**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 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 Morrison2010 | Undergraduate, Gonzaga University | Summer research mentor | Gastroenterology Fellow, University of North Carolina, Chapel Hill  |
| Ashley Song2018 | Undergraduate, Dartmouth College | Summer research mentor | Undergraduate student, Dartmouth College |
| Emily Johnson2014-2016 | 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 Kuffel2020- | 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, MD2011-2012; 2014 | * Resident, Pediatrics
* Fellow, pediatric pulmonary medicine, UCSOM
 | Longitudinal block mentor Clinical Preceptor | Assistant Professor of Pediatrics, UCSOM |
| Tom Flass, MD2010-2012 | Fellow, Pediatric gastroenterology, UCSOM | Scholarly oversight committee member  | Pediatric gastroenterologist, Billings MT |
| Nidhya Navanandan, MD2013-2016 | Fellow, Pediatric emergency medicine, UCSOM | Scholarly oversight committee member | Assistant Professor of Pediatrics, UCSOM |
| Heather De Keyser (Hoch), MD MSCS2014-2016 | Fellow, Pediatric pulmonary medicine, UCSOM | Research mentorClinical Preceptor | Assistant Professor of Pediatrics, UCSOM |
| Michelle Sobremonte-King, MD2016-2017 | 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, MD2017-2020 | Fellow, Pediatric emergency medicine, UCSOM | Scholarly Oversight Committee | Assistant Professor of Pediatrics, UCSOM |
| Patricia Lenhart-Pendergrass, MD PhD2018-2020 | Fellow, Pediatric pulmonary medicine, UCSOM | Sponsor, CFF Clinical Fellowship Award | Instructor/ Research fellow, UCSOM  |
| Racha Khalaf, MD MSCS2018-2020  | Fellow, Pediatric gastroenterology, UCSOM | Research co-mentor, SOC committee memberMSCS Dissertation Committee  | Assistant Professor of Pediatrics, University of South Florida, Tampa FL |
| Daniel Hinds, MD2019-2022 | Fellow, Pediatric pulmonary medicine, UCSOM | Sponsor, CFF Clinical Fellowship Award | Faculty, University of Iowa |
| Spencer Poore, MD MSCS2018-present | Fellow, Pediatric pulmonary medicine, UCSOM | Research mentor, Sponsor CFF award MSCS Dissertation Committee  | Assistant Professor of Pediatrics, University of Alabama Birmingham  |
| Mfon Udoko, MD2020- 2022 | Fellow, Pediatric pulmonary medicine, UCSOM | Scholarly oversight committee member | Faculty, Cincinnati Children’s |
| Annemarie Wolfe, MD2020-2023 | Fellow, Pediatric pulmonary medicine, UCSOM | Sponsor, CFF Clinical Fellowship Award | Faculty, University of Texas Austin |
| Taylor Curry, MD2021-2023 | Fellow, Pediatric pulmonary medicine, UCSOM | Scholarly oversight committee | Sleep fellow, UCSOM |
| Emily Holmes, MD2021-  |  Fellow, Pediatric pulmonary medicine, UCSOM | Sponsor, CFF Clinical Fellowship Award | Pediatric pulmonary fellow |
| Kamyron Jordan, MD2022- | 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 mentorScholarly 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, MD2016- | 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, Complete2020-2022 |
| 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 BirminghamComplete11/2017- 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, PICo-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, Complete2020-2023 |
| 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, CFFComplete10/2018- 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, CFFTComplete1/2017- 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 Hospitalc. 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/ TDNComplete3/2011- 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, 2018-2020Complete |
| Effect of Acid blockade on microbiota and inflammation in CF (**IRB** **14-1645**) | Co-I, completed  | CFF, CHCO single center, Complete2014-2020  |
| 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/ CFFTComplete4/2011- 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 | CHCOZemanick |
| 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 | CHCODominquez/ 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)

