# STATISTICS IN REGULATORY AFFAIRS IN WWW.WIKIPEDIA.ORG

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

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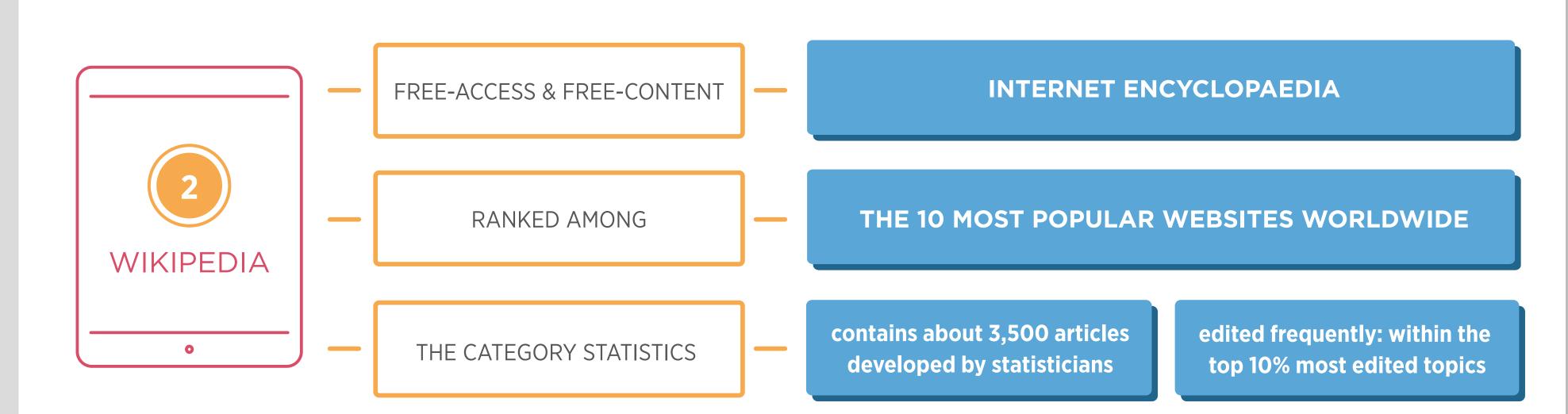
## **OUR OBJECTIVES**



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** 





#### STATISTICS WITHIN A REGULATED ENVIRONMENT

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** 



International level – ICH **CAN BE** 

> — National level -EMA - Europe, NICE - UK, IQWiG - Germany, FDA - USA, PMDA - Japan

CONTAINS

**FOUND** 

**General topics** 

(e.g. Good Clinical Practice [ICH-E6])

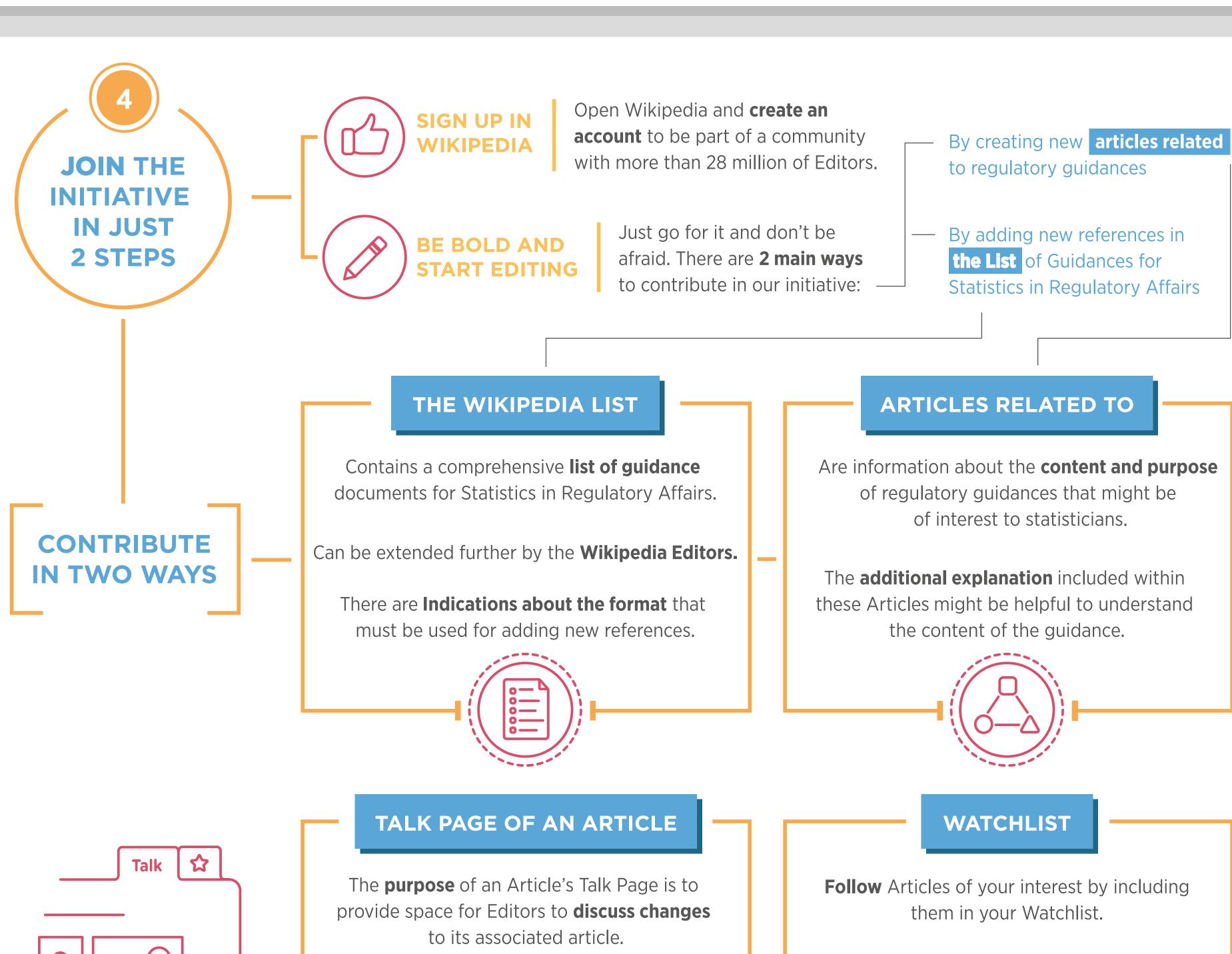
**Specific topics** 

- 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])

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.





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.** 

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.



# **BASIC EDITING TIPS**

Description	What you type	What you get
Italics, bold, and both	"italics", "bold", and ""both""	italics, <b>bold</b> , and <b>both</b>
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 <u>Mean</u>
Change the link's text	Link to [[Mean Average]]	Link to <u>Average</u>
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 <sup>[1]</sup>
References (subsequent uses)	FDA again <ref name="fda"></ref>	FDA again <sup>[1]</sup>

Description	What you type	What you get
Add comments within the text	—Invisible comment	
Section headings	==Level 2==	Level 2
	===Level 3===	
	====Level 4====	Level 3
	====Level 5====	Level 4
	=====Level 6=====	Level 5
	=Level 1= is reserved for the page title	Level 6
Bulleted list	* One	• One
	* Two	• Two
	** Two point one	<ul><li>Two point one</li></ul>
	* Three	• Three
Numbered list	# One	1. One
	# Two	2. Two
	## Two point one	1. Two point one
	# Three	3. Three

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