Researchers say that China has reasons beyond climate change to implement emission caps. In the past few years, rampant air pollution has caused increased public resentment and social unrest across the country. "China may not have a choice any more," says Knut Alfsen, head of research at the Centre for International Climate and Environmental Research in Oslo. "It's just much better to control total emissions."

A commitment from China to cap emissions "would breathe new life into climate talks", adds Alfsen, who is also a member of the China Council for International Cooperation on Environment and Development, an international think tank that works closely with China's cabinet and the NDRC. At the next climate-change summit, in Paris in 2015, nearly 200 countries will aim to reach a legally binding global agreement on emissions cuts, which would take effect in 2020. Kelly Sims Gallagher, an expert on energy and environmental policy at Tufts University in Medford, Massachusetts, says that an ambitious emissions cap from China "would send a strong political signal to the world" and would make it easier to pass more aggressive climate legislation in the United States, where there is strong political resistance to national climate regulations.

Most researchers contacted by *Nature* are only cautiously optimistic that China can cap its emissions. A carbon ceiling for China "depends in part on how successful the pilot schemes will be", says Lei Ming, an environmental economist at Peking University in Beijing. "We will have to cross the river by feeling the stones," he says, citing the famous one-liner by the late reformist leader Deng Xiaoping.

"The energy market in China is not entirely free and has a lot of government interference and monopoly."

One of the main challenges for the nationwide cap-and-trade scheme will be establishing its credibility. Verifying emissions, for instance, will be difficult in such a large country, says Gallagher. David Yuetan Tang, board secretary of the Tianjin Climate Exchange, which is in charge of one of the seven pilot emission-trading schemes, says that there is an institutional void about who will do this — and also a legal void about how companies will be punished for fraudulent claims or emissions excesses. "This is absolutely paramount, because emission quotas are money," he adds.

Moreover, whether emissions trading can work under China's political system remains to be seen, critics say. "The energy market in China is not entirely free and has a lot of government interference and monopoly," says Qi Ye, an environmental-policy researcher at Tsinghua University and director of the Beijing office of the international think tank Climate Policy Initiative. The price of electricity, for instance, is heavily controlled, he says, which could seriously diminish the impact of imposing a carbon price on electricity producers.

Emissions trading is just one of a series of energy and pollution policies due to be introduced in the next few years. For instance, Beijing is considering implementing a carbon tax to rein in pollution by sectors not covered by cap and trade, and continues to invest aggressively in renewable energy. It has also pledged to reduce the production and use of hydrofluorocarbons, powerful greenhouse gases used in refrigeration and air conditioning. ■

PERSONALIZED MEDICINE

'Master protocol' aims to revamp cancer trials

Pilot project will bring drug companies together to test targeted lung-cancer therapies.

BY HEIDI LEDFORD

In the push to match medical therapies to the genetic underpinnings of disease, lung-cancer treatments have been at the frontier. But the 1.6 million people diagnosed with this cancer every year will take scant comfort in knowing that of the past 20 late-stage trials of drugs to treat it, only two yielded positive results. And in only one of those 20 were patients chosen systematically by screening for biomarkers such as relevant blood proteins or DNA sequences.

Now, an ambitious project aims to improve those success rates and speed new treatments to market by matching companies with the patients whose tumours are most genetically relevant to the therapies they are trying to develop. The project is slated to launch next year and, if successful, could be expanded to other cancers.

The project was spearheaded by the Friends of Cancer Research, a think tank and advocacy group in Washington DC, and has won the support of the US National Cancer Institute and the US Food and Drug Administration (FDA). The idea is to streamline the drug-approval process by bringing pharmaceutical companies together to test multiple experimental drugs in late-stage clinical trials under a single, 'master' protocol. "The drive is to make the whole process of personalized medicine more efficient," says Eric Rubin, vice-president of oncology clinical research at Merck, a pharmaceutical firm based in Whitehouse Station, New Jersey.

PLUG AND PLAY

Launching a large, late-stage clinical trial typically takes more than two years and requires some three dozen administrative and regulatory approvals. To simplify this tangle, the master protocol will create an experimental plan to test several candidate drugs in hundreds of clinics across the United States. The initial protocol is expected to include up to six drugs; others may be added later, without the need for fresh protocol approval each time. "It's like a Plug and Play," says David Gandara, an oncologist at the University of California, Davis, who is in charge of drafting the plan. "So you don't waste time over and over."

Gandara has advocated this approach for the past decade, but the FDA and the pharmaceutical industry voiced support only recently — swayed by a growing body of data revealing that cancers are, in effect, many rare diseases with different genetic roots (see *Nature* **455,** 148; 2008). A genetically targeted drug may work, but only in a fraction of cases. Such rare effects could easily be overlooked in a trial that contains a mix of patients whose cancers have heterogeneous causes, and the costs for drug companies to sort them all and run scores of separate trials are prohibitive.

Under the master protocol, by contrast, patients will be screened for various biomarkers and assigned to trials for drugs that are most likely to be effective. The approach does away with the need for patients to undergo multiple screenings: participating companies could enrol them from a large, central pool. It also eases pressure on the (often minute) tissue samples taken during lung biopsies, because many tests can be done at the same time, says Rubin.

