



# Recognition for You First Services Inc, as a partner of NY State in the fight against COVID-19

Governor Andrew M. Cuomo announced that New York State has selected You First Services Inc as a partner in the fight against the COVID-19 pandemic. 12 New York companies have received support from the State to produce needed supplies to help combat COVID-19. While the state currently has some of the lowest transmission rates in the United States, preparing for a possible "second wave" is vital in protecting essential healthcare workers and the public. Grant funding will help alleviate product shortages due to supply chain issues that could lead to unfair pricing practices. These companies will also increase the State's manufacturing capacity while creating new jobs and market opportunities. To date, more than \$11 million in grants have been awarded to 20 qualifying New York-based companies to retool their business lines and pivot to manufacturing vital supplies for ongoing response and recovery efforts. "During the pandemic, the nation has learned a hard lesson about not having a supply chain for vital supplies based at home in the U.S. and as a result we had to scour the globe for life-saving products that are mainly manufactured overseas," Governor Cuomo said. "This won't happen again in New York - we are building the infrastructure needed for the future and by supporting local companies' pivot to new areas of production, we will be in a better position to avoid supply and demand issues and secure the items we need both quickly and at reasonable prices."

# In This Issue

Gut microbiome's development, determinants, and dysbiosis in cancers

COVID-19 and Cardiovascular Disease

COVID-19 and transplant patients

It is time to address airborne transmission of COVID-19

Product Updates

**Clinical Studies Updates** 

Welcome New Employees

You First Services, specializes in disinfection and sterilization systems. Our patented technology includes SteriSpace, an air sterilizations technology that reduces transmission of airborne pathogens. Licensed through the SUNY Research Foundation and SUNY Buffalo. SteriSpace capable of killing 99.9999% of airborne biological contaminants, including SARS, anthrax, influenza, tuberculosis and Coronavirus.



**EXPL**ØRE



# Gut microbiome's development, determinants, and dysbiosis in cancers

#### John F Gibbs, MD, FACS

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The microbiome refers to a population of microbes that colonize the skin, nasopharynx, oral cavity, gastrointestinal tract, and urogenital tract. The human microbiome consists of bacteria, archaea, fungi, viruses, and phages. Recent advances in genomic sequencing have catalyzed a deeper understanding of complex microbe-microbe and host-microbe interactions. Dysregulation of these interactions, or dysbiosis of the gastrointestinal tract, has been implicated in a growing list of pathologies including nonalcoholic fatty liver disease, cardiovascular disease, obesity, diabetes, depression, Parkinson's disease, autism, and various gastrointestinal microbiome and its potential risk factors for dysbiosis in order to tailor its application to the individual patient and create an era of highly personalized, precision medicine.

The "germ theory of disease" or the idea that microscopic pathogens are responsible for disease, has served as a foundational concept of our understanding of the human body for the past two centuries. Robert Koch and Louis Pasteur prompted the departure from miasma theory in which a poisonous vapor from an unhygienic environment was thought to be the culprit for infection. Koch is credited with formalizing criteria to establish the causation of a disease by a microbe: the pathogen must be present in all diseased subjects; the pathogen should be isolated from the diseased subject and grown in culture; when the cultured pathogen is introduced to a healthy experimental host, disease should be cancers. Gastric and esophageal cancer, for example, continue to remain as two of the most common causes of cancer-related deaths worldwide, therefore there is an increased emphasis on investigating the role of dysbiosis on these cancers. Further clarification of these pathways and discovery of diagnostic or therapeutic targets could have broad impacts on global subpopulations. It is important to understand the nature of the gastrointestinal tract observed; the pathogen should be re-isolated from the experimental host and be identical to the originally isolated pathogen (1). In this model of disease, the single pathogen role is overemphasized, and the host factors are unaccounted for. Antoine Bechamp, a vocal rival of Pasteur, believed that "there is an independently living microanatomical element in the cells and fluids of all living organisms" which he termed the "microzyma". Bechamp posited that the disruption of the host's inherent "microzymia" was a predisposition to disease (2). Though Bechamp's "microzymia" was largely ignored by the scientific community then, it has remarkable conceptual similarities to what we now know as the microbiome.

