



Guardian Partners,

With summer coming to a close, we find ourselves facing another surge of COVID 19. We recognize the critical role our Partner research teams have played by working tirelessly to conduct trials and rapidly make vaccines a life-saving reality. The dedication of the staff in working under stressful conditions while maintaining the utmost compliance in study conduct is incredibly admirable.

As this virus continues to put a strain on all healthcare workers, the GRN team has only the highest esteem for the work each of you has been doing and the contributions you have made to fight through some of the most difficult times in the healthcare and research industries.

As always, we'd love to hear your ideas or thoughts during this strenuous time.

Your Feedback/Ideas

<i>Content in This Edition</i>	<i>Read time ~ 8 minutes total</i>
July GRN Studies	< 1 minute, plus chart
In the News	< 1 minute, plus links
Dr. Lee Hicks & Community Research	~ 3 minutes
Friends of Cancer	~ 1 minute
FDA Meetings	< 30 seconds
Partners Book Club	> 1 minute
Kudos & Compliments	< 30 seconds

Enrollment Status: July Studies

Read time < 1 minute

Enrollment status reporting is moving from monthly to quarterly. Based on feedback from many of you, quarterly reporting is sufficient for providing an updated status because the numbers do not change dramatically from month to month. Thank you for providing your thoughtful input.

For this report, a few new studies have been added and completed studies removed.

- **Checkmate Pharmaceuticals** - Recurrent or metastatic HNSCC; TLR9 agonist + pembro.
- **Exact Sciences 2018-01**- Newly diagnosed solid tumors; liquid Bx: Closed on 7/31/2021.
- **Freenome FRNM-004** - Patients due for routine CRC screening; liquid Bx.
- **Razor ENCORE** - Stage I/IIa NSCLC identified as high/intermediate-risk by Razor's assay; examining whether 4 cycles of adjuvant chemo impacts DFS and OS.
- **Exact Sciences ASCEND 2** - Newly diagnosed solid tumors, liquid Bx and non-cancer patients.
- **VastBiome PARADIGM** – Blood and stool study of gut microbiome while on immune checkpoint inhibitors for 4 cancer types.

Please reach out to your GRN contact should you have any questions on the following. ♦

* All data as of July. 1, 2021

FPI = First patient enrolled

Site	ENROLLING STUDIES					
	Checkmate Pharmaceuticals	Exact Sciences 2018-01	Freenome FRNM-004	Razor ENCORE	Exact Sciences ASCEND 2	VastBiome PARADIGM
	Enrollment	Enrollment	Enrollment	Consented	Enrollment	Enrollment
Baptist Corbin					FPI ~Aug 2021	FPI ~Sep 2021
Baptist Floyd					FPI ~Aug 2021	FPI ~Sep 2021
Baptist Hardin					FPI ~Aug 2021	FPI ~Sep 2021
Baptist Lexington		50		3	FPI ~Aug 2021	
Baptist Louisville		47		4	FPI ~Aug 2021	FPI ~Sep 2021
Baptist Madisonville					FPI ~Aug 2021	
Baptist Paducah		32		0	FPI ~Aug 2021	FPI ~Sep 2021
Bon Secours Greenville	1	57		1		
Mercy Ft. Smith		22			FPI ~Aug 2021	
Mercy Joplin		72		1	FPI ~Aug 2021	
Mercy OKC		41		2	FPI ~Aug 2021	
Mercy South				1	FPI ~Aug 2021	
Mercy Springfield		48			FPI ~Aug 2021	
Mercy St. Louis		48		1	FPI ~Aug 2021	
Mercy Washington			59			
Spartanburg					FPI ~Aug 2021	FPI ~Sep 2021
External partners managed by GRN						10 sites to be activated Sept/Oct 2021
TOTALS	1	417	59	14		

IN THE NEWS

Our Sponsors and Partners are Making News!

Read time < 1 minute, plus links

Two GRN partner health systems were in the July 2021 edition of [ONCOLOGY ISSUES](#), a publication for members of the Association of Community Cancer Centers.

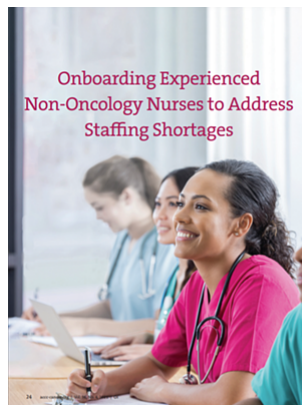
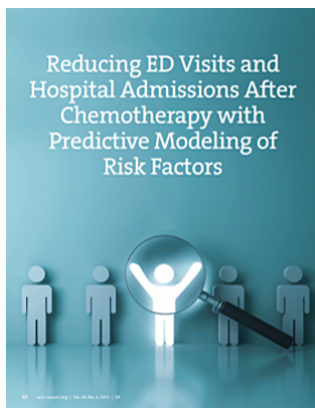
- [Mercy Cancer Care: Receives ACCC Innovator Award](#)

The ACCC Innovator Award was conveyed to Mercy Cancer Care, St. Louis, MO, for [Reducing ED Visits and Hospital Admissions after Chemotherapy with Predictive Modeling of Risk Factors](#). Co-authored by Jay Carlson, DO (GRN Board member) and Michelle Smith, DC, they developed a predictive algorithm to identify patients at risk for an emergency department visit or inpatient admission based on review of more than 100,000 chemotherapy encounters.

