

ROBERT HARDI, M.D., AGAF, CPI
GASTROENTEROLOGIST



ROBERT HARDI

MEDICAL LICENSE: D0030771 MARYLAND
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Fellow, Academy of Physicians in Clinical Research

Fellow, American Gastroenterological Association

Certified Physician Investigator



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EDUCATION

1972 – 1974	Postdoctoral - Biochemistry, Genetics, Semmelweis University Medical School, Budapest, Hungary
1966 – 1972	MD - Semmelweis University Medical School, Budapest, Hungary - Summa cum Laude
1962 – 1966	Apaczai Gymnasium Budapest, Hungary

TRAINING

1982 – 1984	GI Fellowship, Cornell University Medical College, New York, New York
1982 – 1982	Senior Resident - Internal Medicine - University of New Mexico Medical School, Albuquerque, New Mexico
1979 – 1982	Hematology - Oncology Fellowship, University of New Mexico Medical School Albuquerque, New Mexico
1978 – 1979	Residency, Internal Medicine: Medical University of Hannover Hannover, West Germany
1977 – 1978	Residency, Internal Medicine: St. Bonifatius Hospital, Lingen, West Germany
1976 – 1977	Internship: First Medical Clinic, Semmelweis University Medical School, Budapest, Hungary
1975 – 1976	Post-doctoral Fellowship - State University of New York at Buffalo and Roswell Park Memorial Institute; Department of Medical Viral Oncology, Buffalo, New York

WORK EXPERIENCE

2020 - Present	Chief Clinical Scientist, Medipredict, Budapest, Hungary
2020 - Present	Medical Director; Director of Clinical Development, Altimune, US
2018 - Present	Principal, Chevy Chase Gastroenterology; Gastroenterology Consultant, Physician Associates
2009 - 2018	Physician, Capital Digestive Care
1997 – 2018	Consultant, Gastroenterologist - World Bank, US Dept. of State
1996 - 2018	Principal Investigator and Medical Director- Metropolitan Gastroenterology Group, P.C., Chevy Chase Clinical Research, Chevy Chase, Maryland
1996 - 2018	Physician - Metropolitan Gastroenterology Group, P.C. (Private Practice, Gastroenterology & Internal Medicine), Chevy Chase, Maryland & Washington, DC
1990 – Present	Physician - Embassy of the Federal Republic of Germany, Washington, District of Columbia
1984 – 1996	Physician - Private Practice of Gastroenterology, Washington, District of Columbia

ACADEMIC APPOINTMENTS

1992 - Present	Clinical Assistant Professor of Medicine, Georgetown University Medical School, Washington, District of Columbia
1984 - 2011	Clinical Assistant Professor of Medicine, George Washington University Medical School, Washington, District of Columbia
2011 - Present	Clinical Associate Professor of Medicine, George Washington University Medical School, Washington, D.C.
1973 - 1975	Assistant Professor of Genetics, Eotvos University of Sciences, Budapest, Hungary

PROFESSIONAL APPOINTMENTS

2015- 2017	President, Board of Trustees , Academy of Physicians in Clinical Research
2014 – 2016	Board of Trustees-Association of Clinical Research Professionals
2013 – 2014	Board of Managers, Capital Digestive Care
2012 – Present	Board of Trustees – Academy of Physicians in Clinical Research (APCR)
2011 – 2016.	Chairman, Research Committee, Capital Digestive Care
2011 – 2013	Member, APCR representative on the Professional Development Committee of the ACRP
1984 – Present	Member, Medical Advisory Committee, CCFA, National Capital
2015 – 2016	President Academy of Physicians in Clinical Research
1990 – 2001	Chairman of Gastroenterology, Columbia Hospital for Women, Washington, District of Columbia
1995 – 1998	Board of Directors, Capitol Physicians Network
1994 – 1998	Member, National Board of CCFA
1994 – 1996	Judicial Council, Medical Society of the District of Columbia
1988 – 1994	Chairman, National Capital Area Medical Advisory Committee for CCFA,
1993 – 1995	Vice Chairman, Utilization Review Committee, Sibley Memorial

HOSPITAL AFFILIATIONS

1992 – 2019	Staff Physician, Georgetown University Hospital, Washington, District of Columbia
1984 – 2019	Staff Physician, Suburban Hospital, Bethesda, Maryland
1984 – 2019	Staff Physician, Sibley Memorial Hospital, Washington, District of Columbia
1984 – 2016	Staff Physician, George Washington University Hospital, Washington, District of Columbia
1984 – 2001	Staff Physician, Columbia Hospital for Women, Washington, District of Columbia

MEMBERSHIPS

American Gastroenterological Association - Fellow

Academy of Physicians in Clinical Research

Crohn's and Colitis Foundation of America

RESEARCH ACTIVITY

Robert Hardi has been Principal Investigator on more than 350 gastroenterology clinical trials encompassing all phases and all areas of Gastroenterology including polyp prevention, sedation trials and therapeutic device trials and several trials in arthritis, hyperlipidemia and pain control. Experience includes small molecules, biologics, biosimilars. More than half of these trials were in Inflammatory Bowel Disease.

PUBLICATIONS

1. Hardi R, Hughes RG, Ho YK, Chadha KC, Bardos TJ. Differential Effects of 5-Methylmercapto-2'-Deoxyuridine on the Replication of Herpes Simplex Virus Type 1 in 2 Cell Systems. *Antimicrobial Agents and Chemotherapy*, Oct 1976 p. 682-686.
2. Balsalazide Is Superior to Mesalamine in the Time to Improvement of Signs and Symptoms of Acute Mild-to-Moderate Ulcerative Colitis; "The American Journal of Gastroenterology", Vol. 97, Number 12, Dec, 2002.
3. Katz S., Novick, J., Hardi R., Rose M., Karlstadt R., Lottes S., Ettinger N. "Efficacy and Safety Profile of Older Patients Using Oral INKP-102 as a Bowel Purgative Prior to Colonoscopy Compared to Visicol". Poster presented at ACG. 2005
4. Hanauer S.B., Sandborn W.J., Kornbluth A., Hardi R., Regalli G., Yeh C. Delayed-release oral mesalamine 4.8 g/day (800mg tablet) versus 2.4 g/day (400mg tablet) for treatment of moderately active ulcerative colitis: combined analysis of two randomized, double-blind, controlled trials. *Gastroenterology* 2005 Apr; 128(4, Suppl 2): A-74. Abstract 492.
5. Hanauer S.B., Sandborn W.J., Kornbluth A., Hardi R., Regalli G., Yeh C. Delayed-release oral mesalamine 4.8 g/day (800mg tablet) versus 2.4 g/day (400mg tablet) for treatment of moderately active ulcerative colitis: combined efficacy analysis of two randomized, double-blind, controlled trials. *Can J Gastroenterology* 2005 Sept; 19 (Suppl C): Abstract R.0470.
6. Hanauer S.B., Sandborn W.J., Kornbluth A., Hardi R., Regalli G., Yeh C. Modified-release oral mesalazine 4.8 g/day (800mg tablet) versus 2.4 g/day (400mg tablet) for treatment of moderately active ulcerative colitis: combined analysis of two randomised, double-blind, controlled trials. *Gut* 2005 Oct; 54(Suppl VII): A56. Abstract OP-G-236.

7. Hanauer S.B., Sandborn W.J., Kornbluth A., Hardi R., Regalli G., Yeh C. Modified-release oral mesalazine 4.8 g/day (800mg tablet) versus 2.4 g/day (400mg tablet) for treatment of moderately active ulcerative colitis: combined analysis of two randomized, double-blind, controlled trials. *Colorectal Dis* 2006 Jul; 8 (Suppl 2): Abstract O17.
8. Aue, G., Carroll, N., Kressel, B. R., Hardi, R., Horne III, M. K. Disseminated Intravascular Couagulation in an Ambulatory Young Woman. *Journal of Laboratory and Clinical Medicine*, Vol.146 #3, Sept 2005 192-196.
9. Gan T.G., Hardi R., Ekman E., Shore N. "Safety of Fospropofol for Minimal-to-Moderate Sedation in Patients Undergoing Minor Surgical Procedures", Poster, Presented at the Society for Ambulatory Anesthesia 23rd Annual Meeting, Miami, May 2008.
10. Pambianco, D., Bray, W., Hardi, R., Kodali, V., Pruitt, R., Shubert, T., Vargo, J., Weinstein, M. L. "A Computer-Assisted Personalized Sedation System To Administer Propofol Versus Standard Of Care Sedation For Colonoscopy And EGD: A 1000 Subject Randomized, Controlled, Multi-center, Pivotal Trial". Presentation DDW 2008.
11. Weinstein ML, Hardi R, Vargo J, Pambianco D: Psychomotor Recovery After Endoscopic Procedures Using a Computer-Assisted Personalized Sedation System to Administer Propofol or Standard of Care Sedation: Implications for Care Efficiency. Poster Abstract. Orlando, Florida. ACG Sept 2008.
12. Abreu MT, von Tirpitz C, Hardi R, et al. "Extracorporeal photopheresis for the treatment of refractory Crohn's disease: results of an open-label pilot study"; Crohn's Disease Photopheresis Study Group. *Inflamm Bowel Dis*. 2009 Jun; 15(6):829-36
13. Hardi R., Weinstein, M. L., Vargo, J., Pambianco, D. "Correlation of Hypoxia, Clinician Satisfaction (CSSI), Patient Satisfaction (PSSI) and Recovery Time (RT) with Level of Sedation", Poster, Presented at the American Gastroenterology Association, Chicago, June 2009.
14. Daniel J. Pambianco, MD, John J. Vargo, MD, MPH, Ronald E. Pruitt, MD, Robert Hardi, MD, James F. Martin, PhD. "Computer-assisted personalized sedation for upper endoscopy and colonoscopy: a comparative, multicenter randomized study", *Gastrointestinal Endoscopy* 2010.
15. Update on Colorectal Cancer Screening in the United States *Gastro Update* 2009.
16. The debate for nonanesthesiologist-administered propofol sedation in endoscopy rages on by Daniel J. Pambianco, Robert Hardi *Gastrointestinal Endoscopy* (Vol.74, Issue 2).
17. Hardi R, Mayer L, Targan SR, et al. 704 A Phase 1 Open-Label, Single-Dose, Dose-Escalation Study of MDX-1100, a High-Affinity, Neutralizing, Fully Human IgG1[kappa] Anti-CXCL10 (ip10) Monoclonal Antibody, in Ulcerative Colitis. *Gastroenterology* 2008; 134:A-99-A-100.

