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ROCHE TO ACQUIRE FLATIRON HEALTH FOR \$2.1 BILLION, WITH FOCUS ON REAL-WORLD DATA

Roche has signed an agreement to acquire all shares of Flatiron Health, a health care technology and services company headquartered in New York City, for \$1.9 billion.

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Associate Director for Research Administration, UPMC Hillman Cancer Center, Pittsburgh, PA

UPMC Hillman Cancer Center (Hillman) seeks a talented and experienced individual to step into a highly supportive environment as Associate Director (AD) / Deputy Director (DD) for Research Administration. This is a very exciting time for a new AD for Administration to join Hillman. Hillman is strongly supported by UPMC and the University of Pittsburgh School of Medicine. The Hillman Foundation recently committed a large amount of continued support for our Center over the next 10 years. The new AD / DD will help promote and invest these funds in new projects, recruits, shared resources, and pilot programs. With our re-naming as UPMC Hillman Cancer Center, a new Director, and upcoming expansion of space for Hillman researchers, Hillman is unified and supportive of cancer research and therapy.

The AD for Research Administration reports directly to the Hillman Director, and is a member of Hillman's executive leadership team. Duties and responsibilities include:

- supervising a supporting team of administrators and PhD-level scientists,
- coordinating vision setting and strategic planning; overseeing CCSG Programs and Shared Resources;
- developing Center policies and procedures;
- working with the Hillman Fiscal Office to develop budgets and monitor spending; developing staffing and space utilization plans and overseeing facility operations;
- managing Hillman's membership and grants portfolio; and
- communicating research outcomes to Hillman investigators, the NCI, and the public.

To facilitate and advance Hillman science, the AD / DD will also:

- coordinate CCSG preparation and submission;
- grow the funded research base, with emphasis on multi-disciplinary collaboration;
- work with the Hillman Development Office to promote and increase philanthropic donations; assist in recruitment of faculty.

Located in the City of Pittsburgh's Shadyside neighborhood, (Pittsburgh is routinely ranked as one of the top-most livable and affordable U.S. cities), Hillman is a National Cancer Institute (NCI)-designated matrix cancer center focused on state-of-the-art cancer research, training the next generation of cancer researchers, and community outreach. In 2015, Hillman celebrated its 30th anniversary and the renewal of its 5-year NCI Cancer Center Support Grant (CCSG). Hillman has over 330 members, 10 scientific programs, 13 CCSG-supported shared resources, and an FY17 institutional funding base of nearly \$157 million. In FY16 the University of Pittsburgh ranked #5 in overall NIH funding. During its 2015 CCSG review, Hillman Research Administration scored exceptional.

Candidates for the position must have a PhD or master's degree in business, administration, policy, or other research administration-relevant field. Candidates also must have 5+ years in research administration, which includes an understanding of the regulatory requirements and complexities pertaining to animal and clinical research; familiarity with NCI CCSG requirements; experience with NCI-funded cancer centers; and excellent written and oral communication, computer, people management, and interpersonal skills.

The successful candidate will be hired as an employee of the University of Pittsburgh, with a very competitive salary and benefits package (see www.hr.pitt.edu/benefits). The University of Pittsburgh is an equal opportunity employer. EEO / AA / M / F / Vets / Disabled

To apply for the position of Associate Director for Research Administration at UPMC Hillman Cancer Center, please send a 1-page personal statement highlighting your qualifications and experience, along with your CV or resume, to Hillman Director Robert L. Ferris, MD, PhD (care of thompsonla3@upmc.edu).

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ROCHE TO ACQUIRE FLATIRON HEALTH FOR \$2.1 BILLION, WITH FOCUS ON REAL-WORLD DATA

By *Matthew Bin Han Ong*

Roche has signed an agreement to acquire all shares of Flatiron Health, a health care technology and services company headquartered in New York City, for \$1.9 billion.

The deal, which would raise Roche's stake from 12.6 percent to outright ownership, is subject to regulatory approval and is expected to close in the first half of 2018. The total price tag is closer to \$2.1 billion, including about \$200 million in cash balances.

Flatiron will retain autonomy in its operations and continue to be able to share data with collaborators beyond Roche, officials said.

"Flatiron's objective is, of course, to clearly improve the patient experience with the provider base and provide regulatory-quality real-world data that allows researchers, academics, industry to create insights from that data to make better decisions on new medicines and new interventions," Roche Pharmaceuticals CEO Daniel O'Day said to The Cancer Letter. "So, the objectives are all aligned, and therefore creating autonomy within the Roche Group, we think, makes sense to make sure that Flatiron maintains its inde-

pendent decision-making towards providers and towards other life sciences customers.

"We're confident that when that happens Roche will also benefit as a leader in cancer medicine and our mission of developing transformational cancer medicines."

A conversation with O'Day appears on [page 9](#).

The Roche-Flatiron deal is the first, specific purchase of a health tech startup by a pharmaceutical company—a move that, some say, signals a turning point in cancer Big Data.

"It's an acknowledgement by the Roche Group that evidence development is fundamentally changing. This is a conversation you and I have been having for a while now, Matt," said Amy Abernethy, chief medical officer, chief scientific officer, and senior vice president of oncology at Flatiron

Health. "We are turning of the corner from real-world evidence being cute to real-world evidence being substantive and credible enough to be able to make real decisions.

"Why such a high valuation? Roche isn't buying a traditional health care company, nor a biotech company. Flatiron is a tech company and so that kind of acquisition comes with pretty substantive growth opportunities made possible by a rapidly scalable tech infrastructure," Abernethy said to The Cancer Letter. "And does the investment stop there? If you're Roche, if you're going to pay something like \$2 billion for an organization, then you're not going to let it wither on the vine. You're going to keep investing in it for the future."

The Roche price tag is "exciting" for other health technology companies watching the acquisition, said Brigham Hyde, CEO Precision Health AI, a company that uses artificial intelligence

to define cancer datasets for precision oncology.

“I think what is probably more interesting is that pharma would not have been considered a buyer, classically, for this type of business, and they’re now entering the space,” Hyde said to *The Cancer Letter*. “I also think this signals the importance in oncology in particular.

“Although, it’s important to realize Roche is unique. They’ve always had a diagnostics difference, which puts them a little bit in the data space already, and also in the clinical decision support space. They have run that successfully, and somewhat separately for years.

“It’s a question mark to wait and see how providers react to the idea of the EMR they use being owned by a pharma company. Even though that would be highly regulated, and I do take Roche at their word, that they will operate Flatiron separately. But it is an open question.

A conversation with Hyde appears on [page 14](#).

PH.AI recently announced a deal with Tempus and the American Society of Clinical Oncology to curate and license more than one million patient care records contained in CancerLinQ, the professional society’s venture into Big Data (*The Cancer Letter*, [Jan. 5](#)).

Flatiron will continue to operate the EHR completely independently, said Bobby Green, senior vice president of clinical oncology at Flatiron and a medical oncologist at Florida Cancer Specialists in West Palm Beach.

“I think one of the most notable and short-to-medium term changes that we’re going to see is more resources put in to our OncoCloud suite of products,” Green said to *The Cancer Letter*. “Not only is community oncology important for cancer delivery in this country, but

it’s really important to us as a company, and and community oncology is one of our core clients and partners.

“A rising tide lifts all boats”

Flatiron, which is currently backed by Google Ventures, First Round Capital, Roche, and others, has partnerships with over 265 community cancer clinics, six academic cancer centers, and 14 therapeutic oncology companies.

“The Roche acquisition amplifies the positive signals we are seeing in the real-world data and oncology evidence development space,” Abernethy said. “I think that you’re going to likely see more investments go into organizations that have been historically been our competitors like, for example, Tempus or Precision Health AI, or maybe Cota.

“Honestly, I think the Roche acquisition of Flatiron is good for everybody. It’s actually one of those ‘a rising tide lifts all boats’ activities, because it alerts the whole pharma and healthcare industry to the role of data and tech in evidence development”

The acquisition also signals that different players in oncology are converging to use Big Data in a meaningful way, said Jonathan Hirsch, president and founder of Syapse, a precision medicine company that integrates oncology data from electronic health records with genomic data.

“The Roche-Flatiron deal validates what we’ve believed for a long time at Syapse: to advance the fight against cancer, the entire health care ecosystem must come together,” Hirsch said to *The Cancer Letter*. “At Syapse, we’re focused on using precision medicine to defeat cancer, and to do that, we believe that continued collaboration across the ecosystem is necessary to bring critical data and insights to the

health systems and oncologists who need it most.

“We expect to see more partnerships across the health care ecosystem in the future that further this goal. When we can do this effectively, we can more rapidly improve patient care and make precision medicine a reality for more patients.”

In January, Roche and Syapse announced a collaboration that will focus on developing four specific software analytics to measure health outcomes and economic impact of precision medicine (*The Cancer Letter*, [Jan. 12](#)).

Flatiron’s OncoCloud suite, the company’s electronic health record solutions portfolio, allows Flatiron researchers to aggregate de-identified data and observe drug use and uptake, as well as patient outcomes in real time.

This information can be used to measure effectiveness, inform drug approval decisions—both for new and supplementary indications—and to also track adverse outcomes.

O’Day said Flatiron’s data helped Roche expand access to one of its drugs—specifically, Alecensa (alectinib), which was approved by FDA in November 2017 as first-line treatment for people with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer.

“In order to support the access of this medicine in different countries around the world, different countries wanted to see more data on how the control arm of the trial would be used, given their regimen in their country,” O’Day said. “We were able to access the Flatiron database and give them confidence on how patients on the current standard of care medicine would perform and then they were able to compare that to the way that Alecensa performed in a clinical trial.

“It satisfied many questions that regulators and payers had in different countries to be able to support the quicker access of Alecensa for patients. We used this data in more than 20 countries around the world and it accelerated the access for patients by more than a year for this medicine in many of those countries.”

Creating regulatory-grade data

Roche’s investment is expected to accelerate Flatiron’s work on creating a data analytics infrastructure that could be used to generate “regulatory-grade” real-world evidence.

“Our expectation is Roche is going to bring more resources to the table and champion the building of a lot of solutions that we need on the real-world evidence side—such as real-world endpoints and improved data quality,” Abernethy said. “Another one that’s high in my mind is building out remarkably new and forward-thinking solutions for widespread adverse event monitoring. This will take us a couple of years, but they are the kinds of things that we now start to design and invest in, because we’re able to take the long view.

“I do feel that the Roche Group sees themselves as leaders in the space of, frankly, skating where the puck is going as it relates to development of new medicines, and they particularly see themselves as leaders in oncology.”

Roche understands Flatiron’s commitment to community oncologists, because these clinics are important to Roche’s vision of “doing exciting things” with real-world evidence, Flatiron’s Green said.

“The first way I think we’re going to really see change is being able to put more resources into the things that community oncologists care about, as we continue to operate as a rel-

atively autonomous subsidiary of the Roche Group,” Green said.

Flatiron has been partnering with FDA to expand the role of real-world evidence in drug development. The 21st Century Cures Act requires the agency to establish, within two years from Dec. 13, 2017, a draft framework for combining real-world data and regulatory science.

Utilization data compiled by Flatiron and made available to The Cancer Letter in 2017 mark a fundamental shift in how cancer researchers can now understand and interpret clinical data in real-time (The Cancer Letter, [June 2](#), [June 9](#), 2017).

Together with Roche, Flatiron plans to boost their clinical portfolio by translating more rich datasets into results in drug development, and by expanding the company’s cloud services suite for community practices, company officials said.

“We’re just starting to turn the corner into the prospective evidence development side, so clinical trials and such, and I think that while that isn’t what has been the predominant attractant for Roche to acquire Flatiron, it’s certainly something that’s of high interest to them,” Abernethy said.

“Roche is very aware, and has said numerous times to us that they acknowledge that our ability to work independently with oncology practices and build software that delights oncologists has got to be something that we focus on. So, we can’t let Roche’s interest in real-world evidence distract us from that task, because otherwise, the real-world evidence, it just doesn’t exist.”

It’s a chicken-and-egg process, Green said.

“From the life sciences standpoint, I think more regulatory use cases, and ultimately seeing drugs get approved or expanded labels for existing treatments are going to be future milestones in that respect,” Green said.

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We used [Flatiron’s] data in more than 20 countries around the world and it accelerated the access for patients by more than a year for [Alecensa] in many of those countries.

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– Daniel O’Day

“From a provider standpoint, other than just continuing to build better products that we seek for our providers, ultimately being able to use real-world data, use analysis of unstructured data, bringing information back to clinicians that actually helps them to take better care of patients. We’re really building a learning healthcare system.

“We started to do some early pilots where we’ve been able to, using structured and unstructured data in a lot of the work that we’ve been doing, been able to look at bringing quality metrics like chemotherapy at the end of life, back to clinicians at a couple of our institutions and allowing them to benchmark against other clinicians within their institution, and to use that as a tool to actually change how doctors are taking care of patients and allow those institutions to do it.

“Every time you sit with a patient, one of the core things you want to answer is, what’s their expected outcome? What’s their prognosis?

“One of the things that we’re exploring: instead of me looking at the patient and then saying, ‘Well, I know that people with your disease treated in a clinical trial are this likely to be alive after this period of time or have this median survival,’ to be able to give them information that’s not based on a clinical trial, where the patient population may have been very different from that individual you’re looking at.

“But really, to be able to base it on, ‘What happens to an 80-year-old with underlying lung disease and underlying heart disease who has renal insufficiency? What happens to those patients when I treat them, rather than your ideal clinical trial patients?’

“So, I think being able to bring data like that back to clinicians is one of the things that really excites a lot of the folks at Flatiron and will be a pretty big milestone for us.”

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O'Day spoke with
Matthew Ong, a reporter with
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CONVERSATION WITH
THE CANCER LETTER

Roche CEO O'Day: Our investment in Flatiron will accelerate their mission

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[Flatiron's] data will be available to the oncology community for sure, as it has in the past. So, basically no difference to the way that Flatiron operates today; we will keep Flatiron as an autonomous unit within the Roche Group.

