



# Annual Report 2020 (Jan. – Dec.)

**Apr. 23, 2021**  
**Japan CRO Association**

# JCROA 2020

**Total Number of Members: 47 companies**

**Regular Member: 15 companies**

**Supporting Member: 32 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 31 companies in 2020, excluding 16 supporting members in this report.

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

\* Please note that the errors in breakdown of employees in 2019 have been corrected.

# 2020 JCROA Annual Business Results

## 1. Total Sales Volume

- ① Total turnover decreased by 83.3/100 Mil. Yen (1,866.9/100 Mil.Yen from 1,949.9/100 Mil.Yen in 2019), 4.3% in 2020.
- ② Total Sales volume of medical products (Pharmaceuticals), medical devices, regeneration, food & nutrition, academia clinical research decreased by 157.9/100 Mil.Yen (1,704.4/100 Mil.Yen from 1,862.3/100 Mil.Yen), 8.5%. While the sales of medical products sharing 84.1%, 161.4/100 Mil.Yen decreased (1,569.3/100 Mil Yen from 1,730.7/100 Mil.Yen) by 9.3%, the medical devices increased by 13.9/100 Mil.Yen, 26.9%.

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

- ① Monitoring decreased by 88.2/100 Mil.Yen. (- 8.6%)
- ② DM&Bio.Stat decreased by 46.1/100 Mil.Yen. (- 15.7%)
- ③ GVP reached 158.1/100 Mil Yen.(-2.4%)
- ④ Academia Clinical Researches reached 40.4/100 Mil.Yen, decreased by 12.5/100 Mil.Yen. (-23.6%)

## 3. Medical Products Sales by Clinical Phases

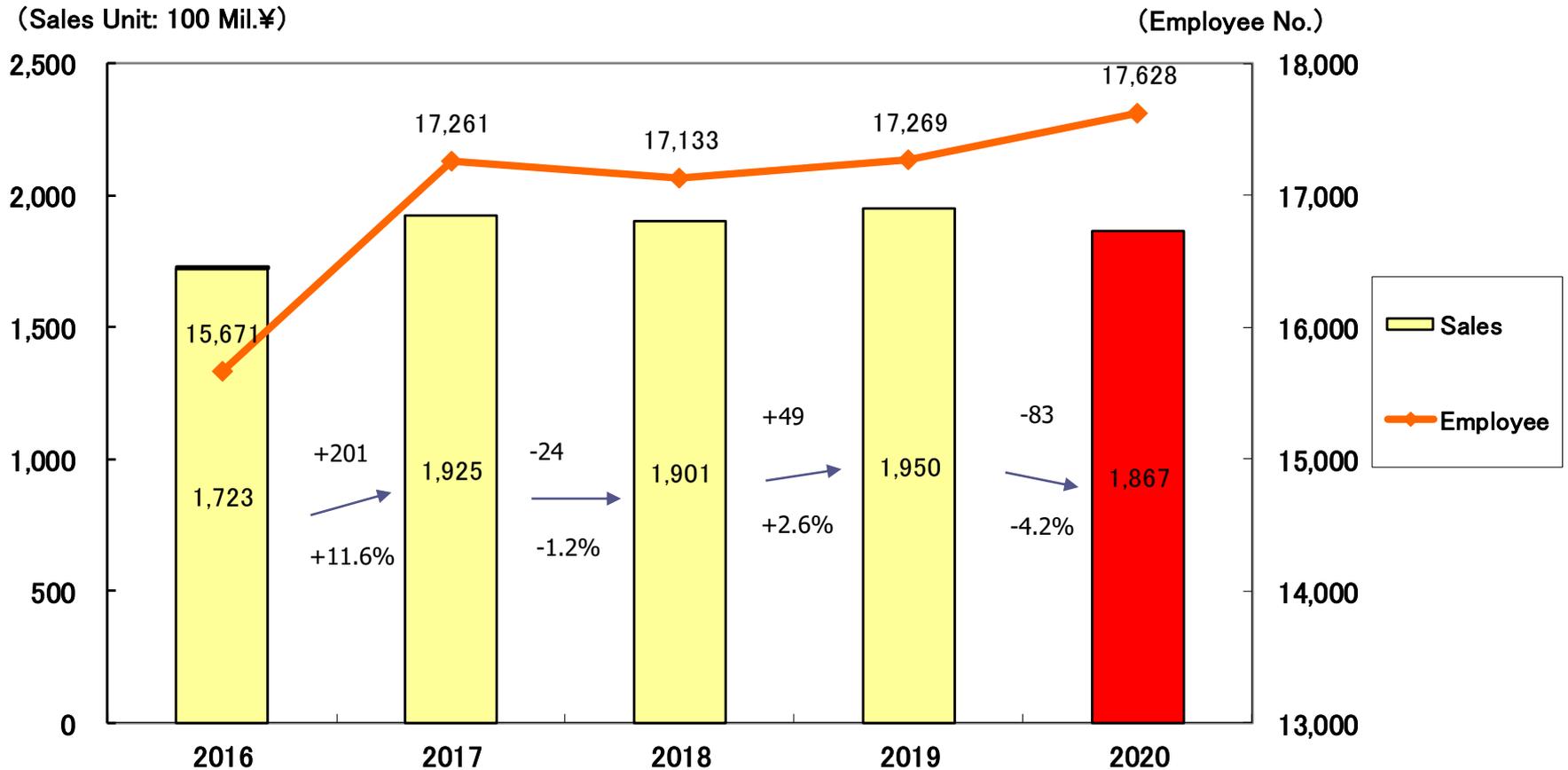
- ① Phase I to III decreased by 7.5%. Post-marketing Clinical Trials increased by 88.8%, while PMS decreased by 20.1%. The business sectors of temporary placement increased by 5.1/100 Mil.Yen, (+15.6%).
- ② In other business sectors, the project management & SOP compilation business respectively with 11 companies reached the biggest portion with 23 companies out of 32 companies. The consulting and IRB management are going to increase in contracted business area.

