

TRANSLATIONAL MEDICINE
DEVELOPMENT CORE GROUP

Your Partner for EU-MDR & IVDR Success
Comprehensive Project Management – From Idea
to Notification

- We leverage HCEMM's full research and infrastructure capacities to drive your project forward.
- End-to-end Regulatory Planning and Development Strategy tailored to your needs.
- Expertise in Proof of Concept (POC) and Performance Studies.
- Complete management of Human Sample Collection Studies.
- Seamless Vendor Management, CRO coordination, and Site Logistics.
- Integration of internal and collaborative laboratory capacities.
- We identify the best regulatory pathway for your project.
- Full FSP Project Management support from planning to submission.
- Guiding you through every step — from concept to EU-MDR / IVDR notification.



ABOUT THE HEADQUARTERS

Located in Szeged, Hungary, the headquarters of the Hungarian Center of Excellence for Molecular Medicine (HCEMM) serve as the operational and administrative Center of the organization. It provides the infrastructure and coordination necessary to connect HCEMM's nationwide research network and international partnerships.

The Szeged headquarters play a key role in ensuring efficient communication between research groups, project management teams, and external collaborators. It also supports the strategic planning and implementation of HCEMM's scientific programs, fostering collaboration between academia and industry.

Beyond coordination, the headquarters represent HCEMM's commitment to creating a dynamic research environment that drives innovation, strengthens Hungary's scientific landscape, and promotes the translation of discoveries into realworld healthcare benefits.

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SERVICES
AT HCEMM

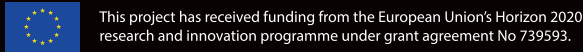


ABOUT THE HCEMM

The Hungarian Center of Excellence for Molecular Medicine is a distributed Institute whose scientists develop advanced diagnostics for the early detection of diseases, companion diagnostics to monitor disease progress and treatment options supporting healthy aging in collaboration with industrial and academic partners.

The HCEMM program is currently funded by an H2020 Teaming Grant (where Semmelweis University, the University of Szeged and the Hun- Ren Biological Research Center, Szeged, cooperate with their advanced partner, the European Molecular Biology Laboratory, headquartered in Heidelberg, Germany), a Thematic Excellence award, as well as a National Laboratory award from the Hungarian government.

The various activities are coordinated by HCEMM Kft., headquartered in Szeged, Hungary. HCEMM operates at the intersection of academic and industrial research, focusing on topics related to translational medicine up to Phase I Clinical trials. The goal is to enhance the quality of life for an aging Hungarian population while simultaneously reducing the cost of healthcare provision through innovative applications in the field of molecular medicine.



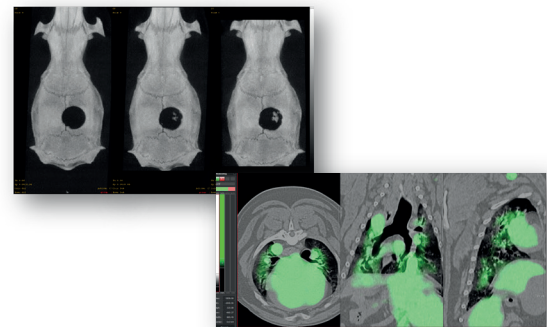
HCEMM-SU IN VIVO IMAGING

The short way from design concept to clinical studies. Medical Device Development Services. Preclinical PET/CT/MRI. Large animal CT/SPECT/PET.

Provision of customised animal studies in cancer, neurology and immunology. Full scale pre-clinical and clinical imaging services using CT, MRI, PET/CT, PET/MRI and SPEC/CT. with tracer development.

Large animal study expertise including spontaneous tumors of dogs. Radiomic outcome measures from clinical images.

