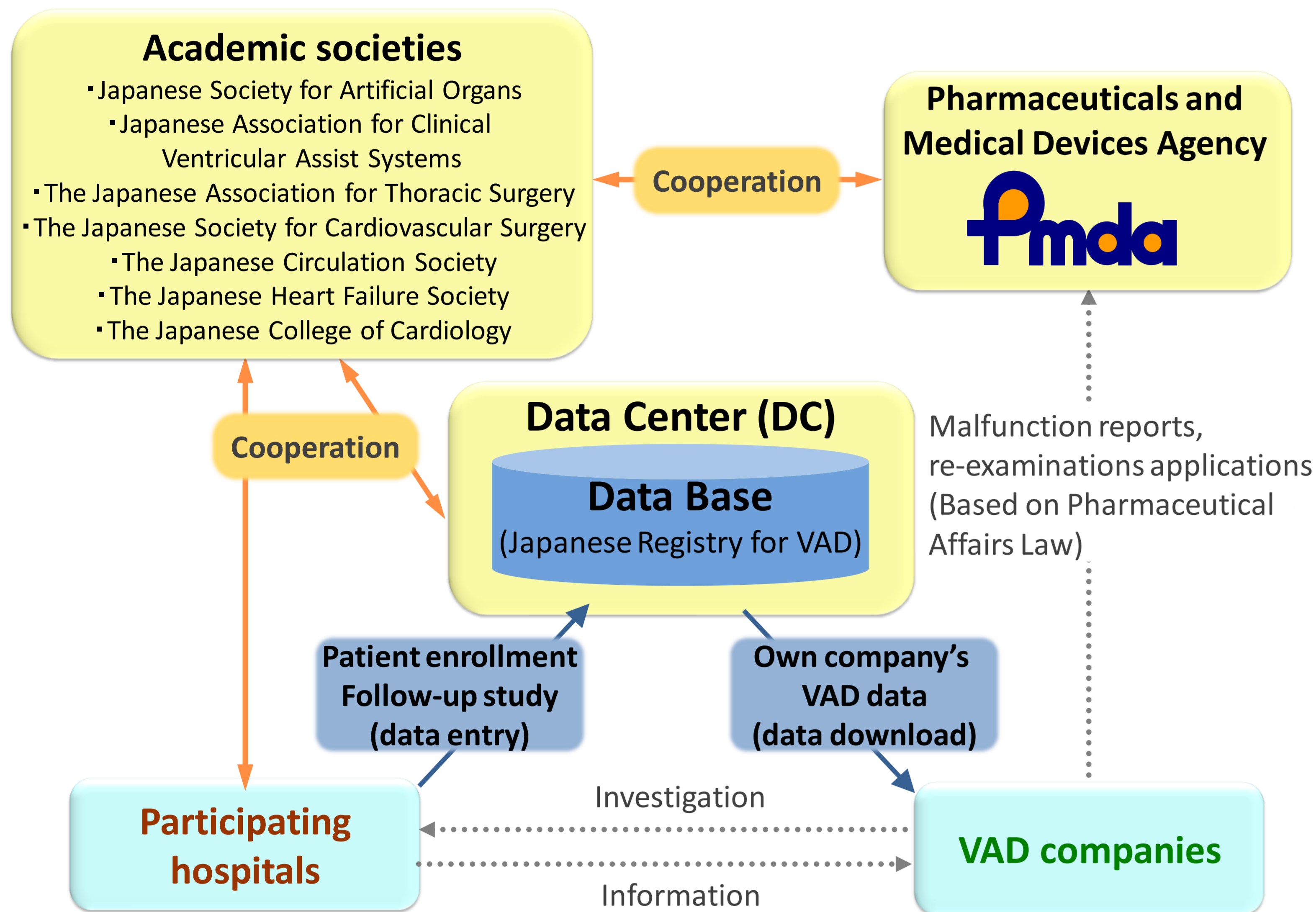


WHAT IS J-MACS?

- J-MACS is a post-market data-collection project related to ventricular assist device (VAD) in Japan.
- The PMDA launched a project of the J-MACS based on the mid-term plan, as part of new efforts for post-marketing safety measures for medical devices.
 - Mid-term Plan of the PMDA
 - Construct a system for gathering and evaluating data on the operational status of high risk, implantable tracking medical devices (implantable ventricular-assist devices), such as the occurrence rate of malfunctions over time, and appropriately utilize such system in the development of safety measures.

