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## **SUMMARY**

I am currently a full-time professor in the Statistics Department of Temple University, Fox School of Business. As a Ph.D. statistician in clinical trials with twenty years of experience at Merck Research Laboratories – USA, I provided leadership in designing studies, analyzing data and writing clinical study reports, interacting with regulatory agencies and marketing teams. My work experience includes delivering statistical support for clinical trials and post-marketing studies across numerous therapeutic areas and all phases of drug development, functionally managing scientific staff. I have published over 50 papers in peer-reviewed publications.

## **EDUCATION**

Ph.D., Department of Statistics, Temple University, Philadelphia  
M.S., Department of Mathematics, University of Bucharest, Romania

## **EXPERIENCE**

Provided Analysis Sections for numerous clinical trial protocols, statistical analyses and coordination for a plethora of studies (early, late development and post-marketing phases of clinical trials), in various therapeutic areas (oncology, antibiotics, cardiovascular, vaccines), interacted with Regulatory agencies around the world (FDA, EMEA, China and India local agencies) in the context of NDA submissions. As the statistical lead in cross-functional teams I have collaborated with external and internal clinical experts on strategic points in the development of Merck products, on presentations, training and manuscripts. In the oncology area, participated in the development of the CINV (chemotherapy-induced nausea and vomiting) drug EMEND, from the discovery of its active novel molecule and new mechanism of action, throughout all the clinical trials of phase II and III, and to its approval worldwide. I was invited as a speaker at different forums, presenting clinical trial results.

- Professor of Statistics at Fox School of Business, Temple U 2012 – present
- Associate Director, Scientific Staff/Manager at Merck and Co. 2002 – 2012
- Senior Biometrician at Merck and Co. 1999 – 2002
- Biometrician at Merck and Co. 1992 – 1999
- Researcher - Center of Mathematical Statistics -Bucharest, Romania 1989 – 1991
- Instructor (Mathematics) - Romania 1981 – 1989
- Liaison between the Clinical Biostatistics Department (MRL) and the Marketing groups
  - Attended and presented at the Global Advisory Meetings between 2007-2011
  - Interacted with external advisors on strategic points of development for EMEND for CINV
  - Collaborated on publications, posters, presentations with other Merck and external groups
  - Provided training for use at Merck and external presentations
  - Collaborated to review and approve worldwide Investigator Initiated clinical trial protocols for EMEND (CINV medications) and INVANZ (antibiotic drugs)

**SOCIETY MEMBERSHIPS:**ASA, MAA, DIA; **PUBLICATIONS :** Over 50 publications.

M. Aapro, **A. Carides**, ET AL. (accepted for publication in 2014) Aprepitant/Fosaprepitant: A 10-Year Review of Efficacy and Safety, *The Oncologist*

R. Azadarmaki, **Carides, A.** (Submitted and accepted for publication May 2014). Clinical Significance of the Wong-Baker FACES Pain Scale in a Pediatric Otolaryngology Patient Population. *The International Journal of Pediatric Otolaryngology* (www.IJPORL.com)

Adiga, R., **Carides, A.**, Chitturi, P. Changes in PINCH and hpTau levels in the CSF of HIV patients. *Journal of NeuroVirology*, May 2014, www.jneurovirol.com/

**Carides, A.** (2013). A Phase 3, randomized, double-blind study of single-dose fosaprepitant for prevention of cisplatin-induced nausea and vomiting: Results of an Indian population subanalysis. *Indian J Cancer* 50(4)(2013 Oct-Dec), 285-91.

MS Aapro, HJ Schmoll, F Jahn, **AD Carides**, RT Webb (2013) Review of the efficacy of aprepitant for the prevention of chemotherapy-induced nausea and vomiting in a range of tumor types, *Cancer treatment reviews* 39 (1), pp113-117.

A Molassiotis, AM Nguyen, CN Rittenberg, A Makalinao, **A Carides** (2013). Analysis of aprepitant for prevention of chemotherapy-induced nausea and vomiting with moderately and highly emetogenic chemotherapy. *Future Oncology* 9(No. 10,), Pages 1443-1450.

