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Current Controversies, Recent Developments and Emerging Strategies in the Practical Management of Breast Cancer

Proceedings from a Clinical Investigator Think Tank

FACULTY

Adam M Brufsky, MD, PhD
Lisa A Carey, MD
William J Gradishar, MD
Sara A Hurvitz, MD
Monica Morrow, MD
Ruth O'Regan, MD
Edith A Perez, MD
Hope S Rugo, MD

MODERATOR

Neil Love, MD

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Current Controversies, Recent Developments and Emerging Strategies in the Practical Management of Breast Cancer

A Continuing Medical Education Audio Program

OVERVIEW OF ACTIVITY

Breast cancer is one of the most rapidly evolving fields in medical oncology. Published results from ongoing clinical trials lead to the continuous emergence of new therapeutic agents and changes in the indications for existing treatments. In order to offer optimal patient care — including the option of clinical trial participation — clinicians must be well informed of these advances. To bridge the gap between research and practice, this program features leading oncology investigators debating the merits, applications and limitations of emerging data sets. By providing access to the latest research developments and expert perspectives, this CME program assists medical oncologists, hematologists and hematology-oncology fellows with the formulation of up-to-date clinical management strategies.

LEARNING OBJECTIVES

- Appropriately use biomarkers to assess risk and individualize therapeutic decision-making for patients with early breast cancer.
- Develop evidence-based treatment approaches for patients diagnosed with HER2-positive breast cancer in the neoadjuvant, adjuvant and metastatic settings.
- Formulate individualized approaches to later-line therapy for patients with HER2-negative metastatic breast cancer.
- Assimilate new clinical trial evidence evaluating the use of mTOR inhibition to reverse endocrine resistance into the therapeutic algorithm for patients with progressive ER-positive metastatic breast cancer.
- Evaluate recently presented data supporting the extended use of adjuvant tamoxifen beyond 5 years for patients with ER-positive early breast cancer and, where appropriate, integrate these findings into clinical practice.
- Counsel appropriately selected patients with breast cancer about participation in ongoing clinical trials.

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FACULTY

Adam M Brufsky, MD, PhD
Professor of Medicine, University of Pittsburgh; Associate Director for Clinical Investigation, University of Pittsburgh Cancer Institute; Co-Director, Comprehensive Breast Cancer Center; Associate Division Chief University of Pittsburgh, Department of Medicine, Division of Hematology/Oncology
Pittsburgh, Pennsylvania

Monica Morrow, MD
Anne Burnett Windfohr Chair of Clinical Oncology; Chief of Breast Service
Department of Surgery
Memorial Sloan-Kettering Cancer Center
Professor of Surgery
Weill Medical College of Cornell University
New York, New York

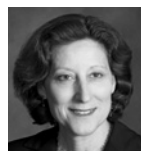
Lisa A Carey, MD
Richardson and Marilyn Jacobs Preyer Distinguished Professor for Breast Cancer Research; Chief, Division of Hematology and Oncology; Physician-in-Chief
North Carolina Cancer Hospital
Associate Director for Clinical Research
Lineberger Comprehensive Cancer Center
Chapel Hill, North Carolina

Ruth O'Regan, MD
Professor and Vice-Chair for Educational Affairs, Department of Hematology and Medical Oncology; Chief of Hematology and Medical Oncology, Georgia Cancer Center for Excellence at Grady Memorial Hospital
Louisa and Rand Glenn Family Chair in Breast Cancer Research
Winship Cancer Institute of Emory University
Atlanta, Georgia

William J Gradishar, MD
Betsy Bramsen Professor of Breast Oncology
Professor of Medicine; Director, Maggie Daley Center for Women's Cancer Care
Robert H Lurie Comprehensive Cancer Center, Northwestern University
Feinberg School of Medicine
Chicago, Illinois

Edith A Perez, MD
Deputy Director at Large, Mayo Clinic Cancer Center; Group Vice Chair
Alliance of Clinical Trials in Oncology
Serene M and Frances C Durling Professor of Medicine, Mayo Clinic
Jacksonville, Florida

Sara A Hurvitz, MD
Assistant Clinical Professor of Medicine
University of California, Los Angeles
Director, Breast Oncology Program
Medical Director, Clinical Research Unit
Jonsson Comprehensive Cancer Center
Los Angeles, California



Hope S Rugo, MD
Professor of Medicine
Director, Breast Oncology and Clinical Trials Education, University of California, San Francisco, Helen Diller Family Comprehensive Cancer Center
San Francisco, California

MODERATOR

Neil Love, MD
Research To Practice
Miami, Florida

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FACULTY — **Drs Gradishar and Morrow** had no real or apparent conflicts of interest to report. The following faculty (and their spouses/partners) reported real or apparent conflicts of interest, which have been resolved through a conflict of interest resolution process: **Dr Brufsky** — Advisory Committee: Roche Laboratories Inc; Consulting Agreements: Celgene Corporation, Genentech BioOncology, Genomic Health Inc, Novartis Pharmaceuticals Corporation; Speakers Bureau: Celgene Corporation, Genentech BioOncology, Novartis Pharmaceuticals Corporation. **Dr Carey** — Advisory Committee, Consulting Agreements and Speakers Bureau: Amgen Inc, Bristol-Myers Squibb Company, Genentech BioOncology, Novartis Pharmaceuticals Corporation, Pfizer Inc, Sanofi; Research Support: Genentech BioOncology, GlaxoSmithKline, Sanofi. **Dr Hurvitz** — Contracted Research: Boehringer Ingelheim Pharmaceuticals Inc, Eisai Inc, Genentech BioOncology, GlaxoSmithKline, Novartis Pharmaceuticals Corporation, Roche Laboratories Inc, Sanofi; Paid Travel: Novartis Pharmaceuticals Corporation. **Dr O'Regan** — Advisory Committee: Celgene Corporation, Novartis Pharmaceuticals Corporation; Consulting Agreements: Novartis Pharmaceuticals Corporation, Roche Laboratories Inc; Contracted Research: Genentech BioOncology. **Dr Perez** — Contracted Research: Genentech BioOncology, Genomic Health Inc, GlaxoSmithKline. **Dr Rugo** — Paid Research: Bristol-Myers Squibb Company, Celgene Corporation, Genentech BioOncology, GlaxoSmithKline, ImClone Systems, a wholly owned subsidiary of Eli Lilly and Company, Novartis Pharmaceuticals Corporation, Roche Laboratories Inc, Sanofi.

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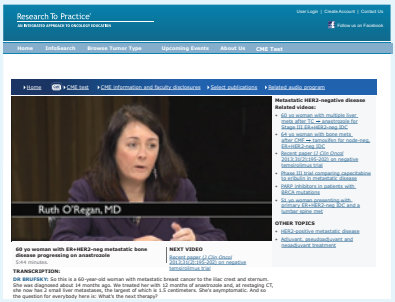
Video Highlights of the Clinical Investigator Think Tank



Check out highlight clips and transcripts from this fascinating Think Tank meeting featuring our esteemed clinical investigator panel discussing and debating some of the key clinical management issues in the field of breast cancer. Visit www.ResearchToPractice.com/BCUTT113/Video for more information.

TRACKS 1-24

Track 1 **Case discussion:** A 60-year-old woman with ER-positive, HER2-negative breast cancer (BC) presents with 2 small liver metastases after 12 months of anastrozole for metastatic disease

Track 2 Response, side effects and clinical experience with everolimus/exemestane in ER-positive metastatic BC (mBC)

Track 3 Results of a Phase II trial of everolimus and tamoxifen for ER-positive, HER2-negative mBC

Track 4 Results of a Phase III trial of letrozole in combination with temsirolimus as first-line therapy for postmenopausal women with locally advanced or metastatic ER-positive BC

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Track 8 Results of a Phase III trial of eribulin versus capecitabine for locally advanced or metastatic BC

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Track 13 Pertuzumab in combination with trastuzumab and docetaxel as first-line therapy for HER2-positive mBC: Overall survival, biomarker analysis and evaluation of elderly patients in the CLEOPATRA study

