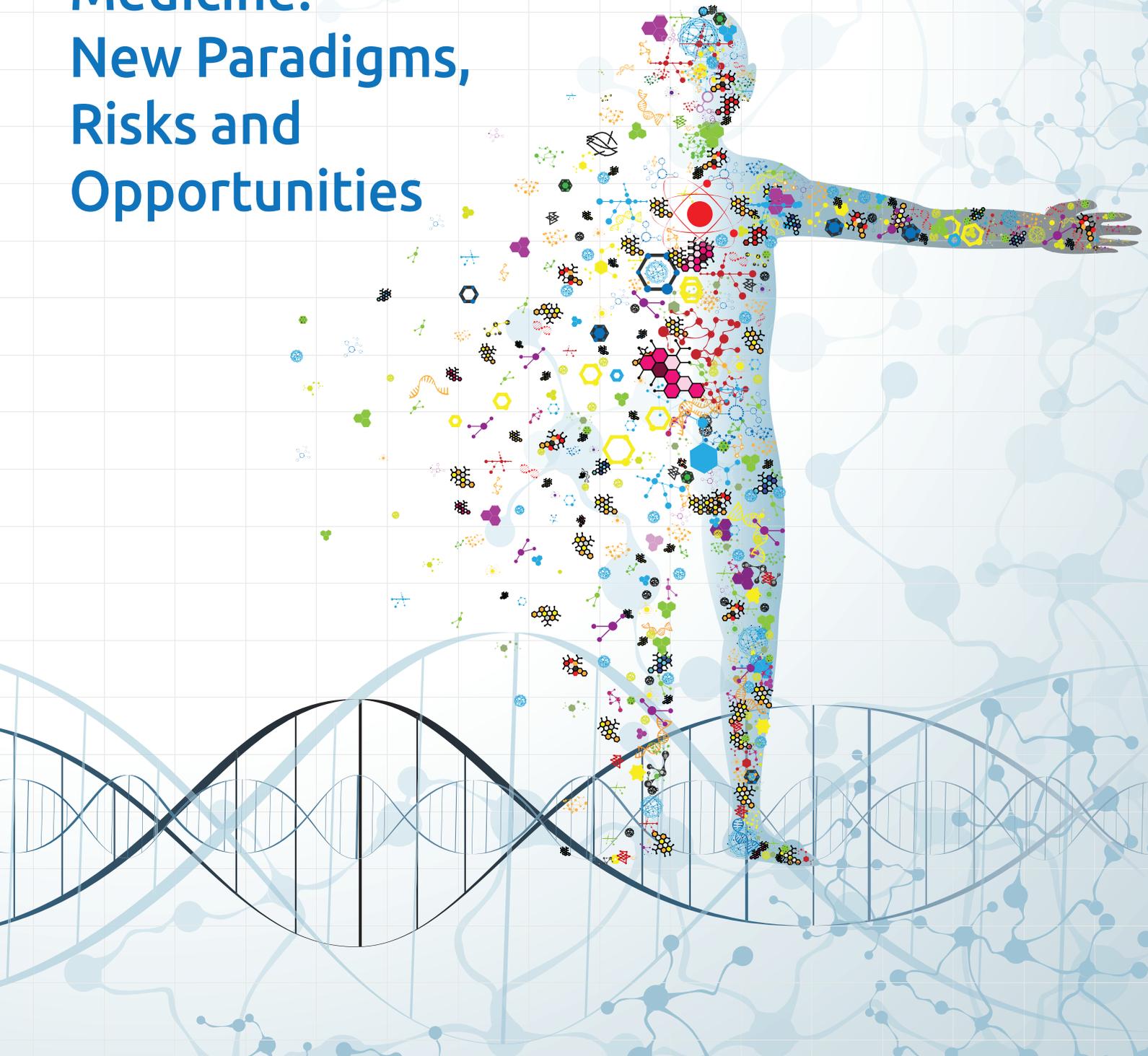


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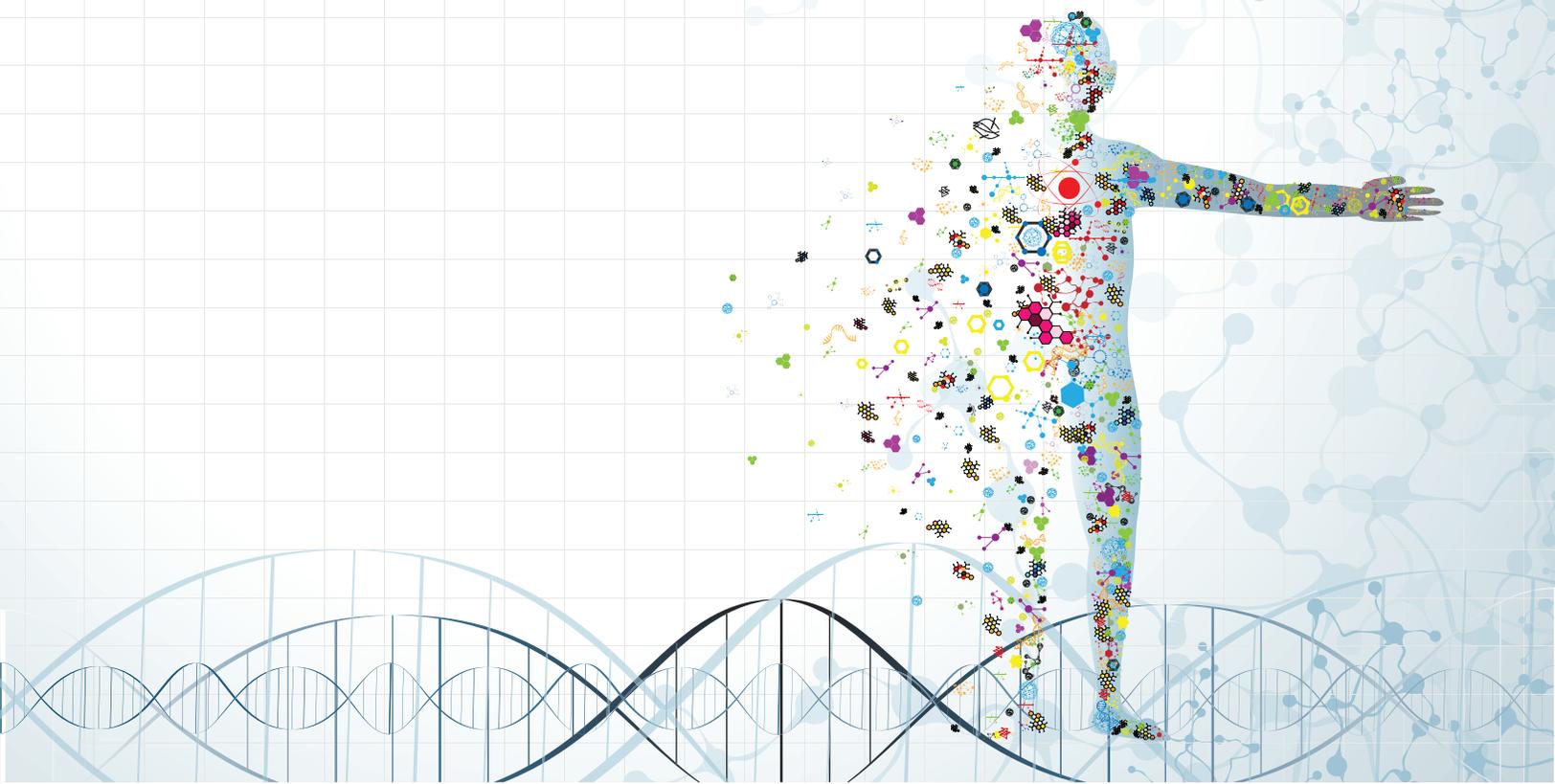
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# Precision Medicine: New Paradigms, Risks and Opportunities



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# Precision Medicine: New Paradigms, Risks and Opportunities

Precision medicine is fundamentally changing the way therapies are being developed. Its targeted, customized approach to health care has a widespread impact on everything from genomics to medical devices, and as a result it is creating new business models for enterprises across the sector. Importantly, precision medicine provides the backdrop for researchers as they explore how genetic, environmental and lifestyle factors interact in our bodies to foster health or develop disease.

New technologies are enabling precision medicine to bring its critical benefits to market. These include the ability to improve patient outcomes on chronic diseases, an increase in the product pipeline and speed-to-market for life sciences companies, as well as the ability to quickly eliminate development paths unlikely to pan out.

This paper highlights emerging opportunities and trends in precision medicine that could potentially revolutionize drug and therapy development as well as lead to disease

prevention and management. It also investigates the scientific, medical, regulatory and financial barriers that must be overcome in order for the field to keep moving forward.

