

Population Survey Report on Clinical Data Managers in Japan

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SCDM Japan Steering Committee

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2. Survey background and objectives

In February 2019, the Society for Clinical Data Management (SCDM), an international academic organization for clinical data management, established the Japan Steering Committee (Japan Chapter). The SCDM Japan Chapter is working to develop education for clinical data managers (CDM personnel) through Good Clinical Data Management Practice (GCDMP) and Certified Clinical Data Manager (CCDM), and to support the formation of career paths. As a non-profit organization that provides information and education on CDM, we have decided to conduct a survey of the CDM personnel population in Japan. We believe that understanding the number of CDM personnel in Japan will provide important information that will serve as a basis for developing education that meets the actual needs of Japan. We are planning to publish the results of this survey on the SCDM website, and we would appreciate your cooperation in the survey.

3. Survey method

3.1 Target organizations:

The survey targeted total 184 organizations, including major pharmaceutical companies, Contract Research Organization (CROs), and academic institutions in Japan.

As for pharmaceutical companies, we asked 66 organizations belonging to the Data Science Subcommittee of the Drug Evaluation Committee of the Japan Pharmaceutical Manufacturers Association to participate in the survey. For CROs, the survey was requested through the Japan CRO Association to 47 organizations that are regular and supporting members of the association. As for academic institutions, we requested 71 organizations, including 42 hospitals that are members of the National University Hospital Clinical Research Promotion Initiative (NUH-CRPI), 18

universities that are members of the Metropolitan Academic Research Consortium (MARC) composed of private universities in the Tokyo metropolitan area, 7 hospitals that are members of the National Institute of Research Advancement, and 4 organizations that are not members of any of the aforementioned organizations but are designated as core hospitals for clinical research under the Medical Service Act or are corporate academic members of the Academic Research Organization (ARO) Council to complete the survey.

Responses were requested from the head of the data management department or other departments that perform data management tasks in each organization, or from a person in an appropriate position.

3.2 Research Method

The data were collected electronically using a Google Form between July 15 and August 6, 2021. The survey consisted of 11 items: one question on organizational attributes, four questions on the number of CDM personnel and their years of experience, and six questions on awareness of education and career paths for CDM personnel. (See Appendix 1). We did not collect any information that would identify the organization or individual, such as the organization name, respondent's name, or email address. Responding to this survey was considered as consent for cooperation in this survey.

4. Result

4.1 Response rate

Of the total 184 organizations surveyed, 118 organizations responded. The response rate was 64%, and the total number of CDM personnel was 1348.5.

Of these responses, 82% were from academic institutions (58/71), with a total of 304.5 CDM personnel. Pharmaceutical companies (44/66) accounted for 67%, with 413 CDM personnel, and CRO associations (16/47) accounted for 34%, with 631 CDM personnel.

Table 4.1 Response Rate

Target group	Target Number	Number of responses	Response rate (%)	Number of CDM personnel
Academia	71	58	82%	304.5 *
NUH-CRPI	42	39	93%	162
MARC (Private University)	19	10	53%	24.5
National Center, National Hospital Organization, Public interest incorporated foundation	10	9	90%	118

Pharmaceutical company	66	44	67%	413
domestic capital	–	33	50%	265
foreign capital	–	11	17%	148
CRO Association	47	16	34%	631
domestic capital	–	11	23%	520
foreign capital	–	4	9%	107
Unknown	–	1	2%	4
ALL	184	118	64%	1348.5

*One response indicated “0.5 person” and was added directly to the total.

4.2 Number of enrolled CDM personnel and years of experience

The median number of CDM personnel in an organization was 3 for academic institutions, 6.5 for pharmaceutical companies, and 14.5 for CROs and 5 for the total (Table 4.2.1). CROs had the highest median number of CDM personnel with less than 4 years of experience, which was 4.5, compared to 1 overall (Table 4.2.2). For those with more than 4 and less than 10 years of experience, the median number of CDM personnel was highest for pharmaceutical companies, at 2, and for the total, at 1 (Table 4.2.3). For those with 10 or more years of experience, the median was highest for CROs, 6.5, and for the total, 2 (Table 4.2.4).

