Informed Prostate Cancer Support Group Inc.
"A 501 C 3 CORPORATION ID # 54-2141691"

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JUNE 2023 NEWSLETTER

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Next Meeting Saturday, June 17, 20, 2023 IPCSG—10:00am PT.

- **Bernadette M. Greenwood** Chief Research Officer at HALO Diagnostics will be presenting the history, updates and results of the **focal therapy clinical trial** NCT 02243033 that she and her team have been conducting. She will be joined by Dr. Aaron Harman, who will share some real-life scenarios as case studies. **Decipher** (Veracyte Labs SD) will also be on-hand to provide information and answers regarding tissue-based genomics.
- As always, spouses/partners and caregivers are welcome and encouraged to attend!
- *After the meeting a light lunch will be served in the foyer outside the meeting room*
- **For links to further Reading: https://ipcsg.blogspot.com/ (includes member suggested links)**
- **If you have Comments, Ideas or Questions,** email Newsletter@ipcsg.org
- **For more information, please send email to bill@ipcsg.org or call Bill at (619) 591-8670 or Gene at (619) 890-8447**

May 2023 Informed Prostate Cancer Support Group Meeting
Summary by Bill Lewis

Provenge Immunotherapy and Sparrow Search Introduction

Provenge Immunotherapy is a personalized immunotherapy developed by Dendreon, that activates the immune system to help fight advanced prostate cancer and has been proven to help certain men live longer. It works differently from other cancer treatments, such as chemotherapy or hormone therapy.

Dr. Jim Hsiang is a Radiation Oncologist at the Corpus Christi Urology Group & Cancer Center. He has a special interest in prostate cancer and heads the Advanced Prostate Cancer Clinic. He spoke about managing prostate cancer and treatment options available, including Provenge, which was FDA approved as a treatment for metastatic castration-resistant prostate cancer (mCRPC) in 2010. Then "Tom" gave a firsthand account of a patient's experience living with prostate cancer and receiving Provenge therapy.

The Provenge therapy is accomplished by first separating out immune system cells from the patient's blood (It's a ~3 hour procedure called leukapheresis and is done at the local Red Cross. If a patient – like

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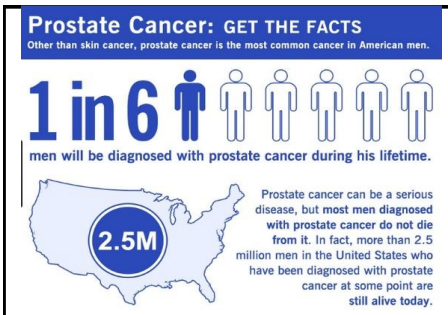

Organization

a 501c3 non-profit organization - all positions are performed gratis

IPCSG

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NEWSLETTER
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PROSTATE CANCER—*2 WORDS, NOT A SENTENCE*

What We Are About

Our Group offers the complete spectrum of information on prevention and treatment. We provide a forum where you can get all your questions answered in one place by men that have lived through the experience. Prostate cancer is very personal. Our goal is to make you more aware of your options before you begin a treatment that has serious side effects that were not properly explained. Impotence, incontinence, and a high rate of recurrence are very common side effects and may be for life. Men who are newly diagnosed with PCa are often overwhelmed by the frightening magnitude of their condition. Networking with our members will help identify what options are best suited for your life style.

Join the IPCSG TEAM

If you consider the IPCSG to be valuable in your cancer journey, realize that we need people to step up and HELP. Call **President** Bill Lewis @ (619) 591-8670 "bill@prostatecancerhelp.info"; or **Director** Gene Van Vleet @ 619-890-8447.

From the Editor

In this issue:

Bill Lewis produced a summary of the talks last meeting. For further articles see the blog at https://ipcsg.blogspot.com/ .To follow up on last months meeting, we've focused on clinical trials:

1. Leal Health provides a patient facing web site to aid in finding clinical trials.
2. UC San Diego Health rebuts claim that patient safety is 'at risk' at Moores Cancer Center—shake-up in Clinical Trial administration.