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Daniel O'Day
CEO of Roche Pharmaceuticals

Roche's purchase of Flatiron Health will accelerate the development of real-world data suitable for supporting regulatory decisions, said Daniel O'Day, CEO of Roche Pharmaceuticals.

"They have very good coverage of cancer lives in the United States, but it's roughly 30 percent, so they have the scale in terms of the number," O'Day said. "As we know, in electronic medical records systems, up to 50 percent of the data is unstructured and uninterpretable in a digital format. The wealth of information that exists in that unstructured data is exceptionally important.

"So, they've been able to structure that data, make sense of it, and they've done it at scale and uniquely compared to other companies in the field.

"We really want to shape the field for the benefit of patients, and when we do that right and do that well, that will transform the way that we do our business in oncology, in terms of research and development, and the regulators, I think, will be able to achieve their objectives of getting transformational medicine and innovations to patients quicker and faster and more reliably."

O'Day spoke with Matthew Ong, a reporter with The Cancer Letter.

Matthew Ong: With the acquisition, will Flatiron's data now belong solely to Roche?

Daniel O'Day: I think this is a really important question. The answer is, of course, no. Our strategy and objective here is to bring two leaders in the field together. So, we're a leader in cancer medicines and diagnostics and Flatiron is a leader in, obviously, health technology in cancer, and our objective here is to accelerate the Flatiron mission for the benefit of all stakeholders in the system.

We're going to leverage this experience together to make sure that we are good partners with industry, with academia, with regulators, and most importantly, with providers and patients to make sure that we advance the field of care of oncology for everyone. I think this is a strategy that two leaders in the field can come together on, because we understand and we certainly hope that the entire cancer ecosystem will benefit here and, of course, we'll benefit as well.

So, Flatiron will be able to share its data with third-party organizations?

DO: That's correct. Yes, the answer is that the data will be available to the oncology community for sure, as it has in the past. So, basically no difference to the way that Flatiron operates today; we will keep Flatiron as an autonomous unit within the Roche Group.

We'll certainly set up appropriate firewalls to make sure that data is protected from a patient perspective, a physician perspective, and other life sciences companies. This is something we have a lot of experience with; we do this today with Foundation Medicine, for instance, and we've done with other collaborators in the past. So, it's something we believe very, very strongly that the data is for the benefit of the cancer and health care community.

How will Roche allow Flatiron to maintain autonomy over its community practice portfolio?

DO: Well, I think the good news is our interests are aligned and that's why we feel very comfortable with the setup that provides that autonomy. In other words, our focus at Roche is to discover and develop transformational

medicines in many disease states, but certainly in our leading disease area of cancer. The reason we're able to do that is because we have a real focus on patients' needs and the science, our ability to evolve the science.

Flatiron's objective is, of course, to clearly improve the patient experience with the provider base and provide regulatory-quality real-world data that allows researchers, academics, industry to create insights from that data to make better decisions on new medicines and new interventions.

So, the objectives are all aligned and therefore creating autonomy within the Roche Group, we think, makes sense to make sure that Flatiron maintains its independent decision-making towards providers, towards other life science customers.

We're confident that when that happens, Roche will also benefit as a leader in cancer medicine and our mission of developing transformational cancer medicines.

Would the Roche ownership in any way affect or change Flatiron's ability to form new partnerships and collaborations?

DO: Absolutely not. We feel that our investment in Flatiron will only help accelerate their mission. In other words, being able to advance more quickly their product offerings to providers or their research base, or their information base to the researchers in the industry community. I mean, we feel we can accelerate that mission, make it even more attractive to the partners that they work with today. We plan to invest in this business and make it stronger and better.

Right, with a \$2 billion price tag, you're not going to let Flatiron wither on the vine.

DO: No, no, no.

What does Flatiron offer that other health tech companies do not?

DO: Well, I think that they've definitely differentiated themselves on their ability to both support the patient experience with their OncoEMR system—their electronic medical records system—and the practice and providers.

They also have done a terrific job of creating regulatory-grade, real-world data, and what I mean by that is really high quality data on aggregated patients' experience that allows us to more deeply understand how cancer is evolving in groups of patients, and how we might, as significant investors in research and development on the medicine side, how we might better improve the patient experience, either by discovering more quickly a new medicine or accelerating the way we do clinical trials or finding ways to bring ways to bring those medicines to patients more effectively. So we think this is all very much core to their mission and how we would support it.

Could you share an example about meaningful use of Flatiron's data that convinced you that the company is worth acquiring?

DO: Yes, we've been partners with Flatiron now for more than two years, really working on an opportunity to use their data to accelerate access to medicine. So, what I would say is, for instance, with one of our medicines called Alecensa, which is a medicine for a rare, but particularly difficult to treat lung cancer—I'm sure you're aware of it.

Because of the effect of that medicine in clinical trials on patients, it was approved very quickly through the regulatory authorities, and in order to support the access of this medicine in different countries around the world, different countries wanted to see more data on how the control arm of the trial would be used, given their regimen in their country.

We were able to access the Flatiron database and give them confidence on how patients on the current standard-of-care medicine would perform, and then they were able to compare that to the way that Alecensa performed in a clinical trial.

It satisfied many questions that regulators and payers had in different countries to be able to support the quicker access of Alecensa for patients. We used this data in more than 20 countries around the world and it accelerated the access for patients by more than a year for this medicine in many of those countries.

I mean, it's particularly great news for patients, because you of all people know how fast cancer development is going and we need to be able to keep up with robust databases that are seen by regulators and payers as highly validated and highly controlled, so that gives them the confidence that the patients are going to get the benefit on our new

medicines that they expect them to get and therefore accelerate the access.

How is Flatiron positioned to set the standard for creating a data analytics infrastructure that can reliably generate regulatory-grade data?

DO: Well, I think they're very well positioned for two reasons. Number one, they have very good coverage of cancer lives in the United States, but it's roughly 30 percent, so they have the scale in terms of the number.

And secondly, what they've done very differently than other companies in this field is that they've structured the unstructured data. As we know, in electronic medical records systems, up to 50 percent of the data is unstructured and uninterpretable in a digital format. The wealth of information that exists in that unstructured data is exceptionally important.

So, they've been able to structure that data, make sense of it, and they've done it at scale and uniquely compared to other companies in the field. We're very interested in partnering with leaders in the field and there's no doubt to us that Flatiron is a leader in this field and significantly ahead of other companies, and we intend to invest to accelerate that into the future.

How will the nature of Roche's work with Flatiron differ from your development efforts with other companies that you have a stake in or a collaboration with?

DO: Our objective is to work with different companies in the field and make sure we experiment with different technologies and when we, of course, identify a leader in the field, we increase our interest and our desire to invest in them.

That was certainly the case, first, with Foundation Medicine, a company that we had collaborations with and decided that they were leaders in their field of clinical genomic profiling and it's been the same with Flatiron and, by the way, the intersection of those two companies—FMI having the depth of genomic sequencing on a particular point in time in a patient, and Flatiron following the patient journey in a very structured and methodical way, we think also can lead to some interesting insights.

