

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel
DO NOT EXCEED FIVE PAGES.

NAME: Melmed, Gil

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

POSITION TITLE: Associate Professor of Medicine

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

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Pennsylvania	BA	1995	Biology / Chemistry
Albert Einstein College of Medicine	MD	2000	Medicine
University of California, Los Angeles	MS	2006	Clinical Research
Cedars-Sinai Medical Center	Resident	2003	Internal Medicine
University of California, Los Angeles	NIH training grant	2006	
University of California, Los Angeles	Fellow	2006	Gastroenterology

A. Personal Statement

I have been fortunate to have had outstanding mentorship and formal training in IBD clinical care and research methods, leadership training, and motivation to successfully develop a clinical research program in IBD. I have a broad background in outcomes research including health services research, clinical trials, and clinical expertise in inflammatory bowel disease, with specific training and expertise in key research areas for this application. During my residency and fellowship, I was engaged in clinical and health services research and completed a 2 year K30 Master's degree in Clinical and Translational Investigation at UCLA, where I gained skills in clinical trial design, biostatistics, and quality improvement methods. After joining the Cedars-Sinai Inflammatory Bowel Disease Center as Director of Clinical Trials, I have contributed to the design of drug and device trials in IBD, and have been the primary or senior author on dozens of IBD clinical research publications. My research areas of interest include vaccination and preventive health measures and quality of care in IBD, and I have been PI or co-Investigator on several investigator-initiated or industry-sponsored clinical trials, and co-author on recent preventive care guidelines for IBD through the American College of Gastroenterology. I direct the Adult Clinical IBD Program and lead an experienced clinical trial team. I am co-PI on IBD Qorus, a 30-site learning health system in IBD collecting patient-reported outcomes, and was the primary author on the development of Quality Measures for IBD and co-author on the PCPI Quality Measure set developed by the American Gastroenterology Association. Within our gastroenterology division at Cedars-Sinai, I have several successful prior and ongoing collaborations with our Health Services Group and have collaborated successfully with the IBD Partners cohort and the Crohn's and Colitis Foundation.

1. Farraye FA, Melmed GY, Lichtenstein GR, Kane SV. ACG Clinical Guideline: Preventive Care in Inflammatory Bowel Disease. *Am J Gastroenterol.* 2017 Feb;112(2):241-258
2. Melmed GY, Siegel CA, Spiegel BM, Allen JI, Cima R, Colombel JF, Dassopoulos T, Denson LA, Dudley-Brown S, Garb A, Hanauer SB, Kappelman MD, Lewis JD, Lynch I, Moynihan A, Rubin DT, Sartor RB, Schwartz RM, Wolf DC, Ullman TA. Quality indicators for inflammatory bowel disease: development of process and outcome measures. *Inflamm Bowel Dis.* 2013 Mar;19(3):662-8. PubMed PMID: 23388547
3. Melmed GY, Ippoliti AF, Papadakis KA, Tran TT, Birt JL, Lee SK, Frenck RW, Targan SR, Vasiliauskas EA. Patients with inflammatory bowel disease are at risk for vaccine-preventable illnesses. *Am J Gastroenterol.* 2006 Aug;101(8):1834-40. PubMed PMID: [16817843](https://pubmed.ncbi.nlm.nih.gov/16817843/).

B. Positions and Honors

Positions and Employment

2000 - 2003	Intern and Resident, Internal Medicine, Cedars-Sinai Medical Center, Los Angeles, CA
2003 - 2006	Fellow, Div of Gastroenterology, David Geffen School of Medicine UCLA, Los Angeles, CA
2004 - 2006	K30 Program in Clinical and Translational Research, UCLA, Los Angeles, CA
2006 - 2007	Clinical Instructor, David Geffen School of Medicine at UCLA, Los Angeles, CA
2008 -	Director, Clinical Trials, IBD Center, Cedars-Sinai Medical Center, Los Angeles, CA
2008 - 2012	Assistant Clinical Professor, David Geffen School of Medicine at UCLA, Los Angeles, CA
2010 - 2018	Director, Advanced IBD Fellowship Program, Cedars-Sinai Medical Center, Los Angeles, CA
2012 -	Director, Clinical IBD, Cedars-Sinai Medical Center, Los Angeles, CA
2012 - 2017	Associate Professor, David Geffen School of Medicine at UCLA, Los Angeles, CA
2017-	Professor of Medicine, David Geffen School of Medicine at UCLA, Los Angeles, CA

