



By Carolyn Gretton

▶ GSMA Forecasts Robust Mobile Health Market Growth

TREND: With the increasing penetration of smartphones and other mobile-connected devices and the proliferation of mobile broadband networks and services worldwide, mobile will likely play a far greater role in healthcare in both developed and developing countries in the future.

A report conducted by PwC for the GSMA predicts the growth of the mobile health (mHealth) market will result in \$23 billion worth of revenue opportunity by 2017.

The report, *Touching Lives through Mobile Health: Assessment of the Global Market Opportunity*, notes that in spite of the advancements in medical technologies and a general increase in income levels, healthcare continues to pose challenges of affordability, complexity, and access across the world. By contrast, mobile access is almost ubiquitous.

“By 2017, mobile technology will be a key enabler of healthcare delivery reaching every corner of the globe,” says Jeanine Vos, executive director, mHealth at GSMA. “With developed countries needing to reduce the cost of universal healthcare, and developing countries looking to roll out life-saving services to in-need communities, mobile technology offers the ability to deliver highly effective, scalable, and affordable healthcare beyond the confines of a hospital or doctor’s surgery.”

According to the report, the provision of pervasive mHealth services and applications worldwide could provide mobile operators with an estimated \$11.5 billion in revenue by 2017. In addition, device vendors could benefit from a revenue opportunity of \$6.6 billion, content and application providers \$2.6 billion, and healthcare providers \$2.4 billion.

To enable this opportunity, however, governments, regulators, and healthcare providers need to work with mobile operators and organizations in the broader mHealth ecosystem, including device vendors and content and application players, to support the rollout and adoption of new mHealth services.

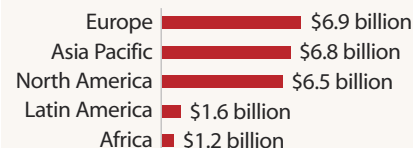
“mHealth is not only here to stay, but is expected to drive major changes in the delivery of healthcare worldwide,” Ms. Vos says. “But it is critical that governments and regulators the world over, as well as the healthcare profession, embrace this opportunity and work with the mobile industry to ensure that it is fully realized.”

▼ For more information, visit gsma.com.



Jeanine Vos

REGIONAL MHEALTH MARKET VALUE BY 2017



Source: GSMA, *Touching Lives through Mobile Health: Assessment of the Global Market Opportunity*. For more information, visit gsma.com.

Kalorama researchers see the primary growth drivers in the IVD market being the discovery of biomarkers with clinical utility and better reimbursement for testing. But the missing piece making the concept a reality is recent technology improvements.

“Cost-effective multiplex platforms, high-powered software, assays using saliva, urine, and blood instead of biopsied tissue are the technological tools that make more sensitive and specific tests possible,” says Shara Rosen, Kalorama’s lead diagnostic analyst.

One of the more dynamic market sectors is the tissue tests that determine therapy for cancer, which is expected to post better-than-average IVD industry revenue growth rates in the next five years.

“Tissue-based diagnostic testing continues to serve as one of the gold standards for cancer diagnosis,” Ms. Rosen says. “There is no other technology that can capture the biological context of the disease and the critical parameters that factor into patient outcomes.”

▼ For more information, visit kaloramainformation.com.

Cancer Diagnostics Driving Personalized

MEDICINE TESTING MARKET

Personalized medicine has long been part of diagnostic testing, but new, proven biomarkers and a desire to better target cancer therapy have grown personalized medicine testing to an estimated market value of \$28 billion in 2011.

The Kalorama Information report, *World Mar-*

ket for Personalized Medicine Diagnostics, notes that matching a drug’s effectiveness with a patient’s genetics has been considered since the 1950s. But the study acknowledges that the current excitement surrounding in vitro diagnostics (IVD), and a share of the growth in this market, is coming from new molecular tests and the profiling of solid cancer tumors, which are creating an entirely new paradigm for diagnosing and choosing treatment options.

