HOW DRUGS GO VIRAL: FLATIRON’S REAL-WORLD DATA SHOW HOW UPTAKE HAPPENS

The graphs make it seem simple: Doctors learn about a new therapy. They start to prescribe it. A standard of care is born. In a matter of months.

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And you can see it all in utilization data compiled by Flatiron Health and made available to The Cancer Letter. Data gleaned from electronic health records of nearly 35,000 cancer patients make it possible to correlate landmark events—presentation, publication, approval—with real-world prescribing patterns.

The data, presented in line graphs published here, show expanding use of targeted agents and immunotherapies over the past two years in the treatment of patients with advanced non-small cell lung cancer and Hodgkin’s disease. The graphs show how physicians rely on clinical trial results immediately after they are presented or published—well before FDA approval.

Flatiron’s dataset focused on utilization of the following drugs:

- Nivolumab (Opdivo) and pembrolizumab (Keytruda), programmed death-1 checkpoint inhibitors, in advanced NSCLC patients,
- Nivolumab in patients with Hodgkin’s lymphoma, and
- Crizotinib (Xalkori), an anaplastic lymphoma kinase and c-ros onco-gene-1 inhibitor, in NSCLC patients.

The immediacy of reporting is unprecedented: it’s not a surprise that oncologists use early trial data to guide clinical decision-making prior to FDA approval, but no one has aggregated this information in real time.

Flatiron’s analysis, which relies on data from their collaboration with FDA as well as other data, allows researchers to study drug utilization as the market evolves, enabling pharmaceutical companies and payers to make quick production and reimbursement decisions in tandem with evolution of the standard of care.

Maria Koehler, vice president of oncology strategy, innovation and collaborations at Pfizer Oncology, said the NSCLC data from the bioinformatics company is particularly valuable.

“It shows how the market changes and the speed of the change. This is tremendously important,” Koehler said to The Cancer Letter. “It shows which other drugs are replaced in the therapeutic setting by the introduction of the new PD-1 drugs.”

For instance, the dataset that tracks the uptake of nivolumab and pembrolizumab for treatment of advanced NSCLC illustrates how the proportion of NSCLC patients receiving PD-1 inhibitors went from zero to nearly 40 percent in 27 months.

“These data show when the uptake happens. It begins to rise a little bit with publication—and a lot with FDA approval,” Koehler said. “What’s stunning in the uptake of PD-1 inhibitors is how fast it happened—the speed of the adoption.”

Pfizer is working on several real-world data projects to develop a reliable method for making the data useful to FDA.
Lag time? What’s that?

The Flatiron dataset is evidence that practitioners are adopting new therapies very quickly, contrary to conventional wisdom, said Amy Abernethy, chief medical officer, chief scientific officer, and senior vice president of oncology at Flatiron.

“What you see is rapid expansion of a new treatment across the cancer care setting. The usual story is that clinicians take a decade or more to change their practice when new evidence comes along. This is not what we see in oncology,” Abernethy said. “Maybe one of the reasons that this story is so unprecedented, truthfully, is we’ve never been able to see it before.

“If we’re going to use real-world evidence for guiding research and for improving clinical care, then the datasets must be complete and accurate. We’ve got to be able to get to the key data points that live within unstructured documents. For example, information about histology is embedded in the path report, which is lodged in the chart as a PDF. Somebody has got to look through that path report in some way, shape or form and pull out the key critical data points. That’s one of our big areas of focus.”

The data show significant off-label use of certain drugs prior to FDA approval for particular indications—in the first-line setting for NSCLC, for instance. The uptake of nivolumab in patients with Hodgkin’s disease is especially dramatic: off-label use doubled within six months before the agency approved the drug for Hodgkin’s disease in May 2016.

“Some of what you see here is oncologists starting to practice first-line management before the approval, based on what they knew from the evolving literature,” Abernethy said. “Why is this happening? If we look at the medical records, we can see that oncologists are writing those clinic notes citing the literature.

“Other factors probably include oncologists believing it’s a better drug, or the patient has specifically requested that they get a PD-1 inhibitor,” Abernethy said to The Cancer Letter. “This illustrates the need to aggregate across many, many sites of care with many patients and generate big datasets to tell stories like the one you’re seeing here.”

Before bioinformatics companies started to aggregate real-world evidence in a meaningful way, researchers had to comb through information sources such as claims data and billing records to explore how products were being used, said Jeff Allen, president and CEO of Friends of Cancer Research.

“I found it to be pretty interesting in terms of how quickly different products kind of permeate the market, and I would imagine that PD-1 inhibitors have done so with great efficiency, just given the amount of publicity and the excitement around the effect of the drugs,” Allen said to The Cancer Letter. “In the past, there’s been much more of a lag time in understanding uptake and patterns of use than what’s possible now through electronic data capture.”

The rapid uptake of these new agents into clinical practice underscores the need for evaluating the effectiveness of these drugs in the real-world, said Cary Gross, professor of medicine and of epidemiology at Yale School of Medicine.

Gross and Jeremy O’Connor, a postdoctoral fellow at Yale, are co-authors of a study on disparities in access to PD-1 agents. The initial findings of the study, which is based on Flatiron’s data, were presented at the 2017 annual meeting of the American Society of Clinical Oncology in Chicago.

“We hope that the work we presented at the ASCO meeting will encourage investigators to consider novel ways to explore equity issues in a timely manner as well,” Gross said to The Cancer Letter. “That way, the real-world data
are really being put to use across several sectors within the health care system—by investigators who are interested in whether the drugs work—and also, among the drugs that are indeed effective, other investigators, policy makers, and advocates can determine whether there is equal access.”

By testing for disparities by race and sex over the first year after PD-1 drugs were approved by FDA, using data from Flatiron, O’Connor and Gross were able to find over 4,000 patients who received these drugs.

“Part of our motivation for using these data was the fact that disparities are very well known in cancer treatment, both in access to clinical trials, as well as access to treatment and engagement in treatment,” O’Connor said.

“So, in an environment where many new cancer treatments are being approved and the landscape for cancer is changing very rapidly, we think it’s useful to be able to look for disparities and monitor for those differences by using real-world evidence.”

In their initial analysis, they found disparities by sex in the use of these anti-PD1 drugs among patients with lung cancer.

“Specifically, we found that men were significantly more likely to receive either nivolumab or pembrolizumab than women. We think this finding is important and worthy of further study,” O’Connor said. “There may be additional factors that affected the use of these drugs among male vs. female patients. That’s something that needs to be clarified with additional data.”

The Flatiron dataset allowed O’Connor and Gross to quickly process evidence on how frequently these drugs are used in real-world practice. In this particular project, they were able include data through August 2016, and finish their analysis within four or five months.

“When you can gather high-quality data so quickly, you can monitor for disparities in almost real-time,” O’Connor said.

