GUIDANCES FOR STATISTICS IN REGULATORY AFFAIRS IN WIKIPEDIA

Initiative of the ISCB Statistics in Regulatory Affairs Subcommittee (SiRA SC)

Harbajan Chadha-Boreham[1]
Christopher J. Weir[2]

Nicole C. Close[3]
Martin Schumacher[4]

Tim Friede[5]
Jonathan Siegel[6]

Christoph Gerlinger[7-8]
Ralf Bender[9]

Christos Nakas[10]
Jorgen Seldrup[11]

Stanislav Katina[12]
Juan V. Torres[13]

On Behalf of the ISCB SiRA SC

At the ISCB Utrecht conference (2015) the SiRA SC decided to commence the Wikipedia Initiative for statistics in regulatory affairs guidance for the Pharmaceutical and Medical Devices Industry. In 2016 the SiRA SC presented a poster at the ISCB Conference about the Wikipedia Initiative, dealing mostly with the generalities of Wikipedia, its use for statistics in the regulatory environment and how users could contribute to the Wikipedia Initiative[1].

1. OBJECTIVES

The main objective of the SiRA SC was to **initiate a comprehensive source of references** for statistical regulatory affairs guidance documents and related articles in **Wikipedia**[1].

The secondary objective was to **create a related Wikipedia User Guide**.

2. WIKIPEDIA ARTICLE

An **Outline for the Wikipedia Article** was prepared by the SiRA SC in Word format and agreed upon (see "Wikipedia Article: Table of Contents" in the side-panel).

In addition, the **SC members agreed upon the Leading Text and History** (§1) of the Wikipedia Article. The writing of these two sections and some other sections in Wikipedia was initiated by one member (HCB) in January-2017[2].

The article was assigned the category **"Biostatistics"**, classified under **"Statistics"**, comprising various relevant topics (e.g. Medical Statistics, Clinical Trials and Epidemiology).

WIKIPEDIA
The Free Encyclopedia

3. WIKIPEDIA LIST

A SiRA SC member (JVT) initiated a **Wikipedia "List" of guidance documents** in July-2016[3].

A brief description and references to thirty relevant regulatory guidelines/guidances have been entered in the Wikipedia List by the SiRA SC members to date.

4. WIKIPEDIA USER GUIDE FOR SiRA GUIDANCES

Basic edits for Wikipedia were presented in the above-mentioned poster[1].

A **more detailed User Guide for editing/reviewing** the content in Wikipedia has been produced to aid potential volunteers to contribute to the **SiRA Wikipedia Article and List**[4].

[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. (2016) Statistics in Regulatory Affairs in www.wikipedia.org: Initiative of the ISCB SiRA SC. ISCB Conference Poster. Available at http://www.syntaxforscience.com/web/wikisira/
[2] https://en.wikipedia.org/wiki/Guidances_for_statistics_in_regulatory_affairs

[3] https://en.wikipedia.org/wiki/List_of_Guidances_for_Statistics_in_Regulatory_Affairs
[4] Chadha-Boreham H, Torres-Martin JV and Katina S on behalf of ISCB SiRA SC (2017). Statistics in Regulatory Affairs in www.wikipedia.org: Initiative of the ISCB SiRA SC – USER GUIDE. Available at http://www.syntaxforscience.com/web/wikisira/

5. DISSEMINATION OF THE WIKIPEDIA INITIATIVE

The SiRA Article and the List **have already undergone Wikipedia's internal review process** and were "accepted". Hence, they are both open to contributions from volunteers.

Formal dissemination of the material from the Wikipedia Initiative to the ISCB members and the wider statistical community is planned when a Viewpoint paper, which was submitted to the journal, Pharmaceutical Statistics (12 June 2017), has been published. A **six-month free open-access to the Viewpoint paper** has been negotiated by the SiRA SC with Wiley publisher.

Relevant information about the Initiative will then be uploaded on the ISCB SiRA SC page for access to the ISCB and non-ISCB members.

6. HOW DO I CONTRIBUTE?

Wikipedia is a **free-access and free-content internet encyclopedia** for reading, writing and editing. You are encouraged to participate in the development of the SiRA Wikipedia Article and List.

Download the SiRA Wikipedia User Guide[4] and follow the instructions to create a Wikipedia login account.

Thereafter, **follow the instructions for editing** the existing sections or writing new ones, according to the "Wikipedia Article: Table of Contents" shown in the side-panel.

WIKIPEDIA ARTICLE: TABLE OF CONTENTS

1. History
2. General guidance
3. Specific statistical guidance
4. Special populations guidance
5. Therapeutic areas guidance
6. Country specific guidance
7. See also
8. Notes
9. References
10. Further reading
11. External links

The following key sections under §2 to §6 of the Article are planned to be written in Wikipedia by volunteers:

2. General guidance
(List according to the sequence in which we design, conduct and report the study)
Good Clinical Practice
Study Design
Study Monitoring
Study Reporting
Marketing Authorization
...

3. Specific statistical guidance
Statistical principles for clinical trials
(List in alphabetic order from here on)
Adjustment by covariate
Adverse events
Endpoints
Exposure to study drug
Laboratory data
Missing data
Multiplicity
Randomization
...

4. Special populations guidance
(List in alphabetic order)
Geriatric
Pediatric
Pregnant and lactating women
Rare Diseases/Disorders
- Orphan Drugs Designation
...

5. Therapeutic areas guidance
(List in alphabetic order)
Cardiovascular
Diabetes
Oncology
...

6. Country specific guidance
(List in alphabetic order)
AHRQ (USA)
CADTH (Canada)
EUnetHTA (EU)
IQWiG (Germany)
NICE (UK)
...

AFFILIATIONS

1. Clinical Biostatistics Consultancy, Dijon, 21440 France
2. University of Edinburgh, Edinburgh, EH8 9YL UK
3. EmpiriStat, Inc., Mount Airy, MD 21771-3900 USA
4. Institute for Medical Biometry and Statistics, Faculty of Medicine and Medical Center - University of Freiburg, Freiburg, 79104 Germany
5. Dept. Medical Statistics, University Medical Center Göttingen, Göttingen, 37073 Germany

6. Bayer HealthCare Pharmaceuticals Inc., Whippany, NJ 07981 USA **7.** Bayer AG, Berlin, 13353 Germany
8. Gynecology and Obstetrics, University Medical School of Saarland, Homburg/Saar, 66421 Germany
9. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, 50670 Germany
10. Institute for Clinical Chemistry, Inselspital, Bern University Hospital, University of Bern, Bern, 3010 Switzerland

11. jStatConsult, Barr, 67140 France
12. Institute of Mathematics and Statistics, Faculty of Science, Masaryk University, Brno, 61137 Czech Republic
13. Syntax for Science S.L., Palma de Mallorca, 07121 Spain

ISCB