



Annual Report 2018 (Jan. – Dec.)

May 20, 2019
Japan CRO Association

JCROA 2018

Total Number of Members: 39 companies

Regular Member: 16 companies

Supporting Member: 23 companies

(Note)

* The business results are calculated in four business areas such as 1) Pharmaceutical Development, 2) Medical Devices Development, 3) Food & Nutrition-Supplement Development, and 4) Others (including SMO/CRC) from 33 companies in 2018, excluding 6 supporting members in this report.

* The estimated figures are included and calculated on the basis of approximate figures from average values of valid responses.

2018 JCROA Annual Sales Report in detailed

1. Total Sales Volume

① Total turnover has decreased 23.1/100 Mil. Yen (1,901.3/100 Mil.Yen from 1,924.5/100 Mil.Yen in 2017) by 1.2% in 2018. This is due to spinning off of business such as CSO business classified as other sector, not been included in medical products, devices and Food & Nutrition Development. The turnover of other sector has decreased 65.1/100 Mil.Yen by 35.5%.

② Sales of medical products shared 91.5%, 47/100 Mil.Yen increased (1,740/100 Mil Yen from 1,693 100/ Mil.Yen) by 2.8%.

Medical Devices have decreased 6/100 Mil.Yen, by 12.7%. The total sales of medical products, devices, Food & Nutritions, Clinical Researches increased 46/100 Mil.Yen (1,824/100 Mil.Yen from 1,777/100 Mil.Yen) by 2.6%.

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

① Monitoring has increased 42/100 Mil.Yen by 4.1%, .

② DM&Bio.Stat has decreased 3/100 Mil.Yen by 1.1%,

③ GVP has increased 186/100 Mil Yen by 8.2%, occupying 10.4% of total sales.

④ Clinical Researches, not for the registration, have increased 40.5/100 Mil.Yen by 4.5/100 Mil.Yen, 12.6%.

3. Medical Products Sales by Clinical Phases

① Phase I, II and III have increased. Post–marketing Clinical Trials/Surveillances have decreased by 17.9%. Total of GVP related tasks, regulatory affairs & consulting, audit have shared 3.5%, 61/100 Mil.Yen, same ratio as 2017. The business sectors of temporary placement decreased by 9%.

② In other business sectors, IT support business area has demonstrated the biggest portion by 13 companies with 23 respondents out of 33. The consulting in contracted business is going to increase.

4. Total number of employees joining JCROA has reached to 17,133 by decrease of 128 due to influence of demerging. The CRA joining JCROA has reached 7,399 by increase of 174 engaged with clinical studies including QC. The number of ST/DM and other sector jobs have equally decreased as sales volume.

5. Ratio of monitoring project numbers by only effective replies

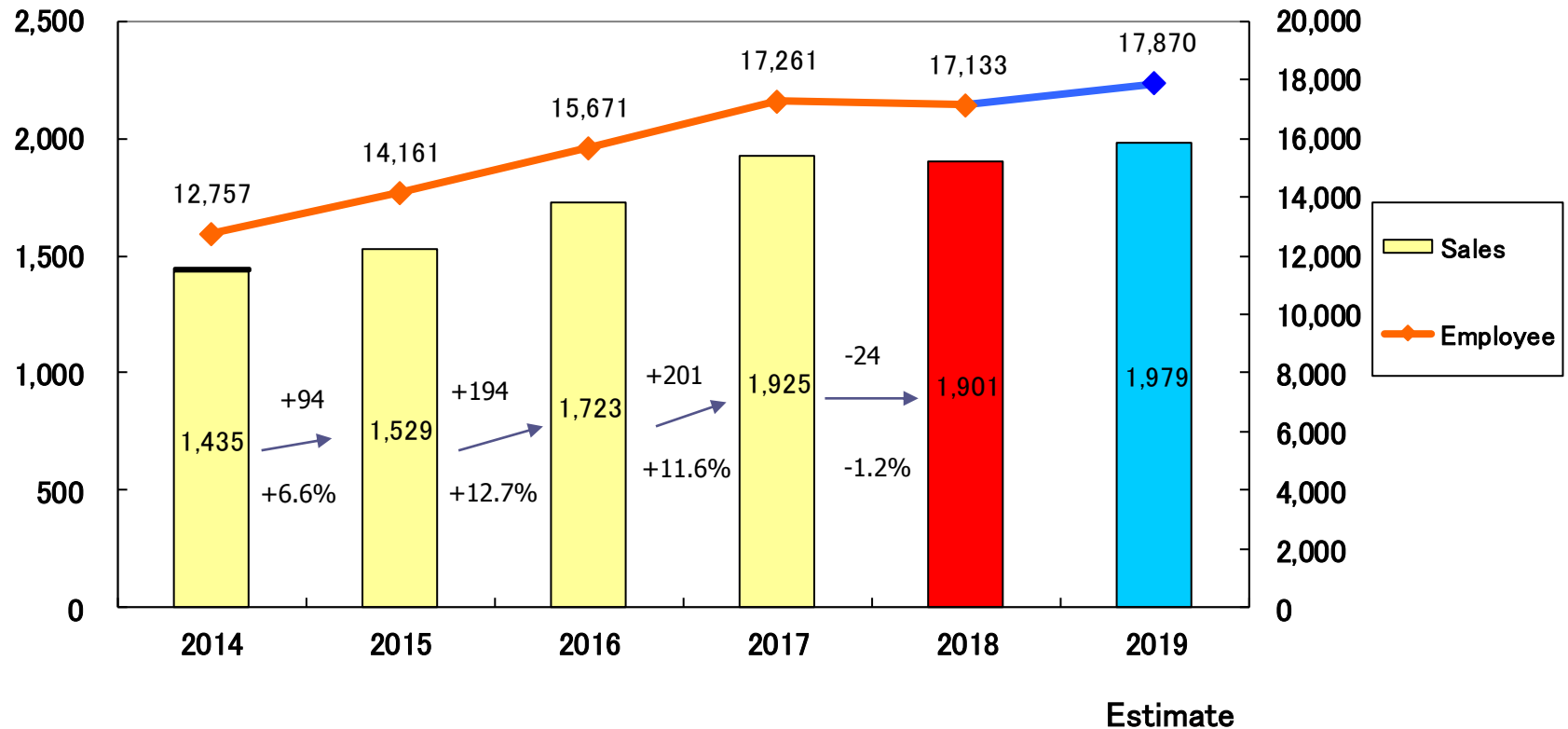
① Anti–cancer has shown remarkable increase, following metabolism and CNS in view of therapeutic areas.

