



Annual Report 2019 (Jan. – Dec.)

May. 29, 2019
Japan CRO Association

JCROA 2019

Total Number of Members: 41 companies

Regular Member: 16 companies

Supporting Member: 25 companies

(Note)

* The business results are calculated in three business areas such as 1) Pharmaceutical Development, 2) Medical Devices and Food & Nutrition-Supplement Development and 3) Others (including Academia Clinical Research and non-clinical research etc.) from 32 companies in 2019, excluding 9 supporting members in this report.

* The approximate figures in the missing values are calculated on the basis of average values of valid responses.

2019 JCROA Annual Sales Report in detailed

1. Total Sales Volume

- ① Total turnover increased by 48.57/100 Mil. Yen (1,949.9/100 Mil.Yen from 1,901.3/100 Mil.Yen in 2018), 2.6% in 2019.
- ② Total Sales volume of medical products (Pharmaceuticals), devices, regeneration, food & nutrition, academia clinical research increased by 38.9 Mil.Yen (from 1,823.4/100 Mil.Yen to 1,862.3/100 Mil.Yen), 2.1%. While the sales of medical products sharing 88.8%, 9.6/100 Mil.Yen decreased (from 1,740.3/100 Mil Yen to 1,730.7/100 Mil.Yen) by 0.6%, the medical devices increased by 10.8/100 Mil.Yen, 26.6%.

2. Sales Volume of Medical Products/Devices/Regeneration/Food & Nutrition-Supplement/Academia Clinical Researches by Business Services

- ① Monitoring decreased by 21.9/100 Mil.Yen. (- 2.1%)
- ② DM&Bio.Stat decreased by 13/100 Mil.Yen. (- 4.2%)
- ③ GVP reached 161.9/100 Mil Yen.(-12.9%)
- ④ Academia Clinical Researches reached 52.9/100 Mil.Yen, increased by 12.3/100 Mil.Yen. (+30.4%)

3. Medical Products Sales by Clinical Phases

- ① Phase I to III increased by 0.6%. Post-marketing Clinical Trials decreased by 33%, while PMS increased by 25.7%. The business sectors of temporary placement increased by 8.8/100 Mil.Yen, 15.6%.
- ② In other business sectors, the project management business with 11 companies reached the biggest portion with 23 companies out of 32 companies. The consulting in contracted business is going to increase.

4. Total number of employees joining JCROA reached 17,296 by increase of 136. The CRA joining JCROA, engaged with clinical trials including QC, reached 7,465 by increase of 126. The number of GVP(PV) and registration/data center decreased in the same manner as the sales volume.

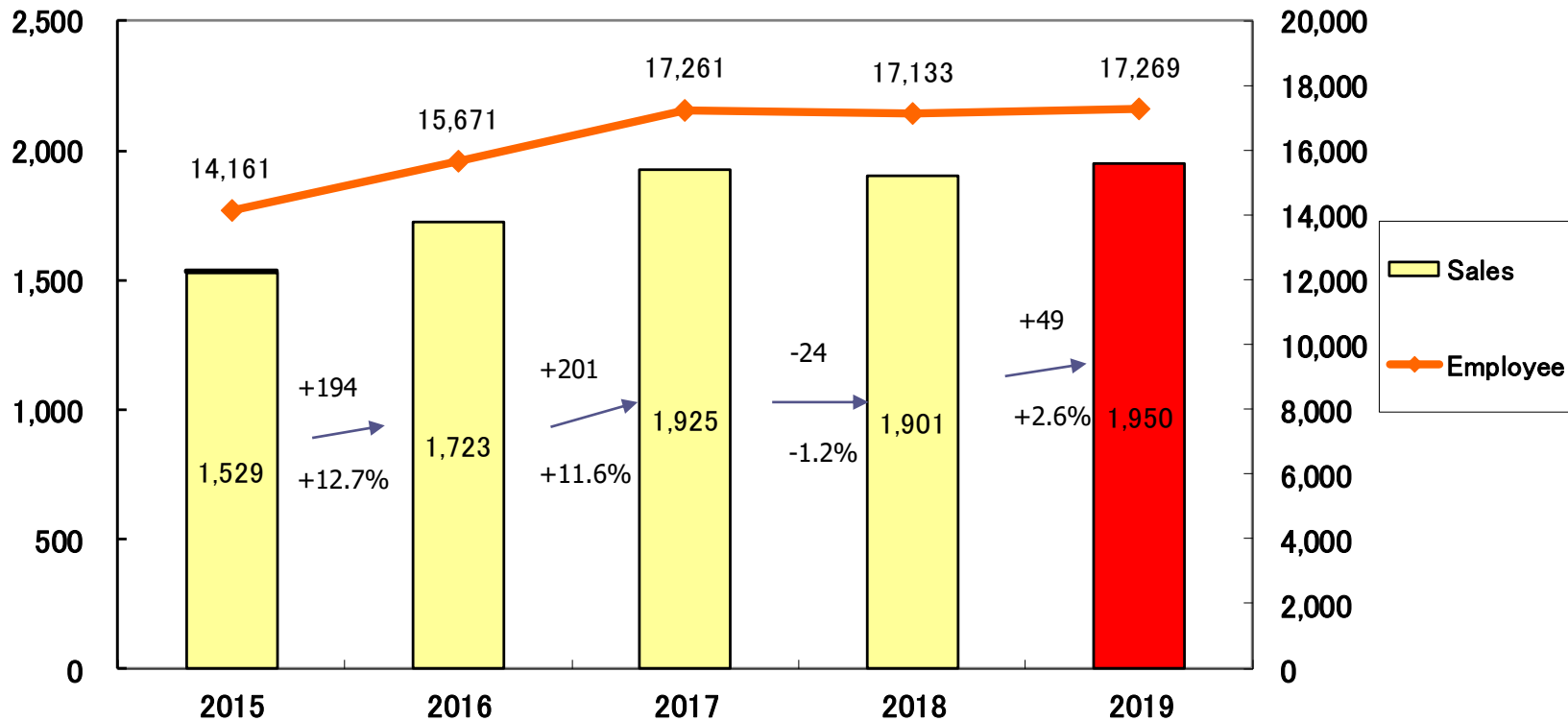
5. Ratio of monitoring project numbers by only effective replies

- ① Tumors occupied the large part of project numbers by disease area, following by CNS and metabolism.
- ② The ratio by phase indicated the almost same results.