## The Need for New Business Models

As more blockbuster drugs tumble off the patent cliff, resulting in price competition and margin pressure, the pharmaceutical industry recognizes the need for new approaches. Armin Furtwaengler, the global senior medical director

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*"We will have to provide even more value-added services for patients in the future."*

— Armin Furtwaengler, Boehringer Ingelheim

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and contributor to the 'Global Medicine Innovation Framework @ Boehringer Ingelheim,' says he is tasked with taking his company "beyond the pill" and notes that "100% of my working time is dedicated to innovation."

At the same time, expensive drug launches have led to controversies and social blowback. Furtwaengler cites Gilead's \$1,000 pill for hepatitis C, which, according to *The Wall Street Journal*, forced U.S. Medicaid spending to soar last year; and Turing Pharmaceuticals' overnight spike in the price of Daraprim — a drug long used to treat life-threatening infections — from \$13 to \$750 per tablet. "Not only politicians, but society, cannot afford [these situations]," he says.

The bottom line is that the need for change is urgent. "We will have to provide even more value-added services for patients in the future," Furtwaengler continues. "Whether that's with digital approaches, or whatever that may be, it's up in the air. ... The current business model is just not sustainable and we have to have a more holistic approach."

Meanwhile, R&D productivity continues to face major challenges. According to a recent report by PhRMA, the Pharmaceutical Research and Manufacturers of America, it takes on average at least 10 years to bring a new medicine to market.

