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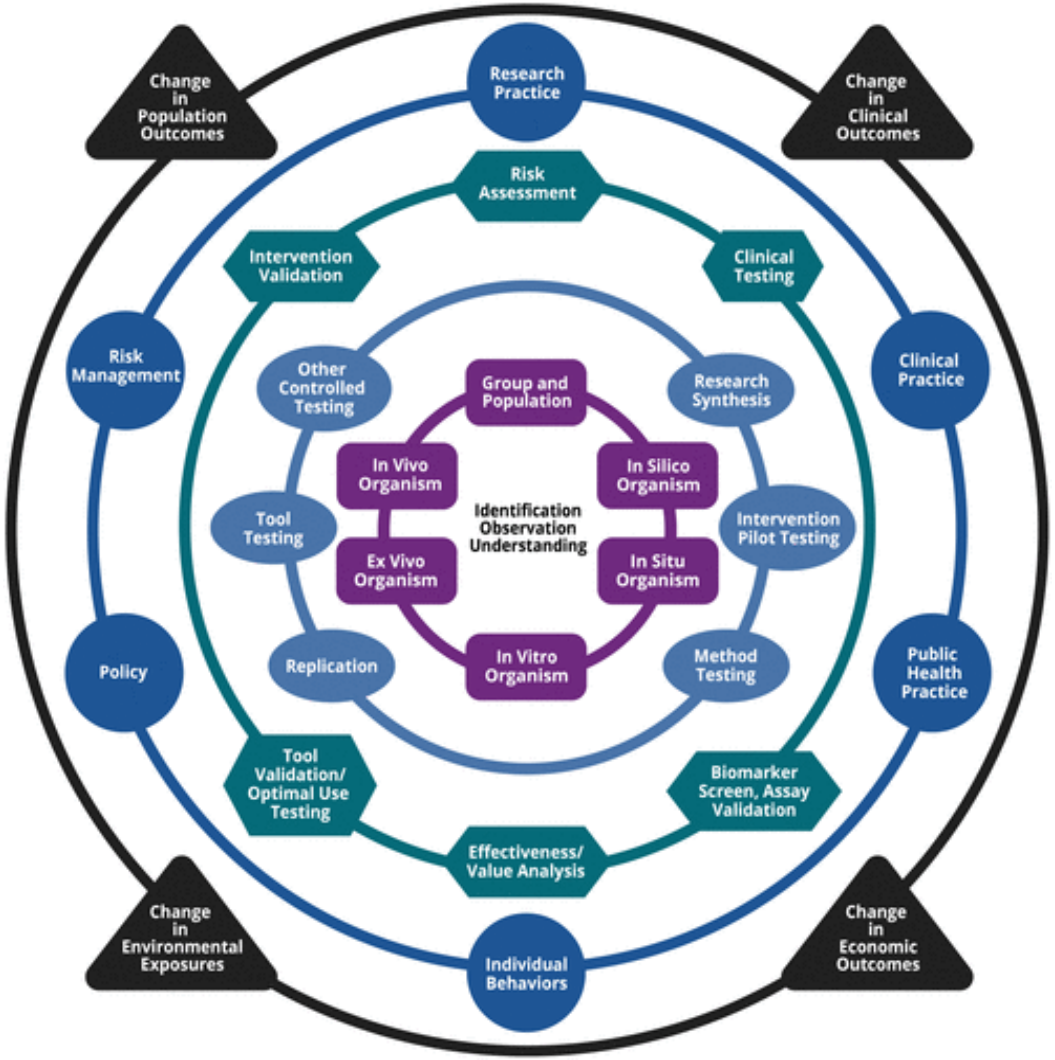
Translational Research Support Core (TRSC)

The National Institute of Environmental Health Sciences (NIEHS) introduces a new translational research framework that builds upon previous biomedical models to create a more comprehensive and integrated environmental health paradigm."
-- Pettibone et al.



EHP July 2018

Director - Clinical: Alejandro Comellas, MD
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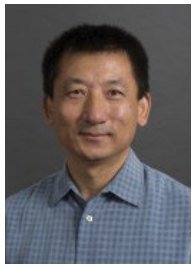
Associate Director - Imaging: Eric A. Hoffman, PhD
eric-hoffman@uiowa.edu



Biostatistician: Kai Wang, PhD, MS
kai-wang@uiowa.edu

TRSC

Components

- Research participant recruitment
- Lung physiology
- Imaging Component (Dr. Eric Hoffman)
- Biologic Sampling
- Vascular Health
- Ecological momentary assessment and health-symptom sampling for environmental health researchers.

