



Annual Report 2016 (Jan. – Dec.)

March 30, 2017

Japan CRO

Association

JCROA 2016

Total Number of Members: 34 companies

Regular Member: 17 companies

Supporting Member: 17 companies

(Note)

* The business results are calculated in business areas such as 1) Pharmaceutical Development, 2) Medical Devices Development, 3) Food & Nutrition-Supplement Development, and 4) Others (including SMO/CRC) from 26 companies in 2016, excluding 8 supporting member in this report.

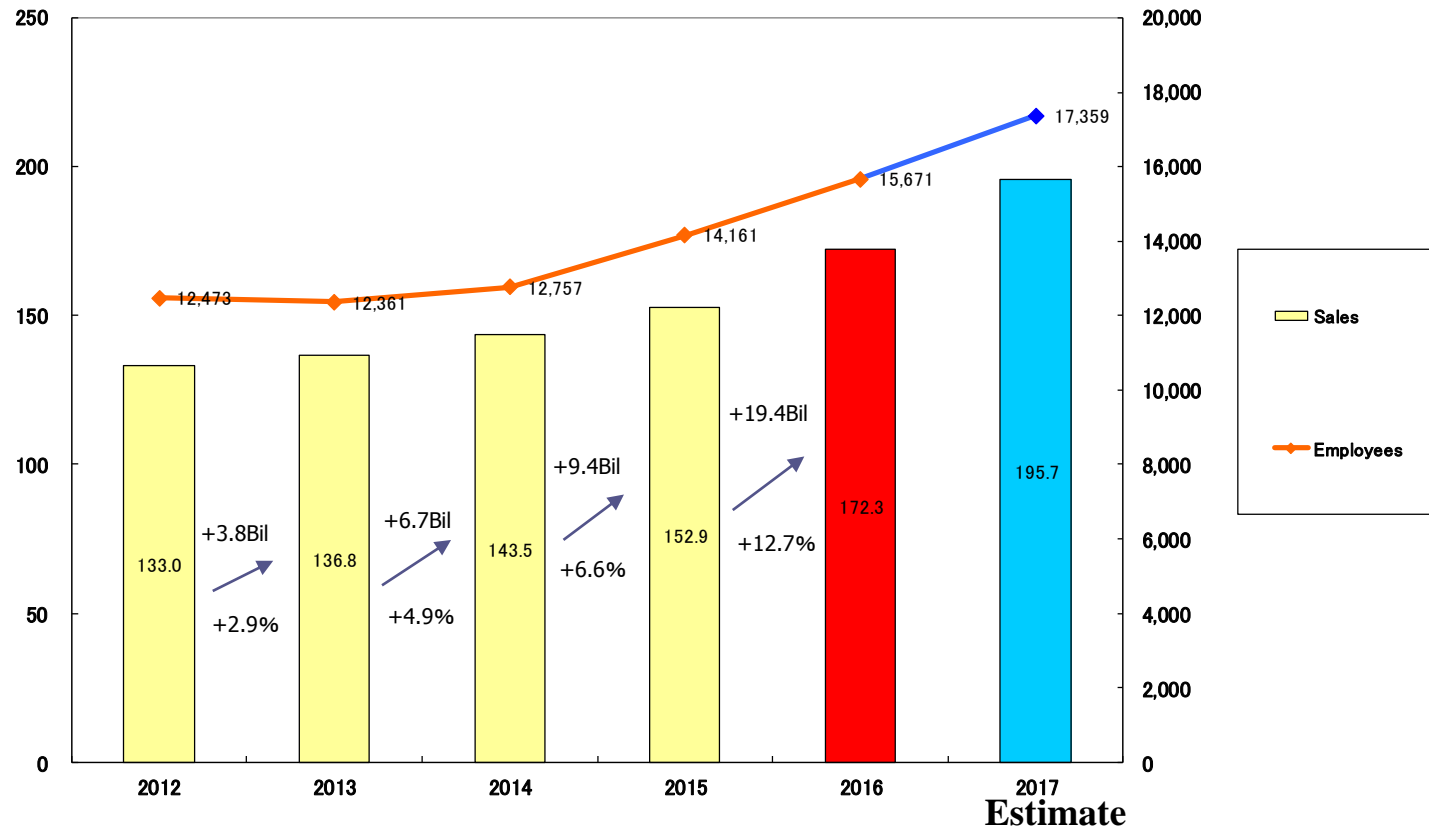
* The estimated figures are calculated on the basis of approximate figures from average values of valid responses.

Sales and Employees 2012-2016

35.5 Bil. ¥ increased since 2013 (25.9% up)

(Sales Unit: Bil.¥)

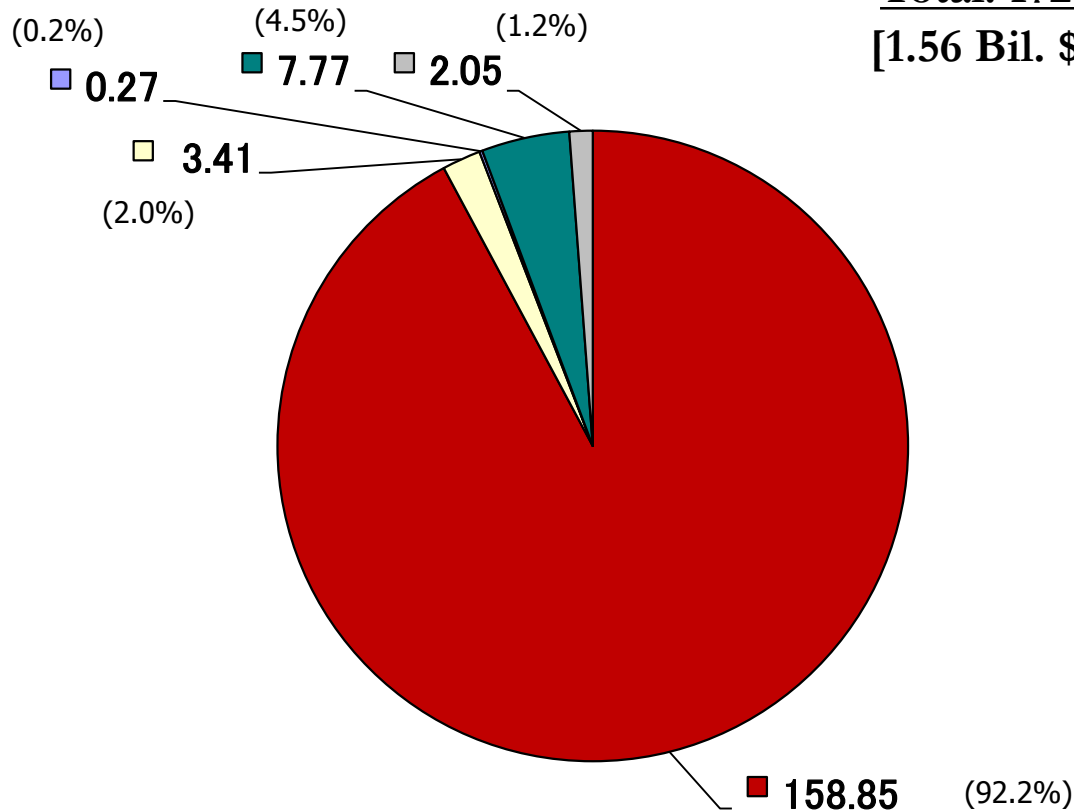
(Employee No.)



