1. Personal History

Name:	**Edith Towler Zemanick, MD MSCS**
Current Position:	Professor of Pediatrics Department of Pediatrics University of Colorado School of Medicine
Professional Address:	Children's Hospital Colorado 13123 E. 16th Avenue B-395 Aurora, CO 80045 Office: 720-777-5426 Fax: 720-777-7284 Email: edith.zemanick@childrenscolorado.org

2. Education

University of California, Berkeley, B.S. Chemistry	Berkeley, CA	1989-1993
Albert Einstein College of Medicine, MD Yeshiva University,	Bronx, NY	1995-1999
Children's National Medical Center George Washington University Residency, Pediatrics	Washington, DC	1999-2002
University of Colorado School of Medicine Fellowship, Pediatric Pulmonology	Denver, CO	2004-2007
University of Colorado School of Medicine Research Fellow, Pediatric Pulmonology	Aurora, CO	2007-2008
University of Colorado Denver and Health Sciences Center MSCS, Clinical Science Thesis, "Molecular detection of microbes in children with cystic fibrosis"	Aurora, CO	2005-2009

3. Academic appointments

University of Colorado School of Medicine, Aurora, CO	
Instructor, Department of Pediatrics	2007-2008
Assistant Professor, Department of Pediatrics	2008- 2015
Associate Professor, Department of Pediatrics	2015- 2022
Professor, Department of Pediatrics	2022-
Graduate Faculty (Special), Univ of Colorado Clinical Science Program	2017-

4. Hospital, government or other professional positions

Hospital positions

Pediatric Associate, Department of Emergency Medicine Children's National Medical Center, Washington, DC	2002-2004
General Pediatrician, Department of Neonatology Washington Adventist Hospital, Takoma Park, MD	2002- 2004
Memorial Hospital, Colorado Springs, CO, Medical Staff	2008- 2018

Children's Hospital Colorado/ University of Colorado School of Medicine

Children's Hospital Colorado, Aurora, CO, Medical Staff	2007-
Children's Hospital Colorado, Colorado Springs, Medical Staff	2019-
University of Colorado Hospital, Aurora, CO, Medical Staff	2007-
Associate Director, University of Colorado Pediatric Cystic Fibrosis Center	2012-
Director, Cystic Fibrosis Foundation Therapeutics Development Center Children's Hospital Colorado	2016-
Clinical Research Medical Director, Breathing Institute	2021-
Research Director, Pediatric Pulmonary Medicine Fellowship	2022-
Clinical Research Medical Director, BI, Dept. of Pediatrics	2023-

Other Professional Positions

Associate Medical Director, Center for Biochemical Markers National Resource Center, Cystic Fibrosis Foundation Therapeutics	2016- 2018
Medical Director, Center for Sweat Analysis National Resource Center, Cystic Fibrosis Foundation Therapeutics	2017-

Consulting

OptiNose, Inc., Yardley, PA	2017-2018
Cystic Fibrosis Foundation, Sweat Testing Advisory Committee	2018-
Vertex Pharmaceuticals, Sweat Chloride Advisory Board	2021
Vertex Pharmaceuticals, Global CF Virtual Medical Advisory Board VX-121	2022

5. Honors, Special Recognitions and Awards

American Medical Women's Association, Janet M. Glasgow Achievement Citation, 1998

Alpha Omega Alpha Honor Society, 1998
Albert Einstein College of Medicine, Yeshiva University

The Maynard Cohen Award in Pediatrics, 2002
Children's National Medical Center, George Washington University

Cystic Fibrosis Foundation First- and Second-Year Clinical Fellowship, 2004-2006

Outstanding Master of Science in Clinical Sciences Student Award, 2006

NIH/NHLBI T32 Training grant, "Academic training program in pediatric pulmonary diseases" T32HL007670, PI: Abman, 2007-2008

University of Colorado SOM Nominee, Doris Duke Charitable Foundation Clinical Scientist Development Award, 2011

Society for Pediatric Research, Elected Member, 2011

Women's Leadership Training, University of Colorado Anschutz Medical Campus, Invited participant, 2013-2014

Professional Leadership Award, Women in Medicine and Science Office, University of Colorado School of Medicine. Award provides funding to attend the American Association of Medical Colleges (AAMC) Early Career Women Faculty Professional Development Seminar, 2014.

AAMC 2014 Early Career Women Faculty Professional Development Seminar invited participant, July 2014.

NIH/NHLBI Loan Repayment Program recipient, 2008-2012, 2014- 2016

CF Foundation CF Center Quality Care award, 2018

CU Anschutz Graduate School Dean's Master's Mentoring Award, 2021

6. Membership in professional organizations

American Medical Student Association, 1997-
American Academy of Pediatrics, 2001-2024
American Thoracic Society, 2005-
    ATS Training Committee, 2018-2019
Society for Pediatric Research, 2011-2024

7. Major Committee and Service Responsibilities

Children's Hospital Colorado and Department of Pediatrics, University of Colorado School of Medicine

Current

Associate Director, Pediatric Cystic Fibrosis Center, 2012-
CF Center Quality Improvement and Clinical Guidelines committee, 2009-
Breathing Institute Research Subcommittee, 2016-2020; Chair 2021-
    This committee develops research education and infrastructure for pediatric pulmonary fellows and junior faculty to support individuals pursuing a career in research.
Infection Prevention and Control for Cystic Fibrosis working group, Chair 2017-
Breathing Institute Research Operations Committee, Chair 2021-
    This committee addresses operational research needs within the Breathing Institute
Clinical Liaison, Precision Medicine Institute, 2023-
Promotions and Tenure Committee, Department of Pediatrics, 2024-
Digitalization of Research Records RFP Selection Committee, 2024

Previous

Chair, CF Center Quality Improvement and Clinical Guidelines committee, 2012-2016
CF Education Workshop planning committee, 2011-2017
Research Compliance Committee, Children's Hospital Colorado Research Institute, 2013-2016
Clinical Competency Committee, Pediatric Pulmonary Fellowship Program, 2015; 2017-2018
    This committee reviews the progress and performance of all pediatric pulmonary fellows as part of ACGME requirements.
Faculty Scorecard Development Committee, Pediatric Pulmonary Medicine, 2015
Internal Advisory Committee, Colorado CF Research Development Program [CFF RDP Grant #NICK15R0], 2016-2019
Search committee, Pediatric pulmonary fellowship coordinator, 2021

National

Current

Co-Chair, Physician Training Programs Committee, Cystic Fibrosis Foundation (CFF), 2019-
Medical Advisory Committee, CFF, 2020-
Sweat Testing Advisory Committee, CFF, 2018-
National Resource Core Working Group, CFF, 2018-
TDN Steering Committee, Chair 2023 –
    Member, 2020-
    Vice-Chair, 2022

CFF Clinical Research Executive Committee, 2023-
CFF/TDN Regional Cooperatives Leadership Committee, 2022-
Advisory Board, Indiana University School of Medicine CME Cystic Fibrosis Online Education Program, 2024-

Previous
Preschool Clinical Guidelines Development Committee, CFF, 2013-2015
CF Foundation Therapeutics Development Network Steering Committee, OPTIMIZE clinical trial, 2013-2017
Anti-fungal Interest Group, CFF Therapeutics Development Network, 2015-2016
Co-Chair, Pediatric-track, American Thoracic Society Resident Bootcamp, ATS International Meeting, Denver, CO, May 2015
Co-Chair, Pediatric-track, American Thoracic Society Resident Bootcamp, ATS International Meeting, San Francisco, CA, May 2016
Chair, Pediatric-track, American Thoracic Society Resident Bootcamp, ATS International Meeting, Washington DC, May 2017
Chair, Pediatric-track, American Thoracic Society Resident Bootcamp, ATS International Meeting, San Diego, May 2018
Invited member, Antimicrobial Resistance in CF International Working Group, 2017- 2019
Member, Editorial Board, CFF Therapeutics Development Network Newsletter (TDN Times), 2013-2015
Physician Training Program Evaluation Working Group, CFF, 2018-2019
Chair, Transitioning/ Career Development Subgroup
Training Committee, American Thoracic Society, 2018-2019
ATS Research Core Training
ATS Pediatric Fellows Reading List working group
ATS Pediatric Resident Bootcamp
Protocol Review Committee, CFF Therapeutics Development Network, 2018-2020
Co-Chair, Telehealth and Home Monitoring Workshop, CFF, 2020-2021
Invited participant, CFF Fungal working group, 2020-2021
Associate Editor, CFF Therapeutics Development Network Newsletter (TDN Times), 2015-2021
North American Cystic Fibrosis Conference Planning Committee, CF Foundation, 2017-2023

Community
Current
Community Outreach and Missions Committee, Central Presbyterian Church, Denver, CO 2018-
Children's Hospital Colorado Courage Classic, Team Leader for Breathing Institute, 2013-2014, 2016-2024 (Total fundraising 2016-2024 ≈ $155,000)

Previous
Member, Board of Directors, Highline Academy, Denver Public Schools, 2011-2015
Chair, School Health and Wellness Committee, Highline Academy, 2012-2018
Member, Task Force, Health Assistance Site, Central Presbyterian Church, Denver CO. Supported by a grant from Connect for Colorado. 2013-2015
Co-Chair, Children's Education and Family Missions Committee, Central Presbyterian Church, Denver, Colorado, 2014-2016

Advocacy Training, Day at the Capital, LiveWell Colorado, April 2017
Pediatric Advocacy Action Team, American Academy of Pediatrics and Children's Hospital Colorado committee, 2019-2021

8. Equity, Diversity, and Inclusion Activities

2021	Presented a talk at pediatric pulmonary conference for faculty and fellows entitled, "DEI Issues in Research".
2021-2024	Participated in anti-bias training for pediatric residency and pediatric pulmonary fellowship recruitment interviews
2024	NIH Mitigating Bias in Peer Review course, CRS Learning module
2024	NIH Review Integrity course, CRS Learning module
2025	Destination Equity Training, Children's Hospital Colorado

9. Licensure and Board Certification

Pediatric Pulmonology, ABPID#: 657791	2008-2025
Colorado Medical License	2004-2025
DEA	2004-2025
Pediatric Advanced Life Support (PALS)	2002-2026
Basic Life Support (BLS)	2002-2026

10. Inventions, intellectual property and patents held or pending

None

11. Review and Referee Work

Peer-review record for journals available at:

Web of Science Researcher Profile- Zemanick

External grant reviews
Study sections
NIH/NIDDK CF Clinical and Translation Centers (P30) review panel, 2017 and 2019
Co-Chair, CFF Physician Training Programs Committee, 2019-
CFF Infection Research Initiative Review Committee, 2019-2020
CF Canada Grant Review Panel, 2019, 2021-2025

Individual grant reviews
National Children's Research Center, Dublin, Ireland, 2011
Health Research Board, Republic of Ireland, 2012
Research Office, Food and Health Bureau, Hong Kong SAR China, 2012
GACR Sparks for Children's Health, Sparks Charity, UK, 2013
Czech Science Foundation, Czech Republic, 2013
Medical Research Council, UK, 2014