TRSC

- TRSC is currently supporting several clinical projects that are determining the lung structural changes in subjects with Chronic Obstructive Pulmonary Disease (COPD), such as:
  - Phase-4 NIH funded COPDGene: One of the largest studies (10,000 participants ever to investigate the underlying genetic factors of COPD
  - SPIROMICS: (3000 participants) SubPopulations and InteRmediate Outcome Measures In COPD Study (SPIROMICS) supports the prospective collection and analysis of phenotypic, biomarker, genetic, genomic, and clinical data from subjects with COPD for the purpose of identifying subpopulations and intermediate outcome measures
  - Source: (700 participants) looks for early signs of lung changes in younger smokers to better understand the first stages of COPD

TRSC

- Lung Health Study: (4000 participants) overarching objective of the ALA-LHC is to establish a national cohort of young adults for the purpose of defining lung health and developing targets to intercept chronic lung disease at its earliest stages
- University of Iowa Post-COVID cohort: > 700 participants are part of the UI registry

TRSC Research Cohorts

In addition, new initiatives include:

- Clean-Air-2 (770 participants). Examine the effectiveness of a clean air intervention in patient with COPD
- Participation in All of Us. Heartland Consortium. We will recruit 800-900 participants every year for four years (3,000 in Iowa alone.

Pilot Projects include: Cardiopulmonary effects of vaping in 18-25 years old; Iowa Post-COVID Cohort, 3 year follow up Post-COVID cohort lung imaging, RECOVER trial.

Clinical Research Unit

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- Provide unique resources to:
  - Enable high quality clinical research
  - Support the recruitment of new faculty interested in clinical research
  - Support the career development of early-stage clinical and translational investigators
- Promote interactions between basic and clinical research faculty and the translation of laboratory discoveries to humans.

Clinical Research Unit

- 100 new protocols annually; >200 protocols currently open
- Investigators from UI College of Medicine, Public Health, Pharmacy, Nursing, Dentistry, Liberal Arts, Law, Engineering, Education, and Business
- Sponsors include NIH, Veterans Affairs, Foundations, Pharmaceutical/Device Industry, and Internal funds.

2024-2025 (CC & RC)

CC Personnel	43
Clinical Research Manager	1
Nurse Clin. Trial Research Specialist	1
Nurse Clin. Trial Research Associate	7
Clinical Research Specialist	2
Clin. Research Associate	12
Clin. Trials Research Assistant	12
Admin Service Coordinator	2
Students	4
Financial Analyst	1
Senior Business Analyst	1

RC Personnel	6
Clin. Regulatory Manager	1
Clin Trials Regulatory Research Associate	2
Clin. Trials Regulatory Research Assistant	2
Student	1

Coordinator Core Support

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Early Study Development

- Interact early to develop study conduction plan.
- Develop recruitment plans.
- Budget development and negotiations.

Study Support for Life of Study

- Provide ongoing study conduction support throughout a study.
- Initiate, recruit, conduct, and long-term follow-up support
- Continued financial support for study.

Education and Training

- We can provide individual/group education and training to researchers and study staff on study conduction and coordination.
- Hire and train new coordinators for PIs across the University of Iowa

Regulatory Core Support

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Early Regulatory Development

- Interaction to develop regulatory plan. This can include sIRB assistance prior to grant submission, FDA IND/IDE consultation or submission, feasibility visits with sponsors, assistance with protocol and Data Safety Monitoring Board creation, and clinicaltrials.gov consultation and submission.

Regulatory Submissions and Maintenance

- Prepare, submit, and maintain HawkIRB, commercial IRB, and sIRB submissions. Assist investigators, coordinators, and study staff in their submissions.

Education and Training

- Provide individual or group regulatory education and training to researchers and study staff / groups.
- Collaboration with the Human Subjects Office/IRB to bring training and materials to University of Iowa research staff.

FDA Inspections

- Resource to researches and study staff when preparing for an FDA inspection or preparing and implementing responses to the FDA inspection.

Regulatory Core Support

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Walk in Office Hours

- Virtual walk-in hour support three times per week.

Department Specific Regulatory Support

- Hire, train, and manage department specific regulatory staff. This allows for department specialization while also giving them access to Regulatory Core expertise and knowledge.

DocuSign

- Collaborated with the Carver College of Medicine to bring a Part 11 Compliant DocuSign system to the University of Iowa research community. This will allow for FDA regulated trials to use electronic consents.

Clinicaltrials.gov

- We participate in the local and national clinicaltrials.gov working groups.

University of Iowa Research SOP Development

- Lead a group of University of Iowa stakeholders to develop SOPs that are available for research staff to utilize.

Start Up and Hand Off Meetings

- Coordinate meetings between Regulatory, Finance, and Coordination teams for initiating studies at the University of Iowa.

Collaborative Activities

Iowa Clinical Trials Management System (Advarra)

- Led OnCore, eREG, and EDC implementations
- Presented at departmental meetings to expand awareness

Clinical Trial Management Ecosystem (CTME) Maturity Model

- Team members in Maturity Model Working Group
- Presented this model at Advarra Onsemble Conference 2023

CRU Remote SOP Development

- Collaborated with another institution to develop a remote visit SOP.

Clinical Trials Investigator Training Program

- Participated in the development and presented to the clinicians

Collaborative Activities

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Novartis Preferred Partnership Program

- Collaborated with other University of Iowa stakeholders and Novartis to develop a standardized informed consent, rate card, and contractual language.

