

Annual Report 2023 (Jan. – Dec.)

Apr. 24, 2024
Japan CRO
Association

JCROA 2023

Total Number of Members: 49 companies

Regular Member: 14 companies Associate 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 29 companies,
 excluding 20 associate members in this report in 2023.
- * The approximate figures in the missing values are calculated in the basis of average values of valid responses.

2023 JCROA Annual Business Results

1. Total Sales Volume

- ① Total turnover increased by 11.88 Billion Yen(253.73 Billion Yen from 241.85 Billion Yen in 2022), 4.9% in 2023.
- 2 Total Sales volume of pharmaceuticals, medical devices, regenerative medical products, food & nutrition supplement, academia clinical research increased by 10.18 Billion Yen (231.62 Billion Yen from 221.44 Billion Yen), 4.6%. While the sales of pharmaceuticals sharing 82.6%, 6.39 Billion Yen increased (209.64 Billion Yen from 203.25 Billion Yen) by 3.1%, the medical devices also increased by 1.57 Billion Yen, 20.4%.

2. <u>Sales Volume of Pharmaceuticals/Medical Devices/Regenerative Medical Products/Food & Nutrition Supplement /Academia Clinical Researches by Business Services</u>

- ① Monitoring increased by 6.29 Billion Yen. (+ 5.7%)
- ② Data Management/Statistical Analysis increased by 1.89 Billion Yen. (+6.3%)
- ③ Pharmacovigilance reached 33.95 Billion Yen, increased by 8.12 Billion Yen. (+31.4%)
- 4 Academia Clinical Researches reached 8.71 Billion Yen, increased by 2.33 Billion Yen. (+36.5%)

3. Pharmaceuticals Sales by Clinical Phases

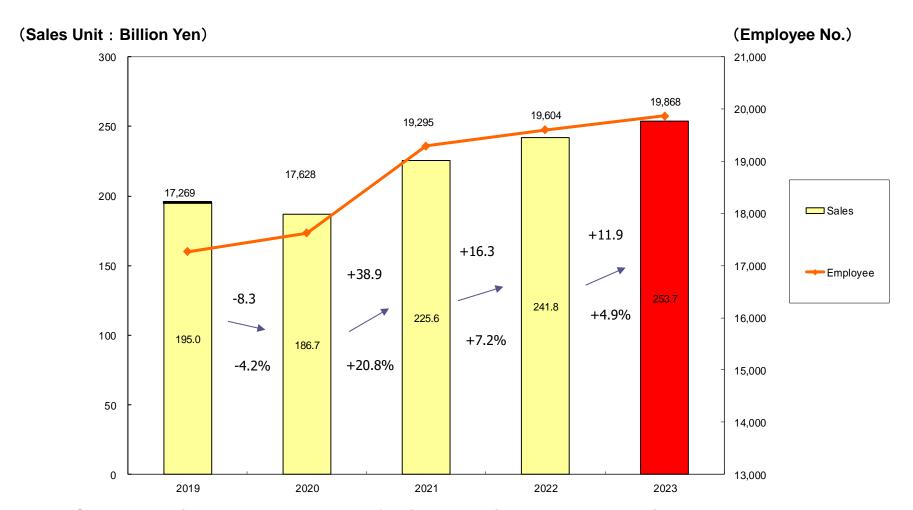
- ① Sales volume of Phase I to III decreased by 4.1%. Post-marketing Clinical Trials increased by 28.1%, also Post-Marketing Surveillance increased by 3.8%. The business sectors of temporary employee placement increased by 530 Million Yen, (+3.6%).
- ② In the business services classified as "Others", "SOP preparation" was the most abounding in the last year, and next, "Project Management", "Education & Training" and "Medical Report Preparation" were abounding.
- **Total number of employees joining JCROA** reached 19,868 by increase of 264. The CRA joining JCROA, engaged with clinical trials including QC, reached 7,179 by increase of 519. The employee number of pharmacovigilance and registration/data center decreased due to downsizing, while the sales volume has increased.