Sales and Employees 2015–2019*

(Sales Unit: 100 Mil.¥)

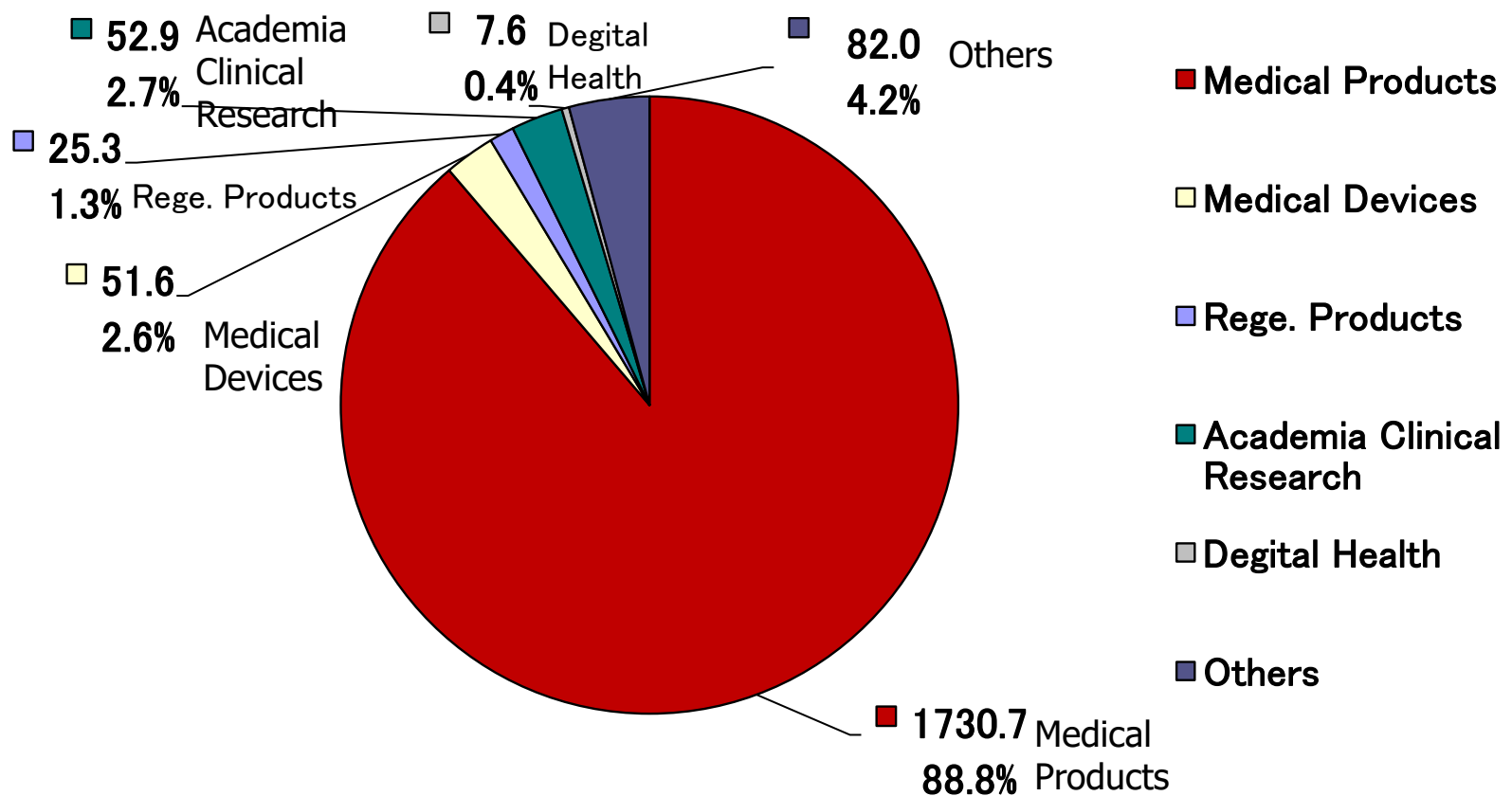
(Employee No.)



* Count and estimate based on data of 26 in 2015/2016, 32 in 2017, 33 in 2018, 32 member companies in 2019.

2019 Sales by Business Fields

Total: 1950/100 Mil. ¥
 [1,773 Mil. \$ (1\$=110¥)]