FRAMEWORK



ORGANIZATION

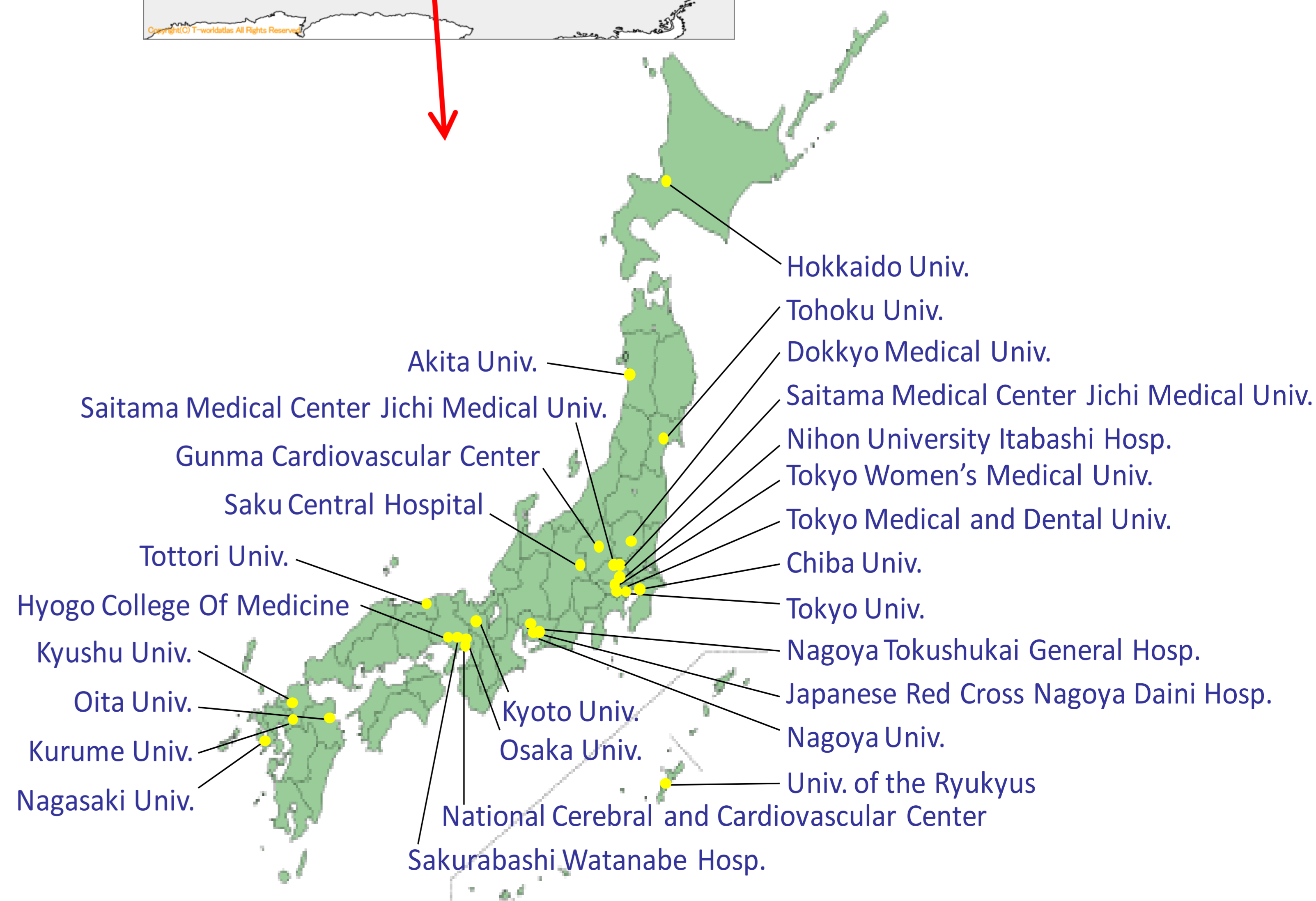
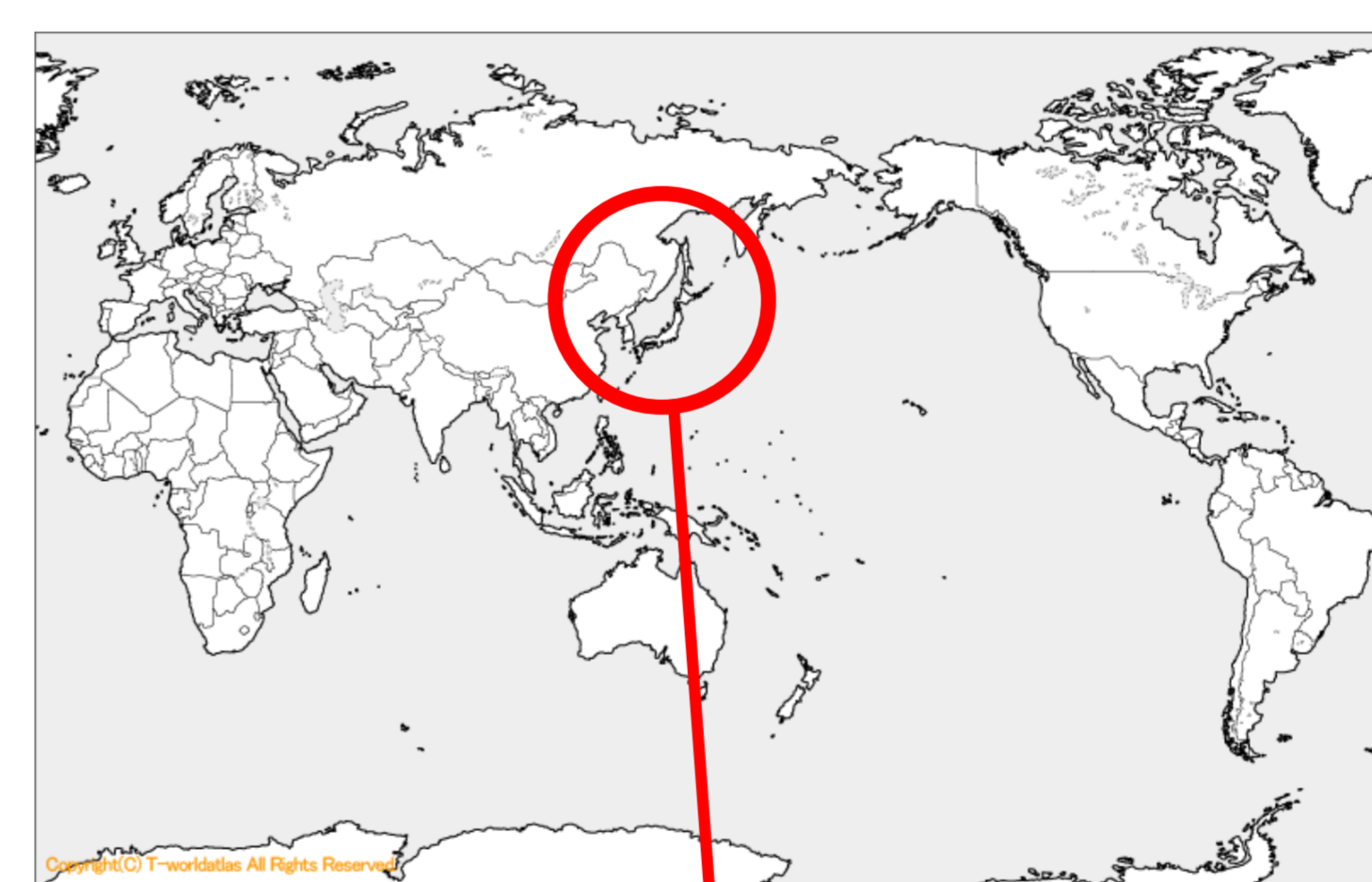
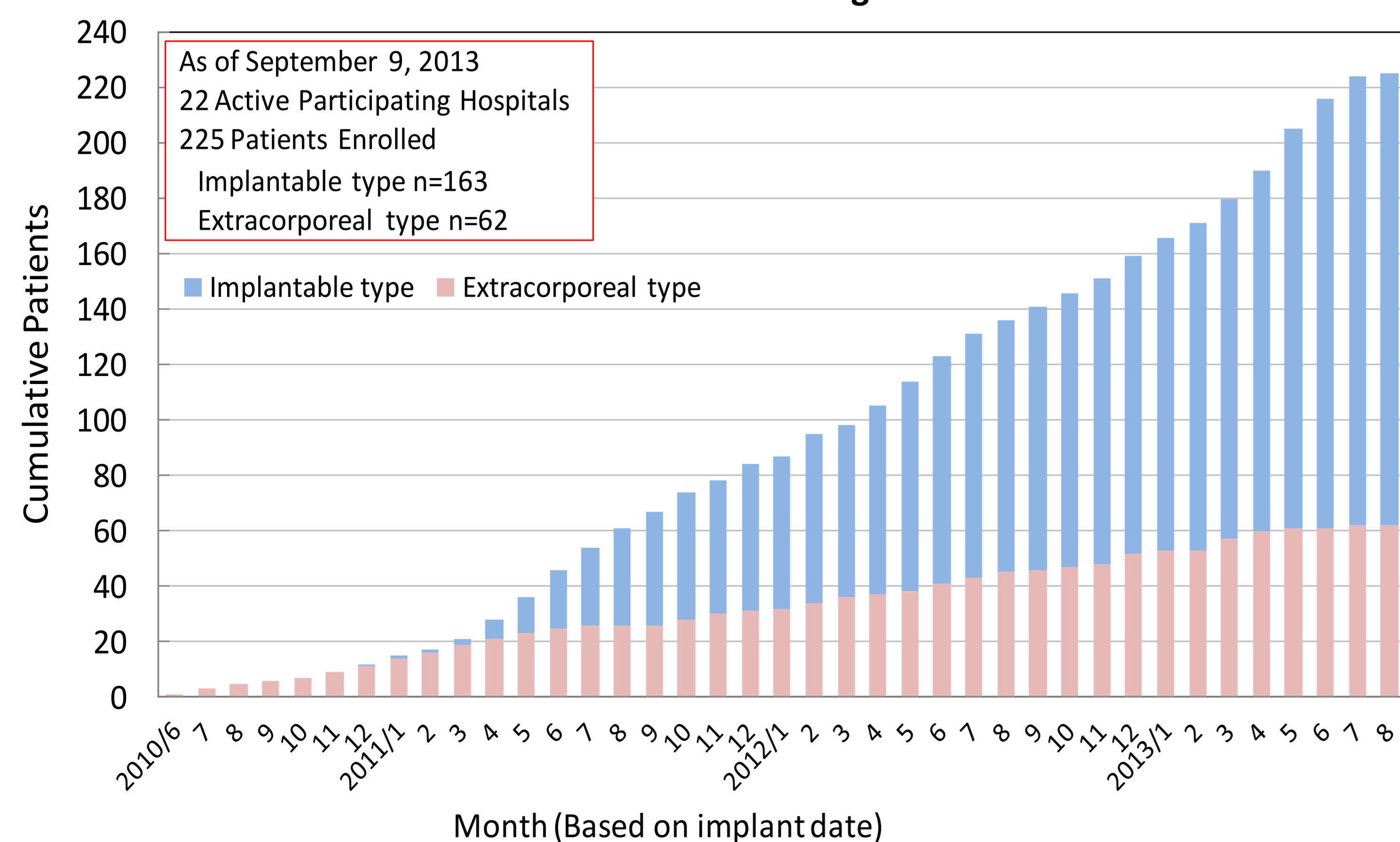
- J-MACS has established the Steering Committee consisting of representatives from academic societies and a manufacturers association and the Operating Committee consisting of a principal investigator (PI), co-PIs, experts from hospitals and the VAD companies.
- As an independent organization to oversee the registry, the Observational Study Monitoring Board has been established.
- Adverse events reports including deaths from VAD companies are reviewed by the Adverse Event and Adjudication Committee which is also an independent organization and the committee provides advice for safe use of VAD.