But in addition to that, we at Roche will continue to partner with other collaborators and others that are either involved in data aggregation or analysis of that data, creating insights from that data through different types of technologies, like artificial intelligence or machine learning. We think this partnership strategy is going to enhance the overall area of personalized health care for Roche.

At the end of the day, we believe that the use of digital data and being able to analyze that data is going to transform the patient experience in terms of personalized health care, making sure that, in this very complex world of oncology, we're always looking to get the right treatment to the right patient at the right time.

And so, this will be done through ownerships, like we have with Flatiron, and complemented by other partnerships that can add to the strong foundation.

Some observers have said that this acquisition is a way for Roche to assert leadership in this space as well as a pre-emptive move ahead of other health care and tech companies. What is your response?

DO: The good news for patients is there's a lot of investment in this space, both on the innovation medicine side and also on harnessing Big Data in health care. All of that is good news for patients, so we welcome a lot of companies investing in this area, because at the end of the day, it's going to move the field and it's going to move the patient experience and patient benefit.

What is Roche hoping to achieve with Flatiron over the next year?

DO: Well, the milestones are to get the acquisition completed, first and foremost. So we believe in them and we believe in their mission, we want to do whatever we can to accelerate that mission to, as I said before, continue to honor that autonomy but accelerate the mission that they were on before.

The milestones will be driven by Flatiron, and by Nat [Turner, co-founder and CEO of Flatiron] and Zach [Weinberg, co-founder, president, and COO of Flatiron] and the team, and we're going to sit down with them and say, "How can we get there faster? How can we potentially leverage relationships outside of the Roche Group or inside the Roche Group to accelerate their mission?" We're very much looking forward to seeing where they want to go and supporting them in their investment and their journey.

How do you envision Flatiron to change the way Roche interacts with FDA?

DO: I think we've been great partners in working with FDA and with other regulatory authorities around the room, and I think we're respected for our individual expertise in competency, but coming together in looking at, very importantly, things like virtual control arms for trials in the field of oncology or looking at real-world data endpoints that will allow us to use real-world data to demonstrate the effectiveness of our medicines in broader populations.

These are things that we have been collaborating with Flatiron on and working with Flatiron on and we'll continue to. We really want to shape the field for the benefit of patients, and when we do that right and do that well, that will transform the way that we do our business in oncology, in terms of research and development, and the regulators, I think, will be able to achieve their objectives of getting transformational medicine and innovations to patients quicker and faster and more reliably.

Did we miss anything?

DO: I don't think so. I think you asked the questions that allow me to articulate my enthusiasm in this acquisition and just the belief in what Flatiron has achieved so far. I think this is really an opportunity to really accelerate the efficient delivery of care to cancer patients and that's we're all about, and I think together, we're going to do that even stronger and even better.

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

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CONVERSATION WITH
THE CANCER LETTER

PH.AI CEO Hyde: With Big Data, pharma will focus on the measurement of value

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Will providers accept clinical decision support from pharmaceutical companies, or will they be viewed as somewhat biased? I'm in the camp that providers and pharma are actually natural partners.

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Brigham Hyde
CEO and founder of Precision Health AI

Roche's acquisition of Flatiron Health signals the pharmaceutical industry's interest in using real-world data to measure value, said Brigham Hyde, CEO and founder of Precision Health AI, a company that uses artificial intelligence to define cancer datasets for precision oncology.

"If I were a pharmaceutical company, having more detailed information about my customers, be it patients or physicians, is always a strong place to be and I think they will probably focus on the measurement of value," Hyde said. "I think outcomes quality data is the key to all of this."

"If I was pharma, I would look in the mirror and say, 'We really need to know our customers.' I think that involves data and we need to be able to digitally engage them. And for Roche and Flatiron, they get that. They've got an EMR facing the patient-physician interchange, and they get really unique data to track and profile their patients. It makes sense."

PH.AI is not involved in the Roche-Flatiron deal.

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

Matthew Ong: Is the Roche acquisition a signal that oncology bioinformatics is moving away from the startup space into billion-dollar investment from pharmaceutical companies?

Brigham Hyde: I think the price tag is obviously exciting for those of us in this space. I think what is probably more interesting is that pharma would not have been considered a buyer, classically, for this type of business,

and they're now entering the space. That's really interesting.

I also think this signals the importance in oncology in particular. That market is incredibly competitive and deep EMR clinical data is a real important differentiator for the brands in that space.

Has anyone else bought an oncology bioinformatics startup?

BH: Not to date, that I am aware of. I do think there are some companies who have made investments. Actually, AstraZeneca was announced as an early partner on CancerLinQ and continues to be a partner going forward. I think there are others who look around that have, I think, small investments in different places. Novartis has made a number of digital and RWD based investments over the last several years.

Although, it's important to realize Roche is unique. They've always had a diagnostics business, which puts them a little bit in the data space already and also in the clinical decision support space. They have run that successfully, and somewhat separately for years. Not many other pharmaceutical companies have that sort of combo.

They're certainly a unique player, but our perception is, this is at least related—maybe not directly, but certainly indirectly, to the noise around Amazon as well as a lot of public consolidations between players like Aetna-CVS, or Amerisource Bergen and Walgreens, because data is power when it comes

to negotiating price and value of therapeutics. So, a very exciting time.

Do you think all of this will speed up evolution of clinical decision support infrastructure that can also generate regulatory-grade data in precision medicine?

BH: I think that's the big question. Will providers accept clinical decision support from pharmaceutical companies, or will they be viewed as somewhat biased? I'm in the camp that providers and pharma are actually natural partners, because they both face the insurance companies in terms of negotiating value for their care, so I actually think there are examples in other parts of the space where pharmaceutical companies do a lot now with ACO's and IDN's to help support care coordination, and patient communication and outreach and things like that.

So, yes, I think that's the directions it's heading. I think the potentially interesting question here is: is Roche trying to be a precision medicine company and make individual decisions for patients alongside doctors? I think that's an exciting question.

And with Roche now at the steering wheel, do you think that we might be seeing more of a push to set standards for health records?

BH: You know, that's an interesting question. I've been in the business a long time, so I'm a little cynical about making that change over night for standards. I've seen a lot of those come and go.

On the other hand, I think you have a very progressive and forward-think-

ing FDA at the moment, who is really interested in having active discussions about how to regulate the use of AI and RWD in clinical decision support. I expect active discussions to continue between the FDA and a number of industry players.

The 510(k) pathway for approval of the decision support algorithms is out there. I do think there's going to be some new and updating, at least guidances, if not as the more defined pathways yet to emerge. I for one am excited for that, being in the artificial intelligence space, I think there's a lot to do, a lot of low-hanging fruit are available, given the right data to empower doctors to make increasingly more precision decisions for individual patients.

Do you expect other pharma companies to start snapping up more health tech companies?

BH: I do. I certainly think it's possible. One of the things I would say: if I was a pharmaceutical company and I was trying to figure out what Amazon was going to do, I wouldn't look at Amazon's ability to manufacture drugs and run clinical trials and probably not be particularly concerned. On the other hand, their ability to distribute profitability and efficiency, as well as the general approach around the data they gather about their customers to better serve them goods and services, I think is a potential concern.