In prior work exploring disparities in health and health care, the lag between the actual care delivery and the published report was frequently measured in years.

“The typical cancer registry data usually has a lag time of a couple of years,

**UPTAKE OF PD-1 SHARE OF THERAPY IN ADVANCED NSCLC PATIENTS**

1. **Mar 2015:** FDA approval of nivolumab (nivo) for treatment of patients with metastatic squamous NSCLC with progression on or after platinum-based chemotherapy

2. **May 2015:** ASCO announcement that CheckMate 057 trial data showed nivo has OS advantage (over docetaxel) in non-squamous NSCLC

3. **Oct 2015:** FDA accelerated approval of pembrolizumab (pembro) for treatment of patients with metastatic, PD-L1 positive NSCLC, as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy

4. **Oct 2015:** FDA approval of nivo for treatment of patients with metastatic non-squamous NSCLC with progression on or after platinum-based chemotherapy

5. **Jun 2016:** ASCO announcement that KEYNOTE-024 trial was stopped for positive results, including PFS and OS

6. **Oct 2016:** FDA approval of pembro for first-line treatment of patients with metastatic NSCLC whose tumors express PD-L1 as determined by an FDA-approved test
and most publications that use administrative claims such as Medicare can be lagging three, four, five years behind," Gross said. “By the time you're looking at a publication, you're looking at a view of the world from five years ago, and some of the pertinent clinical issues and equity concerns may have already evolved considerably since then.”

**Allen: Incentivizing industry with real-world data**

Real-world data, as demonstrated by Flatiron, could become a powerful instrument for tracking patient outcomes in the long run, Allen said.

“A pilot project in the PD-1 space is trying to look at, based on real-world evidence, whether they can correlate information about tumor mutational load in terms of the response to PD-1 inhibitors,” Allen said. “For example, if patients in a defined dataset that had broad genomic screening information, algorithms to determine mutational frequency could be developed to assess if higher rates of mutational frequency correlate to response to PD-1 inhibitors.”

Real-time data curation will soon make it possible for pharmaceutical companies to generate alternative sources of information to support their pre-market packages.

Currently, changes to an FDA-approved product are made through the Supplemental New Drug Application process, which pharmaceutical companies use to establish different uses for drugs that are already on the market. Towards the end of the life cycle of a drug, companies usually throttle back investment in ongoing research for the product.

“Over time, drugs that have evolved with additional information in the post-market space are worth examining to see how that information might be incorporated into the FDA label,” Allen said. “With real-world data, FDA can play a role in adjudicating the quality of that evidence over time, more so than they perhaps have in the past.”

By having additional data late in the life cycle of a drug, companies will be incentivized to update FDA labels for their drugs.

“Right now, it is the company’s responsibility, at least for information outside of serious safety events, to proactively bring that information and submit for a change of their label,” Allen said. “It would be beneficial if a more clarified path, for example, could be identified in which a label could be updated, particularly later on when there isn’t the motivation to conduct the immediate studies for an sNDA, for example, in the case of a generic drug.”

“Through investigator-initiated trials, there may be emerging information about the use of those drugs. So, is there

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**UPTAKE OF NIVOLUMAB IN PATIENTS WITH HODGKIN’S DISEASE**

1. **Dec 2014**: ASH data release on use of nivolumab (nivo) in Hodgkin’s Disease (HD)

2. **Jan 2015**: NEJM article on use of nivo in HD

3. **Feb 2015**: First observed use of nivo in HD (in Flatiron data)

4. **Dec 2015**: ASH data update on promising use of nivo in HD

5. **May 2016**: FDA approval of nivo in HD
a way to try and encourage the information to be brought to the FDA, when it is of the high enough quality so that the label could reflect that? Is that incentive enough for additional investment into generating the highest quality data?

“Those are questions that I think are a little bit open-ended, but given the investment—both in private and now in the public sectors—to look at the different roles of real-world evidence, it is important to think about the end result, i.e. what is the optimal utilization of this data in the long run?”

Real-world evidence should not be used to circumvent the sNDA process, which remains the gold standard and most appropriate way to amend the label for new indications based on additional studies, Allen said.

“However, in the life cycle of the drug—as we’re able to collect more information about its use over time—that there may be situations where the label should appropriately reflect different conditions of use for the drug, that have not prior been formally studied or supplied back to the FDA,” Allen said. “It’s a good conversation worth having, about what the role the FDA approved label should be.”

FDA’s commitment to creating a regulatory framework for real-world evidence is what prompted Pfizer to work with the agency to process post-market data, Koehler said.

“It’s a two-way street,” Koehler said. “The acceptance of the real-world data will change Pfizer’s approach mostly to life-cycle management of drugs. We will probably design our development plans to have a broader usage, because we would be able to evaluate, for example, patients with diabetes, who are excluded from the original trials.”

Ideally, real-world evidence should be used as a “dashboard” to not only track patterns of care, but also to track equity, access and outcomes for prompt assessment of the impact of new treatments on patients, Gross said.

“Wouldn’t it be great if we could see whether there are differences in the quality of care—in the patient experiences—in patient survival in real time, rather than waiting years?” Gross said. “ Heck, we have updated information on the stock market indices or the unemployment rate scrolling across the bottom of our TV or computer screens, updated constantly. Should we have similar systems for health and healthcare data?

“These new Big Data efforts can be bringing us a step closer to having actionable real-time data that can help to inform efforts to improve population health and equity.”

UPTAKE OF CRIZOTINIB IN ALK-, ROS-1 PATIENTS

1. Nov 2013: FDA regular approval of crizotinib
2. Sep 2014: NEJM article on use of crizotinib in ROS1-rearranged NSCLC patients
3. Mar 2015: JCO publication and editorial on use of crizotinib in ROS1-rearranged NSCLC patients
4. Sep 2015: ESMO abstract from the European Journal of Cancer on biomarker-driven access to crizotinib in ALK, MET or ROS1 positive (+) malignancies
5. Mar 2016: FDA approval of crizotinib for ROS-1 patients
Maria Koehler: Real-world data is "truly a revolution"

“This is truly a revolution. Real-world data teach us about how the patients stay on the drug, or don’t stay on the drug, or want this drug, or don’t. It provides insight for FDA, the payers, and the patients. And it teaches us about the value patients and physicians ascribe to our medicines. It’s just good.”

Maria Koehler
Vice president of oncology strategy, innovation and collaborations, Pfizer Oncology
Koehler spoke with Matthew Ong, a reporter with The Cancer Letter.
Real-world evidence is more than just another way of tracking post-market patterns in drug utilization, said Maria Koehler, vice president of oncology strategy, innovation and collaborations at Pfizer Oncology.

New technology for tracking real-world data may soon change the way pharmaceutical companies approach drug development. By analyzing real-time data, industry can use robust evidence from oncology practices to update drug labels, track market trends, and adjust production.