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this writer -- has poorly accessible veins in the arms, a central venous catheter may be placed in the upper chest.). These cells are sent to Dendreon in Costa Mesa, where they are activated to seek and destroy prostate cancer cells. On return after 3 days, the activated cells are infused back into the patient at his doctor's office, over 1-3 hours. The process is repeated twice more after two-week intervals. Leukapheresis has minimal side effects, but the re-infusions gave temporary chills / severe fatigue and diarrhea to this writer – especially the second cycle. Other common side effects are temporary headaches and fever. See the video or internet for less common side effects.

After Provenge treatment, stained photomicrographs show more infiltration of (activated) T cells into the tumor, compared to control samples. So, it is believed that these activated T cells from the patient's own blood are suppressing the cancer and prolonging life.

However, the gold standard for tracking prostate cancer progression and regression, the PSA test, does not drop as might be hoped for, after Provenge treatment. There has been no scientific explanation for this lack of a PSA decline. However, Xofigo (radium-223) infusions apparently also have little or no effect on PSA.

The three "E's" of cancer are escape (from treatment, leading to poor survival), elimination (the best outcome), and equilibrium – where the cancer is kept in check, and becomes a chronic but not life-shortening disease. Provenge apparently falls into the equilibrium category. Recently introduced therapies, including Zytiga (abiraterone), Xtandi (enzalutamide), Orgovyx (relugolix) and Nubeqa (darolutamide) have also helped men with this equilibrium.

Initial data from the IMPACT trial (512 men) that led to FDA approval showed a 4.1 month survival benefit (beyond the 22 months average survival for the control group). [This writer finds that unimpressive, and said so in speaking to the group in October – but mistakenly referred to a "4-<u>year</u> benefit" as not worth paying for. The procedure is expensive. Dendreon bills $100K for each of the three procedures, and Medicare pays a little over $150,000 for the total protocol. Despite the initial unimpressive survival results, about 40,000 men have received Provenge treatment since its FDA approval.]

However, more encouraging data have been forthcoming. A subgroup analysis of the IMPACT study showed that patients who had a low PSA at the start of treatment did better. In contrast to (very ill) patients who had a PSA greater than 134 at the start of treatment, and nevertheless obtained a 2.8 month survival benefit, patients with a PSA less than 22 survived 13 months longer on average than the control group.

[Besides PSA, cancer progression is always tracked using various scans (Technetium-99 or MRI or PSMA), but no data was presented on delay of progression based on scans or on patient symptoms.]

A later study of 2000 men, but without a control group, called PROCEED, showed that men with a PSA less than 5.27 lived almost 48 months after Provenge treatment. [This at first seems impressive, but this is actual survival, not improved survival vs non-Provenge patients -- who were undoubtably getting better cancer-suppressing drugs and treatments than those available in and before 2010 to the men in the IMPACT study control group who died after about 22 months on average. In contrast to these men who had low PSA's at the start of Provenge treatment, those with a PSA greater than 46 died on average within about 18 months – despite typically receiving other advanced drugs/treatments in addition to Provenge.]

[As summarized on https://www.cancerabcs.org/advanced-prostate-cancer-blog/2019/9/10/xafmagoimtpg0q4f1rw1a0ygny40qg, "Furthermore, PROCEED spanned a period of unprecedented progress in mCRPC management as 4 life-extending therapies became available: abiraterone acetate, enzalutamide, cabazitaxel, and radium 223. Thus, in PROCEED, the median OS (30.7 months) likely, in part, re-

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flects use of these life-prolonging drugs with sipuleucel-T in contrast to the IMPACT (median OS, 25.8 months1) era, in addition to the use of sipuleucel-T (Provenge) in patients with lower PSA levels." Emphasis added.]

