CHUGAI PHARMA FRANCE

STATISTICAL ANALYSIS PLAN

Cross-sectional, multicentre, non-interventional study to assess Giant Cell Arteritis medical practices in France

ARTEMIS STUDY

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CROSS-SECTIONAL, MULTICENTRE, NON-INTERVENTIONAL STUDY TO ASSESS GIANT CELL ARTERITIS MEDICAL PRACTICES IN FRANCE

ARTEMIS STUDY

CHUGAI PHARMA FRANCE

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1 ABBREVIATIONS

BMI	Body Mass Index
CNIL	Commission Nationale de l'Informatique et des Libertés
CPF	CHUGAI PHARMA FRANCE
CRF	Case Report Form
CT	Computed Tomography
CRO	Contract Research Organization
EGB	Echantillon Généraliste des Bénéficiaires
EQ5D	EuroQol-5 Dimensions
EULAR	European League Against Rheumatism
FACIT-Fatigue	Functional Assessment of Chronic Illness Therapy - Fatigue
FAS	Full Analysis Set
GCs	GlucoCorticoids
GCA	Giant Cell Arteritis
LTD	Long-Term Disease
MedDRA	Medical Dictionary for Regulatory Activities
MTX	Methotrexate
MRI	Magnetic Resonance Imaging
PET	Positron Emission Tomography
PMR	PolyMyalgia Rheumatica
PT	Preferred Term
SAP	Statistical Analysis Plan
SAS®	Statistical Analysis System®
SD	Standard Deviation
SF-36	36-Item Short Form Survey Instrument
SOC	System Organ Class
STROBE	STrengthening the Reporting of OBservational studies in Epidemiology
TAB	Temporal Artery Biopsy
TIA	Transient Ischaemic Attack
VAS	Visual Analog Scale
WHO- DD	World Health Organization – Drug Dictionary

2 STUDY OBJECTIVES

2.1 Primary objective

The primary objective is to describe medical practices in patients with GCA in terms of patient journey, diagnostic methods and specific GCA treatments since diagnosis.

2.2 Secondary objectives

The secondary objectives of this study are:

- To describe comorbidities related to GCs and associated treatments
- To describe GCA characteristics in terms of GCA duration, initial presentation, clinical form and GCA activity
- To describe the health status of GCA patients
- To describe physician and patient characteristics

3 STUDY DESIGN

3.1 Type of study

This is a cross-sectional, non-interventional, national (France), multicentre study, conducted on a population of 300 patients with GCA, to describe GCA management and patient characteristics

3.2 Study plan

The study will be conducted in accordance with the professional code of ethics and the good epidemiological practice guidelines developed by the Association of French-Speaking Epidemiologists) and the STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) recommendations for the drafting of reports and publications related to the study.
The information will be collected during a single visit to the internist or rheumatologist as part of the usual management of the patient with GCA. This study does not require any additional specific examination. Data will be collected from the medical file and from patient questionnaires on health status (SF-36 [36-Item Short Form Survey Instrument], EQ5D [EuroQol-5 Dimensions] and fatigue [FACIT-fatigue]. In addition, GCA activity will be evaluated using a global arteritis activity Visual Analog Scale (VAS) to be completed by the patient and the physician.

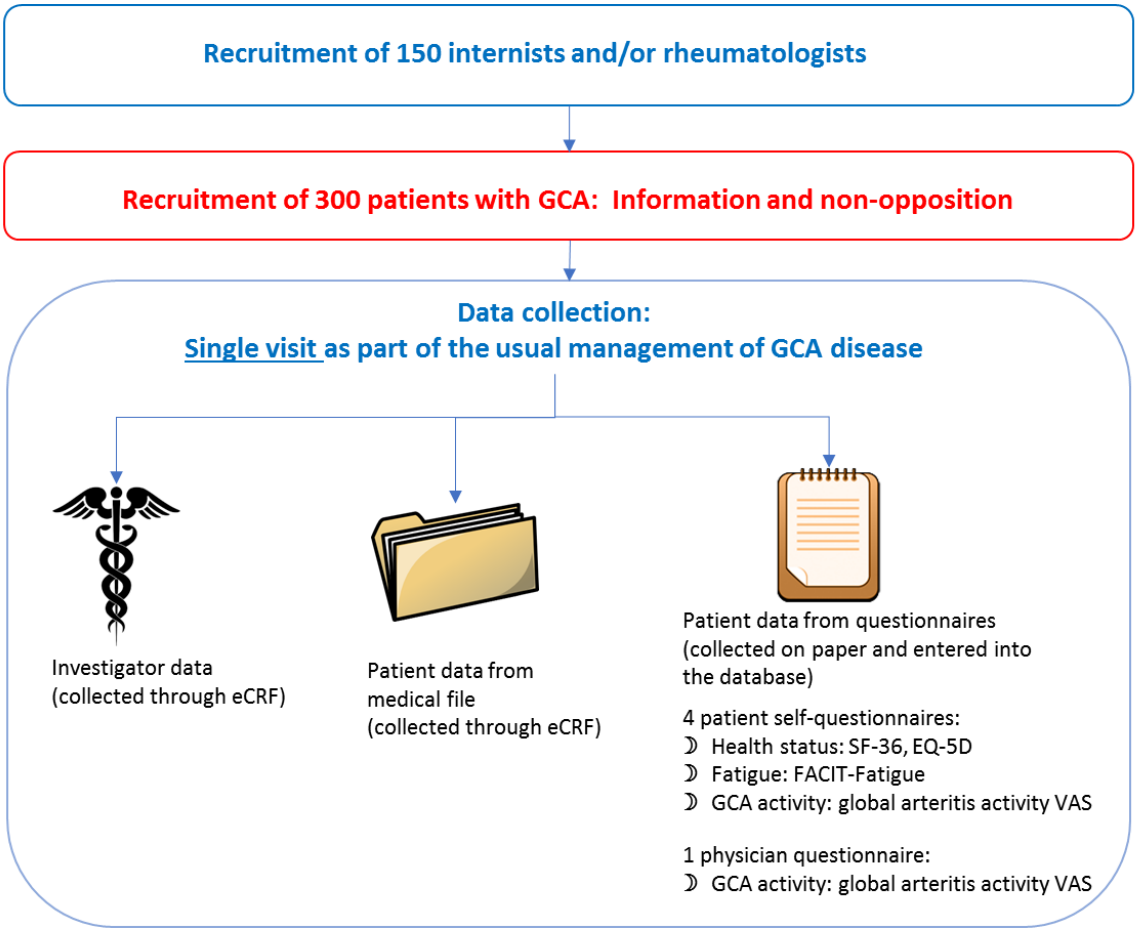

Figure 1 : Study design

3.3 Duration of the study

The planned period for recruiting patients will be 3 months, from the 1st of august to the 31th of October 2018.

The planned dates for the study milestones are provided in the following table

Milestone	Planned Date
Study start date (start of enrolment and data collection)	01/08/2018
Study end date (end of enrolment and data collection)	31/10/2018
Interim analysis	NA
Final report of study results	Q2 2019

The overall duration of the study or the duration of the patient recruitment period may vary depending on the rate at which patients are included or the time it takes to obtain regulatory authorisations.

3.4 Physician recruitment and study initiation

The physician population in this study will include internists and rheumatologists who manage patients suffering from GCA in hospitals or private clinics in France and agree to take part in the study.
A national data base provided by an independent company (CEGEDIM) including approximately 2600 internists and rheumatologists practicing in hospitals or private clinics in Metropolitan France will be used to recruit 150 active physicians for the study.
Physician will be selected by the Sponsor following rules and recommendations on relations between industry and health professionals.

3.5 Patient selection

3.5.1 Patient selection method

Physicians will start patient inclusion only when the study is initiated at their site and when all regulatory authorisations are obtained.
It is expected that 300 patients (prevalent or incident cases) will be recruited in this study. Based on the previous EGB database analysis, there are 2300 incident patients/year in France. Thus, including 300 incident and prevalent patients during the recruitment period, even excluding summer holidays, seems realistic
Each physician will be requested to include consecutively during the inclusion period all the patients meeting the eligibility criteria listed below and accepting to participate in the study.

3.5.1.1 Inclusion criteria

Patients must meet the following criteria to be included in the study:

- At least 50 years old.
- Suffering from GCA as per investigator judgement, newly diagnosed or not.
- Starting or under treatment for GCA.
- Informed verbally and in writing about this study and not objecting to their data being electronically processed or subjected to data quality control.

3.5.1.2 Non-inclusion criteria

Patients fulfilling the following criteria cannot be included in the study:

- Unable to consent
- Participation to a randomised controlled clinical trial

3.5.2 Information and consent

The physician must inform the patient about the study before inclusion and seek her/his non-opposition. A patient information form will be given to each patient by the physician. It will explain the purpose of collecting and processing the data, the nature of data collected, the persons who will receive the data, the patient's right to access and correct the data and also the patient's right to object to transmission of the data (as specified by the CNIL). The original will be kept by the investigator and a copy will be given to the patient.
Patients who are eligible to take part in the study and who verbally agree to their data undergoing automated processing (as defined by CNIL), will be included in the study by the physicians, who will enter the corresponding data in the eCRF. The patient agreement will be only verbal and will NOT include the collection of a non-opposition form.
Patient decision to participate or not in the study will be written in his/her medical file by the physician.

4 STUDY POPULATIONS

Three populations will be defined for the analyses:

- Population of Physicians: all the specialists who have included at least one patient meeting the eligibility criteria for the study
- Enrolled Population: all included patients
- Analysis Population: all included patients meeting the inclusion and non-inclusion criteria

5 STATISTICAL METHODOLOGY

The statistical analysis will be performed by ITEC Services - 3 Avenue Georges Clemenceau - 33150 CENON - FRANCE.

5.1 Descriptive statistics

Each modality of qualitative data will be presented with their number and percentage.

For quantitative data, mean, median, minimum and maximum as well as standard deviation and interquartile range will be described.

For all the variables, number of available and missing observations will be specified. If necessary, 95 % CI will also be presented.

Data will be presented using an appropriate number of decimal places (i.e. the number of decimal places used does not imply undue precision):

- Raw data : same number of decimal as collected,
- Derived data: The appropriate number of decimal places will be determined by general practice, mathematical rationale or scientific rationale (e.g. age should be presented in whole numbers),
- Mean, median and standard deviation : reported to one decimal place greater than the raw/derived data that they summarise,
- Minimum and maximum : same precision as the raw data,
- Percentage : one decimal place,
- P-values : four decimal places (e.g.: p=0.0037), after rounding. P-values which are less than 0.0001 will be presented as '<0.0001'.

5.2 Management of missing values

5.2.1 Missing data

Missing data will not be replaced.

5.2.2 Missing or incomplete dates

For all dates

- if only the day part is missing, it will be replaced by 15 (only when date is in format DD/MM/YYYY)
- if only the month part is missing and it is a former date (for example the date of diagnosis), it will be replaced by June
- if the day and month parts are missing and it is a former date (for example the date of diagnosis), day will be replaced by 1 and month will be replaced by July

- if the year part is missing or the complete date is missing, no replacement will be performed and calculation will be considered as missing

5.2.3 Outliers

Any outlier identified prior to database lock which is impossible/implausible will be excluded from the analysis. A search of outliers should be performed before the database lock and actions with the sponsor should be defined (during data review meeting).

5.3 Disposition of patients

Key information of the study (including date of inclusion of the first patient and the last patient, enrollment duration (APPENDIX), number of participating physicians) will be presented.