- [Miami Cancer Institute won an ACCC Innovator Award for its Transactional Oncology Nursing Academy](#). This successful program has a 97% graduation rate, with 100% of graduates earning their ONS/ONCC Chemotherapy Immunotherapy Certification. Today these graduates make up 13% of the institute's workforce.

[Grail reports positive study results on early detection of 50 cancers assay](#)

At ASCO 2021, GRAIL announced the debut of a multi-cancer early detection (MCED) test called Galleri™. Able to detect more than 50 types of cancers through a simple blood draw, Galleri is intended to complement U.S. guideline-recommended cancer screenings. [GRN's involvement in the study](#) included identifying nearly 20% of patients for enrollment from just 7% of the study's active trial sites.



PHYSICIAN SPOTLIGHT:

Baptist's Dr. Lee Hicks on the Power of Community Research

Read time ~ 3 minutes

If you've heard the idiom about the definition of crazy (repeating the same unsuccessful process and expecting successful results), then you know how Lee Hicks, MD, feels about the standard of care for cancer patients. He refers to it as the current "sub-standard of care," because there is no cure yet for cancer, and the only way to find cures is through clinical trials that bring about discovery.

"There's no way to do proper cancer care without cancer research," shared this Director of Medical Oncology & Infusion Services at [Baptist Health, Lexington](#) (KY). "If we are not curing people and not doing anything to change that standard of care, we are regularly failing patients. In my mind, practicing oncology without research is unethical and immoral," he stressed. "Thankfully, Baptist understood this moral imperative early in my career and is now benefiting from it, both in funding and reputation."

While Hicks admits research may not be efficiency-producing for physicians in the short term, he profoundly believes research is well worth it in the long run—both for patients and providers.

"I have a pancreatic cancer patient whose entire history of therapy has been researched at Baptist, starting with Gemcitabine, a current standard of care established by research I participated in 20 years ago," he noted.

"The patient's subsequent therapies have included liposomal abraxane and FGFR mutation-directed therapy, both studied here in clinical trials. He also had aggressive surgical intervention for removal of minimal residual liver metastases. Currently, he is still alive 5 years out and disease-free. That's a great example of the benefit of cancer clinical research," he claimed.

Worth it in many ways

For doctors who perceive the inefficiency or lack of clinical support to outweigh the need for research, Dr. Hicks' goal is to get them to realize the effort still has merit. "Clinical research not only offers treatment options for patients, but it also builds the physician collegiality needed to leverage insights driven by molecular biology and precision medicine-directed treatments," he added.

In many community hospitals, oncologists are expected to know everything about all cancers, which of course is impossible. "It used to be that we lumped cancers into broad pathologic categories. Today, it is imperative to know the molecular basis of the cancer. As more nuanced treatments come into play, you need to have many minds, more people thinking and knowing about different care options," he explained.

From his perspective, participating in research offers access to early molecularly-directed clinical trials. "Being involved makes physicians more research-alert. As community researchers help direct and conduct research, and connect with other researchers, local oncologists stay at the forefront of current and upcoming cancer treatment options. Being a community clinical cancer researcher simply makes for a more complete clinician," he affirmed.

Convincing patients to participate

As a local hospital, research brings prominence not only to the health system, but options to patient treatment that can impact quality and length of life. "Without community clinical cancer research, patients, by necessity, often have to travel farther for research opportunities. This introduces inconvenience and complexity of care, along with bias, into the trial results. Patients healthy enough to travel long distances do not realistically represent the average cancer patient whose infirmity would preclude travel and make them ineligible for a trial. The results, therefore, may not be generalizable to the average community care patient," he asserted.

The biggest challenge now is convincing patients to participate in trials, according to Hicks. "Patients willing to travel for research are already research aware. You don't have to sell them on the benefit of research," he expounded. "However, with the community cancer program, patients are not necessarily aware of or motivated toward cancer trials.

"When a patient comes into our facility, it takes more time to build a vision of the need for research. A 15-minute office visit is a difficult place to start a 45-minute discussion of research. Yet, everyone should be made aware of the opportunity, if not the obligation," he continued.