② The ratio by phase has shown the almost same results.

Sales and Employees 2014–2018*

(Sales Unit: 100 Mil.¥)

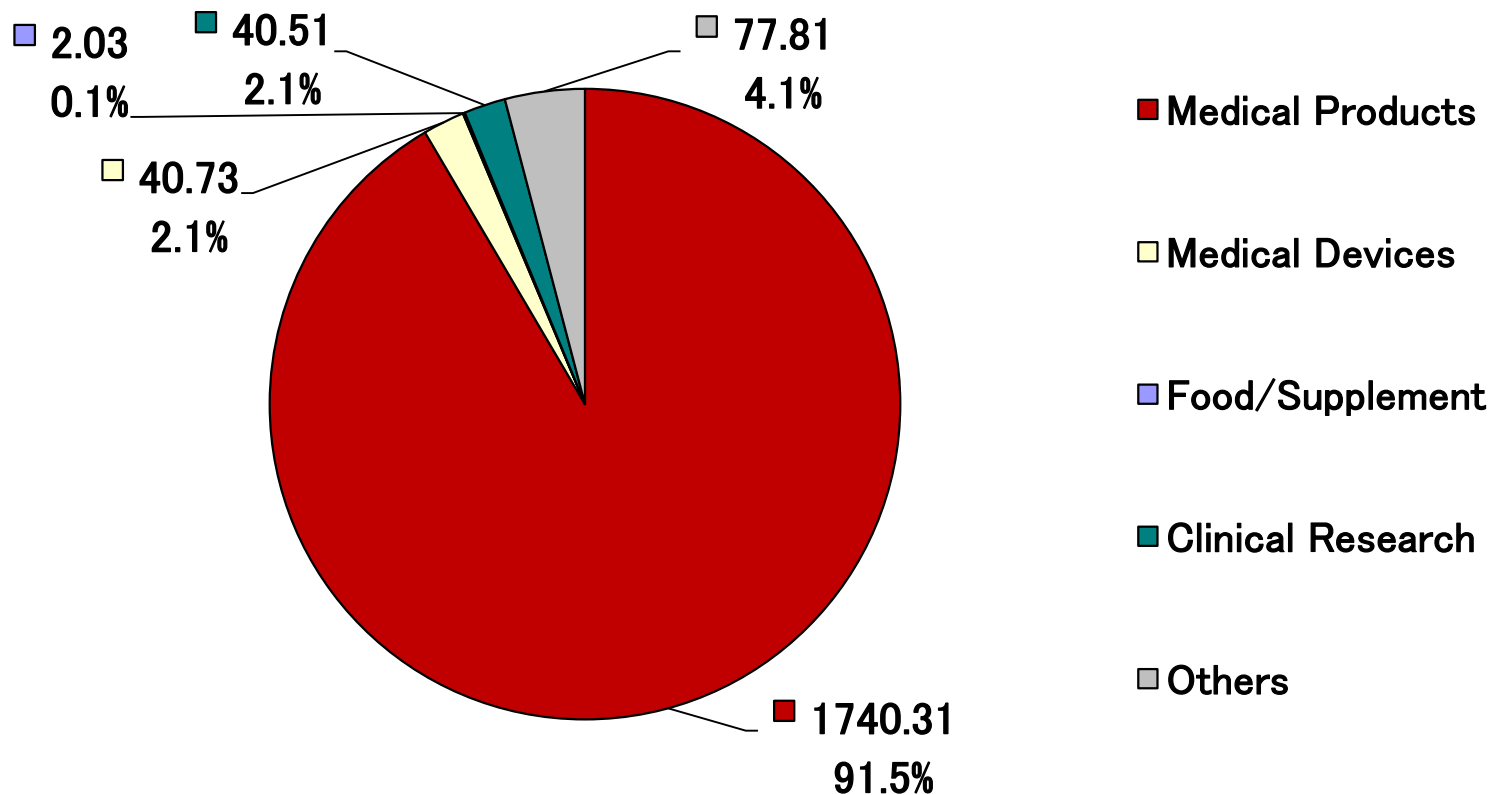
(Employee No.)



* Count and estimate based on data of 23 in 2014, 26 in 2015 through 2016, and 32 in 2017, 33 in 2018 through 2019.

2018 Sales by Business Fields

Total: 1901.3/100 Mil. ¥
[1,730 Mil. \$ (1\$=110¥)]

