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# Industry Sponsored Trials Fall Sharply In Challenging Indian Environment

by Deborah Jeanfavre

A rise in bureaucracy and increased liability for clinical trial sponsors have impacted the popularity of India as a location for pharmaceutical companies' clinical studies. Trialtrove's Deborah Jeanfavre examines the data, which show a continuing decrease in new industry-sponsored trials starting in India over the past five years.

The rosy view of India as a location for relatively low-cost clinical trials with a readily available, treatment-naïve patient population became shaded over the past five years by an untenable time to approval. With the prolonged online review process, combined with increased liability for sponsors and other trial-related restrictions by the Indian government, it is not surprising that India became a less attractive clinical trial location to pharma. (Also see "*NIH confirms cut-back in Indian trials but large sponsors hope for reform*" - Scrip, 18 Jul, 2013.) Taking a look in Trialtrove, we examined industry-sponsored study starts in India in the aftermath of these regulations, drilling down to explore the effect across major therapeutic areas, sponsors and diseases.

## Have New Regulations Impacted Indian Trial Activity?

Multiple factors have contributed to an increased approval time in India during the last 5 years. The country transitioned to a mandatory, online filing process in 2009 (*IPP clin trials reg india.pdf*), extending review completion to as long as 9 months by 2012. (Also see "*China now leads India 2:1 in clinical trials* " - Scrip, 3 Jul, 2012.) In 2013, the Indian government also shifted greater responsibility to sponsors for the liability in the running of trials and implemented restrictions regarding ongoing trial numbers for each investigator and the site size required for trials. Repercussions due to the overall changes were evident in 2013 when the NIH stopped as many as 40 ongoing trials in India. It was then speculated that pharma might follow suit. Trialtrove data for trials in all phases support this supposition, showing a marked decline, by 50%, in the number of industry-sponsored trial starts between 2012 and 2013 (Figure 1).

Figure 1

Industry Sponsored Trials Started In India 2010-2015

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Trialtrove, July 2016

*Trial numbers are limited to those for which a start date is provided in the public domain. The numbers for recent years may also be impacted by delayed reporting of trial activity.*

## India Alone Experienced Decreased Trial Starts Across APAC

With growing interest in Asia Pacific countries (APAC) as emerging markets and recognition as important locations for clinical trials, we looked into whether India's policies might set it apart from other countries in the region. Data in Figure 2 indicates that most of the nine other major APAC countries maintained, or even increased, the number of trial starts in the same period. There was an increase between 2010 and 2013 across Japan, South Korea, China and Turkey. Although a few of these countries may have benefited from India's lost trials, the data does not highlight a clear migration of trial activity to specific members of APAC.

Figure 2

Top Asia Pacific Trial Countries in 2010 And Trial Starts By Year

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## Did The Changes Impact All Therapeutic Areas And Industry Sponsors?

To dig a bit deeper into this trend, the percentage of trial starts in India (per therapeutic area), was queried for this period (Figure 3). Clearly, the decreased trial initiations can be observed across all areas. The largest changes were observed in CNS and Infectious Diseases, followed by Metabolic/Endocrinology, Cardiovascular and Oncology, all of which exhibit a > 50% decrease from 2010 to 2015. The Autoimmune/Inflammation diseases exhibited a smaller, but sustained, decrease by ~30% during this period.

Figure 3

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Major Therapeutic Areas: % In India Of Total Industry Sponsored Trial Starts By Year

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*Percent is based on the number of industry-sponsored starts in India for each therapeutic area relative to the total number of industry-sponsored starts worldwide for each therapeutic area.*

The collective drop in trial starts observed during this period, might be attributed to specific sponsors choosing to avoid India's approval delays and increased regulations. However, it can be seen that the top 10 industry sponsors in 2010 all decreased their trial starts in India by 2013, and most dropped even further in 2015 (Table 1A). Interestingly, seven of these 10 companies, highlighted in Table 1B, still dominated the top positions in 2015, indicating that many of the 2010 primary players chose to stay active in India, but at a lower level.