Six thousand Medicare beneficiaries were retrospectively studied in 2020 by Dr. Rana Mckay and colleagues, comparing men who had Provenge plus ASPI's (androgen-receptor signaling pathway inhibitors, i.e., Zytiga or Xtandi) to those who only received the ASPI's. Adding Provenge therapy gave a 14.5 month survival benefit. No info on PSA levels was included, so this was presumably "all-comers," and definitely supports the value of Provenge immunotherapy.]

Going back to the PROCEED registry, there was a surprisingly greater survival benefit for African-American men vs. PSA-matched Caucasian men. For those in each (Provenge-treated) group with a PSA less than 30, the African-American men out-survived the Caucasians, living on average 54.3 months vs. 33.4.

Funding for the therapy is often available through third-party charitable organizations. Check with your doctor's office, as they may be able to help find funds. Otherwise, contact this writer.

In Summary, Provenge is customized immune therapy based on the patient's own immune cells. The greatest benefit is obtained if the PSA is low at the start of therapy. It does not lower the patient's PSA! But it's still working, to extend survival. [Based on the overall data picture, this writer chose to get the therapy in February 2023, and his formerly rising PSA has remained stable for three months so far. Recommended therapy for those who qualify.]

Sparrow Search is a patient-friendly search engine that allows prostate cancer patients to directly search for and match to clinical trials. Patients who match to clinical trials are connected by Sparrow Search with clinical research sites, thereby increasing the pool of potential study candidates and expediting the recruitment process. The software uses artificial intelligence and natural language processing. Teresa Gallagher and David Kriegman (sparrowsearch.health) gave a demonstration of the search engine, which can be viewed and interacted with at https://clinicaltrial-stage.bitcotapps.com/

The site is still under development, so not all features are active yet, but we at ipcsg.org felt it important to let our attendees and viewers know about this important upcoming tool. We will announce in a future meeting and newsletter when the site is ready for full use.

For the video of this May 2023 meeting, see https://www.youtube.com/watch?v=sdTdVWRqT8c Note that you can skip directly to the talks (Sparrow Search Engine - 12:06 and Dr. Hsiang - 1:04:30) using links in the information section under the video.

DVD's of IPCSG meetings are no longer being made. See the talk online on your own device, or on that of a friend or relative, or elsewhere.

Special Webinar Notice

PLEASE REGISTER for NASPCC's upcoming **Webinar this coming Thursday, June 15 at 7:00 pm Eastern, to be presented by Dr. Neeraj Agarwal of the Huntsman Institute. The Webinar is entitled "CLINICAL TRIALS IN PROSTATE CANCER USING PARP INHIBITORS"**. The webinar is free and will consist of 45 minutes of presentation, and 15 minutes of Q&A.

Register on our website, at https://www.naspcc.org/index.php/naspcc-webinar-series

Items of Interest

Focus on Clinical Trials

Medical oncology clinical trials find candidate patients in a variety of ways. Some of the most common methods include:

- **Direct patient recruitment:** This is when researchers or clinical trial staff contact patients who may be eligible for a trial. This can be done through letters, phone calls, or in-person visits.
- **Patient registries:** These are databases that collect information about patients with specific diseases. Researchers can search these databases to find patients who meet the eligibility criteria for a clinical trial.
- **Hospital and clinic referrals:** Physicians can refer patients to clinical trials that they believe may be beneficial.
- **Public awareness campaigns:** These campaigns are designed to educate the public about clinical trials and to encourage people to consider participating.

Once a patient has been identified as a potential candidate for a clinical trial, they will be screened to determine if they meet the eligibility criteria. If they do, they will be invited to meet with the study team to discuss the trial in more detail. During this meeting, the patient will be able to ask questions and learn more about the risks and benefits of participating in the trial.

It is important to note that not all patients who are eligible for a clinical trial will choose to participate. Some patients may be hesitant to participate because of the risks involved, while others may not be able to afford the travel and/or lodging expenses associated with participating in a trial.

