



## **Pre-Clinical and Clinical Study Policy**

Tata Chemicals recognizes that the conduct of Pre-clinical and Clinical Studies to evaluate the safety and effectiveness of ingredients and their applications is a critical aspect. Tata Chemicals has adopted the following principles with respect to the disclosure of information relating to the Pre-clinical and Clinical Studies that it sponsors.

### **Pre-Clinical Studies:**

All Pre-clinical studies sponsored by Tata Chemicals

- will be conducted by competent Clinical Research Organizations.
- will be conducted in accordance with the applicable guidelines where the study is being conducted. The company will ensure that all animals are handled humanely with due regard for their welfare and complied with the Assessment and Accreditation of Laboratory Animal Care (AAALAC) International guidelines.
- will be approved by the Institutional Animal Ethics of the Clinical Research organization.
- will follow all applicable national laws and regulations where the Pre-clinical study is being conducted.

### **Clinical Studies:**

All Clinical Studies sponsored by Tata Chemicals

- will be conducted by competent Clinical Research Organizations.
- will be conducted by the identified Clinical Research Organizations, shall be in agreement with the Declaration of Helsinki principles and adhere to the pertinent requirements of the International Council for Harmonization (ICH) of Technical Requirements for Pharmaceutical and Human Use and Good Clinical Practice (GCP) Guidelines.
- will be approved by the Institutional Ethics Committee of the Clinical Research Organization.
- will be registered in a publicly accessible clinical trials registry, such as [www.ctri.nic.in](http://www.ctri.nic.in) or [www.clinicaltrials.gov](http://www.clinicaltrials.gov).
- will follow all applicable national laws and regulations where the Clinical Study is being conducted.

For advancement of scientific research, Tata Chemicals Limited will continue to engage with stakeholders regarding sharing the findings in the form of scientific communications/white papers or likewise while maintaining the confidentiality of study subjects, partners and the company.