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How's Your Mustache Looking this Month?

Forget the razor, remember men's health

If you're participating in the Movember campaign throughout November, either you're growing out your mustache, supporting someone who is, or you're making sure you're participating in an activity every day this month, all for a worthy cause.

The Movember Foundation was established in 2003, and for the past dozen years, it has sponsored events and helped raise money and awareness with the goal of helping men live longer, healthier lives through investing in four primary areas: prostate cancer, testicular cancer, poor mental health, and physical inactivity.

In November, men and women are encouraged to participate in Movember by growing and grooming a mustache, supporting someone who is growing their mustache, or by pledging to MOVE every day during the month to improve your health. Whichever way you choose to participate, you can help raise funds and awareness for men's health issues. Prostate cancer, one of the four issues targeted by the Movember Foundation, is our focus in this issue of the AlphaBioCom newsletter.

For more information and for ways to help the cause, please visit http://us.movember.com. For more information on prostate cancer awareness, please visit the Prostate Cancer Foundation's website at http://www.pcf.org. And to join the foundation's Movember team, click here (https://us.movember.com/team/1944345) to join Team PCF MoNinjas.

Whether you're taking a Movember challenge or not, you're always welcome to check out the new and improved AlphaBioCom website (www.AlphaBioCom.com) and feel free to leave comments and suggestions about our newsletter and our organization. We can be found on Twitter at @alphabiocom, and you can connect with us on LinkedIn.

ADVANCES IN PROSTATE CANCER TREATMENT

2015 October: The US Food and Drug Administration grants pre-market approval of Sonablate® 450 (a high-intensity focused ultrasound device) (SonaCare Medical, LLC) for treatment of prostate cancer

2014 The PREVAILs trial, a double blind, phase 3, randomized trial conducted in 1717 patients, showed that enzalutamide (previously approved for metastatic prostate cancer patients who progressed after chemotherapy) significantly decreased the risk of radiographic progression and death and delayed the initiation of chemotherapy in chemotherapy-naïve men with metastatic prostate cancer

2013 May: The FDA approves Xofigo (radium Ra 223 dichloride) (Bayer Pharmaceuticals) to treat men with symptomatic late-stage (metastatic) castration-resistant prostate cancer that has spread to bones but not to other organs

2012 August: The FDA approves enzalutamide (Xtandi® Capsules) (Medivation, Inc.; and Astellas Pharma US, Inc.), for the treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel

2011 April: The FDA approves ZYTIGA® (abiraterone acetate) (Janssen Biotech, Inc.) in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer who have received prior chemotherapy containing docetaxel

2010 June: The FDA approves cabazitaxel (Jevtana® Injectio) [Sanofi-Aventis] for use in combination with prednisone for treatment of patients with metastatic hormone-refractory prostate cancer (mHRPC) previously treated with a docetaxel-containing regimen

2009 October: The FDA approves the VIDAS fPSA rt Assay (Biomerieux Inc.) for the diagnosis of prostate cancer by measuring levels of free prostate-specific antigen (fPSA) in blood

2008 December: The FDA approves degarelix for injection (Ferring Pharmaceuticals Inc.), a new gonadotropin-releasing hormone (GnRH) receptor antagonist, for the treatment of patients with advanced prostate cancer

2007 May: The FDA approves the IMMULITE®/IMMULITE® 1000 and IMMULITE® 2000 Free PSA tests (Siemens Medical Solutions Diagnostic) for the diagnosis of prostate cancer by measuring levels of free prostate-specific antigen (fPSA) in blood

2006 April: The FDA approves mitoxantrone hydrochloride for injection (Teva Pharmaceutical Industries Ltd.; Hospira, Inc; and Mylan); used as palliative treatment in advanced disease that is hormone-refractory (does not respond to hormone treatment)

2005 February: The GEC/ESTRO (European Society for Radiotherapy and Oncology) recommendations for template and transrectal ultrasound (TRUS) guided transperineal temporary interstitial prostate brachytherapy using a high dose rate iridium-192 stepping source and a remote afterloading technique as an effective technique to achieve dose escalation in the radical treatment of localized prostate cancer were published. These guidelines were updated in 2013

On the Road to the Future

New technologies have made our commutes safer, more comfortable

The Tom Cruise movie *Minority Report* predicted completely autonomous, self-driving cars. *Total Recall* featured robot-driven Johnny Cabs. *Back to the Future II* famously predicted that 2015 would see vehicles that could fly as well as travel on roads.

