Clinical trials driving excellence in healthcare industry

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ONCE a new drug is developed, it is essential to conduct clinical trial that allows the drug to be tested regarding safety and efficacy in human volunteers. Generally, the company files an "investigational new drug" application with the Food and Drug Administration to allow the investigational drug to be tested in human volunteers in clinical trials. A clinical trial is a study that is carefully designed to test the benefits and risks of a specific medical treatment or intervention, such as a new drug. Every clinical trial is led by a principal investigator, who is usually a medical doctor, and a research team of nurses and others. The authority requires a multi-phase clinical trials process to be completed before deciding if an investigational medicine is safe and effective for a broader patient population; progress in the development of innovative medicines cannot be made without the people who volunteer to participate in clinical trials.

Unfortunately, a high proportion of trial does not adequately describe important methodological details, decreasing their utility for trial implementation and critical appraisal of trials, all of which have been associated with biased trial results and conclusions. There is no difference in Bangladesh as there was no guideline for trials on pharmaceutical products.

But to drive excellence in the healthcare industry, the Directorate General of Drug Administration of Bangladesh has introduced a new guideline on clinical trial as one of the six functions according to the World Health Organisation. This guideline for good clinical practice for trials on pharmaceutical product has been prepared harmonising with ICH (International Conference on Harmonisation), GCP (Good Clinical Practice) guideline, WHO GCP guideline, Malaysian GCP guideline, Pan American Health Organisation GCP guideline, and Indian GCP guideline. A working committee was made to prepare this GCP guideline suitable for Bangladesh in every aspect. This guideline not only introduces an escort to conduct a trial but also a landmark for time-saving and safe clinical trial.

The guideline contains eight chapters and four annexes. There is a detailed glossary list to understand the terminologies. The chapters discuss details about the principle of GCP, formation of ethics committee, role of sponsors, monitors, investigators, ethics committee and regulatory authorities. It also contains structure of protocol, informed consent form and investigators' brochure. There are two specific annexes -- one is for regulatory requirement for BE studies and another one is for regulatory requirement for clinical trials of biosimilar and vaccines.

This guideline is addressed not only to investigators, but also to ethics review committees, pharmaceutical manufacturers and other sponsors of research and drug regulatory authorities. By providing a basis both for the scientific and ethical integrity of research involving human subjects and for generating valid observations and sound documentation of the findings, the guidelines serve the interests of the parties actively involved in the research process. The guidelines thus also protect the rights and safety of subjects, including patients, and ensure that the investigations are directed to the advancement of the healthcare system. In response to the gaps in protocol content of different trial projects in Bangladesh, the guidelines introduce a well-directed proposal guideline that will facilitate an appropriate assessment of scientific, ethical, and safety issues before a trial begins; consistency and rigor of trial conduct; and full appraisal of the conduct and results after trial completion.

Moreover, the guideline should also provide a resource for editors to determine the acceptability of reported research for publication and, specifically, of any study that could influence the use or the terms of registration of a pharmaceutical product. Not least, they provide an educational tool that should become familiar to everyone engaged in biomedical research and, in particular, to every newly-trained doctor.

After getting approval of guideline of GCP by the health ministry, DGDA is now giving permission for two CROs (contract research organisation) and in future it will increase. The quality of biosimilar products will increase in Bangladesh. The increasing number of clinical trials will attract more international organisations to Bangladesh. All these activities will generate new employment. DGDA is ensuring safe, effective and quality products for the people of Bangladesh.

The writer is the director general of the Directorate General of Drug Administration, Ministry of Health & Family Welfare.

Oil prices slip under pressure of economic worries

REUTERS, *London*

Oil prices fell on Monday, weighed down by gloomy economic prospects in Europe and Asia and a related strengthening in the US dollar, which makes fuel imports for countries using other currencies more expensive.

The softening comes a week after crude prices hit 2016 highs on the back of a quicker-than-expected rebalancing in physical oil markets.

Brent crude oil futures LCOc1 fell to $50.02 per barrel, at 1205 GMT, down 52 cents, after trading as low as $49.80.

US crude CLc1 was down 55 cents at $48.52 a barrel.

Commerzbank analyst Carsten Fritsch said rising worries that Britain will vote later this month to leave the European Union, which sent stocks spiralling lower on Monday, could also erase more of oil's recent gains.

"The most recent oil price increase was driven by bullish market sentiment," Fritsch said. "A Brexit could turn market sentiment around."

The dollar has risen 1.2 percent from June lows against a basket of currencies .DXY, lifted by Brexit worries, concerns over Asia's economy and the prospect of a potential hike in US interest rates.

Renewable energy to attract two-thirds of power plant investments

REUTERS

RENEWABLE energy sources such as wind and solar will attract two-thirds of all investment in power-generating plants between 2016 and 2040 in spite of persistently cheap coal and gas prices, a new report has found.

The forecast by Bloomberg New Energy Finance, the energy research unit of information company Bloomberg, expects some $7.8 trillion to be invested globally in renewables over the period, compared with $1.2 trillion for new coal plants - largely in India and other Asian emerging markets.

Gas will attract a relatively small $892 billion, it said, despite a projected glut of the fuel leading to lower power generating costs.

"One conclusion that may surprise is that our forecast shows no golden age for gas, except in North America," according to report co-author Elena Giannakopoulou.

"As a global generation source, gas will be overtaken by renewables in 2027. It will be 2037 before renewables overtake coal," she said.

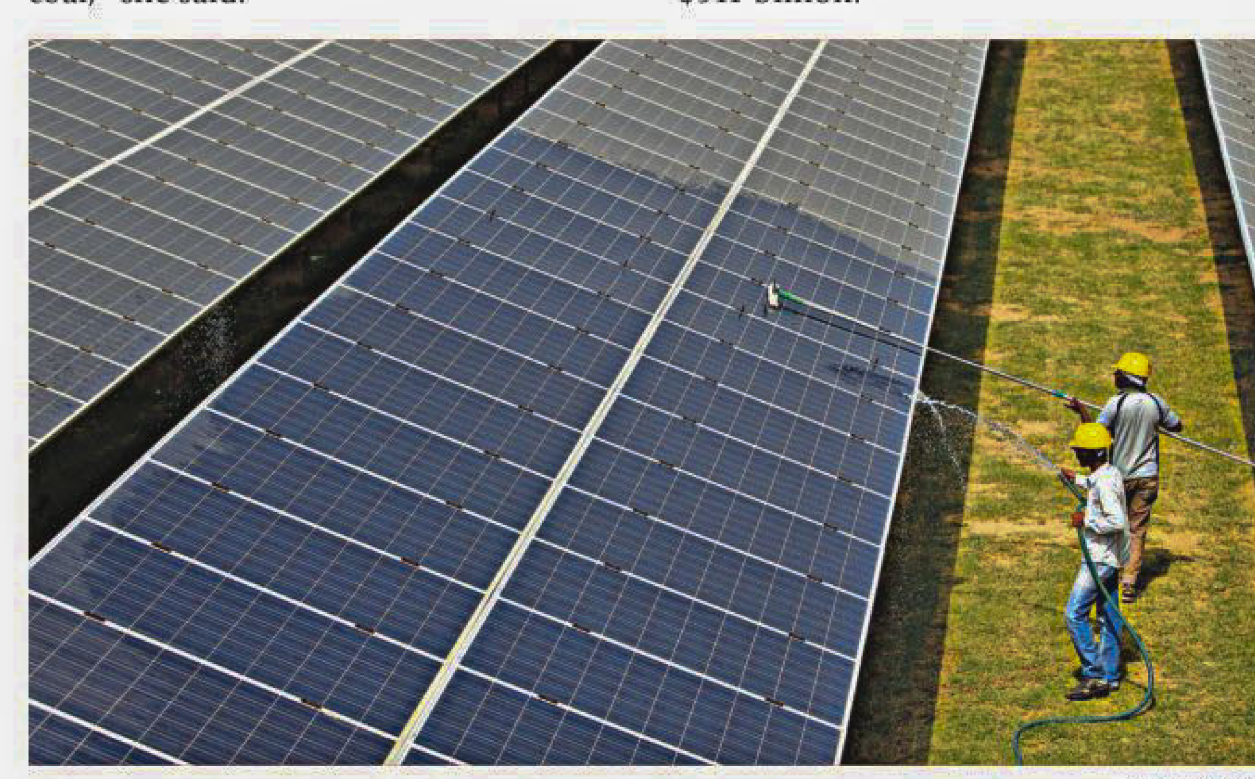
While good news for helping decarbonise the world's electricity system, it is still not enough to meet the United Nations target to limit global warming below 2 degrees Centigrade.

Another $5.3 trillion in zero-carbon power investment by 2040 is needed to prevent carbon dioxide levels in the atmosphere rising above the limit of 450 parts per million, the report says.

Rising coal use in India and emerging Asia will push global carbon emissions five percent above 2015 levels by 2040, to 700 megatonnes, it said. In China, weaker growth and a rebalancing of the economy away from heavy industry, as well as more renewables, will mean emissions peak by as early as 2025.

For Europe renewables will dominate with a 70 percent share in the continent's power mix by 2040, while the United States' share will jump from 14 percent last year to 44 percent.

A breakdown of renewable investments shows that of the $7.8 trillion overall, onshore and offshore wind accounts for $3.1 trillion, with solar taking $3.4 trillion and hydro-electric $911 billion.



REUTERS/FILE

Workers clean photovoltaic panels inside a solar power plant in Gujarat, India.

NAVANA

Shafiul Islam Kamal, chairman of Navana Ltd, an exclusive distributor of Toyota vehicles in Bangladesh, attends the launch of a new model of a car—Toyota Avanza—at Toyota 3s Centre at Tejgaon area in Dhaka on June 12. The car with 1500 CC 2NR-VE dual VVT-I engine can transport up to seven passengers.

