

March, 2019

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CAREER THEME

Applied Pharmacology and Drug Development/Regulation:
Relationships among concepts, experiments *in vitro*, animal models, and clinical trials

ACADEMIC BACKGROUND

Lecturer in Medicine, Johns Hopkins University, 1983-2005

Associate Professor of Pharmacology, Georgetown University, 1989-2005

Adjunct Faculty, Division of Clinical Pharmacology and Medical Toxicology,
Uniformed Services University of the Health Sciences, 1988-present

Consultant in Research, George Washington University, Department of Pharmacology, 1984-93

Postdoctoral Fellow in Clinical Pharmacology, Johns Hopkins University, 1976 to 1979

Ph.D., Chemical and Biochemical Engineering, University of Pennsylvania, 1976; M.S., 1974
Ford Foundation Fellow, University of Pennsylvania, 1972-73

B.S. (with honors), Chemical Engineering, Drexel University, 1972.
President, Debate Society. Vice-President, Student Government

Food and Drug Administration

2008-2012 Member, Pharmaceutical Sciences Advisory Committee
2005-2010 Guest Researcher, Laboratory of Clinical Pharmacology, CDER, FDA
2004-2005: Co-Chair, Novel Imaging Probes Subcommittee, NCI-FDA Oncology Task Force
2004-2005: Co-Chair, FDA-Wide Working Group on Imaging in Drug Development
2003-2005: Acting Director, Division of Applied Pharmacology Research, CDER, FDA
1990-2005: Director, Laboratory of Clinical Pharmacology, CDER, FDA
1990-1995: Director, Office of Research Resources, CDER, FDA
1988-1990 Pharmacologist, Office of Research Resources, Center for Drug Evaluation
and Research

National Institutes of Health

2005-present Associate Director for Developmental Therapeutics,
Division of Cancer Treatment and Diagnosis, NCI, NIH
1983-1988: Chief, Pharmacokinetics Section, Clinical Pharmacology Branch, NCI
1982-1988: Chair, Blood Level Working Group, NCI
1977-1983: Senior Staff, Biomedical Engineering and Instrumentation Branch, Office
of Research Services, NIH
1977-1979: Guest Researcher, Laboratory of Toxicology, Developmental Therapeutics, NCI

Publications: Author or co-author of more than 200 articles and 9 patents issued

Employment History

Jerry M. Collins

2005-present: Associate Director for Developmental Therapeutics,
Division of Cancer Treatment and Diagnosis, NCI, NIH

Supervisor for the Developmental Therapeutics Program at the National Cancer Institute. Line manager for preclinical drug development activities, with full responsibility for budget, space, and personnel. Program includes 70 Federal employees and about 200 contractors. As part of the senior management team for the Division, I coordinate preclinical activities with other Programs to facilitate entry of new drugs into clinical testing, as well as the integration of emerging technologies such as noninvasive imaging into clinical therapeutics.

1988-2005: Director, Laboratory of Clinical Pharmacology, CDER, FDA

After a pilot and planning phase with recruitment and equipping a new facility, this lab was formally launched in 1990. The staff in this lab conduct research encompassing laboratory experiments and collaborative clinical studies in the areas of drug metabolism, drug-drug interactions, hepatotoxicity, and positron emission tomography (PET). Over a 15-year period, the size of this group has ranged from 6 to 20 scientists. Lab staff, including myself, also serve as consultants to FDA review operations. My review and policy activities have focused upon the interface between preclinical and clinical trials.

2003-2005: Acting Director, Division of Applied Pharmacology Research, CDER, FDA

The preclinical teams emphasize pharmacogenomics and molecular toxicology, as well as animal studies in vivo that focus upon the cardiopulmonary system, including the effects of anthracyclines on the heart. While continuing my duties as Director of the Laboratory of Clinical Pharmacology, I have full responsibility for allocation of budget, space, and personnel for both groups.

1990-95: Director, Office of Research Resources, CDER, FDA, Senior Executive Service

I managed a diverse group of 212 federal employees, including reviewers of NDA/IND submissions, preclinical and clinical researchers, and drug quality testers. I had full budget, space, and personnel authority for:

-- Division of Biopharmaceutics: reviewed all human pharmacokinetic data related to new drugs. This group traditionally focused upon drug applications in the final stage before marketing (NDAs), but I increased their involvement in evaluation of drugs at earlier stages of investigation (INDs). Division staff analyze of cross-study trends [such as effects of age, gender, organ function] using advanced bio-statistical methods.

-- Division of Research and Testing: included laboratory programs for analytical methods validation for antibiotics and hormones and the certification of insulin. This Division also conducted research into the pharmacology and toxicology of drugs across the entire spectrum of the mission of CDER. Our emphasis was particularly geared towards the replacement of animal testing in vivo with testing in vitro or via chemical-physical methods.

-- Division of Drug Analysis: tested finished drug products and bulk drug substances for adherence to compendial and ANDA/NDA specifications. This group also developed and evaluated technology related to methods for drug testing.

-- Clinical Pharmacology: While serving as ORR Director, I also continued to direct the Clinical Pharmacology Lab <described above>, which was part of ORR.

Additional Duties:

FDA Commissioner's CRADA Review Board. Member, 1994-2005.

SBRS Credentialing Committee. Member, 1995-2005.

Drug Metabolism/Drug Interaction Working Group. Chair and Member, 1994-2005.

FDA Pharmacogenomics Working Group. Member, 2002-2005.

FDA Cross-Center Imaging Initiative. Co-Chair, 2003-2005.

NCI-FDA Inter-Agency Oncology Task Force. Co-Chair, Novel Imaging Probes Subcommittee, 2004-2005.

Institutional Official for CDER's radioactivity license, Nuclear Regulatory Commission, 1990-2005

Other Assignments:

Institutional Official for oversight of CDER's Animal Care and Use Committee (IACUC)

Supervisor for the operations of the CDER Laboratory Scientist Peer Review Committee.

Supervisor for laboratory safety issues at CDER

CDER Liaison, National Center for Toxicology Research

1983-1988: Chief, Pharmacokinetics Section, Clinical Pharmacology Branch, NCI, NIH

I was recruited as the founding director for this group. Our mission was to conduct research on the pharmacokinetics of anticancer drugs, especially those under investigation at the NIH Clinical Center. Specific areas of interest included regional drug delivery, re-evaluation of established agents, and improvements in the testing of new drugs. Collaborative projects included other groups at NCI, other Federal Agencies, and universities.

Additional Duty: Member, Decision Network Committee, DCT/NCI, 1984-88.

1982-1988: Chair, Blood Level Working Group, NCI, NIH

Evaluation of pharmacologically-guided phase 1 clinical trials as an alternative to modified Fibonacci design. Worked with NCI staff in DTP to modify Pharmacology Task Order contracts to provide essential preclinical data for comparison with initial human pharmacology. Served as co-investigator on NCI-CTEP-supported clinical studies that implemented new phase 1 designs.

1977-1983: Staff, Biomedical Engineering and Instrumentation Branch,
Office of Research Services, NIH

Initially, I served in this position via the Intergovernmental Personnel Act (IPA) while maintaining my appointment at Johns Hopkins University. I was appointed to a full-time federal position in 1979. Most of my research activities focused upon the application of pharmacokinetics to the design and analysis of clinical trials of anticancer drugs.

1977-1979: Guest Researcher, Laboratory of Toxicology, Developmental Therapeutics Program (DTP), NCI, NIH.

Conducted independent laboratory research on the pharmacokinetics and toxicity of the drugs under consideration for clinical use via intraperitoneal therapy.