UIOWA/Advarra Strategic Partnership

- Collaborate with the Holden Comprehensive Cancer Center, the University of Iowa IRB/HSO, and Advarra to develop a relationship to streamline and ensure overall success with the Advarra products and services. (Advarra IRB and Clinical Trial Management System)

Educational Activities

- Clinical Lecture Series planning and presenters.
- ICTS/HSO collaboration to ongoing effort to educate University of Iowa research community
- Present at Graduate Certificate in Translational and Clinical Investigation
- Present at Undergraduate Certificate in Translational and Clinical Investigation

ICTMS Enterprise Expansion for General Research

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Phase 1 Complete

OnCore Expansion

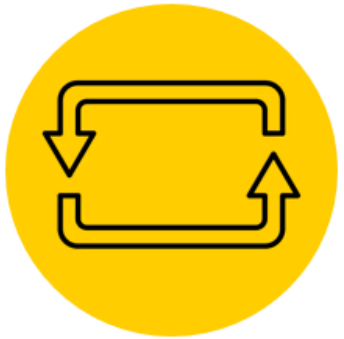
- Available for use by all research studies
- Centralizes participant & visit tracking
- Sponsor invoicing
- Sponsor Payment tracking
- Interface
  EPIC, HawkIRB, Vestigo

Complete Spring 2024

eReg Expansion

- Electronic regulatory binder
- Remote monitoring capability
- Electronic signatures
- Real-time document routing
- Enhance Compliance

Phase 3 Start Sept 2024



EDC Expansion

- Internal Electronic data capture
- Resource for Iowa Investigator Initiated Trials
- Part 11 Compliant
- Multi-site Studies
- FHIR integration

Phase 4 Spring 2025

Epic Research Billing & CRPC Grid

- Automated identification and separation of sponsor, patient and insurance billable research procedures

ICTMS Improvements for Research

- Single solution across the enterprise
- Integrates with Epic, IRB, financial systems (Possibly ICART?)
- Reduces duplication of effort/entry
- Financial consistency
- Regulatory consistency (centralized, more efficient)
- Efficiencies – CVs, re-useable forms, e-sigs
- Provides streamlined management and regulatory oversight of multi-site trials
- Part 11 Compliant electronic regulatory binders and electronic data capture system

2024-2025 CC and RC initiatives

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- Initiation of Mentor Program with new staff for both Regulatory and Coordinator personnel
- Develop a remote research visit process
- Work with Human Resources to develop an institutional research career ladder
- Develop an instructional onboarding process for all research professionals.

Providing the Tools for Exploring Environmental Impact on Lung Structure and Function

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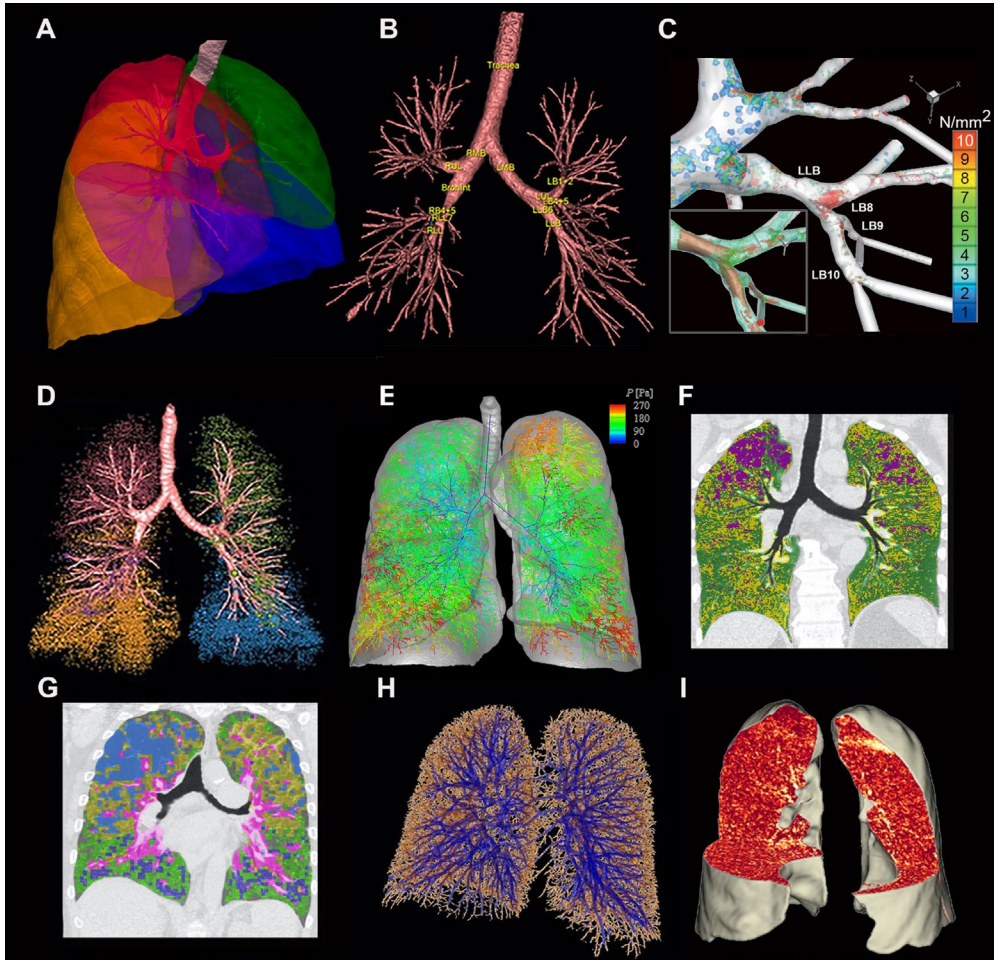
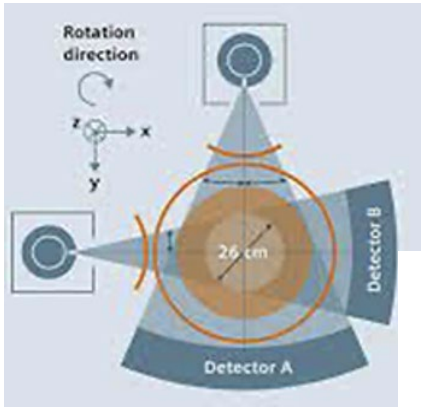


