AIFA provides guidance on critical aspects relating to the management of clinical trials in Italy during the COVID-19 emergency

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Due to the COVID-19 emergency and the consequent lockdown that is affecting non-essential services in Italy, including some health care services, on March 12, 2020 the Italian Medicines Agency (AIFA) issued a Guidance, where it provides directions to sponsors, non-profit organisations and CROs involved in clinical trials (Guidance).

The Guidance tackles criticalities that the sponsors are experiencing in clinical trials due to the restrictions to patients' access to the trial sites. AIFA sets out conditions for alternative arrangements in compliance with Good Clinical Practice (GCP) with a view to ensuring therapeutic continuity in clinical trials.

The Guidance covers all the various phases of the clinical trial, from the electronic submissions of applications and amendments, to the management of activities, such as the delivery of the Investigational Medicinal Product (IMP) directly to the patients or the remote monitoring of the trial.

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