**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

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**2. Education**

## University of California, Berkeley, B.S. Chemistry Berkeley, CA 1989-1993

## Albert Einstein College of Medicine, MD Bronx, NY 1995-1999

Yeshiva University,

Children’s National Medical Center Washington, DC 1999-2002 George Washington University

Residency, Pediatrics

University of Colorado School of Medicine Denver, CO 2004-2007

Fellowship, Pediatric Pulmonology

University of Colorado School of Medicine Aurora, CO 2007-2008

Research Fellow, Pediatric Pulmonology

University of Colorado Denver and Health Sciences Center Aurora, CO 2005-2009

MSCS, Clinical Science

Thesis, “Molecular detection of microbes in children with cystic fibrosis”

**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 2002-2004

Children’s National Medical Center, Washington, DC

General Pediatrician, Department of Neonatology 2002- 2004

Washington Adventist Hospital, Takoma Park, MD

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 2016-

Children’s Hospital Colorado

Research Medical Director, Breathing Institute 2021-

Clinical Research Medical Director, BI, Dept. of Pediatrics 2023-

**Other Professional Positions**

Associate Medical Director, Center for Biochemical Markers 2016- 2018

National Resource Center, Cystic Fibrosis Foundation Therapeutics

Medical Director, Center for Sweat Analysis 2017-

National Resource Center, Cystic Fibrosis Foundation Therapeutics

**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-

American Thoracic Society, 2005-

ATS Training Committee, 2018-2019

Society for Pediatric Research, 2011-

**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, 2020- and Chair 2021-

This committee addresses operational research needs within the Breathing Institute

***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, CFF, 2019-

Medical Advisory Committee, CFF, 2020-

Sweat Testing Advisory Committee, CFF, 2018-

National Resource Core Working Group, CFF, 2018-

TDN Steering Committee, 2020-

Vice-Chair, 2022

Chair, 2023 -

***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 2016-2023 ≈ $95,000)

***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 Participated in anti-bias training for resident and fellowship interviews

2021 Presented a talk at pediatric pulmonary conference for faculty and fellows entitled, “DEI Issues in Research”.

2023 Participated in anti-bias training for pediatric residency and pediatric pulmonary fellowship recruitment interviews

**9. Licensure and Board Certification**

Pediatric Pulmonology**,** ABPID#: 657791 2008-2025

Colorado Medical License 2004-2025

DEA 2004-2025

Pediatric Advanced Life Support (PALS) 2002-2024

Basic Life Support (BLS) 2002-2024

**10. Inventions, intellectual property and patents held or pending**

None

**11. Review and Referee Work**

**Peer-review record for journals available at:**

<https://publons.com/author/1235134/edith-t-zemanick#profile>

**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, 2021-2024

***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

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.

**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)

**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.

**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**

1. **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 |

1. **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 | Pulmonary Fellows Conference | 2021 |
| BI Research Council - CF registry/databases | Pulmonary Fellows Research Conference | 2021 |
| Strategies for working with a biostatistician | Pulmonary Fellows Research Conference | 2021 |
| Research in the Breathing Institute | Pulmonary Fellows Research Conference | 2021 |
| Diversity, Equity and Inclusion in Research | Pulmonary Fellows Research Conference | 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 |

1. **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)](https://cme.epocrates.com/a/KZTKFE)

1. **Mentees/ Trainees**
2. **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 | Undergraduate student, Dartmouth College |
| 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 | Medical student, UCSOM |
| Helene Kuffel  2020- | Medical student, UCSOM | Research mentor | Medical student, UCSOM |
| Alexandra Hernandez  2020-2021 | Medical student, UCSOM | Research mentor | Medical student, UCSOM |
| Adrianne Colborg, MD (Eyman)  2018 - 2019 | Resident, Pediatrics UCSOM | NACFC travel award sponsor, Research mentor | Hospitalist, Lurie Children’s Hospital, |
| Christina Osborne, MD, 2016-2017 | Resident, Pediatrics UCSOM | Clinical mentor | Clinical Instructor, Dept. of Pediatrics, UCSOM |
| Angela Metcalf, MD, 2022-2023 | Resident, Pediatrics; UCSOM | Research mentor | Fellow, pediatric pulmonary medicine |

1. **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-present | 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 | Sleep fellow, UCSOM |
| Emily Holmes, MD  2021- | Fellow, Pediatric pulmonary medicine, UCSOM | Sponsor, CFF Clinical Fellowship Award | Pediatric pulmonary fellow |
| Kamyron Jordan, MD  2022- | Fellow, Pediatric pulmonary medicine, UCSOM | Fellow, Pediatric pulmonary medicine, UCSOM | Fellow, Pediatric pulmonary medicine, UCSOM |
| Lilah Melzer, MD | Fellow, Pediatric pulmonary medicine, UCSOM | Sponsor, CFF Clinical Fellowship Award  Research Mentor | Fellow, UCSOM |
| Katie Enzer, MD | Fellow, Pediatric pulmonary medicine, UCSOM | Scholarly Oversight Committee | Fellow, UCSOM |
| Angela Metcalf, MD | Fellow, Pediatric pulmonary medicine, UCSOM | Sponsor, CFF Clinical Fellowship Award | Fellow, UCSOM |

1. **Faculty**

|  |  |  |  |
| --- | --- | --- | --- |
| Trainee,  Years | Stage of Training | My Role | Current Position |
| Jordana Hoppe, MD MSCS  2011 - | * Resident, Pediatrics * Fellow, Pediatric pulmonary medicine * Assistant Professor of Pediatrics- Pulmonary Medicine, UCSOM | Research mentor  Scholarly oversight committee  MSCS Dissertation Committee | Assistant 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- | 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 | Research instructor, Pediatrics |
| Tim Vigers MS Biostatistics  2021-2023 | Research instructor, Pediatrics | Research sponsor for biostatistical training award (STAT-Net award) | Research instructor, Pediatrics |

**14. Grant Support**

***Current Grant Support***

ZEMANI17K0 7/1/2017-6/30/2024

Clinical Research Award, Cystic Fibrosis Foundation, Therapeutics, Inc

Characterizing CFTR modulated changes in sweat chloride and clinical outcomes

NCT03350828

Role: PI (15%)

Award: $556,647 ($497,006 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.