Other Experience and Professional Memberships

2004 - 2006	Member, UCLA Digestive Disease Fellowship Program, Curriculum Committee
2006 -	Member, Endoscopy Unit Management Committee, Gastroenterology, Cedars-Sinai Medical Center
2008 - 2014	Chair, Crohn's and Colitis Foundation of America (CCFA), Los Angeles Chapter Medical Advisory Committee
2009 - 2011	Chair, Cedars-Sinai Leadership Development Committee
2009 - 2015	Clinical Research Editor, <i>Inflammatory Bowel Disease</i>
2013 -	Co-Chair, CCFA National Scientific Advisory Committee, Quality of Care Committee
2014 - 2015	Chair, American Gastroenterology Association, IBD Section of Quality Measures Committee
2015 - 2018	Associate Editor, <i>American Journal of Gastroenterology</i>

Honors

1999	Alpha Omega Alpha Medical Honors Society, Albert Einstein College of Medicine
2005	Outstanding Research Award, 16th Annual North American Conference of GI Fellows
2005	Centocor Award (Top 5 IBD Research Abstracts), American College of Gastroenterology
2006	Outstanding Research Award, 17th Annual North American Conference of GI Fellows
2009	Presidential Poster Award, American College of Gastroenterology
2011	Excellence in Mentorship and Teaching Award, UCLA Gastroenterology Fellowship Program

C. Contribution to Science

1. For over a decade, I have been interested in identifying and closing the significant gap in the uptake of routine vaccinations among patients with IBD on immunosuppressive therapy. Immunosuppression in IBD is common, yet the majority of patients were not receiving appropriate immunizations, thus placing them at incremental risk for infections. This finding has subsequently been replicated by others in over 2 dozen health care settings around the world, many of which used our survey instrument. My subsequent research in this area includes prospective clinical trials assessing the immunological response to routine vaccinations among patients with IBD receiving different classes of immunosuppressive treatments. These publications found that thiopurine immunomodulators, but not anti-TNF agents, appeared to blunt the immune response to pneumococcal and pertussis vaccines, and that these vaccines are safe in this population. This body of work has changed the standards of care for patients with IBD, with increased awareness of the need for vaccinations prior to the initiation of immunosuppression, and with the incorporation of vaccination strategies for these patients in international guidelines and performance measure sets. I served as the primary investigator in all of these studies.

- a. Dezfoli S, Horton HA, Thepyasuwan N, Berel D, Targan SR, Vasiliauskas EA, Dubinsky M, Shih DQ, Kaur M, McGovern DP, Ippoliti A, Feldman EJ, Melmed GY. Combined Immunosuppression Impairs Immunogenicity to Tetanus and Pertussis Vaccination Among Patients with Inflammatory Bowel Disease. *Inflamm Bowel Dis*. 2015 Aug;21(8):1754-60. PubMed PMID: [25985242](#).
 - b. Agarwal N, Ollington K, Kaneshiro M, Frenck R, Melmed GY. Are immunosuppressive medications associated with decreased responses to routine immunizations? A systematic review. *Vaccine*. 2012 Feb 14;30(8):1413-24. PubMed PMID: [22197580](#).
 - c. Melmed GY, Agarwal N, Frenck RW, Ippoliti AF, Ibanez P, Papadakis KA, Simpson P, Barolet-Garcia C, Ward J, Targan SR, Vasiliauskas EA. Immunosuppression impairs response to pneumococcal polysaccharide vaccination in patients with inflammatory bowel disease. *Am J Gastroenterol*. 2010 Jan;105(1):148-54. PubMed PMID: [19755964](#).
 - d. Melmed GY, Ippoliti AF, Papadakis KA, Tran TT, Birt JL, Lee SK, Frenck RW, Targan SR, Vasiliauskas EA. Patients with inflammatory bowel disease are at risk for vaccine-preventable illnesses. *Am J Gastroenterol*. 2006 Aug;101(8):1834-40. PubMed PMID: [16817843](#).
2. The studies above prompted a broader interest in the assessment of the quality of care for patients with IBD. My work in this area has explored the variation of care as a surrogate for poor quality of care among specialty providers for IBD. This has coincided with efforts on a broader, national level to rigorously develop quality indicators for IBD which I have led and continue to actively pursue. In particular, I am co-PI on a multicenter (currently 30 sites), nation-wide quality improvement program (IBD Qorus) that integrates and aggregates patient-reported outcomes, electronic medical record-based clinical data, care pathways, and quality metrics through a shared data platform.
- a. Devlin SM, Melmed GY, Irving PM, Rubin DT, Kornbluth A, Kozuch PL, Raffals LE, Velayos FS, Sparrow MP, Baidoo L, Bressler B, Cheifetz AS, Jones J, Kaplan GG, Siegel CA. Recommendations for Quality Colonoscopy Reporting for Patients with Inflammatory Bowel Disease: Results from a RAND Appropriateness Panel. *Inflamm Bowel Dis*. 2016 Jun;22(6):1418-24. PubMed PMID: [27057680](#).
 - b. Bradford K, Melmed GY, Fleshner P, Silverman N, Dubinsky MC. Significant variation in recommendation of care for women of reproductive age with ulcerative colitis postileal pouch-anal anastomosis. *Dig Dis Sci*. 2014 Jun;59(6):1115-20. PubMed PMID: [24549832](#).
 - c. Siegel CA, Allen JI, Melmed GY. Translating improved quality of care into an improved quality of life for patients with inflammatory bowel disease. *Clin Gastroenterol Hepatol*. 2013 Aug;11(8):908-12. PubMed PMID: [23747710](#).
 - d. Melmed GY, Siegel CA, Spiegel BM, Allen JI, Cima R, Colombel JF, Dassopoulos T, Denson LA, Dudley-Brown S, Garb A, Hanauer SB, Kappelman MD, Lewis JD, Lynch I, Moynihan A, Rubin DT, Sartor RB, Schwartz RM, Wolf DC, Ullman TA. Quality indicators for inflammatory bowel disease: development of process and outcome measures. *Inflamm Bowel Dis*. 2013 Mar;19(3):662-8. PubMed PMID: [23388547](#).
3. The measurement of disease activity and quality of life among patients with IBD is of paramount importance both in the clinical and research settings. There has been an increased recognition of the need for valid and reliable measures of gastrointestinal symptoms, disease activity, and quality of life among patients with IBD. As a clinician and clinical researcher, I have led and participated in several efforts to develop valid instrument for disease symptom, activity, and quality of life assessments critical to endpoint determinations for IBD clinical research and trials. I was involved as the IBD expert in the development of NIH PROMIS GI symptom scales.
- a. Khanna P, Agarwal N, Khanna D, Hays RD, Chang L, Bolus R, Melmed G, Whitman CB, Kaplan RM, Ogawa R, Snyder B, Spiegel BM. Development of an online library of patient-reported outcome measures in gastroenterology: the GI-PRO database. *Am J Gastroenterol*. 2014 Feb;109(2):234-48. PubMed PMID: [24343547](#); PubMed Central PMCID: [PMC4275098](#).