5. <u>Monitoring Projects by Therapeutic Aria</u>

As in the last year, Oncology was the most prevalent therapeutic area in the monitoring project, followed by CNS, Metabolism.

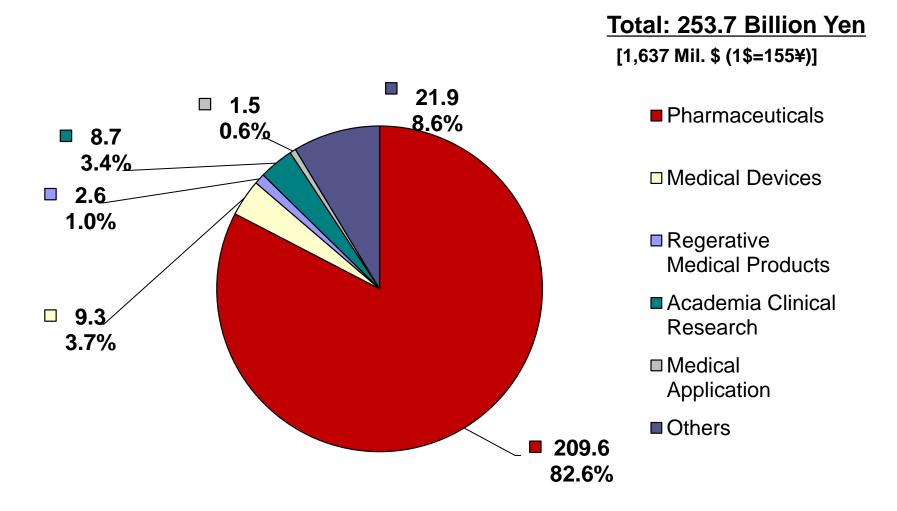
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Sales and Employees 2019-2023*



^{*} Count and estimate are based on data of 32 in 2019, 31 in 2020 and 2021, 32 in 2022, 29 member companies in 2023, respectively.