Joe Miles, global vice president for the life sciences industry at SAP, says that

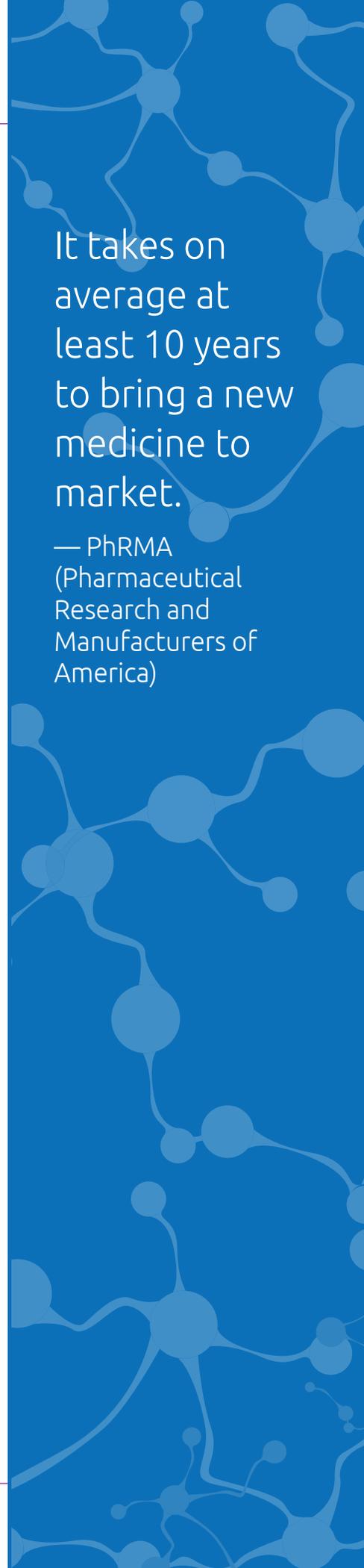
the drug companies' "ability to turn their investments into products — getting products into the process, identifying a successful compound that can meet requirements — is a very, very difficult process."

While some studies have estimated that it takes between \$2 billion to \$3 billion on average to bring a new drug to market, other reports suggest the cost is much higher. Miles notes, "If you look at total R&D spend over a period of time and divide it by the number of new drug products produced, the numbers quickly approach the \$5 billion to \$8 billion range."

Regardless, the pressing need to rebuild the pipeline has fueled "an enormous amount" of M&A activity in the industry over the past few years, in Miles's view. "They're either spinning off companies so they can focus on specific therapeutic areas, or they're acquiring a pipeline to new or existing therapeutic areas that could create the next big blockbuster drug or product."

One high-profile example is the GSK and Novartis \$20 billion dollar asset swap in 2015. "That was a unique M&A where GSK acquired the vaccine business from Novartis. Novartis acquired the oncology business from GSK," Miles says. In addition, Novartis's veterinary health business was sold to Eli Lilly.

"The current situation for the pharmaceutical industry is very challenging, with lots of very



It takes on average at least 10 years to bring a new medicine to market.

— PhRMA  
(Pharmaceutical Research and Manufacturers of America)

significant and dynamic changes coming from limited budgets of payer organizations and governments, and ever increasing expectations and aspirations by patients, physicians and society of what ‘modern healthcare, research and new technologies’ might potentially accomplish,” Furtwaengler adds.

Will precision medicine offer the bold new model that pharma and biotech are looking for? Trends supporting precision medicine are on the rise. For example, the use of electronic medical records is becoming more widespread. That means larger amounts of patient data are increasingly available, and can be sliced and diced to yield clinical insights about more targeted treatments. In fact, medical data in general — including clinical, genomic research, and health care data from the Internet of Things — is expected to increase five-fold between 2013 and 2020, according to market research firm IDC.

Another major shift is that genomic analysis — a linchpin of precision medicine — has been experiencing a significant reduction in cost, enabling wider use of this technology.

But many hurdles still exist. Traditional health care entities such as insurance companies may resist the new paradigm. And genetic markers are still poorly understood by most people, even by many physicians. Physicians in turn

need to understand how to counsel patients about genetic testing. A comprehensive education campaign would be needed going forward.

Moreover, some emerging approaches in precision medicine clash with existing FDA procedures and classifications. For instance, an analysis of a patient’s biomarkers may suggest that instead of a single drug, a “cocktail” of three different drugs — not necessarily used for that type of cancer before — would yield the patient’s best chance of beating the disease. But the FDA currently approves cancer drugs at specific doses and based on the cancer’s location in the body. Indeed, the advent of precision medicine would entail changes to every facet of modern health care.

To be sure, new partnerships are emerging with technology companies such as Google and Apple, among others. As Thomas Wilckens, CEO of Tel Aviv-based life sciences startup InnVentis, observes, “The convergence of technologies — NGS sequencing and multi-omics Big Data, machine-learning, that is, artificial intelligence — is simply overwhelming large companies.” Thus, partnership becomes an increasingly attractive option.

