(Form 2)

※記載されたTitle, Name, Affiliation, Department, Position titleは、採択後そのままウェブ掲載されますので、間違いの無いよう記入をお願いします。研究開発提案書の記載内容と齟齬がないよう作成して下さい。

**R&D Proposal**

**(Research on Regulatory Science of Pharmaceuticals and Medical Devices, AMED FY2021)**

**1. Research outline and objectives**

**1.1 Outline of R&D project**

|  |  |  |
| --- | --- | --- |
| 1. Title of proposed R&D project |  | |
| 2. R&D period | Date contract concluded in 2020 to March 2023, (scheduled) | |
| 3. R&D funds | 1st year (FY2021)  2nd year (FY2022)  3rd year (FY2023) | yen  yen  yen |
| 4. Name and title of R&D Principal Investigator |  | |
| 5. Affiliation, department and position of R&D Principal Investigator |  | |
| 6.Research category  (select as many as appropriate) | Pharmaceuticals (Chemical compounds / Biologics) Medical devices  Cellular and tissue-based products Gene therapy  Diagnostic methods  Others (\_\_\_\_\_\_\_\_\_\_\_\_\_\_) | |
| 7. Research type  (select as many as appropriate） | Research contributing to guideline development Construction of research infrastructure Research on new analysis method International harmonization of regulatory issues  Real world data  Biomarker development Basic research  Others (\_\_\_\_\_\_\_\_\_\_\_\_\_\_) | |
| 8. Highlights: 1) Objectives 2 ) Uniqueness/Originality 3) Feasibility of accomplishment 4) Expected outcomes  1)  2)  3)  4) | | |
| 9.Research keywords  (10 or less) | 1( ) 2( ) 3( )  4( ) 5( ) 6( )  7( ) 8( ) 9( )  10( ) | |

**1.2 Overall details of R&D plan**

|  |
| --- |
| 1. Outline etc. |
| **Research objectives**  **Expected outcomes** |

|  |
| --- |
| **Outline diagram** |

**2. R&D plan and methods**

**2.1 Overview of R&D schedule**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| R&D item  Milestone(s) | Name of Researcher(s) | 1st year (FY2021) | | | | 2nd year (FY2022) | | | | 3rd year (2023) | | | |
| 1Q | 2Q | 3Q | 4Q | 1Q | 2Q | 3Q | 4Q | 1Q | 2Q | 3Q | 4Q |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (2) |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (3) |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (4) |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (5) |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (6) |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (7) |  |  |  |  |  |  |  |  |  |  |  |  |  |

**2.2 R&D outline by item**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| R&D item (1) | | |  | | |
| Name of researcher | | |  | | |
| Affiliation/department/position | | |  | | |
| **R&D outline**  **Milestone 1**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2021:  FY2022:  FY2023:    **Milestone 2**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2021:  FY2022:  FY2023:  **Milestone 3**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2021:  FY2022:  FY2023: | | | | | |
| R&D item (2) | |  | | |
| Name of Researcher | |  | | |
| Affiliation/department/position | |  | | |
| **R&D outline**  **Milestone 1**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2021:  FY2022:  FY2023:    **Milestone 2**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2021:  FY2022:  FY2023:  **Milestone 3**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2021:  FY2022:  FY2023: | | | | |
| R&D item (3) |  | | |
| Name of Researcher |  | | |
| Affiliation/department/position |  | | |
| **R&D outline**  **Milestone 1**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2021:  FY2022:  FY2023:  **Milestone 2**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2021:  FY2022:  FY2023:  **Milestone 3**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2021:  FY2022:  FY2023: | | | |

1. **International activities**
2. **Research achievements**

・R&D Principal Investigator:

＜Paper / Author＞

＜Acquisition and application status of patent rights or other intellectual property rights＞

＜Policy recommendations＞

Annex 1

**Implementation System Diagram**

Attach an implementation system diagram showing the Principal Institution and Subsidiary Institution organizations (in the event that the affiliated institution and the main place of research are different bodies also provide details of the main place of research), frameworks, collaboration and cooperation organizations, etc. The diagram should clearly show the roles of each institution. Also note the frameworks and methods for R&D project administration, promotion and progress management, etc.