**Papers Published in Peer Reviewed journals**

***# Indicates mentee***

1. Hand IL, Noble L, Wilks M, Towler E, Kim M, and JJ Yoon. Hering-Breuer reflex and sleep state in the preterm infant. Pediatr Pulmonol 2004;37:61-64. PMID: 14679491
2. Harris JK, De Groote MA, Sagel SD, Zemanick ET, Kapsner R, et al. Molecular identification of bacteria in bronchoalveolar lavage fluid from children with cystic fibrosis. Proc Natl Acad Sci USA 2007;104:20529-33. PMID: 18077362;  PMCID: PMC2154465.
3. Zemanick ET, Harris JK, Conway S, Konstan MW, Marshall B et al. Measuring and improving respiratory outcomes in cystic fibrosis lung disease: Opportunities and challenges to therapy. J Cyst Fibros 2010; 9:1-16 DOI:10.1016/j.jcf.2009.09.003. PMID 19833563; PMCID: PMC2830746
4. Zemanick ET, Wagner BD, Harris JK, Wagener JS, Accurso FJ and Sagel SD. Pulmonary exacerbations in cystic fibrosis with negative bacterial cultures. Pediatr Pulmonol, 2010 Jun;45(6):569-77. PMID: 20503282; PMCID; PMC2937349.
5. Zemanick ET, Wagner BD, Sagel SD, Stevens MJ, Accurso FJ and Harris JK. Reliability of quantitative real-time PCR for bacterial detection in cystic fibrosis airway specimens. PLoS One 2010 Nov 30;5(11):e15101. PMID: 21152087; PMCID; PMC2994853.
6. Sagel SD, Wagner BD, Anthony MM, Emmett P, and Zemanick ET. [Sputum Biomarkers of Inflammation and Lung Function Decline in Children with Cystic Fibrosis.](http://www.ncbi.nlm.nih.gov/pubmed/22904182) Am J Respir Crit Care Med. 2012 Nov 1;186(9):857-65. PMID:22904182; PMCID: PMC3530222
7. Zemanick ET, Harris JK, Wagner BD, Robertson CE, Sagel SD et al. Inflammation and Airway Microbiota during Cystic Fibrosis Pulmonary Exacerbations. PLoS ONE 2013; 8(4): e62917. doi:10.1371/journal.pone.0062917 PMID:23646159; PMCID: PMC3639911.
8. Zemanick ET, Emerson J, Thompson V, McNamera S et al. Clinical outcomes after initial Pseudomonas acquisition in cystic fibrosis. Pediatr Pulmonol, 2014 Mar 18. doi: 10.1002/ppul.23036. PMID: 24644274
9. #Hoppe JE, Towler EE, Wagner BD, Accurso FJ, Sagel SD and Zemanick ET. Sputum induction improves detection of pathogens in children with cystic fibrosis. Ped Pulmonol, 2015 Jul;50(7):638-46. doi: 10.1002/ppul.23150. PMID:25565628
10. Zemanick ET, Wagner BD, Robertson CE, Stevens MJ et al. Assessment of airway microbiota and inflammation in cystic fibrosis using multiple sampling methods. Ann Am Thorac Soc. 2015 Feb;12(2):221-9. PMID: 25474078 PMC4342834
11. #Flass T, Tong S, Frank DN, Wagner BW, Robertson CE, Kotter CV, Sokol RJ, Zemanick ET, Accurso F et al. Intestinal Lesions are Associated with Altered Intestinal Microbiome and are More Frequent in Children and Young Adults with Cystic Fibrosis and Cirrhosis. PLoS ONE, 2015 Feb 6;10(2):e0116967. PMC4319904
12. Ma DC, Yoon AJ, Faull KF, Desharnais R, Zemanick ET, Porter E. Cholesteryl Esters are Elevated in Bronchoalveolar Lavage Fluid Collected from Pediatric Cystic Fibrosis Patients and May Serve as Markers for Disease, PLoS ONE, 2015 April 28;10(4):e0125326. PMID 25919295
13. #Johnson EJ, Zemanick ET, Accurso FJ, Wagner BD, Roberson CE, Harris JK. Molecular Identification of *Staphylococcus aureus* in Airway Samples from Children with Cystic Fibrosis. PLoS One. 2016 Jan 25;11(1):e0147643. PMID:26808658
14. Lahiri T, Hempstead S, Brady C, Cannon C, Clark K, Condren M, Guill M, Guillerman R, Leone C, Maguiness K, Monchil L, Powers S, Rosenfeld M, Schwarzenberg SJ, Tompkins C, Zemanick ET, Davis S. Clinical practice guidelines from the Cystic Fibrosis Foundation for preschoolers with cystic fibrosis. Pediatrics, 2016 Apr;137(4). PMID 27009033
15. Muhlebach MS, Beckett V, Popowitch E, Miller MB, Baines A, Mayer-Hamblett N, Zemanick ET, et al. Microbiologic efficacy of early MRSA treatment in cystic fibrosis in a randomized controlled trial. Thorax 2017 Apr;72(4):318-326. PMID: 27852955
16. Laguna TA, Wagner BD, Williams CB, Stevens MJ, Robertson CE, Bradford CW, Moen CE, Zemanick ET, Harris JK. Airway microbiota in bronchoalveolar lavage fluid from clinically well infants with cystic fibrosis. PLoS One, 2016 Dec 8;11(12):e0167649
17. Donaldson SH, Solomon GM, Zeitlin PL, Flume PA, Casey A, McCoy K, Zemanick ET et al. Pharmacokinetics and safety of cavosonstat (N91115) in healthy and cystic fibrosis adults homozygous for F508DEL-CFTR. J Cyst Fibros. 2017 16(3):371-379. PMID: 28209466
18. Williamson KM, Wagner BD, Robertson CE, #Johnson EJ, Zemanick ET, Harris JK. Impact of enzymatic digestion on bacterial community composition in CF airway samples. PeerJ. 2017 May 30;5:e3362. PMID 28584706, PMC 5452939.
19. Zemanick ET, Wagner BD, Robertson C, Ahrens R et al. Airway microbiota across age and disease spectrum in cystic fibrosis. Eur Respir J 2017; Nov 16;50(5). PMID: 29146601
20. #Hoppe JE, Wagner BD, Sagel SD, Accurso FJ and Zemanick ET. Pulmonary exacerbations and clinical outcomes in a longitudinal cohort of infants and preschool children with cystic fibrosis. BMC Pulm Med. 2017; 11;17(1):188. PMID 29228933, PMC5725640
21. Nasir M, Bean HD, Smolinska A, Rees CA, Zemanick ET and Hill JE. Volitile molecules from bronchoalveolar lavage fluid can ‘rule-in’ *Pseudomonas aeruginosa* and ‘rule-out’ *Staphylococcus aureus* infections in cystic fibrosis patients. Sci Rep. 2018 Jan 16;8(1):826.
22. Wagner B, Grunwald G, Zerbe G, Mikulich-Gilbertson S, Robertson C, Zemanick ET and Harris JK. On the use of diversity measures in longitudinal sequencing studies of microbial communities. Frontiers Microbiology, 2018 May 22;9:1037. PMID: 29872428
23. Li A, Vigers T, Pyle L, Zemanick E, Nadeau K, Sagel SD, Chan CL. Continuous glucose monitoring in youth with cystic fibrosis treated with lumacaftor-ivacaftor. J Cyst Fibros. 2018 Aug 10. pii: S1569-1993(18)30718-5. PMID: 30104123.
24. #Hoppe JE, Wagner BD, Accurso FJ, Zemanick ET, Sagel SD. Characteristics and outcomes of oral antibiotic treated pulmonary exacerbations in children with cystic fibrosis. J Cyst Fibros. 2018 Nov;17(6):760-768. PMID: 29921503.
25. DeBoer EM, Wagner BD, Popler J, Harris JK, Zemanick ET, Accurso FJ, Sagel SD, Deterding RR. Novel Application of Aptamer Proteomic Analysis in Cystic Fibrosis Bronchoalveolar Lavage Fluid. Proteomics Clin Appl. 2018 Nov 15:e1800085. PMID: 30431231.
26. Juarez-Colunga E, Rosenfeld M, Zemanick ET, Wagner B. Analysis of recurrent pulmonary exacerbations in Cystic Fibrosis Children: EPIC Observational Study. *J Cyst Fibros*. 2019;S1569-1993(18)30943-3.
27. #Hahn A, Fanous H, Jensen C, Chaney H, Sami I, Perez GF, Koumbourlis AC, Louie S, Bost JE, van den Anker JN, Freishtat RJ, Zemanick ET, Crandall KA. Changes in microbiome diversity following beta-lactam antibiotic treatment are associated with therapeutic versus subtherapeutic antibiotic exposure in cystic fibrosis. *Sci Rep*. 2019 Feb 22;9(1):2534. doi: 10.1038/s41598-019-38984-y. PMID: 30796252; PMCID: PMC6385179.
28. Theprungsirikul J, Skopelja-Gardner S, Meagher RE, Clancy JP, Zemanick ET, Ashare A, Rigby WFC. Dissociation of systemic and mucosal autoimmunity in cystic fibrosis. *J Cyst Fibros*. 2019 Jun 28;S1569-1993(19)30807-0. doi: 10.1016/j.jcf.2019.06.006. [Epub ahead of print]. PMID: 31262645.
29. Zemanick E, Burgel PR, Taccetti G, et al. Antimicrobial resistance in cystic fibrosis: A Delphi approach to defining best practices. *J Cyst Fibros*. 2019;S1569-1993(19)30919-1. doi:10.1016/j.jcf.2019.10.006
30. Martiniano SL, Esther CR, Haworth CS, Kasperbauer SH, Zemanick ET, Caverly LJ. Challenging scenarios in nontuberculous mycobacterial infection in cystic fibrosis [published online ahead of print, 2019 Dec 10]. *Pediatr Pulmonol*. 2019;10.1002/ppul.24604. doi:10.1002/ppul.24604
31. Harris JK, Wagner BD, Zemanick ET, et al. Changes in Airway Microbiome and Inflammation with Ivacaftor Treatment in Patients with Cystic Fibrosis and the G551D Mutation. *Ann Am Thorac Soc*. 2020;17(2):212–220. doi:10.1513/AnnalsATS.201907-493OC
32. #Hahn A, Burrell A, Ansusinha E, Peng D, Chaney H, Sami I, Perez GF, Koumbourlis AC, McCarter R, Freishtat RJ, Crandall KA,Zemanick ET. Airway microbial diversity is decreased in young children with cystic fibrosis compared to healthy controls but improved with CFTR modulation. *Heliyon*. 2020;6(6):e04104. Published 2020 Jun 1. doi:10.1016/j.heliyon.2020.e04104
33. Jewell MP , Saccomano SC , David AA , Harris JK , Zemanick ET , Cash KJ . Nanodiagnostics to monitor biofilm oxygen metabolism for antibiotic susceptibility testing. *Analyst*. 2020;145(11):3996-4003. doi:10.1039/d0an00479k
