

Cyclic Innovation for Clinical Empowerment (CiCLE)

**Japan Agency for Medical Research and Development (AMED),
National Research and Development Agency**

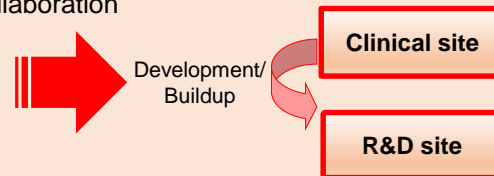
Aiming to

- Establish foundations for future-generation medical innovation
- Develop new drugs, medical devices, regenerative medicine products, medical technologies and others

CiCLE supports as follows;

- **Development and/or buildup of foundations for reverse translational research (rTR)**

- Industry-academia-government collaboration (company demanded)
- Application of human clinical data
- Application of biobanks or advanced ICT
- Human resource development



- **Development and/or buildup open innovated foundations in medical fields**

- Collaboration of organization in non-competitive field
- Collaboration among companies (demanded), hospitals, universities and research institutes.
- Strategic development of drug discovery with the intellectual property consolidation.



- **Practical implementation in medical fields**

- Industry-academia-government collaboration (company demanded)
- Development of drugs, medical devices, regenerative medicine products, medical technologies and others

Merits

➤ Available to various projects as follows;

- For (1) **medical R&D** or (2) **improving the environment for medical R&D**.
- From the basic research to practical realization development. The intellectual property are attributed to the contracted founding company. (Japanese version of the US Bayh-Dole Act)
- For **clinical trials**.
- For company's in-house technology being conditional on industry-academia-government collaboration.

➤ Available to long-term and/or large-scale budget for fiscal years

- AMED and the representative organization make agreement for fiscal years contract.
- The project period extends **within 10 years** in principle.
- The total budget is **from 100 million to 10 billion yen** per project.
- The contracted funds for awarded projects **can be used freely a large injections or urgent requirements through each fiscal years**.

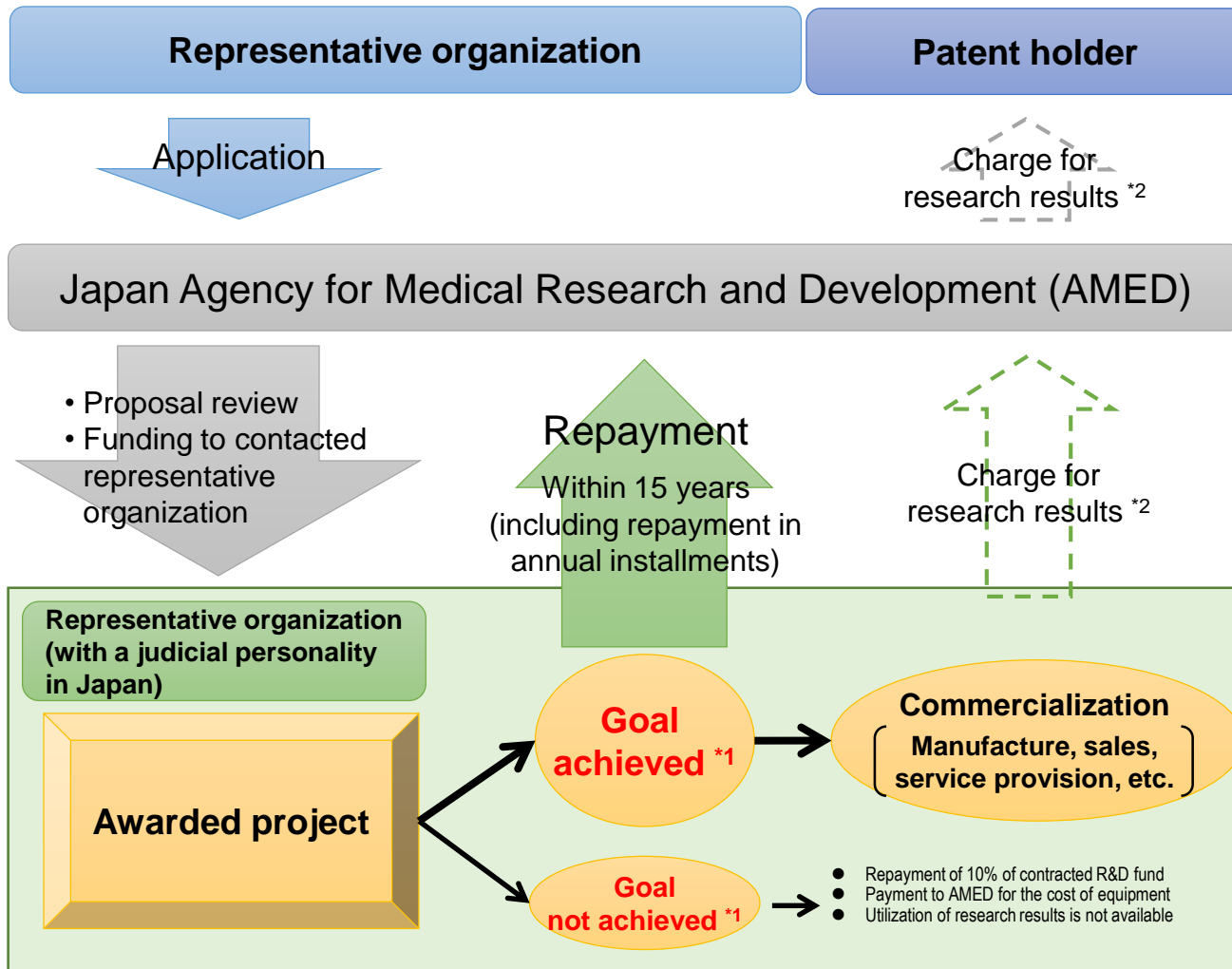
➤ AMED share a part of R&D risks.