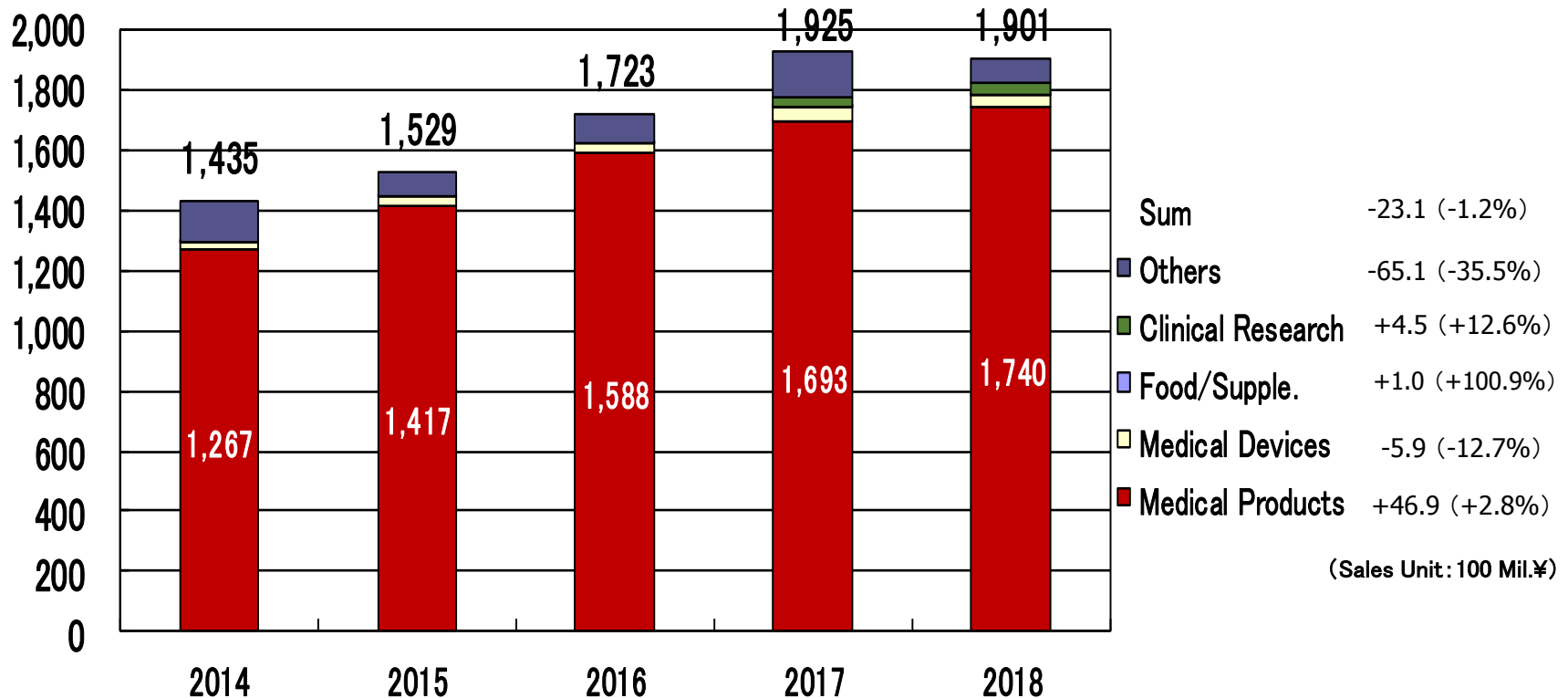


Sales (Unit: 100 Mil. ¥)

Sales by Business fields 2014–2018

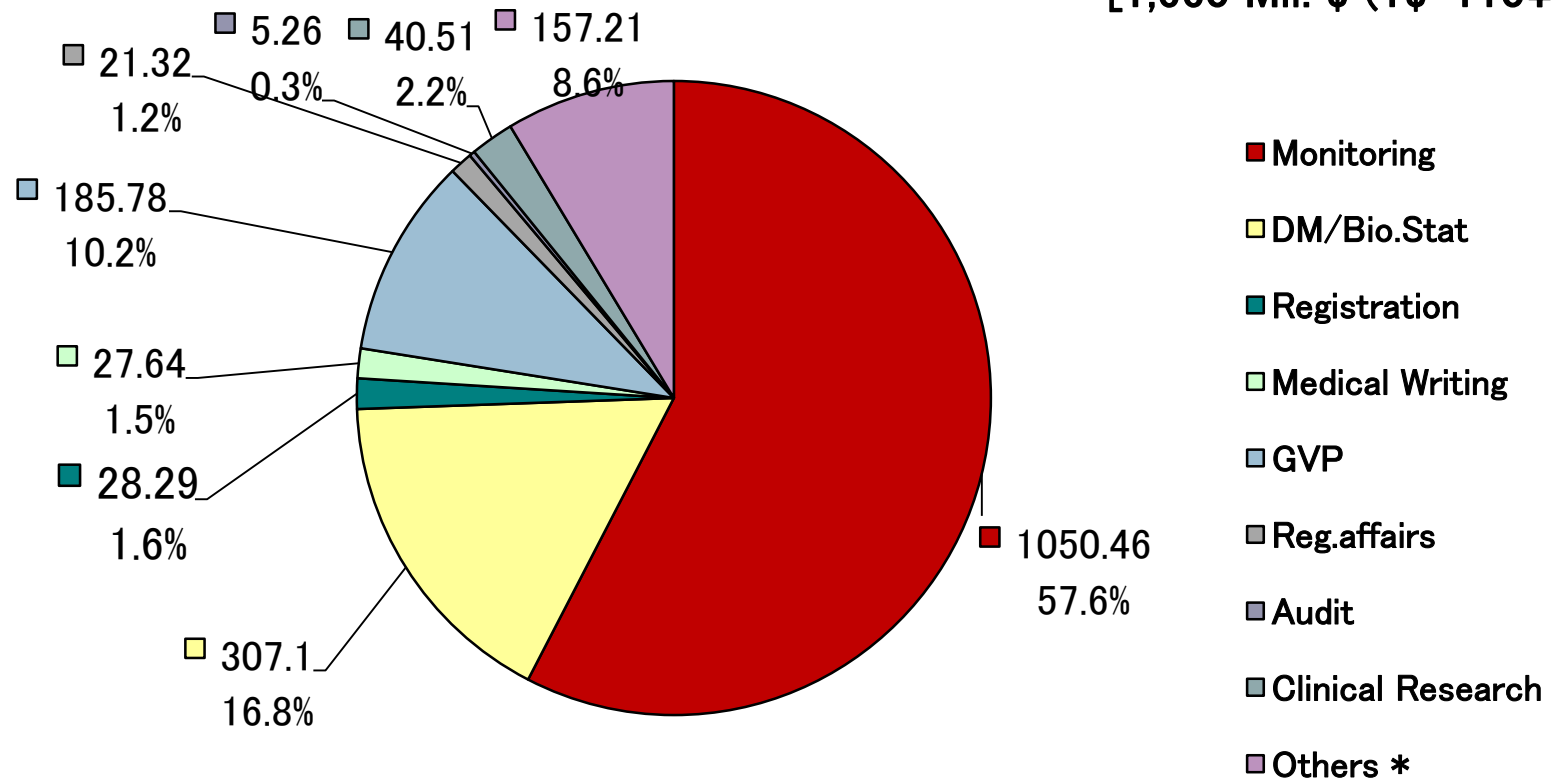
(Sales Unit: 100 Mil.¥)

compared to 2017



2018 Medical Products/Devices/Food & Nutrition- Supplement/Clinical Research Sales by Business Services

Total: 1824/100 Mil.¥
[1,660 Mil. \$ (1\$=110¥)]



