



Deliverable D 9.5 Ethics

OEI - Requirement No. 6

Work Package	Ethics
Task(s)	NA
Author(s)	Jana Mertens, Michael Kramer, Matthias Hemmje
Document ID	D9.5_OEI - Requirement No. 6_M1
Approver	Jana Mertens
Creation date	30/09/2024
Last update	29/10/2024
Version	V1
Supersedes	20241029_V1
Dissemination Level	SEN

*All dates in dd/mm/yyyy format

Document Log

Date	Author	Changes	Version	Status
15/09/2024	Jana Mertens	Creation of Document and adding content	V1	In progress
29/10/2024	Michael Kramer	Checking document and finalizing CV and publications	V1	final

Executive Summary

An independent Ethics Advisor (EA) must be appointed at month 1 of the project. The consortium must submit the Appointment Letter and CV of the EA and the reports provided by the EA as deliverables.

The Appointment letter must indicate the name and surname of the Advisor, their area of professional expertise in ethics, including a confirmation that the professional background makes the Advisor knowledgeable in the various ethics aspects of the project, and that this is in line with the Advisor's mandate set in the Ethics Summary Report (EthSR).

The Ethics Advisor must demonstrate expertise in data protection, AI and medical diagnostics.

In summary, the role of the independent Ethics Advisor will be to:

- monitor and advise on data privacy and security;
- ensure compliance with the AI Act (specifically, explainability of models and systems, fairness and bias);
- check and advise on obtaining informed consent from participants and ensure appropriate approvals are obtained; and
- update REA on the use of biometric data and emotion recognition on the interactive visualisations with the end users.

1 Letter of Appointment

The GenDAI consortium will appoint Prof. Dr. med. M. Kramer, founder, managing director and shareholder (via ImmBioMed GmbH) of ImmBioMed Business Consultants GmbH & Co. KG, as Independent Ethical Advisor in the GenDAI project.

Beside his work as Ethical Advisor, Prof. Dr. med. M. Kramer has no conflict of interest.

Prof. Dr. med. M. Kramer, in his role as Independent Ethical Advisor will oversee the ongoing activities of the project, offer advice on ethics issues and ensure continuing compliance with the ethics standards and guidelines.

At the end of each project period (Month 24 and Month 36), Prof. Dr. med. M. Kramer will submit a report about project ethics compliance.



Signature of Independent Ethics Advisor



Place and date of signature

2 Curriculum Vita


Michael Kramer was born 1958 in Jugenheim (Germany) and started his medical studies 1977 at Heidelberg University. 1985 he was board-certified as medical doctor and was promoted to M.D. by Heidelberg University. 1992 he was appointed Assistant Professor at Heidelberg University. 1999 he was board-certified for Laboratory Medicine and Medical Quality Management; in 2000 also for Transfusion Medicine. In December 1992 he was appointed as Adjunct Professor for Applied Immunology at Heidelberg University. In 2023 he was appointed as a member to the Ethics Committee of Heidelberg University Medical School. Michael Kramer is married and has two children.

Prof. Kramer served as Study Director and Principal Investigator for several studies listed below. In his capacity as Study Director he was involved in designing and writing the study protocols. He was fully responsible for obtaining the EC vote, which included authoring of the respective documents and driving the negotiation and communication with the ethics committee of Heidelberg University Medical Center. All these studies were in the area of diagnostics development:

Studienerfahrung gemäß MPG: Leitung einer Klinischen Prüfung / Hauptprüfer / Prüfer
Prof. Dr. med. M. Kramer, Facharzt für Laboratoriumsmedizin, Transfusionswesen, Ärztliches Qualitätsmanagement

Titel der Studie	Eudamed-Nr. Prüfplancode	Indikationsbereich	Phase	Eigene Funktion	Zeitraum der Mitwirkung
Biomarkers in COPD		COPD	I/II	Mitarbeit bei Erstellung des Prüfplans	2007 - 2009
Impfstudie		Induktion spezifischer T-Zell-Immunität	I	Mitarbeit bei Erstellung des Prüfplans	2006 - 2012
Immunonkologische Studie		Anti-tumorale Lymphozyten-Aktivierung/Immunität	II	Mitarbeit bei der Erstellung des Prüfplans; inkl. Methoden-Auswahl, -Entwicklung und -Validierung	2006 - 2012
Zytokinsynthese-Induktion („Cytokine Storm“)		Immunmodulation Vorbereitung „First-into-Man“-Studien	FIM I	Mitarbeit bei Erstellung des Prüfplans, Mitarbeit bei Probanden-Rekrutierung	2006 - 2012
Mehrere Studien		Lymphozyten-Typisierung als Aktivierungsmarker	I/II	Mitarbeit bei der Erstellung des Prüfplans; inkl. Methoden-Auswahl, -Entwicklung und -Validierung	2006 - 2012
TID-1	DRKS00014254	Probensammlung für Entwicklung neuartiger Tuberkulose-Diagnostik	N/A	Hauptprüfer des Studienzentrums	2018 - 2022
TID-2	DRKS00027129	Probensammlung für Entwicklung neuartiger Tuberkulose-Diagnostik	N/A	Hauptprüfer des Studienzentrums	2022 - 2023
IVDR-AII/NC-01	DRKS00024808	Probensammlung zur analytischen Leistungsbewertung von IVDs für Allergien und Nahrungsmittelunverträglichkeiten	N/A	Hauptprüfer des Studienzentrums	2021 - 2022

10.29.2024
Ort, Datum


Stempel und Unterschrift
Immbiomed
Business Consultants
GmbH & Co KG
Bergstrasse 85
D-64319 Pfungstadt