Note) Count and estimate data of 25 in 2012, 24 in 2013, 23 in 2014 and 26 2015/2016 and 2017.

2016 Sales by Business Fields

(Sales Unit: Bil.¥)



Total: 172.3 Bil. ¥
[1.56 Bil. \$ (1\$=110¥)]

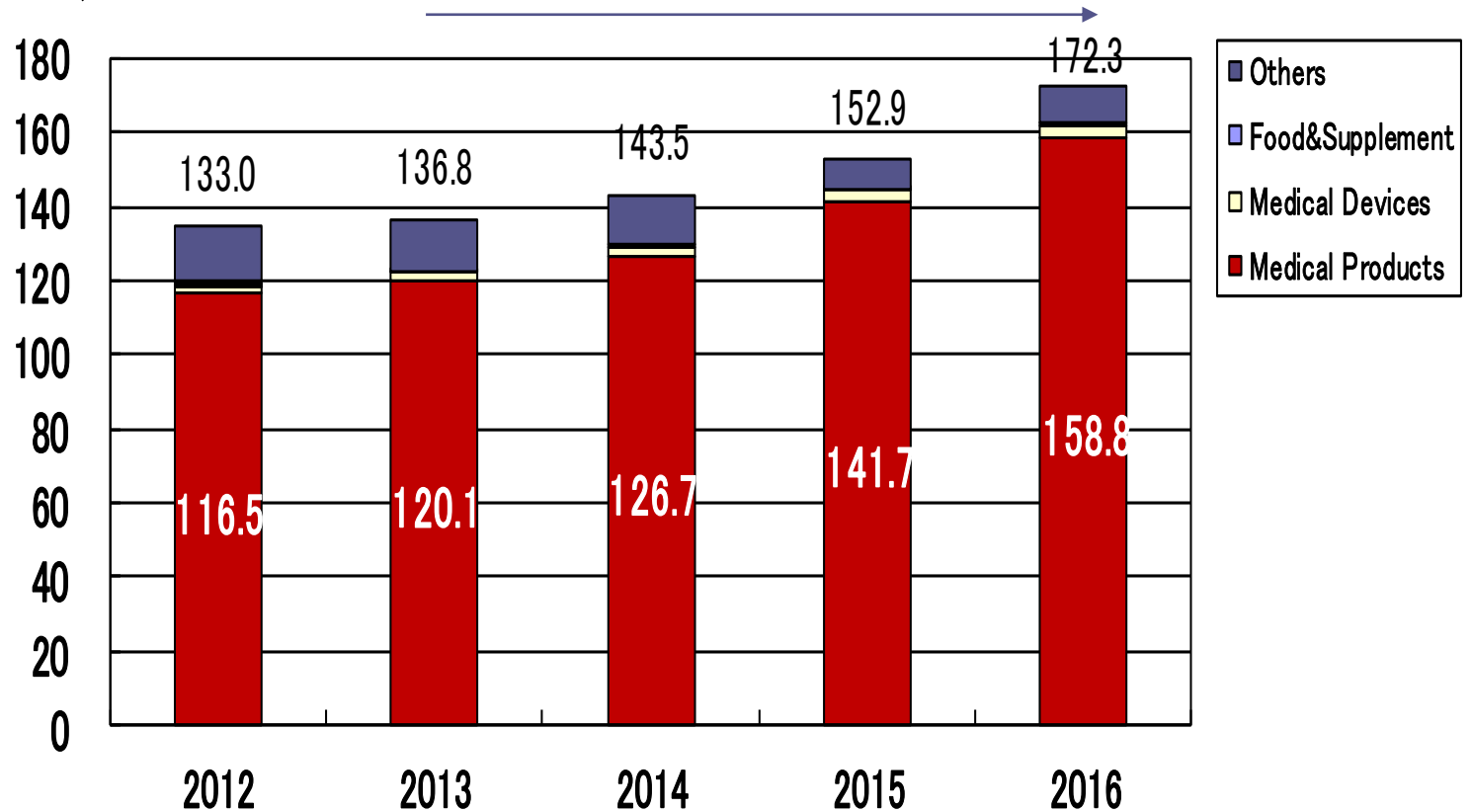
- Medical Products
- Medical Devices
- Food&Supplement
- CSO
- Others

100.1% in sum

Sales by Business fields 2012-2016

Medical devices increased by 0.77 Bil.¥ since 2013(29.3%up)
 Medical products increased by 38.7 Bil.¥ since 2013(32.2%up)