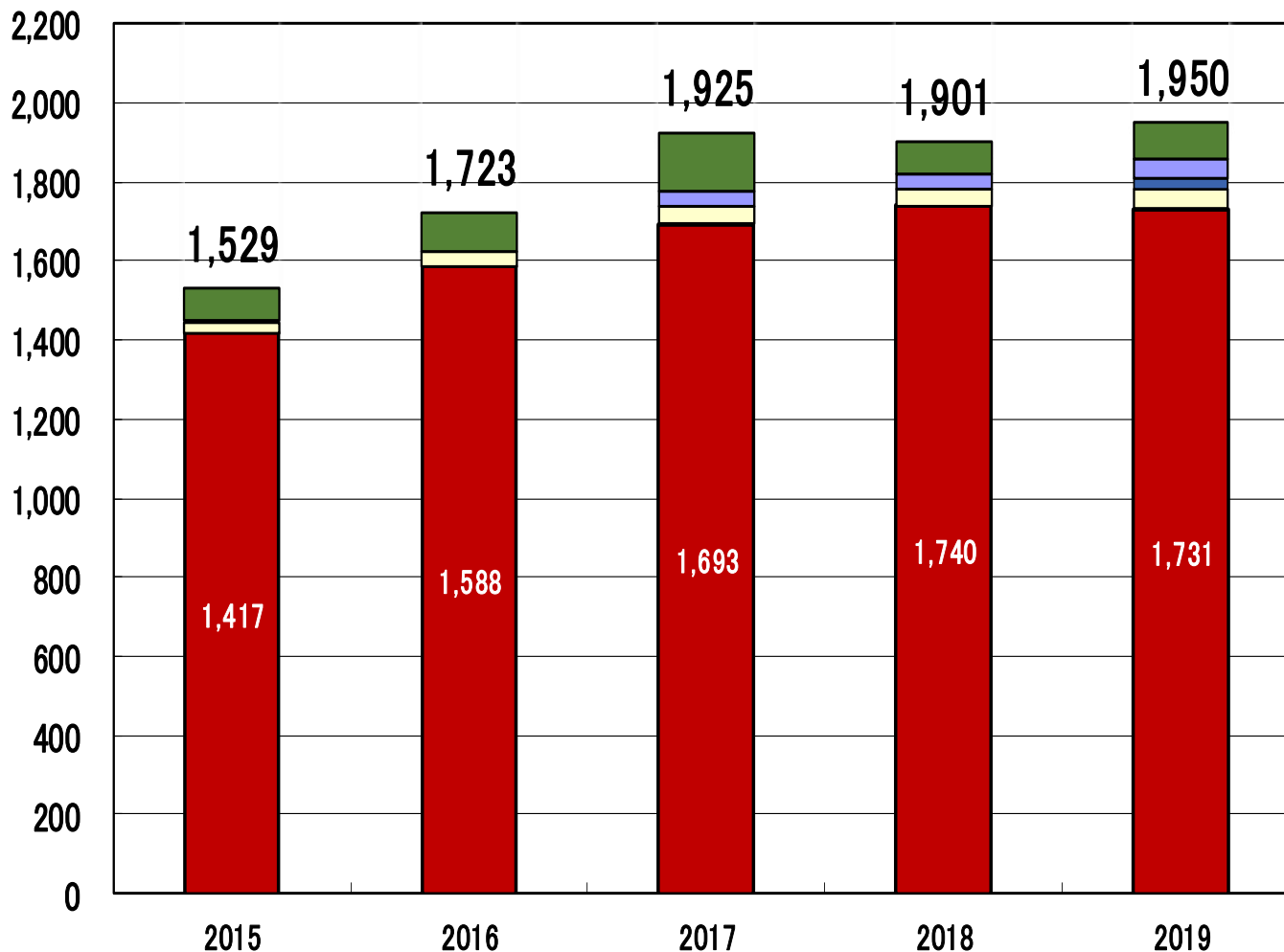


Sales (Unit: 100 Mil. ¥)

Sales by Business fields 2015–2019

(Sales Unit: 100 Mil.¥)

compared to 2018

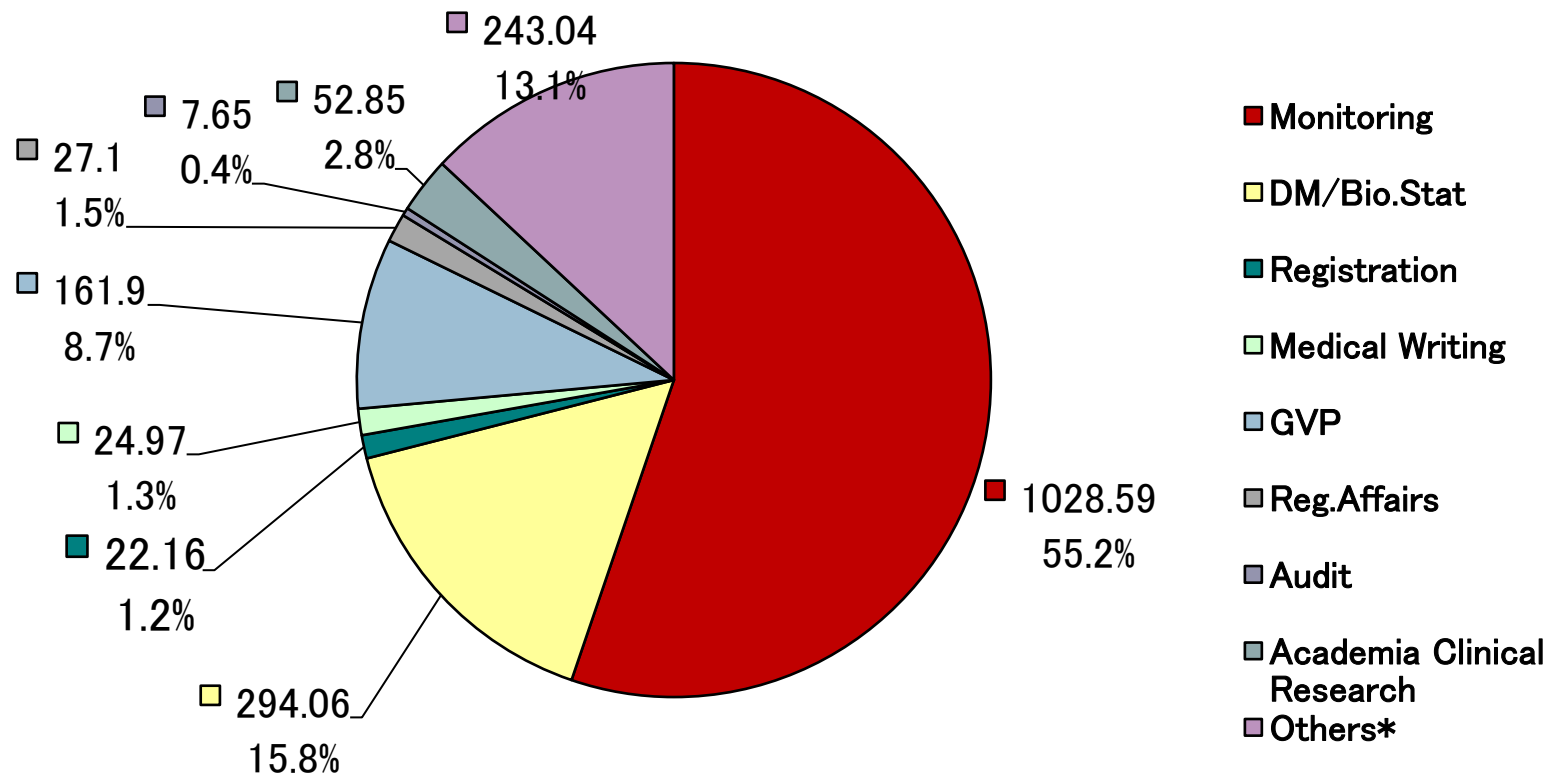


Sum	+48.6(+2.6%)
Others	+9.7(+12.5%)
Academia Clinical Research	+12.3(+30.5%)
Rege. Products	25.3
Medical Devices	+10.8(+26.6%)
Medical Products	-9.6(-0.6%)

