|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **APPEL À CANDIDATURES 2024**  **APPLICATION FILE -** DESIGNATION OF EARLY PHASE CLINICAL TRIAL CENTRES IN ADULT / PEDIATRIC ONCOLOGY  **CLIP² 2024 – 2029**   |  |  | | --- | --- | | Name of the CLIP² candidate |  | | Affiliated administrative institution of the CLIP² candidate and the coordinator |  | | Project coordinator - Name & First Name |  | | Pediatrics project coordinator *(if applicable)* - Name & First Name |  | | Designated centre in 2019 as a CLIP² | * Yes  No | | Requested budget for the whole project (€) (**60** months) |  |   **DATE LIMITE DE SOUMISSION DES PROJETS : 15 novembre 2023 - 16h**  **Soumission en ligne du dossier électronique :**  <https://www.e-cancer.fr/Institut-national-du-cancer/Appels-a-projets/Appels-a-projets-en-cours/CLIP2-2024-2029> |

|  |
| --- |
| **Information relative au traitement des données personnelles qui seront renseignées dans le dossier de candidature**  Dans le cadre de ses missions d’intérêt public, l’Institut national du cancer conduit des appels à projets dans le domaine de la cancérologie.  Afin d’effectuer l’évaluation des projets reçus et d’assurer le recensement et le suivi des appels à projets financés par l’Institut, ce dernier doit recueillir des données relatives à l’identité et la vie professionnelle du coordonnateur, du représentant légal ou de la personne dûment habilitée de l’organisme bénéficiaire, de la personne chargée du suivi administratif du dossier, du responsable d’équipe et, le cas échéant, du personnel de l’équipe et des personnes désignées par le coordonnateur ne devant pas avoir connaissance du projet, ces dernières pouvant de par leurs liens en tirer un avantage direct ou indirect.  Les personnes dont les données personnelles figurent dans le dossier de candidature doivent être informées par celui qui les a désigné que l’Institut les utilisera selon les modalités ici décrites.  L’Institut est le responsable de l’utilisation de ces données. Il les conservera 10 ans à compter de la dernière intervention sur un ou plusieurs projets de la personne qui a déposé la lettre d’intention (par exemple signature d’un engagement, dépôt d’un document sur le Portail Projets).  Sauf opposition de votre part, vos données (nom, prénom, mail) alimenteront l’outil de gestion de contacts de l’Institut qui permet également de vous adresser des informations plus ponctuelles concernant les activités de l’Institut.  Conformément au Règlement général sur la protection des données 2016/679 et à la loi informatique et libertés n°78-17 modifiée, vous disposez durant la durée du traitement d’un droit d’opposition, d’un droit d’accès, de rectification, d’effacement et d’un droit à la limitation du traitement de vos données. Pour les exercer, veuillez adresser votre demande par mail à l’adresse suivante : [dpo@institutcancer.fr](mailto:servicejuridique@institutcancer.fr). Vous trouverez les coordonnées de l’Institut, de son représentant et de sa déléguée à la protection des données sur [e-cancer.fr](http://www.e-cancer.fr/).  Vous disposez, par ailleurs, du droit d’introduire une réclamation auprès de la Commission nationale de l’informatique et des libertés (CNIL). |

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# Summary

|  |
| --- |
| **Summary of the CLIP² application** |
| max 3500 caractères espaces compris – Marianne taille 11 |

|  |
| --- |
| **Résumé de la candidature CLIP²** |
| max 3500 caractères espaces compris – Marianne taille 11 |

# General presentation of the CLIP² candidate

A CLIP² candidate consists of a main site (early phase unit) which can be associated to one or more clinical partner sites belonging or not to the same health institution.

It could be clinical units or departments conducting phase II studies in connection with the phase I unit (for example, the hematology department from a hospital university associated to the early phase unit of an anticancer centre or vice versa) or a pediatrics unit conducting early phase trials. In the case of pediatrics, additional fields should be completed.

\*N° ORCID (Open Researcher and Contributor ID provides a persistent digital identifier that distinguishes you from every other researcher and, through integration in key research workflows such as manuscript and grant submission, supports automated linkages between you and your professional activities ensuring that your work is recognized (<https://orcid.org/register>)

## Identity sheet of differents sites

|  |  |
| --- | --- |
| **Main site** | |
| Coordinator - name and first name  Title and function :  Medical speciality  N°ORCID |  |
| Department/unit  (Name / Adress / City / Zip Code)  Phone / Fax  Email adress:  Affiliated administrative institution  (Name / Adress / City / Zip Code) |  |

For coordinator, attach a short CV with the list of publications relative to early phase clinical trials (Annex 3)

|  |  |
| --- | --- |
| **Partner site(s)** | |
| Unit/department |  |
| Health institution |  |
| Legal responsible |  |
| Referent - Name and first name  Title and function :  Medical speciality  N°ORCID |  |
| Department/unit  (Name / Adress / City / Zip Code)  Phone / Fax  Email adress:  Affiliated administrative institution  (Name / Adress / City / Zip Code) |  |

For referent of each partner site, attach a short CV with the list of publications relative to early phase clinical trials. (Annex 3)

Add as many tables as there are partner sites.

|  |  |
| --- | --- |
| **Pediatric Main site** | |
| Coordinator - name and first name (if applicable)  Title and function:  Medical speciality  N°ORCID |  |
| Department/unit  (Name / Adress / City / Zip code)  Phone / Fax  Email adress:  Affiliated administrative institution  (Name / Adress / City / Zip code) |  |

For pediatric coordinator, attach a short CV with the list of publications relative to early phase clinical trials (Annex 3)

|  |  |
| --- | --- |
| **Pediatric partner site 1** | |
| Referent - name and first name (if applicable)  Title and function:  Medical speciality  N°ORCID |  |
| Department/unit  (Name / Adress / City / Zip code)  Phone / Fax  Email adress:  Affiliated administrative institution  (Name / Adress / City / Zip code) |  |

For referent of each pediatric partner site, attach a short CV with the list of publications relative to early phase clinical trials. (Annex 3)

Add as many tables as there are pediatric partner sites

# Impact of the previous designation for designated centres in 2019 as a CLIP²

Describe the impact of the designation on the site in 2019 and in particular:

* The progression of the early phase activity,
* The development of the structuration put in place,
* The governance put in place,
* Any site strategies put in place to develop early phase activity
* The use of allocated resources
* New collaborations (national or international, with other CLIP², with pharmaceutical companies, with translational research teams…)

NB: Relate the evolution of the early phase activity to the structuring and organizational elements or strategies put in place. For example, you would mention the repartition of the dedicated budgets to early phase research, ie. part allocated by the establishment / hospital, and part obtained from industrial sponsors.

|  |
| --- |
| **Describe the impact of the designation for early phase adult activity** |
| Marianne 11, 3 pages maximum |
|  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Allocation of staff and budget dedicated to early phase adult activity** | | | | | | | |
| Job Category / Function | Status (Holder, CDI, CDD) | **2018** | | | **2022** | | |
| % of establishment funding | % of CLIP² funding | % of others funding (project, industrial, other) | % of establishment funding | % of CLIP² funding | % of others funding (project, industrial, other) |
| Medical staff | Holder |  |  |  |  |  |  |
| Medical staff | CDI |  |  |  |  |  |  |
| Medical staff | CDD |  |  |  |  |  |  |
| Non-medical staff\* | Holder |  |  |  |  |  |  |
| Non-medical staff\* | CDI |  |  |  |  |  |  |
| Non-medical staff\* | CDD |  |  |  |  |  |  |

\* Clinical research staff (including clinical research associate, clinical study technician, clinical research nurse)

|  |
| --- |
| **Describe the impact of the designation for early phase pediatric activity** |
| Marianne 11, 3 pages maximum |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Allocation of staff and budget dedicated to early phase pediatric activity** | | | | | | | |
| Job Category / Function | Status (Holder, CDI, CDD) | **2018** | | | **2022** | | |
| % of establishment funding | % of CLIP² funding | % of others funding (project, industrial, other) | % of establishment funding | % of CLIP² funding | % of others funding (project, industrial, other) |
| Medical staff | Holder |  |  |  |  |  |  |
| Medical staff | CDI |  |  |  |  |  |  |
| Medical staff | CDD |  |  |  |  |  |  |
| Non-medical staff\* | Holder |  |  |  |  |  |  |
| Non-medical staff\* | CDI |  |  |  |  |  |  |
| Non-medical staff\* | CDD |  |  |  |  |  |  |

\* Clinical research staff (including clinical research associate, clinical study technician, clinical research nurse)

# New CLIP² application

## CLIP² candidate’s description

Describe briefly the Health institutions and the facilities dedicated to the early phase research: main site and partner site (s), total area, location within the institution, number of beds, active patient files by localisation, etc…

|  |
| --- |
| **Describe the CLIP² candidate including its different sites** |
| Marianne 11, 3 pages maximum |

## CLIP² candidate’s organization

Each of the following part should describe the CLIP² candidate's organization

### Organization of the early phase activity

You should focus, either for adult and pediatric part:

* The governance of the CLIP² candidate, including the modalities of organization, coordination/animation and management that the CLIP² candidate will put in place.
* The modalities of deployment of the human resources between the different sites.
* The articulations and cooperation arrangements, between the main site and the partner site(s) whether they belong or not to the same institution;
* Management of patient care in the framework of early phase activity (medical consultations, examinations, drug administration, samples management, etc..)

