This small startup wants to change FDA clinical trials by making control groups unnecessary

Could a startup founded by two guys in their 20s change the way medical researchers study patients? The Food and Drug Administration is open to the possibility.

Flatiron Health began as a small New York tech company trying to use real-world data from patient electronic medical records to replace more traditional clinical trial data. Then it raised $328 million, launched a modest collaboration with the FDA to study the use of its so-called “real-world” data in 2016, and entered partnerships with just about every major drug firm.

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Traditional clinical trials, which generally randomly assign some patients to a control group, are the gold standard for determining that a new medicine is safe and effective for its intended use… . But they don’t always represent what happens to patients in the real world.

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Zach Weinberg, 32, Flatiron’s co-founder … promised Flatiron will soon publish results showing it is possible to achieve one of the major goals of the field: using data collected from health records to mimic a control group.

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That idea is not without controversy, and in emailed responses to questions, the FDA was more tentative about the prospect of perhaps replacing control groups one day.

Read full, original post: Can Roche’s little tech startup help the FDA change clinical trials?