34. #Hoppe JE, Hinds DM, Colborg A, Wagner BD, Morgan WJ, Rosenfeld M, Zemanick ET, Sanders DB. Oral antibiotic prescribing patterns for treatment of pulmonary exacerbations in two large pediatric CF centers. *Pediatr Pulmonol.* 2020 Dec;55(12):3400-3406. doi: 10.1002/ppul.25092. Epub 2020 Oct 8. PMID: 32970375.
35. #Khalaf RT, Furuta GT, Wagner BD, Robertson CE, Andrews R, Stevens MJ, Fillon SA, Zemanick ET, Harris JK. Influence of acid blockade on the aerodigestive tract microbiome in children with cystic fibrosis. *J Pediatr Gastroenterol Nutr.* 2021 Apr 1;72(4):520-527. PMID: 33394582
36. Wagner BD, Berkalieva A, Borges M, Fleming G, Graham N, Peterson E, Jin X, Zemanick ET. Change in circulating proteins during treatment of pulmonary exacerbation in patients with cystic fibrosis. *Health Sci Rep*. 2021; Feb 10;4(1):e246. PMID: 33614983
37. Zemanick ET, Konstan MW, VanDevanter DR, Rowe SM, Clancy JP, Odem-Davis K, Skalland M, Mayer-Hamblett N. Measuring the impact of CFTR modulation on sweat chloride in cystic fibrosis: Rationale and design of the CHEC-SC study. *J Cyst Fibros*. 2021 Feb 8:S1569-1993(21)00034-5. PMID: 33573995
38. 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. PMID: 33870323
39. Lenhart-Pendergrass PM, Anthony M, Sariyska S, Andrews A, Scavezze H, Towler E, Martiniano SL, Hoppe JE, Zemanick ET. Detection of bacterial pathogens using home oropharyngeal swab collection in children with cystic fibrosis. Pediatr Pulmonol. 2021 Jul;56(7):2043-2047. PMID: 33847465.
40. Zemanick ET, Taylor-Cousar JL, Davies J, Gibson RL, Mall MA, McKone EF, McNally P, Ramsey BW, Rayment JH, Rowe SM, Tullis E, Ahluwalia N, Chu C, Ho T, Moskowitz SM, Noel S, Tian S, Waltz D, Weinstock TG, Xuan F, Wainwright CE, McColley SA; VX18-445-106 Study Group. A Phase 3 Open-Label Study of ELX/TEZ/IVA in Children 6 Through 11 Years of Age with CF and at Least One *F508del* Allele. Am J Respir Crit Care Med. 2021 Jun 15;203(12):1522-1532. PMID: 33734030.
41. #Hahn A, Burrell A, Chaney H, Sami I, Koumbourlis AC, Freishtat RJ, Zemanick ET, Louie S, Crandall KA. Importance of beta-lactam pharmacokinetics and pharmacodynamics on the recovery of microbial diversity in the airway of persons with cystic fibrosis. J Investig Med. 2021 May 21:jim-2021-001824. PMID: 34021052.
42. Bozzella MJ, Chaney H, Sami I, Koumbourlis AC, Bost JE, Zemanick ET, Freishtat RJ, Crandall KA, #Hahn A. Impact of anaerobic antibacterial spectrum on cystic fibrosis airway microbiome diversity and pulmonary function. *Pediatr Infect Dis* J 2021 July 15. PMID: 34269323
43. Poore TS, Meier M, Towler E, Martiniano SL, Brinton JT, DeBoer EM, Sagel SD, Wagner BD, Zemanick ET. Clinical characteristics of people with cystic fibrosis and frequent fungal infection. Pediatr Pulmonol. 2021 Oct 23. doi: 10.1002/ppul.25741. PMID: 34687280.
44. Broderick DTJ, Waite DW, Marsh RL, Camargo CA Jr, Cardenas P, Chang AB, Cookson WOC, Cuthbertson L, Dai W, Everard ML, Gervaix A, Harris JK, Hasegawa K, Hoffman LR, Hong SJ, Josset L, Kelly MS, Kim BS, Kong Y, Li SC, Mansbach JM, Mejias A, O'Toole GA, Paalanen L, Pérez-Losada M, Pettigrew MM, Pichon M, Ramilo O, Ruokolainen L, Sakwinska O, Seed PC, van der Gast CJ, Wagner BD, Yi H, Zemanick ET, Zheng Y, Pillarisetti N, Taylor MW. Bacterial Signatures of Paediatric Respiratory Disease: An Individual Participant Data Meta-Analysis. Front Microbiol. 2021 Dec 23;12:711134. doi: 10.3389/fmicb.2021.711134. PMID: 35002989; PMCID: PMC8733647.
45. Rice JD, Johnson RL, Juarez-Colunga E, Zemanick ET, Rosenfeld M, Wagner BD. Application of gap time analysis with flexible hazards to pulmonary exacerbations in the EPIC observational study. Biom J. 2022 Apr 18. doi: 10.1002/bimj.201900255. Epub ahead of print. PMID: 35434808.
46. Mayer-Hamblett N, Zemanick ET, Odem-Davis K, et al. Characterizing CFTR modulated sweat chloride response across the CF population: Initial results from the CHEC-SC study. J Cyst Fibros. 2022;S1569-1993(22)00625-7. doi:10.1016/j.jcf.2022.07.008
47. Inam Z, Felton E, Burrell A, Chaney H, Sami I, Koumbourlis AC, Freishtat RJ, Zemanick ET, Crandall KA, #Hahn A. Impact of Antibiotics on the Lung Microbiome and Lung Function in Children With Cystic Fibrosis 1 Year After Hospitalization for an Initial Pulmonary Exacerbation. Open Forum Infect Dis. 2022 Sep 12;9(9):ofac466. doi: 10.1093/ofid/ofac466. PMID: 36168550; PMCID: PMC9511275.
48. Mayer-Hamblett N, Zemanick ET, Odem-Davis K, VanDevanter D, Warden M, Rowe SM, Young J, Konstan MW, For-The-Chec-Sc-Study-Group. Characterizing CFTR modulated sweat chloride response across the cf population: Initial results from the CHEC-SC study. J Cyst Fibros. 2023 Jan;22(1):79-88. doi: 10.1016/j.jcf.2022.07.008. Epub 2022 Jul 21. PMID: 35871974; PMCID: PMC10103635.
49. Shumyatsky G, Burrell A, Chaney H, Sami I, Koumbourlis AC, Freishtat RJ, Crandall KA, Zemanick ET, #Hahn A. Using metabolic potential within the airway microbiome as predictors of clinical state in persons with cystic fibrosis. Front Med (Lausanne). 2023 Jan 9;9:1082125. doi: 10.3389/fmed.2022.1082125. PMID: 36698799; PMCID: PMC9868313.
50. #Hahn A, Burrell A, Chaney H, Sami I, Koumbourlis AC, Freishtat RJ, Crandall KA, Zemanick ET. Therapeutic beta-lactam dosages and broad-spectrum antibiotics are associated with reductions in microbial richness and diversity in persons with cystic fibrosis. Sci Rep. 2023 Jan 21;13(1):1217. doi: 10.1038/s41598-023-27628-x. PMID: 36681756; PMCID: PMC9867719.
51. VanDevanter DR, Zemanick ET, Konstan MW, Ren CL, Odem-Davis K, Emerman I, Young J, Mayer-Hamblett N; CHEC-SC Study Group. Willingness of people with cystic fibrosis receiving elexacaftor/tezacaftor/ivacaftor (ETI) to participate in randomized modulator and inhaled antimicrobial clinical trials. J Cyst Fibros. 2023 Jul;22(4):652-655. doi: 10.1016/j.jcf.2023.04.007. Epub 2023 Apr 24. PMID: 37100705; PMCID: PMC10523954.
52. Harris JK, Wagner BD, Robertson CE, Stevens MJ, Lingard C, Borowitz D, Leung DH, Heltshe SL, Ramsey BW, Zemanick ET. Upper airway microbiota development in infants with cystic fibrosis diagnosed by newborn screen. J Cyst Fibros. 2023 Jul;22(4):644-651. doi: 10.1016/j.jcf.2023.04.017. Epub 2023 May 1. PMID: 37137746; PMCID: PMC10524365.
53. Gifford AH, Hinton AC, Jia S, Nasr SZ, Mermis JD, Lahiri T, Zemanick ET, Teneback CC, Flume PA, DiMango EA, Sadeghi H, Polineni D, Dezube RH, West NE, Dasenbrook EC, Lucas FL, Zuckerman JB. Complications and Practice Variation in the Use of Peripherally Inserted Central Venous Catheters in People With Cystic Fibrosis: The Prospective Study of Peripherally Inserted Venous Catheters in People With Cystic Fibrosis Study. Chest. 2023 Sep;164(3):614-624. doi: 10.1016/j.chest.2023.03.043. Epub 2023 Apr 3. PMID: 37019356; PMCID: PMC10504599.
54. Mayer-Hamblett N, Clancy JP, Jain R, Donaldson SH, Fajac I, Goss CH, Polineni D, Ratjen F, Quon BS, Zemanick ET, Bell SC, Davies JC, Jain M, Konstan MW, Kerper NR, LaRosa T, Mall MA, McKone E, Pearson K, Pilewski JM, Quittell L, Rayment JH, Rowe SM, Taylor-Cousar JL, Retsch-Bogart G, Downey DG. Advancing the pipeline of cystic fibrosis clinical trials: a new roadmap with a global trial network perspective. Lancet Respir Med. 2023 Oct;11(10):932-944. doi: 10.1016/S2213-2600(23)00297-7. Epub 2023 Sep 9. PMID: 37699421.
55. Wagner BD, Zemanick ET, Sagel SD, Robertson CE, Stevens MJ, Mayer-Hamblett N, Retsch-Bogart G, Ramsey BW, Harris JK. Limited effects of azithromycin on the oropharyngeal microbiome in children with CF and early pseudomonas infection. BMC Microbiol. 2023 Oct 27;23(1):312. doi: 10.1186/s12866-023-03073-8. PMID: 37891457; PMCID: PMC10612347.
56. Sanders DB, Bartz TM, Zemanick ET, Hoppe JE, Hinckley Stukovsky KD, Cogen JD, Bendy L, McNamara S, Enright E, Kime NA, Kronmal RA, Edwards TC, Morgan WJ, Rosenfeld M. A Pilot Randomized Clinical Trial of Pediatric Cystic Fibrosis Pulmonary Exacerbations Treatment Strategies. Ann Am Thorac Soc. 2023 Dec;20(12):1769-1776. doi: 10.1513/AnnalsATS.202303-245OC. PMID: 37683122.
57. Miller JE, Liu CM, Zemanick ET, Woods JC, Goss CH, Taylor-Cousar JL, Beswick DM. Olfactory loss in people with cystic fibrosis: Community perceptions and impact. J Cyst Fibros. 2023 Nov 17:S1569-1993(23)01677-6. doi: 10.1016/j.jcf.2023.11.006. Epub ahead of print. PMID: 37981480.

