



## Editorial

# [Translated article] Making research accessible, breaking down barriers: the new frontier of clinical trials

## Acercar la investigación, derribar barreras: La nueva frontera de los ensayos clínicos

Clinical research in Spain is hale and healthy. A decade after Royal Decree 1090/2015 –which developed EU Regulation N°536/2014– came into force, over 900 clinical trials will be in course by 2026.<sup>1</sup> Such figures not only reflect the robustness of our research system but also the maturity of our regulatory, monitoring, and participation processes. However, it will be necessary to adjust clinical research processes to maintain momentum and confront growing global competitiveness, social changes and technological progress. Advances in digitization, boosted by the COVID-19 pandemic, have facilitated the development of **decentralized elements** as the natural evolutionary step in clinical research.<sup>2,3</sup>

In 2022, the European Medicines Agency (EMA) issued a recommendation paper that defined “decentralization” as “trial-related procedures taking place outside of the clinical trial site”, thereby taking research to the participant’s home.<sup>4</sup> This change does not involve a rupture with the traditional model, but the integration of new channels such as telemedicine, digital technologies and advanced logistics into research. The incorporation of these advances improves study accessibility, reduces participant burden and increases the representativeness of the populations included. The good news is that digitization and decentralization can be implemented without jeopardizing two crucial aspects: patient safety and scientific validity. European laws and regulations have significantly advanced into clearly defined technical standards, albeit with an uneven implementation across member states. These inconsistencies stem from differences in local regulations, especially in relation to the dispensing and shipping of medicinal products to the patient’s home, informed consent requirements, and remote monitoring.<sup>4</sup>

In 2024, the Food and Drug Administration (FDA) released the “Conducting Clinical Trials With Decentralized Elements Guidance”<sup>5</sup>. Both the EMA and FDA suggest decentralized elements to be integrated into best clinical practices (ICH E6). This means that tasks and duties should be documented to ensure an auditable trail. The two regulatory agencies place particular emphasis on data, noting that decentralized elements may introduce additional variability. Accordingly, these organizations underscore the importance of implementing measures that ensure data integrity. The EMA and FDA recommend adopting a risk-focused approach whereby a clinical trial is designed and conducted according to the trial population, the disease to be treated, and the type of medicinal product. The EMA places a special focus on the patient’s well-being and recommends that the potential benefits of using

decentralized elements should be previously weighed against participant burden.<sup>4</sup>

In 2024, the Spanish Agency for Medicines and Medical Devices (AEMPS), in collaboration with a panel of experts from different fields and scientific societies, issued the “*Guía de Elementos Descentralizados en los Ensayos Clínicos*” (“Guide to decentralized elements in clinical trials”). This Guide identifies six key elements, including digital recruitment; electronic informed consent forms (*eConsent*); telehealth; telehealth apps; shipping of medicinal products to the patient’s home; and networked inter-site collaboration<sup>6</sup>. Each of these elements has a specific aim, namely, extending clinical trial access; facilitating the collection of informed consent; reducing on-site visits; allowing trial-related activities to occur at locations convenient for participants; reducing drop-outs; and favoring the inclusion of populations with geographic or functional barriers.

The delivery and collection of the medicinal product at the participant’s home are probably the decentralized element with the greatest impact on hospital pharmacies (HPS). The AEMPS guidelines specify that the secure storage and dispensing of investigational medicinal products are the responsibility of the hospital pharmacist rather than the sponsor. Beyond legal considerations, these guidelines recognize the central role of hospital pharmacies in the conduct of clinical trials. Among their duties, hospital pharmacists ensure the appropriate storage, dispensing, and traceability of investigational medicinal products, as well as provide counseling to study participants. Coordination with pharmaceutical logistics providers requires the establishment of clear agreements and standardized procedures, including temperature monitoring, data privacy provisions, and verification of the delivery, return, counting, and disposal of medicinal products. In collaboration with Farmaindustria, the Working Group on Clinical Trials of the Spanish Society of Hospital Pharmacy recently developed the “*Guía de Excelencia para la realización de ensayos clínicos en la Farmacia Hospitalaria*” (“Guide to excellence for conducting clinical trials in Hospital Pharmacy”). This Guide encourages sponsors, contract research organizations (CROs) and hospital pharmacies to get involved in clinical trials from very initial stages (selection and contracting) to define expectations and needs.<sup>7</sup>

