

Epigenomics down but is it out?



[Madeleine Armstrong](#)

A second FDA rejection for Epigenomics' colorectal cancer blood test Epi proColon has sent the company's stock down as much as 47% today and raised the question of whether it can continue as a going concern. It looks likely that the German group will need to carry out yet another study of the troubled diagnostic and might need to raise more funds in order to do so.

However, Epigenomics seems determined to limp on for at least a while longer, saying it remains "highly committed" to providing an alternative screening option to the likes of faecal immunochemical testing (FIT) and colonoscopy. Chief executive Thomas Taapken told *EP Vantage* that he saw the "positives in the negative", stressing that it was not a non-approval decision, but rather "a situation where more data could make [the test] approvable".

He believes the new study might be similar in design to the recent Admit trial, but added that it was difficult at this point to say how long it could take. The company plans to meet the FDA to hash out the trial's details.

All this could eat into Epigenomics' cash pile, which stood at €10.6m as of August. This should still keep it going until the second half of 2016, as anticipated, said Mr Taapken – but it is "not improbable" that the group will need to drum up more investment to get to the point of approval, depending on the new study's duration.

Improving compliance

Although the efficacy of Epi proColon has been questioned, Epigenomics had hoped to show an improvement in compliance with screening programmes – colonoscopy has notoriously low attendance rates due to its invasive nature, while FIT and Cologuard can be hampered by people's reluctance to handle stool samples.

After its first knock-back last year, the company carried out the Admit trial to evaluate compliance. But while it [found](#) a 99.5% adherence rate with Epi proColon, there was also higher-than-expected compliance with FIT testing, at 88% – meaning it fell short of its statistical goal. By comparison, a passive control arm found adherence to standard of care colorectal cancer screening of less than 25%.

The FDA's current issue seems to be that the Admit enrollees did not represent the target population for Epi proColon: people with a history of noncompliance to screening programmes.

However, Mr Taapken insisted that the Admit population had been previously non-compliant and twice turned down offers for screening, so the high adherence rate seen with FIT is something of a mystery. Now the aim is to find "truly non-compliant" participants for the new study, he added.

Although another nail in the coffin for Epigenomics, the news is a boost to rival Exact Sciences, which has not exactly had a smooth ride of late with its stool-based colorectal cancer diagnostic Cologuard – recently shunned by a US expert panel ([Double whammy is Exactly the wrong prescription for Cologuard, October 07, 2015](#)).

While Exact has the alternative testing market to itself for a bit longer, it looks like both companies have a way to go to prove that their products provide real competition to the current gold standards.

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