We're not there yet. While Google and Uber have reportedly been testing self-driving vehicles, we're not quite at the levels of 2054 Washington, DC, or even Hill Valley 2015. But recent advances in automotive technology have made our driving experiences safer and more enjoyable.

Not surprisingly, automotive advances go hand-in-hand with technological advances. As many of us spend more than an hour in our cars every weekday making our round-trip commutes to and from the office, integrating your ride with all the technologies that help make your home life so much easier has been a major selling point for car manufacturers in recent years.

Of course, new technology doesn't just end with an onboard computer that reads your texts and Facebook posts back to you. One of the most important new technologies introduced in the last 10 years was the MyKey system, first offered in Ford's 2010 Escape Hybrid and Mercury Mariner Hybrid, but is now available in all Fords. Designed for parents with teenage drivers, MyKey, when activated, limits the car's speed to 80 mph and can be programmed to limit the radio volume and to emit a continuous alarm if seatbelts remain unfastened.

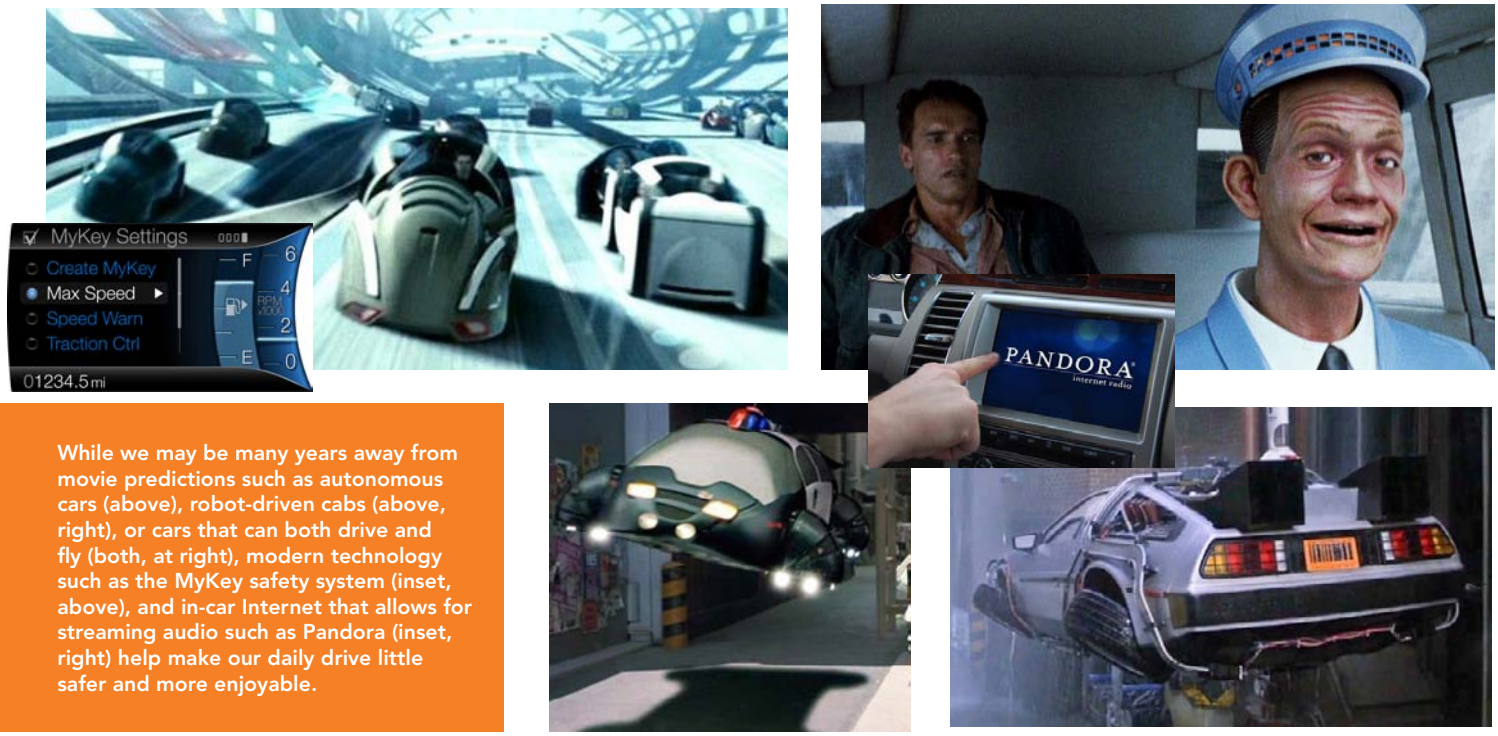
Remember the LoJack vehicle recovery system? As technology has advanced, many cars now come with standard GPS tracking. Tracking devices are small and portable and can be placed in and moved to any car. Parents, police, even businesses that need to keep track of their fleet vehicles, can keep tabs on their cars and trucks from a home computer or cell phone.

