



# Annual Report 2021 (Jan. – Dec.)

**May 25, 2022**  
**Japan CRO Association**

# JCROA 2021

**Total Number of Members: 45 companies**

**Regular Member: 15 companies**

**Supporting Member: 30 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 2021, excluding 14 supporting members in this report.

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

# 2021 JCROA Annual Business Results

## 1. Total Sales Volume

- ① Total turnover increased by 389.0/100 Mil. Yen (2,255.6/100 Mil.Yen from 1,866.6/100 Mil.Yen in 2020), 20.8% in 2021.
- ② Total Sales volume of medical products (Pharmaceuticals), medical devices, regeneration, food & nutrition, academia clinical research increased by 359.2/100 Mil.Yen (2,063.6/100 Mil.Yen from 1,704.4/100 Mil.Yen), 21.1%. While the sales of medical products sharing 83.8%, 320.9/100 Mil.Yen increased (1,890.2/100 Mil Yen from 1,569.3/100 Mil.Yen) by 20.5%, the medical devices also increased by 2.5/100 Mil.Yen, 3.9%.

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

- ① Monitoring increased by 111.3/100 Mil.Yen. (+ 11.8%)
- ② DM&Bio.Stat increased by 54.3/100 Mil.Yen. (+ 21.9%)
- ③ GVP reached 277.2/100 Mil Yen, being increased by 119.2 Mil. Yen (75.4%)
- ④ Academia Clinical Researches reached 53.5/100 Mil.Yen, increased by 13.1/100 Mil.Yen. (32.5%)

## 3. Medical Products Sales by Clinical Phases

- ① Phase I to III increased by 25.5%. Post-marketing Clinical Trials increased by 144.4%, while PMS decreased by 8.2%. The business sectors of temporary placement increased by 24.5/100 Mil.Yen, (+34.9%).
- ② In other business sectors, SOP compilation business with 3 companies reached the biggest portion with responses from 23 companies out of 31 companies. The IT supporting with 3 companies and randomization with 2 companies are going to be increased with the diversification of business area.

## 4. Total number of employees joining JCROA reached 19,295 by increase of 1,667. The CRA joining JCROA, engaged with clinical trials including QC, reached 7,074 by increase of 39. The number of GVP (PV) and registration/data center increased in the same manner as the sales volume.

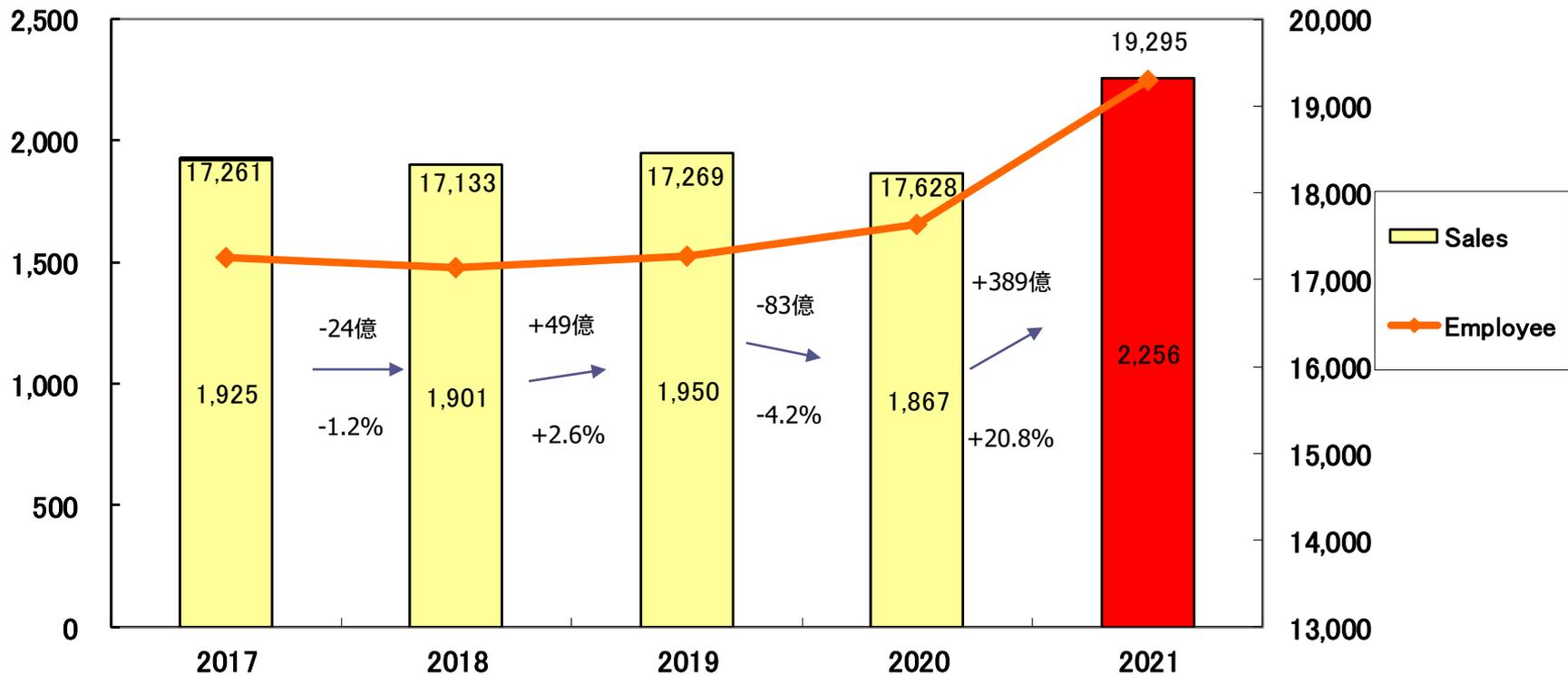
## 5. Ratio of monitoring project numbers by only effective replies