A. Lung and Lobe Segmentation
B. Airway segmentation and labeling
C. CFD estimates of particle deposition
D. Air trapping at RV (<-856HU)
E. 1D CFD prediction of pressure distribution at peak expiration (asthma)
F. Disease Probability Method (DPM) Normal, Emphysema, fSAD.
G. AMFM texture map
H. Small Vessel Volume (<0.75mm radius) vs. Total Vessel Volume ($SSV_{.75}$/TVV)
I. DECT derived Pulmonary Perfused Blood Volume (PBV)



Regional Pulmonary V/Q via Dual Energy CT (DECT)

ehsrc

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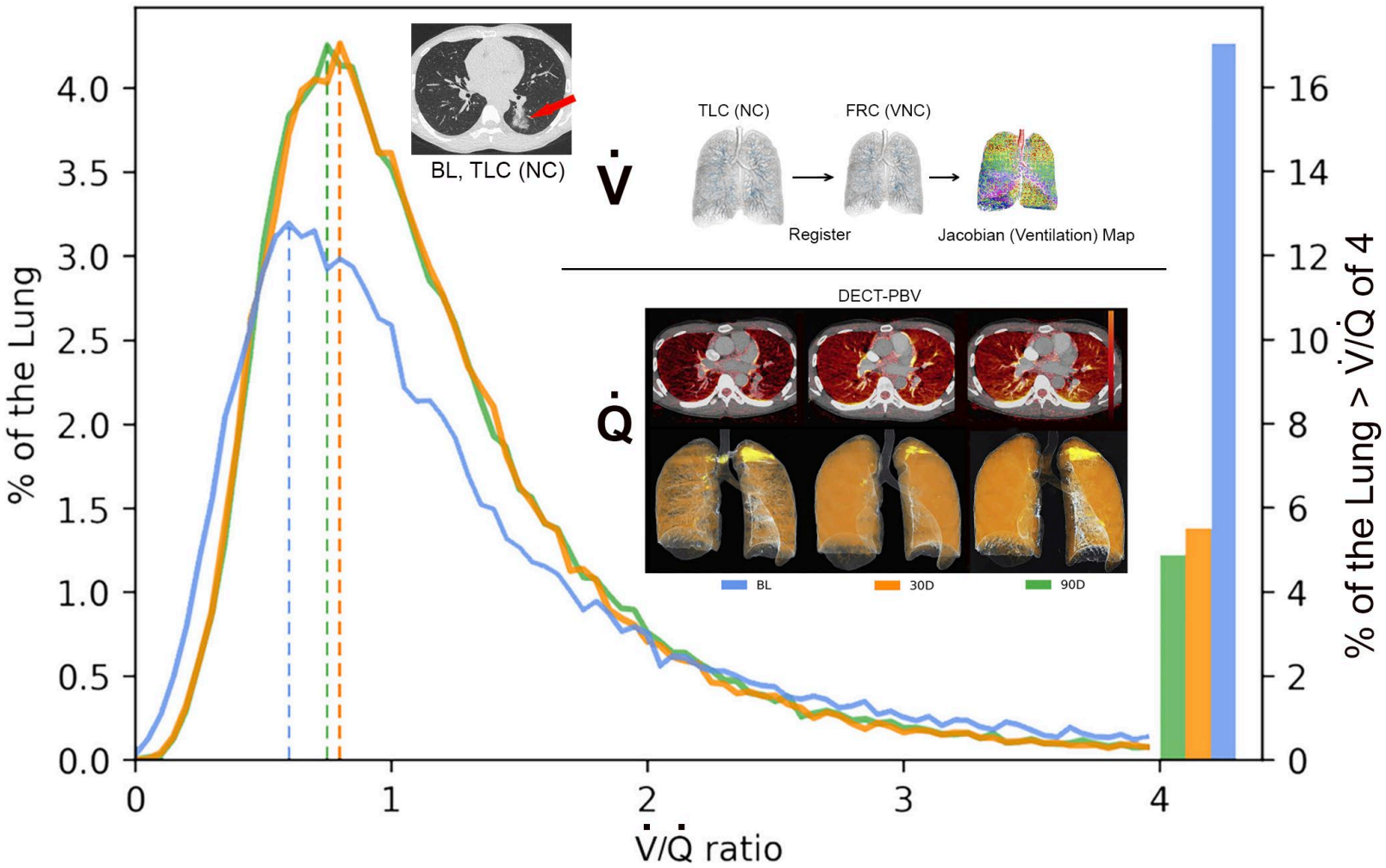
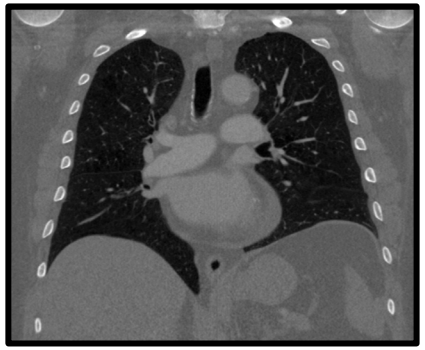
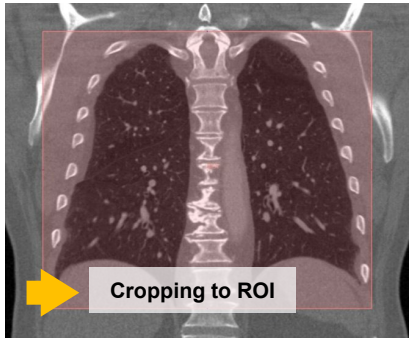
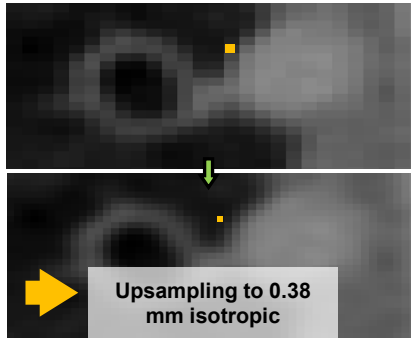
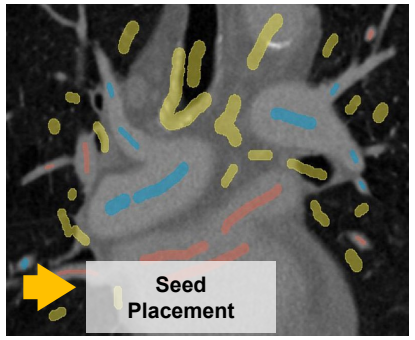


