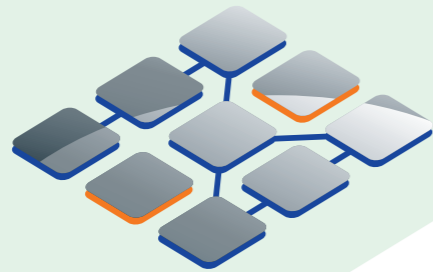


Post-marketing  
database  
study  
version



**MID-NET**<sup>®</sup>  
Medical Information Database Network

# わかる! MID-NET<sup>®</sup>

## (Introduction to MID-NET<sup>®</sup>)

MID-NET<sup>®</sup> is a database that is managed and operated by the Pharmaceuticals and Medical Devices Agency (PMDA) with the collaboration of cooperating hospitals (10 organizations) in order to contribute to the improvement of safety measure operations.

Participation by 10 organizations including over 20 hospitals across Japan  
Tohoku University Hospital, The University of Tokyo Hospital, Chiba University Hospital, Kitasato Institute Group, NTT Hospital Group, Hamamatsu University Hospital, Tokushukai Group, Kagawa University Hospital, Kyushu University Hospital, Saga University Hospital

This document introduces the characteristics of MID-NET<sup>®</sup> and presents a clear and easy-to-understand explanation of how to assess the possibility of using MID-NET<sup>®</sup> to conduct a post-marketing DB study, starting from the stage before the application for utilization.



### Access to PMDA (Tokyo)

Shin-kasumigaseki Bldg., 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo



The nearest exit of each station

- Subway Ginza Line ..... Toranomon Station Exit No.11, Exit No.5
- Subway Hibiya Line / Chiyoda Line / Marunouchi Line ... Kasumigaseki Station Exit A13
- Subway Chiyoda Line / Marunouchi Line ..... Kokkai-gijidoumae Station Exit No.3
- Subway Namboku Line / Ginza Line ..... Tameike-sanno Station Exit No.8

This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail. PMDA shall not be responsible for any consequence resulting from use of this English version. All the information of this version is of January 2024.

Related websites

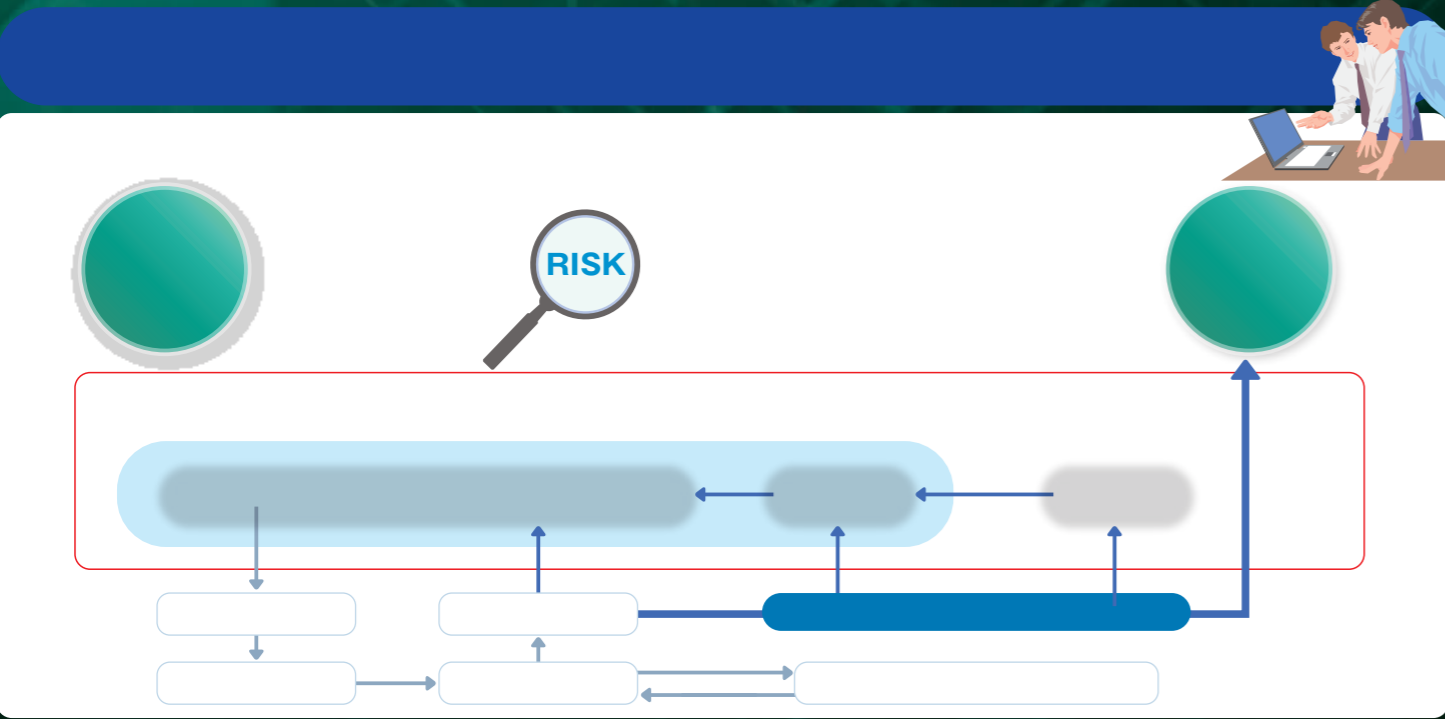
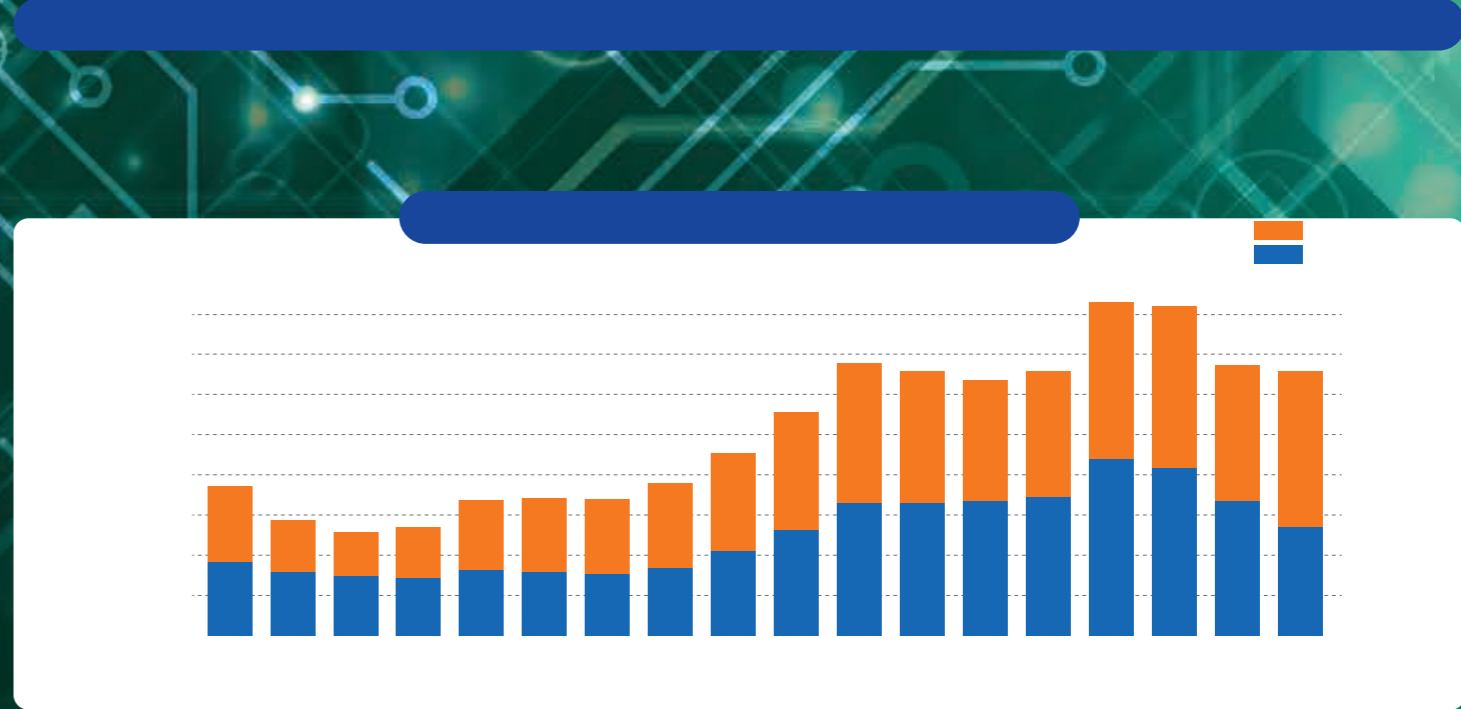
PMDA website: <https://www.pmda.go.jp/>  
MID-NET<sup>®</sup> website: <https://www.pmda.go.jp/safety/mid-net/0001.html>

For inquiries,  
please contact

Office of Medical Informatics and Science,  
Pharmaceuticals and Medical Devices Agency  
Shin-Kasumigaseki Building, 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo  
Email : [wakaru-midnet@pmda.go.jp](mailto:wakaru-midnet@pmda.go.jp)  
Phone: 03-3506-9473







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## Full customer service

### Easy access to the information you need!

- Information and documents required at each stage can be obtained from MID-NET® website
- Complete range of Materials for GPSP inspection that can be used from database selection to compliance review
- ✓ Our website was completely updated in November 2023! Improved environment for easier access
- ✓ When you select the database to use, a detailed explanation of necessary information, tailored to DB study management tool, etc., can be provided via web conference system.

