NUKLEUS - A Technical and Organisational Research Infrastructure to Support Timely, High Quality and FAIR Clinical Studies

Dagmar KREFTING[a,b,1], Gabi ANTON[c], Irina CHAPLINSKAYA-SOBOL[a], Sabine HANSS[a], Wolfgang HOFFMANN[d], Sina M. HOPFF[e,f], Monika KRAUS[c], Roberto LORBEER[g], Bettina LORENZ-DEPIEREUX[c], Thomas ILLIG[h], Christian SCHÄFER[i], Jens SCHALLER[g], Anne SCHONEBERG[a], Dana STAHL[j], Heike VALENTIN[j], Peter HEUSCHMANN[k] and Janne VEHRESCHILD[e,l]

[a]*Dpt. of Medical Informatics, University Medical Center Göttingen, German Center for Cardiovascular Research (DZHK) partner site Göttingen, Germany*

[b]*Campus Institute Data Science (CIDAS), Georg-August-University Göttingen,*

[c]*Institute of Epidemiology, Helmholtz Zentrum München, German Research Center for Environmental Health, Neuherberg, Germany*

[d]*Institute for Community Medicine, University Medicine Greifswald, Germany*

[e]*Faculty of Medicine, University of Cologne, Department I of Internal Medicine, University Hospital Cologne, Germany*

[f]*Center for Integrated Oncology Aachen Bonn Cologne Duesseldorf, Cologne, Germany*

[g]*Deutsches Herzzentrum der Charité,Charité – Universitätsmedizin Berlin, Institute of Computer-assisted Cardiovascular Medicine, German Center for Cardiovascular Research (DZHK) partner site Berlin, Germany*

[h]*Hannover Unified Biobank, Hannover Medical School, Hannover, Germany*

[i]*Institute of Clinical Chemistry and Laboratory Medicine,University Medicine Greifswald, Germany*

[j]*Independent Trusted Third Party of the University Medicine Greifswald, Germany*

[k]*Institute of Clinical Epidemiology and Biometry, University of Würzburg; Clinical Trial Center, University Hospital Würzburg, Germany*

[l]*German Centre for Infection Research (DZIF), partner site Bonn- Cologne, Cologne, Department II for Internal Medicine, Hematology/Oncology, University Hospital Frankfurt, Frankfurt am Main, Germany.*

The Network University Medicine Clinical and Epidemiology Platform (NUKLEUS) has been founded 2022 as a long-term research infrastructure. It aims at supporting researchers to efficiently plan and conduct clinical-epidemiological studies and enable broad reuse of the study data. NUKLEUS combines the methodological core units of the National Pandemic Cohort Network (NAPKON [1]) and the study infrastructure adopted from the German Center for Cardiovascular Research [2], funded within the Network University Medicine (NUM [2]). Currently, NUKLEUS consists of four dedicated data management systems: The clinical data capture system secuTrial® for eCRFs, the laboratory information system CentraXX®for biospecimen metadata and Trialconnect®for DICOM data are connected by the trusted third party managing identifying data, digital consents and system-specific pseudonyms with the open source tools gICS®, E-PIX®and gPAS®. Performance and data quality reports are automatically generated on aggregated data and delivered to lead investigators and participating sites. Fast implementation of a study is supported by coordination of harmonized study and proband documents for ethics approval, transparent cost calculations for using NUKLEUS, and provision of an up-and-running research data infrastructure. Epidemiological consultancy is offered throughout the full study lifetime – from the planning phase to the statistical analysis. The Interaction Core Unit (ICU) coordinates internal and external communication and implements and optimizes the required processes. The Biosample Core Unit (BCU) ensures high-quality biospecimen collection including site audits. The Epidemiology Core Unit is responsible for quality assurance. NUKLEUS is specifically designed to implement and support FAIR data stewardship[5]. Data usage requests are managed through the Proskive application management system, Use and Access committees are organized by the ICU and data provision is carried out by the transfer office – for biospecimen the BCU. Again methodological consultancy is offered for the data request application. To date, more than 100 usage applications have been approved, of which so far 55 received data. About 32.000 reviewed visits from more than 6.500 NAPKON

[1] Corresponding Author: Dagmar Krefting, University Medical Center Göttingen, Germany, dagmar.krefting@med.uni-goettingen.de

participants are ready for reuse. From a total of 83.300 primary biospecimen, 12 sample usage applications received a total of 36.600 sample aliquots.

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