Consumers Remain Wary OF EHR DATA SECURITY

The federal government is providing incentives for the use of health information technology, investing tens of billions of dollars in its adoption, and health

THERAPEUTIC FAST TRAX... ▶▶

ANEMIA

The existing market for anemia therapeutics is moderate with significant unmet needs, as the majority of the treatment options presently available for anemia have poor safety profiles. The global anemia therapeutics market was worth an estimated \$10.5 billion in 2010 and is projected to post a compound annual growth rate (CAGR) of 2.9% to reach \$13.1 billion by 2018. This forecast is primarily attributed to the presence of promising molecules in the anemia therapeutics pipeline that are expected to be launched during the forecast period.

Source: GlobalData, Anemia Therapeutics - Pipeline Assessment and Market Forecasts to 2018.

▼ For more information, visit globaldata.com.

CANCER

The global non-small-cell lung cancer (NSCLC) therapeutics market was valued at about \$4.5 billion in 2010 and is forecast to grow at a CAGR of 9.7% to reach \$9.5 billion by 2018. Growth is expected to be driven by the expected launch of Xalkori (crizotinib) by Pfizer in early 2012 for NSCLC patients with the ALK gene mutation.

Source: GlobalData, Non - Small Cell Lung Cancer (NSCLC) Therapeutics - Pipeline Assessment and Market Forecasts to 2018.

▼ For more information, visit globaldata.com.

The world market for cancer-treating drugs is projected to reach \$75 billion for 2012, with overall revenue for anticancer treatments expected to increase strongly from 2012 to 2022. Roche is expected to continue to be the leading company in the cancer-treating drugs market throughout the forecast period.

Source: visiongain, Leading Anti-Cancer Drugs and Associated Market 2012-2022.

▼ For more information, visit visiongain.com.

CARDIOVASCULAR

Managed care and prescription plans appear to be working to switch patients to generic atorvastatin despite Pfizer's efforts to reduce patient costs for branded Lipitor. Although Lipitor currently has 41% market share of all dispensed prescriptions of atorvastatin, it holds only 35% of the payer approval volume. Rejected claims for Lipitor increased immediately after the availability of generic atorvastatin to almost 8% in December. In addition, patient reversals also increased to almost 10%. Reversals are when a patient abandons a prescription at the pharmacy often because the co-payment is deemed too high.

Source: Wolters Kluwer Pharma Solutions' inThought research group, Source Dynamic Claims data.

▼ For more information, visit wolterskluwerpharma.com.

CENTRAL NERVOUS SYSTEM

The total Alzheimer's disease drug market is pro-

jected to almost triple over the next decade, increasing from \$5.4 billion in 2010 to \$14.4 billion in 2020 in the United States, France, Germany, Italy, Spain, United Kingdom, and Japan. A key driver of market growth will likely be the launches of solanezumab and bapineuzumab, two agents currently in Phase III trials that could demonstrate greater efficacy than currently available agents and, in particular, may affect disease progression.

Source: Decision Resources analysis of the Alzheimer's disease drug market.

▼ For more information, visit decisionresources.com.

In the next few years the global central nervous system (CNS) disorder market will witness patent expiries of major drugs, but the rapid uptake of new molecules is expected to stabilize the resulting market decline. The global CNS disorder therapeutics market was valued at about \$53.1 billion in 2010 and is expected to record a CAGR of 1.4% for the 2010-to-2017 period to reach \$58.6 billion in 2017. The anticipated launch of late-stage and novel molecules is expected to fulfill unmet patient requirements and drive the growth of the global CNS disorders therapeutics market in upcoming years.

Source: GBI Research, Central Nervous System Disorders Therapeutics Market to 2017 - Multiple Sclerosis, Major Depressive Disorder and Schizophrenia Accounted for Half the Market Value in 2010.

▼ For more information, visit gbiresearch.com.

