# Initial Report of Japanese registry for Mechanically Assisted Circulatory Support (J-MACS)

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J-MACS
Japanese registry for Mechanically Assisted Circulatory Support

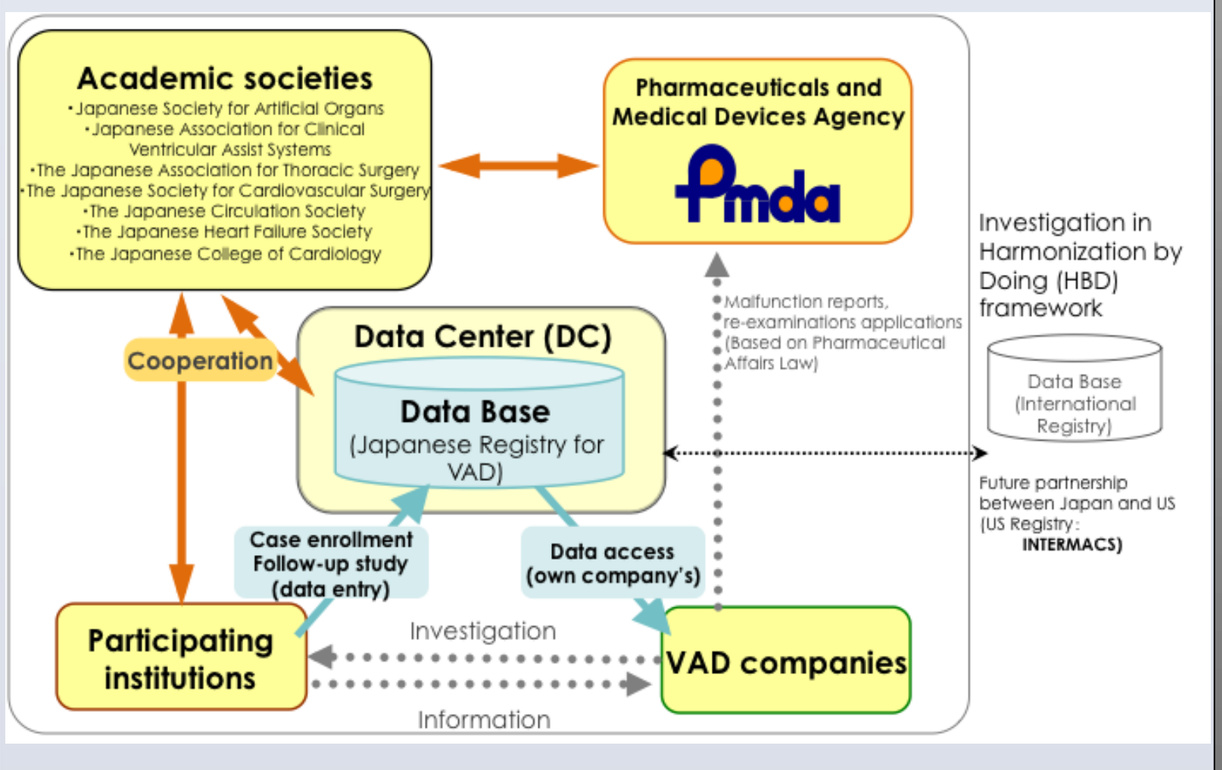
## Background

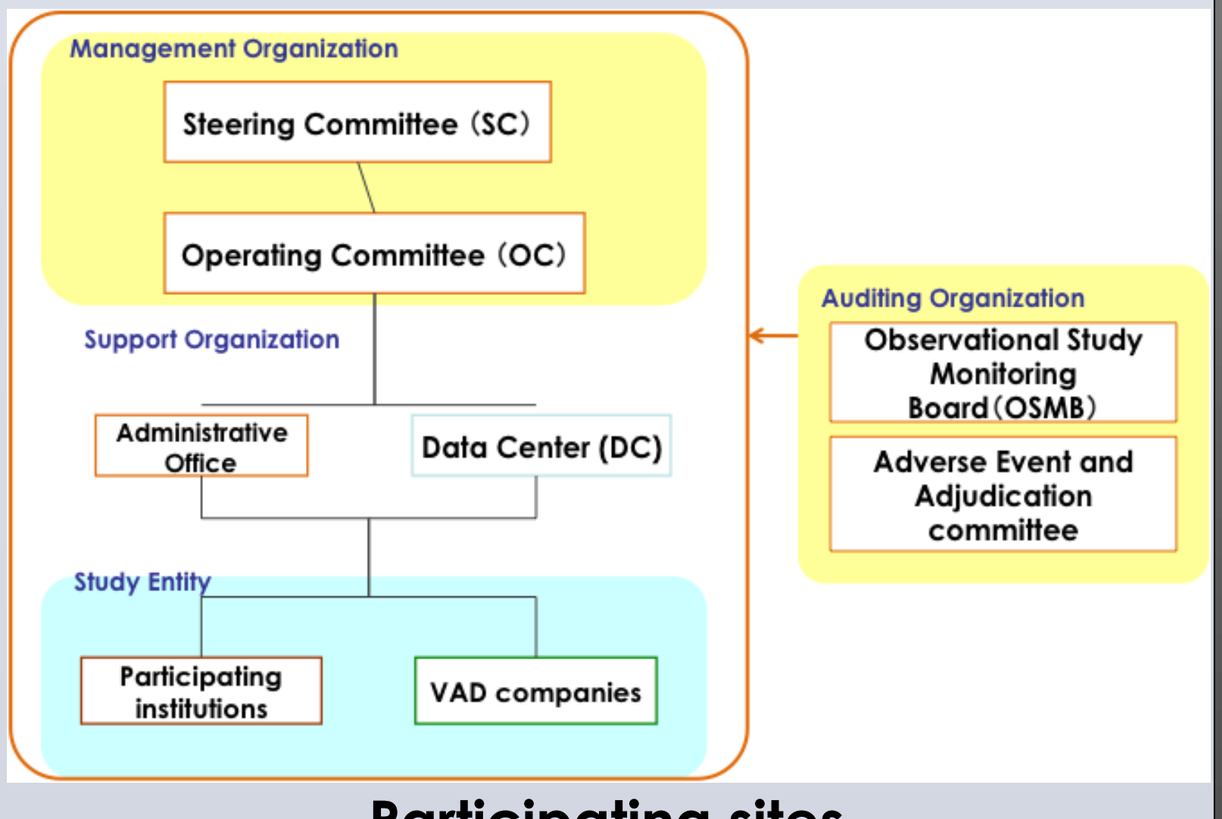
Clinical application of ventricular assist device (VAD) in Japan began in 1980 and 1343 cases were reported to Japanese Association for Clinical Ventricular Assist Systems, up to September 2011. Of those, 610 received various types of VAD (extracorporeal, n=460: implantable, n=150) as a bridge to transplantation. The mean support time was 383 days and 137 cases later underwent transplantation. Establishment of a database of mechanical circulatory support device (MCSD) cases is needed for development and promotion of clinical applications of new devices. For this purpose, INTERMACS was organized in USA and began data collection in 2006.

## Methods

Japanese government has launched a Japanese database - Japanese registry for Mechanically Assisted Circulatory Support (J-MACS) - as an enterprise based on the Pharmaceuticals and Medical Devices Agency (PMDA) interim plan. The framework was constructed from discussion with 7 academic societies, participating hospitals (6 at start), manufactures (4 at start), and PMDA. All patients who receive a durable VAS, approved in Japan, are included. J-MACS is a prospective registry and post-marketing observational research systems designed to collect clinical data, including from follow-up examinations. All data are entered using the J-MACS web-based data entry system. Membership in J-MACS is one of the essential conditions for authorization of hospitals to use an implantable left VAD under national medical insurance coverage.

## Framework of J-MACS




## Participating sites

- Tohoku U
- Tokyo U
- Tokyo Women's Medical U
- National Cerebral & Cardiovascular Center
- Osaka U
- Kyusyu U
- Hokkaido U
- Saitama Medical U International Medical Center
- Tokyo Medical and Dental University
- Hyogo Medical University
- Gunma Prefectural Cardiovascular Center
- Sakurabashi Watanabe Hospital

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## Data Candidates for J-MACS

- Nipro-Toyobo
- EVAHEART (March 2011)
- DuraHeart (March 2011)
- Jarvik 2000
- Heartmate II

Nipro-Toyobo Extracorporeal type
Intended long-term use as BTT

## J-MACS : Registry Design

Prospective design

J-MACS is a prospective registry and post-marketing observational research, that will collect clinical data, including follow up, essentially as it happens.

