CFDA sets out punishments for counterfeit clinical trial data

The China Food and Drug Administration (CFDA) has released a notification setting out "Punishments in Relation to Problematic Clinical Trial Data During Inspections". The notice is described as following in the wake of the State Council-ordered reforms to the drug and medical device review and approval system, and the self-audit campaign initiated by the CFDA from July 2015. The latest notice is open for public feedback on punishments.

The notice defines data fraud as follows:

1. Modification or fabrication of candidate information, trial data, trial records, test drug information, without reasonable explanation
2. Replacing the listed reference preparation with an alternative test drug; or using false test drugs such as purchasing drugs already available on the market to replace the self-developed candidate drug, etc.
3. Concealment, abandonment or selective use of trial data
4. Concealment or omission of possible serious adverse events associated with the drug in clinical trials
5. Concealment or omission of prohibited drugs in consolidation trials
6. Deliberately destroying or concealing clinical trial data, or data storage medium
7. Other deliberate acts that compromise the authenticity of drug clinical trial data

Upon discovery of acts of data fraud listed above, all drug registration applicants, clinical trial institutions, contract research organizations and other directly responsible persons will be subject to criminal investigation according to the relevant laws and regulations, and transferred to the judicial authorities.

The CFDA also sets out a range of actions that will be taken against drug sponsors and clinical trial institutions implicated in fraudulent behaviors. In relation to drug sponsors, all other applications from that sponsor made within the previous 12 months will be refused, and previously accepted applications will not be processed, while further applications from the sponsor will not be accepted for a period of three years.

In relation to clinical trial institutions and researchers, a "three strikes" policy is adopted, with clinical trial accreditation to be withdrawn from institutes involved in three separate instances of fraud, and all registration applications from the specialty that have been accepted will be suspended. Other registration applications linked to a lead researcher implicated in such cases will also not be approved.