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TA SANTÉ EN QUESTIONS

ANCILLARY STUDY APPLICATION FORM

University of Bordeaux / i-Share study

Version table

Version	Date	Updated by	Reason for update
1.0	01/10/2015	Clothilde Pollet *Operational project manager*	
2.0	26/10/2017	Catherine Fagard *Inserm research engineer;* *Research/quality expert*	Update of ancillary studies quality documents

This ancillary study application form must be completed by the lead researcher of the ancillary study after **acceptance of the letter of intent by the i-Share team**.

This is sent to the operational project manager of the cohort with the application package, which includes:

- ☐ Ancillary study protocol
- ☐ The signed i-Share cohort ancillary studies charter
- ☐ Data collection questionnaires (if applicable)

Remove any notes in italics which are guidance for completing the document

Ancillary study no.	**EA _ _ _**
Full ancillary study title	
Abridged ancillary study title	*ACRONYM*
Ancillary study lead researcher Title, Name Institution Address	*Project applicant who will be responsible for the ancillary study*
Co-researchers	
Sponsor/Promoter	*In accordance with the French Jardé law, any interventional research, interventional research with minimal risk, or non-interventional research must have a sponsor (unless the research only pertains to data that has already been collected by the i-Share study (type ❶ see charter Appendix 1). This corresponds to the institution promoting the ancillary study.*
Persons involved in the ancillary study	*Name, role and responsibilities* *Specify the main point of contact*

Main objective	*1 main objective which responds to 1 question*
Secondary objectives	
Target cohort population (definition of inclusion criteria)	*All i-Share cohort participants with available data* *Specific population: participants with migraines (definition: responded "Yes" to question Qxx)*
Study outline	*Cross-sectional study of i-Share participants; ...*
Type of ancillary study	❶ ❷*a* ❷*b* ❸ ❹*a* ❹*b* *(according to the classifications in Appendix 1 of the charter)*
Regulatory framework	*Defined in collaboration with the operational project manager*
Planned schedule/duration of the study	**Start of study:** *year* **Study duration:** *[x]* months ***Data analysis**: month/year* ***Writing and submission of article**: quarter/half-year-year*
Study details	*List the key steps in the study (inclusion, follow-up, etc.)*
Cohort data required for the ancillary study	*Sociodemographic data, other data, etc. (by category)*
Additional data collection	*By category*
Statistical aspects (study size, methods of analysis)	**Study size:** *N = number of people* ***Analysis methods**: Descriptive analysis, classic multivariate analyses (logistical and linear regression models, etc.), ...* ***Software**:*
Collection of biological samples	*If applicable, specify methods*
Access to biological samples	*If applicable, specify methods*
Access to biological data	*If applicable, specify methods*
Access to genetic data	*If applicable, specify methods*

Institutional partners	
Private partners (if applicable)	
Planned sub-contractors	
Provisional budget	*The provisional budget may be provided as an attachment*
Provisional funding	*Provisional funding may be provided as an attachment*
	Other information if required

I the undersigned, ……., ancillary study lead researcher,

- request the participation of this ancillary study in the i-Share cohort,
- guarantee the accuracy and honesty of the information provided,
- accept the terms of the i-Share cohort ancillary studies charter.

At ……, on ……

Signature: