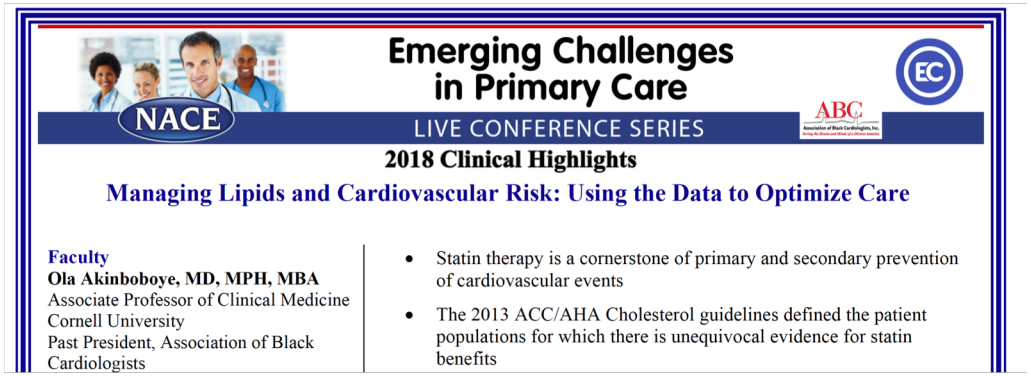
Available at: http://bit.ly/2018ECLipidsWebcast

**Speaker**
David Montgomery, MD
Preventive Cardiologist
Piedmont Heart Institute
Atlanta, GA




### Clinical Highlights eMonograph

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

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# 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 $p \leq .05$. | 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=.2-.8 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

| 2018 Meeting/Simulcast | Date | Attendees |
|---|---|---|
| Anaheim, CA | 8/11/18 | 204 |
| Houston, TX | 8/18/18 | 245 |
| Troy, MI | 8/25/18 | 220 |
| Troy, MI Simulcast | 8/25/18 | 306 |
| Ft. Lauderdale, FL | 9/8/18 | 308 |
| Nashville, TN | 9/15/18 | 162 |
| Virtual Symposium | 9/22/18 | 601 |
| Uniondale, NY | 10/6/18 | 286 |
| Uniondale, NY Simulcast | 10/6/18 | 355 |
| San Mateo, CA | 10/13/18 | 94 |
| Denver, CO | 10/20/18 | 128 |
| San Diego, CA | 10/27/18 | 110 |
| **Total** | | **3,019** |

**Level 1**
Participation
Demographics
Patient Reach

## Participation

**3,019***
Total Attendees

**9 Cities**

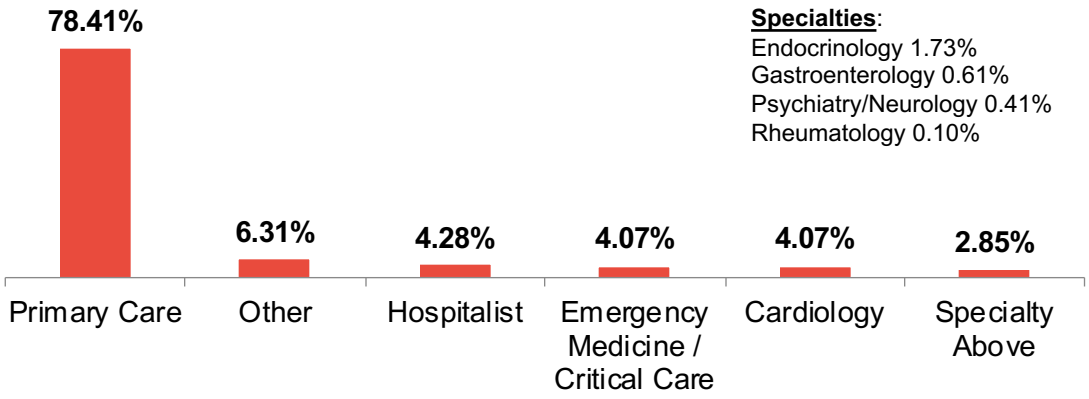
**1,757***
On Site

**1,262***
Simulcast / Virtual Symposium

*These numbers represent the total number of attendees, irrespective of assessment participation

