

Overall Strategy for CompoSIT Trials



ORIGINAL ARTICLE
Double-blind, randomized clinical trial assessing the efficacy and safety of early initiation of sitagliptin during metformin uptitration in the treatment of patients with type 2 diabetes: The CompoSIT-M study
 Juan P. Felix MD¹ | Zachary Zimmer PhD² | Raymond L.H. Lam PhD² | Catherine Nabholz MPH¹ | Carol Treddle MD³ | Guillermo Amorin Lic⁴ | Samuel S. Engel MD⁵ | Keith D. Kaufman MD² | Edward A. O'Neill PhD² | Michael F. Cruickshank MD⁶

CompoSIT^M

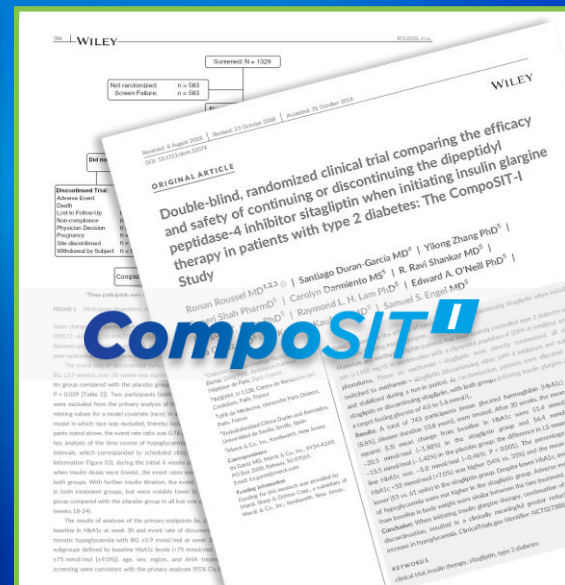
Early in Disease Progression



ORIGINAL ARTICLE
A randomized clinical trial of the efficacy and safety of sitagliptin compared with dapagliflozin in patients with type 2 diabetes mellitus and mild renal insufficiency: The CompoSIT-R study
 Russell Scott MD¹ | Jerry Morgan BS² | Samuel S. Engel MD³ | Edward A. O'Neill PhD² | Keith D. Kaufman MD² | Ziming S. Engel MD⁴ | Edward A. O'Neill PhD² | Keith D. Kaufman MD² | Ziming S. Engel MD⁴ | Edward A. O'Neill PhD² | Keith D. Kaufman MD² | Ziming S. Engel MD⁴

CompoSIT^R

Mildly Renally Impaired Patients



ORIGINAL ARTICLE
Double-blind, randomized clinical trial comparing the efficacy and safety of continuing or discontinuing the dipeptidyl peptidase-4 inhibitor sitagliptin when initiating insulin glargine therapy in patients with type 2 diabetes: The CompoSIT-II Study
 Roman Roussel MD^{1,2,3} | Santiago Duran-Garcia MD⁴ | Yilong Zhang PhD⁵ | Carolyn Shih PharmD⁶ | Raymond L.H. Lam PhD⁷ | R. Raj Shankar MD⁸ | Edward A. O'Neill PhD⁹ | Samuel S. Engel MD¹⁰

CompoSIT^{II}

Maintain Later in Disease Progression

How to Use This Guide

This Strategy and Execution Guide has been created to help you execute on the marketing strategy for the CompoSIT Trials and confidently engage your customers in discussions for JANUVIA.

The guide is based on the Customer Focused Interactions (CFI) Selling Model, with which you are well familiar. Based on that, you can plan and prepare for your sales call and pose the right questions to your customers to determine which resources might be best for your sales discussions.

For each CompoSIT Study, you will find sample verbalizations using CFI to communicate the appropriate key selling messages for JANUVIA, using the appropriate approved selling resources.

Navigation Instructions



Selecting an icon takes you to the CFI Selling Model page. You can then click through the different steps of the call to view call planning ideas and verbalization examples for each CompoSIT trial.



Clicking on this icon takes you back to the patient type selection page. Try it now!

CompoSIT Trials – Strategy



Strategic Intent

The CompoSIT Trial results are now approved for promotion in your marketplace. This Strategy and Execution Guide will provide direction to help you determine which customers to focus on for each study.

Global Brand Strategy

Our Global Brand Strategy for JANUVIA is to convince HCPs to choose JANUVIA as the first partner to metformin.

