

## Breaking News on Pharmaceutical Technology - Europe

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### Are you prepared for Mother Nature?

By Kirsty Barnes

05/04/2007- **Many sites are utterly unprepared in the face of a natural disaster and are paying a heavy price if they are unlucky enough to be affected, delegates heard at last week's Drug Information Association (DIA) conference in Vienna.**

While clinical trial sites can be more acutely affected by unforeseen disasters than large scale manufacturing facilities, pharma firms would be wise to take a look and see how their plants and those of their outsourcing partners would be affected were the worst to happen.

As companies scramble to save time and money in clinical development and production, the number of trials and manufacturing operations being farmed out to new global locations is increasing year on year - especially in the Asia-Pacific - however, so too is the likelihood that these sites may be held hostage to the whims of Mother Nature.

*"Amidst implementing all our clinical trial globalisation strategies, we have forgotten to factor Mother Nature into our business plan,"* warned Nadina Jose, president of consulting firm Research Strategies during a presentation.

*"When operating trials in such areas, training and drills are very important. A lack of both staff and patient knowledge of what to do in such situations and a lack of adequate communication will always be the weak links that make a disaster situation even worse,"* she said.

Logistical support should be in place for staff who are working remotely, as well as an established central meeting point for staff (and patients should they wish), said Jose, who also suggested that sponsors should speak with the local emergency authorities in their area and seek advice as part of the development of a disaster preparedness plan - something that was deemed essential.

It is also vital that clinical trial sponsors and firms put in place standard operating procedures (SOP) for both preventing a disaster - natural or otherwise - and dealing with one should it be pending or occur, stressed both Jose and Alicia Pouncey, managing director of Aureus Research Consultants, during a separate presentation.

Failure to do so could result in precious sample- and-datasets from trials being unexpectedly wiped out in one go, losing months of work and the dollars to match - something no sponsor can afford to risk in today's tough drug development climate.

Concentrating manufacturing operations in a single location can also prove a risky option, with manufacture of a particular drug potentially grinding to a halt if a facility is affected by a natural disaster - costing a manufacturer time, money and possibly even customers.

Citing the recent Hurricane Katrina that ravaged New Orleans, Pouncey was speaking from personal experience.

*"In this instance we thought we were prepared but we were woefully underprepared,"* she said.

*"For example, there had been no prior prioritisation of key study facilities, data and materials, or equipment and staff were unaware of what was essential to take with them in the event of an office evacuation."*

Some of the consequences of ill-preparedness can include the loss of valuable original data, be it case report forms (CRFs), trial results or patient details, said Pouncey.

*"As a result of Hurricane Katrina we lost all the original identity cards of our study participants so we were no longer able to identify who was taking part in the trial and what treatment regimen they had been on,"* she gave as an example, while stressing that data stored on a computer is not safe either unless it is continuously backed up to an offsite location as hard drives can easily be destroyed or damaged in such situations.

Other critical trial items at risk highlighted by Pouncey included laboratory samples and the study drugs.

*"In the case of Katrina it was known for several days beforehand that a potentially-devastating hurricane was approaching New Orleans, however, we asked the sponsor if we could send our samples early to another "safer" site in light of the emergency but we were told that this was not possible because no other site was ready to receive them."*

*"Not much could be done to minimise the damage that was to occur to our clinical trial site because the sponsor simply wasn't prepared," she said.*

As a result, Pouncey said that blood samples were contaminated by flooding but even if they had escaped the flooding, the site was isolated and without power for so long that the samples would have been ruined regardless.

*"In this particular disaster situation, looting in the town was also rife and we would have lost the study drug too had it not been inconspicuously stored away in an unmarked location in the clinic."*

Either way, there was no backup site that could accommodate any of the patients into its facilities so that they could continue the trial and so the whole site was basically a write-off, she added.

Trials affected by the infamous tsunami in Southeast Asia, the devastating earthquake in Pakistan and mudslides in the Philippines that wiped out a village, including a hospital where clinical trials had been underway, were also given as recent examples of trial sponsors paying the price for ill-preparedness.

The need for a preparedness plan is most pressing for trials being conducted in regions around the world that are at high risk of natural disasters such as hurricanes, floods, earthquakes, tsunamis and mudslides.

However, natural disasters were not the only threat to trials, delegates heard.

Jose listed a violent hail storm in Australia that saw golf-ball sized hail stones smash through hospital windows and ruin cardiac trial materials; a study site in the US that was located near the airport (as many are) and reduced to rubble when a light aircraft crashed into the building; as well as numerous accounts of fires breaking out on premises, where if materials and data were not destroyed by the fire itself, they were destroyed instead by the sprinkler system.

The resounding message: always be prepared!

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