Table 4.2.1 Number of CDM personnel (total)

	Average	±SD	Median	Min	Max
Academia (n=58)	5.3	6.6	3	0	31
Pharma (n=44)	9.4	4.5	6.5	1	42
domestic capital	8	6.6	6	1	27
foreign capital	13.5	12	8	1	42
CRO (n=16)	39.4	66.3	14.5	0	250
domestic capital	47.3	79	12	0	250
foreign capital	26.8	17.9	31	2	43
Unknown	4		4	4	4
All (n=118)	11.4	27.2	5	0	250

Table 4.2.2 Number of CDM personnel (Years of experience: <4 Years)

	Average	±SD	Median	Min	Max
Academia (n=58)	1.8	2.5	1	0	13
Pharma (n=44)	1.6	2	1	0	7

domestic capital	1.85	2.07	1	0	7
foreign capital	0.8	1.83	0	0	6
CRO (n=16)	13.2	25.5	4.5	0	100
domestic capital	17.8	29.7	6	0	100
foreign capital	3.8	6.18	1	0	13
Unknown	0		0	0	0
All(n=118)	3.3	10.2	1	0	100

Table 4.2.3 Number of CDM personnel (Years of experience: 4 Years < 10 years)

	Average	±SD	Median	Min	Max
Academia(n=58)	2.3	3.2	1	0	17
Pharma (n=44)	2.3	2.5	2	0	10
domestic capital	2.4	2.6	2	0	10
foreign capital	1.8	2.3	1	0	7
CRO (n=16)	13.4	26.3	1.5	0	100
domestic capital	16.5	31.2	2	0	100
foreign capital	8	9.8	6	0	20
Unknown	1		1	1	1
All(n=118)	3.8	10.5	1	0	100

Table 4.2.4 Number of CDM personnel (Years of experience: 10 years<)

	Average	±SD	Median	Min	Max
Academia(n=58)	1.2	2.2	0	0	9
Pharma (n=44)	5.7	5.9	4	0	29
domestic capital	4	3.3	3	0	17
foreign capital	10.8	8.8	8	1	29
CRO (n=16)	12.8	17.4	6.5	0	57
domestic capital	12.9	20.4	5	0	57
foreign capital	15	9.23	16.5	2	25
Unknown	3		3	3	3
All(n=118)	4.4	8.3	2	0	57

4.3 Reality of CDM education

“What kind of education does CDM incorporate?” (multiple answers allowed), 85.5% (100/117 organizations) responded with “On the Job Training (OJT),” of which 78.9% (45/57 organizations)

were in academia, 93.2% (41/44 companies) were in pharmaceutical companies, and 87.5% (14/16 companies) were in CROs. The overall percentage was high (Table 4.3.1). This was followed by 91 (77.8%) organizations selecting “outside seminars” (Table 4.3.2), 52 (44.4%) organizations selecting “in-house training materials” (Table 4.3.3), and 37 (31.6%) organizations opting for “outside e-learning” (Table 4.3.4). Table 4.3.5 shows the five other free text responses.

Table 4.3.1 On the Job Training (OJT)

	YES (%)	NO (%)
Academia (n=57)	45 (78.9%)	12 (21.1%)
Pharma (n=44)	41 (93.2%)	3 (6.8%)
domestic capital	30	3
foreign capital	11	0
CRO (n=16)	14 (87.5%)	2 (12.5%)
domestic capital	9	2
foreign capital	4	0
Unknown	1	0
All (n=117)	100 (85.5%)	17 (14.5%)

Table 4.3.2 External seminars

	YES (%)	NO (%)
Academia (n=57)	42 (73.7%)	15 (26.3%)
Pharma (n=44)	40 (91.0%)	4 (9.0%)
domestic capital	30	3
foreign capital	10	1
CRO (n=16)	9 (56.3%)	7 (43.7%)
domestic capital	6	5
foreign capital	3	1
Unknown	0	1
All (n=117)	91 (77.8%)	26 (22.2%)

