STATISTICS IN REGULATORY AFFAIRS IN WWW.WIKIPEDIA.ORG

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

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1 — OUR OBJECTIVES

Initiate in Wikipedia a comprehensive source of:
- References for statistical guidance documents
- Related articles relevant to regulatory affairs

Encourage the international community of statisticians to contribute to the SiRA Wikipedia Initiative

2 — WIKIPEDIA

FREE-ACCESS & FREE-CONTENT	**Internet Encyclopaedia**
RANKED AMONG	**The 10 most popular websites worldwide**
THE CATEGORY STATISTICS	**contains about 3,500 articles developed by statisticians** — **edited frequently: within the top 10% most edited topics**

3 — STATISTICS WITHIN A REGULATED ENVIRONMENT

REGULATORY GUIDANCE FOR THE PHARMACEUTICAL AND MEDICAL DEVICES INDUSTRY

CAN BE FOUND
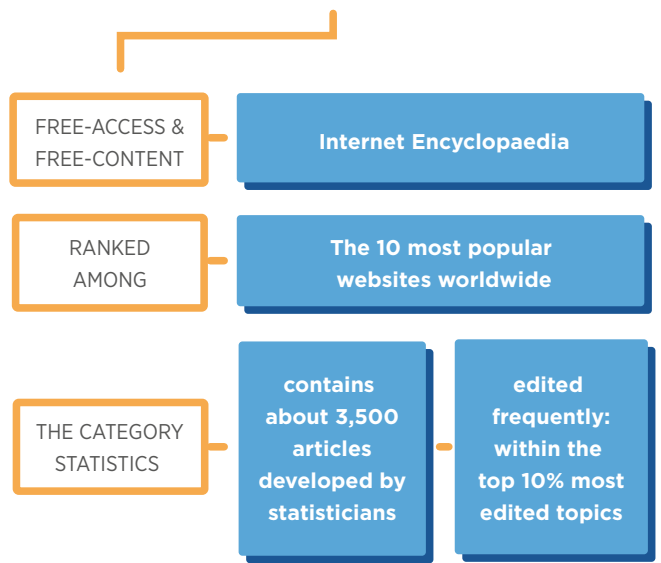- International level — **ICH**
- National level —
  - **EMA** - Europe, **NICE** - UK,
  - **IQWiG** - Germany, **FDA** - USA,
  - **PMDA** - Japan

CONTAINS
- **General topics**
  (e.g. Good Clinical Practice [ICH-E6])
- **Specific topics**
  - Explicitly related to statistics
    (e.g. Statistical Principles for Clinical Trials [ICH-E9])
  - Not explicitly related to statistics
    (e.g. Special Populations: Geriatrics [ICH-E7] or Clinical Trial Endpoints in Oncology [FDA])

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.

There is a large volume and diversity of documents and information sources that are subject to regular revisions.

Hence, individual statisticians devote considerable time and effort to keep themselves adequately informed and educated about regulatory requirements.

Therefore, it is important to create a free-access, free-content SiRA resource in Wikipedia for the international statistics community

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ISCB

4 — JOIN THE INITIATIVE IN JUST 2 STEPS

SIGN UP IN WIKIPEDIA
Open Wikipedia and **create an account** to be part of a community with more than 28 million of Editors.

BE BOLD AND START EDITING
Just go for it and don't be afraid. There are **2 main ways** to contribute in our initiative:

- By creating new **articles related** to regulatory guidances
- By adding new references in **the List** of Guidances for Statistics in Regulatory Affairs

CONTRIBUTE IN TWO WAYS

THE WIKIPEDIA LIST
Contains a comprehensive **list of guidance** documents for Statistics in Regulatory Affairs.

Can be extended further by the **Wikipedia Editors.**

There are **Indications about the format** that must be used for adding new references.

ARTICLES RELATED TO
Are information about the **content and purpose** of regulatory guidances that might be of interest to statisticians.

The **additional explanation** included within these Articles might be helpful to understand the content of the guidance.

TALK PAGE OF AN ARTICLE
The **purpose** of an Article's Talk Page is to provide space for Editors to **discuss changes** to its associated article.

In the Talk Pages **related to this initiative**, you will find:

The **format** that the Articles must follow.
A **To-Do List** for anyone interested to collaborate.
A space for **open discussion.**

WATCHLIST
Follow Articles of your interest by including them in your Watchlist.

You will be notified anytime there is a **change** on the Articles you follow.

This might be very useful to **keep you updated** about any new document included in The List of Guidances for Statistics in Regulatory Affairs.

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5 — BASIC EDITING TIPS

Description	What you type	What you get
Italics, bold, and both	''italics'', '''bold''', and '''''both'''''	*italics*, **bold**, and ***both***
Underline	<u>Underline this</u>	Underline this
Strike	<s>Strike this</s>	~~Strike this~~
Link to another article within Wikipedia	Link to [[Mean]]	Link to Mean
Change the link's text	Link to [[Mean|Average]]	Link to Average
Link to a section	[[Mean#Truncated_mean Truncated mean]]	Truncated mean
Link to a website	[http://www.wikipedia.org Wikipedia]	Wikipedia
References	FDA,<ref name="fda"> [fda.gov FDA website]</ref>	FDA[1]
References (subsequent uses)	FDA again<ref name="fda" />	FDA again[1]

Description	What you type	What you get
Add comments within the text	<!—Invisible comment-->	
Section headings	==Level 2== ===Level 3=== ====Level 4==== =====Level 5===== ======Level 6====== =Level 1= is reserved for the page title	**Level 2** **Level 3** **Level 4** **Level 5** **Level 6**

Bulleted list	* One
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