- The representative organization bear the repayment fully when achieved, partially when not achieved.

➤ Interest-free and within 15 years repayment periods

- Repayment starts after the completion of project.
- **Interest-free** and **within 15 years**.
- Flexible repayment options.

Schemes Implemented



Within 10 years in principle
100 million – 10 billion yen /project

Includes general administrative expenses.
100 million – 5 billion yen per project in principle for practical realization development programs

***1 Whether the goal has been achieved or not is determined by the attainment degree of the minimum technical level/improvement level at the time of proposal submission.**

***2 The charge for research results is to be paid to AMED in accordance with sales (with some exceptions). If seed patents exist, AMED pay the charge for research results to patent holder.**

This program is classified into three types:

(A) Improving the environment for medical R&D type

Improving the environment for development of collaborative foundation that contributes to R&D for the practical application of drugs, medical devices, regenerative medicine products, medical technologies and human resource training.

(B) R&D type

R&D geared towards practical application of drugs, medical devices, regenerative medicine products, medical technologies with a mixed team of companies, universities and institutes based on industry-academia collaboration or industry-industry collaboration.

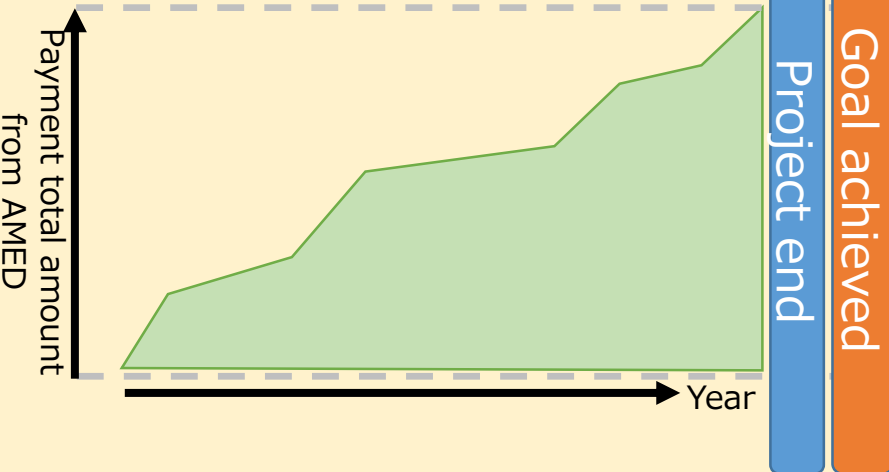
(C) Practical realization development type

Practical realization development of drugs, medical devices, regenerative medicine products, medical technologies, implemented in industry-academia collaboration based on seeds (patents, etc.)