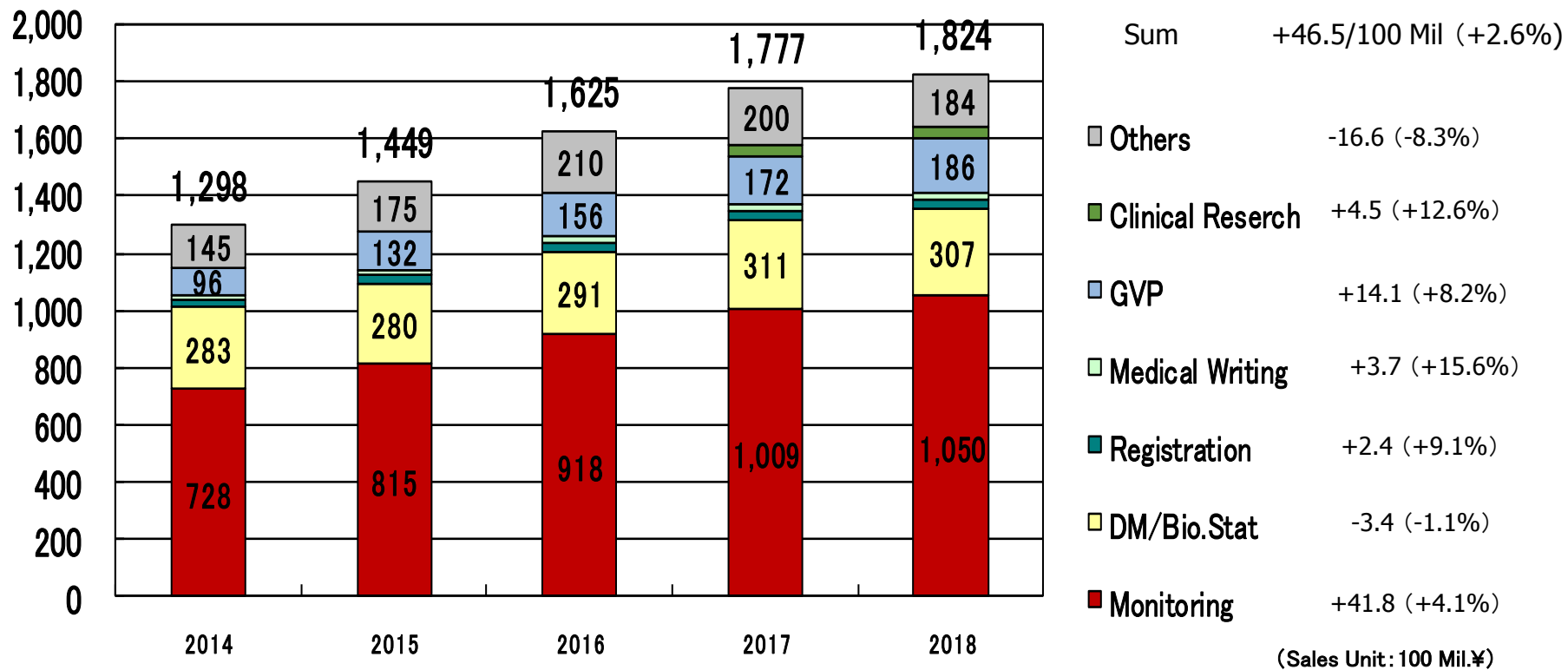
Sales (Unit: 100 Mil. ¥)

*Please refer to page 10 for "others".

Medical Products/Devices/Food & Nutrition-Supplement Sales/Clinical Research by Clinical Services 2014-2018

(Sales Unit: 100 Mil.¥)

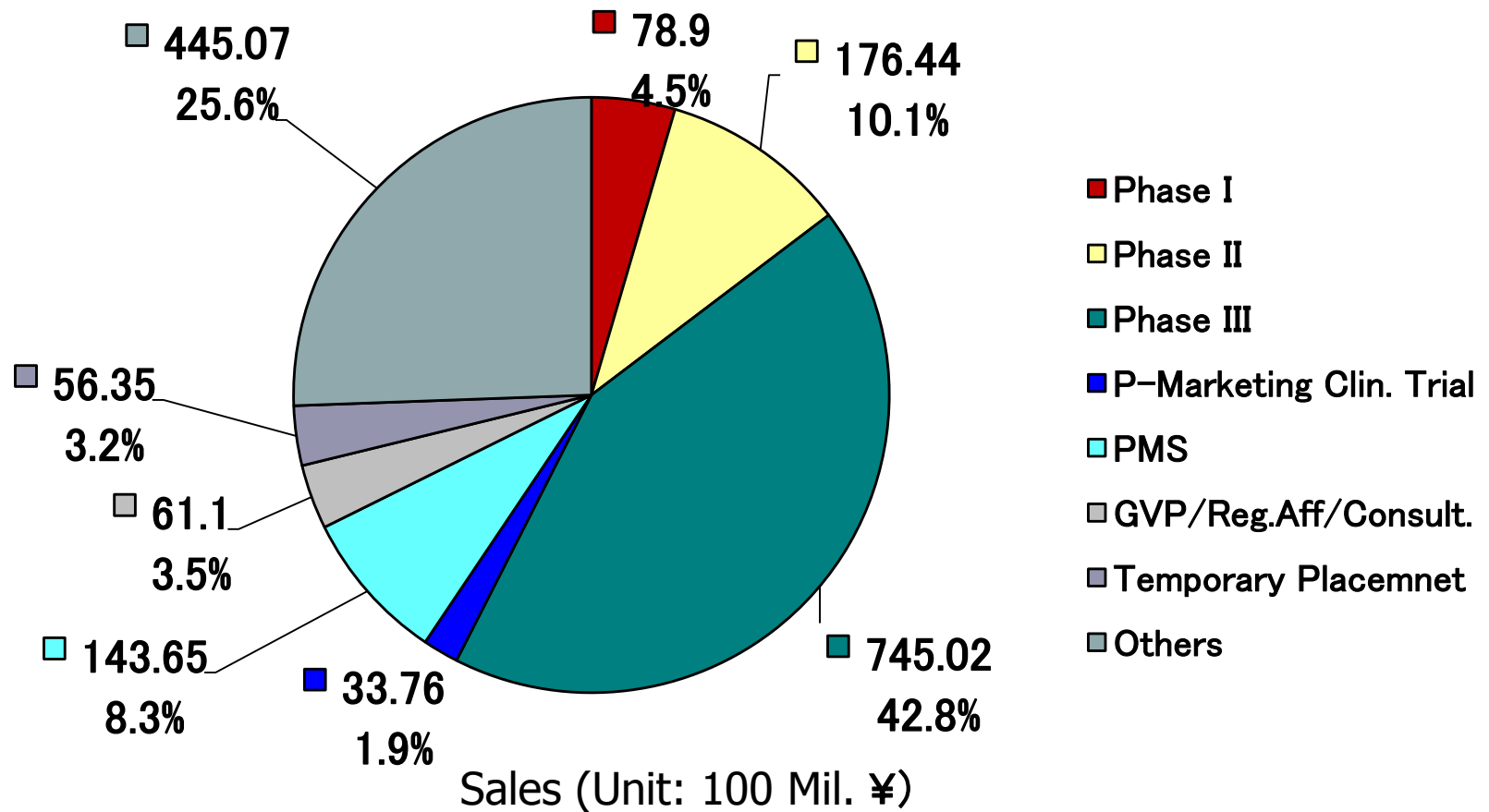
compared to 2017



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

2018 Medical Products Sales by Clinical Phases

Total: 1740.3/100 Mil.¥
[1,582 Mil. \$ (1\$=110¥)]