(Sales Unit: 100 Mil.¥)

2019 Medical Products/Devices/Regeneration/Food & Nutrition-Supplement/Academia Clinical Research Sales by Business Services

Total: 1862.3/100 Mil.¥
[1,694 Mil. \$ (1\$=110¥)]



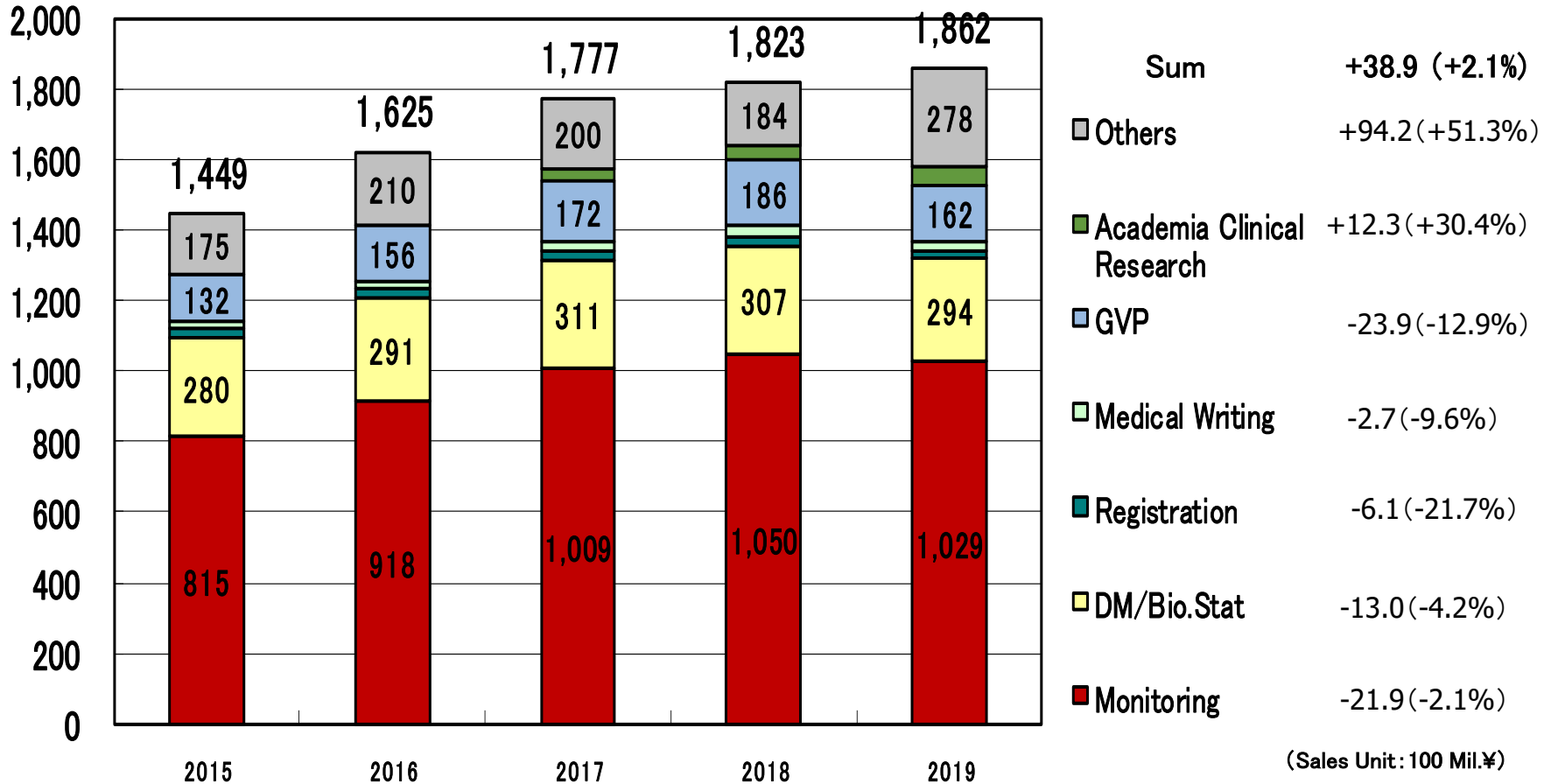
Sales (Unit: 100 Mil. ¥)

*Please refer to page 10 for "others".

2019 Medical Products/Devices/Regeneration/Food & Nutrition- Supplement/Academia Clinical Research Sales by Business Services

(Sales Unit: 100 Mil.¥)