Table 4.3.3 Internal training materials

	YES (%)	NO (%)
Academia (n=57)	15 (26.3%)	42 (73.7%)
Pharma (n=44)	27 (61.4%)	17 (38.6%)
domestic capital	18	15

foreign capital	9	2
CRO (n=16)	10 (62.5%)	6 (37.5%)
domestic capital	6	5
foreign capital	3	1
Unknown	1	0
All (n=117)	52 (44.4%)	65 (55.6%)

Table 4.3.4 External e-learning

	YES (%)	NO (%)
Academia (n=57)	27 (47.4%)	30 (52.6%)
Pharma (n=44)	5 (11.4%)	39 (88.6%)
domestic capital	1	32
foreign capital	4	7
CRO (n=16)	5 (31.3%)	11 (68.7%)
domestic capital	4	7
foreign capital	0	4
Unknown	1	0
All (n=117)	37 (31.6%)	80 (68.4%)

Table 4.3.5 Other

Affiliation	Other (details)
National University Hospital	No training
National University Hospital	No training programs that we are working on independently.
Private University (Hospital)	Consultation by CRO
Private University (Hospital)	Unstaffed and unmaintained.
CRO (domestic)	Not applicable

5. Good Clinical Data Management Practice (GCDMP) Usage Status

Overall, 26.5% (31 organizations) use the GCDMP, which provides guidance on CDM work, in their education and operations (Table 5.1). By industry, pharmaceutical companies were the most frequent users at 31.8%, followed by CROs at 31.3%, and academic institutions at 21.1%.

Table 5.1 Status of GCDMP use in education and practice

	YES (%)	NO (%)
Academia (n=57)	12 (21.1%)	45 (78.9%)
Pharma (n=44)	14 (31.8%)	30 (68.2%)
domestic capital	11	22
foreign capital	3	8
CRO (n=16)	5 (31.3%)	11 (68.7%)
domestic capital	3	8
foreign capital	1	3
Unknown	1	0
All (n=117)	31 (26.5%)	86 (73.5%)

6. Interest in CDM education provided by SCDM

In response to the question of whether they would be interested if the SCDM Japan offered CDM education, 93.1% (108/116 organizations) of all respondents (Table 6.1) indicated that they would be interested. Academic institutions, pharmaceutical companies, and CROs all showed high interest at 92.9% (52/56 organizations), 93.2% (41/44 companies), and 93.8% (15/16 companies), respectively.

Table 6.1 Interest in CDM education from SCDM

	YES (%)	NO (%)
Academia (n=56)	52 (92.9%)	4 (7.1%)
Pharma (n=44)	41 (93.2%)	3 (6.8%)
domestic capital	31	2
foreign capital	10	1
CRO (n=16)	15 (93.8%)	1 (6.2%)
domestic capital	11	0
foreign capital	3	1
Unknown	1	0
All (n=116)	108 (93.1%)	8 (6.9%)

7. Do you want them to obtain CCDM as a career path for CDM?

Regarding the question of whether they would like to have CDM personnel in their departments obtain the SCDM CCDM as a career path for CDM, 67.2% of all respondents (78/118 organizations) indicated they would like to have CDM personnel in their departments obtain the CCDM. Of these, 78.6% (44/56 organizations) were in academia institutions, a high percentage. Pharmaceutical companies and CROs were 54.5% (24/44 organizations) and 62.5% (10/16 organizations), respectively.

Table 7.1 Interest in CCDM

	YES (%)	NO (%)
Academia (n=56)	44 (78.6%)	12 (21.4%)
Pharma (n=44)	24 (54.5%)	20 (45.5%)
domestic capital	16	17
foreign capital	8	3
CRO (n=16)	10 (62.5%)	6 (37.5%)
domestic capital	6	5
foreign capital	3	1
Unknown	1	0
All (n=116)	78 (67.2%)	38 (32.8%)

8. Would you like to receive information from the SCDM Japan?

“Would you like to receive information from the SCDM Japan?” 81.7% (94/115) of all respondents indicated that they would like to receive information (Table 8.1). Of these, 83.6% (46/55 organizations) were from academia and 88.6% (39/44 organizations) were from pharmaceutical companies, both of which received more than 80% of the responses, indicating a high level of interest in obtaining CDM-related information.

