

MINUTES OF MEETING

Venue: CDAC Office, NOIDA

Date: 24 Aug 2016

Time: 11:00 - 18:00

The workshop on "Online Process for Grant of NOC for Clinical Trials" has been a very good experience and a hands-on training on completion and uploading the relevant data required for online application of CT NoC.

Mock Form 12, Form 44 were completed and documents as per the checklist were uploaded to verify if the system takes up heavy files. Dr Somani, ADCGI, was available and asked to share any discrepancies and difficulties as well as any updates and improvements required on the form.

Dr Somani addressed the workshop informing that he was pleased and grateful to see the attendance from the industry as there were more than 38 attendants. He further requested all the attendants to be thoroughly involved in the workshop offerings and provide honest feedback to improve the accuracy of the online form. He further requested more collaboration from the industry with the CDSCO to make this a successful endeavour for regulator as well as industry. He requested for teams of volunteers to upload authentic documents for ongoing or closed trial. Total 9 volunteers were picked for the exercise
CRO - 3 (PRAHS, Clianza & Inventiv)
Pharma - 5 (Lilly, Sun Pharma, Wockhardt, Dr. Reddy's & Sanofi)
Regulatory Consultancy company - 1 (Global Regulatory & Consumer Insights)

The purpose of the exercise with these hand picked people are

1. To validate the system is functioning properly to upload the documents by applicant and to review the documents by DCGI officials
2. To check the understanding of requirement for online application at Industry level.

Updated form with comments provided, for this session is expected by Monday, 29th Aug and the accounts created on website during the workshop will be kept alive for the volunteers (picked by ADCGI) as they will update the form with relevant documents from ongoing trial. These volunteers will be given the benefit for online registration as well.

Finally Dr. Somani thanks all the audience to attend the meeting and also informed once online application for CT is live, the DCGI office will start working on Biologicals.