



# Annual Report 2022 (Jan. – Dec.)

**May 24, 2023**  
**Japan CRO Association**

# JCROA 2022

**Total Number of Members: 49 companies**

**Regular Member: 14 companies**

**Supporting Member: 35 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 2022, excluding 17 supporting members in this report.

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

# 2022 JCROA Annual Business Results

## 1. Total Sales Volume

- ① Total turnover increased by 162.9/100 Mil. Yen (2,418.5/100 Mil.Yen from 2,255.6/100 Mil.Yen in 2021), 7.2% in 2022.
- ② Total Sales volume of medical products (Pharmaceuticals), medical devices, regeneration, food & nutrition, academia clinical research increased by 150.8/100 Mil.Yen (2,214.4/100 Mil.Yen from 2,063.6/100 Mil.Yen), 7.3%. While the sales of medical products sharing 84.0%, 142.4/100 Mil.Yen increased (2,032.5/100 Mil. Yen from 1,890.1/100 Mil.Yen) by 7.5%, the medical devices also increased by 9.1/100 Mil.Yen, 13.4%.

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

- ① Monitoring increased by 136.5/100 Mil.Yen. (+ 13.0%)
- ② DM & Bio.Stat decreased by 4.1/100 Mil.Yen. (- 1.3%)
- ③ GVP (PV) reached 237.7/100 Mil Yen, being decreased by 39.5 Mil. Yen. (-14.3%)
- ④ Academia Clinical Researches reached 63.8/100 Mil.Yen, increased by 10.3/100 Mil.Yen. (+19.3%)

## 3. Medical Products Sales by Clinical Phases

- ① Phase I to III increased by 11.6%. Post-marketing Clinical Trials decreased by 60.8%, while PMS increased by 47.7%. The business sectors of temporary placement increased by 46.8/100 Mil.Yen, (+49.4%).
- ② In other business sectors, SOP compilation business reached the highest status with responses from 22 companies out of 32 companies. The business services of project management, education & training and randomization are going to increase gradually.

## 4. Total number of employees joining JCROA reached 19,604 by increase of 309. The CRA joining JCROA, engaged with clinical trials including QC, reached 6,660 by decrease of 414. The employee number of GVP (PV) and registration/data center increased, while the sales volume has decreased.

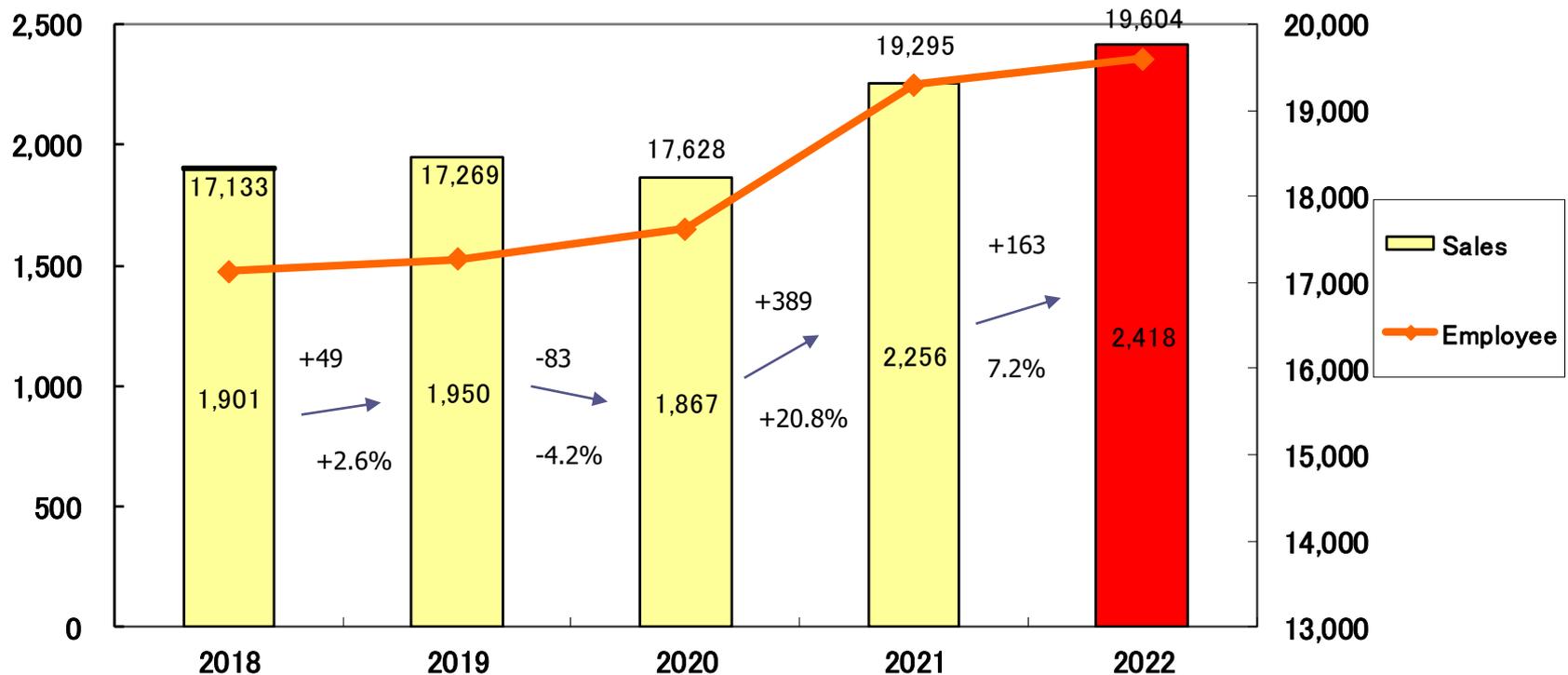
## 5. Ratio of monitoring project numbers by only effective responses

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

# Sales and Employees 2018–2022\*

(Sales Unit : 100 Mil. Yen)

(Employee No.)

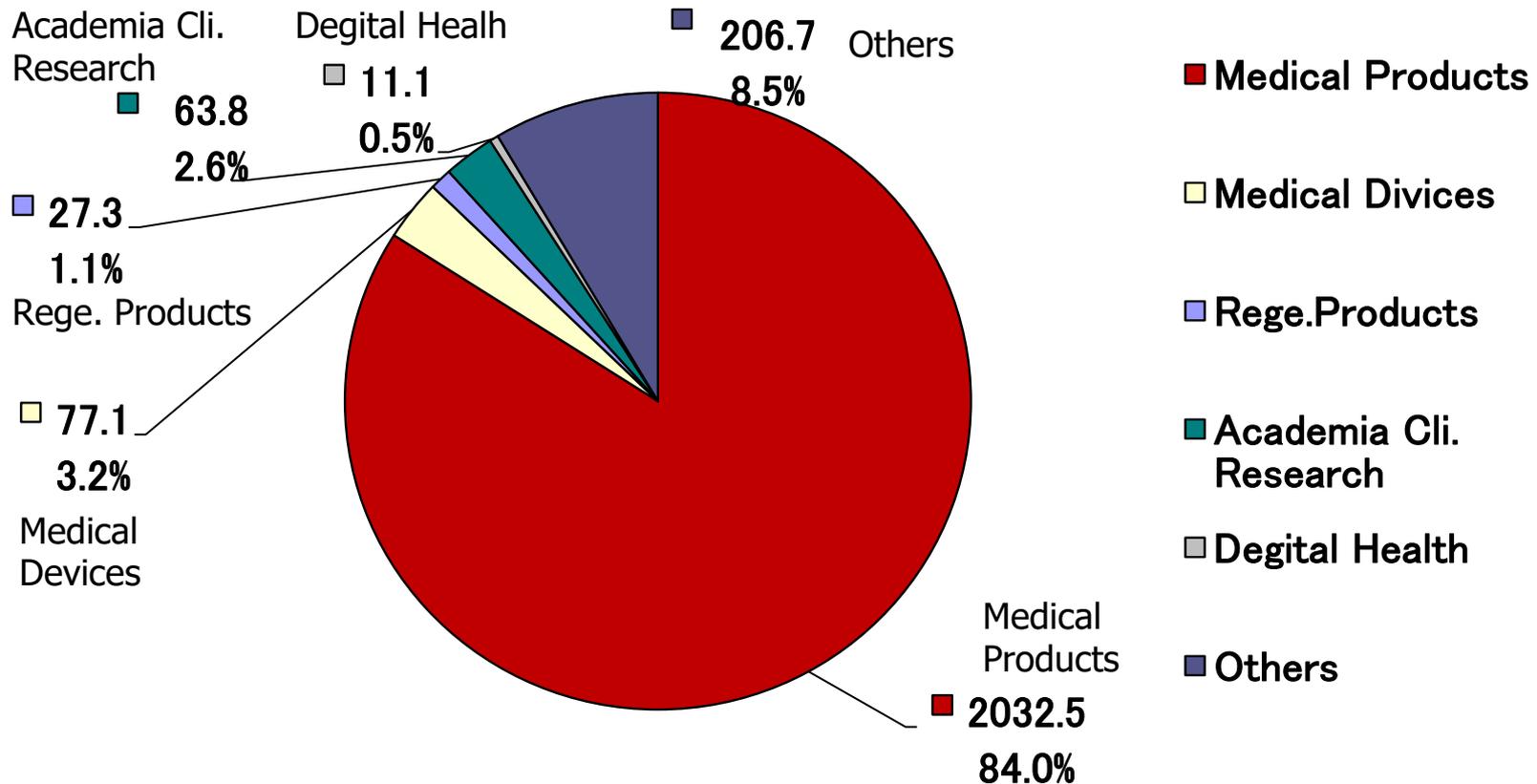


\* Count and estimate are based on data of 33 in 2018, 32 in 2019, 31 in 2020 and 2021, 32 member companies in 2022, respectively.

