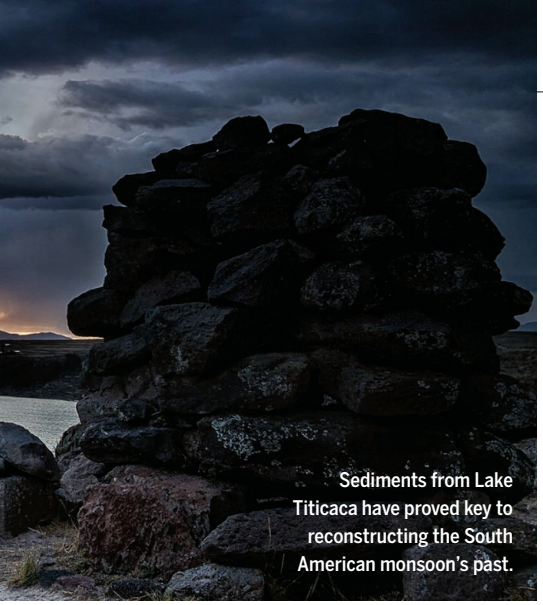

Sediments from Lake Titicaca have proved key to reconstructing the South American monsoon's past.

When researchers use computer models to create a world with twice as much atmospheric carbon dioxide as today and temperatures several degrees higher, they get mixed results. "Half of the models say … it's going to get wetter in the monsoon area, and the other half say it's going to be drier," Baker says. "Half the models are right, but we don't know which half."

The models do, however, tend to suggest the winter dry season could get longer. That may already be happening: The dry season is now "about 3 weeks to 1 month longer" than in recent decades, with the rains beginning in November instead of October, notes José Marengo, a senior scientist at the Brazilian National Institute for Space Research in São Paulo. Such extended dry spells could spell trouble for farmers and hydropower dams. (Brazil gets 80% of its electricity from dams, Marengo notes.) If the trend continues, the historic 2005 drought could become "the new norm" in southern Amazonia by the late 21st century, a team of climate researchers concluded in a 2013 paper in the *Proceedings of the National Academy of Sciences*.

Some models also hint that wet seasons could become shorter but more intense, says Hervé Douville, a climate modeler at the National Centre for Meteorological Research in Toulouse, France. That's worrying because extreme rainfall can lead to flash floods and landslides, a particular concern because the monsoon belt includes hilly, densely populated cities.

Delegates heading to the Lima climate negotiations hope they can reduce such climate threats. The goal is to advance a follow-on pact to the 2005 Kyoto Protocol, which would be finalized in December 2015 at a meeting in Paris and then enter into force in 2020. Although South America's monsoon isn't likely to be a major topic in Lima, the meeting's outcome could loom large in its future. ■

MEDICAL RESEARCH

U.S. to expand public access to clinical study results

Proposals would require sponsors to report data on thousands of additional trials each year

By **Jocelyn Kaiser**

The amount of clinical data that drug companies must share with the public would vastly expand under new rules proposed last week. A proposal from the U.S. Department of Health and Human Services (HHS) would require trial sponsors to report summary results for drugs and devices that are never approved, not just for those that reach the market. And a draft policy from the National Institutes of Health (NIH) would expand the requirement—which now applies only to trials regulated by the U.S. Food and Drug Administration (FDA)—to all trials funded by the health agency.

Sharing these results should not only be useful for researchers, but also "helps fulfill society's ethical responsibility" to people who volunteer for trials, said NIH Director Francis Collins during a press teleconference. "We owe to our patients, to our participants in these trials, the explanation of what happened."

> ***Sharing clinical trial results "helps fulfill society's ethical responsibility. … We owe to our patients, to our participants in these trials, the explanation of what happened."***
>
> **Francis Collins**, National Institutes of Health

The results would be posted on ClinicalTrials.gov, a public database launched in 2000 that now contains registration data for more than 178,000 trials regulated by FDA. Under existing rules, drug companies must also submit summary results that include information such as the number of participants, their age and gender, outcomes, and adverse events. These results have been posted for more than 15,000 trials.

But the summary results requirement applies only to drugs and devices approved by FDA. Under the HHS proposal, companies will also need to report results for unapproved products—although only for late-stage trials, not early safety trials, known as phase I. The new requirement together with the NIH proposal, which would require reports from roughly 650 trials a year, should add another 100 to 150 reports to the 100 that the database now receives each week, said Deborah Zarin, director of ClinicalTrials.gov.

NIH officials cite a 2014 analysis of 400 clinical trials that found that 4 years after completion, 30% of the studies had not shared results in a journal or ClinicalTrials.gov. Under both the NIH and HHS draft rules, which won't take effect until after the final policies are published, results must be reported within a year after the trial ends. Noncompliance could be punished by withholding funding for NIH grantees or imposing fines on companies regulated by FDA, said Kathy Hudson, NIH's deputy director for science, outreach, and policy.

Peter Doshi of the University of Maryland School of Pharmacy in Baltimore, an advocate of clinical data sharing, welcomes the new requirements. Hidden trial results are "not good from an evidence perspective and it's embarrassing from a policy perspective," he says. Requiring that trial results for unapproved drugs be shared is also a positive step, Doshi says. "You're reducing the chance that somebody will redo experiments that were already done and put people in harm's way because the research wasn't shared." But Doshi says the U.S. plans compare unfavorably with Europe's, where the European Medicines Agency plans to make detailed clinical data reports publicly available for approved drugs and to provide data on individual patients to researchers.

Doshi is an associate editor of *The BMJ*, which is part of a group called AllTrials that is pushing for release of detailed clinical trial data. "The white elephant in the room is that FDA sits on more data, across more drugs, across more therapeutic indications than anybody else on the planet," he says. "And their attitude is, 'Great idea [to make the data public], let somebody else take care of this.' " ■

Science

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