Tumors occupied the large part of project numbers by disease area, following by CNS and metabolism.

# Sales and Employees 2017–2021\*

(Sales Unit: 100 Mil.¥)

(Employee No.)

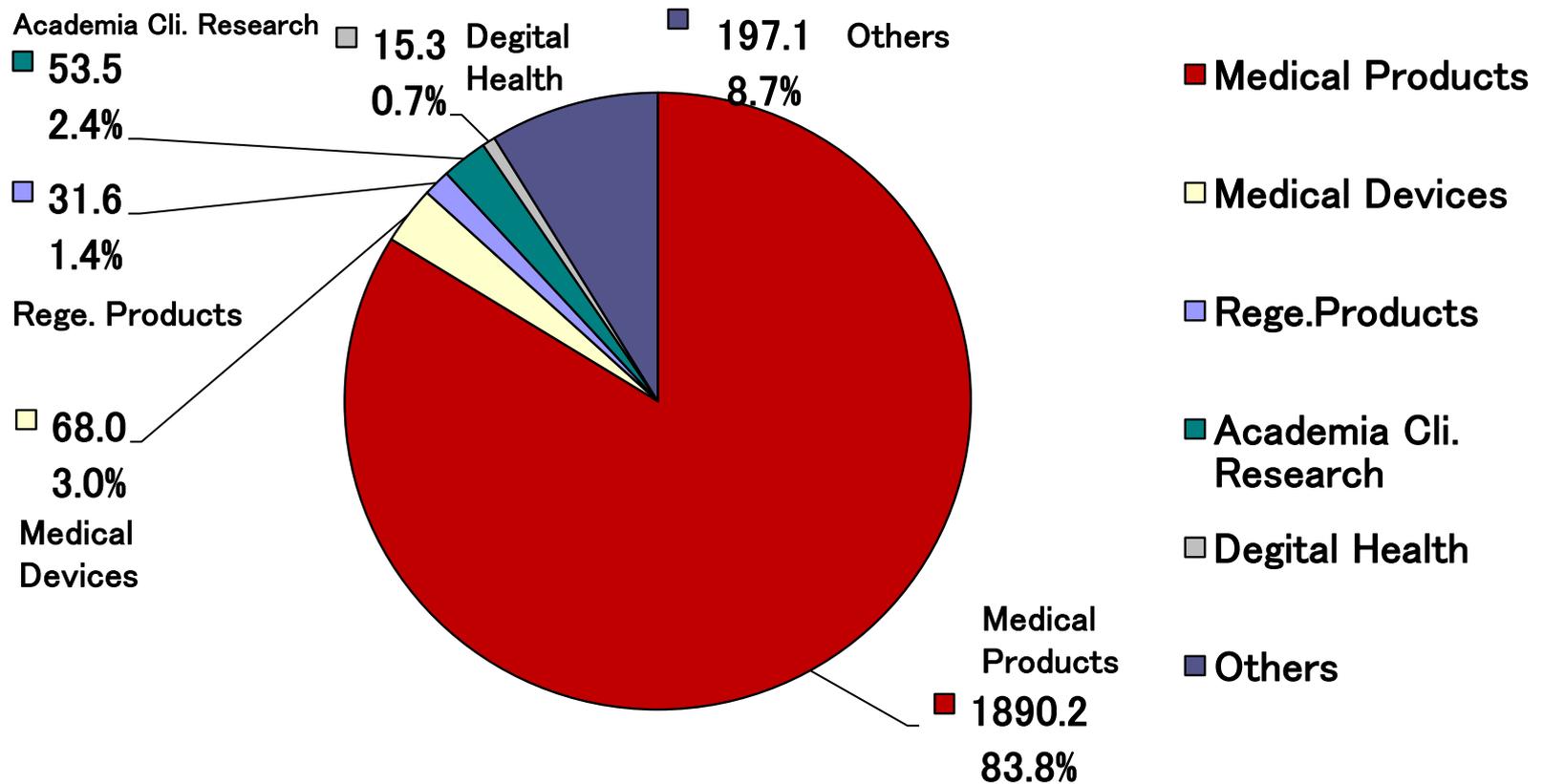


\* Count and estimate based on data of 32 in 2017, 33 in 2018, 32 in 2019, 31 member companies in 2020 and 2021.

# 2021 Sales by Business Fields

**Total: 2256/100 Mil. ¥**

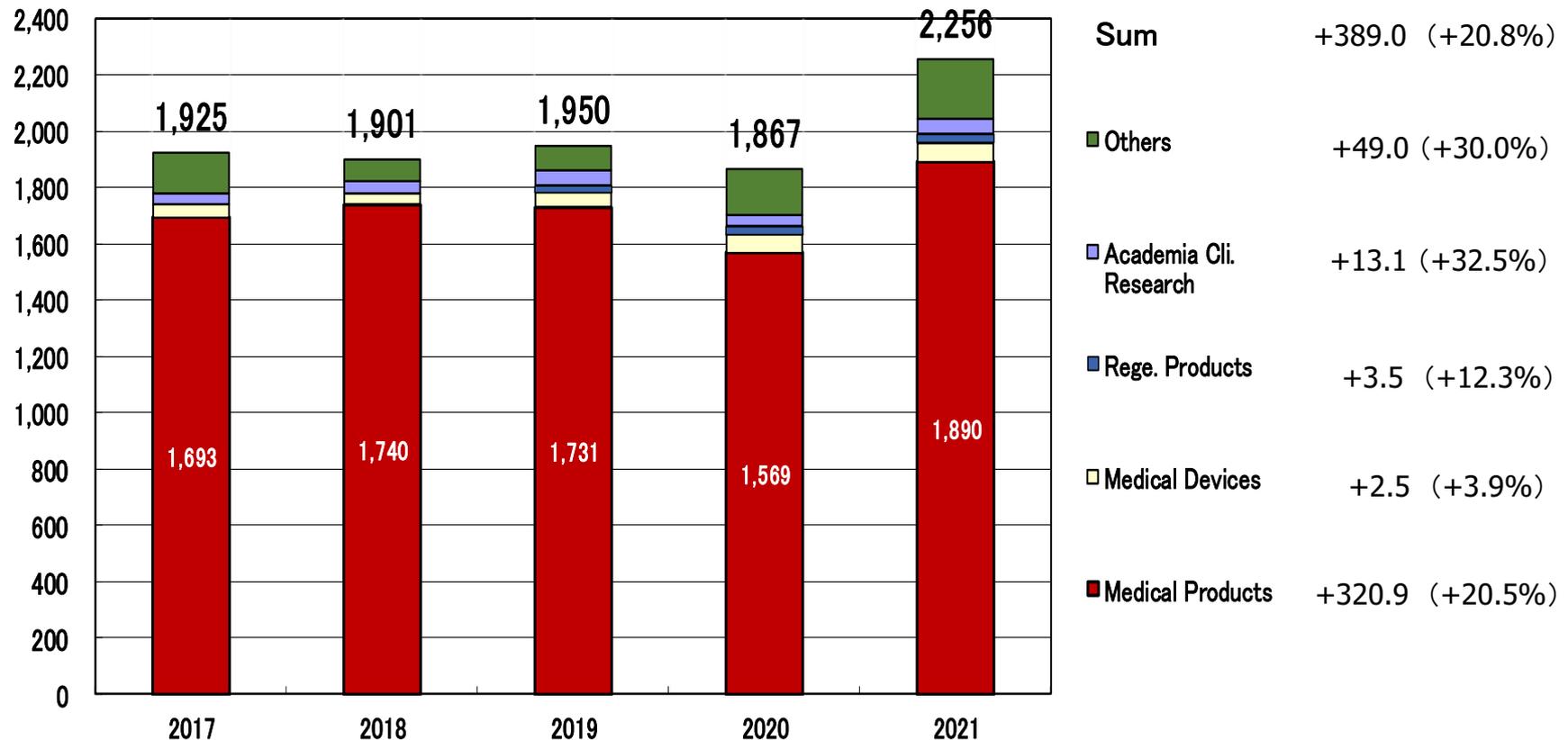
[1,749 Mil. \$ (1\$=129¥)]