Table 8.1 Interest in receiving information from the SCDM Japan Chapter

	YES (%)	NO (%)
Academia (n=55)	46 (83.6%)	9 (16.4%)
Pharma (n=44)	39 (88.6%)	5 (11.4%)
domestic capital	28	5
foreign capital	11	0
CRO (n=16)	9 (56.3%)	7 (43.7%)
domestic capital	5	6
foreign capital	3	1
Unknown	1	0
All (n=115)	94 (81.7%)	21 (18.3%)

9. Free comments (n=27)

Table 9.1 Breakdown of free comment responses (n=27)

Affiliation	Number of responses
National University Hospitals Clinical Research Promotion Initiative	10

pharmaceutical company	6
National research institutes (6 national centers)	4
Japan CRO Association	3
Public Interest Incorporated Foundation	2
National Hospital Organization	1
Metropolitan Academic Research Consortium	1

Table 9.2 Free Comment Details

	Affiliation	Comments
1	NUH-CRPI	The number of respondents to this survey includes temporary staff, as well as staff specializing only in EDC construction. We are having difficulties in recruiting DM staff, and we are also having difficulties retaining them because we cannot find a suitable career path. I came to know about SCDM only recently. We believe that we have limited education and experience internally, and would appreciate it if you would consider providing training.
2	NUH-CRPI	I would like to request for CDM education provided by the SCDM, Japan.
3	NUH-CRPI	In clinical research, the status of DM is often seen as low compared to other industries, so please aim to improve the status of DM.
4	NUH-CRPI	Academic certifications are not taken into account for full-time employment or promotion, so they do not attract a high level of interest. The turnover rate is not low, and the cost of education and training cannot be ignored.
5	NUH-CRPI	It is difficult for an organization to be recognized as professional because it is not certified and it is difficult for the person to recognize themselves as professional. I always feel that it is necessary to set easy-to-understand goals such as acquiring qualifications and to stimulate interactions within the same occupation. While CRC and statisticians have a central organization, there is no such organization for CDM, so we expect SCDM to play a central role in domestic CDM.

6	NUH-CRPI	Please send information about DM education and provide templates for materials related to DM.
7	NUH-CRPI	We do not have a CDM yet, so we would appreciate it if you could provide information about the same. Thank you.
8	NUH-CRPI	I expect that the work of DM, such as the certification system, will be further recognized and that there will be an environment where you can play an active role for a long time.
9	NUH-CRPI	I would like to disseminate any information about seminars, letters or news about international trends to the department.
10	NUH-CRPI	Establish competencies and skill sets related to CDM in academia.
11	Pharmaceutical company (domestic)	I would like to have a Japanese version of GCDMP.
12	Pharmaceutical company (domestic)	When I heard your presentation at the Drug Information Association (DIA) a few years ago, I signed up for the newsletter with two of my enrolled students, however, both did not receive any newsletter afterward. I was speculating if the newsletter was never sent out or if it was only sent to us.
13	Pharmaceutical company (domestic)	The scope of the work of the DM is diverse and is changing with the times. Therefore, we hope that you will conduct educational activities in collaboration with the global headquarters, based on the current requirements.
14	Pharmaceutical company (domestic)	It would be helpful if there was a Japanese version of CDM certification.
15	Pharmaceutical company (domestic)	Ongoing GCDMP updates, timely response to new technologies. Reference to GCDMP as career path for CDM.
16	Pharmaceutical company (foreign)	Since we are a foreign pharmaceutical company, we are influenced by the trends of the global headquarters (for example, SCDM is more focused on ACDM than SCDM). However, I am interested in exchanging information with SCDM and its participants, especially in defining the capabilities required for CDM, the knowhow to develop it,