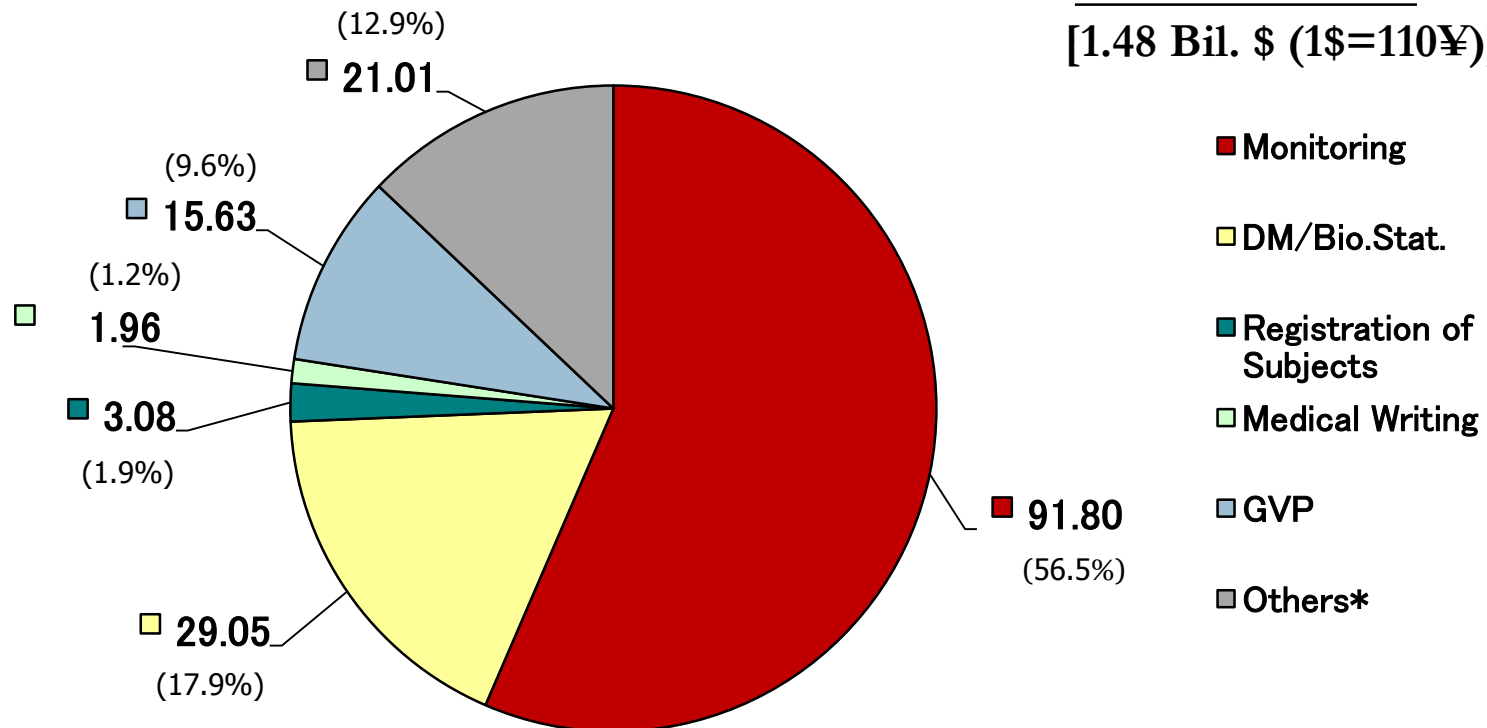
(Sales Unit : Bil.¥)



2016 Medical Products/Devices/Food & Nutrition-Supplement Sales by Business Services

(Sales Unit: Bil.¥)

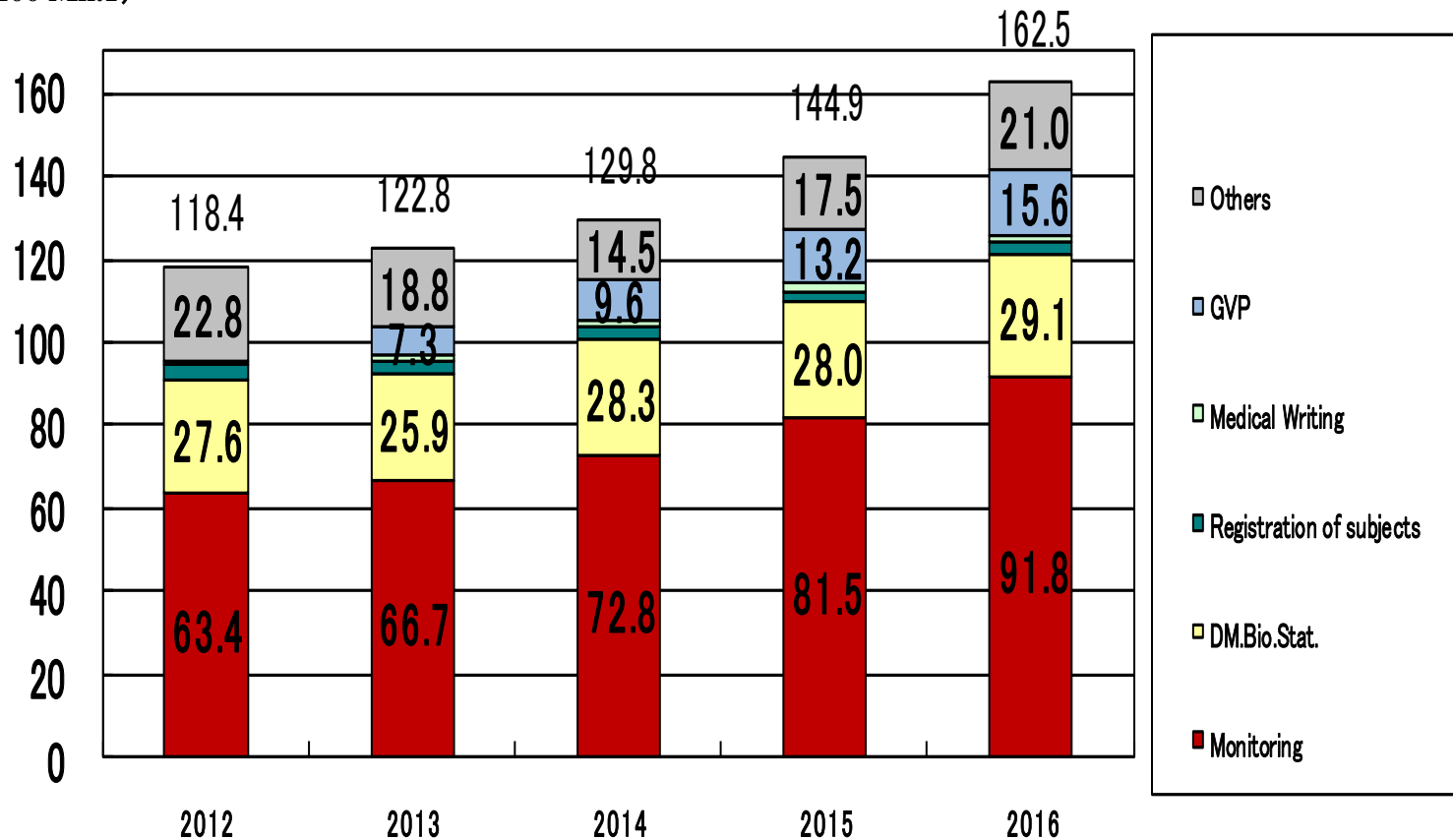
Total: 162.5 Bil.¥
[1.48 Bil. \$ (1\$=110¥)]



Medical Products/Devices/Food & Nutrition-Supplement Sales by Clinical Services 2012-2016