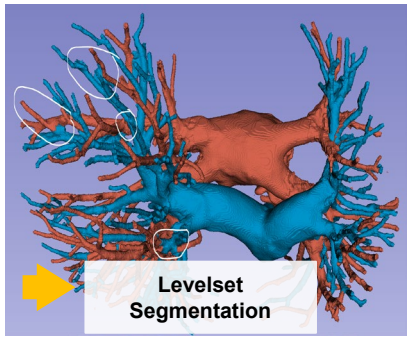
Training AI to Extract Independent Pulmonary Arterial and Venous Trees

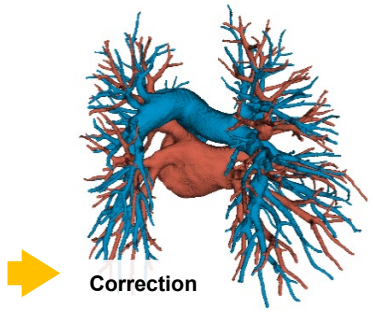


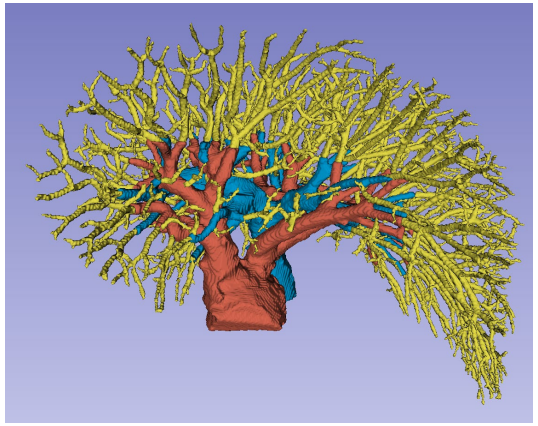


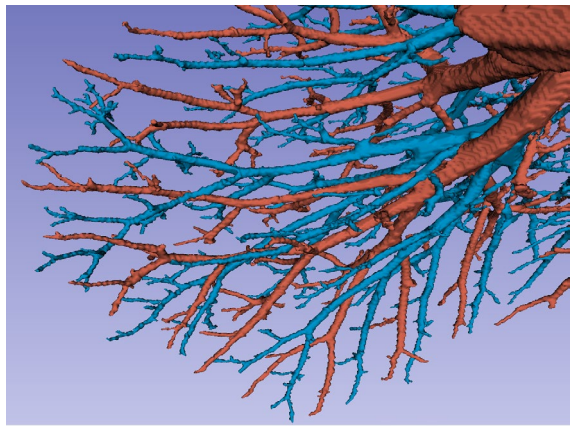


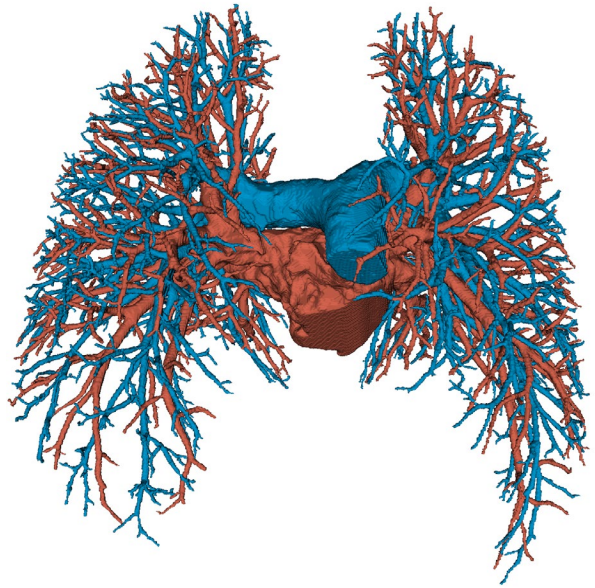












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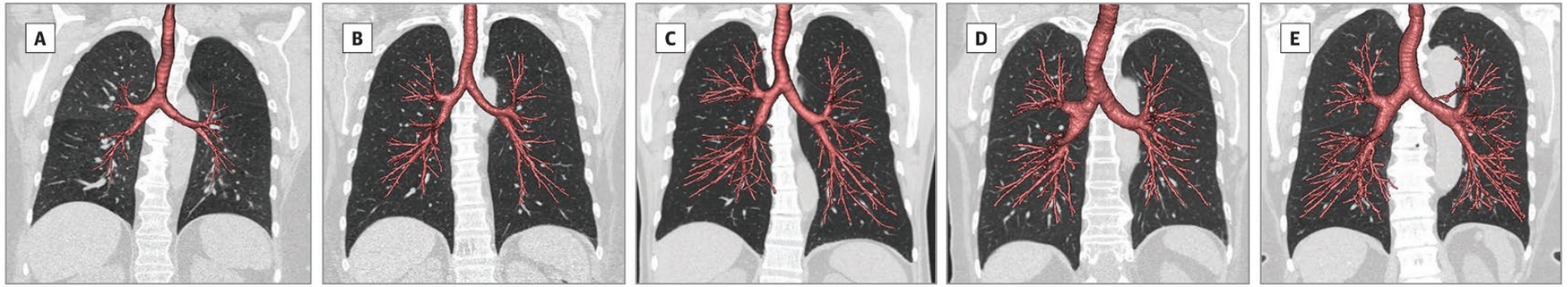