# Level 1: Demographics and Patient Reach

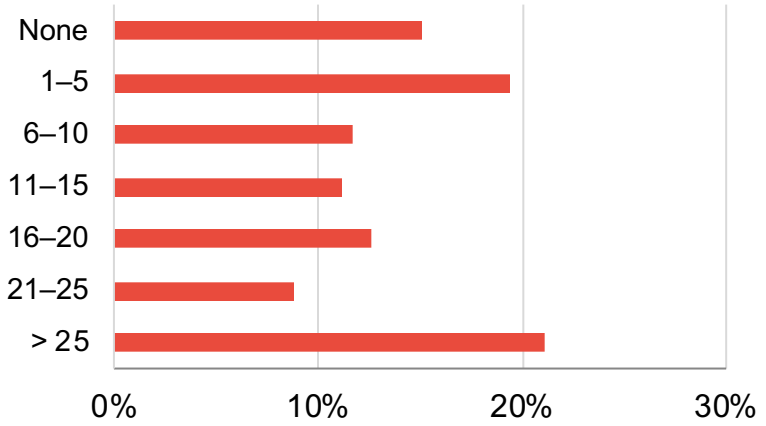
## Specialty




**Specialties**:
Endocrinology 1.73%
Gastroenterology 0.61%
Psychiatry/Neurology 0.41%
Rheumatology 0.10%

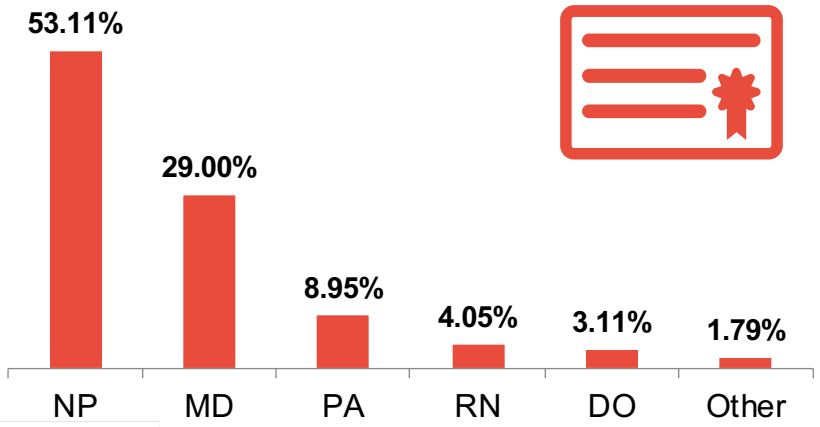
**Patient Care Focus: 91%**

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

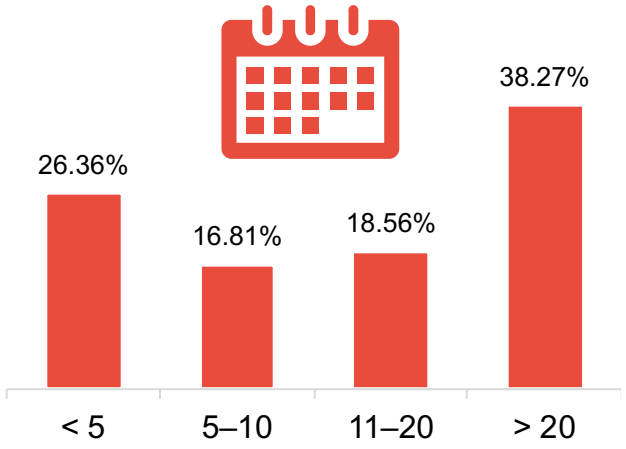



**Average number of patients with hyperlipidemia seen each week per clinician: 13**

## Profession




## Years in Practice

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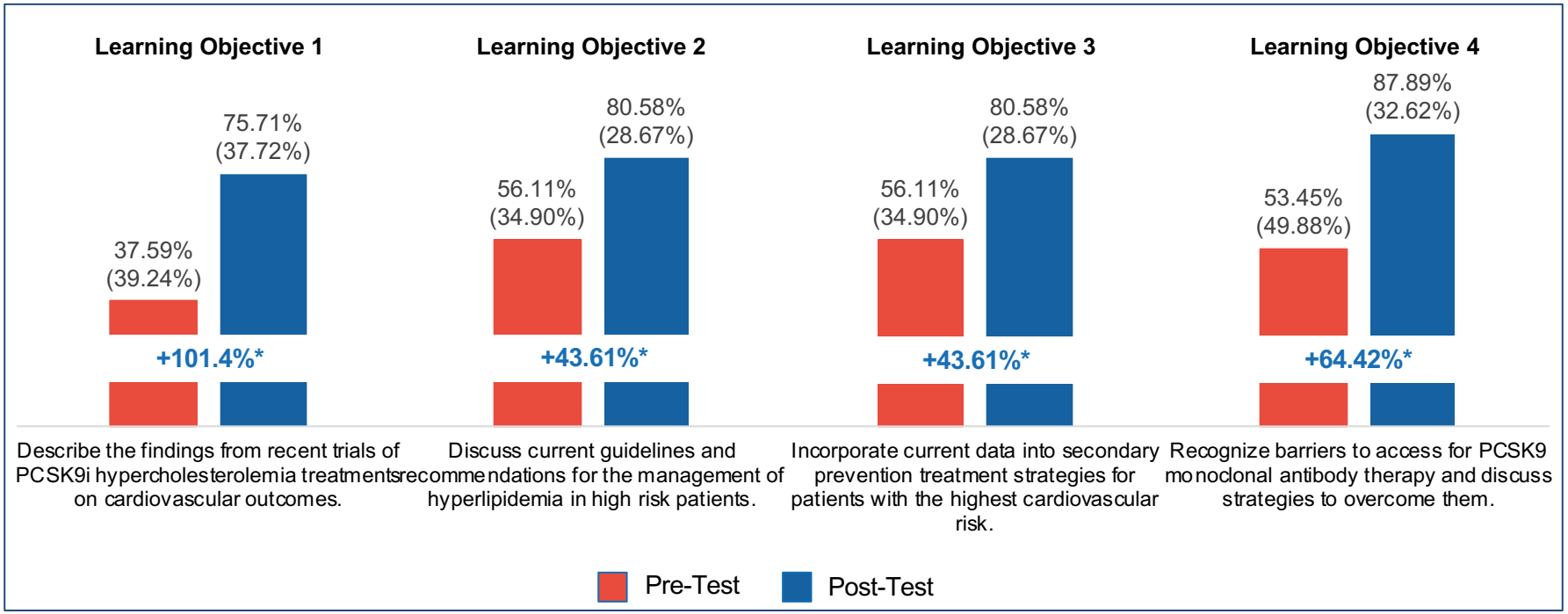
# Learning Objectives Analysis

(*N* = 1057–1454)

