American Journal of
Biomedical Science & Research

www.biomedgrid.com
ISSN: 2642-1747

Letter to Editor

COVID-19 Researchers to Meet Hades

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To Cite This Article: *Martti Antila. COVID-19 Researchers to Meet Hades. Am J Biomed Sci & Res. 2022 17(4) AJBSR.MS.ID.002371,* DOI: 10.34297/AJBSR.2022.17.002371

Received: September 14, 2022; **Published:** December 07, 2022

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Before the COVID-19 pandemic to encounter Hades was a somewhat romantic affair as it was inevitable but far away in the future [1]. However, COVID-19 has spread globally, affecting an increasing number of countries. On March 11, 2020, WHO characterized the COVID-19 outbreak as a pandemic as global rates of cases and deaths continued to increase [2,3]. After the start of the pandemic, healthcare workers, especially the doctors in many countries appeared victims of this serious, highly lethal disease taking them quickly to meet Hades [4,5].

From the beginning, the clinical researchers were in special danger, together with their teams, in addition to the hospital staff who accompany COVID-19 patients in the struggle between life and death. Thus, they began to "flirt" with Hermes as psychopompós (guide of souls) having a coin available for immediate payment to Charon (ferryman to Hades), and facing Cerberus, who would not allow them to return.

Real-life haunted us, and having COVID-19, and meeting Hades, became not a matter of "if" but "when". We researchers lived in the pseudo-comfort of our institutions, together with the sponsors, to look for treatments that could minimize the suffering of billions of people. Some of the new drugs could be the key to cure, or effective early treatment. All over the world, thousands of Clinical Trials were takenin a short period of time [6], while waiting for the vaccines to reach their global effect.

Even before, but especially after the Ketek case in 2007 [7], the paradigm of sharing clinical trial data and off-label use of drugs changed even among researchers, most of whom are doctors and follow strict rules not only from general institutions such as FDA, EMA, but also from the medical societies that started to standardize and deliberate on this topic [8].

The fine line between right and wrong in off-lable use of drugs can lead to discomfort and exaggeration in both sides, almost as if it were a continuous witch hunt. We have to answer certain questions about off-label issues of research results [9]. What studies are used to convince the authorities that a product of a certain drug company should be a priority? What are the sponsors' true roles in financing these studies? Are the studies conclusive? Is the sponsor offering a fair balance in terms of effectiveness and safety? What is the researchers' role in making the conclusions and recommendations? [9].

During the COVID-19 pandemic, situations that were difficult to imagine have become a reality! Clinical researchers are hit by the disease while helping to find a new therapy. And often, having in hand a medication that could save their own life, they become hostages to being part of the study without an option to receive the obviously active drug. Would it be sensible, in agreement with the sponsor and authorities, that the clinical scientists can receive the active (off-label) drug even without formal indication? They are dedicated doctors, not included in the active/control groups. Would it be better to keep them outside of the mortality statistics, like the former US President Donald Trump, who received an unapproved treatment [10]?

The fine line between off-label and officially approved use of life saving drugs should be discussed, without being considered as a negative bias to the study. The doctor´s suffering is not gifted away with a pen, dinner or a conference trip. We can postpone our meeting with Hades, but for this we have to understand the intricacies already recognized in the Greek mythology.

Principal Investigator

Martti Antila has participated in clinical studies funded by AbbVie, Astra Zeneca, EMS, Eurofarma, Glaxo Smith Kline, Humanigen, Janssen, Novartis, Sanofi Genzyme; Angion Biomedica, Beigene, Rigel, Participated in conferences and consultancy activities for Abbott, Aché, Astra Zeneca, Chiesi, Eurofarma, IPI ASAC Brasil, Zambon and Sanofi.

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