

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow the sample format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME S. Gail Eckhardt, MD		POSITION TITLE Professor of Medicine	
EDUCATION/TRAINING (<i>Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.</i>)			
INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
Stephen F. Austin State University, Nacogdoches, TX	BS	1981	Chemistry
University of Texas Medical Branch, Galveston, TX	MD	1985	Medicine

Positions and Employment

1985-1988	Medical Residency, Internal Medicine, University of Virginia Medical Center, Charlottesville VA
1988-1990	Postdoctoral Fellowship, Division of Experimental and Molecular Medicine, Scripps Clinic and Research Foundation, La Jolla CA
1990-1992	Medical Oncology Fellowship, University of California at San Diego, CA
1991-1992	Research Fellowship, Departments of Medicine and Biology, University of California at San Diego, CA
1992-1999	Clinical Faculty, Department of Medicine, Division of Medical Oncology, University of Texas Health Science Center at San Antonio TX
1992-1995	Assistant Member, Institute for Drug Development, Cancer Therapy and Research Center, San Antonio, TX
1995-1999	Associate Director, Clinical Research, Institute for Drug Development, Cancer Therapy and Research Center, San Antonio, TX
1998-1999	Director, Drug Development Fellowship Training Program, Cancer Therapy Research Center, Institute for Drug Development, San Antonio, TX
1999-2002	Associate Professor of Medicine, Director of Phase I and GI Malignancies Programs, Division of Medical Oncology, University of Colorado Health Sciences Center, Denver, CO
2002-Present	Professor of Medicine, University of Colorado Health Sciences Center, Denver, CO
2004-Present	Professor of Medicine with Tenure, University of Colorado Health Sciences Center, Denver, CO.
2004-Present	Program Leader, Developmental Therapeutics, UCCC
2006-	Division Head, Medical Oncology

Other Experience and Professional Memberships:

Member, NCI Clinical Trials Working Group (CTWG) Evaluation Committee 2006-present; Member, NCI GI Steering Committee 2006-present; Member, NCI Investigational Drug Steering Committee 2006-present; Member, FDA Oncology Drugs Advisory Committee (ODAC) 2005-2009; Member, ASCO Board of Directors, 2004-2007; ASCO Board Liaison, Clinical Research Committee 2005-2007; Co-Chair ASCO Translational Research Task Force 2005-2006; Member, NCI Developmental Therapeutics Study Section 2005-2006; Steering Committee, ASCO GI Malignancies Symposium, 2006-2007; Co-Chair, ASCO GI Malignancies Symposium, 2004; Vice-Chair (2002) and Chair (2003) ASCO Program Committee; Member, ASCO Publications Committee, 2002-2005; Member, EORTC Early Clinical Trials Review Panel, 2002-present.; Member, ASCO Molecular Oncology Task Force, 2001-2003.; Member, GI Steering Committee, SWOG 2001-2004; Reviewer, ET-1 Study section, NCI/NIH, 2001.; Faculty, ASCO/ AACR/MOG Pan-Asian Clinical Research Methods Workshop, Australia, 2004, 2006; Faculty, ASCO/AACR Clinical Research Methods Workshop, Vail, CO 2000-2003, and Course Director 2007-2009; Program Committee, FECS/ASCO/AACR Methods in Clinical Cancer Research, Flims, Switzerland; 2001-2003.; Member, Molecular Markers Study Section, NCI; Sept and Oct, 2000.; External Reviewer, Drug Development Group, National Cancer Institute, 2000- present; Co-Chair, Angiogenesis Symposium, American Association for Cancer Research 91st Annual Meeting, 2000.; Member, American Association for Cancer Research Cain Memorial Award Selection Committee, 2000.; Member, Angiogenesis Working Group, National Cancer Institute 1998-2000.; Member, RAID study section, National Cancer Institute 1998-2000.

Journals

Clinical Cancer Research- Editorial Board 2001-2006
Journal of Clinical Oncology- Associate Editor, 2002-2005
Investigational New Drugs- Associate Editor

Honors

Gamma Sigma Epsilon, 1981; Alpha Omega Alpha, 1985

Selected publications (selected from 80 peer reviewed publications).