The gut microbiome has been linked to gastric and esophageal cancers, which represent the third and sixth most common causes of cancer-related deaths worldwide (3,4,). Both cancers have plausible explanations for carcino-



genesis rooted in dysbiosis. Further clarification of these pathways and discovery of diagnostic or therapeutic targets could have broad impacts on global subpopulations (5). As sequencing technology becomes increasingly sophisticated and accessible, researchers will be empowered to elucidate causal, rather than just correlative relationships (6). By reframing the microbiome as a determinant of global health and tailoring its application to the individual patient, we have the power to usher in the era of highly personalized, precision medicine.

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**EXPL**ØRE



# COVID-19 and Cardiovascular disease

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The coronavirus disease 2019 (Covid-19) pandemic has spread around the globe. There is growing concern that people with underlying increased heart disease risk may be disproportionately affected. There have been several case series that have noted cardiac arrhythmias, cardiomyopathy (weakened heart function), and cardiac arrest as terminal events in patients with Covid-19.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative agent of Covid-19, has been shown to establish itself in the host through the use of angiotensin-converting enzyme 2 (ACE2) as its cellular receptor. ACE2 is a membrane-bound monocarboxypeptidase found ubiquitously in humans and expressed predominantly in heart, intestine, kidney, and pulmonary alveolar (type II) cells. Entry of SARS- CoV-2 into human cells is facilitated by the interaction of a receptor-binding domain in its viral spike glycoprotein ectodomain with the ACE2 receptor. The interaction between the viral spike (S) protein and angiotensin- converting enzyme 2, which triggers entry of the virus into host cells, is likely to be involved in the cardiovascular manifestations of COVID-19. 3,4,5,6

The presence of underlying heart issues in patients with COVID-19 is associated with high mortality. Multiple studies have shown that underlying cardiovascular disease is independently associated with an increased risk of in-hospital death. COVID-19 can cause cardiovascular disorders, including heart attacks, arrhythmias, and venous thromboembolism (blood clots). Several medications used for the treatment of COVID-19 have uncertain safety and efficacy profiles. Many studies have reported the independent relationship of older age, underlying cardiovascular disease (coronary artery disease, heart failure, and cardiac arrhythmias), current smoking, and COPD (emphysema) with death in Covid-19. Some studies have suggested that women are proportionately more likely than men to survive the infection.

### **Coronavirus Precautions**

The universal precautions that have been recommended against Covid-19 also applies to patients with heart disease because they are currently our best defense against the virus:7

- Continue social distancing, at least 6 feet apart. In fact, stay home as much as you can if possible.
- Wash your hands frequently with soap and water for 20 seconds.
- Do not touch surfaces out in public.
- Wear a mask or cloth face covering when you are out in areas where it is hard to social distance.
- Cover coughs and sneezes with a tissue and then throw it away. If you do not have a tissue handy, cough or sneeze into your long sleeve at the elbow fold.
- Try not to touch your mouth, nose, or eyes.
- If you do have an emergency, such as heart attack or stroke symptoms, call 911. Getting care as soon as possible improves the chances of survival, and first responders are well trained to avoid spreading germs.



Please see the chart below for the links to the resources available for additional information from e various national and international organizations.

#### Useful web links for COVID-19 information Genetics The COVID-19 Host Genetic Initiative: https://www.covid19hg.org/ Single-cell RNA sequencing data COVID-19 Cell Atlas: https://www.covid19cellatlas.org/ Virus genome GenBank severe acute resporatory syndrome coronavirus 2 sequence: https://www.ncbi.nlm.nih.gov/ genbank/sars-cov-2-seqs/ China National Center for Bioinformation: https://bigd.big.ac.cn/ncov?lang=en Virus protein data ViralZone: https://viralzone.expasy.org COVID-19 Molecular Structure and Therapeutics Hub: https://covid.molssi.org/ Literature LitCovid: https://www.ncbi.nlm.nih.gov/research/coronavirus/ COVID-19-related preprints (medRxiv and bioRxiv): https://connect.biorxiv.org/relate/content/181 Materials Addgene COVID-19 and Coronavirus Plasmids & Resources: https://www.addgene.org/collections/ covid-19-resources/ ATCC Coronavirus Resources: https://www.atcc.org/Landing\_Pages/Coronavirus\_Resources.aspx Other resources NIH COVID-19 webpage: https://www.nih.gov/health-information/coronavirus CDC COVID-19 webpage: https://www.cdc.gov/coronavirus/2019-nCov/hcp/ Johns Hopkins Coronavirus Resource Centre: https://coronavirus.jhu.edu/map.html AHA COVID-19 Professional Resources: https://professional.heart.org/en/covid-19-content-an-aha-compendium ACC COVID-19 Hub: https://www.acc.org/latest-in-cardiology/features/accs-coronavirus-disease-2019covid-19-hub ESC COVID-19 and cardiology: https://www.escardio.org/Education/COVID-19-and-Cardiology COVID-19.coronavirus disease 2019.

