Center for Discovery & Innovation

Member of Hackensack Meridian *Health*

PROFILE OF THE CDI TRANSLATIONAL MODEL

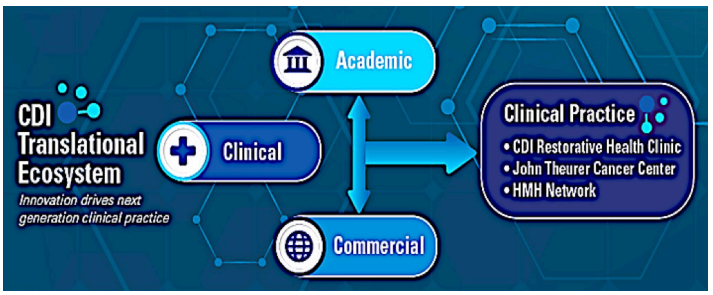
Real-time Translational Science amid COVID-19, and beyond

The Center for Discovery & Innovation (CDI) was established as an academic-based translational research institute embedded in New Jersey's largest healthcare network, **Hackensack Meridian *Health***, to deliver innovations in science to patients in real time. Mere months after its May 2019 founding, COVID-19 swept the globe. Even before SARS-CoV-2 arrived in the New York-New Jersey Metropolitan Area, the scientists at CDI were already anticipating and addressing critical clinical needs. Over three years of the pandemic, CDI scientists contributed major innovations for the clinic involving novel diagnostics, therapy, and surveillance to meet the unprecedented pressures brought by the deadly virus. In addition, CDI also supported Pfizer by providing training, space, and equipment to their COVID-19 vaccine development.

Accomplishments in Responding to the COVID Pandemic

- **PCR Diagnostics**
- **Surveillance**
- **Convalescent Plasma Therapy**
- **Next-gen Antivirals**

CDI's highly successful enterprise model transcends the ordinary by making science innovation actionable for patients in real-time. This approach in which 'clinical need drives our science' embodies the epitome of modern impactful translational research. Founded in 2019 with a mission to confront clinical challenges head-on, CDI has **revolutionized the speed of discovery**, not only for Hackensack Meridian *Health* but beyond. Breaking down traditional silos between laboratories and the clinical setting, CDI swiftly responded to the global viral pandemic, unveiling a **bold visionary approach fueled by expertise, world-class facilities/ technologies, creative collaborations with key stakeholders, and transformative academic-commercial partnerships**. This 21st-century model of scientific enterprise embraces change and challenge, earning the attention and admiration of many. Beyond COVID-19, CDI stands **ready to combat future pandemics, infectious diseases, a myriad of cancer types, and even preemptive cancer prevention**. With a mission to reshape our world today, CDI has already demonstrated its mettle amidst the crucible of COVID-19 and aims to touch countless more lives in the present.



CDI aims to be **Disruptive; Bold; Relevant and Responsive** to address unmet medical needs by effectively engaging the unique capabilities of academic science to create public-private partnerships with clinicians and industry to accelerate innovation and drive clinical solutions within a common discovery ecosystem.

CDI Translational Ecosystem accelerates science application for patients by developing tests, treatments, and preventions for unmet clinical needs. This involves CDI scientific teams collaborating with experienced medical professionals and researching specific diseases in-depth, in order to introduce more effective mechanisms for improving clinical outcomes and thereby alter or redefine existing standards of care. CDI translational-science model is driven by a combination of incentive-based systems that have improved patient outcomes as a key metric. It is agile and dynamic to rapidly address novel challenges. The principal outcome is disease intervention and/or prevention, often resulting in a change in standard-of-care, which may involve development of a **marketable drug, vaccine or diagnostic**.