Grunberg S, Chua D, Maru A, Dinis J, DeVandry S, Boice JA, Hardwick JS, Beckford E, Taylor A, **Carides A**, Roila F, Herrstedt J. "Single-dose fosaprepitant for the prevention of chemotherapy-induced nausea and vomiting associated with cisplatin therapy: randomized, double-blind study protocol—EASE"  
J Clin Oncol. 2011 Apr 10;29(11):1495-501. Epub 2011 Mar 7

Hesketh PJ, Warr DG, Street JC, **Carides AD**. "Differential time course of action of 5-HT<sub>3</sub> and NK1 receptor antagonists when used with highly and moderately emetogenic chemotherapy (HEC and MEC)"  
Support Care Cancer. 2011 Sep;19(9):1297-302. Epub 2010 Jul 11.

Warr DG, Street JC, **Carides AD**. "Evaluation of risk factors predictive of nausea and vomiting with current standard-of-care antiemetic treatment: analysis of phase 3 trial of aprepitant in patients receiving adriamycin-cyclophosphamide-based chemotherapy."  
Support Care Cancer. 2011 Jun;19(6):807-13. Epub 2010 May 13.

Hesketh PJ, Aapro M, Street JC, **Carides AD**. "Evaluation of risk factors predictive of nausea and vomiting with current standard-of-care antiemetic treatment: analysis of two phase III trials of aprepitant in patients receiving cisplatin-based chemotherapy."  
Support Care Cancer. 2010 Sep;18(9):1171-7. Epub 2009 Sep 12.

Rapoport BL, Jordan K, Boice JA, Taylor A, Brown C, Hardwick JS, **Carides A**, Webb T, Schmoll HJ. "Aprepitant for the prevention of chemotherapy-induced nausea and vomiting

associated with a broad range of moderately emetogenic chemotherapies and tumor types: a randomized, double-blind study”

Support Care Cancer. 2010 Apr;18(4):423-31. Epub 2009 Jul 1.

Kaplan SA, Roehrborn CG, Meehan AG, Liu KS, **Carides AD**, Binkowitz BS, Heyden NL, Vaughan ED Jr. “PCPT: Evidence that finasteride reduces risk of most frequently detected intermediate- and high-grade (Gleason score 6 and 7) cancer”

Urology. 2009 May;73(5):935-9. Epub 2009 Mar 28.

Gore L, Chawla S, Petrilli A, Hemenway M, Schissel D, Chua V, **Carides AD**, Taylor A, Devandry S, Valentine J, Evans JK, Oxenius B; Adolescent Aprepitant in Cancer Study Group “Aprepitant in adolescent patients for prevention of chemotherapy-induced nausea and vomiting: a randomized, double-blind, placebo-controlled study of efficacy and tolerability.”

Pediatr Blood Cancer. 2009 Feb;52(2):242-7.

**Carides A**, Reiss T, Lines C, McKeon B, Diemunsch P. “Comparisons of aprepitant and ondansetron”

Am J Health Syst Pharm. 2007 Dec 1;64(23):2422-4; author reply 2424-6.

Cohen YC, Liu KS, Heyden NL, **Carides AD**, Anderson KM, Daifotis AG, Gann PH. “Detection bias due to the effect of finasteride on prostate volume: a modeling approach for analysis of the Prostate Cancer Prevention Trial”

J Natl Cancer Inst. 2007 Sep 19;99(18):1366-74. Epub 2007 Sep 11.

Diemunsch P, Apfel C, Gan TJ, Candiotti K, Philip BK, Chelly J, **Carides AD**, Evans JK, Ho TW, Reiss T. “Preventing postoperative nausea and vomiting: post hoc analysis of pooled data from two randomized active-controlled trials of aprepitant”

Curr Med Res Opin. 2007 Oct;23(10):2559-65.

Diemunsch P, Gan TJ, Philip BK, Girao MJ, Eberhart L, Irwin MG, Pueyo J, Chelly JE, **Carides AD**, Reiss T, Evans JK, Lawson FC; Aprepitant-PONV Protocol 091 International Study Group “Single-dose aprepitant vs ondansetron for the prevention of postoperative nausea and vomiting: a randomized, double-blind phase III trial in patients undergoing open abdominal surgery”

Br J Anaesth. 2007 Aug;99(2):202-11. Epub 2007 May 30.

Gan TJ, Apfel CC, Kovac A, Philip BK, Singla N, Minkowitz H, Habib AS, Knighton J, **Carides AD**, Zhang H, Horgan KJ, Evans JK, Lawson FC; Aprepitant-PONV Study Group. “A randomized, double-blind comparison of the NK1 antagonist, aprepitant, versus ondansetron for the prevention of postoperative nausea and vomiting”

Anesth Analg. 2007 May;104(5):1082-9, tables of contents.