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# COVID-19 and transplant patients

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# What is Coronavirus and what is COVID-19?

Coronaviruses are common viruses that cause the common cold, and do not usually cause serious symptoms. When new strains of viruses emerge, they can cause more severe diseases, as seen with the recent novel coronavirus called the Severe Acute Respiratory Syndrome 2 virus (SARS- CoV-2). This new coronavirus causes the disease called Coronavirus disease 2019 (COVID-19). This coronavirus appeared in December 2019 and has quickly spread all over the world.

# How is COVID-19 Spread?

This new coronavirus, SARS-CoV-2, spreads from person to person through close contact, most often by respiratory droplets that are spread when an infected person coughs, sneezes or talks. It can also be spread by close contact interactions like hand shaking and hugging. It may be possible to catch the virus from a contaminated surface (such as door handles, tabletops, shopping carts) if you subsequently touch your mouth, nose or eyes. People are thought to be most contagious when they have symptoms, but even those who are not experiencing symptoms or have mild symptoms can spread the virus. Recent studies indicate that COVID-19 can be transmitted before infected individuals begin to show symptoms.

# What are the symptoms of COVID-19?

- Fever
- Cough
- Shortness of breath or difficulty breathing
- Chills/repeated shaking
- Muscle pains
- Headache
- Sore throat
- Fatigue
- Nausea, diarrhea, abdominal pain
- New loss of smell and/or taste
- Some transplant recipients may develop pneumonia
- Rash

This list is not all-inclusive. If you develop symptoms concerning for COVID-19, contact your transplant center right away.

# How is COVID-19 treated?

Most people with COVID 19 who have mild to moderate symptoms will recover on their own with supportive care. Less commonly, COVID-19 may be severe and have serious complications requiring hospitalization or death.



Currently, there are no treatments approved by the U.S. Food and Drug Administration (FDA) for COVID-19. There are many ongoing clinical trials for potential antiviral and immune based therapies for the treatment of COVID-19. Remdesivir, an antiviral medication, may be beneficial and the FDA has issued an Emergency Use Authorization (EUA}, which allows for emergency use of Remdesivir for the treatment of COVID-19.

At this time, there are no vaccines effective against this virus, although studies to develop these are ongoing.

There are several things you can do to protect yourself. Some examples include:

- Wash your hands or use hand sanitizer frequently
- Avoid touching your eyes, mouth, and nose
- Avoid large crowds
- Practice social distancing by staying at least six feet from other people and groups
- Frequently clean and disinfect high contact surfaces such as tables, door knobs,and faucets
- Stay at home if you are sick
- Wear a face covering when you leave the house
- Practice cough and sneeze etiquette (see figure below)

Q: What should I do if I have COVID or flu-like/respiratory symptoms?

A: The first step is to separate yourself from others. There are many different causes for fever, cough, shortness of breath, stomach upset, and flu-like symptoms, but you should get tested for COVID-19. It is important to remember that most people, including transplant candidates and recipients, experience only mild to moderate symptoms recover from

COVIO-19 without problems. Many do not need hospitalization but are able to stay at home in isolation.

#### Other steps to take include:

- Contact your transplant center FIRST before going to a hospital or clinic.
- If you must leave home, place a surgical mask or cloth covering on when in public to avoid the spread of infection to anyone else.
- Wash your hands often with soap and water for at least 20 seconds. This is especially important after blowing your nose, coughing, or sneezing; going to the bathroom; and before eating or preparing food.
- Clean and disinfect high-touch surfaces" in your "sick room" and bathroom; wear disposable gloves while disinfecting.
- If you are in home isolation, monitor your symptoms and seek emergency attention if you have trouble breathing, chest pain, confusion, severe fatigue.