Monitoring increased by 25 Bil. ¥ since 2013(37.6% up)
GVP increased by 8.3 Bil.¥ since 2013(114.8% up)

(Sales Unit: 100 Mil.¥)

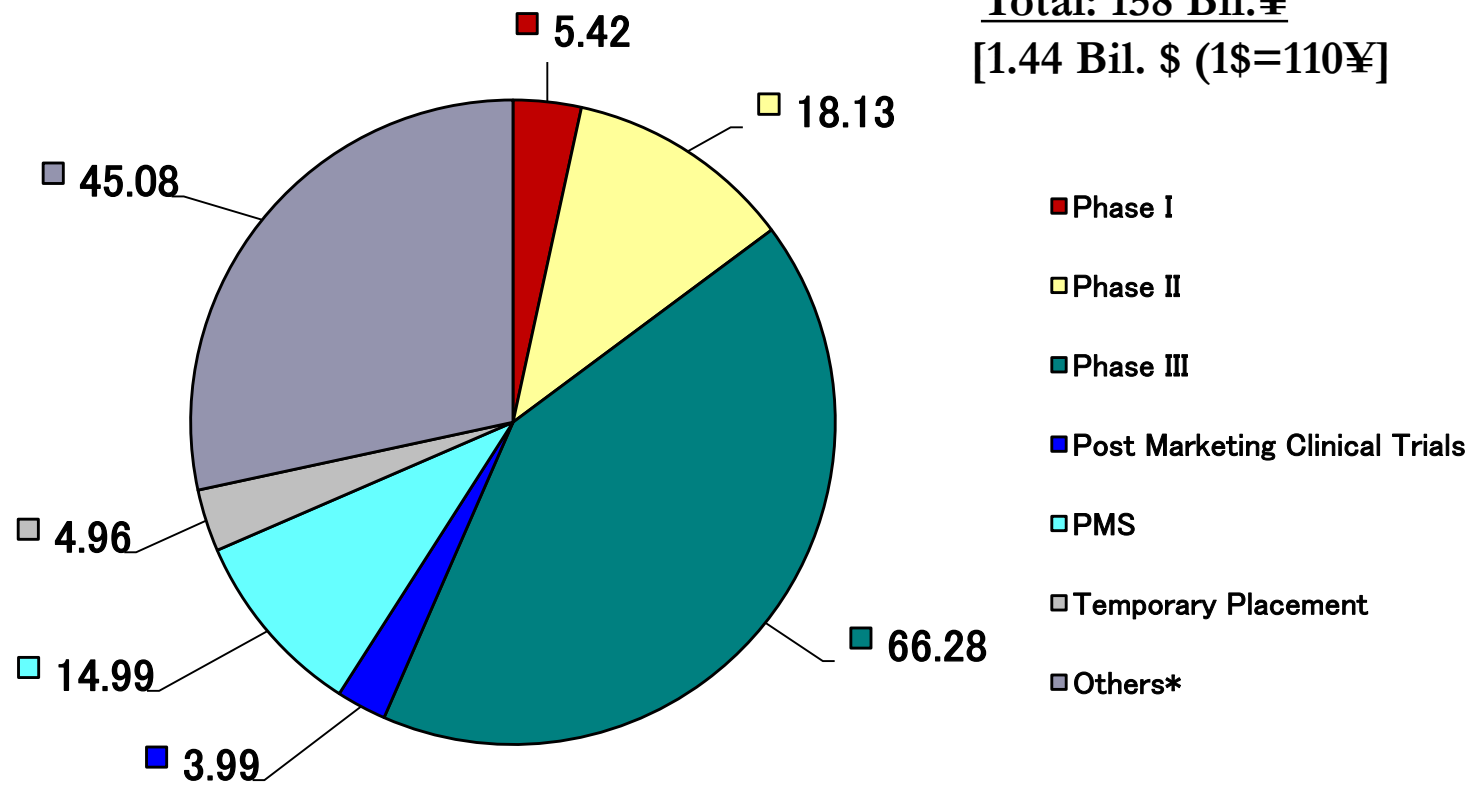


*Business activities relating to GVP were newly categorized from others since 2013.

2016 Medical Products Sales by Clinical Phases

(Sales Unit: Bil.¥)

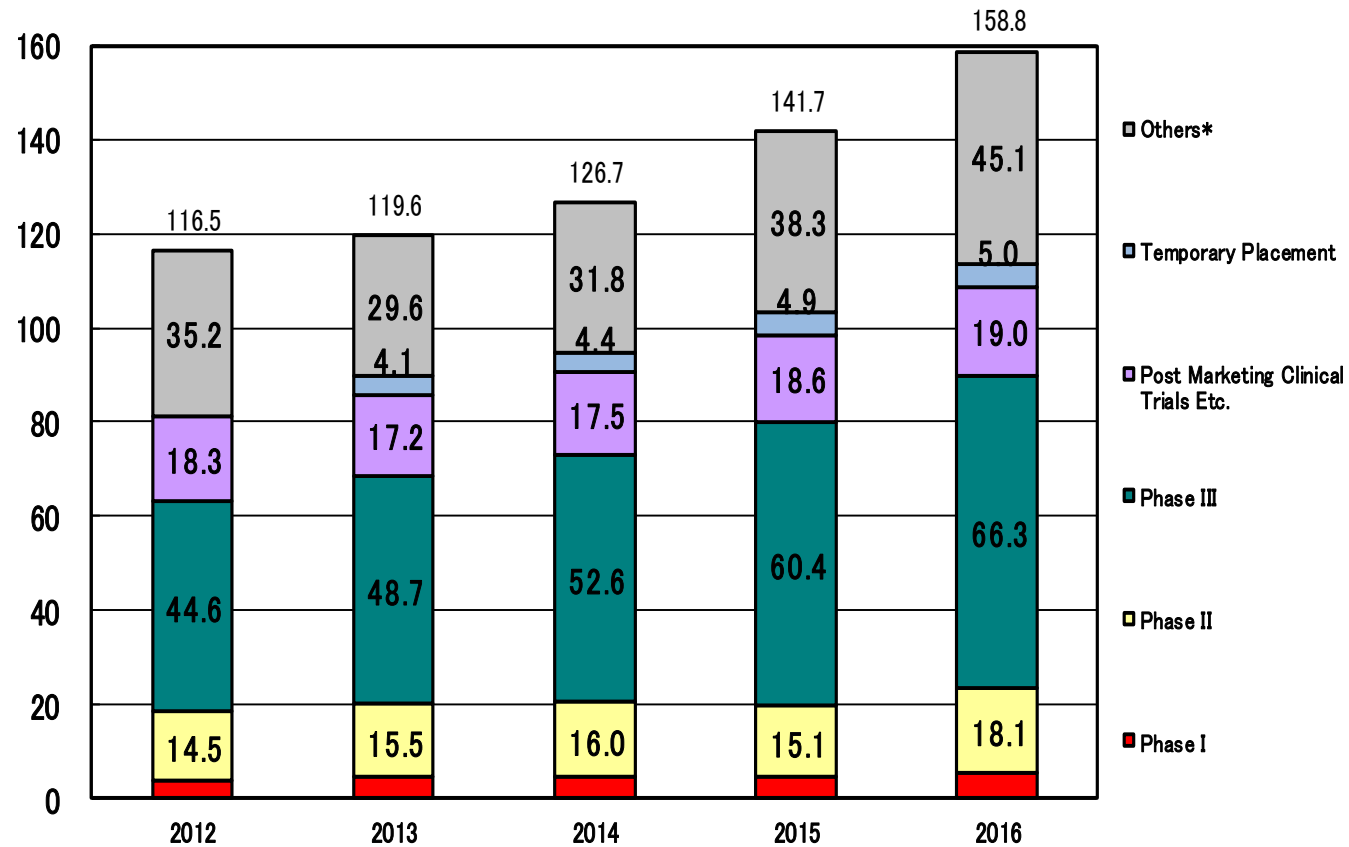
Total: 158 Bil.¥
[1.44 Bil. \$ (1\$=110¥)]



*Refer to slide No. 10 regarding other services.

Medical Products Sales by Clinical Phases 2012-2016

(Sales Unit: Bil.¥)



*Temporary placement was newly categorized out of others since 2013.

Other services Conducted in relation to Medical Products

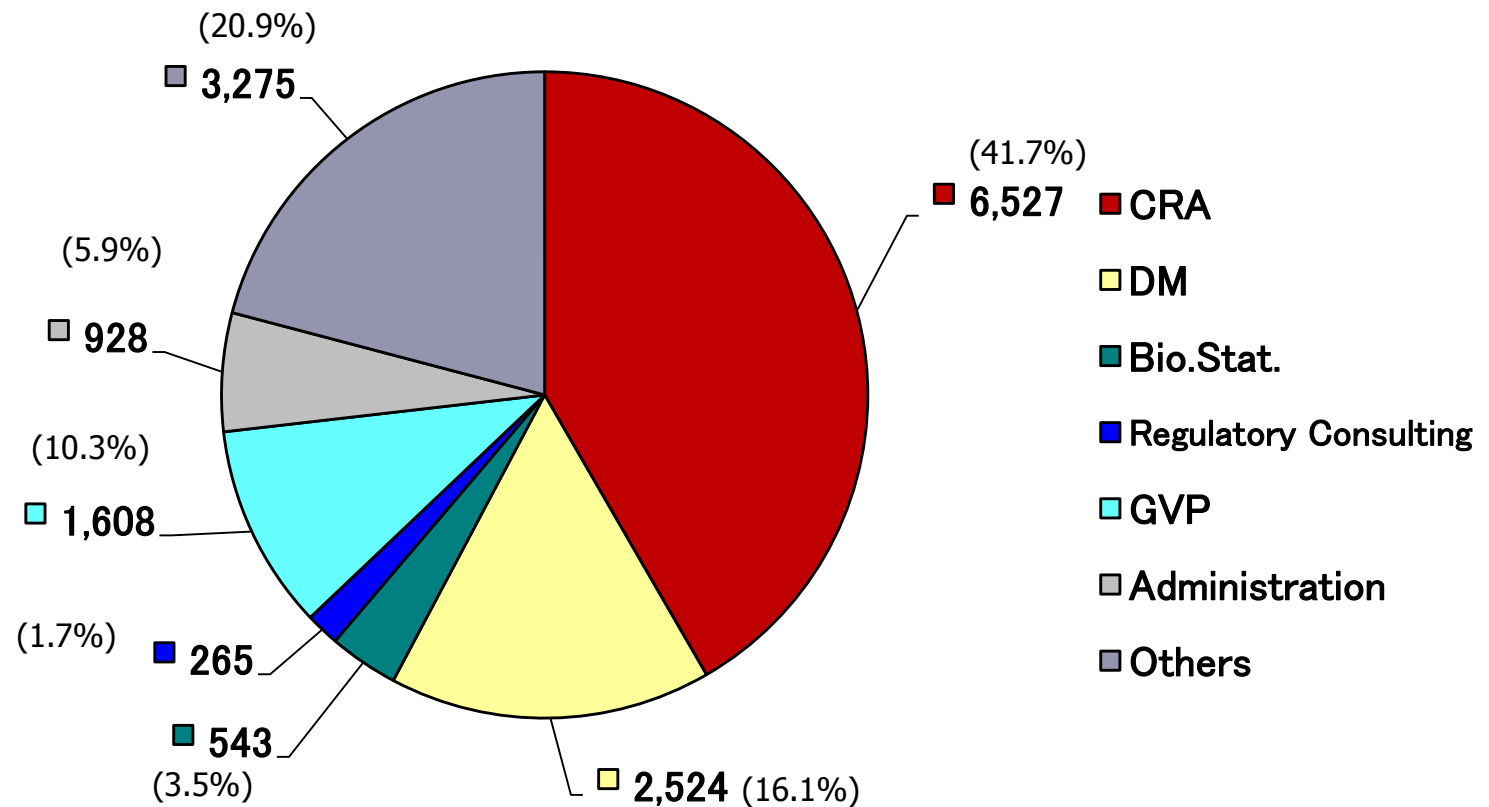
(No. represent the number of CRO conducting those business services.)

