



# Annual Report 2017 (Jan. – Dec.)

April 3, 2018

Japan CRO Association

# JCROA 2017

**Total Number of Members: 37 companies**

**Regular Member: 16 companies**

**Supporting Member: 21 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 32 companies in 2017, excluding 5 supporting members in this report.

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

# JCROA Annual Sales Report in detailed 2017

## 1. Total Sales Volume

① Total turnover has increased 20.1 Bil.Yen ( 192.5 Bil.Yen from 172.3 Bil.Yen in 2016) in 2017 by 11.7%. This increase has been contributed by join of six new members, occupying 3.6% of increase. Namely, actual sales has increased by 8.1% than 2016.

② Sales of medical products shared 88.0%, 10.5 Bil.Yen (16.93BilYen from 15.88Bil.Yen) by 6.6%.  
Medical Devices have reached 4.7 Bil.Yen, 36.8% increase from 1.3Bil.Yen.

## 2. Medical Products/Devices/Food & Nutrition-Supplement Sales by Business Services

① Monitoring has increased by 9.9%, 9.07 Bil.Yen.

② DM has increased by 5.0%, 1.16 Bil.Yen, Bio.Stat has increased by 14.4%, 0.84 Bil. respectively.

③ GVP has increased by 9.8%, totally 17.2BilYen occupying 10.1% of total sales.

## 3. Medical Products Sales by Clinical Phases

① Phase II has slightly decreased. GVP, regulatory affairs, consulting audit including self-inspection have been excluded from other category, 2017. This change has shared 3.5%, 6.0 Bil.Yen. out of total sales 2017.

② The category of Clinical Trial In-Country Care Taker, ICCT, has increased to 13 from 7. Project Management also has increased to 13 from 9 in other services, showing no particular changes in others.

## 4. Total number of employees joining JCROA has reached to 17, 261. by increase of 1, 590 and 4900 from 2013.

The CRA joining JCROA has reached 7165 with increase of 638 engaged with clinical works including QC.

The number of newly employed are estimated 1022.

## 5. Ratio of project numbers by only effective replies

① No major changes has been occurred in medical products/devices/food&nutrition-supplement.

The number of clinical research projects, investigators' initiated clinical trials, has reached to 368 by separate analysis.

② Monitoring

1) Tumors have shown remarkable increase, following metabolism and CNS.

Both multi-national studies as well as EDC have increased 37.2% from 31.8%, 77.8% from 66.0%.

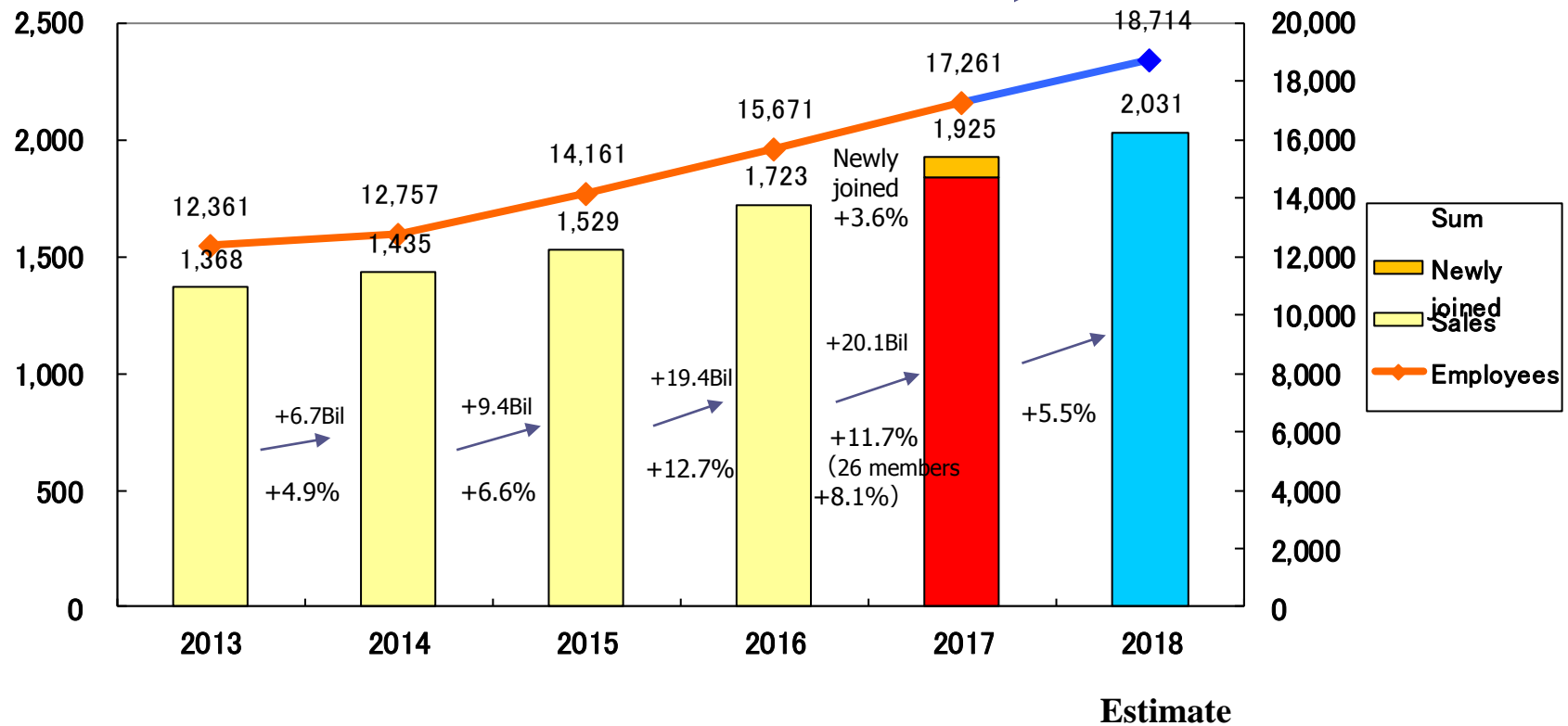
2) Phase III has increased to 50.3% from 45.2% and BE decreased to 6.8% from 13.4%.

# Sales and Employees 2013-2017

(Sales Unit: Bil.¥)