18. Novel STAT3 selective inhibitor Natta-a shows great promises in treating moderate-to-severe ulcerative colitis in a randomized, double-blind, placebo-controlled Phase II clinical trial by Louis G Wang, Simon K Mencher, Sunil K Khurana, Barry P Kaufman, Robert Hardi, Terry R Kaylor, Ronald Pruitt, Dennis Riff, Daniel J Geenen, Jakey Patwari, Allen Tsao, Maxime Melikian, Gildas Bertho and Balfour Sartor (ACG October 2012)
 19. Enema Administration of RBX2660 (microbiota suspension) for Recurrent *C. difficile* Infection: Lessons Learned from the PUNCH CD Study (ACG September 2014)
 20. Mark T. Osterman, Faten N. Abera, Raymond Cross, Steven Liakos, Robert McCabe, Ira Shafran, Douglas Wolf, Robert Hardi, et al. Mesalamine Dose Escalation Reduces Fecal Calprotectin in Patients with Quiescent Ulcerative Colitis. *Clinical Gastroenterology and Hepatology* 2014; 12: 1887-1893
 21. Does the Donor Matter? Donor vs. Patient Effects in the Outcome of Next-Generation Fecal Transplant for Recurrent *Clostridium difficile* Infection. Courtney Jones, BS, Robert Hardi, MD, Bill Shannon, PhD. (DDW Poster May 2015)
 22. Safety and Durability of RBX2660 (microbiota suspension) for Recurrent *Clostridium difficile* Infection: Results of the PUNCH CD Study. Robert Orenstein, Erik Dubberke, Robert Hardi, et al. *Clinical Infectious Diseases* 2015; doi: 10.1093/cid/civ938
 23. The validity of breath collection bags using the novel BreathID®Hp Lab System: A multicenter clinical study in 257 Subjects
Haim Shirin MD, Jeff O Gonzalez MD, Sabine Hazan MD, Gary Gottlieb MD, Keith Friedenberg MD, David Gatof MD, Ravi Ganeshappa MD, Shmuel Delgado MD, Dov Abramowitz MD, Robert Hardi MD, et al. (Abstract April 2017)
- Sustained Clinical with Vedolizumab in moderate-to-severe Crohn's Disease: A GEMINI 2 post hoc analysis of week 14 remitters
Robert Hardi, Bernd Bokemeyer, William Sandborn, Walter Rheinisch, et al
Poster, ECCO 2018
- Sustained Clinical with Vedolizumab in moderate-to-severe Crohn's Disease: A GEMINI 2 post hoc analysis of week 14 remitters
Robert Hardi, Bernd Bokemeyer, William Sandborn, Walter Rheinisch, et al

Poster, DDW 2018

Correlation of Biomarkers of Inflammation with Clinical and Endoscopic Endpoints in Patients with Moderate-to-Severe Crohn's Disease: Data from CELEST

J-F Colombel, L. Peyrin-Biroulet, S. Danese, S. Travis, G. Dryden, R. Hardi et al
Poster 26th UEGW 2018 Conference and Congress, Vienna, Austria, October 20-24, 2018

Phase III Randomized, Double Blind, Placebo-controlled, Multicenter, Parallel Group Study to Assess the Efficacy and Safety of Add-On Fixed-dose Combination RHB-104 in Subjects with Moderately to Severely Active Crohn's Disease (MAP US)

D. Y. Graham MD¹, R. Hardi, B.R. Bhandari, T. Welton, H. Sarles, S. Levenson, P. Anderson², P. McLean², C. Fehrmann², I. Kalfus MD

Poster, UEGW 2018, Vienna, Austria

Gut Microbiome identifies risk for colorectal cancer

BMJ Open Gastroenterology, 27May2019

E. Dadkhah, M. Sikaroodi, L. Korman, R. Hardi et al

PRESENTATIONS

Hardi, R, Mayer, L., Targan, S., Yellin, M., Cardarelli, P., Witte, A., & Das, K. A Phase 1 Open-label, Single-dose, Dose-escalation Study of MDX-1100, a High-affinity, Neutralizing, Fully Human IgG1 κ anti-CXCL10 (IP-10) Monoclonal Antibody, in Ulcerative Colitis. DDW 2008, San Diego

ASCEND: Assessing the Safety & Clinical Efficacy of a New Dose of 5-ASA (4.8 /day) (800 mg tablet)
Association of ColoProctologists of Great Britain and Ireland; 2006 , Newcastle



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