1. **Eckhardt, S. G.**, Milich, D. R. and McLachlan, A. Hepatitis B virus core antigen has two nuclear localization sequences in the arginine-rich carboxy terminus. *Journal of Virology*, February, V65 N2:575-582, 1991.

2. **Eckhardt, S. G.**, Dai, A., Davidson, K.K., Forseth, B., Wahl, G., Von Hoff, D.D. Induction of differentiation in HL60 cells by the reduction of extrachromosomally amplified *c-myc*. *Proc Natl Acad Sci* 91:6674-6678, 1994.
3. Honghui Z, Choi L, Lau H, Bruntsch U, DeVries EG, **Eckhardt SG**, Van Oosterom A, Verweij J, Schran H, Barbet N, Linnarz R, Capdeville R. Population pharmacokinetics/toxicokinetics (PK/TD) relationship of SAM486A in phase I studies in patients with advanced cancers. *J Clin Pharmacol* 40:275-283, 2000.
4. Ganly I., Kirn D., **Eckhardt SG**, Rodriguez GI, Soutar D, Otto R, Robertos AG, Park O, Gulley ML, Heise C, Von Hoff DD, Kaye SB. First Evidence of Biological Activity of ONYX-015, an E1B Attenuated Adenovirus, in Patients with Recurrent p53 Overexpressing Head and Neck Cancer. *Clin Cancer Res* 6: 798-806, 2000.
5. Hammond LA, Hilsenbeck SG, **Eckhardt SG**, Marty J, Mangold G, MacDonald J, Rowinsky EK, Von Hoff DD, Weitman S. Enhanced Antitumor Activity of 6-Hydroxymethylacylfulvene in Combination with Topotecan or Taxol in the MV522 Lung Carcinoma Xenograft Model. *Eur J Can* 36: 2430-6, 2000.
6. Rowinsky EK, Johnson TR, Geyer CE, Drengler R, **Eckhardt SG**, Hammond LA, Smetzer L, Coyle J, Rizzo J, Schwartz G, Tolcher A, DeJager RL. DX-8951F (Exatecan Mesylate), a hexacyclic camptothecin analog on a daily x 5 schedule: A phase I and pharmacokinetic study in patients with advanced solid malignancies. *JCO* 18: 3151-63, 2000.
7. **Eckhardt SG**, Baker SD, Britted CD, Hidalgo M, Siu L, Hammond L, Weiss G, Villalona-Calero MA, Felton S, Drengler R, Kuhn JG, Garner A, Smith L, Rothenberg ML, Smith SL, MacDonald J, Weitman S, Moczygemba J, Von Hoff DD, Rowinsky EK. A Phase I and Pharmacokinetic Study of MGI 114, a Novel Mushroom-derived Cytotoxin Administered for Five Consecutive Days Every Four Weeks. *JCO* 18: 4086-97, 2000.
8. Amita Patnaik, Eric K. Rowinsky, Brinda K. Tammara, Manuel Hidalgo, Ronald L. Drengler, Allison M. Thurman, Lillian L. Siu, Lisa A. Hammond, Sally Felton, Suresh Mallikaarjun, Daniel D. Von Hoff, and **S. Gail Eckhardt**. A phase I and pharmacokinetic (pk) study of the differentiating agent, vesnarinone, in combination with gemcitabine in patients with advanced cancer. *JCO* 18: 3974-85, 2000.
9. Vonderheide RH, Dutcher JP, Anderson JE, **Eckhardt SG**, Stephans KF, Razvillas B, Garl S, Butine MD, Perry VP, Armitage RJ, Ghalie R, Caron DA, Gribben JG. Phase I study of recombinant human CD40 ligand in cancer patients. *J Clin Oncol* 19(13):3280-7, 2001.
10. Hidalgo M, Siu LL, Nemunaitis J, Rizzo J, Hammond LA, Takimoto C, **Eckhardt SG**, Tolcher A, Britten CD, Denis L, Ferrante K, Von Hoff DD, Silberman S, Rowinsky EK. Phase I and pharmacologic study of OSI-774, an epidermal growth factor receptor tyrosine kinase inhibitor, in patients with advanced solid malignancies. *J Clin Oncol* 19(13):3267-79, 2001.
