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Inside information on cancer research and drug development

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It took the Multiple Myeloma Research Foundation nearly a decade and over $40 million to create what the foundation describes as the largest disease-specific cancer genome dataset in existence.

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MMRF CONTRIBUTES LARGEST DISEASE-SPECIFIC CANCER GENOME DATASET TO NCI'S GENOMIC DATA COMMONS

By Matthew Bin Han Ong

It took the Multiple Myeloma Research Foundation nearly a decade and over $40 million to create what the foundation describes as the largest disease-specific cancer genome dataset in existence.

> "There are 38 other cancers on the GDC site, and multiple myeloma is now the largest by far, given this data contribution."

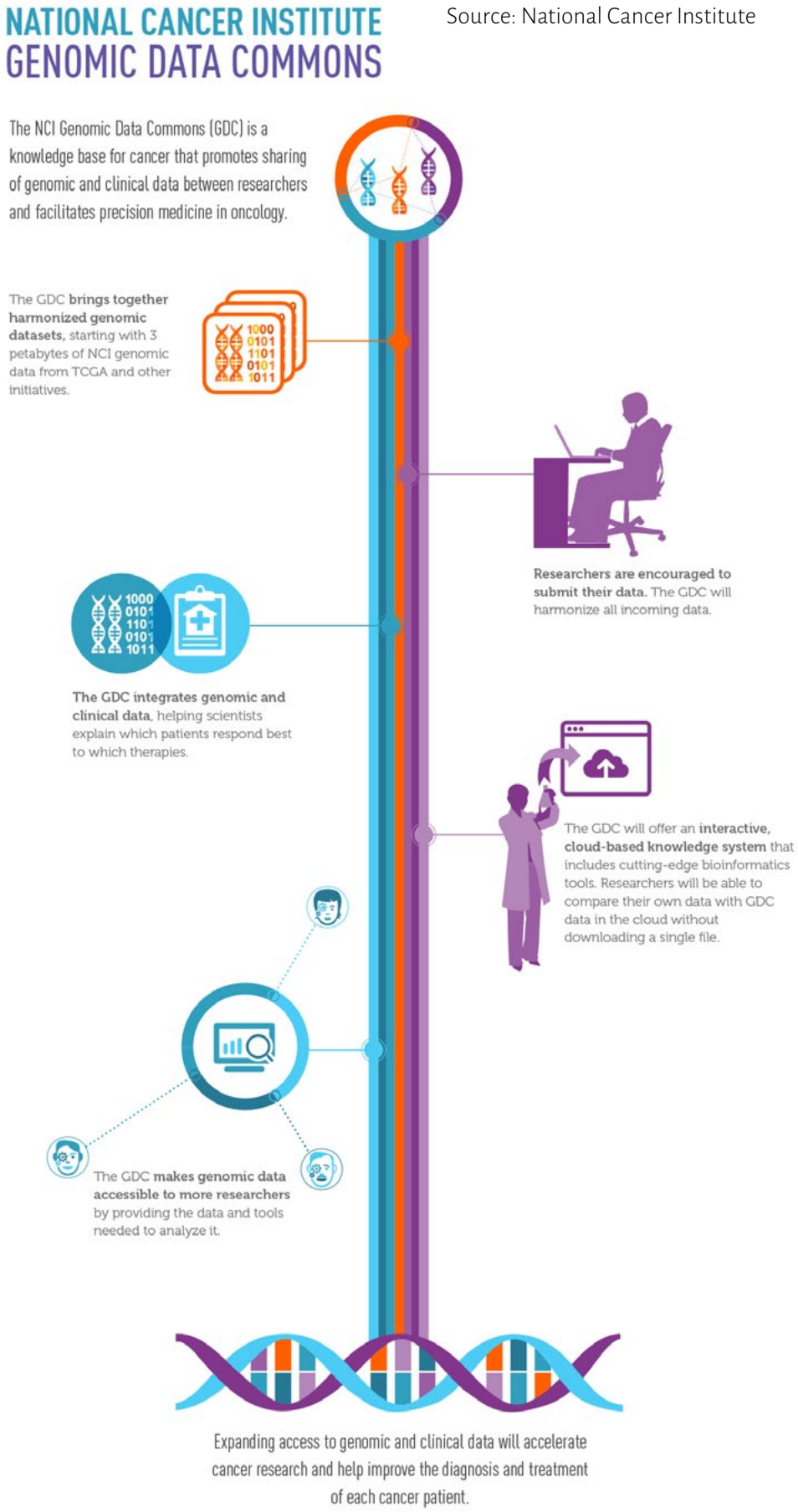
The first installment of the dataset is now posted on NCI's Genomic Data Commons, which places the information in the public domain, making it available to researchers.

When MMRF learned of NCI's efforts to build the central repository of cancer genomic data, the foundation decided that MMRF would become the first nonprofit research foundation to contribute data.

"There are 38 other cancers on the GDC site, and multiple myeloma is now the largest by far, given this data contribution. One of the things we're very proud of is that we are the first research foundation to contribute data to the GDC," Paul Giusti, MMRF president and CEO, said to The Cancer Letter. "Our hope is that this will inspire other nonprofits and research foundations to look at the GDC as a common data aggregation site where we can all place data and be able to provide it to researchers to access."

The MMRF was established in 1998 by twin sisters Kathy Giusti and Karen Andrews, after Kathy was diagnosed with the blood cancer. In the 90s, no treatment had been developed for multiple myeloma in decades, and what was available wasn't very effective.

Kathy ran the MMRF for the first 17 years and created the CoMMpass study, a $40 million longitudinal effort that has conducted full genome sequencing of almost 1,200 multiple myeloma patients at the time of diagnosis. This information is now a part of the GDC.



Source: National Cancer Institute

Since 2003, FDA has approved 10 new multiple myeloma drugs—averaging about one every 18 months.

In 2015 alone, FDA approved four drugs that had received support from MMRF. One of them was **Farydak** (panobinostat), a Novartis agent, and the first histone deacetylases (HDAC) inhibitor approved to treat multiple myeloma.

The other three drugs, approved in a single month—November 2015—are:

- **Darzalex** (daratumumab), sponsored by Janssen Biotech, became the first human anti-CD38 monoclonal antibody approved for multiple myeloma,
- **Empliciti** (elotuzumab), also a monoclonal antibody sponsored by Celgene, and
- **Ninlaro** (ixazomib), a proteasome inhibitor sponsored by Takeda Pharmaceuticals.

"We have always been advocates of getting data into the public domain as quickly as we can," Paul Giusti said. "In our conversation with Lou Staudt [director of the NCI Center for Cancer Genomics], he was very interested in having a nonprofit foundation that has such well-curated data get that into the GDC. We were very excited about working with him to make that happen."

> Data-sharing is essential to advancing cancer research, and I cannot overstate the value of the data that MMRF is providing—not only genomic data, but also full clinical data. Combining genomic and clinical information will create an invaluable resource for all researchers worldwide studying this disease who are working toward new, more effective treatments.

Paul Giusti took over as president and CEO of MMRF in February 2016, when Kathy was appointed chair of the Harvard Business School (HBS) Kraft Precision Medicine Accelerator, a bioinformatics initiative designed to speed medical breakthroughs in precision medicine. It convenes best-in-class leaders to identify and solve challenges slowing the advancement of precision medicine, disseminate best practices and models to overcome these challenges, and, ultimately, enable the faster commercialization of high-impact innovations.

"The MMRF participated in a meeting as part of the Kraft Precision Medicine Accelerator in June where one of the big topics that we talked about was data sharing," Paul Giusti said. "The Kraft Accelerator's goal is to accelerate precision medicine so it certainly helped to move this along."