Jerry M. Collins - - - Publications List

- (1) J. M. Collins, D. A. Blake, P. G. Egner. Phenytoin metabolism in the rat: Pharmacokinetic correlation between in vitro hepatic microsomal enzyme activity and in vivo elimination kinetics. *Drug Metab Disp* 6:251-257, 1978
- (2) D. A. Blake, J. M. Collins, B. C. Miyasaki, F. Cohen. Influence of pregnancy and folic acid on phenytoin metabolism by rat liver microsomes. *Drug Metab. Disp.* 6:246-250, 1978.
- (3) J. M. Collins. Isobaric inert gas supersaturation: observations, theory, and predictions. *J Appl Physiol* 44:914-917, 1978.
- (4) J. M. Collins. Peritoneal dialysis for methyprylon intoxication. *J. Pediatrics* 92:519, 1978. (Letter)
- (5) B. I. Sikic, J. M. Collins, E. G. Mimnaugh, T. E. Gram. Improved therapeutic index of bleomycin when administered by continuous infusion in mice. *Cancer Treat. Rep.* 62:2011-2017, 1978.
- (6) J. L. Speyer, J. M. Collins, R. L. Dedrick, M. F. Brennan, A. R. Buckpitt, H. Londer, V. T. DeVita, C. E. Myers. Phase I and pharmacological studies of intraperitoneal 5-fluorouracil. *Cancer Res.* 40:567-572, 1980.
- (7) J.M. Collins, R.L. Dedrick, F.G. King, J.L. Speyer, C.E. Myers. Nonlinear pharmacokinetic models for 5-fluorouracil in man: Intravenous and intraperitoneal routes. *Clin. Pharmacol. Ther.* 28:235-246, 1980.
- (8) R.B. Jones, J.M. Collins, C.E. Myers, A.E. Brooks, S.M. Hubbard, J.E. Balow, M.F. Brennan, R.L. Dedrick, V.T. DeVita. High-volume intraperitoneal chemotherapy with methotrexate in patients with cancer. *Cancer Res.* 41:55-59, 1981.
- (9) J. L. Speyer, P. H. Sugarbaker, J. M. Collins, R. L. Dedrick, R. W. Klecker, C. E. Myers. Portal levels and hepatic clearance of 5-fluorouracil after intraperitoneal administration in man. *Cancer Res.* 41:1916-1922, 1981.
- (10) J.M. Collins. Inert gas exchange rates of subcutaneous and intraperitoneal gas pockets in piglets. *Resp. Physiol.* 46:391-404, 1981.
- (11) M. E. McManus, A. Monks, J. M. Collins, R. White, J. M. Strong. Nonlinear pharmacokinetics of misonidazole and desmethylmisonidazole in the isolated perfused rat liver. *J. Pharmacol. Exp. Ther.* 219:669-674, 1981.
- (12) C. L. Litterst, J. M. Collins, M. C. Lowe, S. T. Arnold, D. M. Powell, A. M. Guarino. Local and systemic toxicity resulting from large-volume ip administration of doxorubicin in the rat. *Cancer Treat. Rep* 66:157-161, 1982
- (13) J. M. Collins, R. L. Dedrick. Contribution of the lungs to total body clearance: linear and nonlinear effects. *J. Pharm. Sci.* 71:66-70, 1982.
- (14) J. M. Collins, R. L. Dedrick. Pharmacokinetics of Anticancer Drugs, pp. 77-99 in Pharmacologic Principles of Cancer Treatment edited by B. A. Chabner. W.B. Saunders, Philadelphia, 1982.
- (15) J. M. Collins, R. L. Dedrick, M. F. Flessner, A. M. Guarino. Concentration-dependent disappearance of fluorouracil from peritoneal fluid in the rat: Experimental observations and distributed modeling. *J. Pharm. Sci.* 71:735-738, 1982.
- (16) N. R. Bachur, J. M. Collins, J. A. Kelley, D. A. Van Echo, R. S. Kaplan, M. Whitacre. Diaziquone, 2,5-diaziridinyl- 3,6-biscarbo ethoxyamino-1,4-benzoquinone, plasma and cerebrospinal fluid kinetics. *Clin. Pharmacol. Ther.* 31:650-655, 1982.
- (17) R. L. Dedrick, M. F. Flessner, J. M. Collins, J. S. Schultz. Is the peritoneum a membrane? *ASAIO J.* 5:1-8, 1982.
- (18) C. E. Myers, J. M. Collins. Pharmacology of intraperitoneal chemotherapy. *Cancer Investigation* 1:395-407, 1983.
- (19) I. G. Kerr, J. Jolivet, J. M. Collins, J. Drake, B. A. Chabner. Test dose for predicting high-dose methotrexate infusions. *Clin. Pharmacol. Ther.* 33:44-51, 1983.

- (20) J.F. Spiegel, M.J. Egorin, J.M. Collins, B.D. Lerner, N.R. Bachur. The murine disposition and pharmacokinetics of the antineoplastic agent, diaziquone (NSC 182986). *Drug Metab. Dispos.* 11:41-46, 1983.
- (21) F. G. King, R. L. Dedrick, J. M. Collins, H. B. Matthews, L.S. Birnbaum. Physiologic model for the pharmacokinetics of 2,3,7,8-tetrachloro-dibenzofuran in several species. *Tox. Appl. Pharm.* 67:390-400, 1983.
- (22) L. Gianni, J. Jenkins, R. Greene, A. S. Lichter, C. E. Myers, J. M. Collins. Pharmacokinetics of the hypoxic radiosensitizers misonidazole and desmethylmisonidazole after intraperitoneal administration in humans. *Cancer Res.* 43:913-916, 1983.
- (23) S. Zimm, J.M. Collins, R. Riccardi, D. O'Neill, P.K. Narang, B. Chabner, D.G. Poplack. Variable bioavailability of oral mercaptopurine: Is maintenance chemotherapy in acute lymphoblastic leukemia being optimally delivered? *New Engl. J. Med.* 308:1005-1009, 1983.
- (24) R.F. Greene, J.M. Collins, J.F. Jenkins, J.L. Speyer, C.E. Myers. Plasma pharmacokinetics of adriamycin and adriamycinol: Implications for the design of in vitro experiments and treatment protocols. *Cancer Res.* 43:3417-3421, 1983.
- (25) J.M. Collins, R.L. Dedrick. Distributed model for drug delivery to the CSF and brain tissue. *Amer. J. Physiol.* 245:R303-R310, 1983.
- (26) G.A. Curt, J.J. Grygiel, B.J. Corden, R.F. Ozols, R.B. Weiss, D. Tell, C.E. Myers, J.M. Collins. A phase I and pharmacokinetic study of carboplatinum (CBDCA) NSC 241240. *Cancer Res.* 43:4470-4473, 1983.
- (27) S. Zimm, J.M. Collins, D. O'Neill, B. Chabner, D.G. Poplack. Inhibition of first-pass metabolism in cancer chemotherapy: the interaction of 6-mercaptopurine and allopurinol. *Clin. Pharmacol. Ther.* 34:810-817, 1983.
- (28) G.A. Curt, J.A. Kelley, C.V. Kufra, B.H. Smith, P.L. Kornblith, R.C. Young, J.M. Collins. A Phase II and pharmacokinetic study of aziridinybenzoquinone (AZQ, diaziquone, NSC 182986) in high grade glioma. *Cancer Res.* 43:6102-6105, 1983.
- (29) E.H. Oldfield, R.L. Dedrick, D.C. Chatterji, R.L. Yeager, M.E. Girton, J.M. Collins, J.L. Doppman, P.L. Kornblith. Reduced systemic drug exposure by combining intracarotid chemotherapy with hemoperfusion of jugular drainage. *Surg. Forum* 34:535-537, 1983.
- (30) J.M. Collins. Pharmacokinetics of intraventricular administration. *J. Neuro-Oncol.* 1:283-290, 1983.
- (31) R.L. Dedrick, E.H. Oldfield, J.M. Collins. Arterial drug infusion with extracorporeal removal. I. Theoretical basis with particular reference to the brain. *Cancer Treat. Rep.* 68: 373-380, 1984.
- (32) R.F. Ozols, B.J. Corden, J. Collins, R.C. Young. High dose cisplatin in hypertonic saline: Renal effects and pharmacokinetics of a 40 mg/m² qd x5 schedule, pp. 321-329 in *Platinum Coordination Complexes in Cancer Chemotherapy*, edited by M.P. Hacker, E.B. Double, I.H. Krakoff. M. Nijhoff, Boston, 1984.
- (33) R.W. Klecker, J.M. Collins. Quantification of tiazofurin in plasma by high-performance liquid chromatography. *J. Chrom./Biomed. Appl.* 307:361-369, 1984.
- (34) T.J. Kinsella, A. Russo, J.B. Mitchell, J. Rowland, J. Jenkins, J. Schwade, C.E. Myers, J.M. Collins, J. Speyer, P. Kornblith, B. Smith, C. Kufra, E. Glatstein. A phase I study of intermittent intravenous bromodeoxyuridine (BUdR) with conventional fractionated irradiation. *Int. J. Radiat. Oncol. Biol. Phys.* 10:69-76, 1984.
- (35) S. Zimm, J.M. Collins, G.A. Curt, D. O'Neill, D.G. Poplack. The cerebrospinal fluid pharmacokinetics of intraventricular and intravenous aziridinybenzoquinone. *Cancer Res.* 44:1698-1701, 1984.
- (36) A. Russo, L. Gianni, T.J. Kinsella, R.W. Klecker, J. Jenkins, J. Rowland, E. Glatstein, J.B. Mitchell, J. Collins, C. Myers. Pharmacological evaluation of intravenous delivery of 5-bromodeoxyuridine to patients with brain tumors. *Cancer Res.* 44:1702-1705, 1984.
- (37) J. M. Collins. Pharmacologic rationale for regional drug delivery. *J. Clin. Oncology* 2:498-504, 1984.
- (38) M. J. Egorin, E. H. Bellis, M. Salcman, J. M. Collins, J. F. Spiegel, N. R. Bachur. The pharmacology of

diaziquone given in intravenous or intracarotid infusion to normal and intracranial tumor-bearing puppies. *J. Neurosurg.* 60:1005-1013, 1984.