The global epilepsy therapeutics market was valued at about \$2.9 billion in 2010 and is forecast to register CAGR of 3.5% annually to reach \$3.8 billion by 2018. Generic erosion of leading second-generation antiepileptic drugs such as Keppra (levetiracetam), Lamictal (lamotrigine), and Topamax (topiramate) is the major factor expected to restrict growth of the epilepsy therapeutics market during the forecast period.

Source: GlobalData, Epilepsy Therapeutics - Pipeline Assessment and Market Forecasts to 2018.

▼ For more information, visit globaldata.com.

Drugs developed to treat central nervous system (CNS) diseases take 35% longer to complete clinical trials and receive regulatory approval compared to other new prescription medicines. Between 1996 and 2010, mean clinical-plus-approval phase time for U.S.-approved CNS drugs was 32 months, 35% longer than that for non-CNS drugs approved during the same period.

Source: Tufts Center for the Study of Drug Development, March/April 2012 Tufts CSDD Impact Report study.

▼ For more information, visit tufts.csdd.edu.

DERMATOLOGY

The dermatology sector has seen an expansion of the range of therapeutic options available to physicians, driven by growth and aging of the global population, new products and technologies, and focus on lifestyle treatments that improve the effects of aging and damage to the skin. The global market for prescription dermatological products reached \$11.6 billion in 2011, growing at a rate of 6.2% from 2009 to 2011. The antiaging and photodamage hair loss and hair removal, psoriasis, and skin cancer treatment segments showed the most dramatic gains during this period, with growth rates of between 6.1% and 21.6%.

Source: Kalorama Information, The World Market for Prescription Dermatological Drugs, 8th Edition.

▼ For more information, visit kaloramainformation.com.

DIABETES

Driven by an increasing diabetes population in the developed countries of the United States, the United Kingdom, and Germany, the global diabetes therapeutics market is forecast to record 7.1% CAGR to reach \$47.2 billion by 2017, with the type 1 and type 2 diabetes markets expected to account for \$13.2 billion and \$34 billion, respectively. Novo Nordisk, Sanofi, and Takeda currently dominate the global diabetes therapeutics market, contributing almost 60% of the total market share.

Source: GBI Research, Diabetes Therapeutics Market to 2017 - Better Glycemic Control and Reduced Potential Risk of Hypoglycemia to Increase the Market Share of DPP-IV Inhibitors and GLP-1 Agonists.

▼ For more information, visit gbiresearch.com.

The diabetes market is anticipated to experience a new level of drug diversity and competitive pricing, presenting customers with remarkable choice. The global type 2 diabetes therapeutics market was valued at an estimated \$23.7 billion in 2011, and is expected to record a compound annual growth rate (CAGR) of 7.4% during the 2011-to-2020 period, reaching \$45.1 billion by 2020.

Source: GlobalData, Type 2 Diabetes - Global Drug Forecasts and Treatment Analysis to 2020.

▼ For more information, visit globaldata.com.

GASTROINTESTINAL

Celiac disease is becoming more widespread, increasing the value of the related therapeutics market. The global celiac disease therapeutics market is projected to be worth an estimated \$512.3 million by 2017 and \$664.4 million by 2019, primarily attributable to an increase in diagnosis rates and the resulting uptake of alleviating therapies.

Source: GlobalData, Celiac Disease Therapeutics - Pipeline Assessment and Market Forecasts to 2018.

▼ For more information, visit globaldata.com.

KIDNEY DISEASE

A recent survey of 100 U.S. nephrologists found that there is an extremely high need for new therapies targeted at polycystic kidney disease (PKD), a genetic disorder characterized by the growth of numerous cysts in the kidneys. There is no existing effective treatment to significantly slow PKD progression and currently, no pharmaceutical agents are specifically indicated for use in these PKD patients.

Source: BioTrends Research Group, TreatmentTrends: Polycystic Kidney Disease.

▼ For more information, visit bio-trends.com.