A flowchart and an associated table will be provided to present overall and by type of physicians who follows the patient

- The number of patients enrolled
- The number of patients not included and their reason for non-inclusion

5.4 Analyses of primary objectives

To describe medical practices in patients with GCA, the following endpoints will be described on the analysis population:

- Patient journey
    - Proportion of each medical speciality of the physician who has referred the patient (General practitioner/ Ophthalmologist / Neurologist/ Emergency/ Internist/ Rheumatologist/Other)

  A listing of Other will be presented.
    - Proportion of each medical speciality of physicians who follows the patient for his/her GCA (Internist/ Rheumatologist/Other)

  A listing of Other will be presented.
    - Time between the first medical events related to GCA and diagnosis (months) (type of diagnosis) described as quantitative variable and as qualitative variable. (Early diagnosis (if < 1month) / Diagnosis in the standard time (if between 1 month and 3 months) / Late diagnosis (if > 3 months)) (APPENDIX)
    - Proportion of patients considered with late diagnosis by the physician who referred the patient (Yes/No)
    - Proportion of patient who encountered each medical speciality since the first events related to GCA (Horton).
    - Number of type of medical specialities encountered by the patient since the first events related to GCA (Horton). If a patient encountered a medical speciality more than one time, this speciality will be counted only once.

The first 2 endpoints will be described overall and by time between first medical events and diagnosis (Early diagnosis/ diagnosis in the standard time/ late diagnosis)
The 1st,3rd and 4th endpoints will be described overall and by type of physicians who follows the patient.

- Diagnostic elements used for GCA diagnosis
    - Proportion of each diagnostic element
        - Signs/symptoms (Yes/No/ intermediate)
        - Erythrocyte Sedimentation Rate (ESR) done (Yes/ No)

    - If yes, contributing to diagnosis (Yes/ No/ intermediate)
  - C-Reactive protein (CRP) done (Yes/ No)
    - If yes, contributing to diagnosis (Yes/ No/ intermediate)
  - Biopsy of the temporal artery (TAB) done (Yes/ No)
    - If yes, contributing to diagnosis (Yes/ No/ intermediate)
  - High resolution color Doppler ultrasound of the temporal arteries done (Yes/ No)
    - If yes, contributing to diagnosis (Yes/ No/ intermediate)
  - MRI scanner of the temporal arteries done (Yes/ No)
    - If yes, contributing to diagnosis (Yes/ No/ intermediate)
  - 18FDG PET positron emission tomography done (Yes/ No)
    - If yes, contributing to diagnosis (Yes/ No/ intermediate)
  - Aortic angiography by CT (angio-CT) done (Yes/ No)
    - If yes, contributing to diagnosis (Yes/ No/ intermediate)
  - Magnetic resonance angiography done (Yes/ No)
    - If yes, contributing to diagnosis (Yes/ No/ intermediate)
  - Other (Yes/No/ intermediate)

A listing of other methods will be presented.

Only diagnostic methods done in the previous month of date of diagnosis, the current month of the day of diagnosis and the month following the date of diagnosis will be considered. The diagnostic methods will be described overall, by time between first medical events related to GCA and diagnosis (qualitative variable), and by type of physicians who follows the patient.

- Previous and ongoing specific GCA treatments since diagnosis other than GCs

  - Number of patients who has taken at least one immunosuppressant since diagnosis and stopped before inclusion and the frequency of each type (Methotrexate, Cyclophosphamide, Cyclosporine, Azathioprine, Mycophenolate Mofetil, Leflunomide, Other) and duration of each treatment taken (months), (APPENDIX)
  - Number of patients with at least one immunosuppressant ongoing at inclusion and frequency of each type (Methotrexate, Cyclophosphamide, Cyclosporine, Azathioprine, Mycophenolate Mofetil , Leflunomide, Other), dose at the initiation (mg), maximal dose (mg), current dose (mg) and duration of each treatment taken (months).(APPENDIX)
  - Number of patients who has taken at least one targeted biological therapy since diagnosis and stopped before inclusion and the frequency of each type (Adalimumab, Etanercept, Abatacept, Tocilizumab, Infliximab, Other) dose at the initiation (mg) and duration of each treatment taken (months) (APPENDIX)
  - Number of patients with at least one targeted biological therapy ongoing at inclusion and the frequency of each type (Adalimumab, Etanercept, Abatacept, Tocilizumab, Infliximab, Other) dose at the initiation current dose and duration of each treatment taken (months) (APPENDIX)

  - Number of patients who has taken at least one other long-term treatment for the medical care of GCA since diagnosis and stopped before inclusion and the frequency of each type (Baricitinib, Dapsone, Hydroxychloroquine, Tofacitinib, Other), dose at the initiation, maximal dose and duration of each treatment taken (months) (APPENDIX))
  - Number of patients with at least one other long-term treatment for the medical care of GCA ongoing at inclusion and the frequency of each type (Baricitinib, Dapsone, Hydroxychloroquine, Tofacitinib, Other) dose at the initiation, maximal dose, current dose and duration of each treatment taken (months) (APPENDIX)

A listing of specifications of other treatments (immunosuppressants, targeted biological therapy, and other long-term treatments) will be presented.

5.5 Analyses of secondary objectives

The analysis of the secondary objectives will be also performed on the analysis population.

5.5.1 Description of comorbidities related to GCs

Current and past comorbidities of GCA patients (comorbidities related to GCs intake) will be coded using the medical dictionary MedDRA®. They will be described by MedDRA SOC and PT overall and by type of physicians who follows the patient.

Among the patients with comorbidities related to GCs intake the number and percentage of patients with at least one ongoing specific treatments(s) will be calculated.
A listing of treatments taken by patients with comorbidities related to GCs will be presented.

5.5.2 Description of GCA characteristics

First the following parameters will be presented:

- Time between diagnosis and inclusion will be described as quantitative variable (months) (APPENDIX)
- Type of patient
    - Proportion of incident patients (newly diagnosed): patients with a diagnosis of GCA ≤ 6 weeks from inclusion
    - Proportion of prevalent patients (not newly diagnosed): patients with a diagnosis of GCA > 6 weeks from inclusion.

Then the following endpoints will be described overall and by type of patient (prevalent/incident), by type of diagnosis (time between the first medical events related to GCA and diagnosis to GCA as qualitative variable in 3 classes early/in standard time/late diagnosis), and by type of physicians who follows the patient.

- Initial presentation:
    - Proportion of patients with at least one cranial manifestation at diagnosis and the proportion of each symptom of this family (Headaches/ Scalp sensitivity / Anomalies of the temporal arteries (temporal artery sensitivity or decreased pulsation) / Ischemia-related vision impairment and-or loss / Mouth pain or jaw claudication during mastication / Stroke or transient ischemic attack (TIA) / Other)

Listing of Ischemia-related vision impairment / loss and other cranial manifestation at diagnosis will be presented.

- Proportion of patients with at least one PMR symptom at diagnosis and the proportion of each symptom of this family (Morning stiffness and-or pain in the shoulder girdle/ Morning stiffness and-or pains in the pelvic girdle/ Inflammatory arthromyalgia/ Peripheral arthritis/ Other)

A listing of other PMR symptom will be presented.

- Proportion of patients with at least one extracranial event (excluding PMR) at diagnosis and the proportion of each symptom of this family (Thoracic or abdominal aortic aneurysm and-or dilatation/ Aortitis and-or involvement of aortic branch(s) in imaging/ Angina and-or Myocardial infraction/ Claudication of an upper limb and-or claudication of a lower limb/ Sign of subclavian stenosis (asymmetry of pulse, blood pressure, subclavian murmur)/ Other)

A listing of other extracranial events (excluding PMR) will be presented.

- Value of ESR (mm/1st h) and CRP (mg/L) at diagnosis and at inclusion.
- Proportion of patients having abnormal value of ESR (ESR>50 mm/h)/CRP (CRP> 25 mg/L) at diagnosis
- Proportion of patients having abnormal value of ESR (ESR>50 mm/h)/CRP CRP> 25 mg/L) at inclusion
- Proportion of patients with at least one general sign at diagnosis and the proportion of each sign (fever>38°C with no other etiology than GCA, weight loss and its value (%), alteration of the general condition)

For the value of ESR and CRP at diagnosis, only value measured in the previous month, the current month and the month following the date of diagnosis will be considered. For values at inclusion, only measures done within 6 month before the date of inclusion will be considered.
A listing of other initial characteristics related to GCA at diagnosis will be presented.

- Clinical form:
  - Proportion of patients with at least one relapse
  - In patient with at least one relapse:
    - Number of relapses per patient
    - Time between first relapse and diagnosis (months) (APPENDIX)
    - Mean time between 2 consecutive relapses (months) (APPENDIX)

  - The following information will be summarized by relapse:
    - Proportion of used criteria to assess relapse (Clinical/ Biological/ Imagery/ Other)
    - Proportion of patients using GCs just before the relapse
    - GCs dose at relapse diagnosis (mg/day)
    - Proportion of relapses of patients with Immunosuppressants just before the relapse
    - Proportion of relapses of patients with Targeted biologic therapy just before the relapse
    - Proportion of relapses of patients using other treatments just before the relapse
    - Proportion of relapses for which Glucocorticoids (GCs) were used as medical care for the relapse
    - GCs dose used for relapse medical care (mg/day)
    - Proportion of relapses for which Immunosuppressants were used as medical care for the relapse
    - Proportion of relapses for which Targeted biologic were used as medical care for relapse
    - Proportion of relapses for which other GCA (HORTON) treatments were used as medical care for relapse.

  - Distribution of GCs dependence
    - Current dose at inclusion (mg/day)
    - Number of kinetics per patient since diagnosis
    - Time between first kinetic and diagnosis (months) (APPENDIX)
    - Proportion of patients with at least one kinetic ongoing at inclusion
    - Mean time between 2 consecutive kinetics (months) (APPENDIX)
    - Total cumulative GCs dose according to investigator (excluding IV bolus) since diagnosis (mg) (APPENDIX)
    - The following information will be summarized by Kinetic:
      - Kinetic duration (months) (APPENDIX)
      - Proportion of kinetics with IV initial administration (bolus) (Yes/No)
        - If yes, total number of days
      - IV bolus dose (mg)
      - Switch PO dose (mg/day)
      - Cumulative dose according to investigator (mg)
      - Proportion of kinetics for which a corticotherapy for GCA (Horton) care has restarted after the kinetic

  - Proportion of patients with at least one GCA complication
  - Proportion of patients with ongoing specific treatment(s) for GCA complications

Current and/or past GCA complications according to the investigator judgment will be coded using the medical dictionary MedDRA®. They will be described by SOC and PT overall and by type of physicians who follows the patient.

To determine the potential factors associated to relapse, a logistic regression will be used. The outcome variable will be relapse (Yes/ No). First, a univariate analysis will be conducted. All significant

factor at the 20% threshold will be selected for a multivariate analysis. A backward elimination procedure will be used with a threshold of 5%.
The associated factors that will be studied are:

- Age (in classes)
- Gender (Male/Female)
- BMI at diagnosis (in classes)
- Smoking status (Smoker/ Former smoker/ Non-smoker ever / Unknown)
- Type of patient (Prevalent or incident)
- Physician who referred the patient (General practitioner/ Ophthalmologist / Neurologist/ Emergency/ Internist/ Rheumatologist/Other),
- Patient considered with late diagnosis by the physician who referred him (Yes/ No)
- Patient considered with late diagnosis according to calculated time interval between the first medical events related to GCA and diagnosis : (Yes/No)
- Patient with at least one cranial GCA symptom at diagnosis (Yes/No),
- Patients with at least one PMR symptom at diagnosis (Yes/No),
- Patient with at least one extracranial GCA symptom at diagnosis (Yes/No),
- Patient with abnormal value of ESR at diagnosis (ESR>50 mm/h)
- Patient with abnormal value of CRP at diagnosis (CRP> 25 mg/L) (Yes/No),
- Patient with fever (>38°C) at diagnosis (Yes/No),
- Patient with weight loss at diagnosis (Yes/No),
- Patient with alteration of the general condition at diagnosis (Yes/No),
- Patient has taken at least one immunosuppressant since diagnosis (Yes/No)
- Patient has taken at least one targeted biological therapy since diagnosis (Yes/No)
- Patient has taken at least one other long-term treatment for the medical care of GCA since diagnosis (Yes/No)
- VAS score (global arteritis activity) by patient (>50mm/≤50mm)
- VAS score (global arteritis activity) by physician (>50mm/≤50mm)
- Cumulative dose of GCs (mg)

- GCA activity

    - Scores of the physician global arteritis activity VAS will be analysed as quantitative variables and in classes (≤ 50 ; > 50 mm).
    - Scores of the patient global arteritis activity VAS will be analysed as quantitative variables and in classes (≤ 50 ; > 50 mm).