So, if I were a pharmaceutical company, having more detailed information about my customers, be it patients or physicians, is always a strong place to be and I think they will probably focus on the measurement of value. I think outcomes quality data is the key to all of this.

And speaking of Amazon, do you know if they're doing anything in the informatics and precision medicine space?

BH: I know as much and as little as anybody else does, but I think it's natural to assume that they serve the patients that pharmaceutical companies serve. Today they're delivering them paper towels and bottled water today, or they could be delivering them other types of things tomorrow that are close to the pharmaceutical setting. I think that would make sense.

I know that they've gone into the consumer health product space and there's some discussion about them going into the medical technology or device setting, at least as the distributor. I think that makes sense for their business.

I think what's equally relevant as Amazon are the Googles and Facebooks of the world. I think these are the people who are capturing tons of information about how patients are experiencing care, and the behaviors they have that are leading to potential health outcomes. So, I think all of these companies will be heard from in one way or another.

If I was pharma, I would look in the mirror and say, "We really need to know our customers." I think that involves data and we need to be able to digitally engage them. And for Roche and Flatiron, they get that. They've got an EMR facing the patient-physician interchange, and they get really unique data to track and profile their patients. It makes sense.

You're saying that Roche's is responding in a preemptive fashion to take the lead in shaping the health tech space?

BH: I think that's very clear, absolutely. Pharma has dabbled in this for many years and they've tried different forms of digital engagement. It's important to recognize that they're regulated in what they can say about the benefits of their drugs, etc., most of their investments are centered around that. If you look at different apps that are out there, for instance, they're mostly around decision support, or information for a given patient population.

This is a bigger step in that direction. It's a question mark to wait and see how providers react to the idea of the EMR they use being owned by a pharma company. Even though that would be highly regulated, and I do take Roche at their word, that they will operate Flatiron separately. But it is an open question.

If you think about outpatient oncology treatment and you think about the drugs today that are sold as buy and bill—situations where the provider is a partner with the pharmaceutical company already. They purchase drugs ahead of time and they are responsible for selling them to their patients. There's already a lot of alignment between providers and pharma. So this may be the natural next step.

I'm actually in the camp of, in the right setting, when they work together, they can actually provide a lot of value to patients, and coordination can drive that value. I'm sure that's the message that Roche will be taking out around this topic.

Is Precision Health AI funded by any pharmaceutical companies at this point in time?

BH: We're privately funded and we are not funded by any particular industry partner. That is somewhat deliberate, we like to be able to be Switzerland—sort of, a trusted independent, if you will, for a couple of reasons.

I think, number one, it allows us to gather data from multiple sources. So, I'm not an EMR. Flatiron is somewhat restricted by the amount of data they can capture, based on whether or not their EMR is installed. So, I don't have that problem. I can buy data from everybody, both on the EMR side and on the genomic side. I'm not a genomic testing lab, so I can partner with those folks.

From that perspective, that's important to me because when I'm trying to serve my pharma clients or my provider clients, it's important that I have the biggest, deepest, richest dataset I can get my hands on. We are an AI company, AI only works when you have a lot of data to train it on. I need a good training set, so it's important for us to stay independent at this moment.

I certainly work with pharmaceutical clients all the time and that's the discussion, which has amplified a bit over the last couple of weeks for sure, but for now, I think it's important to them to have a neutral party.

One of the other question marks is, how will other pharmaceutical companies react to the fact that Roche may own a data partner that they have worked with? And I think that Nat [Turner, co-founder and CEO of Flatiron] in his [blog post](#) made it very clear that they are going to operate independently

and Roche has a history of being able to do that in their diagnostics business. So we will see how it plays out.

But that is definitely going to be a question mark, particularly where there are competitive assets. Be it Pfizer or BMS competing with Roche Genentech, how will they feel about this? So, that's yet to be answered.

So, in the meantime, for PH.AI, we are trying to stay independent, and grow our data assets and be as useful as I can to pharma and these other types of partnerships.

Could you briefly describe PH.AI's business model? Also, what does artificial intelligence in oncology mean for physicians and hospital administrators?

BH: We work with pharma and providers, and a little bit with payers, but pharma is our primary client. We sell three things. We sell data that can be used by those companies for research. We sell applications, maybe it's tools for designing clinical trials or doing outcome-based research, so, software tools. And then we have our AI platform, which is called the Eureka Health Oncology AI Platform.

What AI means to me, and I'll try to be as simple as I can about this: in AI 1.0, you have Watson, and you have basically a big tool box. You could load your data up into it, you could pick an algorithm, you could run it, do what you need it to do. You usually have to have people who know what they're doing to do that, and then you have to know what to do with the outcome.

You're talking about IBM Watson, right?

BH: Yes, that's an example. They're sort of the ground breaker. They laid the groundwork for a lot of what's been done in AI in health care. And we know they've also had some struggles, places like MD Anderson and others.

So, what we're doing with Eureka, is that we basically pre-trained AI on the data that we have to do specific things. And we have about 60 or 70 pre-trained AI models where somebody has gone in, come up with an important question, and with the data, they have tested out a whole bunch of algorithms.

Sometimes you have deep learning, sometimes it's something more basic, just depends on what works best. We have built these productized modules to sit on top of our data, or any other data to make predictions and serve specific functions.

And I'll give you an example. We have a number of algorithms focused on adverse events that can predict which patients are likely to have adverse events to things like chemotherapeutics, so neutropenia is big problem.

When giving chemotherapy, knowing who to give it to and who not to give it to are very important. And our models are essentially trained to predict that, offer suggestions to a physician, and they can take action from there and look at the evidence.

Right now, most of the time we work with pharma, these things are meant to better help profile their populations. So, help predict who's going to take their drugs, who's going to do well, things like that.

We have not rolled these out into practice in a big way, so we're still in

discussions with regulatory bodies and going through the peer review process and things like that, to make sure these things are really validated by the community.

But I imagine a world in which inside your EMR, if you're a doctor, you could run one of our algorithms—think of them almost like an app—and I could run the adverse event app, and it would give me a prediction on that individual patient. And you could make a decision on how to use that data.

That's what we're doing. I think that's why we're gathering the data we're gathering, is how do we build these prediction tools that are pre-trained for specific things that are oncology specific that can do work and help physicians.

Is clinical decision support an avenue you plan on exploring for PH.AI?

BH: It's really too early to say anything specific, but it is certainly core to our roadmap. But all I can say is, stay tuned. We'll have more to say about that in a couple of months.

How are things coming along in terms of your work with Tempus on ASCO's Cancer-LinQ?

BH: It's going great. It's been fun diving in and getting deep into their data, which we've had access to for a while, but now it's flowing on a regular basis and we're prioritizing it, we're in the market with it. In short, I think the data is of extremely high quality from the perspective of its representation of cancer patients globally.

There's a great mix of communities and academic centers, so it's got a lot of bulk and it has its own set of challenges like every dataset does. It represents over a dozen different types of EMR, so it's very diverse. We were expecting that. We've worked through the data cleansing and all of these things, and are really getting some value out of it. I think you'll see a number of exciting publications from us and our partners over the next couple of months. We're very excited about it.