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Track 17 PERTAIN: A Phase II study of trastuzumab/taxane or trastuzumab and an aromatase inhibitor with or without pertuzumab as first-line therapy for ER-positive, HER2-positive mBC

Track 18 VELVET: A 2-cohort Phase II trial of vinorelbine/trastuzumab/pertuzumab as first-line therapy for HER2-positive locally advanced or metastatic BC

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Track 20 EMILIA study: T-DM1 versus capecitabine and lapatinib for HER2-positive mBC

Track 21 Monitoring and management of T-DM1-associated thrombocytopenia

Track 22 **Case discussion:** A 52-year-old woman with HER2-positive mBC is enrolled on a T-DM1 arm of the MARIANNE trial

Track 23 MARIANNE: A Phase III trial of T-DM1 with or without pertuzumab versus taxane/trastuzumab for HER2-positive mBC

Track 24 **Case discussion:** A 55-year-old woman with ER/PR-positive, HER2-negative infiltrating lobular carcinoma desires breast-conserving therapy

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Track 25 Use of the Onco*type* DX® assay in ER-positive, node-negative BC in the adjuvant and neoadjuvant settings

Track 26 **Case discussion:** A 76-year-old woman with Grade II, highly ER/PR-positive, HER2-negative infiltrating ductal carcinoma (IDC) and multiple comorbidities

Track 27 Results of the NSABP-B-38 study: Adjuvant dose-dense AC → paclitaxel with or without gemcitabine versus TAC in node-positive BC

Track 28 **Case discussion:** A healthy 83-year-old woman with a 4.5-cm, Grade III, triple-negative, node-positive BC

Track 29 **Case discussion:** A 45-year-old woman previously treated for a T1N0 ER/PR-positive, HER2-positive BC presents with a triple-negative ipsilateral BC

Track 30 CALOR (IBCSG 27-02, NSABP-B-37, BIG 1-02) trial: Adjuvant chemotherapy prolongs survival for patients with isolated local or regional recurrence of BC

Track 31 Importance of rebiopsy in patients with recurrent mBC

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Track 33 Onco*type* DX to guide adjuvant chemotherapy decision-making for patients with limited nodal involvement

Track 34 Utility of the Onco*type* DX assay in large, node-negative BC

Track 35 NSABP-B-28 study: Prognostic impact of the Onco*type* DX Recurrence Score in patients with ER-positive, node-positive BC treated with adjuvant chemotherapy

Track 36 MINDACT: A Phase III trial comparing MammaPrint® to Adjuvant! Online in selecting patients with negative nodes or 1 to 3 positive nodes for adjuvant chemotherapy

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Track 38 Increased incidence of endometrial cancer in postmenopausal women receiving longer-duration adjuvant tamoxifen

Track 39 Reduction in the risk of second BC with longer-duration adjuvant tamoxifen

Track 40 **Case discussion:** A 37-year-old woman previously treated 11 years ago for a Stage IA, ER/PR-positive, HER2-negative BC with chemotherapy and 5 years of tamoxifen inquires about reinitiating endocrine therapy

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Track 42 CALGB-40601: A Phase III trial of paclitaxel in combination with trastuzumab or trastuzumab/lapatinib as neoadjuvant therapy for HER2-positive primary BC

Track 43 ALTTO: A Phase III study of adjuvant trastuzumab, lapatinib, the combination or the sequence for HER2-positive primary BC

Track 44 Methodological concerns with neoadjuvant trial designs and endpoints

Track 45 **Case discussion:** A 48-year-old perimenopausal woman with an ER/PR-negative, HER2-positive IDC

Track 46 Optimal duration of adjuvant trastuzumab

SELECT PUBLICATIONS

Bachelot T et al. **Randomized phase II trial of everolimus in combination with tamoxifen in patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative metastatic breast cancer with prior exposure to aromatase inhibitors: A GINECO study.** *J Clin Oncol* 2012;30(22):2718-24.