A similar model is already being tested in two smaller clinical trials for breast and lung

cancers (see *Nature* **464,** 1258; 2010). Both trials involve multiple biomarkers, drugs and clinics, and both won support from pharmaceutical companies. But that does not mean that drug companies will embrace a larger, more developed venture, says Roy Herbst, an oncologist at the Yale School of Medicine in New Haven, Connecticut, who chairs the steering committee of the master-protocol project. It is much easier to coax a company into a group effort for a small, early trial than to persuade it to give up any measure of control over a late-stage one crucial for gaining regulatory approval.

Companies also prefer to maintain control of proprietary information rather than deposit early results into centralized databases. "It's a challenge," says Herbst. "Many of them might think they can do it alone, and may worry about losing autonomy."

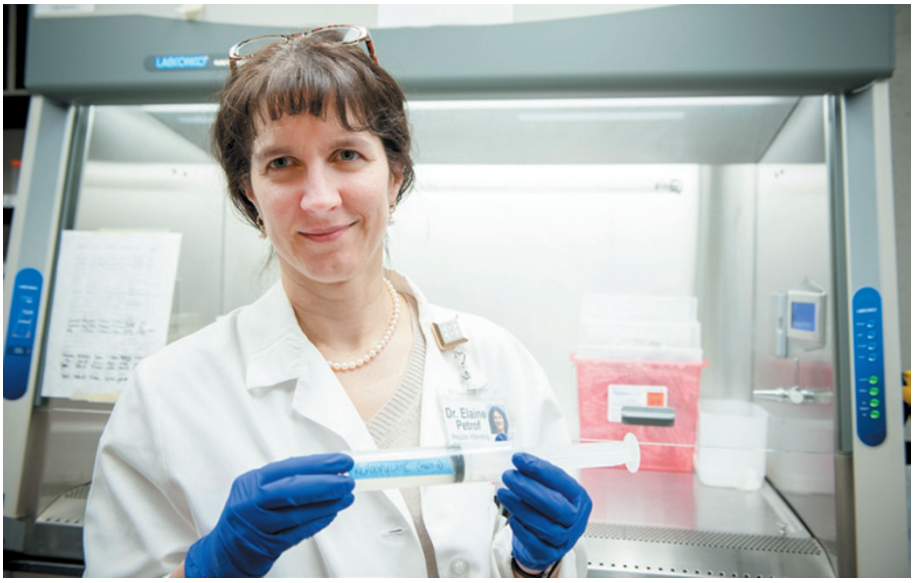
The project's organizers tried to address industry concerns early on, says Ellen Sigal, founder and chairwoman of Friends of Cancer Research. At a planning meeting in March, representatives from more than 20 drug companies were assured that the FDA supports the protocol and has statisticians working to help shape it — making the agency more likely to feel comfortable basing approval decisions on data from the trial. Organizers also pledged to have a neutral third party monitor the trial, to ensure that drugs made by competing companies would not be directly compared.

Gandara hopes that the speed and lower costs will also draw industry partners. Late-stage clinical trials can cost between US$50 million and $100 million; Gandara estimates that the master protocol could cut that to $25 million or less.

Companies might also be wooed by easy access to the National Cancer Institute's vast network of treatment centres and clinicians who are experienced in conducting clinical trials. That network will allow the trial to be conducted at 500 sites in the United States and Canada and enable it to enrol up to 1,000 patients a year.

Thus far, the downside of participating seems minimal, says Richard Gaynor, head of oncology-product development at Eli Lilly, a pharmaceutical firm based in Indianapolis, Indiana. "It will be an interesting experiment," he says. ■

KINGSTON GENERAL HOSPITAL



Elaine Petrof has invented a synthetic stool that could reset a patient's gut bacteria to cure infections.

GASTROENTEROLOGY

FDA gets to grips with faeces

Regulator triggers efforts to standardize faecal transplants.

BY BETH MOLE

The brown slurry is piped through tubes into the top of the human body — or the bottom. It can even come in pill form. For years, doctors have been transferring faeces into ill people's intestines to replace resident microbes with a fresh batch. The procedure is often a therapeutic success, but protocols for it vary wildly. As it steadily grows more popular, regulators are now working to define what a standard faecal transplant should be, and how to deliver one safely.

During a public workshop last month at the US National Institutes of Health in Bethesda, Maryland, the Food and Drug Administration (FDA) reaffirmed that it has authority over faecal transplants. The agency had said this for years to researchers and companies who asked privately, but the workshop was the first public forum in which the FDA broadcast that it regulates faeces like a drug.

Clinical trials of the procedures are not affected, because they were already subject to approvals from the agency. But US doctors performing faecal transplants as treatments must now submit an Investigative New Drug application to the FDA with details about their protocols. (The agency then has 30 days in which it can intercede and stop an experiment.) Jay Slater, director of the division of bacterial, parasitic and allergenic products at the FDA in Silver Spring, Maryland, says that the move is a crucial way for the agency to make sure that protocols are safe. But he adds that the FDA wants to avoid being too prescriptive for ▶

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