

**BIOGRAPHICAL SKETCH**

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NAME: Hochster, Howard S.

eRA COMMONS USER NAME (credential, e.g., agency login): HOCHSH01

POSITION TITLE: Professor of Medicine

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	END DATE MM/YYYY	FIELD OF STUDY
Yale University, New Haven, CT	MS	05/1976	Chemistry
Yale University, New Haven, CT	BS	05/1976	Chemistry
Yale University, School of Medicine, New Haven, CT	MD	05/1980	Medicine

**A. Personal Statement**

I serve the Rutgers Cancer Institute of New Jersey as Associate Director for Clinical Research and Director of Oncology Research for the RWJBarnabas Health System. I have a long record of clinical trial experience and publications relating to new drug development in medical oncology. I have published widely on the use of topoisomerase-1 inhibitors and developed pharmacodynamic measures in conjunction with improved drug scheduling. I investigated intracellular pharmacology of gemcitabine metabolism in clinical trials using PBMC tissue and 19F Magnetic Resonance Spectroscopy (for which I was awarded an R01 grant). I have also published numerous phase II and III trials both investigator-initiated and through ECOG, where I was a major contributor. I served on the ECOG GI Steering Committee for more than 10 years and also served among the GI leadership at NSABP. I am the immediate past Chair of the SWOG GI Committee. In this capacity, I have led the intergroup activities on trial development for BRAF mutated colon cancer, MSI-high advanced colon cancer, resectable pancreatic cancer, and triple-drug therapy of cholangiocarcinoma through SWOG and the NCTN leadership. I have been a member of the NCTN Colon Task Force (2010 – 2020) and served on the GI Steering Committee from 2013-2018.

I lead the oncology clinical research efforts at Rutgers Cancer Institute and RWJBarnabas Health. In this role, my goals are to improve the research support infrastructure for day-to-day trial accrual, to streamline and further support the protocol development process and regulatory approval process. I have a major focus on extending clinical trial access to all the hospitals of the RWJBarnabas Health System. I am working to encourage and develop translational investigator-initiated trials by securing tissue access coupled to robust clinical data and assist investigators in securing funding for such trials. I am also working to develop cooperative group participation and use high priority cooperative group protocols to serve as the foundation for invigorating and expanding a regional network of collaborating physicians and institutions of RWJBarnabas Health. Under my leadership, the CINJ affiliation with ECOG-ACRIN has been recognized with commendations for performance in 2020 – 2022, with more than 100 NCTN accruals in 2022. We expect that we will continue to increase accrual to therapeutic trials, reaching 750 accruals to treatment trials per year in the 2023 period. Much of this will be focused on CTEP trials, with strengthening of cross-campus relationships that result in increased referrals for trials, particularly of rare tumors, and with the ability to open trials at select sites which have departments integrated with Rutgers Cancer Institute and faculty who are skilled in clinical research.

Ongoing and recently completed projects that I would like to highlight include:

5P30CA072720

Libutti (PI)

03/07/2019-02/29/2024

Cancer Center Support Grant (CCSG) Role: Associate Director for Clinical Research

2P30CA072720-21S

Libutti (PI), Role: Contact PI /Project Leader

09/01/2020--08/31/2021

Development of Standardized Electronic Treatment Plans for Clinical Trials Across Clinical Research Sites

U10CA180826

Hochster (PI)

03/01/2014-02/28/2019

YCC Cooperative Group Support Grant (Lead Academic Participating Site)

P30CA016359

Fuchs (PI) Role: Associate Director for Clinical Sciences

08/01/2013-07/31/2018

Cancer Center Support Grant (CCSG)

P01CA154295

Cheng (PI) Role: Co-Investigator

09/15/2011-08/31/2017

Chinese Herbal Medicine as a Novel Paradigm for Cancer Chemotherapy

Citations:

1. **Hochster H**, Liebes L, Wadler S, Oratz R, Wernz JC, Meyers M, Green M, Blum RH, Speyer JL. Pharmacokinetics of the cardioprotector ADR-529 (ICRF-187) in escalating doses combined with fixed-dose doxorubicin. *J Natl Cancer Inst.* 1992 Nov 18;84(22):1725-30. PubMed PMID: 1433357.
2. **Hochster H**, Green MD, Speyer JL, Wernz JC, Blum RH, Muggia FM. Activity of epirubicin in pancreatic carcinoma. *Cancer Treat Rep.* 1986 Feb;70(2):299-300. PubMed PMID: 3456273.
3. **Hochster HS**, Green MD, Blum RH, Wernz JC, Speyer JL, Muggia FM. Oral 4-demethoxydaunorubicin (idarubicin) in bronchogenic lung cancer; phase II trial. *Invest New Drugs.* 1986;4(3):275-8. PubMed PMID: 3469171.
4. **Hochster HS**, Green MD, Speyer J, Fazzini E, Blum R, Muggia FM. 4'Epidoxorubicin (epirubicin): activity in hepatocellular carcinoma. *J Clin Oncol.* 1985 Nov;3(11):1535-40. PubMed PMID: 2997408.