And for the first time, drug companies are partnering with diagnostic companies to develop therapies. “That hadn’t happened

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*“People usually think all the cells in a tumor are the same and that’s not true.”*

— Jennifer  
Morrissette, Center  
for Personalized  
Diagnostics,  
University of  
Pennsylvania

Genomic analysis — a linchpin of precision medicine — has been experiencing a significant reduction in cost, enabling wider use of this technology.

# The advent of precision medicine would entail changes to every facet of modern health care.



before,” notes Jeff Voigt, principal of Medical Device Consultants of Ridgewood. He predicts that in precision medicine “moving forward, there’s going to be some kind of diagnostic tied to a therapeutic.”

Meanwhile, techniques such as CRISPR genome editing are gaining ground in the sector. Recently, the scientific journal *Nature* described how the CRISPR-Cas9 tool allows molecular biologists to target and study particular DNA sequences within the larger genome. In addition to editing DNA, scientists can send proteins to DNA targets to toggle genes on or off. Biological circuits can be engineered.

The goal is to better understand cellular systems and perhaps even to edit genes within human embryos. Currently, researchers are experimenting with CRISPR-Cas9 to create animal models of cancers in the hope of eventually treating human disease more precisely.

## **Precision Medicine Trends: Breaking New Ground in Personalized Cancer Diagnostics**

Cancer is arguably the area in which the most progress in precision medicine has been made to date. Miles says that it is now possible to

sequence not only a cancer patient’s genome, but also the genome of his or her tumor. That is the province of Jennifer Morrisette and the team at the Center for Personalized Diagnostics at the University of Pennsylvania in Philadelphia.

Rather than performing whole genome sequencing for patients, Morrisette and her colleagues run targeted panels for particular conditions, such as a solid tumor panel or a heme malignancies panel. The team tries to target genes that are anticipated to be diagnostic, prognostic or therapeutic.

“Let’s say we have a lymphoma patient and we find a mutation in p53. That patient would go on a more aggressive chemotherapy regimen. Whereas if the p53 mutation was found in a lung cancer, that wouldn’t change how the clinician might treat that patient, but a mutation in EGFR might,” she says. “So we find that mutations and their meaning — how they’re going to be used clinically — often depend upon the tumor type in which it was found.”

One area of breaking development in cancer is tumor heterogeneity. “People usually think all the cells in a tumor are the same and that’s not true,” Morrisette adds. Even a tumor as small as one centimeter can have multiple, different clonal abnormalities. As a result, a breast

cancer patient, for example, whose condition is classified as low-risk may be given standard surgery and a year of treatment, only to have the cancer metastasize.

An intriguing alternative now being explored is to analyze what is referred to as circulating tumor DNA. Morrisette explains: “You can have circulating tumor material escaping from a tumor. And if it is free DNA — little fragments of DNA that are mixed with little fragments of DNA that are in your plasma — and you can isolate those and sequence them, you can try to find mutations, and those could be representative of a rapidly growing tumor.” Researchers are looking into the concept of sequencing multiple different regions of a tumor and then following patients serially in their peripheral blood. Morrisette says she assumes that within the next few years, this process will become the standard of care.

### Precision Medicine Trends: Confronting the Riddle of Alzheimer’s, Genetically

Precision medicine also holds promise in the treatment of Alzheimer’s. Jason Karlawish, University of Pennsylvania professor of medicine, medical ethics, and health policy, sees the opportunities and challenges of personalized medicine for the brain. He believes that fields such as cancer and cystic fibrosis have made notable advances using genetic tests to carve out drug-responsive forms of diseases. One day, he thinks Alzheimer’s disease may do the same.

Genetic testing can suggest one’s risk of developing the disease. The APOE gene has three forms (APOE 2, 3, and 4) and every

person inherits six possible genotypes. Karlawish points to multiple studies showing that the more copies of the APOE4 gene someone has, the greater is the risk after age 60 of developing Alzheimer’s disease dementia.

Karlawish co-directs the Penn Memory Center, a clinical and research center dedicated to diagnosing, treating and doing research on older adults with cognitive impairment. He is also part of the Penn Program for Precision Medicine on the Brain, or P3MB. “What we’re interested in looking at is the interrelated clinical, ethical, social and legal issues raised by the practice of personalized medicine or precision medicine for the brain,” he says.

Karlawish notes that the U.S. government is making a big push to prevent or find effective treatments for Alzheimer’s by 2025, courtesy of the National Alzheimer’s Project Act. Much of the current research on Alzheimer’s, he says, focuses on the “application of gene or biomarker technologies designed to better identify the strata of risk and then intervene, with experiments and test drugs to see if they can change the natural history of the disease — which is precisely what precision med is about.”

Looking ahead, Karlawish sees many promising opportunities to image the brain and its pathologies — the amyloid plaques and neurofibrillary tangles that are the hallmarks of the disease, “and also a lot of opportunities with drugs that target various points along the cascade of the development of the pathologies. There are also opportunities in the space of cognitive aging, namely, to try to intervene to prevent not the death of neurons, but their dysfunction that occurs with aging.”

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— Jason Karlawish, Penn Program for Precision Medicine on the Brain, University of Pennsylvania

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## Precision Medicine Trends: One Disease or Many?