The MMRF, located in Norwalk, Conn., is contributing patient data from over 1,400 cases to the GDC.

"All of [MMRF data] is in the real world, it isn't just a clinical trial with a couple of arms, and this is why it's so exciting," Paul Giusti said. "The database is very well curated and very well organized, and it's the gold standard of myeloma data."

The GDC is NCI's latest Big Data effort in consolidating its separate cancer databases into one portal that researchers can access to download and study raw genomic data (The Cancer Letter, April 29, 2016).

During its launch, the $20 million initiative received a high-profile endorsement in June 2016, when Vice President Joe Biden called it the "foundational element" in building a knowledge network for cancer and the National Cancer Moonshot Initiative (The Cancer Letter, June 10, 2016).

A month later, Foundation Medicine announced it would contribute 18,000 cases, increasing the GDC's genomic information from 14,500 patients to 32,500 (The Cancer Letter, July 29, 2016).

The GDC is a core component of the Cancer Moonshot and the President's Precision Medicine Initiative, and it benefits from $70 million allocated to NCI to lead efforts in cancer genomics as part of the initiative.

According to NCI, multiple myeloma is the second most common blood cancer, but large amounts of genomic data about this disease and other cancers have not been readily accessible to researchers.

"Data-sharing is essential to advancing cancer research, and I cannot over-

state the value of the data that MMRF is providing—not only genomic data, but also full clinical data," said NCI Acting Director Doug Lowy. "Combining genomic and clinical information will create an invaluable resource for all researchers worldwide studying this disease who are working toward new, more effective treatments."

NCI hopes other disease groups will share their data

MMRF's contribution draws data from its Multiple Myeloma Genomics Initiative and CoMMpass study.

The MMGI, a progressive genome-mapping program, was launched in 2005 to molecularly profile 250 relapsed and refractory patients, with the goal of accelerating targeted therapies for specific subgroups. Through this initiative, whole genome sequencing of the myeloma genome was completed for the first time.

The CoMMpass study, also known as the Relating Clinical Outcomes in Multiple Myeloma to Personal Assessment of Genetic Profile (NCT01454297) study, is a an eight-year study partnership between more than 70 academic and community centers, four pharmaceutical companies, and the Department of Veterans Affairs.

African Americans represent about 18 percent of the patients enrolled CoMMpass, based on an interim analysis. The participation of African Americans in this study is significant, given that multiple myeloma occurs about twice as often in blacks than in whites.

Over the next eight years or longer, patients in CoMMpass will get a repeat biopsy and a new genomic analysis at each six-month checkup or at disease progression. Tumor samples are being collected and analyzed when possible at the time of any relapse. The genomic data from these analyses will be immediately deposited in the GDC, with an anticipated sample size of near 1,000 cases by the spring of 2017. New data will be deposited every six months at a minimum.

CoMMpass is the largest single-disease genomic database in any cancer. Moreover, it has follow-up to track trends and progress, Giusti said.

"Our hope is, someday, that you'll be able to look at their genomic information, their profile, at the point of diagnosis and be predictive about whether they were high risk, whether they're going to be great responders to treatment, and what treatments are they responding best to," Giusti said.

The MMRF contribution to the GDC is noteworthy for its scope and potential to provide new insights into the pathogenesis and treatment of multiple myeloma, said NCI's Staudt.

"The GDC currently has no genomic data from patients with multiple myeloma, so this will dramatically expand the GDC into the realm of lymphoid malignancies," Staudt said The Cancer Letter. "The size of the MMRF dataset is so large that most researchers studying multiple myeloma are unable to analyze the raw data on their own."

The GDC will allow researchers to browse the data and make discoveries within the GDC environment, and then download only the subset of the data that is useful for their research.

"Data from whole genome sequencing, exome sequencing and/or RNA sequencing will be available on over 1,000 patients, which is coupled to comprehensive clinical data regarding disease status at regular intervals and response to therapy, "Staudt said. "We expect that the GDC will facilitate precision medicine approaches to multiple myeloma by enabling discoveries regarding genomic correlates of treatment response or resistance."

The GDC site continues to have many visitors each day, Staudt said, and NCI is getting inquiries about new submissions to the database. Among these are many users who have privileges to view controlled access TCGA and TARGET data.

"The MMRF data donation to the GDC is a remarkable step by a non-profit patient advocacy group to accelerate cancer research," Staudt said. "We hope that this decision by the MMRF will lead other such cancer advocacy groups to share their genomic and clinical data through the GDC."

MMRF will continue to aggregate data and build on the CoMMpass database, Giusti said.

"We need to innovate in clinical trials to speed the process," Giusti said. "This includes work in using minimal residual disease (MRD) as a surrogate endpoint for clinical trial design.

"With 10 new drugs approved by the FDA to treat multiple myeloma in the past 10 years, we need to better understand which drugs in which combinations are most efficacious for each patient."

Giusti: The $40 million multiple myeloma dataset will help predict risk and clinical response

Paul Giusti
President and CEO of MMRF

Q & A

Giusti spoke with Matthew Ong, a reporter with The Cancer Letter.

CONVERSATION WITH THE CANCER LETTER

> Our hope is that this will inspire other nonprofits and research foundations to look at the GDC as a common data aggregation site where we can all place data and be able to provide it to researchers to access.

The world's biggest genomic database on multiple myeloma is being integrated into NCI's Genomic Data Commons.

The data on the second most common blood cancer—with genomic information from about 1,400 patients—was compiled by the Multiple Myeloma Research Foundation through a genome mapping initiative and a $40 million network of clinical trials.

"There are 38 other cancers on the GDC site, and multiple myeloma is now the largest by far, given this data contribution," said Paul Giusti, president and CEO of MMRF. "One of the things we're very proud of is that we are the first research foundation to contribute data to the GDC.

"Our hope is that this will inspire other nonprofits and research foundations to look at the GDC as a common data aggregation site where we can all place data and be able to provide it to researchers to access."

What was the impetus for MMRF to contribute data to the GDC? How did those conversations come about?

Paul Giusti:
It's very much within the mission of the MMRF to place data into the public domain. We feel that by having more researchers, more individuals having access to the data, that the research will be faster, you'll have more people looking at it, it will advance the science more quickly, and we'll get to a cure faster.

So, we have always been advocates of getting data into the public domain as quickly as we can, and we saw this opportunity with the GDC and working with Lou Staudt [director of the NCI Center for Cancer Genomics] as a way that we can demonstrate leadership in that regard.

In our conversation with Lou, he was very interested in having a nonprofit foundation that has such well-curated data get that into the GDC. We were very excited about working with him to make that happen.

Did this involve the Harvard Business School Kraft Precision Medicine Accelerator that Kathy [Giusti] is working on?

PG:
The data transfer was directly between the MMRF and the GDC. However, the MMRF participated in a meeting as part of the Kraft Precision Medicine Accelerator in June where one of the big topics that we talked about was data sharing. The Kraft Accelerator's goal is to accelerate precision medicine so it certainly helped to move this along. Kathy has a long history of working with Lou Staudt, as does Daniel Auclair, who is our senior vice president. The HBS/Kraft effort also did a terrific job in outlining the data landscape.

Since we're talking about data, we're talking about the aggregation, we're talking about analytics, and this acted as a catalyst to move the effort forward.

Kathy is part of the White House Precision Medicine Initiative, and Daniel Auclair monitors this very closely. We certainly have kept abreast with all of this, and we are well attuned to what was going on in the efforts on the GDC.

How many patient cases will the CoMMpass genomic study contribute to GDC, say, by 2020, or when the study has been completed?