Business services	No.	Business services	No.
Audit(including self-check)	16	Re-examination documents preparation	8
Academic clinical research	13	SOP preparation	7
Consultation	12	Clinical Trial In-Country Care-taker	7
Randomization	12	Recruiting clinical study subjects, site-selection	6
Education & training	11	Translation	6
Academic papers writing	10	Logistics and storage of IMP	6
IT support, system building (excluding EDC)	10	MF application, generics application	4
Project management	9	Holding research conference	4
BE studies	9	Establishing analytical methods, validation	2

Also include clinical laboratory testing, regeneration medicine, preparation of clinical trial notification

2016 Employees by Business Services

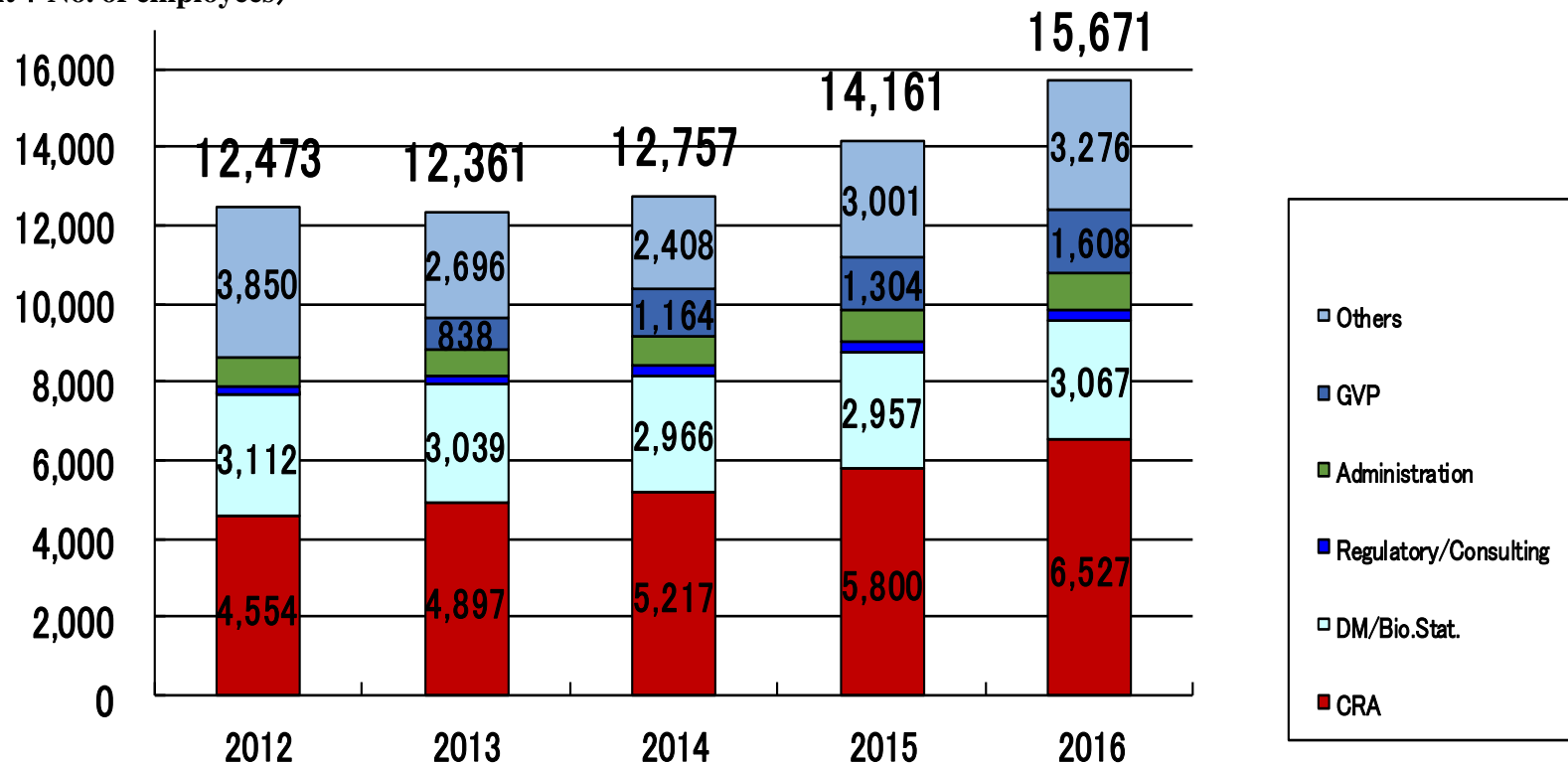
Total No. of employees: 15,671



Employees by Business Services 2012-2016

3,310 employees increased since 2013 (26.8% up)

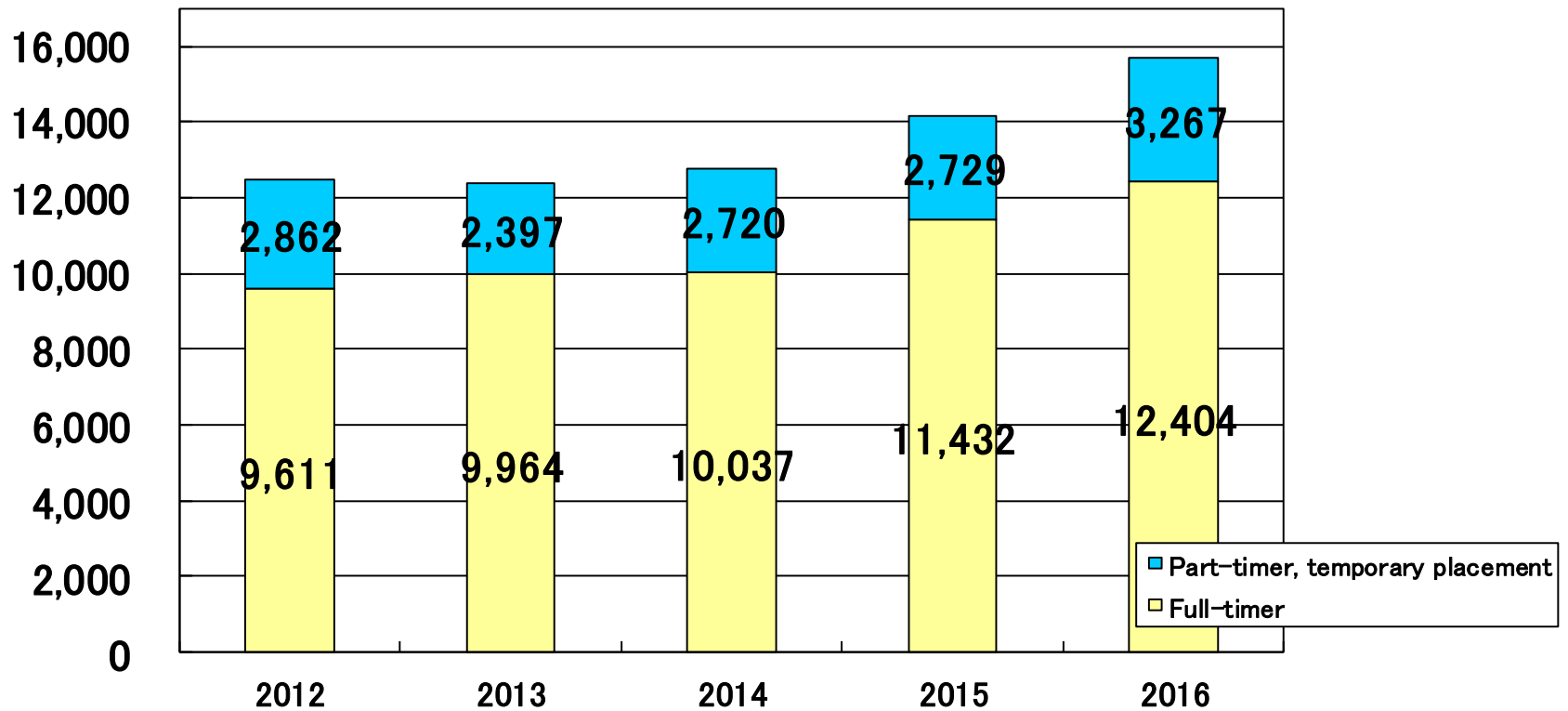
(Unit : No. of employees)