CFF 002884121 (Zemanick) 1/1/2022-12/31/2024

TDN Steering Committee Leadership

CFF

Role: PI (10% FTE)

Award: $119,576

Goal: To support leadership as chair of the TDN Steering Committee.

RARE-OB-16 (Solomon) 09/2016-08/2024

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 # ZEMANI22Y0 - Zemanick 4/1/2023-06/30/2024

Cystic Fibrosis Foundation

Therapeutics Development Center

Role: Principal Investigator (15%)

The goal of this grant is to implement multicenter clinical trials in cystic fibrosis

Award:

2022/23: $265,565 ($237,111 Direct), extended to 6/30/2024, additional 25%

2023/24: TBD

CFF #ZEMANI20Y2-SVC (Zemanick) 4/1/2020- 3/31/2024

Cystic Fibrosis Foundation

CFF Core Clinical Research Services

Role: PI (5%)

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.

Award:

Year 1: $42,139 ($37,624 *Direct Costs*)

Year 2: $42,755 ($38,174 *Direct Costs*)

Year 3: $43,357 ($38,712 *Direct Costs*)

Year 4: $43,978 ($39,266 *Direct Costs*)

CC009 (PI Sagel) 07/2023-06/2024

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**

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.

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.

***Completed mentee awards***

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 #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 (FEV1). 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** |
| Immune Profiles in CF Fungal Infections (**IRB 20-0099**) | Mentor (PI: S.Poore) | CFF, CHCO, single center,  **Data analysis**  2020- |
| STOP-PEDS Pilot (Streamlined Treatment of Pulmonary Exacerbations in Pediatrics Pilot) (**IRB 20-1231; NCT04608019**) | Co-PI | 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, ancillary study | CFF, Seattle Children’s Hospital,  **Active**  2020- |
| Sinus Disease in Young Children with Cystic Fibrosis **(IRB 22-1712; NCT06191640 )** | Co-I, Site PI | CFF, UCLA (Beswick)  **Active**  2023- |
| Improving P. aeruginosa detection with Breath-based diagnostics (IMPACT-Breath) (**IRB 17-1404)** | Co-I, 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-I, Site PI | CFF  **Active**  11/2017- |
| CHEC-SC Pharmacokinetics/ Pharmacodynamics sub-study **(IRB 17-1915)** | Co-I, Site PI | CFF, U. Alabama Birmingham  Complete  11/2017- 2023 |
| 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  **Active**  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:   1. Edith Porter, Cal State Univ. Los Angeles, 2016 2. Preston Bratcher, NJH, 8 CF BALF samples, 2017 3. William Rigby, Dartmouth, 20 BALF (15 CF/ 5 DC), 2017 4. Ezster Vladar, UCSOM, (nasal cell) 2019- 5. Terri Laguna, Lurie Children’s Hospital, BALF, 2019- 6. Vanessa Phelan, UCSOM (sputum), 2018- 7. Orlando Esparza, UCSOM CHCO Fellow, Hematology, 2020 (blood specimen) 8. Hara Levy, NJH (blood) | PI | CHCO  **Active** |
| 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 | Lead PI | 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, 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 | Vertex  **Active** | 2021- |
| 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 | 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, Completed | 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  **Active** | 2020- |
| 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)** | Site PI | Vertex  **Active** | 2019- |
| 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, Completed | 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, Completed | 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, completed | 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, completed | 1/2018- 3/2019 |
| Compassionate use of Kalydeco **(IRB 15-2421)** | PI | Vertex, completed | 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, completed | 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, completed | 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.,  Completed | 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, completed | 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, completed | 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, completed | 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, completed | 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,  completed | 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,  completed | 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,  completed | 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, completed | 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) | Active | 330  (total for studies =1,524) |
| CFFT, TDN  (2018-2019) | Multicenter Prospective Longitudinal Study of CFTR-dependent Disease Profiling in Cystic Fibrosis (PROSPECT) | 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 | 135 |
| Nivalis/ N30 (2015-2016) | Clinical trials of Cavosonstat (N91115) | Completed | 172  (total for studies = 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 Pharmaceuticals, Inc.  2017 | Sweat collection training and certification | Completed |  |
| Abbvie, Contract pending 2019- | Sweat collection training and certification, sample analysis for clinical trial | Pending | Pending |
| Calithera Biosciences, 2020- | Sweat analysis for clinical trial | Active | ~ 130 |
| CFF, TDN, 2020 - | A Prospective Study to Evaluate Biological and Clinical Effects of Significantly Corrected CFTR Function (PROMISE) | Active | 800 |
| National Jewish Health, 2020-2021 | Glycerol Phenylbutyrate Corrector Therapy for CF (PI: Pam Zeitlin, National Jewish Health, Denver CO) | Active | 110 |
| 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 | 500 |

**15. Bibliography**

[Link to NCBI PubMed Bibliography](https://www.ncbi.nlm.nih.gov/pubmed/?term=zemanick+e)

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NACFC Preview, Summer Edition 2016-2019

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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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***Updated January 10, 2024***