from the Consumers' Health Forum in Australia, who believes that, over time, registration will have to be made compulsory. "Either that, or other regulatory and funding mechanisms will have to penalize manufacturers that do not register," she says.

Medical and public health editors argue that the ability to publish results on clinical trials and, in future, secure FDA approval, provides some incentive for companies and other institutions to register ongoing any trials they are planning. "A degree of enforcement has been achieved by the requirement from the International Committee of Medical Journal Editors (ICMJE) for trials to be registered at inception if the results are to be considered for publication," Fiona Godlee, Editor of the *BMJ*, wrote in a *BMJ* editorial in May.

WHO and its partners also hope that theirs is a formula for success. The WHO initiative aims to bring together participating registers of clinical trials around the world in one global network. This will provide a single point of access to the information stored in them and a web-based search platform where members of the public can obtain basic information about ongoing and completed clinical trials, including contact details for the study.

The goal is to increase transparency and accountability on the part of companies and institutions that do clinical research, and, in turn, boost public trust and confidence in that research. WHO experts say that even once the platform is up and running at the end of this year, it will be important to continue the discussion on how to improve the system.

"The debate on trials registration will no doubt continue for many years to come. But now is the time for progress and action while continuing to allow for robust debate and reasonable disgreements," said Dr Tikki Pang, Director of WHO's Research Policy and Cooperation department.

Whatever the difficulties involved in dragging the pharmaceutical companies to the registration table, few doubt the value of the exercise. Ironically, it is precisely the information drug companies are most sensitive about — the results of phase I and II trials — which patients facing regimen failures or resistance problems are most in need of.

"There are a huge number of novel targeted therapies in pre-clinical and early clinical trials," says Jan Geissler, vice president of the European Cancer Patient Coalition, and a cancer survivor himself. "Patients with resistant cancers often seek out these trials on the net as their last and only chance." Nor is this just a matter of blind desperation. Geissler cites a recent study showing that on average the response rate to phase I clinical trials in cancer patients is over 10%. "In my personal case," Geissler adds, "I joined a phase I/II trial after I was diagnosed with a cancer which, five years later, 98% of patients are surviving. The standard treatment offered at the time would have given me a 40–60% chance of survival."

It's not everyone who can bounce back from a devastating diagnosis to go searching on the internet, and Geissler believes that such courage deserves better than it currently gets.

"The registers for ongoing clinical trials are frequently inaccurate, incomplete and out-of-date," he says. Meg Gaines, who once faced "salvage chemotherapy" as her only hope to survive ovarian cancer, and who now runs the Center for Patient Patnerships in Wisconsin, is similarly dismayed

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No delayed disclosure for registration of clinical trials

In a major step towards making clinical trials more transparent and publicly accountable, WHO unveiled the disclosure rules for pharmaceutical companies and others when they register trials they are planning with human participants under the International Clinical Trials Registry Platform initiative.

WHO said on 19 May that there would be no delayed disclosure of any of the 20 key details that companies or other research institutions need to submit when they register clinical trials. WHO called on these research institutions to register all clinical trials prior to enrolment, regardless of the type of study, as participation for these institutions is voluntary.

WHO has already announced the 20-item data set (see box on opposite page), which must be provided when a trial is registered under the initiative.

The decision on disclosure rules comes after two years of consultations, culminating in a 26 April meeting with representatives from the pharmaceutical, biotechnology and device industries; patient and consumer groups; governments; medical journal editors; ethics committees; and academia.

During those consultations some groups raised concerns that academic or commercial competitive advantage could be jeopardized by the immediate disclosure when a trial is registered of five of the 20 items: the name of the intervention(s) tested; the primary outcome; key secondary outcomes; the target sample size; and the scientific title for registered trials.

But in the end, WHO concluded that registration and immediate disclosure of registered data prior to recruiting participants for all clinical trials — including early trials involving patients or healthy volunteers — were the only way to ensure transparency and fulfil ethical responsibilities to patients and study participants.

Commenting on the decision, Dr An-Wen Chan, who is helping coordinate the project at WHO, said: "This is a major step forward. We hope it will contribute significantly to making clinical trials more transparent and to enhancing public trust in science".

The clinical trials initiative comes in response to a growing chorus of scientists, academic leaders and editors of top medical journals calling for new standards and rules for the registration of all clinical trials, i.e. studies in which treatments are tested on humans.

Currently, there are several hundred registers of clinical trials around the world but little coordination among them. The WHO International Clinical Trials Registry Platform is a major initiative to bring participating registers together in a global network to provide a single point of access to the information stored in them.

For more information please see: http://www.who.int/ictrp/en/ and for the link to a web site inviting public comments please see: http://www.who.int/ictrp/comments4/en/index.html

Fiona Fleck, *Bulletin*