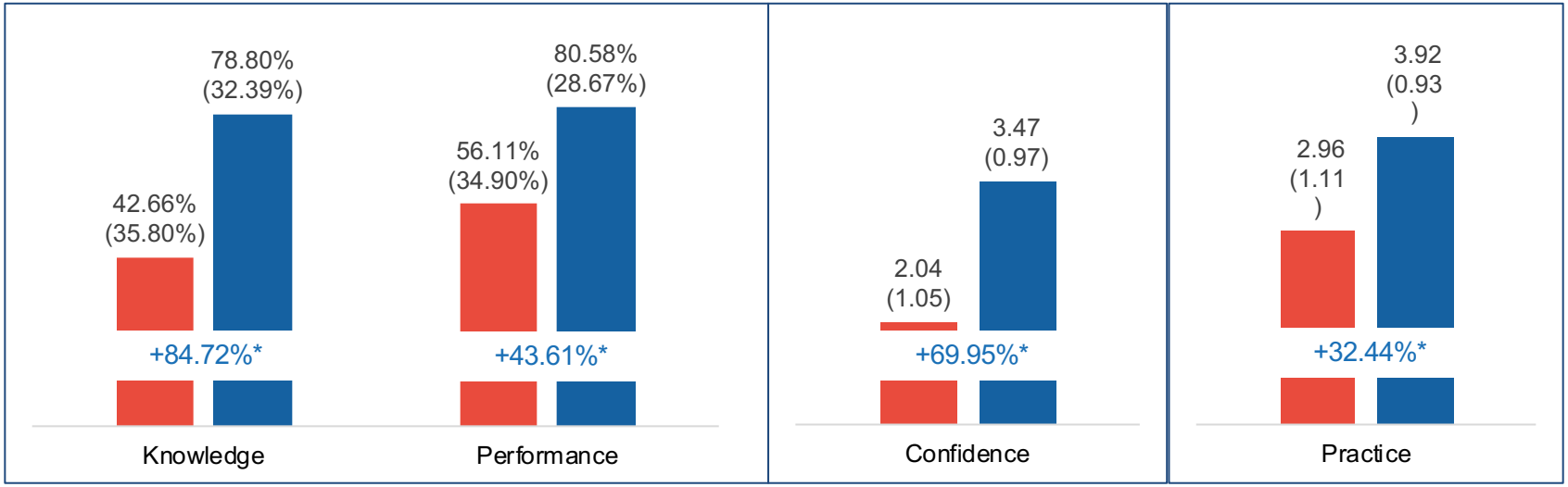



***significant at the p ≤ 0.05 level***

- Substantial and significant gains (ranging from 44% to 101%) from low Pre-Test averages were achieved on all Learning Objectives.
- The Post-Test average remained comparatively low (76%) on the Learning Objective related to PCSK9i trials, despite a substantial gain (101%) from Pre-Test. Other Learning Objectives showed higher Post-Test scores (81% and 88%).
  - The substantial score increase on the Learning Objective on PCSK9i trials was driven by the score increases on two Knowledge questions about the FOURIER and ODYSSEY trials.

# Learning Domain Analysis

(*N* = 1107–1454)




***significant at the p ≤ 0.05 level, matched data***

- Significant gains (32%–85%) were achieved in all learning domains.
- The substantial 85% increase in Knowledge was due to increases of 96% and 102% on two Knowledge questions related to the FOURIER and ODYSSEY trials on the PCSK9 inhibitors evolocumab and alirocumab.
- The 44% increase in Performance was due to increases (ranging from 15% to 57%) on the use of atorvastatin, ezetimibe and PCSK9 inhibitors for a patient with hyperlipidemia who is currently taking a statin.
- Learners substantially (70%) increased their reported Confidence in their ability to determine which patients may benefit from the use of a PCSK9 inhibitor, from a low Pre-Test average rating of 2.0 to a moderate Post-Test rating of 3.5.
- There was also a substantial (32%) increase (from an average rating of 3.0 to 3.9) in learners' reported intent to consider non-statin therapies for patients with high ASCVD risk and LDL-C not at recommended target, despite the use of maximally tolerated statin.

# Curriculum/Activity Intervention Effect

| Learning Domain | Effect Size* | % Non-Overlap |
|---|---|---|
| Knowledge | 1.058 | 62.59% |
| Performance | 0.766 | 50.34% |

Effect Size Definition: This is a standardized measure of the strength/magnitude of the change in scores, irrespective of sample size. This metric quantifies the association between outcome and exposure to education, in a way which makes meta-analysis possible. There exist many types of effect size measures, each appropriate in different situations. We select Cohen's *d* for this analysis, which is a standardized difference in mean. Most commonly, *d* ranges from 0–1: $d < 0.2$ is a small effect, $d = 0.2–0.8$ is a medium effect, and $d > 0.8$ is a large effect.

# Learning Domain by Professional Cohort

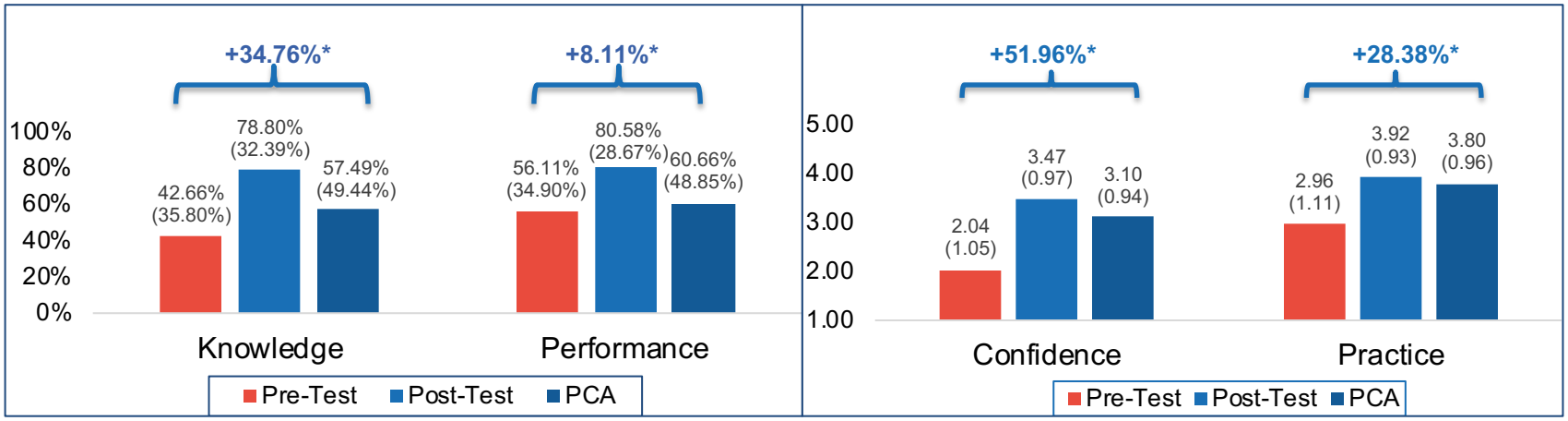
| Learning Domain | Nurse Practitioner | | | | Physician | | | |
|---|---|---|---|---|---|---|---|---|
| | *N* | Pre-Test | Post-Test | % Change | *N* | Pre-Test | Post-Test | % Change |
| Knowledge | 328 | 37.32% (35.70%) | 77.71% (35.09%) | **+108.22%*** | 210 | 40.52% (34.72%) | 78.12% (31.83%) | **+92.79%*** |
| Performance | 358 | 54.07% (34.64%) | 82.82% (26.71%) | **+53.16%*** | 214 | 57.90% (33.28%) | 79.73% (27.55%) | **+37.70%*** |
| Confidence | 272 | 1.90 (1.01) | 3.41 (0.95) | **+79.15%*** | 179 | 2.12 (1.11) | 3.53 (0.97) | **+66.75%*** |
| Practice | 297 | 2.90 (1.11) | 3.96 (0.87) | **+36.47%*** | 190 | 3.02 (1.11) | 3.90 (0.90) | **+29.32%*** |

