

STATISTICS IN REGULATORY AFFAIRS IN WWW.WIKIPEDIA.ORG

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

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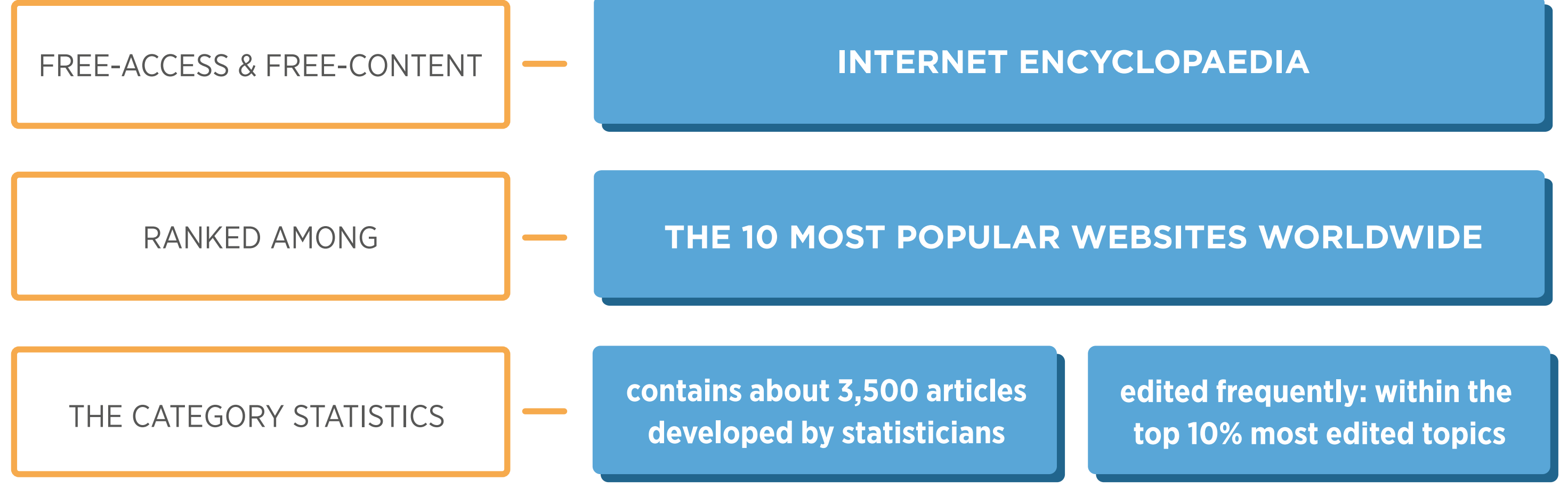
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On Behalf of the ISCB SiRA SC