- b. Nagaraja V, Hays RD, Khanna PP, Spiegel BM, Chang L, Melmed GY, Bolus R, Khanna. Construct validity of the Patient-Reported Outcomes Measurement Information System Gastrointestinal symptom scales in systemic sclerosis. *Arthritis Care Res (Hoboken)*. 2014 Nov;66(11):1725-30. PubMed PMID: [24692332](#); PubMed Central PMCID: [PMC4182150](#).
 - c. Spiegel BM, Hays RD, Bolus R, Melmed GY, Chang L, Whitman C, Khanna PP, Paz SH, Hays T, Reise S, Khanna D. Development of the NIH Patient-Reported Outcomes Measurement Information System (PROMIS) gastrointestinal symptom scales. *Am J Gastroenterol*. 2014 Nov;109(11):1804-14. PubMed PMID: [25199473](#); PubMed Central PMCID: [PMC4285435](#).
 - d. Surti B, Spiegel B, Ippoliti A, Vasiliauskas EA, Simpson P, Shih DQ, Targan SR, McGovern DP, Melmed GY. Assessing health status in inflammatory bowel disease using a novel single-item numeric rating scale. *Dig Dis Sci*. 2013 May;58(5):1313-21. PubMed PMID: [23250673](#); PubMed Central PMCID: [PMC4161217](#).
4. After training in clinical trial methodology and participating in clinical trials, I have been involved in the design and analysis of clinical trials for inflammatory bowel disease. I was involved in the design, analysis, and writeup for 2 early phase clinical trials of PDA001 (pluripotent placenta-derived cells) for Crohn's disease, and have served as lead PI for other trials as well. I have also conducted several posthoc and meta-analyses of clinical trials using primary data.
- a. Hazlewood GS, Rezaie A, Borman M, Panaccione R, Ghosh S, Seow CH, Kuenzig E, Tomlinson G, Siegel CA, Melmed GY, Kaplan GG. Comparative effectiveness of immunosuppressants and biologics for inducing and maintaining remission in Crohn's disease: a network meta-analysis. *Gastroenterology*. 2015 Feb;148(2):344-54.e5; quiz e14-5. PubMed PMID: [25448924](#).
 - b. Jones JL, Kaplan GG, Peyrin-Biroulet L, Baidoo L, Devlin S, Melmed GY, Tanyingoh D, Raffals L, Irving P, Kozuch P, Sparrow M, Velayos F, Bressler B, Cheifetz A, Colombel JF, Siegel CA. Effects of Concomitant Immunomodulator Therapy on Efficacy and Safety of Anti-Tumor Necrosis Factor Therapy for Crohn's Disease: A Meta-analysis of Placebo-controlled Trials. *Clin Gastroenterol Hepatol*. 2015 Dec;13(13):2233-40.e1-2; quiz e177-8. PubMed PMID: [26142167](#).
 - c. Melmed GY, Pandak WM, Casey K, Abraham B, Valentine J, Schwartz D, Awais D, Bassan I, Lichtiger S, Sands B, Hanauer S, Richards R, Oikonomou I, Parekh N, Targan S, Johnson K, Hariri R, Fischkoff S. Human Placenta-derived Cells (PDA-001) for the Treatment of Moderate-to-severe Crohn's Disease: A Phase 1b/2a Study. *Inflamm Bowel Dis*. 2015 Aug;21(8):1809-16. PubMed PMID: [25985246](#).
 - d. Shah ED, Siegel CA, Chong K, Melmed GY. Evaluating Study Withdrawal Among Biologics and Immunomodulators in Treating Ulcerative Colitis: A Meta-analysis of Controlled Clinical Trials. *Inflamm Bowel Dis*. 2016 Apr;22(4):933-9. PubMed PMID: [26818417](#).