PG:
The CoMMpass data increases the amount of data stored in the GDC by 50 percent. We are contributing data from our CoMMpass study as well as our Multiple Myeloma Genomics Initiative (MMGI) that we had instituted a while ago.

There are 38 other cancers on the GDC site, and multiple myeloma is now the largest by far, given this data contribution. One of the things we're very proud of is that we are the first research foundation to contribute data to the GDC. Our hope is that this will inspire other nonprofits and research foundations to look at the GDC as a common data aggregation site where we can all place data and be able to provide it to researchers to access.

It's not only that we are the first, but also that we are the largest, that helped move the needle in regard to the amount of data on the GDC.

What is unique about the data that MMRF will be contributing?

PG:
The reason the CoMMpass data is so valuable is that we took almost 1,200 newly-diagnosed multiple myeloma patients and, before they received treatment, we did full genomic sequencing of those patients. So, we have that initial genomic profile at the time of their diagnosis and before they received any treatment.

Then, these patients are all being followed in a longitudinal study. In other words, we're keeping track of what treatments they are getting, when they are getting those treatments, how they respond to those treatments, and we're doing that for a period of eight years. In the event that a patient progresses and their disease advances, there will be another bone marrow biopsy and another genomic profile done to see what's changed and why that has changed.

First of all, it's hard to do this and it's expensive. This is a more than $40 million effort, so not everybody is doing this and they just can't afford to conduct a study like CoMMpass put the data in the public domain.

What's unique is that it is one of the best-curated databases, it's the largest genomic database in all cancers and it follows these patients all longitudinally for all these years so that you can see trends and progress. Our hope is, someday, that you'll be able to look at their genomic information, their profile, at the point of diagnosis and be predictive about whether they were high risk, whether they're going to be great responders to treatment, and what treatments are they responding best to.

All of this is in the real world, it isn't just a clinical trial with a couple of arms, and this is why it's so exciting. The database is very well curated and very well organized, and it's the gold standard of myeloma data. It helps drive the precision medicine model forward, because we're very proud to have one of the only—or the only—end-to-end precision medicine models in oncology in that we have a data bank, a learning network, and the clinic.

That's where we're able to take data—and CoMMpass is a big part of generating that data—and then look at it in this learning network and do these correlative studies so that we can see whether this looks predictive, whether it works, and then based on that, put together clinical trials that are able to drive new treatments for our patients.

You mentioned that this is a $40 million effort—how did MMRF raise the funds?

PG:
It was a combination: roughly half of it was from our pharmaceutical partners, and half of it was from philanthropists—we went out as the MMRF and raised that money and then our pharma partners contributed half of it in a precompetitive consortium. What that allowed them to do is to get a first look at the data, and before it all went out into the public domain. It was a 50-50 partnership.

What else is MMRF currently working on?

PG:
We're looking at three major initiatives. First, we will continue to advance the precision medicine model by aggregating more data—building on our CoMMpass database. Second, we will use data analytics to better understand that data. In particular, with 10 new drugs approved by the FDA to treat multiple myeloma in the past 10 years, we need to better understand which drugs in which combinations are most efficacious for each patient. Third, we need to innovate in clinical trials to speed the process. This includes work in using minimal residual disease (MRD) as a surrogate endpoint for clinical trial design.

While we have experienced remarkable progress, there is so much more to do. We always keep our patients at the center of everything—answering the questions they're asking, helping them make decisions in their treatment and ultimately finding a cure.

Steve Hahn takes over day to day operations at MD Anderson

By Paul Goldberg

Steve Hahn, a radiation oncologist, was named deputy to the president and chief operating officer at MD Anderson Cancer Center.

The Houston-based institution reported an operating loss of $169.4 million during the first four months of fiscal 2017 (The Cancer Letter, Jan. 27). During the previous fiscal year, the losses were at $267.1 million (The Cancer Letter, Nov. 4, 2016). Last month, the institution shed about 900 staff members (The Cancer Letter, Jan. 6).

In an email to the faculty and staff, MD Anderson President Ronald DePinho, who assumed his position in September 2011, portrayed the decision to place Hahn in charge of day to day operations as his own.

"I'm pleased to announce I have appointed Steve Hahn, M.D., to the senior leadership role of deputy to the president and chief operating officer, effective immediately," DePinho wrote in an email Feb. 3. "As the institution continues to change and grow and my responsibilities have expanded to include greater focus on philanthropy, federal and local policy and global activities, I felt it necessary to appoint a leader to execute on the vision and strategic direction of MD Anderson while overseeing its complex daily operations."

Hahn, who joined MD Anderson in 2014, appears to have earned an excellent reputation with the faculty. He has been a member of MD Anderson's Shared Governance Committee and the Executive Clinical Operations Team Finance Committee.

The Shared Governance Committee, an unusual structure that gives more power to the faculty, was formed in the summer of 2015 pursuant to orders from the UT System Chancellor Bill McRaven in order to improve the faculty morale at the cancer center (The Cancer Letter, Sept. 4, 2015).

Hahn is the division head, department chair, and professor of radiation oncology. He was previously the chair of the Department of Radiation Oncology at the University of Pennsylvania Perelman School of Medicine.

Observers and insiders at MD Anderson and the UT System see Hahn's appointment as a sign of the beginning of change at the institution as it struggles to streamline its operations.

"I am going to be very surprised if Dr. Hahn and Dr. DePinho can co-exist without permanent refereeing by Chancellor McRaven and I cannot imagine Dr. DePinho tolerating that very long," Len Zwelling, a former MD Anderson executive, wrote on his blog.

"Either he will find a new job (Director of the NCI?) or Chancellor McRaven will have to supplant him by force just as Dr. DePinho did to a number of high ranking academic appointees. Ron only responds to power greater than his own."

The DePinho years at MD Anderson have been controversial. Big projects were being started as surveys chronicled the plunging of the faculty morale, and as many of the faculty's stars were decamping for other institutions.

The president's blast email suggests that the powerful troika of MD Anderson's top executives will now be reporting to Hahn.

"In this leadership role, Steve reports directly to me and carries full authority to act on my behalf and in my absence," DePinho wrote. "He is responsible for day-to-day management of MD Anderson, ensuring excellence across all business, clinical and faculty matters. He will serve as the intermediary between Dan Fontaine, executive vice president (EVP) of Administration, Ethan Dmitrovsky, M.D., provost and EVP, and Tom Buchholz, M.D., EVP and physician-in-chief. Steve also will co-chair the institution's Shared Governance Committee, which includes executive leaders, division heads and faculty senate representatives."

The Shared Governance Committee includes all MD Anderson division heads, the chair of the Faculty Senate, as well as the chair-elect, the immediate past chair, and MD Anderson senior executives.

"The single most important issue, in my opinion, is assuring that bidirectional trust flourishes within the MD Anderson family," McRaven wrote in a letter to DePinho at the time. "Toward that end, I believe that a new shared governance structure will be transformative."

"I am pleased to announce..."

From: Dr. Ronald DePinho
Sent: Friday, February 03, 2017 1:40 PM
To: *MD Anderson Employees*
Subject: Leadership Announcement

I'm pleased to announce I have appointed Steve Hahn, M.D., to the senior leadership role of deputy to the president and chief operating officer, effective immediately.

As the institution continues to change and grow and my responsibilities have expanded to include greater focus on philanthropy, federal and local policy and global activities, I felt it necessary to appoint a leader to execute on the vision and strategic direction of MD Anderson while overseeing its complex daily operations. Steve has been an engaged and thoughtful member of numerous institutional efforts, including the Executive Clinical Operations Team Finance Committee and Shared Governance Committee. He also is known for his clinical expertise, collaborative approach and deep understanding of the changing health care environment.

