

# CLINICAL RESEARCH UNIT, SCHOOL OF MEDICINE, PAPAGEORGIOU GENERAL HOSPITAL, ARISTOTLE UNIVERSITY OF THESSALONIKI (CRU-AUSoM)

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**Institution**

Educational Institution

Hospital/Clinic/Other health care facility

Laboratory/Research/Testing facility

## Institution identification

### Institution ID

1000000004

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### Institution countries

 Greece

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### Type of institution

Educational Institution

Hospital/Clinic/Other health care facility

Laboratory/Research/Testing facility

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### Institution role

Data holder

Researcher

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### **Institution website**

<https://bresu.auth.gr/en/research/clinical-studies-unit-csu/>

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### **ENCePP partner**

Yes

## **Institution description**

The Clinical Research Unit is based in a tertiary Hospital, Papageorgiou General Hospital in Thessaloniki and extends over an area of 500 square meters at the 4th floor having 18 beds dedicated to early phase clinical trials and bioequivalence studies (healthy volunteers or patients in early phase trials e.g Ib). The CRU complies with the national and international regulations for phase I clinical trials having a contract with the Papageorgiou hospital's ICU for always available ICU beds during trial periods. Noteworthy, it is the only one Phase I Unit in Greece established by law meeting all requirements for conducting Phase I studies as stipulated in Ministerial Decree Γ5α/59676, 22-12-2016 FEK4131 article 7. Its purpose is to support and promote biomedical research based on interdisciplinary approaches, with the main objectives of conducting: phase I clinical trials: I-α healthy, I-β first in human (FIH) and bioequivalence studies but also pharmacoepidemiology and pharmacovigilance studies (disproportionality analysis of global PV databases). The CRU received recently ISO 9001:2015 for research activities purposes: Design and conduct of clinical studies. The Laboratory of the CRU received in 2024 the ISO/IEC 17025:2017 Accreditation Certificate from the Hellenic Accreditation System. It has Certified personnel (medical doctors and nurses) in ALS (Advanced Life Support) and GCP. The CRU is member of the European research network VACCELERATE and registered in EUVAP, a platform for experienced clinical trial

sites interested in conducting COVID-19 vaccine studies. The CRU offers several Clinical trials Services including: Volunteer Recruitment, Full Baseline Assessment (Toxicological screen, biochemistry) Pharmacokinetic analysis , Medical Writing (full protocol), Statistical analysis, Final report, Medical specialties Consultation, Clinical Toxicology services. The CRU is the official Training center for Greece of the Medical subspecialty of Clinical Pharmacology

## Institution details

**Experience with collecting data directly from individual patients or respondents:**

Yes

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**Interest in carrying out research that is funded by pharmaceutical companies:**

Yes

## Contact

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