Complete List of Published Work in My Bibliography: <http://1.usa.gov/28AYzLz>

D. RESEARCH SUPPORT

Grants

Miraca Life Sciences, Inc.	04/13/2018-04/12/2021	0.12 calendar
Role: Site PI		
Title: Therapeutic drug monitoring of anti-TNF maintenance therapy in patients with inflammatory bowel disease: A prospective, multi-center study to compare two different assays		
Crohn's and Colitis Foundation	01/01/2015 – 12/31/2020	6.0 calendar
Role: Co-Principal Investigator, Site PI		
Title: CCFA Quality of Care Program for Adult Patients with Inflammatory Bowel Disease.		
Pfizer	01/02/2018 – 01/01/2020	1.2 calendar
Role: co-Principal Investigator		
Other co-PI's: Spiegel, Almario; Grant ID 37998665		
Title: IBD&me: Optimizing Selection of Biologic and Small Molecule Therapies in IBD		

Clinical Trials

Janssen Pharmaceuticals Role: Site PI Title: (Protocol CNTO1275UCO3001) A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Subjects with Moderately to Severely Active Ulcerative Colitis	1/30/2015 – 01/31/2022	0.72 calendar
Gilead Sciences, Inc. Role: Site PI Title: (Protocol GS-US_419-3896) A Long-Term Extension Study to Evaluate the Safety of Filgotinib in Subjects with Crohn's Disease.	11/10/2017 – 11/09/2020	0.12 calendar
Gilead Sciences, Inc. Role: Site PI Title: (Protocol GS-US-418-3899) A Long-Term Extension Study to Evaluate the Safety of Filgotinib in Subjects with Ulcerative Colitis.	11/10/2017 – 11/09/2020	0.12 calendar
Gilead Sciences, Inc. Role: Site PI Title: (Protocol GS-US-419-3895) Combined Phase 3, Double-blind, Randomized, Placebo-Controlled Studies Evaluating the Efficacy and Safety of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Crohn's Disease.	08/04/2017 – 08/03/2020	0.36 calendar
Gilead Sciences, Inc. Role: Site PI Title: (Protocol GS-US-418-3898) Combined Phase 3, Double-blind, Randomized, Placebo-Controlled Studies Evaluating the Efficacy and Safety of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Ulcerative Colitis.	08/04/2017 – 08/03/2020	0.36 calendar
Atlantic Pharmaceuticals Ltd. Role : Site PI Title: (Protocol ACH UCP-301) A Randomised, Double-Blind, Placebo-Controlled Trial of the Safety and Efficacy of Topical Alicaforsen Enema in Subjects with Active, Chronic, Antibiotic Refractory Primary Idiopathic Pouchitis	02/29/2016 – 02/28/2019	0.12 calendar
Takeda Development Center Americas Role : Site PI Title: (Protocol C13008) A Phase 3, Open-label Study to Determine the Long-term Safety and Efficacy of Vedolizumab (MLN0002) in Patients with Ulcerative Colitis and Crohn's Disease.	10/05/2009-12/31/2018	0.24 calendar
Janssen Pharmaceuticals Role : Site PI Title: (Protocol CNTO1275CRD3003) A Phase 3 Open Label Studies to Determine the Short- and Long-term Safety and Efficacy of Ustekinumab in Patients with Crohn's Disease.	10/11/2012-09/30/2018	0.24 calendar
Pfizer Pharmaceuticals Role : Site PI Title: (Protocol A3921139) Phase 3 Open Label Studies to determine the Short- and Long-term Safety and Efficacy of Tofacitinib in Patients with ulcerative colitis.	05/29/2012 – 07/31/2018	0.12 calendar