I'll point out that while ASCO CancerLinQ is a great source for us and a good starting place, we have also added additional data to that. We continue to expand both our size, scale, and detail and all of that. Other EMRs and other sites, whether it's other genomics data or data that helps round that out, we are full speed ahead on all of those fronts.

What can we expect to hear from you over the next few months?

BH: I think the next thing you'll see from us will be around [the Healthcare Information and Management Systems Society 2018 conference]—a couple of key partnerships and product announcements around our Eureka AI platform, which we've been somewhat quiet about, but we'll soon be very loud about.

And then a number of exciting things about the types of critical decision predictions where there will be new key clients working with us going into ASCO. So, it'll be a busy three to four months.

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IN BRIEF



Frederick Lab and Georgetown launch research, education collaboration

A collaboration between Georgetown University and the Frederick National Laboratory for Cancer Research aims to expand research and training missions in the biomedical sciences for both institutions.

Representatives from Georgetown and the Frederick National Laboratory signed a memorandum of understanding that paves the way for appointments and exchange of scientific staff, sabbatical opportunities, student training, postdoctoral fellowships and student internships aimed at enhancing the institutions' quality of science, technology, and education.

The new framework builds on past collaborations between Georgetown and Frederick researchers and formalizes an ongoing relationship.

Yale joins BMS International Immuno-Oncology Network

Bristol-Myers Squibb Company said the Yale Cancer Center has joined the International Immuno-Oncology Network, a global peer-to-peer collaboration between Bristol-Myers Squibb and academia that aims to advance translational Immuno-Oncology science.

Formed in 2012 by Bristol-Myers Squibb, the II-ON was one of the first networks to bring academia and industry together to further the scientific understanding of I-O, and has since expanded from 10 to 16 sites across North America, Europe, Japan and Australia.

The partners collaborate to generate innovative I-O science, launch biology-driven trials and apply cutting-edge technologies with the goal of translating research findings into clinical trials and, ultimately, supporting efforts to improve survival outcomes across tumor types.

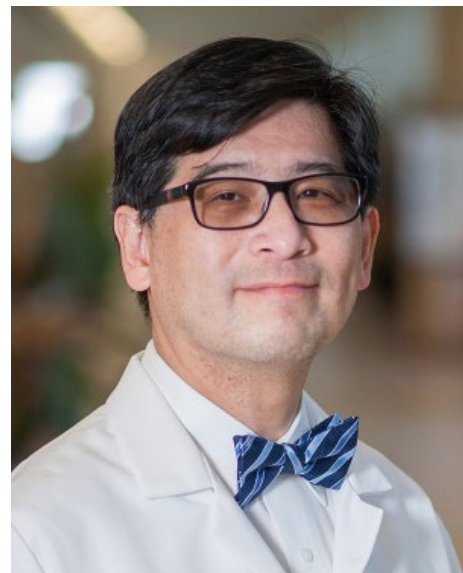
The II-ON was formed on the foundation of three fundamental scientific pillars aimed at addressing key research priorities in I-O: understanding the mechanisms of resistance to immunotherapy; identifying patient populations likely to benefit from immunotherapy; and exploring novel combination therapies that may enhance anti-tumor response through complementary mechanisms of action. By providing a streamlined framework for peer-to-peer collaboration among global cancer research leaders, the network is able to more rapidly facilitate I-O innovation and drug discovery.

In addition to the II-ON, the company has invested in several other models of scientific collaboration with academic partners across the globe, including

the Global Expert Centers Initiative, the Immuno-Oncology Integrated Community Oncology Network, and the Oncology Academic Research Group.

In addition to Bristol-Myers Squibb, the II-ON currently comprises 16 cancer research institutions, including: Clínica Universidad Navarra, Dana-Farber Cancer Institute, The Earle A. Chiles Research Institute (Providence Health & Services), Institut Gustave Roussy, Istituto Nazionale per lo Studio e la Cura dei Tumori "Fondazione G. Pascale", Bloomberg-Kimmel Institute for Cancer Immunotherapy at the Johns Hopkins Kimmel Cancer Center, Memorial Sloan Kettering Cancer Center, National Cancer Center Japan, The Netherlands Cancer Institute, The Royal Marsden NHS Foundation Trust and The Institute of Cancer Research, University College London, The University of Chicago, West German Cancer Center/University Hospital Essen, Columbia University Medical Center, Peter MacCallum Cancer Centre, and now, Yale Cancer Center.

Fung and the Fox Chase BMT Program receives "Game Changer Award"



Henry Fung and the Fox Chase-Temple University Hospital Bone Marrow Transplant Program will receive the Andy Talley Bone Marrow Foundation's first "Game Changer Award" during the 7th Annual Bash March 3.

The Fox Chase-Temple University Hospital BMT Program is one of only three institutions in the country to provide bloodless transplant procedures for patients who request this complex technique. They earned the status of a "Blue Distinction Center for Transplants" by IBC in 2015 in recognition of the Fox Chase-Temple University Hospital Bone Marrow Transplant Program's expertise in performing adult bone marrow transplants.

The program is fully accredited by the Foundation for the Accreditation of Cellular Therapy—the gold standard of excellence for blood and bone marrow transplant programs in the United States—and the National Marrow Donor Program.

Fung came to Fox Chase from Rush University Medical Center, where he was a professor of medicine since 2005. He served as director of the section of bone marrow transplant and cell therapy; director of the Coleman Foundation Blood and Marrow Transplant Center, where he also held the Coleman endowed chair; clinical leader of hematologic malignancies; and senior attending physician.

Recognition will also be given to Joseph Pawlowski, a Lycoming College Football player who registered as a potential donor at Lycoming Football's first "Get in the Game, Save A Life" drive in the spring of 2015, was selected as a match, and in November 2015, he had the opportunity to save a football game on Saturday, and a life just four days later. Pawlowski will be recognized, as will the patient who got a second chance, together for the first time in public.

MD Anderson and RaySearch form alliance to advance radiation therapy

MD Anderson Cancer Center and RaySearch Laboratories formed a strategic alliance with the aim of enhancing cancer radiation therapy through several initiatives, including more precisely targeting of tumors and improving upon, and making more available, an existing radiation therapy called adaptive radiation therapy, currently only used at highly specialized care centers.

Traditionally, additional margins are set around the target area to allow for tumor movement and variations in how patients are positioned during treatment.

However, these margins do not always compensate for unexpected changes in the tumor and surrounding normal tissue over the full course of radiation treatment. Adaptive radiation therapy uses frequent imaging to give an up-to-date assessment of physical changes and enable precisely tailored treatment for each patient.

The partnership, which builds upon a previously established relationship between RaySearch and MD Anderson centered on RayCare, RaySearch's new oncology information system, combines MD Anderson's clinical data and expertise with the latest technology and platforms available through RaySearch and will focus on the following areas:

- Integration of advanced imaging into the treatment planning process to help define the tumor targets better.
- Management of changes in the tumor that may occur during treatment, and monitoring and adjusting treatment to accommodate each patient's individual circumstances at any point during therapy.

- Building software components with the aim of creating a new standard of care in radiation therapy.

