Life Sciences & Healthcare Briefing: Special Edition

Greece's New Ministerial Decision on Clinical Trial Contracts: Standardization, Timelines and E-Signatures

A. **Introduction**
B. **Scope and Contractual Framework**
C. **Parties, Signing, Standardization**
D. **Documentation and Internal Workflows**
E. **Mandatory Timelines for Trial Sites and ELKE/ELKEA**
F. **Use of Electronic Signatures**
G. **Conclusion**

A. Introduction

1. Greece's new Ministerial Decision (**MD**)[1] introduces a standardized contractual regime for clinical research, aligning Greek procedures with the EU Clinical Trials Regulation, MDR and IVDR to simplify and accelerate contract execution.

B. Scope and Contractual Framework

1. The MD governs the contractual relationship between the sponsor, the principal investigator, and the legal representative of the clinical trial site, whether public or private. Where relevant, it also involves the head of the competent financial management body of the Special Account for Research Funds (**ELKE**) or the Special Account for Research and Development Funds (**ELKEA**).

2. The framework introduces standardized contractual structure through the mandatory use of standardized contracts for:

a. clinical trials;

b. non-interventional and non-medicinal research; and

[1] Α3(α) 52922/2025 (GG B' 230/22.01.2026).

c. clinical research with medical devices and IVD studies, within or outside intended use.

Uniform accompanying forms cover acceptance of project management, research team designation and budget approval. These documents are annexed to the contract and form an integral part of the agreement, thereby ensuring consistency and legal certainty across trial sites. Any additional terms or clarifications proposed by the sponsor shall be included in an appendix to the standardized contract, provided they do not deviate from or contradict the contract's provisions.

C. Parties, Signing, Standardization

1. The sponsor (or a contract research organization acting on its behalf), the principal investigator, the legal representative of the trial site and, where applicable, the head of ELKE or ELKEA must all execute the standardized contract.
2. By relying on pre-approved documentation[2], the MD eliminates site-specific drafting and prolonged negotiations. This reduces administrative burden, accelerates contract execution, and minimizes interpretative discrepancies across sites.

D. Documentation and Internal Workflows

1. From the outset, the framework requires submission of a complete documentation package, as outlined in the MD.
2. The documentation package should also cover procedures conducted at the participant's home, where applicable, as part of the clinical trial. All documents must be submitted to the competent site administration and to ELKE or ELKEA, minimizing iterative exchanges and reducing avoidable delays.

E. Mandatory Timelines for Trial Sites and ELKE/ELKEA

1. To further preserve momentum in the signing process, the MD introduces binding internal deadlines. Once the legal representative of the trial site has signed, the fully signed contract and complete documentation file must be signed and sent to ELKE or ELKEA. Subsequently, upon receipt of a complete dossier, ELKE or ELKEA must finalize its review and sign the contract[3].

[2] Annexes A' 1 to A' 4 for contracts; B, C, D for forms.

[3] Where documentation is incomplete, however, the deadline begins to run from the date on which the missing information is provided, maintaining clarity and predictability for all parties involved.

F. Use of Electronic Signatures

1. In addition to procedural streamlining, the framework explicitly recognizes the validity of qualified electronic signatures in accordance with the eIDAS Regulation. This provision enables digital execution of both the contract and the accompanying forms and, as a consequence, reduces reliance on physical documentation and manual circulation supporting shorter timelines and greater procedural efficiency.

G. Conclusion

1. By combining standard contracts and forms with clear hand-offs and fixed internal deadlines, the framework shortens study start-up timelines, smoothens contracting processes and reduces uncertainty for sponsors and trial sites alike. Moreover, it limits document iterations, reduces idle time between signatures, and facilitates efficient financial onboarding through ELKE or ELKEA. At the same time, it ensures closer alignment with Greece's implementation of the EU clinical research framework. Overall, the MD represents a substantive step towards a more predictable and transparent clinical trial landscape in Greece. This reform aims to attract more clinical studies to the country, benefiting both patients who gain access to innovative treatments and the wider pharmaceutical and research ecosystem.



KEY CONTACTS

Ria Venaki
Senior Associate
rvenaki@bernitsaslaw.com



Anastasia Iliopoulou
Associate
ailiopoulou@bernitsaslaw.com

This Briefing is intended to provide general information and is not meant to constitute a comprehensive analysis of the matters set out herein or to be relied upon as legal advice. It is not meant to create a lawyer-client relationship. Legal and other professional advice should be sought before applying any of the information in this Briefing to a specific situation.
Bernitsas Law Firm is a partnership of attorneys regulated by Presidential Decree 81/2005 and Law 4194/2013, as currently in force, with its registered address at 5 Lykavittou Street, Athens 106 72, Greece. If you no longer wish to receive Briefings from us, please click here to Unsubscribe.