OPINION

On the right track

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In the U.S., moving a drug from the lab bench to the pharmacy's shelves takes about 10 years. That's because the **Food and Drug Administration** (FDA) sets a high bar — the rigorous three-stage clinical trial system — to ensure that drugs are safe and effective.

Late last month, the agency announced that it's pushing **a controversial autism treatment** through the system a bit more quickly.

CM-AT, a drug made by New York biotech **CureMark**, is a powder that helps children with autism digest proteins and, supposedly, improves brain function. Its creators haven't published any information yet about the drug's effectiveness or how it works. But last year, after submitting positive preliminary results to the FDA, the company began a **stage-III clinical trial** at 12 medical centers.

Their data continues to impress the FDA, apparently, because CM-AT can now boast official '**fast-track**' status. That means the regulatory agency will communicate early and often with the company during the trial to try to expedite the approval process. The FDA only gives fast-track status to drugs that "treat serious diseases and fill an unmet medical need."

CureMark's news came three days before director of the National Institutes of Health **Francis**

Collins announced a 'regulatory science program' that builds bridges between his agency and the FDA. The main goal of the collaboration — one of **seven projects** funded by $200 million of Collins' discretionary budget — is to speed up drug development.

The program is offering $6.75 million over three years in grants for work on new methods or technologies that will make the regulatory process more efficient. With any luck, the changes will lead to many more autism therapies being placed on the track to success.