G.S.R.227(E) 19 Mar 2019

Highlights for Clinical Trials and EC

General:

Effective from 19 Mar 2019

EC composition and registration clauses from 2019 (180 days from 19 mar 2019)

Applicable to Clinical trials, BA and BE studies, Academic studies, Biomedical and health research

Academic studies- data/results not to be used for regulatory submission or promotion

Biomedical and health research- biomedical and health research" means research including studies on basic, applied and operational research or clinical research, designed primarily to increase scientific knowledge about diseases and conditions (physical or socio-behavioral); their detection and cause; and evolving strategies for health promotion, prevention, or amelioration of disease and rehabilitation but does not include clinical trial

Orphan drug- affects not more than 5 lakh population

Ethics Committee:

Two types defined-

- For CT, BA and BE
- For Biomedical and health research

S. No.	For CT, BA and BE	Biomedical and health research
1.	Registration with DCGI	Registration with authority designated by MOH & FW
2.	Function as per Indian GCP	Function as per ICMR guidelines
3.	Registration for 5 years	Provisional registration for 2 years and final registration for 5 years
4.	EC has to be in same city and within 50 kms of site	No such specification
5.	Application for registration (Form CT-01) asking for copy of Accreditation if any	Application for registration (Form CT-01) asking for copy of Accreditation if any

For EC reviewing CT, BA and BE-

- Key change 50% members non-affiliated.
- Minimum members 7
- Inform membership change in 30 days to DCGI

Sponsors of CT, BA and BE studies

1. If drug discovered and developed in India-
- DCGI decision timeline 30 days.
- If no response from DCGI – automatic approval. Begin and inform DCGI with Form CT-4A
2. If drug discovered outside- timeline 90 days for DCGI decision. No automatic approval.
3. Conditions post approval-

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a. Inform DCGI EC decisions of approval rejection within 15 days
b. Enrolment status to DCGI quarterly
c. 6-month status report on SUGAM
d. Termination of study inform within 30 days
e. Initiate trial within 2 years

4. Conditions for post-trial access of study drug to trial participants outlined
5. BA and BE centres to be registered with CLA- apply>>inspection>>approval. Registration valid for 5 years
6. Clinical trials, BA and BE studies to be registered on CTRI