Exploring current data management plans within clinical research trials – reported 15/03/17

Due to such a small response rate across the board, we have decided to close this survey and use the data as a pilot survey for our further research. The pilot survey results are currently being written up for publication and aim to be presented at the Health Informatics Conference, 6-9 August 2017 in Brisbane.

Email was forwarded onto 294 clinical trial COSA sites, 19th October 2016. A total of six (2%) participants responded to the online survey. COSA participant demographics are given in Table 1.

Table 1: Demographic characteristics of COSA participants

Variable	**n(%)**
Gender	
Male	0(0)
Female	6(100)
Highest level of education	
Bachelor degree	4(67)
Doctoral degree	2(33)
Duration of current employment (years)	
0 – 4	0(0)
5 – 9	4(67)
10 – 15	2(33)
+ 15	0(0)
Appointment (current job or position)	
Continuing employment (no specified end date)	4(76)
Fixed-term contract (specified time or ascertainable period)	2(33)
Contract duration (years) < 1 2 >3	 1(50) 0(0) 1(50)

Question 1 - Does your institution currently have a clinical data management plan in place?	**n(%)**
Yes	3(50)
No	1(17)
Don't know	2(33)

Question 2 – What type of clinical research does your institute conduct? (Select all that apply)	n(%)
Treatment	4(67)
Prevention	3(50)
Diagnostic	-
Screening	3(50)
Quality of life	3(50)
Genetic	1(17)
Epidemiological	3(50)
Phase I trial	3(50)
Phase II trial	4(67)
Phase III trial	4(67)
Phase IV	3(50)

Question 3 – Does your institute have any of the following procedures in place to ensure high-quality data is produced? (Select all that apply)	n(%)
Logic, range and consistency checks	3(50)
Statistical techniques	1(17)
Risk-based targeted monitoring	-
Risk-based triggered monitoring	1(17)
On-site source data verification	4(67)
Remote monitoring	3(50)
Centralised monitoring	5(83)

Question 4 – What percentage of your data is monitored?	n(%)
75%	2(33)
100%	3(50)
Don’t know	1(17)

Question 5 – Does your institute have an error acceptance level?	n(%)
<5%	1(17)
No	2(33)
Don’t know	3(50)

Question 6 – Following on from question 5, if the error rate is found to be higher than the approved level does your institute implement further follow-up monitoring?	n(%)
No	1(100)

Yes	-

Question 7 – How often does your institute conduct internal data monitoring?	**n(%)**
Every 9 months	1(17)
Not applicable	2(33)
Don't know	2(33)
Other - Different irregular quality projects	1(17)

Question 8 – What variables are included in data monitoring?	**n(%)**
Critical data points (key/primary data)	1(17)
Non-critical data points (non-key/secondary data)	-
Critical and non-critical data	-
All data points (100%)	2(33)
Not applicable	1(17)
Don't know	1(17)
Other, please specify - Trial dependent either 100% or select critical and non-critical	1(17)

Question 9 – Does your institute use any pf the following sampling methods to select what data points are monitored? (Select all that apply)	**n(%)**
Simple random sampling	-
Systematic sampling	1(17)
Stratified sampling	-
Cluster sampling	-
Multi-stage sampling	-
Not applicable	2(33)
Don't know	3(50)

Question 10(a) – Please specify the type of staff training/development you conduct that is devoted to data quality for clinical trials. (Select all that apply)	**n(%)**
One-on-one education and training	2(33)
Group education and training	4(67)
Education throughout clinical trial (as needed)	5(83)
Educate prior to research	4(67)
Skills training/development	3(50)
ICH-GCP training	4(67)
SOP training	5(83)

10(b) Average amount of time spent on staff training/development per person, per clinical trial over a 12 month period.

Ranged from 5-30 years (M=15.00, SD=11.01, SEM=4.52)

Hours	n(%)	Hours	n(%)
0-9	3(50)	20-29	2(33)
10-19	0(0)	30+	1(17)

Question 11 – Who reviews the reports of data quality and consistency? (Select all that apply)	**n(%)**
Chief investigator	4(67)
Sponsor	4(67)
Auditor/monitor	4(67)
Data manager	5(83)
Senior staff management	4(67)
Data entry staff	3(50)
Data analyst	-
Administration staff	-