
Statistics in Regulatory Affairs in www.wikipedia.org: Initiative of the ISCB Statistics in Regulatory Affairs Subcommittee (SiRA SC)

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6: *Bayer HealthCare Pharmaceuticals Inc., Whippany, New Jersey, USA.*

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8: *Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, Germany.*

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Wikipedia is a free-access, free-content Internet encyclopaedia, which is ranked among the ten most popular websites worldwide. The category “Statistics” in Wikipedia contains about 3,500 articles, which have been gradually developed mainly by statisticians.

Statisticians working in a regulated environment (e.g. the pharmaceutical and healthcare industry) are obliged to have a sound knowledge and understanding of the regulatory requirements that affect the design, conduct, analysis and reporting of their studies. Regulatory guidance for the pharmaceutical and medical devices industry can be found at the international level (e.g. ICH), as well as at the regional/national level (e.g. EMA in Europe, NICE in UK, IQWiG in Germany, FDA in USA and PMDA in Japan). Furthermore, statistical regulatory guidance is found under general topics (e.g. Good Clinical Practice [ICH-E6]) and specific ones explicitly related to statistics (e.g. Statistical Principles for Clinical Trials [ICH-E9]) or not explicitly (e.g. Special Populations: Geriatrics [ICH-E7] or Clinical Trial Endpoints in Oncology [FDA]).

This large volume and diversity of documents and information sources is subject to regular revisions. Hence, individual statisticians devote considerable time and effort to keep themselves adequately informed and educated about regulatory requirements.

The objective of this project is to initiate in Wikipedia a comprehensive source of references for statistical guidance documents and related articles that are relevant to regulatory affairs. The project will be rolled out in two stages: 1) initiation of a structure for making entries into Wikipedia under the term “List of Guidances for Statistics in Regulatory Affairs”; 2) initiation of a process for creating articles. Contributions from the ISCB members and the statistical community will be welcome and sought actively.

The poster presentation will include a project description, a plan and a simple user guide for creating, editing, and reviewing the content in Wikipedia.