- (39) S. Zimm, J. M. Collins, J. Miser, D.C. Chatterji, D. G. Poplack. Cerebrospinal fluid pharmacokinetics of ara-C following intrathecal administration in pediatric patients. *Clin. Pharmacol. Ther.* 35:826-830, 1984.
- (40) J. M. Collins. Therapeutic monitoring of antineoplastic agents. *Cancer Bull.* 36:191-196, 1984.
- (41) I. G. Kerr, S. Zimm, J. M. Collins, D. O'Neill, D. G. Poplack. Effect of intravenous dose and schedule on cerebrospinal fluid pharmacokinetics of 5-fluorouracil in the monkey. *Cancer Res.* 44:4929-4932, 1984.
- (42) J. M. Collins. Pharmacokinetic rationale for intraarterial therapy, In: *Intra-Arterial and Intracavitary Cancer Chemotherapy*, edited by S.B. Howell. M. Nijhoff, Boston, 1985. Pages 1-10.
- (43) J. M. Collins. Pharmacokinetic rationale for intracavitary therapy, In: *Intra-Arterial and Intracavitary Cancer Chemotherapy*, edited by S.B. Howell. M. Nijhoff, Boston, 1985. Pages 41-51.
- (44) B.J.Corden, R. L. Fine, R.F.Ozols, J. M. Collins. Clinical pharmacology of high-dose cisplatin. *Cancer Chemother. Pharmacol.* 14:38-41, 1985.
- (45) J. M. Collins. Pharmacokinetics of 5-fluorouracil infusions in the rat: comparison with man and other species. *Cancer Chemother. Pharmacol.* 14:108-111, 1985.
- (46) S. Zimm, L. Ettinger, J. Holcenberg, B.A.Kamen, T.J.Viotti, J. Belasco, N. Shutta, F. Balis, J.M. Collins, D. G. Poplack. Pediatric phase I and clinical pharmacologic study of mercaptopurine administered as a prolonged intravenous infusion. *Cancer Res.* 45:1869-1873, 1985.
- (47) J.J. Grygiel, F.M. Balis, J.M. Collins, C.M. Lester, D.G. Poplack. Pharmacokinetics of tiazofurin in the plasma and cerebrospinal fluid of rhesus monkeys. *Cancer Res.* 45:2037-2039, 1985.
- (48) R.W. Klecker, J.F. Jenkins, T.J. Kinsella, R.L. Fine, J.M. Strong, J.M. Collins. Clinical pharmacology of 5-iodo-2'-deoxyuridine and iodouracil endogenous pyrimidine modulation. *Clin. Pharmacol. Ther.* 38:45-51, 1985.
- (49) R. W. Klecker, Jr., and J. M. Collins. Quantification of suramin by reverse-phase ion-pairing high-performance liquid chromatography. *J. Liq. Chrom.* 8:1685-1696, 1985.
- (50) G.A.Curt, J.A.Kelley, R.L.Fine, P.N.Huguenin, J.S.Roth, G.Batist, J.Jenkins, J.M.Collins. A Phase I and pharmacokinetic study of dihydro-5-azacytidine (NSC-264880). *Cancer Res.* 45:3359-3363, 1985.
- (51) J.M.Collins and B.J.Corden. Plasma half-life of cisplatin. *Cancer Chemother. Pharmacol.* 15:183-184, 1985. (Letter)
- (52) J.M.Collins and I.G.Kerr. CSF Pharmacology of 5-fluorouracil. *Cancer Res.* 45:3399, 1985. (Letter)
- (53) J.M.Collins, R.Riccardi, P.Trown, D.O'Neill, D.G.Poplack. Plasma and CSF pharmacokinetics of recombinant leucocyte interferon A in monkeys: Comparison of intravenous, intramuscular, and intraventricular delivery. *Cancer Drug Delivery* 2:247-253, 1985.
- (54) T.J.Kinsella, A.Russo, J.B.Mitchell, J.M.Collins, J.Rowland, D.Wright, E.Glatstein. Phase I study of intravenous iododeoxyuridine as a clinical radiosensitizer. *Int. J. Radiat. Oncol. Biol. Phys.* 11:1941-1946, 1985.
- (55) S.Broder, R.Yarchoan, J.M.Collins, H.C.Lane, P.D.Markham, R.W.Klecker, R.R.Redfield, H.Mitsuya, D.F.Hoth, E.Gelmann, J.E.Groopman, L.Resnick, R.C.Gallo, C.E.Myers, A.S.Fauci. Effects of suramin on HTLV-III/LAV infection presenting as Kaposi's sarcoma or AIDS-related complex: clinical pharmacology and suppression of virus replication in vivo. *Lancet* ii:627-630, 1985.
- (56) G.Batist, R.W.Klecker, Jr., H.N.Jayaram, J.F.Jenkins, J.Grygiel, R. Fine, D.C.Ihde, J.L.Eddy, I.G.Kerr, J.M.Collins. Phase I and pharmacokinetic study of tiazofurin (TCAR, NSC 286193) administered by continuous infusion. *Inv. New Drugs* 3:349-356, 1985.

- (57) J.M.Collins. Site-selective and rate-controlled drug delivery by implantable infusion pumps. *Topics in Pharmaceutical Sciences* 1985. Edited by D.D. Breimer and P. Speiser. Elsevier. Amsterdam. pp. 133-141. 1985.
- (58) J.M.Collins. Pharmacologic rationale for hepatic arterial therapy. *Recent Results in Cancer Research* 100:140-147, 1986.
- (59) J.M.Collins, D.S.Zaharko, R.L.Dedrick, B.A.Chabner. Potential roles for preclinical pharmacology in Phase I trials. *Cancer Treat. Rep.* 70:73-80, 1986.
- (60) J.M.Collins, R.W.Klecker, Jr., R.Yarchoan, H.C.Lane, A.S.Fauci, R.R.Redfield, S.Broder, C.E.Myers. Clinical pharmacokinetics of suramin in patients with HTLV-III/LAV infection. *J. Clin. Pharmacol.* 26:22-26, 1986.
- (61) R.L.Dedrick, M.F.Flessner, J.M.Collins, J.S.Schultz. A distributed model of peritoneal transport. *Frontiers in Peritoneal Dialysis*. J. F. Maher and J. F. Winchester, Eds. Field, Rich, and Associates. New York. 1986. pp. 31-36.
- (62) R.Yarchoan, R.W.Klecker, K.J.Weinhold, et al., J.M.Collins, D.P.Bolognesi, C.E.Myers, S.Broder. Administration of 3'-azido-3'-deoxythymidine, an inhibitor of HTLV-III/LAV replication, to patients with AIDS or AIDS-related complex. *Lancet* i:575-580, 1986.
- (63) J.M.Collins. Pharmacokinetic modeling. *Clin. J., North Shore Univ. Hosp.* 9:23-26, 1986.
- (64) J.M.Strong, J.M.Collins, C.M.Lester, D.G.Poplack. Pharmacokinetics of intraventricular and intravenous thiotepa in the rhesus monkey and man. *Cancer Res.* 46:6101-6104, 1986.
- (65) K.Belanger, R.W.Klecker, J.Rowland, T.J.Kinsella, J.M.Collins. Incorporation of iododeoxyuridine into DNA of granulocytes in patients. *Cancer Res.* 46:6509-6512, 1986.
- (66) J.M.Collins. Clinical pharmacokinetics for the pediatric oncologist. In: *The Role of Pharmacology in Pediatric Oncology*. D.G.Poplack, L.Massimo, and P.Cornaglia-Ferraris, Eds. Martinus Nijhoff. Boston. 1987. pp. 3-13.
- (67) J.M.Collins. Regional therapy: an overview. In: *The Role of Pharmacology in Pediatric Oncology*. D.G.Poplack, L.Massimo, and P.Cornaglia-Ferraris, Eds. Martinus Nijhoff. Boston. 1987. pp. 125-135.
- (68) J.M.Collins, C.K.Grieshaber. Role of toxicology in anticancer drug development. *Cancer Topics* 6:38-39, 1987
- (69) A.Sulkes, J.M.Collins. Commentary: a reappraisal of some dosage adjustment guidelines. *Cancer Treat. Rep.* 71:229-233, 1987
- (70) R.W.Klecker, J.M.Collins, R.Yarchoan, R.Thomas, J.F.Jenkins, S.Broder, C.E.Myers. Plasma and cerebrospinal fluid pharmacokinetics of 3'-azido-3'-deoxythymidine: a novel pyrimidine analog with potential application for the treatment of patients with AIDS and related diseases. *Clin. Pharmacol. Ther.* 41:407-412, 1987
- (71) G.A.Curt, J.M.Collins. The clinical pharmacology of infusional chemotherapy. In: *Cancer Chemotherapy by Infusion*, J.J.Lokich, Editor. Precept Press. Chicago. 1987, pp. 35-40.
- (72) F.M.Balis, J.S.Holcenberg, S.Zimm, D.Tubergen, J.M.Collins, R.F.Murphy, G.S.Gilchrist, D.Hammond, D.G.Poplack. The effect of methotrexate on the bioavailability of oral 6-mercaptopurine. *Clin Pharmacol Ther* 41:384-387, 1987
- (73) K.Belanger, J.M.Collins, R.W.Klecker. Technique for detection of DNA nucleobases by reversed-phase high-performance liquid chromatography optimized for quantitative determination of thymidine substitution by iododeoxyuridine. *J. Chrom.* 417:57-63, 1987.
- (74) J.M.Collins, B.Leyland-Jones, C.K.Grieshaber. Role of preclinical pharmacology in Phase I clinical trials: considerations of schedule-dependence. *Concepts in Cancer Chemotherapy*, F.M.Muggia (Ed.) Martinus Nijhoff. Boston. 1987. pp. 129-140.