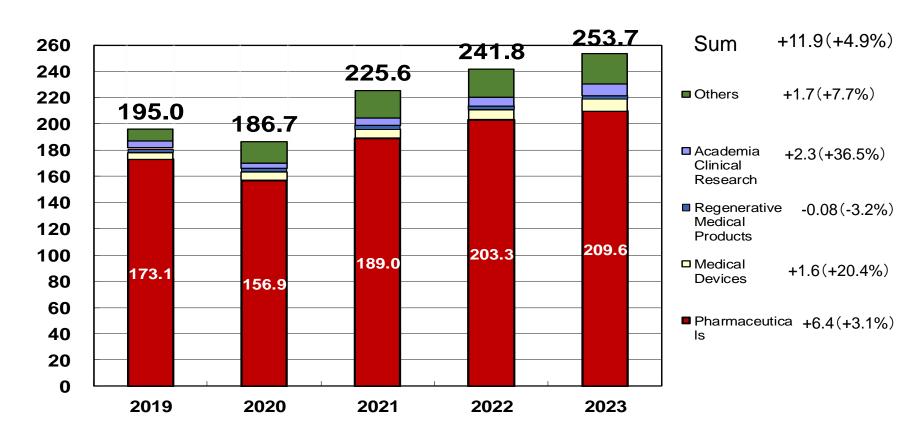
2023 Sales by Business Fields



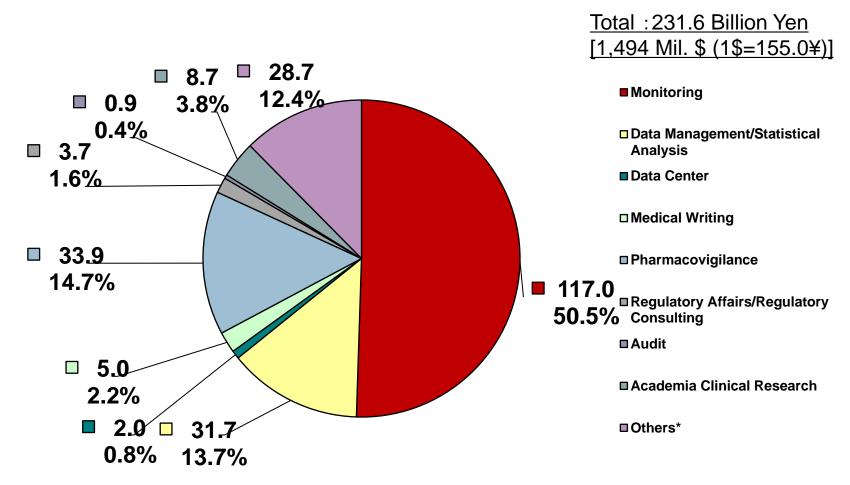
*Others includes non-clinical and SMO business, etc.

Sales by Business fields 2019-2023

(Sales Unit: Billion Yen) Compared to 2022



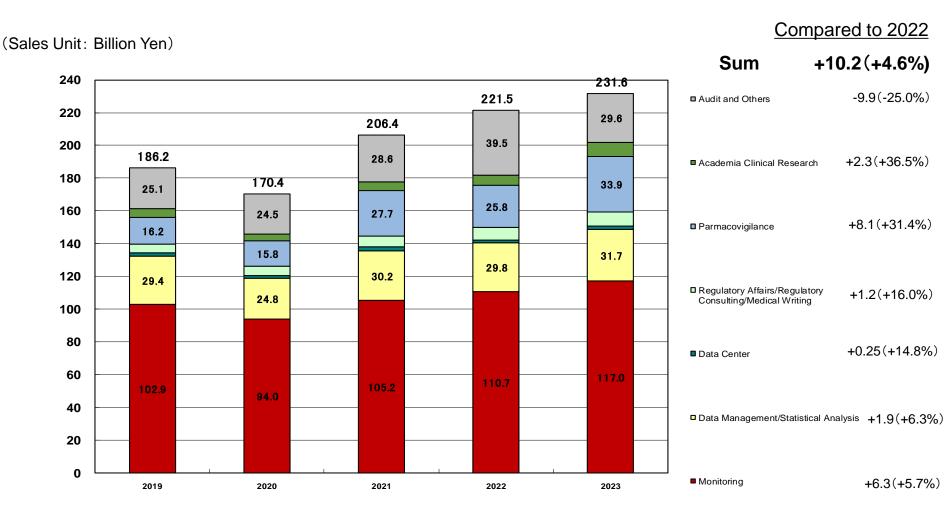
2023 Sales by Business Services (Pharmaceuticals/Medical Devices/ Regenerative Medical Products/Food & Nutrition Supplement/ Academia Clinical Research



^{*}Please refer to page 10 for "others".

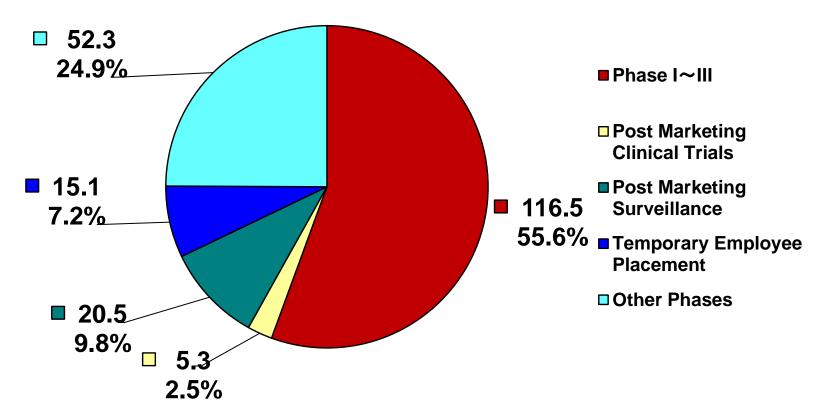
Sales by Business Services 2019-2023 (Pharmaceuticals/Medical

