(Form 2)

※研究開発提案書（日本語版）の記載内容と齟齬がないよう作成して下さい。提出する際には、青字の記載例を削除してください。

**R&D Proposal**

**(Research on Regulatory Science of Pharmaceuticals and Medical Devices, AMED FY2023)**

**1. Research outline and objectives**

**1.1 Outline of the proposal**

|  |  |  |
| --- | --- | --- |
| 1. Title of proposed R&D project | Study of ○○ | |
| 2. R&D period | Start：August, 2023  End：March, 2026 | |
| 3. R&D funds | 1st year (FY2023) ：○○yen  2nd year (FY2024) ：○○yen  3rd year (FY2025) ：○○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.Research keywords  (10 or less) | 1( ) 2( ) 3( )  4( ) 5( ) 6( )  7( ) 8( ) 9( )  10( ) | |

**1.2 Background information**

○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○。○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○

**1.3 Research objectives**

○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○。○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○

**1.4 Previous study results including competitive advantages**

○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○。○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○

**1.5 Goals of the proposal**

○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○。○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○

**1.6 Expected outcomes**

○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○。○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○

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

**2.1 Overview of R&D plan**

○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○。○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○

**2.2 Overview of R&D plan (diagram)**

研究の概略を示す図を記載してください。

**2.3 R&D schedule**

研究開発提案書（日本語版）の別紙2の「研究開発の主なスケジュール」を記載してください。

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| R&D item  Milestone(s) | Name of Researcher(s) | 1st year (FY2023) | | | | 2nd year (FY2024) | | | | 3rd year (2025) | | | |
| 1Q | 2Q | 3Q | 4Q | 1Q | 2Q | 3Q | 4Q | 1Q | 2Q | 3Q | 4Q |
|  |  |  |  | ▲  Milestone: XXXXXXXX |  |  |  |  |  |  |  |  |  |
| (2) |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (3) |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (4) |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (5) |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (6) |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (7) |  |  |  |  |  |  |  |  |  |  |  |  |  |

**2.4 R&D plan by item**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| R&D item (1) | | |  | | |
| Name of researcher | | |  | | |
| Affiliation/department/position | | |  | | |
| **R&D plan**  **Milestone 1**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2023:  FY2024:  FY2025:    **Milestone 2**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2023:  FY2024:  FY2025:  **Milestone 3**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2023:  FY2024:  FY2025: | | | | | |
| R&D item (2) | |  | | |
| Name of Researcher | |  | | |
| Affiliation/department/position | |  | | |
| **R&D plan**  **Milestone 1**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2023:  FY2024:  FY2025:    **Milestone 2**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2023:  FY2024:  FY2025:  **Milestone 3**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2023:  FY2024:  FY2025: | | | | |
| R&D item (3) |  | | |
| Name of Researcher |  | | |
| Affiliation/department/position |  | | |
| **R&D plan**  **Milestone 1**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2023:  FY2024:  FY2025:  **Milestone 2**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2023:  FY2024:  FY2025:  **Milestone 3**  Name of Researcher:  Objectives, details, and accomplishments to be achieved  FY2023:  FY2024:  FY2025: | | | |

1. **International activities**

国際的な活動の実績（ICHの会議への参加など）がある場合には、実績と現状を記載してください。また、国際的な活動の計画や構想があれば記載してください。

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1. **Research achievements**

・R&D Principal Investigator:

＜Paper / Author＞

研究開発代表者と研究開発分担者ごとに学術雑誌等に発表した論文・著書のうち主なもの（過去5年間）を直近年度から順に記載してください。

●M.Marusankaku, J.Aaaa, H.Bbbbb, A.Ccccc, Treatment of Hepatic……, Nature, 2020 , 1,10-20

M.Marusankaku, T.Aaaa, A.Bbbbb, T.Ccccc, Risk factors for Fungal…, Nature, 2019, 2,17-26

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

特許権等知的財産権の取得及び申請状況を記載してください。

○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○

＜Policy recommendations＞

研究開発課題の実施を通じた政策提言（寄与した指針又はガイドライン等）を記載してください。

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Annex 1

**R&D Scheme and Structure Diagram**

研究開発提案書（日本語版）の別紙3の「研究開発実施体制図」を記載してください。

【Example】

Rounded rectangles: Universities etc.

Oval: Companies

Rectangle: AMED

Dotted lines: Agreements/contracts

Double arrows: Exchange of samples and information etc./ role sharing

R&D Principal Investigator

Affiliated institution (main place research)

Name

R&D item responsible for: XXXX

AMED

R&D Co-Investigator

Affiliated institution (main place research)

Name

R&D item responsible for: XXXX

R&D Co-Investigator

Affiliated institution (main place research)

Name

R&D item responsible for: XXXX

Analysis

Data provision

Sample provision

Processing