However, for those patients who do choose to participate in a clinical trial, the potential benefits can be great. Clinical trials offer the opportunity to receive new and innovative treatments that may not be available through standard medical care. Additionally, participating in a clinical trial can help to advance the understanding of cancer and to develop new and improved treatments for future patients.

If you are interested in learning more about clinical trials, you can talk to your doctor or visit the following websites:

- **ClinicalTrials.gov:** This website is a searchable database of clinical trials that are being conducted around the world.
- **National Cancer Institute (NCI):** The NCI has a website that provides information about clinical trials for cancer patients.
- **American Cancer Society (ACS):** The ACS has a website that provides information about clinical trials for cancer patients.

there are several companies that assist in conducting the match of cancer patients with clinical trials. Some of these companies use artificial intelligence (AI) to help identify patients who are eligible for trials and to connect them with researchers.

Here are a few examples of companies that use AI to match cancer patients with clinical trials:

- **Mendel.ai:** Mendel.ai is a clinical trial matching platform that uses AI to scan patient medical records and identify trials that may be a good fit. The company's platform is used by oncologists and other healthcare providers to help patients find trials that could improve their chances of survival.

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- **MyTomorrows:** MyTomorrows is a patient-facing platform that allows patients to search for clinical trials that are a good fit for them. The company's platform also provides patients with information about clinical trials, including eligibility criteria, study details, and side effects. MyTomorrows has been used by over 1 million patients to find clinical trials.
- **Leal Health (formerly TrialJectory):** Leal Health (https://www.leal.health/) is a clinical trial matching platform that uses AI to connect patients with trials that are a good fit for them. The company's platform is used by patients, clinicians, and researchers to find and participate in clinical trials. Leal Health has matched over 50,000 patients with clinical trials.

These are just a few examples of the efforts by companies and organizations to match patients with clinical trials. As AI technology continues to evolve, it is likely that more companies and organizations will develop similar services. Here are some of the benefits of these efforts:

- **Increased efficiency:** These platforms can help to streamline the process of identifying and enrolling patients in clinical trials. This can free up time for researchers and clinicians to focus on other aspects of their work.
- **Improved accuracy:** These platforms can help to ensure that patients who are eligible for clinical trials are actually enrolled in them. This can help to improve the chances of success for clinical trials and to make new treatments available to more patients.
- **Increased patient access:** These platforms can help to make clinical trials more accessible to patients who live in rural areas or who have limited access to healthcare. This can help to ensure that all patients have the opportunity to benefit from new treatments.

Here are some of the challenges that these platforms face:

- **Data privacy:** These platforms must be careful to protect the privacy of patient data.
- **Accuracy:** These platforms must be accurate in order to ensure that patients who are eligible for clinical trials are actually enrolled in them.
- **Cost:** Developing and maintaining these platforms can be expensive.

Despite these challenges, these platforms are a promising new technology that has the potential to improve the efficiency and accuracy of clinical trial recruitment and to make new treatments available to more patients.

*Your editor accessed the **Leal Health** website, and found it to be easy to use, and to provide useful results.*

A video of the founder is online at https://www.youtube.com/watch?v=lFil06bCA8k&t=54s

They provided a useful toolkit for selection of the right treatment: https://www.trialjectory.com/wp-content/uploads/2020/01/5_steps_finding_treatment.pdf

They provided a printout of 1 trial which fit my background in the San Diego area. NCT05288166 A Study of targeted treatment (Abemaciclib) with Abiraterone in men with Prostate Cancer that has spread to other parts of the body and is expected to respond to hormonal treatment (Metastatic Hormone-Sensitive Prostate Cancer) (CYCLONE 3). Email this list to your physician, or print it and take it with you to your next appointment. Tell your doctors that you've been matched with and are interested in a clinical trial andthat their input would be appreciated. Update the missing information for the trial you're interested in. Your doctor will be glad to help you with this.