- (75) J.M.Collins. Prospective predictions and validations in anticancer therapy. Pharmacokinetics in Risk Assessment. Drinking Water and Health, Vol. 8. National Academy Press. Washington, 1987. pp. 431-440.
- (76) J.-G.Park, B.S.Kramer, S.M.Steinberg, J.Carmichael, J.M.Collins, A.F.Gazdar, J.D.Minna. Chemosensitivity testing of human colorectal carcinoma cell lines using of a tetrazolium-based colorimetric assay. *Cancer Res.* 47:5875-5879, 1987.
- (77) J.M.Collins. Pharmacology and Drug Delivery Systems. In: *Infusion Systems In Medicine*, W.D.Ensminger, J.-L.Selam, Ed., Futura Publishing Co., Mt. Kisco, New York, 1987. pp. 3-18.
- (78) D.Jackson, T.Kinsella, J.Rowland, D.Wright, D.Katz, D.Main, J.Collins, P.Kornblith, E.Glatstein. Halogenated pyrimidines as radiosensitizers in the treatment of glioblastoma multiforme. *Am J Clin Oncol* 10:437-443, 1987
- (79) R.Yarchoan, R.V.Thomas, M.A.Fischl, et al., J.M.Collins, et al., S.Broder. Treatment of human immunodeficiency virus-associated neurological disease with 3'-azido-2',3'-dideoxythymidine. In: *Human Retroviruses, Cancer, and AIDS*. D.Bolognesi, Ed. A.R.Liss, Inc. New York. 1987. pp. 393-406.
- (80) T.J.Kinsella, J.M.Collins, J.Rowland, R.Klecker, D.Wright, D.Katz, S.Steinberg, E.Glatstein. Pharmacology and Phase I/II study of continuous intravenous infusions of iododeoxyuridine (IdUrd) and hyperfractionated radiotherapy in patients with glioblastoma multiforme. *J. Clin. Oncol.* 6:871-879, 1988.
- (81) R.Yarchoan, C.F.Perno, R.V.Thomas, et al., J.M.Collins, C.E.Myers, S.Broder. Phase I studies of 2',3'-dideoxycytidine in severe human immunodeficiency virus infection as a single agent and alternating with zidovudine (AZT). *Lancet* i:76-81, 1988.
- (82) P.A.J.Speth, T.J.Kinsella, K.Belanger, R.W.Klecker, Jr., R.Smith, J.B.Rowland, J.M.Collins. Fluorodeoxyuridine modulation of the incorporation of iododeoxyuridine into DNA of granulocytes: a Phase I and clinical pharmacologic study. *Cancer Res.* 48:2933-2937, 1988.
- (83) J.M.Collins. Pharmacology and drug development (Editorial). *J. Natl. Cancer Inst.* 80:790-792, 1988.
- (84) J. M. Collins, R. W. Klecker, Jr., J. A. Kelley, J. S. Roth, C. L. McCully, F. M. Balis, D.G.Poplack. Pyrimidine dideoxyribonucleosides: selective penetration into cerebrospinal fluid. *J Pharmacol Exp Ther* 245:466-470, 1988
- (85) J. M. Collins. Improving the use of anticancer drugs: clinical pharmacokinetic approaches. *Israel J. Med. Sci.* 24:483-487, 1988.
- (86) R.W. Klecker, Jr., J.M. Collins, R.C.Yarchoan, R.Thomas, N.McAtee, S.Broder, C.E.Myers. Pharmacokinetics of 2',3'-dideoxycytidine in patients with AIDS and related disorders. *J. Clin. Pharmacol.* 28:837-842, 1988.
- (87) P.A.J. Speth, T.J. Kinsella, A.E. Chang, R.W. Klecker, Jr., K. Belanger, and J.M. Collins. Selective incorporation of iododeoxyuridine into DNA of hepatic metastases versus normal human liver. *Clin Pharmacol Ther* 44:369-375, 1988
- (88) R.B.Weiss, R.F.Greene, R.D.Knight, J.M.Collins, J.J.Pelosi, A.Sulkes, G.A.Curt. Phase I and clinical pharmacology study of flavone acetic acid (NSC 347512). *Cancer Res.* 48:5878-5882, 1988.
- (89) J.-G.Park, J.M.Collins, A.F.Gadzar, C.J.Allegra, S.M.Steinberg, R.F.Greene, B.S.Kramer. Enhancement of fluorinated pyrimidine-induced cytotoxicity by leucovorin in human colorectal carcinoma cell lines. *J. Natl. Cancer Inst.* 80:1560-1564, 1988.
- (90) A.E. Chang, J.M. Collins, P.A.J. Speth, R.Smith, J.B. Rowland, L.Campbell, M.G. Begley, E. Glatstein, T.J. Kinsella. Phase I study of intraarterial iododeoxyuridine in patients with colorectal liver metastases. *J. Clin. Oncol.* 7:662-668, 1989.
- (91) P. A. Speth, T. J. Kinsella, A. E. Chang, R W. Klecker, Jr., K. Belanger, R. Smith, J. Rowland, J. E. Cupp, J. M. Collins. Iododeoxyuridine (IdUrd) incorporation into DNA of human hematopoietic cells, normal liver, and hepatic metastases in man: its application as a radiosensitizer and as a marker for cell kinetic studies. *Int. J. Radiat. Oncol. Biol. Phys.* 16:1247-1250, 1989.

- (92) J.M. Collins and J. Unadkat. Zidovudine pharmacokinetics. *Clin. Pharmacokin.* 17:1-9, 1989.
- (93) A. Elias, L. Ryan, A. Sulkes, J. Collins, J. Aisner, K. H. Antman. Response to mesna, adriamycin, ifosfamide and dacarbazine (DTIC): 108 patients with no prior chemotherapy for metastatic or unresectable sarcoma. *J. Clin. Oncol.* 7:1208-1216, 1989.
- (94) K.J. Lorentsen, C.W. Hendrix, J.M. Collins, D.M. Kornhauser, B.G. Petty, R.W. Klecker, C.Flexner, R.H. Eckel, P.S. Lietman. Dextran sulfate is poorly absorbed after oral administration. *Ann Int Med* 111:561-566, 1989
- (95) J. M. Collins. Pharmacology of infusional therapies. In: *Update in Drug Delivery Systems*, Ensminger WD, J.-L. Selam (Ed). Futura Publishing Company, Mt. Kisco, N.Y. pp. 3-12. 1989.
- (96) J.M. Collins. Pharmacokinetic rationale for intraarterial therapy. In: *Cancer Chemotherapy. Challenges for the Future, Volume 4.* K. Kimura et al (Eds). Excerpta Medica. Tokyo. pp. 3-10. 1989.
- (97) J.M. Collins. Pharmacokinetics and clinical monitoring. In: *Cancer Chemotherapy: Principles and Practice.* Chabner BA, Collins JM (Eds). Lippincott. Philadelphia. pp. 16-31. 1990.
- (98) C.C. Peck, J.M. Collins. First time in man studies: a regulatory perspective--art and science of Phase I trials. *J. Clin. Pharmacol.* 30:218-222, 1990.
- (99) L.Gianni, L.Vigano, A.Surbone, D.Ballinari, P.Casali, C.Tarella, J.M.Collins, G.Bonadonna. Pharmacology and clinical toxicity of 4'-iodo-4'-deoxydoxorubicin: an example of successful application of pharmacokinetics to dose escalation in Phase I trials. *J. Natl. Cancer Inst.* 82:469-477, 1990.
- (100) M.M. Ames, C. Loprinzi, J.M. Collins, C. van Haelst-Pisani, R.L. Richardson, J. Rubin, C.G. Moertel. Phase I and clinical pharmacologic evaluation of pirozantrone hydrochloride (oxantrazole). *Cancer Res.* 50:3905-3909, 1990.
- (101) J.M. Collins, C.K. Grieshaber, B.A. Chabner. Pharmacologically-guided Phase I trials based upon preclinical development. *J. Natl. Cancer Inst.* 82:1321-1326, 1990.
- (102) R.F. Greene, J.M. Collins. Effects of leucovorin on idoxuridine cytotoxicity and DNA incorporation. *Cancer Res.* 50:6652-6656, 1990.
- (103) E.M. Voisin, M. Ruthsatz, J.M. Collins, E.C. Cooper, P.C. Hoyle. Extrapolation of animal toxicity data to humans: interspecies comparisons in drug development. *Regul. Toxicol. Pharmacol.* 12:107-116, 1990.
- (104) G.A. Curt, J.M. Collins. The clinical pharmacology of infusional chemotherapy. In: *Cancer Chemotherapy by Infusion, Second Edition*, J.J. Lokich, Editor. Precept Press. Chicago. 1990. pp 35-41.
- (105) J.M. Collins. Pharmacokinetic aspects of arterial fluoropyrimidine delivery. *Annals N.Y. Acad. Sci.* 618:345-349 1991.
- (106) L.W.Anderson, R.J.Parker, J.M.Collins, J.D.Ahlgren, D.Wilkinson, J.M.Strong. Gas chromatographic-mass spectrometric method for routine monitoring of 5-fluorouracil in plasma of patients receiving low-level protracted infusions. *J Chromatogr* 581:195-201, 1992.
- (107) C.C.Peck, W.H.Barr, L.Z.Benet, J.Collins, R.E.Desjardins, et al. Opportunities for integration of pharmacokinetics, pharmacodynamics, and toxicokinetics in rational drug development. *Pharm Res* 9:826-33, 1992. Co-published in: *J Pharm Sci* 81:605-10, 1992; *Int J Pharm* 82:9-19, 1992; *Clin Pharmacol Ther* 51:465-73, 1992.
- (108) J.M.Collins. Dose Levels: Role of Pharmacokinetics/Exposure. In: *The Carcinogenicity Debate.* J.A.N.McAuslane, C.E.Lumley, S.R.Walker, Eds. Quay Publishing. London. pp. 153-158. 1992.
- (109) J.M.Collins. Use of pharmacokinetics and pharmacodynamics in preclinical studies to guide dosage escalation schemes in Phase I studies of anticancer drugs. In: *Integration of Pharmacokinetics, Pharmacodynamics, and Toxicokinetics in Rational Drug Development.* A.Yacobi, J.P.Skelly, V.P.Shah, L.Z.Benet, Eds. Plenum. New York. pp. 49-53. 1993.