# 2022 Sales by Business Fields

**Total: 2419/100 Mil. ¥**

[1,766 Mil. \$ (1\$=137¥)]

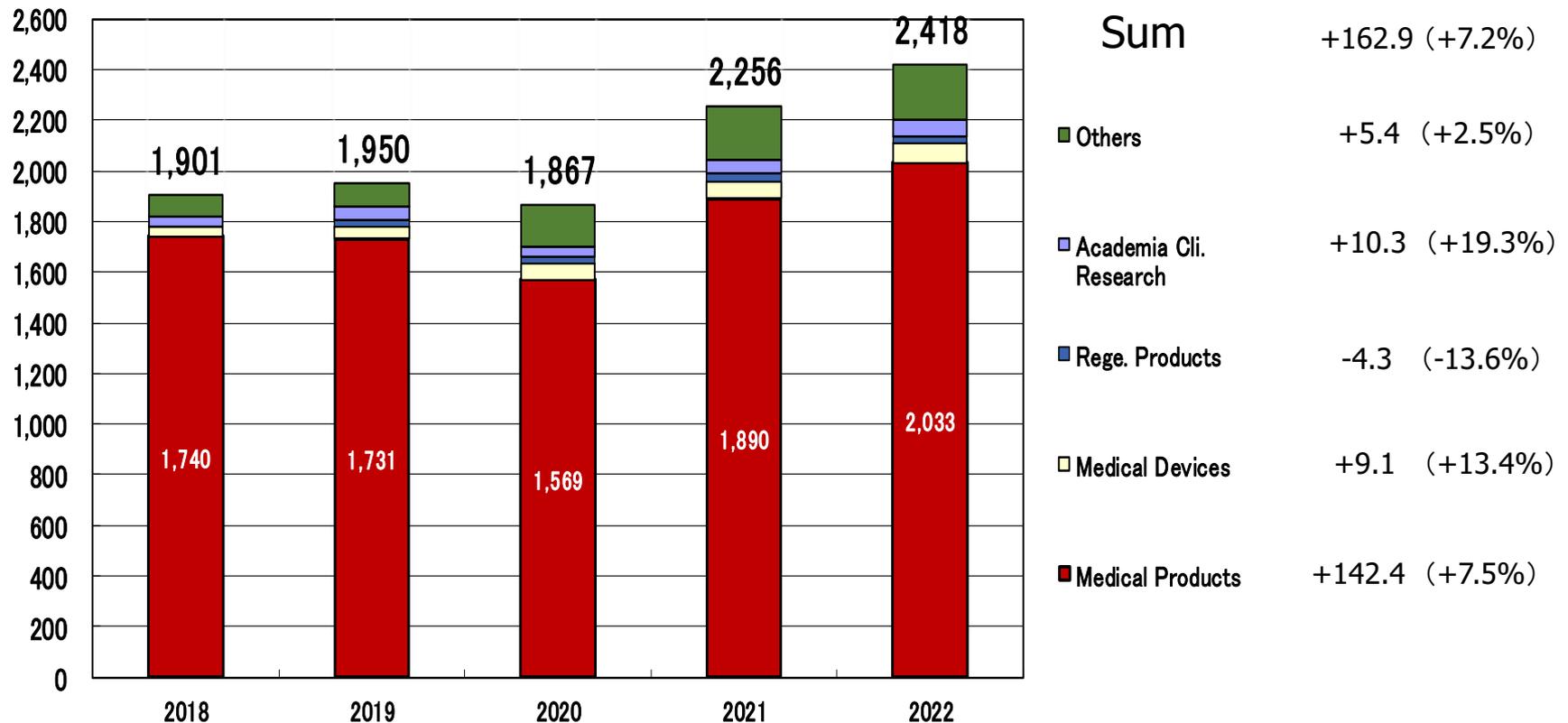


※Others includes non-clinical and SMO business, etc.

# Sales by Business fields 2018–2022

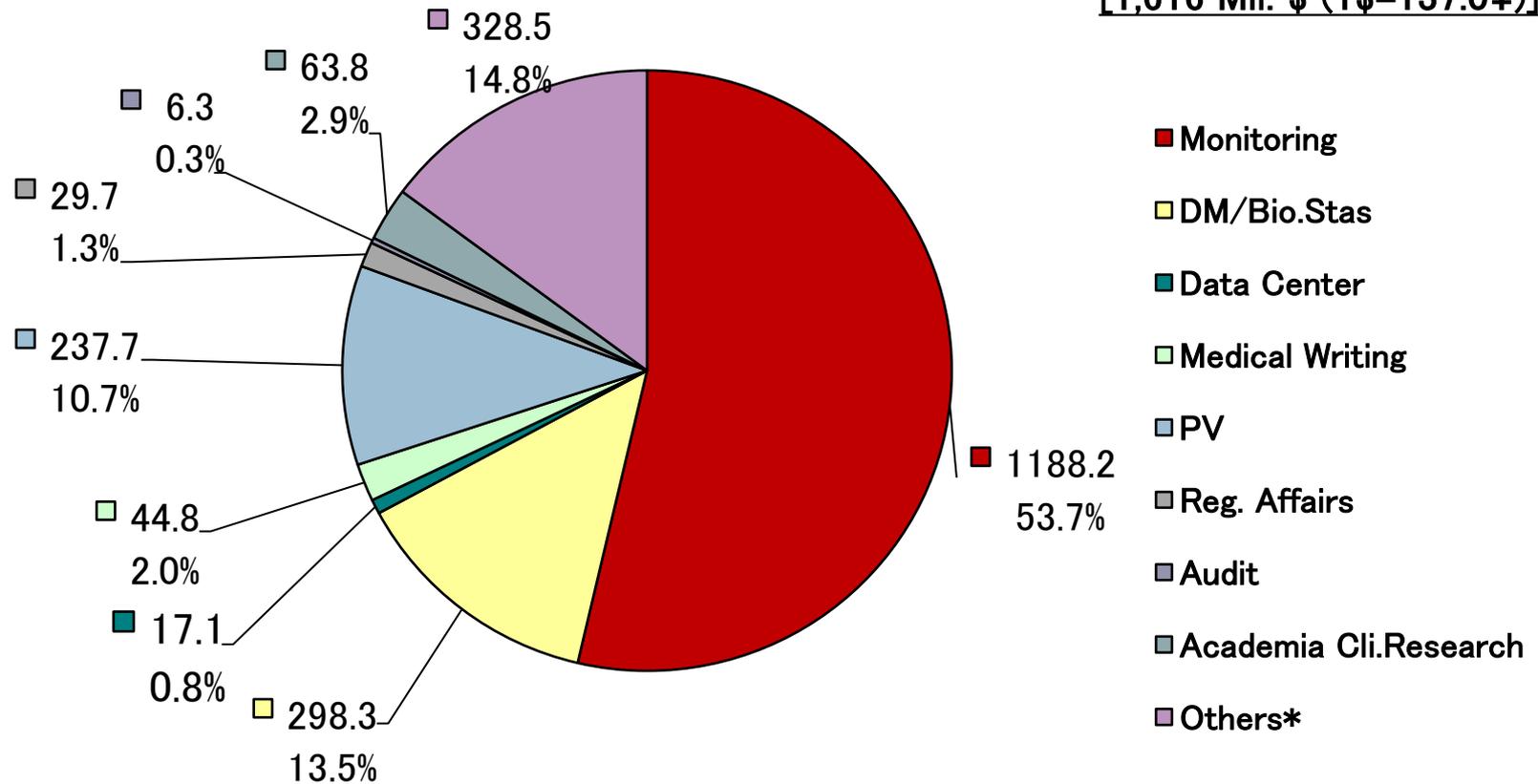
(Sales Unit: 100 Mil.¥)

Compares to 2021



## 2022 Medical Products/Devices/Regeneration/Food & Nutrition-Supplement/Academia Clinical Research Sales by Business Services

**Total : 2214 Mil.¥**  
**[1,616 Mil. \$ (1\$=137.0¥)]**

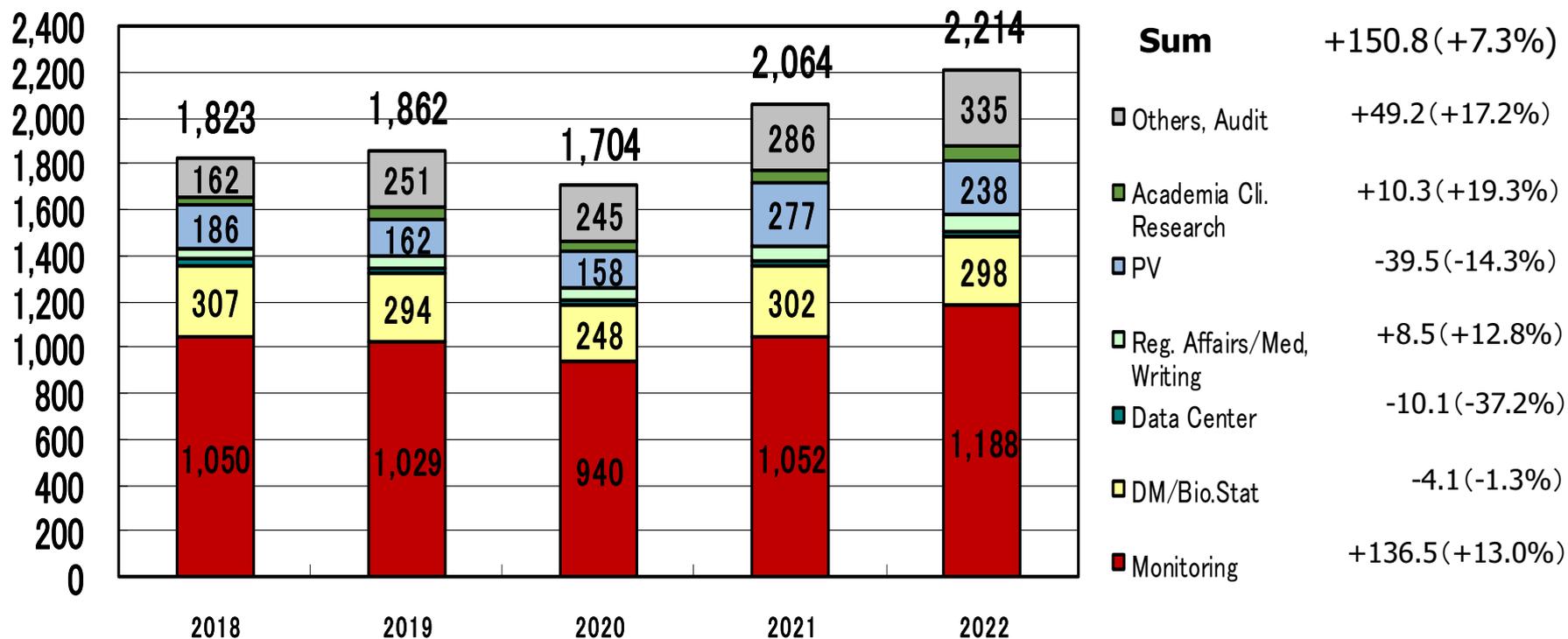


\*Please refer to page 10 for "others".