In this leadership role, Steve reports directly to me and carries full authority to act on my behalf and in my absence. He is responsible for day-to-day management of MD Anderson, ensuring excellence across all business, clinical and faculty matters. He will serve as the intermediary between Dan Fontaine, executive vice president (EVP) of Administration, Ethan Dmitrovsky, M.D., provost and EVP, and Tom Buchholz, M.D., EVP and physician-in-chief. Steve also will co-chair the institution's Shared Governance Committee, which includes executive leaders, division heads and faculty senate representatives.

Steve has served as division head, department chair and professor of Radiation Oncology, which he assumed on Jan. 1, 2015. A recognized international leader in the field of radiation oncology, he joined MD Anderson from the University of Pennsylvania's Perelman School of Medicine, where he served as chair of the Radiation Oncology department from 2005 to 2014.

An active clinician who is board certified in radiation oncology, medical oncology and internal medicine, Steve's clinical interests and expertise include both lung cancer and sarcoma. His research focuses on the molecular causes of the tumor microenvironment, particularly the study of chemical signals that go awry (known as aberrant signal transduction pathways), and the evaluation of proton therapy as a means to improve the efficiency of radiation therapy. Steve's research has resulted in numerous publications in peer-reviewed journals. He is highly respected for his clinical expertise, collaborative nature, and deep understanding of the rapidly changing health care environment.

Steve earned his undergraduate degree from Rice University and his M.D. at Temple University in Philadelphia, and completed his internship and residency at the University of California, San Francisco Hospitals. He completed a medical oncology fellowship and radiation oncology residency at the National Cancer Institute.

This is an important time for MD Anderson. We must be strategic and thoughtful while developing creative solutions and taking decisive actions. My appointment of Steve is one such action. With the support and engagement from the entire MD Anderson community, we will deliver on our mission to end cancer together.

Ron

Ronald DePinho, M.D.
President

THE CANCER LETTER | FEBRUARY 10, 2017 | VOL 43 | ISSUE 06

GAO report: FDA underestimated actual cancer risk, clearing 25 versions of morcellators in over 20 years

By Matthew Bin Han Ong

The Government Accountability Office Feb. 8 released an analysis of FDA's failure to detect the health hazards of power morcellation, a once widely used procedure that has been shown to upstage uterine cancers.

The upstaging has been estimated to occur in about one in 350 women.

GAO notes that between 1991 and 2014 FDA cleared 25 submissions for power morcellators to be marketed in the U.S. The report doesn't provide value judgments or recommendations, but the evidence collected by the GAO team attributes the harm caused by power morcellators to:

- An anemic adverse events reporting system at FDA,
- A medical device clearance process that doesn't reliably and consistently assess risk for potentially harmful devices, and
- An underestimation of the risk of sarcomas occurring in uterine tissue, despite acknowledgement on FDA's part that agency officials were "aware of the potential for spreading tissue during procedures that involved the use of power morcellators ... since the agency cleared the first device in 1991.

The report is posted here.

Power morcellators, surgical devices with spinning blades, were used to perform hysterectomies and myomectomies on at least 100,000 women a year in the United States. The "minimally invasive" procedure is now known to disseminate unsuspected uterine cancer, thereby worsening a patient's prognosis.

The report was requested by 12 members of Congress, who asked the GAO to provide a root cause analysis for harm related to morcellation, "In light of these concerns, we respectfully request you investigate the root cause failure that ultimately led to the FDA's black box warning on the use of laparoscopic power morcellators," legislators wrote in an Aug. 7, 2015 letter to the GAO.

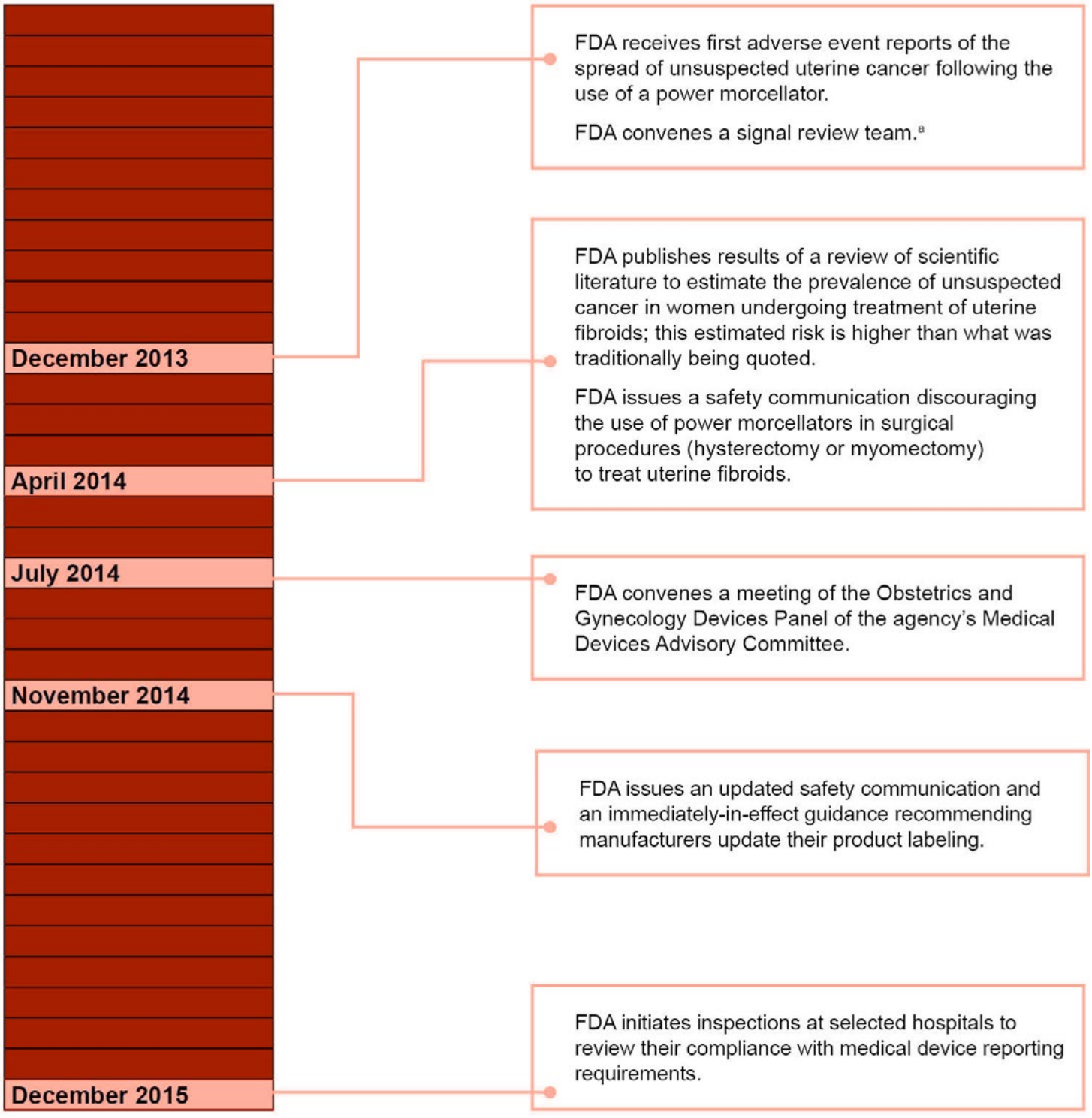
The problem came to light as a result of an aggressive campaign by physicians Amy Reed and Hooman Noorchashm—along with extensive media coverage—prompted FDA to review the procedure and severely limit the use of power morcellation in November 2014.