11. Tolcher AW, **Eckhardt SG**, Kuhn J, Hammond L, Weiss G, Rizzo J, Aylesworth C, Hidalgo M, Patnaik A, Schwartz G, Felton S, Campbell E, Rowinsky EK. Phase I and pharmacokinetic study of NSC 655649, a rebeccamycin analog with topoisomerase inhibitory properties. *J Clin Oncol* 19(11):2937-47, 2001.
12. Hidalgo M, **Eckhardt SG**. Development of matrix metalloproteinase inhibitors in cancer therapy. *J Natl Cancer Inst* 93(3):178-93, 2001.
13. Villalona-Calero MA, **Eckhardt SG**, Weiss G, Hidalgo M, Beijnen JH, van Kesteren C, Rosing H, Campbell E, Kraynak M, Lopez-Lazaro L, Guzman C, Von Hoff DD, Jimeno J, Rowinsky EK. A phase I and pharmacokinetic study of ecteinascidin-743 on a daily x 5 schedule in patients with solid malignancies. *Clin Cancer Res* 8(1):75-85, 2002.
14. LL Siu, EK Rowinsky, LA Hammond, GR Weiss, M Hidalgo, GM Clark, J Moczygemba, L Choi, R Linnartz, NC Barbet, IT Sklenar, R Capdeville, CW Porter, DD Von Hoff, **SG Eckhardt**. A Phase I and Pharmacokinetic Study of SAM486A, a Novel Polyamine Biosynthesis Inhibitor, Administered on a Daily-Times-Five Every-Three-Week Schedule in Patients with Advanced Solid Malignancies. *Clin Cancer Res* 8(7):2157-66, 2002.
15. Amita Patnaik, Eric K. Rowinsky, Sally A. Felton, Miguel A. Villalona, Lisa A. Hammond, Carolyn D. Britten, Lillian L. Siu, A Goetz, Susan Burton, Harold Keer, and **S. Gail Eckhardt**. A phase I study of the differentiating agent, an-9; a prodrug of butyric acid, in patients with advanced cancer. *Clin Cancer Res* 8(7):2142-8, 2002.
16. Pierson AS, Gibbs P, Richards J, Russ P, **Eckhardt SG**, Gonzalez R. A phase II study of Irofulven (MGI 114) in patients with stage IV melanoma. *Invest New Drugs* 20(3):357-62, 2002.
17. + **Hao D**, Hammond LA, **Eckhardt SG**, Patnaik A, Takimoto CH, Schwartz GH, Goetz AD, Tolcher AW, McCreery HA, Mamun K, Williams JI, Holroyd KJ, Rowinsky EK. A Phase I and pharmacokinetic study of squalamine, an aminosterol angiogenesis inhibitor. *Clin Cancer Res* 9(7):2465-71, 2003.
18. Gustafson DL, Long ME, Zirrolli JA, Duncan MW, Holden SN, Pierson AS, **Eckhardt SG**. Analysis of docetaxel pharmacokinetics in humans with the inclusion of later sampling time-points afforded by the use of a sensitive tandem LCMS assay. *Cancer Chemother Pharmacol* 52(2):159-66, 2003.
19. + **Patnaik A**, **Eckhardt SG**, Izbicka E, Tolcher AA, Hammond LA, Takimoto CH, Schwartz G, McCreery H, Goetz A, Mori M, Terada K, Gentner L, Rybak ME, Richards H, Zhang S, Rowinsky EK. A phase I, pharmacokinetic, and biological study of the farnesyltransferase inhibitor tipifarnib in combination with gemcitabine in patients with advanced malignancies. *Clin Cancer Res* 9:4761-71, 2003.
20. Syed S, Takimoto C, Hidalgo M, Rizzo J, Kuhn JG, Hammond LA, Schwartz G, Tolcher A, Patnaik A, **Eckhardt SG**, Rowinsky EK. A phase I and pharmacokinetic study of Col-3 (Metastat), an oral tetracycline derivative with potent matrix metalloproteinase and antitumor properties. *Clin Cancer Res* 10:6512-21, 2004.