PARTICIPATING HOSPITALS

- Membership in J-MACS is one of the essential conditions for authorization of hospitals to use implantable VADs under the national medical insurance coverage.
- All hospitals which use implantable VADs provide information about the post-marketing data of the VADs approved in Japan, which is on a long term basis through WEB based data entry system.
- As of September 2013, 27 hospitals are participating.

- The implementation plan was developed as an observational study in collaboration with 7 academic societies, participating hospitals, the relevant VAD companies and PMDA under the cooperation among industry-government-academia.
- The VAD companies utilize the patients' data collected through J-MACS to report medical device malfunction and conduct post-marketing surveillance required under the Pharmaceutical affairs law.
- Between June 2010, and August 2013, 225 patients into the J-MACS database.

The number of Patient Enrollment
Jun. 2010 - Aug. 2013



REGISTRY DESIGN

➤ J-MACS is a prospective registry in a post-marketing observational research that collects clinical data, including follow up, essentially as it happens.

➤ Eligibility : Inclusion criteria

1. Patients who receive a durable VAD which is approved in Japan.
2. Patients who receive a VAD after hospital activated.
3. Patients who have signed informed consent for the registry.

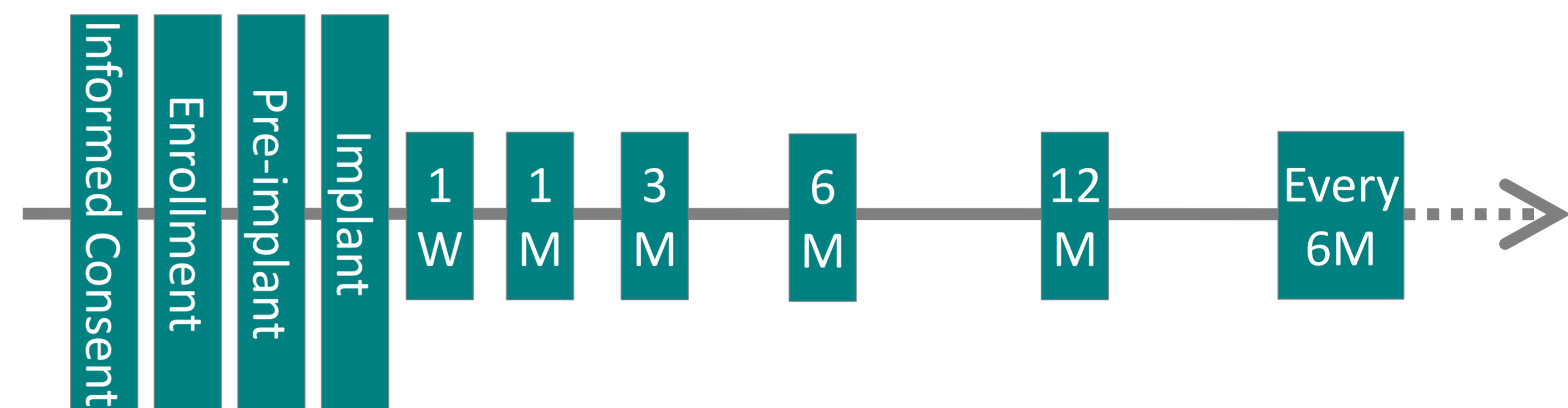
➤ Devices

- EVAHEART
- DuraHeart
- Jarvik 2000 (Under review)
- Heart Mate II
- Nipro-Toyobo (Extracorporeal type)



➤ Data collection

- Post implant follow up data are to 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, are to be entered as they occur and also as part of the defined follow-up scheduled intervals.



STATISTICAL SUMMARY

➤ Patients included in analysis

• Of the total 181 patients who were implanted with VAD between June 2010 and March 2013, 135 patients who met the following criteria were included (The data available as of July 9, 2013 were used.) :

- ✓ Patients who have never used VAD at the time of enrollment in J-MACS
- ✓ Patients who were assisted only by LVAD at the time of enrollment in J-MACS
- ✓ Patients who were 19 years of age or older at the time of implantation of LVAD

➤ Patients demographics (Primary LVAD population)

• Gender

Gender	Total(%)	Implantable(%)	Extracorporeal(%)
Male	110(81)	79(87)	31(70)
Female	25(19)	12(13)	13(30)
Total	135	91	44

• Age

Age	Total	Implantable	Extracorporeal
Mean ± SD	41 ± 11.4	42.5 ± 11.0	36.8 ± 11.4

• Pre-implant patient profile

Profile	Total (%)	Implantable (%)	Extracorporeal (%)
Level 1: Critical cardiogenic shock	26(19)	3(3)	23(52)
Level 2 : Progressive decline	73(54)	53(58)	20(45)
Level 3 : Stable but inotrope dependent	33(24)	32(35)	1(2)
Level 4 : Recurrent advanced HF	3(2)	3(3)	0(0)
Level 5-7 *	0(0)	0(0)	0(0)
Total	135	91	44

