

Novotech Update – July 2017

India streamlines clinical trial approval process and reduces regulatory timelines

While India is home to almost 17% of the world’s population and 20% of its disease burden, it has one of the lowest clinical trial densities in the world¹; and while this ratio is not unexpected given its population size, India’s clinical trial industry was once much more buoyant.

Minuted in June 2017, the Drug Controller General of India (DCGI) and Secretary of Health and Family Welfare have made significant changes to India’s regulatory approval process, in effort to rebuild its clinical trial industry. These changes are focused on streamlining regulatory pathways, reducing approval timelines and enhancing India’s clinical trial attractiveness to sponsors.

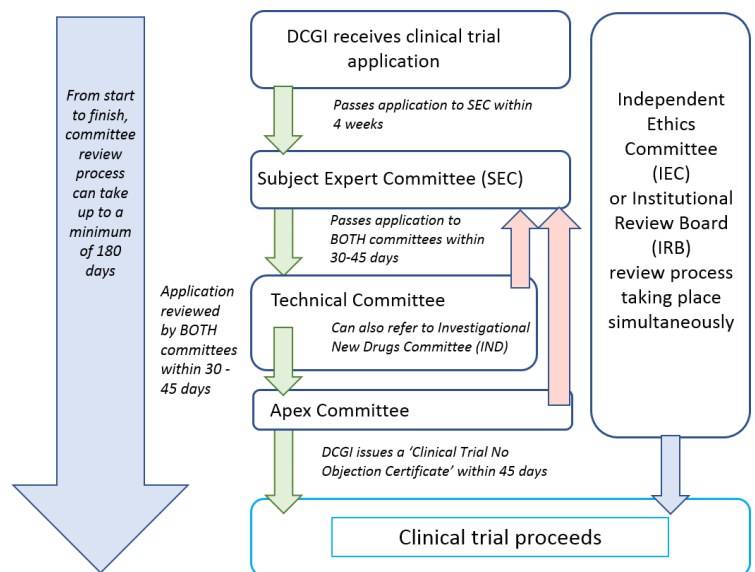
On the back of the new regulatory changes, the Indian Society for Clinical Research has already commented it is observing an increase in the number of clinical trials being approved².

Building the path forward from past difficulties

Between 2010 – 2013, India’s clinical trial industry was rocked by the discovery that several principal investigators had falsified trial data, of patients not being properly consented and a legal submission claiming the Indian government had been negligent its monitoring of clinical trials.

In 2010, the DCGI created a new entity, the New Drug Advisory Committee (NDAC), to ensure all protocols submitted were reviewed by experts³. The unforeseen result of this new review process was a virtual standstill of the country’s clinical trial industry. Clinical trial approval timelines stretched out to almost 18 months and the clinical trial approval rate dropped from 500 in 2010 to just 107 in 2013³.

In 2013, to address this sharp decrease, the DCGI developed a three-tiered regulatory process⁴ to review all clinical trial applications; while Independent Ethics Committees (IEC) or Institutional Review Boards (IRB) undertook a simultaneous review³. The three key regulatory review committees were:



1. The **Subject Expert Committee (SEC)**: Replacing the NDAC and almost 25 other committees, the SEC was the starting point for most clinical trial applications.

¹ Perspectives in Clinical Research, Vol 8, Issue 1, January-March 2017; A.Bhave, S.Menon, ‘Regulatory environment for clinical research: Recent past and expected future’- www.picronline.org/article.asp?issn=2229-3485%3Byear%3D2017%3Bvolume%3D8%3Bissue%3D1%3Bpage%3D11%3Bepage%3D16%3Baulast%3DBhave : “India’s share in all clinical studies being undertaken worldwide is ~1.4%”

² EconomicTimes.com, ‘Number of clinical trials in India may surge by 2018-19: Dr Chirag Trivedi’, Priyanka V Gupta - <http://health.economictimes.indiatimes.com/news/industry/number-of-clinical-trials-in-india-may-surge-by-2018-19-dr-chirag-trivedi/59571004>

³ Pharm-Olam: *Reconsidering India as a clinical trial location*; www.pharm-olam.com/content/reconsidering-india-clinical-trial-location

⁴ In 2013, the DCGI implemented the findings from the Prof. Ranjit Roy Choudhury Expert Committee, report submitted July 2013 - www.cdsc.nic.in/writereaddata/Report_of_Dr_Ranjit_Roy.pdf

- Following the SEC's review and decision, applications were first reviewed by the **Technical Committee** and was able to override the SEC and request it review its decision. The Technical Committee was also able to refer to an **Investigational New Drugs Committee (IND)** if required.
- Once passing through the Technical Committee, applications were then reviewed by the **Apex Committee**; which was also able to override the SEC and request a review of the its decision.