Image from start of project to completion of repayment (Goal achieved)

Project period

- Within the total budget, payments from AMED is issued according to progress.



Repayment period

- After the completion of project

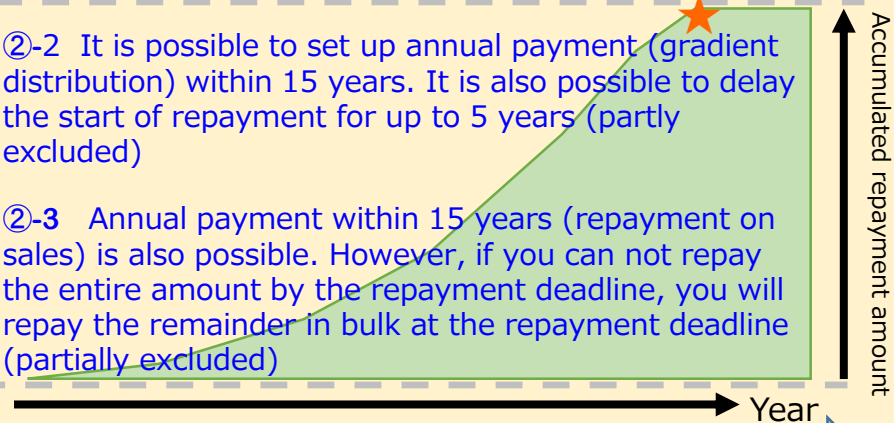
- ① Collective repayment

- ②-1 Annual payment within 15 years (equal repayment). It is also possible to delay repayment start for up to 5 years (light green)



- ②-2 It is possible to set up annual payment (gradient distribution) within 15 years. It is also possible to delay the start of repayment for up to 5 years (partly excluded)

- ②-3 Annual payment within 15 years (repayment on sales) is also possible. However, if you can not repay the entire amount by the repayment deadline, you will repay the remainder in bulk at the repayment deadline (partially excluded)



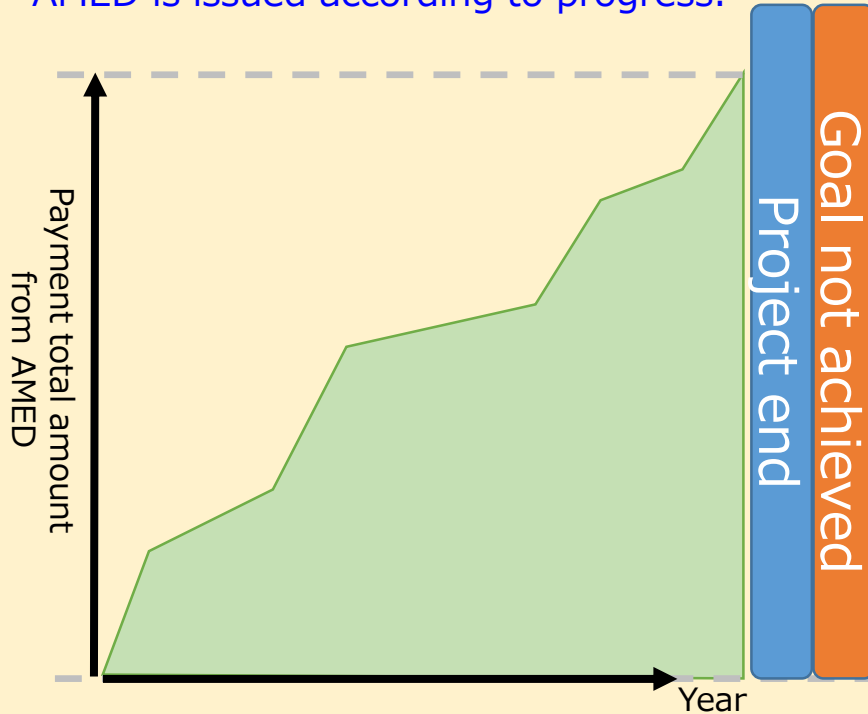
★ Repayment complete

The project period extends within 10 years in principle. Repayment within 15 years.
Total period is within 25 years.