# Review articles

1. Zemanick ET, Sagel SD and JK Harris. The airway microbiome in cystic fibrosis and implications for treatment. *Curr Opin Pediatr*, 2011, 23:319-324. PMID:21494150
2. Wagener JS, Zemanick ET and MK Sontag. Newborn Screening for Cystic Fibrosis. *Curr Opin Pediatr*, 2012 Jun;24(3):329-35. PMID 22491493
3. Martiniano SL, Hoppe JE, Sagel SD and Zemanick ET. Advances in the Diagnosis and Treatment of Cystic Fibrosis. *Adv Pediatr.* 2014 Aug;61(1):225-43; DOI: 10.1016/j.yapd.2014.03.002. PMID:25037130
4. Martiniano SL, Sagel SD, Zemanick ET. Cystic Fibrosis: a model system for precision medicine. *Curr Opin Pediatr*, 2016 Jun;28(3):312-7. PMID 27031658
5. Zemanick ET, Ong T, Daines CL, Dellon EP, Muhlebach MS, Esther CR Jr. Highlights from the 2015 North American Cystic Fibrosis Conference. *Pediatr Pulmonol*. 2016 Jun;51(6):650-7. PMID 27074261
6. Zemanick ET and Hoffman LR, Cystic Fibrosis: Microbiology and Host Response, In *Pediatr Clin N Am*, 2016, Aug;63(4):617-36. PMID 27469179
7. Hoppe JE, Harris JK and Zemanick ET. Assessing the airway microbiota in cystic fibrosis. *Clinical Microbiology Newsletter* 2016;38(22): 179-184.
8. Zemanick ET, Daines CL, Dellon EP, Esther CR Jr, Kinghorn B, Ong T and Muhlebach MS. Highlights from the 2016 North American Cystic Fibrosis Conference. *Pediatr Pulmonol*. 2017 Aug;52(8):1103-1110. PMID 28696526
9. Martiniano SL, Toprak D, Ong T, Zemanick ET, Daines CL et al. Highlights from the 2017 North American CF Conference, *Pediatr Pulmonol*. 2018 Jul;53(7):979-986. PMID: 29660839
10. Zemanick ET, Bell SC. Prevention of chronic infection with *Pseudomonas aeruginosa* infection in cystic fibrosis. *Curr Opin Pulm Med*. 2019;25(6):636–645. PMID: 31397692
11. Martiniano SL, Daines CL, Dellon EP, Esther CR Jr, Muhlebach MS, Ong T, Rabinowitz EC, Toprak D, Zemanick ET. Highlights from the 2018 North American cystic fibrosis conference. *Pediatr Pulmonol*. 2019 Jul;54(7):941-948. doi: 10.1002/ppul.24356. PMID: 31091021.
12. #Poore TS, Taylor-Cousar J, Zemanick ET. Cardiovascular Complications in Cystic Fibrosis: A Review of the Literature. *J Cyst Fibros* 2021 Jun 14:S1569-1993(21)00126-0. PMID: 34140249
13. #Poore TS, Hong G, Zemanick ET. Fungal infection and inflammation in cystic fibrosis. *Pathogens* 2021 May 18;10(5):618. PMID: 34069863
14. #Poore TS, Zemanick ET. Infection, Allergy, and Inflammation: The Role of Aspergillus fumigatus in Cystic Fibrosis. Microorganisms. 2023 Aug 5;11(8):2013. doi:10.3390/microorganisms11082013. PMID: 37630573; PMCID: PMC10458351.
15. #Jordan KD, Zemanick ET, Taylor-Cousar JL, Hoppe JE. Managing cystic fibrosis in children aged 6-11yrs: a critical review of elexacaftor/tezacaftor/ivacaftor combination therapy. Expert Rev Respir Med. 2023 Feb;17(2):97-108. doi: 10.1080/17476348.2023.2179989. Epub 2023 Feb 26. PMID: 36803356.