Airway and Vascular Structure Defines Disease Susceptibility

Airway Dysanapsis: Size of Airways vs. Lung



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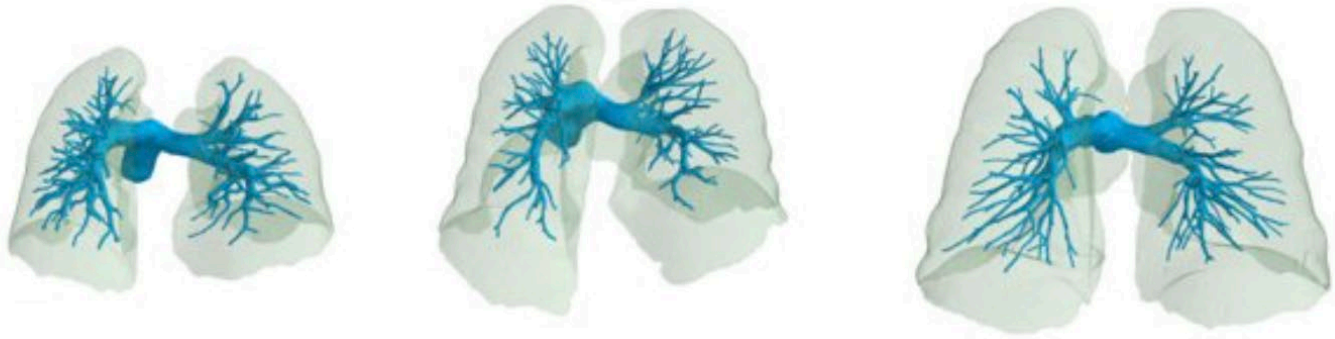
Imparts an increased risk of COPD, even in non-smokers

Smith BM, Kirby M, Hoffman EA, Ket al. JAMA. 2020 Jun 9;323(22):2268-2280.PMCID: PMC7284296.

