Lung-MAP study explores alternative therapies for cancer treatment

With cancer therapy advancing rapidly, having cancer trials at Baystate allows our standard of cancer care to stay state-of-the-art. There are nearly 30 active clinical trials for cancer researchers across our region, the country, and the world. Lung cancer, the most common type of advanced cancer, relies heavily on clinical trials help to discover more effective and less toxic treatments.

One of the latest lung cancer trials, the Lung-MAP study, is an innovative protocol to evaluate biomarker-driven therapies and immunotherapies in previously treated non-small cell lung cancer. Like the name of the trial suggests, Lung-MAP evaluates a patient’s cancer molecular profile and provides a “map” of the molecular changes that may be targets for new treatments. This trial offers an opportunity to investigate treatment regimens to determine a new standard of care. Lung-MAP is considered an “umbrella trial”: an interconnected network of trials subdivided by medication/treatment type. Depending on which branch of lung cancer the patient falls under, a specific medication or combination of medications/therapies is prescribed. One of the treatment options under this umbrella is immunotherapy.

“Immunotherapy has been a great advance in cancer research, and it’s very exciting,” says John McCann, MD, Baystate Principal Investigator for the Eastern Cooperative Oncology Group (ECOG). “With certain types of lung cancer, we are able to skip chemo entirely and go straight to immunotherapy.” Both chemotherapy and immunotherapy are administered intravenously. Chemotherapy targets and damages a cancer cell’s ability to multiply, which can have adverse effects on normal cells and cause side effects. On the contrary, immunotherapy does not affect the cancer cell directly and has fewer side effects. Instead, it tells the body’s own immune cells to identify the cancer cells as harmful and attack them, like if you had an infection. Molecular targeting is also a treatment option, using medications that target the molecular changes in cancer cells. Driver mutations control the activity of the cancer and drugs that attack the driver mutation can slow the multiplication of the cells. Since not all cancer cells are the same, “it is becoming mandatory to see what molecular/cellular profiles exist within the cancer cells,” Dr. McCann says. “Molecular abnormalities can be targets for new types of treatment.”

The Lung-MAP trial allows the research team to obtain a detailed molecular profile by sending a patient’s pathology specimen out for analysis. If a molecular driver is identified, the patient may be able to receive a new investigation therapy at Baystate. This capability allows the patient to have cutting-edge treatment close to home.

“It’s very rewarding for the patients as well as the investigators,” adds Dr. McCann. “Through these clinical trials, patients get to have access to medications they wouldn’t normally have access to.”

Research Question? Call the Office of Research at our central number: (413) 794-3391
Engaging Springfield students in research

With a grant from the National Institute of Environmental Health Sciences (NIEHS), Baystate investigator Sallie Schneider, PhD and her team will be able to bring hands-on research experience to students in Springfield’s middle and high schools. As part of the National Institutes of Health (NIH), NIEHS supports a research grant at Baystate that studies how environmental exposures affect growth and development of breast cancer. One goal of the grant focuses on community involvement, aiming to promote education among local students. To that end, she is collaborating with Ron St. Armand, Director of Science in the Springfield Public School System (SPSS) and Peter Blain, BSEP, to devise a city-wide research project to study exposures to chemicals that act like estrogen during puberty and their effects on changes in the breast, as well as other organs. SPSS received a Massachusetts Life Science grant to purchase equipment, supplies and to develop a professional development course aimed at supporting this community initiative.

This summer, Dr. Schneider will begin educating Springfield high school science teachers in a professional development course to prepare them for the upcoming school year. She will help teachers to incorporate research into their current biology curriculum and develop critical thinking ability. In the fall she will provide reagents so that each student can analyze a small aspect of the study. The goal will be to combine the analyses performed across the schools and classrooms to have a better perspective of changes that occur when exposed to chemicals during critical periods. Dr. Schneider hopes the students feel excited or empowered by contributing to a research study, but more importantly that they have a new understanding for how various chemicals in the environment can impact their health. The school has suggested four strategic priorities that will ensure that effective instruction occurs in every class and that there are shared expectations for all students. These priorities include:

• Coaching, developing and evaluating educators based on a clear vision of strong instruction
• Implementing a consistent, rigorous curriculum built on common standards with common unit assessments
• Deploying data that is timely, accurate and accessible to make decisions for students, schools and the district
• Strengthening social, emotional and academic safety nets and supports for all students and families

“This is a fantastic collaboration between Baystate and the Springfield schools,” says Dr. Schneider. “We are investing time to involve students in research in hopes that the real life experience will help them to get excited about science and increase awareness.” It is Dr. Schneider’s hope that AP students will eventually visit the Baystate Research labs to do simple stains of cells and learn more about hands-on biomedical research themselves.

“We are excited to see what will come out of this grant,” she concludes. “It’s a collaboration that our research department hasn’t gotten to do before.”
Infectious diseases clinical research with Dr. Daniel Skiest

The field of Infectious Diseases (ID) is one of several subspecialties of Internal Medicine. It differs from other fields in Internal Medicine, such as cardiology, pulmonary, nephrology etc., which primarily focus on a single organ system. Since microbes (including bacteria, viruses, fungi, parasites) can affect a single organ (for example pneumonia) or the entire body (systemic infection), such as bacterial sepsis or HIV, ID doctors need to have knowledge of the whole body. They interact with nearly all medical specialties and treat a wide spectrum of patients.

Since new types of infections are continuously being discovered, ID doctors need to constantly stay up to date. In only the last few years, numerous infections have been either discovered or have affected new populations or new clinical manifestations. West Nile virus, SARS, bird flu, Middle East Respiratory Syndrome (MERS), Zika virus, Chikungunya fever, are only a few of these. The clinical manifestations and treatment of newly discovered infections, as well as the ability to develop resistance to medications, creates a continuous need for both laboratory and clinical researchers. New treatments need to be evaluated in several phases of clinical trials and often require the inclusion of several thousand patients prior to approval for the general public.