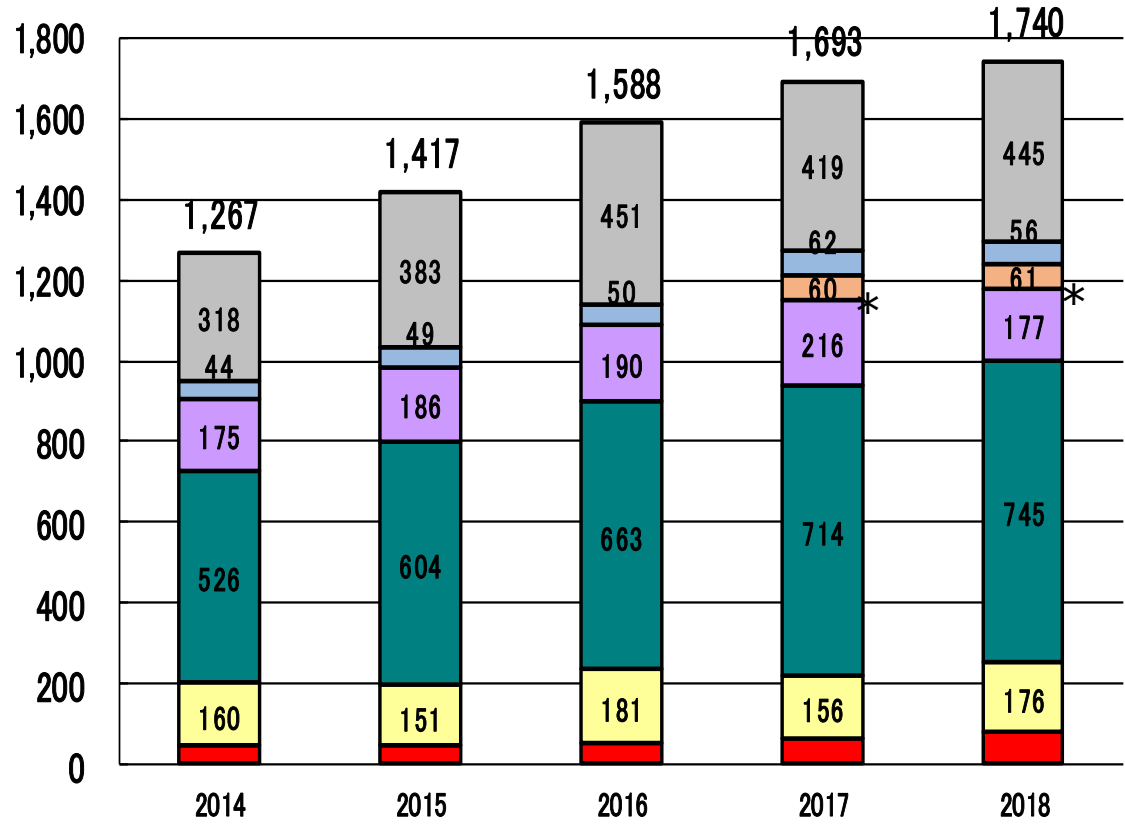


Phase I/PMS included GVP, regulatory affairs, consulting, audit etc. that are not classified in each phase.
Clinical research has not been included since that has not been investigated by relevant area.

Medical Products Sales by Clinical Phases 2014-2018

(Sales Unit: 100 Mil.¥)

compared to 2017



Sum	+46.9 (+2.8%)
Others	+25.6 (+6.1%)
Temporary Placement	-5.5 (-8.9%)
GVP/Reg. Aff/Consult	+1.5 (+2.4%)
Post Marketing Clinical Trial	-38.6 (-17.9%)
Phase III	+30.6 (+4.3%)
Phase II	+20.0 (+12.8%)
Phase I	+13.3 (+20.3%)

(Sales Unit: 100 Mil.¥)

*Please note that GVP, regulatory affairs, consulting, audit has been summed up as Phase I/PMS since 2017. Clinical research has not been included since that has not been investigated by relevant area.