Precision medicine is also deconstructing the very concept of what constitutes a particular disease, says Wilckens, whose company InnVentis uses multi-omics and real-world Big Data and machine-learning to provide solutions in diagnostics, monitoring and therapy for chronic inflammatory diseases. “We do not look at the primary diagnosis, because that’s man-made and it’s not precise simply because we do not really know what we are looking at. That is, there are no molecular definitions of most chronic diseases that must be regarded as look-alike syndromes.”

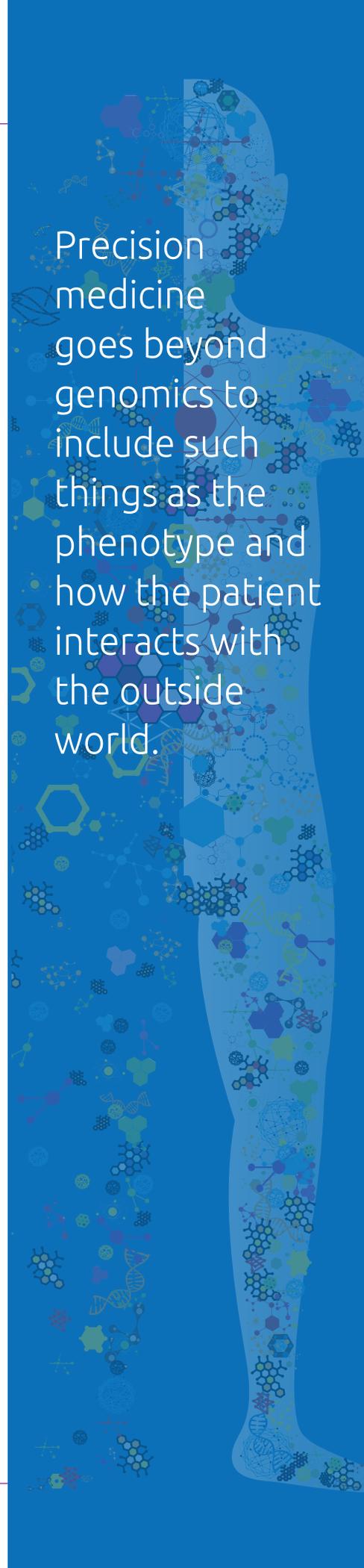
For example, in arthritis, sub-types of the disease have already been identified, such as psoriatic arthritis and rheumatoid arthritis. Yet the percentages of drug effectiveness are still not very high. The best drugs available for rheumatoid arthritis only work in 20% to 25% of patients, no matter how the dose is adjusted. Wilckens says this is “highly suggestive” that there are different conditions within the rheumatoid arthritis category. “It’s even worse with multiple sclerosis,” he adds. “Copaxone, Teva’s lead product, works only in one out of 18 patients. Imagine the consequences of overtreatment with drugs, which generate side effects and unnecessary costs while missing an early stage ‘window of opportunity’ to treat debilitating diseases to remission — once more creating a tremendous burden to patients and society.”

The solution lies in generating molecular signatures or maps of diseases. For instance, “we have to look without any hypothesis at the chronic conditions in an early stage. For example, [researchers] at Mt. Sinai, New York, used topological mapping of clinical data and realized that there are perhaps six sub-types of diabetes,” Wilckens says. “Today, a patient at Mt. Sinai will instantly be stratified in one of those six subgroups, and then he gets what we would call preciser treatment.” Thus, it is necessary to extend this to the molecular level for all chronic diseases in its earliest stage of detection or even engage in prospective data harvesting to eventually enable prevention.

Karlawish agrees. “We’re busting diseases up. That’s what’s happened in cystic fibrosis. There are forms of cystic fibrosis that respond to certain treatments, and they almost become different diseases in that sense, given differences in both their markers and response to treatment.”

## Rise of Wearables and other Devices

Precision medicine goes beyond genomics to include such things as the phenotype (for example, height, blood type, eye color or other observable physical traits) and how the patient interacts with the outside world. “Some people call precision medicine ‘genomics medicine’ as if blueprint genomics would solve all problems of medicine, which is ridiculous — it does not,” asserts



Precision medicine goes beyond genomics to include such things as the phenotype and how the patient interacts with the outside world.

Wilckens. “Lifestyle, nutrition, everything is influencing our longevity. ... We have to learn much more how, actually, our lifestyle affects our body and what it exactly does” at the molecular level.

A simple blood draw may someday be used to tell your physician much more about how your health and disease changes over time, states Wilckens. He describes a concept in which thousands of parameters might be analyzed from one blood sample, and that sample is compared with the results of others taken on previous dates. The data points would include proteomics, antibody profiling, viral exposure and metabolomics. Due to the scale of the technology, small diagnostic kits will have no future, because it simply becomes cheaper to capture everything in one profile and detect minute changes that pinpoint the development of disease early on.

Precision medicine also will foster Amazon-like business models: Patient or customer A looks like customer or patient B and thus needs drug, nutraceutical or intervention XY. Health and disease management will become a consumer-driven business and will require completely new Standard Operating Procedures (SOPs), logistics as well as ICT/AI (information and communications technology/artificial intelligence) data analytics capabilities.