55.6 Bil. ¥ increased since 2013 (40.6% up)

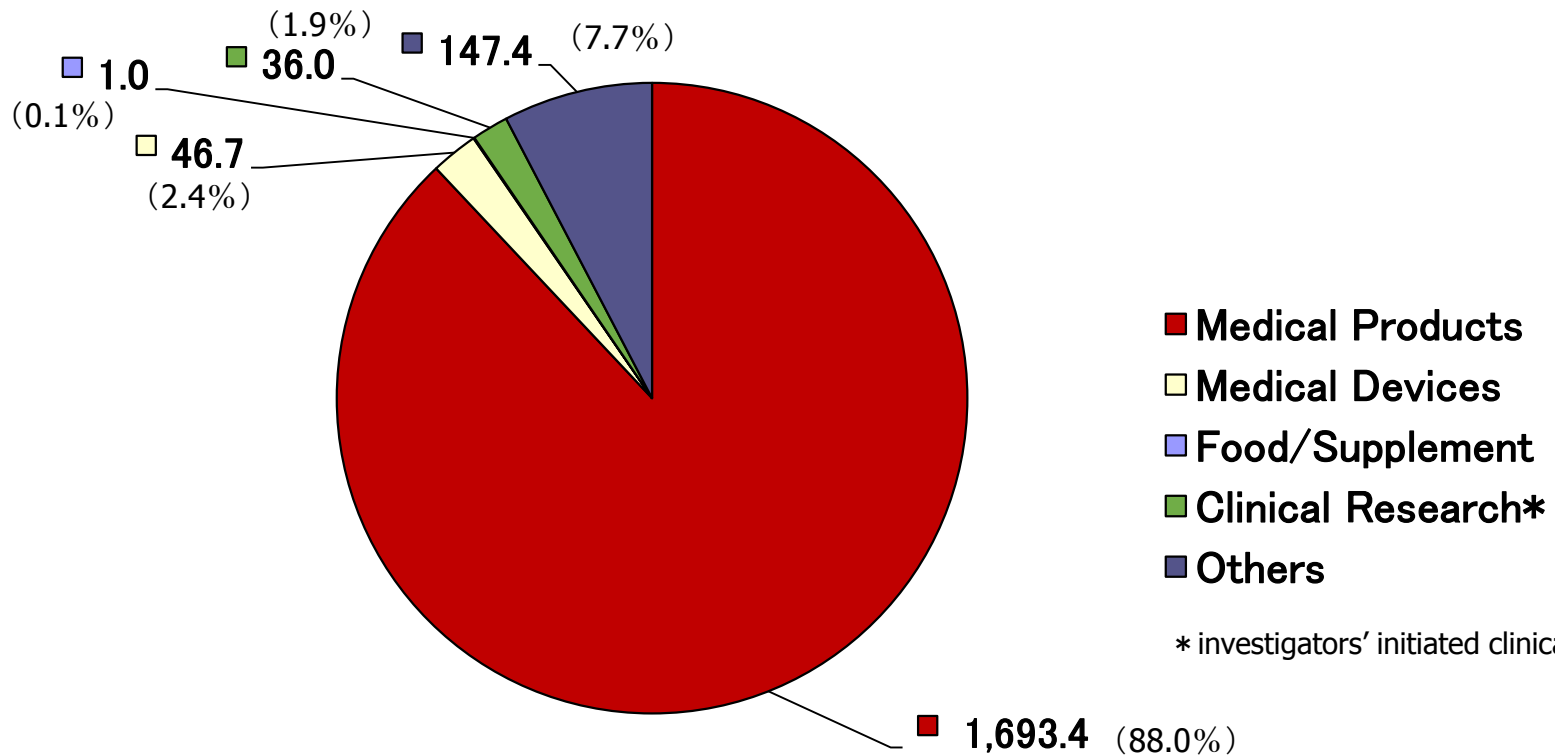
(Employee No.)



Note) Count and estimate based on data of 24 in 2013, 23 in 2014, 26 in 2015 through 2016, and 32 2017 through/2018.

# 2017 Sales by Business Fields

Total: 192.4 Bil. ¥  
[1.83 Bil. \$ (1\$=105¥)]

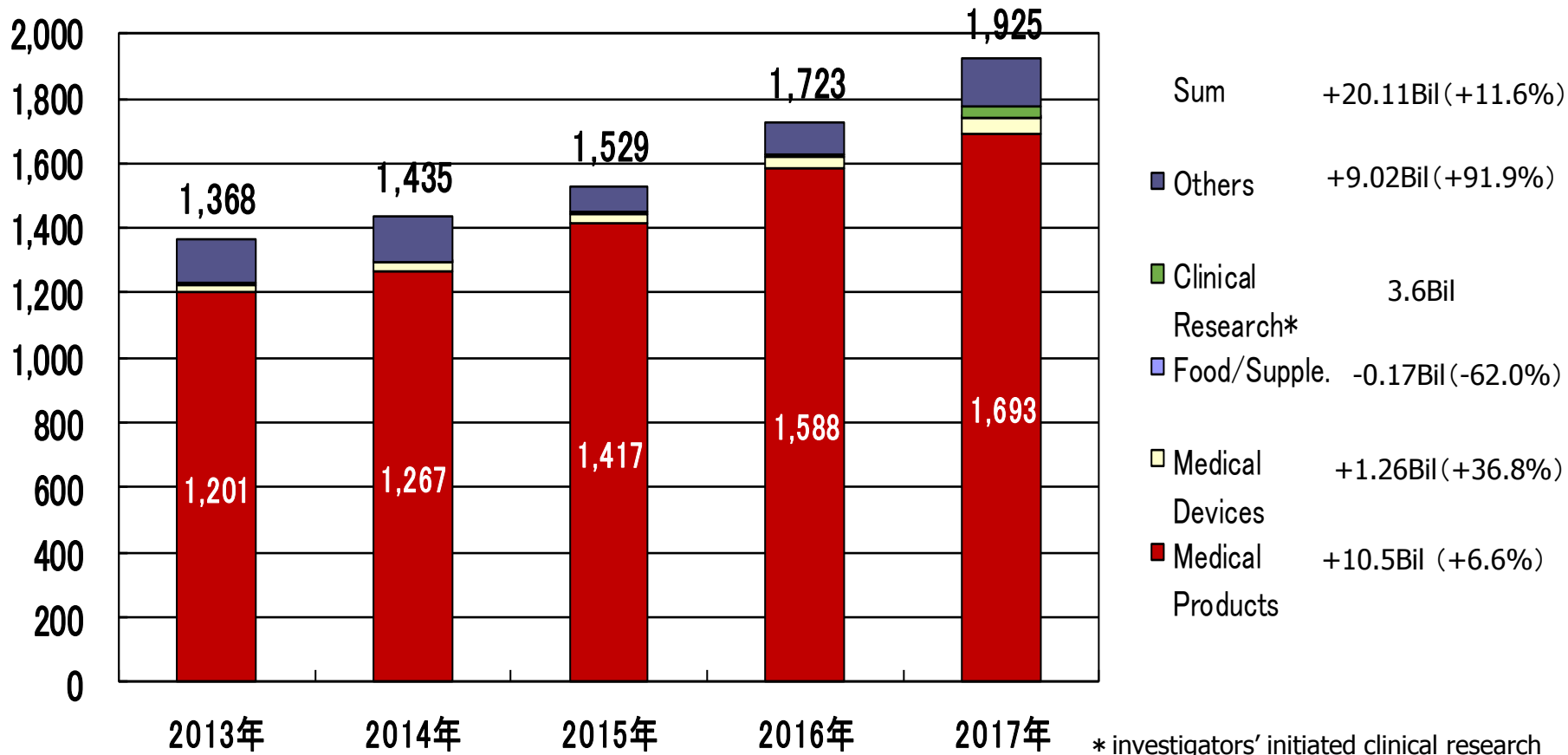


# Sales by Business fields 2013-2017

Medical devices increased by 2.03 Bil.¥ since 2013 (76.9%up)  
 Medical products increased by 49.25 Bil.¥ since 2013 (41.0%up)

