laboratories in Wuhan. Ghebreyesus, WHO's Director-General said: "We are asking actually China to be transparent, open and cooperate." Zeng Yixin, vice minister in the National Health Commission, China, responded: "I feel that the plan ignores common sense. It defies science."

In science, we should draw conclusions based on what is most likely. It is by far the most likely explanation that the pandemic is not a natural one but is caused by a man-made virus that escaped from a laboratory in Wuhan [1].

It is clear that if the Wuhan Institute had not conducted gain-of-function experiments, and therefore had not collected over 1000 samples of coronaviruses from bat caves in Yunnan 1500 km away from the outbreak in Wuhan [1], there would have been no pandemic.

This type of research should never have been funded and should never have been performed. The WHO and the United Nations should issue a call to stop such research permanently. All governments should make it illegal, with stiff penalties for breaking the law. This research is a great threat to mankind and must stop.

Competing interests and funding: *None declared.*

Peter C Gøtzsche *(pcg@scientificfreedom.dk), Institute for Scientific Freedom, 2970 Hørsholm, DENMARK.*

References

1. Wade N. The origin of COVID: Did people or nature open Pandora's box at Wuhan? *Bulletin of the Atomic Scientists.* 2021 May 5[cited 2021 May 22}. Available from: https://thebulletin.org/2021/05/the-origin-of-covid-did-people-or-nature-open-pandoras-box-at-wuhan.
2. Calisher C, Carroll D, Colwell R, Corley RB, Daszak P, Drosten C, et al. Statement in support of the scientists, public health professionals, and medical professionals of China combatting COVID-19. *Lancet.* 2020;395:e42-3.
3. Woodward A. The coronavirus likely traveled 800 miles to Wuhan from farms that breed wild animals for food, a WHO report found. *Business Insider.* 2021 Mar 31 [cited 2021 May 21]. Available from: https://www.businessinsider.in/science/news/the-coronavirus-likely-traveled-800-miles-to-wuhan-from-farms-that-breed-wild-animals-for-food-a-who-report-found/articleshow/81770095.cms.
4. Segreto R, Deigin Y. The genetic structure of SARS-CoV-2 does not rule out a laboratory origin: SARS-COV-2 chimeric structure and furin cleavage site might be the result of genetic manipulation. *Bioessays.* 2021;43:e2000240. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7744920/
5. Bostock B. China is guarding ancient bat caves against journalists and scientists seeking to discover the origins of the coronavirus. *Insider.* 2020 Dec 30 [cited 2021 May 21]. Available from: https://www.businessinsider.com/china-policing-bat-caves-scientists-hope-coronavirus-clues-inside-2020-12?r=US&IR=T.
6. Bloom JD, Chan YA, Baric RS, Bjorkman PJ, Cobey S, Deverman BE, et al. Investigate the origins of COVID-19. *Science.* 2021May 14;372(6543): 694.
7. Gøtzsche PC. The head of WHO's COVID-19 mission reveals China's total cover up on Danish TV. *Institute for Scientific Freedom.* 2021 Aug 21 [cited 2021 Aug 21]. Available from: https://www.scientificfreedom.dk/2021/08/20/the-head-of-whos-covid-19-mission-reveals-Chinas-total-cover-up-on-danish-tv/.

Harmonising terminology with MedDRA for plain language summaries

Published online first on September 18, 2021. DOI: 10.20529/IJME.2021.070

Keywords: *lay person terms, MedDRA, clinical trials, trial participants, terminolog*

Human volunteers are key stakeholders in any clinical research. For inclusiveness it is ethically imperative to ensure data transparency even after the completion of clinical trials. This is also supported by the Declaration of Helsinki, which in a statement of ethical principles, provides guidance to physicians and other participants in medical research involving human volunteers, suggesting that they have the full right to the results of a trial [1].