## 2022 Medical Products/Devices/Regeneration/Food & Nutrition- Supplement/Academia Clinical Research Sales by Business Services

(Sales Unit: 100 Mil.¥)

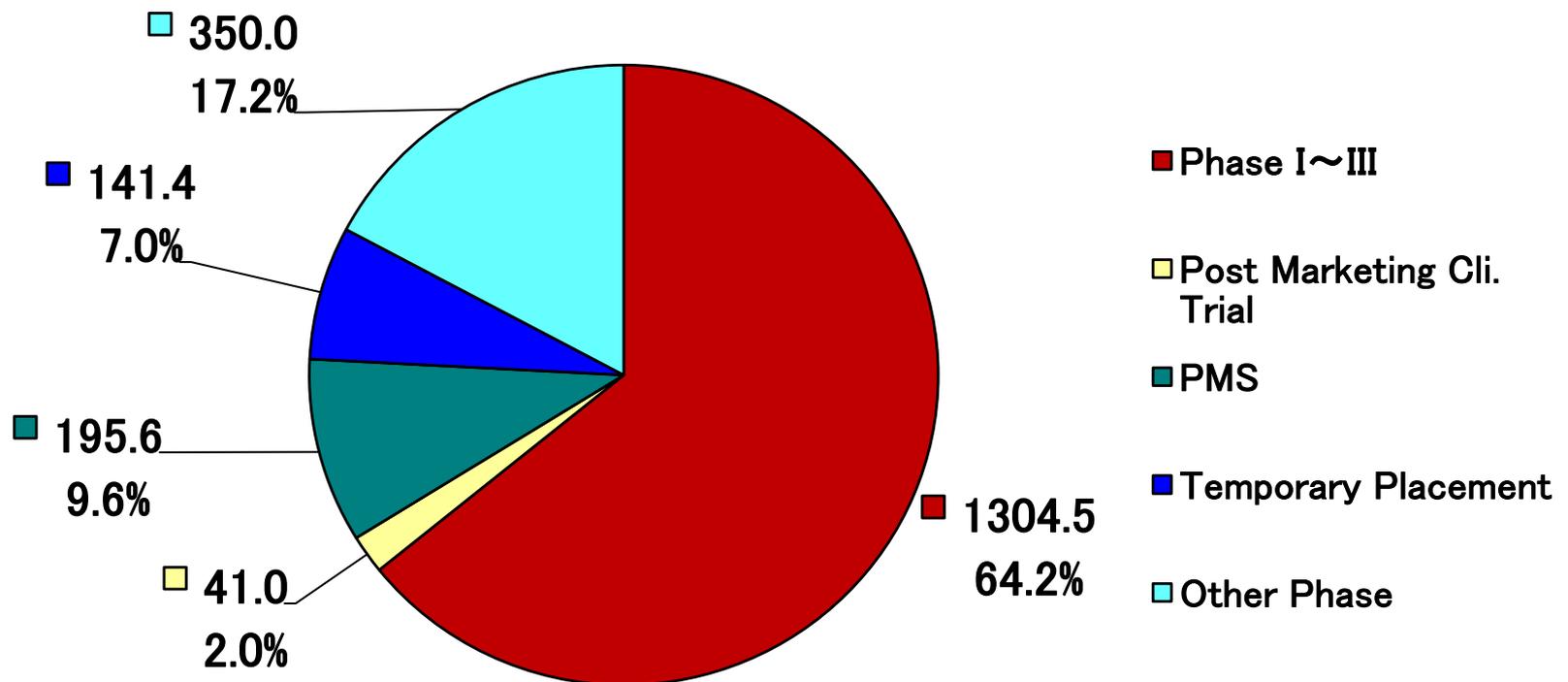
compared to 2021



# 2022 Medical Products Sales by Clinical Phases

Total : 2,033 Mil.¥

[1,484 Mil. \$ (1\$=137.0¥)]