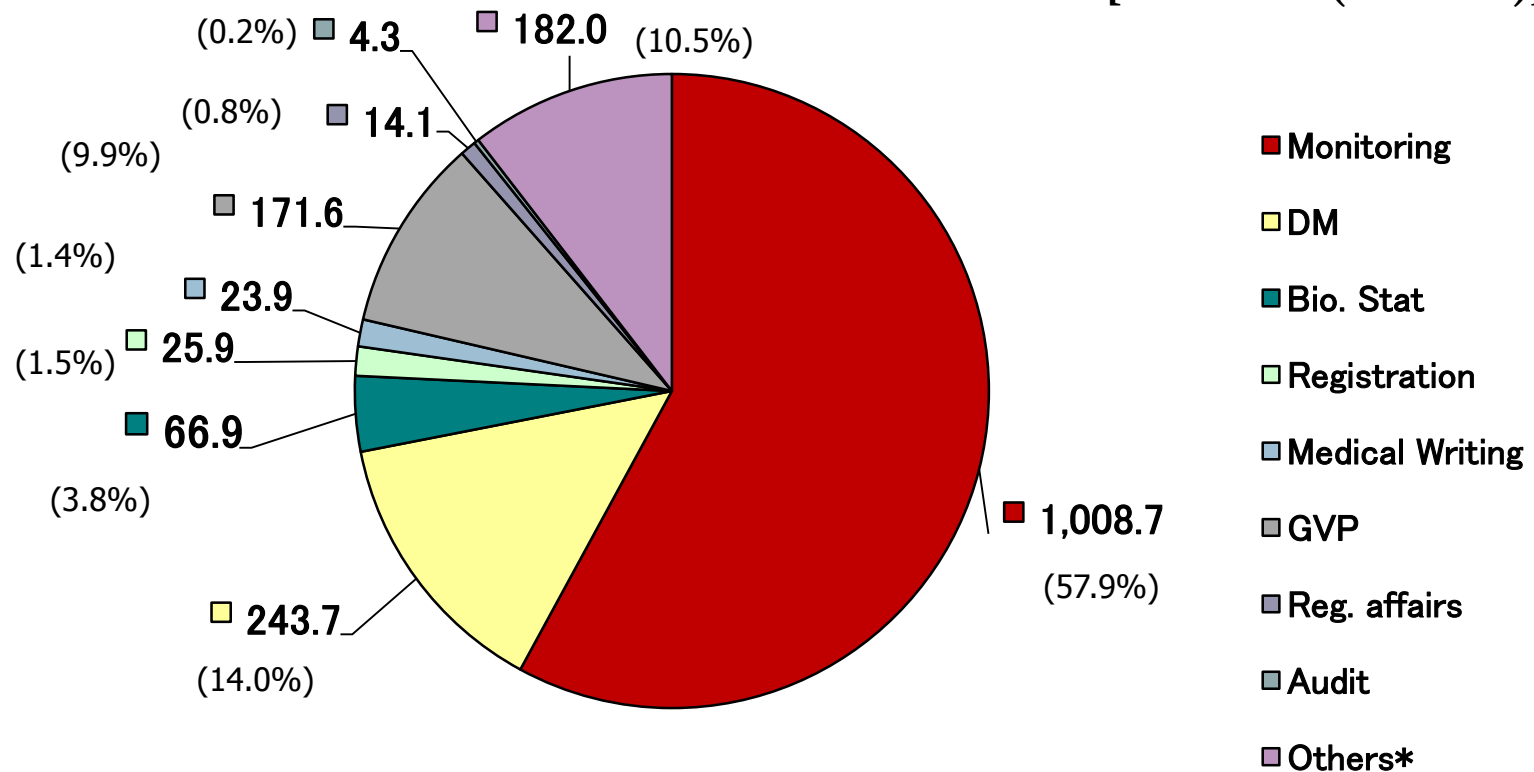
compared to 2016

(Sales Unit : Bil.¥)



## 2017 Medical Products/Devices/Food & Nutrition-Supplement Sales by Business Services

Total: 174.1 Bil.¥  
[1.65 Bil. \$ (1\$=105¥)]



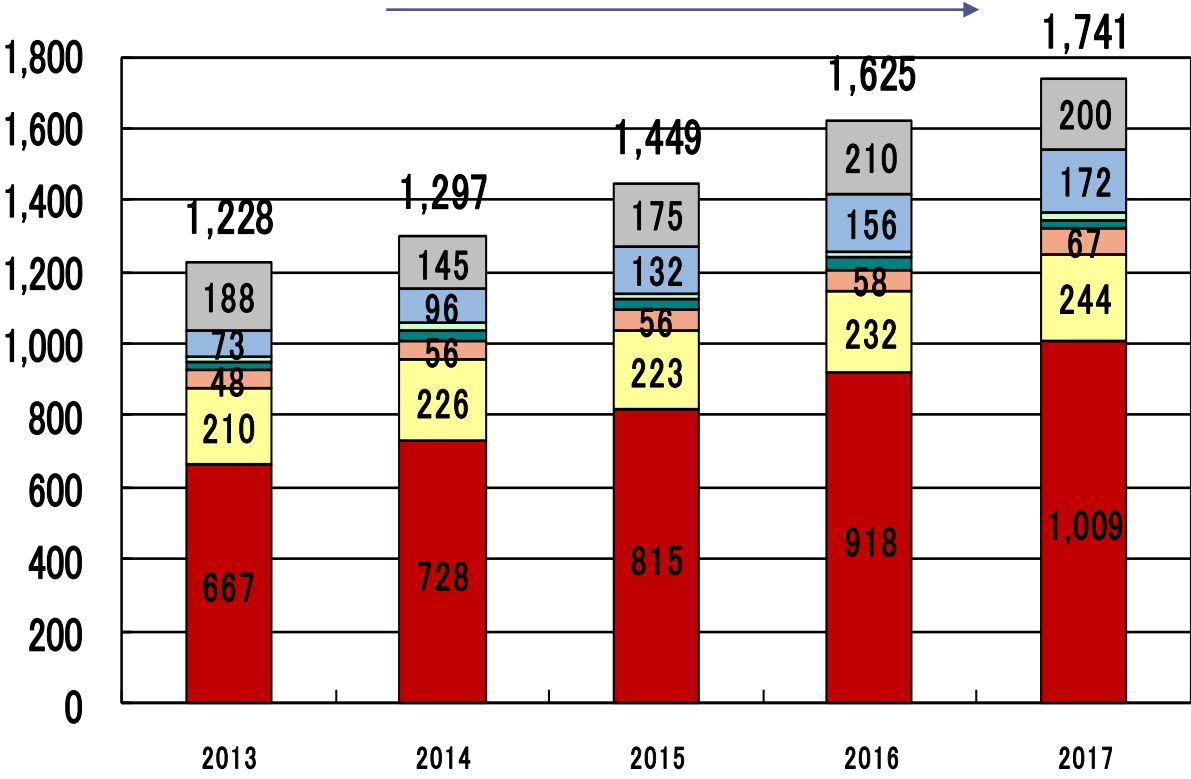
\*Excluding regulatory affairs, consulting, audit from others in 2017

# Medical Products/Devices/Food & Nutrition-Supplement Sales by Clinical Services 2013-2017

Monitoring increased by 34.2 Bil. ¥ since 2013(51.2% up)  
 GVP increased by 9.9 Bil.¥ since 2013(135.6% up)

compared to 2016

(Sales Unit: 100 Mil.¥)