Geneva University Hospitals and Faculty of Medicine Research Foundation, Switzerland, 2015
Cystic Fibrosis Foundation, Bethesda, Maryland, USA, 2015
PhD Thesis, The University of Western Australia, 2017
German Cystic Fibrosis Association, 2018
Swiss National Science Foundation, 2017-2018
CF Canada reviewer, 2018-2020
CF Trust, UK 2024

North American Cystic Fibrosis Conference, abstract reviewer, 2011-2013; 2017-2020
American Thoracic Society International Meeting, abstract reviewer, 2018-2019
ATS Fellows Case Conferences abstracts
ATS Innovations in Education abstracts

Internal grant reviews
Grant Reviewer, K to R Transition Program, University of Colorado SOM, 2013
Grant Reviewer, Children's Hospital Colorado Research Institute, Research Scholars Award, 2013, 2019-2020
Grant Reviewer, CCTSI Child and Maternal Health Pilot Grant program, 2020
EPID 7912 Study Section for Grant Writing Course, 2019- 2020

12. Invited extramural lectures, presentations and visiting professorships

Regional

1. A 9-year-old girl with cystic fibrosis and advanced lung disease. University of Colorado Section of Pediatric Pulmonary Medicine Retreat, Breckenridge, CO, February 2005.
2. Molecular detection of microbes in children with cystic fibrosis. University of Colorado Section of Pediatric Pulmonary Medicine Retreat, Breckenridge, CO, February 2007.
3. Pediatric airway emergencies. Grand Rounds, Denver Health Medical Center, Denver, CO, December 2009.
4. Cystic Fibrosis vs. PCD: Clinical and Testing Comparisons. Rocky Mountain American Association for Clinical Chemistry Section Conference, Children's Hospital Colorado, Aurora CO, March 2010.
5. Evaluation and management of chronic cough in children. Kaiser Permanente Colorado Continuing Medical Education Program, Denver, CO, February 2011.
6. The airway microbiome in children with cystic fibrosis. Grand Rounds, Department of Pediatrics, University of Colorado School of Medicine, Children's Hospital Colorado, Aurora, CO, May 2011.
7. The airway microbiome in children with cystic fibrosis. SomaLogic, Inc, Boulder, Colorado, August 2011
8. The airway microbiome in children with cystic fibrosis: Pulmonary exacerbations. Research presentation, Pace Laboratory, University of Colorado Boulder, Boulder, CO, November 2011.
9. The airway microbiome in children with cystic fibrosis. Basic and Translational Pediatric Research Seminar Series, Children's Hospital Colorado Research Institute, Aurora, CO, April 2012.

10. Evaluation and management of chronic cough in children. Grand Rounds, Denver Health Medical Center, Denver, CO, April 2012.
11. Longitudinal airway microbiome in clinically stable children with CF. Research in Progress, University of Colorado Denver/ Anschutz Medical Campus, Microbiome RIP Campus-wide Conference Series, December 2013.
12. Cystic fibrosis update. Grand Rounds, Children's Hospital Colorado Briargate Network of Care Clinic, Colorado Springs, CO, April 2014.
13. Advances in CF microbiology: what's new in the airway? Cotton Conference, Children's Hospital Colorado Fellows Retreat, February 2016.
14. Center for Sweat Analysis (CSA), national resource center overview. Presented as part of CFF TDN laboratory site visit, July 2017.
15. CF clinical research overview. Presented as part of CFF site visit to the Colorado CF Center, September 2017.
16. Characterizing CFTR modulated changes in sweat chloride and clinical outcomes in CF: the CHEC-SC Study. Children's Hospital Colorado Pediatric Pulmonology Annual Cotton Conference, Frasier, Colorado, March 2018.
17. CFTR modulator-induced sweat chloride changes: Initial results from the CHEC- SC study. Children's Hospital Colorado Pediatric Pulmonology Annual Cotton Conference, Snowmass, Colorado, February 2020.
18. Research telehealth update. Breathe better: Promoting healthy lungs together. Children's Hospital Colorado Breathing Institute, Colorado, September 2020.
19. Transformational Therapies: Entering a new era in cystic fibrosis care, University of Colorado Department of Pediatrics Grand Rounds, invited speaker, March 2024.
20. Genetic based therapies for cystic fibrosis. Gene Team Lecture Series, Precision Medicine Institute, Children's Hospital Colorado, April 2024.

National

1. Identification of novel microbes using molecular detection techniques in a nine-year-old girl with cystic fibrosis and advanced lung disease. Pediatric Clinical Fellows Session, North American Cystic Fibrosis Conference, Baltimore, MD, October 2005.
2. Respiratory issues in Moebius syndrome. Moebius Syndrome Foundation conference, San Francisco, CA, July 2006.
3. Microbial communities in children with cystic fibrosis and clinically stable lung disease. Platform Presentation, Pediatric Academic Societies Meeting, Honolulu, HI, May 2008.
4. Reliability and validity of quantitative real-time PCR microbial detection from CF airway specimens. Platform presentation at workshop, NACFC, Minneapolis, MN, October 2009.
5. Respiratory issues in Moebius syndrome. Moebius Syndrome Foundation conference, Broomfield, CO, July 2010
6. Oropharyngeal bacterial microbiome in young children with cystic fibrosis and healthy controls. Workshop presentation, North American CF Conference, Baltimore, MD, October 2010
7. Relationship between lung microbiome, lung function and inflammation during treatment of CF pulmonary exacerbation. Workshop presentation, North American CF Conference, Anaheim, CA, November 2011.

8. Identification of circulating biomarkers of pulmonary exacerbation using a multiplex SOMAmer assay. Workshop presentation, North American CF Conference, Anaheim, CA, November 2011.
9. The role of the airway microbiome in antibiotic treatment failure. Symposium presentation, North American CF Conference, Salt Lake City, Utah, CA. October 2013.
10. Airway microbiome in cystic fibrosis. Invited presentation. Mountain West CF Consortium Conference, Billings, MT, May 2014.
11. Airway microbiota detected from clinically obtained BALF samples from CF patients and disease controls. Workshop presentation, North American CF Conference, Atlanta, GA, October 2014.
12. Utility of microbiota analyses as clinical outcome measures in young children with CF. Symposium presentation, North American CF Conference, Atlanta, GA, October 2014.
13. Microbiome in cystic fibrosis. Presented as part of ATS Postgraduate Course, Understanding the lung microbiome: current state and clinical implications. American Thoracic Society International Meeting, Denver, CO, May 2015.
14. How and when to submit abstracts, papers and chapters. ATS Resident Bootcamp, American Thoracic Society International Meeting, Denver, CO, May 2015.
15. The airway microbiome in children with cystic fibrosis. University of Washington and Seattle Children's Hospital CF Biostatistics and Epidemiology Workshop, Seattle WA, July 2015.
16. Evolution of the airway microbiome in infants with cystic fibrosis (CF). Scientific Symposium, ATS International Meeting, Washington D.C., May 2017.
17. Cystic Fibrosis, ATS Pediatric Resident Bootcamp, Washington D.C., May 2017
18. What are the challenges in identifying bacterial and fungal organisms in specimens from CF patients? Symposium speaker, American Society of Microbiology, ASM Microbe, New Orleans, LA, June 2017.
19. Efforts to advance CFTR therapies, Part II: Population Based Biomarkers. CF Foundation, Therapeutics Development Network General Meeting, Indianapolis, IN, November 2017.
20. Characterizing CFTR modulated changes in sweat chloride and associated clinical outcomes. CF Clinical Research Scholars Program Research Seminar, Seattle, WA, November 2017
21. Longitudinal changes in airway microbiota in infants with CF enrolled in the BONUS study. Workshop Presentation, North American CF Conference, Indianapolis, IN, November 2017.
22. Cystic Fibrosis, ATS Pediatric Resident Bootcamp, San Diego, CA May 2018
23. Recommendations for use of antimicrobial resistance testing in clinical practice, Symposium speaker, North American CF Conference, Denver, CO, October 2018.
24. Academic careers in CF: CF Foundation working group recommendations. CFF Therapeutics Development Network Spring Meeting, Austin, TX, April 2019.
25. Moving breakthrough therapies to children- rapidly, safely and ethically. Plenary Panel Discussion, CFF Therapeutics Development Network Spring Meeting, Austin, TX, April 2019
26. How to prevent RC burnout. Breakout session, CFF Therapeutics Development Network Spring Meeting, Austin, TX, April 2019
27. Making the mentor-mentee relationship work. CFF Career Development Retreat, Ellicott City, MD September 2019.

28. Achieving optimal growth in children with cystic fibrosis: a multidisciplinary approach. Pediatric Feeding and Swallowing National Conference Breakout Session, Children's Hospital Colorado, Aurora, CO, September 2019.
29. Pediatric pulmonary exacerbations: approach and research priorities of caregivers and CF center directors. Workshop Presentation, North American CF Conference, Nashville, TN, November 2019.
30. Current treatments in cystic fibrosis: Where are we and how did we get here? Cotton Conference, Denver, February 2021 (virtual)
31. Respiratory sampling for fungal infection in CF, CFF Fungal Workshop, February 2021 (virtual)
32. Microbiology of the CF Lung and *Pseudomonas*: Impact and eradication, Invited content expert, Leadership and Education for Advanced Practice Providers (LEAPP) program, October 2021.
33. CFF Infection Detection and Diagnosis workshop, invited presenter, October 2021 (virtual)
34. Remote monitoring and sweat chloride measurements. Invited presenter, CFF Remote Endpoints Working Group, virtual, May 2022
35. Challenging cases of *Staphylococcus aureus*: All the questions you were afraid to ask. Lunch and learn, co-moderator and speaker. North American CF Conference, Philadelphia, PA November 2022.
36. Current state of sweat testing, invited presenter at CF Foundation Sweat Device Meeting, November 2022 (virtual).
37. Scientific symposium, Invited speaker at University of Washington, Dr. Bonnie Ramsey Retirement Celebration and Scientific Symposium, Seattle, WA, December 8, 2022.
38. Invited mentor; co-leader for mock grant review session; breakout group leader, "Grantsmanship", CFF Career Development Retreat, Oceanside, CA February 2023.
39. International investigator-initiated studies to support and complement the trial pipeline: learning from the past, planning for the future. Invited presenter and participant, Global Therapeutic Development Research Meeting, Cystic Fibrosis Foundation, Bethesda MD, March 2023.
40. Knowledge gap to be addressed- informed by CF Community, invited presenter and investigator/ participant at study design day for Streamlined treatment of pulmonary exacerbations in pediatrics (STOP Peds) study held at the CFF Therapeutics Development Network Coordinating Center, Seattle, WA, May 2023.
41. Sweating the Small Stuff: Best practices for sweat testing to diagnose cystic fibrosis. Symposium Speaker, Association for Diagnostic and Laboratory Medicine (previously AACC), Anaheim, CA, July 2023.
42. Microbiology of the CF Lung. Invited content expert, Leadership and Education for Advanced Practice Providers (LEAPP) program, January 2024. (virtual)
43. Invited mentor; co-leader for mock grant review session; session leader, "Professional breakout: Leadership and Mentorship", CFF Career Development Retreat, Albuquerque, NM, March 2024.

International

1. The airway microbiota during cystic fibrosis pulmonary exacerbations. German meeting of Microbiology and Hygiene, Hamburg, Germany, October 2012.