When you were learning to drive, seeing what was behind you was often accompanied by the phrase "Objects in mirror are closer than they appear." It sure made it challenging to parallel park, didn't it? Nowadays, numerous car dealers have equipped their cars with rear (often multiple) cameras to help provide a clear and precise field of view for the driver. Some systems offer a rear-mounted radar as well, issuing the driver a warning signal when your car is getting too close to a nearby object.

Along similar lines, how many times have you tried to change lanes on a busy highway only to get honked at by a fellow motorist whose car was lost in your blind spot? First introduced on the 2007 Volvo S80 sedan, the Blind Spot Information System provides drivers with a visible alert when a car enters the blind spot using two door-mounted lenses to keep tabs on the blind spot area. Since then, Mazda, Ford, Mercury, and Lincoln have all adopted BLIS technology.

Another new technology is Adaptive Cruise Control, which maintains a preset distance between your car and the vehicle directly in front of you. The 2015 Hyundai Genesis offers this technology, which can even bring the car to a complete stop in order to maintain the distance between cars.

That's just a quick look at some of the technologies and options that make our daily commutes safer and more comfortable. What does the future hold? Electronic sun visors, Doze Control systems that alert a drowsy driver if the car is drifting, and biometric vehicle access are three technologies that might become standard features of automobiles in the very near future. What other surprises await us on the highway into the future? Buckle up, set it in cruise control, and let's find out together.



While we may be many years away from movie predictions such as autonomous cars (above), robot-driven cabs (above, right), or cars that can both drive and fly (both, at right), modern technology such as the MyKey safety system (inset, above), and in-car Internet that allows for streaming audio such as Pandora (inset, right) help make our daily drive little safer and more enjoyable.

Early Detection the Key

Prostate cancer among the most diagnosed cancers among men

Excluding nonmelanoma skin cancer, prostate cancer (PCa) is the most common cancer diagnosed in men in the United States, with an estimated 220,800 new cases diagnosed in 2015. Detection rates of PCa, particularly early stage, increased significantly in the late 1980s and early 1990s due to the wide-spread adoption of the prostate-specific antigen (PSA) blood test for PCa screening. Controversy persists regarding the use of PSA screening, particularly among low- and average-risk men, as it can lead to overdiagnosis and overtreatment. For many men, PCa is an indolent disease; more men die with PCa than from it. Men at high risk for developing PCa are those ≥65 years of age, with African ancestry, a family history of disease, or certain inherited conditions. In addition, lifestyle factors—including high dietary intake of processed meats or dairy foods, obesity, and smoking—may increase a man's risk for developing PCa or influence disease aggressiveness.

PCa is the second leading cause of cancer-related deaths; approximately 27,000 men in total will die from the disease in 2015. For all stages of PCa combined, the 5-year survival rate is close to 100%; this is considerably higher than the rate in the late 1980s (83%) and can be attributed both to earlier detection due to PSA screening and to improvements in treatment options. However, when broken out by stage, the 5-year survival rate is >99% for both local and regional disease, but once the disease has metastasized, 5-year survival drops to 28%.

