



WHITE PAPER



# 10 Healthcare Business Trends to Observe in 2012

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# Business Trends to Observe in 2012

As in past years, TCG offers its predictions of key industry developments in 2012. We present them briefly here for your review, but please contact us if you wish to discuss any points in greater detail.

## Trend 1: FDA's Recent IDE Actions

Current estimates identify that 95% of first-in-human and later clinical studies that are necessary to support marketing approval of novel medical devices are done outside of the US. There are signs that the FDA is responding to Device Industry pressure to reverse this trend. The FDA has introduced a mechanism called "staged approval" wherein it may grant IDEs, with conditions, while outstanding regulatory questions are being addressed. The FDA is also launching a pilot program allowing initiation of first-in-human studies by applying new draft guidance recommendations. We hope the FDA reduces the clinical burden now being imposed by collaborating with Industry to increase speed and decrease the cost of clinical activities in the US while continuing to preserve patient safety.



## Trend 2: Sunshine Act Further Delayed

The implementation of the Sunshine Act will require every company to disclose donations and payments of more than \$10 to any medical practitioner. Even though implementation has been delayed we can expect it to be in force sometime in 2012. More importantly, regulations may vary from state to state and among different institutions. It is important for companies to understand the institutions' or states' regulations in order to comply.

## Trend 3: US Firms Focus More on Europe



Despite the economic crises in European countries, many US companies will step up their commercial operations in Europe and launch there before the US, even though the US remains the largest single market in the world. Those who got a CE mark for an innovative technology will try to start generating sales and cash flow to support the company. This is due primarily to the unpredictability and delays of the FDA adding significant risk for potential investors. In fact, the US is losing its position of being the first place for patients to get access to new technologies.

## Trend 4: The Year of Electronic Health Records

Many countries (such as the US and Germany) made significant progress launching systems to modernize and standardize provider access to patient information. Within the next two years, the standardization of Electronic Health Records will enable long distance access to any type of information. Manufacturers have to make sure that their devices have the capability of communicating with these files and are compliant with HIPAA requirements and encryption standards set by the Hitech Act.

## Trend 5: New Tax on Medical Devices



One of the controversial points of the Affordable Care Act is a provision that Medical Device companies pay a 2.3% tax on all sales of their products. This provision has caused industry companies to unite in protest on Capitol Hill in order to have the provision removed. However, the outcome of the protest remains unclear, and a number of industry companies have already begun to modify cost structures in case the tax becomes a reality.

## Trend 6: 510k Procedures and FDA User Fees

Some of the FDA proposals to modify the clearance process for most medical devices (510k) will be adopted this year. However, the negotiations with Congress over the federal budget and the expiring User Fee law (MDUFA) will be linked and, therefore the changes should be less significant.



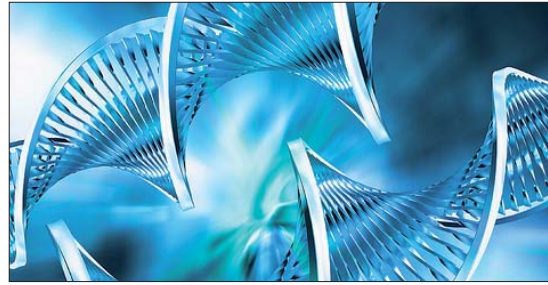
## Trend 7: Euro Crisis to Affect European Healthcare



Many European economies are struggling with the debt crisis. The reaction of most countries is to introduce fiscal cost reductions that will include heavy cutbacks in healthcare spending. The most affected countries are expected to include the UK, France, Spain and Italy. Even in the relatively stable German economy, there is no spending growth forecast over the coming decade. To counter expected revenue reductions, many European Medical Device companies are expanding sales efforts geographically. Among the most promising regions are the BRIC countries: Brazil, Russia, India and China.

## Trend 8: Biotech Profits of Expiring Drug Patents

In the forthcoming 10 years drug patents worth more than \$50 Billion will expire. That will be a milestone on the way from blockbuster drugs to individual drugs. For small biotech companies with interesting products, this may be a good opportunity for potential collaborations, even if the products are in an early stage. They should seek experienced professional help for partnering.



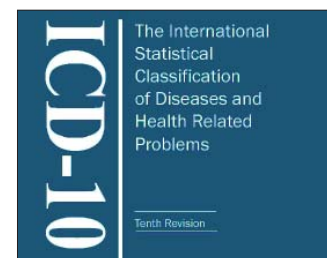
## Trend 9: Tablets as Intelligent Companions



The tablet computers (and smart phones) have evolved over the last two years to have the potential to serve as intelligent companions for patients and health care providers. They are relatively inexpensive and have enough computing power and connectivity to serve as terminals for large database applications. Many device manufacturers are developing custom applications to support and improve the delivery of care.

## Trend 10: ICD-10 – Increasing Number of Codes

ICD-9 will be replaced by ICD-10 in 2013. There are currently 15,000 codes, and the number will increase to 240,000, leading to increased costs and complexity for many medical device and pharmaceutical manufacturers. Moreover, the increase or decrease in payment levels may well affect the utilization of devices. Be sure to have this transition on your radar screen and prepare accordingly.



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### Dennis Burns

Mr. Burns has 30 years of management, market development, R&D and licensing experience in large and small firms including three divisions of Johnson & Johnson.



### Kenneth West

Mr. West's background includes 25 years of business development experience in medical devices, specialty materials, veterinary, and information technology.



### John Icardi

Mr. Icardi has built 25+ years of experience in companies and physician organizations like The Heart Rhythm Society and The American College of Preventive Medicine.



### James Woodward

Mr. Woodward has spent over 25 years in medical device, diagnostic, and healthcare service companies with strong experience in financial direction and management.



### Robert Keefer

Dr. Keefer has 25+ years of experience in business, finance, and marketing in a number of emerging biotech, diagnostic and pharmaceutical companies.



### Reinhard Merz

Based in our European office in Heidelberg, Germany, Dr. Merz has 20 years of experience in medical research, healthcare marketing and e-business.

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