A few of the key CDI successes since its founding, a growing list:

COVID

PCR Diagnostics – CDI developed one of the first PCR tests for the virus in the first days of the pandemic, which was approved by the FDA under its Emergency Use Authorization. This rapid, highly-sensitive test shortened the time for results from 8 to 10 days, down to just two hours. It enabled hospital emergency departments to quickly triage and help severely-ill patients – and thereby save lives. CDI test has been used to diagnose tens of thousands of patients in New Jersey, and it has been used more broadly following licensing to T2 diagnostics to diagnose millions of patients across the country.

Therapy – Early in the pandemic, at a time of nearly no proven therapies, CDI offered hope to patients with a novel high-titer convalescent plasma therapy. CDI scientists partnered with clinicians from John Theurer Cancer Center (JTCC), to transplant antibodies from the blood of survivors into severely-ill patients to help them fight off the virus. This approach using ultra high-titer serum from virus infected survivors containing huge amounts of neutralizing antibodies, was nearly 90% effective in preventing

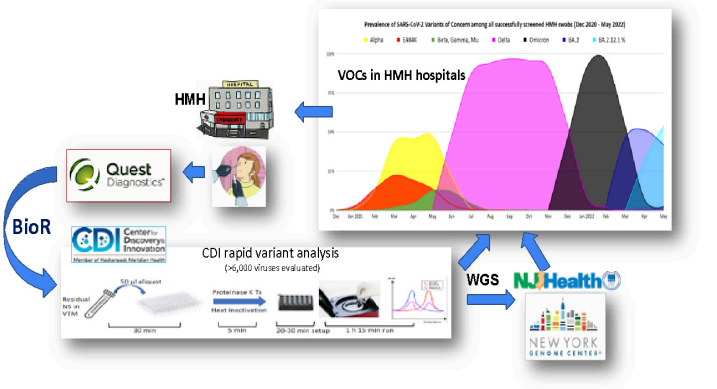
patients from progressing to more severe disease, especially when used early. This program was profiled by The New York Times and 60 Minutes in 2020.

Surveillance – As SARS-CoV-2 evolved and virus variants of concern started emerging in Fall 2020, CDI identified the need to develop a diagnostic test that was high-throughput, rapid, and cost effective to detect virus variants of concern (VOCs). The novel platform allowed scientists to detect numerous VOCs including alpha, delta, omicron, and omicron sub-variants. The information provided partner clinicians with a real-time handle on the types of viruses patients would be presenting to emergency departments to help them make better informed treatment choices. By partnering with multiple public and private groups including Quest Diagnostics, the New Jersey Department of Health and the New York Genome Center, CDI provided comprehensive information about viruses of concern and trends across our State involving the evaluation of nearly 20,000 viruses.

Pharma Partnerships – Commercial partnerships are a key ingredient in CDI's ability to deliver science innovation to the clinic. CDI scientists are engaged in discovery and early-stage development of diagnostics, therapeutics, vaccines and other interventions. But it is the partnerships with Pharma, Biotech, Diagnostics and Device manufacturers that bring them to life in a sustainable way in the clinic.

CDI used its experience to support and partner with major pharmaceutical companies in the COVID-19 time of need. CDI's expertise in working with neutralizing antibody titers and virus

Highly Integrated Partnerships for Real-Time Clinical Impact



under biological safety level 3 (BSL-3) conditions to support Pfizer's accelerated evaluation of patient sera from initial clinical trials of their COVID-19 vaccine, which was performed in our BSL-3 labs. CDI trained more than 50 Pfizer scientists to work under containment. CDI also worked with Merck to help discover next generation antiviral drugs targeting SARS-CoV-2 and other coronaviruses, including the first FDA approved drug Molnupiravir, forming the basis for the Metropolitan Antiviral Drug Accelerator (MAVDA, see more below). CDI has also worked with Regeneron to examine host genetic factors in patients who developed severe COVID-19 in the absence of any known risk factors. Finally, CDI partnered with Quest Diagnostics to evaluate T-cell responses and antibody formation following vaccination in cancer patients.