Little is Known Regarding Arterial Dysanapsis and its Relation To Airway Dysanapsis



Scanner Upgrade via NIH High End Instrumentation S10 Grant

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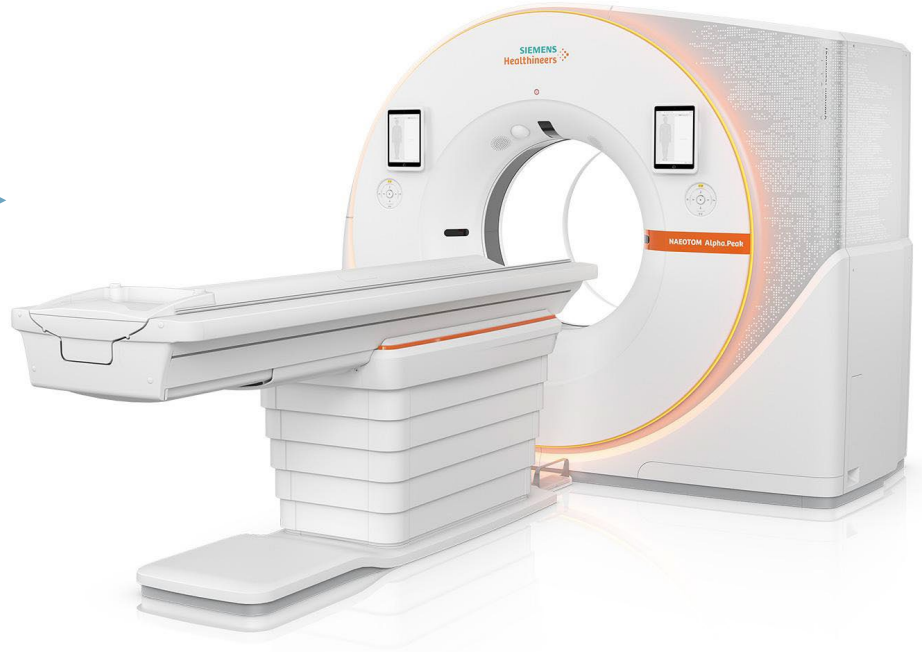
Siemens Somatom Force EID-CT

EID: Energy Integrating Detector

Siemens Naeotom Alpha.Peak PCD-CT



PCD: Photon Counting Detector

Vascular Health

- Vascular aging
- Endothelial function
- Arterial stiffness
- Central blood pressure
- Exercise physiology
- Oxidative stress and Inflammation

Vascular Health

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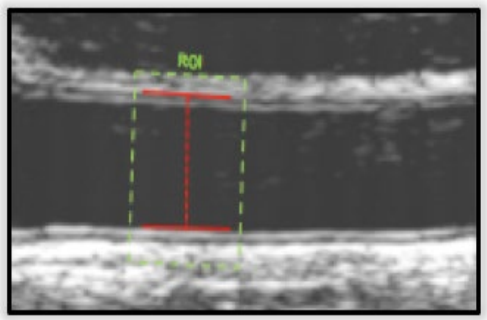
Carotid artery stiffness

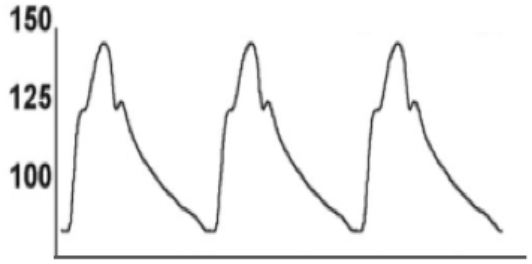
Acquire changes in carotid diameter and pressure for each cardiac cycle (for 15 sec)

Carotid diameter



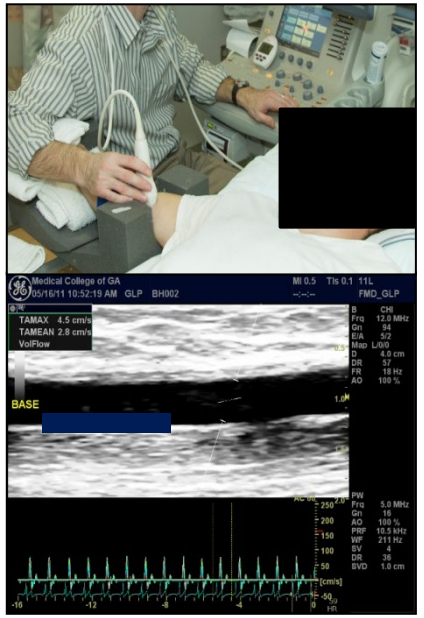
High-resolution ultrasonography

Carotid pressure



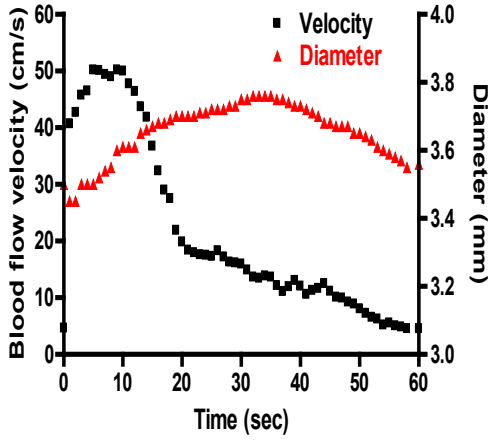
Applanation tonometry

Brachial artery flow-mediated dilation (FMD)