2. Do CFTR modulators change treatment of infection and clinical outcomes? Invited symposium speaker, S7: Infection beyond CFTR modulators. European CF Society conference, Rotterdam, Netherlands, June 2022
3. Sweat testing overview and training. Invited speaker and educator. As an invited trainer, I presented a talk on sweat testing in cystic fibrosis and co-led 2 training sessions, one for clinical sweat testing for representatives from lower- and middle-income countries (Eastern European and African countries) and one for research coordinators from EU CF Clinical Trials Network sites. European CF Society Conference, Vienna, Austria, June 2023
4. Airway microbial communities in young children with CF and implications for clinical care. Keynote Speaker, Early CF Disease CF Symposium, SickKids Cystic Fibrosis Centre, Toronto, Canada, November 2023.

Conference leadership

1. Co-moderator, Emerging pathogens: questions and controversies. Workshop at North American CF Conference, Baltimore, MD, October 2010.
2. Co-moderator, Infectious Disease Management Workshop at North American CF Conference, Anaheim, CA, November 2011
3. Co-moderator, Defending the CF Airways Workshop at North American CF Conference, Orlando, FL, October 2012
4. Co-moderator for Roundtable, Microbiome and CF, North American CF Conference, Orlando, FL, October 2012
5. Co-moderator, Symposium: Omics of CF Airway Infection, North American CF Conference, Atlanta, GA, October 2014.
6. Co-moderator, Faculty Mentoring and Career Development in CF: Current status, needs and opportunities CF Foundation Therapeutics Development Network Annual Spring Meeting, Herndon, VA, April 2015.
7. Co-moderator, Symposium: Assessing presymptomatic children, North American CF Conference, Phoenix, AZ, October 2015.
8. Facilitator, Mechanisms in Cystic Fibrosis and other bronchiectatic diseases, Thematic Poster Session, ATS International Conference, Washington D.C. May 2017
9. Co-moderator, Symposium: Early infection and host response. North American CF Conference, Indianapolis, IN, November 2017.
10. Co-moderator, Brown Bag Session: Challenging cases in NTM management. North American CF Conference, Denver, CO, October 2018.
11. Co-moderator, Symposium: Impact of CFTR- modulation on infection. North American CF Conference, Nashville TN, November 2019.
12. Co-moderator, Symposium: Tackling CF infections in the modern era. North American CF Conference, November 2021 (Virtual)
13. Panelist, An Interactive Brainstorm: How can my research team build trust with people with CF who do not have access to CFTR modulators? TDN Spring meeting, Kissamee, Florida, April 2022.
14. Co-moderator, Current and Future Research Needs in the Era of Highly Effective Modulator Therapies for Cystic Fibrosis Virtual Workshop, Breakout session: The risks and benefits of starting HEMT in people with CF and minimal disease, June 2022.
15. Co-moderator, E poster session- Pathogenesis and treatment of CF pathogens, European CF Society conference, Rotterdam, Netherlands, June 2022

16. Co-leader, TDN Site Summit, held at Cystic Fibrosis Foundation, Bethesda, MD, September 2023.
17. Co-leader, Sweat Testing and Advisory Committee, in-person meeting held at Cystic Fibrosis Foundation, Bethesda, MD, September 2023.
18. Conference organizer, TDN Spring Meeting, Charlotte, NC, April 2023
19. Conference organizer, TDN Spring Meeting, National Harbor, MD, April 2024
20. Workshop Co-Moderator, CF Care in Transition: Strategies for managing a pediatric clinical research program, TDN Spring Meeting, National Harbor, MD, April 2024

Other Presentations

1. CF Research update. CHCO CF Family Education Event, held annually, 2010-2018
2. CF lung infections: Myth and facts. CHCO CF Family Education Event, 2014
3. Parade of PI's: Overview of clinical trials, TDN Spring Meeting, San Antonio, AZ, April 2016.
4. Fellow and Junior Faculty Q&A panel. Small group discussion leader, ATS Resident Bootcamp, San Francisco, CA, May 2016.
5. Sweat testing in cystic fibrosis. Training lecture provided to clinical study team from Flately Discovery Laboratory (6 training participants), May 2017.
6. CHEC-SC Investigator Meeting: Study overview. Investigators Meeting held at North American CF Conference, Indianapolis, IN, November 2017.
7. CF Research update. CHCO CF Family Education Virtual Town Hall, 2020-2021
8. Novel culture independent approaches to fungal detection, Breakout session group lead, CFF Fungal Workshop, February 2021 (virtual)
9. Panelist, Silver Linings Playbook: Lessons from the pandemic. Therapeutics Development Network Spring Meeting, April 2021
10. Panelist, Utilizing existing CF resources to enhance investigator-initiated research, Therapeutics Development Network Spring Meeting, April 2021
11. Roundtable Moderator, Respiratory Cultures in CF: How and What? North American CF Conference, November 2021 (Virtual)
12. CFF and Therapeutics Development Network Regional Cooperatives Initiative. Presented at North American CF Conference, Philadelphia, PA, November 2022.
13. CF Research: Modulators and Beyond, Family Education Night, Children's Hospital Colorado, November 2023
14. CFF and Therapeutics Development Network Regional Cooperatives Initiative. Presented at North American CF Conference, Phoenix, Arizona, November 2023.

13. Teaching record

A. Classroom Instructional Activities

Course/number	Trainee/ Participants	Year	Role	# Trainees
Molecules to Medicine IDPT 500	Medical Students, UCSOM	2011	Lecture, *Cystic fibrosis*	120
Molecules to Medicine IDPT 500	Medical Students, UCSOM	2012	Lecture, *Cystic fibrosis*	120

Molecules to Medicine IDPT 500	Medical Students, UCSOM	2013	Lecture, *Cystic fibrosis*	120
Grant Writing CLSC 7101, Clinical Sciences	MSCS/PhD students	2017	Small group guest leader	10
Research Grant Writing EPID 7912, Clinical Sciences	MSCS/PhD students	2019	Mock Study Section	10
Grant Writing CLSC 7101, Clinical Sciences	MSCS/PhD students	2020	Mock Study Section	10

B. Local presentations to medical students, pediatric residents, fellows and others

Topic	Conference	Year
Control of ventilation: How gas exchange is regulated	Pulmonary Fellows Conference	2005
CF case presentations	Pulmonary Resident Lecture	2007
Interpretation of pulmonary function testing	Pulmonary Resident Lecture	2007
Emerging infections in cystic fibrosis	Pulmonary Fellows Conference	2008
CF case presentations	Pulmonary Resident Lecture	2008
Interpretation of pulmonary function testing	Pulmonary Resident Lecture	2008
Pediatric airway emergencies	Pediatric Resident Conference	2009
RIP: Characteristics of CF patients admitted for pulmonary exacerbation	Pulmonary Fellows Conference	2009
Evaluation and management of chronic cough in children	Pulmonary Fellows Conference	2009
ABCs – The pediatric airway	Medical Students, Pediatric rotation conference	2010
Evaluation and management of chronic cough in children	Pulmonary Fellows Conference	2010
CF research overview and update	CF Bootcamp Continuing Education Program, CHCO	2011
ABCs – The pediatric airway	Medical Students, Pediatric rotation conference	2011
Careers in medicine and cystic fibrosis	HOSA Colorado Future Health Professionals	2012
ABCs – The pediatric airway	Medical Students, Pediatric rotation conference	2012
Journal club, co-led with fellow	Pediatric pulmonology journal club	2012
Cystic fibrosis: Mechanisms of disease	CF Bootcamp Continuing Education Program, CHCO	2013
CF emergencies	CHCO Emergency Department Fellows Conference	2013
RIP: The airway microbiota during CF pulmonary exacerbations	Pulmonary Fellows Conference	2013
Bronchiectasis: Diagnosis and treatment	Allergy and Immunology Fellows Conference, National Jewish	2014

CF emergencies	Pulmonary Fellows Conference	2014
Cystic fibrosis: update and recent advances	Pediatric Surgery Conference	2015
Aspergillus and the lung	Pulmonary Fellows Conference	2015
Introduction to CF	Pulmonary Fellows Conference	2015
Journal club, co-led with fellow	Pediatric pulmonology journal club	2016
CF emergencies	Pulmonary Fellows Conference	2016
Infection prevention and control, and lung function testing in CF	Respiratory Therapists, CHCO	2016
Introduction to CF	Feeding therapy group, CHCO	2016
CF Microbiome research program	Breathing Institute Research council	2016
Entering the era of personalized medicine: advances in CF research	CF Bootcamp Continuing Education Program, CHCO	2017
Journal club, co-led with fellow	Pediatric pulmonology journal club	2018
CF emergencies	Pulmonary Fellows Conference	2018
CF 101	Pulmonary Fellows Conference	2018
Study of outpatient pulmonary exacerbations in CF (STOP-PEDS)	CF Family Advisory Board, CHCO	2019
Cystic fibrosis: clinical and research implications for neonatal providers	Neonatology noon conference, CHCO	2019
Journal club, co-led with fellow	Pediatric pulmonology journal club	2019
Approach to bronchiectasis: Diagnosis and treatment	Pulmonary Fellows Conference	2019
Cystic fibrosis	Respiratory Therapists, CHCO	2019
CF clinical research update	CF Research and Clinical team, CHCO	2020
Cystic Fibrosis Jeopardy for pulmonary resident bootcamp, CHCO	Pediatric residents, medical students, advanced practice providers	2020-2023
Crafting a clear & memorable presentation	Pediatric Pulmonary Grand Rounds Research Series	2021
BI Research Council - CF registry/databases	Pediatric Pulmonary Grand Rounds Research Series	2021
Strategies for working with a biostatistician	Pediatric Pulmonary Grand Rounds Research Series	2021
Research in the Breathing Institute	Pediatric Pulmonary Grand Rounds Research Series	2021
Diversity, Equity and Inclusion in Research	Pediatric Pulmonary Grand Rounds Research Series	2021
Journal Club, co-led with fellow, Annie Wolfe	Pediatric pulmonology journal club	2022
Cystic fibrosis jeopardy	Pediatric Resident Bootcamp for pulmonary service, CHCO	2021-2023
Introduction to research in the Breathing Institute	Pediatric Pulmonary Grand Rounds Research Series	2024

C. Clinical Teaching Activities

Site	Teaching Activity	Dates	Trainees

CHCO Pulmonary inpatient attending	Bedside Rounds, informal lectures	2007-present, 2-4 weeks/year	Med students/pediatric residents/pediatric pulmonary fellows, APP
CHCO Pulmonary consult or NICU consult attending	Bedside Rounds	2007-present, 2-5 weeks/year	Pediatric pulmonary fellows, APP
CHCO Pediatric pulmonary clinic	Ambulatory Care Preceptor	2007-present, 3-4 ½-day clinics/month	Med students/pediatric residents/pediatric pulmonary fellows
CHCO Pulmonary fellows' clinic	Ambulatory Care Preceptor	2010-present, 4 ½-day clinics/year	Pediatric pulmonary fellows
CHCO Briargate clinic Colorado Springs, CO	Ambulatory Care Preceptor	2017-2020, 1 full day clinic/month	Pediatric pulmonary fellows
CHCO Network of care clinic, Colorado Springs, CO	Ambulatory Care Preceptor	2008-2017, 1 full day clinic/month	Pediatric pulmonary fellows, med students
CHCO Pediatric CF continuity clinic	Ambulatory Care Preceptor	2015-present, ½ day clinic/month	Pediatric pulmonary fellows

D. Course leadership and curriculum development

Co-chair, American Thoracic Society Pediatric Resident Bootcamp, 2015-2018

Developed the first Pediatric track for the ATS Resident Bootcamp held at the ATS International Annual Conference in 2015, and co-chaired annually through 2018. This 2-day conference provided lecture, case-based and hands-on learning for Incoming pediatric pulmonary, critical care and neonatology fellows. Since 2015 more than 100 incoming fellows have participated in the bootcamp. The program consistently received excellent to outstanding ratings from learners.