“For example, let’s look at anti-VEGF drugs like Avastin,” Koehler said. “If Avastin is used in non-small cell lung cancer, but a better drug is coming, then, of course, the Avastin segment would decrease dramatically, because the new drug is presumably better.

“This is the key here—presumably better, because there is no direct comparison between angiogenesis inhibitors and PD-1. But the market is telling us how it interprets the trial data or how physicians interpret the data. This is where the value is—truly.”

Koehler agreed to review drug utilization data compiled by Flatiron Health and made available to The Cancer Letter. The dataset tracks the uptake of PD-1 checkpoint inhibitor drugs in nearly 35,000 non-small cell lung cancer patients over two years.

Before advanced techniques for data aggregation became available, companies were unable to reliably assess the value of a drug on the market after receiving FDA approval.

“Now the technology is here, but it needs Flatiron—there are several other companies working on evaluation—to interpret the data,” Koehler said. “If one can make the datasets clean enough, precise enough, and sufficiently robust, they can be submitted to FDA.”

The data generated by Flatiron are specifically interesting for Pfizer as well as many other pharma companies, because they concern the booming growth of PD-1 inhibitors in NSCLC.

The Flatiron data include 24,000 patients in first line NSCLC, and many thousands in the second line and third line. The collection of these data is something that was not possible even a few years ago, when we did not have electronic health records and did not have the technology to understand how to use the rich data available in EHRs.

We are going to use the data not only for our purposes, but also for FDA as outlined in the 21st Century Cures.

Number one, we are doing a lot of clinical trials, some of which are carried out in artificial populations. In clinical trials, patients enrolled never reach the numbers that you see here, in this dataset—24,000 patients in first line. You never can do a trial like this, at least in oncology.

Number two, the data presented are truly real-world. This is what FDA is currently focused on, because they are asking the question, “Okay, we are putting drugs on the market based on clinical trials, but does anyone know how the drugs are really doing in the market?”

Nobody was following up on the data in great detail and with large numbers, because technology to interpret the data and follow up didn’t exist. Now the technology is here, but it needs Flatiron—there are several other companies working on evaluation—to interpret the data.

We need to find a reliable method for utilizing the data: to make this data useful to FDA, to patients, payers, and the pharmaceutical industry. If one can make the datasets clean enough, precise enough, and sufficiently robust, they can be submitted to FDA.

That’s what Flatiron and Pfizer are working on with FDA. We have additional projects to make these data from the real world useful. The data then could be presented in lieu of clinical trials in some instances, but also expand our understanding of how the drugs are really working in general patient populations, how they are really used. Ergo, what is the value of these drugs in the market?

You don’t really know what the value of a drug is when it’s launched. All you know is the results of clinical trials—the survival, response rate, PFS etc.—but you really don’t know anything more.

Are Pfizer drugs included in the Flatiron dataset?

MK: The data include several drugs from Pfizer. For example, ALK inhibitors. We have the first ever ALK inhibitor, crizotinib, which was a pioneer in this space. These data are useful for confirming our expectations of how the drugs are doing in the market.

We also have a PD-1 inhibitor, but the PD-1 inhibitor is not launched in any of the diseases analyzed in the Flatiron dataset. Avelumab is launched in Merkel Cell cancer and in urothelial cancer. It’s not in the NSCLC dataset.
We have done extensive work on real-world data, both with crizotinib as well as palbociclib. We are also working on a couple of real-world approaches for our angiogenesis inhibitors—axitinib, sunitinib and several other drugs in our portfolio.

None of this work is used for regulatory submission yet, because you need to have data that are of certain regulatory quality. And this is what we are working on: making these data so reliable that FDA would be able to interpret them.

The time course data is what makes the Flatiron set particularly valuable. You have data from 2015 to 2017, basically month by month. It shows you how the market changes and the speed of the change. This is tremendously important.

Coming back to the question of value: it shows which other drugs are replaced in the therapeutic setting by the introduction of the new PD-1 drugs.

For example, let’s look at anti-VEGF drugs like Avastin. If Avastin is used in non-small cell lung cancer, but a better drug is coming, then, of course, the Avastin segment would decrease dramatically, because the new drug is presumably better.

This is the key here—presumably better, because there is no direct comparison between angiogenesis inhibitors and PD-1. But the market is telling us how it interprets the trial data or how physicians interpret the data. This is where the value is—truly.

Also, these data show when the uptake happens. It begins to rise a little bit with publication—and a lot with FDA approval.

What’s stunning in the uptake of PD-1 inhibitors is how fast it happened—the speed of the adoption.

All of this is very informative, including that, sadly, 28 percent of patients in first line are just not treated at all, which was a surprise to me. Would you expect it? Probably not.

When you have a successful drug, does the segment of non-treated patients decrease?

Actually, it does, and it goes down from 23 percent to 15 percent.

Now, what is real-world data in this set? These are electronic health records. These are not research data. These are records that were created, basically, for payment and for reimbursement—not data that can be relied upon in the context of clinical trials.

FDA is saying, “Okay, we would love to see your real-world data, but these data are not acceptable to us, because we cannot trust or validate them.”

Every physician is recording the same thing in a different way. Nothing gets standardized. So here comes Flatiron—obviously not the only company—there’s U.S. Oncology and a few others. This whole industry is interpreting electronic health records to make them suitable for research and make them suitable for back-feeding the data to FDA.

We are working on a project with FDA and Flatiron to make the data precise enough so that they can be used for regulatory purposes. This is a complete breakthrough, because this type of data—previously used for publication, some payer support, and outcomes research—has never been used for regulatory support.

Now, you can create a database of 24,000 patients with data points that are readable in a language that can be submitted to FDA, so that an FDA reviewer can look at it and say, “Oh, if I want to check this vs. this, I can do it. And if I can check whether young patients are doing better than older patients, that women are doing better than men, and how are diabetic patients faring, who never were in clinical trials, etc.”

If FDA can now do this review, of course they will accept it. Will they accept it for all purposes in regulatory work? No. Will they accept it for most, especially for rare diseases or for agents that are already on the market and just need an extension of the label? We hope the answer is, “Of course,” because that would be based on good quality real-world data that the agency wants and can trust.

Another problem: the data physicians report are not precise. That’s because they don’t have time and there is not enough space in the electronic health record. Thus, approvals based on EHR data are probably not applicable to the new drugs we have minimal information on, but it may be most practical for drugs that are on the market and are going for expansion of the label.

This is how I imagine the future: we launch a new drug in an indication with a good safety profile, and from then on, everything else is done in the real world, because this is what matters. All
the dose schedules and other combinations and indications, all this can be done, because we have basically established the safety profile since the original launch, and follow-up safety monitoring in the real world is possible.