OBESITY

Existing antiobesity medicines are unpopular among their huge global target population due to multiple shortcomings, creating opportunities for pharmaceutical companies to tap into the lucrative obesity market. The global market for antiobesity therapeutics stood at about \$890.3 million in 2010, and growth is forecast at a CAGR of 9.3% to almost \$1.82 billion by 2018. Several late-stage pipeline molecules have displayed effectiveness and safety in medical trials, which may provide significant breakthroughs in the near future.

Source: GlobalData, Anti-Obesity Therapeutics — Pipeline Assessment and Market Forecasts to 2018.

For more information, visit globaldata.com.

IT is a foundation for health reform and for many of the new models of care now being developed or tested. As more consumers see their doctors using EHRs, trust in doctors is high and patients have confidence that health IT can improve the quality and coordination of care.



Christine Bechtel

According to Making IT Meaningful: How Consumers Value and Trust Health IT, a study commissioned by the National Partnership for Women & Families and conducted by Harris Interactive, those with online access to their own medical records are especially supportive of health IT, but consumers have concerns that data breaches will occur.

"For health IT to deliver on its promise, consumers must support it; if they don't, we will see political pressure for repeal and the promise will be squandered," observes Christine Bechtel, VP at the National Partnership. "What we found is encouraging, but there are still potential landmines ahead."

The survey findings show concerns about data breaches and current privacy laws. Three in five respondents whose doctors use EHRs (59%) agree that widespread adoption of EHRs will lead to even more personal information being lost or stolen, as do 66% of respondents whose doctors use paper records. Similarly, 51% of those whose doctors use EHRs and 53% of those whose doctors use paper records agree that the privacy of personal medical

records and personal health information is not currently well-protected by federal and state laws and organizational practices.

▼ For more information, visit nationalpartnership.org.

Taking Care to Comply with OIG POSTMARKETING GUIDELINES

Companies that run afoul of the Office of Inspector General's (OIG) compliance guidelines for postmarketing studies risk paying a heavy price in dollars and time, with infractions increasingly resulting in settlements requiring the company to create much more formal processes to handle different types of interactions with physicians.

According to the Cutting Edge Information report, Investigator Initiated Trial Management, these "corporate integrity agreements" (CIAs) are now in effect for nine of the top 10 pharmaceutical companies.

"Entering into a CIA with the OIG is not the end of the world, but it can be costly," notes Ryan McGuire, senior research analyst and the study's lead author. "In fact, increased costs were a key factor for the 23% of companies reporting OIG oversight as their top investigator initiated trial (IIT) management challenge."

The study recommends three key improvement opportunities for pharmaceutical companies to avoid direct OIG oversight: conducting FMV analysis for investigator payments, documenting aggregate spend on both an individual and investigator-site level, and using milestone payments to act as confirmation that the company is compensating investigators for actual services rendered.

▼ For more information, visit cuttingedgeinfo.com.

Other market insights...

MSLs Expected to Serve Increasingly

DIVERSE CUSTOMER GROUPS

Given the expanding role of medical science liaisons (MSLs), Best Practices notes that it's critical for organizations to continually improve their MSL group's activities and services to ensure they are creating value for diverse customer groups.

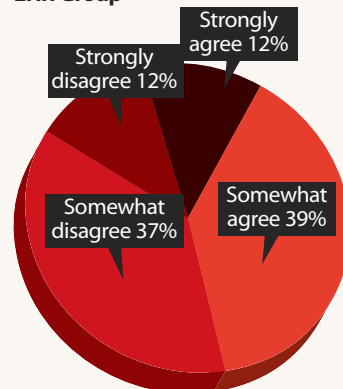
The Best Practices report, Medical Science Liaison Services Excellence: Generating Value for Diverse Customer Groups within the Medical Device Industry, found that 75% of research participants believe that internal managed care groups will be users of MSL support services in the next two years.

Currently, only about 25% of device companies regularly support internal payer groups, according to the study.