**Telehealth** (or telepharmacy) is defined as the virtual visit of a patient with an investigator or delegated person. Telepharmacy is a key component of decentralized trial elements. Prior to its implementation,

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participant privacy must be ensured, patient education provided, and contingency plans developed. This modality allows hospital pharmacists to enhance pharmacotherapeutic monitoring through medication reconciliation, assessment of treatment adherence, and delivery of patient counseling on the appropriate use and administration of home-based therapies. Hospital Pharmacies have extensive experience in patient counseling and follow-up. However, this role dilutes in the context of clinical trials. Telepharmacy opens the way for hospital pharmacists to become aware of their own value and encourage participation in clinical trials.

Spain is characterized by a decentralized healthcare system, with the population being concentrated in cities and large rural areas having a small population. As a result, people living in rural areas have limited access to clinical trials, thereby challenging equity, one of the pillars of the Spanish healthcare system. **Collaborating/satellite sites** emerge as a potential solution to facilitate access to patients living far from their hospitals or to clinical trials on uncommon diseases. In this scenario, it is essential to coordinate teams and clearly define and document responsibilities, with the principal investigator being ultimately responsible for monitoring all activities. The duties of hospital pharmacies include coordinating medicinal product logistics within the network (including shipping medicinal products to the collaborating sites or to the participant's home); verifying personnel education and training; and ensuring the implementation and recording of standardized operational procedures. The experience gained in other networked operating models, such as the “*Plan de Abordaje de las Terapias Avanzadas en el Sistema Nacional de Salud: Medicamentos CAR*” (“Consensus document on the management and implementation of CAR-T therapy in the Spanish Healthcare System”) is a significant landmark.

Remote monitoring of source data is implemented both in centralized and decentralized clinical trials. In the particular case of clinical trials, it facilitates the implementation of decentralized elements, including real-time auditing and verification, as well as the participation of collaborating sites. However, this approach also poses some challenges in terms of privacy and cybersecurity. The AEMPS, in collaboration with the Spanish Agency for Data Protection (AEPD), provides detailed instructions for remote monitoring in compliance with the EU Regulation (EU) 2016/679, the General Data Protection Regulation (GDPR) and Organic Law 3/2018 on Personal Data Protection and Guarantee of Digital Rights.<sup>8</sup> For hospital pharmacies, implementation may be straightforward for certain data sources—such as drug accountability records, documentation of medication returned by patients, or temperature monitoring systems. However, it may also entail a substantial workload when manual digitization of documents is required, including compounding or dispensing records. We should not overlook the role that hospital pharmacies play in blind trials when they act as “unblind” when other members of the research group are “blind”. Undoubtedly, hospital pharmacies will need to closely collaborate with developers of compounding and quality control applications to evolve toward fully digital environments that are aligned with current regulatory requirements.

Integrating these elements into healthcare institutions will not always be straightforward. The digital gap among certain populations—such as older adults, patients with limited resources, or those with cognitive impairments—cannot be overlooked. From the perspective of research teams, decentralized elements may lead to an increased administrative burden and greater coordination demands, which must be accompanied by additional resources. Nevertheless, they also create important opportunities, including improved inclusion of underrepresented populations, reduction of geographical inequalities, optimization of healthcare resources, and the extension of services already provided by HPS in the clinical setting, such as telepharmacy and home delivery of medications. The COVID-19 pandemic demonstrated that many of these tools are feasible and well accepted by both patients and healthcare professionals, provided that adequate institutional support and clear regulatory frameworks are in place. In this context,

establishing strategic partnerships between HPS and sponsors is essential to align objectives, validate processes, avoid duplication of efforts, and ensure the availability of the necessary resources.