Eligibility: Inclusion criteria

1. Patients who receive a durable VAS (Ventricular Assist Systems) which is approved.
2. Patients who receive a VAS after hospital activated.
3. Patients who have signed informed consent for the registry.

Data collections

J-MACS basically collect data in the same way (in Japanese) as INTERMACS.
- Data items, Timing for data collection, Definitions of adverse event, QOL (EuroQOL ED-5D), Neuro-congnitive data (Trail making test Part B) , etc.
- Add or alter the item/definitions which need for Japanese data
- Post implant follow up data will be collected at 1 week, 1 month, 3 months, 6 months and every 6 months after that.
- Major outcomes after implant, e.g. transplant, death, explant, rehospitalization, and adverse events, will be entered as they occur and also as part of the defined follow-up scheduled intervals.

## Results

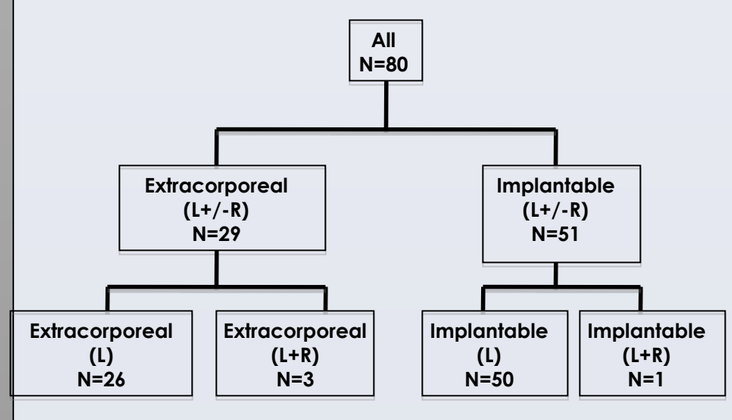


Figure1:Device types (June,2010- December,2011)

**Table 1: Demographics for patients (gender)**

| Gender | Imppantabe | Extracorporeal | total |
|---|---|---|---|
| male | 42 | 18 | 60 |
| female | 9 | 11 | 20 |
| total | 51 | 29 | 80 |

**Table 2: Demographics for patients (age)**

| Age | Impalantabe | Extracorporeal | total |
|---|---|---|---|
| 0-18 | 2 | 3 | 5 |
| 19-29 | 7 | 10 | 17 |
| 30-39 | 17 | 6 | 23 |
| 40-49 | 15 | 5 | 20 |
| 50-59 | 9 | 5 | 14 |
| 60-69 | 0 | 0 | 0 |
| 70-79 | 1 | 0 | 1 |
| total | 51 | 29 | 80 |