Any other information to help the evaluation committee to understand the functioning of each part of the CLIP² candidate and how patient safety will be managed.

|  |
| --- |
| **Description of the organization of adult early phase activity including partnership and relation between the main and partner(s) site(s)** |
| Marianne 11, 3 pages maximum |

|  |
| --- |
| **Description of the organization of pediatric early phase activity, including partnership and relation between the main and partner(s) site(s)** |
| Marianne 11, 3 pages maximum |

Only for applications involving both adult and pediatric valencies, explain how mutualization will be put in place, and describe the articulation between adult and pediatric parts for the early phase clinical research activity.

|  |
| --- |
| **Description of the articulation between adult and pediatric parts for the early phase clinical research activity.** |
| Marianne 11, 2 pages maximum |

### Other services linked to the CLIP² candidate (clinical units are excluded)

List and shortly describe, either for adult and pediatric part, the other services (clinical units/departments are excluded) involved in the design and/or conduct of early phase trials of the CLIP² candidate

* Sponsor unit/department, ie. structure in charge of the sponsorship and the coordination (pharmacovigilance budget, legal, etc.).
* Biostatistics unit/department
* Pharmacology laboratory, Pharmacokinetic laboratory, Pharmacy
* Genetic molecular platforms,
* Translational research or medical biology laboratories,
* Radiotherapy, imaging and/or surgery units
* Biological resource center
* Other medical specialties ensuring specific safety monitoring examinations in early phase trials
* Etc.

Focus on the articulation and cooperation arrangements, between the adult and/or pediatric part of the CLIP² candidate, and each of theses other actors linked to the early research.

|  |
| --- |
| **Adult Part** |
| Marianne 11, 3 pages maximum |

|  |
| --- |
| **Pediatric Part** |
| Marianne 11, 3 pages maximum |

### Dedicated staff of the CLIP² candidate

List of the dedicated staff for the conduct of early phase clinical trials: physicians, nurses, site monitors, TEC, pharmacists… Specify the type of funding (holder, research projects, CLIP², other)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Main site** | | | | |
| Job Category / Function | Status (Holder, CDI, CDD) | FTE dedicated to early phase trials | Name & first name | Funding (project, CLIP², other) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| *Add as many lines as there are dedicated staff* | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Partner Site 1** | | | | |
| Job Category / Function | Status (Holder, CDI, CDD) | FTE dedicated to early phase trials | Name & first name | Funding (project, CLIP², other) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| *Add as many lines as there are dedicated staff* | | | | |

*Add as many tables as there are partner sites*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Pediatric main site** | | | | |
| Job Category / Function | Status (Holder, CDI, CDD) | FTE dedicated to early phase trials | Name & first name | Funding (project, CLIP², other) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| *Add as many lines as there are dedicated staff* | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Pediatric partner Site 1** | | | | |
| Job Category / Function | Status (Holder, CDI, CDD) | FTE dedicated to early phase trials | Name & first name | Funding (project, CLIP², other) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| *Add as many lines as there are dedicated staff* | | | | |

*Add as many tables as there are partner sites*

### Accrual capability

Detail by type of tumor (adults) the number of new patients cared in the institution in 2022 and the number of patients enrolled in early phase clinical trials

|  |  |  |  |
| --- | --- | --- | --- |
| **Main site** | | | |
| Tumor type | New patients | Number of patients enrolled in early phase clinical trials | % |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| *Add as many lines as there are tumor types* | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Partner site 1** | | | |
| Tumor type | New patients | Number of patients enrolled in early phase clinical trials | % |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| *Add as many lines as there are tumor types* | | | |

*Add as many tables as there are partner sites*

|  |  |  |  |
| --- | --- | --- | --- |
| **Pediatric main site** | | | |
| Tumor type | New patients | Number of patients enrolled in early phase clinical trials | % |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| *Add as many lines as there are tumor types* | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Pediatric partner site 1** | | | |
| Tumor type | New patients | Number of patients enrolled in early phase clinical trials | % |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| *Add as many lines as there are tumor types* | | | |

*Add as many tables as there are partner sites*

|  |
| --- |
| **Describe the tools and relationships developed for addressing patients in the institution or others institutions or others CLIP² to the early phase unit, and describe the new organization and tools aimed at promoting patient referral** |
| Marianne 11, 2 pages maximum |

## CLIP² candidate’s adult activity

This section should reflect the **adult activity** of the early phase clinical trials of the CLIP² candidate for the past three years from 2020 to 2022. Relevant activities are: phases I, I/II and II (are excluding phase II / III or III and part of phase II of phase II / III studies).

The following tables provide the total number of new clinical trials for which the CLIP² candidate (main site and partner(s) site(s)) is sponsor or participant site (industrial or academic trial) and the number of patients enrolled in these trials over a period of 3 years.

**A separate Excel Sheet containing a detailed list of these trials is to be completed (Activity Annex)**

### Clinical trials

You should focus, either for adult and pediatric part:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Therapeutical Clinical trials | | Academic-sponsored trials | | | CLIP² candidate sponsored trials | | | Industrial-sponsored trials | | |
| 2020 | 2021 | 2022 | 2020 | 2021 | 2022 | 2020 | 2021 | 2022 |
| Number of new trials open to enrollment | Phase I |  |  |  |  |  |  |  |  |  |
| Phase I/II |  |  |  |  |  |  |  |  |  |
| Phase II |  |  |  |  |  |  |  |  |  |

*The detail of the institutions or pharmaceutical laboratories promoting the studies should be provided in the paragraph ‘’3.D. External partners’’*

### Enrollment

You should focus, either for adult and pediatric part:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Therapeutical Clinical trials | | Academic-sponsored trials | | | CLIP² candidate sponsored trials | | | Industrial-sponsored trials | | |
| 2020 | 2021 | 2022 | 2020 | 2021 | 2022 | 2020 | 2021 | 2022 |
| Number of enrolled patients | Phase I |  |  |  |  |  |  |  |  |  |
| Phase I/II |  |  |  |  |  |  |  |  |  |
| Phase II |  |  |  |  |  |  |  |  |  |

*The detail of the institutions or pharmaceutical laboratories promoting the studies should be provided in the paragraph ‘’3.D. External partners’’*

### Audits / Inspections

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of audit / Inspection  [ex : centre, trial… over the period 2020-2022] | year | Audited site | Cause / sponsor of audit | conclusion |
|  |  |  |  |  |
|  |  |  |  |  |
| *Add as many lines as there are audit / inspection* | | | | |

### External partners

List of institutions / pharmaceutical companies which have worked with the centre to conduct early phase clinical trials

|  |  |  |
| --- | --- | --- |
| Name of institution/ pharmaceutical company | Number of early phase clinical trials (2020-2022) | Investigational drug(s) |
|  |  |  |
|  |  |  |
| *Add as many lines as there are institutions or pharmaceutical companies* | | |

## CLIP² candidate’s pediatrics activity (if applicable)

This section should reflect the **pediatric activity** of the early phase clinical trials of the CLIP² candidate for the past three years from 2020 to 2022. Relevant activities are: phases I, I/II and II (are excluding phase II / III or III and part of phase II of phase II / III studies).

The following tables provide the total number of new clinical trials for which the CLIP² candidate (main site and partner(s) site(s)) is sponsor or participant site (industrial or academic trial) and the number of patients enrolled in these trials over a period of 3 years.

**A separate Excel Sheet containing a detailed list of these trials is to be completed (Activity Annex).**

### Clinical trials

You should focus, either for adult and pediatric part:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Therapeutical Clinical trials | | Academic-sponsored trials | | | CLIP² candidate sponsored trials | | | Industrial-sponsored trials | | |
| 2020 | 2021 | 2022 | 2020 | 2021 | 2022 | 2020 | 2021 | 2022 |
| Number of new trials open to enrollment | Phase I |  |  |  |  |  |  |  |  |  |
| Phase I/II |  |  |  |  |  |  |  |  |  |
| Phase II |  |  |  |  |  |  |  |  |  |

*The detail of the institutions or pharmaceutical laboratories promoting the studies should be provided in the paragraph ‘’3.D. External partners’’*

### Enrollment

You should focus, either for adult and pediatric part:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Therapeutical Clinical trials | | Academic-sponsored trials | | | CLIP² candidate sponsored trials | | | Industrial-sponsored trials | | |
| 2020 | 2021 | 2022 | 2020 | 2021 | 2022 | 2020 | 2021 | 2022 |
| Number of enrolled patients | Phase I |  |  |  |  |  |  |  |  |  |
| Phase I/II |  |  |  |  |  |  |  |  |  |
| Phase II |  |  |  |  |  |  |  |  |  |

