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## Guidances for statistics in regulatory affairs in [Wikipedia](#): Initiative of the ISCB Statistics in Regulatory Affairs Subcommittee (SiRA SC)

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Statistics in regulatory affairs guidance for the Pharmaceutical and Medical Devices Industry has been issued for more than 25 years world-wide. However, there is no unique shared free open-access depository that offers a synthetic view of the international-, regional- and country-level regulatory guidance. At the ISCB Utrecht conference (2015) the SiRA SC decided to fill this gap via Wikipedia, which is a free Internet encyclopaedia, ranked among the ten most popular websites worldwide.

The objective of SiRA SC was to initiate a comprehensive source of references for statistical regulatory affairs guidance documents and related articles in Wikipedia [1]. A suitable location in Wikipedia for the SiRA guidances was identified as the category “Biostatistics”, classified under “Statistics”, comprising various relevant topics (e.g. Medical Statistics, Clinical Trials and Epidemiology). The SiRA SC initiated a Wikipedia “List” of guidance documents in July-2016 and a related Wikipedia “Page” in January-2017 [2].

The poster presentation will include a description of the Wikipedia Project implementation (Wikipedia List and Wikipedia Page), an update to the Wikipedia User Guide [1] for editing/reviewing the content in Wikipedia and a plan for dissemination of the Wikipedia Project to the wider statistical community.

1. Torres JV, Weir CJ, Close NC, Schumacher M, Friede T, Siegel J, Gerlinger C, Bender R, Nakas C, Seldrup J and Chadha-Boreham H. (2015) Statistics in Regulatory Affairs in [www.wikipedia.org](http://www.wikipedia.org): Initiative of the ISCB SiRA SC. ISCB Conf. Poster.
2. [https://en.wikipedia.org/wiki/List\\_of\\_Guidances\\_for\\_Statistics\\_in\\_Regulatory\\_Affairs](https://en.wikipedia.org/wiki/List_of_Guidances_for_Statistics_in_Regulatory_Affairs); [https://en.wikipedia.org/wiki/Draft:Guidances\\_for\\_statistics\\_in\\_regulatory\\_affairs](https://en.wikipedia.org/wiki/Draft:Guidances_for_statistics_in_regulatory_affairs)