Development and outcomes from this program were published in 2020: Drake MG, Shah NG, Lee M, Brady A, Connors GR, Clark BJ, Kritek PA, McCallister JW, Burkart KM, Pedraza I, Jamieson D, Ingram JL, Lynch L, Makani SS, Siegel-Gasiewski J, Larsson EM, Zemanick ET, Liptzin DR, Good R, Crotty Alexander LE. **Development of a National Academic Boot Camp to Improve Fellowship Readiness.** *ATS Sch.* 2020 Dec 22;2(1):49-65. doi: 10.34197/ats-scholar.

Curriculum Development:

Indiana University School of Medicine, CF Educational Courses
Mary Cross, Aimee LeDoux, Edith Zemanick; Course Four: Guide to Sweat Testing for the Clinical Laboratory, The Role of Sweat Testing in the Diagnosis of Cystic Fibrosis; February 2021. Available online for CME/CE and MOC Part 2 credit at https://medicine.iu.edu/cme/specialized/Cystic-Fibrosis

Adherence: a key to successful treatment of cystic fibrosis. Taylor-Cousar JL, Nichols D, Riekert K and Zemanick ET. Epocrates CME Released 3/17/2023, Expires 3/16/2024. Available online at Adherence: A Key to Successful Treatment of Cystic Fibrosis (epocrates.com)

D. **Mentees/ Trainees**

1. Undergraduates, medical students, and residents

Trainee, Years	Stage of Training	My Role	Current Position
Seth Morrison 2010	Undergraduate, Gonzaga University	Summer research mentor	Gastroenterology Fellow, University of North Carolina, Chapel Hill
Ashley Song 2018	Undergraduate, Dartmouth College	Summer research mentor	Software engineer
Emily Johnson 2014-2016	Medical Student, UCSOM	Research mentor	Family medicine physician, Colorado Springs, CO
Ben Massey 2019-2020	Medical student, UCSOM	Research mentor, Scholarly project	Internal medicine, Univ of Arizona
Helene Kuffel 2020-	Medical student, UCSOM	Research mentor	Anesthesiology residency, Stanford
Alexandra Hernandez (Maness) 2020-2021	Medical student, UCSOM	Research mentor	Medix, Inc, Dallas TX
Adrianne Colborg, MD 2018 - 2019	Resident, Pediatrics UCSOM	NACFC travel award sponsor, Research mentor	Pediatric pulmonary fellowship, Texas Children's Hospital
Christina Osborne, MD, 2016-2017	Resident, Pediatrics UCSOM	Clinical mentor	Faculty, Children's Hospital of Philadelphia
Angela Metcalf, MD, 2022-2023	Resident, Pediatrics; UCSOM	Research mentor	Fellow, pediatric pulmonary medicine

2. Fellows

Trainee, Years	Stage of Training	My Role	Current Position
Stephen Hawkins, MD 2011-2012; 2014	• Resident, Pediatrics • Fellow, pediatric pulmonary medicine, UCSOM	Longitudinal block mentor Clinical Preceptor	Assistant Professor of Pediatrics, UCSOM
Tom Flass, MD 2010-2012	Fellow, Pediatric gastroenterology, UCSOM	Scholarly oversight committee member	Pediatric gastroenterologist, Billings MT
Nidhya Navanandan, MD 2013-2016	Fellow, Pediatric emergency medicine, UCSOM	Scholarly oversight committee member	Assistant Professor of Pediatrics, UCSOM
Heather De Keyser (Hoch), MD MSCS 2014-2016	Fellow, Pediatric pulmonary medicine, UCSOM	Research mentor Clinical Preceptor	Assistant Professor of Pediatrics, UCSOM

Michelle Sobremonte-King, MD 2016-2017	Fellow, Pediatric pulmonary medicine, UCSOM	Clinical mentor	Assistant Professor, University of Washington, Seattle WA
Nancy Hong, MD 2016-2019	Fellow, Pediatric pulmonary medicine, UCSOM	Clinical Preceptor Research Mentor	Assistant Professor, University of Nebraska, Omaha, NE
Melisa S. Tanverdi, MD 2017-2020	Fellow, Pediatric emergency medicine, UCSOM	Scholarly Oversight Committee	Assistant Professor of Pediatrics, UCSOM
Patricia Lenhart-Pendergrass, MD PhD 2018-2020	Fellow, Pediatric pulmonary medicine, UCSOM	Sponsor, CFF Clinical Fellowship Award	Instructor/ Research fellow, UCSOM
Racha Khalaf, MD MSCS 2018-2020	Fellow, Pediatric gastroenterology, UCSOM	Research co-mentor, SOC committee member MSCS Dissertation Committee	Assistant Professor of Pediatrics, University of South Florida, Tampa FL
Daniel Hinds, MD 2019-2022	Fellow, Pediatric pulmonary medicine, UCSOM	Sponsor, CFF Clinical Fellowship Award	Faculty, University of Iowa
Spencer Poore, MD MSCS 2018-2021	Fellow, Pediatric pulmonary medicine, UCSOM	Research mentor, Sponsor CFF award MSCS Dissertation Committee	Assistant Professor of Pediatrics, University of Alabama Birmingham
Mfon Udoko, MD 2020- 2022	Fellow, Pediatric pulmonary medicine, UCSOM	Scholarly oversight committee member	Faculty, Cincinnati Children's
Annemarie Wolfe, MD 2020-2023	Fellow, Pediatric pulmonary medicine, UCSOM	Sponsor, CFF Clinical Fellowship Award	Faculty, University of Texas Austin
Taylor Curry, MD 2021-2023	Fellow, Pediatric pulmonary medicine, UCSOM	Scholarly oversight committee	Assistant Professor of Pediatrics, Indiana University/Riley Children's Hospital
Emily Holmes, MD 2021- 2024	Fellow, Pediatric pulmonary medicine, UCSOM	Sponsor, CFF Clinical Fellowship Award	Assistant Professor of Pediatrics, UCSOM
Kamyron Jordan, MD 2022-2024	Fellow, Pediatric pulmonary medicine, UCSOM	Fellow, Pediatric pulmonary medicine, UCSOM	Assistant Professor of Pediatrics, University of New Mexico
Lilah Melzer, MD 2022-2025	Fellow, Pediatric pulmonary medicine, UCSOM	Sponsor, CFF Clinical Fellowship Award (2022-24); CFF Clinical Fellowship Award: Research (2024-25) Research Mentor	Fellow, UCSOM Faculty, Maine Medical Center, Portland, ME

Katie Enzer, MD 2022-2024	Fellow, Pediatric pulmonary medicine, UCSOM	Scholarly Oversight Committee	Assistant Professor of Pediatrics, UCSOM
Angela Metcalf, MD 2023-	Fellow, Pediatric pulmonary medicine, UCSOM	Sponsor, CFF Clinical Fellowship Award	Fellow, UCSOM
Jorge Valencia-Rico 2024-	Fellow, Pediatric pulmonary medicine, UCSOM	Sponsor, CFF Clinical Fellowship Award	Fellow, UCSOM

3. Faculty

Trainee, Years	Stage of Training	My Role	Current Position
Jordana Hoppe, MD MSCS 2011 - 2024	• Resident, Pediatrics • Fellow, Pediatric pulmonary medicine • Assistant Professor of Pediatrics- Pulmonary Medicine, UCSOM	Research mentor Scholarly oversight committee MSCS Dissertation Committee	Associate Professor of Pediatrics- Pulmonary Medicine, UCSOM
Sophie Fillon, PhD 2014-2017	Assistant Professor, Gastroenterology, UCSOM	Research mentor, Co-investigator	Moved to Germany for family reasons
Andrea Hahn, MD 2016-2024	Assistant Professor, Infectious Diseases, Children's National Health System, Washington DC	Research Sponsor and co-mentor	Associate Professor of Pediatrics and Genomics & Precision Medicine, The George Washington University School of Medicine
Maxene Meier, MS Biostatistics 2020- 2021	Research instructor, Pediatrics	Research sponsor for biostatistical training award	Left the institute
Tim Vigers MS Biostatistics 2021-2023	Research instructor, Pediatrics	Research sponsor for biostatistical training award (STAT-Net award)	Research instructor, Pediatrics
Spencer Poore, MD MSCS 2021-	Assistant Professor of Pediatrics, University of Alabama Birmingham	Research co-mentor, CFF Harry Shwachman Career Development Award	Assistant Professor of Pediatrics, University of Alabama Birmingham

14. Grant Support

Current Grant Support

ZEMANI17K0 7/1/2017-6/30/2025

Clinical Research Award, Cystic Fibrosis Foundation, Therapeutics, Inc

Characterizing CFTR modulated changes in sweat chloride and clinical outcomes
NCT03350828
Role: PI (15%)
Award: $580,613 ($510,939 Direct costs)
Goals: To determine sweat chloride (SC) variability and the association of SC with patient characteristics and clinical outcomes independent of CFTR modulation, to characterize patterns of SC response associated with commercially-available CFTR modulator treatments and determine patient characteristics associated with SC response, and to determine the relationship between SC values with long term clinical outcomes by measuring SC in a large epidemiologic study of patients treated with CFTR modulators.

BEGIN-ZEMANI20K0 1/1/2020-12/31/2026
Cystic Fibrosis Foundation
A Prospective Study to Evaluate Biological and Clinical Effects of Significantly Corrected CFTR Function in Infants and Young Children (BEGIN)
NCT04509050
Role: PI (5%)
Award: $805,353 ($720,852 Directs)
Goals: To measure the direct and indirect effects of elexacaftor/tezacaftor/ivacaftor by collecting and analyzing clinical research outcomes and biomarkers on infants and toddlers with CF both before and after they begin treatment, focusing on the earliest stages of disease.

STOP PEDS RCT 4/01/24-03/31/2029
CFF 006810A124 (SANDER24A0-AP, PI:Sanders)
Role: Co-I (5%)
Streamlined treatment of pulmonary exacerbation in pediatrics randomized clinical trial
Goals: To evaluate the long and short-term safety and efficacy of two antibiotic strategies in the outpatient management of pulmonary exacerbations in children with cystic fibrosis.

CFF 002884121 (Zemanick) 1/1/2022-12/31/2024
TDN Steering Committee Leadership (renewal in progress)
CFF
Role: PI (10% FTE)
Award: $93,204 ($83,218 Directs)
Goal: Support leadership as chair of the TDN Steering Committee.