Contact trial site by clicking on "Contact the trial oncologist" under trial details

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UC San Diego Health rebuts claim that patient safety is 'at risk' at Moores Cancer Center

Paul Sisson sandiegouniontribune.com

UC San Diego Health leaders are pushing back against a recent article in an influential oncology publication that makes dire statements about the viability and safety of Moores Cancer Center.

Published in The Cancer Letter, a weekly digital publication that details industry news nationwide, the piece says that patient safety and clinical trials at Moores are "at risk" due to ongoing difficulties in the organization's clinical trials office.

One of 54 designated comprehensive cancer centers in the nation, Moores earned its designation in 1978, meeting rigorous requirements to prove that it is capable of broad and deep research in addition to quality patient care.

Citing the recent decision by Dr. Joseph Califano III to leave his job as the center's director as soon as a replacement can be found after just six months on the job, and the recent departure of other key leaders, the piece makes the case — quoting unnamed sources and leaked documents — that Moores' entire portfolio of more than 200 clinical trials should be suspended and that "they are risking patient safety by not doing so."

The university objected most strongly to any suggestion of possible patient harm and the notion, expressed in the piece's headline, that Moore's designation as a comprehensive cancer center "is in trouble."

"I take exception to the innuendo that there has been any patient harm from clinical trials or that our comprehensive cancer center status is in jeopardy," said Dr. John M. Carethers, vice chancellor for health services at UCSD.

All human research programs in the United States are required to have institutional review boards (IRB) to make sure that patient rights are protected and to collect reports of "adverse events" for investigation if something goes wrong while trials are underway.

Carethers, who has been on the job for about five months, said he examined two years of adverse event reports made to UCSD's IRB by cancer trials and found no spike in overall numbers.

"The number of events you can essentially count on one hand, and most of these things are not serious, someone didn't document something on time, that sort of thing," Carethers said. "And, has there been corrective action from the (institutional review board) when these events are reported?

"Absolutely, there has."

Audits of the clinical trials office by the university's compliance office and by the U.S. Food and Drug Administration, he said, have identified no problems with adverse event reporting in the program.

Moores, as the Cancer Letter report notes, has recently enjoyed a positive reputation in the industry, receiving "its best-ever score of 20, which placed it in the 'outstanding' range" in its most recent government support grant renewal review. Scores in U.S. News and World Report cancer care assessments have also climbed "from No. 45 to the top 20 over the past two years."

Comprehensive Cancer Centers such as Moores are also required to maintain external advisory boards made up of cancer experts not affiliated with the university.

The Cancer Letter report indicates that Moores' advisory board has weighed in, stating that the program's clinical trials organization, "In addition to having no permanent leader, is starved for resources and

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is in such profound disarray that, according to an outside consultant and the (external advisory board), it poses a danger to patients."

Dr. Eric Small, a cancer researcher at UC San Francisco and a member of the Moores advisory board, said in an email that the full panel responded to the writeup with a letter, signed by all members, indicating that "we are not aware of any incident at (Moores Cancer Center) in which patient safety was affected and that UCSD and MCC leadership have our full vote of confidence."

Paul Goldberg, editor and publisher of The Cancer Letter and the author of the piece, said in an email Thursday that he stands by his work. He said readers are going further on the patient harm angle than he did in the text.

"At no point do I — or anyone I quote — state that harm to patients has occurred," Goldberg said. "Discussion is focused on the *risk* of harm and the safeguards against it."

A significant part of the Cancer Letter writeup focuses on a report from a consultant which reportedly found problems with the functioning of clinical trials at Moores, recommending a revamp of the office. Provided to Goldberg by an unnamed source, the university is not releasing the document, calling it an unfinished draft. Carethers did not refute the assertion that the clinical trials infrastructure at Moores needs some attention.

"We've had high turnover of individuals that help run the clinical trials, and we have had some changes in leadership, there's no doubt about that," he said.

Another factor reportedly listed in the consultant's report is an overall decrease in the number and type of **cancer clinical trials** offered to patients. Here, too, Carethers said that work is underway to increase the number of trials and also the percentage that involve novel locally generated research.