Other services Conducted in relation to Medical Products 2018

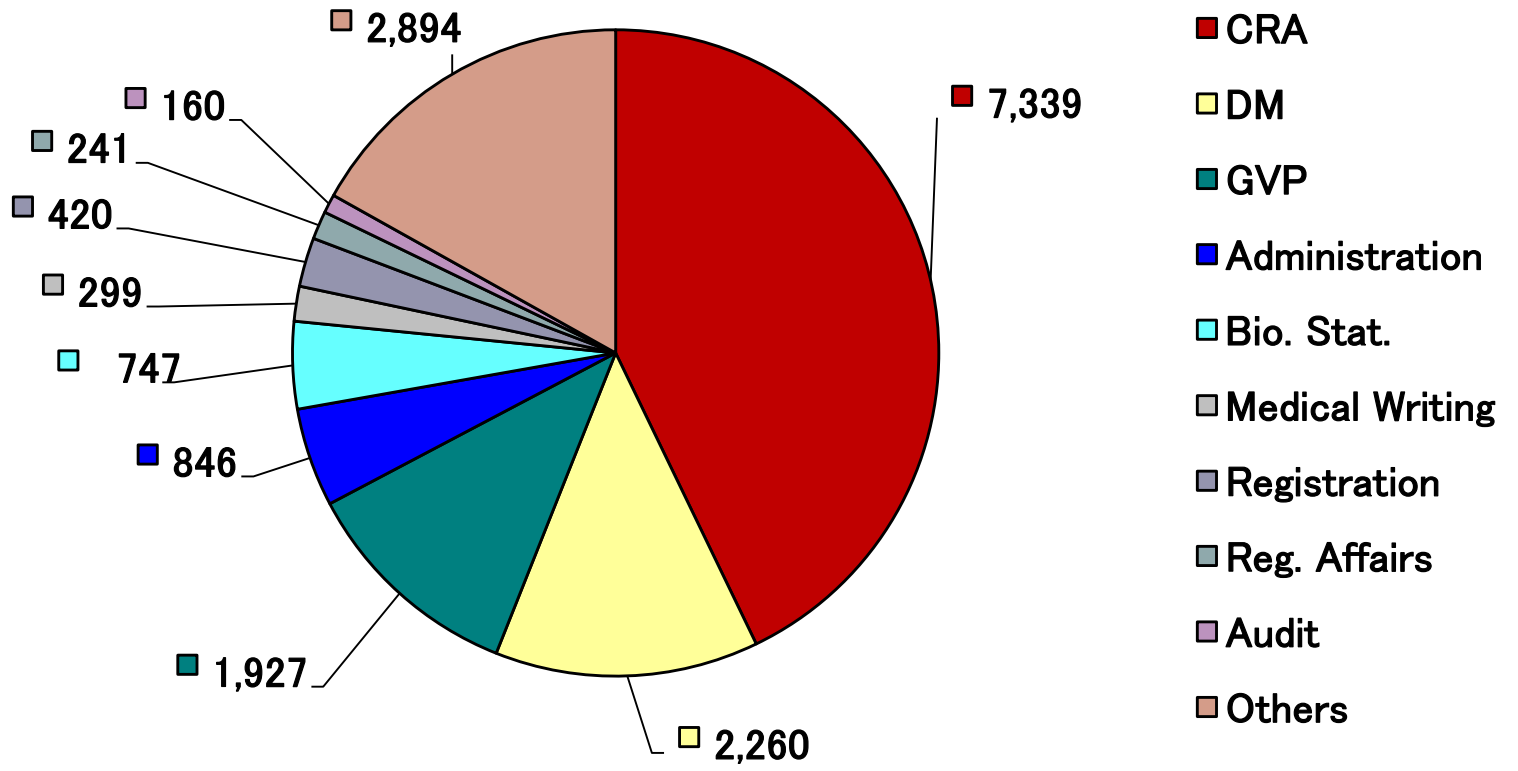
(The figures represent the number of CRO conducting those business services. Responding from 23 members.)

Business services	No.	Business services	No.
IT support, system building (excluding EDC)	13	Academic papers writing	7
Project management	12	Translation	7
Education & training	10	Holding research conference	7
Randomization	8	Logistics and storage of IMP	7
SOP preparation	8	Advertisement of recruiting clinical study subjects, site-selection	6
Clinical Trial In-Country Care-taker	8	Establishing analytical methods, validation	4
BE studies	7		

Consulting (statistical analysis etc.), Preparation for compliance assessment review by PMDA, Regulatory affairs relating business (CTD preparation, CMC, etc.)、 Secretarial business (IDMC, Pharmacovigilance management), IT system maintenance support, Document management, Clinical laboratory test, Emergency responses

2018 Employees by Business Services

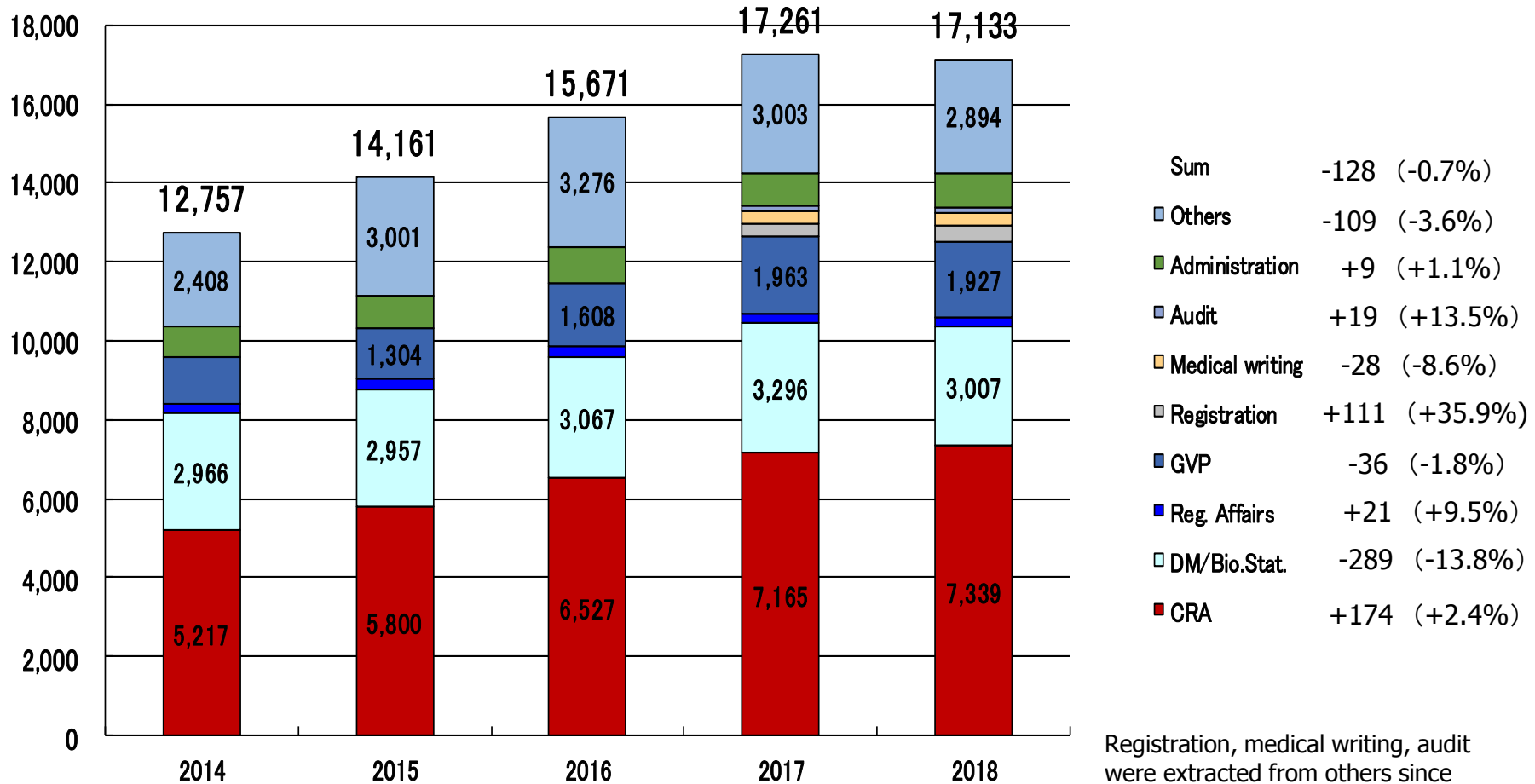
Total No. of employees: 17,133



Employees by Business Services 2014-2018

(Unit: No. of employees)

