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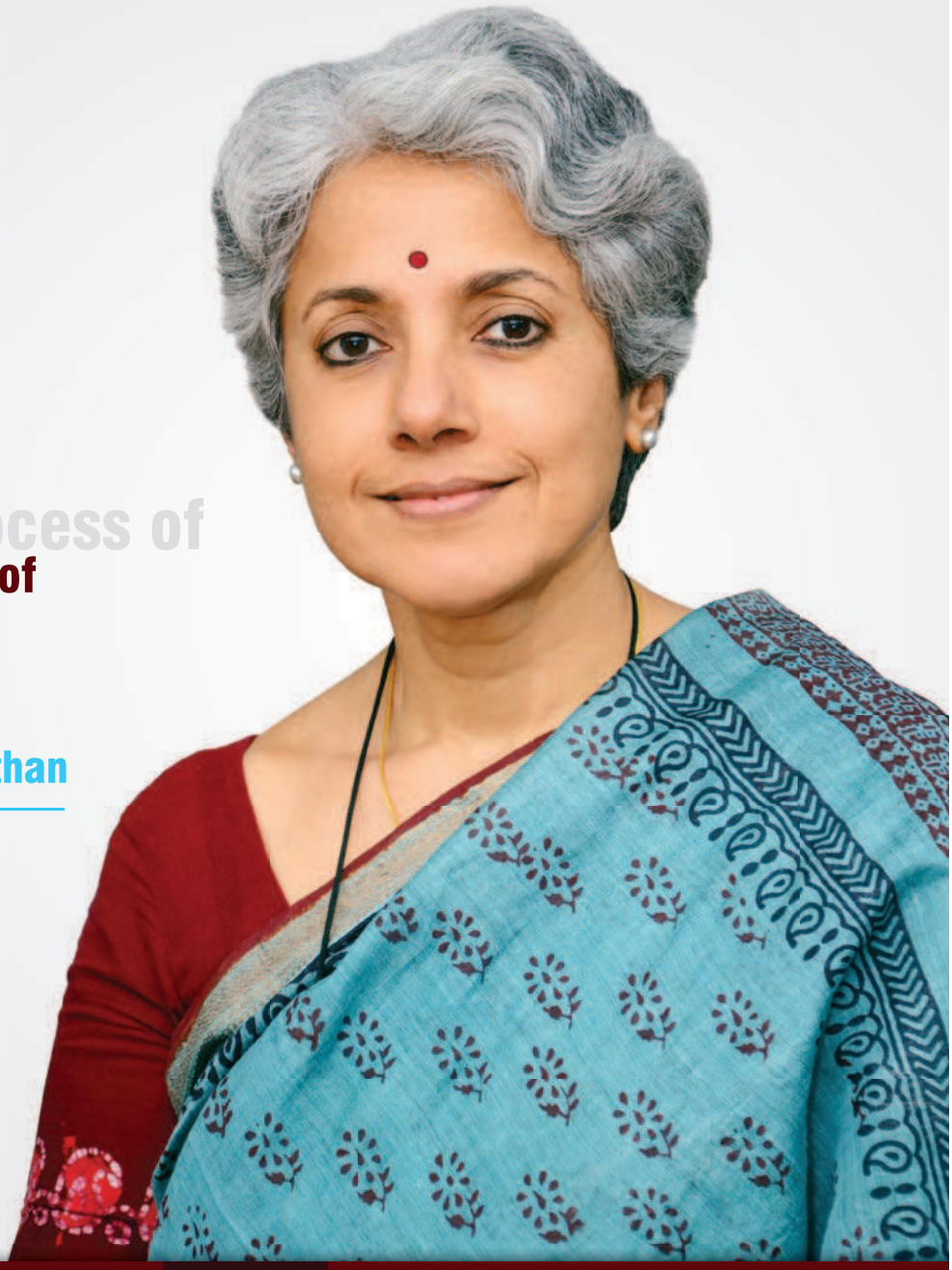

"We have streamlined the whole process of reviewing & approval"

Dr Soumya Swaminathan

Director General,
Indian Council of Medical Research & Secretary,
Department of Health Research

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India to bounce back as clinical research hub

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"We remain very optimistic about the future of clinical trials in India"

The Indian CRO market has undoubtedly contracted over the last few years following the effective shutdown of clinical trial activity after the 2012 Supreme Court petition by the NGO Swasthya Adhikar Manch.