Global Messaging Strategy

In support of our Global Brand Strategy, our messaging has 3 foundational pillars:

- 1) Strong HbA1c Reductions
- 2) Established Safety Profile
- 3) Extensive Experience

Each of the CompoSIT Trials can be used to further support the 3 message pillars by demonstrating the safety and efficacy of JANUVIA in different situations. As you review this guide, we will show you how this can be done and which HCPs might be most appropriate for each trial.

PLAN

IMPLEMENT

EVALUATE

Early in Disease Progression CompoSIT-M Call Flow



CompoSIT-M Summary

CompoSIT-M Strategy

CompoSIT-M Approved Resources

MSD Customer Focused Interactions





SUMMARY

The CompoSIT-M Trial compares the effect of initiating sitagliptin during metformin uptitration versus metformin uptitration alone in patients with type 2 diabetes.

Key results include (sitagliptin vs placebo, respectively):

- Significantly greater HbA1c reductions (-0.4 difference vs placebo, $P < 0.001$)
- Greater proportion of patients achieving treatment goal of HbA1c $< 7\%$ (28.8% vs 16.6%)
 - Results for patients in a subgroup with baseline HbA1c $\geq 8.5\%$: 15.6% vs 5.7%
- Initiating sitagliptin during metformin uptitration did not increase the risk of weight gain versus metformin uptitration alone

CompoSIT^M

PLAN

IMPLEMENT

EVALUATE



Strategic Objective

The CompoSIT-M content can be used to further support these 3 message pillars by demonstrating the safety and efficacy of initiating sitagliptin in patients who are uptitrating metformin.



Communication & Behavioral Objectives

Communication Objective: To make HCPs aware that early initiation of sitagliptin in patients with type 2 diabetes who are uptitrating metformin results in greater efficacy without increasing the risk of weight gain.

Behavioral Objective: Convince HCPs to confidently prescribe sitagliptin as the first partner to metformin because sitagliptin has demonstrated greater HbA1c reductions and goal attainment without a greater risk of weight gain when it is initiated in patients uptitrating metformin.



HCP Segmentation

CompoSIT-M is appropriate to use with the following HCP segments:

- Sitagliptin Supporter
- SGLT2-i Supporter
- DPP4-i Supporter

**Note to Countries: HCP segmentation can be based on local strategies. Remove and rename as necessary.*

CompoSIT^M

PLAN

IMPLEMENT

EVALUATE



Approved Resources for CompoSIT-M

Approved Promotional Resources

- Overview CompoSIT
- Long Form Card
- Medium Form Card
- Short Form Card

Approved Training Resources

- Self-Study Interactive Guide
- Live Workshop
- WebEx Workshop
- Self-Study 2-sided QRC Card
- Self-Study Video

CompoSIT^M

PLAN

IMPLEMENT

EVALUATE



Plan the Call

Have you...

- ✓ Defined your objective for the call?
- ✓ Identified resources that you will use during the discussion?
- ✓ Planned an interest-generating opening?
- ✓ Identified open-ended, thought-provoking questions which may uncover belief(s) that will help you meet your call objective?
- ✓ Anticipated questions or concerns that the customer may raise in connection with the discussion?
- ✓ Prepared a tentative closing question and call to action to execute on your objective?

CompoSIT^M

PLAN

IMPLEMENT

EVALUATE



Open the Interaction



DOCTOR,

During our previous discussions, you've told me that you typically start with metformin for a newly diagnosed patient with type 2 diabetes and then titrate as needed.

Today I have some new information that could further help those patients in getting to the HbA1c goals.



CompoSIT^M

PLAN

IMPLEMENT

EVALUATE



Identify/Confirm Needs



DOCTOR,

What has been your experience with HbA1c reductions in your patients with type 2 diabetes, while increasing the dose of metformin?

Are you satisfied with the number of patients achieving their HbA1c treatment goals?

Can adding JANUVIA during metformin uptitration help patients to reach their treatment goals?



CompoSIT^M

PLAN

IMPLEMENT

EVALUATE



Share Information



DOCTOR,

In the CompoSIT-M study, early initiation of sitagliptin during metformin uptitration provided greater HbA1c reductions versus metformin uptitration alone (-0.4 difference vs placebo, $P < 0.001$).

A greater proportion of patients reached HbA1c goal of $<7\%$ with early initiation of sitagliptin during metformin uptitration versus metformin uptitration alone (28.8% vs 16.6%).

