East Lancashire Prostate Cancer Support Group Newsletter

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What's Inside

VA Research works with industry, other partners to launch COVID-19 clinical trials

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VA Office of Research and Development

"Together, VA and industry can rapidly generate desperately needed knowledge for the prevention and treatment of COVID-19."

As the COVID-19 pandemic unfolded across the country, VA was invited to take part in a clinical trial of remdesivir, a promising but not yet FDA-approved treatment for COVID-19. Within a record-setting four days, on March 18, the first VA site in the trial, Palo Alto, was approved to start enrolling Veterans hospitalized with the illness.

"This was a huge milestone for VA research—we cut start-up time for collaborative research from months to days," says Dr. Molly Klote, a retired Army Medical Corps colonel who now runs the Office of Research Policy, Protections, and Education, part of VA's Office of Research and Development (ORD).

The multisite trial is sponsored by the National Institute of Allergy and Infectious Diseases. That agency is led by Dr. Anthony Fauci, now a household name for his role in the White House response to the pandemic.

NIAID had contracted with a commercial institutional review board (IRB) to oversee the study. VA had to jump through extra regulatory hoops to join in the arrangement, but Klote's dedicated team made it happen quickly—and made history in the process.

"This was the first

time a VA research program was able to rely on a commercial IRB for the required ethical review," notes Klote. No small feat, considering VA started doing multisite clinical trials in the 1940s.

Importantly, adds Klote, VA's ability to now use commercial IRBs when needed "positions us to be a much more viable research partner for industry."

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Two additional VA sites, Denver and New Orleans, have since joined the NIAID remdesivir trial.

Remdesivir trial among several COVID-19 studies in VA

The trial is one of several focused on COVID-19 that VA medical centers are now involved in, and more trials are in the works.

"VA research is embedded in the largest integrated health care system in the country," says Dr. Rachel Ramoni, VA's chief research and development officer. "We're in a position to do things that no one else in the world can do to improve the health of our Veterans, the country, and the world."

Since assuming her role in 2017, Ramoni has made it a top priority to increase Veterans' access to clinical trials.

With the advent of the COVID-19 pandemic, her office convened a response team that huddles daily to identify and advance research opportunities for VA investigators nationwide. They work closely with a steering committee of VA experts in virology, infectious disease, and epidemiology. That group has been doing expedited reviews of incoming ideas and proposals from VA investigators to identify the most viable and promising studies to fund.

The ORD response team is particularly focused on linking with the pharmaceutical industry. That happens through legal arrangements known as "cooperative research and development agreements." The agreements have been used for years to allow VA to partner with companies to test promising drugs or medical devices with Veteran study volunteers.

Now these public-private contracts are especially crucial. Drug companies with promising vaccines or treatments for COVID-19 need to urgently get their products into clinical trials. "Together, VA and industry can rapidly generate desperately needed knowledge for the prevention and treatment of COVID-19," says Ramoni.

New landscape for clinical trials between VA, industry

In past years, regulatory hurdles were more cumbersome—in some cases, prohibitive. Many companies were deterred from partnering with VA to test new treatments.

Under Ramoni's leadership, that landscape has shifted. There's been a concerted effort since 2018, in the framework of an initiative that ORD calls Access to Clinical Trials (ACT) for Veterans, to educate potential partners—from industry as well as the federal sector—and break down barriers to collaboration.

VA is now a far more attractive partner for industry. The organization has a nationwide cadre of experienced investigators, a clinical trial infrastructure that is tested and ready to move quickly, and a large pool of potentially eligible Veterans study participants.

"We want to become the partner of choice for industry," says Ramoni.

That's true for COVID-19 and for other conditions, like cancer.

Ramoni points out that in the past, the average time it took to start up an industry-sponsored trial in VA was 285 days, nearly 10 months. In comparison, academic medical cen-

ters were doing it in around five months. Her office has committed to cut the VA average to about six months by October 2021, "to even the playing field."

VA RESEARCH
TOPIC PAGES

Infectious diseases

That's all during normal times. During the COVID-19 pandemic, as noted above, VA is finding ways to slash the time frame more dramatically.

"A lot of what we've been working on is rolling out more standardized, streamlined approaches," says Ramoni.

About a decade before it became required under 2018 federal regulations, VA implemented a central IRB to review studies for human subjects protection. That move set the stage for many of the innovations that were to follow, in terms of creating a smooth, efficient infrastructure for clinical trials involving multiple VA medical centers across the country. The central IRB solves the problem of multisite trials having to rely on multiple local IRBs, each with its own way of doing things. In the old days, that could add weeks and months to trial start-ups.

The VA central IRB currently services more than 250 multisite clinical trials in VA. Most are funded directly by VA, but many are funded by industry.

"The system ensures standardized forms and processes across all VA medical centers, so that if you want to start up a study at 10 different sites, you don't have to fill out 10 different sets of forms," says Ramoni.

More recently, in 2019, VA instituted an enterprise-wide software system to provide a common platform for all VA research sites to manage trials. The pandemic has slowed but not stopped the roll-out of the system nationwide.

Fostering trial start-ups at multiple VA sites

As the country continues to cope with COVID-19, Ramoni envisions companies partnering with VA to quickly stand up their trials at numerous VA medical centers at once—at least five or so at a time.

"It takes virtually the same time to set up a trial for 20 sites as for one site," she notes.

The nationwide scale of VA, which in the past has been part of the difficulty in organizing large trials, can be a huge research asset nowadays, given the newer infrastructure, she says.

As of May 7, VA was reporting more than 10,000 cumulative VA COVID-19 cases (active cases, plus convalescent cases and known deaths). Veterans enrolled in VA care tend to be older, often with several chronic medical conditions. This puts them at higher risk for developing severe illness from the virus.