# Book Chapters

1. Zemanick ET and Federico MJ. Evaluation of cough and pulmonary disorders and Chronic cough. In: Bajaj L, Hambidge SJ, Kerby G and Nyquist AC, editors. Berman’s Pediatric Decision Making, Fifth Edition. Elsevier Mosby, Philadelphia, PA, 2011.
2. Federico MJ, Kerby GS, Deterding RR, Baker CD., Balasubramaniam V, Zemanick ET, Sagel SD, Cavanaugh KL, and Accurso FJ. Respiratory tract and mediastinum. In: Hay WW, Levin MJ, Sondheimer JM and Deterding RR, editors. Current Diagnosis and Treatment: Pediatrics, Twentieth Edition. McGraw-Hill Companies, New York, NY, 2011.
3. Federico MJ, Stillwell P, Deterding RR, Baker CD., Balasubramaniam V, Zemanick ET, Sagel SD, Halbower A, Burg CJ and Kerby GS. Respiratory tract and mediastinum. In: Hay WW, Levin MJ, Deterding RR, Abzug MJ, and Sondheimer JM, editors. Current Diagnosis and Treatment: Pediatrics, Twenty-First Edition. McGraw-Hill Companies, New York, NY, 2012.
4. Zemanick, ET and Harris, JK. The Human Airway Microbiome. In, DN Fredricks, editor. The Human Microbiota: How Microbial Communities Affect Health and Disease. John Wiley & Sons, Inc., Hoboken, NJ, USA. doi: 10.1002/9781118409855.ch62, 2013.
5. Federico MJ, Baker CD, Balasubramaniam V, Deboer EM, Deterding RR, Halbower A, Kupfer O, Martiniano SL, Sagel SD, Stillwell P and Zemanick ET. Respiratory tract and mediastinum. In: Hay WW, Levin MJ, Deterding RR, and Abzug MJ, editors. Current Diagnosis and Treatment: Pediatrics, Twenty-second Edition. McGraw-Hill Companies, New York, NY, 2014.
6. Federico MJ, Baker CD, Deboer EM, Halbower A, Kupfer O, Martiniano SL, Sagel SD, Stillwell P, Zemanick ET, Caraballo M, and Hawkins S. Respiratory tract and mediastinum. In: Hay WW, Levin MJ, Deterding RR, and Abzug MJ, editors. Current Diagnosis and Treatment: Pediatrics, Twenty-third Edition. McGraw-Hill Companies, New York, NY, 2016.
7. Federico MJ, Baker CD, DeBoer EM, Halbower A, Kupfer O, Martiniano SL, Sagel SD, Stillwell P, Zemanick ET, Caraballo, M, Hawkins S. In: Current Diagnosis and Treatment Pediatrics, Twenty-Fourth Edition. Ed: WW Hay, MJ Levin, RR Deterding, MJ Abzud. New York, New York: McGraw-Hill; 2018.
8. Caverly LJ, Hoffman L, Zemanick ET. The Microbiome in Cystic Fibrosis. in: Yvonne Huang, Stavros Garantziotis, editors. The Microbiome in Respiratory Disease. Springer International Publishing; 2021. p.251–306*.*

**Editorials**

1. Harris JK and Zemanick ET. Microbes in bronchiectasis: The forest or the trees? Am J Respir Crit Care Med, 2013 May 15;187(10):1044-5. PMID: 23675713.
2. Zemanick ET and Accurso FJ. Cystic fibrosis transmembrane conductance regulator and *Pseudomonas*. Am J Respir Crit Care Med, 2014 Apr 1;189(7):763-5. PMID:24684355, PMCID: PMC4225835
3. Zemanick ET, Hoffman L and Rosenfeld M. Narrowing in on Early CF Lung Disease. Am J Respir Crit Care Med, 2014 Nov 15;190(10):1082-4.
4. Zemanick ET and Laguna TA. *Pseudomonas aeruginosa* eradication: How do we measure success? Clin Infect Dis 2015 Sep 1;61(5):716-8. Epub 2015 May 13. PMID 2597202
5. Zemanick ET and Wainwright C. Alterations of the nasopharyngeal microbiota in infants with CF: CFTR and antibiotic effects. Am J Respir Crit Care Med, 2016 Mar 1;193(5):473-4.
6. Hoppe JE and Zemanick ET. Lessons from the lower airway microbiome in early CF. Thorax. 2017 Apr 27 [epub ahead of print]. PMID: 28450530
7. Zemanick ET, Polineni D. Unraveling the CFTR Function-Phenotype Connection for Precision Treatment in Cystic Fibrosis. *Am J Respir Crit Care Med*. 2019;199(9):1053–1054. doi:10.1164/rccm.201903-0696ED
8. Hahn A, Zemanick ET. Bacterial community variability: outliers may be leading us astray. *Ann Am Thorac Soc*. 2019;16(12):1499–1501. doi:10.1513/AnnalsATS.201909-716ED
9. Zemanick ET, Accurso FJ. Entering the era of highly effective CFTR modulator therapy. *Lancet*. 2019;394(10212):1886–1888. doi:10.1016/S0140-6736(19)32676-5
10. Hoppe JE, Zemanick ET, Martiniano SL. Evidence for early CFTR modulator treatment for children with cystic fibrosis keeps growing Am J Respir Crit Care Med. 2022;10.1164/rccm.202208-1507ED. doi:10.1164/rccm.202208-1507ED

**Publications from multicenter trials with acknowledged participation**

1. Rowe SM, Heltshe SL, Gonska T, Donaldson SH, Borowitz D et al. Clinical mechanism of the cystic fibrosis transmembrane conductance regulator potentiator ivacaftor in G551D-mediated cystic fibrosis. Am J Respir Crit Care Med. 2014 Jul 15;190(2):175-84. PMID 2492734 PMC 4226057 [Enrolling site]
2. Muhlebach MS, Heltshe SL, Popowitch EB, Miller MB, Thompson V, Kloster M, Ferkol T, Hoover WC, Schechter MS, Saiman L; the STAR-CF Study Team. Multicenter Observational Study on Factors and Outcomes Associated with Different MRSA Types in Children with Cystic Fibrosis.Ann Am Thorac Soc. 2015 Jun;12(6):864-71.PMID: 25745825 [Enrolling site]
3. Flume PA, Biner RF, Downey DG, Brown C, Jain M, Fischer R, De Boeck K, Sawicki GS, Chang P, Paz-Diaz H, Rubin JL, Yang Y, Hu X, Pasta DJ, Millar SJ, Campbell D, Wang X, Ahluwalia N, Owen CA, Wainwright CE; VX14-661-110 study group. Long-term safety and efficacy of tezacaftor-ivacaftor in individuals with cystic fibrosis aged 12 years or older who are homozygous or heterozygous for Phe508del CFTR (EXTEND): an open-label extension study. Lancet Respir Med. 2021 Feb 10:S2213-2600(20)30510-5. doi: 10.1016/S2213-2600(20)30510-5. Epub ahead of print. PMID: 33581080. [Enrolling site]
4. Abreu SC, Hampton TH, Hoffman E, Dearborn J, Ashare A, Singh Sidhu K, Matthews DE, McKenna DH, Amiel E, Barua J, Krasnodembskaya A, English K, Mahon B, Dos Santos C, Cruz FF, Chambers DC, Liu KD, Matthay MA, Cramer RA, Stanton BA, Rocco PRM, Wargo MJ, Weiss DJ, Rolandsson Enes S. Differential effects of the cystic fibrosis lung inflammatory environment on mesenchymal stromal cells. Am J Physiol Lung Cell Mol Physiol. 2020 Dec 1;319(6):L908-L925. doi: 10.1152/ajplung.00218.2020. Epub 2020 Sep 9. PMID: 32901521; PMCID: PMC7792680. [CFF BALF Specimen Bank study, IRB 11-0234]
5. Abreu SC, Enes SR, Dearbron J, Goodwin M, Coffey A, Borg ZD, dos Santos CC, Wargo MJ, Cruz FF, Loi R, DeSarno M, Ashikaga T, Antunes MA, Rocco PRM, Liu KD, Lee JW, Matthay MA, McKenna DH, Weiss DJ. Lung Inflammatory Environments Differentially Alter Mesenchymal Stromal Cell Behavior. Am J Physiol Lung Cell Mol Physiol. 2019 Dec 1;317(6):L823-L831. [CFF BALF Specimen Bank study, IRB 11-0234]