"The GAO report confirmed the fact that literally hundreds, if not thousands, of unsuspecting American women have been harmed or died unjustifiably because of cancer upstaging by power morcellators for over two decades," Noorchashm said to The Cancer Letter. "And it confirms that the adverse outcome reporting requirements for physicians is dangerously inadequate in the case of medical devices."

Describing the report as "long-awaited," Rep. Brian Fitzpatrick (R-PA) and Rep. Louise Slaughter (D-NY) said the GAO's findings confirmed regulatory lapses at FDA that had been brought to public attention as a result of the controversy.

Fitzpatrick's brother, Mike Fitzpatrick—whom Brian succeeded in the recent election—and Slaughter introduced in 2016 the Medical Device Guardians Act, which would require individual practitioners to report adverse events. The bill was not taken up in the 21st Century Cures Act, passed in December.

"The release of this long-awaited report won't do anything to help women battling cancer who have had their lives devastated by power morcellators, or provide much comfort to the families of those already lost," Brian Fitzpatrick and Slaughter said in a joint statement Feb. 8. "It does, however, shed light on the broken system that allowed this devastation to happen and include a roadmap to address it.



Source: GAO analysis of Food and Drug Administration (FDA) documentation. | GAO-17-231

"The GAO report confirms what we had long expected: there are serious gaps in the FDA's device reporting system and that immediate Congressional action is needed to reform the process and save lives. Additionally, given the associated risks, it's clear that this device is no longer appropriate in the treatment of uterine fibroids.

"Armed with this information, we will move forward to find bipartisan legislative solutions to address these shortcomings and ensure a system is in place that provides real, accurate information to patients, professionals and regulators."

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Clinical Care/Translational Research

Gastrointestinal/Hepatobiliary Medical Oncology Posting #: 0836458

Hematologic Malignancies, Stem Cell Transplantation, and Cell-Based Immunotherapies Posting #: 0836427

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The University of New Mexico Comprehensive Cancer Center

Join Our Scientific Teams

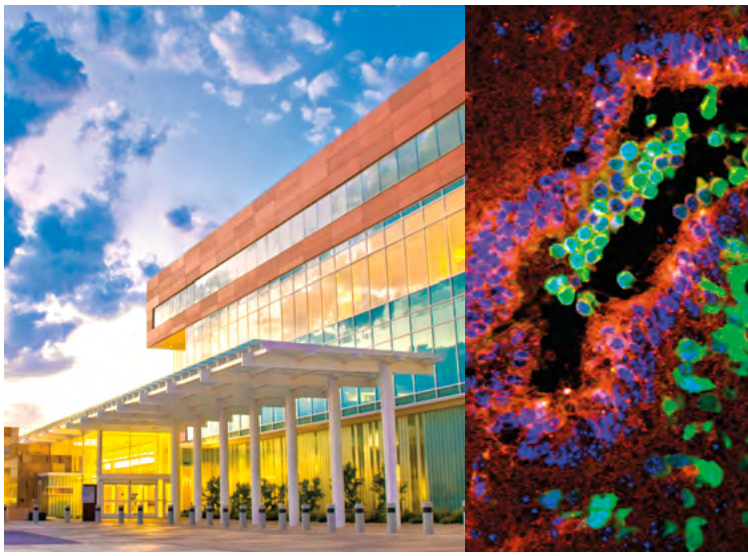
Join a dynamic and rapidly growing team of more than 250 world-class scientists and physicians at the UNM Comprehensive Cancer Center. As one of the nation's 47 National Cancer Institute Designated Comprehensive Cancer Centers, our team is particularly focused on discovering the causes and cures for cancers that disproportionately affect the people of the American Southwest – primarily Hispanic, American Indian, and Non-Hispanic White – with strikingly different patterns of cancer incidence, mortality and disparity.

Supported by more than $70 million annually in cancer-focused funding, the UNM Cancer Center has outstanding research programs in:

- **Cancer Control and Cancer Health Disparities**
- **Cancer Genetics, Epigenetics, and Genomics**
- **Cancer Cell and Systems Biology**
- **Cancer Therapeutics**

These programs house several national centers including:

- The Molecular Discovery and High Throughput Target Screening Center: one of the nation's 6 Chemical Biology Consortium Centers of Excellence in The NCI NExT Program
- The New Mexico Center for the Spatiotemporal Modeling of Cell Signaling: one of 13 NIH National Centers for Systems Biology
- A NIH Clinical and Translational Sciences Center



Rich collaborations with UNM Cancer Center consortium partners (Sandia and Los Alamos National Laboratories; Lovelace Respiratory Research Institute) with unparalleled computing infrastructure and outstanding scientific teams enhance computational, informatics, and systems biology research, inform clinical intervention strategies, and support cutting-edge training programs. The UNM Cancer Center is also a member of the ORIEN National Network engaged in cancer precision medicine, genome sequencing, data sharing, cancer clinical trials and collaborative research.

Scientists and Physician-Scientists Openings

Cancer Computational Biology, Bioinformatics, and Computational Modeling Posting #: 0836558

Genomic Biostatistics and Cancer Biostatistics Posting #: 0836525

Cancer Epigenetics and Epigenomics Posting #: 0836557

Functional Genomics, Transcription, and RNA Metabolism Posting #: 0836556

Cancer Cell Signaling and Systems Biology Posting #: 0836529

Cancer Experimental Therapeutics Posting #: 0836530

Cancer Molecular or Genetic Epidemiology Posting #: 0836528

APPLY ONLINE

For detailed descriptions and requirements for all positions, visit cancer.unm.edu/JoinTheBest or apply online at https://unmjobs.unm.edu

Questions? Contact Amanda Leigh: ALeigh@salud.unm.edu, (505) 272-2201. UNM is an Equal Opportunity/Affirmative Action Employer and Educator

IN BRIEF

International teams win £100 million in Cancer Research UK competition

Cancer Research UK said four international teams are the first recipients of its global £100 million Grand Challenge competition, which aims to overcome the biggest challenges facing cancer researchers in a global effort to beat cancer sooner.

This new Cancer Research UK initiative was overseen by a panel of researchers, chaired by Rick Klausner, former NCI director. The four winning teams will:

- Study cancer samples from five continents to understand the DNA damage associated with different cancers, to understand what causes them and if they can be prevented. The project will be led by Mike Stratton at the Wellcome Trust Sanger Institute, Cambridge, with collaborators from France, the US and UK.

- Distinguish between those women with DCIS who need treatment and those who don't, to reduce over-treatment of the condition. This project will be led by Jelle Wesseling at the Netherlands Cancer Institute with collaborators from the U.S., U.K., and the Netherlands.

- Develop a way to combine new and existing technologies to create virtual representations of tumors, and a global database that catalogues their genetic make-up and metabolism, which could lead to new ways to diagnose and treat the disease. This project will be led by Josephine Bunch at the National Physical Laboratory, London, with collaborators from the U.S. and multiple U.K. research centers.

- Create a virtual reality 3-D tumor map, which will allow scientists and doctors to examine—for the first time and in unprecedented detail—the cellular and molecular make-up of a patient's entire tumor to improve diagnosis and treatment for the disease. This project will be led by Greg Hannon at the University of Cambridge, with collaborators from Switzerland, Ireland, Canada, the U.S. and U.K.