According to the National Cancer Institute, Moores received $5.2 million in cancer center support grant funding during the 2021 fiscal year. But that level of annual support, on top of funding for specific research projects, comes with expectations. Centers are expected to engage not just in drug trials on behalf of the pharmaceutical industry, but also in "investigator initiated trials" that test novel new ideas dreamed up by a center's resident researchers.

A criticism mentioned in the Cancer Letter report, and one that was reportedly highlighted in the consultant report, is that the ratio of novel trials to industry trials has skewed too far away from new investigation. Carethers said he agrees with that assessment.

"In my view, we have to help support the investigator-initiated side, because that's where the NCI designation and renewal of grants come in," Carethers said. "We've already been doing a lot of things to try to reverse those ratios, putting money more into the clinical trials office."

One key change that is already under way, he added, is installing a new clinical trials management system that directly interfaces with the university's electronic health records system.

As to why Dr. Joseph Califano decided to leave Moores so shortly after taking the job as its director, the head and neck cancer researcher said in an email Thursday that he is stepping down "so I can devote my time and efforts to care of patients with head and neck cancer, directing a laboratory focused on head and neck cancer research."

He said he intends to continue doing that work at Moores.

Dr. Ezra Cohen is among those Moores researchers who have recently moved on.

A well-known cancer researcher, Cohen had a prominent leadership role in Moores' clinical trials hierarchy and recently announced that he has accepted a job at Tempus, a Chicago-based company using artificial intelligence to personalize clinical care.

Echoing others' statements that he is unaware of any instance of patient harm at Moores, Cohen said that he believes the organization can fix the issues that have surfaced.

"There are certainly issues, but they are all things that can be fixed, and I'm fully confident that UCSD will succeed," Cohen said.

On The Lighter Side
Celebrate July 4th

If the Trojan horse were delivered today

"I'll double check, but I'm pretty sure that hole shouldn't be there."

"High sodium, high cholesterol, lots of toxins - your blood test is remarkably similar to a potato chip."

DON'T CALL YOURSELF A GAMER IF YOU HAVEN'T PLAYED "PROSTATE EXAMINATION SIMULATOR 4"

NETWORKING

Please help us in our outreach efforts. Our speakers bureau consisting of Gene Van Vleet and Bill Lewis is available to speak to organizations of which you might be a member. Contact Gene 619-890-8447 or gene@ipcsg.org or Bill 619-591-8670 (bill@prostatecancerhelp.info) to coordinate.

Member John Tassi is the webmaster of our website and welcomes any suggestions to make our website simple and easy to navigate. Check out the Personal Experiences page and send us your story. Go to: https://ipcsg.org/personal-experience

FINANCES

We want to thank those of you who have made special donations to IPCSG. Remember that your gifts are tax deductible because we are a 501(c)(3) non-profit organization.

We again are reminding our members and friends to consider giving a large financial contribution to the IPCSG. This can include estate giving as well as giving in memory of a loved one. You can also have a distribution from your IRA made to our account. We need your support. We will, in turn, make contributions from our group to Prostate Cancer researchers and other groups as appropriate for a non-profit organization. Our group ID number is 54-2141691. Corporate donors are welcome!

DIRECTIONS TO MEETINGS

Directions to Sanford-Burnham-Prebys Auditorium
10905 Road to the Cure,
San Diego, CA 92121

- Take I-5 (north or south) to the Genesee exit (west).
- Follow Genesee up the hill, staying right.
- Genesee rounds right onto North Torrey Pines Road.
- **Do not turn into the Sanford-Burnham-Prebys Medical Discovery Institute or Fishman Auditorium**
- Turn right on Science Park Road. Watch for our sign here.
- Turn Left on Torreyana Road. Watch for our sign here.
- Turn Right on Road to the Cure (formerly Altman Row). Watch for our sign here.