\*High-touch surface include phones, remote controls, counters, doorknobs, bathroom fixtures, toilets, keyboards, bedside tables

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- 3. For information on COVID-19 Treatment: https://www.covid19treatmentguidelines.nih.gov/ whats-new/
- 4. For information on specific clinical trials underway for treatment of patients with COVID-19 infection: clinicaltrials.gov.
- 5. Information from the American Society of Transplantation: https://power2save.org/
- 6. CDC information for COVID-19 and children: Caring for Children
- 7. COVID-19 information for parents from Pediatric Infectious Disease Society: COVID-19 Resources





# It is Time to Address Airborne Transmission of COVID-19

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For months, scientists and public health experts have warned of mounting evidence that the novel coronavirus is airborne, transmitted through tiny droplets called aerosols that linger in the air much longer than the larger globs that come from coughing or sneezing.

Now, the Centers for Disease Control and Prevention agrees. The CDC recently changed its official guidance to note that aerosols are "thought to be the main way the virus spreads" and to warn that poorly ventilated indoor spaces are particularly dangerous. It took over ten months for CDC to reach this conclusion. Understanding the transmission of respiratory infections indoors requires expertise in many distinctly different areas of science and engineering, including virology, aerosol physics, flow dynamics, exposure and epidemiology, medicine, and building engineering, to name the most significant. No one person has expertise in all these areas.

Airborne transmission was evident from the shocking spread of COVID-19 in the quarantined Diamond prince Cruise. In February 2020, the Diamond Princess Cruise, which left Japan, was obliged to stay at sea for 14 days-quarantine after it was found that a Hong Kong passenger had been diagnosed SARS-COV2 pneumonia after disembarking. As a result shocked the world, an outbreak of infection occurred on board; the number of infected people increased rapidly; and about 20% of the population infected. Finally, the quarantine is completely failed and has to be ended officially. The crowd was evacuated back to their own country. The inci-

dent can be seen as an experimental model of virus infection in an independently enclosed building, showing powerful air-borne transmission of the virus to pass through public ventilation ducts and crevices in doors and windows.

Several retrospective studies conducted after the SARS-CoV-1 epidemic demonstrated that airborne transmission was the most likely mechanism explaining the spatial pattern of infections. Retrospective analysis has shown the same for SARS-CoV-2 [1-4]. In particular, a study in their review of records from a Chinese restaurant, observed no evidence of direct or indirect contact between the three parties. In their review of video records from the restaurant, they observed no evidence of direct or indirect contact between the three parties [4]. Many studies conducted on the spread of other viruses, including respiratory syncytial virus (RSV) [5], Middle East Respiratory Syndrome coronavirus (MERS-CoV) [6], and influenza [7], show that viable airborne viruses can be exhaled and/or detected in the indoor environment of infected patients [6,7]. This poses the risk that people sharing such environments can potentially inhale these viruses, resulting in infection and disease. There is every reason to expect that SARS-CoV-2 behaves similarly, and that transmission via airborne microdroplets [4] is an important pathway. It is understood that there is not as yet universal acceptance of airborne transmission of SARS-CoV2; but in our collective assessment there is more than enough supporting evidence so that the precautionary principle should apply. In order to control the



pandemic, pending the availability of a vaccine, all routes of transmission must be interrupted.

We are concerned that the lack of recognition of the risk of airborne transmission of COVID-19 and the lack of clear recommendations on the control measures against the airborne virus will have significant consequences: people may think that they are fully protected by adhering to the current recommendations, but in fact, additional airborne interventions are needed for further reduction of

The current guidance from numerous international and national bodies focuses on hand washing, maintaining social distancing, and droplet precautions. Most public health organizations, including the World Health Organization (WHO), do not recognize airborne transmission [8] except for aerosol-generating procedures performed in healthcare settings. Hand washing and social distancing are appropriate, but in our view, insufficient to provide protection from virus-carrying respiratory microdroplets released into the air by infected people. This problem is especially acute in indoor or enclosed environments, particularly those that are crowded and have inadequate ventilation relative to the number of occupants and extended exposure periods. For example, airborne transmission appears to be the only plausible explanation for several superspreading events investigated which occurred under such conditions,

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In spite of the shutdown caused by the COVID-19 pandemic New York Pause, we were able to perform well with many remarkable achievements and breakthroughs in the past few months.

