

GUIDANCE DOCUMENTS FOR REGULATORY SUBMISSIONS

In an effort to help stakeholders get over the regulatory complexities involved in their interactions with the Health Authorities, ministries or regulators, Indian Society for Clinical Research (ISCR) has attempted to provide a gist of the various process documents that are required for submission in the various categories of trials and what needs to be done / submitted, in a simple, easy to understand format.

DISCLAIMER

Whilst Indian Society for Clinical Research (ISCR) has taken every possible care in the compilation, preparation and presentation of the information published in the document, no liability whatsoever can be accepted for the contents or their accuracy. The contents of the document should not be construed as legal or regulatory advice. Readers are advised to seek specific legal and regulatory advice from a qualified professional person before undertaking any action in reliance on the contents of this publication. The materials in this document and site could include technical inaccuracies or typographical errors and are provided "as is" and without warranties of any kind either expressed or implied, to the fullest extent permissible pursuant to applicable law and regulation. ISCR disclaims all warranties of fitness for a particular purpose. ISCR does not warrant or make any representations regarding the use of or the results of the use of the materials in this site in terms of their correctness, accuracy, reliability, or otherwise. ISCR makes no commitment to update the materials on this site.

For document see below



Clinical Trial For Registering A New Drug In India (Drug Manufactured In India)

Submission of IND (Investigational New Drug Application) with Clinical Trial (CT) Protocol (For list of the documents to be submitted – [click here](#))

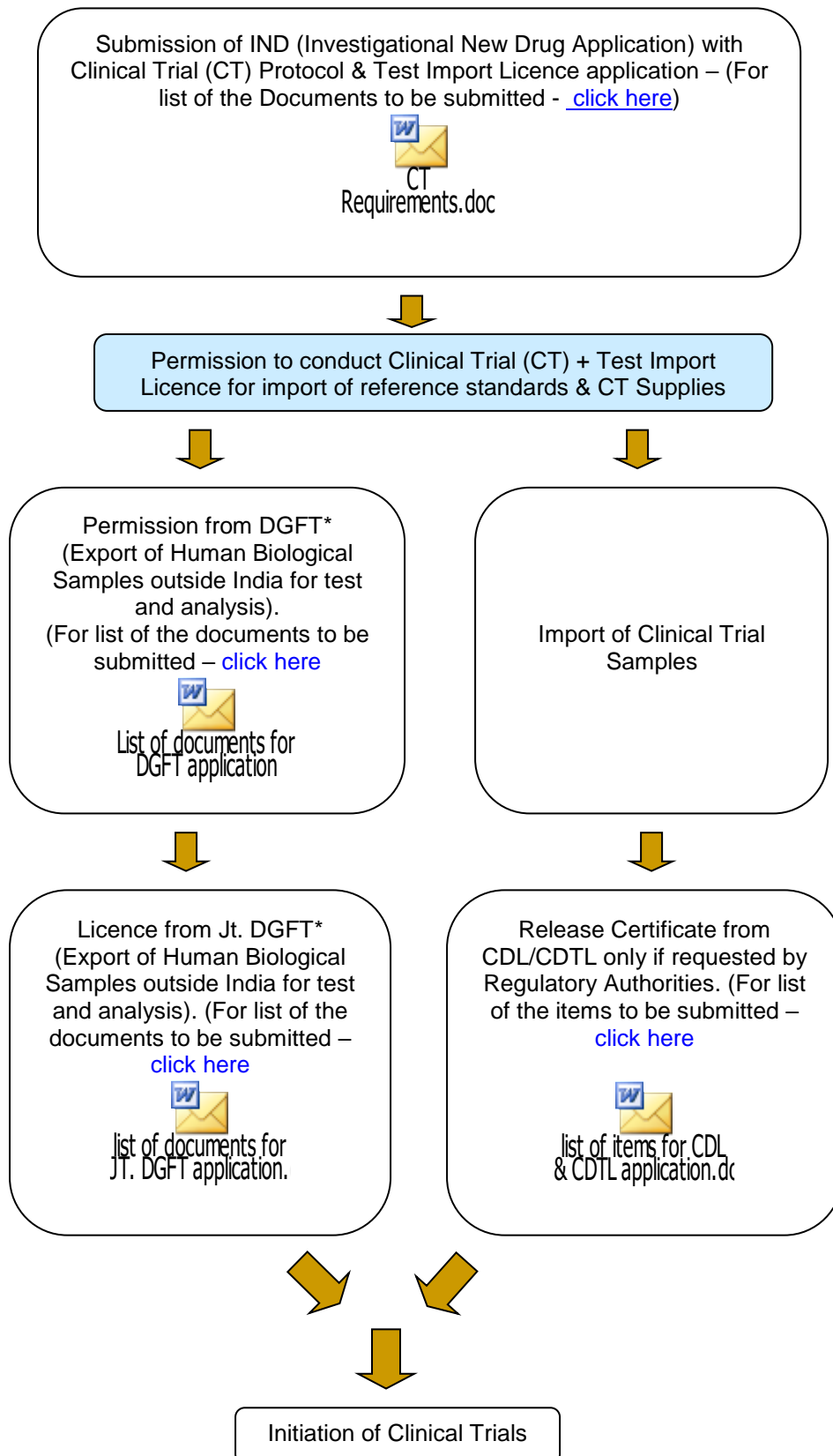


Permission to conduct Clinical Trial (CT)



Initiation of Clinical Trials

Clinical Trial For Registering A New Drug In India (Drug Manufactured Outside India)



**Note: Permission / Licence from DGFT / Jt. DGFT is not required for testing of human biological samples within India.*

Clinical Trial For A New Drug Already Registered In India

