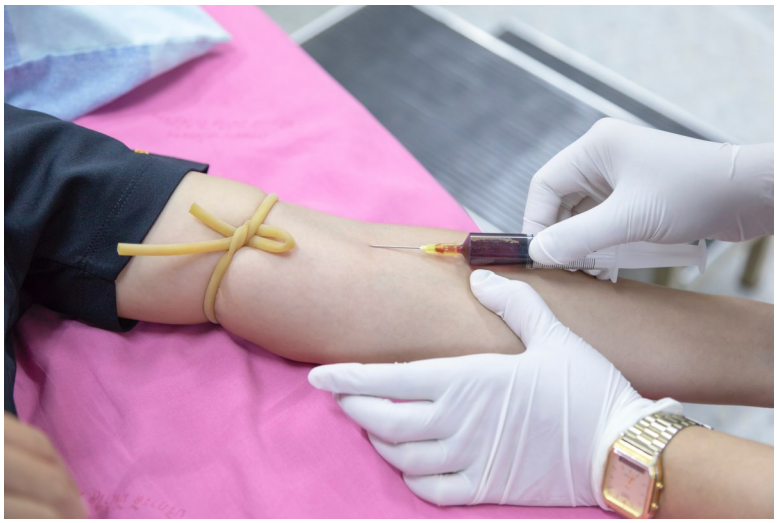
DHRHealth Institute for Research & Development
To Discover · To Innovate · To Excel

March 2020

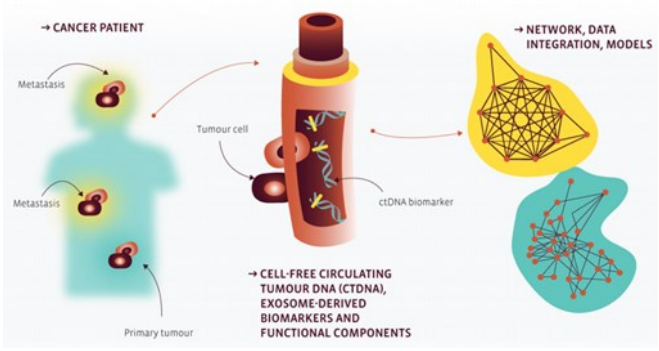
The Research Spectator



Are Liquid Biopsies As Accurate As Tissue Biopsies in Diagnosing Cancers?

Prospective Longitudinal Study in Patients with Solid Organ Tumors

The prevalence of various types of cancers in the Rio Grande Valley community is proportionally higher than the national average. The existing techniques to diagnose cancers in solid organs invariably involves tissue biopsy with its attended consequences. It is therefore imperative to find a less invasive technique to accurately diagnose cancers, determine their prognosis, and to create models for predicating relapse in individual patient. Given the fact that there are circulating tumor-specific cell-free DNA, exosome biomarkers, and functional components in the peripheral blood of cancer patients, investigators have taken advantage of this observation and are creating new and innovative techniques to identify cancer-specific biomarkers in the blood – a process known as LIQUID BIOPSIES. If successful, liquid biopsies will replace the more invasive techniques and would provide additional and much needed tools for the physicians in managing the clinical care of their patients. "This technique can provide real-time information regarding patient staging and the molecular profile of the tumor to be used for mutation-targeted drug therapy. Of added benefit is the fact that liquid biopsies can be repeated with the desired frequency for close monitoring of progress and treatment", said Sohail Rao, MD, MA, DPhil., President and Chief Executive Officer, DHR Health Institute for Research and Development. **CONTINUED ON PG. 3**



ARCADIA – A New Clinical Trial to Evaluate the Role of Blood-Thinning Drugs in the Prevention of Cryptogenic Stroke

Stroke is a leading cause of death in the United States and is a particularly prevalent problem in the Rio Grande Valley. In one-third of the cases, the cause of stroke cannot be determined – CRYPTOGENIC STROKE. Recent studies have suggested that in some patients, cryptogenic stroke maybe caused by a blot clot that originated in the heart that is not recognized due to absence of atrial fibrillation. However, there is also evidence that blood clots can occur in patients with atrial cardiomyopathy in the absence of atrial fibrillation.