# Sales by Business fields 2017–2021

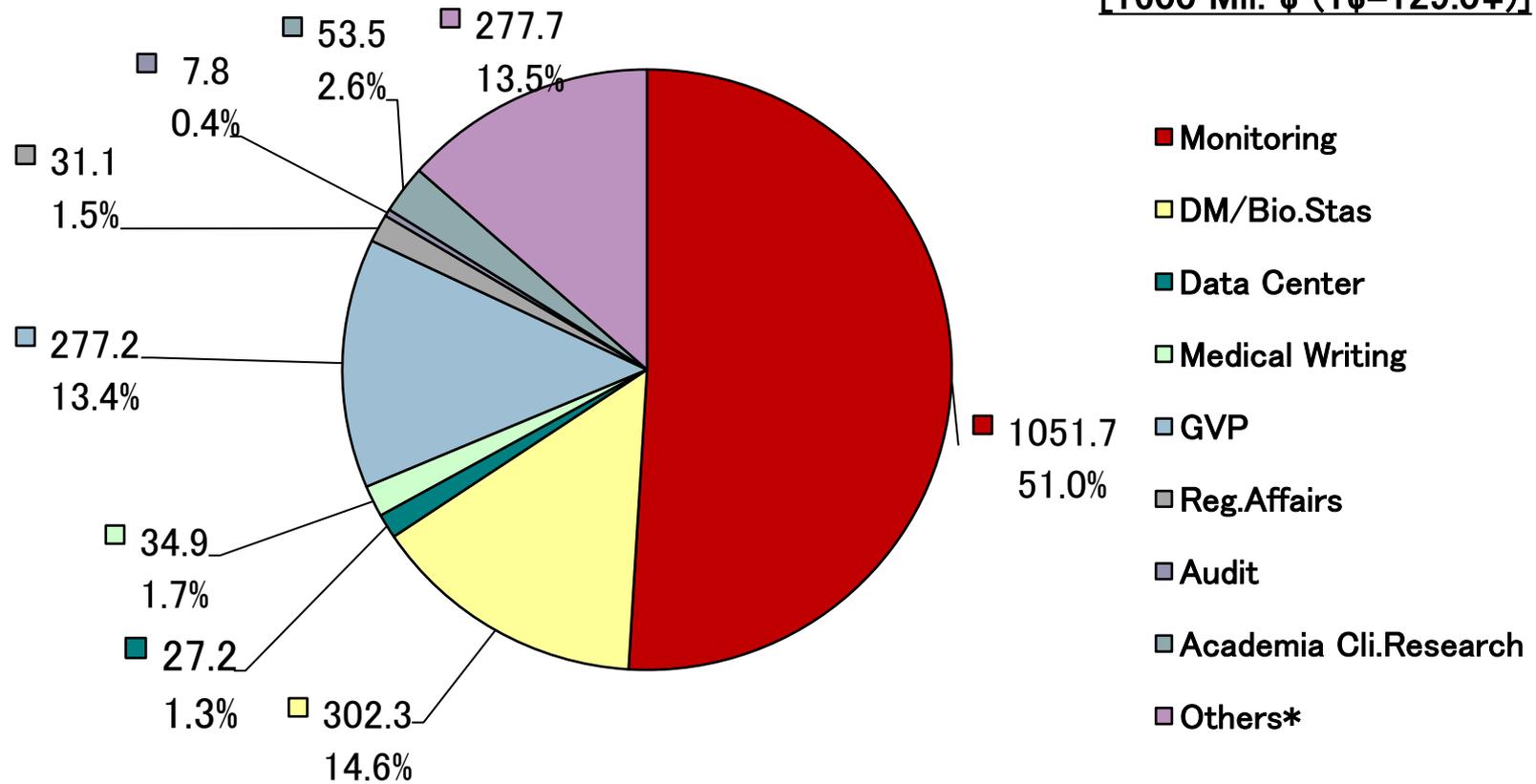
(Sales Unit: 100 Mil.¥)

Compared to 2020



## 2021 Medical Products/Devices/Regeneration/Food & Nutrition-Supplement/Academia Clinical Research Sales by Business Services

**Total : 2064 Mil.¥**  
**[1600 Mil. \$ (1\$=129.0¥)]**



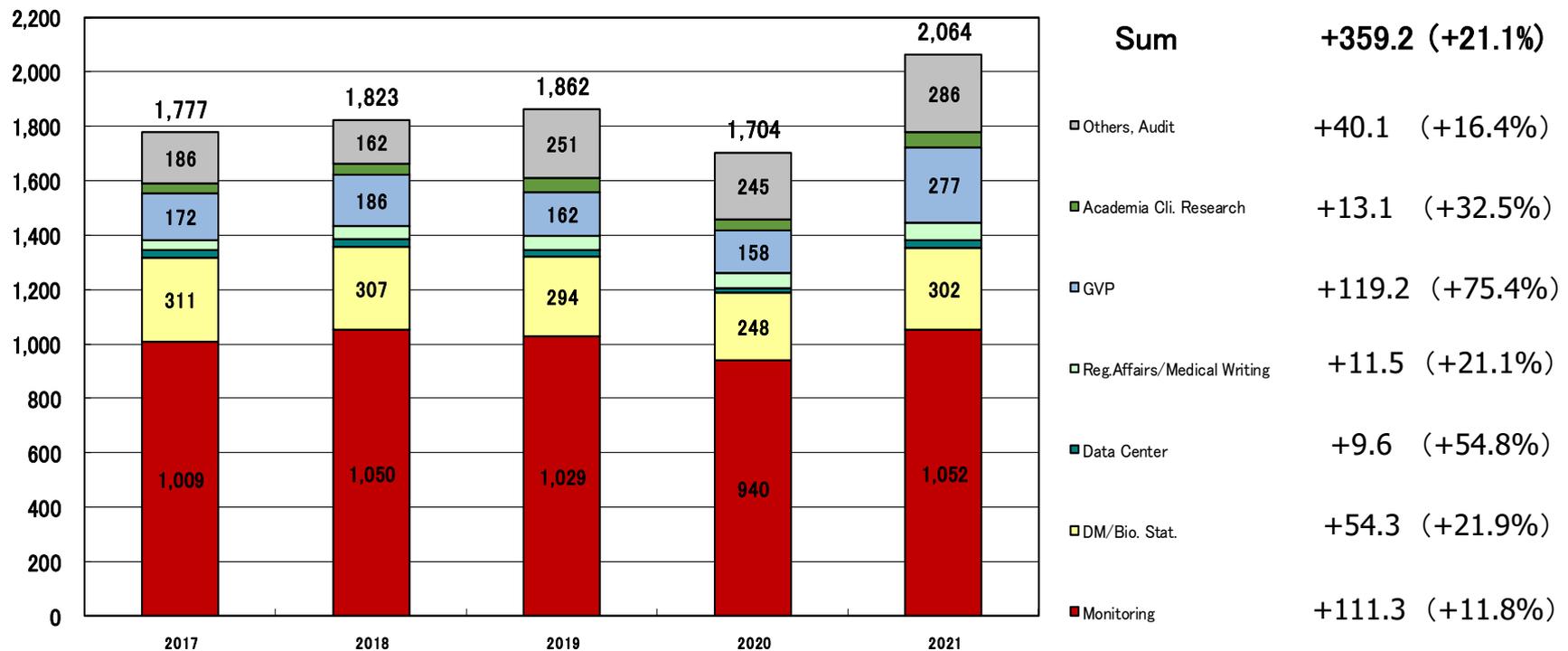
Sales (Unit: 100 Mil. ¥)