- (110) A.D. Seidman, L. Norton, B.S. Reichman, J.P.A. Crown, T.J. Yao, R. Heelan, T.B. Hakes, D.E. Lebwohl, T.A. Gilewski, A. Surbone, V. Currie, C.A. Hudis, R. Klecker, C. Jamis-Dow, J.Collins, S.Quinlivan, R. Berkery, F. Toomasi, R. Canetta, J. Fisherman, S. Arbuck. Preliminary experience with paclitaxel (Taxol[®]) plus recombinant human granulocyte colony-stimulating factor in the treatment of breast cancer. *Semin Oncol* 20:40-45, 1993.
- (111) C.C.Peck, R.Temple, J.M.Collins. Understanding consequences of concurrent therapies. *J Amer Med Assoc* 269:1550-1552, 1993.
- (112) C.A.Jamis-Dow, R.W.Klecker, G.Sarosy, E.Reed, J.M.Collins. Steady-state plasma concentrations and effects of taxol for a 250 mg/sq.m dose in combination with granulocyte-colony stimulating factor in patients with ovarian cancer. *Cancer Chemother Pharmacol* 33:48-52, 1993.
- (113) B.S.Reichman, A.D.Seidman, J.P.A.Crown, R.Heelan, T.B.Hakes, D. E.Lebwohl, T.A.Gilewski, A.Surbone, V.Currie, C.A.Hudis, T.J.Yao, R.Klecker, C.Jamis-Dow, J.Collins, S.Quinlivan, R.Berkery, F.Toomasi, R.Canetta, J.Fisherman, S.Arbuck, L.Norton. Paclitaxel and recombinant human granulocyte colony-stimulating factor as initial chemotherapy for metastatic breast cancer. *J Clin Oncol* 11:1943-1951, 1993.
- (114) C.C.Peck, R.J.Temple, J.M.Collins. Drug interactions: the death pen [Letter]. *JAMA* 270:1317, 1993.
- (115) A.D. Seidman, B.S. Reichman, J.P.A. Crown, T.J. Yao, R. Heelan, T.B. Hakes, D.E. Lebwohl, T.A. Gilewski, A. Surbone, V. Currie, C.A. Hudis, R. Klecker, C. Jamis-Dow, J.Collins, S. Quinlivan, R. Berkery, F. Toomasi, R. Canetta, L.Norton. Taxol plus recombinant human granulocyte-colony stimulating factor as initial and as salvage chemotherapy for metastatic breast cancer: a preliminary report. *Monogr Natl Cancer Inst* 15:171-175, 1993
- (116) J.W.Harris, A.Katki, L.W.Anderson, G.N.Chmurny, J.V.Paukstelis, J.M.Collins. Isolation, Structural Determination, and Biological Activity of 6-alpha-Taxol, the Principal Human Metabolite of Taxol. *J Med Chem* 37:706-709, 1994.
- (117) J.G.Dain, J.M.Collins, W.T.Robinson. A regulatory and industrial perspective on the use of carbon-14 and tritium isotopes in human ADME studies. *Pharmaceutical Res* 11:925-928, 1994.
- (118) R.W.Klecker, C.A.Jamis-Dow, M.J.Egorin, K.Erkmen, R.J.Parker, R.Stevens, J.M.Collins. Effect of cimetidine, probenecid, and ketoconazole on the distribution, biliary secretion and metabolism of 3H-taxol in the Sprague-Dawley rat. *Drug Metab Dispos* 22:254-258, 1994.
- (119) J.W.Harris, A.Rahman, B.-R.Kim, F.P.Guengerich, J.M.Collins. Metabolism of taxol by human hepatic microsomes and liver slices: Participation of cytochrome P450 3A4 and an unknown P450 enzyme. *Cancer Res* 54:4026-4035, 1994.
- (120) R.W.Klecker, A.G.Katki, J.M.Collins. Toxicity, metabolism, DNA incorporation with lack of repair, and lactate production of 1-(2'-fluoro-2'-deoxy-B-D-arabinofuranosyl)-5-iodouracil (FIAU) in U-937 and MOLT-4 cells. *Mol Pharmacol* 46:1204-1209, 1994.
- (121) A.D. Seidman, L. Norton, B.S. Reichman, J.P.A. Crown, T.J. Yao, T.B. Hakes, D.E. Lebwohl, T.A. Gilewski, C.A.Hudis, A.Surbone, V. Currie, R. Klecker, C. Jamis-Dow, J.Collins, L.Marks, S Quinlivan, R. Berkery, R. Canetta, N.Onetto, S.Arbuck. Taxol (paclitaxel) plus recombinant human granulocyte colony-stimulating factor in the treatment of breast cancer. *Oncology* 51(Suppl 1):33-39, 1994.
- (122) L.K.Ludden, J.M.Strong, E.C.Kohn, J.M.Collins. Similarity of metabolism for CAI in human liver tissue in vitro and in humans in vivo. *Clinical Cancer Res* 1:399-405, 1995.
- (123) C.A.Jamis-Dow, R.W.Klecker, A.G.Katki, J.M.Collins. Metabolism of taxol by human and rat liver in vitro: A screen for drug interactions and interspecies differences. *Cancer Chemother Pharmacol* 36:107-114, 1995.
- (124) J.M.Collins. Pharmacokinetics and Clinical Monitoring. In: *Cancer Chemotherapy and Biotherapy*. B.A.Chabner and D.L.Longo, eds. Lippincott-Raven. Philadelphia. pp. 17-29. 1996.
- (125) N.R.Hartman, S.O'Reilly, E.K.Rowinsky, J.M.Collins, J.M.Strong. Murine and human in vivo penclomedine metabolism. *Clin Cancer Res* 2:953-962, 1996.

- (126) J.M.Collins, R.W.Klecker, A.E.Chang, T.J.Kinsella. Incorporation of IUdR and BUdR into DNA [Letter]. *Cancer Res* 56:2677-78, 1996.
- (127) L.W.Anderson, T.-L. Chen, O.M.Colvin, L.B.Grochow, J.M.Collins, M.J.Kennedy, J.M.Strong. Cyclophosphamide and 4-hydroxy-cyclophosphamide/aldophosphamide kinetics in patients receiving high-dose cyclophosphamide chemotherapy. *Clin Cancer Res* 2:1481-1487, 1996.
- (128) R.J.Parker, J.M.Collins, J.M.Strong. Identification of 2,6-xylidine as a major lidocaine metabolite in human liver slices. *Drug Metab Disposit* 24:1167-73, 1996.
- (129) M.E.Fitzsimmons, J.M.Collins. Selective biotransformation of the HIV protease inhibitor saquinavir by human small intestinal cytochrome P450 3A4: potential contribution to high first-pass metabolism, *Drug Metab Disposit* 25:256-266, 1997.
- (130) C.B.Trapnell, C.Jamis-Dow, R.W.Klecker, J.M.Collins. Metabolism of rifabutin and its 25-desacetyl metabolite, LM565, by human liver microsomes and recombinant human cytochrome P450 3A4: relevance to clinical interactions with fluconazole. *Antimicrob Agents Chemother* 41:924-26, 1997.
- (131) L.K.Ludden, T.M.Ludden, J.M.Collins, H.S.Pentakis, J.M.Strong. Effect of albumin on the estimation, in vitro, of phenytoin Vmax and Km values: Implications for clinical correlation. *J Pharmacol Exp Ther* 282:391-96, 1997.
- (132) R.W.Klecker, J.M.Collins. Stereoselective metabolism of fenoldopam and its metabolites in human liver microsomes, cytosol, and slices. *J Cardiovascular Pharmacol* 30:69-74, 1997.
- (133) R.Simon, B.Freidlin, L.Rubinstein, S.G.Arbus, J.Collins, M.C.Christian. Accelerated titration designs for Phase I clinical trials in oncology. *JNCI* 89:1138-47, 1997.
- (134) C.A.Jamis-Dow, M.L.Pearl, P.B.Watkins, D.S.Blake, R.W.Klecker, J.M.Collins. Predicting drug interactions in vivo from experiments in vitro: human studies with paclitaxel and ketoconazole. *Amer J Clin Oncol* 29:592-9, 1997
- (135) D.E.Moody, M.E.Alburges, R.J.Parker, J.M.Collins, J.M.Strong. The involvement of cytochrome P450 3A4 in the N-demethylation of l-alpha-acetylmethadol (LAAM), norLAAM, and methadone. *Drug Metab Disposit* 25:1347-53, 1997.
- (136) C.Jamis-Dow, A.G.Katki, J.M.Collins, R.W.Klecker. Rifampin and rifabutin are metabolized by human liver esterases. *Xenobiotica* 27:1015-24, 1997.
- (137) J.M.Collins. Foreword. In, *Drug-Drug Interactions: Scientific and Regulatory Perspectives*. A.P.Li, Editor. Academic Press. San Diego. pp. xv-xvi, 1997.
- (138) T.J.Kinsella, K.A.Kunugi, K.A.Vielhuber, D M Potter, M.E.Fitzsimmons, J.M.Collins. Preclinical evaluation of 5-iodo-2'-deoxyribose (IPdR) as a prodrug for IUdR-mediated radiosensitization in mouse and human tissues. *Clin Cancer Res* 4:99-109, 1998.
- (139) C.B.Trapnell, C.Jamis-Dow, R.W.Klecker, J.M.Collins. Glucuronidation of 3'-azido-3'-deoxythymidine (zidovudine) by human liver microsomes: relevance to clinical pharmacokinetic interactions with atovaquone, fluconazole, methadone, and valproic acid. *Antimicrob Agents Chemother* 42: 1592-1596, 1998.
- (140) C.B.Trapnell, S.R.Donahue, J.M.Collins, D.A.Flockhart, D.Thacker, D.R.Abernethy. Thalidomide does not affect the pharmacokinetics of ethinyl estradiol and norethindrone. *Clin Pharmacol Ther* 64:597-602, 1998.
- (141) J.M. Collins, A.Katki, R.W.Klecker. Suicide prodrugs activated by thymidylate synthase: rationale for treatment and noninvasive imaging of tumors with deoxyuridine analogs. *Clin Cancer Res* 5: 1976-81, 1999.
- (142) A.P.Li, N.R.Hartman, C.Lu, J.M.Collins, J.M.Strong. Effects of cytochrome P450 inducers on 17 β -ethynylestradiol (EE2) conjugation by primary human hepatocytes. *Brit J Clin Pharmacol* 48:733-42, 1999.