In collaboration with other VA offices, Ramoni's team has been monitoring patient locations and diagnosis trends to strategically select sites most appropriate for clinical trials. As the pandemic moves through the U.S., the team plots VA cases and research efforts on a heat map to provide a visual overview of the rapidly changing situation.

Her office has set up a dedicated email address for COVID-19 research, and pharmaceutical and biotechnology companies can use it to make contact and learn how to partner with VA on trials, either for COVID-19 or other conditions: ordcovid19@va.gov.

To learn more about VA research in general, visit www.research.va.gov.

BREAKING NEWS: FDA Approves Rucaparib For Treatment of Advanced Prostate Cancer (PCF 15th May 20)

Today we are thrilled to announce that the U.S. Food and Drug Administration (FDA) approved rucaparib, a new medication to treat some patients with advanced prostate cancer. PCF science is proud to have been involved since the beginning, in every stage of the research that lead to this development. This is a historical first, in what PCF hopes will be a long line of personalized medicines for prostate cancer.

As with most FDA approvals, the journey from idea to approval is long and thorough. In 2015, the PCF-SU2C International Prostate Cancer Dream Team published a landmark study demonstrating that about a third of mCRPC (metastatic castration-resistant prostate cancer) cases have mutations in certain genes, including about 13% of prostate cancer patients with a BRCA2 mutation in their tumor. This study was momentous, providing the motivation to test PARP inhibitors such as rucaparib in prostate cancers.

The PCF Dream Team's findings (73 researchers in all) ignited a race among pharmaceutical companies to develop precision medications for prostate cancer. The PCF Team quickly initiated a Phase II clinical trial of a similar drug called olaparib, which demonstrated anti-tumor activity in mCRPC patients with DDR (DNA Damage Repair) gene alterations.

Rucaparib is one of a class of drugs called PARP inhibitors and is already FDA-approved for the treatment of other cancers, including ovarian cancer. This is the first approval for a PARP inhibitor in the treatment of prostate cancer. It represents a groundbreaking advance in the care of patients with advanced disease, for whom solutions are urgently needed. One of the benefits of rucaparib is that it has fewer side effects than chemotherapy. This drug, a pill taken by mouth, is approved for patients whose prostate cancer has spread outside of the prostate and has developed resistance to hormone therapy and who also have specific genetic changes.

What is PARP and why is it such an important target for prostate cancer? Early data that PARP could be the key to finding treatments for prostate cancer came from a PCF-funded team led by Dr. Karen Knudsen of Thomas Jefferson University. Dr. Knudsen's team proved that PARP is a driver of prostate cancer and that PARP inhibitors can suppress prostate tumor growth and progression. When DNA (your genetic code) is damaged and not repaired properly, a cell may become cancer. The genes called BRCA1 and BRCA2, which first became well-known for breast and ovarian cancer by Angelina Jolie's public campaign, are also important in prostate cancer. Rucaparib exploits a lethal vulnerability in tumors with mutations in these genes, essentially eliminating prostate cancer's ability to survive.

Today's approval of rucaparib is based on results from a phase 2 clinical trial led by PCF Young Investigator Dr. Wassim Abida of Memorial Sloan Kettering Cancer Center, which was presented at the 2019 European Society of Medical Oncology (ESMO) Congress.

"This is a leap forward in helping men with mCRPC." says PCF CEO Dr. Jonathan Simons. "PCF is proud to have funded the patient genomics research that catapulted rucaparib into global clinical trials. This kind of DNA-driven precision medicine is the future of treatment and brings us one step closer to our mission to eliminate all death and suffering from prostate cancer"

PSA Self Testing Kit Now Available

Hi everybody, I had a phone call from Graham Fulford the other day about the self testing.

Trials have almost been completed and have been 100% accurate. The intention now is to 'go live' beginning of June.

The cost to the men will be £12, - & £13 if they would like the Free to Total test. Results are expected to be back to them within 3 days. (electronically)

Graham has asked if any group members would be interested in having a FREE test, as they just want to finalise the technology side of it.

He is offering up to 4 men from each Support Group the opportunity and he will require names and addresses etc. ASAP this week.

I will contact you all during the next couple of days.

Graham is confident that this will become the norm in future. I feel this will greatly reduce the need for

testing events as we know them, although I think that there may still be opportunities at certain places such as workplaces etc where they are subsidised by the business and other charity events.

We can meet about it soon, in the meantime let me have the names etc if you require a FREE testing kit.

Stu

From Left to Right Hazel Goulding (Treasurer) Leon D Wright (IT Admin) Stuart Marshall (Secretary) Steve Laird (Vice Chairman) Dave Riley (Chairman)

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We are a group of local people who know about prostate cancer. We are a friendly organisation dedicated to offering support to men who have had or who are experiencing the effects of this potentially life threatening disease.

The East Lanc's Prostate Cancer Support Group offers a place for free exchange of information and help for local men and their supporters (family and friends) who may be affected by this increasingly common form of male cancer.

At each meeting we strive to be a happy, supportive and upbeat group of people; encouraging open discussion on what can be a very difficult and perhaps for some an embarrassing subject. We have lively, informative, interactive, sharing and above all supportive meetings.

Prostate Cancer Foudation (Download Guide)

You can access the PDF version of the guide here.

https://res.cloudinary.com/pcf/image/upload/v1576856971/Patient-Guide_Interactive_Q4update_Final_12.19.19_1_s1kkoa.pdf

Latest Incontinence Treatment

(Courtesy of our Illustrious Chairman Dave)