HAMA COHORT: Proposal for ancillary study

Accessing the HAMA cohort data for a research project involves three essential steps:

- Signing the HAMA cohort data access convention (located on page 2).
- Completing the HAMA cohort data access submission form (found on page 4).
- Obtaining approval from the Scientific Board of HAMA for the submitted application.

For assistance throughout the submission process, including verifying the absence of overlapping projects, understanding the collected data, data availability, the number of included subjects, or any other inquiries, please feel free to reach out to Mrs. Alice Seris, HAMA's ARC Coordinator, at alice.seris@ch-pau.fr

HAMA cohort Data access convention

The HAMA project endeavors to revolutionize our understanding of Malignant Hypertension's pathophysiology, epidemiology, definition, target organ damage, and treatment. At the core of this initiative lies the HAMA cohort (NCT03755726), a prospective, multicentric, multidisciplinary European cohort compiling clinical, paraclinical, therapeutic, and follow-up data from patients experiencing MHT crises. This collaborative project aims to share its data with investigators for both funded and unfunded substudies initiated by researchers. The outcomes of such studies are anticipated to be disseminated through congress presentations and peer-reviewed publications. The HAMA scientific council plays a pivotal role in ensuring the appropriate utilization, equitable access, and optimal exploitation of the data for all investigators. Additionally, it aims to prevent redundancy in projects and safeguard against the premature disclosure of data slated for publication. In this regard, investigators are suggested to meticulously review, complete, and endorse the provided convention and proposal form. At any time, the scientific council stands ready to offer guidance and support for funding submissions.

By signing this convention, investigators acknowledge the following:

- Prior to completing the proposal form, they will contact the HAMA team to ensure no similar studies are currently underway or imminent.
- The data provided by the HAMA team are confidential and must not be disclosed to anyone except the partners specified in the proposal.
- Presentation or publication of HAMA data requires prior approval from the HAMA scientific council.
- Upon acceptance of their project by the HAMA Scientific Board, a specified timeframe will be allotted for initiating analysis, presenting results, and submitting data for publication. Compliance with this deadline is necessary for continued access to the data, and regular communication with the HAMA board will be maintained. Prolonged failure to meet this deadline may result in the withdrawal of approval by the HAMA Scientific Board.
- They agree to present the progress of their project at the HAMA project monitoring committees, to which they will be invited.

- Authorship guidelines will be determined in consultation with the HAMA scientific board prior to the beginning of the study and documented accordingly. Typically, the primary author of the study is listed as the first author. If the primary author differs from the investigator leading the project, the latter is designated as co-last author. Other positions will be assigned based on specific contributions to the cohort and the article, including recruitment, expert review, analysis, and figure creation. All contributors to HAMA (investigators, experts, adjudication committee) will be acknowledged as contributors according to PubMed guidelines.

Convention acceptation

Project Title:

Date:

Name and Signature of the Project Coordinator:

HAMA cohort – Substudy application form

This document must be completed in English.

Date of submission
Name and city of the project coordinator
List of the partners identities and functions for this study
Title
Abstract (Brief summary of the study, 250 words maximum)
Background and rational (300 words maximum, provide a brief statement of the clinical and scientific rationale to conduct the study, including hypothesis)
Primary aim of the study Provide only one and unique primary aim
Primary outcome Provide the outcome related to the primary aim by checking that it is available on the CRF(give the name of the variable) Give the time of outcome measurement (upon admission, during the hospitalization, 6-month of F/U, 12-month of F/U…)
Secondary aims of the study (optional, ≤ 5) Give the time of outcomes measurement (upon admission, during the hospitalization, 6-month of F/U, 12-month of F/U…)
Description of the target population Provide a brief description of the population to be included in this ancillary study (give any specific inclusion and exclusion criteria among the overall HAMA population. **In particular, please specify if you request data from the overall population or from one or several specific countries)**
Data from the overall HAMA population / from specific country (countries) *Inclusion criteria:* - X *Non-inclusion/Exclusion criteria:* - X
Sample size calculation (optional) *Provide sample size and power considerations (risk alpha, risk beta…)*

Please mention if you want to apply any correction of alpha risk to account for multiple testing.

Main exposure variables

List of the main variables of interest to be used for the statistical analysis of this ancillary study (check that they are all present in the CRF/thesaurus please, and use their variable name).

Potential covariates

List of the potential covariates (from literature data) to be considered for potential multivariate analysis in this ancillary study (check that they are all present in the CRF/thesaurus please, and use their variable name)..

Request for methodological support from HAMA's biostatistics team to design and /or conduct the study

Yes □ No □

(if affirmative, please contact Mrs. Alice Seris, HAMA's ARC Coordinator, at alice.seris@ch-pau.fr to estimate the required biostatistical time and budget for this support. If negative, detail in the statistical methodology below the organization of the statistical analysis (who? How?))

Statistical Methodology +++(very important to detail each step please)

Describe the statistical methodology to be used regarding primary and secondary outcomes, including handling of missing information (if required). If any of the methods are not standard, provide references please.
Define the list of groups comparisons with a clear definition of the population groups.
Give, for specific analyses as Kaplan-Meier or multivariate analyses, very detailed needs as strata for KM, covariates list for multivariate analyses...

Budget (optional)

Proposed timeline

(Provide here the estimated time before starting the analysis, presenting the results, writing and submitting the article)

Keywords

(6 maximum)

References

(15 maximum, Vancouver style)

Signature of the project coordinator