## 4. Total number of employees joining JCROA reached 17,628 by increase of 359. The CRA joining JCROA, engaged with clinical trials including QC, reached 7,035 by increase of 50. 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 increased in Phase I and II while Phase III decreased

# Sales and Employees 2016–2020\*

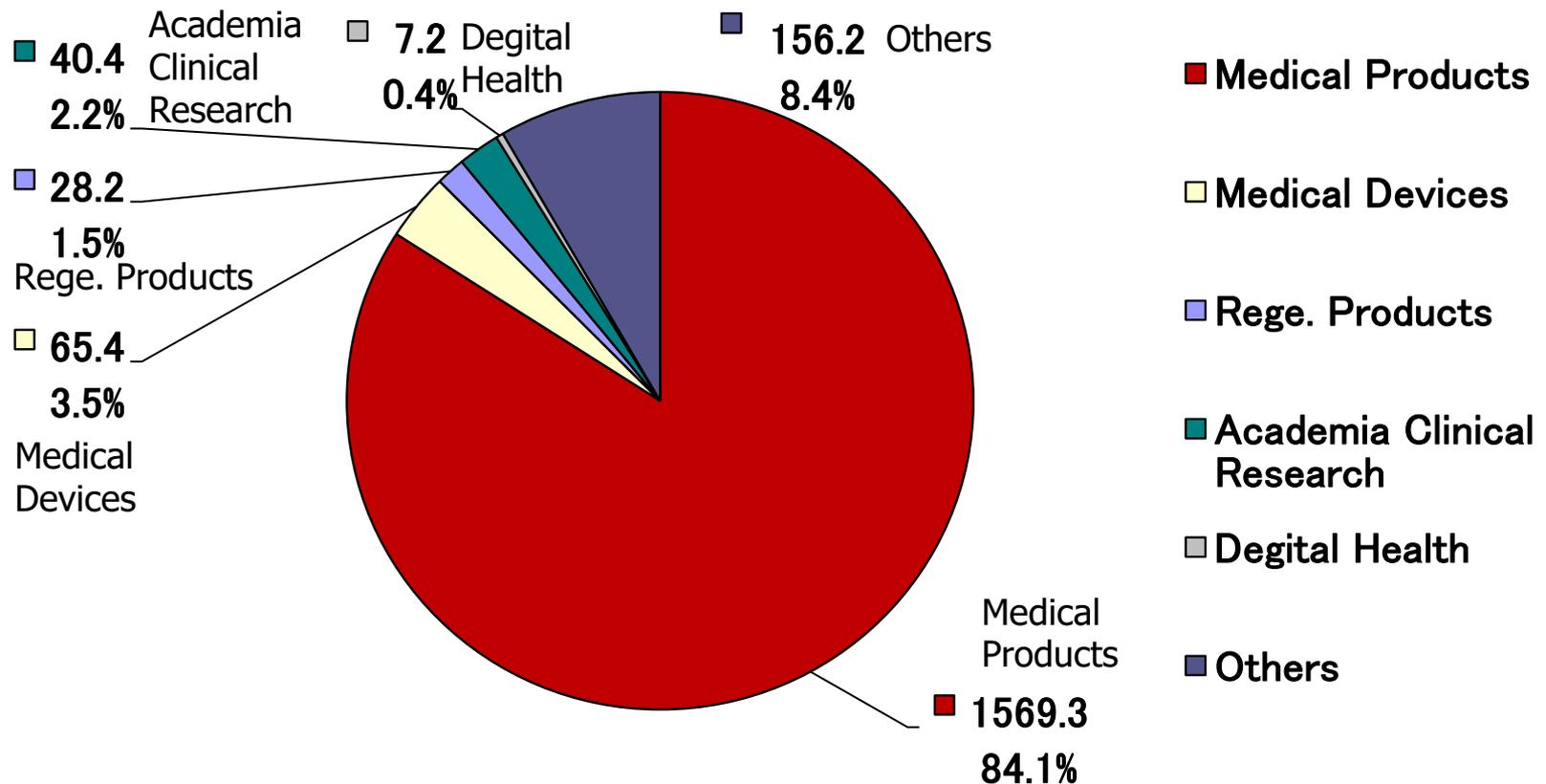


\* Count and estimate based on data of 26 in 2016, 32 in 2017, 33 in 2018, 32 in 2019, 31 member companies in 2020.

