FDAAA Title VIII: How did we get here (and where exactly is here)?

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To enhance patient enrollment and provide a mechanism to track subsequent progress of trials, FDAAA expands the data bank at ClinicalTrials.gov to include more drug trials, and adds a requirement to include registration information for device trials. Previously, only clinical trials of drugs for serious and life-threatening conditions were required to be registered in the data bank. In addition, to ensure that results of trials are made public, and that patients and providers have the most up-to-date information, results information for approved products would be added to this database. Results information would first come from existing FDA and NIH documents, as well as peer-reviewed scientific publications, before being expanded to include more detailed, standardized entries. The database would apply to both privately and publicly-funded clinical trials, and would be available to the public through the Internet. Finally, the new law provides civil monetary penalties (CMPs) for noncompliance with registration or results reporting requirements.

Notes: