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Letter to Editor

Analysis of Consistency of Prime-boost Covid-19 Baseline and Safety Data

Dragutin Novosel[1]* and Matija Alanović[2]

[1]*Glaserbergstrasse 23, CH-4056 Basel, Switzerland*

[2]*SIPA Elektronika d.o.o., Ruđera Boškovića 17, 47000 Karlovac, Croatia*

***Corresponding Author:** Dragutin Novosel, Glaserbergstrasse 23, 4056 Basel, Switzerland. **E-mail:** d.novosel@bluewin.ch

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Recently, some concerns [1-3] have been raised about the reliability of data presented in the current paper [4], which reported results from a non-randomised phase 1/2 study of a novel vaccine from Russia. The critics of the study [4] concentrated on potential data inconsistencies [1-3] in figures and analyzed them visually (here we ignore theoretical discussions about special features of the vaccine and/or vector). However, the baseline data and results of the safety data should be considered as well.

Benford's law (also known as the Newcomb-Benford Law, the law of anomalous numbers, and the first-digit law) is used in data analysis, particularly in financial analysis and fraud detection as well as the analysis of medical data [5].

The statistical analysis was performed using the X^2 Test. Differences with P-values less than 0.1%, "(P < 0.001)", were considered statistically significant, and differences between groups that were not found to be statistically significant were noted as "p = not significant (n.s.)". n = number of observations.

The frequency distribution of the first digit of the absolute values was extracted from tables 1 and 2 (4) and analyzed according to Benford's law (percentages were excluded from table 1, as they represent a duplication of data).

The distribution of the first digit of the values in table 1 (baseline values) did not follow Benford's law. However, the distribution of the first digit of the values in table 2 (adverse events) did follow Benford's law. Our results suggest inconsistencies in the baseline data and the reliability of the safety data.

A final judgment cannot be made without the availability of raw data on immune response. We are convinced that the analysis of data should be done based on careful analysis and not on an overall visual impression.

The Covid-19 topic is of worldwide importance. Unfortunately, this topic is under extreme political as well as sociological pressure. In order to increase confidence in science, we encourage the publication and/or availability of all raw data by request of the scientific community.

	Table 1		Table 2	
First Digit	**Expected (n = 72)**	**Baseline (observed; n = 72)**	**Expected (n = 59)**	**Adverse events (observed; n = 59)**
1	21.67	27	17.76	24
2	12.68	9	10.39	9
3	9.00	1	7.37	7
4	6.98	3	5.72	5
5	5.70	5	4.67	3
6	4.82	6	3.95	3
7	4.18	6	3.42	3
8	3.68	5	3.02	3
9	3.29	10	2.70	2

Table: Baseline and safety data from Logunov D., *et al* [4].

Baseline values: P < 0.001 (X^2 Test) Adverse Events: P = n.s. (X^2 Test; P = 0,896).

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