# 2020 Sales by Business Fields

Total: 1867/100 Mil. ¥

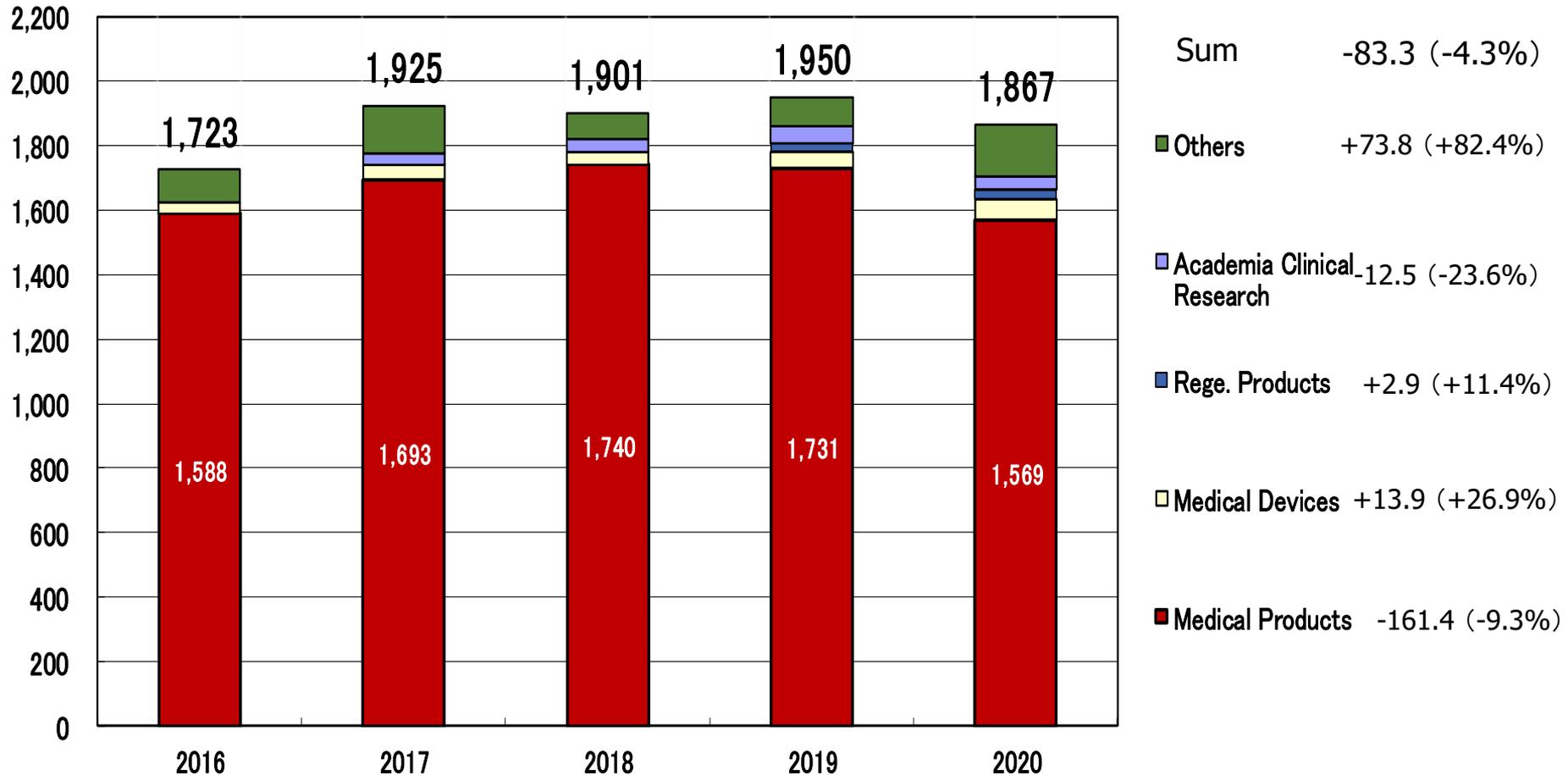
[1,729 Mil. \$ (1\$=108¥)]



# Sales by Business fields 2016–2020

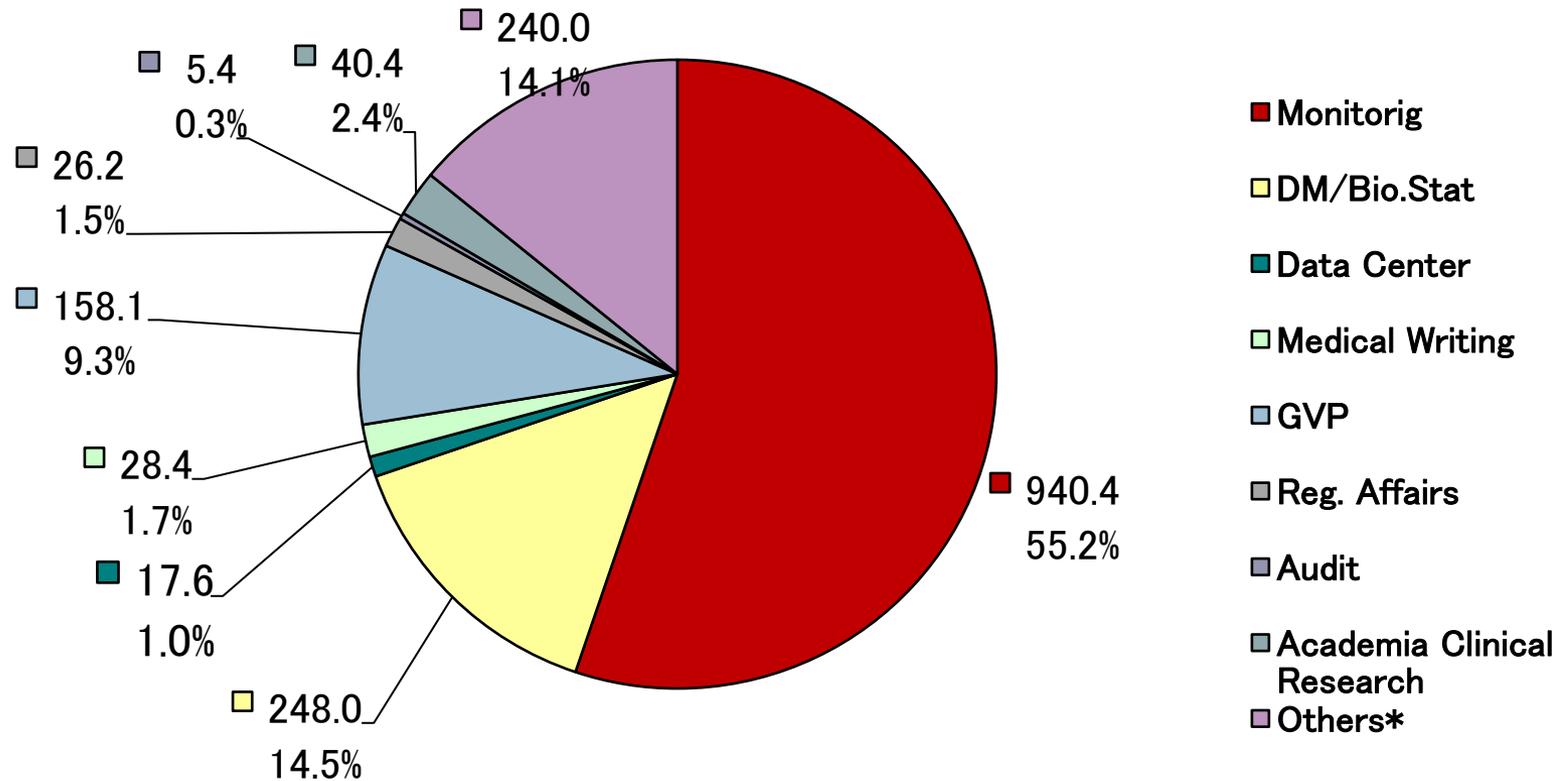
(Sales Unit: 100 Mil.¥)

compared to 2019



## 2020 Medical Products/Devices/Regeneration/Food & Nutrition-Supplement/Academia Clinical Research Sales by Business Services

**Total: 1704/100 Mil.¥**  
 [1578 Mil. \$ (1\$=108¥)]



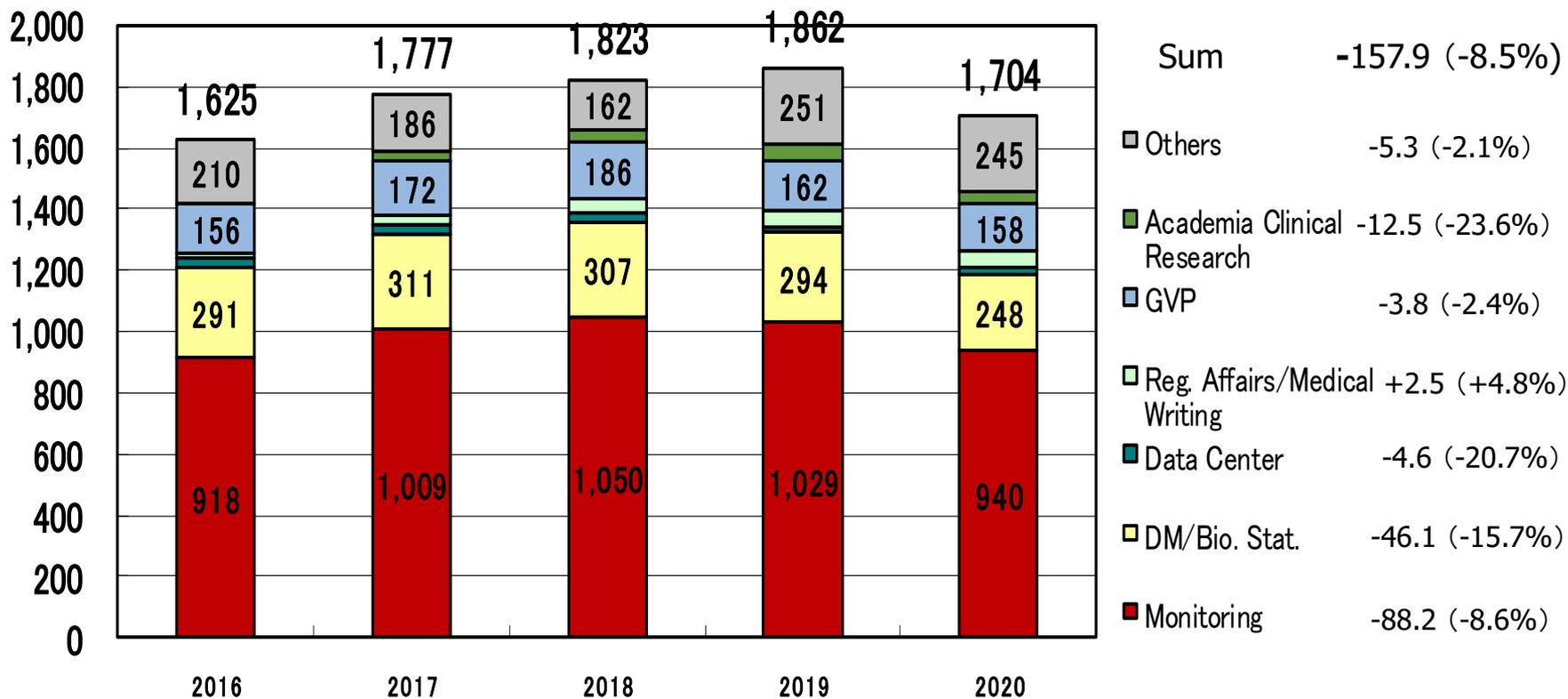
Sales (Unit: 100 Mil. ¥)

\*Please refer to page 10 for "others".

# 2020 Medical Products/Devices/Regeneration/Food & Nutrition-Supplement/Academia Clinical Research Sales by Business Services

(Sales Unit: 100 Mil.¥)

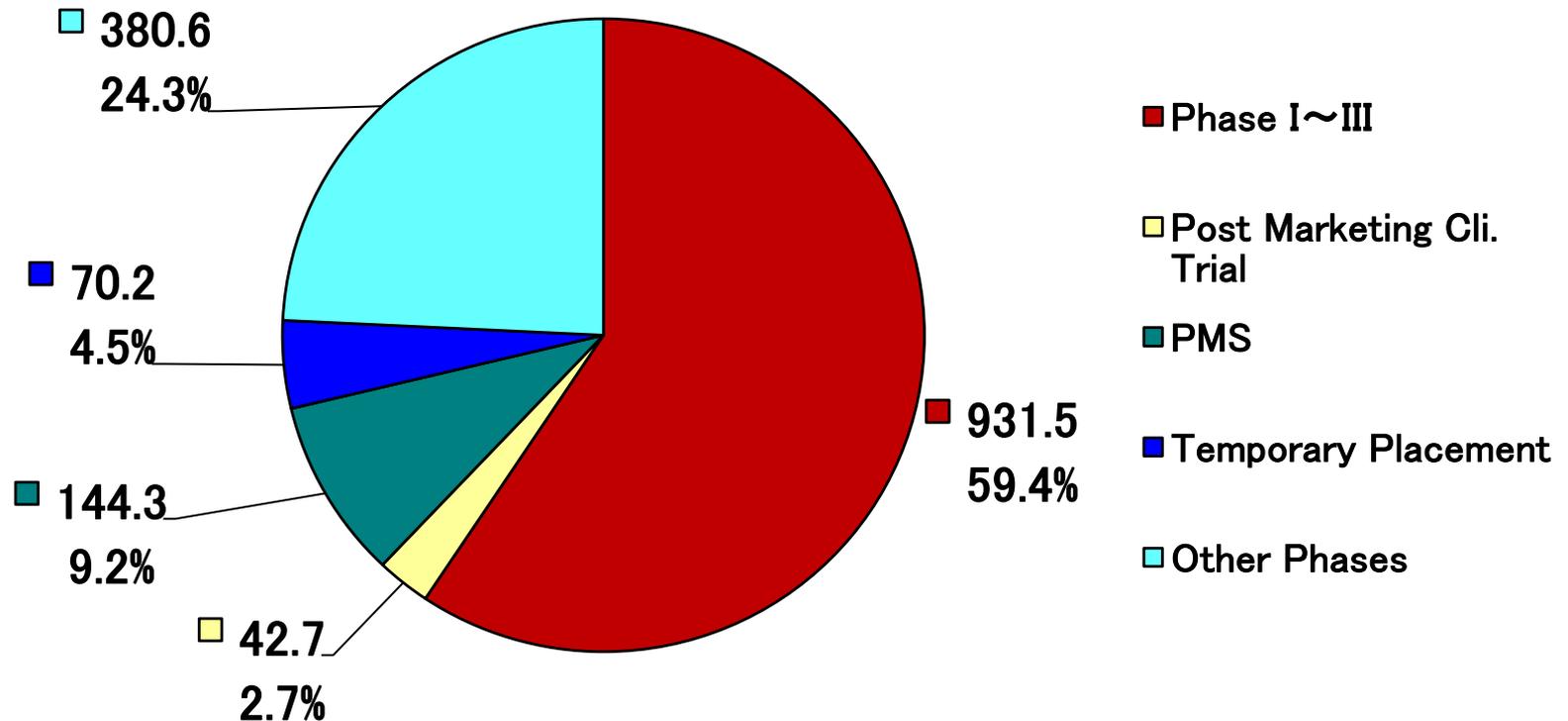
compared to 2019



The Regulatory Affairs has been combined with Medical writing, being separated from others since 2017. Academia clinical Research has also been separated.

## 2020 Medical Products Sales by Clinical Phases

Total: 1569/100 Mil.¥  
[1,453Mil. \$ (1\$=108¥)]

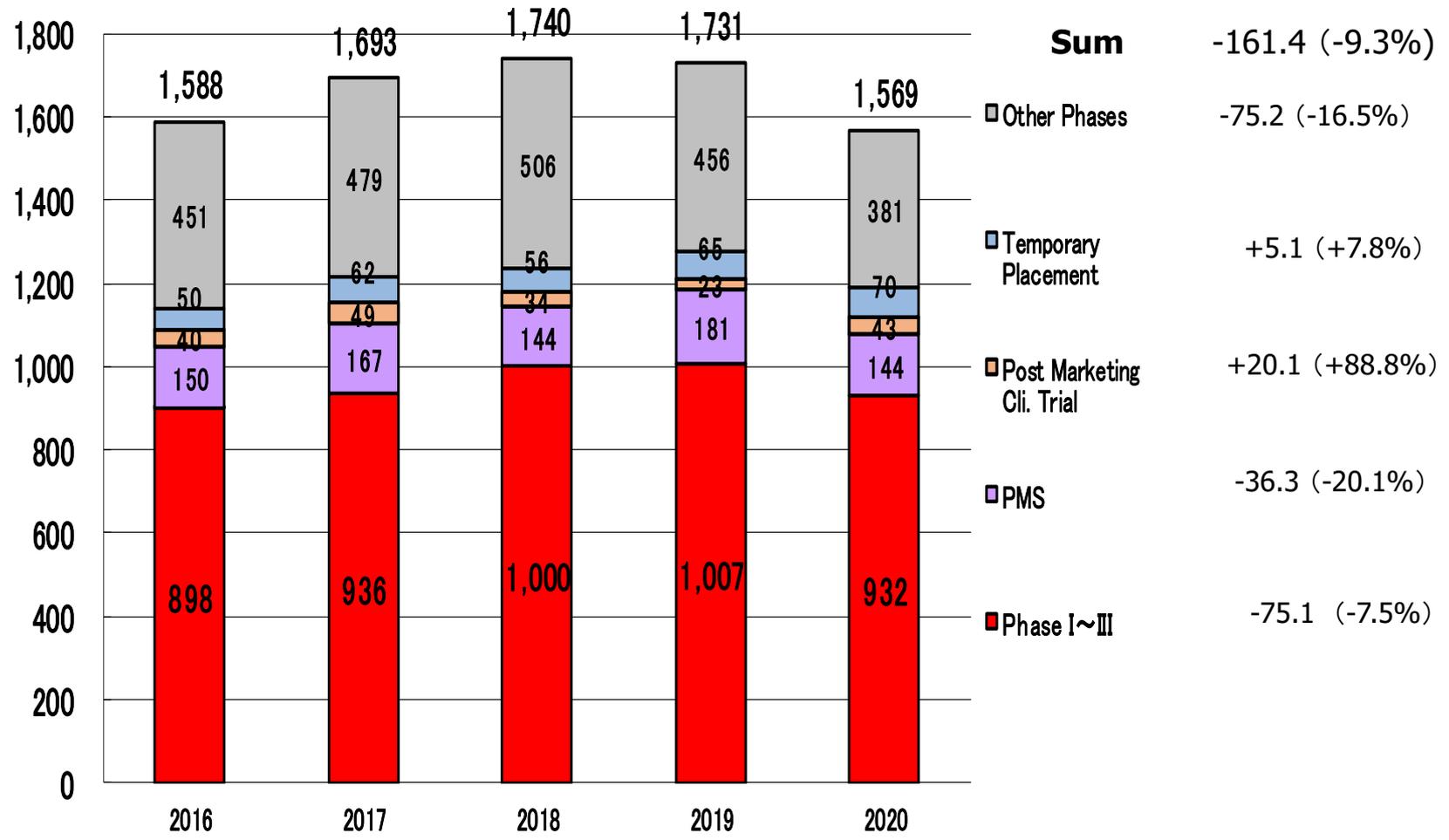


The sales volume of Phase I to III were combined. The ones of GVP, regulatory consulting were summarized in other phases. Academia Clinical research has not been included since that has not been investigated by relevant area and phase.

# Medical Products Sales by Clinical Phases 2016–2020

(Sales Unit: 100 Mil.¥)

compared to 2019



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 2020

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

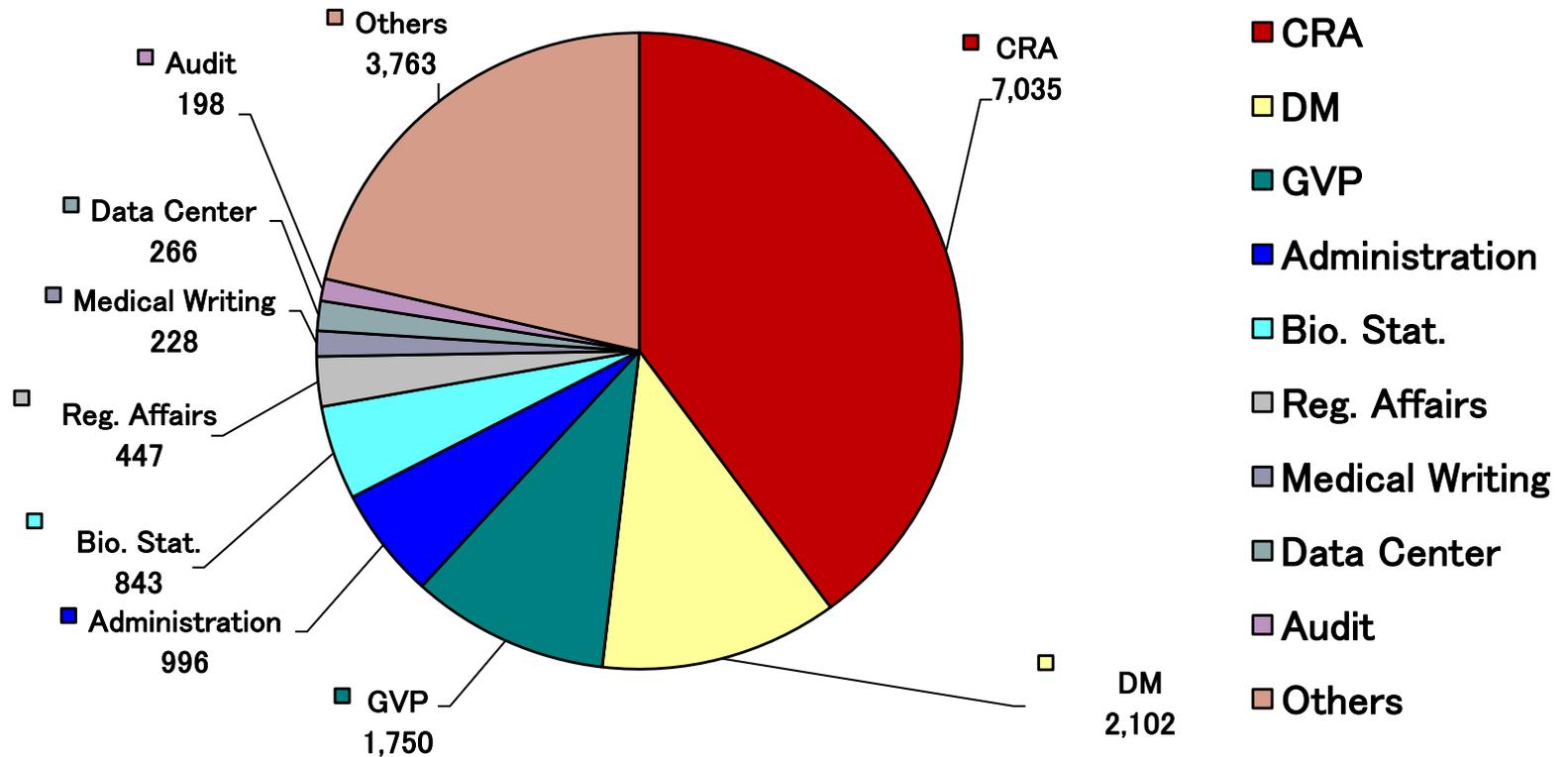
Business services	No.	Business services	No.
Project management	11	Logistics and storage of IMP	7
SOP preparation	11	IT support, system building (excluding EDC)	6
Education & Training	10	Holding research meetings	3
Medical Report	8	Establishing analytical methods, validation	3
Translation	8	Advertisement of recruiting clinical study subjects, site-selection	2
Randomization	7		

### Others

- IDMC operation, management & support, IRB management support
- Real world evidence management    ▪ Medical monitoring
- Assistance of RBM, Diagnostic imaging system, Pharmacovigilance management
- Central clinical laboratory test
- Consulting
- Regulatory affairs relating business, Assistance for preparation for PMDA Audit
- Management of archived documents, Support of Electric Data Application

# 2020 Employees by Business Services

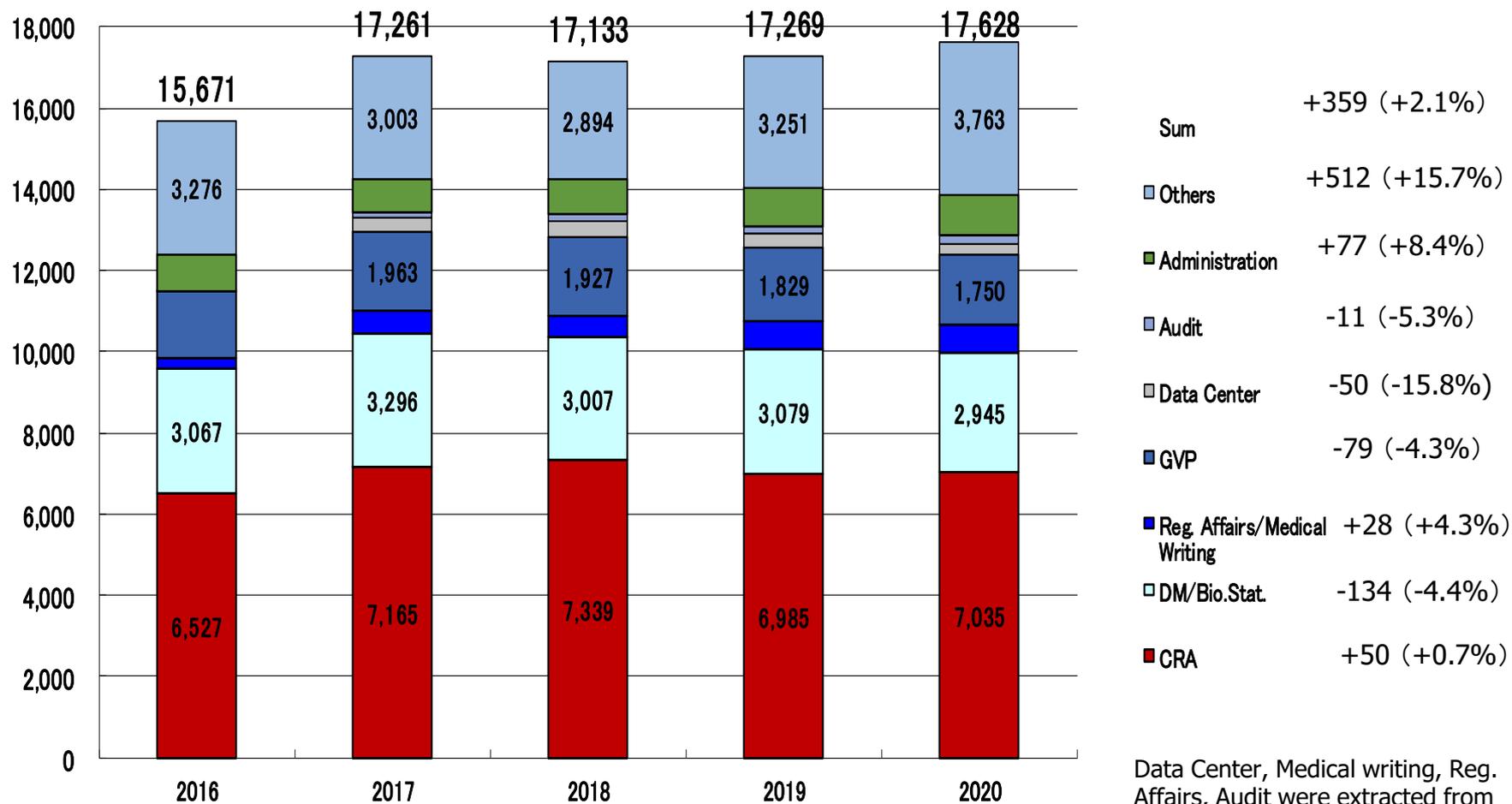
Total No. of employees: 17,628



# Employees by Business Services 2016–2020

(Unit: No. of employees)