2.1 Career History

- 1979 – 1985 Student Assistant at the German Cancer Research Centre in Heidelberg
- 1985 – 1987 Military Service at the Central Institute of the Medical Corps of the Germany Army in Koblenz
- 1987 – 1998 Various clinical and laboratory institutions at the Heidelberg University Medical Center;
- 1992 – 1998 senior assistant at the Institute for Immunology of Heidelberg University and head of the Immuno-Pathology Laboratory
- 1999 – 2003 Managing Director of LYNX Therapeutics GmbH in Heidelberg; a subsidiary of Lynx Therapeutics Inc., Hayward, CA, USA
- Since 2003 Founding and developing ImmBioMed Business Consultants GmbH & Co. KG

2.2 Scientific Awards

- 1985 Julius-Redel-Prize of the Medical Faculty of Heidelberg University
- 1989 Paul-Gersson-Unna-Prize of the German Dermatological Society
- 1998 Robert-Pfleger-Preis for Biomedical research

2.3 Selected Publications

Schott D., C.-E. Dempfle, P. Beck, A. Liermann, A. Mohr-Pennert, M. Goldner, P. Mehlem, H. Azuma, V. Schuster, A.-M. Mingers, H.P. Schwarz, and M.D. Kramer. 1998
Therapy with a purified plasminogen concentrate in an infant with ligneous conjunctivitis and homozygous plasminogen deficiency.
New Engl. J. Med. 339:1679-1686.

Schaefer M.D., C. Jaeger, and M.D. Kramer. 1996.
The plasminogen activator system in pemphigus vulgaris.
Br. J. Dermatol. 135:726-732.

Schaefer B.M., J. Reinartz, M.J. Bechtel, S. Inndorf, E. Lang, M.D. Kramer. 1996.
Dispace-mediated basal detachment of cultured keratinocytes induces urokinase-type plasminogen activator (uPA) and its receptor (uPA-R, CD87).
Exp. Cell. Res. 228:246-253.

Schaefer B., C. Jaeger, E. Drepper, and M.D. Kramer. 1996.
Plasminogen activation in bullous pemphigoid. Immunohistology reveals uPA, uPA-R, and PAI-2 in lesional epidermis.
Autoimmunity 23:155-164.

Bechtel M. J., J. Rox, S. Inndorf, J. Reinartz, B. Schaefer, and M.D. Kramer. 1996.
Upregulation of cell surface-associated plasminogen activation in cultured keratinocytes by Interleukin-1beta and Tumor-Necrosis-Factor-alpha.
Exp. Cell. Res. 223:395-404.

Fuchs H., M.M. Simon, R. Wallich, M. Bechtel, and M.D. Kramer. 1996.
Borrelia burgdorferi induces the secretion of pro-urokinase-type plasminogen activator by human monocytes.
Infect. Immun. 64:4307-4312

Foekens J.A., F. Buessecker, H.A. Peters, U. Krainick, W.L.J. van Putten, and M.D. Kramer. 1995.
Plasminogen activator inhibitor-2 (PAI-2): prognostic relevance in 1012 patients with primary breast cancer.
Cancer Res. 55:1423-1427.

Moter, S.E., H. Hofmann, R. Wallich, M.M. Simon, and M.D. Kramer. 1994.
Detection of Borrelia burgdorferi sensu lato in lesional skin of erythema migrans and acrodermatitis chronica atrophicans by OspA-specific polymerase chain reaction.
J. Clin. Microbiol. 32:2980-2988.

Fuchs H., R. Wallich, M.M. Simon, and M.D. Kramer. 1994.
The outer surface protein A of the spirochete Borrelia burgdorferi is a plasminogen receptor.
Proc. Natl. Acad. Sci: USA 91: 12594-12598.

Reinartz J., R. Batrla, P. Boukamp, N. Fusenig, and M.D. Kramer. 1993.
Binding and activation of plasminogen at the surface of human keratinocytes.
Exp. Cell Res. 208:197-208.

Kramer, M.D. and J. Reinartz. 1993.
The autoimmune blistering skin disease bullous pemphigoid: The presence of plasmin/ α 2-antiplasmin complexes in skin blister fluid indicates plasmin generation in lesional skin.
J. Clin. Invest. 92:978-983.

Simon M.M., U.E. Schaible, R. Wallich, and M.D. Kramer. 1991.
A mouse model for *Borrelia burgdorferi* infection: approach to a possible vaccine against Lyme disease.
Immunology Today 12:11-16.

Schaible, U.E., M.D. Kramer, K. Eichmann, M. Modolell, C. Museteanu, and M.M. Simon. 1990
Monoclonal antibodies specific for the outer surface protein A (OspA) of *Borrelia burgdorferi* prevent Lyme borreliosis in severe combined immunodeficiency (scid) mice.
Proc. Natl. Acad. Sci. USA 87:3768-3772.

Kramer, M.D., U.E. Schaible, R. Wallich, S.E. Moter, D. Petzoldt, M.M. Simon. 1990
Characterization of *Borrelia burgdorferi* associated antigens by monoclonal antibodies.
Immunobiol. 181:357-366.

Kramer, M.D. and Simon M.M. 1987
Are proteinases functional molecules of T lymphocytes?
Immunology Today 8:140-142.

Simon, M.M., H. Hoschützky, U. Fruth, H.-G. Simon, and M.D. Kramer. 1986
Purification and characterization of a T cell specific serine proteinase (TSP-1) from cloned cytolytic T lymphocytes.
EMBO J. 5:3267-3274.