1R01HL174913 (Beswick) 07/01/24-06/30/29
NIH
Sinus disease in young children with cystic fibrosis
Role: Co-I (5%)
Goals: The goals of this proposal are to characterize chronic rhinosinusitis and olfactory dysfunction in young children with cystic fibrosis and to test the hypothesis that highly effective modulator therapy improves chronic rhinosinusitis and olfactory dysfunction in young children with CF

BESWIC22A0 (Beswick) 11/23-10/2024

CFF
Sinus disease in young children with cystic fibrosis
Role: Co-I (1%)
Goals: The aims of this study are (1) to characterize chronic rhinosinusitis (CRS) and olfactory dysfunction in young children with CF and test the hypothesis that these CF disease complications are associated with worse pulmonary health and nutritional status, (2) to test the hypothesis that highly effective modulator therapy improves chronic rhinosinusitis and olfactory dysfunction utilizing sinus MRI opacification and sinonasal symptom burden, and (3) to test the hypothesis that highly effective modulator therapy improves olfactory dysfunction using olfactory bulb volume, quantitative olfactory function, olfactory cleft opacification, and olfactory-specific quality of life measures.

RARE-OB-16 (Solomon) 09/2016-12/31/2024
Rare CFTR Mutation Cell Collection Protocol
Cystic Fibrosis Foundation
Role: Site PI (1% FTE)
Total Award: $65,689
Major Goals: Children's Hospital Colorado will participate in this study by enrolling patients in order to collect specimens (blood and nasal cells) from people with rare CFTR mutations, as well as to create induced pluripotent stem cells (iPSCs). The specimens collected during this study and the iPSCs created from them will be stored for use in future research to learn more about CF and study the effects of new medications, which may help people with rare CFTR mutations.

CFF #006993Y124 - Zemanick 7/1/2024-6/30/2025
Cystic Fibrosis Foundation
Therapeutics Development Center
Role: Principal Investigator (15%)
Total award: $208,612 ($186,262 Direct)
The goal of this grant is to implement multicenter clinical trials in cystic fibrosis

CFF #ZEMANI20Y2-SVC (Zemanick) 4/1/2020- 3/31/2025
Cystic Fibrosis Foundation
CFF Core Clinical Research Services
Role: PI (5%)
Total award: $172,229 ($153,777 Directs)
The goals of the CFF TDN Center for Sweat Analysis are to serve as a National Resource Center to standardize sweat collection, handling, analysis and validation; to serve as a centralized laboratory for measuring sweat electrolytes as a CFTR-related outcome measure in CF clinical studies; to train and qualify site personnel in sweat collection; and, to provide consultative services to investigators and companies interested in sweat electrolyte measurements.

CC009 (PI Sagel) 07/2023-06/2025
Cystic Fibrosis Care Center Award
Cystic Fibrosis Foundation
Renewed annually
Role: Co-I (10% FTE)

Total award: $257,129
Goals: This award helps to fund key personnel and infrastructure support for our accredited CF clinical care center. Dr. Sagel is the Director of the University of Colorado CF Center and Pediatric CF Program and Dr. Zemanick is the Associate Director of the CF Center.

Mentee awards

POORE22Q0 (Poore) 7/2022 – 06/2025
Cystic Fibrosis Foundation
Harry Shwachman Clinical Investigator Award
The Intersection Between Atopy and Aspergillus Infection in Cystic Fibrosis
Role: Mentor

005308B123 - Metcalf 7/1/2023-6/30/2025
Cystic Fibrosis Foundation
First and Second Year Clinical Fellowship
Role: Mentor
Award: Y1: 62,000 (Direct costs only)
Y2: 67,000
Goal: To provide specialized training and early career development for physicians interested in chronic pulmonary and gastrointestinal disease of children, adolescents and adults with CF, and to prepare well-qualified candidates for careers related to CF.

007021B124 - Jorge Valencia-Rico 7/1/2024-6/30/2026
Cystic Fibrosis Foundation
First and Second Year Clinical Fellowship
Role: Mentor
Award: Y1: 62,000 (Direct costs only)
Y2: 67,000
Goal: To provide specialized training and early career development for physicians interested in chronic pulmonary and gastrointestinal disease of children, adolescents and adults with CF, and to prepare well-qualified candidates for careers related to CF.

006728D123 -- Melzer 7/1/2024-6/30/2025
Cystic Fibrosis Foundation
Assessing the feasibility of home nighttime cough monitoring in children with cystic fibrosis
Clinical Fellowship: Research
Role: Mentor
Award: 101,000

Completed mentee awards
003559B122 - Melzer 7/1/2022-6/30/2024
Cystic Fibrosis Foundation
First and Second Year Clinical Fellowship
Role: Mentor
Award: Y1: 62,000 (Direct costs only)

Y2: 67,000
Goal: To provide specialized training and early career development for physicians interested in chronic pulmonary and gastrointestinal disease of children, adolescents and adults with CF, and to prepare well-qualified candidates for careers related to CF.

HOLMES21B0 7/1/2021-6/30/2023
Cystic Fibrosis Foundation
First and Second Year Clinical Fellowship
Role: Mentor
Award: Y1: 62,000 (Direct costs only)
Y2: 67,000
Goal: To provide specialized training and early career development for physicians interested in chronic pulmonary and gastrointestinal disease of children, adolescents and adults with CF, and to prepare well-qualified candidates for careers related to CF.

003233H221 – Kuffel 04/01/2022-9/30/2022
Student Traineeship
Cystic Fibrosis Foundation
Improvement in fat-soluble vitamin levels following highly-effective CFTR modulator use in children with CF
Role: Co-mentor
Goal: Determined changes in fat-soluble vitamin levels after initiation of ivacaftor or elexacaftor/tezacaftor/ivacaftor

HAHN18A0-Q (Hahn) 4/1/2018-9/30/2021
Harry Shwachman Clinical Investigator Award, Cystic Fibrosis Foundation
Subtherapeutic B-lactam pharmacokinetics impact the CF airway microbiome
Role: Co-Mentor
Award: $130,000 per year
Goals: To determine (1) the association between sub-therapeutic β-lactam exposure and airway microbiome taxonomic diversity, (2) the association between broader antibiotic spectrum use and airway microbiome taxonomic diversity, and (3) to evaluate the concerted association between β-lactam exposure and antibiotic spectrum on pulmonary function.

POORE20D0 Poore (PI) 7/1/2020-6/30/2022
CFF
Third- and Fourth-Year Clinical Fellowship Award
Immune Profiles in CF Fungal Infection
NCT04476758
Role: Mentor
Award: Y1: 100,000 (Direct costs only)
Y2: 100,000 (Transitioned to UAB, Co-mentors Zemanick and Rowe)
Goals: To compare Th2 inflammation in patients with and without fungal infections in patients with CF and to those with ABPA, and to investigate allergic sensitization to fungal elements in patients with CF fungal infection without ABPA compared to those without fungal infection and to those with ABPA.

WOLFE20B0 (Wolfe) 7/1/2020-6/30/2022
Cystic Fibrosis Foundation
First and Second Year Clinical Fellowship
Role: Mentor
Award: Y1: 62,000 (Direct costs only)
Y2: 67,000
Goal: To provide specialized training and early career development for physicians interested in chronic pulmonary and gastrointestinal disease of children, adolescents and adults with CF, and to prepare well-qualified candidates for careers related to CF.

HINDS19BO (Hinds) 7/1/2019-6/30/2021
Cystic Fibrosis Foundation
First and Second Year Clinical Fellowship
Role: Mentor
Award: Y1: $61,750 (Direct costs only)
Y2: $66,750
Goal: To provide specialized training and early career development for physicians interested in chronic pulmonary and gastrointestinal disease of children, adolescents and adults with CF, and to prepare well-qualified candidates for careers related to CF.

LENHAR18B0 (Lenhart-Pendergrass) 7/1/2018-6/30/2020
Cystic Fibrosis Foundation
First and Second Year Clinical Fellowship
Role: Mentor
Award: $61,750 Y1; $66,750 Y2
Goal: To provide specialized training and early career development for physicians interested in chronic pulmonary and gastrointestinal disease of children, adolescents and adults with CF, and to prepare well-qualified candidates for careers related to CF.

Completed grant support

HILL18A0 (Hill) 4/1/2018-3/31/2023
Clinical Research Award, Cystic Fibrosis Foundation
Improving *P. aeruginosa* detection in non-expectorators via breath testing
NCT04735952
Role: Co-I (1%)
Award: 367,057 (350,000 direct) (University of Colorado $247,040, $228,741 Directs)
Goal: To (1) refine and validate volatile biomarkers in the breath of adult and pediatric CF patients for detecting established *P. aeruginosa* lung infections, and (2) quantify intra-subject breath variability of the target pediatric population.

CFF #00843I221 (Harris) 5/1/2021- 4/30/2023
Detection of pathogens using plasma microbial cell-free DNA
Cystic Fibrosis Foundation Pilot and Feasibility Award
Role: Co-I

Award: $111,795 ($99,817 Direct Costs)
Goal: The aims of this study are to compare bacteria detection by microbial cell free DNA to sputum culture results over the course of a pulmonary exacerbation. Banked serum samples from a previously conducted clincial study of exacerbations will be used for mcf-DNA analyses and results compared to microbiologic culture results.

ZEMANI20Y7 Zemanick (PI) , Vigers 09/01/20-8/31/2023
Deep machine learning for automated bronchiectasis scoring from CT
STAT-Net Award
CFF
Role: PI, Mentor (5%)
Award: Y1: 51,158 (Direct costs only)
Y2: 41,817
Y3: 37,241
The goal of this proposal is to support Mr. Timothy Vigers, a biostatistician and Research Instructor in the Department of Pediatrics at the University of Colorado School of Medicine, as he expands his support for cystic fibrosis (CF) focused investigators at the Children's Hospital Colorado (CHCO) CF Center. The award will promote collaboration with CF investigators and biostatisticians within the CF Statistical Research Network (CF StatNet).

CFF #002923Y121 - Zemanick 4/1/2022-06/30/2024
Cystic Fibrosis Foundation
Therapeutics Development Center
Role: Principal Investigator (15%)
The goal of this grant is to implement multicenter clinical trials in cystic fibrosis
Total award: $672,805 ($592,068 Directs)

CFF #ACCURS09Y0 (Zemanick) 1/1/14 – 3/31/2023
Cystic Fibrosis Foundation
Therapeutics Development Center
Role: Principal Investigator (5/1/16) (15%)
The goal of this grant is to implement multicenter clinical trials in cystic fibrosis
Award:

2016:	$168,167	($155,710 Direct)
2017:	$174,161	($161,260 Direct)
2018:	$177,909	($164,731 Direct)
2019:	$177,142	($164,020 Direct)
2020:	$44,286	($40,743 Direct) - *bridge funding for Jan- March 2020*
2020:	$134,028	($124,100 Direct) - *April 2020- March 2021*
2021:	$191,881	($177,668 Direct)
2022:	$47,970	(NCE)

SANDER20A0-AP Sanders (PI) 7/1/2020-5/31/2022
Streamlined Treatment of Pulmonary Exacerbations in Pediatrics (STOP-PEDS)
NCT04608019

CFF
Role: Co-I (4%)
Award (CHCO subaward): 51,256 (45,764 Directs)
Goal: To assess the acceptability and feasibility of a multicenter randomized trial of the intensity of oral antibiotic treatment for mild outpatient pulmonary exacerbations in children with CF.