If you know what to look for, you can amend the electronic health records to include a pop-up window that says, “Does the patient have abdominal pain? Does the patient have fatigue?” The physician is prompted to answer these questions, thereby making information more reliable. This cannot be done in all instances for all drugs, but this can be a very good addition and alternative for many compounds.

MK: The acceptance of the real-world data will change Pfizer’s approach mostly to life cycle management of drugs. We will probably design our development plans to have a broader usage, because we would be able to evaluate, for example, patients with diabetes, who are excluded from the original trials.

Meanwhile, patients with diabetes are being treated in the real world—and in real practices.

If we can go back to the electronic health records and ask the records to show us all patients with diabetes, and then follow the patients and say, “Patients with diabetes are doing, on this drug, equally well—or not—as the patients with no diabetes,” that would be very valuable information for patients and physicians.

Then, if we can prove to FDA that they are doing equally well, this information can go on the label.

Or, for example, we are launching a new drug in combination with cisplatin. We then note that in the real world, physicians are also, or predominantly, using it with gemcitabine. Then, we would be able to design a real-world trial using our new drug with both gemcitabine and some other drugs. If this information is sufficiently precise, then we would be able to request to include it in the label without doing an official Pfizer-sponsored trial, which is what we would have to do otherwise.

Which would take five, six years or however long.

MK: Exactly, because the number of patients available for a trial is never 24,000, and Flatiron presented 24,000 patients over two years. We could never enroll 24,000 patients in two years. Not only will it cost billions of dollars, but it’s just practically impossible.

How would this new regulatory framework specifically affect Pfizer? What would change at Pfizer?

MK: For payers, it’s sort of a double-edged sword, as usual. I am confident that payers will likely accept these data, given how the field is evolving.

So if you have a drug that has trial data with statistical significance—for example, Tarceva for pancreatic cancer, or Avastin for non-small cell lung cancer with survival benefits—as a payer, basically, you would have little choice but to approve this drug for reimbursement.

But then go to the real-world data and you see that the usage of these drugs is, like, 0.3 percent—Avastin, for instance, was never used very much in non-small cell lung cancer despite a survival benefit. Why? Because, likely, factors in physicians’ clinical judgment precluded them from prescribing Avastin.

So the payer can say, “Okay, these are the data. Is it good to spend my money even if there is a survival benefit, but physicians are not using it? But then, here is another drug that has only progression-free survival benefits, and it’s used all over. Maybe there is something wrong with my thinking? Maybe my way of analyzing the data and making decisions are not really aligned with the practical needs of health care providers.”

I think that this will revolutionize not only how regulators look at the world, but also how payers look at the world, because we never had this type of data.

Previously, the only way to get this type of data was to go to very many clinics and look at tons of charts. And who would do this today for all the drugs we have? Nobody.

So it’s not about Flatiron. It’s not about FDA. It is actually about the global movement towards electronic data collection and the ability to have access to this data and then process it.

It’s about the processing, which is what these companies are doing so that the information can be utilized. It’s a very complex development.

Did we miss anything?

MK: This is truly a revolution. Real-world data teach us about how the patients stay on the drug, or don’t stay on the drug, or want this drug, or don’t.

It provides insight for FDA, the payers, and the patients. And it teaches us about the value patients and physicians ascribe to our medicines.

It’s just good.
Francis Collins to stay on as NIH director in Trump administration

By Paul Goldberg
Donald Trump has asked Francis Collins to remain in his job as NIH director.

The move means that, as an official of the Trump administration, Collins will have to at least make an appearance of supporting its FY 2018 budget proposal, which would slash NIH by 21 percent and cut indirect costs charged by institutions that house NIH-funded researchers (The Cancer Letter, May 26).

This could occur on June 22, when Collins is slated to appear before the Senate Appropriations Committee’s Subcommittee on Labor, HHS, Education and Related Agencies. The House subcommittee held its hearing before the White House released its budget proposal.

While Trump's FY2018 budget proposal is viewed as an expression of his administration’s low regard for science, the decision to retain Collins could enable the geneticist to defend NIH against the administration that places a high value on defense and border control.

Many insiders believe that Congress will not go along with the administration’s plan to cut funding for NIH.

Even though Collins will have to be silent or even supportive of the administration’s budget proposal, Collins has considerable bipartisan support on Capitol Hill, and his presence will provide continuity with—or at least serve as a reminder of—the 21st Century Cures Act and the Obama administration’s moonshot program.

The appointment also bodes well for the NIH All of Us Research Program, which seeks to enroll a million volunteers to enable research for a wide range of diseases.

For NCI, the selection of Collins means that, once again, NIH will have a permanent director while its largest institute, is headed by an acting director.

The NCI and NIH agendas have clashed in recent months, primarily over additional funds coming from the moonshot program. Last year, NCI was prevented from publishing its Bypass Budget (The Cancer Letter, Oct. 14, 2016). That document, mandated as part of the institute’s unique authorities established under the National Cancer Act, is yet to be published.

Collins announced his appointment in an email June 6:

Dear NIH Family:

I received word today that President Trump has made it fully official: he wants me to continue in the role of NIH Director. I am truly grateful for the President’s vote of confidence, and I will be honored to continue to serve this noble institution. This is a time of unprecedented scientific opportunity in biomedical research, as we seek together to advance health and relieve suffering. It will be my distinct pleasure to continue working with you, my valued colleagues at NIH—as well as with our counterparts at the Department of Health and Human Services, the White House, the Congress, and the broader community, including universities, philanthropy, industry, and patient groups. There is much work to do!

Finally, I want to thank all of you who dedicate yourselves so passionately to the goals of NIH. I will continue to rely on your brilliance and dedication as we move forward.

With thanks and best regards to all,

Francis S. Collins, M.D., Ph.D.
Director,
National Institutes of Health

In a short version, on Twitter, Collins posted:

Honored to be selected by @POTUS to continue as #NIH Director. I consider it a privilege to continue to lead this noble enterprise.

I am truly grateful for the President’s vote of confidence, and I will be honored to continue to serve this noble institution.

Trump chose not to appoint an NIH critic, a businessperson or an ideologue to the top job at NIH. Two weeks ago, a group of 41 House members urged Trump to replace Collins with someone more “pro-life.”

The Obama administration urged NIH to make use of embryonic cells produced in private labs.

“Our underlying concern remains that Dr. Francis Collins will continue to pursue unethical human embryonic research priorities left over from the previous administration,” the legislators wrote.

“While we deeply respect Dr. Collins’s Christian faith and commitment to public service, the stances that Dr. Collins has taken in the past regarding embryonic stem cell research and human cloning are not life-affirming and directly conflict with the pro-life direction of your new presidency.”
I think I can make the case that in the payback to the community with good cancer research and a healthy comprehensive cancer center is enormous. And that I think, at least on my level, the cancer center director needs to make that case.
Birrer spoke with Paul Goldberg, editor and publisher of The Cancer Letter.
Michael Birrer, an expert in early detection and treatment of gynecologic cancers, was named director of the University of Alabama at Birmingham Comprehensive Cancer Center.

