

IN brief

HIV vaccine controversy

The New York-based International AIDS Vaccine Initiative (IAVI) denies that it violated ethics by testing a US-made HIV vaccine in India, even though it already knew the vaccine had failed to protect trial participants in Europe. The vaccine, tgAAC09, uses an adeno-associated viral vector and was developed by Targeted Genetics, of Seattle, which conceded in early 2005 that the vaccine did not “elicit significant immune responses at the doses evaluated” in Germany and Belgium. The IAVI-sponsored trial involved 30 volunteers recruited by India's National AIDS Research Institute (NARI) in Pune. The Indian Council of Medical Research (ICMR) stopped the trial in December, saying the vaccine gave “poor” immune responses. Critics have questioned IAVI's rationale for continuing the trial after knowing that only 20% of volunteers in Europe responded to the vaccine. Antara Sinha, IAVI spokesperson, points out that European trial results were communicated promptly to ICMR and the trial continued only after clearance from NARI's ethics committee. IAVI claimed the trial was justified because “the safety and immunogenicity among Indian and European volunteers may be completely different” owing to ethnicity and genetic factors, and the ICMR says the volunteers were fully informed about the European data and given the option to withdraw. But Chandra Gulhati, editor of the *Monthly Index of Medical Specialties*, says IAVI is stuck in an ethical quagmire it must resolve, as trial participants now test seropositive for HIV and are “unable to convince their employers that their HIV status was vaccine induced.” *KSJ*

1000 Genomes project

A new international research consortium that aims to sequence the genomes of at least 1,000 people has just been set up. The project is expected to cost between \$30 million and \$50 million, and its aim is to uncover more detailed genetic factors involved in human health and disease. The consortium will sequence genomes from at least 1,000 volunteers worldwide to ensure representation of African, Asian and European populations. Support will come from several international institutions, including the Wellcome Trust Sanger Institute in the UK, the Beijing Genomics Institute, Shenzhen, in China, and the US National Human Genome Research Institute (NHGRI), which is part of the National Institutes of Health in Bethesda, Maryland. NHGRI will support and fund three of the large genome centers in the US which will primarily be responsible for producing sequence data for the project. Adam Felsenfeld, NHGRI's director, says that “the project goals are explicit: we want to produce a catalog of human variation down to variants that occur at 1% frequency or less over the genome, and 0.5–0.1% in genes.” He adds that the intention of the project “is to provide a resource that will greatly increase the ability of scientists to do genetic studies on common human disease. If that happens, any of the causal variants thus found would be a significant advance.” *NS*

Investor malaise stalks UK, European biotech

As the dust settles on 2007's stock market performance, two things are clear. First, the European biotech sector lost significant value compared with the US industry. Second, though things were sour in the EU overall, the UK industry was by far the weakest performer in Europe.

The numbers show that European biotech stock prices fell by 23% on average, says Peter Welford, a London-based biotech analyst at merchant bank Lehman Brothers. Within that, UK stocks were down 26%. But when weighted for market capitalization to reflect actual company valuations, the UK biotech industry performed woefully: down by nearly 40%, according to Thomson Financial figures, whereas market cap-weighted biotech shares fell by only 8% for the year European-wide, says Welford. Over the same period, the US biotech sector, as measured by the AMEX or NASDAQ biotech indices, rose 4–5%—not a boom, exactly, but respectable in the face of global instability.

What happened to the once-proud UK sector? The disaster has less to do with nationality than with its industry's structure. Britain's public biotech sector is composed mostly of very small companies—and worldwide, it was that type of company that lost the most value in 2007, as investors retreated from risk (Fig. 1). Senior research analyst Sam Fazeli at Piper Jaffray in London says the larger biotech, although also down, far outperformed smaller-cap stocks. And those larger-cap bio-

techs are exclusively continental European companies, such as Actelion, of Allschwil, Switzerland, and Speedel in Basel.

Moreover, the UK's few remaining mid-cap companies fared badly on the financial markets themselves. Robin Davison of Edison Investment in London says 2007 was the culmination of two parallel strands—recurring cash problems combined with several years' attrition of the industry's product pipeline. Companies such as Vernalis in Winnersh, UK, and SkyePharma, of London, once considered sector leaders with high market caps and respectable cash reserves, have run through their funds and need to redeem big loans in the coming year. Refinancing those loans is not going to be easy given the credit crunch, and the companies both had bad news last year regarding products. Vernalis lost 90% of its market value in 2007, largely as a result of the FDA's rejection in October of Frova (frovatriptan succinate, approved for migraine) for menstrual migraine, and in August the FDA delayed approval of SkyePharma's Flutiform (formoterol plus fluticasone), pushing the company's shares down >50% for the year.

Davison thinks the UK sector will continue to flounder, because “there is this very long tail of micro-cap companies, as well as some formerly large firms that may now be played out.” Moreover, the sector has little promising product news flow on the way. The general despair has crossed over and is tainting

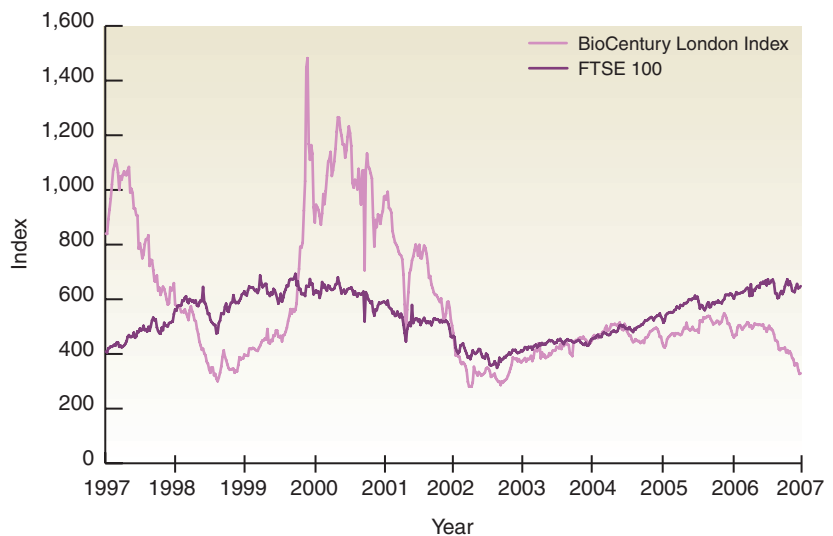


Figure 1 London biotech stocks (BioCentury London Index, the combined market capitalization for 14 bioscience stocks listed on the London Stock Exchange (LSE) or LSE's Alternative Investment Market (AIM)) versus FTSE 100 (Financial Times Stock Exchange 100 stock index). Source: BioCentury