In this study, initiating sitagliptin during metformin uptitration did not increase the risk of weight gain versus metformin uptitration alone.



CompoSIT^M

PLAN

IMPLEMENT

EVALUATE



Close the Interaction



DOCTOR,

Would you agree that early initiation of sitagliptin during metformin uptitration provides greater HbA1c reductions, greater proportion of patients reaching HbA1C, and similar weight change versus metformin uptitration alone?



CompoSIT^M

PLAN

IMPLEMENT

EVALUATE

Mild Renally Impaired Patient CompoSIT-R Call Flow

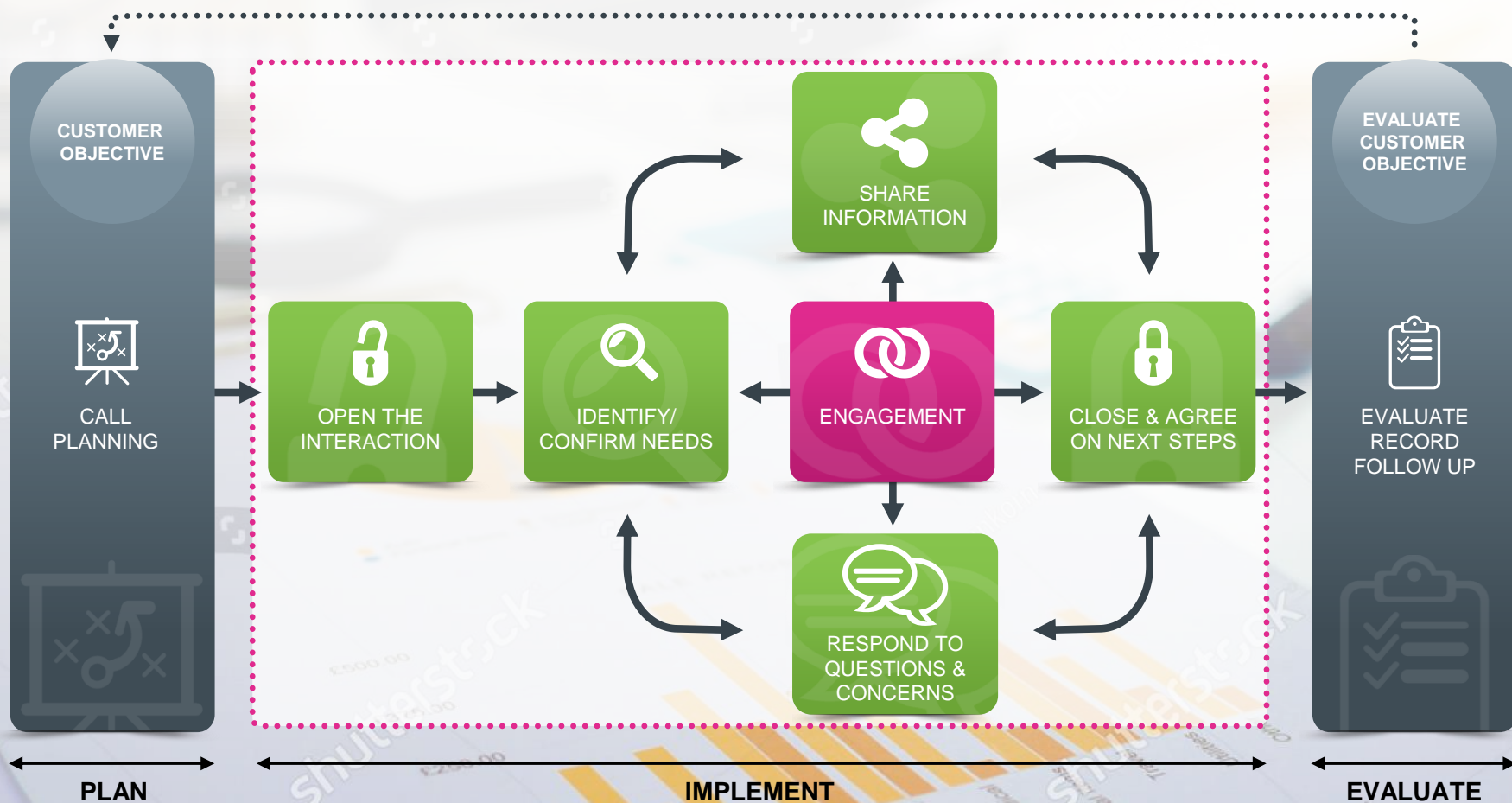


CompoSIT-R Summary

CompoSIT-R Strategy

CompoSIT-R Approved Resources

MSD Customer Focused Interactions





SUMMARY

The CompoSIT-R Trial compares the efficacy and safety of sitagliptin versus dapagliflozin in adult patients with type 2 diabetes and mild renal impairment (eGFR ≥ 60 to < 90 mL/min/1.73 m²).

