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GRAIL receives breakthrough device designation from FDA

15 May 2019 | News

Proprietary Methylation Technology Selected for Continued Development of Multi-Cancer Test



GRAIL, Inc., a US based healthcare company whose mission is to detect cancer early, when it can be cured, has announced that its multi-cancer test has been granted Breakthrough Device designation from the U.S. Food and Drug Administration (FDA).

The investigational blood test is in development for the early detection of multiple cancer types in individuals aged 50 or older. The FDA grants Breakthrough designation to devices that have the potential to provide for more effective diagnosis of life-threatening diseases such as cancer. The goal of the FDA's Breakthrough Devices Program is to provide patients and healthcare providers with timely access to medical devices granted the designation by speeding up their development, assessment, and review.

GRAIL previously reported data from the first pre-planned sub-study of its Circulating Cell-free Genome Atlas (CCGA) study, which showed that its three prototype next-generation sequencing (NGS) blood tests were able to detect multiple deadly cancer types from a single blood draw, with a low rate of false positive results (high specificity).[1] The company has since selected methylation as its preferred approach and has developed a methylation sequencing blood test that preferentially targets the most informative regions of the genome to both detect the presence of multiple types of cancer and identify the tissue of origin (the part of the body where the cancer originated). The blood test is currently being evaluated in the second pre-planned sub-study of CCGA.