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

- Nurse practitioners (NPs) and physicians demonstrated statistically significant gains in all learning domains.
- In all learning domains, NPs demonstrated modestly lower Pre-Test scores compared to physicians; however, the greater gains achieved by NPs minimized or eliminated any Post-Test score differences.
  - In Performance and practice strategy, the greater gains of NPs resulted in Post-Test (final) scores modestly exceeding those of physicians.

# 4-Week Retention Analysis

(*N* = 694)




***significant at the p ≤ 0.05 level***

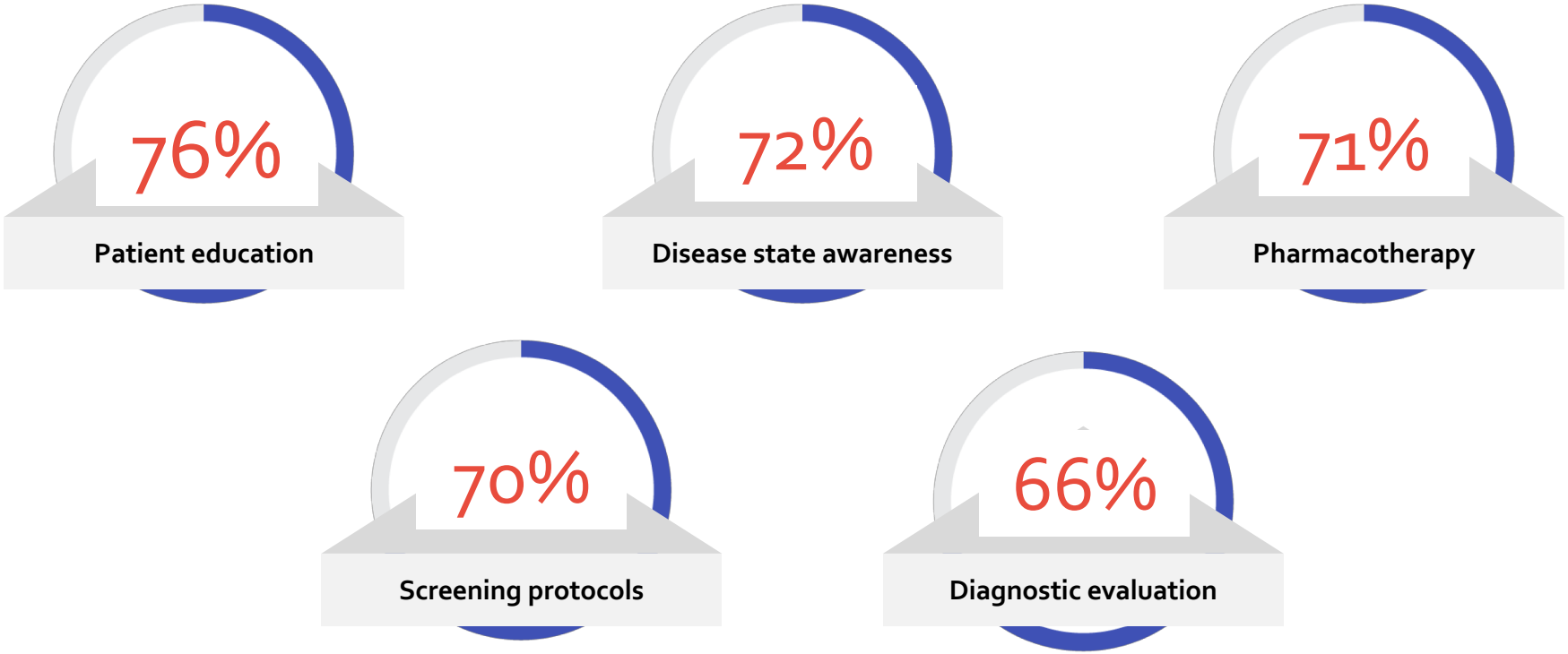
At follow-up:

- Statistically significant net gains were measured from Pre-Test to the Post Curriculum Assessment (PCA) in all learning domains.
- In all learning domains, score slippage from Post-Test to the PCA occurred, particularly in the Knowledge and Performance domains, reinforcing the need for continued education on the management of hyperlipidemia.