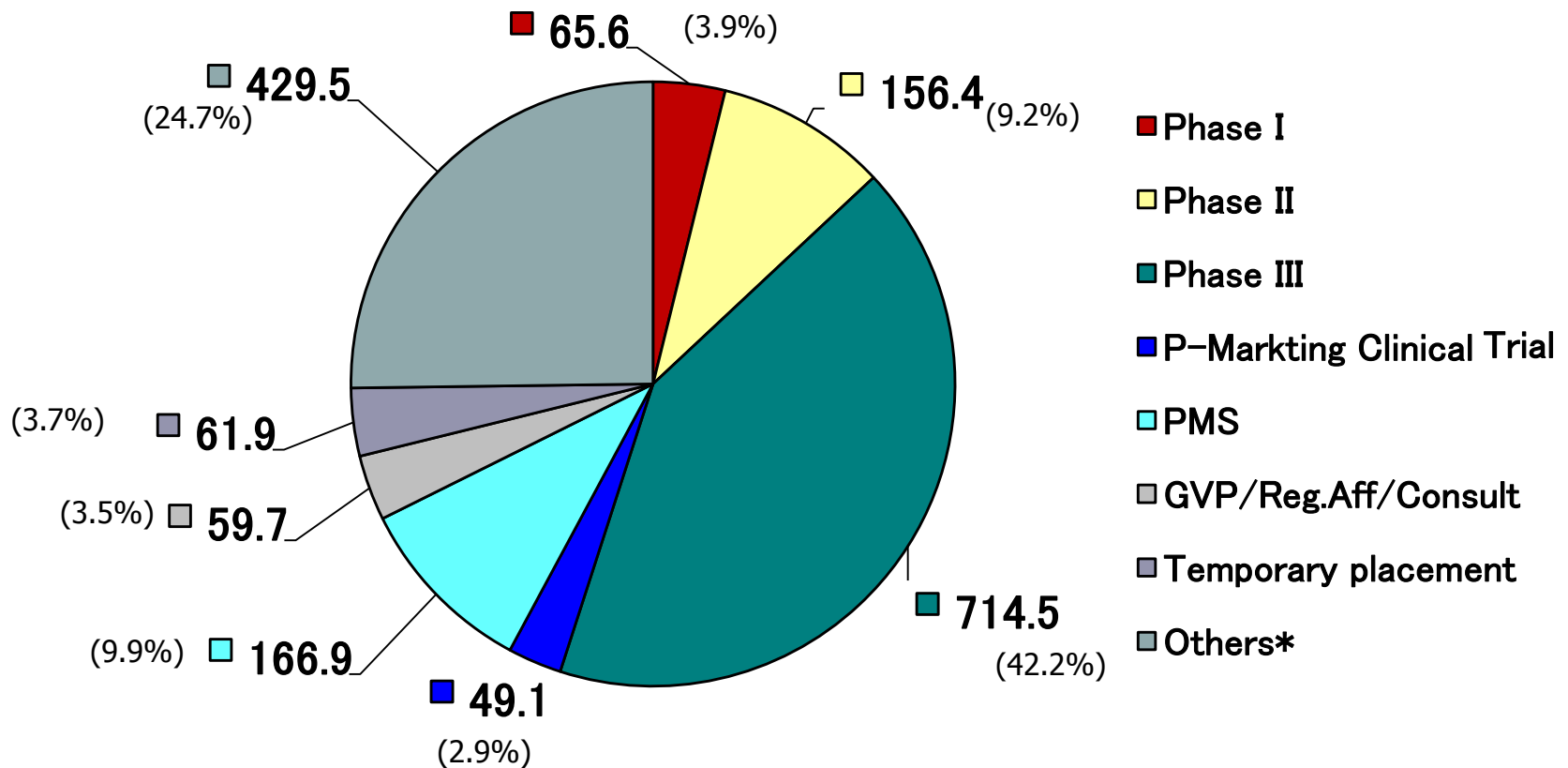


- Others Including reg.affairs, consulting, audit – 0.96Bil.Y (-4.6%)
- GVP +1.53Bil.Y(+9.8%)
- Medical Writing +0.43Bil.Y(+22.2%)
- Registration -0.48Bil.Y(-15.7%)
- Bio. Stat. +0.84Bil.Y(+14.4%)
- DM +1.16Bil.Y(+5.0%)
- Monitoring +9.07Bil.Y(+9.9%)



# 2017 Medical Products Sales by Clinical Phases

**Total: 169.3 Bil.¥**  
**[1.61 Bil. \$ (1\$=105¥)]**

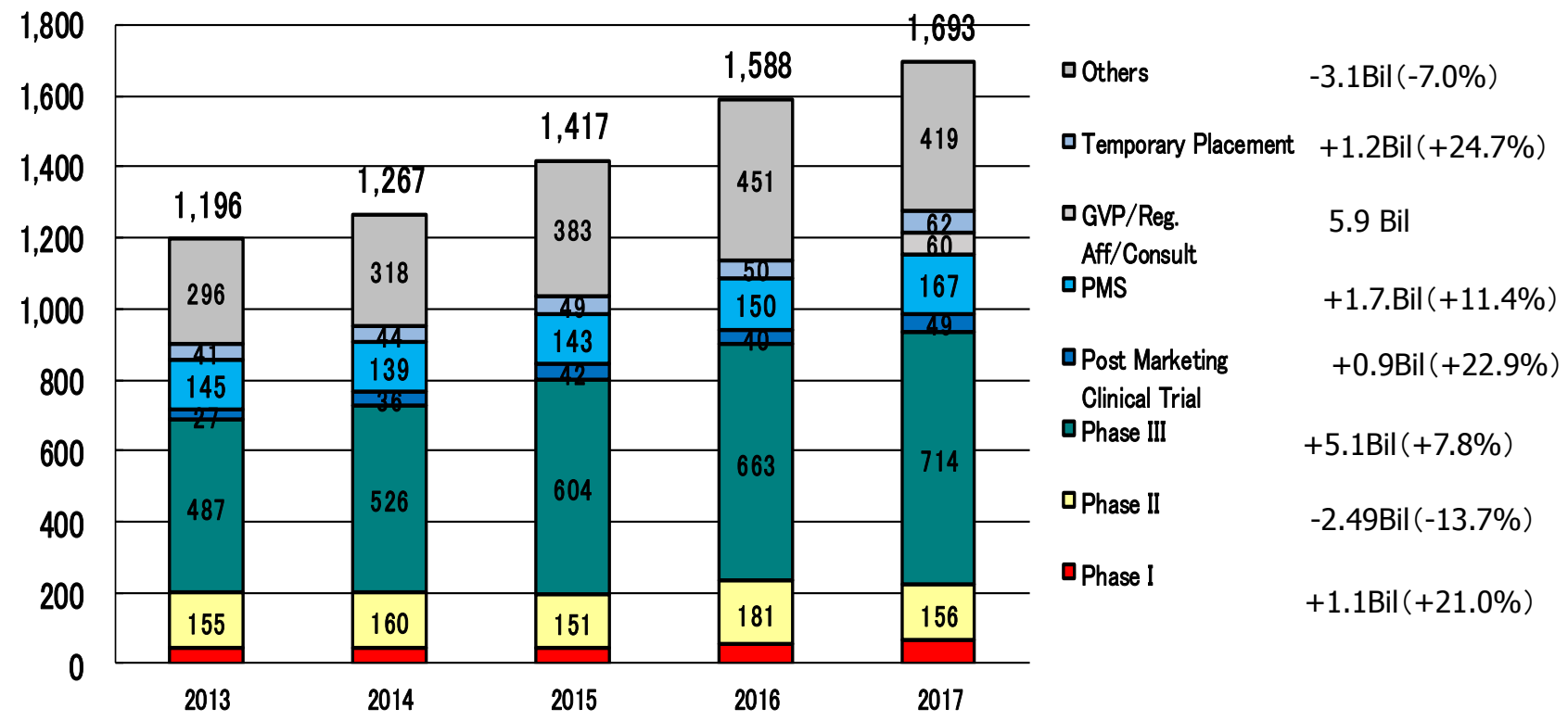


\*Refer to slide No. 10 regarding other services.

