

# registering approval

Pharmaceuticals company GSK has taken a leadership position in its sector by deciding to disclose the full results of clinical trials on a dedicated website. In doing so, it has begun to cultivate a culture of greater openness and to win the trust of a sometimes sceptical public

A new strain of tuberculosis is set to break out across the world, and a multinational pharmaceutical company is desperate to get its drugs to market first. So it shortcuts its trials and hides the negative side effects from the regulators and patients.

The fictitious plot for the blockbuster film *The constant gardener* makes for great cinema, but it also plays on public suspicions about how multinational corporations – and pharmaceutical companies in particular – deal with information.

‘The balance of trust has shifted’, explains Duncan Learmouth, senior vice president of corporate communications and community partnerships at the pharmaceutical company GlaxoSmithKline (GSK). ‘Now we have to give people more information so they understand what we’re doing and can see that we’re not trying to hide anything.’

The crux of the transparency debate for a company such as GSK is in the core business of drug research and development. ‘We need to make sure the information behind our drugs is comprehensive and available for people to review if needed,’ says Learmouth.

One of the key pieces of information about any medicine is its clinical trial results. In 2003, GSK took the decision to make its clinical trials data available to the public on a register through the internet. There are 40–60 trials for every new compound, so a great deal of work was required.

The company assigned a team of more than 40 people to accumulate the huge number of trial results for all marketed products, dating back to GSK’s formation as a merged company in 2000. Additional results for key products developed prior to the merger were also retrieved.

‘It took many months to get the initial list of data ready’, explains Frank Rockhold, senior vice president of statistics and epidemiology for GSK and leader on the clinical trial register project. ‘After a year we’d published approximately 1500 trials, and today that number is over 3000.’ The clinical trial register is available to any internet user at <http://ctr.gsk.co.uk> and has 25,000 visitors a month.

GSK aims to publish trial results summaries on the internet site for all new products within 12 months of the product reaching the market. The same timeline is set for new trials for existing products

## the company

GlaxoSmithKline is a £23 billion (\$45.8bn) turnover pharmaceuticals company that employs around 100,000 people in more than 114 countries. Its core activity is developing and launching new medicines and vaccines, and it spends nearly £400,000 an hour on research to find new medicines. It:

- is pursuing 13 clinical research and development programmes for medicines and vaccines against seven diseases that are particularly relevant to the developing world
- donated £16 million (\$31m) worth of life-saving antibiotics and other medicines in 2007 to support disaster relief efforts in more than 100 countries
- invested around £3.2bn in research and development in 2007
- has its vaccines included in public immunization

already on the market. The total number of products with trials covered on the register is now 87. In addition to results, the company also publishes summary information about the preparatory plans for its forthcoming trials. These plans, known as ‘protocols’, are designed to protect the participants and ensure valid trial methodology and therefore results.

‘We believe we’re now well ahead of competitors in terms of transparency on results’, claims Rockhold. ‘As far as we can see, no one has gone as far as we have.’ Eli Lilly, Roche and Novartis also have dedicated websites for their clinical trial results, albeit their registers are limited to a specific number of drugs and trials. Others in the industry tend to publish minimum trial data on generic websites, such as those run by the UK-based International Standard Randomised Controlled Trial Number Register.

Even though GSK operated a less advanced form of the register prior to its merger, the decision to reveal all its clinical trial information led to considerable debate within the company. ‘The research and development division put forward the idea of a clinical trials register, but we didn’t really know what it signified at the time’, Rockhold says. So the company liaised with external organizations such as the International Committee of Medical Journal Editors, to determine the needs of the scientific and health community.

Issues of competitive advantage provoked particular discussion within the company. For example, releasing data about trial protocols, some feared, could lead rival companies to copy the tests. To resolve the problem, it was agreed that GSK’s scientists could apply to the

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■ GSK's decision to publish clinical trials data on the internet is 'no magic bullet', but it appears to be helping to build greater trust between the company and its stakeholders

company's chief medical officer for an exemption on specific information categories. This exemption clause, which serves to delay the release of commercially sensitive data, has been enacted only twice. In essence, though, GSK's criteria for inclusion of data are straightforward, says Rockhold: 'If you put yourself in the position of a patient, or a relative of a patient, what would you want to know? Answer: Everything.'

The company intends to launch a revised site in the third quarter of this year with more user-friendly search capabilities. Making highly technical information accessible to patients presents a further challenge. Most of it is intelligible only to medical experts. Some patient groups say they would prefer a summary paragraph, somewhere in each register entry, that is written in layman's terms. Providing a conclusion, however, could be interpreted as marketing and promotion – something that is not allowed under UK industry codes of practice. To date, therefore, GSK has declined to do so.

It remains too early to say whether GSK's experiment in transparency has had any major impact on public trust. Most likely not yet, but it is a step in the right direction. The register is 'no magic bullet', says Rockhold. But word is getting out, and the scientific community and regulators are certainly more aware of what the company is doing.

'GSK was the first company to get its act together', points out Liz Wager, a member of the World Health Organization's science advisory group for clinical trial registration. 'The register is important because if you have a drug, you want to know all the information, not just the filtered good news that the company wants to tell you.' Medical experts also note the initiative's impact in reducing the potential bias of medical journals. Invariably, journal editors favour publishing clinical trials with a positive outcome. GSK's register, by contrast, reports all trials independent of the result.

The media is also slowly picking up on the presence of the register. Last year GSK received considerable

press interest about its trial data on Seroxat, an anti-depressant. Journalists were surprised to learn the data was already available on the trial register website. There have also been significant impacts internally. As Rockhold puts it: 'Five years ago the industry would have said it wasn't going to have this discussion [about transparency]. Now people are debating not on whether to be transparent, but on how to do it.'

The business benefits are twofold, according to GSK. First, full disclosure filters through into the way the company works, helping to make it more transparent at every level of business. Second, it begins to break down barriers with external audiences. The pharmaceutical industry has generally done a poor job of explaining the complexity, time and risks involved in bringing a drug to market. By being more open about its internal processes, it stands a better chance of gradually improving public trust.

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For various reasons, public trust in pharmaceutical companies and in particular clinical trials is at a low point. So GSK's initiative – of proactively publicizing the results of all clinical trials – is very important. It raises the bar on transparency for all other companies – and sends out the message that a company willing to share good, and not so good news, is likely to be more trusted and more highly regarded than its competitors.

### Notable features are:

- the register includes all trials independent of the result
- there has been a positive effect on internal morale and the initiative has opened up discussion about how to disclose information
- there remains the difficulty of communicating complex technical information in an accessible way

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