*Business activities relating to GVP were newly categorized from others since 2013.

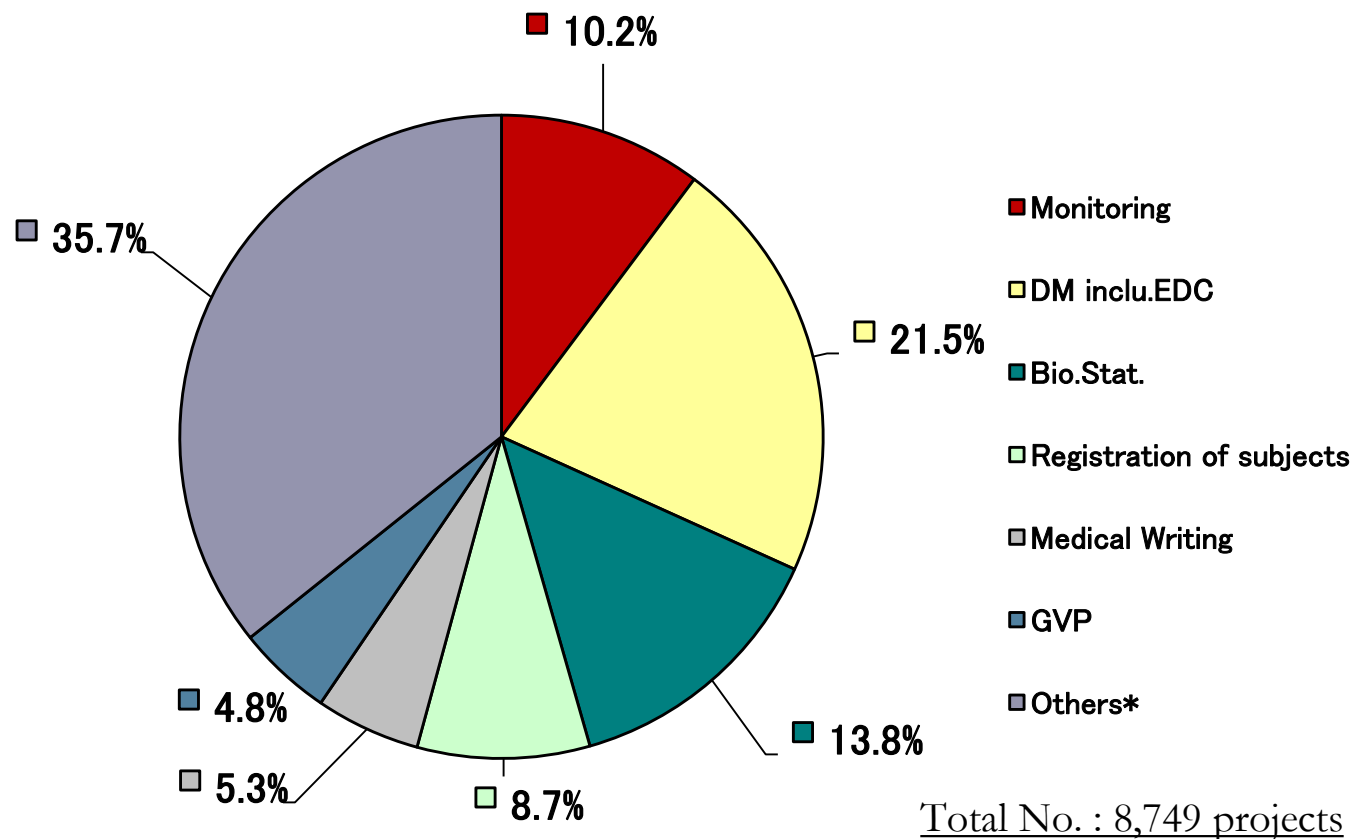
Employees by Business Services 2012-2016

2016 Total No. of employees :15,671



2016 Medical Products/Devices/Food & Nutrition-Supplement Outsourced Projects by Business Services

★1 Project =1 service per protocol, not including any projects associating temporary placement



*Others: Academic clinical researches, audit, consultation, education and training, IT support-system building, translation, BE studies, Randomization, clinical laboratory testing. etc.

