

## Twitter Thread by [JayEnAar](#)

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[@GorwayGlobal](#)



**I actually have sympathy for [@BharatBiotech's](#) scientists and the volunteers who took part in their clinical trials so far. They have been let down by bad science and poor regulatory processes. The company should never have submitted #Covaxin for regulatory approval w/o Ph 3 data**

That mistake -the original sin, if you like- has led to a series of mis-steps, errors, cover-ups, linguistic contortions, and lack of clarity. The regulator shd have held the #Covaxin approval request and said, "we'll look at it when you have at least some preliminary ph 3 data"

Instead, they clubbed their approval of 3 separate products into one press release. That was Mistake No 3, driven I suspect by the desire to have a wholly Indian offering (Covishield though made in Pune was already labelled, don't forget as an #Angrez product.

But the regulators had this problem: How do you conjure of an efficacy number in the absence of ANY Ph 3 data? They could not and so they didn't. Instead they gave it a half-arsed approval, underwent a linguistic contortion to come up with "Clinical Trial Mode".

The trouble with #AliceInWonderland words and novel phraseology is this: people ask, as indeed they should, "But what does it mean?". Here's the difficulty: No one knows. Not the CEO of [@BharatBiotech](#), not anyone in [@MoHFW\\_India](#) nor indeed anyone in [@ICMRDELHI](#).

Health journalists have been asking Questions. Their investigations on the ground led to uncovering some damning and damaging facts in #Bhopal. Was it research misconduct or was it #researchfraud? Who knows but it does not smell nice.

Instead of taking on all these questions and dealing with the issues with integrity, someone in New Delhi thought it would be a good idea to get a few dozen worthies to put their signatures to a statement condemning those who raised the Questions. "Antinational, Anti-India"!!

But science and vaccine policy cannot be determined on the basis of who can rent a bigger mob to drown out the quiet insistent critics asking uncomfortable Questions. Now on #VaccinationDay, they unveil a ConsentForm, presumably specific for those centres offering #Covaxin.

This form repeats the "Clinical Trial Mode" obfuscatory phrase. So people coming for the vaccine are entitled to ask further Questions.

"Am I taking part in a trial?"

"If so is this a registered trial

"What is the efficacy of this vaccine?"

"Why not no-fault compensation scheme?"

You couldn't have created a bigger fiasco if you had deliberately tried, to mark the start of what was to be the largest immunisation programme of any country ever. And instead of taking accountability the authorities and their #loyal #apologists are blaming the journalists!!!

[@FaheemYounus](#) may have the answer. India may have lost sight of this aphorism.

<https://t.co/uMKTSyqT2i>

Vaccines are designed to save lives, not political parties

— Faheem Younus, MD ([@FaheemYounus](#)) [January 16, 2021](#)

<https://t.co/T0EOMWav1g>

[#Covaxin](#), [#Coronavirus](#), [#Covid19](#). <pic.twitter.com/l8Kwfb5Bp>

— JayEnAar ([@GorwayGlobal](#)) [January 16, 2021](#)