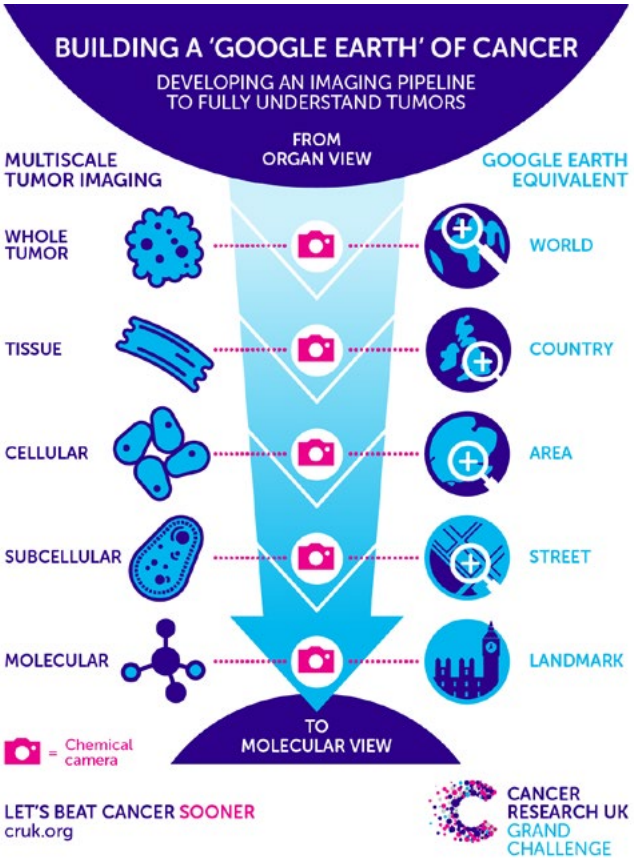
Cancer Research UK set up Grand Challenge in 2015 and committed up to £100m to this new approach to help increase the pace of research. To help decide the specific challenges that could transform progress against cancer, Cancer Research UK brought together cancer researchers, doctors, engineers, physicists, behavioral scientists, epidemiologists, technologists and patients.

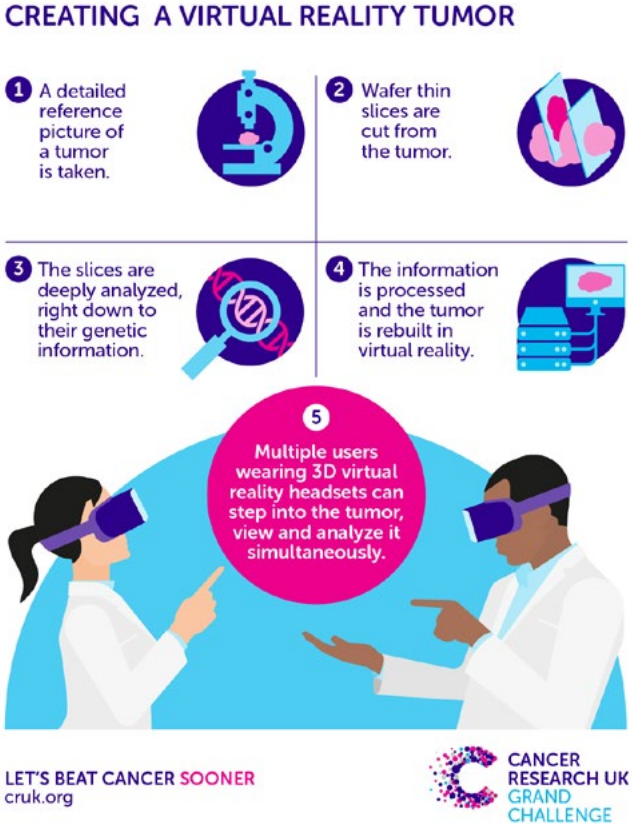
Seven grand challenges were then announced, each of which identified some of the greatest barriers preventing progress in cancer research. The international research community were asked to form multidisciplinary teams and submit proposals to answer the challenges.

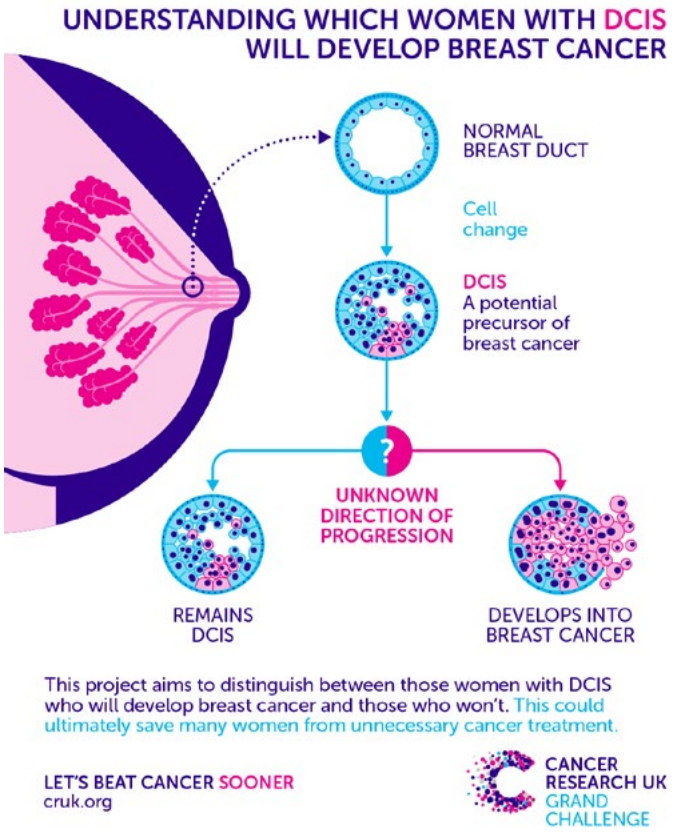
In February 2016, applications were submitted from more than 200 institutes, spanning 25 countries, uniting more than 400 research groups. Originally, the plan was for Grand Challenge to fund one new team every year for five years, with each team receiving up to £20m over five years for their research. But the panel were felt to be too important not to fund.

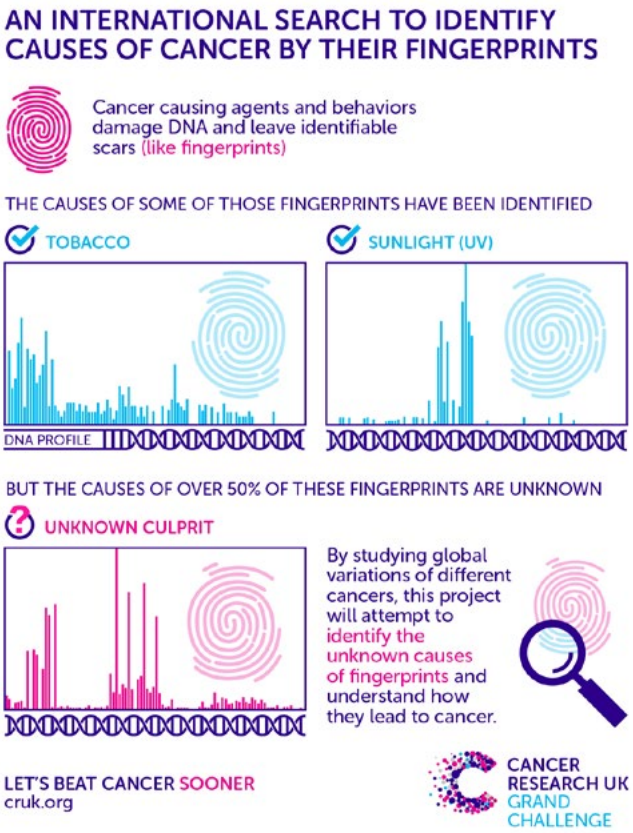
Cancer Research UK has now secured a partnership with the Dutch Cancer Society and an anonymous donor to enable a total of four proposals to be funded. As a result, the commitments in the first round of Grand Challenge funding will now be up to £71 million. Phase two of Grand Challenge, when Cancer Research UK plans to issue a set of revised challenges, will launch this summer.