(4-week Post Assessment)

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

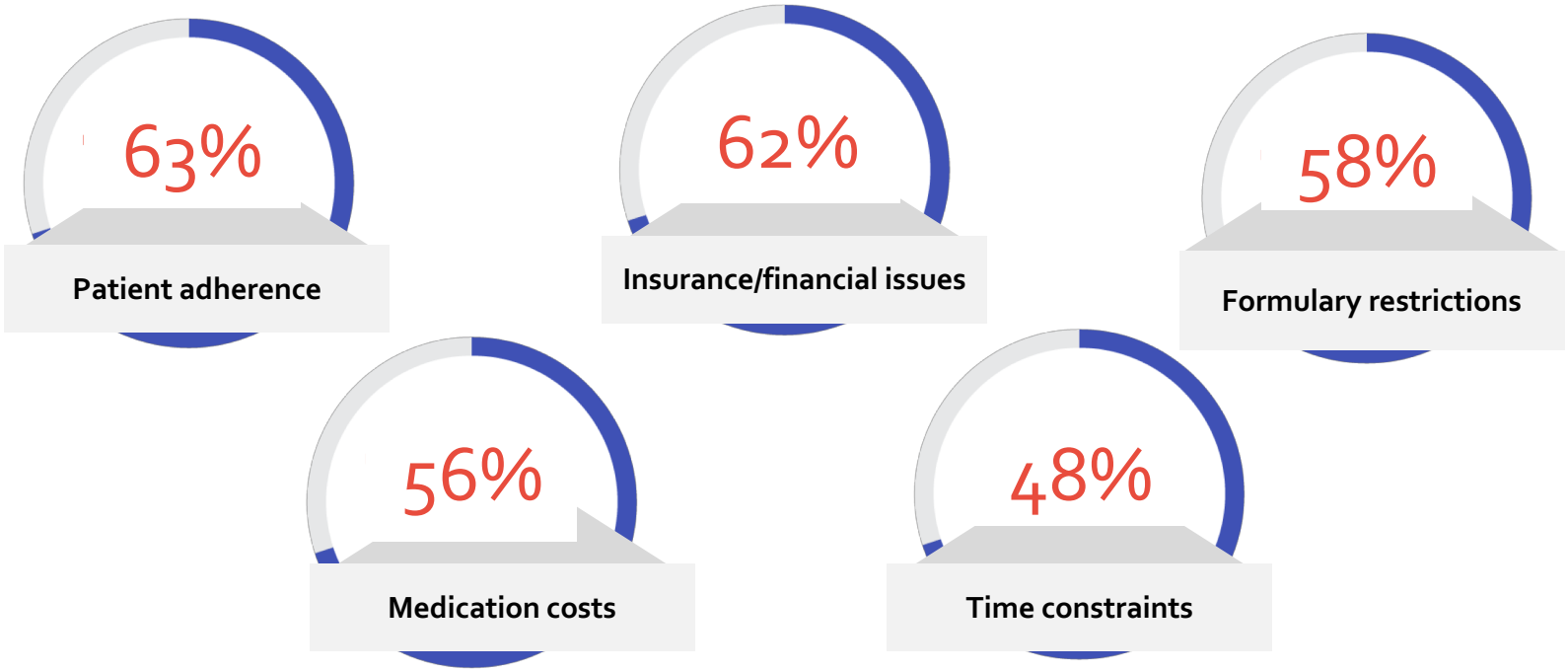
N=694



(4-week Post Assessment)

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

N=694



# Identified Learning Gap 1 of 2:

## *Recent clinical trials on PCSK9 inhibitors*

Despite an improvement of 102%, learners remained challenged on a Knowledge question which addressed a recent clinical trial on a PCSK9 inhibitor (alirocumab) and its impact on risk for major cardiovascular events.

**In the ODYSSEY trial, what was the relative risk reduction in the primary outcome (major cardiovascular events) with alirocumab compared to placebo?**

**Results:**

- At Post-Test, 68% of learners correctly answered: “15%.”

# Identified Learning Gap 2 of 2:

## *Treatment selection for patients at high cardiovascular risk*

Learners also demonstrated low final scores on two RealIndex (Performance) items related to treatment selection for a patient with a history of hypertension and dyslipidemia, specifically whether atorvastatin and a PCSK9 inhibitor should be initiated.

**70-year-old woman, 15-year history of hypertension, 10-year history of dyslipidemia. NSTEMI 1 year ago, LDL-C is 88 mg/dL. Current medications include lisinopril/hydrochlorothiazide 40/25 mg qd, metoprolol tartrate 100 mg bid, rosuvastatin 40 mg qd, and aspirin 81 mg qd.**

**After reviewing the brief scenario above, please rate these statements as consistent with or not consistent with best clinical practice:**

**Results:**

- In learners' final RealIndex, 65% of learners correctly classified as **not consistent:** "switch to atorvastatin 80 mg".

# Overall Educational Impact

- Significant improvements (ranging from 32% – 85%) were seen across all learning domains.
  - The cohort analysis of professions showed that NPs demonstrated greater score increases from modestly lower Pre-Test (baseline) scores compared to physicians; these increases minimized their Post-Test (final) score differences.
  - Live onsite learners demonstrated substantially higher Post-Test (final) averages than online participants in the Knowledge domain (83% for live onsite vs. 67% for live online), with comparable scores in Performance, Confidence and Practice strategy.
  - Analysis of learning retention in the PCA showed that significant net gains from Pre-Test (baseline) were measured in all learning domains (8% – 52%). The greatest net increase was measured in learners' reported Confidence in their ability to determine which patients may benefit from the use of a PCSK9 inhibitor (2.0 at Pre-Test to 3.1 in PCA).
- Significant improvements (ranging from 44% – 101%) were measured across all Learning Objectives. An especially high Post-Test score (88%) was measured on the Learning Objective on recognizing barriers to access for PCSK9 monoclonal antibody therapy and discussing strategies to overcome them. Moderately high Post-Test scores (76% – 81%) were measured on the other three Learning Objectives.
  - Across three of the four Learning Objectives, onsite learners achieved similar Post-Test scores compared to live online learners, from similar Pre-Test scores. The exception was Learning Objective 1 (describing the finding of recent trials of PCSK9i treatments), in which live onsite learners demonstrated substantially greater score increases from similar Pre-Test scores..
- The analysis of the Knowledge and Performance domains identified two **persistent learning gaps related to recent trials on PCSK9 inhibitors and treatment selection for patients with high cardiovascular risk.**
  - Despite an improvement of 102%, learners remained challenged on the results of the ODYSSEY trials, only 68% of learners correctly answered at Post-Test that there was a 15% risk reduction of cardiovascular events when comparing the PCSK9 inhibitor alirocumab to a placebo.
  - On the RealIndex Performance metric, which presented a 70-year-old woman with a 15-year history of hypertension and a 10-year history of dyslipidemia, only 65% of learners correctly classified "Switch to atorvastatin 80 mg" as **not consistent.**

