

Staying up to date with regulatory guidance without third party assistance requires an organizational method and diligence.

A simple method is as follows:

The screenshot shows a web browser with a navigation bar at the top containing tabs for 'Regulatory Guidances', 'FDA', 'FDA Workshops', 'Related Resources', 'ICH', '21 CFR', and 'EMA'. A search bar is on the right. The main content area displays the title '[Bioequivalence] Statistical Approaches to Establishing Bioequivalence Guidance for Industry - Draft' and the date 'Thursday, December 15, 2022 10:59 AM'. Below this is a table with three rows: 'Date' (December 2022 (To replace Feb 2001 guidance)), 'Link' (a blue hyperlink to the FDA website), and 'Scope' (a detailed paragraph about the guidance's purpose and scope). At the bottom left, there is a PDF icon and the text 'Annotated Guidance'.

Date	December 2022 (To replace Feb 2001 guidance)
Link	Statistical Approaches to Establishing Bioequivalence (fda.gov)
Scope	This guidance provides recommendations to sponsors and applicants who intend to use equivalence criteria in analyzing in vivo or in vitro BE studies for INDs, NDAs, ANDAs, and supplements to these applications. This guidance discusses statistical approaches for BE comparisons and focuses on how to use these approaches both generally and in specific situations. When finalized, this guidance will replace the guidance for industry Statistical Approaches to Establishing Bioequivalence, which was issued in February 2001 (2001 guidance). This guidance provides recommendations on the topics covered in the 2001 guidance as well as recommendations on additional topics, including missing data and intercurrent events, adaptive design, and specific situations, such as narrow therapeutic index drugs and highly variable drugs.

annotated... Annotated Guidance

Coding can be used for more fancy setups (data scraping for metadata or automatic onboarding of a new guidance) if one has time.