Wilckens adds that although it may seem like a trivial point, today’s blood sampling is not sufficiently standardized. That hurdle would have to be overcome first. “We have some robust markers that are comparable and reproducible, but they may not be comparable between institutions.” For example, he cites findings showing that to apply metabolomics accurately, it makes a difference whether the

patient sits, stands, or lies down; what time of day it is, and whether the blood is processed in 15 minutes or 30 minutes. “This is a major challenge. A lot of people like to ignore it ... but we have a garbage-in, garbage-out problem.”

Miles agrees that the genome is not the complete answer: “It’s not just about taking your drugs; it’s making sure that you’re eating right, exercising, being active and having a good care circle. All of these environmental factors can have a significant impact on the outcome.” He notes that pharmaceutical companies are trying to work more closely with physicians to develop solution-based programs with a more holistic or “beyond the pill” view of patients’ health, which should dramatically improve therapeutic outcomes. He believes such non-traditional partnerships are a growing trend.

Furtwaengler agrees and refers to a “gold rush mentality” in precision medicine right now, especially in the areas of wearable technology, e-health and mobile health. One new project he references is a collaboration between Novartis and Google to develop a “smart” contact lens that helps diabetics monitor their blood glucose levels. “It’s a novel contact lens with an insulin sensor ... with the capability to continuously measure glucose levels in the lining fluid of the cornea.”

Another example of a novel strategic relationship for advancing precision medicine and improving health care is the partnership between CancerLinQ LLC, a wholly-owned nonprofit subsidiary of the American Society of Clinical Oncology (ASCO) and SAP. In 2015, the two organizations announced that they are collaborating to develop CancerLinQ™, a state-of-the-art health information technology

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— Joe Miles, SAP

platform. According to SAP, the goal is to provide cancer patients with a new level of care that is “informed by the data of nearly every patient treated before them.”

It uses a flexible, multipurpose in-memory data management and application platform, analyzes Big Data from a growing number of patient records and makes the information readily accessible to practicing oncologists. This means physicians can now take advantage of clinical insights from massive amounts of data from patients in the United States. The platform is currently being used by a number of practices across the country.

In a recent ASCO *Daily News* article, ASCO CEO Clifford Hudis noted that with the platform, “we can also learn from the care given to 97% of adult patients who do not currently participate in clinical trials.”

Using the system’s aggregated data, a physician will be able to determine with greater accuracy whether a molecular marker is significant to a patient’s cancer, and if it indicates the use of a particular treatment. Doctors will also have better access to information on how similar patients have responded to treatment regimens, and what side effects they experienced.

Wilckens has been observing some novel partnerships. Microsoft co-founder Bill Gates

and Amazon founder Jeff Bezos are investing in Grail, a start-up by gene sequencing firm Illumina that is led by a former Google executive. Grail is developing a cancer-screening blood test for people even if they are showing no symptoms. “The technology is coming from Illumina, which is in liquid biopsy. They want to harvest as much data as they can, use machine-learning or deep learning, and then stratify all kinds of diseases with that technology where it’s applicable.”

Furtwaengler’s company, Boehringer Ingelheim, also testifies to the rise of innovative partnerships. It is in discussions with major technology companies, as well as automotive and telecommunications firms. “I’m sitting also on multinational consortia with four or five other big companies, and looking at digital health and technology work streams under the auspices of a patient advocacy group.” He adds that the effort to initiate new collaboration models is being supported by national health care bodies in the U.K. and the EU, including the Innovative Medicines Initiative of the European Union (IMI).

In Furtwaengler’s opinion, there is a need in the industry to “join forces for the greater good,” which he says he is trying to help facilitate. “Instead of the Googles, Facebooks, Jawbones, Fitbits, and Apples of this world all trying to double-dip with each and every

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*“What is currently driving costs is actually data analytics. (The genome can be sequenced for \$1,000), but it will cost you approximately \$15,000 to make sense of that.”*

— Thomas Wilckens,  
InnVentis

Health and disease management will become a consumer-driven business and will require completely new Standard Operating Procedures (SOPs), logistics as well as ICT/AI data analytics capabilities.

# At this early stage of development, precision medicine therapies tend to be more expensive than conventional therapies.

individual company, we're trying to turn that around and ask them to join us in an effort for the greater good of patient health."

Specifically, Boehringer Ingelheim is working on the interaction of biomarkers and wearables. It is supporting an IMI project called PRO-active for chronic obstructive pulmonary disease (COPD). The project assesses different kinds of tri-axial accelerometers, which is a device he describes as "like a step count or pedometer, but with technology in the X, Y, and Z axes." It uses artificial intelligence and machine-learning algorithms. He explains that more advanced versions of these devices can detect when the patient is going up a flight of stairs, going down, or moving across level ground.

## The Cost Benefit Analysis of Precision Medicine

At this early stage of development, precision medicine therapies tend to be more expensive than conventional therapies. Proof needs to be shown to payers, whether in Europe's national health care systems or in the U.S., that the outcome is superior to the current standard of care.