# Appendix

# Learning Objectives Analysis – Live Onsite vs. Live Online Audience

- "Live onsite learners" include only those attending in-person meetings.
- "Live online learners" include those from both the Simulcast and Virtual Symposium.

| Learning Objective | Live Onsite Learners | | | | Live Online Learners | | | |
|---|---|---|---|---|---|---|---|---|
| | *N* | Pre-Test | Post-Test | % Change | *N* | Pre-Test | Post-Test | % Change |
| Describe the findings from recent trials of PCSK9i hypercholesterolemia treatments on cardiovascular outcomes. | 985 | 38.32% (38.51%) | 80.10% (34.17%) | +109.01%* | 325 | 35.34% (41.31%) | 62.35% (44.29%) | +76.42%* |
| Discuss current guidelines and recommendations for the management of hyperlipidemia in high risk patients. | 1064 | 56.53% (34.60%) | 81.08% (27.85%) | +43.42%* | 390 | 54.95% (35.70%) | 79.21% (30.78%) | +44.15%* |
| Incorporate current data into secondary prevention treatment strategies for patients with the highest cardiovascular risk. | 1064 | 56.53% (34.60%) | 81.08% (27.85%) | +43.42%* | 390 | 54.95% (35.70%) | 79.21% (30.78%) | +44.15%* |
| Recognize barriers to access for PCSK9 monoclonal antibody therapy and discuss strategies to overcome them. | 858 | 51.86% (49.97%) | 87.88% (32.64%) | +69.44%* | 199 | 60.30% (48.93%) | 87.94% (32.57%) | +45.83%* |

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

- On three of the four Learning Objectives, live onsite learners and live online learners had similar Post-Test scores.
- On the Learning Objective related to the findings of recent trials of PCSK9i treatments, live onsite learners demonstrated substantially greater score increases and Post-Test scores, from similar Pre-Test scores, compared to live online learners.
- On the Learning Objective related to barriers to access for PCSK9 monoclonal antibody therapy, live online learners demonstrated a higher score at Pre-Test. However, the greater gain of live onsite learners eliminated any Post-Test score difference.

# Learning Domain Analysis – Live Onsite vs. Live Online Audience

- "Live onsite learners" include only those attending in-person meetings.
- "Live online learners" include those from both the Simulcast and Virtual Symposium.

| Learning Domain | Live Onsite Learners | | | | Live Online Learners | | | |
|---|---|---|---|---|---|---|---|---|
| | *N* | Pre-Test | Post-Test | % Change | *N* | Pre-Test | Post-Test | % Change |
| Knowledge | 1064 | 43.20% (34.45%) | 82.71% (27.91%) | **+91.44%*** | 353 | 41.00% (39.57%) | 66.90% (41.01%) | **+63.18%*** |
| Performance | 1064 | 56.53% (34.60%) | 81.08% (27.85%) | **+43.42%*** | 390 | 54.95% (35.70%) | 79.21% (30.78%) | **+44.15%*** |
| Confidence | 831 | 2.08 (1.09) | 3.56 (0.97) | **+71.21%*** | 276 | 1.93 (0.92) | 3.20 (0.90) | **+65.85%*** |
| Practice | 848 | 2.96 (1.12) | 3.92 (0.94) | **+32.52%*** | 301 | 2.98 (1.06) | 3.94 (0.92) | **+32.22%*** |

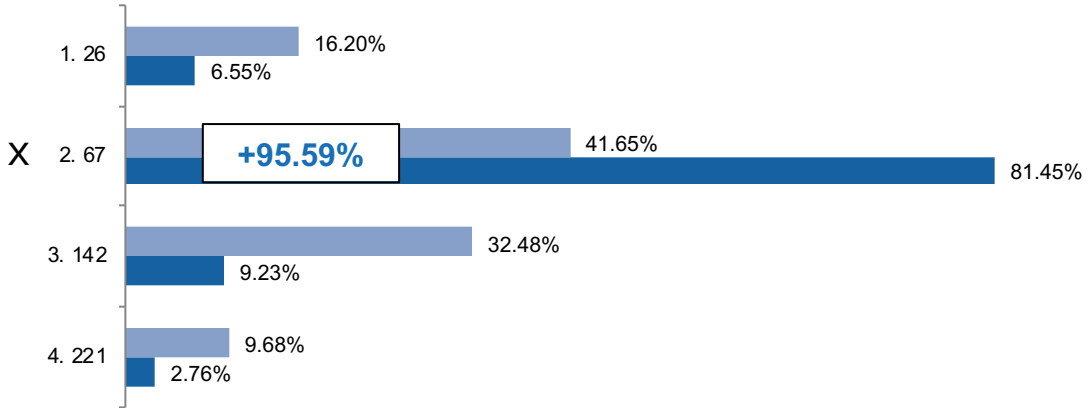
***significant at the $p \leq 0.05$ level***

- Live onsite and live online learners achieved substantial and significant score improvements across all learning domains.
- Live onsite learners demonstrated moderately higher Pre-Test (baseline) scores in Knowledge, Performance, and Confidence compared to live online learners. The greater gains of live onsite learners in these domains resulted in substantially higher Post-Test (final) scores.
- In practice strategy, scores and gains were comparable.