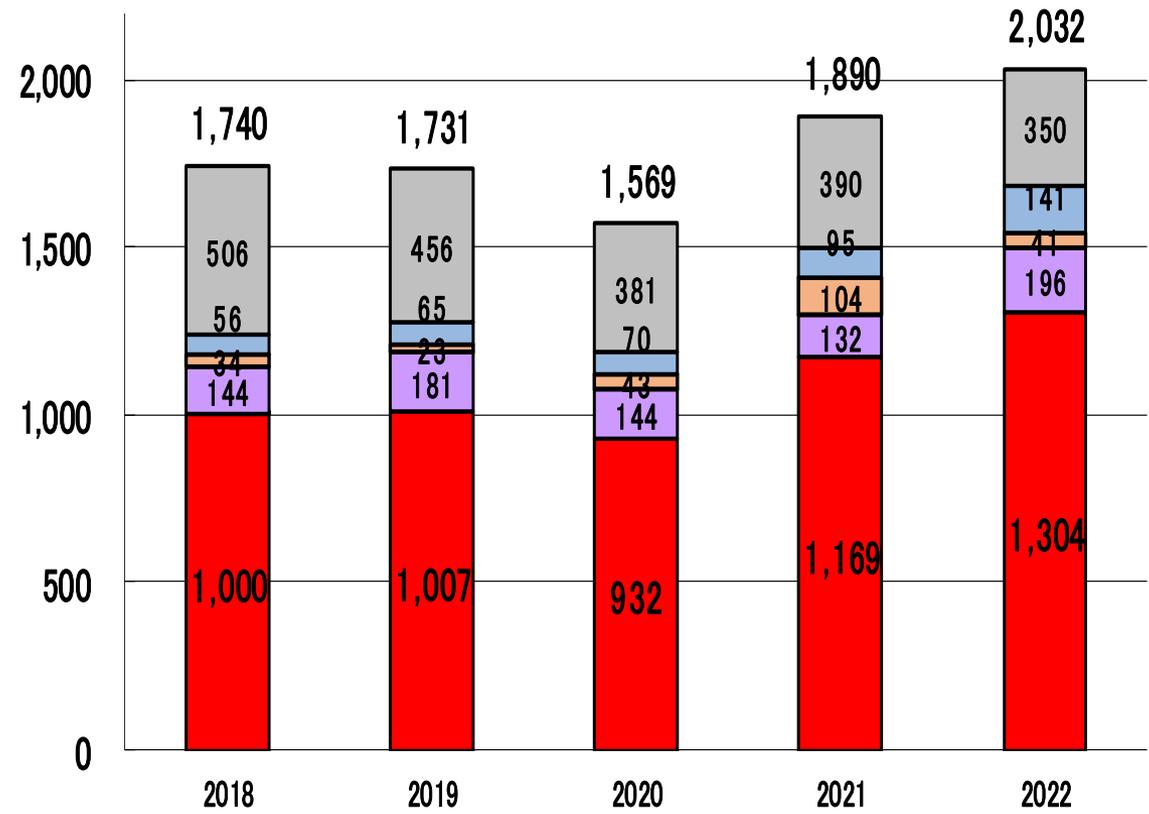


The sales volume of Phase I to III were combined. The ones of GVP, regulatory consulting were summarized in other phases. Academia Clinical research has not been included since that has not been investigated by relevant area and phase.

# Medical Products Sales by Clinical Phases 2018-2022

(Sales Unit.: 100 Mil.¥)

Compared to 2021



Category	Change (2022 vs 2021)
<b>Sum</b>	<b>+142.4 (+7.5%)</b>
Other Phase	-39.5 (-10.2%)
Temporary Placement	+46.8 (+49.4%)
Post Marketing Cli.Trial	-63.5 (-60.8%)
PMS	+63.2 (+47.7%)
Phase I~III	+135.4 (+11.6%)

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 2022

(The figures represent the number of CRO conducting those business services. Responding from 22 members.)

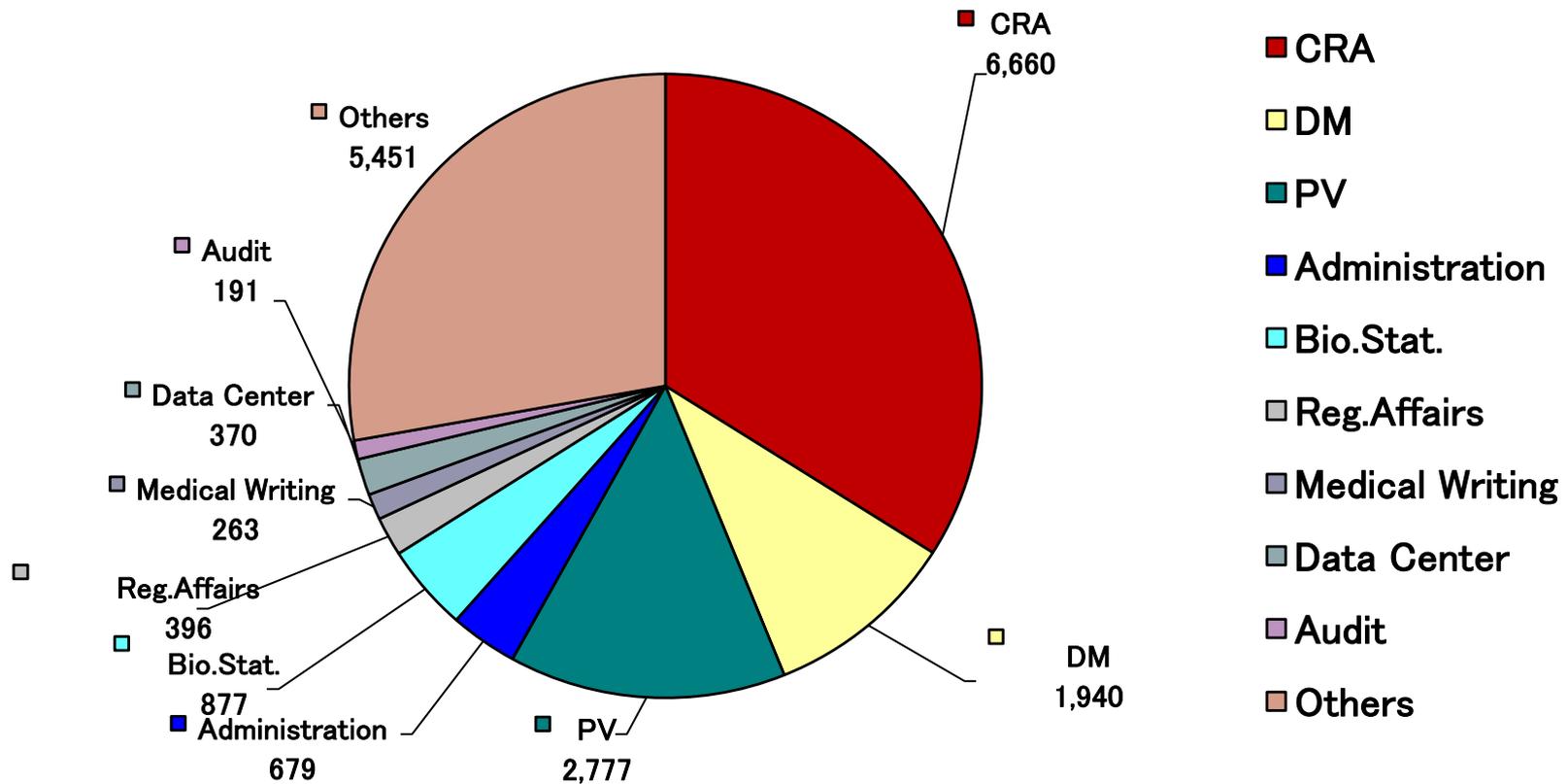
Business Services	No.	Business Services	No.
SOP preparation	11	Translation	6
Project Management	10	Medical Report Preparation	5
Education & Training	8	Advertisement of recruiting clinical study subjects, site-selection	3
Randomization	8	Establishing analytical methods, Validation	2
Logistics and storage of IMP	7	Holding Research Meetings	2
IT support, system setup (excluding EDC)	6	IDMC operation	2