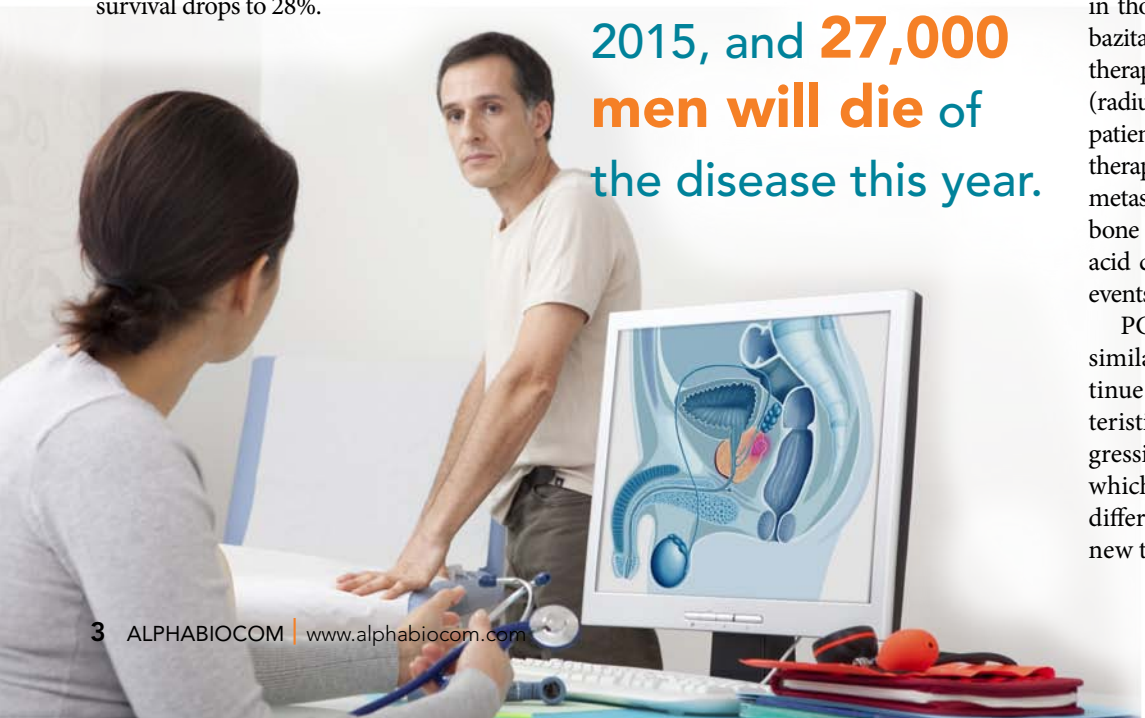
Treatment options for men diagnosed with early stage, localized disease include active surveillance, surgery (prostatectomy), external beam radiation, or brachytherapy (implanted radioactive seeds). Active surveillance is a good treatment option for men with less aggressive disease or with limited life expectancy. Androgen deprivation therapy (ADT) may be administered as adjuvant or neoadjuvant therapy to surgery or radiation when the disease is considered to be more aggressive and more likely to recur. It is always important for men to discuss with their physician the possible treatment options, as they are all associated with risk of side effects, including erectile dysfunction and urinary incontinence, both of which can significantly impact quality of life.

ADT as monotherapy is recommended for men with regional or metastatic disease or recurrence after prostatectomy or radiation. For men who have been treated for localized disease primarily with surgery or radiation, approximately 20% to 30% will fail therapy and go on to develop advanced PCa. The goal of pharmacologic ADT is to suppress testosterone levels down to what is observed in men who have undergone surgical castration. Castration levels of testosterone can significantly hinder tumor growth and alleviate symptoms, but are associated with increased risk for cardiovascular disease, type 2 diabetes, sexual side effects, loss of muscle mass, osteoporosis, fatigue, and depression. ADT is palliative, not curative, treatment. Most men treated with ADT will go on to progress to castration-resistant PCa (CRPC), which can range from asymptomatic disease with no radiographic evidence of metastasis and primarily indicated by rising PSA levels, to symptomatic, metastatic disease (mCRPC). It is estimated that there are 35,000 men in the United States who have mCRPC.

Estimates predict that **220,800 new cases** of prostate cancer will be diagnosed in 2015, and **27,000 men will die** of the disease this year.

The management of mCRPC was considered palliative until 2004, when docetaxel—a microtubule stabilizing agent that demonstrated significant survival benefit in mCRPC patients, contrary to secondary hormonal manipulations—was approved. Since 2010, the number of approved therapies that increase survival for mCRPC has greatly increased and include the hormonal therapies abiraterone acetate and enzalutamide, the immunotherapy agent sipuleucel-T, and the chemotherapy agent cabazitaxel. Both abiraterone acetate and enzalutamide can be used for treatment in men with mCRPC who have relapsed after docetaxel therapy or in those who are docetaxel-naïve, while cabazitaxel, sipuleucel-T, and the radioactive therapeutic agent radium Ra 223 dichloride (radium-223), are specific to treatment in patients who have relapsed after docetaxel therapy. For mCRPC patients with bony metastases, denosumab—which targets the bone microenvironment—or zoledronic acid can reduce the risk for skeletal-related events, such as fractures.