The VAS scores of physician and patient will be divided into classes. The same cut-off (≤ 50 ; > 50 mm) for the two scores will be defined by CHUGAI according to their medical relevance.
In this case, the concordance between the scores of the patient and physician global arteritis activity VAS will be evaluated using the kappa K coefficient, which will be interpreted as follows:

- K < 0.0: No match
- 0.0 ≤ K ≤ 0.2 : Poor agreement
- 0.2 < K ≤ 0.4 : Fair agreement
- 0.4< K ≤ 0.6 : Moderate agreement
- 0.6< K ≤ 0.8 : Good agreement
- K >0.8 : Very good agreement

To evaluate the GCA activity, the score of the physician global arteritis activity VAS will be used. For this score a threshold value = 10 mm was defined and validated by CHUGAI.
Patients with physician's VAS score less than or equal to 10 mm will be considered with "non-active GCA", while patients with physician's VAS score greater than 10 mm will be considered with "active GCA".
In this case, the potential associated factors with the increase of the GCA activity will be studied by logistic regression.

The outcome variable will be GCA (active/ Non-active). First, a univariate analysis will be conducted. All significant factor at the 20% threshold will be selected for a multivariate analysis. A backward elimination procedure will be used with a threshold of 5%.
The associated factors that will be studied are:

- Age (in classes)
- Gender (Male/Female)
- BMI at diagnosis (in classes)
- Smoking status (Smoker/ Former smoker/ never smoker/unknown)
- Prevalent or incident patient,
- Physician who referred the patient,
- Patient considered with late diagnosis by the physician who referred him (Yes/ No)
- Patient with at least one cranial GCA symptom at diagnosis (Yes/No),
- Patients with at least one PMR symptom at diagnosis (Yes/No),
- Patient with at least one extracranial GCA symptom at diagnosis (Yes/No),
- Patient with abnormal value of ESR (ESR>50 mm/h) at diagnosis
- Patient with abnormal value of CRP (CRP> 25 mg/L) at diagnosis (Yes/No),
- Patient with fever at diagnosis (Yes/No),
- Patient with weight loss at diagnosis (Yes/No),
- Patient with alteration of the general condition at diagnosis (Yes/No),
- Number of relapses
- Patient has taken at least one immunosuppressants since diagnosis (Yes/No)
- Patient has taken at least one targeted biological therapy since diagnosis (Yes/No)
- Patient has taken at least one other long-term treatment for the medical care of GCA since diagnosis (Yes/No)
- Patient considered with late diagnosis according to calculated time interval between the first medical events related to GCA and diagnosis (Yes/No)
- Cumulative dose of GCs

5.5.3 Description of the health status of GCA patients

The following data will be presented:

- SF-36 questionnaire

The SF-36 is a self-report, 36 item survey measuring health-related quality-of-life. The SF-36 consists of eight scaled scores. A score ranging from 0 (indicating the worse health status) to 100 (indicating the best health status) is assigned for each domain.
Scoring and handling missing data of the SF-36 will be performed by Optium's scoring solution software. This software is provided now with the licence of the SF-36v2 survey and allows to score data from SF36v2 with high accuracy. Only 300 questionnaires with the fewest missing data will be analyzed
In case of double answer or more, the question will be considered as missing data.
The proportion of patients having completed the SF-36 questionnaire will be presented.
Then for patients who have completed SF-36 questionnaire, total scores for each of the eight health domains and psychometrically-based physical component summary (PCS) and mental component summary (MCS) scores will be provided by Optium's scoring solution software.
The score for each item of SF-36 will be presented (as qualitative variables) as well as the total score for each domain (as quantitative variables). Psychometrically-based physical component summary (PCS) and mental component summary (MCS) scores will be also presented as quantitative variables.

- EQ5D-3L questionnaire

The EQ5D-3L consists of five questions relating to five dimensions of health. Respondents indicate which of a possible three statements best describe their current health state for each dimension. Each

dimension has 3 levels: no problems, some problems, extreme problems. Respondents are asked to repeat this process for the five dimensions by indicating one level for each dimension, giving rise to scores ranging from 1 to 3, with scores of 3 on each dimension indicating the most severe impairment. Binary variables will be computed for each dimension dichotomising the levels into 'No problems' (level 1) and 'Problems' (levels 2 and 3). Perceived current health state will be measured by asking respondents to indicate their current health state on a VAS with endpoints labelled 0 'Worst imaginable health state' and 100 'Best imaginable health state.
In case of double answer or more, the question will be considered as missing data.
The proportion of patients having completed the EQ5D-3L questionnaire will be presented.
Then for patients who have completed the EQ5D-3L, the score for each item of EQ5D-3L will be presented (in qualitative variable at 2 and 3 modalities for the 5 dimensions and in quantitative for VAS).

- FACIT-Fatigue

The proportion of patients having completed the FACIT_Fatigue questionnaire will be presented.
In case of double answer, the question will be considered as missing data.
If FACIT_Fatigue questionnaire was completed, the score for each items of FACIT-Fatigue (13 items) will be presented (as qualitative variable) as well as the total score (quantitative variable). (APPENDIX)

5.5.4 Description of physician and patient characteristics

5.5.4.1 Description of physicians

The following physicians' characteristics will be described:

- Gender (Female/ Male)
- Number of years since medical school graduation (APPENDIX)
- Investigator's medical specialty (Internal medicine/ Rheumatologist / Other).

A listing of other specialties will also be provided.

- Number of GCA cases (Horton) personally treated within the last year (prior to the date of inclusion of your first patient) (1-2 / 3-5/ 6-10/ 11-20/ >20)
- Investigator's main activity (University Hospital/ General Services Hospital/ Liberal activity)
- Investigator's activity location (Auvergne-Rhône-Alpes / Bourgogne-Franche-Comté / Bretagne/ Centre-Val de Loire/ Corse / Grand Est / Hauts-de-France / Île-de-France/ Normandie/ Nouvelle-Aquitaine / Occitanie / Pays de la Loire/Provence-Alpes-Côte d'Azur)

5.5.4.2 Description of patients

The following patients' characteristics will be described overall and by type of physician who follows the patient:

- Type of the patient's visit (Outpatient visit/Day hospital/ In-patient hospitalization)
- Age (years) as quantitative variable and in classes ([50 ; 70[/ ≥ 70) (APPENDIX)
- Gender
- Weight at diagnosis (kg)
- Weight at inclusion (kg)
- Height at diagnosis (cm)
- Body mass index (BMI) (kg/m²) at diagnosis (APPENDIX)
- BMI in classes (kg/m²) (<18.5 / [18.5 ; 25[/ [25.0 ; 30[/ ≥ 30) at diagnosis
- Smoking status (Smoker/ Former smoker/ Non-smoker ever / Unknown)
- Significant medical and surgical history and comorbidities (excluding those related / aggravated by the use of glucocorticoids according to the investigator's judgment and complications related to GCA (Horton) according to the investigator's judgment

- Significant medical and surgical history and comorbidities overall by MedDRA System Organ Class (SOC) and Preferred Term (PT)
- Significant medical and surgical history and comorbidities presented before the GCA (HORTON) diagnosis
- Significant medical and surgical history and comorbidities with ongoing specific treatment(s)

A listing of other significant medical and surgical history and comorbidities (excluding those related / aggravated by the use of glucocorticoids according to the investigator's judgment and complications related to GCA (Horton) according to the investigator's judgment) will be presented.

- Treatments administered by the patients at/after diagnosis of GCA (Horton)
  - Proportion of patients taking at least one treatment of Antiplatelets
  - Proportion of patients taking at least one treatment of Statins
  - Proportion of patients taking at least one treatment of Antiosteoporotic
  - Proportion of patients taking at least one treatment of Antihypertensives
  - Proportion of patients taking at least one treatment of Antidiabetics
  - Proportion of patients taking at least one treatment of Inhibitors of the proton pump
  - Proportion of patients taking at least one treatment of Hypnotics
  - Proportion of patients taking at least one treatment of Antidepressants
  - Proportion of patients taking at least one other treatment

- Concomitant treatments administered by the patients at diagnosis of GCA (Horton)
  - Proportion of patients taking at least one treatment of Antiplatelets
  - Proportion of patients taking at least one treatment of Statins
  - Proportion of patients taking at least one treatment of Antiosteoporotic
  - Proportion of patients taking at least one treatment of Antihypertensives
  - Proportion of patients taking at least one treatment of Antidiabetics
  - Proportion of patients taking at least one treatment of Inhibitors of the proton pump
  - Proportion of patients taking at least one treatment of Hypnotics
  - Proportion of patients taking at least one treatment of Antidepressants
  - Proportion of patients taking at least one other treatment

- Concomitant treatments at the out-patient/hospitalization visit of inclusion
  - Proportion of patients taking at least one treatment of the Antiplatelet agents family
  - Proportion of patients taking at least one treatment of Statins family
  - Proportion of patients taking at least one treatment of Antiosteoporotic family
  - Proportion of patients taking at least one treatment of Antihypertensive family
  - Proportion of patients taking at least one treatment of Antidiabetics
  - Proportion of patients taking at least one treatment of Inhibitor(s) of the proton pump
  - Proportion of patients taking at least one treatment of Hypnotics
  - Proportion of patients taking at least one treatment of Antidepressants
  - Proportion of patients taking at least one other treatment

A listing of other treatments will be presented.

5.6 Changes from protocol

Current and past treatments used for comorbidities related to GCs will not be described as mentioned in the protocol regarding to the modifications of the CRF from version 1.2 to version 3.0 according to sponsor's decision. Indeed the dedicated table for specific treatments for comorbidities related to GCs was deleted.
This listing will include all treatments taken by patients with comorbidities related/aggravated by the use of glucocorticoids according to investigator's judgment.

6 INTERIM ANALYSIS

Not applicable

7 COMPUTER SYSTEMS, SOFTWARE AND VALIDATION OF PROGRAMS

7.1 Hardware

The statistical analysis will be performed using Windows 7 professional and a 64-bit operating system.

7.2 Software

All tables, listings and figures will be produced and statistical analysis performed using SAS® version 9.3 or above. All outputs will be edited in Microsoft Word Format.

7.3 Validation of programs

Validations will be done according to the procedure of the CRO ITEC Services.

The program reviewer is responsible for reviewing each project program and output provided to the sponsor. Program logs are reviewed for logical, syntax and fatal errors. The review in SAS® includes, but is not limited to, all ERRORS, WARNINGS, BY-VALUE merge messages, NOTES, and UNINITIALIZED variables. Program logs are also reviewed for accurate and consistent variable and observation counts following each procedure and data step.

The reviewing statistician is responsible for checking and reviewing the work produced using whatever method he/she feels is appropriate (e.g., SAS® code review, hand calculation, etc.) to reassure of the quality of the output.