Since then the Indian government has worked hard to restructure clinical trial oversight and governance, and as we know there were some challenges implementing a number of the new rules. Notable examples were issues around video consenting and patient compensation.

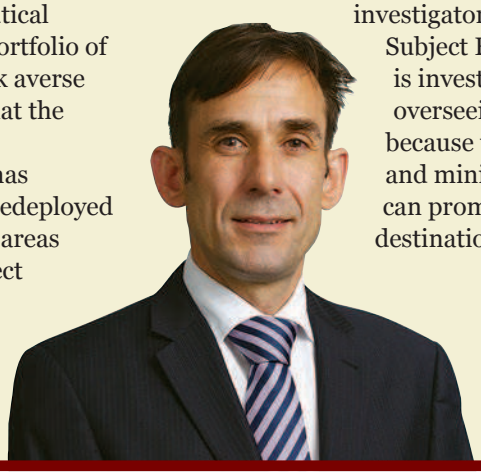
Many of these challenges have now been resolved, but the reality is that sponsors have been much slower to re-enter the Indian market than expected.

If we look at data from clinicaltrials.gov, there were 101 "Industry Funded" trials started in 2012, but only 27 recorded in 2016. Novotech's key customer group is small to midsized biopharmaceutical companies, and they have fallen from 44% of trial activity in 2012 to 15% in 2016. This shift is understandable as the larger pharmaceutical companies often have experience in India and established JV relationships, while smaller biopharmaceutical companies, with a smaller portfolio of compounds will be more risk averse until they are very certain that the environment has improved.

As clinical trial activity, has declined, many CROs have redeployed their very talented staff into areas such global or regional project management, biometrics, pharmacovigilance, risk-based monitoring and administrative support, and so the contraction of the industry won't reflect the decline in clinical trial activity. Indeed, Novotech's Indian workforce has increased by around six-fold since 2012. While setting up any business in Asia has it's complexities with a range of regulations, and bureaucratic institutions needing to be navigated, we have found India to be a relatively business-friendly environment,, with notable improvements over the last three years.

We remain very optimistic about the future of clinical trials in India, and the key macro factors that will influence the market are: i) huge treatment naïve population, with India expected to surpass China as the most populous county in the world in coming decades ii) highly educated technical staff iii) A well-established pharmaceutical manufacturing sector ensuring sponsors continue to invest in infrastructure and talent iv) An attractive cost base.

We are currently starting a couple of clinical trials in India for smaller biopharma clients and we are very excited by the progress. Regulatory timelines have been faster than expected, and everyone is very engaged including sites, investigators, ethics committees, and Subject Expert Committees. Novotech is investing additional resources in overseeing our Indian clinical trials because we are very keen to anticipate and minimise any issues, so that we can promote India as the clinical trial destination it deserves to be.



- Dr John Moller
CEO, Novotech, a Sydney-based full-service contract research organisation (CRO), having operations in India, with a focus on clinical monitoring

positive step forward," Dr Saral Thangam added.

With regulatory reforms in place, India is certainly once again on an upward cycle as its appeal to both international and local sponsor companies recognize the advantages and opportunities available. The understanding of trials continues to grow in this relatively young trial arena providing strong data quality to match its recruitment abilities.

"India will continue to increase in appeal as it increases its culture of quality alongside its protection of patient safety maturity in the trials arena. Improved regulations, training and education of research professionals, increased base of qualified and trained investigators and supporting staff, high quality data will once again make India an attractive destination for global clinical trials," concludes Dr Aparna Parikh, of PRA Health Sciences. BS

Narayan Kulkarni
(With inputs from Aishwarya Venkatesh and Dr Manbeena Chawla)