Hesketh PJ, Grunberg SM, Herrstedt J, de Wit R, Gralla RJ, **Carides AD**, Taylor A, Evans JK, Horgan KJ. “Combined data from two phase III trials of the NK1 antagonist aprepitant plus a 5HT 3 antagonist and a corticosteroid for prevention of chemotherapy-induced nausea and vomiting: effect of gender on treatment response.”

Support Care Cancer. 2006 Apr;14(4):354-60. Epub 2006 Feb 1.

Gralla RJ, de Wit R, Herrstedt J, **Carides** AD, Ianus J, Guoguang-Ma J, Evans JK, Horgan KJ. "Antiemetic efficacy of the neurokinin-1 antagonist, aprepitant, plus a 5HT3 antagonist and a corticosteroid in patients receiving anthracyclines or cyclophosphamide in addition to high-dose cisplatin: analysis of combined data from two Phase III randomized clinical trials." *Cancer*. 2005 Aug 15;104(4):864-8.

**Carides A.D.**, Liu, K, Anderson, K "Surrogate Endpoint in a Clinical Trial", Mid-Western Biopharm Workshop, Munice, IN, 2005

Warr DG, Grunberg SM, Gralla RJ, Hesketh PJ, Roila F, Wit R, **Carides** AD, Taylor A, Evans JK, Horgan KJ. "The oral NK(1) antagonist aprepitant for the prevention of acute and delayed chemotherapy-induced nausea and vomiting: Pooled data from 2 randomised, double-blind, placebo controlled trials." *Eur J Cancer*. 2005 Jun;41(9):1278-85.

Cutler NR, Jhee SS, Majumdar AK, McLaughlin D, Brucker MJ, **Carides** AD, Kramer MS, Matzura-Wolfe D, Reines SA, Goldberg MR. "Pharmacokinetics of rizatriptan tablets during and between migraine attacks." *Headache*. 1999 Apr;39(4):264-9.

Pendergrass K, Hargreaves R, Petty KJ, **Carides** AD, Evans JK, Horgan KJ. "Aprepitant: an oral NK1 antagonist for the prevention of nausea and vomiting induced by highly emetogenic chemotherapy." *Drugs Today (Barc)*. 2004 Oct;40(10):853-63. Review.

**Carides A.D.**, Ma JG., Evans JK., Horgan KJ, deWit R. "Transitional probability approach to assess efficacy of the novel antiemetic aprepitant in patients receiving repeated cycles of chemotherapy: pooled data from 2 randomized, double-blind, placebo controlled trials", Mid-Western Biopharm Workshop, Munice, IN, 2004

Ortiz-Ruiz G, Vetter N, Isaacs R, **Carides** A, Woods GL, Friedland I. "Ertapenem versus ceftriaxone for the treatment of community-acquired pneumonia in adults: combined analysis of two multicentre randomized, double-blind studies." *J Antimicrob Chemother*. 2004 Jun;53 Suppl 2:ii59-66.

Kraft WK, McCrea JB, Winchell GA, **Carides** A, Lowry R, Woolf EJ, Kusma SE, Deutsch PJ, Greenberg HE, Waldman SA. "Indinavir and rifabutin drug interactions in healthy volunteers." *J Clin Pharmacol*. 2004 Mar;44(3):305-13.

de Wit R, Herrstedt J, Rapoport B, **Carides** AD, Guoguang-Ma J, Elmer M, Schmidt C, Evans JK, Horgan KJ. "The oral NK(1) antagonist, aprepitant, given with standard antiemetics provides protection against nausea and vomiting over multiple cycles of cisplatin-based chemotherapy: a combined analysis of two randomised, placebo-controlled phase III clinical trials" *Eur J Cancer*. 2004 Feb;40(3):403-10.

de Wit R, Herrstedt J, Rapoport B, **Carides** AD, **Carides** G, Elmer M, Schmidt C, Evans JK, Horgan KJ. "Addition of the oral NK1 antagonist aprepitant to standard antiemetics provides protection against nausea and vomiting during multiple cycles of cisplatin-based chemotherapy"

J Clin Oncol. 2003 Nov 15;21(22):4105-11. Epub 2003 Oct 14.