Others: • IRB management support

- Clinical Trial Notification
- Real world evidence & DB Research
- CMC Reg. Affairs
- Assistance of Diagnostic imaging system
- Remote medical care
- Responding inquiries and reviews for new drug application
- Assistance of Emergency
- Support of Reg. Affairs
- Assisting compliance assessments/reviews
- Management of archived documents, e-Patient Reported Outcome

# 2022 Employees by Business Services

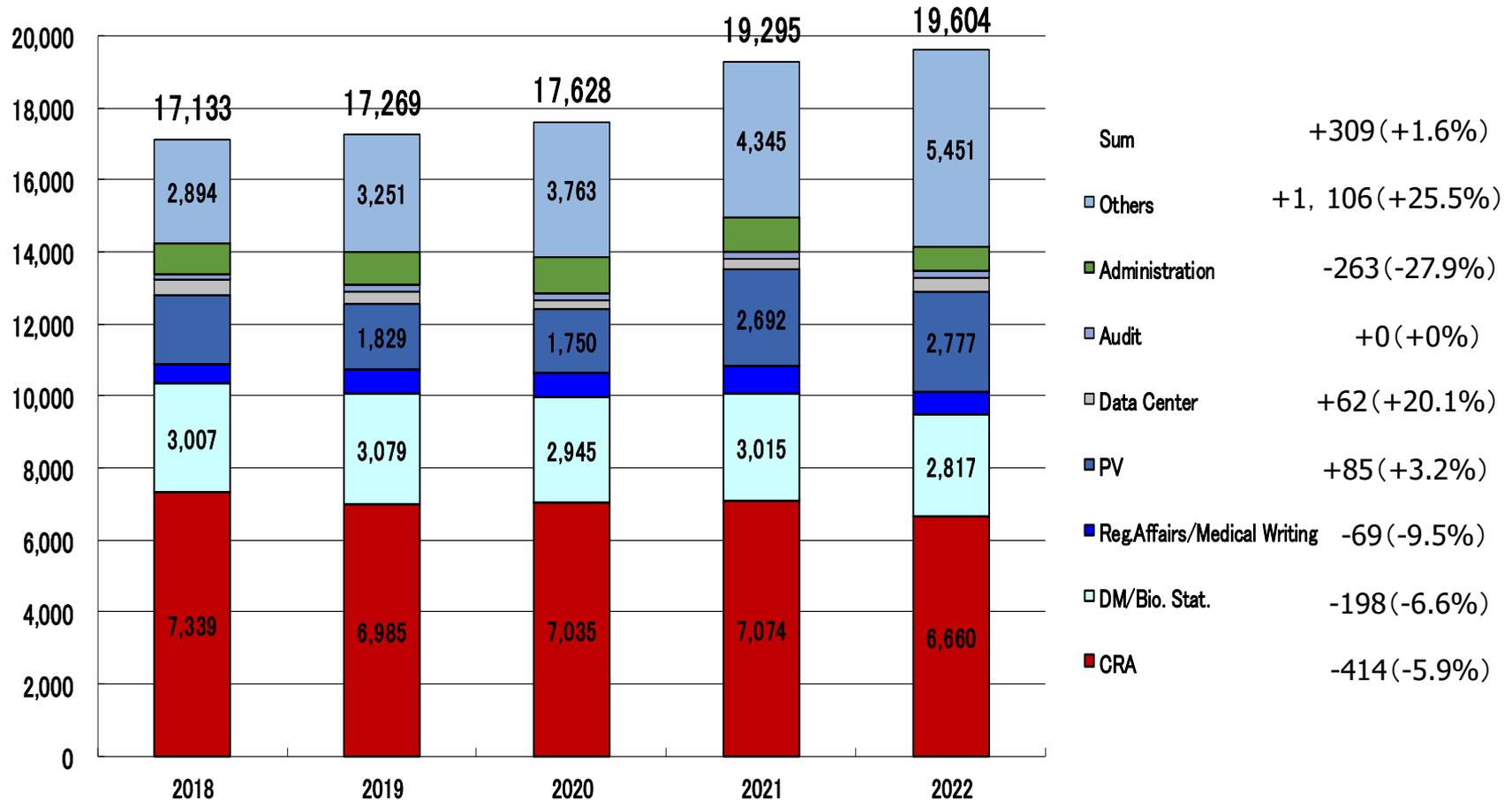
Total No. of employees: 19,604