Birrer, whose job at UAB starts Aug. 1, is director of Medical Gynecologic Oncology and director of the Gynecologic Cancer Research Program at the Massachusetts General Hospital Gillette Cancer Center. Also, he serves as the leader of the Dana Farber/Harvard Cancer Center program in gynecologic cancers and is a professor of medicine at Harvard Medical School.

“Having spent the better part of my oncology career trying to better the lives of women with gynecologic cancers both on a clinically level and a research level, the question was, ‘What’s next and how could I impact and help potentially larger numbers of patients?’” Birrer said to The Cancer Letter. “And so it certainly dawned on me that the cancer center director position would have the reach to do that: to be able to design how a cancer center can work efficiently, to conduct great trials, to work with good researchers.

“It was something in the back of my mind, and I looked a bit—not real aggressively. But when UAB came along and I went down there, and saw what was there, the fact it was already comprehensive, and a great history to the place, it really excited me.”

Birrer will succeed Edward E. Partridge, the Evalina B. Spencer Chair in Oncology, who is retiring from UAB after a 48-year career, which included 10 years as director of the cancer center.

UAB is the only NCI-designated comprehensive cancer center located in the five-state area that includes Alabama, Mississippi, Louisiana, Arkansas and South Carolina. The center treats an estimated 5,000 new patients each year and is home to a faculty of nearly 250 physicians and researchers.

Birrer’s research interests include the molecular origins of gynecologic cancers, as well as the identification and characterization of aberrations in oncogenes and tumor suppressor genes in these cancers.

His bench research is focused on the genomic characteristics of ovarian, cervical and endometrial cancers and using the data to form the basis for early detection assays, prevention strategies and novel therapies.

He began his career in 1988 as an investigator at NCI, becoming a senior investigator and chief of the Molecular Mechanisms Section of NCI’s Center for Cancer Research. He became the deputy chief of the Cell and Cancer Biology Branch at the Center for Cancer Research in 2000. He joined Massachusetts General and has served in his current roles since 2008.

First of all, congratulations on this job. Why did you decide that this is the right thing to do right now?

Michael Birrer: Having spent the better part of my oncology career trying to better the lives of women with gynecologic cancers both on a clinically level and a research level, the question was, “What’s next and how could I impact and help potentially larger numbers of patients?”

And so it certainly dawned on me that the cancer center director position would have the reach to do that: to be able to design how a cancer center can work efficiently, to conduct great trials, to work with good researchers.

It was something in the back of my mind, and I looked a bit—not real aggressively. But when UAB came along and I went down there, and saw what was there, the fact it was already comprehensive, and a great history to the place, it really excited me.

Yeah, let’s get to that in a little bit. What are the strengths of the place right now and what are the weaknesses?

MB: I think its strength is its traditions and its history. I think that sort of sets the pace for the place. The hospital is, again you probably know all this, third largest public hospital in the country.

And my impression is it’s well run.

Clinical competence is pretty high-level, and I think they have excellent research programs, both in terms of translational basic science departments, but also programs within the comprehensive cancer center.

I think the weaknesses, which they, and now I, acknowledge, is that, for instance, in the cancer center programs, the research is excellent, but the bench is not real deep.

So, we need to be aggressive about expanding and recruiting scientists into those programs. Particularly, in immunology, which they’ve always had a very good tradition of immunotherapy. It’s obviously a hot area.

And then I think, also, they’ve got the basics of a great clinical trial structure with early drug development. The cancer center director two back, before Ed Partridge was it, had a really great interest in early drug development. But I think it could be so much better.

I think the patient accrual could double or triple if the right strategic work is done. And then, more importantly, one of the visions is to get it out of the mother ship and try to export it into the surrounding community, poten-
tially all the way into Mississippi, up to Arkansas, across the panhandle.

These are areas where again patients are not particularly served well, and certainly either have to travel long distance or simply never see a clinical trial, which I think is tragic.

**MB:** That's going to be an effort.

**MB:** I think it's both. I'll do it till the money runs out. I think, for reasons I outlined, they need expansions in both regards. The hem/onc Department is in the process of expanding also, and I think there's a lot of growth potential in terms of hem/onc faculty.

**Wow.**

**MB:** Yeah. That's a good question.

So, the model, as I understand it, has been, to date, affiliations. And so, I think there's a track record there to doing that.

The problem with affiliations, or at least the challenge, is the rub is in the details. Are these affiliations that allow UAB-trained staff to have privileges and see patients?

And can, for instance, the cancer center, do selective hiring and bring in research individually into that arrangement?

It may be that in certain circumstances, purchasing practices or purchasing small hospitals would be more effective.

**Oh, that's fascinating.**

**MB:** Yup.

**Now, what about the Deep South Initiative? Are you planning to strengthen it? How would you do that?**

**MB:** Absolutely.

This is described as one of the visionary programs of the place.

**MB:** Yup. I agree. No doubt about it. I think that's going to receive a fair amount of attention from me. I just want to get a few more of the details about how I can best do that.

In the beginning, you started to talk about research among the underserved. Maybe we could talk about it now.

**MB:** Sure. So, I think it's probably going to manifest itself on multiple levels.

There are some obvious areas of interaction. For instance, there's been a serious proposal, and in my interviews I actually expanded on it, and described a potential project, which is to build a project in metabolomics and its relationship to cancer.

This would work nicely, I think, in populations within the South, because, quite frankly, as is true for many other parts of the country—but I think it's particularly true for the South—there is a large obesity problem. And that is disproportionately involving minority populations.

And so, this could be a laboratory-based effort utilizing patients and members of the community, both in terms of understanding the relationship between metabolism and cancer, but to then designing trials that would address selective interventions, either in terms of altering the metabolism or exploiting those pathways within the tumors.

That's an example of something maybe a little bit closer to the laboratory, but I like it, because it's bench to bedside.

Alternative approaches would be—and this is already ongoing—large studies looking at SNP profiles and GWAS within these populations, and having them done systematically, in the larger studies, because of the lack of minority recruitment, the increase of clinical trials will be directed specifically at these populations.
And I really do think that’s important.

As somebody who works in gynecologic oncology in Boston at a premier hospital, I can tell you that minority recruitment into those kinds of clinical trials is extremely challenging. We simply don’t do that well. I think UAB has a chance to really provide the nation with information about toxicity response rates within these populations.

What about the Affordable Care Act; how will that affect you? What are your thoughts on this?

**MB:** Well, it’s a really great question. First of all, I asked it when I was interviewing, and then it’s been asked to me since I’ve agreed to come to UAB.

I think you can lose your mind at some point by thinking about all the potential variations and options and how that might affect a cancer center, let alone an institute like UAB.