Voigt provides some insight into the process of getting U.S. payers to understand and agree to cover new therapies. At Medical Device Consultants of Ridgewood, he works with early-stage medical technology companies, providing cost-effectiveness analyses for their innovations. For example, a company with a new ECG implantable alerts high-risk patients and their doctors to signs of a heart attack, thus helping patients get the critical care they need sooner.

Voigt uses a formula that compares the product with the standard of care, and divides the increased cost by the increased benefit to generate an incremental cost-effectiveness ratio. He notes that such a formula is used frequently in the U.K., where the threshold of deciding to incorporate or not incorporate a new technology into the national health care system is about \$45,000 per quality-adjusted life year. "This kind of rigor in evaluating technology is moving quickly in the United States." Currently the cost threshold in the U.S. for new technologies is about \$100,000. (The ECG implantable came in at \$32,000.)

Other proof points are often required as well, according to Voigt, but unfortunately these can critically strain the limited resources of many startups. "[Companies may] have to spend a ton of money showing they can change a physician's behavior; they may have to do randomized controlled trials and follow these patients for months, sometimes years."

One company driven out of business by this process was one that had invented a test to identify previously unknown primary cancers in cases of metastatic cancer, Voigt says. He adds that its demise was a "sad thing, because I think ultimately it was a good test, and it was helping patients who really didn't have any other options."

While acknowledging that precision medicine is relatively expensive, and that some research models predict it becoming more so, Wilckens argues that costs will actually go down. With sequencing, for example, "what is currently driving costs is actually data analytics," he says. The genome can be



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sequenced for \$1,000, “but it will cost you approximately \$15,000 to make sense of that.” Automating the process will drive costs down, he says, as will scaling, standardizing and rolling out other precision medicine technologies. Regarding clinical trials, a paradigm shift is expected towards intra-individual, longitudinal multi-omics analysis, which

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*DNA extraction and analysis can cost up to \$1 million, but new sequencers and data analysis tools could bring the cost down below \$1,000.*

may make randomized controlled trials almost obsolete, not least since it will be unethical to continue a treatment in a patient that obviously does not respond to a drug. Under the precision medicine paradigm, firms will see faster and more precise responses to drugs, which will save billions in the long run.

For instance, J. Craig Venter’s Human Longevity Inc. currently offers a service that Wilckens refers to as “a physical on steroids.” For \$25,000, the service includes multi-omics, MRI and data analytics. If that kind of test could be scaled to the level of costing perhaps \$2,500, people could take it once a year to prevent and manage diseases more effectively than is possible today, leading to additional cost savings in avoidable and unnecessary treatments.

In addition, the cost for wasted drugs can be reduced. Wilckens points to the

autoimmune disease drug Humira as an example. “It may only work in one out of five patients, depending on the condition, and one shot costs \$10,000. So imagine if you could really figure out which are the responders, and you’re not treating other patients with a drug that costs \$10,000. This will drive down costs dramatically, and foremost, ensures better quality of life and productivity.”

But to get there, says Wilckens, “we have to do massive investment — in new data systems, in new business models and in new procedures.”

### **The Role of Information Technology in the Growth of Precision Medicine**

New technologies are making advances in precision medicine possible, but there is more work to be done. R&D directors in the life sciences need to keep harnessing new technologies in order to speed time-to-market and stay ahead of trends in precision medicine. They are working with enormous, disparate data sets, and must be able to store and analyze them accurately and quickly. The data can include genomic or proteomic data (large-scale studies of organic proteins), scientific texts, clinical studies and data from universities and laboratories, all in different formats and from various sources. “To get intelligent insights from that diverse, big amount of data is really difficult,” says Susan Rafizadeh, SAP director of global industry marketing for life sciences.

New technologies are making advances in precision medicine possible, but there is more work to be done.

Moreover, a lab's databases may hold older but key information — Rafizadeh calls them hidden treasures — that could not be analyzed previously because the IT capability did not exist. Furtwaengler agrees: "We even have to look at our own in-house data because there's a lot of jewels buried in there ... questions that can only now, with the computational power, be addressed."

Unstructured data, such as information from electronic medical records or from research documents, pose a special problem for life sciences companies. "A large part of the focus over the years has been on documents and not data. Consequently, analyzing and identifying causality across those documents has been very difficult if not impossible," Miles says. There is "a significant amount of productivity to be gained with technology that is able to scan those documents across any language in order to identify any trends, patterns or effects in the research and is a critical step in improving the R&D productivity for health sciences companies."

"We see organizations struggle with the ability to have robust and productive capabilities in this area that allows you to review large amounts of documents and text across a variety of strategies," Miles continues. "For example, an organization may want to look at thousands of documents for character strings across any language, focus on a primary term such as 'oncology' but include additional references such as 'carcinoma,' identify associated phrases that are linked to the target phrases like 'palliative care' but not currently known and to do this in a matter of seconds or minutes. Subsequent searches can benefit from the knowledge gained in the previous

searches as the self-learning capabilities increase the accuracy with each attempt."