- (143) F.Shtern, D.Winfield, J.M.Collins, W.C.Eckelman, J.L.Evelhoch, M.S.Feld, S.E.Harms, R.K.Jain, S.Lam, J.L.Mulshine, R.L.Wahl, J.N.Weinstein. Report of the Joint Working Group on Quantitative In Vivo Functional Imaging in Oncology. *Academic Radiology* 6:Suppl.6:S259-S300, 1999.
- (144) J.M.Collins. Prediction of drug interactions from in vitro studies: Regulatory Viewpoint. In: *Metabolic Drug Interactions*. R.H.Levy, K.E.Thummel, W.F.Trager, P.Hansten, M.Eichelbaum, Eds. Lippincott-Raven, Philadelphia. 2000. pp. 41-47.
- (145) J.M.Collins. Cytochrome P-450 and other determinants of pharmacokinetics, toxicity, and efficacy in humans. *Clin Cancer Res* 6:1203-04, 2000.
- (146) J.M.Collins. Innovations in phase 1 trial design: where do we go next? *Clin Cancer Res* 6: 3801-2, 2000
- (147) N.R.Cutler, P.Chaikin, D.J.Greenblatt, J.Collins. Defining the maximum tolerated dose – an update. *J Clin Pharmacol* 40:1183-1204, 2000.
- (148) J.T.MacGregor, J.M.Collins, Y.Sugiyama, C.A.Tyson, et al. In vitro human tissue models in risk assessment : report of a consensus-building workshop. *Toxicol Sci* 59:17-36, 2001.
- (149) J.M.Collins. Inter-species differences in drug properties. *Chemico-Biological Interactions*. 134:237-42, 2001.
- (150) S.A.Cherstniakova, D.Bi, D.R.Fuller, J.Z.Moisiak, J.M.Collins, L.R.Cantilena. Metabolism of vanoxerine, 1-[2-[bis(4-fluorophenyl)methoxy]ethyl]-4-(3-phenylpropyl)piperazine by human cytochrome P450 enzymes. *Drug Metab Dispos* 29:1216-20, 2001.
- (151) J.M.Collins. Phase 1 clinical trials. In: *Principles of Clinical Pharmacology*. A.Atkinson, Ed. Academic Press. San Diego. pp. 395-400. 2001.
- (152) S.O'Reilly, N.R.Hartman, K.Bowling, E.Rowinsky, R.C.Donehower, J.Collins, J.Strong. Bioavailability of penclomedine and systemic exposure to 4-O-demethylpenclomedine in patients receiving oral and intravenous penclomedine. *Cancer Chemother Pharmacol* 48:223-28, 2001.
- (153) J.M.Collins. Pharmacokinetics and Clinical Monitoring. In: *Cancer Chemotherapy and Biotherapy*. B.A.Chabner and D.L.Longo, eds. Lippincott Williams & Wilkins. Philadelphia. pp. 37-49. 2001.
- (154) R.W.Klecker, J.M.Collins. Thymidine phosphorylase as a target for imaging and therapy with thymine analogs. *Cancer Chemother Pharmacol* 48:407-412, 2001.
- (155) J.M.Collins. Understanding metabolic drug interactions: from occasional curiosity to routine practical applications. In: *Preclinical and Clinical Evaluation of Drug-Drug Interactions*. Advances in Drug Development A.Li, Y.Sugiyama, Eds. ISE Press. St.Louis. pp. 95-107. 2002.
- (156) H.T.Ravert, R.W.Klecker, Jr., J.Collins, W.B.Mathews, M.Pomper, R.Wahl, R.F.Dannals. Radiosynthesis of [¹¹C]paclitaxel. *J Labelled Compounds and Radiopharm* 45:471-477, 2002
- (157) J.M.Collins. PET imaging and cancer. In: *Encyclopedia of Cancer*, 2nd Edition. J.S. Bertino, Ed. Vol. 3, pp. 419-424. Academic Press. San Diego. 2002.
- (158) J.M.Collins, R.W.Klecker, Jr. Evaluation of highly bound drugs: interspecies, intersubject, and related comparisons. *J Clin Pharmacol* 42:971-75, 2002.
- (159) J.M.Collins. PET and drug development. In: *Principles and Practice of Positron Emission Tomography*. R.L.Wahl, Editor. pp. 411-419. Lippincott, Williams & Wilkins. Philadelphia. 2002.
- (160) J.M.Collins. Idiosyncratic drug toxicity. *Chemico-Biological Interactions* 142: 3-6, 2002
- (161) H.Sun, J.M.Collins, T.J.Mangner, O.Muzik, A.F.Shields. Imaging [¹⁸F]FAU [1-(2'-deoxy-2'-fluoro-beta-D-arabinofuranosyl) uracil] in dogs. *Nuclear Med Biol* 30:25-30, 2003

- (162) L.J.Lesko, R.A.Salerno, B.B.Spear, D.C.Anderson, T.Anderson, C.Brazell, J.Collins, A.Dorner, D.Essayan, B.Gomez-Mancilla, J.Hackett, S.M.Huang, S.Ide, J.Killinger, J.Leighton, E.Mansfield, R.Meyer, S.G.Ryan, V.Schmith, P.Shaw, F.Sistare, M.Watson, A.Worobec. Pharmacogenetics and pharmacogenomics in drug development and regulatory decision making: report of the first FDA-PWG-PhRMA-DruSafe Workshop. *J Clin Pharmacol* 43:342-58, 2003
- (163) J.M.Collins. Functional imaging in phase I studies: decorations or decision-making? *J Clin Oncol* 21:2807-9, 2003
- (164) J.M.Collins, M.J.Egorin. Measurements of endpoints in phase 1 drug design: toxicity versus alternatives. In: *Handbook of Anticancer Drug Development*. Budman D, Calvert AH, Rowinsky E., Eds. Lippincott, Williams, and Wilkins. Philadelphia. pp. 319-329. 2003
- (165) R.K.Benjamin, F.H.Hochberg, E.Fox, P.M.Bungay, W.F.Elmquist, C.F.Stewart, J.M.Gallo, J.M.Collins, R.P.Pelletier, J.F.deGroot, R.C.Hickner, I.Cavus, S.A.Grossman, O.M.Colvin. Microdialysis in brain tumors: from concept to application. *Neuro-oncology* 6:65-74, 2004
- (166) G.Ruaño, J.M.Collins, A.J.Dorner, S.-J.Wang, R.Guerciolini, S.-M.Huang. Pharmacogenomic Data Submissions to FDA: Clinical Pharmacology Case Studies. *Pharmacogenomics* 5:513-517, 2004
- (167) J.L.Eiseman, C.Brown-Proctor, P.Kinahan, J.M.Collins, L.Anderson, E.Joseph, D.R.Hamburger, S.-S.Pan, C.A.Mathis, M.J.Egorin, R.W.Klecker. Distribution of 1-(2-deoxy-2-fluoro-beta-D-arabinofuranosyl) uracil in colorectal cancer xenografts: rationale for therapeutic use and as a positron emission tomography probe for thymidylate synthase. *Clin Cancer Res* 10:6669-6676, 2004
- (168) L.R.Cantilena, A.G.Katki, R.W.Klecker, J.M.Collins. Metabolism by N-Acetyltransferase 1 In Vitro and in Healthy Volunteers: A Prototype for Targeted Inhibition. *J Clin Pharmacol* 44:1405-1411, 2004
- (169) H.Sun, A.Sloan, T.J.Mangner, U.Viashampayan, O.Muzik, J.M.Collins, K.Douglas, A.F.Shields. Imaging DNA synthesis with [F-18]FMAU and positron emission tomography in patients with cancers. *Eur J Nuc Med* 32:15-22, 2005
- (170) H.Sun, T.J.Mangner, J.M.Collins, O.Muzik, K.Douglas, A.F.Shields. Imaging DNA synthesis in vivo with [F-18]FMAU and positron emission tomography. *J Nucl Med* 46:292-296, 2005
- (171) L.W.Anderson, J.M.Collins, R.W.Klecker, A.G.Katki, R.Parchment, R.Boinpally, P.M.LoRusso, S.P.Ivy. Metabolic profile of XK469 (2(R)-[4-(7-chloro-2-quinoxalinyloxy)phenoxy]-propionic acid; NSC698215) in patients and in vitro: low potential for active or toxic metabolites or for drug-drug interactions. *Cancer Chemother Pharmacol* 56:351-357, 2005
- (172) J.M.Collins. Imaging and Other Biomarkers in Early Clinical Studies: One Step at a Time, or Re-Engineering Drug Development? *J Clin Oncol* 23:5417-5419, 2005
- (173) A.F.Shields, D.Briston, S.Chandupatla, K.A.Douglas, J.Lawhorn-Crews, B.S., J.M. Collins T.J.Mangner, L.K.Heilbrun, O.Muzik. A simplified analysis of [F-18] 3'-deoxy-3'-fluorothymidine metabolism and retention. *Eur J Nuc Med* 32:1269-1275, 2005
- (174) S.Nimmagadda, T.J.Mangner, H.Sun, R.W.Klecker Jr, O.Muzik, J.M.Lawhorn-Crews, K.A.Douglas, J.M.Collins, A.F.Shields. Biodistribution and radiation dosimetry estimates of (1-(2'-deoxy-2'-[18F] fluoro-1-beta-D-arabinofuranosyl)-5-bromouracil): PET imaging studies in dogs. *J Nucl Med* 46:1916-1922, 2005
- (175) J.Collins, J.G.Supko. Pharmacokinetics. In: *Cancer Chemotherapy and Biotherapy*. B.A.Chabner and D.L.Longo, Editors, 4th edition. Lippincott Williams & Wilkins. Philadelphia. 2006 pp. 31-44
- (176) R.W.Klecker, R.L.Cysyk, J.M.Collins. Zebularine metabolism by aldehyde oxidase in hepatic cytosol from humans, monkeys, dogs, rats, and mice: Influence of sex and inhibitors. *Biorg Med Chem* 14:62-66, 2006
- (177) H.Sun, J.M.Collins, T.J.Mangner, O.Muzik, A.F.Shields. Imaging the pharmacokinetics of [F-18]FAU in patients with tumors: PET studies. *Cancer Chemother Pharmacol* 57:343-348, 2006
- (178) J.M.Collins. The NCI Developmental Therapeutics Program. *Clinical Adv Hematol Oncol*. 4:271-3, 2006