### Simplification, shortening, and streamlining of various procedures!

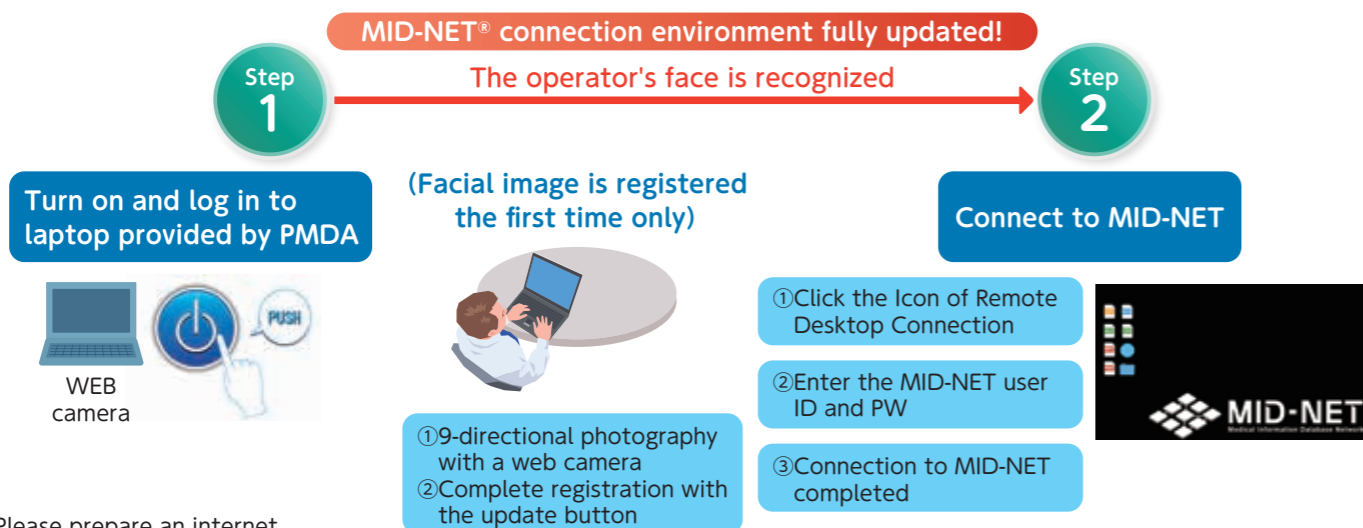
- As-needed revision of notifications and guidelines to make them easier to understand
- Get training on MID-NET® utilization through e-learning  
Please see MID-NET® website for how to implement MID-NET training, etc.
- Planning to start accepting online appointments for onsite center (around April 2024)

### Enhanced predictability of data extraction timing!

- Flexible adjustment to changing conditions
- ✓ We coordinate with individual situations so that the various procedures can be carried out smoothly
- ✓ Even before you apply for utilization, we anticipate the timing of the start of utilization when coordinating your schedule to enhance predictability

### Remote access for analytic work!

- Easy access through MID-NET® connection environment at any time from your office



Safety management measures will change as the system evolves but cannot be fully implemented by system functions alone. We will continue to establish operating rules. Please check the current rules.

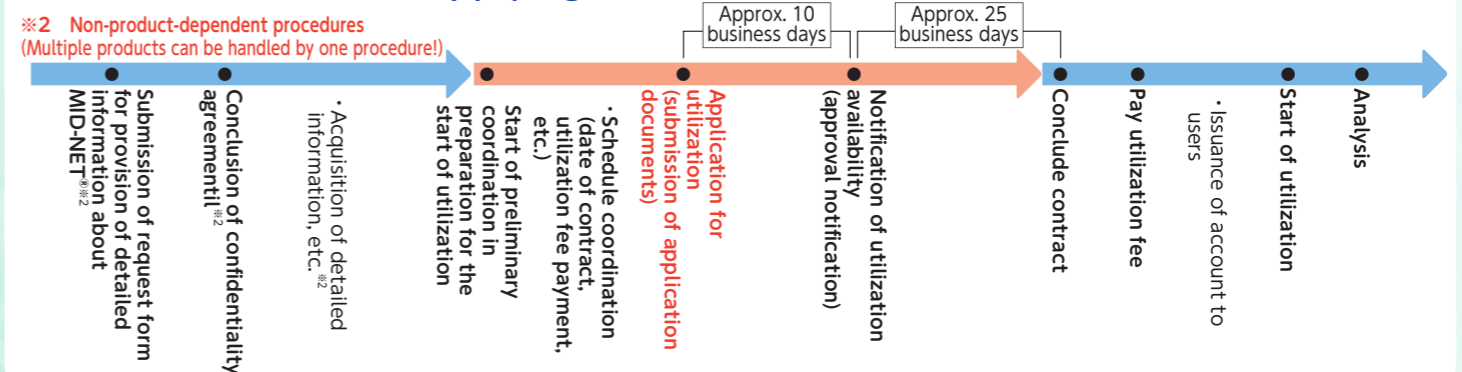
### Clear action scheme for re-examination application!