Outputs are reviewed for typographical errors, misspellings and nonsensical values or results and to check the consistency with the statistical and analysis plan. Outputs are cross-checked against each other for accuracy and consistency. For statistical tables, listings, appendix listings, and figures, this procedure includes comparison of subject group numbers, counts of subjects at each observation point, and consistency of results for variables between outputs.

Findings of the quality control reviews are communicated to the party responsible for making necessary changes. The programs will be retested after modifications.

After final review, and when no further changes are required to produce the deliverable, the program reviewer and the statistician in charge of the study need to complete and sign a validation checklist, to indicate that they have successfully performed all of their responsibilities.

Copies of the internal quality control forms produced for the validation process and the sign-off forms will be provided to the sponsor to support the validation if asked.

7.4 Restitution of the programs

All programs (including Macros and SAS® analysis datasets) producing the tables, listings and statistical output along with associated logs should be given to the sponsor when the tables, listings, figures and statistical analysis has been finalised.

8 STATISTICAL APPENDICES

APPENDIX (Derived data)

The following derived data will be calculated and included in the listings:

(1) **Enrollment duration**

Enrollment duration (days) **=** date of inclusion of the last patient – date of inclusion of the first patient

(2) **Time between first medical events related to GCA and diagnosis**

For prevalent patients (not newly diagnosed):

Time between between first medical events related to GCA and diagnosis (months) **=** date of diagnosis – date of first medical events related to GCA

For incident patient (newly diagnosed):

Time between first medical events related to GCA and diagnosis (months) = date of diagnosis (in MM/YY format) – date of first medical events related to GCA
The date of diagnosis which is in format (DD/MM/YYYY) will be transformed into (MM/YYYY)

(3) **Time between diagnosis and inclusion**

For prevalent patients:

Time between between diagnosis and inclusion (months) **=** (date of inclusion – date of diagnosis)/30.4375

If the date of diagnosis in format (DD/MM/YYYY) is not completed, the diagnosis date in format (MM/YYYY) will be used and the inclusion date will be transformed into (MM/YYYY).

For incident patients:

Time between between diagnosis and inclusion (months) **=** (date of inclusion – date of diagnosis)/30.4375

The date of diagnosis in format (DD/MM/YYYY) will be used.

(4) **Duration of treatment taken**

Duration of treatment taken (months) = End date – start date +1

if ongoing treatment at inclusion:

Duration of treatment taken=Date of inclusion – start date+1

For this calculation, the date of inclusion which is in format (DD/MM/YYYY) will be transformed in to (MM/YYYY) as the start date of treatment.

(5) **Time between first relapse and diagnosis**

Time between first relapse and diagnosis (months) **=** date of first relapse after diagnosis – date of diagnosis.

For this calculation, the date of diagnosis (for incident patient) which is in format (DD/MM/YYYY) will be transformed in to (MM/YYYY) as the date of relapse.

(6) **Mean time between 2 consecutive relapses**

Time between 2 consecutive relapses (months) **=** [date of relapse (i+1) – date of relapse (i)]/(Total number of relapses per patient-1)

(7) **Time between first kinetic and diagnosis**

Time between first kinetic and diagnosis (months) **=** date of initiation of first kinetic – date of diagnosis

For this calculation, the date of diagnosis (for incident patients) which is in format (DD/MM/YYYY) will be transformed in to (MM/YYYY) as the date of kinetic.

(8) **Mean time between 2 consecutive kinetics**

Mean time between 2 consecutive kinetics (months) **=** [date of kinetic (i+1) – date of kinetic (i)]/Total number of kinetics per patient

(9) **Duration of kinetic**

Duration of kinetic (months) **=** Stop date of kinetic – Initiation date of kinetic +1

if ongoing kinetic at inclusion:

Duration of kinetic (months) =Date of inclusion – Initiation date of kinetic +1

For this calculation, the date of inclusion which is in format (DD/MM/YYYY) will be transformed in to (MM/YYYY) as the Initiation date of kinetic.

(10) **Total cumulative GCs dose since diagnosis**

Total cumulative GCs dose (mg) **=** ΣCumulative dose according to the investigator (excluding IV bolus) taken in each kinetic since diagnosis

(11) **Age**

Age (years) = (date of inclusion – birth date)/365.25 and truncated to the lowest whole integer.

(12) **BMI**

BMI (kg/m^2) = Current weight (kg)/ [Height (cm)/100]^2 and rounded to the nearest decimal.

(13) **Number of years since the medical school graduation**

Number of years since graduation (years) = Year of inclusion date – year of medical school graduation

(14) FACIT-Fatigue score

The FACIT-Fatigue is an instrument that measures overall fatigue and its effects on the general functioning and daily activities through 13 questions.
The FACIT-Fatigue is a patient-reported rating scale of 13 items rated from 0 (not at all) to 4 (very much), including 11 negative items with a reversed score for calculating the score:

N° item	Reversed item?	Not at all	A little bit	Some what	Quite a bit	Very much
1	Yes	4	3	2	1	0
2	Yes	4	3	2	1	0
3	Yes	4	3	2	1	0
4	Yes	4	3	2	1	0
5	Yes	4	3	2	1	0
6	Yes	4	3	2	1	0
7	No	0	1	2	3	4
8	No	0	1	2	3	4
9	Yes	4	3	2	1	0
10	Yes	4	3	2	1	0
11	Yes	4	3	2	1	0
12	Yes	4	3	2	1	0
13	Yes	4	3	2	1	0

The total score of FACIT-Fatigue varies from 0 to 52 and is calculated with respect to the items answered:

[(ΣAnswered items scores) / number of items answered] * 13

This calculation method allows for the management of missing data and remains acceptable if more than 50% of the items (i.e. at least 7 items) have been answered[1].
A score of less than 30 indicates severe fatigue. The higher the score, the better the quality of life is.

[1] Webster, K., Cella, D., & Yost, K. (2003). The Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System: properties, applications, and interpretation. Health and Quality of Life Outcomes, 1,79.http://doi.org/10.1186/1477-7525-1-79

9 TABLES AND LISTINGS

9.1 Disposition of patients

Keys information of the study:
- Date of inclusion of the first patient: DD/MM/YYYY
- Date of inclusion of the last patient: DD/MM/YYYY
- Enrollment duration (months): XX months
- Number of participating physicians: XX

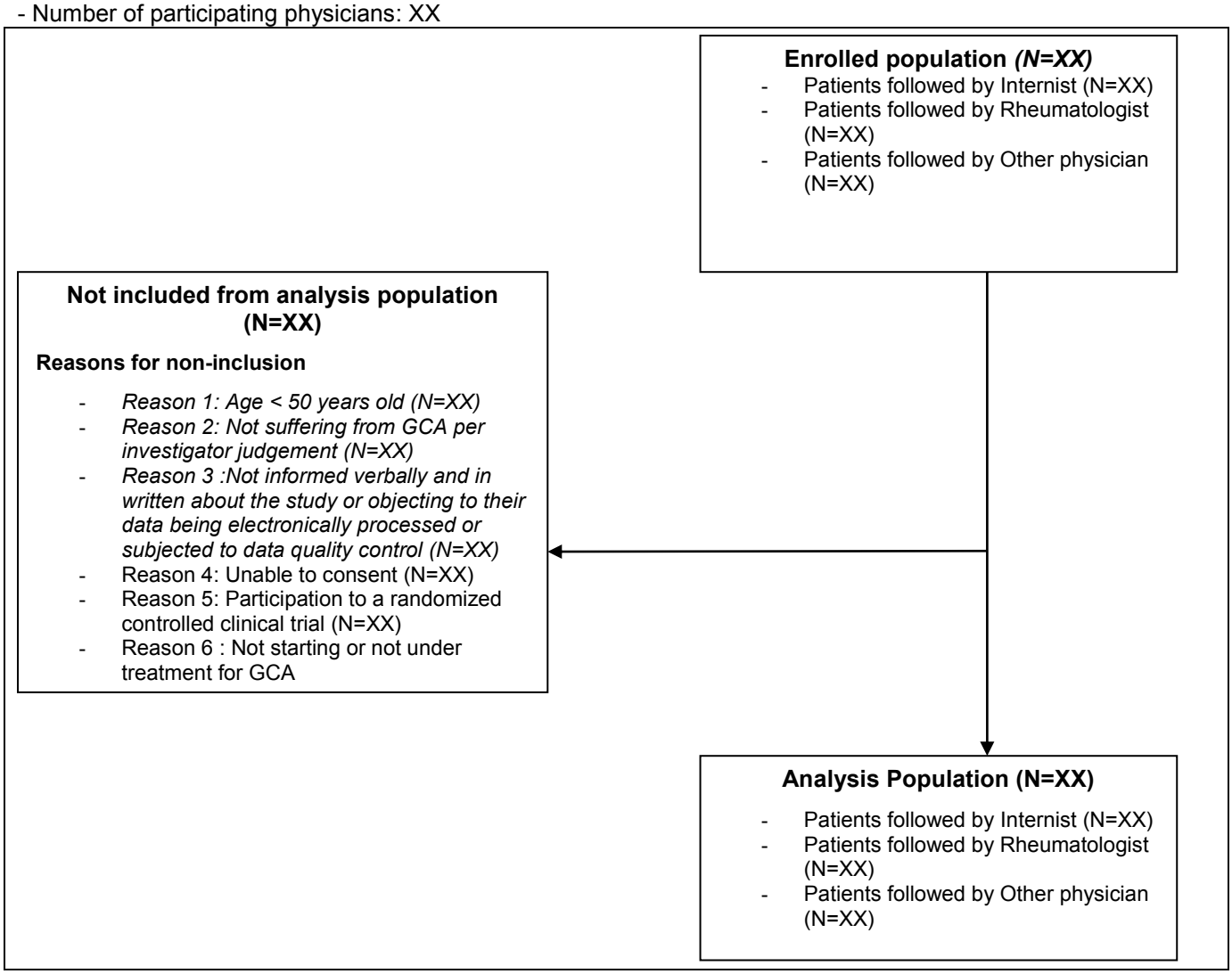

Figure 2: Dispostion of subjects

Table 1 - Subject Disposition - Study populations – Enrolled subjects (N=XX)

Parameter	Statistics	Total *(N=XX)*
Enrolled population		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Analysis population		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Reasons for non-inclusion from analysis population		
Reason 1: Age < 50 years old	*n(%)*	
Reason 2: Not suffering from GCA per investigator judgement	*n(%)*	
Reason 3: Not informed verbally and in written about the study or objecting to their data being electronically processed or subjected to data quality control	*n(%)*	
Reason 4: Unable to consent	*n(%)*	
Reason 5: Participation to a randomized controlled clinical trial	*n(%)*	
Reason 6 : Not starting or not under treatment for GCA	*n(%)*	

The percentages are calculated compared to filled data
STUDY : CHUGAI-ARTEMIS - Edition date: DDMMYY
Pgm : DESCR\DISPO.SAS

9.2 Analyses of primary objectives

Table 2 - Efficacy analysis – Patient journey – Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
Physician who referred the patient		
General practitioner	*n(%)*	
Ophthalmologist	*n(%)*	
Neurologist	*n(%)*	
Emergency	*n(%)*	
Internist	*n(%)*	
Rheumatologist	*n(%)*	
Other	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Physician encountered by the patient since the first events related to GCA*†		
General practitioner	*n(%)*	
Ophthalmologist	*n(%)*	
Neurologist	*n(%)*	
Emergency	*n(%)*	
Internist	*n(%)*	
Rheumatologist	*n(%)*	
Other	*n(%)*	
Number of type medical specialities encountered by the patient since the first events related to GCA†	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Physician who follows the patient for his/her GCA		
Internist	*n(%)*	
Rheumatologist	*n(%)*	
Other	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Time between the first medical events related to GCA and diagnosis*		
Early diagnosis	*n(%)*	
Diagnosis in the standard time	*n(%)*	
Late diagnosis	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Patients considered with late diagnosis by the physician who referred the patient		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	