The rub ultimately, for all you know is gonna be in the details of what they actually change. Right now, under the circumstances—and I have not seen all the details—but to get to this point and accept the job, I have seen a fair amount of it, the hospital is extremely healthy. Alabama did not, as far as I understand, expand its Medicaid program.

But they have a lot of patients in those government programs. The hospital nevertheless remains quite healthy, with a healthy margin. And they don’t anticipate that changing in the near future, but we’ll see what the future holds; right?

Yeah. What about the research funding, the possibility that the administration might get its way and drop NIH funding by 20 percent? What would that do to you?

**MB:** Well, it’s a disaster, of course, but we won’t be alone in the effects. So, if that’s any solace, I’ll take that. As cancer center director, part of my job is going to be to soften that effect, if in fact that takes place. We’re going to …

And again the dean was very gracious, and the CEO of the hospital is, I think, in lockstep with the dean in terms of what they think of the value of the cancer center.

So, the funding for the position is quite robust. And part of that’s going to go into a research fund for potentially investigators who we deem are good investigators, who lose their funding and desperately need interim funding, and we want to retain them.

That money would be made available. Near-miss loss will also be funded. Not fully, but certainly we’ll have some sort of support for R21s and R01s that are the 11th percentile and don’t get funded. Been there, done that. So, I think those are some efforts that the director can do to help out.

And then I, as opposed to some of my colleagues, actually enjoy philanthropic fundraising very much. I’ve done it up here at Harvard, I thought, fairly successfully. So, we’ll be digging into that very aggressively to try and raise funds, particularly in the setting of a shrinking NIH dollar.

I would think you would be in a position to educate some of the legislators on the subject of research—its importance?

**MB:** Well, there’s no issue about that. I’ve already been asked what I feel about going, at least at the state level, to the capital, and I’m more than willing to do that.

I think I can make the case that in the payback to the community with good cancer research and a healthy comprehensive cancer center is enormous. And that I think, at least on my level, the cancer center director needs to make that case. Federal law is at another level. But I would certainly be more than willing to work to demonstrate what the impact is of both NIH funding and potentially reimbursement rates.

What about indirect costs?

Have you tried to project what the administration’s proposal and the indirect costs might do to you?

**MB:** The good news is, having been at Harvard, my indirect rates are gonna go down.

Right. Well, is there anything we’ve missed and anything you’d like to focus on?

**MB:** I’m just very excited about going down and my wife’s excited to going to Birmingham. She’s a country gal. So, I think that’s all going to work out, and I would hope that maybe we could talk in a year or two, when some of these visionary issues have been already implemented and we’re making progress.

That would be great.
Angela Hartley Brodie, pioneer in the development of breast cancer treatment, dies at 82

Source: University of Maryland Greenebaum Comprehensive Cancer Center

Angela Hartley Brodie, professor emeritus in the Department of Pharmacology at the University of Maryland School of Medicine and a scientist whose groundbreaking research is considered among the greatest advances in treating breast cancer, died of complications from Parkinson’s disease at her home in Fulton, MD. She was 82.
Brodie pioneered the development of aromatase inhibitor. Her work developing aromatase inhibitors was a paradigm-shifting effort that began in the 1970s and was designed to reduce the level of the estrogen in the body and thereby block the growth of cancer cells.

Aromatase is an enzyme that plays a key role in the biosynthesis of estrogen, which fuels the growth of cancer cells.

"Dr. Angela Brodie’s impact on the treatment of breast cancer has been unparalleled. It is because of her work that a disease that was once almost a certain death sentence, can now, for many, be successfully treated and managed," said E. Albert Reece, vice president for Medical Affairs at the University of Maryland and the John Z. and Akiko K. Bowers Distinguished Professor and Dean of the University of Maryland School of Medicine.

"She never gave up on her vision of finding a new treatment with fewer side effects, and many women around the world have benefitted from her perseverance."

Brodie’s research spanned decades and built upon her initial discoveries to create more powerful and specific aromatase inhibitors.

"Dr. Brodie’s pioneering research is equal to the greatest advances in treating breast cancer in the last 150 years," said Kevin Cullen, the Marlene and Stewart Greenebaum Distinguished Professor of Oncology at the University of Maryland School of Medicine and director of the University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center.

"Her work with aromatase inhibitors has saved the lives of thousands of women worldwide."

"Despite the incredible impact of her science, Angela was perhaps the most generous and unassuming scientist I have ever known. She was extraordinarily humble about her achievements and never sought attention for what she accomplished. She mentored dozens of students and junior faculty over the years and so the impact of her work will live on for years to come," Cullen said.

Brodie began investigating compounds to inhibit aromatase while at the Worcester Foundation for Experimental Biology in Shrewsbury, MA, initially working in a laboratory with her husband, Harry Brodie, a chemist who synthesized the first selective inhibitors in the early 1970s, including a potent compound called 4-hydroxyandrostenedione (4-OHA).

She continued her research with 4-OHA after coming to the University of Maryland School of Medicine in 1979, spearheading its development through clinical trials into a treatment for breast cancer. Released as Formestane for worldwide use in 1994, it was the first new agent in a decade specifically designed to treat breast cancer.

Early on, few other scientists gave her research much credence.

Brodie’s first paper reporting the laboratory success of aromatase inhibitors at reducing estrogen levels was rejected because “they thought the finding was too obvious,” Brodie recalled. She tried to interest pharmaceutical companies, but many thought her work was unnecessary and that chemotherapy was the answer. It was only through her persistence that her experimental compound ever made it to clinical trial.

She ended up making small batches of the aromatase inhibitor in her laboratory at the University of Maryland School of Medicine and shipping it to the Royal Marsden Hospital in London where it was given to 11 women with advanced breast cancer as part of a clinical trial.

Among her many awards are the prestigious Charles F. Kettering Prize from the General Motors Cancer Research Awards in 2005, the Dorothy P. Landon-AACR Prize for Translational Cancer Research in 2006, recognizing “seminal contributions to our understanding of cancer through basic and translational research,” and the Brinker Award for Scientific Distinction from the Susan G. Komen Breast Cancer Foundation in 2000.

Brodie was the first woman to receive the Kettering Prize, given for the most outstanding recent contribution to the diagnosis or treatment of cancer. She was also nominated for the Lasker Award.

In 2013, she was selected by the American Association for Cancer Research as a fellow of the newly created AACR Academy. AACR created the academy “to recognize and honor distinguished scientists whose major scientific contributions have propelled significant innovation and progress against cancer.”

Dr. Brodie’s pioneering research is equal to the greatest advances in treating breast cancer in the last 150 years.
She also received the Pharmacia Award of the American Society for Experimental Therapeutics in 2012.

Brodie’s career at the University of Maryland School of Medicine spanned 37 years until her retirement in 2016. She was a professor of pharmacology at the School of Medicine and a researcher in the Hormone Responsive Cancers Program at the University of Maryland Marlene and Stewart Greenbaum Comprehensive Cancer Center.

