Deliverable D 1.3
POPD - NEC - Requirement No. 3
Midterm Report by the Independent Ethics Advisor

Funding Programme	HORIZON EUROPE
Call	WIDERA-2021-ACCESS-03 (Twinning)
Grant Agreement Number	101078950
Acronym	GAIN
Project Title	Georgian Artificial Intelligence Networking and Twinning Initiative
Project start date-end date	1st October 2022- 30 September 2025
Period covered	October 2022- March 2024

1. Name and contact details

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2. Area of expertise and concise description of educational and professional background

I am a Doctor of Biology, Senior Researcher at the Institute of Cognitive Neurosciences, Free University of Tbilisi.
My scientific interest involves cognitive and clinical features of people with mental disorders and healthy population, and psychopharmacology.
I studied Biology, Human and animal physiology at the I. Javakhishvili Tbilisi State University (1992-98); in 2004 I earned a Ph.D in biology under the supervision of Prof. Kezeli at the Ivane Beritashvili Center of Experimental Biomedicine.
As a researcher I have leaded the multicentre projects:
2016-2018 – Cognitive and Perceptual features of Unipolar Depression. NCCR consortium (National Centres of Competence in Research – Swiss National Research Foundation). "SYNAPSY– Synaptic Bases of Mental Diseases";
2014-2016 –The Neuropsychological Markers of Mental Disorders. Research grant of Agricultural University of Georgia;
2012-2014 - Prevention of clinical, social and cognitive deterioration of patients with first episode psychoses. Research grant of Agricultural University of Georgia;
2010 – 2014 – "The search for behavioural endophenotypes of schizophrenia" - supported by the "NCCR SYNAPSY" (National Centres of Competence in Research – Swiss National Research Foundation) "SYNAPSY – Synaptic Bases of Mental Diseases".

Since 2018 I have been coordinating the clinical trials:
1. A double-blind, oral, multiple-dose, parallel, randomized study to evaluate efficacy and safety of Endoxifen in bipolar I disorder patients with acute mania episodes with or without mixed features.
2. Randomized double blind placebo control studies MIN-101C07 (2018-2020);
3. Randomized double blind placebo control studies MIN-117C03 (2018-2019).

Currently I am a leader of scientific project "EEG patterns of Mental Disorders (Schizophrenia, Bipolar disorder, depression). NCCR consortium ((National Centres of Competence in Research – Swiss National Research Foundation), that is carried out at "Tbilisi State Medical University" in cooperation with Swiss scientists from "École Polytechnique Fédérale de Lausanne (EPFL).

About forty scientific papers and one monograph have been published under my authorship and co-authorship.

3. Annex 1: Declaration on independence and absence of conflicts of interest

See Annex 1

4. Description of the independent Ethics Advisor's / Board's mandate, including starting and ending dates of involvement

As an Ethics Advisor of the project GAIN, I was selected and assigned in December 2023. The previous ethics Advisor, Professor Eka Chkonia, introduced me to the studies, which are planned to be implemented at the Tbilisi Mental Health Centre in the frame of the project GAIN. I had a meeting with the project coordinator and the members of the GAIN MICM team, who gave description of technical side for the project implementation and handed me previous 2 deliverables (D. 1.1 and D. 1.2) including the ethical protocol for the study.
Since October 2022 to December 2023 the preparatory work has been carried out: the clinicians at the Tbilisi Mental Health Centre have been given the necessary equipment, 1 computer, 2 specialized cameras and 2 wristbands for the biosignals. Cameras for recording interviews between the patient and the doctor are installed in accordance with the study design specified in the study protocol.
Since February 2024 the experimental recoding has stared in accordance with study protocol.

5. Overview of ethics issues raised by the project activities.

The "Pilot Research Project at MICM" with the title "Digital Phenotyping for Psychiatric Disorders from Social Interaction", which is the subproject of the Twinning Research and Innovation Programme (TRIP) of the project GAIN, is conducted in Georgia at Tbilisi Mental Health Center, where the clinical data is collected. The data is stored on the computer server at MICM for further investigation by the project partners and will be handled in accordance with the Consortium Agreement, GDPR and the study protocol (D. 1.2). The subproject is based on the ideas of the joint (INRIA-DFKI) large-scale interdisciplinary project MePheSTO with the same title, which deals with the Artificial Intelligence (AI) methods for the identification and classification of digital phenotypes of psychiatric disorders, such as mental, affective, and mood illnesses/disorders.
In the reporting period from October 2022 to March 2024, the pilot recordings have been done and two participants are involved in the study. The patients are inpatients at the Tbilisi Mental Health Centre. After providing the related documents, I have made the following observations:

- Participants are identified by their psychiatrist, a member of the GAIN project research team.
- Inclusion and exclusion criteria are fulfilled
- Work is in progress and clinical researchers are conducting the study strictly in accordance with the specifications of the study protocol
- **Consenting participants**: Participants have been invited to participate in this study during their consultation in the clinic; the participant information sheets were provided in paper version and 24 hours were given to make decision; participants provided informed consent via on consent form with their names and a contact phone number, which are stored on the clinics' servers. This information was clearly described to participants in the participant information sheet, and they were asked to explicitly consent for this data to be stored; On receipt of a completed consent form, psychiatrist arranged a first study appointment with the research participant. At the start of this baseline assessment the researcher has reviewed the study information and the consent form and confirmed that the participant understands the purpose of the study and what is expected of their participation and whether they are happy to continue with the study.
- The staff delegated to this task has been appropriately trained beforehand; Senior staff is available to discuss any concerns about a participant's capacity to consent.
- **Data collection**: The speech and video of the participants was recorded as audio-video files during clinical interactions; physiological measures were recorded via a device placed on the body (Empatica wristband). All the procedures defined by the study protocol have been fulfilled.
- **Data management:**
  - ✓ Personnel data is stored according to the study protocol.

- ✓ During the Face-to-Face interviews, the recording of data is done on local servers, not connected to the internet; The local servers are encrypted, and the access is contingent on an authorized password.

- **Transfer of Data:**
  - ✓ To transfer data from the clinical recording sites to the technical partners at MICM, an end-to-end encryption methodology, using asymmetric encryption is employed. The data will be kept encrypted at the technical sites and only be de-crypted right before de-crypted data is needed (e.g. to re-structure, annotate, extract features, or train machine learning models with the data).
  - ✓ The Mental Health Center and MICM are the data controllers.

Conclusion: The clinical study, conducted during the reporting period (October 2022 – March 2023) is in full compliance with the ethics protocol. As such, no ethical issues have been detected.

6. Ethics Analysis:

I have carefully studded and followed the approved ethics protocol (approved by the Biomedical Research Ethics committee of Tbilisi State medical University on 2 March, 2023) of the study and guidance of the Ethics Advisory Boards in EU-funded projects and Horizon Europe Programme Guide.

The following document have been assessed: The records of study participants, informed consent forms, signed documents by participants, appropriateness to the conditions and timing to the study protocol.

After revision of the provided relevant documentations, I would conclude that the clinical study, conducted during the reporting period (October 2022 – March 2023) is in full compliance with the ethics protocol. Therefore, no ethical issues have been detected.

7. Recommendations to the Beneficiary/Coordinator/Principal investigator

The main advice and recommendation to the principal investigator included to follow the approved ethics protocol (approved by the Biomedical Research Ethics committee of Tbilisi State medical University on 2 March, 2023) of the study and guidance of the Ethics Advisory Boards in EU-funded projects and Horizon Europe Programme Guide.

8. Recommendations to the Commission/Executive Agency/Funding Body

N/A

Date: ***29 March, 2024*** ***Signature:***

Annex 1: Declaration on independence and absence of conflicts of interest

The undersigned Maya Roinishvili, appointed as independent Ethics Advisor / Ethics Advisory Board Member, for the project [ACRONYM] [GA Number], declares that:

- she will execute her responsibilities in full independence of other professional and academic commitments;
- she is not affected by any conflict of interest arising in particular from any economic or professional interests, from family or other personal links, or from any other relationships or common interests which may compromise the independent nature of the report provided;
- there are no other professional or financial constraints to carry out the required assignment or that would compromise the independent nature of the report provided:
- She will notify the Beneficiary/Coordinator/Principal Investigator without delay if the above situation changes, particularly in such a way as to compromise the independent nature of the report.
- She will not reveal any information about the project's activities and its outcomes, without the express written approval of the Beneficiary/ies or the Commission/Executive Agency/Funding Body.

Date: 29 March, 2024 Signature: