

Download Guide For Investigator Initiated Trials

INVESTIGATOR INITIATED TRIALS. Investigator initiated clinical trials represent an increasing and extremely important portion of medical research, especially in development of medical devices. The special programme for Investigator Initiated Clinical Trials (IICTs) of the Swiss National Science Foundation (SNSF) supports clinical trials as defined in the Federal Act on Research involving Human Beings (Human Research Act, HRA)* and regulated by the Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance, ClinO)**.

- Eliminate orphaned footnote reference in recruitment materials section
- Update timelines related to continuing review report forms
- Add note about upcoming process change to stop adding “-as submitted” to documents listed on Certificate of Action Guide for Researchers 10 April 2019 Page 2 of 83

In early May, the FDA issued a draft guidance entitled “Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators Guidance for Industry.” This is a 23-page document with much information on Investigator Initiated Trials / Studies (IITs/IISs) and which is aimed not so much at the industry but at the individual investigators doing studies on marketed drugs or ... - Guide For Investigator Initiated Trials