21. Ramnath N, Hamm J, Schwartz G, Holden S, **Eckhardt SG**, Vredenburg MR, Bernacki RJ, Lathia C, Kanter P, Creaven PJ. A phase I and pharmacokinetic study of BAY59: a novel taxane. *Oncology*: 67(2):123-9, 2004.
22. Witta SE, Gustafson DL, Pierson AS, Menter A, Holden SN, Basche M, Persky M, O'Bryant CL, Zeng C, Baron A, Long ME, Gibbs A, Kelly K, Bunn PA Jr, Chan DC, Pallansch P, **Eckhardt SG**. A phase I and pharmacokinetic study of exisulind and docetaxel in patients with advanced solid tumors. *Clin Cancer Res*:10:7229-37, 2004.
23. Ratain MJ, **Eckhardt SG**. Phase II studies of modern drugs directed against new targets: if you are fazed, too, then resist RECIST. *J Clin Oncol* 22:4442-5, 2004.
24. Gottschalk S, Anderson N, Hainz C, **Eckhardt SG**, Serkova NJ. Imatinib (STI571)-mediated changes in glucose metabolism in human leukemia BCR-ABL-positive cells. *Clin Cancer Res* 10:6661-8, 2004.
25. de Bono JS, Rha SY, Stephenson J, Schultes BC, Monroe P, **Eckhardt SG**, Hammond LA, Whiteside TL, Nicodemus CF, Cermak JM, Rowinsky EK, Tolcher AW. Phase I trial of a murine antibody to MUC1 in patients with metastatic cancer: evidence for the activation of humoral and cellular antitumor immunity. *Ann Oncol* 15:1825-33, 2004.
26. + Holden SN, **Eckhardt SG**, Basser R, de Boer R, Rischin D, Green M, Rosenthal MA, Wheeler C, Barge A, Hurwitz HI. Clinical evaluation of ZD6474, an orally active inhibitor of VEGF and EGF receptor signaling, in patients with solid, malignant tumors. *Ann Oncol* 16(8):1391-7, 2005.
27. Morelli MP, Cascone T, Troiani T, De Vita F, Orditura M, Laus G, **Eckhardt SG**, Pepe S, Tortora G, Ciardiello F. Sequence-dependent antiproliferative effects of cytotoxic drugs and epidermal growth factor receptor inhibitors. *Ann Oncol* 4:61-68, 2005.
28. + Kobayashi H, **Eckhardt SG**, Lockridge JA, Rothenberg ML, Sandler AB, O'bryant CL, Cooper W, Holden SN, Aitchison RD, Usman N, Wolin M, Basche ML. Safety and pharmacokinetic study of RPI.4610 (ANGIOZYME), an anti-VEGFR-1 ribozyme, in combination with carboplatin and paclitaxel in patients with advanced solid tumors. *Cancer Chemother Pharmacol* 56(4):329-36, 2005.
29. Abou-Alfa GK, Rowinsky EK, Patt YZ, Schwartz GK, Kelsen DP, Sharma S, Siegel E, Becerra CR, **Eckhardt SG**, Feit K, De Jager R, O'Reilly EM. A Phase II study of intravenous exatecan administered daily for 5 days, every 3 weeks to patients with biliary tract cancers. *Am J Clin Oncol* 28(4):334-9, 2005.
30. Tolcher AW, Hao D, de Bono J, Miller A, Patnaik A, Hammond LA, Smetzer L, Van Wart Hood J, Merritt J, Rowinsky EK, Takimoto C, Von Hoff D, **Eckhardt SG**. Phase I, pharmacokinetic, and pharmacodynamic study of intravenously administered Ad5CMV-p53, an adenoviral vector containing the wild-type p53 gene, in patients with advanced cancer. *J Clin Oncol* 24(13):2052-8, 2006.
31. Morelli MP, Cascone T, Troiani T, Tuccillo C, Bianco R, Normanno N, Romano M, Veneziani BM, Fontanini G, **Eckhardt SG**, De Pacido S, Tortora G, Ciardiello F. Anti-tumor activity of the combination of cetuximab, an anti-EGFR blocking monoclonal antibody and ZD6474, an inhibitor of VEGFR and EGFR tyrosine kinases. *J Cell Physiol* 208(2):344-53, 2006
32. Teresa Troiani, Owen Lockerbie, Mark Morrow, Fortunato Ciardiello' **S.Gail Eckhardt**. Sequence-Dependent Inhibition of Human Colon Cancer Cell Growth and of Pro-Survival Pathways by Oxaliplatin in combination with ZD6474 (ZACTIMA™), an inhibitor of VEGFR and EGFR Tyrosine Kinases *Molecular Cancer Therapeutics* 5(7):1883-94, 2006.
33. Lisa J. Green, Philip Marder, Chad Ray, Carolyn A. Cook, Susan Jaken, Luna C Musib, Roy S. Herbst, Michael Carducci, Carolyn D. Britten, Michele Basche, **S. Gail Eckhardt**, and Donald Thornton. Development and Validation of a Drug Activity Biomarker that Demonstrates Target Inhibition in Cancer Patients Receiving Enzastaurin, a Novel Phospho-Kinase C-β Inhibitor. *Clin Cancer Res* 12(11): 3408-3415, 2006.
34. Michele Basche, Daniel L Gustafson, Scott N. Holden, Cindy L. O'Bryant, Lia Gore, Samir Witta, Mary Kay Schultz, Mark Morrow, Adrah Levin, Brian R. Creese, Michael Kangas, Kaye Roberts, Thu Nguyen, Kat Davis, Russell S. Addison, Jane C. Moore, **S. Gail Eckhardt**. A Phase I Biologic and Pharmacologic Study of the Heparanase Inhibitor PI-88 in Patients with Advanced Solid Tumors. *Clin Cancer Res* 12: 5471- 80, 2006
35. Ramaswamy B, Elias AD, Kelbick NT, Dodley A, Morrow M, Hauger M, Allen J, Rhoades C, Kendra K, Chen HX, **Eckhardt SG**, Shapiro CL. Phase II trial of bevacizumab in combination with weekly docetaxel in metastatic breast cancer patients. *Clin Cancer Res* 12(10):3124-9, 2006.
36. Lia Gore, Scott N. Holden, Roger B. Cohen, Mark Morrow, A. Scott Pierson, Cindy L. O'Bryant, Martha Persky, Daniel Gustafson, Christine Mikule, Susan Fisher, Stephen Zhang, Peter A. Palmer, **S. Gail Eckhardt** .A Phase I Safety, Pharmacological, and Biological Study of the Farnesyl Protein Transferase Inhibitor, Tipifarnib, and Capecitabine in Advanced Solid Tumors. *Annals of Oncology* 17(11):1709-17, 2006.
37. Abou-Alfa GK, Letourneau R, Harker G, Modiano M, Hurwitz H, Tchekmedyan NS, Feit K, Ackerman J, De Jager RL, **Eckhardt SG**, O'reilly EM. Randomized Phase III Study of Exatecan and Gemcitabine Compared With Gemcitabine Alone in Untreated Advanced Pancreatic Cancer. *J Clin Oncol* 24(27):4441-7, 2006.
38. Medeiros BC, Landau HJ, Morrow M, Lockerbie RO, Pitts T, **Eckhardt SG**. The farnesyl transferase inhibitor, tipifarnib, is a potent inhibitor of the MDR1 gene product, P-glycoprotein, and demonstrates significant cytotoxic synergism against human leukemia cell lines. *Leukemia Apr*; 21(4):739-46, 2007.
39. Messersmith WA, Hidalgo M, Carducci M, **Eckhardt SG**. Novel targets in solid tumors: MEK inhibitors. *Clin Adv Hematol Oncol* 4(11):831-6, 2006.