Hesketh PJ, Grunberg SM, Gralla RJ, Warr DG, Roila F, de Wit R, Chawla SP, **Carides** AD, lanus J, Elmer ME, Evans JK, Beck K, Reines S, Horgan KJ; Aprepitant Protocol 052 Study Group "The oral neurokinin-1 antagonist aprepitant for the prevention of chemotherapy-induced nausea and vomiting: a multinational, randomized, double-blind, placebo-controlled trial in patients receiving high-dose cisplatin--the Aprepitant Protocol 052 Study Group."

J Clin Oncol. 2003 Nov 15;21(22):4112-9. Epub 2003 Oct 14.

Martin AR, **Carides** AD, Pearson JD, Horgan K, Elmer M, Schmidt C, Cai B, Chawla SP, Grunberg SM. "Functional relevance of antiemetic control. Experience using the FLIE questionnaire in a randomised study of the NK-1 antagonist aprepitant"

Eur J Cancer. 2003 Jul;39(10):1395-401.

Poli-Bigelli S, Rodrigues-Pereira J, **Carides** AD, Julie Ma G, Eldridge K, Hipple A, Evans JK, Horgan KJ, Lawson F; Aprepitant Protocol 054 Study Group. "Addition of the neurokinin 1 receptor antagonist aprepitant to standard antiemetic therapy improves control of chemotherapy-induced nausea and vomiting. Results from a randomized, double-blind, placebo-controlled trial in Latin America."

Cancer. 2003 Jun 15;97(12):3090-8.

Hesketh PJ, Van Belle S, Aapro M, Tattersall FD, Naylor RJ, Hargreaves R, **Carides** AD, Evans JK, Horgan KJ. "Differential involvement of neurotransmitters through the time course of cisplatin-induced emesis as revealed by therapy with specific receptor antagonists."

Eur J Cancer. 2003 May;39(8):1074-80.

Chawla SP, Grunberg SM, Gralla RJ, Hesketh PJ, Rittenberg C, Elmer ME, Schmidt C, Taylor A, **Carides** AD, Evans JK, Horgan KJ. "Establishing the dose of the oral NK1 antagonist aprepitant for the prevention of chemotherapy-induced nausea and vomiting."

Cancer. 2003 May 1;97(9):2290-300.

Solomkin JS, Yellin AE, Rotstein OD, Christou NV, Dellinger EP, Tellado JM, Malafaia O, Fernandez A, Choe KA, **Carides** A, Satishchandran V, Teppler H; Protocol 017 Study Group. "Ertapenem versus piperacillin/tazobactam in the treatment of complicated intraabdominal infections: results of a double-blind, randomized comparative phase III trial." *Ann Surg.* 2003 Feb;237(2):235-45.

Vetter N, Cambroner-Hernandez E, Rohlf J, Simon S, **Carides** A, Oliveria T, Isaacs R; Protocol 020 Study Group "A prospective, randomized, double-blind multicenter comparison of parenteral ertapenem and ceftriaxone for the treatment of hospitalized adults with community-acquired pneumonia." *Clin Ther.* 2002 Nov;24(11):1770-85.

Van Belle S, Lichinitser MR, Navari RM, Garin AM, Decramer ML, Riviere A, Thant M, Brestan E, Bui B, Eldridge K, De Smet M, Michiels N, Reinhardt RR, **Carides** AD, Evans JK, Gertz BJ. "Prevention of cisplatin-induced acute and delayed emesis by the selective neurokinin-1 antagonists, L-758,298 and MK-869" *Cancer.* 2002 Jun 1;94(11):3032-41.

Ortiz-Ruiz G, Caballero-Lopez J, Friedland IR, Woods GL, **Carides** A; Protocol 018 Ertapenem Community-Acquired Pneumonia Study Group. "A study evaluating the efficacy, safety, and tolerability of ertapenem versus ceftriaxone for the treatment of community-acquired pneumonia in adults." *Clin Infect Dis.* 2002 Apr 15;34(8):1076-83. Epub 2002 Mar 18.

Cocquyt V, Van Belle S, Reinhardt RR, Decramer ML, O'Brien M, Schellens JH, Borms M, Verbeke L, Van Aelst F, De Smet M, **Carides** AD, Eldridge K, Gertz BJ. "Comparison of L-758,298, a prodrug for the selective neurokinin-1 antagonist, L-754,030, with ondansetron for the prevention of cisplatin-induced emesis" *Eur J Cancer.* 2001 May;37(7):835-42.