# Medical Products Sales by Clinical Phases 2013-2017

(Sales Unit: Bil.¥)

compared to 2016



# Other services Conducted in relation to Medical Products 2017

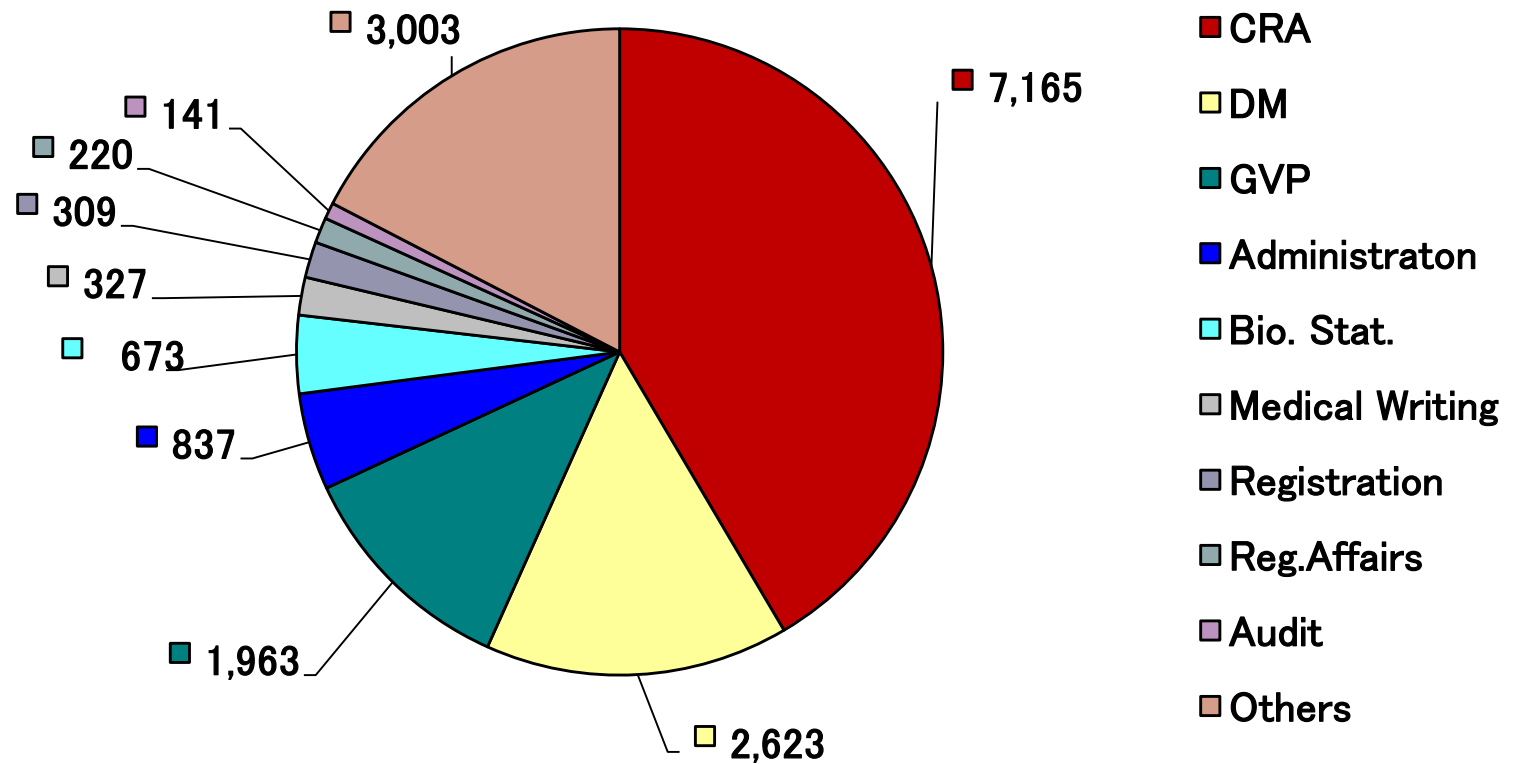
(No. represent the number of CRO conducting those business services.)

<b>Business services</b>	<b>No.</b>	<b>Business services</b>	<b>No.</b>
Project management	13	Academic papers writing	8
Clinical Trial In-Country Care-taker	13	SOP preparation	8
Education & training	11	Holding research conference	7
Randomization	11	Logistics and storage of IMP	6
IT support, system building (excluding EDC)	9	Advertisement of recruiting clinical study subjects, site-selection	4
Translation	9	Establishing analytical methods, validation	3
BE studies	9		

Other services also include consulting such as support for application of reexamination, generic medical products, cellular and tissue-based products, statistical analysis in general, support for new drug application, QC, CTD preparation, prior assessment consultation with PMDA, preparation for compliance assessment review by PMDA.