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

## 2021 Medical Products/Devices/Regeneration/Food & Nutrition-Supplement/Academia Clinical Research Sales by Business Services

(Sales Unit: 100 Mil.¥)

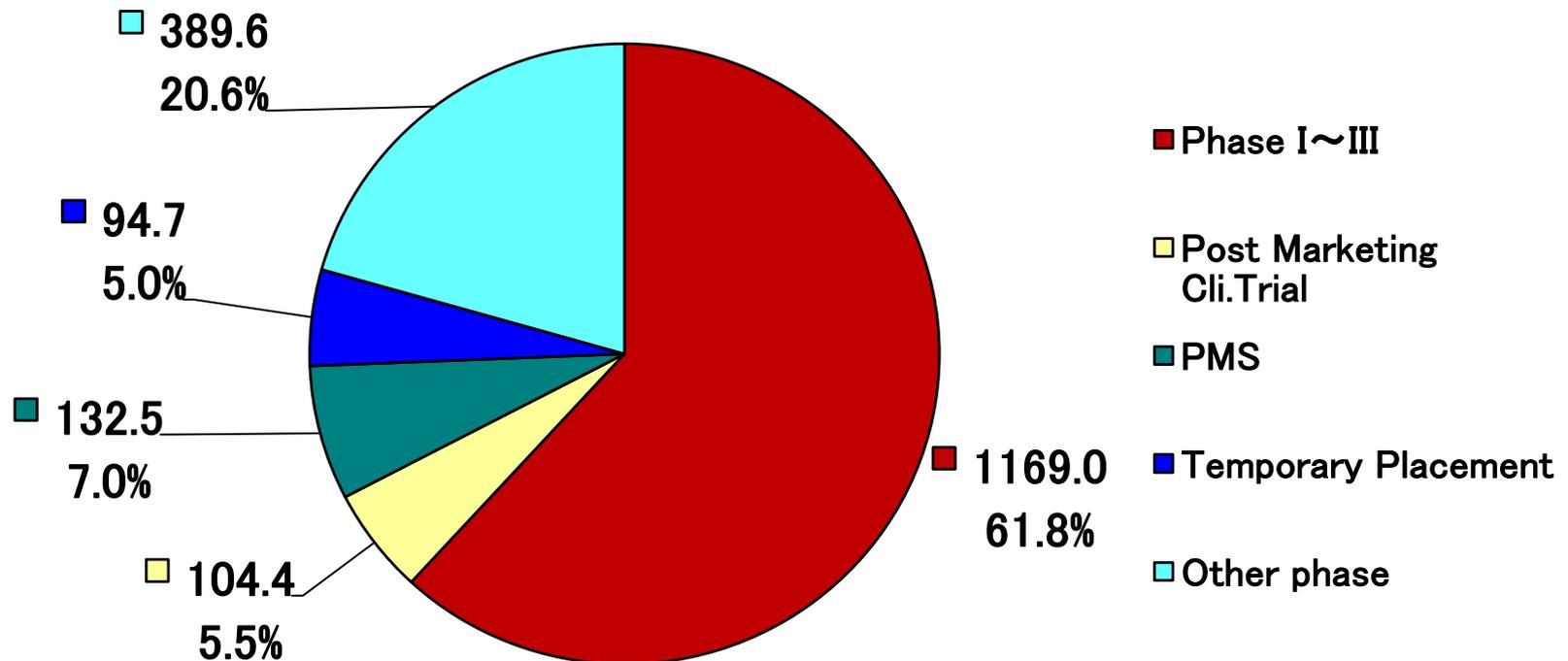
compared to 2020



# 2021 Medical Products Sales by Clinical Phases

Total : 1890 Mil.¥

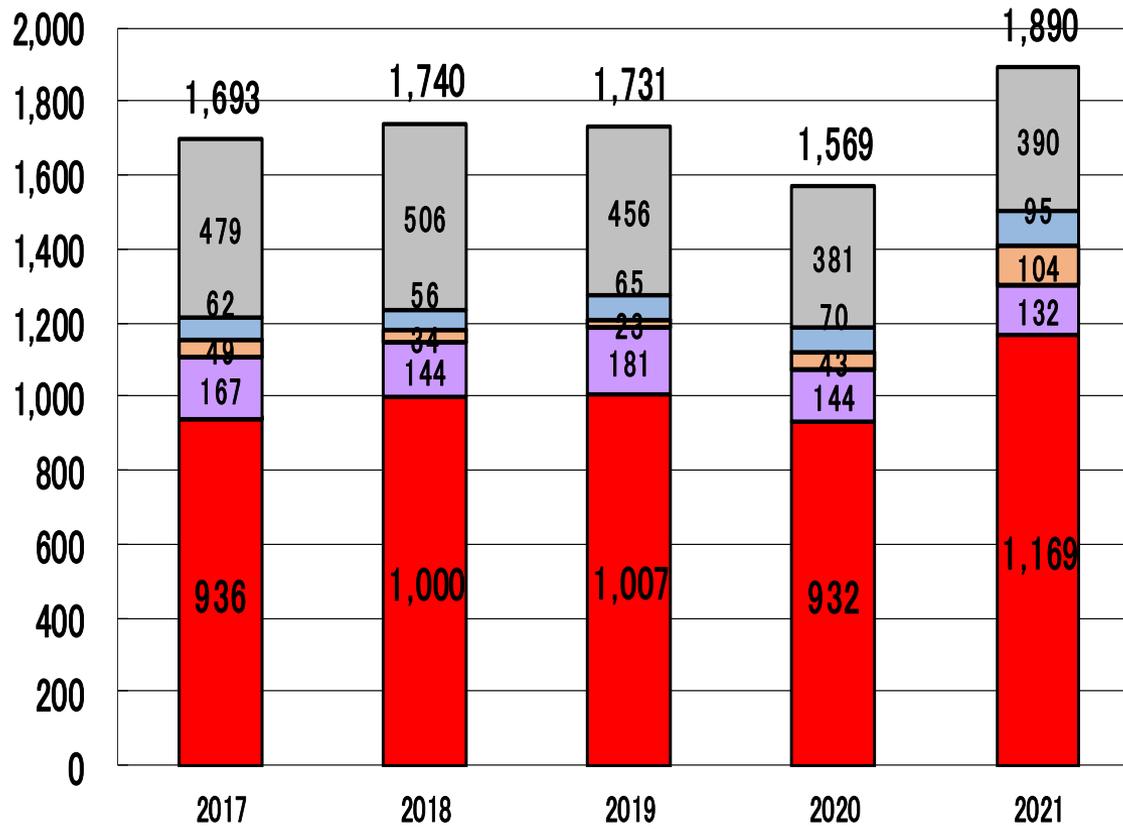
[1465 Mil. \$ (1\$=129.0¥)]



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 2017-2021

(Sales Unit.: 100 Mil.¥)



Compared to 2020	
Sum	320.9 (+20.4%)
Other Phases	+9.0 (+2.4%)
Temporary Placement	+24.5 (+34.9%)
Post Marketing Clinical Trial	+61.7 (+144.4%)
PMS	-11.8 (-8.2%)
Phase I~III	+237.5 (+25.5%)