- (179) J.M.Collins. Phase 1 clinical trials. In: Principles of Clinical Pharmacology, Second Edition. A.Atkinson, Ed. Elsevier. Burlington, MA. pp. 473-478. 2006
- (180) S.Kummar, R.Kinders, L.Rubenstein, R.Parchment, A.Murgo, J.Collins, O.Pickeral, J.Low, S.Steinberg, M.Gutierrez, S.Yang, L.Helman, R.Wiltrout, J.Tomaszewski, J.H.Doroshov. Compressing drug development timelines in oncology using phase '0' trials. *Nature Reviews Cancer* 7:131-9, 2007
- (181) Y.H.Ryu, J.-S.Liow, S.Zoghbi, M.Fujita, J.Collins, D.Type, J.Sangare, J.Hong, V.W.Pike, R.B.Innis. Disulfiram inhibits defluorination of [18F]FCWAY, reduces bone radioactivity, and enhances visualization of radioligand binding to serotonin 5-HT1A receptors in human brain.. *J Nucl Med* 48:1154-61, 2007
- (182) R.Kinders, R.E.Parchment, J.Ji, S.Kummar, A.J.Murgo, M.Gutierrez, J.Collins, L.Rubenstein, O.Pickeral, S.M.Steinberg, S.Yang, M.Hollingshead, A.Chen, L.Helman, R.Wiltrout, M.Simpson, J.E.Tomaszewski, J.H.Doroshov. Phase 0 clinical trials in cancer drug development: from FDA guidance to clinical practice. *Molecular Interventions* 7:325-334, 2007
- (183) J.M.Collins. Pharmacokinetics, Pharmacodynamics, and Pharmacogenetics. *The Molecular Basis of Cancer*, Third Edition. J. Mendelsohn et al, Eds. pp. 547-552. Saunders/Elsevier. Philadelphia. 2008
- (184) R.S.Uppoor, P.Mummaneni, E.Cooper, H.H.Pien, A.G.Sorensen, J.Collins, M.U.Mehta, S.U.Yasuda. The use of imaging in early development of neuropharmacological drugs: a survey of approved NDAs. *Clin Pharmacol Ther* 84:69-74, 2008
- (185) S.Kummar, L.Rubenstein, R.Kinders, R.E.Parchment, M.E.Gutierrez, A.J.Murgo, J.Ji, B.Mroczkowski, O.K.Pickeral, M.Simpson, M.Hollingshead, S.X.Yang, L.Helman, R.Wiltrout, J.Collins, J.E.Tomaszewski, J.H.Doroshov. Phase 0 Clinical Trials: Conceptions and Misconceptions.*Cancer J* 14:133-137, 2008
- (186) J.M.Collins. PET and drug development. In: Principles and Practice of Positron Emission Tomography, 2nd Ed.. R.L.Wahl, Editor. pp. 634-643. Wolters Kluwer, Lippincott, Williams & Wilkins. Philadelphia. 2008
- (187) A.J.Murgo, S.Kummar, L.Rubenstein, M.Gutierrez, J.Collins, R.Kinders, R.E.Parchment, J.Ji, S.M.Steinberg, S.X.Yang, M.Hollingshead, A.Chen, L.Helman, R.Wiltrout, J.E.Tomaszewski, J.H.Doroshov. Designing Phase 0 Cancer Clinical Trials. *Clin Cancer Res* 14:3675-82, 2008.
- (188) J.M.Collins. Phase 0 clinical studies in oncology. *Clin Pharmacol Ther* 85:204-7, 2009
- (189) S.Kummar, R.Kinders, M.E.Gutierrez, L.Rubenstein, R.E.Parchment, L.R.Phillips, J.Ji, A.Monks, J.A.Low, A.Chen, A.J.Murgo, J.Collins, S.M.Steinberg, H.Eliopoulos, V.L.Giranda, G.Gordon, L.Helman, R.Wiltrout, J.E.Tomaszewski, J.H.Doroshov, Phase 0 clinical trial of the poly (ADP-ribose) polymerase (PARP) inhibitor ABT-888 in patients with advanced malignancies. *J Clin Oncol* 27:2705-2711, 2009
- (190) S.Holbeck, J.M.Collins, J.H.Doroshov. Analysis of Food and Drug Administration–Approved Anticancer Agents in the NCI60 Panel of Human Tumor Cell Lines *Mol Cancer Ther* 9:1451-60, 2010
- (191) S.Kummar, H.Chen, J.Wright, S.Holbeck, M.Davis Millin, J.Tomaszewski, J.Zweibel, J.Collins, JH. Doroshov. Utilizing targeted cancer therapeutic agents in combination: novel approaches and urgent requirements. *Nature Rev Drug Develop* 9:843-856, 2010
- (192) M.J.Ratain, J.M.Collins, J.H.Doroshov. Merrill Jon Egorin, MD, 1948–2010. *Clin Pharmacol Ther* 89:163-165, 2011
- (193) J.Collins, J.G.Supko. Principles of Pharmacokinetics. In: *Cancer Chemotherapy and Biotherapy*. B.A.Chabner and D.L.Longo, Editors, 5th edition. Lippincott Williams & Wilkins. pp. 50-61, 2011
- (194) S.Kummar, M.E.Gutierrez, A.Chen, I.B.Turkbey, D.Allen, Y.R.Horneffer, L.Juwara, L.Cao, Y.Sang Kim, J.Trepel, H.Chen, P.Choyke, G.Melillo, A.J.Murgo, J.Collins, J.H.Doroshov. Phase I Trial of Vandetanib and Bevacizumab Evaluating the VEGF and EGF Signal Transduction Pathways in Adults With Solid Tumors and Lymphomas. *Eur J Cancer* 47:997-1005, 2011.