# Employees by Business Services 2018–2022

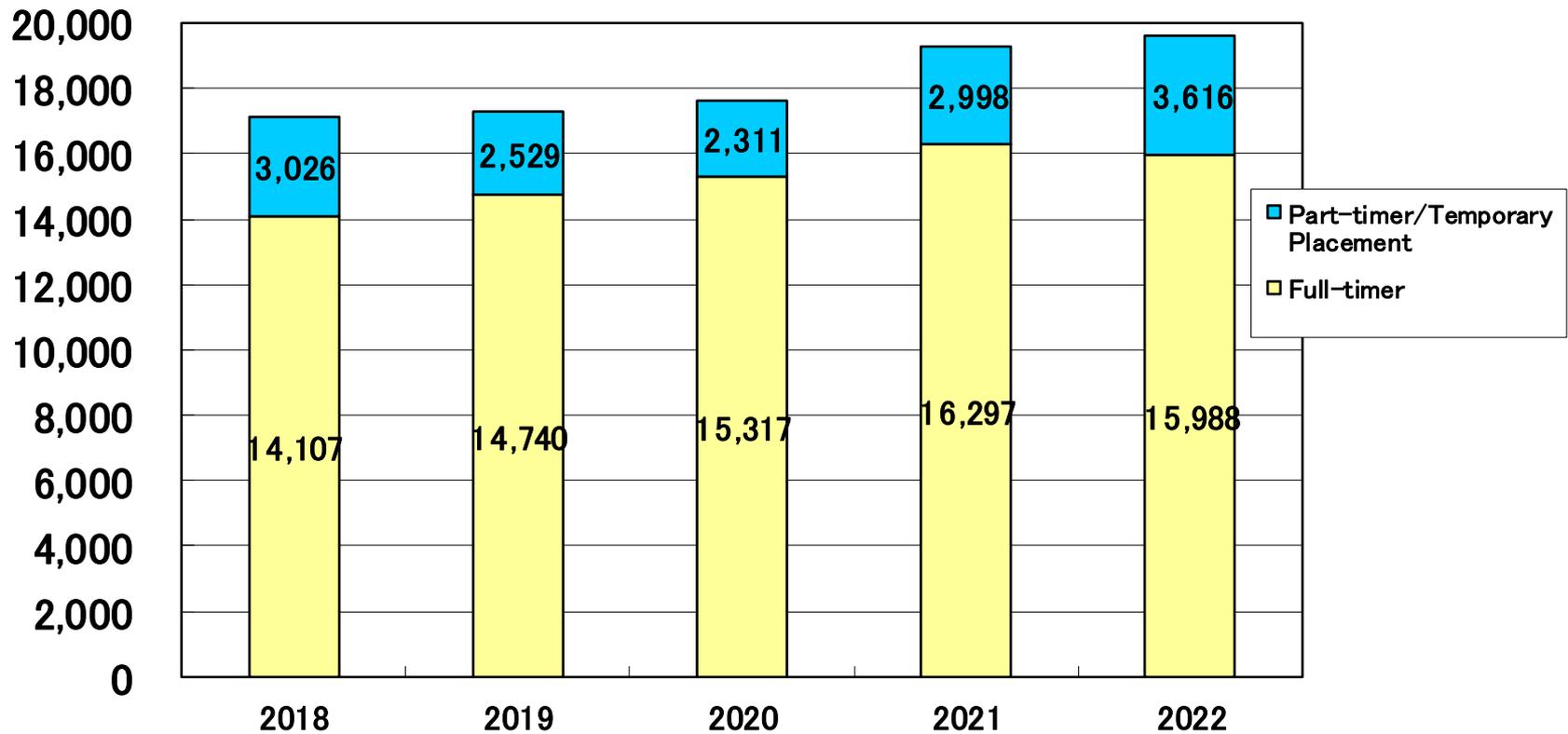
(Unit: No. of employees)

Compared to 2021



# Employees by Business Services 2018–2022

2022 Total No. of employees :19,604



## 2022 Monitoring Projects\* by Therapeutic Area

\* Only valid responded projects, 889, are categorized out of total monitoring projects .

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

The 361 (40.6%) multinational studies were conducted out of 889 projects.

The multinational studies occupied 46.4% in 2021.

(Unit: No. of projects)