** Multiple answers possible*
† If a patient encountered a medical speciality more than one time, this speciality will be counted only once
The percentages are calculated compared to filled data
Early diagnosis if time < 1 month
Diagnosis in the standard time if time between 1 and 3 months
Late diagnosis if time > 3 months
STUDY : CHUGAI-ARTEMIS - Edition date: DDMMYY
Pgm : EFFICACY\JOURN.SAS

Listing 1 : Other physician who follow patient (N= XX)

Physician ID	Gender	Specialty	Year of medical school graduation	Number of GCA case personally treated within the last year	Main activity	Location

STUDY : CHUGAI-ARTEMIS - Edition date: DDMMYY
Pgm : EFFICACY\JOURN.SAS

Table 3 - Efficacy analysis – Physicians who referred and follow the patients by time between first medical event related to GCA and diagnosis* – Analysis population (N=XX)

Parameter	Statistics	Early diagnosis (N=XX)	Diagnosis in standard time (N=XX)	Late diagnosis *(N=XX)*
Physician who referred the patient				
General practitioner	*n(%)*			
Ophthalmologist	*n(%)*			
Neurologist	*n(%)*			
Emergency	*n(%)*			
Internist	*n(%)*			
Rheumatologist	*n(%)*			
Other	*n(%)*			
	Filled, n(%)			
	Missing, n(%)			
Physician who follows the patient for his/her GCA				
Internist	*n(%)*			
Rheumatologist	*n(%)*			
Other	*n(%)*			
	Filled, n(%)			
	Missing, n(%)			

Early diagnosis if time < 1 month/ Diagnosis in the standard time if time between 1 and 3 months/Late diagnosis if time > 3 months
The percentages are calculated compared to filled data
STUDY : CHUGAI-ARTEMIS - Edition date: DDMMYY
Pgm : EFFICACY\JOURN.SAS

Table 4 - Efficacy analysis – Time between first medical event related to GCA and diagnosis by type of physicians who follows the patient – Analysis population (N=XX)

Parameter	Statistics	Internist (N=XX)	Rheumatologist (N=XX)	Other *(N=XX)*
Physician who referred the patient	*n(%)*			
General practitioner	*n(%)*			
Ophthalmologist	*n(%)*			
Neurologist	*n(%)*			
Emergency	*n(%)*			
Internist	*n(%)*			
Rheumatologist	*n(%)*			
Other	*n(%)*			
	Filled, n(%)			
	Missing, n(%)			
Time between the first medical events related to GCA and diagnosis*	*n(%)*			
Early diagnosis	*n(%)*			
Diagnosis in standard time	*n(%)*			
Late diagnosis	*n(%)*			
	n(%)			
	n(%)			
Patients considered with late diagnosis by the physician who referred the patient				
No	*n(%)*			
Yes	*n(%)*			
	Filled, n(%)			
	Missing, n(%)			

Early diagnosis if time < 1 month
Diagnosis in the standard time if time between 1 and 3 months
Late diagnosis if time > 3 months
The percentages are calculated compared to filled data
STUDY : CHUGAI-ARTEMIS - Edition date: DDMMYY
Pgm : EFFICACY\JOURN.SAS

Table 5 - Efficacy analysis – Diagnostic elements used for GCA diagnosis – Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
Signs/symptoms		
Yes	*n(%)*	
No	*n(%)*	
Intermediate	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Erythrocyte Sedimentation Rate (ESR) done		
Yes	*n(%)*	
No	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
If Yes, contributing to the diagnosis		
Yes	*n(%)*	
No	*n(%)*	
Intermediate	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
C-Reactive protein (CRP) done		
Yes	*n(%)*	
No	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
If Yes, contributing to the diagnosis		
Yes	*n(%)*	
No	*n(%)*	
Intermediate	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Biopsy of the temporal artery (TAB) done		
Yes	*n(%)*	
No	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
If Yes, contributing to the diagnosis		
Yes	*n(%)*	
No	*n(%)*	
Intermediate	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
High resolution color Doppler ultrasound of the temporal arteries done		
Yes	*n(%)*	
No	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
If Yes, contributing to the diagnosis		
Yes	*n(%)*	
No	*n(%)*	
Intermediate	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
MRI scanner of the temporal arteries done		
Yes	*n(%)*	
No	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
If Yes, contributing to the diagnosis		
Yes	*n(%)*	

Table 5 - Efficacy analysis – Diagnostic elements used for GCA diagnosis – Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
No	*n(%)*	
Intermediate	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
18FDG positron emission tomography (PET) done		
Yes	*n(%)*	
No	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
If Yes, contributing to the diagnosis		
Yes	*n(%)*	
No	*n(%)*	
Intermediate	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Aortic angiography by CT (angio-CT) done		
Yes	*n(%)*	
No	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
If Yes, contributing to the diagnosis		
Yes	*n(%)*	
No	*n(%)*	
Intermediate	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Magnetic resonance angiography done		
Yes	*n(%)*	
No	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
If Yes, contributing to the diagnosis		
Yes	*n(%)*	
No	*n(%)*	
Intermediate	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Other diagnostic method		
Yes	*n(%)*	
No	*n(%)*	
Intermediate	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	

The percentages are calculated compared to filled data
STUDY : CHUGAI-ARTEMIS - Edition date: DDMMYY
Pgm : EFFICACY\JOURN.SAS

The same table will be presented by type of diagnosis (Early /in standard time/late) and by type of physicians who follows the patient.

Listing 2 : Other diagnostic elements used for GCA diagnosis (N= XX)

Patient ID	Newly /not newly diagnosed patient	Type of diagnosis	Physician who follows the patient	Date of used diagnostic element	Other diagnostic element	Contribution to the diagnosis

STUDY : CHUGAI-ARTEMIS - Edition date: DDMMYY
Pgm : EFFICACY\JOURN.SAS

Table 6 - Efficacy analysis – Immunosuppressants for GCA taken since diagnosis and stopped before inclusion – Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
Patient has taken at least one immunosuppressants since diagnosis and stopped before inclusion		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
IF YES		
Used immunosuppressants		
Azathioprine	*n(%)*	
Cyclophosphamide	*n(%)*	
Cyclosporine	*n(%)*	
Leflunomide	*n(%)*	
Methotrexate	*n(%)*	
Mycophenolate Mofetil	*n(%)*	
Other	*n(%)*	
IF Azathioprine		
Duration of treatment (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]*	

Table 6 - Efficacy analysis – Immunosuppressants for GCA taken since diagnosis and stopped before inclusion – Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
	Filled, n(%)	
	Missing, n(%)	
If *Cyclophosphamide*		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
IF Cyclosporine		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
If *Leflunomide*		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
If *Methotrexate*		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
If *Mycophenolate Mofetil*		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	

The percentages are calculated compared to filled data
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Table 7 - Efficacy analysis – Immunosuppressants for GCA ongoing at inclusion – Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
Patient with at least one immunosuppressants ongoing at inclusion		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	

Table 7 - Efficacy analysis – Immunosuppressants for GCA ongoing at inclusion – Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
IF YES		
Used immunosuppressants		
Azathioprine	*n(%)*	
Cyclophosphamide	*n(%)*	
Cyclosporine	*n(%)*	
Leflunomide	*n(%)*	
Methotrexate	*n(%)*	
Mycophenolate Mofetil	*n(%)*	
Other	*n(%)*	
IF Azathioprine		
Duration of treatment (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
If *Cyclophosphamide*		
Duration of treatment (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
IF Cyclosporine		
Duration of treatment (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
If *Leflunomide*		
Duration of treatment (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
If *Methotrexate*		
Duration of treatment (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
If *Mycophenolate Mofetil*		
Duration of treatment (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	

The percentages are calculated compared to filled data
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Table 8 - Efficacy analysis – Targeted biologic therapy for GCA taken since diagnosis and stopped before inclusion – Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
Patient has taken at least one targeted biologic therapy since diagnosis and stopped before inclusion		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
IF YES		
Used targeted biologic therapy		
Abatacept	*n(%)*	
Adalimumab	*n(%)*	
Etanercept	*n(%)*	
Infliximab	*n(%)*	
Tocilizumab	*n(%)*	
Other	*n(%)*	
IF Abatacept		
Duration of treatment (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
IF Adalimumab		
Duration of treatment (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
IF Etanercept		
Duration of treatment (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
IF Infliximab		
Duration of treatment (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
If *Tocilizumab*		
Duration of treatment (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	

The percentages are calculated compared to filled data
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Table 9 - Efficacy analysis – Targeted biologic therapy for GCA ongoing at inclusion – Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
Patient with targeted biologic therapy ongoing at inclusion		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
IF YES		
Used targeted biologic therapy		
Abatacept	*n(%)*	
Adalimumab	*n(%)*	
Etanercept	*n(%)*	
Infliximab	*n(%)*	
Tocilizumab	*n(%)*	
Other	*n(%)*	
IF Abatacept		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
IF Adalimumab		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
IF Etanercept		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
IF Infliximab		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
If *Tocilizumab*		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	

The percentages are calculated compared to filled data
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Table 10 - Efficacy analysis – Other long-term treatments for GCA taken since diagosis and stopped before inclusion – Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
Patient has taken at least one long-term treatment since diagnosis and stopped before inclusion		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
IF YES		
Used long-term treatment		
Baricitinib	*n(%)*	
Dapsone	*n(%)*	
Hydroxychloroquine	*n(%)*	
Tofacitinib	*n(%)*	
Other	*n(%)*	
IF Baricitinib		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
IF Dapsone		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
IF Hydroxychloroquine		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
If *Tofacitinib*		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	

The percentages are calculated compared to filled data
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Table 11 - Efficacy analysis – Other long-term treatments for GCA ongoing at inclusion – Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
Patient with at least one long-term treatment ongoing at inclusion		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
IF YES		
Used long-term treatment		
Baricitinib	*n(%)*	
Dapsone	*n(%)*	
Hydroxychloroquine	*n(%)*	
Tofacitinib	*n(%)*	
Other	*n(%)*	
IF Baricitinib		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
IF Dapsone		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
IF Hydroxychloroquine		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
If *Tofacitinib*		
Duration of treatment (months)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	

The percentages are calculated compared to filled data
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Listing 3 : Other previous and ongoing specific GCA treatments excluding GCs (N= XX)

Patient ID	Newly /not newly diagnosed patient	Type of diagnosis	Physician who follows the patient	Family of treatment	Specification of treatment	Start date	End date	Ongoing	Date of inclusion	Current dose	Dose at initiation	Maximal dose	Duration of treatment (months)

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9.3 Analyses of secondary objectives

9.3.1 Description of comorbidities related to GCs and associated treatment

Table 12 - Efficacy analysis – Comorbidities related/ aggravated by the use of GCs according to the investigator's judgment by MedDRA SOC and PT – Analysis population (N=XX)

System Organ Class Preferred Term	**Total** *(N=XX)*	
	# Patients (%)	# MHs (%)
Patients with at least one comorbidity related/aggravated by GCs use		
Number of medical and surgical history and comorbidities		
SOC1		
PT1.1		
PT1.2		
...		
SOC2		
PT2.1		
PT2.2		
…		
…		

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 # Patients (%): Number of patients (percentages with number of patients as reference)
 # MHs (%): Number of medical/surgical history and comorbidities (multiple occurrences of the same medical/ surgical history or comorbidities in one patient are counted multiple times) (percentages with number of medical / surgical history events or comorbidities as reference)
The same table will be presented according to the type of physicians who follows the patient.

