

Hurricane Katrina: There's More Where that Came From

By Norman M. Goldfarb

Hurricane Katrina is a wake-up call for the clinical research industry. Hurricane Rita followed up with much less damage, but the message is clear: Mother Nature will be back.

Let's Look at the Numbers

Natural disasters in the United States are not uncommon – the Federal Emergency Management Agency (FEMA) declared 68 of them last year. Chart 1 presents the number of natural disasters per year. Table 1 lists the largest natural disasters in recent years. Table 2 lists all the FEMA-declared natural disasters in 2004. Natural disasters affect most parts of the nation – 41 states and territories had a least one in 2004. In 2004, there was at least one natural disaster in 10 of the twelve months.

Global warming (man-made or otherwise) and increasing population densities in disaster-prone areas are likely to increase both the frequency and severity of natural disasters. The frequency of category 4 and 5 hurricanes, cyclones and typhoons has increased 80% over the past 35 years.¹ The Association of British Insurers projects a 75% increase in wind-related (not flood-related) insured losses from hurricanes in the U.S. over the next 80 years, equivalent to an extra two or three Hurricane Andrews per year.² These hurricanes will not restrict themselves to the Gulf Coast; states as far north as the mid-Atlantic are vulnerable. As clinical research globalizes, disasters such as famine and epidemic disease will impact the industry. The threat of un-natural disasters such as war and terrorism is probably here to stay.

Business as Usual

Most businesses buy insurance to protect against potential losses. However:

- Most property owners in New Orleans did not have flood insurance.
- Large disasters can bankrupt insurance companies.
- How do you recover the value of study records – and subjects – that have been washed away?

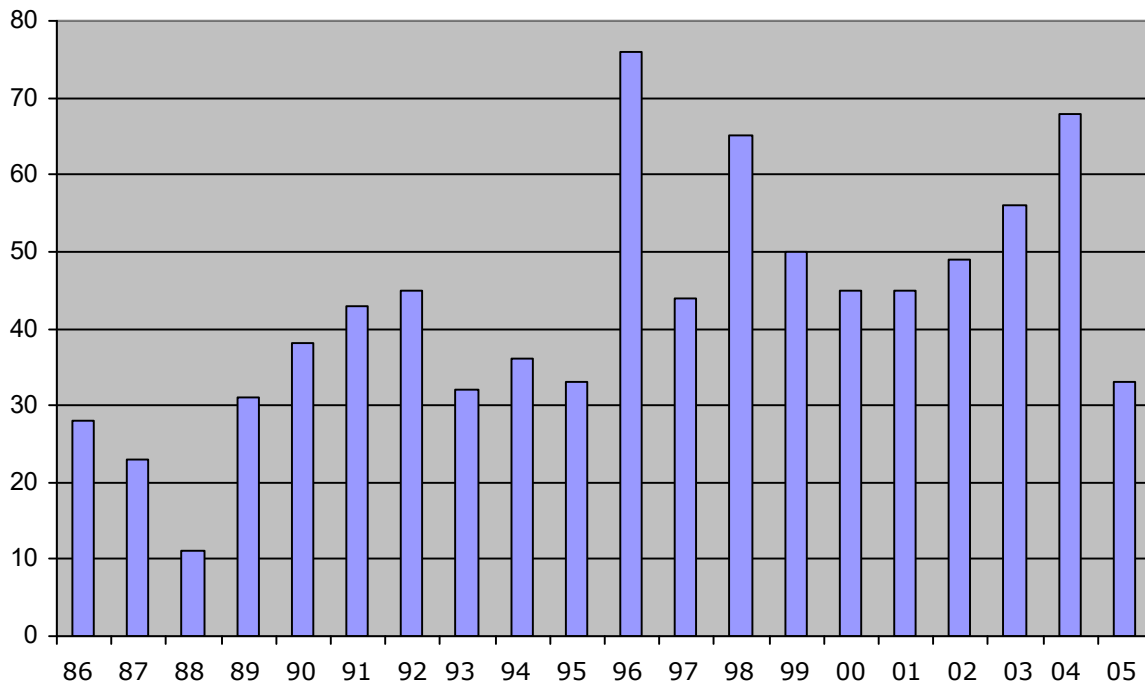
Most business contracts include force majeure (act of God) clauses that exclude contractual protections in a natural disaster. ("Gee, we thought the files would be safe in the basement. Sorry about that.") Hurricane Katrina did not just wash away buildings; entire clinical research sites are gone and will never return.

Now What?

