

[MDREX] MFDS accepts RWE for medical device with 3D printer or digital technology(wearable, big data, AI etc.)

The Ministry of Food and Drug Safety ("MFDS") has issued a notice on amending the the "Rules on Medical Device Approval/Certificate/Registration and Evaluation" to allow Real World Evidence ("RWE") as a factor in clinical trials for medical device products that incorporate 3D printer or digital technology (wearables, big data, AI etc.) when such products apply for product approval and certificate in Korea. As a reference, Real World Data ("RWD") is collected in various settings through medical devices and also can be collected through electronic medical records and other medical information provided by medical institutions when treating a patient. RWE is evidence collected from real world uses of RWD and through medical devices, and can be used for clinical trial purposes by assessing the potential benefits and risks collected from the real world setting.

In addition, if applicants plan to use RWE when applying for product approval, the MFDS has provided the following requirements:

- 1) Feasibility of RWD type, source, collection method, selection standard, exclusion standard (including the gender, age, medical history of medical device user)
- 2) Information on the used medical device (product name, model number, characteristics, raw materials, functions, purpose, instructions on use, product use warning etc.)
- 3) Information on individuals that participated in collecting and analyzing the RWD
- 4) Efficacy, Performance, use method and analysis of RWD

Thus, if you or your company is planning to enter the Korean market with a medical device that utilizes digital technology, please consider this update on RWE acceptance by the MFDS. The notice period on this amendment by the MFDS will last until May 5, 2023 and the actual implementation of the amendment will be publicized by the MFDS at a later date. If you have any questions on RWE and how it will be used by the MFDS, please feel free to reach out to us at MDREX (pro@mdrex.co.kr).

Kind regards,