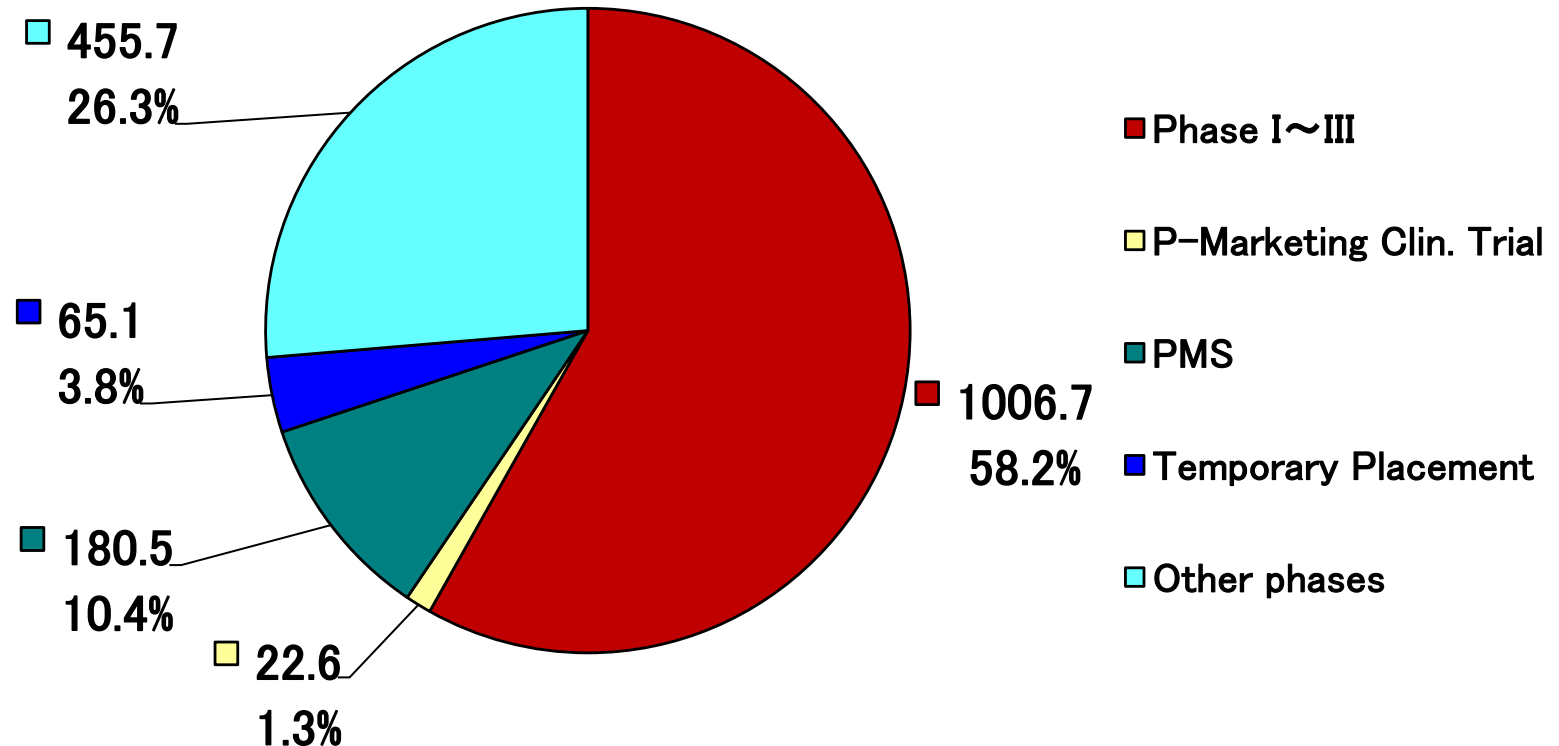
compared to 2018



Academia Clinical research sector has been included since 2018.
The sales volume for 2017 has been revised including the academia clinical research.

2019 Medical Products Sales by Clinical Phases

Total: 1731/100 Mil.¥
[1,574Mil. \$ (1\$=110¥)]

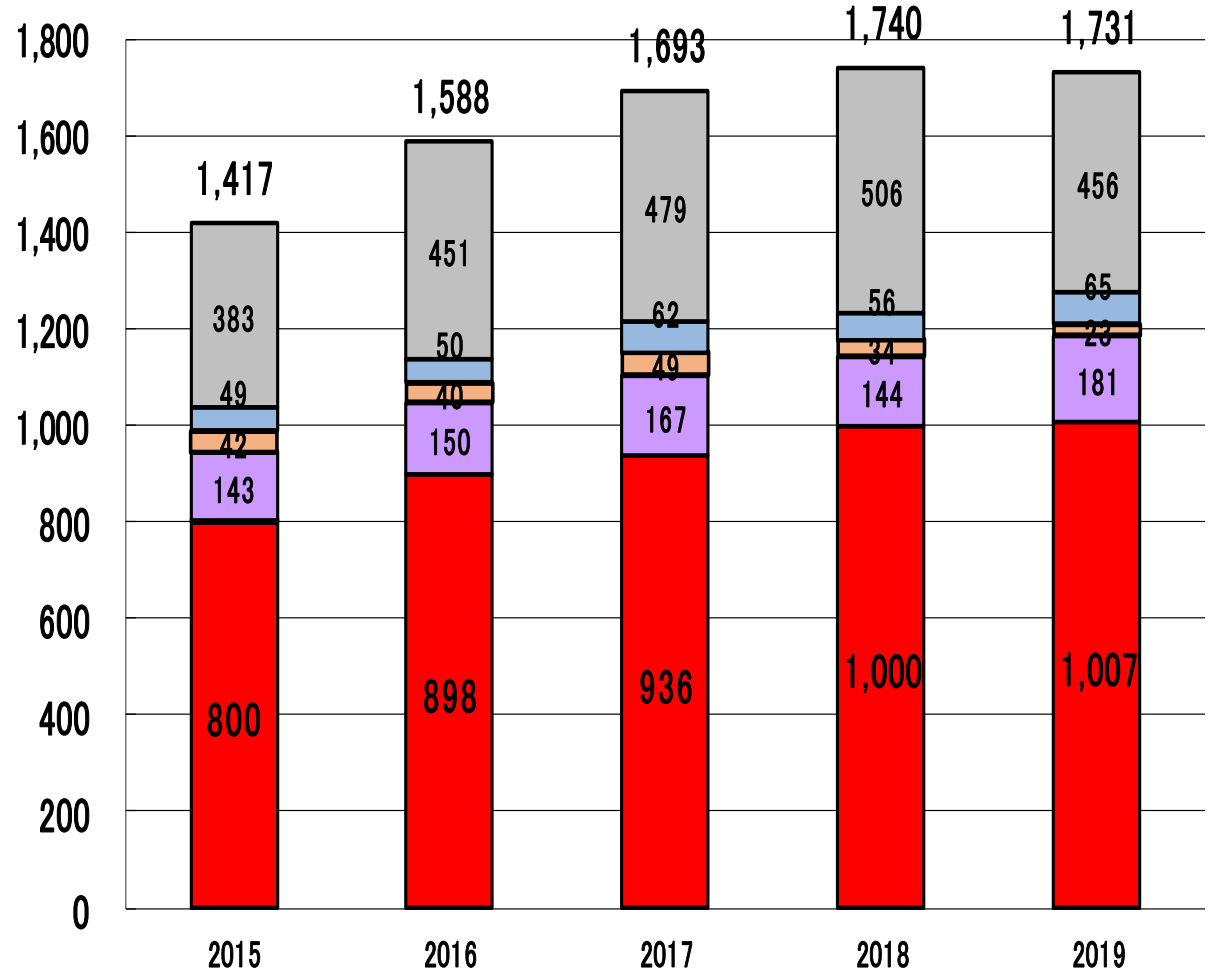


The sales volume of Phase I to III were combined. The ones of GVP, regulatory consulting were summarized in other phases. Academia Clinical research has not been included since that has not been investigated by relevant area and phase.

