

7 Item à compléter si le projet a déjà été soumis à un appel à projets de la DGOS.

8 In the case of a re-submission, complete the entry field EXPERTS COMMENTS AND CORRESPONDING ANSWERS

Lettre d'intention version anglaise

GENERAL INFORMATION

Project title (eng)

Acronym

[15 characters max]

First submission to DGOS calls for proposals ?

[Tick {Yes ; No} If "No", mention the year of previous submission]

First name and name of the coordinator

[+ town, hospital, email, tel, speciality]

Previous grants in the frame of DGOS calls

[list with : year, ref number, progress [list]]

Physician, Dental practitioner / Biologist / Nurse, other paramedical

[tick]

Affiliated institution responsible for the budget from the ministry of health

Research Domain

[list of keywords] / Oncology [tick]

[if oncology, organ, tumor location]

Name of the methodologist (+ tel + email)

Name of the economist (if any) (+ tel + email)

Organization responsible for project management

Organization responsible for quality assurance

Organization responsible for data management and statistics

Anticipated number of recruiting centres (NC)

Co-investigators (1 à N)

[Table {Name Surname Town Country Hospital EMail Tel Speciality}]

RESEARCH PROJECT

Rational (context and hypothesis)

[max. 320 words]

Originality and innovative aspects

[max. 160 words]

Focus of Research

Health technology [tick & then detail] : drugs ; devices ; procedures and organizational systems used in health care (including Health services⁹).

⁹ <http://htaglossary.net>

¹⁰ Studies designed to determine the causes of a disease, the risk of being exposed to a drug, a pollutant etc

¹¹ Example : reduction of myocardial infarction incidence, of mortality

¹² Example : reduction of serum cholesterol, improvement of a pain scale

If relevant : date of CE mark / market authorization

Keywords [5]

Main Objective

[detail, max 48 words]

[Tick one : Hypothesis ; Description Feasibility ; Tolerance Efficacy ; Safety Efficiency ; Budget Impact ; Organisation of Care]

[Tick one : Etiology Causality¹⁰ ; Diagnosis ; Prognosis ; Therapeutics (impact on clinical end-points¹¹) ; Therapeutics (impact on intermediate end-points¹²) ; Compliance ; Effective Practice ; Research methodology ; Qualitative Research ; Others]

Secondary Objectives

[detail, max 160 words]

Primary End Point (linked with the main objective)

Secondary End Points (linked with the secondary objectives)

Study Population

Main inclusion and exclusion criteria

Design

[tick + detail max 320 words]

Meta analysis

Randomized clinical trial

If yes : Open - Single Blind - Double Blind *[tick]*

Systematic reviews

Pragmatic studies

Quasi-experimental studies (non randomized cohorts, ...)

Prospective cohort study

Case-control study

Cross-sectional study

Retrospective cohort

Administrative / hospital inpatient database research

Modelisation

Case Series

Others

Qualitative study

If Health-Economics Analysis

[tick + detail max 320 words]

Cost-utility analysis

Cost-effectiveness analysis

Cost-benefit analysis

Budget impact analysis

Cost-minimization analysis

Cost-consequence analysis

Cost of illness analysis

Others

Technology Readiness Level¹³

¹³ <https://www.medicalcountermeasures.gov/federal-initiatives/guidance/about-the-trls.aspx>

[1 digit + 1 letter]

In the case of a drug trial, phase :

[tick {I, II, I/II, III, IV}]

If comparison groups :

Experimental group *[detail max 48 words]*

Control group *[detail max 48 words]*

Duration of participation of each patient

[3 digits + days / months / years]

Anticipated Duration of Recruitment (DUR)

[2 digits, in months]

Total number of scheduled patients / observations to be recruited (NP)

[3 digits + Justification of sample size max 80 words]

Number of patients / observations to be recruited / month / centre ((NP/DUR)/NC)

[2 digits + justification if more than 2 patients/month/centre]

Expected number of patients eligible in the centres

[Table : {Name ; Surname ; Town ; Country ; Expected recruitment/month ; Total}]

Participation of a research network

[Detail max 32 words]

Participation of industry

[Detail max 64 words]

Other aspects to insure the feasibility of the project

[Detail max 64 words]

Expected patient or public health benefit

[Detail max 320 words]

REFERENCES

Please join a maximum of 5 articles that justify the project in the national / international context.

APPROXIMATE LEVEL OF FUNDING REQUIRED

[en k euros]

KEY WORDS

Coordinator domain

Wished rapporteur domain

EXPERTS COMMENTS *[quote]* AND CORRESPONDING ANSWERS¹⁴

[max 320 words]