Accelerating Next-gen Antivirals – CDI received a $108 million fedveral grant to create the **Metropolitan Antiviral Drug Accelerator (MAVDA)** in May 2022, as one of nine national antiviral centers of excellence funded by the National Institutes of Health (NIH)/ National Institute of Allergy and Infectious Diseases (NIAID) under the Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Concern. AViDD research centers target SARS-CoV-2 and other viruses with pandemic potential. The MAVDA program engages world-class virologists and academic drug discovery experts, as well as industry professionals centered largely in New Jersey and New York City to develop small molecule drugs suitable for outpatient use against SARS-CoV-2, and other coronaviruses and viruses of pandemic potential. Led by CDI CSO and Dr. David Perlin along with Nobel Laureate Dr. Charles Rice from Rockefeller University, the MAVDA is a true public-private partnership involving five academic centers: CDI, Rockefeller, Columbia, MSKCC, University of California San Diego and Rutgers and three commercial partners: Merck, Aligos and the Tri-I TDI/Takeda.

MAVDA
METROPOLITAN ANTI-VIRAL DRUG ACCELERATOR

BEYOND THE PANDEMIC

CDI was able to act swiftly in response to the pandemic, largely due to its expertise in infectious disease and singular focus on developing rapid solutions for unmet clinical needs. Our remarkable infrastructure, strategic partnerships with academic and commercial organizations, and the adaptive leadership of our institute enabled us to generate real-time clinical solutions at an unprecedented speed. Beyond this success at a time of critical need, our research and expertise extends far beyond this to include Cancer, Immunology,

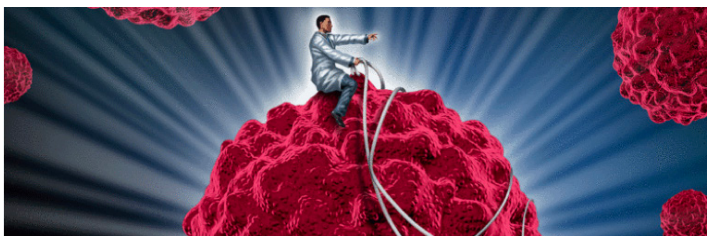
and Behavioral Sciences - areas where our scientists have made significant translational advances.

Finding New Drugs: Center of Excellence in Translational Research – CDI **Center of Excellence in Translational Research (CETR)** was established with a $33 million grant from NIH/NIAID to discover new drugs against high-threat bacterial pathogens led by PI/PD Dr. David Perlin. This CETR is an enterprise-style Center composed of world-class academic and biopharma investigators with innovative and well-established drug discovery platforms focused on clinically validated and novel targets, promising leads, and innovative approaches for new compound discovery. Public-private partnerships with industry ensure that promising drug candidates advance to clinical trials. The program has resulted in 4 drug classes in preclinical development against Mycobacterium tuberculosis, non-tuberculous Mycobacteria, and Neisseria gonorrhoeae. Related grant programs have also resulted in highly promising compounds in preclinical development that target deadly infections due to Acinetobacter.

NIH National Institute of Allergy and Infectious Diseases

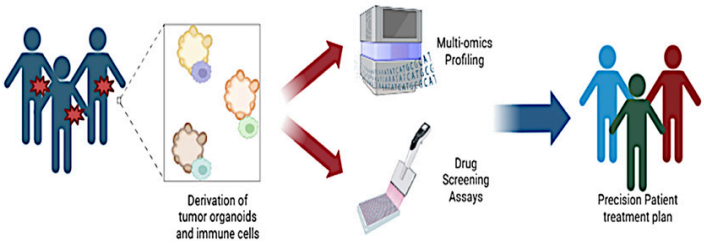
New Company – EValuate Diagnostics – The first spin-out company based on CDI science has taken shape, with the aim of creating tests which will establish a new "threshold of detection" for cancer and other diseases. EValuate Diagnostics will market a new system for the efficient capture of extracellular vesicles (EVs), including exosomes, which have been elusive to medicine thus far. Novel diagnostic assays derived from this technology will help select and identify disease biomarkers for earlier-than-ever detection of cancer and a wide range of other diseases and appear to have great promise in better diagnosing metastatic cancers.

eValuate DIAGNOSTICS



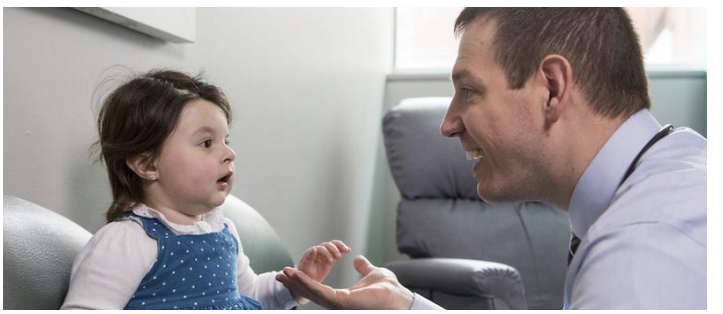
Harnessing the Immune System to Fight Cancer – The Institute for Immunologic Intervention (I3) at CDI investigates T cell development in the thymus and T cell immune responses in peripheral tissues. The program's mission is to improve the knowledge of T cell development, infection immunity, autoimmune inflammation, tumor immunity and alloimmunity. CDI program aims at translating this knowledge for next-generation approaches to improve the efficacy of cancer immunotherapy especially those involving CAR-T cell, other cellular and cytokine therapies, and development of better vaccines, and preventions.

Precision Medicine Initiative for Colorectal Cancer Treatment – Working in partnership, the laboratories of Kevin Tong and Binfeng Lu at CDI are pioneering a breakthrough in treating a particularly difficult cancer: colorectal cancer. The Tong Lab is cultivating organoids from patient-derived cancer cells, in order to test different drugs and uncover the stage and variety of the cancer. Meanwhile, the Lu Lab is applying its immunology expertise to discover the most effective approach to halting the tumor cells. The ultimate aim is to move laboratory successes to the bedside as quickly and safely as possible, bringing much needed relief to those suffering from this cancer.



Cancer Prevention and Precision Control Institute – The Cancer Prevention Precision Control Institute (CPPCI) was recently established at CDI with the goal of developing a world-class population science program of scientists, clinicians, and key stakeholders in the community to connect science to practice to reduce cancer-related disparities in New Jersey and beyond. The CPPCI connects science to practice with a tripartite mission focused on reducing disparities, improving patient outcomes through improved patient-clinician communication leveraging novel digital and social media outreach tools, and community-engaged participatory research methods. Among their goals: to leverage opportunities for community engagement in the greater New Jersey area to improve patient outcomes through cross-cutting cancer prevention and control-focused research; and to increase the 'precision' of cancer prevention and control through tailored interventions as opposed to a 'one size fits all' approach.

Detection and Treatment of Rare Pediatric Brain Tumors – The Pediatric Neuro-oncology Laboratory at the Joseph M. Sanzari Children's Hospital at Hackensack University Medical Center is making a huge difference in the lives of young people. Through a partnership with CDI and clinical experts in the Hackensack Meridian *Health* network, Dr. Claire Carter and Dr. Derek Hanson, the Section Chief of Pediatric Neuro-oncology, are leading New Jersey's first translational research program dedicated to finding cures for children with deadly brain tumors. In particular, the team is among the foremost experts in a rare pediatric tumor known as embryonal tumor with multilayer rosettes (ETMR). As a result, they are contacted by the families of patients from all over the world in search of help and hope. With the support of the Tackle Kids Cancer Foundation, these experts are striving to improve the lives of children everywhere.



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111 Ideation Way, Nutley NJ 07110 ■ 201-880-3100 ■ HMH-CDI.org

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