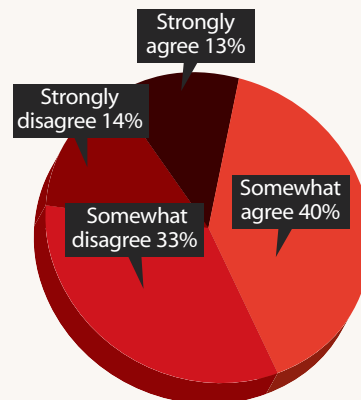
▼ For more information, visit best-in-class.com.

RESPONSES TO STATEMENT: "THE PRIVACY OF PERSONAL MEDICAL RECORDS AND HEALTH INFORMATION IS NOT CURRENTLY WELL-PROTECTED BY FEDERAL AND STATE LAWS AND ORGANIZATIONAL PRACTICES."

EHR Group



Paper Group



Source: The Freedonia Group Inc., Drug Delivery Products. For more information, freedoniagroup.com.

Monoclonal Antibody DRUG MARKET

The period of dynamic growth for humanized and fully human antibodies, along with the continued rollout of antibody-drug conjugates, also called immunoconjugates, is expected to result in stagnating sales of chimeric antibodies from the period 2011 through 2016.

The BCC Research report, Antibody Drugs: Technologies and Global Markets, forecasts sales of therapeutic monoclonal antibodies (mAbs) to grow from an estimated \$44.6 billion in 2011 to almost \$58 billion in 2016, for a compound annual growth rate (CAGR) of 5.3%.

Sales of humanized and fully human antibodies for autoimmune/inflammatory diseases such as rheumatoid arthritis, ulcerative colitis, and multiple sclerosis are likely to experience the fastest growth,

the report notes.

▼ For more information, visit bccresearch.com.

BD to Ascend to Top Spot in PREFILLED SYRINGE CATEGORY

The visiongain report, Top Pre-Filled Syringe Manufacturers: Market Outlook 2012-2022, predicts that Becton, Dickinson and Co. (BD) will be the largest player in the prefilled syringe market through to 2022. In 2012, BD's prefilled syringe and related technology revenue is forecast to reach \$1.14 billion and is expected to post CAGR of 8.5% for the 2012-2022 period.

▼ For more information, visit visiongain.com.

Tissue Engineering Field Expected TO DOUBLE IN VALUE

Advancements of novel therapies in the fields of tissue engineering and regenerative medicine

have opened up new avenues for addressing a range of major diseases such as cancer, skin, cardiovascular conditions, urology, dental, and neurological disorders.


According to the Industry Experts report, Tissue Engineering: The Combination of Cells & Engineering — A Global Market Overview, the global market for tissue engineering is projected to reach a value of \$11 billion in 2012 and reach \$27 billion by 2018.

▼ For more information, visit industry-experts.com.

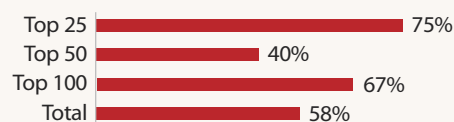
India Faces Rapid HEALTHCARE GROWTH, CHALLENGES

The rapidly growing and aging population, lifestyle changes, and the rise of the middle class are all factors that are creating significant opportunities, as well as challenges, for India's strained healthcare sector. Clearstate's recent India Disease Incidence & Prevalence Report projects India's healthcare system to grow to an estimated \$77 Billion by the end of 2012.

But the report notes, India's healthcare infrastructure has not kept pace with the economy's growth, and the physical infrastructure is inadequate to meet today's healthcare demands. This is despite the healthcare system being one of the country's largest economic sectors both in terms of revenue and employment, accounting for about 6% of India's GDP.

▼ For more information, visit clearstate.com. 

PERCENTAGE OF COMPANIES WITH COMPLETE IIT ELECTRONIC SUBMISSION SYSTEMS IN PLACE



Source: Cutting Edge Information, Investigator Initiated Trial Management. For more information, visit cuttingedgeinfo.com.

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