## **B. Positions, Scientific Appointments and Honors**

### **Positions and Scientific Appointments**

2018 - Associate Director for Clinical Research, Rutgers Cancer Institute of New Jersey, Director of Oncology Clinical Research, RWJ-Barnabas Health System

2018 - Distinguished Professor of Medicine, Rutgers School of Medicine

2010 - 2017 Associate Cancer Director for Clinical Sciences, Yale Cancer Center

2010 - 2017 Professor of Medicine, Division of Medical Oncology, Yale School of Medicine

2002 - 2010 Professor of Medicine, Divisions of Medical Oncology and Clinical Pharmacology, New York University School of Medicine (with tenure)

2001 - 2008 Director of Clinical Trials, NYU Cancer Center and Institute

2000 - 2010 Associate Professor of Clinical Pharmacology, New York University School of Medicine

1995 - 2002 Associate Professor of Clinical Medicine, New York University School of Medicine

1989 - 1995 Assistant Professor of Medicine, , New York University Medical Center

1986 - 2010 Attending Physician, Bellevue Hospital Center

1986 - 2010 Attending Physician, NYU Tisch Hospital

1986 - 1989 Instructor of Medicine, , New York University Medical Center

1983 - 1986 Fellow in Hematology and Oncology, NYU

1982 - 1985 Attending Physician, Department of Emergency Services, New York University Medical Center

1980 - 1985 Teaching Assistant, Department of Medicine, New York University School of Medicine

1980 - 1983 Resident in Medicine, NYU-Bellevue Program, New York

## Honors

2005 - 2020	America's Top Doctors for Oncology, US
2003 - 2020	America's Top Doctors, US
2011 - 2016	New York Magazine Best Doctor, New York
2000 - 2007	New York Magazine Best Doctor, New York
1986 - 1989	American Cancer Society Career Development Award, American Cancer Society
1985 - 1986	Fulbright Scholar, New York University
1983 - 1984	Stanley H. and Rita Kaplan Fellowship in Clinical Oncology, New York University
1983	Fellow, American College of Physicians
1983	American Cancer Society Institutional Grant Awardee, American Cancer Society
1976	Werner Bergmann Prize (Outstanding Chemistry Major), Yale College
1976	Departmental Honors (Chemistry), Yale College

## **C. Contribution to Science**

1. I predominantly work in the area of drug development. My initial efforts were in pharmacology and development of anthracycline analogs including epirubicin, idarubicin and esorubicin and others. I reported on the pharmacokinetics and pharmacology of oral anthracyclines and also developed the use of the cardioprotector, Zinecard, leading to its approval for clinical use.
  - a. **Hochster H**, Liebes L, Wadler S, Oratz R, Wernz JC, Meyers M, Green M, Blum RH, Speyer JL. Pharmacokinetics of the cardioprotector ADR-529 (ICRF-187) in escalating doses combined with fixed-dose doxorubicin. *J Natl Cancer Inst.* 1992 Nov 18;84(22):1725-30. PubMed PMID: 1433357.
  - b. **Hochster H**, Green MD, Speyer JL, Wernz JC, Blum RH, Muggia FM. Activity of epirubicin in pancreatic carcinoma. *Cancer Treat Rep.* 1986 Feb;70(2):299-300. PubMed PMID: 3456273.
  - c. **Hochster HS**, Green MD, Blum RH, Wernz JC, Speyer JL, Muggia FM. Oral 4-demethoxydaunorubicin (idarubicin) in bronchogenic lung cancer; phase II trial. *Invest New Drugs.* 1986;4(3):275-8. PubMed PMID: 3469171.
  - d. **Hochster HS**, Green MD, Speyer J, Fazzini E, Blum R, Muggia FM. 4'Epidoxorubicin (epirubicin): activity in hepatocellular carcinoma. *J Clin Oncol.* 1985 Nov;3(11):1535-40. PubMed PMID: 2997408.
2. I also was responsible for developing fludarabine in low grade lymphoma through ECOG with a phase II study, a phase 1 combination with Cyclophosphamide, and eventually a definitive phase III trial, E1496. This latter study demonstrated convincingly that maintenance rituximab had a huge influence on disease free survival and borderline survival effects in low grade lymphoma. Data from this study are still being analyzed for survival and benefit of maintenance rituximab.
  - a. Barta SK, Li H, **Hochster HS**, Hong F, Weller E, Gascoyne RD, Habermann TM, Gordon LI, Colocci N, Bengtson EM, Horning SJ, Kahl BS. Randomized phase 3 study in low-grade lymphoma comparing maintenance anti-CD20 antibody with observation after induction therapy: A trial of the ECOG-ACRIN Cancer Research Group (E1496). *Cancer.* 2016 Oct;122(19):2996-3004. PubMed Central PMCID: PMC5030179.
  - b. **Hochster H**, Weller E, Gascoyne RD, Habermann TM, Gordon LI, Ryan T, Zhang L, Colocci N, Frankel S, Horning SJ. Maintenance rituximab after cyclophosphamide, vincristine, and prednisone prolongs progression-free survival in advanced indolent lymphoma: results of the randomized phase III ECOG1496 Study. *J Clin Oncol.* 2009 Apr 1;27(10):1607-14. PubMed Central PMCID: PMC2668968.
  - c. **Hochster HS**, Kim KM, Green MD, Mann RB, Neiman RS, Oken MM, Cassileth PA, Stott P, Ritch P, O'Connell MJ. Activity of fludarabine in previously treated non-Hodgkin's low-grade lymphoma: results of an Eastern Cooperative Oncology Group study. *J Clin Oncol.* 1992 Jan;10(1):28-32. PubMed PMID: 1727921.
  - d. **Hochster HS**, Oken MM, Winter JN, Gordon LI, Raphael BG, Bennett JM, Cassileth PA. Phase I study of fludarabine plus cyclophosphamide in patients with previously untreated low-grade lymphoma: results and long-term follow-up--a report from the Eastern Cooperative Oncology Group. *J Clin Oncol.* 2000 Mar;18(5):987-94. PubMed PMID: 10694548.