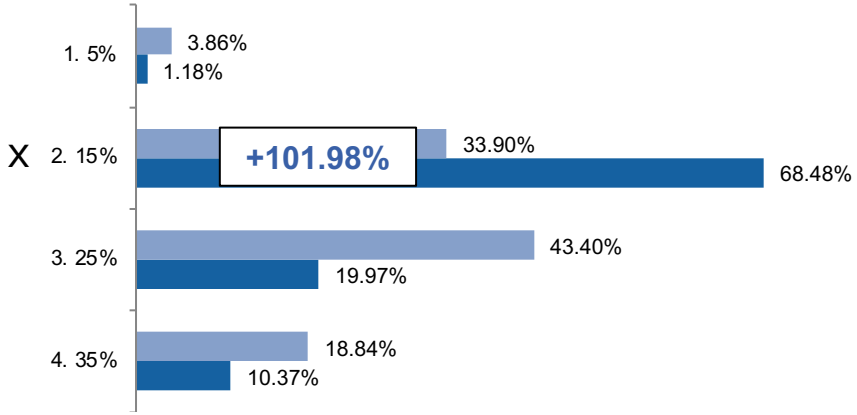
# Knowledge Questions:

N = (1151–1391)

**In the FOURIER trial, what was the number-needed-to-treat to prevent an instance of the primary outcome (major cardiovascular events) with evolocumab compared to placebo?**




**In the ODYSSEY trial, what was the relative risk reduction in the primary outcome (major cardiovascular events) with alirocumab compared to placebo?**




Pre-Test  Post-Test

Note: Data is unmatched

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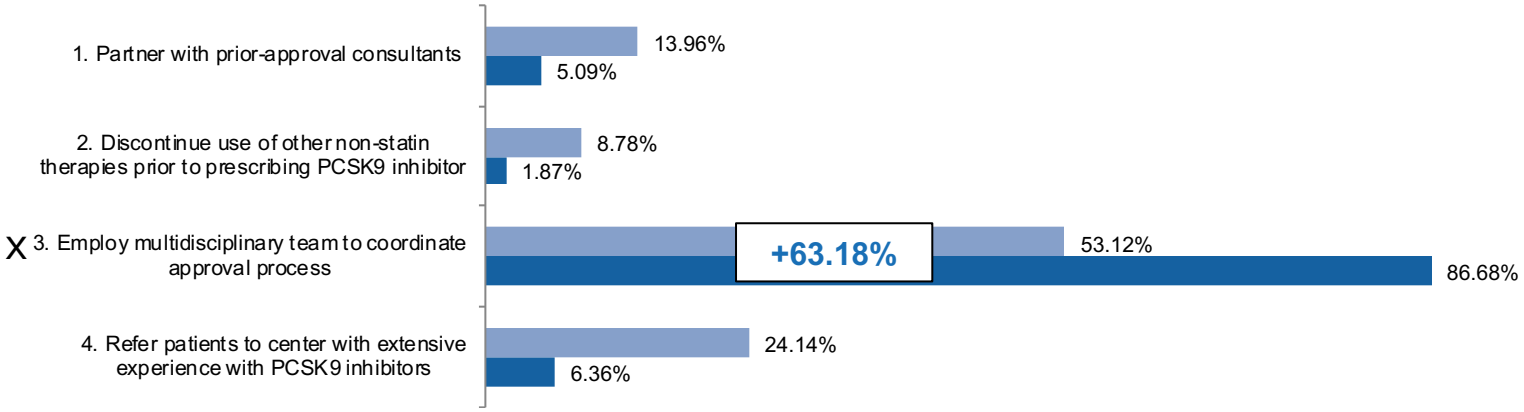
# Knowledge Questions (continued):

N = (1139–1336)

**Which of the following strategies has demonstrated high rates of approval for the use of PCSK9 inhibitors?**




Pre-Test Post-Test

Note: Data is unmatched

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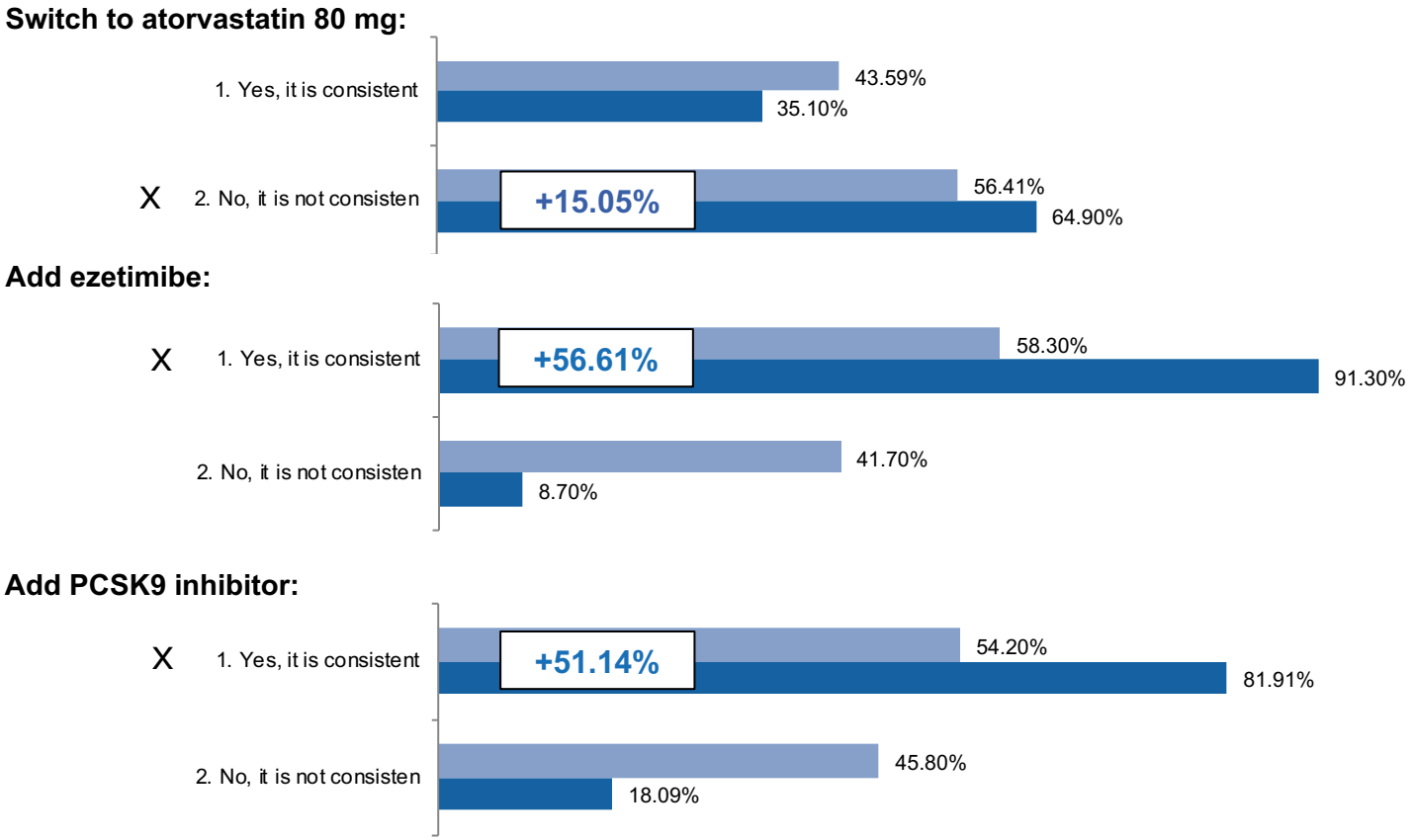
# Performance Questions