40. Chow LQM, **Eckhardt SG**. Sunitinib: From Rational Design to Clinical Efficacy. *J Clin Oncol* Mar 1;25(7):884-96, 2007.
41. S. Hariharan, D. Gustafson, S. Holden, D. McConkey, D. Davis, M. Morrow, M. Basche, L. Gore, C. Zang, C. L. O'Bryant, A. Baron, D. Galleman, D. Colevas & **SG Eckhardt**. Assessment of the biological and pharmacological effects of the $\alpha_v\alpha_3$ and $\alpha_v\alpha_5$ Integrin Receptor Antagonist, cilengitide (EMD 121974), in patients with advanced solid tumors. *Ann Oncol* (In Press), 2007.
42. O'dwyer PJ, **Eckhardt SG**, Haller DG, Tepper J, Ahnen D, Hamilton S, Benson AB 3rd, Rothenberg M, Petrelli N, Lenz HJ, Diasio R, DuBois R, Sargent D, Sloan J, Johnson CD, Comis RL, O'Connell MJ; Gastrointestinal Scientific Leadership Council of the Coalition of Cancer Cooperative Groups. Priorities in colorectal cancer research: recommendations from the Gastrointestinal Scientific Leadership Council of the Coalition of Cancer Cooperative Groups. *J Clin Oncol* Jun 1;25(16):2313-21, 2007.
43. Bradshaw-Pierce EL, **Eckhardt SG**, Gustafson DL. A physiologically based pharmacokinetic model of docetaxel disposition: from mouse to man. *Clin Cancer Res* May 1;13(9):2768-76, 2007.
44. Chiappori AA, **Eckhardt SG**, Bukowski R, Sullivan DM, Ikeda M, Yano Y, Yamada-Sawada T, Kambayashi Y, Tanaka K, Javle MM, Mekhail T, O'bryant CL, Creaven PJ. A phase I pharmacokinetic and pharmacodynamic study of S-3304, a novel matrix metalloproteinase inhibitor, in patients with advanced and refractory solid tumors. *Clin Cancer Res* Apr 1;13(7):2091-9, 2007.
45. Lia Gore, Mace L. Rothenberg, Cindy L. O'Bryant, Dan Gustafson, Mary Kay Schultz, Candice McCoy, Astrid Schott, Catherine Scholz, and **S. Gail Eckhardt**. A Phase I and Pharmacokinetic Study of the Oral Histone Deacetylase Inhibitor, MS-275, in Patients with Refractory Solid Tumors and Lymphomas. *Clin Cancer Res* (In Press), 2007.
46. Teresa Troiani, Natalie J. Serkova, Daniel L. Gustafson, Thomas K. Henthorn, Owen Lockerbie, Andrea Merz, Michael Long, Mark Morrow, Fortunato Ciardiello, **S.Gail Eckhardt**. Investigation of Two Dosing Schedules of Vandetanib (ZD6474), an Inhibitor of VEGFR and EGFR Signaling, in Combination with Irinotecan in a Human Colon Cancer Xenograft Model. *Clin Cancer Res* (In Press), 2007.