#### GloTran<sup>™</sup>

GloTran has been registered with the FDA as a high level disinfectant. Second generation GloTran were delivered to customers and they were successfully trained in disinfection of different devices. Production of more units are fast progressing. In the most recent collaborations with the University of Tennessee at Chattanooga Clinical Infectious Disease Control Research Group, the GloTran disinfection device underwent a 1½ month clinical investigation. Stethoscopes, otoscopes, ophthalmoscope, computer mice, blood pressure cuffs, pulse oximeters, and pulmonary breathing tubes were treated with automatic disinfection cycles.



**GloTran Second Generation** 

Engineers designed an iteration of GloTran which is a table top model rather than a standalone model. It has the chamber volume of 35 liters, which is three times the volume of the previous model. The device is now front loaded compared to the previous model. The requisite efficacy testing was successfully completed. An automated disinfection cycle with an average load size will take approximately 20 minutes to achieve a 6-log kill rate.

#### **SteriSpace**<sup>TM</sup>



The design and construction of a SteriSpace 250 CFM model to be integrated with a Patient Isolation Shelter has been tested and shown to reach the treatment temperature needed to destroy bacterial spores and viruses. Additionally, the test achieved negative pressure in the shelter as well as the number of air changes per hour (ACH)that meet the CDC guidelines for patient isolation. Commercialization of the 250 CFM SteriSpace model has now begun.

You First Services is currently exploring numerous business opportunities with the Department of Defense, Homeland Security, healthcare industry and other partners for installation of Sterispace.

Commercialization of the 250 CFM SteriSpace model is also being pursued for hospital rooms, either for isolation or protection applications, as well as other clinical settings such as dental offices.

The SteriSpace system is being expanded to provide larger units for use in larger spaces. A 5,000 CFM prototype SteriSpace was designed, built and tested as part of an R&D program funded by the U.S. Army Corps of Engineers Research Center. A mobile trailer-based prototype was built and successfully tested. The current effort to manufacture larger SteriSpace models will leverage off this earlier program. It will be directed at building different size models, mobile or fixed site, ranging in size from 1,200 CFM to 5,000 CFM.

You First Services, Inc. was one of twelve companies in New York State to develop technologies to defeat the virus and combat the pandemic. The SteriSpace technology is the only one of its type to receive funding.



# SteriSpace in fight against COVID-19

It is exciting to know the wide coverage and attention SteriSpace is getting from media as well as potential customers. Governor Cuomo listed You First Services as a partner in the fight against COVID and provided financial incentives. That can be read <u>here</u>. University of Buffalo included in their widely read newsletter about Sterispace and the efforts to fight COVID. That information is available <u>here</u>. Channel 7 featured SteriSpace in local evening news. These coverages did help increase the awareness about Sterispace and its capabilities. You First Services is actively engaging with different agencies in the fight against COVID.



### **Oral Healthcare**

The Oral Healthcare division continues to add multiple distributors to its fold. YFS will be introducing additional specialty products following the completion of clinical trials. Two flagship products Lubricity and MetaQil continue to be well appreciated by the end users. Lubricity and MetaQil were featured in the Sjogren's Syndrome Foundation quarterly magazine. You First Services, Inc. participated in the Foundation's webinars, virtual conferences also Sjogren's Strong podcast. With all these efforts the online sales went up by 830%. Cardinal Health distribution featured a Lubricity banner across the online ordering portal which helped brand recognition for Lubricity.



# **Call Centre**

The Second phase of the customer care call center with 20 employees started functioning in 4000 sq. ft. of newly added space following all NY state mandated social distancing regulations. This call center will serve and support the sales and after sales support of the oral care products. It will be expanded by employing up to a total of 63 employees The call center is being managed and integrated to a new phone service and CRM software for analytics.

# YFS Pharma

YFS Pharma manufactures, tests, and package specialty over-the-counter cosmetic products and custom manufacturing solutions.

We are equipping the manufacturing facility with new instruments and capabilities. Recently FTIR, first of an array of analytical instruments, was installed by Shimadzu. A newly installed stability chamber will enable in-house stability testing of the various manufactured products. It will help keep cost of production under control. Our cGMP-compliant manufacturing and analytical facilities are ready to support the development of early clinical and commercial products with formulation capabilities, stability evaluations and more. YFS pharma gives high importance to the quality control of production. We ensure all cGMP standards are followed.