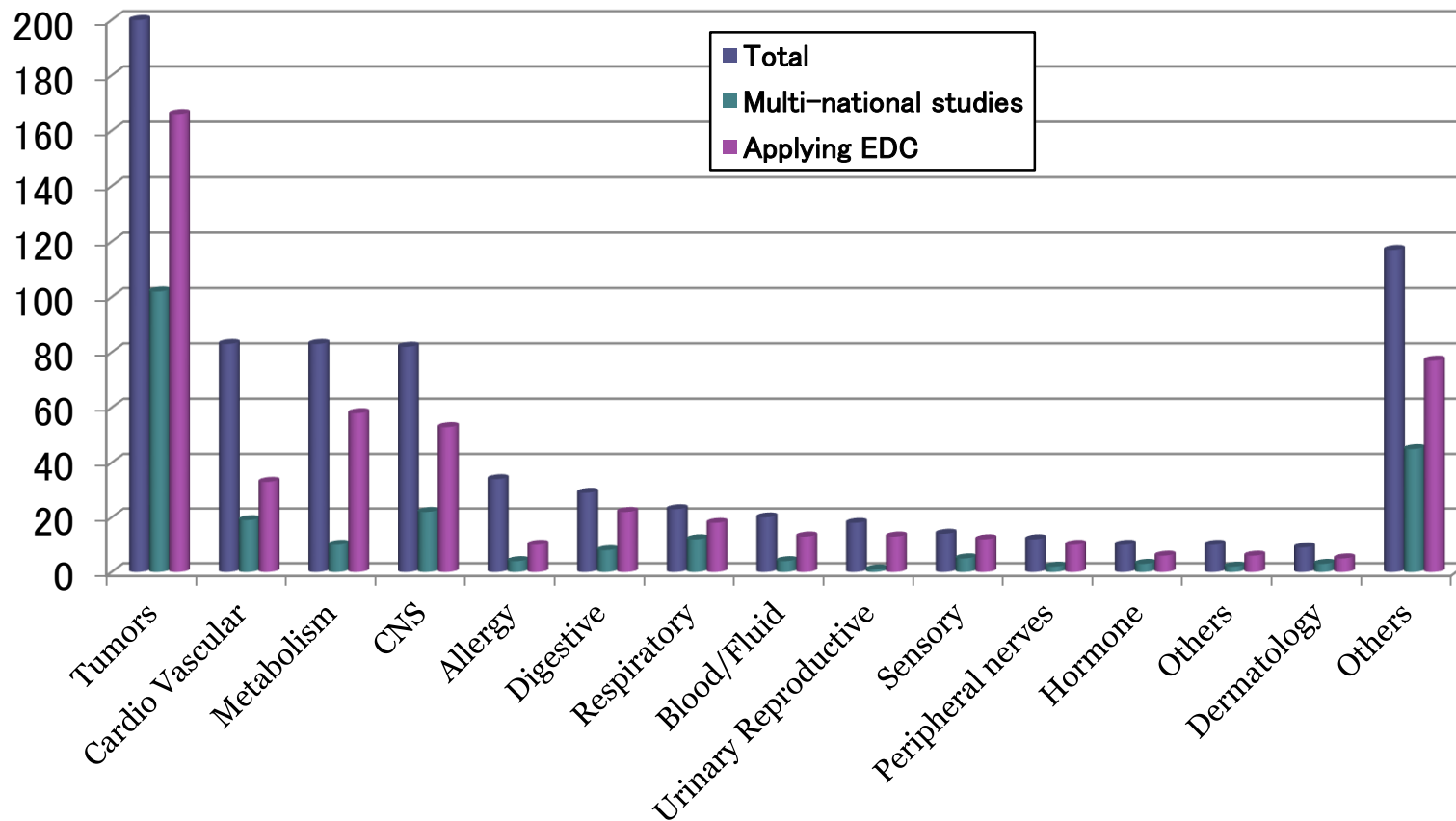
2016 Monitoring Projects* by Therapeutic Area

- Only valid responded projects, 761, are categorized out of total monitoring projects .
- * Multi-National Studies: Studies conducted in multi countries simultaneously with the same protocol.

Multinational studies counted 242 (31.8%), EDC studies 502 (66.0%) out of 761 projects.

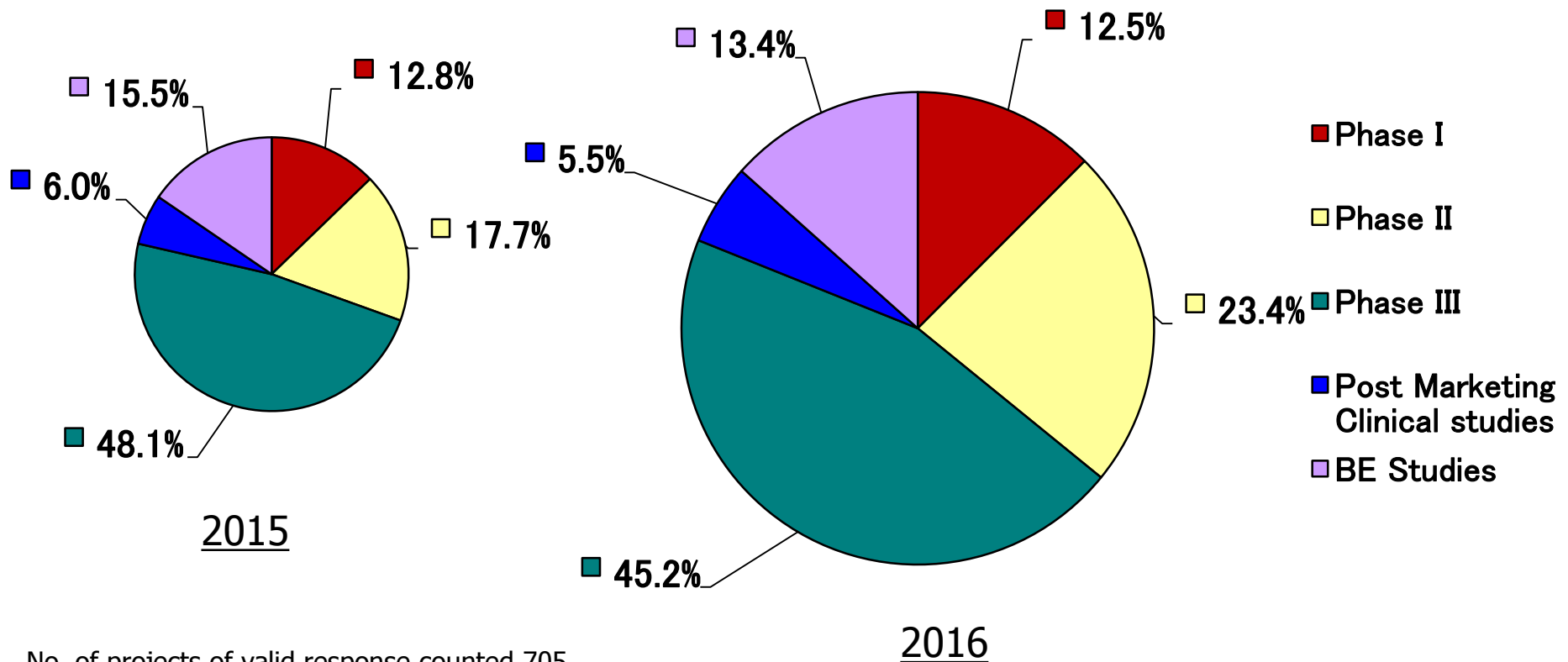
Multinational studies obtained 193 responses (27.4%), EDC studies 458 (65.0%) out of 705 valid responses in2015

(Units:No. of projects)



2016 Monitoring Projects* by Clinical Phases

Note: Only valid responded projects, 761, are categorized out of total monitoring projects.



No. of projects of valid response counted 705 in 2015