Table 1A: Top 10 Industry Sponsors In India In 2010 And Trial Starts By Year

| | Number Of Trial Starts By Year | | |
|---|---|---|---|
| Sponsor | 2010 | 2013 | 2015 |
| *Novartis AG* | 27 | 17 | 17 |
| *Eli Lilly & Co.* | 19 | 6 | 1 |
| *AstraZeneca PLC* | 16 | 6 | 5 |
| *Pfizer Inc.* | 16 | 4 | 4 |
| *Merck & Co. Inc.* | 14 | 4 | 0 |
| *Boehringer Ingelheim GMBH* | 13 | 8 | 5 |
| *GlaxoSmithKline PLC* | 12 | 11 | 5 |
| *Johnson & Johnson* | 12 | 4 | 0 |
| *Intas Pharmaceuticals Ltd.* | 11 | 2 | 6 |
| *Roche* | 11 | 4 | 3 |

Source: Trialtrove, July 2010

Table 1B: Top 10 Industry Sponsors In India In 2015

| Sponsor | Number Of Trial Starts in 2015 |
|---|---|
| Novartis AG | 17 |
| Intas Pharmaceuticals Ltd. | 6 |

| | |
|---|---|
| AstraZeneca PLC | 5 |
| Boehringer Ingelheim GMBH | 5 |
| GlaxoSmithKline PLC | 5 |
| *Novo Nordisk AS* | 4 |
| Pfizer Inc. | 4 |
| *Cadila Pharmaceuticals Ltd.* | 3 |
| *Gilead Sciences Inc.* | 3 |
| *Glenmark Pharmaceuticals Ltd.* | 3 |
| *Lupin Ltd.* | 3 |
| Roche | 3 |
| *Sanofi* | 3 |
| *Serum Institute of India Ltd.* | 3 |

Source: Trialtrove, July 2016

*The highlighted companies were among the top 10 by number of study starts in India in 2010.*

## Diversity Of Diseases In New Trials Also Dropped

Since most of the top sponsors did not change, the disease focus of study starts in India might have been expected to also show little change. However, Trialtrove data indicates that the overall diversity of diseases dropped from 92 to 55 diseases, a decrease of about 40% (data not shown). While the top 10 diseases in India varied widely across these five years, the disease with the most starts in 2010, Type 2 diabetes, remained at the top, but with an 80% decrease in new trial starts between 2010 and 2015 (Table 2).

Table 2: Top Diseases By Number Of Trial Starts And By Year

| Top 10 Diseases In 2010 | Number Of Trial Starts | Top 10 Diseases In 2013 | Number Of Trial Starts | Top 10 Diseases In 2015 | Number Of Trial Starts |
|---|---|---|---|---|---|
| Type 2 Diabetes | 59 | Type 2 Diabetes | 21 | Type 2 Diabetes | 11 |
| Hypertension | 20 | Rheumatoid Arthritis | 9 | Asthma | 10 |
| Respiratory Infections | 19 | Dyslipidemia | 6 | Breast Cancer | 9 |
| Schizophrenia | 14 | Hypertension | 6 | Pain (nociceptive) | 7 |
| Anemia | 12 | Thrombotic Disorders | 6 | Non-Small Cell Lung | 6 |

| | | | | | |
|---|---|---|---|---|---|
| Breast Cancer | 12 | Coronary Artery Disease | 5 | Cancer Thrombotic Disorders | 6 |
| Influenza Vaccines | 12 | Asthma | 4 | Osteoarthritis | 5 |
| Rheumatoid Arthritis | 12 | Hemostasis/Hemophilia | 4 | Type 1 Diabetes | 5 |
| Non-Small Cell Lung Cancer | 11 | Non-Small Cell Lung Cancer | 4 | Hepatitis B | 4 |
| Pain (nociceptive) | 11 | Lupus | 4 | Hepatitis Vaccines | 4 |
| | | | | Respiratory Infections | 4 |

Source: Trialtrove, July 2016

## Will 2016 See A Rebound In Industry Trial Starts?

This analysis demonstrated how a dramatic decrease in Indian trial initiations followed the introduction of more arduous registration and approval processes there several years ago. Through 2015, this trend has continued, but there is an expectation that recent changes to more moderate Indian regulations for clinical trials, implemented early in 2016, may revive the country's attractiveness for industry sponsored trial activity. (Also see "*NIH Resumes Indian Trials, Will Others Follow?* " - Scrip, 18 Jan, 2016.) It is still too early to tell if this year will see a rebound in study starts.

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*Trialtrove is the pharmaceutical and biotechnology industries' leading authority on clinical trials, helping you understand the competitive landscape and offering in-depth insights on global clinical trial outcomes. For more information on the research covered in this article and how Trialtrove can help your business, click here .*