Medical Products Sales by Clinical Phases 2015–2019

(Sales Unit: 100 Mil.¥)

compared to 2018



Sum	-9.6 (-0.5%)
Other phases	-50.4 (-10.0%)
Temporary Placement	+8.8 (+15.6%)
P-Marketing Clin. Trial	-11.1 (-33.0%)
PMS	+36.9 (+25.7%)
Phase I~III	+6.3 (+0.6%)

(Sales Unit: 100 Mil.¥)

The sales volume of Phase I to III were combined. The ones of GVP, regulatory consulting were summarized in other phases. Academia clinical research has not been included since that has not been investigated by relevant area and phase.

Other services Conducted in relation to Medical Products 2019

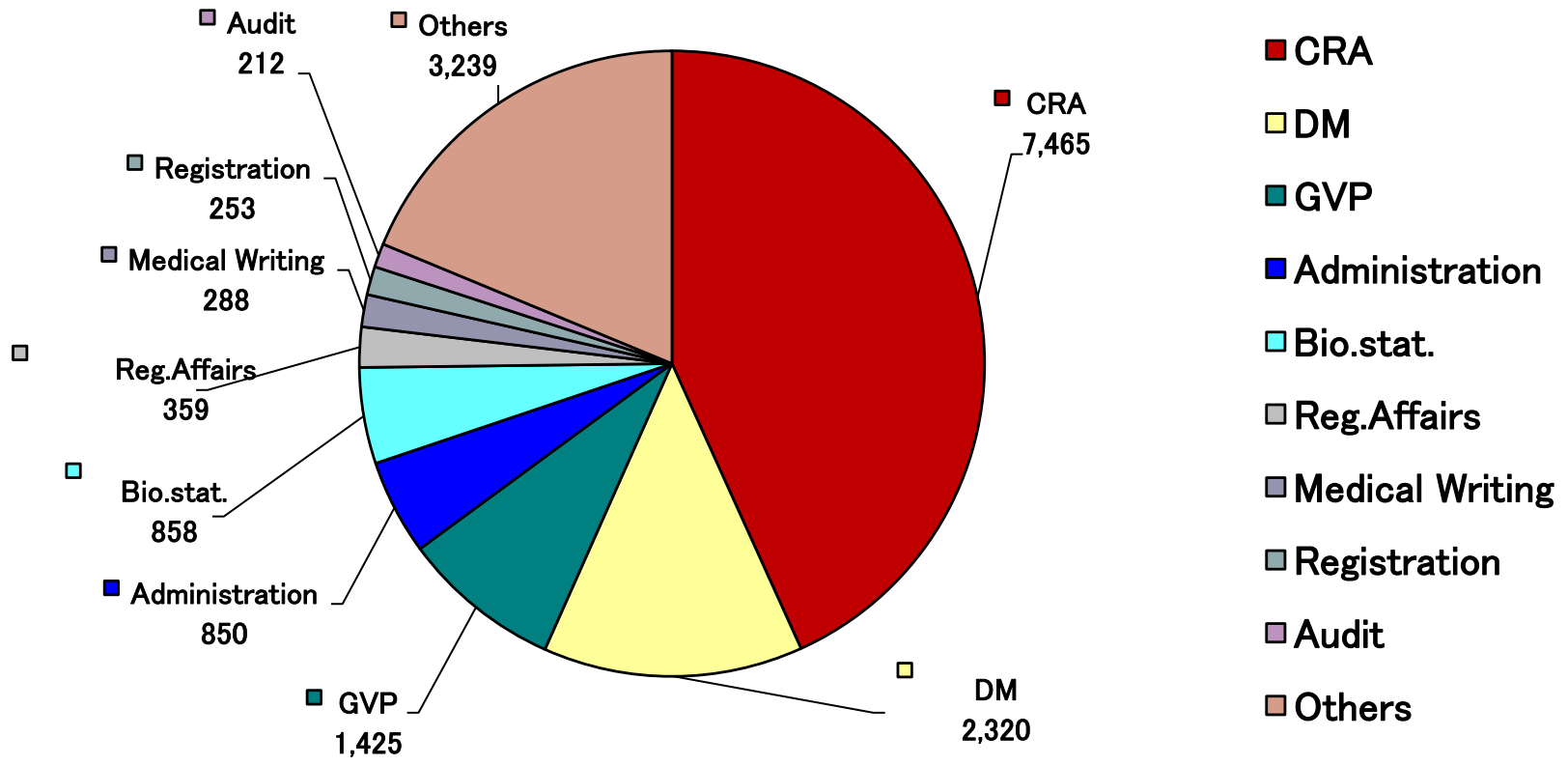
(The figures represent the number of CRO conducting those business services. Responding from 23 members.)

Business services	No.	Business services	No.
Project management	11	SOP preparation	7
IT support, system building (excluding EDC)	10	Randomization	6
Education & training	10	Logistics and storage of IMP	5
Academic paper writing	8	Establishing analytical methods, validation	4
Translation	8	Advertisement of recruiting clinical study subjects, site-selection	3
Holding research holding	7		

- IDMC operation, management & support
- IRB secretariat administration
- Medical writing
- RBM/Diagnostic imaging system
- Assistance of Pharmacovigilance management
- Central clinical laboratory test
- Consulting
- Regulatory affairs relating business, assistance for preparation for compliance assessment review by PMDA
- Storage of documents

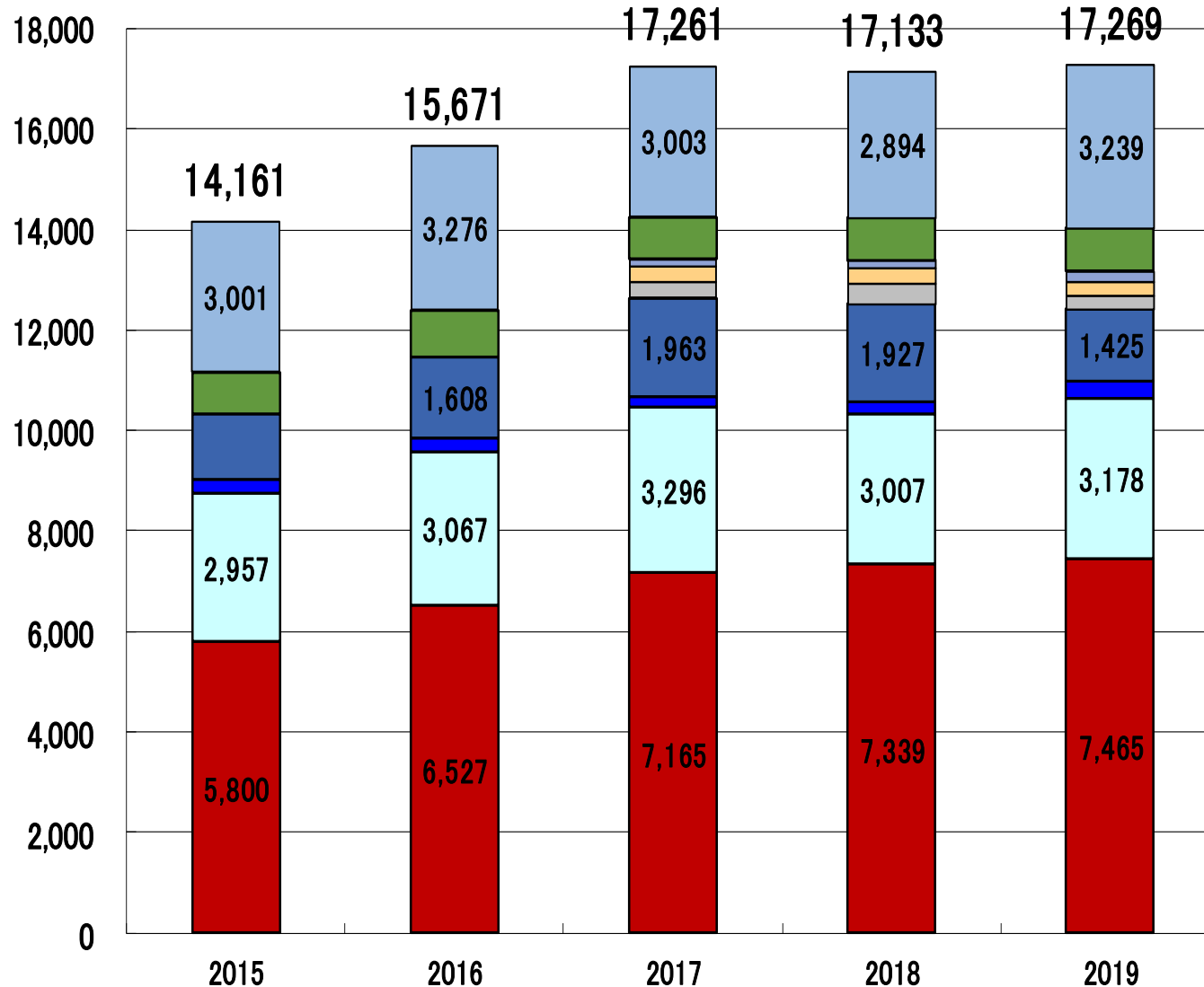
2019 Employees by Business Services

Total No. of employees: 17,269



Employees by Business Services 2015–2019

(Unit: No. of employees)