In Rafizadeh's view, in-memory technology offers great potential to speed up the work of life sciences companies grappling with Big Data. This is a platform that processes data stored in the main memory rather than having to retrieve it from a traditional database, thus dramatically increasing the speed of the analysis.

Rafizadeh notes an observation by an R&D manager that what used to be a master's thesis work can now be done in days. "It's really a different world that we're now in," she says. Moreover, in-memory technology enables faster elimination of bad data. It helps researchers refine and revise their algorithms, in real time, to enhance the quality of the data while accelerating the ability to calculate outcomes of the research.

Petra Streng, solution manager with SAP for life sciences, agrees that to facilitate precision medicine, "heavy number-crunching" is necessary. "This is only possible if you not only have the content, the nice ideas and the analytics and tools, but also the computational power underneath." Only then can researchers obtain the results of their analyses in a feasible timeframe.

Streng remembers SAP working with a team at a U.S. research institute that was trying to analyze 500 genomes. She says the 500 genomes entailed processing 22 billion records, with the need to be able to "slice and dice" the data in milliseconds.

"It was run on a conventional disk-and-file system: The computer was running for two weeks and still hadn't returned any results,"

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*"A large part of the focus over the years has been on documents and not data. Consequently, analyzing and identifying causality across those documents has been very difficult if not impossible."*

— Joe Miles, SAP

Streng says. But after upgrading to a system with in-memory technology, “the information was available in real time. Now the customer can run this analysis and within a second you have the result of all these combinations.”

Another organization using in-memory technology is Mitsui Knowledge Industry (MKI). MKI is a Japanese technology consultancy with a specialty in bioinformatics. MKI tried running same-query comparisons between an in-memory database and a conventional one, and found that the in-memory database completed one process an astonishing 400,000 times faster. The speedier technology will also lower costs. According to MKI, DNA extraction and analysis can cost up to \$1 million, but new sequencers and data analysis tools could bring the cost down below \$1,000.

Precision medicine means new collaborations, too. But the collaboration piece can trip up a project if the company is not working as effectively as it could with contract research organizations, scientists and hospitals as well as internal stakeholders in regulatory, marketing and R&D itself.

This is where cloud computing is invaluable, according to Rafizadeh. “You can really speed up collaboration because everybody uses the same platform. You can communicate directly — use and work on the same data. You don’t need to worry about versioning and so on. And it’s very cost-effective.”

Streng adds, “It’s connecting the dots that is so important, because no individual, no institution, no single technology has it all.” For instance, in certain types of cancer, one institution — or one country, for that matter — might not have enough of that type of cancer patient to yield a large enough sample size for proper analysis.

Streng recalls her experiences participating in meetings in hospital tumor boards where doctors discussed their more difficult cancer cases. “The need for information is so drastic, you could almost start crying when you see the lack they are dealing with on a day-to-day basis,” she says. Doctors would discuss what else they could offer to lessen pain, make life more bearable, or find any kind of other treatment options still open to a patient. “And then there are discussions around, ‘Well in some scientific journal, wasn’t there a mention of someone with a similar cancer or maybe another co-morbidity? What was done with them, does anyone know, can we find out?’”

In addition to the dearth of information for the most unusual cases, there is also the risk that more commonplace cancers are treated without adequate statistical information to back up therapy decisions. “Many treatment options and alternatives given to the patient are based on an individual physician and his team’s knowledge,” Streng says. “There is very little statistics applied to that, so you have a certain bias from what this physician has experienced.”

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It is the job of technology to facilitate that process and bring together diverse information, analyze it and try to identify patterns.

Personal bias based on experience can pose a danger, and statistics based on small numbers can be inaccurate. Only with a large enough number of cases can there be adequate identification of different types of responders to a treatment, the proper building of sub-cohorts and the design of appropriate precision medicine therapies — enabling the robust sharing of those therapies across medical institutions and countries.

It is the job of technology to facilitate that process and bring together diverse information, analyze it and try to identify patterns. “Without the speed of the data systems, and without the technical ability to look at all this information ... no human brain can process millions and billions of iterations and compounds. This is where IT needs to play a key role,” Streng says.



## Conclusion

The emerging field of precision medicine is speeding ahead, marked by non-traditional new partnerships across different groups in medicine, health care, technology, academia and government. It is increasingly viewed as mainstream treatment, especially in cancer research and diagnostics. Many pharmaceutical, biotechnology and device firms are taking the plunge, looking to precision medicine as a way to improve patient outcomes by reimagining their business models that simultaneously reduces the cost but improves the quality of care.

Meanwhile, new IT technologies and the convergence of multi-omics with real-world data including lifestyle and nutrition have arisen to provide capabilities that would not have been possible a few years ago. These innovations are providing the tools needed to perform the extraordinary analysis of the massive amounts of data against the various genomically, precisely, genotypically and phenotypically defined patient or better customer (in terms of prevention) populations. This will allow researchers to identify patterns that will lead to the next breakthrough health care drug or product that will improve the fight against deadly and debilitating diseases like cancer, arthritis, Alzheimer’s and Parkinson’s as well as the many currently poorly defined and underserved pathologies.

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