Campos D, Pereira JR, Reinhardt RR, Carracedo C, Poli S, Vogel C, Martinez-Cedillo J, Erazo A, Wittreich J, Eriksson LO, **Carides** AD, Gertz BJ. "Prevention of cisplatin-induced emesis by the oral neurokinin-1 antagonist, MK-869, in combination with granisetron and dexamethasone or with dexamethasone alone" *J Clin Oncol.* 2001 Mar 15;19(6):1759-67.

McCrea J, Prueksaritanont T, Gertz BJ, **Carides** A, Gillen L, Antonello S, Brucker MJ, Miller-Stein C, Osborne B, Waldman S. "Concurrent administration of the erythromycin breath test (EBT) and oral midazolam as in vivo probes for CYP3A activity"  
J Clin Pharmacol. 1999 Dec;39(12):1212-20.

Shahinfar S, Simpson RL, **Carides** AD, Thiyagarajan B, Nakagawa Y, Umans JG, Parks JH, Coe FL. "Safety of losartan in hypertensive patients with thiazide-induced hyperuricemia"  
Kidney Int. 1999 Nov;56(5):1879-85. Erratum in: Kidney Int 2000 Jan;57(1):370.

**Carides, A.D.**, Horgan, K.J. et. al "Novel Approaches to Analysis of Nausea associated with cancer chemotherapy",  
Proceedings of Canadian Drug Information Symposium, June 1999.

Yeh KC, Stone JA, **Carides** AD, Rolan P, Woolf E, Ju WD. "Simultaneous investigation of indinavir nonlinear pharmacokinetics and bioavailability in healthy volunteers using stable isotope labeling technique: study design and model-independent data analysis"  
J Pharm Sci. 1999 May;88(5):568-73.

Navari RM, Reinhardt RR, Gralla RJ, Kris MG, Hesketh PJ, Khojasteh A, Kindler H, Grote TH, Pendergrass K, Grunberg SM, **Carides** AD, Gertz BJ. "Reduction of cisplatin-induced emesis by a selective neurokinin-1-receptor antagonist. L-754,030 Antiemetic Trials Group"  
N Engl J Med. 1999 Jan 21;340(3):190-5.

De Wit S, Debier M, De Smet M, McCrea J, Stone J, **Carides** A, Matthews C, Deutsch P, Clumeck N. "Effect of fluconazole on indinavir pharmacokinetics in human immunodeficiency virus-infected patients."  
Antimicrob Agents Chemother. 1998 Feb;42(2):223-7.

**Carides, A.D.**, Thiyagarajan, B. and Zhang, Z. "Comparison of the mixed model with the derived univariate models in repeated ANCOVA models",  
Technical Report #062, Oct. 1998.

Goldberg MR, Lo MW, Christ DD, Chiou R, Furtek CI, Amit O, **Carides** A, Biollaz J, Piguat V, Nussberger J, Brunner HR. "DuP 532, an angiotensin II receptor antagonist: first administration and comparison with losartan"  
Clin Pharmacol Ther. 1997 Jan;61(1):59-69.

**Carides, A.D.**, and Iglewicz B. “A property for an equidistributional contour applied to group sequential designs”  
Biopharmaceutical Section of the ASA Joint Statistical Meetings 1997

Chiou, R., Deutch, P., **Carides, A.D.**, et. al. “Indinavir absorption following extended-release formulations in man and in dog”,  
Proceedings American Association of Pharmaceutical Scientists, 1996.

**Carides, A.D.**, and Iglewicz, B. “A simplified approach for group sequential testing”  
Proceedings Joint Statistical Meetings, Chicago, Illinois 1996 and ENAR, Richmond, Virginia 1996.

Winchell, G. A., McCrea, J.B., **Carides, A.D.**, et. al. “Pharmacokinetic interaction between indinavir and rifabutin”,  
Proceedings American Association of Pharmaceutical Scientists, 1996.

McCrea, J., Wyss, D., Stone, J., **Carides, A.D.**, Kusma, S. et al.  
“Pharmacokinetic interaction between indinavir and rifampin”  
Proceedings American Society for Clinical Pharmacology and Therapeutics, 1996.

**Carides, A.D.**, and Iglewicz B. “Multi-treatment group sequential plans”,  
Proceedings Biopharmaceutical Section of the ASA Joint Statistical Meetings 1995.