Baselga J et al. **Biomarker analyses in CLEOPATRA: A Phase III, placebo-controlled study of pertuzumab in HER2-positive, first-line metastatic breast cancer.** San Antonio Breast Cancer Symposium 2012;**Abstract S5-1**.

Bender BC et al. **A population pharmacokinetic/pharmacodynamic model of thrombocytopenia characterizing the effect of trastuzumab emtansine (T-DM1) on platelet counts in patients with HER2-positive metastatic breast cancer.** *Cancer Chemother Pharmacol* 2012;70(4):591-601.

Datko F et al. **Phase II study of pertuzumab, trastuzumab, and weekly paclitaxel in patients with metastatic HER2-overexpressing metastatic breast cancer.** San Antonio Breast Cancer Symposium 2012;**Abstract P5-18-20**.

Dees EC, Carey LA. **Improving endocrine therapy for breast cancer: It's not that simple.** *J Clin Oncol* 2013;31(2):171-3.

Di Leo A et al. **Final analysis of overall survival for the Phase III CONFIRM trial: Fulvestrant 500 mg versus 250 mg.** San Antonio Breast Cancer Symposium 2012;**Abstract S1-4**.

Drucker AM et al. **Risk of rash with the anti-HER2 dimerization antibody pertuzumab: A meta-analysis.** *Breast Cancer Res Treat* 2012;135(2):347-54.

Isakoff SJ et al. **A randomized, Phase 2 study of the poly (ADP-ribose) polymerase (PARP) inhibitor veliparib (ABT-888) in combination with temozolomide or in combination with carboplatin (C) and paclitaxel (P) versus placebo plus C/P in subjects with BRCA1 or BRCA2 mutation and metastatic breast cancer.** San Antonio Breast Cancer Symposium 2012;**Abstract OT2-3-07**.

Kaufman PA et al. **A Phase III, open-label, randomized, multicenter study of eribulin mesylate versus capecitabine in patients with locally advanced or metastatic breast cancer previously treated with anthracyclines and taxanes.** San Antonio Breast Cancer Symposium 2012;**Abstract S6-6**.

Mamounas EP et al. **Association between the 21-gene Recurrence Score (RS) and benefit from adjuvant paclitaxel (Pac) in node-positive (N+), ER-positive breast cancer patients (pts): Results from NSABP B-28.** San Antonio Breast Cancer Symposium 2012;**Abstract S1-10**.

Mamounas EP et al. **Prognostic impact of the 21-gene recurrence score (RS) on disease-free and overall survival of node-positive, ER-positive breast cancer patients (pts) treated with adjuvant chemotherapy: Results from NSABP B-28.** Breast Cancer Symposium 2012;**Abstract 1**.

Miles D et al. **Pertuzumab in combination with trastuzumab and docetaxel in elderly patients with HER2-positive metastatic breast cancer in the CLEOPATRA study.** San Antonio Breast Cancer Symposium 2012;**Abstract P5-18-01**.

NSABP-B-41: A randomized Phase III trial of neoadjuvant therapy for patients with palpable and operable HER2-positive breast cancer comparing the combination of trastuzumab plus lapatinib to trastuzumab and to lapatinib administered with weekly paclitaxel following AC accompanied by correlative science studies to identify predictors of pathologic complete response. NCT00486668

Robidoux A et al. **Evaluation of lapatinib as a component of neoadjuvant therapy for HER2+ operable breast cancer: NSABP protocol B-41.** *Proc ASCO* 2012;**Abstract LBA506**.

Swain SM et al. **Confirmatory overall survival analysis of CLEOPATRA: A randomized, double-blind, placebo-controlled Phase III study with pertuzumab, trastuzumab, and docetaxel in patients with HER2-positive first-line metastatic breast cancer.** San Antonio Breast Cancer Symposium 2012;**Abstract P5-18-26**.

Swain SM et al. **NSABP B-38: Definitive analysis of a randomized adjuvant trial comparing dose-dense (DD) AC-paclitaxel (P) plus gemcitabine with DD AC-P and with docetaxel, doxorubicin, and cyclophosphamide in women with operable, node-positive breast cancer.** *Proc ASCO* 2012;**Abstract LBA1000**.