		and providing a platform for it.
17	National research institutes (6 national centers)	There is a conference in my country every year, however, I expect it will be held in Japan too. It would be helpful if there were workshops and study groups on specific clinical research and support. For example, I would like to see support for capacity building related to DM, such as when it is held before and after approval as a core hospital for clinical research.
18	National research institutes (6 national centers)	We would like to have our students obtain CCDM, however, it is somewhat challenging, so we would appreciate it if the SCDM Japan Chapter had a certification program to help them move toward CCDM.
19	National research institutes (6 national centers)	Since it is in English, the course materials are translated into Japanese. Cost consideration for personnel striving for ARO.
20	National research institutes (6 national centers)	The CCDM exam is difficult to qualify, including the fact that it is in English, so I think that a Japanese version would increase the number of examinees.
21	Japan CRO Association (domestic)	I would like to suggest that the Japanese people be educated mainly in Japanese.
22	Japan CRO Association (domestic)	No Comments
23	Japan CRO Association (domestic)	Compared to statisticians, DM staff has limited opportunities to make presentations outside the company, so I expect this will lead to opportunities to communicate not only domestically but also overseas in English.
24	Public Interest Incorporated Foundation	I look forward to participate in workshops and training sessions.
25	Public Interest Incorporated Foundation	There are several data managers working in the same organization. However, they have different affiliations, and we do not know who the data manager is in terms of personnel information. For example, a research assistant may be working as a local data manager. In addition, we found out that there are some employees who have the job

		title of clinical trial data manager but are not in charge of data management at all. Although the job title is known by HR, there is no systematic understanding of the work content and years of experience as a data manager in the skills inventory.
26	National Hospital Organization	<p>It is still difficult to understand the benefits of obtaining and maintaining SCDM, CCDM certification.</p> <p>It would be helpful if the costs of obtaining and maintaining the certification were easier to understand.</p> <p>I think it would be good if there were a system for academics to obtain the Japanese version of SCDM educational materials at low cost.</p> <p>There is also the Data Manager Certification System of the Japanese Association for Cancer Therapy and the Data Management Seminar of the Japan Science and Technology Federation.</p>
27	Metropolitan Academic Research Consortium	<p>We are aware of the need to improve the system, however, as a university we have not taken any steps yet.</p> <p>If you can provide us relevant information, we will strive to keep pace with the developments.</p>

10. Considerations

Number of CDM personnel

The response rate in this survey was 64%, with 118 of the 184 organizations responding. The total number of CDM personnel in the 118 responding organizations was 1348.5. The purpose of this survey was to determine the actual number of CDM personnel in Japan. The overall number of CDM personnel is estimated to be 2102 when calculated proportionally from the 118 organizations that responded. However, since this survey did not collect information on the size, and other attributes of the organizations that responded, the results cannot be directly applied to organizations that did not respond, and it is difficult to estimate the exact number of respondents. The number of CDM personnel in Japan is estimated to be in the range of approximately 1,500 to 2,000.

Academia Organizations

In this survey, 39 out of 42 (93%) member institutions of the National University Hospital Clinical

Research Promotion Initiative responded, and 10 out of 19 (53%) member institutions of the Metropolitan Academic Research Consortium (MARC), which consists of private universities, 9 out of 10 organizations with ARO functions, including national research and development corporations including 6 national centers, the National Hospital Organization, and public interest foundations, responded. Total 57 organizations responded.

They were cooperative in the CDM survey, and the large number of responses indicates that the survey was of significant interest to AROs.

The total number of CDM personnel was 304.5 (22.6% of all organizations), with a mean \pm standard deviation of 5.3 ± 6.6 and a median of 3.

While some institutions had a maximum of 31 staff, most institutions had about 3 staff working on the job, and the average number of years of experience of the institutions was

Less than 4 years Mean \pm standard deviation 1.8 ± 2.5 persons

More than 4 years but less than 10 years Mean \pm standard deviation 2.3 ± 2.5

More than 10 years Mean \pm standard deviation 1.2 ± 2.2

The distribution was about 1–2 people in each of the career levels of beginner, mid-career, and skilled. The distribution of the number of people from skilled to novice is not wide, and it is not a continuous employment. The number of employees is not widespread, ranging from skilled to novice researchers, and it is possible that the employment structure is such that the staff is supplemented when there is a shortage at each level, rather than being employed continuously.

In many cases, AROs do not have sufficient research funds, and there are few opportunities to outsource data management work with a small number of CDM personnel in the organization. In addition, the distribution of the number of people by years of experience indicates that even skilled people have to work as practitioners (people who actually work on individual projects) rather than just supervising beginners.

As for the education of CDM, 45 out of 57 organizations (78.9%) adopted on-the-job training (OJT), and only 15 organizations (26.3%) had educational materials within their organization.