“Angela was the heart and soul of the department of pharmacology,” said Margaret McCarthy, the department chair. “She was just as willing to serve on the thesis committee of a graduate student as to provide major leadership to the school in its research and outreach efforts. Angela was never too busy or too important, she participated in every activity asked of her and was a favored lecturer by the medical students.

“Although she had recently retired you wouldn’t have known it, as she was regularly in her office working on manuscripts, advising students and meeting with colleagues. Angela was a rare gem, and while she will be dearly missed, her impact will endure by the shining example of her scientific excellence, mentorship and deep commitment to her community,” McCarthy said.

In recent years, Brodie continued her work with aromatase inhibitors and expanded her research into a new area, prostate cancer. She teamed up with colleague Vincent Njar and others to investigate inhibitors of androgen synthesis as potential agents for treating prostate cancer.

Commenting on the collaboration he shared with Angela Brodie, Njar recalled that he was just a visiting professor when he came to University of Maryland School of Medicine, Department of Pharmacology and UMGCCC in 1996.

“Today, I have my own independent laboratory and research programs, and much of that is due to Angela’s support. She has been a truly wonderful friend and colleague, unbelievably brilliant and an encouraging partner. May her soul rest in perfect peace,” Njar said.

She published more than 200 papers in peer-reviewed scientific journals and at one time was an associate editor for Cancer Research and edited articles for numerous other journals.

Her hobbies included horseback riding, hiking and gardening.

The School of Medicine is establishing an endowed professorship in honor of Dr. Brodie’s scientific achievements: The Drs. Angela and Harry Brodie Distinguished Professorship in Translational Cancer Research.

Brodie is survived by her husband, a retired NIH Executive Secretary for grant review; a son, Mark Brodie, a drama teacher in San Fernando, CA; and two grandchildren. Another son, John Hartley Brodie, a theoretical physicist, died in 2006.

Although she had recently retired you wouldn’t have known it, as she was regularly in her office working on manuscripts, advising students and meeting with colleagues.
Aggressive marketing transforms tobacco use into social justice issue, report states

By Claire Dietz

Tobacco use should be addressed as a social justice issue, according to a recent report by Action on Smoking and Health.

“Aggressive industry marketing targeted at African-Americans, Native American, and the LGBTQI community and others has resulted in a disproportionate level of the overall tobacco burden being borne by those who can financially least endure it,” states a report released for World No Tobacco Day on May 31.

While smoking prevalence has decreased nationally over the past two decades, tobacco remains the number one cause of preventable deaths in the U.S. Tobacco accounts for one in four deaths daily—for a total of 480,000 annually—and costs the U.S. economy more than $300 billion a year, the report states.

Nepal, India, Thailand, and 102 other countries require tobacco companies to print images depicting lung and oral cancer and other tobacco-related diseases on over 80 percent of cigarette packages on the market. The U.S. ranks 205th in a 2016 Canadian Cancer Society report, which examines requirements for pictorial warnings on cigarette packages in 205 countries.

Nationally, about 15 percent of adults smoke, down from nearly 50 percent in the 1960s. However, progress has been far from uniform. The following demographics smoke at much higher rates:

- Racial minorities i.e. Native Americans (21.9%, or 1 in 5 of Native Americans)
- Marginalized groups, including the LGBTQI community (23.9%, or 1 in 4 LGTBQI adults)
- Poor communities with lower levels of education (In Washington D.C. an estimated 80% of all smokers have an income of less than $35,000)
- Southern and Midwestern states i.e. Oklahoma, Arkansas, South Dakota, and Louisiana

According to a 2015 report from the American Cancer Society and World Lung Foundation, “tobacco use is a risk factor for the four most prevalent non-communicable disease killers—heart disease and stroke, cancer, diabetes, and chronic lung disease—and causes 6.3 million deaths a year.”

The 1969 Public Health Cigarette Smoking Act prohibits tobacco companies from advertising on television and in print. The law also requires the surgeon general’s warning label to be printed on tobacco packages.

In 1990, San Luis Obispo, California, passed a law eliminating public smoking. The city was the first in the world to implement the public safety measure.

There is no federal law that would ban all smoking in indoor workplaces and public spaces. However, 27 states and 50 countries passed clean air ordinances.
The tobacco industry has a long history of targeting marginalized communities.

1 in 4 LGBTQI adults smoke.


To make national progress, it is vital to consider disparities – otherwise there is little chance of significantly driving down overall consumption. And health disparities exacerbate myriad other social problems in the U.S.
Ben Melson rejoins MD Anderson as chief financial officer

Ben Melson will become the institution’s senior vice president and chief financial officer at MD Anderson Cancer Center. Melson previously worked at MD Anderson for six years, mostly as CFO, before moving to Texas Children’s Hospital, the nation’s largest pediatric health care system. There he oversaw operating revenue growth from $900 million to more than $3 billion over 12 years.

“I’m extremely optimistic about the future and the trajectory of MD Anderson,” Melson said in a statement. “We’ll continue to lead the nation in cancer care and cancer research, and will do so in a financially responsible manner as this wonderful institution continues Making Cancer History and serving many future generations.”

Among his accomplishments at Texas Children’s Hospital are: developing and implementing an enterprise risk management tool, aggregating the purchasing efforts of 30 freestanding children’s hospitals across the U.S., negotiating more than $700 million in tax-exempt bond and debt transactions, creating and maintaining a strategic financial plan known as the Economic Forecasting Model, and directing multiple academic affiliation negotiations with Baylor College of Medicine.

Jeffrey Molter named director of communications at NYU Perlmutter Cancer Center

Jeffrey Molter joined NYU Langone Medical Center in a newly-created position of director of cancer center communications of its Laura and Isaac Perlmutter Cancer Center.

Molter comes to Perlmutter after serving for the past four years as director of media and public relations for the American Association for Cancer Research in Philadelphia.

“Jeff will team up with the Department of Marketing & Communications to plan, implement and manage communication initiatives for our rapidly growing Perlmutter Cancer Center,” said Kathy Lewis, senior vice president for Marketing & Communications at NYU Langone.

ACCC delivers immunotherapy education in community setting

The Institute for Clinical Immuno-Oncology of the Association of Community Cancer Centers launched two initiatives that support community cancer programs in implementing and advancing access to new and emerging immunotherapies for cancer.

Through these initiatives, ICLIO faculty engage multidisciplinary care teams in robust discussions on the real-world challenges and complexities of delivering immunotherapy to patients in the community setting.

It is estimated that 85 percent of the nation’s cancer patients receive care in the community setting.