HILL17P0 (Hill) 2/1/2018-12/31/2021
Cystic Fibrosis Foundation
Improving outcomes in CF patients: Toward rapid detection of *P. aeruginosa*
NCT04735952
Role: Co-I (2%)
Award: $120,294 (University of Colorado $20,536)
Goal: To develop standard operating procedures for breath collection at three clinics and evaluate inter-site variability and evaluate intra-subject breath variability in pediatrics through longitudinal breath sampling at three clinics.

ZEMANI17Y5 11/1/2017-10/31/2021
CFFT Clinical Research Scholars Program
Sweat Chloride changes and clinical outcomes in response to CFTR modulation
Role: PI (20%)
Award: $186,245 Direct Costs (no indirects)
Goal: The goal of this career development training award is to enhance clinical research proficiency and develop the necessary clinical research capabilities to become an independent investigator who can formulate and lead multi-center, clinical research studies.

R56HL139846 (Hill) 9/20/2018- 3/31/2021
NIH/NHLBI
Improving outcomes in CF patients: Toward rapid detection of *P. aeruginosa*
NCT04735952
Role: Co-I
Award: $514,347 (University of Colorado budget $18,875)
Goals: To refine volatile biomarkers in the breath of adult and pediatric CF patients for detecting established *P. aeruginosa* lung infections, and to quantify intra-subject breath variability of the target pediatric population.

CFF # ACCURS14Y4 (Zemanick) 12/1/14-3/31/2021
Cystic Fibrosis Foundation
Additional Resource Coordinator (ARC) award
Role: PI (7/1/16)
This project supports the salaries for new Cystic Fibrosis Research Coordinators.
Award:

2016: $168,167 ($155,710 Direct)
2017: $81,548 ($75,507 Direct)
2018: $65,367 ($60,525 Direct)
2019: $49,571 ($45,899 Direct)
2020: $16,524 ($15,200 Direct) – *bridge funding for Jan- March 2020. No cost extension granted 4/20-3/21, $69,356*

SANDER18A1 (PI: Sanders) 10/1/2018-6/30/2020
Clinical Research Award
Standardizing treatment of pulmonary exacerbations in pediatrics (STOP-PEDS)
Role: Co-I
Award $213,625 total; $203,208 direct (Site budget: $20,825 total, $19,282 Direct)
Goals: The goals of this proposal are to (1) describe differences in patient and pulmonary exacerbation characteristics among children with CF treated with oral antibiotics over the phone and in clinic, (2) determine the range and variability of outcomes in the 1-3 months following treatment among those treated with oral antibiotics, and (3) identify predictors of treatment with IV antibiotics and failure to recover following treatment with oral antibiotics.

FILLON15A0 (PI: Harris) 10/1/15-09/30/20
Cystic Fibrosis Foundation Clinical Research Award
Effect of acid blockade on microbiota and inflammation in CF
Role: Co-investigator
Award: $193,139 ($179,648 Direct); Current year (18-19): $99,972.79
The goals of this project are to determine whether esophageal microbial composition in children with CF changes after withdrawal of acid blockade, to determine whether esophageal microbiota in children with CF changes after initiation of acid blockade in patients started for clinical indications, and to examine the relation between acid blockade medication and inflammation in association with bacterial communities.

HARRIS18G0 (Harris) 4/1/2018-3/31/2020
Cystic Fibrosis Foundation
Early Epidemiology and Succession of CF airway Microbiota
Role: Co-I (3%)
Award: $100,000
The focus of this proposal is young children with CF to capture clinical interventions from birth. Our Central Hypothesis is that biological systems are highly dependent on prior conditions and longitudinal surveillance of the upper airway microbiota from as close to birth as feasible will provide important information on bacterial succession and delineate the relationship with specific interventions and clinical outcomes.

University of Colorado/ Colorado School of Mines Collaboration Pilot Award 7/1/17-6/30/20
Investigating Medical Biofilm Oxygen Gradients with Nanosensors
Role: Co-PI (Zemanick/ Cash)
Award: $40,000
Goal: To develop and optimize ratiometric nanosensors for oxygen detection in *Pseudomonas aeruginosa* biofilms, and to determine oxygen gradients under antibiotic response in biofilms grown from clinical isolates.

CFF # ACCURS08Y2 (Zemanick) 1/1/2017-3/31/2020
Cystic Fibrosis Foundation Therapeutics
CFFT TDN National Resource Center – Center for Sweat Analysis
Role: PI (12/1/2017)

The goals of the CFFT TDN Center for Sweat Analysis are to serve as a National Resource Center to standardize sweat collection, handling, analysis and validation; to serve as a centralized laboratory for measuring sweat electrolytes as a CFTR-related outcome measure in CF clinical studies; to train and qualify site personnel in sweat collection; and, to provide consultative services to investigators and companies interested in sweat electrolyte measurements.
Award:
2017: $ 43,662 ($40,428 Direct)
2018: $38,006 ($35,191 Direct)
2019: $38,635 ($35,773 Direct)
2020 (partial): $9,659 ($8,886 Direct) - *bridge funding for Jan- March 2020*

CFF #ACCURS03Y2 (Sagel) 1/1/03 – 3/31/2021
Cystic Fibrosis Foundation
Therapeutics Development Center – Biochemical Marker Laboratory
Role: Associate Medical Director, Biochemical Marker Laboratory (7/1/16)
The goal of this grant is to develop and perform assays of biochemical mediators relevant to clinical trials performed through the Cystic Fibrosis Foundation Therapeutics Development Network.

ZEMANI16A0 4/1/2016-3/31/2018
Clinical Research Award, Cystic Fibrosis Foundation, Therapeutics, Inc
Longitudinal airway microbiota in infants with CF enrolled in BONUS
Role: PI
Award: $214,964 ($199,041 Direct Costs)
Goal: To longitudinally characterize airway microbiota detected in oropharyngeal (OP) swabs collected during a prospective observational clinical study, the Baby Observational and Nutritional Study (BONUS); to determine the relationship between microbial ecologic characteristics, specific bacterial taxa, and changes in the microbiota over time with nutritional, respiratory and inflammatory outcomes; and, to determine the relationship between OP and gastrointestinal microbiota.

NIH/ NHLBI 1K23HL114883 1/1/2014-12/31/2017
K23 Mentored Patient-Oriented Research Award
Airway Microbiome in Cystic Fibrosis Pulmonary Exacerbations
Role: Principal Investigator
Award: $615,060 ($170,640 per year, $158,000 direct costs)
Goal: To determine the relationship between the airway microbiome, host-response biomarkers and lung function in pediatric CF subjects hospitalized for pulmonary exacerbation, to determine changes in the microbiome and host-response with IV antibiotic treatment, and to determine the relationship between *Prevotella* and clinical response to treatment. COMIRB Approved protocol #07-0365.

WAGNER15A0 (Wagner) 4/1/2015-3/31/2017
Cystic Fibrosis Foundation Clinical Research Award
Joint Longitudinal Modeling of *Pseudomonas aeruginosa* and pulmonary exacerbations in CF
Role: Co-investigator (5%)

Award: $171,680 ($158,963 Direct)
The goals of this project are to characterize the temporal progression of *Pseudomonas aeruginosa* infection from initial to chronic infection and pulmonary exacerbations using data from large clinical trials and to elucidate the longitudinal associations between *P. aeruginosa* and pulmonary exacerbations.

Dean's Fund Award (Zemanick) 3/5/15-9/30/16
University of Colorado School of Medicine
Airway Microbiome in Cystic Fibrosis Pulmonary Exacerbations
Role: PI
Award: $50,000 ($25,000 current year)
Goal: This internal award provides additional support for my K23 Mentored Patient-Oriented Research Award project.

Clinical Research Award, Cystic Fibrosis Foundation, Therapeutics, Inc 4/1/2012-3/31/2016
Host-microbial biomarkers of pulmonary exacerbation
(Award #ZEMANI12A0)
Role: Principal Investigator
Award: $324,000 (108,000 per year; 100,000 direct costs)
Goal: To determine changes in the CF airway microbiota and circulating and sputum protein biomarkers in response to treatment of a pulmonary exacerbation, and to determine the relationship between the airway microbiota and host-response biomarkers in order to identify microbial communities or individual microbes associated with increased host-response. We also plan to explore the utility of microbial and host-response biomarkers in predicting clinical response to treatment. COMIRB Approved protocol #07-0365.

Clinical Research Award, Cystic Fibrosis Foundation, Therapeutics, Inc. 7/1/2011-6/30/2014
Bronchoalveolar lavage fluid (BALF) specimen bank and lower airway microbiome in children with Cystic Fibrosis (Award #ZEMANI11A0)
Role: Principal Investigator
Award: $122,725 ($113,634 direct costs)
Goal: To establish a multi-center specimen bank of BALF from people with and without CF, in order to provide investigators studying pathogenesis of CF lung disease clinically characterized lower airway samples, and to determine the lower airway microbiome in these BALF samples using molecular analyses and standard microbial culture. COMIRB protocol #11-0234.

Research Scholars Award 2/1/2012-12/31/2013
Children's Hospital Colorado Research Institute
Microbial biomarkers of pulmonary exacerbation in cystic fibrosis
Role: Principal Investigator
Award: $95,000 ($25,000, current year)
Goal: To determine changes in the CF airway microbiota and host defense biomarkers in response to treatment of a pulmonary exacerbation, to identify microbial communities or individual microbes associated with increased host response, and to explore the utility of microbial and host-response biomarkers in predicting clinical response to treatment (FEV_1). COMIRB Approved protocol #07-0365.

Cystic Fibrosis Foundation Therapeutics, Inc. 10/1/2010-09/30/2015
CFF# STAR-too-10K0 (Muhlebach)
Early MRSA therapy in CF- culture based vs. observant therapy (treat or observe)
Role: Site Principal Investigator
Award: Funding dependent on patent enrollment
Goals: Randomized, open-label, multi-center trial in CF patients with new Methicillin-resistant *Staphylococcus aureus* (MRSA) isolated from the respiratory tract that seeks to determine the effectiveness of an early eradication protocol for MRSA.

Harry Shwachman Young Investigator Clinical Research Award 7/1/2008-6/30/2012
Cystic Fibrosis Foundation Therapeutics, Inc.
Early staphylococcal and polymicrobial bacterial infection in CF
(Award # ZEMANI08A0)
Role: Principal investigator
Award: $255,000 ($85,000/year; $236,112 direct costs)
Goals: To determine the longitudinal development of polymicrobial bacterial airway infections in young children with cystic fibrosis.