1 OUR OBJECTIVES



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

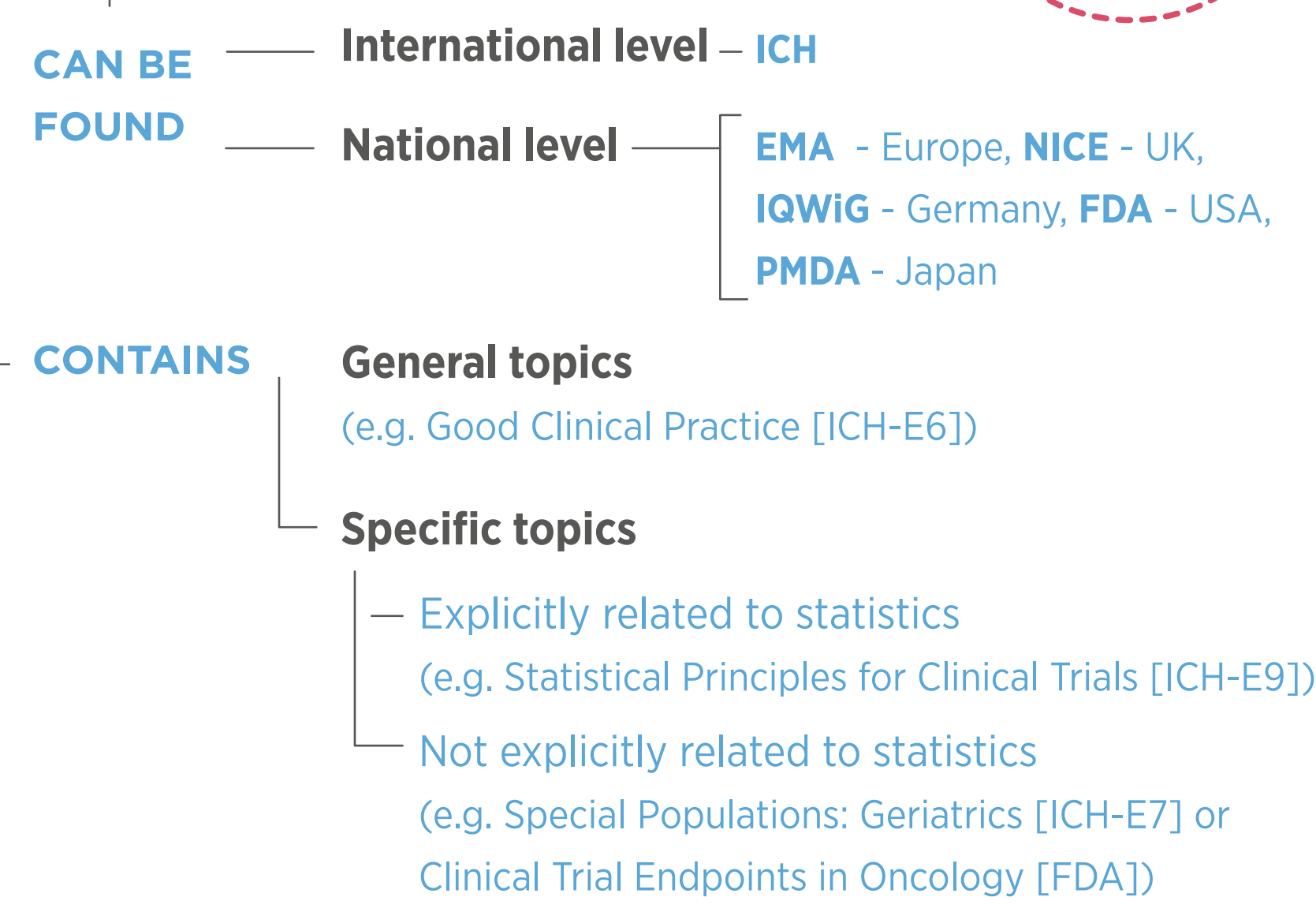
Encourage the international community of statisticians to contribute to the SiRA Wikipedia Initiative



3 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

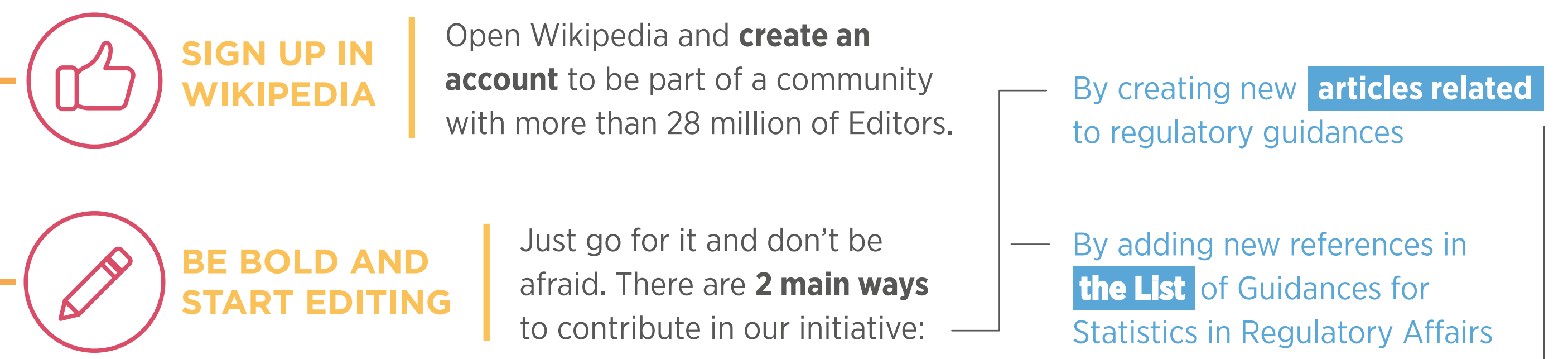


There is a large volume and diversity of documents and information sources that are subject to regular revisions.