Decentralized elements are not a passing fad but a structural change in the research paradigm. Hospital pharmacists are committed to their strategic role as the guarantors of safety, traceability and quality in this new paradigm. Integrating home-based dispensing, telepharmacy, networked research, and remote monitoring will pave the way to advance toward more accessible, inclusive and efficient research while ensuring scientific excellence. The undeniable challenges we are facing should not hinder us from taking the opportunity to set the pace in this new era where research synchronizes with patient needs.

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## Conflict of interest

The authors declare that no conflicts of interest exist in relation to this editorial.

## References

1. Agencia Española de Medicamentos y Productos Sanitarios (AEMPS). Memoria de actividades de la AEMPS 2024; 2025. [consultado 5 de noviembre de 2025]. Disponible en: <https://memoria.aemps.gob.es/docs/memoria-2024.pdf>.
2. Agencia Española de Medicamentos y Productos Sanitarios (AEMPS). Medidas excepcionales aplicables a los ensayos clínicos para gestionar los problemas derivados de la urgencia por COVID-19; 2020. [consultado 5 Nov 2025]. Disponible en: [https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/2020/NI-MUH\\_04-2020-ensayos-clinicos-COVID-19-actualizado-01-julio.pdf](https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/2020/NI-MUH_04-2020-ensayos-clinicos-COVID-19-actualizado-01-julio.pdf).
3. European Commission. European Medicines Agency (EMA). Heads of Medicines Agencies (HMA). Guidance on the management of clinical trials during the Covid-19 (Coronavirus) Pandemic (v5); 2022. [accessed on 5 November 2025]. Disponible en: [https://health.ec.europa.eu/document/download/74386d75-e5fd-4d9c-9dfcec7d60758da9\\_en](https://health.ec.europa.eu/document/download/74386d75-e5fd-4d9c-9dfcec7d60758da9_en).
4. European Commission. European Medicines Agency (EMA). Heads of Medicines Agencies (HMA). Recommendation paper on decentralized elements in clinical trials (v2); 2025. [accessed on 5 November 2025]. Available from: [https://health.ec.europa.eu/system/files/2023-03/mp\\_decentralised-elements\\_clinical-trials\\_rec\\_en.pdf](https://health.ec.europa.eu/system/files/2023-03/mp_decentralised-elements_clinical-trials_rec_en.pdf).
5. U.S. Department of Health and Human Services. Food and Drug Administration (FDA). Center for Drug Evaluation and Research (CDER). Center for Biologics Evaluation and Research (CBER). Center for Devices and Radiological Health (CDRH). Oncology Center of Excellence (OCE). Conducting clinical trials with decentralized elements guidance for industry, investigators, and other interested parties; 2024. [accessed on 5 November 2025]. Available from: <https://www.fda.gov/media/167696/download>.
6. Agencia española de medicamentos y productos sanitarios (AEMPS). Guía para la realización de elementos descentralizados en ensayos clínicos, (v1); 2024. [consultado 5 de noviembre de 2025]. Disponible en: <https://www.aemps.gob.es/medicamentosUsoHumano/docs/2024/Guia-DCT-03-12-2024.pdf>.
7. Sociedad Española de Farmacia Hospitalaria (SEFH). Farmaindustria. Consejo general de colegios farmacéuticos, vocalía de farmacia

hospitalaria. Guía de excelencia para la realización de ensayos clínicos en la farmacia hospitalaria; 2025. [consultado 5 de nov de 2025]. Disponible en: [www.farmaindustria.es/web/wp-content/uploads/sites/2/2025/09/Guia\\_Excelencia\\_EECC\\_2025-final.pdf](http://www.farmaindustria.es/web/wp-content/uploads/sites/2/2025/09/Guia_Excelencia_EECC_2025-final.pdf).

8. Agencia Española de Protección de Datos (AEPD). Monitorización remota de datos fuente; 2020. [consultado 5 de noviembre de 2025]. Disponible en: <https://www.aepd.es/documento/monitorizacion-remota-verificacion-datos-fuente.pdf>.

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