

**CLINICAL TRIAL AGREEMENT**

**Date:** 21.04.2017

An agreement made in Mumbai between Macleod's Pharmaceuticals Ltd, (also called the sponsor) G-2, Mahakali Caves Road, Shanti Nagar, Andheri (East) Mumbai – 400093, India

**AND**

Dr. Rajendra Bohra (MBBS, MS ENT) at MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

**AND**

Grapecity Research Solutions LLP, a legal entity, having its registered office at Block no. 2, Prakash Housing society, Thergaon, Pune-411033. Maharashtra, India. duly represented by Dr Sushil R Chaudhary hereinafter referred to as " \_ Grapecity Research Solutions LLP ."

**AND**

Dr. Pravin Suryawanshi (Deputy Dean), Mahatma Gandhi Missions Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

Whereas Macleod's Pharmaceuticals Ltd wishes to conduct the following Study with Dr. Rajendra Bohra as the Principal Investigator:

1. Title: A Two arm, Comparative, Parallel, Randomized, double-blind, double-dummy Clinical study to evaluate and compare the efficacy and safety of Cefrine (combination of cefdinir 300 mg + lactobacillus 60 million cells) Capsule versus Cefuroxime 250 mg Tablet in the treatment of patients with Upper Respiratory Tract Infections.

Protocol No.: CT-211-CELA(F)-2016

2. The objective of the trial is to compare the safety and efficacy safety and efficacy Cefrine (combination of cefdinir 300 mg + lactobacillus 60 million cells) Capsule versus Cefuroxime 250 mg Tablet in the treatment of patients with Upper Respiratory Tract Infections.

**Corporate Office :**

304-Atlanta Arcade, Marol-Church Road,  
Andheri (East), Mumbai 400059, INDIA  
Phone : +91 22 66762800  
Fax : +91 22 29256599/29256229  
Website: [www.macleodspharma.com](http://www.macleodspharma.com)  
CIN : U24239MH1989PLC052049

**Research Centre :**

G-2, Mahakali Caves Road, Shanti Nagar,  
Andheri (East), Mumbai 400 093,  
INDIA  
Phone: +91 22 28306435/28314611  
Fax : +91 22 28304641

1. The site of the trial would be MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India
2. The trial will be conducted as per the provision of 'Declaration of Helsinki'.
3. The Principal investigator will be paid a sum of INR 12000 plus Laboratory Investigation Charges per patient enrolled and as per the visits completed in the study.

No. of Visits	Payment (Rs.)
Visit 1	4000/-
Visit 2	4000/-
Visit 3	4000/-

### Role and responsibilities of Dr. Rajendra Bohra (Principal Investigator)

- 1) To conduct the above referenced Study as the Principal Investigator.
- 2) The Principal investigator has to complete 20 patients. The number of patients can be increased by Macleod's Pharmaceuticals Ltd.
- 3) The recruitment period for the study is one months. The sponsor expects a total of 20 patients from the site during the recruitment period. Any changes in achieving the target enrolment would have to be discussed among all the 4 signatories and decisions to be made accordingly.
- 4) The Principal investigator should be aware of, and should comply with, GCP and the applicable Ethics committee requirements.
- 5) The investigator/Co - investigator should be available and permit monitoring and auditing by the sponsor, and inspection by the appropriate authority
- 6) The investigator along with Co - investigator should ensure that all persons assisting with the study are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.
- 7) The investigator should conduct the trial in compliance with the protocol agreed to by the sponsor and, which was given approval/favorable opinion by the IEC.
- 8) The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favorable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects.

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# MACLEODS PHARMACEUTICALS LIMITED



It is hereby agreed by and between Macleod's Pharmaceuticals Ltd, Grapecity Research Solutions LLP, MGM Medical College and hospital and Dr. Rajendra Bohra (Principal Investigator) to all the terms and conditions as mentioned in this agreement

Signature

Name: Dr. Ashish Mungantiwar  
Designation: President -Medical Service  
Address: Macleods Pharmaceuticals Ltd  
G-2, Mahakali Caves Road,  
Shanti Nagar, Andheri (East),  
Mumbai - 400 093.

Signature

Name : Dr. Pravin Suryawanshi  
Designation- Deputy Dean  
Address: MGM Medical College and  
Hospital, N-6, Cidco, Aurangabad -  
431003, Maharashtra, India

Signature

Name : Dr. Rajendra Bohra  
Designation: Principal Investigator  
Address: MGM Medical College  
and Hospital, N-6, Cidco,  
Aurangabad - 431003,  
Maharashtra, India



Signatory

Dr Sushil Chaudhary  
Designation-Director-  
Grapecity Research  
Solutions LLP.  
Address; Block no. 2,  
Prakash Housing society,  
Thergaon, Pune-411033.  
Maharashtra, India.

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