3. Later work in GI cancer, brought oxaliplatin into the clinic with various fluoropyrimidine combinations, then adding bevacizumab and cetuximab. I planned and lead two key studies, first piloting the bolus FOL regimen and then conducting the randomized TREE-1 and TREE-2 studies investigating oxaliplatin with various fluoropyrimidine regimens, and then a second cohort with bevacizumab (refs 67 and 103). I then led a study investigating the correct way to manage oxaliplatin neurotoxicity in the CONcePT (Combined Neurotoxicity Prevention Trial) trial (ref 131), which clearly showed that cation infusions with Ca<sup>+2</sup> and Mg<sup>+2</sup> salts did not prevent onset of neurotoxicity and that scheduled reintroduction of oxaliplatin could lead to longer TTP and TTF.
  - a. **Hochster H**, Chachoua A, Speyer J, Escalon J, Zeleniuch-Jacquotte A, Muggia F. Oxaliplatin with weekly bolus fluorouracil and low-dose leucovorin as first-line therapy for patients with colorectal cancer. *J Clin Oncol.* 2003 Jul 15;21(14):2703-7. PubMed PMID: 12860947.
  - b. **Hochster HS**, Sargent DJ. One good DNA-damage deserves another: Oxaliplatin in MSI-high colon cancer. *J Natl Cancer Inst.* 2016 Jul;108(7) PubMed PMID: 26851803.
  - c. **Hochster HS**, Grothey A, Hart L, Rowland K, Ansari R, Alberts S, Chowhan N, Ramanathan RK, Keaton M, Hainsworth JD, Childs BH. Improved time to treatment failure with an intermittent oxaliplatin strategy: results of CONcePT. *Ann Oncol.* 2014 Jun;25(6):1172-8. PubMed Central PMCID: PMC4207881.
  - d. **Hochster HS**, Hart LL, Ramanathan RK, Childs BH, Hainsworth JD, Cohn AL, Wong L, Fehrenbacher L, Abubakr Y, Saif MW, Schwartzberg L, Hedrick E. Safety and efficacy of oxaliplatin and fluoropyrimidine regimens with or without bevacizumab as first-line treatment of metastatic colorectal cancer: results of the TREE Study. *J Clin Oncol.* 2008 Jul 20;26(21):3523-9. PubMed PMID: 18640933.
4. I have been a leader in GI Cancer medical oncology and have participated in most of the major drug studies to develop newer agents including oral fluoropyrimidines, irinotecan, regorafenib and TAS-102. I currently lead a randomized phase 2 trial in NCTN investigating the combination of an anti-EGFR and an anti-VEGFR antibody in second line therapy of colorectal cancer (E7208).
  - a. **Hochster HS**, Uboha N, Messersmith W, Gold PJ, O'Neil BH, Cohen D, Denlinger C, Cohen S, Leichman CG, Leichman L, Lenz HJ. Phase II study of selumetinib (AZD6244, ARRY-142886) plus irinotecan as second-line therapy in patients with K-RAS mutated colorectal cancer. *Cancer Chemother Pharmacol.* 2015 Jan;75(1):17-23. PubMed PMID: 25322874.
  - b. Kasi PM, Kotani D, Cecchini M, Shitara K, Ohtsu A, Ramanathan RK, **Hochster HS**, Grothey A, Yoshino T. Chemotherapy induced neutropenia at 1-month mark is a predictor of overall survival in patients receiving TAS-102 for refractory metastatic colorectal cancer: a cohort study. *BMC Cancer.* 2016 Jul 13;16:467. PubMed Central PMCID: PMC4944251.
  - c. Mayer RJ, Van Cutsem E, Falcone A, Yoshino T, Garcia-Carbonero R, Mizunuma N, Yamazaki K, Shimada Y, Tabernero J, Komatsu Y, Sobrero A, Boucher E, Peeters M, Tran B, Lenz HJ, Zaniboni A, **Hochster H**, Cleary JM, Prenen H, Benedetti F, Mizuguchi H, Makris L, Ito M, Ohtsu A. Randomized trial of TAS-102 for refractory metastatic colorectal cancer. *N Engl J Med.* 2015 May 14;372(20):1909-19. PubMed PMID: 25970050.
  - d. Saltz LB, Lenz HJ, Kindler HL, **Hochster HS**, Wadler S, Hoff PM, Kemeny NE, Hollywood EM, Gonen M, Quinones M, Morse M, Chen HX. Randomized phase II trial of cetuximab, bevacizumab, and irinotecan compared with cetuximab and bevacizumab alone in irinotecan-refractory colorectal cancer: the BOND-2 study. *J Clin Oncol.* 2007 Oct 10;25(29):4557-61. PubMed PMID: 17876013.
5. More recently I was selected for a key leadership in the GI Oncology efforts of the NCTN, through chairing the GI Committee at SWOG and serving on the GI Steering Committee. In this capacity, I have worked to develop the portfolio of the entire SWOG group across all GI sub-sites including the S1313 trial of PEGPH20 with FOLFIRINOX, S1505 trial of neoadjuvant FOLFIRINOX vs. Gem and nab-paclitxel in resectable pancreatic cancer, and S1513, A trial of FOLFIRI +/- veliparib in 2nd line therapy of pancreatic cancer. In the latter, we are working with national and local investigators on determining the sensitivity of DNA damage repair pathways with PARP inhibition.
  - a. Ahmad SA, Duong M, Sohal DPS, Gandhi NS, Beg MS, Wang-Gillam A, Wade JL 3rd, Chiorean EG, Guthrie KA, Lowy AM, Philip PA, **Hochster HS**. Surgical Outcome Results From SWOG S1505: A