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THE CLINICAL CANCER LETTER



TRIALS & TRIBULATIONS

A phase III trial seeks to determine whether diet and exercise can cure breast cancer



By Jennifer A. Ligibel

Director of the Leonard P. Zakim Center for Integrative Therapies and Healthy Living, Senior physician at the Dana-Farber Cancer Institute and associate professor of medicine at Harvard Medical School

Could diet and exercise really cure breast cancer?

For more than 50 years, studies have shown that women who are obese at the time of breast cancer diagnosis have an increased risk of cancer recurrence and mortality, as compared to women who are leaner at diagnosis.

Animal models have shown that caloric restriction and increased physical activity prevent breast tumor formation and slow cancer growth. Dietary intervention studies in women with early

breast cancer suggest that reduction in dietary fat intake, combined with modest weight loss, leads to a reduction in the risk of breast cancer recurrence whereas dietary fat reduction without weight loss does not impact prognosis.

This research has contributed to the countless headlines promising patients that eating organic/vegan/paleo/keto/etc. will prevent their cancer from recurring, but the actual evidence that changes in diet and exercise after diagnosis could affect outcomes in women with breast cancer has been scant.



Now, a randomized trial will test the impact of a weight loss program, based on caloric restriction and increased exercise, on the risk of cancer recurrence and mortality in overweight and obese women with breast cancer.

The Breast Cancer Weight Loss (BWEL) trial is a phase III trial, sponsored by the Alliance for Clinical Trials in Oncology, that will enroll 3136 women with newly diagnosed breast cancer and a BMI of at least 27 kg/m² and randomize them to a telephone-based weight loss intervention or health education control group. The trial is powered to detect a 20% improvement in invasive disease-free survival in the weight loss group versus controls. The weight loss program is based upon the Diabetes Prevention Program; however, unlike the DPP, which was delivered in person in small groups, we designed the BWEL weight loss program to be delivered

out the intervention period to follow changes in metabolic, immune and inflammatory pathways. Tumor and benign tissue from participants' breast surgery is also collected to explore predictive biomarkers for the effect of the weight loss program, providing critical information not only about whether the program works, but also in whom it is most successful in reducing the risk of recurrence and mortality.

It is always difficult to predict the adoption of a randomized trial, especially a trial like BWEL that tests an unconventional treatment program. In designing the trial, we had hoped to enroll patients in over about 4 years, recognizing that a recruitment rate of almost 800 patients per year was an ambitious goal for the first large scale lifestyle intervention study conducted by the Alliance. We were hopeful when the first patient was registered the day

typically involved in oncology studies, including Fitbit and Nestlé Health Science, who have made in-kind product donations of activity trackers, wireless scales and protein meal replacements to support participants in achieving weight loss goals.

This in-kind support has been especially helpful given the complex funding considerations of the trial. Given that the study is being conducted through the Alliance and was approved by the Breast Cancer Steering Committee, funding for central administrative costs and per-patient reimbursement is supported by CTEP.

However, there is no funding for lifestyle interventions through this mechanism. Two other NCI divisions, DCP and DCCPS have supported most of the costs of administering the BWEL weight loss program, but the brisk rate of accrual and unanticipated costs associated with conducting a large-scale lifestyle intervention trial in multiple countries and languages has led to the need for other groups, such as the Susan G. Komen Foundation, the Breast Cancer Research Foundation, and the American Cancer Society to also provide financial support to ensure a consistent and robust weight loss intervention for study participants. Successful conduct of this trial has thus required extensive collaboration across the breast cancer community and beyond.

Over the next few years, the BWEL study will finally give us conclusive evidence of the impact of changes in diet and exercise on breast cancer recurrence and mortality. Early signs from the study suggest that patients are eager to incorporate lifestyle changes into their cancer treatment, allowing them to play a more active role in their care and hopefully to help establish a new standard of care for the generations of breast cancer patients who follow them.



This research has contributed to the countless headlines promising patients that eating organic/vegan/paleo/keto/etc. will prevent their cancer from recurring, but the actual evidence that changes in diet and exercise after diagnosis could affect outcomes in women with breast cancer has been scant.



through the telephone and web, making the program accessible to a diverse population of breast cancer survivors across the US and beyond.

The trial also includes a translational component to explore the mechanisms underlying the obesity-cancer link. Participants in both groups undergo serial collection of fasting blood through-

after the study opened in August of 2016 and have been incredibly gratified to continue to experience robust enrollment, with more than 1000 participants, representing 48 states and 2 Canadian provinces, randomized within the first 17 months after study activation. BWEL has also resonated outside the oncology community, attracting a number commercial partners not

CLINICAL ROUNDUP



NCCN guidelines for patients with HIV seek to reduce cancer care gaps

The National Comprehensive Cancer Network has released a new NCCN Clinical Practice Guidelines in Oncology intended to help make sure people living with HIV who are diagnosed with cancer receive safe, necessary treatment.

In 2010, an estimated 7,760 PLWH in the United States were diagnosed with cancer, representing an approximately 50% higher rate than the general population. However, studies have found PLWH are treated for cancer at significantly lower rates than HIV-negative people with cancer, despite most treatment courses being safe and effective in this population.

The most-common types of cancer occurring in people living with HIV are, in order of incidence: non-Hodgkin's lymphoma, Kaposi sarcoma, lung cancer, anal cancer, prostate cancer, liver cancer, colorectal cancer, Hodgkin lymphoma, oral/pharyngeal cancer, female breast cancer, and cervical cancer.

The new NCCN Guidelines for Cancer in People Living With HIV includes general advice—while highlighting the importance of working in collaboration with an HIV specialist—as well as specific treatment recommendations for non-small cell lung cancer, anal cancer, Hodgkin lymphoma, and cervical cancer.

Additional recommendations can be found in the recently-released NCCN Guidelines for AIDS-Related Kaposi Sarcoma as well as the AIDS-related B-cell lymphomas section of the NCCN Guidelines for B-cell Lymphomas.

Among the recommendations found in the new NCCN Guidelines:

- Most PLWH who develop cancer should be offered the same cancer therapies as HIV-negative individuals, and modifications to cancer treatment should not be made solely on the basis of HIV status.
- Care for patients diagnosed with HIV should be co-managed with an oncologist and an HIV specialist.
- Oncologists and HIV clinicians, along with HIV and oncology pharmacists, if available, should review proposed cancer therapy and ART for possible drug-drug interactions and overlapping toxicity concerns prior to initiation of therapy.

The NCCN Guidelines Panel for Cancer in People Living With HIV included oncologists, radiologists, infectious disease specialists, surgical oncologists, pharmacists, and a patient advocate. The panel stressed the importance of increasing the number of PLWH who participate in clinical trials for cancer treatments. Clinicians working with PLWH who have cancer should use clinicaltrials.gov to help patients find appropriate trials.

CancerCare publishes findings from oncology provider study

CancerCare published a white paper highlighting perspectives from oncology providers on the importance and utility of including patient priorities in treatment decisions.