Research Support:

Ongoing Federal Research Support:

U01 CA099176 Eckhardt (PI) 04/07/2003 to 02/28/2008
NCI

Early Clinical Trials with Phase I Emphasis

The major goal of this study is to determine the MTD, biological activity, and PK of agents that are distributed through CTEP/NCI.

Role: PI
2T32 CA079446 Eckhardt (PI) 07/01/2005-06/30/10
NCI

Training in Pharmacology of Antineoplastic Agents

The major goal of this proposal is to provide training for post-doctoral fellows (MD and Ph.D) in the pharmacology of anticancer agents.

Role: PI
P30 CA46934 Bunn (PI) 02/01/2001 to 01/31/2011
NCI

University of Colorado Cancer Center Support Grant

The major goal of this grant is to provide developmental and infrastructure support of cancer-related programs and core (shared) services.

Role: Developmental Therapeutics Program Leader
1K24 CA106349 Eckhardt (PI) 02/01/2005 to 1/31/2009
NIH/NCI

Mechanism Based Anti-Cancer Therapy

The major goal is to conduct mechanism-based translational studies in colorectal cancer and to mentor fellows and faculty in patient oriented research.

Role: PI
R01 CA101988-01A1 Gustafson (PI) 01/01/2005 to 12/31/2009
NIH/NCI

Dual Compartmental Targeting of Cancer

The major goal is to investigate MTD and metronomic schedules of chemotherapy with a dual VEGFR/EGFR inhibitor using PBPK modeling *in vivo*.

Role: Co-Investigator