compared to 2017

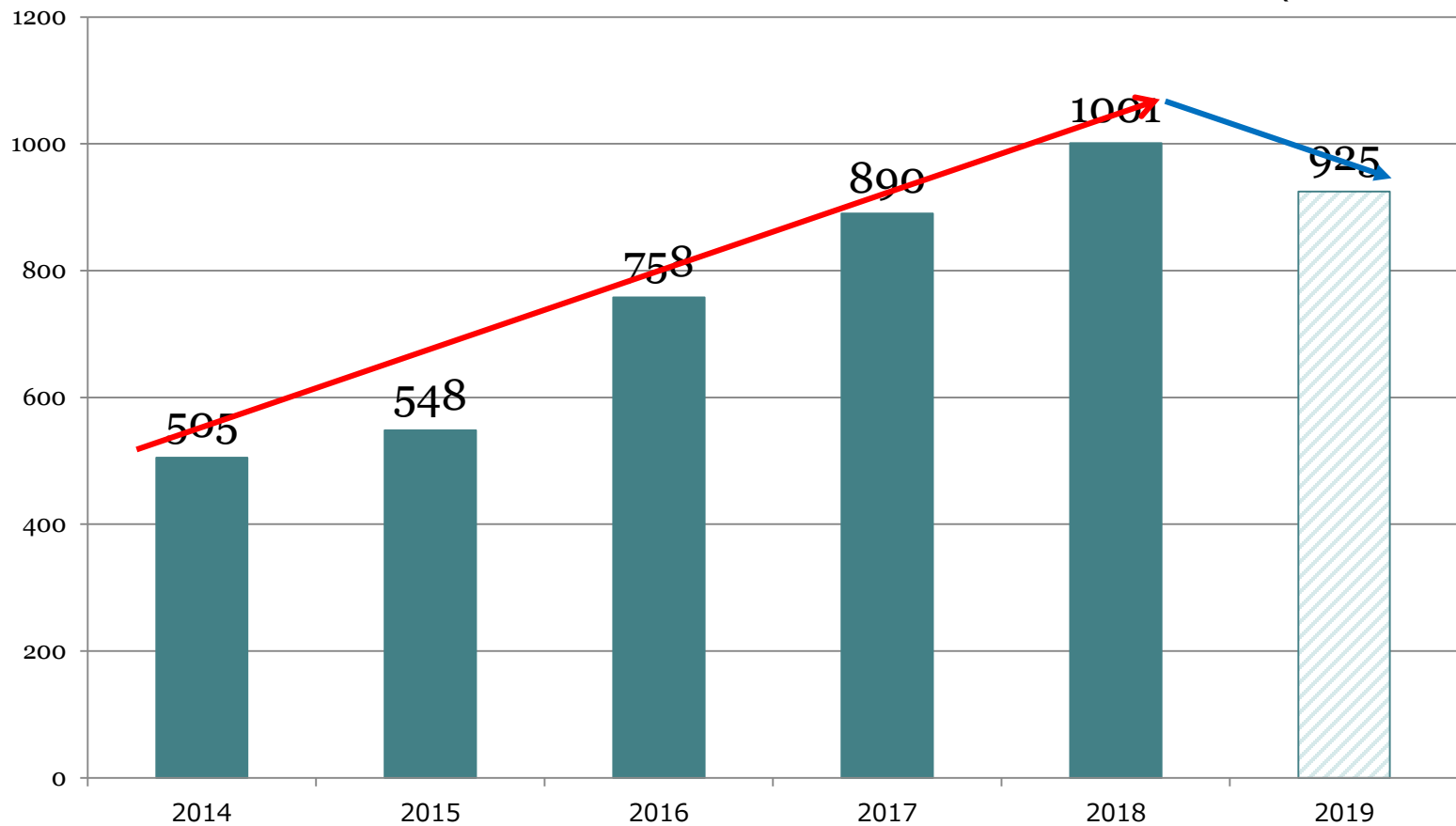


Registration, medical writing, audit were extracted from others since 2017.