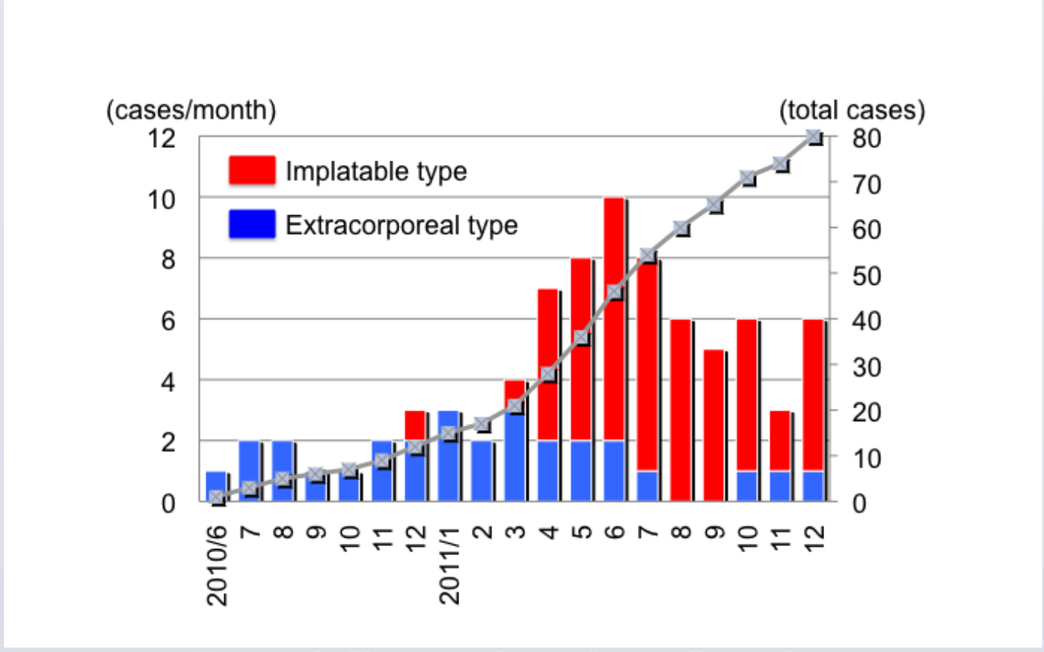


**Figure 2: The number of enrollment from June,2010 to December,2011.**

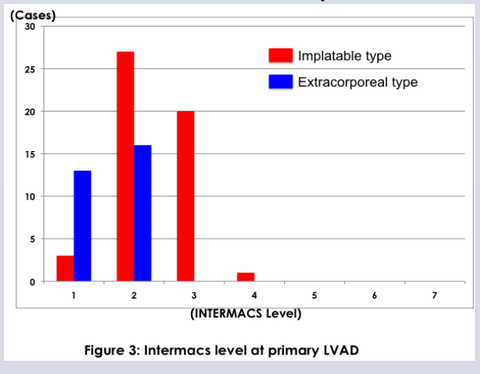


Figure 3: Intermacs level at primary LVAD

**Figure 3: Intermacs level at primary LVAD(Implantabe:51, Extracorporeal:29)**

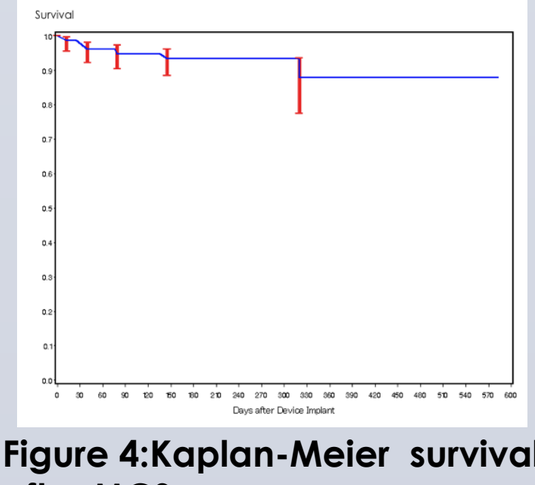


**Figure 4:Kaplan-Meier survival after MCS**

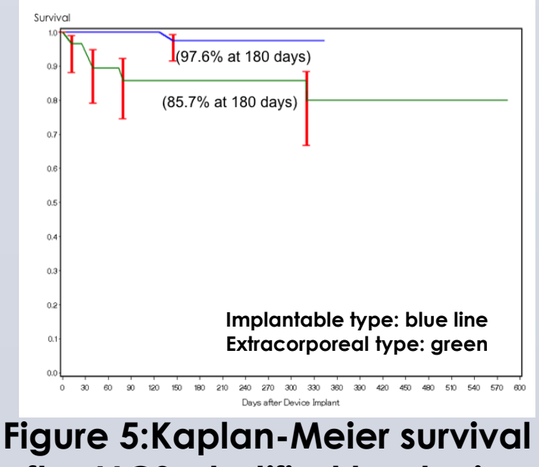


**Figure 5:Kaplan-Meier survival after MCS, stratified by device types.**

## Conclusion

J-MACS will be useful for improving clinical assessment, management, treatment, and development of new technologies for MCSD. The data are expected to be beneficial for assuring patient safety, when developing new devices by clarifying the risks and benefits, with the resulting data assessments useful for implementation of appropriate safety measures.

Relevant Financial Relationship Disclosure Statement
The authors have no financial conflicts of interest to disclose concerning the presentation.