**Other publications**

1. Chronic cough in Children: Diagnosis and Management in Primary Care, co-authored with Dr. Jeffrey J. Cain for the CAFP News, a Publication from the Colorado Academy of Family Physicians, Winter 2010.
2. Updated Infection Control Guidelines from the CF Foundation, Children’s Hospital Colorado CF Clinic Family Newsletter, January 2014.
3. Clinical care guidelines: *Pseudomonas aeruginosa* eradication, published in CF News from The Mike McMorris CF Center at Children’s Hospital Colorado, March 2011.
4. Cystic Fibrosis and Methicillin-Resistant *Staphylococcus Aureus* (MRSA) webcast for the CF Foundation Education series, [www.cff.org/LivingWithCF/Webcasts/ArchivedWebcasts/Germs](http://www.cff.org/LivingWithCF/Webcasts/ArchivedWebcasts/Germs), 2012.
5. News from the North American Cystic Fibrosis Conference (NACFC), Children’s Hospital Colorado CF Clinic Family Newsletter, January 2013.
6. Cystic Fibrosis: Introduction for Primary Care Providers. Informational sheet provided to Primary Care Physicians at the time of CF diagnosis. 2013
7. Exercise and Pulmonary Exacerbations at Children’s Colorado, Children’s Hospital Colorado CF Clinic Family Newsletter, Fall 2016.

Articles written for **The TDN Times,** a publication for the members and associates of the Cystic Fibrosis **Therapeutics Development Network** (Associate Editor, 2015- present):