Since blood thinning drugs, such as *apixiban* has already shown to be more effective than *aspirin*, one could argue that they would also be more therapeutic than aspirin in stroke prevention in patients with cryptogenic stroke.

ARCADIA– Atrial Cardiopathy and Antithrombotic Drugs in Prevention After Cryptogenic Stroke is a clinical trial comparing apixiban vs. aspirin in their efficacy in preventing recurrent stroke in patients who have atrial cardiopathy and have had cryptogenic stroke.

This advanced clinical trial will recruit 1100 participants over a course of 30 months at 200 participating sites in the NIH strokeNet Consortium of which, DHR Health Institute for Research and Development is a recognized site.

If you need more information about this study or other innovative state-of-the-art studies conducted at DHR Health Institute for Research and Development please call (956) 362-2390 or visit our website, www.dhrresearch.org.

DHR Health Institute for Research and Development Implements a State-of-the-Art Clinical Trial Management System

Clinical Research or Advance Clinical Care is a highly regulated process that requires stringent maintenance of documentation and compliance with study requirements. The ability of a research entity to engage patients and to ensure compliance with study protocol is critical to the success of any clinical trial.

To manage this rather complex process, DHR Health Institute for Research and Development has gone live with one of the industry leaders in cloud-based Clinical Trial Management System (CTMS) – ***REALTIME***. As an industry standard, RELATIME is the first complete Site Operations Management System that allows clinical research entities and investigators involved in clinical research to bundle every solution needed to manage all aspects of complex Phases I-IV clinical trials.

REALTIME consists of a suite of five robust modules all of which are dedicated to managing the daily operations of a clinical research enterprise including the patients participating in clinical trials. These modules work seamlessly together as an integrated product to streamline operations and eliminate redundancies. This partnership between DHR Health Institute for Research & Development and REALTIME will enhance clinical trial capacity in the Rio Grande Valley allowing us to offer most advanced clinical care to our patients.

A brief overview of various modules of REALTIME that DHR Health Institute for Research & Development has implemented is provided below:

CTMS

Provides rapid access to study participant information with ultimate navigation options allowing easy access to subject or study information, assisting with study startup and all the required tools to manage the study throughout its entire duration.

eSOURCE

Provides clinical trial sites with a tool to streamline the process by which sites collect study data. As a Part II compliant application, this module allows for the creation of custom-built electronic source documents, facilitates utmost compliance with safe and secure cloud hosting and eSignatures.

eDOCS

By creating a paperless environment, this module is essential for sites engaged in clinical trials to maintain timely communication with satellite sites, sponsors and clinical research organizations. It also allows management of regulatory documents electronically, online and mobile eSignatures, and secured central filing. Additionally, it facilitates inspection readiness and remote site auditing.

SitePAY

This module streamlines the payment of stipends to study participants in a secure and paperless environment. Study participants are provided with a PAYcard which can be easily loaded electronically by the study site thus making the funds available instantaneously.

TEXT

This feature takes patient engagement in clinical trials to whole new level. It allows investigators and clinical trial sites to readily communicate (two-way) with participants about their upcoming visits and reminders to maintain daily study regimen. Automated reminders and texts reduce no-show rates, boost retention and enhance patient experience.

To learn more about clinical research studies offered at DHR Health Institute for Research & Development, please visit our website: www.dhrresearch.org or email us at dhrresearch@dhr-rgv.com.

New Master Clinical Trial Agreement With MEDPACE Accelerates Study Startup Process at DHR Health Institute for Research and Development

The DHR Health Institute for Research and Development has executed a Master Clinical Trial Agreement (MCTA) with MEDPACE, Inc. MEDPACE is a full service Contract Research Organization that facilitates clinical trial management on behalf of hundreds of biopharmaceutical and medical device sponsors, nationally and globally. MEDPACE manages a myriad of clinical trials in areas such as Autoimmune Diseases, Cardiovascular, Endocrine and Metabolic, Obesity, Liver Disease, Oncology and many others. With the execution of a MCTA, DHR Health Institute for Research and Development will be able to more readily accelerate the execution of clinical trial-specific agreements, thus allowing for a much more rapid turnaround time to first enrollment of patients in life-saving clinical trials.