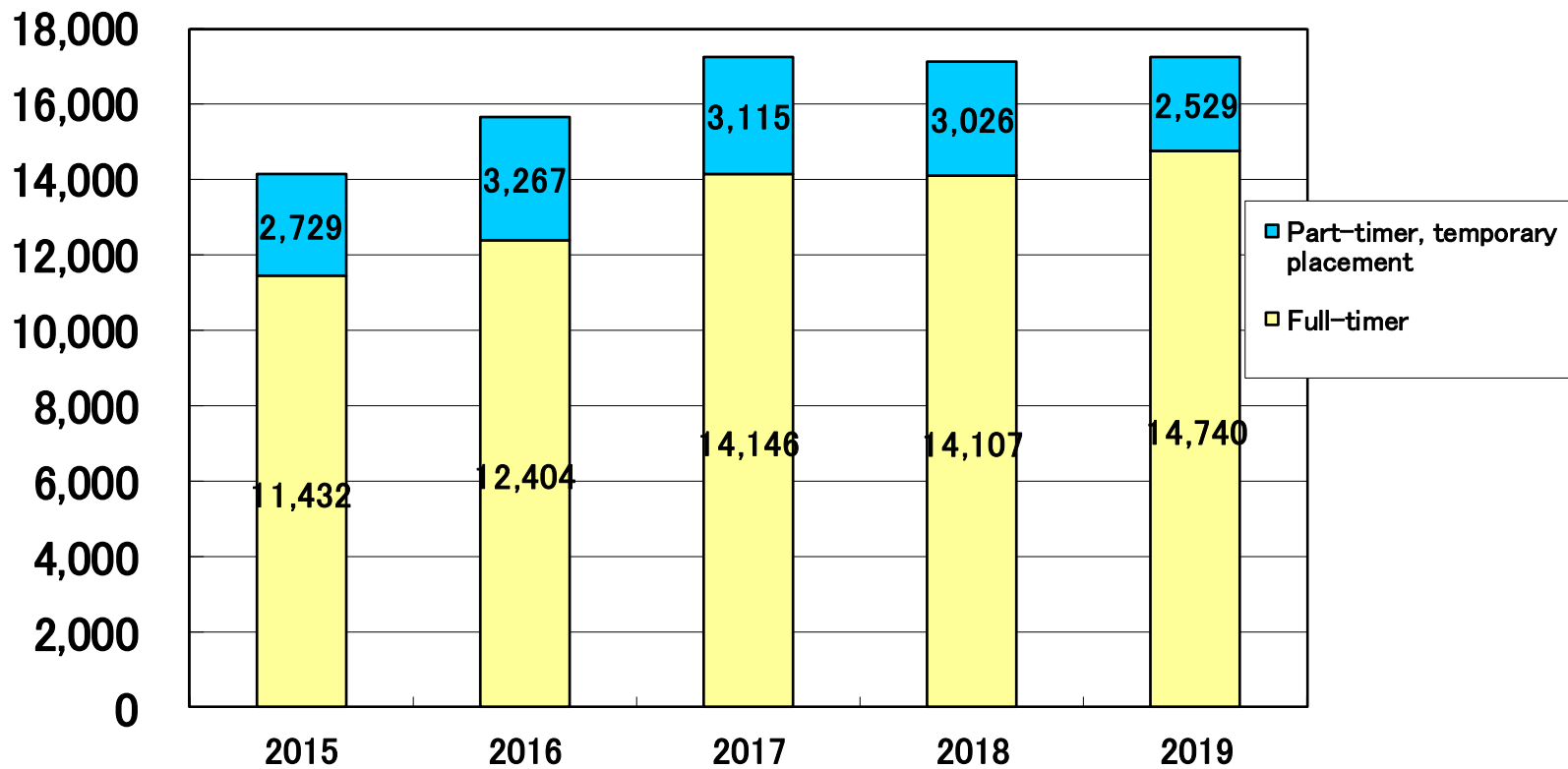
compared to 2018

Sum	+136 (+0.8%)
Others	+345 (+11.9%)
Administration	+4 (+0.5%)
Audit	+52 (+32.5%)
Medical writing	-11 (-3.7%)
Registration	-167 (-35.9%)
GVP	-502 (-26.1%)
Reg.Affairs	+118 (+49.0%)
DM/Bio.Stat	+171 (+5.7%)
CRA	+126 (+1.7%)

Registration, medical writing, audit were extracted from others since 2017.

Employees by Business Services 2015–2019

2019 Total No. of employees :17,269



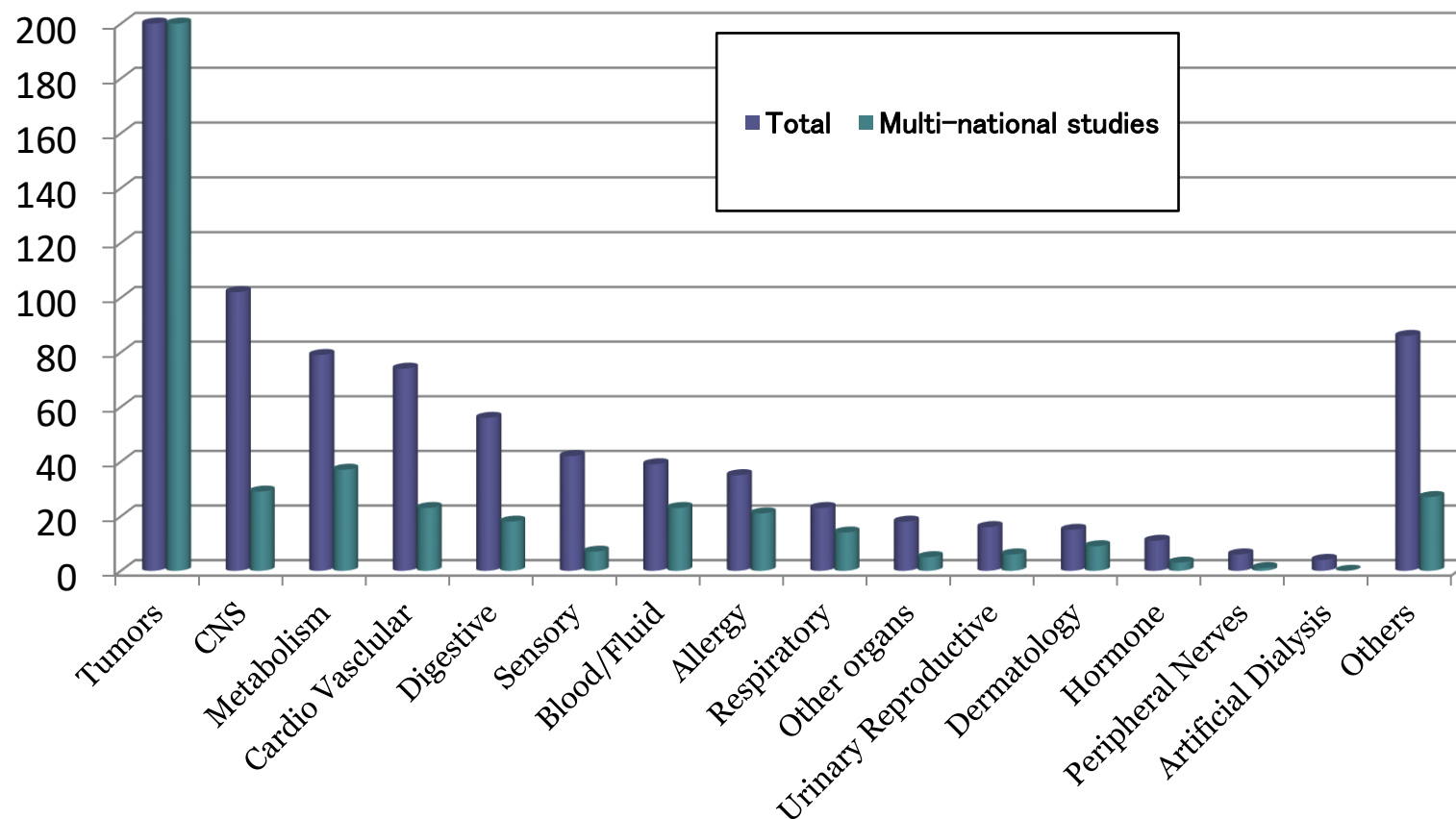
2019 Monitoring Projects* by Therapeutic Area

* Only valid responded projects, 980, are categorized out of total monitoring projects .

• **Multi-National Studies:** Studies conducted in multi countries simultaneously with the same protocol.

The 454 (46.3%) multinational studies were conducted 454 out of 980 projects.

The multinational studies occupied 32.8% in 2018.



2019 Monitoring Projects by Clinical Phases

Note: Only valid responded projects are categorized out of total monitoring projects.