Table 13 - Efficacy analysis – Ongoing specific treatments for patients with comorbidities related to the use of GCs - Patients with comorbidities related to the use of GCs (N=XX)

Parameter	**Statistics**	**Total** ***(N=XX)***
Patients with at least one ongoing specific treatments for comorbidities related to the use of GCs		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	

The percentages are calculated compared to filled data
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9.3.2 Description of GCA characteristics

Table 14 - Efficacy analysis – Description of GCA characteristics - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
Time between diagnosis and inclusion (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Type of patient *		
Incident	*n(%)*	
Prevalent	*n(%)* ***Filled, n(%)*** ***Missing, n(%)***	

**Incident if diagnosis of GCA ≤6 weeks from inclusion*
Prevalent if diagnosis of GCA >6 weeks from inclusion
The percentages are calculated compared to filled data
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Table 15 - Efficacy analysis – Initial presentation of GCA - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
Patient with at least one cranial manifestation at diagnosis		
No	*n(%)*	
Yes	*n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
Cranial manifestation*		
Headaches	*n(%)*	
Scalp sensitivity	*n(%)*	
Anomalies of the temporal arteries	*n(%)*	
Ischemia-related vision impairment and-or loss	*n(%)*	
Mouth pain or jaw claudication during mastication	*n(%)*	
Ischemia-related vision impairment and-or loss	*n(%)*	
Stroke or transient ischemic attack (TIA)	*n(%)*	
Other	*n(%)*	
Patient with at least one PMR symptom at diagnosis		
No	*n(%)*	
Yes	*n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
PMR symptom *		
Morning stiffness and-or pain in the shoulder girdle	*n(%)*	
Morning stiffness and-or pains in the pelvic girdle	*n(%)*	
Inflammatory arthromyalgia	*n(%)*	
Peripheral arthritis/	*n(%)*	
Other	*n(%)*	
Patient with at least one extracranial event (excluding PMR) at diagnosis		
No	*n(%)*	
Yes	*n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
Extracranial event (excluding PMR)*		
Thoracic or abdominal aortic aneurysm and-or dilatation	*n(%)*	
Aortitis and-or involvement of aortic branch(s) in imaging	*n(%)*	
Angina and-or Myocardial infraction	*n(%)*	
Claudication of an upper limb and-or claudication of a lower limb	*n(%)*	
Sign of subclavian stenosis	*n(%)*	

Table 15 - Efficacy analysis – Initial presentation of GCA - Analysis population (N=XX)

Parameter	Statistics	Total (N=XX)
Other	*n(%)*	
Value of ESR (mm/1st h) at diagnosis	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Value of ESR (mm/1st h) at diagnosis in classes *≤50 mm/h* *>50mm/h*	 *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
Value of ESR (mm/1st h) at inclusion	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Value of ESR (mm/1st h) at inclusion in classes *≤50 mm/h* *>50mm/h*	 *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
Value of CRP (mg/L) at diagnosis	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Value of CRP (mg/L) at diagnosis in classes *≤25 mg/L* *>25 mg/L*	 *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
Value of CRP (mg/L) at inclusion	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Value of CRP (mg/L) at inclusion in classes *≤25 mg/L* *>25 mg/L*	 *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
Patient with at least one general signe at diagnosis *No* *Yes*	 *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
Clinical signs and symptoms* *Fever>38°C* *Weight loss* *Alteration of the general condition*	 *n(%)* *n(%)* *n(%)*	
If weight loss: value of weight loss (%)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)***	

Table 15 - Efficacy analysis – Initial presentation of GCA - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
	Missing, n(%)	

** multiple response possible*
PMR : PolyMyalgia Rheumatica
ESR : Erythrocyte Sedimentation Rate
CRP : C Reactive Protein
The percentages are calculated compared to filled data
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This table will be presented by type of patient (prevalent/incident), by type of diagnosis and the physician who follows the patient.

Listing 4 : Specification of Ischemia-related vision impairment / loss at diagnosis (N= XX)

Patient ID	Type of patient	Type of diagnosis	Physician who follows the patient	Specification of Ischemia-related vision impairment/loss

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Listing 5 : Specification of other cranial manifestation at diagnosis (N= XX)

Patient ID	Type of patient	Type of diagnosis	Physician who follows the patient	Specification of other cranial manifestation

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Listing 6 : Specification of other PMR symptom at diagnosis (N= XX)

Patient ID	Type of patient	Type of diagnosis	Physician who follows the patient	Specification of other PMR symptom

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Listing 7 : Specification of other extracranial events (excluding PMR) at diagnosis (N= XX)

Patient ID	Type of patient	Type of diagnosis	Physician who follows the patient	Specification of other extracranial events

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Listing 8 : Specification of other initial characteristics related to GCA at diagnosis (N= XX)

Patient ID	Type of patient	Type of diagnosis	Physician who follows the patient	Specification of other initial characteristics related to GCA

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Table 16 - Efficacy analysis – Clinical Form - Number of relapses and time between relapses and diagnosis per patient - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
Patient with at least one relapse *No* *Yes*	 *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
In patients with at least one relapse		
Number of relapses per patient	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Time between first relapse and diagnosis (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Mean time between 2 consecutive relapses (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	

The percentages are calculated compared to filled data
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Table 17 - Efficacy analysis – Clinical Form - Description of relapses - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX relapses)*
Used criteria to assess relapse*		
Clinical	*n(%)*	
Biological	*n(%)*	
Imagery	*n(%)*	
Other	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Patient using GCs therapy just before relapse		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
GCs dose at relapse (mg/day)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
Patients with immunosuppressants just before the relapse		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Patients with targeted biologic therapy just before the relapse		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Patients using other treatments just before the relapse		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Relapse for which GCs were used for the medical care of relapse		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
GCs dose used (mg/day)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
Relapse for which immunosuppressants were used for the medical care of relapse		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Relapse for which targeted biologic therapy was used for the medical care of relapse		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Relapse for which other GCA (Horton) treatments were used for the medical care of relapse		

Table 17 - Efficacy analysis – Clinical Form - Description of relapses - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX relapses)*
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	

** Multiple responses possible*
The percentages are calculated compared to filled data
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Listing 9 : Specification of other treatments used just before relapse (N= XX)

Patient ID	Number of relapse	Type of patient	Type of diagnosis	Physician who follows the patient	Specification of other treatments used just before relapse

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Listing 10 : Specification of other treatments used for the medical care of relapse (N= XX)

Patient ID	Number of relapse	Type of patient	Type of diagnosis	Physician who follows the patient	Specification of other treatments used as medical care for relapse

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Table 18 - Efficacy analysis – Clinical Form - Distribution of GCs dependance - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
Current GCs dose at inclusion (mg/day)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Number of kinetics per patient since diagnosis	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Time between first kinetic and diagnosis (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Patient with at least one kinetic ongoing at inclusion *No* *Yes*	 *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
Mean time between 2 consecutive kinetics (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Total cumulative GCs dose according to investigator (excluding IV bolus) since diagnosis (mg)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	

The percentages are calculated compared to filled data
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Table 19 - Efficacy analysis – Clinical Form - Description of Corticotherapy (per kinetic) - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX kinetics)*
Kinetic duration (months)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Kinetic with IV initial administration (bolus) *No* *Yes*	 *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
If yes, Total number of days	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
IV bolus dose (mg)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Switch PO dose (mg/day)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Cumulative dose according to investigator (mg)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Kinetics for which a corticotherapy for GCA (Horton) care has restarted after the kinetic *No* *Yes*	 *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	

IV : Intravenous PO : Per Oral
The percentages are calculated compared to filled data
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Pgm : EFFICACY\GCA.SAS

Table 20 - Efficacy analysis – Clinical Form - GCA complications - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
Patient with at least one GCA complication		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
If yes, Patient with ongoing specific treatment(s) for GCA complications		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	

The percentages are calculated compared to filled data
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Table 21 - Efficacy analysis – Complications related to GCA according to the investigator's judgment by MedDRA SOC and PT – Analysis population (N=XX)

System Organ Class Preferred Term	**Total** *(N=XX)*	
	# Patients (%)	# Comps (%)
Patients with at least one complication related to GCA		
Number of complications related to GCA		
SOC1		
PT1.1		
PT1.2		
...		
SOC2		
PT2.1		
PT2.2		
…		
…		

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 # Patients (%): Number of patients (percentages with number of patients as reference)
 # Comps (%): Number of complications (multiple occurrences of the same complication in one patient are counted multiple times) (percentages with number of complications as reference)

This table will be presented also by type of physicians who follows the patient.

Table 22 - Efficacy analysis – Univariate analysis* of the effect of the patients characteristics on the relapse (outcome variable : at least one relapse / no relapse) – Analysis population (N=XX)

Parameter	OR [CI 95%]	pvalue
Age in classes		x.xxxx
[50 – 70[(reference)	1.00	
≥ 70 years	X.XX [X.XX ; X.XX]	
Gender		…
Male (reference)	…	
Female	…	
BMI in classes (kg/m²)		
Normal (BMI between [18.5-25[) (reference)		
Under weight (BMI <18.5)		
Over weight (BMI between [25.0 ; 30[)		
Obesity (BMI ≥ 30)		
Smoking status		
Non-smoker ever (reference)		
Former smoker		
Smoker		
Unknown		
Type of patient		
Prevalent (reference)		
Incident		
Physician who referred the patient		
General practitioner (reference)		
Ophthalmologist		
Neurologist		
Emergency		
Internist		
Rheumatologist		
Other		
Patient considered with late diagnosis by the physician who referred him		
No (reference)		
Yes		
Patient considered with late diagnosis according to time between first symptom and diagnosis		
No (reference)		
Yes		
Patient with at least one cranial GCA symptom at diagnosis		
No (reference)		

Table 22 - Efficacy analysis – Univariate analysis* of the effect of the patients characteristics on the relapse (outcome variable : at least one relapse / no relapse) – Analysis population (N=XX)

Parameter	OR [CI 95%]	pvalue
Yes		
Patient with at least one PMR symptom at diagnosis		
No (reference)		
Yes		
Patient with at least one extracranial GCA symptom at diagnosis		
No (reference)		
Yes		
Patient with abnormal value of ESR at diagnosis (ESR>50 mm/h)		
No (reference)		
Yes		
Patient with abnormal value of CRP at diagnosis (CRP> 25 mg/L)		
No (reference)		
Yes		
Patient with fever (> 38°C) at diagnosis		
No (reference)		
Yes		
Patient with weight loss at diagnosis		
No (reference)		
Yes		
Patient with alteration of the general condition at diagnosis		
No (reference)		
Yes		
Patient has taken at least one immunosuppressants since diagnosis		
No (reference)		
Yes		
Patient has taken at least one targeted biological therapy since diagnosis		
No (reference)		
Yes		
Patient has taken at least one other long-term treatment since diagnosis		
No (reference)		
Yes		
VAS score of the patient		
<50 mm (reference)		
>50 mm		

Table 22 - Efficacy analysis – Univariate analysis* of the effect of the patients characteristics on the relapse (outcome variable : at least one relapse / no relapse) – Analysis population (N=XX)

Parameter	OR [CI 95%]	pvalue
VAS score of the physician		
≤ 50 mm (reference)		
>50 mm		
Cumulative dose of GCs (or in classes that will be defined according to the distribution of this variable)		

PMR : PolyMyalgia Rheumatica
ESR : Erythrocyte Sedimentation Rate
CRP : C Reactive Protein
OR : Odd ratio
CI : Confidence interval
VAS : Visual Analog Scale
GCs : GlucoCorticoids

**Univariate logistic regression*
The percentages are calculated compared to filled data
STUDY : CHUGAI-ARTEMIS - Edition date: DDMMYY
Pgm : EFFICACY\GCA.SAS

Table 23 - Efficacy analysis – Multivariate analysis* of the effect of the patients characteristics on the relapse (outcome variable : at least one relapse / no relapse) – Analysis population (N=XX)