# 2017 Employees by Business Services

Total No. of employees: 17,261

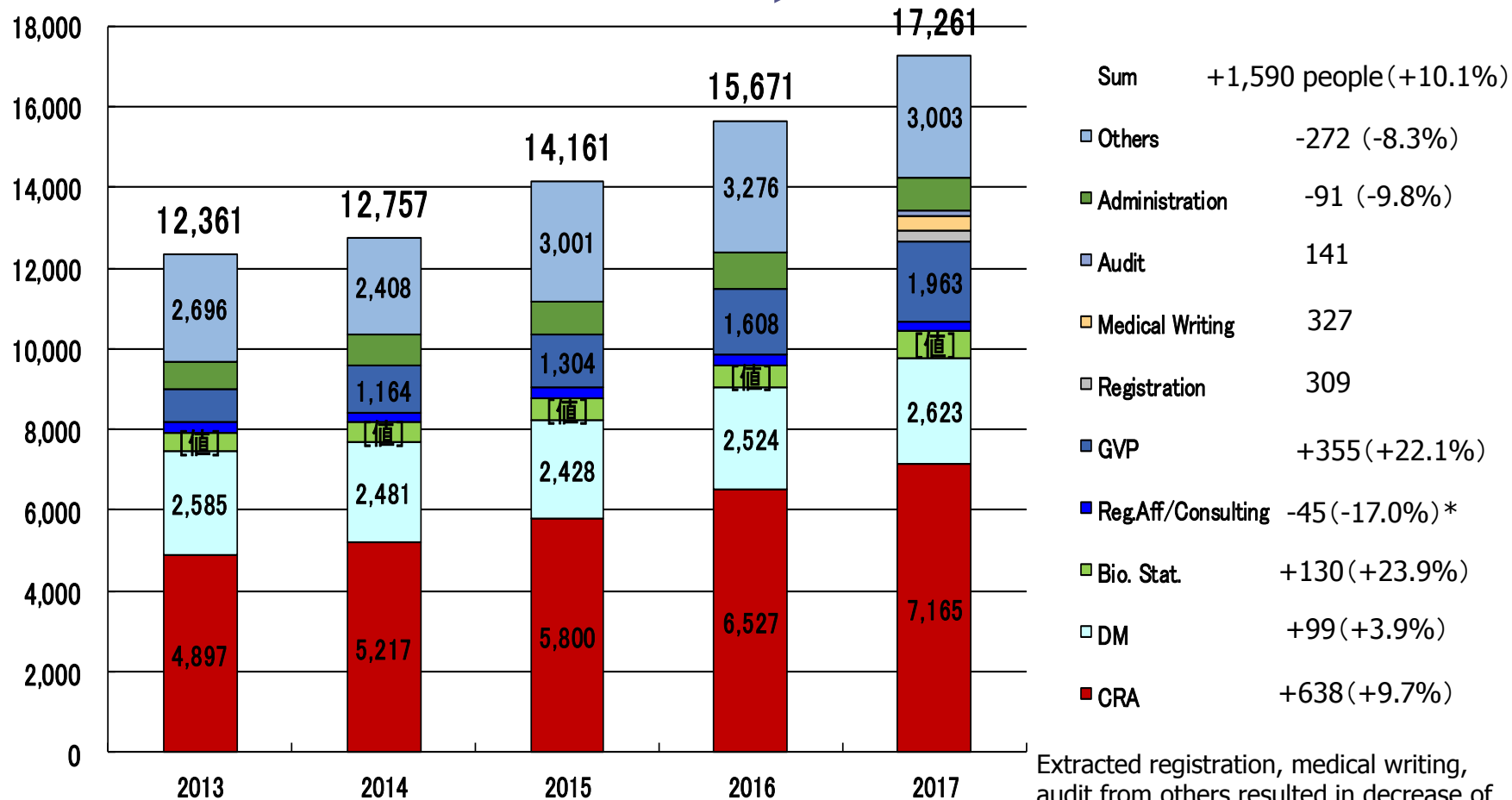


# Employees by Business Services 2013-2017

(Unit : No. of employees)

4900 employees increased since 2013 (39.6% up)

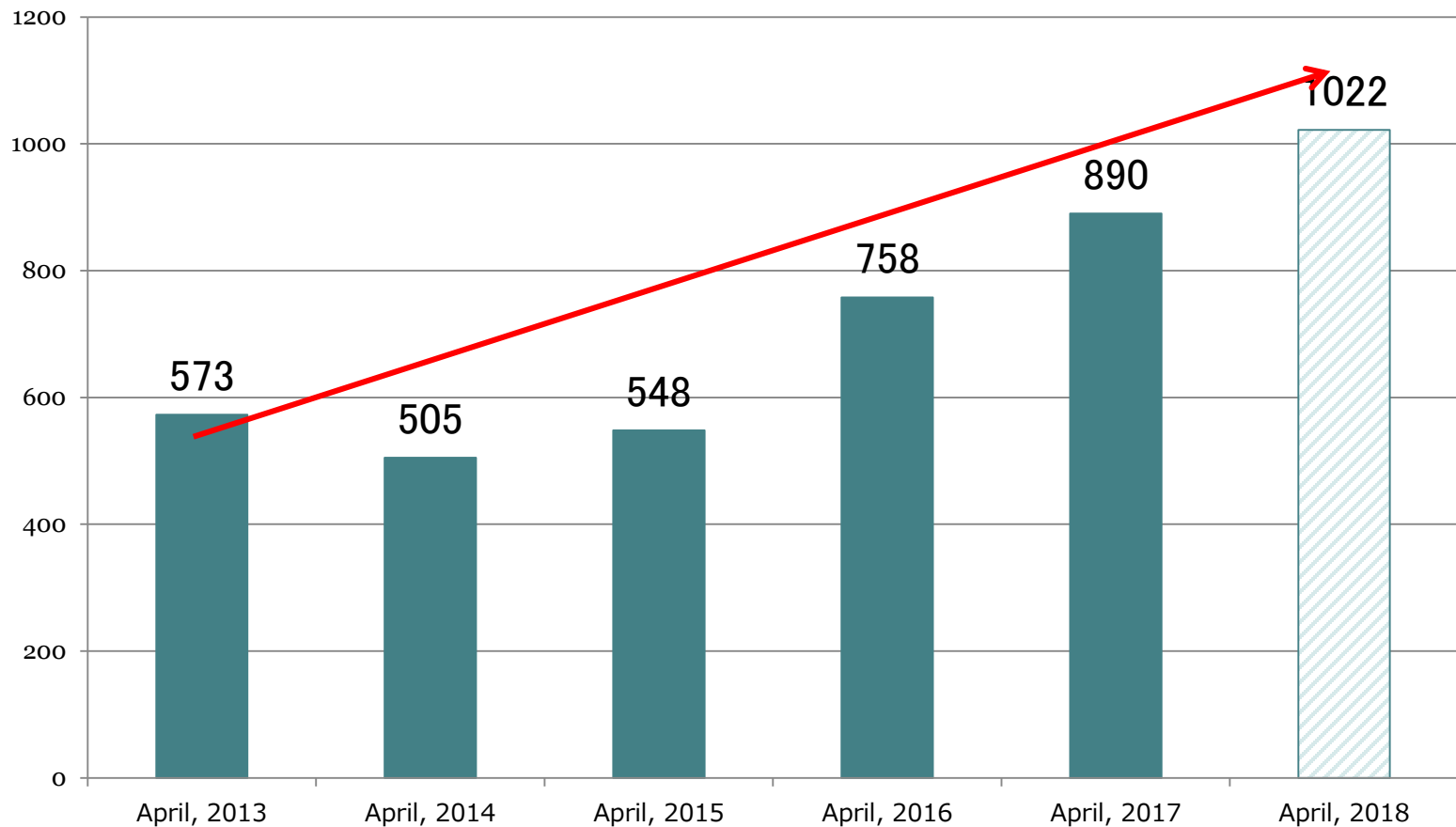
compared to 2016



Extracted registration, medical writing, audit from others resulted in decrease of reg. affairs/consulting 2017.

