Council for International Organizations of Medical Sciences

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**Comments on draft CIOMS Working Group XIV report – Artificial intelligence in pharmacovigilance**

Posted for comment on 29 April 2025 at: <https://cioms.ch/working_groups/working-group-xiv-artificial-intelligence-in-pharmacovigilance/>

**Please return your comments by 6 June 2025 to:**[hills@cioms.ch](mailto:hills@cioms.ch); **cc:** [info@cioms.ch](mailto:info@cioms.ch)

**Name of reviewer: ……………….…….\*, Affiliation: …………………………\***\*I agree to my above name and affiliation being included in the List of Commentators in the final report: (**yes/no**) ………..   
*(No reply to the above question will be interpreted to mean that you have no objection to your details being included)*

***Notes:***

* *Please note that the layout will be improved in the final version and best efforts will be made to correct remaining typographical and/or grammatical errors, as well those pertaining to references. They are not the focus of this review, but if you happen spot such errors, please include them below.*
* *Permissions are being sought to reproduce some of the illustrative materials in this report.*
* *Only comments submitted in the table format below will be taken into account. An example is provided below.*

***Thank you!***

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| **General comments:**   * *[Type your comment(s) here]* |

| **Section** | **Line no (start)** | **Line no (end)** | **Concern or text in question** | **Comment / suggestion for re-wording**  **Please provide suggestions on how to resolve the concern.** |
| --- | --- | --- | --- | --- |
| ***[Example: ]***Chapter *2* | 407 | 408 | “Duplicate detection methods based on ML and probabilistic record linkage have been implemented for VigiBase[[1]](#endnote-1) and FAERS.[[2]](#endnote-2)” | Add EudraVigilance as a third example. |
|  |  |  |  |  |

(Please add more lines as needed)

1. Norén GN, Orre R, Bate A, Edwards IR. Duplicate detection in adverse drug reaction surveillance. Data Mining and Knowledge Discovery. 2007;Jun;14:305-328. [(Journal abstract)](https://link.springer.com/article/10.1007/s10618-006-0052-8#citeas) <https://doi.org/10.1007/s10618-006-0052-8> [↑](#endnote-ref-1)
2. Kreimeyer K, Menschik D, Winiecki S, Paul W, Barash F, Woo EJ, Alimchandani M, Arya D, Zinderman C, Forshee R, Botsis T. Using probabilistic record linkage of structured and unstructured data to identify duplicate cases in spontaneous adverse event reporting systems. Drug Safety. 2017;Jul;40:571-582. (Journal abstract) [↑](#endnote-ref-2)