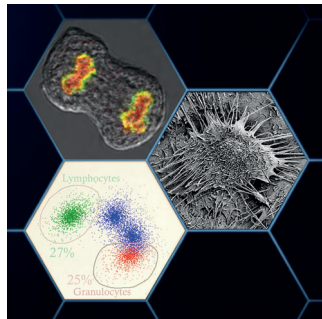
- Experience in Small and Large Animal Models for Proof-of-Concept and Preclinical Development.
- Specific Radioactive Tracer Development Support for Tailored Biodistribution and Effect Studies.
- State-of-the-Art Quantification and Result Reporting with Own High-Throughput Computing Facility.
- Fully Owned Data Supply Chain.
- Understanding of MDR-Compliance and FDA-Submission Challenges.
- A Deep Dish of In-House Mechanistic, Multiomics and Cellular Level Studies if needed.



HCEMM-USZ FUNCTIONAL CELL BIOLOGY AND IMMUNOLOGY

FCBI Advanced Microscopy Imaging and FACS Core Facility

- Deep Cellular Insights (3D & Live Imaging): Gain detailed, sub-cellular information with our Confocal Laser Scanning Microscopes, perfect for studying dynamic processes in live cells, visualizing complex 3D tissue architecture, and quantifying molecular co-localization.
- Ultra-High Resolution Structural Analysis: Use our Electron Microscope (SEM/STEM) to visualize materials, nano-structures, and cellular ultrastructure with nanometre precision.
- Precise Quantification of Molecular Events: Utilize our Flow Cytometer/Cell Sorter for rapid, quantitative, multi-parameter analysis of thousands of cells per second.
- Expert Antibody Immunodetection Optimization: Save time and resources with our specialized service for antibody immunolocalization optimizations. We develop and validate robust staining protocols for your specific target and sample type (tissue, cells, etc.), ensuring high-quality, reproducible imaging results.
- Validated Single Cell Isolation: Achieve high-purity isolation of specific cell populations using our Single Cell Sorting capabilities, enabling downstream -omics applications or generation of homogeneous cell lines for functional studies.

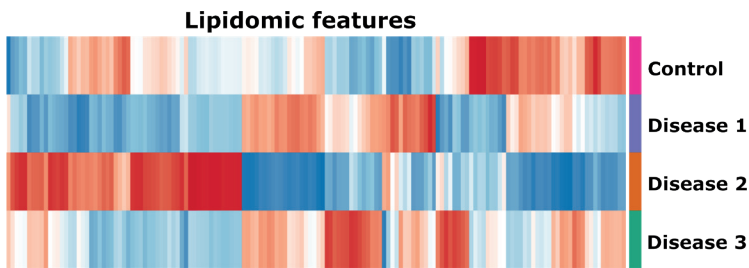


HCEMM-BRC SINGLE CELL OMICS

Your Partner in Advanced Omics Research

Comprehensive Support – From Study Design to Data Delivery

- Integrated mass spectrometry-based proteomics and lipidomics services for diverse biological samples.
- Single-cell sequencing (10x Genomics) library preparation for transcriptomic and multiomic studies.
- Tailored workflows designed around your research goals and sample types.
- Expert guidance from experimental planning through data interpretation and validation.
- Ensuring precision, reproducibility, and publication-ready results for every project.



SCIENTIFIC COMPUTING

Medical research now runs on data. Every new therapy begins with information, and making sense of that information is what we do.

The PULI supercomputer is our engine:

- A high-performance computing environment fully built and managed in-house. Powered by the diverse expertise of our team, PULI has repeatedly turned raw patient data into biomedical insights towards clinical application.
- We are able to extract every bit of meaning from your data. We have implemented the core bioinformatics pipelines refined by the scientific community over the past twenty years.
- We are able to go beyond data analysis, by building in-silico models that reproduce complex biological and medical problems - the kind that are difficult or impossible to capture in the lab.
- Our collaborations reach across Europe, connecting us with some of the best European research groups and national laboratories.

If your goal is to understand your data and transform it into actionable medicine, the Scientific Computing ACF is your strategic partner.