Parameter	Complete model		Backward elimination**	
	OR [CI 95%]	pvalue	OR [CI 95%]	pvalue
Variable 1				x.xxxx
XXX (reference)	1.00			
XX	X.XX [X.XX ; X.XX]			
Variable 2				x.xxxx
XXX (reference)	1.00			
XX	X.XX [X.XX ; X.XX]			
……				

**Multivariate logistic regression on the significant variables at 20% in the univariate analysis*
*** Model after backward elemination at 5%*
The percentages are calculated compared to filled data
STUDY : CHUGAI-ARTEMIS - Edition date: DDMMYY
Pgm : EFFICACY\GCA.SAS

Table 24 - Efficacy analysis – GCA activity (VAS score) - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
VAS score of the patient	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
VAS score of the patient (in classes) *≤ 50 mm* *> 50 mm*	 *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
VAS score of the physician	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
VAS score of the physician (in classes) *≤ 50 mm* *> 50 mm*	 *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	

VAS : Visual Analog Scale
The percentages are calculated compared to filled data
STUDY : CHUGAI-ARTEMIS - Edition date: DDMMYY
Pgm : EFFICACY\GCA.SAS

Table 25 - Efficacy analysis - Agreement between VAS of the patient and the physician - Analysis population (N=XX)

		VAS of the physician	
Parameter	**Statistics**	*≤ 50 mm (N=XX)*	>50 mm *(N=XX)*
VAS of the patient *≤ 50 mm* *> 50 mm*	 *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***		
Kappa coefficient **P-value**			

VAS : Visual Analog Scale
The percentages are calculated compared to filled data
STUDY : CHUGAI-ARTEMIS - Edition date: DDMMYY
Pgm : EFFICACY\GCA.SAS

Table 26 - Efficacy analysis – Univariate analysis* of the effect of the patients characteristics on the GCA activity (VAS> 10mm) (outcome variable : GCA active / non-active) – Analysis population (N=XX)

Parameter	OR [CI 95%]	pvalue
Age in classes		x.xxxx
[50 – 70[(reference)	1.00	
≥ 70 years	X.XX [X.XX ; X.XX]	
Gender		…
Male (reference)	…	
Female	…	
BMI in classes (kg/m²)		
Normal (BMI between [18.5-25[) (reference)		
Under weight (BMI <18.5)		
Over weight (BMI between [25.0 ; 30[)		
Obesity (BMI ≥ 30)		
Smoking status		
Non-smoker ever (reference)		
Former smoker		
Smoker		
Unknown		
Type of patient		
Incident (reference)		
Prevalent		
Physician who referred the patient		
General practitioner (reference)		
Ophthalmologist		
Neurologist		
Emergency		
Internist		
Rheumatologist		
Other		
Patient considered with late diagnosis by the physician who referred him		
No (reference)		
Yes		
Patient considered with late diagnosis according to time between first symptom and diagnosis		
No (reference)		
Yes		
Patient with at least one cranial GCA symptom at diagnosis		
No (reference)		
Yes		

Table 26 - Efficacy analysis – Univariate analysis* of the effect of the patients characteristics on the GCA activity (VAS> 10mm) (outcome variable : GCA active / non-active) – Analysis population (N=XX)

Parameter	OR [CI 95%]	pvalue
Patient with at least one PMR symptom at diagnosis		
No (reference)		
Yes		
Patient with at least one extracranial GCA symptom at diagnosis		
No (reference)		
Yes		
Patient with abnormal value of ESR at diagnosis (ESR>50 mm/h)		
No (reference)		
Yes		
Patient with abnormal value of CRP at diagnosis (CRP> 25 mg/L)		
No (reference)		
Yes		
Patient with fever at diagnosis		
No (reference)		
Yes		
Patient with weight loss at diagnosis		
No (reference)		
Yes		
Patient with alteration of the general condition at diagnosis		
No (reference)		
Yes		
Patient has taken at least one immunosuppressants since diagnosis		
No (reference)		
Yes		
Patient has taken at least one targeted biological therapy since diagnosis		
No (reference)		
Yes		
Patient has taken at least one other long-term treatment since diagnosis		
No (reference)		
Yes		
Cumulative dose of GCs (or in classes that will be defined according to the distribution of this variable)		

**Univariate logistic regression*
The percentages are calculated compared to filled data
STUDY : CHUGAI-ARTEMIS - Edition date: DDMMYY
Pgm : EFFICACY\GCA.SAS

Table 27 - Efficacy analysis – Multivariate analysis* of the effect of the patients characteristics on the GCA activity (VAS>10 mm) (outcome variable : GCA active / non-active) – Analysis population (N=XX)

Parameter	Complete model		Backward elimination**	
	OR [IC95%]	pvalue	OR [CI 95%]	pvalue
Variable 1				x.xxxx
XXX (reference)	1.00			
XX	X.XX [X.XX ; X.XX]			
Variable 2				x.xxxx
XXX (reference)	1.00			
XX	X.XX [X.XX ; X.XX]			
.....				

**Multivariate logistic regression on the significant variables at 20% in the univariate analysis*
*** Model after backward stepwise (backward elemination) at 5%*
The percentages are calculated compared to filled data
STUDY : CHUGAI-ARTEMIS - Edition date: DDMMYY
Pgm : EFFICACY\GCA.SAS

9.3.3 Description of the health status of GCA patients

Table 28 - Descriptive analysis - SF-36 Quality of life questionnaire- Analysis population (N=XX)

Parameter	Statistics	Total
Q1. In general, would you say your health is:		
Excellent	*n(%)*	
Very good	*n(%)*	
Good	*n(%)*	
Fair	*n(%)*	
Poor	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q2. Compared to one year ago, would you rate your health in general is :		
Much better now than one year ago	*n(%)*	
Somewhat better now than one year ago	*n(%)*	
About the same	*n(%)*	
Somewhat worse now than one year ago	*n(%)*	
Much worse than one year ago	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Physical functioning: **The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?**		
Q3a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports		
Yes, Limited a Lot	*n(%)*	
Yes, Limited a Little	*n(%)*	
No, Not limited at All	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q3b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf		
Yes, Limited a Lot	*n(%)*	
Yes, Limited a Little	*n(%)*	
No, Not limited at All	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q3c. Lifting or carrying groceries		
Yes, Limited a Lot	*n(%)*	
Yes, Limited a Little	*n(%)*	
No, Not limited at All	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q3d. Climbing several flights of stairs		
Yes, Limited a Lot	*n(%)*	
Yes, Limited a Little	*n(%)*	
No, Not limited at All	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q3e. Climbing one flight of stairs		
Yes, Limited a Lot	*n(%)*	
Yes, Limited a Little	*n(%)*	
No, Not limited at All	*n(%)*	
	Filled, n(%)	

Table 28 - Descriptive analysis - SF-36 Quality of life questionnaire- Analysis population (N=XX)

	Missing, n(%)	
Q3f. Bending, kneeling, or stooping		
Yes, Limited a Lot	*n(%)*	
Yes, Limited a Little	*n(%)*	
No, Not limited at All	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q3g. Walking more than a mile		
Yes, Limited a Lot	*n(%)*	
Yes, Limited a Little	*n(%)*	
No, Not limited at All	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q3h. Walking several blocks		
Yes, Limited a Lot	*n(%)*	
Yes, Limited a Little	*n(%)*	
No, Not limited at All	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q3i. Walking one block		
Yes, Limited a Lot	*n(%)*	
Yes, Limited a Little	*n(%)*	
No, Not limited at All	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q3j. Bathing or dressing yourself		
Yes, Limited a Lot	*n(%)*	
Yes, Limited a Little	*n(%)*	
No, Not limited at All	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q4a. Cut down the amount of time you spent on work or other activities		
All of the time	*n(%)*	
Most of the time	*n(%)*	
Some of the time	*n(%)*	
A little of the time	*n(%)*	
None of the time	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q4b. Accomplished less than you would like		
All of the time	*n(%)*	
Most of the time	*n(%)*	
Some of the time	*n(%)*	
A little of the time	*n(%)*	
None of the time	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q4c. Were limited in the kind **of work or other activities**		
All of the time	*n(%)*	
Most of the time	*n(%)*	
Some of the time	*n(%)*	
A little of the time	*n(%)*	
None of the time	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q4d. Had difficulty performing the work or other activities (for example, it took extra effort)		
All of the time	*n(%)*	
Most of the time	*n(%)*	
Some of the time	*n(%)*	
A little of the time	*n(%)*	
None of the time	*n(%)*	

Table 28 - Descriptive analysis - SF-36 Quality of life questionnaire- Analysis population (N=XX)

	Filled, n(%) ***Missing, n(%)***	
Emotional role functioning: **During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**		
Q5a. Cut down the amount of time you spent on work or other activities		
All of the time	*n(%)*	
Most of the time	*n(%)*	
Some of the time	*n(%)*	
A little of the time	*n(%)*	
None of the time	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q5b. Accomplished less than you would like		
All of the time	*n(%)*	
Most of the time	*n(%)*	
Some of the time	*n(%)*	
A little of the time	*n(%)*	
None of the time	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q5c. Didn't do work or other activities as carefully as usual		
All of the time	*n(%)*	
Most of the time	*n(%)*	
Some of the time	*n(%)*	
A little of the time	*n(%)*	
None of the time	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?		
Not at all	*n(%)*	
Slightly	*n(%)*	
Moderately	*n(%)*	
Quite a bit	*n(%)*	
Extremely	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q7. How much bodily pain have you had during the past 4 weeks?		
None	*n(%)*	
Very mild	*n(%)*	
Mild	*n(%)*	
Moderate	*n(%)*	
Severe	*n(%)*	
Very severe	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?		
Not at all	*n(%)*	
A little bit	*n(%)*	
Moderately	*n(%)*	
Quite a bit	*n(%)*	
Extremely	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q9a. Did you feel full of pep?		
All of the time	*n(%)*	
Most of the time	*n(%)*	
A good bit of the time	*n(%)*	

Table 28 - Descriptive analysis - SF-36 Quality of life questionnaire- Analysis population (N=XX)

Some of the time	*n(%)*	
A little of the time	*n(%)*	
None of the time	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q9b. Have you been a very nervous person?		
All of the time	*n(%)*	
Most of the time	*n(%)*	
Some of the time	*n(%)*	
A little of the time	*n(%)*	
None of the time	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q9c. Have you felt so down in the dumps that nothing could cheer you up?		
All of the time	*n(%)*	
Most of the time	*n(%)*	
Some of the time	*n(%)*	
A little of the time	*n(%)*	
None of the time	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q9d. Have you felt calm and peaceful?		
All of the time	*n(%)*	
Most of the time	*n(%)*	
Some of the time	*n(%)*	
A little of the time	*n(%)*	
None of the time	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q9e. Did you have a lot of energy?		
All of the time	*n(%)*	
Most of the time	*n(%)*	
A good bit of the time	*n(%)*	
Some of the time	*n(%)*	
A little of the time	*n(%)*	
None of the time	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q9f. Have you felt downhearted and blue?		
All of the time	*n(%)*	
Most of the time	*n(%)*	
Some of the time	*n(%)*	
A little of the time	*n(%)*	
None of the time	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q9g. Did you feel worn out?		
All of the time	*n(%)*	
Most of the time	*n(%)*	
A good bit of the time	*n(%)*	
Some of the time	*n(%)*	
A little of the time	*n(%)*	
None of the time	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q9h. Have you been a happy person?		
All of the time	*n(%)*	
Most of the time	*n(%)*	
Some of the time	*n(%)*	
A little of the time	*n(%)*	
None of the time	*n(%)*	
	Filled, n(%)	

Table 28 - Descriptive analysis - SF-36 Quality of life questionnaire- Analysis population (N=XX)