Not just universities anymore

In addition to the challenge of building the patients' vision, there are others to be concerned with too. "We have to get hospitals, insurance companies, and drug companies onboard with community clinical cancer research. Research is no longer the purview of universities alone. Baptist Health System is now building a multi-city community-based [clinical cancer research program](#) available to all oncologists and their patients throughout the state, whether they are within the Baptist system or not," Hicks acknowledged.

"Now that there is less need to convince patients," he said, "the task moves to convincing busy oncology providers to take the time to participate in cancer clinical research." It is Dr. Hicks' hope that through the success of cancer research, one day there will be no such need. ♦

Medical Director,
Medical Oncology & Infusion Services,
Baptist Health, Lexington



Baptist is now growing its multi-state community-based research network with multiple campuses, a centralized IRB, and access to multiple clinical trials for a range of cancers. It also touts association with molecular-based researchers as well as cooperative group studies including a network partnership with Guardian Research Network (GRN). ♦

<https://8654888.hubspotpreview-na1.com/hcms/preview/content/52607607960?portalId=8654888&preview=true&cacheBust=1629984683212&prev...> 5/8

policy, and regulation that speed life-saving treatments to patients.

Resources can be found on multiple science and policy topics, including:

>



- Breakthrough Therapies
- Data-Driven Insights
- Clinical Trials
- Cell Therapies
- Drug Labeling
- ctNDA
- HRD Harmonization
- Tumor Mutational Burden (TMB)
- COVID-19 and much more

For more information watch this brief [video](#) or visit www.friendsofcancerresearch.org/. ♦

FDA and Guardian Research Network

Read time > 30 seconds

On June 29, 2021, the Guardian Research Network participated in a web conference with members of the [FDA's Oncology Center of Excellence](#) regarding the use of EMR data in the development and regulation of oncology products for patients with cancer.

The 16-person panel included FDA regulatory staff, medical officers, research fellows, clinical reviewers, practicing oncologists, and statisticians. The FDA expressed interest in several areas of GRN expertise including EMR data heterogeneity, data harmonization, and socio-economic equity.

GRN looks forward to an ongoing dialogue with the FDA regarding innovative uses of curated medical record data from the Guardian Program® to dramatically improve patient outcomes and reduce nationwide health disparities. ♦



Partner Book Club

Read time > 1 minute

With each newsletter edition, we'll bring you a new book from one of our GRN employees or from one of you. Take a look at this month's read.

Shirley's Pick:

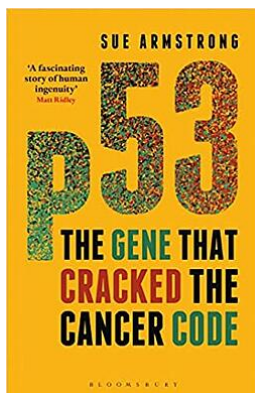
p53: THE GENE THAT CRACKED THE CANCER CODE

By Sue Armstrong

August's book recommendation is the story of the search for p53—the most important gene in medicine. It is brought to you by Shirley Trainor-Thomas, vice president, Network Partners, GRN.

"This book is written in laymen's terms in a story format, following personal accounts of researchers searching for cancer cures. It is a "genomics for dummies" kind of book. Still scientific, but easier to follow than a textbook."

— Shirley Trainor-Thomas



From Amazon:

"All of us have lurking in our DNA a most remarkable gene: it is known simply as p53 and its job is to protect us from cancer. [This book] tells the story of the discovery of the gene and of medical science's mission to unravel its mysteries and get to the heart of what happens in our cells when they turn cancerous. ... Not surprisingly, p53 is the most studied single gene in history."

"Through the personal accounts of key researchers, the book reveals the excitement of the hunt for new cures—the hype, the enthusiasm, the lost opportunities, the blind alleys, and the thrilling breakthroughs. As the long-anticipated revolution in cancer treatment tailored to each individual patient's symptoms starts to take off at last, p53 is at the cutting edge. This is a timely tale of scientific discovery and advances in our understanding of a disease that still affects more than one in three of us at some point in our lives...." ♦

Remember, let us know if you have read a good book lately. We'd love to hear from you.

Share a Good Read

Kudos & Compliments

Read-time ~ 30 seconds

Check out this terrific effort by a Partner staff member. Many are recognized by GRN, trial sponsors and patients for their outstanding work. Let us know if you have someone's effort to share.

Mercy, St. Louis, and study coordinator Jess Blacke showed diligence and dedication to this clinical trial and to her patients' care options.

Jess had two patients who appeared eligible for the ENCORE/RAZOR study. These patients had a narrow window for enrollment. Jess worked diligently communicating with GRN, as well as with the sponsor, to ensure items for enrollment were completed in the timeframe needed. Her efforts and prompt communication with the sponsor allowed for both of these patients to be enrolled into the study in time.

Thank you Jess!

Guardian Research Network, 101 East Wood Street, Spartanburg, South Carolina 29303, 864-777-7165

[Unsubscribe](#) [Manage preferences](#)

Send free email today

HubSpot