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

**Scientific abstracts published or presented at scientific meetings.**

\* Workshop (Slide) Presentation

\*\* Platform (Slide) Presentation

**# indicates mentee**

1. Harris JK, Zemanick ET, Sagel SD, Accurso FJ, Pace NR. Molecular Identification of Bacteria in the CF Airway, *Pediatric Pulmonol*, 2007;42:S30: 312. Presented at the North American Cystic Fibrosis Conference, Anaheim, CA, October 2007.
2. \*\*Zemanick ET, Harris JK, Sagel SD, Accurso FJ. Microbial Communities in Children with Cystic Fibrosis and Clinically Stable Lung Disease. E-PAS 2008:3450.3 and *Am J Resp Crit Care Med* 2008 A461. Presented as a platform presentation at the Pediatric Academic Society Meeting, Honolulu, HI, May 2008 and as a poster at the American Thoracic Society International Meeting, Toronto, Canada, May 2008.
3. \*Harris JK, Zemanick ET, Wagner BD, Accurso FJ and Sagel SD. Large scale multiplex sequencing for ribosomal RNA metagenomics from cystic fibrosis airway samples. *Pediatric Pulmonol* 2008:Suppl 31:323. Selected for presentation at the North American Cystic Fibrosis Conference, Orlando, FL, October 2008.
4. Zemanick ET, Harris JK, Wagner BD, Accurso FJ and Sagel SD. Characteristics of cystic fibrosis patients with pulmonary exacerbation and no detectable CF airway pathogens. *Am J Resp Crit Care Med* 179; 2009: A1787. American Thoracic Society International Meeting, San Diego, CA, May 2009
5. \*Harris JK, Wagner BD, Zemanick ET, Accurso FJ and Sagel SD. Prevalence of Anaerobic Bacteria in CF Respiratory Tract Samples from Routine Clinical Practice. *Pediatric Pulmonol Suppl* 32:313. Presented at the North American Cystic Fibrosis Conference, Minneapolis, MN, October 2009.
6. \*Zemanick ET, Harris JK, Wagner BD, Accurso FJ and Sagel SD. Reliability and validity of quantitative real-time PCR microbial detection from CF airway specimens. *Pediatric Pulmonol* 2009; 44(Suppl 32):338. Presented as a poster and workshop presentation at the North American Cystic Fibrosis Conference, Minneapolis, MN, October 2009
7. Zemanick ET, Towler E, Accurso FJ, DeVoogd R, Wagener J and Sagel SD. Success in eradicating *Pseudomonas aeruginosa* at a large CF center using a quality improvement initiative. *Pediatric Pulmonol* 2010; 45(Suppl 33):409. North American Cystic Fibrosis Conference, Baltimore, MD, October 2010
8. \*Zemanick ET, Wagner BD, Accurso FJ, Sagel SD and Harris JK. Oropharyngeal bacterial microbiome in young children with cystic fibrosis and healthy controls. *Pediatric Pulmonol* 2010; 45(Suppl 33):324. Presented as a poster and workshop presentation at the North American Cystic Fibrosis Conference, Baltimore, MD, October 2010
9. \*Harris JK, Wagner BD, Zemanick ET, Accurso FJ and Sagel SD. Anaerobic Bacteria As Biomarkers Of Lung Function Decline In Cystic Fibrosis. *Am J Respir Crit Care Med* 183;2011:A6119. Presented at the American Thoracic Society International Conference, Denver, CO, May 2011.
10. #Ellway JE, Zemanick ET, Towler E and Sagel SD. Clinical Value Of Sputum Induction To Diagnose Infection In Cystic Fibrosis. *Am J Respir Crit Care Med* 183;2011:A1129. Presented at the American Thoracic Society International Conference, Denver, CO, May 2011.
11. \*Zemanick ET, Harris JK, Wagner BD, Robertson CE, Sagel SD and Laguna TA. Relationship between lung microbiome, lung function and inflammation during treatment of CF pulmonary exacerbation. *Pediatric Pulmonol* 2011; 46(Suppl 34):306. Presented as a poster and workshop presentation at the North American Cystic Fibrosis Conference, Anaheim, CA, November 2011
12. \*Zemanick ET, Harris JK, Nikrad MP, Stewart A, Williams SA, Sagel SD and Accurso FJ. Identification of circulating biomarkers of pulmonary exacerbation using a multiplex SOMAmer assay. *Pediatric Pulmonol* 2011; 46(Suppl 34):241. Presented as a poster and workshop presentation at the North American Cystic Fibrosis Conference, Anaheim, CA, November 2011
13. Sagel SD, Harris JK, Wagner BD, Zemanick ET, Emmett P, Taylor-Cousar JL, Oermann CM, Billings JL, Rubenstein RC and Rowe SM. Effects of ivacaftor on airway microbiome and inflammation in G551D patients. *Pediatric Pulmonol* 2013; Suppl 36:224.Presented as a poster at the North American Cystic Fibrosis Conference, Salt Lake City, UT, October 2013.
14. Ma D, Yoon A, Bartlett J, Faull KF, McCray Jr PB, Zemanick ET, and Porter E. Antimicrobial cholesteryl esters in cystic fibrosis airway secretions. *Pediatric Pulmonol* 2013; Suppl 36:123. Presented as a poster at the North American Cystic Fibrosis Conference, Salt Lake City, UT, October 2013.
15. Martiniano S, Sagel, S, Zemanick, E, DeVoogd, R, Accurso, F, Nick, J, Saavedra, M, Nichols, D, Taylor-Cousar, J, Levin, A, Czaja, C, Huitt, G, Kasperbauer, S, Daley, C. Use of clofazimine in difficult to treat nontuberculous mycobacterial infections. *Pediatr Pulmonol* Suppl 38: A356, 2014.
16. Donaldson SH, Taylor-Cousar JL, Rosenbluth D, Zeitlin P, Chmiel J, Jain M, McCoy KS and Zemanick ET. Safety, tolerability and pharmacokinetics of the intravenous S-nitrosoglutathione reductase inhibitor N6022: an ascending-dose study in subjects homozygous for the F508del-CFTR mutation. *Pediatric Pulmonol* 2014; Suppl 38:A258.
17. #\*Flass T, Frank D, Zemanick ET, Wagner B and Narkewicz MR. CF subjects with cirrhosis have increased Firmicutes and reduced Bacteroidetes in their fecal microbiome and correlate with severe disease. *Pediatric Pulmonol* 2014; Suppl 38:A523. Presented as a poster and workshop presentation at the North American Cystic Fibrosis Conference, Atlanta, GA, October 2014.
18. Chan CL, Pyle L, Retamal-Munoz C, Morehead R, Zemanick ET, Sagel SD and Klingensmith G. Lung function decline and glycemic patterns in youth with CF characterized by a standardized approach to continuous glucose monitoring (CGM) analysis. *Pediatric Pulmonol* 2014; Suppl 38:A569.
19. \*Zemanick ET, Wagner BW, Robertson CE, Accurso FJ and Harris JK on behalf of the CFFT BALF Study group. Airway microbiota detected from clinically obtained bronchoalveolar lavage fluid samples from CF patients and disease controls. *Pediatric Pulmonol* 2014; Suppl 38:A297. Presented as a poster and workshop presentation at the North American Cystic Fibrosis Conference, Atlanta, GA, October 2014.
20. Taylor-Cousar JL, Zemanick E, Solomon G, The pharmacokinetics of N91115, an inhibitor of S-nitrosoglutathione reductase, in cystic fibrosis patients. *Pediatric Pulmonol* 2015; Suppl 41:A250.
21. DeVoogd R, Hammond J, Gallo K, Lingard C, Fulton J, Retamal-Munoz C, Chan C, Martiniano S, Zemanick E and Sagel SD. An epidemic of CF-related diabetes? Or are we doing a better job of screening for CFRD. Improving oral glucose tolerance screening in individuals with CF 10 of ages and older without CFRD. *Pediatric Pulmonol* 2015; Suppl 41:A547.
22. Chan CL, Pyle L, Vigers T, Zemanick ET, Zeitler PS and Sagel SD. Continuous glucose monitoring reveals glucose abnormalities in CF youth despite normal oral glucose tolerance testing. *Pediatric Pulmonol* 2015; Suppl 41:A598.
23. #Hoppe J, Wagner B, Accurso FJ, Sagel SD and Zemanick E. Clinical outcomes of outpatient management of pulmonary exacerbations in children with CF. *Pediatric Pulmonol* 2016; Suppl 45:A445.
24. Vigers TB, Pyle L, DeVoogd R, Zemanick ET, Martiniano SL, Sagel SD, Chan CL. Continuous glucose monitoring in CF youth before and after ivacaftor/lumacaftor. *Pediatric Pulmonol* 2016; Suppl 45:A650.
25. Chan CL, Wagner B, Vigers T, Towler E, DeVoogd R, Hoppe J, Martiniano SL, Zemanick E and Sagel SD. Pulmonary and nutritional outcomes in youth with cystic fibrosis related diabetes before and after diagnosis and insulin treatment- a center experience. *Pediatric Pulmonol* 2016; Suppl 45:A652.
26. Hill J, Nasir M, Bean H, Zemanick E, Ashare A, Gifford A and Smolinska A. Determining lung infection etiology in CF patients using breath and other biofluids. AJRCCM 2017;195:A4848.
27. #Osborne CM, Stillwell PC, Zemanick E and Dominguez S. An unusual case of high fever in a patient with cystic fibrosis (CF): Kawasaki Disease. AJRCCM 2017;195:A6096.
28. #Sobremonte-King MY, Prager J, Villavicencio K and Zemanick E. A pulmonary vascular sling in a pediatric patient presenting with high altitude related symptoms. AJRCCM 2017;195:A2183.