S Korea's Park urges 'bone-crushing' reform on shipbuilders

AFP, *Seoul*

SOUTH Korean President Park Geun-Hye on Monday urged "bone-crushing" efforts to overhaul the nation's ailing shipbuilders faced with mounting losses caused by slowing global demand and increased competition.

The South's mighty shipbuilders including Hyundai Heavy Industries and Daewoo Shipbuilding and Marine Engineering have dominated the global market for past decades.

But a slump in oil prices and global economic slowdown sapped demand for tankers and container ships, while overcapacity, regional rivalry and the emergence of cheaper Chinese shipbuilders has squeezed profit margins.

The South Korean government and creditor banks, including state-run Korea Development Bank, have urged intense restructuring efforts including mass job cuts in recent months.

"The (shipbuilding) companies, along with creditor banks, should make bone-crushing efforts to revive their businesses," Park said in a speech to Seoul lawmakers.

"If we don't carry out a bold restructuring by downsizing the overgrown workforce... and cutting costs, the future of not only the shipbuilders but also the whole economy will be in jeopardy."

Park warned of mass job cuts and an economic slump in the country's southern region where the shipbuilders are based.

"The road for reform is painful... but, if we try to avoid it, our economy would be devastated and we would face even bigger pain in the end," Park said, adding Seoul would offer financial assistance and job training for those who are laid off.

The nation's so-called "Big Three" shipbuilders including Hyundai, Daewoo and Samsung Heavy Industries racked up collective losses of 8.5 trillion won ($7.2 billion) last year.

They were hailed as a major driver of the country's export-reliant economy -- Asia's fourth-largest -- before being forced since last year to shed thousands of jobs and assets to stay afloat.

As exports sputtered and domestic demand slowed, South Korea's central bank in April slashed the country's growth outlook for this year to 2.8 percent from the previous three percent.

The economy expanded 2.6 percent last year, the lowest since 2012, as crushing household debts prompted more South Koreans to tighten wallets.

Total household debts have snowballed to reach a record 1,223 trillion won as of late March as wages stagnated and housing prices continued to rise.

The central bank also cut last week the key interest rate to a record low of 1.25 percent, saying it was aimed at easing the impact of corporate restructuring.

China's investment growth slows, bucking signs of stabilisation

AFP, *Beijing*

China's fixed asset investment, an important gauge of infrastructure spending, slowed to its weakest pace in 16 years, government statistics showed Monday, a worrying trend despite other signs of economic stabilisation in the Asian giant.

The moderation comes after a record credit binge in the first quarter of the year, a splurge aimed at stimulating China's slowing economy.

Fixed asset investment rose 9.6 percent in the first five months of the year, according to the National Bureau of Statistics. The world's number two economy, a key driver of global expansion, grew just 6.9 percent in 2015, the weakest rate in a quarter of a century.

The investment results fell far short of economists' median forecast of 10.4 percent in a survey by Bloomberg News and was the slowest pace of expansion since May 2000. But factory production and consumer spending showed steady growth for the period, the government data indicated, as industrial output rose 6.0 percent year-on-year in May, matching the figure for April, while retail sales were up 10.0 percent.

"The national economy extended a stabilising and progressing trend that emerged since the start of the year with positive factors accumulating," said Sheng Laiyun, spokesman for the National Bureau of Statistics.

Microsoft buys professional network LinkedIn for $26b

AFP, *Washington*

MICROSOFT said Monday it was buying the professional social network LinkedIn for $26.2 billion in cash, a move that helps refocus the US tech giant around cloud computing and services.

"This deal brings together the world's leading professional cloud with the world's leading professional network," Microsoft chief executive Satya Nadella said in a statement.

According to a statement from the two firms, LinkedIn "will retain its distinct brand, culture and independence," with Jeff Weiner remained at CEO of LinkedIn.

"Just as we have changed the way the world connects to opportunity, this relationship with Microsoft, and the combination of their cloud and LinkedIn's network, now gives us a chance to also change the way the world works," Weiner said.

The two firms said they had reached a "definitive" agreement that would close later this year, with the support of LinkedIn chairman and controlling shareholder Reid Hoffman.

The move comes with Microsoft refocusing its efforts away from being a pure software firm, and LinkedIn seeking ways to boost growth.

LinkedIn, which enables members to connect with similar-minded professionals and facilitates job hunting, has some 433 million members worldwide. But LinkedIn in the past quarter reported a loss of $46 million and a $166 million loss for 2015, which let its shares at multiyear lows early this year.

Nadella, in an email to staff, said the deal reflects Microsoft's new focus on cloud computing and services.

"We are in pursuit of a common mission centered on empowering people and organizations," he said.

He added that the deal "is key to our bold ambition to reinvent productivity and business processes.

Think about it: How people find jobs, build skills, sell, market and get work done and ultimately find success requires a connected professional world."

LinkedIn, which calls itself "the world's largest and most valuable professional network," has been seeking to expand its offerings with more messaging, mobile applications and revamped its "newsfeed" to help boost engagement.

Microsoft said it would finance the deal mostly by issuing new debt.

AP

LinkedIn chief executive Jeff Weiner will continue in his role.