Cystic Fibrosis Foundation Fourth Year Clinical Fellowship Award 7/1/2007-6/30/2008
Pilot Study of Molecular Detection of Microbes in Children with Cystic Fibrosis(ZEMANI07DO)
PI: Zemanick, E.
Award: $62,600
Mentor: Frank Accurso, MD
Goals: To determine the reproducibility of 16S rRNA gene sequencing for microbial identification in longitudinally collected airway samples from children with cystic fibrosis (CF).
Colorado Multiple Institutional Review Board (COMIRB) Protocol # 05-1172
Clinical Translational Research Center (CTRC) Protocol # 819

Clinical Research and Therapeutics Development Network Activities

A. Investigator-initiated studies

Study	Role	Primary Site/ Sponsor/ Study Status
STOP PEDS RCT: Streamlined treatment of pulmonary exacerbations in pediatrics **(NCT06654752; Advarra IRB)**	Co-I	CFF, Indiana University **Active** 2024-
Assessing the feasibility of home nighttime cough monitoring in children with cystic fibrosis (CF) (**COMIRB 23-0382; NCT06587126**)	Mentor/ Co-I (PI Melzer)	CFF, Single center **Active** 2023-
Immune Profiles in CF Fungal Infections (**IRB 20-0099; NCT04476758**)	Mentor / Co-I (PI: S.Poore)	CFF, UAB, two center, **Data analysis** 2020-
STOP-PEDS Pilot (Streamlined Treatment of Pulmonary Exacerbations in Pediatrics Pilot) (**IRB 20-1231; NCT04608019**)	Co-PI, study lead	CFF, Riley Children's Hospital, Complete

		2020-2022
Baby and Early Childhood Endocrine Factors and Growth in Cystic Fibrosis (BEGIN) Study (**IRB 20-1602; NCT 04509050**)	Co-PI, study lead, PI BALF ancillary sub-study	CFF, Seattle Children's Hospital, **Active** 2020-
Sinus Disease in Young Children with Cystic Fibrosis **(External IRB (UCLA), COMIRB #22-1712; NCT06191640)**	Co-PI, study lead; Site PI	CFF, UCLA (Beswick) **Active** 2023-
Improving P. aeruginosa detection with Breath-based diagnostics (IMPACT-Breath) (**IRB 17-1404; NCT04735952)**	Co-PI, study lead; Site PI	Univ. British Columbia, Arizona State, CFF/NIH **Data analysis** 9/2018- 2023
The CHEC-SC Cohort Study: Characterizing CFTR modulated changes in sweat chloride and their association with clinical outcomes **(IRB 17-1915; NCT03350828)**	Co-PI, study lead Site PI	CFF **Active** 11/2017-
CHEC-SC Pharmacokinetics/ Pharmacodynamics sub-study **(IRB 17-1915)**	Co-I, Site PI	CFF, U. Alabama Birmingham **Data analysis** 11/2017-
PROMISE: A Prospective Study to Evaluate Biological and Clinical Effects of Significantly Corrected CFTR Function; PROMISE-Peds: The PROMISE Pediatric Study 6 to 11 year old. **(IRB 18-1678; NCT04038047 and NCT04613128)**	Sagel, PI Co-I	CFF, UAB **Active** 2018-
Prospective Evaluation of a Standardized Approach to Diagnosis (PREDICT) and Treatment(Patience) of Nontuberculous Mycobacteria Disease in Cystic Fibrosis (**IRB 17-1784**)	Site Co-I	CHCO and NJH, CFF, **Active** 2017-
A master protocol to test the impact of discontinuing chronic therapies in people with cystic fibrosis on highly effective CFTR modulator therapy (SIMPLIFY) (**IRB- 20-0386**)	Site Co-I	Seattle Children's, CFF, Complete 2020-2023
Rare CFTR Mutation Cell Collection Protocol (RARE) **(IRB 16-2421)**	Site PI	UAB/ CFFT/TDN **Active** 2016-
Evaluation of Peripherally Inserted Catheter Complications in CF Patient **(IRB 18-1664)**	Site PI	Maine Med Ctr, CFF Complete 10/2018- 2023
Assessing Effectiveness of CF Infection Prevention and Control Guidelines **(IRB 19-2077)**	Site PI	UNC, CFF **Data analysis** 10/2019-
Longitudinal airway microbiota in infants with cystic fibrosis enrolled in the Baby Observational and Nutritional Study (BONUS) **(IRB 17-0064)**	PI, ancillary study	CHCO, CFFT Complete 1/2017- 2023
Specimen collection in subjects with and without cystic fibrosis **(IRB 99-113)** Collaborations based on Specimen Collection: a. Edith Porter, Cal State Univ. Los Angeles, 2016 b. Preston Bratcher, NJH, 8 CF BALF samples, 2017 c. William Rigby, Dartmouth, 20 BALF (15 CF/ 5 DC), 2017 d. Ezster Vladar, UCSOM, (nasal cell) 2019- e. Terri Laguna, Lurie Children's Hospital, BALF, 2019- f. Vanessa Phelan, UCSOM (sputum), 2018- g. Orlando Esparza, UCSOM CHCO Fellow, Hematology, 2020 (blood specimen) h. Hara Levy, NJH (blood)	PI	CHCO **Active** 1999-

Bronchoalveolar lavage fluid (BALF) specimen bank and lower airway microbiome analysis in children and adults with and without cystic fibrosis **(IRB 11-0234)** Collaborations / specimen bank studies: a. Jane Hill, Heather Bean, Dartmouth/ Arizona State Univ. b. Terri Laguna, Lurie Children's Hospital c. Dan Weiss, Univ. of Vermont i. Abreu SC et al. Am J Physiol Lung Cell Mol Physiol. 2020 Dec 1;319(6):L908-L925. ii. Abreu SC et al. Am J Physiol Lung Cell Mol Physiol. 2019 Dec 1;317(6):L823-L831. d. William Rigby, Dartmouth College	PI, study lead	CHCO (multisite)/ CFFT/ TDN Complete 3/2011- 2022
Microbial biomarkers of pulmonary exacerbation in cystic fibrosis **(IRB 07-0365)**	PI	CHCO Data analysis 5/2008-
Early staphylococcal and polymicrobial bacterial infection in CF **(IRB 07-0839)** Collaborations based on Protocol: - Alex Horswill, UCSOM, Staph Isolates, 2018-2020	PI	CHCO Data analysis 4/2008-
Design CF: Developing e-Health Systems to Improve Growth and Nutrition in CF (Phase II)	Site PI	STRC Study, 2018-2020 Complete
Effect of Acid blockade on microbiota and inflammation in CF (**IRB 14-1645**)	Co-I, completed	CFF, CHCO single center, Complete 2014-2020
Single patient IND for VX445 – Elexacaftor **(IRB 19-1793)**	PI	Closed, 2019
Early MRSA therapy in CF- culture based versus observant therapy (treat or observe)- STAR-too- Staph aureus resistance- treat or observe **(IRB 11-0334)**	Site PI	UNC/ CFFT Complete 4/2011- 5/2015

B. Clinical trials

Study	Role	Sponsor/ Study Status	Dates
A Phase 3, Open-label Study Evaluating the Long-term Safety and Efficacy of Vanzacaftor/Tezacaftor/Deutivacaftor Triple Combination Therapy in Cystic Fibrosis Subjects 1 Year of Age and Older (COMIRB 23-0313; **VX22-121-106**; Advarra Pro00069883)	Co-I (PI: Hoppe)	Vertex **Active**	2023-
A Phase 3, Open-label Study Evaluating the Long-term Safety and Efficacy of VX-121 Combination Therapy in Subjects With Cystic Fibrosis (COMIRB 22-0978; **VX22-121-104,** Advarra Pro00062561)	Co-I (PI: Hoppe)	Vertex **Active**	2022-
A Phase 3 Study Evaluating the Pharmacokinetics, Safety, and Tolerability of VX-121/Tezacaftor/Deutivacaftor Triple Combination Therapy in Cystic Fibrosis Subjects 1 Through 11 Years of Age (COMIRB 22-0309. Vertex Study Number: **VX21-121-105** Advarra Protocol No. Pro00060543)	Co-I (PI: Hoppe)	Vertex **Active**	2022-

A Phase 3, Randomized, Double-blind, Controlled Study Evaluating the Efficacy and Safety of VX-121 Combination Therapy in Subjects with Cystic Fibrosis Who Are Heterozygous for F508del and a Minimal Function Mutation (F/MF) **(VX20-121-102)**	Co-I (PI: Hoppe)	Vertex Closed	2021-2024
A Phase 3, Randomized, Double-blind, Controlled Study Evaluating the Efficacy and Safety of VX-121 Combination Therapy in Subjects With Cystic Fibrosis Who Are homozygous for F508del or Heterozygous for F508del and a Gating (F/G) or Residual Function Mutation (F/RF) (**VX20-121-103**)	Co-I (PI: Hoppe)	Vertex Closed	2021-2024
A phase 3 open-label study evaluating the long-term safety and efficacy of elexacaftor/tezacaftor/ivacaftor triple combination therapy in cystic fibrosis subjects 2 years and older (COMIRB 21-4620, **VX20-445-112**; Advarra Pro00057920)	Co-I (PI: Hoppe)	Vertex **Active**	2021-
Evaluation of VX 445/TEZ/IVA in Cystic Fibrosis Subjects 6 Through 11 Years of Age **(VX18-445-106; IRB 19-1444; NCT03691779)**	Lead Co-PI, site PI	Vertex Closed	2019-2020
A Phase 3, Open-label, and Rollover Study to Evaluate the Long-term Safety and Tolerability of Lumacaftor/Ivacaftor Treatment in Subjects with Cystic Fibrosis Who Are Homozygous for *F508del* and 12 to <24 Months of Age at Treatment Initiation (**VX19-809-124; IRB 19-2603**)	Site PI	Vertex Closed	2020-2024
A Phase 3, Open-label Study Evaluating the Long-term Safety and Efficacy of VX-445/TEZ/IVA Combination Therapy in Subjects with Cystic Fibrosis Who Are 6 Years of Age and Older **(VX19-445-107; IRB 19-2312)**	Lead PI, Site PI	Vertex Closed	2019-2024
A Phase 3, Open-label Study Evaluating the Long-term Safety of VX-445 Combination Therapy in Subjects with Cystic Fibrosis **(VX18-445-113; IRB 19-1432)**	Site PI	Vertex Closed	9/2019-2021
A Phase 3, 2-part, Open-label Study to Evaluate the Safety and Pharmacokinetics of Lumacaftor/Ivacaftor in Subjects 1 to Less Than 2 Years of Age with Cystic Fibrosis, Homozygous for F508del **(VX16-809-122; IRB 19-0255)**	Site PI	Vertex Closed	7/2019-2020
A Phase 3, Open-label, Rollover Study to Evaluate the Safety and Efficacy of Long-term Treatment with Tezacaftor in Combination with Ivacaftor in Subjects With Cystic Fibrosis Aged 6 Years and Older, Homozygous or Heterozygous for the F508del-CFTR Mutation **(VX17-661-116; IRB 18-0075)**	Site PI	Vertex Closed	4/2018-2020
A Post-approval Observational Study to Evaluate the Long-term Effectiveness and Safety of Orkambi in US Patients Who Completed Study VX12-809-105, Retrospective study **(VX16-809-120; IRB 18-0082)**	Site PI	Vertex Closed	1/2018-3/2019
Compassionate use of Kalydeco **(IRB 15-2421)**	PI	Vertex Closed	4/2016-10/2019
A Phase 3, Randomized, Double-blind, Controlled Study Evaluating the Efficacy and Safety of VX-659 Combination Therapy in Subjects with Cystic Fibrosis Who Are Heterozygous for the F508del Mutation and a Minimal Function Mutation (F/MF) **(VX17-659-102; IRB 17-0932**)	Site PI	Vertex Closed	2/2018-3/2019