Organizations using external e-learning were 27 (47.3%) and 42 organizations (73.7%) attended external seminars, indicating that they are seeking outside educational opportunities to supplement OJT. However, as mentioned earlier, while AROs are required to perform all aspects of clinical data management work, they are supplemented by external seminars, which suggest that a systematic and comprehensive educational system has not been introduced.

Consequently, 52 AROs (92.9%) out of 56 organizations are highly interested in the CDM education provided by SCDM. The fact that only 12 organizations (21.0%) are currently using the GCDMP, which is a systematic education material, indicates that they have high expectations from the systematic education provided by SCDM.

From the aforementioned distribution of personnel in the organizations, it can be inferred that

there is a high level of interest in both certification as a result of systematic acquisition of knowledge and skills and career development within their own organizations.

As can be seen from the comments in the free comments section, there are high expectations from the SCDM Japan, not only for the training and education of data managers, but also as a guidepost for career paths and status improvement, and as a place for data managers to interact.

Pharmaceutical industry

In this survey, 44 out of 66 (66.7%) pharmaceutical companies responded, and the number of CDM personnel totaled to 413, with a mean \pm standard deviation of 9.4 ± 4.5 , of which 265 were domestic (33 companies), with a mean \pm standard deviation of 8 ± 6.6 , and 148 were foreign (11 companies), with a mean \pm standard deviation of 13.5 ± 12 . There were a few foreign-invested companies with one organization, but overall the number of employees tended to be higher than that of domestic companies. Regarding the number of employees in pharmaceutical companies as a whole, for the 22 companies that did not respond to the survey, assuming that the ratio of domestic and foreign capital is about the same as that of the responding companies, the number of employees would be 207 if calculated proportionally from the 44 responding companies, and the number of employees in 66 companies would be estimated to be 620.

In pharmaceutical companies, when data management personnel started to be recognized in drug development and began to be responsible for so-called data management operations such as data quality assurance, Case Report Form (CRF) creation for data collection, EDC construction, and so on, they were often assigned from statisticians, monitoring personnel, and system-related personnel. The results of this survey also show that the number of years of experience is increasing. In the results of this survey, the small number of respondents with less than four years of experience may be in part owing to the fact that few new graduates are hired. However, the small number of respondents with less than four years of experience may also have an impact on the future prospects of data management operations in pharmaceutical companies and the company's policy to secure internal staff. Under such circumstances, the results of the survey on data management education show that most of the respondents rely on on-the-job training and external seminars, which has been the trend in the industry since the beginning of the need for data management work in drug development. Whereas, in order to examine the relationship between the size of the organization and the status of education, we looked at the median number of data management staff in companies with more than 7 staff and companies with less than 7 staff. Nineteen companies (86.4%) with more than 7 staff have in-house educational materials and 19 companies use external seminars. In the 22 companies with less than 7 employees, 8 companies have internal training materials (36.3%) and all 22 companies have external seminars. As for external e-learning, only up to 5 companies utilized it, but 5 out of 5 companies had more than 7

employees. Regarding the education of CDM personnel in pharmaceutical companies, on-the-job training and external seminars are the main methods regardless of the size of the organization or whether it is internally or externally funded, and as the scale of the company increases, they tend to prepare a variety of opportunities such as internal training materials and external e-learning. Companies with a sufficient number of employees tend to have more opportunities to conduct business in-house and to have a greater need to educate their CDM personnel, so they tend to have more training programs in place. Companies with a small number of employees have more opportunities to outsource their CDM personnel training and have not changed significantly from the traditional OJT and external seminars. On the other hand, there was a high level of interest in educational opportunities from SCDM and in acquiring CCDM regardless of the size of the organization (organizations with more than 7 people: 21 companies (95.5%); organizations with less than 7 people: 20 companies (91%)). Organizations with more than 7 employees: 14 companies (63.6%), organizations with less than 7 employees: 10 companies (45.5%). Although it is difficult for pharmaceutical companies to determine at what scale they will maintain their data management organizations, at least in the future, data management operations are expected to change, diversify, and become more specialized. However, unless they are large organizations, it will be difficult for them to provide education that covers all the changes that will occur in the future, so they are interested in using materials from external educational institutions and participating in educational opportunities.