### **Clinical Studies**

A Clinical study to evaluate the ability of a Hyaluronic Acid (HA) formulation to provide relief to vaginal dryness is in progress. This randomized study at the Department of Gynecology at the University at Buffalo will investigate the tolerability of a lubricating solution in patients with symptomatic vaginal dryness and its efficacy in minimizing the symptoms associated with dyspareunia. Please call (716)-323- 0725 for more information or enrollment.

Dry skin can be very uncomfortable and causeddue to various reasons including the weather. A randomized study is enrolling patients at Buffalo Amherst Allergy Associates and will investigate the tolerability of a novel lubricating solution in patients with symptomatic skin dryness and its efficacy in minimizing the symptoms associated with dry skin and to evaluate patients' perception of efficacy of a dry skin spray. The randomized double blind study is nearing its completion.

There is a need for an oral care product to provide comfort to patients suffering from speech articulation problems after orthodontic treatments. This randomized, single center, crossover study at Jacksonville University will evaluate how effective the HA formulation is in minimizing the articulation impairments after Invisalign treatment is nearing completion.

Obstructive Sleep Apnea (OSA) significantly impacts quality of life. Patients with OSA wake up with a dry mouth. The IRB has approved the study to alleviate dry mouth in OSA patients at the sleep clinic of the Veterans Affairs (VA) Hospital of WNY, using a Hyaluronic Acid containing formulation.

Xerostomia (dry mouth) has been reported to be a common complaint of patients with diabetes. A clinical study to test the ability of an HA formulation to alleviate dry mouth in diabetic patients is complete. Majority of patients in the study rated Lubricity better than the placebo.

# Clinical Investigation of GloTran Low Temperature Plasma/ $H_2O_2$ Disinfection Device in a Pulmonary Outpatient Clinic

An 8 week study was conducted by members of University of Tennessee, Chattanooga's (UTC's) Clinical Infectious Disease Control (CIDC) research group in collaboration with co-investigators at Erlanger Hospital. The first objective of this study was to determine if small reusable medical devices currently serve as potential vectors of bacterial contamination from patient to patient. The second objective of this study was focused on determination of the ability of the GloTran to reduce bacterial contamination of small, reusable medical devices in the KOC Pulmonary unit. Using data generated in the first phase of this study we determined the most contaminated small pieces of reusable equipment and perform a follow up study on those devices.

These small medical devices, if contaminated, were contaminated with low levels of the bacteria. Before the GloTran device was set up, the average number of positive swabs (swabs showing colony growth) for all sample sites was 8.3 per date sampled (four dates total). Once GloTran was set up, and through the end of the study, the average number of positive swabs for all sample sites was 2.4 per date sampled (11 dates total). The average reduction in bacterial contamination over the entire study was very significant. For two of the medical devices (blood pressure cuffs and otoscopes) the reduction in bacterial contamination when the GloTran device was in use was even higher.



#### Awards and Grants Partnership award

You First Services, Inc. has been awarded \$250,000 incentive from NY state to produce needed supplies to help combat the COVID-19 pandemic. Preparing for a possible "second wave" is vital to protecting essential healthcare workers and the public. These grant funds will help alleviate product shortages due to supply chain issues that could lead to unfair pricing practices. You first services is 1 of 12 companies selected for the award. These select 12 companies will also increase the State's manufacturing capacity while creating new jobs and market opportunities.

# CAT grant

You First Services received a University at Buffalo Center for Advanced Technology in Big Data and Health Sciences (UBCAT) grant to study the airflow pattern in a closed room. The UB CAT is a project cost-sharing grant program funded by Empire State Development, and designed to drive the growth of life and health science businesses in New York State. Using Computational Fluid Dynamics (CFD), airflow patterns within an HVAC system of a patient room was simulated. You First services is partnering with Francine Battaglia, Chair, Department of Mechanical & Aerospace Engineering University at Buffalo for this \$100000 project.

#### Welcome New Employees



Himashini Perera M.D. Medical Liaison Officer



Michael Yannazio Plant Manager (YFS Pharma)



Brian Corbett Sales Representative-Sterilization



Joe Seitz Mechanical Engineer



Michael Vangelista Assistant Electrical Engineer



Varun Kumar Engineering Intern



Michael Clough Engineering Intern Case Western Uni.



Alexandra Plante Digital Marketing Associate