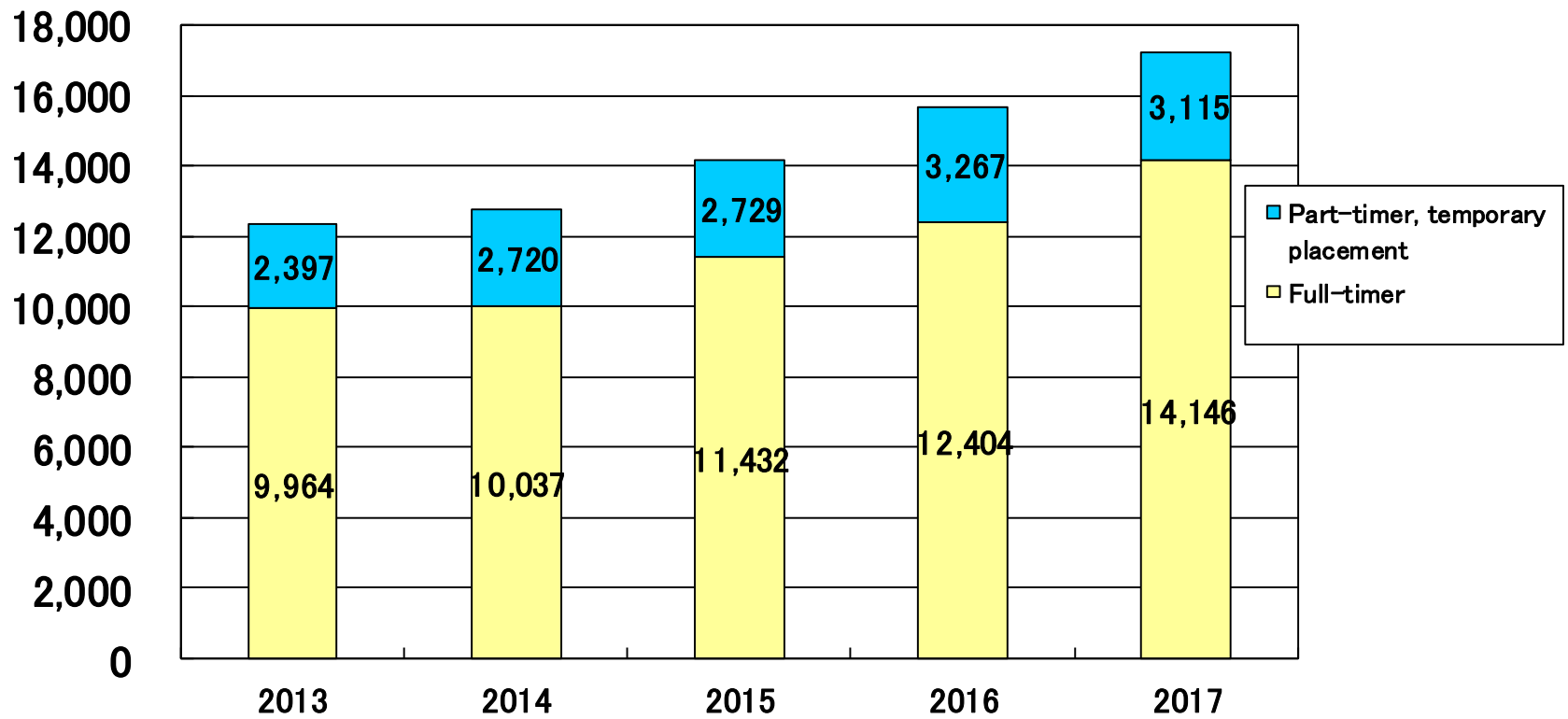
# Employees by Business Services 2013-2017

1022 new employees estimated in April 2018



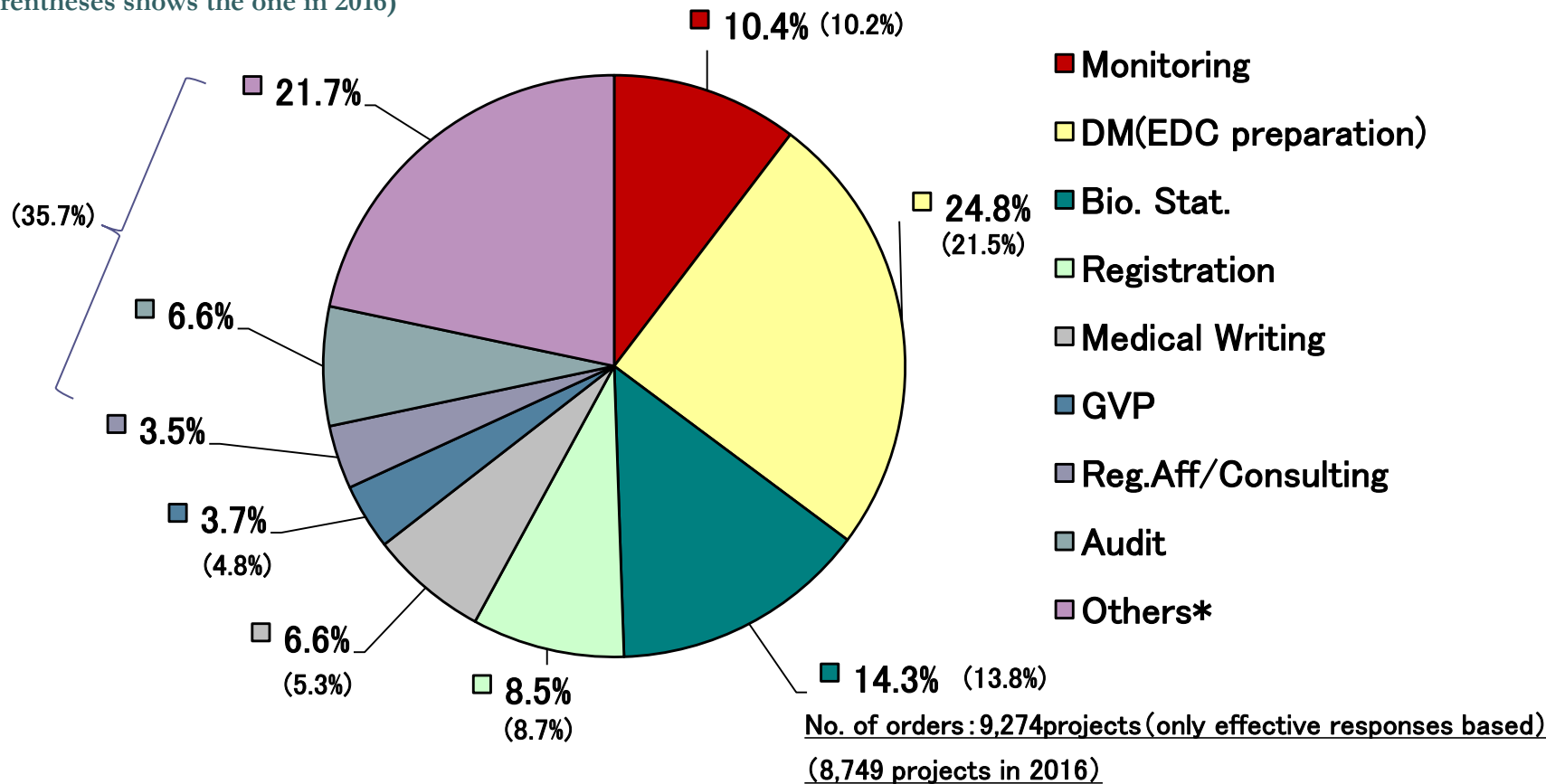
# Employees by Business Services 2013-2017

2017 Total No. of employees :17,261



# 2017 Medical Products/Devices/Food & Nutrition-Supplement Outsourced Projects by Business Services

★1 Project =1 service per protocol, not including any projects associating temporary placement (the ratio in parentheses shows the one in 2016)



\*Others include project management, education and training, randomization, IT support-system building, translation, BE studies, academic study report writing, SOP preparation, etc.