	Missing, n(%)	
Q9i. Did you feel tired?		
All of the time	*n(%)*	
Most of the time	*n(%)*	
A good bit of the time	*n(%)*	
Some of the time	*n(%)*	
A little of the time	*n(%)*	
None of the time	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?		
All of the time	*n(%)*	
Most of the time	*n(%)*	
Some of the time	*n(%)*	
A little of the time	*n(%)*	
None of the time	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q11a. I seem to get sick a little easier than other people		
Definitely true	*n(%)*	
Mostly true	*n(%)*	
Don't know	*n(%)*	
Mostly false	*n(%)*	
Definitely false	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q11b. I am as healthy as anybody I know		
Definitely true	*n(%)*	
Mostly true	*n(%)*	
Don't know	*n(%)*	
Mostly false	*n(%)*	
Definitely false	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q11c. I expect my health to get worse		
Definitely true	*n(%)*	
Mostly true	*n(%)*	
Don't know	*n(%)*	
Mostly false	*n(%)*	
Definitely false	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Q11d. My health is excellent		
Definitely true	*n(%)*	
Mostly true	*n(%)*	
Don't know	*n(%)*	
Mostly false	*n(%)*	
Definitely false	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	

The percentages are calculated compared to filled data
STUDY : CHUGAI-ARTEMIS - Edition date: DDMMYY
Pgm : DESCR\QUEST.SAS

Table 29 - Descriptive analysis – SF-36 Quality of life questionnaire - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
Patients having completed SF-36 questionnaire		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
IF YES		
Physical Health		
Physical functioning	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
Physical role functioning	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
Bodily pain	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
General health	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
Psychometrically-based physical component summary (PCS)	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
Mental Health		
Emotional role functioning	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
Vitality	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
Emotional well-being	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
Social functioning	*Mean*	
	SD	

Table 29 - Descriptive analysis – SF-36 Quality of life questionnaire - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
	Median *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)***	
Mental component summary (MCS)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	

The percentages are calculated compared to filled data
STUDY : CHUGAI-ARTEMIS - Edition date: DDMMYY
Pgm : DESCR\QUEST.SAS

Table 30 - Descriptive analysis – EuroQol-5 Dimensions -3 Level version (EQ-5D-3L) questionnaire - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
EQ-5D-3L questionnaire was completed		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
IF YES		
Mobility		
I have no problems in walking about	*n(%)*	
I have some problems in walking about	*n(%)*	
I am confined to bed	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Mobility		
No problems	*n(%)*	
Problems	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Self-Care		
I have no problems with self-care	*n(%)*	
I have some problems washing or dressing myself	*n(%)*	
I am unable to wash or dress myself	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Self-Care		
No problems	*n(%)*	
Problems	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Usual Activities		
I have no problems with performing my usual activities	*n(%)*	
I have some problems with performing my usual activities	*n(%)*	
I am unable to perform my usual activities	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Usual Activities		

Table 30 - Descriptive analysis – EuroQol-5 Dimensions -3 Level version (EQ-5D-3L) questionnaire - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
No problems *Problems*	*n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
Pain/Discomfort *I have no pain or discomfort* *I have moderate pain or discomfort* *I have extreme pain or discomfort*	 *n(%)* *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
Pain/Discomfort *No problems* *Problems*	 *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
Anxiety/Depression *I am not anxious or depressed* *I am moderately anxious or depressed* *I am extremely anxious or depressed*	 *n(%)* *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
Anxiety/Depression *No problems* *Problems*	 *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
Perceived current health state		
EQ_VAS score	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	

EQ_VAS : EuroQol Visual Analog Scale
The percentages are calculated compared to filled data
STUDY : CHUGAI-ARTEMIS - Edition date: DDMMYY
Pgm : DESCR\QUEST.SAS

Table 31 - Descriptive analysis – Functional Assessment of Chronic Illness Therapy (FACIT) - Fatigue questionnaire - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
FACIT-Fatigue questionnaire was completed		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
IF YES		
I feel fatigued		
Not at all	*n(%)*	
A little bit	*n(%)*	
Some-what	*n(%)*	
Quite a bit	*n(%)*	
Very much	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
I feel weak all over		
Not at all	*n(%)*	
A little bit	*n(%)*	
Some-what	*n(%)*	
Quite a bit	*n(%)*	
Very much	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
I feel listless ("washed out").		
Not at all	*n(%)*	
A little bit	*n(%)*	
Some-what	*n(%)*	
Quite a bit	*n(%)*	
Very much	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
I feel tired		
Not at all	*n(%)*	
A little bit	*n(%)*	
Some-what	*n(%)*	
Quite a bit	*n(%)*	
Very much	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
I have trouble starting things because I am tired		
Not at all	*n(%)*	
A little bit	*n(%)*	
Some-what	*n(%)*	
Quite a bit	*n(%)*	
Very much	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
I have trouble finishing things because I am tired		
Not at all	*n(%)*	
A little bit	*n(%)*	
Some-what	*n(%)*	
Quite a bit	*n(%)*	
Very much	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
I have energy		
Not at all	*n(%)*	
A little bit	*n(%)*	
Some-what	*n(%)*	
Quite a bit	*n(%)*	
Very much	*n(%)*	

Table 31 - Descriptive analysis – Functional Assessment of Chronic Illness Therapy (FACIT) - Fatigue questionnaire - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
	Filled, n(%)	
	Missing, n(%)	
I am able to do my usual activities		
Not at all	*n(%)*	
A little bit	*n(%)*	
Some-what	*n(%)*	
Quite a bit	*n(%)*	
Very much	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
I need to sleep during the day		
Not at all	*n(%)*	
A little bit	*n(%)*	
Some-what	*n(%)*	
Quite a bit	*n(%)*	
Very much	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
I am too tired to eat		
Not at all	*n(%)*	
A little bit	*n(%)*	
Some-what	*n(%)*	
Quite a bit	*n(%)*	
Very much	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
I need help doing my usual activities		
Not at all	*n(%)*	
A little bit	*n(%)*	
Some-what	*n(%)*	
Quite a bit	*n(%)*	
Very much	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
I am frustrated by being too tired to do the things I want to do		
Not at all	*n(%)*	
A little bit	*n(%)*	
Some-what	*n(%)*	
Quite a bit	*n(%)*	
Very much	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
I have to limit my social activity because I am tired		
Not at all	*n(%)*	
A little bit	*n(%)*	
Some-what	*n(%)*	
Quite a bit	*n(%)*	
Very much	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
FACIT-Fatigue total score		
FACIT-Fatigue total score	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	

The percentages are calculated compared to filled data
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9.3.4 Description of physicians and patients characteristics

Table 32 - Descriptive analysis – Characteristics of physicians - Physician population (N=XX)

Parameter	Statistics	Total *(N=XX)*
Gender		
Male	*n(%)*	
Female	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Number of years since medical school graduation	*Mean*	
	SD	
	Median	
	[Q1 ; Q3]	
	[Min ; Max]	
	Filled, n(%)	
	Missing, n(%)	
Medical specialty		
Internal medicine	*n(%)*	
Rheumatologist	*n(%)*	
Other	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Number of GCA cases (Horton) personally treated within the last year prior to the date of inclusion of first patient		
1-2	*n(%)*	
3-5	*n(%)*	
6-10	*n(%)*	
11-20	*n(%)*	
>20	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Main activity		
University Hospital	*n(%)*	
General Services Hospital	*n(%)*	
Liberal activity	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Activity location		
Auvergne-Rhône-Alpes	*n(%)*	
Bourgogne-Franche-Comté	*n(%)*	
Bretagne	*n(%)*	
Centre-Val de Loire	*n(%)*	
Corse	*n(%)*	
Grand Est	*n(%)*	
Hauts-de-France	*n(%)*	
Île-de-France	*n(%)*	
Normandie	*n(%)*	
Nouvelle-Aquitaine	*n(%)*	
Occitanie	*n(%)*	
Pays de la Loire	*n(%)*	
Provence-Alpes-Côte d'Azur	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	

The percentages are calculated compared to filled data
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Listing 11 : Other investigator's medical specialities (N= XX)

Physician ID	Specification of other medical speciality

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Table 33 - Descriptive analysis – Characteristics of patients - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
Type of visit *Outpatient visit* *Day hospital* *In-patient hospitalization*	 *n(%)* *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
Age	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Age in classes *[50-70[* *≥70 years*	 *n(%)* *n(%)* ***Filled, n(%)*** ***Missing, n(%)***	
Gender *Male* *Female*	 ***n(%)*** ***n(%)*** ***Filled, n(%)*** ***Missing, n(%)***	
Weight at diagnosis (kg)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Weight at inclusion (kg)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
Height at diagnosis (kg)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]* ***Filled, n(%)*** ***Missing, n(%)***	
BMI at diagnosis (kg/m²)	*Mean* *SD* *Median* *[Q1 ; Q3]* *[Min ; Max]*	

Table 33 - Descriptive analysis – Characteristics of patients - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
	Filled, n(%)	
	Missing, n(%)	
BMI (kg/m²) at diagnosis in classes		
<18.5	*n(%)*	
[18.5 – 25[	*n(%)*	
[25.0-30[	*n(%)*	
≥30	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Smoking status		
Smoker	*n(%)*	
Former smoker	*n(%)*	
Non-smoker ever	*n(%)*	
Unknown	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	

The percentages are calculated compared to filled data
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This table will be presented by type of physician who follows the patient.

Table 34 - Descriptive analysis – Significant medical and surgical history and comorbidities (excluding those related to the use of GCs and complications related to GCA) overall by MedDRA SOC and PT – Analysis population (N=XX)

System Organ Class Preferred Term	**Total** *(N=XX)*	
	# Patients (%)	# MHs (%)
Patients with at least one significant comorbidity		
Number of medical and surgical history and comorbidities		
SOC1		
PT1.1		
PT1.2		
...		
SOC2		
PT2.1		
PT2.2		
…		
…		

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 # Patients (%): Number of patients (percentages with number of patients as reference)
 # MHs (%): Number of medical history and comorbidities (multiple occurrences of the same medical history in one patient are counted multiple times) (percentages with number of medical history events as reference)

The same table will be presented for significant medical and surgical history and comorbidities presented before the GCA (Horton) diagnosis and those with ongoing specific treatment(s) overall and according to the type of physicians who follows the patient.

Listing 12 : Other significant medical and surgical history and comorbidities (excluding complicated related to GCA and to the use of GCs) (N= XX)

Patient ID	Newly /not newly diagnosed patient	Type of diagnosis	Physician who follows the patient	Specification of other comorbidities	Start date	Date of inclusion	Present before GCA diagnosis	Ongoing specific treatment

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Table 35 - Descriptive analysis – Administration of treatments at/after diagnosis of GCA - Analysis population (N=XX)

Parameter	Statistics	Total *(N=XX)*
Patients taking at least one treatment of Antiplatelets		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Patients taking at least one treatment of Statins		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Patients taking at least one treatment of Antiosteoporotic		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Patients taking at least one treatment of Antihypertensives		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Patients taking at least one treatment of Antidiabetics		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Patients taking at least one treatment of Inhibitors of the proton pump		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Patients taking at least one treatment of Hypnotics		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Patients taking at least one treatment of Antidepressants		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	
Patients taking at least one other treatment		
No	*n(%)*	
Yes	*n(%)*	
	Filled, n(%)	
	Missing, n(%)	

The percentages are calculated compared to filled data
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The same table will be repeated for treatment administered by the patients at diagnosis and treatments concomitant to the out-patient/hospitalization visit of inclusion.

Listing 13 : Other treatments of interest (N= XX)

Patient ID	Newly /not newly diagnosed patient	Type of diagnosis	Physician who follows the patient	Specification of other treatment	Start date	Date of inclusion	Concomitant to diagnosis	Concomitant to out-patient/hospitalization visit of inclusion

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