Normal FMD%: 8-12%
Abnormal FMD%: 0-4%

FMD expressed as relative change (%Δ) and absolute change (mmΔ)



NEW to EHSRC: Regional Gas Exchange Via Polarized Xenon MRI

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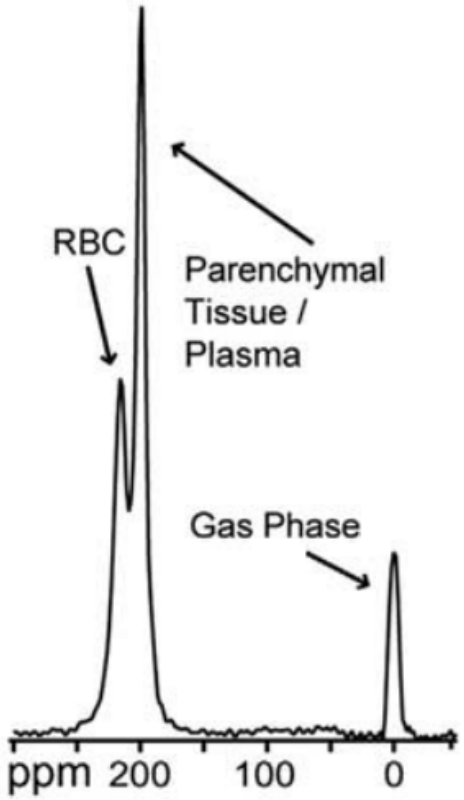
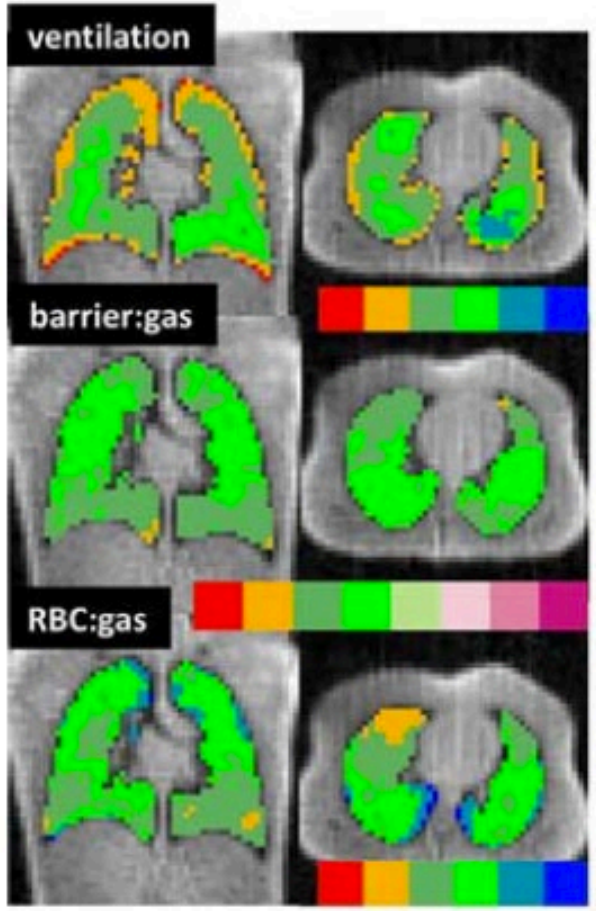
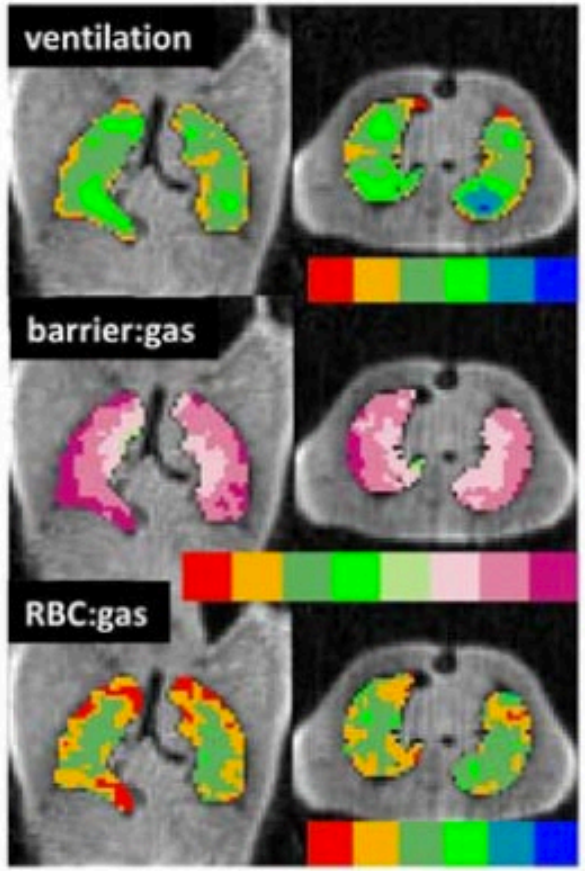


Normal



IPF



Sean Fain, PhD

Mammarappallil JG, Rankine L, Wild JM, Driehuys J Thorac Imaging. 2019 Mar;34(2) 136-150