Employees by Business Services 2014–2018

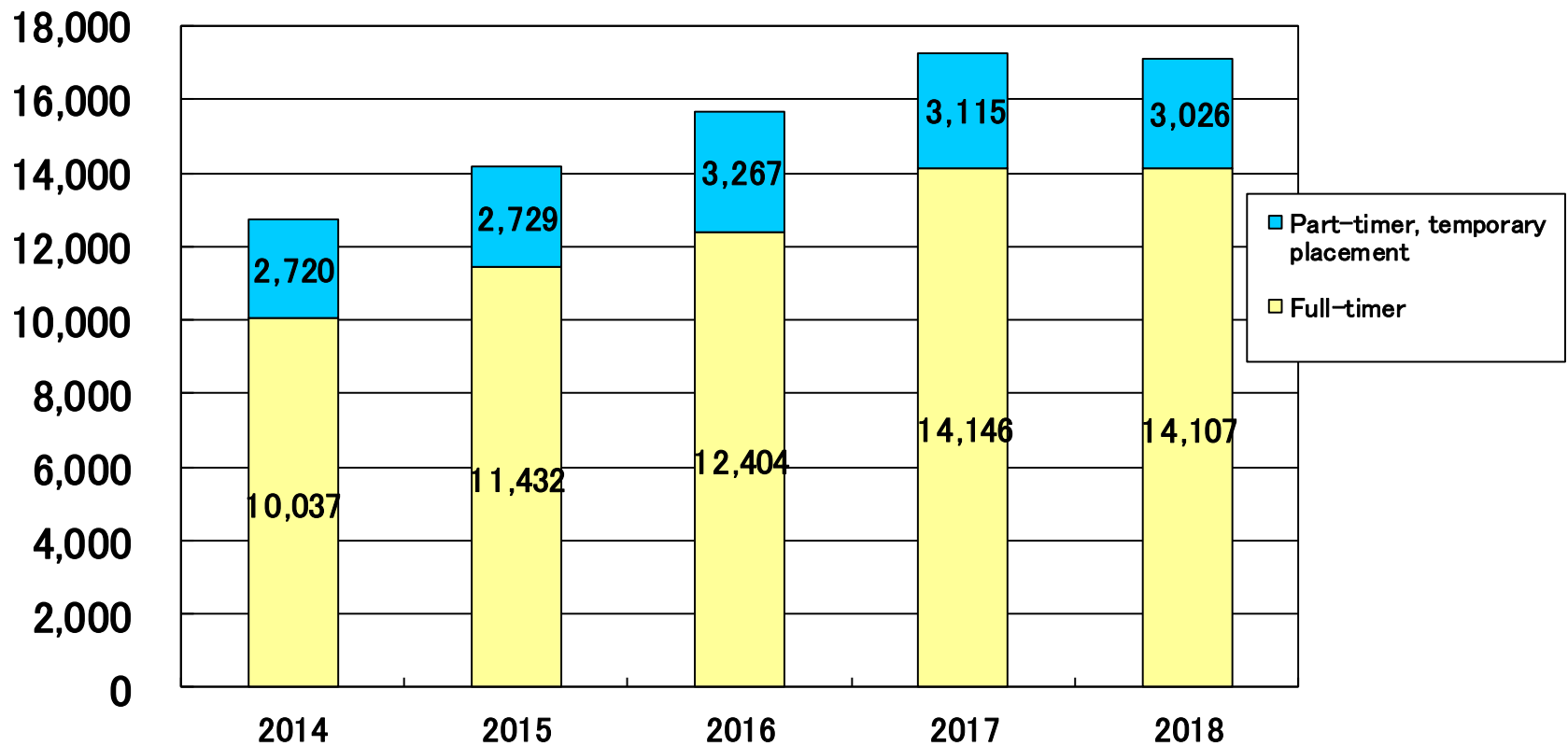
925 new employees estimated in April 2019

(As of Dec. 2018)



Employees by Business Services 2014-2018

2018 Total No. of employees :17,133

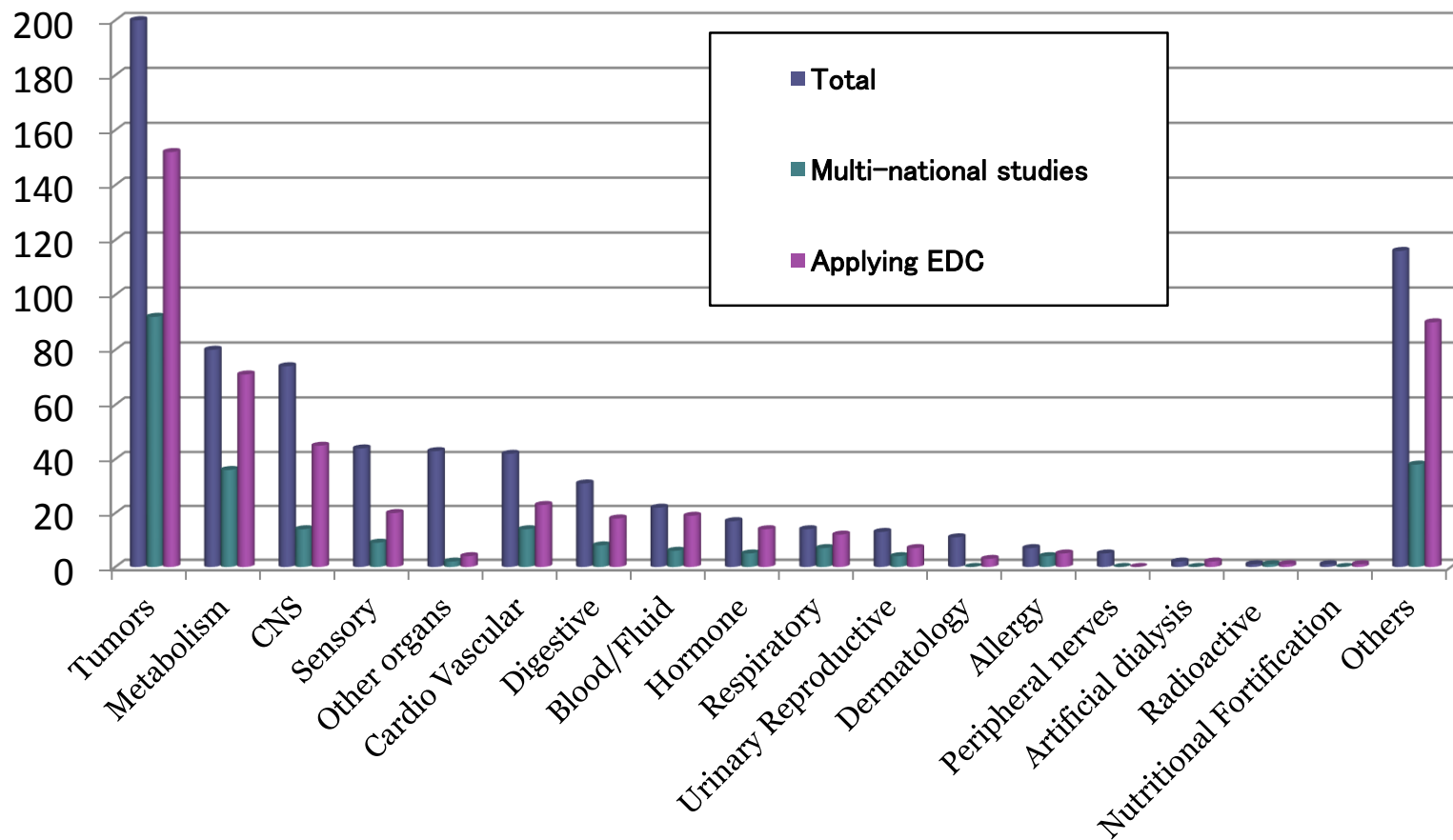


2018 Monitoring Projects* by Therapeutic Area

- Only valid responded projects, 732, are categorized out of total monitoring projects .
- * Multi-National Studies: Studies conducted in multi countries simultaneously with the same protocol.

Multinational studies counted 240 (32.8%), EDC studies 487 (66.5%) out of 732 projects.
 Multinational studies obtained 37.2%, EDC studies 65.9%.

(Units : No. of projects)



2018 Monitoring Projects by Clinical Phases

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