- (195) G.Speranza, M.Gutierrez, S.Kummar, J.Strong, R.Parker, J.Collins, Y.Yu, L.Cao, A.Murgo, J.Doroshov, A. Chen. Phase I Study of the Synthetic Triterpenoid, 2-Cyano-3, 12-Dioxoolean-1, 9-Dien-28-Oic Acid (CDDO), in Advanced Solid Tumors. *Cancer Chemother Pharmacol* 69:431-438, 2012
- (196) J.M.Collins. Phase 1 clinical trials. pp.541-546 In: *Principles of Clinical Pharmacology*, Third Edition. A.Atkinson, Editor. Elsevier. Burlington, MA, 2012
- (197) S.Kummar, L.Anderson, K.Hill, E.Majerova, D. Allen, Y.Horneffer, S. P.Ivy, L.Rubinstein, P.Harris, J.H. Doroshov, J.M.Collins. First-in-Human Phase 0 Trial of Oral 5-iodo-2-pyrimidinone-2'-deoxyribose (IPdR) in patients with Advanced Malignancies. *Clin Cancer Res* 19:1852-1857, 2013
- (198) S.R.Park, G.Speranza, R.Piekarz, J.Wright, R.J.Kinders, L.Wang, P.Balasubramania, J.B.Trepel, M.-J.Lee, S.Alarcon, S.M.Steinberg, J.Collins, J.H Doroshov, S.Kummar. A multi-histology trial of fostamatinib disodium (R935788) in patients with advanced colorectal, non-small cell lung, head and neck, thyroid, hepatocellular and renal cell carcinomas, and pheochromocytomas. *Cancer Chemother Pharmacol* 71:981-990, 2013
- (199) J.M.Collins. *Pharmacology of Anticancer Drugs*. Abeloff's *Textbook of Clinical Oncology*. Fifth Edition. J.Niederhuber et al, Editors. Elsevier. pp.434-484, 2013
- (200) S.Kummar, M.Gutierrez, L.W.Anderson, R.W.Klecker, Jr., A.J.Murgo, J.H.Doroshov, J.M. Collins. Pharmacogenetically-Driven Patient Selection for a First-in-Human Phase I Trial of Batracyclin in Patients with Advanced Solid Tumors and Lymphomas. *Cancer Chemother Pharmacol*, 72:917-923, 2013
- (201) M.G.Hollingshead, L.H.Stockwin, S.Y.Alcoser, D.L.Newton, B.C.Orsburn, C.A.Bonomi, S.D Borgel, R.Divelbiss, K.M.Dougherty, E.J.Hager, S.L.Holbeck, G.Kaur, D.J.Kimmel, M.W.Kunkel, A.Millione, M.E.Mullendore, H.Stotler, J.Collins. Gene expression profiling of 49 human tumor xenografts from in vitro culture through multiple in vivo passages-strategies for data mining in support of therapeutic studies. *BMC Genomics* 15:393, 2014
- (202) K.Do, D.Wilsker, J.Ji, J.Zlott, T.Freshwater, R.J.Kinders, J.Collins, A.P.Chen, J.H.Doroshov, S.Kummar. Phase I Study of Single Agent AZD1775 (MK-1775), a WEE1 Kinase Inhibitor, in Patients with Refractory Solid Tumors. *J.Clin.Oncol.* 33:3409-15, 2015
- (203) K.Do, G.Speranza, L.-C.Chang, E.C.Polley, R.Bishop, W.Zu, J.B.Trepel, S.Lee, M.-J.Lee, R.J.Kinders, L. Phillips, J.Collins, J.Lyons, W.Jeong, R.Antony, A.P.Chen, L.Neckers, J.H.Doroshov, S.Kummar. Phase I Study of the Heat Shock Protein 90 (Hsp90) Inhibitor, AT13387, Administered on a Daily for 2 Consecutive Days per Week Dosing Schedule, in Patients with Advanced Solid Tumors. *Invest. New Drugs* 33:921-30, 2015
- (204) R.Gorlick, E.A.Kolb, S.T.Keir, J.M.Maris, R.B.Lock, C.Hernan, C.P.Reynolds, M.H.Kang, C.A.Billups, J.Collins, R.T.Kurmasheva, P.J. Houghton, M.A.Smith. Initial Testing of NSC 750854, a novel purine analog, against pediatric tumor models by the Pediatric Preclinical Testing Program. *Pediatr Blood Cancer*. 2016 63:443-50, 2016
- (205) S.Kummar, A.Chen, M.Gutierrez, T.D.Pfister, L.Wang, C.Redon, W.M.Bonner, W.Yutzy, Y.Zhang, R.J.Kinders D.Allen, J.M.Covey, J.L.Eiseman, J.L.Holleran, J.H.Beumer, L.Rubinstein, J.Collins, J.Tomaszewski, R.Parchment, Y.Pommier, J.H.Doroshov. Pharmacodynamic and Pharmacokinetic Evaluation of Two Dosing Schedules of Indotecan (LMP400), a Novel Indenoisoquinoline, in Patients with Advanced Solid Tumors. *Cancer Chemotherapy and Pharmacology*, 78:73-81, 2016
- (206) C.I.McHugh, J.Lawhorn-Crews, D.Modi, K.A. Douglas, S.K.Jones, T.J.Mangner, J.M.Collins, A.F.Shields. Effects of capecitabine treatment on the uptake of thymidine analogs using exploratory PET imaging agents: 18-FAU, 18F-FMAU and 18F-FLT. *Cancer Imaging* 16:34, 2016
- (207) F.I.Lin, E.M.Gonzalez, S.Kummar, K.Do, J.Shih, S.Adler, K.A.Kurdziel, A.Ton, B.Turkbey, P.M.Jacobs, S.Bhattacharyya, A.P.Chen, J.M.Collins, J.H.Doroshov, P.L.Choyke, M.L.Lindenberg. Utility of 18F-Fluorestradiol (FES) PET/CT Imaging as a Pharmacodynamic Marker in Patients with Refractory Estrogen Receptor-positive Solid Tumors Receiving Z-endoxifen therapy. *Eur.J.Nucl.Med.Mol.Imaging* 44:500-508, 2017
- (208) S.L.Holbeck, R.Camalier, J.Crowell, J.Prasaad, M.Hollingshead, :L.W.Anderson, E.Polley, L.Rubinstein, A.Srivastava, D.Wilsker, J.M.Collins, J.H.Doroshov. *The National Cancer Institute ALMANAC: A*

Comprehensive Screening Resource for the Detection of Anticancer Drug Pairs with Enhanced Therapeutic Activity: (A Large Matrix of Anti Neoplastic Agent Combinations). *Cancer Res.* 77:3564-3576, 2017

- (209) M.P.Goetz, V.J.Suman, J.M.Reid, D.W.Northfelt, M.A.Mahr, A.T.Ralya, M.Kuffel, S.A.Buhrow, S.L.Safgren, R.M.McGovern, J.Black, T.Dockter; T.Haddad, C.Erichman, A.A.Adjei, D.Visscherf, Z.R.Chalmers, G.Frampton, B.R.Kipp, M.C.Liua, J.R.Hawse, J.H.Doroshov, J.M.Collins, H.Streicher, M.M.Ames, J.N.Ingle. First-in-human phase I study of the tamoxifen metabolite, Z-Endoxifen, in women with endocrine refractory metastatic breast cancer. *J. Clin. Oncol.* 35:3391-3400, 2017
- (210) G.Speranza, L.Anderson, A.P.Chen, K.Do, M.Eugeni, M.Weil, L.Rubinstein, E.Majerova, J.Collins, Y.Horneffer, L.Juwara, J.Zlott, R.Bishop, B.A.Conley, H.Streicher, J.Tomaszewski, J.H.Doroshov, S.Kummar. First-in-human study of the epichaperome inhibitor PU-H71: clinical results and metabolic profile. *Invest New Drugs* 36:230-239, 2018
- (211) C.R.Young, S.Adler, J.F.Eary, M.L.Lindenberg, P.M.Jacobs, J.Collins, S.Kummar, K.A.Kurdziel, P.L.Choyke E.M.Gonzalez. Biodistribution, tumor detection and radiation dosimetry of F-18 5-Fluoro-2'-deoxycytidine (18F-FdCyd) with tetrahydrouridine in solid tumors. *J.Nucl.Med.* accepted, -Sept 12, 2018
- (212) J.G.Supko, J.M.Collins. Principles of Pharmacokinetics. In: *Cancer Chemotherapy, Immunotherapy and Biotherapy.* B.A.Chabner and D.L.Longo, Editors, 6th edition. Wolters Kluwer. pp. 37-48, 2018
- (213) T.Grkovic, J.R.Evans, R.K.Akee, L.Guo, M.Davis, J.J.Jato, P.G.Grothaus; M.Ahalt-Gottholm; M.Hollingshead; J.M.Collins; D.J. Newman; B.R.O'Keefe. Erythrofordins D and E, two new cassaine-type diterpenes from *Erythrophleum suaveolens*, *Bioorganic & Medicinal Chemistry Letters* 29:134-137, 2019
- (214) J.M.Collins. Pharmacology of Anticancer Drugs. *Abeloff's Textbook of Clinical Oncology.* Sixth Edition. J.Niederhuber et al, Editors. Elsevier, 2019.

BOOK

Cancer Chemotherapy: Principles and Practice. Chabner BA, Collins JM (Eds). Lippincott. Philadelphia. 1990.

U.S. PATENTS ISSUED, all assigned to U.S.Government

- 6,235,761 Compound, composition, and method for treating cancer. (demethylpenclomedine).
Issued: 22-May-2001
- 6,423,696 Inhibition of Arylamine N-Acetyl Transferase. Issued: 23-July-2002
- 6,753,309 Nucleosides for imaging and treatment applications Issued: 22-June-2004
- 6,703,374 Nucleosides for imaging and treatment applications Issued: 09-March-2004
- 6,683,045 Nucleosides for imaging and treatment applications Issued: 27-January-2004
- 6,682,715 Nucleosides for imaging and treatment applications Issued: 27-January-2004
- 6,677,315 Nucleosides for imaging and treatment applications Issued: 13-January-2004
- 6,677,314 Nucleosides for imaging and treatment applications Issued: 13-January-2004
- 7,141,234 Imaging of Drug Accumulation as a Guide for Tumor Therapy. Issued: 28-November-2006
- 7,175,830 Imaging of Drug Accumulation as a Guide for Tumor Therapy. Issued: 13-February-2007