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FDA warns Genentech researcher for trial data validity

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Singapore: The US FDA has given a warning to Dr Bernard Doft, a phase III investigator of Genentech's Lucentis macular degeneration treatment, for failing to follow the protocol and maintain accurate case histories of patients. Dr Doft's omissions and mistakes raised concerns about the "validity, reliability and integrity of the data".

Dr Doft participated in the Harbor study, which compared low and high dose versions of Lucentis among patients with the eye affliction. The trial did not provide the results that were initially estimated. Higher 2mg dose did not provide better visual acuity than the standard 0.5mg dose.

Furthermore, the FDA inspected his clinical site in Pittsburgh during September 2012 and found two subjects did not meet inclusion criteria, but were included in the study; the best corrected visual acuity test was measured by uncertified personnel in five subjects, and visual acuity examiners measured eye pressure without being masked to the study eye in nine subjects.

The FDA also found that the site failed to ensure that Genentech visual acuity worksheets accurately listed the person who conducted exams as documented in subject medical charts. There were 10 examples in which the examiner listed in the Genentech worksheets was not the person conducting the exams as documented in the charts, and these violations occurred in five of the 23 total subjects at the site.

The physician was also cited for failing to obtain informed consent properly on two occasions in which subjects began their participation but signed the proper documentation later. In addition, it appeared to FDA inspectors that one subject could not read the informed consent form, because the form was provided to the subject after the subject's eyes were dilated.