“[Decision Making at the Point of Care: Voices of Oncology Providers](#)” was developed as part of CancerCare’s Patient Values Initiative, a multi-pronged effort aimed at reframing the national healthcare policy framework to ensure that patient engagement in treatment decision-making becomes the true standard of care.

This newly published white paper builds on the findings from the first PVI white paper, “[Patient Values Initiative: The Many Voices of Value](#)”, published in 2017. The first white paper provided findings from focus group interviews with oncology social workers and patients, highlighting the importance and value of including what’s important to patients in their treatment plans, and reinforced the need for resources to help patients articulate their quality of life priorities before treatment begins.

The latest white paper includes information from in-depth interviews with 15 oncology providers including physicians, advanced practice nurses, practice managers and health IT experts. Focused on the provider perspective, it demonstrates that while many oncology providers have a desire to learn more about their patients, both personally and clinically, there are significant barriers to ensuring that patient priorities are part of treatment decision making.

These barriers include the absence of formal procedures to capture personal

information and share it among care team members, the challenges of interoperability between data sources, and the lack of electronic medical records fields that prompt the collection of patients' quality of life priorities.

Looking to the future, over the next several months, CancerCare will conduct a quantitative survey among oncology clinicians to better understand the findings from this qualitative research.

Along with the perspectives from the patient and provider focus groups, it will inform the development and pilot testing of turnkey, low cost tools to facilitate the communication of patients' quality of life priorities during treatment planning. The ultimate goal of the PVI is to ensure that genuine patient engagement in cancer treatment decision making becomes the standard of care, so that treatment plans reflect the true priorities, goals and needs of each patient.

CancerCare sponsors included: AbbVie, Bristol Myers Squibb, Celgene Corporation, EMD Serono, Lilly, Merck, Pfizer, PhRMA, Takeda Oncology.

A third of patients with lymph node-positive penile cancer don't receive recommended care

One third of men with lymph node-positive penile cancer don't receive a lymph node dissection, the recommended care associated with an overall survival advantage, researchers from Fox Chase Cancer Center have found. The paper appears in JAMA Oncology.

The researchers used the National Cancer Database to evaluate patient care at hospitals nationwide, and found that men had a better overall survival

rate after undergoing a lymph node dissection, while neither chemotherapy nor radiation was associated with a survival benefit. But, they found that one third of patients did not undergo a lymph node dissection.

The National Comprehensive Cancer Network guidelines advocate for lymph node dissection or radiotherapy with consideration of perioperative chemotherapy for all patients with lymph node-positive penile cancer without metastasis.

Researchers also found that while the use of chemotherapy has increased over the past decade, rates remain below 50 percent. Older patients in particular were less likely to receive chemotherapy.

DRUGS & TARGETS



Lilly receives additional FDA approval for Verzenio for advanced breast cancer

Eli Lilly and Co. said FDA has approved Verzenio (abemaciclib) in combination with an aromatase inhibitor as

initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor-positive, human epidermal growth factor receptor 2-negative advanced or metastatic breast cancer.

This additional FDA approval marks the third indication for Verzenio within five months. In September 2017, Verzenio became the first and only cyclin-dependent kinase 4 & 6 inhibitor approved in combination and as a single agent in metastatic breast cancer.

Verzenio was approved for use in combination with fulvestrant for the treatment of women with HR+, HER2-advanced or metastatic breast cancer with disease progression following endocrine therapy, and as monotherapy for the treatment of adult patients with HR+, HER2-advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

This approval of Verzenio as initial therapy in combination with an AI is based on the efficacy and safety demonstrated in the pivotal MONARCH 3 clinical trial. MONARCH 3 is a phase III, randomized, double-blind, placebo-controlled trial evaluating Verzenio in combination with an AI as initial endocrine-based therapy that enrolled 493 postmenopausal women with HR+, HER2-advanced breast cancer who had no prior systemic treatment for advanced disease.

In patients who received neoadjuvant/adjuvant endocrine therapy, a disease-free interval of more than 12 months since completion of endocrine therapy was required. This Verzenio new drug application was given Priority Review as part of the FDA's Expedited Programs for Serious Conditions, a program used for therapies that address an unmet medical need in the treatment of serious or life-threat-

ening conditions, such as metastatic breast cancer. Verzenio was also granted Breakthrough Therapy Designation in 2015 based on the phase I JPBA trial.

In MONARCH 3, Verzenio dosed orally at 150 mg twice daily on a continuous schedule with an AI demonstrated a greater than 28-month median progression-free survival in patients who received initial endocrine-based therapy for metastatic disease (28.2 months [95% CI: 23.5-NR] vs 14.8 months [95% CI: 11.2-19.2] with placebo plus an AI [HR: 0.54; 95% CI: 0.418-0.698, $P < 0.0001$]).

In patients with measurable disease who received Verzenio plus an AI ($n=267$), an objective response rate of 55.4 percent was achieved (defined as complete response plus partial response [CR + PR], and based upon confirmed responses; PR defined as $\geq 30\%$ reduction in target lesions)¹ ($n=148$; 95% CI: 49.5-61.4), with 52.1 percent of patients having achieved a PR ($n=139$) and 3.4 percent having achieved a CR ($n=9$).² In comparison, in the placebo-plus-AI group of patients with measurable disease ($n=132$), ORR was 40.2 percent ($n=53$; 95% CI: 31.8-48.5), with all women being partial responders. Median duration of response was 27.4 months with Verzenio plus an AI (95% CI: 25.7-NR) versus 17.5 months with placebo plus an AI (95% CI: 11.2-22.2).

MONARCH 3 is a phase III, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of Verzenio (abemaciclib), a CDK4 & 6 inhibitor, in combination with an AI (anastrozole or letrozole), as initial endocrine-based therapy for postmenopausal women with HR+, HER2- advanced (locoregionally recurrent or metastatic) breast cancer who have had no prior systemic treatment for advanced disease.

If neoadjuvant/adjuvant endocrine therapy was administered, a dis-

ease-free interval of more than 12 months since completion of endocrine therapy was required. A total of 493 patients were randomized 2:1 to receive 150 mg of Verzenio or placebo orally twice a day, without interruption, given in combination with either 1 mg of anastrozole or 2.5 mg of letrozole once daily until disease progression or unacceptable toxicity. The primary endpoint of the study was PFS, with key secondary endpoints of ORR, DoR, overall survival and safety.

Yisheng's biological product for pancreatic cancer gets Orphan Drug Designation

Yisheng Biopharma Co., Ltd., said the FDA has granted orphan drug designation for its lead immuno-oncology candidate, YS-ON-001, for pancreatic cancer.

To date, FDA has granted YS-ON-001 two ODDs for the treatment of pancreatic cancer and hepatocellular carcinoma. YS-ON-001 is a clinical-stage immuno-oncology biologic product with unique immunomodulating mechanism and broad spectrum of anti-tumor activity.

YS-ON-001 is a clinical stage biological product based on our proprietary immunomodulating cell technology developed in-house at Yisheng Biopharma. It is a multi-component complex with broad immunomodulating properties, such as promoting Th1-biased immunity, inducing the activation and proliferation of dendritic cell, B and natural killer cells, promoting macrophage M1 polarization and downregulating regulatory T cells.

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