*The detail of the institutions or pharmaceutical laboratories promoting the studies should be provided in the paragraph ‘’3.D. External partners’’*

### Audits / Inspections

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of audit / Inspection  [ex : centre, trial… over the period 2020-2022] | year | Audited site | Cause / sponsor of audit | conclusion |
|  |  |  |  |  |
|  |  |  |  |  |
| *Add as many lines as there are audit / inspection* | | | | |

### External partners

List of institutions / pharmaceutical companies which have worked with the centre to conduct early phase clinical trials

|  |  |  |
| --- | --- | --- |
| Name of institution/ pharmaceutical company | Number of early phase clinical trials (2020-2022) | Investigational drug(s) |
|  |  |  |
|  |  |  |
| *Add as many lines as there are institutions or pharmaceutical companies* | | |

## 

## CLIP² candidate‘ scientific and organizational project

Describe how the CLIP² candidate (either for adult and pediatric parts) plans **to complete the all tasks and missions described in the scientific and organizational specifications section** of the call for applications and what are its goals during the period of the designation, including the articulation between the adult and/or pediatric part of the CLIP² candidate, and all the actors linked to the early research.

|  |
| --- |
| **Describe the scientific and organizational project for adult part** |
| Marianne 11, 4 pages maximum |

|  |
| --- |
| **Describe the scientific and organizational project for pediatric part** |
| Marianne 11, 4 pages maximum |

## CLIP² candidate budget

### Justification

Detail and justify human resources and running costs needs to implement the project

|  |
| --- |
| **Adult Part** |
| Marianne 11, 1 page maximum |
| **Pediatrics Parts** |
| Marianne 11, 1 page maximum |

### Funding requested

See financial annex, excel sheet

# Annexes

## Annex 1 - CLIP² candidate’s early phase adult bibliography

List the major scientific publications indexed in peer-reviewed journals with international editorial board or any other significant publications during the last three years (title and references), **related to the early phase adult activity of the CLIP² candidate**.

|  |
| --- |
| List of scientific publications reporting the results of early phase adult clinical trials of the CLIP² candidate for the past three years |
| Bibliography of the adult main site |
| 1. |
| 2. |
| 3. |
| 4. |
| 5. |
| 6. |
| 7. |
| 8. |
| 9. |
| 10. |
| Etc... |
| Bibliography of the partner site 1 |
| 1. |
| 2. |
| 3. |
| 4. |
| 5. |
| 6. |
| 7. |
| 8. |
| 9. |
| 10. |
| Etc... |

*NB1 : Highlight in bold the authors belonging to the concerned site*

*NB2: Add as many candidate’s bibliography as there are partner sites*

## Annex 2 - CLIP² candidate’s early phase pediatric bibliography

List the major scientific publications indexed in peer-reviewed journals with international editorial board or any other significant **publications during the last three years** (title and references), **related to the early phase pediatric activity of the CLIP² candidate**

|  |
| --- |
| List of scientific publications reporting the results of early phase pediatric clinical trials of the CLIP² candidate for the past three years |
| Bibliography of the pediatric main site |
| 1. |
| 2. |
| 3. |
| 4. |
| 5. |
| 6. |
| 7. |
| 8. |
| 9. |
| 10. |
| Etc... |
| Bibliography of the pediatric partner site 1 |
| 1. |
| 2. |
| 3. |
| 4. |
| 5. |
| 6. |
| 7. |
| 8. |
| 9. |
| 10. |
| Etc... |

*NB1: Highlight in bold the authors belonging to the concerned site*

*NB2: Add as many Pediatrics site’s bibliography as there are partner sites*

## Annex 3 - CLIP² candidate’s CVs

**CLIP² candidate’s english CVs** have to include all the significant publications during the last three years (title and references), related to the early phase activity

### Coordinator’s CV

|  |
| --- |
| Coordinator of main site’s CV |

* *to insert*

|  |
| --- |
| Coordonator of pediatric main site’s CV |

* *to insert*

### Referents of partner site’s CV

|  |
| --- |
| Referent of partner site 1’s CV |

* *to insert*

|  |
| --- |
| Referent of partner site 2’s CV |

* *to insert*

*Add as many referent’s CV as there are partner sites*

### Referents of pediatric partner site’s CV

|  |
| --- |
| Referents of pediatric partner site 1’s CV |

* *to insert*

|  |
| --- |
| Referents of pediatric partner site 2’s CV |

* *to insert*

*Add as many pediatric referent’s CV as there are pediatric partner sites*