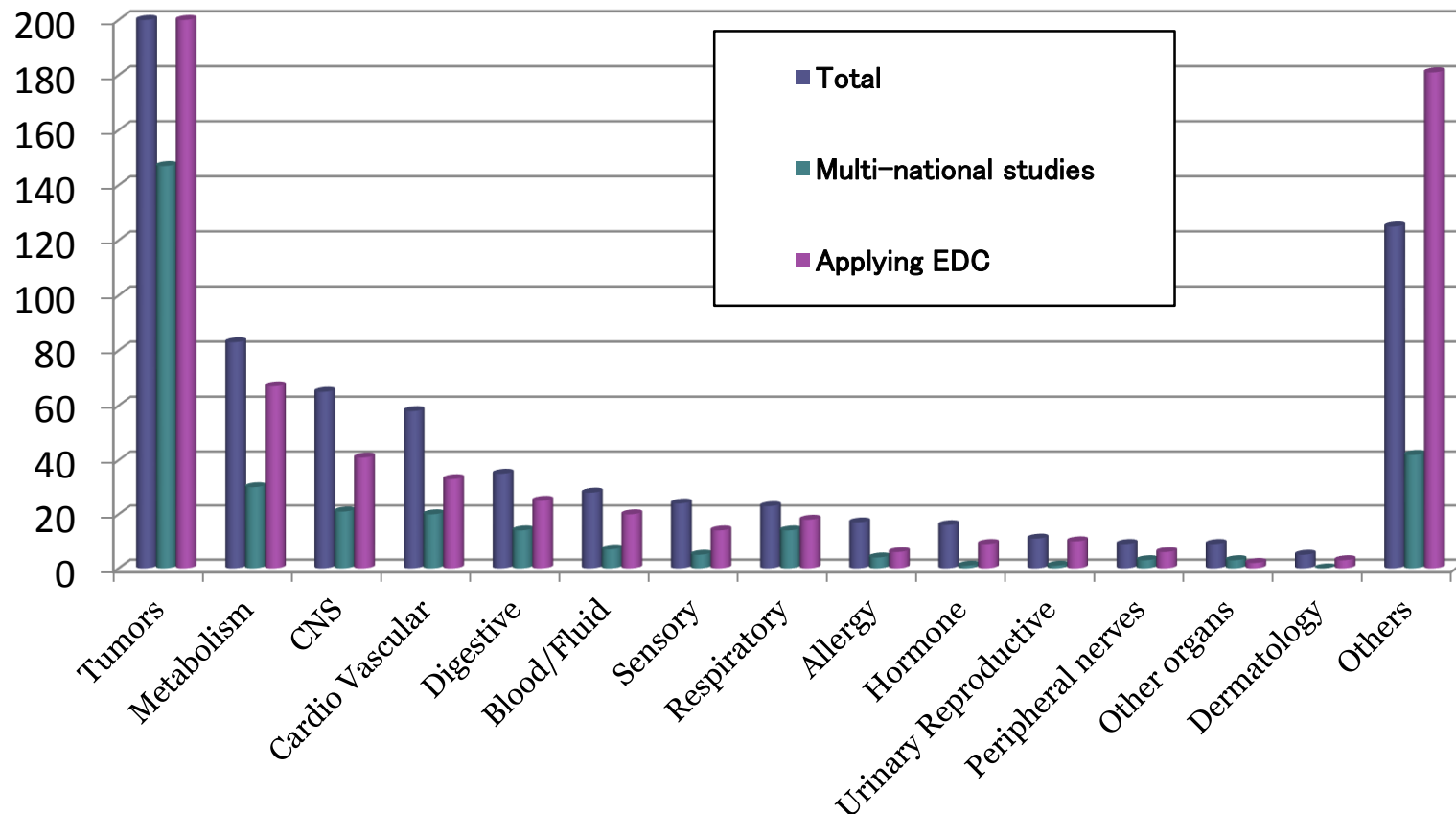
## 2017 Monitoring Projects\* by Therapeutic Area

- Only valid responded projects, 839, are categorized out of total monitoring projects .
- \* Multi-National Studies: Studies conducted in multi countries simultaneously with the same protocol.

Multinational studies counted 312 (37.2%), EDC studies 653 (77.8%) out of 839 projects.

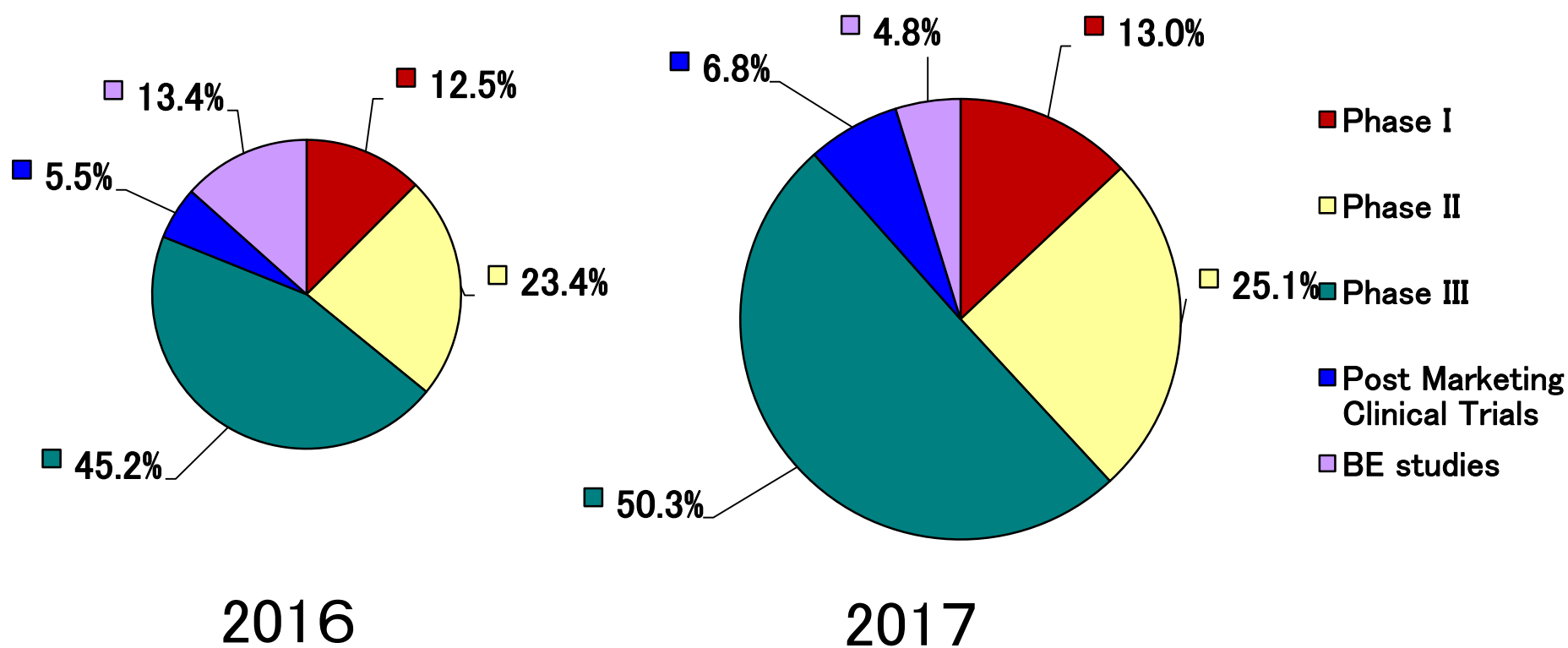
Multinational studies obtained 242 responses (31.8%), EDC studies 502 (66.0%) out of 761 valid responses in 2016

(Units: No. of projects)



# 2017 Monitoring Projects\* by Clinical Phases

Note: Only valid responded projects, 839, are categorized out of total monitoring projects.



No. of projects of valid response counted 761 in 2016