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 2021

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

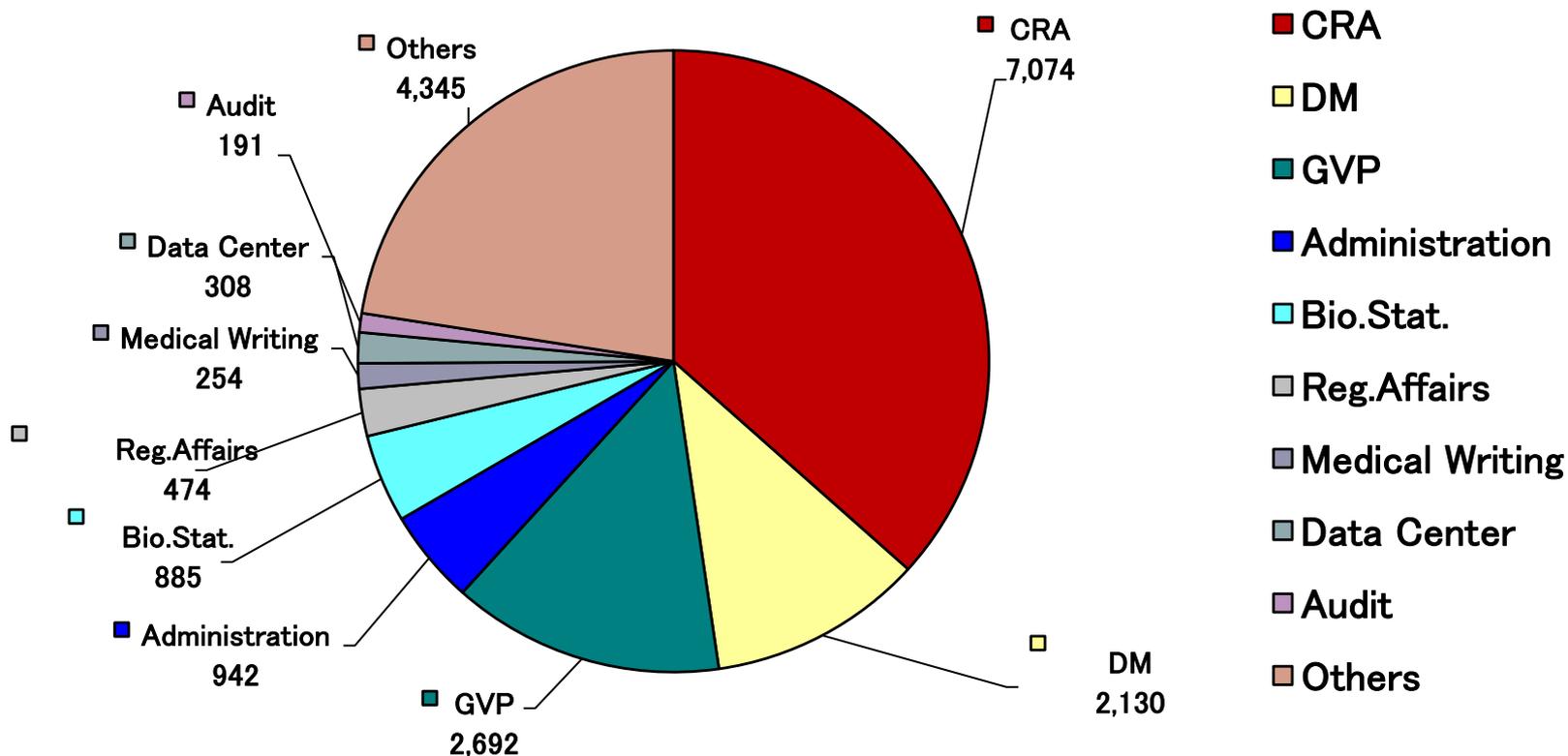
Business services	No.	Business services	No.
SOP preparation	14	Translation	9
Project management	12	Logistics and storage of IMP	7
Education & Training	10	Holding research meetings	4
Medical Report	9	Establishing analytical methods, validation	2
IT support, system building (excluding EDC)	9	Advertisement of recruiting clinical study subjects, site-selection	2
Randomization	9		