A Phase 3, Open-label Study Evaluating the Long-Term Safety and Efficacy of VX-659 Combination Therapy in Subjects with Cystic Fibrosis Who Are Homozygous or Heterozygous for the F508del Mutation **(VX16-659-105; IRB 17-0933)**	Site PI	Vertex Closed	7/2018-10/2019
A phase 3 randomized, double-blind, placebo-controlled study of Aerovanc for the treatment of persistent methicillin-resistant *Staphylococcus aureus* lung infection in cystic fibrosis patients. **(SAV005-04; IRB 17-0958)**	Site PI	Savara, Inc. Closed	9/2017-2020
A Phase 3, open-label study to evaluate the pharmacokinetics, safety and tolerability of VX-661 in combination with ivacaftor in subjects 6 to 11 years of age and CF homozygous or heterozygous for the F508del CFTR mutation **(VX-661-113; IRB 16-1623)**	Site PI	Vertex Closed	11/2016-11/2018
A Phase 3, Open-label, rollover study to evaluate the safety and efficacy of long-term treatment with VX-661 in combination with ivacaftor in subjects ages 12 years and older with CF homozygous or heterozygous for the F508-del-CFTR mutation **(VX 14 661-110; IRB 15-1174)**	Site PI	Vertex Closed	6/2016-4/2019
A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Crossover Study to Evaluate the Efficacy and Safety of Ivacaftor and VX-661 in Combination With Ivacaftor in Subjects Aged 12 Years and Older With Cystic Fibrosis, Heterozygous for the *F508del-CFTR* Mutation, and a Second Allele With a *CFTR* Mutation Predicted to have Residual Function. **(VX14 661-108; IRB 15-0190)**	Site PI	Vertex Closed	5/2015-4/2017
An ocular safety study of ivacaftor-treated pediatric patients 11 years of age or younger with cystic fibrosis **(VX 12-770-115; IRB 13-1528)**	Site PI	Vertex Closed	7/2013-8/2016
A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of N91115 to Evaluate Efficacy and Safety in Patients with Cystic Fibrosis who are Homozygous for the F508del-CFTR Mutation and Being Treated with lumacaftor/ivacaftor **(SNO-6; IRB 15-1763)**	Site PI	Nivalis Closed	11/2015-12/2016
A Phase 1b, Randomized, Double-Blind, Placebo-Controlled, Parallel, Group Study of N91115 to Evaluate Safety and Pharmacokinetics in Patients with Cystic Fibrosis Homozygous for the *F508del-CFTR* Mutation. **(SNO-4; IRB 14-1901)**	Site PI	Nivalis Closed	2/2015-9/2015
A Phase 1, Open-Label Study Evaluating the Pharmacokinetics of N91115 in Cystic Fibrosis Patients **(SNO-3; IRB 14-1604)**	Site PI	Nivalis Closed	10/2014-2/2015
A Phase 1b, Randomized, Double-Blind, Placebo-Controlled, Dose Escalation Study of N6022 to Evaluate Safety and Pharmacokinetics in Subjects with Cystic Fibrosis Homozygous for the F508del-CFTR Mutation **(N6022-1CF1-04; IRB 12-1628)**	Site PI	N30 Pharmaceuticals Closed	1/2013-6/2014

C. **COMIRB Expedited Protocols Retrospective Studies**

Protocol	Role	Primary Site/ Sponsor/ Study Status
Relationship of infection, inflammation and clinical outcomes in cystic fibrosis **(IRB 17-0729; Study 600)**	PI	CHCO
Retrospective Review of *Inquilinus* Infection in Cystic Fibrosis at the Colorado CF Center (**IRB 15-2376**)	Co-I	CHCO
Sweat electrolytes and serum biomarkers in the era of CFTR modulators (**IRB 20-2558**)	PI	CHCO

D. **Organizational Research Risk & QI Review Panel (ORRQIRP) approved projects**

Protocol	Role	Primary Site/ Lead
Home respiratory sample collection for children with cystic fibrosis (ORRQIRP # 2005-1; Approval date 05-26-2020)	Project Lead	CHCO Zemanick
Improving Outcomes for Pulmonary Exacerbation through PT & RT Treatment in Patients with Cystic Fibrosis (ORRQIRP 31902-14; Approval date 3/6/2019)	Project Lead	CHCO Zemanick
Viral Symptoms, Detection, and Isolation in Patients with Cystic Fibrosis Admitted for Pulmonary Exacerbation to Children's Hospital Colorado (ORRQIRP # 1912-1; Approval date 12/12/2019)	Collaborator	CHCO Dominquez/ Rusin

E. CFFT National Resource Center, Center for Sweat Analysis Contracts

Sponsor or Institute	Study	Status	Number of samples
CFFT, TDN, NIDDK (2018-2019)	Baby Observational and Nutrition Study (BONUS)	Completed	167
Flatley Discovery Laboratory (2017-18)	Phase 1/2 clinical trials of novel CFTR modulators	Completed	179
CFFT, TDN (2017-present)	G551D Observational Study - Expanded to Additional Genotypes and Extended for Long Term Follow up (GOAL-OB-11 and GOAL-e2; NCT01521338)	Completed	~1,600
CFFT, TDN (2018-2019)	Multicenter Prospective Longitudinal Study of CFTR-dependent Disease Profiling in Cystic Fibrosis (PROSPECT, NCT02477319)	Completed	452
Concert Pharmaceuticals (2017-2019)	Clinical trials of CPT 656	Completed	44
CFFT, TDN (2017-present)	Characterizing CFTR modulated changes in sweat chloride and their association with clinical outcomes (CHEC-SC). Sweat analyses performed for 3 research sites (Children's Colorado, National Jewish Health and Case Western Research University)	Active	200
Nivalis/ N30 (2015-2016)	Clinical trials of Cavosonstat (N91115)	Completed	1,525
St. Luke's Health System, Boise, ID, 2018	Validation of Macroduct Sweat Collection System and Chloridometer for St. Luke's clinical laboratory	Completed	10

Case Western Reserve, Cleveland, OH, 2018-2019	Pilot study of a new method of sweat chloride analysis (PI: Dr. Erica Roesch)	Completed	12
National Jewish Health, Denver CO, 2019	Effects of Sildenafil on CFTR-dependent Ion Transport Activity (PI: Dr. Jennifer Taylor-Cousar, see LOS)	Completed	36
Bayer Pharm., Inc. 2017	Sweat collection training and certification	Completed	n/a
Calithera Biosciences, 2020-2023	Study to Evaluate the Safety of CB-280 in Patients with Cystic Fibrosis	Completed	31
CFF, TDN 2020 -	A Prospective Study to Evaluate Biological and Clinical Effects of Significantly Corrected CFTR Function (PROMISE)	Active	2,120
CFF, TDN 2021 -	PROMISE Peds: A Prospective Study to Evaluate Biological and Clinical Effects of Significantly Corrected CFTR Function in Children 6-11 years.	Active	508
National Jewish Health, 2020-2021	Glycerol Phenylbutyrate Corrector Therapy for CF (PI: Pam Zeitlin, National Jewish Health, Denver CO)	Completed	23
CFF, TDN, 2020-	Prospective study designed to evaluate biological and clinical effects of significantly corrected cystic fibrosis transmembrane conductance regulator (CFTR) function in infants and young children (BEGIN)	Active	256
CFF, Northwestern University 2023-	Remote exercise in cystic fibrosis patients: an observational study using a wearable patch to measure sweat biomarkers (PI: Jain)	Active	27
TDN, 2008-	Qualification sweat samples for research site personnel	Active	~ 1650

15. Bibliography

Link to NCBI PubMed Bibliography

Papers Published in Peer Reviewed journals

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Cystic Fibrosis and the Airway Microbiome, Winter 2012
TDN Spring Meeting Goes Virtual, Spring 2020

Regular feature articles:

TDN Spring Meeting Update, Summer Edition 2016- 2019
NACFC Preview, Summer Edition 2016-2019
TDN Spring Meeting Preview, Winter Edition 2017-2021
NACFC Update, Winter Edition 2017-2021

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Other Products of Scholarship:
Through our CF quality improvement and clinical care guidelines working group at Children's Hospital Colorado, I have contributed to the development and implementation of the following protocols and guidelines for CF individuals followed at our center:

1. Guidelines for routine CF-specific health care maintenance for patients with CF. Purpose: To provide guidelines for routine CF-specific health care maintenance and outpatient laboratory monitoring for CF patients.
2. Guidelines for admission of patients with CF pulmonary exacerbations who are seen and evaluated in the ambulatory setting. Purpose: To provide formal criteria to assist in the decision of whether to admit a patient with CF who presents to the clinic and/or Emergency Department with signs/symptoms of a pulmonary exacerbation.
3. Oral antibiotic options for outpatient management of CF pulmonary exacerbations. Purpose: To provide a consistent approach to prescribing oral antibiotics for outpatient management of lower respiratory infections and/or pulmonary exacerbations when deemed clinically indicated in patients with CF.
4. *Pseudomonas aeruginosa* new isolate in patients with CF. Purpose: To provide rapid response to new isolation of *Pseudomonas aeruginosa* bacteria in the respiratory culture of patients over 1 month old with CF.
5. Allergic bronchopulmonary aspergillosis (ABPA) in patients with CF: Evaluation and Management. Purpose: To provide a consistent approach for the identification, evaluation, and management of ABPA in patients with CF.
6. Cystic fibrosis related diabetes screening by oral glucose tolerance testing. Purpose: To standardize screening for CF-related diabetes (CFRD) using the oral glucose tolerance test (OGTT).
7. Elevated liver function test (LFT) results in patients with CF. Purpose: To optimize CF patient care by providing a consistent response to elevated AST, ALT, and GGTP.
8. Infection Control Policy: Management of CF Patients. Purpose: To provide appropriate infection control precautions for cystic fibrosis patients in the inpatient hospital and outpatient clinic setting.
9. CF Patient Algorithm for Exiting the Drug Resistant Organism (DRO) List. Purpose: To provide guidelines for being removed from the hospital's DRO list.
10. Guidelines for routine screening for nontuberculous mycobacteria in patients with CF. Purpose: To provide guidelines for routine screening for nontuberculous mycobacterial infection in patients with cystic fibrosis.
11. *Burkholderia cepacia* complex isolation in patients with CF. Purpose: To provide rapid response to new isolation of *Burkholderia cepacia* complex (BCC) bacteria in the airway culture of patients over one month old with cystic fibrosis.
12. Methicillin resistant *Staphylococcus aureus* (MRSA) isolation in patients with CF. Purpose: To provide rapid response to new isolation of MRSA bacteria in the airway culture of patients over one (1) month old with CF.
13. Clinical guidelines for treatment of inpatient CF pulmonary exacerbations. Purpose: To provide a consistent approach to management of inpatient pulmonary exacerbations in order to improve clinical response and prevent treatment failures and early readmissions in patients with CF.

14. Recommendations for inpatient and outpatient management of distal intestinal obstructive syndrome (DIOS). Purpose: To provide clinical guidance on management of DIOS, a common gastrointestinal complication in patients with cystic fibrosis.
15. Nutrition Approach to Improve Growth in CF Patients with BMI < 50th %tile. Purpose: To improve the nutrition health of all patients with cystic fibrosis (CF) between the ages of 2-19 years.(Guimbellot, Natt et al. 2022)

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