The clinical industry is now faced with three important questions:

1. How do we recover from Hurricane Katrina?
2. Do we want to prepare, as an industry, for the next natural disaster?
3. If we do prepare, what do we do, to accomplish what objectives?

**Chart 1. Number of U.S. Natural Disasters by Year
(As Declared by FEMA, 2005 is Year-to-Date)^{a,b,3}**



- a. FEMA counts each affected state or territory as a separate disaster.
- b. Something changed in 1996 that increases the reported counts.

Answer to Question 1

The clinical research community clearly was not prepared – as an industry – for Hurricane Katrina. (What industry was?) Many individuals, businesses, hospitals, etc. have made heroic efforts to do what they can, but such efforts are, by definition, fragmentary. Relief efforts by some industry associations and the new Clinical Research Relief Organization (CRRO) are only now gearing up.^{4,5}

The impact of Hurricane Katrina will last for months, if not years, so we still have plenty of time to help the victims put their lives back together.

The answer to Question 1 seems clear: we each contribute what we can, with as much collaboration as possible for maximum effect.

Answer to Question 2

If the clinical research industry had had a proper disaster management plan and relief organization in place, study records would have been located or backed-up in secure off-site locations, sites would have relocated and been fully operational in a few days, and far fewer subjects would have been lost to follow-up. Who is going to file all the SAE reports?

The impact of the alternative we now face is far broader than individual people and sites; entire studies (and their sponsors) have been compromised. Even worse, we have broken faith with our study subjects by not being there when they needed us most. How many study subjects were unable to evacuate New Orleans because they could not afford transportation? How many were relying on clinical studies for medications and other treatment?

The answer to Question 2 seems clear: our efforts will be ten-times more effective with an organization and plan in place. We do not need a single organization; a network of collaborating organizations that can quickly mobilize their members will be more effective.

**Table 1. Top Recent U.S. Natural Disasters
(Measured in FEMA Relief Costs)⁶**

Event	Year	Cost (\$B)
Hurricane Hugo	1989	1.3
Hurricane Andrew	1992	1.8
Midwest Floods	1993	1.1
Northridge Earthquake	1994	7.0
Hurricane Georges	1998	2.3
Tropical Storm Allison	2001	1.4
Hurricane Frances	2004	1.4
Hurricane Jeanne	2004	1.4
Hurricane Charley	2004	1.6
Hurricane Ivan	2004	1.9
Hurricane Katrina	2005	???

Answer to Question 3

Disasters will be a continuing feature of the clinical research landscape, so it is worth the effort to put in place the following elements of an industry disaster management program:

- Network of collaborating organizations ready to ramp-up quickly when a disaster appears on the horizon
- Individuals and organizations standing by to help locate victims and provide transportation, housing, office space, frequent flyer miles, etc.
- Standards, procedures, inspections and certification for disaster preparedness, e.g., for records storage, site evacuation, and continuing contact with subjects
- Handbook to manage disaster recovery

With these measures in place, we can answer Question 3 with the following objectives:

- Minimize losses and disruption to people and organizations
- Reduce business risk to the industry
- Build our community, resulting in significant benefits not just in morale but in research quality, timeliness and cost
- Improve the industry's reputation with study subjects and the public in general

We can help ourselves in ways that the Red Cross and other relief organizations cannot. You are now officially on notice. When the next Hurricane Katrina blows into town, how are you going to explain to your boss, your employees, your study subjects, and yourself why you did absolutely nothing to prepare?