- We also offer support for submission of necessary data at the time of application for re-examination by the prescribed procedure (no additional fee)
- Utilization history: Used by 9 companies for 12 products (Re-examination completed for 2 companies of 2 products) (as of December 2023)

## For efficient utilization

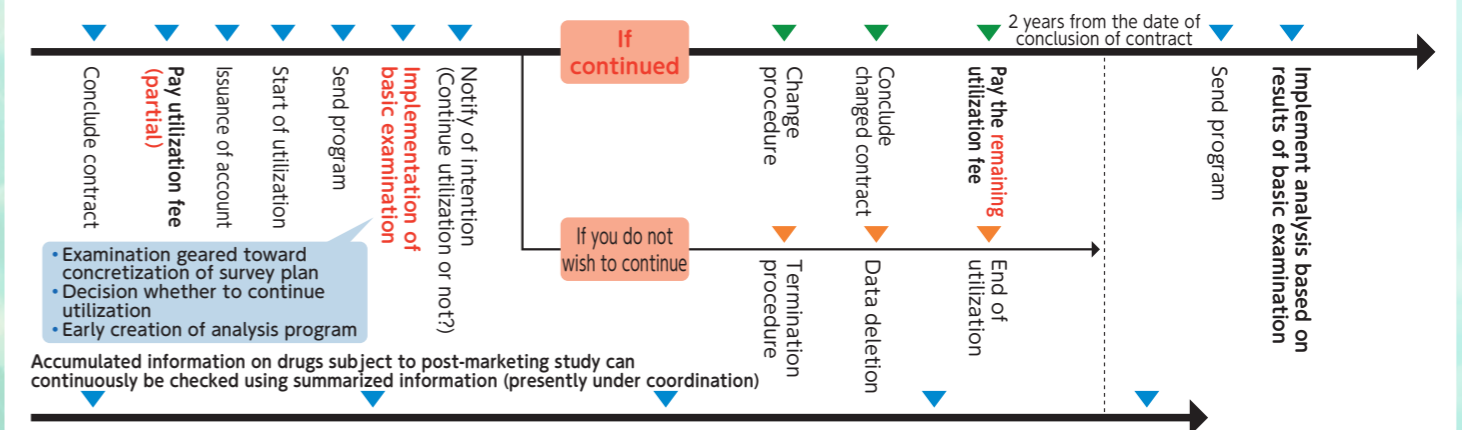
- Please see below for minimum time requirements for procedures from application for utilization to conclusion of contract.
- Please apply for utilization about 35 business days before the date of utilization fee payment and conclusion of contract.
- If you take the start time for utilization into consideration when determining the desired contract conclusion date, it will be easier to coordinate the schedule leading up to utilization.

### Flow before and after applying for utilization



## Key points of the basic examination

- At the initial stage of utilization, you can check whether the database contains sufficient information to enable you to develop a concrete survey plan. This check is called the basic examination.
- The basic examination is available if you make a partial payment of the utilization fee.
- You can decide whether or not to continue based on the results of the basic examination. If you decide to continue utilizing MID-NET®, you will then complete the necessary change procedures and pay the remaining utilization fee by the due date.



## Utilization categories and utilization fees

	Amount of utilization fee (per utilization) <sup>※3</sup>		
	If no basic examination is performed (Full payment)	If basic examination is performed (Partial payment of utilization fee)	If utilization is continued after implementation of basic examination (Remaining amount)
Post-marketing study (assuming utilization of individual patients level data)	42,123,000 JPY	5,410,000 JPY	36,713,000 JPY
Investigations other than post-marketing studies (when individual patients level data is utilized <sup>※4</sup> )	21,061,500 JPY	5,410,000 JPY	15,651,500 JPY

※3 If NCDA data is utilized, a separate utilization fee will be added.

※4 There is also a category for no utilization of individual patients level data (utilization of summary table)

You pay the same total utilization fee whether you continue utilization after performing basic examination or utilize without performing basic examination!  
If you are utilizing MID-NET® for the first time, performing a basic examination is definitely recommended!