“It seems that every time we are about to catch up, the microbes seem to get ahead,” says Dr. Daniel Skiest, Director of ID Clinical Research and the Adult HIV/AIDS Program at Baystate Health and Vice Chair for Academic Affairs in the Department of Medicine. “Research will always be an important aspect of ID.”

Dr. Skiest gained experience in HIV clinical trials as a faculty member of University of Texas Southwestern Medical Center.

“Our HIV clinic cared for 3,500 patients and we were able to enroll many patients in novel and ultimately lifesaving treatments for HIV in the mid to late 1990s and the early 2000s,” he says. Shortly after being recruited to Baystate in 2005, Dr. Skiest started the ID trials unit. To date, Dr. Skiest and his team have enrolled over 300 individuals in clinical studies, mostly in HIV, but also influenza, pneumonia and hepatitis C.

One trial in progress, the REPREVE trial, has recruited 7,500 participants from over 100 sites across the globe. Thirty of these participants are enrolled at Baystate. REPREVE is the largest study ever involving HIV-infected individuals and is sponsored by the NIH (National Institutes of Health). This study will evaluate whether the use of a statin medication will prevent vascular events (heart attacks, strokes) in patients with HIV between 40-75 years old and without known heart disease. The study is important since individuals living with HIV are 50-100% more likely to develop heart disease than people without HIV.

Another ongoing study, The Respiratory Virus Hospitalization Study (FLU 003), an international observational study, aims to better characterize the manifestations and complications of influenza. It includes adults hospitalized with influenza and other flu-like illness. Since it began eight years ago Baystate has enrolled over 130 individuals. Participants must be 18 years or older and have been admitted to the hospital for influenza or a targeted non-influenza viral respiratory infection.

Other ongoing studies are a study of novel 2 drug regimen for treatment of HIV (GEMINI), a study of novel 3 drug combination treatment for HIV (Gilead-1489) and the Cooperative Re-Engagement Controlled Trial (CoRECT, sponsored by the CDC), which seeks to improve outcomes for HIV-infected individuals who are not in care.

The research team includes Dr. Armando Paez, Dr. Durane Walker, and Caroline Hinestroza (regulatory specialist), Mary Lee Bertrand, RN (study coordinator), Victoria Cobb (study coordinator), and Maribella Gonzalez (research assistant). They are located at 3300 Main Street, which is also the location of the main ID clinic.

“It’s exciting and gratifying to be able to play a role in bringing new treatments to our patients,” concludes Dr. Skiest.

For questions and more information about these and other ID trials, call (413) 794-5376.
The Common Rule is a framework for federally funded research studies in the United States that ensures ethical standards and protects human participants in clinical research. As of January 20, 2019, the Common Rule implemented new changes for the first time since its inception. This long-overdue change is much-needed, considering the scientific and technological advancements since the early 1990s. Any project already approved under previous rule prior to January 2019 will remain as such.

Changes to the Common Rule as of January 2019 include:
- Revised, comprehensive consent forms
- Fewer details required annually for smaller, less-risky studies
- Any multi-site studies will be housed under a single IRB (January 2020)

Although the Common Rule changes are finally implemented, direction is still needed.

“How we go about handling the changes in Common Rule will be tricky,” explains Jennifer Pacheco, Director of Healthcare Research Compliance and Chief Research Compliance Officer at Baystate Health. “There is no federal guidance or ‘rule book’ yet and that is the biggest challenge. Until we are issued the federal guidelines document, we are unsure if our interpretation will be the same as other institutions.” Since there is more documentation and precision in the new rule, it doesn’t reduce the administrative burden as hoped. Fortunately, the Common Rule will continue to change, with a new minimum revision period of every four years. This will introduce more frequent opportunities for growth and development of the rules already in place.

“This means that our research community needs to be open to change from time to time,” adds Pacheco. Overall, Pacheco supports the majority of the changes. She suggests keeping an ear open for various educational series presented by the Baystate IRB/HRPP throughout the year. If you’d like to learn more about the IRB/HRPP, visit baystatehealth.org/education-research/research/for-researchers.

Jennifer Pacheco, MPH, CIM, CIP

Research & Education Celebration

May 15, 2019 • 8 AM - 6 PM • Chestnut Conference Center

WORKSHOPS:
- Visualizing Complexity In Medical Training & Care
- Research Mentorship For Faculty: A Panel Discussion
- One Scholarly Approach, Many Educational Innovations
- Qualitative Data Analysis 101
- Generating Rigorous Qualitative Insights
- Strategies For Writing Up Your Educational Innovations: A Workshop To Get You Started
- Research On The Cheap
- Building Sustainability In Times Of Uncertainty
- How To Be An Efficient Site Investigator

POSTER VIEWING/SESSION • AWARD CEREMONY

FEATURED PRESENTER:
Kori LaDonna, PhD
Department of Innovation in Medical Education, University of Ottawa

For more information/full schedule call 413-794-3391 or visit baystatehealth.org/REC

The Innovator travels to Orlando

Carolanne Lovewell, RLATG, CPIA, Director of the Baystate Research Facility and Pioneer Valley Life Sciences Institute, takes a break to read the last issue of The Innovator with Minnie Mouse during a recent trip to Walt Disney World.

We are interested in ensuring that Baystate employees and patients (and their families) are aware of the important research that goes on at Baystate and how it contributes to better patient care. The Innovator welcomes feedback and story ideas. Contact Allison Litera at allison.litera@baystatehealth.org to submit yours.