



FAMILY

“Running in the FAMILY – Understanding and predicting the intergenerational transmission of mental illness”

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Registration numbers of the clinical studies (WHO Registry criteria)

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SUMMARY

The deliverable provides information about registration of clinical studies in registries operating according to WHO Registry criteria.

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1 INTRODUCTION

1.1 Purpose and Scope

According to the World Health Organization (WHO), clinical trial registration is the process of recording and disclosing key information about a clinical trial in a public registry before it begins enrolling participants. WHO requires registering all interventional clinical trials in a registry operating according to WHO Registry criteria¹, meaning a publicly accessible registry that meets certain standards for content, quality, and accessibility. This requirement applies to interventional trials of medicines, medical devices, and other interventions, including non-pharmacological interventions regardless of the phase or funding source of the trial. A clinical trial is defined by WHO as: “[..]any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.”²

The registration is aimed at ensuring that information about clinical trials is transparent and easily accessible to researchers, healthcare professionals, and the general public.

2 STATUS OF REGISTRATION OF *FAMILY* TRIALS

FAMILY involves only observational epidemiological studies that do not fall in the scope of clinical trials definition as defined by WHO. Therefore, there are no clinical studies registered in registries operating according to WHO Registry criteria.

The initiation packages of the four observational studies have been submitted as

D5.1 Study initiation package POBI-EMC

D5.2 Study initiation package POBI-FCRB

D5.3 Study initiation package POBI-FIBHGM

D5.4 Study initiation package POBI-CHUV

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¹ <https://www.who.int/clinical-trials-registry-platform/network/registry-criteria>

² <https://www.who.int/news-room/questions-and-answers/item/clinical-trials>