This continuing practice over the past decade has probably benefited all the stakeholders of the clinical drug development process. The continued efforts of regulatory and other stakeholders of the drug development process have resulted in clinical data appearing in the public domain in the form of clinical trial disclosures and plain language summaries (PLS) [2]. Although clinical trial disclosures are extensively followed by pharmaceutical companies with respect to their trial protocols and results, these are primarily written in scientific language which is difficult for a participant, or potential participant, or any layperson to understand. To solve this problem, PLS were introduced post regulation (EU) No 536/2014 (2014) [3]. The regulation mandated pharmaceutical companies to provide clinical trial results in a language that is understandable to a layperson, within the defined timelines. The PLS would be a huge boon to the public as it would help them to better understand the procedures and the results of clinical trials, so that they could make informed treatment decisions if required. Major regulators such as the US Food and Drug Administration (FDA) are also warming up to this initiative, and other regulators across the globe will soon follow in their footsteps.

This presents the new challenge to provide a single set of standardised international "lay person terms" (LPT) for medical terminology, especially difficult adverse event terms, which can be used in the industry. We propose that it would be worthwhile to harmonise medical PLS terminology across the globe as has been done for the Medical Dictionary for Regulatory Activities (MedDRA) [4] through the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). The LPT can be matched to already logically structured MedDRA terms and inserted as a sixth level of hierarchy of scientific terms along with "lowest level terms" (LLTs), "preferred terms" (PTs), "high

level terms" (HLTs), "high level group terms" (HLGTs), and "system organ classes" (SOCs)'. For instance, the high level term "vascular hypotensive disorder" for which the "low level term" is "hypotension" could be referred to in lay terms simply as "low blood pressure".

A patient friendly term list in MedDRA v21.0, a subset of lay terms from pharmacovigilance (PV) databases could be a starting point for developing this hierarchy of terms. As PLS is now a regulatory requirement, the terms should be in line with MedDRA with a view to providing a single and standardised international medical terminology that can be used both as a regulatory requirement and for evaluation of data pertaining to medicinal products for human use.

Aligning MedDRA and present practices with evolving requirements

A MedDRA aligned with LPT as the sixth level of hierarchy will help pharmaceutical companies in developing PLS, and also help in developing information consent forms (ICFs), especially for multicentre trials that are spread across countries and where different terms are used for the same indication. Additionally, not all pharmaceutical companies can afford PLS services. Thus, small pharmaceutical companies can easily refer to the MedDRA level LPT, and disseminate trial results to the lay public at minimal cost, using the resources available in their organisation. Academics and healthcare providers can also access LPT through MedDRA from the Maintenance and Support Services Organization (MSSO) at no cost, and from the Japanese Maintenance Organization (JMO) at a nominal cost. For regulators, mapping CT.gov and EudraCT the European drug regulatory authority database or other result disclosure websites, with a PLS template using LPT, will help in harmonising medical terminology leading to ease in assessing quality for an effective analysis and decision making.

As stated in the MedDRA vision statement, a standardised terminology with the addition of LPT will free regulators, and other stakeholders including laypersons, from the need to convert data from one terminology to another, prevent the loss and/or distortion of data, and allow savings in resources. This would be a big advance in the movement for transparency in science

Conflict of interest: *None declared.*

Gaurav Anand (corresponding author–Gaurav.Anand3@tcs.com) , Medical Writing, Tata Consultancy Services, Noida, Uttar Pradesh, INDIA; ***Mohit Joshi*** *(joshimohit4@yahoo.in)*, *Medical Writing, Tata Consultancy Services, Noida, Uttar Pradesh, INDIA*.

References

1. World Medical Association (WMA). The Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. 9th July 2018. Available from https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medicalresearch-involving-human-subjects/. [Last accessed on 2021 Aug 21]
2. Joshi M, Bhardwaj P. Impact of data transparency: Scientific publications. Perspect Clin Res. 2018;9(1):31-36.
3. Regulation (EU) no 536/2014 of the European Parliament and of the Council of 16 April 2014 on Clinical Trials on Medicinal Products for Human Use, and Repealing Directive 2001/20/EC. Official Journal of the European Union. 27th May 2014 Available from: https://www.gmp-compliance.org/guidelines/gmp-guideline/eu-536-2014-on-clinical-trials-on-medicinal-products-. [Last accessed on 2021 Aug 21].
4. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Medical Dictionary for Regulatory Activities (MedDRA). 1st September 2021. Available from: https://www.meddra.org/. [Last accessed on 2021 Aug 21].