N = (1365–1490)

**70-year-old woman, 15-year history of hypertension, 10-year history of dyslipidemia. NSTEMI 1 year ago, LDL-C is 88 mg/dL. Current medications include lisinopril/hydrochlorothiazide 40/25 mg qd, metoprolol tartrate 100 mg bid, rosuvastatin 40 mg qd, and aspirin 81 mg qd.**

**After reviewing the brief scenario above, please rate these statements as consistent with or not consistent with best clinical practice:**

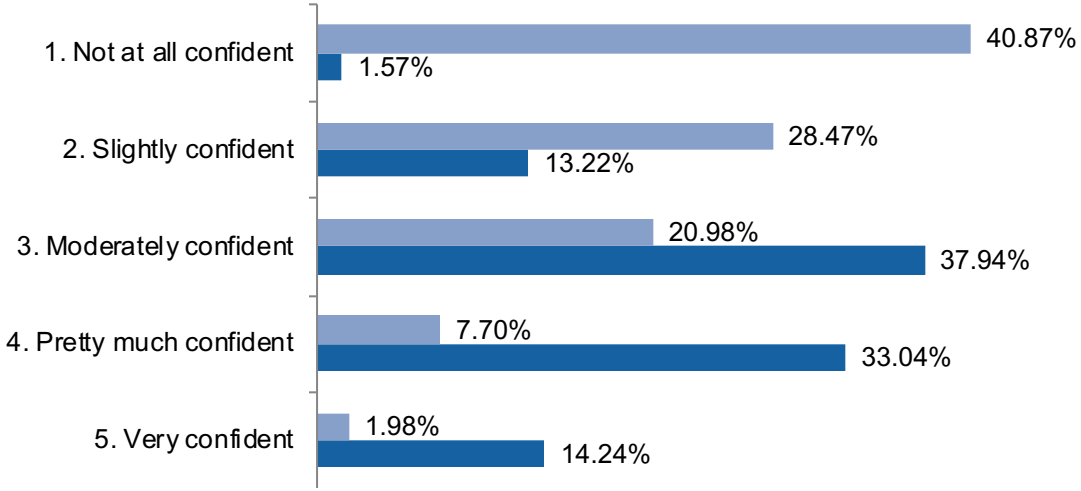



Note: Data is unmatched

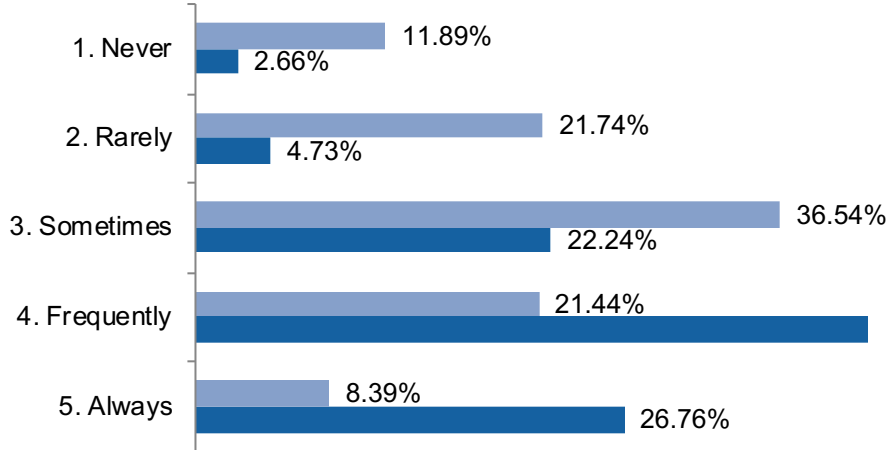
# Confidence & Practice Questions

N = (1363–1502)

**Confidence Question:**
**How confident are you in your ability to determine which patients may benefit from use of a PCSK9 inhibitor?**




**Practice Question:**
**How often do you consider non-statin therapies for patients with high ASCVD risk and LDL-C not at recommended target, despite use of maximally tolerated statin?**




RealCME

Note: Data is unmatched

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