Verma S et al. **Trastuzumab emtansine for HER2-positive advanced breast cancer.** *N Engl J Med* 2012;367(19):1783-91.

Wolff AC et al. **Randomized Phase III placebo-controlled trial of letrozole plus oral temsirolimus as first-line endocrine therapy in postmenopausal women with locally advanced or metastatic breast cancer.** *J Clin Oncol* 2013;31(2):195-202.

POST-TEST

Current Controversies, Recent Developments and Emerging Strategies in the Practical Management of Breast Cancer

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **The second interim analysis of the CLEOPATRA study, which evaluated the addition of pertuzumab to trastuzumab and docetaxel as first-line therapy for HER2-positive mBC, demonstrated a statistically significant improvement in overall survival.**
   a. True
   b. False

2. **A Phase III trial evaluating eribulin mesylate versus capecitabine for patients with locally advanced or metastatic BC previously treated with anthracyclines and taxanes _____ demonstrate statistically significant superiority of eribulin over capecitabine.**
   a. Did
   b. Did not

3. **A retrospective analysis of data from the NSABP-B-28 trial, which evaluated AC with or without paclitaxel, demonstrated that the Onco*type* DX Recurrence Score was a significant predictor of disease-free survival and overall survival for patients with ER-positive, node-positive BC treated with adjuvant chemotherapy.**
   a. True
   b. False

4. **The Phase III EMILIA study for patients with HER2-positive advanced BC demonstrated a significant increase in _____ with T-DM1 versus capecitabine and lapatinib.**
   a. Progression-free survival
   b. Overall survival
   c. Both a and b

5. **The Phase III NSABP-B-41 trial of neoadjuvant chemotherapy with trastuzumab, lapatinib and the combination for HER2-positive BC reported a higher pathologic complete response rate with the trastuzumab/lapatinib combination versus either single agent, but the difference was not statistically significant.**
   a. True
   b. False

6. **The Phase III CALOR trial evaluating no chemotherapy versus chemotherapy as adjuvant therapy for isolated local or regional recurrence of BC did not demonstrate a significant improvement in disease-free and overall survival for patients who received chemotherapy.**
   a. True
   b. False

7. **An ongoing Phase II study is evaluating the PARP inhibitor _____ in combination with temozolomide or carboplatin/paclitaxel in BRCA1/2 mutation-positive mBC.**
   a. Iniparib
   b. Olaparib
   c. Veliparib
   d. None of the above

8. **The ongoing BOLERO-6 trial, on which patients receive up-front therapy with everolimus in combination with letrozole followed by continuation of everolimus upon disease progression in combination with exemestane, contains a second randomization to prophylactic steroid solution to prevent mucositis.**
   a. True
   b. False

9. **The MammaPrint assay continues to require fresh frozen tissue specimens for analysis.**
   a. True
   b. False

10. **The 5-year definitive analysis of the Phase III adjuvant NSABP-B-38 trial evaluating 3 chemotherapy regimens demonstrated significant improvements in _____ with dose-dense AC → paclitaxel with gemcitabine compared to dose-dense AC → paclitaxel.**
    a. Disease-free survival
    b. Overall survival
    c. Neither a nor b

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Current Controversies, Recent Developments and Emerging Strategies in the Practical Management of Breast Cancer

Research To Practice is committed to providing valuable continuing education for oncology clinicians, and your input is critical to helping us achieve this important goal. Please take the time to assess the activity you just completed, with the assurance that your answers and suggestions are strictly confidential.

PART 1 — Please tell us about your experience with this educational activity

How would you characterize your level of knowledge on the following topics?