CROs

In this survey, 16 (34%) of the 47 CROs that are members of the Japan CRO Association (including 32 supporting members) responded, and the number of CDM personnel totaled to 631, with a mean \pm standard deviation of 39.4 ± 66.3 , of which 520 (11 domestic companies) and 47.3 ± 79.0 (mean \pm standard deviation), and 107 (4 foreign companies). The number of foreign employees (4 companies) totaled 107, with a mean \pm standard deviation of 26.8 ± 17.9 . The number of employees varied greatly among the companies, but it can be inferred that some companies included temporary staff in their numbers, while others were supporting members and had no CDM function. The number of DM employees in 2020, according to the Japan CRO Association, was 2,102. We assume that this number includes temporary employees such as input staff.

Many data management tasks tend to be outsourced to CROs, and the number of people involved in data management tasks is on the rise. Alternatively, data management operations are becoming more multifunctional, and those in charge of coding only, central monitoring in RBA (Risk-based Approach), and Study Data Tabulation Model (SDTM) creation for Clinical Data Interchange Standards Consortium (CDISC), and so on, are developing out of data management operations. In some cases, they have evolved from data management operations and are functioning as a new

organization. The mean \pm standard deviation of the number of people with each year of experience in data management is 13.2 ± 25.5 people with less than 4 years of experience, 13.4 ± 26.3 people with 4 to 10 years of experience, and 12.8 ± 17.4 people with all age groups. We believe that this is due to the fact that this type of work involves more internal work than monitoring work, making it easier to work for a long time according to life events.

As for the education of CDM, 14 of 16 companies (87.5%) provide on-the-job training (OJT), and 10 of 16 companies (62.5%) have in-house training materials. As a contract research organization, CROs are expected to work immediately as soon as possible. For this reason, we believe that on-the-job training (OJT) tends to be used more frequently, in which employees are trained step-by-step and learn the work by being assigned to actual tasks. Since the emphasis is on practical experience rather than systematic education, few companies use external e-learning or external seminars: 5 out of 16 companies (31.3%) and 9 out of 16 companies (56.3%), respectively. Whereas, data management operations are becoming more multifunctional, and it is becoming more difficult to perform operations with knowledge of DM operations only. Against this background, 15 out of 16 CROs (93.8%) expressed interest in the CDM education provided by SCDM. In addition, 10 of 16 CROs (62.5%) are interested in obtaining the CCDM certification offered by SCDM, because CROs are fiduciary organizations, and having some kind of certification can be an indicator of the quality of their work. It is becoming increasingly difficult to cover the training of data management operations, which are becoming increasingly multifunctional, through on-the-job training, and the need for systematic training in data management operations is likely to increase in the future.

11. Summary

This is the first nationwide survey of the number of CDM personnel in Japan, conducted across industries (academic institutions, pharmaceutical companies, and CROs), with the aim of ascertaining the actual number of CDM personnel in Japan. Based on the results of this survey, the number of CDM personnel in Japan is estimated to be around 1,500 to 2,000. The results of the survey on CDM education and career paths suggest that there is a tendency to seek comprehensive and systematic CDM education from external institutions, and this confirms the issues and needs that the SCDM Japan will face in developing CDM education in Japan in the future.

Acknowledgements

We would like to express our deepest gratitude to the organizations that responded to this survey. We would also like to thank the Secretariat of the National University Hospital Clinical Research Promotion Initiative, the Data Science Committee of the Japan Pharmaceutical Manufacturers

Association, the Secretariat of the Japan CRO Association, and the Secretariat of the Metropolitan Academic Research Consortium (MARC) for their cooperation in distributing the survey forms.



Survey on Clinical Data Manager

《Survey background and purpose》

In February 2019, the Society for Clinical Data Management (SCDM), an international academic organization for clinical data management, established the Japan Steering Committee (Japan Chapter). The SCDM Japan Chapter is working to develop education for clinical data managers (CDM) through Good Clinical Data Management Practice (GCDMP) and Certified Clinical Data Manager (CCDM), and to support the formation of career paths. As a non-profit organization that provides information and education on CDM, we have decided to conduct a survey of the CDM population in Japan. We believe that understanding the number of CDM in Japan will provide important information that will serve as a basis for developing education that meets the actual needs of Japan. We are planning to publish the results of this survey on the SCDM website, and we would appreciate your cooperation in the survey.