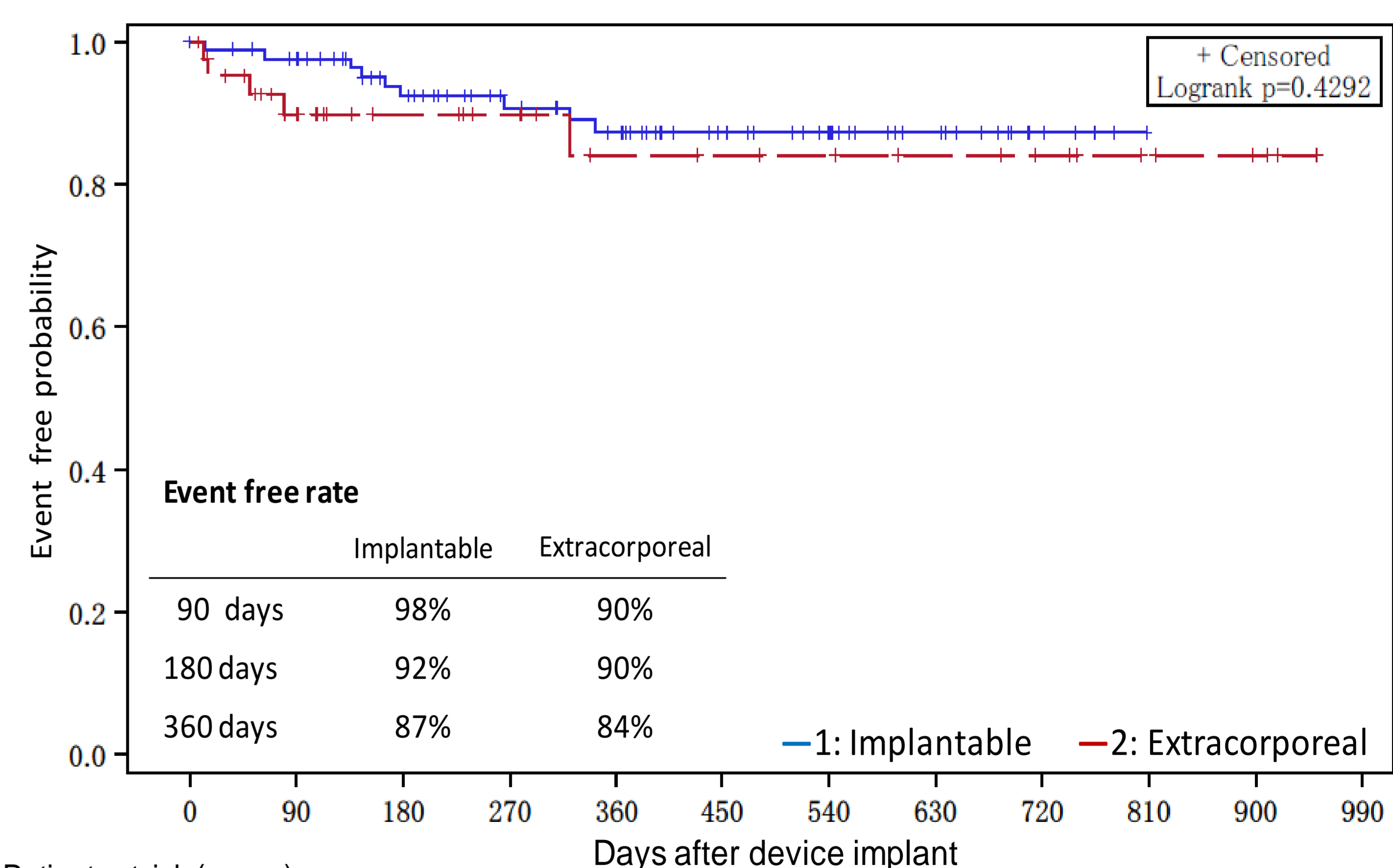
* Level 5,6,7 : Exertion intolerant, Exertion limited, Advanced NYHA class III

➤ Number of patients (Primary LVAD population)

Device	Cases (%)
Implantable	91(67)
Extracorporeal*	44(33)
Total	135

* :10 cases were converted to implantable type

➤ Survival by device type(Primary LVAD population)



Patients at risk (cases)	0	90	180	270	360	450	540	630	720	810	900	990
Implantable	91	83	69	55	49	35	29	15	5	0		
Extracorporeal	44	30	22	19	14	13	12	10	8	5	3	0

[Reference] <http://www.pmda.go.jp/english/service/j-macs.html>