PCa is a very heterogeneous disease, similar to breast cancer. Researchers continue to investigate the molecular characteristics of the disease to identify more aggressive variants of the disease, determine which patients may be more responsive to different types of therapy, and to elucidate new therapeutic targets.



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Audiovision Lends its Voice

The New Jersey State Library Talking Book and Braille Center offers a 24/7 radio reading service called Audiovision to New Jersey residents unable to read standard print because of a physical impairment. This service provides access to local and national news as well as special interest programming. Audiovision is staffed mostly by volunteers serving as news narrators whose recordings are broadcast on the audio channels of local cable TV and via the internet.

News narrators focus primarily on local and regional news as well as magazine articles. Typically, a set of volunteers creates a selection of potential articles from the local and national newspapers for that day, which the news narrator selects from and then organizes for a 28- or 58-minute recording. There are five small recording studios available for use during a typical day, with one or two recording engineers providing technical assistance. Sources range from *The Asbury Park Press* to *The Wall Street Journal*. Often, a narrator will focus on reading for one locale and in doing so, will develop a feel for the style of the local reporters. While the focus is on local events in the many communities in New Jersey, listeners from all around the region can listen either live or on demand via the links provided on the Audiovision site.

AlphaBioCom Scientific Director Paul Hale has lent his voice to the New Jersey State Library Talking Book and Braille Center's Audiovision service.

Readers can graduate to recording books, usually about something specific to the state, but the time commitment is substantial as the recording must match exactly what the author has written and include appropriate voicings.

I came across Audiovision while looking for something similar to a program I had participated in when I was back in graduate school in St. Louis and occasionally had some free time. Volunteering as a news narrator seemed easy enough but the role requires good time management and organizational skills (your recording session has to end within a 20-second window) as well as the need to focus on clear elocution. Giving my time and voice to Audiovision allowed me to not only provide a needed service to many individuals in the state, but it also helped me fulfill a fantasy of mine, that of being a radio DJ, albeit a news-oriented one. *—by Paul Hale*

MEET THE STAFF

Ewa Wandzioch, PhD, *Scientific Communications Manager*

As a Scientific Communications Manager, Ewa works with the scientific lead and assists with development of abstracts, posters, slide decks, and both primary data and review manuscripts.

Ewa earned a PhD in Molecular Biology from Umeå Center for Molecular Medicine, Umeå, Sweden. She was a Postdoctoral Fellow at the Fox Chase Cancer Center, Philadelphia; and worked as a Research Associate at the University of Pennsylvania. Thereafter, she held the position of a Research Scientist in the pharmaceutical company Venenum BioDesign. She started medical writing in 2012 at Complete Healthcare Communications.

Ewa has experience in the fields of embryonic stem cells, oncology, hematology, hepatology, and developmental biology. She has co-authored numerous articles for various peer-reviewed scientific journals.

Ewa began working at AlphaBioCom in August 2013.

Paul Hale, PhD, BS Pharm; *Scientific Director*

As Scientific Director at AlphaBioCom, Paul leads content development for scientific communications strategies and tactics, conducts literature reviews and research, serves as a liaison with authors, and develops tactical plans.

Paul has nearly 30 years of domestic and international industry experience in Scientific Communications and Medical Affairs. He earned his BS in Pharmacy and a PhD in Pharmacology and has therapeutic area expertise in infectious disease, diabetes, hypertension, oncology, and Alzheimer's. Skilled in integrating scientific and business needs, Paul has experience leading international project groups for both developmental and life-cycle assets.

Paul spent 14 years at Bristol-Myers Squibb in areas of increasing responsibility. He has also worked for Cubist Pharmaceuticals, Astellas Pharma, and Hoechst AG.

Paul joined AlphaBioCom in September 2015.

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640 Freedom Business Center Drive | Suite 340 | King of Prussia, PA 19406
610.962.1040 | alphabiocom@alphabiocom.com