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

	BEFORE	AFTER
Updated results from the CLEOPATRA study of pertuzumab in combination with trastuzumab and docetaxel as first-line therapy for HER2-positive mBC: Confirmatory overall survival analysis, biomarker analysis and evaluation of elderly patients	4 3 2 1	4 3 2 1
ATLAS trial: Benefits and risks associated with continuing adjuvant tamoxifen to 10 years versus stopping at 5 years for ER-positive early BC	4 3 2 1	4 3 2 1
Results of the Phase III 301 Study of eribulin versus capecitabine in locally advanced or metastatic BC	4 3 2 1	4 3 2 1
NSABP-B-28: Prognostic impact of the Onco*type* DX Recurrence Score in patients with ER-positive, node-positive BC treated with adjuvant chemotherapy	4 3 2 1	4 3 2 1
Ongoing investigation of the PARP inhibitor veliparib in patients with BRCA1/2 mutation-positive mBC	4 3 2 1	4 3 2 1

Was the activity evidence based, fair, balanced and free from commercial bias?

☐ Yes ☐ No If no, please explain: .....

Please identify how you will change your practice as a result of completing this activity (select all that apply).

☐ This activity validated my current practice
☐ Create/revise protocols, policies and/or procedures
☐ Change the management and/or treatment of my patients
☐ Other (please explain): .....

If you intend to implement any changes in your practice, please provide 1 or more examples:

.....

The content of this activity matched my current (or potential) scope of practice.

☐ Yes ☐ No If no, please explain: .....

Please respond to the following learning objectives (LOs) by circling the appropriate selection:

4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = LO not met N/A = Not applicable

As a result of this activity, I will be able to:

- Appropriately use biomarkers to assess risk and individualize therapeutic decision-making for patients with early breast cancer. . . . . 4 3 2 1 N/M N/A
- Develop evidence-based treatment approaches for patients diagnosed with HER2-positive breast cancer in the neoadjuvant, adjuvant and metastatic settings. . . . . 4 3 2 1 N/M N/A
- Formulate individualized approaches to later-line therapy for patients with HER2-negative metastatic breast cancer. . . . . 4 3 2 1 N/M N/A
- Assimilate new clinical trial evidence evaluating the use of mTOR inhibition to reverse endocrine resistance into the therapeutic algorithm for patients with progressive ER-positive metastatic breast cancer. . . . . 4 3 2 1 N/M N/A
- Evaluate recently presented data supporting the extended use of adjuvant tamoxifen beyond 5 years for patients with ER-positive early breast cancer and, where appropriate, integrate these findings into clinical practice. . . . . 4 3 2 1 N/M N/A
- Counsel appropriately selected patients with breast cancer about participation in ongoing clinical trials. . . . . 4 3 2 1 N/M N/A

Please describe any clinical situations that you find difficult to manage or resolve that you would like to see addressed in future educational activities:

.....

Would you recommend this activity to a colleague?

☐ Yes ☐ No

If no, please explain: .....

Additional comments about this activity:

.....

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☐ Yes, I am willing to participate in a follow-up survey.
☐ No, I am not willing to participate in a follow-up survey.

PART 2 — Please tell us about the faculty and moderator for this educational activity

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

Faculty	Knowledge of subject matter				Effectiveness as an educator			
Adam M Brufsky, MD, PhD	4	3	2	1	4	3	2	1
Lisa A Carey, MD	4	3	2	1	4	3	2	1
William J Gradishar, MD	4	3	2	1	4	3	2	1
Sara A Hurvitz, MD	4	3	2	1	4	3	2	1
Monica Morrow, MD	4	3	2	1	4	3	2	1
Ruth O'Regan, MD	4	3	2	1	4	3	2	1
Edith A Perez, MD	4	3	2	1	4	3	2	1
Hope S Rugo, MD	4	3	2	1	4	3	2	1
Moderator	**Knowledge of subject matter**				**Effectiveness as an educator**			
Neil Love, MD	4	3	2	1	4	3	2	1

Please recommend additional faculty for future activities:

.....

Other comments about the faculty and moderator for this activity:

.....

REQUEST FOR CREDIT — Please print clearly

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Professional Designation:

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Neil Love, MD
Research To Practice
One Biscayne Tower
2 South Biscayne Boulevard, Suite 3600
Miami, FL 33131

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