The ICLIO Visiting Experts program brings a multidisciplinary team of oncology professionals experienced in the delivery of immunotherapy for cancer into ACCC member cancer programs for a one-day workshop. The
workshops delve into clinical, operational, and programmatic issues specific to these innovative new therapies. The curriculum centers on evolving challenges in this field, including patient selection, management of immune-related side effects, support for patients and caregivers, and effective approaches for educating clinical colleagues in allied specialties on the unique intricacies of immunotherapy for cancer.

All ACCC member programs are invited to apply for this opportunity.

Both the ICLIO Visiting Experts and the Case Studies in Immuno-Oncology initiatives are opportunities for in-depth bi-directional learning, allowing the ICLIO expert presenters to learn from the experiences of the local multidisciplinary teams successfully providing immunotherapy in the community while discussing difficult, real-world cases and sharing their own best practices and care delivery experiences.

Andy North & Friends raise $1.05 million for UW Carbone Cancer Center

Launching in summer 2017, Case Studies in Immuno-Oncology will bring an ICLIO expert to ACCC Cancer Program Members for a 60-minute, case-based tumor board discussion on immunotherapy treatment decision-making and the management of associated immune-related adverse events.

Professional golfer Andy North and his friends raised more than $1 million for the University of Wisconsin Carbone Cancer Center at a dinner and golf tournament.

The figure includes money raised at an event at Wisconsin Aviation by auctioning off items, such as a trip to golf as North's amateur partner in the Smith-Cole Invitational at Cherry Hills, the golf course near Denver where North won his first U.S. Open in 1978.

Over the past nine years, North and friends have raised more than $9 million for the cancer center.

Two-time U.S. Open champion Andy North is an analyst for ESPN. He's also a survivor of skin cancer and prostate cancer, and committed to supporting the work of the UW Carbone Cancer Center, where he received treatment.

Money from the North event helped Carbone researchers Ryan Mattison and Robert Jeraj launch a national clinical trial to use imaging rather than putting patients through a potentially painful bone marrow biopsy to check on the status of leukemia. The event has helped support UW Carbone pilot research projects on topics ranging from a novel therapeutic for head and neck cancer, a prostate-cancer vaccine and a study of follow-up care for breast cancer patients, among others.
BMS, Novartis announce collaboration focused on metastatic colorectal cancer

Bristol-Myers Squibb and Novartis announced a clinical research collaboration to investigate the safety, tolerability, and efficacy of Mekinist (trametinib) in combination with Opdivo (nivolumab) and Opdivo + Yervoy (ipilimumab) regimen as a potential treatment for patients with metastatic colorectal cancer (mCRC) where the tumors are proficient in mismatch repair (MSS mCRC pMMR).

The study, which will be conducted by BMS, is aimed at establishing recommended dose regimens and the preliminary anti-tumor activity of the combination therapies. Both BMS and Novartis will evaluate the results to determine optimal approaches and potential clinical development of these combinations.

Mekinist is a kinase inhibitor indicated, as a single agent or in combination with dabrafenib, for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.

Roche announces FDA approval of companion diagnostic to identify ALK-positive non-small cell lung cancer patients

FDA approved the Ventana ALK CDx Assay as a companion diagnostic to identify ALK-positive non-small cell lung cancer patients eligible for treatment with the Novartis drug Zykadia (ceritinib).

The Ventana ALK (D5F3) Assay is the only immunohistochemistry test approved by the FDA as a companion diagnostic for ZYKADIA.

The assay is sponsored by Roche.

FDA Approves Hologic’s Genius 3D Mammography Exam

Hologic Inc. said the Genius 3D Mammography exam has become the only mammogram that is FDA-approved as superior to standard 2D mammography for routine breast cancer screening of women with dense breasts.

The Genius exam has been commercially available in the U.S. since 2011, and the newly approved physician labeling is based on clinical studies proving that the exam improves invasive breast cancer detection while reducing unnecessary recalls among women of all breast densities, including those with dense breasts.

Separately, subgroup data analysis from a previously published retrospective multicenter clinical study (JAMA 2014) supporting breast tomosynthesis as the standard of care in women starting at age 40 has recently been made available.

This study, “Effect of age on breast cancer screening using tomosynthesis in combination with digital mammography,” led by Elizabeth Rafferty, of Lawrence General Hospital, was published online in advance of print in Breast Cancer Research and Treatment and analyzed the performance of tomosynthesis in specific age groups. The study showed that with the addition of tomosynthesis to digital mammography, detection rates for invasive cancer increased significantly for women ages 40 to 69. At the same time, there was a significant decrease in recall rates for all age groups, with the largest performance gains seen in women age 40 to 49.

Amgen and Allergan announce FDA advisory committee meeting to review ADP 215, a biosimilar candidate to Bevacizumab

Amgen and Allergan said the FDA Oncologic Drugs Advisory Committee will review data supporting the Biologics License Application for ABP 215, a biosimilar candidate to Avastin (bevacizumab), an agent sponsored by Genentech, a unit of Roche.

The committee will review analytical, pharmacokinetic and clinical data from studies involving ABP 215, including results from a phase III study in patients with non-squamous non-small cell
lung cancer. The phase III study met its primary endpoint, showing clinical equivalence to bevacizumab. Safety and immunogenicity of ABP 215 were also comparable to bevacizumab, the companies said.

FDA has set a Biosimilar User Fee Act (BsUFA) target action date of Sept. 14.

**Hitachi and MD Anderson to collaborate in research in oropharyngeal cancer**

Hitachi Healthcare Americas Corp. and MD Anderson Cancer Center announced an agreement to collaborate on a randomized clinical trial comparing the outcomes and side-effects of intensity-modulated proton beam therapy versus intensity-modulated photon therapy for the treatment of oropharyngeal cancer of the head and neck.

The randomized clinical trial is expected to involve up to 10 additional centers and will be led by Steven Frank, professor and deputy division head of radiation oncology and medical director of the Proton Center.

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**DOD publishes research opportunities in prostate cancer**

The DOD prostate cancer program seeks to focus applications and direct funding on four “overarching challenges” and seven “focus areas” to address critical needs in prostate cancer research and clinical management.

**Overarching Challenges:**

1. Distinguish aggressive from indolent disease in men newly diagnosed with prostate cancer.
2. Develop strategies to prevent progression to lethal prostate cancer.
3. Develop effective treatments and address mechanisms of resistance for men with high-risk or metastatic prostate cancer.
4. Develop strategies to optimize the physical and mental health of men with prostate cancer.

**Focus Areas:**

1. Precision Medicine, Screening, and Surveillance,
2. Imaging and Targeted Radionuclide Therapy,
3. Therapy and Mechanisms of Resistance and Response,
4. Survivorship, Including Psychosocial Impact on the Patient and Family,
5. Tumor and Microenvironment Biology,
6. Data Science and Analytics,
7. Population Science

Additional information is posted [here](http://cancerletter.com/advertise/).

CDMRP Help desk 301-682-5507 help@eBrap.org