compared to 2019

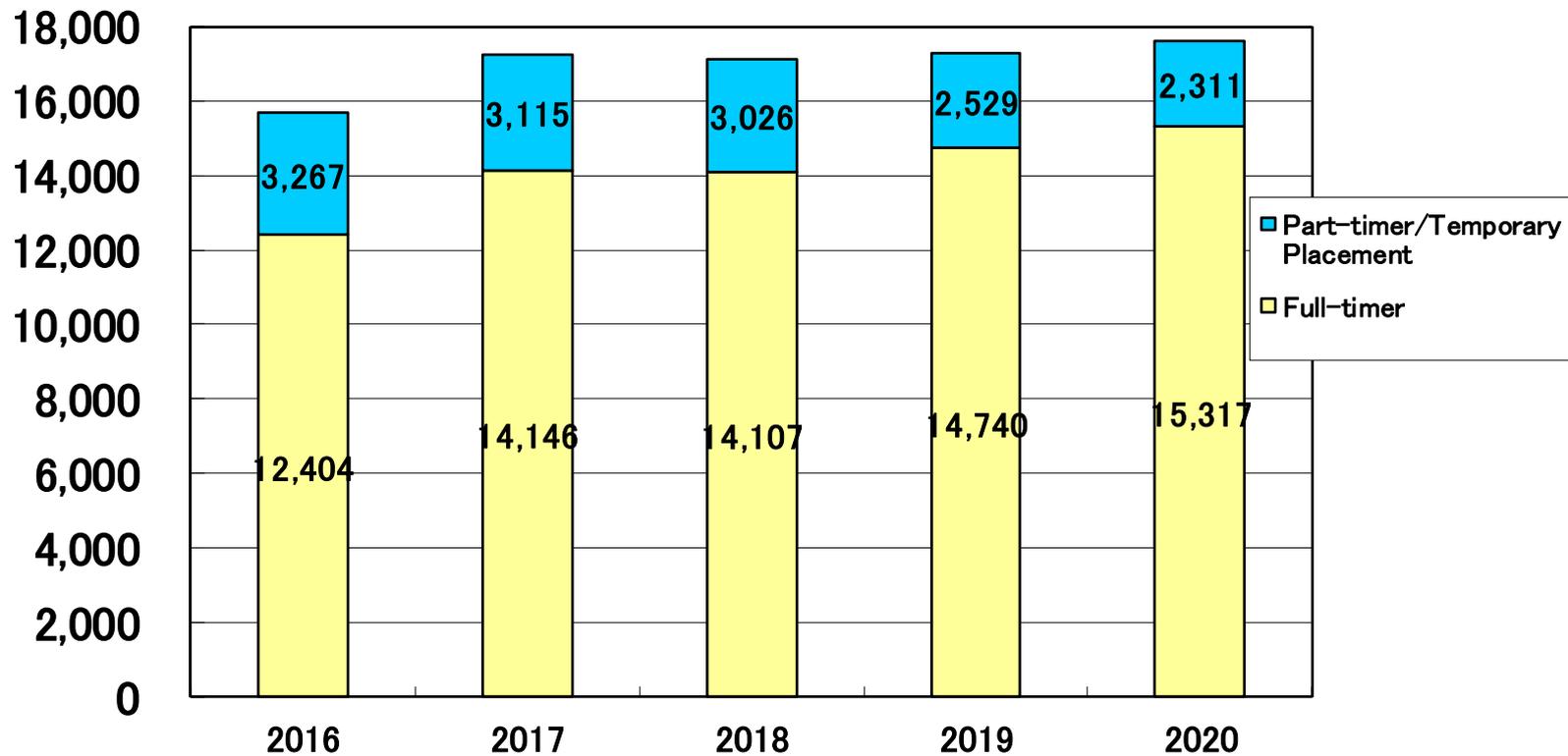


\* The number of employees in 2019 was revised.

Data Center, Medical writing, Reg. Affairs, Audit were extracted from others since 2017.

# Employees by Business Services 2016–2020

2020 Total No. of employees :17,628



## 2020 Monitoring Projects\* by Therapeutic Area

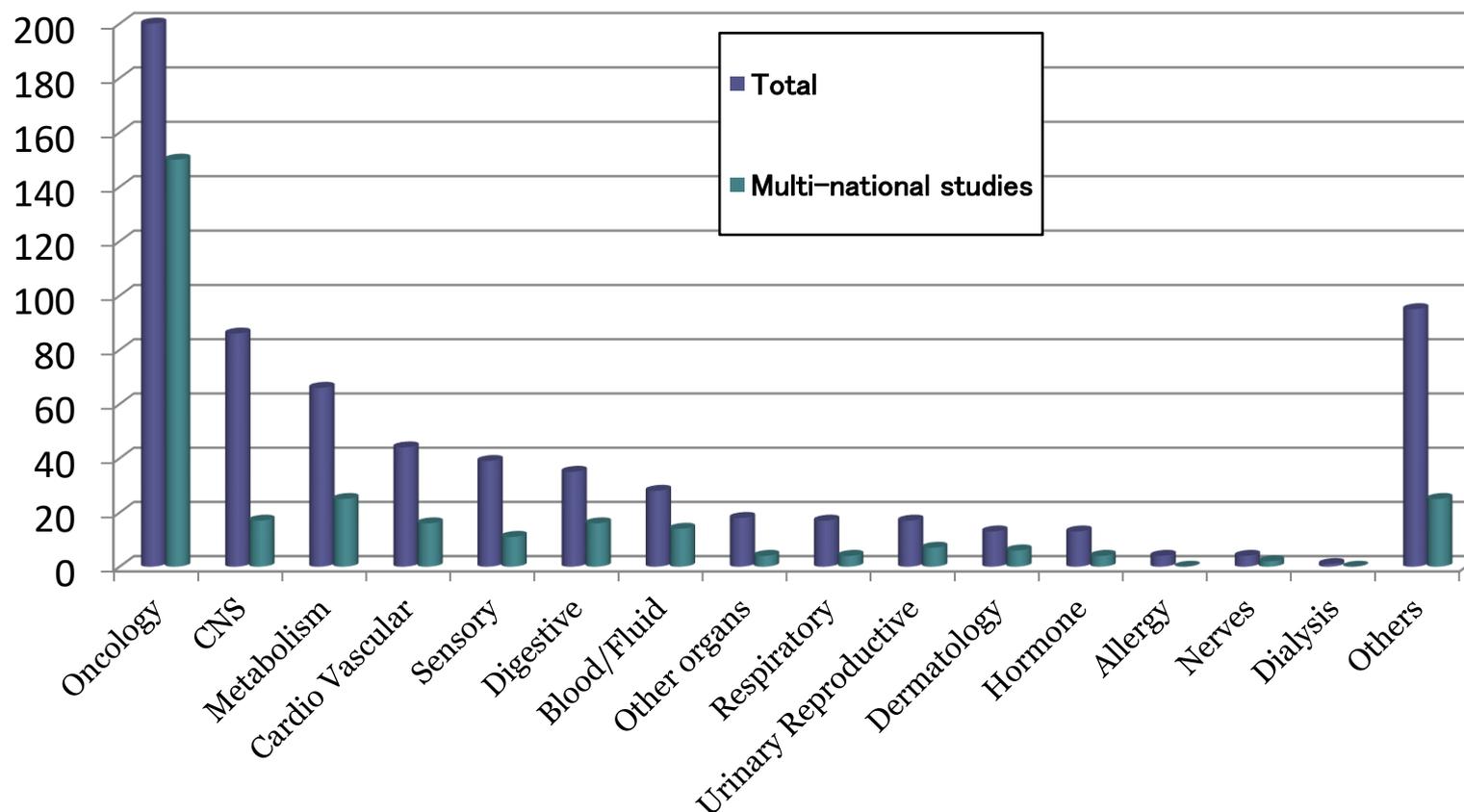
\* Only valid responded projects, 980, are categorized out of total monitoring projects .

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

The 301 (41.0%) multinational studies were conducted out of 980 projects.

The multinational studies occupied 46.3% in 2018.

(Unit: No. of Projects)



# 2020 Monitoring Projects by Clinical Phases

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