Randomized Clinical Trial of mFOLFIRINOX Versus Gemcitabine/Nab-paclitaxel for Perioperative Treatment of Resectable Pancreatic Ductal Adenocarcinoma. *Ann Surg.* 2020 Sep 1;272(3):481-486. PubMed Central PMCID: PMC7856053.

- b. Kopetz S, Guthrie KA, Morris VK, Lenz HJ, Magliocco AM, Maru D, Yan Y, Lanman R, Manyam G, Hong DS, Sorokin A, Atreya CE, Diaz LA, Allegra C, Raghav KP, Wang SE, Lieu CH, McDonough SL, Philip PA, **Hochster HS**. Randomized Trial of Irinotecan and Cetuximab With or Without Vemurafenib in BRAF-Mutant Metastatic Colorectal Cancer (SWOG S1406). *J Clin Oncol.* 2021 Feb 1;39(4):285-294. PubMed Central PMCID: PMC8462593.
- c. Sohal DPS, Duong M, Ahmad SA, Gandhi NS, Beg MS, Wang-Gillam A, Wade JL 3rd, Chiorean EG, Guthrie KA, Lowy AM, Philip PA, **Hochster HS**. Efficacy of Perioperative Chemotherapy for Resectable Pancreatic Adenocarcinoma: A Phase 2 Randomized Clinical Trial. *JAMA Oncol.* 2021 Mar 1;7(3):421-427. PubMed Central PMCID: PMC7821078.
- d. Venook AP, Niedzwiecki D, Lenz HJ, Innocenti F, Fruth B, Meyerhardt JA, Schrag D, Greene C, O'Neil BH, Atkins JN, Berry S, Polite BN, O'Reilly EM, Goldberg RM, **Hochster HS**, Schilsky RL, Bertagnolli MM, El-Khoueiry AB, Watson P, Benson AB 3rd, Mulkerin DL, Mayer RJ, Blanke C. Effect of First-Line Chemotherapy Combined With Cetuximab or Bevacizumab on Overall Survival in Patients With KRAS Wild-Type Advanced or Metastatic Colorectal Cancer: A Randomized Clinical Trial. *JAMA.* 2017 Jun 20;317(23):2392-2401. PubMed Central PMCID: PMC5545896.

Complete List of Published Work in My Bibliography:

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