Gregg Wendorf, MD
Gastroenterologist

Dr. Gregg Wendorf is a gastroenterologist, and Clinical Research Scientist, Research Academy at DHR Health Institute for Research and Development. Dr. Wendorf received his medical degree from the University of Texas Health Science Center in San Antonio, Texas. He completed his residency training at the University of Louisville in Kentucky, where he also continued his a fellowship in gastroenterology.

Dr. Wendorf is currently an investigator for three clinical trials at DHR Health Institute for Research and Development. These studies are in the area of Non-alcoholic Fatty Liver Disease (NAFLD) and Non-alcoholic Steatohepatisis (NASH).

Research Protocol Amendments

True or False? Once your study has been approved by an Institutional Review Board, you must stick to that protocol no matter what?

False. Study protocols must be followed very strictly. However, if an investigator wants to change any aspect of the study protocol, they have to submit an amendment which must be reviewed and approved by the Institutional Review Board. This does not mean the entire study must be reviewed, just the change in the protocol, especially if it alters the risk/benefit relationship for participants.

Filing an amendment for a protocol consists of submitting an *Amendment Form* which can be found on IRBNet.org. Depending on the type of amendment, you may need to submit revised informed consent forms, waiver of HIPAA authorization, or other documents that reflect the change.

Depending on the nature of the amendment, it can be reviewed administratively, via expedited review, or may require full board review.

Minor amendments to a study may be reviewed administratively or via an expedited review process. Examples of minor amendments include:

- **Additional or removal of study team members**
- **Addition of procedures that do not increase risk to the participants**
- **Addition of non-sensitive survey or interview questions**
- **Editorial changes that clarify but do not alter the existing meaning of the protocol**

Major amendments that may increase the risk or discomfort to the research participants, or that significantly change the study aims or design, would mandate a review by the full board.

Examples of major amendments include:

- **Addition of a new subject population**
- **Addition or removal of a treatment**
- **Updated study documents distributed to participants that includes information that is significantly different to previously approved materials**
- **Escalation of drug dosages**
- **Replacement of Principal Investigator**

For more information about study protocol amendments, contact the Office of Human Research Protection Program at (956) 362-2379 or irb@dhr-rgv.com.

March 2020

Institutional Review Board Meeting
March 25, 2020 | 12:30 PM
DHR Health Institute for Research and Development Collaboration Room | 5323 S. McColl Road, Edinburg, TX

CONTINUED FROM PG. 1— **Are Liquid Biopsies As Accurate As Tissue Biopsies in Diagnosing Cancers?**

DHR Health Institute for Research and Development is involved in numerous funded studies aimed at identifying biomarkers in the blood that would replace the more invasive techniques for the diagnosis of cancers. Working with an external sponsor and in partnership with medical and surgical oncologists at DHR Health, the DHR Health Research Institute for Research and Development is involved in a prospective longitudinal study that will validate this concept in cancer patients. This $1.80 million, five (5)-year long study is designed to employ liquid biopsies to identify biomarkers in the blood of patients suffering from colorectal, ovarian, and prostate cancers. We anticipate adding other cancers to this abbreviated list in the very near future.

If you need more information about this or any other clinical study currently offered by DHR Health Institute for Research and Development, please visit our website, www.dhrresearch.org or send us an email at dhrresearch@dhr-rgv.com.

Team Spotlight: John Rodriguez

John Rodriguez received his medical degree from the University of Monterrey in 1983. In addition to post-graduate clinical trials, John has been involved various medical specialties performing industry sponsored Phase 1 - 4 clinical trials since 1989.

Since joining the DHR Health Institute for Research and Development in 2014, John has played an integral role in coordinating some of the first clinical trials at the Institute. He coordinated an NIH study called VRC 705, which evaluated the safety and efficacy of a vaccine in preventing disease caused by the Zika virus. Currently, John is involved with a number of the clinical trials at the Institute in the areas of NAFLD, NASH, diabetes, oncology, and cardiology.

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