### 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 Electronic Data Application

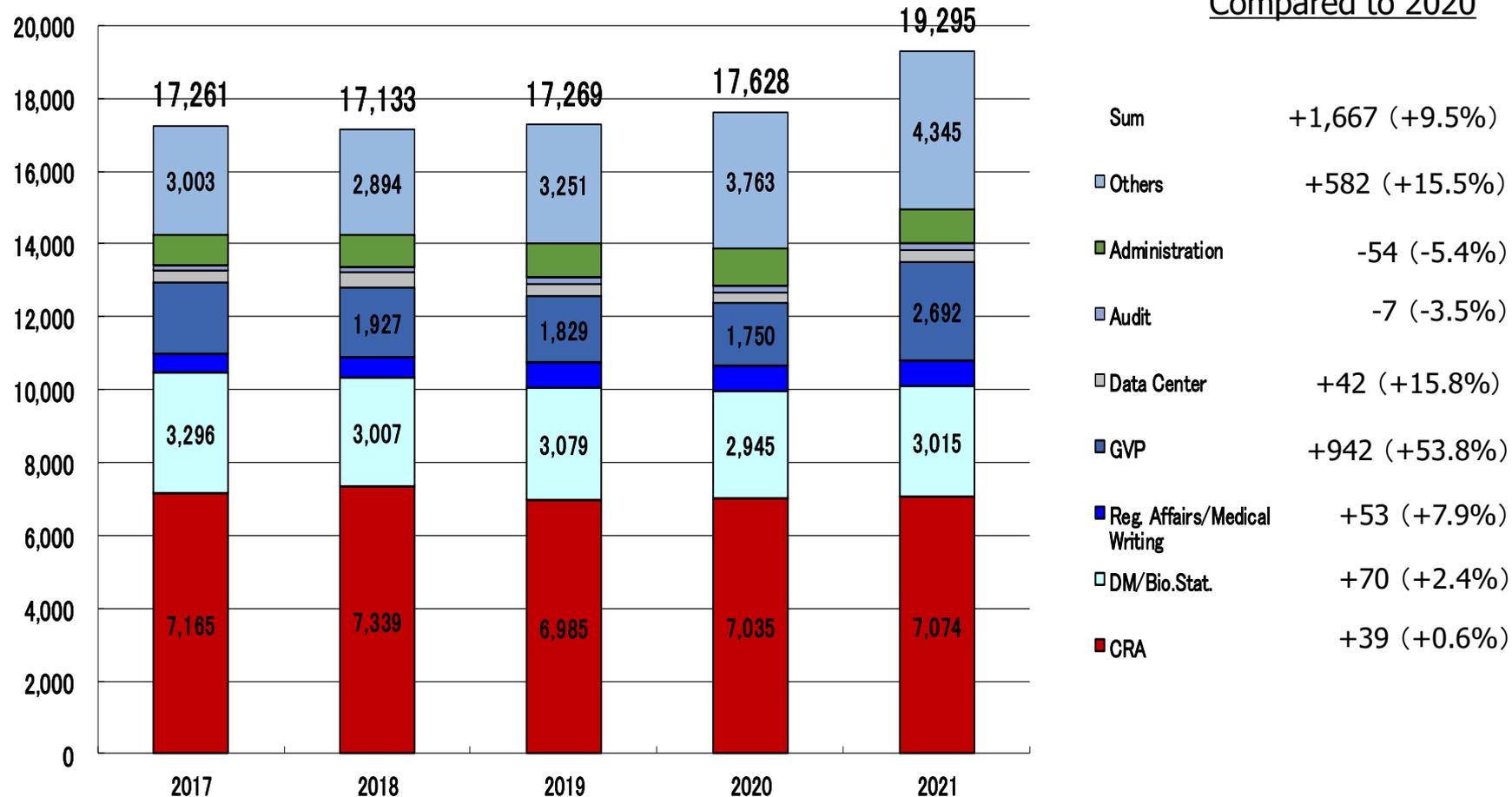
# 2021 Employees by Business Services

Total No. of employees: 19,295



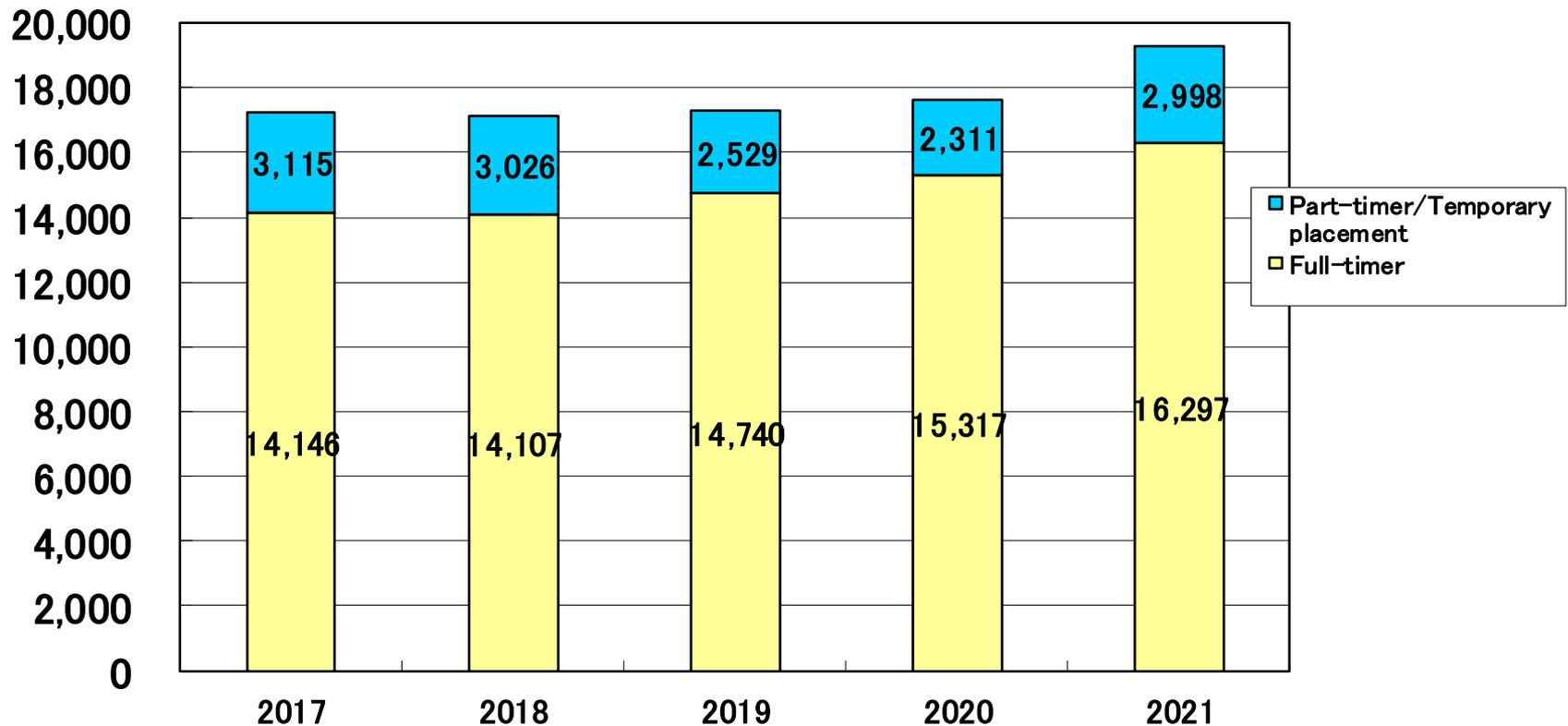
# Employees by Business Services 2017–2021

(Unit: No. of employees)



# Employees by Business Services 2017–2021

2021 Total No. of employees :19,295



## 2021 Monitoring Projects\* by Therapeutic Area

\* Only valid responded projects, 722, are categorized out of total monitoring projects .

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

The 335 (46.4%) multinational studies were conducted out of 722 projects.

The multinational studies occupied 41.0% in 2020.

(Unit: No. of Projects)