Table 2. 2004 U.S. Natural Disasters Declared by FEMA³

Date	Event	State or Territory
Jan 13	Earthquake	California
Jan 13	High Winds, High Surf and Heavy Rainfall Associated With Tropical Cyclone Heta	American Samoa
Jan 26	Severe Storms, Flooding, Mudslides and Landslides	Ohio
Feb 5	Severe Storms, Flooding, Snow Melt, and Ice Jams	Maine
Feb 13	Severe Ice Storm	South Carolina
Feb 19	Severe Winter Storms	Oregon
Apr 10	Typhoon Sudal	Federated States of Micronesia
Apr 21	Flooding	Massachusetts
Apr 23	Severe Storms and Tornadoes	Illinois
Apr 29	Severe Storms and Flooding	New Mexico
May 5	Severe Storms, Flooding, and Ground Saturation	North Dakota
May 7	Severe Storms, Flooding and Landslides	Arkansas
May 25	Severe Storms, Tornadoes and Flooding	Nebraska
May 25	Severe Storms, Tornadoes, and Flooding	Iowa
Jun 3	Severe Storms and Flooding	Ohio
Jun 3	Severe Storms, Tornadoes, and Flooding	Indiana
Jun 8	Severe Storms and Flooding	Louisiana
Jun 7	Severe Storms, Flooding and Landslides	West Virginia
Jun 10	Severe Storms, Tornadoes, Flooding, and Mudslides	Kentucky
Jun 11	Severe Storms, Tornadoes, and Flooding	Missouri
Jun 15	Severe Storms, Tornadoes, and Flooding	Virginia
Jun 18	Severe Storms and Flooding	Wisconsin
Jun 30	Severe Storms, Tornadoes and Flooding	Michigan
Jun 30	Severe Storms and Flooding	Arkansas
Jun 30	Flooding As A Result Of A Levee Break	California
Jul 16	Severe Storms and Flooding	New Jersey
Jul 20	Severe Storms and Flooding	South Dakota
Jul 29	Flooding, High Surf, High Winds, and Wind-Driven Rain associated with Typhoon Tingting	Northern Mariana Islands
Jul 29	High Winds, Flooding and Mudslides as a result of Tropical Storm Tingting	Guam
Aug 3	Severe Storms and Flooding	New York
Aug 3	Severe Storms, Flooding and Tornadoes	Kansas
Aug 6	Severe Storms, Flooding, and Landslides	West Virginia
Aug 6	Severe Storms and Flooding	Kentucky
Aug 6	Severe Storms and Flooding	Pennsylvania
Aug 13	Hurricane Charley and Tropical Storm Bonnie	Florida
Aug 26	Wildland Fire	Nevada
Aug 26	Flooding, High Surf, Storm Surge, and High Winds as a result of Super Typhoon Chaba	Northern Mariana Islands
Sep 1	Tornadoes and Flooding	Indiana
Sep 1	Hurricane Charley	South Carolina
Sep 3	Severe Storms, Flooding and Tornadoes Associated with	Virginia

	Tropical Depression Gaston	
Sep 4	Hurricane Frances	Florida
Sep 10	Tropical Storm Frances	North Carolina
Sep 15	Tropical Storm Gaston	South Carolina
Sep 15	Hurricane Ivan	Louisiana
Sep 15	Hurricane Ivan	Alabama
Sep 15	Hurricane Ivan	Mississippi
Sep 16	Hurricane Ivan	Florida
Sep 17	Tropical Storm Jeanne and Resulting Landslides and Mudslides	Puerto Rico
Sep 18	Hurricane Ivan	North Carolina
Sep 18	Hurricane Ivan	Georgia
Sep 19	Severe Storms and Flooding associated with Tropical Depression Frances	Pennsylvania
Sep 19	Severe Storms and Flooding	Ohio
Sep 19	Tropical Depression Ivan	Pennsylvania
Sep 20	Severe Storms, Flooding and Landslides	West Virginia
Sep 23	Severe Storms and Flooding	Vermont
Sep 24	Tropical Storm Frances	Georgia
Sep 26	Hurricane Jeanne	Florida
Sep 30	Severe Storms, Flooding, and Tornadoes	Kansas
Oct 1	Tropical Depression Ivan	New Jersey
Oct 1	Severe Storms and Flooding	New York
Oct 1	Tropical Depression Ivan	New York
Oct 7	Tropical Storm Frances	South Carolina
Oct 7	Tropical Storm Jeanne	US Virgin Islands
Oct 7	Severe Storms and Flooding	Tennessee
Oct 7	Severe Storms and Flooding	Minnesota
Oct 18	Severe Storms and Flooding from the remnants of Hurricane Jeanne	Virginia
Nov 15	Severe Winter Storm, Tidal Surges and Flooding	Alaska
Nov 15	Severe Storms, Tornadoes and Flooding from the remnants of Hurricane Jeanne	Delaware

References

1. "Changes in Tropical Cyclone Number, Duration, and Intensity in a Warming Environment", P. J. Webster, G. J. Holland, J. A. Curry, H.-R. Chang, Science, September 16, 2005
2. "Financial Risks of Climate Change", Association of British Insurers, 2005
3. "Federally Declared Disasters by Calendar Year", FEMA, last accessed 9/10/05 at <http://www.fema.gov/library/drcys.shtm>
4. <http://www.firstclinical.com/CRRO/CRRO.html>
5. "Hurricane Katrina: The Clinical Research Community Takes Action", Journal of Clinical Research Best Practices, September 2005, available at http://www.firstclinical.com/resources/journal/Disaster_Relief.pdf
6. "Top Ten Natural Disasters ", FEMA, last accessed 9/10/05 at http://www.fema.gov/library/df_8.shtm

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