Key results include (sitagliptin vs dapagliflozin, respectively):

- Significantly greater HbA1c reductions (-0.51% vs -0.36% , $P = 0.006$)
- Greater proportion of patients achieving HbA1c goal (43% vs 27%)
- Similar overall adverse events and fewer treatment-related adverse events

CompoSIT^R

PLAN

IMPLEMENT

EVALUATE



Strategic Objective

The CompoSIT-R content can be used to further support these 3 message pillars, and the results can be used to support either brand choice or class choice differentiation (sitagliptin is the only DPP4 inhibitor with these data; results can be particularly compelling when competing with linagliptin given the renal patient; results can be used vs SGLT2 class).



Communication & Behavioral Objectives

Communication Objective: To instill confidence in HCPs that sitagliptin is a safe and more effective choice vs dapagliflozin for patients with type 2 diabetes and mild renal impairment who are uncontrolled on metformin alone.

Behavioral Objective: Convince HCPs to confidently choose sitagliptin as the first partner to metformin, ahead of other DPP4 inhibitors and SGLT2 inhibitors like dapagliflozin, for a broad range of their patients uncontrolled on metformin alone, including those with all stages of renal impairment.



HCP Segmentation

CompoSIT-R is appropriate to use with the following HCP segments:

- Sitagliptin Supporter
- DPP4-i Supporter
- SGLT2-i Supporter

**Note to Countries: HCP segmentation can be based on local strategies. Remove and rename as necessary.*

CompoSIT^R

PLAN

IMPLEMENT

EVALUATE



Approved Resources for CompoSIT-R

Approved Promotional Resources

- Overview CompoSIT
- Long Form Card
- Medium Form Card
- Short Form Card

Approved Training Resources

- Self-Study Interactive Guide
- Live Workshop
- WebEx Workshop
- Self-Study 2-sided QRC Card
- Self-Study Video

CompoSIT^R

PLAN

IMPLEMENT

EVALUATE



Plan the Call

Have you...

- ✓ Defined your objective for the call?
- ✓ Identified resources that you will use during the discussion?
- ✓ Planned an interest-generating opening?
- ✓ Identified open-ended, thought-provoking questions which may uncover belief(s) that will help you meet your call objective?
- ✓ Anticipated questions or concerns that the customer may raise in connection with the discussion?
- ✓ Prepared a tentative closing question and call to action to execute on your objective?

CompoSIT^R

PLAN

IMPLEMENT

EVALUATE



Open the Interaction



DOCTOR,

In the past, you've told me that you typically use a SGLT2 inhibitor, like dapagliflozin when treating your type 2 diabetes patients with mild renal impairment.

Today I have some new information about treating those patients that I think you'll find very interesting.



CompoSIT^R

PLAN

IMPLEMENT

EVALUATE



Identify/Confirm Needs



DOCTOR,

What has been your experience with HbA1c reductions in your patients with type 2 diabetes and mild renal impairment?

Which add-on to metformin would you choose that will safely get your patient to their HbA1c treatment goals?



CompoSIT^R

PLAN

IMPLEMENT

EVALUATE



Share Information



DOCTOR,

In the CompoSIT-R study, sitagliptin demonstrated significantly greater HbA1c reductions (-0.51% vs -0.36% , $P = 0.006$).

A greater proportion of patients treated with sitagliptin achieved HbA1c goal of $<7\%$ versus dapagliflozin (-0.51% versus -0.36% , respectively, $P = 0.006$).

Also, there were fewer treatment-related adverse events with sitagliptin.



CompoSIT^R

PLAN

IMPLEMENT

EVALUATE



Close the Interaction



DOCTOR,

Would you agree that sitagliptin provides significantly greater reductions in HbA1c at week 24 versus dapagliflozin, with more patients achieving their HbA1c treatment goals?



