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LETTER TO THE EDITOR

Implementation of the ICH E6(R3) Guideline for Good Clinical Practice: an opportunity to decentralize and democratize clinical research in Peru

Implementación de la Guía de Buenas Prácticas Clínicas ICH E6(R3): una oportunidad para descentralizar y democratizar la investigación clínica en Perú

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Dear Editor:

In July 2025, the new E6(R3) Guideline for Good Clinical Practice of the International Council for Harmonisation (ICH) [(1)] came into effect, marking an important shift in the regulation of clinical trials globally. This new version incorporates modern concepts such as data governance, informed consent as an ongoing process, a risk-based approach, and—critically for countries like Peru—the possibility of conducting decentralized clinical trials [(2)].

In Peru, where there are areas with limited infrastructure, connectivity, and access to healthcare services, this model could represent a true opportunity. Decentralization allows research to reach participants' environments without requiring them to constantly visit a research center. This creates opportunities for more inclusive and flexible working methods, adapted to the cultural and geographical realities of many communities, especially in rural or hard-to-reach areas [(3)].

This research approach is particularly useful in the context of diseases such as dengue, malaria, and other vector-borne diseases, which primarily affect vulnerable populations and require research conducted where these diseases occur. It can also be applied to non-communicable diseases with diagnostic or treatment gaps, such as childhood anemia, chronic malnutrition, or rare diseases, which require studies tailored to specific populations. In all these cases, bringing the study closer to the participant can make a significant difference in obtaining more useful and contextualized evidence [(2)].

From a practical perspective, this model facilitates the use of remote monitoring, digital data collection, and the participation of field staff who can follow up directly in communities. Additionally, these tools can help cover more territory, save resources, and reduce implementation time [(4)]. However, for this to be feasible in Peru, it is essential to have more flexible and updated regulations, along with technical and ethical guidelines outlining how decentralized processes should be monitored [(5)].

Furthermore, in decentralized settings, informed consent, as an ongoing process, becomes even more critical. When there is little face-to-face contact, clear and adapted strategies are needed to ensure that participants truly understand, agree to, and remain informed throughout the study. This is especially important when working with populations facing social, economic, or language barriers. In these cases, it is not enough to simplify

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the document; intercultural communication tools that truly work in the field need to be developed [6].

On the other hand, data governance presents significant challenges, especially considering that in Peru, the digitalization of the healthcare system is still partial and uneven [7]. The platforms used for data collection must be secure, auditable, and validated. There is also a need to train personnel and establish clear rules to protect participants' privacy. In this regard, ethics committees must strengthen their capacity to evaluate not only scientific aspects but also digital security and data management [8].

The new guideline also promotes a risk-based quality approach, allowing processes to be adjusted based on study complexity, the type of intervention, or the characteristics of the population. This flexibility is useful for less experienced centers or those located in remote areas to also participate without being required to allocate disproportionate resources [9]. This approach can foster a more accessible culture of quality, focusing on what truly matters.

Together, the implementation of the ICH E6(R3) Guideline for Good Clinical Practice in Peru could be a significant opportunity to democratize clinical research, bring it closer to communities, and strengthen a more ethical and responsible practice. Nevertheless, for this to remain more than just a good intention, concrete actions are needed: updating national regulations, developing specific guidelines for decentralized research and data governance, and continuing to train personnel and ethics committees on these new approaches.

In this regard, it is necessary to review the Clinical Trial Regulations (Supreme Decree No. 021-2017-SA) [10], which currently does not include concepts such as decentralization, digital governance, or dynamic consent. Its update would be crucial to align national regulations with new international standards and ensuring a robust and ethical environment for clinical research.

From my experience in this field, I am clear that implementing the ICH E6(R3) Guideline for Good Clinical Practice will not be an automatic process, but rather a collective effort requiring commitment, coordination, and political will. However, it is also a unique opportunity to review our practices, close gaps, and move toward a fairer research model that takes into account the cultural and social particularities of Peru. The participant must remain at the center of it all—not merely as a source of data, but as a person with rights, context, and dignity, to be respected at every stage of the study.

BIBLIOGRAPHIC REFERENCES

1. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Guideline. Guideline for Good Clinical Practice [Internet]. Geneva: ICH; June 6, 2025 [cited 2025 Jun 17]. Available from: https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
2. Vayena E, Blasimme A, Sugarman J. Decentralized clinical trials: opportunities and ethical challenges. Lancet Digit Health [Internet]. 2023 [cited 2025 Jun 17];23(6):43-51. doi: 10.1016/S2589-7500(23)00052-3
3. Jean-Louis G. Seixas AA. The value of decentralized clinical trials: Inclusion, accessibility, and innovation. Science [Internet]. 2024 [cited 2025 Jun 17];385(6711):eadq4994. doi: 10.1126/science.adq4994
4. Heads of Medicines Agencies. Recommendation paper on decentralised elements in clinical trials [Internet]. 2022 [cited 2025 Jun 10]. Available from: https://health.ec.europa.eu/system/files/2023-03/mp_decentralised-elements_clinical-trials_rec_en.pdf
5. Kaye J. Whitley EA. Lund D. Morrison M. Teare H. Melham K. Dynamic consent: a patient interface for twenty-first century research networks. Eur J Hum Genet. [Internet]. 2015 [cited 2025 Jun 10];23(2):141-6. doi: 10.1038/ejhg.2014.71
6. Heads of Medicines Agencies. Guideline on computerized systems and electronic data in clinical trials [Internet]. 2023 [cited 2025 Jun 16]. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-computerised-systems-electronic-data-clinical-trials_en.pdf
7. Ponce de León Sierra J, Merma-Pillaca A. Transformación digital en el sector salud peruano: retos y avances recientes. Rev Panam Salud Publica [Internet]. 2024 [cited 2025 Jun 10];48:e138. doi: 10.26633/RPSP.2024.138
8. Dai H, Young P, Durant T, Gong G, Kang M, Krumholz HM, et al. TrialChain: A Blockchain-Based Platform to Validate Data Integrity in Large, Biomedical Research Studies [Internet]. 2018. [cited 2025 Jun 10]. Available from: https://arxiv.org/abs/1807.03662
9. Bhatt A. The revamped Good Clinical Practice E6(R3) guideline: Profound changes in principles and practice! Perspect Clin Res. [Internet]. 2023 [cited 2025 Jun 10];14(4):167-71. doi: 10.4103/picr.picr_184_23
10. Reglamento de ensayos clínicos. Decreto Supremo N.° 021-2017/AS (June 30, 2017). Available from: https://www.digemid.minsa.gob.pe/webDigemid/normas-legales/2017/decreto-supremo-n-021-2017-sa/

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