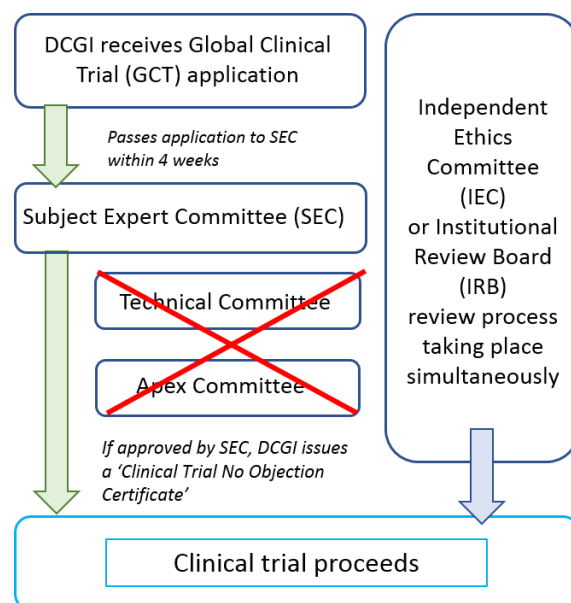
New changes to streamline process and reduce timelines even further

In Minutes tabled in June 2017⁵, the Apex Committee outlined four major changes to the current regulatory process, streamlining it further and significantly shortening timelines – **all great news for sponsors and India's clinical trial industry. These four important changes include:**

1) Global clinical trial applications will be reviewed by the SEC only

*'Proposals relating to global clinical trials should be placed before the SEC only; and regardless of whether they are accepted or rejected by the SEC, no further approval from the Technical or APEX Committee is required.'*³

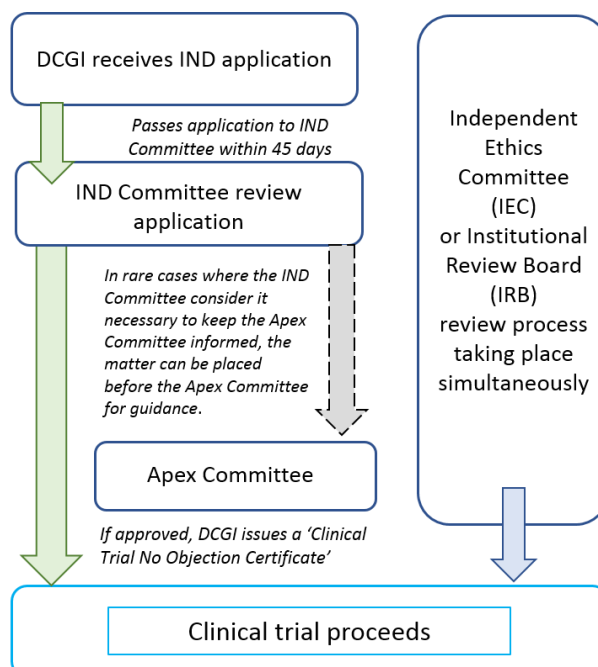
This change simplifies the regulatory approval process and reduces approval timelines. While dependent on each application, **approval timelines are expected to shorten from 6 – 9 months to just 3 – 5 months**; allowing sponsors to expedite site start up and patient recruitment sooner.



2) The IND approval process is being simplified

*'IND clinical trial applications are to be placed before the IND Committee and their decision will be final. In rare cases where the IND Committee consider it necessary to keep the Apex Committee informed, the matter can be placed before the Apex Committee for guidance.'*³

The IND clinical trial application process has been streamlined. Previously sitting within the Technical Committee, the IND Committee has been given structural independence and final decision making authority.



⁵ Central Drugs Standard Control Organisation, Director General of Health Services, Ministry of Health and Family Welfare, Government of India – Recommendations of Apex Committee, 34th Dated 02.06.2017 - www.cdsc.nic.in/forms/list.aspx?lid=1880&ld=32

3) Applications rejected by the SEC can be put before the Technical Committee for consideration

'In cases rejected by the SEC and should the applicant feel aggrieved, these cases can be placed before the Technical Committee for its consideration. Should the Technical Committee disagree with the SEC decision, it can overrule and its decision will be final'.³

The Technical Committee has been given a clearer regulatory position for sponsors. Should a sponsor's application be rejected by the SEC or the DCGI disagree with the SEC's decision, this change provides sponsors with a second line of regulatory approach.

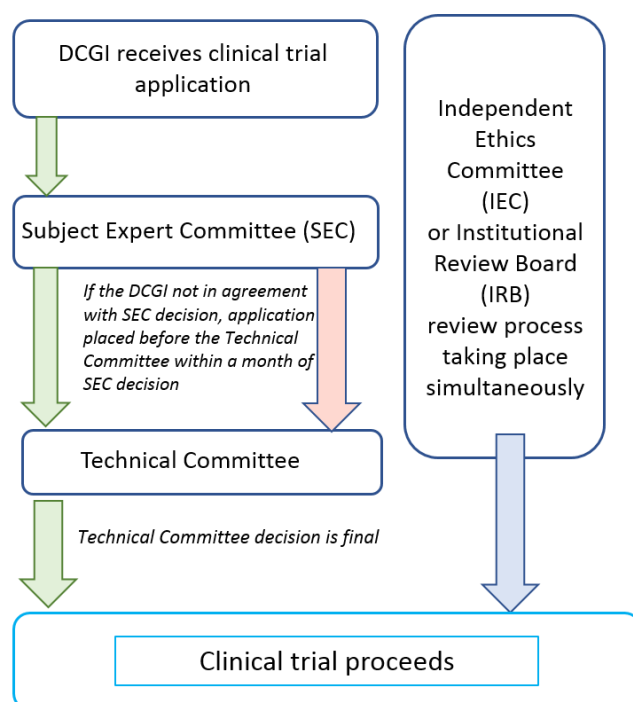
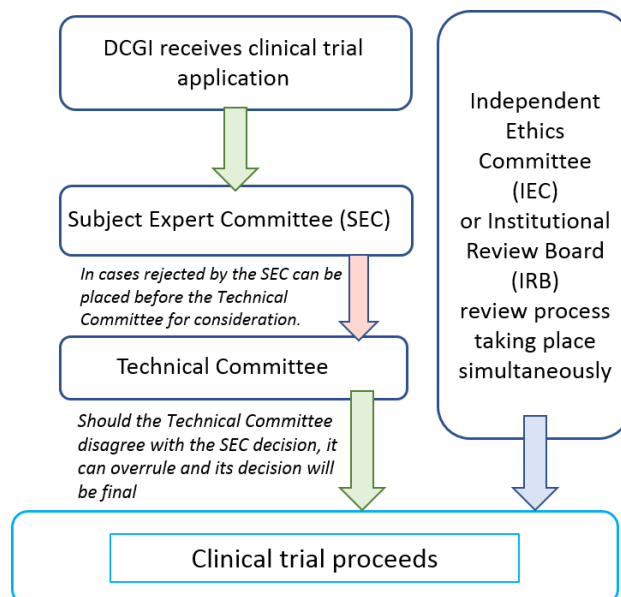
4) Should the DCGI disagree with the SEC, the Technical Committee will review and decide

'In cases where the DCGI is not in agreement with the SEC's recommendations of a clinical trial application, the matter may be placed before the Technical Committee for a final decision within a month of the SEC recommendation.'³

This change confirms DCGI oversight on the approval process.

India will soon be a key international clinical trial destination

Commenting on the regulatory changes, Novotech CEO Dr. John Moller said, "By 2030, India will be one of the top 5 emerging middle class markets in the world. Rising disposable incomes and health awareness makes India an important consumer market and warrants early clinical trial engagement by biopharma companies⁶. India also has one of the lowest clinical trial penetration rates in Asia. These regulatory changes are great step in reestablishing India's clinical trial industry."⁷



For more information about the untapped benefits available in India and the Asia Pacific region, download our free joint Frost & Sullivan white paper, '[Asia: Preferred Destination for Clinical Trials](#)'. Or to find out more about undertaking a clinical trial in India, feel free to [contact us](#).

For more information about India's clinical trial system, please refer the Indian Council of Medical Research's *Handbook for Applicants and Reviewers of Clinical Trials of New Drugs in India*, January 2017 - www.cdsc.nic.in/writereaddata/Scan1.pdf

⁶ Frost & Sullivan white paper, '[Asia: Preferred Destination for Clinical Trials](#)', May 2017 - www.novotech-cro.com/clinically-speaking/new-frost-sullivan-research-reveals-asia-preferred-destination-clinical-trials

⁷ Other sources reviewed in the development of this article include:

- Applied Clinical Trials, '[Regulatory approval India updated review](#)', 6 May 2016 - www.appliedclinicaltrials.com/regulatory-approval-india-updated-review
- Pharmabiz, '[What are the different types of committees involved in clinical trial approval?](#)', Monali Barbare, 5 August 2015 - www.pharmabiz.com/ArticleDetails.aspx?aid=89864&sid=16
- The Hindu, '[Two committees set up to supervise clinical trial: Centre to SC](#)', 30 September 2013 - www.thehindu.com/news/national/two-committees-set-up-to-supervise-clinical-trial-centre-to-sc/article5186519.ece