29. Somayaji R, Muhlebach MS, Ramos KJ, Beckett V, Popowitch E, Miller M, Baines A, Hamblett NM, Zemanick ET, Hoover W, Goss CH. Risk factors for Methicillin-resistant *Staphylococcus aureus* (MRSA) persistence in persons with cystic fibrosis (CF): analysis of the STAR-too cohort. *Pediatric Pulmonol* 2017; 52:Suppl 47:A355.
30. Zemanick ET, Wagner BD, Robertson CE, Stevens M, Borowitz D, Leung DH, Ramsey BW and Harris JK. Longitudinal changes in upper airway microbiota in infants with CF enrolled in the Baby Observational and Nutritional Study. *Pediatric Pulmonol* 2017; 52:Suppl 47:A332.
31. Hill J, Nasir M, Bean HD, Zemanick ET, Ashare A, Gifford AH, Smolinska A. Host-pathogen metabolic signature of P. aeruginosa: diagnostic value and insight into pathogenesis. *Pediatric Pulmonol* 2017; 52:Suppl 47:A364.
32. Wagner BD, Williamson K, Sagel S, Harris JK, Juarez-Colunga E, Zemanick ET. Association between *Pseudomonas aeruginosa* airway infection and systemic inflammation measured longitudinally in children with cystic fibrosis. *Pediatric Pulmonol* 2017; 52:Suppl 47:A504.
33. Fulton J, Hammond J, Lingard C, Gallo K, Zemanick ET, Wagner B, Sagel S. Initiative to education cystic fibrosis patients on the proper administration of Orkambi. *Pediatric Pulmonol* 2017; 52:Suppl 47:A619.
34. #Hong N, Sagel SD, Zemanick ET, Shi Y, #Hoppe J. Gotta catch em all: delayed diagnosis of CF in an infant with a novel CFTR mutation. AJRCCM 2018;197:A5593.
35. #Hong NY, Brinton J, Towler E, Sagel S, Hoppe J, Zemanick ET. Eradication of Burkholderia cepacia complex in children with cystic fibrosis using a standardized protocol. *Pediatric* *Pulmonol* 2018; 53:Suppl 2: A379.
36. Jewell MP, Galyean AA, Harris JK, Zemanick ET, Cash KJ. Optical nanosensors for monitoring 3-D oxygen gradients in *Pseudomonas aeruginosa* biofilms. *Pediatric Pulmonol* 2018; 53:Suppl 2: A393.
37. #Hahn A, Burrell A, Ansusinha E, Chaney H, Sami I, Perez GF, Koumbourlis AC, McCarter R, Freishtat R, Crandall K and Zemanick ET. Young Children with Cystic Fibrosis Have Decreased Airway Microbial Diversity Compared to Healthy Controls of Similar Age. AJRCCM 2019: 119:A10284
38. #Eyman A, Wagner B, Zemanick ET, #Hoppe J. Oral antibiotic prescribing patterns for children with CF followed at a large CF center. *Pediatric Pulmonol* 2018; 53:Suppl 2: A494.
39. \*#Hoppe JE, #Colborg A, Hinds DM, Wagner BD, Morgan WJ, Rosenfeld M, Zemanick ET, Sanders DB. Outcomes of Oral Antibiotic Treatment for Pulmonary Exacerbations in Children with CF. *Pediatric Pulmonol* 2019; 54:S2: A705.
40. Theprungkirikul J, Skopelja-Gardner, S, Meagher R, Clancy JP, Zemanick ET, Ashare A et al. Dissociation of systemic and mucosal autoimmunity in cystic fibrosis. *Pediatric Pulmonol* 2019; 54:S2:A295
41. Harris JK, Robertson C, Stevens M, Towler E, Zemanick ET, Wagner B. Bacterial community succession in children with cystic fibrosis. *Pediatric Pulmonol* 2019; 54:S2: A298.
42. #Hahn A, Burrell A, Chaney H, Sami I, Perez G, Koumbourlis AC, Freishtat R, Zemanick ET, Crandall K. Antibiotic resistance in the cystic fibrosis airway microbiome is associated with decreased bacterial richness. *Pediatric Pulmonol* 2019; 54:S2: A422.
43. Martiniano SL, Zemanick ET, Sorano DE, Wagner B, Sagel S, Accurso FJ. Salt balance and growth in CF infants diagnosed by newborn screen. *Pediatric Pulmonol* 2019; 54:S2: A472.
44. \*Zemanick ET, #Hoppe J, Morgan WJ, Rosenfeld M, Aliaj E, Patterson A, Sanders DB. Pediatric pulmonary exacerbations: approach and research priorities of caregivers and CF center directors. *Pediatric Pulmonol* 2019; 54:S2: A702
45. \*Mayer-Hamblett N, Zemanick ET, Odem-Davis K, VanDevanter DB, Rowe S, Konstan M. CFTR modulator-induced sweat chloride changes across the cystic fibrosis population: first results from the CHEC-SC study. *Pediatric Pulmonol* 2019; 54:S2: A202.
46. #Hahn A, Burrell A, Chaney H, Sami I, Koumbourlis AC, Freishtat R, *Zemanick E*, Crandall K. Beta-lactam exposure is associated with recovery of microbial diversity in the CF airway. *J Investigative Medicine* 2020;68:4;916-917:A19.
47. #Khalaf R, Furuta G, Wagner B, Robertson C, Andrews R, Stevens M, Fillon S, Zemanick ET, Harris J. Acid blockade effects on microbiota and inflammation in CF. *Pediatric Pulmonol* 2020; 55:S2: A219.
48. #Poore TS, Meier M, Towler E, Brinton J, Martiniano SL, Zemanick ET. Lung function decline in patients with CF and fungal infection. *Pediatric Pulmonol* 2020; 55:S2: A308.
49. # Lenhart-Pendergrass PM, Anthony M, Sariyska S, Andrews A, Scavezze H, Towler E, Martiniano SL, Hoppe J, Zemanick ET. Home respiratory specimen collection in children with cystic fibrosis. *Pediatric Pulmonol* 2020; 55:S2: A718.
50. #Poore TS, Towler E, Qadri S, Dominguez S, Rusin K, Zemanick ET. Reliability of provider assessment to predict respiratory pathogen positivity in children with CF admitted for pulmonary exacerbation. *Pediatric Pulmonol* 2020; 55:S2: A737.
51. #Hernandez A, Meier M, Wagner B, Towler E, Martiniano S, Zemanick E. Relationship between sweat electrolytes and genotype severity in cystic fibrosis. *J Cyst Fibros* 2021;20 (S2);S16-17.
52. #Kuffel H, Hoppe J, Meier M, Mark J, Wagner B, Towler E, Zemanick E. Improvement in fat-soluble vitamin levels following highly effective CFTR modulator use in children with CF. *J Cyst Fibros* 2021;20 (S2);S105.
53. Davis T, Wagner B, Azmir J, Khan M, Phipps K, Zemanick E, Hill J, Bean H. Exhaled breath as a novel diagnostic for *Pseudomonas aeruginosa* lung infections. *J Cyst Fibros* 2021;20 (S2);S255-256.
54. #Hahn A, Burrell A, Chaney H, Sami I, Koumbourlis A, Freishtat R, Crandall K, Zemanick E. Bacteriophage and antibiotic resistance detected by metagenomic sequencing in the cystic fibrosis airway microbiome. *J Cyst Fibros* 2021;20 (S2);S235.
55. Mayer-Hamblett N, Clancy J, Odem-Davis K, Pearson K, Zemanick E, Konstan M, VanDevanter D. Clinical trial interest after establishment of modulator therapy: Interim CHEC-SC survey results. *J Cyst Fibros* 2021;20 (S2);S262.
56. Zuckerman J, Hinton A, Mermis J, Flume P et al. A multi-center study of peripherally inserted central venous catheters: Predictors of difficult line insertion, malfunction, and soft tissue injury. *J Cyst Fibros 2022:* Vol. 21 Supplement: S17–S18.
57. Sanders DB, Hoppe J, Zemanick E, Morgan W, Bartz T, Kime N et al. The Streamlined Treatment of Pulmonary exacerbations in Pediatrics pilot study of oral antibiotic timing in pediatric cystic fibrosis pulmonary exacerbations. J Cyst Fibros 2022: Vol. 21 Supplement: S83–S84.
58. Guimbellot J, Natt J, Ryan K, Dowell A, Odem-Davis K, Konstan M et al. Concentrations of elexacaftor/tezacaftor/ivacaftor in the cystic fibrosis population: Interim analysis of the CHEC-Pharmacokinetics study. J Cyst Fibros 2022: Vol. 21 Supplement: S154.
59. Davis T, Wagner B, Seitz A, Zemanick E, Phipps K, Bean H et al. A breath test for Pseudomonas. aeruginosa? The results look promising …J Cyst Fibros 2022: Vol. 21 Supplement: S266.
60. Harris J, Graham B, Zemanick E and Wagner B. Evaluation of bacterial detection by microbial cell–free deoxyribonucleic acid using plasma collected during admission for cystic fibrosis pulmonary exacerbation. J Cyst Fibros 2022: Vol. 21 Supplement: S272.
61. Konstan M et al. Cystic fibrosis transmembrane conductance regulator modulator–induced sweat chloride changes in the cystic fibrosis population from the Characterizing Cystic Fibrosis Transmembrane Conductance Regulator–Modulated Changes in Sweat Chloride Study: 2022 Update. Journal of Cystic Fibrosis, 2022 Volume 21, S26 - S27
62. Hamner B, Nguyen D, Mhaskar R, Salemi J, Zemanick E, Goldenberg N, Khalaf R. 550 Prevalence of acid blockade use and its association with social determinants of health in people with cystic fibrosis: Preliminary analysis of Cystic Fibrosis Foundation registry data. Journal of Cystic Fibrosis. 2023;22:S291-S292.
63. Hoppe J, Vigers T, Trujillo A, Zemanick E. Impact of home collection and shipping on cystic fibrosis pathogen detection. Journal of Cystic Fibrosis, 2023; Volume 22, S52

**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)

******

***Updated January 10, 2024***