Target of the questionnaire :

Target organizations: Academia institutions, pharmaceutical companies, CROs in Japan

Respondents: Heads of departments that perform data management operations such as data management departments, or persons with appropriate positions *

Answer time: 3-5 minutes (11 questions in total)

Survey period: August 2021

Investigator: SCDM Japan Steering Committee Co-Chairs

Takuhiro Yamaguchi: Tohoku University Hospital Clinical Trial Data Center

Tempei Miyaji: The University of Tokyo, Department of Clinical Trial Data Management

Contact for inquiries: Society for Clinical Data Management (SCDM) Japan Chapter

Person in charge: Miyaji, Ogawa

Contact e-mail address: scdm.secretary@gmail.com

I. CDM Population Survey

1. Tell me about your organization

Organization type	<input type="checkbox"/> National University Hospital (National University Hospital Clinical Research Promotion Initiative (NUH-CRPI)) <input type="checkbox"/> Public Interest Incorporated Foundation <input type="checkbox"/> National Research and Development Agency (6NC) <input type="checkbox"/> National Hospital Organization <input type="checkbox"/> Private University Hospital <input type="checkbox"/> Other _____
	<input type="checkbox"/> Pharmaceutical company (<input type="checkbox"/> domestic capital <input type="checkbox"/> foreign capital)
	<input type="checkbox"/> CRO (<input type="checkbox"/> domestic capital <input type="checkbox"/> foreign capital)

2. Please tell us about the number of CDM* enrolled in your organization as of July 2021

[]

* Definition of CDM in this survey: Persons involved in CDM operations within the organization. Including the person in charge of system construction such as EDC. Excludes auxiliary personnel who only enter data.

3. We would like to ask about the breakdown of years of experience in CDM.

3.1 Please enter the number of persons with 0 to less than 4 years of experience. []

3.2 Please enter the number of persons with more than 4 years to less than 10 years of experience. []

3.3 Please enter the number of persons with years of experience 10 years or more. []

II. Survey on attitudes toward education and career paths for CDM

SCDM publishes “The Good Clinical Data Management Practices (GCDMP ©)” as guidance for CDM practices, which is also used as a guidance tool in training and education for CDM. The SCDM also operate the “Certified Clinical Data Manager (CCDM®)” as a professional certification system for CDM, and certify professionals who have acquired the knowledge, education and experience required for CDM. The SCDM Japan Chapter is planning

to support the development of CDM education and career paths based on the GCDMP and CCDM, and would appreciate your cooperation in conducting a survey on the following questions.

4. What kind of education do you provide for CDM? (Multiple answers are acceptable)

- On the Job Training (OJT) In-house educational materials
- External seminar External e-learning

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In addition, please tell us if there is any training that you are working on independently at your facility.

5. Do you incorporate Good Clinical Data Management Practice (GCDMP) * into your internal education and operations? * <https://scdm.org/gcdmp/>

- Yes No

6. Are you interested in providing CDM education by SCDM Japan Chapter?

- Yes No

7. Do you want the CDM in your department to acquire SCDM CCDM * as a carrier path for CDM?

- Yes No

* <https://scdm.org/get-certified/>

*Certified Clinical Data Manager: CDM certification system by SCDM

8. Would you like to receive information from the SCDM Japan Chapter?

- Yes No

9. Free text

Please send us your opinions on anything you expect or want from SCDM

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10. About SCDM Japan Network

The SCDM Japan Chapter operates a mailing list called the SCDM Japan Network, which provides information about SCDM's publications and data management related events. The SCDM Japan Network can be registered even if you are not the main member of SCDM, and it is free of charge, so please register if you are interested.

You can register for the SCDM Japan Network using the application form below.

Application form: <https://forms.gle/2Ui7dV5XLQbtbFtX8>

That is all for the survey items. Thank you for your cooperation.