Retrospective survey on the approved antibody drugs in Japan for the perspective of antibody "microdose" dose.

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A microdose (MD) of antibody drugs for clinical study is still not defined by any guidance.
In this survey, we studied retrospectively on the starting dose in the first in human (FIH) clinical trials of antibody drugs. We survey 52approved antibody drugs that were listed in the National Institute of Health Sciences' website as of October, 2018. We used the database survey of Pharmaceuticals and Medical Devices Agancy (PMDA) web homepage and reviewed the information from package insert, interview form, and review report. We defined the lowest dose of a human-equivalent dose of no-observed-adverse-effect levels (NOAEL) calculated from nonclinical studies as NHD and the smallest start dose treated for clinical trial as FHD. NHD in 10 items of the antineoplastic drugs was unknown as a toxicity appeared at the minimum dose set in toxicity studies. FHD in 3 items was less than 100 micrograms. FHD is normally selected and assumed the lower than the dose expected not to exert any pharmacological actions. The MD is also expected to be lower than the effect level. When NHD is unknown, 100 micrograms seems to be low enough for MD dose of antibody.