Image from start of project to completion of repayment (Goal not achieved)

Project period

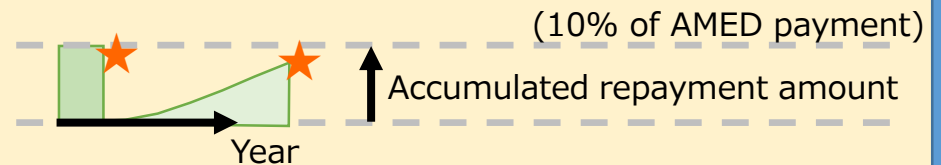
- Within the total budget, payments from AMED is issued according to progress.



Repayment period

- After the completion of project

- ① Repayment of 10% of AMED payments.
- ② Payment to AMED for the cost of equipment.
- ③ Utilization of research results is not available.



Repayment complete

Contracted project of CiCLE

Second supplementary budget
for FY2016:
55 billion yen

1st Solicitation (7 project) (Published August 1, 2017)

Project title	Representative company
Establishment of a world-leading special peptide drug manufacturing CMO	PeptiDream Inc.
Empirical research to platformize oral rice-based biopharmaceuticals	Astellas Pharma Inc.
Industry-medico collaboration laboratory for dementia to create new promising drug targets	Eisai Co., Ltd.
Development of an innovative therapeutic drug for fibrodysplasia ossificans progressiva (FOP)	Daiichi Sankyo Co., Ltd.
Drug discovery research aiming at development of agents against infections with bacteria showing antimicrobial resistance (AMR)	Sumitomo Dainippon Pharma Co., Ltd.
Development of malaria vaccine and establishment of its commercial manufacturing process	Nobelpharma Co., Ltd.
Development of a novel vaccine technology based on nucleic acid encapsulated in nanoparticle for protection against viral disease	Daiichi Sankyo Co., Ltd.

2nd Solicitation (10 project) (Published January 10, 2018. Updated on April 13, 2018)

Project title	Representative company
がん医療推進のための日本人がん患者由来PDXライブラリー整備事業	LSI Medience Corporation
創薬ライブラリーの共同管理・運用及び産官学連携によるその相互利用推進	CAC Croit Corporation
手足口病VLPワクチンの開発	The Research Foundation for Microbial Diseases of Osaka University (BIKEN Foundation)
新規の核酸合成とデリバリー技術を用いた核酸創薬研究	KAN Research Institute, Inc.
ゲノム編集により作製した疾患iPS心筋細胞を用いた肥大型心筋症治療薬の開発	Takeda Pharmaceutical Co., Ltd.
オピオイドδ受容体活性化を機序とする画期的情動調節薬の開発	Nippon Chemiphar Co., Ltd.
タンパク質構造解析のハイスループット化へ向けた装置開発	JEOL Ltd.
セラノスティクス概念を具現化するための創薬拠点整備を伴う、抗体等標識治療薬（アルファ線）とコンパニオン診断薬の開発	Nihon Medi-Physics Co.,Ltd.
サイトメガロウイルス（CMV）特異的完全ヒト型モノクローナル抗体の臨床POC確立	Nobelpharma Co., Ltd.
クローン病を対象とした産学連携による本邦発バイオ医薬品と新規薬効予測マーカーの開発	EA Pharma Co., Ltd.

background color

Improving the environment for medical R&D type

R&D type

Practical realization development type

3rd Solicitation (Solicitation Period: March 7, 2018 - May 31, 2018 noon)

Newly established

○ Start-up type (ViCLE, “ヴィークル”)

~ Venture Innovation for Clinical Empowerment ~

AMED supports R&D and improving the environment by start-up companies as follows.

- The proposer must be an unlisted company within 10 years of establishment.
- Technology and business model have novelty and innovation.
- There are exit strategies such as stock listing (IPO), derivation (technology selling), M&A (business divestiture, corporate divestiture) etc, which grows in a short period of time.
- Industry-academia-government collaboration (company demanded)
- Development of drugs, medical devices, regenerative medicine products, medical technologies and others

The project period extends within 3 years in principle.
The total budget is from 100 million to 300 million yen per project.

※There are mitigation measures in collateral or guarantee of obligation.

○ Normal type

Normal type is recruiting under almost the same conditions as 1st & 2nd Solicitation.
For details please read the application guidelines.

Contact

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