CompoSIT^R

PLAN

IMPLEMENT

EVALUATE

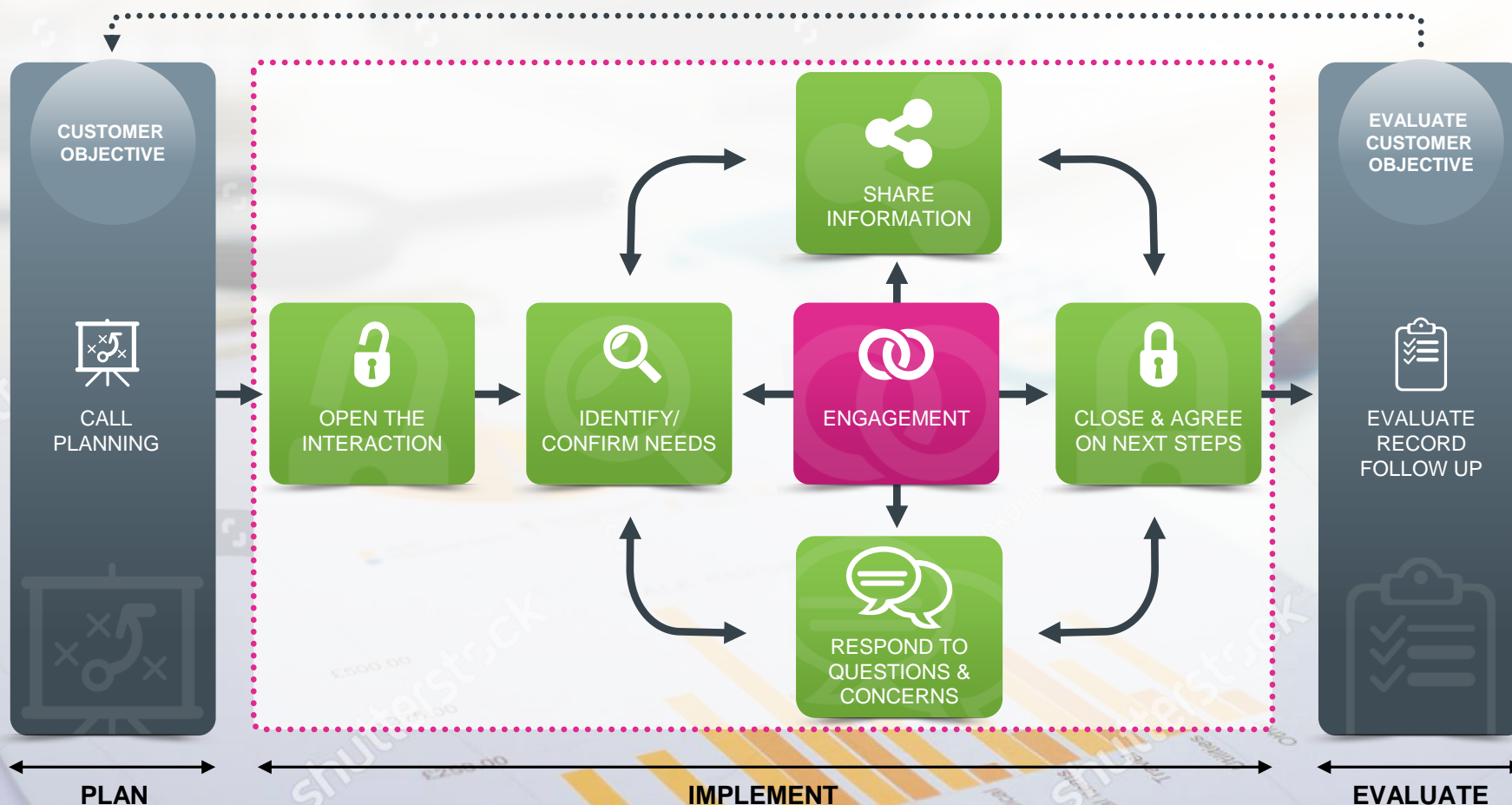


CompoSIT-I Summary

CompoSIT-I Strategy

CompoSIT-I Approved Resources

MSD Customer Focused Interactions





SUMMARY

The CompoSIT-I Trial compares the effect of maintaining sitagliptin during insulin glargine initiation and uptitration versus withdrawal in patients with type 2 diabetes.

Key results include (sitagliptin vs placebo, respectively):

- Significantly greater reductions in HbA1c (-0.46 difference vs placebo, $P < 0.001$)
- More patients achieved treatment goal of HbA1c $< 7\%$ (54% vs 35%)
- Patients maintaining sitagliptin needed less insulin (53 IU/day vs 61 IU/day, $P = 0.016$)
- Maintaining sitagliptin did not increase the risk of hypoglycemia, and resulted in comparable overall adverse events
- Maintaining JANUVIA when initiating and uptitrating insulin glargine did not increase the risk of hypoglycemia vs insulin glargine initiation and uptitration alone

CompoSIT-I

PLAN

IMPLEMENT

EVALUATE



Strategic Objective

The CompoSIT-I content can be used to further support these 3 message pillars by demonstrating the safety and efficacy of maintaining sitagliptin in patients who are initiating and uptitrating insulin glargine.



Communication & Behavioral Objectives

Communication Objective: To make HCPs aware that maintaining sitagliptin in patients with type 2 diabetes who are initiating and uptitrating insulin glargine results in greater efficacy without increasing the risk of hypoglycemia.

Behavioral Objective: Convince HCPs to confidently prescribe sitagliptin as the first partner to metformin because sitagliptin has demonstrated greater HbA1c reductions and goal attainment without a greater risk of hypoglycemia when it is maintained in patients initiating and uptitrating insulin glargine.



HCP Segmentation

CompoSIT-I is appropriate to use with the following HCP segments*:

- Sitagliptin Supporter
- SGLT2-i Supporter
- DPP4-i Supporter

**Note to Countries: HCP segmentation can be based on local strategies. Remove and rename as necessary.*

CompoSIT-I

PLAN

IMPLEMENT

EVALUATE



Approved Resources for CompoSIT-I

Approved Promotional Resources

- Overview CompoSIT
- Long Form Card
- Medium Form Card
- Short Form Card

Approved Training Resources

- Self-Study Interactive Guide
- Live Workshop
- WebEx Workshop
- Self-Study 2-sided QRC Card
- Self-Study Video

CompoSIT¹

PLAN

IMPLEMENT

EVALUATE



Plan the Call

Have you...

- ✓ Defined your objective for the call?
- ✓ Identified resources that you will use during the discussion?
- ✓ Planned an interest-generating opening?
- ✓ Identified open-ended, thought-provoking questions which may uncover belief(s) that will help you meet your call objective?
- ✓ Anticipated questions or concerns that the customer may raise in connection with the discussion?
- ✓ Prepared a tentative closing question and call to action to execute on your objective?

CompoSIT¹

PLAN

IMPLEMENT

EVALUATE



Open the Interaction



DOCTOR,

When initiating or uptitrating insulin for your patients with type 2 diabetes, why should you maintain JANUVIA?



PLAN

IMPLEMENT

EVALUATE



Identify/Confirm Needs



DOCTOR,

What has been your experience with HbA1c reductions in JANUVIA patients with type 2 diabetes who are initiating and/or uptitrating insulin glargine?

Are you satisfied with the number of patients achieving their HbA1c treatment goals?

Do you typically maintain or add a DPP4 inhibitor, like JANUVIA, for your patients with type 2 diabetes who are on an insulin regimen?



CompoSIT

PLAN

IMPLEMENT

EVALUATE



Share Information



DOCTOR,

In the CompoSIT-I study, maintaining sitagliptin during insulin glargine initiation and uptitration resulted in significantly greater reductions in HbA1c (-0.46 difference vs placebo, $P < 0.001$).

More patients in the study achieved the treatment goal of HbA1c $< 7\%$ (54% vs 35%).

Significant reduction in insulin glargine dose with sitagliptin 53 IU/day vs 61 IU/day (-8 IU difference vs placebo $P = 0.016$).

In addition, maintaining sitagliptin did not increase the risk of hypoglycemia and resulted in comparable overall adverse events.



CompoSIT

PLAN

IMPLEMENT

EVALUATE



Close the Interaction



DOCTOR,

Would you agree that maintaining sitagliptin during initiation and uptitration of insulin glargine versus withdrawal can provide greater reductions in HbA1c, with more patients achieving their HbA1c treatment goals without increasing their risk of hypoglycemia?



CompoSIT-I

PLAN

IMPLEMENT

EVALUATE