Devices/Regenerative Medical Products/Food & Nutrition Supplement/ Academia Clinical Research



2023 Sales of Business Services for Pharmaceuticals by Clinical Phases

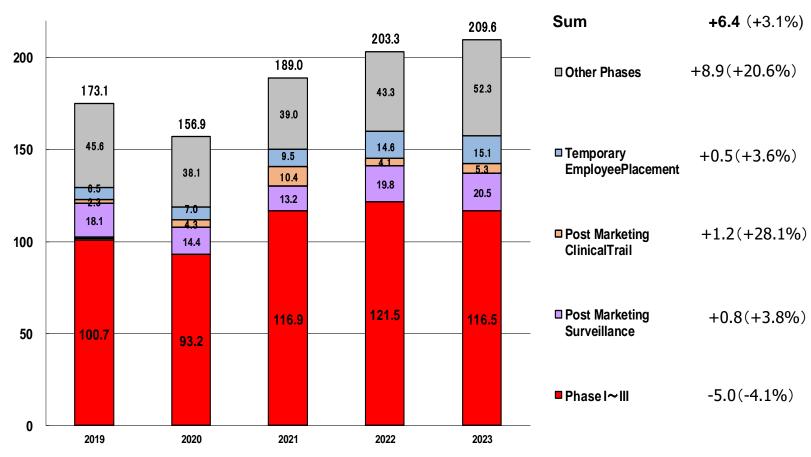
<u>Total</u> : 209.6 Billion Yen [1,352 Mil. \$ (1\$=155.0¥)]



The sales volume of Pharmacovigilance and Regulatory Affairs/Consulting are included in "Other Phases". The sales of Academia Clinical Research are not included in this figure.

Sales of Business Service for Pharmaceuticals by Clinical Phases 2019-2023





The sales volume of Pharmacovigilance and Regulatory Affairs/Consulting are included in "Other Phases". The sales of Academia Clinical Research are not included in this figure.

Other services Conducted in relation to Medical Products 2023

Business Services	No.	Business Services	No.
SOP preparation	11	IT support, system setup (excluding EDC)	6
Project Management	10	Transportation/storage of labo. test materials & Investigational products	5
Education & Training	8	Translation	4
Medical Report Preparation	8	Advertisement of recruiting clinical study subjects, site-selection	3
Investigational Product Allocation	7	Facilitating service for Investigator Meeting	3

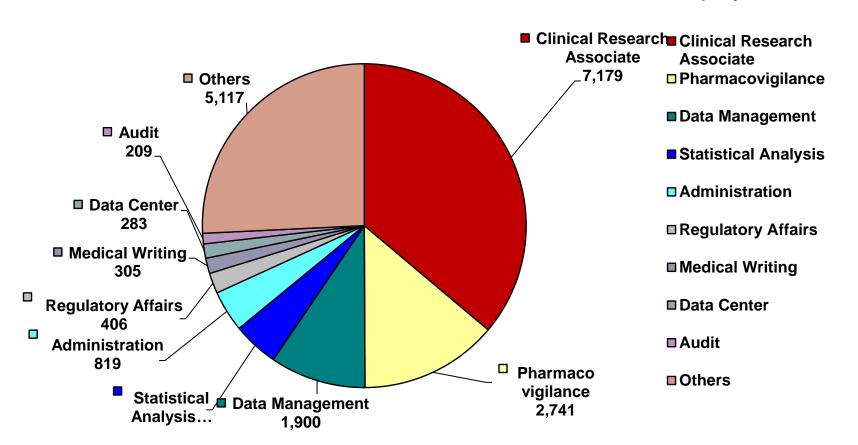
No: Number of responses

Other Services with Less Than Two Responses:

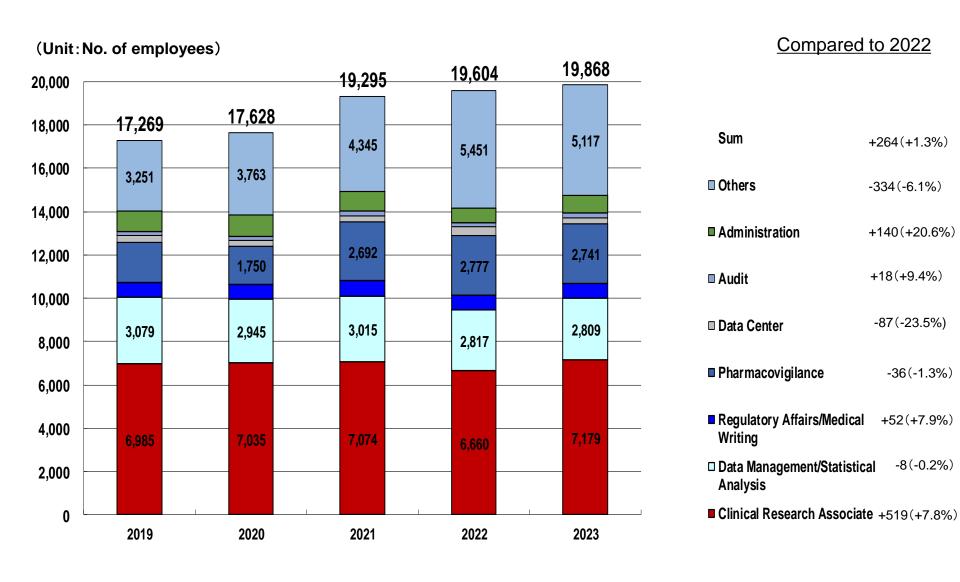
- •Management and Operation of the Effectiveness and Safety Evaluation Committee, Committee Correspondence
- ·Support for Clinical Trial Office of Sites
- · Support for Clinical Trial Notifications
- Real-World Evidence and Database Research
- System Development for Decentralized Clinical Trials (DCT)
- ·Compliance Inspection Response
- Emergency Reception Tasks
- ·Help Desk Operations
- ·Registration Tasks for "Japan Registry of Clinical Trials"
- Creation of Materials for Patients Participating in Clinical Trials
- •EDC User Training
- Document Storage Tasks
- ·Provision of electronic Patient Reported Outcome

2023 Employees Numbers by Job Title

Total No. of employees:19,868

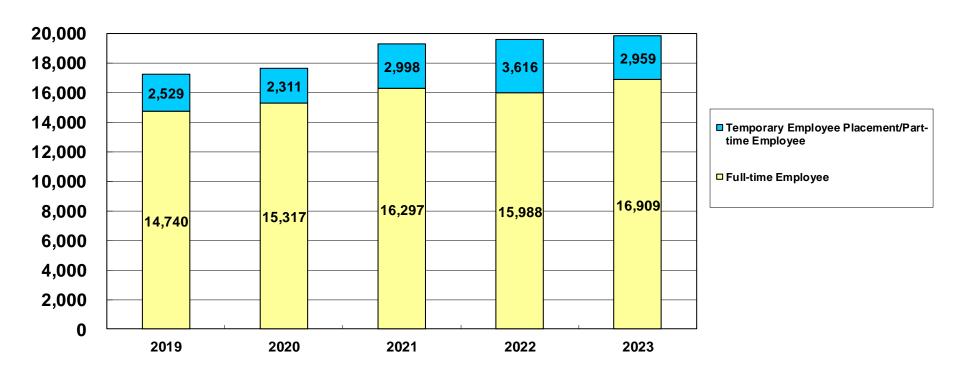


Employee Numbers by Job Title 2019-2023



Employee Numbers by Employment Type 2019-2023

2023 Total No. of employees:19,868



2023 Monitoring Projects by Therapeutic Area

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

(Unit: No. of projects)