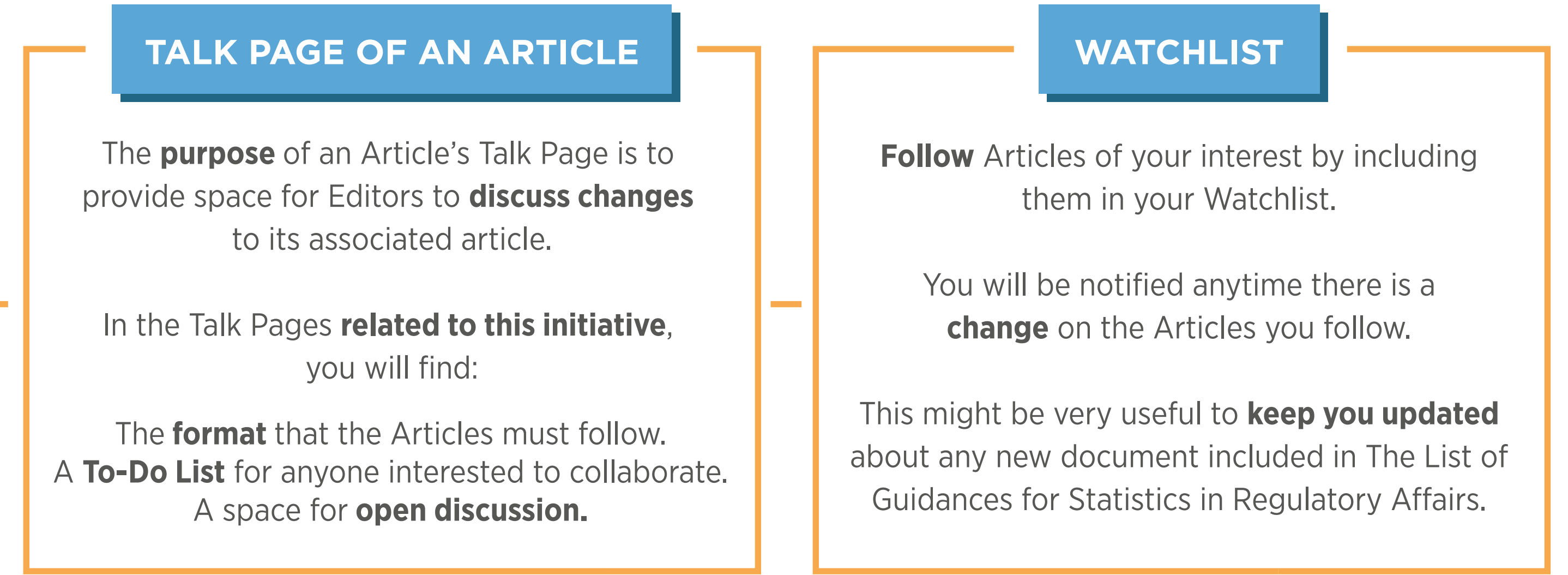
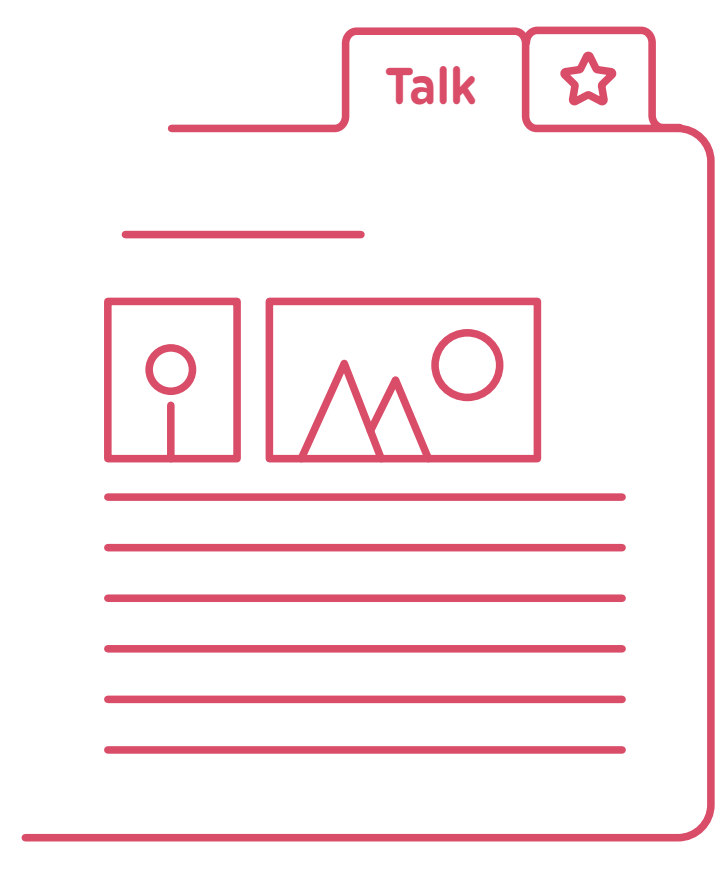
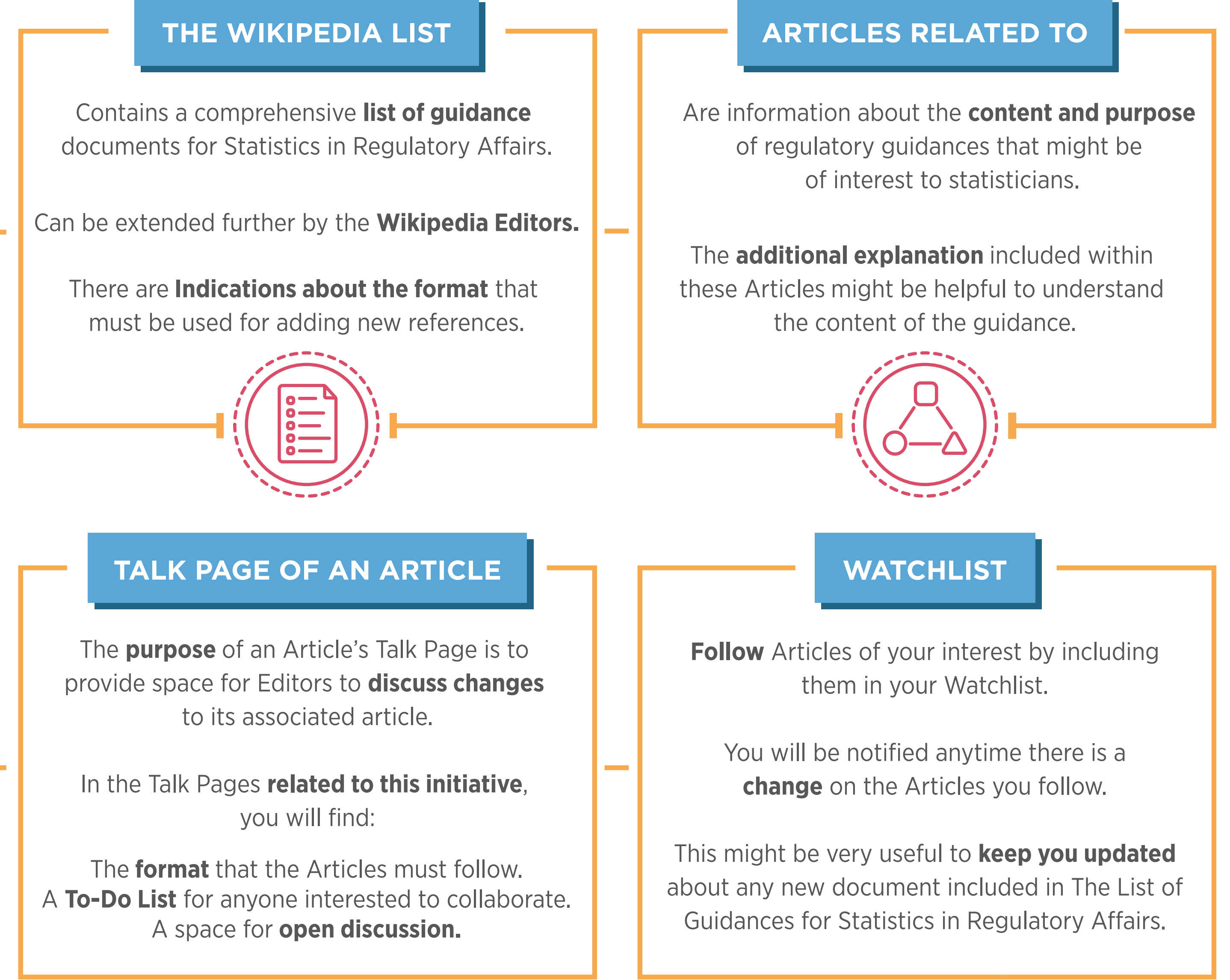
Hence, individual statisticians devote considerable time and effort to keep themselves adequately informed and educated about regulatory requirements.

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

4 JOIN THE INITIATIVE IN JUST 2 STEPS



CONTRIBUTE IN TWO WAYS



5 BASIC EDITING TIPS

Description	What you type	What you get
Italics, bold, and both	" <i>italics</i> ", " bold ", and " <i>both</i> "	<i>italics</i> , bold , and <i>both</i>
Underline	<u>Underline this</u>	<u>Underline this</u>
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]]	<u>Truncated mean</u>
Link to a website	[http://www.wikipedia.org Wikipedia]	<u>Wikipedia</u>
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 2 Level 3 Level 4 Level 5 Level 6
Bulleted list	* One * Two ** Two point one * Three	• One • Two • Two point one • Three
Numbered list	# One # Two ## Two point one # Three	1. One 2. Two 1. Two point one 3. Three

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The design of this poster has been sponsored by Syntax for Science S.L.