"When we began the Grand Challenge, we sought scientific adventurers—people willing to come together









THE FOUR PROPOSALS THAT WON THE £100 MILLION GRAND CHALLENGE COMPETITION – Source: Cancer Research UK

in new ways, to think differently, and bring novel approaches to answer the big questions in cancer. These unique teams have done just that," Klausner, chair of the Grand Challenge advisory panel, said in a statement. "Cancer is a complex, and often brutal disease. Cancer Research UK's Grand Challenge is helping us change the way we to tackle it—bringing together different disciplines, ideas, and people on a global scale. We've got our sights set on the horizon of discovery, and I'm confident these Grand Challenge teams will lead to life-changing results."

Horning receives Duane Roth Memorial Award

Sandra Horning, chief medical officer and executive vice president of global development at Roche/Genentech, will be presented with the 2017 Duane Roth Memorial Award on Feb. 16 at the annual Industry/Academia Translational Oncology Symposium at the UC San Diego Moores Cancer Center.

Horning, a cancer survivor, was a practicing oncologist, investigator and professor at Stanford University for 25 years before moving to Genentech in 2009. Her focus has been on developing new treatments for lymphoma. She is also a past president of the American Society of Clinical Oncologist.

"Throughout her impressive career, Sandra Horning has been an unwavering champion of personalized therapies and shifting the focus from treatment of cancer to a more holistic approach of treating the patient as an individual, mindful of his or her family and anticipating survivorship issues, such as fertility, secondary malignancies, cardiopulmonary and endocrine side-effects and more," said Ida Deichaite, director of the Moores Cancer Center's Office of Industry Relations.

The award celebrates Duane Roth, who was chief executive officer of Connect, a San Diego-based organization that promotes technology innovation and entrepreneurship. Roth died in 2013 from injuries suffered in a bicycling accident.

Deichaite said the Roth award is given to leaders in health care whose work has overcome numerous scientific, financial, institutional, political and cultural obstacles to create new paradigms in research and treatment.

Chang and Moore win Ehrlich-Darmstaedter Prize

Yuan Chang and Patrick Moore, researchers at the University of Pittsburgh Cancer Institute, have been awarded the 2017 Paul Ehrlich and Ludwig Darmstaedter Prize.

The prize is given annually to medical researchers who have made significant contributions in the fields of immunology, cancer research, microbiology and chemotherapy. Chang and Moore's Chang-Moore Laboratory at the UPMC Cancer Center is credited with discovering two of the seven known human viruses that directly cause cancer.

"Drs. Chang and Moore's contributions to cancer research have been significant and lasting, touching the lives of people around the world," said Arthur Levine, Pitt's senior vice chancellor for the health sciences and the John and Gertrude Petersen Dean of the School of Medicine. "They are the first Pitt faculty members to ever be honored with the Paul Ehrlich and Ludwig Darmstaedter Prize. The University community congratulates them and celebrates this well-deserved tribute to the pioneering work that has come to define their careers."

Chang and Moore discovered the Kaposi's sarcoma-associated herpes virus, or human herpesvirus 8 (KSHV/HHV8) in 1994. The virus causes Kaposi's sarcoma, the most common AIDS-related malignancy and one of the most frequently occurring cancers

in Africa. Prior to this discovery, medical researchers had worked for nearly 15 years to find an infectious agent associated with Kaposi's sarcoma. The pair also identified Merkel cell polyomavirus (MCV)—the cause of Merkel cell carcinoma, one of the world's most clinically aggressive skin cancers—in 2008.

Both researchers have been widely recognized for their work, including the 2012 Marjorie Stephenson Prize from the Society of General Microbiology in the United Kingdom; the 2003 Charles S. Mott Award from the General Motors Cancer Research Foundation; the 1998 Robert Koch Prize; and the 1997 Meyenburg Prize. Chang and Moore also are elected fellows of the National Academy of Sciences.

Chang's current research centers on viral oncogenesis with efforts specifically focused on KSHV, MCV, and new pathogen discovery. Moore's research focuses on addressing cancers caused by viruses and how this information can be used to understand molecular causes for non-infectious cancers.

The prize is given by the Paul Ehrlich Foundation, which is managed by the Association of Friends and Sponsors of the Goethe University in Frankfurt. The foundation presents the honor annually in Frankfurt on Ehrlich's birthday, March 14.

ESMO to present new award at first annual Immuno-Oncology Congress

The European Society for Medical Oncology announced the creation of a new award honoring individuals for achievements in cancer immunotherapy. The award will be presented at ESMO's newly launched Immuno-Oncology Congress in Geneva this December.

"Immunotherapy is an exciting and rapidly evolving area in oncology," said ESMO President Fortunato Ciardiello. "Recognizing excellence in this emerging area is a duty and an honor for us, as the society of reference committed to improving outcomes for cancer patients."

The new ESMO Award for Immuno-Oncology memorializes Georges Mathé, a French oncologist and immunologist who performed the first bone marrow graft between unrelated donors in 1958. Mathé also co-founded ESMO in 1975.

"I am very proud that ESMO is honoring my father's achievements with this prestigious award, recognizing the growing importance of immunotherapies applied to cancer care," said Catherine Gaston-Mathé. "As the descendant of one of ESMO's founders and immunotherapy pioneers, I am grateful for the appreciation of his work which has brought new hope for cancer patients."

ESMO organized an educational meeting on the basics of immunology in 2007 and in 2013 a series of smaller annual events dedicated to immune-oncology was started with the ESMO Symposium on Immuno-Oncology. The Immuno-Oncology Congress will offer an expanded program and sessions dedicated to different tumor types for basic, translational and clinical researchers, immunologists, and oncology clinicians.

"Immunotherapy provides medical oncologists with another tool to treat cancer patients. The ESMO Immuno-Oncology Congress will help to increase the overall understanding of the potential of this therapy and its implications for clinical practice, today and in the future," said George Coukos, scientific co-chair of the congress and director of the Department of Oncology at the University Hospital of Lausanne and the Ludwig Cancer Research Centre, Lausanne.

Jupiter Medical Center to use IBM Watson for Oncology technology

Jupiter Medical Center said it will adopt IBM's Watson for Oncology trained by Memorial Sloan Kettering Cancer Center, which will go live at the beginning of March.

Watson for Oncology is a cognitive technology developed by IBM that processes information more like a human than a computer, by understanding natural language, generating hypotheses based on evidence, and learning as it goes. It provides information to oncologists to help them deliver evidence-based treatment options by analyzing massive volumes of medical literature to identify individualized treatment options and scaling access to oncology expertise.

Watson draws from more than 300 medical journals, more than 200 textbooks, and nearly 15 million pages of text to provide insights about different treatment options and also provides oncologists with information regarding drug options and administration instructions. Watson also ranks the evidence-based treatment options, linking to peer reviewed studies and clinical guidelines. Its machine-learning capability means it continuously learns.

IBM and MSK have been accelerating Watson for Oncology's training and it is now available to assist clinicians in developing treatment plans for breast, lung, colorectal, cervical, ovarian and gastric cancers. IBM and MSK plan to train Watson on at least nines additional cancer types this year, covering nearly 80 percent of the worldwide incidence of cancer.

Fox Chase, Temple earn accreditation for BMT program

The joint program of Fox Chase Cancer Center and Temple University Hospital earned accreditation by the Foundation for the Accreditation of Cellular Therapy at the University of Nebraska Medical Center for adult allogeneic and autologous hematopoietic progenitor cell transplantation, peripheral blood cellular therapy product collection, and cellular therapy product processing with minimal manipulation.

FACT is an internationally recognized accrediting body for hospitals and medical institutions offering stem cell transplant, and indicates the accredited institution has met the most rigorous standards in every aspect of stem cell therapy. This covers the entire spectrum of stem cell therapy, from clinical care to donor management, cell collection, processing, storage, transportation, administration, and cell release.

By demonstrating compliance with the FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing and Administration, the bone marrow transplant program has been found to be in compliance with those standards, as well as governmental regulations.

"We sought FACT accreditation because it has evolved into an all-but-necessary qualification to be accepted and competitive in the field of cellular therapy," said Henry Fung, vice chair of hematology at Fox Chase and director of the Fox Chase-Temple BMT Program. "We believe FACT accreditation will make patients aware that our facility strives to achieve the highest quality care for cellular therapy treatment."

FACT accreditation is attained through evaluation of submitted documentation and on-site inspection to determine if an organization is in compliance with current FACT Standards and the United States Food and Drug Administration's current rules for Good Tissue Practice. FACT Standards are defined by leading experts based on the latest knowledge of the field of cellular therapy.

Cota, Hackensack integrate patient data into Epic EHR system

Data and technology platform Cota and Hackensack Meridian Health in New Jersey have partnered to help improve clinical and cost outcomes for cancer patients.

HMH will integrate Cota Nodal Addresses (CNAs) directly into its Epic Electronic Health Record system to help support decision-making by oncologists at the point of care.

CNAs are generated by a unique, patented digital data classification methodology that maps all of cancer by organizing patients into groups based on all the personal and clinical factors that matter to the individual. Each patient with the same CNA can be considered medically identical, and thus should have similar treatments and outcomes. Physicians guided by CNAs are better able to personalize treatment for each individual patient based on their individual biology and disease.

"Incorporating CNAs directly into EHR systems to help guide decision-making in real-time is the next step in helping healthcare professionals increase individual patient outcomes and lower the total cost of care for the population they serve," said Andrew Pecora, Cota's founder and executive chairman. "Physicians and healthcare administrators at Hackensack Meridian Health have already been using our web-based CNA Guided Care technology platform to derive insights that improve overall practice decisions and we're excited to expand this capability to the point of care for each individual patient."

NCCN creates Quick Guide for patients with Waldenström's Macroglobulinemia

The National Comprehensive Cancer Network said it has published a Guidelines for Patients and NCCN Quick Guide sheet for Waldenström's Macroglobulinemia—a rare, but manageable type of Non-Hodgkin's Lymphoma.

Provided through support from the NCCN Foundation, NCCN's goal is to give patients access to the same treatment information their doctors use for Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma. Waldenström's Macroglobulinemia affects approximately 1,500-2,000 people in the U.S. each year. While not curable, Waldenström's Macroglobulinemia is slow growing and, in many patients, manageable as a chronic disease.

"The treatment approach to patients with Waldenström's Macroglobulinemia has significantly changed in the recent years with better understanding of the disease biology and its natural history and availability of new drugs, allowing for a more individualized approach. The revised guidelines reflect these changes and will be a valuable guide for patients in shared decision-making with their oncologists," said Shaji Kumar, of the Mayo Clinic Cancer Center and chair of the NCCN Guidelines Panel for Waldenström's Macroglobulinemia.

NCCN Guidelines for Patients, patient-friendly adaptations of the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines), are easy-to-understand resources based on the same clinical practice guidelines used by health care professionals around the world to determine the best way to treat a patient with cancer. Each resource features guidance from the nation's leading cancer centers designed to help people living with cancer talk to their physicians about the best treatment options for their disease.

NCCN Guidelines for Patients and NCCN Quick Guide sheets—one-page summaries of key points in the patient guidelines—are written in plain language and include patient-friendly elements, such as questions to ask your doctor, a glossary of terms, and medical illustrations of anatomy, tests, and treatment.

DRUGS & TARGETS

FDA approves Opdivo for urothelial carcinoma indication

FDA approved the nivolumab (Opdivo) injection for intravenous use for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

This indication was approved based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. The recommended dose for mUC is 240 mg administered as an intravenous infusion over 60 minutes every two weeks until disease progression or unacceptable toxicity.

The FDA granted the application priority review and previously granted Breakthrough Therapy Designation to Opdivo for the treatment of patients with locally advanced or mUC who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

"Most people don't know how common bladder cancer is and that it is the fifth most diagnosed cancer. That's why we are dedicated to raising awareness and supporting research efforts that may offer more treatment options to patients who need them," said Stephanie Chisolm, director of education and research at Bladder Cancer Advocacy Network. "This approval is another exciting step forward for the bladder cancer community and provides needed hope to patients and their families."

In the CheckMate -275 trial, 19.6% (95% CI: 15.1-24.9; 53/270) of patients responded to treatment with Opdivo. The percentage of patients with a complete response was 2.6% (7/270) and the percentage of patients with a partial response was 17% (46/270). Among responders, the median duration of response was 10.3 months (range: 1.9+-12.0+ months). The median time to response was 1.9 months (range: 1.6-7.2). CheckMate -275 is a Phase 2, open-label, single-arm, multicenter study evaluating Opdivo in patients with locally advanced or mUC who have disease progression during or following treat-

ment with a platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. In this study, 270 patients received Opdivo 3 mg/kg administered intravenously every two weeks until disease progression or unacceptable toxicity. The recommended dose is 240 mg administered as an intravenous infusion over 60 minutes every two weeks until disease progression or unacceptable toxicity. The primary endpoint was confirmed objective response rate as defined by an independent radiographic review committee.

GenomeDx, Astellas work to identify genomic drivers of Xtandi response

GenomeDx Biosciences and Astellas announced a collaboration to apply genomic tumor profiling using GenomeDx's Decipher Classifier and Decipher GRID as a potential aid in identifying prostate cancer patients undergoing active surveillance who may benefit from treatment with enzalutamide (Xtandi).

As part of the agreement, Astellas will provide GenomeDx with tumor samples from its phase II ENACT trial, which compares the time to prostate cancer progression between patients treated with enzalutamide versus patients undergoing active surveillance. GenomeDx will profile all samples to provide Astellas with an analysis of tumor aggressiveness based on its Decipher Classifier score, and a Decipher GRID profile which will assess the biological behavior of a patient's tumor based on a set of signatures that may be associated with enzalutamide response.

GenomeDx's Decipher Genomics Resource Information Database (GRID) contains genomic profiles of thousands of tumors from patients with urological cancers. According to GenomeDx, it is the largest shared genomic expression database in urologic cancer as well as one of the world's largest global RNA expression databases using cloud-based analytics.

GRID is a platform for interactive research collaboration and may enable more rapid discovery, development, commercialization and adoption of new genomic solutions for key clinical questions in cancer treatment. Derived from GRID, GenomeDx's Decipher Prostate Cancer Classifier tests are commercially available genomic tests that provide a genomic assessment of tumor aggressiveness for individual patients. Decipher Biopsy is indicated for men with localized prostate cancer at diagnosis, and Decipher Post-Op is indicated for men after prostate removal surgery.

The Decipher tests are used by physicians to stratify patients into more accurate risk groups than determined by traditional diagnostic tools and to better determine which patients may be more likely to benefit from additional treatment. Each tumor analyzed with a Decipher test adds new data points to the GRID database, which is compiled into a Decipher GRID Profile that may reveal additional biological characteristics of the tumor for ongoing research purposes. Going beyond risk stratification, Decipher and GRID makes genetic information accessible for researchers to potentially better predict responses to therapy and more precisely guide treatment.