



## Rosetta Public Relations – Communications Briefing

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### CLINICAL TRIALS GONE WRONG – THE TEGENERO STORY AND CRISIS COMMUNICATIONS

Only six years after being spun out of the University of Würzburg, TeGenero AG had a €14 million (about US\$19 million) war chest thanks to venture capitalists and a promising new drug about to enter human trials. It was an enviable position – enough cash to sustain the burn of drug development, a lead product well-positioned for out-licensing to a bigger pharma sector player and good relationships with funders. What's more, its drug was granted 'orphan drug status' by the regulatory authorities in Europe, giving TeGenero access to incentives to offset the cost of development.

Less than five months after the catastrophic failure of its trial, the company was bankrupt. It's difficult to say whether a more effective crisis communications strategy could have mitigated the damage but there are lessons to be learned.

### WHAT HAPPENED

It was what some in the biotech sector call 'unwanted biological activity.' In the early hours of the morning of March 15<sup>th</sup> six men were rushed to a London hospital after being dosed with the experimental drug – TGN 1412. During the course of the first day, shortly after the dosing was complete, a trial participant complained of a headache, fever and pain. He took his shirt off, saying he felt like he was burning. His fellow trial participants followed suit shortly thereafter. All the test subjects who got the real drug (two got a placebo) ended up in an intensive care unit.

Clinical trials are complicated things with multiple players. In the TeGenero case the parties included:

- TeGenero, the company itself
- Parexel, the contract research organization that ran the trial
- Boehringer-Ingelheim, a pharma company that manufactured the drug used in the trial
- The British government agency that approved the trial

Their individual responses are instructive. We add our opinion of how the message was likely received by the public. While there are likely solid reasons for the nature and tone of these responses, our focus is on how they would have been interpreted.

Organization	Response	Likely interpretation
TeGenero	The results were “completely unexpected” and “did not reflect the results we obtained from initial laboratory studies.”	We don’t know what happened or why.
Parexel	“Such an adverse drug reaction occurs extremely rarely and this is an unfortunate and unusual situation.”	That was weird.
British government	“Our immediate priority has been to ensure that no further patients are harmed.”	We don’t know what happened either.

Additionally, all three organizations were quick to stress that every appropriate protocol had been followed and that the drug had performed well in animal tests. Gestures of sympathy were made but they sounded like they were vetted by lawyers. The British government also halted similar trials until an expert panel reports back. The lawsuits of course continue.

The media coverage was naturally intense. The immune response caused in the people participating in the trials prompted their family members to describe them to the media as “elephant men.” One man’s girlfriend tearfully told the media that “the doctors say he needs a miracle.” Companies involved, and their public relations counsel, will recognize this tone of coverage as disastrous.

From a crisis communications perspective, what could have been done differently? Everyone seems to have recognized it as a crisis issue – a challenge that had the potential to interrupt business or cause corporate failure. But what we contend are the four core elements of any crisis response were not adhered to or were not sufficiently clear. Perhaps in the battle for message control the lawyers won out over the PR professionals. Here are what we see as the four elements of a successful crisis communications strategy.

1. The humbling moment. You have to say you’re sorry. The public demands it and the media is looking for this gesture. This is different from taking blame. No one involved in this debacle seems to have said cleanly and without reservation “we’re really sorry.”
2. You need to talk about the people who got hurt as human beings, not test subjects. There is no way that any faceless corporation can win in the court of media/public opinion against a crying girlfriend (or worse, a grieving widow) but acknowledging the humanity of the people involved goes far.
3. Tell us how you will make this right (if possible) and what you will do to make sure this won’t happen again. Credit goes to the British government for halting testing of agents like TGN 1412 and launching a full investigation. Fuller detail (as much as possible without breaching patient privacy) on the likely causes and treatments would have shown everyone as more pro-active.
4. And, what the lawyers hate, make restitution if you can. TeGenero made an early effort to settle the issue with a payment of a mere £5,000 (about US\$10,000) to each person harmed. By comparison the average amount awarded by a US jury in malpractice cases is about \$800,000. It turns out that TeGenero was under-insured and hid this fact. Another corrosive effect on reputation.

One should also remember that communications is never a substitute for action and therefore has to be combined with a response plan (compensation, clean-up, etc.).

We would add a modest proposal. Mitigating damage from clinical trial failures where human lives are harmed (some of the participants in the TeGenero trial have suffered permanent injury to their organs) could have benefited from a stronger and deeper connection with participants and their families, before, during and after the trials.

1. Risk communication. In the aftermath of the TeGenero situation, we sought out and spoke to three 'healthy male participants.' While not statistically robust, this mini-survey suggests that perhaps the people who volunteer for these trials are not fully apprised of the risks involved in a simple, understandable way. There is likely opportunity here at the front end of the trials process. After all, clear communications can help build goodwill that may be needed if things go awry.
2. Continuous communication with participants and their families. What if it were possible to bring this audience into the trial, involve them more in communications at the beginning, during and after? What if they saw the benefits of their participation by being advised of the progress (and approval) of the drug?
3. If things do go bad we should talk about the participants who were harmed almost as 'everyday heroes' who made sacrifices to help others – for example 'they knew the risks, and they took them in the hope that they could help people with diseases like leukemia.'

The intent of all of this is to generate some goodwill to help a company through the crisis and emerge with its reputation dented but not broken beyond repair. And that is, at the end of the day, all that a good crisis communications can offer.

#### ABOUT THE AUTHOR

Paul McIvor is the founder of Rosetta Public Relations Inc., a Toronto-based communications firm focused on health care and life sciences. Prior to establishing Rosetta, Paul managed communications at the Ontario Ministry of Health and Long-Term Care and provided investor relations counsel to public companies. His crisis communications experience includes the Northeastern North America electricity blackout of 2003 and SARS, during which he spent ten days in quarantine.

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